Clinical Oncology Society of Australia

Queensland Government

CHECKLIST TO ESTABLISH A TELETRIAL CLUSTER FOR SPONSORS AND SITES

Steps	Sponsors	Date Complete	Comments
1.	Sponsor and primary site consider the clinical trial protocol for suitability for the Teletrial model.		
2.	Conduct site evaluation visits at each satellite site if required. Consult with CRO (if applicable) and quality advisors for monitoring purposes.		
3.	Add satellites sites to the central ethics notification and transfer SSA form to satellite site(s). If IMP is stored at the satellite(s) make required notifications to add satellite site(s) to existing CTN. All satellite sites within a cluster are covered under the CTN registered with the TGA.		
4.	Amend CTRA to add the satellite site(s) as study sites to Schedule 1. and to add additional pharmacy costs according to the number of sites which will be in receipt of the Investigational Product (IP) in Schedule 2. Create a new indemnity per site. Indemnities are added to Schedule 3 of the subcontract.		
5.	Review and approve Supervision Plan developed between primary and satellite(s).		
6.	Approve the cluster PICF developed by primary site from the master PICF for the trial. Send Submission package including cluster PICF to Primary site to accompany the Primary site RGO submission package for satellite sites (satellite sites receive the complete submission package from sponsor and primary site combined).		
7.	Request access for all staff involved in the clinical trial at the primary and satellite site(s) to complete training in GCP and in the clinical trial protocol and any non-specific protocol training. Ensure satellite sites have access to GCP if required.		
8.	Sponsor and CRA check that all staff conducting trial related activity at primary and satellite site(s) are on delegation and signature logs and have completed all training required and this is entered on the training logs.		
9.	Sponsor and the CRA conduct the Site Initiation Visit with the Teletrial cluster sites including all confirmed satellites and once completed the official letter to open the satellite site(s) is sent.		

Steps	Primary Site	Date Complete	Comments
1.	Determine the suitability of the clinical trial protocol for the Teletrial Model in collaboration with the sponsor.		
2.	Collaborate with satellite sites to assess their willingness and capacity to participate in the Teletrial cluster and complete the feasibility assessment. Assist sponsor with satellite site evaluation visits as required.		
3.	Provide the sponsor with all contact details, finance information and addresses including the e-mail address of satellites for the transfer of the online SSA form.		
4.	Sign a CTRA Teletrials Subcontract with each satellite site. This is submitted with RGO submission documents for Chief Executive sign off and approval. (It is recommended that a first draft of the subcontract be provided to the sponsor for feedback prior to sign off).		
5.	Develop a mutually agreed Supervision Plan in collaboration with each satellite site and ensure these are approved by the sponsor. The supervision plan details all accountability and responsibilities of both primary and satellite site(s) as outlined in the Australian ICH GCP SOPs (including teletrials) and the COSA Australasian Teletrial Model National Implementation Guide. The Supervision Plan will outline the matrix of responsibilities for all trial activity.		
6.	Submit all documentation to primary site RGO for approval to open the clinical trial at the primary site. Primary site RGO will acknowledge all other documents submitted to assist the satellite RGO with their approval. Documents for primary site submission are: • PI signed letter to RGO • HREC Amendment approval letter • CTRA Teletrial subcontract for each satellite site • Supervision plan for each satellite site • CTRA Amendment x 3 copies • Teletrial Cluster Specific Patient Informed Consent Forms (Master PICFs do not need to be submitted to the Primary site RGO if the clinical trial is already approved at the primary site).		
	Send RGO submission package and sponsor package to each of the satellite sites for satellite site RGO submission (pending receipt of approval letter from primary site RGO).		
7.	Participate in all protocol related training and assist Sponsor with satellite site training as required.		
8.	Ensure all staff conducting trial related activity at primary site are recorded in delegation and signature logs and have completed all training required.		
9.	Primary site receives notification from the sponsor that the satellite site is approved to open. Participate in Site Initiation for all sites within the Teletrial cluster. Site initiation can be conducted using telehealth or videoconferencing.		

Steps	Satellite Site	Date Complete	Comments
1.	Review proposed Clinical Trial Protocol for suitability for site participation in the proposed teletrial cluster.		
2.	Participate in feasibility assessment with primary site and site evaluation visit with the sponsor.		
3.	Complete online SSA form once transferred from the sponsor and complete all required documentation such as FDA forms, privacy consents etc. as required by the sponsor.		
4.	Review and sign CTRA subcontract with the primary site.		
5.	Develop the Supervision Plan in collaboration with the primary site.		
6.	Prepare and submit documents for satellite site RGO approval including the documents received from the sponsor and primary site including: • Copy of primary site RGO Teletrial approval and acknowledgment • CTRA Amendment HREC approval, CTRA Teletrial Subcontract, Clinical Trial Notification, signed Supervision Plan, Cluster PICFs, current approved protocol, Investigator Brochure • Satellite site SSA form, indemnities, insurance etc plus any other documentation required for RGO submission approval • Radiation safety letter • All patient Diaries, Thank you cards, Quality of life Questionnaires		
7.	Complete all required training for working in clinical trials as required by the sponsor and complete training for the specific protocol/ clinical trial once the CTRA amendment is approved by ethics.		
8.	Ensure all staff conducting trial related activity at satellite site are on delegation and signature log and have completed all training required and entered on the training log.		
9.	Once RGO approval is gained, attend Site Initiation Visit organised by primary site. The clinical trial can now commence at the satellite site. It is recommended that close supervision occur for the informed consent visit and subsequent patient activity/treatment visits for the first patient until the primary site and satellite site are confident that the satellite site is fully supported to conduct trial activity.		