

Questions and Answers - Steps to Establish the Teletrial Model

Sponsor:

Q1. When is the sponsor required to conduct a site evaluation visit?

The sponsor or the CRO should conduct a site evaluation for a new site not previously assessed and/or when the trial requires a new service not previously assessed.

Q2. Does the sponsor need to notify Ethics of a teletrial cluster?

Yes, the sponsor is required to seek ethics approval to add the additional sites.

Q3. When is the sponsor required to make a notification to add the satellite sites to the CTN?

The CTN lists sites where IMP is **stored** only. If the IMP is not stored at the satellite site(s) they do not need to be listed on the CTN. However, where the sponsor does store (not ship) IMP to satellite site then they need to be added to the CTN.

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.
- b) A subcontract between the primary and satellite sites.
- c) A current HREC approved master PICF.
- d) A supervision plan 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?

Yes satellite sites can be added to an existing teletrial at any time with the agreement of the Primary Site.

Q7. How do we manage the IMP for a teletrial cluster?

For a new teletrial cluster when the IMP is being stored at all sites the pharmacy fees need to be added to the CTRA.

When a satellite site is added to an open trial at the primary site the pharmacy fees at each satellite site 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 primary site will include the shipment costs to the satellite site

Q8. How do we manage the source documents for a teletrial model?

Where EMR is used by both primary and satellite sites documents are uploaded/scanned 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 number 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.

Q9. How do we manage the patient consent for a teletrial model?

Consent occurs through telehealth clinic visit when required. This needs to be documented in the supervision plan. If the Sub Investigator (SI) is in the clinic visit with the patient, 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 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.

Q10. How do we 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 keeps 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.