

Questions and Answers – Steps to Establish the Teletrial Model

Primary site:

Q1. When is the primary site required to conduct a site feasibility/evaluation visit of a satellite site?

A primary site or sponsor should conduct a site feasibility/evaluation when there is a new site not previously been assessed and/or when the trial requires a new service not previously assessed. Site feasibility is assessed according to the requirements of the trial protocol

Q2. What does the primary site need to know about the satellite site(s)?

The primary site is required to understand the capabilities of the satellite site(s) before requesting the sponsor to consider adding the additional sites to the ethics notification.

Q3. What does the primary site do on receipt of the notification to add the satellite sites to the CTN or on receipt of the ethics approval to add the satellite site(s)?

The CTN only records where IMP is **stored**. The satellite sites do not need to be listed on the CTN unless IMP is stored at the satellite sites (as opposed to shipped).

Q4. What extra documents are required to establish a teletrial model?

- a) CTRA amendment to add the additional sites to schedule 1 and to add any additional costs to schedule 2 (from sponsor). Ethics approval letter and CTN Notification if required (from sponsor).
- b) Primary site prepares a subcontract between the primary and satellite sites (using the approved template).
- c) Primary site prepares the Cluster PICF from the HREC approved master PICF.
- d) The primary site prepares the supervision plan documenting the oversight and supervision between the primary and satellite site(s).

Q5. Is a new indemnity required for each satellite site?

Each satellite site needs to be indemnified. A direct indemnity between the sponsor and the satellite site is preferred.

Q6. Can we add a satellite site if we have a patient that is eligible for the clinical trial?

The teletrial model allows the primary site to add a satellite site at the time of a patient being identified at a satellite site. However this is at the discretion of the sponsor.

Q7. How do we manage the IMP for a teletrial model as a primary site?

When IMP is shipped directly to the satellite site and stored in the satellite site pharmacy, fees equivalent to the primary site need to be added to the CTRA amendment. When the IMP is being shipped to the satellite site(s), pharmacy costs for the primary site include shipment costs to the satellite site. Cost associated with shipping to satellite sites at the feasibility stage may not be known so, it is recommended any extra cost is added as a pass-through cost to the CTRA amendment.

Q8. How do we manage the Standard of Care (SOC) chemotherapy or oral drug for a teletrial model as a primary site?

Internal Supply/Insourcing.

Determine if SOC medication will be centrally stored at the primary site or stored at both primary and satellite sites. If stored centrally at the primary site and shipped to the satellite site, the primary site/sponsor will need to set up a vendor for the courier service and a third-party agreement with a manufacturer if required. The manufacturer will need to be credentialed, have temperature logging and conduct a test run to ensure compliance with sponsor requirements

If SOC is stored as a distributed model (i.e. within each satellite site) then usual processes apply.

External Supply/Outsourcing

Determine if SOC will be sourced using PBS manufactured items. If yes, each site (primary and satellite) can order SOC via usual PBS mechanisms.

Q9. How does the primary site manage the source documents for a teletrial model?

Where EMR is used by both primary and satellite sites documents are uploaded/scanned into EMR and can be viewed at each site and by the CRA (once read only access is granted). For any paper source documents, the originals are stored at the relevant site and can be viewed securely through a videoconference meeting (for a limited numbers of documents). Source documents can also be uploaded to a secure dropbox for sharing or emailed (as per local data custodian guidelines);. Source documents can be sent by secure post to the primary site and all documents will be sent to the primary site at close out in preparation for archiving (costs need to be added to the CTRA amendment). The CRA may also arrange a monitoring visit to the satellite site to view source documents directly.

Q10. How do we manage the patient consent at the satellite site for a teletrial model?

Consent occurs through telehealth clinic visit when supervision of consent is required. This needs to be documented in the supervision plan. If the Sub Investigator is in the clinic visit with the patient at the satellite site, they will sign the declaration on the same PICF as the patient. If the PI or SI from the primary site is signing the declaration on the PICF via telehealth, then an exchange of PICFs is required once completed. The informed consent process is documented in real time at both the primary and satellite site in EMR and the declaration is written by the PI or SI and the version and date of the PICF is entered. The patient PICF is uploaded into EMR, the patient has a copy, the sites can fax or scan immediately to make a complete signed PICF or if preferred mail the patient consent to the primary site by registered post. If the patient consent is posted the PI will sign on the date of receipt not the date they obtained consent from the patient.

Q11. How does the primary site manage the delegation and signature logs, training logs etc?

To add additional trials staff to delegation and training logs a new page is used by the satellite site(s) and once signed the satellite site keep a copy along with a scanned copy of the front pages of each log held at the primary site. This allows the satellite site to hold a complete copy of the logs and return the wet ink/signed logs to the primary site by registered mail so that the primary site holds the complete wet ink/signed logs as required for the conduct of a clinical trial.