



REQUEST FOR PROPOSALS (RFP)

Electronic Trial Master File (eTMF) and services

Invitation

The COG Research Foundation, LLC (Research Foundation) is initiating this Request for Proposals (RFP) to provide:

An electronic Trial Master File (eTMF) solution and associated services to support the management, maintenance, oversight, and archival of essential clinical trial documentation.

Organizational Profile

COG Research Foundation, LLC (Research Foundation) is a California 501(c)(3) entity founded in 2024 to serve as a fiscal sponsor to support research programs by providing legal, fiduciary, and administrative oversight for the program. The Research Foundation serves as the fiscal sponsor for the Children's Oncology Group (COG).

COG, a member of the National Cancer Institute (NCI) National Clinical Trials Network (NCTN), is the world's largest organization devoted exclusively to childhood and adolescent cancer research. COG unites over 13,500 experts in childhood cancer at more than 220 leading children's hospitals, universities, and cancer centers across the United States, Canada, Australia, New Zealand, and Saudi Arabia to conduct more than 50 active clinical trials, with approximately 9,500 participants registered each year in the fight against childhood cancer.

COG recognizes that the increasing pace of scientific discovery will demand ongoing and farther-reaching collaborations, greater diversity in our multidisciplinary teams of disease and translational science experts to innovate new methods and prioritize clinical research goals, and unprecedented participation of the childhood cancer clinical research community to take full advantage of the current era of discovery.

Five pillars (values) that form the foundation upon which COG conducts its research:

- **Science** - COG's clinical-translational research must integrate the best science to drive studies that have high impact, with particular focus on studies that bridge key gaps in scientific knowledge.
- **Ethics** - As advances in science enable the study of a spectrum of novel therapeutic approaches for children with cancer, COG must be ever-vigilant in assuring that the research it conducts is done to the highest ethical standards, including compliance with federal standards for the special protections afforded to children who participate in research.

- **Collaboration** - The transformation of childhood cancer from diseases that were almost uniformly fatal to ones in which the overall 5-year survival rate now exceeds 85% has only occurred through the collaboration of successive generations of experts committed to improving the outcome for children with cancer
- **Participation** - Improvements in outcome can only be achieved through the active participation of children and families, patient advocates, frontline clinical investigators, the NCI, and industry partners. COG has a long-established culture of engaging the entire research community in the development and conduct of its research.
- **Responsibility** - Childhood cancer remains the leading cause of disease related death in children older than one year of age. As the only pediatric focused NCI-funded cooperative group within the National Clinical Trials Network (NCTN), COG leadership and its more than 12,000 members recognize the responsibility we have to our patients and families, to the scientific community, and to our funding organizations.

Required Services & Specifications

Summary

The purpose of this RFP is to identify a vendor that can provide a secure, reliable, compliant, and user-friendly eTMF platform capable of supporting COG's current and future clinical research activities. The selected vendor will work collaboratively with COG stakeholders to implement and maintain an eTMF environment that supports document management, oversight, inspection readiness, and efficient collaboration across COG studies and participating organizations.

Vendor Requirements

Qualified vendors must meet the following minimum requirements:

- Must be a SAM.gov registered vendor.
- Demonstrate relevant experience with projects of similar scope and complexity
- Provide references from previous clients upon request
- Vendors should describe how their solution supports applicable requirements, including, as relevant:
 - FDA 21 CFR Part 11.ICH Good Clinical Practice (GCP).
 - Applicable FDA guidance.
 - Applicable Health Canada requirements.

- Applicable international regulatory requirements.
- Electronic records and electronic signatures requirements.
- Data integrity principles.
- Records retention requirements.
- Audit trail requirements.

Scope of Work, Deliverables, and Communication

The selected vendor will be expected to provide the eTMF platform and associated implementation and support services described below.

1. eTMF Platform:

- Create and maintain electronic Trial Master Files.
- Organize documents according to an appropriate TMF reference model.
- Support study-, country-, site-, and document-level organization, as applicable.
- Upload, classify, index, version, review, approve, and manage documents.
- Support document metadata and configurable fields.
- Maintain document version history.
- Prevent unauthorized alteration or deletion of controlled records.
- Provide document search and retrieval capabilities.
- Support bulk document upload and processing.
- Support document lifecycle management.
- Identify and manage duplicate documents.
- Support document expiration and review dates where applicable.
- Provide configurable workflows.
- Support electronic signatures where required.
- Provide audit trails for relevant activities.
- Support document locking and controlled access.
- Support retention and archival requirements.
- Should integrate with Medidata products such as CTMS, etc.

2. Study and Site Management: the system should support management of documentation across multiple clinical trials and participating institutions.

3. Workflows: the proposed solution should support configurable workflows.

4. Reporting and Dashboards: the solution should provide configurable reporting and dashboards to support oversight and inspection readiness.

Proposal Requirements

The following components must be included for full consideration:

1. Consultant/Organization Profile:
 - a. Primary contact name, title, and contact information;
 - b. Overview of organization.
 - c. Description of services offered.
2. Qualifications and Experience:
 - a. Description of experience relevant to the Scope of Work;
 - b. Identification and background of key personnel.
3. Budget
 - a. Detailed cost proposal including itemized breakdown of fees, taxes, expenses
4. Timeline
 - a. Estimated schedule for deliverables or completion
5. Page Limit
 - a. Maximum of 8 pages (excluding appendices, samples, or references).

Proposal Evaluation

All proposals will be evaluated based on the following criteria:

1. Understanding of and approach to the Scope of Work;
2. Experience and qualifications of proposed personnel;
3. Past performance on similar projects;
4. Total cost and overall value

Top proposals may be invited for interviews or presentations. Final selection will be made based on the best overall value and alignment with the Research Foundation and its needs.

Conflict of Interest and Contractual Disclaimer

Vendors must disclose any real or potential conflicts of interest must be disclosed in the proposal. Submission of a proposal indicates acceptance of all terms and conditions contained in this RFP.

The Research Foundation complies with all applicable federal laws and regulations, including but not limited to 2 CFR Part 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. All vendors must agree to comply with relevant federal requirements related to procurement, cost allowability, recordkeeping, and debarment status (including verification through SAM.gov).

By submitting a proposal, the vendor certifies that they are not debarred, suspended, or otherwise excluded from participation in federal programs under Executive Order 12549 (Debarment and Suspension) and that they will comply with all applicable requirements under federal funding that may be used to support the resulting contract.

The Research Foundation reserves the right to reject any or all proposals, cancel this RFP, or reissue a new RFP at its sole discretion. Issuance of this RFP does not obligate the Research Foundation to award a contract.

Proposal Submission

Submit proposals to:

Name of contact: Harley Ding

Email of contact: hding@childrensoncologygroup.org

Deadlines

All times listed below are Pacific Time.

Clarifying questions must be submitted to the contact listed above by: 10/9/2026 12:00 AM

Proposals are due by: 10/16/2026 12:00 AM