Request for Proposal # 2020-014

Master Service Agreement for Contract Research Organization of electronic Common Technical Document (eCTD)

I. Summary of Deadlines

Release of Request for Proposal	March 23, 2020
Confirmation of interest due	March 27, 2020
Fact-finding questions received by	April 3, 2020
Response to fact-finding questions	April 10, 2020
Proposals due	**May 1, 2020**
Selection of short-listed suppliers	May 15, 2020
Interviews with short-listed suppliers	June 1, 2020
Bidders notified of decision	June 8, 2020

Note that PATH reserves the right to modify this schedule as needed. All parties will be notified simultaneously by email of any changes.

II. PATH Statement of Business

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

III. Project Background

Electronic publishing and submission of regulatory documents/dossiers in eCTD Format:

A. Project Background: As of May 5, 2018, the US FDA mandated that all Investigational New Drug (IND) applicants and Master Files (MF) must be submitted using the eCTD format. PATH is looking for an organization who can serve as a partner in publishing electronic regulatory submissions.

B. Purpose of the RPF: To allow potential partners to provide a proposal that outlines their experience and budget to be a partner with PATH's Center for Vaccine Innovation and Access (CVIA) for publishing electronic regulatory submissions. This partnership would be in the form of a Master Service Agreement and would apply to multiple projects for all types of electronic regulatory submissions. This list of services is shown in the Scope of Work section of this RFP. PATH is seeking an organization who can meet the needs and resource constraints of a non-profit.

Please respond to this request for proposal using the two submission examples below:

Table 1 – Submission Example 1: Initial IND Submission

Section	**Number of pages**
Module 1	66
Module 2	66
Module 3, Drug Substance 1	44
Module 3, Drug Substance 2	104
Module 3, Drug Substance 3	91
Module 3, Drug Substance 4	77
Module 3, Drug Product	92
Module 3, Appendices	1
Module 3, Literature	47
Module 4 Study 1	22
Module 4 Study 2	1,333
Module 5	98
Grand Total	2,041

Table 2 – Submission Example 2: Annual Report

Page Number info	24
1.13.2	1
1.13.3	4
1.13.5	8
1.13.6	1
1.13.7	1
1.13.8	3
1.13.9	4
1.13.10	1
1.13.11	1

IV. Scope of Work

Table 3 – Scope of Work

Requirements for every submission	CRO will prepare and submit regulatory documents as defined below, through the electronic gateway to the FDA, in compliance with US FDA eCTD requirements. Specifically, the following work will be conducted: - Render Word documents to pdf and adjust to be compliant with eCTD requirements. - Add Bookmarks and hyperlinks in documents per eCTD requirements. - Build eCTD submissions on an xml backbone. - Conduct a Quality Control (QC) review of overall submission structure and the accuracy of bookmarks and links. - Validate the eCTD submission according to FDA specifications. - File the eCTD submission to the FDA via the electronic submissions gateway. - Provide final published submission to PATH via a document exchange system or on media. - Provide PATH with a proof of receipt (acknowledgment of submission). - Provide all finalized source documents via a document exchange system or on media.
Types of Submissions that would be included in the Master Service Agreement	Examples of possible submissions include the following: - Initial INDs, some of which might have multiple drug substance and or drug product sections in Module 3 - Annual Reports - IND Amendments - IND Safety Reports (within required timeframes) - Master Files - Master File Amendments - Sponsor's response to FDA's request for additional information - Meeting requests and briefing documents

V. Proposal Requirements – Financial

Provide itemized costs based on the examples provided in Tables 1 and 2 in Section III (Project Background), based on the scope of work outlined in Section IV (Scope of Work). Bids should include itemized costs for key elements of the scope of work, as follows:

1. Cost drivers (e.g., per page, submission type, etc.)
2. Percent participation in total level of effort according to key staff.
3. Rates of key staff.

4. Estimated total level of effort and associated costs.
5. Itemization of all other costs not specified in 1-4 above.

Special Note on Indirect costs
Indirect costs are overhead expenses incurred as a result of the project but not easily identified with the project's activities. These are administrative expenses that are related to overall general operations and are shared among projects and/or functions. Examples include executive oversight, existing facilities costs, accounting, grants management, legal expenses, utilities, and technology support.

Indirect rate allowances: These rates are maximum allowances. If the organization has lower rates, the lower rates should be used. To the extent that indirect costs are applicable, they are subject to the following limits:

- Up to 10% for US universities and other academic institutions.
- Up to 15% for non-US academic institutions, and all private, voluntary, and nongovernmental organizations, regardless of location.
- No indirect costs will be paid to US Government agencies, other private foundations and for-profit organizations.
- Rates apply both to the primary grantee, subgrantees, and subcontracts that are part of the proposal.

Please note, in so far as possible, identifiable (allocable) costs should be documented and justified in the proposal as direct costs, including those for dedicated ongoing project management and support. Newly acquired facilities costs that can be allocable to the project are acceptable as direct costs.

VI. Proposal Requirements – Technical

Provide a narrative on your technical approach to accomplish the Scope of Work based on the examples in Tables 1 & 2 per Section IV, including:

1. Description of technical approach, including software used for submission and process for distribution of final submission back to PATH.
2. Description of proposed interaction with PATH, please include project management, meetings, and process for managing large submissions.
3. Description and inventory of the available templates to share with PATH.
4. Description of available eCTD viewer to share with PATH.
5. Description of timeline to make submissions using examples provided in Section III, Project Background. Please include your timeline required to accommodate scheduling.
6. Describe your process for IND safety reporting, including timelines.
7. Identify potential obstacles and your plan to overcome them.

Provide information on your overall qualifications, including:

8. Description of the organization including number of years in business and roles of the team that would work on these projects.
9. Qualifications of key members of the proposed project team (attach CVs and provide details of back-up/standby teams).

10. Description and examples of your experience with eCTD submissions to the FDA outlined in Section III, Project Background.
11. Description and examples of your experience with electronic submission outside the US.
12. Experience working with non-profits.
13. If your company has more than one location, please indicate these qualifications for the site that is responding.

VII. Proposal Evaluation Criteria

The following is a list of significant criteria against which proposals will be assessed. The criteria are listed in order of priority; however, they are not weighted.

A. Technical experience with all items listed under Section VI, (Proposal Requirements – Technical).
B. Costs (as detailed in Section V, (Proposal Requirements – Financial))

Note: PATH reserves the right to include additional criteria.

VIII. Instructions and Deadlines for Responding

A. PATH contacts

Technical/Program Contact: Carlos Fernandez, cfernandez@path.org

Procurement Contact: Jessica Nguyen, jenguyen@path.org

Finance Contact: Christine Bounds-Poulin, cbounds@path.org

B. Confirmation of interest

Please send a statement acknowledging receipt of this solicitation and your intent to respond or not respond no later than March 27, 2020. Send the confirmation to the contacts listed above.

C. Fact-finding questions

Questions on this solicitation will be accepted via email to the contacts listed above through April 3, 2020. Questions and answers to all questions will be provided on April 10, 2020 to all participants who confirmed interest. Please note that responses will not be confidential except in cases where proprietary information is involved. Inquiries after this date cannot be accommodated.

D. Proposals due: May 1, 2020

Completed proposals should be submitted by email to the contacts listed above. The subject line of the email should read: RFP # 2020-014 your company name.

E. Selection of short-list

PATH reserves the right to select a short list from the bids received. PATH has the option to interview and discuss specific details with those candidates who are on the short-list.

F. Conclusion of process

Applicants will be notified of PATH's decision by June 8, 2020. Final award is subject to the terms and conditions included in this solicitation, as well as successful final negotiations of all applicable terms and conditions affecting this work.

IX. Terms and Conditions of the Solicitation

A. Notice of non-binding solicitation

PATH reserves the right to reject any and all bids received in response to this solicitation, and is in no way bound to accept any proposal.

B. Confidentiality

All information provided by PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed. Proposals, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

C. Conflict of interest disclosure

Suppliers bidding on PATH business must disclose, to the procurement contact listed in the RFP, any actual or potential conflicts of interest. Conflicts of interest could be present if; there is a personal relationship with a PATH staff member that constitutes a significant financial interest, board memberships, other employment, and ownership or rights in intellectual property that may be in conflict with the supplier's obligations to PATH. Suppliers and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, PATH will create a management plan that provides mitigation of potential risks presented by the disclosed conflict of interest.

D. Communication

All communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section VIII, Instructions for Deadlines for Responding. A. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest, and could result in disqualification of the proposal.

E. Acceptance

Acceptance of a proposal does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the finalists' proposals, as well as the option of accepting partial components of a proposal if appropriate.

F. Right to final negotiations

PATH reserves the option to negotiate on the final costs and final scope of work, and also reserves the option to limit or include third parties at PATH's sole and full discretion in such negotiations.

G. Third-party limitations

PATH does not represent, warrant, or act as an agent for any third party as a result of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.

H. Proposal Validity

Proposals submitted under this request shall be valid for 90 days from the date the proposal is due. The validity period shall be stated in the proposal submitted to PATH.