A flipbook for facilitated discussions between study staff and potential research participants
Solidarity Trial Vaccines (STV)
This flipbook is for staff of the Solidarity Trial Vaccines (STV). It will guide conversation and information exchange with healthy subjects who are invited to take part in the trial.
What is the Solidarity Trial Vaccines (STV)?

The Solidarity Trial Vaccines is a large international research study that aims to identify more promising vaccines that are safe and work against COVID-19.

More vaccines are urgently needed to protect the world’s population against the virus, and all its different strains.

This study is being run in many different parts of the world. The success of the trial relies on many people working together in different ways to find a vaccine.

Thank you for coming to this session. Our aim today is to share information with you about the trial that can help you make a decision about whether or not you would like to take part. We will answer any questions you have.
You have a choice about whether or not you would like to take part in the study. If you do decide to take part, you can also change your mind and leave the study at any time.
Why are we doing this trial?

COVID-19, and measures to control it, have reached deep into our lives, often affecting people’s health, education, income, and limiting how they are able to gather with others. The development of a large number of safe and effective vaccines is our best hope of slowing the spread of the disease and bringing people back to work and being able to gather again with family and friends.

Research is happening all the time to develop different vaccines that could prevent people from getting COVID-19. An expert group in the World Health Organization regularly reviews the dozens of different COVID-19 vaccines being developed. This is to see which are the most promising when tested in a laboratory and among smaller groups of people.

We cannot be 100% sure that vaccines that seem promising will work to prevent people from getting COVID-19 among large groups of people unless we do a large clinical trial like the Solidarity Trial Vaccines. This trial aims to identify new promising vaccines that work and are safe and that can be fairly distributed across the world.
What vaccines are being tested?

The Solidarity Trial Vaccines is designed to test new vaccines as and when they become available.

The trial will only use vaccines that have been tested in earlier studies and have been shown to be safe. It will test a number of different vaccines at the same time.

Each person in the trial will receive either a study vaccine or a comparison.

The comparison will either be a placebo – which is a harmless substance like water – or a vaccine that is already available in your country.

We use a comparison to see how much protection the trial vaccine offers. Whether you receive the trial vaccine or the comparison will be decided randomly, like the flip of a coin. Participants will be carefully followed up for at least one year to measure results.
What will happen if you choose to take part?

There are some important steps you will follow and activities you will participate in if you choose to take part in the study.

We will take you step-by-step through the journey you will be going on if you to take part in the trial. Your journey starts with signing up to participate in the trial and ends when the trial has come to an end.

The study team will stay in contact with you throughout the trial. If you do decide to take part in the study, there will always be a member of the study team available to speak with you about any questions or concerns you may have.
Step 1: Checking you are eligible to take part in the trial

To check that you are able to take part in the trial, a member of the study team will ask you some questions.

This study is open to people over the age of 16 years who have not had a COVID-19 vaccine or been diagnosed with COVID-19 before and who live in an area with high levels of the disease. The study team will ask you some specific questions to check you are eligible.
**Next step: Joining a group that will give blood so we can better understand how the vaccines work**

The study team will ask if you are willing to give blood at regular time points throughout the trial so we can better understand how the vaccines might be working.

It is your choice whether or not to give blood. You can still take part in the trial if you would like to even if you do not want to give blood.

If you give blood, your sample will be stored for around 5-10 years.

The exact length of time will depend on the vaccine you receive and regulatory guidelines in this country.

The samples will be destroyed after storage.

If you agree to give blood, we will give you more information about how the samples will be used.
Next step: Receiving information and providing your consent

When you have finished answering questions and are found to be eligible to take part in the trial, a study team member will give you more information on the trial, including how we will identify you, how we will keep in contact throughout the trial and what is expected of you if you agree to take part. We will answer any more questions you may have.

You will then be asked to confirm that you have received information about the trial and have had all your current questions answered. We will then ask you to sign a consent form so we both have a record of your decision to take part in the study. Remember you can change your mind at any stage and decide not to participate.
Next step: How we will identify trial participants and protect their privacy

To take a record of your identification, we will ask for a snapshot of your eyes using an iris scanner.

We will also send you a message on your mobile phone to confirm you are part of the study.

Any of the information that we collect from you as part of the study will be made anonymous - this means that nobody outside the study team will be able to see your name or personal details. This information will not be shared with anybody without asking you first. We will not tell anyone outside the trial records and staff that you are taking part. However, you will be able to tell people that you are taking part in this study if you would like to.
Next step: You will then receive a vaccination

Once we have checked you are eligible, taken your signed consent and recorded your ID, you will receive the vaccine.

You will be asked to wait for 30 minutes after receiving the vaccine dose. After that you will be able to go home.
What happens next?

You will have a follow-up visit with the study team seven days after receiving your first vaccine.

The study team will also contact you each week of the trial to ask you some questions about how you are feeling.

Some vaccines might need you to come back for a second dose. If you have a second dose of the vaccine, you will have another follow up visit seven days after that too.

The study team will remind you of these visits.
What are possible side-effects?

Most people do not experience any side-effects from vaccines. And the vaccines that are being tested in this trial have already gone through extensive testing to make sure they are safe. But all vaccines can have some side-effects. The most common side-effects are headache, tiredness, sore arm, muscle or joint pain, fever. These are not signs of COVID-19. Vaccines cannot give you COVID-19.

If you become ill following your vaccine or experience any unusual symptoms or are worried about any side-effects, contact a member of the study team at any time.

If we think you (or others) may be ill because of the vaccine, we will find out which vaccine you received and let you know this information and make sure you get the right health care that you need. We will provide this care free of charge.
What to do if you feel ill?

If you have potential symptoms of COVID-19 such as a high temperature, continuous cough or loss of taste or smell, please contact the study team. You will need to have a simple swab test of your nose and mouth to confirm whether you have the virus. The team will help you if you need medical attention.

Please contact the study team using the emergency number provided.
It is really important to remember to continue all the steps that help protect you from COVID-19

We do not know for sure if the vaccine being tested in this study will protect you from COVID-19.

It is very important to remember to keep following all recommendations to prevent the spread of COVID-19. These include:

- Washing hands regularly for 30 seconds each time;
- Keeping a good distance away from people;
- Opening a window for good ventilation;
- Wearing a mask properly when indicated.

The study team will stay in contact with you by mobile and you can contact us at any time.
Thank you for thinking about taking part in the trial. Your interest is important to the success of the trial and will help us to find a life-saving vaccine, even if you decide not to be a part of the trial. Your support as we host the trial in your community is a big step in finding a safe vaccine that works.