

DCRF - DKWO: Recommendation filing in an electronic investigator site file

This document defines the minimum requirements for an electronic investigator site file (Figure 1). In the current landscape of clinical trials there is a growing need to store documents electronically. The site file, held by the investigator, is no exception.

As defined in ICH GCP, under chapter 8 'Essential documents for the conduct of a clinical trial' a minimum amount of documents need to be kept by an investigator. These files can be kept either on paper, or electronically, or a combination of both.

The defined requirements below need to be considered when filing documents in an electronic manner, either on a shared drive but preferably in a web based filing system. When using a web based filing system, the items mentioned under recommended should also be adhered to.

When conducting an audit or monitoring of the electronic site file, the below can also be used to check if the system complies with the minimum requirements.

Furthermore, the Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) dated 06 Dec 2018 written by the EMA was used as a reference (applicable parts to eISF only).

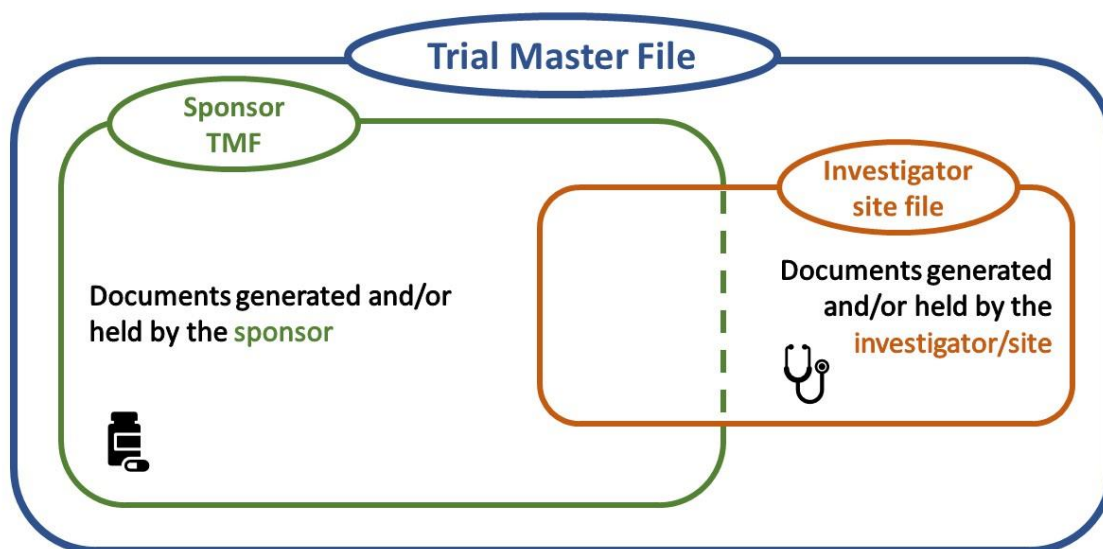


Figure 1: Illustration to define the difference between sponsor Trial Master File and Investigational Site File. Together they are combined in the Trial Master File (or Trial Center File).

Minimal requirements:

Access related

1. Unique ID / password to access system.
2. Access only for delegated site staff, based on role and permission description.
3. Access via guest account based on role and permission description (traceable to who has used the account and when). Use of a personal account is recommended.
4. Access to be inactivated when no longer required, checked at least every year.

5. Restricted access to the backup file (preferred only vendor/host of system).
6. Recommended: conduct and track adequate training on the electronic site file system used.
7. Recommended: the electronic site file should be remotely accessible (including guest access) within the limits as defined by local data protection law and guidance.
8. In case of blinded study data, access should be restricted to unblinded staff and unblinded third party only.

Security related

1. Password changed every 6 months or more often.
2. Automatic logoff from system after 30 minutes or less of inactivity.
3. Prevent access after several failed login attempts. To be defined based on the IT environment and robustness of the system used.
4. Accessible password reset option (no helpdesk involved).
5. Documents should be downloadable, if changes are made a new version should be created with a new unique identifier.
6. Recommended: at least two-factor authentication will be required when data is accessed under the (guest) account.
7. Recommended: use of electronic signature or certified copies as allowed per local law and guidance.

Backup/archiving

1. Backup of system available daily (preferred via synchronized backup of system).
2. Archiving after study end as per legal requirements.
3. Accessible/legible after study end: any migration of data and documents to new media or a new format should be verified to ensure long-term readability and to maintain integrity.
4. Process defined to check if the back-up system is working properly.

Document management

1. In case e-signing is not used, wet inks to be stored separately.
2. In case wet ink documents are stored as well, reference should be made to paper storage location within electronic filing system.
3. Documents should be transferred to the system in a secure manner.
4. Different file types should be supported by the system, on the condition that each (concept and final) version is locked for editing, and that there is version control.
5. Documents should uniquely identifiable by document name and date/version.
6. There should be an index with references to the location of the documents; also when documents are filed outside the primary ISF.
7. Recommended: it should be possible to search for a document.