PROTOCOL TITLE: European Clinical Research Alliance on Infectious Diseases – PRIMary care adaptive platform trial for pandemics and Epidemics

EudraCTIS number: 2022-501707-27

A randomised, comparative trial to investigate the effect of Investigational Products and Usual Care in non-hospitalised patients with COVID-19 or COVID-like-illness

ECRAID-Prime: Participant Information Sheet – For Remote Recruitment

For the Nitric Oxide Nasal Spray, Saline Nasal Spray and Usual Care evaluation

We would like to invite you to take part in a clinical trial. You have received this invitation because you are experiencing symptoms of a respiratory infection, COVID-19 or COVID-like-complaints, and/or have contacted your GP/primary care provider or us, the Oxford ECRAID-Prime Team at the Primary Care-Clinical Trials Unit, University of Oxford, about such symptoms. Please take time to read the following information carefully before deciding if you wish to take part. Your participation is entirely voluntary.

1. Who is organising (sponsoring) and funding this trial?

This trial is being sponsored by the University Medical Center Utrecht (UMCU), the Netherlands; UMCU is referred to as "Sponsor". This trial is operationally managed by Ecraid (European Clinical Research Alliance on Infectious Diseases) in the Netherlands. Ecraid works to identify, prevent, and treat infectious diseases in Europe, through this ECRAID-Prime trial and other related studies.
You can find the contact details of the Sponsor and other relevant persons in **Appendix A.**
ECRAID-Prime is a collaboration between the UMCU, the University of Oxford (United Kingdom), the University of Antwerp (Belgium), ECRIN (European Clinical Research Infrastructure Network, France) and Ecraid. Funding has been provided by the European Union (No: 101046109).
The study product that you might receive in this trial is produced and supplied by SaNOtize.

2. Who will be recruited to the trial?

This trial will enrol patients with a respiratory infection in about eight countries across Europe. We anticipate enrolling approximately 1000 patients in the trial so that we can test several different study products. You are being invited to take part because you have been referred by your GP/primary care provider to get in touch with us, the Oxford ECRAID-Prime team, or you have been informed about the ECRAID-Prime trial through other advertising channels and contacted us directly with symptoms suggestive of a respiratory infection, COVID-19 or COVID-like-complaints.

3. What is the purpose of the ECRAID-Prime trial?

Most people with a respiratory infection (this can be COVID-19 or COVID-like-illness) do not become seriously ill. Some people, however, do go on to have more serious symptoms and may even need to be admitted to the hospital.
The ECRAID-Prime trial is an intervention trial that is investigating how well study products to treat respiratory infections work and the safety of these products in non-hospitalised adult patients across Europe. In this trial we want to investigate whether study products:

- Help you to recover faster
- Reduce the severity of your symptoms
- Reduce complications that require treatment in hospital
- Prevent spread to your family members/house mates

4. What does the ECRAID-Prime trial involve?

If you decide to participate, you will be asked to take a combined throat/nose self-swab at home so that we can find out what is causing your respiratory infection. Respiratory infections can be caused by various organisms (germs) such as SARS-CoV-2 (the virus that causes COVID-19), influenza virus, respiratory syncytial virus, rhinovirus, other coronaviruses, or a bacterium. This swab will be analysed at a later date. You will not receive the swab results.

You will be randomised (allocated purely by chance) to receive one of the study products in addition to usual care, or to receive usual care without a study product. The study product you might be allocated to are described below. If you are randomised to receive one of the study products, neither you nor the investigator will know which one it is. You are requested to take the study product according to the instructions (for instructions see document “Instructions for use study product”).

To find out how well the study product works and how safe it is, we will collect health information and a throat/nose swab from you. We will also ask you to answer questions at the end of each day for 28 days about how you are feeling, the symptoms you are experiencing, your recovery, any side effects, and whether members in your household are experiencing respiratory symptoms. Additionally, we ask you to take a combined throat/nose self-swab on the day of receiving the participant pack before you start taking the study product (if you are randomised to receive one) and 4 days later (for instructions see document “Instructions combined throat/nose self-swab”).

5. Study products

NONS

NONS (Nitric Oxide Nasal Spray) is a nasal spray containing Nitric Oxide, a naturally occuring chemical which is also produced in your body and is involved in various processes. Nitric Oxide may inactivate viruses in the nasal cavity and prevent viruses from entering the nasal mucosa cells. It could thereby reduce the amount of virus and reduce spreading of the virus into the lungs. NONS is approved as prophylactic medical device in several countries. In this trial we will test whether it can treat symptoms of a respiratory tract infection.

Saline

Regular use of saline (0.9% NaCl) nasal spray may wash out viruses from the nasal cavity, thereby reducing viral load and spreading of the virus into the lungs. Saline is a worldwide approved medical device.

If you are randomised to one of the study products, you will be asked to use the nasal spray 6 times a day for 7 days.

6. How long will participation in the trial take?

Your participation will take 3 months. We will ask you to tell us about how you are feeling each day for 28 days via a daily diary. After 3 months you will receive an online questionnaire or a telephone call to ask about any long-term effects from your respiratory infection.

7. *What is the difference with usual care?*

Participation in the trial will not affect the care you receive and will not replace any usual care. Your GP will decide what care is best for you; your GP might prescribe medication and/or provide you with self-care advice. If you decide not to participate in the trial, your care will not be affected in any way.

8. What medications are not allowed to be used during the trial?

You are not allowed to use the following medications for 7 days before participating in the trial and for 7 days after starting the trial:

- Nitric Oxide donors/derivatives: isosorbide dinitrate, isosorbide mononitrate, nitroglycerine/glyceryl trinitrate, nitroprusside, nicorandil
- Phosphodiesterase inhibitors: avanafil, sildenafil, tadalafil, vardenafil
- Guanylate cyclase activators: riociguat, linaclotide.

Please discuss with the study doctor, prescribing pharmacist, or qualified research nurse from the Oxford ECRAID-Prime clinical team whether the medications you use would mean that you should not take part in this trial. You will be asked to tell the name of the medications you are using or show the medication packagings during the conversation with one of the Oxford ECRAID-Prime clinical team members either by phone or video call.

9. *What will happen if you take part?*

Pre-screening

You might have seen information about the ECRAID-Prime trial from the healthcare or research platforms like Be Part of Research or TrialeX, to which you are registered to hearing about new research opportunities. When you contact us for the first time because you are interested in taking part, we will explain the trial to you, ask you a few questions about you and how you are feeling to see if you are eligible. If from this pre-screening we think you are eligible to take part, we will arrange the best suitable option for the informed consent interview with you. The informed consent interview can be either on the same phone/video call or at a later time on the same day if it suits you better, using an electronic consent platform (e-consent).

Informed Consent

You will be given time to consider whether or not to take part in this trial. If you would like to take part, you will be asked to sign an electronic consent form. A qualified member of the Oxford ECRAID-Prime team will go through the consent form with you. Instructions on how to fill out the electronic consent form will be provided, so you will know what to do. Once completed, we will ask you to download the form or we will send you a copy of your informed consent form. If you choose to have the paper version of the form.

Eligibility Assessment

After you have signed the consent form, a study doctor, prescribing pharmacist or qualified research nurse from the Oxford ECRAID-Prime clinical team will complete a short questionnaire including some details about you (age, sex, and chronic diseases and ethnicity; ethnicity is part of the data collected as we need to differentiate the susceptibility and severity of respiratory infections between ethnic groups) and symptoms you have been experiencing. Based on the eligibility criteria, the study doctor, prescribing pharmacist or qualified research nurse from the Oxford ECRAID-Prime clinical team will decide whether you can participate in the trial. We will also record your name, email address, home address and telephone number so that we can contact you.

Inclusion

Upon inclusion in the trial, the following will be done:

- We will collect information from you about smoking, vaccinations, if you have had COVID-19, your usual care provided by your GP or delegate, body mass index and temperature.
- Combined throat/nose swab(s) to be self-taken at home when you receive the participant pack.
- You will be randomised to receive one of the study products in addition to usual care, or usual care without a study product (see section 4).

Arrangements will be made for the participant pack either to be collected by you, or someone on your behalf, at the GP practice or to be delivered to you the following day. The participant pack contains: the participant information sheet, signed informed consent form (if a printed copy was requested by you), swab kit(s), an instruction booklet on how to take and store the swab(s). If you are allocated to a trial arm with a study product, you will also receive a study product pack, a participant card, and instructions detailing how to take the study product. You will also receive pre-paid postage materials so that you can post your swab(s) and unused study product (if applicable) to the Oxford ECRAID-Prime team.
You will receive a phone call the day after your inclusion. A qualified research nurse (if you have been allocated to study product group) or a member of the Oxford ECRAID-Prime team (if you have been allocated to Usual Care group) will call you to confirm you have got your study materials and study product (if applicable), to advise on how to do the self-swabbing and how to take the study product (if applicable), to answer any questions and to confirm follow-up procedures.

Follow-Up

A member of the Oxford ECRAID-Prime team will provide you with a link to an online diary or can send you a paper diary, if you prefer. They will explain how to complete the diary. You will be asked to complete the diary at the end of each day for 28 days, starting on the day you have taken the study product for the first time. The diary will include questions about your symptoms, possible side effects, other medication, swab(s) self-taken, recovery, visits to the GP or hospital and whether people you are living with develop respiratory symptoms. It should take about ten minutes to complete the diary every day.

If you completed the paper diary, you return it to the Oxford ECRAID-Prime team in the addressed envelope provided. If you complete your diary online it will automatically be included in the online database. If the diary is not complete, we will call you after day 28 to ask some remaining questions about your illness. This call will take about ten minutes.

You will also receive a phone call by the Oxford ECRAID-Prime team on approximately day 14. During this call, you will be asked about the diary and specific health issues related to the trial you might experience. This call will take about five to ten minutes.

We will keep in regular contact with you during the follow up period. If you have chosen to complete the diary online, we will send you an email with a link to your web-based daily symptom diary every day for 28 days. We may also send you text reminders to take your swab sample, and to complete the diary on the first day of your participation in the trial and on Day 4, and at Month 3. However, you will have the opportunity to opt out of this if you wish.

You may also participate in an interview about your experience of your consultation and participation in this trial. This is an optional interview and you will only participate if you give consent for this.

Swab collection and collection of unused medical product

You are being asked to take you to take a self-swab on the day of receiving the participant pack before you start taking the study product (if you are randomised to receive one) and 4 days later. You will receive materials for this, and an instruction booklet on how to take and store the swab(s). You will also receive pre-paid postage materials so that you can post your swab(s) to the Oxford ECRAID-Prime team. After completing the course of study product (if you are randomised to receive one), you will also need to post your remaining study product back to the Oxford ECRAID-Prime team. Instructions for packaging and posting the swab(s) and study product can also be found in the swab instruction booklet.

Contact after 3 months

After 3 months, we will contact you by telephone or you will receive an online questionnaire with questions related to any long-term effects of your respiratory infection, impact of specific symptoms and GP and hospital visits. **Appendix B** contains a schedule of all follow-up procedures.

If at any point during the trial you decide to no longer take part, please let the Oxford ECRAID-Prime team know. No further follow up questionnaires will be send or calls will be made. You do not have to explain why you want to stop. A decision to withdraw will not affect the usual care you receive in any way, now, or in the future.

10. What agreements do we make?

We want the trial to go well, so if you do take part, we ask you:

- To take the study product according to the instructions for use (in the participant pack).
- To NOT take part in any other trial with a study product while you are part of this trial.
- To fill in the diary at the end of each day for 28 days and after 3 months.
- To keep the participant card of the trial with you at all times, in your wallet, for example. It states that you are taking part in this trial, and who should be contacted in an emergency. Please, show this card each time you visit another doctor.
- *For women of child bearing potential:*
  - To use highly effective contraception for 30 days before and after starting the trial: sterilisation, long-acting reversible contraceptive methods (intrauterine devices and implants), combined hormonal methods (oral, transdermal, or intravaginal), or the progestogen only pill or injection; or
  - To be abstinent of heterosexual sex for 30 days before and after taking the medication where this is in line with your preferred and usual lifestyle.

  In case you do become pregnant despite these contraceptive measures, we will need to follow up the pregnancy until you give birth. In this case, you will be contacted after 28 days.
- To contact your GP practice, or the coordinating team as outlined in **Appendix A**, if:
  - You are admitted to a hospital, or get treatment in a hospital for your respiratory infection
  - You suddenly have problems with your health
  - You no longer want to take part in the trial
  - You became pregnant
  - Your telephone number, address or email address changes

11. *What side effects, adverse effects, or discomforts could you experience?*

The study products may cause side effects. Side effects are problems you can experience after use of the study product. You may experience the following side effects:

- Nasal burning or irritation (may affect up to 2 in 100 people (2%))
- Skin rash on your face and hands, if you accidentally spray on your face or hands (may affect less than 1 in 100 people (<1%))
- Headache (may affect less than 1 in 10000 people (<0.01%))
- Nosebleeds (may affect less than 1 in 10000 people (<0.01%))

In prior medical studies, these side effects were mild and resolved quickly. You should discontinue treatment in case of headache, nose bleed, or persistent burning sensation immediately after use of the study product. If nasal burning persists more than 10 minutes, or the other symptoms are severe or persistent, contact the Oxford ECRAID-Prime team as outlined in **Appendix A**.

The study products we are investigating can have side effects that we do not know about at the moment. Notify the Oxford ECRAID-Prime team as outlined in **Appendix A** if you experience or are concerned about unexpected symptoms.

12. *Will you get the results of the trial?*

We will not personally contact you about the results of the trial. Results of this trial will be published in scientific academic journals that can be accessed, as well as in the European database: https://euclinicaltrials.eu when the summaries become available after the trial is closed. This can take some time (years) after your participation. Findings will also be made available within one year after the trial ends on the Ecraid website: www.ecraid.eu. The information included in any trial publication cannot identify any trial participant.

13. *How will we use information about you?*

We will need to use information from you during the course of your respiratory infection and from your medical records supplied by your GP for this trial This information will include your:

- name, age, sex
- email address, home address, telephone number
- number of hospitalizations and GP consultations
- current and previous health status
    - o symptoms of your respiratory infection
    - o assessments conducted as part of standard of care
- medical information that we collect during the trial
    - o the types of treatments you received as part of usual care.

People will use this information to do the research or to check whether 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. Some of your information will be sent to countries outside the UK. They must follow our rules about keeping your information safe. Once we have finished the trial, 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 trial.

As part of the trial recruitment process we may need to view your general practice and hospital medical records, for example Summary Care Records (SCR) in England, to check your medication, allergies, adverse reactions and 'Additional Information' to make sure that it is safe for you to take study 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, and vaccinations you have had in the past. SCRs can be seen and used by authorised staff in other areas of the health and care system involved in your direct care. The table below gives you an overview of the type of medical records in each of the 4 nations of the UK.

For participants in England	Summary Care Records (SCR)	https://digital.nhs.uk/services/summary-care-records-scr/summary-care-records-scr-information-for-patients
For participants in Scotland	Emergency Care Summary (ECS)	https://www.communitypharmacy.scot.nhs.uk/nhs-lothian/pages/ecs-emergency-care-summary/
For participants in Wales	GP or Medical Records and information in the Welsh Clinical Portal	https://dhcw.nhs.wales/systems-and-services/secondary-care/welsh- clinical-portal
For participants in Northern Ireland	Northern Ireland Electronic Care Record (NIECR);	https://www.nidirect.gov.uk/articles/northern-ireland-electronic-care-record-niecr

We will ask for your consent to view your medical records. Medical records will not be retained by the trial team. If your summary care record is unavailable or you do not consent for us to access it, you may still take part in the trial as we may be able to assess your eligibility based on the information we received from you directly during the conversation with you (see section 8).

14. What will be done with your data and swabs?

If you agree to participate, you also give your consent to collect, use and store the data captured during inclusion and provided during the trial, as well as the combined throat/nose swabs. This is needed to answer the research questions of this trial and to be able to publish the results. In reports and publications about the trial, nobody will be able to see that you participated, because all data will be fully anonymised.

To protect your privacy, we give a code to your data and swabs, a "participant ID". This process is called "pseudonymisation". When we process your trial data and swabs we always use that code instead of your name. The code in itself contains no specific information about you by which you may be identifiable. We keep the key to that code in a safe place at the trial centre at the University of Oxford. Only the Oxford ECRAID-Prime team will have access to the key of that code. Only your pseudonymised trial data and swab material will be shared with partners in the ECRAID-Prime collaboration.

Where and for how long are your pseudonymised data stored?

Your pseudonymised trial data will be stored for 25 years in a centralised secure database at UMCU in the Netherlands.

Where do we store/process your swabs?

Your swabs will initially be stored at a local laboratory and, at a later stage, transported to the Laboratory of Medical Microbiology of the University of Antwerp for analysis. Your swabs will be stored for 25 years in the "Biobank Antwerp" (BB190007) which is managed in accordance with the Royal Decree on Biobanks (Belgium). Your swabs will be registered with your participant ID in a fully secure laboratory management system. Your pseudonymised trial data will be linked to your swabs' analysis results, in accordance with General Data Protection Regulation (GDPR) rules.

Who can see your personal information?

Any identifying information such as your name, telephone number, email address and home address will only be accessed by the Oxford ECRAID-Prime team. The provider of the systems to securely store your personal information is called YourResearch (YR) and Castor eConsent based in the Netherlands. Your personal data entered in YR and Castor eConsent will never be exported or linked to any other database system used to store your pseudonymised trial data. At the end of the trial the data held in YR and Castor eConsent will be deleted. The system administrators will not have access to any of your personal information.

Some designated people will be able to see your data, including the data which is not pseudonymised. This is necessary to check whether the investigators are carrying out the trial properly and reliably, and to be able to run the trial and collect follow-up information. Persons who can have access to your data for review are: 1) A so-called monitor checking data on behalf of UMCU or Ecraid; 2) Auditors or (inter)national supervisory authorities; 3) Members of the Oxford ECRAID-Prime team in order to be able to run the trial and collect follow-up information; 4) Members of a committee monitoring data and safety of the trialThese persons are bound by a confidentiality agreement. These people will keep your personal information confidential.

If you are registered and have an account with a healthcare or research platform like Be Part of Research or TrialeX, you already consented them to collect, store and use some of your personal information (e.g. name, sex, age, address, contact details, gender, ethnicity, location). At the time of registering to the platform, you were made aware that you were not signing up to take part in a specific study when you joined the register and that you were only to be signposted to studies. As you are interested in taking part in ECRAID-Prime, you have been given information how to contact us directly. Your personal information will only be shared with us if you consented when you signed up for ECRAID-Prime.

What happens to your data and swabs if you consent for other research?

Your data and swabs may also be important for other related scientific research following this trial. It is very important to learn more about how various respiratory viruses affect people, change, as well as affect the population. As such, the Sponsor would also like to store your anonyimised trial data and pseudomised swab material for 25 years for other research. In the consent form you can indicate whether you agree to this or not. If you agree, you can always decide later to withdraw your consent for future use at any time. If you do not agree, you can still take part in this trial. If you do agree to have your trial data and swab material stored for other research, your trial data and swab material can be used by the Sponsor to answer related research questions in ongoing observational studies, or future studies. When the Sponsor shares your data with other research institutions for other related scientific research, pseudonymised swab material and anonymised trial data will be shared. Such studies outside the Sponsor need to be approved by an independent ethics committee. The Sponsor will take appropriate measures to ensure that they will protect your trial data and swab materials in the same way that they are protected under the privacy rules of the UK.

Will we send your data to countries outside the European Economic Area?

The European Economic Area (EEA) includes all EU countries, Iceland, Liechtenstein, and Norway. Ecraid includes researchers in Australia, and the UK, which are outside of the EEA. We might send your pseudonymised trial data and swab materials to partners in the ECRAID-Prime collaboration located inside and outside the UK. Other parties such as the study product manufacturer (SaNOtize) which is located outside the UK will only receive anonymized trial data.

15. What are your choices about how your information is used?

You can stop being part of the trial 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. Your pseudonymised data and swab collected up to that point will still be used by the investigators for the ECRAID-Prime trial. They may also be used for other ongoing and possible other studies if you agree to this. Upon withdrawal, you will be asked whether you are okay with the continued use of your swab collected or if you wish for your swab to be destroyed.

If you wish to withdraw from the trial, please contact the trial team immediately using the details in **Appendix A**. You do not have to explain why you want to stop. However, we appreciate hearing why you no longer wish to take part as this helps us to improve our research processes. A decision to withdraw will not affect the standard of care you receive in any way, now, or in the future.

16. What are the possible disadvantages of taking part?

Taking part in the trial can have disadvantages:

- You may experience side effects of the study product, as described in section 11
- There may be a brief period of discomfort from (self-)taking the combined throat/nose swabs
- Taking part in the trial will take up some of your time
- You are expected to comply with the requirements of the trial

17. What are the possible benefits of taking part?

You might benefit from the effects of any study product you could be given. However, you might not receive a study product as part of the trial, and we do not yet confidently know how well any of the study products work. Nevertheless, even though taking part may not benefit you personally, your participation will help researchers and doctors learn about the safety and any benefits from the study products we are testing. Thereby, the treatment of other patients with respiratory infections might be improved. If you participate, it does not necessarily mean that your respiratory infection will recover any faster.

18. When does your participation in the trial end?

1. After follow-up at month 3, or
2. The trial team decides to stop your participation, or
3. You want to stop participating in the trial yourself (see below), or
4. One of the following authorities decides that the trial should stop:
    - European Commission
    - The Medical Ethics Review Committee that reviews the conduct of the trial
    - The UK government.

19. Will you be contacted again for other studies?

You may also be contacted to take part in an interview about your experiences with the consultation and participation in the ECRAID-Prime trial. You are likely to be contacted about 2-4 weeks after your inclusion in the trial. The interview can be done at a time convenient to you either over the telephone, online, such as Teams teleconferencing, or in person if possible. Consent will be obtained verbally, or in writing, at the start of the interview. Interviews will be audio recorded on an encrypted device and sent securely to an independent transcription company (Bristol Transcription Services), who has signed a confidentiality agreement with the University of Oxford. If you are contacted, the Oxford ECRAID-Prime team will provide you with a separate Information Sheet with the specific details of that trial and what it would involve for you.

20. Expenses and Payments

You will not have to pay anything for the study product you might receive as part of the trial. However, you will not receive any payment for taking part. You will be re-imbursed for any travel you do that the trial requires. Please contact the local coordinating team for more information about this. Upon completing the trial you will receive a £20 gift voucher as a thank you for your participation.

21. Who has reviewed the trial?

This trial has been reviewed and was approved by the Independent Ethics Committee in the UK. The Ethics Committee ensures the protection of your safety, rights, wellbeing, and dignity.

22. Are you insured during the trial?

Insurance has been taken out for everyone who takes part in this trial. The insurance pays for damage caused by the trial. You can find more information about the insurance in **Appendix C**. It also says who you can report damage to.

23. What if there are any problems?

If you have general questions or complaints about this programme of work or to exercise your rights as a research participant, please contact the complaints officer at UMC Utrecht. **Appendix A** includes their contact details.

NHS England can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. NHS England is unable to provide information about this trial. If you wish to get in touch with the NHS England team please contact them at england.contactus@nhs.net. If you are making a complaint please state: '**For the attention of the complaints team**' in the subject line.

24. Do you have any questions?

You can ask questions about the trial to the Oxford ECRAID-Prime team.
Appendix A includes the the Oxford ECRAID-Prime team contact details.

Appendices to this information

A. Contact details
B. Trial schedule
C. Information about the insurance
D. Informed Consent Form

Appendix A: Contact details

Sponsor:

University Medical Center Utrecht

Coordinating Investigator: Alike van der Velden, PhD

Phone: +31 (0)6 3111 8081

E-mail: a.w.vandervelden@umcutrecht.nl

Oxford ECRAID-Prime team:

Name: Primary Care Clinical Trials Unit

Phone number: 0800 1380880

Email: ecraid-prime@phc.ox.ac.uk

For complaints:

Should you have any complaints, please, report them to your GP practice or the the Oxford ECRAID-Prime team. If you are dissatisfied how this trial is being carried out and want to submit a complaint, contact the complaint mediators at the University Medical Center Utrecht:

By phone via: +31 (0)88 755 62 08

Online via: https://www.umcutrecht.nl/en/submitting-a-complaint

Information regarding your rights can be found at: https://www.umcutrecht.nl/nl/privacyverklaring

Data Protection Officer:

Email: datasecurity@phc.ox.ac.uk

Data Protection Officer of the University Medical Center Utrecht:

Email: functionaris.gegevensbescherming@umcutrecht.nl

Appendix B: Tests or procedures you will undergo

	1 day prior Day 0	Day 0	Day 1-28																											Month 3
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
Consent	X																														
Questions at screening/eligibility assessment	X																														
BMI	X																														
Clinical assessments[1]	X																														
Taking a nose/throat self-swab		X				X																									
Study product use[2]		X	X	X	X	X	X	X																							
Fill in daily diary (paper or online)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Telephone call																X														X[3]	
Long-term consequences (call or online)																															X
Returning swabs		X				X																									
Returning unused study products									X																						

[1] Clinical assessments exclude body temperature, oxygen saturation, respiratory rate and heart rate when recruit remotely.
[2] Study product use is 7 days, which will start on Day 0.
[3] Only if daily diary is not complete.

Appendix C: information about the insurance

The Sponsor (University Medical Center Utrecht, the Netherlands) of the ECRAID-Prime trial has taken out insurance for everyone who takes part in the trial. The insurance pays for damage in case you have suffered because you participated in the trial. This concerns damage in case you suffer during the trial. You must report damage to the insurer within 12 months.

Have you suffered damage as a result of the trial? Please, report this to this insurer:

The insurer of the trial is:	
Name:	MCI Life Sciences & Healthcare Consortium 4985 Lloyd's
Address:	Medical & Commercial International Limited, 1st Floor, 145 Leadenhall Street, London, EC3V 4QT
Telephone:	+44 (0) 7718563782
Policy number:	MCIROW23003
Contact person:	Dan Starmer

The claims representative of the trial is:

Name: Andrew Missen

Address: 1st Floor, 3160 Park Square, Birmingham, B37 7YN

Email: Andrew.missen@uk.sedgwick.com

Telephone number: +44 (0) 7803211700

Appendix D: Informed Consent Form

PROTOCOL TITLE: European Clinical Research Alliance on Infectious Diseases – PRIMary care adaptive platform trial for pandemics and Epidemics

ECRAID-Prime: Informed Consent Form

Local/National Ethics Committee Number: 23/LO/0892 **IRAS Number: 1008573**

Chief Investigator: Professor Christopher Butler **Participant ID:**

	If you agree, initial the box
1. I confirm that I have read and understood the Participant Information Sheet version ……., dated …… for this trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. My data and swabs collected until withdrawal can be used for the ECRAID-Prime trial.	
3. I understand that data collected during the trial may be looked at by authorised individuals from the host organizations, regulatory authorities, and ECRAID-Prime for research purposes. I allow these individuals access to my trial data.	
4. I understand that throat/nose swabs will be (self-)taken and stored in a licensed biobank in Antwerp for analysis and further research, and that I will not receive the results of these analyses. I understand I will not gain any direct personal benefit from this, or financial compensation.	
5. I understand that my pseudonymised trial data and throat/nose swabs collected during the trial will be stored and used within the scope of ECRAID-Prime.	
6. I understand that my anonymised trial data collected during the trial will be shared outside Ecraid within the scope of ECRAID-Prime.	
7. I understand that I will be required to provide information to the Oxford ECRAID-Prime team via a diary and potentially telephone questionnaires. I understand that this will require me to provide my contact details to the Oxford ECRAID-Prime team and these contact details may be stored securely and by the Oxford ECRAID-Prime team.	
8. I have had enough time to think about it and talk about it with a confidant (e.g. friends, family, doctor).	
9. I agree to take part in this trial.	
10. OPTIONAL: understand that members of the Oxford ECRAID-Prime team may view my general practice and hospital medical records, including the summaries of my medical records, to check my medication, allergies, adverse reactions, and additional information to make sure that it is safe for me to participate in the trial. I give permission for these individuals to access my medical records for this purpose.	Yes ☐ No ☐
11. OPTIONAL: My pseudonymised trial data and throat/nose swabs collected during the trial may be stored and used for *other* health, medical, or biomedical research related to infectious diseases within the ECRAID-Prime collaboration to gain a better understanding of the disease, its treatment and the response to that treatment.	Yes ☐ No ☐

12. OPTIONAL: My anonymised trial data and pseudonymised throat/nose swabs collected during the trial may be used for other health, medical, or biomedical research related to infectious diseases outside the ECRAID-Prime collaboration.	Yes ☐ No ☐
13. OPTIONAL: I give consent to be contacted to take part in a telephone or online interview about my consultation and participation in this trial. I understand giving consent to be contacted does not commit me to taking part in an interview.	Yes ☐ No ☐

Participant First name and Surname: ……..

Signature: …… Date : __/__/__

I declare that I have fully informed this trial participant about the trial mentioned.

If any information becomes known during the trial that could influence the trial participants' consent, I will let this trial participant know in good time.

Oxford ECRAID-Prime team member name: .....

Signature:…… Date: __/__/__

You will have the opportunity to print a copy of this consent form after submission. Please let the Oxford ECRAID-Prime team member know if you would like a copy sent to you.

By submitting, I confirm that I am the person whose name is stated above.