PARTICIPANT INFORMATION SHEET:

Comparing COVID-19 Vaccine Schedule Combinations – Stage 2 (Com-COV2)

We are recruiting people 50 years of age and over to a study of 'mixed' schedules of different COVID-19 vaccines. Please express an interest if you want to help!

Study Summary Box	
Purpose of the study	To find out if having doses of two different types of COVID-19 vaccines gives as good an immune system response as having two doses of the same vaccine
Who can be in the study	Adults aged 50 years and above who have already had ONE dose of COVID-19 vaccine (AstraZeneca or Pfizer)

Design of the study	- Adults who have received their first dose of COVID-19 vaccine will receive their second dose through the trial, instead of from the NHS
	- Participants will be allocated at random to receive either
	  ○ The same vaccine as their first dose (AstraZeneca or Pfizer)
	  ○ Moderna vaccine
	  ○ Novavax vaccine
	- Participants will not know which vaccine they have received (single-blind trial)
	- The boost dose will be given between 8-12 weeks after their first dose

Are these vaccines approved for use in the UK?	The AstraZeneca, Pfizer and Moderna vaccines are approved for use in the UK. The Novavax vaccine has not yet been approved for use outside of research studies however ongoing clinical trials have demonstrated the vaccine prevents COVID-19 and have raised no safety concerns.

What is involved in being in the study?	- There is a blood test at every visit
	- All participants attend at least 5 visits at the study centre over 10 months
	- Participants at some sites can choose to be enrolled in the 'immunology cohort', to have two extra blood tests and provide nasal fluid and saliva samples at each visit
	- Participants must also
	  ○ Complete an electronic diary for up to three months after vaccination
	  ○ Notify the study team and attend an extra visit if you test positive for COVID-19
	  ○ Allow the study team to contact your GP
	NB – you would not be able to take up the COVID-19 vaccine boost (second dose) you were originally planned to receive from the NHS

Who is funding the study?	- The trial is funded by the UK Vaccine Task Force, the National Institute for Health Research (NIHR - a UK government funded research agency), and the Collaboration for Epidemic Preparedness Innovations (CEPI). - The Novavax vaccine is being supplied to this study by Novavax; all other vaccines are coming from NHS supplies. - None of the researchers are making a direct profit from this trial
For full details of the trial please read the rest of this information sheet	

Participation could really make a difference during a public health emergency.

Thank you for reading this participant information sheet. Your help, whatever your final decision, is very much valued. We would like to invite you to take part in our Comparing COVID-19 Vaccine Schedule Combinations - Stage 2 study (Com-COV2). Before you make any decision, it is important you take the time to understand why we are doing this research and what it would involve. Please read the following information carefully and consider discussing it with friends, relatives, or others as you wish.

What is the purpose of this research trial?

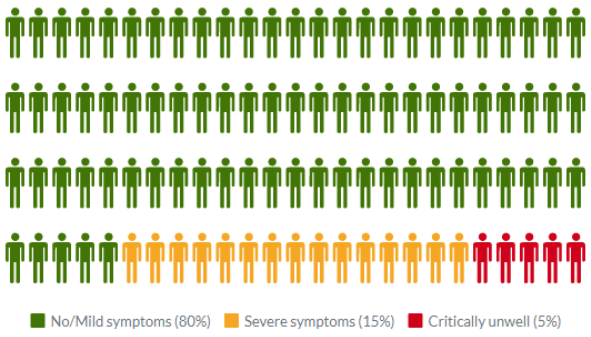
There are now a number of vaccines in the UK that have been approved to prevent COVID-19, and others are expected to be approved in the near future. Currently, these use, or propose to use, two-doses, a 'prime' first dose followed by a 'boost' second dose some weeks later. The purpose of this trial is to see how well people's immune systems respond when their second "boost" dose is a different type of vaccine to their first "prime" dose. We will also be looking at the occurrence of common vaccine reactions, such as fever, in such 'mixed' schedules. This is important, as being able to use different vaccines in this way creates a more flexible immunisation programme; potentially allowing more people to be immunised more quickly.

In this study we will be enrolling men and women aged 50 years and over who have already had one dose of a COVID-19 vaccine. Our focus is on this age group as the risk of COVID-19 increases with increasing age. We are enrolling from all ethnicities and would particularly welcome participants from the Black, Asian and Minority Ethnic (BAME) community.

What are the vaccines against?

These vaccines are against the coronavirus SARS-CoV2 that causes the disease COVID-19.

Common symptoms of COVID-19 include fever, tiredness, dry cough, and changes to taste and smell. Whilst about 80% of infected people have no or mild symptoms and will recover from the infection without needing special treatment, approximately 10-15% of cases (2-3 in 20) progress to develop severe symptoms, and about 5% (1 in 20) become critically ill.



There are some treatments that have been shown to be effective in reducing the severity of disease and the risk of death; but at present, there is no cure. Older people and those with underlying medical conditions are more likely to develop serious illness. It has also been seen that people of some ethnic groups (Black and Asian) might be at a greater risk of severe illness.

More than 2.7 million people globally have died from COVID-19 as of 22nd March 2021. Some people also have symptoms that last a long time after they have recovered from the acute infection (commonly referred to as "long-COVID"). Effective vaccines can prevent infection in the first place, which is why they are so important.

Summary of the trial

In this study, participants will receive a second dose of a COVID-19 vaccine that may differ from their first dose received through the national immunisation programme. The aim is to recruit approximately 1050 participants. As new COVID-19 vaccines become available, more vaccines may be included in the trial and so the total number of participants may increase.

- Participants must be 50 years and over, and have had one dose of a COVID-19 vaccine through the national immunisation programme approximately 8 to 12 weeks before being enrolled in the study. They cannot have received their boost dose already.
- Participants will be allocated, at random, to receive the same vaccine as their first dose "prime", or a different COVID-19 vaccine.
- They will not know which vaccine they have received for their boost (i.e. they will be "blinded") for the duration of the trial.
- Most participants will have 5 blood tests taken over 10 months to look at the immune responses to the vaccine.
- Participants at some sites will be given the opportunity, if they wish, of providing an additional 2 blood samples in the 2 weeks after immunisation, and to provide nasal fluid and saliva samples at each visit (these participants are referred to as the 'Immunology cohort').
- Participants might also be asked to attend for a repeat blood test if there were any safety concerns.
- Participants will need to complete an online diary daily for 28 days, and intermittently from 28 days to three months following vaccination in the trial
- Participants should expect their involvement in the trial to last approximately 10 months
- We would not be offering diagnostic COVID-19 testing as part of this trial, but it is important that participants in this trial access COVID-19 testing outside of the trial following normal government guidance.
- If a participant was to test positive for the virus causing COVID-19 we might ask them to attend for an extra visit.
- Once a participant has received their vaccine through the trial, unless specifically advised by us, they would not be eligible to receive any further vaccine dose via the national vaccination scheme. This will be reviewed if government guidance changes.

What vaccines are being used in this trial?

At present, the vaccines in this trial are:

- Oxford/AstraZeneca ChAdOx1 nCoV-19 (hereafter referred to as AstraZeneca)
- Pfizer/BioNTech BNT162b2 (hereafter referred to as Pfizer)
- COVID-19 Vaccine Moderna (hereafter referred to as Moderna)
- Novavax NVXCoV2373 (hereafter referred to as Novavax)

The Pfizer, Moderna, and AstraZeneca vaccines have been approved for emergency use in the UK under regulation 174 of the Human Medicines Regulations 2012.

The Novavax vaccine has been tested in clinical trials that have enrolled over 45 000 people; and has been shown to be highly effective at preventing COVID-19. The process of obtaining approval for emergency use of this vaccine by the UK Medicines Healthcare Regulatory Agency (MHRA) has commenced, but as of March 2021 approval was pending.

The potential schedule of how the vaccines would be given is detailed below.

<table>
<tr><th>Vaccine received in routine Immunisation Programme</th><th>Trial boost vaccine – one of the following options
8-12 weeks from first vaccine</th></tr>
<tr><td>Approximately 525 participants in each group</td><td>Approximately 175 participants in each group</td></tr>
<tr><td rowspan="3">AstraZeneca</td><td>AstraZeneca</td></tr>
<tr><td>Moderna</td></tr>
<tr><td>Novavax,</td></tr>
<tr><td rowspan="3">Pfizer</td><td>Pfizer</td></tr>
<tr><td>Moderna</td></tr>
<tr><td>Novavax</td></tr>
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AstraZeneca

This vaccine has been tested in more than 50,000 people worldwide and has been found to be both safe, and effective in preventing COVID-19.

The AstraZeneca vaccine is made from a virus (ChAdOx1), which is a weakened version of a common cold virus (adenovirus). This has been genetically changed so that it is impossible for it to grow in humans. Added to this virus is a small amount of the genetic coding material of the SARS-CoV-2 spike (S) protein, which plays an essential role in SARS-CoV-2 infection. Your cells then start producing the SARS-CoV-2 spike protein. Your immune system then "sees" these spike proteins, and makes a protective immune reaction against them that helps stop SARS-CoV-2 infections.

Pfizer

This is a messenger RNA (mRNA) vaccine. This vaccine uses a small amount of the genetic coding material (mRNA) of the SARS-CoV-2 spike (S) protein packaged inside very small fatty particles (lipid nanoparticles). When these are injected into your body, your cells take up these fatty particles, and then start producing the SARS-CoV-2 spike protein. Your immune system then "sees" these spike proteins, and makes a protective immune reaction against

them. The original mRNA that has been taken into your cells is broken down within a few days, and cannot be incorporated into your own genetic code.

This vaccine has been tested in more than 40,000 people worldwide and has been shown to be both safe, and effective in preventing COVID-19.

Moderna

This is also an mRNA vaccine, so works in a similar way to the Pfizer vaccine. This vaccine has been tested in more than 30,000 people worldwide, and has been shown to be both safe and effective in preventing COVID-19

Novavax

This vaccine is based on the spike protein from the SARS-CoV-2 virus in combination with an adjuvant, a substance that increases the response of the immune system to the protein. The adjuvant is called "Matrix-M1™" and consists of saponin (which is derived from the soapbark tree) and natural fats.

None of these vaccines contain live SARS-CoV-2 coronavirus and therefore cannot give you COVID-19. The potential side effects of these vaccines are discussed in more detail in the section 'What are the risks of taking part in this trial?'.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep (or be sent it electronically) and will be asked to sign a consent form. You are free to withdraw at any time and without having to give a reason, but you may be asked to come for an extra visit for a follow up appointment for safety reasons.

Am I suitable to take part?

Adults that are aged 50 and over are able to take part. In order to be enrolled in the trial:

- You must have had your first dose of COVID-19 vaccine through the national immunisation programme between 31/01/2021 and 26/02/2021
- You must be able to provide documentation of this to the trial team, or allow the trial team to check this information via NHS systems
- You must be willing to tell the trial staff about your medical history, and you may be asked to allow the trial staff to check this with your General Practitioner (GP). Bear in mind that we would also notify your GP if you joined the trial (even if we did not need to check your medical history with them in advance).
- If you are able to become pregnant you must be willing to practice continuous effective contraception for three months after boost and have a negative pregnancy test on the day of any vaccination
- You must agree not to donate blood during the trial

You cannot take part in this trial if you:

- Have already received more than one dose of any COVID-19 vaccine

- Are already taking part in any trial looking to prevent COVID-19 through vaccines or medications
- Receive any other vaccine in the 30 days before or after COVID-19 vaccination in this study. The exceptions to this are the seasonal influenza vaccine and the pneumococcal vaccine (known as Pneumovax, which is routinely given to over 65-year olds). If you are offered these by your GP or your place of work, we ask that you have these at least 7 days before or after you receive the boost vaccine dose in this study.
- Have previously received certain vaccines (such as non-COVID adenovirus-based vaccines) that might impact on understanding your results. If you are not sure about this, please contact us to discuss.
- Have received a transfusion of any blood products, or immunoglobulins (antibodies) in the 3 months before having the trial vaccine
- Have immunosuppression or immunodeficiency – this includes being on medications that reduce the immune system such as steroid tablets
- Have ever had a severe allergic reaction (anaphylaxis)
- Have an allergy to any of the component of the COVID-19 vaccines used in this study. Specific allergies of concern are latex and polyethylene glycol/macrogol (PEG). PEGs are a group of known allergens commonly found in medicines, many household products and cosmetics, and are contained in the Pfizer and Moderna vaccines. Known allergy to PEG is very rare.
- Are pregnant, breastfeeding or intend to become pregnant within 3 months after vaccination
- Have received immunosuppressive chemotherapy or radiotherapy for treatment of cancer within the 6 months prior to enrolment.
- Have a bleeding disorder
- Continuously take medicines that reduce your blood clotting, such as coumarins and related anticoagulants (i.e. warfarin) or novel oral anticoagulants (i.e. apixaban, rivaroxaban, dabigatran and edoxaban)
- Have current alcohol or drug dependency
- Have severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, rheumatological disease, renal disease, endocrine disorder or neurological illness
- Have a history of confirmed COVID-19 by a validated test or have previously had a blood test that shows that you have had contact with the COVID-19 virus (antibody test)

To assess if you are eligible to be involved in the trial you can complete the online eligibility questionnaire as described below.

What will happen if I decide to take part?

Online questionnaire – *5-20 minutes*

If you decide you would like to participate in this trial there is a two-part online questionnaire to check initial eligibility.

Part-One

The first part broadly checks whether you can or cannot take part in the trial. The information you provide will not be stored unless you progress to part two.

Part-Two

If you are found to be eligible on completing the first part, you will be asked to give your consent to:

- Provide us with details of your medical history and allow us to store this information. Some participants will be advised they are unable to take part on the basis of this additional information
- Have a researcher contact you by phone to clarify the medical information given (if needed)
- Provide details of your registered GP, and consent for the trial team to contact them if needed
- Provide us with information about yourself such as your date of birth, address and ethnicity
- Upload evidence of your first COVID-19 vaccine received through a routine immunisation programme, and allow the trial team to check this against your medical records.

If you do not consent to these things, then you would not be able to join the trial. If you consent and the second part of the questionnaire does not identify any obvious reason why you should not participate, we will review the information you provide, and a trial doctor or nurse may telephone you to go through this in more detail if required.

If, after this process, you are eligible to join the trial, you will be invited to an in-person screening and vaccination visit.

IMPORTANT: If you develop a fever or cough, or loss of sense of smell or taste, or become unwell then you must contact the study team on 01482 875 875 for advice before attending any visit.

Please note that it may not be possible to enrol everybody that wishes to take part in the trial, and passing through the screening process does not guarantee participation in the trial. In the case that you are not enrolled in the trial, your data would not be stored beyond the end of the trial.

What should I do if I am offered my boost vaccination dose via the NHS programme before I am called for the first study visit?

It is up to you to decide, but if you have not yet received an appointment for a study visit then we would advise you to take up the NHS offer of your second COVID-19 dose as there is no

guarantee we will be able to enrol everyone who is interested in the study. However, if you have your second dose of NHS vaccination before the start of the study, you would no longer be eligible to join.

First study visit

Screening and boost vaccination visit - *1.5 hours (review of medical history, vital signs, blood test, urine pregnancy test (for participants who are able to get pregnant), receive vaccine, up to 30 minute observation in clinic after the vaccine)*

Screening component

If you qualify to be in the trial, we will ask you to attend on the boost vaccination day (Day 0). We will outline the nature of the trial either through a video presentation or in person, and this will explain what to expect by taking part, the risks involved and what side-effects you might experience. There will be an opportunity to ask any questions you may have about the trial, and if you decide to take part we will ask you to sign a consent form.

If you sign the consent form a member of the medical team will check details of your medical history and may perform a physical examination. This could involve listening to your heart and lungs with a stethoscope, examining your abdomen as well as feeling for lymph nodes around your neck and in your armpits. We will measure and record your:

- Height
- Weight
- Temperature
- Blood pressure
- Pulse rate
- Respiratory rate
- Non-invasive blood oxygen level (saturations)

We would also check the dates and type of COVID-19 vaccine you received as your first dose, and may ask you to bring documentation to show this.

Blood samples will be taken just before vaccination to check later for:

- Whether you have previously been infected with the COVID-19 virus (antibody test). Please note:
    - We would not give you the result of this test until the end of the trial and would only give it to you if you wished to receive it at this point.
    - If you do decide to receive the results of your antibody test at the end of the trial you should bear in mind that, like all medical tests, it is not 100% accurate. The results cannot be used to provide certainty of prior infection nor of protection from future infection.
    - Before asking for your results, you should consider whether they would have any effect on any private insurance you may have.

- Whether you are anaemic or have any other blood, kidney or liver abnormalities. Sometimes these blood tests need to be repeated, and we would ask you to come for an extra visit to have these taken. If, once available, the results indicate that it would not be safe to carry on in the trial we would let you know this. Additionally, regardless of whether you continue in the trial, we may ask for your permission to contact your GP or a specialist so that any further required treatment or investigation can be organised.

We would also (in some participants) ask to take nasal fluid and saliva samples which are to look at the immune response in the lining of the airways. This is not a test which would have clinically interpretable results; thus you would not be given these results. This test would be repeated at subsequent visits if you had it at the first visit.

Vaccination

Once your eligibility and consent are confirmed, you will be randomly allocated to receive one of the boost vaccine doses. You will not be told which vaccine you are going to receive. You will only be told this at the end of the trial. The only exception to this would be if you were to become ill and it was felt to be medically necessary for you to know which vaccine you had received.

We will give you an injection with the vaccine into your arm. We will need to keep an eye on you for 15 – 30 minutes after the vaccine has been administered.

Follow-up after vaccination

Electronic Symptom Diary "e-diary" – *Completed at home*

We will give you an "e-diary" account, a thermometer, tape measure and to record all your symptoms, your temperature and your vaccination site every day for 7 days after your boost vaccine.

After these 7 days, and for the next 3 weeks, we will ask you to record if you feel unwell or if you take any new medications. The research staff will monitor the e-diary and may telephone you to ask for more information.

You will also be asked to record in the diary any medical conditions for which you see a doctor/dentist until three months after your boost vaccine, and any serious medical illnesses or hospital visits you may have over the course of the entire trial.

Follow-up visits – 30 minutes (vital signs, blood tests, nasal fluid and saliva tests (for some participants) and check for side effects or new health problems)

Following vaccination, we will ask you to attend a series of short follow-up visits to ensure everything is fine, to check your symptoms and to have blood tests done as well as nasal fluid and saliva tests for some participants.

Note: due to the high number of planned volunteers in this trial, visits may take longer than the estimates given here

During the course of the trial you may be asked to attend for an extra visit, for example, if a blood test needs to be repeated.

In the unlikely event of you having a problem with your arm where the vaccination was given, we might ask to photograph your arm. Consent for this is included when you are enrolled to the study. You would not be identifiable in these photographs, as only the vaccination site and your unique trial number would be visible. These photographs could be shown to other professional staff, used for educational purposes, or included in a scientific publication.

How many visits will I have to attend?

The number of visits you attend will be the same regardless of which boost vaccine dose you are randomly assigned to receive. However, each study group will also have an 'immunology' cohort who will have some extra visits, blood tests and nasal fluid and saliva tests; enrolment to this cohort is limited to 150 participants. The purpose of this will be to better understand the response of the immune system to the vaccine. If you would prefer not to be in the immunology cohort, then this is not a problem. Participants who are not in the 'immunology' cohort will be in the 'general' cohort and will be asked to attend five visits. Participants who are in the immunology cohort will be asked to attend seven visits, and will also be asked for nasal fluid and saliva samples.

General cohort (Regular frequency sampling cohort)

The table below represents the visit schedule for participants in the general cohort:

Visit schedule for participants in the general cohort					
Trial timeline	**Day 0**	**Day 28**	**Day 56**	**Day 112**	**Day 294**
Vaccination	Boost	-	-	-	
Blood tests	Yes	Yes	Yes	Yes	Yes
Nasal fluid & saliva tests	No	No	No	No	No

Immunology cohort (More frequent sampling cohort)

The table below represents the visit schedule for participants in the immunology cohort:

Visit schedule for participants in the immunology cohort							
Trial timeline	**Day 0**	**Day 7**	**Day 14**	**Day 28**	**Day 56**	**Day 112**	**Day 294**
Vaccination	Boost	-	-	-	-	-	-
Blood tests	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nasal fluid & saliva tests	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Should you be unable to attend a scheduled visit (for example because you are self-isolating or quarantining), then a researcher might do this visit over the phone with you instead.

Also, regardless of which group or cohort you are in, if you were to test positive for COVID-19 outside of the trial, we would ask you to inform us of this and we would then ask you to attend for a medical check and to take further blood tests and a nose and throat swab. We would only ask you to come in for this specific visit if you were able to attend using your own transport; and didn't need anyone to come with you. We would ask you to fill in another electronic diary for at least a week after you were diagnosed with COVID-19. You would need to follow current government guidance for people with positive COVID-19 tests.

What things should I consider before taking part in this study?

If you are of female sex and able to have children, you must be willing to practise continuous effective contraception for three months after boost; methods of effective contraception are listed in the eligibility questionnaire.

Blood Donation

Under current UK regulations, participants will not be able to donate blood during the trial.

Private Insurance

If you have private medical or travel insurance you are advised to contact your insurance company before participating in this trial, as involvement may affect the cover provided.

Are there things I will be asked to avoid doing during the trial?

You should not donate blood during the trial or take part in other studies that involve blood sampling or the administration of drugs or vaccines, including trials testing other preventative interventions for COVID-19. Once you have received a boost dose of vaccine in this study, you will also not be able to receive the boost dose that you were originally planned to receive through the national immunisation programme.

If during the trial you require any other vaccinations for health, travel, or occupational reasons, you should inform the trial team beforehand. We will discuss with you the most appropriate time to receive them.

What are the risks of taking part in this trial?

The risks and side effects of the proposed vaccinations and trial procedures are detailed here:

Receiving an unapproved vaccine

This trial includes the Novavax vaccine. It has been tested in clinical trials which have shown it to be effective at preventing COVID-19, without raising safety concerns. It is not, however, already approved for use in the UK outside research studies. As the trial is randomised, there is a chance that you could receive this unapproved vaccine as your boost vaccine allocation. You would not know this, as you would be "blinded" to which vaccine you had received.

Blood samples

Drawing blood may cause slight pain and occasionally bruising at the site where the needle enters. Some people feel light-headed or even faint when having blood taken. The approximate volumes of blood taken during the course of the trial are between 20-80ml of

blood at a single visit, with the total amount being approximately 160-270ml if you are in the general cohort, or (approximately) 380ml if you are in the immunology cohort. An additional 35-80ml would be taken at the COVID-19 pathway visit if you were to develop confirmed COVID-19 during the study. If repeat bloods are requested for safety reasons at a visit this will be up to 7ml. These amounts over the course of the year, should be below the limit of 470mL every 3 – 4 months for blood donations to the National Blood Transfusion Service.

If abnormal results or undiagnosed conditions are found during the trial these will be discussed with you and, if you agree, your GP (or a hospital specialist, if more appropriate) will be informed. Any newly diagnosed conditions will be looked after within the NHS. Participants will not be informed of the results of their levels of post-vaccine immunity against the COVID-19 virus as these are not clinically validated tests.

Nasal fluid samples

This will involve insertion of a small swab of soft synthetic material about 2cm into your nostril and leaving it in there, pressed up against the inside of your nose for about one minute. This can cause some eye-watering, but should not cause any damage to your nostrils. Some people might have more sensitive nostril linings and this might rarely cause a small amount of bleeding.

Saliva samples

We aim to collect approximately 1-1.5mls saliva using a funnel and collection tube. Participants may find the saliva collection process unsavoury as it is involves drooling and spitting into a collection device. We would ask participants who are giving saliva samples not to eat, drink, smoke, chew gum, brush their teeth or use mouthwash for at least 30 minutes prior to their appointment.

Vaccination Side Effects

Common side effects

People very often have tenderness, pain, warmth, redness, itching, swelling or bruising or less commonly have a small lump in their arm where they have been vaccinated.

Other common side effects

Some people can develop these symptoms after vaccination. They usually last for less than a week after you are vaccinated (more commonly 24-48 hours afterwards).

- Tiredness
- Headaches
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- Muscle aches
- Joint aches
- Feeling generally unwell (malaise)
- Feeling sick or nauseated or vomiting

Other less common side effects:

- Abdominal pain
- Decreased appetite
- Feeling dizzy
- Swollen lymph nodes (glands)
- Excessive sweating, itching skin or rash
- Rashes

Many of these symptoms can be reduced by use of paracetamol around the time of immunisation and over the next 24 hours. We would not routinely recommend the use of ibuprofen or other anti-inflammatory medication at this time.

After immunisation with the Pfizer vaccine, difficulty sleeping has been observed in fewer than 1 in 100 people, and weakness of the muscles on one side of the face has been observed in fewer than 1 in 1000 people.

Serious Reactions

With any vaccination there is a small risk of rare serious adverse events, such as an allergic reaction. Severe allergic reactions to vaccines (anaphylaxis) are rare, but can be fatal. Anaphylaxis is known to occur in approximately 2.5-4.7 per million doses of the Moderna/Pfizer vaccines. More generally anaphylaxis occurs in 1 in 1,000,000 doses of all vaccines, but can occur in response to any vaccine or medication. In case of the unlikely event of anaphylaxis, medication for treating allergic reactions is available and the researchers are appropriately trained in the management of anaphylaxis.

These are new vaccines, and there may be side effects that we are not yet aware of. Further information about vaccine safety is being actively gathered as the vaccines are being used in the UK and globally.

Following reports of blood clots with lowered platelets following immunisation with the AstraZeneca vaccine a review has been undertaken by the MHRA and the EMA (European Medicines Agency). The reports were into a very rare type of blood clot in the brain, known as cerebral venous sinus thrombosis (CVST), and in some other organs together with low levels of platelets (thrombocytopenia) that might be associated with vaccination with the AstraZeneca vaccine. Up to and including 31 March 2021 there have been 79 UK reports of these blood clots and unfortunately 19 people died. By 31 March 2021 20.2 million doses of the AstraZeneca vaccine had been given in the UK. This means the overall risk of these blood clots is extremely rare, approximately 4 people in a million who receive the vaccine.

The full reports released by MHRA and JCVI can be found at the following links:

https://www.gov.uk/government/publications/use-of-the-astrazeneca-covid-19-vaccine-jcvi-statement/jcvi-statement-on-use-of-the-astrazeneca-covid-19-vaccine-7-april-2021

https://www.gov.uk/government/news/mhra-issues-new-advice-concluding-a-possible-link-between-covid-19-vaccine-astrazeneca-and-extremely-rare-unlikely-to-occur-blood-clots

Additional side effects to be alert for in the 28 days following vaccination are;

- Sudden severe headache that does not improve with usual pain killers or is getting worse

- An unusual headache which seems worse when lying down or bending over, or may be accompanied by blurred vision, nausea and vomiting, difficulty with speech, weakness, drowsiness or seizures
- New and unexplained pinprick bruising or bleeding
- Shortness of breath, chest pain, leg swelling or persistent abdominal pain.

You will be informed of any significant change in the vaccine safety profile.

You will be provided with a 24h trial mobile number. If you experience unexpected events or experience a headache that lasts for more than 4 days after vaccination, or bruising beyond the site of vaccination after a few days, or become in any way concerned you can use this to contact one of the trial doctors at any time. We will ask you to record these symptoms in the e-diary too.

Theoretical risks - Could immunisation make COVID-19 disease worse?

In the past, experimental vaccines were developed by different research groups against the SARS virus, which is in the same family as the COVID-19 virus and also infects the lungs. In some cases, animals that received certain types of experimental SARS vaccines appeared to develop *more severe* lung inflammation when they were later infected with SARS compared with unvaccinated animals. There has also been one report of this increased disease-associated inflammation being seen in a mouse study for a vaccine against MERS-CoV (another related virus), but this has not been observed in any other reported animal studies, and has not been seen in any of the trials of the vaccines being used in this trial. Importantly, this has not been seen in any of the human studies of these vaccines, which have shown immunisation with the vaccines used in this trial does provide protection against COVID-19 disease.

Will I be protected against COVID-19 from having the vaccines in this trial?

If you participate in this trial you might not receive the same level of protection as that provided by standard vaccinations. The vaccines in this trial have been tested and shown to be protective against COVID-19 when given as a two-dose schedule with the same vaccine at both doses. We do not know whether having two different vaccines would give you the same protection against getting COVID-19 as having two doses of the same vaccine, which is why we are doing this trial. The answers to this question, which you would be helping us to provide, are really important. There are various reasons why it might not be possible to give two doses of the same vaccine in the future, such as shortage of supply generally or availability at a local level. Participation in the trial will mean that you might overall receive two doses of the same vaccine or two doses of different vaccines. The results of the trial will allow us to make comparisons between the two possibilities. You will not know whether the boost dose you receive through the trial is the same as the one you had for your prime through the national immunisation programme. You should still continue to follow up-to-date national guidelines regarding social distancing and other coronavirus precautions as appropriate.

It is possible that people who receive different vaccines for their first and second doses might develop a better immune response than someone who receives the same vaccine for first and second dose. This has the potential to be beneficial and we will be looking at the kind of immune responses that are produced by different vaccine schedules.

If you find out that having two different vaccines does not give good immune responses against COVID-19 will you give me another vaccine?

This study is being overseen by a safety monitoring board and a steering committee, who will evaluate part-way through the trial whether there are signs that any of the vaccine combinations are not giving a good enough immune response. If they were to find any sign that any of the different combinations of vaccine were significantly less effective than the standard approach of two doses of the same vaccine you would be informed. We would then take the oversight committee's advice in deciding whether an additional dose of vaccine would be appropriate, and what vaccine this should be, based on all available information at that time.

Of note, the current national guidance for COVID-19 vaccines recommends that individuals who have received two doses of any combination of approved COVID vaccine do not require any additional doses, and it is anticipated that this will apply to the Novavax vaccine if it is approved. This advice may of course change depending on future changes to the national immunisation policy.

What if I decide I would like to take up my boost dose from the NHS as well, just in case?

Participation in this trial means that, unless the trial team specifically advise otherwise, you will not be able to receive your originally scheduled boost in the national programme. We will ask your GP to add the receipt of your vaccine to your medical record, however, during the trial, your medical record will not state which vaccine you received. Once the trial has finished, and you have been told which vaccine you had, we will write to your GP and ask them to update your records.

Why can't I know what vaccine I've had in the trial?

Participants in this trial will not know which vaccine schedule they have received until after the end of the trial. This procedure is known as blinding and is a critical part of the trial to avoid bias. For example: If you know which vaccine you have, you might, subconsciously be more or less likely to report certain symptoms. For this purpose, we would not unblind you (tell you which vaccines you received) until the end of the trial, even if you withdrew from the trial, as it would seriously affect our ability to interpret the trial data. We would, however, unblind participants if:

- It became apparent that one schedule was producing an immune response that was thought to be inadequate
- There was an urgent safety need

Will I be given proof of immunisation from the trial? If "vaccine passports" are introduced, will I get one from being in the trial?

At the vaccination visit your COVID-19 vaccination card that you got at your prime visit in the national programme will be updated to note that you have now had a boost dose. The

difference will be that this entry will not give the name and batch number of the vaccine you have received (as this would "unblind" you). Instead, the card will be marked with "COVID-19 vaccine" "Com-COV2 Trial" and the date. We will also write to your GP to ask them to enter this information into your medical record. The UK has not, as yet, introduced any kind of official certification system in relation to vaccinations and it is unclear whether they will do so. We are working together with the vaccine task force and NHS digital to ensure that there is a digital record of the COVID vaccines received during the trial, for our participants. As an interim measure, we will provide all participants with an official letter addressed to "to whom it may concern" stating their involvement in the trial, the premise of the trial and the dates of their vaccines. We will always seek to not disadvantage our participants and will be responsive to any of these kinds of potential changes - taking advice from the trial oversight committees.

What are the advantages of taking part?

We anticipate that participating in the trial will mean that you gain some protection against the coronavirus (but cannot guarantee this). You may also receive your boost dose of vaccine a few weeks earlier than you were planned to receive it from the national immunisation programme. Most importantly, the information gained from the trial will make a valuable contribution to the pandemic response.

What should you do if you believe you may have developed COVID-19 during the trial?

A common and expected side effect of COVID-19 vaccines is fever. If you develop fever in the first 48 hours post-vaccination only, you would not need to self-isolate unless you had other symptoms of COVID-19. If your fever continued (or you had another episode of fever) after 48 hours then you would need to follow the current government advice around seeking testing. We would also ask you to record any fever that you have in your e-diary. If the fever didn't continue, then it is likely that it was a vaccine effect and you can carry on as normal.

Excluding the above, if you develop symptoms that meet the UK government COVID-19 testing criteria, then you must arrange an NHS test as soon as possible, following the normal routes. If this test is positive, you would need to follow government guidance regarding self-isolation as usual. We would also ask you to contact the trial team on hyp-tr.huth-comcov2trial@nhs.net. If you test positive on an alternative route such as via work or a commercial test then please let the trial team know as well.

If you have a positive test, we may invite you for a visit in our clinic which would involve a blood test a nose swab (and a mucosal fluid and a saliva sample if this is something you have done at other visits) and a review by a doctor. These swabs would be looking for the SARS-CoV-2 virus, but may not be processed immediately – we would not inform you of the results as they are a repeat of the positive result you already have. We may have to inform Public Health England of the results of this swab and convey to them details about you including your name as a legal public health requirement.

Please do not attend the clinical trial site until you have been asked by the trial team to do so. Although, in general, you should adhere to government guidance and stay at home when

required (for instance during self-isolation or lockdown), **attending the trial site for visits during these periods (once asked to do so) is exempt from these rules**.

If you are unwell and unable to contact the trial team directly then contact the NHS 111 service or phone 999 if you are severely unwell.

If you are admitted to hospital during the trial then you should inform the medical or nursing staff that you are taking part in this trial. We will provide a contact card for you to give to these staff which will have a link to a website for them to fill in details about your admission. We would also like you to let us know (if you are able) that this has happened.

Do I get access to extra medical treatment from being in the trial?

It is important that you understand that if you do become seriously unwell and need to be admitted to hospital, the standard referral routes within the NHS will be used. Participants will be treated the same way as the general population in this context of the COVID-19 pandemic. We are unable to offer extra medical support outside what is available from the NHS for the general public.

Will I be compensated for taking part in this trial?

Once enrolled you will be compensated for your time, the inconvenience of having blood tests and procedures, and your travel expenses. The total amount compensated will be between approximately **£225-£315** depending on the total number of visits attended. Additional visits will be paid at a rate of £45/visit. Payments will be made following: Day 28 visit, Day 112 visit and Day 294 visit. For those who attend for final screening and vaccination visit (Day 0) but are not eligible to proceed further in the trial, payment will be initiated that day.

Trial reimbursement will be made by bank transfer throughout the trial, so please bring your bank details with you to your screening visit (no cash payments can be made). Should you decide to withdraw from the trial before it is completed, payment will be *pro rata* (you will receive a proportion of the total amount).

What if the area I live in, or where the trial is, goes back into lockdown or high-level restrictions?

Travel for visits for trial purposes are exempt from government restriction, as it is considered an essential journey.

What if new information becomes available?

Sometimes during a trial, new information relevant to the trial becomes available. If this happens, we will tell you about it and discuss whether you want to, or should, continue in the trial. If you decide to continue to take part, you may be asked to sign an updated consent form. On receiving new information, we may consider it to be in your best interests to withdraw you from the trial. Your participation in this trial may also be stopped at any time by the trial doctor or the Sponsor for other reasons.

What will happen if I do not want to carry on with the trial?

If, after enrolment, you change your mind about being involved with this trial you are free to withdraw, at any time, without giving a reason. If you withdraw we would not usually perform any more research procedures; although occasionally we might need to offer you a follow up

visit for safety purposes, for example for blood tests. You would not have to agree to this. Your decision will not result in any penalty. Unless you state otherwise, any samples taken whilst you have been in the trial will continue to be stored and used for research as detailed above. You are free to request that your samples are destroyed at any time during or after the trial. Your data would be managed as laid out in the section 'What will happen to my data'. If you choose to withdraw from the trial, your standard medical care will not be affected.

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 University of Oxford, as the research Sponsor, has arrangements in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial.

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. The trial doctor can advise you of further action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which may be provided if you needed to be admitted to hospital.

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 trial, you should contact the research investigators who will do their best to address your concerns by sending us an email to hyp-tr.huth-comcov2trial@nhs.net. Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email ctrg@admin.ox.ac.uk

Would my taking part in this trial be kept confidential?

All information that is collected about you during the course of the research will be coded with a trial number and kept confidential. The information is available to the trial team, authorised collaborators, ethical review committees, Hull University Teaching Hospitals NHS Trust, government regulatory agencies and the Sponsor (University of Oxford), who can ask to access the trial data. Responsible independent monitors may be given access to data for monitoring and/or audit of the trial to ensure we are complying with regulations. They are bound by the same confidentiality rules. The electronic diary is sent to you by email to complete online. Your email address will be stored on a secure University of Oxford server, access to the diary system is password controlled and only trial site staff and sponsor IT management can view the email address.

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 restricted access office at the Hull University Teaching Hospitals NHS Trust or at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), University of Oxford. Trial results will be published in a scientific journal but nothing that could identify you will be included in any

report or publication. Your de-identified data collected in the trial may also be used in future research projects that may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide. We would not share anything that could identify you.

If you are not enrolled on the trial, either because you were not eligible after screening or there was not capacity to enrol you, then any data collected will be kept until the end of the trial.

What will happen to my data?

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 is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records in order to undertake this trial and will use the minimum personally-identifiable information possible. We will keep identifiable information about you such as contact details for a minimum of 5 years, but with a review of this every 5 years after the trial has finished. This includes a copy of your consent form. The need to store this information for longer will be subject to ongoing review, taking into account the value of retaining this information for participant safety (e.g. to inform participants of unexpected safety signals emerging from post-licensing surveillance), as a resource for the participants (e.g. if they wish to check which vaccine they have received in the study) and any regulatory requirements. De-identified research data will be stored indefinitely. If you have agreed that samples can be retained for future research then your personally identifiable information 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 will store research data securely at the University of Oxford indefinitely following removal of identifiable information. If you agree to your details being held to be contacted regarding future research, we will retain a record of this consent until such time as your details are removed from our database but will keep this separate from your research data.

The trial team will use your name and contact details, to contact you about the research trial, and make sure that relevant information about the trial is recorded for your care, in relation to your health during the trial and to oversee the quality of the trial.

At the completion of the trial, unless you consent otherwise (e.g. if you request to be informed of other trials), your personal details will not be used to contact you other than exceptional circumstances concerning your safety. If you consent to take part in another trial carried out by the Hull University Teaching Hospitals NHS Trust, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

Your bank details will be stored for 7 years in line with university financial policy.

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

Note that in order to check that we are conducting the trial to high standards we will be engaging trial monitors, who will have access to your data (including personal identifying information). They will not be retaining data beyond the end of the study. Minimal information about you (not including any identifiable information) may also be shared with third parties such as Public Health England or laboratories undertaking analysis of your blood samples (including, but not limited to, Oxford Immunotec, Nexelis and laboratories outside of the UK) to help us conduct this research. Retention of data by these third parties will be as per PHE/local policies. Anonymised reports on safety information related to the AstraZeneca and Novavax vaccines will be shared with AstraZeneca or Novavax, respectively.

Some participants will have signed up to NHS Digital's *'Sign up to be contacted for coronavirus vaccine studies'* service. Further information regarding how we will inform NHS Digital of your enrolment in this trial, will be supplied in a Supplementary Privacy Notice for volunteers who are enrolled in the trial.

Involvement of the General Practitioner (GP)/Family doctor

In order to enrol into this trial, you will be required to sign a form documenting that you consent for us to contact your GP if we need to. This is in case we need to contact your GP to check there are no medical reasons that they are aware of that would make your participation inadvisable. Your GP may be asked to share information about your medical history and give access to any other medical records as required. The researchers will not enrol you in the trial if your GP has relevant concerns about your eligibility or safety.

If you are enrolled in the trial we will write to your GP to let them know this. This will be done regardless of whether we check any medical information with them. It is important to do this so that your medical records are kept up to date.

If you have up to date copies of your medical records or GP summary records please bring these to your screening visit.

What will happen to any samples I give?

If you consent, some of your leftover blood samples can be stored and used for future infectious disease or vaccine-related research in the Oxford BioBank. This is optional; your participation in this trial will not be affected by your decision whether to allow storage and future use of your leftover samples. Upon your request at any time, your remaining blood samples will be destroyed.

Your trial samples will be analysed in the site Hull University Teaching Hospitals NHS Trust laboratories, University of Oxford research laboratories or other specialist laboratories. Other tests to look at the response of your body to the vaccine or to COVID-19 disease will be done with collaborating laboratories in the UK and in other countries, including North America. Any samples or data sent to them would not include information (such as your name) that identifies you.

Will any genetic tests be done?

We would also ask for your permission to store your DNA for research related to infectious diseases and vaccination; you can still take part in the trial if you did not want us to do this. Your DNA is unique to you so it can never be completely anonymous, but again this would not be associated with any personal identifying information.

We are not planning to perform any genetic tests within this trial.

What will happen to the results of the research trial?

The results of this research trial may be presented at scientific meetings or conferences and published in a scientific medical journal. This may not happen until 1 or 2 years after the trial is completed. If you contact the researchers in the future, you can obtain a copy of the results. You will not be identified in any report or publication.

The de-identified data from this trial will be shared with the collaborating partners who are organising and funding this research work. You will not be paid for any part of this. Data from this trial may be used as part of a student post-graduate degree, for example a MD or PhD.

Taking part in future vaccine-related research

With your consent, we would like to keep your contact details after the trial is complete, so we may inform you of opportunities to participate in future vaccine-related research. This is entirely optional and your participation in this trial will not be affected by your decision to allow or not allow storage of your contact details beyond your participation in this trial.

Your details will be stored electronically on a secure server and only authorised individuals at the Hull University Teaching Hospitals NHS Trust will have access to it. We will not, under any circumstances, share your contact details with any third party institutions without your permission. Being contacted does not oblige you to agree to take part in future research and you can ask us to have your contact details removed from our database at any time.

Who is sponsoring, organising and funding the research? Does the University of Oxford have a financial interest in the results of this trial?

The trial is organised and sponsored by the University of Oxford. The trial is funded through financial support to the University of Oxford from the UK Vaccine Task Force, the National Institute for Health Research (NIHR - a UK government funded research agency), and the Collaboration for Epidemic Preparedness Innovations (CEPI). Neither your GP nor the researchers are paid for recruiting you into this trial. The AstraZeneca vaccine was developed as a partnership between the University of Oxford, who are sponsoring and coordinating this study, and AstraZeneca UK Limited. AstraZeneca holds an exclusive commercial license for this vaccine and has committed to making the vaccine available on a 'not for profit' basis for the duration of the current pandemic. Both parties could potentially profit from this vaccine in the future. AstraZeneca do not have any direct involvement in the conduct of this trial. The Novavax vaccine is being supplied to this study by Novavax; all other vaccines are coming from NHS supplies.

Who has reviewed the trial?

This trial has been reviewed by the NHS Research Ethics Service (RES) – South Central – Berkshire and has been given a favourable ethical opinion. The MHRA, which regulates the use of all medicines in the UK, has reviewed the trial design and has granted permission to use these unlicensed vaccine schedules in this clinical trial.

Further information and contact details

If you relocate during the course of the trial and would like to continue taking part, it may be possible if there is a trial site nearby that are able to perform the remainder of your trial visits. If this were the case, we may transfer copies of your research notes including consent forms. The responsibility for your continued care in the trial would be transferred to the new trial site.

We hope this information sheet has answered all your questions. If you would like further information about participating in research please visit the following website: http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx. For independent advice about participating in this trial you may wish to contact your GP. If you would like to speak to one of our team members to discuss any aspect of this trial or **if you are interested in taking part in the trial, please contact us**:

Dr Patrick Lillie & Research Team
Castle Hill Hospital, Castle Road, Cottingham, HU16 5JQ
hyp-tr.huth-comcov2trial@nhs.net

01482 875875

Supplementary Privacy Notice for Enrolled Participants

This privacy notice is for the Comparing COVID-19 Vaccine Schedule Combinations (Com-COV) study participants who have signed up to NHS Digital's *'Sign up to be contacted for coronavirus vaccine studies'* service.

Data Protection

In the course of enrolling in the Comparing COVID-19 Vaccine Schedules (Com-COV) study you have provided information about yourself ('personal data'). We (University of Oxford as Sponsor of the study) are the 'data controller' for this information, which means we decide how to use it and are responsible for looking after it in accordance with the General Data Protection Regulation and associated data protection legislation.

How we use your data

NHS Digital contacted you on behalf of the University of Oxford to invite you to join our Comparing COVID-19 Vaccine Schedule Combinations (Com-COV). This is because you signed up to NHS Digital's '*Sign up to be contacted for coronavirus vaccine studies service*'. You were contacted because you were eligible to take part in our study based on the information you provided to NHS Digital when you signed up to its service (namely your age and geographical location).

You can only be enrolled in one vaccine study at a time. This means we need to let NHS Digital know that you are now enrolled in our study. We will do this so that NHS Digital can update its records and so you are not contacted unnecessarily about any joining any other vaccine studies or inadvertently enrolled in more than one study at a time.

Each site will review which of their participants had signed up to NHS Digital's *Sign up to be contacted for coronavirus vaccine studies'* service. If you had signed up to this service, the site you are enrolled with will share your name with NHS Digital to confirm your enrolment. They will keep a record of having confirmed your enrolment with NHS Digital.

We need to process your data for the above purpose in order to effectively carry out research, which is a task we carry out in the public interest. Data concerning health and ethnicity is special category data, which means that we must meet additional requirements to process it. The additional requirement we meet to process this data is that the processing is necessary for the purpose of research.

We will only use your data for the purposes for which we collected it, unless we reasonably consider that we need to use it for another related reason and that reason is compatible with the original purpose. If we need to use your data for an unrelated purpose, we will seek your consent to use it for that new purpose.

Who has access to your data?

Access to your data will be provided to those who need to view it as part of their work in carrying out the purposes described above.

Where we share your data will with NHS Digital, we will seek to share the minimum amount necessary (please see NHS Digital's privacy notice for how it uses your data).

Retaining your data

Once we have confirmed your enrolment to NHS Digital, we will securely destroy the list of people that NHS Digital contacted about our study on our behalf.

We will retain a record of having confirmed your enrolment with NHS Digital along with other identifiable information about you for 5 years and with a review of this every 5 years after the trial has finished. The need to store this information for longer in relation to licensing of the vaccine will be subject to ongoing review.

Security

Your data will be held securely in accordance with the University's or equivalent Hull University Teaching Hospitals NHS Trust policies and procedures. Further information is available on the University's Information Security website here.

Where we store and use your data

We store and use your data electronically on a secure server, and paper notes will be kept in a key-locked filing cabinet or restricted access office at the Hull University Teaching Hospitals NHS Trust or on University premises.

Your rights

Information on your rights in relation to your personal data are explained here.

Contact

If you wish to raise any queries or concerns about our use of your data, please contact us at hyp-tr.huth-comcov2trial@nhs.net. Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email ctrg@admin.ox.ac.uk

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