|  |  |  |  |
| --- | --- | --- | --- |
| Form number | **Form 51.016L** | Version | **2.0** |
| Title | **Vendor TMF Plan Template** | | |

The objective of the Trial Master File (TMF) plan is to describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction.

The Sponsor/Co-sponsor Research Co-ordinator will liaise with the vendor and draft a vendor TMF plan using this form as a template and include it in the contractual arrangement between the Sponsor/Co-Sponsors and the vendor involved in the trial. The vendor TMF plan should cover the following information:

* Details on who holds the official TMF (or which parts each party holds when this is divided)
* The process of filing documentation in the TMF
* Documents as evidence of plan execution including, but not limited to: plan, reports, checklists, etc
* The structure of indexing of the TMF
* When eTMF is used - details of the system
* Access arrangements in place for both parties for oversight and trial management
* How TMF would be available if either party was inspected
* Arrangements for when the trial is completed - Archiving

|  |  |
| --- | --- |
| **Trial R&I Ref:** |  |
| **Trial title:** |  |
| **Chief Investigator:** |  |
| **Sponsor/Co-Sponsor details and point of contact:** |  |
| **Vendor details and point of contact:** |  |
| **eTMF or Paper TMF:**  *if eTMF provide details of the system* |  |

1. **Instructions for Vendor TMF preparation and maintenance:**

The complete TMF for [name] trial is divided in the sections stated below and covers the following Sponsor/Co-sponsor teams and third parties:

1. R&I Sponsor Research Co-ordinator (Sections 1-9 )
2. Pharmacy (Section 10)
3. Pharmacovigilance (Section 11)
4. Monitor (Section 12)
5. Governance (Section 13)
6. Project Management (Section 14)
7. Data management (Section 15)
8. Vendors (i.e Laboratories) (Section 16)

The vendor is responsible for preparing, maintaining and archiving their corresponding part of the TMF independently of the other parties according to their local processes and/or as per Sponsor/Co-sponsor instructions included in this document. Vendor related documentation saved as part of Sponsor/Co-Sponsor TMF folder are detailed at Section D of this document.

Sections of the Vendor TMF will be maintained by the appropriate member of staff and updated regularly for the whole length of the trial. The individual(s) responsible for the Vendor TMF section will assume responsibility for maintenance throughout the lifetime of the study (unless otherwise delegated to an appropriate individual). If other individuals wish to add/amend/remove a document from the Vendor TMF, they must make the responsible individual(s) aware.

The vendor will be expected to maintain and store the documents that they are responsible for as per their local processes or as per [Section 15 for Data management / Section 16 for Laboratories (delete as appropriate)] of the Form 51.016A (Sponsor TMF indices) The Vendor will make the vendor TMF documents available for Sponsor/Co-sponsor audit/inspection as required. Storage and maintenance of trial documents will be clearly documented in the appropriate contracts.

**B. Quality Control**

It is the responsibility of the vendor to carry out QC checks at regular intervals and document this activity and file it in the vendor TMF. All sections of the Vendor TMF may be subject to QC review multiple times during the lifetime of a trial: during set-up, conduct, close-out/reporting and before archiving.

The QC review will be performed according to local policies [Please include the local TMF QC processes here if applicable].

If it is agreed that the Sponsor/Co-sponsor TMF indices will be used for the TMF plan, the Sponsor/Co-sponsor recommends completing [Section 15 for Data management / Section 16 for Laboratories (delete as appropriate)] of Form 51.016K and completes the QC process using guideline GUI 51.016A which will be recorded in the log. The Form 51.016K and GUI 51.016A will be provided as Appendices.

**C. Archiving of Vendor TMF**

Vendor TMF Archiving should not start before Sponsor/Co-Sponsor confirmation. At the end of the trial, when archiving can start, the trial project manager will contact the vendor and give permission to archive their documentation.

Trial retention period will commence from the date of receipt of MHRA notification of the end of trial declaration (by the Sponsor/Co-sponsor). The vendor TMF should be archived for at least five years or as amended after the conclusion of the trial and clearly stated in the contract.

If archiving will be performed on behalf of the Sponsor/Co-Sponsor according to vendor policies, the costs should be communicated and agreed with the Sponsor/Co-sponsor before trial set-up and included in the contract between Sponsor/Co-Sponsor and the vendor.

Vendor TMF Archiving should be completed within six months from notification by Sponsor/Co-sponsor. Furthermore vendor should communicate to the Sponsor/Co-Sponsor the location of the archived material. Once the archiving period ends, the Sponsor/Co-sponsor archiving representative will contact the vendor to inform that the Vendor TMF can be destroyed.[Please include the local Archiving processes here:….]

If it is agreed for archiving process to be completed as per Sponsor/Co-Sponsor policies, then the vendor will inform the Sponsor/Co-Sponsor when vendor TMF files are ready to be archived (we recommend within six months of Sponsor/Co-sponsor notification). The Sponsor/Co-sponsor will arrange for a company to pick-up the boxes to be archived from the vendor site as per Sponsor/Co-sponsor policies.

**D. Vendor related documentation saved as part of Sponsor/Co-Sponsor TMF folder:**

* Vendor assessment documentation
* Contractual agreement between Sponsor/Co-sponsor and the Vendor
* Relevant email communication

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website.  Any copy reproduced from the website may not, at time of reading, be the current version. |