CMC Regulatory Requirements Database Partner: Request for Proposal

Proposal Deadline: April 12, 2017

Overview

Introduction

The goal of this project is to establish a long-term, sustainable database of the Chemistry, Manufacturing, and Controls (CMC) Regulatory Requirements for low and middle income countries (LMICs) with respect to small molecule products. The purpose of this database is to increase efficiency, accuracy, and transparency into Global Health small molecule medical product development.

While the pharmaceutical industry and the Global Health community have made great strides in advancing drug delivery to people all around the world, the varying CMC regulatory requirements from country to country and procurer to procurer create a great challenge to efficient development and delivery of medicines. Some of these countries have an evolving regulatory landscape that has increased the complexity and unpredictability of the development and registration process. The difficulty in ascertaining CMC requirements and the differences in these requirements between countries and procurers can create barriers to the efficient development and delivery of registered quality pharmaceuticals in one country from reaching people in another country. These challenges also impede pharmaceutical companies from efficiently planning their product development and regulatory strategy pathways, unnecessarily wasting time and resources.

To that end, the Bill & Melinda Gates Foundation (the foundation) is soliciting proposals to develop and sustain a routinely updated CMC regulatory requirements database platform with respect to small molecule medical products. The platform will house a database of CMC regulatory information from specified LMICs, bringing much easier access to this information for product developers, regulators, procurers, and others interested in Global Health. The aim is to establish a long-term, sustainable database of CMC regulatory requirements with respect to small molecules for the Global Health community so that the foundation's product development partners (PDPs) and others can optimize their product development plans and regulatory strategies, thus accelerating product introduction. This contributes to the foundation's strategic goal to strengthen the CMC capabilities and capacity of the PDP network.

The foundation has already assembled CMC regulatory requirement data for small molecule products from over 60 LMICs and procurement agencies in a pilot database tool. This database focuses on small molecules and covers oral dosage forms and simple injectables. The selected partner will receive this pilot tool and will create a user-friendly, web-based, searchable platform. The partner is then responsible for ensuring that the database is kept current and relevant, and will ideally provide support to users.

Although this database will be made accessible to non-profits at no- or low-cost and to regulatory authorities and the WHO at no cost, there is high demand for this product across sectors. Potential revenue streams, both from access fees and support services, may present a meaningful business opportunity. When the concept of the database was shared with some of the leading multinational pharmaceutical companies, global and regional generics manufacturers, pharmacopoeias, and consultancies, all expressed strong interest in the product.

This work is envisioned as an initial grant to develop the web-based database platform, with an expected sustainability plan in place to generate revenue for the selected partner in the long-term. The current pilot database will be given to the selected partner who will own the IP moving forward.

Background

To accelerate the introduction of quality new drugs to treat Global Health diseases among vulnerable populations, product developers must manufacture products according to local regulatory requirements in order to avoid delays in regulatory approvals to supply product for clinical trials and to register drugs for commercial marketing and distribution. In addition, even after regulatory marketing authorization, procurers often have their own requirements that must be addressed in order for a product to meet specifications and be purchased by procurement agencies. Today, product developers lack full visibility into the CMC requirements of national regulatory authorities (NRAs), particularly in LMICs, and of Global Health product procurers. For some product developers, this has caused delays and cost overruns resulting from the need to repeat manufacturing development activities or complete new activities to comply with country-specific or procurer-specific CMC regulatory requirements.

The CMC requirements established by regulatory authorities, such as the US Food & Drug Administration (FDA), European Medicines Agency (EMA), and by the WHO's Prequalification of Medicines Programme, are generally easily obtainable and well understood. In contrast, the specific requirements for many LMICs, procurers, and NRAs are often unfamiliar, unpublished, unknown, or inconsistent.
However, for Global Health medicines, compliance with LMICs’ and procurers’ requirements is critical for market access and successful and timely delivery of new treatments to those who need them most. In short, minimal transparency into LMIC and procurer CMC regulatory requirements makes it unlikely that new product manufacturing development and regulatory strategies are optimized to accelerate product development, registration, procurement, and delivery.

For instance, product developers have:

- Been required to repeated a study or a part of a study resulting in delays (e.g., performing a stability study at different conditions to meet previously unknown regulatory requirements)
- Improperly used excipients and starting materials from prohibited sources resulting in product development rework and/or reformulation
- Overlooked requirements for product approval in the country of manufacturing when selecting manufacturing site
- Omitted unique data and analyses required in regulatory filings resulting in registration delays

These situations lead to delays in product registration and introduction, as well as higher product development costs. Moreover, CMC activities are often time consuming and must occur before and/or in parallel to clinical development activities. Delays to CMC activities can thus cause significant downstream delays to product development, registration, commercialization, procurement, and ultimately, introduction to Global Health populations.

The foundation’s current pilot tool is an excel-based database that has the functionality to search by target country/agency or individual requirement, and shows a schematic of each country’s registration pathway. The tool can also compare requirements in cross-country tables, with the option of sorting by disease burden or region. The selected partner will receive this pilot tool and will expand its capabilities in a web-based, user-friendly platform.

Anticipated Outcomes

This CMC Regulatory Requirements Database intends to address the problems described above through the creation of a database of CMC regulatory requirements for small molecule products, increasing transparency, efficiency, and accuracy for the Global Health product development and regulatory communities. This will ensure more timely delivery of cost-effective, high quality drug products for clinical investigation and post-approval use.

Scope and Approach

**Scope:** The long-term partner will be expected to create a platform that includes:

- A web-based tool
- Search functions by target country/procurer and requirement category
- Links to country/procurement guidelines and expert contacts
- Ability to filter requirements by product type and target registration pathway
- Schematization of available registration pathways, procedures, and timelines (official and practical)
- Comparative tables of specific country/procurer requirements
- Cross-country/procurer comparison of pathways and relative complexity
- Help desk services to assist users (tiered pricing may apply)
- Ongoing maintenance of database to ensure updated current information

**Approach:** The Foundation has CMC regulatory requirement data for small molecule products from over 60 LMICs and procurement agencies in a preliminary database tool which will be provided to the selected long-term partner. The partner is expected to:

- Translate the preliminary database into an interactive, dynamic, searchable, and user-friendly web-based platform
- Maintain the database and ensure the information is kept current
- Design a financially self-sustaining business model
Rules & Guidelines

Eligibility

Funding Criteria

We will consider funding organizations that:

• Are open to collaboration
• Will be committed to underserved markets
• Are open to a no- or low-cost model for nonprofits and no-cost model for National/Regional Regulatory Authorities, the WHO, and the Bill & Melinda Gates Foundation
• Have overall financial health

Exclusion Criteria

We will NOT consider funding for organizations that:

• Present conflicts of interest

Evaluation Criteria

Submissions received by the deadline will be evaluated on the following criteria:

• Alignment with the foundation’s mission
• Ability to keep the CMC regulatory requirements database up-to-date
• Aptitude for user-friendly, searchable, and accessible technology
• Strength of the proposed business model and the ability to follow through
• Ability to manage the risks and uncertainties of the database
• Ability to bring expertise in other areas and complementary services to strengthen long-term viability of the product

Successful submissions (i.e., those chosen as “finalists) will:

• Closely align with the goals of the foundation’s CMC Regulatory Requirements mission;
• Clearly propose a project that will improve transparency of global CMC regulatory requirements
• Clearly propose a model that will expand and become financially self-sustaining
• Clearly propose a process that will keep the database up-to-date and relevant
• Have a project duration of at least 5 years; ideal candidate will maintain the database for 10+ years
• Present a reasonable budget for start-up costs

Finalists will be invited to the foundation to present their proposals in more detail.

Activities and Timeline

February 8, 2017 – 1:00PM (PST): Pilot tool demo. Email CMCDatabase@gatesfoundation.org to sign up.
February 21, 2017 – 8:30AM (PST): Pilot tool demo. Email CMCDatabase@gatesfoundation.org to sign up.
June 2017 (TBD): Finalist presentations.
July 2017 (TBD): Award announced.
Q4 2017: Transition of pilot tool to selected-long term partner and project work begins.
January 1, 2018: Transition period ends, selected long-term partner is fully independent.

How to Submit a Proposal

Response Requirements

To apply, please submit a proposal that includes the attachments listed below:

• Concept memo describing the proposed project (up to 10 pages, template and guidelines provided)
• Budget/financial model for the proposed activities
• Most recent organizational financial statements (audited, if available)
• Prototype, mock-up, or analog of proposed database platform (optional; will be required of finalists)

Submission Instructions

Submit your response online. You must complete the online submission form and attach your completed proposal forms for the foundation to process your request. To submit an application, follow these steps:

1. Create an account on the Application Portal
2. Start a new application by clicking here (you can save the application and return to it later)
3. Edit your existing draft application by logging back into the Application Portal
4. If you plan on applying, please notify CMCDatabase@gatesfoundation.org so we know to expect your application

Please do not mail a duplicate hard copy after submitting your proposal online or send any additional attachments or information (videos, books, program materials, etc.)

Help Contact(s)

See the FAQ Document (under Reference Documents) and the foundation’s Grantseeker FAQ for more detailed information, or contact CMCDatabase@gatesfoundation.org with other questions.

More Information

Key Terms and Conditions

A. Disclosure Notice

To help the foundation with its review of RFP responses, the foundation may disclose proposals, documents, communications, and associated materials submitted to the foundation in response to this RFP (collectively, “Submission Materials”) to its employees, contingent workers, consultants, independent subject matter experts, and potential co-funders. Please carefully consider the information included in the Submission Materials. If you (the “Applicant”) have any doubts about the wisdom of disclosure of confidential or proprietary information, the foundation recommends you consult with your legal counsel and take any steps you deem necessary to protect your intellectual property. You may wish to consider whether such information is critical for evaluating the submission or if more general, non-confidential information may be adequate as an alternative for these purposes.

Notwithstanding the Applicants characterization of any information as being confidential, the foundation the foundation is under no obligation to treat such information as confidential.

B. Disclaimer

This RFP is not an offer to contract or award grant funds. The foundation assumes no responsibility for the Applicants cost to respond to this RFP. All responses generated by this RFP become the property of the foundation.

C. Release and Verification

In exchange for the opportunity to be awarded a grant or contract, the Applicant agrees that the foundation may, in its sole discretion: (1) amend or cancel the RFP, in whole or in part, at any time; (2) extend the deadline for submitting responses; (3) determine whether a response does or does not substantially comply with the requirements of the RFP; (4) waive any minor irregularity, informality or nonconformance with the provisions or procedures of the RFP; (5) issue multiple awards; (6) share responses generated by this RFP with foundation staff, consultants, contingent workers, subject matter experts, and potential co-funders; and (7) copy the responses.

Applicant agrees not to bring a legal challenge of any kind against the foundation relating to the foundation’s selection and award of a grant or contract arising from this RFP.

Applicant represents that it has responded to the RFP with complete honesty and accuracy. If facts provided in Applicant’s response change, Applicant will supplement its response in writing with any deletions, additions or changes within ten days of the changes. Applicant will do this, as necessary, throughout the selection process. Applicant understands that any material misrepresentation, including omissions, may disqualify it from consideration for a grant or contract award.

By responding to this RFP, you are representing: (i) that you have authority to bind the named Applicant to the terms and conditions set forth above, without amendment; and (ii) that you agree to be bound by them.
D. Global Access and Intellectual Property

Intellectual property (IP) rights and the management of IP rights are likely to play an important role in achieving the goals of this project. To this end, the foundation requires that, even at this stage, all applicants seriously consider their willingness to submit a response in compliance with the foundation’s response requirements, a portion of which may ask for certain information and intentions regarding intellectual property concerns and Global Access. Specifically, the foundation requires that:

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of the Agreement. “Funded Developments” means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). “Background Technology” means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. “Global Access” means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

The foundation will be selecting applicants based on the conclusion that their technologies and expertise will be most appropriate for the success of this RFP.

As part of the foundation’s review and evaluation of each response, the foundation will conduct due diligence with respect to each applicant’s ability and commitment to manage intellectual property in a manner consistent with the stated scientific and charitable goals of the foundation. Due diligence activities may include inquiry into an applicant’s:

1) Freedom to operate (FTO) and ability to freely use and acquire needed background technology;

2) Commitment to promote the utilization, commercialization and availability of Funded Developments for public benefit.

The foundation encourages you to include this information in your response.

About the Bill & Melinda Gates Foundation

Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. We work with partner organizations worldwide to tackle critical problems in four program areas. Our Global Development Division works to help the world’s poorest people lift themselves out of hunger and poverty. Our Global Health Division aims to harness advances in science and technology to save lives in developing countries. Our United States Division works to improve U.S. high school and postsecondary education and support vulnerable children and families in Washington State. And our Global Policy & Advocacy Division seeks to build strategic relationships and promote policies that will help advance our work. Our approach to Grantmaking emphasizes collaboration, innovation, risk-taking, and, most importantly, results.

To learn more about the foundation’s work, visit www.gatesfoundation.org.