Medidata Introduces New Collaborative Workspace for Sites, Sponsors, and CROs to Manage TMF Content

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New Feature Creates the Only eTMF Solution with Centralized Environment for Document Sharing

- *Medidata is the first to offer a centralized workspace to manage TMF content*
- *New feature enables real-time collaboration on documents between sites, sponsors, and CROs*
- *The Medidata eTMF workspace reduces cycle times and increases audit success rates*

NEW YORK--(BUSINESS WIRE)--Jan. 22, 2019-- Over 35 percent of inspections are delayed because the TMF is not complete or readily available[1].To enable efficient, real-time collaboration on TMF documents between sponsors, CROs and sites, Medidata (NASDAQ:MDSO) today introduced a new workspace feature of its eTMF solution.

As the industry's first regulated shared workspace, Medidata eTMF supports document synchronization and accurate filing between all trial stakeholders to maintain inspection readiness.

“One of the biggest challenges experienced by sites, sponsors, and CROs is how to collaborate on managing trial documents. Our new Medidata eTMF feature is the first and only workspace enabling TMF content collaboration. All stakeholders will now increase audit-ready accuracy and decreased re-work by managing TMFs correctly from the outset,” said Perry Steinberg, vice president, product, Medidata.

The new Medidata eTMF feature delivers a centralized location for faster discrepancy reconciliation, document reclassification and filing. Workspace benefits include:

- Documents are synchronized between sponsors, CROs and sites
- Supports ICH E6 guidelines with real-time monitoring of TMF status (completion, quality and accuracy)
- Documents are managed and added through a single interface

Medidata eTMF is connected to the full suite of Medidata solutions, including Rave EDC, CTMS, Risk Based Monitoring and Payments, delivering the industry’s most dynamic and comprehensive real-time, end-to-end TMF management platform - unifying content, data, and workflows.

Medidata is at the TMF Summit this week. Stop by booth 201 or attend Medidata’s panel session (Jan. 24, 12:10 p.m. ET) on how different companies apply automation, AI and machine learning with:

Perry Steinberg, *vice president, product, Regulatory Content Management,* Medidata
Andy Chu, *director, Regulatory Affairs, Regulatory Systems Strategy*, BIOGEN
Debra Wells,*manager, TMF and Compliance*, EISAI
Robert Willis*, director, Merck Research Labs IT,* MERCK

About Medidata

Medidata is leading the digital transformation of life sciences, with the world's most used platform for clinical development, commercial, and real-world data. Powered by artificial intelligence and delivered by the #1 ranked industry experts, the Intelligent Platform for Life Sciences helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata serves more than 1,000 customers and partners worldwide and empowers more than 100,000 certified users every day to create hope for millions of patients. Discover the future of life sciences: www.medidata.com

[1]UK MHRA statement, 2014

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