Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
PICF Development and Writing	To develop the Master PICFs for the trial. This includes country-specific Master PICFs for International Trials.	Collaborative trial PICF development and preparation, review, and writing with Sponsor-Investigators and Trial Team.	
Clinical Trial Agreements	To develop Clinical Trial Research Agreements based on relevant jurisdictional templates.	Collaborative CTRA development and review with Sponsor-Investigators and MCRI Legal Team. Negotiations of CTRAs with participating sites.	
Essential Document Management	Trial Master File (TMF), Site Investigator File (SIF) and Investigator Site File (ISF) essential document preparation & management.	Maintain the TMF and associated SIFs and essential document's (via electronic eTMF Platform). Advise and train participating sites on the requirements and maintenance of their ISF in accordance with Sponsor requirements.	
SITE MANAGEMENT			
Site Management	To provide invaluable support to participating sites within the trial, those new to multi-centre research, and to mitigate risks to poor trial conduct.	Act as the point of contact for all trial-related enquiries, operations, logistics and data management queries from participating sites.	
Site Start-Up Meetings	Trial provide ongoing support to participating sites during the site start-up phase of the trial (pre Site Initiation Meeting). Opportunity to discuss trial protocol, procedures, and challenges in an open forum.	Participate in teleconference calls/meetings with participating sites during the site start-up phase, as required.	
Site Training	Provide all relevant trial training to site staff at participating sites.	Trial specific support to site research teams and coordinators. Act as the point of contact for all trial-related training enquiries.	
Site Initiation Meetings	Undertake Site Initiation Meetings with each participating site, training each site on full trial process during in-person or virtual meeting. Prepare and provide start up packages to sites.	Assist the Sponsor-Investigator in performing site initiation visits and follow-up any outstanding action items.	

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
Site Data Management Support	To aid participating sites with all local data management issues (i.e., outstanding data issues, recruitment issues, other data quality issues and data entry questions).	Respond to participating site queries regarding outstanding data issues, recruitment issues, other data quality issues and/or data entry questions.	
Monthly Trial Update e-Newsletters	To promote trial progress and activity across its participating sites, achievements, recruitment rates, trial specific challenges and opportunities, disseminate updates and news.	Trial updates and news are routinely disseminated.	
Site Payments	Facilitate site payments to participating sites based on the payment schedule outlined in the Clinical Trial Research Agreement.		
ETHICS, GOVERNANCE AND REGULATORY SUPPORT			
Ethics and Research Governance Support	To facilitate participating sites with site-specific ethics committee and/or research governance submissions. Navigate complex ethics and governance processes that vary between sites, states, and country. Support international participating sites with their ethics requirements. Submit protocol amendments and safety related reports (adverse event reporting) to the HREC.	Assist participating sites in their ethics submission and approval process. Submit protocol amendments and fulfil reporting requirements to the HREC.	
Regulatory Agency Submissions (e.g. Clinical Trial Notification or Clinical Trial Exemption to the TGA)	To fulfil clinical trial registration and reporting requirements in accordance with national and international regulations.	Preparing submissions to regulatory agencies for participating sites across both the Australia and internationally.	

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
Clinical Trial Registry Registration	To register the clinical trial on a recognised platform.	Assist in the preparing, review and submission of clinical trial registry entries (i.e. ClinicalTrials.gov) for Sponsor-Investigators and Research Teams.	
BIOSTATISTICAL SUPPORT *(Note Biostatistical support provided by CEBU)*			
Protocol development	Provide statistical input into the protocol, protocol amendments and interactions with ethics committees. Statistical input to the protocol focuses primarily on clarifying the research question, study endpoints, study design, data to be collected, sample size and statistical analysis.	Protocol writing and consultations during protocol writing. Conduct sample size calculation.	Note: services provided by CEBU, separate charges apply. Contact: CEBU.admin@mcri.edu.au
Randomisation	Design the randomisation plan for the study, and write standard operating procedures (SOP) (e.g. if there is a complex randomisation plan) or provide input to other documents where randomisation process is detailed (e.g. pharmacy manual) if needed. Oversee provision of randomisation schedule for the study by an independent biostatistician. (Including the provision of a randomisation database or manual randomisation envelopes if required)	Develop randomisation SOPs and randomisation schedule	
Statistical Analysis Plan (SAP)	To develop and maintain the Statistical Analysis Plan (SAP) for the trial.	Development of SAP	
Interim and Final Statistical Analyses	Plan and conduct the analysis required to address the primary and secondary objectives, as specified in the study protocol and/or SAP, the results of which will be provided in a statistical report.	Production of statistical report	
Safety Review Committees Statistical Analysis and reports for Data Safety Monitoring Committees	Review and provide input on Safety Review/Data Safety Monitoring Committee (DSMC) meetings, attend Safety Review meetings, including generation and reporting of statistical analyses for Safety Reviews, where required, as outlined in the protocol/SAP. In the case of unblinded Safety Reviews, the trial	Preparation of safety review report	

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
	statistician will not generate the unblinded closed report, but will oversee the production of this by an independent biostatistician		
Statistical advice	Provide continued consultation on all aspects of the trial that might affect the statistical analysis or interpretation of the trial results. This includes how to handle dropouts, protocol violations, study amendments, randomisation errors, etc.	May attend regular management meetings or via onsultation when required	
Manuscript Preparation	To assist with manuscript preparation and interpretation of study data.	Oversee statistical methods and results section of the manuscript.	
DATABASE DESIGN & MANAGEMENT			
CRF Design/eCRF Design	Develop the trial CRF/eCRF including field validation, data dictionary, meta-data, automated data queries, automated email notifications and user permissions have been established.	Advise Sponsor-Investigator on eCRF design and validation ensuring data protection regulation compliance. Pilot and complete User Acceptance Testing (UAT) of CRF.	
Database Development	To develop the trial's database in accordance with the requirements of the protocol to ensure all study endpoints are met.	Advise Sponsor-Investigator on best practice database development.	
Database Maintenance	To maintain and update the trial's database in accordance with any protocol amendments to ensure all study endpoints are met.	Assist the Sponsor-Investigator in adequately managing changes to live databases in order to ensure regulatory compliance.	
Data Management Documents	To develop and maintain all data management associated documents for the trial.	Develop the following data management associated documents for the trial in collaboration with the Sponsor-Investigator: - CRF Completion Guidelines - Data Management Plan (DMP) - Data Validation Plan (DVP)	

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
		- Data Sharing Plan (DSP) - All data management related SOPs identified as required for the clinical trial.	
Data Queries, Data Validation and Data Cleaning	To address data queries on a daily basis to ensure high quality data entry and timely follow-ups.	Manage and monitor site performance (enrolment rates, completion of follow-up, data quality, etc.)	
Medical Coding	To advise on appropriate medical coding or a trial and where available, provide medical coding services, where required.		
SAFETY MONITORING / PHARMOCOVIGILANCE			
Safety Reporting	To develop Serious Adverse Event Reporting guidelines in accordance with published NHRMC guidelines and international regulations, as required. Timely reporting of serious adverse events to regulators (national and international). Ensure protocol adequately describes all safety reporting requirements.	Generate SUSAR/URSAE/SAE Line Listings and annual safety reports.	
Safety Event/SAE Report Form	To create the SAE Report Form participating sites use to report SAEs to the Sponsor.		
Safety Monitoring Plan	To develop the safety monitoring plan for the trial.		
Establish Panel of Medical Monitors	To establish a panel of independent medical monitors to review and assess safety events for the trial.	Medical Monitors will be independent to the Trial team and delegated the role to assess each SAE for relatedness and expectedness and identify whether the event is a SUSAR/URSAE.	

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Safety Database	To develop and maintain a Safety Database for storing of SAE data and review outcome from Medical Monitors.		
INVESTIGATIONAL PRODUCT (IP) / INVESTIGATIONAL DEVICE (ID) / INTERVENTION / PLACEBO *(applicable to drug and/or device trials only)*			
IMP/Device Management & Oversight	To oversee all aspects of IMP/Device requirements. Generate IMP/Device forecast, as applicable.		
IMP/Device Procurement	To procure Drug/Device/Intervention/Placebo and other supplies as required for the trial.	Assist with negotiation of agreements for the supply of IMPs/Devices for the trial, to ensure availability prior to first participant enrolled.	
IMP/Device Distribution	To establish Drug/Device/Intervention/Placebo distribution procedure to participating sites. To establish Drug Destruction procedures and Device Return Procedures.	Assist with establishing the operations and logistics of IMP/Device shipments to participating sites, and their return and/or destruction at the end of the trial.	
IMP Labelling	To prepare IMP Packaging and Labelling i.e. copy of Secondary Approved Label.	Assist with the design of the master drug label and country specific drug labels; translated to local language as required. Ensure requirements of the drug supply vendor are met and labelled in accordance with Annex 13 *Guide to Good Manufacturing Practice for Medical Products Annexes,* and local regulations.	

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
Prepare and Maintain IMP/Device Documentation	To prepare and maintain all required IMP/Device documentation in the Trial Master File and distribution to participating site.	Assist with developing the Drug Order Form (or equivalent instructions). Prepares copies of: - Pharmacy Manul (in collaboration with key stakeholders) - Device Manuals (in collaboration with key stakeholders) - Drug Accountability Logs for Sites - Device Accountability Logs for sites - Drug Destruction Forms Obtains and maintains current copies of the following documents in the Trial Master File (TMF): - IB or PI - Material Safety Data Sheets (MSDS) for each IMP, where applicable - Certificate of Analysis (CoA), where applicable	
RESEARCH SUB-STUDIES / CENTRAL LABORATORY			
Research Sub-Studies	To develop SOPs and processing protocols for the collection of research bio-samples as required by the trial.	Assist the Sponsor-Investigator in setting up processes and logistics for the safe transport of samples and associated data for research sub—studies.	
Laboratory Manual	To develop and maintain the Laboratory Manual for the trial.		
Lab Kits	To establish lab kits for the collection of bio-samples and distribution procedures of kits to participating sites.	Assist with negotiation of any third-party agreements for the provision of lab kits (as required), to ensure processes are in place prior to first participant enrolled.	

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
Courier/Sample Transport	To establish courier and sample transport guidelines and procedures from participating sites to a central laboratory.	Assist with negotiation of any third-party agreements for the provision of courier services for the safe transport of bio-samples, to ensure processes are in place prior to first participant enrolled.	
MONITORING			
Prepare and Maintain Clinical Monitoring Plan (CMP)	Develop and maintain the Clinical Monitoring Plan for the trial. Prepare, update, and maintain a Risk Assessment of the trial.	Assists the Sponsor-Investigator and trial team in developing, preparing, writing, and maintaining the CMP, including undertaking a Risk Assessment of the trial.	
Monitoring Visits	Undertake Monitoring Visits in accordance with the trial's clinical monitoring plan to ensure sites are adhering to trial protocol, data is of high quality and timely follow-up.	To provide support to participating sites during the trial conduct and identify any issues requiring rectification and/or Sponsor-Investigator oversight.	
Close-Out Visits	Undertake Close-Out Visits in accordance with the trial's clinical monitoring plan to ensure sites have followed the requirements of the protocol, no outstanding matters remain and confirm that the trial can be archived. To provide support to participating sites during the close-out process.		
MEETINGS			
Data Safety Monitoring Committee (DSMC) Meetings	To facilitate DSMC meetings as outlined in the Trial DSMC charter.	Facilitates meeting schedules, agenda and minutes with the trial team, statisticians and DSMC. Development, review, and maintenance of DSMC charter and DSMC report in collaboration with the trial statistician.	
Trial Steering Committee (TSC) Meetings	To facilitate TSC meetings as outlined in the TSC charter.	Facilitates meeting schedules, agenda and minutes with the trial team, steering committee, statisticians and TSC. Development, review, and maintenance of TSC charter and TSC reports.	

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
Investigator Meetings	To facilitate Investigator Meetings as required.	Facilitates all aspects of Investigator Meetings, including preparing the Agenda and IM Presentation.	
Committee Management *(Operational Committee, Data Quality Committee, Independent endpoint adjudication committee, Writing Committee)*	To facilitate Committee Meetings as outlined in respective terms of reference. Facilitate committee meetings.	Assist the Sponsor-Investigator in facilitating and conducting all required meetings for the trial. Develop Terms of Reference, schedule meetings, prepare papers, reports, agendas and minutes for meetings. Prepare data reports with database manager and statisticians.	
GENERAL			
Study Manuals, Guidelines and Templates	To develop and maintain the Manual of Procedures (MoP), Pharmacy manual, Laboratory Manual, site logs, letters, guidelines, forms, screening and recruitment logs, checklists etc.	Assist the Sponsor-Investigator in developing all required trial documentation to aid in trial conduct and training of participating sites.	
Trial Risk Matrix and Management Plan	To develop a trial risk management plan to ensure study teams adhere to protocol.	Assist the Sponsor-Investigator to develop a trial risk management plan to ensure study teams adhere to protocol.	
Trial Communications – Website and Newsletter	To register a domain name and develop a website for the trial. To provide secure access to study documents, newsletters, and information about the trial. To disseminate newsletters routinely to participating sites informing of trial progress and important announcements.		