

STUDY TITLE:

R&D NO:

RESPONSIBILITY ALLOCATION MATRIX

Investigator:

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 <i>Add Royal Devon/UoE</i>	CI	CTU <i>Add Name or delete as applic. Further columns may be added</i>	
<u>KEY DOCUMENT PREPARATION</u>				
<i>Protocol writing</i>		<i>eg L</i>	<i>X</i>	
<i>Protocol review</i>				
<i>Ensure protocol is compliant with applicable regulations and guidelines</i>				
<i>Protocol amendment writing</i>				
<i>Protocol amendment review</i>				
<i>Participant Information Sheet / Consent Form writing</i>				
<i>Participant Information Sheet / Consent Form review</i>				
<i>Case Report Form (CRF) design (paper or e-CRF)</i>				
<i>CRF review (including updates) and approval. (If eCRF validation of e-CRF)</i>				
<i>CRF printing</i>				
<i>eCRF / CRF training</i>				
<i>Preparation of study-specific SOPs/work instructions</i>				
<i>Study-specific SOPs/work instructions review</i>				
<i>Preparation of instructional manuals including amendments (eg lab manual, randomisation manual)</i>				
<i>Instructional manual review</i>				
<i>Preparation of other study-specific documents (eg recruitment materials, pocket cards etc)</i>				
<i>Other study-specific documents review</i>				

<u>FINANCE</u>				
<i>Negotiation of study budget (identification of activities)</i>				
<i>Cost attribution</i>				
<i>Maintain oversight of trial budget</i>				
<i>Provide financial reports to funder</i>				
<u>AGREEMENTS</u>				
<i>Ensure collaboration agreements are in place</i>				
<i>Selection, negotiation, management of vendors (eg central labs, drug suppliers, couriers)</i>				
<i>Ensure 3rd party agreements are in place (name)</i>				
<i>Ensure insurance and indemnity arrangements are in place</i>				
<i>Ensure all Sponsor agreements are in place prior to commencement</i>				
<i>Provide and obtain sign off for Site Agreements (model or Organisation Information Document/OID) to participating sites</i>				
<u>APPROVALS</u>				
<i>Portfolio adoption application</i>				
<i>Preparation of initial Health Research Authority (HRA) & Research Ethics Committee (REC) application</i>				
<i>Review of initial HRA & REC application</i>				
<i>Submission of initial HRA & REC application</i>				
<i>Preparation of amendments (non-substantial and substantial)</i>				
<i>Review of amendments (non-substantial and substantial)</i>				
<i>Judge substantiality of amendments</i>				
<i>Submission of amendments to HRA, REC (as applicable)</i>				
<i>Ensure REC approvals (including amendments) are in place</i>				
<i>Ensure trial is registered (eg ClinicalTrials.gov) before recruitment starts. Update registration as necessary</i>				
<i>Provide local document pack to sites and R&D offices</i>				
<i>Provide HRA approval & updated documents to sites</i>				
<i>Ensure CI has R&D approval in place</i>				

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<i>Confirm R&D approvals and agreements are in place and issue 'green light' for recruitment can begin</i>				
<u>TRIAL INTERVENTION & SUPPLIES MANAGEMENT</u>				
<i>Trial intervention/supplies procurement including trial ancillaries (eg needles, syringes, infusion bags etc)</i>				
<i>Providing defined kit/supplies to sites</i>				
<i>Reordering stock</i>				
<i>Preparation and management of randomisation list if applicable</i>				
<u>SAFETY REPORTING</u>				
<i>Development of Adverse Event (AE) & Serious Adverse Event (SAE) reporting plan</i>				
<i>Provide Investigator training on safety reporting responsibilities</i>				
<i>Receipt SAE's from investigators and follow up as required</i>				
<i>Review SAE's for accuracy and completeness</i>				
<i>Maintain safety database</i>				
<i>Review all SAE's (Assess seriousness, causality and severity)</i>				
<i>Review all SAE's for relatedness</i>				
<i>Review all SAE's for expectedness</i>				
<i>Compile and send periodic reports of all reported SAEs to sponsor</i>				
<i>Reporting of adverse incidents that affect the health and safety of participants</i>				
<i>Ensure emergency unblinding procedures are in place</i>				
<u>MONITORING, COMPLIANCE AND QUALITY ASSURANCE</u>				
<i>Provide Trial Master File (TMF) template</i>				
<i>Compile and maintain TMF</i>				
<i>Perform and review risk assessment of trial to include proposed intervention</i>				
<i>Perform and review risk assessment of trial management</i>				
<i>Generate and review Monitoring Plan</i>				

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<i>Design of monitoring process and provide template materials / training to monitoring personnel</i>				
<i>Perform central data monitoring</i>				
<i>Generate data queries</i>				
<i>Resolve data queries</i>				
<i>Perform Investigator site monitoring visits as dictated by monitor plan and compile monitoring reports</i>				
<i>Maintain log of all Investigator site monitoring visits</i>				
<i>Maintain file of all monitoring reports</i>				
<i>Perform trial audits as required</i>				
<i>Maintain log of protocol / GCP non-compliance reports</i>				
<i>Record serious breaches</i>				
<i>Adjudge whether violations constitute serious breach</i>				
<i>Report serious breaches to REC as applicable</i>				
<u>TRIAL OVERSIGHT (MEETINGS, REPORTS)</u>				
<i>Provide day to day management of trial</i>				
<i>Monitor on-going safety and ethics of trial</i>				
<i>Formalise & arrange Trial Management Group (TMG)</i>				
<i>Prepare and circulate minutes of TMG</i>				
<i>Identify and appoint Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) members</i>				
<i>Prepare TSC and DMC charters</i>				
<i>Arrange TSC & DMC meetings</i>				
<i>Prepare and circulate minutes of TSC and DMC</i>				
<i>Provide progress reports to DMC & TSC</i>				
<i>Provide reports and attend Sponsor Oversight Meetings on request</i>				
<i>Provide annual progress reports to Regulatory Authorities (REC) and Sponsor</i>				
<i>Provide annual reports to funder as required</i>				
<u>GENERAL TRIAL MANAGEMENT AND TRAINING</u>				
<i>Trial Site selection (distribution Expression of Interests/ EOs, feasibility assessment)</i>				

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Investigator:

<i>Provide study-specific training to staff</i>				
<i>Site Initiation</i>				
<i>Day-to-day correspondence with Investigators' research teams</i>				
<i>Specify content of TMF, Investigator Site File (ISF)</i>				
<i>Collate and maintain TMF</i>				
<i>Collate and provide ISF to sites (including your 'home' site)</i>				
<i>Maintain ISF</i>				
<i>Distribution of trial documentation to sites</i>				
<i>Newsletters</i>				
<u>DATA MANAGEMENT</u>				
<i>Build and test study database</i>				
<i>Database validation</i>				
<i>Maintain study database</i>				
<i>Develop Data Management Plan</i>				
<i>Review Data Management Plan</i>				
<i>Trial data receipt from sites and query management</i>				
<i>Data locking prior to analysis</i>				
<u>STATISTICS</u>				
<i>Create and revise Statistical Analysis Plan (SAP) as required</i>				
<i>Approval of SAP</i>				
<i>Provide statistical analysis (including interim analysis, input for meetings, presentations & publications)</i>				
<u>END OF TRIAL AND DISEMINATION</u>				
<i>Send end of study notification to REC, MHRA</i>				
<i>Close out visit and archive notification to sites</i>				
<i>Archive TMF, ISF and CRFs</i>				
<i>Develop Publication Plan</i>				

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Investigator:

<i>Prepare trial results for publication</i>				
<i>Prepare and submit trial results reports to regulatory bodies in a timely fashion (eg REC)</i>				
<i>Post study results on registry in a timely fashion (eg ClinicalTrials.gov)</i>				
<i>Inform participants of results</i>				

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SIGNATURE PAGE

Signed by Sponsor Representative							
Name (Print)		Position		Signature		Date	

Signed by Chief Investigator							
Name (Print)		Position		Signature		Date	

Signed by CTU (<i>delete as applicable</i>)							
Name (Print)		Position		Signature		Date	