PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

There are [4] parts to this document:

Part I: the "**Study Information**" essential to your decision to take part in the clinical study,

Part II: the "**Future Research Information**" which explains the possibility to contribute to future research, subject to an optional consent,

Part III: your "**Consent Form**" which summarise what you may agree to.

Part IV: supplementary information in the "***Additional information for participant***" Section, including a glossary.

STUDY INFORMATION

Part I:

Study title: A Phase I/III Randomized, Double blind Study to Evaluate the Safety and Neutralizing Activity of AZD5156 for Pre exposure Prophylaxis of COVID 19 in Participants with Conditions Causing Immune Impairment

Study protocol: D7000C00001

Study drug: AZD5156, referred throughout the document as the 'study drug'

Sponsor of the study: AstraZeneca AB

Investigator: Dr Paola Cicconi

Participant Name: _____

Participant Number: _____

Dear Madam/Sir,

You are invited to take part in this study investigating a potential new preventative (prophylactic) protection for coronavirus disease (COVID-19). Participation requires your written consent. Before you decide whether you want to participate in this study, you will be given an explanation about what the study involves.

All research studies are reviewed by an independent group of people, called a research ethics committee to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favourable opinion by London Harrow - Research Ethics Committee.

It has also been reviewed and approved by the UK regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA). Joining this study may or may not improve your health, but the information we get from this study might help other people in the future.

1 What is this study about?

We are doing this study to learn more about the safety of a study drug called AZD5156, and to better understand if it may protect people from COVID-19. The study drug (AZD5156) is made up of a combination of 2 proteins called 'monoclonal antibodies' (AZD1061 [cilgavimab] and AZD3152). Antibodies are made by the body to help fight infections. Monoclonal antibodies are made in a laboratory. They act just like the antibodies made by the body and are designed as possible medical treatments. The study is also being done to better understand the studied disease and associated health problems.

COVID-19 is a respiratory disease caused by SARS-CoV-2, a coronavirus discovered in 2019. The virus spreads mainly from person to person through respiratory droplets produced when an infected person coughs, sneezes, or talks. Some people who are infected may not have symptoms. For people who have symptoms, illness can range from mild to severe. Those that are at higher risk for severe illness are adults 65 years of age or older and those with underlying medical conditions.

There are 2 parts of this study: Phase I and Phase III. Phase I will include healthy people and Phase III will include people with conditions that lead to impaired immune systems. You are being asked to participate in the Phase I part of the study.

Some parts of this study are experimental which means the study drug (AZD5156) is not approved by any health authority, except for use in research studies like this.

If you take part in this study, you will receive either the study drug (AZD5156) or a placebo. A placebo looks just like the study drug but does not contain any active medication.

This is a double-blind study. This means that you, the study doctor and study personnel will not know if you receive the study drug (AZD5156) or the placebo until the study is completed. If there is a need to know because of an emergency, it is possible for your study doctor to find out if you received the study drug (AZD5156) or the placebo.

About 56 healthy people between 18-55 years of age, weighing at least 45 kg (kilograms) but under 110 kg, will take part in this portion (Phase I) of this study. The Phase I part of the study will be conducted at 3 sites in the UK.

In total, about 1200 people of 12 years of age or older, weighing at least 40 kilograms (kg) will take part in Phase III part of this study. The study will be conducted at approximately 66 sites in approximately 15 countries.

2 Do I have to take part?

You have a choice whether or not you would like to participate in this study.

Please take as much time as you need to make a decision about whether or not you would like to participate in this study. It may be helpful to talk with your friends and family as you make this decision.

If you join the study, you can leave at any time (see “Section 13” for more details). Leaving will not affect your care. If you choose to leave the study, please let your study doctor know as soon as possible. Please consider the study time commitments and responsibilities as a research participant when you are deciding to take part.

If you do not join the study, this will not affect your future ability to receive care for COVID-19. Your study doctor or general practitioner (GP) will talk to you about other possible preventative measures, including their risks and benefits.

3 What will happen if I join the study?

You will be in the study for approximately 12 months (for about 1 year).

Before you can receive the study drug (AZD5156) or placebo, you will undergo a series of tests. This is called screening. If you do not meet the screening criteria, the reasons will be explained. Your study doctor or GP will talk to you about other possible treatments.

If you meet the screening criteria, you will be randomly assigned a study treatment. “Randomly assigned” means that whatever treatment you get will be by chance, like flipping a coin or drawing names out of a hat. You have a 5-in-7 chance of being given the study drug (AZD5156). Additionally, all 56 participants will be randomly assigned to 1 of 4 groups to receive the study drug (AZD5156) or placebo in different muscles. The 4 groups are:

- **Group 1a**: 5 people will receive a 600 milligram (mg) dose of the study drug (AZD5156) and 2 people will receive placebo in their buttock

- **Group 1b**: 5 people will receive a 600 milligram (mg) dose of the study drug (AZD5156) and 2 people will receive placebo in their thigh
- **Group 2a**: 15 people will receive a 600 milligram (mg) dose of the study drug (AZD5156) and 6 people will receive placebo in their buttock
- **Group 2b:** 15 people will receive a 600 milligram (mg) dose of the study drug (AZD5156) and 6 people will receive placebo in their thigh

Group 1a and Group 1b will each include 7 people first. If the review of the safety information from the first 14 people demonstrates that the study drug (AZD5156) has an acceptable safety profile, the study will proceed to enrol people into Group 2a and Group 2b. Group 2a and Group 2b will each have 21 people. The group you will be in depends on the time you join the study. You cannot choose which group to participate in. The table below explains what is involved for each group in more detail:

Study Groups	**How many participants will receive the study drug (AZD5156)?**	**How many participants will receive placebo?**
Group 1a – Injections in buttock	5	2
Group 1b – Injections in thigh	5	2
Group 2a – Injections in buttock	15	6
Group 2b – injections in thigh	15	6

You will have:

- 11 study visits over a period of 12 months.

If you cannot come to a visit, you must tell your study doctor.

You will only be given the study drug (AZD5156) or placebo once while the study is going on but not after the study has ended.

The study drug (AZD5156) or placebo will be administered at one time via 2 intramuscular (IM) injections. An IM injection is a technique used to deliver a medication deep into the muscle. You will be monitored for at least 1 hour after you receive the study drug (AZD5156) or placebo to check for any reactions or side effects.

Please note that the study, and your participation in the study, may be stopped earlier than expected, for example for scientific or safety reasons (see “Section 9” for more details).

4 What are the required tests and procedures?

To conduct the study, some tests and procedures will have to be performed on you.

The following tests and procedures will be included:

Collection of personal information and medical history: personal information including your year of birth, sex, and race will be collected. You will need to tell the study doctor about:

- any current or previous health conditions (including previous COVID-19 infection)
- any medications you have taken in the past (including COVID-19 vaccine status)
- any medications you are currently taking
- any past medical procedures or surgeries

Check if the study is right for you: the study team will check that you meet the eligibility criteria and that this study is right for you.

Physical examination: the study doctor will perform a full physical examination at screening. This means the study doctor will check your head, eyes, nose, throat, neck, skin, heart, breathing, abdominal and nervous systems, and your height and weight. At Visit 1-4 (Day 1, 3, 5 and 8), the study doctor will focus on specific parts of your body.

Check your current medications and treatments: the study team needs to know if you start or stop any medications or treatments during the trial. Certain medications and treatments may not be allowed during the study and the study doctor can advise you about this.

Review of symptoms and side effects: the study doctor will ask you about any symptoms or side effects you may have during the study. Even if you think a symptom has nothing to do with the study, please inform the study doctor about it.

Vital signs: your blood pressure, heart rate, breathing rate, and body temperature will be measured at screening, Visits 1-4 (Days 1, 3, 5 and 8) and if you leave the study early.

Electrocardiogram (ECG): you may have an ECG at the screening visit. An ECG is a simple medical test used to look at the rhythm and electrical activity of the heart. An ECG technician will put small adhesive patches on your chest and limbs. Wire is attached to the patches and connected to the ECG machine. The machine records and prints a report of the rhythm of your heart. An ECG is painless. No electricity is sent through the body.

Safety laboratory tests: you will need to give blood samples, which will be used to check your general health and blood clotting functions at screening, Visit 1 (Day 1) and Visits 4-6 (Days 8, 15 and 29). If you are a woman under 50 years old and have not had your periods for 12 months, the blood sample at screening will also be used to check the level of a hormone that helps control your period cycles.

Samples will be taken for:

- **Biomarker research:** blood samples will be taken so that biomarker tests and tests for SARS-CoV-2 virus can be performed. A biomarker is a biological substance found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.

  Pharmacokinetic (PK) tests: blood and nasal lining fluid samples will be used to look at the way the body absorbs, distributes, and gets rid of the study drug.
- **Immunogenicity tests:** blood and nose swab samples will be used to see how the body's immune system reacts to the study drug. The study doctor will look to see if your body produces antibodies against the study drug.

The total amount of blood that will be taken from you during the full length of this study will be approximately 298.4 mL (millilitres) (about 20 tablespoons).

Pregnancy test: if you are able to get pregnant, you will need to take a urine pregnancy test at the screening visit to confirm that you are not pregnant. You must have a negative pregnancy test before receiving the study drug or placebo.

SARS-CoV-2 tests: a SARS-CoV-2 rapid antigen test will be performed before receiving the study drug or placebo at Visit 1 (Day 1). A nose swab will also be collected for a SARS-CoV-2 RT-PCR (reverse transcription – polymerase chain reaction) test.

5 What are the risks of joining the study?

Like all medicines, the study drug (AZD5156) can potentially cause side effects, although not everybody gets them. If you notice any side effects, please tell your doctor.

It is possible that some participants could have side effects that we do not know about yet.

The following potential side effects of the study drug (AZD5156) are those that have been seen when other similar monoclonal antibodies have been given to people.

Allergic reactions

Similar to other monoclonal antibodies and to other medications, the study drug (AZD5156) may cause allergic reactions. These reactions can sometimes happen within minutes, hours, or days after the injection. Symptoms may include itching, flushing, a rash including hives, swelling (e.g., lips, face, or throat), wheezing, shortness of breath or difficulty breathing, chest discomfort or pain, feeling lightheaded, dizziness and sweating, a drop in blood pressure, gastrointestinal problems (e.g., nausea, vomiting, diarrhoea), headache, weakness, or loss of consciousness. Allergic reactions can potentially be life-threatening. After receiving the study drug, you will be monitored for any immediate signs or symptoms of an allergic reaction. If this happens, medication for treating allergic reactions will be available. The research team is trained to treat allergic reactions.

Serious allergic reactions, which may include anaphylaxis, could occur in participants taking the study drug. Anaphylaxis is a rare, life-threatening allergic reaction, which would be diagnosed by a doctor. The initial symptoms include severe difficulty breathing, a drop in blood pressure and a rash. Without immediate medical treatment this condition can be fatal. Please inform your doctor immediately if you think you may be having a reaction.

Injection site reactions

Injection of the study drug or placebo through a needle may cause local inflammation, redness, pain, itching, bruising, soreness, swelling, and possible bleeding or infection at the injection site. The study doctor and study personnel will monitor you closely for about 1 hour after you receive the study drug to check for signs and symptoms of an injection site reaction and for any other immediate side effects. The study doctor and study staff will continue to monitor you for any injection site reactions at Visits 2-4 (Days 3, 5 and 8).

Cardiac (heart) events:

As mentioned before, the study drug (AZD5156) is a combination of 2 monoclonal antibodies:

- AZD1061 [cilgavimab] and AZD3152

The study drug (AZD5156) has been developed to be similar to another product that is also a combination of 2 monoclonal antibodies. This other product is called EVUSHELD (or AZD7442), and is a combination of:

- AZD1061 [cilgavimab] and AZD8895

EVUSHELD is approved or authorised for early access/emergency use in over 40 countries worldwide for COVID-19. The study drug (AZD5156) includes 1 of the monoclonal antibody components (AZD1061 [cilgavimab]) of EVUSHELD. The study drug (AZD5156) is designed to potentially have a better ability to help fight different variants of the SARS-CoV-2 virus.

In a clinical trial studying EVUSHELD for the prevention of COVID-19, serious cardiac adverse events have happened but were not common. The serious cardiac events occurred in both people who did or did not receive EVUSHELD, and more people with risk factors for cardiac events (including a history of heart attack) who received EVUSHELD experienced serious cardiac events than people who did not receive EVUSHELD. It is not known if these events are related to EVUSHELD or underlying medical conditions. Contact your healthcare provider or get medical help right away if you get any symptoms of cardiac events, including pain, pressure, or discomfort in the chest, arms, neck, back, stomach or jaw, as well as shortness of breath, feeling tired or weak (fatigue), feeling sick (nausea), or swelling in your ankles or lower legs.

Other potential side effects

Your body may have an immune response (e.g., make antibodies) to this study drug (AZD5156). We will be testing for these antibodies during the study. It is possible that if you have an immune response to this study drug (AZD5156), you may develop joint pain and swelling, rash, fever, or inflammation of your heart, blood vessels, nerves, and/or kidneys. You may also experience low platelets (cells that help the blood to clot), which can lead to bleeding in the mouth and gums, bruising, nose bleeds, and pinpoint red spots on the skin. Participants who develop these types of reactions during the course of the trial are advised to seek immediate medical help in managing their medical condition. In studies with EVUSHELD, no study participants have developed any of these immune response symptoms.

The potential impact of the study drug (AZD5156) on other medicinal products including vaccines (including any COVID-19 vaccine) is not known. There is a possibility that

receiving the study drug (AZD5156) prior to COVID-19 vaccination may result in the vaccine being less effective for up to 9 months to 1 year or more or may cause a vaccine to have other currently unknown side effects.

It is possible that some participants could have side effects that we do not know about yet. There is always a risk involved in taking a new medication and you are encouraged to report anything that is troubling you.

Risks and discomforts of study procedures

Taking blood samples is done by inserting a small needle into your vein, and dosing the study drug (AZD5156) is done by an injection into a muscle. This can cause discomfort, pain, redness, itching, bruising, inflammation, and possible bleeding or infection at the site where the needle is inserted. Blood sample collections can also cause light-headedness and, rarely, fainting. This can be avoided by taking the blood sample while you are seated or lying down.

Having an ECG involves attaching small adhesive patches to your chest and limbs. The patches may feel cold when first applied. When the patches are removed, it may feel like a plaster being taken off.

The risks of SARS-CoV-2 rapid antigen and RT-PCR tests include temporary discomfort from when the swab is gently inserted into the back of your nose. You may experience a mild headache after the swab has been removed.

Please tell the study doctor or study personnel if you do not feel well or experience any discomfort during and/or after receiving the study drug or having a study procedure.

To read more about the other risks, turn to the additional risk information provided in

"Part IV." *Additional information for participants*".

6 Are there any other considerations or risks I need to know about?

If you take part in this study, it is very important that you follow all the instructions provided by the study doctor and study personnel:

- To participate in the study, you cannot have an active infection with hepatitis B or C, or a confirmed COVID-19 infection within 6 months before receiving the study drug (AZD5156) or placebo.

- You cannot take part in the study if you have a known or suspected immunodeficiency condition that you were born with or have developed, and you should not be receiving any medicines that suppress your immune system, including treatment with some glucocorticoid (steroid) therapies within 6 months before screening.
- You must not take part in any other clinical studies where you may be given another investigational medication. If you have any contact with a healthcare provider such as with a doctor or dentist, tell them that you are in this research study.
- You must not donate blood 30 days before receiving the study drug (AZD5156) or placebo or within 15 months after receiving the study drug or placebo.
- You must not receive a COVID-19 vaccine within 3 months before receiving the study drug (AZD5156) or placebo, or any other routine vaccine e.g., influenza within 14 days before or after being given the study drug (AZD5156) or placebo. You must also not receive a COVID-19 vaccine during the study until after the Day 29 assessments. Please talk to the study doctor if you are planning to receive any vaccines during the study.
- You must tell the study doctor if you experience any changes in your current medications or treatments.
- You must tell the study doctor immediately about symptoms you may experience, even if you think they are not related to the study drug.

Pregnancy, contraception, and breast-feeding

Because the effects of the study drug (AZD5156) on an unborn child or infant are not yet known, you must not get pregnant or breastfeed a child during the study. If you are a person able to get pregnant, you must use highly effective birth control for at least 4 weeks before receiving the study drug (AZD5156) or placebo and at least 6 months after receiving the study drug (AZD5156) or placebo. The study doctor can discuss acceptable birth control methods with you. Highly effective birth control methods include:

- Total sexual abstinence (for entire time period outlined above)
- A vasectomised partner
- Bilateral blockage (occlusion), ligation, or removal of fallopian tubes
- Intrauterine device (IUD) or other hormonal birth control methods (implant, injections, patch, ring, pill/oral contraceptive)

If you become pregnant, you must tell the study doctor immediately.

7 What are the possible benefits of taking part?

There is no certainty that you will have any benefit from the study drug.

The information the study **Sponsor** receives from this study may help prevent COVID-19 disease in the future.

It is not certain that you will directly benefit from the participation in the study. Your participation may, however, help patients in the future by improving the knowledge of diseases and improving medical care.

8 What happens if something changes while I am in the study, e.g., if new information is found?

Changes may happen in the study that could make you change your mind about continuing to take part. If something changes, we will tell you as soon as possible.

You can choose to leave the study at any time. For more details see "Section 13".

The study doctor can also choose to take you out of the study if they believe that it is best for you.

Your participation in the study also stops when the Sponsor, health authorities (such as the Medicines and Healthcare products Regulatory Agency (MHRA))), the ethics committee, or regulatory agencies decide that the study must be stopped.

9 What happens if I am harmed or injured during the study?

If there is an emergency, call your local emergency services right away or go to the accident and emergency department and contact your study doctor as soon as you can. All relevant contact details can be found in Part IV: "*Additional information for participants*".

If you become ill or are injured while you are in this research study, you must tell your study doctor straight away.

Injuries that have been caused by the study drug, tests, or procedures are called 'research injuries'. Injuries caused by your usual medical care or your condition are not research injuries.

Any compensation payable for any injury caused to you by taking part in this study will be in line with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). The Sponsor will not compensate you where the injury has happened because a

procedure has been carried out that is not in line with the study protocol or where the study doctor has acted negligently.

The Sponsor has taken out an insurance policy to cover compensation for any personal injury resulting from your taking the study drug, provided such personal injury is not due to fault or negligence of the study doctor or his team.

If you have private medical insurance, please check with your insurance company that taking part in this research study will not affect your policy.

The Sponsor may also compensate you in accordance with the law of the United Kingdom and by signing this form you do not give up any legal right you may have.

10 What will happen to my data and biosamples gathered in the study?

a. Which data and biosamples are collected?

In order to conduct the study, the **Study site** will have to collect and register information about your identity (such as your name, address, telephone number, and health insurance number) as well as data that is necessary to assess your health conditions such as your medical condition and medical history (this may include information from your physicians/ available in your medical records), your lifestyle, your demographics (age, sex, ethnic and racial background]). Data collected via smartphone or websites devices and apps will also be part of your coded data. Your answers to questionnaires using a smartphone or handheld device will also be collected. For more details about which data that is collected in the study, see further details at the end of this document in "Part IV: Additional information for participants".

In addition, the study site will collect biosamples from you (such as blood or body fluid). These will be analysed, and the data derived from the analysis will be part of your **coded data**.

b. What are my data and biosamples needed for?

Your data and biosamples are needed for the **Sponsor** to develop the drug, get permission to introduce and keep it on the market, monitor its safety and get it reimbursed by

governments i.e., throughout the drug development programme. Therefore, your data and biosamples will be used as planned in this study as well as within related research activities necessary for this drug development programme in order to:

- understand how the study drug(s) and similar drugs work in the body (i.e., evaluate the study drug mode of action, alone or in combination with other study drugs).
- better understand the studied disease and associated health problems,
- develop diagnostic tests for the disease,
- learn from past studies to plan new studies or improve scientific analysis methods,
- publish research results in scientific journals or use them for educational purposes,

*The **legal basis** for the use of your data for the above purpose is based on Sponsor's legal requirements that cover the conduct of clinical studies and public interest. (Further details can be found at the end of this document in Part IV: "Additional information for participants")*

c. Who can access my data and biosamples?

Your name and contact details will be accessible to the study doctor and the study team to conduct the study only at the study site. Non-medical personnel acting on behalf of the Sponsor and being bound by a duty of confidentiality as well as **Health authorities** and Ethics Committees may also be given access to this data only to verify that the study is carried out in compliance with legal and quality requirements.

The study site will share your data and biosamples with the Sponsor but only after they have been coded (which means that your name, contact details, or health insurance number have been replaced by a code. For more information about coding, see details at the end of this document in P*art IV: "Additional information for participants*").

The Sponsor may share your coded data and biosamples with its **Research partners** and **Service providers** for the purposes of the drug development programme.

In order to ensure proper conduct and accurate results of the study and to get permission to market the drug, the Sponsor will share your coded data with authorities and possibly with ethics committees. They may also be shared with scientific journals, so the study results can be reviewed by independent scientists and to ensure the accuracy of results.

In **none** of these cases your identity will be revealed.

Some of the above-mentioned persons may be located outside your country. If this other country does not have equivalent personal data protection standards than your country, appropriate **safeguards** (such as contracts and technical **security measures**) will be adopted to protect and maintain the confidentiality of your data and biosamples as further described at the end of the document in Part *IV: "Additional information for participants"*.

In case another organisation takes over development or commercialisation of the study drug, your coded data or biosamples may be transmitted to them. They will then have to protect your data and biosamples in the same way as described herein.

d. Who else may have access to my contact information and why?

Your name or contact details may be shared with **Service providers** in order to:

- Allow the service provider to reach out to you either during or after the study to ask your opinion on the provided Clinical Trial Transparency materials such as the Thank you card, Trial Result Summary, or Study Arm Postcard.
- *Allow **call-centres** to reach you for telephone interviews related to the study.*

The **Service providers** must keep your name or contact details private and will **NOT** share any information that can directly identify you with the Sponsor.

You must not take part in too many studies because it's not good for you. So to help research units, the Health Research Authority (HRA) keep a database of healthy volunteers and when they take part in studies, this is called TOPS. Site personnel will enter into the database: your National Insurance number (if you're a UK citizen), or your passport number and country of origin (if you're not a UK citizen) and the date of your last dose of study medicine. If you withdraw from the study before you receive any study medicine, the database will show that you never received a dose. Only personnel at your study centre and other medicines research units can use the database. We may call other units, or they may call us, to check your details. Data entered in TOPS is retained for the minimum period required and this is determined based on whether you receive a dose of the study medicine or not. If you receive a dose of the study medicine, this data will be retained in TOPS. If you do not receive a dose, your data will be retained in TOPS for two years. If we need to contact you about the study after you've finished it, but we can't because you've moved or lost contact with your GP, we might be able to trace you through the information in the database.

e. How long will my coded data and biosamples be kept?

The study site and the Sponsor are obliged to keep all study data and biosamples for a maximum of 15 years after the end of the study, unless there is a legal requirement for keeping them longer. Your coded data will then be deleted or anonymised, and your biosamples destroyed as soon as possible after the tests listed in Section 4 for the drug development program are completed unless you authorise the Sponsor to use them for future research (a tick-box available in Part *III: "Consent Form*" will allow you to make this choice). For more details about anonymising, see Part I Section 10g: *"What does anonymised data mean?" for internal Document Retention policy you may go to www.astrazenecapersonaldataretention.com*

f. What are my rights under data protection law?

You have the right to review which of your data are collected and being used; you can also ask for a copy of this data, ask for restriction of use of this data, or ask to have incorrect data rectified: In case you consent to Future Research (see Part II), you may also ask the study doctor to receive a copy of the data you have provided for the future research in a standardised electric format or to have them transmitted to another person of your choice.

To ensure the scientific integrity of the study, you will not be able to review some of the data or receive a copy of it until the study ends, because in this study, neither you nor the study doctor know if you are receiving the study drug or the placebo.

To exercise these **restricted rights**, please contact preferably the study doctor. *Contact details of the **Data Protection Officer** (**DPO**)* are provided in Part IV: Additional information for participants". If there are issues related to the use of your data, you have the right to file a complaint with your local data protection authority or with the sponsor's one..

g. What does anonymised data mean?

Health authorities as well as pharmaceutical companies believe that access to clinical studies data advances clinical science and medical knowledge and is in the best interest of patients and public health, provided that patient privacy is protected. Therefore, the Sponsor may generate and share internally or with other researchers an anonymised set of your data collected in the study (e.g., on www.clinicalstudydatarequest.com). This means your coded data will be stripped of your participant code as well as of any other information that could reasonably be used to identify you such as your date of birth.

11 What are the costs of taking part?

You will not be charged anything to participate in this study. Study drug, study visits, tests, and examinations are free of charge.

If applicable, you will be reimbursed for reasonable study-related expenses incurred due to your participation in the study (for example: travel). You will also receive an inconvenience fee for your taking part in this study. If you agree to take part in this research study, you will receive £50.00 per completed onsite study visit for your time and effort. Talk to the study doctor or study personnel if you have any questions about reimbursement.

12 How to find out more after the study?

Trial Result Summaries are a short and easy to understand summary of the results of this study. These will be added to www.trialsummaries.com within 1 year of the last study participants last site visit. You can visit www.trialsummaries.com website anytime to sign up to be notified via email when the trial results summary of your study is available or please let your study doctor know if you need a printed copy of the document. You will also receive information on the treatment you received in this study. This will be shared with you around the same time as the Trial Results Summary.

Technical Information about this research study will be posted on http://astrazenecaclinicaltrials.com, http://www.clinicaltrials.gov and https://www.clinicaltrialsregister.eu . These websites do not contain any information about you.

13 What will happen if I want to quit the study?

Your participation in the study is voluntary which means you can stop your participation at any time. If you want to stop taking the study drug, want to have a modified visit schedule or if you want to stop your participation, you should tell the study doctor.

If you stop participating in the study, the study doctor will stop the collection of your data, but your previously collected data and biosamples will be kept and used to guarantee the validity of the study and comply with regulatory requirements, as allowed by law. The study doctor will then invite you to have an end of study examination to check your wellbeing. If you don't show up at a planned visit, the study doctor will try to reach you.. This is important for study results. It is not mandatory but would be helpful for the study if you explain to your

study doctor why you wish to stop your participation, in particular if you have experienced any discomfort.

If you would like your data or biosamples not to be used after you quit the study, you must inform the study doctor and your remaining biosamples will be destroyed as soon as possible, but your coded data previously collected will be kept as required by clinical regulations.

14 Who can answer any questions I may have?

Remember, there are no stupid questions! Feel free to ask at ANY TIME! It is your right to be fully informed before deciding to take part in this study as well as in the future research proposed in Part II. You can contact the study doctor at any time at the address indicated in Part IV: *"Additional information for participants".*

15 Involvement of the General Practitioner (GP) /Family Doctor

Your study doctor will tell your general practitioner about you taking part in the study and may ask them for medical information about you.

Part II: FUTURE RESEARCH INFORMATION

In addition to participating in the clinical study, we would like to know if you would be willing that your coded data and leftover biosamples collected in Part I are used in future research projects with appropriate ethical approval.

You are free to consent to the use of your coded data and biosamples for future research. If you decide not to do so, you may still take part in the clinical study.

1 What is future research?

Future research is important to advance science and public health. At present, however, it is not possible to foresee all details of future **scientific research** projects. These future scientific research projects are beyond the scope of the clinical study and use of sample and data as outlined in Part I and may occur whilst the study is ongoing or after the study has finished.

Your coded data and biosamples may only be used for scientific health-related research to find new ways to detect, treat, prevent, or cure health problems.

They may also be used jointly with information from other sources outside typical clinical research settings, e.g. from public research databases. However, they will not be combined with other information in a way that could identify you. Your coded data and biosamples may also be anonymised for some of the future **scientific research**.

Some research projects may require the analysis of your genetic information. You can think of genetic information as a large instruction book that your body reads to understand how it should be built and function. All humans have the same instruction book in their body, but some words or letters may be different from one person to the other. Some of those differences have no effect on your health but others can influence the likelihood of developing a disease or affect how medicine to treat a disease will work. How will my coded data and biosamples for future research be handled?

All biosamples will be securely stored on behalf of the Sponsor for up to **15 years** and will be destroyed thereafter. Please note that the location of the biosamples may be outside ofthe UK and may change at the request of the Sponsor.The current designated biobank address GREENFIELD BIOREPOSITORY, Labcorp Drug Development Biorepository, Building 210, 671 South Meridian Road, Greenfield, Indiana, USA 46140

Any additional data generated from your biosamples will be stored as long as necessary for scientific research objectives and allowed by law and will be destroyed or anonymised thereafter. For more information on Sponsors internal Document Retention policy, you may go to www.astrazenecapersonaldataretention.com

2 May my coded data and biosamples be shared?

The Sponsor may share your coded data and biosamples with **Research partners** *or* ***deposit*** *them in* ***scientific databases*** as described at the end of the document in Part *IV: "Additional information for participants*". This may include researchers from universities, research hospitals, and companies.

Some of the above-mentioned recipients may be located outside your country. The data protection laws which apply in those countries may not be as stringent as the laws in your country. Nevertheless, appropriate safeguards and security measures will be taken in order to protect and maintain the confidentiality of your biosamples and coded data as described at the end of the document in Part IV*: "Additional information for participants".*

3 How will my privacy be protected?

Your coded data and biosamples will be subject to appropriate safeguards, as specified in Part *IV: "Additional information for participants*" and will only be used for the purpose of scientific health related research. They will not be used to contact you or to affect your care or any other decision affecting your life such as insurance rates or employment opportunities.

You have the same rights as the ones described in the section "*What are my rights under data protection law?".*

4 What if I want to withdraw from future research?

Your participation in future research is voluntary. You are entitled to withdraw your consent for future research at any time, without giving a reason and without a negative effect on your standard of medical care. If you wish to withdraw, please inform your study doctor or study personnel.

You may still continue to participate in the clinical study even if you choose to withdraw from future research.

If you withdraw from future research, your coded data and biosamples will not be used for future research and your samples will be destroyed as soon as possible. Your coded data (either copied from the clinical study database or newly generated) will also be destroyed unless this information is already included in analyses or used in scientific publications or if the coded data been anonymised, and therefore we can't identify your data or biosamples.

5 Results from Future Research?

We may have to study coded data and biosamples from many people over many years before we can know if the results of future research are meaningful.

Therefore, you should not expect to receive individual results from future research projects. We will not give any such data to your doctor and we will not put them in your medical record as they are not individual valid results.

You are free to consent to the use of your coded data and biosamples for FUTURE RESEARCH. If you agree, you can indicate this in the CONSENT FORM.

Part III: CONSENT FORM

Study title: Phase I/III Study of AZD5156 for the Prevention of COVID-19 in People with Conditions Causing Immune Impairment

Study protocol: D7000C00001

Study drug: AZD5156, referred throughout the document as the 'study drug'

Sponsor of the study: AstraZeneca AB

Investigator: Dr Paola Cicconi

Participant Name: _____

Participant Number: _____

I confirm that:

• The study doctor or study personnel delegated by the study doctor or the study personnel have explained the study has explained the study to me comprehensively.	*Participant initials*
• I have had the opportunity to discuss the study with the study doctor and all my questions were answered.	*Participant initials*
• I have had an adequate amount of time to consider the study.	*Participant initials*
• I have read and understood all the above information related to the study.	*Participant initials*
• I understand that I will receive a copy of this document once I have signed it.	*Participant initials*
• I understand that my decision to take part in the study is entirely voluntary. If I decide not to participate in the study or to stop my participation during the study, this will not affect my standard medical care.	*Participant initials*
• I have truthfully answered all questions about my medical history and will follow all rules listed in the document.	*Participant initials*

• The study doctor will notify your general practitioner (GP) of your participation in the study and may share relevant medical information with him/ her, if necessary, for managing your health and safety throughout.	*Participant initials*
I consent to take part in the clinical study and study procedures described herein. I understand that my participation also entails:	*Participant initials*
• My name and contact details being collected during the study as described to me, and accessed and reviewed by listed authorised people;	*Participant initials*
• My coded data being used by the Sponsor or by people or companies acting on its behalf or working with the Sponsor;	*Participant initials*
• My coded data being used by persons or organisations located in countries that do not have data protection rules equivalent to those of my country. I understand that the Sponsor monitors these uses and takes all possible measures to protect my privacy;	*Participant initials*
• My biosamples being collected and analysed as described.	*Participant initials*

I further understand that I can make a choice about the topics listed below and that by ticking "Yes" I do give consent and that by ticking "No" I do not give consent:

The use of my coded data and biosamples for future research, as described in Part II: Future Research Information", and where necessary for the research, possible analyses of my genetic information.	Yes ·	No ·	*Participant initials*

	STUDY PARTICIPANT
FULL NAME (capital letters)	
DATE (dd-Mmm-Year)	
SIGNATURE	

	Signature of person conducting the informed consent discussion
FULL NAME (capital letters)	
DATE (dd-Mmm-Year)	
SIGNATURE	

	Impartial witness (if applicable, for example participant is unable to read and write)
FULL NAME (capital letters)	
DATE (dd-Mmm-Year)	
SIGNATURE	

Part IV: ADDITIONAL INFORMATION FOR PARTICIPANTS

1 Contact details

Study Doctor Name: Dr Paola Cicconi

Study Doctor Phone: N/A

Volunteer Recruitment Co-ordinator, E-mail: vaccinetrials@ndm.ox.ac.uk, Tel: 01865 611424

Study Nurse Name: N/A

Study Nurse Phone: N/A

24 hours Emergency Contact Phone: details will be provided upon entry into the study

Address:
Jenner Vaccine Trials – NDM
Jenner Institute, Centre for Clinical Vaccinology and Tropical Medicine
University of Oxford
Churchill Hospital
Oxford, OX3 7LE

2 Detailed list of visits and test/procedures

Table 1: Schedule of assessments.

Assessment	Screening	Treatment and follow-up period											Early discontinuation visit
	Visit	1	2	3	4	5	6	7	8	9	10	11	
	Up to 14 days before Day 1	Day 1	Day 3	Day 5	Day 8	Day 15	Day 29 (Month 1)	Day 58 (Month 2)	Day 91 (Month 3)	Day 181 (Month 6)	Day 271 (Month 9)	Day 361 (Month 12)	If you leave the study early
Informed consent	X												
Check that the study is right for you	X	X[a]											
Personal information and medical history	X												
ECG	X												
Physical examination	X	X[a]	X	X	X								
Vital signs	X	X[a]	X	X	X								X
Urine pregnancy test[b]	X												
Review of current medications	X	Throughout ← →											
Review of symptoms and side effects	X	Throughout ← →											
Randomization		X[a]											
COVID-19 tests		X[a]											

Assessment	Screening	Treatment and follow-up period											Early discontinuation visit
	Visit	1	2	3	4	5	6	7	8	9	10	11	
	Up to 14 days before Day 1	Day 1	Day 3	Day 5	Day 8	Day 15	Day 29 (Month 1)	Day 58 (Month 2)	Day 91 (Month 3)	Day 181 (Month 6)	Day 271 (Month 9)	Day 361 (Month 12)	If you leave the study early
Blood samples	X	X[a]	X	X	X	X	X	X	X	X	X	X	X
Nasal lining fluid samples for PK		X[a]	X	X	X		X		X	X			
Receive study drug or placebo		X											
Monitoring of injection site reaction and immediate side effects[c]		X	X	X	X								

[a] Before receiving the study drug (AZD5156) or placebo. The study team will check vital signs again about 10-15 minutes after both injections are given.

[b] Only for people who are able to get pregnant. Must be negative to receive dose.

[c] The study team will monitor you closely for about 1 hour after receiving the study drug (AZD5156) or placebo to check for signs and symptoms of an injection site reaction and for any other immediate side effects. The study team will continue to monitor for any injection site reactions at Visits 2-4.

3 Detailed Study tests and procedures schedules

Table 2. List of study tests and procedures.

Assessment	Amount collected	Screening	Treatment and follow-up period											Early discontinuation visit
			Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	
		Up to 14 days before Day 1	Day 1	Day 3	Day 5	Day 8	Day 15	Day 29 (Month 1)	Day 58 (Month 2)	Day 91 (Month 3)	Day 181 (Month 6)	Day 271 (Month 9)	Day 361 (Month 12)	If you leave the study early
Urine pregnancy test[a]	*Amount required by local lab*	X												
Serum samples for routine health checks	*8 mL*	X[b]	X[c]			X	X	X						X
Serum sample to measure coagulation (how quickly your blood clots)	*5 mL*	X	X[c]			X	X	X						X
Serum SARS-CoV-2 serology	*2.5 mL*		X[c]					X		X	X		X	X
Serum sample for SARS-CoV-2 neutralizing antibodies	*6 mL*		X[c]	X	X	X	X	X	X	X	X	X	X	

Assessment	Amount collected	Screening	Treatment and follow-up period											Early discontinuation visit
			Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	
		Up to 14 days before Day 1	Day 1	Day 3	Day 5	Day 8	Day 15	Day 29 (Month 1)	Day 58 (Month 2)	Day 91 (Month 3)	Day 181 (Month 6)	Day 271 (Month 9)	Day 361 (Month 12)	If you leave the study early
Serum sample for antidrug antibodies	*6 mL*		X[c]					X		X	X	X	X	
Serum samples for PK	*6 mL*		X[c]	X	X	X	X	X	X	X	X	X	X	X
Nasal lining fluid sample for PK	*N/A*		X[c]	X	X	X		X		X	X			
Serum samples for exploratory analysis	*6 mL*		X[c]			X		X	X	X	X	X	X	

[a] Only for people who are able to get pregnant.

[b] If you are a woman under 50 years old and have not had your periods for 12 months, the blood sample will also be used to check the level of a hormone that helps control your period cycles.

[c] Before receiving the study drug (AZD5156) or placebo.

4 Complete List of Risks, Side Effects, and discomforts

- There is a possibility that the study drug (AZD5156) does not treat COVID-19 symptoms
- There is a possibility of no benefit at all if you receive placebo
- There is a possibility that receiving the study drug (AZD5156) prior to a vaccine (including any developed COVID-19 vaccine) may result in the vaccine being less effective up to 1 year or more or may cause a vaccine to have other currently unknown side effects.
- Unknown side effects
- Severe side effects
- Possible allergic reactions
    - Itching
    - Flushing
    - Rash including hives
    - Swelling (e.g., lips, face or throat)
    - Breathing problems
    - Chest discomfort or pain
    - Feeling lightheaded
    - Dizziness and sweating
    - Nausea
    - Vomiting
    - Diarrhoea
    - Headache
    - Weakness
    - Fainting or loss of consciousness
- Anaphylaxis – a life-threatening allergic reaction
    - Rash including hives

- Severe difficulty breathing (e.g., wheezing, shortness of breath)
- Drop in blood pressure

- Cardiac (heart) and thromboembolic (blood clot) events
  - Pain, pressure, or discomfort in the chest, arms, neck, back, stomach or jaw
  - Shortness of breath
  - Felling tired or weak (fatigue)
  - Feeling sick (nausea)
  - Swelling in the ankles or lower legs
- Antibody dependent enhanced disease
  - potential risk of more severe infections, especially viral ones.
- Redness, itching, tenderness, or a rash at the site of the study drug or placebo injection
- Pain or bruising at the site of the blood draw; occasional light-headedness, and fainting, which are relatively rare when having your blood drawn
- Discomfort or irritation as a result of the nasal or nasopharyngeal swab collection. This irritation or discomfort should resolve shortly after completion of this procedure.

5 Complete List of Personal Data collected

- Name
- Address
- Telephone Number
- Health Insurance Number
- Medical History data (from your doctor/medical records)
- Lifestyle data
- Demographics: age, date of birth, sex, ethnic and racial background
- Biosamples
- Answers to questionnaires

- Study related data collected via smartphone/website devices and apps
- Vital signs
- Overall health status

6 Glossary

Your biosamples	All your biological samples collected during this study and related to you, such as blood, urine, biopsy, as appropriate and listed in Section 4: "*What are the required tests and procedures?*". All your biosamples are coded which means that your name will not be associated with them.
Your coded data	All your data collected at the study site with your name and contact details have been replaced by a code. This is done by the study doctor who keeps the link between your name/ contact details and the code to ensure your safety and confidentiality. Coded information cannot identify you unless your study doctor provides your name or contact details, where allowed by applicable law. *Coded data is just another term for "pseudonymised data", which is used in the GDPR and UK Data Privacy law, which was preferred to render the document more readable.*
Sponsor details	Sponsor: *AstraZeneca AB, s-151 85 Södertälje, Sweden* For this study, your coded data will be managed by IQVIA, an international company headquartered in the US. The Sponsor has the overall responsibility for a clinical study.
Study site details	The place where the clinical study is taking place and where you will have to go for the planned visits.

Health authorities	Authorities who supervise the study, who approve the commercialisation of the drug or who receive the adverse events reporting, whether in your country or in other countries.
Research partners	Any organisation which collaborates with the Sponsor within the drug development programme or for future research.
Service providers	Any organisation bound to the Sponsor by a contract, which may conduct activities on behalf of the Sponsor under its strict instructions. This may include other researchers including so-called “contracted research organisations” (CROs) and IT companies hosting clinical data or providing IT services.
Safeguards	Appropriate safeguards will be implemented to protect coded data during and after the study and may include that: – Access to the coded data will be limited to specific individuals subject to confidentiality obligations (including the obligation to not attempt to re-identify individuals/decode the clinical data). – The coded data will be protected with security measures to avoid data alteration, loss and unauthorised accesses and further de-identification techniques may be applied. – A data protection impact assessment (DPIA) will apply to identify and mitigate privacy risks, if any, associated with each scientific research. – When required by applicable law, scientific research is subject to the approval of ethics committees. – The coded data will not be shared for direct marketing purposes or other purposes that are not legal duties or are not considered scientific research according to the applicable data protection legislation. In particular, it will not be used to make decisions about future services available to you, such as insurance.

Security measures: How is my data protected in other countries?	The processing of your data starts at the study site. Your data will then be transferred to several data experts to be verified and for results to be calculated. In addition to having your data and biosamples coded, your data is also protected by high standard technical security means such as strong access control and encryption. They are also protected legally by the following means: • Those countries are recognised by the UK as providing an equivalent level of data protection • :Within the sponsor group, your coded data are protected by **Binding Corporate Rules (BCR)**. You can find more information about the Sponsor's BCRs here: www.astrazenecabindingcorporaterules.com . • In all other cases, your coded data are protected by contractual arrangements, Codes of Conduct or certifications which set the rules for personal information protection to those available in the UK or other alternatives set forth in the law. You may obtain further information as well as a copy of these measures by asking your study doctor.
Restricted rights	Please note that the rights provided by the GDPR and UK Privacy Law to get data discarded (i.e., the right to be forgotten) as well as to get data transmitted in a standard electronic format (i.e., right of portability) do not apply to such studies.

DPO (Data Protection Officer) details	Study site DPO: **James Bristow** **information.compliance@admin.ox.ac.uk.** **University of Oxford** **University Offices** **Wellington Square** **Oxford** **OX1 2JD** If you wish to contact the DPO of the Sponsor, please be aware that your name is not known there. You would need to link your identity to your study participant number which may compromise the coding of your data. Sponsor DPO: AstraZeneca has assigned a data protection officer responsible for overseeing AstraZeneca's compliance with EU and UK data protection law, which you may contact at privacy@astrazeneca.com
Scientific research	Scientific research includes technological development and demonstration, fundamental research, applied research, and privately funded research as well as studies conducted in the public interest in the area of public health. This means that we may use the data to advance our understanding of how to make new medicines, medical devices, diagnostic products, tools and/or other therapies, to treat diseases. We may also use this data to improve the design and execution of future clinical studies, services and treatments, for outcome research activities, and to aid in pricing and reimbursement activities.

Deposit in scientific databases	To do more powerful research, it is helpful for researchers to share data by placing data into one or more scientific databases. Researchers can then study the data combined from several research projects and learn even more about health and disease. If you agree to take part in future research, some of your coded data might be placed into one or more scientific database. Researchers with an approved scientific research project may be able to see and use your coded data, along with that from many other people. Your name and other information that could directly identify you (such as address) will never be placed into such a scientific database. Researchers will always have a duty to protect your privacy and to keep your information confidential.
Binding Corporate Rules	*Internal rules of multinational groups which set the minimum rules for data protection to those available in European countries. You can find more information about AstraZeneca's BCRs here* http://www.astrazenecabindingcorporaterules.com/*]*
EEA (European Economic Area)	All European Union Member States as well as Norway, Liechtenstein, and Iceland.
Trial Result Summaries	Also referred to by the EU as Lay Language Summaries

Legal basis	You will participate in the clinical study only if you consent to it. If you do so, data related to your health and to the study drug must be collected and processed to evaluate the efficacy and the safety of the tested drug, in accordance with legal requirements from: • The clinical trials (i.e., the EU clinical trial regulation 536/2014 which requires the Sponsor to collect and analyse such data before they are submitted to health authorities), • The EU regulations on pharmacovigilance[3] which requires follow-up and reporting of adverse events to the health authorities, and • Any other applicable law including UK laws and statutory instruments relating to clinical trials The use of your coded data and biosamples for future research will only be possible if you provide optional consent for it.