



I-Vault rSDV



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rSDV (remote Source Document Verification)

I-Vault rSDV is the first commercially available, technology based Remote Source Document Verification System (rSDV) in the industry, providing ongoing data monitoring independent of site visits ---saving both time and significant costs in your development. I-Vault rSDV enables our clients to control all of their assets for the first time, including:

- Copies of Source Documents
- Electronic Trial Master Files
- Electronic Case Report Forms

Process of rSDV

Data is verified by rSDV monitors, leaving the site monitors extra time for verifying more complex data, building site relationships, critical scientific review, safety, identifying fraud and drug misconduct, recruiting and training. PharmaVigilant provides the only commercial approach to deliver the control required.

Firstly, I-Vault uploads a copy of the source document worksheet into the system. The benefit of having a copy of the source document worksheet is that not only do you have a signed copy of the source available to you; you know the version of the source and can reconstruct any and all monitoring exercises. This provides the sponsor with greater control of **all of their data** that they will be responsible for during the submission process.

With I-Vault rSDV, the source document worksheets are collected, stored, and maintained in a 21 CFR Part 11 compliant system, indefinitely. The source worksheets are confirmed by eSignature to be exact replicas of the site-based source documents. The document upload history is maintained through an audit trail. No changes can be made to the stored source documents. The user roles and audit trail maintain and confirm the integrity of the source documents stored in I-Vault.

Benefits of rSDV

PharmaVigilant's I-Vault eTMF and InSpire EDC systems are used in conjunction to provide a cost effective and efficient approach to data verification. I-Vault provides many advantages with rSDV over traditional monitoring:

- Provides fast feedback on data quality issues, benefitting site and sponsor.
- 100% assurance data is accurate
- Total control over source (can do QC at any time)
- Lower risk of FDA site findings
- Simplifies source documentation
- Reduces the Degree of site disruption
- Reduces the time of the onsite SDV
- Early alerts & identification of issues

Implementations

PharmaVigilant has successfully implemented this new technology in over 10 studies in the USA, saving sponsors millions of dollars in monitoring costs, while improving the quality and accuracy of the data. It has been used in large pivotal Phase III trials. The technology, the quality and the savings are all documented.