PhlexTMF+ Simplifies Compliance While Delivering Ongoing TMF Health
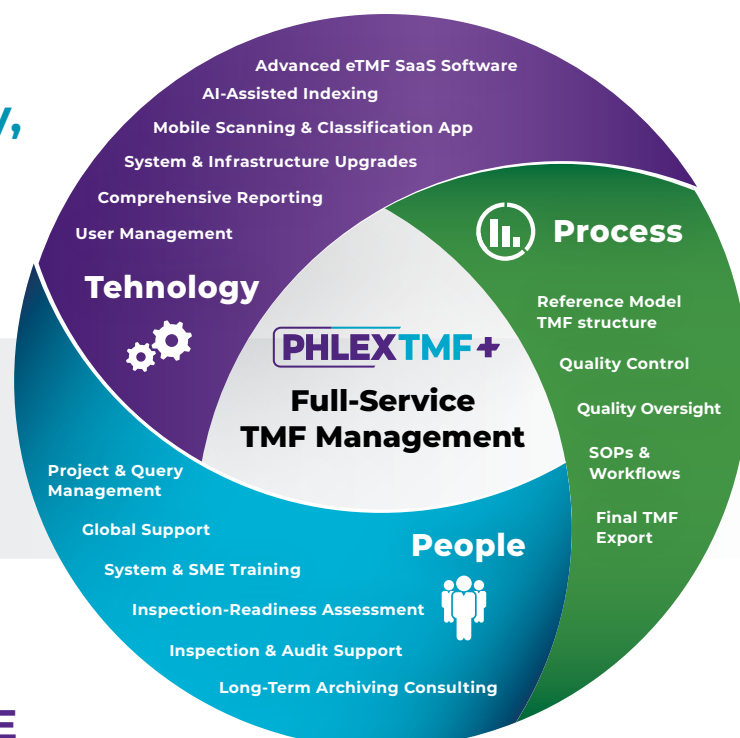
INDUSTRY'S ONLY COMPLETELY TURNKEY, END-TO-END TMF MANAGEMENT SOLUTION FROM A SINGLE EXPERT PROVIDER

Free Up Resources for Critical Study Tasks

PhlexTMF+ provides all components required for expert TMF management to ensure quality, completeness, and timeliness of your Trial Master File

Outsource Complete TMF Management to the TMF Authority

Advanced eTMF SaaS Software
AI-Assisted Indexing
Mobile Scanning & Classification App
System & Infrastructure Upgrades
Comprehensive Reporting
User Management

Tehnology

PHLEXTMF+
Full-Service TMF Management

Process
Reference Model TMF structure
Quality Control
Quality Oversight
SOPs & Workflows
Final TMF Export

Project & Query Management
Global Support
System & SME Training
Inspection-Readiness Assessment
Inspection & Audit Support
Long-Term Archiving Consulting

People

1 TMF PLANNING & SETUP

- ☐ PhlexTMF Advanced eTMF SaaS Software
- ☐ Reference Model TMF Structure
- ☐ Best Practice SOPs & Workflows
- ☐ TMF Roles
- ☐ Query Setup
- ☐ System Training
- ☐ Company SME Training

2 TMF MAINTENANCE

- ☐ Mobile Scanning App
- ☐ Document Processing
  - ☐ AI-Assisted Indexing
  - ☐ Quality Control (QC)
- ☐ Ongoing Quality Oversight
- ☐ Project & Query Management
- ☐ Global Support
- ☐ User Management
- ☐ System & Infrastructure Upgrades
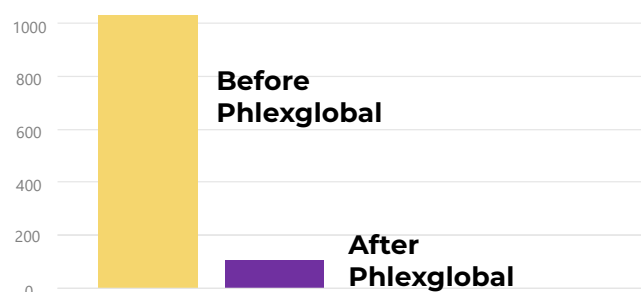- ☐ Wide Variety of File Formats

3 TMF CLOSEOUT

- ☐ Completeness Assessment (inspection-readiness)
- ☐ Secure Short-Term Storage
- ☐ Inspection/Audit Support
- ☐ Final TMF Export
- ☐ Long-Term Archiving Consultation

Case Study: Productivity Boost from Leveraging Phlexglobal TMF Expertise

Clinical Operations Person-Hours/Month: Document Processing
(customer LOE for document filing, indexing, QC, etc.)

Before Phlexglobal

After Phlexglobal

RESULTS

Internal clinical operations resources shifted to critical study tasks:

>850 PERSON-HOURS PER MONTH
Equivalent to hiring 5 clinical operations FTEs

Key Benefits
Provided by PhlexTMF+

IMPROVE TMF HEALTH

Leverage unmatched, global TMF expertise to reduce risk of inspection findings and submission delays

Optimize all aspects of TMF management critical to ongoing TMF health across technology, people, and process

Take advantage of the latest TMF management best practices such as risk-based QC, ongoing quality review, and completeness heatmaps

Quickly bring on the expert resources you need to manage TMF management demands, with the ability to scale to any volume

REDUCE EFFORT & RISK

Benefit from advanced technologies that improve TMF management speed and quality, including artificial intelligence and a mobile scanning and classification app

Obtain budget predictability with a fixed-price model encompassing best-of-breed eTMF software, infrastructure, and expert services critical to ongoing TMF health

Free key internal resources from time-consuming tasks such as document filing, software management, and query management

Eliminate potential delays through earlier identification and correction of issues around quality, completeness, and timeliness of the Trial Master File

OBTAIN A SINGLE, EXPERT MANAGEMENT VIEW THAT REMOVES INFORMATION SILOS AND OVERSIGHT ISSUES THAT PLAGUE MANY TMFS

PHLEXGLOBAL
RAISE YOUR STANDARD

Discover more @ Phlexglobal.com