Trial Master File / Investigator Site File Index
Clinical Trials of Investigational Medicinal Products

SECTION	TITLE	DOCUMENTS
1.	Contact List	Including details of relevant study site staff, responsible HRA/ REC, R&D contacts, laboratory and other relevant departments involved in the study
2.	Protocol	Current Protocol signed and dated by Principal Investigator Superseded Protocol(s) Protocol Deviation Log Master Template Completed Protocol Deviation Log Evidence of peer review File note template *At TMF site level file:* *Signed protocol signature page* *- If applicable, local version and approval of translated version*
3.	Health Research Authority/ Ethics Committee	Signed and dated IRAS Application Statement of Activities /Schedule of Events HRA Initial Assessment Letter (Where applicable) 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 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 Site Specific Assessment / Statements of Activities/ 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 (paper copy and electronic copy) CTA acceptance letter Submission / Acknowledgement of amendment letters (paper copy and electronic copy) Notice to MHRA of trial completion MHRA Correspondence *<u>At TMF site level file:</u>* *First acceptance and acknowledgement letters for amendments*
5.	R & D / R&I	R & I application 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 Delegation of Authority Log Original signed and dated current CVs for all study personnel Evidence of GCP training/consent training e.g. certificate Evidence of study specific training *<u>At TMF site level file:</u>* *Copy of completed delegation of duties / authorised signatures forms, original CV for PI, CVs for other site staff* *Trial Training documentation:-* *- GCP Training* *- Pharmacovigilance Training* *- Protocol-related training / Investigator Meeting documentation*
7.	Standard Operating Procedures	All Current Standard Operating Procedures must be accessed via the UoL College of Medicine, Biological Sciences and Psychology Website, Research Governance pages. There is no requirement to keep hard copies in the File but the relevant SOPs must be accessed and read by all study staff members and the read log signed. Standard Operating Procedures Read Log for all study staff members.
8.	Study Documentation	Template of all current approved Participant Information Sheets and Informed Consent Forms- approved versions printed on Host Institution headed paper (make sure the versions number and date is entered) Superseded Participant Information Sheets and Informed Consent Forms Template of GP letter Any other study related material e.g. invitation letters, posters questionnaires) Sample Case Report Form *<u>At TMF site level file:</u>*

		Sample of Participant Information Sheets and Informed Consent Forms (local version)
9.	Subject Documentation	Template Screening Log Completed Screening Log/s containing non identifiable participant data only 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 process Details of randomisation 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.	Data	Statistical Analysis Plan Details of electronic/paper case report form storage/security
12.	Informed Consent	Copies of all completed consent forms 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*
13.	Pharmacovigilance /Safety Reporting	SAE reporting Guidelines and Pharmacovigilance contact Current SAE form template and SAE form completion guidance document. Completed Serious Adverse Events/Serious Adverse

		Reactions/ Suspected Unexpected Serious Adverse Reactions (SUSARs) forms and sponsor acknowledgment documentation. SUSAR reporting guidelines SAE/SAR/SUSAR Tracking Log Annual Development Safety Update Report and acknowledgement correspondence (MHRA & REC) Evidence of Data Monitoring Committee Meetings agenda/minutes. *<u>At TMF site level</u>* *Copies of all collaborating centre SAE/SUSARs reports and acknowledgements/adjudication* *Evidence of provision/receipt by Chief Investigator of DSUR to all Collaborating centres*
14.	Reference Safety Information	Investigator Brochure / Summary of Products Characteristics with evidence of annual review and update- (signed and dated) Safety alert updates
15.	Monitoring	Agenda and minutes from Initiation/ Pre-trial Meeting Study Specific Monitoring Plan Initiation visit report Master monitoring log template Completed monitoring log Interim Monitoring Documentation e.g. Monitoring visit report and CI/PI responses Final Trial Close out monitoring report External Audit reports and responses Associated correspondence Data management/Source document clarification Data query management *<u>At Trial Master File level:</u>*

		Copies of all monitoring reports and associated site responses for all centres. External audits and responses. Data query requests and response.
16.	Clinical Laboratory	Central Laboratories Certificates of accreditation, if applicable Central Laboratories Normal Reference Ranges (including revisions) if applicable Local Laboratories Certificates of accreditation, if applicable Local Laboratories Normal Reference Ranges (including revisions) if applicable Lab Manual/sample processing instructions, if applicable Details of sample storage facilities/ processes/relevant personnel contact details Sample Shipment Receipt/ Tracking, if applicable Temperature logs for sample storage Sample storage instructions/Inventory of samples/specimens, if 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*
17.	Pharmacy	Sponsor Green Light approval documents Investigational Medicinal Product packaging (label specification, copies of labels) Instructions for handling and storage of trial medication and trial related materials (randomisation, re-supply,

		return / destruction. Code breaking (unblinding) documentation(IVRS if applicable) Master template prescription form Completed prescription forms Template of Accountability forms / Inventory Forms / Dispensing logs / Temperature logs for all sites. Drug Destruction documentation. Completed Accountability/Inventory/Dispensing Forms Drug destruction template Completed drug destruction forms The following is applicable when Pharmacy is involved with Investigational Medicinal Product Manufacturing: - GMP certificate - Certificate of Analysis - Authorisation of release by Qualified Person *<u>At Trial Master File level:</u>* *For all collaborating centres:* *Sponsor green light documentation* *Confirmation of drug receipt/ IMP destruction.* *Pharmacy correspondence*
18.	Study Related Supplies	Shipment/delivery Collection/return Supplies Re-order form templates 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*
19.	Financial / Legal	Contracts / Contract Addendums with all investigators and Sub-contractors

		Confirmation of Sponsorship Funding Letter(s)/ Financial Agreement Insurance and Indemnity Statement for all investigators Financial Correspondence Records of subject expenses *<u>At TMF Site Level File:</u>* *Copies of all agreements*
20.	Annual /Final report	Annual Reports to REC / HRA , Competent Authority and R&D/ R&I Notice to REC/ HRA, Competent Authority and R&D /R&I of trial completion *<u>At Trial Master File level:</u>* *Evidence of supply and acknowledgement of documentation to all collaborating centres*
21.	Publications	Copies of all study analysis publications
22.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including Newsletters and other study specific correspondence. Meeting Agendas and Minutes General correspondence *<u>At TMF Site Level File:</u>* *Relevant correspondence/notifications to sites*
23.	Miscellaneous	