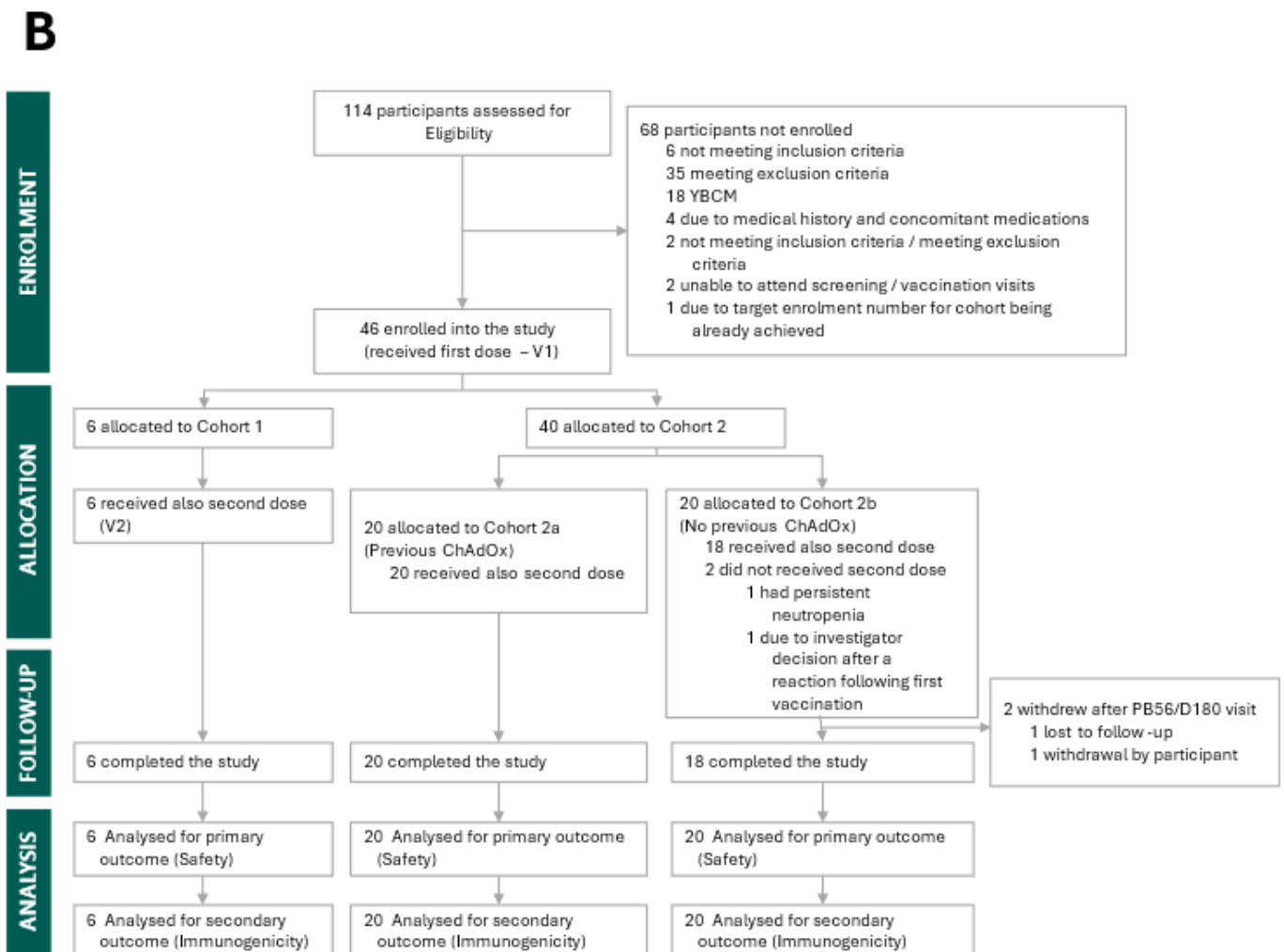


A phase 1 safety and immunogenicity study of a Crimean-Congo haemorrhagic fever virus vaccine, ChAdOx2 CCHF, in healthy adult volunteers in the UK

Participant Flow:



CCHF01 (UK) CONSORT diagram. Between Aug 31, 2023, and Jan 31, 2024, 46 participants were enrolled into the CCHF01 trial and received a first dose of ChAdOx2 CCHF vaccine. The first six participants were enrolled into a vanguard safety cohort (Cohort 1), and the subsequent 40 participants were enrolled into the main study cohort (Cohort 2).

Baseline characteristics:

The total cohort enrolled had a median age of 34.8 years (IQR 26.6-49.5). Cohort 2 were stratified by prior receipt of a ChAdOx-vectored vaccine: ChAdOx-naïve participants had a median age of 27.8 years (IQR 23.6-35.5), whereas ChAdOx-exposed participants had a median age of 48.3 years (IQR 30.7-50.7). Across both cohorts, 25 (54.3%) participants reported their sex as male and 21 (45.7%) as female. 37 participants (80.4%) identified as White. Two participants who received a first dose of vaccine did not receive a follow-up vaccination and in total 44 participants received two doses of ChAdOx2 CCHF. Below is the table of baseline characteristics:

Table 1: baseline characteristics of participants within CCHF01 study

Characteristic	Cohort 1 N=6	Cohort 2		All N=46
		ChAdOx naïve N=20	Prior ChAdOx N=20	
Previous ChAdOx exposure	3 (50.0%)	0 (0%)	20 (100%)	23 (50.0%)
Age at enrollment (years)				
Median (IQR)	43.7 [23.6, 53.9]	27.8 [23.6, 35.5]	48.3 [30.7, 50.7]	34.8 [26.6, 49.5]
Ethnicity				
White	6 (100%)	13 (65.0%)	18 (90.0%)	37 (80.4%)
Mixed	0 (0%)	3 (15.0%)	1 (5.0%)	4 (8.7%)
Asian	0 (0%)	3 (15.0%)	1 (5.0%)	4 (8.7%)
Black	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Arab	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other*	0 (0%)	1 (5.0%)	0 (0%)	1 (2.2%)
Sex at birth				
Male	4 (66.7%)	11 (55.0%)	10 (50.0%)	25 (54.3%)
Female	2 (33.3%)	9 (45.0%)	10 (50.0%)	21 (45.7%)

*The other ethnicity reported was Persian

Outcome measures

Below are the primary and secondary objectives of CCHF01:

Primary and Secondary Objective(s)	<p>Primary</p> <ul style="list-style-type: none"> To assess the safety and tolerability of ChAdOx2 CCHF in healthy volunteers <p>Secondary</p> <ul style="list-style-type: none"> To assess the immunogenicity of ChAdOx2 CCHF vaccine in healthy adult volunteers (at key timepoints) To compare the immunogenicity of ChAdOx2 CCHF vaccine in individuals previously vaccinated with a ChAdOx vaccine with ChAdOx naïve individuals (at key timepoints)
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Table 2: Summary of adverse events

Group	Participants with ≥1 AE within 28 days post vaccinations	AEs within 28 days post-vaccinations	AEs within 28 days post-first dose	AEs within 28 days post-second dose	Causality				AEs of severity grade ≥3	AESIs	SAEs
					No relationship	Possible	Probable	Definite			
Cohort 1 (n=6)	5/6 (83.3%)	10/71 (14.1%)	6/45 (13.3%)	4/26 (15.4%)	5/10 (50.0%)	3/10 (30.0%)	2/10 (20.0%)	0/10 (0%)	1/10 (10.0%)	0/10 (0%)	0
Cohort 2a (ChAdOx naïve) (n=20)	13/20 (65.0%)	27/71 (38.0%)	18/45 (40.0%)	9/26 (34.6%)	16/27 (61.5%)	10/27 (38.5%)	0/27 (0%)	0/27 (0%)	1/27 (3.7%)	2/27 (7.4%)	0
Cohort 2b (Prior ChAdOx) (n=20)	14/20 (70.0%)	34 (47.9%)	21/45 (46.7%)	13/26 (50.0%)	23/34 (67.6%)	8/34 (23.5%)	2/34 (5.9%)	1/34 (2.9%)	0/34 (0%)	0/34 (0%)	0
All (n=46)	32/46 (69.6%)	71	45/71 (63.4%)	26/71 (36.6%)	44/71 (62.9%)	21/71 (30.0%)	4/71 (5.7%)	1/71 (1.4%)	2/71 (2.8%)	2/71 (2.8%)	0

Table 3: Summary table of immunogenicity of ChAdOx2 CCHF vaccine

Population	Antigen	Timepoint (days)	ChAdOx exposure status	Median (IQR)	GMT (95% CI)
All participants	GP38	0	Prior ChAdOx (n=23)	7.50 (7.50-7.50)	10.10 (7.55, 13.50)
			ChAdOx naïve (n=23)	7.50 (7.50-7.50)	9.70 (7.29, 12.90)
			Pooled (n=46)	7.50 (7.50-7.50)	9.90 (8.14, 12.03)
		1	Prior ChAdOx (n=20)	7.50 (7.50-7.50)	10.00 (6.99, 14.29)
			ChAdOx naïve (n=20)	7.50 (7.50-7.50)	8.53 (6.52, 11.17)
			Pooled (n=40)	7.50 (7.50-7.50)	9.23 (7.45, 11.45)
		14	Prior ChAdOx (n=23)	7.50 (7.50-33.67)	15.14 (9.41, 24.36)
			ChAdOx naïve (n=23)	29.77 (7.50-84.76)	36.34 (20.36, 64.85)
			Pooled (n=46)	21.10 (7.50-60.81)	23.46 (15.99, 34.41)
		28	Prior ChAdOx (n=23)	54.48 (7.50-178.85)	48.99 (25.40, 94.47)
			ChAdOx naïve (n=23)	225.04 (67.53-547.68)	189.60 (104.32, 344.59)
			Pooled (n=46)	92.74 (35.30-360.32)	96.38 (60.10, 154.55)
56	Prior ChAdOx (n=3)	56.01 (31.76-69.78)	32.74 (1.32, 810.65)		
	ChAdOx naïve (n=3)	130.34 (102.27-369.14)	180.49 (12.07, 2698.39)		

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		Pooled (n=6)	78.88 (60.56-118.64)	76.87 (17.32, 341.10)	
	84 (V2)	Prior ChAdOx (n=23)	26.06 (7.50-57.53)	24.90 (15.06, 41.18)	
		ChAdOx naïve (n=23)	88.87 (21.83-169.02)	65.59 (34.21, 125.75)	
		Pooled (n=46)	47.99 (7.50-99.23)	40.42 (26.53, 61.57)	
	85 (V2+1)	Prior ChAdOx (n=19)	19.30 (7.50-52.80)	20.32 (12.70, 32.51)	
		ChAdOx naïve (n=18)	72.16 (10.27-205.21)	55.25 (24.85, 122.82)	
		Pooled (n=37)	25.62 (7.50-84.48)	33.05 (20.75, 52.66)	
	98 (V2+14)	Prior ChAdOx (n=23)	1400.20 (346.25-1866.51)	800.51 (473.47, 1353.43)	
		ChAdOx naïve (n=21)	1351.49 (808.21-1889.98)	1209.62 (792.94, 1845.27)	
		Pooled (n=44)	1375.85 (559.07-1902.11)	974.84 (698.86, 1359.81)	
	112 (V2+28)	Prior ChAdOx (n=23)	650.00 (224.04-1437.98)	560.73 (318.80, 986.27)	
		ChAdOx naïve (n=23)	1230.30 (521.32-2055.36)	1041.94 (644.46, 1684.57)	
		Pooled (n=46)	854.82 (384.68-1631.41)	764.36 (529.05, 1104.32)	
	180 (V2+96)	Prior ChAdOx (n=23)	372.33 (111.58-798.24)	290.52 (151.69, 556.40)	
		ChAdOx naïve (n=23)	589.14 (231.64-1105.18)	547.65 (340.00, 882.14)	
		Pooled (n=46)	488.27 (188.61-976.95)	398.88 (267.77, 594.17)	
	365 (V2+281)	Prior ChAdOx (n=22)	70.06 (34.50-236.95)	77.20 (41.28, 144.38)	
		ChAdOx naïve (n=21)	239.21 (55.29-408.00)	175.64 (100.54, 306.82)	
		Pooled (n=43)	87.68 (47.32-328.50)	115.34 (75.59, 175.98)	
	Gc	0	Prior ChAdOx (n=23)	7.50 (7.50-7.50)	9.13 (7.22, 11.54)
			ChAdOx naïve (n=23)	7.50 (7.50-7.50)	9.08 (7.05, 11.68)
			Pooled (n=46)	7.50 (7.50-7.50)	9.10 (7.72, 10.74)
		1	Prior ChAdOx (n=20)	7.50 (7.50-7.50)	9.37 (7.18, 12.23)
			ChAdOx naïve (n=20)	7.50 (7.50-7.50)	8.81 (6.29, 12.36)
			Pooled (n=40)	7.50 (7.50-7.50)	9.09 (7.40, 11.16)
		14	Prior ChAdOx (n=23)	7.50 (7.50-7.50)	9.87 (7.53, 12.95)
			ChAdOx naïve (n=23)	7.50 (7.50-24.71)	15.72 (9.35, 26.42)
			Pooled (n=46)	7.50 (7.50-18.13)	12.46 (9.32, 16.65)
	28	Prior ChAdOx (n=23)	7.50 (7.50-31.36)	14.20 (9.50, 21.24)	
		ChAdOx naïve (n=23)	34.25 (23.11-127.43)	52.02 (27.32, 99.04)	
		Pooled (n=46)	26.17 (7.50-72.82)	27.18 (17.98, 41.10)	
	56	Prior ChAdOx (n=3)	7.50 (7.50-15.03)	10.83 (2.23, 52.55)	
		ChAdOx naïve (n=3)	43.61 (30.42-331.48)	77.51 (0.77, 7846.28)	
		Pooled (n=6)	19.90 (9.93-38.35)	28.97 (5.15, 162.80)	
	84 (V2)	Prior ChAdOx (n=23)	7.50 (7.50-30.73)	14.67 (10.19, 21.10)	
		ChAdOx naïve (n=23)	32.27 (7.50-137.55)	39.49 (20.65, 75.50)	
		Pooled (n=46)	17.59 (7.50-50.26)	24.06 (16.35, 35.42)	
	85 (V2+1)	Prior ChAdOx (n=19)	7.50 (7.50-28.53)	14.76 (9.80, 22.24)	
		ChAdOx naïve (n=18)	29.54 (16.40-160.67)	46.79 (22.34, 97.96)	
		Pooled (n=37)	25.85 (7.50-52.12)	25.87 (16.65, 40.20)	
	98 (V2+14)	Prior ChAdOx (n=23)	86.08 (22.71-150.78)	61.03 (32.98, 112.93)	
		ChAdOx naïve (n=21)	183.49 (49.49-286.94)	144.99 (76.71, 274.06)	
		Pooled (n=44)	103.18 (36.91-237.12)	92.24 (59.14, 143.86)	
	112 (V2+28)	Prior ChAdOx (n=23)	64.56 (27.72-107.71)	55.02 (30.59, 98.98)	
		ChAdOx naïve (n=23)	131.71 (47.72-506.28)	148.65 (73.15, 302.08)	
		Pooled (n=46)	88.20 (34.82-226.23)	90.44 (56.72, 144.20)	

	180 (V2+96)	Prior ChAdOx (n=23)	53.14 (21.67-86.65)	46.09 (28.67, 74.09)
		ChAdOx naïve (n=23)	87.69 (28.80-332.57)	105.92 (52.94, 211.92)
		Pooled (n=46)	58.51 (26.69-141.59)	69.87 (45.80, 106.60)
	365 (V2+281)	Prior ChAdOx (n=22)	44.28 (31.18-90.28)	50.64 (32.31, 79.39)
		ChAdOx naïve (n=21)	96.96 (34.45-227.89)	87.51 (46.38, 165.10)
		Pooled (n=43)	48.49 (32.00-141.20)	66.15 (45.28, 96.63)

Table 4: Summary table of vaccine-induced antibody geometric mean fold rise

Assay	Timepoint	ChAdOx status	GMFR (95% CI)
GP38	V1+ 28/D0	Previous ChAdOx	4.85 (2.48 - 9.49)
		ChAdOx naïve	19.55 (10.31 - 37.05)
	V2 + 28/V2	Previous ChAdOx	22.52 (12.76 - 39.72)
		ChAdOx naïve	15.89 (7.96 - 31.70)
GC	V1 + 28/D0	Previous ChAdOx	1.56 (1.08 - 2.25)
		ChAdOx naïve	5.73 (3.26 - 10.08)
	V2 + 28/V2	Previous ChAdOx	3.75 (2.16 - 6.52)
		ChAdOx naïve	3.76 (2.15–6.58)

Adverse events:

No safety concerns observed during CCHF01 study, reactions were generally mild. There were no serious adverse events associated with this study.

Table 5: Maximum severity of solicited adverse events after vaccine dose 1

Symptom	None	Mild	Moderate	Severe	Hospitalisation	Any
Redness	46 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Swelling	46 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pain	17 (37.0%)	27 (58.7%)	2 (4.4%)	0 (0%)	0 (0%)	29 (63.0%)
Itch	45 (97.8%)	1 (2.2%)	0 (0%)	0 (0%)	0 (0%)	1 (2.2%)
Warmth	41 (89.1%)	4 (8.7%)	1 (2.2%)	0 (0%)	0 (0%)	5 (10.9%)
Chills	41 (89.1%)	4 (8.7%)	1 (2.2%)	0 (0%)	0 (0%)	5 (10.9%)
Fatigue	20 (43.5%)	18 (39.1%)	8 (17.4%)	0 (0%)	0 (0%)	26 (56.5%)
Feverish	39 (84.8%)	7 (15.2%)	0 (0%)	0 (0%)	0 (0%)	7 (15.2%)
Headache	24 (52.2%)	17 (37.0%)	5 (10.9%)	0 (0%)	0 (0%)	22 (47.8%)
Joint pain	35 (76.1%)	11 (23.9%)	0 (0%)	0 (0%)	0 (0%)	11 (23.9%)
Muscle pain	20 (43.5%)	24 (52.2%)	2 (4.4%)	0 (0%)	0 (0%)	26 (56.5%)
Nausea	39 (84.8%)	7 (15.2%)	0 (0%)	0 (0%)	0 (0%)	7 (15.2%)
Fever	43 (93.5%)	2 (4.4%)	1 (2.2%)	0 (0%)	0 (0%)	3 (6.5%)
Malaise	30 (65.2%)	13 (28.3%)	3 (6.5%)	0 (0%)	0 (0%)	16 (34.8%)

Table 6: Maximum severity of solicited adverse events after vaccine dose 1

Symptom	None	Mild	Moderate	Severe	Hospitalisation	Any
Redness	44 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Swelling	44 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pain	17 (38.6%)	25 (56.8%)	2 (4.6%)	0 (0%)	0 (0%)	27 (61.4%)
Itch	39 (88.6%)	5 (11.4%)	0 (0%)	0 (0%)	0 (0%)	5 (11.4%)
Warmth	36 (81.8%)	8 (18.2%)	0 (0%)	0 (0%)	0 (0%)	8 (18.2%)
Chills	38 (86.4%)	5 (11.4%)	1 (2.3%)	0 (0%)	0 (0%)	6 (13.6%)
Fatigue	24 (54.6%)	12 (27.3%)	7 (15.9%)	1 (2.3%)	0 (0%)	20 (45.5%)
Feverish	33 (75.0%)	10 (22.7%)	1 (2.3%)	0 (0%)	0 (0%)	11 (25.0%)
Headache	25 (56.8%)	16 (36.4%)	3 (6.8%)	0 (0%)	0 (0%)	19 (43.2%)
Joint pain	41 (93.2%)	2 (4.6%)	1 (2.3%)	0 (0%)	0 (0%)	3 (6.8%)
Muscle pain	29 (65.9%)	14 (31.8%)	1 (2.3%)	0 (0%)	0 (0%)	15 (34.1%)
Nausea	41 (93.2%)	3 (6.8%)	0 (0%)	0 (0%)	0 (0%)	3 (6.8%)
Fever	43 (97.7%)	1 (2.3%)	0 (0%)	0 (0%)	0 (0%)	1 (2.3%)
Malaise	32 (72.7%)	8 (18.2%)	3 (6.8%)	1 (2.3%)	0 (0%)	12 (27.3%)

Table 7: Unsolicited adverse event summary

Characteristic ¹	Cohort 1, N = 6	Cohort 2		Overall, N = 46
		ChAdOx naïve, N = 20	Previous ChAdOx, N = 20	
Number of participants experiencing at least one unsolicited adverse event	<u>5 (83.3%)</u>	<u>13 (65.0%)</u>	<u>14 (70.0%)</u>	<u>32 (69.6%)</u>

Number of unsolicited adverse events	<u>10</u>	<u>27</u>	<u>34</u>	<u>71</u>
Timing of start date of adverse event				
<u>Between first and second vaccination</u>	<u>6 (60.0%)</u>	<u>18 (66.7%)</u>	<u>21 (61.8%)</u>	<u>45 (63.4%)</u>
<u>After second vaccination</u>	<u>4 (40.0%)</u>	<u>9 (33.3%)</u>	<u>13 (38.2%)</u>	<u>26 (36.6%)</u>
Severity grade*				
<u>Grade 1</u>	<u>7 (70.0%)</u>	<u>20 (74.1%)</u>	<u>20 (58.8%)</u>	<u>47 (66.2%)</u>
<u>Grade 2</u>	<u>2 (20.0%)</u>	<u>6 (22.2%)</u>	<u>14 (41.2%)</u>	<u>22 (31.0%)</u>
<u>Grade 3</u>	<u>1 (10.0%)</u>	<u>1 (3.7%)</u>	<u>0 (0%)</u>	<u>2 (2.8%)</u>
Causality				
<u>No relationship</u>	<u>5 (50.0%)</u>	<u>16 (61.5%)</u>	<u>23 (67.6%)</u>	<u>44 (62.9%)</u>
<u>Possible</u>	<u>3 (30.0%)</u>	<u>10 (38.5%)</u>	<u>8 (23.5%)</u>	<u>21 (30.0%)</u>
<u>Probable</u>	<u>2 (20.0%)</u>	<u>0 (0%)</u>	<u>2 (5.9%)</u>	<u>4 (5.7%)</u>
<u>Definite</u>	<u>0 (0%)</u>	<u>0 (0%)</u>	<u>1 (2.9%)</u>	<u>1 (1.4%)</u>
Adverse event of special interest				
<u>No</u>	<u>10 (100%)</u>	<u>25 (92.6%)</u>	<u>34 (100%)</u>	<u>69 (97.2%)</u>
<u>Yes - Haematological/Vascular</u>	<u>0 (0%)</u>	<u>2 (7.4%)</u>	<u>0 (0%)</u>	<u>2 (2.8%)</u>
Outcome				
<u>Ongoing at end of study</u>	<u>0 (0%)</u>	<u>2 (7.4%)</u>	<u>0 (0%)</u>	<u>2 (2.8%)</u>
<u>Resolved</u>	<u>10 (100%)</u>	<u>25 (92.6%)</u>	<u>34 (100%)</u>	<u>69 (97.2%)</u>
Duration of resolved adverse event (days)	<u>6.5 [4.3, 14.0]</u>	<u>4.0 [1.0, 13.0]</u>	<u>5.5 [1.0, 13.0]</u>	<u>5.0 [1.0, 13.0]</u>

¹For continuous variables, the median and inter-quartile range are reported as median [IQR].

²n (%)

*Severity was graded 1-5, no unsolicited AEs 28 days following each vaccination was graded 4-5

Table 8: List of all unsolicited AEs:

Days 0-28 following each vaccination for unsolicited AEs, and throughout entire trial duration for serious adverse events (SAEs) and adverse events of special interest (AESIs). No SAEs were reported. *Participant not reviewed by doctor; causality recorded as “unknown” and protocol deviation form completed.

ID	Cohort	Days since first vaccination	Days since second vaccination	Diagnosis	Severity grade	Causality	AESI	Duration of AE (days)
AA00	Cohort 1	10	-	Dental procedure	Grade 3	No relationship	No	68
AA07	Cohort 1	28	-	COVID-19	Grade 1	No relationship	No	11
AA43	Cohort 2 (Prior ChAdOx)	1	-	Urea rise	Grade 2	Possible	No	13
AA43	Cohort 2 (Prior ChAdOx)	70	0	Neutropenia	Grade 2	No relationship	No	13
AA43	Cohort 2 (Prior ChAdOx)	83	13	Raised Urea	Grade 2	Possible	No	21
AA43	Cohort 2 (Prior ChAdOx)	70	0	Low heart rate	Grade 1	No relationship	No	1
AA44	Cohort 2 (ChAdOx naïve)	1	-	Thrombocytopenia	Grade 2	Possible	Yes - Haematological/Vascular	5
AA44	Cohort 2 (ChAdOx naïve)	8	-	Purpuric rash	Grade 1	No relationship	No	2
AA44	Cohort 2 (ChAdOx naïve)	84	1	Thrombocytopenia	Grade 2	Possible	Yes - Haematological/Vascular	254
AA44	Cohort 2 (ChAdOx naïve)	0	-	Low heart rate	Grade 1	No relationship	No	1
AA45	Cohort 2 (ChAdOx naïve)	90	6	Viral URTI	Grade 2	No relationship	No	12
AA08	Cohort 2 (Prior ChAdOx)	0	-	Earache	Grade 1	Probable	No	1
AA08	Cohort 2 (Prior ChAdOx)	16	-	Severe headache	Grade 1	Possible	No	0
AA08	Cohort 2 (Prior ChAdOx)	25	-	Earache	Grade 2	No relationship	No	1
AA08	Cohort 2 (Prior ChAdOx)	25	-	Earache	Grade 1	No relationship	No	4
AA08	Cohort 2 (Prior ChAdOx)	80	1	Respiratory tract infection	Grade 2	Possible	No	23
AA09	Cohort 1	2	-	Increased urea	Grade 2	Possible	No	17
AA09	Cohort 1	78	1	Raised urea	Grade 1	Possible	No	1
AA09	Cohort 1	84	7	Urea raised	Grade 2	No relationship	No	7
AA10	Cohort 2 (Prior ChAdOx)	91	0	Urea raised	Grade 2	No relationship	No	29
AA11	Cohort 2 (Prior ChAdOx)	98	14	Drop in hb	Grade 2	Possible	No	91
AA13	Cohort 2 (Prior ChAdOx)	105	12	Respiratory Tract Infection	Grade 2	No relationship	No	13
AA14	Cohort 2 (ChAdOx naïve)	3	-	Earache	Grade 1	Possible	No	3
AA14	Cohort 2 (ChAdOx naïve)	0	-	Low pulse -50 mins post vaccination	Grade 1	Unknown*	No	0

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ID	Cohort	Days since first vaccination	Days since second vaccination	Diagnosis	Severity grade	Causality	AESI	Duration of AE (days)
AA14	Cohort 2 (ChAdOx naïve)	1	-	Blocked sebaceous glands of arm	Grade 1	No relationship	No	7
AA14	Cohort 2 (ChAdOx naïve)	1	-	Macular rash of forearm	Grade 1	No relationship	No	7
AA16	Cohort 2 (ChAdOx naïve)	18	-	Migraines	Grade 1	No relationship	No	16
AA16	Cohort 2 (ChAdOx naïve)	100	2	Hyperbilirubinemia	Grade 1	Possible	No	33
AA02	Cohort 1	2	-	Increased CRP	Grade 1	Probable	No	5
AA02	Cohort 1	92	0	Grade 1 WCC rise	Grade 1	No relationship	No	1
AA02	Cohort 1	105	13	Anaemia	Grade 1	Possible	No	15
AA02	Cohort 1	105	13	Upper respiratory tract infection	Grade 1	No relationship	No	6
AA19	Cohort 2 (Prior ChAdOx)	3	-	Lower back pain	Grade 1	No relationship	No	3
AA19	Cohort 2 (Prior ChAdOx)	115	1	Raised urea	Grade 2	Possible	No	12
AA19	Cohort 2 (Prior ChAdOx)	115	1	PR bleed due to haemorrhoids	Grade 1	No relationship	No	0
AA19	Cohort 2 (Prior ChAdOx)	17	-	Cuts left leg and knee	Grade 1	No relationship	No	12
AA19	Cohort 2 (Prior ChAdOx)	5	-	Mild cough	Grade 1	No relationship	No	13
AA19	Cohort 2 (Prior ChAdOx)	17	-	Musculoskeletal back pain (second episode)	Grade 1	No relationship	No	7
AA19	Cohort 2 (Prior ChAdOx)	10	-	Lower back pain	Grade 1	No relationship	No	1
AA03	Cohort 1	2	-	Increased CRP	Grade 1	Probable	No	4
AA21	Cohort 2 (Prior ChAdOx)	16	-	Headache	Grade 2	No relationship	No	0
AA24	Cohort 2 (Prior ChAdOx)	13	-	Cold	Grade 1	No relationship	No	3
AA24	Cohort 2 (Prior ChAdOx)	27	-	Pain on the right distal leg	Grade 1	No relationship	No	4
AA25	Cohort 2 (ChAdOx naïve)	84	7	Cold symptoms	Grade 1	No relationship	No	8
AA27	Cohort 2 (ChAdOx naïve)	1	-	Syncope	Grade 1	Possible	No	0
AA27	Cohort 2 (ChAdOx naïve)	90	13	Cold	Grade 1	No relationship	No	4
AA27	Cohort 2 (ChAdOx naïve)	104	27	Syncope secondary to minor injury	Grade 1	No relationship	No	0
AA29	Cohort 2 (ChAdOx naïve)	0	-	Neutropenia	Grade 2	No relationship	No	
AA30	Cohort 2 (Prior ChAdOx)	0	-	Neutropenia	Grade 1	No relationship	No	15
AA30	Cohort 2 (Prior ChAdOx)	6	-	COVID-19 infection	Grade 1	No relationship	No	7
AA30	Cohort 2 (Prior ChAdOx)	9	-	Root canal procedure	Grade 2	No relationship	No	0

CCHF01 (UK) Basic Results Summary (ISRCTN12351734)

Oxford Vaccine Group, University of Oxford

20th March 2026 V1.0

ID	Cohort	Days since first vaccination	Days since second vaccination	Diagnosis	Severity grade	Causality	AESI	Duration of AE (days)
AA31	Cohort 2 (Prior ChAdOx)	107	28	Deranged LFTs	Grade 1	Possible	No	13
AA31	Cohort 2 (Prior ChAdOx)	93	14	Mild raise diastolic blood pressure	Grade 1	No relationship	No	0
AA32	Cohort 2 (ChAdOx naïve)	0	-	Mild allergic reaction	Grade 1	Possible	No	1
AA32	Cohort 2 (ChAdOx naïve)	10	-	Cold	Grade 1	No relationship	No	3
AA06	Cohort 2 (ChAdOx naïve)	26	-	Viral illness	Grade 3	No relationship	No	3
AA06	Cohort 2 (ChAdOx naïve)	83	2	Decrease in Hb from baseline	Grade 2	Possible	No	27
AA33	Cohort 2 (Prior ChAdOx)	1	-	Lymphopenia	Grade 2	Probable	No	6
AA35	Cohort 2 (ChAdOx naïve)	17	-	Cold	Grade 1	No relationship	No	3
AA35	Cohort 2 (ChAdOx naïve)	79	1	Hyperbilirubinemia	Grade 2	No relationship	No	112
AA36	Cohort 2 (ChAdOx naïve)	14	-	Neutropenia	Grade 1	Possible	No	78
AA36	Cohort 2 (ChAdOx naïve)	105	14	Neutropenia	Grade 1	Possible	No	63
AA37	Cohort 2 (ChAdOx naïve)	15	-	Cold	Grade 1	No relationship	No	13
AA37	Cohort 2 (ChAdOx naïve)	1	-	Sore throat	Grade 1	Possible	No	0
AA38	Cohort 2 (Prior ChAdOx)	25	-	Cold	Grade 1	Possible	No	3
AA39	Cohort 2 (Prior ChAdOx)	81	5	Flu-like symptoms	Grade 2	No relationship	No	5
AA39	Cohort 2 (Prior ChAdOx)	93	17	Low heart rate	Grade 1	No relationship	No	0
AA40	Cohort 2 (ChAdOx naïve)	10	-	Body aches	Grade 1	No relationship	No	1
AA41	Cohort 2 (Prior ChAdOx)	17	-	Lower respiratory tract infection	Grade 2	No relationship	No	11
AA41	Cohort 2 (Prior ChAdOx)	70	0	Shivering	Grade 1	Definite	No	1
AA41	Cohort 2 (Prior ChAdOx)	89	19	COVID-19 infection	Grade 1	No relationship	No	8