

The PANORAMIC Trial Summary Sheet

We are inviting you to join this trial because we understand you currently have COVID-19.

What you need to know:

- **TRIAL AIM:** To find new treatments to help those with COVID-19 to get better quicker and prevent them being hospitalised and even dying
- Taking part is voluntary

REQUIREMENTS TO TAKE PART:

- Feel unwell with symptoms of Covid-19 which have started in the last 5 days
- A positive test for Covid-19 (SARS-Co-V2) infection
- Aged 18-49, with an underlying medical condition that may increase the chance of experiencing severe Covid-19.
- Aged 50 and over with or without underlying conditions

WHAT DOES TAKING PART IN THE STUDY MEAN?

- Some people will receive new antiviral treatment to take daily, in addition to their regular standard NHS care as normal
- Some people will receive no antiviral treatment but will continue to receive regular standard NHS care as normal
- The selection is random and is not by any choice
- Participants will either complete a daily diary for 28 days through the PANORAMIC website or receive a phone call from the trial team on day 7, 14 and 28, to tell us about your symptoms and any contacts you may have had with healthcare professionals.

SIDE EFFECTS

- The antiviral treatment has already been taken by people in other studies.
- If you have any side effects from the antiviral treatment, or if you are admitted to hospital for any reason during the 28 day trial period, it's important for you to let us know as soon as possible.

CONFIDENTIALITY and DATA PROTECTION

- People allowed to look at your health information will be limited, to include the research team, individuals from University of Oxford, the Sponsor, and the regulatory authorities who check that the trial is being carried out correctly. In addition, in order for us to obtain additional healthcare data about you which is relevant to the trial, your date of birth and NHS Number will be shared with NHS Digital to enable them securely link, extract and to supply the study team with the data we require. A privacy notice is on the trial website for your information XXXX

TO TAKE PART: Fill in a short form by telephone or on the internet to check that you are eligible.

- Read this information sheet in full
- Fill in a consent form to agree to take part

Need more information?

If you would like to speak to a member of the trial team, please feel free to get in touch:

Freephone: 0800 XXXXXXXX

Email address: panoramic@phc.ox.ac.uk

Platform Adaptive trial of NOvel antivirals for eArly treatMent of covid-19 In the Community: The PANORAMIC Trial

PARTICIPANT INFORMATION LEAFLET

The PANORAMIC Trial is trying to find new antiviral treatments for COVID-19 that can be used in the community. We want to test how effective new treatments are at helping people recover sooner and without needing to be admitted to hospital. We are inviting you to join this trial because we understand you currently have COVID-19.

This leaflet provides information about the trial, including its aims, and tells you about the risks and benefits of taking part.

What is the purpose of the trial?

COVID-19

The risk of complications from COVID-19 is increased in people with underlying health conditions, unvaccinated people, and those in whom the vaccine is less effective. In these people, COVID-19 can sometimes lead to significant medical problems, hospitalisation, and death.

Most people with COVID-19 are treated in the community and so we need to find treatments that are suitable for use in the community.

The Trial

COVID-19 can cause great suffering, and it stops people from performing their daily activities, affecting their work, education, and caring responsibilities. **The purpose of this clinical trial is to find new treatments that help those suffering with COVID-19 at home and in the community get better quicker and without needing to be treated in hospital.** To be able to do this, we aim to test individual possible treatments as soon as they become available.

We are testing new antiviral treatments which might have beneficial effects for the treatment of COVID-19, but which may not yet have a license for use in the UK.

All of the treatments in the PANORAMIC trial have been approved by the UK Medicines and Health Care Products Regulatory Agency (MHRA) for use in the study. The MHRA regulates the use of all medicines in the UK.

Please see Appendices for specific information about each antiviral treatment.

Can I take part?

To take part, you need to have had a **positive test** for coronavirus (SARS-Co-V2) infection AND you must be unwell with symptoms of COVID-19 illness, which started in the last 5 days. *These symptoms may include, but are not limited to, a high temperature, a new and continuous cough, loss or change to your sense of smell or taste, a sore throat, shortness of breath, a general feeling of being unwell, muscle pain, diarrhoea, or vomiting.*

Also, to join the trial, you need to be either:

Aged ≥50 years

OR

Aged 18-49 with any of the following underlying health condition that makes you more vulnerable to COVID-19:

- Chronic respiratory disease (including chronic obstructive pulmonary disease (COPD), cystic fibrosis and asthma requiring at least daily use of preventative and/or reliever medication)
- Chronic heart or vascular disease
- Chronic kidney disease
- Chronic liver disease
- Chronic neurological disease (including dementia, stroke, epilepsy)
- Severe and profound learning disability
- Down's syndrome
- Diabetes mellitus

- Immunosuppression due to disease or treatment (e.g. sickle cell, HIV, cancer, chemotherapy)
- Solid organ, bone marrow, or stem cell transplant recipients
- Morbid obesity (BMI >35)
- Severe mental illness
- Care home resident
- Considered by recruiting clinician to be clinically vulnerable

Do I have to take part?

No, taking part is entirely your choice and voluntary. It is up to you to decide whether to take part in the trial or not. A decision to not to take part will not affect the standard of care you receive from the NHS in any way, now or in the future.

In certain circumstances, we are contacting people who may have recently tested positive for COVID-19, and information about this has been provided to the trial by NHS Digital in these unique pandemic circumstances. You have the right to opt out of any future communications from PANORAMIC should you wish to do so. PANORAMIC will not keep your data should you choose not to take part. Please see the General Notice under the Health Service Control of Patient Information Regulations 2002 for more information

(<https://www.gov.uk/government/publications/coronavirus-covid-19-notification-of-data-controllers-to-share-information>)

We will make a maximum of three attempts to contact you about the trial.

What will happen to me if I take part?

If you are interested in taking part, we will ask you to complete a short online form to see if you are eligible. If you do not have internet access or would like to telephone us instead, then you can contact us using the contact details at the end of the document.

Informed Consent

You will be asked to complete a consent form online or by telephone. Instructions on how to fill out the form will be provided, so you will know what to do. You will be able to download and keep a copy of your informed consent form. Before deciding whether or not to take part, you will be able to discuss the risks, benefits, and what you need to do to take part, with a trial Doctor or Research Nurse.

Initial Questionnaire - online

You will then complete some questions online about you and how you are feeling. We will also collect some contact details such as your name, email address, and telephone number. We will also ask you to provide details of a Trial Partner, if there is someone suitable for this. This could be a relative, spouse, friend or carer, if such a person is available, who we will contact for information about you if we are unable to get hold of you for whatever reason. If you are a person of child-bearing potential (ie. Participants who are physically able to become pregnant regardless of their current contraception methods or relationship status), you will need to agree to taking a urine pregnancy test as part of the screening process. You will only need to take a pregnancy test, if you are allocated to an antiviral treatment. A negative pregnancy test result is needed before starting treatment and we will discuss this with you and provide further details, if you are allocated to one of these treatments.

If you receive an invalid test result, please contact the trial team using the contact details at the bottom of this leaflet to request a replacement a pregnancy test kit as soon as possible. If the delay caused by the need to send a replacement test kit causes you to become ineligible for the trial (you are now feeling recovered from your illness), we will need to withdraw you from the trial.

Randomisation

After you have registered for the trial, your GP, trial doctor, or research nurse will telephone you to confirm consent and ask you a few questions to check that you are eligible to take part (**Day 0 telephone call**). If you are eligible, during the same telephone call, you will be randomly (like rolling a dice) put into one of the trial groups (antiviral treatment with Standard Care or Standard Care) by our computer system. Neither you, your GP, nor the trial team can decide which group you will be in, it will be decided purely by chance. If you are allocated to an antiviral treatment, the risk, benefits, and follow-up procedures, will be explained to you at that time.

All participants will receive standard best available care (outside of the trial), regardless of whether they are given an antiviral or not. Responsibility for your clinical care remains with the NHS and not the trial team. The trial team should be contacted about matters relating to the study and NHS services should be contacted about your medical care. If you are randomised to the Usual Care Group, you will receive standard NHS Services available as normal but we will still follow you up regardless of which group you are in. This is so we can compare the symptoms and healthcare contacts between those who do and don't receive antiviral treatment. We will inform your GP of which group you have been allocated to.

Trial Treatment

If you are randomised to an antiviral treatment group, arrangements will be made for the medication to be delivered to you the following day. You will also receive instructions on how to take it and for how long, and you will be asked to confirm receipt of the medication via text or telephone call. Should your COVID-19 illness worsen at any time during the trial, you should not contact the trial team about this, but contact your GP or other HealthCare services that are open to you i.e. go to the accident and emergency (A&E) department at your local hospital, or contact 111 or 999.

Please see the PIS appendices for further details about the antiviral treatments. You will also be able to call us at any time if you have any concerns about side-effects you think maybe caused by the treatment, using the trial free-phone number: 0800 xxx. We will contact you to ask if you have experienced any symptoms that could be side-effects of the study treatment. If we are unable to contact you or your study partner, with your consent we may contact your GP directly. We will ask you to return any unused medication in a pre-paid envelope provided if it is decided to stop the treatment before the course is completed.

Follow-Up

After being randomly allocated to a trial group, you will receive a text message from us asking you to complete the online questions relating to your symptoms and how well you feel every day for the 28 day trial period. If the trial team does not receive your daily diary answers online, they will text or telephone you on day 7, day 14 and day 28 of the follow up period and ask you a brief set of questions over the phone.

Day 1 telephone call:

If you are of child-bearing potential (regardless of current contraception methods or relationship status) and you are allocated to an antiviral treatment, during this call, we will confirm that you have taken the pregnancy test and obtained a negative pregnancy test result. You will be asked not to take any study medication if the pregnancy test is positive.

Day 2 telephone call: All Participants, regardless of what group they are allocated to, will receive a call on Day 2 (2 days after registration).

If you have been allocated to an antiviral treatment, your GP, trial doctor, or research nurse will call you the day after you receive your medication to discuss any potential side-effects which you may have experienced since starting the medication, and to answer any questions that you may have.

If you have been allocated to Usual Care Group, you will receive this Day 2 call to confirm you have got your study materials, to answer any questions and to confirm follow up procedures.

Long-term follow-up: We will also contact you (email, text message, and/or telephone call) at 3 and 6 months after you have started the trial to collect information about ongoing symptoms and contacts with healthcare providers. We will collect information from your GP records and data held by central NHS bodies (such as NHS Digital) for long-term follow-up for up to 10 years, to help us better understand the long-term effects of COVID-19 and the trial treatments.

Summary of Trial Procedures

Day 0 - All Participants

- Telephone call from a trial Doctor/Research Nurse to: explain risks, benefits, and trial processes; confirm your consent; check that you're suitable to take part and if so, you will be randomly allocated to a trial treatment.
- After entering the trial, you will receive a link to complete your Day 1-28 Daily Diary.

Day 1 - Participants receiving an antiviral treatment

- If you are **of child-bearing potential (regardless of current contraception methods or relationship status) and are allocated to be on antiviral treatment arm**, a trial team member will confirm that the trial pregnancy test has been completed and that the result is negative before you start any study medication.

Day 2 - All Participants

- For participants on **Antiviral Treatment** Arm, telephone call will be made from a trial Doctor/Research Nurse to ask whether you have experienced any side-effects since starting the antiviral treatment.
- For participants on **Usual Care** Arm, telephone call will be made to confirm receipt of study materials, confirm follow-up procedures and answer queries.

Day 7, 14 and 28 - For Participants not completing Daily Diaries

- A member from the trial team will call you to collect information about your symptoms and contact with healthcare providers, if you are unable to complete your daily diaries.

Months 3 and 6 after you start the trial

- You will receive a link to complete a questionnaire online about any ongoing symptoms and contact with healthcare providers. We may also call or text you to gather this information.

10 Years after you start the trial

- With your consent, we will collect information from your GP records and data held by central NHS bodies for long-term follow-up for up to 10 years.

What happens if I am admitted to Hospital?

It is really important that we know if you are admitted to hospital at any point during the 28 day follow up period. We need to know about this whether or not you are taking the trial medication. We will give you a card that you can carry to let other healthcare professionals know that you are taking part in this trial. It is also really important that someone close to you knows that you are

taking part in the trial, so that if you do get admitted to hospital, they can use the details on the card to let us know.

We may also access your medical records and data held about you in central NHS registries and databases (including NHS Digital, Public Health England, other equivalent bodies, and genetic or other research databases if you have provided samples to them) to collect information on any hospital admission that you may have during the follow up period.

We will send your date of birth and NHS Number to NHS Digital to enable them to supply the study team with additional healthcare data about you, which is relevant to the trial. You are free to withdraw your consent for data linkage with NHS Digital at any time and it will not affect your ongoing care.

What are the possible disadvantages or side effects of taking part?

With any medicine, including ones that are already used within the NHS, there is a risk of side effects. Please see Appendices for details of the side-effects common to each drug. You will be asked to tell us if you are experiencing any of these symptoms in your daily diary, or you can contact the trial freephone number. On a daily basis, the trial's clinical team will monitor specific, pre-defined potential side-effects that you report in your daily diaries, and contact you if required. Please see the medication specific appendices for details about which side-effects will be monitored for each treatment.

What are the possible benefits of taking part?

We do not know if the treatments being tested will have additional benefits. Your antiviral treatment may, or may not, help you personally, but we hope this trial will help future patients to receive the best evidence –based care.

What will happen if I do not want to continue with the trial?

If you decide to take part, you can still withdraw at any time without giving a reason. Information collected up to that point will still be used. If you have informed the trial team of certain moderate or major side effects from taking a trial medicine not licenced in the UK, the trial team would like to contact you and/or your GP until you feel better.

If you wish to withdraw from the trial, please contact the trial team using the contact details at

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the end of this document. The decision to withdraw will not affect the standard of care you receive from the NHS in any way, now or in the future. We will ask you to return any unused medication in a pre-paid envelope provided if you withdraw before the treatment course is completed.

Expenses and Payments

You will be reimbursed for your participation through gift vouchers worth a total of £10. You will receive the voucher at the end of your follow up period, once we have received your completed symptom diary for the 28 day study period. There will be no prescription charges for trial antiviral agents incurred by trial participants.

What if there are any problems?

If you have any questions about this trial, please contact the Trial Team (See the last page for contact details).

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this trial, you should contact the trial team on panoramic@phc.ox.ac.uk or **0800 xxxxx** or you may contact the University of Oxford Research Governance Ethics and Assurance Team (RGEA) office on 01865 616480, or the head of RGEA, email ctrng@admin.ox.ac.uk.

What will happen to my data?

All information about you and your health will be kept private. The only people allowed to look at the information will be the doctors running the trial, the trial team and Sponsor, and the regulatory authorities who check that the trial is being carried out correctly. A privacy notice is on the trial website **XXXX**

As part of the trial enrolment process we may need to view your Summary Care Records (SCR) (<https://digital.nhs.uk/services/summary-care-records-scr/summary-care-records-scr->

[information-for-patients](#)) to check your medication, allergies, adverse reactions and ‘Additional Information’ to make sure that it is safe for you to take trial medication. A SCR is an electronic record of important patient information, created from GP medical records. SCR ‘Additional Information’ includes information recorded in your GP record about your significant illnesses and health problems, operations and vaccinations you have had in the past, how you would like to be treated (such as where you would prefer to receive care), what support you might need and who should be contacted for more information about you. SCRs can be seen and used by authorised staff in other areas of the health and care system involved in your direct care.

We will ask for your consent to view your SCR. The SCR will not be retained by the trial team. If your SCR is unavailable or you do not consent for us to access it, you can still take part in the trial as we will obtain this information from your GP.

The analysis of some of the data from the trial will be performed by Berry Consultancy with support from statisticians at the University of Oxford. The company is based in the USA, however no information that could identify you will be given to them during this process.

What if relevant new information becomes available during the trial?

Sometimes during the course of a research project, new information becomes available about the treatment that is studied.

If this happens, the trial team will tell you about it and discuss with you whether you want to continue in the trial or not.

If you decide to continue you may be asked to sign an updated consent form.

What will happen to the results of the trial?

Results will be published in scientific journals, presented at scientific conferences, and published on the Oxford University departmental website, and may be reported in news media. It will not be possible to identify you in any report, publication or presentation. If you would like to receive copies of any publications arising from this trial, please contact the trial team (details are on the last page).

Who is organising and funding the research?

Funding has been provided the by UKRI and National Institute for Health Research. PANORAMIC has been set up by the Primary Care Clinical Trials Unit at the University of Oxford. In-kind contributions: Department of Health and Social Care provided the study medication free of charge to the trial.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The REC is there to protect your safety, rights, wellbeing and dignity. This trial has been ethically reviewed and was approved by the xxx Research Ethics Committee (REC Reference:TBC).

This trial has also received approval from the Medicines and Healthcare products Regulatory Agency (MHRA).

Trial Team:

Tel. 0800 xxxxx

Trial Email Address:

panoramic@phc.ox.ac.uk