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## Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Voysey M, Clemens SAC, Madhi SA, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *Lancet* 2020; published online Dec 8. http://dx.doi.org/10.1016/S0140-6736(20)32661-1.

# Supplementary Information

**Supplementary Laboratory Methods**

Serum samples were measured at baseline in a validated serological assay using the nucleocapsid antigen of SARS-COV-2 and run at PPD Central Labs (Zaventum, Belgium and Highland Heights, KY, USA). The Roche Elecsys Anti-SARS-CoV-2 serology test is an electroluminescence immunoassay-based modality that allows for the qualitative detection of IgG reactive to the SARS-CoV-2 nucleoprotein in human sera. Further details available at: https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3358-a001.pdf

**Table S1 Summary of trials included in the analysis**

| **Study** | **COV001** | **COV002** | **COV003** | **COV005** |
|---|---|---|---|---|
| Country | United Kingdom | United Kingdom | Brazil | South Africa |
| Blinding | Single Blind | Single Blind | Single Blind | Double Blind |
| Control Group | MenACWY | MenACWY | MenACWY (first dose)<br>Saline (second dose) | Saline Placebo |
| Funding | UK Research and Innovation, Coalition for Epidemic Preparedness Innovations, National Institute for Health Research (NIHR), NIHR Oxford Biomedical Research Centre, Thames Valley and South Midland's NIHR Clinical Research Network | United Kingdom National Institute for Health Research (NIHR), Coalition for Epidemic Preparedness Innovations, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midlands NIHR Clinical Research Network, and AstraZeneca. | University of Oxford, Fundação Lemann, Fundação Brava, Fundação Telles, Instituto D'or de Ensino e Pesquisa and AstraZeneca Brasil. | UK Research and Innovation (For Vaccine supply only), The Bill and Melinda Gates Foundation and South African Medical Research Council |
| Study Sites | 1. Centre for Clinical Vaccinology and Tropical Medicine, University of Oxford;<br>2. NIHR Southampton Clinical Research Facility, University Hospital Southampton NHS Foundation Trust, Southampton;<br>3. Clinical Research Facility, Imperial College London;<br>4. St Georges University of London and | 6. University Hospitals Birmingham NHS Foundation Trust<br>7. University Hospitals Bristol and Weston NHS Foundation Trust<br>8. NIHR Cambridge Clinical Research Facility<br>9. Aneurin Bevan Local Health Board Headquarters, Wales<br>10. Lothian NHS Board<br>11. Greater Glasgow and Clyde NHS Board<br>12. Guy's and St Thomas' NHS Foundation Trust<br>13. Hull University Teaching Hospitals NHS Trust | 1. Centro de Referência para Imunobiológicos Especiais, Universidade Federal de São Paulo - São Paulo, SP<br>2. Instituto D'Or de Pesquisa e Ensino – Rio de Janeiro, RJ<br>3. Instituto D'Or de Pesquisa e Ensino – Salvador, BA .<br>4. Universidade Federal de Santa Maria - Santa Maria, RS<br>5. Hospital de Clínicas de Porto Alegre, | 1. Respiratory and Meningeal Pathogens Research Unit - Johannesburg<br>2. Setshaba Research Centre (SRC) – Gauteng<br>3. Wits RHI Shandukani Research Centre – Johannesburg<br>4. Perinatal HIV Research Unit - Kliptown.<br>5. Family Centre for Research with Ubuntu |

| | | | | |
|---|---|---|---|---|
| | 5. University Hospital NHS Foundation Trust; and University Hospitals Bristol and Weston NHS Foundation Trust). | 14. NIHR Imperial Clinical Research Facility Imperial College London<br>15. Liverpool School of Tropical Medicine<br>16. North Bristol NHS Trust<br>17. NIHR Newcastle Clinical Research Facility, The Newcastle upon Tyne Hospitals NHS Foundation Trust<br>18. Northwick Park Hospital<br>19. University of Nottingham Health Service<br>20. Oxford University Hospitals NHS Foundation Trust<br>21. Sheffield Teaching Hospitals NHS Foundation Trust University Hospital Southampton NHS Foundation Trust<br>22. St Georges University Hospital NHS Foundation Trust<br>23. University College London Hospitals NHS Foundation Trust | Universidade Federal do Rio Grande do Sul - Porto Alegre, RS<br>6. Centro de Pesquisas Clinicas – Natal, RN | (FAMCRU) – Cape Town<br>6. Soweto Clinical Trials Centre (SCTC)<br>7. University of Cape Town Lung Institute and Centre for Lung Infection and Immunity (CLII) – Cape Town<br>8. Soweto Clinical Trials Centre (SCTC) - Johannesburg |

**Figure S1 CONSORT participant flow diagram**

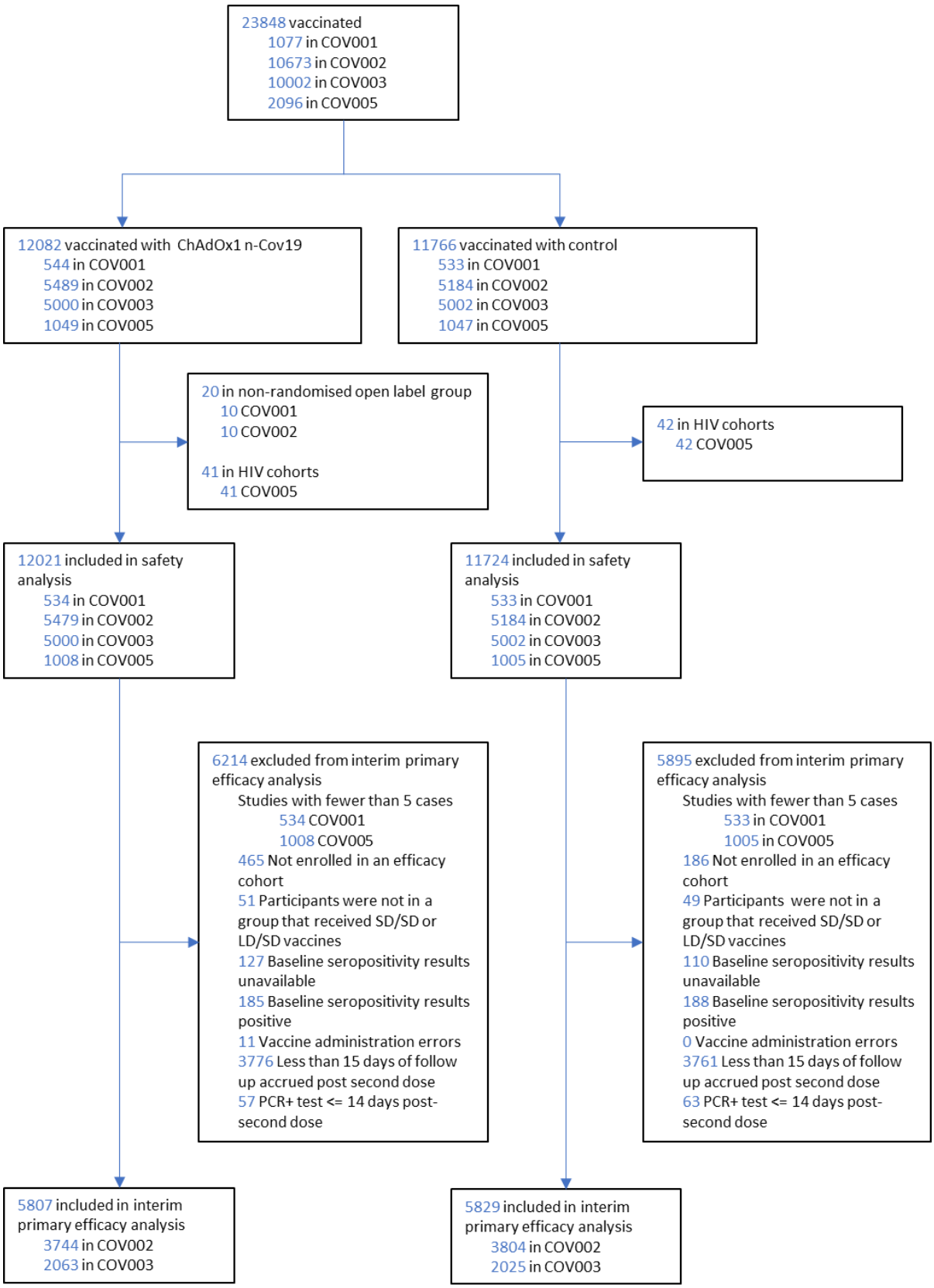


**Table S2 Participant disposition for primary analysis in COV002 and COV003**

| **Exclusion from primary analysis** | **COV002** | | | | **COV003** | |
|---|---|---|---|---|---|---|
| | **LD/SD** | | **SD/SD** | | | |
| | **ChAdOx1 nCoV-19*** | **Control*** | **ChAdOx1 nCoV-19*** | **Control*** | **ChAdOx1 nCoV-19*** | **Control*** |
| **N Total number vaccinated with at least one dose** | **10673** | | | | **10002** | |
| 1. Non-randomised groups⁑ | 10 | | | | 0 | |
| 2. Not enrolled in an efficacy cohort | 465 (ChAdOx1 nCoV-19)<br>186 (Control) | | | | 0 | |
| 3. Participants were not in a group that received SD/SD, LD/SD vaccines‡ | 51 (ChAdOx1 nCoV-19)<br>49 (Control) | | | | 0 | |
| 4. Baseline seropositivity results unavailable ♯ | 4 | 4 | 27 | 23 | 96 | 83 |
| 5. Baseline seropositivity results positive | 19 | 17 | 53 | 49 | 113 | 122 |
| 6. Vaccine administration errors | 6 (LDSD:1, SDSD:5)† | | | | 5† | |
| 7. Less than or equal to 14 days of follow up accrued post second dose | 264 | 261 | 816 | 766 | 2696 | 2734 |
| *7.1 Chose not to receive a second dose* | 145 | 119 | 152 | 134 | 0 | 0 |
| *7.2 Yet to reach 28 days post first dose, so not yet eligible for second dose* | 0 | 0 | 248 | 247 | 1807 | 1823 |

| | | | | | | |
|---|---|---|---|---|---|---|
| *7.3 All others yet to receive second dose* | 113 | 138 | 231 | 197 | 509 | 562 |
| *7.4 Received a second dose but did not reach the 14 days post boost time point* | 6 | 4 | 183 | 188 | 380 | 348 |
| *7.5 The participant withdrew early* | 0 | 0 | 2 | 0 | 0 | 1 |
| 8. PCR+ test <= 14 days post-second dose (by arm) | 11 | 5 | 19 | 20 | 27 | 38 |
| **N included in efficacy analysis** | **1367** | **1374** | **2377** | **2430** | **2063** | **2025** |
| | | | | | | |

† These participants received two different vaccines and were excluded. One SDSD participant in COV002 was randomised to control but received two doses of ChAdOx1 nCoV-19. Two participants in COV003 were randomised to control but received two doses of ChAdOx1 nCoV-19, and three participants were randomised to ChAdOx1 nCoV-19 but received two doses of control vaccine. These participants who, in error, received two doses of the same vaccine were included in the primary analysis under the vaccine they received. ‡COV002 included a non-randomised open-label immunogenicity group of participants who had received a prior non-COVID ChAdOx1 vaccine and these participants are excluded.‡ This cohort received LD/LD vaccines.
♯Results were unavailable from some samples as the quantity of sample was not sufficient for the assay.

**Table S3 Participant disposition for secondary analysis in COV002 and COV003**

| | COV002 | | COV003 | |
|---|---|---|---|---|
| | **ChAdOx1 nCoV-19*** | **Control*** | **ChAdOx1 nCoV-19*** | **Control*** |
| **N Total number vaccinated with at least one dose** | **10673** | | **10002** | |
| 1. Non-randomised groups‡ | 10 | | 0 | |
| 2. Not enrolled in an efficacy cohort | 465 | 186 | 0 | 0 |
| 3. Participants were not randomised to receive SD vaccines as the first dose | 1715 | 1712 | 0 | 0 |
| 4. Baseline seropositivity results unavailable ♯ | 27 | 23 | 96 | 83 |
| 5. Baseline seropositivity results positive | 53 | 49 | 113 | 122 |
| 6. Vaccine administration errors | 1† | | 2† | |
| 7. Less than or equal to 21 days of follow up accrued post first dose | 150 | 149 | 1508 | 1526 |
| *7.1 Did not reach the 21 days post-prime time point* | 150 | 146 | 1508 | 1526 |
| *7.2 The participant withdrew early* | 0 | 3 | 0 | 0 |
| 8. PCR+ test <= 14 days post-second dose | 6 | 3 | 34 | 38 |
| **N included in efficacy analysis** | **3060** | **3064** | **3247** | **3233** |

† These participants received two different vaccines with the 1st dose as MenACWY and 2nd dose as ChAdoOx1 nCoV-19 were excluded. ‡COV002 included a non-randomised open-label immunogenicity group of participants who had received a prior non-COVID ChAdOx1 vaccine and these participants are excluded.

♯Results were unavailable from some samples as the quantity of sample was not sufficient for the assay.

**Table S4 Baseline characteristics of participants included in the any dose for safety population***

| | **COV001 (UK) N=1067** | | **COV002 (UK) N=10663** | | **COV003 (Brazil) N=10002** | | **COV005 (South Africa) N=2013** | |
|---|---|---|---|---|---|---|---|---|
| **Study** | **ChAdOx1 nCoV-19 N=534 N (%)** | **MenACWY N=533 N (%)** | **ChAdOx1 nCoV-19 N=5479 N (%)** | **MenACWY N=5184 N (%)** | **ChAdOx1 nCoV-19 N=5000 N (%)** | **MenACWY N=5002 N (%)** | **ChAdOx1 nCoV-19 N=1008 N (%)** | **Saline N=1005 N (%)** |
| Age | | | | | | | | |
| *18-55 years* | 533 (99.8%) | 532 (99.8%) | 4160 (75.9%) | 4110 (79.3%) | 4146 (82.9%) | 4192 (83.8%) | 961 (95.3%) | 954 (94.9%) |
| *56-69 years* | 0 (0.0%) | 0 (0.0%) | 635 (11.6%) | 553 (10.7%) | 717 (14.3%) | 692 (13.8%) | 47 (4.7%) | 51 (5.1%) |
| *70+ years* | 0 (0.0%) | 0 (0.0%) | 684 (12.5%) | 521 (10.1%) | 137 (2.7%) | 118 (2.4%) | 0 (0.0%)£ | 0 (0.0%)£ |
| *missing* | 1 (0.2%) | 1 (0.2%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Sex (female) n% | 259 (48.5%) | 271 (50.8%) | 3251 (59.3%) | 3150 (60.8%) | 2764 (55.3%) | 2688 (53.7%) | 437 (43.4%) | 440 (43.8%) |
| BMI (median, IQR) $kg/m^2$ | 24.2 [22.2-26.6] | 24.4 [22.1-26.9] | 25.4 [22.9-28.8] | 25.5 [22.9-28.9] | 26.0 [23.2-29.4] | 25.9 [23.3-29.4] | 23.8 [20.6-28.3] | 23.5 [20.8-28.4] |
| Ethnicity | | | | | | | | |
| *White* | 485 (90.8%) | 485 (91.0%) | 5023 (91.7%) | 4784 (92.3%) | 3395 (67.9%) | 3434 (68.7%) | 126 (12.5%) | 132 (13.1%) |
| *Black* | 4 (0.7%) | 2 (0.4%) | 28 (0.5%) | 21 (0.4%) | 452 (9.0%) | 464 (9.3%) | 714 (70.8%) | 709 (70.5%) |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *Asian*† | 23 (4.3%) | 28 (5.3%) | 289 (5.3%) | 258 (5.0%) | 127 (2.5%) | 100 (2.0%) | | |
| *Mixed* | 11 (2.1%) | 9 (1.7%) | 95 (1.7%) | 80 (1.5%) | 994 (19.9%) | 972 (19.4%) | 148 (14.7%)€ | 143 (14.2%)€ |
| *Other* | 11 (2.1%) | 9 (1.7%) | 44 (0.8%) | 41 (0.8%) | 32 (0.6%) | 32 (0.6%) | 20 (2.0%) | 21 (2.1%) |
| *missing* | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| % Health and social care setting workers | 105 (19.7%) | 91 (17.1%) | 3504 (64.0%) | 3481 (67.1%) | 3291 (65.8%) | 3252 (65.0%) | 79 (7.8%) | 88 (8.8%) |
| Co-morbidities¥ | | | | | | | | |
| *Cardiovascular disease* | 0 (0.0%) | 0 (0.0%) | 682 (12.4%) | 598 (11.5%) | 801 (16.0%) | 782 (15.6%) | 30 (3.0%) | 23 (2.3%) |
| *Respiratory disease* | 0 (0.0%) | 0 (0.0%) | 663 (12.1%) | 655 (12.6%) | 502 (10.0%) | 494 (9.9%) | 31 (3.1%) | 20 (2.0%) |
| *Diabetes* | 0 (0.0%) | 0 (0.0%) | 117 (2.1%) | 99 (1.9%) | 218 (4.4%) | 186 (3.7%) | 3 (0.3%) | 5 (0.5%) |

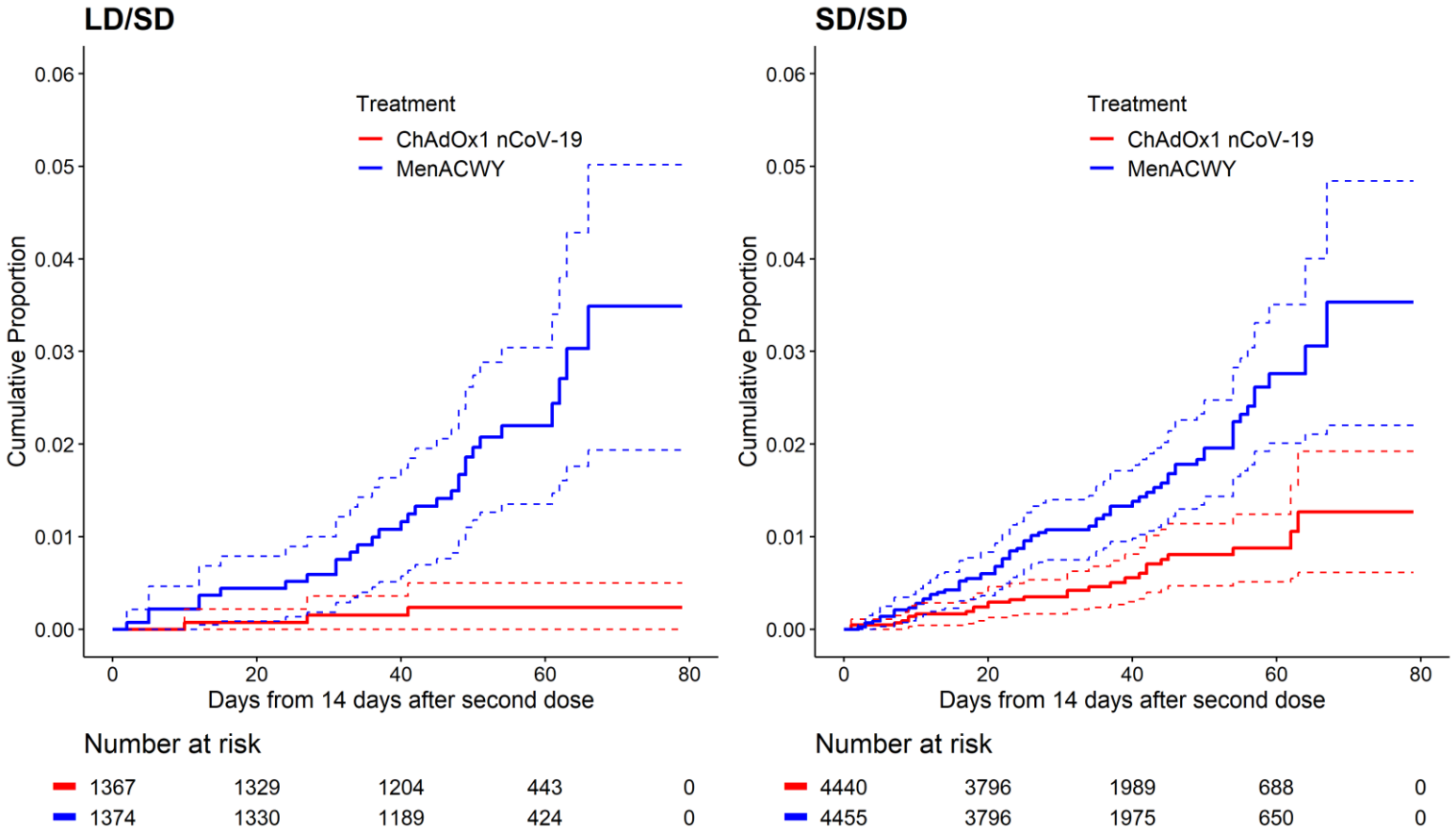
*Any dose for safety population as defined in the statistical analysis plan. † Asian not recorded as a category in South Africa. £ Maximum age at enrolment for eligibility was 65 years in South Africa. € This category recorded as 'Coloured' in original data. ¥ As an early-phase trial COV001 excluded participants with co-morbidities.

**Table S5 Timing of vaccine administration in those included in the primary analysis***

| | COV002 (UK) | | COV003 (Brazil) | |
|---|---|---|---|---|
| **Study** | **ChAdOx1 nCoV-19 N (%)** | **MenACWY N (%)** | **ChAdOx1 nCoV-19 N (%)** | **MenACWY N (%)** |
| Time between first and second dose LD/SD | | | | |
| < 6 weeks | 0 (0.0%) | 0 (0.0%) | | |
| 6-8 weeks | 10/1367 (0.7%) | 12/1374 (0.9%) | | |
| 9-11 weeks | 624/1367 (45.6%) | 636/1374 (46.3%) | | |
| ≥12 weeks | 733/1367 (53.6%) | 726/1374 (52.8%) | | |
| Time between first and second dose SD/SD | | | | |
| < 6 weeks | 453/2377 (19.1%) | 454/2430 (18.7%) | 1249/2063 (60.5%) | 1244/2025 (61.4%) |
| 6-8 weeks | 517/2377 (21.8%) | 464/2430 (19.1%) | 430/2063 (20.8%) | 431/2025 (21.3%) |
| 9-11 weeks | 595/2377 (25.0%) | 665/2430 (27.4%) | 285/2063 (13.8%) | 275/2025 (13.6%) |
| ≥12 weeks | 812/2377 (34.2%) | 847/2430 (34.9%) | 99/2063 (4.8%) | 75/2025 (3.7%) |

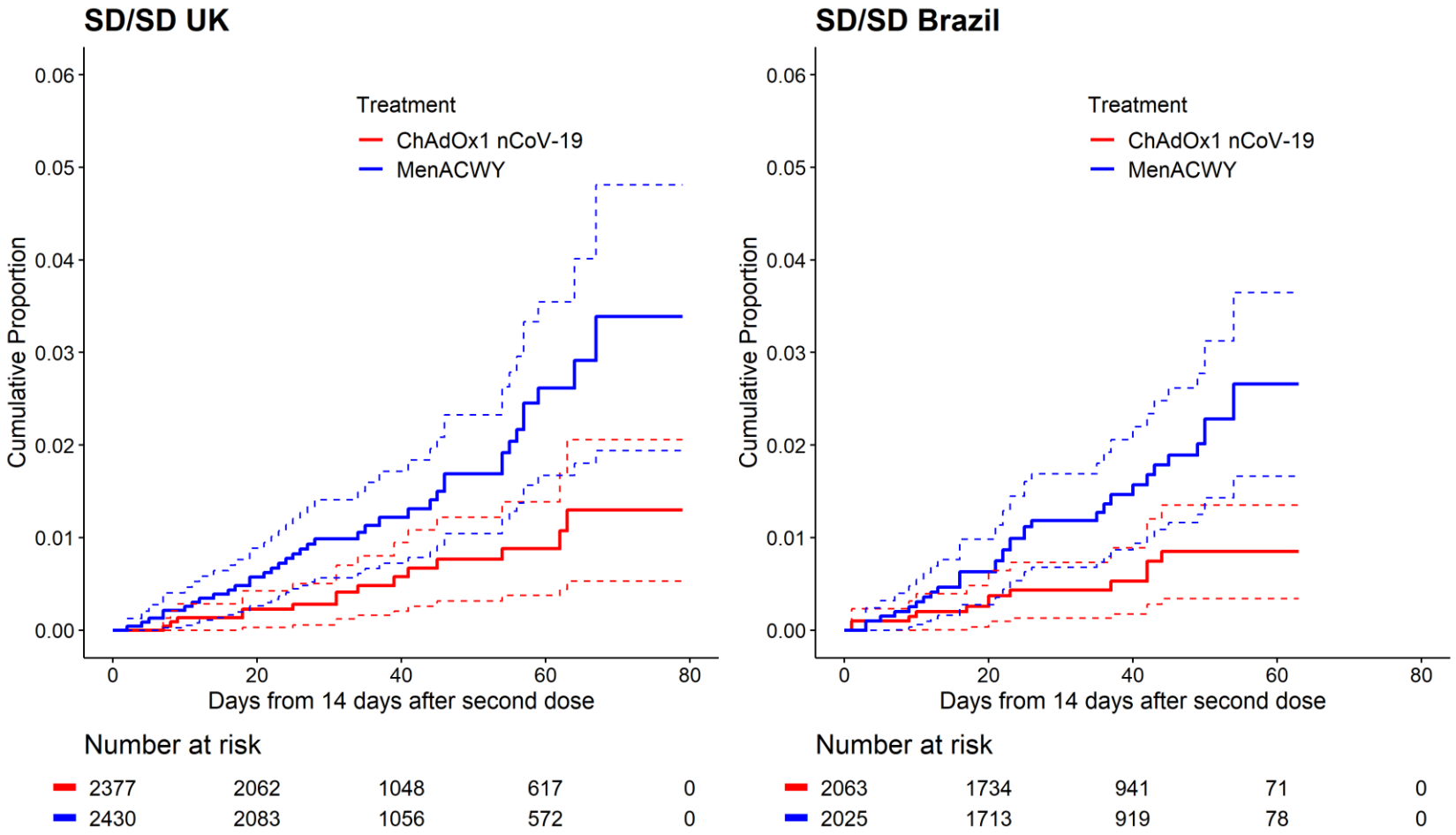
*The LDSD, SDSD efficacy population as defined in the statistical analysis plan.

**Figure S2 Kaplan-Meier cumulative incidence of primary symptomatic COVID-19 in LD/SD recipients in the UK, and in SD/SD recipients in the UK and Brazil**




Cumulative incidence of symptomatic COVID-19 after low dose followed by standard dose (LD/SD) (left) or after two standard doses (right). Dotted lines show 95% confidence region.

**Figure S3 Kaplan-Meier cumulative incidence of primary symptomatic COVID-19 in SD/SD recipients in the UK, and in SD/SD recipients in the Brazil**



Cumulative incidence of primary symptomatic COVID-19 after two standard doses in the UK (left) and in Brazil (right). Dotted lines show 95% confidence region.

**Table S6 Serious adverse events by MedDRA system organ class and preferred term at any time during the study, in randomised participants who received at least one dose of vaccine**

| | ChAdOx1 nCoV-19 (N = 12021) | | Control (N = 11724) | |
|---|---|---|---|---|
| **System Organ Class**<br>**Preferred Term (MedDRA version 23.1)** | **Number (%) of Participants[a]** | **Number of Events** | **Number (%) of Participants[a]** | **Number of Events** |
| **Participants with any SAE** | **79 (0.7)** | **84** | **89 (0.8)** | **91** |
| **Blood and lymphatic system disorders** | **0** | **0** | **1 (<0.1)** | **1** |
| Autoimmune haemolytic anaemia | 0 | 0 | 1 (<0.1) | 1 |
| **Cardiac disorders** | **5 (<0.1)** | **5** | **6 (0.1)** | **6** |
| Angina pectoris | 3 (<0.1) | 3 | 0 | 0 |
| Angina unstable | 0 | 0 | 1 (<0.1) | 1 |
| Atrial flutter | 1 (<0.1) | 1 | 0 | 0 |
| Atrioventricular block complete | 1 (<0.1) | 1 | 0 | 0 |
| Atrioventricular block second degree | 0 | 0 | 1 (<0.1) | 1 |
| Palpitations | 0 | 0 | 1 (<0.1) | 1 |
| Pericarditis | 0 | 0 | 2 (<0.1) | 2 |
| Supraventricular tachycardia | 0 | 0 | 1 (<0.1) | 1 |
| **Congenital, familial and genetic disorders** | **0** | **0** | **1 (<0.1)** | **1** |
| Syringomyelia | 0 | 0 | 1 (<0.1) | 1 |
| **Ear and labyrinth disorders** | **1 (<0.1)** | **1** | **0** | **0** |
| Auricular chondritis | 1 (<0.1) | 1 | 0 | 0 |
| **Eye disorders** | **2 (<0.1)** | **2** | **0** | **0** |
| Retinal detachment | 1 (<0.1) | 1 | 0 | 0 |
| Retinal tear | 1 (<0.1) | 1 | 0 | 0 |
| **Gastrointestinal disorders** | **8 (0.1)** | **9** | **11 (0.1)** | **11** |
| Abdominal pain lower | 0 | 0 | 1 (<0.1) | 1 |
| Anal incontinence | 0 | 0 | 1 (<0.1) | 1 |
| Diarrhoea | 1 (<0.1) | 1 | 0 | 0 |
| Enteritis | 0 | 0 | 1 (<0.1) | 1 |
| Epiploic appendagitis | 0 | 0 | 1 (<0.1) | 1 |
| Gastritis | 1 (<0.1) | 1 | 0 | 0 |
| Gastrointestinal haemorrhage | 1 (<0.1) | 1 | 0 | 0 |
| Gastrooesophageal reflux disease | 0 | 0 | 1 (<0.1) | 1 |
| Haematemesis | 0 | 0 | 1 (<0.1) | 1 |
| Incarcerated inguinal hernia | 1 (<0.1) | 1 | 0 | 0 |
| Pancreatitis | 0 | 0 | 1 (<0.1) | 1 |
| Pancreatitis acute | 1 (<0.1) | 1 | 1 (<0.1) | 1 |
| Small intestinal obstruction | 0 | 0 | 1 (<0.1) | 1 |
| Volvulus | 2 (<0.1) | 3 | 0 | 0 |
| Vomiting | 1 (<0.1) | 1 | 2 (<0.1) | 2 |
| **General disorders and administration site conditions** | **3 (<0.1)** | **3** | **2 (<0.1)** | **2** |
| Chest pain | 2 (<0.1) | 2 | 0 | 0 |
| Non-cardiac chest pain | 0 | 0 | 1 (<0.1) | 1 |

| | | | | |
|---|---|---|---|---|
| Pain | 0 | 0 | 1 (<0.1) | 1 |
| Pyrexia | 1 (<0.1) | 1 | 0 | 0 |
| **Immune system disorders** | **0** | **0** | **1 (<0.1)** | **1** |
| Allergy to arthropod sting | 0 | 0 | 1 (<0.1) | 1 |
| **Injury, poisoning and procedural complications** | **10 (0.1)** | **10** | **14 (0.1)** | **14** |
| Animal bite | 0 | 0 | 1 (<0.1) | 1 |
| Cervical vertebral fracture | 1 (<0.1) | 1 | 0 | 0 |
| Craniocerebral injury | 1 (<0.1) | 1 | 1 (<0.1) | 1 |
| Fibula fracture | 1 (<0.1) | 1 | 0 | 0 |
| Forearm fracture | 0 | 0 | 1 (<0.1) | 1 |
| Gun shot wound | 1 (<0.1) | 1 | 0 | 0 |
| Humerus fracture | 0 | 0 | 1 (<0.1) | 1 |
| Injury | 0 | 0 | 1 (<0.1) | 1 |
| Intentional overdose | 0 | 0 | 2 (<0.1) | 2 |
| Joint dislocation | 0 | 0 | 1 (<0.1) | 1 |
| Ligament rupture | 1 (<0.1) | 1 | 0 | 0 |
| Limb injury | 1 (<0.1) | 1 | 0 | 0 |
| Lower limb fracture | 0 | 0 | 1 (<0.1) | 1 |
| Meniscus injury | 1 (<0.1) | 1 | 0 | 0 |
| Post procedural complication | 0 | 0 | 1 (<0.1) | 1 |
| Procedural nausea | 1 (<0.1) | 1 | 0 | 0 |
| Road traffic accident | 0 | 0 | 2 (<0.1) | 2 |
| Synovial rupture | 1 (<0.1) | 1 | 0 | 0 |
| Thermal burn | 1 (<0.1) | 1 | 0 | 0 |
| Upper limb fracture | 0 | 0 | 1 (<0.1) | 1 |
| Wrist fracture | 0 | 0 | 1 (<0.1) | 1 |
| **Infections and infestations** | **18 (0.1)** | **20** | **27 (0.2)** | **27** |
| Acute sinusitis | 0 | 0 | 1 (<0.1) | 1 |
| Appendicitis | 6 (<0.1) | 6 | 5 (<0.1) | 5 |
| COVID-19 | 2 (<0.1) | 2 | 11 (0.1) | 11 |
| COVID-19 pneumonia | 0 | 0 | 2 (<0.1) | 2 |
| Campylobacter colitis | 1 (<0.1) | 1 | 0 | 0 |
| Complicated appendicitis | 0 | 0 | 1 (<0.1) | 1 |
| Diverticulitis | 2 (<0.1) | 2 | 0 | 0 |
| Gastroenteritis | 0 | 0 | 1 (<0.1) | 1 |
| Haematoma infection | 0 | 0 | 1 (<0.1) | 1 |
| Hepatitis infectious mononucleosis | 1 (<0.1) | 1 | 0 | 0 |
| Intervertebral discitis | 1 (<0.1) | 1 | 0 | 0 |
| Large intestine infection | 1 (<0.1) | 1 | 0 | 0 |
| Pilonidal cyst | 0 | 0 | 2 (<0.1) | 2 |
| Pneumonia bacterial | 1 (<0.1) | 1 | 0 | 0 |
| Pneumonia fungal | 1 (<0.1) | 1 | 0 | 0 |
| Pulmonary tuberculosis | 1 (<0.1) | 1 | 0 | 0 |
| Pyelonephritis | 3 (<0.1) | 3 | 0 | 0 |
| Sepsis | 0 | 0 | 1 (<0.1) | 1 |
| Subcutaneous abscess | 0 | 0 | 1 (<0.1) | 1 |
| Tonsillitis | 0 | 0 | 1 (<0.1) | 1 |

| | | | | |
|---|---|---|---|---|
| **Investigations** | **2 (<0.1)** | **2** | **1 (<0.1)** | **1** |
| C-reactive protein increased | 1 (<0.1) | 1 | 1 (<0.1) | 1 |
| Liver function test abnormal | 1 (<0.1) | 1 | 0 | 0 |
| **Metabolism and nutrition disorders** | **0** | **0** | **1 (<0.1)** | **1** |
| Diabetic ketoacidosis | 0 | 0 | 1 (<0.1) | 1 |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **4 (<0.1)** | **4** | **5 (<0.1)** | **5** |
| Benign neoplasm | 1 (<0.1) | 1 | 0 | 0 |
| Colorectal cancer metastatic | 0 | 0 | 1 (<0.1) | 1 |
| Haemangioma | 0 | 0 | 1 (<0.1) | 1 |
| Lip squamous cell carcinoma | 0 | 0 | 1 (<0.1) | 1 |
| Malignant melanoma | 1 (<0.1) | 1 | 0 | 0 |
| Neoplasm malignant | 1 (<0.1) | 1 | 0 | 0 |
| Papillary thyroid cancer | 0 | 0 | 1 (<0.1) | 1 |
| Renal cancer | 1 (<0.1) | 1 | 0 | 0 |
| Uterine leiomyoma | 0 | 0 | 1 (<0.1) | 1 |
| **Nervous system disorders** | **7 (0.1)** | **7** | **4 (<0.1)** | **4** |
| Facial spasm | 1 (<0.1) | 1 | 0 | 0 |
| Ischaemic stroke | 1 (<0.1) | 1 | 0 | 0 |
| Migraine | 1 (<0.1) | 1 | 0 | 0 |
| Multiple sclerosis | 1 (<0.1) | 1 | 0 | 0 |
| Myelitis | 0 | 0 | 1 (<0.1) | 1 |
| Myelitis transverse | 1 (<0.1) | 1 | 0 | 0 |
| Presyncope | 1 (<0.1) | 1 | 0 | 0 |
| Serotonin syndrome | 1 (<0.1) | 1 | 0 | 0 |
| Subarachnoid haemorrhage | 0 | 0 | 1 (<0.1) | 1 |
| Syncope | 0 | 0 | 1 (<0.1) | 1 |
| Transient ischaemic attack | 0 | 0 | 1 (<0.1) | 1 |
| **Musculoskeletal and connective tissue disorders** | **5 (<0.1)** | **5** | **2 (<0.1)** | **2** |
| Arthritis reactive | 0 | 0 | 1 (<0.1) | 1 |
| Costochondritis | 0 | 0 | 1 (<0.1) | 1 |
| Intervertebral disc protrusion | 4 (<0.1) | 4 | 0 | 0 |
| Myalgia | 1 (<0.1) | 1 | 0 | 0 |
| **Pregnancy, puerperium and perinatal conditions** | **1 (<0.1)** | **1** | **2 (<0.1)** | **2** |
| Abortion incomplete | 0 | 0 | 1 (<0.1) | 1 |
| Abortion spontaneous | 1 (<0.1) | 1 | 1 (<0.1) | 1 |
| **Psychiatric disorders** | **1 (<0.1)** | **1** | **1 (<0.1)** | **1** |
| Substance abuse | 1 (<0.1) | 1 | 0 | 0 |
| Substance-induced psychotic disorder | 0 | 0 | 1 (<0.1) | 1 |
| **Renal and urinary disorders** | **4 (<0.1)** | **4** | **6 (0.1)** | **6** |
| Acute kidney injury | 1 (<0.1) | 1 | 0 | 0 |
| Calculus urethral | 0 | 0 | 1 (<0.1) | 1 |
| Calculus urinary | 1 (<0.1) | 1 | 1 (<0.1) | 1 |
| Nephrolithiasis | 0 | 0 | 2 (<0.1) | 2 |
| Renal colic | 2 (<0.1) | 2 | 2 (<0.1) | 2 |
| **Reproductive system and breast disorders** | **7 (0.1)** | **8** | **2 (<0.1)** | **2** |
| Adnexal torsion | 1 (<0.1) | 1 | 0 | 0 |

| | | | | |
|---|---|---|---|---|
| Dysmenorrhoea | 1 (<0.1) | 1 | 0 | 0 |
| Endometriosis | 2 (<0.1) | 2 | 0 | 0 |
| Haemorrhagic ovarian cyst | 1 (<0.1) | 1 | 0 | 0 |
| Ovarian germ cell teratoma benign | 0 | 0 | 1 (<0.1) | 1 |
| Ovulation pain | 1 (<0.1) | 1 | 0 | 0 |
| Uterine haemorrhage | 1 (<0.1) | 1 | 1 (<0.1) | 1 |
| Vaginal haemorrhage | 1 (<0.1) | 1 | 0 | 0 |
| **Respiratory, thoracic and mediastinal disorders** | **1 (<0.1)** | **1** | **1 (<0.1)** | **1** |
| Dyspnoea exertional | 1 (<0.1) | 1 | 0 | 0 |
| Haemoptysis | 0 | 0 | 1 (<0.1) | 1 |
| **Skin and subcutaneous tissue disorders** | **1 (<0.1)** | **1** | **1 (<0.1)** | **1** |
| Angioedema | 0 | 0 | 1 (<0.1) | 1 |
| Cellulitis | 1 (<0.1) | 1 | 0 | 0 |
| **Social circumstances** | **0** | **0** | **1 (<0.1)** | **1** |
| Homicide | 0 | 0 | 1 (<0.1) | 1 |
| **Vascular disorders** | **0** | **0** | **1 (<0.1)** | **1** |
| Peripheral ischaemia | 0 | 0 | 1 (<0.1) | 1 |

[a] Participants with multiple events in the same preferred term are counted only once in each of those preferred term. Participants with events in more than 1 preferred term are counted once in each of those preferred term.

**Table S7 Adverse events of special interest by special interest category and preferred term in randomised participants who received at least one dose of vaccine (Any Dose for Safety Population)**

| Special Interest Category<br>Preferred Term<br>(MedDRA version 23.1) | Number (%) of Participants [a] | |
|---|---|---|
| | ChAdOx1 nCoV-19 (N=12021) | Control (N=11724) |
| **Participants with any AESI** | **95 ( 0.8)** | **126 ( 1.1)** |
| **Anaphylaxis** | **1 (<0.1)** | **0** |
| Anaphylactic reaction | 1 (<0.1) | 0 |
| **Generalized convulsion** | **1 (<0.1)** | **1 (<0.1)** |
| Seizure | 0 | 1 (<0.1) |
| Tonic convulsion | 1 (<0.1) | 0 |
| **Neurologic events-other** | **64 ( 0.5)** | **79 ( 0.7)** |
| Dysaesthesia | 4 (<0.1) | 1 (<0.1) |
| Gait disturbance | 1 (<0.1) | 1 (<0.1) |
| Hyperaesthesia | 1 (<0.1) | 1 (<0.1) |
| Hypoaesthesia | 13 ( 0.1) | 19 ( 0.2) |
| Muscular weakness | 7 ( 0.1) | 9 ( 0.1) |
| Neuralgia | 2 (<0.1) | 1 (<0.1) |
| Neuritis | 1 (<0.1) | 0 |
| Neuropathy peripheral | 1 (<0.1) | 0 |
| Paraesthesia | 37 ( 0.3) | 48 ( 0.4) |
| Sensory disturbance | 2 (<0.1) | 1 (<0.1) |
| Sensory loss | 3 (<0.1) | 3 (<0.1) |
| Visual impairment | 3 (<0.1) | 6 ( 0.1) |
| **Potential Immune Mediated Conditions - Gastrointestinal disorders** | **1 (<0.1)** | **3 (<0.1)** |
| Coeliac disease | 1 (<0.1) | 0 |
| Colitis ulcerative | 0 | 2 (<0.1) |
| Crohn's disease | 0 | 1 (<0.1) |
| **Potential Immune Mediated Conditions- Musculoskeletal disorders** | **1 (<0.1)** | **1 (<0.1)** |
| Ankylosing spondylitis | 1 (<0.1) | 0 |
| Arthritis reactive | 0 | 1 (<0.1) |
| **Potential Immune Mediated Conditions- Neuroinflammatory disorders** | **5 (<0.1)** | **4 (<0.1)** |
| Facial paralysis | 3 (<0.1) | 3 (<0.1) |
| Multiple sclerosis | 1 (<0.1) | 0 |
| Myelitis | 0 | 1 (<0.1) |
| Myelitis transverse | 1 (<0.1) | 0 |
| **Potential Immune Mediated Conditions- Skin disorders** | **3 (<0.1)** | **4 (<0.1)** |
| Alopecia areata | 0 | 1 (<0.1) |
| Psoriasis | 1 (<0.1) | 2 (<0.1) |
| Rosacea | 1 (<0.1) | 1 (<0.1) |
| Vitiligo | 1 (<0.1) | 0 |
| **Potential Immune Mediated Conditions- Vasculitides** | **0** | **1 (<0.1)** |

| | | |
|---|---|---|
| Vasculitic rash | 0 | 1 (<0.1) |
| **Potential Immune Mediated Conditions- other** | **3 (<0.1)** | **3 (<0.1)** |
| Autoimmune haemolytic anaemia | 0 | 1 (<0.1) |
| Raynaud's phenomenon | 1 (<0.1) | 0 |
| Uveitis | 2 (<0.1) | 2 (<0.1) |
| **Thrombotic, thromboembolic, and neurovascular events** | **4 (<0.1)** | **8 ( 0.1)** |
| Blindness transient | 0 | 1 (<0.1) |
| Coronary artery occlusion | 1 (<0.1) | 1 (<0.1) |
| Deep vein thrombosis | 0 | 1 (<0.1) |
| Hemiparesis | 0 | 1 (<0.1) |
| Ischaemic stroke | 1 (<0.1) | 0 |
| Monoparesis | 0 | 1 (<0.1) |
| Pulmonary embolism | 1 (<0.1) | 0 |
| Thrombophlebitis | 0 | 1 (<0.1) |
| Thrombosis | 1 (<0.1) | 0 |
| Transient ischaemic attack | 0 | 2 (<0.1) |
| **VAERD** | **12 ( 0.1)** | **23 ( 0.2)** |
| COVID-19 | 10 ( 0.1) | 21 ( 0.2) |
| COVID-19 pneumonia | 0 | 2 (<0.1) |
| Suspected COVID-19 | 2 (<0.1) | 0 |

AESI = Adverse events of special interest.

[a] Number (%) of participants with AEs, sorted in alphabetical order for special interest category and preferred term. Participants with multiple events in the same preferred term are counted only once in each of those preferred term. Participants with events in more than 1 preferred term are counted once in each of those preferred term.

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## Acknowledgements


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| Michael Breese |
| **BioIndustry Association** |
| Annette England |
| Ian McCubbin |
| **Cell & Gene Therapy Catapult** |
| Stephen Ward |
| **CobraBio** |
| Mike Austin |
| Richard Condliffe |
| Peter Coleman |
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