## Is my trial suitable for a Teletrial?

# This questionnaire helps determine if a clinical trial can be conducted as a teletrial. It can be completed at the point of site feasibility for new trials (with a confirmed protocol) or if satellite sites (with identified potential participants) are introduced into an established clinical trial. You can also submit this form to Sponsors when seeking approval to conduct the trial under the Australian Teletrial Model. This is an example; please consult the relevant state RCCC for state-specific applicable guidance.

# Complete this questionnaire as far as possible before consulting with your sponsor/CRO!

*Red text is instructional and should be deleted prior to submission.*

*Please mark sections not applicable to your trial as N/A.*

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| --- | --- |
| Trial Title: |  |
| Sponsor Type: | Commercial / Collaborative Group / Institution |
| Sponsor Name: |  |
| Sponsor Representative and contact details: | **Name:**  **T:**  **E:**  NB: it is recommended that one primary contact is nominated to reduce burden of information sharing between site/departments |
| Site Name: |  |
| Principal Investigator: |  |
| Site Contact Person and contact details: | **Name:**  **T:**  **E:** |

|  |  |
| --- | --- |
| **Trial Design and Study Visits:** | |
| Are there additional investigations or tests not mentioned above that are required in this clinical trial? | E.g: Echocardiograms, Cardiopulmonary Exercise tests (CPET), specific respiratory function tests |
| Is there specific testing or measuring equipment required for this clinical trial | E.g: 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 at a Satellite Site? | E.g. fully delegated to SS, supported by PS, in-person, telephone or video conferencing supported visit |
| Based on the responses in this section, are there specific timepoint visits or procedures that must be done at the Primary Site? If so, please identify. | Consider using protocol schedule of assessment to confirm |
| Will the Sponsor contribute to participant travel costs from Satellite Sites to Primary Site? | E.g: Would travel or accommodation vouchers be provided to assist? |
| Will monitoring be conducted at both Primary Site and Satellite Sites |  |
| How will monitoring be undertaken? | E.G Remote (SiteDocs/TrialDocs)/Onsite at PS/Onsite at PS and SS.  Consider increased IMV frequency for additional monitoring support if required |
| If onsite monitoring is only conducted at Primary Site, where and how will Satellite Site study documentation be stored and transmitted during the trial? |  |
| How will data be entered into the Electronic Data Capture database? | E.g. fully delegated to SS, completed by PS, consider implications of delegating, does SS require separate site ID? |
| Where will study documentation from Satellite Sites be archived at the end of the study? |  |
| Does the Sponsor accept validated electronic signatures? If so, which formats are accepted? |  |
| Are there additional investigations or tests not mentioned above that are required in this clinical trial? | E.g: Echocardiograms, Cardiopulmonary Exercise tests (CPET), specific respiratory function tests |
| Is there specific testing or measuring equipment required for this clinical trial | E.g: 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? |  |
| Based on the responses in this section, are there specific timepoint visits or procedures that must be done at the Primary Site? If so, please identify. | Consider using protocol schedule of assessment to confirm |
| **Pharmacy and Investigational Medicinal Product (IMP):** | |
| How is the IMP administered? | Delete whichever is not relevant.  Oral / Parenteral / Other (please specify) |
| Is special equipment required to administer IMP or other study medication? | E.g: 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? Will Sponsor provide necessary equipment? | E.g: shelf life after reconstitution; storage requirements, sterile prep, temperature monitoring device? |
| If IMP requires reconstitution, who can do this? | E.g: 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? | Consider CTN implications |
| Can IMP be easily transported to the site? | E.g: dry ice etc |
| Who meets these costs? | Consider CTRA implications |
| How will IMP get to satellite sites during extreme weather events such as floods? | E.g: Royal Flying Doctor Service (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? (Consider CTN implications, including chain of custody paperwork). |
| 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 and by whom? 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? | Consider delegation log, same day dosing and staffing implications |
| 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? | Delete whichever is not relevant.  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. | E.g: specific centrifuge process or processing equipment, time specific processing, -80oC freezer, sample processing log |
| If additional training for processing specimens is required, who provides this training? How is training delivered? | Virtually/face to face/other (please specify) |
| Are there specific specimen transport requirements? Such as dry ice. | Will specimens be held & sent in batches, or sent on the day of the study visit? |
| If dry ice is required, can the sponsor pay for it? | E.g: Courier companies can provide this to site at a cost if not available on site. |
| If the protocol requires specimens to be stored at -80oC, is there any capacity for short term alternate storage arrangements? | Consider maximum timeframes and parameters for alternate storage arrangements |
| If specimens need --80oC storage and it is not available on site, will the sponsor pay for a freezer or other infrastructure associated costs required? |  |
| 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? | E.g: Ultrasound, X rays, MRI, PET/ CT 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 software upgrades during the conduct of the study? |  |
| Is there an uploading requirement for imaging? What is the data file transfer platform and are there any limitations for consideration? | E.g. limitation on platform access |
| Is there any specific training required for uploading the imaging? Is so, how is the training delivered? | Virtually/face to face/other (please specify) |
| Are there specific training requirements for imaging? If so, how is training delivered? | Virtually/face to face/other (please specify) |
| Are sites required to pass qualification testing for imaging? |  |
| **Regulatory:** | |
| What contract is intended to be used for this trial? | Delete whichever is not relevant (consider 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? | NB. If indemnity is being provided by the sponsor of this trial to primary/stand alone sites, satellite sites must be provided indemnity by the sponsor of the study.  Sponsor / Site Institution / Other (please specify). |
| Will the Sponsor provide Investigator Site 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** | |
|  | |
| **Post Site Evaluation:** |  |
| Was this trial suitable to be conducted via the Teletrial model? | Yes/no (please specify why and provide any supporting documents) |
| Did the sponsor agree to conduct this trial via the Teletrial model? | Yes/no (please specify why and provide any supporting documents) |

**Please send this completed form to your jurisdictional Regional Clinical Trials Coordinating Centre, along with any supporting documents.**

Can this form be improved? Let us know at [Australian\_Teletrial\_Program@health.qld.gov.au](mailto:RCCCQLD@health.qld.gov.au)