Multisite Clinical Trials vs Teletrials Matrix

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Regulatory requirements	Multisite Clinical Trials	Teletrials
Contracts	• Commercially sponsored trials ○ Medicines Australia Clinical Trial Research Agreement (CTRA) • Investigator Initiated trials ○ Investigator Initiated CTRA for use in Victoria	• Commercially sponsored trials ○ the Head Agreement between the sponsor and Institution (Primary Site) remains the Medicines Australia CTRA **and** ○ the Clinical Trial Research Agreement Subcontract For Studies Conducted Under A Tele-Trials Model is between the Primary Site and each Satellite Site (Subcontractor) • Investigator Initiated trials Contract arrangements may differ depending on the teletrial parties ○ The Collaborative or Cooperative Research Group (CRG) clinical trial research agreement may be modified for a teletrial Head Agreement **OR alternatively** ○ In Victoria a *Clinical Trial Activities Agreement* for an Investigator initiated study by Tele-trial is between the Primary Site (in Victoria) and the Satellite Site. There may be no Head Agreement and is dependent on the organisation.
Insurance and Indemnity	• Medicines Australia CTRA	• 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

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	• Medicines Australia Form of Indemnity	• 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
Clinical Trial Notification (CTN) – Site details	• Participating sites complete the Trial Site Details (sub-form) for each site including contact details of Principal Investigator	• The Principal Investigator is responsible for listing all sites, both Primary and Satellite on the CTN Each site that administers the investigational product must be included in the CTN.

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 • Satellite Site Sub-Investigator has appointment/employment arrangements at the Satellite Site
Site Initiation	• Site initiation meeting is conducted by Sponsor with Principal Investigator and research staff assisting in clinical trial including protocol training	• Site initiation meeting is conducted by Sponsor at Primary Site with Principal Investigator and research staff including Satellite Site staff in person or via Telehealth
Supervision Plan	• Coordinating Principal Investigator takes responsibility for the overall conduct, management, monitoring & reporting of research conducted at sites	• The Principal Investigator is responsible for the overall conduct of a clinical trial and any related Satellite Sites

Operational requirements	Multisite Clinical Trials	Teletrials

	• Supervision plans are the responsibility of the site Principal Investigator
	  ○ the manner and frequency of supervision of other study staff should be documented
	  ○ the oversight to any third party outsourced for study related duties/functions should be documented
	• The study contact at each site is the site Study Coordinator
		• The Principal Investigator is responsible for the Supervision Plan at each Satellite Site
		  ○ study responsibilities delegated to Satellite Site and frequency of supervision undertaken by the Principal Investigator with Satellite Site staff should be documented
		  ○ 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
		• The Study Coordinator at the Primary Site is the study contact for all Satellite Sites

Recruitment and Consent process	• Principal Investigator to demonstrate a recruitment potential from principal site
	• Principal Investigator is responsible for consent process at their site
		• Principal Investigator to demonstrate a recruitment potential from Primary Site and/or from Satellite Site
		• Principal Investigator has the responsibility to assess eligibility criteria for first few patients at Satellite Site via Telehealth accompanied by appropriate health practitioner
		• Consent process undertaken by Principal Investigator for a Satellite Site participant
		  ○ Principal Investigator conducts consent process via Telehealth
		  ○ Patient and Satellite Site Coordinator present in the same room at Satellite Site
		  ○ Principal Investigator signs the PICF at the Primary Site and participant signs the PICF at the Satellite Site
		or
		• Consent process is delegated and documented by Principal Investigator to Satellite Site Sub-Investigator if appropriate

Operational requirements	Multisite Clinical Trials	Teletrials
		○ Principal Investigator to be present via Telehealth where possible ○ Satellite Site Sub-Investigator and participant sign the PICF at the Satellite Site
Randomisation	• Individual sites are responsible for randomisation of participants	• Randomisation for Satellite Sites ○ The Primary Site 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 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 • Principal Investigator is responsible for medical care and supervision of participants at the site • Principal Investigator is responsible for patient documentation in medical notes and Case Report Form/*e*CRF • Unblinding procedures ○ Principal Investigator is responsible for premature unblinding procedures of investigational product • Principal Investigator has responsibility regarding maintenance of the Study Master File (SMF) and associated essential documents at study site	• Follow-up consultations of study participants performed in presence of Principal Investigator, Satellite Site Sub Investigator, main Study Coordinator as needed, nurse at Satellite Site as needed (via Telehealth) • Clinical care decisions - If a study participant is admitted to any hospital, the Principal Investigator should be notified and provide appropriate advice as outlined in Supervision Plan • Satellite Site Sub-Investigator is responsible for patient documentation in medical notes and Case Report Form/eCRF. Clinical notes are filed at both Primary and Satellite Sites • 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 (outlined in Supervision Plan) should be conducted via videoconference • 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

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		• Sponsor / Clinical Trial Coordinator at Primary Site to oversee Satellite Site study file regularly
Infrastructure	• Appropriate and suitable facilities at sites	• Appropriate and suitable facilities at Satellite Site • Consideration to be given whether telehealth communication i.e. telehealth technology is suitable for teletrial consultations between the Primary Site and Satellite Site
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 ○ Funding /Payment details provided in the Head Agreement (Medicines Australia CTRA) Schedule 2 **and** ○ Funding /Payment details provided in the *Clinical Trial Research Agreement Subcontract For Studies Conducted Under A Tele-Trials Model* (Schedule 2) • Investigator Initiated trials Arrangements may differ depending on the teletrial parties ○ The Collaborative or Cooperative Research Group (CRG) clinical trial research agreement may be modified for a teletrial head agreement. Funding / Payment details provided in Schedule 2. ○ Funding / Payment details provided in the *Clinical Trial Activities Agreement* for an Investigator initiated study by Tele-trial (Schedule 4)
Ethics and Governance applications	• Coordinating Principal Investigator has overall clinical and research responsibility for the ethics application and submission • Principal Investigator at each site has responsibility for the site-specific assessment application and submission	• The Primary Site has clinical and research responsibility for the ethics application and submission • Each Satellite Site is responsible for a site-specific assessment application Submission can be assigned to the Satellite Site or to the Primary Site.

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@health.vic.gov.au>.

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