REQUEST FOR PROPOSALS

CLINICAL TRIAL MANAGEMENT SYSTEM

Amendment 1

May 2023

iavi Translating science into global health impact

Table of Contents

125 Broad Street, 9th Floor, New York, NY 10004 | iavi.org • tel.212.847.1111 • fax.212.847.1112

REQUEST FOR PROPOSAL (RFP) – Amendment 1 | The request has been revised to extend the proposal due date.

Type of Contract: Fixed Price
Attachments to RFP: Attachment 1- System Requirements Criteria

ABOUT US:

International AIDS Vaccine Initiative (IAVI)
Global Headquarter: 125 Broad Street, 9th Floor, New York, NY 10004
Regional Locations: United States, United Kingdom, Canada, Netherlands, Kenya, South Africa, Uganda, and India
Employees: 300-350

IAVI OVERVIEW:

IAVI is a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, including HIV and tuberculosis. Our mission is to translate scientific discoveries into affordable, globally accessible public health solutions. Through scientific and clinical research in Africa, India, Europe, and the U.S., IAVI is pioneering the development of biomedical innovations designed for broad global access. We develop vaccines and antibodies in and for the developing world and seek to accelerate their introduction in low-income countries.

To learn more about IAVI, please visit our site https://www.iavi.org/about

STATEMENT OF PURPOSE:

IAVI's objective is to identify a Clinical Trial Management Services System Solution to facilitate all steps required to administer research studies. The system should, at minimum, be able to:

- Provide robust and streamlined reporting and dashboard capturing site performance metrics per study and across studies.

125 Broad Street, 9th Floor, New York, NY 10004 | iavi.org • tel.212.847.1111 • fax.212.847.1112

- Provide robust metrics (eTMF reconciliation, Quality Metrics (monitoring visit compliance, study deviations, site study status, EDC data quality metrics, study milestones, training,
- Support study budgeting and generation of Invoices
- Automate key workflows (monitoring visit management, contact management, site management, issue tracking, vendor management, regulatory and IRB submission and approval management, protocol management, document development and management)
- Ability to integrate with other critical systems (Veeva eTMF, QMS, QualityDocs, and various EDC systems)

Please refer to Attachment 1- System Requirements Criteria for a detailed breakdown of the requirements.

CURRENT SYSTEM OVERVIEW

Functionality	Current Tool
Collection of CTT quality Metrics	Metrics are collected and reported manually by CTT members using the various systems that are currently in place such as Veeva eTMF, Veeva QMS and EDC systems.
Study / site management	Workflows to manage site preparation, monitoring visits, contacts, issues, vendors, submission and approvals, protocols etc. are currently described in IAVI SOPs (Veeva QualityDocs) and automated workflows are not available to facilitate site management.

TECHNICAL REQUIREMENTS:

- User-friendly interface (Look & Feel, End-User Experience, Performance, Self-sufficient support)
- Cloud Readiness
- Single Sign-on (SSO)
- Multi-factor Authentication (MFA)
- Ability to support, at a minimum, Google Chrome
- Capable of supporting integration with third-party enterprise systems

125 Broad Street, 9th Floor, New York, NY 10004 | iavi.org • tel.212.847.1111 • fax.212.847.1112

- The system must provide an audit trail feature that tracks all users who edit the data
- The system must be a validated system with controls for 21 part 11

PROFESSIONAL REQUIREMENTS

The proposal should include an implementation methodology, approach, a draft project timeline, and an end-user training timeline. The proposal shall also have post-go live support service and SLA.

PROJECT TIMELINE:

The following defines the **estimated** timeline for the procurement process:

Key Milestone	Date (2023)
RFP Issue Date	May 15th
Proposal Submission Due Date	**June 5th**
Initial Demo	June 5th – June 16th
2nd Demos for Shortlisted Vendors	June 26th- June 30th
Anticipated Selection and Notification	July 17th
Anticipated Contract Review and Negotiations	July 19th – August 4th
Anticipated Contract Award	August 8th

SELECTION PROCESS AND EVALUATION CRITERIA:

- Prospective vendors will be invited to submit a written proposal, conduct an online-demo of their product, and provide a sample of the project schedule
- Shortlisted vendors might be invited back for a follow-up Q&A/demo session.
- The final decision will be rendered once all the due diligence is completed.

PROPOSAL INFORMATION:

IAVI invites qualified firms and organizations (“Offerors”) to submit a best-price proposal for the requested services detailed above. Issuance of this solicitation does not in any way, obligate IAVI to award a contract, not will IAVI pay for any costs incurred in

125 Broad Street, 9th Floor, New York, NY 10004 | iavi.org • tel.212.847.1111 • fax.212.847.1112

the preparation and submission of a proposal. Proposals are expected to be comprehensive and include the information set forth below. Offerors are also invited to send any additional information or supplemental material they believe will aid IAVI in properly evaluating their service offerings. The successful Offeror will be chosen based on the following evaluation factors, 1) Ability to meet the requirements, 2) Ability to meet project schedule needs, 3) Cost.

The selected Offeror will be subject to any Funder Provisions identified at the time of Agreement issuance.

CONTACT INFORMATION:

Please send all questions to:

Rahwa Keleta, Manager, Business Systems (rkeleta@iavi.org)

125 Broad Street, 9th Floor, New York, NY 10004 | iavi.org • tel.212.847.1111 • fax.212.847.1112