# Trial Master File Contents

**Example index of required documents for the Trial Master File**

**Insert instructions or guidance on using the TMF content page here.** For example:

Not all documents listed below will necessarily be applicable to all studies/trials. Where an entire section is irrelevant, it should be marked as NOT APPLICABLE, but the original numbering of the contents page retained, to maintain a consistent filing system across all studies. Where specific documents are deliberately absent, a file note should be included to record the justification for the absence.

If a listed document is stored elsewhere, a file note should be included to record its location. Superseded documents should be placed after the current document.

|  |  |
| --- | --- |
| **SECTION** | **TITLE** |
| **One** | **Externally Approved Documents** |
| 1.1 | Protocol, signed and dated by CI |
| 1.2 | Participant Information Sheet |
| 1.3 | Informed Consent Form |
| 1.4 | Any letter / information for participant’s GP or consultant (if applicable) |
| 1.5 | Recruitment literature / advertisement (if applicable) |
| 1.6 | Other written information provided to participants |
| 1.7 | Protocol Registration |
| **Two** | **Internal Trial Documents** |
| 2.1 | Sample CRFs, questionnaires and diaries (if applicable) |
| 2.2 | CRF correction procedure |
| 2.3 | Data Management Plan / data processing document |
| 2.4 | Database specification, build and validation documents |
| 2.5 | Statistical Analysis Plan (SAP) |
| 2.6 | Working Instructions / Guidance Notes |
| 2.7 | Training material e.g. presentations, agenda for training days |
| 2.8 | Dose escalation review/report documentation (if applicable) |
| **Three** | **Sponsorship** |
| 3.1 | Letter of Acceptance of Sponsorship |
| 3.2 | Division of Responsibilities |
| **Four** | **Contracts & Agreements/Finance/Indemnity** |
| 4.1 | Grant Application (if applicable) |
| 4.2 | Funding arrangements including funding letter and peer review |
| 4.3 | Fully Executed Agreement between involved parties |
| 4.4 | Other fully executed agreements e.g. IMP supplier |
| 4.5 | Cheque request forms/invoices |
| 4.6 | Insurance/Indemnity (if not covered in Agreement) |
| 4.7 | Correspondence |
| **Five** | **Research Ethics Committee (REC)** |
| 5.1 | REC application form |
| 5.2 | REC approval letter and composition |
| 5.3 | REC correspondence |
| **Six** | **Health Research Authority (HRA)** |
| 6.1 | HRA application |
| 6.2 | HRA approval letter |
| 6.3 | HRA correspondence |
| **Seven** | **NHS Trust R&D Capability and Capacity** |
| 7.1 | Approval letter(s) or equivalent |
| 7.2 | Correspondence |
| **Eight** | **Regulatory** |
| 8.1 | Regulatory application |
| 8.2 | Regulatory authorisation |
| 8.3 | Regulatory correspondence |
| **Nine** | **Amendments** |
| 9.1 | Amendment 1 including amendment submission, covering letters and approval letters. Approved version of new document to be filed in section 1. |
| 9.2 | Amendment 2 (repeat as required 9.3, 9.4 etc.) |
| **Ten** | **Study Personnel** |
| 10.1 | Contact details (including emergency contact) |
| 10.2 | Delegation of Authority and Signature Log |
| 10.3 | Signed and dated Curriculum Vitae |
| 10.4 | Evidence of training including protocol and GCP |
| **Eleven** | **Safety Reporting** |
| 11.1 | Investigator Brochure/Summary of Product Characteristics and updates |
| 11.2 | Serious Adverse Event (SAE) Reports |
| 11.3 | Suspected Unexpected Serious Adverse Reaction (SUSAR) reports |
| 11.4 | Safety information sent to PIs, if a multi-centre study |
| 11.5 | Procedure for randomisation and unblinding/code break (if applicable) |
| 11.6 | Code break envelopes (if applicable) |
| 11.7 | Blank SAE forms |
| 11.8 | Correspondence |
| **Twelve** | **Investigational Medicinal Product (IMP) information** |
| 12.1 | Investigator’s Brochure (IB) and / or Summary of Product Characteristics (SmPC) |
| 12.2 | Safety alert updates |
| 12.3 | Certificate of IMP analysis and placebo if relevant |
| 12.4 | Documentation of IMP destruction |
| **Thirteen** | **Pharmacy (to be kept in pharmacy department whilst study is ongoing if using Pharmacy Services)** |
| 13.1 | Delegation of Authority and Signature Form |
| 13.2 | Pharmacy Agreement |
| 13.3 | Cheque request form/invoices |
| 13.4 | Documentation of shipment |
| 13.5 | IMP packaging including sample of labelling |
| 13.6 | Instructions for handling of IMP |
| 13.7 | Notification of unblinding |
| 13.8 | Retrieval of code-break envelopes |
| 13.9 | Drug accountability / inventory forms (Pharmacy) / dispensing logs / temperature logs |
| 13.10 | Pharmacy correspondence |
| **Fourteen** | **Local laboratory (if applicable)** |
| 14.1 | Normal ranges |
| 14.2 | Accreditation |
| 14.3 | Sampling instructions / lab manual |
| 14.4 | Sample shipment receipt / tracking |
| 14.5 | Laboratory correspondence |
| **Fifteen** | **Equipment (if applicable)** |
| 15.1 | Calibration certificates |
| 15.2 | Related correspondence |
| **Sixteen** | **Other Local Service Providers** |
| 16.1 | Correspondence |
| **Seventeen** | **Monitoring** |
| 17.1 | Risk Assessment |
| 17.2 | Monitoring Plan |
| 17.3 | Site Initiation Report (or equivalent) |
| 17.4 | Monitoring Visit Reports/Log |
| 17.5 | Study Close-out Report |
| 17.6 | Protocol Deviations report |
| 17.7 | Correspondence |
| **Eighteen** | **Audit (if applicable)** |
| 18.1 | Audit certificate (If a certificate is issued by the auditor) |
| **Nineteen** | **Trial Management Group / Committees** |
| 19.1 | Trial Management Group (members, codes of reference, agendas, minutes and correspondence) |
| 19.2 | Data Monitoring Committee (members, codes of reference, agendas, minutes and correspondence) |
| 19.3 | Trial Steering Committee (members, codes of reference, agendas, minutes and correspondence) |
| **Twenty** | **Trial Reports** |
| 20.1 | Annual reports to REC, HRA, R&D and Sponsor |
| 20.2 | Development Safety Update Report (DSUR) |
| 20.3 | Notification of end of study to relevant parties |
| 20.4 | Final report to REC, HRA, Sponsor, R&D and Funder if applicable |
| 20.5 | Final report to MHRA |
| 20.6 | EudraCT result database upload |
| **Twenty One** | **Study Report/Publication** |
| 21.1 | Publication |
| 21.2 | Clinical Study Report |
| **Twenty Two** | **General Correspondence** |
| 22.1 | Correspondence |
| 22.2 | Record of all significant telephone conversations and emails relating to the study |