Consulting

Fact Sheet

eTMF Site and Country Quality Reviews

Site and country-level reviews are critical for electronic Trial Master File (eTMF) quality—and for staying inspection-ready. With every country following its own regulatory requirements and each site applying unique SOPs, global trials introduce complexity that demands precision.

Our expert review process uncovers hidden risks and quality gaps early, helping sponsors align with ICH-GCP and avoid costly setbacks. Gain confidence in your submission readiness with a smarter, streamlined review strategy.

Gathering study information

It all starts with insight. Our proven approach begins by building an extensive and tailored understanding of your study—because high-impact reviews require more than just surface-level information. They demand strategic, study-specific intelligence that sets the stage for superior eTMF quality and inspection readiness.

To develop this comprehensive understanding of your study, Premier creates a custom study guidance document consolidating details from:

- TMF Management Plan
- Monitoring Plan
- Safety Management Plan
- Data Management Plan
- Pharmacy Manual
- Relevant SOPs

This living document captures study nuances and streamlines reviews at the study, country, and site levels. Our experts swiftly identify gaps and drive resolution through seamless collaboration with sponsors, CROs, and vendors—ensuring nothing is overlooked ahead of inspection.

Country-level reviews

Premier develops custom country templates for each participating country to align with key regulatory and ethics submission requirements.

Templates include:

- Regulatory Authority and Central Ethics Committee (CEC/CIRB) submissions and approvals
- Documentation for:
  - Protocols and amendments
  - Informed Consent Forms (ICFs)
  - Subject-facing materials
  - Investigator Brochures (IBs)
  - SUSARs, DSURs, IMPDs

Premier ensures all documentation is in place and evaluates timeliness. Delays or inconsistencies are flagged for sponsor action.

Site-level reviews

Each site requires a tailored review approach based on the study's complexity.

Premier creates site-level templates that cover:

- Site-specific agreements (1572s/equivalents, CDAs, CTAs)
- Investigator/staff qualifications:
  - CVs, Medical Licenses (MLs), Financial Disclosure Forms (FDFs), GCP and protocol-specific training
- IRB/EC documentation and approvals
- Monitoring visit reports and ICF documentation

Missing or misfiled documents are flagged via checklist for remediation.

All inspections start with the eTMF

Effective eTMF management supports regulatory compliance, operational efficiency, and trial data integrity.

Our comprehensive reviews result in a robust, inspection-ready eTMF and uncover potential issues before they impact trial success.

With Premier, your eTMF is accurate, organized, and ready for inspection. Contact us today to discuss how we can support your quality review strategy.

Visit us at premier-research.com or
contact us at info@premier-research.com