Multisite Clinical Trials vs Teletrials Matrix

OFFICIAL

Multisite Clinical Trials vs Teletrials Matrix

Regulatory requirements	Multisite Clinical Trials	Teletrials
Contracts	• Commercially sponsored trials ○ Medicines Australia Clinical Trial Research Agreement (CTRA)	• Commercially sponsored teletrials ○ The Head Agreement between the Sponsor and the Institution (Primary Site) is the Medicines Australia Clinical Trial Research Agreement (CTRA). Schedule 1 should include particulars of the Primary Site and Satellite Site(s). Schedule 2 should include additional teletrial-related costs in the budget as agreed, payments and invoicing, and terms and conditions for the Satellite Site(s). When additional Satellite Sites join a cluster, the Sponsor should amend Schedules 1 and 2 of the CTRA. **and** ○ Medicines Australia Teletrials Subcontract between the Institution (Primary Site) and the subcontractor (Satellite Site) complements the Head Agreement. It should detail the management of clinical trial activities and formalise its relationship with each Satellite Site. ○ No contract is required between the Sponsor and any Satellite Site.
	• Investigator Initiated trials ○ Investigator Initiated CTRA for use in Victoria	• Investigator Initiated teletrials Contract arrangements may differ depending on the teletrial parties • The Clinical Trial Research Agreement (CTRA) for Investigator-Initiated Teletrials where the **Institution is acting as the Sponsor** and the **Other Institution acting through Satellite Site/s** is available for Victoria only.

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Insurance	• Commercially Sponsored trials
	  ○ Insurance Certificate meeting minimum requirements
		• The party of the Head agreement is the jurisdiction-based hospital or public service and is insured by the VMIA. A Satellite Site that is a private entity should hold sufficient insurance arrangements
		• In Victoria, public hospitals and clinicians are covered for professional and medical indemnity within their VMIA insurance.
		• Private hospitals and non-employed clinicians must have their own professional and medical indemnity
		  ○ Each Satellite Site should maintain professional indemnity and public liability insurance and provide a Certificate of Insurance

Indemnity	• Commercially Sponsored trials
	  ○ Standard Indemnity Form on Medicines Australia Website or Standard Indemnity Form for a Clinical Investigation on Medical Technology Association of Australia Website.
		• Commercially Sponsored teletrials
		  ○ Standard Indemnity Form on Medicines Australia Website or Standard Indemnity Form for a Clinical Investigation on Medical Technology Association of Australia Website provided to both the Primary Site and Satellite Site.
		• Non-commercial clinical trials
		  ○ If indemnity is provided by the Sponsor or Collaborative Group, the Satellite Sites should be named and individually covered. Where indemnity is not provided by the Sponsor, each participating site (Primary or Satellite) must hold valid insurance to conduct the teletrial.

Clinical Trial Notification (CTN) – Site details	• It is the responsibility of the Sponsor to complete and submit the CTN via the TGA online portal • Participating sites complete the Trial Site Details (sub-form) for each site including contact details of Principal Investigator	• It is the responsibility of the Sponsor to complete and submit the CTN via the TGA online portal • The CTN should be updated as Satellite Sites are on-boarded to the study (if applicable)

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Operational requirements	Multisite Clinical Trials	Teletrials
Institutional appointment	• Principal Investigator has appointment/employment arrangements at a study site	• The Primary Site Principal Investigator has appointment/employment arrangements at the Primary Site • The Satellite Site Associate Investigator has appointment/employment arrangements at the Satellite Site
Site Initiation	• Site Initiation Visit is conducted by Sponsor with Principal Investigator and research staff assisting in clinical trial including protocol training	• The Sponsor is responsible for: o Conducting the Site Initiation Visit at the Primary Site. If Satellite Site(s) are known at the time of Site Initiation, they should participate in the Site Initiation Visit electronically (or in person if possible) **Or** o Provide the Primary Site Principal Investigator with necessary training resources to use when on-boarding new Satellite Sites • This will be documented in the Supervision Plan
Supervision	• The Principal Investigator at each site is responsible for the overall conduct of a clinical trial at their site.	• The Primary Site Principal Investigator of a cluster is responsible for the overall conduct of a clinical trial at their site and all associated Satellite Sites • The Primary Site Principal Investigator is responsible for developing a detailed Supervision Plan for each Satellite Site. o The Supervision Plan should outline study responsibilities delegated to Satellite Site and frequency of supervision undertaken by the Principal Investigator with Satellite Site staff o The Primary Site Principal Investigator should ensure all investigational staff at both Primary and Satellite Sites, or Independent Third party and External Service Providers are qualified to perform delegated duties
Recruitment and Consent process	• Principal Investigator to demonstrate a recruitment potential from principal site • Principal Investigator is responsible for consent process at their site	• The Primary Site Principal Investigator to demonstrate a recruitment potential from Primary Site and/or from Satellite Site • The Primary Site Principal Investigator is responsible for consent process at both Primary and Satellite Sites. • Consent process can either:

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Operational requirements	Multisite Clinical Trials	Teletrials
		○ be undertaken by the Primary Site Principal Investigator for a Satellite Site participant via Telehealth or as agreed in the Supervision Plan **or** ○ delegated by the Primary Site Principal Investigator to Satellite Site Associate Investigator as documented in the Supervision Plan and the delegation of duties log.
Randomisation	• Individual sites are responsible for randomisation of participants	○ Randomisation for Satellite Sites ○ The Primary Site Principal Investigator is responsible for the randomisation of participants and notifies the randomisation result (treatment group) to the Satellite Site **or** ○ The randomisation process is delegated by the Primary Site Principal Investigator to the Satellite Site as documented in the Supervision Plan.
Follow ups	• Principal Investigator/delegate is present during follow-up consultations of study participants • Unblinding procedures ○ Principal Investigator is responsible for premature unblinding procedures of investigational product	• Follow up consultations of study participants can occur at the Primary Site and/or Satellite Site according to the process outlined in the Supervision Plan • Unblinding procedures ○ Principal Investigator is responsible for premature unblinding procedures of investigational product at a Satellite Site. Trial related decisions made with a Satellite Site should be conducted as outlined in the Supervision Plan
Study Master File	• Principal Investigator has responsibility regarding maintenance of the Study Master File (SMF) and associated essential documents at study site	• Principal Investigator to establish maintenance rules of the Study Master File (SMF) and relationships between Primary Site SMF and the Satellite Site study file i.e. the contents, filing arrangements and archiving of Satellite Site study file
Infrastructure	• Appropriate and suitable facilities at sites	• Appropriate and suitable facilities at Primary Site and Satellite Site depending on the trial-related activities that would be conducted at the site, and as documented in the Supervision Plan and the delegation of duties log.

Operational requirements	Multisite Clinical Trials	Teletrials
		• Satellite Site does not have to have the capacity or capability to conduct all aspects of the trial.
Funding and Payments	• Commercially sponsored trials ○ Funding /Payment details provided in Medicines Australia CTRA (Schedule 2) • Investigator Initiated trials ○ Funding / Payment details provided in Investigator Initiated CTRA (Schedule 2) for use in Victoria	• Commercially sponsored trials Schedule 2 of the Medicines Australia Clinical Trial Research Agreement (Head Agreement) between the Sponsor and the Primary Site should include payment amounts, invoicing, and terms and all teletrial related payments. **and** ○ Schedule 2 of Medicines Australia Teletrial Subcontract between the Primary Site and Satellite Site should include payment information. If these fees are supported via the Teletrial Support Program funding, it would need to be included • Investigator Initiated trials Arrangements may differ depending on the teletrial parties ○ Funding / Payment details provided in the *Clinical Trial Research Agreement (CTRA) for Investigator-Initiated Teletrials* (Schedule 3).
Ethics and Governance applications	• In a single site trial, the Principal Investigator has overall clinical and research responsibility for the ethics application including sign-off. Submission can be delegated to other members of the research team. • In a multisite clinical trial, the Coordinating Principal Investigator has overall clinical and research responsibility for the ethics application including sign-off. Submission can be delegated to other members of the research team. • Principal Investigator at each site has responsibility for the site-specific assessment application including sign-	• In a single cluster trial, The Primary Site Principal Investigator has overall clinical and research responsibility for the ethics application including sign off. Submission can be delegated to other members of the research team. • In a multisite clinical trial with a teletrial component, the Coordinating Principal Investigator is responsible for communications including ethics applications and reporting to the reviewing HREC. • In a multisite clinical trial with a teletrial component, the Coordinating Principal Investigator is responsible for notifying the Primary Site Principal Investigator of the Sponsor's agreement to conduct the trial under the Australian Teletrial Model • The Principal Investigator at the Primary Site has responsibility for the site-specific assessment application including sign off at their site. Submission can be delegated to other research team members.

Operational requirements	Multisite Clinical Trials	Teletrials
	off. Submission can be delegated to other members of the research team.	• The Associate Investigator of each Satellite Site has responsibility for the stie specific assessment application and submission at their site. The Satellite Site SSA declaration by Principal Investigator section is signed by the AI at the Satellite Site. • Satellite Site *Authorisation* can only occur after Primary Site *Authorisation*.

To receive this document in another format, phone 0408 274 054, using the National Relay Service 13 36 77 if required, or email Coordinating Office for Clinical Trial Research <multisite.ethics@safercare.vic.gov.au>.

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.