AstraZeneca COVID-19 Vaccine Update

DCO2 7th Dec SDSD

Johan Vekemans
Global Clinical Head

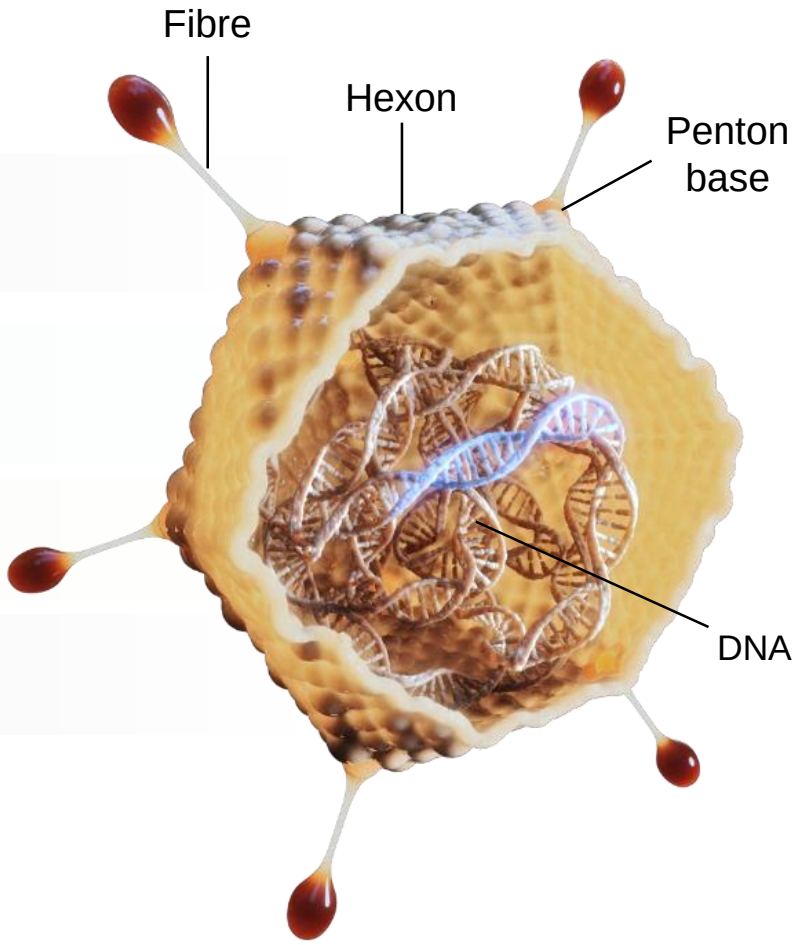
Outline of presentation

- AstraZeneca COVID-19 Vaccine Adenoviral Vectored Platform
- Pooled analysis of four University Oxford-sponsored studies
  - Safety
  - Efficacy
    - Primary Analysis and other estimates (hospitalisation, severe disease)
    - The effect of dose interval
    - Vaccine efficacy after dose 1, before dose 2
    - Vaccine efficacy in participants with stable co-morbidities
    - Vaccine efficacy in elderly
- Clinical development status update
- Regulatory status and global access plans

Adenoviral Vector Platform

Adenovirus vector vaccine technology : ChAdOx1 nCoV-19 / AZD1222

- Non-replicating (E1 and E3 gene-deleted) Chimpanzee adenovirus vector vaccine expressing SARS-CoV-2 Spike[1]
- Simian adenovirus avoids issues with pre-existing immunity to human adenoviruses[2]
- Induces strong B- and T-cell responses after a single vaccination[2]
- Dose is 5 x 10^{10} viral particles (vp) as an IM injection, 0.5 ml



1 Dicks MDJ, et al. PLoS One 2012;7:e40385; 2 Folegatti PM, et al. Lancet 2020;396:467–478

Description of studies included in the pooled analysis

Four studies included in the pooled analysis

UK COV001 (N=1067)	UK COV002 (N=10,740)	Brazil COV003 (N=10,416)	S. Africa COV005 (N=2,021)
Phase I/II single-blinded, adults aged 18–55 years	Phase II/III single-blinded, ≥18 years (including elderly)	Phase III single-blinded, ≥18 years (including elderly)	Phase I/II double-blinded, adults aged 18–65 yrs

Primary efficacy endpoint: virologically confirmed symptomatic COVID-19:

- PCR-confirmed SARS-CoV-2
- At least one of the following symptoms: objective fever (defined as ≥37.8 °C), cough, shortness of breath, anosmia, or ageusia
- Confirmed by a blinded adjudication committee, according to the WHO severity scale

- **Predefined statistical analysis plan**
- **Developed with input from regulators**
- **Agreed before any analysis was concluded**

Dec 7th **23,570**

Participants in COV001, COV002, COV003 and COV005 included in the any dose efficacy analysis set

The median follow-up (AZD1222 group)
post-dose 1: 133 days
post-dose 2: 81 days

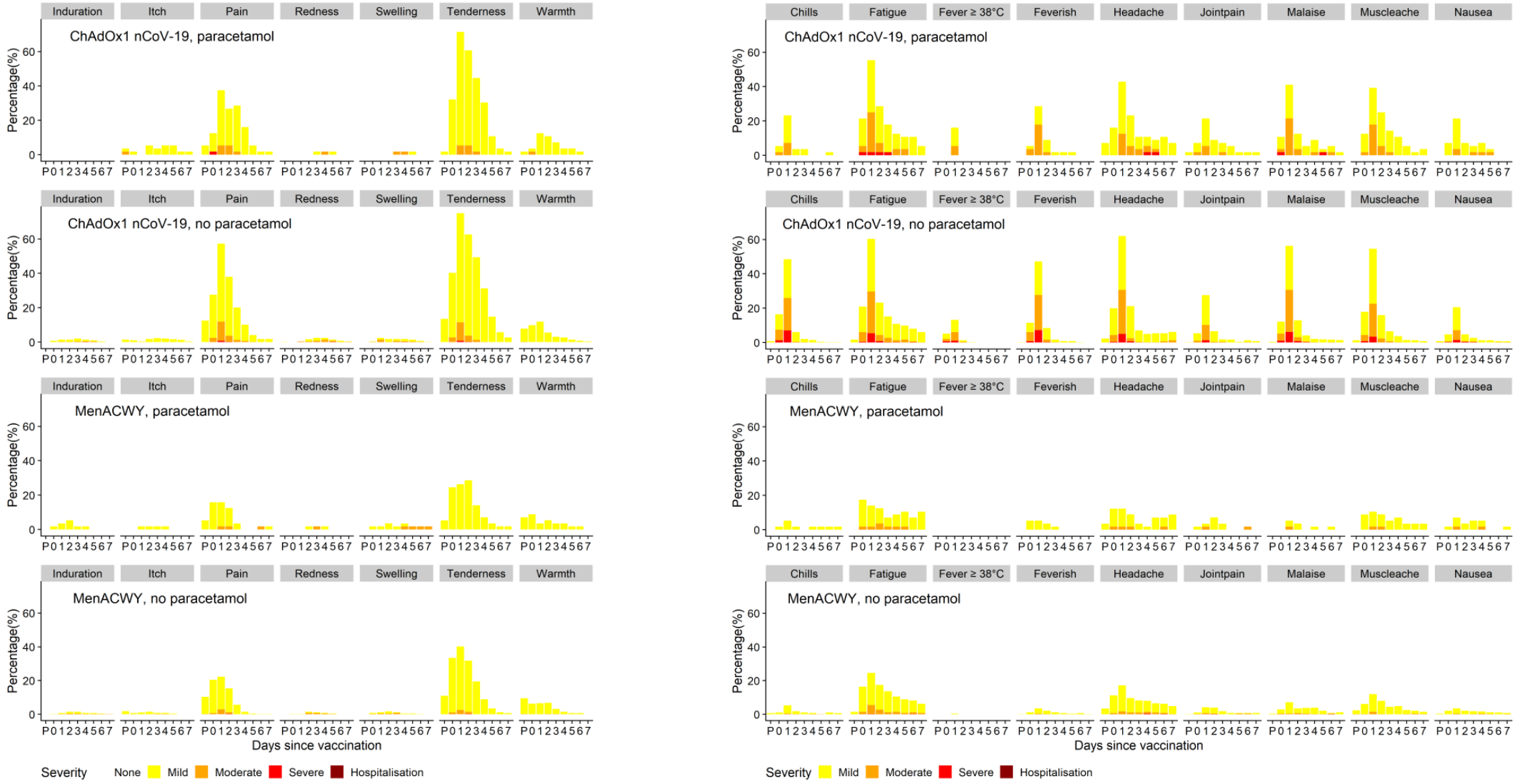
24,244

in all 4 studies met the inclusion criteria and were included in the any dose safety analysis set

The median follow-up (AZD1222 group)
post-dose 1: 137 days
post-dose 2: 81 days

Safety Profile

COV001: reactogenicity is reduced after the second dose; mild symptom reduction associated with paracetamol use



Folegatti PM et al. Lancet. 2020;396:467–478. https://dx.doi.org/10.1016/S0140-6736(20)31604-4. Accessed January 21st , 2021.

AZD1222 safety profile: SAEs, unsolicited AEs
Pooled analysis, 4 Nov dataset

Across all four studies, SAEs occurred in 168 participants (<1%)
79 of whom received AZD1222 (0.7%) and 89 of whom received MenACWY or saline control (0.8%)

4 SAEs were considered possibly related to intervention (experimental vaccine or control)

AZD1222 group

- **Pyrexia:** 2 days after dose 1; treated with paracetamol and resolved the same day
- **Transverse myelitis:** 14 days after dose 2

Control group

- **Autoimmune hemolytic anemia:** 10 days after MenACWY
- **Transverse myelitis**: 2 months after first control dose

Unsolicited AEs balanced between the groups as from Day 7 post vaccination ; mild increase in expected events in AZD1222 recipients relative to controls, in the first 7 days

MenACWY = meningococcal group A, C, W, and Y conjugate vaccine; SAE = serious adverse event.
Data on file.

Description of the efficacy dataset

Baseline characteristics

Heterogeneity in dosing and interval regimen

- Late decision to implement a two dose regimen and product availability led to heterogeneity in dosing interval (range 3-26 weeks).

- Early in the program, discrepancies in product concentration measures from various analytical methodologies led to administration of a dose lower ($2.2x10^{10}$ vp) than intended (about 8% of the total pooled analysis population).

- A great majority of participants vaccinated with the low dose received the second dose after a long interval. Interval confounded analysis of vaccine efficacy according to dose level.

- Efficacy results from participants having received two standard doses ($5x10^{10}$ vp) only (SDSD) will be referred to in this presentation, unless specified.

Efficacy Analysis Set

- Except when indicated, the Efficacy Analysis Set presented here is:
  - **Data cut-off 2 (DCO2), 07 December 2020**
  - **All 4 studies: COV001, COV002, COV003, COV005**
  - **Participants vaccinated with 2 standard doses (SDSD), seronegative at baseline**
  - **Any dosing interval**

DCO2 7th Dec, COV001-2-3-5, SDSD, any interval

Baseline characteristics of participants included in the primary efficacy population

Characteristic	Statistics	AZD1222 (N = 7201)	Control (N = 7179)	Total (N = 14380)
Sex, n (%)	Female	3916 (54.4)	3942 (54.9)	7858 (54.6)
	Male	3285 (45.6)	3237 (45.1)	6522 (45.4)
	Transgender	0	0	0
Race or ethnic group, n (%)	White	5173 (71.8)	5260 (73.3)	10433 (72.6)
	Asian	243 (3.4)	226 (3.1)	469 (3.3)
	Black	851 (11.8)	804 (11.2)	1655 (11.5)
	Other	584 (8.1)	540 (7.5)	1124 (7.8)
	Mixed	338 (4.7)	336 (4.7)	674 (4.7)
	Unknown	11 (0.2)	11 (0.2)	22 (0.2)
	Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Country, n (%)	United Kingdom	3048	3136	6184 (43)
	Brazil	3414	3339	6753 (47)
	South Africa	739	704	1443 (10)
Age group, n (%)	18 to 64 years	6498 (90.2)	6499 (90.5)	12997 (90.4)
	≥ 65 years	703 (9.8)	680 (9.5)	1383 (9.6)
Age (years) at screening	Median	40	40	40
	Range	18 – 86	18 – 88	18 – 88
Comorbidity[a]	Yes	2592 (36.0)	2632 (36.6)	5223 (36.3)

DCO2 7th Dec, COV001-2-3-5, SDSD, any interval

[a] BMI ≥30, cardiovascular disorder, respiratory disease, or diabetes at baseline. Available from: Source Tables 1.1.3.5, 1.1.4.5, 3.1.3.5a, 3.1.3.5b, 3.1.3.5c.

Description of dose interval in the analysis population

Dose schedule (SDSD)	AZD1222 N=7201 n (%)	Control N=7179 n (%)
<4 weeks	206 (2.9)	203 (2.8)
4 - <8 weeks	4294 (59.6)	4183 (58.3)
8 - 12 weeks	1555 (21.6)	1580 (22.0)
>12 weeks	1146 (15.9)	1213 (16.9)

DCO2 7th Dec, COV001-2-3-5, SDSD, any interval

Source: IEMT Table 223.1, IEMT Table 226.1

Clinical Efficacy

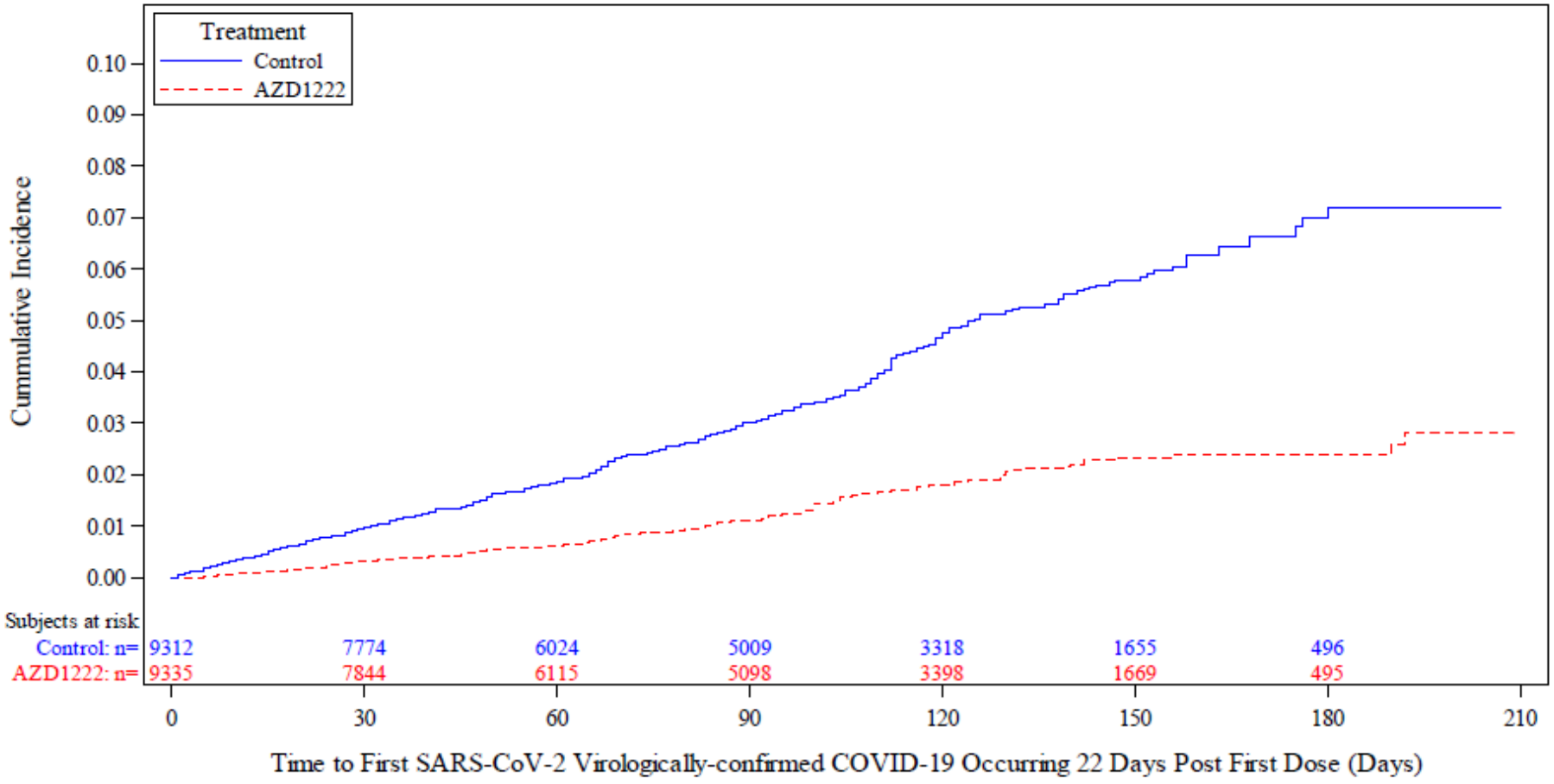
Primary outcome: Vaccine efficacy ≥ 15 days post-second dose

Analysis set	Participants with events		Vaccine Efficacy (%)	95% CI (%)	P-value
	AZD1222	Control			
Events	n / N (%)	n / N (%)			
SDSD seronegative for efficacy analysis set, any dosing interval (271 cases total)					
COVID-19	74 / 7201 (1.03)	197 / 7179 (2.74)	63.09	(51.81, 71.73)	<0.001

DCO2 7th Dec, COV001-2-3-5, SDSD, any interval

VE of AZD1222 versus control, the 95% CI and p value were estimated based on Poisson regression with robust variance including the term of study code, treatment, age group at screening (18-55 years, 56-69 years, and ≥70 years) as covariates as well as the log of the follow-up time as an offset.
Source: Tables 1.3.1.1 and 1.3.1.2; Supplemental Table IEMT 141.1.1.2

Cumulative incidence plot of time to 1st COVID-19 occurring ≥ 22 days post-dose 1 (Dose 1 SD seronegative analysis set)



DCO2 7th Dec, COV001-2-3-5, any interval

Source: Figure 1.4.11.1.

Vaccine efficacy according to WHO severity progression scale

Vaccine Efficacy against COVID-19, COVID-19 hospitalisation, severe disease, and death occurring ≥22 Days Post-Dose 1

Analysis set Events	Participants with events		Vaccine Efficacy (%)	95% CI (%)
	AZD1222 n / N (%)	Control n / N (%)		
COVID-19 (WHO score ≥ 2)	129 / 9335 (1.38)	331 / 9312 (3.55)	61.55	(52.91, 68.61)
Hospitalisation (WHO score ≥4)	0 / 9335 (0)	14* / 9312 (0.15)	100	(69.92, NE)
Severe (WHO score ≥6)	0 / 9335 (0)	2 / 9312 (0.02)	–	–
Death (WHO score ≥10)	0 / 9335 (0)	1 / 9312 (0.01)	–	–

* 8 occurred ≥ 15 Days Post-Dose 2

DCO2 7th Dec, COV001-2-3-5, any interval

VE of AZD1222 versus control, the 95% CI and p value were estimated based on Poisson regression with robust variance including the term of study code, treatment, age group at screening (18-55 years, 56-69 years, and ≥70 years) as covariates as well as the log of the follow-up time as an offset.
Source: Tables 1.4.10.1, 1.4.3.1, 1.4.15.1, and 1.4.18.1 (All participants).

Vaccine immunogenicity and efficacy as a function of dose interval

Longer dosing interval is associated with higher immunogenicity (anti-S binding antibodies)

Dose Interval	Baseline GMT (95% CI)	28 days after dose 1 GMT (95% CI)	28 days after dose 2 GMT (95% CI)
4 - <8 weeks	(N=691) **60.02** (54.7, 65.9)	(N=665) **8003.77** (7323.5, 8747.2)	(N=672) **22069.86** (20578.3, 23669.6)
8 - 12 weeks	(N=560) **54.12** (49.4, 59.3)	(N=513) **8681.29** (7866.4, 9580.6)	(N=553) **35258.11** (32712.7, 38001.5)
>12 weeks	(N=256) **55.40** (48.0, 64.0)	(N=256) **8162.34** (7098.4, 9385.7)	(N=256) **53475.18** (47719.1, 59925.6)

Similar trends observed with pseudoneutralisation / neutralisation assays

Source: Supplemental Tables IEMT 193.1.1.2.a, 193.1.1.2.b, 193.1.1.2.c, 193.1.1.2.e.

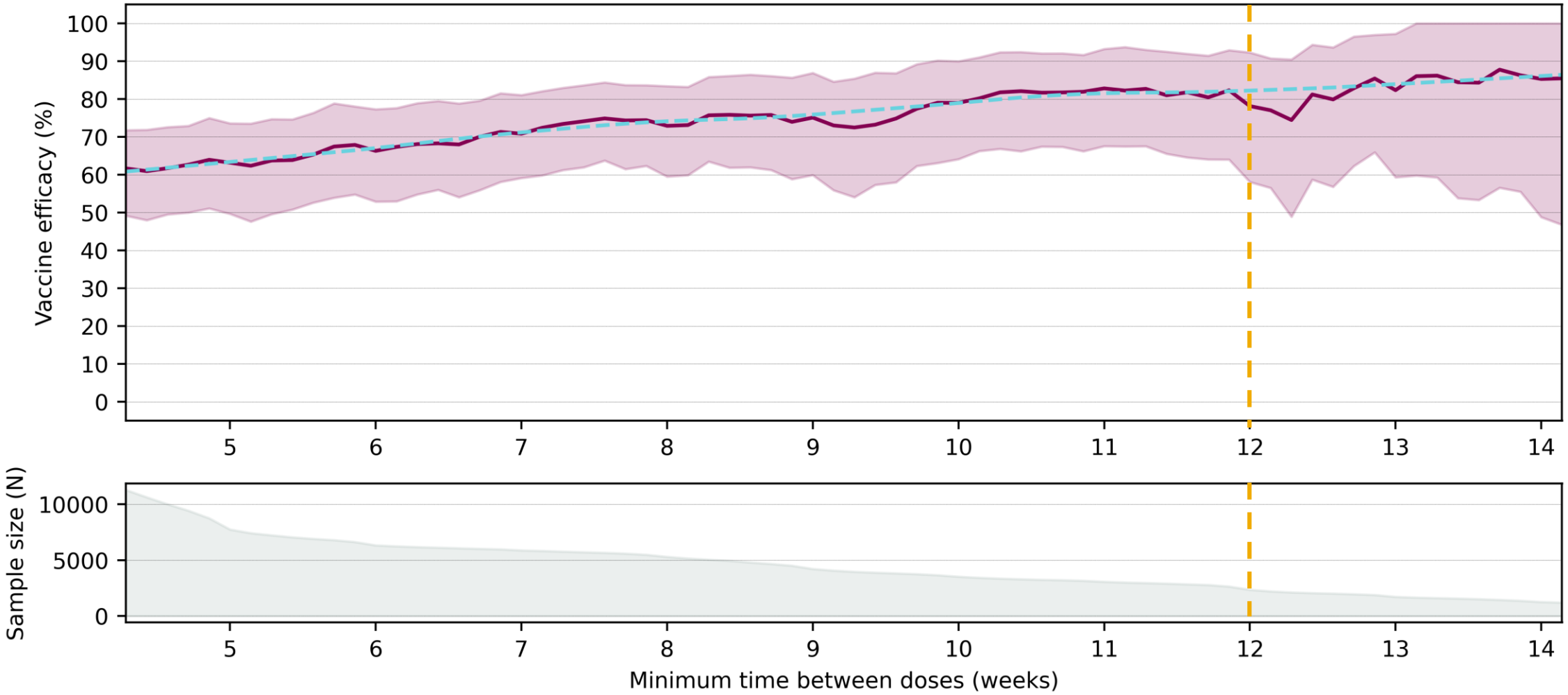
Vaccine efficacy ≥ 15 days post-second dose by interval between doses

Analysis set Time interval between Dose 1 and Dose 2	Participants with events		Vaccine Efficacy (%)	95% CI (%)	P-value
	AZD1222 n / N (%)	Control n / N (%)			
≥ 4 to 8 weeks	54 / 4796 (1.13)	117 / 4662 (2.51)	**56.42**	(39.86, 68.43)	<0.001
9 to 12 weeks	11 / 1053 (1.04)	39 / 1101 (3.54)	**70.48**	(42.41, 84.87)	<0.001
> 12 weeks	8 / 1146 (0.70)	38 / 1213 (3.13)	**77.62**	(51.98, 89.57)	<0.001
< 6 weeks	35 / 3890 (0.90)	76 / 3856 (1.97)	**55.10**	(33.00, 69.91)	<0.001
≥ 6 to 8 weeks	20 / 1112 (1.80)	44 / 1009 (4.36)	**59.92**	(32.01, 76.37)	<0.001
9 to 11 weeks	11 / 906 (1.21)	32 / 958 (3.34)	**63.65**	(27.96, 81.66)	0.004
≥ 12 weeks	8 / 1293 (0.62)	45 / 1356 (3.32)	**81.31**	(60.31, 91.20)	<0.001

DCO2 7th Dec, COV001-2-3-5, SDSD, any interval

Abbreviations: CI = Confidence Interval. VE = Vaccine Efficacy.
Source: Supplemental Tables IEMT 142.1.1.2.1, 142.1.1.2.2, 142.1.1.2.3, and 142.1.1.2.4; Supplemental Tables IEMT 143.1.1.2.1, 143.1.1.2.2, 143.1.1.2.3, and 143.1.1.2.4.

Modelling of vaccine efficacy as a function of interval (bootstrapping)



DCO2 7th Dec, COV001-2-3-5, SDSD, any interval

Vaccine efficacy before the second dose

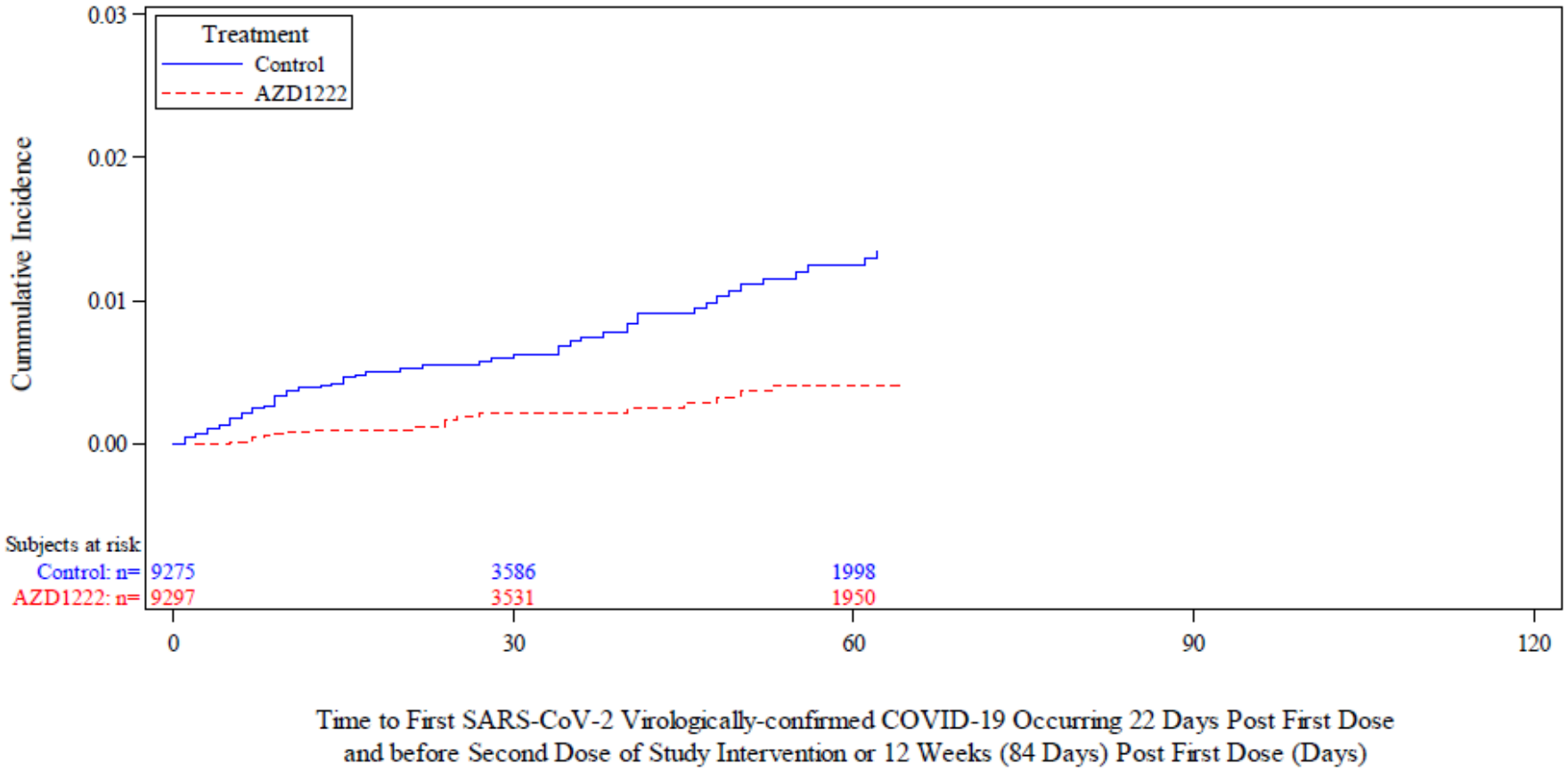
Vaccine efficacy from 22 days post dose 1 and before second dose

	AZD1222 n/N (%)	Control N/n (%)	Vaccine Efficacy	95% CI (%)	P-value
22 days post Dose 1 to dose 2 up to *4 weeks*	5 / 9335 (0.05)	20 / 9312 (0.21)	75.25	(32.02, 92.74)	0.004
22 days post Dose 1 to dose 2 up to *6 weeks*	9 / 9335 (0.10)	40 / 9312 (0.43)	77.54	(52.97, 90.42)	<0.001
22 days post Dose 1 to dose 2 up to *8 weeks*	13 / 9335 (0.14)	46 / 9312 (0.49)	71.78	(46.87, 86.01)	<0.001
22 days post Dose 1 to dose 2 up to *10 weeks*	17 / 9335 (0.18)	56 / 9312 (0.60)	69.65	(46.99, 83.47)	<0.001
22 days post Dose 1 to dose 2 up to *12 weeks*	18 / 9335 (0.19)	63 / 9312 (0.68)	**71.42**	**(51.11, 84.08)**	<0.001
22 days post Dose 1 to dose 2 up to *14 weeks*	19 / 9335 (0.20)	70 / 9312 (0.75)	72.84	(54.38, 84.56)	<0.001
22 days post Dose 1 to dose 2 (no censoring)	32 / 9335 (0.34)	82 / 9312 (0.88)	60.99	(41.37, 74.05)	<0.001

DCO2 7th Dec, COV001-2-3-5, any interval

[a]VE of AZD1222 versus control, the 95% CI and p value were estimated based on Poisson regression with robust variance including the term of study code, treatment, age group at screening (18-55 years, 56-69 years, and >=70 years) as covariates as well as the log of the follow-up time as an offset. VE is defined as 1-(incidence from the AZD1222 arm / incidence from the control arm) expressed as a percentage.
Source: Supplemental Tables IEMT 157.1-7.

Cumulative incidence plot of time to first COVID-19 occurring ≥22 Days post dose 1 and before dose 2 or up to 12 weeks post 1st Dose (Dose 1 SD Seronegative Set)



DCO2 7th Dec, COV001-2-3-5, any interval

Date of first SARS-CoV-2 virologically-confirmed test occurring 22 days post first dose before second dose or 12 weeks (84 Days) post first dose – (date of first dose of study intervention + 22) + 1. For censored participants, the censoring time is from date of first dose of study intervention to last observed time during the analysis period.
Source: Supplemental Figure IEMT 212.4.1.

Immunogenicity in participants with SARS-CoV-2 NP seropositivity at baseline

Important increase in anti-S antibody geometric mean titres after the first dose

	SDSD Seronegative			SDSD Seropositive		
Dose Interval	**Baseline GMT (95% CI)**	**28 days after dose 1 GMT (95% CI)**	**28 days after dose 2 GMT (95% CI)**	**Baseline GMT (95% CI)**	**28 days after dose 1 GMT (95% CI)**	**28 days after dose 2 GMT (95% CI)**
<4 weeks	(N=31) **62.36** (37.9, 102.7)	(N=32) **13523.33** (8968.3, 20391.9)	(N=30) **28940.42** (20505.2, 40845.7)	(N=4) **14121.27** (1249.9, 159535.7)	(N=4) **213180.23** (101213.8, 449007.8)	(N=4) **156984.28** (69341.4, 355402.0)
4 - <8 weeks	(N=691) **60.02** (54.7, 65.9)	(N=665) **8003.77** (7323.5, 8747.2)	(N=672) **22069.86** (20578.3, 23669.6)	(N=19) **15620.23** (7493.6, 32560.2)	(N=19) **152530.59** (86245.5, 269759.8)	(N=19) **120500.50** (61515.8, 236042.9)
8 - 12 weeks	(N=560) **54.12** (49.4, 59.3)	(N=513) **8681.29** (7866.4, 9580.6)	(N=553) **35258.11** (32712.7, 38001.5)	(N=6) **3583.43** (498.0, 25786.3)	(N=5) **63446.15** (11815.4, 340691.0)	(N=6) **73689.13** (42349.7, 128220.1)
>12 weeks	(N=256) **55.40** (48.0, 64.0)	(N=256) **8162.34** (7098.4, 9385.7)	(N=256) **53475.18** (47719.1, 59925.6)	(N=7) **9534.19** (2953.5, 30777.7)	(N=7) **148196.40** (72427.2, 303230.9)	(N=7) **73333.35** (41353.2, 130045.1)

Similar results were seen with the neutralizing antibody responses

Source: Supplemental Tables IEMT 193.1.1.2.a, 193.1.1.2.b, 193.1.1.2.c, 193.1.1.2.e.

Vaccine efficacy according in participants with stable comorbidities

Vaccine efficacy in participants with stable co-morbidities

Comorbidity was defined as having a BMI ≥30 kg/m^2, cardiovascular disorder, respiratory disease or diabetes

- Proportion of subjects vaccinated with AZD1222 with comorbidities at baseline : **36%**
  - Obesity (19.6%)
  - Cardiovascular disease (13.5%)
    - Mainly hypertension (9.9%)
  - Respiratory disease (10.2%)
    - Mainly asthma (6.2%)
  - Diabetes (3.3%)
- Results in this subgroup were consistent with the overall vaccine efficacy result

Comorbidity at baseline: Yes	Participants with events		Vaccine Efficacy (%)	95% CI (%)	P-value
	AZD1222 n / N (%)	Control n / N (%)			
Dose 1 SD seronegative	28 / 2592 (1.08)	76 / 2631 (2.89)	62.20	41.71, 75.49	<0.001

DCO2 7th Dec, COV001-2-3-5, any interval

Source: table 1.1.4.5, , Supplemental Tables IEMT 175.2.a, 175.2.b, IEMT175.1.a, and IEMT175.1.b

Vaccine immunogenicity and efficacy in the elderly

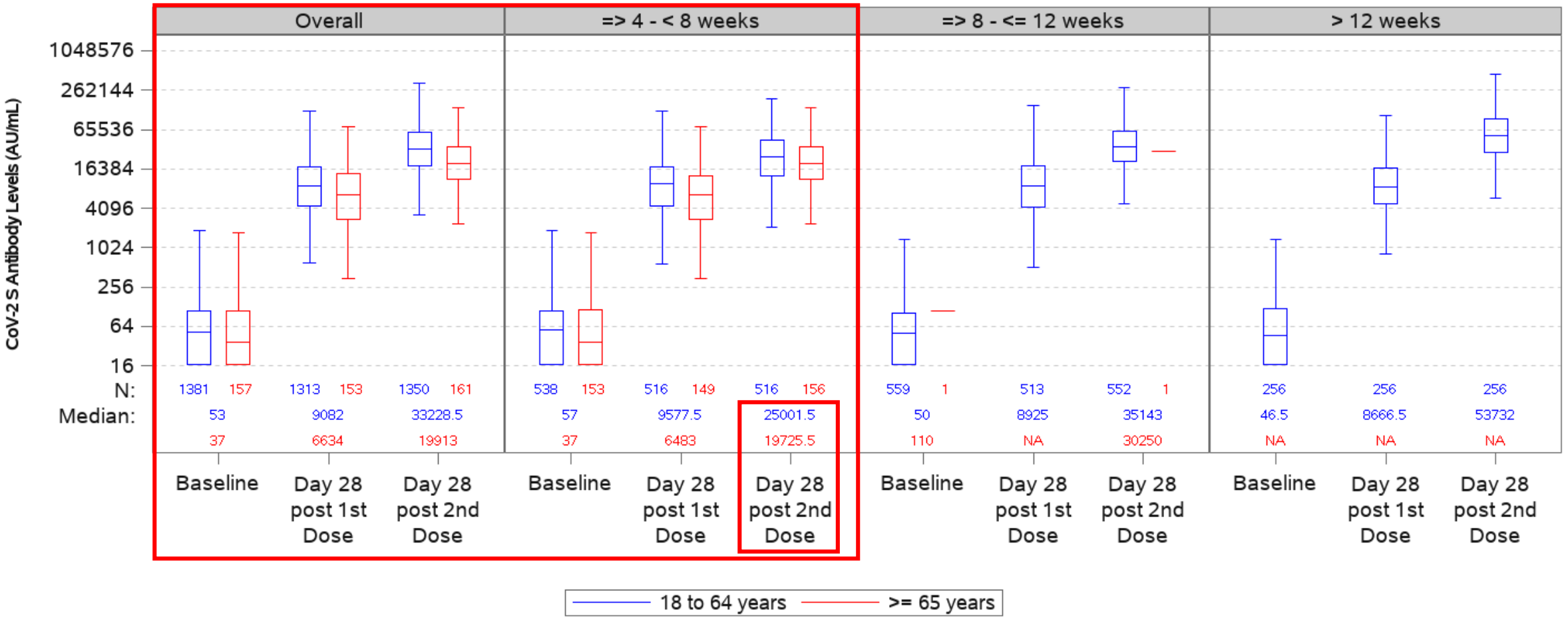
Elderly population – 65 years and above

Characteristic		AZD1222	Control	Total
Any Dose Analysis Set		**1256**	**1018**	**2274**
- Duration of follow-up since first dose	Median, days	76	71	-
- Duration of follow-up since second dose	Median, days	48	42	-
Dose 1 SD for Efficacy Analysis Set		**945**	**896**	**1841**
- COV002 (United Kingdom)		600 (63.5)	609 (68.0)	1209 (65.7)
- COV003 (Brazil)		344 (36.4)	286 (31.9)	630 (34.2)
- COV005 (South Africa)		1 (0.1)	1 (0.1)	2 (0.1)
- Age	Median (Range)	71 (65-88)	71 (65-88)	71 (65-88)
- Sex	Male/Female %	58.2/41.8	57.1/42.9	57.7/42.3
- Race	White, n (%)	864 (91.4)	838 (93.5)	1702 (92.4)
- Comorbidity at baseline[a]	Yes, n (%)	59.4	56.5	58.0
Elderly participants, SDSD for Efficacy Analysis Set		**703**	**680**	**1383**
Dose Interval	<4 weeks, n (%)	16 (2.3)	14 (2.1)	30 (2.2)
	4 - <8 weeks, n (%)	682 (97.0)	660 (97.1)	1342 (97.0)
	8 - <12 weeks, n (%)	5 (0.7)	6 (0.9)	11 (0.8)

DCO2 7th Dec, COV001-2-3-5, any interval

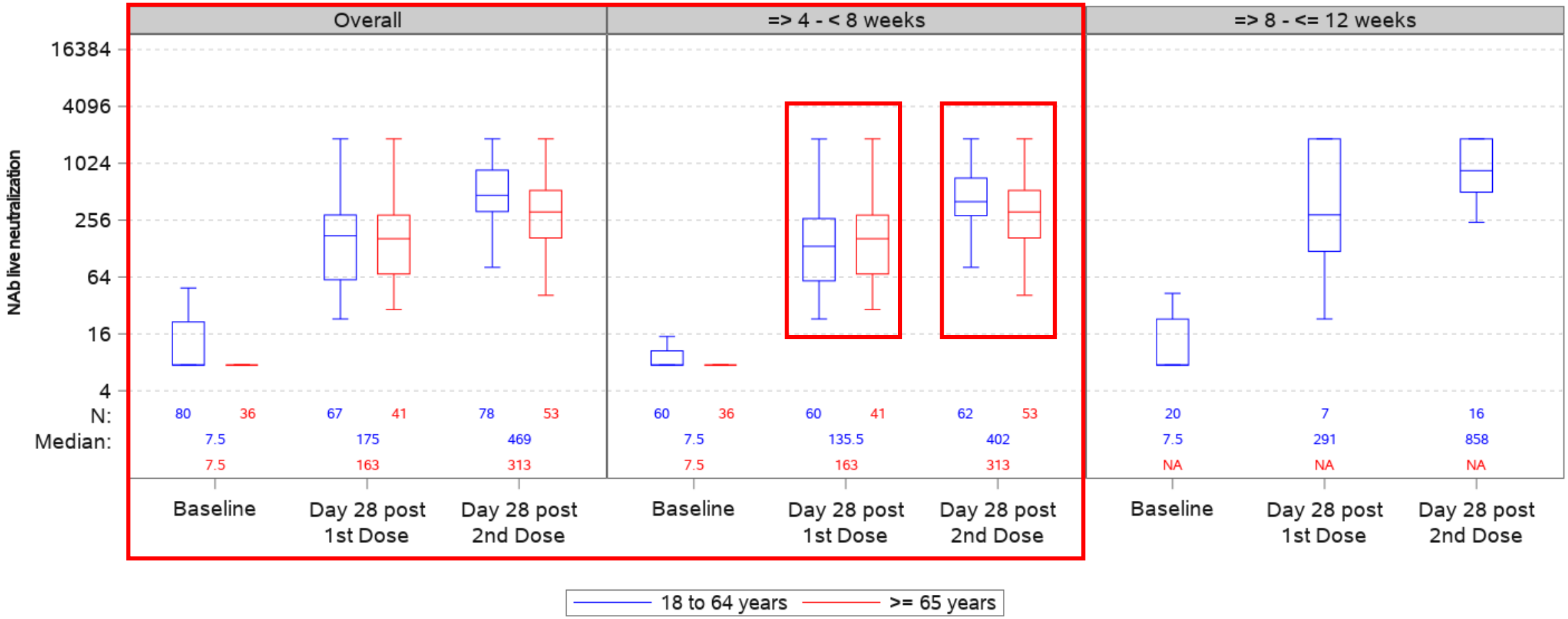
- [a] BMI ≥30, cardiovascular disorder, respiratory disease, or diabetes at baseline
  Source: Tables 3.1.3.8.a-c, 4.1.1.1.b, 4.1.3.8.b, 4.1.4.8.b, IEMT Table 226.1

Immunogenicity according to age and interval (Anti-S binding antibodies)



Source: Supplemental Figure IEMT 197.3.1.

Immunogenicity according to age and interval (Neutralising antibodies)

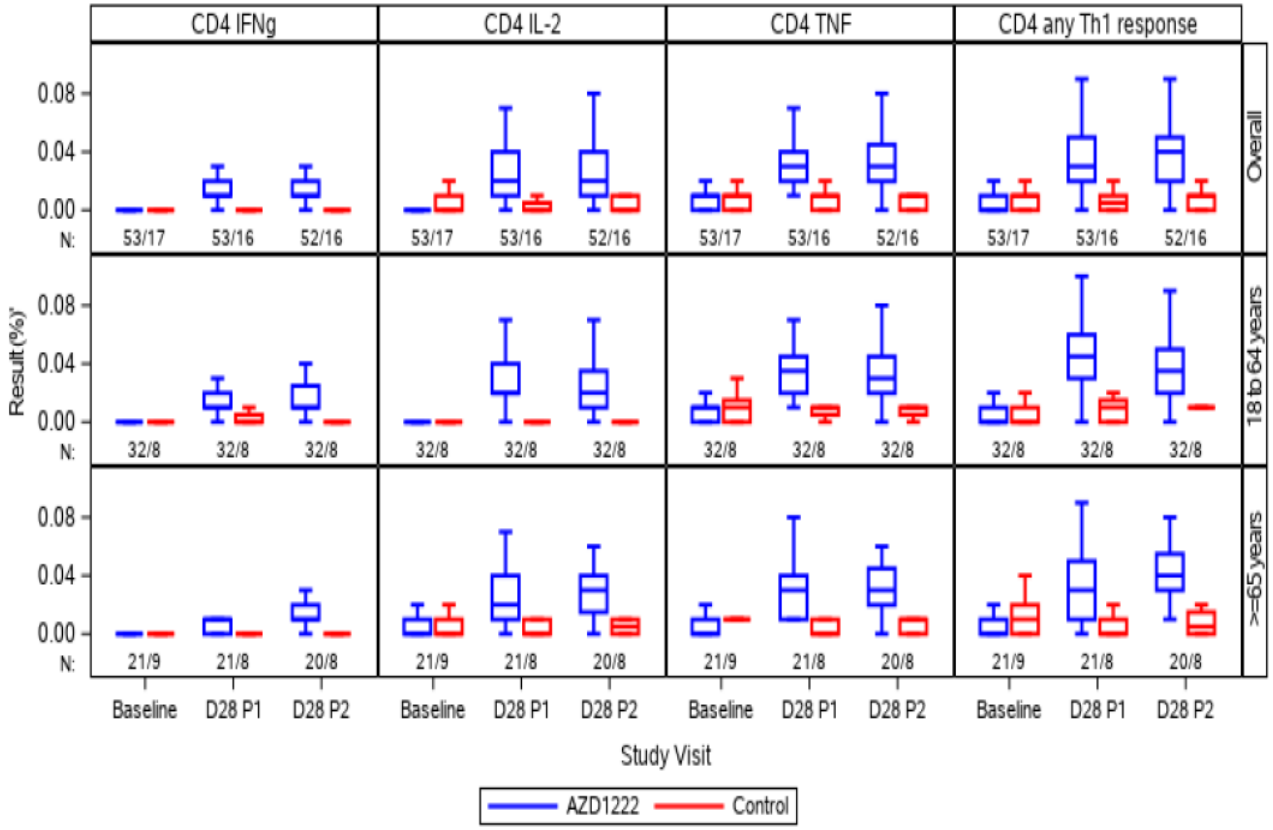


Source: Supplemental Figure IEMT 197.3.2.

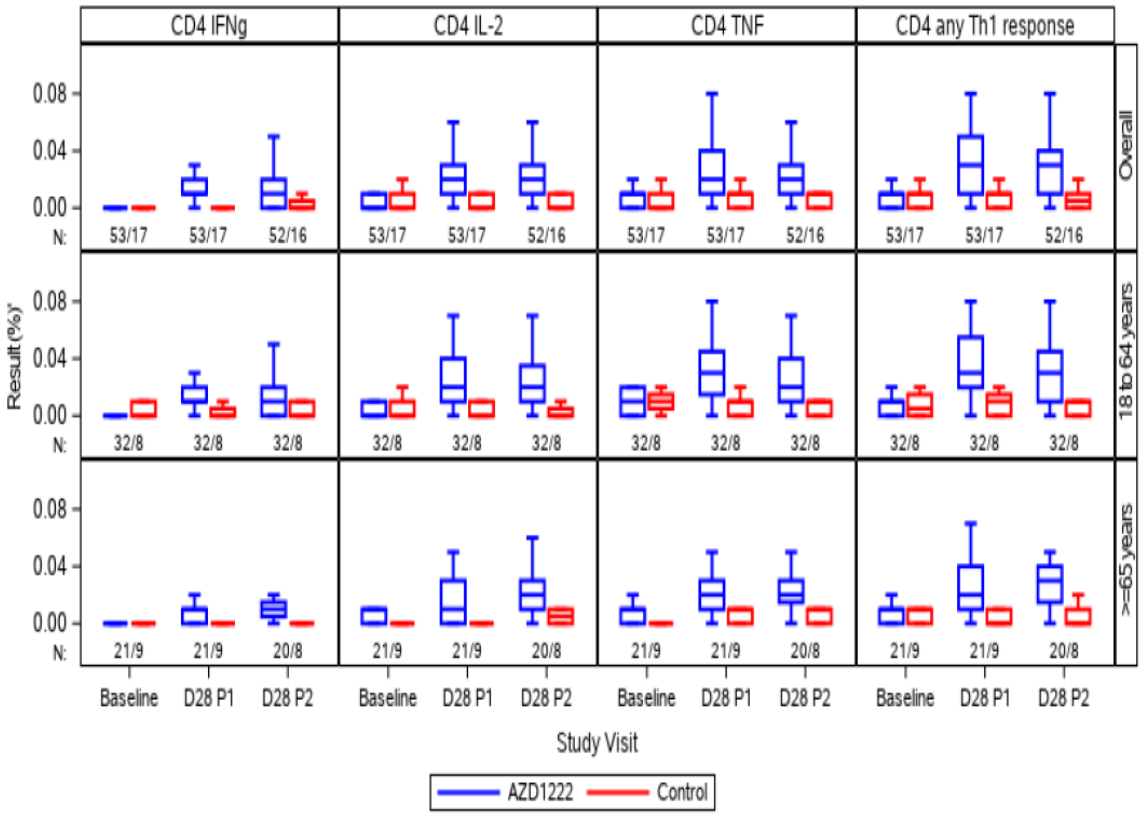
Vaccine-induced T-cell responses

Th1 Cytokines were induced following stimulation with overlapping SARS-CoV-2 S peptides

CD4 Th1 Responses, S1 Stimulation, by Age Subgroup and Overall



CD4 Th1 Responses, S2 Stimulation, by Age Subgroup and Overall



Boxplots display the median and 1st and 3rd quartiles. Whiskers extend to the minimum and maximum values, excluding outliers. Baseline is defined as the last non-missing measurement taken prior to the first dose of study intervention. Background percentage was subtracted from the stimulated percentage prior to analysis. Stimulated percentages less than the background percentage were set to 0%.

Abbreviations: D28 P1 = Day 28 post Dose 1; D28 P2 = Day 28 post Dose 2.

Source: Supplemental Figure IEMT 194.1.1.1.; Supplemental Figure IEMT 194.1.1.2

Exploratory analysis, Unpublished results

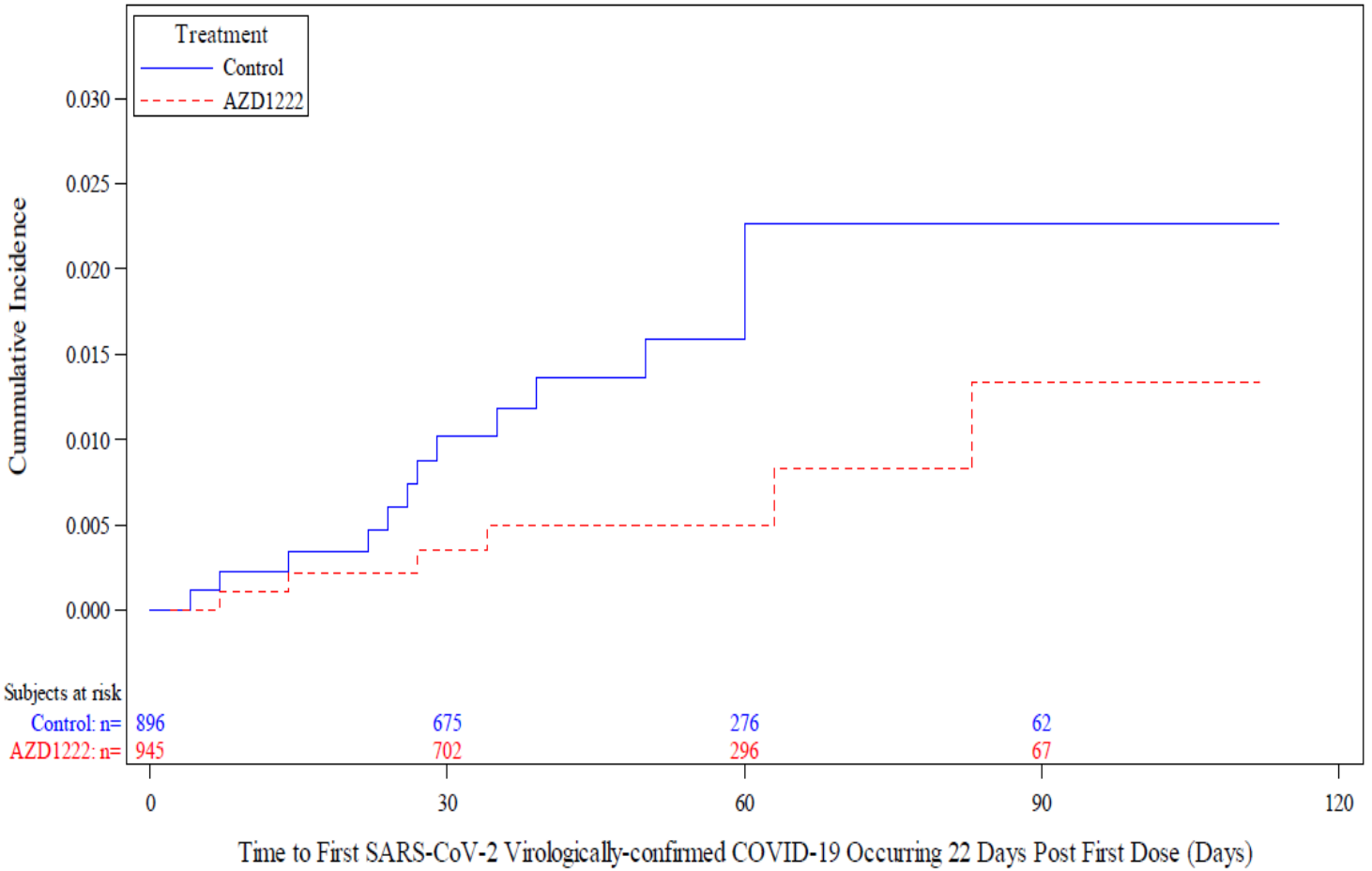
Vaccine efficacy in elderly (65 years and above)

	AZD1222 n/N (%)	Control n/N (%)	Vaccine Efficacy (95% CI)	P-value
≥15 days post-dose 2 (primary efficacy)	4/703 (0.57)	8/680 (1.18)	51.91 (-59.98, 85.54)	0.233
≥ 22 days post-dose 1	6/945 (0.63)	13/896 (1.45)	55.87 (-16.08, 83.22)	0.097
Post-dose 1	10/1038 (0.96)	20/973 (2.06)	52.99 (-0.45, 78.00)	0.051
- Hospitalisations	0/1038	4/973 (0.41)	-	-

DCO2 7th Dec, COV001-2-3-5, any interval

Source: Tables 4.3.1.2, 4.4.8.1, 4.4.10.1, 4.4.13.2, 4.4.14.1, 4.4.15.1.

Cumulative incidence plot of time to 1st COVID-19 occurring ≥ 22 days post dose 1 in the ≥ 65 years age category



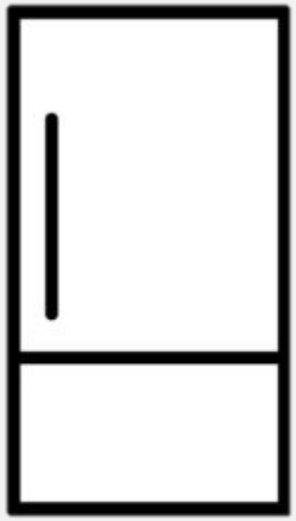
DCO2 7th Dec, COV001-2-3-5, any interval

Source: Figure 4.4.11.1.

Storage and Administration

AZD1222 storage and administration

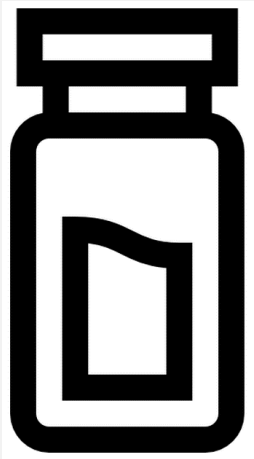
Storage



Refrigerator

- Store in refrigerator (2-8°C)
- Shelf life 6 months
- Do not freeze
- Keep vials in outer carton to protect from light

Handling

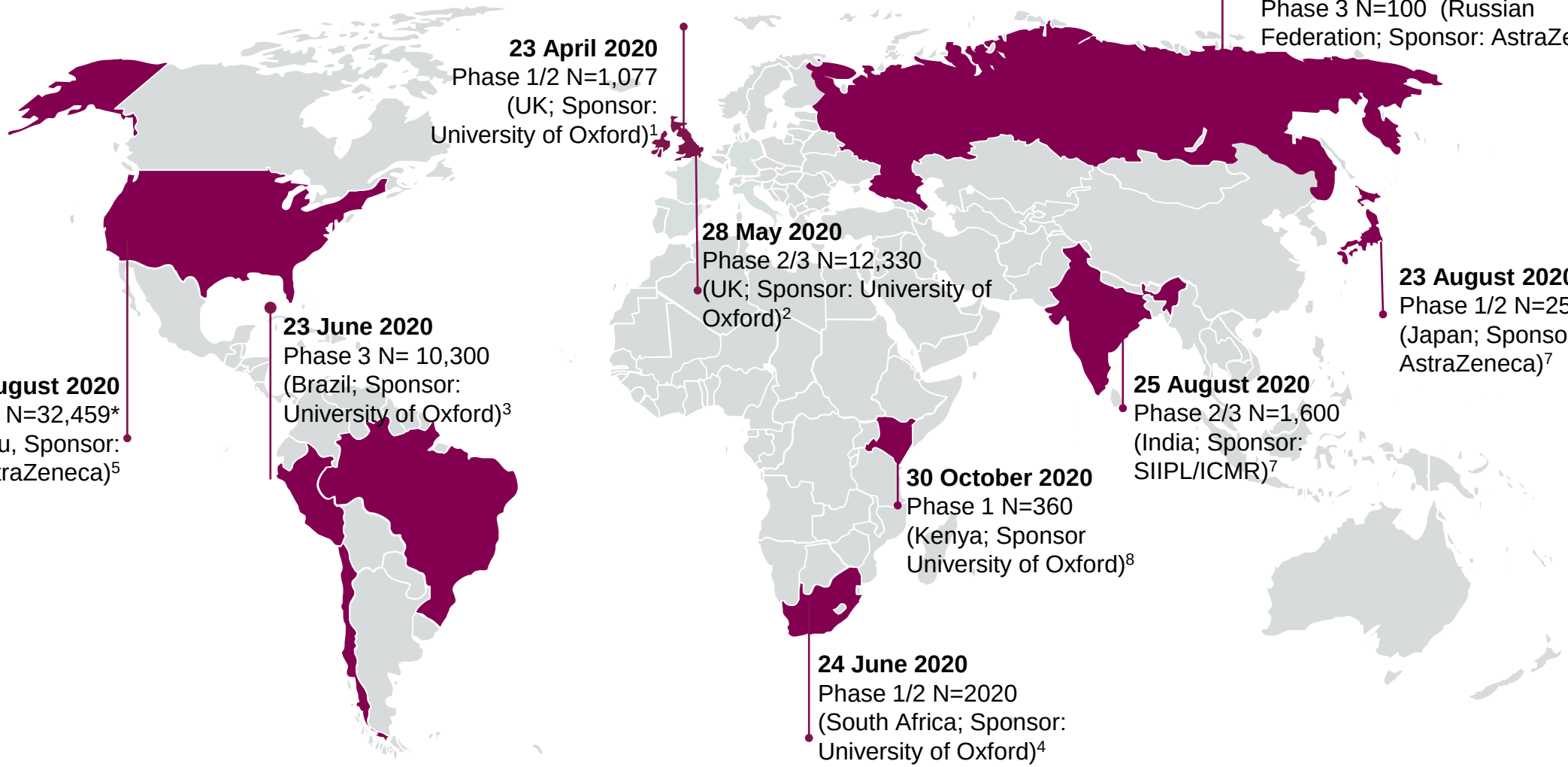


Multi-dose Vial

- After first puncture cumulatively store up to 6 hours at room temperature or up to 48 hours at 2-8°C with total storage time not to exceed 48 hours.
- No dilution or reconstitution

Clinical Development Update

AZD1222 Clinical Development Plan



02 September 2020
Phase 3 N=100 (Russian Federation; Sponsor: AstraZeneca)[6]

23 April 2020
Phase 1/2 N=1,077
(UK; Sponsor: University of Oxford)[1]

28 May 2020
Phase 2/3 N=12,330
(UK; Sponsor: University of Oxford)[2]

23 August 2020
Phase 1/2 N=256
(Japan; Sponsor: AstraZeneca)[7]

23 June 2020
Phase 3 N= 10,300
(Brazil; Sponsor: University of Oxford)[3]

28 August 2020
Phase 3 N=32,459*
(USA, Chile, Peru, Sponsor: AstraZeneca)[5]

25 August 2020
Phase 2/3 N=1,600
(India; Sponsor: SIIPL/ICMR)[7]

30 October 2020
Phase 1 N=360
(Kenya; Sponsor University of Oxford)[8]

24 June 2020
Phase 1/2 N=2020
(South Africa; Sponsor: University of Oxford)[4]

1. Study NCT04324606. ClinicalTrials.gov website; 2. Study NCT04400838. ClinicalTrials.gov website; 3. Study NCT04536051. ClinicalTrials.gov website 4. Study NCT04444674. ClinicalTrials.gov website, 5. Study NCT04516746. ClinicalTrials.gov website; 6. Study NCT04540393 ClinicalTrials.gov website; 7. AstraZeneca. Data on File; 8. University of Oxford press release. (Accessed 05 November 2020).*Participants enrolled by January 15, 2021

Phase III study D8110C00001 to evaluate safety and efficacy of AZD1222 currently ongoing in the United States, Chile, and Peru

32,459 participants enrolled

26,327 received second dose by 21 Jan 2021

Race	Enrolled*
Hispanic/Latin	11.2%
Black or African American	9.8%
Asian	5.3%
American Indian	1.8%
Hawaiian or Pacific Islander	0.4%
White	71.5%

* US enrollment only

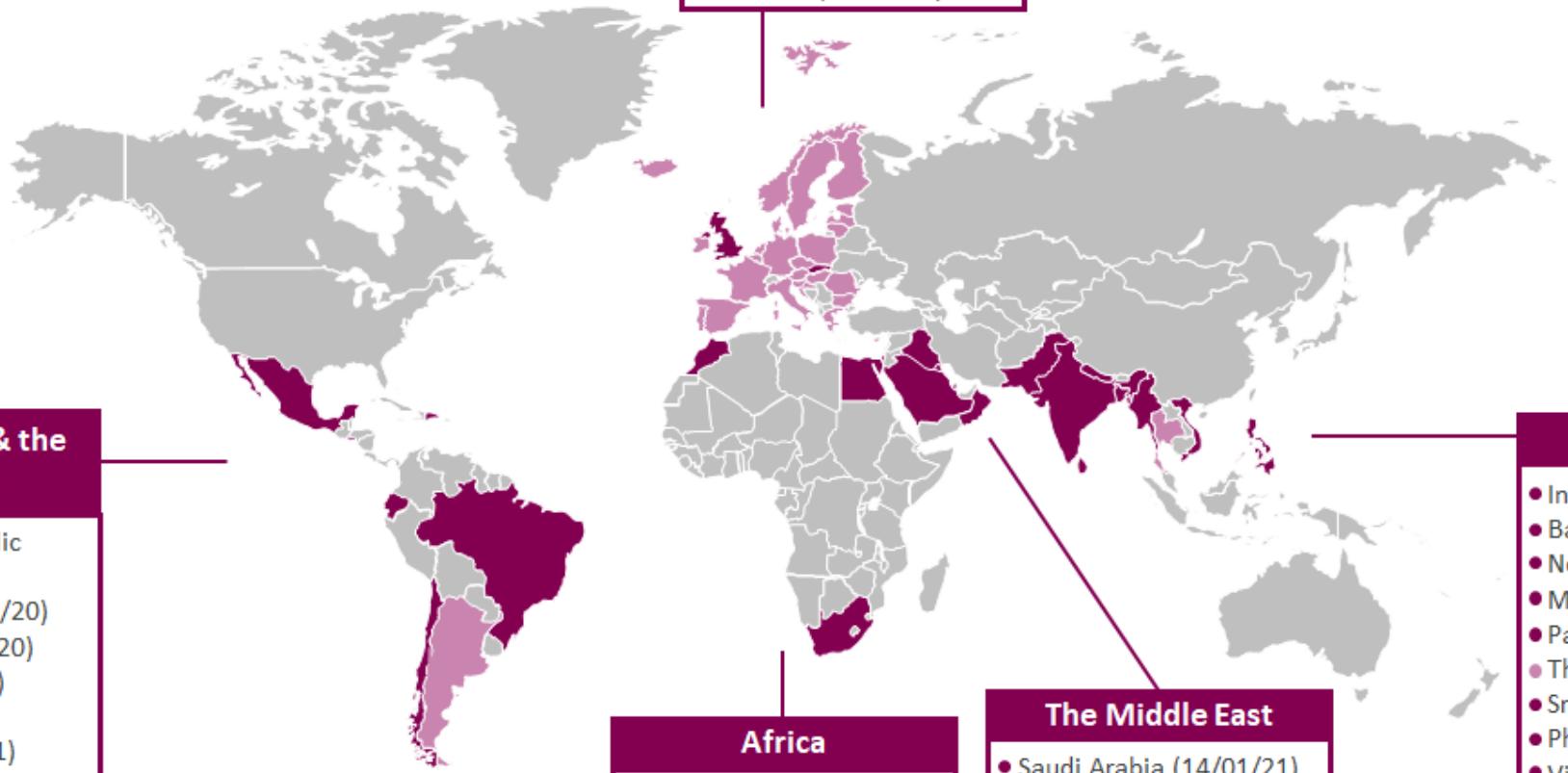
Age groups and comorbidities[1]	Enrolled
65+ years old	23.6%
<65 years old	76.4%
Has comorbidity	57.8%
No comorbidity	42.2%

[1]Comorbidities include: Chronic Kidney Disease, COPD, Heart Failure, Coronary Artery Disease, Diabetes, Asthma, High Blood Pressure, Liver Disease, BMI 30+.

1. Study NCT04516746. ClinicalTrials.gov website; 2. AstraZeneca Pharmaceuticals LP. Clinical Study Protocol (D8110C00001).

Global access plans

Regulatory status update



- Conditional marketing authorisation
- Emergency use authorisation

Europe
- UK (29/12/20)
- Hungary (21/01/21)
- EU/EMA (29/01/21)

Latin America & the Caribbean
- Dominican Republic (30/12/20)
- El Salvador (30/12/20)
- Argentina (30/12/20)
- Mexico (04/01/21)
- Brazil (17/01/21)
- Ecuador (23/01/21)
- Chile (27/01/21)

Africa
- Morocco (06/01/21)
- South Africa (22/01/21)
- Egypt (01/02/21)

The Middle East
- Saudi Arabia (14/01/21)
- Iraq (19/01/21)
- Bahrain (24/01/21)
- Kuwait (31/01/21)
- Oman (unknown)
- Palestine (unknown)

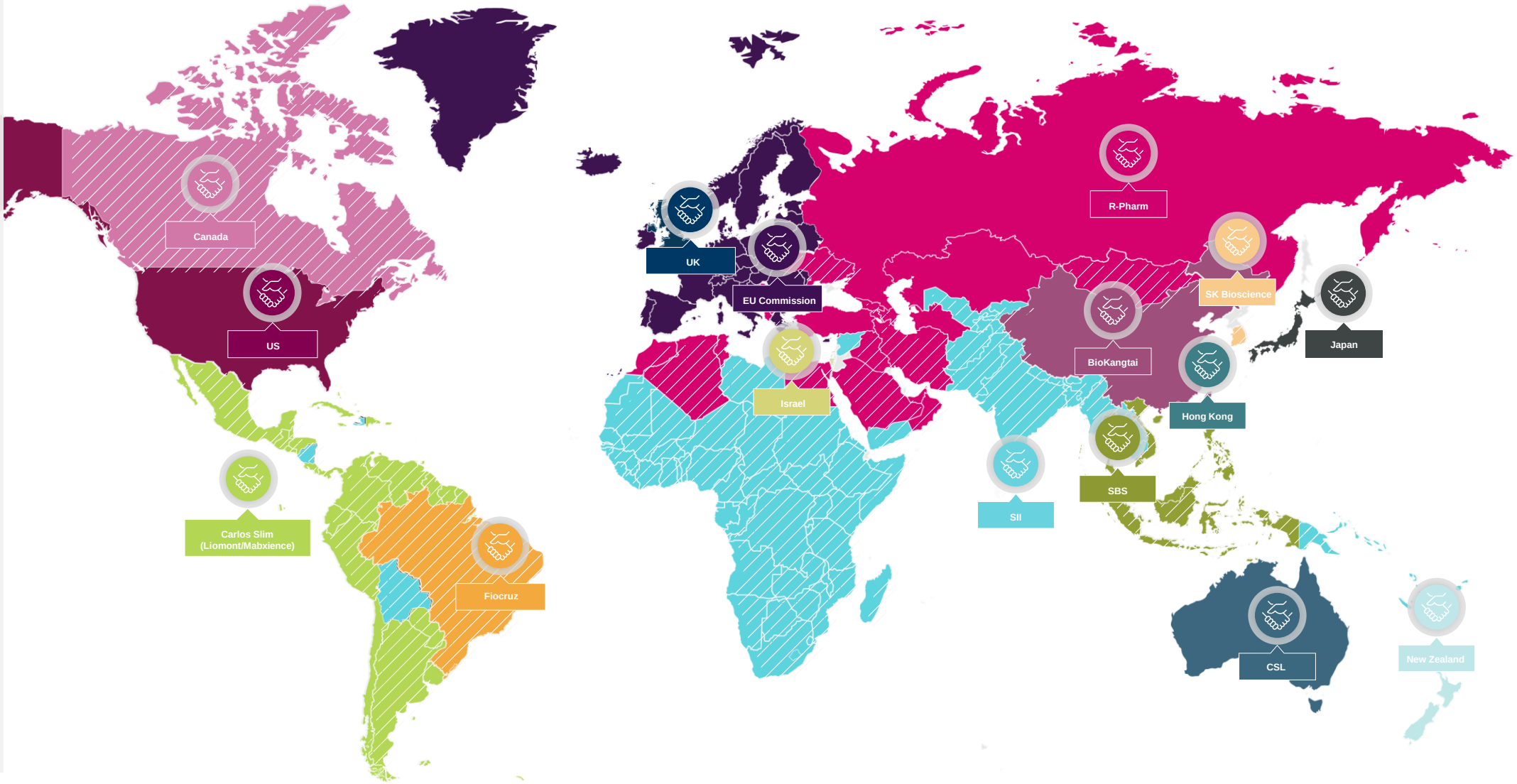
Asia
- India (03/01/21)
- Bangladesh (07/01/21)
- Nepal (15/01/21)
- Myanmar (20/01/21)
- Pakistan (21/01/21)
- Thailand (22/01/21)
- Sri Lanka (22/01/21)
- Philippines (28/01/21)
- Vietnam (30/01/21)

EMA, European Medicine Agency; EU, European Union; UK, United Kingdom

Established supply capacity to enable broad, equitable access

Establishing parallel supply agreements to ensure global access:

- April — UK
- May — USA
- June — Serum Institute of India (SII)
- CEPI-GAVI COVAX
- July — R-Pharm
- South Korea
- August — Europe
- Brazil (Fiocruz)
- LatAm (ex Brazil)
- Japan
- China
- September — Australia
- October — SE Asia
- November — Canada
- Israel
- December — New Zealand
- Hong Kong



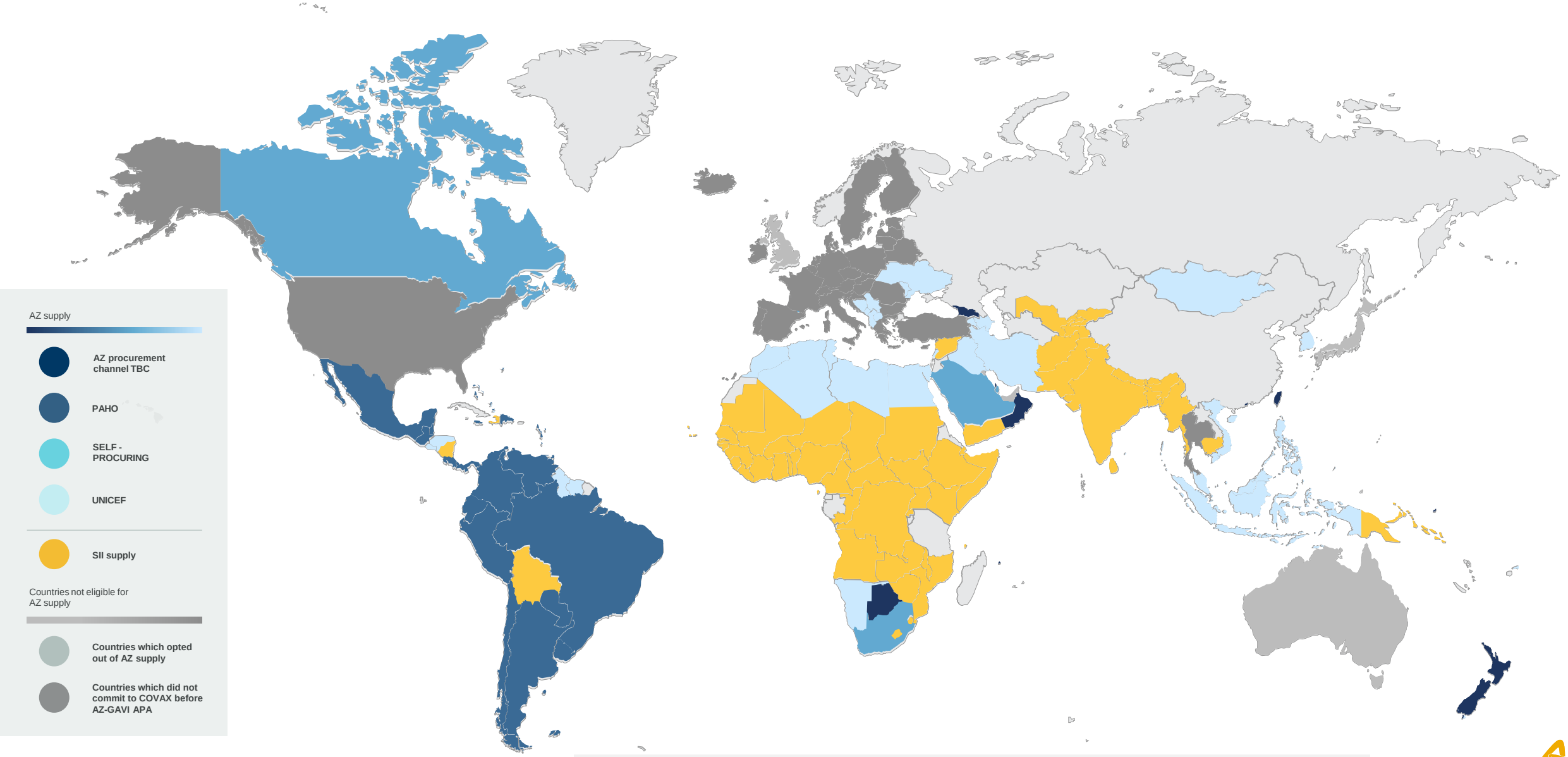
*= AZ is Marketing Authorisation Holder

CEPI-Gavi / COVAX -
= Countries eligible to receive AZ vaccine through COVAX

Continued engagement with intl. orgs and govts to drive equitable access

CEPI · Gavi The Vaccine Alliance · World Health Organization

145 countries to receive AZD1222 through COVAX Facility in H1 2021



Continued engagement with intl. orgs and govts to drive equitable access

CEPI Gavi The Vaccine Alliance World Health Organization

Conclusions

Summary

- Vaccine immunogenicity, efficacy, and safety were demonstrated through a pooled analysis of four Oxford University-sponsored trials performed in the United Kingdom, Brazil, and South Africa.
  - Overall Vaccine Efficacy against COVID-19 of 63.1% (95% CI 51.8–71.7)
  - No COVID-19 hospitalisation or severe disease in vaccinees as from 22 days post Dose 1
  - Evidence of a better response when dose 2 is administered around week 12 as compared to week 4
  - Vaccine efficacy of 71.4% (95%CI 51.1-84.1) between 22 days post dose 1 and dose 2 or 12 weeks
  - Vaccine efficacy in participants with comorbidities consistent with that observed in the general population
  - Elderly: limited number of cases but efficacy and immunogenicity trends point towards a favorable risk benefit balance
  - Vaccine was well tolerated in studied populations
- Data supported either full licensure or emergency use authorization for use in more than 45 countries
- AstraZeneca in partnership with Oxford University is committed to ensure broad and equitable vaccine access globally, not for profit during the pandemic

Thank You

to collaborators, investigators and subjects:

- University of Oxford
- Universidade Federal de São Paulo
- Wits Health Consortium
- All Clinical Research centres
- The Bill and Melinda Gates Foundation
- South African Medical Research Council
- The AstraZeneca Team

- All trial participants and their families