Evaluation of a Trial as a Teletrial checklist

ver 01 Jul 2022

*Use this checklist to guide the decision making about whether a clinical trial is suitable to be conducted as a teletrial. This evaluation may be undertaken with the site feasibility for new trials (with a confirmed protocol), or as needed if considering introducing satellite sites (with identified potential participants) into an already running clinical trial.*

*This form may also be submitted to the Sponsor when seeking approval to have the trial conducted under the Australian Teletrial Model.*

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| **Trial Title** |  |
| **Sponsor Type** | Commercial / Collaborative Group / Institution |
| **Sponsor Name:** |  |
| **Sponsor Representative:** |  |
| **Contact details for Sponsor Representative** | **T:** **E:** |
| **Site Name** |  |
| **Principal Investigator** |  |
| **Site Contact Person** |  |
| **Contact Details for Site Contact Person** | **T:** **E:** |

| **Pharmacy and Investigational Medicinal Product (IMP):** |
| --- |
| How is the IMP administered? | Delete whichever is not relevant.Oral / Parenteral / Other |
| Is special equipment required to administer IMP or other study medication? | Eg specific giving sets |
| If special equipment is required to administer IMP, who supplies the equipment? Sponsor or site? |  |
| Is special training required for Site Staff to administer IMP? |  |
| Does the IMP have specific storage or preparation requirements?  | Eg: shelf life after reconstitution; storage requirements, sterile prep?  |
| If IMP requires reconstitution, who can do this? | Eg: Site staff, Site Pharmacy, External provider |
| Will IMP be sent to the Primary Site only or will the Sponsor also send IMP to Satellite Sites? | CTN implications |
| Can IMP be easily transported to the site?  | Eg: Is cold chain transport required with temperature data loggers etc  |
| Who meets these costs? |  |
| How will IMP get to satellite sites during extreme weather events such as floods? | Eg: RFDS agrees to take a box of IP on routine visit, for collection by research staff. |
| Does the dose vary throughout the trial or is the same dose given throughout? |  |
| Where will the IMP be stored and who is responsible for the accountability log? Who will dispense IMP? | Will Sponsor agree to store IP at Satellite Sites? (CTN implications). |
| Is IMP supplied per participant for the entire study at the outset? Or is it sent in batches throughout the study? |  |
| If doses vary, what are they based on and is there a sufficient visit window to allow for dispensing of new IP? |  |
| What are the requirements or instructions for destruction of the IMP?  |  |
| Is IMP to be assigned via a pharmacy portal? If yes, when can this be assigned? For example, can IMP only be assigned on the day of the clinic visit or can IMP be assigned a week in advance to ensure adequate time for delivery from the primary site? |  |
| What are the identified adverse events and suspected unexpected serious adverse reactions for the IMP? |  |
| **Pathology:** |
| Are specimens processed locally or through a Central Laboratory? | All processing locally / Basic processing locally / Central Lab |
| Are there specific pathology processing requirements? If necessary, liaise with the relevant jurisdictional manager for regional pathology laboratories. The laboratory manual for the trial may be required. | Eg specific centrifuge process, time specific processing, -80oC freezer |
| If additional training for processing specimens is required, who provides this training? |  |
| If dry ice is required, who provides this? |  |
| Are there specific specimen transport requirements? | Will specimens be held & sent in batches, or sent on the day of the study visit? |
| If the protocol requires specimens to be stored at -80oC, will the sponsor agree to allow these to be stored at -20oC in the short term, until shipped to the Primary site for longer storage or batch shipping? Or can it be stored at -20oC until shipped directly to the central lab in the next day or week? |  |
| Will Sponsor pay costs associated with transporting specimens from Satellite Sites? |  |
| **Imaging** |
| Is there complex and specific imaging required for this clinical trial? Is there an imaging protocol for the study? | Eg: echocardiograms, MRI, PET Scans etc? |
| If so, are the scanners or other required imaging equipment available in rural and remote areas? |  |
| Are there other specific requirements such as no software upgrades during the conduct of the study? |  |
| Is there an uploading requirement for the imaging? What is the data file transfer platform? |  |
| Are there specific training requirements for imaging? |  |
| Are sites required to pass qualification testing for imaging? |  |
| **Trial Design and Study Visits:** |
| Are there additional investigations or tests not mentioned above that are required in this clinical trial?  | Eg Cardiopulmonary Exercise tests (CPET), specific respiratory function tests  |
| Is there specific testing or measuring equipment required for this clinical trial eg cognitive testing kits, Intravascular Ultrasound, sponsor provided 12 lead ECG machines? |  |
| If specialist equipment IS required for this clinical trial, is it available at all potential Satellite Sites or will Sponsor agree to provide it to all Satellite Sites? |  |
| Does the trial design allow for some or all visits to be undertaken via telehealth at a Satellite Site? |  |
| Are there specific timepoints or procedures that must be done at the Primary Site? |  |
| Will the Sponsor contribute to participant travel costs from Satellite Sites to Primary Site? |  |
| How will monitoring be undertaken?  |  |
| Does the Sponsor accept electronic signatures? |  |
| Where will Satellite Site study documentation be stored during the trial? At the Satellite Site or sent to the Primary Site? |  |
| Where will study documentation from Satellite Sites be archived at the end of the study? |  |
| **Regulatory:** |
| What contract is intended to be used for this trial? | Delete whichever is not relevant (indemnity implications).MA CTRA Std; MA CTRA CRO; MA CTRA CRG; MTAA CIRA; Other (please specify). |
| Who will provide indemnity to any potential Satellite Sites? | Sponsor / Site Institution / Other (please specify). |
| Will the Sponsor provide Site Investigator File to Satellite Sites or will Primary Site have the only SIF and Satellite Sites have a subset of documents? |  |
| Will this trial be conducted under the CTN / CTA scheme? |  |
| **Other Comments** |
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If there are items that you consider should be included in this document, please let us know.
E: Australian\_Teletrial\_Program@health.qld.gov.au

*If it is decided that this trial is not suitable to be conducted under the teletrials model, please send this completed form to your jurisdictional Regional Clinical Trials Coordinating Centre, along with any additional information about why the trial was not suitable, as it will assist in analysis and reporting of the success of the teletrials model.*

*If the trial appears suitable to be conducted under the teletrials model, but the Sponsor chooses not to allow this, please also send this form, along with the Sponsor’s rationale, to the Australian Teletrial Program office as it will assist us in identifying barriers and obstruction in implementing this model.*

*Please use the email address provided above.*