Dossier zur Nutzenbewertung gemäß § 35a SGB V

Selpercatinib (Retsevmo®)

Lilly Deutschland GmbH

Modul 4C – Anhang 4-L

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

Fortgeschrittenes Schilddrüsenkarzinom mit RET-Fusion nach Sorafenib und/oder Lenvatinib

Stand: 12.03.2021

Inhaltsverzeichnis

Tabelle 003: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Safety Analysis Set

Merkmal	Selpercatinib Subpopulation C – TC (N=21)
Demographische Charakteristika und Baseline Charakteristika	
Geschlecht, n (%)	
Männer	7 (33,3)
Frauen	14 (66,7)
Ethnische Zugehörigkeit, n (%)	
Weiß	14 (66,7)
Schwarz oder Afroamerikaner	2 (9,5)
Asiaten	3 (14,3)
Amerikanische Indianer oder Ureinwohner Alaskas	0 (0,0)
Ureinwohner Hawaiis oder andere pazifische Inselbewohner	0 (0,0)
Andere	2 (9,5)
Fehlend	0 (0,0)
Geografische Region, n (%)	
Nordamerika	19 (90,5)
Europa	0 (0,0)
Rest der Welt	2 (9,5)
Altersgruppen, n (%)	
18 bis < 45 Jahre	6 (28,6)
45 bis < 65 Jahre	8 (38,1)
65 bis < 75 Jahre	1 (4,8)
≥ 75 Jahre	6 (28,6)
Alter in Jahren	
Anzahl der Patienten	21
Mittelwert (SD)	57,3 (18,37)
Median (min–max)	53,0 (27-88)
ECOG Performance Status, n (%)	
0	8 (38,1)
1	11 (52,4)
2	2 (9,5)
Erkrankungshistorie	
Primäre Diagnose, n (%)	
Papilläres Schilddrüsenkarzinom	17 (81,0)
Gering differenziertes Schilddrüsenkarzinom	2 (9,5)
Anaplastisches Schilddrüsenkarzinom	1 (4,8)
Hürthle-Zell-Schilddrüsenkarzinom	1 (4,8)
Krankheitsstadium bei der Erstdiagnose, n (%)	
I	0 (0,0)
II	0 (0,0)
III	0 (0,0)
IV	20 (95,2)
Fehlend	1 (4,8)
Zeit seit der Erstdiagnose in Monaten	

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/T003_bc_tc.rtf

Tabelle 003: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Safety Analysis Set

Merkmal	**Selpercatinib** **Subpopulation C – TC (N=21)**
Anzahl der Patienten	21
Mittelwert (SD)	166,7 (130,99)
Median (min–max)	135,1 (10-495)
Metastasierte Erkrankung bei Baseline, n (%)	
Ja	21 (100,0)
Nein	0 (0,0)
Metastasen im zentralen Nervensystem (ZNS) bei Baselinea[a], n (%)	
Ja	6 (28,6)
Nein	15 (71,4)
Vortherapien	
Vorherige systemische Therapie, n (%)	
Ja	21 (100,0)
Nein	0 (0,0)
Art der vorherigen systemischen Therapie[b], n (%)	
Multikinase-Inhibitoren (MKI)	21 (100,0)
- Cabozantinib	1 (4,8)
- Vandetanib	1 (4,8)
- Sorafenib	8 (38,1)
- Lenvatinib	14 (66,7)
- Andere MKI	5 (23,8)
Chemotherapie	2 (9,5)
- Platinhaltige Chemotherapie	0 (0,0)
- Taxanhaltige Chemotherapie	0 (0,0)
- Andere Chemotherapien	2 (9,5)
Radiojodtherapie	17 (81,0)
PD1/PD-L1 Inhibitoren	3 (14,3)
Selektive RET Inhibitoren	0 (0,0)
Andere systemische Therapie	8 (38,1)
Anzahl der vorherigen systemischen Therapien, n (%)	
0	0 (0,0)
1-2	5 (23,8)
3 oder mehr	16 (76,2)
Anzahl der vorherigen systemischen Therapien	
Anzahl der Patienten	21
Mittelwert (SD)	3,9 (1,84)
Median (min–max)	4,0 (1-7)
Vorherige Strahlentherapie, n (%)	
Ja	10 (47,6)
Nein	11 (52,4)
Vorherige Krebsbedingte Operation, n (%)	
Ja	18 (85,7)
Nein	3 (14,3)

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/T003_bc_tc.rtf

Tabelle 003: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Safety Analysis Set

Merkmal	Selpercatinib Subpopulation C – TC (N=21)
RET-Alterationsstatus	
Art der RET-Alteration, n (%)	
Fusion	21 (100,0)
- KIF5B	0 (0,0)
- CCDC6	10 (47,6)
- NCOA4	7 (33,3)
- Andere	4 (19,0)
- Unbekannt	0 (0,0)
Mutation	0 (0,0)
- M918T	0 (0,0)
- V804 M/L	0 (0,0)
- Extrazelluläre Cystein Mutation	0 (0,0)
- Andere	0 (0,0)
Andere	0 (0,0)
Methode zur Identifizierung der vorliegenden RET-Alteration, n (%)	
Next-Generation-Sequencing (NGS) mit Tumormaterial	18 (85,7)
Next-Generation-Sequencing (NGS) mit Blut oder Plasma	2 (9,5)
PCR	0 (0,0)
FISH	0 (0,0)
Andere	1 (4,8)
Krankheitscharakteristika zu Baseline	
Messbare Erkrankung[c], n (%)	
Ja	20 (95,2)
Nein	1 (4,8)
Tumorlast in mm[d]	
Anzahl der Patienten	20
Mittelwert (SD)	66,0 (39,76)
Median (min–max)	56,2 (11-156)

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; PCR: Polymerase-Kettenreaktion; PD1: Programmed Cell Death Protein 1; PD-L1: Programmed Cell Death Ligand 1; RET: Rearranged during Transfection; SD: Standardabweichung; T: Threonin; TC: Schilddrüsenkarzinom; 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/T003_bc_tc.rtf

Tabelle 003: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Safety Analysis Set

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/T003_bc_tc.rtf

Tabelle 003: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Merkmal	Selpercatinib Subpopulation C – TC (N=18)
Demographische Charakteristika und Baseline Charakteristika	
Geschlecht, n (%)	
Männer	6 (33,3)
Frauen	12 (66,7)
Ethnische Zugehörigkeit, n (%)	
Weiß	13 (72,2)
Schwarz oder Afroamerikaner	2 (11,1)
Asiaten	1 (5,6)
Amerikanische Indianer oder Ureinwohner Alaskas	0 (0,0)
Ureinwohner Hawaiis oder andere pazifische Inselbewohner	0 (0,0)
Andere	2 (11,1)
Fehlend	0 (0,0)
Geografische Region, n (%)	
Nordamerika	18 (100,0)
Europa	0 (0,0)
Rest der Welt	0 (0,0)
Altersgruppen, n (%)	
18 bis < 45 Jahre	5 (27,8)
45 bis < 65 Jahre	8 (44,4)
65 bis < 75 Jahre	1 (5,6)
≥ 75 Jahre	4 (22,2)
Alter in Jahren	
Anzahl der Patienten	18
Mittelwert (SD)	55,8 (17,76)
Median (min–max)	53,0 (27-88)
ECOG Performance Status, n (%)	
0	7 (38,9)
1	9 (50,0)
2	2 (11,1)
Erkrankungshistorie	
Primäre Diagnose, n (%)	
Papilläres Schilddrüsenkarzinom	15 (83,3)
Gering differenziertes Schilddrüsenkarzinom	2 (11,1)
Anaplastisches Schilddrüsenkarzinom	0 (0,0)
Hürthle-Zell-Schilddrüsenkarzinom	1 (5,6)
Krankheitsstadium bei der Erstdiagnose, n (%)	
I	0 (0,0)
II	0 (0,0)
III	0 (0,0)
IV	17 (94,4)
Fehlend	1 (5,6)
Zeit seit der Erstdiagnose in Monaten	

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/T003_bc_tc.rtf

Tabelle 003: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Merkmal	**Selpercatinib** **Subpopulation C – TC (N=18)**
Anzahl der Patienten	18
Mittelwert (SD)	168,3 (138,12)
Median (min–max)	118,6 (10-495)
Metastasierte Erkrankung bei Baseline, n (%)	
Ja	18 (100,0)
Nein	0 (0,0)
Metastasen im zentralen Nervensystem (ZNS) bei Baselinea[a], n (%)	
Ja	4 (22,2)
Nein	14 (77,8)
Vortherapien	
Vorherige systemische Therapie, n (%)	
Ja	18 (100,0)
Nein	0 (0,0)
Art der vorherigen systemischen Therapie[b], n (%)	
Multikinase-Inhibitoren (MKI)	18 (100,0)
- Cabozantinib	1 (5,6)
- Vandetanib	1 (5,6)
- Sorafenib	7 (38,9)
- Lenvatinib	11 (61,1)
- Andere MKI	5 (27,8)
Chemotherapie	1 (5,6)
- Platinhaltige Chemotherapie	0 (0,0)
- Taxanhaltige Chemotherapie	0 (0,0)
- Andere Chemotherapien	1 (5,6)
Radiojodtherapie	15 (83,3)
PD1/PD-L1 Inhibitoren	3 (16,7)
Selektive RET Inhibitoren	0 (0,0)
Andere systemische Therapie	7 (38,9)
Anzahl der vorherigen systemischen Therapien, n (%)	
0	0 (0,0)
1-2	5 (27,8)
3 oder mehr	13 (72,2)
Anzahl der vorherigen systemischen Therapien	
Anzahl der Patienten	18
Mittelwert (SD)	3,9 (1,91)
Median (min–max)	4,0 (1-7)
Vorherige Strahlentherapie, n (%)	
Ja	10 (55,6)
Nein	8 (44,4)
Vorherige Krebsbedingte Operation, n (%)	
Ja	15 (83,3)
Nein	3 (16,7)

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/T003_bc_tc.rtf

Tabelle 003: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Merkmal	Selpercatinib Subpopulation C – TC (N=18)
RET-Alterationsstatus	
Art der RET-Alteration, n (%)	
Fusion	18 (100,0)
- KIF5B	0 (0,0)
- CCDC6	7 (38,9)
- NCOA4	7 (38,9)
- Andere	4 (22,2)
- Unbekannt	0 (0,0)
Mutation	0 (0,0)
- M918T	0 (0,0)
- V804 M/L	0 (0,0)
- Extrazelluläre Cystein Mutation	0 (0,0)
- Andere	0 (0,0)
Andere	0 (0,0)
Methode zur Identifizierung der vorliegenden RET-Alteration, n (%)	
Next-Generation-Sequencing (NGS) mit Tumormaterial	17 (94,4)
Next-Generation-Sequencing (NGS) mit Blut oder Plasma	1 (5,6)
PCR	0 (0,0)
FISH	0 (0,0)
Andere	0 (0,0)
Krankheitscharakteristika zu Baseline	
Messbare Erkrankung[c], n (%)	
Ja	17 (94,4)
Nein	1 (5,6)
Tumorlast in mm[d]	
Anzahl der Patienten	17
Mittelwert (SD)	59,1 (36,15)
Median (min–max)	54,0 (11-156)

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; PCR: Polymerase-Kettenreaktion; PD1: Programmed Cell Death Protein 1; PD-L1: Programmed Cell Death Ligand 1; RET: Rearranged during Transfection; SD: Standardabweichung; T: Threonin; TC: Schilddrüsenkarzinom; 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/T003_bc_tc.rtf

Tabelle 003: Charakterisierung der Studienpopulation – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

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/T003_bc_tc.rtf

Loxo Oncology Inc. Page 1 of 3
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.
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

Loxo Oncology Inc. Page 1 of 3
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
Efficacy Analysis Set
by Subpopulation

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

Percentage is calculated using the number of patients in the column heading as the denominator.
[1] 160 mg BID is the Recommended Phase 2 Dose.
[2] Time on Study (TOS) (months) = (study exit date - first dose date + 1)/30.4375 for subjects who exited the study on or before the data cutoff date; TOS (months) = (data cutoff date - first dose date + 1)/30.4375 for subjects who were still in the treatment phase as of the data cutoff date; TOS (months) = (last visit date - first dose date + 1)/30.4375 for subjects who were in the long-term follow-up as of the data cutoff date.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_spdisp.sas
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_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)
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.
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_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.
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_eff.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)
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
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)
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.
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
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.
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)
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.
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)
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.
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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)

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
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)
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 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)

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)
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)

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)
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)

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)
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
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)
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)

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)
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.
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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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 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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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 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)

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 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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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 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)

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 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)

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)
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)

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 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)

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 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)

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)
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)

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)
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)

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)
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)

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 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)

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)
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)

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)
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)

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 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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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 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)

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)
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)

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 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)

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)
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)

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)
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)

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)
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)

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 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)

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 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)

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 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)

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)
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)

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)
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)

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 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)

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)
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)

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)
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)

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)
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)

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 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)

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)
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)

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)
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)

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)
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)

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 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)

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)
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)

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 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)

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)
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)

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)
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)

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)
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)

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 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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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
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)
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
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)
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)

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)
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
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)
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
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)
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)

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 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)

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)
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
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 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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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 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)

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)
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)

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)
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)

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)
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)

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)
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
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)
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
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)
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
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)
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
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)
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
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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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.
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 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)

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 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)

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)
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)

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)
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)

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)
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)

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)
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)

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)
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

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 15:10 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 15:10 22DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:19 23DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:19 23DEC2020
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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 - C

Weight / Start Dose	160 mg BID	120 mg BID	Other	Total
< 50 kg	1 (4,8%)	1 (4,8%)	0 (0,0%)	2 (9,5%)
≥ 50 kg	13 (61,9%)	0 (0,0%)	6 (28,6%)	19 (90,5%)
Total	14 (66,7%)	1 (4,8%)	6 (28,6%)	21 (100,0%)

Efficacy Population - C

Weight / Start Dose	160 mg BID	120 mg BID	Other	Total
< 50 kg	1 (5,6%)	1 (5,6%)	0 (0,0%)	2 (11,1%)
≥ 50 kg	10 (55,6%)	0 (0,0%)	6 (33,3%)	16 (88,9%)
Total	11 (61,1%)	1 (5,6%)	6 (33,3%)	18 (100,0%)

Tabelle 006: Behandlungsdauer – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

	Selpercatinib **Subpopulation C – TC** **(N=18)**
Behandlungsdauer in Monaten	
Anzahl der Patienten	18
Mittelwert (SD)	15,5 (7,14)
Median (min–max)	14,75 (5,52-28,88)
max: Maximum; min: Minimum; RET: Rearranged during Transfection; SD: Standardabweichung; TC: Schilddrüsenkarzinom.	

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/T006_tte_tc.rtf

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

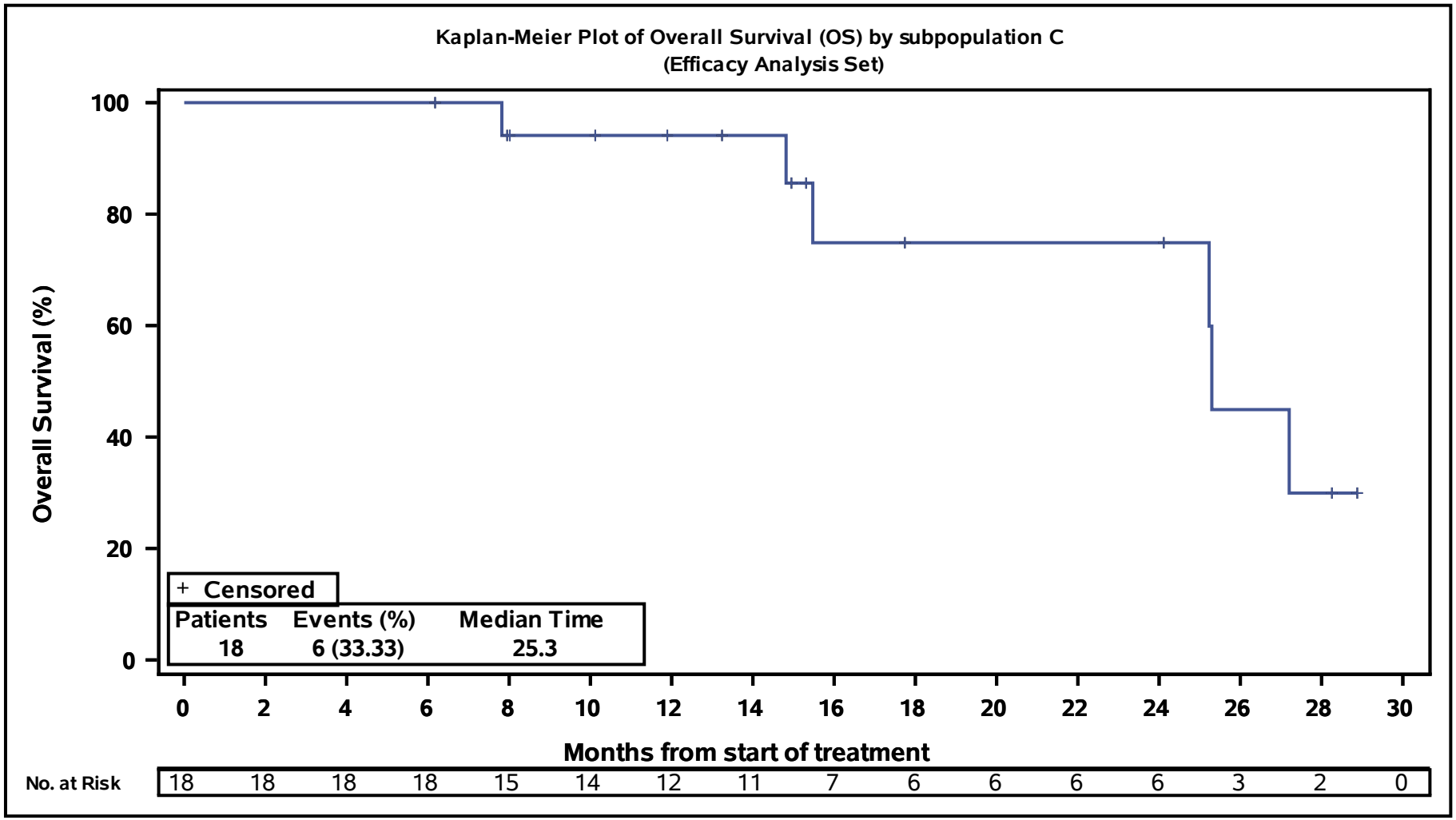
Endpunkt	**Selpercatinib** **Subpopulation C – TC** **(N=18)**
Gesamtüberleben	
Überlebensstatus[a], n (%)	
Tot	6 (33,3)
Lebend	12 (66,7)
Medianes Gesamtüberleben (Monate) [95%-KI][b,c]	25,30 [15,5; NE]
Überlebensrate (≥ 12 Monate), % [95%-KI][b,d]	94,1 [65,0; 99,1]
Mediane Beobachtungsdauer (Monate)[b]	17,7

KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.

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_2.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T007_os_tc_eff.rtf

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F001_3_os_c_tc_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

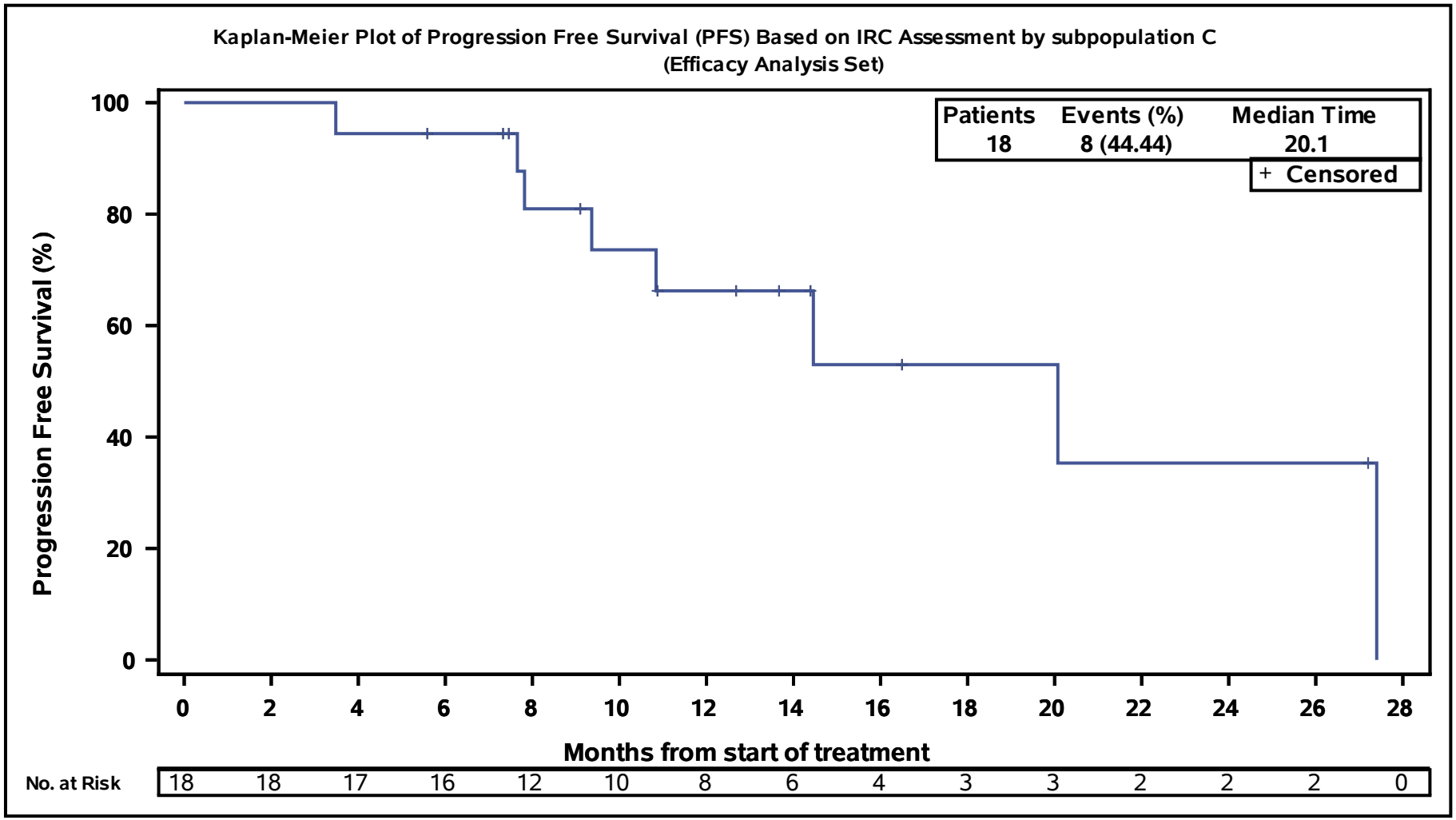
Tabelle 008: Ergebnisse für den Endpunkt progressionsfreies Überleben aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation C – TC (N=18)
Progressionsfreies Überleben	
Progressionsstatus[a,c], n (%)	
Progression	7 (38,9)
Tod (ohne vorherigen Progress)	1 (5,6)
Zensiert	10 (55,6)
Grund für Zensierung, n (%)	
Am Leben ohne Progress[b]	9 (50,0)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[b]	0 (0,0)
Abbruch der Studie ohne Progress[b]	1 (5,6)
Medianes progressionsfreies Überleben (Monate) [95%-KI][d,e]	20,07 [9,4; NE]
Dauer des progressionsfreien Überlebens nach Kategorie, n (%)	
< 6 Monate	2 (11,1)
≥ 6 bis < 12 Monate	8 (44,4)
≥ 12 bis < 18 Monate	5 (27,8)
≥ 18 bis < 24 Monate	1 (5,6)
≥ 24 Monate	2 (11,1)
Progressionsfreie Überlebensrate[d,f], % [95%-KI]	
≥ 6 Monate	94,4 [66,6; 99,2]
≥ 12 Monate	66,2 [36,5; 84,5]
Mediane Beobachtungsdauer (Monate)[d]	14,4

KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.
Der Prozentsatz wird basierend auf der Anzahl an Patienten in der Spaltenüberschrift als Nenner berechnet.
a: Status basiert auf der letzten Krankheitsbewertung des Patienten am oder vor dem Datenschnitt des 30. März 2020.
b: Ohne dokumentierte Krankheitsprogression.
c: Beurteilung erfolgte durch ein unabhängiges Expertenkomitee (Independent Review Committee [IRC]) anhand der RECIST Kriterien (Version 1.1).
d: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar.
e: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet.
f: Das 95%-KI wurde mittels Greenwood Formel berechnet.
Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_pfs_ge_2.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T008_pfs_tc_eff.rtf

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F002_3_pfs_c_tc_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

Eli Lilly and Company 08JAN2021:07:39
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
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/qa/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/OS_PFS_24mth.xls

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

Endpunkt	Selpercatinib Subpopulation C – TC (N=18)
Objektive Ansprechrate (CR+PR), n (%)	
Objektive Ansprechrate [95%-KI][a,b]	14 (77,8) [52,4; 93,6]

CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); PR: partielles Ansprechen; RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.

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_2.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T012_orr_tc_eff.rtf

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

Endpunkt	Selpercatinib Subpopulation C – TC (N=18)
Bestes Gesamtansprechen, n (%)	
Komplettes Ansprechen (CR)	1 (5,6)
Partielles Ansprechen (PR)	13 (72,2)
Stabile Erkrankung (SD)	4 (22,2)
SD*	4 (22,2)
Progressive Erkrankung (PD)	0 (0,0)
Nicht auswertbar	0 (0,0)
Krankheitskontrollrate, n (%)[a]	
Krankheitskontrollrate [95%-KI][a,b]	18 (100,0) [81,5; 100,0]

CR: komplettes Ansprechen; KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); PD: progressive Erkrankung; PR: partielles Ansprechen; RET: Rearranged during Transfection; SD: stabile Erkrankung; TC: Schilddrüsenkarzinom.

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_2.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T014_borcbr_tc_eff.rtf

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

Endpunkt	**Selpercatinib** **Subpopulation C – TC (N=18)**
Patienten mit Ansprechen, n[a,e]	14
Status des Ansprechens, n (%)[b,c]	
Progression	6 (42,9)
Tod (ohne vorherigen Progress)	1 (7,1)
Zensiert	7 (50,0)
Grund für Zensierung, n (%)	
Am Leben ohne Progress[d]	6 (42,9)
Anschl. Krebstherapie oder krebsbedingte Operation ohne Progress[d]	0 (0,0)
Abbruch der Studie ohne Progress[d]	1 (7,1)
Dauer des Ansprechens	
Dauer des Ansprechens (Monate), Median [95% KI][a,c,f,g,]	18,43 [7,6; NE]
Dauer des Ansprechens nach Kategorie, n (%)[a,c]	
< 6 Monate	4 (28,6)
≥ 6 bis < 12 Monate	3 (21,4)
≥ 12 bis < 18 Monate	4 (28,6)
≥ 18 bis < 24 Monate	1 (7,1)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_dor_ge_2.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T009_dor_tc_eff.rtf

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

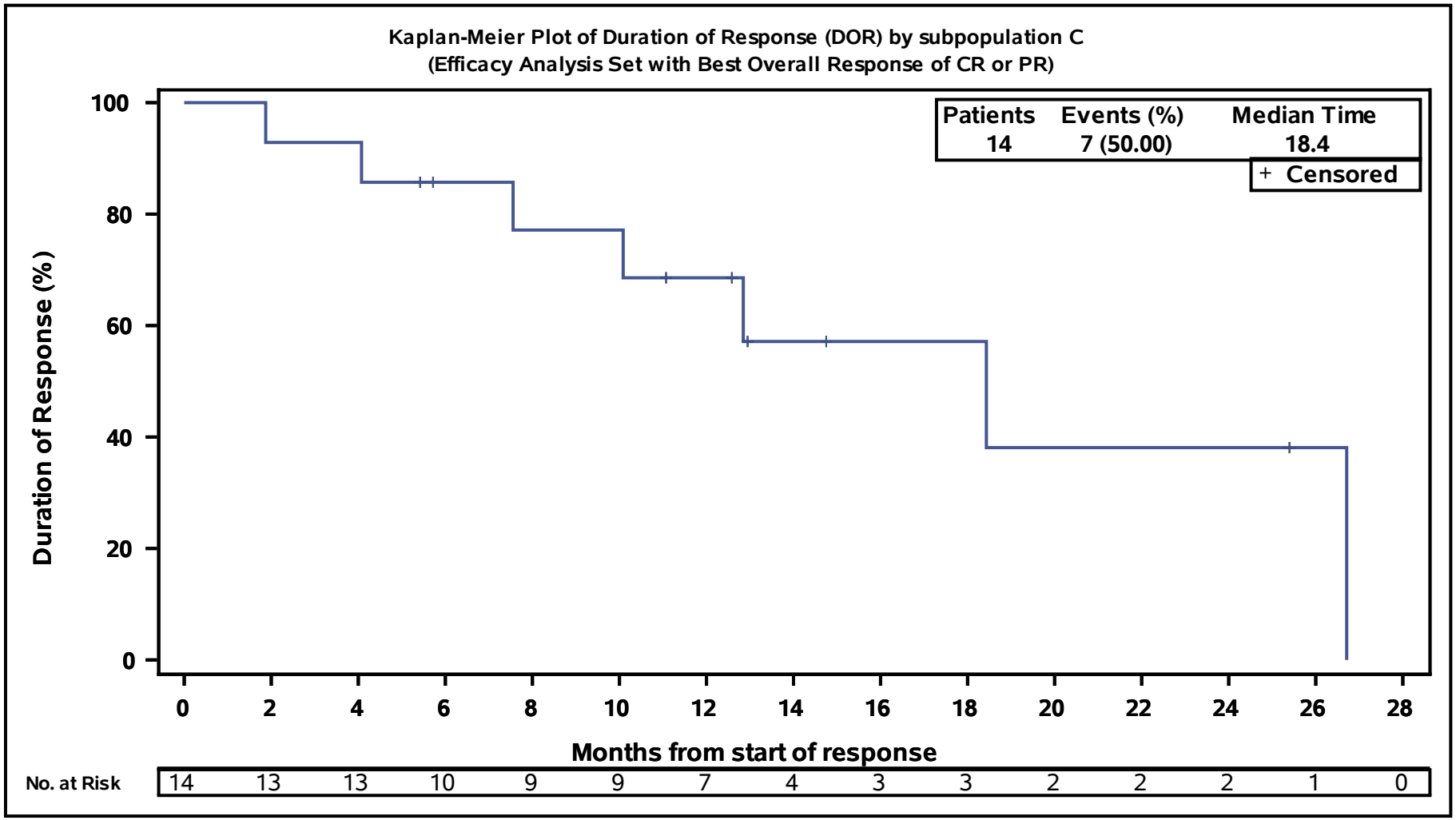
Endpunkt	**Selpercatinib** **Subpopulation C – TC (N=18)**
≥ 24 Monate	2 (14,3)

KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_dor_ge_2.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T009_dor_tc_eff.rtf

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



Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F003_3_dor_c_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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

Endpunkt	**Selpercatinib** **Subpopulation C – TC (N=18)**
Patienten mit Ansprechen, n[a,c]	14
Zeit bis zum Ansprechen	
Zeit bis zum Ansprechen (Monate), Median [95%-KI][b]	1,66 [0,8; 1,8]
Zeit bis zum Ansprechen nach Kategorie, n (%)[b]	
< 2 Monate	12 (85,7)
≥ 2 und < 4 Monate	2 (14,3)
≥ 4 und < 6 Monate	0 (0,0)
≥ 6 und < 9 Monate	0 (0,0)
≥ 9 Monate	0 (0,0)

KI: Konfidenzintervall; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Efficacy Analysis Set); RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.

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.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_ttr_ge_2.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T011_ttr_tc_eff.rtf

Tabelle 030.v3: Compliance-Rate für den Fragebogen EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020)
- Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation C - TC (N'=9) (N=18)
Gesamtrate[a] über alle Zeitpunkte	46/56 (82,1)
Compliance-Rate[b] pro geplante Visite	
Baseline	9/18 (50,0)
Zyklus 3, Tag 1	7/18 (38,9)
Zyklus 5, Tag 1	8/18 (44,4)
Zyklus 7, Tag 1	7/18 (38,9)
Zyklus 9, Tag 1	7/18 (38,9)
Zyklus 11, Tag 1	3/18 (16,7)
Zyklus 13, Tag 1	3/18 (16,7)
Zyklus 16, Tag 1	1/18 (5,6)
Zyklus 19, Tag 1	1/18 (5,6)
Visite bei Ende der Behandlung	0/18 (0,0)

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; QLQ-C30: Core Quality of Life Questionnaire C30;
RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.
a: Die Gesamtrate wird berechnet, in dem die Gesamtzahl an Patienten, für die der EORTC QLQ-C30 bei jeder Visite erhoben wurde, durch die Gesamtzahl an Patienten, die bei jeder Visite unter Behandlung waren, geteilt wird.
b: Die Compliance-Rate ist definiert als der prozentuale Anteil der Patienten, für die der EORTC QLQ-C30 bei der entsprechenden Visite erhoben wurde, an den Patienten, die bei dieser Visite unter Behandlung waren. Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqcomp_tc_ge.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/csr2/data/analysis/shared
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T030_sp_qlqcomp_tc_eff.rtf

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

Endpunkt	Selpercatinib Subpopulation C - TC (N') (N=18)
EORTC QLQ-C30 – Symptomskalen	
Fatigue	9
Patienten mit Ereignis	
Verbesserung, n (%)	6 (66,7)
Zensierte Patienten, n (%)	3 (33,3)
Verschlechterung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	1,9 [1,64; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	7,3 [1,87; NE]
Schmerzen	9
Patienten mit Ereignis	
Verbesserung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Verschlechterung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Übelkeit und Erbrechen	9
Patienten mit Ereignis	
Verbesserung, n (%)	2 (22,2)
Zensierte Patienten, n (%)	7 (77,8)
Verschlechterung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,81; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Dyspnoe	9
Patienten mit Ereignis	
Verbesserung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Verschlechterung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [3,71; NE]
Schlaflosigkeit	9
Patienten mit Ereignis	
Verbesserung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Verschlechterung, n (%)	5 (55,6)
Zensierte Patienten, n (%)	4 (44,4)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	7,3 [1,87; NE]

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_ge.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T031_sp_qlqc30_tte_tc_eff.rtf

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

Endpunkt	Selpercatinib Subpopulation C - TC (N') (N=18)
Appetitverlust	9
Patienten mit Ereignis	
Verbesserung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Verschlechterung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	6,5 [1,81; NE]
Verstopfung	9
Patienten mit Ereignis	
Verbesserung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Verschlechterung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Diarrhoe	9
Patienten mit Ereignis	
Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Verschlechterung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	7,4 [1,87; NE]

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;
LQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.
a: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar.
b: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet.
Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.
Verbesserung ist definiert als Anstieg im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline.
Verschlechterung ist definiert als Reduktion im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline.
Zeit bis zur ersten Verbesserung bzw. Verschlechterung ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und dem ersten Auftreten einer Verbesserung bzw. Verschlechterung in den jeweiligen Symptomskalen.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_ge.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T031_sp_qlqc30_tte_tc_eff.rtf

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

Endpunkt	Selpercatinib Subpopulation C - TC (N') (N=18)
EORTC QLQ-C30 - Globaler Gesundheitsstatus	9
Patienten mit Ereignis	
Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Verschlechterung, n (%)	5 (55,6)
Zensierte Patienten, n (%)	4 (44,4)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	5,6 [1,64; NE]
EORTC QLQ-C30 – Funktionsskalen	
Physische Funktion	9
Patienten mit Ereignis	
Verbesserung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Verschlechterung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,81; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [3,75; NE]
Emotionale Funktion	9
Patienten mit Ereignis	
Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Verschlechterung, n (%)	5 (55,6)
Zensierte Patienten, n (%)	4 (44,4)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [3,71; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	6,5 [1,87; NE]
Rollenfunktion	9
Patienten mit Ereignis	
Verbesserung, n (%)	2 (22,2)
Zensierte Patienten, n (%)	7 (77,8)
Verschlechterung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	7,4 [1,81; NE]
Kognitive Funktion	9
Patienten mit Ereignis	
Verbesserung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Verschlechterung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	14,5 [1,81; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,64; NE]

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_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/T032_sp_qlqc30_tte_tc_eff.rtf

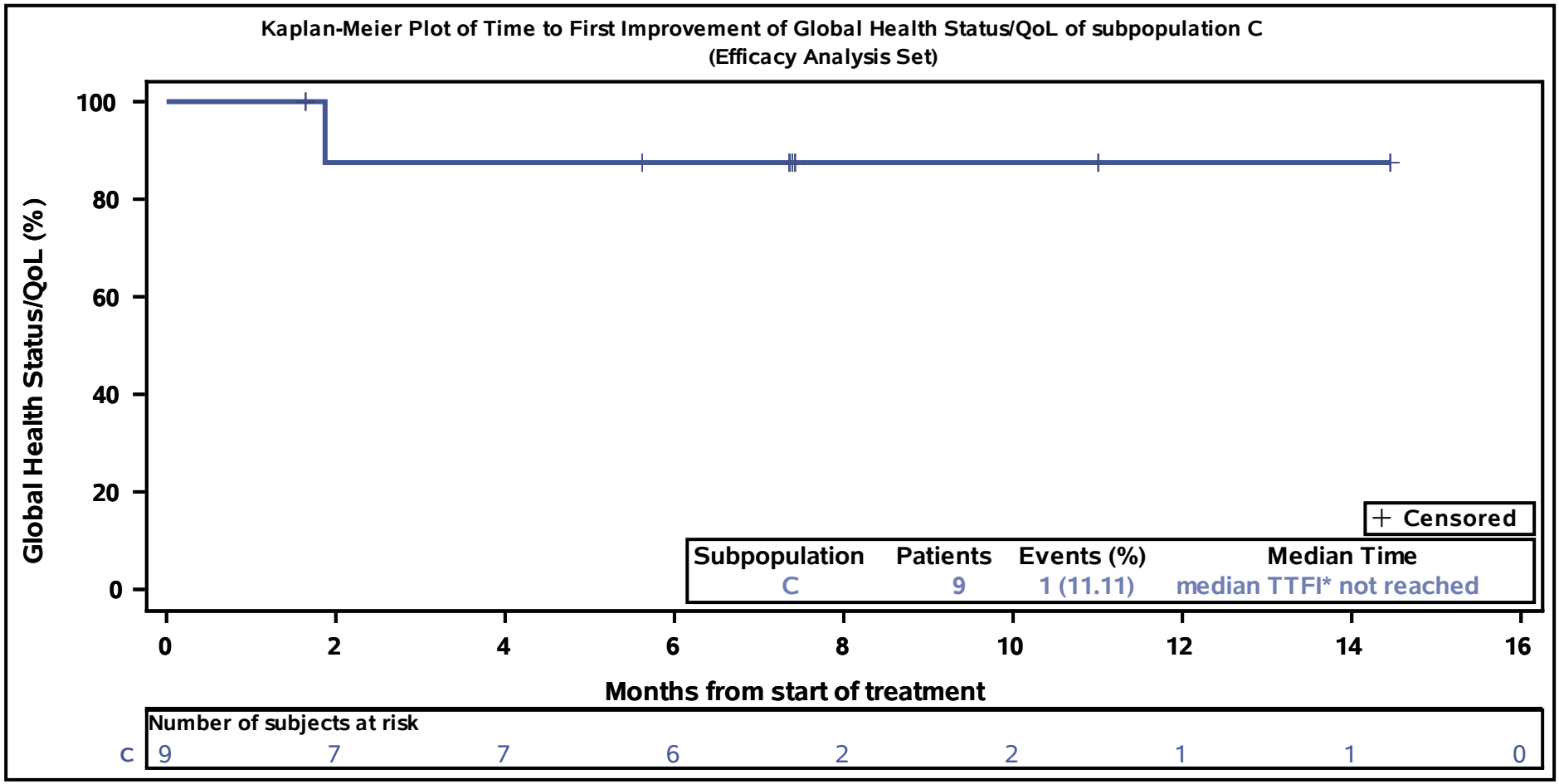
Tabelle 032: Ergebnisse für die Zeit bis zur ersten Verbesserung bzw. Verschlechterung der gesundheitsbezogenen Lebensqualität gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020)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

Endpunkt	Selpercatinib Subpopulation C - TC (N') (N=18)
Soziale Funktion	9
Patienten mit Ereignis	
Verbesserung, n (%)	2 (22,2)
Zensierte Patienten, n (%)	7 (77,8)
Verschlechterung, n (%)	5 (55,6)
Zensierte Patienten, n (%)	4 (44,4)
Mediane Zeit bis zur ersten Verbesserung (Monate) [95%-KI] [a,b]	NE [1,81; NE]
Mediane Zeit bis zur ersten Verschlechterung (Monate) [95%-KI] [a,b]	7,4 [1,64; NE]

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;
LQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.
a: Die Schätzung basiert auf der Kaplan-Meier Methode. NE = nicht schätzbar.
b: Das 95%-KI wurde mittels Brookmeyer und Crowley Methode berechnet.
Patienten im Efficacy Analysis Set mussten die erste Dosis der Prüfmedikation mindestens 6 Monate vor dem Datenschnitt erhalten haben.
Verbesserung ist definiert als Anstieg im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline.
Verschlechterung ist definiert als Reduktion im jeweiligen EORTC QLQ-C30 Score um ≥ 10 Punkte gegenüber Baseline.
Zeit bis zur ersten Verbesserung bzw. Verschlechterung ist definiert als Anzahl der Monate zwischen der ersten Dosis der Prüfmedikation und dem ersten Auftreten einer Verbesserung bzw. Verschlechterung in den jeweiligen Symptomskalen.

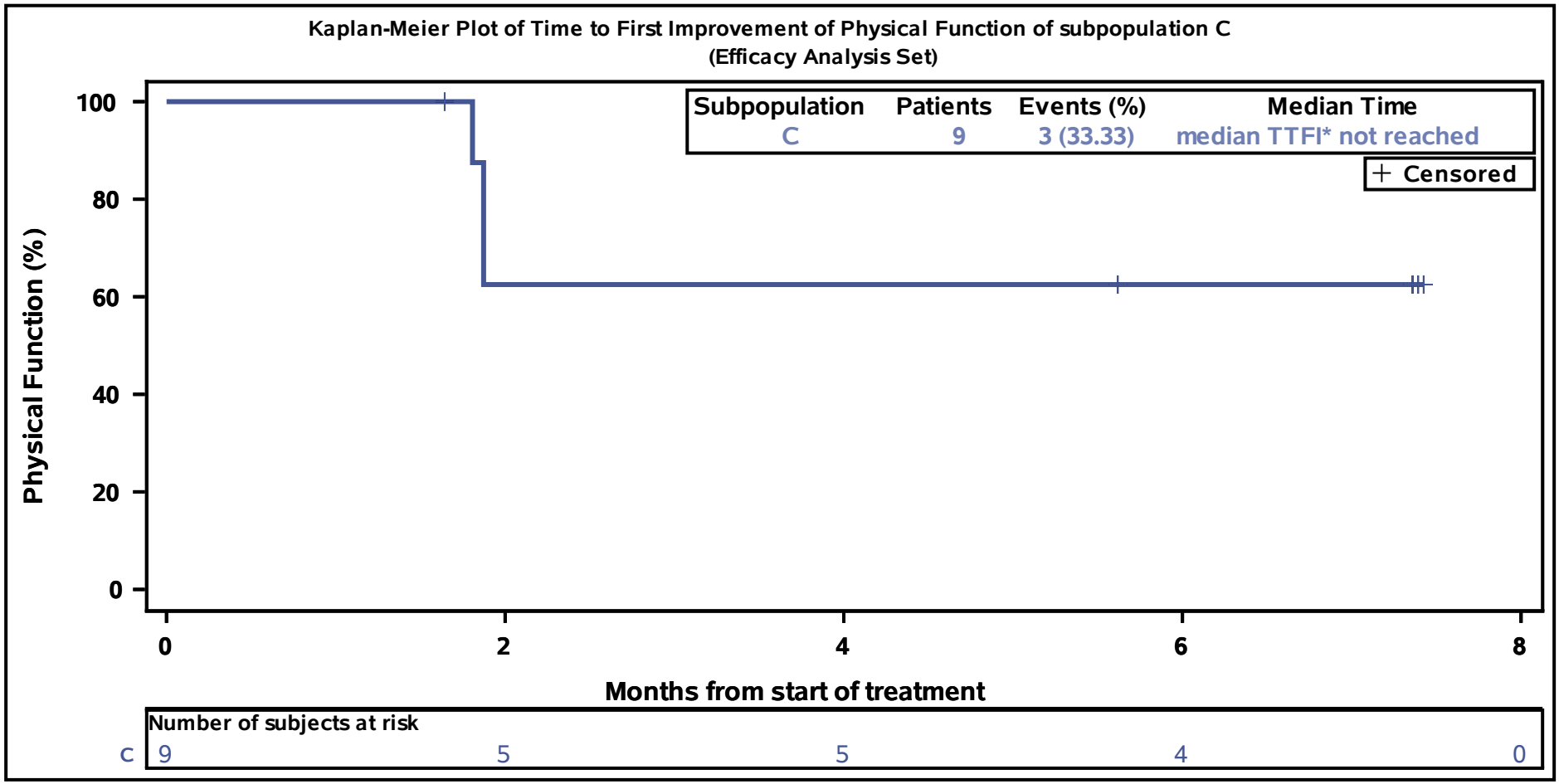
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_ge.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T032_sp_qlqc30_tte_tc_eff.rtf

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



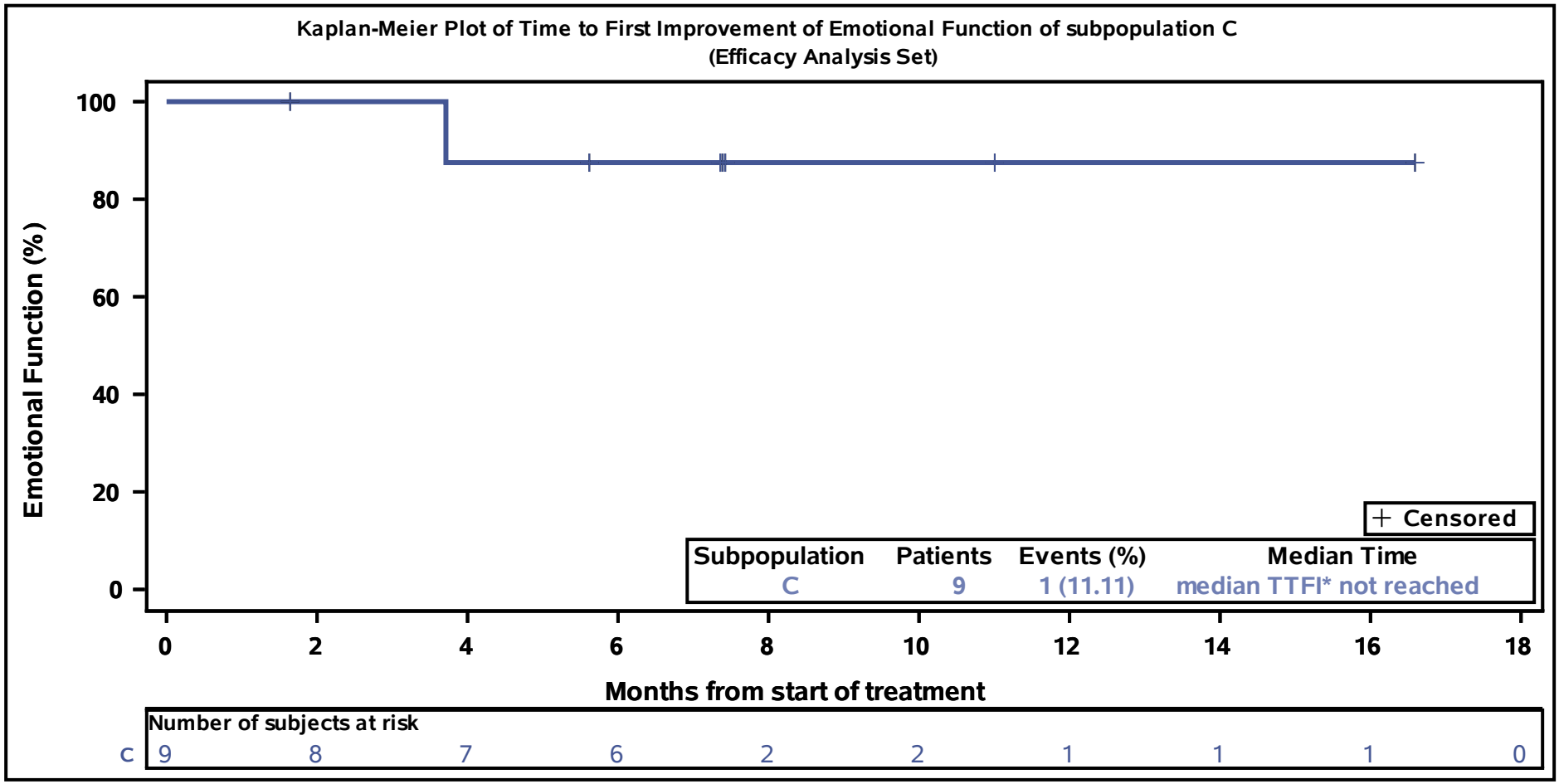
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F005_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



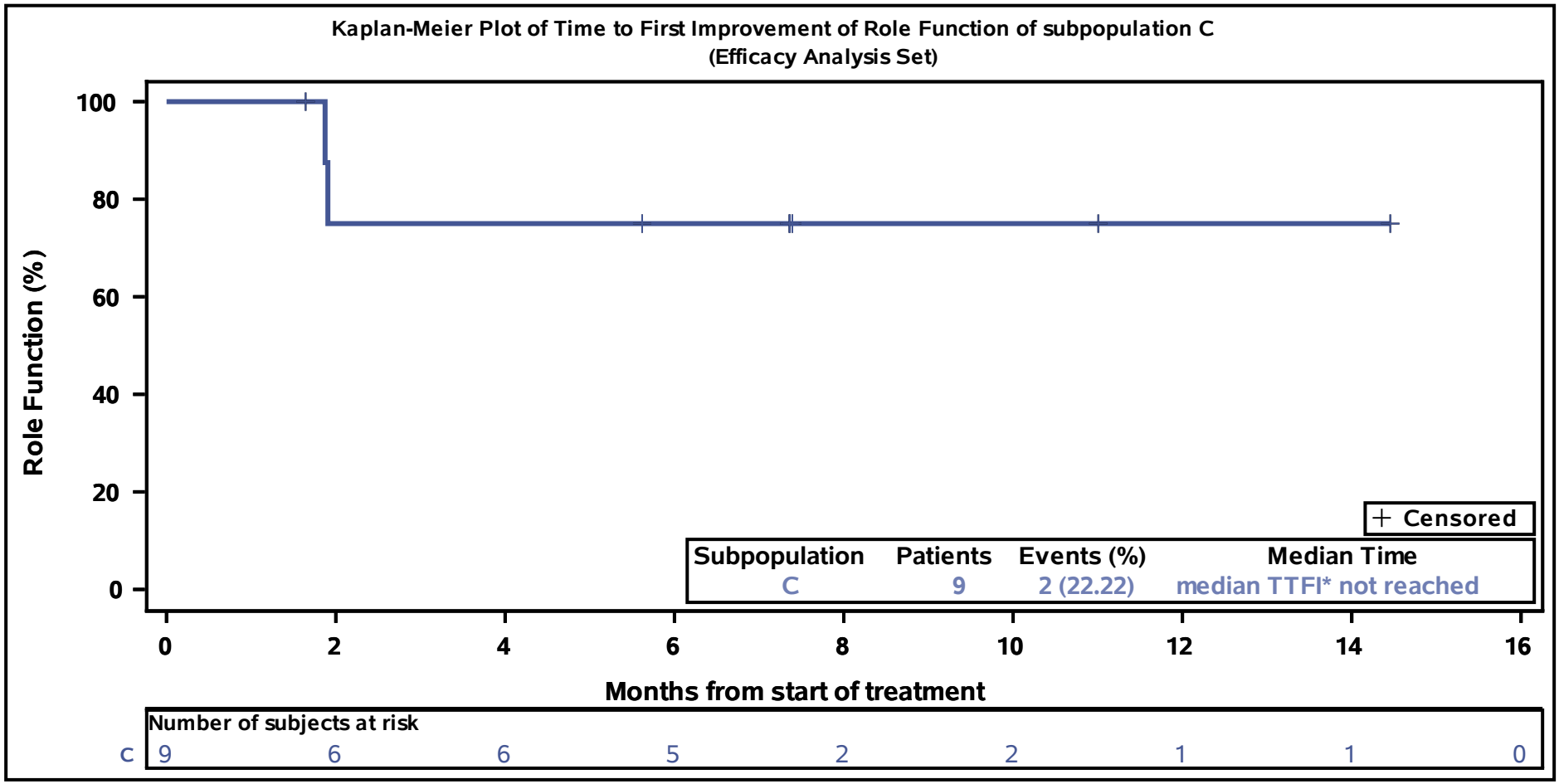
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F006_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



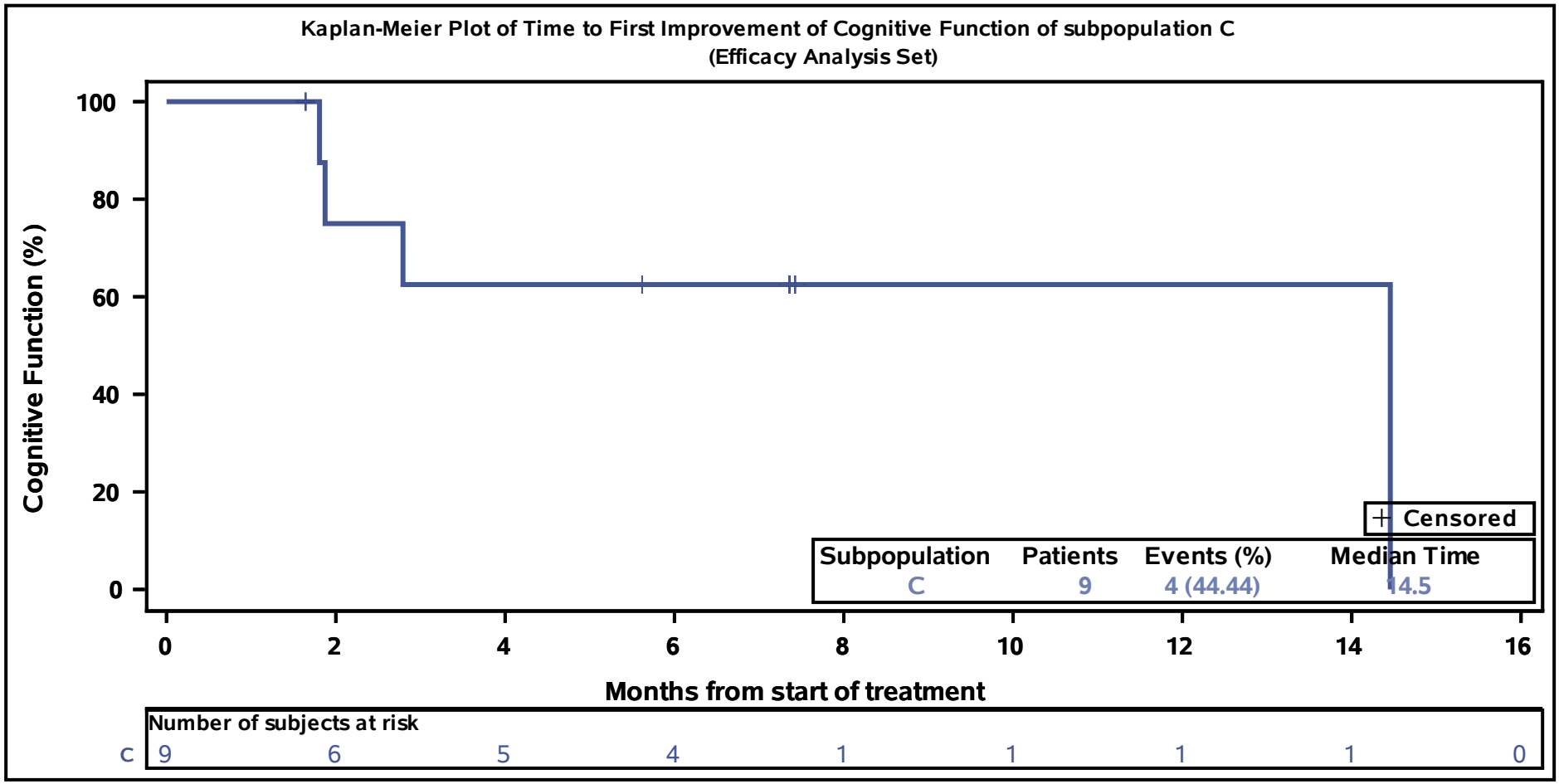
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F007_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



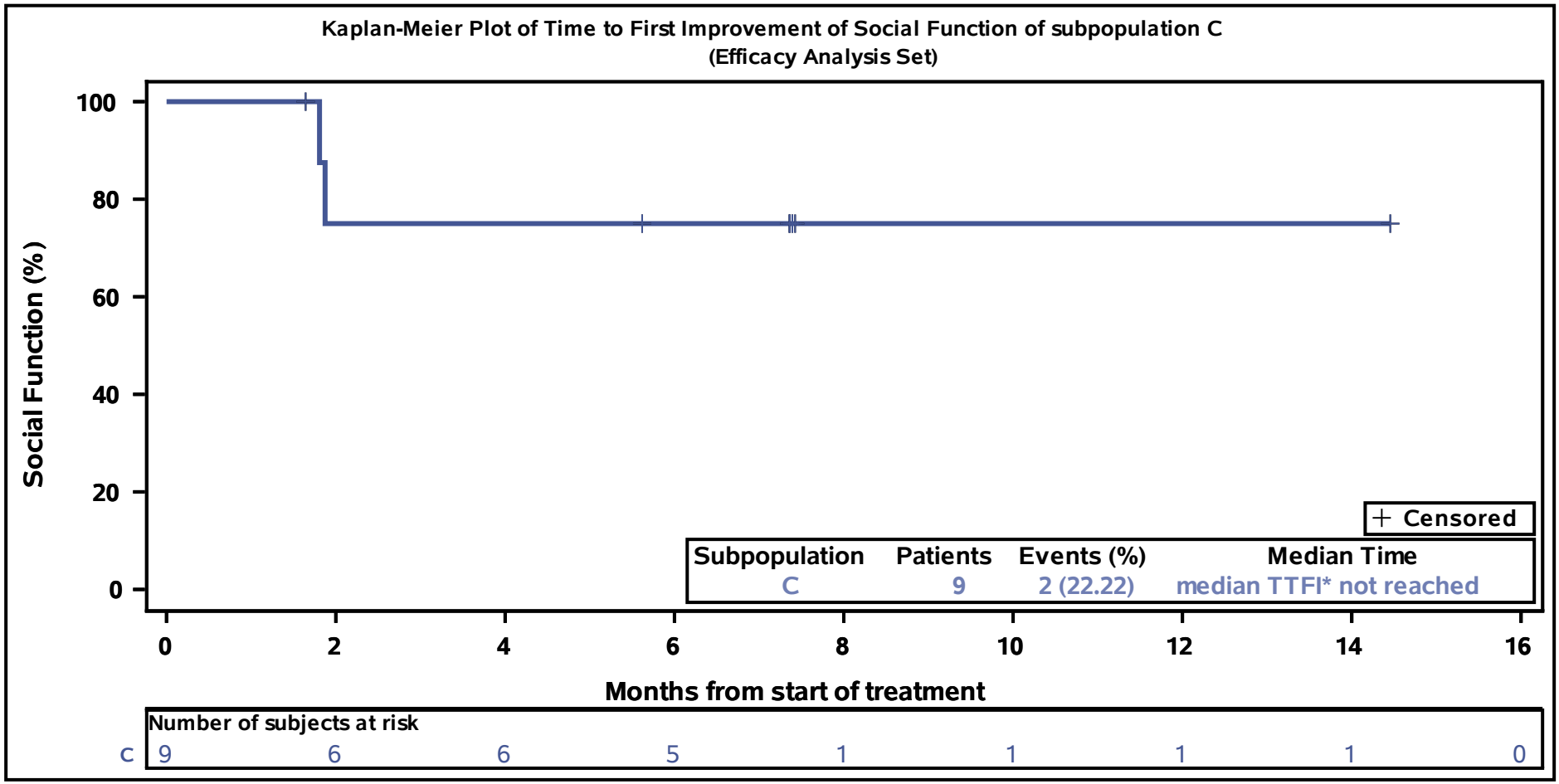
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F008_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



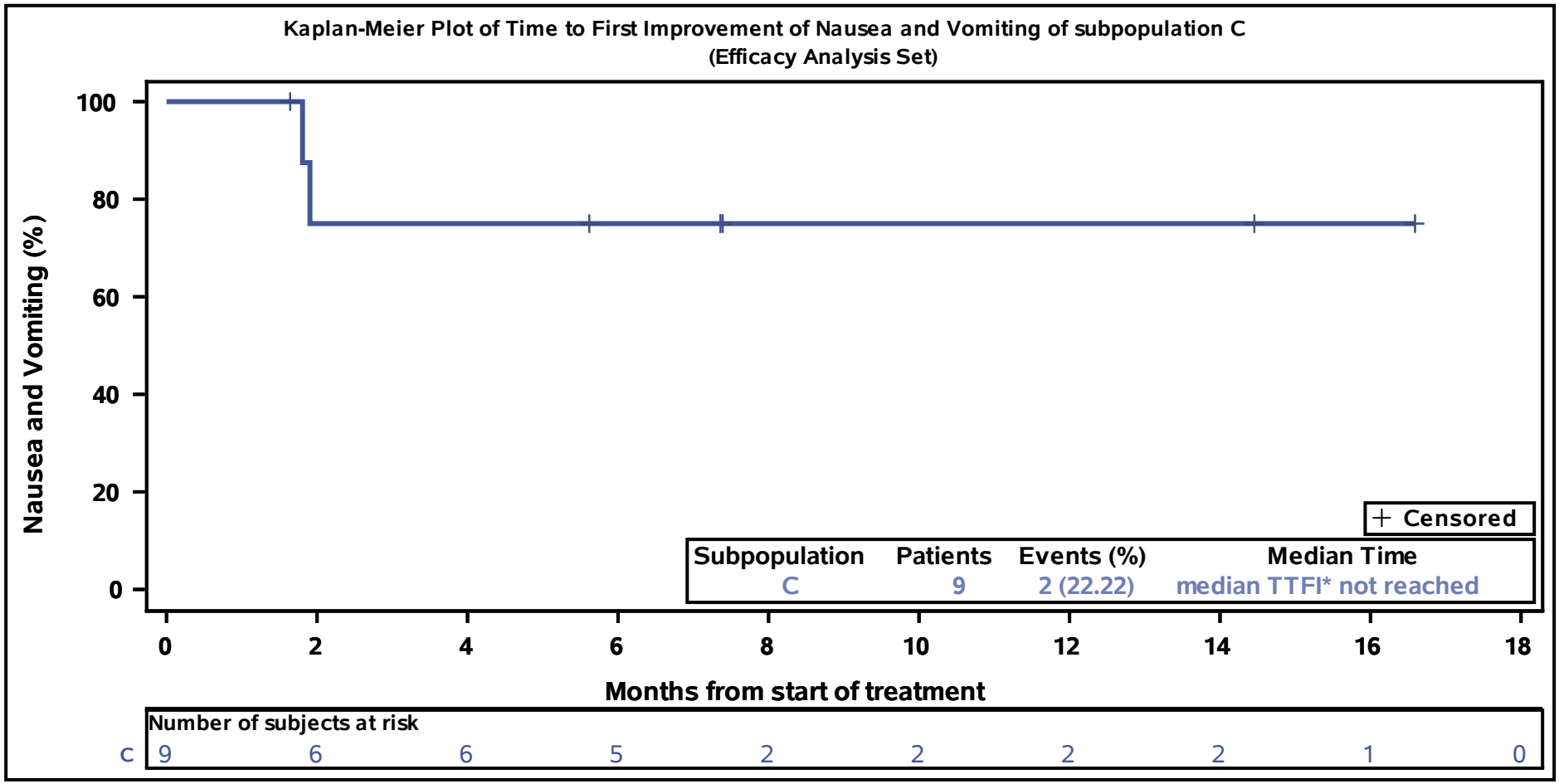
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F009_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



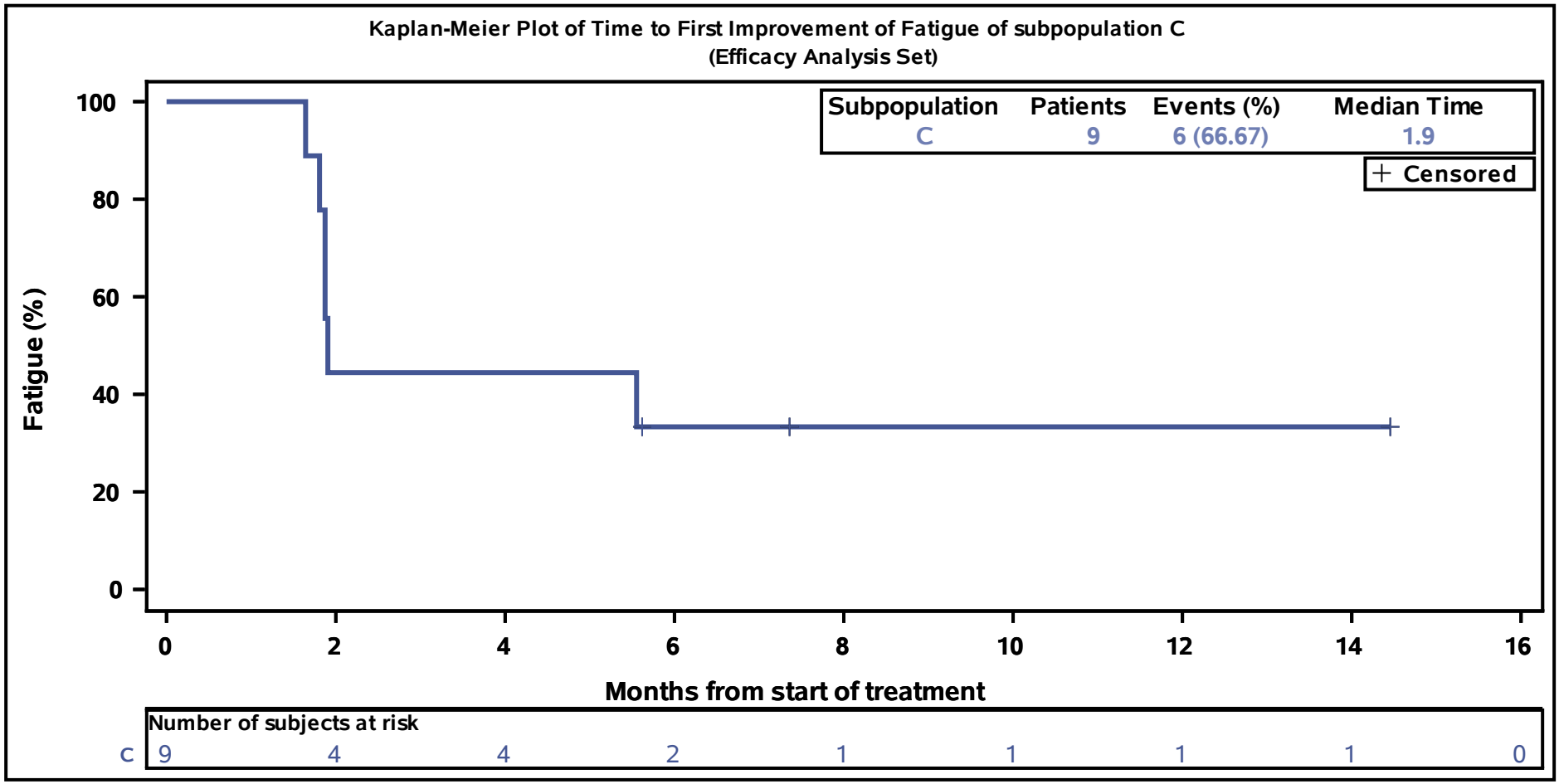
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F010_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



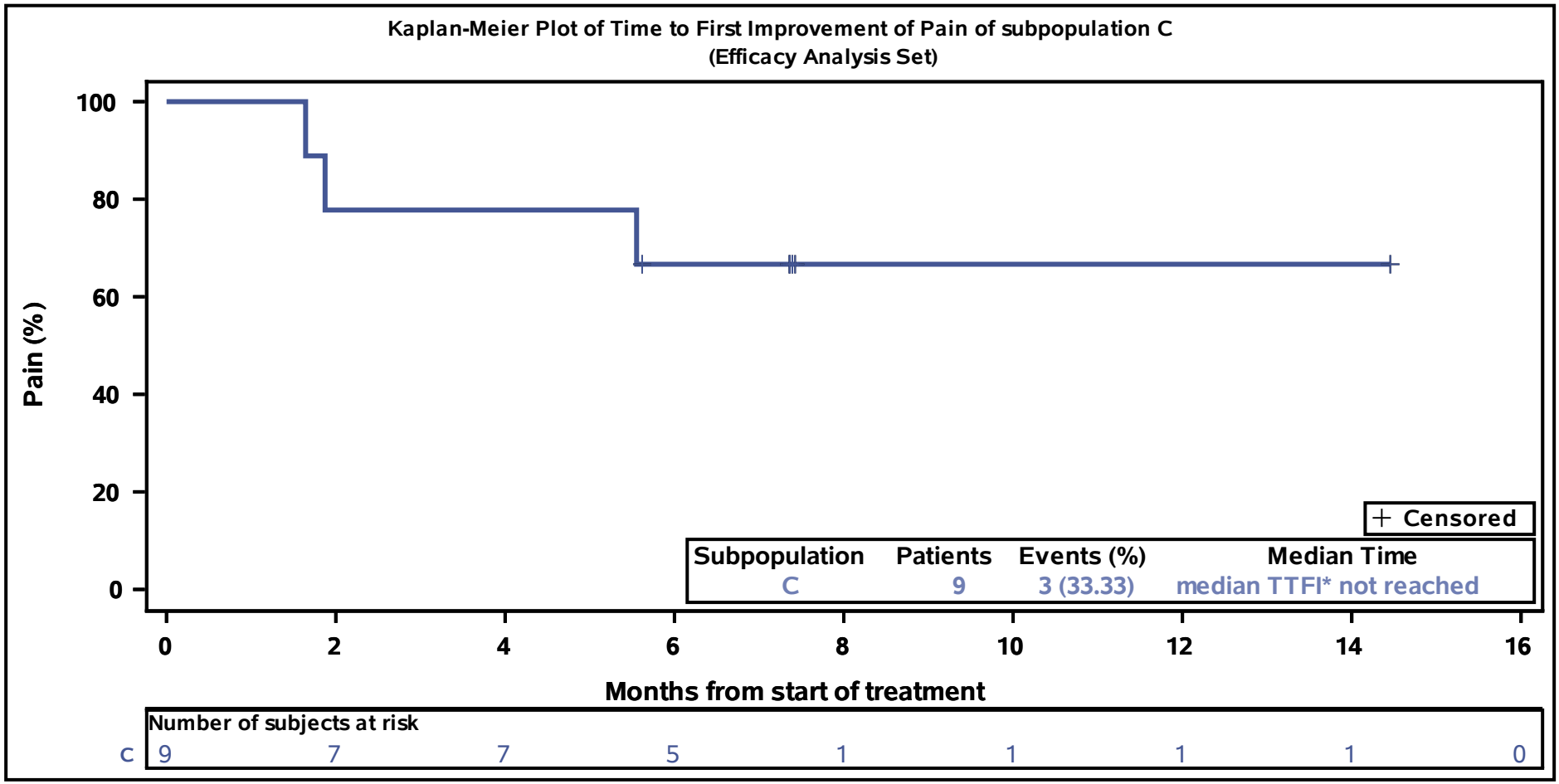
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F011_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



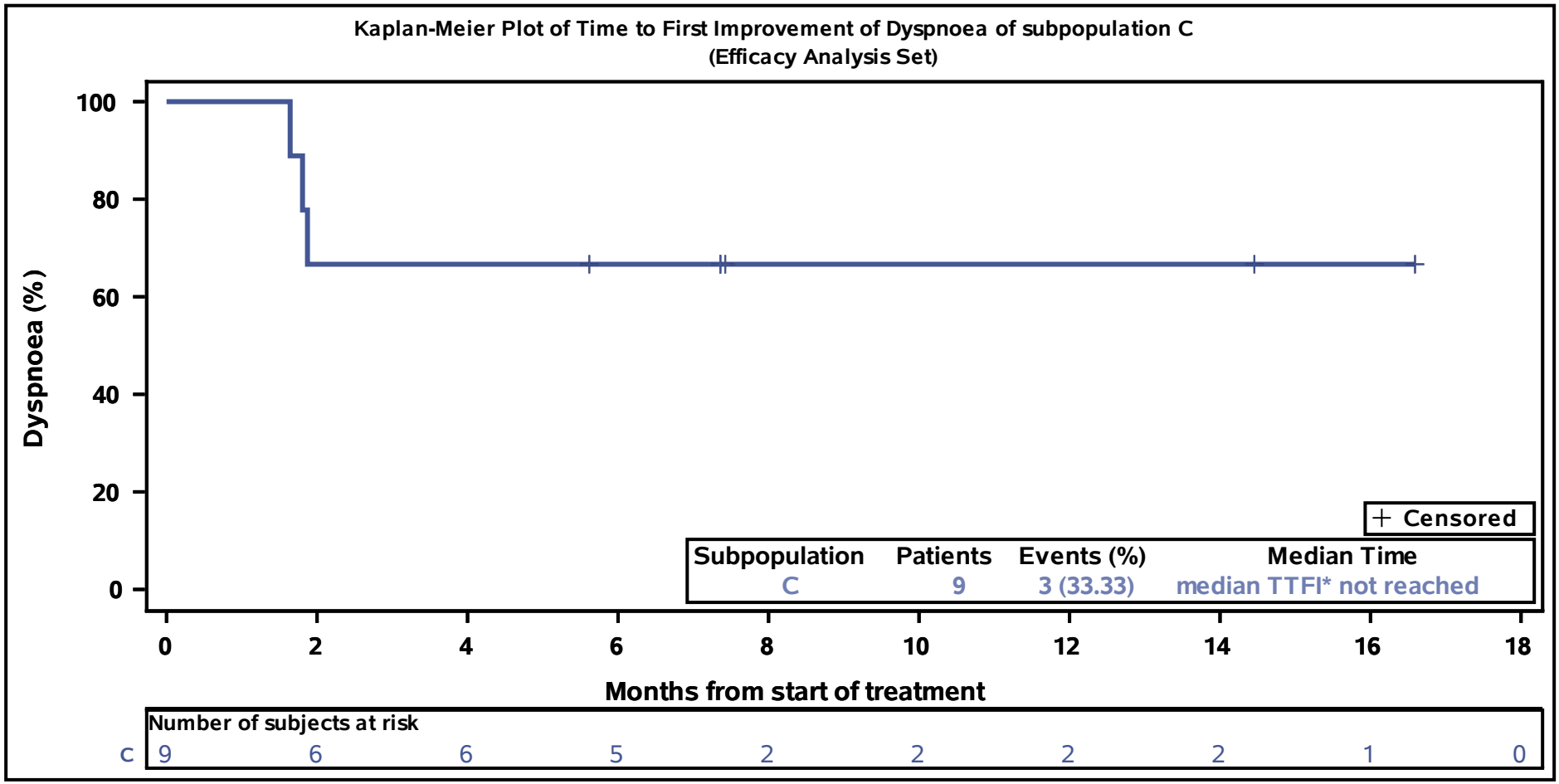
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F012_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



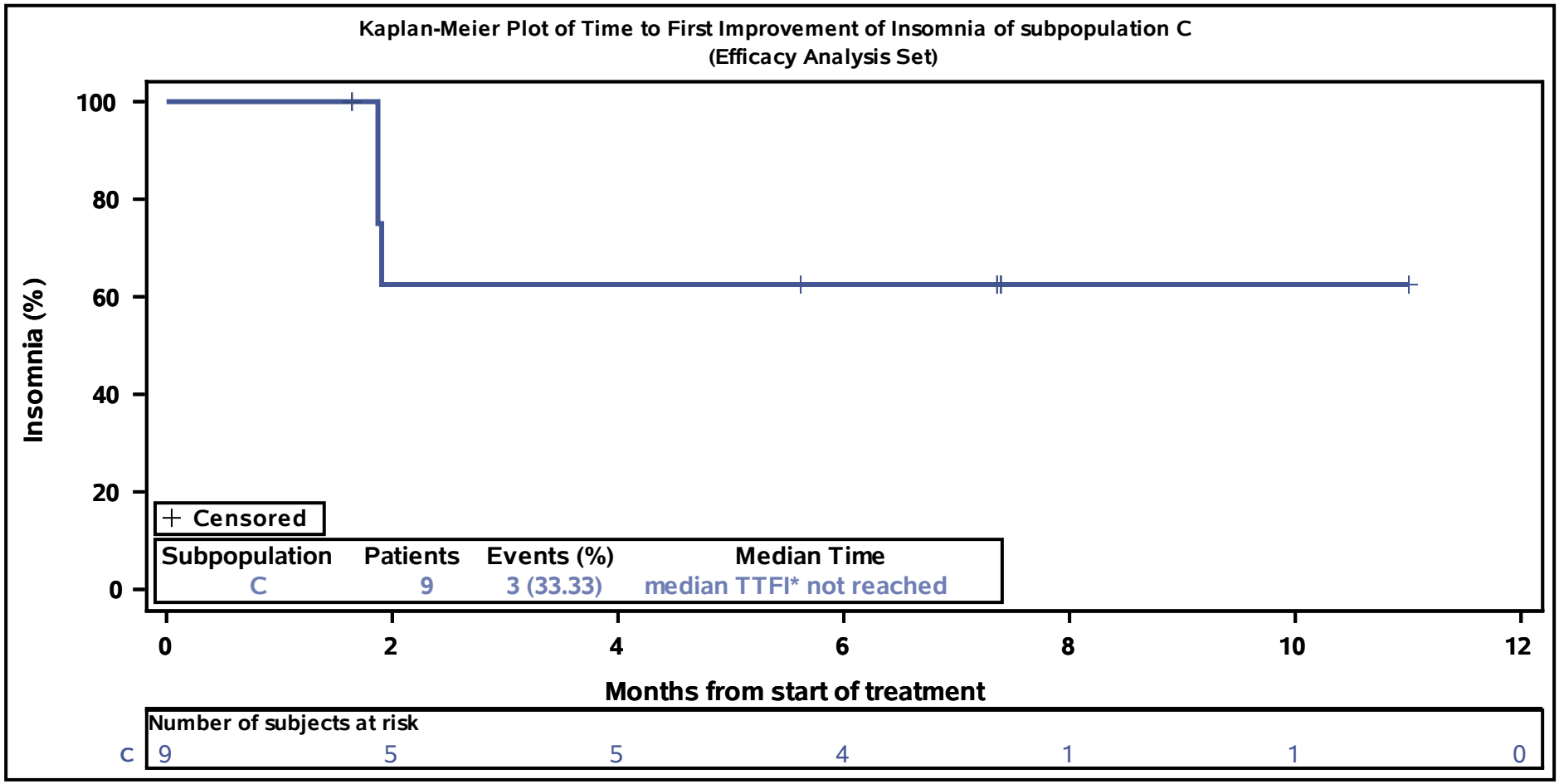
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F013_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



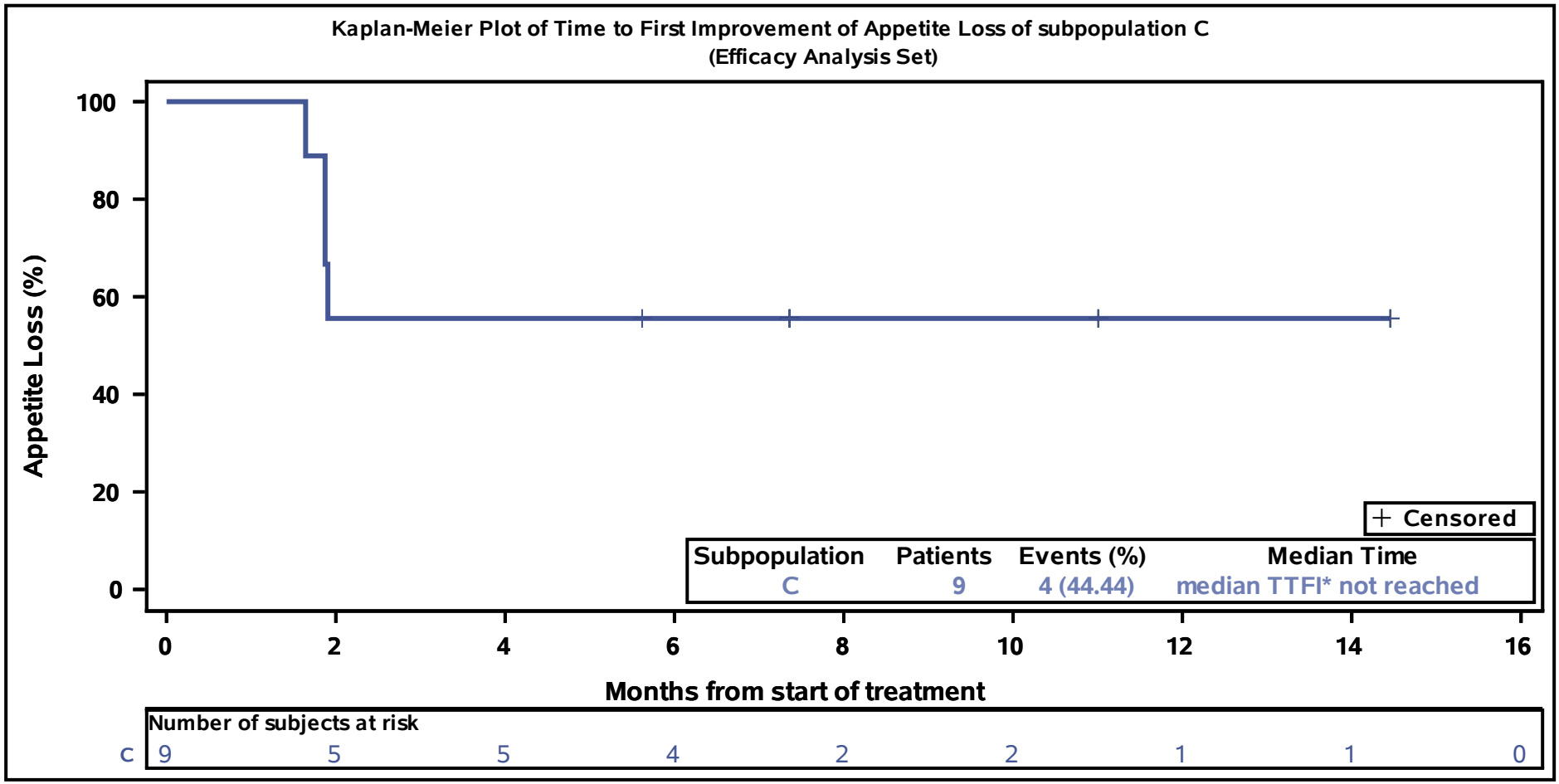
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F014_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



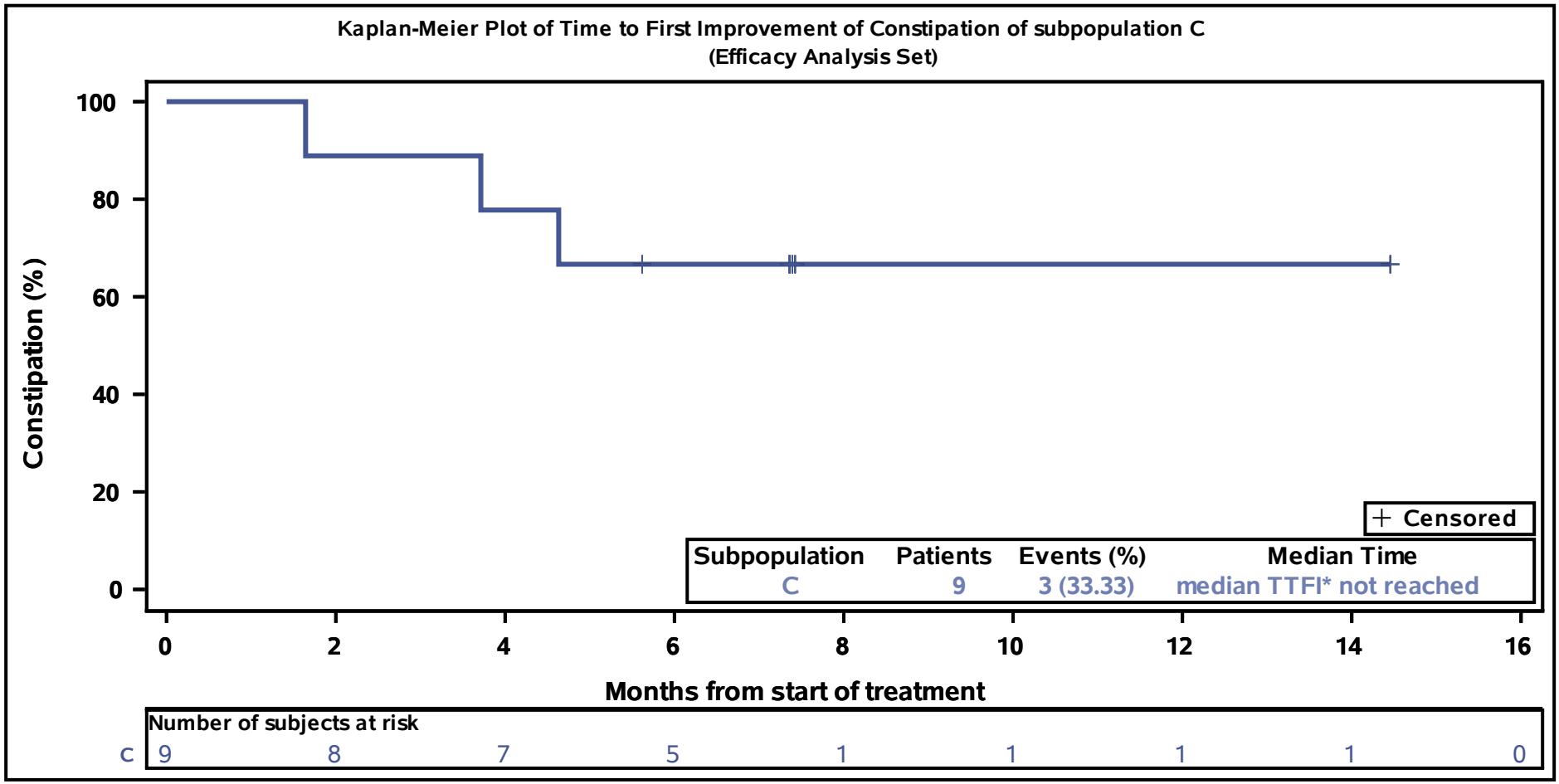
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F015_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



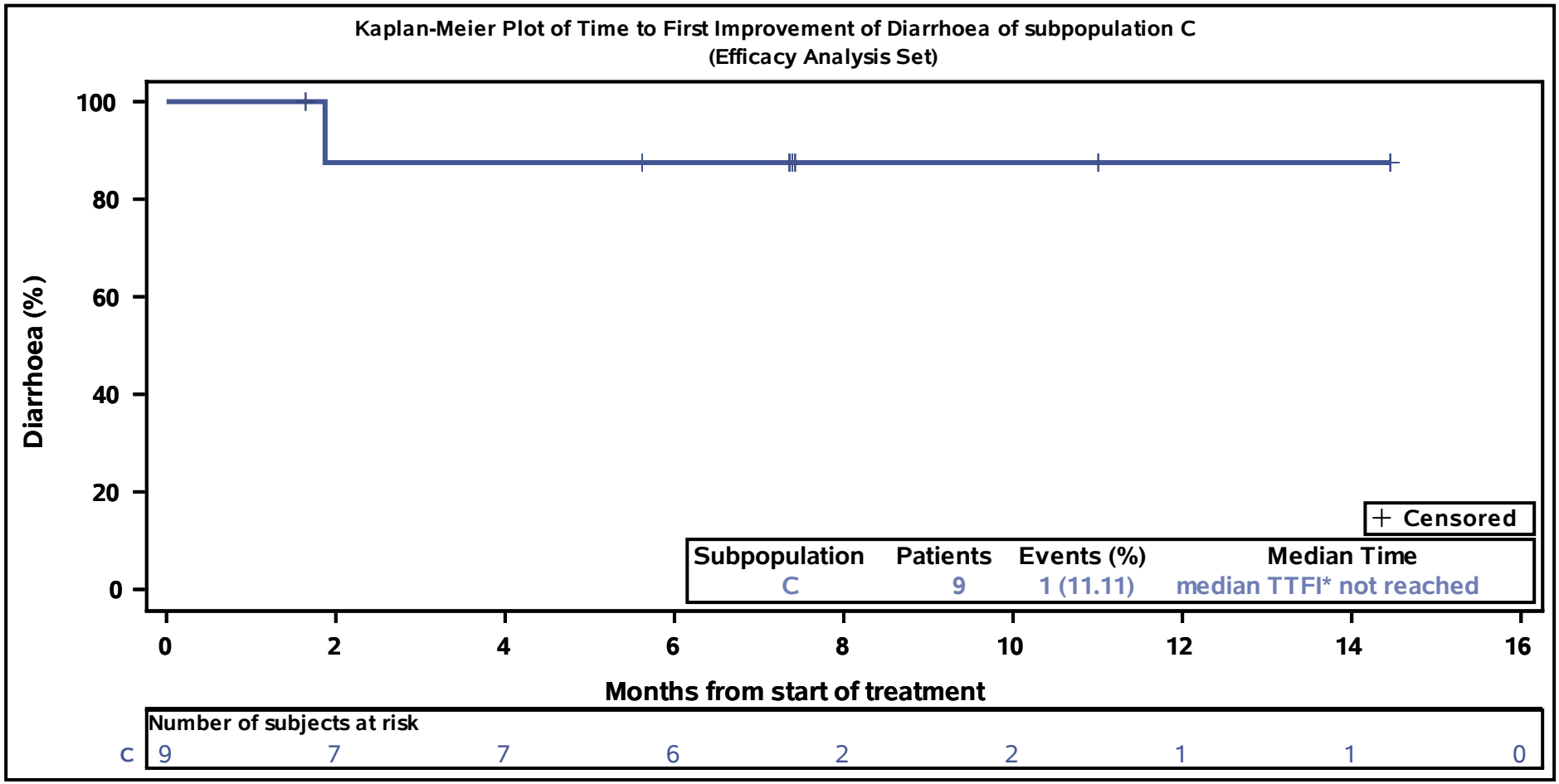
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F016_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



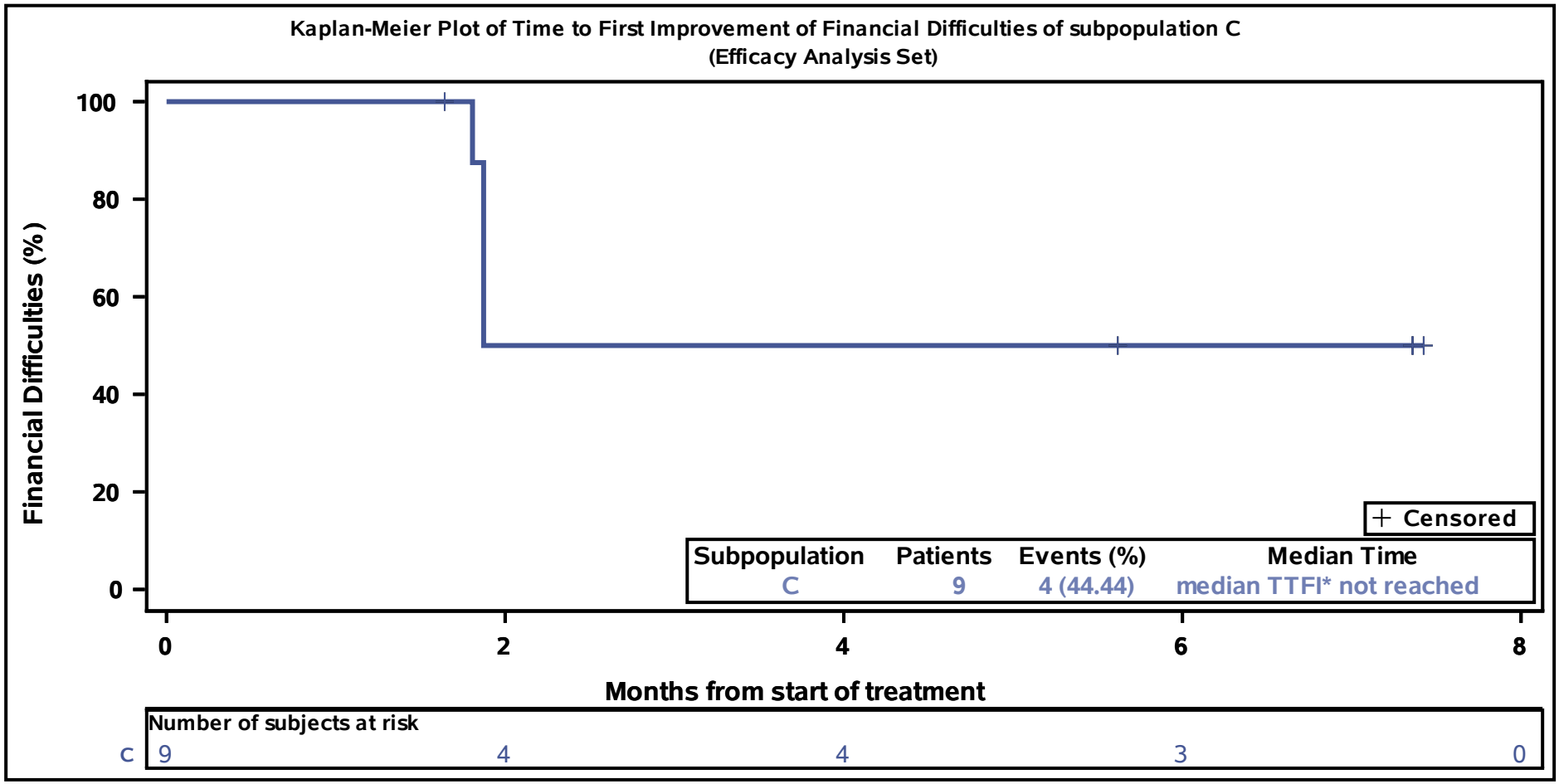
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F017_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



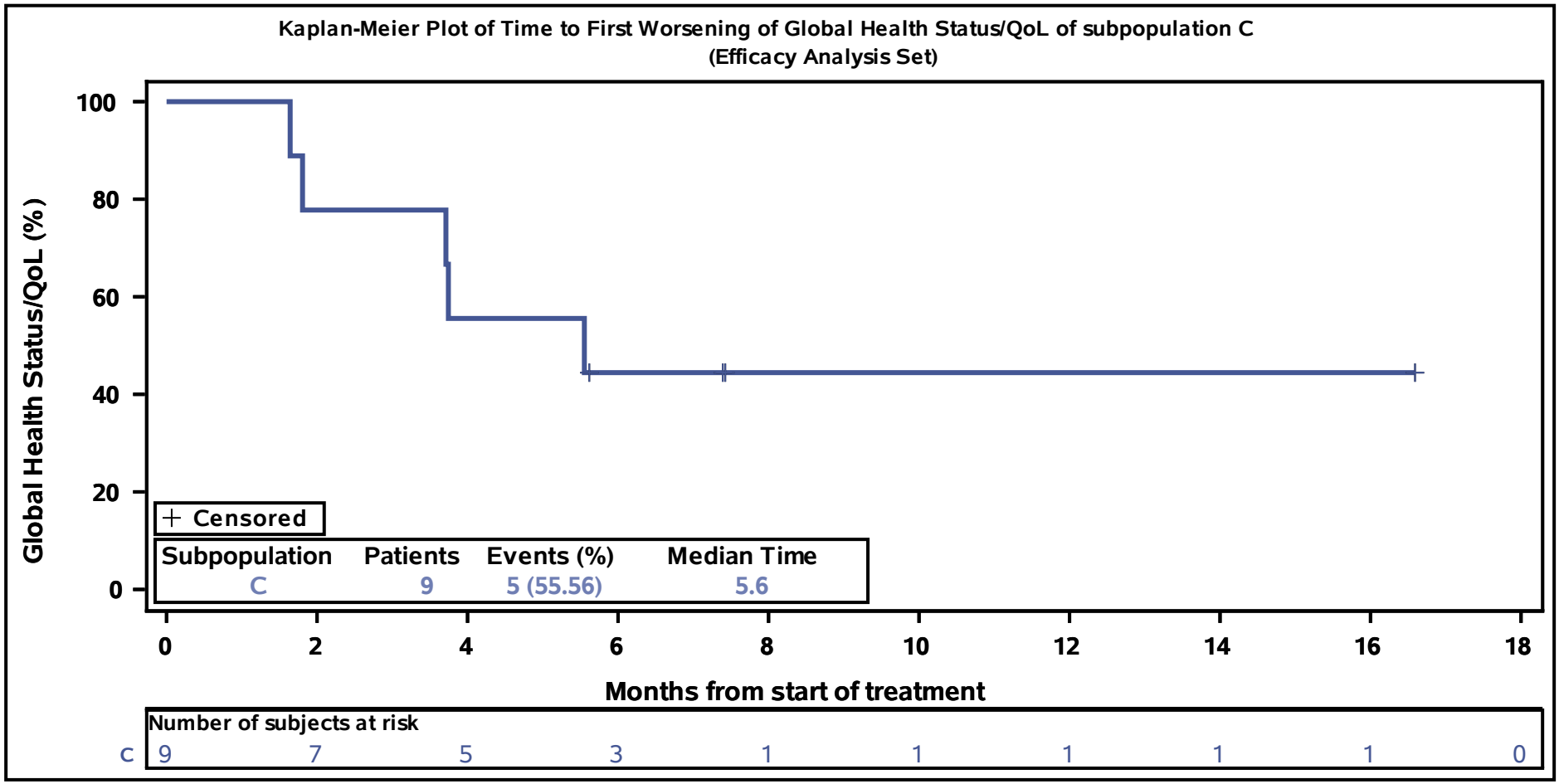
* TTFI = Time-to-First Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F018_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F019_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

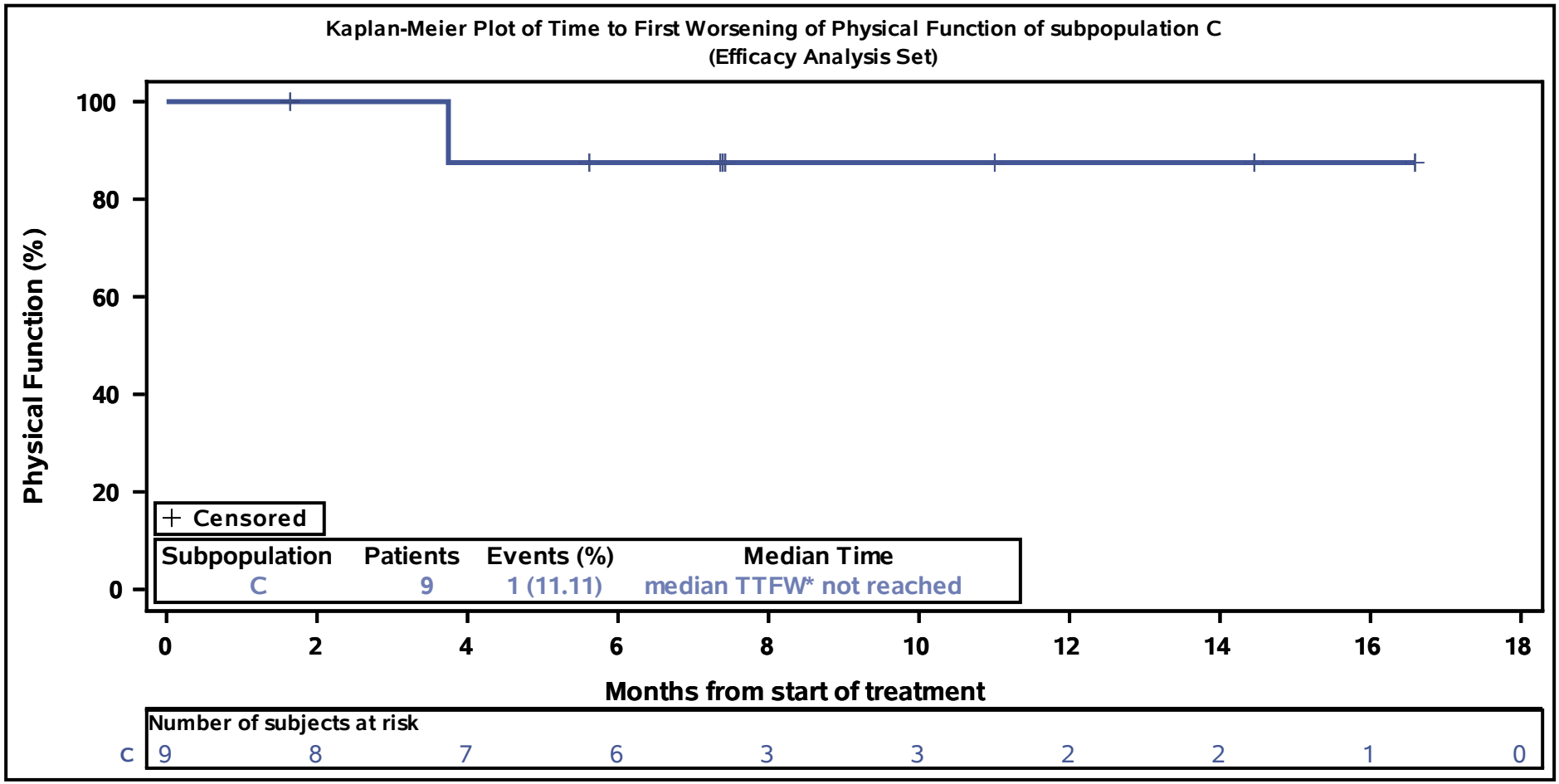
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (Visit Cutoff 30-MAR-2020)



Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F020_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

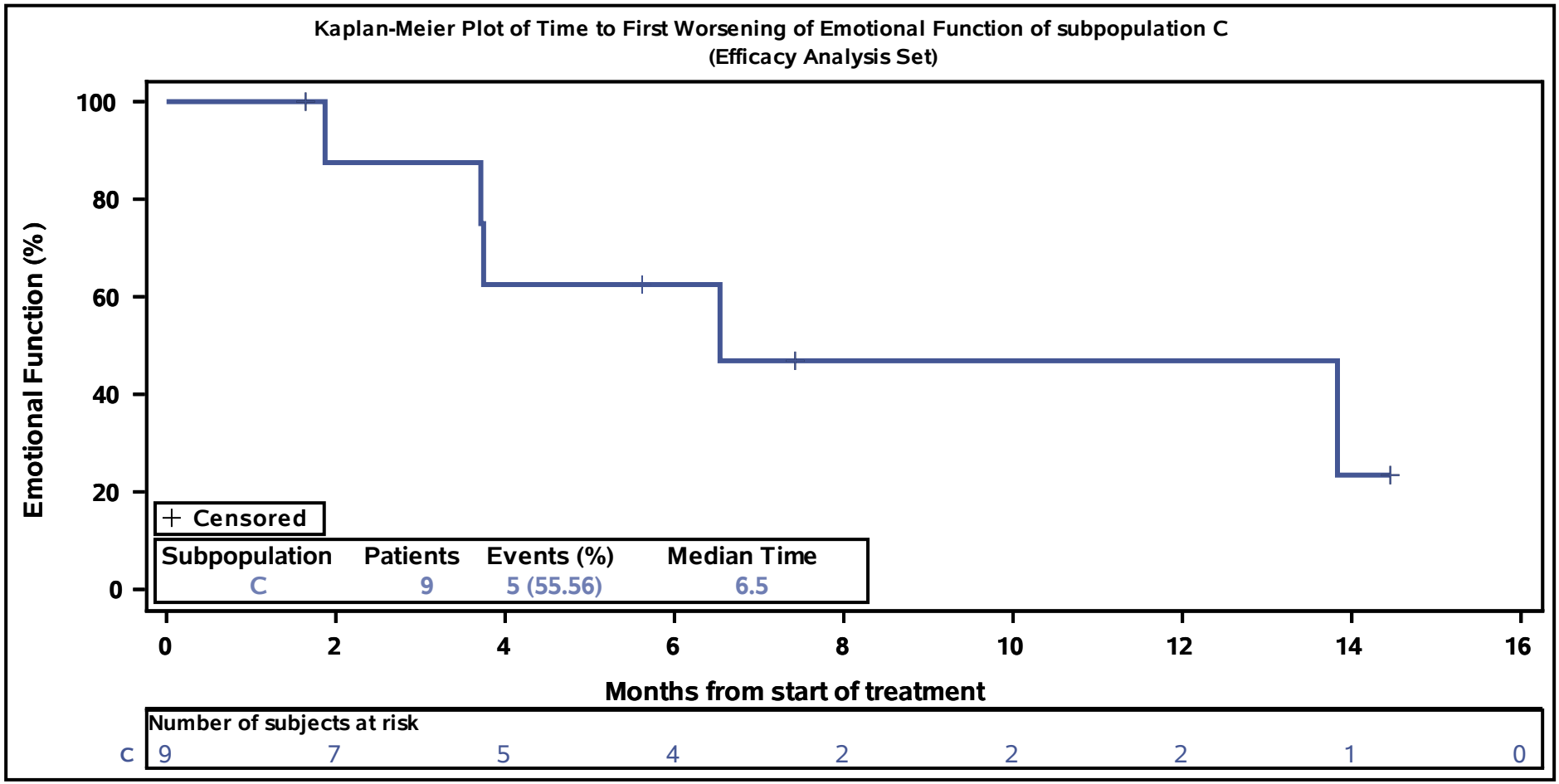
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (Visit Cutoff 30-MAR-2020)

02:11 23DEC2020



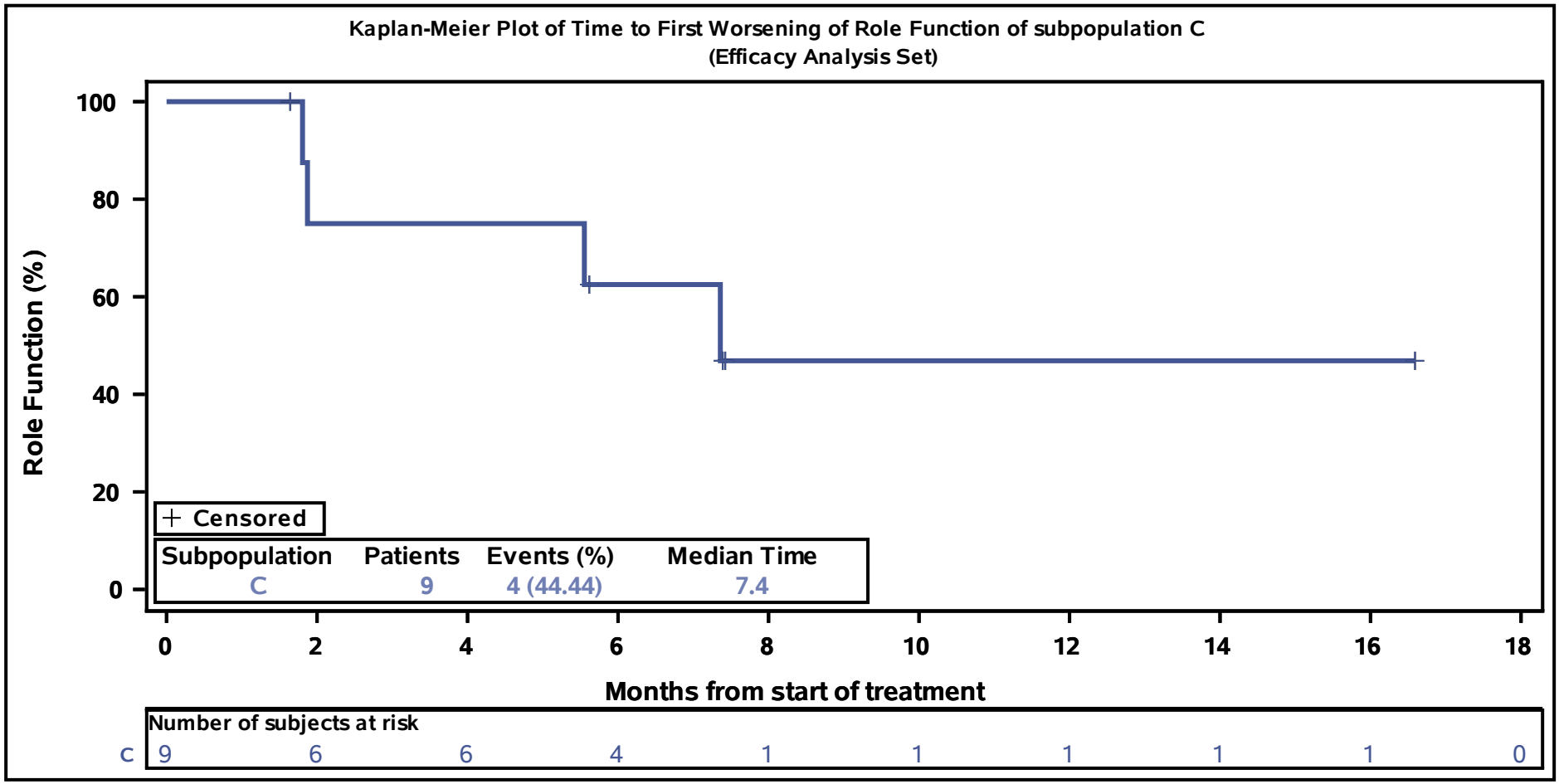
* TTFW = Time-to-First Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F021_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



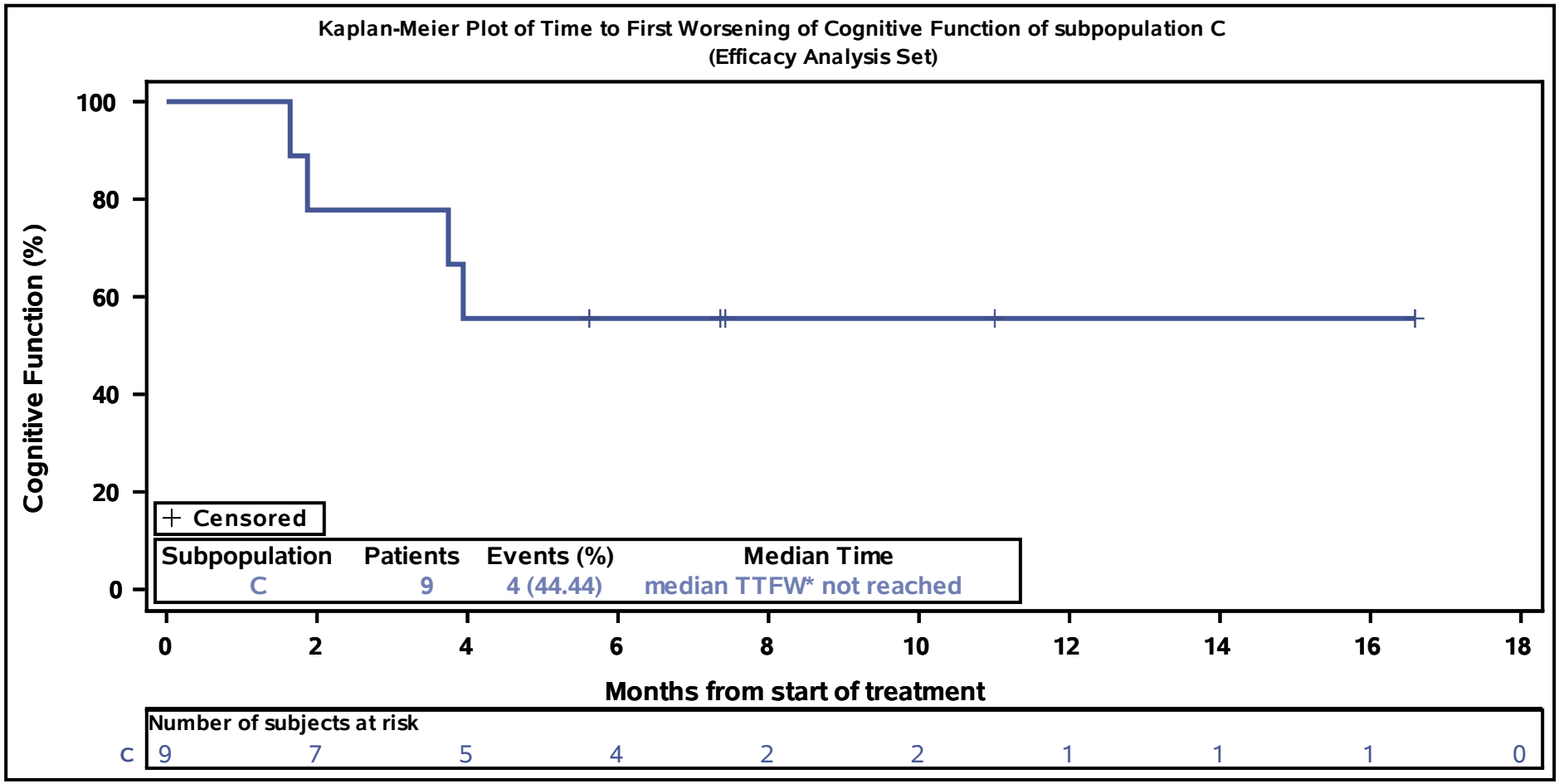
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F022_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



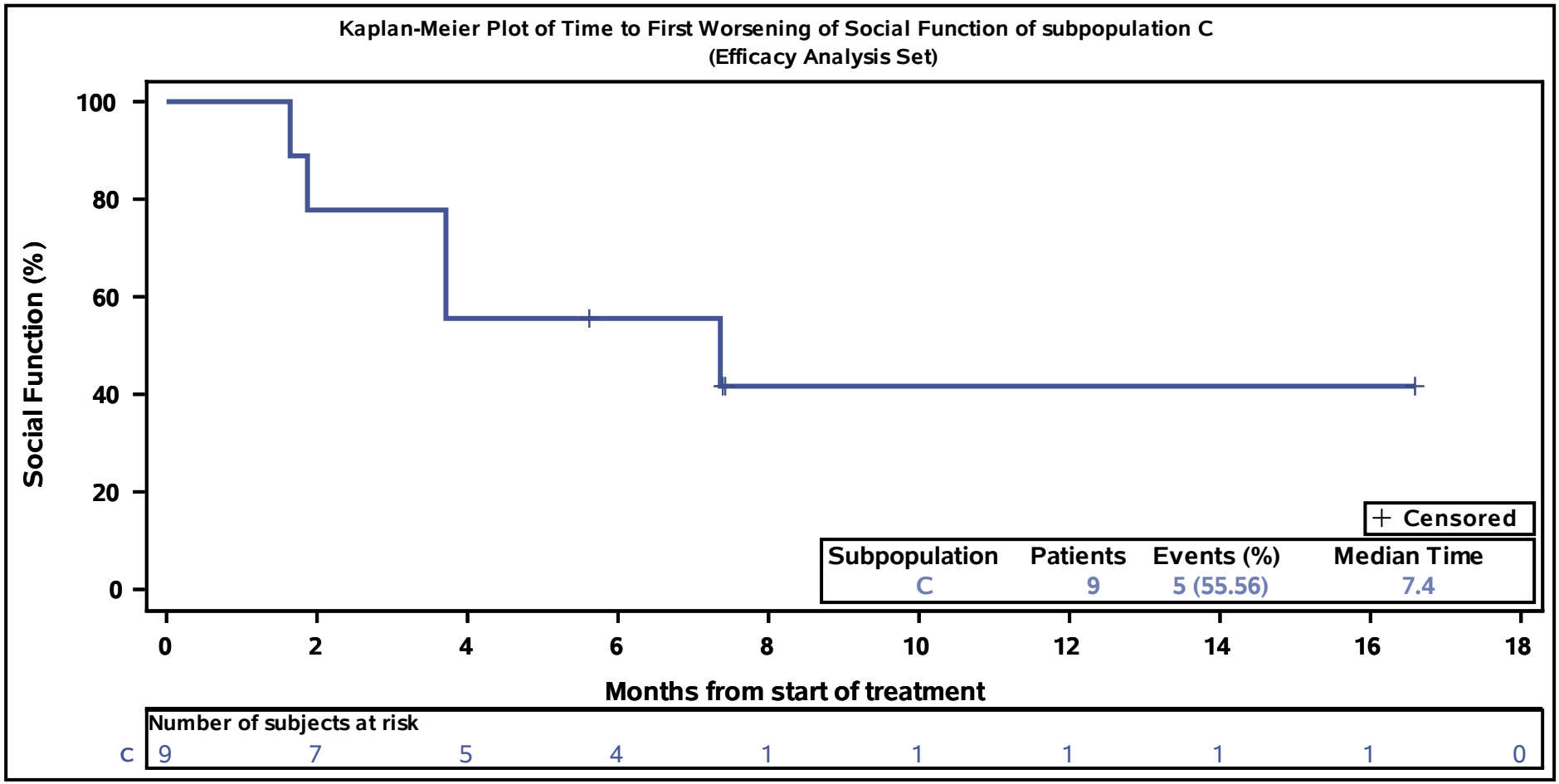
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F023_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



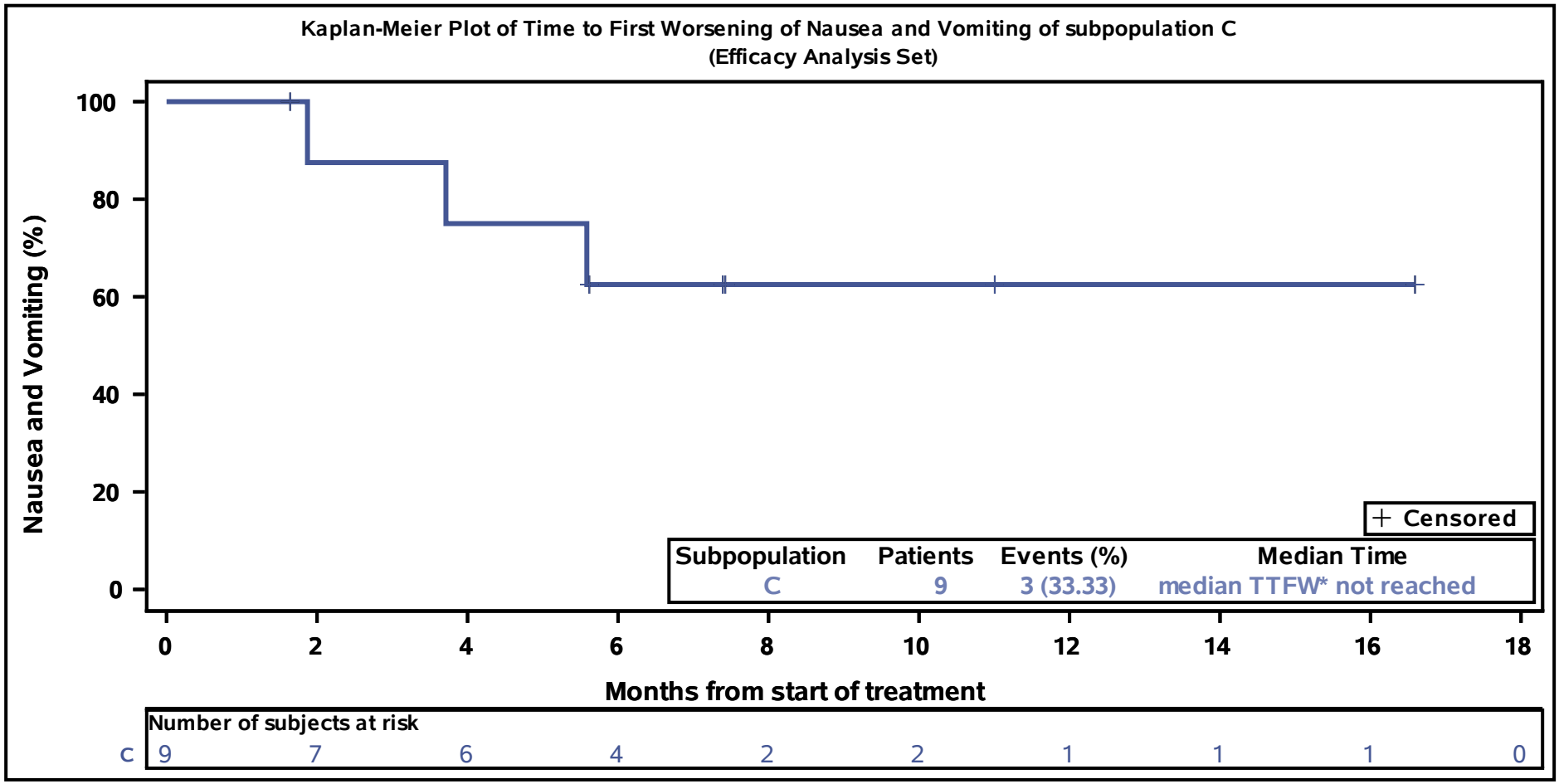
* TTFW = Time-to-First Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F024_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



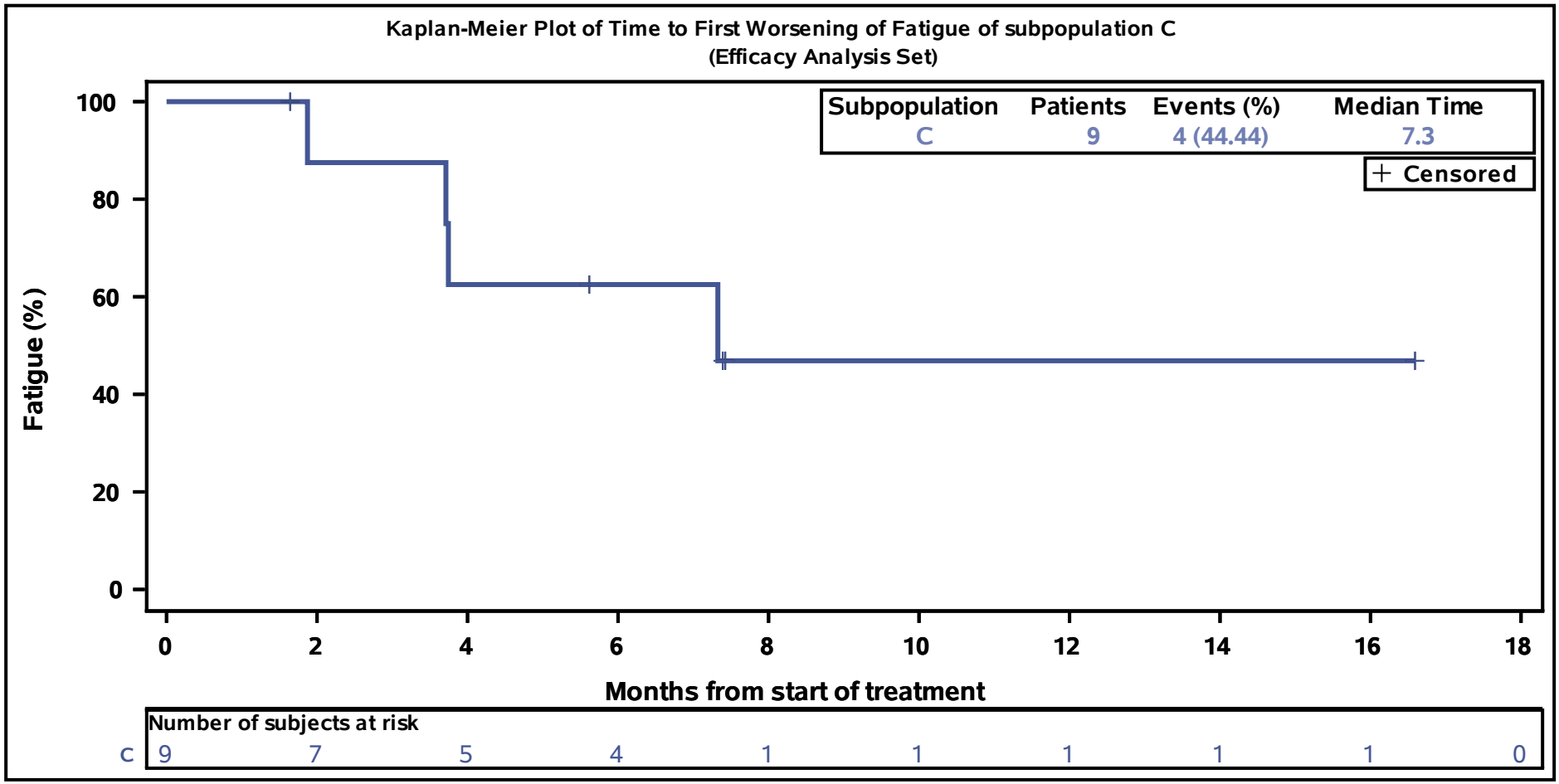
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F025_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



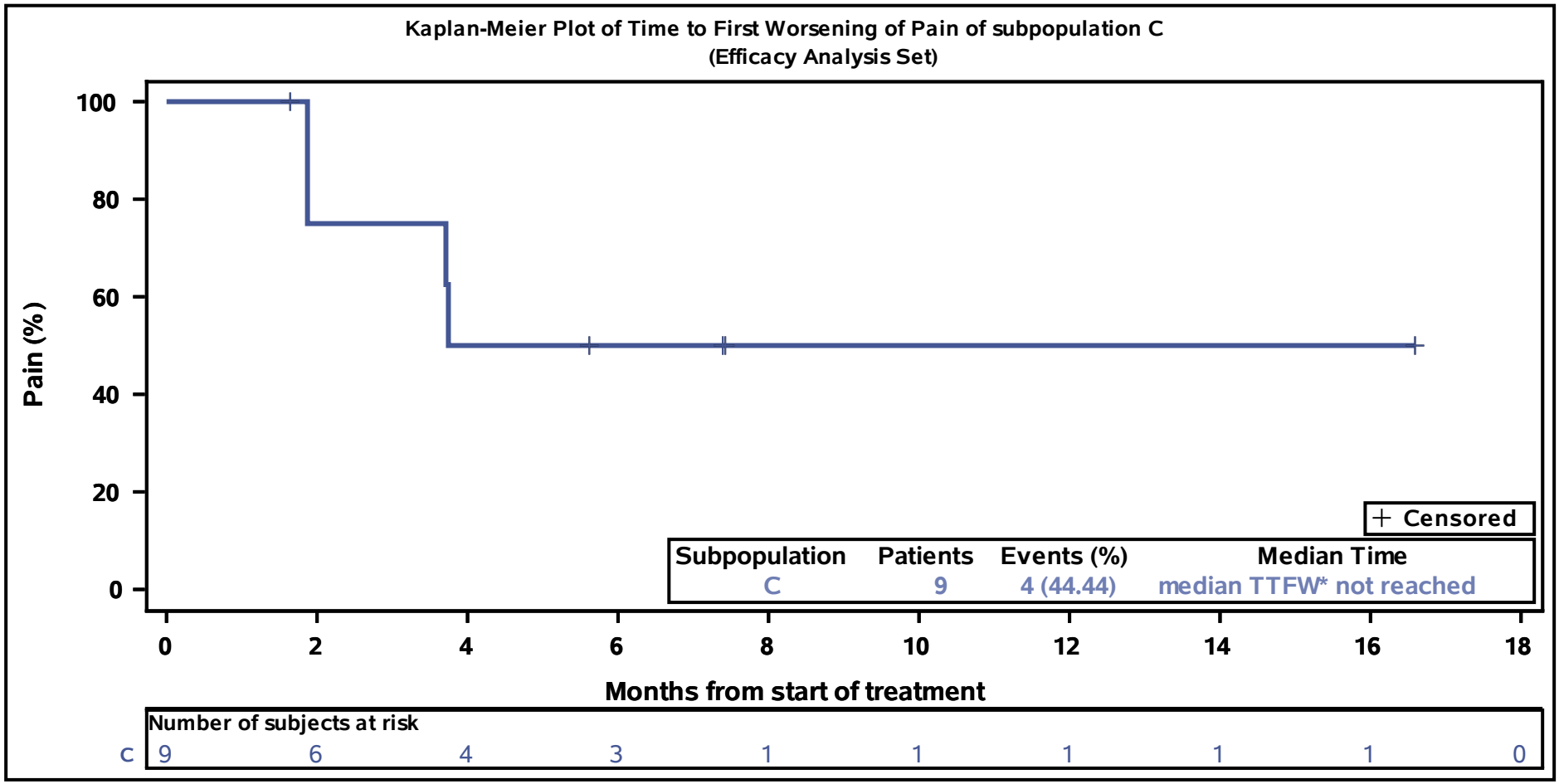
* TTFW = Time-to-First Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F026_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



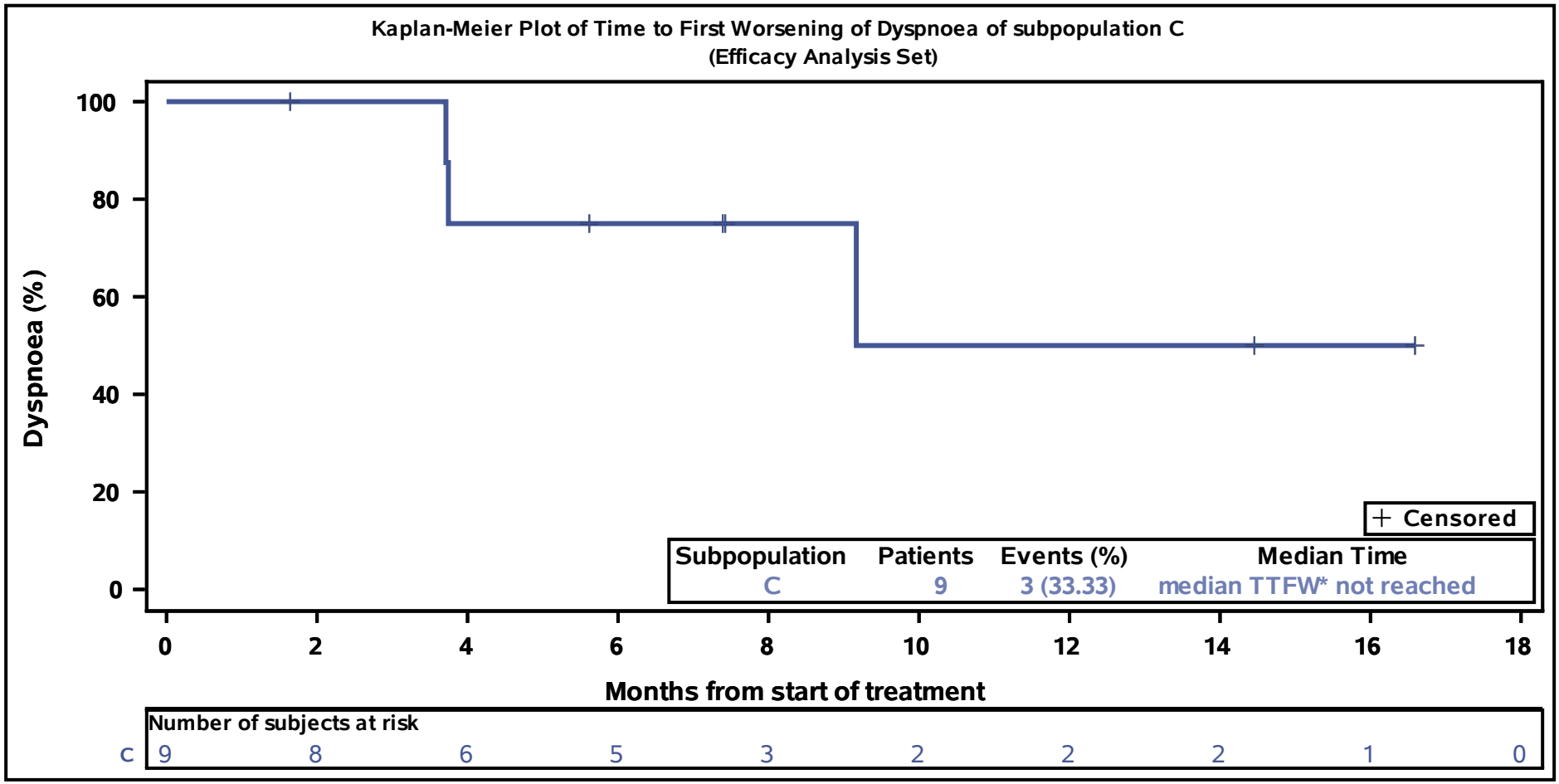
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F027_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



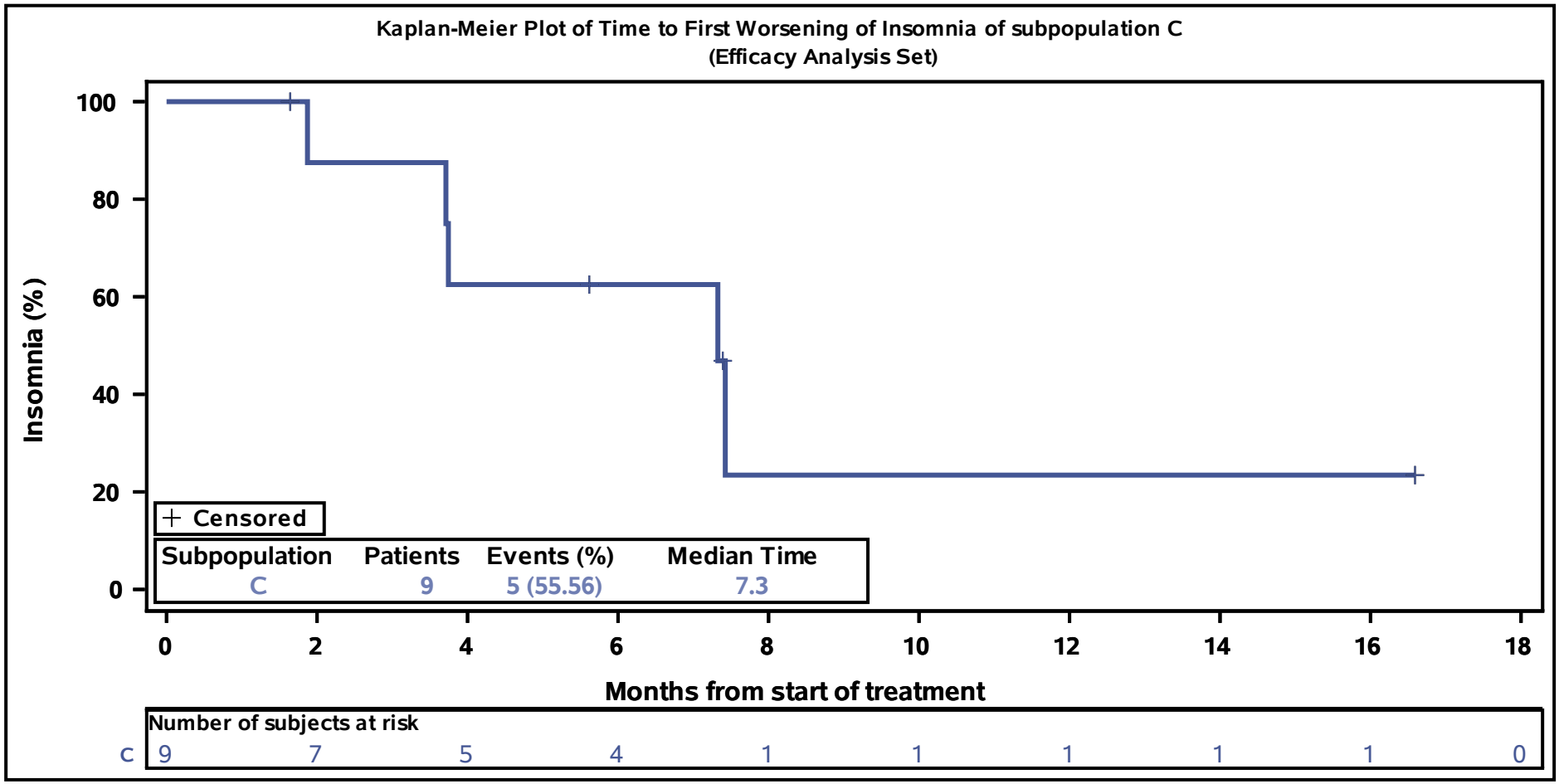
* TTFW = Time-to-First Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F028_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



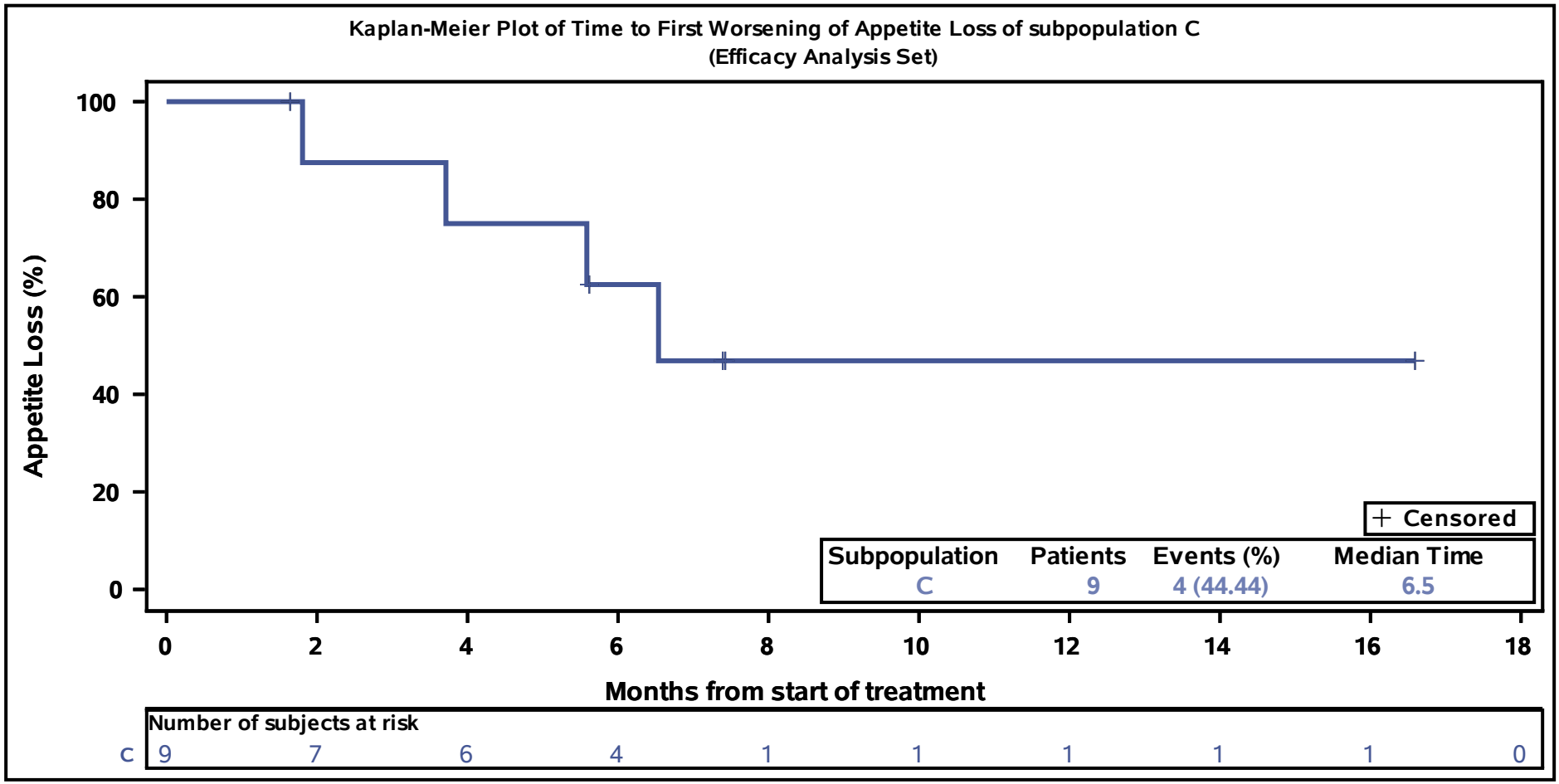
* TTFW = Time-to-First Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F029_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F030_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

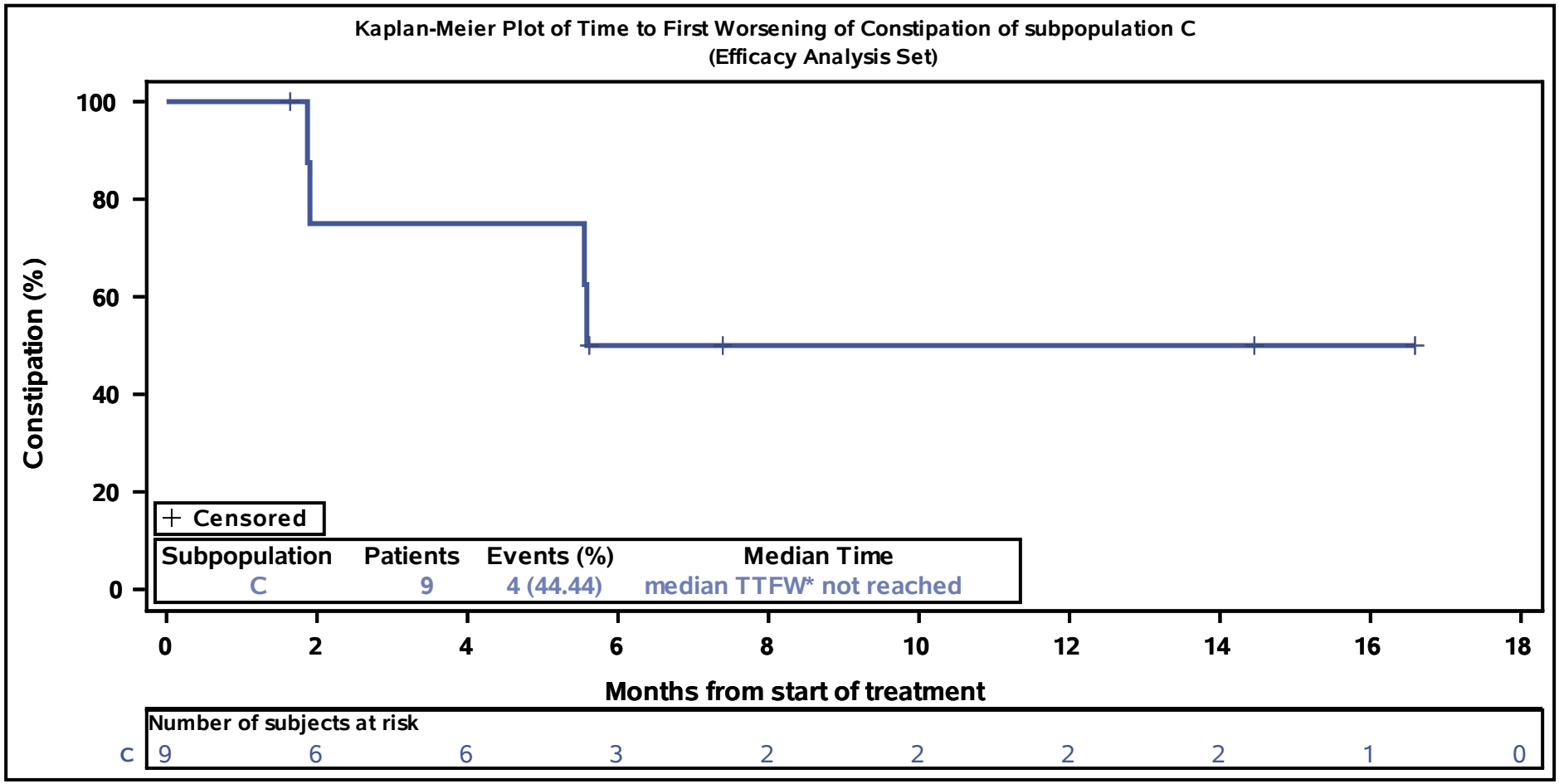
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (Visit Cutoff 30-MAR-2020)



Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F031_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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

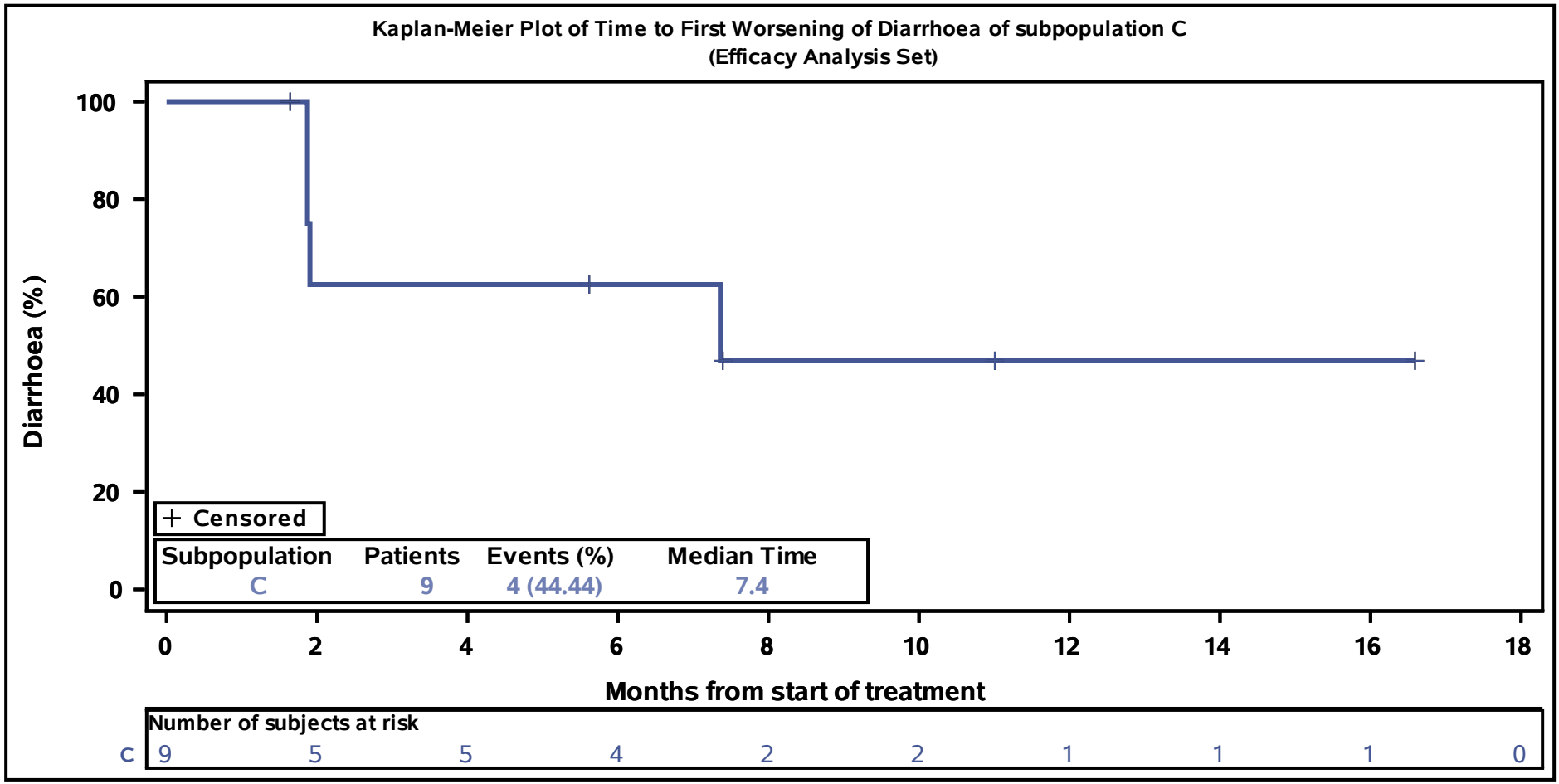
02:11 23DEC2020



* TTFW = Time-to-First Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F032_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

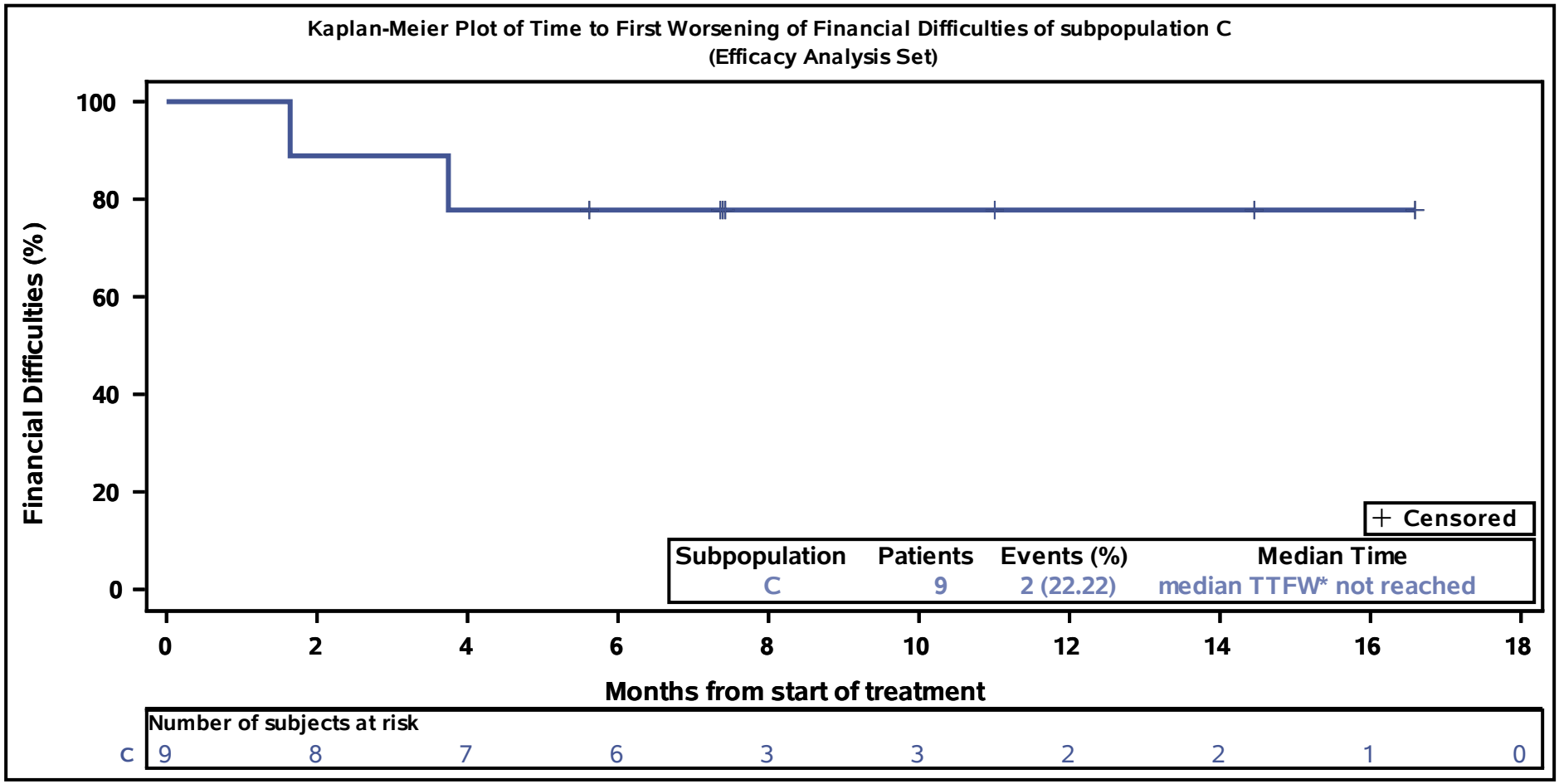
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (Visit Cutoff 30-MAR-2020)

02:11 23DEC2020



Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F033_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F034_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation C - TC (N') (N=18)
EORTC QLQ-C30 – Symptomskalen	
Fatigue	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Anhaltende Verschlechterung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Schmerzen	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	2 (22,2)
Zensierte Patienten, n (%)	7 (77,8)
Anhaltende Verschlechterung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [3,75; NE]
Übelkeit und Erbrechen	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Anhaltende Verschlechterung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,91; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [5,59; NE]
Dyspnoe	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Anhaltende Verschlechterung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [3,75; NE]
Schlaflosigkeit	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	0
Zensierte Patienten, n (%)	9 (100,0)
Anhaltende Verschlechterung, n (%)	3 (33,3)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_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/T033_sp_qlqc30_tte_tc_eff.rtf

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: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	**Selpercatinib** **Subpopulation C - TC** **(N')** **(N=18)**
Zensierte Patienten, n (%)	6 (66,7)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Appetitverlust	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	4 (44,4)
Zensierte Patienten, n (%)	5 (55,6)
Anhaltende Verschlechterung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [5,59; NE]
Verstopfung	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Anhaltende Verschlechterung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,91; NE]
Diarrhoe	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	0
Zensierte Patienten, n (%)	9 (100,0)
Anhaltende Verschlechterung, n (%)	2 (22,2)
Zensierte Patienten, n (%)	7 (77,8)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_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/T033_sp_qlqc30_tte_tc_eff.rtf

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: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation C - TC (N') (N=18)
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,91; NE]

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;
LQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.
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.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_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/T033_sp_qlqc30_tte_tc_eff.rtf

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: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Efficacy Analysis Set

Endpunkt	Selpercatinib Subpopulation C - TC (N') (N=18)
EORTC QLQ-C30 - Globaler Gesundheitsstatus	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Anhaltende Verschlechterung, n (%)	3 (33,3)
Zensierte Patienten, n (%)	6 (66,7)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
EORTC QLQ-C30 – Funktionsskalen	
Physische Funktion	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Anhaltende Verschlechterung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [3,75; NE]
Emotionale Funktion	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	0
Zensierte Patienten, n (%)	9 (100,0)
Anhaltende Verschlechterung, n (%)	2 (22,2)
Zensierte Patienten, n (%)	7 (77,8)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [NE; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [3,75; NE]
Rollenfunktion	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Anhaltende Verschlechterung, n (%)	2 (22,2)
Zensierte Patienten, n (%)	7 (77,8)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Kognitive Funktion	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Anhaltende Verschlechterung, n (%)	3 (33,3)

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_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/T034_sp_qlqc30_tte_tc_eff.rtf

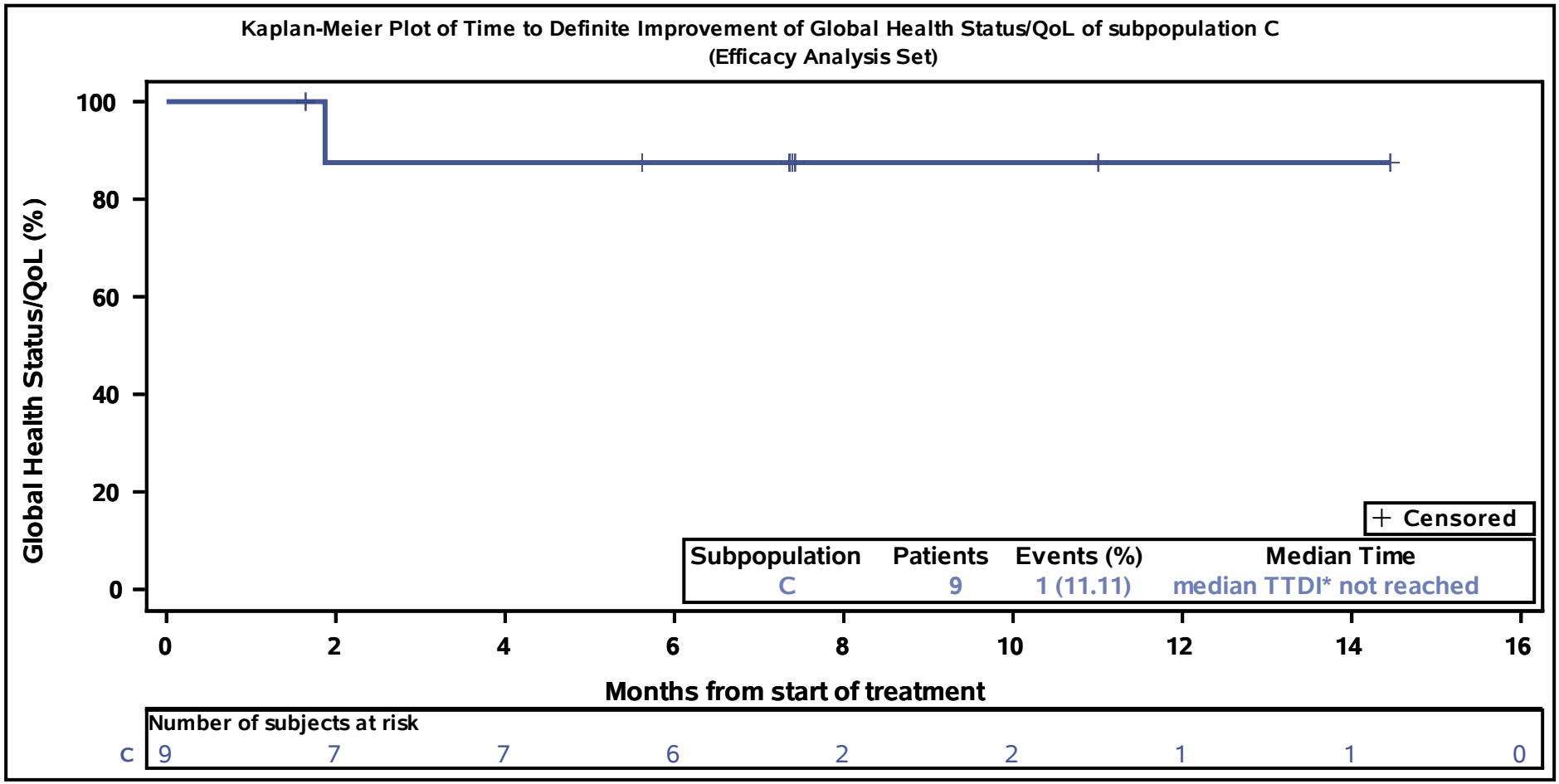
Tabelle 034: Ergebnisse für die Zeit bis zur anhaltenden Verbesserung bzw. Verschlechterung der gesundheitsbezogenen Lebensqualität gemessen anhand des EORTC QLQ-C30 in Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März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

Endpunkt	**Selpercatinib** **Subpopulation C - TC** **(N')** **(N=18)**
Zensierte Patienten, n (%)	6 (66,7)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [14,46; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,64; NE]
Soziale Funktion	9
Patienten mit Ereignis	
Anhaltende Verbesserung, n (%)	1 (11,1)
Zensierte Patienten, n (%)	8 (88,9)
Anhaltende Verschlechterung, n (%)	2 (22,2)
Zensierte Patienten, n (%)	7 (77,8)
Mediane Zeit bis zur anhaltenden Verbesserung (Monate) [95%-KI] [a,b]	NE [1,87; NE]
Mediane Zeit bis zur anhaltenden Verschlechterung (Monate) [95%-KI] [a,b]	NE [1,64; NE]

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;
LQ-C30: Core Quality of Life Questionnaire C30; RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.
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.

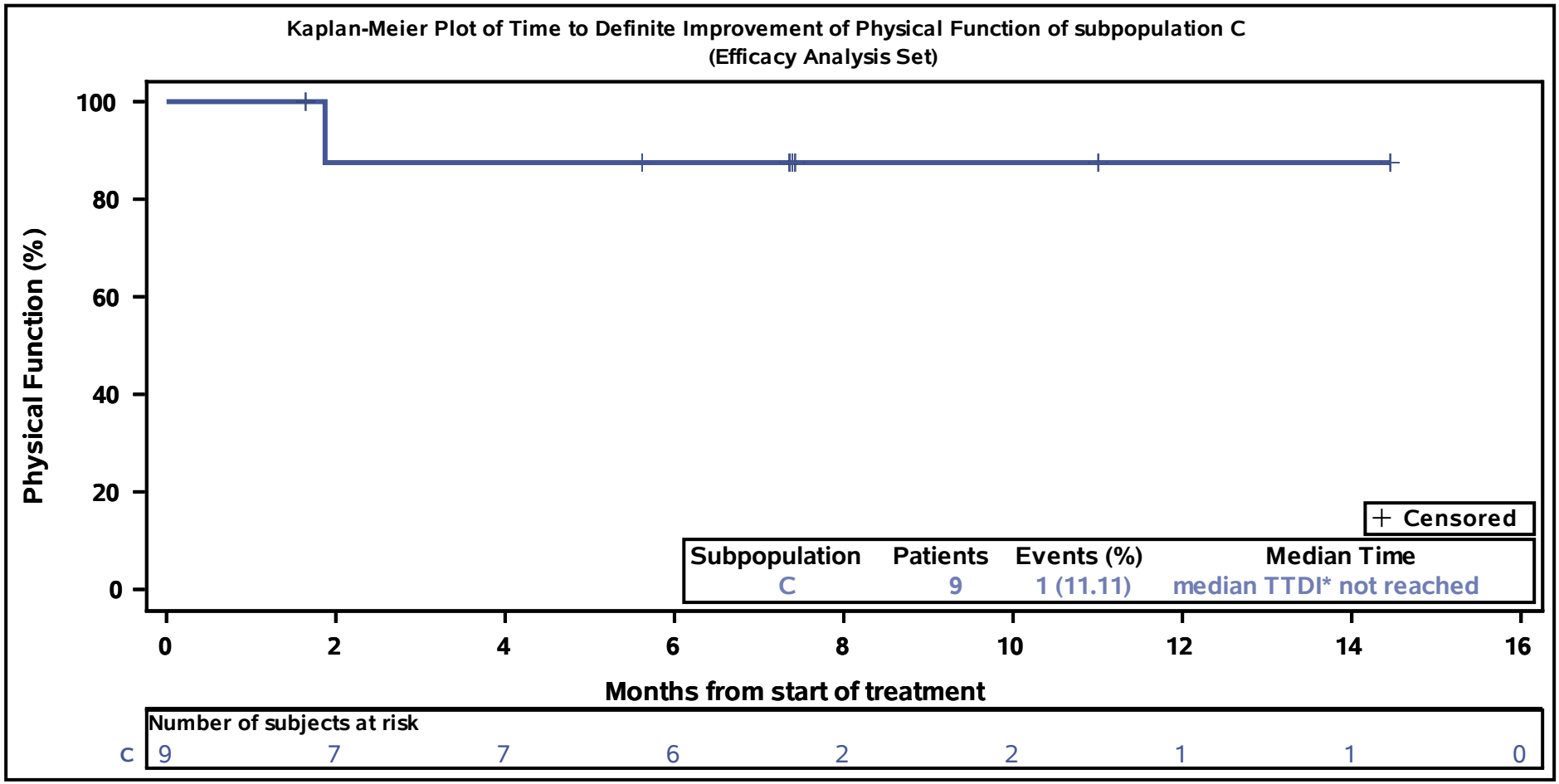
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_tte_tc_ge.sas
Data location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/T034_sp_qlqc30_tte_tc_eff.rtf

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



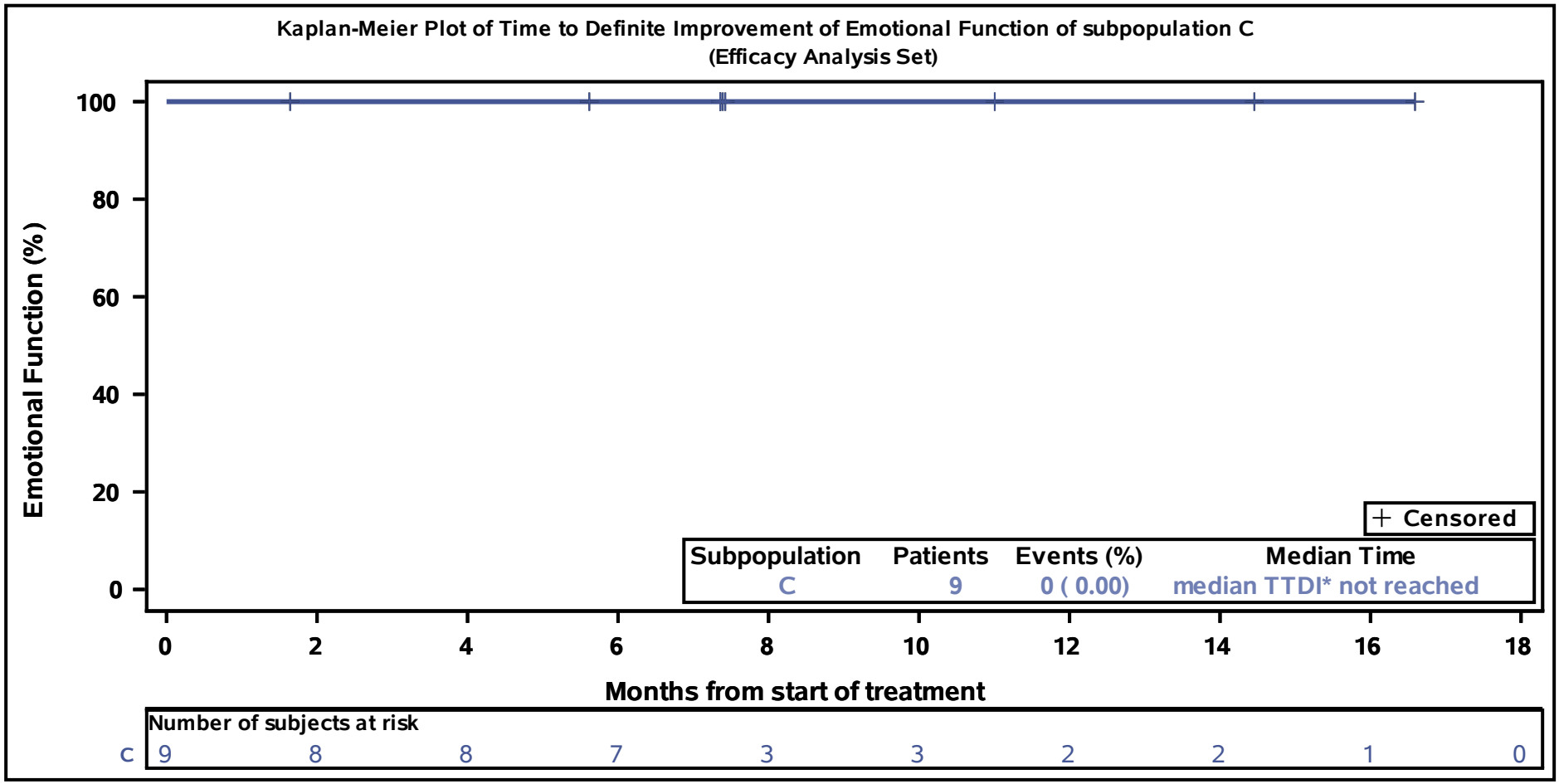
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F005_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



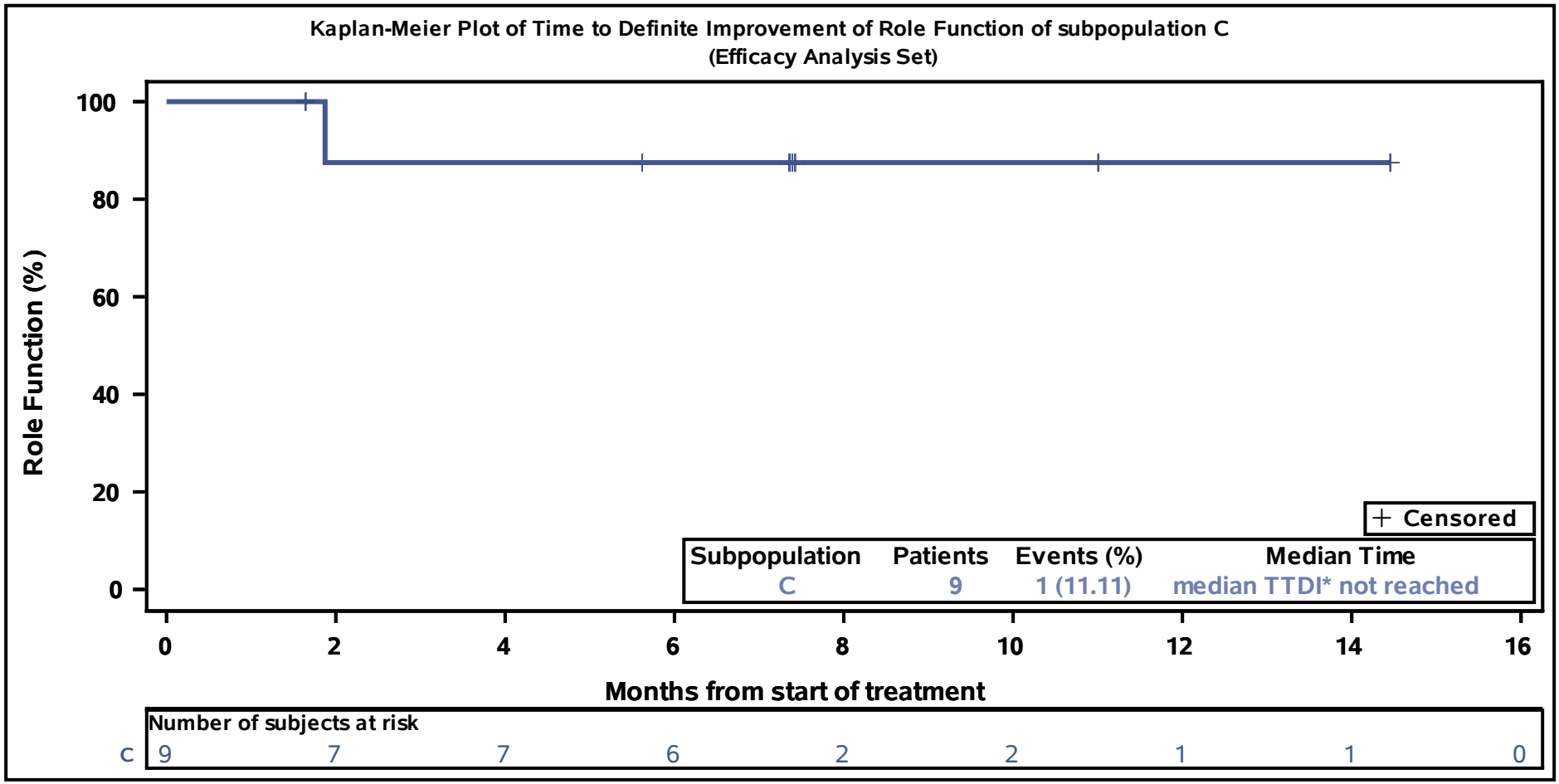
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F006_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



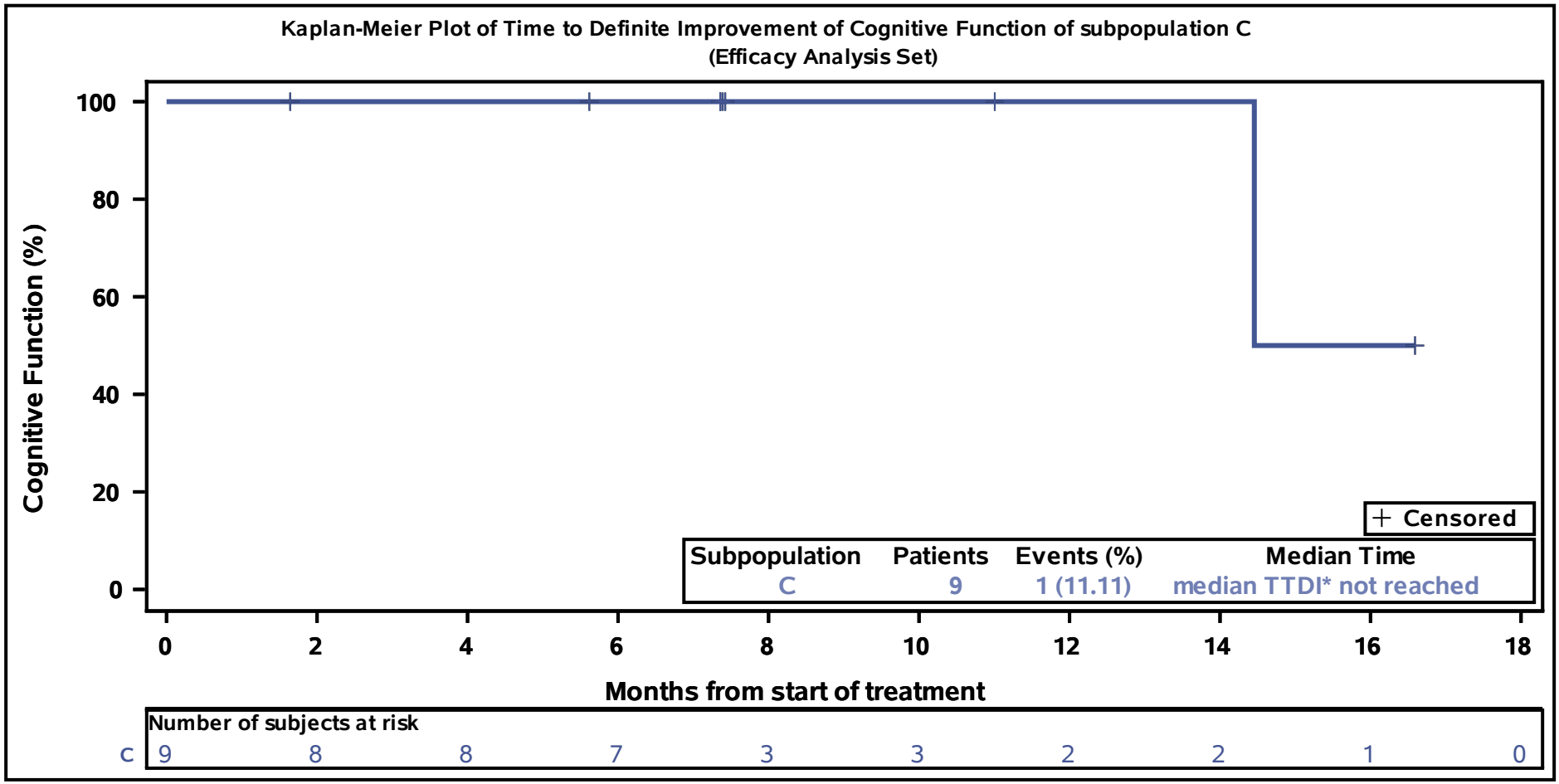
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F007_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



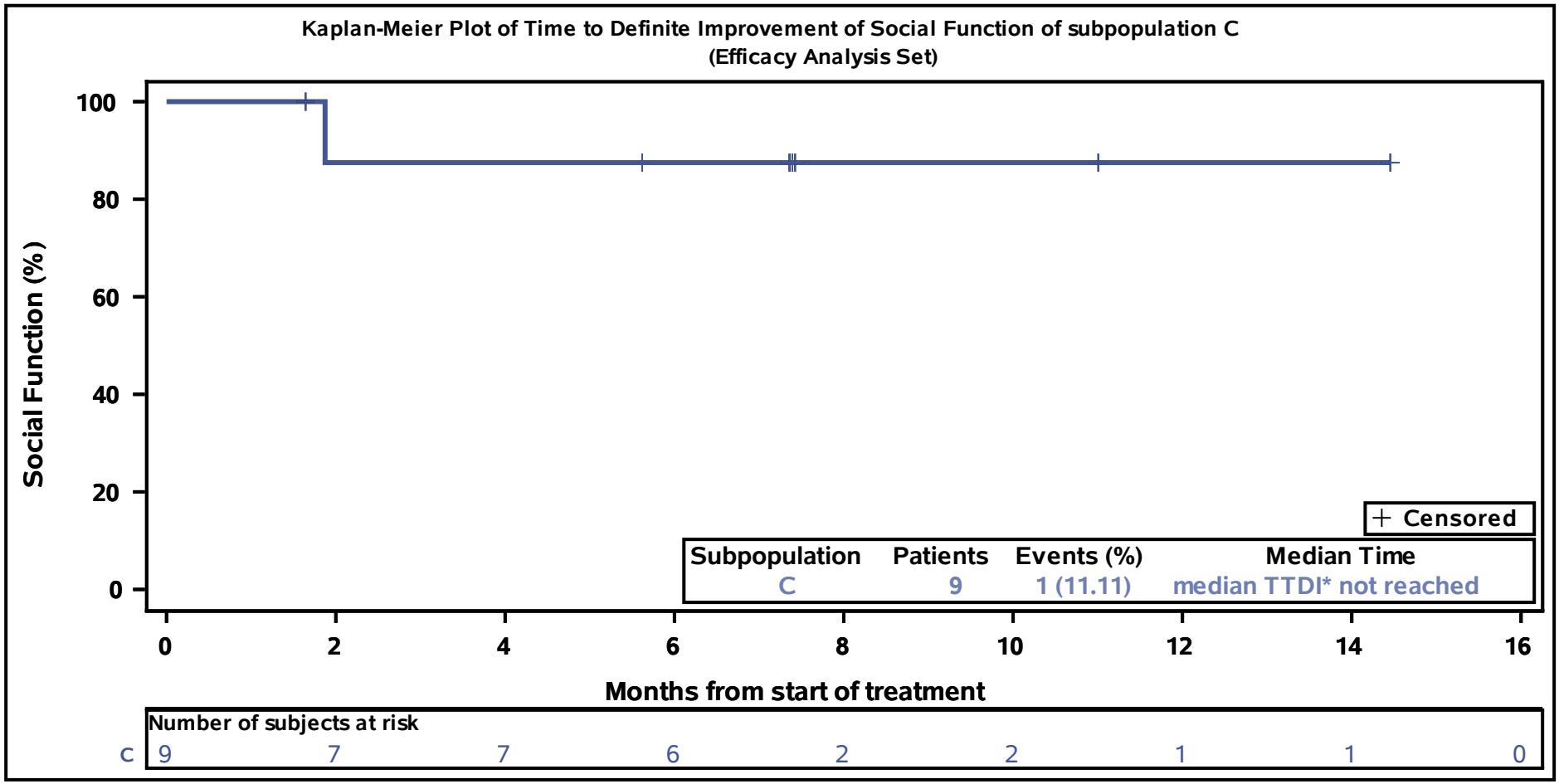
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F008_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



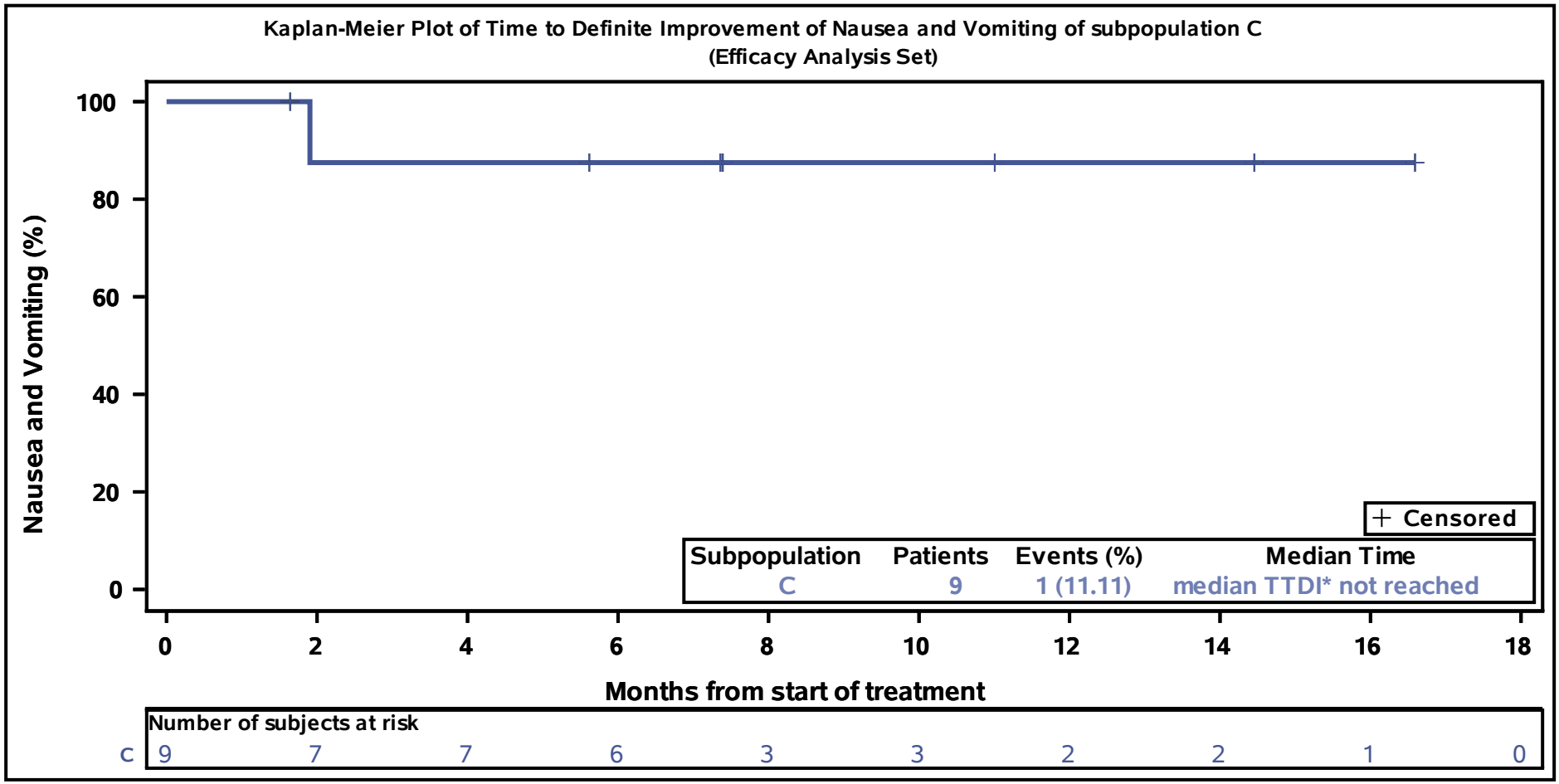
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F009_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



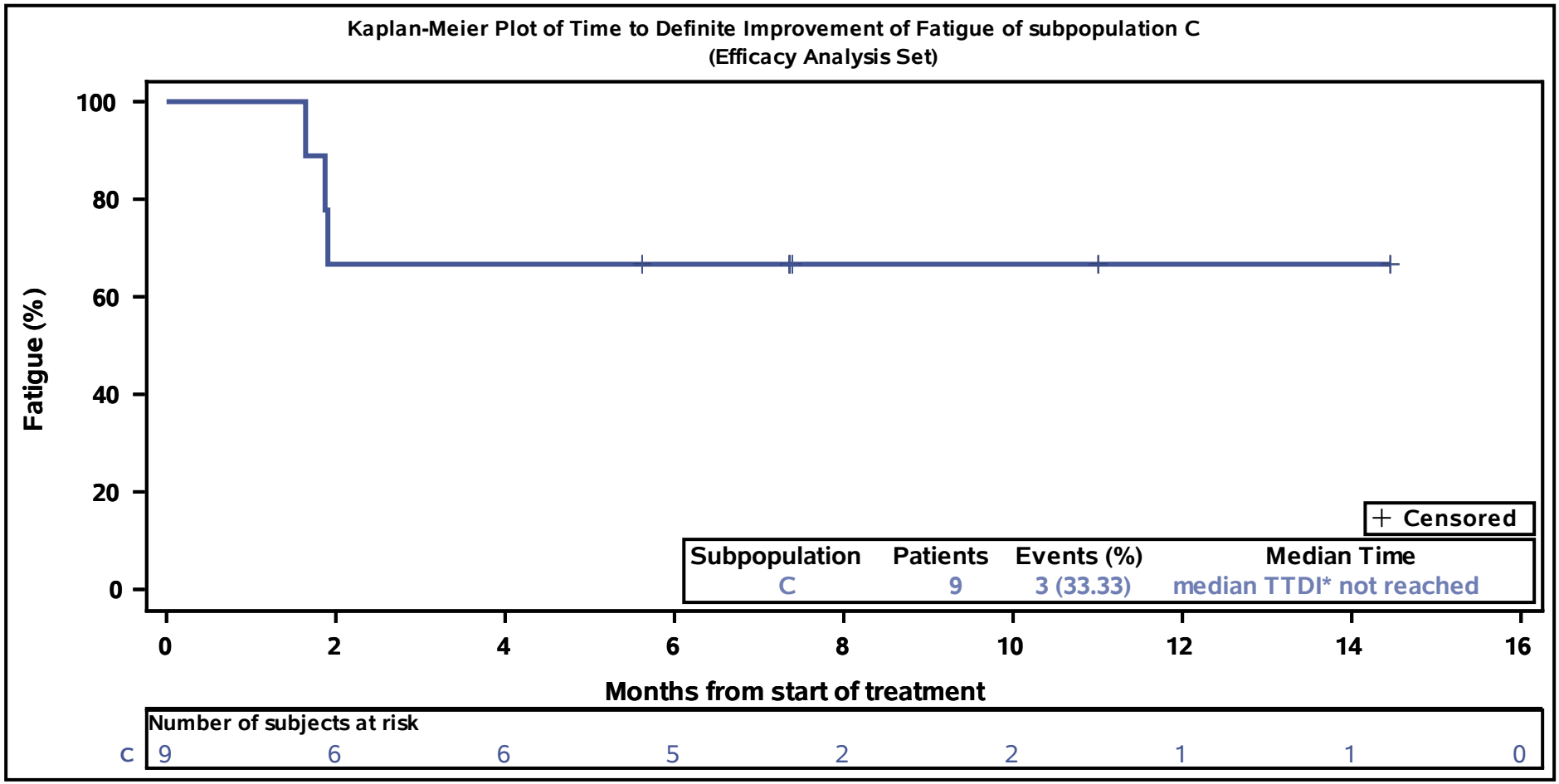
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F010_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



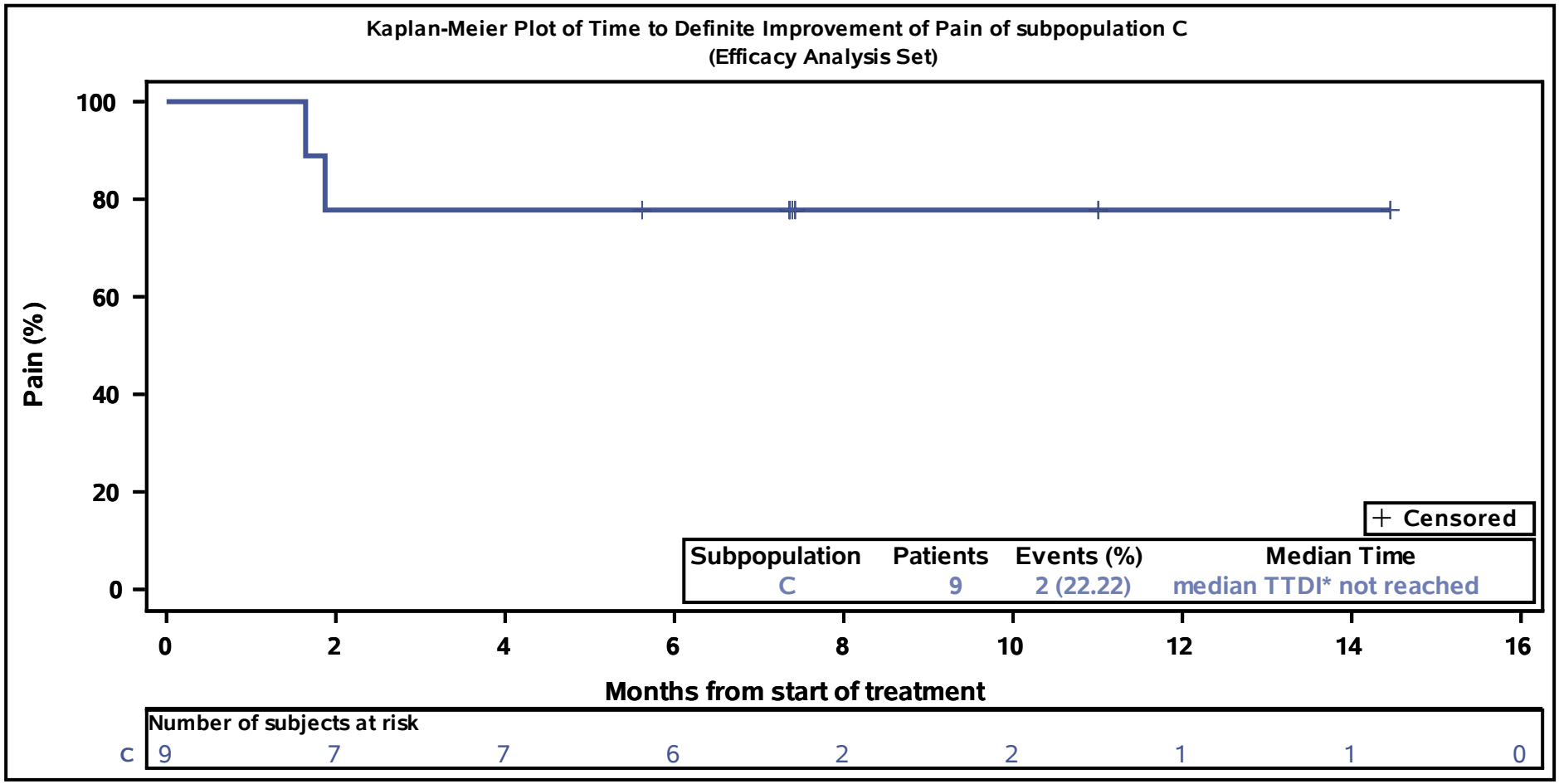
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F011_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



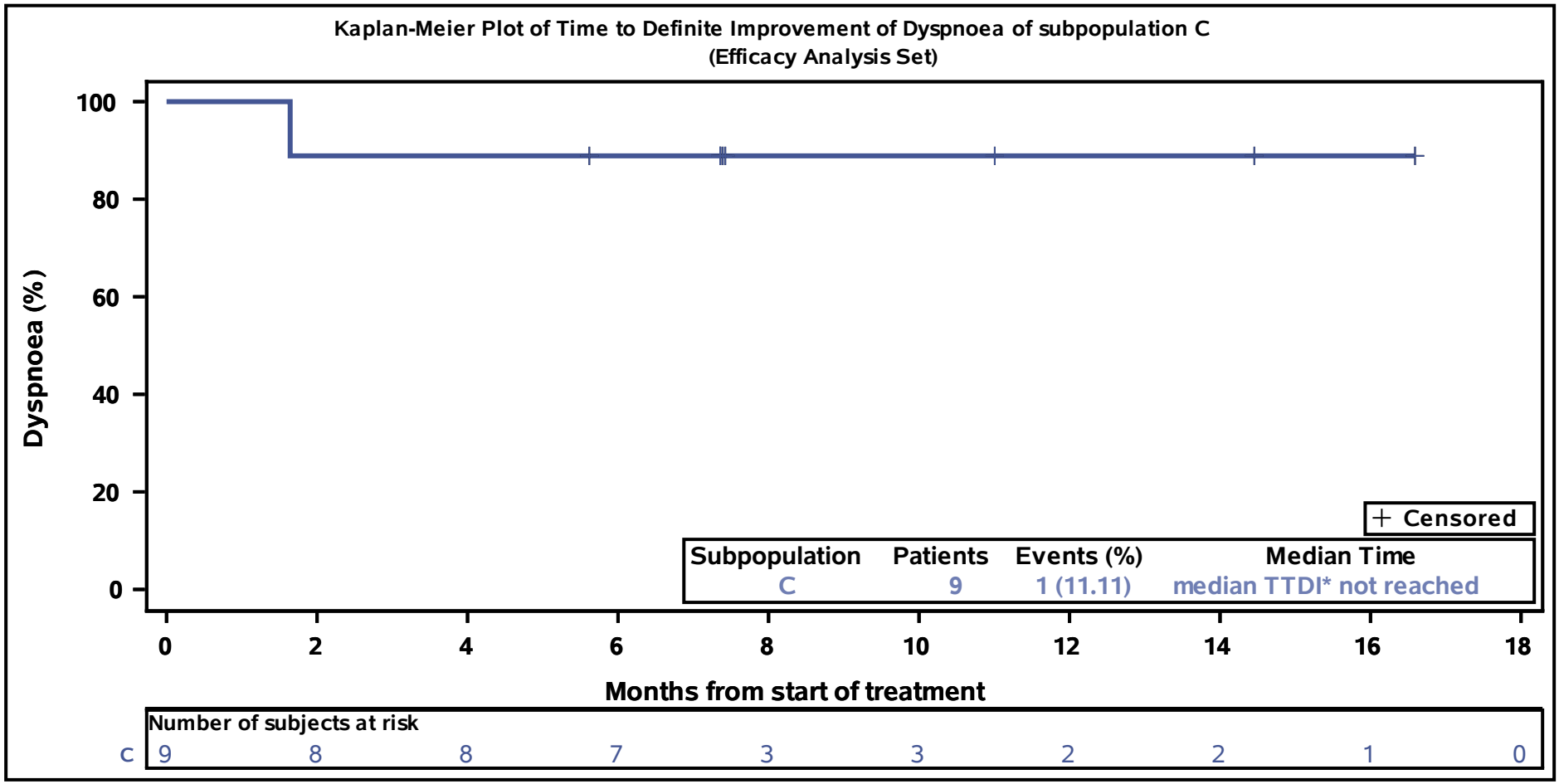
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F012_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



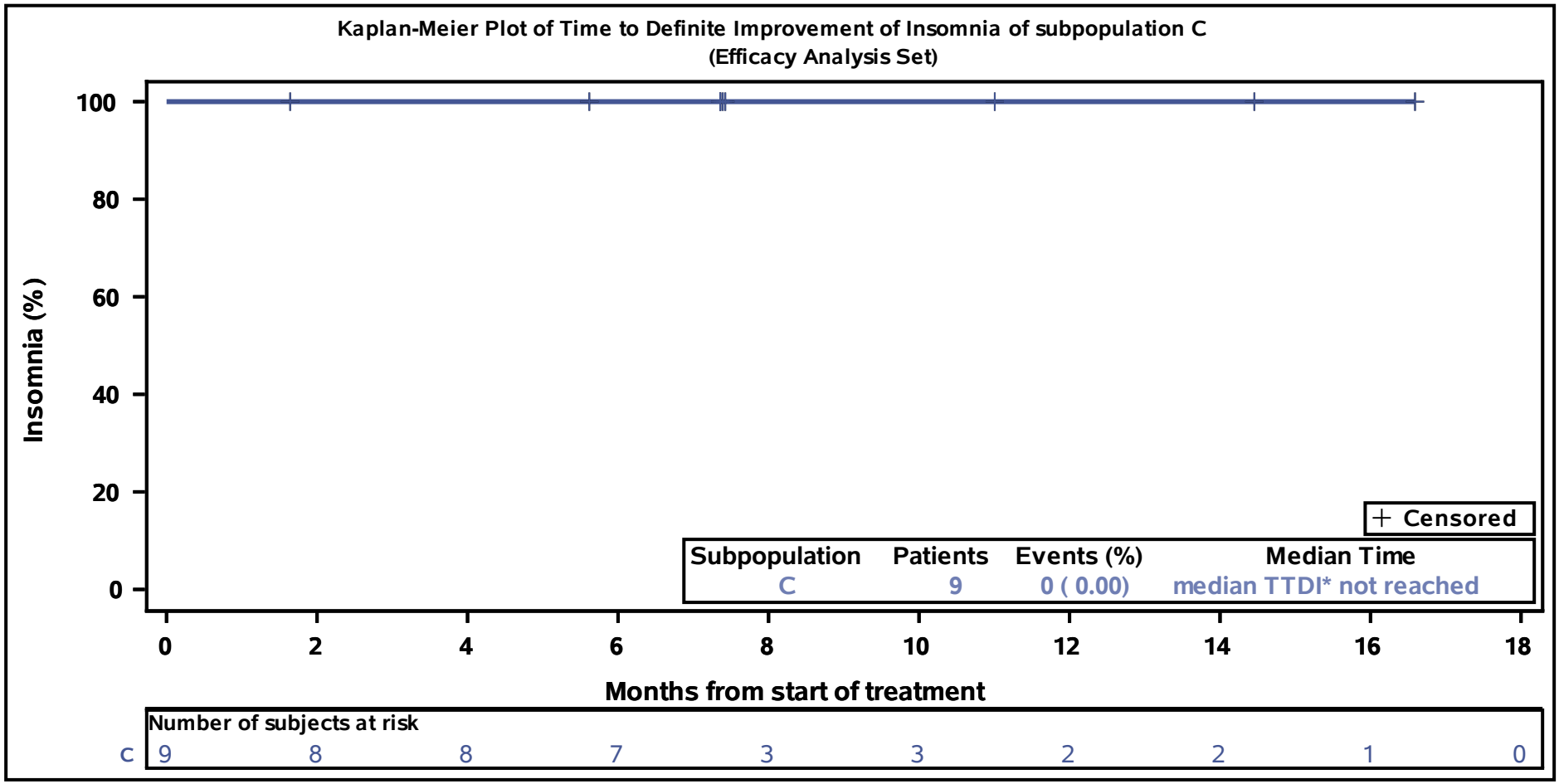
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F013_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



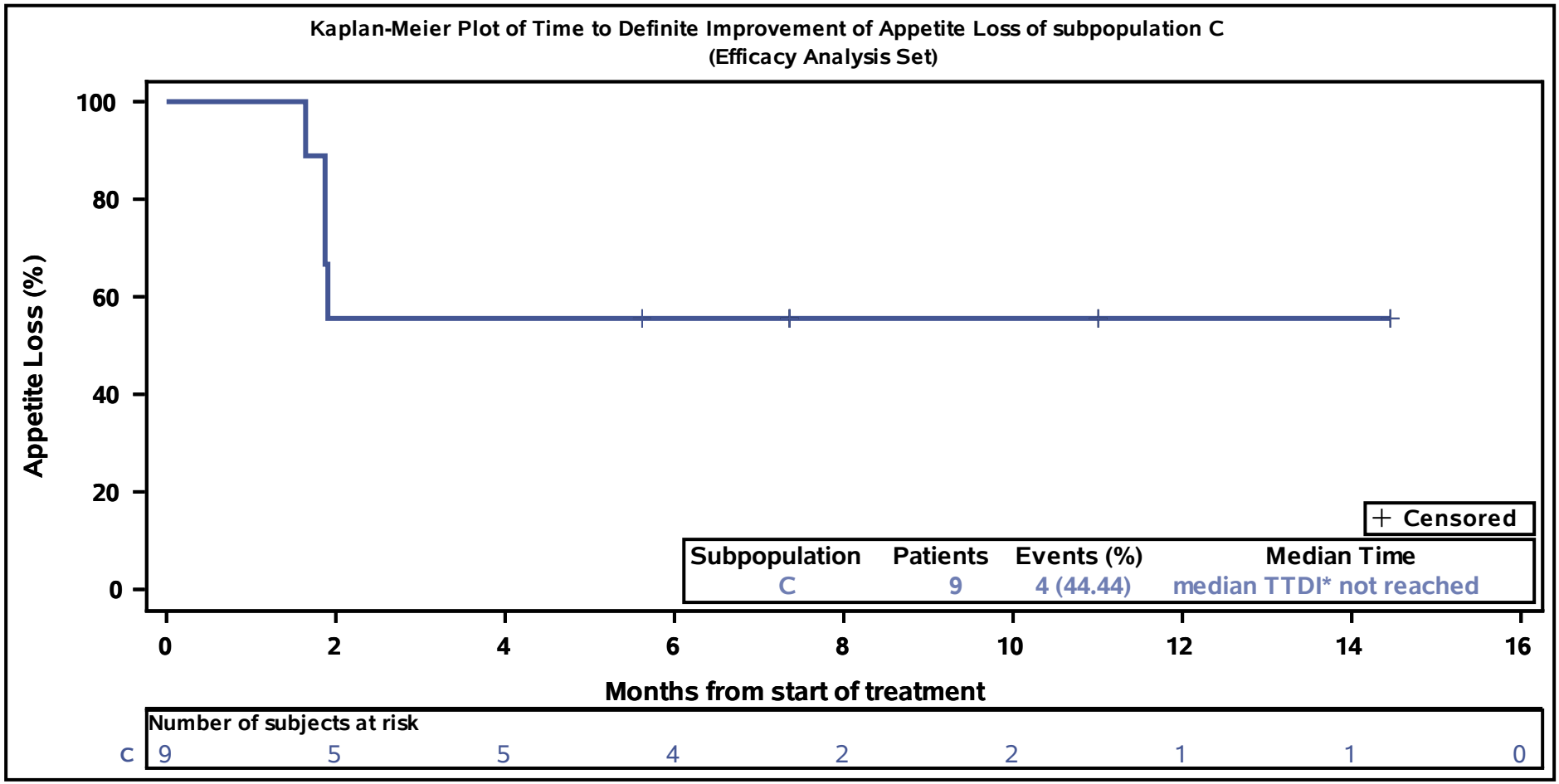
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F014_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



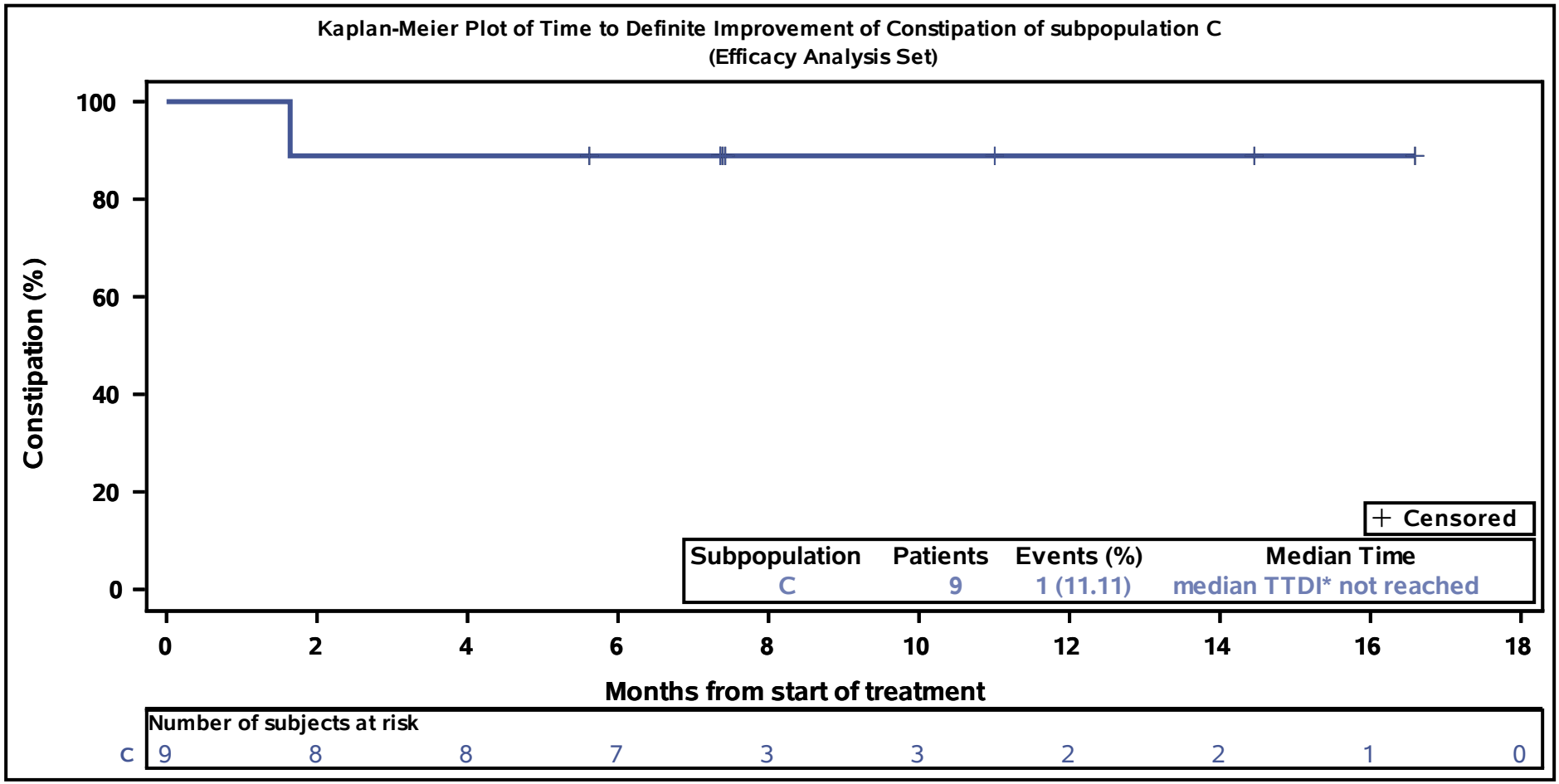
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F015_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



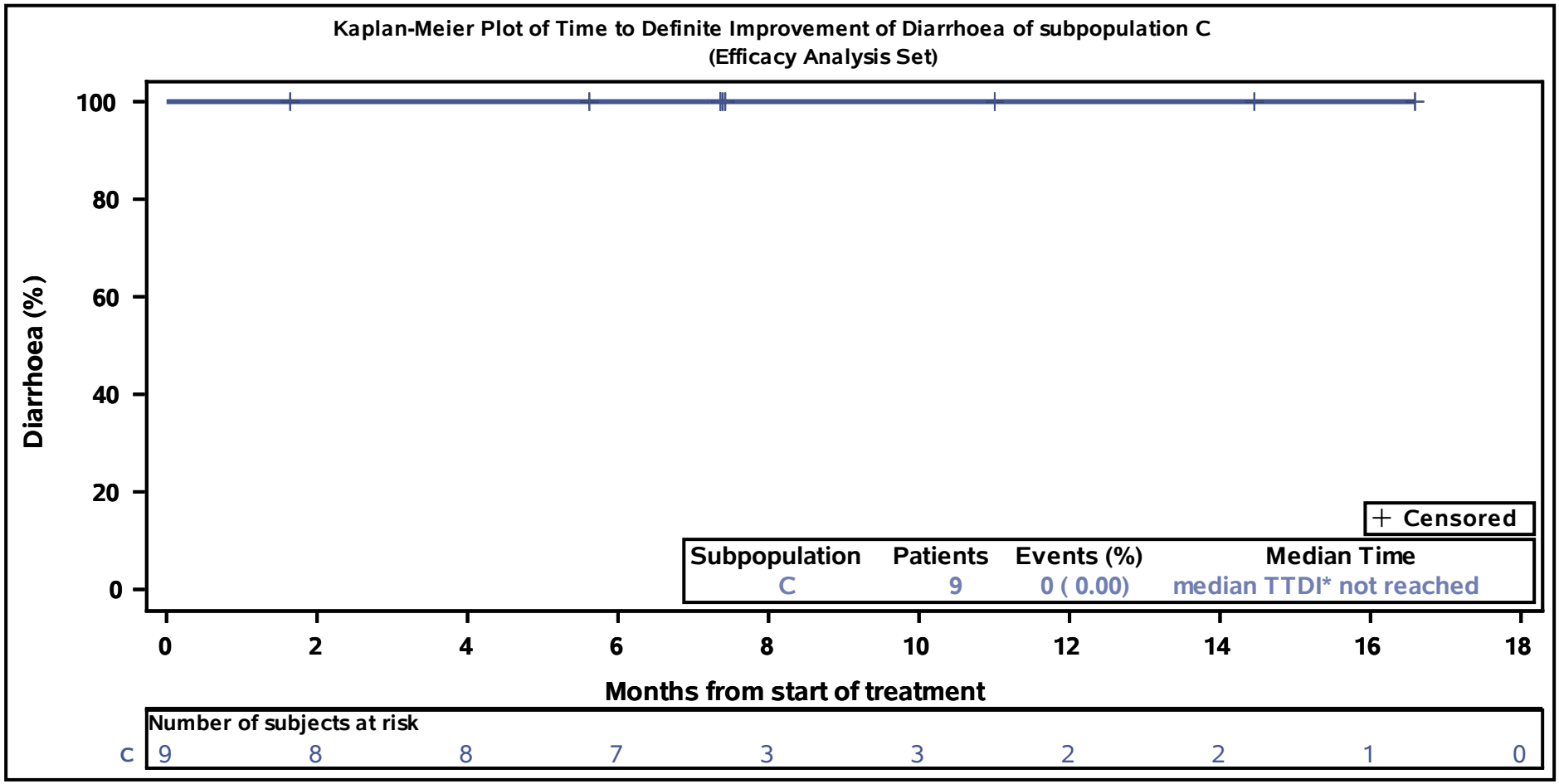
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F016_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



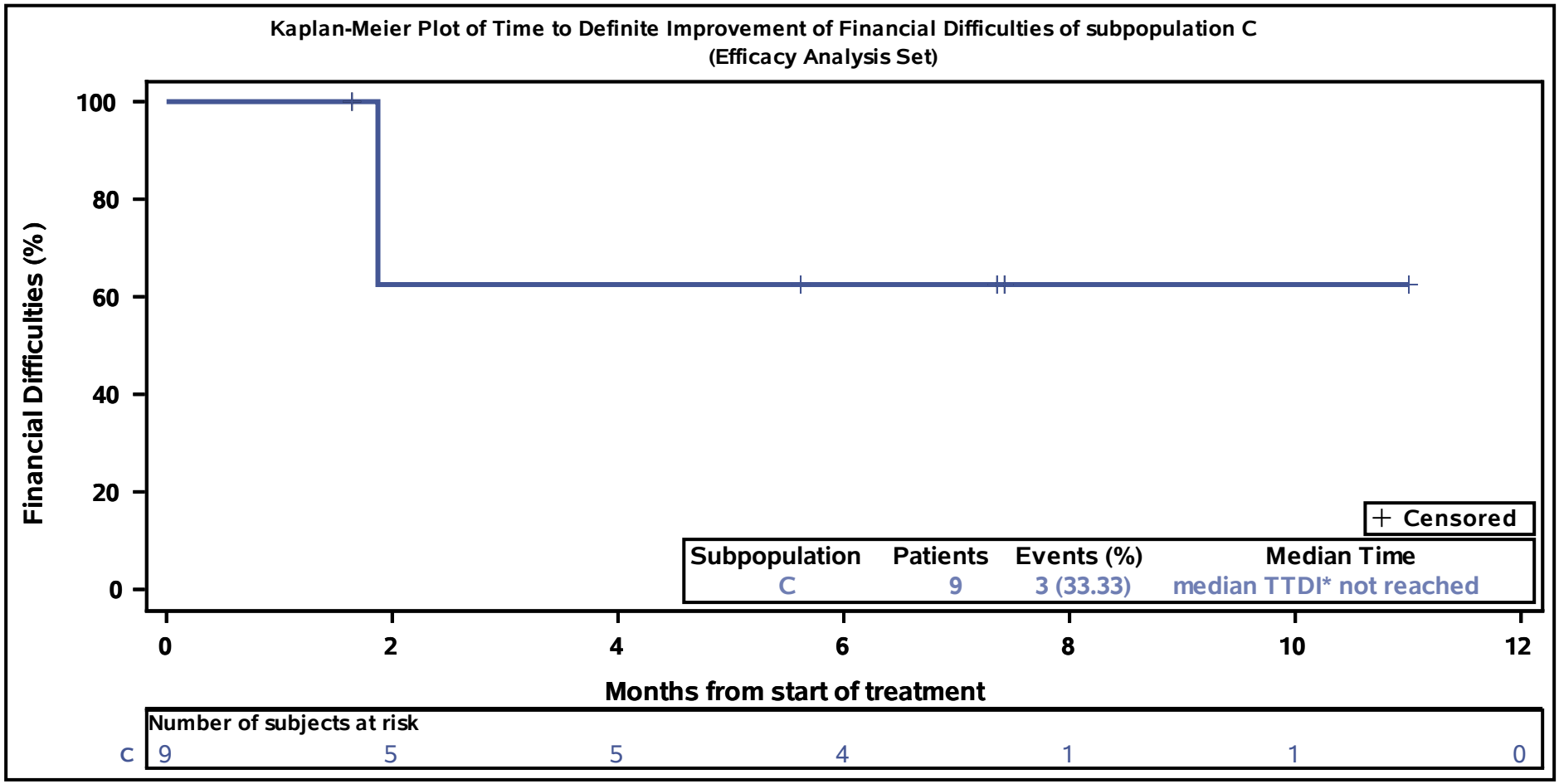
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F017_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



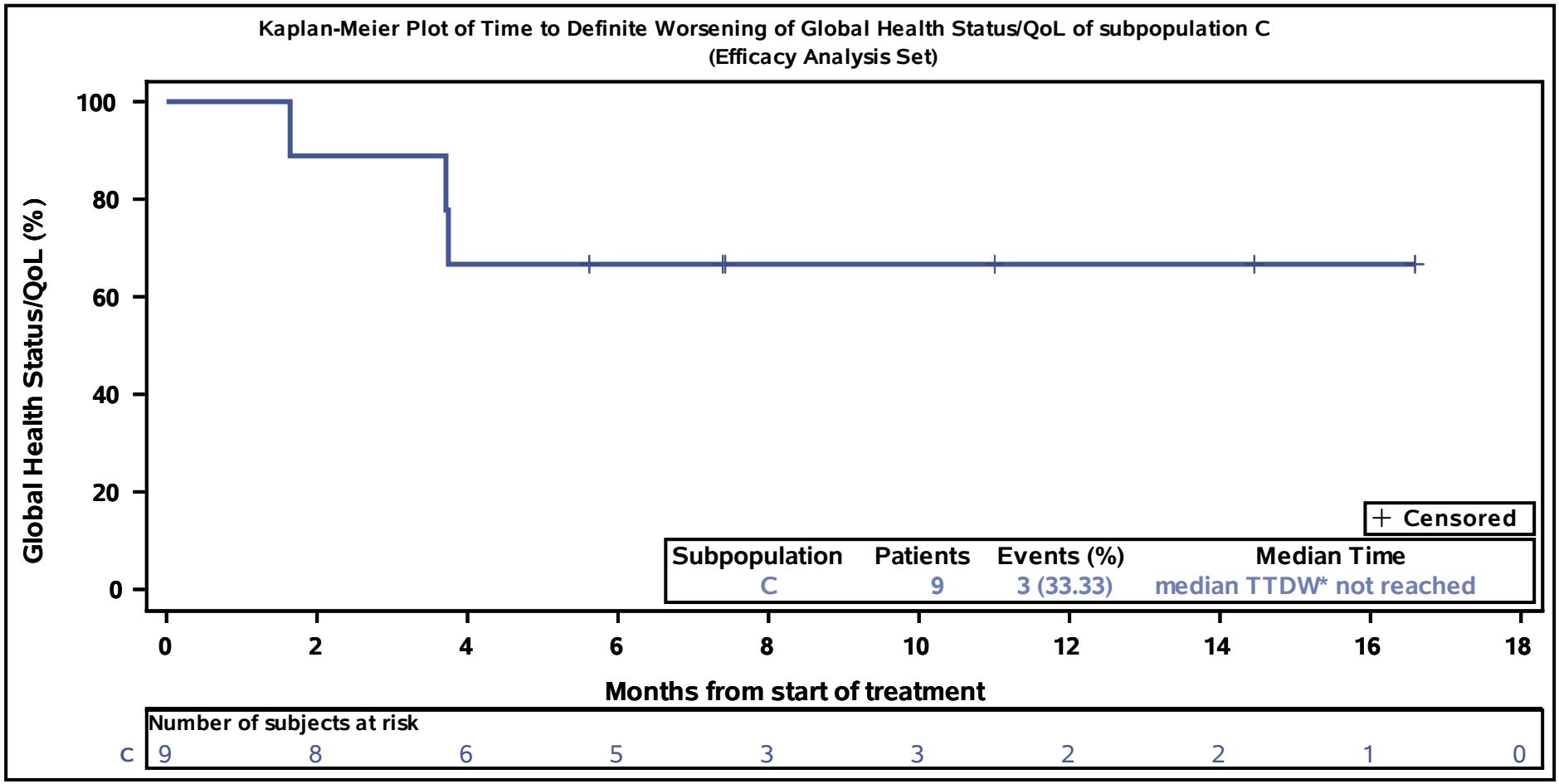
* TTDI = Time-to Definite Improvement
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F018_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F019_1_tti_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

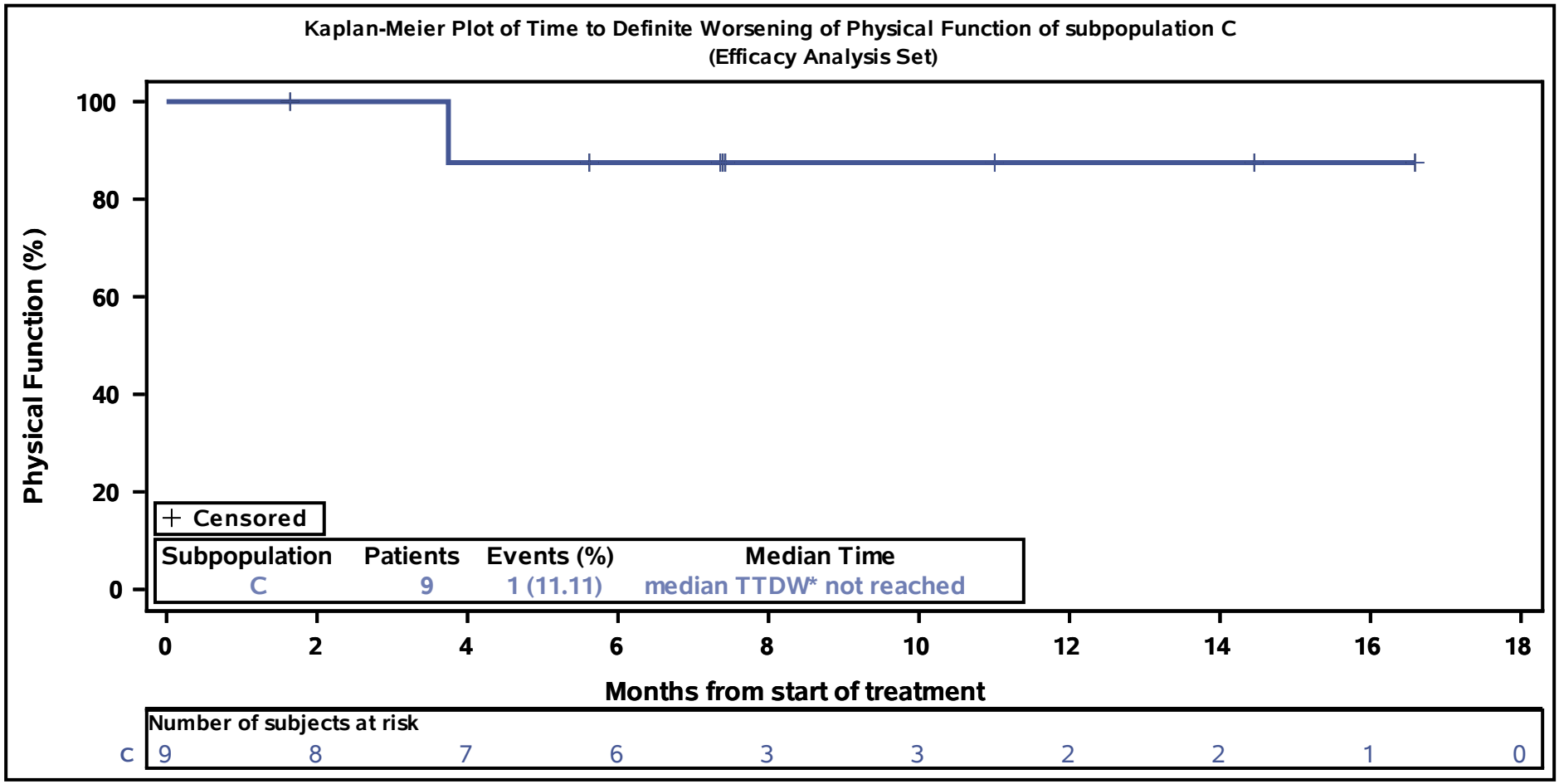
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (Visit Cutoff 30-MAR-2020)



* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F020_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

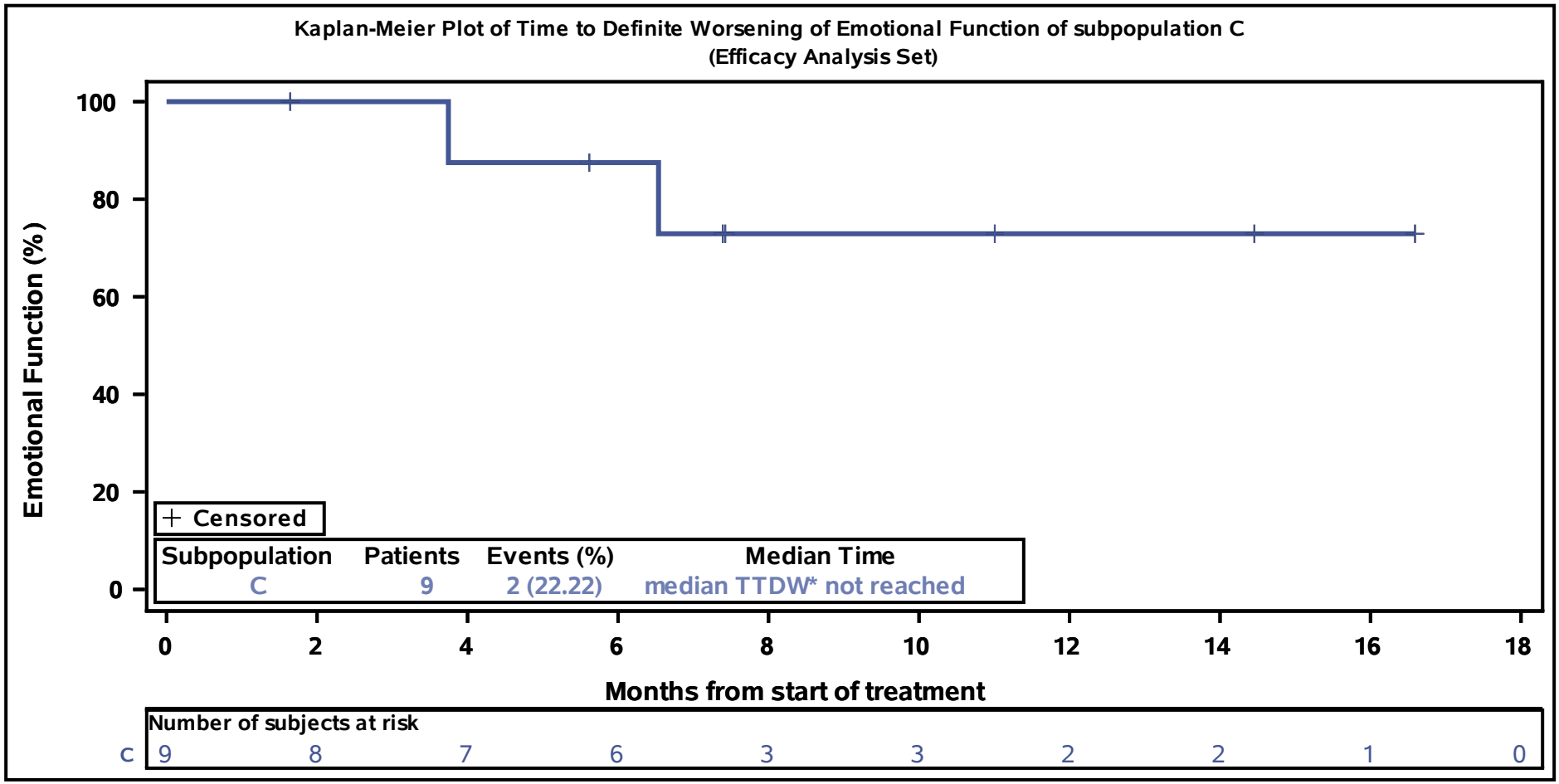
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (Visit Cutoff 30-MAR-2020)

02:11 23DEC2020



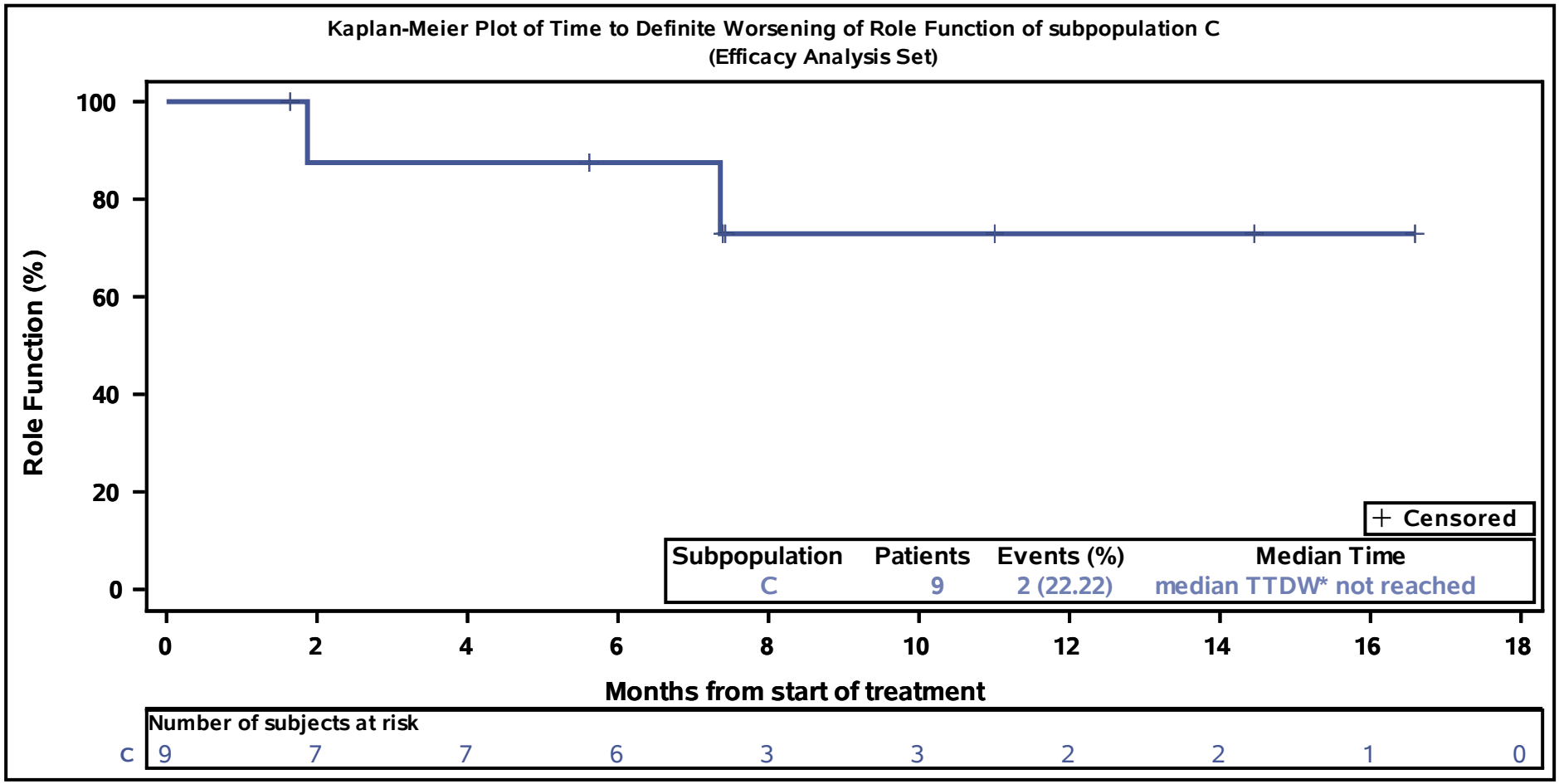
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F021_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



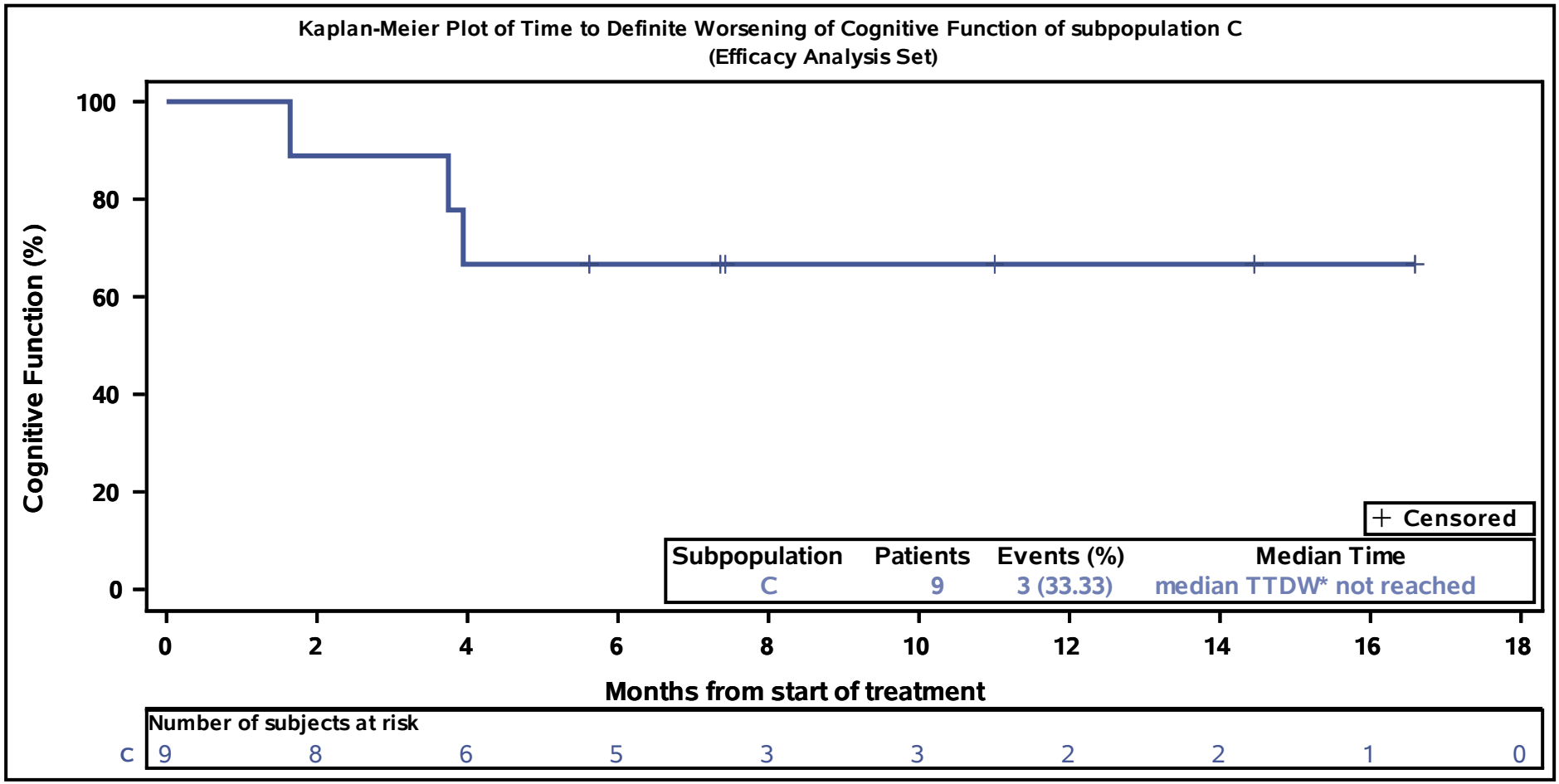
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F022_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



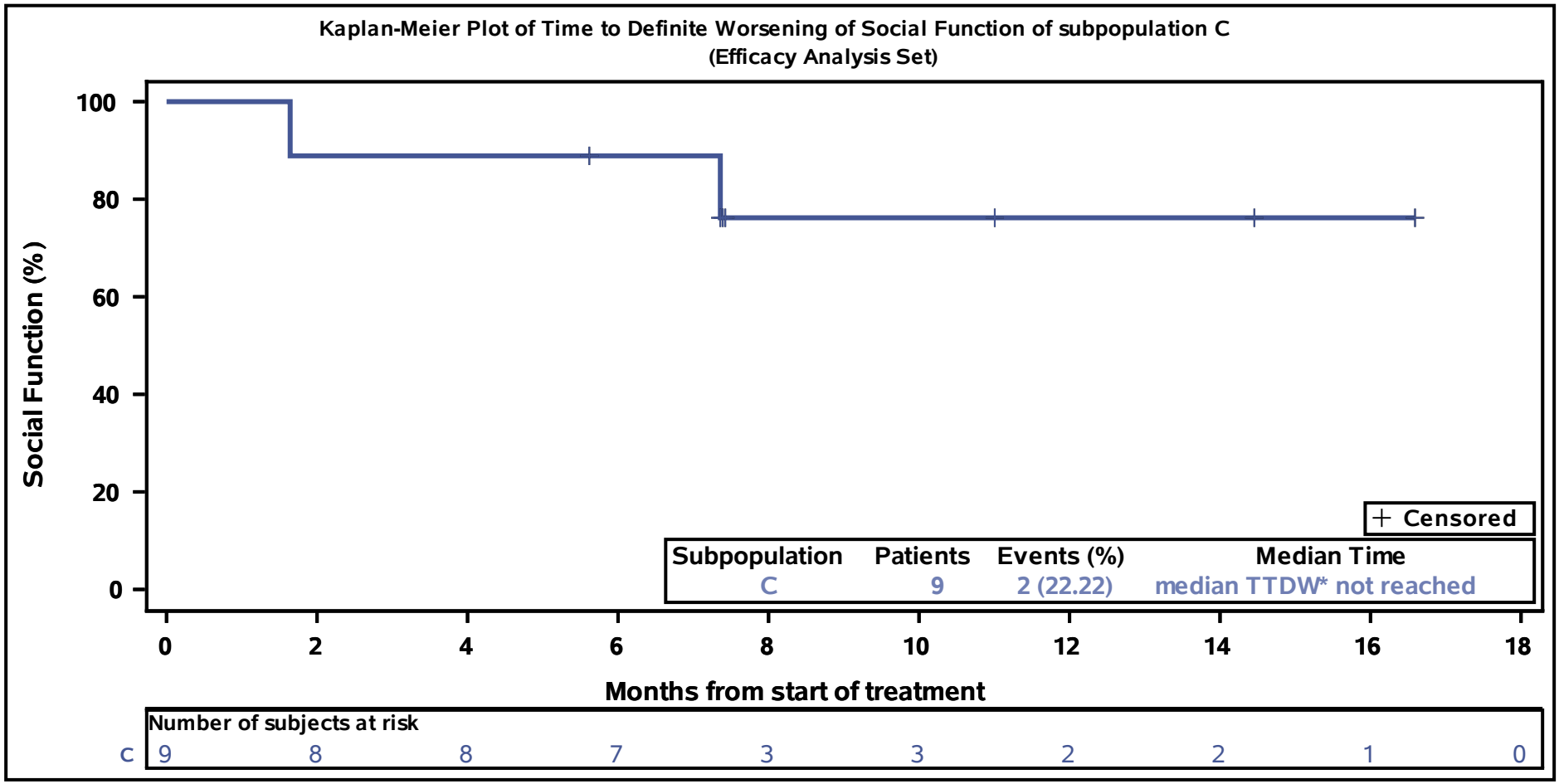
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F023_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



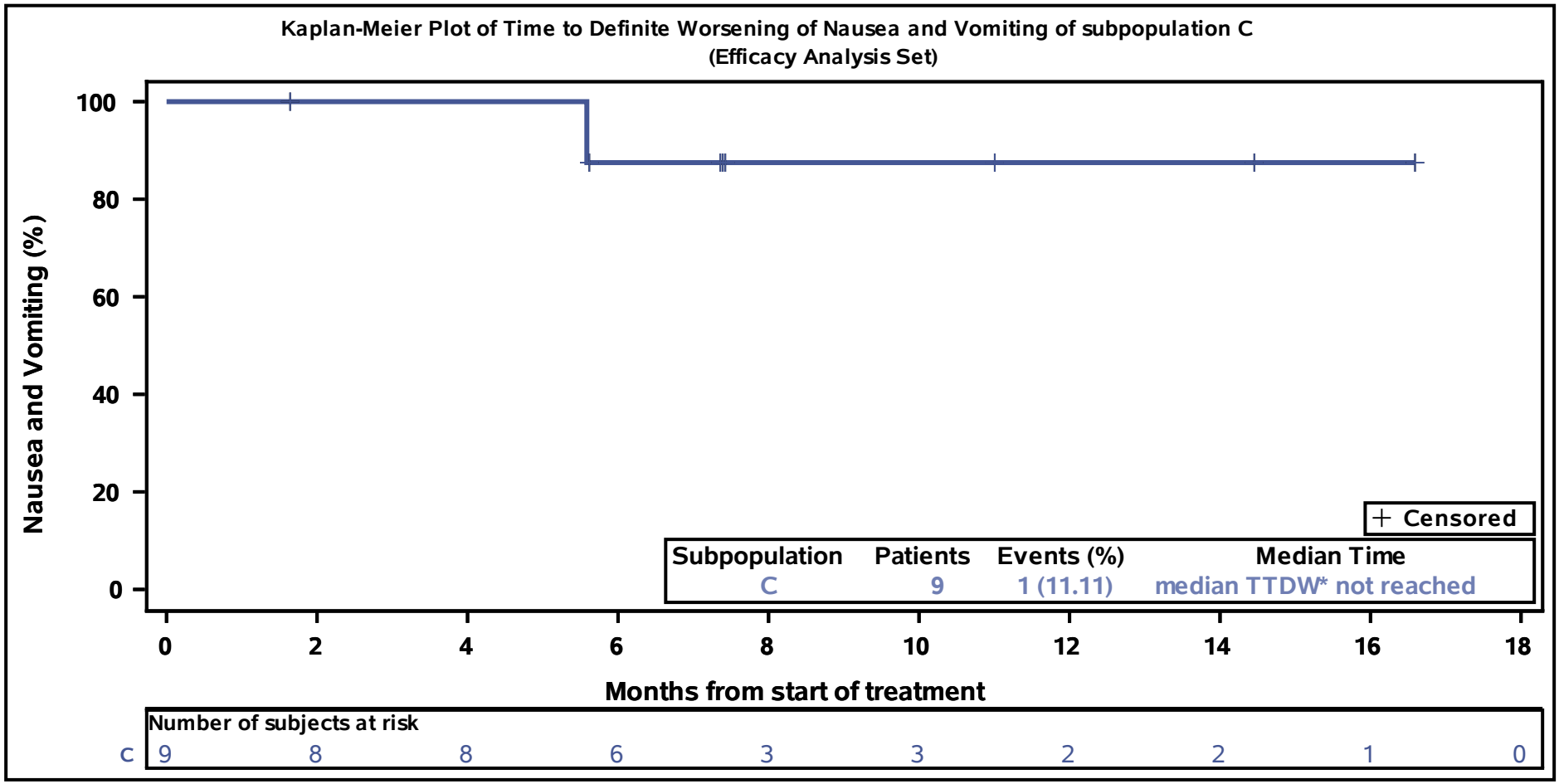
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F024_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F025_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

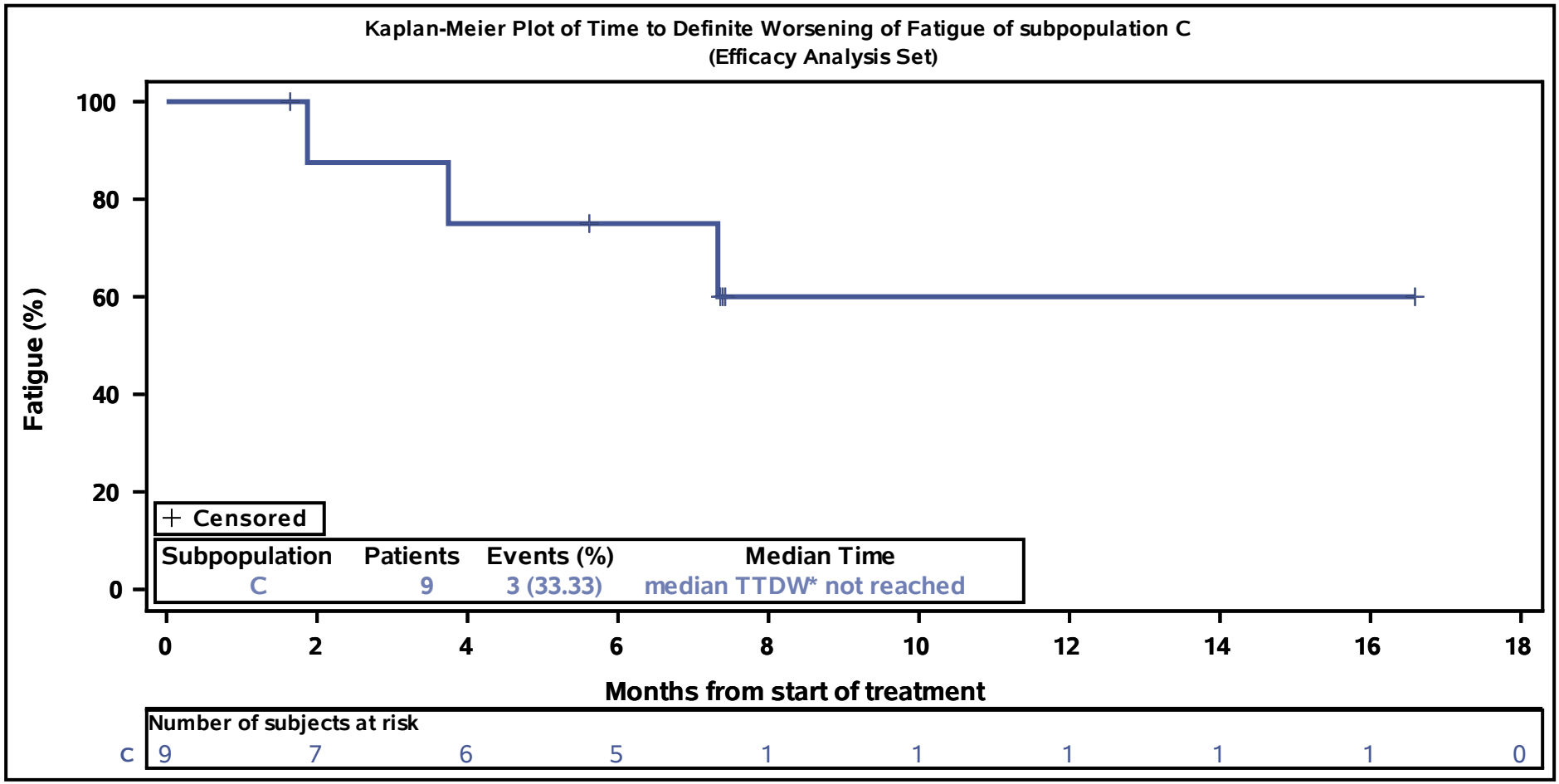
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (Visit Cutoff 30-MAR-2020)



* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F026_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

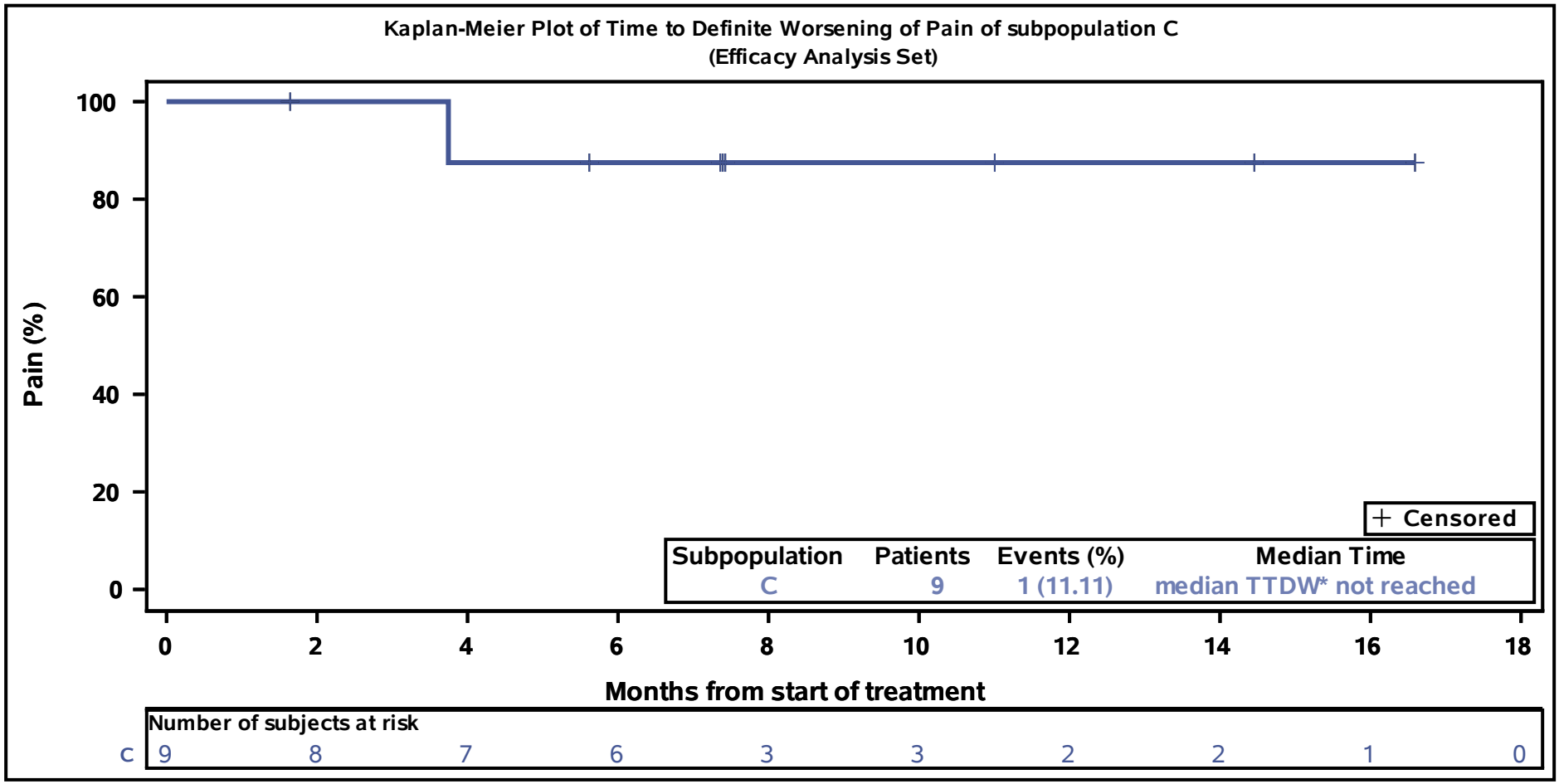
Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (Visit Cutoff 30-MAR-2020)

02:11 23DEC2020



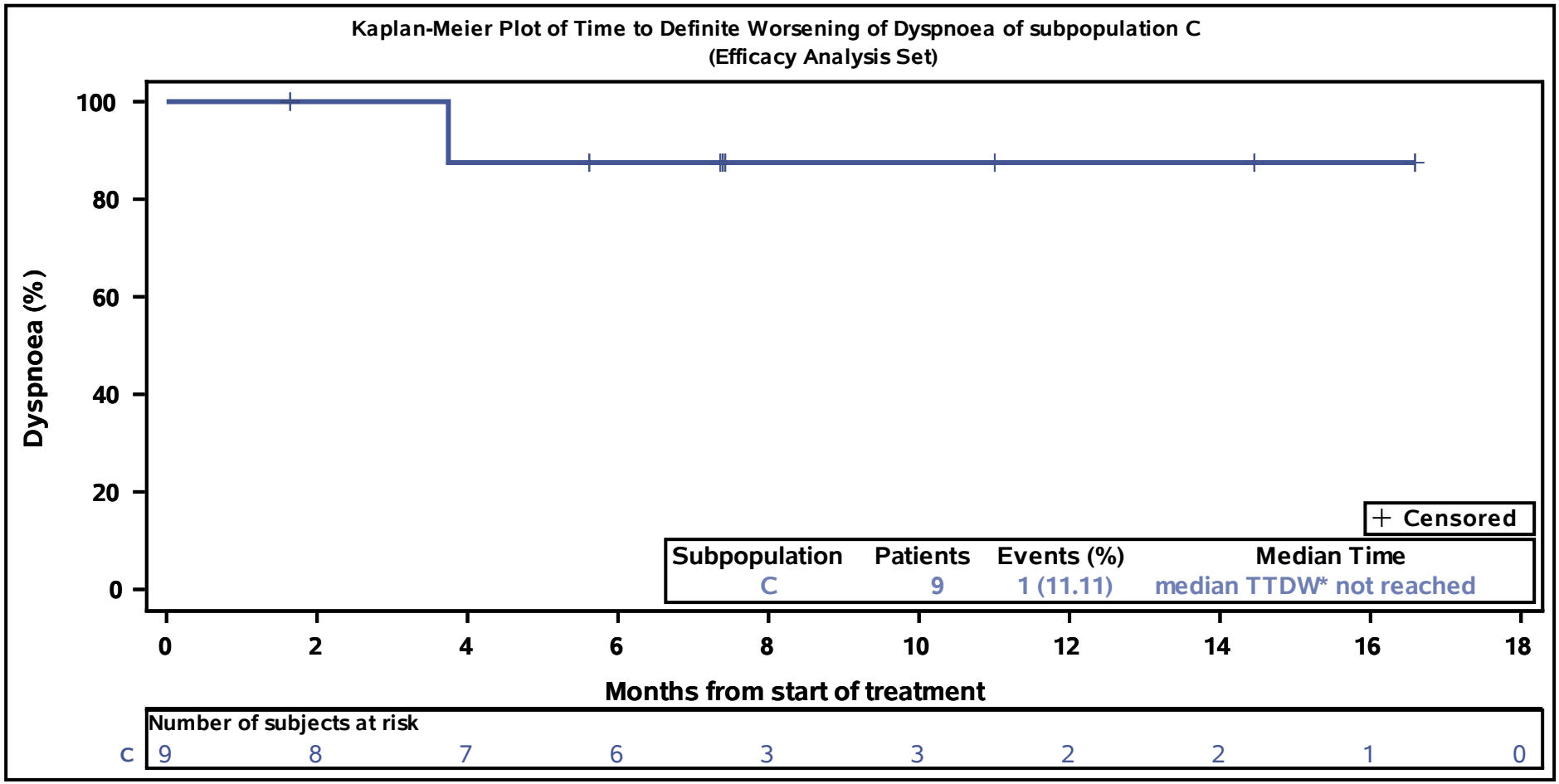
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F027_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



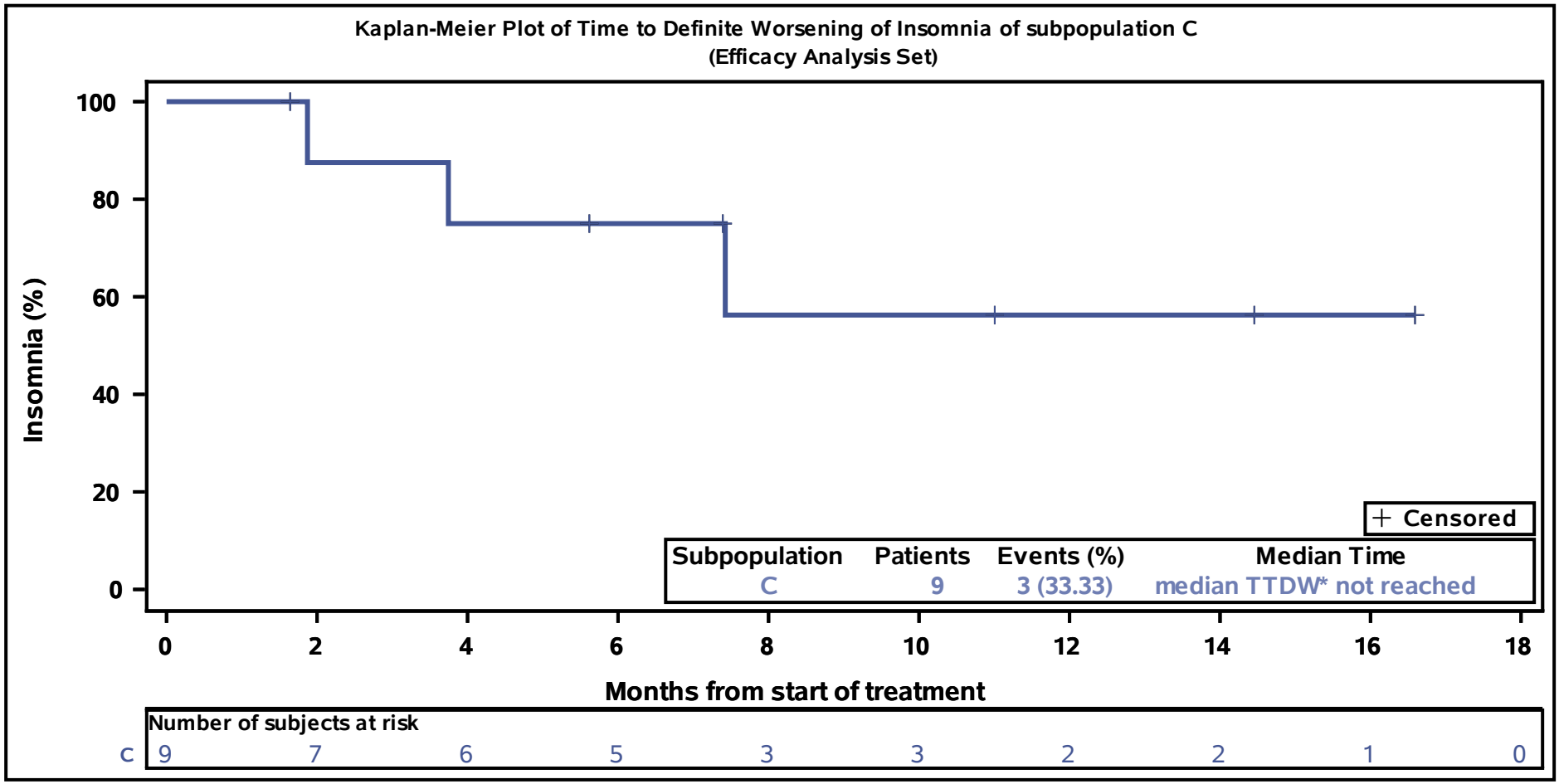
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F028_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



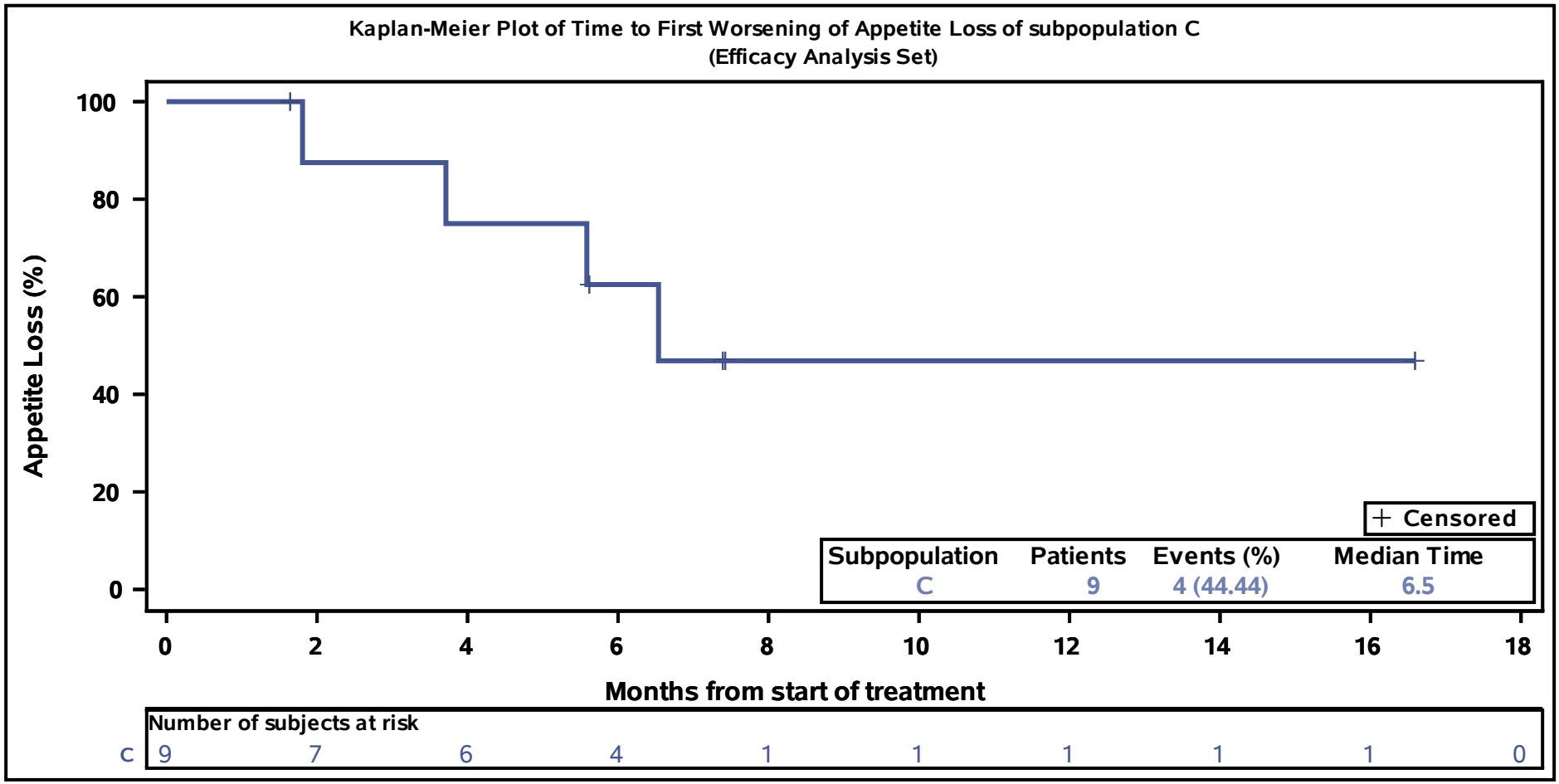
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F029_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



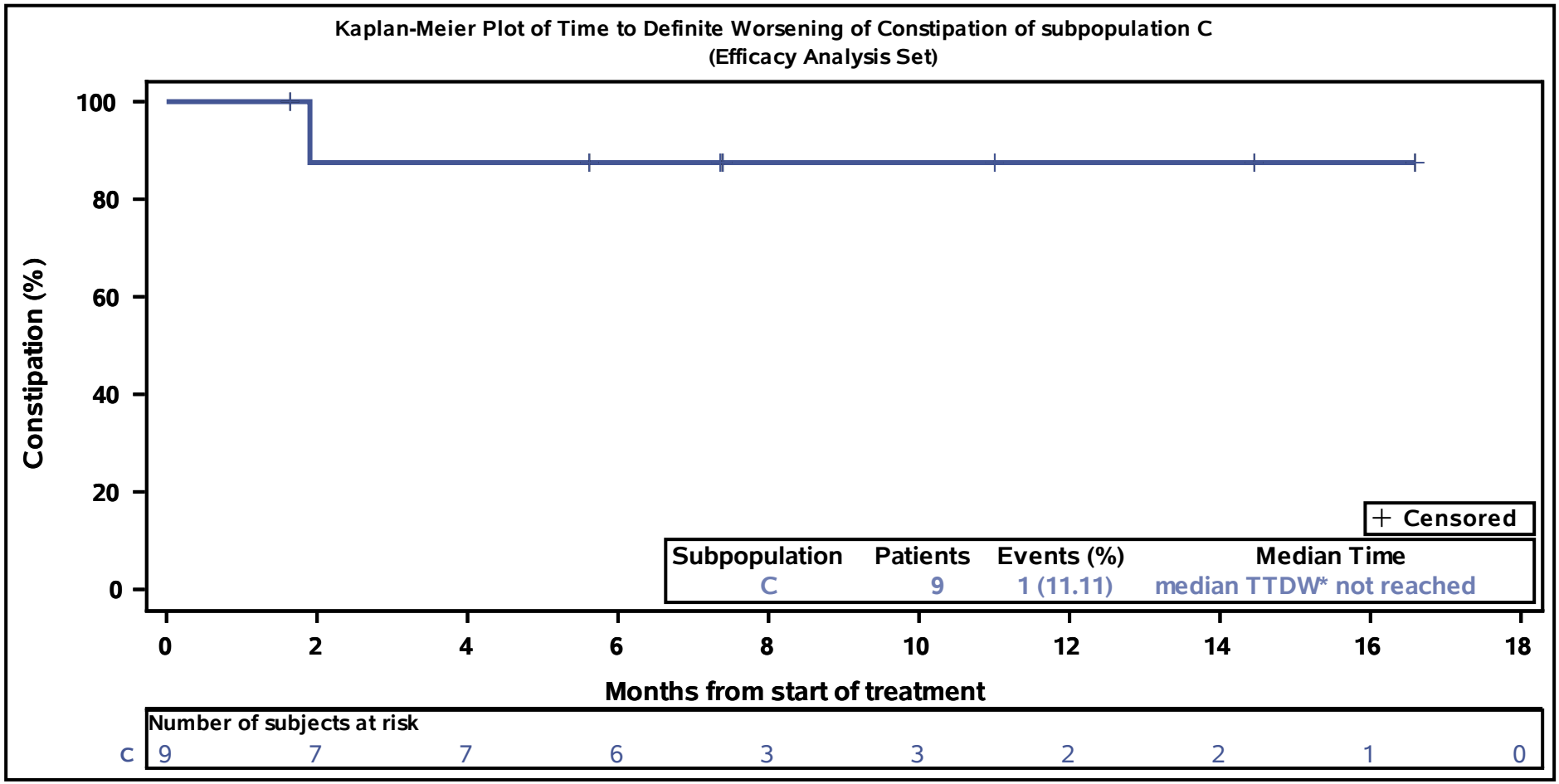
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F030_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



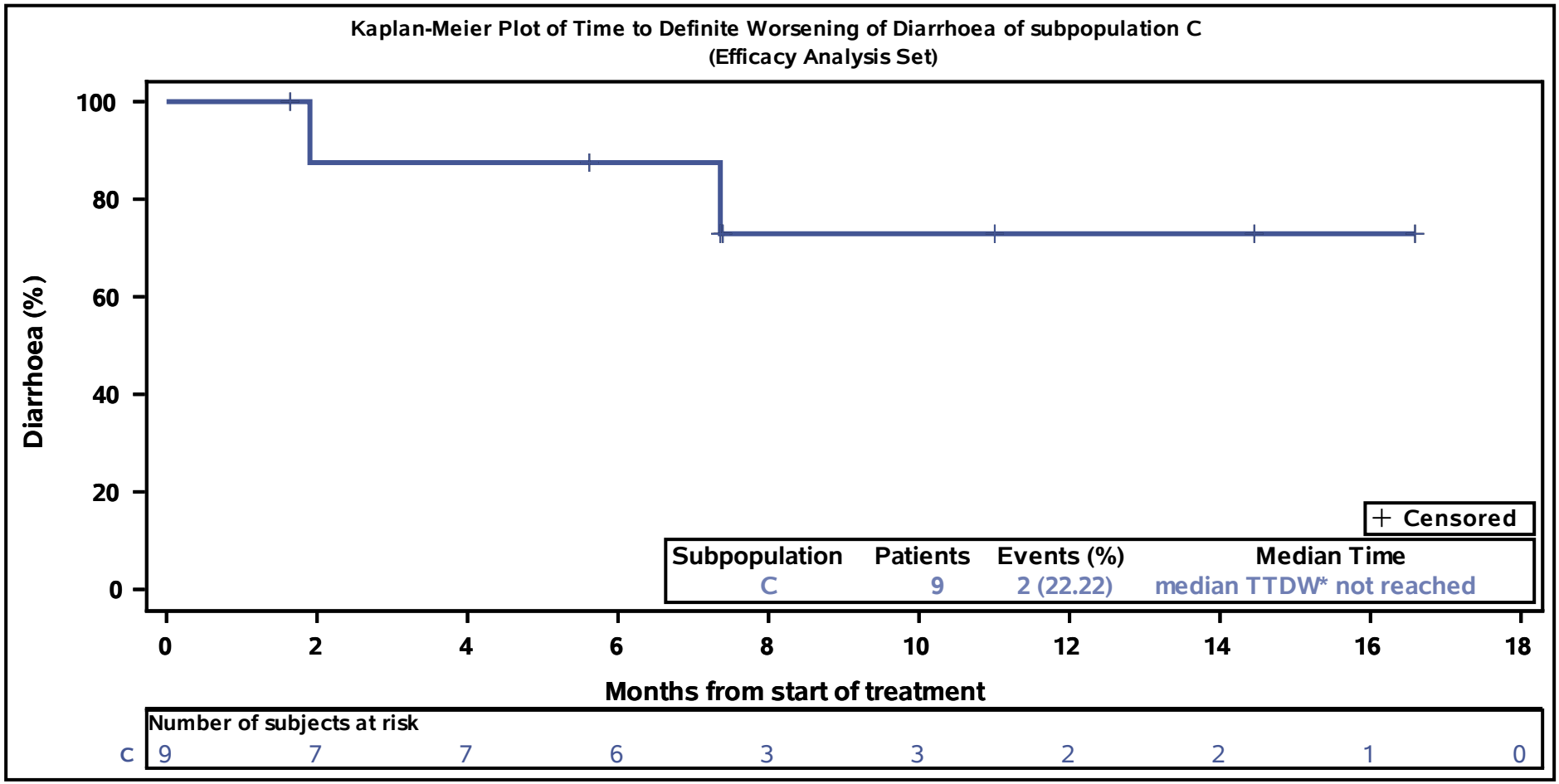
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F031_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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



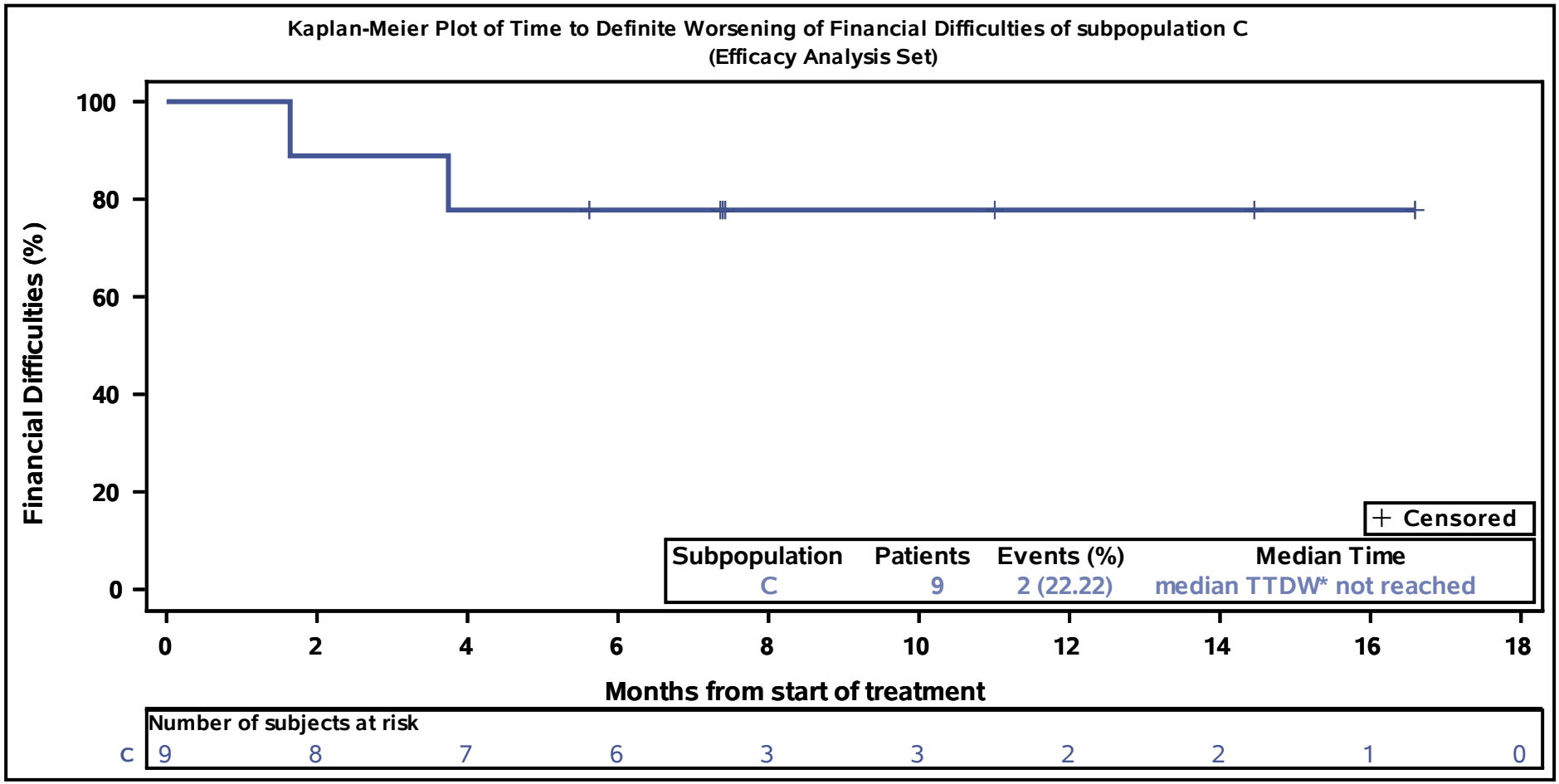
* TTDW = Time-to Definite Worsening
Only patients with a baseline and at least one post-baseline QLQ-C30 assessment have been included
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F032_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F033_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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
Program Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/f_sp_km_b10b.sas
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F034_1_ttw_10pt_tc_eff.rtf
Data Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/data/analysis/shared

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	75.00
Standard Deviation	22.438
Median	75.00
Q1, Q3	66.7, 91.7
Min, Max	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/T14.2.6.1.1_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	79.76
Standard Deviation	21.440
Median	83.33
Q1, Q3	83.3, 91.7
Min, Max	33.3, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	2.38
Standard Deviation	19.670
Median	0.00
Q1, Q3	0.0, 8.3
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (14.3)
Stable	5 (71.4)
Worsened	1 (14.3)

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

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

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	7
Mean	71.43
Standard Deviation	16.567
Median	75.00
Q1, Q3	50.0, 83.3
Min, Max	50.0, 91.7
Change from Baseline to Cycle 5 Day 1	
n [2]	7
Mean	-9.52
Standard Deviation	21.207
Median	-8.33
Q1, Q3	-25.0, -8.3
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (14.3)
Stable	3 (42.9)
Worsened	3 (42.9)

[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/T14.2.6.1.1_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	79.76
Standard Deviation	16.567
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	58.3, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	-1.19
Standard Deviation	22.272
Median	0.00
Q1, Q3	-25.0, 8.3
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (14.3)
Stable	4 (57.1)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	76.19
Standard Deviation	16.962
Median	83.33
Q1, Q3	58.3, 83.3
Min, Max	50.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	-2.38
Standard Deviation	25.781
Median	0.00
Q1, Q3	-16.7, 8.3
Min, Max	-50.0, 33.3
Status [3]	
Improved	1 (14.3)
Stable	4 (57.1)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	69.44
Standard Deviation	12.729
Median	66.67
Q1, Q3	58.3, 83.3
Min, Max	58.3, 83.3
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	2.78
Standard Deviation	26.788
Median	-8.33
Q1, Q3	-16.7, 33.3
Min, Max	-16.7, 33.3
Status [3]	
Improved	1 (33.3)
Stable	1 (33.3)
Worsened	1 (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/T14.2.6.1.1_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	69.44
Standard Deviation	17.347
Median	75.00
Q1, Q3	50.0, 83.3
Min, Max	50.0, 83.3
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	2.78
Standard Deviation	26.788
Median	-8.33
Q1, Q3	-16.7, 33.3
Min, Max	-16.7, 33.3
Status [3]	
Improved	1 (33.3)
Stable	1 (33.3)
Worsened	1 (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/T14.2.6.1.1_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	83.33
Standard Deviation	
Median	83.33
Q1, Q3	83.3, 83.3
Min, Max	83.3, 83.3
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	83.33
Standard Deviation	
Median	83.33
Q1, Q3	83.3, 83.3
Min, Max	83.3, 83.3
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

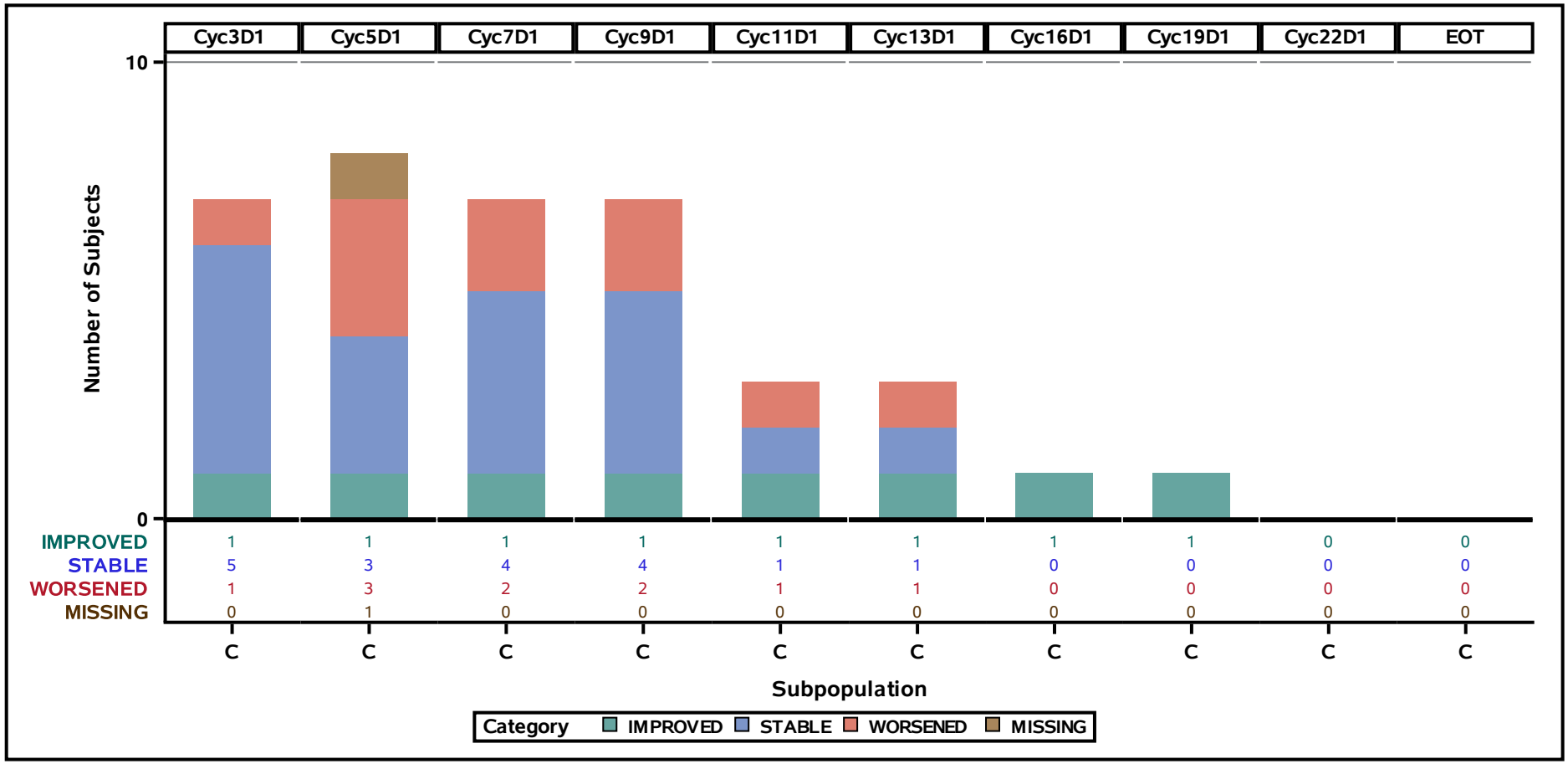
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F040_ql2_10pt_tc_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)

T14.2.6.1.46
EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 75.00 (22.44)	7 3.82 (-10.15, 17.79)
CYCLE 5 DAY 1		7 -5.05 (-19.16, 9.06)
CYCLE 7 DAY 1		7 3.29 (-10.82, 17.40)
CYCLE 9 DAY 1		7 0.07 (-13.93, 14.07)
CYCLE 11 DAY 1		3 -4.91 (-26.52, 16.70)
CYCLE 13 DAY 1		3 -4.91 (-26.52, 16.70)
CYCLE 16 DAY 1		1 11.46 (-26.83, 49.74)

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_mmrm2.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/T14.2.6.1.46.rtf

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

T14.2.6.1.46
EORTC QLQ-C30 (v3.0): Summary of Global Health Status/QoL by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 11.46	(-26.83, 49.74)
CYCLE 22 DAY 1	0 N.E	(N.E, N.E)
END OF TREATMENT	0 N.E	(N.E, N.E)

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_mmrm2.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/T14.2.6.1.46.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	81.48
Standard Deviation	20.757
Median	86.67
Q1, Q3	73.3, 100.0
Min, Max	40.0, 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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	90.00
Standard Deviation	9.623
Median	93.33
Q1, Q3	83.3, 100.0
Min, Max	73.3, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	5.24
Standard Deviation	6.627
Median	0.00
Q1, Q3	0.0, 13.3
Min, Max	0.0, 13.3
Status [3]	
Improved	3 (42.9)
Stable	4 (57.1)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	85.83
Standard Deviation	11.513
Median	90.00
Q1, Q3	76.7, 93.3
Min, Max	66.7, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	-0.83
Standard Deviation	10.947
Median	0.00
Q1, Q3	-6.7, 6.7
Min, Max	-20.0, 13.3
Status [3]	
Improved	2 (25.0)
Stable	5 (62.5)
Worsened	1 (12.5)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	88.57
Standard Deviation	12.599
Median	93.33
Q1, Q3	73.3, 100.0
Min, Max	73.3, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	1.90
Standard Deviation	11.362
Median	0.00
Q1, Q3	0.0, 13.3
Min, Max	-20.0, 13.3
Status [3]	
Improved	2 (28.6)
Stable	4 (57.1)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	87.62
Standard Deviation	8.968
Median	86.67
Q1, Q3	80.0, 93.3
Min, Max	73.3, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	2.86
Standard Deviation	12.084
Median	0.00
Q1, Q3	0.0, 13.3
Min, Max	-20.0, 13.3
Status [3]	
Improved	3 (42.9)
Stable	3 (42.9)
Worsened	1 (14.3)

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

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

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	75.56
Standard Deviation	16.777
Median	73.33
Q1, Q3	60.0, 93.3
Min, Max	60.0, 93.3
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	4.44
Standard Deviation	7.698
Median	0.00
Q1, Q3	0.0, 13.3
Min, Max	0.0, 13.3
Status [3]	
Improved	1 (33.3)
Stable	2 (66.7)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	75.56
Standard Deviation	16.777
Median	73.33
Q1, Q3	60.0, 93.3
Min, Max	60.0, 93.3
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	4.44
Standard Deviation	7.698
Median	0.00
Q1, Q3	0.0, 13.3
Min, Max	0.0, 13.3
Status [3]	
Improved	1 (33.3)
Stable	2 (66.7)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	93.33
Standard Deviation	
Median	93.33
Q1, Q3	93.3, 93.3
Min, Max	93.3, 93.3
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	13.33
Standard Deviation	
Median	13.33
Q1, Q3	13.3, 13.3
Min, Max	13.3, 13.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	93.33
Standard Deviation	
Median	93.33
Q1, Q3	93.3, 93.3
Min, Max	93.3, 93.3
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	13.33
Standard Deviation	
Median	13.33
Q1, Q3	13.3, 13.3
Min, Max	13.3, 13.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

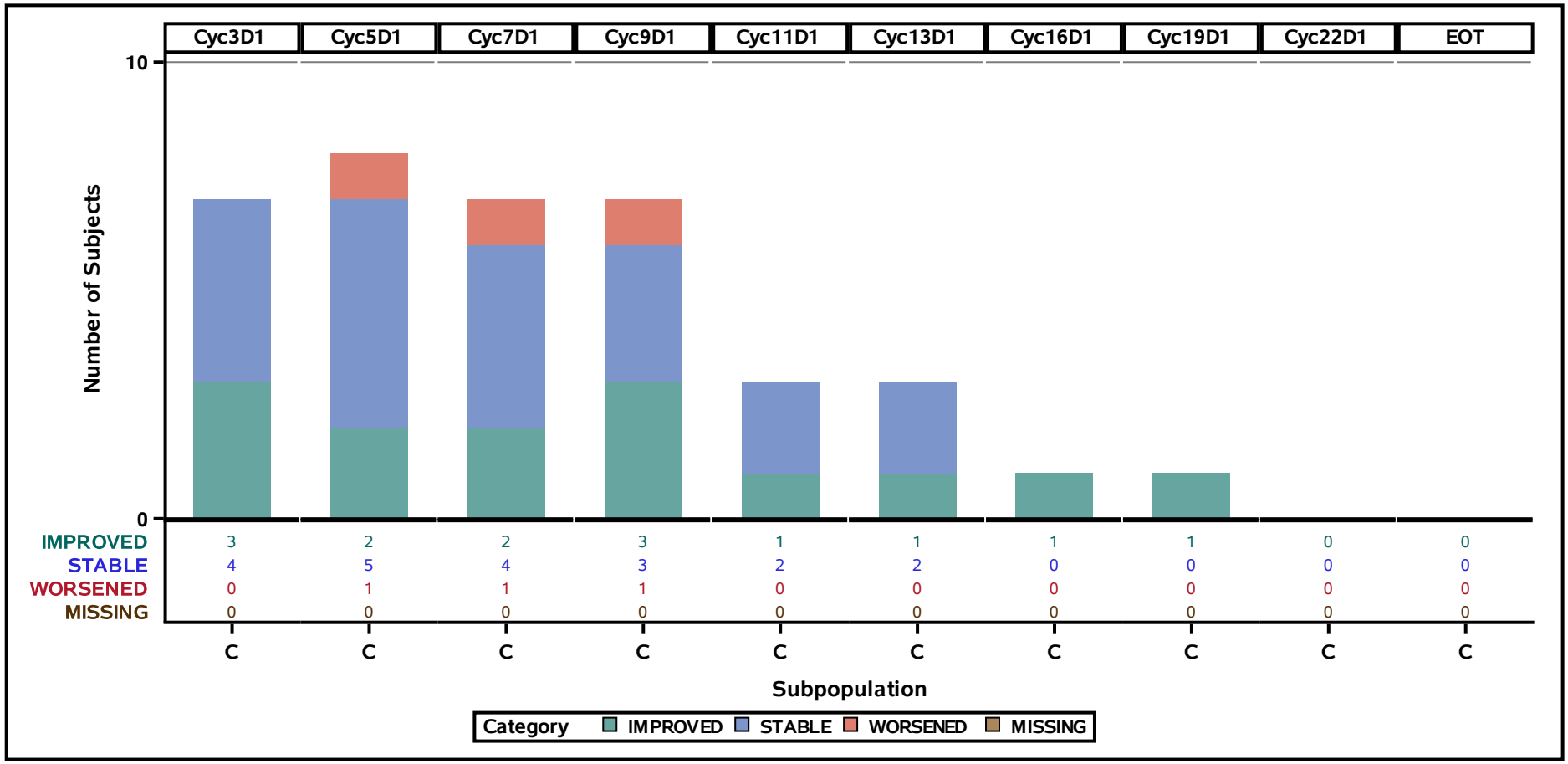
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F041_pf2_10pt_tc_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)

T14.2.6.1.47
EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 81.48 (20.76)	7 5.94 (-0.63, 12.51)
CYCLE 5 DAY 1		8 0.65 (-5.53, 6.84)
CYCLE 7 DAY 1		7 3.39 (-3.21, 10.00)
CYCLE 9 DAY 1		7 3.56 (-3.01, 10.12)
CYCLE 11 DAY 1		3 -0.49 (-10.85, 9.87)
CYCLE 13 DAY 1		3 -0.49 (-10.85, 9.87)
CYCLE 16 DAY 1		1 12.07 (-5.29, 29.42)

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_mmrm2.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/T14.2.6.1.47.rtf

T14.2.6.1.47
EORTC QLQ-C30 (v3.0): Summary of Physical Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 12.07	1 12.07 (-5.29, 29.42)
CYCLE 22 DAY 1	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	0 N.E	0 N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.47.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	81.48
Standard Deviation	26.279
Median	91.67
Q1, Q3	83.3, 100.0
Min, Max	25.0, 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/T14.2.6.1.3_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	82.14
Standard Deviation	20.086
Median	83.33
Q1, Q3	75.0, 100.0
Min, Max	41.7, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	-4.76
Standard Deviation	8.133
Median	-8.33
Q1, Q3	-8.3, 0.0
Min, Max	-16.7, 8.3
Status [3]	
Improved	0 (0.0)
Stable	6 (85.7)
Worsened	1 (14.3)

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

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

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	82.29
Standard Deviation	22.903
Median	87.50
Q1, Q3	75.0, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	-6.25
Standard Deviation	14.605
Median	-4.17
Q1, Q3	-12.5, 0.0
Min, Max	-33.3, 16.7
Status [3]	
Improved	1 (12.5)
Stable	5 (62.5)
Worsened	2 (25.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	79.76
Standard Deviation	23.500
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	-8.33
Standard Deviation	12.729
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-33.3, 0.0
Status [3]	
Improved	0 (0.0)
Stable	5 (71.4)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	73.81
Standard Deviation	29.825
Median	91.67
Q1, Q3	33.3, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	-13.10
Standard Deviation	27.156
Median	0.00
Q1, Q3	-25.0, 0.0
Min, Max	-66.7, 16.7
Status [3]	
Improved	1 (14.3)
Stable	3 (42.9)
Worsened	3 (42.9)

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

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

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	72.22
Standard Deviation	33.679
Median	91.67
Q1, Q3	33.3, 91.7
Min, Max	33.3, 91.7
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	-2.78
Standard Deviation	12.729
Median	0.00
Q1, Q3	-16.7, 8.3
Min, Max	-16.7, 8.3
Status [3]	
Improved	0 (0.0)
Stable	2 (66.7)
Worsened	1 (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/T14.2.6.1.3_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	83.33
Standard Deviation	28.868
Median	100.00
Q1, Q3	50.0, 100.0
Min, Max	50.0, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	8.33
Standard Deviation	8.333
Median	8.33
Q1, Q3	0.0, 16.7
Min, Max	0.0, 16.7
Status [3]	
Improved	1 (33.3)
Stable	2 (66.7)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	75.00
Standard Deviation	
Median	75.00
Q1, Q3	75.0, 75.0
Min, Max	75.0, 75.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	-16.67
Standard Deviation	
Median	-16.67
Q1, Q3	-16.7, -16.7
Min, Max	-16.7, -16.7
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	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/T14.2.6.1.3_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	83.33
Standard Deviation	
Median	83.33
Q1, Q3	83.3, 83.3
Min, Max	83.3, 83.3
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	-8.33
Standard Deviation	
Median	-8.33
Q1, Q3	-8.3, -8.3
Min, Max	-8.3, -8.3
Status [3]	
Improved	0 (0.0)
Stable	1 (100.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

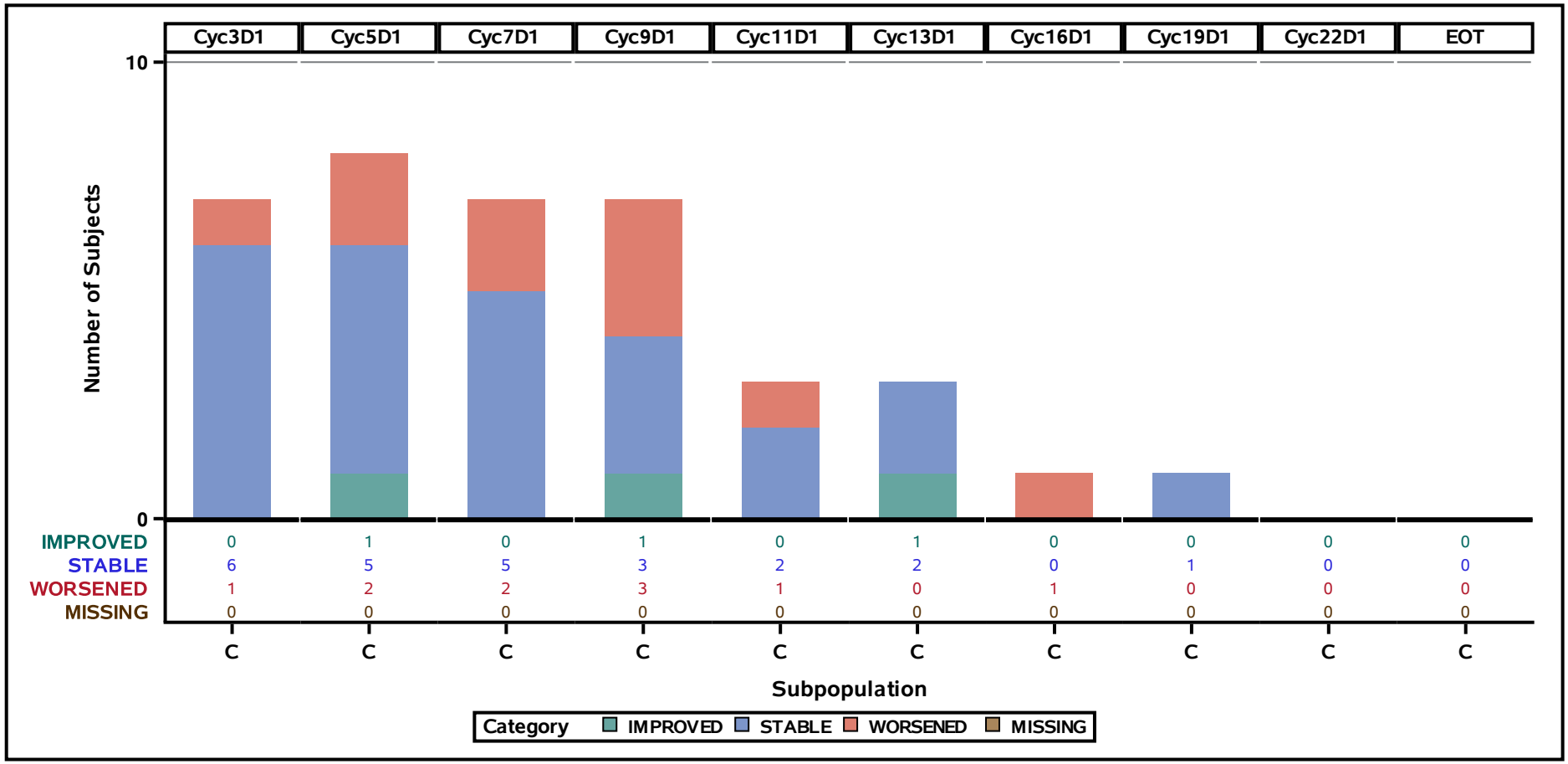
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F042_ef_10pt_tc_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)

T14.2.6.1.48
EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 81.48 (26.28)	7 -4.85 (-17.84, 8.14)
CYCLE 5 DAY 1		8 -6.48 (-18.66, 5.71)
CYCLE 7 DAY 1		7 -8.52 (-21.53, 4.49)
CYCLE 9 DAY 1		7 -13.19 (-26.18, -0.19)
CYCLE 11 DAY 1		3 -1.88 (-22.09, 18.32)
CYCLE 13 DAY 1		3 9.23 (-10.98, 29.43)
CYCLE 16 DAY 1		1 -17.15 (-51.57, 17.27)

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_mmrm2.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/T14.2.6.1.48.rtf

T14.2.6.1.48
EORTC QLQ-C30 (v3.0): Summary of Emotional Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1	1 -8.82 (-43.24, 25.60)
CYCLE 22 DAY 1	0	0 N.E (N.E, N.E)
END OF TREATMENT	0	0 N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.48.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	79.63
Standard Deviation	33.101
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	0.0, 100.0

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

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

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	88.10
Standard Deviation	20.893
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	50.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	0.00
Standard Deviation	21.517
Median	0.00
Q1, Q3	-16.7, 16.7
Min, Max	-33.3, 33.3
Status [3]	
Improved	2 (28.6)
Stable	3 (42.9)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	83.33
Standard Deviation	26.726
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	-6.25
Standard Deviation	28.084
Median	0.00
Q1, Q3	-8.3, 0.0
Min, Max	-66.7, 33.3
Status [3]	
Improved	1 (12.5)
Stable	5 (62.5)
Worsened	2 (25.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	90.48
Standard Deviation	16.265
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	2.38
Standard Deviation	20.250
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-33.3, 33.3
Status [3]	
Improved	2 (28.6)
Stable	4 (57.1)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	83.33
Standard Deviation	16.667
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	-4.76
Standard Deviation	24.934
Median	0.00
Q1, Q3	-33.3, 16.7
Min, Max	-33.3, 33.3
Status [3]	
Improved	2 (28.6)
Stable	2 (28.6)
Worsened	3 (42.9)

[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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	83.33
Standard Deviation	16.667
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	5.56
Standard Deviation	25.459
Median	0.00
Q1, Q3	-16.7, 33.3
Min, Max	-16.7, 33.3
Status [3]	
Improved	1 (33.3)
Stable	1 (33.3)
Worsened	1 (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/T14.2.6.1.4_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	88.89
Standard Deviation	19.245
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	11.11
Standard Deviation	19.245
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Status [3]	
Improved	1 (33.3)
Stable	2 (66.7)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	100.00
Standard Deviation	
Median	100.00
Q1, Q3	100.0, 100.0
Min, Max	100.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	100.00
Standard Deviation	
Median	100.00
Q1, Q3	100.0, 100.0
Min, Max	100.0, 100.0
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

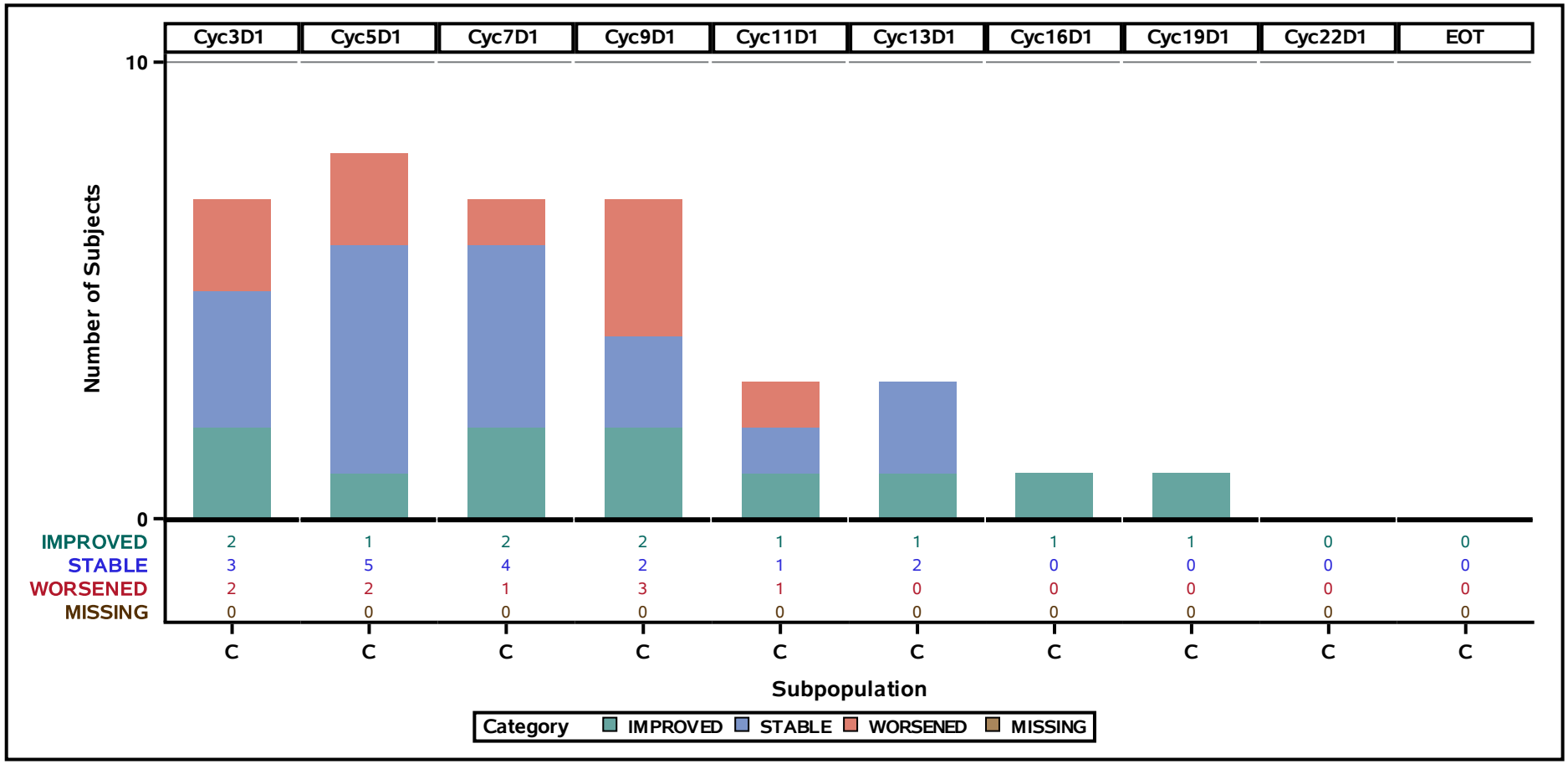
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F043_rf2_10pt_tc_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

T14.2.6.1.49
EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 79.63 (33.10)	7 1.97 (-14.18, 18.12)
CYCLE 5 DAY 1		8 -3.11 (-18.30, 12.08)
CYCLE 7 DAY 1		7 4.35 (-11.80, 20.50)
CYCLE 9 DAY 1		7 -2.79 (-18.94, 13.36)
CYCLE 11 DAY 1		3 -0.58 (-25.47, 24.32)
CYCLE 13 DAY 1		3 4.98 (-19.91, 29.87)
CYCLE 16 DAY 1		1 18.48 (-25.11, 62.07)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmrm2.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/T14.2.6.1.49.rtf

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

T14.2.6.1.49
EORTC QLQ-C30 (v3.0): Summary of Role Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 18.48	1 18.48 (-25.11, 62.07)
CYCLE 22 DAY 1	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	0 N.E	0 N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.49.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	85.19
Standard Deviation	17.568
Median	83.33
Q1, Q3	83.3, 100.0
Min, Max	50.0, 100.0

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

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

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	88.10
Standard Deviation	15.853
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	2.38
Standard Deviation	11.501
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-16.7, 16.7
Status [3]	
Improved	2 (28.6)
Stable	4 (57.1)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	81.25
Standard Deviation	24.296
Median	91.67
Q1, Q3	66.7, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	-6.25
Standard Deviation	23.465
Median	0.00
Q1, Q3	-16.7, 8.3
Min, Max	-50.0, 16.7
Status [3]	
Improved	2 (25.0)
Stable	4 (50.0)
Worsened	2 (25.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	78.57
Standard Deviation	20.893
Median	66.67
Q1, Q3	66.7, 100.0
Min, Max	50.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	-7.14
Standard Deviation	21.207
Median	0.00
Q1, Q3	-33.3, 16.7
Min, Max	-33.3, 16.7
Status [3]	
Improved	2 (28.6)
Stable	2 (28.6)
Worsened	3 (42.9)

[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/T14.2.6.1.5_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	71.43
Standard Deviation	31.497
Median	83.33
Q1, Q3	33.3, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	-14.29
Standard Deviation	31.074
Median	0.00
Q1, Q3	-50.0, 0.0
Min, Max	-66.7, 16.7
Status [3]	
Improved	1 (14.3)
Stable	4 (57.1)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	72.22
Standard Deviation	19.245
Median	83.33
Q1, Q3	50.0, 83.3
Min, Max	50.0, 83.3
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	0.00
Standard Deviation	0.000
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	3 (100.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	83.33
Standard Deviation	16.667
Median	83.33
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	11.11
Standard Deviation	9.623
Median	16.67
Q1, Q3	0.0, 16.7
Min, Max	0.0, 16.7
Status [3]	
Improved	2 (66.7)
Stable	1 (33.3)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	100.00
Standard Deviation	
Median	100.00
Q1, Q3	100.0, 100.0
Min, Max	100.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	16.67
Standard Deviation	
Median	16.67
Q1, Q3	16.7, 16.7
Min, Max	16.7, 16.7
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	100.00
Standard Deviation	
Median	100.00
Q1, Q3	100.0, 100.0
Min, Max	100.0, 100.0
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	16.67
Standard Deviation	
Median	16.67
Q1, Q3	16.7, 16.7
Min, Max	16.7, 16.7
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

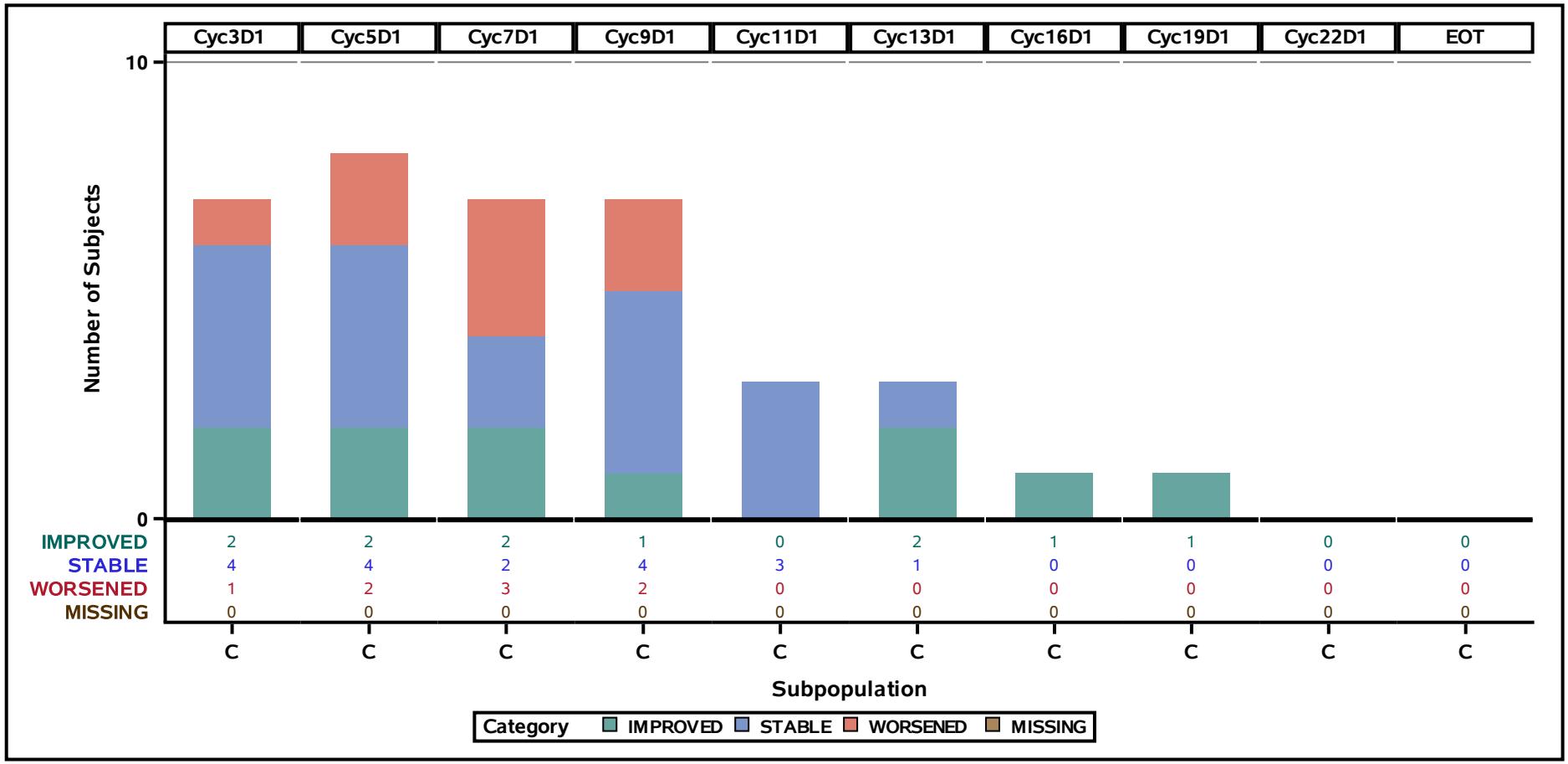
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F044_cf_10pt_tc_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)

T14.2.6.1.50
EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 85.19 (17.57)	7 3.12 (-13.11, 19.35)
CYCLE 5 DAY 1		8 -4.83 (-20.08, 10.42)
CYCLE 7 DAY 1		7 -6.40 (-22.63, 9.82)
CYCLE 9 DAY 1		7 -13.55 (-29.78, 2.68)
CYCLE 11 DAY 1		3 -4.42 (-29.71, 20.86)
CYCLE 13 DAY 1		3 6.69 (-18.59, 31.97)
CYCLE 16 DAY 1		1 16.49 (-26.38, 59.37)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_mmrm2.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/T14.2.6.1.50.rtf

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

T14.2.6.1.50
EORTC QLQ-C30 (v3.0): Summary of Cognitive Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 16.49	1 16.49 (-26.38, 59.37)
CYCLE 22 DAY 1	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	0 N.E	0 N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.50.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	79.63
Standard Deviation	29.788
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	16.7, 100.0

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

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

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	90.48
Standard Deviation	13.113
Median	100.00
Q1, Q3	83.3, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	4.76
Standard Deviation	15.853
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-16.7, 33.3
Status [3]	
Improved	2 (28.6)
Stable	4 (57.1)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	79.17
Standard Deviation	29.209
Median	100.00
Q1, Q3	50.0, 100.0
Min, Max	33.3, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	-8.33
Standard Deviation	25.198
Median	0.00
Q1, Q3	-25.0, 0.0
Min, Max	-50.0, 33.3
Status [3]	
Improved	1 (12.5)
Stable	4 (50.0)
Worsened	3 (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
Data location: /lillyce/prd/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	88.10
Standard Deviation	20.893
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	50.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	0.00
Standard Deviation	19.245
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (14.3)
Stable	5 (71.4)
Worsened	1 (14.3)

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

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

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	90.48
Standard Deviation	13.113
Median	100.00
Q1, Q3	83.3, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	4.76
Standard Deviation	15.853
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-16.7, 33.3
Status [3]	
Improved	2 (28.6)
Stable	4 (57.1)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	88.89
Standard Deviation	19.245
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	16.67
Standard Deviation	16.667
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Status [3]	
Improved	2 (66.7)
Stable	1 (33.3)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	88.89
Standard Deviation	19.245
Median	100.00
Q1, Q3	66.7, 100.0
Min, Max	66.7, 100.0
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	16.67
Standard Deviation	16.667
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Status [3]	
Improved	2 (66.7)
Stable	1 (33.3)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	100.00
Standard Deviation	
Median	100.00
Q1, Q3	100.0, 100.0
Min, Max	100.0, 100.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	100.00
Standard Deviation	
Median	100.00
Q1, Q3	100.0, 100.0
Min, Max	100.0, 100.0
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

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

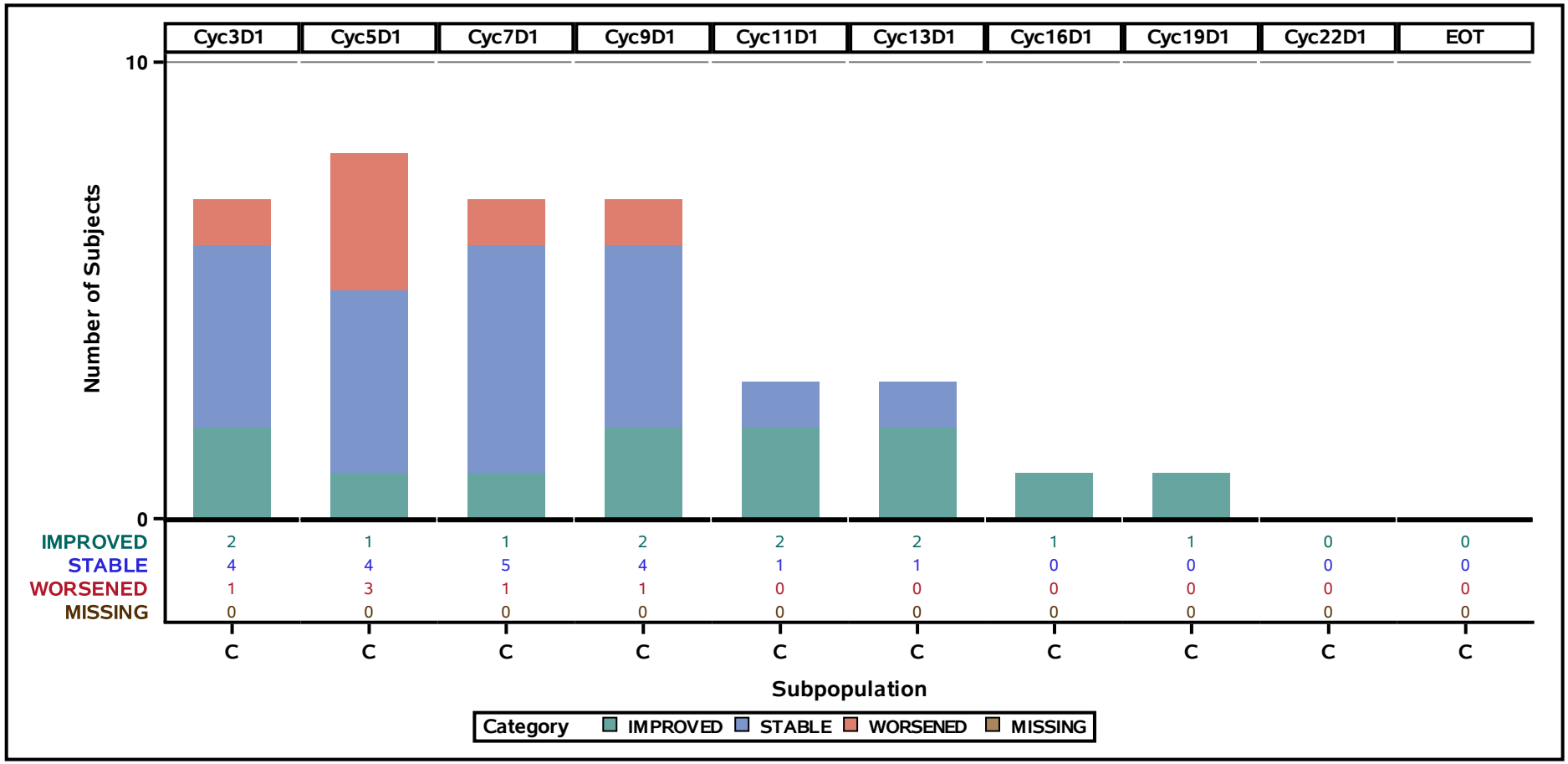
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

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

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F045_sf_10pt_tc_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)

T14.2.6.1.51
EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 79.63 (29.79)	7 5.83 (-7.64, 19.29)
CYCLE 5 DAY 1		8 -6.47 (-19.11, 6.18)
CYCLE 7 DAY 1		7 2.13 (-11.40, 15.66)
CYCLE 9 DAY 1		7 5.83 (-7.64, 19.29)
CYCLE 11 DAY 1		3 11.70 (-9.14, 32.53)
CYCLE 13 DAY 1		3 11.70 (-9.14, 32.53)
CYCLE 16 DAY 1		1 25.88 (-10.08, 61.83)

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_mmrm2.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/T14.2.6.1.51.rtf

T14.2.6.1.51
EORTC QLQ-C30 (v3.0): Summary of Social Function by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 25.88	1 25.88 (-10.08, 61.83)
CYCLE 22 DAY 1	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	0 N.E	0 N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.51.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	9.26
Standard Deviation	14.699
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 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/T14.2.6.1.7_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	4.76
Standard Deviation	12.599
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 33.3
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	-2.38
Standard Deviation	20.250
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	2 (28.6)
Stable	4 (57.1)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	6.25
Standard Deviation	12.400
Median	0.00
Q1, Q3	0.0, 8.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	0.00
Standard Deviation	17.817
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (12.5)
Stable	6 (75.0)
Worsened	1 (12.5)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	4.76
Standard Deviation	8.133
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 16.7
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	-2.38
Standard Deviation	14.996
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 16.7
Status [3]	
Improved	1 (14.3)
Stable	5 (71.4)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	7.14
Standard Deviation	8.909
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 16.7
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	0.00
Standard Deviation	16.667
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-33.3, 16.7
Status [3]	
Improved	1 (14.3)
Stable	4 (57.1)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
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 11 Day 1	
n [2]	3
Mean	-5.56
Standard Deviation	9.623
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-16.7, 0.0
Status [3]	
Improved	1 (33.3)
Stable	2 (66.7)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
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 13 Day 1	
n [2]	3
Mean	-5.56
Standard Deviation	9.623
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-16.7, 0.0
Status [3]	
Improved	1 (33.3)
Stable	2 (66.7)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	1 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	1 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_tc_eff.rtf

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

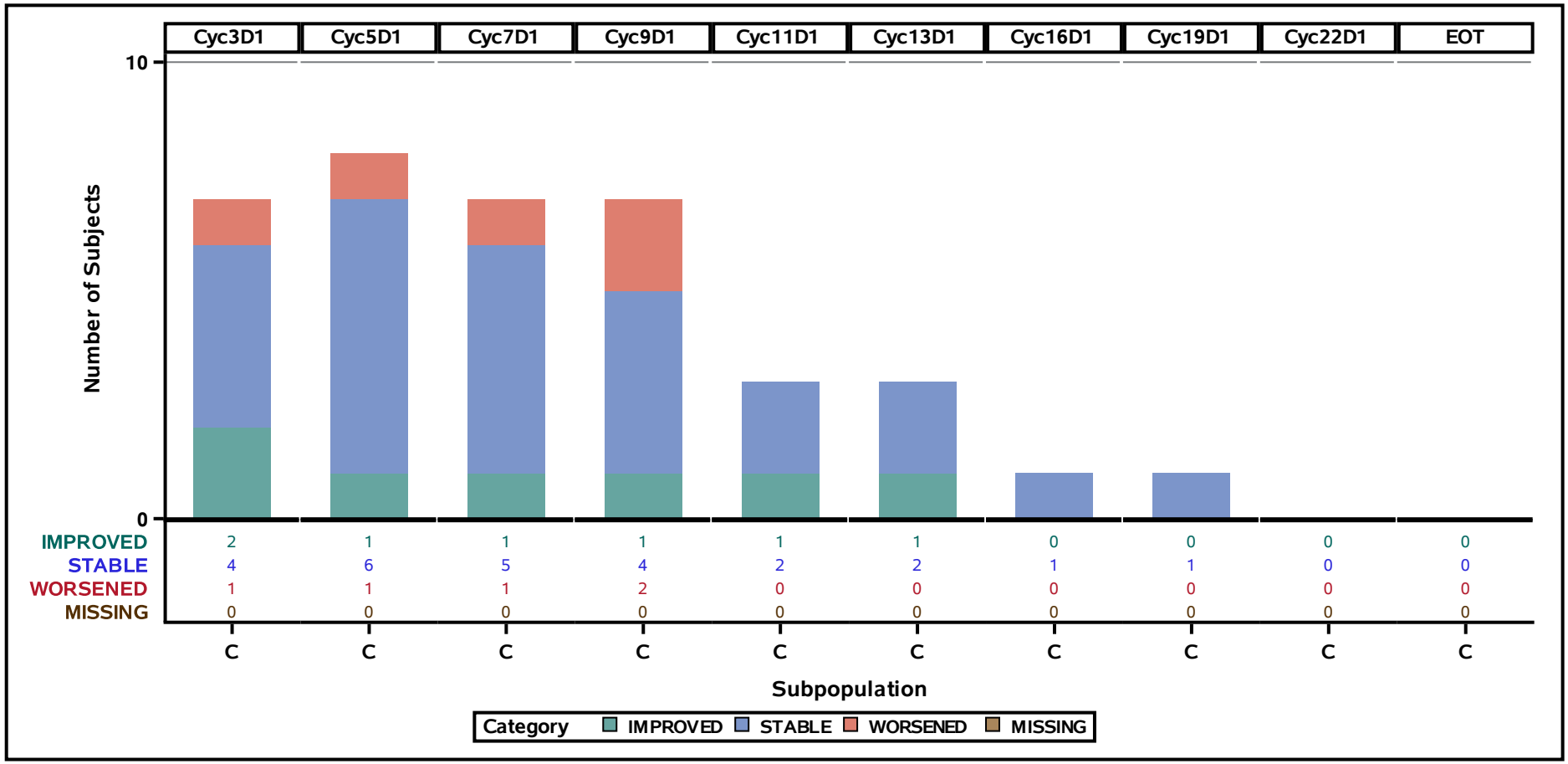
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.7_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F046_nv_10pt_tc_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)

T14.2.6.1.52
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 9.26 (14.70)	7 -1.49 (-9.44, 6.47)
CYCLE 5 DAY 1		8 -0.06 (-7.50, 7.38)
CYCLE 7 DAY 1		7 -1.49 (-9.44, 6.47)
CYCLE 9 DAY 1		7 0.89 (-7.06, 8.85)
CYCLE 11 DAY 1		3 -6.36 (-18.50, 5.79)
CYCLE 13 DAY 1		3 -6.36 (-18.50, 5.79)
CYCLE 16 DAY 1		1 -6.74 (-27.87, 14.39)

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_mmrm2.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/T14.2.6.1.52.rtf

T14.2.6.1.52
EORTC QLQ-C30 (v3.0): Summary of Nausea and Vomiting by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1	-6.74 (-27.87, 14.39)
CYCLE 22 DAY 1	0	N.E (N.E, N.E)
END OF TREATMENT	0	N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.52.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	27.16
Standard Deviation	28.927
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 88.9

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	17.46
Standard Deviation	10.843
Median	22.22
Q1, Q3	11.1, 22.2
Min, Max	0.0, 33.3
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	-4.76
Standard Deviation	14.138
Median	-11.11
Q1, Q3	-11.1, 0.0
Min, Max	-22.2, 22.2
Status [3]	
Improved	4 (57.1)
Stable	2 (28.6)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	25.00
Standard Deviation	17.568
Median	27.78
Q1, Q3	11.1, 33.3
Min, Max	0.0, 55.6
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	5.56
Standard Deviation	21.414
Median	0.00
Q1, Q3	-11.1, 27.8
Min, Max	-22.2, 33.3
Status [3]	
Improved	3 (37.5)
Stable	2 (25.0)
Worsened	3 (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
Data location: /lillyce/prd/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	20.63
Standard Deviation	21.687
Median	22.22
Q1, Q3	0.0, 33.3
Min, Max	0.0, 55.6
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	3.17
Standard Deviation	30.574
Median	-11.11
Q1, Q3	-11.1, 33.3
Min, Max	-33.3, 55.6
Status [3]	
Improved	4 (57.1)
Stable	1 (14.3)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	25.40
Standard Deviation	18.937
Median	11.11
Q1, Q3	11.1, 44.4
Min, Max	11.1, 55.6
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	3.17
Standard Deviation	19.994
Median	11.11
Q1, Q3	-22.2, 11.1
Min, Max	-22.2, 33.3
Status [3]	
Improved	2 (28.6)
Stable	1 (14.3)
Worsened	4 (57.1)

[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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	29.63
Standard Deviation	23.130
Median	22.22
Q1, Q3	11.1, 55.6
Min, Max	11.1, 55.6
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	3.70
Standard Deviation	23.130
Median	11.11
Q1, Q3	-22.2, 22.2
Min, Max	-22.2, 22.2
Status [3]	
Improved	1 (33.3)
Stable	0 (0.0)
Worsened	2 (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/T14.2.6.1.8_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	25.93
Standard Deviation	25.660
Median	11.11
Q1, Q3	11.1, 55.6
Min, Max	11.1, 55.6
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	0.00
Standard Deviation	19.245
Median	11.11
Q1, Q3	-22.2, 11.1
Min, Max	-22.2, 11.1
Status [3]	
Improved	1 (33.3)
Stable	0 (0.0)
Worsened	2 (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/T14.2.6.1.8_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	11.11
Standard Deviation	
Median	11.11
Q1, Q3	11.1, 11.1
Min, Max	11.1, 11.1
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	-22.22
Standard Deviation	
Median	-22.22
Q1, Q3	-22.2, -22.2
Min, Max	-22.2, -22.2
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	11.11
Standard Deviation	
Median	11.11
Q1, Q3	11.1, 11.1
Min, Max	11.1, 11.1
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	-22.22
Standard Deviation	
Median	-22.22
Q1, Q3	-22.2, -22.2
Min, Max	-22.2, -22.2
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_tc_eff.rtf

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

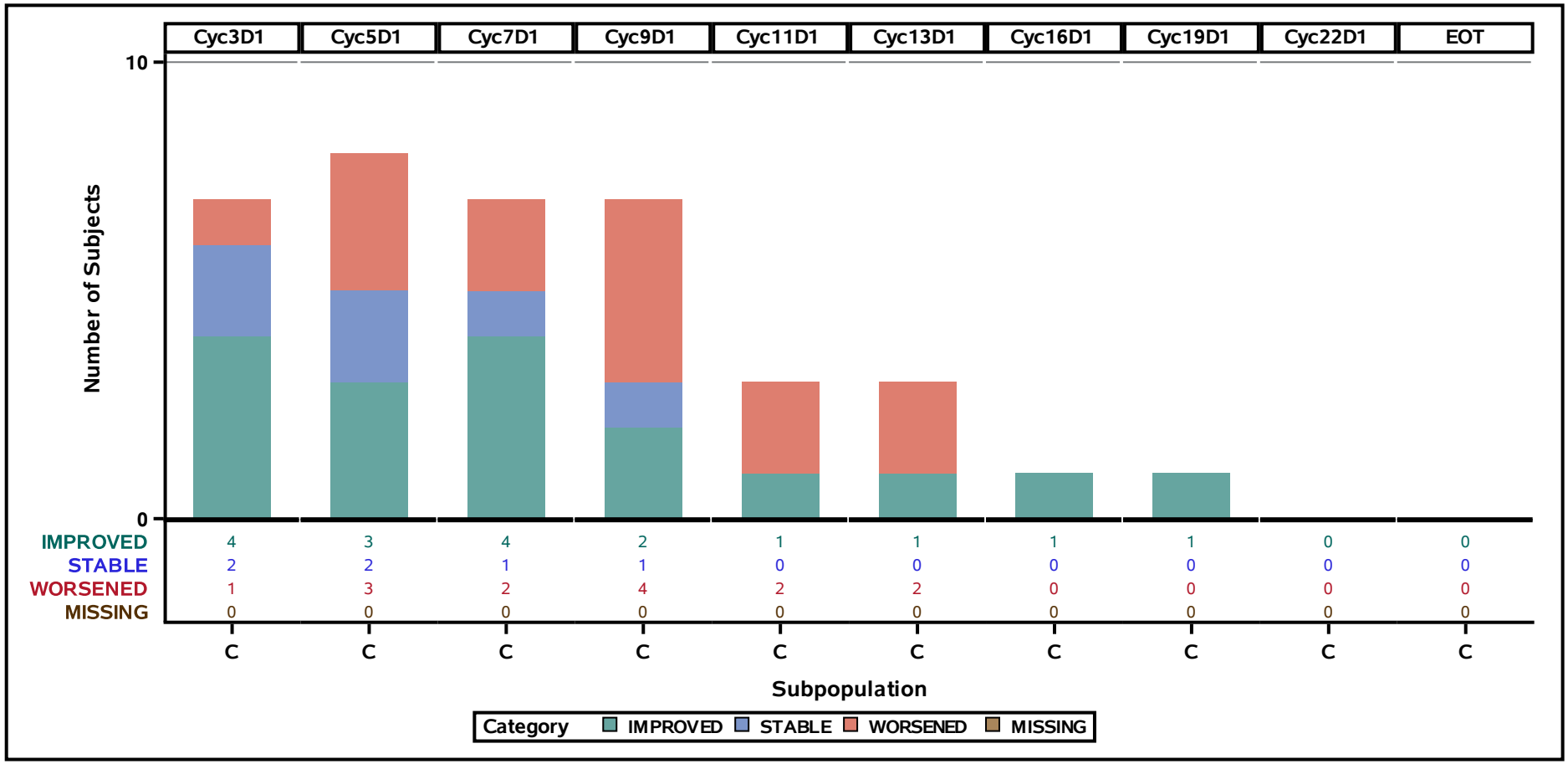
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.8_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F047_fa_10pt_tc_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)

T14.2.6.1.53
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 27.16 (28.93)	7 -4.56 (-18.75, 9.64)
CYCLE 5 DAY 1		8 3.85 (-9.45, 17.16)
CYCLE 7 DAY 1		7 0.11 (-14.18, 14.39)
CYCLE 9 DAY 1		7 3.38 (-10.81, 17.58)
CYCLE 11 DAY 1		3 6.46 (-15.27, 28.19)
CYCLE 13 DAY 1		3 2.75 (-18.98, 24.48)
CYCLE 16 DAY 1		1 -14.38 (-52.16, 23.40)

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_mmrm2.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/T14.2.6.1.53.rtf

T14.2.6.1.53
EORTC QLQ-C30 (v3.0): Summary of Fatigue by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 -14.38 (-52.16, 23.40)	
CYCLE 22 DAY 1	0 N.E (N.E, N.E)	
END OF TREATMENT	0 N.E (N.E, N.E)	

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_mmrm2.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/T14.2.6.1.53.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	16.67
Standard Deviation	23.570
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	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/T14.2.6.1.9_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	14.29
Standard Deviation	11.501
Median	16.67
Q1, Q3	0.0, 16.7
Min, Max	0.0, 33.3
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	2.38
Standard Deviation	11.501
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	-16.7, 16.7
Status [3]	
Improved	1 (14.3)
Stable	4 (57.1)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	22.92
Standard Deviation	17.678
Median	25.00
Q1, Q3	8.3, 33.3
Min, Max	0.0, 50.0
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	12.50
Standard Deviation	19.416
Median	8.33
Q1, Q3	0.0, 33.3
Min, Max	-16.7, 33.3
Status [3]	
Improved	1 (12.5)
Stable	3 (37.5)
Worsened	4 (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/T14.2.6.1.9_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	14.29
Standard Deviation	11.501
Median	16.67
Q1, Q3	0.0, 16.7
Min, Max	0.0, 33.3
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	2.38
Standard Deviation	17.817
Median	0.00
Q1, Q3	-16.7, 16.7
Min, Max	-16.7, 33.3
Status [3]	
Improved	2 (28.6)
Stable	3 (42.9)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	16.67
Standard Deviation	9.623
Median	16.67
Q1, Q3	16.7, 16.7
Min, Max	0.0, 33.3
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	4.76
Standard Deviation	18.545
Median	0.00
Q1, Q3	-16.7, 16.7
Min, Max	-16.7, 33.3
Status [3]	
Improved	2 (28.6)
Stable	2 (28.6)
Worsened	3 (42.9)

[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/T14.2.6.1.9_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	16.67
Standard Deviation	16.667
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	-5.56
Standard Deviation	9.623
Median	0.00
Q1, Q3	-16.7, 0.0
Min, Max	-16.7, 0.0
Status [3]	
Improved	1 (33.3)
Stable	2 (66.7)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	22.22
Standard Deviation	9.623
Median	16.67
Q1, Q3	16.7, 33.3
Min, Max	16.7, 33.3
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	0.00
Standard Deviation	16.667
Median	0.00
Q1, Q3	-16.7, 16.7
Min, Max	-16.7, 16.7
Status [3]	
Improved	1 (33.3)
Stable	1 (33.3)
Worsened	1 (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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	16.67
Standard Deviation	
Median	16.67
Q1, Q3	16.7, 16.7
Min, Max	16.7, 16.7
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	-16.67
Standard Deviation	
Median	-16.67
Q1, Q3	-16.7, -16.7
Min, Max	-16.7, -16.7
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	16.67
Standard Deviation	
Median	16.67
Q1, Q3	16.7, 16.7
Min, Max	16.7, 16.7
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	-16.67
Standard Deviation	
Median	-16.67
Q1, Q3	-16.7, -16.7
Min, Max	-16.7, -16.7
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_tc_eff.rtf

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

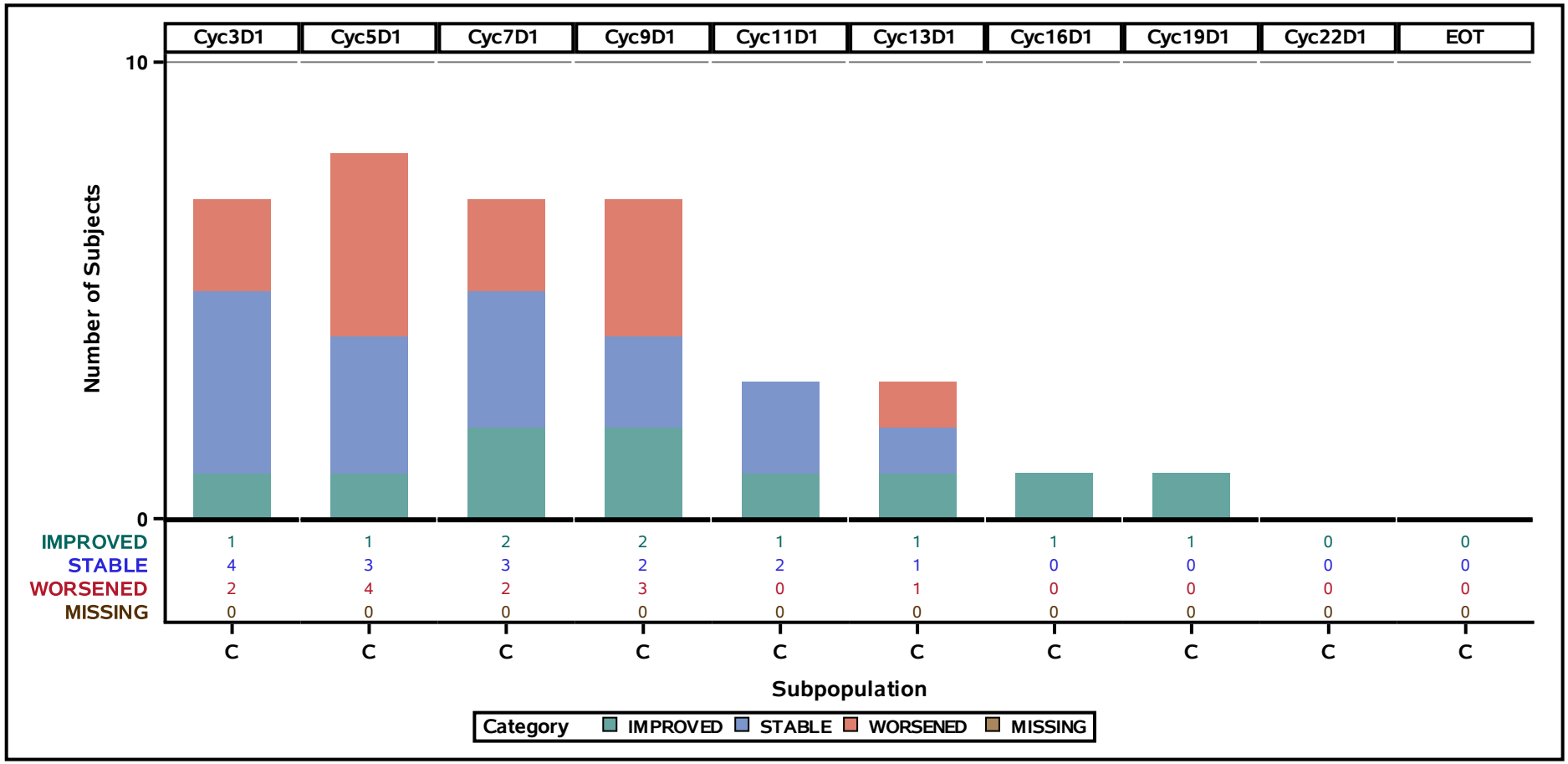
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.9_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F048_pa_10pt_tc_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)

T14.2.6.1.54
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 16.67 (23.57)	7 0.62 (-9.22, 10.46)
CYCLE 5 DAY 1		8 9.70 (0.44, 18.95)
CYCLE 7 DAY 1		7 0.62 (-9.22, 10.46)
CYCLE 9 DAY 1		7 3.00 (-6.84, 12.84)
CYCLE 11 DAY 1		3 -0.08 (-15.25, 15.09)
CYCLE 13 DAY 1		3 5.47 (-9.69, 20.64)
CYCLE 16 DAY 1		1 -3.40 (-29.97, 23.16)

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_mmrm2.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/T14.2.6.1.54.rtf

T14.2.6.1.54
EORTC QLQ-C30 (v3.0): Summary of Pain by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 -3.40 (-29.97, 23.16)	
CYCLE 22 DAY 1	0 N.E (N.E, N.E)	
END OF TREATMENT	0 N.E (N.E, N.E)	

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_mmrm2.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/T14.2.6.1.54.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	29.63
Standard Deviation	26.058
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	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/T14.2.6.1.10_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	14.29
Standard Deviation	17.817
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	-14.29
Standard Deviation	26.227
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 0.0
Status [3]	
Improved	2 (28.6)
Stable	5 (71.4)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	29.17
Standard Deviation	27.817
Median	33.33
Q1, Q3	0.0, 50.0
Min, Max	0.0, 66.7
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	4.17
Standard Deviation	33.034
Median	0.00
Q1, Q3	-16.7, 16.7
Min, Max	-33.3, 66.7
Status [3]	
Improved	2 (25.0)
Stable	4 (50.0)
Worsened	2 (25.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	23.81
Standard Deviation	16.265
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	0.00
Standard Deviation	19.245
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (14.3)
Stable	5 (71.4)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	19.05
Standard Deviation	17.817
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	-9.52
Standard Deviation	31.706
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 33.3
Status [3]	
Improved	2 (28.6)
Stable	4 (57.1)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	44.44
Standard Deviation	50.918
Median	33.33
Q1, Q3	0.0, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	11.11
Standard Deviation	19.245
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Status [3]	
Improved	0 (0.0)
Stable	2 (66.7)
Worsened	1 (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/T14.2.6.1.10_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	33.33
Standard Deviation	33.333
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	0.00
Standard Deviation	0.000
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	3 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	1 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	1 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_tc_eff.rtf

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

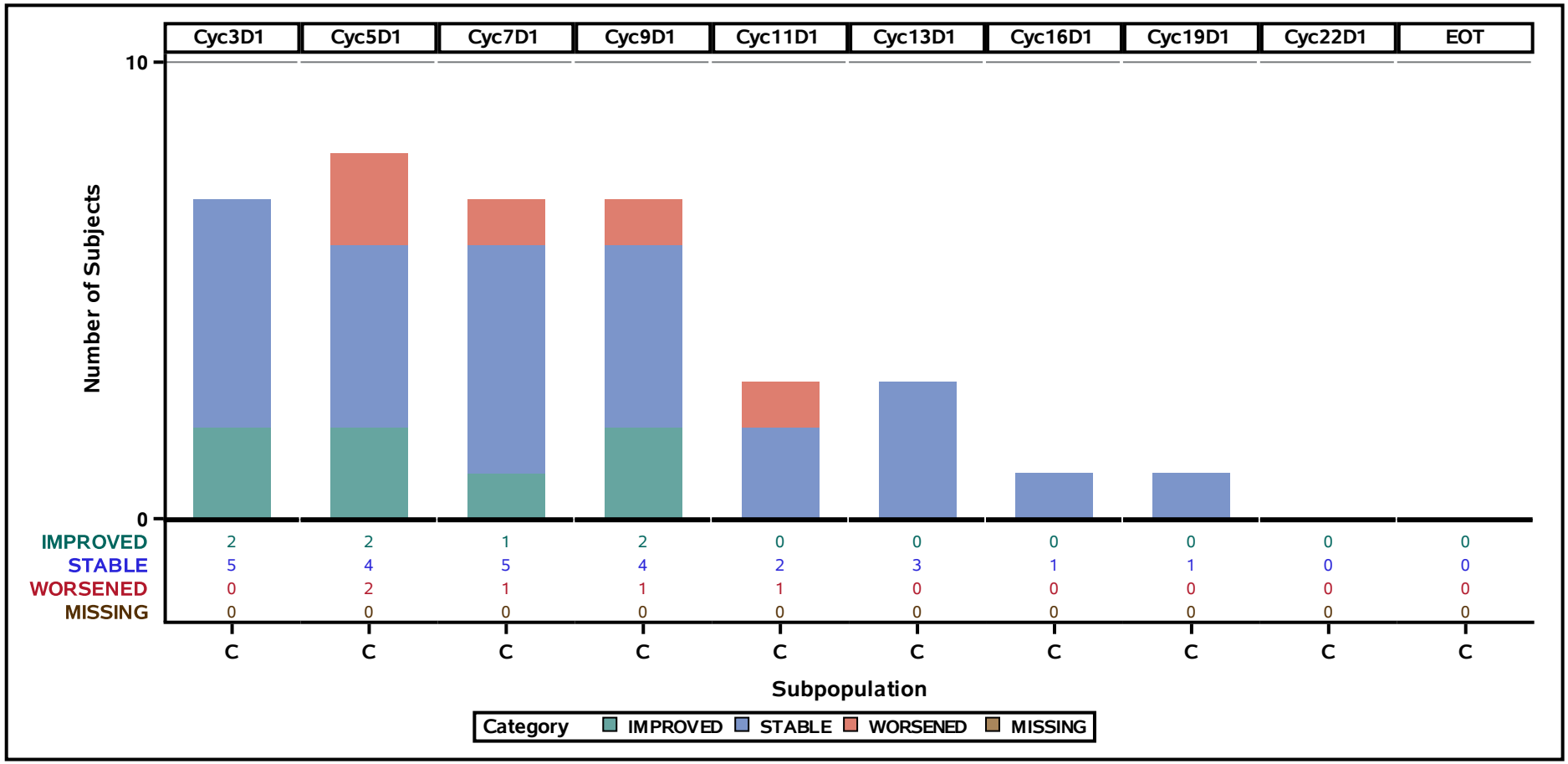
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.10_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F049_dy_10pt_tc_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)

T14.2.6.1.55
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 29.63 (26.06)	7 -13.92 (-31.93, 4.09)
CYCLE 5 DAY 1		8 2.50 (-14.38, 19.38)
CYCLE 7 DAY 1		7 -2.34 (-20.41, 15.73)
CYCLE 9 DAY 1		7 -9.16 (-27.17, 8.85)
CYCLE 11 DAY 1		3 14.19 (-13.39, 41.76)
CYCLE 13 DAY 1		3 3.07 (-24.50, 30.65)
CYCLE 16 DAY 1		1 3.07 (-44.61, 50.76)

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_mmrm2.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/T14.2.6.1.55.rtf

T14.2.6.1.55
EORTC QLQ-C30 (v3.0): Summary of Dyspnoea by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 3.07	1 3.07 (-44.61, 50.76)
CYCLE 22 DAY 1	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	0 N.E	0 N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.55.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	33.33
Standard Deviation	28.868
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	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/T14.2.6.1.11_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	23.81
Standard Deviation	31.706
Median	0.00
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	-9.52
Standard Deviation	25.198
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	3 (42.9)
Stable	3 (42.9)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	41.67
Standard Deviation	29.547
Median	50.00
Q1, Q3	16.7, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	12.50
Standard Deviation	30.538
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 66.7
Status [3]	
Improved	1 (12.5)
Stable	4 (50.0)
Worsened	3 (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
Data location: /lillyce/prd/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	33.33
Standard Deviation	27.217
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	0.00
Standard Deviation	19.245
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (14.3)
Stable	5 (71.4)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	47.62
Standard Deviation	32.530
Median	33.33
Q1, Q3	33.3, 66.7
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	14.29
Standard Deviation	26.227
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (14.3)
Stable	2 (28.6)
Worsened	4 (57.1)

[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/T14.2.6.1.11_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	33.33
Standard Deviation	33.333
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	-11.11
Standard Deviation	19.245
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 0.0
Status [3]	
Improved	1 (33.3)
Stable	2 (66.7)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	22.22
Standard Deviation	38.490
Median	0.00
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	-22.22
Standard Deviation	19.245
Median	-33.33
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 0.0
Status [3]	
Improved	2 (66.7)
Stable	1 (33.3)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	1 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	-33.33
Standard Deviation	
Median	-33.33
Q1, Q3	-33.3, -33.3
Min, Max	-33.3, -33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_tc_eff.rtf

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

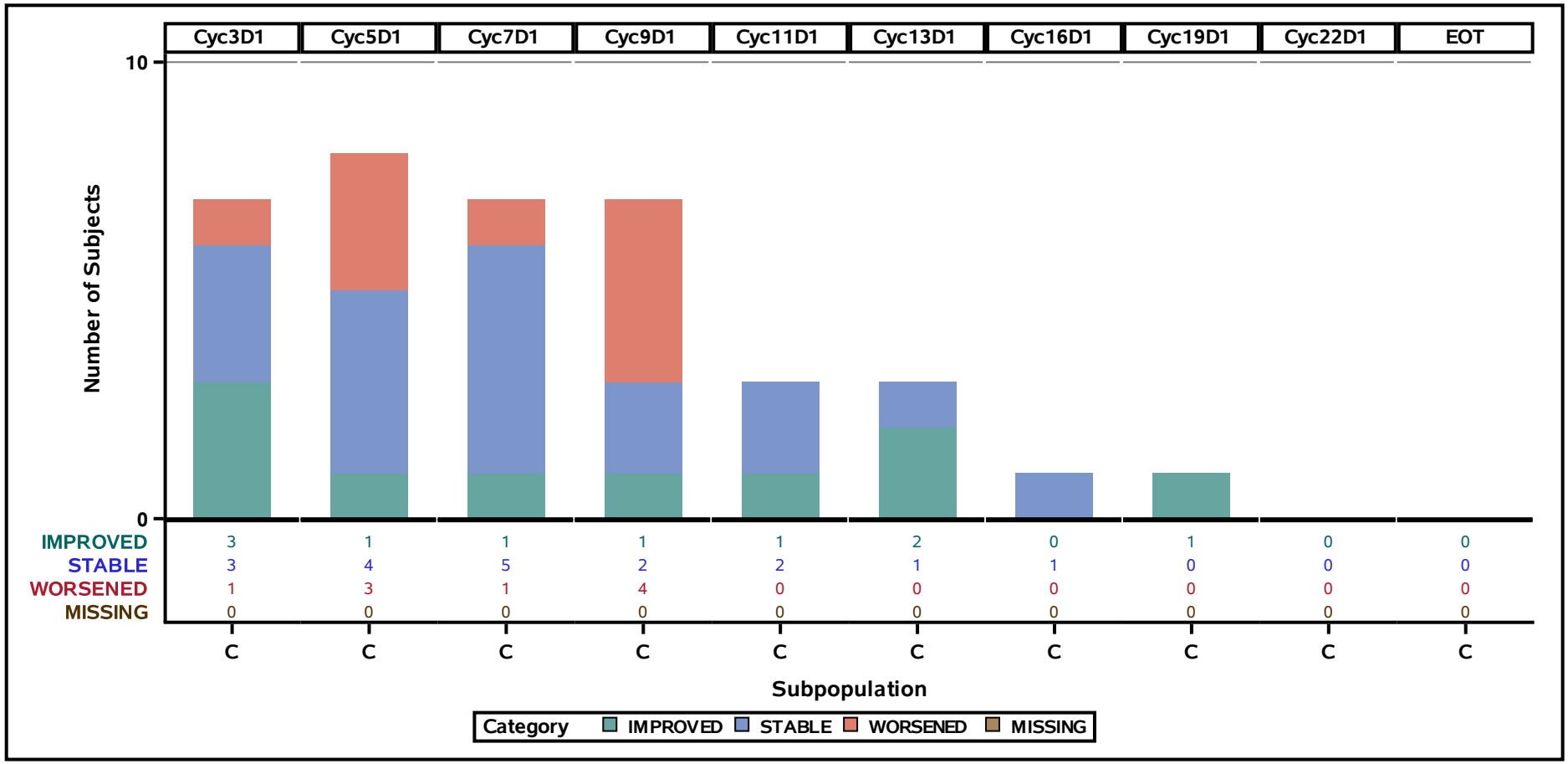
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.11_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F050_sl_10pt_tc_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)

T14.2.6.1.56
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 33.33 (28.87)	7 -9.75 (-28.99, 9.49)
CYCLE 5 DAY 1		8 11.21 (-6.87, 29.30)
CYCLE 7 DAY 1		7 -0.23 (-19.47, 19.01)
CYCLE 9 DAY 1		7 14.06 (-5.18, 33.30)
CYCLE 11 DAY 1		3 -8.52 (-38.13, 21.09)
CYCLE 13 DAY 1		3 -19.63 (-49.24, 9.98)
CYCLE 16 DAY 1		1 -0.23 (-51.12, 50.67)

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_mmrm2.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/T14.2.6.1.56.rtf

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

T14.2.6.1.56
EORTC QLQ-C30 (v3.0): Summary of Insomnia by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1	-33.56 (-84.46, 17.33)
CYCLE 22 DAY 1	0	N.E (N.E, N.E)
END OF TREATMENT	0	N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.56.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	22.22
Standard Deviation	23.570
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	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/T14.2.6.1.12_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	9.52
Standard Deviation	25.198
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 66.7
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	-9.52
Standard Deviation	25.198
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	3 (42.9)
Stable	3 (42.9)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	12.50
Standard Deviation	24.801
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	-4.17
Standard Deviation	33.034
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 66.7
Status [3]	
Improved	3 (37.5)
Stable	4 (50.0)
Worsened	1 (12.5)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	23.81
Standard Deviation	31.706
Median	0.00
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	4.76
Standard Deviation	40.500
Median	0.00
Q1, Q3	-33.3, 33.3
Min, Max	-33.3, 66.7
Status [3]	
Improved	3 (42.9)
Stable	1 (14.3)
Worsened	3 (42.9)

[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/T14.2.6.1.12_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	23.81
Standard Deviation	37.090
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	4.76
Standard Deviation	48.795
Median	0.00
Q1, Q3	-33.3, 33.3
Min, Max	-33.3, 100.0
Status [3]	
Improved	3 (42.9)
Stable	2 (28.6)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	33.33
Standard Deviation	33.333
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	11.11
Standard Deviation	50.918
Median	0.00
Q1, Q3	-33.3, 66.7
Min, Max	-33.3, 66.7
Status [3]	
Improved	1 (33.3)
Stable	1 (33.3)
Worsened	1 (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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	22.22
Standard Deviation	19.245
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	0.00
Standard Deviation	33.333
Median	0.00
Q1, Q3	-33.3, 33.3
Min, Max	-33.3, 33.3
Status [3]	
Improved	1 (33.3)
Stable	1 (33.3)
Worsened	1 (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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	-33.33
Standard Deviation	
Median	-33.33
Q1, Q3	-33.3, -33.3
Min, Max	-33.3, -33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	-33.33
Standard Deviation	
Median	-33.33
Q1, Q3	-33.3, -33.3
Min, Max	-33.3, -33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_tc_eff.rtf

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

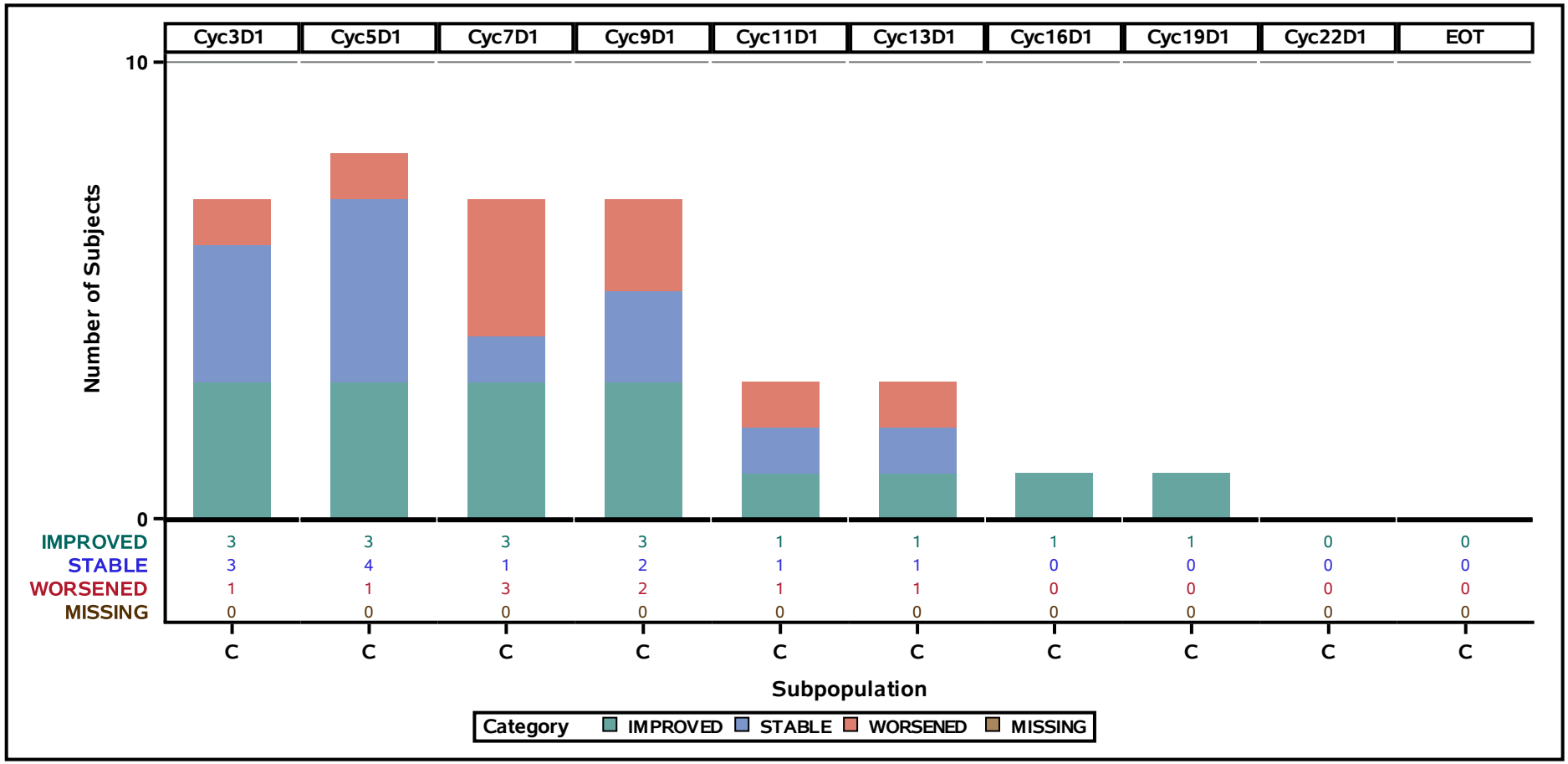
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.12_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F051_ap_10pt_tc_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)

T14.2.6.1.57
EORTC QLQ-C30 (v3.0): Summary of Appetite Loss by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 22.22 (23.57)	7 -10.63 (-33.38, 12.12)
CYCLE 5 DAY 1		8 -8.69 (-30.06, 12.67)
CYCLE 7 DAY 1		7 3.65 (-19.10, 26.40)
CYCLE 9 DAY 1		7 3.65 (-19.10, 26.40)
CYCLE 11 DAY 1		3 14.56 (-20.22, 49.34)
CYCLE 13 DAY 1		3 3.45 (-31.33, 38.23)
CYCLE 16 DAY 1		1 -13.94 (-74.70, 46.83)

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_mmrm2.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/T14.2.6.1.57.rtf

T14.2.6.1.57
EORTC QLQ-C30 (v3.0): Summary of Appetite Loss by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 -13.94 (-74.70, 46.83)	
CYCLE 22 DAY 1	0 N.E (N.E, N.E)	
END OF TREATMENT	0 N.E (N.E, N.E)	

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_mmrm2.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/T14.2.6.1.57.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	14.81
Standard Deviation	24.216
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	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/T14.2.6.1.13_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	28.57
Standard Deviation	35.635
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	19.05
Standard Deviation	37.796
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Status [3]	
Improved	0 (0.0)
Stable	5 (71.4)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	16.67
Standard Deviation	35.635
Median	0.00
Q1, Q3	0.0, 16.7
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	8.33
Standard Deviation	38.832
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 100.0
Status [3]	
Improved	1 (12.5)
Stable	6 (75.0)
Worsened	1 (12.5)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	38.10
Standard Deviation	44.840
Median	33.33
Q1, Q3	0.0, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	28.57
Standard Deviation	40.500
Median	0.00
Q1, Q3	0.0, 66.7
Min, Max	0.0, 100.0
Status [3]	
Improved	0 (0.0)
Stable	4 (57.1)
Worsened	3 (42.9)

[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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	14.29
Standard Deviation	26.227
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	4.76
Standard Deviation	29.991
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 66.7
Status [3]	
Improved	1 (14.3)
Stable	5 (71.4)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
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 11 Day 1	
n [2]	3
Mean	-22.22
Standard Deviation	19.245
Median	-33.33
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 0.0
Status [3]	
Improved	2 (66.7)
Stable	1 (33.3)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	22.22
Standard Deviation	19.245
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	0.00
Standard Deviation	0.000
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	3 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	-33.33
Standard Deviation	
Median	-33.33
Q1, Q3	-33.3, -33.3
Min, Max	-33.3, -33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	-33.33
Standard Deviation	
Median	-33.33
Q1, Q3	-33.3, -33.3
Min, Max	-33.3, -33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_tc_eff.rtf

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

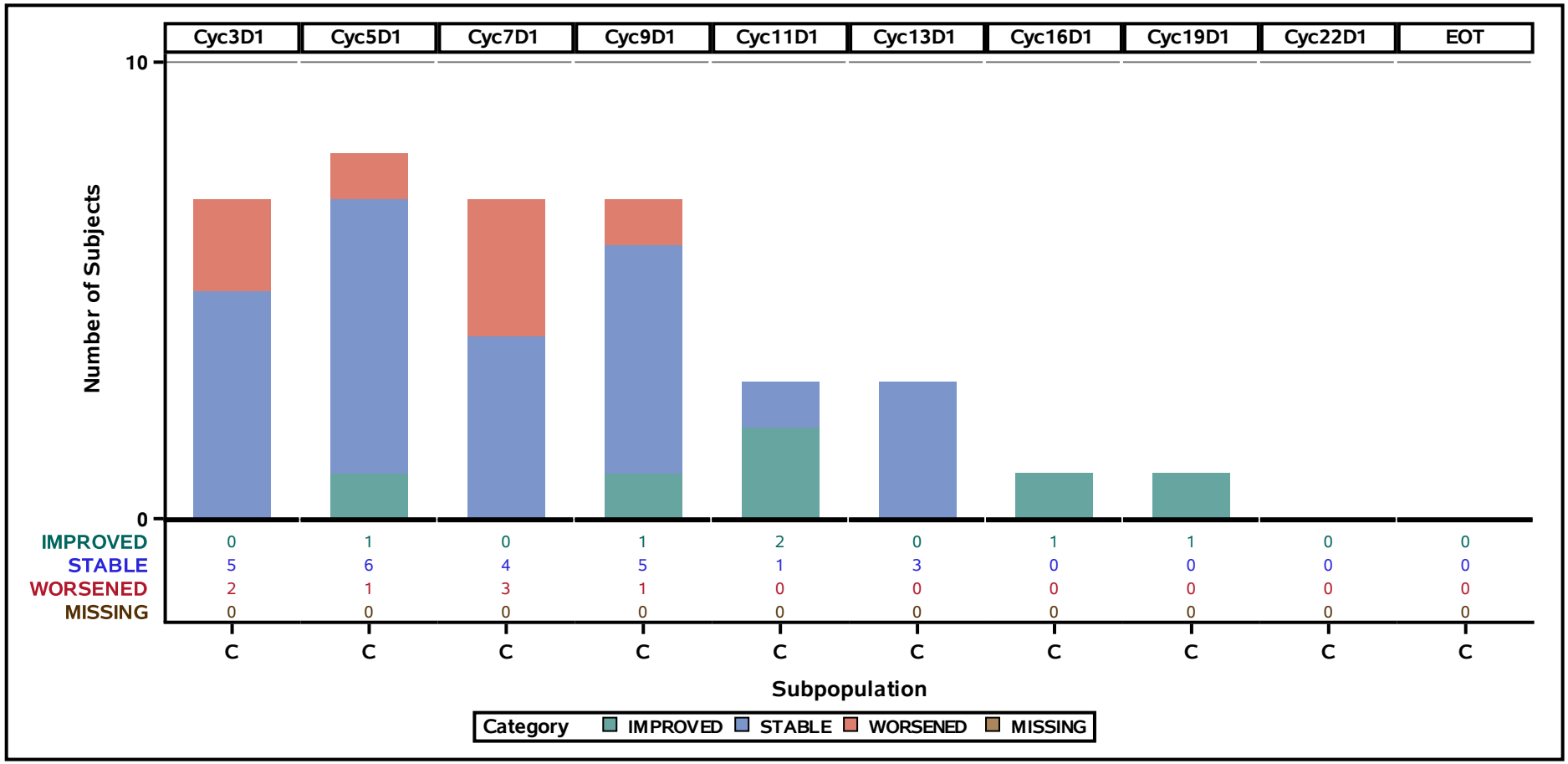
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.13_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F052_co_10pt_tc_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)

T14.2.6.1.58
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 14.81 (24.22)	7 17.18 (-9.52, 43.87)
CYCLE 5 DAY 1		8 5.74 (-19.35, 30.84)
CYCLE 7 DAY 1		7 26.70 (0.01, 53.40)
CYCLE 9 DAY 1		7 2.89 (-23.80, 29.59)
CYCLE 11 DAY 1		3 -16.41 (-57.72, 24.91)
CYCLE 13 DAY 1		3 5.82 (-35.50, 47.13)
CYCLE 16 DAY 1		1 -20.79 (-93.01, 51.43)

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_mmrm2.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/T14.2.6.1.58.rtf

T14.2.6.1.58
EORTC QLQ-C30 (v3.0): Summary of Constipation by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1	-20.79 (-93.01, 51.43)
CYCLE 22 DAY 1	0	N.E (N.E, N.E)
END OF TREATMENT	0	N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.58.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	3.70
Standard Deviation	11.111
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 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/T14.2.6.1.14_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	23.81
Standard Deviation	37.090
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 100.0
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	19.05
Standard Deviation	42.414
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	-33.3, 100.0
Status [3]	
Improved	1 (14.3)
Stable	3 (42.9)
Worsened	3 (42.9)

[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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	12.50
Standard Deviation	35.355
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	8.33
Standard Deviation	38.832
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	-33.3, 100.0
Status [3]	
Improved	1 (12.5)
Stable	6 (75.0)
Worsened	1 (12.5)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	33.33
Standard Deviation	47.140
Median	0.00
Q1, Q3	0.0, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	28.57
Standard Deviation	48.795
Median	0.00
Q1, Q3	0.0, 100.0
Min, Max	0.0, 100.0
Status [3]	
Improved	0 (0.0)
Stable	5 (71.4)
Worsened	2 (28.6)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	28.57
Standard Deviation	29.991
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 66.7
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	23.81
Standard Deviation	37.090
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	-33.3, 66.7
Status [3]	
Improved	1 (14.3)
Stable	2 (28.6)
Worsened	4 (57.1)

[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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	33.33
Standard Deviation	57.735
Median	0.00
Q1, Q3	0.0, 100.0
Min, Max	0.0, 100.0
Change from Baseline to Cycle 11 Day 1	
n [2]	3
Mean	22.22
Standard Deviation	69.389
Median	0.00
Q1, Q3	-33.3, 100.0
Min, Max	-33.3, 100.0
Status [3]	
Improved	1 (33.3)
Stable	1 (33.3)
Worsened	1 (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/T14.2.6.1.14_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	11.11
Standard Deviation	19.245
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 13 Day 1	
n [2]	3
Mean	0.00
Standard Deviation	0.000
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	3 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	-33.33
Standard Deviation	
Median	-33.33
Q1, Q3	-33.3, -33.3
Min, Max	-33.3, -33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	33.33
Standard Deviation	
Median	33.33
Q1, Q3	33.3, 33.3
Min, Max	33.3, 33.3
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Status [3]	
Improved	0 (0.0)
Stable	1 (100.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_tc_eff.rtf

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

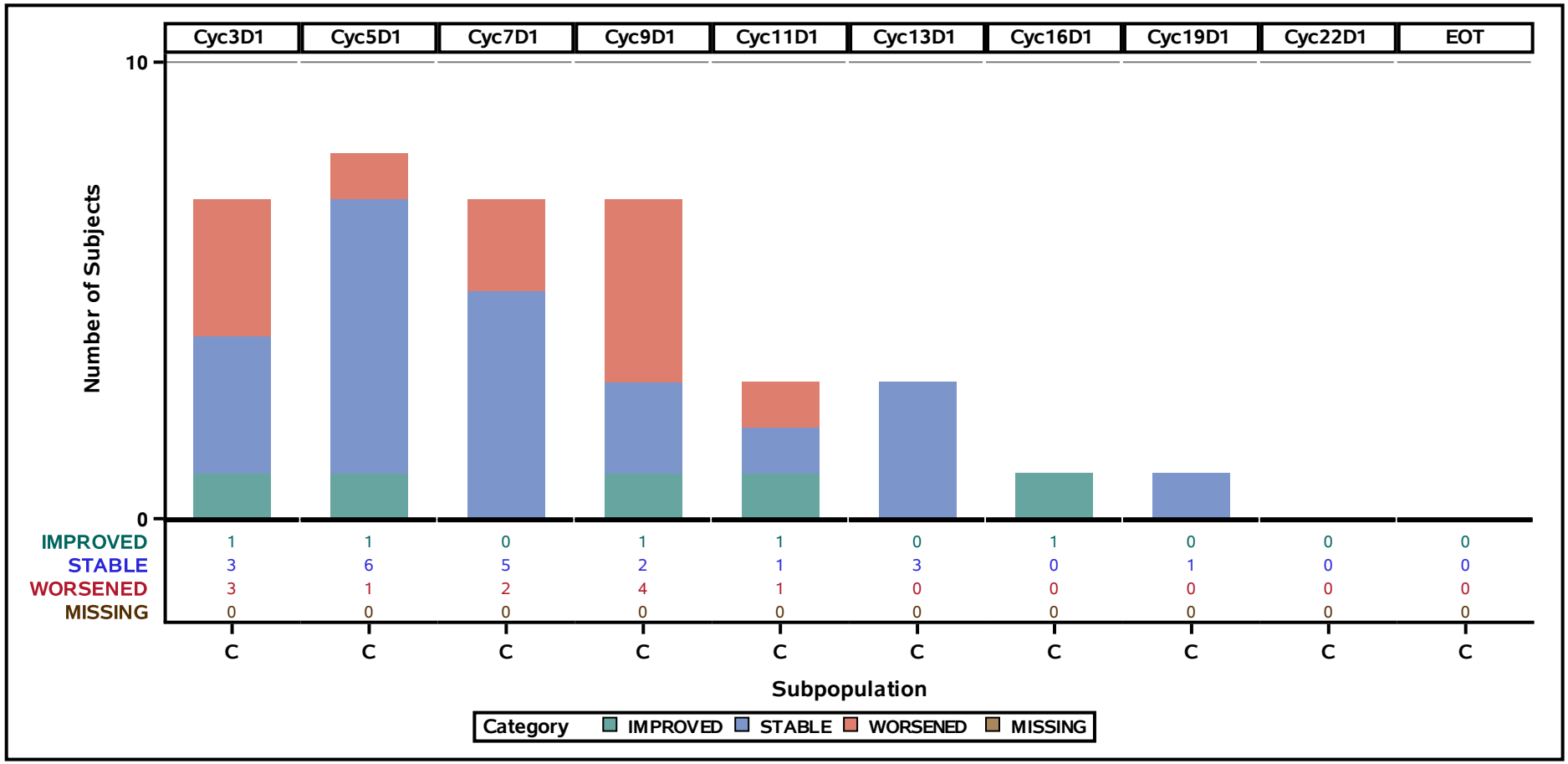
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.14_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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
Output Location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F053_di_10pt_tc_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)

T14.2.6.1.59
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 3.70 (11.11)	7 15.44 (-15.02, 45.89)
CYCLE 5 DAY 1		8 3.84 (-24.73, 32.41)
CYCLE 7 DAY 1		7 24.96 (-5.49, 55.41)
CYCLE 9 DAY 1		7 20.20 (-10.26, 50.65)
CYCLE 11 DAY 1		3 27.99 (-18.55, 74.52)
CYCLE 13 DAY 1		3 5.77 (-40.77, 52.30)
CYCLE 16 DAY 1		1 5.25 (-80.00, 90.51)

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_mmrm2.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/T14.2.6.1.59.rtf

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

T14.2.6.1.59
EORTC QLQ-C30 (v3.0): Summary of Diarrhoea by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1 38.59	1 38.59 (-46.67, 123.85)
CYCLE 22 DAY 1	0 N.E	0 N.E (N.E, N.E)
END OF TREATMENT	0 N.E	0 N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.59.rtf

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

Visit Statistics	C (N= 9)
Baseline [1]	
n [2]	9
Mean	37.04
Standard Deviation	35.136
Median	33.33
Q1, Q3	0.0, 66.7
Min, Max	0.0, 100.0

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 3 Day 1	
n [2]	7
Mean	19.05
Standard Deviation	26.227
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 3 Day 1	
n [2]	7
Mean	-19.05
Standard Deviation	17.817
Median	-33.33
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 0.0
Status [3]	
Improved	4 (57.1)
Stable	3 (42.9)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 5 Day 1	
n [2]	8
Mean	20.83
Standard Deviation	24.801
Median	16.67
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 5 Day 1	
n [2]	8
Mean	-12.50
Standard Deviation	30.538
Median	0.00
Q1, Q3	-33.3, 0.0
Min, Max	-66.7, 33.3
Status [3]	
Improved	3 (37.5)
Stable	4 (50.0)
Worsened	1 (12.5)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/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_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 7 Day 1	
n [2]	7
Mean	19.05
Standard Deviation	26.227
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 7 Day 1	
n [2]	7
Mean	-14.29
Standard Deviation	26.227
Median	-33.33
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	4 (57.1)
Stable	2 (28.6)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 9 Day 1	
n [2]	7
Mean	23.81
Standard Deviation	25.198
Median	33.33
Q1, Q3	0.0, 33.3
Min, Max	0.0, 66.7
Change from Baseline to Cycle 9 Day 1	
n [2]	7
Mean	-14.29
Standard Deviation	26.227
Median	-33.33
Q1, Q3	-33.3, 0.0
Min, Max	-33.3, 33.3
Status [3]	
Improved	4 (57.1)
Stable	2 (28.6)
Worsened	1 (14.3)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 11 Day 1	
n [2]	3
Mean	11.11
Standard Deviation	19.245
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 11 Day 1	
n [2]	3
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	3 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 13 Day 1	
n [2]	3
Mean	11.11
Standard Deviation	19.245
Median	0.00
Q1, Q3	0.0, 33.3
Min, Max	0.0, 33.3
Change from Baseline to Cycle 13 Day 1	
n [2]	3
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	3 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 16 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 16 Day 1	
n [2]	1
Mean	-33.33
Standard Deviation	
Median	-33.33
Q1, Q3	-33.3, -33.3
Min, Max	-33.3, -33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 19 Day 1	
n [2]	1
Mean	0.00
Standard Deviation	
Median	0.00
Q1, Q3	0.0, 0.0
Min, Max	0.0, 0.0
Change from Baseline to Cycle 19 Day 1	
n [2]	1
Mean	-33.33
Standard Deviation	
Median	-33.33
Q1, Q3	-33.3, -33.3
Min, Max	-33.3, -33.3
Status [3]	
Improved	1 (100.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

Visit Statistics	C (N= 9)
Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to Cycle 22 Day 1	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

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

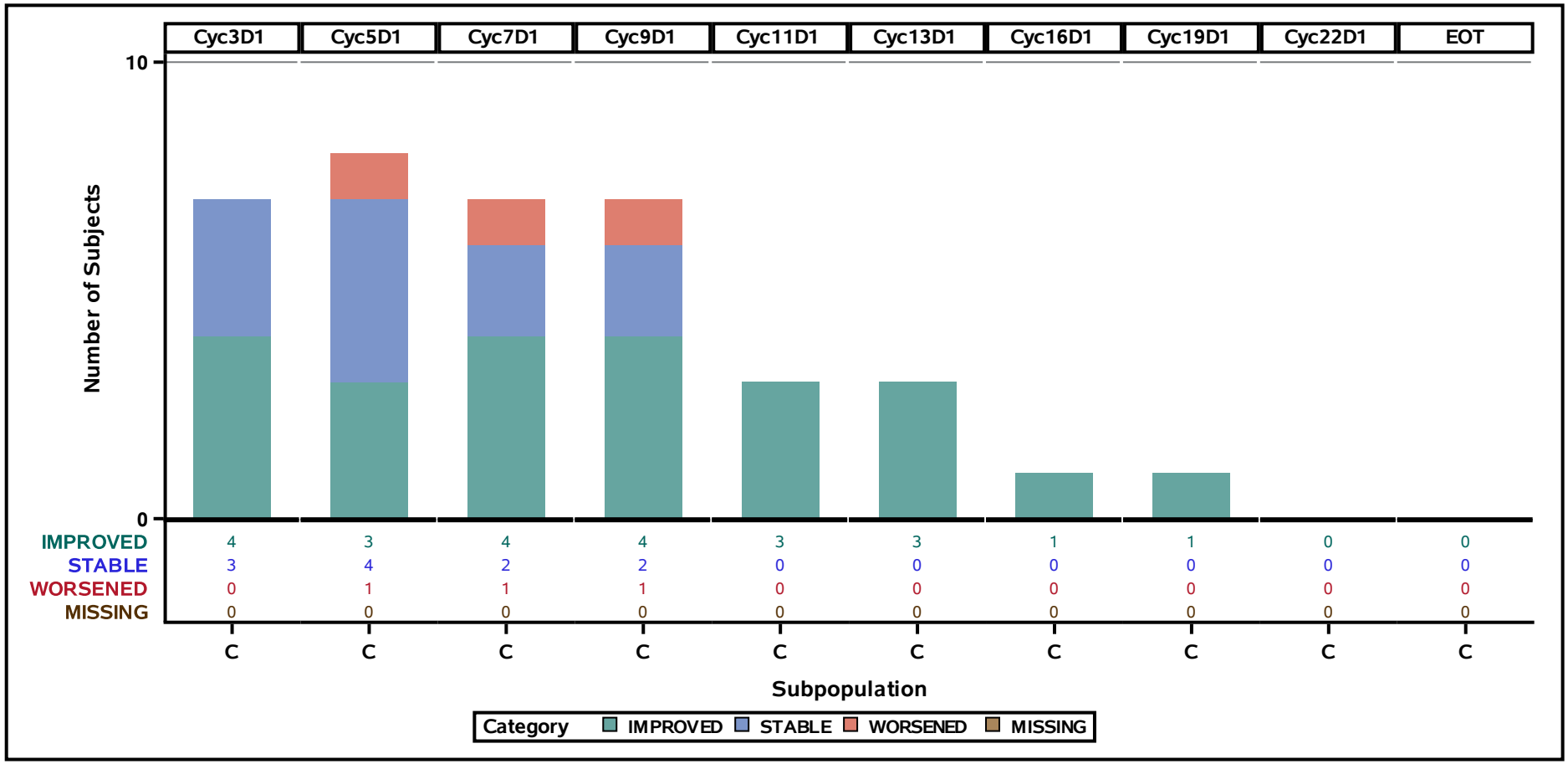
Visit Statistics	C (N= 9)
End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Change from Baseline to End of Treatment	
n [2]	0
Mean	
Standard Deviation	
Median	
Q1, Q3	
Min, Max	
Status [3]	
Improved	0 (0.0)
Stable	0 (0.0)
Worsened	0 (0.0)

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

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_qlqc30_sum.sas
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/misc6/data/analysis/shared
Data location: /lillyce/prd/ly3009806/i4t_mc_jvcy/csr2/data/analysis/shared
Output location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/dec19/T14.2.6.1.15_tc_eff.rtf

Loxo Oncology Inc.
Protocol Number: LOXO-RET-17001
Summary of Clinical Efficacy - TC (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/prd/ly3527723/j2g_ox_jzja/misc6/output/shared/mar20/F054_fi_10pt_tc_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)

T14.2.6.1.60
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 3 DAY 1	9 37.04 (35.14)	7 -18.49 (-32.25, -4.72)
CYCLE 5 DAY 1		8 -14.24 (-27.14, -1.35)
CYCLE 7 DAY 1		7 -16.03 (-29.81, -2.24)
CYCLE 9 DAY 1		7 -13.73 (-27.49, 0.04)
CYCLE 11 DAY 1		3 -29.71 (-50.78, -8.63)
CYCLE 13 DAY 1		3 -29.71 (-50.78, -8.63)
CYCLE 16 DAY 1		1 -35.07 (-71.50, 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_mmrm2.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/T14.2.6.1.60.rtf

T14.2.6.1.60
EORTC QLQ-C30 (v3.0): Summary of Financial Difficulties by Visits (MMRM)
Efficacy Analysis Set
by Subpopulation

	C	
Visit	Baseline N Average (SD)	Change from Baseline N LS mean (95% CI)
CYCLE 19 DAY 1	1	-35.07 (-71.50, 1.35)
CYCLE 22 DAY 1	0	N.E (N.E, N.E)
END OF TREATMENT	0	N.E (N.E, N.E)

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_mmrm2.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/T14.2.6.1.60.rtf

Tabelle 006: Behandlungsdauer – Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Safety Analysis Set

	Selpercatinib **Subpopulation C – TC** **(N=21)**
Behandlungsdauer in Monaten	
Anzahl der Patienten	21
Mittelwert (SD)	13,6 (8,10)
Median (min–max)	13,24 (0,85-28,88)
max: Maximum; min: Minimum; RET: Rearranged during Transfection; SD: Standardabweichung; TC: Schilddrüsenkarzinom.	

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/T006_tte_tc.rtf

Tabelle 022: Ergebnisse für den Endpunkt jegliche unerwünschte Ereignisse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Safety Population

Endpunkt	Selpercatinib Subpopulation C - TC (N=21)
Jegliche unerwünschte Ereignisse, n (%)	
Jegliche unerwünschte Ereignisse	
Jeglicher Schweregrad	21 (100)
CTCAE-Grad < 3	7 (33,3)
CTCAE-Grad ≥ 3	14 (66,7)
CTCAE-Grad 3	11 (52,4)
CTCAE-Grad 4	2 (9,5)
CTCAE-Grad 5	1 (4,8)
Therapiebezogene [a] unerwünschte Ereignisse	20 (95,2)
Therapiebezogene [a] unerwünschte Ereignisse vom CTCAE-Grad ≥ 3	5 (23,8)
Schwerwiegende unerwünschte Ereignisse	8 (38,1)
Therapiebezogene [a] schwerwiegende unerwünschte Ereignisse	0
Behandlungsabbruch aufgrund unerwünschter Ereignisse	2 (9,5)

CTCAE: Common Terminology Criteria for Adverse Events; n: Anzahl der Patienten mit Ereignis; N: Anzahl der Patienten in der Subpopulation (Safety Analysis Set); RET: Rearranged during Transfection;
TC: Schilddrüsenkarzinom.
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_tc_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/T022_sp_anyae_sf.rtf

Tabelle 022.12: Ergebnisse für den Endpunkt unerwünschte Ereignisse von besonderem Interesse aus Studie LIBRETTO-001 mit dem zu bewertenden Arzneimittel (Indikation: TC mit RET-Fusion und MKI-Vorbehandlung; Datenschnitt: 30. März 2020) - Safety Population

Endpunkt	Selpercatinib Subpopulation C - TC (N=21)
Unerwünschte Ereignisse von besonderem Interesse, n (%)	
Erhöhung von AST und ALT	
Jeglicher Schweregrad	6 (28,6)
CTCAE-Grad < 3	5 (23,8)
CTCAE-Grad ≥ 3	1 (4,8)
Schwerwiegend	0
Behandlungsabbruch	0
Überempfindlichkeit	
Jeglicher Schweregrad	1 (4,8)
CTCAE-Grad < 3	1 (4,8)
CTCAE-Grad ≥ 3	0
Schwerwiegend	0
Behandlungsabbruch	0
Hypertonie	
Jeglicher Schweregrad	7 (33,3)
CTCAE-Grad < 3	3 (14,3)
CTCAE-Grad ≥ 3	4 (19,0)
Schwerwiegend	0
Behandlungsabbruch	0
Thrombozytopenie	
Jeglicher Schweregrad	5 (23,8)
CTCAE-Grad < 3	4 (19,0)
CTCAE-Grad ≥ 3	1 (4,8)
Schwerwiegend	0
Behandlungsabbruch	0
Verlängerung der QT-Zeit	
Jeglicher Schweregrad	2 (9,5)
CTCAE-Grad < 3	1 (4,8)
CTCAE-Grad ≥ 3	1 (4,8)
Schwerwiegend	0
Behandlungsabbruch	0

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); RET: Rearranged during Transfection; TC: Schilddrüsenkarzinom.

Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_sp_aesi_tc_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/T022_12_sp_aesi_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.6
Proportions of patients with AE by SOC (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation C

System Organ Class	C (N=21) n (%)
Patients with TEAEs	21 (100)
Gastrointestinal disorders	20 (95.2)
Investigations	17 (81.0)
General disorders and administration site conditions	16 (76.2)
Metabolism and nutrition disorders	15 (71.4)
Musculoskeletal and connective tissue disorders	13 (61.9)
Respiratory, thoracic and mediastinal disorders	13 (61.9)
Nervous system disorders	12 (57.1)
Skin and subcutaneous tissue disorders	12 (57.1)
Infections and infestations	10 (47.6)
Blood and lymphatic system disorders	8 (38.1)
Vascular disorders	8 (38.1)
Psychiatric disorders	5 (23.8)
Cardiac disorders	4 (19.0)
Eye disorders	4 (19.0)
Injury, poisoning and procedural complications	4 (19.0)
Renal and urinary disorders	3 (14.3)

Percentage is calculated using the number of patients in the column heading as the denominator.
Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
Reported adverse event terms were coded using MedDRA (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/T14.4.2.6_sf.rtf

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.12
Proportions of patients with AE by PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation C

Preferred Term	C (N=21) n (%)
Patients with TEAEs	21 (100)
Diarrhoea	11 (52.4)
Constipation	10 (47.6)
Fatigue	10 (47.6)
Dry mouth	9 (42.9)
Decreased appetite	7 (33.3)
Nausea	7 (33.3)
Alanine aminotransferase increased	6 (28.6)
Hypertension	6 (28.6)
Aspartate aminotransferase increased	5 (23.8)
Dry skin	5 (23.8)
Dysphagia	5 (23.8)
Dyspnoea	5 (23.8)
Hyperglycaemia	5 (23.8)
Pyrexia	5 (23.8)
Thrombocytopenia	5 (23.8)
Vomiting	5 (23.8)
Weight increased	5 (23.8)
Abdominal pain upper	4 (19.0)
Arthralgia	4 (19.0)
Back pain	4 (19.0)
Cough	4 (19.0)

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).
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/T14.4.2.12_sf.rtf

Table 14.4.2.12
Proportions of patients with AE by PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation C

Preferred Term	C (N=21) n (%)
Dysphonia	4 (19.0)
Gastrooesophageal reflux disease	4 (19.0)
Hypomagnesaemia	4 (19.0)
Leukopenia	4 (19.0)
Muscular weakness	4 (19.0)
Oedema peripheral	4 (19.0)
Rash	4 (19.0)
Abdominal pain	3 (14.3)
Blood bilirubin increased	3 (14.3)
Blood cholesterol increased	3 (14.3)
Blood creatinine increased	3 (14.3)
Chest discomfort	3 (14.3)
Headache	3 (14.3)
Hyperphosphataemia	3 (14.3)
Hypocalcaemia	3 (14.3)
Hyponatraemia	3 (14.3)
Muscle spasms	3 (14.3)
Musculoskeletal chest pain	3 (14.3)
Musculoskeletal pain	3 (14.3)
Myalgia	3 (14.3)
Stomatitis	3 (14.3)

Percentage is calculated using the number of patients in the column heading as the denominator.
Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
Reported adverse event terms were coded using MedDRA (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/T14.4.2.12_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.18
Proportions of patients with severe AE by SOC (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation C

Analysis Set / System Organ Class	Maximum Severity (n, %) Grade 3	Grade 4	Grade 5	Total
Overall Safety (N=21)				
Any SOC	11 (52.4)	2 (9.5)	1 (4.8)	14 (66.7)
Gastrointestinal disorders	6 (28.6)	0 (0.0)	0 (0.0)	6 (28.6)
Metabolism and nutrition disorders	4 (19.0)	0 (0.0)	0 (0.0)	4 (19.0)
Vascular disorders	4 (19.0)	0 (0.0)	0 (0.0)	4 (19.0)
Blood and lymphatic system disorders	1 (4.8)	2 (9.5)	0 (0.0)	3 (14.3)
General disorders and administration site conditions	3 (14.3)	0 (0.0)	0 (0.0)	3 (14.3)
Investigations	3 (14.3)	0 (0.0)	0 (0.0)	3 (14.3)
Respiratory, thoracic and mediastinal disorders	3 (14.3)	0 (0.0)	0 (0.0)	3 (14.3)
Injury, poisoning and procedural complications	2 (9.5)	0 (0.0)	0 (0.0)	2 (9.5)

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/T14.4.2.18_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.24
Proportions of patients with severe AE by PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation C

Analysis Set / Preferred Term	Maximum Severity (n, %) Grade 3	Grade 4	Grade 5	Total
Overall Safety (N=21)				
Any PT	11 (52.4)	2 (9.5)	1 (4.8)	14 (66.7)
Hypertension	4 (19.0)	0 (0.0)	0 (0.0)	4 (19.0)
Dyspnoea	3 (14.3)	0 (0.0)	0 (0.0)	3 (14.3)
Hyponatraemia	3 (14.3)	0 (0.0)	0 (0.0)	3 (14.3)
Dysphagia	2 (9.5)	0 (0.0)	0 (0.0)	2 (9.5)
Neutropenia	1 (4.8)	1 (4.8)	0 (0.0)	2 (9.5)

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/T14.4.2.24_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.30
Proportions of patients with serious AE by SOC (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation C

System Organ Class	C (N=21) n (%)
Patients with TEAEs	8 (38.1)
Gastrointestinal disorders	4 (19.0)
Cardiac disorders	2 (9.5)
Injury, poisoning and procedural complications	2 (9.5)
Respiratory, thoracic and mediastinal disorders	2 (9.5)

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.
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/T14.4.2.30_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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
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/T14.4.2.37_sf.rtf

Loxo Oncology Inc. Page 1 of 2
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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).
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aespt_tdisc_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/T14.4.2.38_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
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/T14.4.2.38_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.44
Proportions of patients with serious AE by PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation C

Preferred Term	C (N=21) n (%)
Patients with TEAEs	8 (38.1)
Dysphagia	2 (9.5)
Dyspnoea	2 (9.5)

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.
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/T14.4.2.44_sf.rtf

Table 14.4.2.55
Proportions of patients with AE by SOC and PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation C

System Organ Class Preferred Term	C (N=21) n (%)
Patients with TEAEs	21 (100)
Gastrointestinal disorders	20 (95.2)
Diarrhoea	11 (52.4)
Constipation	10 (47.6)
Dry mouth	9 (42.9)
Nausea	7 (33.3)
Dysphagia	5 (23.8)
Vomiting	5 (23.8)
Abdominal pain upper	4 (19.0)
Gastrooesophageal reflux disease	4 (19.0)
Abdominal pain	3 (14.3)
Stomatitis	3 (14.3)
Investigations	17 (81.0)
Alanine aminotransferase increased	6 (28.6)
Aspartate aminotransferase increased	5 (23.8)
Weight increased	5 (23.8)
Blood bilirubin increased	3 (14.3)
Blood cholesterol increased	3 (14.3)
Blood creatinine increased	3 (14.3)
General disorders and administration site conditions	16 (76.2)
Fatigue	10 (47.6)
Pyrexia	5 (23.8)

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
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/T14.4.2.55_sf.rtf

Table 14.4.2.55
Proportions of patients with AE by SOC and PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation C

System Organ Class Preferred Term	C (N=21) n (%)
Oedema peripheral	4 (19.0)
Chest discomfort	3 (14.3)
Metabolism and nutrition disorders	15 (71.4)
Decreased appetite	7 (33.3)
Hyperglycaemia	5 (23.8)
Hypomagnesaemia	4 (19.0)
Hyperphosphataemia	3 (14.3)
Hypocalcaemia	3 (14.3)
Hyponatraemia	3 (14.3)
Musculoskeletal and connective tissue disorders	13 (61.9)
Arthralgia	4 (19.0)
Back pain	4 (19.0)
Muscular weakness	4 (19.0)
Muscle spasms	3 (14.3)
Musculoskeletal chest pain	3 (14.3)
Musculoskeletal pain	3 (14.3)
Myalgia	3 (14.3)
Respiratory, thoracic and mediastinal disorders	13 (61.9)
Dyspnoea	5 (23.8)
Cough	4 (19.0)
Dysphonia	4 (19.0)
Nervous system disorders	12 (57.1)
Headache	3 (14.3)

Percentage is calculated using the number of patients in the column heading as the denominator.
Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
Reported adverse event terms were coded using MedDRA (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
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/T14.4.2.55_sf.rtf

Loxo Oncology Inc. Page 3 of 3
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.55
Proportions of patients with AE by SOC and PT (cut-off: >=10% of patients)
Safety Analysis Set
by Subpopulation C

System Organ Class Preferred Term	C (N=21) n (%)
Skin and subcutaneous tissue disorders	12 (57.1)
Dry skin	5 (23.8)
Rash	4 (19.0)
Infections and infestations	10 (47.6)
Blood and lymphatic system disorders	8 (38.1)
Thrombocytopenia	5 (23.8)
Leukopenia	4 (19.0)
Vascular disorders	8 (38.1)
Hypertension	6 (28.6)
Psychiatric disorders	5 (23.8)
Cardiac disorders	4 (19.0)
Eye disorders	4 (19.0)
Injury, poisoning and procedural complications	4 (19.0)
Renal and urinary disorders	3 (14.3)

Percentage is calculated using the number of patients in the column heading as the denominator.
Treatment-emergent Adverse Events (TEAEs) are defined as adverse events that start on or after the first administration of LOXO-292.
Reported adverse event terms were coded using MedDRA (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
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/T14.4.2.55_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.61
Proportions of patients with Severe AE (CTCAE grade>=3) by SOC and PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation C

System Organ Class Preferred Term	C (N=21) n (%)
Patients with TEAEs	14 (66.7)
Gastrointestinal disorders	6 (28.6)
Dysphagia	2 (9.5)
Metabolism and nutrition disorders	4 (19.0)
Hyponatraemia	3 (14.3)
Vascular disorders	4 (19.0)
Hypertension	4 (19.0)
Blood and lymphatic system disorders	3 (14.3)
Neutropenia	2 (9.5)
General disorders and administration site conditions	3 (14.3)
Investigations	3 (14.3)
Respiratory, thoracic and mediastinal disorders	3 (14.3)
Dyspnoea	3 (14.3)
Injury, poisoning and procedural complications	2 (9.5)

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.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aesocpt_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/T14.4.2.61_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.67
Proportions of patients with Serious AE by SOC and PT (cut-off: >=5% of patients)
Safety Analysis Set
by Subpopulation C

System Organ Class Preferred Term	C (N=21) n (%)
Patients with TEAEs	8 (38.1)
Gastrointestinal disorders	4 (19.0)
Dysphagia	2 (9.5)
Cardiac disorders	2 (9.5)
Injury, poisoning and procedural complications	2 (9.5)
Respiratory, thoracic and mediastinal disorders	2 (9.5)
Dyspnoea	2 (9.5)

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.
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aesocpt_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/T14.4.2.67_sf.rtf

Loxo Oncology Inc. Page 1 of 1
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

Table 14.4.2.73
Proportions of patients with AE by SOC and PT (cut-off: >=10 patients and >=1% of patients)
Safety Analysis Set
by Subpopulation C

System Organ Class Preferred Term	C (N=21) n (%)
Patients with TEAEs	21 (100)
Gastrointestinal disorders	20 (95.2)
Diarrhoea	11 (52.4)
Constipation	10 (47.6)
Investigations	17 (81.0)
General disorders and administration site conditions	16 (76.2)
Fatigue	10 (47.6)
Metabolism and nutrition disorders	15 (71.4)
Musculoskeletal and connective tissue disorders	13 (61.9)
Respiratory, thoracic and mediastinal disorders	13 (61.9)
Nervous system disorders	12 (57.1)
Skin and subcutaneous tissue disorders	12 (57.1)
Infections and infestations	10 (47.6)

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
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/T14.4.2.73_sf.rtf

Loxo Oncology Inc. Page 1 of 3
Protocol Number: LOXO-RET-17001 06:40 06JAN2021
Clinical Study Report (Visit Cutoff 30-MAR-2020)

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).
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aesocpt_tdisc_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/T14.4.2.74_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).
Program location: /lillyce/prd/ly3527723/j2g_ox_jzja/misc6/programs/primary/tfl/t_aesocpt_tdisc_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/T14.4.2.74_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
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/T14.4.2.74_sf.rtf