PhlexTMF for Viewing

Inspectable, Accessible TMF Storage for Studies from a CRO or Third Party
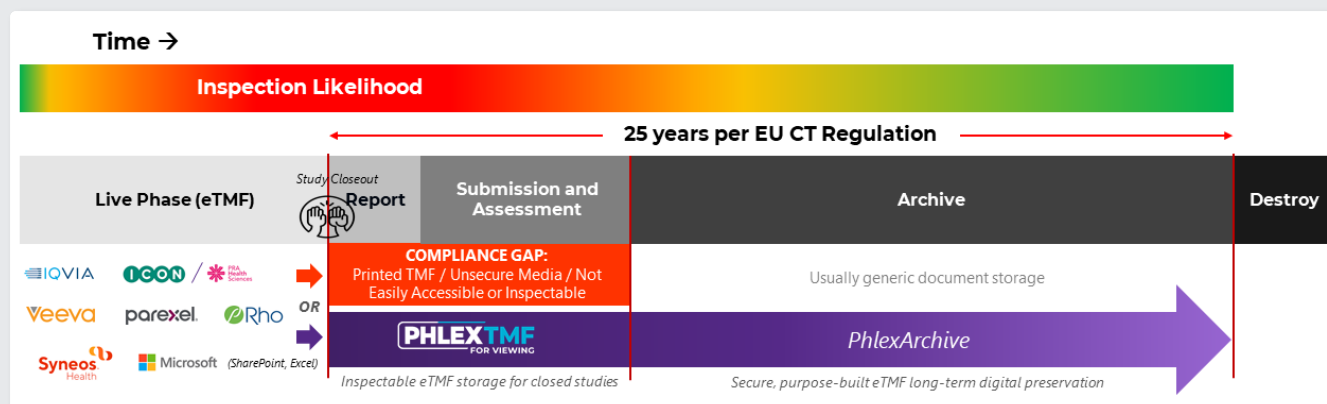
PHLEXGLOBAL
RAISE YOUR STANDARD

Ensure Inspection-Ready Access to TMFs from Closed and Locked Studies

SOFTWARE FILLS CRITICAL "COMPLIANCE GAP" IN THE TRIAL MASTER FILE LIFECYCLE

PhlexTMF for Viewing answers a pressing need in the industry for easily inspectable storage of the TMF after the study is closed or locked. Few CROs and eTMF vendors offer compliant digital preservation of the Trial Master File for most of its lifecycle, usually returning the eTMF on unsecure and hard-to-track media such as USB drives or even printed out. These Trial Master Files are difficult to review and inspect, and 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 Compliance Gap in the TMF Lifecycle

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, and a streamlined 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 & inspectability from anywhere at any time, in an intuitive user interface
- Take eTMFs from your CRO or eTMF provider and make them available for internal use and inspections
- Sponsor documents can be added directly to PhlexTMF for Viewing
- Easy transition to long-term archiving
- Powered by PhlexTMF advanced, purpose-built eTMF software

PhlexTMF for Viewing includes:

▶ Phlexglobal-managed import of 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, zips, non-eTMF content, attachments, deleted documents etc.

▶ Account creation, management, and training for sponsors and inspectors

▶ Maintenance of documents in an on-line system built for contextual TMF navigation with multi-attribute searching

▶ Flexible subscriptions to align with typical inspection timeframes and your own requirements

▶ Simplified transition to long-term archive when needed

READY TO RAISE YOUR STANDARD?
VISIT PHLEXGLOBAL.COM/CONTACT

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