



Request for Assistance:

Assemble a pre-Investigational New Drug meeting package in compliance with United States Food and Drug Administration requirements for a drug microarray patch and lead an initial FDA meeting in Q1 2021, in preparation for a future phase 1 clinical study

MAPs for PrEP project: Dissolving microarray patches (MAPs) for long-acting HIV and pregnancy prevention

This project is made possible by the generous support of the American people through the United States Agency for International Development (USAID) through the United States President's Emergency Plan for AIDS Relief (PEPFAR), under the terms of Cooperative Agreement #AID-OAA-A-17-00015. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID, PEPFAR, or the United States government.



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MAPs for PrEP project

RFA 2020-10

Table 1. Schedule and deadlines

Request for Assistance (RFA) released	February 21, 2020
Expression of interest due by email, including organizational description and any questions about this RFA (<i>see details in Step 1 below</i>)	March 2, 2020, by 5 p.m. PST
PATH emails RFA questions and answers to all organizations	March 9, 2020, by 5 p.m. PST
Application/proposals due (<i>see details in Step 2 below</i>)	March 25, 2020, by 5 p.m. PST
Proposal evaluation complete	April 3, 2020

Note: PATH reserves the right to adjust the schedule, if necessary. All interested parties will be notified as soon as possible.

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.

Background

Health need

Women and adolescents in low- and middle-income countries are at greatest risk of HIV infection and need acceptable products that provide long-acting protection against HIV. Microarray patches (MAPs; also known as microneedle patches) are an easy-to-use, discreet delivery technology, which could improve adherence—a recognized challenge for current HIV pre-exposure prophylaxis (PrEP) regimens.

Project objective

With United States Agency for International Development (USAID) funding, PATH is collaborating with Queen's University Belfast (QUB) and ViiV Healthcare to develop dissolving MAPs for delivery of cabotegravir for HIV prevention. We envision a MAP that could be self-administered and acceptable among target end users, particularly women and young girls in resource-limited settings who bear the highest burden of disease globally.

Purpose of this Request for Assistance

PATH is seeking a regulatory support organization to lead preparation for and implementation of an initial pre-Investigational New Drug (IND) consultation with the United States Food and Drug Administration (FDA), which we aim to hold in Q1 2021. The regulatory services organization will work with PATH, QUB, and a contract manufacturing organization (CMO) to prepare a Chemistry, Manufacturing, and Controls (CMC) data package, in addition to other materials needed for an initial pre-IND consultation with the FDA.

Scope of this work

PATH is seeking regulatory support to lead the following primary activities:

- Develop a strategy and key questions for a pre-IND consultation with the FDA.
- Outline the process and document the materials required to request and hold a pre-IND consultation with the FDA, including logistics, preparation, implementation, and interpretation of feedback and guidance provided by the FDA during the meeting.
- Develop materials required for the initial pre-IND consultation with the FDA, which may include:
 - Outline of the clinical/regulatory plan.
 - Chemistry, Manufacturing, and Controls (the regulatory services organization will support the CMO to ensure the CMC information package is complete and of high quality).
 - Pharmacology/toxicology test plan.
 - Preclinical pharmacology data and test plan.
 - Clinical synopsis for the pre-IND consultation.
 - Draft clinical trial protocol, following confirmation of the clinical trial synopsis during the pre-IND consultation.
 - Investigator's Brochure.

The regulatory services organization will drive regular meetings between PATH, QUB, and the CMO to coordinate activities and implement this scope of work, ensuring that documents are of high quality and are drafted on time.

Budget: Up to US\$450,000. Budget should be detailed, reasonable, and realistic.

Duration: The estimated duration of this work is 14 months; *Table 2* shows the estimated timeline.

Table 2. Estimated timeline.

Activity	Q1 2020 (Jan, Feb, March)	Q2 2020 (Apr, May, June)	Q3 2020 (July, Aug, Sept)	Q4 2020 (Oct, Nov, Dec)	Q1 2021 (Jan, Feb, March)	Q2 2021 (Apr, May, June)
Complete RFA process.						
Select a regulatory services organization, request USAID approval, and establish agreement.						
Work with PATH, QUB, and CMO to develop a clinical/regulatory strategy and plan for conducting the pre-IND consultation with the FDA.						

Activity	Q1 2020 (Jan, Feb, March)	Q2 2020 (Apr, May, June)	Q3 2020 (July, Aug, Sept)	Q4 2020 (Oct, Nov, Dec)	Q1 2021 (Jan, Feb, March)	Q2 2021 (Apr, May, June)
Draft outline of pre-IND meeting, including list of materials and documents.						
Regulatory services organization to draft pre-IND consultation materials and documents and submit a pre-IND consultation request to the FDA.						
Work with PATH, QUB, and CMO to review and revise pre-IND consultation materials and documents.						
Meet with the FDA: PATH expects the regulatory services organization to lead the pre-IND consultation and write meeting notes.						
Provide meeting notes and all other documents to PATH.						

Desired qualifications and accomplishments

- Experience preparing for and holding successful pre-IND consultations with the FDA for combination products (device/drug).
- Project management experience and bandwidth to drive forward all aspects of this scope of work, including managing PATH, QUB, and the CMO to implement a successful pre-IND FDA consultation.
- Specific regulatory experience with microarray patches (also known as microneedle arrays) would be useful.
- Specific regulatory experience with drugs for HIV prevention and/or long-acting formulations would also be useful.

Application evaluation criteria

- Completeness of application/proposal.
- Regulatory capability, expertise, and previous experience that matches desired qualifications and accomplishments.
- Suitability of staff and resources to complete the scope of work.
- Appropriateness of detailed budget; reasonable and realistic cost details.

Deliverables

- Review, agree to, and sign an existing project confidentiality agreement (multi-party) with current project partners.
- Summary of strategy and key questions for pre-IND consultation with the FDA.
- Outline of materials needed, including logistics, for pre-IND consultation with the FDA.
- Draft and finalize each document needed for the pre-IND consultation with the FDA (see *Scope of this work* section).

- Contact the FDA to request the pre-IND consultation, schedule the meeting, lead the meeting, and provide a summary of meeting notes to PATH following the meeting.

How to respond to this Request for Assistance

NOTE: please do not submit proprietary/confidential information.

Step 1. Expression of interest. Email mapsforprep@path.org by the deadline (listed in *Table 1. Schedule and deadlines*) to express your interest, and include the following:

- Questions about this RFA.
- Organizational description (location, number of staff, mission, etc.), including your DUNS number and whether you have previously received United States government funding (directly or indirectly).

Step 2. Application/proposal. Email mapsforprep@path.org by the deadline (listed in the *Schedule and deadlines* table), and include the following:

- a. **Capacity/capability** (up to 1 page)
 - Describe your organization's capabilities and expertise.
 - Past performance references: provide company name, contact name, and email address of two previous or current clients with similar, relevant regulatory needs.
- b. **Proposal** (up to 3 pages)
 - Describe how your organization meets the criteria in the *Desired qualifications and accomplishments* section and how you would work with PATH and its partners to achieve the deliverables.
- c. **CVs** (for relevant personnel only; no page limit).
- d. **Detailed budget** (use template provided).
- e. **Budget narrative** (no page limit). This document should describe how you arrived at the total dollar amount for each line item of your detailed budget.

Step 3. Agreement. Upon selection of the regulatory services organization, PATH will work with the regulatory services organization to execute required agreements to implement the work.

Terms and conditions of the Request for Assistance

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 application. The applications submitted through this RFA process are the responsibility of the submitters and do not necessarily reflect the views of the United States Agency for International Development (USAID), the United States government, or PATH.

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. Applications, 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 contact listed in the RFA, 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/or 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. 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 application.

E. Acceptance

Acceptance of an application 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' applications, as well as the option of accepting partial components of an application 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. Application validity

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