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Trial Master File (TMF) Index

Section N°	Essential Record	Location
0.0	Grant Application and Sponsor Review	
0.1	Pre application work up	
0.2	Grant Information	
0.3	Peer review	
0.4	CRN Portfolio Information	
0.5	Sponsor review	
1.0	Trial Set-up and Management	
1.1	TMF Plan	
1.2	Trial contact lists	
1.3	Version control log/tracker	
1.4	Clinical Trials Registration	
1.5	TMF File Note Tracking Log	
1.6	Template File Note	
1.7	Any other coordinating centre/trial management documents	
2.0	Central Staff Documents <i>Central staff delegation and documentation are applicable where a central team e.g., CTU/central co-ordinating team are providing a trial management function. Refer to SOP S-1010 for further information.</i>	
2.1	Chief Investigator Documents	
2.2	Central Staff Delegation of Activities Log	
2.3	Central Staff Training Documents	
2.4	Central Staff Training tracking log	
3.0	Protocol and Associated Documents	
3.1	Signed Protocol(s)	
3.2	Data Flow Diagram	
3.3	Template Protocol Deviation Tracking Log	
3.4	Contemporaneous Central Site Protocol Deviation Log	
4.0	Trial Documentation	
4.1	Template (non-localised) trial documents	
5.0	Initial Application and Reviewing Body Approvals	
5.1	Application and full submission package	
5.2	*All initial MHRA (or relevant Competent Authority) approvals/correspondence	
5.3	All initial REC approvals/correspondence	
5.4	All initial HRA approvals/correspondence	
5.5	Any other approvals	
5.6	Any further relevant correspondence	

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6.0	<p align="center">Modification Documentation and Regulatory Approval</p> <p>Note: To avoid duplication, where tracked and clean versions of a document are submitted as a modification, only include the tracked versions here. Clean version should be filed in the relevant TMF section e.g., Section 3.0 Protocol and Associated Documents or Section 4.0 Trial Documentation only once the modification has been approved.</p>	
6.1	<p>Substantial Modification Documents (repeat per modification)</p> <p>To include;</p> <ul style="list-style-type: none"> All review body approvals and correspondence Evidence of modification submission Modification documents and cover letter(s) Any further relevant correspondence Note: <i>Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</i> 	
6.2	<p>Minor Modifications Documents (repeat per modification)</p> <p>To include;</p> <ul style="list-style-type: none"> All relevant review body notifications/approvals/correspondence Evidence of modification submission Modification documents Any further relevant correspondence Note: <i>Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</i> 	
6.3	<p>Modifications of Important Detail Documents (repeat per modification)</p> <p>To include;</p> <ul style="list-style-type: none"> All relevant review body notifications/approvals/correspondence Evidence of modification submission Modification documents Any further relevant correspondence Note: <i>Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</i> 	
7.0	Participant Documentation	
7.1	Template Screening Log	
7.2	Template Participant Enrolment Log	
8.0	Standard Operating Procedures (SOPs) and Training Materials	
8.1	Sponsor (Research Governance Office) SOPs Printed versions are to be considered uncontrolled therefore SOPs should be accessed via: https://le.ac.uk/research/regi/standard-operating-procedures	
8.2	Trial specific SOPs	
8.3	Trial Specific Working Instructions/Guidance Notes/Operational Manuals	
8.4	Any other training material	

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Section N°	Essential Record	Location
9.0	Randomisation	
9.1	Randomisation Documents	
9.2	Master Randomisation List	
9.3	Procedure for randomisation/code break for blinded trials	
9.4	Randomisation System Closure Information	
9.5	Other randomisation documents	
9.6	Correspondence	
10.0	Data Management	
10.1	Data Management Plan	
10.2	Template CRFs	
10.3	CRF Review and sign off documents	
10.4	Any other data management documents	
11.0	Programming Information	
11.1	Database design/build/validation/testing/go-live documentation	
11.2	User manuals/Training materials	
11.3	Database Access Logs	
11.4	Database amendment documentation	
11.5	Database Extraction Documentation	
11.6	Database Lock Documentation	
11.7	Database Archiving Documentation	
11.8	Other programming documents	
12.0	Statistics and Analysis	
12.1	Statistical Analysis Plan	
12.2	Analysis Datasets	
12.3	Statistical Analysis Programming Specifications	
12.4	Statistical Validation Documentation	
12.5	Statistical Outputs (Tables, Listings and Figures)	
12.6	Interim Analysis Reports	
12.7	Final Analysis Reports	
12.8	Any other Supporting Documents	
12.9	Relevant Correspondence	
13.0	Pharmacovigilance/Safety Reporting	
13.1	Template Serious Adverse Event (SAE) reporting form	
13.2	SAE/SAR/SUSAR Tracking log (multi-centre studies only)	
13.3	Safety Alerts including evidence of CI notification and review and action to research locations if applicable	

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Section N°	Essential Record	Location
14.0	Investigational Medicinal Product(s)/Pharmacy*	
14.1	Signed Investigator Brochure(s)/Summary of Products Characteristics	
14.2	Investigational Medicinal Product Dossier (IMPD)	
14.3	Template (non-localised) IMP/placebo packaging labels	
14.4	IMP Management/Pharmacy Manual	
14.5	Template IMP Management Documents	
14.6	Central records relating to; <ul style="list-style-type: none"> IMP release Records of any temperature excursions/product defects/recalls and associated acknowledgement correspondence Ordering and shipping records for IMP 	
14.7	Stability Data	
14.8	Correspondence with drug manufacturer/drug management company	
14.9	Any other relevant documentation	
14.10	Any other relevant correspondence	
15.0	Trial Related Supplies	
15.1	Supplies	
15.2	Equipment Maintenance and Calibration records	
16.0	Annual Reports	
16.1	*Annual Development Safety Update Report (DSUR) Documentation (repeat per DSUR)	
16.2	Any other annual reports and supporting documents	
16.3	Any further relevant correspondence	
17.0	Clinical Laboratory (if applicable)	
17.1	Laboratory Manual/Sample Processing Manual (mandatory for CTIMPs)	
17.2	Central Laboratory(s)	
17.2.1	Laboratory documentation (repeat per laboratory)	
18.0	Monitoring and Oversight	
18.1	Trial specific Risk Assessment(s)	
18.2	Trial specific Monitoring Plan(s)	
18.3	Contemporaneous Coordinating Centre Monitoring Visit Log	
18.4	Coordinating Centre/Trial Research Location (Site) Initiation Visit (SIV) documentation	
18.5	Coordinating Centre Monitoring/Audit documentation (repeat per monitoring visit)	
18.6	Coordinating Centre/End of Trial Closedown Documentation	
18.7	Coordinating Centre Quality Control Documentation	
18.8	Coordinating Centre CAPA/Serious Breach/non-compliance documents	
18.9	Relevant correspondence	

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Section N°	Essential Record	Location
19.0	Financial & Legal	
19.1	Trial Specific Indemnity	
19.2	Sponsor Insurance Certificates covering the duration of the trial	
19.3	Agreements e.g., with suppliers and third parties e.g., transcription companies/database providers/IMP providers/randomisation system providers	
19.4	Licence Agreements <i>for validated Questions</i>	
19.5	Funding/Finance Documentation	
19.6	Any other documents/correspondence	
20.0	Participant Identification Centre (PIC) documents (repeat per PIC) <i>Note: Where a PIC feeds into an NHS research location, the relevant PIC documents should be retained in the SSF. This section should be used where the PIC feeds into the UoL as a research location.</i>	
20.1	Sponsor to PIC(s) Sponsor Green Light/Approval	
20.2	PIC Confirmation of Capacity and Capability or equivalent	
20.3	Signed agreement(s)	
20.4	Relevant Correspondence	
20.5	Sponsor to PIC tracker	
21.0	Vendors/Third Parties (repeat per vendor/third party)	
21.1	Vendor/Third Party Oversight Documents	
21.2	Vendor Closedown Documentation (including archive information as appropriate)	
22.0	Meetings (where applicable)	
22.1	Trial Steering Committee (TSC) documentation	
22.2	Data Safety Monitoring Committee (DSMC) documentation	
22.3	Investigator meeting documentation	
22.4	Trial Management Meeting (TMG) meeting documentation	
22.5	Any other relevant meeting documentation	
23.0	End of Trial & Archiving	
23.1	End of Trial Notification	
23.2	End of Trial Sample Declaration Form	
23.3	Final report Documentation	
23.4	End of Trial Lay Summary for participants	
23.5	End of Trial Archive Documentation	
23.6	Any other End of Trial/Archiving documentation/Correspondence	
24.0	Publications	
24.1	Copies of all trial analysis publications	
25.0	Correspondence	
25.1	Important correspondence with CI/Sponsor and internal research location correspondence	
25.2	Newsletters	
25.3	Any other trial specific correspondence	

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Section N°	Essential Record	Location
26.0	<p align="center">Miscellaneous</p> <p><i>This section should be used sparingly. It is a controlled space for items which don't logically fit anywhere within the above referenced sections but contribute to trial conduct, oversight and decision making.</i></p>	

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Site Specific File (SSF) Index

Site number/name:	
Principal Investigator:	

Section N°	Essential Record	Location
1.0	Trial Set-up and Management	
1.1	Research Location contact lists	
1.2	Any other research location management documents	
2.0	Research Location Staff Documents	
2.1	Principal Investigator Documents	
2.2	Research Location Delegation of Activities and Signature Log(s)	
2.3	Research Location Investigator Training Documents	
2.4	Investigator Training tracking log	
3.0	Protocol and Associated Documents	
3.1	Protocol Signature Page(s)	
3.2	Research Location Protocol Deviation Tracking Log	
4.0	Trial Documentation	
4.1	Localised trial documents	
5.0	Initial Application and Research Location Approvals	
5.1	Research Location Sponsor Green Light	
5.2	Research Location R&D/I approval	
5.3	Research Location Pharmacy Green Light	
5.4	Research Location Contracts/Contract Addendums including supporting document and correspondence	
5.5	Schedule of Events (SoE)/Validated SoECAT	
5.6	Research Location Feasibility Assessment	
5.7	Any further relevant correspondence	
6.0	Modification Documentation and Regulatory Approval Note: To avoid duplication, where tracked and clean versions of a document are submitted as a modification, only include the tracked versions here. Clean version should be filed in in the relevant SSF section e.g., Section 3.0 Protocol and Associated Documents or Section 4.0 Trial Documentation only once the modification has been approved.	
6.1	Substantial Modification Documents (repeat per modification) To include; <ul style="list-style-type: none"> • Research location Sponsor Green Light/Approval and R&D/I approval for the implementation of the modification • Evidence of location research team and R&D/I notification of modification • Relevant correspondence Note: <i>Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</i>	
6.2	Minor Modifications Documents (repeat per modification)	

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Section N°	Essential Record	Location
	<p>To include;</p> <ul style="list-style-type: none"> Research location Sponsor Green Light/Approval and R&D/I approval for the implementation of the modification Evidence of location research team and R&D/I notification of modification (ideally stating 35-day implementation date) Relevant Correspondence <p><i>Note: Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</i></p>	
6.3	<p>Modifications of Important Detail Documents (repeat per modification)</p> <p>To include;</p> <ul style="list-style-type: none"> Research location Sponsor Green Light/Approval and R&D/I approval for the implementation of the modification Evidence of location research team and R&D/I notification of modification (ideally stating 35-day implementation date) Relevant Correspondence <p><i>Note: Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</i></p>	
7.0	Participant Documentation	
7.1	Copy of Research Location Screening log	
7.2	Confirmation of participant enrolment numbers at the research including a list of allocated participant IDs	
8.0	Standard Operating Procedures (SOPs) and Training Materials	
8.1	Research Location specific SOPs	
8.2	Research Location Specific Working Instructions/Guidance Notes/Operational Manuals	
8.3	Any other Research Location training material	
9.0	Pharmacovigilance/Safety Reporting	
9.1	Research Location SAE/SAR/SUSAR reports and supporting documents and correspondence	
10.0	Investigational Medicinal Product(s)/Pharmacy*	
10.1	PI Signed Investigator Brochure(s)/Summary of Products Characteristics	
10.2	<p>IMP documentation</p> <ul style="list-style-type: none"> Records of any temperature excursions/recalls and associated correspondence Order/shipment documentation and correspondence 	
10.3	<p>Research Location level template docs e.g.,</p> <ul style="list-style-type: none"> Accountability logs, prescriptions, labels 	
10.4	Any other relevant documentation	
10.5	Any other relevant correspondence	

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Section N°	Essential Record	Location
11.0	Trial Related Supplies	
11.1	Research Location Supplies	
11.2	Equipment Maintenance and Calibration records	
12.0	Clinical Laboratory (Local Laboratory)	
12.1	Laboratory documentation	
13.0	Monitoring and Oversight	
13.1	Signed Source Data Agreement	
13.2	Research Location (Site) Initiation Visit (SIV) documentation	
13.3	Research Location Monitoring/Audit documentation (repeat per monitoring visit)	
13.4	Research Location Quality Assurance Documentation	
13.5	Research Location CAPA/Serious Breach	
13.6	Research Location Closedown Documentation	
14.0	Financial	
14.1	Record of participant payments (if managed centrally)	
14.2	Record of research location payments	
14.3	Any other financial documents/correspondence	
15.0	Participant Identification Centre (PIC) documents (repeat per PIC)	
15.1	Research Location to PIC(s) Sponsor Green Light/Approval	
15.2	PIC Confirmation of Capacity and Capability or equivalent	
15.3	Signed agreement(s)	
15.4	Relevant Correspondence	
15.5	Research Location to PIC tracker	
16.0	Meetings	
16.1	Research Location meetings documentation	
17.0	Correspondence	
17.1	Important Research Location correspondence	
18.0	Miscellaneous <i>This section should be used sparingly. It is a controlled space for items which don't logically fit anywhere within the above referenced sections but contribute to trial conduct, oversight and decision making.</i>	
19.0	End of Trial & Archiving	
19.1	End of Trial Archive Documentation <i>E.g., completed checklist, outstanding actions log and relevant correspondence.</i>	
19.2	Any other End of Trial /Archiving documentation/Correspondence	

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