The following schedule sets out the agreed allocation of study-related duties between the Sponsor (*add name as applicable* Royal Devon University Healthcare NHS Foundation Trust or University of Exeter), the Chief Investigator (CI) and the Clinical Trials Unit (CTU) (if applicable) for the (*add name*) study.

L= Lead responsibility X = Participating N/A= Not Applicable

Task	Allocated to:			Comments
	Sponsor ***Add Royal Devon/UoE***	**CI**	**CTU** ***Add Name or delete as applic. Further columns may be added***	
KEY DOCUMENT PREPARATION				
Clinical Investigation Plan writing				
Clinical Investigation Plan review				
Ensure Clinical Investigation Plan is compliant with applicable regulations and guidelines				
Clinical Investigation Plan amendment writing				
Clinical Investigation Plan amendment review				
Participant Information Sheet / Consent Form writing				
Participant Information Sheet / Consent Form review				
Case Report Form (CRF) design (paper or e-CRF)				
CRF review (including updates) and approval. (If eCRF validation of e-CRF)				
CRF printing				
eCRF / CRF training				
Preparation of study-specific SOPs/work instructions				
Study-specific SOPs/work instructions review				
Preparation of instructional device manual				
Instructional manual review				
Preparation of other study-specific documents (eg recruitment materials, pocket cards etc)				
Other study-specific documents review				

FINANCE				
Negotiation of study budget (identification of activities)				
Cost attribution				
Maintain oversight of trial budget				
Provide financial reports to funder				
AGREEMENTS				
Ensure collaboration agreements are in place				
Selection, negotiation, management of vendors (eg central labs, device suppliers, couriers)				
Ensure 3rd party agreements are in place (name)				
Ensure insurance and indemnity arrangements are in place				
Ensure all Sponsor agreements are in place prior to commencement				
Provide and obtain sign off for Site Agreements (model or Organisation Information Document/OID) to participating sites				
APPROVALS				
Portfolio adoption application				
Preparation of initial Health Research Authority (HRA) & Research Ethics Committee (REC) application				
Review of initial HRA & REC application				
Submission of initial HRA & REC application				
Preparation of amendments (non-substantial and substantial)				
Review of amendments (non-substantial and substantial)				
Judge substantiality of amendments				
Submission of amendments to HRA, REC (as applicable)				
Ensure REC approvals (including amendments) are in place				
Preparation of initial MHRA Clinical Investigation Application (CIA)				
Review of initial MHRA CIA				
Submission of initial MHRA CIA				

Preparation of amendments to CIA				
Review of amendments to CIA				
Submission of amendments to CIA application				
Ensure trial is registered (eg ClinicalTrials.gov) before recruitment starts. Update registration as necessary				
Provide local document pack to sites and R&D offices				
Provide HRA approval & updated documents to sites				
Ensure CI has R&D approval in place				
Confirm R&D approvals and agreements are in place and issue 'green light' for recruitment can begin				
DEVICE & TRIAL SUPPLIES MANAGEMENT				
Device procurement (including necessary import licenses if applicable)				
Provision of bench testing and pre-clinical data of device				
Device labelling and package design (Including translation if required)				
Trial ancillaries (eg needles, syringes, infusion bags etc) purchase, storage and distribution				
Develop Device distribution system				
Storage of Device and distribution to sites (if multicentre)				
Requests for resupply				
Receipt and storage of Device at sites				
Dispensing of Device to participants				
Maintain Device accountability				
Manage Device excursions				
Implement product recall process				
Preparation of Investigator Brochure (IB)				
Distribution of IB and amendments				
Sterilisation Validation Report (if sterile device)				
Risk analysis (cover compatibility of all device components)				
Biological Safety Assessment of patient contacting materials				
Preparation and management of randomisation list				

SOFTWARE DESIGN AND MANAGEMENT (if applicable, otherwise list as N/A)				
Software development plan creation				
Risk Management Plan and Report – specifically including the software hazard analysis.				
Software Configuration Management Plan				
Software System Requirements Specification				
Software System Verification Plan and Report				
Documented Software Problem Resolution Process				
Evidence of review of completeness for software release				
SAFETY REPORTING				
Development Adverse Event (AE), Serious Adverse Event (SAE), Adverse Device Effect (ADE), Serious Adverse Device Effect (SADE) or Unanticipated Serious Adverse Device Effect (USADE) reporting plan				
Provide Investigator training on safety reporting responsibilities				
Receipt SAEs, SADEs from investigators and follow up as required				
Review SAEs, SADEs for accuracy and completeness				
Maintain safety database				
Review all SAEs, SADEs (Assess seriousness, causality and severity)				
Review all SAEs, SADEs for relatedness				
Review all SAEs, SADEs for expectedness				
Compile and send periodic reports of all reported SAEs, SADEs to sponsor				
Reporting of adverse incidents that affect the health and safety of participants (USADEs)				
Unblinding process initiation for potential SUSARs				
Reporting any SADE or USADE to MHRA, REC and Data Monitoring Committee (DMC)				
Notify Principal Investigators (PI's) of any SADE or USADE				
Compile & send annual safety report to MHRA, Sponsor and REC				
Ensure emergency unblinding procedures are in place				

MONITORING, COMPLIANCE AND QUALITY ASSURANCE				
Provide Trial Master File (TMF) template				
Compile and maintain TMF				
Perform and review risk assessment of trial to include proposed intervention				
Perform and review risk assessment of trial management				
Generate and review Monitoring Plan				
Design of monitoring process and provide template materials / training to monitoring personnel				
Perform central data monitoring				
Generate data queries				
Resolve data queries				
Perform Investigator site monitoring visits as dictated by monitor plan and compile monitoring reports				
Maintain log of all Investigator site monitoring visits				
Maintain file of all monitoring reports				
Perform trial audits as required				
Maintain log of protocol / GCP non-compliance reports				
Record serious breaches				
Adjudge whether violations constitute serious breach				
Report serious breaches to REC & MHRA as applicable				
TRIAL OVERSIGHT (MEETINGS, REPORTS)				
Provide day to day management of trial				
Monitor on-going safety and ethics of trial				
Formalise & arrange Trial Management Group (TMG)				
Prepare and circulate minutes of TMG				
Identify and appoint Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) members				
Prepare TSC and DMC charters				
Arrange TSC & DMC meetings				
Prepare and circulate minutes of TSC and DMC				
Provide progress reports to DMC & TSC				
Provide reports and attend Sponsor Oversight Meetings on request				

Provide annual progress reports to Regulatory Authorities (REC, MHRA) and Sponsor				
Provide annual reports to funder as required				
GENERAL TRIAL MANAGEMENT AND TRAINING				
Trial Site selection (distribution EOIs, feasibility assessment)				
Provide study-specific training to staff				
Site Initiation				
Day-to-day correspondence with Investigators' research teams				
Specify content of Trial Master File (TMF), Investigator Site File (ISF) and Pharmacy File				
Collate and maintain TMF				
Collate and provide ISF to sites (including your 'home' site)				
Maintain ISF				
Distribution of trial documentation to sites				
Newsletters				
DATA MANAGEMENT				
Build and test study database				
Database validation				
Maintain study database				
Develop Data Management Plan				
Review Data Management Plan				
Trial data receipt from sites and query management				
Data locking prior to analysis				
STATISTICS				
Create and revise Statistical Analysis Plan (SAP) as required				
Approval of SAP				
Provide statistical analysis (including interim analysis, input for meetings, presentations & publications)				

END OF TRIAL AND DISEMINATION				
Send end of study notification to REC, MHRA				
Close out visit and archive notification to sites				
Archive TMF, ISF and CRFs				
Develop Publication Plan				
Prepare trial results for publication				
Prepare and submit trial results reports to regulatory bodies in a timely fashion (eg MHRA, REC)				
Post study results on registry in a timely fashion (eg ClinicalTrials.gov)				
Inform participants of results				

SIGNATURE PAGE

Signed by Sponsor Representative							
Name (Print)		**Position**		**Signature**		**Date**	

Signed by Chief Investigator							
Name (Print)		**Position**		**Signature**		**Date**	

Signed by CTU							
Name (Print)		**Position**		**Signature**		**Date**	