Tabellenverzeichnis:

Table 1.3.1.1
Summary of TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any TEAEs	53 (65.43)	53 (64.63)
Relative Risk (RR) (95% CI)		0.9878 (0.7887, 1.2372)
P-value vs. TEZ/IVA [1]		0.9149
Odds Ratio (OR) (95% CI)		0.9655 (0.5071, 1.8383)
P-value vs. TEZ/IVA [2]		0.9149
Risk Difference (RD) (95% CI)		-0.0080 (-0.1544, 0.1384)
P-value vs. TEZ/IVA [3]		0.9149
Respiratory, thoracic and mediastinal disorders	18 (22.22)	21 (25.61)
Relative Risk (RR) (95% CI)		1.1524 (0.6652, 1.9967)
P-value vs. TEZ/IVA [1]		0.6129
Odds Ratio (OR) (95% CI)		1.2049 (0.5857, 2.4787)
P-value vs. TEZ/IVA [2]		0.6125
Risk Difference (RD) (95% CI)		0.0339 (-0.0970, 0.1647)
P-value vs. TEZ/IVA [3]		0.6119

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Table 1.3.1.1
Summary of TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Cough	10 (12.35)	1 (1.22)
Relative Risk (RR) (95% CI)		0.0988 (0.0129, 0.7541)
P-value vs. TEZ/IVA [1]		0.0256
Odds Ratio (OR) (95% CI)		0.0877 (0.0109, 0.7018)
P-value vs. TEZ/IVA [2]		0.0218
Risk Difference (RD) (95% CI)		-0.1113 (-0.1867, -0.0358)
P-value vs. TEZ/IVA [3]		0.0039
Gastrointestinal disorders	15 (18.52)	16 (19.51)
Relative Risk (RR) (95% CI)		1.0537 (0.5589, 1.9862)
P-value vs. TEZ/IVA [1]		0.8716
Odds Ratio (OR) (95% CI)		1.0667 (0.4877, 2.3332)
P-value vs. TEZ/IVA [2]		0.8716
Risk Difference (RD) (95% CI)		0.0099 (-0.1105, 0.1304)
P-value vs. TEZ/IVA [3]		0.8716

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Table 1.3.1.1
Summary of TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Infections and infestations	19 (23.46)	13 (15.85)
Relative Risk (RR) (95% CI)		0.6759 (0.3581, 1.2756)
P-value vs. TEZ/IVA [1]		0.2267
Odds Ratio (OR) (95% CI)		0.6148 (0.2806, 1.3471)
P-value vs. TEZ/IVA [2]		0.2242
Risk Difference (RD) (95% CI)		-0.0760 (-0.1975, 0.0455)
P-value vs. TEZ/IVA [3]		0.2201
General disorders and administration site conditions	5 (6.17)	11 (13.41)
Relative Risk (RR) (95% CI)		2.1732 (0.7903, 5.9759)
P-value vs. TEZ/IVA [1]		0.1326
Odds Ratio (OR) (95% CI)		2.3549 (0.7796, 7.1137)
P-value vs. TEZ/IVA [2]		0.1289
Risk Difference (RD) (95% CI)		0.0724 (-0.0181, 0.1629)
P-value vs. TEZ/IVA [3]		0.1167

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Table 1.3.1.1
Summary of TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Investigations	3 (3.70)	9 (10.98)
Relative Risk (RR) (95% CI)		2.9634 (0.8322, 10.5529)
P-value vs. TEZ/IVA [1]		0.0936
Odds Ratio (OR) (95% CI)		3.2055 (0.8351, 12.3040)
P-value vs. TEZ/IVA [2]		0.0896
Risk Difference (RD) (95% CI)		0.0727 (-0.0065, 0.1519)
P-value vs. TEZ/IVA [3]		0.0718
Nervous system disorders	16 (19.75)	7 (8.54)
Relative Risk (RR) (95% CI)		0.4322 (0.1878, 0.9945)
P-value vs. TEZ/IVA [1]		0.0485
Odds Ratio (OR) (95% CI)		0.3792 (0.1469, 0.9787)
P-value vs. TEZ/IVA [2]		0.0450
Risk Difference (RD) (95% CI)		-0.1122 (-0.2179, -0.0065)
P-value vs. TEZ/IVA [3]		0.0376

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Table 1.3.1.1
Summary of TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Headache	11 (13.58)	6 (7.32)
Relative Risk (RR) (95% CI)		0.5388 (0.2092, 1.3878)
P-value vs. TEZ/IVA [1]		0.2002
Odds Ratio (OR) (95% CI)		0.5024 (0.1764, 1.4305)
P-value vs. TEZ/IVA [2]		0.1973
Risk Difference (RD) (95% CI)		-0.0626 (-0.1561, 0.0309)
P-value vs. TEZ/IVA [3]		0.1892
Musculoskeletal and connective tissue disorders	8 (9.88)	6 (7.32)
Relative Risk (RR) (95% CI)		0.7409 (0.2690, 2.0402)
P-value vs. TEZ/IVA [1]		0.5617
Odds Ratio (OR) (95% CI)		0.7204 (0.2383, 2.1776)
P-value vs. TEZ/IVA [2]		0.5612
Risk Difference (RD) (95% CI)		-0.0256 (-0.1116, 0.0604)
P-value vs. TEZ/IVA [3]		0.5597

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any TEAEs	53 (65.43)	53 (64.63)
Relative Risk (RR) (95% CI)		0.9878 (0.7887, 1.2372)
P-value vs. TEZ/IVA [1]		0.9149
Odds Ratio (OR) (95% CI)		0.9655 (0.5071, 1.8383)
P-value vs. TEZ/IVA [2]		0.9149
Risk Difference (RD) (95% CI)		-0.0080 (-0.1544, 0.1384)
P-value vs. TEZ/IVA [3]		0.9149
Grade 1	32 (39.51)	35 (42.68)
Relative Risk (RR) (95% CI)		1.0804 (0.7477, 1.5612)
P-value vs. TEZ/IVA [1]		0.6805
Odds Ratio (OR) (95% CI)		1.1403 (0.6107, 2.1292)
P-value vs. TEZ/IVA [2]		0.6803
Risk Difference (RD) (95% CI)		0.0318 (-0.1192, 0.1827)
P-value vs. TEZ/IVA [3]		0.6801

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 2	18 (22.22)	16 (19.51)
Relative Risk (RR) (95% CI)		0.8780 (0.4822, 1.5989)
P-value vs. TEZ/IVA [1]		0.6706
Odds Ratio (OR) (95% CI)		0.8485 (0.3981, 1.8084)
P-value vs. TEZ/IVA [2]		0.6704
Risk Difference (RD) (95% CI)		-0.0271 (-0.1518, 0.0976)
P-value vs. TEZ/IVA [3]		0.6702
Grade 3	3 (3.70)	2 (2.44)
Relative Risk (RR) (95% CI)		0.6585 (0.1130, 3.8379)
P-value vs. TEZ/IVA [1]		0.6423
Odds Ratio (OR) (95% CI)		0.6500 (0.1057, 3.9964)
P-value vs. TEZ/IVA [2]		0.6420
Risk Difference (RD) (95% CI)		-0.0126 (-0.0656, 0.0403)
P-value vs. TEZ/IVA [3]		0.6398

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Respiratory, thoracic and mediastinal disorders	18 (22.22)	21 (25.61)
Relative Risk (RR) (95% CI)		1.1524 (0.6652, 1.9967)
P-value vs. TEZ/IVA [1]		0.6129
Odds Ratio (OR) (95% CI)		1.2049 (0.5857, 2.4787)
P-value vs. TEZ/IVA [2]		0.6125
Risk Difference (RD) (95% CI)		0.0339 (-0.0970, 0.1647)
P-value vs. TEZ/IVA [3]		0.6119

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 1	14 (17.28)	17 (20.73)
Relative Risk (RR) (95% CI)		1.1995 (0.6342, 2.2685)
P-value vs. TEZ/IVA [1]		0.5759
Odds Ratio (OR) (95% CI)		1.2516 (0.5707, 2.7451)
P-value vs. TEZ/IVA [2]		0.5754
Risk Difference (RD) (95% CI)		0.0345 (-0.0859, 0.1548)
P-value vs. TEZ/IVA [3]		0.5744
Grade 2	4 (4.94)	4 (4.88)
Relative Risk (RR) (95% CI)		0.9878 (0.2557, 3.8160)
P-value vs. TEZ/IVA [1]		0.9858
Odds Ratio (OR) (95% CI)		0.9872 (0.2383, 4.0891)
P-value vs. TEZ/IVA [2]		0.9858
Risk Difference (RD) (95% CI)		-0.0006 (-0.0669, 0.0657)
P-value vs. TEZ/IVA [3]		0.9858

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 3	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

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Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Cough	10 (12.35)	1 (1.22)
Relative Risk (RR) (95% CI)		0.0988 (0.0129, 0.7541)
P-value vs. TEZ/IVA [1]		0.0256
Odds Ratio (OR) (95% CI)		0.0877 (0.0109, 0.7018)
P-value vs. TEZ/IVA [2]		0.0218
Risk Difference (RD) (95% CI)		-0.1113 (-0.1867, -0.0358)
P-value vs. TEZ/IVA [3]		0.0039
Grade 1	8 (9.88)	1 (1.22)
Relative Risk (RR) (95% CI)		0.1235 (0.0158, 0.9650)
P-value vs. TEZ/IVA [1]		0.0462
Odds Ratio (OR) (95% CI)		0.1127 (0.0138, 0.9225)
P-value vs. TEZ/IVA [2]		0.0418
Risk Difference (RD) (95% CI)		-0.0866 (-0.1557, -0.0174)
P-value vs. TEZ/IVA [3]		0.0142

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Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 2	2 (2.47)	0
Relative Risk (RR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		-0.0247 (-0.0585, 0.0091)
P-value vs. TEZ/IVA [3]		0.1521
Grade 3	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

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- [3] Risk difference estimate from 2x2 table.
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Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Gastrointestinal disorders	15 (18.52)	16 (19.51)
Relative Risk (RR) (95% CI)		1.0537 (0.5589, 1.9862)
P-value vs. TEZ/IVA [1]		0.8716
Odds Ratio (OR) (95% CI)		1.0667 (0.4877, 2.3332)
P-value vs. TEZ/IVA [2]		0.8716
Risk Difference (RD) (95% CI)		0.0099 (-0.1105, 0.1304)
P-value vs. TEZ/IVA [3]		0.8716

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 1	11 (13.58)	12 (14.63)
Relative Risk (RR) (95% CI)		1.0776 (0.5048, 2.3004)
P-value vs. TEZ/IVA [1]		0.8468
Odds Ratio (OR) (95% CI)		1.0909 (0.4513, 2.6371)
P-value vs. TEZ/IVA [2]		0.8468
Risk Difference (RD) (95% CI)		0.0105 (-0.0963, 0.1174)
P-value vs. TEZ/IVA [3]		0.8467
Grade 2	3 (3.70)	4 (4.88)
Relative Risk (RR) (95% CI)		1.3171 (0.3043, 5.7004)
P-value vs. TEZ/IVA [1]		0.7126
Odds Ratio (OR) (95% CI)		1.3333 (0.2889, 6.1545)
P-value vs. TEZ/IVA [2]		0.7124
Risk Difference (RD) (95% CI)		0.0117 (-0.0504, 0.0739)
P-value vs. TEZ/IVA [3]		0.7112

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 3	1 (1.23)	0
Relative Risk (RR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		-0.0123 (-0.0364, 0.0117)
P-value vs. TEZ/IVA [3]		0.3143
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Infections and infestations	19 (23.46)	13 (15.85)
Relative Risk (RR) (95% CI)		0.6759 (0.3581, 1.2756)
P-value vs. TEZ/IVA [1]		0.2267
Odds Ratio (OR) (95% CI)		0.6148 (0.2806, 1.3471)
P-value vs. TEZ/IVA [2]		0.2242
Risk Difference (RD) (95% CI)		-0.0760 (-0.1975, 0.0455)
P-value vs. TEZ/IVA [3]		0.2201
Grade 1	10 (12.35)	10 (12.20)
Relative Risk (RR) (95% CI)		0.9878 (0.4346, 2.2450)
P-value vs. TEZ/IVA [1]		0.9766
Odds Ratio (OR) (95% CI)		0.9861 (0.3868, 2.5139)
P-value vs. TEZ/IVA [2]		0.9766
Risk Difference (RD) (95% CI)		-0.0015 (-0.1022, 0.0992)
P-value vs. TEZ/IVA [3]		0.9766

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 2	7 (8.64)	3 (3.66)
Relative Risk (RR) (95% CI)		0.4233 (0.1134, 1.5803)
P-value vs. TEZ/IVA [1]		0.2009
Odds Ratio (OR) (95% CI)		0.4014 (0.1001, 1.6104)
P-value vs. TEZ/IVA [2]		0.1979
Risk Difference (RD) (95% CI)		-0.0498 (-0.1233, 0.0236)
P-value vs. TEZ/IVA [3]		0.1836
Grade 3	2 (2.47)	0
Relative Risk (RR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		-0.0247 (-0.0585, 0.0091)
P-value vs. TEZ/IVA [3]		0.1521

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
General disorders and administration site conditions	5 (6.17)	11 (13.41)
Relative Risk (RR) (95% CI)		2.1732 (0.7903, 5.9759)
P-value vs. TEZ/IVA [1]		0.1326
Odds Ratio (OR) (95% CI)		2.3549 (0.7796, 7.1137)
P-value vs. TEZ/IVA [2]		0.1289
Risk Difference (RD) (95% CI)		0.0724 (-0.0181, 0.1629)
P-value vs. TEZ/IVA [3]		0.1167

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 1	4 (4.94)	11 (13.41)
Relative Risk (RR) (95% CI)		2.7165 (0.9021, 8.1804)
P-value vs. TEZ/IVA [1]		0.0756
Odds Ratio (OR) (95% CI)		2.9824 (0.9083, 9.7930)
P-value vs. TEZ/IVA [2]		0.0716
Risk Difference (RD) (95% CI)		0.0848 (-0.0028, 0.1723)
P-value vs. TEZ/IVA [3]		0.0578
Grade 2	1 (1.23)	0
Relative Risk (RR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		-0.0123 (-0.0364, 0.0117)
P-value vs. TEZ/IVA [3]		0.3143

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 3	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Investigations	3 (3.70)	9 (10.98)
Relative Risk (RR) (95% CI)		2.9634 (0.8322, 10.5529)
P-value vs. TEZ/IVA [1]		0.0936
Odds Ratio (OR) (95% CI)		3.2055 (0.8351, 12.3040)
P-value vs. TEZ/IVA [2]		0.0896
Risk Difference (RD) (95% CI)		0.0727 (-0.0065, 0.1519)
P-value vs. TEZ/IVA [3]		0.0718
Grade 1	3 (3.70)	6 (7.32)
Relative Risk (RR) (95% CI)		1.9756 (0.5114, 7.6319)
P-value vs. TEZ/IVA [1]		0.3234
Odds Ratio (OR) (95% CI)		2.0526 (0.4954, 8.5043)
P-value vs. TEZ/IVA [2]		0.3214
Risk Difference (RD) (95% CI)		0.0361 (-0.0336, 0.1059)
P-value vs. TEZ/IVA [3]		0.3101

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 2	0	2 (2.44)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0244 (-0.0090, 0.0578)
P-value vs. TEZ/IVA [3]		0.1522
Grade 3	0	1 (1.22)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0122 (-0.0116, 0.0360)
P-value vs. TEZ/IVA [3]		0.3143

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Nervous system disorders	16 (19.75)	7 (8.54)
Relative Risk (RR) (95% CI)		0.4322 (0.1878, 0.9945)
P-value vs. TEZ/IVA [1]		0.0485
Odds Ratio (OR) (95% CI)		0.3792 (0.1469, 0.9787)
P-value vs. TEZ/IVA [2]		0.0450
Risk Difference (RD) (95% CI)		-0.1122 (-0.2179, -0.0065)
P-value vs. TEZ/IVA [3]		0.0376

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 1	12 (14.81)	6 (7.32)
Relative Risk (RR) (95% CI)		0.4939 (0.1947, 1.2526)
P-value vs. TEZ/IVA [1]		0.1374
Odds Ratio (OR) (95% CI)		0.4539 (0.1616, 1.2750)
P-value vs. TEZ/IVA [2]		0.1339
Risk Difference (RD) (95% CI)		-0.0750 (-0.1707, 0.0207)
P-value vs. TEZ/IVA [3]		0.1247
Grade 2	4 (4.94)	1 (1.22)
Relative Risk (RR) (95% CI)		0.2470 (0.0282, 2.1622)
P-value vs. TEZ/IVA [1]		0.2065
Odds Ratio (OR) (95% CI)		0.2377 (0.0260, 2.1738)
P-value vs. TEZ/IVA [2]		0.2032
Risk Difference (RD) (95% CI)		-0.0372 (-0.0900, 0.0156)
P-value vs. TEZ/IVA [3]		0.1677

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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 3	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

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- [3] Risk difference estimate from 2x2 table.
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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Headache	11 (13.58)	6 (7.32)
Relative Risk (RR) (95% CI)		0.5388 (0.2092, 1.3878)
P-value vs. TEZ/IVA [1]		0.2002
Odds Ratio (OR) (95% CI)		0.5024 (0.1764, 1.4305)
P-value vs. TEZ/IVA [2]		0.1973
Risk Difference (RD) (95% CI)		-0.0626 (-0.1561, 0.0309)
P-value vs. TEZ/IVA [3]		0.1892
Grade 1	7 (8.64)	5 (6.10)
Relative Risk (RR) (95% CI)		0.7056 (0.2335, 2.1320)
P-value vs. TEZ/IVA [1]		0.5365
Odds Ratio (OR) (95% CI)		0.6865 (0.2086, 2.2591)
P-value vs. TEZ/IVA [2]		0.5359
Risk Difference (RD) (95% CI)		-0.0254 (-0.1056, 0.0547)
P-value vs. TEZ/IVA [3]		0.5339

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- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
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Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 2	4 (4.94)	1 (1.22)
Relative Risk (RR) (95% CI)		0.2470 (0.0282, 2.1622)
P-value vs. TEZ/IVA [1]		0.2065
Odds Ratio (OR) (95% CI)		0.2377 (0.0260, 2.1738)
P-value vs. TEZ/IVA [2]		0.2032
Risk Difference (RD) (95% CI)		-0.0372 (-0.0900, 0.0156)
P-value vs. TEZ/IVA [3]		0.1677
Grade 3	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

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- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
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- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Musculoskeletal and connective tissue disorders	8 (9.88)	6 (7.32)
Relative Risk (RR) (95% CI)		0.7409 (0.2690, 2.0402)
P-value vs. TEZ/IVA [1]		0.5617
Odds Ratio (OR) (95% CI)		0.7204 (0.2383, 2.1776)
P-value vs. TEZ/IVA [2]		0.5612
Risk Difference (RD) (95% CI)		-0.0256 (-0.1116, 0.0604)
P-value vs. TEZ/IVA [3]		0.5597

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once with the maximum severity in that category.
- SOCs and PTs are reported only if corresponding events are either 1) occurring in at least 10% of patients in any treatment group; OR 2) occurring in at least 10 patients in the total study population and also occurring in at least 1% of patients in any treatment group.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 1	7 (8.64)	5 (6.10)
Relative Risk (RR) (95% CI)		0.7056 (0.2335, 2.1320)
P-value vs. TEZ/IVA [1]		0.5365
Odds Ratio (OR) (95% CI)		0.6865 (0.2086, 2.2591)
P-value vs. TEZ/IVA [2]		0.5359
Risk Difference (RD) (95% CI)		-0.0254 (-0.1056, 0.0547)
P-value vs. TEZ/IVA [3]		0.5339
Grade 2	1 (1.23)	1 (1.22)
Relative Risk (RR) (95% CI)		0.9878 (0.0628, 15.5254)
P-value vs. TEZ/IVA [1]		0.9930
Odds Ratio (OR) (95% CI)		0.9877 (0.0607, 16.0635)
P-value vs. TEZ/IVA [2]		0.9930
Risk Difference (RD) (95% CI)		-0.0002 (-0.0340, 0.0337)
P-value vs. TEZ/IVA [3]		0.9930

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once with the maximum severity in that category.
- SOCs and PTs are reported only if corresponding events are either 1) occurring in at least 10% of patients in any treatment group; OR 2) occurring in at least 10 patients in the total study population and also occurring in at least 1% of patients in any treatment group.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.1.1
Summary of TEAEs by SOC and PT, and by Maximum Severity
Safety Set (RF)

System Organ Class Preferred Term Maximum Severity	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Grade 3	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Grade 4	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once with the maximum severity in that category.
- SOCs and PTs are reported only if corresponding events are either 1) occurring in at least 10% of patients in any treatment group; OR 2) occurring in at least 10 patients in the total study population and also occurring in at least 1% of patients in any treatment group.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.2
Summary of Grade 3/4 TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any Grade 3/4 TEAEs	3 (3.70)	2 (2.44)
Relative Risk (RR) (95% CI)		0.6585 (0.1130, 3.8379)
P-value vs. TEZ/IVA [1]		0.6423
Odds Ratio (OR) (95% CI)		0.6500 (0.1057, 3.9964)
P-value vs. TEZ/IVA [2]		0.6420
Risk Difference (RD) (95% CI)		-0.0126 (-0.0656, 0.0403)
P-value vs. TEZ/IVA [3]		0.6398

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- SOCs and PTs are reported only if corresponding events are either 1) occurring in at least 5% of patients in any treatment group; OR 2) occurring in at least 10 patients in the total study population and also occurring in at least 1% of patients in any treatment group.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.3
Summary of Serious TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any serious TEAEs	6 (7.41)	1 (1.22)
Relative Risk (RR) (95% CI)		0.1646 (0.0203, 1.3372)
P-value vs. TEZ/IVA [1]		0.0914
Odds Ratio (OR) (95% CI)		0.1543 (0.0182, 1.3119)
P-value vs. TEZ/IVA [2]		0.0870
Risk Difference (RD) (95% CI)		-0.0619 (-0.1237, -0.0001)
P-value vs. TEZ/IVA [3]		0.0496

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- SOCs and PTs are reported only if corresponding events are either 1) occurring in at least 5% of patients in any treatment group; OR 2) occurring in at least 10 patients in the total study population and also occurring in at least 1% of patients in any treatment group.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.4
Summary of TEAEs Leading to Treatment Discontinuation by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any TEAEs leading to treatment discontinuation	0	1 (1.22)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0122 (-0.0116, 0.0360)
P-value vs. TEZ/IVA [3]		0.3143
Investigations	0	1 (1.22)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0122 (-0.0116, 0.0360)
P-value vs. TEZ/IVA [3]		0.3143

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.4
Summary of TEAEs Leading to Treatment Discontinuation by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Alanine aminotransferase increased	0	1 (1.22)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0122 (-0.0116, 0.0360)
P-value vs. TEZ/IVA [3]		0.3143
Aspartate aminotransferase increased	0	1 (1.22)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0122 (-0.0116, 0.0360)
P-value vs. TEZ/IVA [3]		0.3143

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.5
Summary of AESI: Treatment-emergent Elevated Transaminase Events - Total and by Severity
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any Treatment-emergent Elevated Transaminase Events	1 (1.23)	6 (7.32)
Relative Risk (RR) (95% CI)		5.9268 (0.7297, 48.1398)
P-value vs. TEZ/IVA [1]		0.0959
Odds Ratio (OR) (95% CI)		6.3158 (0.7430, 53.6890)
P-value vs. TEZ/IVA [2]		0.0914
Risk Difference (RD) (95% CI)		0.0608 (-0.0005, 0.1221)
P-value vs. TEZ/IVA [3]		0.0517
Subjects with non-severe events (Maximum Grade 1/2)	1 (1.23)	5 (6.10)
Relative Risk (RR) (95% CI)		4.9390 (0.5899, 41.3525)
P-value vs. TEZ/IVA [1]		0.1407
Odds Ratio (OR) (95% CI)		5.1948 (0.5933, 45.4846)
P-value vs. TEZ/IVA [2]		0.1367
Risk Difference (RD) (95% CI)		0.0486 (-0.0085, 0.1057)
P-value vs. TEZ/IVA [3]		0.0951

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.5
Summary of AESI: Treatment-emergent Elevated Transaminase Events - Total and by Severity
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with severe events (Maximum Grade 3/4)	0	1 (1.22)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0122 (-0.0116, 0.0360)
P-value vs. TEZ/IVA [3]		0.3143
Subjects with serious events	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.6
Summary of AESI: Treatment-emergent Rash Events - Total and by Severity
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any Treatment-emergent Rash Events	4 (4.94)	0
Relative Risk (RR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		-0.0494 (-0.0966, -0.0022)
P-value vs. TEZ/IVA [3]		0.0402
Subjects with non-severe events (Maximum Grade 1/2)	4 (4.94)	0
Relative Risk (RR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		-0.0494 (-0.0966, -0.0022)
P-value vs. TEZ/IVA [3]		0.0402

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.6
Summary of AESI: Treatment-emergent Rash Events - Total and by Severity
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with severe events (Maximum Grade 3/4)	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-
Subjects with serious events	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.7
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events - Total and by Severity
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any Treatment-emergent Infective Pulmonary Exacerbation Events	5 (6.17)	1 (1.22)
Relative Risk (RR) (95% CI)		0.1976 (0.0236, 1.6541)
P-value vs. TEZ/IVA [1]		0.1347
Odds Ratio (OR) (95% CI)		0.1877 (0.0214, 1.6431)
P-value vs. TEZ/IVA [2]		0.1307
Risk Difference (RD) (95% CI)		-0.0495 (-0.1071, 0.0080)
P-value vs. TEZ/IVA [3]		0.0916
Subjects with non-severe events (Maximum Grade 1/2)	3 (3.70)	1 (1.22)
Relative Risk (RR) (95% CI)		0.3293 (0.0350, 3.0999)
P-value vs. TEZ/IVA [1]		0.3315
Odds Ratio (OR) (95% CI)		0.3210 (0.0327, 3.1521)
P-value vs. TEZ/IVA [2]		0.3296
Risk Difference (RD) (95% CI)		-0.0248 (-0.0723, 0.0227)
P-value vs. TEZ/IVA [3]		0.3053

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.7
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events - Total and by Severity
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with severe events (Maximum Grade 3/4)	2 (2.47)	0
Relative Risk (RR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		-0.0247 (-0.0585, 0.0091)
P-value vs. TEZ/IVA [3]		0.1521
Subjects with serious events	3 (3.70)	0
Relative Risk (RR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		-0.0370 (-0.0782, 0.0041)
P-value vs. TEZ/IVA [3]		0.0776

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.8
Summary of Death
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)

No data met the criteria for this table.

- Include death during Treatment-emergent Period for the Treatment Period from two sources: 1) treatment/study discontinuation due to death; 2) TEAEs leading to death
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.9
Summary of TEAEs, Grade 3/4 TEAEs, Serious TEAEs and TEAEs Leading to Treatment Discontinuation
(Excluding Infective Pulmonary Exacerbation of Cystic Fibrosis)
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any TEAEs	53 (65.43)	53 (64.63)
Relative Risk (RR) (95% CI)		0.9878 (0.7887, 1.2372)
P-value vs. TEZ/IVA [1]		0.9149
Odds Ratio (OR) (95% CI)		0.9655 (0.5071, 1.8383)
P-value vs. TEZ/IVA [2]		0.9149
Risk Difference (RD) (95% CI)		-0.0080 (-0.1544, 0.1384)
P-value vs. TEZ/IVA [3]		0.9149
Subjects with any Grade 3/4 TEAEs	1 (1.23)	2 (2.44)
Relative Risk (RR) (95% CI)		1.9756 (0.1827, 21.3620)
P-value vs. TEZ/IVA [1]		0.5751
Odds Ratio (OR) (95% CI)		2.0000 (0.1778, 22.5002)
P-value vs. TEZ/IVA [2]		0.5746
Risk Difference (RD) (95% CI)		0.0120 (-0.0291, 0.0532)
P-value vs. TEZ/IVA [3]		0.5661

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.1.9
Summary of TEAEs, Grade 3/4 TEAEs, Serious TEAEs and TEAEs Leading to Treatment Discontinuation
(Excluding Infective Pulmonary Exacerbation of Cystic Fibrosis)
Safety Set (RF)

	TEZ/IVA N = 81 n (%)	ELX/TEZ/IVA N = 82 n (%)
Subjects with any Serious TEAEs	3 (3.70)	1 (1.22)
Relative Risk (RR) (95% CI)		0.3293 (0.0350, 3.0999)
P-value vs. TEZ/IVA [1]		0.3315
Odds Ratio (OR) (95% CI)		0.3210 (0.0327, 3.1521)
P-value vs. TEZ/IVA [2]		0.3296
Risk Difference (RD) (95% CI)		-0.0248 (-0.0723, 0.0227)
P-value vs. TEZ/IVA [3]		0.3053
Subjects with any TEAEs leading to treatment discontinuation	0	1 (1.22)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0122 (-0.0116, 0.0360)
P-value vs. TEZ/IVA [3]		0.3143

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.1
Treatment by Subgroup Factor Interactions for TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term Subgroup	P-value for Interaction Based on Relative Risk
Subjects with any TEAEs	
Percent predicted FEV_1 at Baseline (<70% vs. ≥70%)	0.6763
Sweat chloride during Run-in (<30 mmol/L vs. ≥30 mmol/L)	0.5796
Age at Screening (< 18 years vs. ≥ 18 years)	N/C
Sex (Male vs. Female)	0.8161
Region (North America vs. Europe (including Australia))	0.9836

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- P-values are for Relative Risk obtained from Generalized Linear Model for Outcome = treatment, subgroup (one factor at a time), treatment*subgroup; Distribution: binomial, link: log. If the log-binomial model does not converge, modified Poisson regression model with log link is used and indicated by '*'.
- P-values are reported at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, p-value will be reported if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- N/C: model does not converge.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.1
Treatment by Subgroup Factor Interactions for TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term Subgroup	P-value for Interaction Based on Relative Risk
Respiratory, thoracic and mediastinal disorders	
Cough	
Percent predicted FEV_1 at Baseline (<70% vs. ≥70%)	-
Sweat chloride during Run-in (<30 mmol/L vs. ≥30 mmol/L)	-
Age at Screening (< 18 years vs. ≥ 18 years)	N/C
Sex (Male vs. Female)	-
Region (North America vs. Europe (including Australia))	-

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- P-values are for Relative Risk obtained from Generalized Linear Model for Outcome = treatment, subgroup (one factor at a time), treatment*subgroup; Distribution: binomial, link: log. If the log-binomial model does not converge, modified Poisson regression model with log link is used and indicated by '*'.
- P-values are reported at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, p-value will be reported if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- N/C: model does not converge.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.1
Treatment by Subgroup Factor Interactions for TEAEs by SOC and PT
Safety Set (RF)

System Organ Class Preferred Term Subgroup	P-value for Interaction Based on Relative Risk
Nervous system disorders	
Percent predicted FEV_1 at Baseline (<70% vs. ≥70%)	0.2202
Sweat chloride during Run-in (<30 mmol/L vs. ≥30 mmol/L)	0.2435
Age at Screening (< 18 years vs. ≥ 18 years)	N/C
Sex (Male vs. Female)	0.0521
Region (North America vs. Europe (including Australia))	0.4057

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- P-values are for Relative Risk obtained from Generalized Linear Model for Outcome = treatment, subgroup (one factor at a time), treatment*subgroup; Distribution: binomial, link: log. If the log-binomial model does not converge, modified Poisson regression model with log link is used and indicated by '*'.
- P-values are reported at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, p-value will be reported if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- N/C: model does not converge.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline <70%

System Organ Class Preferred Term	TEZ/IVA N = 40 n (%)	ELX/TEZ/IVA N = 44 n (%)
Subjects with any TEAEs	26 (65.00)	27 (61.36)
Relative Risk (RR) (95% CI)		0.9441 (0.6810, 1.3087)
P-value vs. TEZ/IVA [1]		0.7297
Odds Ratio (OR) (95% CI)		0.8552 (0.3515, 2.0805)
P-value vs. TEZ/IVA [2]		0.7302
Risk Difference (RD) (95% CI)		-0.0364 (-0.2426, 0.1699)
P-value vs. TEZ/IVA [3]		0.7297

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline <70%

System Organ Class Preferred Term	TEZ/IVA N = 40 n (%)	ELX/TEZ/IVA N = 44 n (%)
Nervous system disorders	8 (20.00)	2 (4.55)
Relative Risk (RR) (95% CI)		0.2273 (0.0513, 1.0076)
P-value vs. TEZ/IVA [1]		0.0512
Odds Ratio (OR) (95% CI)		0.1905 (0.0378, 0.9589)
P-value vs. TEZ/IVA [2]		0.0443
Risk Difference (RD) (95% CI)		-0.1545 (-0.2929, -0.0161)
P-value vs. TEZ/IVA [3]		0.0286

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline ≥70%

System Organ Class Preferred Term	TEZ/IVA N = 41 n (%)	ELX/TEZ/IVA N = 38 n (%)
Subjects with any TEAEs	27 (65.85)	26 (68.42)
Relative Risk (RR) (95% CI)		1.0390 (0.7631, 1.4146)
P-value vs. TEZ/IVA [1]		0.8081
Odds Ratio (OR) (95% CI)		1.1235 (0.4386, 2.8775)
P-value vs. TEZ/IVA [2]		0.8083
Risk Difference (RD) (95% CI)		0.0257 (-0.1815, 0.2328)
P-value vs. TEZ/IVA [3]		0.8081

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline ≥70%

System Organ Class Preferred Term	TEZ/IVA N = 41 n (%)	ELX/TEZ/IVA N = 38 n (%)
Nervous system disorders	8 (19.51)	5 (13.16)
Relative Risk (RR) (95% CI)		0.6743 (0.2416, 1.8823)
P-value vs. TEZ/IVA [1]		0.4519
Odds Ratio (OR) (95% CI)		0.6250 (0.1851, 2.1108)
P-value vs. TEZ/IVA [2]		0.4491
Risk Difference (RD) (95% CI)		-0.0635 (-0.2256, 0.0985)
P-value vs. TEZ/IVA [3]		0.4422

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- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in <30 mmol/L

System Organ Class Preferred Term	TEZ/IVA N = 14 n (%)	ELX/TEZ/IVA N = 13 n (%)
Subjects with any TEAEs	12 (85.71)	10 (76.92)
Relative Risk (RR) (95% CI)		0.8974 (0.6220, 1.2948)
P-value vs. TEZ/IVA [1]		0.5629
Odds Ratio (OR) (95% CI)		0.5556 (0.0770, 4.0086)
P-value vs. TEZ/IVA [2]		0.5599
Risk Difference (RD) (95% CI)		-0.0879 (-0.3813, 0.2054)
P-value vs. TEZ/IVA [3]		0.5570

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in <30 mmol/L

System Organ Class Preferred Term	TEZ/IVA N = 14 n (%)	ELX/TEZ/IVA N = 13 n (%)
Nervous system disorders	6 (42.86)	1 (7.69)
Relative Risk (RR) (95% CI)		0.1795 (0.0248, 1.2972)
P-value vs. TEZ/IVA [1]		0.0887
Odds Ratio (OR) (95% CI)		0.1111 (0.0112, 1.1063)
P-value vs. TEZ/IVA [2]		0.0610
Risk Difference (RD) (95% CI)		-0.3516 (-0.6486, -0.0547)
P-value vs. TEZ/IVA [3]		0.0203

- MedDRA version 23.0.
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- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in ≥30 mmol/L

System Organ Class Preferred Term	TEZ/IVA N = 67 n (%)	ELX/TEZ/IVA N = 69 n (%)
Subjects with any TEAEs	41 (61.19)	43 (62.32)
Relative Risk (RR) (95% CI)		1.0184 (0.7816, 1.3269)
P-value vs. TEZ/IVA [1]		0.8927
Odds Ratio (OR) (95% CI)		1.0488 (0.5251, 2.0946)
P-value vs. TEZ/IVA [2]		0.8927
Risk Difference (RD) (95% CI)		0.0112 (-0.1521, 0.1746)
P-value vs. TEZ/IVA [3]		0.8927

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in ≥30 mmol/L

System Organ Class Preferred Term	TEZ/IVA N = 67 n (%)	ELX/TEZ/IVA N = 69 n (%)
Nervous system disorders	10 (14.93)	6 (8.70)
Relative Risk (RR) (95% CI)		0.5826 (0.2243, 1.5135)
P-value vs. TEZ/IVA [1]		0.2674
Odds Ratio (OR) (95% CI)		0.5429 (0.1855, 1.5884)
P-value vs. TEZ/IVA [2]		0.2648
Risk Difference (RD) (95% CI)		-0.0623 (-0.1705, 0.0459)
P-value vs. TEZ/IVA [3]		0.2590

- MedDRA version 23.0.
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- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening < 18 years

System Organ Class Preferred Term	TEZ/IVA N = 3 n (%)	ELX/TEZ/IVA N = 7 n (%)
Subjects with any TEAEs	0	3 (42.86)
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.4286 (0.0620, 0.7952)
P-value vs. TEZ/IVA [3]		0.0219

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening < 18 years

System Organ Class Preferred Term	TEZ/IVA N = 3 n (%)	ELX/TEZ/IVA N = 7 n (%)
Respiratory, thoracic and mediastinal disorders		
Cough	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

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- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening < 18 years

System Organ Class Preferred Term	TEZ/IVA N = 3 n (%)	ELX/TEZ/IVA N = 7 n (%)
Nervous system disorders	0	0
Relative Risk (RR) (95% CI)		-
P-value vs. TEZ/IVA [1]		-
Odds Ratio (OR) (95% CI)		-
P-value vs. TEZ/IVA [2]		-
Risk Difference (RD) (95% CI)		0.0000 (-, -)
P-value vs. TEZ/IVA [3]		-

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- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening ≥ 18 years

System Organ Class Preferred Term	TEZ/IVA N = 78 n (%)	ELX/TEZ/IVA N = 75 n (%)
Subjects with any TEAEs	53 (67.95)	50 (66.67)
Relative Risk (RR) (95% CI)		0.9811 (0.7866, 1.2238)
P-value vs. TEZ/IVA [1]		0.8659
Odds Ratio (OR) (95% CI)		0.9434 (0.4800, 1.8542)
P-value vs. TEZ/IVA [2]		0.8658
Risk Difference (RD) (95% CI)		-0.0128 (-0.1615, 0.1359)
P-value vs. TEZ/IVA [3]		0.8658

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening ≥ 18 years

System Organ Class Preferred Term	TEZ/IVA N = 78 n (%)	ELX/TEZ/IVA N = 75 n (%)
Respiratory, thoracic and mediastinal disorders		
Cough	10 (12.82)	1 (1.33)
Relative Risk (RR) (95% CI)		0.1040 (0.0136, 0.7927)
P-value vs. TEZ/IVA [1]		0.0290
Odds Ratio (OR) (95% CI)		0.0919 (0.0115, 0.7369)
P-value vs. TEZ/IVA [2]		0.0246
Risk Difference (RD) (95% CI)		-0.1149 (-0.1935, -0.0363)
P-value vs. TEZ/IVA [3]		0.0042

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening ≥ 18 years

System Organ Class Preferred Term	TEZ/IVA N = 78 n (%)	ELX/TEZ/IVA N = 75 n (%)
Nervous system disorders	16 (20.51)	7 (9.33)
Relative Risk (RR) (95% CI)		0.4550 (0.1985, 1.0431)
P-value vs. TEZ/IVA [1]		0.0629
Odds Ratio (OR) (95% CI)		0.3989 (0.1539, 1.0340)
P-value vs. TEZ/IVA [2]		0.0586
Risk Difference (RD) (95% CI)		-0.1118 (-0.2230, -0.0006)
P-value vs. TEZ/IVA [3]		0.0488

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Male

System Organ Class Preferred Term	TEZ/IVA N = 37 n (%)	ELX/TEZ/IVA N = 37 n (%)
Subjects with any TEAEs	24 (64.86)	23 (62.16)
Relative Risk (RR) (95% CI)		0.9583 (0.6783, 1.3540)
P-value vs. TEZ/IVA [1]		0.8093
Odds Ratio (OR) (95% CI)		0.8899 (0.3452, 2.2943)
P-value vs. TEZ/IVA [2]		0.8092
Risk Difference (RD) (95% CI)		-0.0270 (-0.2463, 0.1922)
P-value vs. TEZ/IVA [3]		0.8091

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Male

System Organ Class Preferred Term	TEZ/IVA N = 37 n (%)	ELX/TEZ/IVA N = 37 n (%)
Nervous system disorders	5 (13.51)	5 (13.51)
Relative Risk (RR) (95% CI)		1.0000 (0.3158, 3.1670)
P-value vs. TEZ/IVA [1]		>0.9999
Odds Ratio (OR) (95% CI)		1.0000 (0.2637, 3.7921)
P-value vs. TEZ/IVA [2]		>0.9999
Risk Difference (RD) (95% CI)		0.0000 (-0.1558, 0.1558)
P-value vs. TEZ/IVA [3]		>0.9999

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Female

System Organ Class Preferred Term	TEZ/IVA N = 44 n (%)	ELX/TEZ/IVA N = 45 n (%)
Subjects with any TEAEs	29 (65.91)	30 (66.67)
Relative Risk (RR) (95% CI)		1.0115 (0.7521, 1.3604)
P-value vs. TEZ/IVA [1]		0.9398
Odds Ratio (OR) (95% CI)		1.0345 (0.4295, 2.4916)
P-value vs. TEZ/IVA [2]		0.9397
Risk Difference (RD) (95% CI)		0.0076 (-0.1889, 0.2040)
P-value vs. TEZ/IVA [3]		0.9397

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Female

System Organ Class Preferred Term	TEZ/IVA N = 44 n (%)	ELX/TEZ/IVA N = 45 n (%)
Nervous system disorders	11 (25.00)	2 (4.44)
Relative Risk (RR) (95% CI)		0.1778 (0.0418, 0.7565)
P-value vs. TEZ/IVA [1]		0.0194
Odds Ratio (OR) (95% CI)		0.1395 (0.0289, 0.6730)
P-value vs. TEZ/IVA [2]		0.0142
Risk Difference (RD) (95% CI)		-0.2056 (-0.3470, -0.0642)
P-value vs. TEZ/IVA [3]		0.0044

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Region = North America

System Organ Class Preferred Term	TEZ/IVA N = 28 n (%)	ELX/TEZ/IVA N = 30 n (%)
Subjects with any TEAEs	18 (64.29)	19 (63.33)
Relative Risk (RR) (95% CI)		0.9852 (0.6685, 1.4518)
P-value vs. TEZ/IVA [1]		0.9399
Odds Ratio (OR) (95% CI)		0.9596 (0.3285, 2.8029)
P-value vs. TEZ/IVA [2]		0.9399
Risk Difference (RD) (95% CI)		-0.0095 (-0.2570, 0.2379)
P-value vs. TEZ/IVA [3]		0.9399

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Region = North America

System Organ Class Preferred Term	TEZ/IVA N = 28 n (%)	ELX/TEZ/IVA N = 30 n (%)
Nervous system disorders	6 (21.43)	4 (13.33)
Relative Risk (RR) (95% CI)		0.6222 (0.1959, 1.9761)
P-value vs. TEZ/IVA [1]		0.4210
Odds Ratio (OR) (95% CI)		0.5641 (0.1410, 2.2574)
P-value vs. TEZ/IVA [2]		0.4184
Risk Difference (RD) (95% CI)		-0.0810 (-0.2756, 0.1137)
P-value vs. TEZ/IVA [3]		0.4150

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Region = Europe (including Australia)

System Organ Class Preferred Term	TEZ/IVA N = 53 n (%)	ELX/TEZ/IVA N = 52 n (%)
Subjects with any TEAEs	35 (66.04)	34 (65.38)
Relative Risk (RR) (95% CI)		0.9901 (0.7510, 1.3053)
P-value vs. TEZ/IVA [1]		0.9438
Odds Ratio (OR) (95% CI)		0.9714 (0.4339, 2.1749)
P-value vs. TEZ/IVA [2]		0.9438
Risk Difference (RD) (95% CI)		-0.0065 (-0.1881, 0.1751)
P-value vs. TEZ/IVA [3]		0.9438

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.1.2
Summary of TEAEs by SOC and PT by Each Applicable Subgroup Factor
Safety Set (RF)
Region = Europe (including Australia)

System Organ Class Preferred Term	TEZ/IVA N = 53 n (%)	ELX/TEZ/IVA N = 52 n (%)
Nervous system disorders	10 (18.87)	3 (5.77)
Relative Risk (RR) (95% CI)		0.3058 (0.0892, 1.0484)
P-value vs. TEZ/IVA [1]		0.0595
Odds Ratio (OR) (95% CI)		0.2633 (0.0680, 1.0192)
P-value vs. TEZ/IVA [2]		0.0533
Risk Difference (RD) (95% CI)		-0.1310 (-0.2539, -0.0081)
P-value vs. TEZ/IVA [3]		0.0368

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup analyses are performed at SOC/PT level only if 1) Respective analysis on the study level is done and relative risk of respective treatment effect at study level is statistically significant (p-value <0.05); 2) there are at least 10 subjects in each subgroup (per factor); and 3) there are at least 10 subjects with events in at least one of the subgroups (per factor). For the overall rate, it is performed if conditions (2) and (3) are met.
- Table is sorted in descending order of frequency of the ELX/TEZ/IVA column by System Organ Class, and by Preferred Term within each System Organ Class.
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.1
Treatment by Subgroup Factor Interactions for Grade 3/4 TEAEs
Safety Set (RF)

	P-value for Interaction Based on Relative Risk

No data met the criteria for this table.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- P-values are for Relative Risk obtained from Generalized Linear Model for Outcome = treatment, subgroup (one factor at a time), treatment*subgroup; Distribution: binomial, link: log. If the log-binomial model does not converge, modified Poisson regression model with log link is used and indicated by '*'.
- P-values are reported only if 1) there are at least 10 subjects in each subgroup (per factor); and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- N/C: model does not converge.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline <70%

	TEZ/IVA N = 40 n (%)	ELX/TEZ/IVA N = 44 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline ≥70%

	TEZ/IVA N = 41 n (%)	ELX/TEZ/IVA N = 38 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in <30 mmol/L

	TEZ/IVA N = 14 n (%)	ELX/TEZ/IVA N = 13 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in ≥30 mmol/L

	TEZ/IVA N = 67 n (%)	ELX/TEZ/IVA N = 69 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening < 18 years

	TEZ/IVA N = 3 n (%)	ELX/TEZ/IVA N = 7 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening ≥ 18 years

	TEZ/IVA N = 78 n (%)	ELX/TEZ/IVA N = 75 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Male

	TEZ/IVA N = 37 n (%)	ELX/TEZ/IVA N = 37 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Female

	TEZ/IVA N = 44 n (%)	ELX/TEZ/IVA N = 45 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Region = North America

	TEZ/IVA N = 28 n (%)	ELX/TEZ/IVA N = 30 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.2.2
Summary of Grade 3/4 TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Region = Europe (including Australia)

	TEZ/IVA N = 53 n (%)	ELX/TEZ/IVA N = 52 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.1
Treatment by Subgroup Factor Interactions for Serious TEAEs
Safety Set (RF)

	P-value for Interaction Based on Relative Risk

No data met the criteria for this table.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- P-values are for Relative Risk obtained from Generalized Linear Model for Outcome = treatment, subgroup (one factor at a time), treatment*subgroup; Distribution: binomial, link: log. If the log-binomial model does not converge, modified Poisson regression model with log link is used and indicated by '*'.
- P-values are reported only if 1) there are at least 10 subjects in each subgroup (per factor); and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- N/C: model does not converge.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline <70%

	TEZ/IVA N = 40 n (%)	ELX/TEZ/IVA N = 44 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline ≥70%

	TEZ/IVA N = 41 n (%)	ELX/TEZ/IVA N = 38 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in <30 mmol/L

	TEZ/IVA N = 14 n (%)	ELX/TEZ/IVA N = 13 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in ≥30 mmol/L

	TEZ/IVA N = 67 n (%)	ELX/TEZ/IVA N = 69 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening < 18 years

	TEZ/IVA N = 3 n (%)	ELX/TEZ/IVA N = 7 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening ≥ 18 years

	TEZ/IVA N = 78 n (%)	ELX/TEZ/IVA N = 75 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Male

	TEZ/IVA N = 37 n (%)	ELX/TEZ/IVA N = 37 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Female

	TEZ/IVA N = 44 n (%)	ELX/TEZ/IVA N = 45 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Region = North America

	TEZ/IVA N = 28 n (%)	ELX/TEZ/IVA N = 30 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.3.2
Summary of Serious TEAEs by Each Applicable Subgroup Factor
Safety Set (RF)
Region = Europe (including Australia)

	TEZ/IVA N = 53 n (%)	ELX/TEZ/IVA N = 52 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.1
Treatment by Subgroup Factor Interactions for AESI of Treatment-emergent Elevated Transaminase Events
Safety Set (RF)

	P-value for Interaction Based on Relative Risk

No data met the criteria for this table.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- P-values are for Relative Risk obtained from Generalized Linear Model for Outcome = treatment, subgroup (one factor at a time), treatment*subgroup; Distribution: binomial, link: log. If the log-binomial model does not converge, modified Poisson regression model with log link is used and indicated by '*'.
- P-values are reported only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- N/C: model does not converge.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline <70%

	TEZ/IVA N = 40 n (%)	ELX/TEZ/IVA N = 44 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline ≥70%

	TEZ/IVA N = 41 n (%)	ELX/TEZ/IVA N = 38 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in <30 mmol/L

	TEZ/IVA N = 14 n (%)	ELX/TEZ/IVA N = 13 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in ≥30 mmol/L

	TEZ/IVA N = 67 n (%)	ELX/TEZ/IVA N = 69 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening < 18 years

	TEZ/IVA N = 3 n (%)	ELX/TEZ/IVA N = 7 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening ≥ 18 years

	TEZ/IVA N = 78 n (%)	ELX/TEZ/IVA N = 75 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Male

	TEZ/IVA N = 37 n (%)	ELX/TEZ/IVA N = 37 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Female

	TEZ/IVA N = 44 n (%)	ELX/TEZ/IVA N = 45 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Region = North America

	TEZ/IVA N = 28 n (%)	ELX/TEZ/IVA N = 30 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.5.2
Summary of AESI: Treatment-emergent Elevated Transaminase Events by Each Applicable Subgroup Factor
Safety Set (RF)
Region = Europe (including Australia)

	TEZ/IVA N = 53 n (%)	ELX/TEZ/IVA N = 52 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.1
Treatment by Subgroup Factor Interactions for AESI of Treatment-emergent Rash Events
Safety Set (RF)

	P-value for Interaction Based on Relative Risk

No data met the criteria for this table.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- P-values are for Relative Risk obtained from Generalized Linear Model for Outcome = treatment, subgroup (one factor at a time), treatment*subgroup; Distribution: binomial, link: log. If the log-binomial model does not converge, modified Poisson regression model with log link is used and indicated by '*'.
- P-values are reported only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- N/C: model does not converge.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline <70%

	TEZ/IVA N = 40 n (%)	ELX/TEZ/IVA N = 44 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline ≥70%

	TEZ/IVA N = 41 n (%)	ELX/TEZ/IVA N = 38 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in <30 mmol/L

	TEZ/IVA N = 14 n (%)	ELX/TEZ/IVA N = 13 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in ≥30 mmol/L

	TEZ/IVA N = 67 n (%)	ELX/TEZ/IVA N = 69 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening < 18 years

	TEZ/IVA N = 3 n (%)	ELX/TEZ/IVA N = 7 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening ≥ 18 years

	TEZ/IVA N = 78 n (%)	ELX/TEZ/IVA N = 75 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Male

	TEZ/IVA N = 37 n (%)	ELX/TEZ/IVA N = 37 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Female

	TEZ/IVA N = 44 n (%)	ELX/TEZ/IVA N = 45 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Region = North America

	TEZ/IVA N = 28 n (%)	ELX/TEZ/IVA N = 30 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.6.2
Summary of AESI: Treatment-emergent Rash Events by Each Applicable Subgroup Factor
Safety Set (RF)
Region = Europe (including Australia)

	TEZ/IVA N = 53 n (%)	ELX/TEZ/IVA N = 52 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.1
Treatment by Subgroup Factor Interactions for Treatment-emergent Infective Pulmonary Exacerbation Events
Safety Set (RF)

	P-value for Interaction Based on Relative Risk

No data met the criteria for this table.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- P-values are for Relative Risk obtained from Generalized Linear Model for Outcome = treatment, subgroup (one factor at a time), treatment*subgroup; Distribution: binomial, link: log. If the log-binomial model does not converge, modified Poisson regression model with log link is used and indicated by '*'.
- P-values are reported only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- N/C: model does not converge.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline <70%

	TEZ/IVA N = 40 n (%)	ELX/TEZ/IVA N = 44 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Percent predicted FEV_1 at Baseline ≥70%

	TEZ/IVA N = 41 n (%)	ELX/TEZ/IVA N = 38 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in <30 mmol/L

	TEZ/IVA N = 14 n (%)	ELX/TEZ/IVA N = 13 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sweat chloride during Run-in ≥30 mmol/L

	TEZ/IVA N = 67 n (%)	ELX/TEZ/IVA N = 69 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening < 18 years

	TEZ/IVA N = 3 n (%)	ELX/TEZ/IVA N = 7 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Age at Screening ≥ 18 years

	TEZ/IVA N = 78 n (%)	ELX/TEZ/IVA N = 75 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Male

	TEZ/IVA N = 37 n (%)	ELX/TEZ/IVA N = 37 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Sex = Female

	TEZ/IVA N = 44 n (%)	ELX/TEZ/IVA N = 45 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Region = North America

	TEZ/IVA N = 28 n (%)	ELX/TEZ/IVA N = 30 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.

Table 1.3.2.7.2
Summary of Treatment-emergent Infective Pulmonary Exacerbation Events by Each Applicable Subgroup Factor
Safety Set (RF)
Region = Europe (including Australia)

	TEZ/IVA N = 53 n (%)	ELX/TEZ/IVA N = 52 n (%)

Subgroup criteria are not met for this subgroup factor.

- MedDRA version 23.0.
- A subject with multiple events within a category is counted only once in that category.
- Subgroup Analysis will be performed only if 1) there are at least 10 subjects in each subgroup (per factor), and 2) there are at least 10 subjects with events in at least one of the subgroups (per factor).
- [1] Relative risk from 2x2 table.
- [2] Odds ratio from 2x2 table.
- [3] Risk difference estimate from 2x2 table.
- '-' indicates that point estimate, CI or p-value is not estimable.
- "RF" refers to the subjects in TEZ/IVA comparator group.