



Request for Proposal

Investigator Contracts & Budget Provider

Issue Date: 16-Nov-2020

Closing Date: 25-Nov-2020

Expected Award Date: 07-December-2020

1. 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.

FHI Clinical is seeking an Investigator Contract and Budget service provider to support the management of our Investigator contracts and budget negotiations. The provider will support creation and review of Investigator clinical trial agreement (CTA) and site budget templates with the service line to also negotiate Investigator CTAs and budgets through to finalization and provide consistent status updates to the CRO and CRO client. FHI Clinical intends to award a Master Services Agreement with multiple task orders which will be awarded on a Time and Materials (TM) basis.

2. SCOPE OF WORK

Vendors should provide an overview of their Investigator Contracts and Budget development, review and negotiation capabilities, turn-around times, and functionalities relevant to the regulated clinical research environment and Contract Research Organizations (CROs). Table 1 below contains the list of task areas for which FHI Clinical seeks contractor support. Proposals should demonstrate Contractor capabilities to provide the following services to FHI Clinical.

Table 1: Requested Provider Services

Description of Preferred Commodity or Services Specifications
Detailed service model explanation
CDA Management Capabilities
Template Development (CTA and Site Budgets)
Investigator Pricing Tool to establish Fair Market Value
CTA Negotiations with Investigative Site
Site Budget Negotiations with Investigative Sites
Review and Finalization of CTA and Site Budgets
CRO Client Updates for CTA and Site Budget Status (weekly)
CTA and Site Budget Status Reports – Weekly
Ball Park to execute Investigator Contracts and Budgets for Existing Studies requiring service below



FHI Clinical is a rapidly growing organization with an increasing need for Investigator Contracts and Budgets support. Table 2 below contains information about the existing awarded studies which will require support from the successful Offeror. However, as part of its proposal, the Offeror should provide detailed information about its capacity to support additional studies as requested by FHI Clinical. The Offeror’s proposal should provide its capacity to support up to **15 studies** with a total of **300 clinical sites**.

Table 2: Awarded FHI Clinical studies requiring Contractor support

Existing Studies requiring Service	Number of Sites
Study 1	10
Study 2	Up to 75

3. DELIVERABLES

The Contractor shall submit to FHI Clinical for review and acceptance the deliverables noted in Table 3 below in a form mutually agreed to by Contractor & FHI Clinical.

Table 3: Project Deliverables

No.	Description	Delivered To	Date / Timing
1	Monthly Invoices*	FHIC Technical & Contractual POCs	By the 10 th of the month
2	Monthly Technical & Financial Report	FHIC Technical & Contractual POCs	By the 10 th of the month
3	Project CTA & Site Budget Status Reports	FHIC Technical POC	End working week
4	Final Report	FHIC Technical POC	Within fifteen (15) days of project completion

4. PROPOSAL INSTRUCTIONS

General: The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this solicitation. The Proposal must contain a statement to the effect that it is firm for a period of at least 60 days from the date of receipt by the FHI Clinical.

Delivery: Proposals shall be delivered only via email to fhicprocurement@fhiclinical.com by the closing date & time listed in the solicitation. Proposals shall be addressed to Catherine Turner, Procurement Specialist.

The Offeror’s proposal should consist of a cover page, a table of contents, an executive summary, the Offeror’s technical approach to meet the requirements as outlined in the Statement of Work, information about Offeror personnel, proposed subcontractors/vendors and any other information required to address the solicitation requirements. The Offeror’s proposal should provide pricing on a Time and Materials basis with fixed



hourly rates for each proposed labor category, and an estimated list of materials/supplies with an estimate of cost for those materials.

The Offeror shall discuss in detail how each task identified in the Statement of Work is to be accomplished. The technical proposal shall include information identifying the key Offeror staff, any subcontractors or key vendors, and the breakdown of work scope by Offeror or Subcontractor/Vendor staff.

The proposal should include the following sections:

- A. Objectives, Organizational Experience and Technical Approach:** State the overall objectives you intend to achieve for the entirety of the project and provide an overview of all services and capabilities offered pertaining to Investigator Contract and Budget activities. Offerors should provide an overview of its organizational structure and typical service team infrastructure. Offeror proposals shall demonstrate appropriate legal experience and expertise in the Investigator Contracting & Budgeting workspace in order to be considered for award. Offeror's proposal should also provide a summary on the geographic reach of your business and ability to support service function in low/no-bandwidth environments or developing countries. The Offeror's technical proposal should include an overview of your SOPs and process on executing the service and team integration with CROs. Proposals which merely restate the requirements of the scope of work will not be eligible for award.

- B. Personnel:** Describe the experience and qualifications of all personnel who will be assigned to work on this program, including any personnel the Offeror considers Key Personnel. At a minimum, Offeror shall provide resumes for any roles considered Key Personnel in the Appendices. FHI Clinical reserves the right to review and approve resumes of any staff Offeror intends to use on a Task Order awarded under this MSA.

- C. Subcontractors/Consultants/Vendors:** For all subcontractors or vendors proposed by the Offeror to meet the requirements of the statement of work, the Offeror shall provide detailed information including but not limited to:
 - Organization name and Point-of-Contact authorized to obligate the organization for all proposed subcontractors
 - The statement of work task area(s) the subcontractor will support
 - A summary of the proposed subcontractor's capabilities, capacity, expertise and past performance. Any subcontractor key personnel must be noted in the Personnel section of the technical proposal.

- D. Past Performance**

As part of its proposal, the Offeror should provide information its past performance on programs of a similar size and scope which includes (but is not limited to):

 - List of the last three (3) contracts completed of similar size & scope in the last three (3) years
 - Contact information for each of the three contracts to include:
 - Organization Name

- Name of organization point of contact with knowledge of Offeror’s performance
- Email and phone number of organizations point of contact

E. Proposal Pricing: The Offeror shall provide its proposed pricing in the form of fixed labor rates for each labor category it intends to deliver on any Task Order issued under the MSA. At a minimum, Offeror shall provide pricing information for the labor categories listed in Appendix 1. An awarded Task Order may not include all labor categories for which pricing was provided under the MSA.

F. Sample Contract Revisions: As part of its proposal submission, Offeror shall propose revisions to the Sample MSA (Appendix 2) and Sample Task Order (Appendix 3) attached to this RFP. No revisions to the Sample MSA and TO terms and conditions will be considered if received after the RFP close date.

G. Appendices: The Offeror shall provide any additional information necessary to support the Work Plan, including, without limitation resumes of Offeror personnel, copies of relevant SOPs and any other information necessary to demonstrate contractor capability.

5. SUBMISSION INFORMATION

All responses to this RFP must be submitted electronically and received no later than **5:00 PM Eastern Time on November 25, 2020**. Proposals shall be submitted to fhicprocurement@fhiclinical.com in either Microsoft Word or PDF format. As part of its submission, the Offeror should propose its availability for capabilities presentations/proposal defense for the week of 30-Nov through 04-Dec-2020.

6. QUESTION & ANSWER PERIOD

Questions will be accepted until **1PM on Thursday, November 19, 2020**.

7. AWARD PERIOD

The **MSA** award period will run from **December 7, 2020 – December 6, 2023**.
The initial **task order** periods of performance will run from **December 7, 2020 – December 6, 2021**.

8. LOCATION

Performance will be conducted from Contractor’s location.

9. EVALUATION AND SCORING CRITERIA

Selection will be based on best value scoring against the evaluation factors outlined below:

Number	Evaluation Factors	Weight
I	Organizational Experience	25%
II	Technical Methodology and Approach	25%
III	Contractor Personnel	25%
IV	Subcontractors / Vendors	
V	Proposed Price	20%
VI	Sample MSA & TO Revisions	5%

10. 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

11. RFP Appendices

- Appendix 1 – FHI Clinical Required Labor Categories
- Appendix 2 – FHI Clinical Sample Master Services Agreement (MSA)
- Appendix 3 – FHI Clinical Sample Task Order (TO)

**Appendix 1 –
Required Labor Categories**

REQUIRED LABOR CATEGORIES	
Project Manager	POC for FHI Clinical Project teams to receive updates and mitigate/manager any project specific risks. Will ensure all final documents are provided to FHI Clinical according to the agreed upon timelines.
Juris Doctorate and/or Paralegal	Responsible for final review and oversight all aspects, in terms of negotiation and execution of required contractual agreements associated with investigative sites participating in a clinical study.
Site Budget Analyst/Specialist	Responsible for developing site budget templates and ensuring the fair market value for clinical and non-clinical procedures are captured in the template per the study protocol.
Contract/Budget Negotiator	Responsible for being site facing to negotiate contract language and budget pricing.