Trial Master File / Investigator Site File Index for Non-CE Marked Medical Device Studies

This Trial Master File/ Investigator Site file index template has been produced with regards to the documentation required by UHL, as Sponsor, for the completion of both single and multi-centre Non CE-Marked Medical Device Studies. This Index can be modified to suit individual study requirements.

The documentation detailed in plain text is for individual Site, Investigator Site Files. The additional documentation detailed in italic is with regards to the requirement for the Trial Master file only, held and maintained by the Chief Investigator.

SECTION	TITLE	DOCUMENTS
1.	Contact List	Including details of relevant study site staff, responsible HRA/REC, R&I contacts, Device Manufacturer/Supplier, pharmacy (where applicable), laboratory and other relevant departments involved in the study *<u>At Trial Master File level:</u>* *Copies of contact lists from all collaborating centres*
2.	Clinical Investigation Plan (CIP)/Protocol	Current CIP/ protocol signed and dated by PI Signed and dated CIP/protocol signature page(s) for all CIP/protocol versions. Superseded CIP/ protocol(s) Completed CIP/protocol read log/s for all relevant study personnel CIP/Protocol Deviation Log Master Template Completed CIP/Protocol deviation log File note template *<u>At Trial Master File level:</u>* *Signed CIP/ protocol signature page for current and all superceded CIP/protocols for all collaborating site* *Copy of signed and dated CIP/protocol deviation logs for collaborating centres.* *Completed CIP/protocol read log/s for all relevant study personnel*

3.	Health Research Authority / Ethics Committee	Signed and dated IRAS Application Statement of Activities(where applicable) Organisational Information Document / Schedule of Events HRA Initial Assessment Letter (where applicable) REC letter of acknowledgement REC letter of provisional /full favourable Opinion HRA approval letter Substantial Amendments: Substantial amendment application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA categorisation email HRA Approval letter / REC favourable opinion letter Non Substantial Amendments: Minor amendments application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA approval /REC favourable opinion GCP Compliance / REC Constitution /Composition / List of members (forms part of REC favourable opinion) HRA / Ethics Correspondence *<u>At Trial Master File level:</u>* *Completed Feasibility Form* *Copy of completed Statements of Activities/Organisation Information Document/ Schedule of Events and relevant HRA approvals / REC favourable opinion.* *Evidence of receipt of amendment from all collaborating centres* *Correspondence where appropriate with Sponsor / HRA & REC*

4.	Competent Authority	Clinical Trial Authorisation (CTA) application CTA acceptance letter Submission / Acknowledgement / Approval of amendment/s letter/s MHRA Correspondence *<u>At Trial Master File level:</u>* *CTA and acknowledgement letters for all relevant amendments for all collaborating centres* *Correspondence with MHRA with regards to collaborating centres*
5.	R&I	R & I application/capability assessment R & I approval / authorisation Submission / Notification and R&I acknowledgement/approval / authorisation of all Substantial and Non-Substantial Amendments R & I Correspondence *<u>At Trial Master File level:</u>* *Collaborating sites R&I/R&D submission and approval/ authorisation documentation.* *Notification / receipt of all subsequent amendments/approvals / authorisation* *Local R&I / R&D correspondence*
6.	Investigator Site Personnel	Template of Delegation of Authority Log Completed Delegation of Authority Log(s) Original signed and dated current CVs for all study personnel named on the Delegation Log, covering the period of the study Evidence of GCP training/consent training e.g. certificate / email, covering the total period of the study Evidence of study and device specific training

		<u>At Trial Master File level:</u> *Collaborating centre: Copy of current completed delegation of duties / authorised signatures forms. Signed and dated CVs for PI and all staff named on delegation log.* *Trial Training documentation:-* *- GCP Training evidence for all staff named on delegation log* *- Consent training evidence where required.* *- Study and device training where appropriate* *- CIP/Protocol-related training / Investigator Meeting Documentation*
7.	Standard Operating Procedures	Details of where and how to access current Sponsor SOPs Complete Standard Operating Procedures Read Log for all study staff members. All relevant Sponsor Standard Operating Procedures must be read by all research team members. *<u>At Trial Master File level:</u>* *Completed SOP read log for all staff named on collaborating centres delegation logs.*
8.	Study Documentation	Template of all current approved Participant Information Sheets and Informed Consent Forms printed on UHL headed paper (make sure the versions and date number is entered) Superseded documentation e.g. Participant Information Sheets and Informed Consent Forms Template of GP letter Template of any other study related material e.g. invitation letters, posters questionnaires) Sample Case Report Form *<u>At Trial Master File level:</u>* *Evidence that collaborating sites are utilising the current approved version of all study documentation.*

9.	Subject Documentation	Template Screening Log (where applicable) Completed Screening Log/s containing non identifiable participant data only (where applicable) Template Subject Enrolment/Identification log Completed Subject Enrolment/Identification log (not to be removed from site). <u>*At Trial Master File level:*</u> *Details of Subject enrolment numbers utilised for individual collaborating sites. No patient identifiable data.*
10.	Randomisation	Documentation of randomisation/ Decoding process Details of randomisation/ decoding process and all relevant guidance documentation if utilised. Master Randomisation List (in sealed envelope)/ details of electronic randomisation process/details of where master randomisation list is held and relevant contact details. Evidence (where applicable) of randomisation i.e. envelopes / email / IVRS <u>*At Trial Master File level:*</u> *Details of Randomisation process and relevant contact details for all collaborating centres.*
11.	Informed Consent	Copies of all completed consent forms including all re consent forms where applicable with associated patient information sheets Copy of 100% consent form audit record <u>*At Trial Master File level:*</u> *Copies of 100% consent audits for collaborating centres*

12.	Data Management	Statistical analysis plan -*TMF only* Details of electronic/paper case report form storage/security Data Management Plan- *TMF only* Superceded Data Management Plan Electronic Data Capture (EDC)/ eCase Report Form (eCRF) training records
13.	Source Data	Source Data Schedule Data query/response documentation <u>*At Trial Master File level:*</u> *Site/s source data schedule/s* *Site data query/response document*
14.	Medical Device/ Study Related Supplies	Details of Labelling/Master copy of label (where applicable) Investigator Brochure(IB)(signed and dated) and/or Manufacturer Instructions/Manual Superceded versions of IB/Manufacturer Instructions/Manuals Shipment/Receipt records Device Accountability Log Template Completed Device Accountability Logs Component Supplies order form templates Completed supply request forms Temperature logs (where applicable) Evidence of maintenance/calibration certification of all applicable equipment <u>*At Trial Master File level:*</u> *Copies of all relevant supply documentation and evidence of equipment maintenance/calibration for all collaborating centres*

15.	Safety Reporting	Serious Adverse Event (SAE)/ Serious Adverse Device Effect (SADE) reporting Guideline/Event Categorisation Flow Chart Current SAE/SADE/USADE form template (Form C) Completed SAE/SADE/USADE forms and Sponsor acknowledgement documentation Unexpected Serious Adverse Device Effect (USADE) reporting Guidelines Evidence of notification of USADE to MHRA and REC Adverse Event/Device Effect Record Template Competed Adverse Event/Device Effect Record(s) Medical Device Deficiency Report Form Template Completed Medical Device Deficiency Report Forms Evidence of notification of Device Deficiency (where applicable) to MHRA. Device safety alert updates (Please refer to the Sponsor SOP for safety reporting for medical devices UHL S-1040) *<u>At Trial Master File level:</u>* *Copies of all collaborating centre SAE/SADE/USADE reports and acknowledgements/adjudication (where applicable)* *Serious adverse event/serious adverse device effect line listing for all collaborating centre(where applicable)* *Copies of medical device deficiency report forms for all collaborating centres* *Correspondence*

16.	Monitoring	Agenda and minutes from Initiation/ Pre-trial Meeting Study Specific Monitoring Plan Initiation visit/site/pharmacy report Template monitoring log template Completed monitoring log Interim Monitoring Documentation e.g.Site/Pharmacy monitoring visit report and CI/PI responses Final trial close out/site/pharmacy monitoring reports External Audit reports and responses Associated correspondence <u>*At Trial Master File level:*</u> *Copies of all site/pharmacy monitoring reports and associated responses for all centres. External audits and responses.*
17.	Clinical Laboratory	Central Laboratories Certificates of accreditation, where applicable Central Laboratories Normal Reference Ranges (including revisions) where applicable Local Laboratories Certificates of accreditation, where applicable Local Laboratories Normal Reference Ranges (including revisions) where applicable Lab Manual/sample processing instructions, where applicable Details of sample storage facilities/ processes/relevant personnel contact details Sample Shipment Receipt/ Tracking, where applicable

		Temperature logs for sample storage Sample storage instructions/Inventory of samples/specimens, where applicable Inventory/destruction log of all samples/specimens Details of sample storage arrangements (where applicable) for all samples held for future research <u>*At Trial Master File level:*</u> *Certificates of accreditation and normal Reference Ranges for local labs of all participating sites* *Inventory of samples/specimens storage and temperature logs as applicable* *Contact details of all relevant personnel responsible for sample management*
18.	Financial / Legal	Contracts / Contract addendums with all investigators and Sub-contractors Confirmation of Sponsorship Evidence of Peer Review (where applicable) Funding Letter(s)/ Financial Agreement Insurance and Indemnity Statement for all investigators Clinical Trial Agreement with all investigators Financial Correspondence Records of subject expenses <u>*At Trial Master File level:*</u> *Copies of all contacts and agreements/ amendments with collaborating centres and external vendors*

19.	Annual Report /End of study declaration/Clinical Investigation Report	Annual Reports to HRA / REC and Sponsor Notice to HRA / REC, MHRA and R&I / R&D of trial completion (end of study declaration)-*TMF only* Final Clinical Investigation Report report and acknowledgement from HRA/REC/ MHRA/Sponsor Confirmation that the Final report/study publication has been uploaded to EudraCT and any public databases as detailed in the ethical application. *At Trial Master File level:* *Confirmation that all reports have ben received and acknowledged by collaborating centres*
20.	Publications	Copies of all study analysis publications
21.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including Newsletters and other study specific correspondence. Meeting agendas and minutes General correspondence *At Trial Master File level:* *Relevant trial related correspondence with all collaborating centres*
22.	Miscellaneous (detail documents where applicable)	