PARTICIPANT INFORMATION SHEET AND CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19

PROTOCOL NO.: D8110C00001
IRB Protocol # 20202188

SPONSOR: AstraZeneca AB

INVESTIGATOR: Roger Bedimo, MS, MD, FACP
219 Sunset Avenue
Suite 116-A
Dallas, Texas 75208
United States

STUDY RELATED PHONE NUMBER(S): 972-807-7370 (24 hours)

Key Information

The purpose of this form is to give you information about the research study.

- Joining this research study is voluntary. It is your choice. Whether or not you take part is up to you. You can choose not to take part. You can decide to take part and later change your mind. Your decision will not be held against you.
- Our scientific questions are: does the study vaccine protect people from getting infected with a coronavirus called SARS-CoV-2 or getting COVID-19 illness? Is the study vaccine safe and how well is it tolerated?
- If you join, your participation in this study will last for about 2 years.
- If you join, we will ask you to have injections, blood draws, and swabs of the back of your nose.
- Here are the risks of taking part:
    - The most common risk is symptoms such as pain and tenderness where the study vaccine was injected, muscle aches or headaches after getting the study vaccine.
    - There are other, less serious risks. We will tell you more about them later in this consent form.
- We do not know if getting the study vaccine will benefit you in any way.

Purpose of the Subject Information and Consent Form

This Participant Information and Consent Form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study. If you sign it, you will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, and discomforts of the research study. You should take part in the study only if you want to do so. You can say 'no' or you can say 'yes' then change your mind. You should not sign this form if you have any questions that have not been answered to your satisfaction.

Your study doctor will be paid by the sponsor to conduct this research study.

Introduction

Coronaviruses are respiratory viruses and most often cause common-cold like symptoms every winter.

SARS-CoV-2 is a new coronavirus that first appeared in China in November 2019. It was associated with cases of pneumonia. This virus causes the illness that is now called COVID-19. People with COVID-19 may have symptoms ranging from mild

symptoms or severe illness, even death. Older adults and people with medical conditions like heart or lung disease or diabetes seem to be at higher risk for developing complications from COVID-19 illness.

As of October 18, 2020, there have been more than 40 million confirmed cases and >1.1 million deaths worldwide. As a response to the ongoing pandemic, AstraZeneca is developing an investigational vaccine, also known as AZD1222, for the prevention of COVID-19.

You are invited to take part in a clinical research study. To help you decide, you should understand the study and what you will have to do. To make an informed decision to take part you should know the purpose of the study, the procedures, the benefits and risks, the discomforts and the precautions taken. This process is called 'informed consent'. Please take the time to read the following information carefully and discuss it with others. Please ask your study doctor if there is anything that is not clear or if you would like more information.

It cannot be promised that the study will help you but in the future the information we get from this study may help improve the future vaccine for people with COVID-19.

If you decide that you want to take part, you will be asked to sign the informed consent form. You will be given a copy of the signed form to keep, and the original will stay at the study center.

Why am I being invited to take part in a research study?
We invite you to take part in a research study for a vaccine for COVID-19. This study is for people 18 years old and older.

What should I know about a research study?

- Someone will explain this research study to you.
- Please read all of the following information carefully.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can decide to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide. Do not sign unless you understand the information in it and have had your questions answered to your satisfaction.
- If you sign this form and decide to take part in this research study, keep a copy of the signed form for your records. It has information, including important names and telephone numbers, that you may wish to refer to.

Why is this research being done?
This study is being done to see if a vaccine that is being developed to prevent people from getting sick with COVID-19 is safe and effective and also to see how well it is tolerated.

How long will the research last and what will I need to do?
This study will last for 24 months.

If you take part, you will receive a shot of either the vaccine or a placebo twice: once on Day 1 and a booster shot on Day 29. A placebo will look like the vaccine but will not have any active vaccine in it. After the shots you will have blood drawn several times for the next 24 months to assess your immune system's (how your body fights off the virus) response.

If you get sick, you may also be asked to visit the site to have a test to see if you have COVID-19.

Is there any way being in this study could be bad for me?
This vaccine is 'investigational'. This means that the safety and effectiveness are still being looked at. It is not approved for use in the U.S. by the Food and Drug Administration (FDA). There is a chance you could have a side effect that is severe or that has not been seen before.

Currently, there is no completed clinical study of the vaccine. Over 10,000 people have received the vaccine so far. If you have severe side effects from the vaccine, the study doctor may ask you not to get a second dose of vaccine or placebo.

There is also a potential risk that if you get the vaccine in the study and then become ill with COVID-19 that your illness could be worse than if you hadn't received the vaccine.

More detailed information about the risks of this study can be found under the **"What could be the side effects of the vaccine?"** section.

Will being in this study help me?
We cannot promise any direct benefits to you or others from your taking part in this research. However, possible benefits include being protected from getting sick with COVID-19. As we don't know if this will happen you should continue to take precautions to avoid getting infected with the virus. Your participation will provide information about the vaccine. This might benefit others in the future.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to take part or not to take part. If you decide not to take part in this study, it will not affect your ability to receive medical care. Your decision to not participate or to withdraw later will not result in any penalty or loss of benefits to which you are otherwise entitled.

Study details

What will happen during this study?
This study is a vaccine study. It involves both vaccine and a placebo (which looks like the vaccine but does not contain any actual vaccine). The vaccine is based on a weakened version of a common cold (adenovirus) virus that causes infections in chimpanzees. The adenovirus vaccine has been changed so that it can't replicate

inside your body and so that it presents part of the COVID-19 virus to the body so that an immune response can be made to it. The vaccine can give you side effects that will be explained below. The placebo is made up of salt water.

Both the vaccine and placebo will be given as an injection (a 'shot'). About 40,000 people at approximately 300 sites globally will be in this study. People who are approved to be in the study will be put into two groups at a 2:1 ratio. This means that approximately 27,000 people will receive the vaccine and approximately 13,000 people will receive placebo. You have 2 out of 3 chance (like drawing straws) of receiving the vaccine. A computer program will be used to determine if you get the vaccine or placebo. Whether you get the vaccine or the placebo is random, like flipping a coin.

In addition, the study will have two main parts: a main study and a substudy. Three thousand people will take part in a sub-study in the United States (U.S.) that will measure the body's ability to develop the desired immune response and to see if there are side effects such as fever and swelling at the injection site. The remaining people will be enrolled in the main study. People in the sub-study will be asked how they are feeling for 7 days following their shot. They will also have their blood drawn. All participants will be followed to see if the vaccine prevents them from getting sick with the virus.

This study is "double-blind". This means that neither you nor the study doctor/study staff will know if you are receiving the vaccine. However, if you have a medical emergency the study doctor will be able to find out if you are receiving the vaccine or placebo.

You will also have the choice to provide one extra blood sample to look at your DNA. If you consent on Day 1, one blood sample (approximately 1 teaspoon) would be taken. The risks of giving this blood sample are the same as the risks explained in this informed consent form. You can still take part in this research study, even if you do not agree to donate this extra sample. The purpose of this research is described in a separate Optional Genetic Research Information and Informed Consent Form Addendum.

If you want to join this study, we will screen you to see if you are eligible. Screening will include:

- signing the informed consent form,
- you will tell us about any current medications you are taking,
- a general physical examination, and
- a pregnancy test for women who are able to have children

After you complete these activities, we will be able to tell if you are eligible to be in the study, and whether you will be in the main study or the sub-study.

You will be contacted every week for the first year of the study by telephone or email or text to see if you have any symptoms of being sick with COVID-19. If you show symptoms of being sick with COVID-19 for longer than a day, you will be asked to

call the study site and may be tested for the virus. If you do have the virus, you will be contacted regularly to see how you are doing.

The screening and assessment schedules are shown on the table below:

Table 1. Screening Procedures

Study Period	**Screening**
Procedure / Study Day	**Day -14 to Day -1**
Written informed consents/ assignment of participant number for blinding	X
Review medical history	X
Physical examination including height, weight, vital signs and oxygen levels	X
Pregnancy test (urine or blood test) [a]	X
Assessment of side effects	X
Current medications and supplements	X

[a] Female participants only. Pregnancy test must be negative prior to dosing

Table 2. Schedule of Activities: Treatment and Follow-up Period – Main Study (Excluding Substudy Participants)

Procedure	**Treatment and Follow-up Period**								
Day	**1**	**8 [a]**	**29**	**36 [a]**	**57**	**90**	**180**	**360**	**730**
Window (days)	**NA**	**± 3**	**-3 to +7**	**± 3**	**± 3**	**± 5**	**± 10**	**± 15**	**± 30**
Medical history	X								
Brief physical exam	X								
Vital signs	X								
Pregnancy test – urine or blood [b]	X (predose)		X (predose)						
Review your current medications	X	X	X	X	X				
Blood sample for Genetic Research (optional)	X (predose)								
Vaccine administration	X		X						
Tests to see if the vaccine is effective									
Weekly telephone/email/text contacts - asking about COVID-19 symptoms [c]	←							→	
Nasal swab	X (predose)								
Blood tests	X (predose)		X (predose)		X	X	X	X	X
Immune system assessments									
Blood test to check immune system response	X (predose)		X (predose)		X				
Safety assessments									
Review any side effects	X	X	X	X	X	X	X	X	X
Telephone contact for safety monitoring		X		X					

a. Not a study site visit; participants will be contacted by telephone for safety monitoring
b. If the urine test is positive, or does not confirm whether you are pregnant then a blood test will be done.
c. Weekly contact with participants to remind them to contact the study site for testing if they have symptoms of COVID-19.

Table 3. Schedule of Activities: Treatment and Follow-up Period-Substudy

Procedure	Treatment and Follow-up Period										
Day	**1**	**8** [a]	**15**	**29**	**36** [a]	**43**	**57**	**90**	**180**	**360**	**730**
Window (days)	**NA**	**± 3**	**± 1**	**-3 to +7**	**± 3**	**± 3**	**± 3**	**± 5**	**± 10**	**± 15**	**± 30**
Medical history	X										
Brief physical exam	X										
Vital signs	X										
Pregnancy test – urine or blood test [b]	X (predose)			X (predose)							
Review your current medications	X	X	X	X	X	X	X				
Blood sample for Genetic Research (optional)	X (predose)										
Vaccine administration	X			X							
Weekly telephone/email/text contacts - asking about COVID-19 symptoms [c]	◄———	———	———	———	———	———	———	———	———	———►	
Nasal swab	X (predose)										
Blood tests	X (predose)		X	X (predose)		X	X	X	X	X	X
Blood samples for COVID-19 antibodies	X (predose)		X	X (predose)		X	X		X	X	X
Blood sample for seasonal CoV	X (predose)			X (predose)			X		X	X	
Nasal swab	X (predose)		X	X (predose)		X	X		X	X	
Side effects (recorded daily by the participant in eDiary)	X (through Day 8)			X (through Day 36)							
Side effects (by staff interview)	X	X	X	X	X	X	X	X	X	X	X
Telephone contact for safety monitoring		X			X						

a. Not a study site visit; participants will be contacted by telephone for safety monitoring
b. If the urine test is positive or does not confirm whether you are pregnant then a blood test will be done.
c. Weekly contact with participants to remind them to contact the study site for testing if they have symptoms of COVID-19.

<u>Participants who have COVID-19 symptoms (fever, shortness of breath, difficulty breathing) for any amount of time, as well as participants who have:</u>

- chills,
- cough,
- fatigue,
- muscle aches,

- body aches,
- headache,
- new loss of the sense of taste or smell,
- sore throat,
- congestion,
- runny nose,
- nausea,
- vomiting and/or diarrhea (for two or more days)

will have the following schedule:

Table 4. Schedule of Activities: Illness Visits (Participants with Symptoms)

Procedure [a]	Site Visit	Home Collection by Participant				Site Visit for COVID-19 Positive Participants Only		
Day	**1**	**3**	**5**	**8**	**11**	**14**	**21**	**28**
Window (days)	**NA**	**± 1**	**± 1**	**± 2**	**± 2**	**± 2**	**± 2**	**± 2**
Medical history	X					X	X	X
Brief physical examination	X					X	X	X
Vital signs (including oxygen levels)	X					X	X	X
Review of current medication	←	—	—	—	—	—	—	→
Digital health device	←	—	—	—	—	—	—	→
Symptoms associated with COVID-19 (recorded daily by participant in e-Diary)	←	—	—	—	—	—	—	→
COVID-19 virus assessments								
Nasal swab for COVID-19 (local laboratory)	X							
COVID-19 (to confirm virus type) (central laboratory)	X					X	X	X
Respiratory panel	X							
Saliva sample	X	X	X	X	X	X	X	X
Immune system assessments								
Nasal swab for COVID-19	X					X		X
Blood test for anti-bodies and exploratory tests	X					X		X
Safety assessments								
Side effects	←	—	—	—	—	—	—	→
Telephone contact		X		X				

[a] Only participants who test positive for COVID 19 will continue with the illness visits, including any home saliva-collection tasks. Participants who test negative for COVID 19 will be instructed to stop all illness visit assessments and return the armband digital health device and e-Diary using prepaid envelopes.

What will you have to do?
You will have to:

- go to the study visits,
- follow the instructions the study doctor/study staff give you
- get the shots
- You will have several blood draws during this study. The total amount of blood drawn is about 82 teaspoons.

- You must not take part in any other studies or donate blood while you are taking part in this study.
- Once you finish the study or if you leave early, it is important for you to speak with the study doctor for follow-up care. Exit tests may be needed.
- All routine vaccinations are not allowed (except flu) less than 30 days after the last dose of vaccine. Please talk to your study doctor before you have any other vaccinations.

Armband for vital signs:

- If you agree to be in this study and start having symptoms of COVID-19, you will be asked to wear a device (an armband from Current Health) when you come to the study site for your first illness visit. You will be trained by study staff on the use of the device. It should be worn continuously each day until instructed by study staff to stop.

The device keeps track of your vital signs, such as:

- how fast you are breathing,
- how your heart is beating,
- your temperature,
- how much oxygen in your blood, and
- how much you move.

This information will be wirelessly sent to your care team for them to review. The data from the armband device will be monitored and you may be called by either a monitoring team or the site staff if it looks like the device is not sending out information properly or if there is concern that your vital signs are too high or too low. If there are issues with the device, you will need to call the study center so that study staff can help to fix the problem.

eDiary:

- People in the substudy and those having illness visits will keep a record of their symptoms in an electronic Diary (eDiary). If you do not have a cell phone or a computer with internet access, or if your cell phone will not support the app for the eDiary, the site may lend you an electronic device that you can use. It will look like a cell phone but its only purpose is so you can keep track of your symptoms. If you are not sure how to use the device, the study team will give you instructions. You can have someone fill out the eDiary for you or have someone help you fill out the eDiary. If someone else fills out the eDiary for you or helps you fill it out, they will be able to see your private health information. The information you enter into the eDiary will be sent automatically to your site care team. The site may contact you if any of your symptoms become severe.

Saliva samples:

- If you start having symptoms of COVID-19, you will be asked to provide up to 8 saliva samples, so that we can see if COVID-19 is in saliva. The first saliva collection will be performed at the study site by the study staff. During this first

"illness" visit, you will receive a saliva kit and be shown how to use it. You will collect 4 samples at home. You may be contacted at home with a video call so that someone can help explain how to collect the saliva sample properly. If you don't want to be video-called, you can call the dedicated phone line for support and follow the paper instructions. You will bring the saliva samples back to your next site visit if you are positive with COVID-19. All instructions will be provided to you in the participant training material during the first "illness" visit. You will also have 3 more saliva samples collected at the study site.

- As part of the COVID-19 testing some your personal information will be collected including your name, address and telephone number. This information is collected because by US law positive test results have to be reported to relevant state or local public health agencies. If your test is positive for COVID-19 you may get a phone call from your state or local public health departments to allow them to efficiently track the virus.

What alternative treatments are available?
Taking part in this study is your choice. You may choose to take part or not to take part. Right now, there are no other vaccines or other drugs that have been shown to prevent people from getting sick with COVID-19.

What are the possible disadvantages or risks of taking part?
Getting this vaccine may also involve risks to your health that we don't know about right now.

What could be the side effects of the vaccine?
If you suffer any of these side effects (or any others not listed) or you think you are experiencing a side effect, during this study, please tell your study doctor immediately (see 'Who should you contact with questions?').

Over 10,000 people have received at least 1 dose of the vaccine to date. Approximatley 4800 people have received a second dose.

Reactions to the vaccination:
Following vaccination you may feel some discomfort on your arm where you get the shot. This usually gets better within 5 minutes. Later, you might feel pain when you move your arm, but this should go away in a few days. Pain and tenderness where people received the shot were the most common side effects and these were usually mild.

General reactions:
Chills, fevers, headache, feeling tired, nausea and body aches were common overall side effects. These side effects were usually mild or moderate in nature though a small number of them were also considered severe. Most of reported side effects appeared within 24-48 hours after the shot. These usually went away within 1-7 days.

People who have received the vaccine have also had decreases in their blood counts; in the cells that help fight infections and in the cells that help form blood

clots. These decreases have resolved within a few days and have not been associated with any other side effects so far.

Any side effects or other health issues that happen to you during the study will be followed up by the study doctor.

Serious Reactions:
With any vaccination there is a risk of rare serious side effects, such as an allergic reaction.

The vaccine is not familiar to your body. Your body's immune system may react to this. Strong allergic reactions to vaccines (anaphylaxis) are rare and require treatment right away but can result in death. These reactions can happen hours or days after the injection. Symptoms may include:

- swelling of the lips,
- difficulty breathing,
- fainting,
- dizziness,
- wheezing when you breathe,
- fast pulse,
- sweating,
- hives or rash
- low blood pressure
- diarrhea

If this happens, medication for treating allergic reactions will be available. The research team is trained to treat allergic reactions.

Several types of vasculitis (inflammation of blood vessels) have been reported with use of various vaccines. Vasculitis causes changes in the blood vessel walls which can restrict blood flow, resulting in organ and tissue damage.
If you develop a rash of bluish purple or red spots, bumps or sores, numbness or weakness in a hand or foot,you should promptly notify your healthcare provider and the study team.

Neurological disorders (demyelinating disease) that affect the peripheral and central nervous system (CNS) may occur. They may cause substantial disability, and some can be fatal if not treated promptly.

In another Phase 3 study of the AZD1222 vaccine, two participants who received the AZD1222 vaccine were initially diagnosed with a serious condition called transverse myelitis, or inflammation of the spinal cord. Symptoms of transverse myelitis include weakness, numbness, tingling, trouble walking, and bowel/bladder issues.

One participant (who received AZD1222) was found to have pre-existing multiple sclerosis which had not been diagnosed before. Multiple sclerosis is a known cause of transverse myelitis. However, it is unknown whether the vaccine contributed to

the transverse myelitis event. The second participant, who also received AZD1222, did not have any significant past medical history but developed serious nervous system symptoms and had spinal cord findings consistent with transverse myelitis. An evaluation of this participant's condition, including to identify its cause, is ongoing. A third participant, who did not receive AZD1222, but did receive the control vaccine (an approved vaccine to prevent people from getting infected with a kind of bacteria called meningococcus), also developed transverse myelitis. An investigation into the exact cause of this condition is ongoing for this patient. It is not known whether either AZD1222 or the control vaccine being studied caused these events.

If you develop neurologic symptoms like abnormal sensations, muscle weakness or blurred vision, you should promptly notify your healthcare provider and the study team.

There is also a possible risk that if you get the vaccine in the study and then become ill with COVID-19 that your illness could be worse than if you had not received the vaccine.

In the past, experimental vaccines were studied against another coronavirus (called SARS), which also infects the lungs. In some cases, animals that received certain types of SARS vaccines appeared to develop *more severe* lung inflammation when they were later infected with SARS compared with animals that had not been vaccinated.

An experimental vaccine tested in the 1960s for a different respiratory virus (RSV) resulted in some infants developing *more severe* lung inflammation when they were later infected with the virus. Two of the infants died. Other versions of RSV vaccines have not caused these severe reactions.

In other studies, animals that received two shots of this vaccine (AZD1222) and then were infected with COVID-19 had the virus in the intestinal tract but were not sicker than animals that received one shot. It is possible that people who get two shots of this vaccine could also have the COVID-19 virus present in their intestinal tract if they get infected for a longer period of time than people who get infected but didn't get the vaccine. As a result, you should practice good hygiene like hand washing, to avoid spreading the virus to other people.

You should get medical help and contact the study doctor or staff if you have any of these or any other side effects during the study.

What are the side effects of the study procedures?
Some of the study procedures may create some discomforts. You may experience none, some or all of those listed below:

- As with any injection (shot), the vaccine injection in your muscle may cause the area to become sore or tender, red, bruised, itchy and swollen. These effects usually get better without treatment.

Blood samples:

- Drawing blood may cause slight pain and bruising at the site where the needle enters. Rarely, people feel light-headed or even faint.
- You could have a reaction at the sites where your blood is collected. This could include redness, bruising, swelling, bleeding, or pain.
- The volume of blood drawn over the study period should not affect the health of volunteers.

You may experience the following side effects while wearing the digital health device:

- A very minor skin irritation under the wearable device: This is restricted to minor skin redness that resolves shortly after removal of the device
- Minor discomfort during sleeping
- Ecchymosis (a discoloration of the skin, typically caused by bruising) of the upper arm near to the wearable device in patients who are taking blood thinners.

Nasal and oral swabs:

- You may feel some discomfort (pressure) from having a sample taken with a swab in your nose and/or mouth.

Pregnancy Risks:
We do not know if the vaccine may cause harm to an unborn baby. Women taking part in this study must have a negative pregnancy test during Day 1 and Day 29. During this study, participants must use highly-effective forms of birth control for 28 days prior to Day 1. They also must agree to continue using a highly effective form of birth control for 60 days after their last dose (injection) of the vaccine on Day 29.

Inconsistent abstinence, the rhythm method, and withdrawal are NOT acceptable methods of preventing pregnancy.

Highly effective forms of birth control include:

Barrier methods: Intrauterine devices (IUD), having both ‘tubes tied”, not having sex, or having a partner who has had a vasectomy.

Hormonal methods: Birth control pills, injections and patches that are progestogen only or combine estrogen and progestogen.

If you do become pregnant during the study, we will contact you to see what the outcome of your pregnancy was.

Expenses
There will be no cost to you for taking part in this study. You will be provided with all vaccines, examinations and medical care related to the study at no cost to you.

Payment

Main Study - Visit Type	Amount Per Completed Visit	Number of Visits
Vaccination Visits	$100.00	2
In-Clinic Visits	$50.00	7 (+1 if screening visit is done separately)
Safety Calls	$15.00	2 (Day 8 and 36)
Weekly Symptom Check	$5.00	52
Side Effect Interview	$15.00	9

Sub Study Visit Type	Amount Per Completed Visit	Number of Visits
In-Clinic Visit with Blood Draws	$50.00	2
eDiary Entries	$5.00	14
Nasal Swabs	$15.00	7
Side Effects Interviews	$15.00	2

The total amount you will receive for completing all visits will be $975.00 for the main study, which includes the possibility of 2 illness visits. If you are participating in the sub-study, you will receive an additional $305 for those completed visits.

This money is meant to help pay for things like travel costs, child care, missed hours from work. You will receive the money in equal amounts after each completed visit. If you discontinue early from the study, you will a pro-rated (partial) reimbursement amount based on how many study visits you completed.

What happens when the research study stops?
If the study is stopped, you will be told and your study doctor will make plans for your care, if needed.

You can be withdrawn from the study at any point if the study doctor decides that this is best for your health or you are not following study procedures

If you have a reaction after the injection of vaccine, your participation may be stopped by the study doctor or sponsor without your consent.

After the study is completed, persons who received the placebo may be offered the opportunity to receive the vaccine if there are doses available. The study doctor will consider the best option for your care.

Compensation for study related injury
If there is an emergency, call 911 right away or go to the emergency room and contact your study doctor as soon as you can.

If you become ill or are injured while you are in this research study, you must tell your study doctor straight away. The study doctor will provide medical treatment or refer you for treatment.

Injuries that have been caused by the vaccine, tests or procedures are called ‘research ‘injuries’. Injuries caused by your usual medical care are not research injuries.

The Sponsor has an insurance policy to cover the costs of research injuries as long as you have followed your study doctor´s instructions. Sponsor will pay the costs of medical treatment for research injuries, provided that the costs are reasonable, and you did not cause the injury yourself.

The U.S. National Institutes of Health (NIH) does not have a way to provide direct compensation for a research related injury.

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

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

Due to the coronavirus public health crisis, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19-related clinical study.

If the order applies, it limits your right to sue the researchers, healthcare providers, any Sponsor or manufacturer or distributor involved with the Study. You may be prevented from making claims for injuries that have a causal relationship with the use of the investigational product in this Study, including, but not limited to, claims for death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption loss.

However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. If funds are appropriated by Congress, compensation for injuries may be available to you under this Countermeasures Injury Compensation Program. To find out more about the Countermeasures Injury Compensation Program” go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

What if new information about the vaccine becomes available?
You will be told if any important new information becomes available that may affect your willingness to continue taking part in the study. If this happens, your study doctor will contact you as soon as possible, and will discuss whether you should continue in the study. If you decide not to continue, your study doctor will make arrangements for your care to continue if needed. If you decide to continue in the study, you may be asked to sign a new consent form.

Also, if new information becomes available, your study doctor may stop your participation without your consent. If this happens, the reasons will be explained and arrangements made for your care, if you need follow-care.

What will happen if you don't want to continue with the study?
You can stop taking part in the study at any time without giving any reason. This will not affect your future treatment or your relationship with your study doctor. If you wish to stop taking part, please tell the study doctor immediately. You may be asked to return to the study center for an end-of-study assessment. You may also be asked for permission to be contacted at a later date by your study doctor to collect information about any symptoms you might have. You may also be asked for your permission to have a relative contacted, to have your doctor contacted or for information from your medical records to be shared.

Your study doctor or the sponsor may withdraw you from the study without your consent if the study is not helping you, if you do not follow the study directions, or if you have a serious side effect related to the vaccine. The sponsor, FDA, US Government Office for Human Research Protections or the Institutional Review Board (IRB) may also stop the study at any time for any reason. If your study doctor thinks it is in your best interest to withdraw you from the study, or if the study is stopped for any other reason, he/she will explain the reasons and arrange for your care to continue.

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

Which data and biosamples are collected?
In order to conduct the study, the Study site and some COVID-19 testing vendors (including labs) 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 life style, your demographics (age, gender, ethnic and racial background). COVID-19 testing vendors will need to collect these data from you to be compliant to the CARES Act Section 18115 Federal law (e.g. in order to do contact tracing if you test positive for COVID-19).

In addition, the study site will collect biosamples from you (such as blood samples) and these samples will be labeled with a code and not your name or other information that could identify you. These will be analysed and the data from the analysis will be part of your coded data. The key to the code will be kept by the study staff at the site but will not be shared with the Sponsor or other researchers who may use these samples.

What are my data and biosamples needed for?
Your data and biosamples are needed for the Sponsor to develop the vaccine, get permission to introduce and keep it on the market, monitor its safety and get it reimbursed by governments i.e., throughout the vaccine development program. Therefore, they will be used as planned in this study as well as within related research activities necessary for this vaccine development program in order to:

- understand how the vaccine works in the body,
- better understand the studied disease and associated health problems,
- 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.

Your biosamples will not be used for commercial profit.

Who can access my data and biosamples?
Only at the study site, your name and contact details will be accessible to the study doctor and the study team to conduct the study. Non-medical personnel acting on behalf of the sponsor and being bound by a duty of confidentiality as well as Health authorities, such as the US Food and Drug Administration (FDA) and the Institutional Review Board (IRB) as well as people from the US National Institutes of Health, the Coronavirus Prevention Network and the United States Biomedical Advanced Research and Development Agency 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 and vendors, but only after they have been coded (which means that your name, contact details or health insurance number, have been replaced by a code). Health authorities (such as the FDA) and people helping AstraZeneca to run the study, including members of the AstraZeneca group of companies, contractors, sub-contractors and any company that AstraZeneca goes into business with, or sells all or part of its business to, will be allowed to see your personal information but they will not know who you are unless they are study inspectors.

The sponsor may share your coded data and biosamples with its Research partners and Service providers for the purposes of the vaccine development program.

In order to ensure proper conduct and accurate results of the study and to get permission to market the vaccine, the sponsor will share your coded data with health authorities (such as the FDA) and possibly with the IRB. 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. Researchers from for example AstraZeneca, other health related companies, and universities might ask to use information from this study, including your information and samples for other medical, healthcare or scientific related research. The researchers may combine the results from this study with results from other studies. If AstraZeneca shares your information AstraZeneca will make sure that they cannot find out who you are and that such research is in line with this document. The use of your coded personal information for these scientific research purposes is based on your agreement. If a vaccine is marketed for commercial use, you will not share in any profits.

Your medical files may be reviewed at the study center (or study doctor’s office) or remotely (outside of the study center) in order to confirm that the information collected from you was recorded correctly and to verify that the study procedures were performed properly.

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

Some of the above-mentioned persons may be located outside the United States (US). If this other country does not have equivalent personal data protection standards than the US, appropriate Safeguards (such as contracts and technical Security measures) will be adopted to protect and maintain the confidentiality of your data and biosamples. In case another organization takes over development or commercialisation of the vaccine, 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. You can ask your study doctor to see the information that has been collected about you. If you think any of it is wrong, you can ask your study doctor in writing if it can be changed or removed, in accordance with your country's laws. You can also ask that we restrict the use of your personal information. If you change your mind about taking part, we cannot remove the personal information that was collected for this research study before you stopped.

We have a Certificate of Confidentiality from the US government to help protect your privacy. With the certificate, we do not have to release information about you to someone who is not connected to the study, such as the courts or police. Sometimes we can't use the certificate. Since the US National Institutes of Health funds this research, we cannot withhold information from it.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who else may have access to my contact information and why?
Your name or contact details may be shared with service providers (such as Vault Health and Current Health Real Time Monitoring), 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.
- Reimburse you for your time, effort and certain expenses related to your participation.
- Allow call-centers to reach you for telephone interviews related to the study.
- Set up and manage your accounts for any apps or other devises that are used in the study.
- Collect information on whether you are alive or not ("vital status information").

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.

How long will my coded data and biosamples be kept?
The study site and the sponsor are obliged to keep all study data for 25 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 returned to your study doctor or destroyed as soon as possible after the tests for the vaccine

development program are completed unless you authorise the sponsor to use them for future research (a tick box in the Consent page will allow you to make this choice).

All biosamples will be securely stored on behalf of the sponsor at COVANCE CENTRAL LABORATORY SERVICES and then may be transferred at the end of the study to an AstraZeneca-assigned biobank for long term storage for up to 15 years.

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.

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 vaccine or the placebo.

To exercise these restricted rights, please contact preferably the study doctor. Contact details of the Data Protection Officer (DPO) are: Sponsor Data Protection Officer privacy@astrazeneca.com or c/o the Chief Privacy Officer, AstraZeneca, Academy House, 136 Hills Road, Cambridge CB2 8PA, England". 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 DPO.

What does anonymised data mean?
Health authorities (such as the FDA) 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 Patient code as well as of any other information that could reasonably be used to identify you such as your date of birth.

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. This website does not contain any information about you.

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 are used in future research projects with appropriate ethical review.

You are being asked 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.

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 the use of samples and data as outlined above 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 anonymized for some of the future scientific research.

How will my coded data and biosamples for future research be handled?
All biosamples will be securely stored on behalf of the sponsor at an AZ-assigned biobank for up to 15 years. Please note that the location of the biosamples may change at the request of the sponsor.

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.

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. Research partners 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 in this section.

How will my privacy be protected?
Your coded data and biosamples will be participant to appropriate safeguards 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 your rights under data protection law?".*

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. There will not be any penalty or loss of benefits to which you are otherwise entitled if you decide not to take part or if you withdraw early.

You may 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 anonymized and therefore we can't identify your data or biosamples.

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.

Authorization to use and disclose protected health information for research:
The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your protected health information (PHI). The document you are reading, called an "Authorization," explains how your PHI will be used and disclosed (shared) for purposes of the research study and describes your rights with respect to such information.

In working with the sponsor, your study doctor, will use and share protected health information about you. This is information about your health that also includes your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam and laboratory test results, and certain health information indicating or relating to a particular condition. Some of these tests may have been done as part of your regular care. The study doctor will use this information about you to complete this research.

In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the sponsor. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours. The sponsor and its representatives (which include companies that are contracted by the sponsor to perform services for the study) may review or copy your protected health information at the study site. Regulatory authorities (such as the FDA) and the Institutional Review Board (IRB) may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

By signing this Consent form, you allow the study doctor and his/her team to use your protected health information to carry out and evaluate this study. You also allow the study doctor to share your protected health information with:

- The sponsor and its representatives
- The Institutional Review Board (IRB) that reviewed this research. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects.
- The U.S. Food and Drug Administration (FDA)
- Other local, US and international regulatory entities including people from the US National Institutes of Health, the Coronavirus Prevention Network and the United States Biomedical Advanced Research and Development Agency
- Laboratories for testing biospecimens
- Vendors for this study working for or with the sponsor such as Current Health and Vault Health.

Your protected health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your health information confidential.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Consent form you agree that you might not be able to review or receive your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization to Use and Disclose Protected Health Information for Research at any time, but you must notify the study doctor in writing. If you withdraw your permission, you will not be able to continue being in the research study.

If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns a side effect related to the study. If a side effect occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about a side effect related to the study, will be sent to the study sponsor.

If you withdraw from the study but do not withdraw your Authorization, new protected health information may be collected until this study ends.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin this authorization will expire on 31Dec2070.

There is no expiration of this authorization except for research conducted in the states listed above.

You do not have to sign this Authorization, but if you do not, you cannot participate in this research study or receive study-related treatment. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

What will happen to the results of this clinical study?
The results of this study will be used to make informed clinical decisions for developing this new vaccine. If you want the results to be made available to you, please talk to your study doctor. Results from clinical studies are often published in scientific journals, however, your personal information will remain confidential.

Who has reviewed the study?
All research studies are reviewed by an independent group of people, called a research ethics committee or Institutional Review Board (IRB), to protect your safety, rights, well-being and dignity. This study has been reviewed by an IRB.

Who should you contact with questions?
A short summary of the results will be added to www.trialsummaries.com when the study has ended. You can visit this website for more information or let your study doctor know if you need a printed copy.

If you have any questions or concerns about your participation in this research study, or if you feel that you have experienced a research-related injury or reaction to the vaccine, or have a complaint about the research study, contact the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (888) 303-2224 or (800) 562-4789, irb@cgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Thank you for reading this and considering if you will take part in this study.

Consent and Authorization form

I confirm the following:

• I have read (or had read to me) and understand the information sheet for the study. I have had time to think about taking part.	*Participant initial*
• I am satisfied my questions have been answered.	*Participant initial*
• I agree to be part of this study, to follow the study procedures and to provide the information the study doctor, nurses, or other staff members ask from me.	*Participant initial*
• I understand that I am free to stop taking part in this study at any time without giving a reason and without my medical care or rights being affected.	*Participant initial*
• I will receive a copy of this signed and dated information sheet and consent form to keep for myself.	*Participant initial*
• I agree if the study doctor is not my personal doctor, my personal doctor may be told about my taking part in this study and asked for medical information about me.	*Participant initial*
• I agree to my samples being taken and used as described in this information sheet.	*Participant initial*
• I give permission for my personal information to be collected and used as part of this clinical study and to be: - sent outside of the study center only with my participant identification number; - reviewed at the study center as part of my medical records, which may include my name, address, telephone number, date of birth, gender, race and ethnicity, and other information that could be used to identify me; - reviewed, processed and disclosed by and to the Sponsor and other persons and organizations assisting with the study, including the central laboratory and study monitors for purposes related to the study; - reviewed or audited by appropriately authorized organizations; - reviewed by and sent to regulatory authorities (such as the FDA) or health insurers in my country or other countries; and - sent to other countries where laws protecting my personal information may be less strict than the laws in this country, or to countries without any personal data protection laws.	*Participant initial*
• I understand I may also be contacted at a later date(s) for my permission in connection with this or any related sub-study.	*Participant initial*

I agree to the use of my coded data and biosamples for future research, as described in the Future Research section, including the collection of additional biosamples and where necessary for the research, possible analyses of my genetic information.	Yes ☐	No ☐

By signing this document I agree to take part in this study, as set out in the Information Sheet and Consent Form and authorize the release of my medical records and protected health information related to this study to the sponsor and its representatives, the Institutional Review Board (IRB), laboratories for testing biospecimens (as applicable), the FDA and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Consent and Authorization for my records.

My name:

Signed (by me): **Date:**

Investigator/Authorized Designee:

- ✓ I have fully and carefully explained the study to the person named above and confirm that, to the best of my knowledge, they clearly understand the nature, risks and benefits of taking part in this study.
- ✓ I confirm that I gave them all opportunities to ask questions about the study, and that I answered all the questions they asked correctly and to the best of my ability.
- ✓ I confirm that they have not been forced into giving consent, and that they have given their consent freely and voluntarily.
- ✓ I confirm they will be given a copy of this Information Sheet and Consent Form.

Name of Investigator/Authorized Designee:

Signed: **Date**: