

**UK Registered
Clinical Trials Unit
Network**



UK Registered CTU Network – Considerations regarding the utilisation of Private Healthcare Sites in academic research

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1. Abbreviations

AE – Adverse Event

CAPA – Correct and Preventive Action

CTIMP – Clinical Trial of an Investigational Medicinal Product

CT – Computed Tomography

CTU – Clinical Trials Unit

DoR – Delegation of Responsibilities

EDC – Electronic Data Capture

GCP- Good Clinical Practice

GDPR – General Data Protection Regulation

IMP – Investigational Medicinal Product

IRAS – Integrated Research Application System

mNCA – model Non-Commercial Agreement

MRI – Magnetic Resonance Imaging

NHS – National Health Service

PHF – Private Healthcare Facilities

PIC – Participant Identification Centre

PTC – Primary Treatment Centre

SAE – Serious Adverse Event

SFQ - Site Feasibility Questionnaire

SoECAT – Schedule of Events Cost Attribution Template

SOP – Standard Operating Procedure

2. Background

The Fit for the Future: 10 Year Health Plan for England clearly includes the notion that science and technology which includes research is key to the reinvention of the NHS^{1,2}. This drive to embed research into improvement is, however, occurring against a backdrop in which delays in site set-up for trials within the NHS, have led researchers to look to recruit participants from other healthcare providers in the UK.

There are also those participants that have consultations within the NHS and are then treated within a private facility funded by the NHS or themselves. In times where inclusivity is at the top of everyone's agenda – being able to allow all those suitable for trials to be included in research means that all health providers need to be considered for trial delivery if research is part of their policy.

3. Purpose

This document aims to provide guidance and considerations about the inclusion of private healthcare providers in UK clinical trials and studies.

There have been five scenarios identified:

1. Private Healthcare Facilities (PHFs) that would recruit and follow-up participants to a trial. In this scenario the PHF becomes a Primary Treatment Centre (PTC).
2. NHS patients who enrol in studies but due to capacity within the NHS they may have initial surgery/treatment/intervention/investigations in a PHF funded by the NHS, then continue follow up in an NHS facility. The NHS site is the PTC.
3. NHS patients who enrol in studies but due to capacity within the NHS they then may decide to fund themselves their surgery/treatment/intervention/investigations in PHF, then continue follow up in an NHS facility. The NHS facility is the PTC.
4. NHS patients who enrol in studies but due to capacity they may decide to fund themselves their surgery/treatment/intervention/investigations in a PHF and also be followed up in a PHF. The PHF is the PTC.
5. A PHF as a PIC site who would then enrol the patients via an NHS site.

¹ <https://www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future>

² <https://www.gov.uk/government/news/unprecedented-boost-for-clinical-trials-under-10-year-health-plan>

4. Actions to be undertaken

4.1. Reviewing the potential options and agreeing which options can be utilised

Step 1: Utilise the study SoECAT to identify the tasks as standard care or research specific and the attribution such that all aspects of the trial can be mapped into the patient flow listed in step 2.

Step 2: Produce a Flow Document showing all possible participant flows and potential providers/locations for all aspects of the trial including identification, recruitment, consent, trial investigations, trial interventions, tests, treatments, standard care results, in and out-patient care including rehabilitation, participant follow-up questionnaires and safety oversight.

Note: In the rest of this document, please note the term 'care' will be used as an overview term for inventions/surgeries/tests/clinic appointments/hospital stays.

The document also needs to show where care is to be delivered and by who it is provided, and additionally who is funding the care.

Step 3: Populate, for each flow identified, the 'Risk Profile of each' using the Excel document included as Appendix 1.

Step 4: Meet/have email discussions with your sponsor organisation concerning the Flow Document and Risk Profile to agree content and if they are willing to allow all routes, and if there is a minimal score they require in order to accept a site. Ensure there is a clear agreement about any that will not be permissible for their sponsorship and insurance conditions.

Note: Sponsors may have different policies in place that allow, or not, inclusion of delivery of trial related interventions/associated actions.

Step 5: Where a PHF is to provide any imaging, consideration as to whether potentially higher resolution imaging derived from this source will cause issues within the trial. If so, it should be clear what scanning resolutions would be acceptable for use in the trial.

Note: Where there are investigations to be undertaken such as an MRI scan PHF may often have better scanners (i.e. able to image at higher resolution – 3 or 7 Tesla). This may impact on the study in a positive or a negative way and needs to be captured when assessing a site. Consideration should also be given as to whether this impacts on comparisons of imaging data between sites, or patient safety, as higher resolution increase risks for patients but do decrease scan times).

Step 6: Produce a Delegation of Responsibilities (DoR) document that outlines clearly the expectations of a PHF in each of the flows identified. This should be agreed with the

sponsor and should clearly include which procedures will be indemnified by the sponsor and which will not. This will require oversight by your organisation's contracting team as to what agreements/contracts they will want to produce for each scenario.

Note: A format not dissimilar to the mNCAs, in which responsibilities are listed and assigned to the respective parties of Sponsor/CTU, PTC and PHF may be clear for all parties.

Step 7: Ensure there is clarity within the team regarding indemnities within the trial and the individual that populates the IRAS form the trial ensures that the 'Insurance/indemnity to meet potential legal liabilities' section reflects all scenarios the trial will be allowing the covering arrangements.

Note: Where an NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes – this will almost certainly not apply for PHFs – therefore ensure you have clear unambiguous documentation from sponsor office teams regarding this.

4.2. Discussions/communications with potential sites

Site Feasibility Questionnaires (SFQ) should be sent to PHFs, as per NHS sites, for those wanting to participate as a full site – sending with the SFQ the document produced in Step 6 – the DoR.

Note: For trials where the usage of some PHF is common by sites, ensure your SFQ includes questions regarding this.

4.3. Documentation

Ensure that all documentation is clear regarding the location of trial activities – this will include but not be limited to the protocol, participant information leaflets and the IRAS form – including the locations of research.

4.4. Process for each site

Governance – although the nature of the documents will change, the considerations apply to all of the scenarios of PHF involvement.

1. Legally binding agreement to be set up between PHF and PTC (Research Collaboration agreement) including key elements defined by the CTU and/or Sponsor organisation, with R&D approval demonstrated by full execution of the agreement
2. Delegation logs completed by the PHF and held at PTC, as appropriate. Delegation logs are required where the procedure being performed at the PHF is protocol-defined. i.e. If the protocol requires a standard head CT for example, staff performing

this would not need to appear on the log. If a scan had to be performed under protocol-mandated conditions, then they would need to be on the log.

3. For CTIMPs in which the PHF is providing IMP, the Pharmacy procedures would need to be reviewed by the CTU, pharmacists appear on the delegation log etc. As would be the case for an NHS site.

Initiation – the requirements will vary considerably with the PHF role in the trial.

Prior to initiation local procedures for data collection, AE reporting, IMP management and amendments are set-up by PTC, as appropriate and reviewed by sponsor. Consideration should be given as to the timing of visits to PHFs and whether (S)AEs need reporting by the PHF. Any procedure which may result in the detection of an (S)AE must be able to be reported to the PTC within appropriate parameters.

1. Where a PHF is actively recruiting, treating and following up participants, the PHF becomes a de facto PTC and should be initiated as any NHS Trust would.
2. Where there are shared responsibilities between the PHF and PTC, the Sponsor/CTU should conduct initiation at either of the facilities, attended by PTC and PHF teams. This maps to scenarios 2, 3 and 4, in Section 3.
3. Where a PHF is performing a specific, or a few specific tasks, the site initiation could be shortened to cover those specific tasks accordingly. In the case of the PHF being a specific service provider, such as an imaging service and there are no trial specific modifications to the scan requirements, site initiation may not be required. This would also cover scenario 5, in Section 3, where the sole duty is identification of eligible patients.

Documentation should be provided to the PHF and PTC as appropriate to the range of activities being performed. Again, in the case of a service such as imaging, a file would only be required if the trial required very specific images to be taken

Activation – the document set will vary according to the scenario, but the nature of the document set for each scenario to be used must be established and a checklist maintained to document progress.

1. PTC confirms all documents and agreements are in place for them to be able to recruit in their own right and to have PHFs perform the subset of tasks assigned to it
2. CTUs should notify the PTC and PHF whenever a PHF becomes active for trial

During the trial – which parties are responsible for collection of data and monitoring of data must be clearly delineated in the contracts and indemnities.

1. Monitoring of the PHF via patient data, IMP accountability, amendment implementation and local procedures can be agreed for either PTC oversight or Sponsor oversight.
2. Data collection is potentially particularly problematic. Generally, a PHF will perform a standard procedure such as a knee replacement, for example. It is highly unlikely that they will record the details of the procedure in sufficient detail as required for the trial. The need for this detail needs to be clear to the PHF, as does the timeliness of the data collection/entry. It is likely that the time to complete CRFs will be costed at a

higher rate than in the NHS and this should be factored in when considering PHF use.

4.5. Methodological Considerations

One could reasonably anticipate that treatment at a PHF would improve the time to treatment and reduce the range of time to intervention from randomisation, and therefore not potentially be representative of the general population. Consideration should be given to minimising by type of treatment facility, NHS or PHF.

5. Conclusion

The inclusion of PHFs in facilitating clinical trials does not come without additional set-up, day-to-day and oversight work for managing teams and their wider organisations.

If PHFs are to be proactively included in academic clinical trials, this document should be used as guidance for consideration of the activities that are required and whether there are capacity and allowances within CTUs and trial sponsors for this.

Appendix A – Site Suitability Scoring Tool

Click [here](#) to download an Excel version of this tool.

Category	Checklist Item	Score (0-2)
Regulatory & Governance	Previous trial experience SOPs for trial conduct GDPR compliance Process for confirmation of capacity and capability to participate	
Regulatory & Governance Total		0
Infrastructure & Facilities	Adequate clinical facilities Access to laboratory services Secure IMP/device/equipment storage Biological sample handling system Dedicated research coordinator	
Infrastructure & Facilities Total		0
Data Management & IT	Secure EDC systems Data backup and confidentiality	
Data Management & IT Total		0
Staffing & Training	Qualified investigators with GCP training	
Staffing & Training Total		0
Recruitment & Consent	Robust informed consent process Access to suitable patient population	
Recruitment & Consent Total		0
Financial & Contractual	Clinical Trial Agreements in place Insurance and indemnity coverage	
Financial & Contractual Total		0
Quality Assurance	Sponsor monitoring and audits Deviation handling and CAPA Secure archiving of documentation	
Quality Assurance		0
Safety & Emergency Procedures	Processes for SAE and progress reporting Protocols for adverse event reporting Emergency care availability Staff trained for emergencies	
Safety & Emergency Procedures Total		0
Overall Total		0