THANK YOU

Thank you so much for taking part in the world's first studies of the ChAdOx1 nCoV-19 vaccine.

Picture: Gavi, the Vaccine Alliance

Thanks to your dedication and perseverance, billions of doses of the vaccine have been given globally.

We are asking volunteers to continue for another year in this follow up study. There is limited information about the long-term side effects of the vaccine, and we would like to continue to study how the immune system responds after vaccination. A fourth dose of ChAdOx1 nCoV-19 will be given to a sub-set of individuals from COV002 to help us understand the impact of the vaccine on the immune system and to help inform health policy should further COVID-19 vaccine doses be required in the national vaccination programme.

What is involved?

Should you decide to take part, we would enrol you to this study at the final visit for COV001 or COV002. If this has already happened, we will arrange for you to come to the clinic to sign a consent form and enrol in this study. All visits should take no longer than 30 minutes.

We will ask your permission to:

- Contact your GP and access your medical records – this is in case you were admitted to a hospital or had a serious illness, and we need to get more information

- Access your test results if you have positive COVID-19 test result, to understand more about the SARS-CoV-2 virus that caused your infection.
- Access information about COVID-19 vaccines that you have received outside of the study.
- Share personal data including identifying contact information with University of Oxford as Sponsor of the study, who will further share this with NHS digital or viral sequencing labs to allow matching of study data with positive COVID-19 test results or vaccine information as stated above.
- Copy the data that was collected about you in COV001 or COV002 to this study
- Possibly perform genetic testing on your samples to better understand immune responses to COVID-19
- Keep any remaining samples for future research
- Inform you of opportunities to participate in future vaccine related research

Involvement in future research is optional and your involvement in this study will not be affected by your decision to be contacted about or to allow remaining samples to be used in future research.

Group 1 (no 4th dose): There will be blood tests taken at two further visits at 6 months and 12 months post consent, except group 12. For the majority of people this would be 10ml at each visit. For a small number of participants who have had COVID infection during the trial, up to 50ml of blood would be taken to explore immune responses in more detail.

At each visit we will ask you about any new medical diagnosis or serious illness you may have experienced and any vaccination you have received. We will also collect information about COVID-19 diagnosis and check if you are taking part in any other clinical trials

We will provide £10 per in person visit to cover travel expenses. Although we would ideally conduct the visits in person so that the blood samples can be collected, we can collect the safety information by phone if it is difficult for you to make it to the study site.

Anyone who took part in COV001 or COV002 can take part regardless of:

- how many doses of vaccine you had in the study
- when you received the vaccine in the study
- whether you had the control vaccine and then had any COVID-19 vaccine as part of the national rollout
- have had additional doses of any COVID-19 vaccine

If you are taking part in another COVID-19 vaccine trial such as COV-Boost or COV-Variant you will already be providing long-term safety information to that study team, so we would not enrol you in this study in that case.

At this time, it is not clear if there will be a need for further booster doses of a COVID-19 vaccine. If you receive an invitation to have a booster vaccine you are free to accept the vaccination without any impact on your involvement in this study. We would ask that you bring the details of any such vaccination to your next study visit.

Group 2 (4th dose sub-set): Up to 150 participants from COV002 will be recruited into group 2.

- There will be three in person visits and a phone call. These visits will take the place of the 6 month and 12 month visits.

- if you decide to take part in this sub-study, at the first visit you will be asked to sign a new consent form and the study team will check that you are eligible to take part.
- You will receive a dose of the ChAdOx1 nCoV-19 vaccine and be observed for up to 15 minutes.
- At each in-person visit, we will take up to 50ml of blood.
- After you have received the fourth dose of COVID-19 vaccine, we will provide you with an ediary to complete for 7 days after the vaccine (as you may have done in the original COV001/002 studies).
- The study team will ask you about serious illnesses or hospitalisations at each study visit.

	Boost 4	Post Boost (PB) day 7 (by phone/email)	PB 28	PB 180
	≥ 4 months since 3rd dose Pfizer Vaccine	1 week after 4th dose	1 month after 4th dose	6 months after 4th dose
Consent	X			
Pregnancy test	X			
Blood sampling	X		X	X
ChAdOx1 nCoV-19 vaccine	X			
Ediary set up/review	X	X		

Will I be eligible to take part in this sub-study?

- You can take part in this study if you have received: Two doses of ChAdOx1 nCoV-19/Oxford AZ vaccine during the trial, at any time, with any interval and
- One dose of the Pfizer COVID-19 vaccine more than 4 months before the 4th dose is given

You will not be eligible to take part if you:

- Are pregnant, or plan to get pregnant during the course of the trial
- Have had a previous allergy to vaccination with ChAdOx1 nCoV-19
- Plan to move away from the study site area

What are the vaccine side effects?

Most frequently reported side effects following vaccination with ChAdOx1 nCoV-19 include; injection site tenderness/pain, headache, fatigue, muscle aches, fever, chills, joint pain and nausea. The majority of side effects are mild or moderate and resolve within a few days. Effects can be minimised with the use of paracetamol.

As with all vaccines there is the very small risk of a severe allergic reaction, such as anaphylaxis, and staff are trained to deal with this.

Reimbursement

We will provide £10 per in person visit to cover travel expenses and £20 for the vaccination visit.

You can withdraw at any time. Your decision will not result in any penalty. Unless you state otherwise, any blood taken whilst you have been in the study will continue to be stored and to be used for research. You are free to request that your blood samples are destroyed at any time during

or after the study. Data generated up to the time of your withdrawal may still be used for analysis, unless you request otherwise.

Confidentiality and your data

The information we collect about you will be treated in the same confidential way as the original study you took part in. You will keep the same participant number which will be added to documents and blood samples. The information is available to the study team, authorised collaborators, ethical review committees, government regulatory agencies and the Sponsor (University of Oxford). Responsible independent monitors working for the Sponsor may be given access to data for monitoring and/or audit of the studyto ensure we are complying with regulations.

Your personally identifiable data (such as name, date of birth and NHS number) will be passed by your local study team to the University of Oxford. This may then be shared with NHS digital and viral sequencing labs to allow matching of study data with positive COVID-19 test results or vaccine information.

Every effort will be taken to maintain confidentiality. Information about you may be stored electronically on a secure server, and paper notes will be kept in a key-locked filing cabinet or in a restricted access office at your local site. Study results will be published in scientific journals but nothing that could identify you will be included in any report or publication.

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in United Kingdom is the data controller and is responsible for looking after your information and using it properly.

We will use the minimum personally-identifiable information possible. We will keep identifiable information about you such as contact details for a minimum of five years after the study has finished. The need to store this information for longer in relation to licensing of the vaccine will be subject to ongoing review. Considerations at the time of this review will include the value of retaining this information for your safety (e.g. to inform you of unexpected safety signals emerging from post-licensing surveillance) and any regulatory requirements. If you have agreed that samples can be retained for future research then your personally identifiable information and a copy of your consent form will be kept with restricted access solely for the purposes of sample management for a minimum of five years after the last sample has been either used or disposed of in order to meet regulatory requirements. Samples will be provided for future research only in a form that does not identify you. We store research data securely at the University of Oxford indefinitely following removal of identifiable information. If you agree to your details being held in order that you may be contacted regarding future research, then we will retain a copy of your consent form until such time as your details are removed from our database. However, we will keep the consent form and your details separate.

The study team will use your name and contact details, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, in relation to your health during the study and to oversee the quality of the study. At the completion of the study, unless you consent otherwise (e.g. if you request to be informed of future research), your personal details will not be used to contact you other than exceptional circumstances concerning your safety.

The anonymised data from this study will be shared with the collaborating partners who are organising and funding this research work. Data from this study may be used to file patents, licence vaccines in the future or make profits in other ways. You will not be paid for any part of this. Data from this study may be used as part of a student post-graduate degree, for example a MD or PhD.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights

What if something goes wrong?

The investigators recognise the important contribution that volunteers make to medical research, and make every effort to ensure your safety and well-being. The Sponsor has arrangements in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. In the event of harm being suffered, while the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

Complaints statement

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the research investigators who will do their best to address your concerns by sending us an email to covid19@ndm.ox.ac.uk. Alternatively, you may contact the University of Oxford Research Governance, Ethics & Assurance team (RGEA) office on 01865 616480 or the head of RGEA, email ctrg@admin.ox.ac.uk

The study is sponsored by the University of Oxford and is primarily funded by AstraZeneca. This study has been reviewed by the NHS Research Ethics Service (RES) – South Central – Berkshire and has been given a favourable ethical opinion. The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the use of all medicines in the UK, has reviewed the study design and has granted permission to carry out this study.

Site Contact details

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