TMF Reference Model—tips for implementing V3

Based on feedback from industry stakeholders, the Trial Master File Reference Model (TMF RM) Steering Committee has developed version 3. The purpose of the upgrade was to improve upon the clarity of the content and to simplify the interchange of electronic TMF content between organizations by adding an XML-based mechanism.

LMK Clinical Research Consulting, LLC (LMK) has highlight below some tips for you to consider when implementing V3:

- **Take it step-by-step.**
  - Start with navigating through the document. The revisions are clearly defined and can be easily located on the *Version 3.0 Mark-Up* tab of the document.
- **Decide which Zones/Sections/Artifacts are applicable to your company and work from there.**
  - If the entire Model is applicable, review the entire document keeping in mind which document types have been removed, added, and revised.
- **Involve all of the applicable document submitters/contributors in the review of the revisions.**
  - Everyone should understand how the change affects their contribution(s) to the TMF.
- **Understand that revisions may mean documents that were once filed in one specific Zone/Section/Artifact are now filed in a new location.**
  - As an example, in version 2, the Study Decisions Log was filed under artifact 01.05.02 *Tracking Information*. In version 3, according to the definition/purpose column, the Study Decisions Log should be filed under 01.01.20 *Operational Oversight*.
- **Understand document level changes and how this will impact your TMF.**
  - As an example, *Regulatory Submission* can now be filed at the site level (some submissions are site level [eg, Germany]), and the documentation is expected to be filed at the site level and not the country level.
- **Understand the reason for the change.**
  - You may review the document and think, "Why did they do that?" Review column W, and read the rationale for the change.
- **Do not be afraid to ask for help!**
  - You do not have to try to implement the RM alone. Whether you are in a large corporation with thousands of colleagues or a small company and wear many hats, there are many references to support implementation to the RM. At LMK, our sole focus is on TMF consulting and TMF services. For example, our dedicated professionals can review your Standard Operating Procedures and map them to the RM to meet your individual needs.

If you have any questions or need help with any of these tips or need support implementing the Model, contact us today! If you need support with full implementation or have general questions, we are here for you. Give your TMF the priority it deserves and contact LMK today to discuss how we can help you with your individual TMF needs.

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