Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tixagevimab/Cilgavimab (EVUSHELD®)

AstraZeneca GmbH

Anhang 4-G

Präexpositionsprophylaxe einer COVID-19-Erkrankung bei Erwachsenen und Jugendlichen (ab 12 Jahren und mit mindestens 40 kg Körpergewicht)

Stand: 08.05.2023

Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
The First case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring post dose of IMP and prior to Day 183									
Age at randomization	0.700								
<60 years		199	2 (1.0)	97	6 (6.2)	85.28 (26.77, 97.04)	0.15 (0.03, 0.78) 0.024	0.16 (0.03, 0.79) 0.024	-5.18 (-10.17, -0.19) 0.042
≥60 years		147	1 (0.7)	76	2 (2.6)	74.01 (-187.10, 97.65)	0.25 (0.02, 2.84) 0.266	0.26 (0.02, 2.81) 0.266	-1.95 (-5.79, 1.88) 0.319
Age at randomization	NE								
<65 years		262	3 (1.1)	137	8 (5.8)	81.67 (30.71, 95.15)	0.19 (0.05, 0.72) 0.014	0.20 (0.05, 0.73) 0.015	-4.69 (-8.83, -0.56) 0.026
≥65 years		84	0 (0.0)	36	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
Age at randomization	NE								
<75 years		330	3 (0.9)	168	8 (4.8)	81.91 (31.66, 95.21)	0.18 (0.05, 0.70) 0.013	0.19 (0.05, 0.71) 0.013	-3.85 (-7.23, -0.47) 0.025
≥75 years		16	0 (0.0)	5	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
Residence in long-term care facility	NE								
No		346	3 (0.9)	173	8 (4.6)	82.71 (34.26, 95.45)	0.18 (0.05, 0.68) 0.012	0.19 (0.05, 0.69) 0.012	-3.78 (-7.06, -0.50) 0.024

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increased risk of exposure to infection with SARS-CoV-2	NE								
Yes		99	0 (0.0)	52	2 (3.8)	78.90 (-171.29, NE)	0.11 (0.00, 2.26) 0.150	0.11 (0.01, 2.27) 0.154	-3.79 (-8.98, 1.41) 0.153
No		247	3 (1.2)	121	6 (5.0)	77.94 (10.73, 94.55)	0.23 (0.06, 0.93) 0.039	0.24 (0.06, 0.93) 0.039	-3.83 (-7.94, 0.29) 0.068
Sex	0.652								
Male		216	2 (0.9)	105	4 (3.8)	77.19 (-24.95, 95.83)	0.24 (0.04, 1.33) 0.101	0.25 (0.05, 1.32) 0.102	-2.85 (-6.70, 1.01) 0.148
Female		130	1 (0.8)	68	4 (5.9)	87.16 (-23.03, 98.66)	0.13 (0.02, 1.18) 0.070	0.14 (0.02, 1.15) 0.067	-5.08 (-10.90, 0.74) 0.087
Region	NE								
North America		185	0 (0.0)	106	2 (1.9)	76.84 (-198.15, NE)	0.19 (0.02, 1.84) 0.151	0.19 (0.02, 1.83) 0.152	-1.88 (-4.47, 0.70) 0.154
United Kingdom		80	2 (2.5)	30	3 (10.0)	80.00 (-31.77, 96.96)	0.23 (0.04, 1.45) 0.119	0.25 (0.04, 1.46) 0.123	-7.45 (-18.72, 3.82) 0.195
European Union		81	1 (1.2)	37	3 (8.1)	85.51 (-42.20, 98.52)	0.14 (0.01, 1.42) 0.097	0.15 (0.02, 1.41) 0.098	-6.87 (-15.98, 2.25) 0.140

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Country	NE								
United States		185	0 (0.0)	106	2 (1.9)	NE (NE, NE)	0.19 (0.02, 1.84) 0.151	0.19 (0.02, 1.83) 0.152	-1.88 (-4.47, 0.70) 0.154
United Kingdom		80	2 (2.5)	30	3 (10.0)	80.00 (-31.77, 96.96)	0.23 (0.04, 1.45) 0.119	0.25 (0.04, 1.46) 0.123	-7.45 (-18.72, 3.82) 0.195
Belgium		25	0 (0.0)	16	3 (18.8)	NE (NE, NE)	0.14 (0.01, 1.38) 0.091	0.17 (0.02, 1.43) 0.103	-18.87 (-38.03, 0.30) 0.054
France		38	1 (2.6)	16	0 (0.0)	NE (NE, NE)	1.27 (0.05, 33.97) 0.888	1.25 (0.06, 28.15) 0.888	2.50 (-2.48, 7.48) 0.325
Spain		18	0 (0.0)	5	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
Race	NE								
Black or African American		50	0 (0.0)	28	1 (3.6)	45.88 (-2010.73, NE)	0.19 (0.01, 4.97) 0.317	0.21 (0.01, 4.70) 0.322	-3.48 (-10.28, 3.31) 0.315
White		264	3 (1.1)	126	6 (4.8)	77.63 (10.04, 94.44)	0.23 (0.06, 0.95) 0.043	0.24 (0.06, 0.96) 0.044	-3.57 (-7.48, 0.35) 0.074
Other		28	0 (0.0)	15	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Ethnicity	NE								
Hispanic or Latino		40	0 (0.0)	12	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
Not Hispanic or Latino		275	3 (1.1)	144	8 (5.6)	82.41 (32.77, 95.40)	0.18 (0.05, 0.70) 0.013	0.19 (0.05, 0.72) 0.014	-4.51 (-8.46, -0.57) 0.025
Other		31	0 (0.0)	17	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
COVID-19 co-morbidities at baseline	NE								
None		101	0 (0.0)	46	3 (6.5)	88.73 (-4.96, NE)	0.06 (0.00, 1.20) 0.066	0.07 (0.00, 1.25) 0.070	-6.52 (-13.65, 0.62) 0.073
At least one		245	3 (1.2)	127	5 (3.9)	71.36 (-20.25, 93.18)	0.30 (0.07, 1.28) 0.104	0.31 (0.08, 1.27) 0.104	-2.72 (-6.37, 0.93) 0.144
SARS-CoV-2 RT-PCR status at baseline	NE								
Negative/Missing		346	3 (0.9)	173	8 (4.6)	82.71 (34.26, 95.45)	0.18 (0.05, 0.68) 0.012	0.19 (0.05, 0.69) 0.012	-3.78 (-7.06, -0.50) 0.024

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
High risk for severe COVID-19 at baseline	NE								
Yes		303	3 (1.0)	154	7 (4.5)	80.03 (21.91, 94.89)	0.21 (0.05, 0.81) 0.024	0.22 (0.06, 0.82) 0.025	-3.58 (-7.05, -0.10) 0.044
No		43	0 (0.0)	19	1 (5.3)	55.71 (-1627.29, NE)	0.14 (0.01, 3.76) 0.244	0.16 (0.01, 3.64) 0.248	-5.22 (-15.23, 4.79) 0.306
Obesity (≥ 30 kg/m^2)	0.547								
Yes		119	1 (0.8)	55	4 (7.3)	89.50 (1.33, 98.88)	0.11 (0.01, 1.00) 0.050	0.11 (0.01, 1.03) 0.054	-6.42 (-13.48, 0.64) 0.075
No		225	2 (0.9)	117	4 (3.4)	75.93 (-30.32, 95.55)	0.24 (0.04, 1.37) 0.109	0.25 (0.05, 1.37) 0.110	-2.57 (-6.08, 0.94) 0.151
Obesity (≥ 40 kg/m^2)	NE								
Yes		17	0 (0.0)	13	1 (7.7)	31.12 (-2586.47, NE)	0.18 (0.01, 5.28) 0.317	0.22 (0.01, 4.60) 0.330	-8.42 (-23.49, 6.66) 0.274
No		327	3 (0.9)	159	7 (4.4)	81.09 (25.79, 95.18)	0.20 (0.05, 0.77) 0.020	0.21 (0.05, 0.78) 0.020	-3.52 (-6.87, -0.16) 0.040

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chronic kidney disease	NE								
Yes		38	0 (0.0)	21	1 (4.8)	28.20 (-2700.11, NE)	0.24 (0.01, 6.21) 0.387	0.25 (0.01, 5.83) 0.391	-4.37 (-13.21, 4.47) 0.332
No		308	3 (1.0)	152	7 (4.6)	80.19 (22.84, 94.91)	0.20 (0.05, 0.80) 0.023	0.21 (0.06, 0.81) 0.024	-3.61 (-7.11, -0.11) 0.043
Diabetes	NE								
Yes		40	0 (0.0)	25	1 (4.0)	30.69 (-2603.26, NE)	0.22 (0.01, 5.81) 0.368	0.24 (0.01, 5.55) 0.372	-3.85 (-11.41, 3.72) 0.319
No		306	3 (1.0)	148	7 (4.7)	80.64 (24.55, 95.03)	0.20 (0.05, 0.78) 0.021	0.21 (0.05, 0.79) 0.022	-3.74 (-7.33, -0.15) 0.041
Immunosuppressive disease	NE								
Yes		16	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
No		330	3 (0.9)	164	8 (4.9)	82.83 (34.67, 95.49)	0.18 (0.05, 0.67) 0.011	0.18 (0.05, 0.68) 0.012	-4.00 (-7.45, -0.54) 0.024

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Immunosuppressive treatment	0.711								
Yes		103	1 (1.0)	60	4 (6.7)	86.77 (-29.16, 98.64)	0.14 (0.02, 1.27) 0.081	0.15 (0.02, 1.28) 0.082	-5.70 (-12.33, 0.92) 0.092
No		243	2 (0.8)	113	4 (3.5)	78.28 (-17.56, 95.99)	0.22 (0.04, 1.23) 0.085	0.23 (0.04, 1.23) 0.086	-2.74 (-6.33, 0.85) 0.134
CV disease	NE								
Yes		32	0 (0.0)	22	1 (4.5)	42.02 (-2161.15, NE)	0.21 (0.01, 5.86) 0.355	0.24 (0.01, 5.21) 0.365	-4.51 (-13.19, 4.16) 0.308
No		314	3 (1.0)	151	7 (4.6)	80.73 (24.99, 95.05)	0.20 (0.05, 0.78) 0.020	0.21 (0.05, 0.78) 0.020	-3.69 (-7.21, -0.16) 0.040
COPD	NE								
Yes		23	0 (0.0)	11	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
No		323	3 (0.9)	162	8 (4.9)	82.70 (34.19, 95.45)	0.18 (0.05, 0.68) 0.012	0.19 (0.05, 0.69) 0.012	-4.03 (-7.53, -0.53) 0.024
Chronic liver disease	0.397								
Yes		44	1 (2.3)	26	1 (3.8)	47.89 (-799.43, 96.98)	0.60 (0.04, 9.11) 0.710	0.60 (0.04, 8.74) 0.706	-1.60 (-10.45, 7.26) 0.724
No		302	2 (0.7)	147	7 (4.8)	87.22 (37.13, 97.40)	0.13 (0.03, 0.64) 0.012	0.14 (0.03, 0.65) 0.012	-4.14 (-7.72, -0.56) 0.023

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Hypertension	0.790								
Yes		153	1 (0.7)	75	2 (2.7)	77.32 (-144.44, 97.90)	0.24 (0.02, 2.71) 0.248	0.25 (0.02, 2.65) 0.247	-2.01 (-5.87, 1.85) 0.307
No		193	2 (1.0)	98	6 (6.1)	84.26 (19.22, 96.93)	0.16 (0.03, 0.82) 0.027	0.17 (0.04, 0.82) 0.027	-5.11 (-10.09, -0.12) 0.045
Asthma	0.559								
Yes		55	1 (1.8)	21	1 (4.8)	63.56 (-481.30, 97.72)	0.35 (0.02, 6.17) 0.477	0.38 (0.03, 5.53) 0.475	-2.99 (-12.69, 6.71) 0.545
No		291	2 (0.7)	152	7 (4.6)	86.10 (31.97, 97.16)	0.14 (0.03, 0.70) 0.016	0.15 (0.03, 0.71) 0.016	-3.93 (-7.40, -0.46) 0.026
Cancer	0.795								
Yes		60	1 (1.7)	30	2 (6.7)	77.60 (-145.39, 97.96)	0.25 (0.02, 2.91) 0.268	0.27 (0.03, 2.66) 0.261	-4.85 (-14.31, 4.62) 0.316
No		286	2 (0.7)	143	6 (4.2)	84.54 (21.33, 96.96)	0.16 (0.03, 0.80) 0.026	0.17 (0.03, 0.80) 0.026	-3.52 (-6.96, -0.08) 0.045

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.1.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Smoking	NE								
Yes		63	1 (1.6)	31	0 (0.0)	41.18 (NE, 98.49)	1.81 (0.07, 46.09) 0.718	1.79 (0.08, 42.39) 0.719	1.83 (-1.58, 5.23) 0.293
No		283	2 (0.7)	142	8 (5.6)	89.02 (46.82, 97.73)	0.12 (0.03, 0.56) 0.007	0.12 (0.03, 0.56) 0.007	-5.02 (-8.96, -1.07) 0.013
Sickle cell disease	NE								
No		346	3 (0.9)	173	8 (4.6)	82.71 (34.26, 95.45)	0.18 (0.05, 0.68) 0.012	0.19 (0.05, 0.69) 0.012	-3.78 (-7.06, -0.50) 0.024
COVID-19 vaccination at any time during the study	NE								
Yes		242	3 (1.2)	127	7 (5.5)	79.54 (19.87, 94.78)	0.21 (0.05, 0.82) 0.025	0.22 (0.06, 0.83) 0.025	-4.36 (-8.58, -0.14) 0.043
No		104	0 (0.0)	46	1 (2.2)	55.66 (-1629.14, NE)	0.16 (0.01, 4.11) 0.270	0.17 (0.01, 4.04) 0.273	-2.10 (-6.26, 2.05) 0.321
Increased risk for inadequate response to active immunization	NE								
Yes		344	3 (0.9)	172	8 (4.7)	82.72 (34.32, 95.46)	0.18 (0.05, 0.68) 0.012	0.19 (0.05, 0.69) 0.012	-3.80 (-7.10, -0.50) 0.024

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.
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Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
The First case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring post dose of IMP and prior to Day 366									
Age at randomization	0.863								
<60 years		199	12 (6.0)	97	10 (10.3)	48.60 (-18.56, 77.72)	0.56 (0.23, 1.34) 0.193	0.58 (0.26, 1.31) 0.191	-4.28 (-11.18, 2.62) 0.224
≥60 years		147	10 (6.8)	76	9 (11.8)	42.81 (-37.90, 76.28)	0.54 (0.21, 1.40) 0.207	0.57 (0.24, 1.35) 0.205	-5.04 (-13.37, 3.29) 0.236
Age at randomization	0.283								
<65 years		262	15 (5.7)	137	16 (11.7)	55.41 (10.39, 77.81)	0.46 (0.22, 0.96) 0.039	0.49 (0.25, 0.96) 0.038	-5.95 (-12.02, 0.12) 0.055
≥65 years		84	7 (8.3)	36	3 (8.3)	-0.75 (-275.29, 72.95)	1.00 (0.24, 4.11) 1.000	1.00 (0.27, 3.65) 1.000	0.00 (-10.79, 10.79) 1.000
Age at randomization	0.910								
<75 years		330	20 (6.1)	168	18 (10.7)	47.49 (1.51, 72.00)	0.54 (0.28, 1.05) 0.068	0.57 (0.31, 1.04) 0.067	-4.65 (-9.99, 0.69) 0.088
≥75 years		16	2 (12.5)	5	1 (20.0)	39.57 (-536.69, 94.27)	0.57 (0.04, 8.05) 0.678	0.63 (0.07, 5.53) 0.673	-7.50 (-46.12, 31.12) 0.704
Residence in long-term care facility	NE								

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a] P-value [b]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
No		346	22 (6.4)	173	19 (11.0)	45.98 (0.83, 70.57) 0.070	0.55 (0.29, 1.05) 0.070	0.58 (0.32, 1.04) 0.069	-4.61 (-9.93, 0.71) 0.090

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increased risk of exposure to infection with SARS-CoV-2	0.874								
Yes		99	5 (5.1)	52	4 (7.7)	43.02 (-106.99, 84.31)	0.62 (0.16, 2.43) 0.489	0.64 (0.18, 2.29) 0.489	-2.81 (-11.22, 5.60) 0.513
No		247	17 (6.9)	121	15 (12.4)	48.30 (-2.99, 74.05)	0.52 (0.25, 1.08) 0.080	0.55 (0.29, 1.07) 0.079	-5.55 (-12.22, 1.12) 0.103
Sex	0.809								
Male		216	9 (4.2)	105	8 (7.6)	50.10 (-29.06, 80.71)	0.53 (0.20, 1.42) 0.206	0.55 (0.22, 1.38) 0.204	-3.43 (-9.16, 2.31) 0.241
Female		130	13 (10.0)	68	11 (16.2)	40.14 (-32.25, 72.91)	0.59 (0.25, 1.39) 0.225	0.63 (0.30, 1.32) 0.221	-6.01 (-16.20, 4.18) 0.248
Region	0.768								
North America		185	8 (4.3)	106	10 (9.4)	54.07 (-14.13, 81.52)	0.44 (0.17, 1.17) 0.099	0.47 (0.20, 1.14) 0.097	-4.93 (-11.15, 1.29) 0.120
United Kingdom		80	7 (8.8)	30	5 (16.7)	59.35 (-32.16, 87.50)	0.48 (0.14, 1.66) 0.245	0.53 (0.18, 1.53) 0.239	-7.83 (-22.43, 6.78) 0.294
European Union		81	7 (8.6)	37	4 (10.8)	24.96 (-158.39, 78.21)	0.78 (0.21, 2.88) 0.710	0.80 (0.25, 2.55) 0.709	-2.13 (-13.79, 9.52) 0.720

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Country	NE								
United States		185	8 (4.3)	106	10 (9.4)	54.07 (-14.13, 81.52)	0.44 (0.17, 1.17) 0.099	0.47 (0.20, 1.14) 0.097	-4.93 (-11.15, 1.29) 0.120
United Kingdom		80	7 (8.8)	30	5 (16.7)	59.35 (-32.16, 87.50)	0.48 (0.14, 1.66) 0.245	0.53 (0.18, 1.53) 0.239	-7.83 (-22.43, 6.78) 0.294
Belgium		25	2 (8.0)	16	4 (25.0)	74.27 (-43.67, 95.39)	0.26 (0.04, 1.62) 0.150	0.32 (0.07, 1.53) 0.153	-17.21 (-41.15, 6.74) 0.159
France		38	5 (13.2)	16	0 (0.0)	NE (NE, NE)	5.65 (0.28, 113.33) 0.258	4.58 (0.28, 75.33) 0.286	12.51 (1.93, 23.09) 0.020
Spain		18	0 (0.0)	5	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
Race	NE								
Black or African American		50	0 (0.0)	28	3 (10.7)	86.30 (-27.62, NE)	0.13 (0.01, 1.24) 0.077	0.15 (0.02, 1.28) 0.083	-10.61 (-22.02, 0.81) 0.069
White		264	21 (8.0)	126	15 (11.9)	38.15 (-18.85, 67.81)	0.64 (0.32, 1.28) 0.207	0.67 (0.36, 1.25) 0.205	-3.98 (-10.51, 2.55) 0.232
Other		28	1 (3.6)	15	0 (0.0)	64.47 (NE, 99.09)	1.05 (0.04, 28.57) 0.979	1.04 (0.05, 23.11) 0.979	2.76 (-3.89, 9.41) 0.416

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Ethnicity	NE								
Hispanic or Latino		40	1 (2.5)	12	1 (8.3)	76.07 (-131.10, 97.52)	0.17 (0.01, 4.68) 0.297	0.17 (0.00, 6.54) 0.344	-6.66 (-22.72, 9.40) 0.417
Not Hispanic or Latino		275	20 (7.3)	144	18 (12.5)	46.57 (-0.47, 71.59)	0.55 (0.28, 1.08) 0.082	0.58 (0.32, 1.07) 0.081	-5.19 (-11.40, 1.02) 0.101
Other		31	1 (3.2)	17	0 (0.0)	40.91 (NE, 98.48)	1.76 (0.06, 48.19) 0.738	1.69 (0.08, 37.26) 0.740	3.17 (-3.00, 9.34) 0.314
COVID-19 co-morbidities at baseline	0.658								
None		101	5 (5.0)	46	5 (10.9)	57.39 (-45.52, 87.53)	0.43 (0.12, 1.56) 0.197	0.45 (0.14, 1.49) 0.194	-5.93 (-15.87, 4.01) 0.242
At least one		245	17 (6.9)	127	14 (11.0)	41.83 (-16.65, 70.99)	0.60 (0.29, 1.26) 0.180	0.63 (0.32, 1.24) 0.178	-4.09 (-10.40, 2.22) 0.204
SARS-CoV-2 RT-PCR status at baseline	NE								
Negative/Missing		346	22 (6.4)	173	19 (11.0)	45.98 (0.83, 70.57)	0.55 (0.29, 1.05) 0.070	0.58 (0.32, 1.04) 0.069	-4.61 (-9.93, 0.71) 0.090

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
High risk for severe COVID-19 at baseline	0.436								
Yes		303	19 (6.3)	154	18 (11.7)	50.18 (5.68, 73.69)	0.51 (0.26, 1.00) 0.049	0.54 (0.29, 0.99) 0.048	-5.40 (-11.17, 0.36) 0.066
No		43	3 (7.0)	19	1 (5.3)	-25.58 (-1066.72, 86.48)	1.35 (0.13, 13.84) 0.803	1.32 (0.14, 12.26) 0.804	1.69 (-10.91, 14.30) 0.792
Obesity (≥ 30 kg/m^2)	0.199								
Yes		119	7 (5.9)	55	9 (16.4)	67.67 (12.81, 88.01)	0.32 (0.11, 0.91) 0.033	0.36 (0.14, 0.92) 0.033	-10.49 (-21.19, 0.20) 0.054
No		225	15 (6.7)	117	10 (8.5)	26.12 (-62.23, 66.35)	0.77 (0.33, 1.77) 0.533	0.78 (0.36, 1.70) 0.533	-1.86 (-7.88, 4.17) 0.546
Obesity (≥ 40 kg/m^2)	0.854								
Yes		17	2 (11.8)	13	3 (23.1)	51.90 (-161.70, 91.16)	0.45 (0.06, 3.21) 0.423	0.51 (0.10, 2.68) 0.428	-11.20 (-38.80, 16.40) 0.426
No		327	20 (6.1)	159	16 (10.1)	43.25 (-8.90, 70.43)	0.58 (0.29, 1.16) 0.124	0.61 (0.32, 1.14) 0.123	-3.93 (-9.27, 1.42) 0.150

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.
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Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chronic kidney disease	0.354								
Yes		38	3 (7.9)	21	5 (23.8)	70.42 (-12.90, 92.25)	0.26 (0.05, 1.30) 0.100	0.31 (0.07, 1.33) 0.115	-16.12 (-36.31, 4.07) 0.118
No		308	19 (6.2)	152	14 (9.2)	37.55 (-24.06, 68.57)	0.65 (0.32, 1.33) 0.236	0.67 (0.34, 1.30) 0.235	-3.05 (-8.37, 2.28) 0.262
Diabetes	0.442								
Yes		40	2 (5.0)	25	4 (16.0)	70.48 (-54.77, 94.37)	0.30 (0.05, 1.84) 0.193	0.35 (0.07, 1.73) 0.199	-9.97 (-25.61, 5.66) 0.211
No		306	20 (6.5)	148	15 (10.1)	40.41 (-15.85, 69.35)	0.62 (0.31, 1.25) 0.181	0.65 (0.34, 1.22) 0.180	-3.60 (-9.19, 2.00) 0.208
Immunosuppressive disease	NE								
Yes		16	0 (0.0)	9	1 (11.1)	49.86 (-1855.34, NE)	0.18 (0.01, 5.28) 0.317	0.22 (0.01, 4.60) 0.330	-10.71 (-30.98, 9.55) 0.300
No		330	22 (6.7)	164	18 (11.0)	43.03 (-5.52, 69.24)	0.58 (0.30, 1.12) 0.104	0.61 (0.34, 1.10) 0.102	-4.28 (-9.77, 1.20) 0.126

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Immunosuppressive treatment	0.860								
Yes		103	10 (9.7)	60	9 (15.0)	40.45 (-44.14, 75.40)	0.61 (0.23, 1.60) 0.316	0.65 (0.28, 1.51) 0.314	-5.26 (-15.94, 5.42) 0.334
No		243	12 (4.9)	113	10 (8.8)	47.45 (-21.04, 77.18)	0.53 (0.22, 1.28) 0.159	0.56 (0.25, 1.25) 0.157	-3.91 (-9.82, 1.99) 0.194
CV disease	NE								
Yes		32	0 (0.0)	22	4 (18.2)	88.18 (5.18, NE)	0.12 (0.01, 1.16) 0.067	0.15 (0.02, 1.24) 0.079	-18.20 (-34.32, -2.07) 0.027
No		314	22 (7.0)	151	15 (9.9)	34.03 (-26.56, 65.61)	0.68 (0.34, 1.36) 0.278	0.71 (0.38, 1.32) 0.276	-2.92 (-8.47, 2.62) 0.302
COPD	0.490								
Yes		23	2 (8.7)	11	3 (27.3)	69.92 (-70.49, 94.69)	0.28 (0.04, 1.84) 0.185	0.32 (0.06, 1.71) 0.183	-18.64 (-48.12, 10.85) 0.215
No		323	20 (6.2)	162	16 (9.9)	41.89 (-12.00, 69.85)	0.60 (0.30, 1.20) 0.149	0.63 (0.33, 1.18) 0.147	-3.68 (-8.98, 1.62) 0.173

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chronic liver disease	0.335								
Yes		44	3 (6.8)	26	1 (3.8)	-55.51 (-1422.15, 84.11)	1.79 (0.19, 16.45) 0.608	1.79 (0.20, 16.16) 0.605	3.12 (-7.84, 14.07) 0.577
No		302	19 (6.3)	147	18 (12.2)	51.37 (7.86, 74.34)	0.48 (0.25, 0.95) 0.036	0.52 (0.28, 0.95) 0.035	-5.91 (-11.88, 0.06) 0.052
Hypertension	0.427								
Yes		153	9 (5.9)	75	10 (13.3)	58.58 (-0.29, 82.89)	0.41 (0.16, 1.05) 0.062	0.44 (0.19, 1.04) 0.061	-7.45 (-16.00, 1.10) 0.088
No		193	13 (6.7)	98	9 (9.2)	31.88 (-59.51, 70.91)	0.72 (0.30, 1.74) 0.464	0.74 (0.33, 1.66) 0.463	-2.41 (-9.14, 4.31) 0.482
Asthma	0.841								
Yes		55	5 (9.1)	21	3 (14.3)	38.87 (-151.34, 85.13)	0.61 (0.13, 2.78) 0.519	0.64 (0.17, 2.45) 0.514	-5.16 (-22.03, 11.71) 0.549
No		291	17 (5.8)	152	16 (10.5)	48.41 (-1.34, 73.74)	0.53 (0.26, 1.08) 0.079	0.56 (0.29, 1.07) 0.078	-4.67 (-10.25, 0.90) 0.100

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Cancer	0.491								
Yes		60	4 (6.7)	30	5 (16.7)	64.89 (-29.42, 90.48)	0.36 (0.09, 1.48) 0.157	0.41 (0.12, 1.41) 0.157	-9.70 (-24.31, 4.91) 0.193
No		286	18 (6.3)	143	14 (9.8)	38.79 (-21.80, 69.24)	0.62 (0.30, 1.30) 0.205	0.65 (0.33, 1.27) 0.204	-3.43 (-9.05, 2.19) 0.231
Smoking	NE								
Yes		63	4 (6.3)	31	0 (0.0)	-207.95 (NE, 61.54)	5.82 (0.30, 112.48) 0.243	5.36 (0.30, 95.90) 0.254	7.31 (0.71, 13.90) 0.030
No		283	18 (6.4)	142	19 (13.4)	56.26 (16.45, 77.10)	0.44 (0.23, 0.88) 0.019	0.48 (0.26, 0.88) 0.018	-6.97 (-13.27, -0.67) 0.030
Sickle cell disease	NE								
No		346	22 (6.4)	173	19 (11.0)	45.98 (0.83, 70.57)	0.55 (0.29, 1.05) 0.070	0.58 (0.32, 1.04) 0.069	-4.61 (-9.93, 0.71) 0.090
COVID-19 vaccination at any time during the study	0.364								
Yes		242	20 (8.3)	127	16 (12.6)	38.04 (-18.65, 67.64)	0.63 (0.31, 1.26) 0.188	0.66 (0.35, 1.22) 0.186	-4.32 (-11.06, 2.42) 0.209
No		104	2 (1.9)	46	3 (6.5)	74.54 (-50.47, 95.69)	0.27 (0.04, 1.72) 0.166	0.29 (0.05, 1.69) 0.167	-4.67 (-12.29, 2.94) 0.229

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.
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Table 2.3.1
Efficacy for Incidence of the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Primary Analysis
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

		AZD7442 (N=346)		Placebo (N=173)					
Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increased risk for inadequate response to active immunization	NE								
Yes		344	22 (6.4)	172	19 (11.0)	46.01 (0.88, 70.59)	0.55 (0.29, 1.05) 0.070	0.58 (0.32, 1.04) 0.068	-4.64 (-9.99, 0.71) 0.089

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Body Aches	Age at randomization	0.152								
	<60 years		13	2 (15.4)	11	4 (36.4)	56.00 (-219.41, 93.94)	0.32 (0.05, 2.22) 0.248	0.42 (0.09, 1.89) 0.260	-20.98 (-55.52, 13.56) 0.234
	≥60 years		11	3 (27.3)	6	3 (50.0)	93.48 (64.11, 98.81)	0.38 (0.05, 3.00) 0.355	0.55 (0.16, 1.91) 0.343	-22.73 (-70.62, 25.16) 0.352
	Age at randomization	NE								
	<65 years		16	2 (12.5)	15	7 (46.7)	83.39 (-4.07, 97.35)	0.16 (0.03, 0.98) 0.048	0.27 (0.07, 1.09) 0.066	-34.17 (-64.17, -4.17) 0.026
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	4 (18.2)	16	7 (43.8)	67.38 (-53.35, 93.06)	0.29 (0.07, 1.24) 0.094	0.42 (0.15, 1.18) 0.100	-25.57 (-54.73, 3.60) 0.086
	Residence in long-term care facility	NE								
	No		24	5 (20.8)	17	7 (41.2)	85.41 (16.12, 97.46)	0.34 (0.08, 1.42) 0.139	0.48 (0.18, 1.27) 0.140	-21.67 (-49.85, 6.51) 0.132

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	5 (26.3)	14	5 (35.7)	82.77 (-21.09, 97.55)	0.61 (0.13, 2.80) 0.522	0.72 (0.26, 1.96) 0.518	-10.22 (-41.57, 21.13) 0.523

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Body Aches	Sex	0.794								
	Male		9	1 (11.1)	7	3 (42.9)	79.67 (-153.29, 98.37)	0.17 (0.01, 2.20) 0.173	0.25 (0.03, 2.08) 0.200	-31.91 (-74.11, 10.28) 0.138
	Female		15	4 (26.7)	10	4 (40.0)	85.86 (-73.48, 98.85)	0.45 (0.07, 2.74) 0.388	0.60 (0.19, 1.90) 0.383	-16.67 (-54.04, 20.71) 0.382
	Region	NE								
	North America		7	3 (42.9)	8	3 (37.5)	77.94 (-98.73, 97.55)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	96.85 (27.90, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	2 (22.2)	3	1 (33.3)	56.16 (-726.41, 97.67)	0.67 (0.04, 11.94) 0.783	0.75 (0.10, 5.54) 0.778	-8.33 (-69.54, 52.87) 0.790
	Country	NE								
	United States		7	3 (42.9)	8	3 (37.5)	77.94 (-98.73, 97.55)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	5 (20.8)	13	5 (38.5)	80.78 (-27.01, 97.09)	0.40 (0.09, 1.82) 0.238	0.53 (0.18, 1.51) 0.233	-18.27 (-49.21, 12.67) 0.247

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Body Aches	Ethnicity	NE								
	Not Hispanic or Latino		23	5 (21.7)	16	7 (43.8)	85.35 (16.23, 97.44)	0.34 (0.08, 1.40) 0.135	0.48 (0.19, 1.26) 0.136	-22.77 (-52.03, 6.48) 0.127
	COVID-19 co-morbidities at baseline	0.775								
	None		6	1 (16.7)	6	1 (16.7)	84.27 (-55.08, 98.40)	0.75 (0.03, 18.41) 0.860	0.75 (0.02, 24.53) 0.872	-3.85 (-45.95, 38.26) 0.858
	At least one		18	4 (22.2)	11	6 (54.5)	83.82 (-27.88, 97.95)	0.24 (0.05, 1.21) 0.083	0.41 (0.15, 1.12) 0.082	-32.49 (-67.63, 2.64) 0.070
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	5 (20.8)	17	7 (41.2)	85.41 (16.12, 97.46)	0.34 (0.08, 1.42) 0.139	0.48 (0.18, 1.27) 0.140	-21.67 (-49.85, 6.51) 0.132
	High risk for severe COVID-19 at baseline	0.770								
	Yes		22	4 (18.2)	16	6 (37.5)	85.86 (-18.93, 98.32)	0.35 (0.08, 1.58) 0.173	0.47 (0.16, 1.39) 0.173	-20.12 (-48.74, 8.49) 0.168
	Obesity (≥ 30 kg/m^2)	0.722								
	Yes		8	2 (25.0)	8	5 (62.5)	93.97 (50.46, 99.27)	0.15 (0.01, 1.65) 0.120	0.22 (0.04, 1.18) 0.077	-58.33 (-86.23, -30.44) <.001

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	3 (18.8)	9	2 (22.2)	66.78 (-317.61, 97.36)	0.83 (0.11, 6.33) 0.855	0.86 (0.17, 4.32) 0.855	-3.07 (-36.50, 30.36) 0.857

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Body Aches	Obesity (≥ 40 kg/m^2)	0.364								
	No		22	4 (18.2)	14	5 (35.7)	80.96 (-79.49, 97.98)	0.39 (0.08, 1.84) 0.234	0.50 (0.16, 1.56) 0.232	-17.98 (-47.85, 11.90) 0.238
	Chronic kidney disease	NE								
	No		21	3 (14.3)	15	7 (46.7)	93.71 (60.45, 99.00)	0.16 (0.03, 0.86) 0.032	0.28 (0.08, 0.93) 0.038	-34.44 (-63.19, -5.70) 0.019
	Diabetes	0.403								
	No		22	4 (18.2)	16	6 (37.5)	82.85 (-38.34, 97.87)	0.36 (0.08, 1.60) 0.179	0.47 (0.16, 1.43) 0.183	-19.86 (-48.52, 8.81) 0.175
	Immunosuppressive disease	NE								
	No		24	5 (20.8)	16	7 (43.8)	85.45 (16.61, 97.46)	0.32 (0.08, 1.31) 0.113	0.46 (0.17, 1.21) 0.114	-23.85 (-52.82, 5.13) 0.107
	Immunosuppressive treatment	0.599								
	Yes		12	3 (25.0)	8	3 (37.5)	86.85 (-149.26, 99.31)	0.44 (0.05, 3.47) 0.433	0.60 (0.17, 2.07) 0.416	-16.03 (-55.72, 23.67) 0.429
	No		12	2 (16.7)	9	4 (44.4)	88.45 (10.60, 98.51)	0.26 (0.03, 1.90) 0.182	0.37 (0.08, 1.68) 0.200	-27.50 (-66.49, 11.50) 0.167

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Body Aches	CV disease	NE								
	No		24	5 (20.8)	13	4 (30.8)	69.36 (-179.59, 96.64)	0.52 (0.10, 2.59) 0.422	0.61 (0.18, 2.04) 0.422	-12.10 (-42.26, 18.07) 0.432
	COPD	0.045								
	No		22	3 (13.6)	14	5 (35.7)	87.41 (-27.18, 98.75)	0.24 (0.04, 1.41) 0.114	0.33 (0.08, 1.39) 0.131	-23.82 (-52.92, 5.29) 0.109
	Chronic liver disease	NE								
	No		21	5 (23.8)	17	7 (41.2)	84.20 (-1.53, 97.54)	0.41 (0.10, 1.71) 0.220	0.55 (0.21, 1.44) 0.221	-19.07 (-48.81, 10.66) 0.209
	Hypertension	0.260								
	Yes		10	3 (30.0)	7	2 (28.6)	47.16 (-1475.79, 98.23)	1.05 (0.12, 9.36) 0.962	1.04 (0.23, 4.66) 0.961	1.12 (-45.00, 47.25) 0.962
	No		14	2 (14.3)	10	5 (50.0)	93.81 (39.13, 99.37)	0.15 (0.02, 1.16) 0.070	0.29 (0.07, 1.17) 0.082	-35.45 (-70.85, -0.04) 0.050
	Asthma	0.704								
	No		19	3 (15.8)	14	4 (28.6)	88.22 (-24.26, 98.88)	0.42 (0.07, 2.43) 0.334	0.52 (0.14, 1.95) 0.335	-13.85 (-42.02, 14.32) 0.335

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Body Aches	Cancer	NE								
	Yes		6	1 (16.7)	4	0 (0.0)	66.67 (NE, 99.15)	1.80 (0.04, 79.42) 0.761	1.50 (0.10, 22.62) 0.770	11.11 (-16.05, 38.27) 0.423
	No		18	4 (22.2)	13	7 (53.8)	90.15 (39.28, 98.40)	0.24 (0.05, 1.15) 0.073	0.41 (0.15, 1.11) 0.079	-32.05 (-65.13, 1.04) 0.058
	Smoking	NE								
	No		20	5 (25.0)	17	7 (41.2)	82.73 (-28.71, 97.68)	0.44 (0.10, 1.85) 0.261	0.58 (0.22, 1.50) 0.260	-17.92 (-48.37, 12.54) 0.249
	Sickle cell disease	NE								
	No		24	5 (20.8)	17	7 (41.2)	85.41 (16.12, 97.46)	0.34 (0.08, 1.42) 0.139	0.48 (0.18, 1.27) 0.140	-21.67 (-49.85, 6.51) 0.132
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	5 (21.7)	14	7 (50.0)	88.05 (35.23, 97.79)	0.25 (0.06, 1.12) 0.069	0.42 (0.16, 1.07) 0.068	-29.42 (-60.04, 1.19) 0.060
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	5 (20.8)	17	7 (41.2)	85.41 (16.12, 97.46)	0.34 (0.08, 1.42) 0.139	0.48 (0.18, 1.27) 0.140	-21.67 (-49.85, 6.51) 0.132

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chills	Age at randomization	0.391								
	<60 years		13	1 (7.7)	11	4 (36.4)	82.14 (-105.81, 98.45)	0.15 (0.01, 1.58) 0.113	0.21 (0.03, 1.63) 0.135	-28.67 (-60.58, 3.23) 0.078
	≥60 years		11	3 (27.3)	6	3 (50.0)	94.87 (77.90, 98.81)	0.38 (0.05, 3.00) 0.355	0.55 (0.16, 1.91) 0.343	-22.73 (-70.62, 25.16) 0.352
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	7 (46.7)	92.88 (27.51, 99.30)	0.08 (0.01, 0.73) 0.026	0.13 (0.02, 0.96) 0.046	-40.42 (-68.31, -12.52) 0.005
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	3 (13.6)	16	7 (43.8)	80.79 (5.30, 96.10)	0.20 (0.04, 0.97) 0.046	0.31 (0.09, 1.02) 0.055	-30.11 (-58.34, -1.89) 0.036
	Residence in long-term care facility	NE								
	No		24	4 (16.7)	17	7 (41.2)	92.65 (66.33, 98.40)	0.24 (0.05, 1.11) 0.068	0.37 (0.12, 1.09) 0.072	-26.33 (-53.39, 0.74) 0.057

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	4 (21.1)	14	4 (28.6)	91.00 (46.36, 98.49)	0.58 (0.10, 3.23) 0.535	0.70 (0.23, 2.15) 0.532	-8.84 (-36.99, 19.31) 0.538

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chills	Sex	0.911								
	Male		9	1 (11.1)	7	4 (57.1)	91.18 (-31.66, 99.41)	0.08 (0.01, 1.22) 0.070	0.19 (0.03, 1.36) 0.098	-46.81 (-88.18, -5.44) 0.027
	Female		15	3 (20.0)	10	3 (30.0)	94.92 (76.52, 98.90)	0.32 (0.04, 2.96) 0.318	0.49 (0.12, 1.93) 0.308	-16.67 (-48.48, 15.15) 0.305
	Region	NE								
	North America		7	3 (42.9)	8	3 (37.5)	87.29 (33.60, 97.57)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	2 (33.3)	96.74 (3.94, NE)	0.14 (0.01, 2.08) 0.153	0.23 (0.03, 1.70) 0.149	-38.46 (-75.86, -1.06) 0.044
	European Union		9	1 (11.1)	3	2 (66.7)	98.54 (86.47, 99.84)	0.07 (0.00, 1.73) 0.105	0.19 (0.03, 1.39) 0.101	-54.17 (-100.00, 3.89) 0.041
	Country	NE								
	United States		7	3 (42.9)	8	3 (37.5)	87.29 (33.60, 97.57)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	2 (33.3)	NE (NE, NE)	0.14 (0.01, 2.08) 0.153	0.23 (0.03, 1.70) 0.149	-38.46 (-75.86, -1.06) 0.044

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	4 (16.7)	13	5 (38.5)	90.76 (50.14, 98.29)	0.29 (0.06, 1.45) 0.134	0.41 (0.13, 1.30) 0.131	-22.81 (-52.92, 7.30) 0.138

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chills	Ethnicity	NE								
	Not Hispanic or Latino		23	4 (17.4)	16	7 (43.8)	92.62 (66.25, 98.39)	0.24 (0.05, 1.12) 0.069	0.38 (0.13, 1.09) 0.072	-27.40 (-55.65, 0.85) 0.057
	COVID-19 co-morbidities at baseline	0.819								
	None		6	1 (16.7)	6	2 (33.3)	92.51 (31.37, 99.18)	0.38 (0.02, 6.26) 0.495	0.38 (0.02, 7.89) 0.528	-19.23 (-69.73, 31.27) 0.455
	At least one		18	3 (16.7)	11	5 (45.5)	92.77 (54.14, 98.86)	0.22 (0.04, 1.28) 0.091	0.36 (0.11, 1.18) 0.092	-29.56 (-62.92, 3.80) 0.082
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	4 (16.7)	17	7 (41.2)	92.65 (66.33, 98.40)	0.24 (0.05, 1.11) 0.068	0.37 (0.12, 1.09) 0.072	-26.33 (-53.39, 0.74) 0.057
	High risk for severe COVID-19 at baseline	0.446								
	Yes		22	3 (13.6)	16	6 (37.5)	93.80 (62.92, 98.96)	0.23 (0.04, 1.20) 0.081	0.34 (0.10, 1.17) 0.087	-25.06 (-52.26, 2.13) 0.071
	Obesity (≥ 30 kg/m^2)	0.821								
	Yes		8	2 (25.0)	8	4 (50.0)	96.56 (87.34, 99.06)	0.20 (0.02, 2.23) 0.190	0.25 (0.05, 1.18) 0.080	-50.00 (-78.29, -21.71) 0.001

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	2 (12.5)	9	3 (33.3)	91.64 (29.68, 99.01)	0.31 (0.04, 2.27) 0.247	0.39 (0.08, 1.83) 0.233	-20.74 (-56.53, 15.05) 0.256

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chills	Obesity (≥ 40 kg/m^2)	0.254								
	No		22	3 (13.6)	14	5 (35.7)	90.79 (33.37, 98.73)	0.26 (0.05, 1.40) 0.117	0.36 (0.10, 1.31) 0.122	-23.03 (-51.71, 5.64) 0.115
	Chronic kidney disease	NE								
	No		21	2 (9.5)	15	7 (46.7)	97.40 (88.72, 99.40)	0.07 (0.01, 0.63) 0.017	0.16 (0.03, 0.77) 0.022	-40.00 (-66.76, -13.24) 0.003
	Diabetes	0.423								
	No		22	3 (13.6)	16	6 (37.5)	91.33 (42.73, 98.69)	0.24 (0.05, 1.23) 0.087	0.34 (0.10, 1.21) 0.096	-24.85 (-52.34, 2.63) 0.076
	Immunosuppressive disease	NE								
	No		24	4 (16.7)	16	7 (43.8)	92.67 (66.46, 98.40)	0.23 (0.05, 1.04) 0.057	0.36 (0.12, 1.04) 0.060	-28.41 (-56.38, -0.44) 0.047
	Immunosuppressive treatment	0.455								
	Yes		12	2 (16.7)	8	4 (50.0)	96.69 (85.05, 99.27)	0.11 (0.01, 1.52) 0.100	0.28 (0.06, 1.23) 0.091	-37.18 (-74.31, -0.05) 0.050
	No		12	2 (16.7)	9	3 (33.3)	82.85 (-77.46, 98.34)	0.39 (0.05, 3.11) 0.376	0.49 (0.10, 2.41) 0.381	-16.95 (-54.30, 20.40) 0.374

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chills	CV disease	NE								
	No		24	4 (16.7)	13	5 (38.5)	89.59 (32.23, 98.40)	0.26 (0.05, 1.38) 0.113	0.35 (0.09, 1.34) 0.126	-24.58 (-55.00, 5.83) 0.113
	COPD	0.026								
	No		22	2 (9.1)	14	5 (35.7)	96.09 (80.09, 99.23)	0.11 (0.01, 1.02) 0.052	0.16 (0.02, 1.20) 0.075	-29.76 (-57.08, -2.43) 0.033
	Chronic liver disease	NE								
	No		21	4 (19.0)	17	7 (41.2)	92.35 (63.07, 98.41)	0.28 (0.06, 1.30) 0.104	0.41 (0.14, 1.23) 0.112	-24.82 (-53.07, 3.44) 0.085
	Hypertension	0.189								
	Yes		10	3 (30.0)	7	2 (28.6)	59.01 (-2549.76, 99.37)	1.05 (0.12, 9.36) 0.962	1.04 (0.23, 4.66) 0.961	1.12 (-45.00, 47.25) 0.962
	No		14	1 (7.1)	10	5 (50.0)	97.91 (79.99, 99.78)	0.05 (0.00, 0.97) 0.048	0.15 (0.02, 0.99) 0.049	-42.51 (-75.23, -9.78) 0.011
	Asthma	0.059								
	No		19	3 (15.8)	14	4 (28.6)	88.66 (-14.42, 98.88)	0.42 (0.07, 2.43) 0.334	0.52 (0.14, 1.95) 0.335	-13.85 (-42.02, 14.32) 0.335

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Chills	Cancer	NE								
	Yes		6	1 (16.7)	4	0 (0.0)	80.00 (NE, 99.49)	1.80 (0.04, 79.42) 0.761	1.50 (0.10, 22.62) 0.770	11.11 (-16.05, 38.27) 0.423
	No		18	3 (16.7)	13	7 (53.8)	95.36 (77.01, 99.06)	0.16 (0.03, 0.87) 0.034	0.30 (0.09, 0.95) 0.041	-37.95 (-69.58, -6.33) 0.019
	Smoking	NE								
	No		20	4 (20.0)	17	7 (41.2)	92.02 (59.11, 98.44)	0.29 (0.06, 1.39) 0.122	0.43 (0.14, 1.29) 0.131	-24.14 (-52.97, 4.69) 0.101
	Sickle cell disease	NE								
	No		24	4 (16.7)	17	7 (41.2)	92.65 (66.33, 98.40)	0.24 (0.05, 1.11) 0.068	0.37 (0.12, 1.09) 0.072	-26.33 (-53.39, 0.74) 0.057
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	4 (17.4)	14	7 (50.0)	93.95 (73.73, 98.61)	0.18 (0.03, 0.88) 0.034	0.32 (0.11, 0.92) 0.035	-34.15 (-63.67, -4.63) 0.023
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	4 (16.7)	17	7 (41.2)	92.65 (66.33, 98.40)	0.24 (0.05, 1.11) 0.068	0.37 (0.12, 1.09) 0.072	-26.33 (-53.39, 0.74) 0.057

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Congestion	Age at randomization	0.532								
	<60 years		13	1 (7.7)	11	4 (36.4)	83.00 (-102.45, 98.57)	0.15 (0.01, 1.58) 0.113	0.21 (0.03, 1.63) 0.135	-28.67 (-60.58, 3.23) 0.078
	≥60 years		11	3 (27.3)	6	3 (50.0)	93.48 (64.11, 98.81)	0.38 (0.05, 3.00) 0.355	0.55 (0.16, 1.91) 0.343	-22.73 (-70.62, 25.16) 0.352
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	7 (46.7)	93.22 (29.18, 99.35)	0.08 (0.01, 0.73) 0.026	0.13 (0.02, 0.96) 0.046	-40.42 (-68.31, -12.52) 0.005
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	3 (13.6)	16	7 (43.8)	79.95 (-10.47, 96.36)	0.20 (0.04, 0.97) 0.046	0.31 (0.09, 1.02) 0.055	-30.11 (-58.34, -1.89) 0.036
	Residence in long-term care facility	NE								
	No		24	4 (16.7)	17	7 (41.2)	91.28 (57.60, 98.21)	0.24 (0.05, 1.11) 0.068	0.37 (0.12, 1.09) 0.072	-26.33 (-53.39, 0.74) 0.057

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	0.367								
	No		19	3 (15.8)	14	5 (35.7)	94.18 (71.85, 98.79)	0.26 (0.04, 1.68) 0.157	0.41 (0.12, 1.38) 0.152	-21.27 (-49.32, 6.78) 0.137

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Congestion	Sex	NE								
	Male		9	0 (0.0)	7	2 (28.6)	68.47 (-312.31, NE)	0.20 (0.02, 2.52) 0.213	0.29 (0.04, 2.25) 0.238	-27.66 (-61.06, 5.75) 0.105
	Female		15	4 (26.7)	10	5 (50.0)	88.66 (11.54, 98.55)	0.33 (0.06, 1.89) 0.212	0.49 (0.16, 1.52) 0.219	-25.33 (-63.76, 13.10) 0.196
	Region	NE								
	North America		7	3 (42.9)	8	4 (50.0)	77.94 (-98.73, 97.55)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	96.89 (32.11, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	1 (11.1)	3	0 (0.0)	60.14 (NE, 98.98)	1.40 (0.04, 43.79) 0.848	1.33 (0.07, 26.15) 0.850	12.50 (-10.42, 35.42) 0.285
	Country	NE								
	United States		7	3 (42.9)	8	4 (50.0)	77.94 (-98.73, 97.55)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	4 (16.7)	13	4 (30.8)	87.16 (14.24, 98.08)	0.40 (0.07, 2.09) 0.275	0.50 (0.15, 1.69) 0.268	-15.43 (-43.94, 13.08) 0.289

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Congestion	Ethnicity	NE								
	Not Hispanic or Latino		23	4 (17.4)	16	7 (43.8)	91.23 (57.37, 98.20)	0.24 (0.05, 1.12) 0.069	0.38 (0.13, 1.09) 0.072	-27.40 (-55.65, 0.85) 0.057
	COVID-19 co-morbidities at baseline	NE								
	None		6	2 (33.3)	6	0 (0.0)	-55.02 (NE, 93.94)	3.87 (0.29, 51.95) 0.308	2.60 (0.36, 18.79) 0.345	30.77 (-7.55, 69.09) 0.116
	At least one		18	2 (11.1)	11	7 (63.6)	96.43 (79.98, 99.36)	0.07 (0.01, 0.54) 0.010	0.17 (0.04, 0.70) 0.014	-53.04 (-85.09, -20.99) 0.001
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	4 (16.7)	17	7 (41.2)	91.28 (57.60, 98.21)	0.24 (0.05, 1.11) 0.068	0.37 (0.12, 1.09) 0.072	-26.33 (-53.39, 0.74) 0.057
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	3 (13.6)	16	7 (43.8)	93.33 (62.19, 98.82)	0.19 (0.04, 0.93) 0.041	0.30 (0.09, 0.99) 0.049	-30.99 (-58.87, -3.10) 0.029
	Obesity (≥ 30 kg/m^2)	0.300								
	Yes		8	2 (25.0)	8	6 (75.0)	94.03 (51.66, 99.26)	0.11 (0.01, 1.24) 0.074	0.20 (0.03, 1.15) 0.072	-66.67 (-93.34, -39.99) <.001

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	2 (12.5)	9	1 (11.1)	70.43 (-1149.47, 99.30)	1.45 (0.09, 22.44) 0.789	1.36 (0.13, 14.09) 0.795	3.56 (-21.37, 28.49) 0.780

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Congestion	Obesity (≥ 40 kg/m^2)	0.155								
	No		22	3 (13.6)	14	5 (35.7)	90.70 (32.89, 98.71)	0.26 (0.05, 1.40) 0.117	0.36 (0.10, 1.31) 0.122	-23.03 (-51.71, 5.64) 0.115
	Chronic kidney disease	NE								
	No		21	3 (14.3)	15	7 (46.7)	93.83 (61.89, 99.00)	0.16 (0.03, 0.86) 0.032	0.28 (0.08, 0.93) 0.038	-34.44 (-63.19, -5.70) 0.019
	Diabetes	0.140								
	No		22	3 (13.6)	16	6 (37.5)	91.35 (43.50, 98.68)	0.24 (0.05, 1.23) 0.087	0.34 (0.10, 1.21) 0.096	-24.85 (-52.34, 2.63) 0.076
	Immunosuppressive disease	NE								
	No		24	4 (16.7)	16	7 (43.8)	91.30 (57.76, 98.21)	0.23 (0.05, 1.04) 0.057	0.36 (0.12, 1.04) 0.060	-28.41 (-56.38, -0.44) 0.047
	Immunosuppressive treatment	0.789								
	Yes		12	3 (25.0)	8	4 (50.0)	88.14 (-62.13, 99.13)	0.28 (0.04, 2.09) 0.212	0.46 (0.14, 1.52) 0.205	-27.56 (-68.64, 13.52) 0.188
	No		12	1 (8.3)	9	3 (33.3)	94.25 (37.34, 99.47)	0.16 (0.01, 2.23) 0.172	0.22 (0.02, 2.09) 0.188	-25.99 (-60.13, 8.15) 0.136

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Congestion	CV disease	NE								
	No		24	4 (16.7)	13	4 (30.8)	85.17 (-16.39, 98.11)	0.34 (0.06, 1.94) 0.227	0.43 (0.11, 1.71) 0.234	-17.53 (-46.47, 11.41) 0.235
	COPD	0.408								
	No		22	3 (13.6)	14	5 (35.7)	87.99 (-16.64, 98.76)	0.24 (0.04, 1.41) 0.114	0.33 (0.08, 1.39) 0.131	-23.82 (-52.92, 5.29) 0.109
	Chronic liver disease	NE								
	No		21	4 (19.0)	17	7 (41.2)	90.87 (53.37, 98.21)	0.28 (0.06, 1.30) 0.104	0.41 (0.14, 1.23) 0.112	-24.82 (-53.07, 3.44) 0.085
	Hypertension	0.902								
	Yes		10	2 (20.0)	7	3 (42.9)	89.01 (17.52, 98.54)	0.29 (0.03, 2.94) 0.298	0.39 (0.06, 2.69) 0.336	-25.09 (-70.57, 20.38) 0.279
	No		14	2 (14.3)	10	4 (40.0)	92.87 (10.03, 99.44)	0.23 (0.03, 1.78) 0.159	0.36 (0.09, 1.54) 0.168	-25.36 (-59.77, 9.05) 0.149
	Asthma	0.501								
	No		19	3 (15.8)	14	4 (28.6)	88.51 (-15.17, 98.85)	0.42 (0.07, 2.43) 0.334	0.52 (0.14, 1.95) 0.335	-13.85 (-42.02, 14.32) 0.335

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Congestion	Cancer	0.192								
	Yes		6	1 (16.7)	4	1 (25.0)	42.26 (-657.44, 95.60)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	3 (16.7)	13	6 (46.2)	93.76 (61.82, 98.98)	0.20 (0.04, 1.15) 0.071	0.35 (0.11, 1.12) 0.077	-30.57 (-61.83, 0.70) 0.055
	Smoking	NE								
	No		20	4 (20.0)	17	7 (41.2)	90.42 (48.12, 98.23)	0.29 (0.06, 1.39) 0.122	0.43 (0.14, 1.29) 0.131	-24.14 (-52.97, 4.69) 0.101
	Sickle cell disease	NE								
	No		24	4 (16.7)	17	7 (41.2)	91.28 (57.60, 98.21)	0.24 (0.05, 1.11) 0.068	0.37 (0.12, 1.09) 0.072	-26.33 (-53.39, 0.74) 0.057
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	4 (17.4)	14	7 (50.0)	92.86 (66.80, 98.47)	0.18 (0.03, 0.88) 0.034	0.32 (0.11, 0.92) 0.035	-34.15 (-63.67, -4.63) 0.023
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	4 (16.7)	17	7 (41.2)	91.28 (57.60, 98.21)	0.24 (0.05, 1.11) 0.068	0.37 (0.12, 1.09) 0.072	-26.33 (-53.39, 0.74) 0.057

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Cough	Age at randomization	0.773								
	<60 years		13	3 (23.1)	11	6 (54.5)	68.85 (-100.47, 95.16)	0.25 (0.04, 1.44) 0.121	0.42 (0.14, 1.31) 0.136	-31.47 (-68.76, 5.82) 0.098
	≥60 years		11	5 (45.5)	6	3 (50.0)	78.26 (-6.24, 95.55)	0.83 (0.11, 6.11) 0.858	0.91 (0.32, 2.54) 0.856	-4.55 (-54.21, 45.12) 0.858
	Age at randomization	NE								
	<65 years		16	5 (31.3)	15	9 (60.0)	72.22 (-32.66, 94.18)	0.30 (0.07, 1.33) 0.113	0.52 (0.23, 1.20) 0.126	-28.75 (-62.37, 4.87) 0.094
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	7 (31.8)	16	9 (56.3)	62.05 (-66.75, 91.36)	0.36 (0.10, 1.38) 0.137	0.57 (0.27, 1.20) 0.136	-24.43 (-55.57, 6.71) 0.124
	Residence in long-term care facility	NE								
	No		24	8 (33.3)	17	9 (52.9)	73.84 (6.86, 92.65)	0.42 (0.12, 1.54) 0.191	0.60 (0.28, 1.29) 0.193	-20.85 (-51.29, 9.60) 0.180

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	0.759								
	No		19	7 (36.8)	14	6 (42.9)	72.39 (-9.14, 93.02)	0.73 (0.17, 3.12) 0.670	0.83 (0.36, 1.92) 0.669	-7.18 (-40.14, 25.78) 0.669

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Cough	Sex	0.932								
	Male		9	2 (22.2)	7	4 (57.1)	75.87 (-117.40, 97.32)	0.19 (0.02, 1.86) 0.154	0.37 (0.09, 1.51) 0.166	-36.17 (-80.80, 8.46) 0.112
	Female		15	6 (40.0)	10	5 (50.0)	72.95 (-39.74, 94.76)	0.55 (0.10, 2.93) 0.480	0.71 (0.27, 1.88) 0.488	-14.67 (-54.52, 25.18) 0.471
	Region	NE								
	North America		7	4 (57.1)	8	4 (50.0)	23.08 (-203.67, 80.51)	2.00 (0.19, 20.61) 0.560	1.43 (0.41, 4.99) 0.576	17.14 (-39.32, 73.60) 0.552
	United Kingdom		8	0 (0.0)	6	3 (50.0)	96.87 (30.11, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	4 (44.4)	3	2 (66.7)	85.00 (9.99, 97.50)	0.30 (0.02, 4.91) 0.398	0.56 (0.17, 1.87) 0.347	-29.17 (-92.18, 33.85) 0.364
	Country	NE								
	United States		7	4 (57.1)	8	4 (50.0)	23.08 (-203.67, 80.51)	2.00 (0.19, 20.61) 0.560	1.43 (0.41, 4.99) 0.576	17.14 (-39.32, 73.60) 0.552
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	8 (33.3)	13	6 (46.2)	64.08 (-46.09, 91.17)	0.57 (0.14, 2.25) 0.421	0.70 (0.30, 1.64) 0.415	-13.66 (-47.01, 19.69) 0.422

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Cough	Ethnicity	NE								
	Not Hispanic or Latino		23	8 (34.8)	16	9 (56.3)	73.74 (6.19, 92.65)	0.41 (0.11, 1.51) 0.181	0.60 (0.29, 1.26) 0.179	-22.20 (-53.71, 9.31) 0.167
	COVID-19 co-morbidities at baseline	0.113								
	None		6	4 (66.7)	6	2 (33.3)	-43.88 (-1665.64, 88.28)	3.00 (0.34, 26.84) 0.326	2.00 (0.42, 9.42) 0.381	30.77 (-28.22, 89.76) 0.307
	At least one		18	4 (22.2)	11	7 (63.6)	87.89 (43.59, 97.40)	0.16 (0.03, 0.87) 0.034	0.34 (0.12, 0.93) 0.035	-41.93 (-76.42, -7.44) 0.017
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	8 (33.3)	17	9 (52.9)	73.84 (6.86, 92.65)	0.42 (0.12, 1.54) 0.191	0.60 (0.28, 1.29) 0.193	-20.85 (-51.29, 9.60) 0.180
	High risk for severe COVID-19 at baseline	0.112								
	Yes		22	7 (31.8)	16	8 (50.0)	70.31 (-22.09, 92.78)	0.45 (0.12, 1.72) 0.245	0.62 (0.28, 1.38) 0.245	-18.89 (-50.17, 12.39) 0.237
	Obesity (≥ 30 kg/m^2)	0.108								
	Yes		8	2 (25.0)	8	6 (75.0)	94.02 (51.42, 99.26)	0.11 (0.01, 1.24) 0.074	0.20 (0.03, 1.15) 0.072	-66.67 (-93.34, -39.99) <.001

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	6 (37.5)	9	3 (33.3)	37.47 (-179.97, 86.03)	1.28 (0.24, 6.82) 0.774	1.18 (0.40, 3.50) 0.770	6.01 (-34.50, 46.52) 0.771

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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Cough	Obesity (≥ 40 kg/m^2)	0.451								
	No		22	7 (31.8)	14	7 (50.0)	70.11 (-23.12, 92.75)	0.47 (0.12, 1.84) 0.276	0.63 (0.27, 1.46) 0.276	-18.54 (-51.61, 14.53) 0.272
	Chronic kidney disease	NE								
	No		21	6 (28.6)	15	9 (60.0)	82.62 (34.64, 95.38)	0.24 (0.06, 1.03) 0.055	0.44 (0.19, 1.03) 0.060	-33.33 (-64.65, -2.02) 0.037
	Diabetes	0.548								
	No		22	7 (31.8)	16	8 (50.0)	72.52 (-8.90, 93.06)	0.46 (0.12, 1.73) 0.252	0.62 (0.27, 1.42) 0.257	-18.88 (-50.64, 12.87) 0.244
	Immunosuppressive disease	NE								
	No		24	8 (33.3)	16	9 (56.3)	74.02 (7.42, 92.71)	0.38 (0.10, 1.40) 0.148	0.58 (0.27, 1.21) 0.147	-23.74 (-54.83, 7.36) 0.135
	Immunosuppressive treatment	0.444								
	Yes		12	4 (33.3)	8	5 (62.5)	82.51 (-15.20, 97.34)	0.25 (0.04, 1.82) 0.172	0.49 (0.18, 1.35) 0.169	-32.05 (-73.95, 9.85) 0.134
	No		12	4 (33.3)	9	4 (44.4)	57.24 (-114.63, 91.48)	0.63 (0.11, 3.71) 0.608	0.75 (0.24, 2.30) 0.611	-11.11 (-53.57, 31.35) 0.608

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Cough	CV disease	NE								
	No		24	8 (33.3)	13	6 (46.2)	66.14 (-53.32, 92.52)	0.53 (0.13, 2.17) 0.373	0.66 (0.26, 1.68) 0.382	-15.43 (-49.40, 18.53) 0.373
	COPD	0.023								
	No		22	6 (27.3)	14	7 (50.0)	77.07 (0.29, 94.73)	0.34 (0.08, 1.47) 0.149	0.48 (0.17, 1.36) 0.168	-25.10 (-58.30, 8.09) 0.138
	Chronic liver disease	NE								
	No		21	8 (38.1)	17	9 (52.9)	69.77 (-15.24, 92.07)	0.52 (0.14, 1.95) 0.334	0.70 (0.33, 1.47) 0.341	-16.03 (-47.99, 15.93) 0.326
	Hypertension	0.173								
	Yes		10	4 (40.0)	7	3 (42.9)	27.55 (-299.46, 86.86)	0.91 (0.12, 6.96) 0.929	0.94 (0.26, 3.42) 0.931	-2.25 (-51.78, 47.29) 0.929
	No		14	4 (28.6)	10	6 (60.0)	84.95 (17.60, 97.25)	0.26 (0.05, 1.50) 0.133	0.48 (0.19, 1.25) 0.132	-31.12 (-69.19, 6.95) 0.109
	Asthma	0.083								
	No		19	7 (36.8)	14	6 (42.9)	50.55 (-166.86, 90.84)	0.76 (0.18, 3.10) 0.697	0.84 (0.35, 2.00) 0.697	-6.76 (-40.70, 27.19) 0.696

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Cough	Cancer	0.468								
	Yes		6	1 (16.7)	4	1 (25.0)	42.26 (-657.44, 95.60)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	7 (38.9)	13	8 (61.5)	78.16 (13.50, 94.49)	0.39 (0.09, 1.69) 0.208	0.62 (0.30, 1.30) 0.205	-23.30 (-58.10, 11.50) 0.190
	Smoking	NE								
	No		20	7 (35.0)	17	9 (52.9)	75.77 (10.05, 93.47)	0.44 (0.11, 1.71) 0.234	0.62 (0.27, 1.40) 0.249	-20.11 (-52.16, 11.93) 0.219
	Sickle cell disease	NE								
	No		24	8 (33.3)	17	9 (52.9)	73.84 (6.86, 92.65)	0.42 (0.12, 1.54) 0.191	0.60 (0.28, 1.29) 0.193	-20.85 (-51.29, 9.60) 0.180
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	8 (34.8)	14	9 (64.3)	81.10 (33.88, 94.60)	0.29 (0.07, 1.16) 0.081	0.52 (0.26, 1.07) 0.075	-30.65 (-62.63, 1.34) 0.060
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	8 (33.3)	17	9 (52.9)	73.84 (6.86, 92.65)	0.42 (0.12, 1.54) 0.191	0.60 (0.28, 1.29) 0.193	-20.85 (-51.29, 9.60) 0.180

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Diarrhea	Age at randomization	NE								
	<60 years		13	1 (7.7)	11	2 (18.2)	49.43 (-580.67, 96.24)	0.38 (0.03, 4.81) 0.451	0.42 (0.04, 4.06) 0.456	-10.49 (-37.50, 16.52) 0.446
	≥60 years		11	2 (18.2)	6	0 (0.0)	NE (NE, NE)	3.42 (0.14, 83.60) 0.451	2.92 (0.16, 52.47) 0.468	18.18 (-4.61, 40.97) 0.118
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	2 (13.3)	49.42 (-540.51, 96.01)	0.43 (0.04, 5.35) 0.514	0.47 (0.05, 4.65) 0.518	-7.08 (-27.98, 13.81) 0.506
	≥65 years		8	2 (25.0)	2	0 (0.0)	NE (NE, NE)	1.92 (0.07, 55.84) 0.704	1.67 (0.11, 25.83) 0.715	25.00 (-5.01, 55.01) 0.102
	Age at randomization	NE								
	<75 years		22	2 (9.1)	16	2 (12.5)	10.54 (-636.44, 89.13)	0.70 (0.09, 5.58) 0.736	0.73 (0.11, 4.63) 0.736	-3.41 (-23.58, 16.76) 0.740
	Residence in long-term care facility	NE								
	No		24	3 (12.5)	17	2 (11.8)	-32.33 (-765.57, 79.77)	1.08 (0.16, 7.43) 0.937	1.07 (0.17, 6.80) 0.939	0.82 (-19.44, 21.08) 0.937

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	3 (15.8)	14	0 (0.0)	-211.73 (NE, 66.70)	3.44 (0.34, 34.75) 0.295	2.97 (0.36, 24.27) 0.311	15.47 (-0.84, 31.78) 0.063

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Diarrhea	Sex	0.803								
	Male		9	1 (11.1)	7	1 (14.3)	0.00 (-1971.06, 95.17)	0.67 (0.03, 14.03) 0.794	0.71 (0.06, 8.90) 0.794	-4.26 (-36.68, 28.17) 0.797
	Female		15	2 (13.3)	10	1 (10.0)	-46.33 (-1237.95, 84.00)	1.23 (0.09, 17.51) 0.878	1.23 (0.07, 22.48) 0.889	2.00 (-23.15, 27.15) 0.876
	Region	NE								
	North America		7	2 (28.6)	8	0 (0.0)	-122.67 (NE, 82.69)	5.00 (0.19, 130.02) 0.333	3.75 (0.22, 64.56) 0.363	28.57 (-4.89, 62.04) 0.094
	United Kingdom		8	0 (0.0)	6	1 (16.7)	-175.00 (-10625.0, NE)	0.27 (0.01, 8.46) 0.458	0.33 (0.02, 6.65) 0.472	-15.38 (-44.95, 14.18) 0.308
	European Union		9	1 (11.1)	3	1 (33.3)	81.29 (-379.09, 99.27)	0.29 (0.01, 6.91) 0.441	0.38 (0.03, 4.27) 0.430	-20.83 (-78.89, 37.22) 0.482
	Country	NE								
	United States		7	2 (28.6)	8	0 (0.0)	NE (NE, NE)	5.00 (0.19, 130.02) 0.333	3.75 (0.22, 64.56) 0.363	28.57 (-4.89, 62.04) 0.094
	United Kingdom		8	0 (0.0)	6	1 (16.7)	NE (NE, NE)	0.27 (0.01, 8.46) 0.458	0.33 (0.02, 6.65) 0.472	-15.38 (-44.95, 14.18) 0.308

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Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	3 (12.5)	13	2 (15.4)	10.28 (-509.38, 86.79)	0.80 (0.12, 5.42) 0.816	0.81 (0.14, 4.88) 0.820	-2.77 (-26.70, 21.16) 0.821

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Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Diarrhea	Ethnicity	NE								
	Not Hispanic or Latino		23	3 (13.0)	16	2 (12.5)	-32.28 (-768.21, 79.85)	1.05 (0.16, 7.02) 0.958	1.05 (0.17, 6.29) 0.959	0.58 (-20.95, 22.11) 0.958
	COVID-19 co-morbidities at baseline	0.472								
	None		6	1 (16.7)	6	1 (16.7)	84.53 (-47.61, 98.38)	0.75 (0.03, 18.41) 0.860	0.75 (0.02, 24.53) 0.872	-3.85 (-45.95, 38.26) 0.858
	At least one		18	2 (11.1)	11	1 (9.1)	-132.52 (-2833.04, 81.57)	1.29 (0.10, 16.69) 0.843	1.26 (0.12, 12.99) 0.845	2.31 (-19.87, 24.49) 0.839
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	3 (12.5)	17	2 (11.8)	-32.33 (-765.57, 79.77)	1.08 (0.16, 7.43) 0.937	1.07 (0.17, 6.80) 0.939	0.82 (-19.44, 21.08) 0.937
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	2 (9.1)	16	2 (12.5)	6.76 (-647.16, 88.36)	0.74 (0.09, 6.03) 0.777	0.76 (0.11, 5.30) 0.782	-2.84 (-22.84, 17.17) 0.781
	Obesity (≥ 30 kg/m^2)	0.563								
	Yes		8	1 (12.5)	8	1 (12.5)	-623.79 (-5048.45, -1.75)	1.00 (0.02, 50.40) 1.000	1.00 (0.01, 121.62) 1.000	0.00 (-32.67, 32.67) 1.000

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	No		16	2 (12.5)	9	1 (11.1)	19.49 (-1171.80, 94.90)	1.11 (0.10, 12.63) 0.932	1.10 (0.13, 9.26) 0.929	1.23 (-26.75, 29.20) 0.931

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Diarrhea	Obesity (≥ 40 kg/m^2)	NE								
	No		22	3 (13.6)	14	1 (7.1)	-140.15 (-2386.04, 76.80)	2.00 (0.18, 21.85) 0.570	1.92 (0.19, 19.76) 0.585	6.18 (-13.49, 25.85) 0.538
	Chronic kidney disease	NE								
	No		21	1 (4.8)	15	2 (13.3)	54.80 (-381.98, 95.76)	0.32 (0.02, 4.26) 0.387	0.32 (0.02, 5.32) 0.426	-8.33 (-27.61, 10.94) 0.397
	Diabetes	NE								
	No		22	3 (13.6)	16	2 (12.5)	-26.60 (-734.62, 80.80)	1.09 (0.16, 7.46) 0.931	1.08 (0.17, 6.82) 0.933	0.97 (-20.81, 22.75) 0.930
	Immunosuppressive disease	NE								
	No		24	3 (12.5)	16	2 (12.5)	-31.87 (-763.86, 79.87)	1.01 (0.15, 6.85) 0.992	1.01 (0.16, 6.20) 0.992	0.11 (-20.93, 21.15) 0.992
	Immunosuppressive treatment	0.777								
	Yes		12	1 (8.3)	8	1 (12.5)	3.08 (-1151.43, 92.49)	0.61 (0.03, 11.98) 0.746	0.61 (0.03, 14.29) 0.759	-4.49 (-32.35, 23.37) 0.752
	No		12	2 (16.7)	9	1 (11.1)	-63.47 (-2349.08, 89.09)	1.65 (0.12, 22.26) 0.708	1.55 (0.15, 16.50) 0.715	5.84 (-23.55, 35.22) 0.697

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Diarrhea	CV disease	NE								
	No		24	3 (12.5)	13	2 (15.4)	18.77 (-434.20, 87.65)	0.74 (0.10, 5.73) 0.776	0.76 (0.11, 5.48) 0.789	-3.33 (-26.97, 20.30) 0.782
	COPD	NE								
	No		22	1 (4.5)	14	2 (14.3)	69.94 (-142.17, 96.27)	0.22 (0.01, 3.88) 0.302	0.22 (0.01, 5.91) 0.368	-10.10 (-29.93, 9.73) 0.318
	Chronic liver disease	NE								
	No		21	3 (14.3)	17	2 (11.8)	-48.79 (-858.36, 76.90)	1.32 (0.18, 9.69) 0.783	1.29 (0.19, 8.70) 0.793	3.04 (-18.23, 24.32) 0.779
	Hypertension	0.680								
	Yes		10	2 (20.0)	7	1 (14.3)	-170.43 (-4753.87, 84.93)	2.55 (0.13, 51.76) 0.542	2.03 (0.19, 22.27) 0.561	11.61 (-22.69, 45.91) 0.507
	No		14	1 (7.1)	10	1 (10.0)	11.71 (-1819.76, 95.94)	0.73 (0.05, 11.59) 0.823	0.73 (0.05, 11.11) 0.820	-2.74 (-26.91, 21.43) 0.824
	Asthma	NE								
	No		19	3 (15.8)	14	1 (7.1)	-173.21 (-2719.60, 73.53)	2.34 (0.22, 24.80) 0.481	2.22 (0.22, 21.97) 0.496	8.34 (-13.06, 29.74) 0.445

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Diarrhea	Cancer	NE								
	Yes		6	1 (16.7)	4	0 (0.0)	80.00 (NE, 99.49)	1.80 (0.04, 79.42) 0.761	1.50 (0.10, 22.62) 0.770	11.11 (-16.05, 38.27) 0.423
	No		18	2 (11.1)	13	2 (15.4)	19.66 (-580.71, 90.52)	0.72 (0.09, 5.93) 0.758	0.75 (0.11, 4.99) 0.763	-3.75 (-28.07, 20.57) 0.763
	Smoking	NE								
	No		20	3 (15.0)	17	2 (11.8)	-70.53 (-993.75, 73.41)	1.44 (0.19, 10.88) 0.721	1.40 (0.20, 9.64) 0.735	4.03 (-17.70, 25.76) 0.716
	Sickle cell disease	NE								
	No		24	3 (12.5)	17	2 (11.8)	-32.33 (-765.57, 79.77)	1.08 (0.16, 7.43) 0.937	1.07 (0.17, 6.80) 0.939	0.82 (-19.44, 21.08) 0.937
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	3 (13.0)	14	2 (14.3)	-18.42 (-708.13, 82.65)	0.90 (0.13, 6.14) 0.917	0.91 (0.15, 5.54) 0.919	-1.23 (-24.40, 21.95) 0.917
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	3 (12.5)	17	2 (11.8)	-32.33 (-765.57, 79.77)	1.08 (0.16, 7.43) 0.937	1.07 (0.17, 6.80) 0.939	0.82 (-19.44, 21.08) 0.937

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Difficulty Breathing	Age at randomization	0.264								
	<60 years		13	1 (7.7)	11	5 (45.5)	87.75 (-28.07, 98.83)	0.10 (0.01, 1.06) 0.056	0.17 (0.02, 1.24) 0.080	-37.76 (-70.56, -4.96) 0.024
	≥60 years		11	2 (18.2)	6	1 (16.7)	3.17 (-1435.38, 93.89)	1.11 (0.08, 15.53) 0.938	1.09 (0.12, 9.70) 0.938	1.52 (-36.02, 39.05) 0.937
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	6 (40.0)	89.31 (-2.98, 98.89)	0.10 (0.01, 0.97) 0.047	0.16 (0.02, 1.15) 0.068	-33.75 (-61.23, -6.27) 0.016
	≥65 years		8	2 (25.0)	2	0 (0.0)	NE (NE, NE)	1.92 (0.07, 55.84) 0.704	1.67 (0.11, 25.83) 0.715	25.00 (-5.01, 55.01) 0.102
	Age at randomization	NE								
	<75 years		22	3 (13.6)	16	6 (37.5)	69.27 (-50.74, 93.74)	0.26 (0.05, 1.28) 0.098	0.36 (0.11, 1.24) 0.106	-23.86 (-51.58, 3.86) 0.092
	Residence in long-term care facility	NE								
	No		24	3 (12.5)	17	6 (35.3)	71.74 (-34.66, 94.07)	0.28 (0.06, 1.31) 0.105	0.35 (0.09, 1.34) 0.124	-22.27 (-48.98, 4.44) 0.102

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	3 (15.8)	14	3 (21.4)	44.10 (-240.34, 90.82)	0.68 (0.12, 4.01) 0.672	0.73 (0.17, 3.20) 0.673	-5.80 (-32.95, 21.35) 0.675

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Difficulty Breathing	Sex	0.703								
	Male		9	1 (11.1)	7	3 (42.9)	78.61 (-157.30, 98.22)	0.11 (0.01, 1.78) 0.120	0.24 (0.03, 1.67) 0.149	-34.04 (-73.69, 5.60) 0.092
	Female		15	2 (13.3)	10	3 (30.0)	71.82 (-130.84, 96.56)	0.30 (0.03, 2.59) 0.273	0.36 (0.05, 2.45) 0.298	-18.67 (-51.81, 14.48) 0.270
	Region	NE								
	North America		7	2 (28.6)	8	3 (37.5)	2.94 (-1829.25, 95.12)	1.60 (0.10, 24.70) 0.736	1.43 (0.17, 11.76) 0.740	8.57 (-39.90, 57.04) 0.729
	United Kingdom		8	0 (0.0)	6	1 (16.7)	-171.88 (-10503.1, NE)	0.27 (0.01, 8.46) 0.458	0.33 (0.02, 6.65) 0.472	-15.38 (-44.95, 14.18) 0.308
	European Union		9	1 (11.1)	3	2 (66.7)	95.11 (60.30, 99.40)	0.07 (0.00, 1.73) 0.105	0.19 (0.03, 1.39) 0.101	-54.17 (-100.00, 3.89) 0.041
	Country	NE								
	United States		7	2 (28.6)	8	3 (37.5)	2.94 (-1829.25, 95.12)	1.60 (0.10, 24.70) 0.736	1.43 (0.17, 11.76) 0.740	8.57 (-39.90, 57.04) 0.729
	United Kingdom		8	0 (0.0)	6	1 (16.7)	NE (NE, NE)	0.27 (0.01, 8.46) 0.458	0.33 (0.02, 6.65) 0.472	-15.38 (-44.95, 14.18) 0.308

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	3 (12.5)	13	4 (30.8)	69.24 (-71.80, 94.49)	0.32 (0.06, 1.75) 0.190	0.40 (0.10, 1.62) 0.196	-18.34 (-46.94, 10.26) 0.209

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Difficulty Breathing	Ethnicity	NE								
	Not Hispanic or Latino		23	3 (13.0)	16	6 (37.5)	71.84 (-34.68, 94.11)	0.27 (0.06, 1.26) 0.096	0.34 (0.09, 1.28) 0.111	-24.10 (-52.16, 3.95) 0.092
	COVID-19 co-morbidities at baseline	NE								
	None		6	0 (0.0)	6	2 (33.3)	77.60 (-188.01, NE)	0.16 (0.01, 4.40) 0.275	0.24 (0.01, 3.93) 0.317	-30.77 (-69.09, 7.55) 0.116
	At least one		18	3 (16.7)	11	4 (36.4)	43.86 (-256.65, 91.16)	0.37 (0.07, 2.03) 0.251	0.46 (0.12, 1.77) 0.257	-19.50 (-53.35, 14.36) 0.259
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	3 (12.5)	17	6 (35.3)	71.74 (-34.66, 94.07)	0.28 (0.06, 1.31) 0.105	0.35 (0.09, 1.34) 0.124	-22.27 (-48.98, 4.44) 0.102
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	3 (13.6)	16	5 (31.3)	60.30 (-104.69, 92.30)	0.36 (0.07, 1.78) 0.209	0.43 (0.11, 1.68) 0.224	-17.41 (-44.62, 9.81) 0.210
	Obesity (≥ 30 kg/m^2)	0.129								
	Yes		8	2 (25.0)	8	4 (50.0)	-26.62 (-1683.17, 91.01)	0.20 (0.01, 3.20) 0.255	0.33 (0.04, 2.77) 0.309	-33.33 (-81.42, 14.75) 0.174

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	1 (6.3)	9	2 (22.2)	85.31 (-82.62, 98.82)	0.15 (0.01, 2.29) 0.172	0.23 (0.03, 1.96) 0.178	-18.77 (-47.82, 10.28) 0.205

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Difficulty Breathing	Obesity (≥ 40 kg/m^2)	0.849								
	No		22	2 (9.1)	14	4 (28.6)	70.96 (-86.41, 95.48)	0.27 (0.04, 1.72) 0.167	0.33 (0.06, 1.76) 0.196	-17.98 (-44.52, 8.56) 0.184
	Chronic kidney disease	NE								
	No		21	1 (4.8)	15	6 (40.0)	90.40 (13.49, 98.93)	0.08 (0.01, 0.79) 0.030	0.10 (0.01, 1.10) 0.060	-34.44 (-61.40, -7.49) 0.012
	Diabetes	NE								
	No		22	2 (9.1)	16	6 (37.5)	83.63 (1.30, 97.29)	0.17 (0.03, 1.02) 0.053	0.24 (0.05, 1.13) 0.071	-27.64 (-54.44, -0.85) 0.043
	Immunosuppressive disease	NE								
	No		24	3 (12.5)	16	6 (37.5)	71.91 (-34.17, 94.12)	0.26 (0.05, 1.20) 0.085	0.33 (0.09, 1.24) 0.101	-24.46 (-52.16, 3.24) 0.083
	Immunosuppressive treatment	0.952								
	Yes		12	2 (16.7)	8	4 (50.0)	71.44 (-112.66, 96.16)	0.21 (0.03, 1.64) 0.138	0.29 (0.05, 1.62) 0.159	-34.62 (-76.80, 7.57) 0.108
	No		12	1 (8.3)	9	2 (22.2)	72.88 (-271.22, 98.02)	0.33 (0.02, 5.03) 0.427	0.43 (0.05, 3.64) 0.437	-12.05 (-42.14, 18.04) 0.432

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Difficulty Breathing	CV disease	NE								
	No		24	3 (12.5)	13	6 (46.2)	92.26 (57.48, 98.59)	0.15 (0.03, 0.86) 0.033	0.24 (0.06, 0.98) 0.047	-34.32 (-64.99, -3.64) 0.028
	COPD	NE								
	No		22	1 (4.5)	14	6 (42.9)	97.75 (83.90, 99.68)	0.05 (0.00, 0.65) 0.023	0.07 (0.00, 1.06) 0.055	-39.11 (-66.63, -11.59) 0.005
	Chronic liver disease	NE								
	No		21	3 (14.3)	17	6 (35.3)	68.18 (-51.61, 93.32)	0.33 (0.07, 1.60) 0.168	0.41 (0.10, 1.60) 0.198	-19.72 (-47.39, 7.96) 0.163
	Hypertension	NE								
	Yes		10	3 (30.0)	7	2 (28.6)	-30.22 (-1206.51, 87.02)	1.55 (0.14, 16.67) 0.718	1.37 (0.22, 8.46) 0.737	8.24 (-34.52, 51.00) 0.706
	No		14	0 (0.0)	10	4 (40.0)	90.96 (27.17, NE)	0.10 (0.01, 1.06) 0.056	0.16 (0.02, 1.24) 0.080	-40.06 (-70.42, -9.70) 0.010
	Asthma	0.791								
	No		19	2 (10.5)	14	4 (28.6)	71.57 (-107.32, 96.10)	0.30 (0.05, 1.93) 0.205	0.37 (0.08, 1.80) 0.217	-17.82 (-45.27, 9.62) 0.203

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Difficulty Breathing	Cancer	0.461								
	Yes		6	1 (16.7)	4	1 (25.0)	42.26 (-657.44, 95.60)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	2 (11.1)	13	5 (38.5)	79.20 (-28.11, 96.62)	0.21 (0.03, 1.30) 0.093	0.29 (0.06, 1.33) 0.112	-26.70 (-57.05, 3.64) 0.085
	Smoking	NE								
	No		20	3 (15.0)	17	6 (35.3)	63.68 (-74.27, 92.43)	0.35 (0.07, 1.75) 0.201	0.43 (0.11, 1.72) 0.235	-18.58 (-46.70, 9.54) 0.195
	Sickle cell disease	NE								
	No		24	3 (12.5)	17	6 (35.3)	71.74 (-34.66, 94.07)	0.28 (0.06, 1.31) 0.105	0.35 (0.09, 1.34) 0.124	-22.27 (-48.98, 4.44) 0.102
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	3 (13.0)	14	6 (42.9)	77.03 (-14.71, 95.40)	0.22 (0.05, 1.05) 0.058	0.30 (0.08, 1.11) 0.071	-29.42 (-59.51, 0.66) 0.055
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	3 (12.5)	17	6 (35.3)	71.74 (-34.66, 94.07)	0.28 (0.06, 1.31) 0.105	0.35 (0.09, 1.34) 0.124	-22.27 (-48.98, 4.44) 0.102

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Fatigue	Age at randomization	0.310								
	<60 years		13	4 (30.8)	11	6 (54.5)	53.47 (-216.03, 93.15)	0.37 (0.07, 1.97) 0.244	0.56 (0.21, 1.50) 0.251	-23.78 (-62.45, 14.89) 0.228
	≥60 years		11	4 (36.4)	6	3 (50.0)	87.69 (32.11, 97.77)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-13.64 (-62.72, 35.44) 0.586
	Age at randomization	NE								
	<65 years		16	5 (31.3)	15	9 (60.0)	74.22 (-39.40, 95.23)	0.30 (0.07, 1.33) 0.113	0.52 (0.23, 1.20) 0.126	-28.75 (-62.37, 4.87) 0.094
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	7 (31.8)	16	9 (56.3)	64.78 (-74.41, 92.89)	0.36 (0.10, 1.38) 0.137	0.57 (0.27, 1.20) 0.136	-24.43 (-55.57, 6.71) 0.124
	Residence in long-term care facility	NE								
	No		24	8 (33.3)	17	9 (52.9)	73.05 (-20.91, 93.99)	0.44 (0.12, 1.59) 0.212	0.63 (0.30, 1.30) 0.211	-19.78 (-50.26, 10.71) 0.204

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	0.550								
	No		19	7 (36.8)	14	6 (42.9)	71.76 (-43.75, 94.45)	0.75 (0.18, 3.14) 0.698	0.85 (0.37, 1.96) 0.696	-6.63 (-40.12, 26.86) 0.698

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Fatigue	Sex	0.713								
	Male		9	2 (22.2)	7	4 (57.1)	78.48 (-129.46, 97.98)	0.19 (0.02, 1.86) 0.154	0.37 (0.09, 1.51) 0.166	-36.17 (-80.80, 8.46) 0.112
	Female		15	6 (40.0)	10	5 (50.0)	42.46 (-1109.67, 97.26)	0.63 (0.12, 3.29) 0.584	0.77 (0.31, 1.94) 0.583	-11.33 (-51.65, 28.99) 0.582
	Region	NE								
	North America		7	4 (57.1)	8	4 (50.0)	-42.86 (-398.92, 59.10)	2.00 (0.19, 20.61) 0.560	1.43 (0.41, 4.99) 0.576	17.14 (-39.32, 73.60) 0.552
	United Kingdom		8	0 (0.0)	6	3 (50.0)	96.88 (31.70, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	4 (44.4)	3	2 (66.7)	91.30 (59.21, 98.15)	0.50 (0.03, 7.99) 0.624	0.75 (0.26, 2.16) 0.594	-16.67 (-80.27, 46.94) 0.608
	Country	NE								
	United States		7	4 (57.1)	8	4 (50.0)	-42.86 (-398.92, 59.10)	2.00 (0.19, 20.61) 0.560	1.43 (0.41, 4.99) 0.576	17.14 (-39.32, 73.60) 0.552
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	8 (33.3)	13	6 (46.2)	60.48 (-116.11, 92.77)	0.58 (0.15, 2.33) 0.446	0.72 (0.31, 1.65) 0.438	-12.84 (-46.01, 20.32) 0.448

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Fatigue	Ethnicity	NE								
	Not Hispanic or Latino		23	8 (34.8)	16	9 (56.3)	73.13 (-20.48, 94.01)	0.42 (0.11, 1.54) 0.188	0.62 (0.30, 1.26) 0.186	-21.56 (-52.89, 9.76) 0.177
	COVID-19 co-morbidities at baseline	0.053								
	None		6	4 (66.7)	6	2 (33.3)	-69.32 (-1664.63, 83.75)	3.00 (0.34, 26.84) 0.326	2.00 (0.42, 9.42) 0.381	30.77 (-28.22, 89.76) 0.307
	At least one		18	4 (22.2)	11	7 (63.6)	88.72 (34.27, 98.06)	0.16 (0.03, 0.86) 0.032	0.35 (0.13, 0.93) 0.035	-41.30 (-75.68, -6.92) 0.019
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	8 (33.3)	17	9 (52.9)	73.05 (-20.91, 93.99)	0.44 (0.12, 1.59) 0.212	0.63 (0.30, 1.30) 0.211	-19.78 (-50.26, 10.71) 0.204
	High risk for severe COVID-19 at baseline	0.175								
	Yes		22	7 (31.8)	16	8 (50.0)	66.47 (-94.15, 94.21)	0.47 (0.12, 1.78) 0.267	0.64 (0.29, 1.40) 0.264	-18.02 (-49.43, 13.39) 0.261
	Obesity (≥ 30 kg/m^2)	0.437								
	Yes		8	2 (25.0)	8	6 (75.0)	94.02 (51.61, 99.26)	0.11 (0.01, 1.24) 0.074	0.20 (0.03, 1.15) 0.072	-66.67 (-93.34, -39.99) <.001

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	6 (37.5)	9	3 (33.3)	48.01 (-298.84, 93.22)	1.17 (0.21, 6.54) 0.856	1.11 (0.37, 3.34) 0.855	3.68 (-35.83, 43.19) 0.855

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Fatigue	Obesity (≥ 40 kg/m^2)	0.477								
	No		22	7 (31.8)	14	7 (50.0)	66.65 (-85.21, 94.00)	0.48 (0.12, 1.92) 0.299	0.65 (0.29, 1.46) 0.296	-17.42 (-50.18, 15.35) 0.297
	Chronic kidney disease	NE								
	No		21	6 (28.6)	15	9 (60.0)	82.13 (12.63, 96.35)	0.26 (0.06, 1.09) 0.065	0.47 (0.21, 1.06) 0.069	-31.67 (-63.36, 0.03) 0.050
	Diabetes	0.652								
	No		22	7 (31.8)	16	8 (50.0)	69.59 (-58.97, 94.18)	0.48 (0.13, 1.80) 0.274	0.64 (0.29, 1.43) 0.276	-17.78 (-49.29, 13.73) 0.269
	Immunosuppressive disease	NE								
	No		24	8 (33.3)	16	9 (56.3)	73.29 (-19.93, 94.05)	0.39 (0.11, 1.44) 0.158	0.59 (0.29, 1.22) 0.156	-22.88 (-53.84, 8.08) 0.147
	Immunosuppressive treatment	0.546								
	Yes		12	5 (41.7)	8	5 (62.5)	38.76 (-911.15, 96.29)	0.40 (0.06, 2.58) 0.333	0.64 (0.27, 1.55) 0.324	-22.44 (-65.87, 21.00) 0.311
	No		12	3 (25.0)	9	4 (44.4)	80.85 (-64.24, 97.77)	0.43 (0.07, 2.79) 0.377	0.58 (0.17, 1.96) 0.380	-18.46 (-59.10, 22.18) 0.373

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Fatigue	CV disease	NE								
	No		24	8 (33.3)	13	6 (46.2)	57.18 (-156.53, 92.85)	0.59 (0.14, 2.42) 0.461	0.72 (0.30, 1.74) 0.463	-12.68 (-46.58, 21.22) 0.464
	COPD	0.094								
	No		22	6 (27.3)	14	7 (50.0)	71.81 (-68.98, 95.30)	0.39 (0.09, 1.64) 0.197	0.55 (0.21, 1.41) 0.210	-22.03 (-55.25, 11.20) 0.194
	Chronic liver disease	NE								
	No		21	8 (38.1)	17	9 (52.9)	66.16 (-76.11, 93.50)	0.56 (0.15, 2.09) 0.391	0.73 (0.36, 1.50) 0.391	-14.16 (-46.20, 17.88) 0.386
	Hypertension	0.873								
	Yes		10	3 (30.0)	7	3 (42.9)	69.80 (-275.08, 97.57)	0.64 (0.08, 5.24) 0.677	0.75 (0.19, 2.93) 0.682	-10.11 (-58.13, 37.90) 0.680
	No		14	5 (35.7)	10	6 (60.0)	75.89 (-55.86, 96.27)	0.37 (0.07, 1.99) 0.245	0.60 (0.25, 1.41) 0.240	-24.06 (-63.17, 15.05) 0.228
	Asthma	0.277								
	No		19	6 (31.6)	14	6 (42.9)	62.93 (-160.82, 94.73)	0.61 (0.14, 2.56) 0.498	0.73 (0.29, 1.81) 0.498	-11.55 (-44.93, 21.84) 0.498

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Fatigue	Cancer	0.464								
	Yes		6	1 (16.7)	4	1 (25.0)	42.26 (-657.44, 95.60)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	7 (38.9)	13	8 (61.5)	77.46 (-23.72, 95.89)	0.40 (0.09, 1.73) 0.221	0.63 (0.31, 1.30) 0.216	-22.50 (-57.31, 12.31) 0.205
	Smoking	NE								
	No		20	7 (35.0)	17	9 (52.9)	73.80 (-30.97, 94.76)	0.48 (0.12, 1.85) 0.286	0.66 (0.30, 1.43) 0.293	-17.88 (-50.14, 14.37) 0.277
	Sickle cell disease	NE								
	No		24	8 (33.3)	17	9 (52.9)	73.05 (-20.91, 93.99)	0.44 (0.12, 1.59) 0.212	0.63 (0.30, 1.30) 0.211	-19.78 (-50.26, 10.71) 0.204
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	8 (34.8)	14	9 (64.3)	82.04 (20.63, 95.93)	0.30 (0.07, 1.19) 0.086	0.54 (0.27, 1.08) 0.079	-29.77 (-61.71, 2.16) 0.068
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	8 (33.3)	17	9 (52.9)	73.05 (-20.91, 93.99)	0.44 (0.12, 1.59) 0.212	0.63 (0.30, 1.30) 0.211	-19.78 (-50.26, 10.71) 0.204

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Headache	Age at randomization	0.743								
	<60 years		13	2 (15.4)	11	6 (54.5)	84.87 (-16.55, 98.04)	0.15 (0.02, 1.03) 0.054	0.28 (0.07, 1.13) 0.073	-39.16 (-74.52, -3.80) 0.030
	≥60 years		11	3 (27.3)	6	3 (50.0)	90.22 (50.21, 98.08)	0.38 (0.05, 3.00) 0.355	0.55 (0.16, 1.91) 0.343	-22.73 (-70.62, 25.16) 0.352
	Age at randomization	NE								
	<65 years		16	2 (12.5)	15	9 (60.0)	92.84 (52.58, 98.92)	0.10 (0.02, 0.58) 0.011	0.21 (0.05, 0.81) 0.024	-47.50 (-77.12, -17.88) 0.002
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	4 (18.2)	16	9 (56.3)	85.86 (28.99, 97.18)	0.17 (0.04, 0.75) 0.019	0.32 (0.12, 0.87) 0.025	-38.07 (-67.23, -8.90) 0.011
	Residence in long-term care facility	NE								
	No		24	5 (20.8)	17	9 (52.9)	87.91 (53.80, 96.83)	0.23 (0.06, 0.91) 0.036	0.38 (0.15, 0.97) 0.043	-32.68 (-61.51, -3.85) 0.026

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	0.717								
	No		19	4 (21.1)	14	6 (42.9)	88.64 (51.90, 97.32)	0.33 (0.07, 1.59) 0.165	0.47 (0.16, 1.37) 0.167	-22.65 (-53.71, 8.41) 0.153

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Headache	Sex	0.821								
	Male		9	1 (11.1)	7	4 (57.1)	90.98 (-48.84, 99.45)	0.08 (0.01, 1.22) 0.070	0.19 (0.03, 1.36) 0.098	-46.81 (-88.18, -5.44) 0.027
	Female		15	4 (26.7)	10	5 (50.0)	86.77 (16.56, 97.90)	0.33 (0.06, 1.89) 0.212	0.49 (0.16, 1.52) 0.219	-25.33 (-63.76, 13.10) 0.196
	Region	NE								
	North America		7	3 (42.9)	8	4 (50.0)	69.12 (-153.06, 96.23)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	94.11 (-5.29, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	2 (22.2)	3	2 (66.7)	97.30 (85.00, 99.51)	0.17 (0.01, 2.98) 0.224	0.38 (0.09, 1.59) 0.183	-41.67 (-100.00, 19.54) 0.172
	Country	NE								
	United States		7	3 (42.9)	8	4 (50.0)	69.12 (-153.06, 96.23)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	5 (20.8)	13	6 (46.2)	85.17 (30.96, 96.82)	0.30 (0.07, 1.33) 0.114	0.44 (0.16, 1.21) 0.112	-25.65 (-57.42, 6.13) 0.114

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Headache	Ethnicity	NE								
	Not Hispanic or Latino		23	5 (21.7)	16	9 (56.3)	87.92 (53.75, 96.84)	0.22 (0.05, 0.88) 0.033	0.38 (0.15, 0.95) 0.037	-34.80 (-64.58, -5.02) 0.022
	COVID-19 co-morbidities at baseline	0.558								
	None		6	2 (33.3)	6	2 (33.3)	69.16 (-335.85, 97.82)	1.00 (0.09, 11.03) 1.000	1.00 (0.15, 6.67) 1.000	0.00 (-55.40, 55.40) 1.000
	At least one		18	3 (16.7)	11	7 (63.6)	90.96 (54.89, 98.19)	0.12 (0.02, 0.66) 0.016	0.26 (0.08, 0.81) 0.020	-47.17 (-80.52, -13.82) 0.006
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	5 (20.8)	17	9 (52.9)	87.91 (53.80, 96.83)	0.23 (0.06, 0.91) 0.036	0.38 (0.15, 0.97) 0.043	-32.68 (-61.51, -3.85) 0.026
	High risk for severe COVID-19 at baseline	0.415								
	Yes		22	4 (18.2)	16	8 (50.0)	87.99 (45.05, 97.37)	0.22 (0.05, 0.96) 0.043	0.36 (0.13, 1.00) 0.050	-31.98 (-61.34, -2.61) 0.033
	Obesity (≥ 30 kg/m^2)	0.960								
	Yes		8	2 (25.0)	8	6 (75.0)	88.19 (-4.49, 98.67)	0.11 (0.01, 1.24) 0.074	0.20 (0.03, 1.15) 0.072	-66.67 (-93.34, -39.99) <.001

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	3 (18.8)	9	3 (33.3)	83.91 (-24.32, 97.92)	0.45 (0.07, 2.95) 0.406	0.55 (0.14, 2.16) 0.394	-15.21 (-51.94, 21.51) 0.417

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Headache	Obesity (≥ 40 kg/m^2)	0.094								
	No		22	4 (18.2)	14	7 (50.0)	86.84 (39.77, 97.12)	0.23 (0.05, 1.02) 0.054	0.36 (0.13, 1.05) 0.061	-31.46 (-62.46, -0.47) 0.047
	Chronic kidney disease	NE								
	No		21	3 (14.3)	15	9 (60.0)	93.51 (71.21, 98.54)	0.10 (0.02, 0.54) 0.007	0.22 (0.07, 0.73) 0.013	-46.67 (-75.53, -17.80) 0.002
	Diabetes	0.014								
	No		22	4 (18.2)	16	8 (50.0)	89.25 (48.20, 97.77)	0.23 (0.05, 0.97) 0.046	0.36 (0.13, 1.03) 0.056	-31.67 (-61.25, -2.09) 0.036
	Immunosuppressive disease	NE								
	No		24	5 (20.8)	16	9 (56.3)	87.99 (54.06, 96.86)	0.20 (0.05, 0.83) 0.026	0.36 (0.14, 0.91) 0.031	-35.70 (-65.14, -6.27) 0.017
	Immunosuppressive treatment	0.922								
	Yes		12	3 (25.0)	8	5 (62.5)	86.49 (9.91, 97.97)	0.18 (0.02, 1.34) 0.095	0.38 (0.12, 1.20) 0.099	-39.10 (-80.11, 1.90) 0.062
	No		12	2 (16.7)	9	4 (44.4)	88.79 (15.68, 98.51)	0.26 (0.03, 1.90) 0.182	0.37 (0.08, 1.68) 0.200	-27.50 (-66.49, 11.50) 0.167

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Headache	CV disease	NE								
	No		24	5 (20.8)	13	6 (46.2)	85.79 (19.21, 97.50)	0.29 (0.06, 1.33) 0.112	0.42 (0.14, 1.27) 0.123	-26.21 (-58.50, 6.08) 0.112
	COPD	<.001								
	No		22	3 (13.6)	14	7 (50.0)	92.85 (58.31, 98.77)	0.15 (0.03, 0.81) 0.028	0.24 (0.06, 0.98) 0.046	-36.78 (-67.44, -6.12) 0.019
	Chronic liver disease	NE								
	No		21	5 (23.8)	17	9 (52.9)	86.60 (46.79, 96.63)	0.27 (0.07, 1.12) 0.070	0.44 (0.17, 1.11) 0.082	-29.51 (-59.78, 0.75) 0.056
	Hypertension	0.241								
	Yes		10	3 (30.0)	7	3 (42.9)	61.02 (-246.16, 95.61)	0.64 (0.08, 5.24) 0.677	0.75 (0.19, 2.93) 0.682	-10.11 (-58.13, 37.90) 0.680
	No		14	2 (14.3)	10	6 (60.0)	94.82 (65.68, 99.22)	0.11 (0.01, 0.80) 0.029	0.24 (0.06, 0.94) 0.041	-45.53 (-80.81, -10.26) 0.011
	Asthma	0.483								
	No		19	4 (21.1)	14	6 (42.9)	83.38 (-7.31, 97.43)	0.35 (0.08, 1.64) 0.183	0.49 (0.17, 1.43) 0.189	-21.95 (-53.75, 9.86) 0.176

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Headache	Cancer	0.227								
	Yes		6	1 (16.7)	4	1 (25.0)	42.26 (-657.44, 95.60)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	4 (22.2)	13	8 (61.5)	91.14 (60.63, 98.01)	0.18 (0.04, 0.86) 0.032	0.36 (0.14, 0.95) 0.039	-39.43 (-72.16, -6.71) 0.018
	Smoking	NE								
	No		20	5 (25.0)	17	9 (52.9)	84.94 (36.69, 96.42)	0.29 (0.07, 1.21) 0.091	0.47 (0.18, 1.17) 0.104	-28.11 (-59.03, 2.82) 0.075
	Sickle cell disease	NE								
	No		24	5 (20.8)	17	9 (52.9)	87.91 (53.80, 96.83)	0.23 (0.06, 0.91) 0.036	0.38 (0.15, 0.97) 0.043	-32.68 (-61.51, -3.85) 0.026
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	5 (21.7)	14	9 (64.3)	91.22 (66.09, 97.73)	0.15 (0.03, 0.68) 0.013	0.33 (0.13, 0.81) 0.015	-43.08 (-73.43, -12.73) 0.005
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	5 (20.8)	17	9 (52.9)	87.91 (53.80, 96.83)	0.23 (0.06, 0.91) 0.036	0.38 (0.15, 0.97) 0.043	-32.68 (-61.51, -3.85) 0.026

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increase O_2 Intake	Age at randomization	NE								
	<60 years		13	0 (0.0)	11	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	≥60 years		11	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Age at randomization	NE								
	<65 years		16	0 (0.0)	15	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	≥65 years		8	0 (0.0)	2	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Age at randomization	NE								
	<75 years		22	0 (0.0)	16	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Residence in long-term care facility	NE								
	No		24	0 (0.0)	17	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	0 (0.0)	14	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increase O_2 Intake	Sex	NE								
	Male		9	0 (0.0)	7	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Female		15	0 (0.0)	10	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Region	NE								
	North America		7	0 (0.0)	8	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	United Kingdom		8	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	European Union		9	0 (0.0)	3	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Country	NE								
	United States		7	0 (0.0)	8	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	United Kingdom		8	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Race	NE								
	White		24	0 (0.0)	13	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increase O_2 Intake	Ethnicity	NE								
	Not Hispanic or Latino		23	0 (0.0)	16	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	COVID-19 co-morbidities at baseline	NE								
	None		6	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	At least one		18	0 (0.0)	11	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	0 (0.0)	17	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	0 (0.0)	16	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Obesity (≥ 30 kg/m^2)	NE								
	Yes		8	0 (0.0)	8	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	No		16	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increase O_2 Intake	Obesity (≥ 40 kg/m^2)	NE								
	No		22	0 (0.0)	14	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Chronic kidney disease	NE								
	No		21	0 (0.0)	15	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Diabetes	NE								
	No		22	0 (0.0)	16	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Immunosuppressive disease	NE								
	No		24	0 (0.0)	16	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Immunosuppressive treatment	NE								
	Yes		12	0 (0.0)	8	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	No		12	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increase O_2 Intake	CV disease	NE								
	No		24	0 (0.0)	13	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	COPD	NE								
	No		22	0 (0.0)	14	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Chronic liver disease	NE								
	No		21	0 (0.0)	17	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Hypertension	NE								
	Yes		10	0 (0.0)	7	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	No		14	0 (0.0)	10	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Asthma	NE								
	No		19	0 (0.0)	14	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Increase O_2 Intake	Cancer	NE								
	Yes		6	0 (0.0)	4	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	No		18	0 (0.0)	13	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Smoking	NE								
	No		20	0 (0.0)	17	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Sickle cell disease	NE								
	No		24	0 (0.0)	17	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	0 (0.0)	14	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	0 (0.0)	17	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Loss of Appetite	Age at randomization	NE								
	<60 years		13	0 (0.0)	11	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	≥60 years		11	4 (36.4)	6	3 (50.0)	87.69 (32.11, 97.77)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-13.64 (-62.72, 35.44) 0.586
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	3 (20.0)	70.27 (-238.43, 97.39)	0.27 (0.02, 2.90) 0.278	0.31 (0.04, 2.68) 0.289	-13.75 (-37.21, 9.71) 0.251
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	3 (13.6)	16	3 (18.8)	12.45 (-443.50, 85.90)	0.68 (0.12, 3.93) 0.671	0.73 (0.17, 3.15) 0.670	-5.11 (-29.02, 18.79) 0.675
	Residence in long-term care facility	NE								
	No		24	4 (16.7)	17	3 (17.6)	-16.35 (-558.53, 79.44)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-5.38 (-25.04, 14.28) 0.592
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	4 (21.1)	14	3 (21.4)	15.46 (-416.20, 86.15)	0.80 (0.10, 6.35) 0.833	0.89 (0.30, 2.63) 0.831	-2.49 (-25.65, 20.68) 0.833

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Loss of Appetite	Sex	NE								
	Male		9	0 (0.0)	7	1 (14.3)	0.00 (-3800.00, NE)	0.20 (0.00, 8.82) 0.405	0.33 (0.02, 5.33) 0.437	-12.77 (-37.74, 12.21) 0.316
	Female		15	4 (26.7)	10	2 (20.0)	-91.87 (-1470.36, 76.56)	0.80 (0.08, 8.47) 0.853	0.89 (0.26, 3.02) 0.850	-2.67 (-30.91, 25.57) 0.853
	Region	NE								
	North America		7	4 (57.1)	8	2 (25.0)	-1671.43 (-12283.4, -153.40)	2.00 (0.19, 20.61) 0.560	1.43 (0.41, 4.99) 0.576	17.14 (-39.32, 73.60) 0.552
	United Kingdom		8	0 (0.0)	6	1 (16.7)	96.67 (-30.00, NE)	0.05 (0.00, 3.73) 0.171	0.17 (0.01, 2.51) 0.196	-23.08 (-55.47, 9.31) 0.163
	European Union		9	0 (0.0)	3	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Country	NE								
	United States		7	4 (57.1)	8	2 (25.0)	-1671.43 (-12283.4, -153.40)	2.00 (0.19, 20.61) 0.560	1.43 (0.41, 4.99) 0.576	17.14 (-39.32, 73.60) 0.552
	United Kingdom		8	0 (0.0)	6	1 (16.7)	NE (NE, NE)	0.05 (0.00, 3.73) 0.171	0.17 (0.01, 2.51) 0.196	-23.08 (-55.47, 9.31) 0.163
	Race	NE								
	White		24	4 (16.7)	13	2 (15.4)	-31.09 (-816.14, 81.24)	0.86 (0.10, 7.51) 0.889	0.91 (0.24, 3.43) 0.888	-1.49 (-22.68, 19.70) 0.890

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Loss of Appetite	Ethnicity	NE								
	Not Hispanic or Latino		23	4 (17.4)	16	3 (18.8)	-16.29 (-559.37, 79.49)	0.67 (0.09, 5.13) 0.697	0.80 (0.27, 2.41) 0.692	-3.99 (-24.27, 16.29) 0.700
	COVID-19 co-morbidities at baseline	NE								
	None		6	2 (33.3)	6	0 (0.0)	-100.00 (NE, 94.87)	15.00 (0.18, 1236.18) 0.229	3.33 (0.29, 38.75) 0.336	23.08 (-13.14, 59.29) 0.212
	At least one		18	2 (11.1)	11	3 (27.3)	45.93 (-337.65, 93.32)	0.19 (0.02, 2.06) 0.172	0.37 (0.09, 1.53) 0.169	-17.82 (-44.55, 8.91) 0.191
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	4 (16.7)	17	3 (17.6)	-16.35 (-558.53, 79.44)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-5.38 (-25.04, 14.28) 0.592
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	3 (13.6)	16	3 (18.8)	13.87 (-447.43, 86.45)	0.43 (0.05, 3.48) 0.428	0.60 (0.17, 2.07) 0.419	-8.15 (-28.74, 12.44) 0.438
	Obesity (≥ 30 kg/m^2)	NE								
	Yes		8	2 (25.0)	8	2 (25.0)	-308.57 (-5428.09, 69.80)	0.11 (0.00, 3.35) 0.206	0.33 (0.11, 1.03) 0.057	-33.33 (-60.01, -6.66) 0.014

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	2 (12.5)	9	1 (11.1)	22.41 (-1037.48, 94.71)	2.00 (0.11, 35.81) 0.638	1.60 (0.21, 11.92) 0.646	5.89 (-17.33, 29.11) 0.619

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Loss of Appetite	Obesity (≥ 40 kg/m^2)	NE								
	No		22	3 (13.6)	14	2 (14.3)	-14.91 (-756.13, 84.58)	0.64 (0.07, 6.06) 0.699	0.75 (0.18, 3.14) 0.694	-3.93 (-24.37, 16.50) 0.706
	Chronic kidney disease	NE								
	No		21	3 (14.3)	15	3 (20.0)	2.53 (-512.31, 84.48)	0.29 (0.03, 2.69) 0.274	0.50 (0.15, 1.64) 0.252	-11.67 (-32.91, 9.57) 0.282
	Diabetes	NE								
	No		22	3 (13.6)	16	2 (12.5)	-31.32 (-864.04, 82.11)	0.75 (0.08, 7.21) 0.803	0.83 (0.20, 3.44) 0.801	-2.34 (-20.92, 16.24) 0.805
	Immunosuppressive disease	NE								
	No		24	4 (16.7)	16	3 (18.8)	-15.86 (-556.39, 79.55)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-5.55 (-25.91, 14.80) 0.593
	Immunosuppressive treatment	NE								
	Yes		12	3 (25.0)	8	2 (25.0)	-87.10 (-1649.56, 79.99)	0.50 (0.03, 8.95) 0.638	0.75 (0.24, 2.33) 0.618	-7.05 (-36.16, 22.06) 0.635
	No		12	1 (8.3)	9	1 (11.1)	32.76 (-1262.35, 96.68)	0.50 (0.02, 12.90) 0.676	0.60 (0.06, 6.44) 0.673	-4.90 (-28.57, 18.78) 0.685

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Loss of Appetite	CV disease	NE								
	No		24	4 (16.7)	13	1 (7.7)	-202.62 (-3148.45, 71.81)	1.14 (0.08, 16.95) 0.923	1.09 (0.18, 6.48) 0.924	0.89 (-16.93, 18.71) 0.922
	COPD	NE								
	No		22	3 (13.6)	14	1 (7.1)	-189.92 (-3215.90, 74.65)	0.86 (0.05, 13.48) 0.913	0.90 (0.14, 5.78) 0.912	-0.96 (-18.23, 16.32) 0.914
	Chronic liver disease	NE								
	No		21	4 (19.0)	17	3 (17.6)	-31.08 (-651.58, 77.14)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-5.80 (-26.78, 15.17) 0.588
	Hypertension	NE								
	Yes		10	2 (20.0)	7	1 (14.3)	-93.41 (-3088.16, 88.27)	0.80 (0.04, 14.64) 0.880	0.86 (0.12, 6.23) 0.879	-2.62 (-37.08, 31.84) 0.881
	No		14	2 (14.3)	10	2 (20.0)	17.61 (-678.85, 91.29)	0.50 (0.02, 11.09) 0.661	0.75 (0.21, 2.66) 0.656	-4.90 (-27.15, 17.35) 0.666
	Asthma	NE								
	No		19	3 (15.8)	14	2 (14.3)	-26.92 (-883.72, 83.62)	0.90 (0.09, 8.90) 0.928	0.94 (0.23, 3.79) 0.928	-0.96 (-21.87, 19.95) 0.928

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Loss of Appetite	Cancer	NE								
	Yes		6	1 (16.7)	4	0 (0.0)	66.67 (NE, 99.15)	1.80 (0.04, 79.42) 0.761	1.50 (0.10, 22.62) 0.770	11.11 (-16.05, 38.27) 0.423
	No		18	3 (16.7)	13	3 (23.1)	25.21 (-387.70, 88.53)	0.40 (0.04, 3.96) 0.433	0.63 (0.20, 1.97) 0.421	-9.20 (-32.50, 14.09) 0.439
	Smoking	NE								
	No		20	4 (20.0)	17	3 (17.6)	-48.64 (-764.41, 74.44)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-5.99 (-27.56, 15.57) 0.586
	Sickle cell disease	NE								
	No		24	4 (16.7)	17	3 (17.6)	-16.35 (-558.53, 79.44)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-5.38 (-25.04, 14.28) 0.592
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	4 (17.4)	14	3 (21.4)	-1.75 (-486.85, 82.36)	0.44 (0.05, 3.98) 0.468	0.67 (0.23, 1.89) 0.446	-7.71 (-28.94, 13.52) 0.477
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	4 (16.7)	17	3 (17.6)	-16.35 (-558.53, 79.44)	0.57 (0.08, 4.30) 0.587	0.73 (0.24, 2.23) 0.577	-5.38 (-25.04, 14.28) 0.592

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Muscle Aches	Age at randomization	0.642								
	<60 years		13	1 (7.7)	11	5 (45.5)	86.97 (-39.22, 98.78)	0.10 (0.01, 1.06) 0.056	0.17 (0.02, 1.24) 0.080	-37.76 (-70.56, -4.96) 0.024
	≥60 years		11	3 (27.3)	6	3 (50.0)	93.48 (64.11, 98.81)	0.38 (0.05, 3.00) 0.355	0.55 (0.16, 1.91) 0.343	-22.73 (-70.62, 25.16) 0.352
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	8 (53.3)	94.31 (44.09, 99.42)	0.06 (0.01, 0.56) 0.014	0.12 (0.02, 0.83) 0.032	-47.08 (-74.98, -19.19) 0.001
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	3 (13.6)	16	8 (50.0)	83.16 (14.79, 96.67)	0.16 (0.03, 0.75) 0.021	0.27 (0.09, 0.87) 0.028	-36.36 (-64.75, -7.98) 0.012
	Residence in long-term care facility	NE								
	No		24	4 (16.7)	17	8 (47.1)	91.85 (62.90, 98.21)	0.20 (0.04, 0.90) 0.035	0.33 (0.11, 0.96) 0.041	-31.83 (-59.47, -4.19) 0.024

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	4 (21.1)	14	5 (35.7)	90.05 (45.10, 98.20)	0.42 (0.08, 2.18) 0.305	0.56 (0.19, 1.67) 0.303	-15.75 (-45.60, 14.11) 0.301

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Muscle Aches	Sex	0.665								
	Male		9	1 (11.1)	7	4 (57.1)	86.92 (-43.11, 98.80)	0.08 (0.01, 1.22) 0.070	0.19 (0.03, 1.36) 0.098	-46.81 (-88.18, -5.44) 0.027
	Female		15	3 (20.0)	10	4 (40.0)	93.93 (67.58, 98.86)	0.24 (0.03, 1.93) 0.180	0.39 (0.10, 1.55) 0.180	-25.33 (-59.81, 9.14) 0.150
	Region	NE								
	North America		7	3 (42.9)	8	3 (37.5)	77.94 (-98.73, 97.55)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	96.88 (31.70, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	1 (11.1)	3	2 (66.7)	92.98 (28.50, 99.31)	0.07 (0.00, 1.73) 0.105	0.19 (0.03, 1.39) 0.101	-54.17 (-100.00, 3.89) 0.041
	Country	NE								
	United States		7	3 (42.9)	8	3 (37.5)	77.94 (-98.73, 97.55)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	4 (16.7)	13	6 (46.2)	90.53 (54.82, 98.02)	0.23 (0.05, 1.07) 0.062	0.34 (0.11, 1.06) 0.063	-30.19 (-61.32, 0.94) 0.057

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Muscle Aches	Ethnicity	NE								
	Not Hispanic or Latino		23	4 (17.4)	16	8 (50.0)	91.81 (62.72, 98.20)	0.20 (0.04, 0.89) 0.035	0.33 (0.12, 0.95) 0.039	-33.41 (-62.21, -4.61) 0.023
	COVID-19 co-morbidities at baseline	0.944								
	None		6	1 (16.7)	6	2 (33.3)	90.46 (29.24, 98.71)	0.38 (0.02, 6.26) 0.495	0.38 (0.02, 7.89) 0.528	-19.23 (-69.73, 31.27) 0.455
	At least one		18	3 (16.7)	11	6 (54.5)	91.66 (48.64, 98.65)	0.16 (0.03, 0.91) 0.039	0.30 (0.09, 0.96) 0.043	-38.36 (-72.11, -4.62) 0.026
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	4 (16.7)	17	8 (47.1)	91.85 (62.90, 98.21)	0.20 (0.04, 0.90) 0.035	0.33 (0.11, 0.96) 0.041	-31.83 (-59.47, -4.19) 0.024
	High risk for severe COVID-19 at baseline	0.880								
	Yes		22	3 (13.6)	16	7 (43.8)	93.00 (58.50, 98.82)	0.19 (0.04, 0.93) 0.041	0.30 (0.09, 0.99) 0.049	-30.99 (-58.87, -3.10) 0.029
	Obesity (≥ 30 kg/m^2)	0.901								
	Yes		8	2 (25.0)	8	5 (62.5)	93.98 (50.57, 99.27)	0.15 (0.01, 1.65) 0.120	0.22 (0.04, 1.18) 0.077	-58.33 (-86.23, -30.44) <.001

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	2 (12.5)	9	3 (33.3)	89.31 (12.14, 98.70)	0.31 (0.04, 2.27) 0.247	0.39 (0.08, 1.83) 0.233	-20.74 (-56.53, 15.05) 0.256

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Muscle Aches	Obesity (≥ 40 kg/m^2)	0.097								
	No		22	3 (13.6)	14	6 (42.9)	91.57 (46.65, 98.67)	0.20 (0.04, 1.04) 0.056	0.30 (0.09, 1.07) 0.064	-29.78 (-59.41, -0.14) 0.049
	Chronic kidney disease	NE								
	No		21	2 (9.5)	15	8 (53.3)	96.97 (83.80, 99.43)	0.06 (0.01, 0.51) 0.010	0.14 (0.03, 0.69) 0.015	-46.11 (-73.28, -18.94) 0.001
	Diabetes	0.108								
	No		22	3 (13.6)	16	7 (43.8)	92.09 (53.47, 98.65)	0.19 (0.04, 0.96) 0.045	0.29 (0.08, 1.03) 0.055	-30.76 (-58.98, -2.54) 0.033
	Immunosuppressive disease	NE								
	No		24	4 (16.7)	16	8 (50.0)	91.87 (63.05, 98.21)	0.19 (0.04, 0.83) 0.028	0.31 (0.11, 0.91) 0.033	-34.33 (-62.82, -5.85) 0.018
	Immunosuppressive treatment	0.945								
	Yes		12	2 (16.7)	8	4 (50.0)	95.33 (67.99, 99.32)	0.11 (0.01, 1.52) 0.100	0.28 (0.06, 1.23) 0.091	-37.18 (-74.31, -0.05) 0.050
	No		12	2 (16.7)	9	4 (44.4)	90.01 (19.15, 98.76)	0.26 (0.03, 1.90) 0.182	0.37 (0.08, 1.68) 0.200	-27.50 (-66.49, 11.50) 0.167

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Muscle Aches	CV disease	NE								
	No		24	4 (16.7)	13	5 (38.5)	87.40 (20.35, 98.01)	0.26 (0.05, 1.38) 0.113	0.35 (0.09, 1.34) 0.126	-24.58 (-55.00, 5.83) 0.113
	COPD	<.001								
	No		22	2 (9.1)	14	6 (42.9)	95.73 (76.78, 99.21)	0.10 (0.01, 0.79) 0.029	0.14 (0.02, 1.01) 0.051	-36.24 (-64.72, -7.76) 0.013
	Chronic liver disease	NE								
	No		21	4 (19.0)	17	8 (47.1)	91.42 (58.99, 98.20)	0.23 (0.05, 1.05) 0.059	0.37 (0.12, 1.08) 0.070	-30.04 (-58.83, -1.24) 0.041
	Hypertension	0.096								
	Yes		10	3 (30.0)	7	2 (28.6)	47.16 (-1475.79, 98.23)	1.05 (0.12, 9.36) 0.962	1.04 (0.23, 4.66) 0.961	1.12 (-45.00, 47.25) 0.962
	No		14	1 (7.1)	10	6 (60.0)	98.08 (82.72, 99.79)	0.04 (0.00, 0.69) 0.026	0.12 (0.02, 0.83) 0.031	-52.59 (-85.47, -19.71) 0.002
	Asthma	0.512								
	No		19	3 (15.8)	14	5 (35.7)	89.56 (12.76, 98.75)	0.31 (0.06, 1.70) 0.179	0.42 (0.12, 1.51) 0.185	-20.70 (-50.36, 8.96) 0.171

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Muscle Aches	Cancer	NE								
	Yes		6	1 (16.7)	4	0 (0.0)	66.67 (NE, 99.15)	1.80 (0.04, 79.42) 0.761	1.50 (0.10, 22.62) 0.770	11.11 (-16.05, 38.27) 0.423
	No		18	3 (16.7)	13	8 (61.5)	95.08 (75.70, 99.01)	0.12 (0.02, 0.67) 0.015	0.26 (0.08, 0.83) 0.022	-45.34 (-76.84, -13.84) 0.005
	Smoking	NE								
	No		20	4 (20.0)	17	8 (47.1)	90.94 (54.10, 98.21)	0.24 (0.05, 1.13) 0.071	0.38 (0.13, 1.14) 0.084	-29.24 (-58.59, 0.11) 0.051
	Sickle cell disease	NE								
	No		24	4 (16.7)	17	8 (47.1)	91.85 (62.90, 98.21)	0.20 (0.04, 0.90) 0.035	0.33 (0.11, 0.96) 0.041	-31.83 (-59.47, -4.19) 0.024
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	4 (17.4)	14	8 (57.1)	93.37 (71.19, 98.48)	0.14 (0.03, 0.69) 0.016	0.28 (0.10, 0.80) 0.018	-40.98 (-70.72, -11.24) 0.007

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	4 (16.7)	17	8 (47.1)	91.85 (62.90, 98.21)	0.20 (0.04, 0.90) 0.035	0.33 (0.11, 0.96) 0.041	-31.83 (-59.47, -4.19) 0.024

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Nausea	Age at randomization	NE								
	<60 years		13	0 (0.0)	11	2 (18.2)	NE (NE, NE)	0.14 (0.01, 3.28) 0.222	0.17 (0.01, 3.23) 0.239	-18.18 (-40.97, 4.61) 0.118
	≥60 years		11	3 (27.3)	6	2 (33.3)	55.80 (-418.31, 96.23)	0.75 (0.09, 6.47) 0.794	0.82 (0.18, 3.62) 0.791	-6.06 (-52.05, 39.93) 0.796
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	4 (26.7)	80.31 (-111.95, 98.17)	0.18 (0.02, 1.88) 0.153	0.23 (0.03, 1.87) 0.171	-20.42 (-45.74, 4.91) 0.114
	≥65 years		8	2 (25.0)	2	0 (0.0)	NE (NE, NE)	1.92 (0.07, 55.84) 0.704	1.67 (0.11, 25.83) 0.715	25.00 (-5.01, 55.01) 0.102
	Age at randomization	NE								
	<75 years		22	3 (13.6)	16	4 (25.0)	46.05 (-191.92, 90.03)	0.47 (0.09, 2.50) 0.378	0.55 (0.14, 2.11) 0.379	-11.36 (-36.97, 14.25) 0.384
	Residence in long-term care facility	NE								
	No		24	3 (12.5)	17	4 (23.5)	70.75 (-100.40, 95.73)	0.35 (0.06, 2.16) 0.257	0.45 (0.11, 1.81) 0.258	-13.40 (-36.41, 9.61) 0.254

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	3 (15.8)	14	4 (28.6)	73.85 (-77.14, 96.14)	0.42 (0.07, 2.51) 0.340	0.52 (0.14, 1.98) 0.337	-13.81 (-41.81, 14.19) 0.334

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Nausea	Sex	NE								
	Male		9	0 (0.0)	7	1 (14.3)	0.00 (-3800.00, NE)	0.20 (0.00, 8.82) 0.405	0.33 (0.02, 5.33) 0.437	-12.77 (-37.74, 12.21) 0.316
	Female		15	3 (20.0)	10	3 (30.0)	57.55 (-205.53, 94.10)	0.47 (0.07, 3.37) 0.455	0.55 (0.10, 2.87) 0.474	-13.33 (-48.23, 21.56) 0.454
	Region	NE								
	North America		7	3 (42.9)	8	2 (25.0)	-77.78 (-3055.07, 89.98)	3.00 (0.21, 42.62) 0.417	2.14 (0.30, 15.07) 0.444	22.86 (-27.87, 73.58) 0.377
	United Kingdom		8	0 (0.0)	6	2 (33.3)	96.75 (4.86, NE)	0.14 (0.01, 2.08) 0.153	0.23 (0.03, 1.70) 0.149	-38.46 (-75.86, -1.06) 0.044
	European Union		9	0 (0.0)	3	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Country	NE								
	United States		7	3 (42.9)	8	2 (25.0)	-77.78 (-3055.07, 89.98)	3.00 (0.21, 42.62) 0.417	2.14 (0.30, 15.07) 0.444	22.86 (-27.87, 73.58) 0.377
	United Kingdom		8	0 (0.0)	6	2 (33.3)	NE (NE, NE)	0.14 (0.01, 2.08) 0.153	0.23 (0.03, 1.70) 0.149	-38.46 (-75.86, -1.06) 0.044
	Race	NE								
	White		24	3 (12.5)	13	2 (15.4)	48.23 (-352.98, 94.08)	0.67 (0.09, 5.11) 0.699	0.72 (0.13, 3.88) 0.700	-4.40 (-27.34, 18.54) 0.707

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Nausea	Ethnicity	NE								
	Not Hispanic or Latino		23	3 (13.0)	16	4 (25.0)	70.59 (-101.55, 95.71)	0.37 (0.06, 2.26) 0.284	0.47 (0.12, 1.84) 0.280	-13.35 (-37.63, 10.92) 0.281
	COVID-19 co-morbidities at baseline	NE								
	None		6	1 (16.7)	6	0 (0.0)	96.55 (NE, 99.91)	3.00 (0.06, 151.19) 0.583	2.00 (0.14, 28.42) 0.609	11.54 (-15.20, 38.27) 0.398
	At least one		18	2 (11.1)	11	4 (36.4)	76.41 (-78.26, 96.88)	0.19 (0.03, 1.49) 0.115	0.29 (0.06, 1.36) 0.115	-26.00 (-57.39, 5.40) 0.105
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	3 (12.5)	17	4 (23.5)	70.75 (-100.40, 95.73)	0.35 (0.06, 2.16) 0.257	0.45 (0.11, 1.81) 0.258	-13.40 (-36.41, 9.61) 0.254
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	3 (13.6)	16	4 (25.0)	63.88 (-143.46, 94.64)	0.38 (0.06, 2.33) 0.297	0.48 (0.12, 1.90) 0.296	-13.21 (-37.73, 11.32) 0.291
	Obesity (≥ 30 kg/m^2)	0.593								
	Yes		8	2 (25.0)	8	3 (37.5)	-2.23 (-1560.39, 93.71)	0.25 (0.01, 4.63) 0.352	0.40 (0.05, 3.12) 0.382	-25.00 (-70.47, 20.47) 0.281

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	1 (6.3)	9	1 (11.1)	65.25 (-608.55, 98.30)	0.75 (0.03, 17.51) 0.858	0.80 (0.07, 9.18) 0.858	-1.96 (-23.91, 19.99) 0.861

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Nausea	Obesity (≥ 40 kg/m^2)	NE								
	No		22	2 (9.1)	14	4 (28.6)	95.25 (70.73, 99.23)	0.18 (0.02, 1.46) 0.109	0.27 (0.05, 1.35) 0.110	-21.35 (-46.89, 4.19) 0.101
	Chronic kidney disease	NE								
	No		21	2 (9.5)	15	4 (26.7)	79.28 (-67.71, 97.44)	0.19 (0.02, 1.58) 0.124	0.28 (0.05, 1.45) 0.130	-20.00 (-44.52, 4.52) 0.110
	Diabetes	0.079								
	No		22	2 (9.1)	16	3 (18.8)	67.48 (-162.32, 95.97)	0.36 (0.05, 2.79) 0.329	0.41 (0.07, 2.51) 0.337	-11.03 (-33.17, 11.10) 0.329
	Immunosuppressive disease	NE								
	No		24	3 (12.5)	16	4 (25.0)	70.79 (-100.05, 95.73)	0.34 (0.06, 2.08) 0.243	0.44 (0.11, 1.74) 0.241	-14.32 (-38.34, 9.70) 0.242
	Immunosuppressive treatment	NE								
	Yes		12	3 (25.0)	8	2 (25.0)	-3.04 (-876.08, 89.12)	0.76 (0.08, 7.20) 0.810	0.83 (0.17, 4.07) 0.813	-4.49 (-40.98, 32.01) 0.810
	No		12	0 (0.0)	9	2 (22.2)	95.60 (18.07, NE)	0.19 (0.02, 2.24) 0.189	0.25 (0.03, 2.09) 0.203	-22.79 (-50.16, 4.58) 0.103

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Nausea	CV disease	NE								
	No		24	3 (12.5)	13	1 (7.7)	-13.73 (-959.76, 87.79)	1.14 (0.09, 14.45) 0.921	1.14 (0.07, 19.03) 0.929	0.97 (-17.92, 19.86) 0.920
	COPD	0.601								
	No		22	2 (9.1)	14	2 (14.3)	47.69 (-222.64, 91.52)	0.44 (0.04, 4.60) 0.495	0.44 (0.03, 6.02) 0.540	-7.23 (-28.67, 14.21) 0.509
	Chronic liver disease	NE								
	No		21	3 (14.3)	17	4 (23.5)	69.66 (-111.42, 95.65)	0.37 (0.06, 2.39) 0.298	0.47 (0.11, 1.99) 0.307	-13.02 (-36.94, 10.89) 0.286
	Hypertension	0.686								
	Yes		10	2 (20.0)	7	2 (28.6)	90.23 (37.69, 98.47)	0.43 (0.03, 5.36) 0.513	0.53 (0.08, 3.76) 0.527	-13.86 (-54.87, 27.16) 0.508
	No		14	1 (7.1)	10	2 (20.0)	70.39 (-387.54, 98.20)	0.28 (0.02, 4.51) 0.370	0.37 (0.04, 3.12) 0.361	-12.54 (-39.65, 14.58) 0.365
	Asthma	0.931								
	No		19	2 (10.5)	14	3 (21.4)	68.00 (-161.74, 96.09)	0.39 (0.05, 2.95) 0.365	0.45 (0.08, 2.58) 0.369	-11.79 (-37.14, 13.57) 0.362

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Nausea	Cancer	0.714								
	Yes		6	1 (16.7)	4	1 (25.0)	55.28 (-349.24, 95.55)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	2 (11.1)	13	3 (23.1)	76.10 (-129.34, 97.51)	0.31 (0.03, 2.79) 0.298	0.43 (0.09, 2.08) 0.294	-13.52 (-38.89, 11.84) 0.296
	Smoking	NE								
	No		20	3 (15.0)	17	4 (23.5)	68.48 (-124.64, 95.58)	0.38 (0.06, 2.49) 0.315	0.48 (0.11, 2.07) 0.327	-12.85 (-37.20, 11.49) 0.301
	Sickle cell disease	NE								
	No		24	3 (12.5)	17	4 (23.5)	70.75 (-100.40, 95.73)	0.35 (0.06, 2.16) 0.257	0.45 (0.11, 1.81) 0.258	-13.40 (-36.41, 9.61) 0.254
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	3 (13.0)	14	4 (28.6)	72.46 (-91.65, 96.04)	0.28 (0.04, 1.86) 0.190	0.40 (0.10, 1.53) 0.181	-17.51 (-43.54, 8.51) 0.187
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	3 (12.5)	17	4 (23.5)	70.75 (-100.40, 95.73)	0.35 (0.06, 2.16) 0.257	0.45 (0.11, 1.81) 0.258	-13.40 (-36.41, 9.61) 0.254

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Smell	Age at randomization	NE								
	<60 years		13	0 (0.0)	11	2 (18.2)	NE (NE, NE)	0.14 (0.01, 3.28) 0.222	0.17 (0.01, 3.23) 0.239	-18.18 (-40.97, 4.61) 0.118
	≥60 years		11	2 (18.2)	6	2 (33.3)	73.44 (-243.89, 97.95)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-15.15 (-59.22, 28.92) 0.500
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	4 (26.7)	80.08 (-109.15, 98.10)	0.18 (0.02, 1.88) 0.153	0.23 (0.03, 1.87) 0.171	-20.42 (-45.74, 4.91) 0.114
	≥65 years		8	1 (12.5)	2	0 (0.0)	NE (NE, NE)	1.00 (0.03, 33.32) 1.000	1.00 (0.05, 18.57) 1.000	12.50 (-10.42, 35.42) 0.285
	Age at randomization	NE								
	<75 years		22	2 (9.1)	16	4 (25.0)	65.28 (-124.73, 94.64)	0.30 (0.05, 1.89) 0.200	0.36 (0.08, 1.75) 0.207	-15.91 (-40.29, 8.47) 0.201
	Residence in long-term care facility	NE								
	No		24	2 (8.3)	17	4 (23.5)	81.39 (-47.93, 97.66)	0.22 (0.03, 1.65) 0.141	0.30 (0.06, 1.53) 0.147	-16.99 (-39.22, 5.25) 0.134

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	2 (10.5)	14	2 (14.3)	40.60 (-401.97, 92.97)	0.57 (0.06, 5.77) 0.635	0.67 (0.13, 3.53) 0.633	-4.97 (-25.98, 16.04) 0.643

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Smell	Sex	NE								
	Male		9	0 (0.0)	7	1 (14.3)	37.32 (-2344.37, NE)	0.20 (0.01, 6.04) 0.355	0.25 (0.01, 5.13) 0.368	-14.89 (-41.24, 11.45) 0.268
	Female		15	2 (13.3)	10	3 (30.0)	96.13 (78.55, 99.30)	0.20 (0.02, 2.12) 0.180	0.33 (0.06, 1.65) 0.176	-22.00 (-53.05, 9.05) 0.165
	Region	NE								
	North America		7	1 (14.3)	8	2 (25.0)	66.32 (-798.35, 98.74)	0.67 (0.03, 14.03) 0.794	0.71 (0.06, 8.90) 0.794	-5.71 (-49.32, 37.89) 0.797
	United Kingdom		8	0 (0.0)	6	2 (33.3)	93.64 (-60.35, NE)	0.14 (0.01, 2.08) 0.153	0.23 (0.03, 1.70) 0.149	-38.46 (-75.86, -1.06) 0.044
	European Union		9	1 (11.1)	3	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	0.00 (0.00, 0.00) NE
	Country	NE								
	United States		7	1 (14.3)	8	2 (25.0)	66.32 (-798.35, 98.74)	0.67 (0.03, 14.03) 0.794	0.71 (0.06, 8.90) 0.794	-5.71 (-49.32, 37.89) 0.797
	United Kingdom		8	0 (0.0)	6	2 (33.3)	NE (NE, NE)	0.14 (0.01, 2.08) 0.153	0.23 (0.03, 1.70) 0.149	-38.46 (-75.86, -1.06) 0.044

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	2 (8.3)	13	3 (23.1)	95.58 (75.48, 99.20)	0.22 (0.02, 1.90) 0.167	0.31 (0.06, 1.57) 0.159	-16.32 (-40.55, 7.91) 0.187

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Smell	Ethnicity	NE								
	Not Hispanic or Latino		23	2 (8.7)	16	4 (25.0)	81.30 (-48.56, 97.65)	0.23 (0.03, 1.72) 0.154	0.32 (0.06, 1.55) 0.155	-17.34 (-40.77, 6.09) 0.147
	COVID-19 co-morbidities at baseline	NE								
	None		6	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	At least one		18	2 (11.1)	11	4 (36.4)	73.05 (-113.48, 96.60)	0.19 (0.03, 1.49) 0.115	0.29 (0.06, 1.36) 0.115	-26.00 (-57.39, 5.40) 0.105
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	2 (8.3)	17	4 (23.5)	81.39 (-47.93, 97.66)	0.22 (0.03, 1.65) 0.141	0.30 (0.06, 1.53) 0.147	-16.99 (-39.22, 5.25) 0.134
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	2 (9.1)	16	4 (25.0)	77.70 (-74.00, 97.14)	0.24 (0.03, 1.77) 0.162	0.32 (0.06, 1.60) 0.166	-17.28 (-40.90, 6.33) 0.151
	Obesity (≥ 30 kg/m^2)	0.973								
	Yes		8	1 (12.5)	8	3 (37.5)	58.28 (-997.95, 98.41)	0.11 (0.00, 3.43) 0.209	0.20 (0.01, 3.20) 0.255	-33.33 (-75.51, 8.84) 0.121
	No		16	1 (6.3)	9	1 (11.1)	65.13 (-590.97, 98.24)	0.75 (0.03, 17.51) 0.858	0.80 (0.07, 9.18) 0.858	-1.96 (-23.91, 19.99) 0.861

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Smell	Obesity (≥ 40 kg/m^2)	NE								
	No		22	2 (9.1)	14	2 (14.3)	58.29 (-301.02, 95.66)	0.48 (0.05, 4.47) 0.521	0.54 (0.08, 3.61) 0.524	-6.74 (-27.99, 14.50) 0.534
	Chronic kidney disease	NE								
	No		21	1 (4.8)	15	4 (26.7)	89.73 (-32.25, 99.20)	0.09 (0.01, 1.22) 0.070	0.14 (0.01, 1.31) 0.085	-23.89 (-47.54, -0.24) 0.048
	Diabetes	NE								
	No		22	2 (9.1)	16	4 (25.0)	94.61 (71.22, 98.99)	0.21 (0.03, 1.68) 0.140	0.30 (0.06, 1.49) 0.142	-18.04 (-41.20, 5.12) 0.127
	Immunosuppressive disease	NE								
	No		24	2 (8.3)	16	4 (25.0)	81.41 (-47.64, 97.66)	0.21 (0.03, 1.59) 0.132	0.29 (0.06, 1.47) 0.136	-18.03 (-41.27, 5.21) 0.128
	Immunosuppressive treatment	0.826								
	Yes		12	1 (8.3)	8	2 (25.0)	75.91 (-290.31, 98.51)	0.20 (0.01, 3.53) 0.273	0.28 (0.03, 2.89) 0.282	-18.59 (-51.48, 14.30) 0.268
	No		12	1 (8.3)	9	2 (22.2)	90.92 (4.73, 99.14)	0.24 (0.01, 4.15) 0.327	0.32 (0.03, 3.16) 0.331	-15.44 (-45.58, 14.69) 0.315

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Smell	CV disease	NE								
	No		24	2 (8.3)	13	3 (23.1)	95.98 (73.01, 99.40)	0.16 (0.02, 1.72) 0.131	0.22 (0.03, 1.65) 0.142	-18.57 (-43.13, 5.98) 0.138
	COPD	0.005								
	No		22	1 (4.5)	14	3 (21.4)	97.71 (72.88, 99.81)	0.09 (0.00, 1.65) 0.105	0.13 (0.01, 1.84) 0.130	-19.66 (-42.49, 3.17) 0.091
	Chronic liver disease	NE								
	No		21	2 (9.5)	17	4 (23.5)	80.71 (-56.89, 97.63)	0.23 (0.03, 1.83) 0.166	0.31 (0.06, 1.70) 0.179	-16.89 (-39.84, 6.06) 0.149
	Hypertension	NE								
	Yes		10	2 (20.0)	7	1 (14.3)	-59.04 (-2078.61, 88.39)	1.40 (0.09, 22.75) 0.813	1.40 (0.06, 32.72) 0.834	4.49 (-31.88, 40.87) 0.809
	No		14	0 (0.0)	10	3 (30.0)	98.32 (79.74, NE)	0.12 (0.01, 1.39) 0.090	0.19 (0.02, 1.48) 0.114	-29.68 (-58.06, -1.30) 0.040
	Asthma	NE								
	No		19	2 (10.5)	14	2 (14.3)	27.46 (-518.24, 91.49)	0.50 (0.05, 5.51) 0.571	0.63 (0.12, 3.13) 0.567	-5.75 (-26.18, 14.69) 0.581

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Smell	Cancer	NE								
	Yes		6	1 (16.7)	4	0 (0.0)	90.00 (NE, 99.74)	1.80 (0.04, 79.42) 0.761	1.50 (0.10, 22.62) 0.770	11.11 (-16.05, 38.27) 0.423
	No		18	1 (5.6)	13	4 (30.8)	90.53 (-15.64, 99.22)	0.11 (0.01, 1.33) 0.082	0.16 (0.02, 1.36) 0.094	-26.02 (-52.68, 0.64) 0.056
	Smoking	NE								
	No		20	2 (10.0)	17	4 (23.5)	79.99 (-67.38, 97.61)	0.24 (0.03, 1.91) 0.177	0.32 (0.06, 1.77) 0.193	-16.85 (-40.14, 6.44) 0.156
	Sickle cell disease	NE								
	No		24	2 (8.3)	17	4 (23.5)	81.39 (-47.93, 97.66)	0.22 (0.03, 1.65) 0.141	0.30 (0.06, 1.53) 0.147	-16.99 (-39.22, 5.25) 0.134
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	2 (8.7)	14	4 (28.6)	82.47 (-40.00, 97.80)	0.18 (0.02, 1.42) 0.103	0.27 (0.05, 1.30) 0.102	-21.37 (-46.74, 4.01) 0.099
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	2 (8.3)	17	4 (23.5)	81.39 (-47.93, 97.66)	0.22 (0.03, 1.65) 0.141	0.30 (0.06, 1.53) 0.147	-16.99 (-39.22, 5.25) 0.134

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Taste	Age at randomization	NE								
	<60 years		13	0 (0.0)	11	2 (18.2)	NE (NE, NE)	0.14 (0.01, 3.28) 0.222	0.17 (0.01, 3.23) 0.239	-18.18 (-40.97, 4.61) 0.118
	≥60 years		11	2 (18.2)	6	2 (33.3)	73.44 (-243.89, 97.95)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-15.15 (-59.22, 28.92) 0.500
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	4 (26.7)	79.89 (-110.00, 98.07)	0.18 (0.02, 1.88) 0.153	0.23 (0.03, 1.87) 0.171	-20.42 (-45.74, 4.91) 0.114
	≥65 years		8	1 (12.5)	2	0 (0.0)	NE (NE, NE)	1.00 (0.03, 33.32) 1.000	1.00 (0.05, 18.57) 1.000	12.50 (-10.42, 35.42) 0.285
	Age at randomization	NE								
	<75 years		22	2 (9.1)	16	4 (25.0)	64.95 (-125.33, 94.55)	0.30 (0.05, 1.89) 0.200	0.36 (0.08, 1.75) 0.207	-15.91 (-40.29, 8.47) 0.201
	Residence in long-term care facility	NE								
	No		24	2 (8.3)	17	4 (23.5)	81.34 (-48.41, 97.65)	0.22 (0.03, 1.65) 0.141	0.30 (0.06, 1.53) 0.147	-16.99 (-39.22, 5.25) 0.134

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	2 (10.5)	14	2 (14.3)	40.60 (-401.97, 92.97)	0.57 (0.06, 5.77) 0.635	0.67 (0.13, 3.53) 0.633	-4.97 (-25.98, 16.04) 0.643

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Taste	Sex	NE								
	Male		9	0 (0.0)	7	1 (14.3)	36.62 (-2371.83, NE)	0.20 (0.01, 6.04) 0.355	0.25 (0.01, 5.13) 0.368	-14.89 (-41.24, 11.45) 0.268
	Female		15	2 (13.3)	10	3 (30.0)	96.13 (78.54, 99.30)	0.20 (0.02, 2.12) 0.180	0.33 (0.06, 1.65) 0.176	-22.00 (-53.05, 9.05) 0.165
	Region	NE								
	North America		7	1 (14.3)	8	2 (25.0)	65.26 (-772.34, 98.62)	0.67 (0.03, 14.03) 0.794	0.71 (0.06, 8.90) 0.794	-5.71 (-49.32, 37.89) 0.797
	United Kingdom		8	0 (0.0)	6	2 (33.3)	96.75 (4.63, NE)	0.14 (0.01, 2.08) 0.153	0.23 (0.03, 1.70) 0.149	-38.46 (-75.86, -1.06) 0.044
	European Union		9	1 (11.1)	3	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	0.00 (0.00, 0.00) NE
	Country	NE								
	United States		7	1 (14.3)	8	2 (25.0)	65.26 (-772.34, 98.62)	0.67 (0.03, 14.03) 0.794	0.71 (0.06, 8.90) 0.794	-5.71 (-49.32, 37.89) 0.797
	United Kingdom		8	0 (0.0)	6	2 (33.3)	NE (NE, NE)	0.14 (0.01, 2.08) 0.153	0.23 (0.03, 1.70) 0.149	-38.46 (-75.86, -1.06) 0.044

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	2 (8.3)	13	3 (23.1)	95.58 (75.46, 99.20)	0.22 (0.02, 1.90) 0.167	0.31 (0.06, 1.57) 0.159	-16.32 (-40.55, 7.91) 0.187

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Taste	Ethnicity	NE								
	Not Hispanic or Latino		23	2 (8.7)	16	4 (25.0)	81.25 (-49.05, 97.64)	0.23 (0.03, 1.72) 0.154	0.32 (0.06, 1.55) 0.155	-17.34 (-40.77, 6.09) 0.147
	COVID-19 co-morbidities at baseline	NE								
	None		6	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	At least one		18	2 (11.1)	11	4 (36.4)	72.88 (-114.33, 96.57)	0.19 (0.03, 1.49) 0.115	0.29 (0.06, 1.36) 0.115	-26.00 (-57.39, 5.40) 0.105
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	2 (8.3)	17	4 (23.5)	81.34 (-48.41, 97.65)	0.22 (0.03, 1.65) 0.141	0.30 (0.06, 1.53) 0.147	-16.99 (-39.22, 5.25) 0.134
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	2 (9.1)	16	4 (25.0)	77.62 (-74.60, 97.13)	0.24 (0.03, 1.77) 0.162	0.32 (0.06, 1.60) 0.166	-17.28 (-40.90, 6.33) 0.151
	Obesity (≥ 30 kg/m^2)	0.937								
	Yes		8	1 (12.5)	8	3 (37.5)	56.86 (-960.54, 98.24)	0.11 (0.00, 3.43) 0.209	0.20 (0.01, 3.20) 0.255	-33.33 (-75.51, 8.84) 0.121
	No		16	1 (6.3)	9	1 (11.1)	65.52 (-595.64, 98.29)	0.75 (0.03, 17.51) 0.858	0.80 (0.07, 9.18) 0.858	-1.96 (-23.91, 19.99) 0.861

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Taste	Obesity (≥ 40 kg/m^2)	NE								
	No		22	2 (9.1)	14	2 (14.3)	59.22 (-309.90, 95.94)	0.48 (0.05, 4.47) 0.521	0.54 (0.08, 3.61) 0.524	-6.74 (-27.99, 14.50) 0.534
	Chronic kidney disease	NE								
	No		21	1 (4.8)	15	4 (26.7)	89.71 (-32.77, 99.20)	0.09 (0.01, 1.22) 0.070	0.14 (0.01, 1.31) 0.085	-23.89 (-47.54, -0.24) 0.048
	Diabetes	NE								
	No		22	2 (9.1)	16	4 (25.0)	94.60 (71.16, 98.99)	0.21 (0.03, 1.68) 0.140	0.30 (0.06, 1.49) 0.142	-18.04 (-41.20, 5.12) 0.127
	Immunosuppressive disease	NE								
	No		24	2 (8.3)	16	4 (25.0)	81.36 (-48.12, 97.66)	0.21 (0.03, 1.59) 0.132	0.29 (0.06, 1.47) 0.136	-18.03 (-41.27, 5.21) 0.128
	Immunosuppressive treatment	0.771								
	Yes		12	1 (8.3)	8	2 (25.0)	75.21 (-280.97, 98.39)	0.20 (0.01, 3.53) 0.273	0.28 (0.03, 2.89) 0.282	-18.59 (-51.48, 14.30) 0.268
	No		12	1 (8.3)	9	2 (22.2)	92.83 (10.27, 99.43)	0.24 (0.01, 4.15) 0.327	0.32 (0.03, 3.16) 0.331	-15.44 (-45.58, 14.69) 0.315

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Taste	CV disease	NE								
	No		24	2 (8.3)	13	3 (23.1)	94.83 (73.09, 99.01)	0.16 (0.02, 1.72) 0.131	0.22 (0.03, 1.65) 0.142	-18.57 (-43.13, 5.98) 0.138
	COPD	0.007								
	No		22	1 (4.5)	14	3 (21.4)	97.02 (71.78, 99.69)	0.09 (0.00, 1.65) 0.105	0.13 (0.01, 1.84) 0.130	-19.66 (-42.49, 3.17) 0.091
	Chronic liver disease	NE								
	No		21	2 (9.5)	17	4 (23.5)	80.66 (-57.42, 97.62)	0.23 (0.03, 1.83) 0.166	0.31 (0.06, 1.70) 0.179	-16.89 (-39.84, 6.06) 0.149
	Hypertension	NE								
	Yes		10	2 (20.0)	7	1 (14.3)	-60.02 (-2056.19, 88.12)	1.40 (0.09, 22.75) 0.813	1.40 (0.06, 32.72) 0.834	4.49 (-31.88, 40.87) 0.809
	No		14	0 (0.0)	10	3 (30.0)	98.32 (79.72, NE)	0.12 (0.01, 1.39) 0.090	0.19 (0.02, 1.48) 0.114	-29.68 (-58.06, -1.30) 0.040
	Asthma	NE								
	No		19	2 (10.5)	14	2 (14.3)	27.46 (-518.24, 91.49)	0.50 (0.05, 5.51) 0.571	0.63 (0.12, 3.13) 0.567	-5.75 (-26.18, 14.69) 0.581

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
New Loss of Taste	Cancer	NE								
	Yes		6	1 (16.7)	4	0 (0.0)	90.00 (NE, 99.74)	1.80 (0.04, 79.42) 0.761	1.50 (0.10, 22.62) 0.770	11.11 (-16.05, 38.27) 0.423
	No		18	1 (5.6)	13	4 (30.8)	90.48 (-16.25, 99.22)	0.11 (0.01, 1.33) 0.082	0.16 (0.02, 1.36) 0.094	-26.02 (-52.68, 0.64) 0.056
	Smoking	NE								
	No		20	2 (10.0)	17	4 (23.5)	79.95 (-67.97, 97.61)	0.24 (0.03, 1.91) 0.177	0.32 (0.06, 1.77) 0.193	-16.85 (-40.14, 6.44) 0.156
	Sickle cell disease	NE								
	No		24	2 (8.3)	17	4 (23.5)	81.34 (-48.41, 97.65)	0.22 (0.03, 1.65) 0.141	0.30 (0.06, 1.53) 0.147	-16.99 (-39.22, 5.25) 0.134
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	2 (8.7)	14	4 (28.6)	82.41 (-40.52, 97.80)	0.18 (0.02, 1.42) 0.103	0.27 (0.05, 1.30) 0.102	-21.37 (-46.74, 4.01) 0.099
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	2 (8.3)	17	4 (23.5)	81.34 (-48.41, 97.65)	0.22 (0.03, 1.65) 0.141	0.30 (0.06, 1.53) 0.147	-16.99 (-39.22, 5.25) 0.134

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Runny Nose	Age at randomization	0.026								
	<60 years		13	3 (23.1)	11	4 (36.4)	38.02 (-276.58, 89.80)	0.53 (0.09, 3.12) 0.478	0.63 (0.18, 2.24) 0.481	-13.29 (-49.79, 23.22) 0.476
	≥60 years		11	2 (18.2)	6	3 (50.0)	96.64 (79.05, 99.46)	0.22 (0.02, 2.04) 0.183	0.36 (0.08, 1.61) 0.182	-31.82 (-77.86, 14.23) 0.176
	Age at randomization	NE								
	<65 years		16	3 (18.8)	15	7 (46.7)	76.88 (-20.39, 95.56)	0.26 (0.05, 1.32) 0.106	0.40 (0.13, 1.27) 0.122	-27.92 (-59.59, 3.76) 0.084
	≥65 years		8	2 (25.0)	2	0 (0.0)	NE (NE, NE)	1.92 (0.07, 55.84) 0.704	1.67 (0.11, 25.83) 0.715	25.00 (-5.01, 55.01) 0.102
	Age at randomization	NE								
	<75 years		22	5 (22.7)	16	7 (43.8)	62.15 (-71.57, 91.65)	0.38 (0.09, 1.54) 0.174	0.52 (0.20, 1.34) 0.177	-21.02 (-50.98, 8.94) 0.169
	Residence in long-term care facility	NE								
	No		24	5 (20.8)	17	7 (41.2)	83.45 (-26.56, 97.84)	0.38 (0.10, 1.50) 0.166	0.51 (0.20, 1.32) 0.163	-20.60 (-49.40, 8.20) 0.161

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	0.027								
	No		19	4 (21.1)	14	6 (42.9)	91.17 (48.43, 98.49)	0.35 (0.08, 1.62) 0.179	0.49 (0.17, 1.40) 0.182	-22.10 (-53.80, 9.60) 0.172

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Runny Nose	Sex	0.063								
	Male		9	2 (22.2)	7	2 (28.6)	17.43 (-506.36, 88.76)	0.73 (0.08, 6.61) 0.777	0.77 (0.12, 4.94) 0.782	-6.38 (-50.91, 38.14) 0.779
	Female		15	3 (20.0)	10	5 (50.0)	92.68 (21.19, 99.32)	0.24 (0.04, 1.49) 0.125	0.39 (0.11, 1.34) 0.134	-30.67 (-68.14, 6.80) 0.109
	Region	NE								
	North America		7	2 (28.6)	8	3 (37.5)	91.80 (30.47, 99.03)	0.60 (0.05, 6.79) 0.680	0.71 (0.15, 3.50) 0.678	-11.43 (-65.87, 43.01) 0.681
	United Kingdom		8	0 (0.0)	6	3 (50.0)	96.89 (32.11, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	3 (33.3)	3	1 (33.3)	35.71 (-1081.16, 96.50)	1.20 (0.07, 19.63) 0.898	1.13 (0.18, 7.04) 0.900	4.17 (-58.85, 67.18) 0.897
	Country	NE								
	United States		7	2 (28.6)	8	3 (37.5)	91.80 (30.47, 99.03)	0.60 (0.05, 6.79) 0.680	0.71 (0.15, 3.50) 0.678	-11.43 (-65.87, 43.01) 0.681
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	5 (20.8)	13	5 (38.5)	77.13 (-89.10, 97.23)	0.43 (0.10, 1.89) 0.262	0.55 (0.19, 1.54) 0.254	-17.45 (-48.63, 13.73) 0.273

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Runny Nose	Ethnicity	NE								
	Not Hispanic or Latino		23	5 (21.7)	16	7 (43.8)	83.46 (-25.24, 97.82)	0.36 (0.09, 1.45) 0.149	0.50 (0.19, 1.28) 0.149	-22.14 (-51.83, 7.56) 0.144
	COVID-19 co-morbidities at baseline	0.842								
	None		6	1 (16.7)	6	1 (16.7)	47.37 (-1161.66, 97.80)	1.33 (0.06, 31.12) 0.858	1.25 (0.11, 14.34) 0.858	3.85 (-38.26, 45.95) 0.858
	At least one		18	4 (22.2)	11	6 (54.5)	86.20 (17.52, 97.69)	0.24 (0.05, 1.21) 0.083	0.41 (0.15, 1.12) 0.082	-32.49 (-67.63, 2.64) 0.070
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	5 (20.8)	17	7 (41.2)	83.45 (-26.56, 97.84)	0.38 (0.10, 1.50) 0.166	0.51 (0.20, 1.32) 0.163	-20.60 (-49.40, 8.20) 0.161
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	5 (22.7)	16	6 (37.5)	76.90 (-94.15, 97.25)	0.49 (0.12, 2.00) 0.319	0.60 (0.22, 1.61) 0.313	-15.19 (-45.00, 14.63) 0.318
	Obesity (≥ 30 kg/m^2)	0.949								
	Yes		8	2 (25.0)	8	5 (62.5)	93.98 (50.58, 99.27)	0.15 (0.01, 1.65) 0.120	0.22 (0.04, 1.18) 0.077	-58.33 (-86.23, -30.44) <.001

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	3 (18.8)	9	2 (22.2)	54.42 (-563.92, 96.87)	0.71 (0.09, 5.58) 0.745	0.75 (0.13, 4.30) 0.751	-5.40 (-38.58, 27.78) 0.750

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Runny Nose	Obesity (≥ 40 kg/m^2)	0.390								
	No		22	4 (18.2)	14	5 (35.7)	74.47 (-204.48, 97.86)	0.43 (0.09, 1.96) 0.272	0.53 (0.18, 1.61) 0.263	-16.85 (-47.21, 13.50) 0.277
	Chronic kidney disease	NE								
	No		21	3 (14.3)	15	7 (46.7)	92.78 (26.64, 99.29)	0.20 (0.04, 0.97) 0.045	0.31 (0.10, 0.99) 0.048	-32.78 (-62.77, -2.78) 0.032
	Diabetes	0.556								
	No		22	4 (18.2)	16	6 (37.5)	77.77 (-125.93, 97.81)	0.39 (0.09, 1.70) 0.209	0.50 (0.17, 1.46) 0.207	-18.75 (-47.81, 10.30) 0.206
	Immunosuppressive disease	NE								
	No		24	5 (20.8)	16	7 (43.8)	83.53 (-25.37, 97.84)	0.34 (0.08, 1.37) 0.130	0.48 (0.18, 1.24) 0.128	-22.99 (-52.44, 6.46) 0.126
	Immunosuppressive treatment	0.280								
	Yes		12	3 (25.0)	8	3 (37.5)	86.76 (-159.65, 99.33)	0.44 (0.05, 3.47) 0.433	0.60 (0.17, 2.07) 0.416	-16.03 (-55.72, 23.67) 0.429
	No		12	2 (16.7)	9	4 (44.4)	89.31 (-24.87, 99.08)	0.26 (0.03, 2.11) 0.207	0.41 (0.10, 1.63) 0.206	-25.80 (-64.14, 12.54) 0.187

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Runny Nose	CV disease	NE								
	No		24	5 (20.8)	13	4 (30.8)	54.04 (-302.98, 94.76)	0.62 (0.13, 2.95) 0.544	0.70 (0.22, 2.18) 0.536	-9.34 (-40.15, 21.46) 0.552
	COPD	0.150								
	No		22	3 (13.6)	14	5 (35.7)	78.87 (-165.46, 98.32)	0.31 (0.06, 1.67) 0.174	0.42 (0.12, 1.48) 0.176	-20.74 (-50.66, 9.18) 0.174
	Chronic liver disease	NE								
	No		21	4 (19.0)	17	7 (41.2)	89.13 (7.90, 98.72)	0.33 (0.07, 1.43) 0.138	0.46 (0.16, 1.29) 0.139	-22.94 (-52.21, 6.33) 0.124
	Hypertension	0.605								
	Yes		10	3 (30.0)	7	3 (42.9)	69.80 (-275.08, 97.57)	0.64 (0.08, 5.24) 0.677	0.75 (0.19, 2.93) 0.682	-10.11 (-58.13, 37.90) 0.680
	No		14	2 (14.3)	10	4 (40.0)	89.18 (-359.40, 99.75)	0.28 (0.04, 1.80) 0.181	0.36 (0.07, 1.70) 0.196	-25.65 (-62.50, 11.21) 0.173
	Asthma	0.796								
	No		19	4 (21.1)	14	5 (35.7)	69.65 (-319.39, 97.80)	0.50 (0.11, 2.32) 0.373	0.60 (0.20, 1.82) 0.369	-14.28 (-45.74, 17.18) 0.374

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Runny Nose	Cancer	0.347								
	Yes		6	1 (16.7)	4	1 (25.0)	42.26 (-657.44, 95.60)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	4 (22.2)	13	6 (46.2)	85.72 (-71.95, 98.81)	0.35 (0.08, 1.62) 0.180	0.49 (0.17, 1.38) 0.177	-23.86 (-57.97, 10.24) 0.170
	Smoking	NE								
	No		20	4 (20.0)	17	7 (41.2)	88.16 (-19.57, 98.83)	0.35 (0.08, 1.55) 0.167	0.48 (0.17, 1.36) 0.167	-21.91 (-51.90, 8.07) 0.152
	Sickle cell disease	NE								
	No		24	5 (20.8)	17	7 (41.2)	83.45 (-26.56, 97.84)	0.38 (0.10, 1.50) 0.166	0.51 (0.20, 1.32) 0.163	-20.60 (-49.40, 8.20) 0.161
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	5 (21.7)	14	7 (50.0)	86.84 (7.35, 98.13)	0.28 (0.07, 1.17) 0.082	0.43 (0.17, 1.10) 0.078	-28.55 (-59.83, 2.74) 0.074
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	5 (20.8)	17	7 (41.2)	83.45 (-26.56, 97.84)	0.38 (0.10, 1.50) 0.166	0.51 (0.20, 1.32) 0.163	-20.60 (-49.40, 8.20) 0.161

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Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Shortness of Breath	Age at randomization	0.878								
	<60 years		13	1 (7.7)	11	6 (54.5)	91.81 (13.80, 99.22)	0.07 (0.01, 0.74) 0.027	0.14 (0.02, 1.00) 0.050	-46.85 (-79.65, -14.06) 0.005
	≥60 years		11	3 (27.3)	6	3 (50.0)	93.48 (64.11, 98.81)	0.38 (0.05, 3.00) 0.355	0.55 (0.16, 1.91) 0.343	-22.73 (-70.62, 25.16) 0.352
	Age at randomization	NE								
	<65 years		16	1 (6.3)	15	9 (60.0)	96.14 (62.29, 99.60)	0.04 (0.00, 0.43) 0.007	0.10 (0.01, 0.73) 0.022	-53.75 (-81.23, -26.27) <.001
	≥65 years		8	3 (37.5)	2	0 (0.0)	NE (NE, NE)	3.18 (0.12, 87.92) 0.494	2.33 (0.16, 33.34) 0.532	37.50 (3.95, 71.05) 0.028
	Age at randomization	NE								
	<75 years		22	3 (13.6)	16	9 (56.3)	88.55 (42.57, 97.72)	0.12 (0.03, 0.59) 0.009	0.24 (0.08, 0.76) 0.015	-42.61 (-70.84, -14.39) 0.003
	Residence in long-term care facility	NE								
	No		24	4 (16.7)	17	9 (52.9)	92.93 (70.76, 98.29)	0.17 (0.04, 0.73) 0.018	0.29 (0.10, 0.85) 0.024	-37.33 (-65.31, -9.36) 0.009

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Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	4 (21.1)	14	6 (42.9)	91.40 (58.83, 98.20)	0.33 (0.07, 1.59) 0.165	0.47 (0.16, 1.37) 0.167	-22.65 (-53.71, 8.41) 0.153

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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Shortness of Breath	Sex	0.645								
	Male		9	1 (11.1)	7	4 (57.1)	88.67 (-31.77, 99.03)	0.08 (0.01, 1.22) 0.070	0.19 (0.03, 1.36) 0.098	-46.81 (-88.18, -5.44) 0.027
	Female		15	3 (20.0)	10	5 (50.0)	94.46 (72.94, 98.86)	0.19 (0.03, 1.37) 0.100	0.32 (0.08, 1.29) 0.110	-34.00 (-70.26, 2.26) 0.066
	Region	NE								
	North America		7	3 (42.9)	8	4 (50.0)	77.94 (-98.73, 97.55)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	96.86 (28.98, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	1 (11.1)	3	2 (66.7)	95.32 (60.93, 99.44)	0.07 (0.00, 1.73) 0.105	0.19 (0.03, 1.39) 0.101	-54.17 (-100.00, 3.89) 0.041
	Country	NE								
	United States		7	3 (42.9)	8	4 (50.0)	77.94 (-98.73, 97.55)	1.13 (0.11, 11.60) 0.921	1.07 (0.27, 4.23) 0.922	2.86 (-53.60, 59.32) 0.921
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	4 (16.7)	13	6 (46.2)	90.58 (55.34, 98.01)	0.23 (0.05, 1.07) 0.062	0.34 (0.11, 1.06) 0.063	-30.19 (-61.32, 0.94) 0.057

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Shortness of Breath	Ethnicity	NE								
	Not Hispanic or Latino		23	4 (17.4)	16	9 (56.3)	92.91 (70.67, 98.29)	0.17 (0.04, 0.72) 0.017	0.30 (0.10, 0.84) 0.022	-39.42 (-68.48, -10.36) 0.008
	COVID-19 co-morbidities at baseline	0.795								
	None		6	1 (16.7)	6	2 (33.3)	91.27 (31.88, 98.88)	0.38 (0.02, 6.26) 0.495	0.38 (0.02, 7.89) 0.528	-19.23 (-69.73, 31.27) 0.455
	At least one		18	3 (16.7)	11	7 (63.6)	93.04 (62.56, 98.70)	0.12 (0.02, 0.66) 0.016	0.26 (0.08, 0.81) 0.020	-47.17 (-80.52, -13.82) 0.006
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	4 (16.7)	17	9 (52.9)	92.93 (70.76, 98.29)	0.17 (0.04, 0.73) 0.018	0.29 (0.10, 0.85) 0.024	-37.33 (-65.31, -9.36) 0.009
	High risk for severe COVID-19 at baseline	0.406								
	Yes		22	3 (13.6)	16	8 (50.0)	93.93 (68.44, 98.83)	0.15 (0.03, 0.74) 0.020	0.26 (0.08, 0.86) 0.028	-36.91 (-65.20, -8.63) 0.011

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Obesity (≥ 30 kg/m^2)	0.979								
	Yes		8	2 (25.0)	8	6 (75.0)	94.01 (51.31, 99.26)	0.11 (0.01, 1.24) 0.074	0.20 (0.03, 1.15) 0.072	-66.67 (-93.34, -39.99) <.001
	No		16	2 (12.5)	9	3 (33.3)	90.23 (21.95, 98.78)	0.31 (0.04, 2.27) 0.247	0.39 (0.08, 1.83) 0.233	-20.74 (-56.53, 15.05) 0.256

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Shortness of Breath	Obesity (≥ 40 kg/m^2)	0.001								
	No		22	3 (13.6)	14	7 (50.0)	93.25 (64.40, 98.72)	0.16 (0.03, 0.80) 0.026	0.26 (0.08, 0.91) 0.035	-36.52 (-66.69, -6.35) 0.018
	Chronic kidney disease	NE								
	No		21	2 (9.5)	15	9 (60.0)	97.22 (85.88, 99.45)	0.06 (0.01, 0.43) 0.005	0.13 (0.03, 0.62) 0.011	-52.22 (-79.47, -24.97) <.001
	Diabetes	0.063								
	No		22	3 (13.6)	16	8 (50.0)	93.40 (66.39, 98.70)	0.16 (0.03, 0.77) 0.022	0.26 (0.07, 0.89) 0.032	-36.66 (-65.33, -8.00) 0.012
	Immunosuppressive disease	NE								
	No		24	4 (16.7)	16	9 (56.3)	92.96 (70.92, 98.30)	0.15 (0.04, 0.68) 0.013	0.28 (0.10, 0.80) 0.018	-40.26 (-68.97, -11.56) 0.006
	Immunosuppressive treatment	0.658								
	Yes		12	2 (16.7)	8	5 (62.5)	95.81 (74.14, 99.32)	0.09 (0.01, 1.02) 0.052	0.22 (0.05, 1.02) 0.054	-48.72 (-86.65, -10.79) 0.012

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		12	2 (16.7)	9	4 (44.4)	88.45 (11.28, 98.50)	0.26 (0.03, 1.90) 0.182	0.37 (0.08, 1.68) 0.200	-27.50 (-66.49, 11.50) 0.167

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Shortness of Breath	CV disease	NE								
	No		24	4 (16.7)	13	6 (46.2)	90.31 (51.00, 98.09)	0.20 (0.04, 1.03) 0.054	0.30 (0.08, 1.10) 0.069	-31.64 (-63.03, -0.25) 0.048
	COPD	<.001								
	No		22	2 (9.1)	14	7 (50.0)	96.31 (81.68, 99.26)	0.08 (0.01, 0.63) 0.016	0.12 (0.02, 0.88) 0.037	-42.73 (-71.96, -13.49) 0.004
	Chronic liver disease	NE								
	No		21	4 (19.0)	17	9 (52.9)	92.48 (67.60, 98.26)	0.19 (0.04, 0.87) 0.032	0.33 (0.11, 0.97) 0.044	-35.26 (-64.40, -6.12) 0.018
	Hypertension	0.158								
	Yes		10	3 (30.0)	7	3 (42.9)	66.57 (-335.81, 97.44)	0.64 (0.08, 5.24) 0.677	0.75 (0.19, 2.93) 0.682	-10.11 (-58.13, 37.90) 0.680
	No		14	1 (7.1)	10	6 (60.0)	98.15 (83.57, 99.79)	0.04 (0.00, 0.69) 0.026	0.12 (0.02, 0.83) 0.031	-52.59 (-85.47, -19.71) 0.002
	Asthma	0.959								
	No		19	3 (15.8)	14	6 (42.9)	91.44 (45.00, 98.67)	0.24 (0.05, 1.26) 0.092	0.36 (0.10, 1.23) 0.102	-27.55 (-58.23, 3.13) 0.078

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Shortness of Breath	Cancer	0.131								
	Yes		6	1 (16.7)	4	1 (25.0)	42.26 (-657.44, 95.60)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	3 (16.7)	13	8 (61.5)	95.11 (76.10, 99.00)	0.12 (0.02, 0.67) 0.015	0.26 (0.08, 0.83) 0.022	-45.34 (-76.84, -13.84) 0.005
	Smoking	NE								
	No		20	4 (20.0)	17	9 (52.9)	91.97 (63.58, 98.23)	0.20 (0.04, 0.93) 0.040	0.35 (0.12, 1.02) 0.055	-34.33 (-64.02, -4.64) 0.023
	Sickle cell disease	NE								
	No		24	4 (16.7)	17	9 (52.9)	92.93 (70.76, 98.29)	0.17 (0.04, 0.73) 0.018	0.29 (0.10, 0.85) 0.024	-37.33 (-65.31, -9.36) 0.009
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	4 (17.4)	14	9 (64.3)	94.53 (78.55, 98.60)	0.11 (0.02, 0.55) 0.007	0.25 (0.09, 0.71) 0.009	-47.81 (-77.36, -18.26) 0.002

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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	4 (16.7)	17	9 (52.9)	92.93 (70.76, 98.29)	0.17 (0.04, 0.73) 0.018	0.29 (0.10, 0.85) 0.024	-37.33 (-65.31, -9.36) 0.009

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Sore Throat	Age at randomization	0.076								
	<60 years		13	2 (15.4)	11	4 (36.4)	59.40 (-216.40, 94.79)	0.32 (0.05, 2.22) 0.248	0.42 (0.09, 1.89) 0.260	-20.98 (-55.52, 13.56) 0.234
	≥60 years		11	2 (18.2)	6	3 (50.0)	96.64 (79.05, 99.46)	0.22 (0.02, 2.04) 0.183	0.36 (0.08, 1.61) 0.182	-31.82 (-77.86, 14.23) 0.176
	Age at randomization	NE								
	<65 years		16	2 (12.5)	15	7 (46.7)	84.67 (-1.17, 97.68)	0.16 (0.03, 0.98) 0.048	0.27 (0.07, 1.09) 0.066	-34.17 (-64.17, -4.17) 0.026
	≥65 years		8	2 (25.0)	2	0 (0.0)	NE (NE, NE)	1.92 (0.07, 55.84) 0.704	1.67 (0.11, 25.83) 0.715	25.00 (-5.01, 55.01) 0.102
	Age at randomization	NE								
	<75 years		22	4 (18.2)	16	7 (43.8)	69.87 (-50.01, 93.95)	0.29 (0.07, 1.24) 0.094	0.42 (0.15, 1.18) 0.100	-25.57 (-54.73, 3.60) 0.086
	Residence in long-term care facility	NE								
	No		24	4 (16.7)	17	7 (41.2)	89.89 (25.06, 98.64)	0.27 (0.06, 1.18) 0.082	0.39 (0.14, 1.14) 0.086	-25.26 (-53.01, 2.49) 0.074

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	0.024								
	No		19	3 (15.8)	14	6 (42.9)	94.60 (69.10, 99.06)	0.23 (0.04, 1.24) 0.087	0.36 (0.11, 1.19) 0.095	-27.62 (-57.91, 2.66) 0.074

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Sore Throat	Sex	0.231								
	Male		9	1 (11.1)	7	2 (28.6)	58.94 (-400.02, 96.63)	0.33 (0.02, 4.46) 0.406	0.38 (0.04, 4.06) 0.427	-17.02 (-56.96, 22.92) 0.404
	Female		15	3 (20.0)	10	5 (50.0)	92.63 (20.66, 99.32)	0.24 (0.04, 1.49) 0.125	0.39 (0.11, 1.34) 0.134	-30.67 (-68.14, 6.80) 0.109
	Region	NE								
	North America		7	2 (28.6)	8	3 (37.5)	91.80 (30.47, 99.03)	0.60 (0.05, 6.79) 0.680	0.71 (0.15, 3.50) 0.678	-11.43 (-65.87, 43.01) 0.681
	United Kingdom		8	0 (0.0)	6	3 (50.0)	96.88 (31.29, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006
	European Union		9	2 (22.2)	3	1 (33.3)	58.62 (-802.19, 98.10)	0.67 (0.04, 11.94) 0.783	0.75 (0.10, 5.54) 0.778	-8.33 (-69.54, 52.87) 0.790
	Country	NE								
	United States		7	2 (28.6)	8	3 (37.5)	91.80 (30.47, 99.03)	0.60 (0.05, 6.79) 0.680	0.71 (0.15, 3.50) 0.678	-11.43 (-65.87, 43.01) 0.681
	United Kingdom		8	0 (0.0)	6	3 (50.0)	NE (NE, NE)	0.09 (0.01, 1.25) 0.072	0.18 (0.03, 1.28) 0.087	-53.85 (-92.17, -15.52) 0.006

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Race	NE								
	White		24	4 (16.7)	13	5 (38.5)	86.09 (-25.39, 98.46)	0.32 (0.07, 1.50) 0.147	0.43 (0.14, 1.33) 0.144	-21.99 (-52.37, 8.39) 0.156

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Sore Throat	Ethnicity	NE								
	Not Hispanic or Latino		23	4 (17.4)	16	7 (43.8)	89.87 (25.41, 98.62)	0.26 (0.06, 1.15) 0.076	0.39 (0.14, 1.12) 0.080	-26.76 (-55.50, 1.97) 0.068
	COVID-19 co-morbidities at baseline	0.777								
	None		6	1 (16.7)	6	1 (16.7)	47.83 (-1134.73, 97.80)	1.33 (0.06, 31.12) 0.858	1.25 (0.11, 14.34) 0.858	3.85 (-38.26, 45.95) 0.858
	At least one		18	3 (16.7)	11	6 (54.5)	91.63 (48.31, 98.64)	0.16 (0.03, 0.91) 0.039	0.30 (0.09, 0.96) 0.043	-38.36 (-72.11, -4.62) 0.026
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	4 (16.7)	17	7 (41.2)	89.89 (25.06, 98.64)	0.27 (0.06, 1.18) 0.082	0.39 (0.14, 1.14) 0.086	-25.26 (-53.01, 2.49) 0.074
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	4 (18.2)	16	6 (37.5)	86.15 (-13.06, 98.30)	0.35 (0.08, 1.58) 0.173	0.47 (0.16, 1.39) 0.173	-20.12 (-48.74, 8.49) 0.168
	Obesity (≥ 30 kg/m^2)	0.926								
	Yes		8	2 (25.0)	8	5 (62.5)	93.97 (50.56, 99.27)	0.15 (0.01, 1.65) 0.120	0.22 (0.04, 1.18) 0.077	-58.33 (-86.23, -30.44) <.001

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	No		16	2 (12.5)	9	2 (22.2)	74.84 (-502.97, 98.95)	0.45 (0.05, 4.17) 0.480	0.50 (0.07, 3.52) 0.489	-10.92 (-42.45, 20.61) 0.497

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Sore Throat	Obesity (≥ 40 kg/m^2)	0.241								
	No		22	3 (13.6)	14	5 (35.7)	86.52 (-111.56, 99.14)	0.29 (0.06, 1.50) 0.141	0.39 (0.11, 1.36) 0.140	-21.91 (-51.14, 7.32) 0.142
	Chronic kidney disease	NE								
	No		21	2 (9.5)	15	7 (46.7)	96.54 (69.74, 99.61)	0.11 (0.02, 0.70) 0.019	0.20 (0.05, 0.82) 0.025	-38.33 (-66.53, -10.14) 0.008
	Diabetes	0.341								
	No		22	3 (13.6)	16	6 (37.5)	87.85 (-56.86, 99.06)	0.27 (0.05, 1.31) 0.103	0.37 (0.11, 1.25) 0.109	-23.75 (-51.69, 4.19) 0.096
	Immunosuppressive disease	NE								
	No		24	4 (16.7)	16	7 (43.8)	89.92 (25.59, 98.64)	0.25 (0.06, 1.09) 0.065	0.37 (0.13, 1.08) 0.068	-27.55 (-56.04, 0.95) 0.058
	Immunosuppressive treatment	0.192								
	Yes		12	3 (25.0)	8	3 (37.5)	86.80 (-154.36, 99.32)	0.44 (0.05, 3.47) 0.433	0.60 (0.17, 2.07) 0.416	-16.03 (-55.72, 23.67) 0.429
	No		12	1 (8.3)	9	4 (44.4)	95.40 (8.06, 99.77)	0.11 (0.01, 1.42) 0.091	0.21 (0.03, 1.41) 0.108	-34.84 (-70.85, 1.17) 0.058

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Sore Throat	CV disease	NE								
	No		24	4 (16.7)	13	4 (30.8)	73.34 (-243.28, 97.93)	0.43 (0.08, 2.24) 0.317	0.52 (0.15, 1.84) 0.313	-14.77 (-44.51, 14.96) 0.330
	COPD	0.063								
	No		22	2 (9.1)	14	5 (35.7)	91.61 (-72.39, 99.59)	0.18 (0.03, 1.18) 0.074	0.25 (0.05, 1.23) 0.088	-26.68 (-55.06, 1.70) 0.065
	Chronic liver disease	NE								
	No		21	4 (19.0)	17	7 (41.2)	89.10 (7.59, 98.71)	0.33 (0.07, 1.43) 0.138	0.46 (0.16, 1.29) 0.139	-22.94 (-52.21, 6.33) 0.124
	Hypertension	0.383								
	Yes		10	3 (30.0)	7	3 (42.9)	69.80 (-275.08, 97.57)	0.64 (0.08, 5.24) 0.677	0.75 (0.19, 2.93) 0.682	-10.11 (-58.13, 37.90) 0.680
	No		14	1 (7.1)	10	4 (40.0)	97.16 (-2.16, 99.92)	0.13 (0.01, 1.28) 0.081	0.18 (0.02, 1.45) 0.107	-32.71 (-66.69, 1.27) 0.059
	Asthma	0.564								
	No		19	3 (15.8)	14	5 (35.7)	84.84 (-196.81, 99.23)	0.34 (0.07, 1.77) 0.201	0.45 (0.13, 1.55) 0.204	-19.89 (-50.06, 10.29) 0.197

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Sore Throat	Cancer	0.220								
	Yes		6	1 (16.7)	4	1 (25.0)	42.26 (-657.44, 95.60)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	3 (16.7)	13	6 (46.2)	92.43 (13.48, 99.34)	0.24 (0.05, 1.23) 0.086	0.36 (0.11, 1.18) 0.091	-29.77 (-62.28, 2.73) 0.073
	Smoking	NE								
	No		20	4 (20.0)	17	7 (41.2)	88.14 (-19.66, 98.82)	0.35 (0.08, 1.55) 0.167	0.48 (0.17, 1.36) 0.167	-21.91 (-51.90, 8.07) 0.152
	Sickle cell disease	NE								
	No		24	4 (16.7)	17	7 (41.2)	89.89 (25.06, 98.64)	0.27 (0.06, 1.18) 0.082	0.39 (0.14, 1.14) 0.086	-25.26 (-53.01, 2.49) 0.074
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	4 (17.4)	14	7 (50.0)	91.80 (43.87, 98.80)	0.20 (0.04, 0.92) 0.039	0.34 (0.12, 0.96) 0.041	-33.27 (-63.53, -3.02) 0.031
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	4 (16.7)	17	7 (41.2)	89.89 (25.06, 98.64)	0.27 (0.06, 1.18) 0.082	0.39 (0.14, 1.14) 0.086	-25.26 (-53.01, 2.49) 0.074

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Supplemental Oxygen	Age at randomization	NE								
	<60 years		13	0 (0.0)	11	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	≥60 years		11	0 (0.0)	6	1 (16.7)	NE (NE, NE)	0.16 (0.01, 4.58) 0.284	0.19 (0.01, 4.15) 0.295	-16.67 (-46.49, 13.15) 0.273
	Age at randomization	NE								
	<65 years		16	0 (0.0)	15	1 (6.7)	NE (NE, NE)	0.29 (0.01, 7.76) 0.463	0.31 (0.01, 7.15) 0.467	-6.67 (-19.29, 5.96) 0.301
	≥65 years		8	0 (0.0)	2	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Age at randomization	NE								
	<75 years		22	0 (0.0)	16	1 (6.3)	NE (NE, NE)	0.23 (0.01, 6.01) 0.377	0.25 (0.01, 5.68) 0.382	-6.25 (-18.11, 5.61) 0.302
	Residence in long-term care facility	NE								
	No		24	0 (0.0)	17	1 (5.9)	53.76 (-1703.47, NE)	0.16 (0.01, 4.58) 0.284	0.19 (0.01, 4.15) 0.295	-6.58 (-18.36, 5.21) 0.274
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	0 (0.0)	14	1 (7.1)	53.22 (-1724.56, NE)	0.19 (0.01, 5.60) 0.338	0.23 (0.01, 4.93) 0.350	-7.46 (-21.21, 6.29) 0.288

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Supplemental Oxygen	Sex	NE								
	Male		9	0 (0.0)	7	1 (14.3)	-1000.00 (-42800.0, NE)	0.20 (0.00, 8.82) 0.405	0.33 (0.02, 5.33) 0.437	-12.77 (-37.74, 12.21) 0.316
	Female		15	0 (0.0)	10	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Region	NE								
	North America		7	0 (0.0)	8	1 (12.5)	54.78 (-1663.48, NE)	0.20 (0.01, 6.04) 0.355	0.25 (0.01, 5.13) 0.368	-20.00 (-55.06, 15.06) 0.264
	United Kingdom		8	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	European Union		9	0 (0.0)	3	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Country	NE								
	United States		7	0 (0.0)	8	1 (12.5)	NE (NE, NE)	0.20 (0.01, 6.04) 0.355	0.25 (0.01, 5.13) 0.368	-20.00 (-55.06, 15.06) 0.264
	United Kingdom		8	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Race	NE								
	White		24	0 (0.0)	13	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Supplemental Oxygen	Ethnicity	NE								
	Not Hispanic or Latino		23	0 (0.0)	16	1 (6.3)	53.49 (-1713.95, NE)	0.17 (0.01, 5.04) 0.309	0.21 (0.01, 4.51) 0.320	-6.65 (-18.84, 5.55) 0.285
	COVID-19 co-morbidities at baseline	NE								
	None		6	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	At least one		18	0 (0.0)	11	1 (9.1)	32.48 (-2533.33, NE)	0.16 (0.01, 4.69) 0.286	0.20 (0.01, 4.17) 0.299	-9.43 (-26.68, 7.82) 0.284
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	0 (0.0)	17	1 (5.9)	53.76 (-1703.47, NE)	0.16 (0.01, 4.58) 0.284	0.19 (0.01, 4.15) 0.295	-6.58 (-18.36, 5.21) 0.274
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	0 (0.0)	16	1 (6.3)	44.83 (-2051.72, NE)	0.17 (0.01, 5.04) 0.309	0.21 (0.01, 4.51) 0.320	-6.79 (-19.11, 5.53) 0.280
	Obesity (≥ 30 kg/m^2)	NE								
	Yes		8	0 (0.0)	8	1 (12.5)	43.68 (-2096.55, NE)	0.08 (0.00, 2.99) 0.170	0.14 (0.01, 2.60) 0.189	-25.00 (-56.63, 6.63) 0.121
	No		16	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Supplemental Oxygen	Obesity (≥ 40 kg/m^2)	NE								
	No		22	0 (0.0)	14	1 (7.1)	64.14 (-1298.62, NE)	0.14 (0.00, 4.22) 0.260	0.18 (0.01, 3.81) 0.272	-7.87 (-21.95, 6.22) 0.274
	Chronic kidney disease	NE								
	No		21	0 (0.0)	15	1 (6.7)	45.52 (-2024.83, NE)	0.14 (0.00, 4.22) 0.260	0.18 (0.01, 3.81) 0.272	-7.78 (-21.34, 5.78) 0.261
	Diabetes	NE								
	No		22	0 (0.0)	16	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Immunosuppressive disease	NE								
	No		24	0 (0.0)	16	1 (6.3)	53.76 (-1703.47, NE)	0.16 (0.01, 4.58) 0.284	0.19 (0.01, 4.15) 0.295	-6.79 (-19.10, 5.53) 0.280
	Immunosuppressive treatment	NE								
	Yes		12	0 (0.0)	8	1 (12.5)	56.14 (-1610.53, NE)	0.13 (0.00, 4.32) 0.252	0.19 (0.01, 3.66) 0.271	-14.10 (-38.10, 9.90) 0.249
	No		12	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Supplemental Oxygen	CV disease	NE								
	No		24	0 (0.0)	13	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	COPD	NE								
	No		22	0 (0.0)	14	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Chronic liver disease	NE								
	No		21	0 (0.0)	17	1 (5.9)	53.76 (-1703.47, NE)	0.16 (0.01, 4.58) 0.284	0.19 (0.01, 4.15) 0.295	-7.09 (-19.35, 5.17) 0.257
	Hypertension	NE								
	Yes		10	0 (0.0)	7	1 (14.3)	73.86 (-919.32, NE)	0.11 (0.00, 3.70) 0.219	0.17 (0.01, 3.24) 0.237	-18.35 (-47.18, 10.47) 0.212
	No		14	0 (0.0)	10	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Asthma	NE								
	No		19	0 (0.0)	14	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Supplemental Oxygen	Cancer	NE								
	Yes		6	0 (0.0)	4	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	No		18	0 (0.0)	13	1 (7.7)	44.76 (-2054.55, NE)	0.18 (0.01, 5.28) 0.317	0.22 (0.01, 4.60) 0.330	-8.18 (-23.06, 6.70) 0.281
	Smoking	NE								
	No		20	0 (0.0)	17	1 (5.9)	53.76 (-1703.47, NE)	0.16 (0.01, 4.58) 0.284	0.19 (0.01, 4.15) 0.295	-7.33 (-19.81, 5.16) 0.250
	Sickle cell disease	NE								
	No		24	0 (0.0)	17	1 (5.9)	53.76 (-1703.47, NE)	0.16 (0.01, 4.58) 0.284	0.19 (0.01, 4.15) 0.295	-6.58 (-18.36, 5.21) 0.274
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	0 (0.0)	14	1 (7.1)	54.07 (-1691.28, NE)	0.14 (0.00, 4.22) 0.260	0.18 (0.01, 3.81) 0.272	-7.71 (-21.66, 6.24) 0.279
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	0 (0.0)	17	1 (5.9)	53.76 (-1703.47, NE)	0.16 (0.01, 4.58) 0.284	0.19 (0.01, 4.15) 0.295	-6.58 (-18.36, 5.21) 0.274

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Can Not Think Clearly	Age at randomization	NE								
	<60 years		13	0 (0.0)	11	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	≥60 years		11	2 (18.2)	6	2 (33.3)	72.27 (-304.27, 98.10)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-15.15 (-59.22, 28.92) 0.500
	Age at randomization	NE								
	<65 years		16	0 (0.0)	15	2 (13.3)	NE (NE, NE)	0.16 (0.01, 3.71) 0.256	0.19 (0.01, 3.63) 0.269	-13.33 (-30.54, 3.87) 0.129
	≥65 years		8	2 (25.0)	2	0 (0.0)	NE (NE, NE)	1.92 (0.07, 55.84) 0.704	1.67 (0.11, 25.83) 0.715	25.00 (-5.01, 55.01) 0.102
	Age at randomization	NE								
	<75 years		22	2 (9.1)	16	2 (12.5)	11.30 (-647.58, 89.48)	0.70 (0.09, 5.58) 0.736	0.73 (0.11, 4.63) 0.736	-3.41 (-23.58, 16.76) 0.740
	Residence in long-term care facility	NE								
	No		24	2 (8.3)	17	2 (11.8)	19.00 (-577.50, 90.32)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-5.98 (-23.55, 11.60) 0.505

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	2 (10.5)	14	2 (14.3)	39.10 (-434.32, 93.06)	0.57 (0.06, 5.77) 0.635	0.67 (0.13, 3.53) 0.633	-4.97 (-25.98, 16.04) 0.643

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Can Not Think Clearly	Sex	NE								
	Male		9	0 (0.0)	7	1 (14.3)	0.00 (-3800.00, NE)	0.20 (0.00, 8.82) 0.405	0.33 (0.02, 5.33) 0.437	-12.77 (-37.74, 12.21) 0.316
	Female		15	2 (13.3)	10	1 (10.0)	-63.84 (-2192.13, 88.29)	0.86 (0.05, 13.48) 0.913	0.89 (0.11, 7.20) 0.912	-1.33 (-25.43, 22.77) 0.914
	Region	NE								
	North America		7	2 (28.6)	8	2 (25.0)	-1.64 (-1275.95, 92.49)	0.60 (0.05, 6.79) 0.680	0.71 (0.15, 3.50) 0.678	-11.43 (-65.87, 43.01) 0.681
	United Kingdom		8	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	European Union		9	0 (0.0)	3	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Country	NE								
	United States		7	2 (28.6)	8	2 (25.0)	-1.64 (-1275.95, 92.49)	0.60 (0.05, 6.79) 0.680	0.71 (0.15, 3.50) 0.678	-11.43 (-65.87, 43.01) 0.681
	United Kingdom		8	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Race	NE								
	White		24	2 (8.3)	13	1 (7.7)	-25.86 (-1523.56, 90.24)	0.89 (0.06, 12.88) 0.931	0.91 (0.11, 7.84) 0.931	-0.74 (-17.89, 16.40) 0.932

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Can Not Think Clearly	Ethnicity	NE								
	Not Hispanic or Latino		23	2 (8.7)	16	2 (12.5)	19.06 (-577.78, 90.33)	0.50 (0.05, 4.98) 0.554	0.60 (0.11, 3.21) 0.551	-5.32 (-23.59, 12.95) 0.568
	COVID-19 co-morbidities at baseline	NE								
	None		6	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	At least one		18	2 (11.1)	11	2 (18.2)	3.89 (-782.84, 89.54)	0.43 (0.04, 4.64) 0.486	0.56 (0.11, 2.83) 0.479	-8.39 (-33.05, 16.27) 0.505
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	2 (8.3)	17	2 (11.8)	19.00 (-577.50, 90.32)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-5.98 (-23.55, 11.60) 0.505
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	2 (9.1)	16	2 (12.5)	12.45 (-650.14, 89.78)	0.50 (0.05, 4.98) 0.554	0.60 (0.11, 3.21) 0.551	-5.43 (-24.02, 13.15) 0.567
	Obesity (≥ 30 kg/m^2)	NE								
	Yes		8	2 (25.0)	8	2 (25.0)	-308.57 (-5428.09, 69.80)	0.11 (0.00, 3.35) 0.206	0.33 (0.11, 1.03) 0.057	-33.33 (-60.01, -6.66) 0.014
	No		16	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Can Not Think Clearly	Obesity (≥ 40 kg/m^2)	NE								
	No		22	1 (4.5)	14	1 (7.1)	27.90 (-1209.75, 96.03)	0.44 (0.02, 9.03) 0.598	0.50 (0.04, 6.44) 0.595	-3.93 (-19.56, 11.69) 0.622
	Chronic kidney disease	NE								
	No		21	1 (4.8)	15	2 (13.3)	55.67 (-464.09, 96.52)	0.17 (0.01, 2.56) 0.199	0.25 (0.03, 2.14) 0.206	-11.67 (-30.64, 7.31) 0.228
	Diabetes	NE								
	No		22	1 (4.5)	16	1 (6.3)	18.81 (-1362.80, 95.49)	0.50 (0.02, 10.25) 0.653	0.56 (0.04, 7.09) 0.651	-3.11 (-17.32, 11.09) 0.667
	Immunosuppressive disease	NE								
	No		24	2 (8.3)	16	2 (12.5)	19.31 (-575.36, 90.36)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-6.17 (-24.40, 12.06) 0.507
	Immunosuppressive treatment	NE								
	Yes		12	2 (16.7)	8	2 (25.0)	3.33 (-897.26, 90.63)	0.25 (0.01, 4.73) 0.355	0.50 (0.13, 2.00) 0.327	-14.10 (-44.17, 15.97) 0.358
	No		12	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Can Not Think Clearly	CV disease	NE								
	No		24	2 (8.3)	13	1 (7.7)	-25.86 (-1523.56, 90.24)	0.44 (0.03, 7.67) 0.577	0.55 (0.07, 4.16) 0.559	-4.46 (-21.54, 12.62) 0.609
	COPD	NE								
	No		22	1 (4.5)	14	1 (7.1)	21.23 (-1337.17, 95.68)	0.22 (0.01, 5.28) 0.352	0.30 (0.03, 3.49) 0.336	-6.69 (-22.79, 9.41) 0.415
	Chronic liver disease	NE								
	No		21	2 (9.5)	17	2 (11.8)	10.65 (-652.93, 89.40)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-6.45 (-25.13, 12.23) 0.499
	Hypertension	NE								
	Yes		10	2 (20.0)	7	1 (14.3)	-93.41 (-3088.16, 88.27)	0.80 (0.04, 14.64) 0.880	0.86 (0.12, 6.23) 0.879	-2.62 (-37.08, 31.84) 0.881
	No		14	0 (0.0)	10	1 (10.0)	64.71 (-1276.47, NE)	0.19 (0.01, 6.48) 0.352	0.27 (0.01, 4.93) 0.375	-9.80 (-28.25, 8.65) 0.298
	Asthma	NE								
	No		19	1 (5.3)	14	1 (7.1)	22.52 (-1335.86, 95.82)	0.57 (0.03, 11.85) 0.718	0.63 (0.05, 7.90) 0.716	-2.87 (-18.96, 13.21) 0.726

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[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Can Not Think Clearly	Cancer	NE								
	Yes		6	1 (16.7)	4	0 (0.0)	66.67 (NE, 99.15)	1.80 (0.04, 79.42) 0.761	1.50 (0.10, 22.62) 0.770	11.11 (-16.05, 38.27) 0.423
	No		18	1 (5.6)	13	2 (15.4)	64.93 (-355.83, 97.30)	0.21 (0.01, 3.37) 0.273	0.31 (0.04, 2.62) 0.283	-11.25 (-32.31, 9.81) 0.295
	Smoking	NE								
	No		20	2 (10.0)	17	2 (11.8)	1.14 (-739.66, 88.36)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-6.66 (-25.84, 12.52) 0.496
	Sickle cell disease	NE								
	No		24	2 (8.3)	17	2 (11.8)	19.00 (-577.50, 90.32)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-5.98 (-23.55, 11.60) 0.505
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	2 (8.7)	14	2 (14.3)	28.13 (-508.66, 91.51)	0.38 (0.04, 4.00) 0.417	0.50 (0.10, 2.58) 0.407	-7.71 (-27.48, 12.07) 0.445
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	2 (8.3)	17	2 (11.8)	19.00 (-577.50, 90.32)	0.44 (0.05, 4.37) 0.487	0.55 (0.10, 2.95) 0.482	-5.98 (-23.55, 11.60) 0.505

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			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Vomiting	Age at randomization	NE								
	<60 years		13	0 (0.0)	11	1 (9.1)	NE (NE, NE)	0.26 (0.01, 7.03) 0.423	0.29 (0.01, 6.38) 0.429	-9.09 (-26.08, 7.90) 0.294
	≥60 years		11	2 (18.2)	6	0 (0.0)	NE (NE, NE)	3.42 (0.14, 83.60) 0.451	2.92 (0.16, 52.47) 0.468	18.18 (-4.61, 40.97) 0.118
	Age at randomization	NE								
	<65 years		16	0 (0.0)	15	1 (6.7)	NE (NE, NE)	0.29 (0.01, 7.76) 0.463	0.31 (0.01, 7.15) 0.467	-6.67 (-19.29, 5.96) 0.301
	≥65 years		8	2 (25.0)	2	0 (0.0)	NE (NE, NE)	1.92 (0.07, 55.84) 0.704	1.67 (0.11, 25.83) 0.715	25.00 (-5.01, 55.01) 0.102
	Age at randomization	NE								
	<75 years		22	2 (9.1)	16	1 (6.3)	-86.45 (-2102.95, 84.22)	1.50 (0.12, 18.13) 0.750	1.45 (0.14, 14.69) 0.751	2.84 (-14.04, 19.72) 0.742
	Residence in long-term care facility	NE								
	No		24	2 (8.3)	17	1 (5.9)	-49.11 (-1378.91, 84.97)	1.30 (0.10, 16.23) 0.837	1.30 (0.09, 18.66) 0.845	1.67 (-13.90, 17.24) 0.834

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
	Increased risk of exposure to infection with SARS-CoV-2	NE								
	No		19	2 (10.5)	14	1 (7.1)	-32.00 (-1473.35, 88.93)	1.44 (0.13, 16.48) 0.769	1.44 (0.12, 17.66) 0.776	3.04 (-16.74, 22.82) 0.763

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Vomiting	Sex	NE								
	Male		9	0 (0.0)	7	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Female		15	2 (13.3)	10	1 (10.0)	-37.03 (-1037.29, 83.49)	1.23 (0.09, 17.51) 0.878	1.23 (0.07, 22.48) 0.889	2.00 (-23.15, 27.15) 0.876
	Region	NE								
	North America		7	2 (28.6)	8	1 (12.5)	-132.91 (-3012.98, 82.57)	5.00 (0.19, 130.02) 0.333	3.75 (0.22, 64.56) 0.363	28.57 (-4.89, 62.04) 0.094
	United Kingdom		8	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	European Union		9	0 (0.0)	3	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Country	NE								
	United States		7	2 (28.6)	8	1 (12.5)	-132.91 (-3012.98, 82.57)	5.00 (0.19, 130.02) 0.333	3.75 (0.22, 64.56) 0.363	28.57 (-4.89, 62.04) 0.094
	United Kingdom		8	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Race	NE								
	White		24	2 (8.3)	13	0 (0.0)	-3.99 (NE, 91.91)	2.89 (0.12, 71.93) 0.517	2.50 (0.14, 44.26) 0.532	7.45 (-3.15, 18.05) 0.169

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Vomiting	Ethnicity	NE								
	Not Hispanic or Latino		23	2 (8.7)	16	1 (6.3)	-49.53 (-1391.71, 85.01)	1.33 (0.11, 15.53) 0.822	1.33 (0.10, 16.90) 0.828	1.97 (-14.74, 18.67) 0.818
	COVID-19 co-morbidities at baseline	NE								
	None		6	0 (0.0)	6	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	At least one		18	2 (11.1)	11	1 (9.1)	-108.18 (-2532.30, 83.54)	1.19 (0.10, 13.72) 0.889	1.19 (0.10, 14.55) 0.891	1.68 (-21.43, 24.78) 0.887
	SARS-CoV-2 RT-PCR status at baseline	NE								
	Negative/Missing		24	2 (8.3)	17	1 (5.9)	-49.11 (-1378.91, 84.97)	1.30 (0.10, 16.23) 0.837	1.30 (0.09, 18.66) 0.845	1.67 (-13.90, 17.24) 0.834
	High risk for severe COVID-19 at baseline	NE								
	Yes		22	2 (9.1)	16	1 (6.3)	-72.75 (-1794.65, 84.25)	1.38 (0.11, 16.48) 0.802	1.38 (0.10, 18.41) 0.810	2.22 (-14.71, 19.15) 0.797
	Obesity (≥ 30 kg/m^2)	NE								
	Yes		8	2 (25.0)	8	1 (12.5)	-1089.68 (-6613.83, -110.81)	2.00 (0.07, 55.50) 0.683	2.00 (0.03, 127.85) 0.744	8.33 (-31.40, 48.06) 0.681
	No		16	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Vomiting	Obesity (≥ 40 kg/m^2)	NE								
	No		22	1 (4.5)	14	1 (7.1)	34.21 (-788.12, 95.13)	0.58 (0.03, 10.95) 0.719	0.58 (0.03, 12.56) 0.731	-2.81 (-18.70, 13.08) 0.729
	Chronic kidney disease	NE								
	No		21	1 (4.8)	15	1 (6.7)	14.07 (-900.19, 92.62)	0.64 (0.03, 12.93) 0.769	0.64 (0.03, 15.95) 0.783	-2.22 (-17.39, 12.95) 0.774
	Diabetes	NE								
	No		22	1 (4.5)	16	1 (6.3)	28.81 (-797.82, 94.36)	0.66 (0.03, 12.47) 0.781	0.66 (0.03, 14.35) 0.791	-2.01 (-16.51, 12.49) 0.786
	Immunosuppressive disease	NE								
	No		24	2 (8.3)	16	1 (6.3)	-48.84 (-1379.52, 85.03)	1.25 (0.10, 15.10) 0.861	1.25 (0.09, 16.83) 0.867	1.48 (-14.75, 17.70) 0.859
	Immunosuppressive treatment	NE								
	Yes		12	2 (16.7)	8	1 (12.5)	-88.24 (-1751.56, 80.86)	1.22 (0.10, 15.51) 0.877	1.22 (0.08, 18.27) 0.884	2.56 (-29.45, 34.58) 0.875
	No		12	0 (0.0)	9	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Table 2.8
Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Vomiting	CV disease	NE								
	No		24	2 (8.3)	13	1 (7.7)	26.49 (-533.37, 91.47)	0.76 (0.05, 11.96) 0.844	0.76 (0.04, 15.84) 0.858	-1.71 (-19.20, 15.78) 0.848
	COPD	NE								
	No		22	1 (4.5)	14	1 (7.1)	49.27 (-355.06, 94.34)	0.44 (0.02, 11.85) 0.627	0.44 (0.01, 17.73) 0.665	-3.62 (-18.93, 11.70) 0.644
	Chronic liver disease	NE								
	No		21	2 (9.5)	17	1 (5.9)	-58.23 (-1372.62, 83.00)	1.48 (0.11, 20.21) 0.768	1.48 (0.09, 25.39) 0.786	2.52 (-13.84, 18.87) 0.763
	Hypertension	NE								
	Yes		10	2 (20.0)	7	1 (14.3)	-43.65 (-1528.99, 87.33)	1.40 (0.09, 22.75) 0.813	1.40 (0.06, 32.72) 0.834	4.49 (-31.88, 40.87) 0.809
	No		14	0 (0.0)	10	0 (0.0)	NE (NE, NE)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE
	Asthma	NE								
	No		19	1 (5.3)	14	1 (7.1)	28.44 (-818.39, 94.42)	0.70 (0.04, 12.42) 0.808	0.70 (0.04, 13.57) 0.813	-2.06 (-18.92, 14.80) 0.811

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
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Efficacy for Incidence of Symptoms Associated with COVID-19 Recorded by Participants in an Illness e-Diary from Illness Visits Day 2 Through Day 28 by Subgroup
(Immunosuppressive Patients in Symptomatic COVID-19 analysis Set in Full Pre-exposure Analysis Set)

			AZD7442 (N=24)		Placebo (N=17)					
Symptom	Subgroup	Interaction P-value [a]	n	Observed Events (%)	n	Observed Events (%)	RRR % (95% CI) [a]	OR (95% CI) P-value [b]	RR (95% CI) P-value [b]	ARR % (95% CI) P-value [b]
Vomiting	Cancer	NE								
	Yes		6	1 (16.7)	4	1 (25.0)	39.45 (-614.21, 94.87)	0.50 (0.02, 13.54) 0.680	0.50 (0.01, 19.56) 0.711	-11.11 (-64.45, 42.23) 0.683
	No		18	1 (5.6)	13	0 (0.0)	35.82 (NE, 98.35)	2.20 (0.07, 64.90) 0.648	2.00 (0.10, 41.37) 0.654	5.11 (-5.11, 15.34) 0.327
	Smoking	NE								
	No		20	2 (10.0)	17	1 (5.9)	-69.28 (-1377.33, 80.60)	1.57 (0.11, 22.25) 0.739	1.57 (0.08, 29.04) 0.762	2.90 (-13.82, 19.61) 0.734
	Sickle cell disease	NE								
	No		24	2 (8.3)	17	1 (5.9)	-49.11 (-1378.91, 84.97)	1.30 (0.10, 16.23) 0.837	1.30 (0.09, 18.66) 0.845	1.67 (-13.90, 17.24) 0.834
	COVID-19 vaccination at any time during the study	NE								
	Yes		23	2 (8.7)	14	1 (7.1)	-40.68 (-1395.93, 86.77)	1.13 (0.09, 13.59) 0.924	1.13 (0.08, 14.99) 0.927	0.88 (-16.97, 18.73) 0.923
	Increased risk for inadequate response to active immunization	NE								
	Yes		24	2 (8.3)	17	1 (5.9)	-49.11 (-1378.91, 84.97)	1.30 (0.10, 16.23) 0.837	1.30 (0.09, 18.66) 0.845	1.67 (-13.90, 17.24) 0.834

Abbreviation: ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; RRR = Relative Risk Reduction.
[a]: Estimates are based on Poisson regression with robust variance with log of the follow-up time as an offset, treatment group, age group at the time of randomization (≥60 years vs <60 years), subgroup and treatment*subgroup interaction as covariates. P-values are for the treatment*subgroup interaction. If this full model is not converged, a reduced model with treatment group, subgroup and treatment*subgroup interaction as covariates will be used. If the reduced model is not converged, a stratified exact Poisson regression that stratified by age group at the time of randomization (≥ 60 years and < 60 years) with log of the follow-up time as an offset, treatment group, subgroup, and treatment*subgroup interaction as covariates will be used. For each level of a subgroup, a Poisson regression model with robust variance with the term of treatment and age at the time of randomization (≥60 years vs <60 years) is used. If this full model is not converged, a reduced model with treatment will be used. If the reduced model is not converged, a stratified exact Poisson regression will be used. The 97.5% One-sided CI of RRR is generated if the stratified exact Poisson regression is used. Estimated RRR greater than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the SAP.
[b]: Estimates are based on nonmodeling approach. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442. Additional analysis details are specified in the PAP.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Age at randomization				0.713
<60 years	Number of Participants with event, n (%)	2 (1.0)	6 (6.2)	
	Number of Participants censored, n (%)	197 (99.0)	91 (93.8)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.5 (98.5, 100.5) [n=198]	96.9 (93.4, 100.4) [n=91]	
	Month 2 (Day 60)	99.5 (98.5, 100.5) [n=197]	96.9 (93.4, 100.4) [n=89]	
	Month 3 (Day 90)	99.5 (98.5, 100.5) [n=196]	95.8 (91.8, 99.8) [n=86]	
	Month 4 (Day 120)	99.5 (98.5, 100.5) [n=192]	94.6 (90.1, 99.2) [n=81]	
	Month 5 (Day 150)	99.5 (98.5, 100.5) [n=190]	94.6 (90.1, 99.2) [n=81]	
	Month 6 (Day 180)	99.0 (97.6, 100.4) [n=188]	93.5 (88.4, 98.5) [n=80]	
	Month 6 (Day 183)	99.0 (97.6, 100.4) [n=188]	93.5 (88.4, 98.5) [n=80]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.008		
	Hazard Ratio (95% CI)	0.15 (0.03, 0.75)		
	P-value	0.021		
≥60 years	Number of Participants with event, n (%)	1 (0.7)	2 (2.6)	
	Number of Participants censored, n (%)	146 (99.3)	74 (97.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=145]	98.7 (96.1, 101.2) [n=75]	
	Month 2 (Day 60)	99.3 (98.0, 100.7) [n=143]	98.7 (96.1, 101.2) [n=75]	
	Month 3 (Day 90)	99.3 (98.0, 100.7) [n=143]	98.7 (96.1, 101.2) [n=73]	
	Month 4 (Day 120)	99.3 (98.0, 100.7) [n=141]	98.7 (96.1, 101.2) [n=73]	
	Month 5 (Day 150)	99.3 (98.0, 100.7) [n=139]	98.7 (96.1, 101.2) [n=73]	
	Month 6 (Day 180)	99.3 (98.0, 100.7) [n=139]	97.3 (93.7, 101.0) [n=72]	
	Month 6 (Day 183)	99.3 (98.0, 100.7) [n=138]	97.3 (93.7, 101.0) [n=72]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.241		
	Hazard Ratio (95% CI)	0.26 (0.02, 2.87)		
	P-value	0.272		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Age at randomization				1.000
<65 years	Number of Participants with event, n (%)	3 (1.1)	8 (5.8)	
	Number of Participants censored, n (%)	259 (98.9)	129 (94.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.9, 100.4) [n=260]	97.1 (94.2, 99.9) [n=130]	
	Month 2 (Day 60)	99.2 (98.2, 100.3) [n=258]	97.1 (94.2, 99.9) [n=128]	
	Month 3 (Day 90)	99.2 (98.2, 100.3) [n=257]	96.3 (93.1, 99.5) [n=124]	
	Month 4 (Day 120)	99.2 (98.2, 100.3) [n=251]	95.5 (92.0, 99.0) [n=119]	
	Month 5 (Day 150)	99.2 (98.2, 100.3) [n=248]	95.5 (92.0, 99.0) [n=119]	
	Month 6 (Day 180)	98.8 (97.5, 100.1) [n=246]	93.9 (89.8, 98.0) [n=117]	
	Month 6 (Day 183)	98.8 (97.5, 100.1) [n=245]	93.9 (89.8, 98.0) [n=117]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.006		
	Hazard Ratio (95% CI)	0.19 (0.05, 0.71)		
	P-value	0.013		
≥65 years	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	84 (100.0)	36 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=83]	100.0 (100.0, 100.0) [n=36]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=82]	100.0 (100.0, 100.0) [n=36]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=82]	100.0 (100.0, 100.0) [n=35]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=82]	100.0 (100.0, 100.0) [n=35]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=81]	100.0 (100.0, 100.0) [n=35]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=81]	100.0 (100.0, 100.0) [n=35]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=81]	100.0 (100.0, 100.0) [n=35]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	1.00 (0.00, NE)		
	P-value	1.000		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Age at randomization				1.000
<75 years	Number of Participants with event, n (%)	3 (0.9)	8 (4.8)	
	Number of Participants censored, n (%)	327 (99.1)	160 (95.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=327]	97.6 (95.3, 99.9) [n=161]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=324]	97.6 (95.3, 99.9) [n=159]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=323]	97.0 (94.4, 99.6) [n=154]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=317]	96.4 (93.5, 99.2) [n=149]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=314]	96.4 (93.5, 99.2) [n=149]	
	Month 6 (Day 180)	99.1 (98.0, 100.1) [n=312]	95.1 (91.7, 98.4) [n=147]	
	Month 6 (Day 183)	99.1 (98.0, 100.1) [n=311]	95.1 (91.7, 98.4) [n=147]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.005		
	Hazard Ratio (95% CI)	0.18 (0.05, 0.69)		
	P-value	0.012		
≥75 years	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	16 (100.0)	5 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=5]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=5]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=5]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=5]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=15]	100.0 (100.0, 100.0) [n=5]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=15]	100.0 (100.0, 100.0) [n=5]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=15]	100.0 (100.0, 100.0) [n=5]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	1.00 (0.00, NE)		
	P-value	1.000		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Residence in long-term care facility				NE
No	Number of Participants with event, n (%)	3 (0.9)	8 (4.6)	
	Number of Participants censored, n (%)	343 (99.1)	165 (95.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=343]	97.7 (95.4, 99.9) [n=166]	
	Month 2 (Day 60)	99.4 (98.6, 100.2) [n=340]	97.7 (95.4, 99.9) [n=164]	
	Month 3 (Day 90)	99.4 (98.6, 100.2) [n=339]	97.1 (94.6, 99.6) [n=159]	
	Month 4 (Day 120)	99.4 (98.6, 100.2) [n=333]	96.5 (93.7, 99.2) [n=154]	
	Month 5 (Day 150)	99.4 (98.6, 100.2) [n=329]	96.5 (93.7, 99.2) [n=154]	
	Month 6 (Day 180)	99.1 (98.1, 100.1) [n=327]	95.2 (92.0, 98.5) [n=152]	
	Month 6 (Day 183)	99.1 (98.1, 100.1) [n=326]	95.2 (92.0, 98.5) [n=152]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.005		
	Hazard Ratio (95% CI)	NE (NE, NE)		
	P-value	NE		
Increased risk of exposure to infection with SARS-CoV-2				0.993
Yes	Number of Participants with event, n (%)	0 (0.0)	2 (3.8)	
	Number of Participants censored, n (%)	99 (100.0)	50 (96.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=99]	98.1 (94.3, 101.8) [n=50]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=99]	98.1 (94.3, 101.8) [n=49]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=98]	96.1 (90.7, 101.4) [n=46]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=95]	96.1 (90.7, 101.4) [n=44]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=94]	96.1 (90.7, 101.4) [n=44]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=94]	96.1 (90.7, 101.4) [n=44]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=94]	96.1 (90.7, 101.4) [n=44]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.048		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.992		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	3 (1.2)	6 (5.0)	
	Number of Participants censored, n (%)	244 (98.8)	115 (95.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.8, 100.4) [n=244]	97.5 (94.7, 100.3) [n=116]	
	Month 2 (Day 60)	99.2 (98.1, 100.3) [n=241]	97.5 (94.7, 100.3) [n=115]	
	Month 3 (Day 90)	99.2 (98.1, 100.3) [n=241]	97.5 (94.7, 100.3) [n=113]	
	Month 4 (Day 120)	99.2 (98.1, 100.3) [n=238]	96.6 (93.4, 99.9) [n=110]	
	Month 5 (Day 150)	99.2 (98.1, 100.3) [n=235]	96.6 (93.4, 99.9) [n=110]	
	Month 6 (Day 180)	98.8 (97.4, 100.2) [n=233]	94.9 (90.9, 98.9) [n=108]	
	Month 6 (Day 183)	98.8 (97.4, 100.2) [n=232]	94.9 (90.9, 98.9) [n=108]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.028		
	Hazard Ratio (95% CI)	0.22 (0.06, 0.90)		
	P-value	0.035		
Sex				0.645
Male	Number of Participants with event, n (%)	2 (0.9)	4 (3.8)	
	Number of Participants censored, n (%)	214 (99.1)	101 (96.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.5 (98.6, 100.4) [n=214]	98.1 (95.5, 100.7) [n=101]	
	Month 2 (Day 60)	99.5 (98.6, 100.4) [n=212]	98.1 (95.5, 100.7) [n=99]	
	Month 3 (Day 90)	99.5 (98.6, 100.4) [n=211]	97.1 (93.9, 100.3) [n=95]	
	Month 4 (Day 120)	99.5 (98.6, 100.4) [n=206]	97.1 (93.9, 100.3) [n=91]	
	Month 5 (Day 150)	99.5 (98.6, 100.4) [n=204]	97.1 (93.9, 100.3) [n=91]	
	Month 6 (Day 180)	99.0 (97.7, 100.4) [n=202]	96.0 (92.2, 99.8) [n=90]	
	Month 6 (Day 183)	99.0 (97.7, 100.4) [n=201]	96.0 (92.2, 99.8) [n=90]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.067		
	Hazard Ratio (95% CI)	0.23 (0.04, 1.27)		
	P-value	0.092		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Female	Number of Participants with event, n (%)	1 (0.8)	4 (5.9)	
	Number of Participants censored, n (%)	129 (99.2)	64 (94.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=129]	97.1 (93.0, 101.1) [n=65]	
	Month 2 (Day 60)	99.2 (97.7, 100.7) [n=128]	97.1 (93.0, 101.1) [n=65]	
	Month 3 (Day 90)	99.2 (97.7, 100.7) [n=128]	97.1 (93.0, 101.1) [n=64]	
	Month 4 (Day 120)	99.2 (97.7, 100.7) [n=127]	95.5 (90.6, 100.5) [n=63]	
	Month 5 (Day 150)	99.2 (97.7, 100.7) [n=125]	95.5 (90.6, 100.5) [n=63]	
	Month 6 (Day 180)	99.2 (97.7, 100.7) [n=125]	94.0 (88.3, 99.7) [n=62]	
	Month 6 (Day 183)	99.2 (97.7, 100.7) [n=125]	94.0 (88.3, 99.7) [n=62]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.029		
	Hazard Ratio (95% CI)	0.12 (0.01, 1.08)		
	P-value	0.059		
Region				0.966
North America	Number of Participants with event, n (%)	0 (0.0)	2 (1.9)	
	Number of Participants censored, n (%)	185 (100.0)	104 (98.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=185]	100.0 (100.0, 100.0) [n=105]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=184]	100.0 (100.0, 100.0) [n=103]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=183]	99.0 (97.1, 100.9) [n=100]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=177]	99.0 (97.1, 100.9) [n=97]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=173]	99.0 (97.1, 100.9) [n=97]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=173]	98.0 (95.3, 100.7) [n=96]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=173]	98.0 (95.3, 100.7) [n=96]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.059		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.991		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
United Kingdom	Number of Participants with event, n (%)	2 (2.5)	3 (10.0)	
	Number of Participants censored, n (%)	78 (97.5)	27 (90.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=78]	93.3 (84.4, 102.3) [n=27]	
	Month 2 (Day 60)	98.7 (96.2, 101.2) [n=77]	93.3 (84.4, 102.3) [n=27]	
	Month 3 (Day 90)	98.7 (96.2, 101.2) [n=77]	93.3 (84.4, 102.3) [n=25]	
	Month 4 (Day 120)	98.7 (96.2, 101.2) [n=77]	89.4 (78.1, 100.8) [n=23]	
	Month 5 (Day 150)	98.7 (96.2, 101.2) [n=77]	89.4 (78.1, 100.8) [n=23]	
	Month 6 (Day 180)	97.4 (93.9, 100.9) [n=76]	89.4 (78.1, 100.8) [n=23]	
	Month 6 (Day 183)	97.4 (93.9, 100.9) [n=76]	89.4 (78.1, 100.8) [n=23]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.069		
	Hazard Ratio (95% CI)	0.22 (0.04, 1.31)		
	P-value	0.095		
European Union	Number of Participants with event, n (%)	1 (1.2)	3 (8.1)	
	Number of Participants censored, n (%)	80 (98.8)	34 (91.9)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	98.8 (96.4, 101.2) [n=80]	94.6 (87.3, 101.9) [n=34]	
	Month 2 (Day 60)	98.8 (96.4, 101.2) [n=79]	94.6 (87.3, 101.9) [n=34]	
	Month 3 (Day 90)	98.8 (96.4, 101.2) [n=79]	94.6 (87.3, 101.9) [n=34]	
	Month 4 (Day 120)	98.8 (96.4, 101.2) [n=79]	94.6 (87.3, 101.9) [n=34]	
	Month 5 (Day 150)	98.8 (96.4, 101.2) [n=79]	94.6 (87.3, 101.9) [n=34]	
	Month 6 (Day 180)	98.8 (96.4, 101.2) [n=78]	91.8 (82.9, 100.7) [n=33]	
	Month 6 (Day 183)	98.8 (96.4, 101.2) [n=77]	91.8 (82.9, 100.7) [n=33]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.061		
	Hazard Ratio (95% CI)	0.15 (0.02, 1.42)		
	P-value	0.098		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Country				1.000
United States	Number of Participants with event, n (%)	0 (0.0)	2 (1.9)	
	Number of Participants censored, n (%)	185 (100.0)	104 (98.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=185]	100.0 (100.0, 100.0) [n=105]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=184]	100.0 (100.0, 100.0) [n=103]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=183]	99.0 (97.1, 100.9) [n=100]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=177]	99.0 (97.1, 100.9) [n=97]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=173]	99.0 (97.1, 100.9) [n=97]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=173]	98.0 (95.3, 100.7) [n=96]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=173]	98.0 (95.3, 100.7) [n=96]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.059		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.995		
United Kingdom	Number of Participants with event, n (%)	2 (2.5)	3 (10.0)	
	Number of Participants censored, n (%)	78 (97.5)	27 (90.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=78]	93.3 (84.4, 102.3) [n=27]	
	Month 2 (Day 60)	98.7 (96.2, 101.2) [n=77]	93.3 (84.4, 102.3) [n=27]	
	Month 3 (Day 90)	98.7 (96.2, 101.2) [n=77]	93.3 (84.4, 102.3) [n=25]	
	Month 4 (Day 120)	98.7 (96.2, 101.2) [n=77]	89.4 (78.1, 100.8) [n=23]	
	Month 5 (Day 150)	98.7 (96.2, 101.2) [n=77]	89.4 (78.1, 100.8) [n=23]	
	Month 6 (Day 180)	97.4 (93.9, 100.9) [n=76]	89.4 (78.1, 100.8) [n=23]	
	Month 6 (Day 183)	97.4 (93.9, 100.9) [n=76]	89.4 (78.1, 100.8) [n=23]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.069		
	Hazard Ratio (95% CI)	0.22 (0.04, 1.30)		
	P-value	0.094		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Belgium	Number of Participants with event, n (%)	0 (0.0)	3 (18.8)	
	Number of Participants censored, n (%)	25 (100.0)	13 (81.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=25]	81.3 (62.1, 100.4) [n=13]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=25]	81.3 (62.1, 100.4) [n=13]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.025		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.997		
France	Number of Participants with event, n (%)	1 (2.6)	0 (0.0)	
	Number of Participants censored, n (%)	37 (97.4)	16 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 2 (Day 60)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 3 (Day 90)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 4 (Day 120)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 5 (Day 150)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 6 (Day 180)	97.4 (92.3, 102.5) [n=36]	100.0 (100.0, 100.0) [n=15]	
	Month 6 (Day 183)	97.4 (92.3, 102.5) [n=35]	100.0 (100.0, 100.0) [n=15]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.516		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.997		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Spain	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	18 (100.0)	5 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=18]	100.0 (100.0, 100.0) [n=5]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	0.34 (0.00, NE)		
	P-value	1.000		
Race				1.000
Black or African American	Number of Participants with event, n (%)	0 (0.0)	1 (3.6)	
	Number of Participants censored, n (%)	50 (100.0)	27 (96.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=50]	96.3 (89.2, 103.4) [n=26]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=50]	96.3 (89.2, 103.4) [n=26]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=49]	96.3 (89.2, 103.4) [n=25]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=25]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=25]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=25]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=25]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.174		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.995		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
White	Number of Participants with event, n (%)	3 (1.1)	6 (4.8)	
	Number of Participants censored, n (%)	261 (98.9)	120 (95.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.9, 100.4) [n=261]	97.6 (95.0, 100.3) [n=121]	
	Month 2 (Day 60)	99.2 (98.2, 100.3) [n=259]	97.6 (95.0, 100.3) [n=119]	
	Month 3 (Day 90)	99.2 (98.2, 100.3) [n=259]	97.6 (95.0, 100.3) [n=117]	
	Month 4 (Day 120)	99.2 (98.2, 100.3) [n=256]	96.8 (93.6, 99.9) [n=112]	
	Month 5 (Day 150)	99.2 (98.2, 100.3) [n=253]	96.8 (93.6, 99.9) [n=112]	
	Month 6 (Day 180)	98.8 (97.5, 100.1) [n=251]	95.0 (91.2, 98.9) [n=110]	
	Month 6 (Day 183)	98.8 (97.5, 100.1) [n=250]	95.0 (91.2, 98.9) [n=110]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.023		
	Hazard Ratio (95% CI)	0.23 (0.06, 0.92)		
	P-value	0.038		
Other	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	28 (100.0)	15 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=28]	100.0 (100.0, 100.0) [n=15]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=27]	100.0 (100.0, 100.0) [n=15]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=27]	100.0 (100.0, 100.0) [n=14]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=26]	100.0 (100.0, 100.0) [n=14]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	0.48 (0.00, NE)		
	P-value	1.000		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Ethnicity				1.000
Hispanic or Latino	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	40 (100.0)	12 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=40]	100.0 (100.0, 100.0) [n=12]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=40]	100.0 (100.0, 100.0) [n=12]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=40]	100.0 (100.0, 100.0) [n=12]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=39]	100.0 (100.0, 100.0) [n=12]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=39]	100.0 (100.0, 100.0) [n=12]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=39]	100.0 (100.0, 100.0) [n=12]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=39]	100.0 (100.0, 100.0) [n=12]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	1.16 (0.00, NE)		
	P-value	1.000		
Not Hispanic or Latino	Number of Participants with event, n (%)	3 (1.1)	8 (5.6)	
	Number of Participants censored, n (%)	272 (98.9)	136 (94.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.9, 100.3) [n=272]	97.2 (94.5, 99.9) [n=137]	
	Month 2 (Day 60)	99.3 (98.3, 100.3) [n=269]	97.2 (94.5, 99.9) [n=135]	
	Month 3 (Day 90)	99.3 (98.3, 100.3) [n=268]	96.5 (93.5, 99.5) [n=131]	
	Month 4 (Day 120)	99.3 (98.3, 100.3) [n=264]	95.7 (92.4, 99.1) [n=126]	
	Month 5 (Day 150)	99.3 (98.3, 100.3) [n=261]	95.7 (92.4, 99.1) [n=126]	
	Month 6 (Day 180)	98.9 (97.6, 100.1) [n=259]	94.2 (90.3, 98.1) [n=124]	
	Month 6 (Day 183)	98.9 (97.6, 100.1) [n=259]	94.2 (90.3, 98.1) [n=124]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.006		
	Hazard Ratio (95% CI)	0.18 (0.05, 0.68)		
	P-value	0.012		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Other	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	31 (100.0)	17 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=31]	100.0 (100.0, 100.0) [n=17]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=31]	100.0 (100.0, 100.0) [n=17]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=31]	100.0 (100.0, 100.0) [n=16]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=30]	100.0 (100.0, 100.0) [n=16]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=29]	100.0 (100.0, 100.0) [n=16]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=29]	100.0 (100.0, 100.0) [n=16]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=28]	100.0 (100.0, 100.0) [n=16]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	1.01 (0.00, NE)		
	P-value	1.000		
COVID-19 co-morbidities at baseline				0.993
None	Number of Participants with event, n (%)	0 (0.0)	3 (6.5)	
	Number of Participants censored, n (%)	101 (100.0)	43 (93.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=101]	95.7 (89.8, 101.5) [n=44]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=100]	95.7 (89.8, 101.5) [n=44]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=99]	95.7 (89.8, 101.5) [n=42]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=96]	95.7 (89.8, 101.5) [n=41]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=94]	95.7 (89.8, 101.5) [n=41]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=94]	93.3 (86.0, 100.6) [n=40]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=94]	93.3 (86.0, 100.6) [n=40]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.010		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.992		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
At least one	Number of Participants with event, n (%)	3 (1.2)	5 (3.9)	
	Number of Participants censored, n (%)	242 (98.8)	122 (96.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.8, 100.4) [n=242]	98.4 (96.2, 100.6) [n=122]	
	Month 2 (Day 60)	99.2 (98.0, 100.3) [n=240]	98.4 (96.2, 100.6) [n=120]	
	Month 3 (Day 90)	99.2 (98.0, 100.3) [n=240]	97.6 (94.9, 100.3) [n=117]	
	Month 4 (Day 120)	99.2 (98.0, 100.3) [n=237]	96.8 (93.6, 99.9) [n=113]	
	Month 5 (Day 150)	99.2 (98.0, 100.3) [n=235]	96.8 (93.6, 99.9) [n=113]	
	Month 6 (Day 180)	98.8 (97.4, 100.2) [n=233]	95.9 (92.4, 99.4) [n=112]	
	Month 6 (Day 183)	98.8 (97.4, 100.2) [n=232]	95.9 (92.4, 99.4) [n=112]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.081		
	Hazard Ratio (95% CI)	0.29 (0.07, 1.22)		
	P-value	0.092		
SARS-CoV-2 RT-PCR status at baseline				NE
Negative/Missing	Number of Participants with event, n (%)	3 (0.9)	8 (4.6)	
	Number of Participants censored, n (%)	343 (99.1)	165 (95.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=343]	97.7 (95.4, 99.9) [n=166]	
	Month 2 (Day 60)	99.4 (98.6, 100.2) [n=340]	97.7 (95.4, 99.9) [n=164]	
	Month 3 (Day 90)	99.4 (98.6, 100.2) [n=339]	97.1 (94.6, 99.6) [n=159]	
	Month 4 (Day 120)	99.4 (98.6, 100.2) [n=333]	96.5 (93.7, 99.2) [n=154]	
	Month 5 (Day 150)	99.4 (98.6, 100.2) [n=329]	96.5 (93.7, 99.2) [n=154]	
	Month 6 (Day 180)	99.1 (98.1, 100.1) [n=327]	95.2 (92.0, 98.5) [n=152]	
	Month 6 (Day 183)	99.1 (98.1, 100.1) [n=326]	95.2 (92.0, 98.5) [n=152]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.005		
	Hazard Ratio (95% CI)	NE (NE, NE)		
	P-value	NE		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
High risk for severe COVID-19 at baseline				0.992
Yes	Number of Participants with event, n (%)	3 (1.0)	7 (4.5)	
	Number of Participants censored, n (%)	300 (99.0)	147 (95.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.0, 100.3) [n=300]	97.4 (94.9, 99.9) [n=147]	
	Month 2 (Day 60)	99.3 (98.4, 100.3) [n=297]	97.4 (94.9, 99.9) [n=145]	
	Month 3 (Day 90)	99.3 (98.4, 100.3) [n=296]	96.7 (93.9, 99.5) [n=141]	
	Month 4 (Day 120)	99.3 (98.4, 100.3) [n=291]	96.0 (92.9, 99.1) [n=137]	
	Month 5 (Day 150)	99.3 (98.4, 100.3) [n=289]	96.0 (92.9, 99.1) [n=137]	
	Month 6 (Day 180)	99.0 (97.9, 100.1) [n=287]	95.3 (91.9, 98.7) [n=136]	
	Month 6 (Day 183)	99.0 (97.9, 100.1) [n=286]	95.3 (91.9, 98.7) [n=136]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.013		
	Hazard Ratio (95% CI)	0.20 (0.05, 0.79)		
	P-value	0.021		
No	Number of Participants with event, n (%)	0 (0.0)	1 (5.3)	
	Number of Participants censored, n (%)	43 (100.0)	18 (94.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=43]	100.0 (100.0, 100.0) [n=19]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=43]	100.0 (100.0, 100.0) [n=19]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=43]	100.0 (100.0, 100.0) [n=18]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=42]	100.0 (100.0, 100.0) [n=17]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=40]	100.0 (100.0, 100.0) [n=17]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=40]	94.1 (82.9, 105.3) [n=16]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=40]	94.1 (82.9, 105.3) [n=16]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.125		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.991		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Obesity (≥ 30 kg/m²)				0.553
Yes	Number of Participants with event, n (%)	1 (0.8)	4 (7.3)	
	Number of Participants censored, n (%)	118 (99.2)	51 (92.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=117]	98.2 (94.7, 101.7) [n=52]	
	Month 2 (Day 60)	99.1 (97.5, 100.8) [n=116]	98.2 (94.7, 101.7) [n=51]	
	Month 3 (Day 90)	99.1 (97.5, 100.8) [n=116]	96.3 (91.2, 101.3) [n=48]	
	Month 4 (Day 120)	99.1 (97.5, 100.8) [n=115]	94.3 (87.9, 100.6) [n=47]	
	Month 5 (Day 150)	99.1 (97.5, 100.8) [n=113]	94.3 (87.9, 100.6) [n=47]	
	Month 6 (Day 180)	99.1 (97.5, 100.8) [n=113]	92.2 (84.9, 99.6) [n=46]	
	Month 6 (Day 183)	99.1 (97.5, 100.8) [n=113]	92.2 (84.9, 99.6) [n=46]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.016		
	Hazard Ratio (95% CI)	0.11 (0.01, 0.96)		
	P-value	0.046		
No	Number of Participants with event, n (%)	2 (0.9)	4 (3.4)	
	Number of Participants censored, n (%)	223 (99.1)	113 (96.6)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.7, 100.4) [n=224]	97.4 (94.6, 100.3) [n=113]	
	Month 2 (Day 60)	99.6 (98.7, 100.4) [n=222]	97.4 (94.6, 100.3) [n=112]	
	Month 3 (Day 90)	99.6 (98.7, 100.4) [n=221]	97.4 (94.6, 100.3) [n=110]	
	Month 4 (Day 120)	99.6 (98.7, 100.4) [n=216]	97.4 (94.6, 100.3) [n=106]	
	Month 5 (Day 150)	99.6 (98.7, 100.4) [n=214]	97.4 (94.6, 100.3) [n=106]	
	Month 6 (Day 180)	99.1 (97.8, 100.3) [n=212]	96.5 (93.2, 99.9) [n=105]	
	Month 6 (Day 183)	99.1 (97.8, 100.3) [n=211]	96.5 (93.2, 99.9) [n=105]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.086		
	Hazard Ratio (95% CI)	0.25 (0.05, 1.35)		
	P-value	0.107		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Obesity (≥ 40 kg/m²)				0.993
Yes	Number of Participants with event, n (%)	0 (0.0)	1 (7.7)	
	Number of Participants censored, n (%)	17 (100.0)	12 (92.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=13]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=13]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=12]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=12]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=12]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=16]	91.7 (76.0, 107.3) [n=11]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=16]	91.7 (76.0, 107.3) [n=11]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.248		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.992		
No	Number of Participants with event, n (%)	3 (0.9)	7 (4.4)	
	Number of Participants censored, n (%)	324 (99.1)	152 (95.6)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=325]	97.5 (95.0, 99.9) [n=152]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=322]	97.5 (95.0, 99.9) [n=150]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=321]	96.8 (94.1, 99.6) [n=146]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=315]	96.1 (93.1, 99.2) [n=141]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=311]	96.1 (93.1, 99.2) [n=141]	
	Month 6 (Day 180)	99.1 (98.0, 100.1) [n=309]	95.5 (92.2, 98.8) [n=140]	
	Month 6 (Day 183)	99.1 (98.0, 100.1) [n=308]	95.5 (92.2, 98.8) [n=140]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.010		
	Hazard Ratio (95% CI)	0.20 (0.05, 0.76)		
	P-value	0.018		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Chronic kidney disease				0.993
Yes	Number of Participants with event, n (%)	0 (0.0)	1 (4.8)	
	Number of Participants censored, n (%)	38 (100.0)	20 (95.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=38]	95.2 (86.1, 104.3) [n=20]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=38]	95.2 (86.1, 104.3) [n=19]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=38]	95.2 (86.1, 104.3) [n=19]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=37]	95.2 (86.1, 104.3) [n=19]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=36]	95.2 (86.1, 104.3) [n=19]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=36]	95.2 (86.1, 104.3) [n=19]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=36]	95.2 (86.1, 104.3) [n=19]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.179		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.992		
No	Number of Participants with event, n (%)	3 (1.0)	7 (4.6)	
	Number of Participants censored, n (%)	305 (99.0)	145 (95.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.0, 100.3) [n=305]	98.0 (95.8, 100.2) [n=146]	
	Month 2 (Day 60)	99.3 (98.4, 100.2) [n=302]	98.0 (95.8, 100.2) [n=145]	
	Month 3 (Day 90)	99.3 (98.4, 100.2) [n=301]	97.3 (94.8, 99.9) [n=140]	
	Month 4 (Day 120)	99.3 (98.4, 100.2) [n=296]	96.6 (93.7, 99.5) [n=135]	
	Month 5 (Day 150)	99.3 (98.4, 100.2) [n=293]	96.6 (93.7, 99.5) [n=135]	
	Month 6 (Day 180)	99.0 (97.9, 100.1) [n=291]	95.2 (91.7, 98.7) [n=133]	
	Month 6 (Day 183)	99.0 (97.9, 100.1) [n=290]	95.2 (91.7, 98.7) [n=133]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.011		
	Hazard Ratio (95% CI)	0.20 (0.05, 0.79)		
	P-value	0.021		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Diabetes				0.993
Yes	Number of Participants with event, n (%)	0 (0.0)	1 (4.0)	
	Number of Participants censored, n (%)	40 (100.0)	24 (96.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=38]	96.0 (88.3, 103.7) [n=23]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.206		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.992		
No	Number of Participants with event, n (%)	3 (1.0)	7 (4.7)	
	Number of Participants censored, n (%)	303 (99.0)	141 (95.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.0, 100.3) [n=304]	98.0 (95.7, 100.2) [n=143]	
	Month 2 (Day 60)	99.3 (98.4, 100.3) [n=301]	98.0 (95.7, 100.2) [n=141]	
	Month 3 (Day 90)	99.3 (98.4, 100.3) [n=300]	97.3 (94.6, 99.9) [n=136]	
	Month 4 (Day 120)	99.3 (98.4, 100.3) [n=294]	96.5 (93.6, 99.5) [n=131]	
	Month 5 (Day 150)	99.3 (98.4, 100.3) [n=290]	96.5 (93.6, 99.5) [n=131]	
	Month 6 (Day 180)	99.0 (97.9, 100.1) [n=288]	95.1 (91.5, 98.6) [n=129]	
	Month 6 (Day 183)	99.0 (97.9, 100.1) [n=288]	95.1 (91.5, 98.6) [n=129]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.010		
	Hazard Ratio (95% CI)	0.20 (0.05, 0.77)		
	P-value	0.019		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Immunosuppressive disease				1.000
Yes	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	16 (100.0)	9 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=9]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=9]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	1.03 (0.00, NE)		
	P-value	1.000		
No	Number of Participants with event, n (%)	3 (0.9)	8 (4.9)	
	Number of Participants censored, n (%)	327 (99.1)	156 (95.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=327]	97.5 (95.2, 99.9) [n=157]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=324]	97.5 (95.2, 99.9) [n=155]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=323]	96.9 (94.3, 99.6) [n=151]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=317]	96.3 (93.3, 99.2) [n=146]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=313]	96.3 (93.3, 99.2) [n=146]	
	Month 6 (Day 180)	99.1 (98.0, 100.1) [n=311]	94.9 (91.5, 98.4) [n=144]	
	Month 6 (Day 183)	99.1 (98.0, 100.1) [n=310]	94.9 (91.5, 98.4) [n=144]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.004		
	Hazard Ratio (95% CI)	0.18 (0.05, 0.66)		
	P-value	0.010		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Immunosuppressive treatment				0.720
Yes	Number of Participants with event, n (%)	1 (1.0)	4 (6.7)	
	Number of Participants censored, n (%)	102 (99.0)	56 (93.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=101]	96.7 (92.1, 101.2) [n=57]	
	Month 2 (Day 60)	99.0 (97.1, 100.9) [n=100]	96.7 (92.1, 101.2) [n=55]	
	Month 3 (Day 90)	99.0 (97.1, 100.9) [n=100]	94.9 (89.3, 100.5) [n=52]	
	Month 4 (Day 120)	99.0 (97.1, 100.9) [n=99]	94.9 (89.3, 100.5) [n=52]	
	Month 5 (Day 150)	99.0 (97.1, 100.9) [n=97]	94.9 (89.3, 100.5) [n=52]	
	Month 6 (Day 180)	99.0 (97.1, 100.9) [n=97]	93.1 (86.5, 99.6) [n=51]	
	Month 6 (Day 183)	99.0 (97.1, 100.9) [n=97]	93.1 (86.5, 99.6) [n=51]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.039		
	Hazard Ratio (95% CI)	0.13 (0.01, 1.20)		
	P-value	0.072		
No	Number of Participants with event, n (%)	2 (0.8)	4 (3.5)	
	Number of Participants censored, n (%)	241 (99.2)	109 (96.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.8, 100.4) [n=242]	98.2 (95.8, 100.7) [n=109]	
	Month 2 (Day 60)	99.6 (98.8, 100.4) [n=240]	98.2 (95.8, 100.7) [n=109]	
	Month 3 (Day 90)	99.6 (98.8, 100.4) [n=239]	98.2 (95.8, 100.7) [n=107]	
	Month 4 (Day 120)	99.6 (98.8, 100.4) [n=234]	97.3 (94.2, 100.3) [n=102]	
	Month 5 (Day 150)	99.6 (98.8, 100.4) [n=232]	97.3 (94.2, 100.3) [n=102]	
	Month 6 (Day 180)	99.2 (98.0, 100.3) [n=230]	96.3 (92.8, 99.9) [n=101]	
	Month 6 (Day 183)	99.2 (98.0, 100.3) [n=229]	96.3 (92.8, 99.9) [n=101]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.060		
	Hazard Ratio (95% CI)	0.22 (0.04, 1.21)		
	P-value	0.082		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
CV disease				0.993
Yes	Number of Participants with event, n (%)	0 (0.0)	1 (4.5)	
	Number of Participants censored, n (%)	32 (100.0)	21 (95.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=32]	100.0 (100.0, 100.0) [n=22]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=32]	100.0 (100.0, 100.0) [n=21]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=32]	100.0 (100.0, 100.0) [n=21]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=32]	95.2 (86.1, 104.3) [n=20]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=31]	95.2 (86.1, 104.3) [n=20]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=31]	95.2 (86.1, 104.3) [n=20]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=31]	95.2 (86.1, 104.3) [n=20]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.217		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.992		
No	Number of Participants with event, n (%)	3 (1.0)	7 (4.6)	
	Number of Participants censored, n (%)	311 (99.0)	144 (95.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=311]	97.3 (94.8, 99.9) [n=144]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=308]	97.3 (94.8, 99.9) [n=143]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=307]	96.7 (93.8, 99.5) [n=138]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=301]	96.7 (93.8, 99.5) [n=134]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=298]	96.7 (93.8, 99.5) [n=134]	
	Month 6 (Day 180)	99.0 (97.9, 100.1) [n=296]	95.2 (91.8, 98.7) [n=132]	
	Month 6 (Day 183)	99.0 (97.9, 100.1) [n=295]	95.2 (91.8, 98.7) [n=132]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.009		
	Hazard Ratio (95% CI)	0.20 (0.05, 0.76)		
	P-value	0.018		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
COPD				1.000
Yes	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	23 (100.0)	11 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	1.01 (0.00, NE)		
	P-value	1.000		
No	Number of Participants with event, n (%)	3 (0.9)	8 (4.9)	
	Number of Participants censored, n (%)	320 (99.1)	154 (95.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=320]	97.5 (95.1, 99.9) [n=155]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=317]	97.5 (95.1, 99.9) [n=153]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=316]	96.9 (94.2, 99.6) [n=148]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=310]	96.2 (93.2, 99.2) [n=143]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=306]	96.2 (93.2, 99.2) [n=143]	
	Month 6 (Day 180)	99.1 (98.0, 100.1) [n=304]	94.9 (91.4, 98.3) [n=141]	
	Month 6 (Day 183)	99.1 (98.0, 100.1) [n=303]	94.9 (91.4, 98.3) [n=141]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.005		
	Hazard Ratio (95% CI)	0.18 (0.05, 0.67)		
	P-value	0.011		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Chronic liver disease				0.379
Yes	Number of Participants with event, n (%)	1 (2.3)	1 (3.8)	
	Number of Participants censored, n (%)	43 (97.7)	25 (96.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=24]	
	Month 2 (Day 60)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=23]	
	Month 3 (Day 90)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=23]	
	Month 4 (Day 120)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=21]	
	Month 5 (Day 150)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=21]	
	Month 6 (Day 180)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=21]	
	Month 6 (Day 183)	97.7 (93.3, 102.1) [n=42]	96.0 (88.3, 103.7) [n=21]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.718		
	Hazard Ratio (95% CI)	0.55 (0.03, 8.79)		
	P-value	0.672		
No	Number of Participants with event, n (%)	2 (0.7)	7 (4.8)	
	Number of Participants censored, n (%)	300 (99.3)	140 (95.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=300]	98.0 (95.7, 100.2) [n=142]	
	Month 2 (Day 60)	99.7 (99.0, 100.3) [n=297]	98.0 (95.7, 100.2) [n=141]	
	Month 3 (Day 90)	99.7 (99.0, 100.3) [n=296]	97.3 (94.6, 99.9) [n=136]	
	Month 4 (Day 120)	99.7 (99.0, 100.3) [n=290]	96.5 (93.6, 99.5) [n=133]	
	Month 5 (Day 150)	99.7 (99.0, 100.3) [n=286]	96.5 (93.6, 99.5) [n=133]	
	Month 6 (Day 180)	99.3 (98.4, 100.3) [n=284]	95.1 (91.5, 98.6) [n=131]	
	Month 6 (Day 183)	99.3 (98.4, 100.3) [n=284]	95.1 (91.5, 98.6) [n=131]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.003		
	Hazard Ratio (95% CI)	0.13 (0.03, 0.63)		
	P-value	0.011		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Hypertension				0.791
Yes	Number of Participants with event, n (%)	1 (0.7)	2 (2.7)	
	Number of Participants censored, n (%)	152 (99.3)	73 (97.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=152]	97.3 (93.7, 101.0) [n=72]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=151]	97.3 (93.7, 101.0) [n=70]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=151]	97.3 (93.7, 101.0) [n=69]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=149]	97.3 (93.7, 101.0) [n=69]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=147]	97.3 (93.7, 101.0) [n=69]	
	Month 6 (Day 180)	99.3 (98.0, 100.6) [n=146]	97.3 (93.7, 101.0) [n=69]	
	Month 6 (Day 183)	99.3 (98.0, 100.6) [n=146]	97.3 (93.7, 101.0) [n=69]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.192		
	Hazard Ratio (95% CI)	0.23 (0.02, 2.59)		
	P-value	0.237		
No	Number of Participants with event, n (%)	2 (1.0)	6 (6.1)	
	Number of Participants censored, n (%)	191 (99.0)	92 (93.9)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.5 (98.5, 100.5) [n=191]	97.9 (95.1, 100.8) [n=94]	
	Month 2 (Day 60)	99.0 (97.5, 100.4) [n=189]	97.9 (95.1, 100.8) [n=94]	
	Month 3 (Day 90)	99.0 (97.5, 100.4) [n=188]	96.9 (93.4, 100.4) [n=90]	
	Month 4 (Day 120)	99.0 (97.5, 100.4) [n=184]	95.8 (91.7, 99.8) [n=85]	
	Month 5 (Day 150)	99.0 (97.5, 100.4) [n=182]	95.8 (91.7, 99.8) [n=85]	
	Month 6 (Day 180)	99.0 (97.5, 100.4) [n=181]	93.5 (88.5, 98.5) [n=83]	
	Month 6 (Day 183)	99.0 (97.5, 100.4) [n=180]	93.5 (88.5, 98.5) [n=83]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.013		
	Hazard Ratio (95% CI)	0.16 (0.03, 0.79)		
	P-value	0.024		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Asthma				0.558
Yes	Number of Participants with event, n (%)	1 (1.8)	1 (4.8)	
	Number of Participants censored, n (%)	54 (98.2)	20 (95.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=55]	100.0 (100.0, 100.0) [n=21]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=55]	100.0 (100.0, 100.0) [n=21]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=55]	95.2 (86.1, 104.3) [n=20]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=55]	95.2 (86.1, 104.3) [n=19]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=54]	95.2 (86.1, 104.3) [n=19]	
	Month 6 (Day 180)	98.1 (94.5, 101.8) [n=52]	95.2 (86.1, 104.3) [n=19]	
	Month 6 (Day 183)	98.1 (94.5, 101.8) [n=52]	95.2 (86.1, 104.3) [n=19]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.439		
	Hazard Ratio (95% CI)	0.36 (0.02, 5.83)		
	P-value	0.476		
No	Number of Participants with event, n (%)	2 (0.7)	7 (4.6)	
	Number of Participants censored, n (%)	289 (99.3)	145 (95.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.0, 100.3) [n=288]	97.4 (94.8, 99.9) [n=145]	
	Month 2 (Day 60)	99.3 (98.4, 100.3) [n=285]	97.4 (94.8, 99.9) [n=143]	
	Month 3 (Day 90)	99.3 (98.4, 100.3) [n=284]	97.4 (94.8, 99.9) [n=139]	
	Month 4 (Day 120)	99.3 (98.4, 100.3) [n=278]	96.6 (93.8, 99.5) [n=135]	
	Month 5 (Day 150)	99.3 (98.4, 100.3) [n=275]	96.6 (93.8, 99.5) [n=135]	
	Month 6 (Day 180)	99.3 (98.4, 100.3) [n=275]	95.2 (91.7, 98.7) [n=133]	
	Month 6 (Day 183)	99.3 (98.4, 100.3) [n=274]	95.2 (91.7, 98.7) [n=133]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.006		
	Hazard Ratio (95% CI)	0.14 (0.03, 0.68)		
	P-value	0.014		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Cancer				0.783
Yes	Number of Participants with event, n (%)	1 (1.7)	2 (6.7)	
	Number of Participants censored, n (%)	59 (98.3)	28 (93.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=60]	93.3 (84.4, 102.3) [n=27]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=59]	93.3 (84.4, 102.3) [n=27]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=59]	93.3 (84.4, 102.3) [n=26]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=58]	93.3 (84.4, 102.3) [n=26]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=57]	93.3 (84.4, 102.3) [n=26]	
	Month 6 (Day 180)	98.2 (94.8, 101.7) [n=56]	93.3 (84.4, 102.3) [n=26]	
	Month 6 (Day 183)	98.2 (94.8, 101.7) [n=55]	93.3 (84.4, 102.3) [n=26]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.185		
	Hazard Ratio (95% CI)	0.23 (0.02, 2.59)		
	P-value	0.237		
No	Number of Participants with event, n (%)	2 (0.7)	6 (4.2)	
	Number of Participants censored, n (%)	284 (99.3)	137 (95.8)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (99.0, 100.3) [n=283]	98.6 (96.7, 100.5) [n=139]	
	Month 2 (Day 60)	99.3 (98.3, 100.3) [n=281]	98.6 (96.7, 100.5) [n=137]	
	Month 3 (Day 90)	99.3 (98.3, 100.3) [n=280]	97.9 (95.5, 100.3) [n=133]	
	Month 4 (Day 120)	99.3 (98.3, 100.3) [n=275]	97.1 (94.3, 99.9) [n=128]	
	Month 5 (Day 150)	99.3 (98.3, 100.3) [n=272]	97.1 (94.3, 99.9) [n=128]	
	Month 6 (Day 180)	99.3 (98.3, 100.3) [n=271]	95.6 (92.2, 99.0) [n=126]	
	Month 6 (Day 183)	99.3 (98.3, 100.3) [n=271]	95.6 (92.2, 99.0) [n=126]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.012		
	Hazard Ratio (95% CI)	0.16 (0.03, 0.78)		
	P-value	0.023		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Smoking				0.993
Yes	Number of Participants with event, n (%)	1 (1.6)	0 (0.0)	
	Number of Participants censored, n (%)	62 (98.4)	31 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	98.4 (95.3, 101.5) [n=62]	100.0 (100.0, 100.0) [n=30]	
	Month 2 (Day 60)	98.4 (95.3, 101.5) [n=61]	100.0 (100.0, 100.0) [n=30]	
	Month 3 (Day 90)	98.4 (95.3, 101.5) [n=60]	100.0 (100.0, 100.0) [n=30]	
	Month 4 (Day 120)	98.4 (95.3, 101.5) [n=58]	100.0 (100.0, 100.0) [n=28]	
	Month 5 (Day 150)	98.4 (95.3, 101.5) [n=57]	100.0 (100.0, 100.0) [n=28]	
	Month 6 (Day 180)	98.4 (95.3, 101.5) [n=57]	100.0 (100.0, 100.0) [n=28]	
	Month 6 (Day 183)	98.4 (95.3, 101.5) [n=57]	100.0 (100.0, 100.0) [n=28]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.483		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.994		
No	Number of Participants with event, n (%)	2 (0.7)	8 (5.6)	
	Number of Participants censored, n (%)	281 (99.3)	134 (94.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=281]	97.2 (94.5, 99.9) [n=136]	
	Month 2 (Day 60)	99.6 (98.9, 100.3) [n=279]	97.2 (94.5, 99.9) [n=134]	
	Month 3 (Day 90)	99.6 (98.9, 100.3) [n=279]	96.5 (93.4, 99.5) [n=129]	
	Month 4 (Day 120)	99.6 (98.9, 100.3) [n=275]	95.7 (92.3, 99.1) [n=126]	
	Month 5 (Day 150)	99.6 (98.9, 100.3) [n=272]	95.7 (92.3, 99.1) [n=126]	
	Month 6 (Day 180)	99.3 (98.3, 100.3) [n=270]	94.2 (90.3, 98.1) [n=124]	
	Month 6 (Day 183)	99.3 (98.3, 100.3) [n=269]	94.2 (90.3, 98.1) [n=124]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.001		
	Hazard Ratio (95% CI)	0.11 (0.02, 0.53)		
	P-value	0.006		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Sickle cell disease				NE
No	Number of Participants with event, n (%)	3 (0.9)	8 (4.6)	
	Number of Participants censored, n (%)	343 (99.1)	165 (95.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=343]	97.7 (95.4, 99.9) [n=166]	
	Month 2 (Day 60)	99.4 (98.6, 100.2) [n=340]	97.7 (95.4, 99.9) [n=164]	
	Month 3 (Day 90)	99.4 (98.6, 100.2) [n=339]	97.1 (94.6, 99.6) [n=159]	
	Month 4 (Day 120)	99.4 (98.6, 100.2) [n=333]	96.5 (93.7, 99.2) [n=154]	
	Month 5 (Day 150)	99.4 (98.6, 100.2) [n=329]	96.5 (93.7, 99.2) [n=154]	
	Month 6 (Day 180)	99.1 (98.1, 100.1) [n=327]	95.2 (92.0, 98.5) [n=152]	
	Month 6 (Day 183)	99.1 (98.1, 100.1) [n=326]	95.2 (92.0, 98.5) [n=152]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.005		
	Hazard Ratio (95% CI)	NE (NE, NE)		
	P-value	NE		
COVID-19 vaccination at any time during the study				0.993
Yes	Number of Participants with event, n (%)	3 (1.2)	7 (5.5)	
	Number of Participants censored, n (%)	239 (98.8)	120 (94.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.8, 100.4) [n=241]	97.6 (95.0, 100.3) [n=123]	
	Month 2 (Day 60)	99.2 (98.0, 100.3) [n=239]	97.6 (95.0, 100.3) [n=121]	
	Month 3 (Day 90)	99.2 (98.0, 100.3) [n=239]	96.8 (93.8, 99.9) [n=119]	
	Month 4 (Day 120)	99.2 (98.0, 100.3) [n=238]	96.0 (92.6, 99.4) [n=118]	
	Month 5 (Day 150)	99.2 (98.0, 100.3) [n=238]	96.0 (92.6, 99.4) [n=118]	
	Month 6 (Day 180)	98.8 (97.4, 100.2) [n=236]	94.4 (90.4, 98.4) [n=116]	
	Month 6 (Day 183)	98.8 (97.4, 100.2) [n=235]	94.4 (90.4, 98.4) [n=116]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.015		
	Hazard Ratio (95% CI)	0.21 (0.05, 0.81)		
	P-value	0.023		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.2.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 183 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	0 (0.0)	1 (2.2)	
	Number of Participants censored, n (%)	104 (100.0)	45 (97.8)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=102]	97.8 (93.6, 102.0) [n=43]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=101]	97.8 (93.6, 102.0) [n=43]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=100]	97.8 (93.6, 102.0) [n=40]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=95]	97.8 (93.6, 102.0) [n=36]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=91]	97.8 (93.6, 102.0) [n=36]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=91]	97.8 (93.6, 102.0) [n=36]	
	Month 6 (Day 183)	100.0 (100.0, 100.0) [n=91]	97.8 (93.6, 102.0) [n=36]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.135		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.993		
Increased risk for inadequate response to active immunization				1.000
Yes	Number of Participants with event, n (%)	3 (0.9)	8 (4.7)	
	Number of Participants censored, n (%)	341 (99.1)	164 (95.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=341]	97.7 (95.4, 99.9) [n=165]	
	Month 2 (Day 60)	99.4 (98.6, 100.2) [n=338]	97.7 (95.4, 99.9) [n=163]	
	Month 3 (Day 90)	99.4 (98.6, 100.2) [n=337]	97.1 (94.5, 99.6) [n=158]	
	Month 4 (Day 120)	99.4 (98.6, 100.2) [n=331]	96.4 (93.6, 99.2) [n=153]	
	Month 5 (Day 150)	99.4 (98.6, 100.2) [n=327]	96.4 (93.6, 99.2) [n=153]	
	Month 6 (Day 180)	99.1 (98.1, 100.1) [n=325]	95.2 (91.9, 98.4) [n=151]	
	Month 6 (Day 183)	99.1 (98.1, 100.1) [n=324]	95.2 (91.9, 98.4) [n=151]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.005		
	Hazard Ratio (95% CI)	0.18 (0.05, 0.67)		
	P-value	0.010		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, age group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Age at randomization				0.861
<60 years	Number of Participants with event, n (%)	12 (6.0)	10 (10.3)	
	Number of Participants censored, n (%)	187 (94.0)	87 (89.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.5 (98.5, 100.5) [n=198]	96.9 (93.4, 100.4) [n=91]	
	Month 2 (Day 60)	99.5 (98.5, 100.5) [n=197]	96.9 (93.4, 100.4) [n=89]	
	Month 3 (Day 90)	99.5 (98.5, 100.5) [n=196]	95.8 (91.8, 99.8) [n=86]	
	Month 4 (Day 120)	99.5 (98.5, 100.5) [n=192]	94.6 (90.1, 99.2) [n=81]	
	Month 5 (Day 150)	99.5 (98.5, 100.5) [n=190]	94.6 (90.1, 99.2) [n=81]	
	Month 6 (Day 180)	99.0 (97.6, 100.4) [n=188]	93.5 (88.4, 98.5) [n=80]	
	Month 7 (Day 210)	99.0 (97.6, 100.4) [n=187]	92.3 (86.8, 97.8) [n=77]	
	Month 8 (Day 240)	99.0 (97.6, 100.4) [n=186]	92.3 (86.8, 97.8) [n=77]	
	Month 9 (Day 270)	99.0 (97.6, 100.4) [n=185]	92.3 (86.8, 97.8) [n=77]	
	Month 10 (Day 300)	97.9 (95.9, 99.9) [n=183]	91.1 (85.2, 97.0) [n=76]	
	Month 11 (Day 330)	95.8 (92.9, 98.6) [n=179]	89.9 (83.6, 96.2) [n=73]	
	Month 12 (Day 360)	94.1 (90.7, 97.5) [n=163]	88.7 (82.0, 95.3) [n=68]	
	Month 12 (Day 366)	93.5 (90.0, 97.1) [n=159]	88.7 (82.0, 95.3) [n=66]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.082		
	Hazard Ratio (95% CI)	0.51 (0.22, 1.18)		
	P-value	0.115		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
≥60 years	Number of Participants with event, n (%)	10 (6.8)	9 (11.8)	
	Number of Participants censored, n (%)	137 (93.2)	67 (88.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=145]	98.7 (96.1, 101.2) [n=75]	
	Month 2 (Day 60)	99.3 (98.0, 100.7) [n=143]	98.7 (96.1, 101.2) [n=75]	
	Month 3 (Day 90)	99.3 (98.0, 100.7) [n=143]	98.7 (96.1, 101.2) [n=73]	
	Month 4 (Day 120)	99.3 (98.0, 100.7) [n=141]	98.7 (96.1, 101.2) [n=73]	
	Month 5 (Day 150)	99.3 (98.0, 100.7) [n=139]	98.7 (96.1, 101.2) [n=73]	
	Month 6 (Day 180)	99.3 (98.0, 100.7) [n=139]	97.3 (93.7, 101.0) [n=72]	
	Month 7 (Day 210)	99.3 (98.0, 100.7) [n=138]	96.0 (91.5, 100.4) [n=71]	
	Month 8 (Day 240)	98.6 (96.7, 100.5) [n=137]	94.6 (89.5, 99.8) [n=70]	
	Month 9 (Day 270)	97.9 (95.5, 100.3) [n=135]	94.6 (89.5, 99.8) [n=69]	
	Month 10 (Day 300)	97.9 (95.5, 100.3) [n=135]	94.6 (89.5, 99.8) [n=69]	
	Month 11 (Day 330)	95.7 (92.3, 99.1) [n=129]	89.1 (82.0, 96.2) [n=64]	
	Month 12 (Day 360)	93.4 (89.3, 97.6) [n=116]	89.1 (82.0, 96.2) [n=58]	
	Month 12 (Day 366)	92.6 (88.2, 97.0) [n=110]	87.6 (80.0, 95.2) [n=57]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.195		
	Hazard Ratio (95% CI)	0.57 (0.23, 1.40)		
	P-value	0.219		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Age at randomization				0.278
<65 years	Number of Participants with event, n (%)	15 (5.7)	16 (11.7)	
	Number of Participants censored, n (%)	247 (94.3)	121 (88.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.9, 100.4) [n=260]	97.1 (94.2, 99.9) [n=130]	
	Month 2 (Day 60)	99.2 (98.2, 100.3) [n=258]	97.1 (94.2, 99.9) [n=128]	
	Month 3 (Day 90)	99.2 (98.2, 100.3) [n=257]	96.3 (93.1, 99.5) [n=124]	
	Month 4 (Day 120)	99.2 (98.2, 100.3) [n=251]	95.5 (92.0, 99.0) [n=119]	
	Month 5 (Day 150)	99.2 (98.2, 100.3) [n=248]	95.5 (92.0, 99.0) [n=119]	
	Month 6 (Day 180)	98.8 (97.5, 100.1) [n=246]	93.9 (89.8, 98.0) [n=117]	
	Month 7 (Day 210)	98.8 (97.5, 100.1) [n=244]	93.1 (88.7, 97.5) [n=114]	
	Month 8 (Day 240)	98.8 (97.5, 100.1) [n=243]	92.3 (87.7, 96.9) [n=113]	
	Month 9 (Day 270)	98.8 (97.5, 100.1) [n=241]	92.3 (87.7, 96.9) [n=112]	
	Month 10 (Day 300)	98.0 (96.3, 99.7) [n=239]	91.5 (86.6, 96.3) [n=111]	
	Month 11 (Day 330)	96.8 (94.6, 99.0) [n=233]	88.2 (82.5, 93.8) [n=104]	
	Month 12 (Day 360)	94.2 (91.3, 97.2) [n=207]	87.3 (81.5, 93.1) [n=93]	
	Month 12 (Day 366)	93.8 (90.7, 96.8) [n=201]	87.3 (81.5, 93.1) [n=91]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.012		
	Hazard Ratio (95% CI)	0.44 (0.22, 0.89)		
	P-value	0.022		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
≥65 years	Number of Participants with event, n (%)	7 (8.3)	3 (8.3)	
	Number of Participants censored, n (%)	77 (91.7)	33 (91.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=83]	100.0 (100.0, 100.0) [n=36]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=82]	100.0 (100.0, 100.0) [n=36]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=82]	100.0 (100.0, 100.0) [n=35]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=82]	100.0 (100.0, 100.0) [n=35]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=81]	100.0 (100.0, 100.0) [n=35]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=81]	100.0 (100.0, 100.0) [n=35]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=81]	97.1 (91.6, 102.7) [n=34]	
	Month 8 (Day 240)	98.8 (96.4, 101.2) [n=80]	97.1 (91.6, 102.7) [n=34]	
	Month 9 (Day 270)	97.5 (94.2, 100.9) [n=79]	97.1 (91.6, 102.7) [n=34]	
	Month 10 (Day 300)	97.5 (94.2, 100.9) [n=79]	97.1 (91.6, 102.7) [n=34]	
	Month 11 (Day 330)	92.6 (86.9, 98.3) [n=75]	94.3 (86.6, 102.0) [n=33]	
	Month 12 (Day 360)	92.6 (86.9, 98.3) [n=72]	94.3 (86.6, 102.0) [n=33]	
	Month 12 (Day 366)	91.3 (85.1, 97.5) [n=68]	91.4 (82.2, 100.7) [n=32]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.946		
	Hazard Ratio (95% CI)	1.02 (0.26, 3.95)		
	P-value	0.975		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Age at randomization				0.904
<75 years	Number of Participants with event, n (%)	20 (6.1)	18 (10.7)	
	Number of Participants censored, n (%)	310 (93.9)	150 (89.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=327]	97.6 (95.3, 99.9) [n=161]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=324]	97.6 (95.3, 99.9) [n=159]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=323]	97.0 (94.4, 99.6) [n=154]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=317]	96.4 (93.5, 99.2) [n=149]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=314]	96.4 (93.5, 99.2) [n=149]	
	Month 6 (Day 180)	99.1 (98.0, 100.1) [n=312]	95.1 (91.7, 98.4) [n=147]	
	Month 7 (Day 210)	99.1 (98.0, 100.1) [n=310]	94.4 (90.9, 98.0) [n=144]	
	Month 8 (Day 240)	98.8 (97.5, 100.0) [n=308]	93.8 (90.0, 97.5) [n=143]	
	Month 9 (Day 270)	98.8 (97.5, 100.0) [n=306]	93.8 (90.0, 97.5) [n=142]	
	Month 10 (Day 300)	98.1 (96.6, 99.6) [n=304]	93.1 (89.1, 97.0) [n=141]	
	Month 11 (Day 330)	96.5 (94.5, 98.5) [n=295]	89.8 (85.0, 94.5) [n=133]	
	Month 12 (Day 360)	94.2 (91.5, 96.8) [n=266]	89.1 (84.2, 94.0) [n=122]	
	Month 12 (Day 366)	93.4 (90.7, 96.2) [n=257]	88.4 (83.3, 93.4) [n=119]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.028		
	Hazard Ratio (95% CI)	0.52 (0.28, 0.98)		
	P-value	0.045		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
≥75 years	Number of Participants with event, n (%)	2 (12.5)	1 (20.0)	
	Number of Participants censored, n (%)	14 (87.5)	4 (80.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (185.0, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=5]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=5]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=5]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=5]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=15]	100.0 (100.0, 100.0) [n=5]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=15]	100.0 (100.0, 100.0) [n=5]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=15]	80.0 (44.9, 115.1) [n=4]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=15]	80.0 (44.9, 115.1) [n=4]	
	Month 9 (Day 270)	93.3 (80.7, 106.0) [n=14]	80.0 (44.9, 115.1) [n=4]	
	Month 10 (Day 300)	93.3 (80.7, 106.0) [n=14]	80.0 (44.9, 115.1) [n=4]	
	Month 11 (Day 330)	86.7 (69.5, 103.9) [n=13]	80.0 (44.9, 115.1) [n=4]	
	Month 12 (Day 360)	86.7 (69.5, 103.9) [n=13]	80.0 (44.9, 115.1) [n=4]	
	Month 12 (Day 366)	86.7 (69.5, 103.9) [n=12]	80.0 (44.9, 115.1) [n=4]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.613		
	Hazard Ratio (95% CI)	0.61 (0.05, 6.69)		
	P-value	0.683		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Residence in long-term care facility				NE
No	Number of Participants with event, n (%)	22 (6.4)	19 (11.0)	
	Number of Participants censored, n (%)	324 (93.6)	154 (89.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=343]	97.7 (95.4, 99.9) [n=166]	
	Month 2 (Day 60)	99.4 (98.6, 100.2) [n=340]	97.7 (95.4, 99.9) [n=164]	
	Month 3 (Day 90)	99.4 (98.6, 100.2) [n=339]	97.1 (94.6, 99.6) [n=159]	
	Month 4 (Day 120)	99.4 (98.6, 100.2) [n=333]	96.5 (93.7, 99.2) [n=154]	
	Month 5 (Day 150)	99.4 (98.6, 100.2) [n=329]	96.5 (93.7, 99.2) [n=154]	
	Month 6 (Day 180)	99.1 (98.1, 100.1) [n=327]	95.2 (92.0, 98.5) [n=152]	
	Month 7 (Day 210)	99.1 (98.1, 100.1) [n=325]	94.0 (90.3, 97.6) [n=148]	
	Month 8 (Day 240)	98.8 (97.7, 100.0) [n=323]	93.3 (89.5, 97.1) [n=147]	
	Month 9 (Day 270)	98.5 (97.2, 99.8) [n=320]	93.3 (89.5, 97.1) [n=146]	
	Month 10 (Day 300)	97.9 (96.3, 99.4) [n=318]	92.7 (88.7, 96.7) [n=145]	
	Month 11 (Day 330)	96.0 (93.9, 98.1) [n=308]	89.5 (84.7, 94.2) [n=137]	
	Month 12 (Day 360)	93.8 (91.2, 96.4) [n=279]	88.8 (83.9, 93.7) [n=126]	
	Month 12 (Day 366)	93.1 (90.4, 95.9) [n=269]	88.1 (83.1, 93.1) [n=123]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.029		
	Hazard Ratio (95% CI)	NE (NE, NE)		
	P-value	NE		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Increased risk of exposure to infection with SARS-CoV-2				0.871
Yes	Number of Participants with event, n (%)	5 (5.1)	4 (7.7)	
	Number of Participants censored, n (%)	94 (94.9)	48 (92.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=99]	98.1 (94.3, 101.8) [n=50]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=99]	98.1 (94.3, 101.8) [n=49]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=98]	96.1 (90.7, 101.4) [n=46]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=95]	96.1 (90.7, 101.4) [n=44]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=94]	96.1 (90.7, 101.4) [n=44]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=94]	96.1 (90.7, 101.4) [n=44]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=94]	96.1 (90.7, 101.4) [n=43]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=94]	96.1 (90.7, 101.4) [n=43]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=93]	96.1 (90.7, 101.4) [n=43]	
	Month 10 (Day 300)	98.9 (96.8, 101.0) [n=92]	93.8 (87.1, 100.6) [n=42]	
	Month 11 (Day 330)	97.8 (94.9, 100.8) [n=90]	91.6 (83.7, 99.5) [n=41]	
	Month 12 (Day 360)	94.5 (89.9, 99.2) [n=82]	91.6 (83.7, 99.5) [n=36]	
	Month 12 (Day 366)	94.5 (89.9, 99.2) [n=78]	91.6 (83.7, 99.5) [n=35]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.357		
	Hazard Ratio (95% CI)	0.59 (0.16, 2.18)		
	P-value	0.426		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	17 (6.9)	15 (12.4)	
	Number of Participants censored, n (%)	230 (93.1)	106 (87.6)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.8, 100.4) [n=244]	97.5 (94.7, 100.3) [n=116]	
	Month 2 (Day 60)	99.2 (98.1, 100.3) [n=241]	97.5 (94.7, 100.3) [n=115]	
	Month 3 (Day 90)	99.2 (98.1, 100.3) [n=241]	97.5 (94.7, 100.3) [n=113]	
	Month 4 (Day 120)	99.2 (98.1, 100.3) [n=238]	96.6 (93.4, 99.9) [n=110]	
	Month 5 (Day 150)	99.2 (98.1, 100.3) [n=235]	96.6 (93.4, 99.9) [n=110]	
	Month 6 (Day 180)	98.8 (97.4, 100.2) [n=233]	94.9 (90.9, 98.9) [n=108]	
	Month 7 (Day 210)	98.8 (97.4, 100.2) [n=231]	93.1 (88.5, 97.7) [n=105]	
	Month 8 (Day 240)	98.3 (96.7, 100.0) [n=229]	92.2 (87.4, 97.1) [n=104]	
	Month 9 (Day 270)	97.9 (96.1, 99.7) [n=227]	92.2 (87.4, 97.1) [n=103]	
	Month 10 (Day 300)	97.5 (95.5, 99.5) [n=226]	92.2 (87.4, 97.1) [n=103]	
	Month 11 (Day 330)	94.9 (92.0, 97.7) [n=218]	88.6 (82.8, 94.5) [n=96]	
	Month 12 (Day 360)	93.5 (90.4, 96.7) [n=197]	87.7 (81.7, 93.8) [n=90]	
	Month 12 (Day 366)	92.6 (89.2, 96.0) [n=191]	86.7 (80.5, 93.0) [n=88]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.047		
	Hazard Ratio (95% CI)	0.52 (0.26, 1.04)		
	P-value	0.065		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Sex				0.814
Male	Number of Participants with event, n (%)	9 (4.2)	8 (7.6)	
	Number of Participants censored, n (%)	207 (95.8)	97 (92.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.5 (98.6, 100.4) [n=214]	98.1 (95.5, 100.7) [n=101]	
	Month 2 (Day 60)	99.5 (98.6, 100.4) [n=212]	98.1 (95.5, 100.7) [n=99]	
	Month 3 (Day 90)	99.5 (98.6, 100.4) [n=211]	97.1 (93.9, 100.3) [n=95]	
	Month 4 (Day 120)	99.5 (98.6, 100.4) [n=206]	97.1 (93.9, 100.3) [n=91]	
	Month 5 (Day 150)	99.5 (98.6, 100.4) [n=204]	97.1 (93.9, 100.3) [n=91]	
	Month 6 (Day 180)	99.0 (97.7, 100.4) [n=202]	96.0 (92.2, 99.8) [n=90]	
	Month 7 (Day 210)	99.0 (97.7, 100.4) [n=200]	94.9 (90.6, 99.3) [n=88]	
	Month 8 (Day 240)	99.0 (97.7, 100.4) [n=199]	93.9 (89.1, 98.6) [n=87]	
	Month 9 (Day 270)	98.5 (96.9, 100.2) [n=197]	93.9 (89.1, 98.6) [n=86]	
	Month 10 (Day 300)	98.0 (96.1, 99.9) [n=196]	93.9 (89.1, 98.6) [n=86]	
	Month 11 (Day 330)	96.5 (94.0, 99.1) [n=191]	91.6 (86.1, 97.2) [n=82]	
	Month 12 (Day 360)	96.0 (93.3, 98.7) [n=178]	91.6 (86.1, 97.2) [n=75]	
	Month 12 (Day 366)	95.5 (92.6, 98.4) [n=171]	91.6 (86.1, 97.2) [n=73]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.124		
	Hazard Ratio (95% CI)	0.50 (0.19, 1.29)		
	P-value	0.152		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1

Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode

(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Female	Number of Participants with event, n (%)	13 (10.0)	11 (16.2)	
	Number of Participants censored, n (%)	117 (90.0)	57 (83.8)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=129]	97.1 (93.0, 101.1) [n=65]	
	Month 2 (Day 60)	99.2 (97.7, 100.7) [n=128]	97.1 (93.0, 101.1) [n=65]	
	Month 3 (Day 90)	99.2 (97.7, 100.7) [n=128]	97.1 (93.0, 101.1) [n=64]	
	Month 4 (Day 120)	99.2 (97.7, 100.7) [n=127]	95.5 (90.6, 100.5) [n=63]	
	Month 5 (Day 150)	99.2 (97.7, 100.7) [n=125]	95.5 (90.6, 100.5) [n=63]	
	Month 6 (Day 180)	99.2 (97.7, 100.7) [n=125]	94.0 (88.3, 99.7) [n=62]	
	Month 7 (Day 210)	99.2 (97.7, 100.7) [n=125]	92.5 (86.2, 98.8) [n=60]	
	Month 8 (Day 240)	98.4 (96.3, 100.6) [n=124]	92.5 (86.2, 98.8) [n=60]	
	Month 9 (Day 270)	98.4 (96.3, 100.6) [n=123]	92.5 (86.2, 98.8) [n=60]	
	Month 10 (Day 300)	97.6 (95.0, 100.3) [n=122]	91.0 (84.1, 97.9) [n=59]	
	Month 11 (Day 330)	95.2 (91.5, 99.0) [n=117]	86.3 (78.0, 94.6) [n=55]	
	Month 12 (Day 360)	90.2 (85.0, 95.5) [n=101]	84.8 (76.1, 93.5) [n=51]	
	Month 12 (Day 366)	89.3 (83.8, 94.8) [n=98]	83.1 (74.0, 92.2) [n=50]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.139		
	Hazard Ratio (95% CI)	0.58 (0.26, 1.30)		
	P-value	0.184		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.

Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.

Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.

Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.

[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Region				0.746
North America	Number of Participants with event, n (%)	8 (4.3)	10 (9.4)	
	Number of Participants censored, n (%)	177 (95.7)	96 (90.6)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=185]	100.0 (100.0, 100.0) [n=105]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=184]	100.0 (100.0, 100.0) [n=103]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=183]	99.0 (97.1, 100.9) [n=100]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=177]	99.0 (97.1, 100.9) [n=97]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=173]	99.0 (97.1, 100.9) [n=97]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=173]	98.0 (95.3, 100.7) [n=96]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=173]	97.0 (93.6, 100.3) [n=93]	
	Month 8 (Day 240)	99.4 (98.3, 100.6) [n=171]	95.9 (92.0, 99.8) [n=92]	
	Month 9 (Day 270)	99.4 (98.3, 100.6) [n=169]	95.9 (92.0, 99.8) [n=91]	
	Month 10 (Day 300)	99.4 (98.3, 100.6) [n=169]	95.9 (92.0, 99.8) [n=91]	
	Month 11 (Day 330)	97.7 (95.4, 99.9) [n=162]	91.7 (86.1, 97.2) [n=84]	
	Month 12 (Day 360)	95.8 (92.8, 98.9) [n=141]	90.6 (84.7, 96.4) [n=74]	
	Month 12 (Day 366)	95.1 (91.9, 98.4) [n=134]	89.3 (83.1, 95.6) [n=72]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.057		
	Hazard Ratio (95% CI)	0.44 (0.17, 1.10)		
	P-value	0.080		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
United Kingdom	Number of Participants with event, n (%)	7 (8.8)	5 (16.7)	
	Number of Participants censored, n (%)	73 (91.3)	25 (83.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=78]	93.3 (84.4, 102.3) [n=27]	
	Month 2 (Day 60)	98.7 (96.2, 101.2) [n=77]	93.3 (84.4, 102.3) [n=27]	
	Month 3 (Day 90)	98.7 (96.2, 101.2) [n=77]	93.3 (84.4, 102.3) [n=25]	
	Month 4 (Day 120)	98.7 (96.2, 101.2) [n=77]	89.4 (78.1, 100.8) [n=23]	
	Month 5 (Day 150)	98.7 (96.2, 101.2) [n=77]	89.4 (78.1, 100.8) [n=23]	
	Month 6 (Day 180)	97.4 (93.9, 100.9) [n=76]	89.4 (78.1, 100.8) [n=23]	
	Month 7 (Day 210)	97.4 (93.9, 100.9) [n=75]	89.4 (78.1, 100.8) [n=23]	
	Month 8 (Day 240)	97.4 (93.9, 100.9) [n=75]	89.4 (78.1, 100.8) [n=23]	
	Month 9 (Day 270)	96.1 (91.9, 100.4) [n=74]	89.4 (78.1, 100.8) [n=23]	
	Month 10 (Day 300)	94.8 (89.9, 99.8) [n=73]	85.6 (72.4, 98.7) [n=22]	
	Month 11 (Day 330)	93.5 (88.1, 99.0) [n=72]	81.7 (67.1, 96.3) [n=21]	
	Month 12 (Day 360)	90.9 (84.5, 97.3) [n=70]	81.7 (67.1, 96.3) [n=21]	
	Month 12 (Day 366)	90.9 (84.5, 97.3) [n=70]	81.7 (67.1, 96.3) [n=21]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.131		
	Hazard Ratio (95% CI)	0.44 (0.14, 1.37)		
	P-value	0.156		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
European Union	Number of Participants with event, n (%)	7 (8.6)	4 (10.8)	
	Number of Participants censored, n (%)	74 (91.4)	33 (89.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	98.8 (96.4, 101.2) [n=80]	94.6 (87.3, 101.9) [n=34]	
	Month 2 (Day 60)	98.8 (96.4, 101.2) [n=79]	94.6 (87.3, 101.9) [n=34]	
	Month 3 (Day 90)	98.8 (96.4, 101.2) [n=79]	94.6 (87.3, 101.9) [n=34]	
	Month 4 (Day 120)	98.8 (96.4, 101.2) [n=79]	94.6 (87.3, 101.9) [n=34]	
	Month 5 (Day 150)	98.8 (96.4, 101.2) [n=79]	94.6 (87.3, 101.9) [n=34]	
	Month 6 (Day 180)	98.8 (96.4, 101.2) [n=78]	91.8 (82.9, 100.7) [n=33]	
	Month 7 (Day 210)	98.8 (96.4, 101.2) [n=77]	89.0 (78.9, 99.2) [n=32]	
	Month 8 (Day 240)	98.8 (96.4, 101.2) [n=77]	89.0 (78.9, 99.2) [n=32]	
	Month 9 (Day 270)	98.8 (96.4, 101.2) [n=77]	89.0 (78.9, 99.2) [n=32]	
	Month 10 (Day 300)	97.5 (94.0, 100.9) [n=76]	89.0 (78.9, 99.2) [n=32]	
	Month 11 (Day 330)	94.9 (90.1, 99.8) [n=74]	89.0 (78.9, 99.2) [n=32]	
	Month 12 (Day 360)	92.3 (86.4, 98.2) [n=68]	89.0 (78.9, 99.2) [n=31]	
	Month 12 (Day 366)	90.9 (84.5, 97.3) [n=65]	89.0 (78.9, 99.2) [n=30]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.599		
	Hazard Ratio (95% CI)	0.76 (0.22, 2.59)		
	P-value	0.661		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Country				0.990
United States	Number of Participants with event, n (%)	8 (4.3)	10 (9.4)	
	Number of Participants censored, n (%)	177 (95.7)	96 (90.6)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=185]	100.0 (100.0, 100.0) [n=105]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=184]	100.0 (100.0, 100.0) [n=103]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=183]	99.0 (97.1, 100.9) [n=100]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=177]	99.0 (97.1, 100.9) [n=97]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=173]	99.0 (97.1, 100.9) [n=97]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=173]	98.0 (95.3, 100.7) [n=96]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=173]	97.0 (93.6, 100.3) [n=93]	
	Month 8 (Day 240)	99.4 (98.3, 100.6) [n=171]	95.9 (92.0, 99.8) [n=92]	
	Month 9 (Day 270)	99.4 (98.3, 100.6) [n=169]	95.9 (92.0, 99.8) [n=91]	
	Month 10 (Day 300)	99.4 (98.3, 100.6) [n=169]	95.9 (92.0, 99.8) [n=91]	
	Month 11 (Day 330)	97.7 (95.4, 99.9) [n=162]	91.7 (86.1, 97.2) [n=84]	
	Month 12 (Day 360)	95.8 (92.8, 98.9) [n=141]	90.6 (84.7, 96.4) [n=74]	
	Month 12 (Day 366)	95.1 (91.9, 98.4) [n=134]	89.3 (83.1, 95.6) [n=72]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.057		
	Hazard Ratio (95% CI)	0.43 (0.17, 1.10)		
	P-value	0.079		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
United Kingdom	Number of Participants with event, n (%)	7 (8.8)	5 (16.7)	
	Number of Participants censored, n (%)	73 (91.3)	25 (83.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=78]	93.3 (84.4, 102.3) [n=27]	
	Month 2 (Day 60)	98.7 (96.2, 101.2) [n=77]	93.3 (84.4, 102.3) [n=27]	
	Month 3 (Day 90)	98.7 (96.2, 101.2) [n=77]	93.3 (84.4, 102.3) [n=25]	
	Month 4 (Day 120)	98.7 (96.2, 101.2) [n=77]	89.4 (78.1, 100.8) [n=23]	
	Month 5 (Day 150)	98.7 (96.2, 101.2) [n=77]	89.4 (78.1, 100.8) [n=23]	
	Month 6 (Day 180)	97.4 (93.9, 100.9) [n=76]	89.4 (78.1, 100.8) [n=23]	
	Month 7 (Day 210)	97.4 (93.9, 100.9) [n=75]	89.4 (78.1, 100.8) [n=23]	
	Month 8 (Day 240)	97.4 (93.9, 100.9) [n=75]	89.4 (78.1, 100.8) [n=23]	
	Month 9 (Day 270)	96.1 (91.9, 100.4) [n=74]	89.4 (78.1, 100.8) [n=23]	
	Month 10 (Day 300)	94.8 (89.9, 99.8) [n=73]	85.6 (72.4, 98.7) [n=22]	
	Month 11 (Day 330)	93.5 (88.1, 99.0) [n=72]	81.7 (67.1, 96.3) [n=21]	
	Month 12 (Day 360)	90.9 (84.5, 97.3) [n=70]	81.7 (67.1, 96.3) [n=21]	
	Month 12 (Day 366)	90.9 (84.5, 97.3) [n=70]	81.7 (67.1, 96.3) [n=21]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.131		
	Hazard Ratio (95% CI)	0.43 (0.14, 1.37)		
	P-value	0.154		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Belgium	Number of Participants with event, n (%)	2 (8.0)	4 (25.0)	
	Number of Participants censored, n (%)	23 (92.0)	12 (75.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (190.0, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=25]	87.5 (71.3, 103.7) [n=14]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=25]	81.3 (62.1, 100.4) [n=13]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=25]	75.0 (53.8, 96.2) [n=12]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=25]	75.0 (53.8, 96.2) [n=12]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=25]	75.0 (53.8, 96.2) [n=12]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=25]	75.0 (53.8, 96.2) [n=12]	
	Month 11 (Day 330)	100.0 (100.0, 100.0) [n=25]	75.0 (53.8, 96.2) [n=12]	
	Month 12 (Day 360)	91.6 (80.5, 102.8) [n=19]	75.0 (53.8, 96.2) [n=11]	
	Month 12 (Day 366)	91.6 (80.5, 102.8) [n=17]	75.0 (53.8, 96.2) [n=10]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.090		
	Hazard Ratio (95% CI)	0.26 (0.05, 1.42)		
	P-value	0.120		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
France	Number of Participants with event, n (%)	5 (13.2)	0 (0.0)	
	Number of Participants censored, n (%)	33 (86.8)	16 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 2 (Day 60)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 3 (Day 90)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 4 (Day 120)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 5 (Day 150)	97.4 (92.3, 102.5) [n=37]	100.0 (100.0, 100.0) [n=15]	
	Month 6 (Day 180)	97.4 (92.3, 102.5) [n=36]	100.0 (100.0, 100.0) [n=15]	
	Month 7 (Day 210)	97.4 (92.3, 102.5) [n=35]	100.0 (100.0, 100.0) [n=15]	
	Month 8 (Day 240)	97.4 (92.3, 102.5) [n=35]	100.0 (100.0, 100.0) [n=15]	
	Month 9 (Day 270)	97.4 (92.3, 102.5) [n=35]	100.0 (100.0, 100.0) [n=15]	
	Month 10 (Day 300)	94.6 (87.3, 101.9) [n=34]	100.0 (100.0, 100.0) [n=15]	
	Month 11 (Day 330)	89.0 (78.9, 99.2) [n=32]	100.0 (100.0, 100.0) [n=15]	
	Month 12 (Day 360)	89.0 (78.9, 99.2) [n=32]	100.0 (100.0, 100.0) [n=15]	
	Month 12 (Day 366)	86.2 (75.0, 97.4) [n=31]	100.0 (100.0, 100.0) [n=15]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.137		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.990		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Spain	Number of Participants with event, n (%)	0 (0.0)	0 (0.0)	
	Number of Participants censored, n (%)	18 (100.0)	5 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=18]	100.0 (100.0, 100.0) [n=5]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 11 (Day 330)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 12 (Day 360)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	Month 12 (Day 366)	100.0 (100.0, 100.0) [n=17]	100.0 (100.0, 100.0) [n=5]	
	P-value of 2-sided Wilcoxon Rank Sum test	NE		
	Hazard Ratio (95% CI)	0.98 (0.00, NE)		
	P-value	1.000		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Race				1.000
Black or African American	Number of Participants with event, n (%)	0 (0.0)	3 (10.7)	
	Number of Participants censored, n (%)	50 (100.0)	25 (89.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=50]	96.3 (89.2, 103.4) [n=26]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=50]	96.3 (89.2, 103.4) [n=26]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=49]	96.3 (89.2, 103.4) [n=25]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=25]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=25]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=25]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=24]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=47]	96.3 (89.2, 103.4) [n=24]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=46]	96.3 (89.2, 103.4) [n=24]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=46]	96.3 (89.2, 103.4) [n=24]	
	Month 11 (Day 330)	100.0 (100.0, 100.0) [n=44]	92.1 (81.6, 102.6) [n=22]	
	Month 12 (Day 360)	100.0 (100.0, 100.0) [n=39]	87.9 (75.1, 100.8) [n=18]	
	Month 12 (Day 366)	100.0 (100.0, 100.0) [n=38]	87.9 (75.1, 100.8) [n=17]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.016		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.988		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
White	Number of Participants with event, n (%)	21 (8.0)	15 (11.9)	
	Number of Participants censored, n (%)	243 (92.0)	111 (88.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.9, 100.4) [n=261]	97.6 (95.0, 100.3) [n=121]	
	Month 2 (Day 60)	99.2 (98.2, 100.3) [n=259]	97.6 (95.0, 100.3) [n=119]	
	Month 3 (Day 90)	99.2 (98.2, 100.3) [n=259]	97.6 (95.0, 100.3) [n=117]	
	Month 4 (Day 120)	99.2 (98.2, 100.3) [n=256]	96.8 (93.6, 99.9) [n=112]	
	Month 5 (Day 150)	99.2 (98.2, 100.3) [n=253]	96.8 (93.6, 99.9) [n=112]	
	Month 6 (Day 180)	98.8 (97.5, 100.1) [n=251]	95.0 (91.2, 98.9) [n=110]	
	Month 7 (Day 210)	98.8 (97.5, 100.1) [n=249]	93.3 (88.8, 97.8) [n=107]	
	Month 8 (Day 240)	98.4 (96.9, 100.0) [n=247]	92.4 (87.7, 97.2) [n=106]	
	Month 9 (Day 270)	98.0 (96.4, 99.7) [n=245]	92.4 (87.7, 97.2) [n=106]	
	Month 10 (Day 300)	97.2 (95.2, 99.3) [n=243]	91.6 (86.5, 96.6) [n=105]	
	Month 11 (Day 330)	94.8 (92.1, 97.6) [n=236]	88.0 (82.2, 93.9) [n=99]	
	Month 12 (Day 360)	92.4 (89.1, 95.7) [n=215]	88.0 (82.2, 93.9) [n=93]	
	Month 12 (Day 366)	91.5 (88.0, 95.0) [n=207]	87.1 (81.0, 93.2) [n=91]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.111		
	Hazard Ratio (95% CI)	0.61 (0.32, 1.19)		
	P-value	0.148		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Other	Number of Participants with event, n (%)	1 (3.6)	0 (0.0)	
	Number of Participants censored, n (%)	27 (96.4)	15 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=28]	100.0 (100.0, 100.0) [n=15]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=27]	100.0 (100.0, 100.0) [n=15]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=27]	100.0 (100.0, 100.0) [n=14]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=26]	100.0 (100.0, 100.0) [n=14]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 11 (Day 330)	96.0 (88.3, 103.7) [n=25]	100.0 (100.0, 100.0) [n=14]	
	Month 12 (Day 360)	96.0 (88.3, 103.7) [n=22]	100.0 (100.0, 100.0) [n=13]	
	Month 12 (Day 366)	96.0 (88.3, 103.7) [n=21]	100.0 (100.0, 100.0) [n=13]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.454		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.994		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Ethnicity				0.926
Hispanic or Latino	Number of Participants with event, n (%)	1 (2.5)	1 (8.3)	
	Number of Participants censored, n (%)	39 (97.5)	11 (91.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=40]	100.0 (100.0, 100.0) [n=12]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=40]	100.0 (100.0, 100.0) [n=12]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=40]	100.0 (100.0, 100.0) [n=12]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=39]	100.0 (100.0, 100.0) [n=12]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=39]	100.0 (100.0, 100.0) [n=12]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=39]	100.0 (100.0, 100.0) [n=12]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=38]	100.0 (100.0, 100.0) [n=12]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=38]	100.0 (100.0, 100.0) [n=12]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=38]	100.0 (100.0, 100.0) [n=12]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=38]	100.0 (100.0, 100.0) [n=12]	
	Month 11 (Day 330)	97.4 (92.3, 102.5) [n=38]	91.7 (76.0, 107.3) [n=11]	
	Month 12 (Day 360)	97.4 (92.3, 102.5) [n=37]	91.7 (76.0, 107.3) [n=11]	
	Month 12 (Day 366)	97.4 (92.3, 102.5) [n=36]	91.7 (76.0, 107.3) [n=11]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.361		
	Hazard Ratio (95% CI)	0.30 (0.02, 4.80)		
	P-value	0.394		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Not Hispanic or Latino	Number of Participants with event, n (%)	20 (7.3)	18 (12.5)	
	Number of Participants censored, n (%)	255 (92.7)	126 (87.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.9, 100.3) [n=272]	97.2 (94.5, 99.9) [n=137]	
	Month 2 (Day 60)	99.3 (98.3, 100.3) [n=269]	97.2 (94.5, 99.9) [n=135]	
	Month 3 (Day 90)	99.3 (98.3, 100.3) [n=268]	96.5 (93.5, 99.5) [n=131]	
	Month 4 (Day 120)	99.3 (98.3, 100.3) [n=264]	95.7 (92.4, 99.1) [n=126]	
	Month 5 (Day 150)	99.3 (98.3, 100.3) [n=261]	95.7 (92.4, 99.1) [n=126]	
	Month 6 (Day 180)	98.9 (97.6, 100.1) [n=259]	94.2 (90.3, 98.1) [n=124]	
	Month 7 (Day 210)	98.9 (97.6, 100.1) [n=259]	92.7 (88.3, 97.1) [n=120]	
	Month 8 (Day 240)	98.5 (97.1, 100.0) [n=257]	91.9 (87.3, 96.5) [n=119]	
	Month 9 (Day 270)	98.1 (96.5, 99.8) [n=254]	91.9 (87.3, 96.5) [n=118]	
	Month 10 (Day 300)	97.3 (95.4, 99.3) [n=252]	91.1 (86.3, 95.9) [n=117]	
	Month 11 (Day 330)	94.6 (91.9, 97.4) [n=242]	88.0 (82.5, 93.5) [n=110]	
	Month 12 (Day 360)	93.0 (89.9, 96.1) [n=217]	87.2 (81.5, 92.9) [n=100]	
	Month 12 (Day 366)	92.1 (88.8, 95.4) [n=209]	86.3 (80.4, 92.2) [n=97]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.030		
	Hazard Ratio (95% CI)	0.53 (0.28, 1.00)		
	P-value	0.050		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Other	Number of Participants with event, n (%)	1 (3.2)	0 (0.0)	
	Number of Participants censored, n (%)	30 (96.8)	17 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=31]	100.0 (100.0, 100.0) [n=17]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=31]	100.0 (100.0, 100.0) [n=17]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=31]	100.0 (100.0, 100.0) [n=16]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=30]	100.0 (100.0, 100.0) [n=16]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=29]	100.0 (100.0, 100.0) [n=16]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=29]	100.0 (100.0, 100.0) [n=16]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=28]	100.0 (100.0, 100.0) [n=16]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=28]	100.0 (100.0, 100.0) [n=16]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=28]	100.0 (100.0, 100.0) [n=16]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=28]	100.0 (100.0, 100.0) [n=16]	
	Month 11 (Day 330)	96.4 (89.6, 103.3) [n=28]	100.0 (100.0, 100.0) [n=16]	
	Month 12 (Day 360)	96.4 (89.6, 103.3) [n=25]	100.0 (100.0, 100.0) [n=15]	
	Month 12 (Day 366)	96.4 (89.6, 103.3) [n=24]	100.0 (100.0, 100.0) [n=15]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.450		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.989		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
COVID-19 co-morbidities at baseline				0.673
None	Number of Participants with event, n (%)	5 (5.0)	5 (10.9)	
	Number of Participants censored, n (%)	96 (95.0)	41 (89.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=101]	95.7 (89.8, 101.5) [n=44]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=100]	95.7 (89.8, 101.5) [n=44]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=99]	95.7 (89.8, 101.5) [n=42]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=96]	95.7 (89.8, 101.5) [n=41]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=94]	95.7 (89.8, 101.5) [n=41]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=94]	93.3 (86.0, 100.6) [n=40]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=93]	90.9 (82.4, 99.4) [n=38]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=92]	90.9 (82.4, 99.4) [n=38]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=92]	90.9 (82.4, 99.4) [n=38]	
	Month 10 (Day 300)	98.9 (96.8, 101.0) [n=91]	90.9 (82.4, 99.4) [n=38]	
	Month 11 (Day 330)	96.7 (93.1, 100.4) [n=89]	90.9 (82.4, 99.4) [n=37]	
	Month 12 (Day 360)	94.6 (89.9, 99.2) [n=81]	90.9 (82.4, 99.4) [n=34]	
	Month 12 (Day 366)	94.6 (89.9, 99.2) [n=77]	88.2 (78.4, 98.0) [n=32]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.142		
	Hazard Ratio (95% CI)	0.43 (0.12, 1.47)		
	P-value	0.177		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
At least one	Number of Participants with event, n (%)	17 (6.9)	14 (11.0)	
	Number of Participants censored, n (%)	228 (93.1)	113 (89.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.8, 100.4) [n=242]	98.4 (96.2, 100.6) [n=122]	
	Month 2 (Day 60)	99.2 (98.0, 100.3) [n=240]	98.4 (96.2, 100.6) [n=120]	
	Month 3 (Day 90)	99.2 (98.0, 100.3) [n=240]	97.6 (94.9, 100.3) [n=117]	
	Month 4 (Day 120)	99.2 (98.0, 100.3) [n=237]	96.8 (93.6, 99.9) [n=113]	
	Month 5 (Day 150)	99.2 (98.0, 100.3) [n=235]	96.8 (93.6, 99.9) [n=113]	
	Month 6 (Day 180)	98.8 (97.4, 100.2) [n=233]	95.9 (92.4, 99.4) [n=112]	
	Month 7 (Day 210)	98.8 (97.4, 100.2) [n=232]	95.0 (91.2, 98.9) [n=110]	
	Month 8 (Day 240)	98.3 (96.7, 100.0) [n=231]	94.2 (90.0, 98.4) [n=109]	
	Month 9 (Day 270)	97.9 (96.1, 99.7) [n=228]	94.2 (90.0, 98.4) [n=108]	
	Month 10 (Day 300)	97.5 (95.5, 99.5) [n=227]	93.3 (88.8, 97.8) [n=107]	
	Month 11 (Day 330)	95.3 (92.6, 98.0) [n=219]	88.9 (83.2, 94.6) [n=100]	
	Month 12 (Day 360)	93.5 (90.3, 96.7) [n=198]	88.0 (82.1, 93.9) [n=92]	
	Month 12 (Day 366)	92.6 (89.1, 96.0) [n=192]	88.0 (82.1, 93.9) [n=91]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.094		
	Hazard Ratio (95% CI)	0.58 (0.29, 1.18)		
	P-value	0.130		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
SARS-CoV-2 RT-PCR status at baseline				NE
Negative/Missing	Number of Participants with event, n (%)	22 (6.4)	19 (11.0)	
	Number of Participants censored, n (%)	324 (93.6)	154 (89.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=343]	97.7 (95.4, 99.9) [n=166]	
	Month 2 (Day 60)	99.4 (98.6, 100.2) [n=340]	97.7 (95.4, 99.9) [n=164]	
	Month 3 (Day 90)	99.4 (98.6, 100.2) [n=339]	97.1 (94.6, 99.6) [n=159]	
	Month 4 (Day 120)	99.4 (98.6, 100.2) [n=333]	96.5 (93.7, 99.2) [n=154]	
	Month 5 (Day 150)	99.4 (98.6, 100.2) [n=329]	96.5 (93.7, 99.2) [n=154]	
	Month 6 (Day 180)	99.1 (98.1, 100.1) [n=327]	95.2 (92.0, 98.5) [n=152]	
	Month 7 (Day 210)	99.1 (98.1, 100.1) [n=325]	94.0 (90.3, 97.6) [n=148]	
	Month 8 (Day 240)	98.8 (97.7, 100.0) [n=323]	93.3 (89.5, 97.1) [n=147]	
	Month 9 (Day 270)	98.5 (97.2, 99.8) [n=320]	93.3 (89.5, 97.1) [n=146]	
	Month 10 (Day 300)	97.9 (96.3, 99.4) [n=318]	92.7 (88.7, 96.7) [n=145]	
	Month 11 (Day 330)	96.0 (93.9, 98.1) [n=308]	89.5 (84.7, 94.2) [n=137]	
	Month 12 (Day 360)	93.8 (91.2, 96.4) [n=279]	88.8 (83.9, 93.7) [n=126]	
	Month 12 (Day 366)	93.1 (90.4, 95.9) [n=269]	88.1 (83.1, 93.1) [n=123]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.029		
	Hazard Ratio (95% CI)	NE (NE, NE)		
	P-value	NE		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
High risk for severe COVID-19 at baseline				0.425
Yes	Number of Participants with event, n (%)	19 (6.3)	18 (11.7)	
	Number of Participants censored, n (%)	284 (93.7)	136 (88.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.0, 100.3) [n=300]	97.4 (94.9, 99.9) [n=147]	
	Month 2 (Day 60)	99.3 (98.4, 100.3) [n=297]	97.4 (94.9, 99.9) [n=145]	
	Month 3 (Day 90)	99.3 (98.4, 100.3) [n=296]	96.7 (93.9, 99.5) [n=141]	
	Month 4 (Day 120)	99.3 (98.4, 100.3) [n=291]	96.0 (92.9, 99.1) [n=137]	
	Month 5 (Day 150)	99.3 (98.4, 100.3) [n=289]	96.0 (92.9, 99.1) [n=137]	
	Month 6 (Day 180)	99.0 (97.9, 100.1) [n=287]	95.3 (91.9, 98.7) [n=136]	
	Month 7 (Day 210)	99.0 (97.9, 100.1) [n=285]	93.9 (90.1, 97.8) [n=132]	
	Month 8 (Day 240)	98.6 (97.3, 100.0) [n=284]	93.2 (89.1, 97.3) [n=131]	
	Month 9 (Day 270)	98.3 (96.8, 99.8) [n=281]	93.2 (89.1, 97.3) [n=130]	
	Month 10 (Day 300)	97.9 (96.3, 99.6) [n=280]	92.5 (88.2, 96.8) [n=129]	
	Month 11 (Day 330)	96.2 (94.0, 98.4) [n=271]	88.9 (83.7, 94.0) [n=121]	
	Month 12 (Day 360)	94.0 (91.3, 96.8) [n=245]	88.1 (82.8, 93.4) [n=111]	
	Month 12 (Day 366)	93.2 (90.3, 96.2) [n=237]	87.3 (81.8, 92.8) [n=108]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.019		
	Hazard Ratio (95% CI)	0.49 (0.26, 0.94)		
	P-value	0.032		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	3 (7.0)	1 (5.3)	
	Number of Participants censored, n (%)	40 (93.0)	18 (94.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=43]	100.0 (100.0, 100.0) [n=19]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=43]	100.0 (100.0, 100.0) [n=19]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=43]	100.0 (100.0, 100.0) [n=18]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=42]	100.0 (100.0, 100.0) [n=17]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=40]	100.0 (100.0, 100.0) [n=17]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=40]	94.1 (82.9, 105.3) [n=16]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=40]	94.1 (82.9, 105.3) [n=16]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=39]	94.1 (82.9, 105.3) [n=16]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=39]	94.1 (82.9, 105.3) [n=16]	
	Month 10 (Day 300)	97.4 (92.5, 102.4) [n=38]	94.1 (82.9, 105.3) [n=16]	
	Month 11 (Day 330)	92.3 (83.9, 100.7) [n=37]	94.1 (82.9, 105.3) [n=16]	
	Month 12 (Day 360)	92.3 (83.9, 100.7) [n=34]	94.1 (82.9, 105.3) [n=15]	
	Month 12 (Day 366)	92.3 (83.9, 100.7) [n=32]	94.1 (82.9, 105.3) [n=15]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.873		
	Hazard Ratio (95% CI)	1.29 (0.13, 12.36)		
	P-value	0.828		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Obesity (≥ 30 kg/m^2)				0.197
Yes	Number of Participants with event, n (%)	7 (5.9)	9 (16.4)	
	Number of Participants censored, n (%)	112 (94.1)	46 (83.6)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=117]	98.2 (94.7, 101.7) [n=52]	
	Month 2 (Day 60)	99.1 (97.5, 100.8) [n=116]	98.2 (94.7, 101.7) [n=51]	
	Month 3 (Day 90)	99.1 (97.5, 100.8) [n=116]	96.3 (91.2, 101.3) [n=48]	
	Month 4 (Day 120)	99.1 (97.5, 100.8) [n=115]	94.3 (87.9, 100.6) [n=47]	
	Month 5 (Day 150)	99.1 (97.5, 100.8) [n=113]	94.3 (87.9, 100.6) [n=47]	
	Month 6 (Day 180)	99.1 (97.5, 100.8) [n=113]	92.2 (84.9, 99.6) [n=46]	
	Month 7 (Day 210)	99.1 (97.5, 100.8) [n=113]	92.2 (84.9, 99.6) [n=46]	
	Month 8 (Day 240)	98.3 (95.9, 100.6) [n=112]	92.2 (84.9, 99.6) [n=46]	
	Month 9 (Day 270)	97.4 (94.5, 100.3) [n=111]	92.2 (84.9, 99.6) [n=46]	
	Month 10 (Day 300)	96.5 (93.2, 99.9) [n=110]	90.2 (82.1, 98.4) [n=45]	
	Month 11 (Day 330)	95.6 (91.9, 99.4) [n=106]	84.2 (74.2, 94.3) [n=41]	
	Month 12 (Day 360)	94.7 (90.6, 98.8) [n=98]	82.2 (71.6, 92.7) [n=38]	
	Month 12 (Day 366)	93.7 (89.2, 98.2) [n=96]	82.2 (71.6, 92.7) [n=38]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.015		
	Hazard Ratio (95% CI)	0.32 (0.12, 0.86)		
	P-value	0.023		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	15 (6.7)	10 (8.5)	
	Number of Participants censored, n (%)	210 (93.3)	107 (91.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.7, 100.4) [n=224]	97.4 (94.6, 100.3) [n=113]	
	Month 2 (Day 60)	99.6 (98.7, 100.4) [n=222]	97.4 (94.6, 100.3) [n=112]	
	Month 3 (Day 90)	99.6 (98.7, 100.4) [n=221]	97.4 (94.6, 100.3) [n=110]	
	Month 4 (Day 120)	99.6 (98.7, 100.4) [n=216]	97.4 (94.6, 100.3) [n=106]	
	Month 5 (Day 150)	99.6 (98.7, 100.4) [n=214]	97.4 (94.6, 100.3) [n=106]	
	Month 6 (Day 180)	99.1 (97.8, 100.3) [n=212]	96.5 (93.2, 99.9) [n=105]	
	Month 7 (Day 210)	99.1 (97.8, 100.3) [n=210]	94.7 (90.5, 98.8) [n=101]	
	Month 8 (Day 240)	99.1 (97.8, 100.3) [n=209]	93.7 (89.2, 98.2) [n=100]	
	Month 9 (Day 270)	99.1 (97.8, 100.3) [n=207]	93.7 (89.2, 98.2) [n=99]	
	Month 10 (Day 300)	98.6 (97.0, 100.2) [n=206]	93.7 (89.2, 98.2) [n=99]	
	Month 11 (Day 330)	96.2 (93.6, 98.8) [n=200]	91.8 (86.7, 97.0) [n=95]	
	Month 12 (Day 360)	93.3 (89.9, 96.7) [n=179]	91.8 (86.7, 97.0) [n=87]	
	Month 12 (Day 366)	92.8 (89.2, 96.3) [n=171]	90.7 (85.2, 96.2) [n=84]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.377		
	Hazard Ratio (95% CI)	0.74 (0.33, 1.64)		
	P-value	0.452		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Obesity (≥ 40 kg/m^2)				0.816
Yes	Number of Participants with event, n (%)	2 (11.8)	3 (23.1)	
	Number of Participants censored, n (%)	15 (88.2)	10 (76.9)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (296.0, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=13]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=13]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=12]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=12]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=12]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=16]	91.7 (76.0, 107.3) [n=11]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=16]	91.7 (76.0, 107.3) [n=11]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=16]	91.7 (76.0, 107.3) [n=11]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=16]	91.7 (76.0, 107.3) [n=11]	
	Month 10 (Day 300)	93.8 (81.9, 105.6) [n=15]	83.3 (62.2, 104.4) [n=10]	
	Month 11 (Day 330)	87.5 (71.3, 103.7) [n=14]	75.0 (50.5, 99.5) [n=8]	
	Month 12 (Day 360)	87.5 (71.3, 103.7) [n=12]	75.0 (50.5, 99.5) [n=7]	
	Month 12 (Day 366)	87.5 (71.3, 103.7) [n=12]	75.0 (50.5, 99.5) [n=7]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.403		
	Hazard Ratio (95% CI)	0.45 (0.08, 2.70)		
	P-value	0.383		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	20 (6.1)	16 (10.1)	
	Number of Participants censored, n (%)	307 (93.9)	143 (89.9)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=325]	97.5 (95.0, 99.9) [n=152]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=322]	97.5 (95.0, 99.9) [n=150]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=321]	96.8 (94.1, 99.6) [n=146]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=315]	96.1 (93.1, 99.2) [n=141]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=311]	96.1 (93.1, 99.2) [n=141]	
	Month 6 (Day 180)	99.1 (98.0, 100.1) [n=309]	95.5 (92.2, 98.8) [n=140]	
	Month 7 (Day 210)	99.1 (98.0, 100.1) [n=307]	94.1 (90.3, 97.8) [n=136]	
	Month 8 (Day 240)	98.7 (97.5, 100.0) [n=305]	93.4 (89.4, 97.4) [n=135]	
	Month 9 (Day 270)	98.4 (97.0, 99.8) [n=302]	93.4 (89.4, 97.4) [n=134]	
	Month 10 (Day 300)	98.1 (96.6, 99.6) [n=301]	93.4 (89.4, 97.4) [n=134]	
	Month 11 (Day 330)	96.5 (94.4, 98.5) [n=292]	90.6 (85.9, 95.3) [n=128]	
	Month 12 (Day 360)	94.1 (91.5, 96.8) [n=265]	89.9 (85.0, 94.8) [n=118]	
	Month 12 (Day 366)	93.4 (90.6, 96.2) [n=255]	89.1 (84.1, 94.2) [n=115]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.059		
	Hazard Ratio (95% CI)	0.57 (0.29, 1.09)		
	P-value	0.089		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Chronic kidney disease				0.354
Yes	Number of Participants with event, n (%)	3 (7.9)	5 (23.8)	
	Number of Participants censored, n (%)	35 (92.1)	16 (76.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (327.0, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=38]	95.2 (86.1, 104.3) [n=20]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=38]	95.2 (86.1, 104.3) [n=19]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=38]	95.2 (86.1, 104.3) [n=19]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=37]	95.2 (86.1, 104.3) [n=19]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=36]	95.2 (86.1, 104.3) [n=19]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=36]	95.2 (86.1, 104.3) [n=19]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=36]	90.2 (77.3, 103.1) [n=18]	
	Month 8 (Day 240)	97.2 (91.9, 102.6) [n=35]	90.2 (77.3, 103.1) [n=18]	
	Month 9 (Day 270)	97.2 (91.9, 102.6) [n=35]	90.2 (77.3, 103.1) [n=18]	
	Month 10 (Day 300)	97.2 (91.9, 102.6) [n=35]	90.2 (77.3, 103.1) [n=18]	
	Month 11 (Day 330)	94.4 (87.0, 101.9) [n=33]	74.9 (55.7, 94.0) [n=14]	
	Month 12 (Day 360)	91.5 (82.3, 100.7) [n=28]	74.9 (55.7, 94.0) [n=12]	
	Month 12 (Day 366)	91.5 (82.3, 100.7) [n=27]	74.9 (55.7, 94.0) [n=12]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.068		
	Hazard Ratio (95% CI)	0.29 (0.07, 1.23)		
	P-value	0.094		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	19 (6.2)	14 (9.2)	
	Number of Participants censored, n (%)	289 (93.8)	138 (90.8)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.0, 100.3) [n=305]	98.0 (95.8, 100.2) [n=146]	
	Month 2 (Day 60)	99.3 (98.4, 100.2) [n=302]	98.0 (95.8, 100.2) [n=145]	
	Month 3 (Day 90)	99.3 (98.4, 100.2) [n=301]	97.3 (94.8, 99.9) [n=140]	
	Month 4 (Day 120)	99.3 (98.4, 100.2) [n=296]	96.6 (93.7, 99.5) [n=135]	
	Month 5 (Day 150)	99.3 (98.4, 100.2) [n=293]	96.6 (93.7, 99.5) [n=135]	
	Month 6 (Day 180)	99.0 (97.9, 100.1) [n=291]	95.2 (91.7, 98.7) [n=133]	
	Month 7 (Day 210)	99.0 (97.9, 100.1) [n=289]	94.5 (90.8, 98.2) [n=130]	
	Month 8 (Day 240)	99.0 (97.9, 100.1) [n=288]	93.8 (89.8, 97.7) [n=129]	
	Month 9 (Day 270)	98.7 (97.4, 100.0) [n=285]	93.8 (89.8, 97.7) [n=128]	
	Month 10 (Day 300)	98.0 (96.4, 99.6) [n=283]	93.0 (88.8, 97.2) [n=127]	
	Month 11 (Day 330)	96.2 (94.0, 98.4) [n=275]	91.5 (87.0, 96.1) [n=123]	
	Month 12 (Day 360)	94.1 (91.4, 96.8) [n=251]	90.8 (86.0, 95.6) [n=114]	
	Month 12 (Day 366)	93.3 (90.4, 96.2) [n=242]	90.0 (85.0, 95.0) [n=111]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.135		
	Hazard Ratio (95% CI)	0.62 (0.31, 1.24)		
	P-value	0.177		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Diabetes				0.445
Yes	Number of Participants with event, n (%)	2 (5.0)	4 (16.0)	
	Number of Participants censored, n (%)	38 (95.0)	21 (84.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=39]	96.0 (88.3, 103.7) [n=23]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=38]	96.0 (88.3, 103.7) [n=23]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=38]	96.0 (88.3, 103.7) [n=23]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=38]	96.0 (88.3, 103.7) [n=23]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=38]	96.0 (88.3, 103.7) [n=23]	
	Month 11 (Day 330)	94.7 (87.5, 101.9) [n=35]	83.3 (68.3, 98.3) [n=19]	
	Month 12 (Day 360)	94.7 (87.5, 101.9) [n=33]	83.3 (68.3, 98.3) [n=15]	
	Month 12 (Day 366)	94.7 (87.5, 101.9) [n=33]	83.3 (68.3, 98.3) [n=15]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.143		
	Hazard Ratio (95% CI)	0.29 (0.05, 1.60)		
	P-value	0.156		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	20 (6.5)	15 (10.1)	
	Number of Participants censored, n (%)	286 (93.5)	133 (89.9)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.0, 100.3) [n=304]	98.0 (95.7, 100.2) [n=143]	
	Month 2 (Day 60)	99.3 (98.4, 100.3) [n=301]	98.0 (95.7, 100.2) [n=141]	
	Month 3 (Day 90)	99.3 (98.4, 100.3) [n=300]	97.3 (94.6, 99.9) [n=136]	
	Month 4 (Day 120)	99.3 (98.4, 100.3) [n=294]	96.5 (93.6, 99.5) [n=131]	
	Month 5 (Day 150)	99.3 (98.4, 100.3) [n=290]	96.5 (93.6, 99.5) [n=131]	
	Month 6 (Day 180)	99.0 (97.9, 100.1) [n=288]	95.1 (91.5, 98.6) [n=129]	
	Month 7 (Day 210)	99.0 (97.9, 100.1) [n=287]	93.6 (89.5, 97.6) [n=125]	
	Month 8 (Day 240)	98.7 (97.3, 100.0) [n=285]	92.8 (88.6, 97.1) [n=124]	
	Month 9 (Day 270)	98.3 (96.8, 99.8) [n=282]	92.8 (88.6, 97.1) [n=123]	
	Month 10 (Day 300)	97.6 (95.9, 99.4) [n=280]	92.1 (87.6, 96.6) [n=122]	
	Month 11 (Day 330)	96.2 (94.0, 98.4) [n=273]	90.6 (85.7, 95.5) [n=118]	
	Month 12 (Day 360)	93.7 (90.9, 96.5) [n=246]	89.8 (84.7, 94.9) [n=111]	
	Month 12 (Day 366)	92.9 (89.9, 95.9) [n=236]	89.0 (83.7, 94.3) [n=108]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.092		
	Hazard Ratio (95% CI)	0.59 (0.30, 1.16)		
	P-value	0.129		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Immunosuppressive disease				0.988
Yes	Number of Participants with event, n (%)	0 (0.0)	1 (11.1)	
	Number of Participants censored, n (%)	16 (100.0)	8 (88.9)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (312.0, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=9]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=9]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=16]	100.0 (100.0, 100.0) [n=8]	
	Month 11 (Day 330)	100.0 (100.0, 100.0) [n=16]	87.5 (64.6, 110.4) [n=7]	
	Month 12 (Day 360)	100.0 (100.0, 100.0) [n=15]	87.5 (64.6, 110.4) [n=6]	
	Month 12 (Day 366)	100.0 (100.0, 100.0) [n=15]	87.5 (64.6, 110.4) [n=6]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.157		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.988		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	22 (6.7)	18 (11.0)	
	Number of Participants censored, n (%)	308 (93.3)	146 (89.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=327]	97.5 (95.2, 99.9) [n=157]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=324]	97.5 (95.2, 99.9) [n=155]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=323]	96.9 (94.3, 99.6) [n=151]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=317]	96.3 (93.3, 99.2) [n=146]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=313]	96.3 (93.3, 99.2) [n=146]	
	Month 6 (Day 180)	99.1 (98.0, 100.1) [n=311]	94.9 (91.5, 98.4) [n=144]	
	Month 7 (Day 210)	99.1 (98.0, 100.1) [n=309]	93.6 (89.8, 97.5) [n=140]	
	Month 8 (Day 240)	98.8 (97.5, 100.0) [n=307]	93.0 (88.9, 97.0) [n=139]	
	Month 9 (Day 270)	98.4 (97.1, 99.8) [n=304]	93.0 (88.9, 97.0) [n=138]	
	Month 10 (Day 300)	97.8 (96.2, 99.4) [n=302]	92.3 (88.1, 96.5) [n=137]	
	Month 11 (Day 330)	95.8 (93.6, 98.1) [n=292]	89.6 (84.7, 94.4) [n=130]	
	Month 12 (Day 360)	93.5 (90.7, 96.3) [n=264]	88.9 (83.9, 93.9) [n=120]	
	Month 12 (Day 366)	92.8 (89.9, 95.7) [n=254]	88.1 (83.0, 93.3) [n=117]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.046		
	Hazard Ratio (95% CI)	0.57 (0.30, 1.05)		
	P-value	0.073		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Immunosuppressive treatment				0.871
Yes	Number of Participants with event, n (%)	10 (9.7)	9 (15.0)	
	Number of Participants censored, n (%)	93 (90.3)	51 (85.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=101]	96.7 (92.1, 101.2) [n=57]	
	Month 2 (Day 60)	99.0 (97.1, 100.9) [n=100]	96.7 (92.1, 101.2) [n=55]	
	Month 3 (Day 90)	99.0 (97.1, 100.9) [n=100]	94.9 (89.3, 100.5) [n=52]	
	Month 4 (Day 120)	99.0 (97.1, 100.9) [n=99]	94.9 (89.3, 100.5) [n=52]	
	Month 5 (Day 150)	99.0 (97.1, 100.9) [n=97]	94.9 (89.3, 100.5) [n=52]	
	Month 6 (Day 180)	99.0 (97.1, 100.9) [n=97]	93.1 (86.5, 99.6) [n=51]	
	Month 7 (Day 210)	99.0 (97.1, 100.9) [n=97]	93.1 (86.5, 99.6) [n=49]	
	Month 8 (Day 240)	98.0 (95.2, 100.7) [n=96]	93.1 (86.5, 99.6) [n=49]	
	Month 9 (Day 270)	98.0 (95.2, 100.7) [n=95]	93.1 (86.5, 99.6) [n=49]	
	Month 10 (Day 300)	97.0 (93.6, 100.3) [n=94]	93.1 (86.5, 99.6) [n=49]	
	Month 11 (Day 330)	94.9 (90.5, 99.3) [n=91]	87.3 (78.4, 96.1) [n=44]	
	Month 12 (Day 360)	89.5 (83.3, 95.7) [n=77]	85.3 (75.8, 94.7) [n=39]	
	Month 12 (Day 366)	89.5 (83.3, 95.7) [n=76]	83.1 (72.9, 93.2) [n=38]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.186		
	Hazard Ratio (95% CI)	0.58 (0.24, 1.43)		
	P-value	0.238		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	12 (4.9)	10 (8.8)	
	Number of Participants censored, n (%)	231 (95.1)	103 (91.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.8, 100.4) [n=242]	98.2 (95.8, 100.7) [n=109]	
	Month 2 (Day 60)	99.6 (98.8, 100.4) [n=240]	98.2 (95.8, 100.7) [n=109]	
	Month 3 (Day 90)	99.6 (98.8, 100.4) [n=239]	98.2 (95.8, 100.7) [n=107]	
	Month 4 (Day 120)	99.6 (98.8, 100.4) [n=234]	97.3 (94.2, 100.3) [n=102]	
	Month 5 (Day 150)	99.6 (98.8, 100.4) [n=232]	97.3 (94.2, 100.3) [n=102]	
	Month 6 (Day 180)	99.2 (98.0, 100.3) [n=230]	96.3 (92.8, 99.9) [n=101]	
	Month 7 (Day 210)	99.2 (98.0, 100.3) [n=228]	94.4 (90.1, 98.8) [n=99]	
	Month 8 (Day 240)	99.2 (98.0, 100.3) [n=227]	93.5 (88.8, 98.1) [n=98]	
	Month 9 (Day 270)	98.7 (97.3, 100.2) [n=225]	93.5 (88.8, 98.1) [n=97]	
	Month 10 (Day 300)	98.3 (96.6, 100.0) [n=224]	92.5 (87.5, 97.5) [n=96]	
	Month 11 (Day 330)	96.1 (93.6, 98.6) [n=217]	90.6 (85.0, 96.1) [n=93]	
	Month 12 (Day 360)	95.6 (93.0, 98.3) [n=202]	90.6 (85.0, 96.1) [n=87]	
	Month 12 (Day 366)	94.7 (91.7, 97.6) [n=193]	90.6 (85.0, 96.1) [n=85]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.096		
	Hazard Ratio (95% CI)	0.52 (0.23, 1.22)		
	P-value	0.132		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
CV disease				0.984
Yes	Number of Participants with event, n (%)	0 (0.0)	4 (18.2)	
	Number of Participants censored, n (%)	32 (100.0)	18 (81.8)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=32]	100.0 (100.0, 100.0) [n=22]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=32]	100.0 (100.0, 100.0) [n=21]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=32]	100.0 (100.0, 100.0) [n=21]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=32]	95.2 (86.1, 104.3) [n=20]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=31]	95.2 (86.1, 104.3) [n=20]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=31]	95.2 (86.1, 104.3) [n=20]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=31]	90.5 (77.9, 103.0) [n=19]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=31]	90.5 (77.9, 103.0) [n=19]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=31]	90.5 (77.9, 103.0) [n=19]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=31]	90.5 (77.9, 103.0) [n=19]	
	Month 11 (Day 330)	100.0 (100.0, 100.0) [n=30]	81.0 (64.2, 97.7) [n=16]	
	Month 12 (Day 360)	100.0 (100.0, 100.0) [n=30]	81.0 (64.2, 97.7) [n=14]	
	Month 12 (Day 366)	100.0 (100.0, 100.0) [n=30]	81.0 (64.2, 97.7) [n=14]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.011		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.983		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	22 (7.0)	15 (9.9)	
	Number of Participants censored, n (%)	292 (93.0)	136 (90.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=311]	97.3 (94.8, 99.9) [n=144]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=308]	97.3 (94.8, 99.9) [n=143]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=307]	96.7 (93.8, 99.5) [n=138]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=301]	96.7 (93.8, 99.5) [n=134]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=298]	96.7 (93.8, 99.5) [n=134]	
	Month 6 (Day 180)	99.0 (97.9, 100.1) [n=296]	95.2 (91.8, 98.7) [n=132]	
	Month 7 (Day 210)	99.0 (97.9, 100.1) [n=294]	94.5 (90.8, 98.2) [n=129]	
	Month 8 (Day 240)	98.7 (97.4, 100.0) [n=292]	93.8 (89.8, 97.7) [n=128]	
	Month 9 (Day 270)	98.3 (96.9, 99.8) [n=289]	93.8 (89.8, 97.7) [n=127]	
	Month 10 (Day 300)	97.7 (96.0, 99.4) [n=287]	93.0 (88.8, 97.2) [n=126]	
	Month 11 (Day 330)	95.6 (93.3, 97.9) [n=278]	90.8 (86.0, 95.6) [n=121]	
	Month 12 (Day 360)	93.2 (90.3, 96.1) [n=249]	90.0 (85.1, 95.0) [n=112]	
	Month 12 (Day 366)	92.4 (89.3, 95.5) [n=239]	89.2 (84.1, 94.4) [n=109]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.158		
	Hazard Ratio (95% CI)	0.66 (0.34, 1.27)		
	P-value	0.214		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
COPD				0.476
Yes	Number of Participants with event, n (%)	2 (8.7)	3 (27.3)	
	Number of Participants censored, n (%)	21 (91.3)	8 (72.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (305.0, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=23]	100.0 (100.0, 100.0) [n=11]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=23]	90.9 (73.9, 107.9) [n=10]	
	Month 8 (Day 240)	95.7 (87.3, 104.0) [n=22]	90.9 (73.9, 107.9) [n=10]	
	Month 9 (Day 270)	95.7 (87.3, 104.0) [n=22]	90.9 (73.9, 107.9) [n=10]	
	Month 10 (Day 300)	95.7 (87.3, 104.0) [n=22]	90.9 (73.9, 107.9) [n=10]	
	Month 11 (Day 330)	91.3 (79.8, 102.8) [n=21]	72.7 (46.4, 99.0) [n=8]	
	Month 12 (Day 360)	91.3 (79.8, 102.8) [n=19]	72.7 (46.4, 99.0) [n=8]	
	Month 12 (Day 366)	91.3 (79.8, 102.8) [n=18]	72.7 (46.4, 99.0) [n=8]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.155		
	Hazard Ratio (95% CI)	0.29 (0.05, 1.73)		
	P-value	0.175		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	20 (6.2)	16 (9.9)	
	Number of Participants censored, n (%)	303 (93.8)	146 (90.1)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=320]	97.5 (95.1, 99.9) [n=155]	
	Month 2 (Day 60)	99.4 (98.5, 100.2) [n=317]	97.5 (95.1, 99.9) [n=153]	
	Month 3 (Day 90)	99.4 (98.5, 100.2) [n=316]	96.9 (94.2, 99.6) [n=148]	
	Month 4 (Day 120)	99.4 (98.5, 100.2) [n=310]	96.2 (93.2, 99.2) [n=143]	
	Month 5 (Day 150)	99.4 (98.5, 100.2) [n=306]	96.2 (93.2, 99.2) [n=143]	
	Month 6 (Day 180)	99.1 (98.0, 100.1) [n=304]	94.9 (91.4, 98.3) [n=141]	
	Month 7 (Day 210)	99.1 (98.0, 100.1) [n=302]	94.2 (90.5, 97.9) [n=138]	
	Month 8 (Day 240)	99.1 (98.0, 100.1) [n=301]	93.5 (89.6, 97.4) [n=137]	
	Month 9 (Day 270)	98.7 (97.5, 100.0) [n=298]	93.5 (89.6, 97.4) [n=136]	
	Month 10 (Day 300)	98.1 (96.5, 99.6) [n=296]	92.8 (88.7, 96.9) [n=135]	
	Month 11 (Day 330)	96.4 (94.3, 98.5) [n=287]	90.7 (86.1, 95.4) [n=129]	
	Month 12 (Day 360)	94.0 (91.3, 96.7) [n=260]	90.0 (85.2, 94.8) [n=118]	
	Month 12 (Day 366)	93.3 (90.4, 96.1) [n=251]	89.3 (84.3, 94.3) [n=115]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.071		
	Hazard Ratio (95% CI)	0.58 (0.30, 1.12)		
	P-value	0.105		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Chronic liver disease				0.308
Yes	Number of Participants with event, n (%)	3 (6.8)	1 (3.8)	
	Number of Participants censored, n (%)	41 (93.2)	25 (96.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=24]	
	Month 2 (Day 60)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=23]	
	Month 3 (Day 90)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=23]	
	Month 4 (Day 120)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=21]	
	Month 5 (Day 150)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=21]	
	Month 6 (Day 180)	97.7 (93.3, 102.1) [n=43]	96.0 (88.3, 103.7) [n=21]	
	Month 7 (Day 210)	97.7 (93.3, 102.1) [n=42]	96.0 (88.3, 103.7) [n=21]	
	Month 8 (Day 240)	97.7 (93.3, 102.1) [n=42]	96.0 (88.3, 103.7) [n=21]	
	Month 9 (Day 270)	97.7 (93.3, 102.1) [n=41]	96.0 (88.3, 103.7) [n=21]	
	Month 10 (Day 300)	95.3 (89.0, 101.6) [n=40]	96.0 (88.3, 103.7) [n=21]	
	Month 11 (Day 330)	95.3 (89.0, 101.6) [n=38]	96.0 (88.3, 103.7) [n=21]	
	Month 12 (Day 360)	95.3 (89.0, 101.6) [n=34]	96.0 (88.3, 103.7) [n=19]	
	Month 12 (Day 366)	92.4 (84.0, 100.8) [n=31]	96.0 (88.3, 103.7) [n=18]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.716		
	Hazard Ratio (95% CI)	1.62 (0.17, 15.60)		
	P-value	0.675		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	19 (6.3)	18 (12.2)	
	Number of Participants censored, n (%)	283 (93.7)	129 (87.8)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=300]	98.0 (95.7, 100.2) [n=142]	
	Month 2 (Day 60)	99.7 (99.0, 100.3) [n=297]	98.0 (95.7, 100.2) [n=141]	
	Month 3 (Day 90)	99.7 (99.0, 100.3) [n=296]	97.3 (94.6, 99.9) [n=136]	
	Month 4 (Day 120)	99.7 (99.0, 100.3) [n=290]	96.5 (93.6, 99.5) [n=133]	
	Month 5 (Day 150)	99.7 (99.0, 100.3) [n=286]	96.5 (93.6, 99.5) [n=133]	
	Month 6 (Day 180)	99.3 (98.4, 100.3) [n=284]	95.1 (91.5, 98.6) [n=131]	
	Month 7 (Day 210)	99.3 (98.4, 100.3) [n=283]	93.6 (89.6, 97.7) [n=127]	
	Month 8 (Day 240)	99.0 (97.8, 100.1) [n=281]	92.9 (88.6, 97.1) [n=126]	
	Month 9 (Day 270)	98.6 (97.3, 100.0) [n=279]	92.9 (88.6, 97.1) [n=125]	
	Month 10 (Day 300)	98.3 (96.7, 99.8) [n=278]	92.1 (87.7, 96.6) [n=124]	
	Month 11 (Day 330)	96.1 (93.9, 98.4) [n=270]	88.4 (83.1, 93.8) [n=116]	
	Month 12 (Day 360)	93.6 (90.8, 96.5) [n=245]	87.6 (82.1, 93.2) [n=107]	
	Month 12 (Day 366)	93.2 (90.3, 96.2) [n=238]	86.8 (81.1, 92.5) [n=105]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.014		
	Hazard Ratio (95% CI)	0.48 (0.25, 0.91)		
	P-value	0.025		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Hypertension				0.428
Yes	Number of Participants with event, n (%)	9 (5.9)	10 (13.3)	
	Number of Participants censored, n (%)	144 (94.1)	65 (86.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=152]	97.3 (93.7, 101.0) [n=72]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=151]	97.3 (93.7, 101.0) [n=70]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=151]	97.3 (93.7, 101.0) [n=69]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=149]	97.3 (93.7, 101.0) [n=69]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=147]	97.3 (93.7, 101.0) [n=69]	
	Month 6 (Day 180)	99.3 (98.0, 100.6) [n=146]	97.3 (93.7, 101.0) [n=69]	
	Month 7 (Day 210)	99.3 (98.0, 100.6) [n=146]	95.9 (91.4, 100.4) [n=67]	
	Month 8 (Day 240)	98.6 (96.8, 100.5) [n=145]	94.5 (89.2, 99.7) [n=66]	
	Month 9 (Day 270)	97.9 (95.7, 100.2) [n=142]	94.5 (89.2, 99.7) [n=65]	
	Month 10 (Day 300)	97.9 (95.7, 100.2) [n=142]	93.0 (87.1, 98.9) [n=64]	
	Month 11 (Day 330)	94.5 (90.8, 98.2) [n=136]	87.2 (79.4, 95.0) [n=59]	
	Month 12 (Day 360)	93.8 (89.8, 97.7) [n=121]	85.7 (77.5, 93.9) [n=53]	
	Month 12 (Day 366)	93.8 (89.8, 97.7) [n=118]	85.7 (77.5, 93.9) [n=53]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.039		
	Hazard Ratio (95% CI)	0.41 (0.17, 1.01)		
	P-value	0.052		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	13 (6.7)	9 (9.2)	
	Number of Participants censored, n (%)	180 (93.3)	89 (90.8)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.5 (98.5, 100.5) [n=191]	97.9 (95.1, 100.8) [n=94]	
	Month 2 (Day 60)	99.0 (97.5, 100.4) [n=189]	97.9 (95.1, 100.8) [n=94]	
	Month 3 (Day 90)	99.0 (97.5, 100.4) [n=188]	96.9 (93.4, 100.4) [n=90]	
	Month 4 (Day 120)	99.0 (97.5, 100.4) [n=184]	95.8 (91.7, 99.8) [n=85]	
	Month 5 (Day 150)	99.0 (97.5, 100.4) [n=182]	95.8 (91.7, 99.8) [n=85]	
	Month 6 (Day 180)	99.0 (97.5, 100.4) [n=181]	93.5 (88.5, 98.5) [n=83]	
	Month 7 (Day 210)	99.0 (97.5, 100.4) [n=179]	92.4 (87.0, 97.8) [n=81]	
	Month 8 (Day 240)	99.0 (97.5, 100.4) [n=178]	92.4 (87.0, 97.8) [n=81]	
	Month 9 (Day 270)	99.0 (97.5, 100.4) [n=178]	92.4 (87.0, 97.8) [n=81]	
	Month 10 (Day 300)	97.8 (95.8, 99.9) [n=176]	92.4 (87.0, 97.8) [n=81]	
	Month 11 (Day 330)	96.7 (94.2, 99.3) [n=172]	91.2 (85.4, 97.1) [n=78]	
	Month 12 (Day 360)	93.9 (90.4, 97.4) [n=158]	91.2 (85.4, 97.1) [n=73]	
	Month 12 (Day 366)	92.7 (88.8, 96.5) [n=151]	90.0 (83.7, 96.2) [n=70]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.302		
	Hazard Ratio (95% CI)	0.68 (0.29, 1.58)		
	P-value	0.368		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Asthma				0.845
Yes	Number of Participants with event, n (%)	5 (9.1)	3 (14.3)	
	Number of Participants censored, n (%)	50 (90.9)	18 (85.7)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=55]	100.0 (100.0, 100.0) [n=21]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=55]	100.0 (100.0, 100.0) [n=21]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=55]	95.2 (86.1, 104.3) [n=20]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=55]	95.2 (86.1, 104.3) [n=19]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=54]	95.2 (86.1, 104.3) [n=19]	
	Month 6 (Day 180)	98.1 (94.5, 101.8) [n=52]	95.2 (86.1, 104.3) [n=19]	
	Month 7 (Day 210)	98.1 (94.5, 101.8) [n=52]	95.2 (86.1, 104.3) [n=19]	
	Month 8 (Day 240)	98.1 (94.5, 101.8) [n=52]	95.2 (86.1, 104.3) [n=19]	
	Month 9 (Day 270)	98.1 (94.5, 101.8) [n=52]	95.2 (86.1, 104.3) [n=19]	
	Month 10 (Day 300)	98.1 (94.5, 101.8) [n=52]	90.2 (77.3, 103.1) [n=18]	
	Month 11 (Day 330)	94.3 (88.1, 100.6) [n=51]	85.2 (69.7, 100.7) [n=17]	
	Month 12 (Day 360)	92.4 (85.3, 99.6) [n=45]	85.2 (69.7, 100.7) [n=17]	
	Month 12 (Day 366)	90.4 (82.3, 98.4) [n=44]	85.2 (69.7, 100.7) [n=17]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.418		
	Hazard Ratio (95% CI)	0.60 (0.14, 2.52)		
	P-value	0.486		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	17 (5.8)	16 (10.5)	
	Number of Participants censored, n (%)	274 (94.2)	136 (89.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.0, 100.3) [n=288]	97.4 (94.8, 99.9) [n=145]	
	Month 2 (Day 60)	99.3 (98.4, 100.3) [n=285]	97.4 (94.8, 99.9) [n=143]	
	Month 3 (Day 90)	99.3 (98.4, 100.3) [n=284]	97.4 (94.8, 99.9) [n=139]	
	Month 4 (Day 120)	99.3 (98.4, 100.3) [n=278]	96.6 (93.8, 99.5) [n=135]	
	Month 5 (Day 150)	99.3 (98.4, 100.3) [n=275]	96.6 (93.8, 99.5) [n=135]	
	Month 6 (Day 180)	99.3 (98.4, 100.3) [n=275]	95.2 (91.7, 98.7) [n=133]	
	Month 7 (Day 210)	99.3 (98.4, 100.3) [n=273]	93.8 (89.8, 97.7) [n=129]	
	Month 8 (Day 240)	98.9 (97.8, 100.1) [n=271]	93.0 (88.9, 97.2) [n=128]	
	Month 9 (Day 270)	98.6 (97.2, 100.0) [n=268]	93.0 (88.9, 97.2) [n=127]	
	Month 10 (Day 300)	97.8 (96.1, 99.6) [n=266]	93.0 (88.9, 97.2) [n=127]	
	Month 11 (Day 330)	96.0 (93.7, 98.3) [n=257]	90.1 (85.2, 95.0) [n=120]	
	Month 12 (Day 360)	94.1 (91.3, 96.9) [n=234]	89.3 (84.2, 94.5) [n=109]	
	Month 12 (Day 366)	93.7 (90.8, 96.6) [n=225]	88.5 (83.2, 93.8) [n=106]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.038		
	Hazard Ratio (95% CI)	0.51 (0.26, 1.02)		
	P-value	0.056		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Cancer				0.492
Yes	Number of Participants with event, n (%)	4 (6.7)	5 (16.7)	
	Number of Participants censored, n (%)	56 (93.3)	25 (83.3)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=60]	93.3 (84.4, 102.3) [n=27]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=59]	93.3 (84.4, 102.3) [n=27]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=59]	93.3 (84.4, 102.3) [n=26]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=58]	93.3 (84.4, 102.3) [n=26]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=57]	93.3 (84.4, 102.3) [n=26]	
	Month 6 (Day 180)	98.2 (94.8, 101.7) [n=56]	93.3 (84.4, 102.3) [n=26]	
	Month 7 (Day 210)	98.2 (94.8, 101.7) [n=54]	86.2 (73.5, 98.8) [n=24]	
	Month 8 (Day 240)	96.4 (91.6, 101.3) [n=53]	86.2 (73.5, 98.8) [n=24]	
	Month 9 (Day 270)	94.6 (88.7, 100.5) [n=52]	86.2 (73.5, 98.8) [n=23]	
	Month 10 (Day 300)	94.6 (88.7, 100.5) [n=52]	86.2 (73.5, 98.8) [n=23]	
	Month 11 (Day 330)	94.6 (88.7, 100.5) [n=50]	86.2 (73.5, 98.8) [n=22]	
	Month 12 (Day 360)	94.6 (88.7, 100.5) [n=49]	82.2 (68.0, 96.4) [n=18]	
	Month 12 (Day 366)	92.6 (85.6, 99.6) [n=46]	82.2 (68.0, 96.4) [n=18]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.090		
	Hazard Ratio (95% CI)	0.35 (0.10, 1.32)		
	P-value	0.123		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	18 (6.3)	14 (9.8)	
	Number of Participants censored, n (%)	268 (93.7)	129 (90.2)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (99.0, 100.3) [n=283]	98.6 (96.7, 100.5) [n=139]	
	Month 2 (Day 60)	99.3 (98.3, 100.3) [n=281]	98.6 (96.7, 100.5) [n=137]	
	Month 3 (Day 90)	99.3 (98.3, 100.3) [n=280]	97.9 (95.5, 100.3) [n=133]	
	Month 4 (Day 120)	99.3 (98.3, 100.3) [n=275]	97.1 (94.3, 99.9) [n=128]	
	Month 5 (Day 150)	99.3 (98.3, 100.3) [n=272]	97.1 (94.3, 99.9) [n=128]	
	Month 6 (Day 180)	99.3 (98.3, 100.3) [n=271]	95.6 (92.2, 99.0) [n=126]	
	Month 7 (Day 210)	99.3 (98.3, 100.3) [n=271]	95.6 (92.2, 99.0) [n=124]	
	Month 8 (Day 240)	99.3 (98.3, 100.3) [n=270]	94.8 (91.1, 98.6) [n=123]	
	Month 9 (Day 270)	99.3 (98.3, 100.3) [n=268]	94.8 (91.1, 98.6) [n=123]	
	Month 10 (Day 300)	98.6 (97.2, 100.0) [n=266]	94.1 (90.1, 98.1) [n=122]	
	Month 11 (Day 330)	96.3 (94.1, 98.6) [n=258]	90.2 (85.1, 95.3) [n=115]	
	Month 12 (Day 360)	93.7 (90.8, 96.6) [n=230]	90.2 (85.1, 95.3) [n=108]	
	Month 12 (Day 366)	93.3 (90.2, 96.3) [n=223]	89.3 (84.0, 94.6) [n=105]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.116		
	Hazard Ratio (95% CI)	0.60 (0.30, 1.20)		
	P-value	0.150		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Smoking				0.984
Yes	Number of Participants with event, n (%)	4 (6.3)	0 (0.0)	
	Number of Participants censored, n (%)	59 (93.7)	31 (100.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	98.4 (95.3, 101.5) [n=62]	100.0 (100.0, 100.0) [n=30]	
	Month 2 (Day 60)	98.4 (95.3, 101.5) [n=61]	100.0 (100.0, 100.0) [n=30]	
	Month 3 (Day 90)	98.4 (95.3, 101.5) [n=60]	100.0 (100.0, 100.0) [n=30]	
	Month 4 (Day 120)	98.4 (95.3, 101.5) [n=58]	100.0 (100.0, 100.0) [n=28]	
	Month 5 (Day 150)	98.4 (95.3, 101.5) [n=57]	100.0 (100.0, 100.0) [n=28]	
	Month 6 (Day 180)	98.4 (95.3, 101.5) [n=57]	100.0 (100.0, 100.0) [n=28]	
	Month 7 (Day 210)	98.4 (95.3, 101.5) [n=57]	100.0 (100.0, 100.0) [n=27]	
	Month 8 (Day 240)	98.4 (95.3, 101.5) [n=57]	100.0 (100.0, 100.0) [n=27]	
	Month 9 (Day 270)	98.4 (95.3, 101.5) [n=55]	100.0 (100.0, 100.0) [n=27]	
	Month 10 (Day 300)	98.4 (95.3, 101.5) [n=55]	100.0 (100.0, 100.0) [n=27]	
	Month 11 (Day 330)	96.6 (92.0, 101.2) [n=53]	100.0 (100.0, 100.0) [n=27]	
	Month 12 (Day 360)	94.7 (88.7, 100.6) [n=46]	100.0 (100.0, 100.0) [n=26]	
	Month 12 (Day 366)	92.6 (85.6, 99.6) [n=43]	100.0 (100.0, 100.0) [n=25]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.155		
	Hazard Ratio (95% CI)	NE (0.00, NE)		
	P-value	0.985		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	18 (6.4)	19 (13.4)	
	Number of Participants censored, n (%)	265 (93.6)	123 (86.6)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=281]	97.2 (94.5, 99.9) [n=136]	
	Month 2 (Day 60)	99.6 (98.9, 100.3) [n=279]	97.2 (94.5, 99.9) [n=134]	
	Month 3 (Day 90)	99.6 (98.9, 100.3) [n=279]	96.5 (93.4, 99.5) [n=129]	
	Month 4 (Day 120)	99.6 (98.9, 100.3) [n=275]	95.7 (92.3, 99.1) [n=126]	
	Month 5 (Day 150)	99.6 (98.9, 100.3) [n=272]	95.7 (92.3, 99.1) [n=126]	
	Month 6 (Day 180)	99.3 (98.3, 100.3) [n=270]	94.2 (90.3, 98.1) [n=124]	
	Month 7 (Day 210)	99.3 (98.3, 100.3) [n=268]	92.7 (88.3, 97.0) [n=121]	
	Month 8 (Day 240)	98.9 (97.7, 100.1) [n=266]	91.9 (87.3, 96.5) [n=120]	
	Month 9 (Day 270)	98.5 (97.1, 100.0) [n=265]	91.9 (87.3, 96.5) [n=119]	
	Month 10 (Day 300)	97.8 (96.0, 99.5) [n=263]	91.1 (86.3, 95.9) [n=118]	
	Month 11 (Day 330)	95.9 (93.6, 98.3) [n=255]	87.2 (81.6, 92.9) [n=110]	
	Month 12 (Day 360)	93.7 (90.7, 96.6) [n=233]	86.4 (80.6, 92.3) [n=100]	
	Month 12 (Day 366)	93.2 (90.2, 96.3) [n=226]	85.6 (79.5, 91.6) [n=98]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.005		
	Hazard Ratio (95% CI)	0.43 (0.22, 0.82)		
	P-value	0.010		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Sickle cell disease				NE
No	Number of Participants with event, n (%)	22 (6.4)	19 (11.0)	
	Number of Participants censored, n (%)	324 (93.6)	154 (89.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=343]	97.7 (95.4, 99.9) [n=166]	
	Month 2 (Day 60)	99.4 (98.6, 100.2) [n=340]	97.7 (95.4, 99.9) [n=164]	
	Month 3 (Day 90)	99.4 (98.6, 100.2) [n=339]	97.1 (94.6, 99.6) [n=159]	
	Month 4 (Day 120)	99.4 (98.6, 100.2) [n=333]	96.5 (93.7, 99.2) [n=154]	
	Month 5 (Day 150)	99.4 (98.6, 100.2) [n=329]	96.5 (93.7, 99.2) [n=154]	
	Month 6 (Day 180)	99.1 (98.1, 100.1) [n=327]	95.2 (92.0, 98.5) [n=152]	
	Month 7 (Day 210)	99.1 (98.1, 100.1) [n=325]	94.0 (90.3, 97.6) [n=148]	
	Month 8 (Day 240)	98.8 (97.7, 100.0) [n=323]	93.3 (89.5, 97.1) [n=147]	
	Month 9 (Day 270)	98.5 (97.2, 99.8) [n=320]	93.3 (89.5, 97.1) [n=146]	
	Month 10 (Day 300)	97.9 (96.3, 99.4) [n=318]	92.7 (88.7, 96.7) [n=145]	
	Month 11 (Day 330)	96.0 (93.9, 98.1) [n=308]	89.5 (84.7, 94.2) [n=137]	
	Month 12 (Day 360)	93.8 (91.2, 96.4) [n=279]	88.8 (83.9, 93.7) [n=126]	
	Month 12 (Day 366)	93.1 (90.4, 95.9) [n=269]	88.1 (83.1, 93.1) [n=123]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.029		
	Hazard Ratio (95% CI)	NE (NE, NE)		
	P-value	NE		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
COVID-19 vaccination at any time during the study				0.367
Yes	Number of Participants with event, n (%)	20 (8.3)	16 (12.6)	
	Number of Participants censored, n (%)	222 (91.7)	111 (87.4)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.6 (98.8, 100.4) [n=241]	97.6 (95.0, 100.3) [n=123]	
	Month 2 (Day 60)	99.2 (98.0, 100.3) [n=239]	97.6 (95.0, 100.3) [n=121]	
	Month 3 (Day 90)	99.2 (98.0, 100.3) [n=239]	96.8 (93.8, 99.9) [n=119]	
	Month 4 (Day 120)	99.2 (98.0, 100.3) [n=238]	96.0 (92.6, 99.4) [n=118]	
	Month 5 (Day 150)	99.2 (98.0, 100.3) [n=238]	96.0 (92.6, 99.4) [n=118]	
	Month 6 (Day 180)	98.8 (97.4, 100.2) [n=236]	94.4 (90.4, 98.4) [n=116]	
	Month 7 (Day 210)	98.8 (97.4, 100.2) [n=234]	94.4 (90.4, 98.4) [n=115]	
	Month 8 (Day 240)	98.3 (96.7, 100.0) [n=232]	93.6 (89.3, 97.9) [n=114]	
	Month 9 (Day 270)	97.9 (96.1, 99.7) [n=231]	93.6 (89.3, 97.9) [n=114]	
	Month 10 (Day 300)	97.1 (94.9, 99.2) [n=229]	92.7 (88.2, 97.3) [n=113]	
	Month 11 (Day 330)	94.1 (91.1, 97.1) [n=222]	88.6 (83.0, 94.2) [n=105]	
	Month 12 (Day 360)	92.3 (88.9, 95.7) [n=203]	87.8 (82.0, 93.6) [n=96]	
	Month 12 (Day 366)	91.4 (87.8, 95.0) [n=196]	86.8 (80.8, 92.9) [n=94]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.118		
	Hazard Ratio (95% CI)	0.62 (0.32, 1.19)		
	P-value	0.149		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
No	Number of Participants with event, n (%)	2 (1.9)	3 (6.5)	
	Number of Participants censored, n (%)	102 (98.1)	43 (93.5)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	100.0 (100.0, 100.0) [n=102]	97.8 (93.6, 102.0) [n=43]	
	Month 2 (Day 60)	100.0 (100.0, 100.0) [n=101]	97.8 (93.6, 102.0) [n=43]	
	Month 3 (Day 90)	100.0 (100.0, 100.0) [n=100]	97.8 (93.6, 102.0) [n=40]	
	Month 4 (Day 120)	100.0 (100.0, 100.0) [n=95]	97.8 (93.6, 102.0) [n=36]	
	Month 5 (Day 150)	100.0 (100.0, 100.0) [n=91]	97.8 (93.6, 102.0) [n=36]	
	Month 6 (Day 180)	100.0 (100.0, 100.0) [n=91]	97.8 (93.6, 102.0) [n=36]	
	Month 7 (Day 210)	100.0 (100.0, 100.0) [n=91]	92.4 (84.1, 100.7) [n=33]	
	Month 8 (Day 240)	100.0 (100.0, 100.0) [n=91]	92.4 (84.1, 100.7) [n=33]	
	Month 9 (Day 270)	100.0 (100.0, 100.0) [n=89]	92.4 (84.1, 100.7) [n=32]	
	Month 10 (Day 300)	100.0 (100.0, 100.0) [n=89]	92.4 (84.1, 100.7) [n=32]	
	Month 11 (Day 330)	100.0 (100.0, 100.0) [n=86]	92.4 (84.1, 100.7) [n=32]	
	Month 12 (Day 360)	97.7 (94.5, 100.9) [n=76]	92.4 (84.1, 100.7) [n=30]	
	Month 12 (Day 366)	97.7 (94.5, 100.9) [n=73]	92.4 (84.1, 100.7) [n=29]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.087		
	Hazard Ratio (95% CI)	0.26 (0.04, 1.53)		
	P-value	0.135		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 2.4.1
Time to the First Case of SARS-CoV-2 RT-PCR-positive Symptomatic Illness Occurring Post Dose of IMP and Prior to Day 366 - Treatment Policy by Subgroup - Using Cox Proportional Hazard Mode
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Category	AZD7442 (N=346)	Placebo (N=173)	P-value [a]
Increased risk for inadequate response to active immunization				1.000
Yes	Number of Participants with event, n (%)	22 (6.4)	19 (11.0)	
	Number of Participants censored, n (%)	322 (93.6)	153 (89.0)	
	Kaplan Meier product-limit estimates			
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
	Percent of Participants Without Events (95% CI) [No. at Risk]			
	Month 1 (Day 30)	99.7 (99.1, 100.3) [n=341]	97.7 (95.4, 99.9) [n=165]	
	Month 2 (Day 60)	99.4 (98.6, 100.2) [n=338]	97.7 (95.4, 99.9) [n=163]	
	Month 3 (Day 90)	99.4 (98.6, 100.2) [n=337]	97.1 (94.5, 99.6) [n=158]	
	Month 4 (Day 120)	99.4 (98.6, 100.2) [n=331]	96.4 (93.6, 99.2) [n=153]	
	Month 5 (Day 150)	99.4 (98.6, 100.2) [n=327]	96.4 (93.6, 99.2) [n=153]	
	Month 6 (Day 180)	99.1 (98.1, 100.1) [n=325]	95.2 (91.9, 98.4) [n=151]	
	Month 7 (Day 210)	99.1 (98.1, 100.1) [n=323]	93.9 (90.3, 97.6) [n=147]	
	Month 8 (Day 240)	98.8 (97.6, 100.0) [n=321]	93.3 (89.4, 97.1) [n=146]	
	Month 9 (Day 270)	98.5 (97.2, 99.8) [n=318]	93.3 (89.4, 97.1) [n=145]	
	Month 10 (Day 300)	97.9 (96.3, 99.4) [n=316]	92.6 (88.6, 96.6) [n=144]	
	Month 11 (Day 330)	96.0 (93.9, 98.1) [n=306]	89.4 (84.6, 94.2) [n=136]	
	Month 12 (Day 360)	93.8 (91.1, 96.4) [n=277]	88.7 (83.8, 93.6) [n=126]	
	Month 12 (Day 366)	93.1 (90.3, 95.9) [n=267]	88.0 (83.0, 93.1) [n=123]	
	P-value of 2-sided Wilcoxon Rank Sum test	0.029		
	Hazard Ratio (95% CI)	0.54 (0.29, 0.99)		
	P-value	0.047		

Abbreviation: CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable.
Note: Percentages are based on the number of participants in the analysis set by subgroup and by study arm.
Note: Time to event was fit using the Cox Proportional Hazard model (PH) with treatment group, subgroup and treatment*subgroup interaction as covariates.
Note: Hazard Ratio is from the PH model with Efron method. Estimated Hazard Ratio less than 1 provides evidence in favor of AZD7442 with p-values less than 0.05 indicating statistical significance.
[a] P-values are for the treatment*subgroup interaction from the PH model.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.204				0.204
<60 years	n / N(%)		144 / 199 (72.4)	60 / 97 (61.9)		
	RR, (95% CI)		1.17, (0.98, 1.40)		0.085	
	OR, (95% CI)		1.61, (0.97, 2.70)		0.068	
	ARR %, (95% CI)		10.51, (-0.99, 22.00)		0.073	
≥60 years	n / N(%)		107 / 147 (72.8)	56 / 76 (73.7)		
	RR, (95% CI)		0.99, (0.84, 1.17)		0.886	
	OR, (95% CI)		0.96, (0.51, 1.79)		0.886	
	ARR %, (95% CI)		-0.90, (-13.13, 11.34)		0.886	
Age at randomization		0.951				0.951
<65 years	n / N(%)		184 / 262 (70.2)	89 / 137 (65.0)		
	RR, (95% CI)		1.08, (0.93, 1.25)		0.296	
	OR, (95% CI)		1.27, (0.82, 1.97)		0.283	
	ARR %, (95% CI)		5.27, (-4.45, 14.99)		0.288	
≥65 years	n / N(%)		67 / 84 (79.8)	27 / 36 (75.0)		
	RR, (95% CI)		1.06, (0.86, 1.32)		0.579	
	OR, (95% CI)		1.31, (0.52, 3.31)		0.562	
	ARR %, (95% CI)		4.76, (-11.79, 21.31)		0.573	
Age at randomization		0.072				0.054
<75 years	n / N(%)		237 / 330 (71.8)	114 / 168 (67.9)		
	RR, (95% CI)		1.06, (0.93, 1.20)		0.370	
	OR, (95% CI)		1.21, (0.81, 1.81)		0.360	
	ARR %, (95% CI)		3.96, (-4.61, 12.53)		0.365	
≥75 years	n / N(%)		14 / 16 (87.5)	2 / 5 (40.0)		
	RR, (95% CI)		2.19, (0.74, 6.50)		0.159	
	OR, (95% CI)		10.50, (1.03, 107.17)		0.047	
	ARR %, (95% CI)		47.50, (1.60, 93.40)		0.043	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		251 / 346 (72.5)	116 / 173 (67.1)		
	RR, (95% CI)		1.08, (0.96, 1.22)		0.209	
	OR, (95% CI)		1.30, (0.87, 1.93)		0.196	
	ARR %, (95% CI)		5.49, (-2.94, 13.93)		0.202	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.390				0.390
Yes	n / N(%)		56 / 99 (56.6)	23 / 52 (44.2)		
	RR, (95% CI)		1.28, (0.90, 1.82)		0.169	
	OR, (95% CI)		1.64, (0.83, 3.23)		0.151	
	ARR %, (95% CI)		12.33, (-4.33, 29.00)		0.147	
No	n / N(%)		195 / 247 (78.9)	93 / 121 (76.9)		
	RR, (95% CI)		1.03, (0.91, 1.15)		0.654	
	OR, (95% CI)		1.13, (0.67, 1.90)		0.648	
	ARR %, (95% CI)		2.09, (-6.98, 11.16)		0.652	
Sex		0.358				0.358
Male	n / N(%)		146 / 216 (67.6)	61 / 105 (58.1)		
	RR, (95% CI)		1.16, (0.97, 1.40)		0.112	
	OR, (95% CI)		1.50, (0.93, 2.43)		0.096	
	ARR %, (95% CI)		9.50, (-1.82, 20.81)		0.100	
Female	n / N(%)		105 / 130 (80.8)	55 / 68 (80.9)		
	RR, (95% CI)		1.00, (0.87, 1.15)		0.985	
	OR, (95% CI)		0.99, (0.47, 2.09)		0.985	
	ARR %, (95% CI)		-0.11, (-11.66, 11.43)		0.985	
Region		0.856				0.855
North America	n / N(%)		109 / 185 (58.9)	59 / 106 (55.7)		
	RR, (95% CI)		1.06, (0.86, 1.30)		0.592	
	OR, (95% CI)		1.14, (0.71, 1.85)		0.588	
	ARR %, (95% CI)		3.26, (-8.56, 15.08)		0.589	
United Kingdom	n / N(%)		68 / 80 (85.0)	25 / 30 (83.3)		
	RR, (95% CI)		1.02, (0.85, 1.23)		0.833	
	OR, (95% CI)		1.13, (0.36, 3.54)		0.830	
	ARR %, (95% CI)		1.67, (-13.80, 17.13)		0.833	
European Union	n / N(%)		74 / 81 (91.4)	32 / 37 (86.5)		
	RR, (95% CI)		1.06, (0.91, 1.22)		0.455	
	OR, (95% CI)		1.65, (0.49, 5.60)		0.420	
	ARR %, (95% CI)		4.87, (-7.73, 17.47)		0.449	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		0.789				0.773
United States	n / N(%)		109 / 185 (58.9)	59 / 106 (55.7)		
	RR, (95% CI)		1.06, (0.86, 1.30)		0.592	
	OR, (95% CI)		1.14, (0.71, 1.85)		0.588	
	ARR %, (95% CI)		3.26, (-8.56, 15.08)		0.589	
United Kingdom	n / N(%)		68 / 80 (85.0)	25 / 30 (83.3)		
	RR, (95% CI)		1.02, (0.85, 1.23)		0.833	
	OR, (95% CI)		1.13, (0.36, 3.54)		0.830	
	ARR %, (95% CI)		1.67, (-13.80, 17.13)		0.833	
Belgium	n / N(%)		24 / 25 (96.0)	14 / 16 (87.5)		
	RR, (95% CI)		1.10, (0.90, 1.34)		0.368	
	OR, (95% CI)		3.43, (0.28, 41.32)		0.332	
	ARR %, (95% CI)		8.50, (-9.43, 26.43)		0.353	
France	n / N(%)		35 / 38 (92.1)	15 / 16 (93.8)		
	RR, (95% CI)		0.98, (0.84, 1.15)		0.825	
	OR, (95% CI)		0.78, (0.07, 8.10)		0.833	
	ARR %, (95% CI)		-1.64, (-16.28, 12.99)		0.826	
Spain	n / N(%)		15 / 18 (83.3)	3 / 5 (60.0)		
	RR, (95% CI)		1.39, (0.66, 2.93)		0.387	
	OR, (95% CI)		3.33, (0.38, 29.39)		0.278	
	ARR %, (95% CI)		23.33, (-22.93, 69.60)		0.323	
Race		0.548				0.546
Black or African American	n / N(%)		23 / 50 (46.0)	14 / 28 (50.0)		
	RR, (95% CI)		0.92, (0.57, 1.48)		0.732	
	OR, (95% CI)		0.85, (0.34, 2.15)		0.734	
	ARR %, (95% CI)		-4.00, (-27.10, 19.10)		0.734	
White	n / N(%)		210 / 264 (79.5)	90 / 126 (71.4)		
	RR, (95% CI)		1.11, (0.98, 1.26)		0.095	
	OR, (95% CI)		1.56, (0.95, 2.54)		0.076	
	ARR %, (95% CI)		8.12, (-1.15, 17.38)		0.086	
Other	n / N(%)		15 / 28 (53.6)	9 / 15 (60.0)		
	RR, (95% CI)		0.89, (0.52, 1.53)		0.680	
	OR, (95% CI)		0.77, (0.22, 2.75)		0.686	
	ARR %, (95% CI)		-6.43, (-37.35, 24.49)		0.684	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		0.568				0.565
Hispanic or Latino	n / N(%)		29 / 40 (72.5)	9 / 12 (75.0)		
	RR, (95% CI)		0.97, (0.66, 1.41)		0.861	
	OR, (95% CI)		0.88, (0.20, 3.86)		0.864	
	ARR %, (95% CI)		-2.50, (-30.64, 25.64)		0.862	
Not Hispanic or Latino	n / N(%)		202 / 275 (73.5)	95 / 144 (66.0)		
	RR, (95% CI)		1.11, (0.97, 1.28)		0.125	
	OR, (95% CI)		1.43, (0.92, 2.21)		0.110	
	ARR %, (95% CI)		7.48, (-1.85, 16.82)		0.116	
Other	n / N(%)		20 / 31 (64.5)	12 / 17 (70.6)		
	RR, (95% CI)		0.91, (0.61, 1.37)		0.662	
	OR, (95% CI)		0.76, (0.21, 2.72)		0.670	
	ARR %, (95% CI)		-6.07, (-33.51, 21.37)		0.664	
COVID-19 co-morbidities at baseline		0.473				0.472
None	n / N(%)		63 / 101 (62.4)	28 / 46 (60.9)		
	RR, (95% CI)		1.02, (0.78, 1.35)		0.863	
	OR, (95% CI)		1.07, (0.52, 2.18)		0.862	
	ARR %, (95% CI)		1.51, (-15.47, 18.48)		0.862	
At least one	n / N(%)		188 / 245 (76.7)	88 / 127 (69.3)		
	RR, (95% CI)		1.11, (0.97, 1.27)		0.138	
	OR, (95% CI)		1.46, (0.90, 2.36)		0.121	
	ARR %, (95% CI)		7.44, (-2.17, 17.05)		0.129	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		251 / 346 (72.5)	116 / 173 (67.1)		
	RR, (95% CI)		1.08, (0.96, 1.22)		0.209	
	OR, (95% CI)		1.30, (0.87, 1.93)		0.196	
	ARR %, (95% CI)		5.49, (-2.94, 13.93)		0.202	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.930				0.930
Yes	n / N(%)		225 / 303 (74.3)	106 / 154 (68.8)		
	RR, (95% CI)		1.08, (0.95, 1.22)		0.235	
	OR, (95% CI)		1.31, (0.85, 2.00)		0.220	
	ARR %, (95% CI)		5.43, (-3.39, 14.24)		0.228	
No	n / N(%)		26 / 43 (60.5)	10 / 19 (52.6)		
	RR, (95% CI)		1.15, (0.70, 1.88)		0.579	
	OR, (95% CI)		1.38, (0.46, 4.09)		0.565	
	ARR %, (95% CI)		7.83, (-18.95, 34.62)		0.567	
Obesity (≥ 30 kg/m^2)		0.492				0.491
Yes	n / N(%)		89 / 119 (74.8)	36 / 55 (65.5)		
	RR, (95% CI)		1.14, (0.92, 1.42)		0.232	
	OR, (95% CI)		1.57, (0.78, 3.13)		0.205	
	ARR %, (95% CI)		9.34, (-5.46, 24.13)		0.216	
No	n / N(%)		161 / 225 (71.6)	80 / 117 (68.4)		
	RR, (95% CI)		1.05, (0.90, 1.21)		0.548	
	OR, (95% CI)		1.16, (0.72, 1.89)		0.541	
	ARR %, (95% CI)		3.18, (-7.10, 13.46)		0.545	
Obesity (≥ 40 kg/m^2)		0.579				0.577
Yes	n / N(%)		15 / 17 (88.2)	10 / 13 (76.9)		
	RR, (95% CI)		1.15, (0.81, 1.62)		0.435	
	OR, (95% CI)		2.25, (0.32, 15.97)		0.417	
	ARR %, (95% CI)		11.31, (-16.24, 38.86)		0.421	
No	n / N(%)		235 / 327 (71.9)	106 / 159 (66.7)		
	RR, (95% CI)		1.08, (0.95, 1.23)		0.254	
	OR, (95% CI)		1.28, (0.85, 1.92)		0.240	
	ARR %, (95% CI)		5.20, (-3.60, 14.00)		0.247	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.445				0.444
Yes	n / N(%)		29 / 38 (76.3)	13 / 21 (61.9)		
	RR, (95% CI)		1.23, (0.84, 1.80)		0.280	
	OR, (95% CI)		1.98, (0.62, 6.30)		0.246	
	ARR %, (95% CI)		14.41, (-10.37, 39.19)		0.254	
No	n / N(%)		222 / 308 (72.1)	103 / 152 (67.8)		
	RR, (95% CI)		1.06, (0.93, 1.21)		0.351	
	OR, (95% CI)		1.23, (0.81, 1.87)		0.339	
	ARR %, (95% CI)		4.31, (-4.65, 13.28)		0.345	
Diabetes		0.562				0.561
Yes	n / N(%)		30 / 40 (75.0)	19 / 25 (76.0)		
	RR, (95% CI)		0.99, (0.74, 1.31)		0.927	
	OR, (95% CI)		0.95, (0.30, 3.03)		0.927	
	ARR %, (95% CI)		-1.00, (-22.46, 20.46)		0.927	
No	n / N(%)		221 / 306 (72.2)	97 / 148 (65.5)		
	RR, (95% CI)		1.10, (0.96, 1.26)		0.162	
	OR, (95% CI)		1.37, (0.90, 2.08)		0.146	
	ARR %, (95% CI)		6.68, (-2.47, 15.84)		0.153	
Immunosuppressive disease		0.970				0.126
Yes	n / N(%)		16 / 16 (100.0)	7 / 9 (77.8)		
	RR, (95% CI)		1.29, (0.90, 1.87)		0.169	
	OR, (95% CI)		11.00, (0.47, 258.41)		0.137	
	ARR %, (95% CI)		22.22, (-4.94, 49.38)		0.109	
No	n / N(%)		235 / 330 (71.2)	109 / 164 (66.5)		
	RR, (95% CI)		1.07, (0.94, 1.22)		0.293	
	OR, (95% CI)		1.25, (0.83, 1.87)		0.280	
	ARR %, (95% CI)		4.75, (-3.97, 13.47)		0.286	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.767				0.767
Yes	n / N(%)		81 / 103 (78.6)	43 / 60 (71.7)		
	RR, (95% CI)		1.10, (0.91, 1.32)		0.334	
	OR, (95% CI)		1.46, (0.70, 3.03)		0.315	
	ARR %, (95% CI)		6.97, (-6.91, 20.85)		0.325	
No	n / N(%)		170 / 243 (70.0)	73 / 113 (64.6)		
	RR, (95% CI)		1.08, (0.92, 1.27)		0.327	
	OR, (95% CI)		1.28, (0.80, 2.05)		0.313	
	ARR %, (95% CI)		5.36, (-5.18, 15.89)		0.319	
CV disease		0.954				0.954
Yes	n / N(%)		26 / 32 (81.3)	17 / 22 (77.3)		
	RR, (95% CI)		1.05, (0.79, 1.39)		0.726	
	OR, (95% CI)		1.27, (0.34, 4.84)		0.722	
	ARR %, (95% CI)		3.98, (-18.15, 26.10)		0.725	
No	n / N(%)		225 / 314 (71.7)	99 / 151 (65.6)		
	RR, (95% CI)		1.09, (0.95, 1.25)		0.197	
	OR, (95% CI)		1.33, (0.88, 2.01)		0.181	
	ARR %, (95% CI)		6.09, (-2.98, 15.16)		0.188	
COPD		0.975				0.147
Yes	n / N(%)		19 / 23 (82.6)	11 / 11 (100.0)		
	RR, (95% CI)		0.85, (0.68, 1.06)		0.151	
	OR, (95% CI)		0.19, (0.01, 3.83)		0.277	
	ARR %, (95% CI)		-17.39, (-32.88, -1.90)		0.028	
No	n / N(%)		232 / 323 (71.8)	105 / 162 (64.8)		
	RR, (95% CI)		1.11, (0.97, 1.27)		0.128	
	OR, (95% CI)		1.38, (0.92, 2.07)		0.114	
	ARR %, (95% CI)		7.01, (-1.83, 15.85)		0.120	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.109				0.102
Yes	n / N(%)		39 / 44 (88.6)	18 / 26 (69.2)		
	RR, (95% CI)		1.28, (0.97, 1.69)		0.081	
	OR, (95% CI)		3.47, (0.99, 12.09)		0.051	
	ARR %, (95% CI)		19.41, (-0.66, 39.47)		0.058	
No	n / N(%)		212 / 302 (70.2)	98 / 147 (66.7)		
	RR, (95% CI)		1.05, (0.92, 1.21)		0.457	
	OR, (95% CI)		1.18, (0.77, 1.80)		0.448	
	ARR %, (95% CI)		3.53, (-5.67, 12.73)		0.452	
Hypertension		0.762				0.762
Yes	n / N(%)		112 / 153 (73.2)	52 / 75 (69.3)		
	RR, (95% CI)		1.06, (0.88, 1.26)		0.551	
	OR, (95% CI)		1.21, (0.66, 2.22)		0.542	
	ARR %, (95% CI)		3.87, (-8.71, 16.45)		0.546	
No	n / N(%)		139 / 193 (72.0)	64 / 98 (65.3)		
	RR, (95% CI)		1.10, (0.93, 1.31)		0.256	
	OR, (95% CI)		1.37, (0.81, 2.30)		0.239	
	ARR %, (95% CI)		6.71, (-4.64, 18.07)		0.246	
Asthma		0.494				0.492
Yes	n / N(%)		43 / 55 (78.2)	17 / 21 (81.0)		
	RR, (95% CI)		0.97, (0.75, 1.24)		0.785	
	OR, (95% CI)		0.84, (0.24, 2.98)		0.791	
	ARR %, (95% CI)		-2.77, (-22.80, 17.26)		0.786	
No	n / N(%)		208 / 291 (71.5)	99 / 152 (65.1)		
	RR, (95% CI)		1.10, (0.96, 1.26)		0.184	
	OR, (95% CI)		1.34, (0.88, 2.04)		0.170	
	ARR %, (95% CI)		6.35, (-2.84, 15.53)		0.176	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.936				0.936
Yes	n / N(%)		49 / 60 (81.7)	23 / 30 (76.7)		
	RR, (95% CI)		1.07, (0.85, 1.34)		0.592	
	OR, (95% CI)		1.36, (0.47, 3.95)		0.577	
	ARR %, (95% CI)		5.00, (-13.03, 23.03)		0.587	
No	n / N(%)		202 / 286 (70.6)	93 / 143 (65.0)		
	RR, (95% CI)		1.09, (0.94, 1.25)		0.253	
	OR, (95% CI)		1.29, (0.84, 1.98)		0.239	
	ARR %, (95% CI)		5.59, (-3.84, 15.03)		0.245	
Smoking		0.827				0.827
Yes	n / N(%)		38 / 63 (60.3)	16 / 31 (51.6)		
	RR, (95% CI)		1.17, (0.79, 1.74)		0.440	
	OR, (95% CI)		1.43, (0.60, 3.39)		0.423	
	ARR %, (95% CI)		8.70, (-12.64, 30.05)		0.424	
No	n / N(%)		213 / 283 (75.3)	100 / 142 (70.4)		
	RR, (95% CI)		1.07, (0.94, 1.21)		0.300	
	OR, (95% CI)		1.28, (0.81, 2.00)		0.286	
	ARR %, (95% CI)		4.84, (-4.19, 13.88)		0.293	
Sickle cell disease		NE				NE
No	n / N(%)		251 / 346 (72.5)	116 / 173 (67.1)		
	RR, (95% CI)		1.08, (0.96, 1.22)		0.209	
	OR, (95% CI)		1.30, (0.87, 1.93)		0.196	
	ARR %, (95% CI)		5.49, (-2.94, 13.93)		0.202	
COVID-19 vaccination at any time during the study		0.131				0.131
Yes	n / N(%)		203 / 242 (83.9)	94 / 127 (74.0)		
	RR, (95% CI)		1.13, (1.01, 1.27)		0.036	
	OR, (95% CI)		1.83, (1.08, 3.09)		0.024	
	ARR %, (95% CI)		9.87, (0.94, 18.79)		0.030	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		48 / 104 (46.2)	22 / 46 (47.8)		
	RR, (95% CI)		0.97, (0.67, 1.39)		0.849	
	OR, (95% CI)		0.94, (0.47, 1.87)		0.850	
	ARR %, (95% CI)		-1.67, (-19.00, 15.65)		0.850	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.1
Adverse Events Overview by Subgroup - Participants with at least One AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.999				0.912
Yes	n / N(%)		249 / 344 (72.4)	115 / 172 (66.9)		
	RR, (95% CI)		1.08, (0.96, 1.23)		0.209	
	OR, (95% CI)		1.30, (0.87, 1.93)		0.195	
	ARR %, (95% CI)		5.52, (-2.95, 14.00)		0.201	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.999				0.840
<60 years	n / N(%)		2 / 199 (1.0)	0 / 97 (0.0)		
	RR, (95% CI)		2.45, (0.12, 50.54)		0.562	
	OR, (95% CI)		2.47, (0.12, 51.91)		0.561	
	ARR %, (95% CI)		1.00, (-0.38, 2.39)		0.155	
≥60 years	n / N(%)		1 / 147 (0.7)	0 / 76 (0.0)		
	RR, (95% CI)		1.56, (0.06, 37.86)		0.784	
	OR, (95% CI)		1.57, (0.06, 38.92)		0.784	
	ARR %, (95% CI)		0.68, (-0.65, 2.01)		0.316	
Age at randomization		0.999				0.755
<65 years	n / N(%)		2 / 262 (0.8)	0 / 137 (0.0)		
	RR, (95% CI)		2.62, (0.13, 54.27)		0.533	
	OR, (95% CI)		2.64, (0.13, 55.36)		0.532	
	ARR %, (95% CI)		0.76, (-0.29, 1.82)		0.156	
≥65 years	n / N(%)		1 / 84 (1.2)	0 / 36 (0.0)		
	RR, (95% CI)		1.31, (0.05, 31.32)		0.869	
	OR, (95% CI)		1.31, (0.05, 32.96)		0.869	
	ARR %, (95% CI)		1.19, (-1.13, 3.51)		0.315	
Age at randomization		0.982				0.301
<75 years	n / N(%)		3 / 330 (0.9)	0 / 168 (0.0)		
	RR, (95% CI)		3.57, (0.19, 68.79)		0.399	
	OR, (95% CI)		3.60, (0.18, 70.13)		0.398	
	ARR %, (95% CI)		0.91, (-0.12, 1.93)		0.082	
≥75 years	n / N(%)		0 / 16 (0.0)	0 / 5 (0.0)		
	RR, (95% CI)		0.35, (0.01, 15.90)		0.592	
	OR, (95% CI)		0.33, (0.01, 18.88)		0.594	
	ARR %, (95% CI)		0.00, (-0.41, 0.41)		0.995	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		3 / 346 (0.9)	0 / 173 (0.0)		
	RR, (95% CI)		3.51, (0.18, 67.57)		0.405	
	OR, (95% CI)		3.54, (0.18, 68.83)		0.404	
	ARR %, (95% CI)		0.87, (-0.11, 1.84)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.977				0.421
Yes	n / N(%)		0 / 99 (0.0)	0 / 52 (0.0)		
	RR, (95% CI)		0.53, (0.01, 26.33)		0.750	
	OR, (95% CI)		0.53, (0.01, 26.97)		0.750	
	ARR %, (95% CI)		0.00, (-0.04, 0.04)		0.997	
No	n / N(%)		3 / 247 (1.2)	0 / 121 (0.0)		
	RR, (95% CI)		3.44, (0.18, 66.14)		0.412	
	OR, (95% CI)		3.48, (0.18, 67.88)		0.411	
	ARR %, (95% CI)		1.21, (-0.15, 2.58)		0.081	
Sex		0.975				0.421
Male	n / N(%)		3 / 216 (1.4)	0 / 105 (0.0)		
	RR, (95% CI)		3.42, (0.18, 65.60)		0.415	
	OR, (95% CI)		3.46, (0.18, 67.58)		0.413	
	ARR %, (95% CI)		1.39, (-0.17, 2.95)		0.081	
Female	n / N(%)		0 / 130 (0.0)	0 / 68 (0.0)		
	RR, (95% CI)		0.53, (0.01, 26.26)		0.748	
	OR, (95% CI)		0.52, (0.01, 26.74)		0.748	
	ARR %, (95% CI)		0.00, (-0.03, 0.03)		0.997	
Region		0.999				0.846
North America	n / N(%)		0 / 185 (0.0)	0 / 106 (0.0)		
	RR, (95% CI)		0.58, (0.01, 28.78)		0.782	
	OR, (95% CI)		0.57, (0.01, 29.14)		0.782	
	ARR %, (95% CI)		0.00, (-0.02, 0.02)		0.997	
United Kingdom	n / N(%)		1 / 80 (1.3)	0 / 30 (0.0)		
	RR, (95% CI)		1.15, (0.05, 27.44)		0.932	
	OR, (95% CI)		1.15, (0.05, 29.03)		0.932	
	ARR %, (95% CI)		1.25, (-1.19, 3.69)		0.315	
European Union	n / N(%)		2 / 81 (2.5)	0 / 37 (0.0)		
	RR, (95% CI)		2.32, (0.11, 47.10)		0.585	
	OR, (95% CI)		2.36, (0.11, 50.36)		0.583	
	ARR %, (95% CI)		2.47, (-0.91, 5.85)		0.152	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		1.000				0.952
United States	n / N(%)		0 / 185 (0.0)	0 / 106 (0.0)		
	RR, (95% CI)		0.58, (0.01, 28.78)		0.782	
	OR, (95% CI)		0.57, (0.01, 29.14)		0.782	
	ARR %, (95% CI)		0.00, (-0.02, 0.02)		0.997	
United Kingdom	n / N(%)		1 / 80 (1.3)	0 / 30 (0.0)		
	RR, (95% CI)		1.15, (0.05, 27.44)		0.932	
	OR, (95% CI)		1.15, (0.05, 29.03)		0.932	
	ARR %, (95% CI)		1.25, (-1.19, 3.69)		0.315	
Belgium	n / N(%)		1 / 25 (4.0)	0 / 16 (0.0)		
	RR, (95% CI)		1.96, (0.08, 45.40)		0.674	
	OR, (95% CI)		2.02, (0.08, 52.68)		0.673	
	ARR %, (95% CI)		4.00, (-3.68, 11.68)		0.308	
France	n / N(%)		1 / 38 (2.6)	0 / 16 (0.0)		
	RR, (95% CI)		1.31, (0.06, 30.50)		0.867	
	OR, (95% CI)		1.32, (0.05, 34.13)		0.867	
	ARR %, (95% CI)		2.63, (-2.46, 7.72)		0.311	
Spain	n / N(%)		0 / 18 (0.0)	0 / 5 (0.0)		
	RR, (95% CI)		0.32, (0.01, 14.27)		0.553	
	OR, (95% CI)		0.30, (0.01, 16.79)		0.556	
	ARR %, (95% CI)		0.00, (-0.41, 0.41)		0.994	
Race		1.000				0.841
Black or African American	n / N(%)		0 / 50 (0.0)	0 / 28 (0.0)		
	RR, (95% CI)		0.57, (0.01, 27.90)		0.776	
	OR, (95% CI)		0.56, (0.01, 29.21)		0.776	
	ARR %, (95% CI)		0.00, (-0.08, 0.08)		0.997	
White	n / N(%)		3 / 264 (1.1)	0 / 126 (0.0)		
	RR, (95% CI)		3.35, (0.17, 64.46)		0.422	
	OR, (95% CI)		3.39, (0.17, 66.06)		0.421	
	ARR %, (95% CI)		1.14, (-0.14, 2.42)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Other	n / N(%)		0 / 28 (0.0)	0 / 15 (0.0)		
	RR, (95% CI)		0.55, (0.01, 26.51)		0.763	
	OR, (95% CI)		0.54, (0.01, 28.77)		0.764	
	ARR %, (95% CI)		0.00, (-0.15, 0.15)		0.997	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		0.999				0.505
Hispanic or Latino	n / N(%)		0 / 40 (0.0)	0 / 12 (0.0)		
	RR, (95% CI)		0.32, (0.01, 15.20)		0.561	
	OR, (95% CI)		0.31, (0.01, 16.37)		0.562	
	ARR %, (95% CI)		0.00, (-0.17, 0.17)		0.995	
Not Hispanic or Latino	n / N(%)		3 / 275 (1.1)	0 / 144 (0.0)		
	RR, (95% CI)		3.68, (0.19, 70.71)		0.388	
	OR, (95% CI)		3.71, (0.19, 72.36)		0.387	
	ARR %, (95% CI)		1.09, (-0.14, 2.32)		0.082	
Other	n / N(%)		0 / 31 (0.0)	0 / 17 (0.0)		
	RR, (95% CI)		0.56, (0.01, 27.16)		0.771	
	OR, (95% CI)		0.56, (0.01, 29.24)		0.771	
	ARR %, (95% CI)		0.00, (-0.13, 0.13)		0.997	
COVID-19 co-morbidities at baseline		1.000				0.777
None	n / N(%)		1 / 101 (1.0)	0 / 46 (0.0)		
	RR, (95% CI)		1.38, (0.06, 33.30)		0.842	
	OR, (95% CI)		1.39, (0.06, 34.72)		0.842	
	ARR %, (95% CI)		0.99, (-0.94, 2.92)		0.315	
At least one	n / N(%)		2 / 245 (0.8)	0 / 127 (0.0)		
	RR, (95% CI)		2.60, (0.13, 53.78)		0.536	
	OR, (95% CI)		2.62, (0.12, 54.95)		0.535	
	ARR %, (95% CI)		0.82, (-0.31, 1.94)		0.156	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		3 / 346 (0.9)	0 / 173 (0.0)		
	RR, (95% CI)		3.51, (0.18, 67.57)		0.405	
	OR, (95% CI)		3.54, (0.18, 68.83)		0.404	
	ARR %, (95% CI)		0.87, (-0.11, 1.84)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup – Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.998				0.783
Yes	n / N(%)		2 / 303 (0.7)	0 / 154 (0.0)		
	RR, (95% CI)		2.55, (0.12, 52.77)		0.545	
	OR, (95% CI)		2.56, (0.12, 53.70)		0.544	
	ARR %, (95% CI)		0.66, (-0.25, 1.57)		0.156	
No	n / N(%)		1 / 43 (2.3)	0 / 19 (0.0)		
	RR, (95% CI)		1.36, (0.06, 32.03)		0.847	
	OR, (95% CI)		1.38, (0.05, 35.33)		0.847	
	ARR %, (95% CI)		2.33, (-2.18, 6.83)		0.312	
Obesity (≥ 30 kg/m^2)		0.976				0.369
Yes	n / N(%)		0 / 119 (0.0)	0 / 55 (0.0)		
	RR, (95% CI)		0.47, (0.01, 23.22)		0.702	
	OR, (95% CI)		0.46, (0.01, 23.71)		0.702	
	ARR %, (95% CI)		0.00, (-0.04, 0.04)		0.996	
No	n / N(%)		3 / 225 (1.3)	0 / 117 (0.0)		
	RR, (95% CI)		3.65, (0.19, 70.17)		0.390	
	OR, (95% CI)		3.70, (0.19, 72.17)		0.389	
	ARR %, (95% CI)		1.33, (-0.17, 2.83)		0.081	
Obesity (≥ 40 kg/m^2)		0.983				0.537
Yes	n / N(%)		0 / 17 (0.0)	0 / 13 (0.0)		
	RR, (95% CI)		0.78, (0.02, 36.81)		0.898	
	OR, (95% CI)		0.77, (0.01, 41.44)		0.898	
	ARR %, (95% CI)		0.00, (-0.19, 0.19)		0.999	
No	n / N(%)		3 / 327 (0.9)	0 / 159 (0.0)		
	RR, (95% CI)		3.41, (0.18, 65.71)		0.416	
	OR, (95% CI)		3.44, (0.18, 67.01)		0.415	
	ARR %, (95% CI)		0.92, (-0.12, 1.95)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.977				0.437
Yes	n / N(%)		0 / 38 (0.0)	0 / 21 (0.0)		
	RR, (95% CI)		0.56, (0.01, 27.45)		0.773	
	OR, (95% CI)		0.56, (0.01, 29.16)		0.773	
	ARR %, (95% CI)		0.00, (-0.11, 0.11)		0.997	
No	n / N(%)		3 / 308 (1.0)	0 / 152 (0.0)		
	RR, (95% CI)		3.47, (0.18, 66.68)		0.410	
	OR, (95% CI)		3.49, (0.18, 68.08)		0.409	
	ARR %, (95% CI)		0.97, (-0.12, 2.07)		0.082	
Diabetes		0.976				0.477
Yes	n / N(%)		0 / 40 (0.0)	0 / 25 (0.0)		
	RR, (95% CI)		0.63, (0.01, 30.99)		0.818	
	OR, (95% CI)		0.63, (0.01, 32.74)		0.818	
	ARR %, (95% CI)		0.00, (-0.09, 0.09)		0.997	
No	n / N(%)		3 / 306 (1.0)	0 / 148 (0.0)		
	RR, (95% CI)		3.40, (0.18, 65.35)		0.418	
	OR, (95% CI)		3.43, (0.18, 66.74)		0.416	
	ARR %, (95% CI)		0.98, (-0.12, 2.08)		0.082	
Immunosuppressive disease		0.978				0.449
Yes	n / N(%)		0 / 16 (0.0)	0 / 9 (0.0)		
	RR, (95% CI)		0.59, (0.01, 27.40)		0.787	
	OR, (95% CI)		0.58, (0.01, 31.45)		0.787	
	ARR %, (95% CI)		0.00, (-0.25, 0.25)		0.997	
No	n / N(%)		3 / 330 (0.9)	0 / 164 (0.0)		
	RR, (95% CI)		3.49, (0.18, 67.16)		0.408	
	OR, (95% CI)		3.52, (0.18, 68.47)		0.407	
	ARR %, (95% CI)		0.91, (-0.12, 1.93)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.977				0.464
Yes	n / N(%)		0 / 103 (0.0)	0 / 60 (0.0)		
	RR, (95% CI)		0.59, (0.01, 29.18)		0.789	
	OR, (95% CI)		0.58, (0.01, 29.84)		0.789	
	ARR %, (95% CI)		0.00, (-0.04, 0.04)		0.997	
No	n / N(%)		3 / 243 (1.2)	0 / 113 (0.0)		
	RR, (95% CI)		3.27, (0.17, 62.79)		0.432	
	OR, (95% CI)		3.30, (0.17, 64.49)		0.431	
	ARR %, (95% CI)		1.23, (-0.15, 2.62)		0.081	
CV disease		0.978				0.506
Yes	n / N(%)		0 / 32 (0.0)	0 / 22 (0.0)		
	RR, (95% CI)		0.70, (0.01, 33.87)		0.855	
	OR, (95% CI)		0.69, (0.01, 36.19)		0.855	
	ARR %, (95% CI)		0.00, (-0.11, 0.11)		0.998	
No	n / N(%)		3 / 314 (1.0)	0 / 151 (0.0)		
	RR, (95% CI)		3.38, (0.18, 64.98)		0.420	
	OR, (95% CI)		3.40, (0.17, 66.33)		0.419	
	ARR %, (95% CI)		0.96, (-0.12, 2.03)		0.082	
COPD		0.983				0.399
Yes	n / N(%)		0 / 23 (0.0)	0 / 11 (0.0)		
	RR, (95% CI)		0.50, (0.01, 23.69)		0.725	
	OR, (95% CI)		0.49, (0.01, 26.26)		0.725	
	ARR %, (95% CI)		0.00, (-0.20, 0.20)		0.996	
No	n / N(%)		3 / 323 (0.9)	0 / 162 (0.0)		
	RR, (95% CI)		3.52, (0.18, 67.77)		0.404	
	OR, (95% CI)		3.55, (0.18, 69.12)		0.403	
	ARR %, (95% CI)		0.93, (-0.12, 1.97)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.975				0.459
Yes	n / N(%)		0 / 44 (0.0)	0 / 26 (0.0)		
	RR, (95% CI)		0.60, (0.01, 29.37)		0.797	
	OR, (95% CI)		0.60, (0.01, 30.91)		0.797	
	ARR %, (95% CI)		0.00, (-0.09, 0.09)		0.997	
No	n / N(%)		3 / 302 (1.0)	0 / 147 (0.0)		
	RR, (95% CI)		3.42, (0.18, 65.76)		0.415	
	OR, (95% CI)		3.45, (0.18, 67.18)		0.414	
	ARR %, (95% CI)		0.99, (-0.13, 2.11)		0.082	
Hypertension		0.998				0.829
Yes	n / N(%)		2 / 153 (1.3)	0 / 75 (0.0)		
	RR, (95% CI)		2.47, (0.12, 50.76)		0.558	
	OR, (95% CI)		2.49, (0.12, 52.56)		0.557	
	ARR %, (95% CI)		1.31, (-0.49, 3.11)		0.155	
No	n / N(%)		1 / 193 (0.5)	0 / 98 (0.0)		
	RR, (95% CI)		1.53, (0.06, 37.24)		0.794	
	OR, (95% CI)		1.54, (0.06, 38.03)		0.794	
	ARR %, (95% CI)		0.52, (-0.50, 1.53)		0.316	
Asthma		0.998				0.721
Yes	n / N(%)		1 / 55 (1.8)	0 / 21 (0.0)		
	RR, (95% CI)		1.18, (0.05, 27.85)		0.919	
	OR, (95% CI)		1.18, (0.05, 30.20)		0.919	
	ARR %, (95% CI)		1.82, (-1.71, 5.35)		0.313	
No	n / N(%)		2 / 291 (0.7)	0 / 152 (0.0)		
	RR, (95% CI)		2.62, (0.13, 54.23)		0.533	
	OR, (95% CI)		2.63, (0.13, 55.21)		0.533	
	ARR %, (95% CI)		0.69, (-0.26, 1.64)		0.156	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.998				0.826
Yes	n / N(%)		1 / 60 (1.7)	0 / 30 (0.0)		
	RR, (95% CI)		1.52, (0.06, 36.34)		0.794	
	OR, (95% CI)		1.54, (0.06, 38.88)		0.794	
	ARR %, (95% CI)		1.67, (-1.57, 4.91)		0.313	
No	n / N(%)		2 / 286 (0.7)	0 / 143 (0.0)		
	RR, (95% CI)		2.51, (0.12, 51.91)		0.552	
	OR, (95% CI)		2.52, (0.12, 52.88)		0.551	
	ARR %, (95% CI)		0.70, (-0.27, 1.67)		0.156	
Smoking		0.982				0.398
Yes	n / N(%)		0 / 63 (0.0)	0 / 31 (0.0)		
	RR, (95% CI)		0.50, (0.01, 24.62)		0.727	
	OR, (95% CI)		0.50, (0.01, 25.59)		0.727	
	ARR %, (95% CI)		0.00, (-0.07, 0.07)		0.996	
No	n / N(%)		3 / 283 (1.1)	0 / 142 (0.0)		
	RR, (95% CI)		3.52, (0.18, 67.77)		0.404	
	OR, (95% CI)		3.56, (0.18, 69.32)		0.402	
	ARR %, (95% CI)		1.06, (-0.13, 2.25)		0.082	
Sickle cell disease		NE				NE
No	n / N(%)		3 / 346 (0.9)	0 / 173 (0.0)		
	RR, (95% CI)		3.51, (0.18, 67.57)		0.405	
	OR, (95% CI)		3.54, (0.18, 68.83)		0.404	
	ARR %, (95% CI)		0.87, (-0.11, 1.84)		0.082	
COVID-19 vaccination at any time during the study		0.978				0.355
Yes	n / N(%)		3 / 242 (1.2)	0 / 127 (0.0)		
	RR, (95% CI)		3.69, (0.19, 70.83)		0.387	
	OR, (95% CI)		3.73, (0.19, 72.71)		0.385	
	ARR %, (95% CI)		1.24, (-0.15, 2.63)		0.081	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		0 / 104 (0.0)	0 / 46 (0.0)		
	RR, (95% CI)		0.45, (0.01, 22.22)		0.687	
	OR, (95% CI)		0.44, (0.01, 22.77)		0.687	
	ARR %, (95% CI)		0.00, (-0.05, 0.05)		0.996	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.10
Adverse Events Overview by Subgroup - Participants with at least One Severe AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.992				0.495
Yes	n / N(%)		3 / 344 (0.9)	0 / 172 (0.0)		
	RR, (95% CI)		3.51, (0.18, 67.57)		0.405	
	OR, (95% CI)		3.54, (0.18, 68.84)		0.404	
	ARR %, (95% CI)		0.87, (-0.11, 1.85)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.758				0.758
<60 years	n / N(%)		20 / 199 (10.1)	10 / 97 (10.3)		
	RR, (95% CI)		0.97, (0.47, 2.00)		0.945	
	OR, (95% CI)		0.97, (0.44, 2.17)		0.945	
	ARR %, (95% CI)		-0.26, (-7.61, 7.09)		0.945	
≥60 years	n / N(%)		22 / 147 (15.0)	10 / 76 (13.2)		
	RR, (95% CI)		1.14, (0.57, 2.28)		0.716	
	OR, (95% CI)		1.16, (0.52, 2.60)		0.715	
	ARR %, (95% CI)		1.81, (-7.73, 11.35)		0.710	
Age at randomization		0.314				0.310
<65 years	n / N(%)		27 / 262 (10.3)	16 / 137 (11.7)		
	RR, (95% CI)		0.88, (0.49, 1.58)		0.674	
	OR, (95% CI)		0.87, (0.45, 1.67)		0.675	
	ARR %, (95% CI)		-1.37, (-7.89, 5.14)		0.680	
≥65 years	n / N(%)		15 / 84 (17.9)	4 / 36 (11.1)		
	RR, (95% CI)		1.61, (0.57, 4.51)		0.367	
	OR, (95% CI)		1.74, (0.53, 5.66)		0.358	
	ARR %, (95% CI)		6.75, (-6.39, 19.88)		0.314	
Age at randomization		0.644				0.641
<75 years	n / N(%)		40 / 330 (12.1)	19 / 168 (11.3)		
	RR, (95% CI)		1.07, (0.64, 1.79)		0.791	
	OR, (95% CI)		1.08, (0.61, 1.93)		0.791	
	ARR %, (95% CI)		0.81, (-5.13, 6.76)		0.789	
≥75 years	n / N(%)		2 / 16 (12.5)	1 / 5 (20.0)		
	RR, (95% CI)		0.63, (0.07, 5.53)		0.673	
	OR, (95% CI)		0.57, (0.04, 8.05)		0.678	
	ARR %, (95% CI)		-7.50, (-46.12, 31.12)		0.704	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		42 / 346 (12.1)	20 / 173 (11.6)		
	RR, (95% CI)		1.05, (0.64, 1.73)		0.848	
	OR, (95% CI)		1.06, (0.60, 1.86)		0.848	
	ARR %, (95% CI)		0.58, (-5.30, 6.46)		0.847	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.573				0.571
Yes	n / N(%)		6 / 99 (6.1)	2 / 52 (3.8)		
	RR, (95% CI)		1.58, (0.33, 7.53)		0.569	
	OR, (95% CI)		1.61, (0.31, 8.29)		0.567	
	ARR %, (95% CI)		2.21, (-4.81, 9.24)		0.537	
No	n / N(%)		36 / 247 (14.6)	18 / 121 (14.9)		
	RR, (95% CI)		0.98, (0.58, 1.65)		0.939	
	OR, (95% CI)		0.98, (0.53, 1.80)		0.939	
	ARR %, (95% CI)		-0.30, (-8.02, 7.42)		0.939	
Sex		0.168				0.165
Male	n / N(%)		25 / 216 (11.6)	8 / 105 (7.6)		
	RR, (95% CI)		1.52, (0.71, 3.25)		0.282	
	OR, (95% CI)		1.59, (0.69, 3.65)		0.277	
	ARR %, (95% CI)		3.96, (-2.67, 10.58)		0.242	
Female	n / N(%)		17 / 130 (13.1)	12 / 68 (17.6)		
	RR, (95% CI)		0.74, (0.38, 1.46)		0.386	
	OR, (95% CI)		0.70, (0.31, 1.57)		0.389	
	ARR %, (95% CI)		-4.57, (-15.33, 6.19)		0.405	
Region		0.625				0.618
North America	n / N(%)		18 / 185 (9.7)	12 / 106 (11.3)		
	RR, (95% CI)		0.86, (0.43, 1.71)		0.667	
	OR, (95% CI)		0.84, (0.39, 1.83)		0.668	
	ARR %, (95% CI)		-1.59, (-8.98, 5.80)		0.673	
United Kingdom	n / N(%)		10 / 80 (12.5)	2 / 30 (6.7)		
	RR, (95% CI)		1.88, (0.44, 8.07)		0.398	
	OR, (95% CI)		2.00, (0.41, 9.71)		0.390	
	ARR %, (95% CI)		5.83, (-5.66, 17.33)		0.320	
European Union	n / N(%)		14 / 81 (17.3)	6 / 37 (16.2)		
	RR, (95% CI)		1.07, (0.44, 2.55)		0.886	
	OR, (95% CI)		1.08, (0.38, 3.08)		0.886	
	ARR %, (95% CI)		1.07, (-13.38, 15.52)		0.885	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		0.811				0.804
United States	n / N(%)		18 / 185 (9.7)	12 / 106 (11.3)		
	RR, (95% CI)		0.86, (0.43, 1.71)		0.667	
	OR, (95% CI)		0.84, (0.39, 1.83)		0.668	
	ARR %, (95% CI)		-1.59, (-8.98, 5.80)		0.673	
United Kingdom	n / N(%)		10 / 80 (12.5)	2 / 30 (6.7)		
	RR, (95% CI)		1.88, (0.44, 8.07)		0.398	
	OR, (95% CI)		2.00, (0.41, 9.71)		0.390	
	ARR %, (95% CI)		5.83, (-5.66, 17.33)		0.320	
Belgium	n / N(%)		5 / 25 (20.0)	4 / 16 (25.0)		
	RR, (95% CI)		0.80, (0.25, 2.54)		0.705	
	OR, (95% CI)		0.75, (0.17, 3.35)		0.706	
	ARR %, (95% CI)		-5.00, (-31.38, 21.38)		0.710	
France	n / N(%)		8 / 38 (21.1)	2 / 16 (12.5)		
	RR, (95% CI)		1.68, (0.40, 7.07)		0.477	
	OR, (95% CI)		1.87, (0.35, 9.96)		0.465	
	ARR %, (95% CI)		8.55, (-12.20, 29.30)		0.419	
Spain	n / N(%)		1 / 18 (5.6)	0 / 5 (0.0)		
	RR, (95% CI)		0.95, (0.04, 20.33)		0.972	
	OR, (95% CI)		0.94, (0.03, 26.63)		0.972	
	ARR %, (95% CI)		5.55, (-5.04, 16.14)		0.304	
Race		0.668				0.563
Black or African American	n / N(%)		5 / 50 (10.0)	5 / 28 (17.9)		
	RR, (95% CI)		0.56, (0.18, 1.77)		0.323	
	OR, (95% CI)		0.51, (0.13, 1.95)		0.325	
	ARR %, (95% CI)		-7.86, (-24.30, 8.59)		0.349	
White	n / N(%)		35 / 264 (13.3)	13 / 126 (10.3)		
	RR, (95% CI)		1.28, (0.71, 2.34)		0.413	
	OR, (95% CI)		1.33, (0.68, 2.61)		0.410	
	ARR %, (95% CI)		2.94, (-3.76, 9.64)		0.390	
Other	n / N(%)		2 / 28 (7.1)	1 / 15 (6.7)		
	RR, (95% CI)		1.07, (0.11, 10.87)		0.953	
	OR, (95% CI)		1.08, (0.09, 12.95)		0.953	
	ARR %, (95% CI)		0.48, (-15.35, 16.30)		0.953	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		0.358				0.317
Hispanic or Latino	n / N(%)		2 / 40 (5.0)	2 / 12 (16.7)		
	RR, (95% CI)		0.30, (0.05, 1.91)		0.202	
	OR, (95% CI)		0.26, (0.03, 2.11)		0.208	
	ARR %, (95% CI)		-11.67, (-33.81, 10.47)		0.302	
Not Hispanic or Latino	n / N(%)		37 / 275 (13.5)	16 / 144 (11.1)		
	RR, (95% CI)		1.21, (0.70, 2.10)		0.496	
	OR, (95% CI)		1.24, (0.67, 2.32)		0.494	
	ARR %, (95% CI)		2.34, (-4.18, 8.87)		0.482	
Other	n / N(%)		3 / 31 (9.7)	2 / 17 (11.8)		
	RR, (95% CI)		0.82, (0.15, 4.45)		0.821	
	OR, (95% CI)		0.80, (0.12, 5.35)		0.821	
	ARR %, (95% CI)		-2.09, (-20.60, 16.43)		0.825	
COVID-19 co-morbidities at baseline		0.944				0.944
None	n / N(%)		9 / 101 (8.9)	4 / 46 (8.7)		
	RR, (95% CI)		1.02, (0.33, 3.16)		0.966	
	OR, (95% CI)		1.03, (0.30, 3.52)		0.966	
	ARR %, (95% CI)		0.22, (-9.64, 10.07)		0.966	
At least one	n / N(%)		33 / 245 (13.5)	16 / 127 (12.6)		
	RR, (95% CI)		1.07, (0.61, 1.87)		0.814	
	OR, (95% CI)		1.08, (0.57, 2.05)		0.814	
	ARR %, (95% CI)		0.87, (-6.31, 8.05)		0.812	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		42 / 346 (12.1)	20 / 173 (11.6)		
	RR, (95% CI)		1.05, (0.64, 1.73)		0.848	
	OR, (95% CI)		1.06, (0.60, 1.86)		0.848	
	ARR %, (95% CI)		0.58, (-5.30, 6.46)		0.847	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.947				0.947
Yes	n / N(%)		37 / 303 (12.2)	18 / 154 (11.7)		
	RR, (95% CI)		1.04, (0.62, 1.77)		0.871	
	OR, (95% CI)		1.05, (0.58, 1.91)		0.871	
	ARR %, (95% CI)		0.52, (-5.75, 6.80)		0.870	
No	n / N(%)		5 / 43 (11.6)	2 / 19 (10.5)		
	RR, (95% CI)		1.10, (0.23, 5.20)		0.900	
	OR, (95% CI)		1.12, (0.20, 6.35)		0.899	
	ARR %, (95% CI)		1.10, (-15.70, 17.90)		0.898	
Obesity (≥ 30 kg/m^2)		0.773				0.772
Yes	n / N(%)		14 / 119 (11.8)	7 / 55 (12.7)		
	RR, (95% CI)		0.92, (0.40, 2.16)		0.856	
	OR, (95% CI)		0.91, (0.35, 2.41)		0.856	
	ARR %, (95% CI)		-0.96, (-11.50, 9.58)		0.858	
No	n / N(%)		27 / 225 (12.0)	13 / 117 (11.1)		
	RR, (95% CI)		1.08, (0.58, 2.01)		0.809	
	OR, (95% CI)		1.09, (0.54, 2.20)		0.808	
	ARR %, (95% CI)		0.89, (-6.21, 7.99)		0.806	
Obesity (≥ 40 kg/m^2)		0.720				0.719
Yes	n / N(%)		2 / 17 (11.8)	1 / 13 (7.7)		
	RR, (95% CI)		1.53, (0.15, 15.09)		0.716	
	OR, (95% CI)		1.60, (0.13, 19.84)		0.714	
	ARR %, (95% CI)		4.07, (-17.01, 25.15)		0.705	
No	n / N(%)		39 / 327 (11.9)	19 / 159 (11.9)		
	RR, (95% CI)		1.00, (0.60, 1.67)		0.994	
	OR, (95% CI)		1.00, (0.56, 1.79)		0.994	
	ARR %, (95% CI)		-0.02, (-6.17, 6.12)		0.994	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.731				0.731
Yes	n / N(%)		11 / 38 (28.9)	5 / 21 (23.8)		
	RR, (95% CI)		1.22, (0.49, 3.03)		0.675	
	OR, (95% CI)		1.30, (0.38, 4.44)		0.671	
	ARR %, (95% CI)		5.14, (-18.09, 28.37)		0.665	
No	n / N(%)		31 / 308 (10.1)	15 / 152 (9.9)		
	RR, (95% CI)		1.02, (0.57, 1.83)		0.947	
	OR, (95% CI)		1.02, (0.53, 1.96)		0.947	
	ARR %, (95% CI)		0.20, (-5.61, 6.01)		0.947	
Diabetes		0.824				0.824
Yes	n / N(%)		6 / 40 (15.0)	4 / 25 (16.0)		
	RR, (95% CI)		0.94, (0.29, 3.00)		0.913	
	OR, (95% CI)		0.93, (0.23, 3.67)		0.913	
	ARR %, (95% CI)		-1.00, (-19.14, 17.14)		0.914	
No	n / N(%)		36 / 306 (11.8)	16 / 148 (10.8)		
	RR, (95% CI)		1.09, (0.62, 1.90)		0.765	
	OR, (95% CI)		1.10, (0.59, 2.05)		0.765	
	ARR %, (95% CI)		0.95, (-5.22, 7.12)		0.762	
Immunosuppressive disease		0.481				0.475
Yes	n / N(%)		2 / 16 (12.5)	2 / 9 (22.2)		
	RR, (95% CI)		0.56, (0.09, 3.34)		0.527	
	OR, (95% CI)		0.50, (0.06, 4.33)		0.529	
	ARR %, (95% CI)		-9.72, (-41.35, 21.91)		0.547	
No	n / N(%)		40 / 330 (12.1)	18 / 164 (11.0)		
	RR, (95% CI)		1.10, (0.65, 1.86)		0.710	
	OR, (95% CI)		1.12, (0.62, 2.02)		0.710	
	ARR %, (95% CI)		1.15, (-4.79, 7.09)		0.705	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.617				0.617
Yes	n / N(%)		16 / 103 (15.5)	10 / 60 (16.7)		
	RR, (95% CI)		0.93, (0.45, 1.92)		0.849	
	OR, (95% CI)		0.92, (0.39, 2.18)		0.849	
	ARR %, (95% CI)		-1.13, (-12.87, 10.61)		0.850	
No	n / N(%)		26 / 243 (10.7)	10 / 113 (8.8)		
	RR, (95% CI)		1.21, (0.60, 2.42)		0.592	
	OR, (95% CI)		1.23, (0.57, 2.65)		0.590	
	ARR %, (95% CI)		1.85, (-4.67, 8.37)		0.578	
CV disease		0.224				0.214
Yes	n / N(%)		7 / 32 (21.9)	2 / 22 (9.1)		
	RR, (95% CI)		2.41, (0.55, 10.52)		0.243	
	OR, (95% CI)		2.80, (0.52, 14.99)		0.229	
	ARR %, (95% CI)		12.78, (-5.91, 31.48)		0.180	
No	n / N(%)		35 / 314 (11.1)	18 / 151 (11.9)		
	RR, (95% CI)		0.94, (0.55, 1.60)		0.805	
	OR, (95% CI)		0.93, (0.51, 1.70)		0.806	
	ARR %, (95% CI)		-0.77, (-7.01, 5.46)		0.808	
COPD		0.467				0.465
Yes	n / N(%)		6 / 23 (26.1)	4 / 11 (36.4)		
	RR, (95% CI)		0.72, (0.25, 2.03)		0.532	
	OR, (95% CI)		0.62, (0.13, 2.88)		0.540	
	ARR %, (95% CI)		-10.28, (-43.89, 23.34)		0.549	
No	n / N(%)		36 / 323 (11.1)	16 / 162 (9.9)		
	RR, (95% CI)		1.13, (0.65, 1.97)		0.671	
	OR, (95% CI)		1.14, (0.61, 2.13)		0.670	
	ARR %, (95% CI)		1.27, (-4.47, 7.00)		0.664	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.802				0.801
Yes	n / N(%)		8 / 44 (18.2)	5 / 26 (19.2)		
	RR, (95% CI)		0.95, (0.35, 2.59)		0.913	
	OR, (95% CI)		0.93, (0.27, 3.23)		0.913	
	ARR %, (95% CI)		-1.05, (-20.01, 17.91)		0.914	
No	n / N(%)		34 / 302 (11.3)	15 / 147 (10.2)		
	RR, (95% CI)		1.10, (0.62, 1.96)		0.737	
	OR, (95% CI)		1.12, (0.59, 2.12)		0.737	
	ARR %, (95% CI)		1.05, (-5.00, 7.11)		0.733	
Hypertension		0.915				0.915
Yes	n / N(%)		24 / 153 (15.7)	11 / 75 (14.7)		
	RR, (95% CI)		1.07, (0.55, 2.07)		0.841	
	OR, (95% CI)		1.08, (0.50, 2.35)		0.841	
	ARR %, (95% CI)		1.02, (-8.84, 10.88)		0.839	
No	n / N(%)		18 / 193 (9.3)	9 / 98 (9.2)		
	RR, (95% CI)		1.02, (0.47, 2.18)		0.968	
	OR, (95% CI)		1.02, (0.44, 2.36)		0.968	
	ARR %, (95% CI)		0.14, (-6.89, 7.18)		0.968	
Asthma		0.555				0.554
Yes	n / N(%)		8 / 55 (14.5)	4 / 21 (19.0)		
	RR, (95% CI)		0.76, (0.26, 2.27)		0.628	
	OR, (95% CI)		0.72, (0.19, 2.71)		0.631	
	ARR %, (95% CI)		-4.50, (-23.71, 14.70)		0.646	
No	n / N(%)		34 / 291 (11.7)	16 / 152 (10.5)		
	RR, (95% CI)		1.11, (0.63, 1.94)		0.715	
	OR, (95% CI)		1.12, (0.60, 2.11)		0.715	
	ARR %, (95% CI)		1.16, (-4.96, 7.28)		0.711	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.236				0.231
Yes	n / N(%)		14 / 60 (23.3)	4 / 30 (13.3)		
	RR, (95% CI)		1.75, (0.63, 4.86)		0.283	
	OR, (95% CI)		1.98, (0.59, 6.64)		0.269	
	ARR %, (95% CI)		10.00, (-6.20, 26.20)		0.226	
No	n / N(%)		28 / 286 (9.8)	16 / 143 (11.2)		
	RR, (95% CI)		0.88, (0.49, 1.56)		0.652	
	OR, (95% CI)		0.86, (0.45, 1.65)		0.653	
	ARR %, (95% CI)		-1.40, (-7.61, 4.81)		0.659	
Smoking		0.492				0.488
Yes	n / N(%)		4 / 63 (6.3)	3 / 31 (9.7)		
	RR, (95% CI)		0.66, (0.16, 2.75)		0.565	
	OR, (95% CI)		0.63, (0.13, 3.02)		0.566	
	ARR %, (95% CI)		-3.33, (-15.35, 8.70)		0.587	
No	n / N(%)		38 / 283 (13.4)	17 / 142 (12.0)		
	RR, (95% CI)		1.12, (0.66, 1.92)		0.674	
	OR, (95% CI)		1.14, (0.62, 2.10)		0.673	
	ARR %, (95% CI)		1.46, (-5.20, 8.11)		0.668	
Sickle cell disease		NE				NE
No	n / N(%)		42 / 346 (12.1)	20 / 173 (11.6)		
	RR, (95% CI)		1.05, (0.64, 1.73)		0.848	
	OR, (95% CI)		1.06, (0.60, 1.86)		0.848	
	ARR %, (95% CI)		0.58, (-5.30, 6.46)		0.847	
COVID-19 vaccination at any time during the study		0.199				0.195
Yes	n / N(%)		32 / 242 (13.2)	13 / 127 (10.2)		
	RR, (95% CI)		1.29, (0.70, 2.37)		0.409	
	OR, (95% CI)		1.34, (0.67, 2.65)		0.406	
	ARR %, (95% CI)		2.99, (-3.80, 9.77)		0.388	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		10 / 104 (9.6)	7 / 46 (15.2)		
	RR, (95% CI)		0.63, (0.26, 1.56)		0.318	
	OR, (95% CI)		0.59, (0.21, 1.67)		0.322	
	ARR %, (95% CI)		-5.60, (-17.43, 6.22)		0.353	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.11
Adverse Events Overview by Subgroup - Participants with at least One Severe AE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.978				0.590
Yes	n / N(%)		41 / 344 (11.9)	20 / 172 (11.6)		
	RR, (95% CI)		1.03, (0.62, 1.69)		0.923	
	OR, (95% CI)		1.03, (0.58, 1.82)		0.923	
	ARR %, (95% CI)		0.29, (-5.60, 6.18)		0.923	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	Age at randomization		0.030				0.029
	<60 years	n / N(%)		71 / 199 (35.7)	18 / 97 (18.6)		
		RR, (95% CI)		1.92, (1.22, 3.04)		0.005	
		OR, (95% CI)		2.43, (1.35, 4.38)		0.003	
		ARR %, (95% CI)		17.12, (6.92, 27.33)		0.001	
	≥60 years	n / N(%)		39 / 147 (26.5)	21 / 76 (27.6)		
		RR, (95% CI)		0.96, (0.61, 1.51)		0.860	
		OR, (95% CI)		0.95, (0.51, 1.76)		0.861	
		ARR %, (95% CI)		-1.10, (-13.43, 11.23)		0.861	
	Age at randomization		0.209				0.208
	<65 years	n / N(%)		82 / 262 (31.3)	27 / 137 (19.7)		
		RR, (95% CI)		1.59, (1.08, 2.33)		0.018	
		OR, (95% CI)		1.86, (1.13, 3.05)		0.014	
		ARR %, (95% CI)		11.59, (2.88, 20.30)		0.009	
	≥65 years	n / N(%)		28 / 84 (33.3)	12 / 36 (33.3)		
		RR, (95% CI)		1.00, (0.58, 1.74)		1.000	
		OR, (95% CI)		1.00, (0.44, 2.29)		1.000	
		ARR %, (95% CI)		0.00, (-18.41, 18.41)		1.000	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	Age at randomization		0.414				0.407
	<75 years	n / N(%)		105 / 330 (31.8)	37 / 168 (22.0)		
		RR, (95% CI)		1.44, (1.04, 2.00)		0.027	
		OR, (95% CI)		1.65, (1.07, 2.55)		0.023	
		ARR %, (95% CI)		9.79, (1.76, 17.83)		0.017	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

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Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	≥75 years	n / N(%)		5 / 16 (31.3)	2 / 5 (40.0)		
		RR, (95% CI)		0.78, (0.21, 2.86)		0.709	
		OR, (95% CI)		0.68, (0.09, 5.45)		0.718	
		ARR %, (95% CI)		-8.75, (-57.33, 39.83)		0.724	
	Residence in long-term care facility		NE				0.868
	No	n / N(%)		110 / 346 (31.8)	39 / 173 (22.5)		
		RR, (95% CI)		1.41, (1.03, 1.94)		0.033	
		OR, (95% CI)		1.60, (1.05, 2.44)		0.029	
		ARR %, (95% CI)		9.25, (1.32, 17.18)		0.022	
	Increased risk of exposure to infection with SARS-CoV-2		0.306				0.304
	Yes	n / N(%)		27 / 99 (27.3)	7 / 52 (13.5)		
		RR, (95% CI)		2.03, (0.95, 4.33)		0.069	
		OR, (95% CI)		2.41, (0.97, 5.99)		0.058	
		ARR %, (95% CI)		13.81, (1.04, 26.58)		0.034	
	No	n / N(%)		83 / 247 (33.6)	32 / 121 (26.4)		
		RR, (95% CI)		1.27, (0.90, 1.79)		0.174	
		OR, (95% CI)		1.41, (0.87, 2.28)		0.165	
		ARR %, (95% CI)		7.16, (-2.66, 16.98)		0.153	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	Sex		0.831				0.831
	Male	n / N(%)		59 / 216 (27.3)	19 / 105 (18.1)		
		RR, (95% CI)		1.51, (0.95, 2.39)		0.080	
		OR, (95% CI)		1.70, (0.95, 3.04)		0.073	
		ARR %, (95% CI)		9.22, (-0.24, 18.68)		0.056	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	Female	n / N(%)		51 / 130 (39.2)	20 / 68 (29.4)		
		RR, (95% CI)		1.33, (0.87, 2.04)		0.185	
		OR, (95% CI)		1.55, (0.83, 2.91)		0.173	
		ARR %, (95% CI)		9.82, (-3.88, 23.52)		0.160	
	Region		0.955				0.955
	North America	n / N(%)		44 / 185 (23.8)	19 / 106 (17.9)		
		RR, (95% CI)		1.33, (0.82, 2.15)		0.250	
		OR, (95% CI)		1.43, (0.78, 2.61)		0.244	
		ARR %, (95% CI)		5.86, (-3.68, 15.40)		0.229	
	United Kingdom	n / N(%)		33 / 80 (41.3)	9 / 30 (30.0)		
		RR, (95% CI)		1.38, (0.75, 2.52)		0.303	
		OR, (95% CI)		1.64, (0.67, 4.02)		0.282	
		ARR %, (95% CI)		11.25, (-8.38, 30.88)		0.261	
	European Union	n / N(%)		33 / 81 (40.7)	11 / 37 (29.7)		
		RR, (95% CI)		1.37, (0.78, 2.40)		0.271	
		OR, (95% CI)		1.63, (0.71, 3.74)		0.253	
		ARR %, (95% CI)		11.01, (-7.19, 29.22)		0.236	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	Country		0.977				0.968
	United States	n / N(%)		44 / 185 (23.8)	19 / 106 (17.9)		
		RR, (95% CI)		1.33, (0.82, 2.15)		0.250	
		OR, (95% CI)		1.43, (0.78, 2.61)		0.244	
		ARR %, (95% CI)		5.86, (-3.68, 15.40)		0.229	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

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Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	United Kingdom	n / N(%)		33 / 80 (41.3)	9 / 30 (30.0)		
		RR, (95% CI)		1.38, (0.75, 2.52)		0.303	
		OR, (95% CI)		1.64, (0.67, 4.02)		0.282	
		ARR %, (95% CI)		11.25, (-8.38, 30.88)		0.261	
	Belgium	n / N(%)		11 / 25 (44.0)	6 / 16 (37.5)		
		RR, (95% CI)		1.17, (0.54, 2.54)		0.685	
		OR, (95% CI)		1.31, (0.36, 4.73)		0.681	
		ARR %, (95% CI)		6.50, (-24.18, 37.18)		0.678	
	France	n / N(%)		19 / 38 (50.0)	5 / 16 (31.3)		
		RR, (95% CI)		1.60, (0.72, 3.54)		0.246	
		OR, (95% CI)		2.20, (0.64, 7.55)		0.210	
		ARR %, (95% CI)		18.75, (-8.97, 46.47)		0.185	
	Spain	n / N(%)		3 / 18 (16.7)	0 / 5 (0.0)		
		RR, (95% CI)		2.21, (0.13, 36.99)		0.581	
		OR, (95% CI)		2.48, (0.11, 56.18)		0.567	
		ARR %, (95% CI)		16.67, (-0.56, 33.89)		0.058	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

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Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

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(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	Race		0.040				0.025
	Black or African American	n / N(%)		4 / 50 (8.0)	6 / 28 (21.4)		
		RR, (95% CI)		0.37, (0.12, 1.21)		0.101	
		OR, (95% CI)		0.32, (0.08, 1.25)		0.100	
		ARR %, (95% CI)		-13.43, (-30.39, 3.53)		0.121	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

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Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

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-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	White	n / N(%)		96 / 264 (36.4)	28 / 126 (22.2)		
		RR, (95% CI)		1.64, (1.14, 2.35)		0.008	
		OR, (95% CI)		2.00, (1.23, 3.26)		0.005	
		ARR %, (95% CI)		14.14, (4.85, 23.43)		0.003	
	Other	n / N(%)		8 / 28 (28.6)	2 / 15 (13.3)		
		RR, (95% CI)		2.14, (0.52, 8.84)		0.292	
		OR, (95% CI)		2.60, (0.48, 14.23)		0.270	
		ARR %, (95% CI)		15.24, (-8.76, 39.24)		0.213	
	Ethnicity		0.667				0.662
	Hispanic or Latino	n / N(%)		9 / 40 (22.5)	3 / 12 (25.0)		
		RR, (95% CI)		0.90, (0.29, 2.80)		0.856	
		OR, (95% CI)		0.87, (0.19, 3.91)		0.857	
		ARR %, (95% CI)		-2.50, (-30.21, 25.21)		0.860	
	Not Hispanic or Latino	n / N(%)		94 / 275 (34.2)	33 / 144 (22.9)		
		RR, (95% CI)		1.49, (1.06, 2.10)		0.022	
		OR, (95% CI)		1.75, (1.10, 2.77)		0.018	
		ARR %, (95% CI)		11.27, (2.40, 20.13)		0.013	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	Other	n / N(%)		7 / 31 (22.6)	3 / 17 (17.6)		
		RR, (95% CI)		1.28, (0.38, 4.32)		0.691	
		OR, (95% CI)		1.36, (0.30, 6.13)		0.688	
		ARR %, (95% CI)		4.93, (-18.41, 28.28)		0.679	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
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-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	COVID-19 co-morbidities at baseline		0.971				0.971
	None	n / N(%)		26 / 101 (25.7)	8 / 46 (17.4)		
		RR, (95% CI)		1.48, (0.73, 3.02)		0.280	
		OR, (95% CI)		1.65, (0.68, 3.98)		0.268	
		ARR %, (95% CI)		8.35, (-5.53, 22.23)		0.238	
	At least one	n / N(%)		84 / 245 (34.3)	31 / 127 (24.4)		
		RR, (95% CI)		1.40, (0.99, 2.00)		0.058	
		OR, (95% CI)		1.62, (1.00, 2.62)		0.052	
		ARR %, (95% CI)		9.88, (0.33, 19.42)		0.043	
	SARS-CoV-2 RT-PCR status at baseline		NE				0.868
	Negative/Missing	n / N(%)		110 / 346 (31.8)	39 / 173 (22.5)		
		RR, (95% CI)		1.41, (1.03, 1.94)		0.033	
		OR, (95% CI)		1.60, (1.05, 2.44)		0.029	
		ARR %, (95% CI)		9.25, (1.32, 17.18)		0.022	
	High risk for severe COVID-19 at baseline		0.157				0.128
	Yes	n / N(%)		98 / 303 (32.3)	38 / 154 (24.7)		
		RR, (95% CI)		1.31, (0.95, 1.81)		0.098	
		OR, (95% CI)		1.46, (0.94, 2.26)		0.091	
		ARR %, (95% CI)		7.67, (-0.94, 16.28)		0.081	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

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Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	No	n / N(%)		12 / 43 (27.9)	1 / 19 (5.3)		
		RR, (95% CI)		5.30, (0.74, 37.92)		0.097	
		OR, (95% CI)		6.97, (0.84, 58.11)		0.073	
		ARR %, (95% CI)		22.64, (5.89, 39.39)		0.008	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	Obesity (≥ 30 kg/m^2)		0.528				0.528
	Yes	n / N(%)		44 / 119 (37.0)	13 / 55 (23.6)		
		RR, (95% CI)		1.56, (0.92, 2.66)		0.098	
		OR, (95% CI)		1.90, (0.92, 3.91)		0.084	
		ARR %, (95% CI)		13.34, (-0.85, 27.53)		0.065	
	No	n / N(%)		65 / 225 (28.9)	26 / 117 (22.2)		
		RR, (95% CI)		1.30, (0.87, 1.93)		0.194	
		OR, (95% CI)		1.42, (0.84, 2.40)		0.187	
		ARR %, (95% CI)		6.67, (-2.92, 16.25)		0.173	
	Obesity (≥ 40 kg/m^2)		0.122				0.111
	Yes	n / N(%)		9 / 17 (52.9)	2 / 13 (15.4)		
		RR, (95% CI)		3.44, (0.89, 13.29)		0.073	
		OR, (95% CI)		6.19, (1.04, 36.78)		0.045	
		ARR %, (95% CI)		37.56, (6.77, 68.34)		0.017	
	No	n / N(%)		100 / 327 (30.6)	37 / 159 (23.3)		
		RR, (95% CI)		1.31, (0.95, 1.82)		0.101	
		OR, (95% CI)		1.45, (0.94, 2.25)		0.094	
		ARR %, (95% CI)		7.31, (-0.94, 15.56)		0.082	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

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Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	Chronic kidney disease		0.889				0.889
	Yes	n / N(%)		12 / 38 (31.6)	5 / 21 (23.8)		
		RR, (95% CI)		1.33, (0.54, 3.25)		0.537	
		OR, (95% CI)		1.48, (0.44, 4.98)		0.529	
		ARR %, (95% CI)		7.77, (-15.69, 31.23)		0.516	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

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Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	No	n / N(%)		98 / 308 (31.8)	34 / 152 (22.4)		
		RR, (95% CI)		1.42, (1.01, 2.00)		0.041	
		OR, (95% CI)		1.62, (1.03, 2.54)		0.036	
		ARR %, (95% CI)		9.45, (1.03, 17.87)		0.028	
	Diabetes		0.212				0.210
	Yes	n / N(%)		15 / 40 (37.5)	10 / 25 (40.0)		
		RR, (95% CI)		0.94, (0.50, 1.75)		0.840	
		OR, (95% CI)		0.90, (0.32, 2.51)		0.840	
		ARR %, (95% CI)		-2.50, (-26.87, 21.87)		0.841	
	No	n / N(%)		95 / 306 (31.0)	29 / 148 (19.6)		
		RR, (95% CI)		1.58, (1.10, 2.29)		0.014	
		OR, (95% CI)		1.85, (1.15, 2.96)		0.011	
		ARR %, (95% CI)		11.45, (3.22, 19.68)		0.006	
	Immunosuppressive disease		0.532				0.531
	Yes	n / N(%)		7 / 16 (43.8)	4 / 9 (44.4)		
		RR, (95% CI)		0.98, (0.39, 2.46)		0.973	
		OR, (95% CI)		0.97, (0.19, 5.03)		0.973	
		ARR %, (95% CI)		-0.69, (-41.25, 39.86)		0.973	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

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Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

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-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	No	n / N(%)		103 / 330 (31.2)	35 / 164 (21.3)		
		RR, (95% CI)		1.46, (1.05, 2.04)		0.026	
		OR, (95% CI)		1.67, (1.08, 2.60)		0.022	
		ARR %, (95% CI)		9.87, (1.85, 17.89)		0.016	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

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[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

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-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	Immunosuppressive treatment		0.742				0.742
	Yes	n / N(%)		36 / 103 (35.0)	16 / 60 (26.7)		
		RR, (95% CI)		1.31, (0.80, 2.15)		0.285	
		OR, (95% CI)		1.48, (0.73, 2.98)		0.275	
		ARR %, (95% CI)		8.28, (-6.21, 22.78)		0.262	
	No	n / N(%)		74 / 243 (30.5)	23 / 113 (20.4)		
		RR, (95% CI)		1.50, (0.99, 2.26)		0.055	
		OR, (95% CI)		1.71, (1.01, 2.92)		0.048	
		ARR %, (95% CI)		10.10, (0.69, 19.51)		0.035	
	CV disease		0.287				0.285
	Yes	n / N(%)		11 / 32 (34.4)	8 / 22 (36.4)		
		RR, (95% CI)		0.95, (0.45, 1.96)		0.880	
		OR, (95% CI)		0.92, (0.29, 2.85)		0.880	
		ARR %, (95% CI)		-1.99, (-27.97, 23.99)		0.881	
	No	n / N(%)		99 / 314 (31.5)	31 / 151 (20.5)		
		RR, (95% CI)		1.54, (1.08, 2.19)		0.017	
		OR, (95% CI)		1.78, (1.12, 2.83)		0.014	
		ARR %, (95% CI)		11.00, (2.76, 19.24)		0.009	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

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Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

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-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	COPD		0.434				0.432
	Yes	n / N(%)		10 / 23 (43.5)	5 / 11 (45.5)		
		RR, (95% CI)		0.96, (0.43, 2.12)		0.913	
		OR, (95% CI)		0.92, (0.22, 3.92)		0.914	
		ARR %, (95% CI)		-1.98, (-37.70, 33.75)		0.914	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	No	n / N(%)		100 / 323 (31.0)	34 / 162 (21.0)		
		RR, (95% CI)		1.48, (1.05, 2.07)		0.025	
		OR, (95% CI)		1.69, (1.08, 2.64)		0.021	
		ARR %, (95% CI)		9.97, (1.93, 18.02)		0.015	
	Chronic liver disease		0.786				0.786
	Yes	n / N(%)		15 / 44 (34.1)	7 / 26 (26.9)		
		RR, (95% CI)		1.27, (0.60, 2.69)		0.540	
		OR, (95% CI)		1.40, (0.48, 4.08)		0.533	
		ARR %, (95% CI)		7.17, (-14.90, 29.23)		0.524	
	No	n / N(%)		95 / 302 (31.5)	32 / 147 (21.8)		
		RR, (95% CI)		1.45, (1.02, 2.05)		0.039	
		OR, (95% CI)		1.65, (1.04, 2.62)		0.033	
		ARR %, (95% CI)		9.69, (1.21, 18.17)		0.025	
	Hypertension		0.180				0.179
	Yes	n / N(%)		48 / 153 (31.4)	21 / 75 (28.0)		
		RR, (95% CI)		1.12, (0.73, 1.73)		0.606	
		OR, (95% CI)		1.18, (0.64, 2.16)		0.603	
		ARR %, (95% CI)		3.37, (-9.17, 15.92)		0.598	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	No	n / N(%)		62 / 193 (32.1)	18 / 98 (18.4)		
		RR, (95% CI)		1.75, (1.10, 2.78)		0.018	
		OR, (95% CI)		2.10, (1.16, 3.81)		0.014	
		ARR %, (95% CI)		13.76, (3.65, 23.87)		0.008	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	Asthma		0.682				0.682
	Yes	n / N(%)		21 / 55 (38.2)	5 / 21 (23.8)		
		RR, (95% CI)		1.60, (0.70, 3.70)		0.268	
		OR, (95% CI)		1.98, (0.63, 6.19)		0.242	
		ARR %, (95% CI)		14.37, (-7.91, 36.66)		0.206	
	No	n / N(%)		89 / 291 (30.6)	34 / 152 (22.4)		
		RR, (95% CI)		1.37, (0.97, 1.93)		0.074	
		OR, (95% CI)		1.53, (0.97, 2.41)		0.068	
		ARR %, (95% CI)		8.22, (-0.26, 16.70)		0.058	
	Cancer		0.538				0.537
	Yes	n / N(%)		21 / 60 (35.0)	6 / 30 (20.0)		
		RR, (95% CI)		1.75, (0.79, 3.87)		0.167	
		OR, (95% CI)		2.15, (0.76, 6.09)		0.148	
		ARR %, (95% CI)		15.00, (-3.72, 33.72)		0.116	
	No	n / N(%)		89 / 286 (31.1)	33 / 143 (23.1)		
		RR, (95% CI)		1.35, (0.95, 1.90)		0.090	
		OR, (95% CI)		1.51, (0.95, 2.39)		0.083	
		ARR %, (95% CI)		8.04, (-0.70, 16.79)		0.071	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	Smoking		0.218				0.211
	Yes	n / N(%)		17 / 63 (27.0)	3 / 31 (9.7)		
		RR, (95% CI)		2.79, (0.88, 8.80)		0.080	
		OR, (95% CI)		3.45, (0.93, 12.84)		0.065	
		ARR %, (95% CI)		17.31, (2.19, 32.42)		0.025	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
General disorders and administration site conditions	No	n / N(%)		93 / 283 (32.9)	36 / 142 (25.4)		
		RR, (95% CI)		1.30, (0.93, 1.80)		0.121	
		OR, (95% CI)		1.44, (0.92, 2.27)		0.113	
		ARR %, (95% CI)		7.51, (-1.50, 16.52)		0.102	
	Sickle cell disease		NE				0.868
	No	n / N(%)		110 / 346 (31.8)	39 / 173 (22.5)		
		RR, (95% CI)		1.41, (1.03, 1.94)		0.033	
		OR, (95% CI)		1.60, (1.05, 2.44)		0.029	
		ARR %, (95% CI)		9.25, (1.32, 17.18)		0.022	
	COVID-19 vaccination at any time during the study		0.388				0.387
	Yes	n / N(%)		95 / 242 (39.3)	33 / 127 (26.0)		
		RR, (95% CI)		1.51, (1.08, 2.11)		0.015	
		OR, (95% CI)		1.84, (1.15, 2.95)		0.011	
		ARR %, (95% CI)		13.27, (3.47, 23.07)		0.008	
	No	n / N(%)		15 / 104 (14.4)	6 / 46 (13.0)		
		RR, (95% CI)		1.11, (0.46, 2.67)		0.823	
		OR, (95% CI)		1.12, (0.41, 3.11)		0.822	
		ARR %, (95% CI)		1.38, (-10.47, 13.22)		0.819	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.14
Adverse Events by System Organ Class and Preferred Term - by Subgroup
-- For AEs occurring in at least 10 patients AND in at least 1% of patients in one of the study arms
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

System Organ Class Preferred Term	Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
	Increased risk for inadequate response to active immunization		0.998				0.657
	Yes	n / N(%)		110 / 344 (32.0)	39 / 172 (22.7)		
		RR, (95% CI)		1.41, (1.03, 1.93)		0.033	
		OR, (95% CI)		1.60, (1.05, 2.45)		0.029	
		ARR %, (95% CI)		9.30, (1.34, 17.27)		0.022	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; MedDRA = Medical Dictionary for Regulatory Activities; NE = Not Evaluable; OR = Odds Ratio; PT = Preferred Term; RR = Relative Risk; SOC = System Organ Class.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: AEs are coded using the MedDRA dictionary, version 24.0.

Note: AEs are sorted alphabetically by SOC, and within each SOC, PTs are sorted by decreasing order of total frequency. Only AEs achieving statistical significance for the RR, OR or ARR in the overall AE analysis by SOC and PT are reported.

Note: Participants with more than one event within a SOC or PT are counted only once for that SOC or PT.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.244				0.244
<60 years	n / N(%)		141 / 199 (70.9)	56 / 97 (57.7)		
	RR, (95% CI)		1.23, (1.01, 1.49)		0.037	
	OR, (95% CI)		1.78, (1.07, 2.95)		0.025	
	ARR %, (95% CI)		13.12, (1.44, 24.81)		0.028	
≥60 years	n / N(%)		104 / 147 (70.7)	52 / 76 (68.4)		
	RR, (95% CI)		1.03, (0.86, 1.24)		0.723	
	OR, (95% CI)		1.12, (0.61, 2.03)		0.719	
	ARR %, (95% CI)		2.33, (-10.45, 15.11)		0.721	
Age at randomization		0.824				0.824
<65 years	n / N(%)		180 / 262 (68.7)	82 / 137 (59.9)		
	RR, (95% CI)		1.15, (0.98, 1.35)		0.091	
	OR, (95% CI)		1.47, (0.96, 2.26)		0.078	
	ARR %, (95% CI)		8.85, (-1.10, 18.79)		0.081	
≥65 years	n / N(%)		65 / 84 (77.4)	26 / 36 (72.2)		
	RR, (95% CI)		1.07, (0.85, 1.35)		0.562	
	OR, (95% CI)		1.32, (0.54, 3.21)		0.546	
	ARR %, (95% CI)		5.16, (-11.99, 22.31)		0.555	
Age at randomization		0.090				0.071
<75 years	n / N(%)		231 / 330 (70.0)	106 / 168 (63.1)		
	RR, (95% CI)		1.11, (0.97, 1.27)		0.133	
	OR, (95% CI)		1.36, (0.92, 2.02)		0.120	
	ARR %, (95% CI)		6.90, (-1.91, 15.72)		0.125	
≥75 years	n / N(%)		14 / 16 (87.5)	2 / 5 (40.0)		
	RR, (95% CI)		2.19, (0.74, 6.50)		0.159	
	OR, (95% CI)		10.50, (1.03, 107.17)		0.047	
	ARR %, (95% CI)		47.50, (1.60, 93.40)		0.043	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		245 / 346 (70.8)	108 / 173 (62.4)		
	RR, (95% CI)		1.13, (0.99, 1.30)		0.065	
	OR, (95% CI)		1.46, (0.99, 2.15)		0.054	
	ARR %, (95% CI)		8.38, (-0.28, 17.04)		0.058	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.814				0.814
Yes	n / N(%)		53 / 99 (53.5)	22 / 52 (42.3)		
	RR, (95% CI)		1.27, (0.88, 1.83)		0.208	
	OR, (95% CI)		1.57, (0.80, 3.09)		0.191	
	ARR %, (95% CI)		11.23, (-5.41, 27.87)		0.186	
No	n / N(%)		192 / 247 (77.7)	86 / 121 (71.1)		
	RR, (95% CI)		1.09, (0.96, 1.25)		0.183	
	OR, (95% CI)		1.42, (0.87, 2.33)		0.164	
	ARR %, (95% CI)		6.66, (-2.94, 16.26)		0.174	
Sex		0.196				0.195
Male	n / N(%)		145 / 216 (67.1)	56 / 105 (53.3)		
	RR, (95% CI)		1.26, (1.03, 1.54)		0.025	
	OR, (95% CI)		1.79, (1.11, 2.88)		0.017	
	ARR %, (95% CI)		13.80, (2.38, 25.21)		0.018	
Female	n / N(%)		100 / 130 (76.9)	52 / 68 (76.5)		
	RR, (95% CI)		1.01, (0.86, 1.18)		0.943	
	OR, (95% CI)		1.03, (0.51, 2.05)		0.943	
	ARR %, (95% CI)		0.45, (-11.96, 12.87)		0.943	
Region		0.621				0.620
North America	n / N(%)		106 / 185 (57.3)	56 / 106 (52.8)		
	RR, (95% CI)		1.08, (0.87, 1.35)		0.467	
	OR, (95% CI)		1.20, (0.74, 1.94)		0.461	
	ARR %, (95% CI)		4.47, (-7.41, 16.35)		0.461	
United Kingdom	n / N(%)		68 / 80 (85.0)	23 / 30 (76.7)		
	RR, (95% CI)		1.11, (0.89, 1.38)		0.353	
	OR, (95% CI)		1.72, (0.61, 4.90)		0.307	
	ARR %, (95% CI)		8.33, (-8.70, 25.37)		0.338	
European Union	n / N(%)		71 / 81 (87.7)	29 / 37 (78.4)		
	RR, (95% CI)		1.12, (0.93, 1.35)		0.243	
	OR, (95% CI)		1.96, (0.70, 5.46)		0.199	
	ARR %, (95% CI)		9.28, (-5.80, 24.35)		0.228	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		0.806				0.800
United States	n / N(%)		106 / 185 (57.3)	56 / 106 (52.8)		
	RR, (95% CI)		1.08, (0.87, 1.35)		0.467	
	OR, (95% CI)		1.20, (0.74, 1.94)		0.461	
	ARR %, (95% CI)		4.47, (-7.41, 16.35)		0.461	
United Kingdom	n / N(%)		68 / 80 (85.0)	23 / 30 (76.7)		
	RR, (95% CI)		1.11, (0.89, 1.38)		0.353	
	OR, (95% CI)		1.72, (0.61, 4.90)		0.307	
	ARR %, (95% CI)		8.33, (-8.70, 25.37)		0.338	
Belgium	n / N(%)		22 / 25 (88.0)	12 / 16 (75.0)		
	RR, (95% CI)		1.17, (0.85, 1.61)		0.324	
	OR, (95% CI)		2.44, (0.47, 12.78)		0.290	
	ARR %, (95% CI)		13.00, (-11.75, 37.75)		0.303	
France	n / N(%)		34 / 38 (89.5)	14 / 16 (87.5)		
	RR, (95% CI)		1.02, (0.82, 1.27)		0.839	
	OR, (95% CI)		1.21, (0.20, 7.40)		0.833	
	ARR %, (95% CI)		1.97, (-16.94, 20.89)		0.838	
Spain	n / N(%)		15 / 18 (83.3)	3 / 5 (60.0)		
	RR, (95% CI)		1.39, (0.66, 2.93)		0.387	
	OR, (95% CI)		3.33, (0.38, 29.39)		0.278	
	ARR %, (95% CI)		23.33, (-22.93, 69.60)		0.323	
Race		0.649				0.647
Black or African American	n / N(%)		23 / 50 (46.0)	13 / 28 (46.4)		
	RR, (95% CI)		0.99, (0.60, 1.63)		0.971	
	OR, (95% CI)		0.98, (0.39, 2.49)		0.971	
	ARR %, (95% CI)		-0.43, (-23.50, 22.64)		0.971	
White	n / N(%)		204 / 264 (77.3)	84 / 126 (66.7)		
	RR, (95% CI)		1.16, (1.01, 1.33)		0.038	
	OR, (95% CI)		1.70, (1.06, 2.72)		0.027	
	ARR %, (95% CI)		10.61, (0.95, 20.27)		0.031	
Other	n / N(%)		15 / 28 (53.6)	8 / 15 (53.3)		
	RR, (95% CI)		1.00, (0.56, 1.80)		0.988	
	OR, (95% CI)		1.01, (0.29, 3.55)		0.988	
	ARR %, (95% CI)		0.24, (-31.05, 31.52)		0.988	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		0.529				0.525
Hispanic or Latino	n / N(%)		28 / 40 (70.0)	9 / 12 (75.0)		
	RR, (95% CI)		0.93, (0.64, 1.37)		0.725	
	OR, (95% CI)		0.78, (0.18, 3.39)		0.738	
	ARR %, (95% CI)		-5.00, (-33.32, 23.32)		0.729	
Not Hispanic or Latino	n / N(%)		197 / 275 (71.6)	88 / 144 (61.1)		
	RR, (95% CI)		1.17, (1.01, 1.36)		0.038	
	OR, (95% CI)		1.61, (1.05, 2.46)		0.029	
	ARR %, (95% CI)		10.53, (0.94, 20.11)		0.031	
Other	n / N(%)		20 / 31 (64.5)	11 / 17 (64.7)		
	RR, (95% CI)		1.00, (0.64, 1.54)		0.990	
	OR, (95% CI)		0.99, (0.29, 3.42)		0.990	
	ARR %, (95% CI)		-0.19, (-28.47, 28.09)		0.990	
COVID-19 co-morbidities at baseline		0.280				0.279
None	n / N(%)		61 / 101 (60.4)	27 / 46 (58.7)		
	RR, (95% CI)		1.03, (0.77, 1.37)		0.847	
	OR, (95% CI)		1.07, (0.53, 2.18)		0.845	
	ARR %, (95% CI)		1.70, (-15.43, 18.83)		0.846	
At least one	n / N(%)		184 / 245 (75.1)	81 / 127 (63.8)		
	RR, (95% CI)		1.18, (1.01, 1.37)		0.032	
	OR, (95% CI)		1.71, (1.08, 2.72)		0.023	
	ARR %, (95% CI)		11.32, (1.36, 21.28)		0.026	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		245 / 346 (70.8)	108 / 173 (62.4)		
	RR, (95% CI)		1.13, (0.99, 1.30)		0.065	
	OR, (95% CI)		1.46, (0.99, 2.15)		0.054	
	ARR %, (95% CI)		8.38, (-0.28, 17.04)		0.058	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.746				0.746
Yes	n / N(%)		220 / 303 (72.6)	98 / 154 (63.6)		
	RR, (95% CI)		1.14, (0.99, 1.31)		0.061	
	OR, (95% CI)		1.51, (1.00, 2.29)		0.049	
	ARR %, (95% CI)		8.97, (-0.14, 18.08)		0.054	
No	n / N(%)		25 / 43 (58.1)	10 / 19 (52.6)		
	RR, (95% CI)		1.10, (0.67, 1.81)		0.694	
	OR, (95% CI)		1.25, (0.42, 3.70)		0.687	
	ARR %, (95% CI)		5.51, (-21.35, 32.37)		0.688	
Obesity (≥ 30 kg/m^2)		0.079				0.078
Yes	n / N(%)		88 / 119 (73.9)	30 / 55 (54.5)		
	RR, (95% CI)		1.36, (1.04, 1.76)		0.024	
	OR, (95% CI)		2.37, (1.21, 4.62)		0.012	
	ARR %, (95% CI)		19.40, (4.06, 34.75)		0.013	
No	n / N(%)		156 / 225 (69.3)	78 / 117 (66.7)		
	RR, (95% CI)		1.04, (0.89, 1.21)		0.620	
	OR, (95% CI)		1.13, (0.70, 1.82)		0.615	
	ARR %, (95% CI)		2.67, (-7.79, 13.12)		0.617	
Obesity (≥ 40 kg/m^2)		0.385				0.378
Yes	n / N(%)		15 / 17 (88.2)	9 / 13 (69.2)		
	RR, (95% CI)		1.27, (0.85, 1.90)		0.237	
	OR, (95% CI)		3.33, (0.50, 22.02)		0.211	
	ARR %, (95% CI)		19.00, (-10.39, 48.40)		0.205	
No	n / N(%)		229 / 327 (70.0)	99 / 159 (62.3)		
	RR, (95% CI)		1.12, (0.98, 1.29)		0.100	
	OR, (95% CI)		1.42, (0.95, 2.11)		0.087	
	ARR %, (95% CI)		7.77, (-1.26, 16.79)		0.092	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.360				0.358
Yes	n / N(%)		29 / 38 (76.3)	12 / 21 (57.1)		
	RR, (95% CI)		1.34, (0.89, 2.01)		0.167	
	OR, (95% CI)		2.42, (0.77, 7.58)		0.130	
	ARR %, (95% CI)		19.17, (-5.94, 44.29)		0.135	
No	n / N(%)		216 / 308 (70.1)	96 / 152 (63.2)		
	RR, (95% CI)		1.11, (0.96, 1.28)		0.147	
	OR, (95% CI)		1.37, (0.91, 2.06)		0.133	
	ARR %, (95% CI)		6.97, (-2.24, 16.19)		0.138	
Diabetes		0.664				0.664
Yes	n / N(%)		30 / 40 (75.0)	18 / 25 (72.0)		
	RR, (95% CI)		1.04, (0.77, 1.41)		0.792	
	OR, (95% CI)		1.17, (0.38, 3.61)		0.789	
	ARR %, (95% CI)		3.00, (-19.13, 25.13)		0.790	
No	n / N(%)		215 / 306 (70.3)	90 / 148 (60.8)		
	RR, (95% CI)		1.16, (1.00, 1.34)		0.057	
	OR, (95% CI)		1.52, (1.01, 2.30)		0.045	
	ARR %, (95% CI)		9.45, (0.07, 18.84)		0.048	
Immunosuppressive disease		0.969				0.155
Yes	n / N(%)		16 / 16 (100.0)	7 / 9 (77.8)		
	RR, (95% CI)		1.29, (0.90, 1.87)		0.169	
	OR, (95% CI)		11.00, (0.47, 258.41)		0.137	
	ARR %, (95% CI)		22.22, (-4.94, 49.38)		0.109	
No	n / N(%)		229 / 330 (69.4)	101 / 164 (61.6)		
	RR, (95% CI)		1.13, (0.98, 1.30)		0.096	
	OR, (95% CI)		1.41, (0.96, 2.09)		0.083	
	ARR %, (95% CI)		7.81, (-1.14, 16.76)		0.087	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.741				0.740
Yes	n / N(%)		79 / 103 (76.7)	40 / 60 (66.7)		
	RR, (95% CI)		1.15, (0.93, 1.42)		0.187	
	OR, (95% CI)		1.65, (0.81, 3.33)		0.166	
	ARR %, (95% CI)		10.03, (-4.42, 24.49)		0.174	
No	n / N(%)		166 / 243 (68.3)	68 / 113 (60.2)		
	RR, (95% CI)		1.14, (0.96, 1.35)		0.150	
	OR, (95% CI)		1.43, (0.90, 2.27)		0.133	
	ARR %, (95% CI)		8.14, (-2.62, 18.89)		0.138	
CV disease		0.614				0.614
Yes	n / N(%)		26 / 32 (81.3)	15 / 22 (68.2)		
	RR, (95% CI)		1.19, (0.86, 1.66)		0.298	
	OR, (95% CI)		2.02, (0.57, 7.14)		0.274	
	ARR %, (95% CI)		13.07, (-10.63, 36.77)		0.280	
No	n / N(%)		219 / 314 (69.7)	93 / 151 (61.6)		
	RR, (95% CI)		1.13, (0.98, 1.31)		0.094	
	OR, (95% CI)		1.44, (0.96, 2.16)		0.080	
	ARR %, (95% CI)		8.16, (-1.12, 17.43)		0.085	
COPD		0.974				0.119
Yes	n / N(%)		19 / 23 (82.6)	11 / 11 (100.0)		
	RR, (95% CI)		0.85, (0.68, 1.06)		0.151	
	OR, (95% CI)		0.19, (0.01, 3.83)		0.277	
	ARR %, (95% CI)		-17.39, (-32.88, -1.90)		0.028	
No	n / N(%)		226 / 323 (70.0)	97 / 162 (59.9)		
	RR, (95% CI)		1.17, (1.01, 1.35)		0.035	
	OR, (95% CI)		1.56, (1.05, 2.32)		0.027	
	ARR %, (95% CI)		10.09, (1.04, 19.15)		0.029	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

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[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.151				0.146
Yes	n / N(%)		38 / 44 (86.4)	17 / 26 (65.4)		
	RR, (95% CI)		1.32, (0.98, 1.79)		0.072	
	OR, (95% CI)		3.35, (1.03, 10.92)		0.045	
	ARR %, (95% CI)		20.98, (0.07, 41.89)		0.049	
No	n / N(%)		207 / 302 (68.5)	91 / 147 (61.9)		
	RR, (95% CI)		1.11, (0.95, 1.28)		0.177	
	OR, (95% CI)		1.34, (0.89, 2.02)		0.163	
	ARR %, (95% CI)		6.64, (-2.80, 16.08)		0.168	
Hypertension		0.847				0.847
Yes	n / N(%)		110 / 153 (71.9)	47 / 75 (62.7)		
	RR, (95% CI)		1.15, (0.94, 1.40)		0.180	
	OR, (95% CI)		1.52, (0.85, 2.74)		0.159	
	ARR %, (95% CI)		9.23, (-3.83, 22.29)		0.166	
No	n / N(%)		135 / 193 (69.9)	61 / 98 (62.2)		
	RR, (95% CI)		1.12, (0.94, 1.35)		0.203	
	OR, (95% CI)		1.41, (0.85, 2.35)		0.186	
	ARR %, (95% CI)		7.70, (-3.87, 19.28)		0.192	
Asthma		0.418				0.416
Yes	n / N(%)		41 / 55 (74.5)	16 / 21 (76.2)		
	RR, (95% CI)		0.98, (0.74, 1.30)		0.881	
	OR, (95% CI)		0.92, (0.28, 2.96)		0.882	
	ARR %, (95% CI)		-1.65, (-23.19, 19.90)		0.881	
No	n / N(%)		204 / 291 (70.1)	92 / 152 (60.5)		
	RR, (95% CI)		1.16, (1.00, 1.34)		0.053	
	OR, (95% CI)		1.53, (1.01, 2.31)		0.043	
	ARR %, (95% CI)		9.58, (0.19, 18.96)		0.045	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.582				0.582
Yes	n / N(%)		49 / 60 (81.7)	21 / 30 (70.0)		
	RR, (95% CI)		1.17, (0.90, 1.52)		0.251	
	OR, (95% CI)		1.91, (0.69, 5.29)		0.213	
	ARR %, (95% CI)		11.67, (-7.43, 30.77)		0.231	
No	n / N(%)		196 / 286 (68.5)	87 / 143 (60.8)		
	RR, (95% CI)		1.13, (0.97, 1.31)		0.128	
	OR, (95% CI)		1.40, (0.92, 2.13)		0.114	
	ARR %, (95% CI)		7.69, (-1.95, 17.33)		0.118	
Smoking		0.805				0.805
Yes	n / N(%)		37 / 63 (58.7)	16 / 31 (51.6)		
	RR, (95% CI)		1.14, (0.76, 1.70)		0.525	
	OR, (95% CI)		1.33, (0.56, 3.17)		0.513	
	ARR %, (95% CI)		7.12, (-14.27, 28.50)		0.514	
No	n / N(%)		208 / 283 (73.5)	92 / 142 (64.8)		
	RR, (95% CI)		1.13, (0.99, 1.30)		0.077	
	OR, (95% CI)		1.51, (0.98, 2.33)		0.064	
	ARR %, (95% CI)		8.71, (-0.68, 18.10)		0.069	
Sickle cell disease		NE				NE
No	n / N(%)		245 / 346 (70.8)	108 / 173 (62.4)		
	RR, (95% CI)		1.13, (0.99, 1.30)		0.065	
	OR, (95% CI)		1.46, (0.99, 2.15)		0.054	
	ARR %, (95% CI)		8.38, (-0.28, 17.04)		0.058	
COVID-19 vaccination at any time during the study		0.088				0.087
Yes	n / N(%)		198 / 242 (81.8)	87 / 127 (68.5)		
	RR, (95% CI)		1.19, (1.05, 1.36)		0.008	
	OR, (95% CI)		2.07, (1.26, 3.40)		0.004	
	ARR %, (95% CI)		13.31, (3.89, 22.74)		0.006	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		47 / 104 (45.2)	21 / 46 (45.7)		
	RR, (95% CI)		0.99, (0.68, 1.45)		0.958	
	OR, (95% CI)		0.98, (0.49, 1.97)		0.958	
	ARR %, (95% CI)		-0.46, (-17.74, 16.82)		0.958	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.17
Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.999				0.954
Yes	n / N(%)		243 / 344 (70.6)	107 / 172 (62.2)		
	RR, (95% CI)		1.14, (0.99, 1.30)		0.065	
	OR, (95% CI)		1.46, (0.99, 2.15)		0.054	
	ARR %, (95% CI)		8.43, (-0.27, 17.13)		0.058	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.531				0.530
<60 years	n / N(%)		15 / 199 (7.5)	5 / 97 (5.2)		
	RR, (95% CI)		1.46, (0.55, 3.91)		0.448	
	OR, (95% CI)		1.50, (0.53, 4.25)		0.446	
	ARR %, (95% CI)		2.38, (-3.35, 8.11)		0.415	
≥60 years	n / N(%)		17 / 147 (11.6)	9 / 76 (11.8)		
	RR, (95% CI)		0.98, (0.46, 2.09)		0.951	
	OR, (95% CI)		0.97, (0.41, 2.30)		0.951	
	ARR %, (95% CI)		-0.28, (-9.19, 8.64)		0.951	
Age at randomization		0.373				0.371
<65 years	n / N(%)		21 / 262 (8.0)	8 / 137 (5.8)		
	RR, (95% CI)		1.37, (0.62, 3.02)		0.431	
	OR, (95% CI)		1.41, (0.61, 3.26)		0.429	
	ARR %, (95% CI)		2.18, (-2.95, 7.30)		0.405	
≥65 years	n / N(%)		11 / 84 (13.1)	6 / 36 (16.7)		
	RR, (95% CI)		0.79, (0.31, 1.96)		0.605	
	OR, (95% CI)		0.75, (0.26, 2.22)		0.608	
	ARR %, (95% CI)		-3.57, (-17.72, 10.58)		0.621	
Age at randomization		0.145				0.123
<75 years	n / N(%)		30 / 330 (9.1)	12 / 168 (7.1)		
	RR, (95% CI)		1.27, (0.67, 2.42)		0.462	
	OR, (95% CI)		1.30, (0.65, 2.61)		0.461	
	ARR %, (95% CI)		1.95, (-3.03, 6.93)		0.443	
≥75 years	n / N(%)		2 / 16 (12.5)	2 / 5 (40.0)		
	RR, (95% CI)		0.31, (0.06, 1.68)		0.176	
	OR, (95% CI)		0.21, (0.02, 2.19)		0.194	
	ARR %, (95% CI)		-27.50, (-73.40, 18.40)		0.240	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		32 / 346 (9.2)	14 / 173 (8.1)		
	RR, (95% CI)		1.14, (0.63, 2.08)		0.663	
	OR, (95% CI)		1.16, (0.60, 2.23)		0.662	
	ARR %, (95% CI)		1.16, (-3.93, 6.24)		0.656	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.295				0.285
Yes	n / N(%)		3 / 99 (3.0)	3 / 52 (5.8)		
	RR, (95% CI)		0.53, (0.11, 2.51)		0.420	
	OR, (95% CI)		0.51, (0.10, 2.62)		0.421	
	ARR %, (95% CI)		-2.74, (-9.92, 4.44)		0.455	
No	n / N(%)		29 / 247 (11.7)	11 / 121 (9.1)		
	RR, (95% CI)		1.29, (0.67, 2.50)		0.447	
	OR, (95% CI)		1.33, (0.64, 2.76)		0.444	
	ARR %, (95% CI)		2.65, (-3.86, 9.16)		0.425	
Sex		0.112				0.108
Male	n / N(%)		22 / 216 (10.2)	6 / 105 (5.7)		
	RR, (95% CI)		1.78, (0.75, 4.26)		0.194	
	OR, (95% CI)		1.87, (0.73, 4.76)		0.189	
	ARR %, (95% CI)		4.47, (-1.53, 10.47)		0.144	
Female	n / N(%)		10 / 130 (7.7)	8 / 68 (11.8)		
	RR, (95% CI)		0.65, (0.27, 1.58)		0.345	
	OR, (95% CI)		0.63, (0.23, 1.67)		0.347	
	ARR %, (95% CI)		-4.07, (-13.00, 4.85)		0.371	
Region		0.475				0.452
North America	n / N(%)		15 / 185 (8.1)	10 / 106 (9.4)		
	RR, (95% CI)		0.86, (0.40, 1.84)		0.698	
	OR, (95% CI)		0.85, (0.37, 1.96)		0.698	
	ARR %, (95% CI)		-1.33, (-8.14, 5.49)		0.703	
United Kingdom	n / N(%)		8 / 80 (10.0)	1 / 30 (3.3)		
	RR, (95% CI)		3.00, (0.39, 22.98)		0.290	
	OR, (95% CI)		3.22, (0.39, 26.93)		0.280	
	ARR %, (95% CI)		6.67, (-2.52, 15.86)		0.155	
European Union	n / N(%)		9 / 81 (11.1)	3 / 37 (8.1)		
	RR, (95% CI)		1.37, (0.39, 4.77)		0.621	
	OR, (95% CI)		1.42, (0.36, 5.57)		0.618	
	ARR %, (95% CI)		3.00, (-8.14, 14.15)		0.597	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		0.852				0.819
United States	n / N(%)		15 / 185 (8.1)	10 / 106 (9.4)		
	RR, (95% CI)		0.86, (0.40, 1.84)		0.698	
	OR, (95% CI)		0.85, (0.37, 1.96)		0.698	
	ARR %, (95% CI)		-1.33, (-8.14, 5.49)		0.703	
United Kingdom	n / N(%)		8 / 80 (10.0)	1 / 30 (3.3)		
	RR, (95% CI)		3.00, (0.39, 22.98)		0.290	
	OR, (95% CI)		3.22, (0.39, 26.93)		0.280	
	ARR %, (95% CI)		6.67, (-2.52, 15.86)		0.155	
Belgium	n / N(%)		2 / 25 (8.0)	1 / 16 (6.3)		
	RR, (95% CI)		1.28, (0.13, 12.99)		0.835	
	OR, (95% CI)		1.30, (0.11, 15.69)		0.834	
	ARR %, (95% CI)		1.75, (-14.18, 17.68)		0.830	
France	n / N(%)		5 / 38 (13.2)	2 / 16 (12.5)		
	RR, (95% CI)		1.05, (0.23, 4.87)		0.948	
	OR, (95% CI)		1.06, (0.18, 6.13)		0.948	
	ARR %, (95% CI)		0.66, (-18.79, 20.10)		0.947	
Spain	n / N(%)		2 / 18 (11.1)	0 / 5 (0.0)		
	RR, (95% CI)		1.58, (0.09, 28.53)		0.757	
	OR, (95% CI)		1.67, (0.07, 40.32)		0.753	
	ARR %, (95% CI)		11.11, (-3.41, 25.63)		0.134	
Race		0.998				0.623
Black or African American	n / N(%)		6 / 50 (12.0)	3 / 28 (10.7)		
	RR, (95% CI)		1.12, (0.30, 4.14)		0.865	
	OR, (95% CI)		1.14, (0.26, 4.94)		0.865	
	ARR %, (95% CI)		1.29, (-13.29, 15.86)		0.863	
White	n / N(%)		26 / 264 (9.8)	10 / 126 (7.9)		
	RR, (95% CI)		1.24, (0.62, 2.49)		0.544	
	OR, (95% CI)		1.27, (0.59, 2.72)		0.543	
	ARR %, (95% CI)		1.91, (-4.02, 7.84)		0.528	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Other	n / N(%)		0 / 28 (0.0)	1 / 15 (6.7)		
	RR, (95% CI)		0.18, (0.01, 4.26)		0.291	
	OR, (95% CI)		0.17, (0.01, 4.43)		0.286	
	ARR %, (95% CI)		-6.67, (-19.29, 5.96)		0.301	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		0.130				0.099
Hispanic or Latino	n / N(%)		2 / 40 (5.0)	2 / 12 (16.7)		
	RR, (95% CI)		0.30, (0.05, 1.91)		0.202	
	OR, (95% CI)		0.26, (0.03, 2.11)		0.208	
	ARR %, (95% CI)		-11.67, (-33.81, 10.47)		0.302	
Not Hispanic or Latino	n / N(%)		29 / 275 (10.5)	10 / 144 (6.9)		
	RR, (95% CI)		1.52, (0.76, 3.03)		0.235	
	OR, (95% CI)		1.58, (0.75, 3.34)		0.231	
	ARR %, (95% CI)		3.60, (-1.91, 9.12)		0.201	
Other	n / N(%)		1 / 31 (3.2)	2 / 17 (11.8)		
	RR, (95% CI)		0.27, (0.03, 2.81)		0.276	
	OR, (95% CI)		0.25, (0.02, 2.98)		0.273	
	ARR %, (95% CI)		-8.54, (-25.07, 7.99)		0.311	
COVID-19 co-morbidities at baseline		0.827				0.827
None	n / N(%)		6 / 101 (5.9)	2 / 46 (4.3)		
	RR, (95% CI)		1.37, (0.29, 6.51)		0.695	
	OR, (95% CI)		1.39, (0.27, 7.16)		0.694	
	ARR %, (95% CI)		1.59, (-5.89, 9.07)		0.677	
At least one	n / N(%)		26 / 245 (10.6)	12 / 127 (9.4)		
	RR, (95% CI)		1.12, (0.59, 2.15)		0.726	
	OR, (95% CI)		1.14, (0.55, 2.34)		0.725	
	ARR %, (95% CI)		1.16, (-5.22, 7.55)		0.721	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		32 / 346 (9.2)	14 / 173 (8.1)		
	RR, (95% CI)		1.14, (0.63, 2.08)		0.663	
	OR, (95% CI)		1.16, (0.60, 2.23)		0.662	
	ARR %, (95% CI)		1.16, (-3.93, 6.24)		0.656	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.498				0.491
Yes	n / N(%)		27 / 303 (8.9)	13 / 154 (8.4)		
	RR, (95% CI)		1.06, (0.56, 1.99)		0.867	
	OR, (95% CI)		1.06, (0.53, 2.12)		0.867	
	ARR %, (95% CI)		0.47, (-4.97, 5.91)		0.866	
No	n / N(%)		5 / 43 (11.6)	1 / 19 (5.3)		
	RR, (95% CI)		2.21, (0.28, 17.65)		0.455	
	OR, (95% CI)		2.37, (0.26, 21.79)		0.446	
	ARR %, (95% CI)		6.36, (-7.51, 20.24)		0.369	
Obesity (≥ 30 kg/m^2)		0.918				0.918
Yes	n / N(%)		8 / 119 (6.7)	3 / 55 (5.5)		
	RR, (95% CI)		1.23, (0.34, 4.47)		0.750	
	OR, (95% CI)		1.25, (0.32, 4.90)		0.750	
	ARR %, (95% CI)		1.27, (-6.23, 8.77)		0.740	
No	n / N(%)		24 / 225 (10.7)	11 / 117 (9.4)		
	RR, (95% CI)		1.13, (0.58, 2.23)		0.715	
	OR, (95% CI)		1.15, (0.54, 2.44)		0.714	
	ARR %, (95% CI)		1.26, (-5.39, 7.92)		0.709	
Obesity (≥ 40 kg/m^2)		0.976				0.625
Yes	n / N(%)		1 / 17 (5.9)	0 / 13 (0.0)		
	RR, (95% CI)		2.33, (0.10, 53.03)		0.595	
	OR, (95% CI)		2.45, (0.09, 65.26)		0.592	
	ARR %, (95% CI)		5.88, (-5.30, 17.07)		0.303	
No	n / N(%)		31 / 327 (9.5)	14 / 159 (8.8)		
	RR, (95% CI)		1.08, (0.59, 1.97)		0.810	
	OR, (95% CI)		1.08, (0.56, 2.10)		0.810	
	ARR %, (95% CI)		0.68, (-4.75, 6.10)		0.807	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.913				0.913
Yes	n / N(%)		12 / 38 (31.6)	6 / 21 (28.6)		
	RR, (95% CI)		1.11, (0.49, 2.52)		0.811	
	OR, (95% CI)		1.15, (0.36, 3.71)		0.810	
	ARR %, (95% CI)		3.01, (-21.32, 27.33)		0.809	
No	n / N(%)		20 / 308 (6.5)	8 / 152 (5.3)		
	RR, (95% CI)		1.23, (0.56, 2.74)		0.605	
	OR, (95% CI)		1.25, (0.54, 2.91)		0.604	
	ARR %, (95% CI)		1.23, (-3.26, 5.72)		0.591	
Diabetes		0.902				0.902
Yes	n / N(%)		7 / 40 (17.5)	4 / 25 (16.0)		
	RR, (95% CI)		1.09, (0.36, 3.36)		0.876	
	OR, (95% CI)		1.11, (0.29, 4.27)		0.875	
	ARR %, (95% CI)		1.50, (-17.08, 20.08)		0.874	
No	n / N(%)		25 / 306 (8.2)	10 / 148 (6.8)		
	RR, (95% CI)		1.21, (0.60, 2.45)		0.598	
	OR, (95% CI)		1.23, (0.57, 2.63)		0.597	
	ARR %, (95% CI)		1.41, (-3.66, 6.49)		0.585	
Immunosuppressive disease		0.990				0.990
Yes	n / N(%)		2 / 16 (12.5)	1 / 9 (11.1)		
	RR, (95% CI)		1.13, (0.12, 10.75)		0.919	
	OR, (95% CI)		1.14, (0.09, 14.68)		0.918	
	ARR %, (95% CI)		1.39, (-24.77, 27.55)		0.917	
No	n / N(%)		30 / 330 (9.1)	13 / 164 (7.9)		
	RR, (95% CI)		1.15, (0.61, 2.14)		0.667	
	OR, (95% CI)		1.16, (0.59, 2.29)		0.666	
	ARR %, (95% CI)		1.16, (-4.00, 6.33)		0.659	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.502				0.501
Yes	n / N(%)		11 / 103 (10.7)	7 / 60 (11.7)		
	RR, (95% CI)		0.92, (0.37, 2.23)		0.846	
	OR, (95% CI)		0.91, (0.33, 2.48)		0.846	
	ARR %, (95% CI)		-0.99, (-11.06, 9.09)		0.848	
No	n / N(%)		21 / 243 (8.6)	7 / 113 (6.2)		
	RR, (95% CI)		1.40, (0.61, 3.19)		0.429	
	OR, (95% CI)		1.43, (0.59, 3.47)		0.427	
	ARR %, (95% CI)		2.45, (-3.23, 8.12)		0.398	
CV disease		0.751				0.750
Yes	n / N(%)		8 / 32 (25.0)	4 / 22 (18.2)		
	RR, (95% CI)		1.38, (0.47, 4.01)		0.560	
	OR, (95% CI)		1.50, (0.39, 5.77)		0.555	
	ARR %, (95% CI)		6.82, (-15.20, 28.84)		0.544	
No	n / N(%)		24 / 314 (7.6)	10 / 151 (6.6)		
	RR, (95% CI)		1.15, (0.57, 2.35)		0.693	
	OR, (95% CI)		1.17, (0.54, 2.51)		0.692	
	ARR %, (95% CI)		1.02, (-3.92, 5.96)		0.685	
COPD		0.069				0.059
Yes	n / N(%)		3 / 23 (13.0)	4 / 11 (36.4)		
	RR, (95% CI)		0.36, (0.10, 1.33)		0.126	
	OR, (95% CI)		0.26, (0.05, 1.48)		0.129	
	ARR %, (95% CI)		-23.32, (-54.90, 8.26)		0.148	
No	n / N(%)		29 / 323 (9.0)	10 / 162 (6.2)		
	RR, (95% CI)		1.45, (0.73, 2.91)		0.290	
	OR, (95% CI)		1.50, (0.71, 3.16)		0.287	
	ARR %, (95% CI)		2.81, (-2.04, 7.65)		0.256	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.150				0.139
Yes	n / N(%)		3 / 44 (6.8)	4 / 26 (15.4)		
	RR, (95% CI)		0.44, (0.11, 1.83)		0.260	
	OR, (95% CI)		0.40, (0.08, 1.96)		0.260	
	ARR %, (95% CI)		-8.57, (-24.31, 7.18)		0.286	
No	n / N(%)		29 / 302 (9.6)	10 / 147 (6.8)		
	RR, (95% CI)		1.41, (0.71, 2.82)		0.328	
	OR, (95% CI)		1.46, (0.69, 3.07)		0.325	
	ARR %, (95% CI)		2.80, (-2.45, 8.05)		0.296	
Hypertension		0.519				0.518
Yes	n / N(%)		20 / 153 (13.1)	10 / 75 (13.3)		
	RR, (95% CI)		0.98, (0.48, 1.99)		0.956	
	OR, (95% CI)		0.98, (0.43, 2.21)		0.956	
	ARR %, (95% CI)		-0.26, (-9.63, 9.10)		0.956	
No	n / N(%)		12 / 193 (6.2)	4 / 98 (4.1)		
	RR, (95% CI)		1.52, (0.50, 4.60)		0.455	
	OR, (95% CI)		1.56, (0.49, 4.96)		0.453	
	ARR %, (95% CI)		2.14, (-3.06, 7.33)		0.420	
Asthma		0.358				0.342
Yes	n / N(%)		7 / 55 (12.7)	1 / 21 (4.8)		
	RR, (95% CI)		2.67, (0.35, 20.43)		0.343	
	OR, (95% CI)		2.92, (0.34, 25.27)		0.331	
	ARR %, (95% CI)		7.97, (-4.71, 20.64)		0.218	
No	n / N(%)		25 / 291 (8.6)	13 / 152 (8.6)		
	RR, (95% CI)		1.00, (0.53, 1.91)		0.989	
	OR, (95% CI)		1.00, (0.50, 2.03)		0.989	
	ARR %, (95% CI)		0.04, (-5.45, 5.53)		0.989	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.087				0.061
Yes	n / N(%)		10 / 60 (16.7)	1 / 30 (3.3)		
	RR, (95% CI)		5.00, (0.67, 37.26)		0.116	
	OR, (95% CI)		5.80, (0.71, 47.64)		0.102	
	ARR %, (95% CI)		13.33, (1.92, 24.74)		0.022	
No	n / N(%)		22 / 286 (7.7)	13 / 143 (9.1)		
	RR, (95% CI)		0.85, (0.44, 1.63)		0.617	
	OR, (95% CI)		0.83, (0.41, 1.71)		0.618	
	ARR %, (95% CI)		-1.40, (-7.03, 4.24)		0.627	
Smoking		0.843				0.843
Yes	n / N(%)		4 / 63 (6.3)	2 / 31 (6.5)		
	RR, (95% CI)		0.98, (0.19, 5.08)		0.985	
	OR, (95% CI)		0.98, (0.17, 5.68)		0.985	
	ARR %, (95% CI)		-0.10, (-10.64, 10.44)		0.985	
No	n / N(%)		28 / 283 (9.9)	12 / 142 (8.5)		
	RR, (95% CI)		1.17, (0.61, 2.23)		0.632	
	OR, (95% CI)		1.19, (0.59, 2.42)		0.631	
	ARR %, (95% CI)		1.44, (-4.30, 7.19)		0.623	
Sickle cell disease		NE				NE
No	n / N(%)		32 / 346 (9.2)	14 / 173 (8.1)		
	RR, (95% CI)		1.14, (0.63, 2.08)		0.663	
	OR, (95% CI)		1.16, (0.60, 2.23)		0.662	
	ARR %, (95% CI)		1.16, (-3.93, 6.24)		0.656	
COVID-19 vaccination at any time during the study		0.079				0.073
Yes	n / N(%)		25 / 242 (10.3)	8 / 127 (6.3)		
	RR, (95% CI)		1.64, (0.76, 3.53)		0.206	
	OR, (95% CI)		1.71, (0.75, 3.92)		0.202	
	ARR %, (95% CI)		4.03, (-1.67, 9.74)		0.166	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		7 / 104 (6.7)	6 / 46 (13.0)		
	RR, (95% CI)		0.52, (0.18, 1.45)		0.210	
	OR, (95% CI)		0.48, (0.15, 1.52)		0.213	
	ARR %, (95% CI)		-6.31, (-17.17, 4.55)		0.255	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.18
Serious Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.976				0.622
Yes	n / N(%)		31 / 344 (9.0)	14 / 172 (8.1)		
	RR, (95% CI)		1.11, (0.61, 2.03)		0.741	
	OR, (95% CI)		1.12, (0.58, 2.16)		0.741	
	ARR %, (95% CI)		0.87, (-4.21, 5.96)		0.737	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.633				0.633
<60 years	n / N(%)		17 / 199 (8.5)	7 / 97 (7.2)		
	RR, (95% CI)		1.18, (0.51, 2.76)		0.696	
	OR, (95% CI)		1.20, (0.48, 3.00)		0.695	
	ARR %, (95% CI)		1.33, (-5.12, 7.78)		0.687	
≥60 years	n / N(%)		21 / 147 (14.3)	7 / 76 (9.2)		
	RR, (95% CI)		1.55, (0.69, 3.48)		0.288	
	OR, (95% CI)		1.64, (0.67, 4.06)		0.282	
	ARR %, (95% CI)		5.08, (-3.54, 13.69)		0.248	
Age at randomization		0.758				0.758
<65 years	n / N(%)		24 / 262 (9.2)	10 / 137 (7.3)		
	RR, (95% CI)		1.25, (0.62, 2.55)		0.530	
	OR, (95% CI)		1.28, (0.59, 2.76)		0.528	
	ARR %, (95% CI)		1.86, (-3.72, 7.44)		0.514	
≥65 years	n / N(%)		14 / 84 (16.7)	4 / 36 (11.1)		
	RR, (95% CI)		1.50, (0.53, 4.25)		0.445	
	OR, (95% CI)		1.60, (0.49, 5.25)		0.438	
	ARR %, (95% CI)		5.56, (-7.44, 18.55)		0.402	
Age at randomization		0.500				0.491
<75 years	n / N(%)		36 / 330 (10.9)	13 / 168 (7.7)		
	RR, (95% CI)		1.41, (0.77, 2.59)		0.267	
	OR, (95% CI)		1.46, (0.75, 2.83)		0.264	
	ARR %, (95% CI)		3.17, (-2.09, 8.43)		0.237	
≥75 years	n / N(%)		2 / 16 (12.5)	1 / 5 (20.0)		
	RR, (95% CI)		0.63, (0.07, 5.53)		0.673	
	OR, (95% CI)		0.57, (0.04, 8.05)		0.678	
	ARR %, (95% CI)		-7.50, (-46.12, 31.12)		0.704	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		38 / 346 (11.0)	14 / 173 (8.1)		
	RR, (95% CI)		1.36, (0.76, 2.44)		0.306	
	OR, (95% CI)		1.40, (0.74, 2.66)		0.303	
	ARR %, (95% CI)		2.89, (-2.34, 8.12)		0.279	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.394				0.380
Yes	n / N(%)		6 / 99 (6.1)	1 / 52 (1.9)		
	RR, (95% CI)		3.15, (0.39, 25.49)		0.282	
	OR, (95% CI)		3.29, (0.39, 28.09)		0.276	
	ARR %, (95% CI)		4.14, (-1.86, 10.14)		0.177	
No	n / N(%)		32 / 247 (13.0)	13 / 121 (10.7)		
	RR, (95% CI)		1.21, (0.66, 2.21)		0.545	
	OR, (95% CI)		1.24, (0.62, 2.45)		0.543	
	ARR %, (95% CI)		2.21, (-4.72, 9.14)		0.531	
Sex		0.132				0.126
Male	n / N(%)		23 / 216 (10.6)	5 / 105 (4.8)		
	RR, (95% CI)		2.24, (0.87, 5.72)		0.093	
	OR, (95% CI)		2.38, (0.88, 6.46)		0.088	
	ARR %, (95% CI)		5.89, (0.10, 11.68)		0.046	
Female	n / N(%)		15 / 130 (11.5)	9 / 68 (13.2)		
	RR, (95% CI)		0.87, (0.40, 1.89)		0.728	
	OR, (95% CI)		0.86, (0.35, 2.07)		0.728	
	ARR %, (95% CI)		-1.70, (-11.45, 8.05)		0.733	
Region		0.870				0.869
North America	n / N(%)		17 / 185 (9.2)	8 / 106 (7.5)		
	RR, (95% CI)		1.22, (0.54, 2.73)		0.632	
	OR, (95% CI)		1.24, (0.52, 2.98)		0.631	
	ARR %, (95% CI)		1.64, (-4.89, 8.17)		0.622	
United Kingdom	n / N(%)		10 / 80 (12.5)	2 / 30 (6.7)		
	RR, (95% CI)		1.88, (0.44, 8.07)		0.398	
	OR, (95% CI)		2.00, (0.41, 9.71)		0.390	
	ARR %, (95% CI)		5.83, (-5.66, 17.33)		0.320	
European Union	n / N(%)		11 / 81 (13.6)	4 / 37 (10.8)		
	RR, (95% CI)		1.26, (0.43, 3.69)		0.678	
	OR, (95% CI)		1.30, (0.38, 4.38)		0.676	
	ARR %, (95% CI)		2.77, (-9.71, 15.25)		0.664	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		0.991				0.988
United States	n / N(%)		17 / 185 (9.2)	8 / 106 (7.5)		
	RR, (95% CI)		1.22, (0.54, 2.73)		0.632	
	OR, (95% CI)		1.24, (0.52, 2.98)		0.631	
	ARR %, (95% CI)		1.64, (-4.89, 8.17)		0.622	
United Kingdom	n / N(%)		10 / 80 (12.5)	2 / 30 (6.7)		
	RR, (95% CI)		1.88, (0.44, 8.07)		0.398	
	OR, (95% CI)		2.00, (0.41, 9.71)		0.390	
	ARR %, (95% CI)		5.83, (-5.66, 17.33)		0.320	
Belgium	n / N(%)		4 / 25 (16.0)	2 / 16 (12.5)		
	RR, (95% CI)		1.28, (0.26, 6.20)		0.759	
	OR, (95% CI)		1.33, (0.21, 8.29)		0.758	
	ARR %, (95% CI)		3.50, (-18.16, 25.16)		0.751	
France	n / N(%)		6 / 38 (15.8)	2 / 16 (12.5)		
	RR, (95% CI)		1.26, (0.28, 5.60)		0.759	
	OR, (95% CI)		1.31, (0.24, 7.32)		0.757	
	ARR %, (95% CI)		3.29, (-16.64, 23.21)		0.746	
Spain	n / N(%)		1 / 18 (5.6)	0 / 5 (0.0)		
	RR, (95% CI)		0.95, (0.04, 20.33)		0.972	
	OR, (95% CI)		0.94, (0.03, 26.63)		0.972	
	ARR %, (95% CI)		5.55, (-5.04, 16.14)		0.304	
Race		0.942				0.941
Black or African American	n / N(%)		5 / 50 (10.0)	3 / 28 (10.7)		
	RR, (95% CI)		0.93, (0.24, 3.62)		0.920	
	OR, (95% CI)		0.93, (0.20, 4.20)		0.921	
	ARR %, (95% CI)		-0.71, (-14.87, 13.44)		0.921	
White	n / N(%)		31 / 264 (11.7)	10 / 126 (7.9)		
	RR, (95% CI)		1.48, (0.75, 2.92)		0.259	
	OR, (95% CI)		1.54, (0.73, 3.26)		0.255	
	ARR %, (95% CI)		3.81, (-2.31, 9.92)		0.222	
Other	n / N(%)		2 / 28 (7.1)	1 / 15 (6.7)		
	RR, (95% CI)		1.07, (0.11, 10.87)		0.953	
	OR, (95% CI)		1.08, (0.09, 12.95)		0.953	
	ARR %, (95% CI)		0.48, (-15.35, 16.30)		0.953	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		0.603				0.591
Hispanic or Latino	n / N(%)		2 / 40 (5.0)	1 / 12 (8.3)		
	RR, (95% CI)		0.60, (0.06, 6.06)		0.665	
	OR, (95% CI)		0.58, (0.05, 7.00)		0.667	
	ARR %, (95% CI)		-3.33, (-20.37, 13.70)		0.701	
Not Hispanic or Latino	n / N(%)		33 / 275 (12.0)	11 / 144 (7.6)		
	RR, (95% CI)		1.57, (0.82, 3.01)		0.174	
	OR, (95% CI)		1.65, (0.81, 3.37)		0.170	
	ARR %, (95% CI)		4.36, (-1.43, 10.16)		0.140	
Other	n / N(%)		3 / 31 (9.7)	2 / 17 (11.8)		
	RR, (95% CI)		0.82, (0.15, 4.45)		0.821	
	OR, (95% CI)		0.80, (0.12, 5.35)		0.821	
	ARR %, (95% CI)		-2.09, (-20.60, 16.43)		0.825	
COVID-19 co-morbidities at baseline		0.656				0.655
None	n / N(%)		7 / 101 (6.9)	3 / 46 (6.5)		
	RR, (95% CI)		1.06, (0.29, 3.93)		0.927	
	OR, (95% CI)		1.07, (0.26, 4.33)		0.927	
	ARR %, (95% CI)		0.41, (-8.28, 9.09)		0.926	
At least one	n / N(%)		31 / 245 (12.7)	11 / 127 (8.7)		
	RR, (95% CI)		1.46, (0.76, 2.81)		0.256	
	OR, (95% CI)		1.53, (0.74, 3.15)		0.251	
	ARR %, (95% CI)		3.99, (-2.43, 10.41)		0.223	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		38 / 346 (11.0)	14 / 173 (8.1)		
	RR, (95% CI)		1.36, (0.76, 2.44)		0.306	
	OR, (95% CI)		1.40, (0.74, 2.66)		0.303	
	ARR %, (95% CI)		2.89, (-2.34, 8.12)		0.279	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.788				0.787
Yes	n / N(%)		33 / 303 (10.9)	12 / 154 (7.8)		
	RR, (95% CI)		1.40, (0.74, 2.63)		0.299	
	OR, (95% CI)		1.45, (0.72, 2.89)		0.295	
	ARR %, (95% CI)		3.10, (-2.40, 8.60)		0.269	
No	n / N(%)		5 / 43 (11.6)	2 / 19 (10.5)		
	RR, (95% CI)		1.10, (0.23, 5.20)		0.900	
	OR, (95% CI)		1.12, (0.20, 6.35)		0.899	
	ARR %, (95% CI)		1.10, (-15.70, 17.90)		0.898	
Obesity (≥ 30 kg/m^2)		0.778				0.777
Yes	n / N(%)		13 / 119 (10.9)	4 / 55 (7.3)		
	RR, (95% CI)		1.50, (0.51, 4.40)		0.458	
	OR, (95% CI)		1.56, (0.49, 5.03)		0.454	
	ARR %, (95% CI)		3.65, (-5.21, 12.51)		0.419	
No	n / N(%)		24 / 225 (10.7)	10 / 117 (8.5)		
	RR, (95% CI)		1.25, (0.62, 2.52)		0.537	
	OR, (95% CI)		1.28, (0.59, 2.77)		0.535	
	ARR %, (95% CI)		2.12, (-4.36, 8.60)		0.521	
Obesity (≥ 40 kg/m^2)		0.974				0.419
Yes	n / N(%)		2 / 17 (11.8)	0 / 13 (0.0)		
	RR, (95% CI)		3.89, (0.20, 74.67)		0.368	
	OR, (95% CI)		4.35, (0.19, 98.90)		0.356	
	ARR %, (95% CI)		11.76, (-3.55, 27.08)		0.132	
No	n / N(%)		35 / 327 (10.7)	14 / 159 (8.8)		
	RR, (95% CI)		1.22, (0.67, 2.19)		0.517	
	OR, (95% CI)		1.24, (0.65, 2.38)		0.515	
	ARR %, (95% CI)		1.90, (-3.64, 7.43)		0.501	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.683				0.682
Yes	n / N(%)		9 / 38 (23.7)	3 / 21 (14.3)		
	RR, (95% CI)		1.66, (0.50, 5.47)		0.406	
	OR, (95% CI)		1.86, (0.44, 7.80)		0.395	
	ARR %, (95% CI)		9.40, (-10.77, 29.57)		0.361	
No	n / N(%)		29 / 308 (9.4)	11 / 152 (7.2)		
	RR, (95% CI)		1.30, (0.67, 2.53)		0.439	
	OR, (95% CI)		1.33, (0.65, 2.75)		0.437	
	ARR %, (95% CI)		2.18, (-3.08, 7.43)		0.416	
Diabetes		0.646				0.645
Yes	n / N(%)		6 / 40 (15.0)	2 / 25 (8.0)		
	RR, (95% CI)		1.88, (0.41, 8.58)		0.418	
	OR, (95% CI)		2.03, (0.38, 10.95)		0.411	
	ARR %, (95% CI)		7.00, (-8.35, 22.35)		0.371	
No	n / N(%)		32 / 306 (10.5)	12 / 148 (8.1)		
	RR, (95% CI)		1.29, (0.68, 2.43)		0.431	
	OR, (95% CI)		1.32, (0.66, 2.65)		0.429	
	ARR %, (95% CI)		2.35, (-3.23, 7.93)		0.409	
Immunosuppressive disease		0.871				0.871
Yes	n / N(%)		2 / 16 (12.5)	1 / 9 (11.1)		
	RR, (95% CI)		1.13, (0.12, 10.75)		0.919	
	OR, (95% CI)		1.14, (0.09, 14.68)		0.918	
	ARR %, (95% CI)		1.39, (-24.77, 27.55)		0.917	
No	n / N(%)		36 / 330 (10.9)	13 / 164 (7.9)		
	RR, (95% CI)		1.38, (0.75, 2.52)		0.302	
	OR, (95% CI)		1.42, (0.73, 2.76)		0.298	
	ARR %, (95% CI)		2.98, (-2.35, 8.31)		0.273	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.758				0.758
Yes	n / N(%)		15 / 103 (14.6)	7 / 60 (11.7)		
	RR, (95% CI)		1.25, (0.54, 2.89)		0.604	
	OR, (95% CI)		1.29, (0.49, 3.37)		0.602	
	ARR %, (95% CI)		2.90, (-7.70, 13.50)		0.592	
No	n / N(%)		23 / 243 (9.5)	7 / 113 (6.2)		
	RR, (95% CI)		1.53, (0.68, 3.46)		0.309	
	OR, (95% CI)		1.58, (0.66, 3.81)		0.305	
	ARR %, (95% CI)		3.27, (-2.50, 9.04)		0.267	
CV disease		0.163				0.137
Yes	n / N(%)		7 / 32 (21.9)	1 / 22 (4.5)		
	RR, (95% CI)		4.81, (0.64, 36.41)		0.128	
	OR, (95% CI)		5.88, (0.67, 51.71)		0.110	
	ARR %, (95% CI)		17.33, (0.57, 34.09)		0.043	
No	n / N(%)		31 / 314 (9.9)	13 / 151 (8.6)		
	RR, (95% CI)		1.15, (0.62, 2.13)		0.664	
	OR, (95% CI)		1.16, (0.59, 2.29)		0.663	
	ARR %, (95% CI)		1.26, (-4.30, 6.82)		0.656	
COPD		0.263				0.255
Yes	n / N(%)		4 / 23 (17.4)	3 / 11 (27.3)		
	RR, (95% CI)		0.64, (0.17, 2.37)		0.502	
	OR, (95% CI)		0.56, (0.10, 3.10)		0.508	
	ARR %, (95% CI)		-9.88, (-40.42, 20.66)		0.526	
No	n / N(%)		34 / 323 (10.5)	11 / 162 (6.8)		
	RR, (95% CI)		1.55, (0.81, 2.98)		0.188	
	OR, (95% CI)		1.61, (0.80, 3.28)		0.184	
	ARR %, (95% CI)		3.74, (-1.38, 8.86)		0.153	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.783				0.783
Yes	n / N(%)		8 / 44 (18.2)	4 / 26 (15.4)		
	RR, (95% CI)		1.18, (0.39, 3.54)		0.766	
	OR, (95% CI)		1.22, (0.33, 4.54)		0.764	
	ARR %, (95% CI)		2.80, (-15.15, 20.75)		0.760	
No	n / N(%)		30 / 302 (9.9)	10 / 147 (6.8)		
	RR, (95% CI)		1.46, (0.73, 2.91)		0.281	
	OR, (95% CI)		1.51, (0.72, 3.18)		0.277	
	ARR %, (95% CI)		3.13, (-2.16, 8.42)		0.246	
Hypertension		0.618				0.618
Yes	n / N(%)		22 / 153 (14.4)	7 / 75 (9.3)		
	RR, (95% CI)		1.54, (0.69, 3.44)		0.292	
	OR, (95% CI)		1.63, (0.66, 4.01)		0.286	
	ARR %, (95% CI)		5.05, (-3.57, 13.66)		0.251	
No	n / N(%)		16 / 193 (8.3)	7 / 98 (7.1)		
	RR, (95% CI)		1.16, (0.49, 2.73)		0.733	
	OR, (95% CI)		1.18, (0.47, 2.96)		0.732	
	ARR %, (95% CI)		1.15, (-5.27, 7.56)		0.726	
Asthma		0.837				0.837
Yes	n / N(%)		8 / 55 (14.5)	2 / 21 (9.5)		
	RR, (95% CI)		1.53, (0.35, 6.61)		0.571	
	OR, (95% CI)		1.62, (0.31, 8.32)		0.565	
	ARR %, (95% CI)		5.02, (-10.61, 20.66)		0.529	
No	n / N(%)		30 / 291 (10.3)	12 / 152 (7.9)		
	RR, (95% CI)		1.31, (0.69, 2.48)		0.414	
	OR, (95% CI)		1.34, (0.67, 2.70)		0.411	
	ARR %, (95% CI)		2.41, (-3.12, 7.94)		0.392	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.185				0.173
Yes	n / N(%)		12 / 60 (20.0)	2 / 30 (6.7)		
	RR, (95% CI)		3.00, (0.72, 12.55)		0.132	
	OR, (95% CI)		3.50, (0.73, 16.79)		0.117	
	ARR %, (95% CI)		13.33, (-0.16, 26.83)		0.053	
No	n / N(%)		26 / 286 (9.1)	12 / 143 (8.4)		
	RR, (95% CI)		1.08, (0.56, 2.08)		0.810	
	OR, (95% CI)		1.09, (0.53, 2.23)		0.810	
	ARR %, (95% CI)		0.70, (-4.94, 6.33)		0.808	
Smoking		0.165				0.149
Yes	n / N(%)		3 / 63 (4.8)	3 / 31 (9.7)		
	RR, (95% CI)		0.49, (0.11, 2.30)		0.367	
	OR, (95% CI)		0.47, (0.09, 2.46)		0.369	
	ARR %, (95% CI)		-4.92, (-16.58, 6.75)		0.409	
No	n / N(%)		35 / 283 (12.4)	11 / 142 (7.7)		
	RR, (95% CI)		1.60, (0.84, 3.05)		0.156	
	OR, (95% CI)		1.68, (0.83, 3.42)		0.152	
	ARR %, (95% CI)		4.62, (-1.21, 10.46)		0.121	
Sickle cell disease		NE				NE
No	n / N(%)		38 / 346 (11.0)	14 / 173 (8.1)		
	RR, (95% CI)		1.36, (0.76, 2.44)		0.306	
	OR, (95% CI)		1.40, (0.74, 2.66)		0.303	
	ARR %, (95% CI)		2.89, (-2.34, 8.12)		0.279	
COVID-19 vaccination at any time during the study		0.336				0.333
Yes	n / N(%)		28 / 242 (11.6)	9 / 127 (7.1)		
	RR, (95% CI)		1.63, (0.79, 3.35)		0.182	
	OR, (95% CI)		1.72, (0.78, 3.76)		0.177	
	ARR %, (95% CI)		4.48, (-1.53, 10.50)		0.144	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		10 / 104 (9.6)	5 / 46 (10.9)		
	RR, (95% CI)		0.88, (0.32, 2.44)		0.813	
	OR, (95% CI)		0.87, (0.28, 2.71)		0.813	
	ARR %, (95% CI)		-1.25, (-11.88, 9.38)		0.817	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.19
Severe Adverse Events Excluding Disease Related Events Through End of Study by Subgroup
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.977				0.694
Yes	n / N(%)		37 / 344 (10.8)	14 / 172 (8.1)		
	RR, (95% CI)		1.32, (0.73, 2.38)		0.352	
	OR, (95% CI)		1.36, (0.71, 2.59)		0.349	
	ARR %, (95% CI)		2.62, (-2.62, 7.85)		0.327	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.524				0.516
<60 years	n / N(%)		1 / 199 (0.5)	1 / 97 (1.0)		
	RR, (95% CI)		0.49, (0.03, 7.71)		0.610	
	OR, (95% CI)		0.48, (0.03, 7.83)		0.610	
	ARR %, (95% CI)		-0.53, (-2.77, 1.71)		0.643	
≥60 years	n / N(%)		3 / 147 (2.0)	1 / 76 (1.3)		
	RR, (95% CI)		1.55, (0.16, 14.66)		0.702	
	OR, (95% CI)		1.56, (0.16, 15.28)		0.701	
	ARR %, (95% CI)		0.73, (-2.71, 4.16)		0.679	
Age at randomization		0.976				0.783
<65 years	n / N(%)		3 / 262 (1.1)	2 / 137 (1.5)		
	RR, (95% CI)		0.78, (0.13, 4.64)		0.789	
	OR, (95% CI)		0.78, (0.13, 4.74)		0.789	
	ARR %, (95% CI)		-0.31, (-2.70, 2.07)		0.796	
≥65 years	n / N(%)		1 / 84 (1.2)	0 / 36 (0.0)		
	RR, (95% CI)		1.31, (0.05, 31.32)		0.869	
	OR, (95% CI)		1.31, (0.05, 32.96)		0.869	
	ARR %, (95% CI)		1.19, (-1.13, 3.51)		0.315	
Age at randomization		0.979				0.862
<75 years	n / N(%)		3 / 330 (0.9)	2 / 168 (1.2)		
	RR, (95% CI)		0.76, (0.13, 4.53)		0.766	
	OR, (95% CI)		0.76, (0.13, 4.60)		0.767	
	ARR %, (95% CI)		-0.28, (-2.21, 1.65)		0.775	
≥75 years	n / N(%)		1 / 16 (6.3)	0 / 5 (0.0)		
	RR, (95% CI)		1.06, (0.05, 22.63)		0.971	
	OR, (95% CI)		1.06, (0.04, 30.20)		0.971	
	ARR %, (95% CI)		6.25, (-5.62, 18.12)		0.302	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		4 / 346 (1.2)	2 / 173 (1.2)		
	RR, (95% CI)		1.00, (0.18, 5.41)		1.000	
	OR, (95% CI)		1.00, (0.18, 5.51)		1.000	
	ARR %, (95% CI)		0.00, (-1.95, 1.95)		1.000	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		1.000				0.775
Yes	n / N(%)		0 / 99 (0.0)	0 / 52 (0.0)		
	RR, (95% CI)		0.53, (0.01, 26.33)		0.750	
	OR, (95% CI)		0.53, (0.01, 26.97)		0.750	
	ARR %, (95% CI)		0.00, (-0.04, 0.04)		0.997	
No	n / N(%)		4 / 247 (1.6)	2 / 121 (1.7)		
	RR, (95% CI)		0.98, (0.18, 5.27)		0.981	
	OR, (95% CI)		0.98, (0.18, 5.42)		0.981	
	ARR %, (95% CI)		-0.03, (-2.80, 2.73)		0.981	
Sex		0.966				0.966
Male	n / N(%)		2 / 216 (0.9)	1 / 105 (1.0)		
	RR, (95% CI)		0.97, (0.09, 10.60)		0.982	
	OR, (95% CI)		0.97, (0.09, 10.84)		0.982	
	ARR %, (95% CI)		-0.03, (-2.28, 2.23)		0.982	
Female	n / N(%)		2 / 130 (1.5)	1 / 68 (1.5)		
	RR, (95% CI)		1.05, (0.10, 11.33)		0.970	
	OR, (95% CI)		1.05, (0.09, 11.76)		0.970	
	ARR %, (95% CI)		0.07, (-3.49, 3.63)		0.970	
Region		0.998				0.403
North America	n / N(%)		3 / 185 (1.6)	1 / 106 (0.9)		
	RR, (95% CI)		1.72, (0.18, 16.32)		0.637	
	OR, (95% CI)		1.73, (0.18, 16.85)		0.637	
	ARR %, (95% CI)		0.68, (-1.91, 3.27)		0.608	
United Kingdom	n / N(%)		1 / 80 (1.3)	0 / 30 (0.0)		
	RR, (95% CI)		1.15, (0.05, 27.44)		0.932	
	OR, (95% CI)		1.15, (0.05, 29.03)		0.932	
	ARR %, (95% CI)		1.25, (-1.19, 3.69)		0.315	
European Union	n / N(%)		0 / 81 (0.0)	1 / 37 (2.7)		
	RR, (95% CI)		0.15, (0.01, 3.70)		0.249	
	OR, (95% CI)		0.15, (0.01, 3.75)		0.248	
	ARR %, (95% CI)		-2.70, (-7.93, 2.52)		0.311	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		1.000				0.807
United States	n / N(%)		3 / 185 (1.6)	1 / 106 (0.9)		
	RR, (95% CI)		1.72, (0.18, 16.32)		0.637	
	OR, (95% CI)		1.73, (0.18, 16.85)		0.637	
	ARR %, (95% CI)		0.68, (-1.91, 3.27)		0.608	
United Kingdom	n / N(%)		1 / 80 (1.3)	0 / 30 (0.0)		
	RR, (95% CI)		1.15, (0.05, 27.44)		0.932	
	OR, (95% CI)		1.15, (0.05, 29.03)		0.932	
	ARR %, (95% CI)		1.25, (-1.19, 3.69)		0.315	
Belgium	n / N(%)		0 / 25 (0.0)	1 / 16 (6.3)		
	RR, (95% CI)		0.22, (0.01, 5.04)		0.342	
	OR, (95% CI)		0.20, (0.01, 5.29)		0.337	
	ARR %, (95% CI)		-6.25, (-18.11, 5.61)		0.302	
France	n / N(%)		0 / 38 (0.0)	0 / 16 (0.0)		
	RR, (95% CI)		0.44, (0.01, 21.07)		0.675	
	OR, (95% CI)		0.43, (0.01, 22.53)		0.675	
	ARR %, (95% CI)		0.00, (-0.13, 0.13)		0.996	
Spain	n / N(%)		0 / 18 (0.0)	0 / 5 (0.0)		
	RR, (95% CI)		0.32, (0.01, 14.27)		0.553	
	OR, (95% CI)		0.30, (0.01, 16.79)		0.556	
	ARR %, (95% CI)		0.00, (-0.41, 0.41)		0.994	
Race		0.999				0.855
Black or African American	n / N(%)		2 / 50 (4.0)	2 / 28 (7.1)		
	RR, (95% CI)		0.56, (0.08, 3.76)		0.551	
	OR, (95% CI)		0.54, (0.07, 4.07)		0.551	
	ARR %, (95% CI)		-3.14, (-14.12, 7.83)		0.575	
White	n / N(%)		2 / 264 (0.8)	0 / 126 (0.0)		
	RR, (95% CI)		2.40, (0.12, 49.55)		0.572	
	OR, (95% CI)		2.41, (0.11, 50.56)		0.571	
	ARR %, (95% CI)		0.76, (-0.29, 1.80)		0.156	
Other	n / N(%)		0 / 28 (0.0)	0 / 15 (0.0)		
	RR, (95% CI)		0.55, (0.01, 26.51)		0.763	
	OR, (95% CI)		0.54, (0.01, 28.77)		0.764	
	ARR %, (95% CI)		0.00, (-0.15, 0.15)		0.997	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		1.000				0.832
Hispanic or Latino	n / N(%)		0 / 40 (0.0)	0 / 12 (0.0)		
	RR, (95% CI)		0.32, (0.01, 15.20)		0.561	
	OR, (95% CI)		0.31, (0.01, 16.37)		0.562	
	ARR %, (95% CI)		0.00, (-0.17, 0.17)		0.995	
Not Hispanic or Latino	n / N(%)		4 / 275 (1.5)	2 / 144 (1.4)		
	RR, (95% CI)		1.05, (0.19, 5.65)		0.957	
	OR, (95% CI)		1.05, (0.19, 5.79)		0.957	
	ARR %, (95% CI)		0.07, (-2.31, 2.44)		0.957	
Other	n / N(%)		0 / 31 (0.0)	0 / 17 (0.0)		
	RR, (95% CI)		0.56, (0.01, 27.16)		0.771	
	OR, (95% CI)		0.56, (0.01, 29.24)		0.771	
	ARR %, (95% CI)		0.00, (-0.13, 0.13)		0.997	
COVID-19 co-morbidities at baseline		1.000				0.704
None	n / N(%)		0 / 101 (0.0)	0 / 46 (0.0)		
	RR, (95% CI)		0.46, (0.01, 22.87)		0.697	
	OR, (95% CI)		0.46, (0.01, 23.44)		0.697	
	ARR %, (95% CI)		0.00, (-0.05, 0.05)		0.996	
At least one	n / N(%)		4 / 245 (1.6)	2 / 127 (1.6)		
	RR, (95% CI)		1.04, (0.19, 5.58)		0.967	
	OR, (95% CI)		1.04, (0.19, 5.74)		0.967	
	ARR %, (95% CI)		0.06, (-2.63, 2.74)		0.966	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		4 / 346 (1.2)	2 / 173 (1.2)		
	RR, (95% CI)		1.00, (0.18, 5.41)		1.000	
	OR, (95% CI)		1.00, (0.18, 5.51)		1.000	
	ARR %, (95% CI)		0.00, (-1.95, 1.95)		1.000	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		1.000				0.705
Yes	n / N(%)		4 / 303 (1.3)	2 / 154 (1.3)		
	RR, (95% CI)		1.02, (0.19, 5.49)		0.985	
	OR, (95% CI)		1.02, (0.18, 5.61)		0.985	
	ARR %, (95% CI)		0.02, (-2.18, 2.22)		0.985	
No	n / N(%)		0 / 43 (0.0)	0 / 19 (0.0)		
	RR, (95% CI)		0.45, (0.01, 22.10)		0.691	
	OR, (95% CI)		0.45, (0.01, 23.43)		0.691	
	ARR %, (95% CI)		0.00, (-0.11, 0.11)		0.996	
Obesity (≥ 30 kg/m^2)		0.945				0.945
Yes	n / N(%)		2 / 119 (1.7)	1 / 55 (1.8)		
	RR, (95% CI)		0.92, (0.09, 9.98)		0.948	
	OR, (95% CI)		0.92, (0.08, 10.40)		0.948	
	ARR %, (95% CI)		-0.14, (-4.36, 4.08)		0.949	
No	n / N(%)		2 / 225 (0.9)	1 / 117 (0.9)		
	RR, (95% CI)		1.04, (0.10, 11.35)		0.974	
	OR, (95% CI)		1.04, (0.09, 11.59)		0.974	
	ARR %, (95% CI)		0.03, (-2.04, 2.10)		0.974	
Obesity (≥ 40 kg/m^2)		1.000				0.917
Yes	n / N(%)		0 / 17 (0.0)	0 / 13 (0.0)		
	RR, (95% CI)		0.78, (0.02, 36.81)		0.898	
	OR, (95% CI)		0.77, (0.01, 41.44)		0.898	
	ARR %, (95% CI)		0.00, (-0.19, 0.19)		0.999	
No	n / N(%)		4 / 327 (1.2)	2 / 159 (1.3)		
	RR, (95% CI)		0.97, (0.18, 5.25)		0.974	
	OR, (95% CI)		0.97, (0.18, 5.36)		0.974	
	ARR %, (95% CI)		-0.03, (-2.14, 2.07)		0.974	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.585				0.580
Yes	n / N(%)		1 / 38 (2.6)	1 / 21 (4.8)		
	RR, (95% CI)		0.55, (0.04, 8.39)		0.669	
	OR, (95% CI)		0.54, (0.03, 9.11)		0.669	
	ARR %, (95% CI)		-2.13, (-12.56, 8.30)		0.689	
No	n / N(%)		3 / 308 (1.0)	1 / 152 (0.7)		
	RR, (95% CI)		1.48, (0.16, 14.11)		0.733	
	OR, (95% CI)		1.49, (0.15, 14.40)		0.733	
	ARR %, (95% CI)		0.32, (-1.37, 2.01)		0.714	
Diabetes		0.641				0.638
Yes	n / N(%)		1 / 40 (2.5)	1 / 25 (4.0)		
	RR, (95% CI)		0.63, (0.04, 9.55)		0.735	
	OR, (95% CI)		0.62, (0.04, 10.30)		0.736	
	ARR %, (95% CI)		-1.50, (-10.58, 7.58)		0.746	
No	n / N(%)		3 / 306 (1.0)	1 / 148 (0.7)		
	RR, (95% CI)		1.45, (0.15, 13.83)		0.746	
	OR, (95% CI)		1.46, (0.15, 14.11)		0.746	
	ARR %, (95% CI)		0.30, (-1.42, 2.03)		0.729	
Immunosuppressive disease		1.000				0.804
Yes	n / N(%)		0 / 16 (0.0)	0 / 9 (0.0)		
	RR, (95% CI)		0.59, (0.01, 27.40)		0.787	
	OR, (95% CI)		0.58, (0.01, 31.45)		0.787	
	ARR %, (95% CI)		0.00, (-0.25, 0.25)		0.997	
No	n / N(%)		4 / 330 (1.2)	2 / 164 (1.2)		
	RR, (95% CI)		0.99, (0.18, 5.37)		0.994	
	OR, (95% CI)		0.99, (0.18, 5.48)		0.994	
	ARR %, (95% CI)		-0.01, (-2.06, 2.05)		0.994	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.970				0.612
Yes	n / N(%)		1 / 103 (1.0)	0 / 60 (0.0)		
	RR, (95% CI)		1.76, (0.07, 42.52)		0.728	
	OR, (95% CI)		1.77, (0.07, 44.16)		0.728	
	ARR %, (95% CI)		0.97, (-0.92, 2.86)		0.315	
No	n / N(%)		3 / 243 (1.2)	2 / 113 (1.8)		
	RR, (95% CI)		0.70, (0.12, 4.12)		0.691	
	OR, (95% CI)		0.69, (0.11, 4.21)		0.691	
	ARR %, (95% CI)		-0.54, (-3.33, 2.26)		0.708	
CV disease		0.980				0.556
Yes	n / N(%)		1 / 32 (3.1)	0 / 22 (0.0)		
	RR, (95% CI)		2.09, (0.09, 49.09)		0.647	
	OR, (95% CI)		2.14, (0.08, 55.04)		0.645	
	ARR %, (95% CI)		3.12, (-2.90, 9.15)		0.310	
No	n / N(%)		3 / 314 (1.0)	2 / 151 (1.3)		
	RR, (95% CI)		0.72, (0.12, 4.27)		0.719	
	OR, (95% CI)		0.72, (0.12, 4.35)		0.719	
	ARR %, (95% CI)		-0.37, (-2.49, 1.75)		0.733	
COPD		1.000				0.742
Yes	n / N(%)		0 / 23 (0.0)	0 / 11 (0.0)		
	RR, (95% CI)		0.50, (0.01, 23.69)		0.725	
	OR, (95% CI)		0.49, (0.01, 26.26)		0.725	
	ARR %, (95% CI)		0.00, (-0.20, 0.20)		0.996	
No	n / N(%)		4 / 323 (1.2)	2 / 162 (1.2)		
	RR, (95% CI)		1.00, (0.19, 5.42)		0.997	
	OR, (95% CI)		1.00, (0.18, 5.54)		0.997	
	ARR %, (95% CI)		0.00, (-2.08, 2.09)		0.997	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.977				0.419
Yes	n / N(%)		2 / 44 (4.5)	2 / 26 (7.7)		
	RR, (95% CI)		0.59, (0.09, 3.95)		0.587	
	OR, (95% CI)		0.57, (0.08, 4.32)		0.588	
	ARR %, (95% CI)		-3.15, (-15.10, 8.80)		0.606	
No	n / N(%)		2 / 302 (0.7)	0 / 147 (0.0)		
	RR, (95% CI)		2.44, (0.12, 50.55)		0.564	
	OR, (95% CI)		2.45, (0.12, 51.45)		0.563	
	ARR %, (95% CI)		0.66, (-0.25, 1.58)		0.156	
Hypertension		0.976				0.176
Yes	n / N(%)		4 / 153 (2.6)	1 / 75 (1.3)		
	RR, (95% CI)		1.96, (0.22, 17.24)		0.544	
	OR, (95% CI)		1.99, (0.22, 18.09)		0.542	
	ARR %, (95% CI)		1.28, (-2.34, 4.90)		0.488	
No	n / N(%)		0 / 193 (0.0)	1 / 98 (1.0)		
	RR, (95% CI)		0.17, (0.01, 4.14)		0.277	
	OR, (95% CI)		0.17, (0.01, 4.16)		0.276	
	ARR %, (95% CI)		-1.02, (-3.01, 0.97)		0.315	
Asthma		0.969				0.455
Yes	n / N(%)		2 / 55 (3.6)	0 / 21 (0.0)		
	RR, (95% CI)		1.96, (0.10, 39.30)		0.659	
	OR, (95% CI)		2.01, (0.09, 43.60)		0.657	
	ARR %, (95% CI)		3.64, (-1.31, 8.58)		0.150	
No	n / N(%)		2 / 291 (0.7)	2 / 152 (1.3)		
	RR, (95% CI)		0.52, (0.07, 3.67)		0.514	
	OR, (95% CI)		0.52, (0.07, 3.72)		0.514	
	ARR %, (95% CI)		-0.63, (-2.67, 1.42)		0.547	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		1.000				1.000
Yes	n / N(%)		2 / 60 (3.3)	1 / 30 (3.3)		
	RR, (95% CI)		1.00, (0.09, 10.59)		1.000	
	OR, (95% CI)		1.00, (0.09, 11.49)		1.000	
	ARR %, (95% CI)		0.00, (-7.87, 7.87)		1.000	
No	n / N(%)		2 / 286 (0.7)	1 / 143 (0.7)		
	RR, (95% CI)		1.00, (0.09, 10.94)		1.000	
	OR, (95% CI)		1.00, (0.09, 11.12)		1.000	
	ARR %, (95% CI)		0.00, (-1.67, 1.67)		1.000	
Smoking		0.536				0.529
Yes	n / N(%)		1 / 63 (1.6)	1 / 31 (3.2)		
	RR, (95% CI)		0.49, (0.03, 7.61)		0.612	
	OR, (95% CI)		0.48, (0.03, 8.00)		0.612	
	ARR %, (95% CI)		-1.64, (-8.58, 5.30)		0.644	
No	n / N(%)		3 / 283 (1.1)	1 / 142 (0.7)		
	RR, (95% CI)		1.51, (0.16, 14.34)		0.722	
	OR, (95% CI)		1.51, (0.16, 14.66)		0.722	
	ARR %, (95% CI)		0.36, (-1.46, 2.18)		0.702	
Sickle cell disease		NE				NE
No	n / N(%)		4 / 346 (1.2)	2 / 173 (1.2)		
	RR, (95% CI)		1.00, (0.18, 5.41)		1.000	
	OR, (95% CI)		1.00, (0.18, 5.51)		1.000	
	ARR %, (95% CI)		0.00, (-1.95, 1.95)		1.000	
COVID-19 vaccination at any time during the study		0.610				0.605
Yes	n / N(%)		1 / 242 (0.4)	1 / 127 (0.8)		
	RR, (95% CI)		0.52, (0.03, 8.32)		0.647	
	OR, (95% CI)		0.52, (0.03, 8.43)		0.648	
	ARR %, (95% CI)		-0.37, (-2.11, 1.36)		0.673	
No	n / N(%)		3 / 104 (2.9)	1 / 46 (2.2)		
	RR, (95% CI)		1.33, (0.14, 12.42)		0.804	
	OR, (95% CI)		1.34, (0.14, 13.20)		0.804	
	ARR %, (95% CI)		0.71, (-4.59, 6.01)		0.793	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.2
Adverse Events Overview by Subgroup - Participants with at least One AE with outcome of death
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		1.000				0.832
Yes	n / N(%)		4 / 344 (1.2)	2 / 172 (1.2)		
	RR, (95% CI)		1.00, (0.18, 5.41)		1.000	
	OR, (95% CI)		1.00, (0.18, 5.51)		1.000	
	ARR %, (95% CI)		0.00, (-1.96, 1.96)		1.000	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup – Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.419				0.418
<60 years	n / N(%)		18 / 199 (9.0)	7 / 97 (7.2)		
	RR, (95% CI)		1.25, (0.54, 2.90)		0.598	
	OR, (95% CI)		1.28, (0.52, 3.17)		0.596	
	ARR %, (95% CI)		1.83, (-4.68, 8.34)		0.582	
≥60 years	n / N(%)		17 / 147 (11.6)	11 / 76 (14.5)		
	RR, (95% CI)		0.80, (0.39, 1.62)		0.533	
	OR, (95% CI)		0.77, (0.34, 1.75)		0.535	
	ARR %, (95% CI)		-2.91, (-12.36, 6.54)		0.546	
Age at randomization		0.617				0.617
<65 years	n / N(%)		24 / 262 (9.2)	12 / 137 (8.8)		
	RR, (95% CI)		1.05, (0.54, 2.03)		0.894	
	OR, (95% CI)		1.05, (0.51, 2.17)		0.894	
	ARR %, (95% CI)		0.40, (-5.48, 6.28)		0.894	
≥65 years	n / N(%)		11 / 84 (13.1)	6 / 36 (16.7)		
	RR, (95% CI)		0.79, (0.31, 1.96)		0.605	
	OR, (95% CI)		0.75, (0.26, 2.22)		0.608	
	ARR %, (95% CI)		-3.57, (-17.72, 10.58)		0.621	
Age at randomization		0.194				0.175
<75 years	n / N(%)		33 / 330 (10.0)	16 / 168 (9.5)		
	RR, (95% CI)		1.05, (0.60, 1.85)		0.866	
	OR, (95% CI)		1.06, (0.56, 1.98)		0.866	
	ARR %, (95% CI)		0.48, (-5.02, 5.97)		0.865	
≥75 years	n / N(%)		2 / 16 (12.5)	2 / 5 (40.0)		
	RR, (95% CI)		0.31, (0.06, 1.68)		0.176	
	OR, (95% CI)		0.21, (0.02, 2.19)		0.194	
	ARR %, (95% CI)		-27.50, (-73.40, 18.40)		0.240	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup - Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		35 / 346 (10.1)	18 / 173 (10.4)		
	RR, (95% CI)		0.97, (0.57, 1.67)		0.918	
	OR, (95% CI)		0.97, (0.53, 1.77)		0.918	
	ARR %, (95% CI)		-0.29, (-5.84, 5.26)		0.919	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup – Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.649				0.648
Yes	n / N(%)		4 / 99 (4.0)	3 / 52 (5.8)		
	RR, (95% CI)		0.70, (0.16, 3.01)		0.632	
	OR, (95% CI)		0.69, (0.15, 3.20)		0.633	
	ARR %, (95% CI)		-1.73, (-9.16, 5.70)		0.648	
No	n / N(%)		31 / 247 (12.6)	15 / 121 (12.4)		
	RR, (95% CI)		1.01, (0.57, 1.80)		0.967	
	OR, (95% CI)		1.01, (0.52, 1.96)		0.967	
	ARR %, (95% CI)		0.15, (-7.03, 7.33)		0.966	
Sex		0.153				0.150
Male	n / N(%)		23 / 216 (10.6)	8 / 105 (7.6)		
	RR, (95% CI)		1.40, (0.65, 3.02)		0.394	
	OR, (95% CI)		1.44, (0.62, 3.35)		0.391	
	ARR %, (95% CI)		3.03, (-3.50, 9.56)		0.363	
Female	n / N(%)		12 / 130 (9.2)	10 / 68 (14.7)		
	RR, (95% CI)		0.63, (0.29, 1.38)		0.246	
	OR, (95% CI)		0.59, (0.24, 1.45)		0.248	
	ARR %, (95% CI)		-5.48, (-15.25, 4.30)		0.272	
Region		0.439				0.404
North America	n / N(%)		16 / 185 (8.6)	12 / 106 (11.3)		
	RR, (95% CI)		0.76, (0.38, 1.55)		0.457	
	OR, (95% CI)		0.74, (0.34, 1.63)		0.458	
	ARR %, (95% CI)		-2.67, (-9.94, 4.59)		0.471	
United Kingdom	n / N(%)		8 / 80 (10.0)	1 / 30 (3.3)		
	RR, (95% CI)		3.00, (0.39, 22.98)		0.290	
	OR, (95% CI)		3.22, (0.39, 26.93)		0.280	
	ARR %, (95% CI)		6.67, (-2.52, 15.86)		0.155	
European Union	n / N(%)		11 / 81 (13.6)	5 / 37 (13.5)		
	RR, (95% CI)		1.00, (0.38, 2.69)		0.992	
	OR, (95% CI)		1.01, (0.32, 3.13)		0.992	
	ARR %, (95% CI)		0.07, (-13.24, 13.37)		0.992	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup – Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		0.587				0.523
United States	n / N(%)		16 / 185 (8.6)	12 / 106 (11.3)		
	RR, (95% CI)		0.76, (0.38, 1.55)		0.457	
	OR, (95% CI)		0.74, (0.34, 1.63)		0.458	
	ARR %, (95% CI)		-2.67, (-9.94, 4.59)		0.471	
United Kingdom	n / N(%)		8 / 80 (10.0)	1 / 30 (3.3)		
	RR, (95% CI)		3.00, (0.39, 22.98)		0.290	
	OR, (95% CI)		3.22, (0.39, 26.93)		0.280	
	ARR %, (95% CI)		6.67, (-2.52, 15.86)		0.155	
Belgium	n / N(%)		2 / 25 (8.0)	3 / 16 (18.8)		
	RR, (95% CI)		0.43, (0.08, 2.28)		0.319	
	OR, (95% CI)		0.38, (0.06, 2.56)		0.318	
	ARR %, (95% CI)		-10.75, (-32.63, 11.13)		0.336	
France	n / N(%)		7 / 38 (18.4)	2 / 16 (12.5)		
	RR, (95% CI)		1.47, (0.34, 6.34)		0.602	
	OR, (95% CI)		1.58, (0.29, 8.60)		0.596	
	ARR %, (95% CI)		5.92, (-14.44, 26.28)		0.569	
Spain	n / N(%)		2 / 18 (11.1)	0 / 5 (0.0)		
	RR, (95% CI)		1.58, (0.09, 28.53)		0.757	
	OR, (95% CI)		1.67, (0.07, 40.32)		0.753	
	ARR %, (95% CI)		11.11, (-3.41, 25.63)		0.134	
Race		0.851				0.844
Black or African American	n / N(%)		6 / 50 (12.0)	5 / 28 (17.9)		
	RR, (95% CI)		0.67, (0.23, 2.00)		0.476	
	OR, (95% CI)		0.63, (0.17, 2.28)		0.478	
	ARR %, (95% CI)		-5.86, (-22.66, 10.95)		0.495	
White	n / N(%)		28 / 264 (10.6)	12 / 126 (9.5)		
	RR, (95% CI)		1.11, (0.59, 2.12)		0.743	
	OR, (95% CI)		1.13, (0.55, 2.30)		0.742	
	ARR %, (95% CI)		1.08, (-5.25, 7.41)		0.738	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup - Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Other	n / N(%)		1 / 28 (3.6)	1 / 15 (6.7)		
	RR, (95% CI)		0.54, (0.04, 7.97)		0.650	
	OR, (95% CI)		0.52, (0.03, 8.93)		0.651	
	ARR %, (95% CI)		-3.10, (-17.47, 11.28)		0.673	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup - Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		0.111				0.078
Hispanic or Latino	n / N(%)		2 / 40 (5.0)	3 / 12 (25.0)		
	RR, (95% CI)		0.20, (0.04, 1.06)		0.059	
	OR, (95% CI)		0.16, (0.02, 1.09)		0.061	
	ARR %, (95% CI)		-20.00, (-45.41, 5.41)		0.123	
Not Hispanic or Latino	n / N(%)		31 / 275 (11.3)	13 / 144 (9.0)		
	RR, (95% CI)		1.25, (0.67, 2.31)		0.479	
	OR, (95% CI)		1.28, (0.65, 2.53)		0.477	
	ARR %, (95% CI)		2.24, (-3.75, 8.24)		0.463	
Other	n / N(%)		2 / 31 (6.5)	2 / 17 (11.8)		
	RR, (95% CI)		0.55, (0.08, 3.55)		0.529	
	OR, (95% CI)		0.52, (0.07, 4.04)		0.530	
	ARR %, (95% CI)		-5.31, (-22.90, 12.28)		0.554	
COVID-19 co-morbidities at baseline		0.713				0.712
None	n / N(%)		8 / 101 (7.9)	3 / 46 (6.5)		
	RR, (95% CI)		1.21, (0.34, 4.37)		0.766	
	OR, (95% CI)		1.23, (0.31, 4.88)		0.765	
	ARR %, (95% CI)		1.40, (-7.47, 10.27)		0.757	
At least one	n / N(%)		27 / 245 (11.0)	15 / 127 (11.8)		
	RR, (95% CI)		0.93, (0.52, 1.69)		0.819	
	OR, (95% CI)		0.92, (0.47, 1.81)		0.819	
	ARR %, (95% CI)		-0.79, (-7.64, 6.06)		0.821	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		35 / 346 (10.1)	18 / 173 (10.4)		
	RR, (95% CI)		0.97, (0.57, 1.67)		0.918	
	OR, (95% CI)		0.97, (0.53, 1.77)		0.918	
	ARR %, (95% CI)		-0.29, (-5.84, 5.26)		0.919	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup – Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.290				0.271
Yes	n / N(%)		29 / 303 (9.6)	17 / 154 (11.0)		
	RR, (95% CI)		0.87, (0.49, 1.53)		0.621	
	OR, (95% CI)		0.85, (0.45, 1.61)		0.622	
	ARR %, (95% CI)		-1.47, (-7.42, 4.49)		0.629	
No	n / N(%)		6 / 43 (14.0)	1 / 19 (5.3)		
	RR, (95% CI)		2.65, (0.34, 20.53)		0.351	
	OR, (95% CI)		2.92, (0.33, 26.10)		0.338	
	ARR %, (95% CI)		8.69, (-5.73, 23.12)		0.238	
Obesity (≥ 30 kg/m^2)		0.551				0.550
Yes	n / N(%)		8 / 119 (6.7)	5 / 55 (9.1)		
	RR, (95% CI)		0.74, (0.25, 2.16)		0.581	
	OR, (95% CI)		0.72, (0.22, 2.31)		0.582	
	ARR %, (95% CI)		-2.37, (-11.20, 6.46)		0.599	
No	n / N(%)		27 / 225 (12.0)	13 / 117 (11.1)		
	RR, (95% CI)		1.08, (0.58, 2.01)		0.809	
	OR, (95% CI)		1.09, (0.54, 2.20)		0.808	
	ARR %, (95% CI)		0.89, (-6.21, 7.99)		0.806	
Obesity (≥ 40 kg/m^2)		0.864				0.864
Yes	n / N(%)		1 / 17 (5.9)	1 / 13 (7.7)		
	RR, (95% CI)		0.76, (0.05, 11.11)		0.844	
	OR, (95% CI)		0.75, (0.04, 13.24)		0.844	
	ARR %, (95% CI)		-1.81, (-20.11, 16.49)		0.846	
No	n / N(%)		34 / 327 (10.4)	17 / 159 (10.7)		
	RR, (95% CI)		0.97, (0.56, 1.69)		0.921	
	OR, (95% CI)		0.97, (0.52, 1.79)		0.921	
	ARR %, (95% CI)		-0.29, (-6.13, 5.54)		0.921	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup – Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.709				0.709
Yes	n / N(%)		13 / 38 (34.2)	8 / 21 (38.1)		
	RR, (95% CI)		0.90, (0.45, 1.81)		0.764	
	OR, (95% CI)		0.85, (0.28, 2.56)		0.766	
	ARR %, (95% CI)		-3.88, (-29.55, 21.78)		0.767	
No	n / N(%)		22 / 308 (7.1)	10 / 152 (6.6)		
	RR, (95% CI)		1.09, (0.53, 2.23)		0.823	
	OR, (95% CI)		1.09, (0.50, 2.37)		0.823	
	ARR %, (95% CI)		0.56, (-4.32, 5.44)		0.821	
Diabetes		0.463				0.462
Yes	n / N(%)		7 / 40 (17.5)	6 / 25 (24.0)		
	RR, (95% CI)		0.73, (0.28, 1.92)		0.523	
	OR, (95% CI)		0.67, (0.20, 2.29)		0.525	
	ARR %, (95% CI)		-6.50, (-26.97, 13.97)		0.534	
No	n / N(%)		28 / 306 (9.2)	12 / 148 (8.1)		
	RR, (95% CI)		1.13, (0.59, 2.16)		0.714	
	OR, (95% CI)		1.14, (0.56, 2.31)		0.714	
	ARR %, (95% CI)		1.04, (-4.41, 6.50)		0.708	
Immunosuppressive disease		0.530				0.526
Yes	n / N(%)		2 / 16 (12.5)	2 / 9 (22.2)		
	RR, (95% CI)		0.56, (0.09, 3.34)		0.527	
	OR, (95% CI)		0.50, (0.06, 4.33)		0.529	
	ARR %, (95% CI)		-9.72, (-41.35, 21.91)		0.547	
No	n / N(%)		33 / 330 (10.0)	16 / 164 (9.8)		
	RR, (95% CI)		1.03, (0.58, 1.81)		0.932	
	OR, (95% CI)		1.03, (0.55, 1.93)		0.932	
	ARR %, (95% CI)		0.24, (-5.33, 5.82)		0.932	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup – Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.556				0.556
Yes	n / N(%)		11 / 103 (10.7)	8 / 60 (13.3)		
	RR, (95% CI)		0.80, (0.34, 1.88)		0.610	
	OR, (95% CI)		0.78, (0.29, 2.05)		0.611	
	ARR %, (95% CI)		-2.65, (-13.12, 7.81)		0.619	
No	n / N(%)		24 / 243 (9.9)	10 / 113 (8.8)		
	RR, (95% CI)		1.12, (0.55, 2.25)		0.760	
	OR, (95% CI)		1.13, (0.52, 2.45)		0.759	
	ARR %, (95% CI)		1.03, (-5.41, 7.47)		0.755	
CV disease		0.865				0.865
Yes	n / N(%)		8 / 32 (25.0)	5 / 22 (22.7)		
	RR, (95% CI)		1.10, (0.41, 2.92)		0.848	
	OR, (95% CI)		1.13, (0.32, 4.07)		0.848	
	ARR %, (95% CI)		2.27, (-20.79, 25.33)		0.847	
No	n / N(%)		27 / 314 (8.6)	13 / 151 (8.6)		
	RR, (95% CI)		1.00, (0.53, 1.88)		0.997	
	OR, (95% CI)		1.00, (0.50, 2.00)		0.997	
	ARR %, (95% CI)		-0.01, (-5.45, 5.43)		0.997	
COPD		0.077				0.069
Yes	n / N(%)		4 / 23 (17.4)	5 / 11 (45.5)		
	RR, (95% CI)		0.38, (0.13, 1.15)		0.087	
	OR, (95% CI)		0.25, (0.05, 1.26)		0.093	
	ARR %, (95% CI)		-28.06, (-61.32, 5.19)		0.098	
No	n / N(%)		31 / 323 (9.6)	13 / 162 (8.0)		
	RR, (95% CI)		1.20, (0.64, 2.22)		0.571	
	OR, (95% CI)		1.22, (0.62, 2.39)		0.570	
	ARR %, (95% CI)		1.57, (-3.70, 6.85)		0.559	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup – Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.105				0.094
Yes	n / N(%)		3 / 44 (6.8)	5 / 26 (19.2)		
	RR, (95% CI)		0.35, (0.09, 1.36)		0.131	
	OR, (95% CI)		0.31, (0.07, 1.41)		0.129	
	ARR %, (95% CI)		-12.41, (-29.29, 4.47)		0.150	
No	n / N(%)		32 / 302 (10.6)	13 / 147 (8.8)		
	RR, (95% CI)		1.20, (0.65, 2.21)		0.564	
	OR, (95% CI)		1.22, (0.62, 2.40)		0.562	
	ARR %, (95% CI)		1.75, (-4.00, 7.51)		0.551	
Hypertension		0.324				0.322
Yes	n / N(%)		21 / 153 (13.7)	13 / 75 (17.3)		
	RR, (95% CI)		0.79, (0.42, 1.49)		0.471	
	OR, (95% CI)		0.76, (0.36, 1.61)		0.473	
	ARR %, (95% CI)		-3.61, (-13.76, 6.55)		0.486	
No	n / N(%)		14 / 193 (7.3)	5 / 98 (5.1)		
	RR, (95% CI)		1.42, (0.53, 3.83)		0.487	
	OR, (95% CI)		1.45, (0.51, 4.16)		0.485	
	ARR %, (95% CI)		2.15, (-3.54, 7.84)		0.459	
Asthma		0.639				0.638
Yes	n / N(%)		7 / 55 (12.7)	2 / 21 (9.5)		
	RR, (95% CI)		1.34, (0.30, 5.92)		0.703	
	OR, (95% CI)		1.39, (0.26, 7.28)		0.700	
	ARR %, (95% CI)		3.20, (-12.13, 18.54)		0.682	
No	n / N(%)		28 / 291 (9.6)	16 / 152 (10.5)		
	RR, (95% CI)		0.91, (0.51, 1.64)		0.762	
	OR, (95% CI)		0.90, (0.47, 1.73)		0.763	
	ARR %, (95% CI)		-0.90, (-6.84, 5.04)		0.765	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup – Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.221				0.214
Yes	n / N(%)		11 / 60 (18.3)	3 / 30 (10.0)		
	RR, (95% CI)		1.83, (0.55, 6.08)		0.322	
	OR, (95% CI)		2.02, (0.52, 7.87)		0.311	
	ARR %, (95% CI)		8.33, (-6.20, 22.86)		0.261	
No	n / N(%)		24 / 286 (8.4)	15 / 143 (10.5)		
	RR, (95% CI)		0.80, (0.43, 1.48)		0.476	
	OR, (95% CI)		0.78, (0.40, 1.54)		0.477	
	ARR %, (95% CI)		-2.10, (-8.06, 3.86)		0.490	
Smoking		0.988				0.988
Yes	n / N(%)		4 / 63 (6.3)	2 / 31 (6.5)		
	RR, (95% CI)		0.98, (0.19, 5.08)		0.985	
	OR, (95% CI)		0.98, (0.17, 5.68)		0.985	
	ARR %, (95% CI)		-0.10, (-10.64, 10.44)		0.985	
No	n / N(%)		31 / 283 (11.0)	16 / 142 (11.3)		
	RR, (95% CI)		0.97, (0.55, 1.72)		0.923	
	OR, (95% CI)		0.97, (0.51, 1.84)		0.923	
	ARR %, (95% CI)		-0.31, (-6.66, 6.03)		0.923	
Sickle cell disease		NE				NE
No	n / N(%)		35 / 346 (10.1)	18 / 173 (10.4)		
	RR, (95% CI)		0.97, (0.57, 1.67)		0.918	
	OR, (95% CI)		0.97, (0.53, 1.77)		0.918	
	ARR %, (95% CI)		-0.29, (-5.84, 5.26)		0.919	
COVID-19 vaccination at any time during the study		0.116				0.111
Yes	n / N(%)		27 / 242 (11.2)	11 / 127 (8.7)		
	RR, (95% CI)		1.29, (0.66, 2.51)		0.457	
	OR, (95% CI)		1.32, (0.63, 2.77)		0.455	
	ARR %, (95% CI)		2.50, (-3.80, 8.79)		0.437	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup - Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		8 / 104 (7.7)	7 / 46 (15.2)		
	RR, (95% CI)		0.51, (0.19, 1.31)		0.161	
	OR, (95% CI)		0.46, (0.16, 1.37)		0.164	
	ARR %, (95% CI)		-7.53, (-19.10, 4.05)		0.203	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.3
Adverse Events Overview by Subgroup - Participants with at least One SAE
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.979				0.559
Yes	n / N(%)		34 / 344 (9.9)	18 / 172 (10.5)		
	RR, (95% CI)		0.94, (0.55, 1.62)		0.836	
	OR, (95% CI)		0.94, (0.51, 1.72)		0.836	
	ARR %, (95% CI)		-0.58, (-6.14, 4.97)		0.838	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk; SAE = Serious Adverse Event.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP. SAEs are those events recorded as "Serious" on the AE page of the eCRF.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.597				0.595
<60 years	n / N(%)		16 / 199 (8.0)	3 / 97 (3.1)		
	RR, (95% CI)		2.60, (0.78, 8.71)		0.121	
	OR, (95% CI)		2.74, (0.78, 9.64)		0.116	
	ARR %, (95% CI)		4.95, (-0.17, 10.06)		0.058	
≥60 years	n / N(%)		6 / 147 (4.1)	2 / 76 (2.6)		
	RR, (95% CI)		1.55, (0.32, 7.50)		0.585	
	OR, (95% CI)		1.57, (0.31, 7.99)		0.584	
	ARR %, (95% CI)		1.45, (-3.36, 6.26)		0.555	
Age at randomization		0.215				0.198
<65 years	n / N(%)		18 / 262 (6.9)	3 / 137 (2.2)		
	RR, (95% CI)		3.14, (0.94, 10.47)		0.063	
	OR, (95% CI)		3.30, (0.95, 11.39)		0.060	
	ARR %, (95% CI)		4.68, (0.76, 8.60)		0.019	
≥65 years	n / N(%)		4 / 84 (4.8)	2 / 36 (5.6)		
	RR, (95% CI)		0.86, (0.16, 4.47)		0.855	
	OR, (95% CI)		0.85, (0.15, 4.86)		0.855	
	ARR %, (95% CI)		-0.79, (-9.55, 7.97)		0.859	
Age at randomization		0.974				0.676
<75 years	n / N(%)		21 / 330 (6.4)	5 / 168 (3.0)		
	RR, (95% CI)		2.14, (0.82, 5.57)		0.120	
	OR, (95% CI)		2.22, (0.82, 5.98)		0.117	
	ARR %, (95% CI)		3.39, (-0.29, 7.07)		0.071	
≥75 years	n / N(%)		1 / 16 (6.3)	0 / 5 (0.0)		
	RR, (95% CI)		1.06, (0.05, 22.63)		0.971	
	OR, (95% CI)		1.06, (0.04, 30.20)		0.971	
	ARR %, (95% CI)		6.25, (-5.62, 18.12)		0.302	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		22 / 346 (6.4)	5 / 173 (2.9)		
	RR, (95% CI)		2.20, (0.85, 5.71)		0.105	
	OR, (95% CI)		2.28, (0.85, 6.13)		0.102	
	ARR %, (95% CI)		3.47, (-0.12, 7.05)		0.058	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.975				0.301
Yes	n / N(%)		6 / 99 (6.1)	0 / 52 (0.0)		
	RR, (95% CI)		6.89, (0.40, 119.96)		0.185	
	OR, (95% CI)		7.30, (0.40, 132.16)		0.179	
	ARR %, (95% CI)		6.06, (1.36, 10.76)		0.011	
No	n / N(%)		16 / 247 (6.5)	5 / 121 (4.1)		
	RR, (95% CI)		1.57, (0.59, 4.18)		0.369	
	OR, (95% CI)		1.61, (0.57, 4.50)		0.366	
	ARR %, (95% CI)		2.35, (-2.34, 7.04)		0.327	
Sex		0.754				0.753
Male	n / N(%)		11 / 216 (5.1)	2 / 105 (1.9)		
	RR, (95% CI)		2.67, (0.60, 11.85)		0.195	
	OR, (95% CI)		2.76, (0.60, 12.70)		0.191	
	ARR %, (95% CI)		3.19, (-0.74, 7.12)		0.112	
Female	n / N(%)		11 / 130 (8.5)	3 / 68 (4.4)		
	RR, (95% CI)		1.92, (0.55, 6.64)		0.304	
	OR, (95% CI)		2.00, (0.54, 7.44)		0.299	
	ARR %, (95% CI)		4.05, (-2.78, 10.88)		0.245	
Region		0.475				0.450
North America	n / N(%)		8 / 185 (4.3)	1 / 106 (0.9)		
	RR, (95% CI)		4.58, (0.58, 36.15)		0.148	
	OR, (95% CI)		4.75, (0.59, 38.48)		0.145	
	ARR %, (95% CI)		3.38, (-0.08, 6.84)		0.056	
United Kingdom	n / N(%)		7 / 80 (8.8)	1 / 30 (3.3)		
	RR, (95% CI)		2.63, (0.34, 20.45)		0.357	
	OR, (95% CI)		2.78, (0.33, 23.61)		0.349	
	ARR %, (95% CI)		5.42, (-3.51, 14.34)		0.234	
European Union	n / N(%)		7 / 81 (8.6)	3 / 37 (8.1)		
	RR, (95% CI)		1.07, (0.29, 3.89)		0.923	
	OR, (95% CI)		1.07, (0.26, 4.40)		0.923	
	ARR %, (95% CI)		0.53, (-10.18, 11.25)		0.922	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		0.731				0.661
United States	n / N(%)		8 / 185 (4.3)	1 / 106 (0.9)		
	RR, (95% CI)		4.58, (0.58, 36.15)		0.148	
	OR, (95% CI)		4.75, (0.59, 38.48)		0.145	
	ARR %, (95% CI)		3.38, (-0.08, 6.84)		0.056	
United Kingdom	n / N(%)		7 / 80 (8.8)	1 / 30 (3.3)		
	RR, (95% CI)		2.63, (0.34, 20.45)		0.357	
	OR, (95% CI)		2.78, (0.33, 23.61)		0.349	
	ARR %, (95% CI)		5.42, (-3.51, 14.34)		0.234	
Belgium	n / N(%)		2 / 25 (8.0)	2 / 16 (12.5)		
	RR, (95% CI)		0.64, (0.10, 4.10)		0.638	
	OR, (95% CI)		0.61, (0.08, 4.82)		0.638	
	ARR %, (95% CI)		-4.50, (-23.88, 14.88)		0.649	
France	n / N(%)		4 / 38 (10.5)	1 / 16 (6.3)		
	RR, (95% CI)		1.68, (0.20, 13.92)		0.629	
	OR, (95% CI)		1.76, (0.18, 17.15)		0.624	
	ARR %, (95% CI)		4.28, (-11.08, 19.63)		0.585	
Spain	n / N(%)		1 / 18 (5.6)	0 / 5 (0.0)		
	RR, (95% CI)		0.95, (0.04, 20.33)		0.972	
	OR, (95% CI)		0.94, (0.03, 26.63)		0.972	
	ARR %, (95% CI)		5.55, (-5.04, 16.14)		0.304	
Race		0.999				0.263
Black or African American	n / N(%)		0 / 50 (0.0)	1 / 28 (3.6)		
	RR, (95% CI)		0.19, (0.01, 4.50)		0.304	
	OR, (95% CI)		0.18, (0.01, 4.61)		0.301	
	ARR %, (95% CI)		-3.57, (-10.45, 3.30)		0.309	
White	n / N(%)		22 / 264 (8.3)	4 / 126 (3.2)		
	RR, (95% CI)		2.63, (0.92, 7.46)		0.070	
	OR, (95% CI)		2.77, (0.93, 8.23)		0.066	
	ARR %, (95% CI)		5.16, (0.63, 9.68)		0.025	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Other	n / N(%)		0 / 28 (0.0)	0 / 15 (0.0)		
	RR, (95% CI)		0.55, (0.01, 26.51)		0.763	
	OR, (95% CI)		0.54, (0.01, 28.77)		0.764	
	ARR %, (95% CI)		0.00, (-0.15, 0.15)		0.997	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		1.000				0.690
Hispanic or Latino	n / N(%)		1 / 40 (2.5)	0 / 12 (0.0)		
	RR, (95% CI)		0.95, (0.04, 21.96)		0.975	
	OR, (95% CI)		0.95, (0.04, 24.81)		0.975	
	ARR %, (95% CI)		2.50, (-2.34, 7.34)		0.312	
Not Hispanic or Latino	n / N(%)		21 / 275 (7.6)	5 / 144 (3.5)		
	RR, (95% CI)		2.20, (0.85, 5.71)		0.105	
	OR, (95% CI)		2.30, (0.85, 6.23)		0.102	
	ARR %, (95% CI)		4.16, (-0.17, 8.50)		0.060	
Other	n / N(%)		0 / 31 (0.0)	0 / 17 (0.0)		
	RR, (95% CI)		0.56, (0.01, 27.16)		0.771	
	OR, (95% CI)		0.56, (0.01, 29.24)		0.771	
	ARR %, (95% CI)		0.00, (-0.13, 0.13)		0.997	
COVID-19 co-morbidities at baseline		0.145				0.123
None	n / N(%)		3 / 101 (3.0)	2 / 46 (4.3)		
	RR, (95% CI)		0.68, (0.12, 3.95)		0.670	
	OR, (95% CI)		0.67, (0.11, 4.17)		0.671	
	ARR %, (95% CI)		-1.38, (-8.14, 5.38)		0.690	
At least one	n / N(%)		19 / 245 (7.8)	3 / 127 (2.4)		
	RR, (95% CI)		3.28, (0.99, 10.89)		0.052	
	OR, (95% CI)		3.47, (1.01, 11.97)		0.048	
	ARR %, (95% CI)		5.39, (1.13, 9.66)		0.013	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		22 / 346 (6.4)	5 / 173 (2.9)		
	RR, (95% CI)		2.20, (0.85, 5.71)		0.105	
	OR, (95% CI)		2.28, (0.85, 6.13)		0.102	
	ARR %, (95% CI)		3.47, (-0.12, 7.05)		0.058	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup – Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.422				0.406
Yes	n / N(%)		20 / 303 (6.6)	4 / 154 (2.6)		
	RR, (95% CI)		2.54, (0.88, 7.30)		0.083	
	OR, (95% CI)		2.65, (0.89, 7.90)		0.080	
	ARR %, (95% CI)		4.00, (0.24, 7.76)		0.037	
No	n / N(%)		2 / 43 (4.7)	1 / 19 (5.3)		
	RR, (95% CI)		0.88, (0.09, 9.16)		0.917	
	OR, (95% CI)		0.88, (0.07, 10.31)		0.918	
	ARR %, (95% CI)		-0.61, (-12.46, 11.24)		0.919	
Obesity (≥ 30 kg/m^2)		0.974				0.292
Yes	n / N(%)		7 / 119 (5.9)	0 / 55 (0.0)		
	RR, (95% CI)		7.00, (0.41, 120.42)		0.180	
	OR, (95% CI)		7.40, (0.42, 131.92)		0.173	
	ARR %, (95% CI)		5.88, (1.65, 10.11)		0.006	
No	n / N(%)		15 / 225 (6.7)	5 / 117 (4.3)		
	RR, (95% CI)		1.56, (0.58, 4.19)		0.377	
	OR, (95% CI)		1.60, (0.57, 4.52)		0.375	
	ARR %, (95% CI)		2.39, (-2.51, 7.30)		0.339	
Obesity (≥ 40 kg/m^2)		0.998				0.600
Yes	n / N(%)		0 / 17 (0.0)	0 / 13 (0.0)		
	RR, (95% CI)		0.78, (0.02, 36.81)		0.898	
	OR, (95% CI)		0.77, (0.01, 41.44)		0.898	
	ARR %, (95% CI)		0.00, (-0.19, 0.19)		0.999	
No	n / N(%)		22 / 327 (6.7)	5 / 159 (3.1)		
	RR, (95% CI)		2.14, (0.83, 5.55)		0.118	
	OR, (95% CI)		2.22, (0.83, 5.98)		0.114	
	ARR %, (95% CI)		3.58, (-0.25, 7.42)		0.067	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.977				0.824
Yes	n / N(%)		2 / 38 (5.3)	0 / 21 (0.0)		
	RR, (95% CI)		2.82, (0.14, 56.15)		0.497	
	OR, (95% CI)		2.95, (0.13, 64.26)		0.492	
	ARR %, (95% CI)		5.26, (-1.84, 12.36)		0.146	
No	n / N(%)		20 / 308 (6.5)	5 / 152 (3.3)		
	RR, (95% CI)		1.97, (0.76, 5.16)		0.165	
	OR, (95% CI)		2.04, (0.75, 5.55)		0.162	
	ARR %, (95% CI)		3.20, (-0.75, 7.16)		0.112	
Diabetes		0.343				0.314
Yes	n / N(%)		1 / 40 (2.5)	1 / 25 (4.0)		
	RR, (95% CI)		0.63, (0.04, 9.55)		0.735	
	OR, (95% CI)		0.62, (0.04, 10.30)		0.736	
	ARR %, (95% CI)		-1.50, (-10.58, 7.58)		0.746	
No	n / N(%)		21 / 306 (6.9)	4 / 148 (2.7)		
	RR, (95% CI)		2.54, (0.89, 7.26)		0.082	
	OR, (95% CI)		2.65, (0.89, 7.87)		0.079	
	ARR %, (95% CI)		4.16, (0.31, 8.01)		0.034	
Immunosuppressive disease		0.303				0.271
Yes	n / N(%)		1 / 16 (6.3)	1 / 9 (11.1)		
	RR, (95% CI)		0.56, (0.04, 7.95)		0.670	
	OR, (95% CI)		0.53, (0.03, 9.71)		0.671	
	ARR %, (95% CI)		-4.86, (-28.57, 18.85)		0.688	
No	n / N(%)		21 / 330 (6.4)	4 / 164 (2.4)		
	RR, (95% CI)		2.61, (0.91, 7.48)		0.074	
	OR, (95% CI)		2.72, (0.92, 8.05)		0.071	
	ARR %, (95% CI)		3.92, (0.39, 7.46)		0.030	

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Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.758				0.757
Yes	n / N(%)		5 / 103 (4.9)	1 / 60 (1.7)		
	RR, (95% CI)		2.91, (0.35, 24.35)		0.324	
	OR, (95% CI)		3.01, (0.34, 26.40)		0.320	
	ARR %, (95% CI)		3.19, (-2.08, 8.45)		0.235	
No	n / N(%)		17 / 243 (7.0)	4 / 113 (3.5)		
	RR, (95% CI)		1.98, (0.68, 5.74)		0.210	
	OR, (95% CI)		2.05, (0.67, 6.24)		0.206	
	ARR %, (95% CI)		3.46, (-1.22, 8.14)		0.148	
CV disease		0.974				0.362
Yes	n / N(%)		4 / 32 (12.5)	0 / 22 (0.0)		
	RR, (95% CI)		6.27, (0.35, 110.95)		0.210	
	OR, (95% CI)		7.11, (0.36, 138.99)		0.196	
	ARR %, (95% CI)		12.50, (1.04, 23.96)		0.033	
No	n / N(%)		18 / 314 (5.7)	5 / 151 (3.3)		
	RR, (95% CI)		1.73, (0.66, 4.57)		0.268	
	OR, (95% CI)		1.78, (0.65, 4.88)		0.265	
	ARR %, (95% CI)		2.42, (-1.42, 6.26)		0.217	
COPD		0.998				0.424
Yes	n / N(%)		0 / 23 (0.0)	0 / 11 (0.0)		
	RR, (95% CI)		0.50, (0.01, 23.69)		0.725	
	OR, (95% CI)		0.49, (0.01, 26.26)		0.725	
	ARR %, (95% CI)		0.00, (-0.20, 0.20)		0.996	
No	n / N(%)		22 / 323 (6.8)	5 / 162 (3.1)		
	RR, (95% CI)		2.21, (0.85, 5.72)		0.103	
	OR, (95% CI)		2.30, (0.85, 6.18)		0.100	
	ARR %, (95% CI)		3.72, (-0.10, 7.55)		0.056	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.999				0.500
Yes	n / N(%)		0 / 44 (0.0)	0 / 26 (0.0)		
	RR, (95% CI)		0.60, (0.01, 29.37)		0.797	
	OR, (95% CI)		0.60, (0.01, 30.91)		0.797	
	ARR %, (95% CI)		0.00, (-0.09, 0.09)		0.997	
No	n / N(%)		22 / 302 (7.3)	5 / 147 (3.4)		
	RR, (95% CI)		2.14, (0.83, 5.54)		0.116	
	OR, (95% CI)		2.23, (0.83, 6.02)		0.113	
	ARR %, (95% CI)		3.88, (-0.26, 8.03)		0.066	
Hypertension		0.883				0.883
Yes	n / N(%)		14 / 153 (9.2)	3 / 75 (4.0)		
	RR, (95% CI)		2.29, (0.68, 7.72)		0.182	
	OR, (95% CI)		2.42, (0.67, 8.69)		0.176	
	ARR %, (95% CI)		5.15, (-1.22, 11.52)		0.113	
No	n / N(%)		8 / 193 (4.1)	2 / 98 (2.0)		
	RR, (95% CI)		2.03, (0.44, 9.38)		0.364	
	OR, (95% CI)		2.08, (0.43, 9.97)		0.362	
	ARR %, (95% CI)		2.10, (-1.86, 6.07)		0.299	
Asthma		0.628				0.625
Yes	n / N(%)		8 / 55 (14.5)	1 / 21 (4.8)		
	RR, (95% CI)		3.05, (0.41, 22.96)		0.278	
	OR, (95% CI)		3.40, (0.40, 29.04)		0.263	
	ARR %, (95% CI)		9.78, (-3.25, 22.81)		0.141	
No	n / N(%)		14 / 291 (4.8)	4 / 152 (2.6)		
	RR, (95% CI)		1.83, (0.61, 5.46)		0.280	
	OR, (95% CI)		1.87, (0.60, 5.78)		0.277	
	ARR %, (95% CI)		2.18, (-1.36, 5.72)		0.227	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.970				0.312
Yes	n / N(%)		6 / 60 (10.0)	0 / 30 (0.0)		
	RR, (95% CI)		6.61, (0.38, 113.50)		0.193	
	OR, (95% CI)		7.28, (0.40, 133.60)		0.181	
	ARR %, (95% CI)		10.00, (2.41, 17.59)		0.010	
No	n / N(%)		16 / 286 (5.6)	5 / 143 (3.5)		
	RR, (95% CI)		1.60, (0.60, 4.28)		0.349	
	OR, (95% CI)		1.64, (0.59, 4.56)		0.347	
	ARR %, (95% CI)		2.10, (-1.92, 6.12)		0.306	
Smoking		0.972				0.700
Yes	n / N(%)		3 / 63 (4.8)	0 / 31 (0.0)		
	RR, (95% CI)		3.50, (0.19, 65.72)		0.402	
	OR, (95% CI)		3.64, (0.18, 72.79)		0.397	
	ARR %, (95% CI)		4.76, (-0.50, 10.02)		0.076	
No	n / N(%)		19 / 283 (6.7)	5 / 142 (3.5)		
	RR, (95% CI)		1.91, (0.73, 5.00)		0.190	
	OR, (95% CI)		1.97, (0.72, 5.40)		0.186	
	ARR %, (95% CI)		3.19, (-1.01, 7.40)		0.137	
Sickle cell disease		NE				NE
No	n / N(%)		22 / 346 (6.4)	5 / 173 (2.9)		
	RR, (95% CI)		2.20, (0.85, 5.71)		0.105	
	OR, (95% CI)		2.28, (0.85, 6.13)		0.102	
	ARR %, (95% CI)		3.47, (-0.12, 7.05)		0.058	
COVID-19 vaccination at any time during the study		0.979				0.786
Yes	n / N(%)		19 / 242 (7.9)	5 / 127 (3.9)		
	RR, (95% CI)		1.99, (0.76, 5.22)		0.159	
	OR, (95% CI)		2.08, (0.76, 5.71)		0.155	
	ARR %, (95% CI)		3.91, (-0.87, 8.70)		0.109	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		3 / 104 (2.9)	0 / 46 (0.0)		
	RR, (95% CI)		3.13, (0.17, 59.46)		0.447	
	OR, (95% CI)		3.21, (0.16, 63.35)		0.444	
	ARR %, (95% CI)		2.88, (-0.33, 6.10)		0.079	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.6
Adverse Events Overview by Subgroup - Participants with at least One AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.999				0.548
Yes	n / N(%)		22 / 344 (6.4)	5 / 172 (2.9)		
	RR, (95% CI)		2.20, (0.85, 5.71)		0.105	
	OR, (95% CI)		2.28, (0.85, 6.13)		0.102	
	ARR %, (95% CI)		3.49, (-0.12, 7.09)		0.058	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.575				0.572
<60 years	n / N(%)		14 / 199 (7.0)	3 / 97 (3.1)		
	RR, (95% CI)		2.27, (0.67, 7.73)		0.188	
	OR, (95% CI)		2.37, (0.66, 8.46)		0.183	
	ARR %, (95% CI)		3.94, (-1.01, 8.89)		0.118	
≥60 years	n / N(%)		5 / 147 (3.4)	2 / 76 (2.6)		
	RR, (95% CI)		1.29, (0.26, 6.51)		0.756	
	OR, (95% CI)		1.30, (0.25, 6.88)		0.755	
	ARR %, (95% CI)		0.77, (-3.87, 5.41)		0.745	
Age at randomization		0.177				0.157
<65 years	n / N(%)		16 / 262 (6.1)	3 / 137 (2.2)		
	RR, (95% CI)		2.79, (0.83, 9.41)		0.098	
	OR, (95% CI)		2.91, (0.83, 10.15)		0.095	
	ARR %, (95% CI)		3.92, (0.12, 7.71)		0.043	
≥65 years	n / N(%)		3 / 84 (3.6)	2 / 36 (5.6)		
	RR, (95% CI)		0.64, (0.11, 3.68)		0.620	
	OR, (95% CI)		0.63, (0.10, 3.94)		0.621	
	ARR %, (95% CI)		-1.98, (-10.45, 6.49)		0.646	
Age at randomization		0.975				0.747
<75 years	n / N(%)		18 / 330 (5.5)	5 / 168 (3.0)		
	RR, (95% CI)		1.83, (0.69, 4.85)		0.222	
	OR, (95% CI)		1.88, (0.69, 5.16)		0.220	
	ARR %, (95% CI)		2.48, (-1.07, 6.03)		0.171	
≥75 years	n / N(%)		1 / 16 (6.3)	0 / 5 (0.0)		
	RR, (95% CI)		1.06, (0.05, 22.63)		0.971	
	OR, (95% CI)		1.06, (0.04, 30.20)		0.971	
	ARR %, (95% CI)		6.25, (-5.62, 18.12)		0.302	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		19 / 346 (5.5)	5 / 173 (2.9)		
	RR, (95% CI)		1.90, (0.72, 5.00)		0.194	
	OR, (95% CI)		1.95, (0.72, 5.32)		0.191	
	ARR %, (95% CI)		2.60, (-0.86, 6.06)		0.141	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.976				0.230
Yes	n / N(%)		6 / 99 (6.1)	0 / 52 (0.0)		
	RR, (95% CI)		6.89, (0.40, 119.96)		0.185	
	OR, (95% CI)		7.30, (0.40, 132.16)		0.179	
	ARR %, (95% CI)		6.06, (1.36, 10.76)		0.011	
No	n / N(%)		13 / 247 (5.3)	5 / 121 (4.1)		
	RR, (95% CI)		1.27, (0.46, 3.49)		0.638	
	OR, (95% CI)		1.29, (0.45, 3.70)		0.637	
	ARR %, (95% CI)		1.13, (-3.38, 5.64)		0.623	
Sex		0.992				0.992
Male	n / N(%)		8 / 216 (3.7)	2 / 105 (1.9)		
	RR, (95% CI)		1.94, (0.42, 9.00)		0.395	
	OR, (95% CI)		1.98, (0.41, 9.50)		0.393	
	ARR %, (95% CI)		1.80, (-1.83, 5.43)		0.331	
Female	n / N(%)		11 / 130 (8.5)	3 / 68 (4.4)		
	RR, (95% CI)		1.92, (0.55, 6.64)		0.304	
	OR, (95% CI)		2.00, (0.54, 7.44)		0.299	
	ARR %, (95% CI)		4.05, (-2.78, 10.88)		0.245	
Region		0.338				0.302
North America	n / N(%)		8 / 185 (4.3)	1 / 106 (0.9)		
	RR, (95% CI)		4.58, (0.58, 36.15)		0.148	
	OR, (95% CI)		4.75, (0.59, 38.48)		0.145	
	ARR %, (95% CI)		3.38, (-0.08, 6.84)		0.056	
United Kingdom	n / N(%)		6 / 80 (7.5)	1 / 30 (3.3)		
	RR, (95% CI)		2.25, (0.28, 17.92)		0.444	
	OR, (95% CI)		2.35, (0.27, 20.39)		0.438	
	ARR %, (95% CI)		4.17, (-4.47, 12.80)		0.344	
European Union	n / N(%)		5 / 81 (6.2)	3 / 37 (8.1)		
	RR, (95% CI)		0.76, (0.19, 3.02)		0.698	
	OR, (95% CI)		0.75, (0.17, 3.30)		0.699	
	ARR %, (95% CI)		-1.94, (-12.17, 8.30)		0.711	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		0.560				0.454
United States	n / N(%)		8 / 185 (4.3)	1 / 106 (0.9)		
	RR, (95% CI)		4.58, (0.58, 36.15)		0.148	
	OR, (95% CI)		4.75, (0.59, 38.48)		0.145	
	ARR %, (95% CI)		3.38, (-0.08, 6.84)		0.056	
United Kingdom	n / N(%)		6 / 80 (7.5)	1 / 30 (3.3)		
	RR, (95% CI)		2.25, (0.28, 17.92)		0.444	
	OR, (95% CI)		2.35, (0.27, 20.39)		0.438	
	ARR %, (95% CI)		4.17, (-4.47, 12.80)		0.344	
Belgium	n / N(%)		1 / 25 (4.0)	2 / 16 (12.5)		
	RR, (95% CI)		0.32, (0.03, 3.25)		0.335	
	OR, (95% CI)		0.29, (0.02, 3.52)		0.332	
	ARR %, (95% CI)		-8.50, (-26.43, 9.43)		0.353	
France	n / N(%)		3 / 38 (7.9)	1 / 16 (6.3)		
	RR, (95% CI)		1.26, (0.14, 11.25)		0.834	
	OR, (95% CI)		1.29, (0.12, 13.38)		0.833	
	ARR %, (95% CI)		1.64, (-12.99, 16.28)		0.826	
Spain	n / N(%)		1 / 18 (5.6)	0 / 5 (0.0)		
	RR, (95% CI)		0.95, (0.04, 20.33)		0.972	
	OR, (95% CI)		0.94, (0.03, 26.63)		0.972	
	ARR %, (95% CI)		5.55, (-5.04, 16.14)		0.304	
Race		0.999				0.343
Black or African American	n / N(%)		0 / 50 (0.0)	1 / 28 (3.6)		
	RR, (95% CI)		0.19, (0.01, 4.50)		0.304	
	OR, (95% CI)		0.18, (0.01, 4.61)		0.301	
	ARR %, (95% CI)		-3.57, (-10.45, 3.30)		0.309	
White	n / N(%)		19 / 264 (7.2)	4 / 126 (3.2)		
	RR, (95% CI)		2.27, (0.79, 6.52)		0.129	
	OR, (95% CI)		2.37, (0.79, 7.10)		0.125	
	ARR %, (95% CI)		4.02, (-0.35, 8.39)		0.071	
Other	n / N(%)		0 / 28 (0.0)	0 / 15 (0.0)		
	RR, (95% CI)		0.55, (0.01, 26.51)		0.763	
	OR, (95% CI)		0.54, (0.01, 28.77)		0.764	
	ARR %, (95% CI)		0.00, (-0.15, 0.15)		0.997	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		1.000				0.765
Hispanic or Latino	n / N(%)		1 / 40 (2.5)	0 / 12 (0.0)		
	RR, (95% CI)		0.95, (0.04, 21.96)		0.975	
	OR, (95% CI)		0.95, (0.04, 24.81)		0.975	
	ARR %, (95% CI)		2.50, (-2.34, 7.34)		0.312	
Not Hispanic or Latino	n / N(%)		18 / 275 (6.5)	5 / 144 (3.5)		
	RR, (95% CI)		1.89, (0.71, 4.97)		0.200	
	OR, (95% CI)		1.95, (0.71, 5.36)		0.197	
	ARR %, (95% CI)		3.07, (-1.11, 7.25)		0.150	
Other	n / N(%)		0 / 31 (0.0)	0 / 17 (0.0)		
	RR, (95% CI)		0.56, (0.01, 27.16)		0.771	
	OR, (95% CI)		0.56, (0.01, 29.24)		0.771	
	ARR %, (95% CI)		0.00, (-0.13, 0.13)		0.997	
COVID-19 co-morbidities at baseline		0.106				0.081
None	n / N(%)		2 / 101 (2.0)	2 / 46 (4.3)		
	RR, (95% CI)		0.46, (0.07, 3.13)		0.424	
	OR, (95% CI)		0.44, (0.06, 3.26)		0.425	
	ARR %, (95% CI)		-2.37, (-8.86, 4.12)		0.475	
At least one	n / N(%)		17 / 245 (6.9)	3 / 127 (2.4)		
	RR, (95% CI)		2.94, (0.88, 9.84)		0.081	
	OR, (95% CI)		3.08, (0.89, 10.72)		0.077	
	ARR %, (95% CI)		4.58, (0.44, 8.71)		0.030	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		19 / 346 (5.5)	5 / 173 (2.9)		
	RR, (95% CI)		1.90, (0.72, 5.00)		0.194	
	OR, (95% CI)		1.95, (0.72, 5.32)		0.191	
	ARR %, (95% CI)		2.60, (-0.86, 6.06)		0.141	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.269				0.231
Yes	n / N(%)		18 / 303 (5.9)	4 / 154 (2.6)		
	RR, (95% CI)		2.29, (0.79, 6.64)		0.128	
	OR, (95% CI)		2.37, (0.79, 7.12)		0.125	
	ARR %, (95% CI)		3.34, (-0.32, 7.00)		0.073	
No	n / N(%)		1 / 43 (2.3)	1 / 19 (5.3)		
	RR, (95% CI)		0.44, (0.03, 6.70)		0.556	
	OR, (95% CI)		0.43, (0.03, 7.24)		0.557	
	ARR %, (95% CI)		-2.94, (-13.94, 8.07)		0.601	
Obesity (≥ 30 kg/m^2)		0.975				0.217
Yes	n / N(%)		7 / 119 (5.9)	0 / 55 (0.0)		
	RR, (95% CI)		7.00, (0.41, 120.42)		0.180	
	OR, (95% CI)		7.40, (0.42, 131.92)		0.173	
	ARR %, (95% CI)		5.88, (1.65, 10.11)		0.006	
No	n / N(%)		12 / 225 (5.3)	5 / 117 (4.3)		
	RR, (95% CI)		1.25, (0.45, 3.46)		0.670	
	OR, (95% CI)		1.26, (0.43, 3.67)		0.669	
	ARR %, (95% CI)		1.06, (-3.64, 5.76)		0.658	
Obesity (≥ 40 kg/m^2)		0.999				0.659
Yes	n / N(%)		0 / 17 (0.0)	0 / 13 (0.0)		
	RR, (95% CI)		0.78, (0.02, 36.81)		0.898	
	OR, (95% CI)		0.77, (0.01, 41.44)		0.898	
	ARR %, (95% CI)		0.00, (-0.19, 0.19)		0.999	
No	n / N(%)		19 / 327 (5.8)	5 / 159 (3.1)		
	RR, (95% CI)		1.85, (0.70, 4.86)		0.213	
	OR, (95% CI)		1.90, (0.70, 5.19)		0.210	
	ARR %, (95% CI)		2.67, (-1.05, 6.38)		0.159	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.978				0.743
Yes	n / N(%)		2 / 38 (5.3)	0 / 21 (0.0)		
	RR, (95% CI)		2.82, (0.14, 56.15)		0.497	
	OR, (95% CI)		2.95, (0.13, 64.26)		0.492	
	ARR %, (95% CI)		5.26, (-1.84, 12.36)		0.146	
No	n / N(%)		17 / 308 (5.5)	5 / 152 (3.3)		
	RR, (95% CI)		1.68, (0.63, 4.46)		0.300	
	OR, (95% CI)		1.72, (0.62, 4.75)		0.297	
	ARR %, (95% CI)		2.23, (-1.58, 6.04)		0.252	
Diabetes		0.401				0.379
Yes	n / N(%)		1 / 40 (2.5)	1 / 25 (4.0)		
	RR, (95% CI)		0.63, (0.04, 9.55)		0.735	
	OR, (95% CI)		0.62, (0.04, 10.30)		0.736	
	ARR %, (95% CI)		-1.50, (-10.58, 7.58)		0.746	
No	n / N(%)		18 / 306 (5.9)	4 / 148 (2.7)		
	RR, (95% CI)		2.18, (0.75, 6.32)		0.153	
	OR, (95% CI)		2.25, (0.75, 6.77)		0.149	
	ARR %, (95% CI)		3.18, (-0.53, 6.89)		0.093	
Immunosuppressive disease		0.355				0.329
Yes	n / N(%)		1 / 16 (6.3)	1 / 9 (11.1)		
	RR, (95% CI)		0.56, (0.04, 7.95)		0.670	
	OR, (95% CI)		0.53, (0.03, 9.71)		0.671	
	ARR %, (95% CI)		-4.86, (-28.57, 18.85)		0.688	
No	n / N(%)		18 / 330 (5.5)	4 / 164 (2.4)		
	RR, (95% CI)		2.24, (0.77, 6.50)		0.139	
	OR, (95% CI)		2.31, (0.77, 6.93)		0.136	
	ARR %, (95% CI)		3.02, (-0.39, 6.42)		0.082	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.636				0.633
Yes	n / N(%)		5 / 103 (4.9)	1 / 60 (1.7)		
	RR, (95% CI)		2.91, (0.35, 24.35)		0.324	
	OR, (95% CI)		3.01, (0.34, 26.40)		0.320	
	ARR %, (95% CI)		3.19, (-2.08, 8.45)		0.235	
No	n / N(%)		14 / 243 (5.8)	4 / 113 (3.5)		
	RR, (95% CI)		1.63, (0.55, 4.83)		0.380	
	OR, (95% CI)		1.67, (0.54, 5.18)		0.378	
	ARR %, (95% CI)		2.22, (-2.27, 6.71)		0.333	
CV disease		0.975				0.294
Yes	n / N(%)		4 / 32 (12.5)	0 / 22 (0.0)		
	RR, (95% CI)		6.27, (0.35, 110.95)		0.210	
	OR, (95% CI)		7.11, (0.36, 138.99)		0.196	
	ARR %, (95% CI)		12.50, (1.04, 23.96)		0.033	
No	n / N(%)		15 / 314 (4.8)	5 / 151 (3.3)		
	RR, (95% CI)		1.44, (0.53, 3.90)		0.470	
	OR, (95% CI)		1.46, (0.52, 4.11)		0.468	
	ARR %, (95% CI)		1.47, (-2.24, 5.17)		0.438	
COPD		0.999				0.480
Yes	n / N(%)		0 / 23 (0.0)	0 / 11 (0.0)		
	RR, (95% CI)		0.50, (0.01, 23.69)		0.725	
	OR, (95% CI)		0.49, (0.01, 26.26)		0.725	
	ARR %, (95% CI)		0.00, (-0.20, 0.20)		0.996	
No	n / N(%)		19 / 323 (5.9)	5 / 162 (3.1)		
	RR, (95% CI)		1.91, (0.72, 5.01)		0.191	
	OR, (95% CI)		1.96, (0.72, 5.35)		0.188	
	ARR %, (95% CI)		2.80, (-0.90, 6.49)		0.138	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.999				0.558
Yes	n / N(%)		0 / 44 (0.0)	0 / 26 (0.0)		
	RR, (95% CI)		0.60, (0.01, 29.37)		0.797	
	OR, (95% CI)		0.60, (0.01, 30.91)		0.797	
	ARR %, (95% CI)		0.00, (-0.09, 0.09)		0.997	
No	n / N(%)		19 / 302 (6.3)	5 / 147 (3.4)		
	RR, (95% CI)		1.85, (0.70, 4.86)		0.212	
	OR, (95% CI)		1.91, (0.70, 5.21)		0.208	
	ARR %, (95% CI)		2.89, (-1.12, 6.90)		0.158	
Hypertension		0.906				0.907
Yes	n / N(%)		12 / 153 (7.8)	3 / 75 (4.0)		
	RR, (95% CI)		1.96, (0.57, 6.74)		0.285	
	OR, (95% CI)		2.04, (0.56, 7.47)		0.280	
	ARR %, (95% CI)		3.84, (-2.31, 9.99)		0.221	
No	n / N(%)		7 / 193 (3.6)	2 / 98 (2.0)		
	RR, (95% CI)		1.78, (0.38, 8.39)		0.468	
	OR, (95% CI)		1.81, (0.37, 8.86)		0.466	
	ARR %, (95% CI)		1.59, (-2.26, 5.43)		0.419	
Asthma		0.627				0.624
Yes	n / N(%)		7 / 55 (12.7)	1 / 21 (4.8)		
	RR, (95% CI)		2.67, (0.35, 20.43)		0.343	
	OR, (95% CI)		2.92, (0.34, 25.27)		0.331	
	ARR %, (95% CI)		7.97, (-4.71, 20.64)		0.218	
No	n / N(%)		12 / 291 (4.1)	4 / 152 (2.6)		
	RR, (95% CI)		1.57, (0.51, 4.78)		0.430	
	OR, (95% CI)		1.59, (0.50, 5.02)		0.428	
	ARR %, (95% CI)		1.49, (-1.93, 4.91)		0.392	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.972				0.332
Yes	n / N(%)		5 / 60 (8.3)	0 / 30 (0.0)		
	RR, (95% CI)		5.59, (0.32, 97.87)		0.239	
	OR, (95% CI)		6.05, (0.32, 113.05)		0.229	
	ARR %, (95% CI)		8.33, (1.34, 15.33)		0.020	
No	n / N(%)		14 / 286 (4.9)	5 / 143 (3.5)		
	RR, (95% CI)		1.40, (0.51, 3.81)		0.510	
	OR, (95% CI)		1.42, (0.50, 4.03)		0.509	
	ARR %, (95% CI)		1.40, (-2.52, 5.31)		0.484	
Smoking		0.973				0.614
Yes	n / N(%)		3 / 63 (4.8)	0 / 31 (0.0)		
	RR, (95% CI)		3.50, (0.19, 65.72)		0.402	
	OR, (95% CI)		3.64, (0.18, 72.79)		0.397	
	ARR %, (95% CI)		4.76, (-0.50, 10.02)		0.076	
No	n / N(%)		16 / 283 (5.7)	5 / 142 (3.5)		
	RR, (95% CI)		1.61, (0.60, 4.29)		0.345	
	OR, (95% CI)		1.64, (0.59, 4.58)		0.343	
	ARR %, (95% CI)		2.13, (-1.92, 6.19)		0.302	
Sickle cell disease		NE				NE
No	n / N(%)		19 / 346 (5.5)	5 / 173 (2.9)		
	RR, (95% CI)		1.90, (0.72, 5.00)		0.194	
	OR, (95% CI)		1.95, (0.72, 5.32)		0.191	
	ARR %, (95% CI)		2.60, (-0.86, 6.06)		0.141	
COVID-19 vaccination at any time during the study		0.979				0.697
Yes	n / N(%)		16 / 242 (6.6)	5 / 127 (3.9)		
	RR, (95% CI)		1.68, (0.63, 4.48)		0.300	
	OR, (95% CI)		1.73, (0.62, 4.83)		0.297	
	ARR %, (95% CI)		2.67, (-1.93, 7.28)		0.255	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		3 / 104 (2.9)	0 / 46 (0.0)		
	RR, (95% CI)		3.13, (0.17, 59.46)		0.447	
	OR, (95% CI)		3.21, (0.16, 63.35)		0.444	
	ARR %, (95% CI)		2.88, (-0.33, 6.10)		0.079	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.8
Adverse Events Overview by Subgroup - Participants with at least One injection site reaction
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.998				0.599
Yes	n / N(%)		19 / 344 (5.5)	5 / 172 (2.9)		
	RR, (95% CI)		1.90, (0.72, 5.00)		0.194	
	OR, (95% CI)		1.95, (0.72, 5.32)		0.191	
	ARR %, (95% CI)		2.62, (-0.87, 6.10)		0.141	

Abbreviations: AE = Adverse Event; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Age at randomization		0.999				0.840
<60 years	n / N(%)		2 / 199 (1.0)	0 / 97 (0.0)		
	RR, (95% CI)		2.45, (0.12, 50.54)		0.562	
	OR, (95% CI)		2.47, (0.12, 51.91)		0.561	
	ARR %, (95% CI)		1.00, (-0.38, 2.39)		0.155	
≥60 years	n / N(%)		1 / 147 (0.7)	0 / 76 (0.0)		
	RR, (95% CI)		1.56, (0.06, 37.86)		0.784	
	OR, (95% CI)		1.57, (0.06, 38.92)		0.784	
	ARR %, (95% CI)		0.68, (-0.65, 2.01)		0.316	
Age at randomization		0.999				0.755
<65 years	n / N(%)		2 / 262 (0.8)	0 / 137 (0.0)		
	RR, (95% CI)		2.62, (0.13, 54.27)		0.533	
	OR, (95% CI)		2.64, (0.13, 55.36)		0.532	
	ARR %, (95% CI)		0.76, (-0.29, 1.82)		0.156	
≥65 years	n / N(%)		1 / 84 (1.2)	0 / 36 (0.0)		
	RR, (95% CI)		1.31, (0.05, 31.32)		0.869	
	OR, (95% CI)		1.31, (0.05, 32.96)		0.869	
	ARR %, (95% CI)		1.19, (-1.13, 3.51)		0.315	
Age at randomization		0.982				0.301
<75 years	n / N(%)		3 / 330 (0.9)	0 / 168 (0.0)		
	RR, (95% CI)		3.57, (0.19, 68.79)		0.399	
	OR, (95% CI)		3.60, (0.18, 70.13)		0.398	
	ARR %, (95% CI)		0.91, (-0.12, 1.93)		0.082	
≥75 years	n / N(%)		0 / 16 (0.0)	0 / 5 (0.0)		
	RR, (95% CI)		0.35, (0.01, 15.90)		0.592	
	OR, (95% CI)		0.33, (0.01, 18.88)		0.594	
	ARR %, (95% CI)		0.00, (-0.41, 0.41)		0.995	
Residence in long-term care facility		NE				NE

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		3 / 346 (0.9)	0 / 173 (0.0)		
	RR, (95% CI)		3.51, (0.18, 67.57)		0.405	
	OR, (95% CI)		3.54, (0.18, 68.83)		0.404	
	ARR %, (95% CI)		0.87, (-0.11, 1.84)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk of exposure to infection with SARS-CoV-2		0.977				0.421
Yes	n / N(%)		0 / 99 (0.0)	0 / 52 (0.0)		
	RR, (95% CI)		0.53, (0.01, 26.33)		0.750	
	OR, (95% CI)		0.53, (0.01, 26.97)		0.750	
	ARR %, (95% CI)		0.00, (-0.04, 0.04)		0.997	
No	n / N(%)		3 / 247 (1.2)	0 / 121 (0.0)		
	RR, (95% CI)		3.44, (0.18, 66.14)		0.412	
	OR, (95% CI)		3.48, (0.18, 67.88)		0.411	
	ARR %, (95% CI)		1.21, (-0.15, 2.58)		0.081	
Sex		0.975				0.421
Male	n / N(%)		3 / 216 (1.4)	0 / 105 (0.0)		
	RR, (95% CI)		3.42, (0.18, 65.60)		0.415	
	OR, (95% CI)		3.46, (0.18, 67.58)		0.413	
	ARR %, (95% CI)		1.39, (-0.17, 2.95)		0.081	
Female	n / N(%)		0 / 130 (0.0)	0 / 68 (0.0)		
	RR, (95% CI)		0.53, (0.01, 26.26)		0.748	
	OR, (95% CI)		0.52, (0.01, 26.74)		0.748	
	ARR %, (95% CI)		0.00, (-0.03, 0.03)		0.997	
Region		0.999				0.846
North America	n / N(%)		0 / 185 (0.0)	0 / 106 (0.0)		
	RR, (95% CI)		0.58, (0.01, 28.78)		0.782	
	OR, (95% CI)		0.57, (0.01, 29.14)		0.782	
	ARR %, (95% CI)		0.00, (-0.02, 0.02)		0.997	
United Kingdom	n / N(%)		1 / 80 (1.3)	0 / 30 (0.0)		
	RR, (95% CI)		1.15, (0.05, 27.44)		0.932	
	OR, (95% CI)		1.15, (0.05, 29.03)		0.932	
	ARR %, (95% CI)		1.25, (-1.19, 3.69)		0.315	
European Union	n / N(%)		2 / 81 (2.5)	0 / 37 (0.0)		
	RR, (95% CI)		2.32, (0.11, 47.10)		0.585	
	OR, (95% CI)		2.36, (0.11, 50.36)		0.583	
	ARR %, (95% CI)		2.47, (-0.91, 5.85)		0.152	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Country		1.000				0.952
United States	n / N(%)		0 / 185 (0.0)	0 / 106 (0.0)		
	RR, (95% CI)		0.58, (0.01, 28.78)		0.782	
	OR, (95% CI)		0.57, (0.01, 29.14)		0.782	
	ARR %, (95% CI)		0.00, (-0.02, 0.02)		0.997	
United Kingdom	n / N(%)		1 / 80 (1.3)	0 / 30 (0.0)		
	RR, (95% CI)		1.15, (0.05, 27.44)		0.932	
	OR, (95% CI)		1.15, (0.05, 29.03)		0.932	
	ARR %, (95% CI)		1.25, (-1.19, 3.69)		0.315	
Belgium	n / N(%)		1 / 25 (4.0)	0 / 16 (0.0)		
	RR, (95% CI)		1.96, (0.08, 45.40)		0.674	
	OR, (95% CI)		2.02, (0.08, 52.68)		0.673	
	ARR %, (95% CI)		4.00, (-3.68, 11.68)		0.308	
France	n / N(%)		1 / 38 (2.6)	0 / 16 (0.0)		
	RR, (95% CI)		1.31, (0.06, 30.50)		0.867	
	OR, (95% CI)		1.32, (0.05, 34.13)		0.867	
	ARR %, (95% CI)		2.63, (-2.46, 7.72)		0.311	
Spain	n / N(%)		0 / 18 (0.0)	0 / 5 (0.0)		
	RR, (95% CI)		0.32, (0.01, 14.27)		0.553	
	OR, (95% CI)		0.30, (0.01, 16.79)		0.556	
	ARR %, (95% CI)		0.00, (-0.41, 0.41)		0.994	
Race		1.000				0.841
Black or African American	n / N(%)		0 / 50 (0.0)	0 / 28 (0.0)		
	RR, (95% CI)		0.57, (0.01, 27.90)		0.776	
	OR, (95% CI)		0.56, (0.01, 29.21)		0.776	
	ARR %, (95% CI)		0.00, (-0.08, 0.08)		0.997	
White	n / N(%)		3 / 264 (1.1)	0 / 126 (0.0)		
	RR, (95% CI)		3.35, (0.17, 64.46)		0.422	
	OR, (95% CI)		3.39, (0.17, 66.06)		0.421	
	ARR %, (95% CI)		1.14, (-0.14, 2.42)		0.082	
Other	n / N(%)		0 / 28 (0.0)	0 / 15 (0.0)		
	RR, (95% CI)		0.55, (0.01, 26.51)		0.763	
	OR, (95% CI)		0.54, (0.01, 28.77)		0.764	
	ARR %, (95% CI)		0.00, (-0.15, 0.15)		0.997	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Ethnicity		0.999				0.505
Hispanic or Latino	n / N(%)		0 / 40 (0.0)	0 / 12 (0.0)		
	RR, (95% CI)		0.32, (0.01, 15.20)		0.561	
	OR, (95% CI)		0.31, (0.01, 16.37)		0.562	
	ARR %, (95% CI)		0.00, (-0.17, 0.17)		0.995	
Not Hispanic or Latino	n / N(%)		3 / 275 (1.1)	0 / 144 (0.0)		
	RR, (95% CI)		3.68, (0.19, 70.71)		0.388	
	OR, (95% CI)		3.71, (0.19, 72.36)		0.387	
	ARR %, (95% CI)		1.09, (-0.14, 2.32)		0.082	
Other	n / N(%)		0 / 31 (0.0)	0 / 17 (0.0)		
	RR, (95% CI)		0.56, (0.01, 27.16)		0.771	
	OR, (95% CI)		0.56, (0.01, 29.24)		0.771	
	ARR %, (95% CI)		0.00, (-0.13, 0.13)		0.997	
COVID-19 co-morbidities at baseline		1.000				0.777
None	n / N(%)		1 / 101 (1.0)	0 / 46 (0.0)		
	RR, (95% CI)		1.38, (0.06, 33.30)		0.842	
	OR, (95% CI)		1.39, (0.06, 34.72)		0.842	
	ARR %, (95% CI)		0.99, (-0.94, 2.92)		0.315	
At least one	n / N(%)		2 / 245 (0.8)	0 / 127 (0.0)		
	RR, (95% CI)		2.60, (0.13, 53.78)		0.536	
	OR, (95% CI)		2.62, (0.12, 54.95)		0.535	
	ARR %, (95% CI)		0.82, (-0.31, 1.94)		0.156	
SARS-CoV-2 RT-PCR status at baseline		NE				NE
Negative/Missing	n / N(%)		3 / 346 (0.9)	0 / 173 (0.0)		
	RR, (95% CI)		3.51, (0.18, 67.57)		0.405	
	OR, (95% CI)		3.54, (0.18, 68.83)		0.404	
	ARR %, (95% CI)		0.87, (-0.11, 1.84)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
High risk for severe COVID-19 at baseline		0.998				0.783
Yes	n / N(%)		2 / 303 (0.7)	0 / 154 (0.0)		
	RR, (95% CI)		2.55, (0.12, 52.77)		0.545	
	OR, (95% CI)		2.56, (0.12, 53.70)		0.544	
	ARR %, (95% CI)		0.66, (-0.25, 1.57)		0.156	
No	n / N(%)		1 / 43 (2.3)	0 / 19 (0.0)		
	RR, (95% CI)		1.36, (0.06, 32.03)		0.847	
	OR, (95% CI)		1.38, (0.05, 35.33)		0.847	
	ARR %, (95% CI)		2.33, (-2.18, 6.83)		0.312	
Obesity (≥ 30 kg/m^2)		0.976				0.369
Yes	n / N(%)		0 / 119 (0.0)	0 / 55 (0.0)		
	RR, (95% CI)		0.47, (0.01, 23.22)		0.702	
	OR, (95% CI)		0.46, (0.01, 23.71)		0.702	
	ARR %, (95% CI)		0.00, (-0.04, 0.04)		0.996	
No	n / N(%)		3 / 225 (1.3)	0 / 117 (0.0)		
	RR, (95% CI)		3.65, (0.19, 70.17)		0.390	
	OR, (95% CI)		3.70, (0.19, 72.17)		0.389	
	ARR %, (95% CI)		1.33, (-0.17, 2.83)		0.081	
Obesity (≥ 40 kg/m^2)		0.983				0.537
Yes	n / N(%)		0 / 17 (0.0)	0 / 13 (0.0)		
	RR, (95% CI)		0.78, (0.02, 36.81)		0.898	
	OR, (95% CI)		0.77, (0.01, 41.44)		0.898	
	ARR %, (95% CI)		0.00, (-0.19, 0.19)		0.999	
No	n / N(%)		3 / 327 (0.9)	0 / 159 (0.0)		
	RR, (95% CI)		3.41, (0.18, 65.71)		0.416	
	OR, (95% CI)		3.44, (0.18, 67.01)		0.415	
	ARR %, (95% CI)		0.92, (-0.12, 1.95)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic kidney disease		0.977				0.437
Yes	n / N(%)		0 / 38 (0.0)	0 / 21 (0.0)		
	RR, (95% CI)		0.56, (0.01, 27.45)		0.773	
	OR, (95% CI)		0.56, (0.01, 29.16)		0.773	
	ARR %, (95% CI)		0.00, (-0.11, 0.11)		0.997	
No	n / N(%)		3 / 308 (1.0)	0 / 152 (0.0)		
	RR, (95% CI)		3.47, (0.18, 66.68)		0.410	
	OR, (95% CI)		3.49, (0.18, 68.08)		0.409	
	ARR %, (95% CI)		0.97, (-0.12, 2.07)		0.082	
Diabetes		0.976				0.477
Yes	n / N(%)		0 / 40 (0.0)	0 / 25 (0.0)		
	RR, (95% CI)		0.63, (0.01, 30.99)		0.818	
	OR, (95% CI)		0.63, (0.01, 32.74)		0.818	
	ARR %, (95% CI)		0.00, (-0.09, 0.09)		0.997	
No	n / N(%)		3 / 306 (1.0)	0 / 148 (0.0)		
	RR, (95% CI)		3.40, (0.18, 65.35)		0.418	
	OR, (95% CI)		3.43, (0.18, 66.74)		0.416	
	ARR %, (95% CI)		0.98, (-0.12, 2.08)		0.082	
Immunosuppressive disease		0.978				0.449
Yes	n / N(%)		0 / 16 (0.0)	0 / 9 (0.0)		
	RR, (95% CI)		0.59, (0.01, 27.40)		0.787	
	OR, (95% CI)		0.58, (0.01, 31.45)		0.787	
	ARR %, (95% CI)		0.00, (-0.25, 0.25)		0.997	
No	n / N(%)		3 / 330 (0.9)	0 / 164 (0.0)		
	RR, (95% CI)		3.49, (0.18, 67.16)		0.408	
	OR, (95% CI)		3.52, (0.18, 68.47)		0.407	
	ARR %, (95% CI)		0.91, (-0.12, 1.93)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Immunosuppressive treatment		0.977				0.464
Yes	n / N(%)		0 / 103 (0.0)	0 / 60 (0.0)		
	RR, (95% CI)		0.59, (0.01, 29.18)		0.789	
	OR, (95% CI)		0.58, (0.01, 29.84)		0.789	
	ARR %, (95% CI)		0.00, (-0.04, 0.04)		0.997	
No	n / N(%)		3 / 243 (1.2)	0 / 113 (0.0)		
	RR, (95% CI)		3.27, (0.17, 62.79)		0.432	
	OR, (95% CI)		3.30, (0.17, 64.49)		0.431	
	ARR %, (95% CI)		1.23, (-0.15, 2.62)		0.081	
CV disease		0.978				0.506
Yes	n / N(%)		0 / 32 (0.0)	0 / 22 (0.0)		
	RR, (95% CI)		0.70, (0.01, 33.87)		0.855	
	OR, (95% CI)		0.69, (0.01, 36.19)		0.855	
	ARR %, (95% CI)		0.00, (-0.11, 0.11)		0.998	
No	n / N(%)		3 / 314 (1.0)	0 / 151 (0.0)		
	RR, (95% CI)		3.38, (0.18, 64.98)		0.420	
	OR, (95% CI)		3.40, (0.17, 66.33)		0.419	
	ARR %, (95% CI)		0.96, (-0.12, 2.03)		0.082	
COPD		0.983				0.399
Yes	n / N(%)		0 / 23 (0.0)	0 / 11 (0.0)		
	RR, (95% CI)		0.50, (0.01, 23.69)		0.725	
	OR, (95% CI)		0.49, (0.01, 26.26)		0.725	
	ARR %, (95% CI)		0.00, (-0.20, 0.20)		0.996	
No	n / N(%)		3 / 323 (0.9)	0 / 162 (0.0)		
	RR, (95% CI)		3.52, (0.18, 67.77)		0.404	
	OR, (95% CI)		3.55, (0.18, 69.12)		0.403	
	ARR %, (95% CI)		0.93, (-0.12, 1.97)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Chronic liver disease		0.975				0.459
Yes	n / N(%)		0 / 44 (0.0)	0 / 26 (0.0)		
	RR, (95% CI)		0.60, (0.01, 29.37)		0.797	
	OR, (95% CI)		0.60, (0.01, 30.91)		0.797	
	ARR %, (95% CI)		0.00, (-0.09, 0.09)		0.997	
No	n / N(%)		3 / 302 (1.0)	0 / 147 (0.0)		
	RR, (95% CI)		3.42, (0.18, 65.76)		0.415	
	OR, (95% CI)		3.45, (0.18, 67.18)		0.414	
	ARR %, (95% CI)		0.99, (-0.13, 2.11)		0.082	
Hypertension		0.998				0.829
Yes	n / N(%)		2 / 153 (1.3)	0 / 75 (0.0)		
	RR, (95% CI)		2.47, (0.12, 50.76)		0.558	
	OR, (95% CI)		2.49, (0.12, 52.56)		0.557	
	ARR %, (95% CI)		1.31, (-0.49, 3.11)		0.155	
No	n / N(%)		1 / 193 (0.5)	0 / 98 (0.0)		
	RR, (95% CI)		1.53, (0.06, 37.24)		0.794	
	OR, (95% CI)		1.54, (0.06, 38.03)		0.794	
	ARR %, (95% CI)		0.52, (-0.50, 1.53)		0.316	
Asthma		0.998				0.721
Yes	n / N(%)		1 / 55 (1.8)	0 / 21 (0.0)		
	RR, (95% CI)		1.18, (0.05, 27.85)		0.919	
	OR, (95% CI)		1.18, (0.05, 30.20)		0.919	
	ARR %, (95% CI)		1.82, (-1.71, 5.35)		0.313	
No	n / N(%)		2 / 291 (0.7)	0 / 152 (0.0)		
	RR, (95% CI)		2.62, (0.13, 54.23)		0.533	
	OR, (95% CI)		2.63, (0.13, 55.21)		0.533	
	ARR %, (95% CI)		0.69, (-0.26, 1.64)		0.156	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Cancer		0.998				0.826
Yes	n / N(%)		1 / 60 (1.7)	0 / 30 (0.0)		
	RR, (95% CI)		1.52, (0.06, 36.34)		0.794	
	OR, (95% CI)		1.54, (0.06, 38.88)		0.794	
	ARR %, (95% CI)		1.67, (-1.57, 4.91)		0.313	
No	n / N(%)		2 / 286 (0.7)	0 / 143 (0.0)		
	RR, (95% CI)		2.51, (0.12, 51.91)		0.552	
	OR, (95% CI)		2.52, (0.12, 52.88)		0.551	
	ARR %, (95% CI)		0.70, (-0.27, 1.67)		0.156	
Smoking		0.982				0.398
Yes	n / N(%)		0 / 63 (0.0)	0 / 31 (0.0)		
	RR, (95% CI)		0.50, (0.01, 24.62)		0.727	
	OR, (95% CI)		0.50, (0.01, 25.59)		0.727	
	ARR %, (95% CI)		0.00, (-0.07, 0.07)		0.996	
No	n / N(%)		3 / 283 (1.1)	0 / 142 (0.0)		
	RR, (95% CI)		3.52, (0.18, 67.77)		0.404	
	OR, (95% CI)		3.56, (0.18, 69.32)		0.402	
	ARR %, (95% CI)		1.06, (-0.13, 2.25)		0.082	
Sickle cell disease		NE				NE
No	n / N(%)		3 / 346 (0.9)	0 / 173 (0.0)		
	RR, (95% CI)		3.51, (0.18, 67.57)		0.405	
	OR, (95% CI)		3.54, (0.18, 68.83)		0.404	
	ARR %, (95% CI)		0.87, (-0.11, 1.84)		0.082	
COVID-19 vaccination at any time during the study		0.978				0.355
Yes	n / N(%)		3 / 242 (1.2)	0 / 127 (0.0)		
	RR, (95% CI)		3.69, (0.19, 70.83)		0.387	
	OR, (95% CI)		3.73, (0.19, 72.71)		0.385	
	ARR %, (95% CI)		1.24, (-0.15, 2.63)		0.081	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.

[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
No	n / N(%)		0 / 104 (0.0)	0 / 46 (0.0)		
	RR, (95% CI)		0.45, (0.01, 22.22)		0.687	
	OR, (95% CI)		0.44, (0.01, 22.77)		0.687	
	ARR %, (95% CI)		0.00, (-0.05, 0.05)		0.996	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.
Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.
Note: Percentages are based on the number of participants in the analysis set by treatment group.
Note: Estimates are based on nonmodeling approach stratified by subgroup. Estimated ARR (AZD7442 vs Placebo) less than 0% provides evidence in favor of AZD7442.
[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.
[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.
[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Table 4.9
Adverse Events Overview by Subgroup – Participants with at least One Serious AESI
(Immunosuppressive Patients in Full Pre-exposure Analysis Set)

Subgroup	Statistics	P-value for interaction [a]	AZD7442 (N=346)	Placebo (N=173)	P-value [b]	P-value [c]
Increased risk for inadequate response to active immunization		0.992				0.495
Yes	n / N(%)		3 / 344 (0.9)	0 / 172 (0.0)		
	RR, (95% CI)		3.51, (0.18, 67.57)		0.405	
	OR, (95% CI)		3.54, (0.18, 68.84)		0.404	
	ARR %, (95% CI)		0.87, (-0.11, 1.85)		0.082	

Abbreviations: AE = Adverse Event; AESI = Adverse Event of Special Interest; ARR = Absolute Risk Reduction; CI = Confidence Interval; COPD = Chronic Obstructive Pulmonary Disease; CV = Cardiovascular disease; IMP = Investigational Medicinal Product; NE = Not Evaluable; OR = Odds Ratio; RR = Relative Risk.

Note: AEs are defined as any adverse event that started or worsened in severity on or after the first dose of IMP.

Note: Percentages are based on the number of participants in the analysis set by treatment group.

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[a] P-values for interaction term are reported from a logistic regression model by including treatment, subgroup and treatment-by-subgroup interaction. If the p-value for the treatment-by-subgroup interaction is statistically significant, the Cochran-Mantel-Haenszel (CMH) test will be conducted to investigate incidence of AE stratified by subgroup.

[b] P-values are to test if the RR, OR and ARR are statistically significant from Chi-square test.

[c] P-values are for the Breslow-Day test. With p-value of the Breslow-Day test less than 0.05 indicates non-homogeneity across subgroup levels.

Definition der Folgekomplikationen in der Studie Provent

COVID-19 Related AE	Coded Term
"COVID-19 CONFIRMED	COVID-19
ABDOMINAL PAIN	Abdominal pain
ACUTE KIDNEY INJURY	Acute kidney injury
ACUTE RESPIRATORY FAILURE	Acute respiratory failure
AGEUSIA	Ageusia
ANOSMIA	Anosmia
APPETITE LOSS	Decreased appetite
ASTHENIA	Asthenia
ASYMPTOMATIC COVID	Asymptomatic COVID-19
ASYMPTOMATIC COVID-19	Asymptomatic COVID-19
ASYMPTOMATIC COVID-19 GRADE 1	Asymptomatic COVID-19
ASYMPTOMATIC COVID-19 INFECTION	Asymptomatic COVID-19
ASYMPTOMATIC POSITIVE COVID-19 PCR TEST	Asymptomatic COVID-19
ATRIAL FIBRILLATION WITH RVR	Atrial fibrillation
BODY ACHE	Pain
BODY ACHES	Pain
CHEST CONGESTION	Pulmonary congestion
CHEST TIGHTNESS NON-CARDIAC	Chest discomfort
CHILLS	Chills
COIVD-19 POSITIVE CONFIRMED ON LATERAL FLOW TEST	COVID-19
COLD	Nasopharyngitis
CONFIRMED COVID 19 INFECTION	COVID-19
CONFIRMED COVID-19 INFECTION	COVID-19
COUGH	Cough
COUGH WITH SPUTUM	Productive cough
COUGHING	Cough
COVID	COVID-19
COVID 19	COVID-19
COVID 19 - COUGH	COVID-19
COVID 19 CONFIRMED	COVID-19
COVID 19 INFECTION	COVID-19
COVID 19 INFECTION - POSITIVE PCR 07/JAN/2022	COVID-19
COVID 19 INFECTION CONFIRMED	COVID-19
COVID 19 INFECTION SYMPTOMATIC	COVID-19
COVID 19 PNEUMONIA	COVID-19 pneumonia
COVID 19 POSITIVE	COVID-19
COVID INFECTION	COVID-19
COVID INFECTION (MODERATE)	COVID-19
COVID PNEUMONIA	COVID-19 pneumonia
COVID-19	COVID-19
COVID-19 CONFIRMED	COVID-19
COVID-19 CONFIRMED POSITIVE RESULT	COVID-19
COVID-19 INFECTION	COVID-19
COVID-19 INFECTION - POSITIVE NHS PCR	COVID-19
COVID-19 INFECTION CONFIRMED	COVID-19

COVID-19 INFECTION. FEVER, SOB, DIB, CHILLS, COUGH, FATIGUE, MYALGIA, BODY ACHES, HEADACHE, AGEUSIA, ANOSMIA, SORE THROAT, NASAL CONGESTION, AND NAUSEA	COVID-19
COVID-19 PNEUMONIA	COVID-19 pneumonia
COVID-19 PNEUMONIA WITH ACUTE RESPIRATORY INSUFFICIENCY WITH HYPOXEMIA	COVID-19 pneumonia
COVID-19 POSITIVE	COVID-19
COVID-19 POSITIVE (SYMPTOMATIC)	COVID-19
COVID-19 POSITIVE CONFIRMED	COVID-19
COVID-19 POSITIVE CONFIRMED ON LATERAL FLOW TEST	COVID-19
COVID-19 POSITIVE PCR	COVID-19
COVID19	COVID-19
COVID19 INFECTION	COVID-19
DELAYED COVID 19 RECOVERY - LONG COVID	Post-acute COVID-19 syndrome
DIARRHEA	Diarrhoea
DIARRHOEA	Diarrhoea
DIFFICULTIES IN BREATHING	Dyspnoea
DIFFICULTY BREATHING	Dyspnoea
DIFFICULTY IN BREATHING	Dyspnoea
DYSGEUSIA	Dysgeusia
DYSPHAGIA	Dysphagia
DYSPHONIA	Dysphonia
DYSPNEA	Dyspnoea
DYSPNOE	Dyspnoea
EXACERBATION OF ASTHMA	Asthma
EXPIRATORY WHEEZES	Wheezing
FATAL ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)	Acute respiratory distress syndrome
FATIGUE	Fatigue
FATIGUE (COVID SYMTPOM)	Fatigue
FATIGUE POST COVID INFECTION	Post-acute COVID-19 syndrome
FATIGUE/MALAISE	Malaise
FEVER	Pyrexia
FEVERISH FEELING	Pyrexia
GENERAL BODY ACHES	Pain
HAEDACHE	Headache
HEADACHE	Headache
HEADACHES	Headache
LOSS OF APPETITE	Decreased appetite
LOSS OF APPETITE OR DECREASED FOOD INTAKE	Decreased appetite
LOSS OF APPETITE POST COVID	Post-acute COVID-19 syndrome
LOSS OF SMELL	Anosmia
LOSS OF TASTE	Ageusia
LOWER RESPIRATORY TRACT INFECTION	Lower respiratory tract infection
MALAISE	Malaise
MUCUS DISCHARGE	Secretion discharge
MUSCLE ACHE	Myalgia
MUSCLE ACHES	Myalgia

MUSCLE CRAMPS	Muscle spasms
MUSCLE SORENESS	Myalgia
MYALGIA	Myalgia
NASAL CONGESTION	Nasal congestion
NAUSEA	Nausea
NEW LOSS OF SMELL	Anosmia
NEW LOSS OF TASTE	Ageusia
NIGHT SWEATS	Night sweats
NOSE CONGESTION	Nasal congestion
PETECHIAE, CHEST	Petechiae
PETECHIAE, LEGS	Petechiae
PHARYNGITIS	Pharyngitis
PHLEGM	Productive cough
PHYSICAL FINDING - RIGHT BASAL EXPIRATORY WHEEZE	Wheezing
PNEUMOPATHY COVID 19	COVID-19 pneumonia
POST COVID SHORTNESS OF BREATH	Post-acute COVID-19 syndrome
PYREXIA	Pyrexia
RESPIRATORY DISTRESS	Respiratory distress
RESPIRATORY INFECTION	Respiratory tract infection
RHINITIS	Rhinitis
RHINORRHEA	Rhinorrhoea
RUNNY NOSE	Rhinorrhoea
SARS-COV-2 POSITIVE PCR RESULT (NHS) - SYMPTOMATIC.	COVID-19
SARS-COV2 PNEUMONIA	COVID-19 pneumonia
SEPSIS SECONDARY TO BRONCHOPNEUMONIA	Sepsis
SHORTHESS OF BREATH	Dyspnoea
SHORTNESS OF BREATH	Dyspnoea
SHORTNESS OF BREATH POST COVID	Post-acute COVID-19 syndrome
SINUS CONGESTION	Sinus congestion
SNEEZING	Sneezing
SORE THROAT	Oropharyngeal pain
SORE THROAT (COVID SYMPTOM)	Oropharyngeal pain
SORETHROAT	Oropharyngeal pain
STUFFY NOSE	Nasal congestion
SWOLLEN SUBMANDIBULAR LYMPH NODES	Lymphadenopathy
SYMPTOMATIC COVID 19 INFECTION	COVID-19
SYMPTOMATIC COVID POSITIVE LFT	COVID-19
SYMPTOMATIC COVID-19 INFECTION	COVID-19
UPPER RESPIRATORY INFECTION	Upper respiratory tract infection
VOMITING	Vomiting
WHEEZING	Wheezing
WORSENING CHRONIC OBSTRUCTIVE PULMONARY DISEASE	Chronic obstructive pulmonary disease
WORSENING RIGHT HYDRONEPHROSIS	Hydronephrosis