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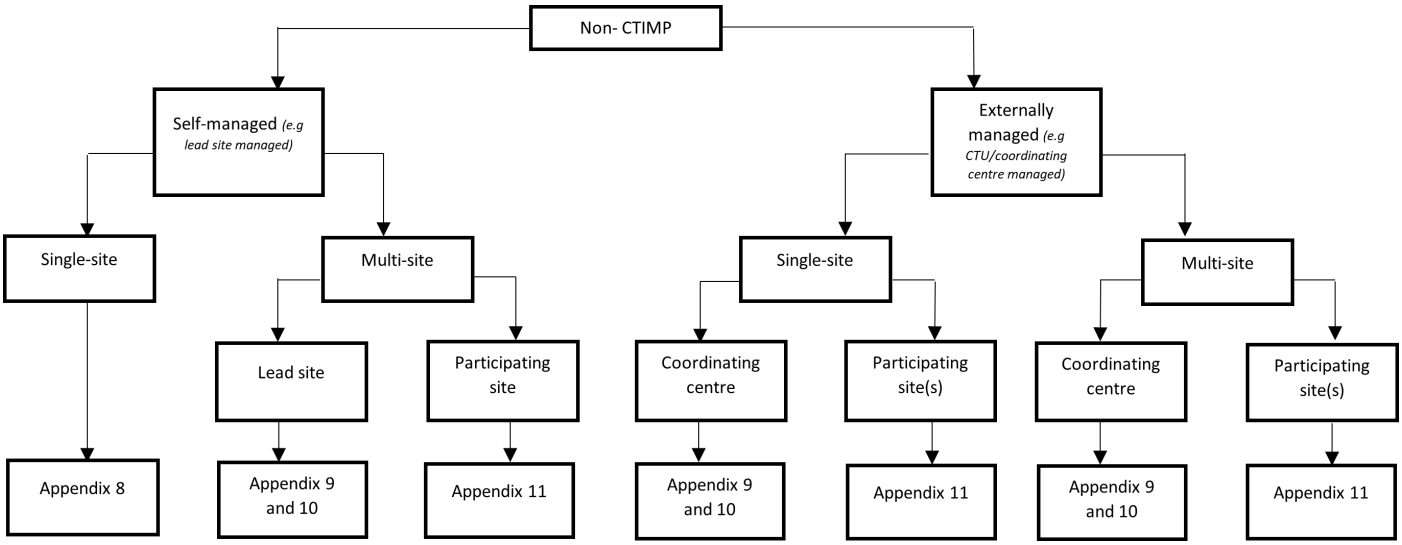
Single Site Trial Master File (TMF) Contents List for studies not involving Clinical Trials of Investigational Medicinal Products (non-CTIMP) – Guidance Page

This contents list should be used by a single site, self-managed non-CTIMP to create a TMF. Where a study is multi-site, or is managed by an external coordinating centre please refer to Appendix 9.

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



Useful definitions

- **Single site – self managed study;** A study which involves only one research site and where the management of the study takes place at the same site.
- **Single site – externally managed study;** A study which involves only one research site but where the management of the study sits outside of the research site e.g. with a Clinical Trials Unit (CTU).
- **Multi-site – self managed study;** A study which involves two or more research sites and where the management of the study takes place at the lead site.
- **Multi-site – externally managed study**; A study which involves two or more research sites but where the management of the study 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 study, 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 study 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.

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Tips for using this contents list:

1. Not all documents/sections listed below will be applicable to all studies.
   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 studies.

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 Site Trial Master File (TMF) Contents List for studies not involving Clinical Trials of Investigational Medicinal Products (non-CTIMP)

Study Title:	
Chief Investigator name:	

Section 1: Study 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, R&D/I department etc.*
1.3	Gantt Chart (Current and Superseded (if applicable))
1.4	Study 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 log *(if applicable) (S-1013 Appendix 4)*
2.9	Evidence of peer review (if applicable) *(S-1002 Appendix 2)*
Section 3: Study Documentation	
3.0	Current, site localised study documents *e.g. Participant Information Sheets, Blank Informed Consent Forms, Letters, Posters, Questionnaires etc*
3.1	Superseded, site localised study documents *e.g. Participant Information Sheets, Informed Consent Forms, Letters, Posters, Questionnaires etc (where applicable)*
Section 4: Initial Regulatory Approvals	
4.1	All initial REC approvals/correspondence *e.g. emails/letters confirming Valid Application, Provision Opinion, Favourable Opinion*
4.2	All initial HRA approvals/correspondence *e.g. emails/letters confirming Initial Assessment, Provision Opinion, Approval*
4.3	Any other applications and approvals *e.g. CAG/ARSAC etc. (if applicable)*
4.4	Evidence of NIHR CRN portfolio adoption *(where applicable)*
4.5	Confirmation/Evidence of study registration *e.g. ISRCTN, clincialtrials.gov etc.*
4.6	IRAS Application
4.7	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 Feasibility Assessment
5.4	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 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 e.g. and supporting documentation CAG/ARSAC *(where applicable)* • IRAS submission confirmation email • 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)* • IRAS submission email • Tracked 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	Any other annual reports and supporting documents *e.g. CAG/funder (if applicable)*
7.3	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 (DoA)
8.3	Site personnel documents *(covering the duration of involvement with the study)* *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 study specific training *e.g. Logs showing protocol training (S-1020 Appendix 1)* • Sponsor SOP read logs *(S-1011 Appendix 3)* • Study 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 study 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 study specific SOPs or note to file signposting the location *(if applicable)*
11.3	Superseded study 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 or CRF sign off by Chief Investigator, Study 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: 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*
Section 15: Clinical Laboratory (if applicable)	
15.1	Lab Manual/Sample Processing Manual
15.2	List of all laboratories used
15.3	Certificates of Accreditation for central laboratories
15.4	Normal Reference Ranges for central laboratories *(including revisions)*
15.5	Site laboratories Certificates of Accreditation
15.6	Site laboratories Normal Reference Ranges *(including revisions)*
15.7	Details of site sample storage facilities/processes
15.8	Site Sample Shipment Receipt(s)/Tracking Log(s)
15.9	Site Temperature Logs for sample storage
15.10	Site sample storage instructions
15.11	Site inventory/destruction log of all samples/specimens
15.12	Details of local sample storage arrangements for all samples held for future research
Section 16: Monitoring	
16.1	Study Specific Risk Assessment *(if applicable)*
16.2	Study specific Monitoring Plan *(if applicable)*
16.3	Template Monitoring Visit Log *(S-1007 Appendix 3)*
16.4	Current site Monitoring Visit Log *(if applicable)*
16.5	Signed site Source Data Agreement *(S-1007 Appendix 4)*
16.6	Site Initiation Visit (SIV) documentation *e.g. agenda, signed closed SIV report and outstanding actions list, signed SIV log and relevant correspondence (if applicable)*
16.7	Site Monitoring documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence (if applicable)*
16.8	Site External Audit documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence (if applicable)*
16.9	Site data query management documentation *e.g. copies of internal audits/quality control checks*
16.10	Site Close out Visit (CoV) documentation *e.g. signed closed COV report and outstanding actions list and relevant correspondence*
Section 17: Financial/Legal	
17.1	Grant Application *(if applicable)*
17.2	Funding Letter(s)/Financial Agreement(s)
17.3	Licence Agreements *e.g. for validated questionnaires (if applicable)*
17.4	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*
17.5	Study Specific Indemnity *(including updates if applicable)*

17.6	Sponsor Insurance Certificates *covering the duration of the study*
17.7	Site signed agreements e.g. OID/mNCA *(including any updates)*
17.8	Schedule of Events (SoE)/Validated SoECAT *(including any updates)*
17.9	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
17.10	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
17.11	Misc. financial/legal documents/correspondence
Section 18: Meetings (where applicable)	
18.1	Trial Steering Committee (TSC) documentation *e.g. Charters, Conflict of Interest Forms, Meeting agendas, reports, minutes and correspondence*
18.2	Data Safety Monitoring Committee (DSMC) documentation *e.g. Charters, Conflict of Interest Forms, Meeting agendas, reports, minutes and correspondence*
18.3	Investigator meeting documentation *e.g. Meeting agendas, reports, minutes and correspondence*
18.4	Trial Management Meeting (TMG) meeting documentation *e.g. Meeting agendas, reports, minutes and correspondence*
Section 19: Publications	
19.1	Copies of all study analysis publications including poster presentations/abstracts
Section 20: End of Study Reporting	
20.1	Signed End of Study Declaration Form
20.2	End of study correspondence *e.g. Evidence of End of Study Declaration submission to and acknowledgement by the Sponsor/REC/HRA and R&D/I offices*
20.3	Final report
20.4	Final report correspondence *e.g. Evidence of final report submission to and acknowledgement by the Sponsor/REC/HRA/CAG/ARSAC/R&D/I offices*
20.5	End of Study Lay Summary for participants
20.6	Completed End of Study Sample Declaration Form and correspondence *(if applicable)*
20.7	Confirmation of completion of publicly accessible database entries *e.g. ISRCTN, clinicaltrials.gov*
20.8	Completed End of Sponsor Green Light Checklist
20.9	Archiving documentation *e.g. archiving checklist, details of archiving location and contact*
Section 21: Correspondence	
21.1	Important correspondence with CI/Sponsor and internal site correspondence
21.2	Newsletters *(where applicable)*
21.3	Any other study specific correspondence *(where applicable)*
Section 22: Miscellaneous	
22.1	