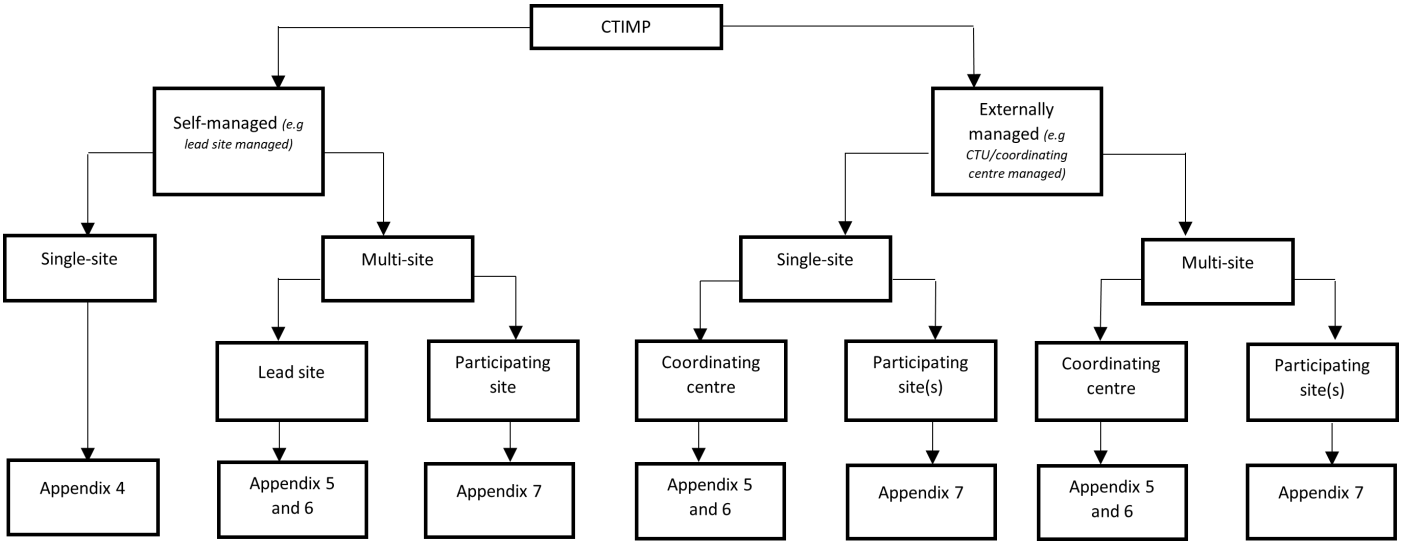
UNIVERSITY OF LEICESTER

Single Site Trial Master File (TMF) Contents List for Clinical Trials of Investigational Medicinal Products (CTIMP) – Guidance Page

This contents list should be used by a single site, self-managed CTIMP to create a TMF. Where a trial is multi-site, or is managed by an external coordinating centre please refer to Appendix 5.

Please use the decision tree below to check which contents list(s) is/are required for your trial



Useful definitions

- **Single site – self managed trial;** A trial which involves only one research site and where the management of the trial takes place at the same site.
- **Single site – externally managed trial;** A trial which involves only one research site but where the management of the trial sits outside of the research site e.g. with a Clinical Trials Unit (CTU).
- **Multi-site – self managed trial;** A trial which involves two or more research sites and where the management of the trial takes place at the lead site.
- **Multi-site – externally managed trial**; A trial which involves two or more research sites but where the management of the trial sits outside of the research sites e.g. with a CTU.
- **Lead Site/Coordinating Centre;** The site/centre which takes responsibility for the management of the trial, this may be the lead research site or an external coordinating centre e.g. a CTU.
- **Participating site;** Any other research site(s) involved in a trial which do not meet the definition of the lead site listed above.
- **Investigational Medicinal Product;** the active substance or placebo being tested or used as a reference product in a clinical trial.

Tips for using this contents list:

1. Not all documents/sections listed below will be applicable to all trials.
   Where an entire section is **not applicable**, it should be marked as such, but the original numbering of the section should be retained, this ensures a consistent filing system across all University of Leicester sponsored trials.

2. If a listed document is stored elsewhere, a note to file should be included to record its location and confirm how access can be gained. Where a document is stored electronically, please include the file path.

3. Documents should be filed in reverse chronological order (newest on top) with superseded documents marked as such.

4. To supersede a document you should;
   - Strike a single line through the front page of the document
   - Write superseded by and add the version and date of the updated document i.e. Superseded by v2.3 01/01/2023
   - Initial or sign and date next to the annotation (please note that anybody undertaking TMF maintenance should be delegated this task on the Delegation of Authority and Signature Log)

5. A copy of the relevant contents list should be placed at the front of each TMF/ISF folder. The guidance pages do not require filing.

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Single Centre Trial Master File (TMF) Contents List for Clinical Trials of Investigational Medicinal Products (CTIMP)

Trial Title:	
Chief Investigator name:	

Section 1: Trial Management	
1.1	List of relevant generic contacts *e.g. Sponsor, CTU (if applicable) REC/HRA etc.*
1.2	List of relevant site contacts *e.g. research team members, laboratory departments, pharmacy department, R&D/I department etc.*
1.3	Gantt Chart *(Current and Superseded (if applicable))*
1.4	Trial Documentation version control log/tracker *(S-1015 Appendix 3)*
Section 2: Protocol and Associated Document	
2.1	Current Protocol *signed and dated by the Chief Investigator, Principal Investigator and Sponsor*
2.2	Superseded Protocol(s) *signed and dated by the Chief Investigator, Principal Investigator and Sponsor*
2.3	Data Flow Diagram *(if separate to protocol)*
2.4	Template Protocol Deviation Log *(S-1013 Appendix 2)*
2.5	Current Site Protocol Deviation Log
2.6	Site CAPA/Serious Breach *notifications and correspondence (if applicable)*
2.7	Template File Note *(S-1013 Appendix 3)*
2.8	Site File Note Tracking log *(if applicable)* *(S-1013 Appendix 4)*
2.9	Evidence of peer review *(if applicable)* *(S-1002 – Appendix 2)*
Section 3: Trial Documentation	
3.1	Current, site localised trial documents *e.g. Participant Information Sheets, Template Informed Consent Forms, Letters, Posters, Questionnaires etc*
3.2	Superseded, site localised trial documents *e.g. Participant Information Sheets, Template Informed Consent Forms, Letters, Posters, Questionnaires etc (where applicable)*
Section 4: Initial Regulatory Approvals	
4.1	All initial MHRA/Competent Authority approvals/correspondence *e.g. emails/letters confirming Valid Application, GNA, Approval*
4.2	All initial REC approvals/correspondence *e.g. emails/letters confirming Valid Application, Provision Opinion, Favourable Opinion*
4.3	All initial HRA approvals/correspondence *e.g. emails/letters confirming Initial Assessment, Provision Opinion, Approval*
4.4	Any other applications and approvals *e.g. CAG/ARSAC etc. (if applicable)*
4.5	Evidence of NIHR CRN portfolio adoption *(where applicable)*
4.6	Confirmation/Evidence of Trial registration *e.g. ISRCTN, clincialtrials.gov etc.*
4.7	Combined Review Application and full submission package
4.8	Relevant Correspondence
Section 5: Initial Site Approvals	
5.1	Site Sponsor Green Light
5.2	Site R & D/I approval *(Confirmation of Capacity and Capability)*
5.3	Site-Specific Pharmacy Green Light *(if applicable)*
5.4	Site Feasibility Assessment
5.5	Relevant correspondence
Section 6: Amendments	
6.1	**Substantial Amendment Documents (repeat per substantial amendment)** • Site Sponsor Green Light for the implementation of the amendment • Site R&D/I amendment approval *(Confirmation of Capacity and Capability) (if applicable)* • Evidence of site R&D/I notification of amendment • All MHRA/Competent Authority approvals/correspondence *e.g. emails/letters confirming Valid Application, GNA, Approval*

	• All REC approvals/correspondence *e.g. emails/letters confirming Valid Application, Provision Opinion, Favourable Opinion* • All HRA approvals/correspondence *e.g. emails/letters confirming Initial Assessment, Provision Opinion, Approval)* • Any other approvals and supporting documentation e.g. CAG/ARSAC *(where applicable)* • Evidence of amendment submission • Tracked changed amendment documents and cover letter *(where applicable)* • Locked amendment tool • Relevant correspondence
6.2	**Non substantial Amendment Documents (repeat per non-substantial amendment)** • Site Sponsor Green Light/Approval for the implementation of the amendment • Site R&D/I amendment approval *(Confirmation of Capacity and Capability) (if applicable)* • Evidence of site research team and R&D/I notification of amendment *(stating 35-day implementation date)* • REC/HRA approval/correspondence *(where applicable)* • Any other approvals and supporting documentation *e.g. CAG/ARSAC (where applicable)* • Evidence of amendment submission • Tracked changed amendment documents *(where applicable)* • Locked amendment tool • Relevant correspondence
Section 7: Annual Reports	
7.1	**Annual Progress Report (APR) Documentation (repeat per APR)** • Sponsor Acknowledgement of APR • REC Acknowledgement of APR • Evidence of submission to REC • Copy of signed report(s)
7.2	**Annual Development Safety Update Report (DSUR) Documentation (repeat per DSUR)** • Evidence of submission to the REC/MHRA (Competent authority) • MHRA/Competent Authority cover letter • Copy of signed IB/SmPC annual review form • Copy of signed report(s)
7.3	Any other annual reports and supporting documents *e.g. CAG/funder (if applicable)*
7.4	Relevant correspondence
Section 8: Investigator Site Personnel	
8.1	Template Delegation of Authority and Signature Log (DoA) *(S-1010 Appendix 2)*
8.2	Current site Delegation of Authority and Signature Log
3.3	Site personnel documents *(covering the duration of involvement with the trial)* *The following documents should be filed as relevant per person listed on the DoA;* • Signed and dated research CV *(HRA template recommended)* • Evidence of GCP training • Evidence of consent training *(if applicable)* • Evidence of trial specific training *e.g. Logs showing protocol training (S-1020, Appendix 1)* • Sponsor SOP read logs *(S-1011, Appendix 3)* • Trial Specific SOP read logs *(if applicable)*
8.4	Site personnel tracking log *(A spreadsheet should be maintained which lists all the individuals involved in the trial at the site and the dates of relevant documents and training (S-1015, Appendix 13)*
Section 9: Participant Documentation	
9.1	Template Screening Log *(S-1011 Appendix 5)*
9.2	Site Screening Log *(containing non identifiable participant data only)*
9.3	Template Participant Enrolment Log *(S-1011 Appendix 6)*
9.4	Site Participant Enrolment log *(not to be removed from site)*

Section 10: Informed Consent	
10.1	Original Completed Consent Forms
Section 11: Standard Operating Procedures (SOPs)	
11.1	Note to file signposting the location of the most current Sponsor SOPs. *e.g. web address/electronic quality management system*
11.2	Current trial specific SOPs or note to file signposting the location *(if applicable)*
11.3	Superseded trial specific SOPs *(if applicable)*
Section 12: Statistics and Analysis	
12.1	Statistical Analysis Plan *(must be in place prior to database lock)*
12.2	Procedure for randomisation/code break *(if applicable)*
12.3	Master Randomisation List or location *e.g. in Sealed Envelope (if applicable)*
12.4	Any other supporting documents
Section 13: Data Management	
13.1	Current CRF Templates
13.2	Superseded CRF Templates *(if applicable)*
13.3	Evidence of CRF sign off by Chief Investigator, Trial Manager and Statistician *(where applicable)*
13.4	File note (or equivalent) providing details of electronic/paper case report form storage/security
13.5	DPIA and/or ROPA
13.6	Data Management Plan
13.7	Any other data management documents *e.g. data management queries/privacy notices/CRF correction procedures*
Section 14: Pharmacovigilance/Safety Reporting	
14.1	Template Serious Adverse Event (SAE) reporting form *(S-1009 Supporting document 1)*
14.2	Superseded template Serious Adverse Event (SAE) reporting form(s) *(if applicable)*
14.3	Site SAE/SAR/SUSAR Tracking Log *(S-1009 Appendix 2 or 5)*
14.4	Site SAE/SAR/SUSAR reports *and associated acknowledgement correspondence*
14.5	Safety alert updates *(if applicable)*
Section 15: Investigational Medicinal Product(s)	
15.1	Current Investigator Brochure/Summary of Products Characteristics *(if applicable with CI,PI and Pharmacist signed RSI section)*
15.2	Superseded Investigator Brochure/Summary of Products Characteristics *(if applicable with CI,PI and Pharmacist signed RSI section)*
15.3	Investigational Medicinal Product Dossier (IMPD) *(if applicable)*
15.4	Current approved IMP/placebo packaging labels
15.5	Superseded IMP/placebo packaging labels *(if applicable)*
15.6	IMP Management/Pharmacy Manual *(must include handling and storage of IMP and temperature excursion/recall procedures)*
15.7	Current IMP Template Documents *e.g. Accountability Logs, Inventory Logs Forms, Dispensing Logs, Prescriptions (if applicable)*
15.8	Superseded IMP Template Documents *e.g. Accountability Logs, Inventory Logs Forms, Dispensing Logs, Prescription (if applicable)*
15.9	Records of any temperature excursions/product defects/recalls and associated acknowledgement correspondence *(if applicable)*
15.10	IMP release documents *(e.g. technical/batch/QP release/Certificates of Analysis (CoA))*
15.11	Shipping records for IMP
15.12	Correspondence with drug manufacturer/drug management company *(where applicable)*
15.13	Other Relevant Correspondence
15.14	Pharmacy Site File amalgamated documents *(end of trial if not stored separately)*
Section 16: Clinical Laboratory (if applicable)	
16.1	Lab Manual/Sample Processing Manual
16.2	List of all laboratories used
16.3	Certificates of Accreditation for central laboratories
16.4	Normal Reference Ranges for central laboratories *(including revisions)*

16.5	Site laboratories Certificates of Accreditation
16.6	Site laboratories Normal Reference Ranges *(including revisions)*
16.7	Details of site sample storage facilities/processes
16.8	Site Sample Shipment Receipt(s)/Tracking Log(s)
16.9	Site Temperature Logs for sample storage
16.10	Site sample storage instructions
16.11	Site inventory/destruction log of all samples/specimens
16.12	Details of local sample storage arrangements for all samples held for future research
Section 17: Monitoring	
17.1	Trial specific Risk Assessment
17.2	Trial specific Monitoring Plan
17.3	Template Monitoring Visit Log *(S-1007 Appendix 3)*
17.4	Current site Monitoring Visit Log
17.5	Signed site Source Data Agreement *(S-1007 Appendix 4)*
17.6	Site Initiation Visit (SIV) Documentation *e.g. agenda, signed closed SIV report and outstanding actions list, signed SIV log and relevant correspondence*
17.7	Site Monitoring Documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence*
17.8	Site External Audit Documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence*
17.9	Site data query management documentation *e.g. copies of internal audits/quality control checks*
17.10	Site Close out Visit (CoV) documentation *e.g. signed closed COV report and outstanding actions list and relevant correspondence*
Section 18: Financial/Legal	
18.1	Grant Application *(if applicable)*
18.2	Funding Letter(s)/Financial Agreement(s)
18.3	Licence Agreements *e.g. for validated questionnaires*
18.4	Contracts/Contract Addendums (and any relevant correspondence/documents) with all investigators and Sub-contractors/vendors *(where applicable) e.g. research agreements, service level agreements, collaboration agreements, safety data exchange agreements, division of responsibilities*
18.5	Trial Specific Indemnity *(including updates if applicable)*
18.6	Sponsor Insurance Certificates covering the duration of the trial
18.7	Site signed agreements e.g. OID/mNCA *(including any updates)*
18.8	Schedule of Events (SoE)/Validated SoECAT *(including any updates)*
18.9	Sponsor to Participant Identification Centre (PIC) documents *(if applicable)* • PIC site tracker *(S-1015, Appendix 12)* Sponsor to PIC site documents *(repeat per PIC site)* • Sponsor to PIC site(s) Sponsor Green Light • PIC site Confirmation of Capacity and Capability *(if applicable)* • Signed agreement(s) *e.g. Sponsor-PIC mNCA* • Relevant Correspondence
18.10	Site to Participant Identification Centre (PIC) documents *(if applicable)* • PIC site tracker *(S-1015 Appendix 12)* Site to PIC site documents (repeat per PIC site) • Site to PIC site(s) Sponsor Green Light • PIC site Confirmation of Capacity and Capability *(if applicable)* • Signed agreement(s) *e.g. site to PIC mNCA* • Relevant Correspondence
18.11	Misc. financial/legal documents/correspondence
Section 19: Meetings (where applicable)	
19.1	Trial Steering Committee (TSC) documentation *e.g. Charters, Conflict of Interest Forms, Meeting agendas, reports, minutes and correspondence*

19.2	Data Safety Monitoring Committee (DSMC) documentation *e.g. Charters, Conflict of Interest Forms, Meeting agendas, reports, minutes and correspondence*
19.3	Investigator meeting documentation *e.g. Meeting agendas, reports, minutes and correspondence*
19.4	Trial Management Group (TMG) meeting documentation *e.g. Meeting agendas, reports, minutes and correspondence*
Section 20: Publications	
20.1	Copies of all trial analysis publications including poster presentations/abstracts
Section 21: End of Trial Reporting	
21.1	Signed End of Trial Declaration Form
21.2	End of trial correspondence *e.g. Evidence of End of Trial Declaration submission to and acknowledgement by the Sponsor/REC/HRA/MHRA or competent authority and R&D/I offices*
21.3	Final report
21.4	Final report correspondence *e.g. Evidence of final report submission to and acknowledgement by the Sponsor/REC/HRA/MHRA/CAG/ARSAC or competent authority/R&D/I offices*
21.5	End of Trial Lay Summary for participants
21.6	Completed End of Trial Sample Declaration Form and correspondence *(if applicable)*
21.7	Confirmation of completion of publicly accessible database entries *e.g. ISRCTN, clinicaltrials.gov*
21.8	Completed End of Sponsor Green Light Checklist
21.9	Archiving documentation *e.g. archiving checklist, details of archiving location and contact*
Section 22: Correspondence	
22.1	Important correspondence with CI/Sponsor and internal site correspondence
22.2	Newsletters *(where applicable)*
22.3	Any other trial specific correspondence *(where applicable)*
Section 23: Miscellaneous	
23.1	