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PROTECT-CH
Prophylactic Therapy in Care Homes Trial

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General Practitioner (GP) Training Module

Final version 1.0 11-Aug-2021

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GP Training Module Overview

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This training module includes the following sections:

1. Brief overview of the trial
2. The role of the GP in PROTECT-CH
3. Therapy (Background and Safety)
4. Eligibility
5. Data Entry - 5.1. Eligibility Assessment;
   5.2. Summary Care Record
6. Safety
7. Data Protection & Confidentiality
8. Good Clinical Practice
9. Record Keeping
10. Final Reminders
11. Self-certification Link & Team Contact Info

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1. Brief overview of the trial

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Impact of COVID-19 on Care Homes

- Major cause of illness
- Major cause of disability
- Major cause of death (more than 42,000 deaths in care homes)
- Major impact on normal care and life in the home
- Limits visits from family and friends
- Impacts on quality of life and mental health of residents and staff

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PROTECT-CH is a platform trial set up to test several medicines to see if they:

Reduce the number of residents infected with COVID-19

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PROTECT-CH is a platform trial set up to test several medicines to see if they:

Reduce the number of residents infected with COVID-19

AND

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PROTECT-CH is a platform trial set up to test several medicines to see if they:

Reduce the number of residents infected with COVID-19

AND

Reduce the severity of the disease and deaths of residents from COVID-19

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...with the **aim** to find

which medications given to prevent COVID-19 infection (following an outbreak within a care home) are the most effective compared to usual care.

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Why is it important?

Despite excellent progress with vaccinations:

- Individuals may still contract the virus due to immunosenescence (changes to the immune system's function due to age).
- Staff vaccination is still suboptimal in many parts of the country.
- New variants are in circulation overseas and in the UK.

- Most models suggest that COVID-19 will become endemic in care homes

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Residents who agree to take part will be allocated as a group to either:

Trial medication plus standard care

OR

Standard care alone (No trial medication)

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2. What is the role of the GP in PROTECT-CH?

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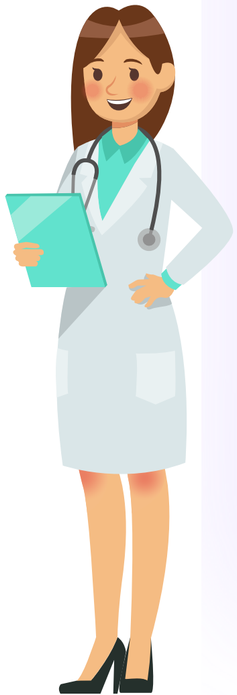
- The main role of the GP in PROTECT-CH is to assess the residents' eligibility to take part. You may see this referred to as Eligibility Stage 1

NEXT

- You may also need to report a Serious Adverse Event or be asked to provide information to the trial doctors, known as Principal Investigators (PIs), in relation to reported Serious Adverse Events. The data you provide will help them with their assessment of causality for the event.

See 'Safety' section of this module for further information.



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3. Therapy (Background & Safety)

Prescribing of trial medication will be the responsibility of the on-duty Principal Investigator (PI).

Once a care home has been randomised, each eligible participant will need to be prescribed the correct trial medication:

- Each participant in a care home randomised to **Ciclesonide**:

  Treatment: 2 x Ciclesonide 160 micrograms per actuation inhaler

  Dosage: Using the spacer device and technique described in the leaflet, inhale ONE puff through the NOSE followed by TWO puffs through the mouth. If you cannot inhale the first dose through your nose, only inhale the two puffs through your mouth.

- Each participant in a care home randomised to **Niclosamide**:

  Treatment: 3 x 8.5 mL Niclosamide ethanolamine (UNI911) 1% (10 mg in 1 mL) nasal spray

  Dosage: ONE spray to be used in EACH nostril TWICE a day

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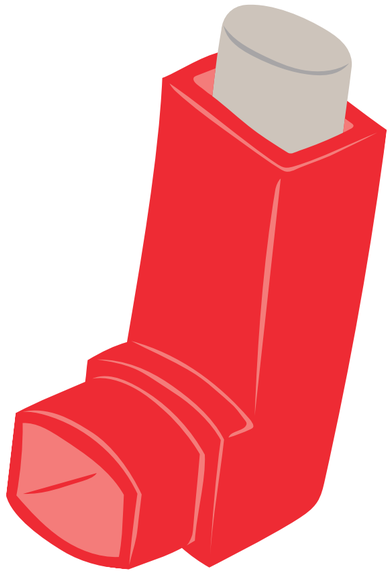
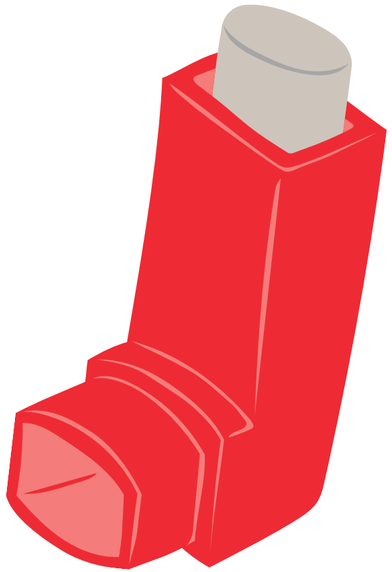
Ciclesonide



- **Ciclesonide** (by inhalation of aerosol) is currently licensed in the UK as a treatment to control persistent asthma in adults and adolescents (12 years and older). Ciclesonide is not licensed for COVID-19 prophylaxis.
- Ciclesonide has been shown to block SARS-CoV-2 RNA replication by targeting the viral replication-transcription complex and inhibiting SARS-CoV-2 cytopathic activity.
- The product being supplied for use in the trial is an unlicensed formulation identical to that of the UK licensed formulation (Alvesco).
- One puff via spacer and mask through nose (where possible) followed by two puffs via spacer and mask through mouth should be administered once daily.
- Further information on Ciclesonide is available in Appendix A of the protocol and the Alvesco SmPC.

Ciclesonide



Appox 5% of patients experienced adverse reactions in clinical trials with Alvesco.
In the majority of cases these were mild and did not require discontinuation of treatment (refer to section 4.8 of Alvesco SmPC for more details).

Side effects sometimes reported with nebulization procedures include bronchospasm and coughing.

Ciclesonide: Exclusions & Contraindications

1. Already taking, or definite need for, an inhaled or intranasal corticosteroid: beclometasone dipropionate (aerosol inhaler and dry powder inhaler), budesonide (dry powder inhaler and single-dose units for nebulization), ciclesonide (aerosol inhaler), fluticasone propionate (dry powder inhaler, aerosol inhaler, and single-dose units for nebulization), mometasone furoate (dry powder inhaler).

2. Known allergy/hypersensitivity to ciclesonide or any excipient.

Ciclesonide: Exclusions & Contraindications

3. Received a live vaccine within last 14 days - ciclesonide increases risk of generalised infection: influenza*, MMR, rotavirus, typhoid, varicella-zoster (shingles), yellow fever.

*Influenza live vaccine is not indicated for older people.

4. Severe liver impairment.

Participants will be made aware that the Ciclesonide formulation contains a small amount of ethanol.

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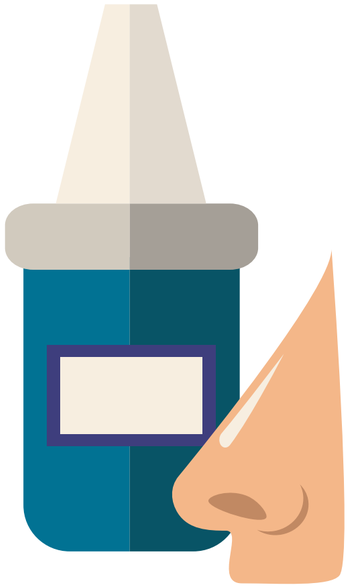
Niclosamide

- Recent studies have shown **Niclosamide** may be a potential treatment for viral infections such as SARS-CoV-2 (COVID-19).
- SARS-CoV-2 initially replicates predominantly in the nasal cavity so the administration of Niclosamide as a nasal spray may be an effective post-exposure prophylactic for early-stage infection when the viral load is the main issue.
- Niclosamide is not licensed for COVID-19 prophylaxis but is approved and marketed overseas for the oral treatment (at 500x dose of that used in PROTECT-CH) of tapeworm infections.
- In PROTECT-CH, one intranasal spray should be administered into each nostril twice daily.
- Further information on Niclosamide is available in Appendix B of the protocol and the investigators brochure.

Niclosamide



Niclosamide has previously been administered as oral tablets. Side effects of the nasal spray are not yet known.

The occasional side effects reported for the oral tablet are detailed below.
These are not expected when using the nasal spray.

Allergic reaction (e.g. patches of skin redness (erythema), itching (and skin rash), nausea, gastrointestinal pain, abdominal pain, gagging, diarrhoea, dizziness, blue colour to skin or lips (cyanosis), excessive sweating (hyperhidrosis) and fatigue.

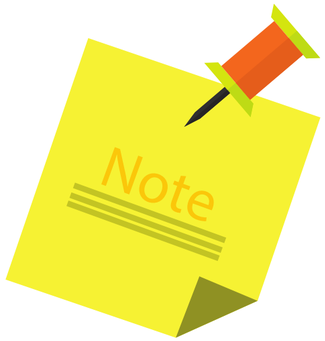
Niclosamide: Contraindications & Anticipated Side Effects

Contraindications

Known allergy
to niclosamide or excipients

Anticipated side effects

Although these are not known, we anticipate nasal itching, nasal irritation, nasal crusting, nasal drip and nasal bleed.



Additional medications may be added during the trial.
In this case, participants and their personal legal representatives (for those participants lacking capacity to consent for themselves) will be reconsented for the additional medications and
the trial team will contact you to ask you to assess eligibility for the new treatments.

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4. Eligibility

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Eligibility Assessment

1. Care Home staff perform initial screening for eligibility.

2. GPs assess eligibility following consent.

3. PIs confirm eligibility following a COVID-19 outbreak.

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Eligibility Stage 1

Once residents have been screened by care home staff and they or their legal representatives have consented to taking part, you will receive a notification asking you to assess their eligibility (Stage 1 eligibility check) in order to determine if the residents are suitable to be included in the trial.

You are asked to assess their eligibility against the following criteria:

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Resident Exclusion Criteria

- Identified by care home staff to have entered end-stage palliative care.
- Resident in care home for short-term respite care.
- Resident’s general practitioner is unable to support their involvement in the trial.

5. Data Entry -
5.1. Eligibility Assessment

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Eligibility Stage 1

- **When is eligibility (Stage 1) scheduled to take place?**

Once the resident or legal representative has given informed consent.

- **How will I be notified that consent has been given?**

You will receive an automatic notification from the PROTECT-CH trial mailbox to the email address you have provided.

- **What do I do next?**

You will need to log in to the secure trial database (REDCap) to perform the eligibility check.

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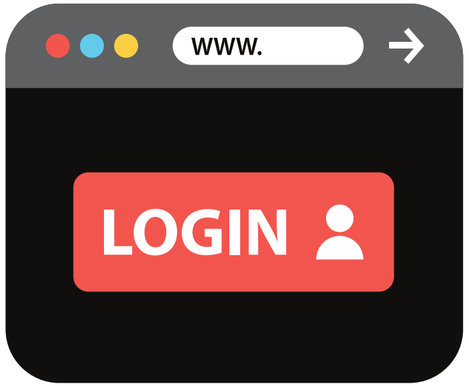
Logging onto the trial database



You will need to complete a database access form in order to be granted permission to access the PROTECT-CH trial database, known as REDCap.

A personal login will be provided.

The trial database can be accessed via the following link:

https://redcap01.nottingham.ac.uk/

or

by scanning this QR code from a mobile device:

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Entering eligibility data on the trial database

- The email notification you receive, after a resident has consented, will contain a link to the GP eligibility report in the trial database.
  The email will also include a link to the Safety Reporting section of the database, should you need to report any serious adverse events during the trial.

- It is recommended that you bookmark both links for future reference.

- You should click the link to the eligibility report in the email, where you will be prompted to enter your trial database login credentials in order to access the eligibility report.

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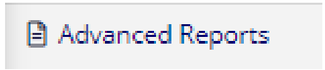
GP eligibility report

The GP eligibility report will display all residents under your care who have given their consent to participate in PROTECT-CH.

Under the 'Eligibility' column, you will see the results of any eligibility checks that you have already completed.

SITE_ID	RECORD	RESIDENT	DOB	NHS	GP_Email	Eligibility	Sign_Date	PDF	Vault
00001	P00001-001	Res1 Online	1939-02-09	1111111111	msznc@nottingham.ac.uk	Either Ciclesonide or Niclosamid	2021-05-24	download	click here
00001	P00001-002	PLR Online	1934-05-09	1222222222	msznc@nottingham.ac.uk	Neither Ciclesonide nor Niclosamide	2021-05-25	download	click here
00005	P00005-001	Res Paper	1923-05-01	5111111111	msznc@nottingham.ac.uk	Niclosamide	2021-05-24	download	click here
00005	P00005-002	Res2 Paper	1944-05-03	3333333333	msznc@nottingham.ac.uk	GP Confirmation Of Eligibility			

For outstanding eligibility checks, 'GP Confirmation of Eligibility' will be displayed in the 'Eligibility' column. You must click on this to access the eligibility form.

To navigate back to this report at any time, click 

in the menu on the left of the screen in the trial database.

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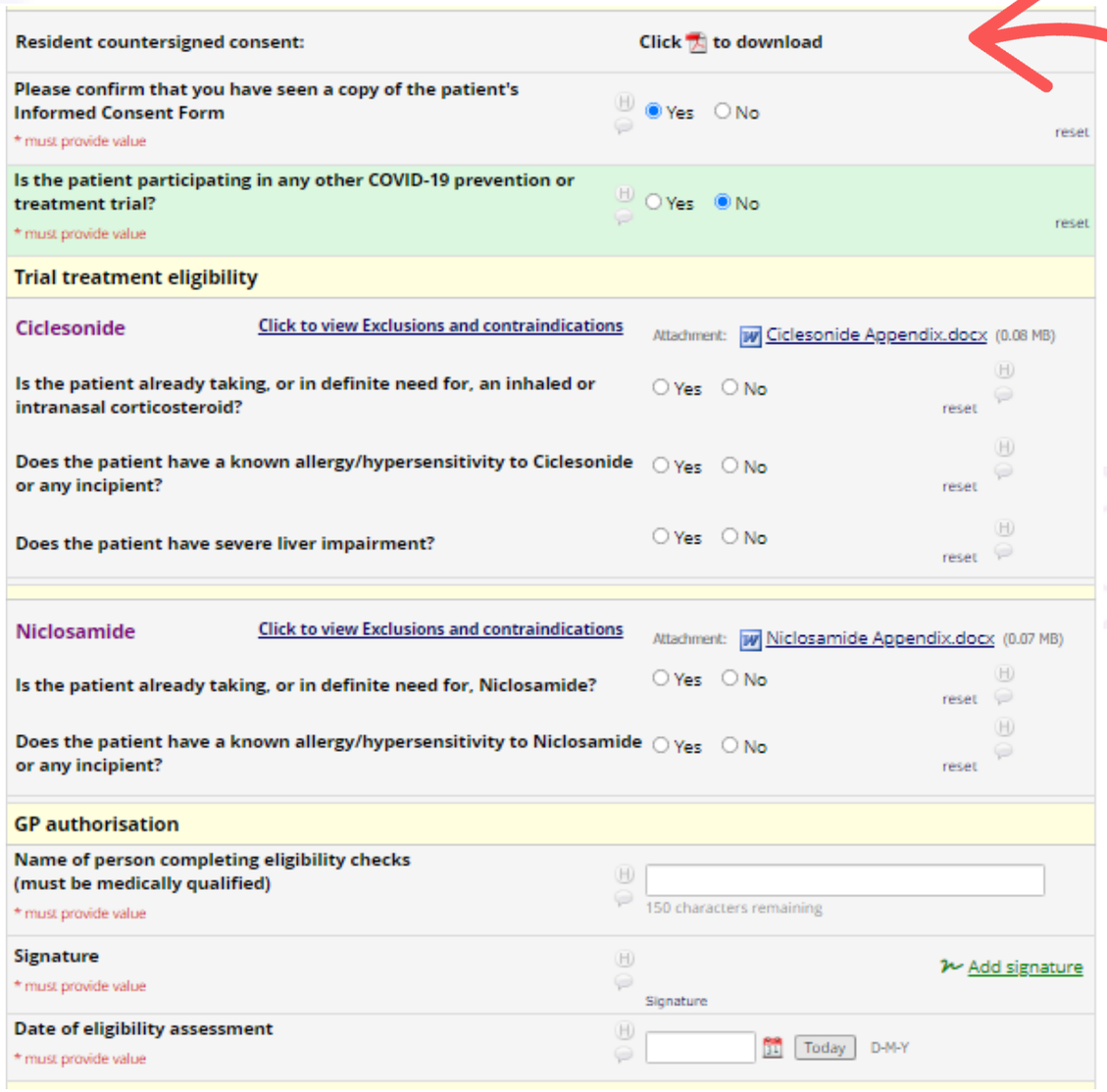
Eligibility form



- A copy of the participant's consent form is available by clicking here.

<u>You must confirm you have reviewed this form</u>.

If the resident/Personal Legal Representative (PLR) has signed a paper version of the consent form, there will be two document links, one with the resident/PLR signature and one with the research nurse countersignature.

- Answer all questions.

- Complete the sign off section at the end, mark as complete and save.

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If the resident is not eligible, there is nothing further to do.

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5. Data Entry -
5.2. Summary Care Record

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If the resident is eligible,
you or a member of your team, will need to upload their Summary Care Record (SCR) onto the PROTECT-CH Documents Vault.

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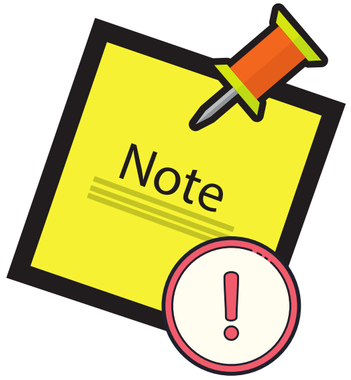
Summary Care Record (SCR)

The SCR is a .pdf version of **your patient's medical history** and should include the following:

- demographics
- active problems
- significant past problems
- current medication
- allergies
- latest lab tests (including blood count, and liver and renal function)

This can be generated by your clinical system and should be accessible when you need to upload the SCR to the Vault.



The **eligibility assessment must be done by a medically qualified GP**, but the SCR can be uploaded by another practice staff member.

Regardless of the role, all must have completed this training module.

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The PROTECT-CH Documents Vault

The PROTECT-CH Documents Vault is an encrypted system separate to the trial database (REDCap).

It is a secure vault that will contain the Summary Care Records (SCRs) uploaded by the residents' GPs and the Medical Administration Records (MARs) that will be uploaded by the care home staff.

When the first resident is consented at a care home that is within your care, you will receive an email notification with a link to follow in order to set up access to the Vault.

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Accessing the PROTECT-CH Documents Vault

In the first instance, you will receive an email with a link to the Vault, where you will be asked to set your password.

Once you have set your password, you may access the vault via the following link:
https://protect-vault.nottingham.ac.uk/
or by scanning this QR code from a mobile device:

PROTECT-CH Documents Vault

There will only be **one login per GP practice**.
The GP or an appropriate member of practice staff (identified by the GP) should hold the login details. These must not be shared with anyone outside the practice.

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PROTECT-CH Documents Vault

Click on the 'Participant ID' that matches the resident that you have confirmed as eligible.

Please select a PROTECT-CH participant for which the summary care records are to be uploaded.

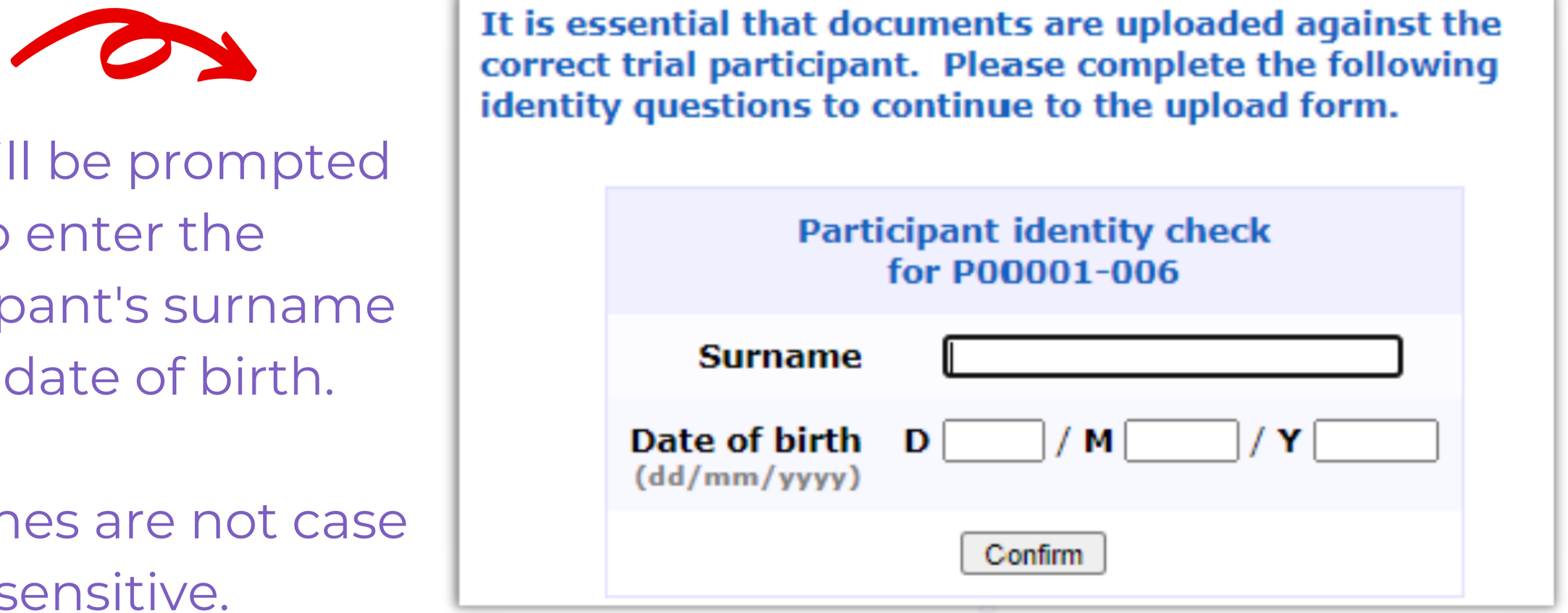
Participant ID	Initials	Documents uploaded
P00001-001	R-O	-
P00001-002	P-O	-
P00005-001	R-P	-

Uploaded documents will be encrypted and can only be viewed by trial office staff.

PROTECT-CH Documents Vault

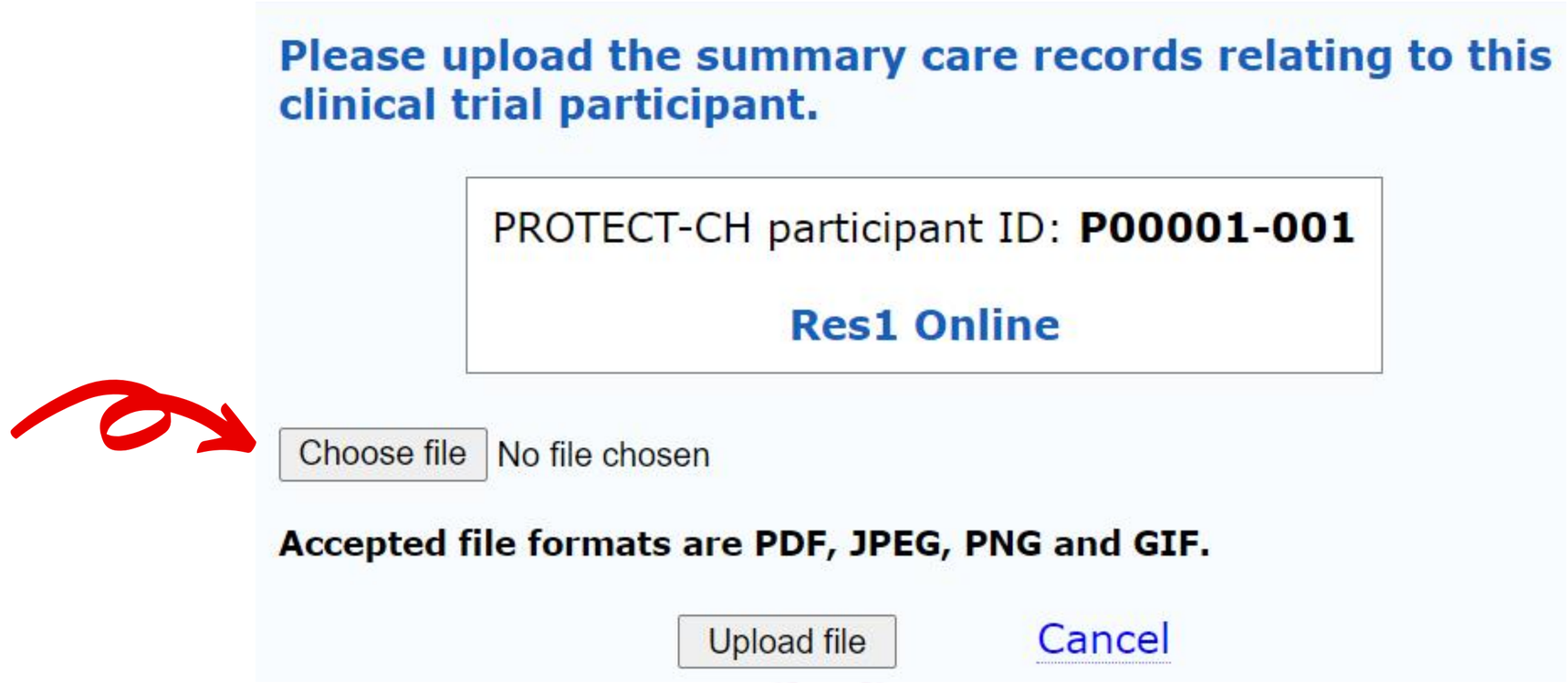
You will be prompted to enter the participant's surname and date of birth.

Surnames are not case sensitive.



PROTECT-CH Documents Vault

Click 'Choose file' to select the SCR document from your computer (a PDF file is advised).

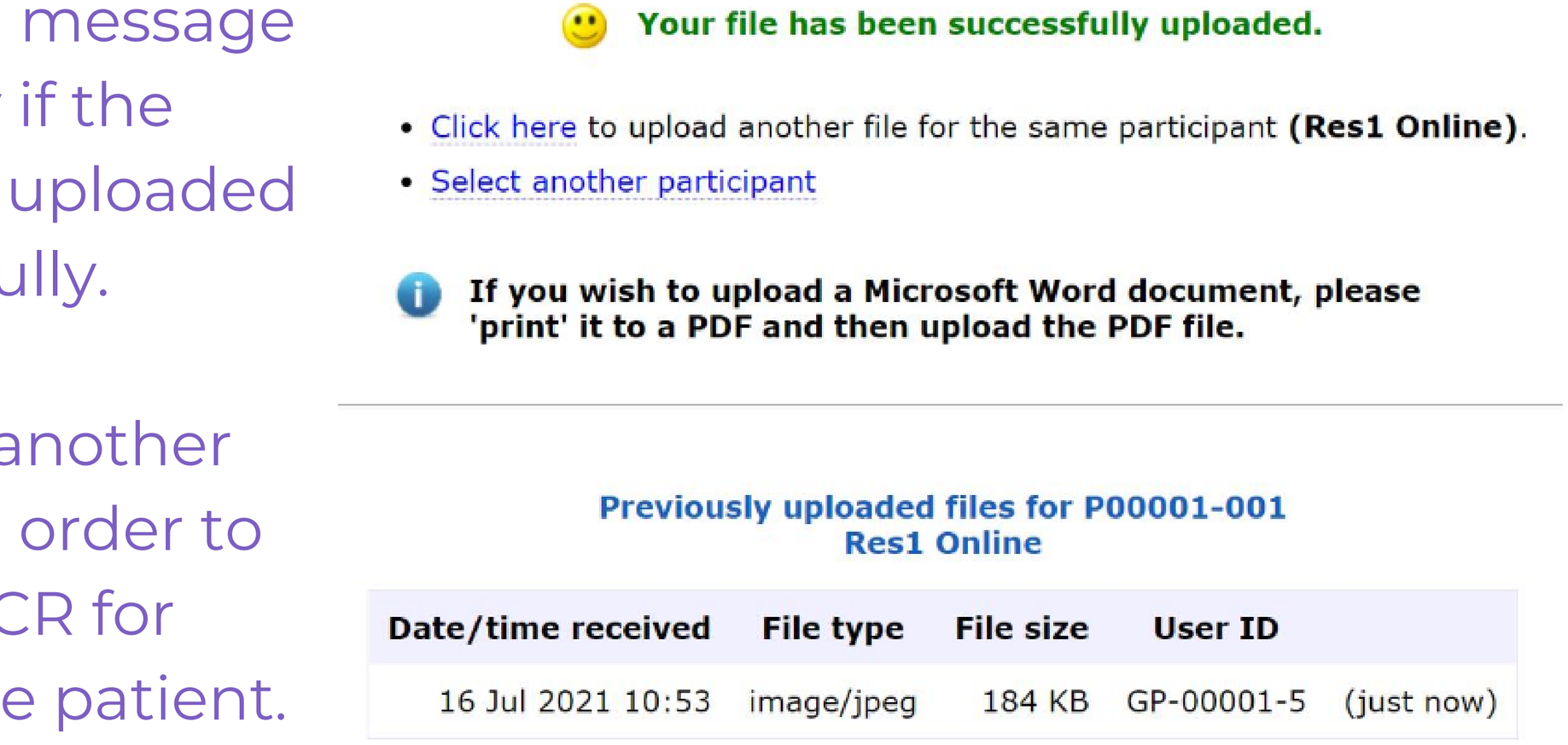


Click 'Upload file'.

PROTECT-CH Documents Vault

A confirmation message will display if the document has uploaded successfully.

Click 'Select another participant' in order to upload a SCR for another eligible patient.



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Notification of Eligibility Assessment Outcome

Personal Legal Representatives of residents lacking capacity to consent for themselves will be notified of the outcome of your eligibility assessment via email.

For residents with capacity, care home staff will be informed of the outcome of your assessment via email and will be responsible for relaying the information to the residents.

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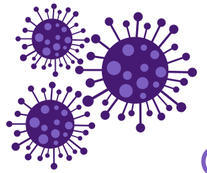
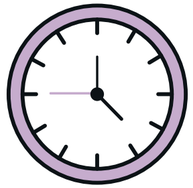
What happens next?



Randomisation of the care home will only occur once a case of COVID-19 (staff or resident) is identified in the home (outbreak).



Once residents' eligibility has been assessed and confirmed by GPs a significant amount of time may pass before an outbreak occurs.

A trial PI will assess eligibility again (stage 2 eligibility check) at the point of outbreak using the information you provided in the trial database, the uploaded Summary Care Record (SCR) and the Medication Administration Record (MAR) provided by the care home.

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Will I be notified of the randomisation outcome?

If the resident is eligible and is randomised, you will receive an email notification from the PROTECT-CH trial team.

The notification will include information on the group (trial medication + standard care or standard care alone) your patient has been allocated to.

6. Safety

Safety reporting

- The safety of trial participants is paramount when conducting a clinical trial.
- Safety monitoring requires the reporting of any untoward medical occurrences that trial participants experience during the course of a trial.
- These untoward medical occurrences, or adverse events, must be closely monitored to ascertain whether there is any possible relationship with the trial medication(s).

Terminology

- Adverse Event (AE) - any untoward medical occurrence (unfavourable sign, symptom, laboratory finding, disease) in a patient administered with a pharmaceutical product whether related to the product or not.

- Serious Adverse Event (SAE) - any AE that:
  - results in death;
  - is life-threatening;
  - requires hospitalisation or prolongation of existing hospitalisation;
  - results in persistent or significant disability or incapacity; and
  - consists of a congenital anomaly or birth defect.

Terminology

- Serious Adverse Reaction (SAR) - any SAE that is deemed to be related to the trial treatment by an assessing medically-qualified person.
- Suspected Unexpected Serious Adverse Reaction (SUSAR) - any SAR that is deemed to be unexpected by an assessing medically-qualified person, because its nature or severity is not consistent with the product/treatment information.

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Important note

Adverse events are common in this population due to the range of comorbidities, therefore events that are expected for this population should not be reported.

Events that do not need to be reported are:

Agitation	Allergic reaction (not related to trial medication)
Bowel obstruction	Confusion
Bruising, ecchymoses	Delirium
COVID-19 (part of the primary outcome)	Diarrhoea during confirmed norovirus or C. Diff outbreak
Dehydration	Heart failure, volume overload
Fall with injury, with/without fracture	Hypotension
Hypoglycaemia	Medication (non-trial) error
Incontinence (urinary, bowel)	Pressure ulcer
Nursing care, missed	Sepsis, bacteraemia
Respiratory infection (non-COVID-19)	Suicide, attempted suicide, self-harm
Skin tear, abrasion, breakdown	Urinary tract infection, with/without catheter
Surgical/procedural site infection	Vomiting during confirmed norovirus outbreak
Venous thromboembolism	

Similarly, diagnoses present at baseline (including any worsening of that condition) and known co-morbidities will not be reported.

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Safety reporting - Roles and responsibilities

Role	Responsibilities
Care home staff	Oversight of resident safety Reporting a weekly summary of adverse events for each resident via the 'weekly data' form of the database Timely reporting of Serious Adverse Events
General Practitioner	Oversight of resident safety Timely reporting of Serious Adverse Events
Principal Investigator (or delegated trial doctor)	Review of all reported Serious Adverse Events Classification of reported Serious Adverse Events
Trial sponsor	Expedited reporting of Suspected Unexpected Serious Adverse Reactions

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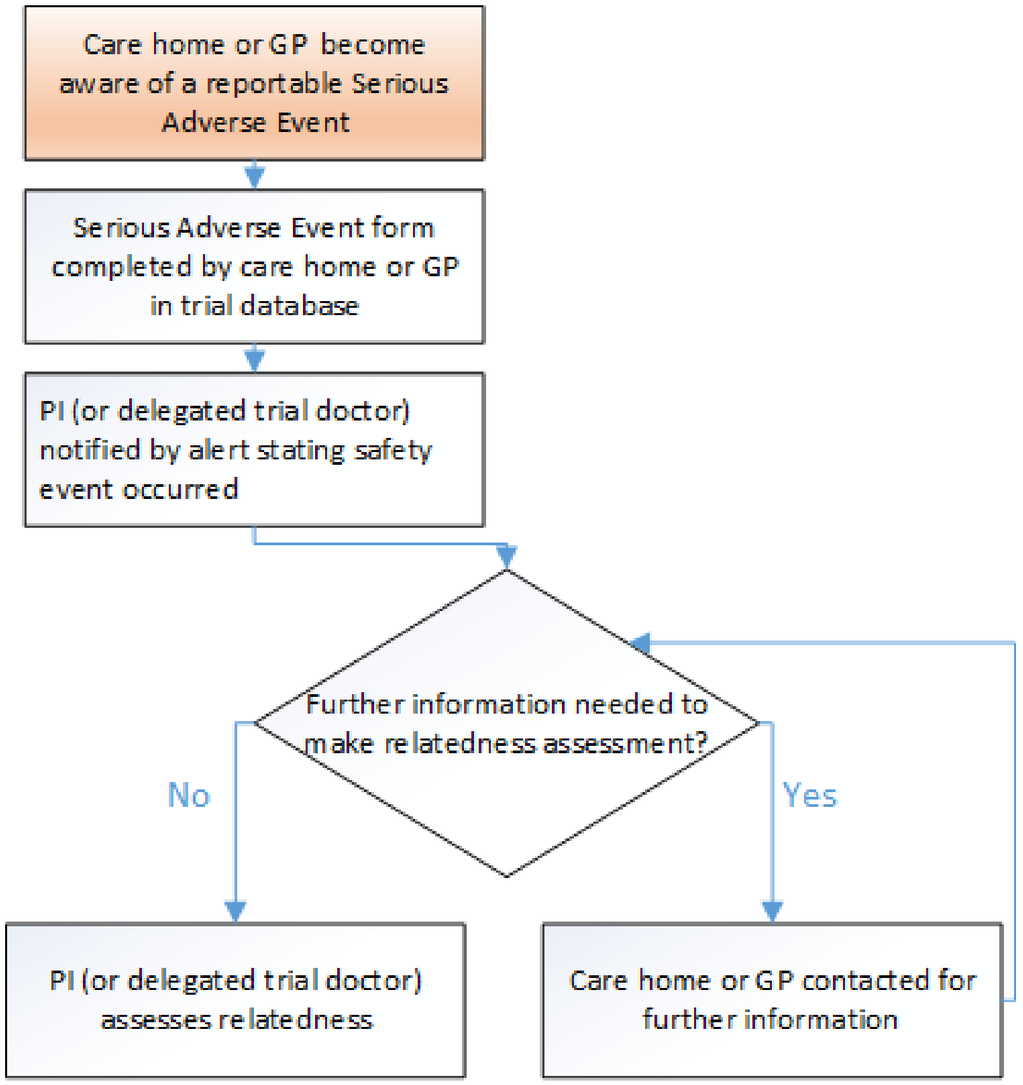
Safety reporting

GPs and care home staff are asked to report any suspected Serious Adverse Events (SAE)s in the trial database (REDCap) within 24 hours of becoming aware of the event.

The Principal Investigators (PI)s will use the information provided on the SAE form to assess the causality of the event and its relatedness to trial interventions. Should the PIs need any further information (e.g. from the resident's medical history) to make an assessment, the trial team will get in touch with you.



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Safety reporting

Should you need to report a serious adverse event (SAE) during the trial, you must follow the safety reporting link contained in the email notificaitons you receive. If you cannot locate the link, you can access the 'GP SAE Form' by selecting 'Advanced reports' from the menu on the left of the screen in the trial database.

GP SAE Form

Back to Advanced Reports Download report

SITE_ID	RECORD	DOB	NHS No	GP Email	SAE URL
00001	P00001-001	1939-02-09	1111111111	msznc@nottingham.ac.uk	Report SAE
00005	P00005-001	1923-05-01	5111111111	msznc@nottingham.ac.uk	Report SAE
00005	P00005-002	1944-05-03	3333333333	msznc@nottingham.ac.uk	Report SAE

The SAE report will show a list of residents under your care who are taking part in the trial.

Click on 'Report SAE' alongside the relevant resident in order to open the SAE reporting form.

Safety reporting form

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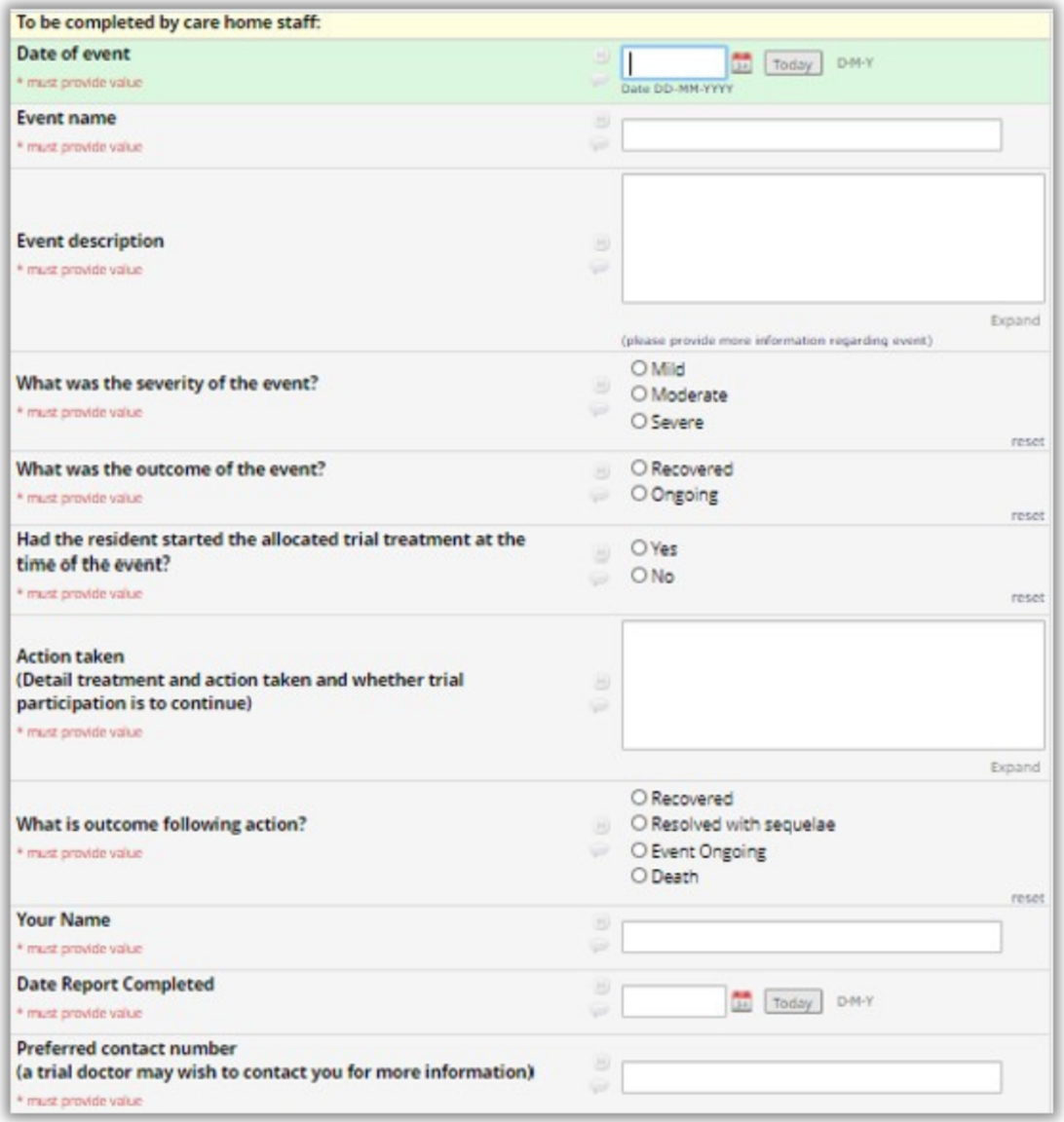
Details must include:

- Date of the event
- Event name (e.g. 'fall' or ' heart attack').
- Event description - please include as much information about what happened; this will help the PI with their assessment of the event.
- Severity - you will be asked to make a judgement on whether you think the event is mild, moderate or severe (see next page for definitions).
- Name and contact details of person completing the form - a PI may need to contact you to obtain more information.



To be completed by care home staff:

Date of event
* must provide value
Today D-M-Y
Date DD-MM-YYYY

Event name
* must provide value

Event description
* must provide value
Expand
(please provide more information regarding event)

What was the severity of the event?
* must provide value
○ Mild
○ Moderate
○ Severe
reset

What was the outcome of the event?
* must provide value
○ Recovered
○ Ongoing
reset

Had the resident started the allocated trial treatment at the time of the event?
* must provide value
○ Yes
○ No
reset

Action taken
(Detail treatment and action taken and whether trial participation is to continue)
* must provide value
Expand

What is outcome following action?
* must provide value
○ Recovered
○ Resolved with sequelae
○ Event Ongoing
○ Death
reset

Your Name
* must provide value

Date Report Completed
* must provide value
Today D-M-Y

Preferred contact number
(a trial doctor may wish to contact you for more information)
* must provide value

Severity

Mild: An event that is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.

Moderate: An event that is sufficiently discomforting to interfere with normal everyday activities.

Severe: An event that prevents normal everyday activities.

Follow-up Resolution

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If a SAE is deemed to be related to one of the trial medications, and the event is marked as ‘ongoing’ then the GP (or care home staff; **depending on who completed the original SAE report**) will be required to complete a 'Serious Adverse Event Follow up' form when the event is resolved.

Serious Adverse Event Follow Up

Please complete the Serious Adverse Event Follow up form.

Please complete the Serious Adverse Event Follow up form once the ongoing event has a final outcome:

Resident Details:

Resident Id	P00002-001
Date of birth	01-06-1945
Gender	Female

Serious Adverse Event Details:

Date of Event	21-06-2021
Event name	Anaphylaxis
Event Description	Resident went into anaphylactic shock shortly after receiving a dose of trial treatment
Event Severity	Severe
Serious Criteria	Life threatening
Serious Criteria Other	____
Event Treatment	Ciclesonide
Last Dose	20-06-2021 10:40:00
Action Taken	Resident currently being treated by paramedic
Action Outcome	Event Ongoing
Resolved with sequelae Details	____
Reported By	Garry Meakin
Preferred Contact Number	123
Reported Date	21-06-2021 00:00
Related to trial treatment	Probably
Evaluated By	Garry
Evaluation Date	21-06-2021

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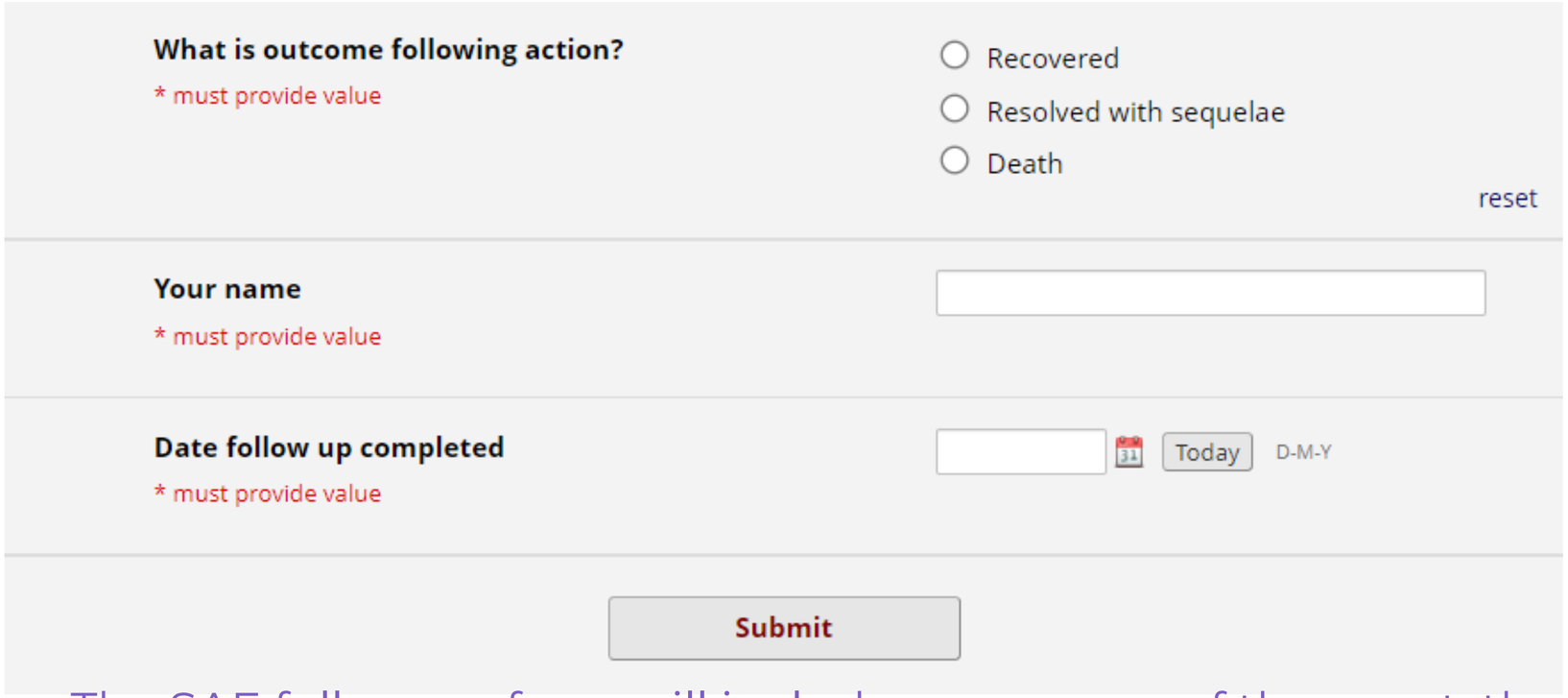
Follow-up Form

If you have submitted the original SAE form, you will receive an email informing you that you need to complete the SAE follow-up form. The email will include the link to the form.



The SAE follow-up form will include a summary of the event, the assessment outcome (see screenshot in previous slide) and a section at the bottom which you will need to complete (see above).

7. Data Protection & Confidentiality

By law, the University of Nottingham research team must tell trial participants/personal legal representatives what they are going to do with their **personal** and **research** data.

Personal data:

Name, DOB, Address, NHS or CHI number

Research data:

Information collected during the trial about a resident

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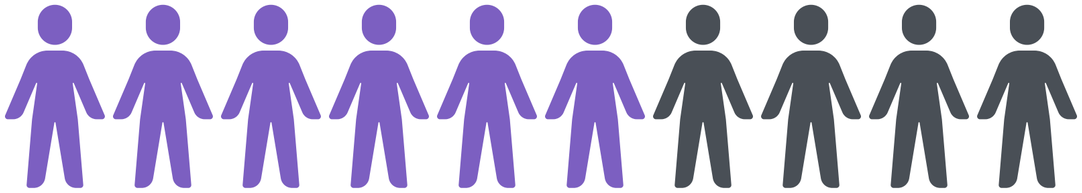

Research data are NOT identifiable.

A unique identifier will be given to each resident which will be added to all trial documents for that resident.
The unique identifier (Trial ID) of each resident can be found on the trial database (REDCap).

No personal data should be contained within the research data i.e if completing an SAE form, please avoid using the resident's name in the narrative about the event.

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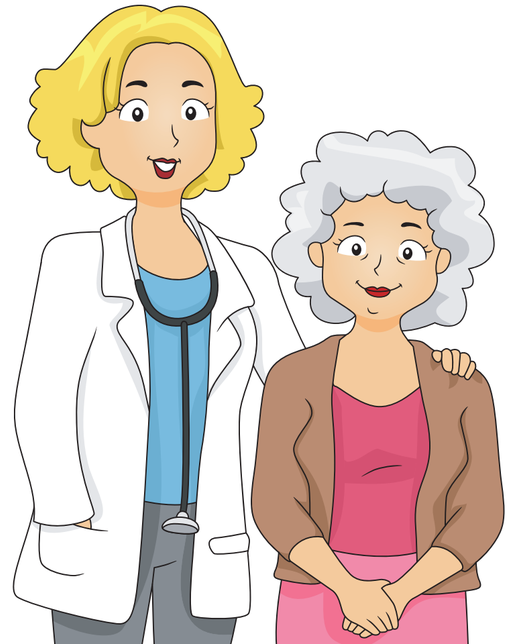
It is essential that to collect and use a resident's personal data AND research data, the research nurse must have taken **consent** from the:

Resident OR
Personal Legal Representative



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Once consent has been obtained, the University of Nottingham has a responsibility to:

- Follow legal and ethical practice
- Follow UK Data Protection laws
- Keep data safe
- Ensure that the least amount of personally identifiable information is stored securely in a password protected database

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Once consent has been obtained, the University of Nottingham has a responsibility to:

- Follow legal and ethical practice
- Follow UK Data Protection laws
- Keep data safe
- Ensure that the least amount of personally identifiable information is stored securely in a password protected database
- Ensure all information about residents is handled in confidence
- Ensure access to information collected about a resident is restricted to only those who have the relevant permissions for the conduct of the trial

Electronic Data Storage

Personal Data

All personal data will be entered into a password protected database. Only the trial team and the regulatory authorities will have access to this database.

Research Data

Research data containing the unique identifier will be stored on a separate database to the personal data and will be password-protected.

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Paper Data Storage

Personal Data

Paper records containing a resident's personal data i.e. consent forms completed on paper, will be kept in a locked cupboard in a restricted-access office at the University of Nottingham.

Research Data

Paper records will be kept in a different locked cabinet to the personal data, also in a restricted-access office at the University of Nottingham.

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Who can look at personal and research data?

- Regulatory authorities i.e. MHRA
- Sponsor
- Research staff working on the trial i.e. care home staff, PROTECT-CH trial team, Research Nurses and Principal Investigators working on the trial

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Routinely collected health data

GPs will not need to perform any actions to allow for the collection of registry data
as part of the trial follow-up (Day 1-120).

However, if you are located in Scotland the request would go to Albasoft and local GPs will need to consent to this data linkage. Further information on this data collection will be provided closer to the time.

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What happens at the end of the trial?

Residents' research data will be kept securely for 7 years, then disposed of securely as per the University of Nottingham policy and clinical trials laws.

Data may be shared with other researchers outside the University of Nottingham for authorised research purposes but will be anonymised (personal details removed). Permission for this is given at consent.

8. Good Clinical Practice

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Good Clinical Practice (GCP)

Before you start working on the trial you must understand and follow the principles of Good Clinical Practice.

GCP is an **internationally agreed** ethical, scientific and practical standard to which all clinical research is conducted.

It is **law in the UK** that researchers follow GCP guidelines whilst conducting clinical trials of Investigational Medicinal Products (i.e. drug trials).

Good Clinical Practice (GCP)

Compliance with GCP provides the public with reassurance that:

- The rights, wellbeing and safety of research participants are protected.
- Research data collected are reliable.

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GCP covers all areas of a trial including:

Design and conduct

Performance and recording

Monitoring and auditing

Analysis

GCP consists of 13 principles:

1. Clinical trials should be conducted in accordance with ethical principles.

2. There should be a balance of risks/inconveniences versus benefits for the resident and society. The anticipated benefits must justify the risks.

3. The rights, safety and well-being of participants are the most important consideration.

4. Sufficient and clear information should be given to participants so that they can make an informed choice about whether to take part or continue.

5. Clinical trials should be scientifically sound and described clearly in the Protocol.

6. A trial should follow the Protocol which has been approved by the Medicines and Healthcare Regulatory Agency (MHRA)(for drug and device trials only), Research Ethics Committee (REC) and Good Clinical Practice (GCP).

7. Standard medical care should be provided for all residents throughout the trial.

8. Each staff member working on the trial should be qualified by education, training and experience to perform their role in the trial.

9. Freely informed consent should be obtained from every participant prior to trial participation.

10. All clinical trial information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and checking.

11. Information should be collected in confidence.

12. The intervention should be manufactured, handled and stored in accordance with Good Manufacturing Practice (GMP).

13. Quality systems should be implemented to assure the quality of every aspect of the trial.

For further information on Good Clinical Practice (GCP) please refer to the Trial-specific GCP module.

9. Record Keeping

As with medical records, in trials, if any event is not recorded, it cannot be confirmed that it happened.

Proper record keeping is absolutely crucial to demonstrate that everyone involved in the research has met all the regulatory requirements, and that the appropriate ethical and scientific standards have been upheld.

Records should meet the ALCOAC criteria. They should be:

- Attributable to a named individual
- Legible
- Contemporaneous
- Original (i.e the original copies of records are kept, not just duplicates)
- Accurate
- Complete

For information on the practical steps to enter and record data, please refer back to the Data Entry section of this training slide deck.

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Please note that any communication with care homes or trial team members in relation to a participant e.g. SAE that is not logged on the trial database (REDCap) needs to be recorded.

This can be done by summarising what has been agreed in an email to the care home while always cc:ing the PROTECT-CH mailbox.

Please remember **not** to include **confidential** information in your **correspondence**.

Please remember **not** to include **confidential** information in your **correspondence**.

If you need to refer to a participant in your correspondence, you may include the following identifiers:

1) their initials,
2) their trial ID number and
3) the name of their care home.

Please include all three identifiers to ensure the correct identification of the individual.

10. Final Reminders

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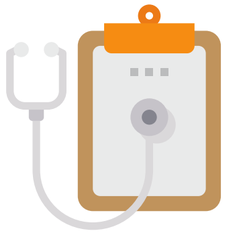
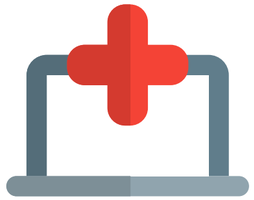
GP Role & Responsibilities' Summary

The GP will need to complete the following activities as part of PROTECT-CH:

- Assess eligibility following participant consent
- Submit summary care record (SCR) or equivalent in devolved nations to the PROTECT-CH Documents vault
- Report Serious Adverse Events (SAEs) within 24 hours of becoming aware
- Provide to the PIs information in relation to Serious Adverse Events as needed


Before you engage in any trial-related activities, please ensure:

- You have signed and returned your contract.
- You have completed this training module (mandatory) and the trial-specific GCP (optional).
- You have obtained your training certificate.
- You have received your trial database and vault login details.
- You have signed the care home delegation log.

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11. Self-certification Link & Team Contact Info

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Thank you for watching!

You have now completed the

General Practitioner (GP)

Training Module.

NEXT

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Please remember to complete your self certification form to confirm you have undertaken this training

This can be found at:

https://w3.abdn.ac.uk/hsru/NCTU-Protect/Public/Public/SelfCertification.cshtml?TrainingModule=12&ModuleVersion=1

Or you can access it via mobile here:

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If you have any questions, please do not hesitate to contact us:

protect-trial@nottingham.ac.uk

0115 74 87710