

Trial Master File (TMF) Index Guidance

Location of Records

The TMF may be maintained in paper format, electronic format, or a combination of both as per the guidance in the SOP.

The 'Location' column should be used to specify **where** each record can be found, using the key below.

Location Column Key:

electronic TMF = eTMF

paper TMF = pTMF

pharmacy site file = PSF

Investigator site file = ISF

Other = If 'other', additional detail **must** be provided. This may be documented within the TMF Plan or in a 'Note to File'.

Contents List Guidance

The records listed below are not exhaustive; rather, they illustrate the types of documents that are typically expected within the TMF. The accompanying italicised guidance offers additional detail on the kinds of documents that may be found within each section.

Not all sections will apply to every trial. Where a document is not applicable, this should be indicated by marking N/A in the Location column.

Please note that the Site-Specific File (SSF) component of the TMF should be repeated for each participating research location** organisation.

**For single-centre studies where the University of Leicester is the only research location you only need to maintain a TMF (note: the SSF component and a ISF are not required). In this instance, you are responsible for adapting the TMF index as appropriate to ensure all the necessary records are captured (e.g., Protocol Deviation logs, Delegation of Activity Logs, Trial Documents, Screening Logs, Consent Forms etc.).

Records marked with an Asterix* are applicable to CTIMPs only.

Filing Guidance

All approved versions of a document should be filed in reverse chronological order, with the most recent version on top. Any version that is no longer current should be clearly marked as superseded, including a note identifying the new version that replaced it. Superseded versions must be retained in the TMF.

Further information on managing essential records is also available [online](https://uniofleicester.sharepoint.com/sites/Research-Governance-Ethics-Integrity/SitePages/Essential-Documents.aspx) (UoL login required) via;
<https://uniofleicester.sharepoint.com/sites/Research-Governance-Ethics-Integrity/SitePages/Essential-Documents.aspx>

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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 <ul style="list-style-type: none"> <i>E.g., Documentation and correspondence relating to trial concept</i> 	
0.2	Grant Information <ul style="list-style-type: none"> <i>E.g., Grant application, review, approval, funding letter and correspondence</i> 	
0.3	Peer review <ul style="list-style-type: none"> <i>Copies of signed peer review forms if separate to the grant application. Or confirmation that the peer review conducted as part of the grant meets NIHR requirements.</i> 	
0.4	CRN Portfolio Information <ul style="list-style-type: none"> <i>E.g., Portfolio application (if available), confirmation of adoption and correspondence</i> 	
0.5	Sponsor review <ul style="list-style-type: none"> <i>E.g., All draft document iterations excluding the final V1.0. Includes the DPIA and/or ROPA/Privacy notices if held outside Infonetica</i> 	
1.0	Trial Set-up and Management	
1.1	TMF Plan <ul style="list-style-type: none"> <i>A template is available to download from the RGO SOP webpages</i> <i>For non-CTIMPs, a TMF Plan is not mandated, but it is recommended.</i> <i>For non-CTIMPs using a hybrid TMF, but not using a TMF plan, please include a 'Note to File' (template is available to download from the RGO SOP webpages) within the paper TMF confirming the location (file path) of the primary electronic component of the TMF.</i> 	
1.2	Trial contact lists <ul style="list-style-type: none"> <i>To include Sponsor, CTU/Coordinating centre staff details, REC/HRA, third party service providers etc.</i> 	
1.3	Version control log/tracker <ul style="list-style-type: none"> <i>A template is available to download from the RGO SOP webpages</i> 	
1.4	Clinical Trials Registration <ul style="list-style-type: none"> <i>E.g., ISRCTN; including updates and results</i> 	
1.5	TMF File Note Tracking Log <ul style="list-style-type: none"> <i>While this document should list all the file notes created, the physical file note should be stored alongside the document to which it refers. The location e.g., relevant section can be detailed on the tracker. A template is available to download from the RGO SOP webpages</i> 	
1.6	Template File Note <ul style="list-style-type: none"> <i>A template is available to download from the RGO SOP webpages</i> 	
1.7	Any other coordinating centre/trial management documents	
2.0	Central Staff Documents <p><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></p>	

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2.1	<p>Chief Investigator Documents</p> <ul style="list-style-type: none"> • Roles and Responsibilities • Signed and dated research CV • Training records e.g., GCP, HTA, SOP Read Logs 	
2.2	<p>Central Staff Delegation of Activities Log</p> <ul style="list-style-type: none"> • To include a localised template page • A template is available to download from the RGO SOP webpages 	
2.3	<p>Central Staff Training Documents</p> <ul style="list-style-type: none"> • Signed and dated research CV • Training records e.g., GCP, consent, HTA, trial specific • Trial specific training • Sponsor SOP Read Logs <p>There should be records present for each person listed on the central staff Delegation of Activities Log, covering the duration their involvement in a trial</p> <ul style="list-style-type: none"> • We recommend the use of the HRA Investigators CV template • Training records should be relevant to an individual's role in the trial e.g., consent certificate is only applicable to those delegated the task of consent. • Trial specific training – See SOP S-1020. Training should be captured on a researcher training log. A template is available to download from the RGO SOP webpages • Individuals should review Sponsor SOPs relevant to their role. A record should be kept via an SOP read log (a template is available to download from the RGO SOP webpages). SOPs should be read and reviewed at regular intervals. 	
2.4	<p>Central Staff Training Tracking Log</p> <ul style="list-style-type: none"> • A template is available to download from the RGO SOP webpages 	
3.0	Protocol and Associated Documents	
3.1	<p>Signed Protocol(s)</p> <ul style="list-style-type: none"> • All versions must be signed and dated by the Chief Investigator and the Sponsor (CTIMPs only). If a version is superseded before it is implemented and therefore is not signed (for example, Version 3.0 is submitted as a modification but the review bodies request changes, resulting in Version 3.1 being approved instead), a Note to File should be completed to explain the discrepancy. Use S-1013 Appendix 5 for this purpose. 	
3.2	<p>Data Flow Diagram</p> <ul style="list-style-type: none"> • If separate to protocol 	
3.3	<p>Template Protocol Deviation Tracking Log(s)</p> <ul style="list-style-type: none"> • Where protocol deviations are not managed exclusively through a research database/eCRF, or where PI review of deviations within a database/eCRF cannot be evidenced, a paper PD Log should be maintained. A paper PD log should be maintained for any PDs which are not participant specific. These can occur either centrally or at a research location. • A template is available to download from the RGO SOP webpages 	
3.4	<p>Contemporaneous Central location Protocol Deviation Log</p> <ul style="list-style-type: none"> • If protocol deviations occur at the central location e.g., relating to data handling/management which may not be attributable to a specific participant, and thus not recorded in a database/eCRF, these should be stored here. 	
4.0	Trial Documentation	

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4.1	<p>Template (non-localised) trial documents</p> <ul style="list-style-type: none"> <i>This should include all of your template documents i.e., documents for which the NHS trust logo or location-specific details e.g., where PI name and contact details need to be added. Localised versions are stored elsewhere (refer to SSF Section 4).</i> <i>Example documents include: Participant Information Sheets, Template Informed Consent Forms, Letters, Posters, Topic Guides, Questionnaires etc</i> 	
5.0	Initial Application and Reviewing Body Approvals	
5.1	<p>Application and full submission package</p> <ul style="list-style-type: none"> <i>E.g., All V1.0 documents, review body application (e.g IRAS, combined review), OID/mNCA templates and SoE/SoECAT(s).</i> 	
5.2	<p>*All initial MHRA (or relevant Competent Authority) approvals/correspondence</p> <ul style="list-style-type: none"> <i>E.g., emails/letters confirming Valid Application, GNA, Approval</i> 	
5.3	<p>All initial REC approvals/correspondence</p> <ul style="list-style-type: none"> <i>E.g., emails/letters confirming Valid Application, Provision Opinion, Favourable Opinion</i> 	
5.4	<p>All initial HRA approvals/correspondence</p> <ul style="list-style-type: none"> <i>E.g., emails/letters confirming Initial Assessment, Provision Opinion, Approval</i> 	
5.5	<p>Any other approvals</p> <ul style="list-style-type: none"> <i>E.g., CAG/ARSAC etc. (if applicable)</i> 	
5.6	Any further relevant correspondence	
6.0	<p>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) once the modification has been approved.</p>	
6.1	<p>Substantial Modification Documents (repeat per modification)</p> <ul style="list-style-type: none"> All HRA approvals/correspondence <ul style="list-style-type: none"> <i>E.g., emails/letters confirming Initial Assessment, Approval</i> *All MHRA/Competent Authority approvals/correspondence <ul style="list-style-type: none"> <i>E.g., emails/letters confirming Valid Application, GNA, Approval</i> All REC approvals/correspondence <ul style="list-style-type: none"> <i>E.g., emails/letters confirming Valid Application, Provision Opinion, Favourable Opinion</i> Any other approvals/notifications and supporting documentation <ul style="list-style-type: none"> <i>E.g., CAG/ARSAC acknowledgement and approval</i> Evidence of modification submission <ul style="list-style-type: none"> <i>E.g., IRAS submission email for modifications submitted via normal IRAS</i> Modification documents and cover letter(s) Locked modification tool Any further relevant correspondence <p>Note: Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</p>	
6.2	<p>Minor Modification Documents (repeat per modification)</p> <ul style="list-style-type: none"> HRA approval/correspondence 	

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	<ul style="list-style-type: none"> Any other approvals/notifications and supporting documentation <ul style="list-style-type: none"> <i>E.g., CAG/ARSAC Notification</i> Evidence of modification submission <ul style="list-style-type: none"> <i>E.g., IRAS submission email</i> Modification documents Locked modification tool Any further relevant correspondence <p>Note: Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</p>	
6.3	<p>Modifications of Important Detail Documents (repeat per modification)</p> <ul style="list-style-type: none"> Relevant regulatory notification/approval/correspondence <ul style="list-style-type: none"> <i>E.g., REC/HRA/MHRA as required</i> Any other approvals/notifications and supporting documentation <ul style="list-style-type: none"> <i>E.g., CAG/ARSAC Notification</i> Evidence of modification submission <ul style="list-style-type: none"> <i>E.g., IRAS submission email</i> Modification documents Locked modification tool Any further relevant correspondence <p>Note: Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</p>	
7.0	Participant Documentation	
7.1	<p>Template Screening Log</p> <ul style="list-style-type: none"> A template is available from the RGO SOP webpages however it may be adapted to suit your trial. It may also be worth creating some working instruction to document which individuals will/won't be added to the screening log to ensure this remains uniform throughout the trial and between individuals undertaking screening i.e., will the screening log contain all individuals invited to take part or will it only include those who return a reply slip/undergo telephone (pre-screening). This document should not be used to obtain any identifiable information or participant characteristics. 	
7.2	<p>Template Participant Enrolment Log</p> <ul style="list-style-type: none"> A template is available from the RGO SOP webpages however you may create your own. 	
8.0	Standard Operating Procedures (SOPs) and Training Materials	
8.1	<p>Sponsor (Research Governance Office) SOPs</p> <p>Printed versions are considered uncontrolled therefore SOPs should be accessed via: https://le.ac.uk/research/regi/standard-operating-procedures</p> <ul style="list-style-type: none"> A 'Note to File' confirming the location of all current and historic Sponsor SOPs should also be filed here. The note to file should be download from the Sponsor SOP webpage. 	
8.2	Trial-specific SOPs	
8.3	Trial-specific Working Instructions/Guidance Notes/Operational Manuals	
8.4	<p>Any other training material</p> <ul style="list-style-type: none"> This provides a place for any further training documents which are not listed elsewhere. Note: this section should not include SIV training, SIV training is captured within the 'Monitoring and Oversight' section below. 	

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9.0	Randomisation	
9.1	Randomisation Documents <ul style="list-style-type: none"> <i>E.g., set-up/stratification documents</i> 	
9.2	Master Randomisation List <ul style="list-style-type: none"> <i>Either provide the list or add a note to file confirming the location e.g., Randomisation list held within Sealed Envelope during the active phase of the trial</i> 	
9.3	Procedure for randomisation/code break for blinded trials <ul style="list-style-type: none"> <i>This section is only applicable if the information pertaining to this sits outside of the protocol.</i> 	
9.4	Randomisation System Closure Information <ul style="list-style-type: none"> <i>E.g., Confirmation of closure, System Downloads where held externally to database.</i> 	
9.5	Other randomisation documents <ul style="list-style-type: none"> <i>Copies of contracts, agreements, financial information where this is not included in Section 19.0</i> 	
9.6	Correspondence	
10.0	Data Management	
10.1	Data Management Plan	
10.2	Template CRFs	
10.3	CRF Review and sign off documents <ul style="list-style-type: none"> <i>Evidence of CRF sign off e.g., by Chief Investigator, Trial Manager and Statistician (where applicable)</i> <i>CRF Tracker (a template is available to download from SOP S-1039) confirming CRF versions, fully executed dates, Sign off dates, implementation dates and dates of corresponding database update (if applicable).</i> 	
10.4	Any other data management documents <ul style="list-style-type: none"> <i>e.g., CRF correction procedures/eCRF user manual</i> 	
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 <ul style="list-style-type: none"> <i>List of all users, roles/permissions granted, activation/deactivation dates, access audit trails</i> 	
11.4	Database amendment documentation <ul style="list-style-type: none"> <i>E.g., review/approval/go-live documentation for each version of the database</i> 	
11.5	Database Extraction Documentation <ul style="list-style-type: none"> <i>E.g., data request and transfer forms for all data extractions</i> 	
11.6	Database Lock Documentation <ul style="list-style-type: none"> <i>Data Query Logs (issues and resolution logs)</i> <i>Data Cleaning Documentation</i> 	
11.7	Database Archiving Documentation	
11.8	Other programming documents	

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	<ul style="list-style-type: none"> • <i>E.g., If you are using non-trial-specific computerised systems such as clinical practice computerised systems, evidence of suitability should be filed.</i> • <i>Copies of contracts, agreements, financial information where this is not included in Section 19.0</i> 	
12.0	Statistics and Analysis	
12.1	Statistical Analysis Plan <ul style="list-style-type: none"> • Note: <i>This must be in place prior to database lock</i> 	
12.2	Analysis Datasets <ul style="list-style-type: none"> • <i>E.g., Final locked datasets used for any statistical analyses</i> 	
12.3	Statistical Analysis Programming Specifications <ul style="list-style-type: none"> • <i>E.g., programming rules/coding for specifications</i> 	
12.4	Statistical Validation Documentation <ul style="list-style-type: none"> • <i>E.g., evidence of QC and validation of statistical outputs</i> 	
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) <ul style="list-style-type: none"> • <i>A template is available to download from the RGO SOP webpages</i> 	
13.3	Dear Investigator Letters and Safety Alerts including evidence of CI notification and review and action to research locations if applicable	
14.0	Investigational Medicinal Product(s)/Pharmacy*	
14.1	Signed Investigator Brochure(s)/Summary of Products Characteristics <ul style="list-style-type: none"> • <i>The CI must sign each version containing the approved Reference Safety Information (RSI) to confirm acknowledgement of the agreed expected events.</i> 	
14.2	Investigational Medicinal Product Dossier (IMPD)	
14.3	Template (non-localised) IMP/placebo packaging labels <ul style="list-style-type: none"> • <i>This should include all of your template labels for which the NHS trust logo or research location-specific details e.g., where PI name and contact details need to be added. Localised versions are stored elsewhere (refer to SSF Section 10).</i> 	
14.4	IMP Management/Pharmacy Manual	
14.5	Template IMP Management Documents <ul style="list-style-type: none"> • <i>E.g., Accountability Logs, Inventory Logs Forms, Dispensing Logs, Prescriptions</i> 	
14.6	Central records relating to; <ul style="list-style-type: none"> • IMP release <ul style="list-style-type: none"> • <i>E.g., technical/batch/QP release/Certificates of Analysis (CoA))</i> • Records of any temperature excursions/product defects/recalls and associated acknowledgement correspondence 	

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	<ul style="list-style-type: none"> Ordering and shipping records for IMP <p><i>These documents are applicable to the central coordinating function prior to the receipt of IMP at research locations. All documentation following receipt at the location will be retained in 'Section 10 IMP' of the SSF.</i></p>	
14.7	<p>Stability Data</p> <ul style="list-style-type: none"> <i>Documentation confirming the stability of a product in the event of temperature excursions should be included here. It should include temperature durations and times at temperature. This is important as it confirm whether or not IMP can be used in the event of a temperature excursion or whether it need to be quarantined and destroyed.</i> 	
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	<p>Supplies</p> <ul style="list-style-type: none"> <i>Records of order, receipt, return and destruction of trial related supplies</i> 	
15.2	<p>Equipment Maintenance and Calibration records</p> <ul style="list-style-type: none"> <i>Where equipment is provided to research locations but the responsibility for maintenance and calibration remains with the University of Leicester (UoL), documentation must be retained within the TMF to demonstrate that each item is fit for purpose. This includes evidence of maintenance, servicing, and calibration for all equipment used in critical trial activities, i.e., those that directly generate data contributing to primary or secondary endpoints. Records must confirm that equipment was maintained and calibrated at appropriate intervals and was functioning within required specifications for the duration of its use in the trial</i> 	
16.0	Annual Reports	
16.1	<p>*Annual Development Safety Update Report (DSUR) Documentation (repeat per DSUR)</p> <ul style="list-style-type: none"> <i>REC/ MHRA (Competent Authority) Submission/Acknowledgement (emails/signed reports)</i> <i>REC/ MHRA (Competent Authority) cover letter(s)</i> <i>Copy of signed IB/SmPC annual review form</i> <i>Signed DSUR report, and all associated appendices</i> 	
16.2	<p>Any other annual reports and supporting documents</p> <ul style="list-style-type: none"> <i>Depending on the approvals of your trial you may also need to provide annual reports to the CAG/funder. Where there are no additional annual reporting requirements the location section can be marked as N/A.</i> 	
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	<p>Laboratory documentation (repeat per laboratory)</p> <ul style="list-style-type: none"> <i>Certificate(s) of Accreditation (including revisions)</i> 	

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	<p><i>E.g., relating to UKAS 15189, ISO 17025, and any evidence of adherence to GCP or Good Laboratory practice</i></p> <ul style="list-style-type: none"> • <i>Calibration and servicing certificates</i> • <i>Temperature monitoring</i> • <i>Normal Reference Ranges (including revisions)</i> • <i>Details of location sample storage facilities/processes</i> • <i>Sample Tracking Logs (receipt/delivery/destruction)</i> • <i>Details of assay analyses, to include;</i> <ul style="list-style-type: none"> ○ <i>Whether conducted for primary/secondary analyses</i> ○ <i>Audit trail of analyses completed including deviations and failed runs and correspondence relating to these</i> ○ <i>Raw data retention and storage</i> • <i>Laboratory specific SOPs (including specific analysis, back-up in the event of storage failure)</i> • <i>Consumable management records</i> • <i>Correspondence</i> 	
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 <ul style="list-style-type: none"> • <i>This should be signed at each Monitoring visit. Template available from SOP S-1007</i> 	
18.4	Coordinating Centre/Trial Initiation Visit documentation <ul style="list-style-type: none"> • <i>E.g., agenda, signed closed report and outstanding actions list, signed attendance log and relevant correspondence</i> 	
18.5	Coordinating Centre Monitoring/Audit documentation (repeat per monitoring visit) <ul style="list-style-type: none"> • <i>E.g., Signed closed report and actions log, relevant supporting documentation and correspondence</i> 	
18.6	Coordinating Centre/End of Trial Closedown Documentation <i>E.g., completed checklist, outstanding actions log and relevant correspondence.</i>	
18.7	Coordinating Centre Quality Control Documentation <ul style="list-style-type: none"> • <i>E.g., copies of internal audits/quality control check of central processes e.g., modification reconciliation, data quality, supporting correspondence</i> 	
18.8	Coordinating Centre CAPA/Serious Breach/non-compliance documents <ul style="list-style-type: none"> • <i>This should include copies of the relevant reports, notifications and supporting documents and correspondence</i> 	
18.9	Relevant correspondence	
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 <ul style="list-style-type: none"> • <i>It may be more appropriate to file contracts, agreements, financial documents relating to third party vendors within the relevant vendor section. Whatever the preferred</i> 	

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	<i>approach, please ensure a consistent approach to filing is maintained and consider using a 'Note to File'.</i>	
19.4	Licence Agreements for validated Questions <ul style="list-style-type: none"> Where validated questions are used either provide copies of the license agreement which have been obtained for their use or provide evidence that specific agreements aren't required. E.g., where there is documentation confirming that they are freely available to use in a non-commercial setting. 	
19.5	Funding/Finance Documentation <ul style="list-style-type: none"> Where all these documents are retained within Worktribe you may wish to link out to Work tribe and provide the work tribe reference here 	
19.6	Any other documents/correspondence	
20.0	Participant Identification Centre (PIC) documents (repeat per PIC) Note: Where a PIC feeds into an NHS research location, the relevant PIC documents should be retained in the SSF. This section should only be used where the PIC feeds into the UoL as a research location.	
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) <ul style="list-style-type: none"> This should be a Sponsor to PIC mNC-PICA signed by a member of the research governance office and a suitable individual from the PIC 	
20.4	Relevant Correspondence	
20.5	Sponsor to PIC tracker <ul style="list-style-type: none"> A template is available to download from the RGO SOP webpages. This should name all the PICs involved in the trial and their date of approval. Approval is considered the date of the fully executed agreement. 	
21.0	Vendors/Third Parties (repeat per vendor/third party)	
21.1	Vendor/Third Party Oversight Documents <ul style="list-style-type: none"> Evidence of Vendor selection/assessments Evidence of procurement Service Provider Management Plan Contracts/Contract Addendums (and any relevant correspondence/documents) <ul style="list-style-type: none"> E.g., research agreements, service level agreements, collaboration agreements, safety data exchange agreements, division of responsibilities Audit/monitoring documentation Oversight records <ul style="list-style-type: none"> E.g., meeting minutes, service reports, certificates, quality and output reports, documentation of any deviations or breaches that have occurred, final reports, data exports, or certificates of analysis (as applicable) 	
21.2	Vendor Closedown Documentation (including archive information as appropriate) <ul style="list-style-type: none"> Guidance on close down activity is available in SOP S-1037. 	
22.0	Meetings (where applicable)	
22.1	Trial Steering Committee (TSC) documentation <ul style="list-style-type: none"> E.g., Charters, Conflict of Interest Forms, Meeting agendas, reports, minutes and correspondence 	

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22.2	Data Safety Monitoring Committee (DSMC) documentation <ul style="list-style-type: none"> • <i>E.g., Charters, Conflict of Interest Forms, Meeting agendas, reports, minutes and correspondence</i> 	
22.3	Investigator meeting documentation <ul style="list-style-type: none"> • <i>E.g., Meeting agendas, reports, minutes and correspondence</i> 	
22.4	Trial Management Meeting (TMG) meeting documentation <ul style="list-style-type: none"> • <i>E.g., Meeting agendas, reports, minutes and correspondence</i> 	
22.5	Any other relevant meeting documentation	
23.0	End of Trial & Archiving	
23.1	End of Trial Notification <ul style="list-style-type: none"> • <i>Signed End of Trial Declaration Form</i> • <i>Evidence of submission and acknowledgement by Sponsor/REC/HRA MHRA or competent authority</i> 	
23.2	End of Trial Sample Declaration Form <ul style="list-style-type: none"> • <i>Signed End of Trial Sample Declaration Form</i> • <i>Evidence of submission and acknowledgement by Sponsor</i> 	
23.3	Final report Documentation <ul style="list-style-type: none"> • <i>Include a copy of final report and evidence of submission to and acknowledgement from the relevant review bodies</i> 	
23.4	End of Trial Lay Summary for participants <ul style="list-style-type: none"> • <i>This should include any documentation pertaining to the distribution of the lay summary of results to individuals who consented to this request.</i> 	
23.5	End of Trial Archive Documentation <ul style="list-style-type: none"> • <i>E.g., completed checklist, outstanding actions log and relevant correspondence.</i> 	
23.6	Any other End of Trial /Archiving documentation/Correspondence	
24.0	Publications	
24.1	Copies of all trial analysis publications <ul style="list-style-type: none"> • <i>This should also include copies of any poster presentations/abstracts. Where applicable include declarations from authors and/or review approval forms for publications.</i> 	
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	
26.0	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>	

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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 <ul style="list-style-type: none"> To include research team members, laboratory departments, pharmacy departments, R&D/I departments etc 	
1.2	Any other research location management documents	
2.0	Research Location Staff Documents	
2.1	Principal Investigator Documents <ul style="list-style-type: none"> Signed and dated research CV Training records e.g., GCP, HTA, SOP Read Logs 	
2.2	Research Location Delegation of Activities and Signature Log(s) <ul style="list-style-type: none"> To include a localised template page A template is available to download from the RGO SOP webpages. 	
2.3	Research Location Investigator Training Documents Note: Copies of research location training documents are not required to be held in the SSF. If they are, they should be filed in this section. If they are not, and are held at the research location only this should be annotated in the location column. Where documents are filed, the following should be available; <ul style="list-style-type: none"> Signed and dated research CV Training records e.g., GCP, consent, HTA, trial specific Trial specific training Sponsor SOP Read Logs There should be records present for each person listed on the Delegation of Activities Log, covering the duration their involvement in a trial) <ul style="list-style-type: none"> We recommend the use of the HRA Investigators CV template Training records should be relevant to an individual's role in the trial e.g. consent certificate is only applicable to those delegated the role of consent. Trial specific training – See SOP S-1020. Training should be captured on a researcher training log; a template is available to download from the RGO SOP webpages. Individuals should review Sponsor SOPs relevant to their role. A record should be kept via an SOP read log (S-1011 Appendix 3). SOPs should be read and reviewed at regular intervals. 	
2.4	Research Location Investigator Training Tracking Log <ul style="list-style-type: none"> While not mandated, to demonstrate oversight of staff training at the research location we recommend the use of an investigator training tracker which documents the staff involved in the trial and the dates of their completed training. A template is available to download from the RGO SOP webpages. 	
3.0	Protocol and Associated Documents	
3.1	Protocol Signature Page(s)	

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	<ul style="list-style-type: none"> All versions must be signed and dated by the Principal Investigator. If a version is superseded before it is implemented and therefore is not signed (for example, Version 3.0 is submitted as a modification but the review bodies request changes, resulting in Version 3.1 being approved instead), a Note to File should be completed to explain the discrepancy. Use S-1013 Appendix 5 for this purpose. 	
3.2	Research Location Protocol Deviation Tracking Log <ul style="list-style-type: none"> A template is available to download from the RGO SOP webpages. 	
4.0	Trial Documentation	
4.1	Localised trial documents <ul style="list-style-type: none"> Example documents include: Participant Information Sheets, Template Informed Consent Forms, Letters, Posters, Topic Guides, Questionnaires etc Note: Copies of localised documents are not required to be held in the SSF. If they are, they should be filed in this section. If they are not, and are held at the research location only, this should be annotated in the location column.	
5.0	Initial Application and Research Location Approvals	
5.1	Research Location Sponsor Green Light	
5.2	Research Location R&D/I approval <ul style="list-style-type: none"> E.g., Confirmation of Capacity and Capability or equivalent 	
5.3	Research Location Pharmacy Green Light <ul style="list-style-type: none"> If required and if issued separately to overall research location approval 	
5.4	Research Location Contracts/Contract Addendums including supporting document and correspondence <ul style="list-style-type: none"> E.g., OID/mNCA/Pharmacy/pathology/laboratory agreements where applicable 	
5.5	Schedule of Events (SoE)/Validated SoECAT <ul style="list-style-type: none"> Only required where research locations are undertaking different activities and therefore the SoE/SoECAT differs per location. Where only one SoE/SoECAT is utilised, this can be located in the main TMF contents list section 5.1 (Application and full submission package). 	
5.6	Research Location Feasibility Assessment	
5.7	Any further relevant correspondence	
6.0	Modification Documentation and Regulatory Approval	
6.1	Substantial Modification Documents (repeat per modification) <ul style="list-style-type: none"> Research location Sponsor Green Light/Approval for the implementation of the modification Research location R&D/I modification approval (Confirmation of continued Capacity and Capability or equivalent) (if applicable) Evidence of location research team and R&D/I notification of modification Relevant correspondence Note: Not all of the documents listed above will be applicable to each and every modification. File as appropriate.	
6.2	Minor Modifications Documents (repeat per modification) <ul style="list-style-type: none"> Research location Sponsor Green Light/Approval for the implementation of modification Research location R&D/I modification approval (Confirmation of Capacity and Capability or equivalent) (if applicable) 	

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	<ul style="list-style-type: none"> Evidence of research location team and R&D/I notification of modification (ideally stating 35-day implementation date) Relevant correspondence <p>Note: Not all of the documents listed above will be applicable to each and every modification. File as appropriate.</p>	
6.3	<p>Modifications of Important Detail Documents (repeat per modification)</p> <ul style="list-style-type: none"> Research location Sponsor Green Light/Approval for the implementation of modification Research location R&D/I modification approval (Confirmation of Capacity and Capability or equivalent) (if applicable) Evidence of research location team and R&D/I notification of modification (ideally stating 35-day implementation date) Relevant correspondence Note: Not all of the documents listed above will be applicable to each and every modification. File as appropriate. 	
7.0	Participant Documentation	
7.1	<p>Copy of Research Location Screening log</p> <ul style="list-style-type: none"> Please ensure that the screening log does not contain any identifiable information. All identifiable information should be retained at the research location. 	
7.2	<p>Confirmation of participant enrolment numbers at the research including a list of allocated participant IDs</p> <ul style="list-style-type: none"> Note: Unless explicit permission has been obtained, this section must not contain any participant identifiable information Where this information is held centrally within a trial database, further details are not required here and this can be marked as N/A. 	
8.0	Standard Operating Procedures (SOPs) and Training Materials	
8.1	Research Location specific SOPs	
8.2	<p>Research Location Specific Working Instructions/Guidance Notes/Operational Manuals</p> <ul style="list-style-type: none"> Only required if not explicitly stated elsewhere 	
8.3	<p>Any other Research Location training material</p> <ul style="list-style-type: none"> Note this excludes SIV documents these should be found in the monitoring section 	
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	<p>PI Signed Investigator Brochure(s)/Summary of Products Characteristics</p> <ul style="list-style-type: none"> The PI and pharmacist must sign each version containing the approved Reference Safety Information (RSI) to confirm acknowledgement of the agreed expected events. 	
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 where applicable 	

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10.3	<p>Research Location level template docs</p> <ul style="list-style-type: none"> E.g., accountability logs, prescriptions, labels Note: Copies of localised documents are not required to be held in the SSF. If they are, they should be filed in this section. If they are not, and are held at the research location only, this should be annotated in the location column. 	
10.4	<p>Any other relevant documentation</p> <ul style="list-style-type: none"> E.g., fridge/freezer maintenance where applicable 	
10.5	Any other relevant correspondence	
11.0	Trial Related Supplies	
11.1	<p>Research Location Supplies</p> <ul style="list-style-type: none"> Records of research location order, receipt, return and destruction of trial related supplies 	
11.2	<p>Equipment Maintenance and Calibration records</p> <ul style="list-style-type: none"> Where equipment is either provided to research locations by the University of Leicester (UoL), or the equipment is the property of the research location but/and the responsibility for maintenance and calibration is the responsibility of the research location, documentation must be retained within the SSF to demonstrate that each item is fit for purpose. This includes evidence of maintenance, servicing, and calibration for all equipment used in critical trial activities, i.e., those that directly generate data contributing to primary or secondary endpoints. Records must confirm that equipment was maintained and calibrated at appropriate intervals and was functioning within required specifications for the duration of its use in the trial 	
12.0	Clinical Laboratory (Local Laboratory)	
12.1	<p>Laboratory documentation</p> <ul style="list-style-type: none"> Name and address of laboratory Certificate(s) of Accreditation (including revisions) E.g., relating to UKAS 15189, ISO 17025, and any evidence of adherence to GCP or Good Laboratory practice Calibration and servicing certificates Temperature monitoring Normal Reference Ranges (including revisions) Details of sample storage facilities/processes Sample Tracking Logs (receipt/delivery/destruction) If analyses are for primary/secondary endpoint, to include; <ul style="list-style-type: none"> Audit trail of analyses completed including deviations and failed runs and correspondence relating to these Raw data retention and storage Laboratory specific SOPs (including specific analysis, back-up in the event of storage failure) Consumable management records Correspondence 	
13.0	Monitoring and Oversight	
13.1	Signed Source Data Agreement	

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	<ul style="list-style-type: none"> A template is available to download from the RGO SOP webpages. 	
13.2	<p>Research Location (Site) Initiation Visit (SIV) documentation</p> <ul style="list-style-type: none"> E.g., agenda, signed closed SIV report and outstanding actions list, signed SIV log and relevant correspondence 	
13.3	<p>Research Location Monitoring/Audit documentation (repeat per monitoring visit)</p> <ul style="list-style-type: none"> E.g., Signed closed report and actions log, relevant supporting documentation and correspondence 	
13.4	<p>Research Location Quality Assurance Documentation</p> <ul style="list-style-type: none"> E.g., Copies of internal audits/ Quality control checks e.g., modification reconciliation, data entry quality control checks, supporting correspondence 	
13.5	<p>Research Location CAPA/Serious Breach</p> <ul style="list-style-type: none"> This should include copies of the relevant reports, notifications and supporting documents and correspondence 	
13.6	<p>Research Location Closedown Documentation</p> <ul style="list-style-type: none"> E.g., completed Research Location Closedown checklist, outstanding actions log, copy of research location archiving SOP and relevant correspondence. 	
14.0	Financial	
14.1	<p>Record of participant payments (if managed centrally)</p> <ul style="list-style-type: none"> E.g., Participant Expenses/Reimbursements 	
14.2	<p>Record of research location payments</p> <ul style="list-style-type: none"> As per agreements, e.g., per consent etc 	
14.3	<p>Any other financial documents/correspondence</p> <ul style="list-style-type: none"> E.g., Pathology/Pharmacy costs. Alternatively, these documents may be stored within their corresponding sections e.g., Pharmacy costings within section 12.0. 	
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	<p>Signed agreement(s)</p> <ul style="list-style-type: none"> This should be a research location to PIC mNC-PICA signed by a member of the research governance office and a suitable individual from the PIC 	
15.4	Relevant Correspondence	
15.5	<p>Research Location to PIC tracker</p> <ul style="list-style-type: none"> A template is available to download from the RGO SOP webpages. This should name all the PICs being used by the research location and their date of approval. Approval is considered the date of the fully executed agreement. 	
16.0	Meetings	
16.1	Research Location meetings documentation	
17.0	Correspondence	
17.1	Important Research Location correspondence	
18.0	Miscellaneous	

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	<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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