

Title: Some Aspects of Digitalization and Digital Transformation in Clinical Research: Bridging TMF Completeness, Work Delivery, and Financial Recognition for Data Quality, Audit Readiness, and Financial Integrity.

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Abstract:

Project scope, cost, and timelines are defined across three key dimensions: contractual agreement, operational plans, and actual work performed [1]. In practice, contracting, planning and execution are often handled by separate departments using disconnected systems and tools. Among these systems, the Trial Master File (TMF) plays a central role by capturing essential documentation of trial activities. While eTMF adoption has marked progress in digitizing documents, digital transformation now enables deeper integration of workflows, data, and governance systems: capabilities previously underutilized. Recent regulatory guidelines also support this direction by promoting electronic data governance and improved system interoperability [2][3][4].

This concept paper proposes treating the Trial Master File (TMF) and its documents as a key final deliverable of contracted work [4], constructing the Work Breakdown Structure (WBS) directly from the list of expected TMF documents and aligning this structure with study timelines to create a Gantt-like schedule [1]. Notably, ICH E6(R3) Section C.2.5 mandates that essential records be collected and filed in a timely manner, with "some essential records should generally be in place prior to the start of the trial", reinforcing the role of documentation as verifiable evidence of completed project work, essential for demonstrating compliance, ensuring quality, and recognizing contractual deliverables [5].

As revenue recognition depends on fulfilled performance obligations [7], aligning clinical systems around TMF completeness transforms eTMFs from passive archives into active governance platforms, promoting timely, quality documentation, improving audit readiness, and strengthening operational and financial integrity in clinical research [3][4][5][7].

Proposal to discussion:

To establish a consistent, audit-ready and financially sound operational-financial model in clinical research, the rationale behind linking TMF readiness to revenue recognition can be summarized as follows:

1. TMF as the Key Contracted Deliverable

The Trial Master File (TMF) is the official repository of essential documents that demonstrate the trial was conducted in accordance with Good Clinical Practice (GCP) and regulatory requirements [5]. As noted in ICH E6(R3) Section C.2.3, the TMF

provides a structured archive of sponsor and investigator responsibilities. Whether maintained by the sponsor, CRO, or both, the TMF forms a core part of the contracted trial deliverables, ensuring readiness for audit and regulatory inspection. Even when specific TMF responsibilities are distributed among parties, the obligation to maintain a complete and timely TMF remains fundamental to trial execution.

2. **TMF Documents = Units of Work**

Each document filed in the TMF is the result of a work performed, which can be associated with job roles (e.g., CRA, Data Manager, Medical Writer), hours worked on the unit (e.g., monitoring visit), contractual deliverables (e.g., budgeted units or milestones), and associated costs. These units of work form the operational basis for time tracking, billing, and budget accountability. Where one document or tracker covers multiple units of work and where these units are important for revenue recognition (e.g., CRF cleaning or centralized monitoring), structured documentation generated from operational systems can be filed with appropriate metadata, allowing units of work to be consistently tracked and validated within the TMF for financial reporting purposes.

3. **TMF Index as Work Breakdown Structure (WBS)**

The TMF Index offers a standardized structure of expected documentation across all phases of a trial. This index can be directly mapped to a Work Breakdown Structure (WBS), providing a structured framework for planning, monitoring, and allocating responsibilities by document type and trial phase.

4. **Expected TMF documents = WBS + Gantt Chart**

While the TMF Index provides a static structure, the list of expected documents tied to timelines transforms it into a forecasting tool. Expected TMF documents represent the project backlog and projected deliverables across time, enabling real-time planning, cost forecasting, and capacity alignment.

5. **Revenue Recognition Aligned with Deliverables**

Both IFRS 15 and ASC 606 require that revenue be recognized only when a performance obligation is satisfied, typically when control of a promised service or deliverable has been transferred to the customer [5]. In the context of clinical trials, this suggests that revenue recognition may be best aligned with the completion and filing of essential documents in the Trial Master File (TMF). While some models under ASC 606 allow for recognition based on progress measures such as incurred costs, or while operational tracking may occur through systems like EDC or CTMS, these records may not consistently provide standardized, verifiable evidence of deliverable completion, particularly when data is manually transferred into financial systems. In contrast, a quality-approved TMF document, such as a monitoring visit report, offers consistent and auditable proof of work performed. Aligning revenue recognition with TMF completeness supports audit readiness, enhances transparency, and provides a standardized mechanism for linking operational delivery to financial reporting. To reduce manual error and strengthen compliance, an automated interface between the TMF system and revenue recognition platforms could support quality review while avoiding manual data entry.

6. **TMF Readiness Bridges Work Completion and Financial Recognition**

When TMF completeness is linked to time billing and milestone tracking, the TMF

becomes a governance mechanism for both operations and finance. Real-time document filing allows project teams and finance departments to monitor trial progress, verify deliverables, and adjust forecasts as needed.

7. Accounting for Non-TMF Work and Documents

Some trial-related work does not result in TMF documentation (e.g., internal planning, system configuration, sponsor-only files). These activities may be classified separately: either bundled into overhead rates, captured in auxiliary systems, or tracked with internal logs. Ensuring transparency about what constitutes billable TMF work versus non-billable support helps maintain contractual clarity and audit resilience.

It may be argued that aligning revenue recognition with TMF completeness could delay financial reporting if documentation or quality control is not performed in a timely manner. However, most essential documents (e.g., monitoring visit reports) are subject to regulatory or contractual requirements to be submitted within defined timelines, and failure to do so may itself indicate a lapse in performance. Therefore, if a report is not filed, in accordance with this approach, the associated revenue should not be recognized. This reinforces, rather than hinders, operational discipline. Furthermore, AI-assisted quality review and real-time validation tools can support prompt processing and reduce delays. Another view may suggest that existing project management workflows may already be built to ensure that work is marked as complete only after documentation is in place, by placing accountability on people and written processes. In this context, a TMF-based model does not alter control points but formalizes them, providing an auditable, standardized, and automated method to confirm delivery, reduce manual risk, and support consistent revenue recognition.

Conclusions

This concept paper proposes a framework for aligning operational delivery with financial recognition in clinical trials by using TMF documents as verifiable evidence of completed work, and TMF completeness as a quality-driven control mechanism. This dual-purpose approach supports real-time accountability while reinforcing audit readiness and financial transparency.

This TMF-driven approach offers several practical benefits, including improved traceability of deliverables, reduced reliance on manual financial inputs, early detection of scope deviations, and tighter alignment between contractual obligations and operational execution. By ensuring that revenue is recognized only when quality-assured documentation is filed, TMF-based revenue recognition implicitly integrates the quality dimension into the project management triangle: affirming that scope, cost, and timelines can only be considered complete when quality is demonstrably achieved.

It is important to note that the number of expected documents, as well as the operational forecast, can be derived from the protocol's Schedule of Activities (SoA) and a monitoring plans, as outlined in our earlier work on co-developing trial protocols alongside study budgets [7]. This closes the loop by integrating protocol design, budgeting, operational reporting, and revenue recognition to support improved quality, data integrity, and financial alignment in clinical research.

Disclaimer

This preprint presents a conceptual framework developed by the author for academic discussion and exploratory analysis. The content reflects the author's interpretation of publicly available standards, regulatory guidelines, and project management practices. It does not constitute legal, financial, or professional advice, nor has it been subject to formal peer or regulatory review. No proprietary or confidential information has been used. ChatGPT was employed as a research assistant to support reference verification, formatting, and language editing prior to publication.

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