TELETRIALS FREQUENTLY ASKED QUESTIONS

Q.1	What is a teletrial cluster?
A.	A primary site and related satellite sites participating in a clinical trial using the tele-trial model.

Q.2	What is the difference between multi-site trials and teletrials?

A.

	Multi-site trials	*Tele-trials*
Nature of site	Trials are conducted at multiple independent sites	Trials are conducted within clusters
Relationship between sites	Sites have no relationship with each other	Primary and satellite sites work in collaboration and are connected by telehealth for some or all aspects of the clinical trial
Trial coordination	At each site, trial coordination is the responsibility of the Principal Investigator (PI) with overall trial coordination across all sites performed by sponsors and Contract Research Organisations (CROs)	Within a cluster, trial coordination is the responsibility of the Principal Investigator at the primary site with contribution from satellite sites, sponsors and CROs.
Site of primary investigator (PI)	PIs are appointed at each site	PI at primary site and sub-Investigators at satellite sites work in collaboration
Regulatory processes	Governance and other regulatory approvals are performed separately by each site	This model paves the path for streamlining of approval processes, and minimisation of duplication due to collaborative nature of research governance officers within clusters

Q.3	How do I set up a teletrial?
A.	Please refer to the resources below available on the COSA website - • Checklist to establish a Tele-Trial cluster for Sponsors and Sites • Checklist of documents for RGO submission Primary and Satellite Sites https://www.cosa.org.au/groups/regional-rural-oncology/tele-trials/

Q.4	How many satellite sites can be included in a teletrial cluster?
A.	Any number of satellites can be added to a teletrial cluster with the agreement of the sponsor and the primary site.

Q.5	How long does it take to set up a teletrial?
A.	If the sites are new to teletrials it may take 3-4 months. Once the sites are familiar with the Model the start-up time should be the same as for standard clinical trials
Q.6	Can any clinical trial be run as a teletrial?
A.	Not all trials are suitable. Phase I trials which require specialised equipment and intense monitoring of participants may not be suitable. Management and transport of IMP at satellite sites is an important consideration when selecting a suitable trial.

Q.7	We have a clinical trial which is already open for recruitment can we add a satellite site using the Teletrial Model?
A.	Yes satellite sites can be added at any time. Opening the primary site initially also allows recruitment to commence while the teletrial model is being established at satellite sites.

Q.8	Can any site participate in a teletrial?
A.	Each satellite site needs to be assessed to ensure they have the required resources and equipment to participate in a teletrial. A trial naïve site can participate in a teletrial under the supervision of an experienced primary site.

Q.9	Where can I find out more information about the teletrial model?

A	The Australasian Tele-Trial Model National Implementation Guide: https://www.cosa.org.au/media/332325/cosa-teletrial-model-final-19sep16.pdf
	
	The Australasian Tele-Trial Model: Lessons from Practice (a supplement to the Asia Pacific Journal of Clinical Oncology): https://onlinelibrary.wiley.com/toc/17437563/2019/15/S8
	
	COSA website – https://www.cosa.org.au/groups/regional-rural-oncology/tele-trials/ An extensive range of resources and templates are available on the COSA website and resources are regularly updated. There are also links to SOPs including tele-trials developed by Queensland, Victoria, and NSW, the Victorian and Queensland tele-trials subcontract and NMA approved tele-trial SOPs and supervision plans.
	
	Resources available are:
	• Introduction to the COSA Australasian Tele-Trial Model
	• Supervision Plan Templates
	  ○ Supervision Plan – Sites without Medical Specialist
	  ○ Supervision Plan – Sites with Medical Specialist
	  ○ Supervision Plan - Sites with Clinical Trials Experience
	• Checklist to establish a Tele-Trial cluster for Sponsors and Sites
	• Checklist of documents for RGO submission Primary and Satellite Sites

	• Post approval steps – teletrial amendments for Sponsors and Sites • Schedule 2 information for Subcontract June 2018 • Primary Site Q&A Steps to establish the Tele-Trial Model • Satellite Site Q&A Steps to establish the Tele-Trial Model • Sponsor Q&A Steps to establish the Tele-Trial Model • IMP Management in Teletrials • Teletrials Primary Site IMP Handling SOP • Remote consent process in Tele-Trials • Sample PICF for Tele Trial Clusters • Tele-Trials Payment Matrix for Schedule 2

Q.10	How do I know which sites are participating in tele-trials?
A	A list of sites participating is available on the COSA website https://www.cosa.org.au/groups/regional-rural-oncology/tele-trials/