

INFORMATION FOR PARTICIPANTS IN LIGHT OF NEWS ABOUT PFIZER/ BIONTECH COVID-19 VACCINE

Thank you for your participation in this COVID-19 vaccine clinical study.

You may have heard the encouraging interim results of the Pfizer/BioNTech clinical trial on their vaccine against COVID-19. This development is thanks to clinical study participants such as yourself and shows the importance of this vaccine research. The vaccine has not yet been approved for use in the UK, but you might have questions about what this means for the clinical study you are taking part in.

1. What does the Pfizer vaccine news mean to people taking part in trials?

There are no changes to current clinical trials at the moment. As soon as a vaccine is approved and rolled out for use in the NHS, we will have a process to make sure people on the clinical trial are not disadvantaged. This will mean being able to have an effective vaccination through the NHS, if they haven't already had one through the study. In the meantime, participants should continue to attend their trial appointments in the normal way, receive booster injections and report safety data. Thank you for your participation - it is thanks to people taking part that we have this encouraging news about a vaccine.

2. Do we still need this and other vaccine clinical trials?

Yes. There is no change to any of the number of clinical trials into COVID vaccines at the moment, and it is essential that these continue. We will need data about a number of vaccines and their safety and effectiveness, in order to protect the population. No one vaccine is likely to be suitable for everyone, the first vaccine may not be the most effective and easiest to use, and we must make sure that the other studies continue to allow us to have a selection of vaccines to protect the whole population.

3. I'm on a trial and in a priority group for vaccination, how will I be offered early protection?

When an approved vaccine is available (called 'deployment'), people in priority groups will be contacted by the NHS and offered an appointment to receive it. These priority groups are likely to include people who live in care homes, people aged over 80, and some front line health and care workers. If you are invited to a vaccine, at this stage, please contact the research team, who will follow an agreed process to advise you. This is likely to include finding out whether you received an active trial vaccine or a placebo (that would offer you no protection against COVID-19), called 'unblinding'.

If you had an active vaccine, the research team will advise you if you still need to have the approved vaccine, taking into account the latest data on the trial vaccine's effectiveness. If you had a placebo, you will be advised to have the approved vaccine. Please continue to attend follow-up appointments and the advice of the research team, so that we can gather important safety information about the trial vaccine. It will be important that we gather information about the safety and effectiveness of all the trial vaccines underway. This is so that we can gather information to allow use of all the effective vaccines, to maximise supply and ensure that we gain a full picture of the effectiveness and use of all the vaccines available.

4. I'm on a trial and not in a priority group for vaccination, what does this mean for me?

Please continue to take part in the clinical trials, attend for your follow-up booster (if applicable), and all your follow-up appointments. People will be called up by the NHS to be offered a vaccine in a priority order determined by experts, based on how at risk they are of becoming ill with or spreading severe infection. It is likely to take some time for healthy people under 50 years of age to be invited to receive an approved vaccine, which could mean many months. We are asking people to continue to take part in clinical research for as long as possible.

5. What if I want to leave the trial as a result of the information about the Pfizer vaccine?

People on the trial are free to leave at any time, and this is a personal choice. However, it is important to note that leaving the trial will not offer you any further protection, as it will not affect when you can receive an approved vaccine. People taking part in the trial will still be able to receive an approved vaccine without delay when they are called up by the NHS. We are also only able to respond to unblinding requests at the end of the trial or for a medical reason, according to agreed protocols that set out how the trial is run. We ask that people continue to attend appointments, receive booster doses and share data on their health and infection with COVID for as long as possible, so that the trials can complete as early as possible.

6. Is it worth me joining a trial if I will be getting an approved vaccine soon?

It's a personal choice but we believe it is. A vaccine is not yet approved, and is unlikely to be available to many people until well into the new year. Once a vaccine is available, we will have a process in place so people on the study are not disadvantaged. You can still have an approved vaccine when this is available, even if you take part in a study. Taking part in a study is the best way to help effective vaccines to be identified and made available to everyone earlier, and may even give you early access to a vaccine later found to be effective.

Thank you for your ongoing participation. If you have any other queries that are not answered here, you can also visit

www.bepartofresearch.org.uk

or speak to your research team.