The TMF forms the basis for an inspection to confirm compliance with regulatory requirements (Directive 2005/28/EC Chapter 4, Article 16). The TMF is normally composed of a **Sponsor TMF**, held by the sponsor organisation (or to whom this function is delegated), and an **Investigator TMF**, held by the investigator. These files together are regarded as comprising the entire TMF for the trial. In addition there may also be a **Pharmacy file** (held by the clinical trial pharmacy), **R&D file** (held by R&D), **Laboratory file** (in a laboratory providing analysis) and **Investigator Site file**(s) where there is more than one site. Each file requires an appropriate index.

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **CI/PI Name:** |  |
| **Sponsor Ref:** |  |
| **REC Ref:** |  |
| **R & D Ref:** |  |
| **EudraCT:** |  |
| **clinicaltrials.gov Ref:** |  |
| * **Please amend as necessary for use in any component part of the Trial Master File (TMF).**
* **Ensure that sections which no not apply to the file are clearly indicated as such.**
 |
| **Section** | **Contents** | **Details** |
| **1.0** | **Contact information** |  |
|  | Contact details sheet |  |
| **2.0** | **Protocol (current and superseded)** |  |
|  | All versions, signed and dated  |  |
| **3.0** | **Participant information** |  |
|  | Participant Information Sheet  |  |
|  | Participant Invitation letter |  |
|  | Advertisement(s) |  |
|  | Informed Consent Form |  |
|  | GP Letter |  |
|  | Other as used ie diary cards |  |
| **4.0** | **Sponsor Review and Approval** |  |
|  | Risk assessment |  |
|  | MHRA grading |  |
|  | Sponsor registration form |  |
|  | Insurance letter |  |
|  | Approval from Sponsor |  |
|  | Regulatory green light |  |
|  | Correspondence |  |
| **5.0** | **Submissions & Approvals: Initial Application** |  |
|  | Submission to REC |  |
|  | Approval from REC |  |
|  | Submission to MHRA |  |
|  | Approval from MHRA |  |
|  | Submission to R&D |  |
|  | Approval from R&D |  |
|  | Local Information Pack documentation |  |
|  | Correspondence |  |
| **6.0** | **Amendments and Approvals** |  |
|  | Submission to and approval from Sponsor |  |
|  | Submission to and approval from REC |  |
|  | Submission to and approval from MHRA |  |
|  | Submission to and approval from R&D |  |
|  | Correspondence |  |
|  | Amendment log |  |
| **7.0** | **Financial Details** |  |
|  | Copy of grant application  |  |
|  | Award letter |  |
|  | NHS support Costs |  |
|  | Other costs |  |
|  | Correspondence |  |
| **8.0** | **Contracts and Agreements** |  |
|  | Sponsor/CI agreement |  |
|  | Third party agreement(s)  |  |
|  | CTU statement of support |  |
|  | Technical agreement(s)  |  |
|  | Site agreement(s)  |  |
|  | Correspondence |  |
| **9.0** | **Study Staff** |  |
|  | CI/PI CV  |  |
|  | CVs of all staff on delegation log |  |
|  | GCP certificates of all staff on delegation log |  |
|  | Copy of delegation of tasks log |  |
|  | Details of location of staff training records |  |
| **10.0** | **Data Management** |  |
|  | Example of approved Case Report Form |  |
|  | Data management plan (if not in protocol) |  |
|  | Statistical analysis plan (if not in protocol) |  |
|  | Correspondence |  |
| **11.0** | **Safety Reporting** |  |
|  | Completed SAE/SUSAR forms |  |
|  | Completed pregnancy forms  |  |
|  | Details of any Urgent Safety Measures |  |
|  | Correspondence |  |
| **12.0** | **IMP (relevant to comparator & placebo also)** |  |
|  | IB/ SmPC  |  |
|  | Sample of IMP label |  |
|  | Example IMP accountability forms |  |
|  | Other |  |
|  | Correspondence |  |
| **13.0** | **Labs** |  |
|  | Accreditation/Certification details  |  |
|  | Lab analytical plan |  |
|  | Reference ranges |  |
|  | Correspondence |  |
| **14.0** | **Monitoring and Audit** |  |
|  | Monitoring plan |  |
|  | Monitoring visit reports (including initiation) |  |
|  | Correspondence |  |
|  | Audit reports |  |
| **15.0** | **Protocol GCP Deviations & Breaches** |  |
|  | Deviation and breach log  |  |
|  | Breach documentation |  |
|  | Correspondence |  |
| **16.0** | **Reports** |  |
|  | DSUR |  |
|  | Annual Progress Report |  |
|  | Other |  |
|  | Correspondence |  |
| **17.0** | **End of Study** |  |
|  | End of trial declaration |  |
|  | End of study report |  |
|  | Archiving details (if not in protocol) |  |
| **18.0** | **Committee Charters** |  |
|  | TSC |  |
|  | DMC |  |
|  | Minutes |  |
| **19.0** | **Research Study Team Meetings** |  |
|  | Location of minutes and agendas |  |
| **20.0** | **Miscellaneous** |  |
|  |  |  |
|  |  |  |