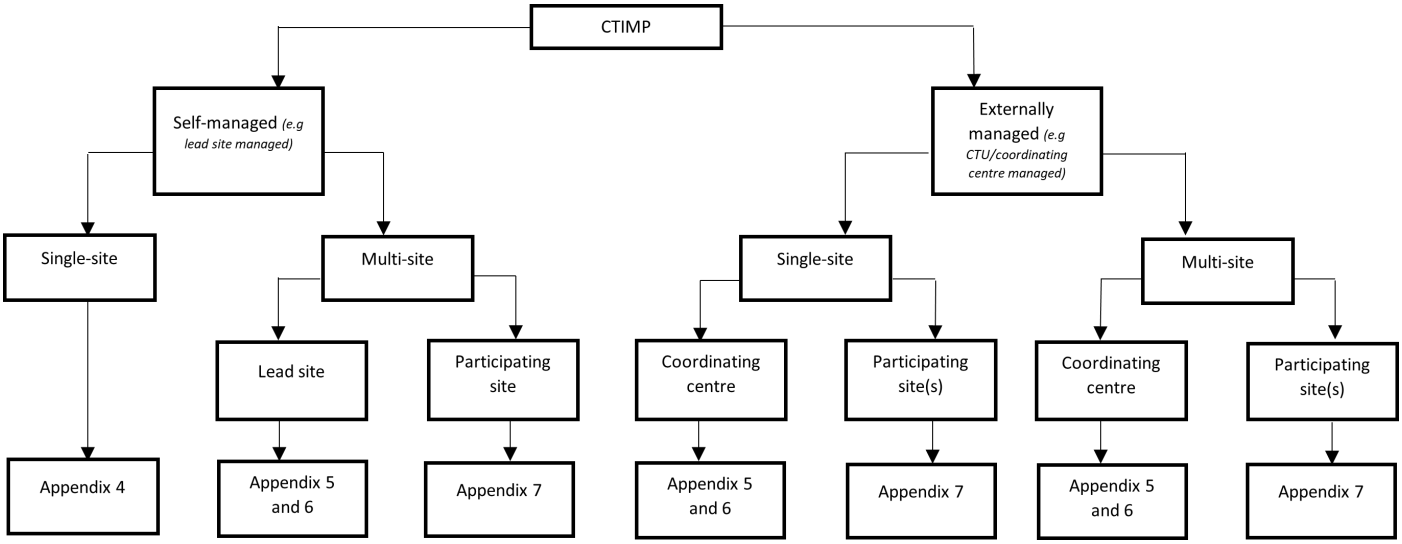
UNIVERSITY OF LEICESTER

Investigator Site File (ISF) Contents List for Clinical Trials of Investigational Medicinal Products (CTIMP) – Guidance Page

This contents list should be used by participating (research) sites in a CTIMP to create an ISF.

Please use the decision tree below to check which contents list(s) is/are required for your 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 Documents should be filed in reverse chronological order (newest on top) with superseded documents marked as such.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   - Write superseded by and add the version and date of the updated document i.e. Superseded by v2.3 01/01/2023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.

UNIVERSITY OF LEICESTER

Investigator Site File (ISF) Contents List for Clinical Trials of Investigational Medicinal Products (CTIMP)

Trial Title:	
Site number/name:	
Principal Investigator:	

Section 1: Trial Management	
1.1	List of relevant site contacts *e.g. research team members, laboratory departments, pharmacy departments, R&D/I departments etc*
1.2	List of relevant central trial contacts *e.g Trial Management team, CTU, CI, Sponsor*
1.3	Trial Documentation version control log/tracker *(S-1015 Appendix 3)*
Section 2: Protocol and Associated Documents	
2.1	Current Protocol *signed and dated by the Principal Investigator*
2.2	Superseded Protocol *signed and dated by the Principal Investigator*
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	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)
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 Site Approvals	
4.1	Site Sponsor Green Light
4.2	Site R & D/I approval *(Confirmation of Capacity and Capability)*
4.3	Site-Specific Pharmacy Green Light *(if applicable)*
4.4	Site Feasibility Assessment
4.5	Relevant correspondence
Section 5: Amendments	
5.1	**Substantial Amendments (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 research team and R&D/I notification of amendment • Copy of the completed amendment tool • Relevant correspondence
5.2	**Non substantial Amendments (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 R&D/I notification of amendment (ideally stating 35-day implementation date) • Copy of the completed amendment tool • Relevant correspondence
Section 6: Investigator Site Personnel	
6.1	Template Delegation of Authority and Signature Log (DoA) *(S-1010 Appendix 2)*
6.2	Site Delegation of Authority and Signature Log (DoA)
6.3	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)*
6.4	Investigator tracking log (A spreadsheet should be maintained which lists all the individuals involved in the trial at the site and the dates of relevant training/documents *(S-1015 Appendix 13)*
Section 7: Participant Documentation	
7.1	Template Screening Log (S-1011 Appendix 5)
7.2	Site Screening Log(s) *containing non-identifiable participant data only*
7.3	Template Participant Enrolment Log (S-1011 Appendix 6)
7.4	Site Participant Enrolment log **(not to be removed from site)**
Section 8: Informed Consent	
8.1	Original Completed Consent Forms
Section 9: Standard Operating Procedures (SOPs)	
9.1	Note to file signposting the location of the most current Sponsor SOPs. *e.g. web address/electronic quality management system*
9.2	Current trial specific SOPs or note to file signposting the location *(if applicable)*
9.3	Superseded trial specific SOPs *(if applicable)*
Section 10: Statistics and Analysis	
10.1	Procedure for randomisation/code break *(if applicable)*
10.2	Master Randomisation List or location *e.g. in Sealed Envelope (if applicable)*
10.3	Any other supporting documents
Section 11: Data Management	
11.1	Current CRF Templates
11.2	Superseded CRF Templates *(if applicable)*
11.3	File note (or equivalent) providing details of electronic/paper case report form storage/security
11.4	Any other data management documents *e.g. data management queries/privacy notices*
Section 12: Pharmacovigilance/Safety Reporting	
12.1	Template Serious Adverse Event (SAE) reporting form (S-1009 Supporting document 1)
12.2	Superseded template Serious Adverse Event (SAE) reporting form(s) *(if applicable)*
12.3	Site SAE/SAR/SUSAR Tracking Log (S-1009 Appendix 5)
12.4	Site SAE/SAR/SUSAR reports *and associated acknowledgement correspondence*
12.5	Evidence of site SUSAR notification *(if applicable)*
12.6	Safety alert updates with evidence of notification of safety alerts *(as relevant)*
Section 13: Investigational Medicinal Product(s)	
13.1	Current Investigator Brochure/Summary of Products Characteristics *(if applicable with PI and Pharmacist signed RSI Section)*
13.2	Superseded Investigator Brochure/Summary of Products Characteristics *(if applicable with PI and Pharmacist signed RSI Section)*
13.3	Records of any temperature excursions/recalls *and associated correspondence (if applicable)*
13.4	Site specific IMP release documents *(e.g. technical/batch/QP release if applicable)*
13.5	Any other relevant documents and correspondence
13.6	Pharmacy Site File amalgamated documents *(end of trial if not stored separately)*
Section 14: Clinical Laboratory (if applicable)	
14.1	Lab Manual/Sample Processing Manual
14.2	List of all laboratories used
14.3	Site laboratories Certificates of accreditation
14.4	Site laboratories Normal Reference Ranges *(including revisions)*
14.5	Details of site sample storage facilities/processes
14.6	Site Sample Shipment Receipt(s)/Tracking Log(s) *(if applicable)*
14.7	Site Temperature Logs for sample storage

14.8	Site sample storage instructions
14.9	Site inventory/destruction log of all samples/specimens
14.10	Details of local sample storage arrangements for all samples held for future research
Section 15: Monitoring	
15.1	Template Monitoring Visit Log *(S-1007 Appendix 3)*
15.2	Current site Monitoring Visit Log
15.3	Signed site Source Data Agreement *(S-1007 Appendix 4)*
15.4	Site Initiation Visit (SIV) documentation *e.g. agenda, signed closed SIV report and outstanding actions list, signed SIV log and relevant correspondence*
15.5	Site Monitoring documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence*
15.6	Site External Audit documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence*
15.7	Site data query management documentation *e.g. copies of internal audits/quality control checks*
15.8	Site Close out Visit (CoV) documentation *e.g. signed closed COV report and outstanding actions list and relevant correspondence*
Section 16: Financial/Legal	
16.1	Site Contracts/Contract Addendums (and any relevant correspondence/documents) *(where applicable)*
16.2	Trial Specific Indemnity *(including updates if applicable)*
16.3	Sponsor Insurance Certificates *covering the duration of the trial*
16.4	Site signed agreements e.g. OID/mNCA *(including any updates)*
16.5	Schedule of Events (SoE)/Validated SoECAT *(including any updates)*
16.6	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
16.7	Misc. financial documents/correspondence
Section 17: Meetings	
17.1	Site/Investigator meetings documentation *e.g Meeting agendas, reports, minutes and correspondence*
Section 18: End of Trial Reporting	
18.1	Signed End of Trial Declaration Form
18.2	Evidence of notification of End of Trial to Local R & D/I department
Section 19: Correspondence	
19.1	Important correspondence with CI/Sponsor and internal site correspondence
19.2	Newsletters *(where applicable)*
19.3	Any other trial specific correspondence *(where applicable)*
Section 20: Miscellaneous	
20.1	