PROTOCOL TITLE: Perpetual Observational Study of Acute Respiratory Infections in primary care settings across Europe (POS-ARI-PC)

Adult Participant Information Sheet

We would like to ask you to take part in an observational study; your participation is entirely voluntary. You have received this invitation because you have contacted your GP about a respiratory infection. Participation in this study will not change your care in any way. You can read about the study in this Information Sheet. Please take time to read the following information carefully and decide if you wish to take part.

If you have been asked to take part in the POS-ARI-PC-001 study, please read the Study-specific Appendix 1 on page 7 for complete information.

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

This study is being sponsored by the European Clinical Research Alliance on Infectious Diseases (Ecraid) Foundation, in the Netherlands, in collaboration with the University of Oxford. This study is being managed by the ECRAID-Base consortium. ECRAID-Base works to identify, prevent, and treat infectious diseases in Europe, in this study and other related studies. Funding for this study has been provided by the European Union's Horizon 2020 research and innovation programme.

2. Who will be recruited to the study?

This study will enrol patients with an acute respiratory infection (ARI) in several countries in Europe. You are being invited to take part because you have visited or contacted your GP with symptoms suggestive of a respiratory infection.

3. What is the POS-ARI-PC study?

The POS-ARI-PC study is a perpetual (long-lasting), observational study (POS), with the aim of describing the nature of ARI in adults and children presenting to primary care (PC) across Europe. Additionally, the study aims to establish a research-ready infrastructure for further studies to investigate how to treat, diagnose and prevent ARI. This approach makes it possible to set up new studies much faster.

4. What is the purpose of the POS-ARI-PC study?

Respiratory infections are one of the most common reasons for patients to visit their GP. Gaining a full understanding of the causes of respiratory infections, and how people with respiratory infections are treated and recover will help identify best practice, with the goal of ultimately improving patient care.

5. How long will participation in the study take?

Your participation in the study will last for 28 days. We will ask you to tell us about how you are feeling today and for the next 14 days via a daily diary. We might telephone you to ask you some questions if you are unable to complete the daily diary. We will contact your GP after day 28 to collect information about consultations and hospital referrals in the 28-day period.

6. What will happen to you if you take part?

Informed Consent

You will be given time to consider whether or not to take part in this study. You will be able to speak to (by telephone if they are not with you) friends or family members if you wish to discuss taking part with others. If you would like to take part, you will be asked to complete a consent form; this may be in writing or verbally. A member of the study team will go through the consent form with you. You will receive a copy of your consent form.

Initial Questionnaire

A member of the study team will complete a short questionnaire collecting your name and contact information, some details about you, and the symptoms you have been experiencing.

Sample

A combined throat/nose swab will be collected from you to determine the cause of your ARI. The swab will be sent to a local laboratory where it will be frozen, it will then be transported to our central laboratory in Antwerp for analysis at a later date. You will not receive the results of this swab.

Follow-Up

The study team will give you a paper diary or link to an online diary, as you prefer. They will explain how to complete the diary and answer any questions. You will be asked to complete the diary for 14 days starting on the day you consulted with your doctor about this ARI. It should take no more than five minutes to complete the diary each day.

The diary will include questions about your illness, symptoms, and recovery. If you have completed a paper diary then you will be provided with a stamped addressed envelope to return it to the study team once completed. These data will then be entered into an online database by the study team. If you complete your diary online this will automatically be entered into the online database each day.

If the study team has not received your diary after 14 days they will contact you by phone to ask you a brief set of questions at some point in the next 10 days. The telephone call will last no more than five 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 14 days. We may also send you text reminders to complete the daily diary on the first day of your participation in the study and on Day 7 and Day 14. However, you will have the opportunity to opt out of this if you wish.

On or after day 28 we will ask your GP to access your medical records to collect information about additional GP consultations for ARI and whether you were hospitalized.

7. What is the difference with standard care?

Participation in the study will not affect the care you receive and will not replace any standard care. We will take a combined throat/nose swab to determine the cause of your ARI. If you decide not to participate in the study, your care will not be affected in any way.

8. How will we use information about you?

We will need to use information from you during the course of your ARI, and from your medical records supplied by your GP for this study. This information will include your:

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

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. 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 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.

9. What will be done with your data and swab?

If you agree to participate in the study, you also give your consent to collect, use and store the data that were captured during inclusion, those you provided during the study, and the combined throat/nose swab. This is needed to answer the research questions of this study and to be able to publish the results. Your data and swab will have a code number. This process is called “pseudonymisation”. When we process your study data and swab we always use that code instead of your name. We keep the key to that code in a safe place at your GP’s practice or at the study centre. Only your pseudonymised study data and swab material will be shared within and outside ECRAID-Base. Your pseudonymised study data and swab can be used by ECRAID-Base and its collaborators, which can include commercial companies, to answer related research questions in future studies.

When we share your data outside ECRAID-Base, or with commercial companies, pseudonymised swab and study data will be shared. Any studies or projects outside ECRAID-Base need to be approved and will be listed on the Ecraid website: www.ecraid.eu.

10. Where and for how long are your pseudonymised data and swab results stored?

Your pseudonymised study data will be stored for a maximum of 25 years in a secure database in the Netherlands managed by UMCU. Long-term storage of your pseudonymised data and swab results may help researchers understand how different people respond to the same infections over time, or how the infectious disease itself changes over time. This understanding might help to modify diagnostic or treatment strategies, or develop new treatments.

11. Where do we store/process your swab?

Your swab 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 swab will be stored for 25 years in the "Biobank Antwerp" (BB190007) which is managed in accordance with the Royal Decree on Biobanks (Belgium). Your swab will be registered with your study ID in a fully secure laboratory management system. Your pseudonymised study data will be linked to your swab's analysis result, in accordance with General Data Protection Regulation (GDPR) rules.

12. 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. Your pseudonymised data and swab collected up to that point will still be used by the investigators for POS-ARI-PC, and potentially future studies. If you wish to withdraw from the study, please contact the study team immediately using the details below. 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.

Upon withdrawal, you will be asked whether you are okay with the continued use of your data and swab collected until that point, or if you wish for your data to be deleted and swab destroyed.

13. Will you get the results of the study?

We will not contact you to tell you the results of the study. Results of this study will be published in scientific academic journals that all can access, and will be made available on the Ecraid website: www.ecraid.eu. No information that could be used to identify any study participant will be included in any study publication.

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

You can find out more about how we use your information by sending an email to the ECRAID-Base Consortium (ecraid-basecoordination@ecraid.eu).

15. Who can see your personal information?

Any identifying information such as your name, telephone number, email address, and home address will only be stored at your GP's practice and by the local study team. The provider of the system to securely store your personal information is called YourResearch (YR) and is based in the Netherlands. Your personal data entered in YR will never be exported or linked to any other database system used to store your pseudonymised study data. At the end of the study the data held in YR 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 identifying information such as: 1) A monitor on behalf of Ecraid; 2) Members of the local study team in order to be able to run the study and collect follow-up information; 3) Auditors or (inter)national supervisory authorities. These people will keep your personal information confidential.

16. Will we send your data and swab to countries outside the European Economic Area?

The European Economic Area (EEA) includes all EU countries, Iceland, Liechtenstein, and Norway. ECRAID-Base includes researchers in Australia, and the UK, which are outside of the EEA.

We might send your pseudonymised study data and swab material to ECRAID-Base members and non-ECRAID-Base members located inside and outside the UK. We will take measures to ensure that they will protect your study data and swab material in the same way that they are protected under the privacy rules of the UK.

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

It is not anticipated that there are any risks involved in taking part in the study.

18. What are the possible benefits of taking part?

You may not personally benefit from taking part, but you will help researchers and doctors learn more about the presentation and treatment of people with respiratory infections.

19. When does your participation in the study end?

1. After 28 days of follow-up, or
2. The study team decides to stop your participation, or
3. You want to stop participating in the study yourself (see below), or
4. One of the following authorities decides that the study should stop:
    - European Commission
    - The Medical Ethics Review Committee that reviews the conduct of the study
    - The government in your country

20. Will you be contacted again for other studies?

You may also be contacted to take part in a telephone or online interview about your experiences with the consultation and participation in the POS-ARI-PC. If so, your local study team will provide you with a separate Information Sheet on that study, with the specific details of that study and what it would involve for you.

21. Expenses and Payments

We will be unable to provide expenses or payments as part of this study.

22. Who has reviewed the study?

This study has been reviewed and was approved by the Medical Ethics Review Committee in your country. The Ethics Committee ensures the protection of your safety, rights, wellbeing, and dignity.

23. Are you insured during the study?

Taking part in the study does not change your care in any way. Your participation in the study has no additional risks. That is why Ecraid does not have to arrange insurance for participants.

24. 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 ECRAID-Base Consortium (ecraid-basecoordination@ecraid.eu).

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 research study. 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.

25. Do you have any questions?

If you would like to take part in the study or if you have any further questions please do not hesitate to get in touch with the researcher using the contact details below.

Contact details of the coordinating team in United Kingdom:

Name: ECRAID-Base Study Team, Primary Care Clinical Trials Unit, Nuffield Department of Primary Care, Health Sciences, University of Oxford

Address: Gibson Building 1st Floor, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG

E-mail: ecraid-base@phc.ox.ac.uk

Telephone: 08001380880

Thank you for your attention.

Study-specific Appendix 1:

Participant Information for the study POS-ARI-PC-001

Study on the incidence of medically-attended respiratory syncytial virus, human metapneumovirus, human parainfluenza virus and rhinovirus amongst older adults in Europe

Who is funding the POS-ARI-PC-001 study?

The study POS-ARI-PC-001 is a collaboration with the French pharmaceutical company called Sanofi. The funding is provided by Sanofi.

What is the purpose of the POS-ARI-PC-001 study?

Respiratory viruses, like respiratory syncytial virus (RSV), human parainfluenza virus (HPIV), human metapneumovirus (HMPV) and rhinovirus (RV), seriously impact health during the winter season. These viral respiratory infections often present like a common cold. But unlike a cold, such infections can progress to become a serious lung infection and cause complications like pneumonia and even death, particularly in high-risk patient groups. Sanofi is developing a combination vaccine that prevents infection and/or serious infection with these viruses.

This POS-ARI-PC-001 study will help to determine the incidence and health impact of these viruses in an older patient population in up to five European countries.

What will happen to you if you take part?

Study procedures will be the same as described in the Participant Information for the POS-ARI-PC, with a few exceptions.

Informed Consent

You will be asked to sign an additional Informed Consent for the study POS-ARI-PC-001.

Follow-Up

You will be given the choice whether or not you would like to continue in the follow-up procedures via a daily diary and your GP practice. Please indicate your decision on the consent form.

In addition to the normal diary, you will be asked to complete the health-related Quality of Life Questionnaire on Day 7 and Day 14; this additional questionnaire should take about 2 minutes to complete.

If you are not recovered from the ARI at Day 14, the study team will contact you by phone again on Day 28 (up to 7 days before or after) to find out when you felt recovered. You may receive a text message in the next 7 days to inform you in advance that we will call you.