**Request for Proposal**

Electronic Trial Master File (eTMF) Provider

Project Code: 900023.000.017

**Issue Date: 19-Oct-2020**

**Closing Date: 28-Oct-2020**

**Expected Award Date: 01-Dec-2020**

# BACKGROUND

FHI Clinical manages complex clinical research projects within resource-limited settings around the world. Our mission is to address unmet research needs and achieve maximum social impact by supporting the development of life-saving vaccines and medicines. We are a proud member of the FHI360 family of organizations with a goal of creating a world in which all individuals and communities have the opportunity to reach their highest potential.

We are currently seeking an electronic trial master file (eTMF) software provider to support the management of our regulated clinical trial documents/content.

The provider will support configuration, validation, implementation and hosting of a cloud-based eTMF technology to enable clinical trial document management in real-time and in compliance with US CFR Part 11 requirements and the current version (3.1.0) of the DIA TMF Reference model.

# SCOPE OF WORK

Vendors should provide an overview of their eTMF technology capabilities and functionality relevant to the regulated clinical research environment and Contract Research Organizations (CROs).

# DELIVERABLES

|  |  |
| --- | --- |
|  |  |
| **Service Required** | 21 CFR Part 11 compliant electronic document management for clinical trials (eTMF) with adherence to the DIA TMF Reference model |
| **Type of Procurement** | Master Service Agreement |
| **Type of Agreement** | Two Year Agreement with option to renew |
| **Submit Proposal to:** | [FHICProcurement@FHIClinical.com](mailto:FHICProcurement@FHIClinical.com)  Cc: LReklis@FHIClinical.com  Respond via email with formal proposal attached. |
| **Date of issue of RFP** | 10/19/2020 |
| **Date Questions Due** | 10/22/2020 |
| **Date Proposal Due** | 10/26/2020 |

**SUBMISSION REQUIREMENTS**

Offerors should read the following proposal instructions carefully. The complete application package includes:

1. Overview of all services and capabilities offered pertaining to eTMF services
2. Proposed project schedule, assuming an overall project start date of **12-Jan-2021**. Please include near-term dates for capabilities presentations and/or proposal defense
3. Details on technology support available during implementation and ongoing use of the software/service
4. Overview of Software Development Lifecycle and requirements for customer review/access to supporting documentation
5. Three (3) client references, relating to the provision of eTMF services, including prior experience with FHI 360/FHI Clinical, if applicable
6. Summary on the geographic reach of your business and ability to support system use in low/no-bandwidth environments or developing countries
7. Demonstrated, proven process and experience working with CROs.
8. Costing/Fee structure as well as preferred payment structure, indicating if there are any upfront fees to commence work. At a minimum, please ensure pricing details (UOM, Unit cost, etc.) for the services below are included, and specify if non-profit pricing is available/provided.

|  |
| --- |
| **Description of Preferred Commodity or Services Specifications** |
| Detailed design/requirements definition |
| System configuration/implementation -Dev/Test |
| System validation support/documentation |
| System configuration/implementation -Production |
| System hosting costs – Dev/Test |
| System hosting costs – Production |
| Migration of current eTMF studies (see table below) |
| Training costs |
| Costs to view/store archived studies |

|  |  |
| --- | --- |
| **Existing eTMF Studies for Migration** | **Number of Sites** |
| Study 1 | 1 |
| Study 2 | 3 |
| Study 3 | 1 |
| Study 4 | 63 |
| Study 5 | 10 |
| Study 6 | 71 |
| Study 7 | 60 |

# Applicants are responsible for the review of the terms and conditions provided in the attachments and listed below. Applicants must provide full, accurate, and complete information as required by this solicitation and its attachments. Incomplete application packages will not be considered for the consultancy.

**EVALUATION AND SCORING CRITERIA**

Selection will be based on best value, weighing price against technical factors as outlined below:

1. Relevance of capabilities in support of FHI Clinical’s business needs – 40
2. Relevant experience and robust SDLC processes and procedures – 20
3. References – 15
4. Total Cost - 25

# SUBMISSION INFORMATION

All responses to this RFP must be submitted electronically and received no later than 5:00 PM ET **October 26, 2020** to **FHI Clinical at** [**FHICprocurement@fhiclinical.com**](mailto:FHICprocurement@fhiclinical.com)and copy **LReklis@FHIClinical.com** in either Word or PDF format.

# QUESTION & ANSWER PERIOD

Questions will be accepted until Oct 22, 2020.

# OFFER

An Offer is expected to be made by Dec 01, 2020.

# AWARD PERIOD

The award period will run from January 1, 2021 through December 31, 2022 or on as needed basis.

**LOCATION**: N/A

# FHI Clinical Disclaimers

* FHI Clinical may cancel the solicitation and not award
* FHI Clinical may reject any or all responses received
* Issuance of the solicitation does not constitute an award commitment by FHI Clinical
* FHI Clinical reserves the right to disqualify any offer based on failure of the offeror to follow solicitation instructions
* FHI Clinical will not compensate any offeror for responding to solicitation
* FHI Clinical reserves the right to issue award based on initial evaluation of offers without further discussion
* FHI Clinical may choose to award only part of the activities in the solicitation, or issue multiple awards based on the solicitation activities
* FHI Clinical reserves the right to waive minor proposal deficiencies that can be corrected prior to award determination to promote competition
* FHI Clinical will be contacting each offeror to confirm contact person, address and that bid was submitted for this solicitation