MCTC IIT Program – Services List

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The MCTC has expertise in conducting high-quality clinical trials and has well established links to other units across Australia and New Zealand, and globally.

MCTC works together with the Clinical Research Development Office (CRDO) to fulfil their aims in supporting, designing, and delivering multicentre MCRI-Sponsored investigator-led clinical trials and conducting workshops.

Various levels of support are available to Sponsor-Investigators and Research Teams of MCRI-sponsored investigator-initiated trials.

The purpose of this document is to provide tiered pricing models for MCTC trial support service packages available to Sponsor-Investigators. This will allow investigators to adequately budget trial specific support from the MCTC in their grant application.

Sponsor-Investigators who are planning to submit a trial for MCRI sponsorship committee support and/or are submitting a grant application which included support services from the MCTC, must contact the MCTC Medical Director to estimate and negotiate services and associated costs before the grant is submitted. These arrangements are not binding as we recognise that grants are not always fully funded.

Note that the FTE fractions are just an example, and it will vary for each trial. Specific services and associated costs must be negotiated considering the size, risk-rating and complexity of the trial.

Services are offered under the following broad packages that can be used as guidance when budgeting for services in grant applications.

Service Level	Assumed Cost
Core Services *MCTC/CRDO Core Services and Support*	No charge to MCRI research teams.
MCRI Sponsorship, Regulatory and Compliance Oversight *(Annual fee)*	Flat-fee or FTE dependent on complexity and risk-rating of the trial. *Applicable to Trials that fall under the scope of the TGA (i.e. CTN/CTA Trials) and multi-centre trials conducted beyond Victoria.*
Extended Trial Advice	Applied on a trial-by-trial basis, charged at an hourly rate. *Example: Ongoing mentoring provided to Sponsor-Investigators and Research Teams throughout trial conduct.*
Full Trial Support Services	MCTC full trial management support including: - Overall Clinical Trial Project Management - Site Management - Data Management - Clinical Trial Administration - Statistical support - Regulatory and QA Support Negotiated on a trial-specific basis, charged via flat-fee or FTE. *Example: For complex, multi-site trial, anticipate 1.0 FTE per year.*
Bespoke Services	Negotiated on a trial-specific basis, charged on an hourly rate, flat-fee, or FTE. *Example: Research Team requires data management services, the writing of a study protocol, ethics submission support only for the project etc.*

**CTN Trials = mandatory fee*

Note that these items can be negotiated on an item-by-item basis. Observational research projects and pilot projects may be supported by MCTC on a case-by-case basis.

Service Level – Core Services

Table Legend:

** Services delivered by CRDO*

*** Services delivered by MCTC*

**** Services delivered by CRDO & MCTC*

Initiatives	Aim/Description of Service	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
Core Services			
***Clinical Trial Manager / Research Coordinator Support and Mentoring	To identify Clinical Trial Managers and Research Coordinators new to MCRI and to support them in their roles. To assign mentors to Clinical Trial Managers and Research Coordinators to provide support and mentorship.	Support Clinical Trial Managers and Research Coordinators in their role to facilitate MCRI-Sponsored trials. Provide mentorship to Clinical Trial Managers and Research Coordinators. Mentorship for Clinical Trial Managers and Research Coordinators conducting MCRI-Sponsored trials.	
*Quality Management System	Develop, maintain and ensure the Melbourne Children's QMS for clinical trials is appropriate for Melbourne Children's Campus and ensure the procedures are embedded within Melbourne Children's as per regulatory and National Clinical Trials Governance Framework Requirements.	Development of clinical trial SOPs, Guidelines, Work Instructions, and other ancillary documents to support researchers in conducting MCRI-Sponsored trials and producing high-quality outcomes.	
***Clinical Research SOPs, Guidelines, Work Instructions, Templates, METIS Document Library	Clinical Trial tools and resources developed and published on the METIS Document Library.	Tools developed specifically for trial teams, for example, SOPs, Templates, Guidelines and Plans.	These tools have been developed with the support of the Melbourne Children's Campus Clinical Trial SOP Working Group.
*CRDO Courses and Workshops	A series of workshops designed, maintained, and delivered to MCRI researchers covering a range of topics relevant to the conduct of clinical trials.	Delivery of clinical trial training courses and workshops to MCRI Researchers and their Teams, in the best practices of conducting clinical trials.	

Initiatives	Aim/Description of Service	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
***Education and Training**	To ensure all Clinical Trial Managers and Research Coordinators are given opportunities for professional development.	Design and deliver bespoke training, guidance and contribute to the professional development of clinical trial staff.	
***Research Coordinator and Clinical Trial Fora**	Part of the delivery of education and training offerings by CRDO. The Human Participant Research Coordinator Fora provide education and regular updates on all aspects of running clinical research, including changes to ethics/regulatory requirements and or required in response to quality improvement initiatives identified by CRDO/Research Ethics & Governance/MCRI Sponsorship Committee. The Clinical Trial Forum is run monthly and gives researchers a chance to consult a range of experienced trialists, and for MCRI staff to understand other campus research projects. Researchers discuss their project, and the group will then provide feedback and discuss strategies to overcome or avoid the common obstacles for clinical trials.		
***CRDO Monthly Drop-In Sessions**	A monthly virtual drop-in session where MCRI Clinical Trial Managers and Research Coordinators bring their topics/items for discussion relevant to their work, to a panel of specialists in the field for advice and/or troubleshooting.	Open discussion Clinical Trial Managers and Research Coordinators to discuss challenges with MCRI-sponsored trials.	
*****Short Consultation and Advice**	Short consultation/advice on clinical trial design, development, and conduct.		
****Grant Reviews**	Review grant proposals including proposed budgets.		

Initiatives	Aim/Description of Service	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
****Essential Document Management (Florence eBinders) Support**	To support Sponsor-Investigator and Research Teams in best practice for filing essential documentation for clinical trials to ensure compliance.	MCTC administer and support the Florence eBinders platform, including providing training and resources to research teams.	
*****Collaborations with External Groups (e.g. A-CTEC, NPEU)**	To collaborate and maintain strong relationships with external stakeholders in the sharing of knowledge, resources and expertise.		
****Staff Recruitment Advice**	To recruit highly qualified and experienced Clinical Trial Managers and Research Coordinators to the team in compliance with MCRI HR policy.	Recruitment of highly qualified and experienced Clinical Trial Managers and Research Coordinators.	
*****Ad-hoc Support and Mentoring**	To ensure research teams are well supported and linked into the broader MCRI network.	Mentor and train new researchers in GCP, ethics applications and other research related issues. Ensure trials staff are familiar with and understand the relevant SOPs.	
*****Career Development – Competency Framework**	To ensure that staff are developed, complete mandatory training in alignment with the Clinical Trial Managers Competency Framework and undergo scheduled performance reviews.	Develop and review the competency frameworks to ensure they are fit-for-purpose, current, address all responsibilities.	
***CRDO Newsletters**	To inform research staff of new developments and initiatives that support best practice research. Includes changes to campus SOPs, national and international regulatory requirements.		
****Facilitate Trial Sponsorship**	To provide advice and support to the Sponsor-Investigator on the MCRI Sponsorship process and support the MCRI Sponsorship Committee members.		

Service Level - MCRI Sponsorship, Regulatory and Compliance Oversight*

**Applicable to all trials that fall under the scope of the TGA (i.e. CTN/CTA Trials) and/or high-risk trials as defined by the Sponsorship Committee (From July 2024)*

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
Service Package – MCRI Sponsorship, Regulatory and Compliance Oversight			
MCRI Sponsorship Committee	To sponsor and oversee high quality investigator-initiated clinical trial research proposals.	MCRI Sponsorship Committee promotes a high standard of clinical trial design, conduct, analysis, and reporting, and is a requirement for initiating a clinical trial at MCRI.	
Trial Oversight	To mentor and educate Sponsor-Investigators and Research Teams in the development, design, management and conduct of high-quality and compliant clinical trials.	Identify clinical trials requiring close support in the early phases of development. Provide mentoring and training to new Clinical Trial Managers and Research Coordinators and undertakes ongoing oversight of the trial.	
Quality Assurance and Risk Management	To identify real and perceived risks within the clinical trial and to assist with developing strategies to mitigate these risks.	Provide guidance to Sponsor-Investigators and Trial Teams on how to identify and mitigate risks.	
Guidance & Assistance in Establishing a Clinical Trial	Provide guidance on how to establish a clinical trial (including but not limited to funding application, pilot and feasibility studies, survey research, trial budgeting, publications, sponsorship, management of essential documents, regulatory & ethics submissions etc).	Provide guidance to Sponsor-Investigators and Trial Teams on how to establish and set-up an investigator-led trial. Administration assistance is establishing Florence eBinders and Florence eConsent accounts for Research Teams.	
Guidance on Team Selection	Guidance on operations of trial (study team, clinical trial manager PD, research coordinator role PDs, database developers, drug supplier, HREC).	Provide guidance to Sponsor-Investigators and Trial Teams on how to select team members or recommendations to utilise the MCTC to deliver the trial.	
***Clinical Trial Registration Support with ClinicalTrials.gov**	To support Sponsor-Investigator and Research Teams in the submission and maintenance of clinical trial registration records.		
*****Regulatory Submission Support e.g., CTN / CTA Submissions**	To support and facilitate Sponsor-Investigator and Research Teams in the submission of clinical trial notifications to the TGA and in doing so, ensure MCRI fulfills its Sponsor responsibilities for the lawful supply of 'unapproved' therapeutic goods to Australian sites participating in the trial when MCRI is Sponsor.		

Service Level – Full Trial Support Services

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
Service Package – Full Trial Support			
PROJECT MANAGEMENT			
Team Meetings, Agenda and Minutes	To facilitate fortnightly Trial Coordinating Team meetings to discuss trial progress, challenge and opportunities and drive the project's success.	Agenda and meeting minutes generated and circulated.	
Team Management and Roles and Responsibilities	To provide leadership to the Trial Coordinating Team and define each team members roles and responsibilities within the trial.	Provides overall clinical trial management leadership in all aspects of the study in order to achieve the outcomes of the trial. Provide a Division of Responsibilities document, which will outline tasks MCTC will deliver as part of the service delivery. This will impact on resources required to successfully deliver your clinical trial.	
Site Feasibility and Selection	To undertake Site Feasibility Assessments on interested participating sites and recommend sites with proven track record in clinical trial delivery for future trials. To maintain an efficient network of preferred participating sites.	Ensures selected participating sites are capable of conducting the trial in accordance with the requirements of the protocol, have access to the patient population. Recommends participating sites with proven track records in clinical trial delivery to Sponsor-Investigators and Trial Teams.	
Trial Management SOPs, Plans and Guidelines	To develop SOPs, Guidelines and Plans in trial management to enable knowledge sharing and best practice with trial teams.	Develops and maintains SOPs and guidelines for the Trial.	
Protocol Development, Writing and Review	To develop, manage and maintain the trial protocol.	Collaborative trial protocol development and preparation, review, and writing with Sponsor-Investigators and Trial Teams.	

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.	

Initiatives	Aim	Support and services to Sponsor-Investigators and Trial Coordinating Teams	Notes
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.		