Covid Vaccine Monitor study Participant Information Sheet

Adult (16 years+)

The Drug Safety Research Unit (DSRU) has been making sure medicines used in the UK are safe for 40 years. We are an independent organisation and not a government agency or pharmaceutical company. We would like to invite you to take part in our study. Before you decide we would like you to understand why the study is being done and what it will involve. Please take the time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you want to take part.

What is the purpose of the study?

The coronavirus (COVID-19) vaccines have been researched thoroughly before being given to the public, and they meet all safety requirements. However, side effects after vaccination can still occur. It is not yet known how frequently they happen or if some people are more likely to experience them. By participating in this study, you can help us gain more insight into this information and make the use of coronavirus vaccines even safer.

The DSRU would like to monitor this information. By doing so we will learn more about possible side effects as quickly as possible.

Further information on COVID-19 vaccines and possible side effects can be found on the NHS or Public Health England websites:
www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/

www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination/what-to-expect-after-your-covid-19-vaccination

Why have I been invited to take part?

You have been invited to take part because you have recently received a coronavirus vaccine, or you will receive one soon.

Some people experience a side effect after receiving the coronavirus vaccine. The DSRU is collecting information on possible side effects (adverse events) after vaccination with coronavirus vaccines and we would like you to participate, even if you do not experience any.

Do I have to take part?

No, the study is completely voluntary, and it is up to you to decide whether you would like to participate once you have read this information sheet. If you do agree to take part, we will ask you to sign a consent form electronically, via the study web app.

What will happen if I agree to take part?

To be able to participate, you must register first using your email address. After registration you will receive an email asking you to log into the web app to complete a questionnaire. This first questionnaire will ask some general questions about you and your health. Seven days after vaccination, you will receive the next questionnaire. In total you will receive seven questionnaires over a period of six months. Questionnaires need to be filled in electronically via the web app. Each questionnaire takes 10-25 minutes to complete. The questions are about the possible side effects that you may have experienced after vaccination. Even if you do not experience any side effects, we ask that you still complete the questionnaires. Participation is completely voluntary. You can stop your participation at any time without explanation.

This UK project is part of a wider European study that is run by the Netherlands Drug Safety Centre, Lareb (https://www.lareb.nl/en). When you click to login or register you will be transferred to the study web app, which is based in the Netherlands. Any personal data you provide will only be accessible by members of the DSRU study team in the UK, not the Netherlands team.

How will we use information about you?

We will need to use information from you for this research project. This information will include your email address, postcode, and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at: www.hra.nhs.uk/information-about-patients/
- a leaflet is available from www.hra.nhs.uk/patientdataandresearch
- by sending an email to the research team: covidmonitor@dsru.org or derek.hall@dsru.org
- or by ringing us on 023 8040 8600

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice, and all information which is collected about you during the study will be kept strictly confidential. Your data will be entered electronically using a secure website. Only authorised members of DSRU staff will have access to any personal information that you provide. We will only share anonymised data with Lareb and our other European partners. Nobody will know that you have taken part in the study. Further information regarding data privacy and data protection rights can be found in the Privacy Notice available at: www.covidvaccinemonitor.co.uk

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason, and this will not affect the standard of care you normally receive. We just ask that you let us know that you no longer want to participate. We will destroy your personal data that we have collected and will not contact you again. We may use any non-personal data collected so far.

In the unlikely event of a loss of your present ability to provide informed consent (and if this is communicated to us), the DSRU will retain and use any information collected up until that point only.

What will happen to the results of this study?

We will present findings of this study to the UK medicines regulator (the Medicines and Healthcare products Regulatory Agency [MHRA]) and the European medicines regulator (European Medicines Agency [EMA]). Results of this study will be submitted for publication in medical/scientific journals and at meetings and posted in the EU PAS publicly accessible database of results. A dashboard for monitoring of results during the study will also be made publicly available. All of these will be anonymous, which means that you will not be able to be identified from them.

Who is organising and funding the study?

The DSRU in Southampton will be carrying out the UK part of the COVID-19 vaccine monitoring study. This forms part of a wider study being carried out by a network of organisations throughout Europe. The study is funded by European Medicines Agency (EMA), and is managed by the Netherlands Pharmacovigilance Centre, Lareb.

Who has reviewed the study?

This study has been reviewed and given a favourable ethical opinion for conduct in the UK by London - Brent Research Ethics Committee (REC reference: 21/HRA/2077)

How can I find out more about this study?

Information about taking part can be found at www.covidvaccinemonitor.co.uk or you can contact the DSRU:

Dr Liz Lynn

Drug Safety Research Unit, Bursledon Hall, Blundell Lane, Southampton SO31 1AA

Tel: 023 8040 8600

Email: covidmonitor@dsru.org

Complaints

If you have a concern about any aspect of this study, please contact:

Derek Hall, Operations Manager

Drug Safety Research Unit, Bursledon Hall, Blundell Lane, Southampton, SO31 1AA

Tel: 023 8040 8600

Email: derek.hall@dsru.org

Thank you for taking the time to read this information sheet.