University of Nottingham
UK | CHINA | MALAYSIA

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

PROTECT-CH

Prophylactic Therapy in Care Homes Trial

Safety

Training Module

Final version 1.0 03-AUG-2021

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Purpose of training

This training module will cover the processes that have been put in place to protect the safety of residents who take part in the trial.

After completing this module, you will have an understanding of:

- What safety monitoring is
- Why safety monitoring is important in clinical trials
- Terminology used in clinical trial safety monitoring
- How to report safety data
- What happens to safety data that is reported
- What happens if there is a safety finding
- Reporting timelines and why these are important

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

What is safety monitoring?

- It is important that the safety of trial participants is regularly monitored when conducting a clinical trial

- Safety monitoring requires the reporting of any medical problems that trial participants experience during the course of a trial

- These medical problems, or 'adverse events', must be closely monitored in case they are caused by the trial medication(s)

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Terminology you might hear:

Adverse event (AE)

Any medical problem in a patient administered a trial medication whether related to the trial medication or not.

Terminology you might hear:

Serious Adverse Event (SAE)

Any adverse event that:

- results in death;
- is life-threatening;
- requires hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability or incapacity;
- consists of a congenital or birth defect

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Safety reporting for PROTECT-CH

Serious Adverse Events

Care home or GP become aware of a reportable Serious Adverse Event (SAE)

↓

Serious Adverse Event form completed by care home or GP in trial database

↓

PI (or delegated trial doctor) reviews safety report

Adverse Events

Weekly report of adverse events (AEs)

↓

Care home records any adverse events on the resident trial MAR chart

↓

Care home enters summary data into 'weekly data' form on REDCap database

↓

All reported safety events are reviewed on a regular basis. Action may be taken (e.g. stopping trial) if there are safety concerns.

Safety reporting for PROTECT-CH

Do we need to report adverse events if we are randomised to 'standard care'?

Yes! We need to understand whether the events would have happened whether the participants had been taking trial medication (treatment) or not.

as an example...

Trial treatment A	Trial treatment B	Usual care	Safety assessment
4% of residents suffer a heart attack	3% of residents suffer a heart attack	4% of residents suffer a heart attack	No relationship to either trial treatment
15% of residents suffer a heart attack	3% of residents suffer a heart attack	4% of residents suffer a heart attack	Safety concern – possible that trial treatment A increases the risk of heart attack

PR·TECT-CH
Prophylactic Therapy in Care Homes Trial

Adverse Event (AE) reporting

Serious Adverse Events

Care home or GP become aware of a reportable Serious Adverse Event (SAE)

↓

Serious Adverse Event form completed by care home or GP in trial database

↓

PI (or delegated trial doctor) reviews safety report

Adverse Events

Weekly report of adverse events (AEs)

↓

Care home records any adverse events on the resident trial MAR chart

↓

Care home enters summary data into 'weekly data' form on REDCap database

↓

All reported safety events are reviewed on a regular basis. Action may be taken (e.g. stopping trial) if there are safety concerns.

PROTECT-CH
...lactic Therapy in Care Homes Trial

Adverse Events

Weekly report of adverse events (AEs)

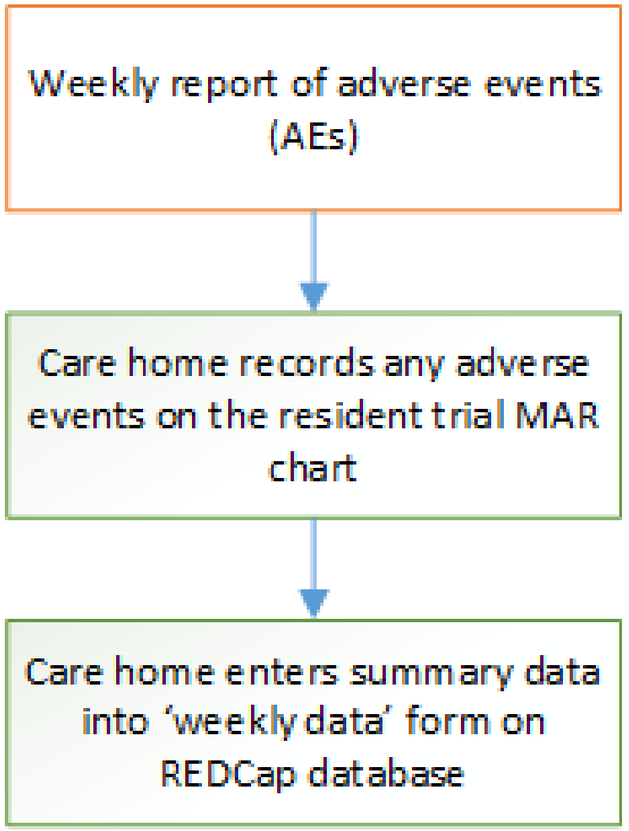
Care home records any adverse events on the resident trial MAR chart

Care home enters summary data into 'weekly data' form on REDCap database

- Adverse events must be reported for **all residents in the trial, during the treatment phase.**

- There is a section on the trial Medication Administration Record (MAR) chart that you can use in order to keep a record of any adverse events a resident has.

- You must report a weekly summary of any adverse events for each resident in the '**weekly data**' form in the trial database (REDCap).
  If a resident has not experienced any adverse events, this can also be recorded on the weekly data form.



Adverse events in the weekly data form are grouped into the following categories:

- Gastrointestinal (e.g. indigestion, loss of appetite)
- Neuro-psychiatric (e.g. anxiety, depression)
- Chest/Respiratory (e.g. cough, hoarse voice)
- Cardiovascular (e.g. racing heart, high blood pressure)
- Skin/Cutaneous (e.g. itching, eczema)
- Nasal (e.g. nose bleed, nasal discomfort)

If any adverse event is experienced that meets the criteria for a Serious Adverse Event (SAE) then it must also be reported as a SAE.

PR·TECT-CH
Prophylactic Therapy in Care Homes Trial

Serious Adverse Event (SAE) reporting

Serious Adverse Events

Care home or GP become aware of a reportable Serious Adverse Event (SAE)

↓

Serious Adverse Event form completed by care home or GP in trial database

↓

PI (or delegated trial doctor) reviews safety report

Adverse Events

Weekly report of adverse events (AEs)

↓

Care home records any adverse events on the resident trial MAR chart

↓

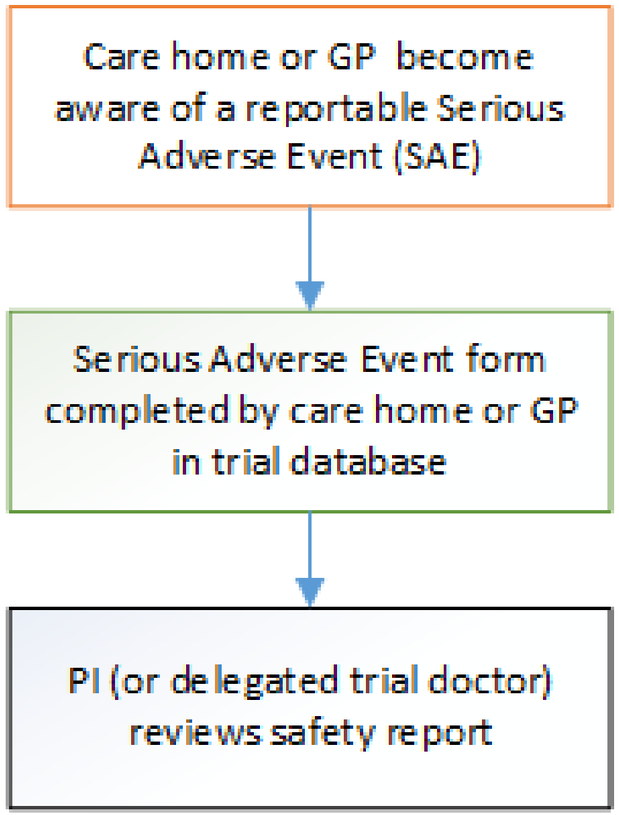
Care home enters summary data into 'weekly data' form on REDCap database

↓

All reported safety events are reviewed on a regular basis. Action may be taken (e.g. stopping trial) if there are safety concerns.

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

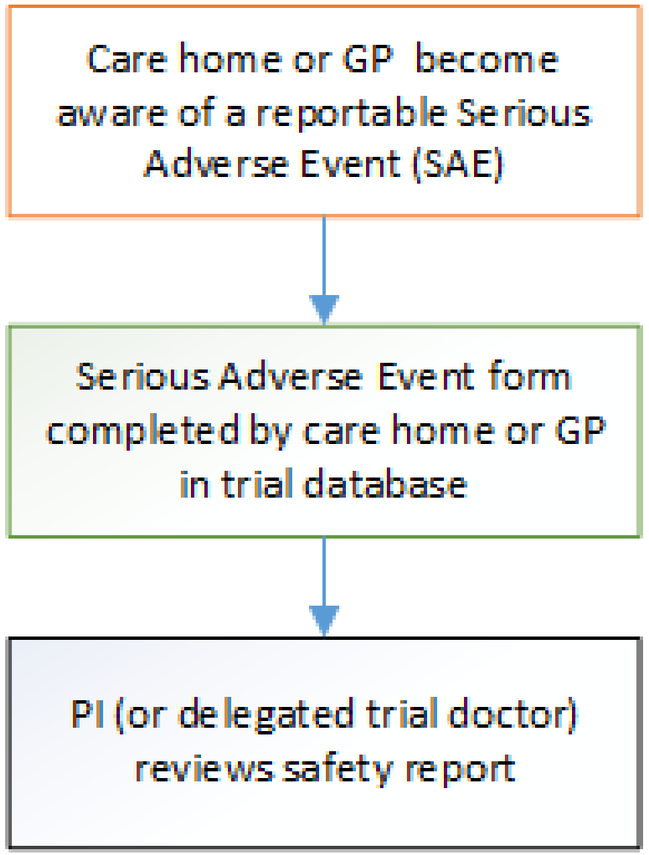
Serious Adverse Events



- You must report a Serious Adverse Event (SAE) via the SAE reporting form within the trial database **within 24 hours of you becoming aware of the event**.

- SAEs can be reported by either care home staff or the residents' GP.

- All SAE reports will be reviewed by your local Principal Investigator (PI) or another one of the PIs. The reviewing PI may contact you for more information.



PROTECT-CH
Prophylactic Therapy in Care Homes Trial

SAE reporting

Admission to hospital/death

- This is what we measure to see whether the treatments work or not and must be reported using the 'Event Log' in the trial database.

- Hospital admissions and deaths in the care home also need to be reported as SAEs.

- When you enter the data in the 'Event Log' you will be given a prompt which will take you to the SAE form.

Other important medical event

If an event does not lead to hospitalisation or death, but leads to disability or is life-threatening this must also be reported as an SAE.

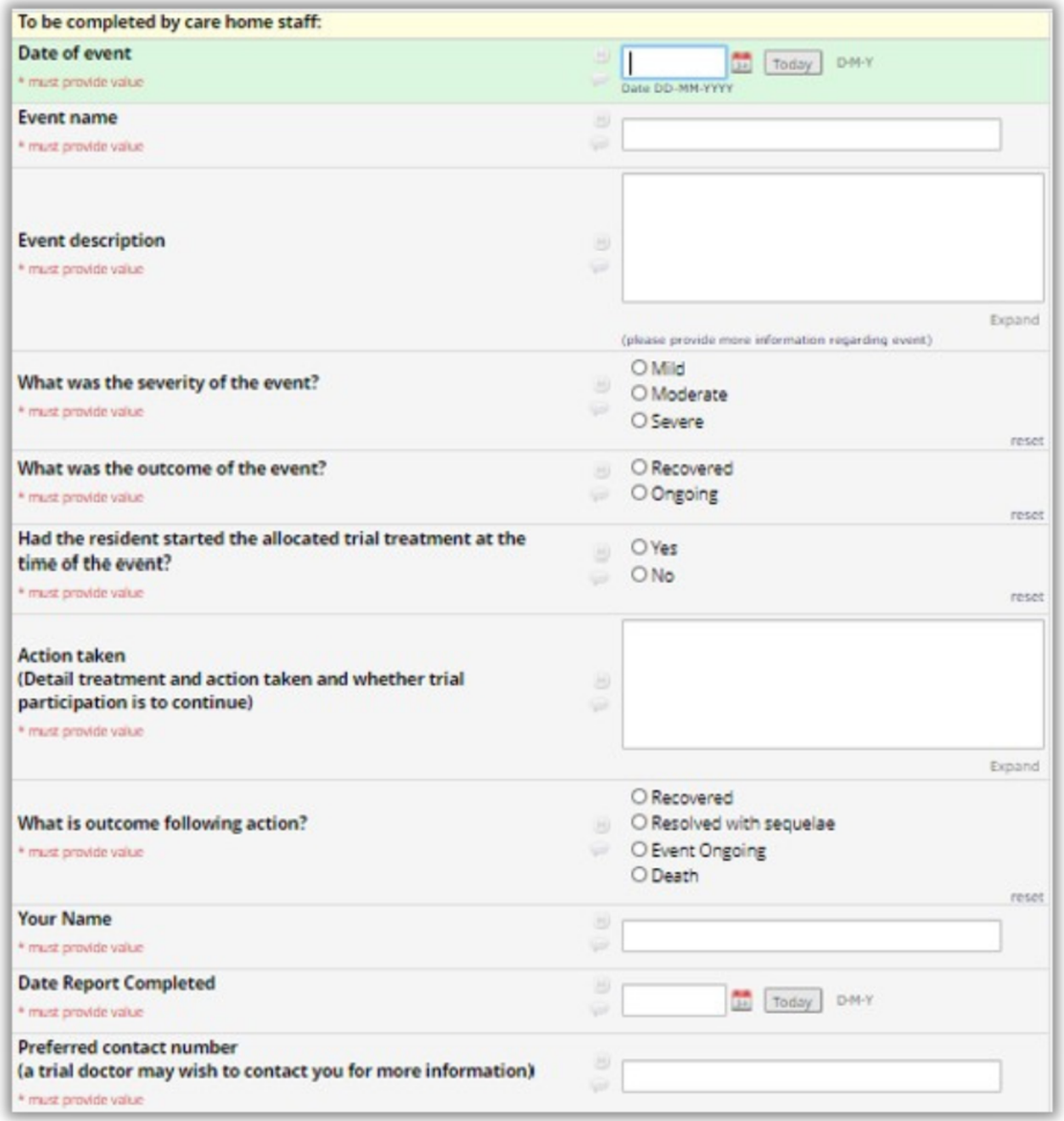
Example: the resident develops severe pneumonia but has an advanced care plan/directive in place to say that they do not wish to be admitted to hospital.

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

SAE reporting form

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 Principal Investigator (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
- Name and contact details of person completing the form - the care home PI may need to contact them 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

Events that do not need reporting

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Events that DO NOT need reporting

The following events are frequent in care home residents and do not need reporting (these events are common in care home residents and unlikely to be related to the study treatments):

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.

What happens to safety data?

Adverse events (AEs) - reported as a part of 'weekly data'

A summary of adverse events reported from all care homes will be reviewed on a regular basis by an independent committee known as the Data Monitoring Committee (DMC).

Serious Adverse Events (SAEs)

- reported within 24 hours of becoming aware of the event

- All reported SAEs will be reviewed by the care home's Principal Investigator (PI). The PI will assess what caused the event, and categorise the event based on whether they feel it is related to the trial medication.

- The DMC will regularly review the data to look for any signs that the trial medication maybe causing adverse events.

Serious Adverse Reactions

- Any SAE that is deemed by the PI as related to the trial medication is classified as a Serious Adverse Reaction (SAR).

Suspected Unexpected Serious Adverse Reactions

- If a SAR is unexpected (i.e. not a known adverse reaction to the trial medication), it is classified as a Suspected Unexpected Serious Adverse Reaction (SUSAR).

Important Note

- It is critical that you report any SAE as soon as you become aware of the event (within the first 24 hours).

- Any delays during the reporting process could jeopardise the safety of residents taking part in the trial.

Reporting timelines

Reporting timelines

Role	Responsibility and timeline
Care home staff	Report any Serious Adverse Events no later than 24 hours after becoming aware of the event
General Practitioner	Report any Serious Adverse Events no later than 24 hours after becoming aware of the event
Principal Investigator (or delegated trial doctor)	Review and classify all reported Serious Adverse Events within 24 hours of the event being reported Any events classified as a SUSAR will be reported automatically to the Sponsor
Trial sponsor	For fatal or life-threatening SUSARs, the Sponsor will ensure expedited reporting to the Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC) within 7 days. For non-fatal or non-life-threatening SUSARs, the sponsor will ensure expedited reporting as soon as possible but no later than 15 days.

What happens if there is a safety finding?

If a resident,

1. has a reaction to the trial medication we don't expect (i.e. it is not in the list of side effects) and
2. the medication is thought to cause more harm than good (i.e. people are made more ill by the trial medication than they would be by the disease itself)

then that ***medication group will be stopped***.

This means that participants already enrolled in the trial will no longer receive this medication and new participants will no longer be allocated to take that medication.

If any safety findings arise that require any change in the progress of the trial, the trial team will work closely with you to ensure that the correct process is followed.

PR·TECT-CH
Prophylactic Therapy in Care Homes Trial

Roles & responsibilities summary

Roles and responsibilities

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

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

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Recording safety data on the trial database

For specific instructions on completing the forms referenced in this module please complete the 'Data Entry' training module.

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Training module summary

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Summary

- Participant safety is the most important aspect of a trial.

- Care home staff are responsible for reporting:
  - Targeted Adverse Events on a weekly basis using the 'weekly data' form in the trial database.
  - Serious Adverse Events within 24 hours of becoming aware of the event using the Serious Adverse Event form in the trial database.

- It is important to avoid any delays in telling us about events.

- If you are unsure about whether an event requires reporting, you should ask your local research nurse, local PI or a member of the trial team.

PR·TECT-CH
Prophylactic Therapy in Care Homes Trial

Training Module
Self-Certification

University of Nottingham
UK | CHINA | MALAYSIA

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Thank you for watching!

You have now completed the

Safety

Training Module

NEXT

University of Nottingham
UK | CHINA | MALAYSIA

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

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=7&ModuleVersion=1

Or you can access it via mobile here:

University of Nottingham
UK | CHINA | MALAYSIA

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

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

protect-trial@nottingham.ac.uk

0115 74 87710