

Freedom of Information Request: 1486 2021/22

The following questions relate to the ChAdOx1 n-CoV-19 vaccine trial conducted at your institution (NCT04400838 (COV002)). The vaccine referred to is also known as the Oxford-AstraZeneca vaccine or Vaxzevira.

Under the Freedom of Information Act 2000, please provide me with all of the following:

- 1) Details of all parties that have contributed funding to the trust in relation to the ChAdOx1 nCoV-19 vaccine trial being conducted at your site/s.**

University Hospitals Birmingham (UHB) have contract (Clinical Trials Agreement) in place with study sponsor, University of Oxford.

Any funding UHB receive for hosting the ChAdOx1 nCoV-19 vaccine trial (Cov02) is received from University of Oxford.

- 2) A list of all sites within your trust that ChAdOx1 n-CoV-19 vaccine trials have been conducted at.**

All vaccines are administered at: Queen Elizabeth Hospital site (QEH), within NIHR/Wellcome Trust Clinical Research Facility (CRF).

Consent/screening procedures have taken place at: QEH, Heartlands Hospital (HH) and Good Hope Hospital (GHH).

Participant follow up procedures are taking place at: QEH, HH.

When/if study participants become symptomatic of Covid-19, to test vaccine efficacy the participant undergoes a medical review and virology swab. To protect vulnerable groups within the Trust all symptomatic visits take place on the Health Research Bus, which is owned and governed by the CRF as part of Birmingham Health Partners. The HRB is a fully functioning mobile CRF and contains all the equipment necessary to perform COV02 symptomatic visits.

- 3) Numbers of ChAdOx1 n-CoV-19 vaccine trial participants at each trial location.**

All 520 vaccines have been administered within the CRF at QEH.

- 4) Number of staff involved in conducting the trial at each trial location, listing their roles.**

Number of UHB staff and study roles involved in Cov02 study to date (28/05/2021)

Medics: 28

Research Nurse: 76

Laboratory/ Pharmacy: 6

Research Assistant: 16

Data Manager: 18

Study Coordinator: 4

Total: 148 staff members have been delegated study specific tasks.

5) What costs were incurred by the trust in order to conduct the vaccine trial?

Study set- up costs, including training, staff time for logistics and organisational set up,

Staffing costs relating to preparing for and performing study visits, data entry, data management and query resolution, study monitoring procedures and source data verification, laboratory processing and sample management, pharmacy time and IMP (investigational medicinal product) management, on call costs and symptomatic study participant oversight,

Consumables costs, Courier costs

6) A breakdown of any funding received from internal and external sources in order to conduct the vaccine trial.

Please break funding down into

- 1) funding from public (governmental) bodies,**
- 2) private entities, and**
- 3) philanthropies/charitable bodies.**

Please include the full name of the funding body. Please specify amounts in GBP. (Please provide this as an excel spreadsheet)

As of 28/05/2021 the amount of £254,104.91 has been received from University of Oxford. Funding received covers trial activity for period May 2020- Nov 2020. All funds invoiced/received are as per Clinical Trial Agreement. Study is still ongoing with further invoices to be raised in line with study follow up activity.

7) A record of all expenses incurred in conducting the ChAdOx1 n-CoV-19 vaccine trial.

This may include: unit costs of test, fees to central laboratories, investigator fees, data management costs.

Table to show record of expenses from May 2020- April 2021 below.

May 2020 - April 2021 Per Participant Costs				
Study Group	Visit Complete	Cost Per Visit	Number of Visits	Total Cost
	Day 0 Enrolment	£200.00	379	£75,800.00
4a or 6a	Day 28	£70.00	363	£25,410.00
No Booster	Day 90	£70.00	61	£4,270.00
	Day 182	£70.00	50	£3,500.00
	Day 364	£70.00	1	£70.00
4b or 6b	2nd Dose Vaccination	£130.00	336	£43,680.00

Booster	Day 28	£70.00	313	£21,910.00
	Day 90	£70.00	303	£21,210.00
	Day 182	£70.00	277	£19,390.00
	Day 364	£70.00	0	
9 or 10	Screening Failure Visit	£25.00	20	£500.00
	Day 0 Enrolment	£200.00	150	£30,000.00
	Day 28 Vaccination Visit	£130.00	150	£19,500.00
	Day 56 (28 days post boost)	£70.00	150	£10,500.00
	Day 118 (90 days post boost)	£70.00	148	£10,360.00
	Day 210 (182 days post boost)	£70.00	131	£9,170.00
	Day 392 (364 days post boost)	£70.00	0	
Any Group	S Day 0 Symptomatic Visit	£90.00	37	£3,330.00
	S Day 7 Symptomatic Visit	£90.00	55	£4,950.00
TOTAL PER PARTICIPANT COSTS				£303,550.00

May 2020 - April 2021			
Consumables		£6,927.25	
Courier Costs		£1,084.15	
Total			£8,011.40