

cencora

PhlexTMF for Viewing

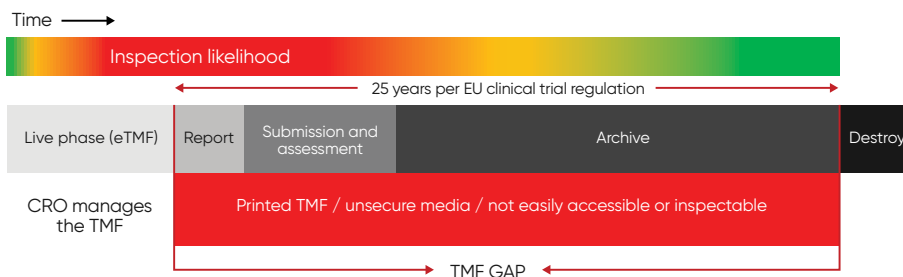
Inspectable, accessible Trial Master File (TMF) storage for studies from a contract research organization (CRO) or third party

Inspection-ready access to TMFs from closed and locked studies

Software fills a critical gap in the Trial Master File life cycle

PhlexTMF for Viewing answers a pressing need in the industry for easily inspectable storage of the TMF after a study is closed or locked. Few CROs offer compliant maintenance of the TMF after study closeout, usually returning the data on unsecure and hard-to-track media, such as USB drives or even print-outs. These TMFs are difficult to review and inspect, and they force sponsors to keep their own study documents separate. Sponsors had limited options for compliance with regulatory requirements—until now.

PhlexTMF for viewing solves a key gap in the TMF lifecycle



Source: A Fisher, MHRA, HSRAA Conference, May 2019 (amended).

PhlexTMF for Viewing gives you a simple and affordable solution for inspectable storage after your CRO or other service provider returns your study's TMF, thus streamlining the transition to long-term archiving.

Key benefits of PhlexTMF for Viewing

- Secure, fully compliant, cloud-based TMF storage for closed and locked studies from a third party*
- Designed for ease of navigation and inspection prior to long-term archiving
- Enables easy-to-use eTMF viewing and inspectability from anywhere at any time, in an intuitive user interface
- Take eTMF data from a CRO or eTMF provider and make them available for internal use and inspection
- Sponsor documents can be added directly to PhlexTMF for Viewing
- Easy transition to long-term archiving
- Powered by PhlexTMF's advanced, purpose-built eTMF software

PhlexTMF for Viewing:

- Cencora-managed import of a CRO or third party's eTMF documents, metadata, and audit trail into PhlexTMF for Viewing:
 - Oversee all interactions with the CRO or service provider
 - Ensure alignment with third party's export format (Excel, XML, CSV) and handle all exceptions such as passwords, encryption, zip files, non-eTMF content, attachments, deleted documents, etc
- Account creation, management, and training for sponsors and inspectors
- Maintenance of documents in an online system built for contextual TMF navigation with multi-attribute searching
- Flexible subscriptions to align with typical inspection timeframes and proprietary requirements
- Simplified transition to long-term archive when needed

*PhlexTMF for Viewing is not required for customers using PhlexTMF eTMF software

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