TMF Reference Model v3 Press Release #1
3rd March 2015

March, 2015 – Version 3.0 of the Trial Master File (TMF) Reference Model to be released at the Drug Information Association Annual Meeting in Washington, DC on June 16, 2015.

What's coming in 3.0?

Building on the most widely leveraged standardized reference in TMF management today, with version 2.0 used by more than a hundred life science sponsors, CROs and technology vendors, the next major release of the TMF Reference Model will incorporate feedback from its extensive industry use to enhance content clarity and add a XML-based mechanism for simplifying the interchange of electronic TMF content between organizations.

The V3.0 development team is currently composed of nearly 100 experts, and more volunteer participation is always welcome. To get involved, please visit http://tmfrefmodel.com/join-the-tmf-reference-model-project-team/join-here/ . We welcome your participation, insight and feedback.

What is the TMF Reference Model?

The TMF Reference Model provides a single, unified interpretation of regulations and TMF practices that has been vetted across the industry. Since its origination in 2009, the TMF Reference Model is managed by a group of Drug Information Association volunteers, comprised of over 350 contributors from more than 200 life science organizations and is a non-profit, vendor-agnostic initiative. The TMF Reference Model presents a consensus position in accordance with industry opinion regarding the standard content of a Trial Master File, to include identifying all the content that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced.

The TMF Reference Model allows for standardization of contents, structure, naming and metadata. The most obvious benefit of standardization is increased efficiency of gathering, managing, and analyzing trial content, but additional benefits of standardization include increased inspection surety and reduced variability when collaborating with business partners. As it does not prescribe any specific structure, nor define the processes required to create or manage TMFs, it can be adapted to any electronic or paper TMF and does not endorse, nor require, any specific technology for application.

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The TMF Reference Model is a valuable tool for:

- Life science clinical trial sponsors of any size, both commercial and institutional
- Clinical study team members, including trial and data management, clinical supplies, biostatistics, etc.
- Contract Research Organizations and vendors servicing TMFs, including technology providers
- Site staff, including investigators and coordinators
- Regulatory inspectors and auditors who conduct trial inspections and audits