

The background of the slide is decorated with several stylized virus icons. Each icon consists of a central circle with multiple lines radiating outwards, each ending in a small circle, resembling a coronavirus. The icons are in a light purple color and are scattered across the slide.

PROTECT-CH

Prophylactic Therapy in Care Homes Trial

Care Home Set-Up

Training Module



Introduction

- All essential documents and FAQs are available on the trial website (www.protect-trial.net).
- Care homes will be provided with a guidance booklet including a checklist to assist with set-up.
- Members of the trial team will be available to guide care homes through the set-up process (& beyond) and answer any questions.
- Email the PROTECT-CH trial team at protect-trial@nottingham.ac.uk or phone 0115 74 87710 if your question is not covered by the FAQs on the trial website.

Please do **NOT** begin trial activities involving residents until your care home has received “**Green Light**” approval email from the PROTECT-CH trial team at the University of Nottingham.



Please see ‘Site Initiation Visit’ training module for more information on ‘Green Light’.



Starting the trial – Step-by-step

Regulatory

- Contract signed
- Insurance check
- Written approval for care home to participate in trial (provided by HQ and care home manager)

Documents

- Receipt of care home file
- Receipt of care home pack including resident facing documents

Training

- Mandatory training **AND**
- Training modules per role on trial for 3 key staff members
- Verification of training

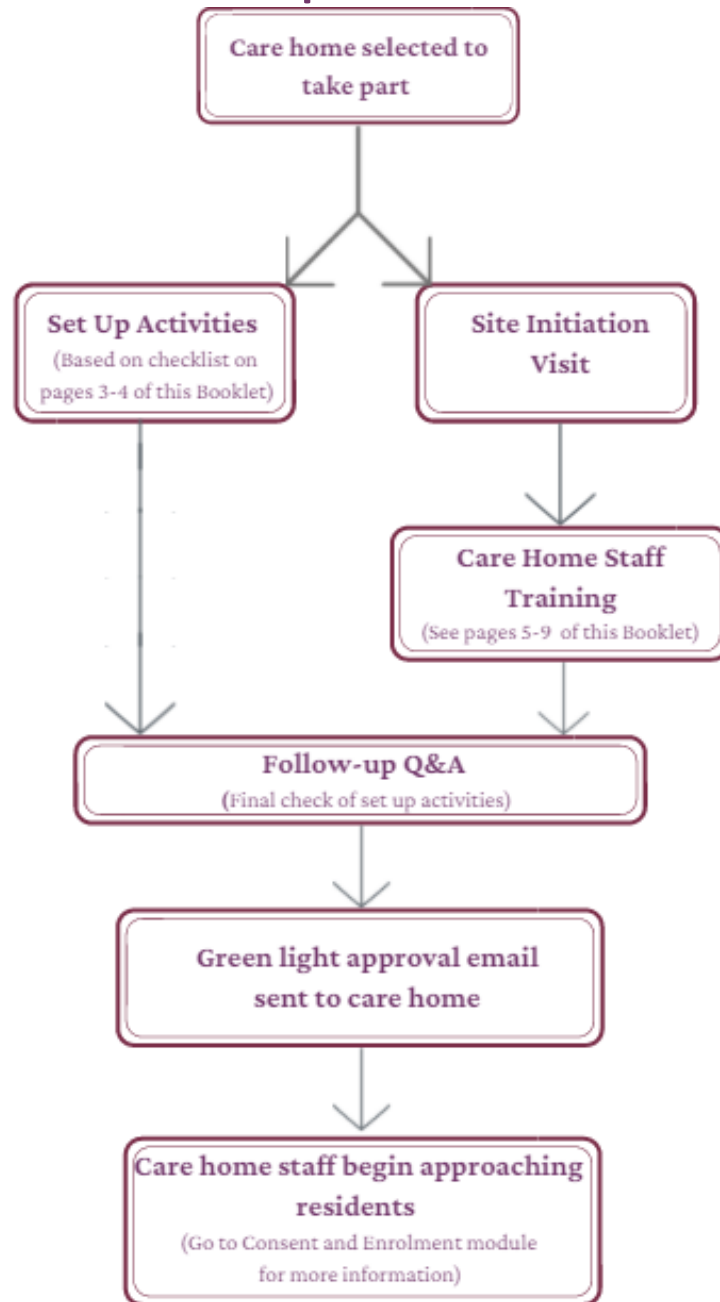
Logistics

- Storage for medication and equipment
- Access to computer and printer

Receipt
of
“green
light”
email



Set Up Flowchart

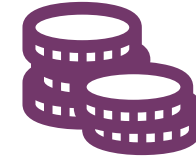


Set-up flowchart available in the PROTECT-CH set-up booklet and within your care home document pack.





Finance



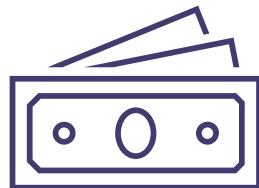
- All care homes will receive payment for:

Trial set up

Each resident who
agrees to
participate

Entering resident
information into
trial database

- Care homes allocated to give the trial medication will also receive payment for:



Giving residents
trial medication*

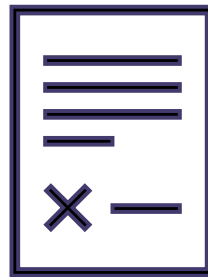
*Trial medications will be provided free of charge





Approvals

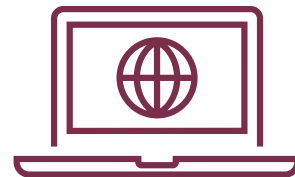
- Written approval must be given from local management (e.g. care home owner and/or care home manager) for the care home to participate in the trial
- Trial contract to be signed by care home and University of Nottingham (PROTECT-CH trial sponsor)





Documents

- Care homes will be provided with a file containing documents needed to run the trial
 - This will include all resident facing documents (e.g. information sheets)
 - Translations of resident documents can also be provided if requested
- Documents will also be available on the trial website www.protect-trial.net
- The care home site file will be based with the care home (and you will be responsible for its maintenance)
- All regulatory documents will be available on the PROTECT-CH website





Training

- This should begin as set-up processes are ongoing and after the care home has completed their online site initiation visit.
- All staff involved in trial at care home must complete (at minimum):
 - Background to Trial
 - Trial specific Good Clinical Practice
 - Data Protection
 - Safety
 - COVID-19 Outbreak Guidance





Training

- This should begin as set-up processes are ongoing and after the care home has completed their online Site Initiation Visit.
- All staff involved in the trial must complete these modules (as a minimum):
 - Background to Trial
 - Trial specific Good Clinical Practice
 - Data Protection
 - Safety
 - COVID-19 Outbreak Guidance
- Other training modules depend on your role:
 - Care home set-up
 - Consent & Enrolment
 - Therapy (information on each trial medication)
 - Data Entry
 - Trial Assessments and Follow Up
 - Close out & Archiving





Training – Requirements for Green Light

- Three key members of staff, care home manager, research champion (if different to the care home manager) and a third staff member involved in the trial should complete all the training modules* and self-certify to confirm completion before the green light can be given.

**except for Close out & Archiving*

- Once these three key staff members have completed all the requisite modules, the care home will be invited to a follow-up Q&A, during which they may ask any questions they have on the processes outlined in the modules.





Confirmation of Training

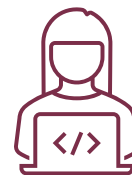
- On completion of each training module, the care home staff member should complete the self-certification form using the link provided at the end of each module.
- Before the care home opens to enrolling residents (“Green Light”), the care home manager will sign the delegation log. Once they have been signed off by the Principal Investigator, all trained staff will be assigned their relevant duties on the delegation log.
- The PROTECT-CH trial team will check that the three key staff members involved in the trial have undertaken the appropriate training and all other set-up activities are complete before issuing the care home with their “Green Light” to enrol residents.





Roles

- Principal Investigator (PI) is a trial doctor that has overall responsibility for the trial at the care home. They will not be based at the care home so trial activities will be delegated to the care home manager (who will, in turn, delegate relevant tasks to the care home staff trained on the trial).
- Each task within the care home is assigned to a trial role and training is provided. A care home staff member may undertake several tasks and will therefore need to complete all associated training.





Roles

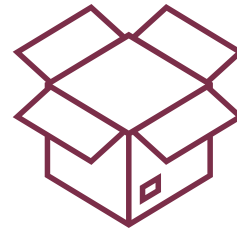
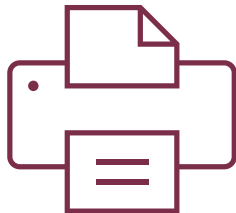
- A person can perform more than one role but this should be within the roles and responsibilities already assigned to them in the care home (i.e. if they are not trained to give residents medication ordinarily they cannot give them trial medication even if they have completed the training module).
- All individuals involved in trial at care home are responsible for reporting safety events on the trial database in a timely manner.





Logistics

- Check that care home has available storage for medication and equipment.
- Ensure that there is access to a computer (with internet access), a printer and electronic tablet.





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=14&ModuleVersion=1>

Or you can access it via
mobile here:





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



Protect-trial@nottingham.ac.uk



0115 74 87710

*Thank
you*

