



I-Vault eTMF



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Overview

I-Vault is PharmaVigilant's **electronic Trial Master File (eTMF)** system designed to electronically collect, store and manage all documents throughout the life of a trial. I-Vault facilitates seamless site startup and closeout, and is fully integrated with PharmaVigilant's InSpire EDC solution so only one password is required to access both systems.

I-Vault's graphic reporting tools enable users to have complete transparency into their entire TMF. Additionally, the system incorporates unlimited rights and roles—enabling global scalability. Lastly, I-Vault supports a robust suite of functionality including the configuration of expiration dates at the individual file level, electronic signatures and notifications.

Fully integrated end-to-end solution for clinical development and submissions

As a document management system, I-Vault allows sponsors to determine which trial documents they wish to collect, and how they would like them organized. Once determined, the system's robust security of roles and privileges enable the sponsor to determine which users can view, upload, and/or electronically sign each of those documents. Documents are scanned/uploaded and I-Vault automatically directs them to their appropriate location, eliminating the need to catalog and index these files. As a result, Sponsors benefit from greater visibility, accuracy and control of the valuable data collected.

How can you use I-Vault eTMF to reduce your study start up, close out and unforeseen regulatory findings?

Start-up:

- Sites can begin the start-up process prior to the first monitoring visit
- Accelerated process of regulatory document collection
- Monitors can facilitate the completion of required documentation at the first monitoring visit

Close-out:

- Sponsors can close out the regulatory component of a trial within days
- Fast review of 100 percent of the FDA-required regulatory documents
- Reduces the likeliness of an FDA 483
- Decreases a sponsor's risk profile

Unforeseen Regulatory Findings:

- Sponsor has electronic access to all documents throughout the life of the trial
- All user activity is monitored via the audit trail
- Patient-specific documents are de-identified
- Expired or Missing documents are flagged
- 21 CFR Part 11 compliant system