Freedom of Information Request	FOI 21-242	24th June 2021

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.**
   The Sponsor – Oxford University

2. **A list of all sites within your trust that ChAdOx1 n-CoV-19 vaccine trials have been conducted at.**
   St Woolos Hospital, Stow Hill, Newport NP20 4SZ

3. **Numbers of ChAdOx1 n-CoV-19 vaccine trial participants at each trial location.**
   439

4. **Number of staff involved in conducting the trial at each trial location, listing their roles.**
   Please note for context: the majority of staff were brought in as and when required. Not all people within the designated categories will have completed all of the specified roles. Hours worked could range from 1 hour to full time. Individuals will have worked on the study for limited periods with another individual taking on that role as the trial progressed. The trial is on-going with a current end date of September 2021.

   38: Research Nurses: consenting participants, pregnancy testing, observations, data entry/collection, randomisation, safety reporting, CRF/case book sign off, participant support, clinic flow management, unblinding.

   1: Principal Investigator: medical and oversight of study, assessing eligibility, physical examinations, consenting participants and reconsenting particpants (following amendments), assessment of adverse event (AE) severity, Serious Adverse Event (SAE) and SAE resolution.

   8: Phlebotomists: taking blood, sample collection.

3: Pharmacists: receive the Interverntial medicical product (IMP), complete accountability logs, vaccine preparation and dispensing.

4: Vaccinators: prepare and administer vaccines, complete documentation.

51: Doctors: consenting, assessing eligibility, collect medical history, physical examination, physical observations, assessment of AE severity management, safety reporting, data entry, case report form/case book sign off, data quality check and query resolution, hold on call trial phone.

6: Pathology: processing samples, data entry, case report form/case book sign off, investigtor site file responsibility, data QC and query resolution.

3: Porters: manage car park, security and patient flow into unit.

30: Administrators: CRF/case book sign off, investigtor site file responsibility, data QC and query resolution, regulatory management, archiving, data managemernt and system development, receptionist - booking in and booking out including booking next appointments, preparing patient packs, quality checking during patient flow, screening applicants and booking first appointments, liaise with Sponsor, day to day management including processing amendments, organising vaccine clinics, unblinding, processing SAEs.

5. **What costs were incurred by the trust in order to conduct the vaccine trial?**
   None.

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)**

   1. Public (governmental bodies) – not applicable
   2. Private entities – not applicable
   3. Philanthropies/charitable bodies – not applicable

   Please note: the only funding received was from the Sponsor, Oxford University please refer to the sponsor for further information https://compliance.admin.ox.ac.uk/submit-foi.

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.

Type	Per Unit	Total
Records for 583 participants Covid antibody tests performed at pre-enrolment stage	Free of charge	Free of charge

Reagent, QC and Calibrators used supplies provided from DoH agreement	Free of charge	Free of charge
Consumable costs for processing	£3.57	£2081.31
Cost of blood tests for symptomatic patients (U&E, LFT, CRP and FBC)	£15.05	£1023.40
Cost of Covid swabs (D0) for symptomatic patients (Eplex)	£100.00	£6800.00
Cost of Covid swabs (D7) for symptomatic patients (Eplex)	£100.00	£3100.00
Total Lab expenditure	N/A	£13,004.71
Investigator costs	N/A	£29,990