**Request for Proposal**

Global Regulatory Subscription Database

**Issue Date:** 26 April 2021

**Closing Date:** 03 May 2021

**Expected Award Date:** 06 May 2021

# BACKGROUND

FHI Clinical Inc. is a full-service contract research organization. Headquartered in Durham, North Carolina. 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 currently seeking a qualified vendor to provide an electronic platform for global regulatory intelligence, including approval process and timelines, in a database format to support to FHI Clinical Inc.

# SCOPE OF WORK

Please see Attachment A.

# DELIVERABLES

|  |  |
| --- | --- |
| **Task** | **Deadline** |
| Service Required | Regulatory intelligence |
| Type of Procurement | Master Service Agreement |
| Type of Agreement | One Year Agreement with option to renew |
| Submit Proposal to: | [JToro@FHIClinical.com](mailto:JToro@FHIClinical.com) with [FHICProcurement@FHIClinical.com](mailto:FHICProcurement@FHIClinical.com) on copy.  Respond via email with formal proposal attached. Offeror’s proposal must be signed, on company letterhead, and must include all items and/or services in order to be considered for evaluation. The offeror agrees to hold the process in its offer firm until the full execution of the resulting contract(s), unless another time is specified in an addendum to this RFP. |
| Date of issue of RFP | 04/26/2021 |
| Date Questions Due | N/A |
| Date Proposal Due | 05/03/2020 |
| Solicitation # | N/A |

**SUBMISSION REQUIREMENTS**

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

1. Demonstrated proven process
2. Cost proposal showing breakdown of pricing details in Attachment B
3. Organizational chart with size of company
4. A statement of your firm’s experience with clinical trial projects with a minimum of three (3) client references, relating to the outlines scope of work including prior experience with FHI 360/FHI Clinical, if applicable.
5. Please comment on the geographic reach of your business and ability to provide services outside of the US.
6. Please comment on training support and access to analysts/other company support for queries

**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: Please outline the evaluation criteria based on a 100 pt. scale. For example:

1. Relevant Experience in CRO industry and/or work on similar projects – 30
2. Proven process and metric - 30
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 April 28, 2021 to **Joy Toro** at [**JToro@FHIClinical.com**](mailto:JToro@FHIClinical.com) and cc[**FHICprocurement@fhiclinical.com**](mailto:FHICprocurement@fhiclinical.com) in either Word or PDF format.

# QUESTION & ANSWER PERIOD

Questions will be accepted until 30-April-2021.

# OFFER

An Offer will be made by 06-May-2021.

# AWARD PERIOD

The award period will run from 06-May-2021 through 06-May-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

**Attachment A:**

**Scope of Work**

**Purpose of RFP:**

Identify a qualified vendor to provide an electronic platform for global regulatory intelligence, including approval process and timelines. The scope of work may include the following:

**Regulatory Intelligence:**

* Provide FHI Clinical with a current and comprehensive view of the regulatory landscape for countries in Asia, Eastern Europe, Latin America and Africa for up to 5 users.
* Provide FHI Clinical with regular updates on latest changes in subscribed countries.
* Provide FHI Clinical with detailed summaries of local regulatory practices and reference documents.
* Provide FHI Clinical with access to expert analysts and regulatory documents for drugs and inspection documents.
* Provide FHI Clinical the ability to compare regulations across countries from a single platform.

**Attachment B:**

**Price List**

**Proposed Budget:**

* Provide a budget estimate for the services listed; include any special offers such as add-ons and pricing breakdowns depended upon number of users.
* Detail any other services that your company offers.
* Indicate payment structure schedules that would be permissible (eg. quarterly), and if there are any upfront fees to commence work.