Medrio eTMF



Know what's missing from your TMF before an auditor does.

Every clinical team already has a trial master file. It might live in a shared drive, a spreadsheet index, or a binder on a shelf. The real question is whether you can defend it to auditors.

Medrio eTMF shows what's filed, what's missing, and who signed off. It's built for growing sponsors and CROs. You get the structure and controls inspectors expect, without the cost or complexity of an enterprise system.

The eTMF is part of the Medrio platform, which eliminates redundant work. When a site or study is created in CTMS, for example, you can add it to eTMF from a dropdown list rather than re-creating it from scratch.

Visibility

See what's filed and what's missing by study, country, and site.

Control

Approve documents with e-signatures meeting 21 CFR Part 11 standards, supported by a full audit trail.

Speed

Build your eTMF structure once and reuse it in every new study.

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Streamlined set up and tracking

Set up your study using the CDISC TMF Reference Model, built into Medrio eTMF. Tracking and oversight is simple. Mark each zone, section, and artifact as expected at the study, country, or site level. A completeness dashboard shows what's filed and what's missing at each site, so you can quickly close gaps before an inspection.

Inspection-ready records

Reviewers approve documents with 21 CFR Part 11-compliant e-signatures or reject them with a required comment, so no decision goes unrecorded. Every version and status change goes into the audit trail, providing complete visibility. Auditors can easily view everything without system access. At closeout, export a searchable archive for auditors to view.

Seamlessly connect to Medrio CTMS

Remove duplicate work by using Medrio eTMF alongside Medrio CTMS. Both products are built into one platform. No integrations are required and the platform only requires one log in. The sites and studies you create in CTMS appear as drop-down options in eTMF. Roles, permissions, monitoring visit reports, and the audit trail are managed once, at the platform level.

FEATURES

- CDISC TMF Reference Model, built in
- Reusable cross-study templates
- Holding zone for documents not yet filed
- Bulk upload and download
- Part 11 review, approval, and audit trail
- Completeness dashboard and PDF/A archive export

Join the Early Adopter Program

Medrio's exclusive program gives existing customers early access to Medrio eTMF, direct insights into the product roadmap, and preferred pricing discounts.

To learn more
scan the QR code or visit
medrio.com/early-adopter-program