



# Request for Applications RFA2024-003: MATRIX Technology Accelerator Domain 1 Seed Grants for HIV Prevention Products

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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## **Abbreviations**

API active pharmaceutical ingredients

CFR Code of Federal Regulations

COI conflict of interest

EU European Union

HIV human immunodeficiency virus

MATRIX Microbicide R&D to Advance HIV Prevention Technologies through Responsive

Innovation and eXcellence

MPT multipurpose prevention technology

PI principal investigator

PrEP preexposure prophylaxis

R&D research and development

RFA request for applications

SAG scientific advisory group

SSA sub-Saharan Africa

TA-D1 Technology Accelerator Domain 1

UK United Kingdom

US United States

USAID United States Agency for International Development

# Opportunity summary

This is an opportunity to apply for funding to advance research applications for development of new primary HIV prevention approaches. For the purposes of this request for applications (RFA), primary HIV prevention is defined as the inhibition of HIV transmission from an infected individual to an uninfected woman using a drug or device that prevents systemic or vaginal virus infection. Applicants from a wide range of **United States (US)**, **European Union (EU)**, **United Kingdom (UK)**, **Kenyan**, **South African**, **and Zimbabwean institutions** (universities; private, for-profit, or nonprofit companies; research consortia or programs; and innovation or incubation hubs) are invited to apply to this RFA, sponsored by the MATRIX (<u>Microbicide R&D to Advance HIV Prevention Technologies through <u>Responsive Innovation and eXcellence</u>) consortium and United States Agency for International Development (USAID).</u>

We are seeking innovative research applications for the development of new primary HIV prevention drugs and strategies, multipurpose prevention technologies (MPTs), and technologies that enable primary HIV prevention strategy development and have the potential to strengthen capacity in targeted countries. Established researchers, research consortia, students, postdoctoral fellows, and new investigators establishing laboratories and/or seeking tenure from the United States, EU, UK, Kenya, South Africa, and Zimbabwe are encouraged to apply. Meritorious applications that significantly involve African collaborators from Kenya, South Africa, and/or Zimbabwe will be prioritized for funding consideration over those that do not involve African collaborators. Proposed research must be driven by milestones, go/no-go criteria, and timelines and must target development of HIV prevention for one or more of the following populations: adolescent girls and young women, pregnant and breastfeeding people, and female sex workers. Applications are limited to projects with costs of US\$150,000 and a duration of 18 months. PATH, a member of the MATRIX consortium, will oversee the application submission and award processes using an oversight structure that draws from US- and Africa-based administrators.

Key words: HIV prevention, multipurpose prevention technology, early-phase technology, adolescent girls and young women, pregnant and breastfeeding people, female sex workers, drugs and delivery technologies

## II. Key dates

Table 1. Summary of key dates

Release of request for applications	February 1, 2024
Letter of intent due	February 22, 2024 (8:00 a.m. Pacific time)
Fact-finding questions due	February 22, 2024 (8:00 a.m. Pacific time)

Responses to fact-finding questions provided to applicants	March 1, 2024 (8:00 a.m. Pacific time)
Applications due	April 1, 2024 (8:00 a.m. Pacific time)
Estimated decision notification	May 15, 2024
Estimated project start date	July 1, 2024

Note that MATRIX reserves the right to modify this schedule, as needed. Parties who express interest will be notified by email of any changes.

This RFA expires on April 2, 2024.

# III. Funding opportunity purpose

#### MATRIX Technology Accelerator Domain 1 (TA-D1)

MATRIX is designed to expedite research and development (R&D) of products for primary prevention of HIV in women (<a href="https://matrix4prevention.org">https://matrix4prevention.org</a>). MATRIX is funded by USAID and is led by Dr. Sharon Hillier (Magee-Womens Research Institute, Pittsburgh, Pennsylvania, United States) and Dr. Thesla Palanee-Phillips (University of the Witwatersrand, Johannesburg, South Africa). MATRIX's scientific and operational priorities focus on ensuring equitable leadership and representation by sub-Saharan Africa (SSA) stakeholders to advance products that meet the diverse HIV prevention needs of adolescent girls and young women, pregnant and breastfeeding people, and female sex workers.

The overarching scientific objective of the MATRIX program is to create a self-sustaining platform that is driven by milestones and go/no-go criteria for the efficient development of primary HIV prevention products that are acceptable, affordable, scalable, and deliverable; that increase end-user choice; and that make a positive public health impact while actively involving SSA researchers and stakeholders. A significant component of MATRIX's SSA product development strategy is the TA-D1, which was designed to accelerate early-phase R&D of **new primary HIV prevention products**, MPTs (specifically, combinations of contraceptives and anti-HIV drugs), and/or technologies that support drug discovery/development. TA-D1 will accomplish this by identifying and funding potentially high-risk proof-of-concept projects with significant innovation for HIV prevention and MPTs and/or their supporting technologies. Funding will be prioritized for applications that are meritorious and address critical gaps in the current HIV prevention toolbox and/or open new pathways to achieving the objectives of MARTIX. *Meritorious applications that significantly involve African collaborators from Kenya, South Africa, and/or Zimbabwe will be prioritized for funding consideration over those that do not involve African collaborators.* 

The scientific objective of this RFA is to support the development of innovative, potentially game-changing primary HIV prevention research by supporting students, new or early-stage investigators, established researchers, and collaborative teams from a broad range of entities.

### Definition of primary HIV prevention used in this RFA

This RFA will only support game-changing applications that address primary HIV prevention. For the purposes of this RFA, primary HIV prevention is defined as the inhibition of HIV transmission from an infected individual to an uninfected woman using a drug or device that prevents systemic or vaginal virus infection. The proposed strategy should target prevention of the initial transmission of HIV to adolescent girls and young women, pregnant and breastfeeding people, and female sex workers, using known HIV prevention strategies such as vaginal topical microbicides and pre-exposure prophylaxis (PrEP, pre-dosing of people with drugs to prevent initial HIV infection). Development of MPTs to prevent HIV and unintended pregnancy are within the scope of this RFA.

In the "significance and innovation" portion of the main application narrative, applicants should specifically highlight how the proposed work and development of their primary HIV prevention product or strategy will contribute to the field of HIV prevention.

#### Areas of research interest

The following areas of research interest are within the scope of this RFA when supporting the overall objective of creating new primary HIV prevention strategies and products:

- Development of novel anti-HIV products, MPTs, and next-generation active pharmaceutical ingredients for prevention of HIV infection.
- Development of broadly neutralizing antibodies for primary HIV prevention. Responsive
  applications may include antibody optimization such as increasing avidity, affinity, stability,
  and/or compatibility with the vaginal microenvironment when these changes are made to
  enable long-acting vaginal or systemic delivery systems for primary HIV prevention in
  AGYM, FSW and PBFP. Applications proposing bNAb development/optimization not
  required for delivery of existing well-characterized bNAbs for primary prevention to enable
  long-acting vaginal or systemic delivery systems and/or discovery of new antibodies for
  neutralization of HIV are not eligible for funding.
- Development of new and/or optimized drug delivery systems that address current gaps in HIV prevention products and MPTs by offering options to MATRIX's target populations.
   Products that are systemic (e.g., injectable) or topical (e.g., vaginal) will be considered.
- Development of laboratory techniques and/or diagnostic tools with increased sensitivity and/or precision that facilitate the preclinical and/or clinical development of new HIV prevention products.
- Development/optimization of new approaches for local manufacture of active pharmaceutical ingredients (APIs) for primary HIV prevention or as an MPT.

- Novel/optimized synthesis approaches for new and established anti-HIV/antiviral and MPTs that reduce the cost of manufacturing and/or facilitate production in low- and middle-income countries are encouraged.
- Research using samples from completed or ongoing clinical trials in support of the
  development of an applicant's primary HIV prevention strategy or product. Applicants must
  have ethics committee approval to propose the use of any tissues and/or secretions
  obtained from any individual to conduct proposed research.
- Significant redesign of a licensed primary HIV drug delivery strategy that provides significant advantages over the current product, such as longer durations of protection, reduced pharmacokinetic tails, and/or increased forgiveness intervals.
- Development of novel, sensitive, and accurate point-of-care HIV diagnostics.

## Nonresponsive areas of research

Applications proposing research that is identified as nonresponsive to this funding opportunity will be returned without review, including:

- Applications that focus solely on HIV treatment—for example, ones that include tracking of drug mutations in treated populations, product development strategies focused on controlling or eliminating HIV after infection, and product development strategies focused on viral reservoirs.
- Applications for secondary HIV prevention based on the monitoring or treatment of HIV-infected individuals with new drugs or drug delivery strategies designed to prevent transmission to uninfected individuals, development of drugs or delivery strategies for U=U (undetectable = untransmissible) strategies, or development of drugs or delivery strategies or devices for post-exposure prophylaxis.
- Applications that focus solely on HIV cure research or analysis of viral reservoirs during establishment of or after infection, as well as ones based on kick/kill strategies.
- Applications that focus on drug discovery or development unrelated to HIV prevention—for example, use of antibodies for HIV treatment or cure research.
- Applications proposing discovery of broadly neutralizing antibodies.
- Manufacturing of products for testing in humans in a proposed or ongoing clinical trial outside this funding opportunity and/or for treatment or for use in providing a product for primary or secondary HIV prevention.
- Research that involves first-in-human, Phase 1, Phase 2, or Phase 3 clinical trials or studies that involve direct intervention with human subjects. Applicants may propose research using samples from completed or ongoing clinical trials. Applicants may not use this RFA to support *any component* of a clinical trial or observational study.
- Applications with MPTs that do not include anti-HIV activity for the purposes of primary HIV prevention.
- Development of any product or process that does not have anti-HIV activity for or application to HIV prevention. Applicants may propose products with a broad spectrum of antiviral/antimicrobial activity or applicability beyond HIV and MPT development, but the

- research application must focus on development of the products' role as potential HIV prevention strategies.
- Development of new drugs, drug delivery systems, diagnostics, and/or technologies that do
  not support the development or advancement of primary HIV prevention or MPT product
  development or strategies.
- Development of rectal topical microbicides or topical products to prevent rectal transmission
  of HIV. Proposed strategies may have the potential for dual-compartment usage (i.e., female
  reproductive tract and gastrointestinal tract), but the proposed research must focus solely on
  the development of the primary prevention strategy for women.
- Applications that propose the development of HIV vaccines (or components of vaccines), including combinations of primary HIV prevention strategies, antivirals, and vaccines in a single drug delivery system or as an MPT.
- Applications with proposed innovations that are not supportive of the primary HIV prevention needs of adolescent girls and young women, pregnant and breastfeeding people, and female sex workers.
- Applications focusing on social behavioral research, such as end-user and marketing studies to determine general end-user perceptions, acceptability, or market interest for a specific or hypothetical primary or secondary HIV prevention strategy or MPT. Applicants may integrate end-user input into the design or identification of a critical feature of a primary prevention strategy or MPT drug delivery system. If end-user research is included in a research application, end-user research that is focused on identifying critical rheological and/or "look and feel" properties of a drug delivery system that is proposed for development must be 25 percent or less of the proposed research and research budget. Furthermore, the research must be concise and proposed early enough in the scope of work such that the results can be incorporated into the proposed prevention product or technology within the funding period.
- Applications that propose optimization of existing PrEP strategies through repackaging or distribution strategies, such as co-packaging of drugs.

# IV. Key term definitions

The following definitions will be used for key terms throughout this document.

- **Activity**: A discrete event that will be performed to achieve a specific goal or milestone. An activity must begin with an active verb.
- **Go/no-go criteria**: Critical decision points stated as absolutes in the development pathway of a product. Go and no-go statements/criteria are an integral part of defining a milestone. "Go" is a decision to continue development. "No-go" is a decision to stop development. A single milestone may have multiple go/no-go criteria depending upon its complexity. A go decision allows the research program to proceed to the next milestone.
- **Milestone**: A measure of progress. Milestones identify critical junctures/steps in the research process that must be accomplished/completed to successfully complete the

- research. A milestone also may incorporate go/no-go criteria in its description as measures of progress in attaining the milestone.
- **Multipurpose prevention technology (MPT)**: A combination of drugs to prevent HIV infection and pregnancy, delivered in a single drug delivery system.
- **Primary HIV prevention**: The inhibition of HIV transmission from an infected individual to an uninfected woman using a drug or device that prevents systemic or vaginal virus infection.
- **Proof of concept**: Evidence generated through experimental methods that a concept meets pre-established criteria for feasibility, such as milestones and/or go/no-go criteria.

#### V. Award information

MATRIX expects the following:

- Number of awards: We anticipate issuing up to two awards. The number of awards is
  contingent on submission of meritorious applications, available funds, and the applications'
  applicability to MATRIX's mission and objectives.
- **Award budget**: MATRIX will award up to \$150,000 per award. Budgets should be detailed, reasonable, and realistic.
- Award project period: The duration of the awarded project is up to 18 months, depending
  on the proposed scope of work and timeline. A single no-cost extension for up to an
  additional 6 months may be requested but is not guaranteed. Extension requests must be
  submitted formally 2 months prior to the end date of the award.

# VI. Eligibility information

Eligibility criteria are as follows:

- The proposed research project must address a critical need for primary HIV prevention product or MPT development that meets the goals and objectives of the MATRIX consortium and USAID. The proposed scope of work MUST focus on primary HIV prevention.
- Applicants from US, EU, UK, Kenyan, South African, or Zimbabwean institutions (universities; private, for-profit, or nonprofit companies; research consortia/programs; and innovation or incubation hubs) that consist of students, postdoctoral fellows, and new/earlystage and established investigators, as well as an active research program, are invited to apply. Foreign nationals from Kenya, South Africa, or Zimbabwe working in the United States are eligible to apply. Applicants from outside the United States, EU, UK, Kenya, South Africa, or Zimbabwe are not eligible to apply. The principal investigator (PI) and organization must be based in an eligible country:
  - Meritorious applications that significantly involve African collaborators from Kenya, South Africa, and/or Zimbabwe will be prioritized for funding consideration over those that do not involve African collaborators.

- Inclusion of personnel from Kenya, South Africa, and/or Zimbabwe whose sole role is to provide samples for a US-/EU-/UK-based research activity does not constitute representation on the research team.
- Applications proposing work in a non-supported country are not eligible.
- The proposed research project must be an original, innovative concept.
- Pls must have the skills, knowledge, and institutional resources necessary to carry out the proposed research.
- For applications proposing mentoring of students, postdoctoral fellows, or new/early-stage investigators, the applicant must identify a mentor or mentor team and document the experience of the mentors. The applicant must provide a mentoring/training plan.
- Projects that would use funds to provide material support or resources to individuals, entities, or organizations of countries that have been identified by the United States Department of State as state sponsors of terrorism are ineligible. The countries currently identified are Cuba, Iran, North Korea, Sudan, and Syria.
- Project applications can be submitted by MATRIX's existing partners.
- Applicant organizations or PIs may submit more than one application, provided that each application does not overlap with, and is scientifically distinct from, other submitted applications.

# VII. Scope of work and deliverables

# Proposed project timeline

Project start date	July 1, 2024
Completed risk register due	August 1, 2024
Completed new project request form due	August 1, 2024
Completed update report form due	January 1, 2025
Completed update report form due	July 1, 2025
Final report due	December 15, 2025

# Scope of work

MATRIX is seeking a diverse pool of investigators in HIV prevention R&D, particularly early-stage researchers, to develop a new, innovative concept in the form of a product, drug delivery system, drug, lab technique, or diagnostic tool. The award may be used to mentor and train a student or postdoctoral fellow.

#### **Deliverables**

Project deliverables are as follows:

- An innovative concept in the form of a product, drug delivery system, drug, lab technique, or diagnostic tool for the **primary prevention of HIV** in women that meets the milestones and "go" criteria set forth in the application.
- A completed risk register following the first month of the project. A template will be provided upon acceptance of an application.
- A completed one-page report every 6 months to update PATH on the project status. A template will be provided upon acceptance of an application.
- A completed new project request form to present at the first MATRIX scientific advisory
  group (SAG) meeting after the award. The SAG is an independent multidisciplinary
  committee of international experts that conducts unbiased data reviews of critical path
  products to help inform prioritization of, and decision-making concerning, MATRIX's product
  portfolio. The goal of the new project request form will be to introduce the project to the
  SAG, MATRIX, and USAID. A template will be provided upon acceptance of an application.
- At the end of the award period, a presentation of project results to the MATRIX steering
  committee and USAID. Each team will need to provide a summary of the project results
  along with any publications for the MATRIX website. Project teams are strongly encouraged
  to publish project results in peer-reviewed journals. Confidential information may be
  excluded from the results presentation and/or from the MATRIX website, as appropriate.

# VIII. How to respond to this request for application

During the application and award process, operational and research oversight for this funding opportunity will be provided by PATH (<a href="www.path.org">www.path.org</a>), a member of the MATRIX consortium. PATH will provide guidance on the RFA application submission processes and budgeting if questions arise prior to the award. Applicants should submit a letter of intent to PATH via email to <a href="mailto:MatrixTechAcceleratorRFA@path.org">MatrixTechAcceleratorRFA@path.org</a>. Applicants may submit questions and applications via the same email. Following submission, applications will be screened for responsiveness to this RFA and scientific priority. The responsive applications with the highest scientific priority will be advanced for review. PATH will manage the review using procedures designed to minimize conflicts of interest and ensure confidentiality of the applications. The review committee will be co-chaired by PATH personnel from the United States and SSA, and the review committee will be composed of internal MATRIX and external subject matter experts. Feedback from the review committee and USAID may be used to modify the final scope of work of the award.

Terms and conditions of the solicitation that apply to the award process and award are included in section XII of this document.

## Step 1. Letter of intent (optional)

By the date listed in section II of this document, prospective applicants are encouraged to submit a nonbinding letter of intent that includes the following information:

- Descriptive title of proposed activity.
- Name(s), address(es), and telephone number(s) of the PI(s).
- Names of other key personnel.
- Name of participating organization(s).
- Number and title of this funding opportunity.
- Names of suggested reviewers or people who should not review the application due to potential conflict(s) of interest.
- Names of any potential conflict(s) of interest with individuals or organizations within MATRIX.

The letter of intent should be sent via email to <a href="MatrixTechAcceleratorRFA@path.org">MatrixTechAcceleratorRFA@path.org</a>.

If a PI intends to submit multiple applications, separate letters of intent should be sent for each application.

The subject line of the email should read as "RFA2024-003\_letter of intent\_organization\_PI name." The PI's name should be first initial and last name, such as J Doe, and the organization name can be abbreviated. For example, an application from PATH would read as "RFA2024-003\_letter of intent\_PATH\_J Doe."

## **Step 2. Fact-finding questions (optional)**

Questions concerning this opportunity are welcome. Questions and answers to all questions will be provided to all participants who confirm interest. See section II of this document for related dates. Questions received after the due date may not be accommodated.

The fact-finding questions should be sent via email to <a href="MatrixTechAcceleratorRFA@path.org">MatrixTechAcceleratorRFA@path.org</a>.

The subject line of the email should read as "RFA2024-003\_organization\_fact-finding questions\_PI name." The PI's name should be first initial and last name, such as J Doe, and the organization name can be abbreviated. For example, an application from PATH would read as "RFA2024-003\_PATH\_fact-finding questions\_J Doe."

# Step 3. Responsiveness (optional)

If you have any questions about whether the research focus of your application meets the definition of primary prevention, please do the following for an immediate reply on responsiveness: Send an email to <a href="MatrixTechAcceleratorRFA@path.org">MatrixTechAcceleratorRFA@path.org</a> with the subject line "Determination of responsiveness to RFA2024-003\_PI name" and a brief description of your proposed research. Descriptions of the research focus should be no more than 50 words in length. Longer descriptions will not be reviewed. The reply will be either "responsive to the RFA" or "nonresponsive to the RFA" with no additional information. Being identified as responsive to

the RFA does not imply any potential for funding. Requests received after March 22, 2024, will not receive a reply prior to the application deadline.

## **Step 4. Application**

#### **Submission requirements**

Completed applications should be submitted by email to <a href="MatrixTechAcceleratorRFA@path.org">MatrixTechAcceleratorRFA@path.org</a>.

The subject line of the email should read as "RFA2024-003\_application\_organization\_PI name." The PI's name should be first initial and last name, such as J Doe, and the organization name can be abbreviated. For example, an application from PATH would read as "RFA2024-003 application PATH J Doe."

A letter of intent is not required to submit an application. Applications received past the indicated deadline will not be considered.

#### Formatting requirements

Applications that do not follow the requirements below will be returned without review:

- Applications must be in English.
- Budgets must be in US dollars.
- The main narrative application and budget narrative must be written in 11-point font or larger in a standard font (e.g., Arial, Calibri, Times New Roman). Pages must be on US letter-sized paper (8.5 x 11 inches or 22 x 28 cm) with 1-inch margins (2.54 cm). Pages must be numbered using an "X of Y" format in the lower-left-hand corner (e.g., "3 of 5"). Tables and charts can be in 10-point font.
- Biographical sketches, or biosketches, should follow the US National Institutes of Health biosketch guidelines, without the "Contributions to Science" section (https://grants.nih.gov/grants/forms/biosketch.htm). An eRA Commons account is not required for application.
- The detailed budget must be submitted in an unlocked Excel file. All other files must be submitted as PDF files. Do not send locked or password-protected PDF files.
- If confidential data or information are contained in the application, the phrase "Confidential—do not disseminate" must be placed in the footer of each page.
- Each submitted document should use the following naming conventions:
  - o RFA2024-003 file name PI name.
  - The PI's name should be first initial and last name, such as "J Doe."

#### **Application components**

Your submission should include the following six attachments:

Main narrative (use the template provided): A template for the main narrative is attached
to this RFA. The template will also be sent to all applicants who express interest. Label this
file "RFA2024-003\_main narrative\_PI name." The narrative should comprise the following:

- a. Technical application (five-page limit): The technical application should describe how your project addresses the objectives of the RFA and how you would work with MATRIX and its partners to achieve the deliverables. See section X of this document for detailed technical application requirements.
- b. Mentorship support statement (one-page limit): For early-stage PIs (e.g., postdocs or graduate students), your mentorship support statement should identify the applicant's mentor(s) and his or her qualifications. For established PIs, your mentorship support statement should detail how project funds will be used to train scientists. It should also indicate what support will be provided through your institution and what support may be needed from MATRIX. The requested support must be congruent with the scope of MATRIX (<a href="https://matrix4prevention.org/">https://matrix4prevention.org/</a>) and limited to mentoring and support of the proposed activities. Note that MATRIX does not guarantee that it can or will fulfill specific support requests.
- c. Future funding (one-page limit): This section should describe the impact of the work on future funding and/or career advancement.
- Biosketches (for relevant personnel only, limited to five personnel; no page limit):
   Label this file "RFA2024-003\_biosketches\_PI name." The suggested format is a US National Institutes of Health biosketch without the "Contributions to Science" section (<a href="https://grants.nih.gov/grants/forms/biosketch.htm">https://grants.nih.gov/grants/forms/biosketch.htm</a>). An eRA Commons account is not required for this application.
- 3. **Detailed budget (use template provided; no page limit)**: See section IX of this document for detailed budget requirements. The template is attached to this RFA; it will also be sent to all applicants who express interest. Label this file "RFA2024-003" detailed budget PI name."
- 4. Budget narrative (use template provided; no page limit): The budget narrative should describe how you arrived at the total dollar amount in each line item of your detailed budget. It should also provide justifications for each proposed budget item. See section IX of this document for detailed budget narrative requirements. The template is attached to this RFA; it will also be sent to all applicants who express interest. Label this file "RFA2024-003 budget narrative\_PI name."
- 5. Tax information (W-9 for US-based entities or W8-BEN-E for non-US entities): Label this file "RFA2024-003\_W9 or W8\_PI name."
- 6. Risk assessment questionnaire (use form provided): The template is attached to the RFA; a form will also be sent to all applicants who express interest. Label this file "RFA2024-003\_RAQ\_PI name." To fill out this form electronically (preferred), the latest version of Adobe Acrobat is required. If you have challenges filling out the form electronically, you may fill out the form in hard copy and send a scanned file with any required sub-attachments.

# **Step 5. Conclusion of process**

Applicants will be notified of MATRIX's and USAID's decision by the date listed in section II of this document. See section XI of this document for the review criteria that will be used to evaluate submissions. Final awards are 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.

Unsuccessful applicants will receive feedback from the review panel. Applicants who were unsuccessful are welcome to modify their applications and submit a new application in future rounds of the RFA.

# IX. Application requirements—financial

## **Detailed budget (use template provided)**

Budgets must be in US dollars.

Budgets must list itemized costs for the total scope of this project based on the scope of work and deliverables outlined in section VII of this document. The final scope of work may be subject to negotiation. However, application selection will be made based on the original scope of work.

The budget template provides more instructions and separates costs into the cost categories outlined below:

#### Personnel—inclusive of salary and leave:

- Salary rates of key staff.
- Total number of days in budget for each staff member.
- Fringe benefits: Costs associated with benefits.

#### Travel:

- Transportation and per diem costs (other travel-related costs, such as vaccines and passports, should be listed in the "other direct costs" section).
- Limited to one scientific meeting annually, plus well-justified travel necessary for coordination among collaborators.

#### Equipment:

- Equipment is defined as an item costing US\$5,000 or more and having a useful life of more than 1 year. Note: At USAID's discretion, equipment may need to be returned at the end of the award period.
- The budget for equipment must not exceed 10 percent of the total budget. Any application requesting an equipment budget greater than 10 percent will be returned without review.
- Electronic equipment—such as computers, tablets, and smartphones—must be well
  justified for the proposed work. They should be listed as a separate line item in the
  budget.

#### Supplies:

- Supplies and materials required to perform the scope of work.
- Animal acquisition and handling costs need to be kept as separate line items.

#### Contractual costs:

- o Consultants.
- o Subagreements.
- Subcontractors.
- Construction—not applicable for this scope of work: Applications with requests for costs
  to construct or modify research spaces to conduct the proposed work will be returned
  without review.

#### Other direct costs:

- o Itemization of all other direct costs that do not fall under the categories above.
- Non-allowable direct costs include construction of, or modifications to, research spaces; rent; general office equipment; and transportation costs not associated with described travel. Applications with such requests will be returned without review.

#### Indirect costs:

- Organizations with a Negotiated Indirect Cost Rate Agreement (NICRA) with the US government may use that rate.
- Organizations that do not have a NICRA may submit an application to PATH justifying an indirect cost rate that will be consistently charged across all of the entity's programs.
   If an indirect rate is budgeted, a NICRA or other supporting documentation that outlines a cost allocation policy and methodology must be provided.

**Cost sharing**: USAID requires a 5% cost sharing for all awards. Awards will not be made without a commitment from your institution or partners for cost sharing. Cost sharing can come from various sources, including but not limited to volunteer services, donated employee time, donated supplies, cash contributions, donated equipment, or project co-funding. Resources must come from non-USAID funds. The cost share requirement can be met throughout the life of the award. In the template for budget narrative, describe how your project will meet the cost sharing requirements.

Please refer to Section XII and 2 CFR [Code of Federal Regulations] 200.306 for additional information.

# Budget narrative (no page limit, use template provided)

The budget narrative should follow the layout of the detailed budget and describe how you arrived at the total dollar amount for <u>each</u> line item of your detailed budget.

If end-user research is included in a research application, end-user research that is focused on identifying critical rheological and/or "look and feel" properties of a drug delivery system that is proposed for development must be 25 percent or less of the proposed research and research budget. Use the budget narrative to highlight costs related to end-user research and provide a breakdown of costs related to that activity.

# X. Application requirements—main narrative

## **Technical application (five-page limit)**

Provide a narrative on your technical approach to accomplish the scope of work and deliverables, per section VII of this document, including:

- PI details: name, title, organization, department, country, email address.
- Discussion of project management and roles of the project team.
- Significance and innovation.
- Description of technical approach broken down into one to three specific aims.
- Timeline to meet the deliverables:
  - Application should include a timeline that describes the research to be performed. It is preferred that the timeline be depicted as a graphical representation (e.g., Gantt chart), although a table format is also acceptable.
  - Applicants must provide appropriate milestone(s) and go/no-go decisions to be achieved at the halfway point and at the end of the proposed research. Milestones and go/no-go criteria should not be restatements of specific aims; rather, they should be independent descriptive statements that quantify success or failure of the research. Examples of milestones and go/no-go criteria are included in the attached main application template.
- Anticipated problems and solutions.
- Brief discussion of major internal and external resources, including facilities and essential equipment available to support the proposed research in this application.
- A one-page statement on mentorship capacities for this project and a one-page statement of how you will leverage this work into future funding and career opportunities.

## XI. Review criteria

The following is a list of significant criteria against which applications will be assessed:

- Significance and innovation:
  - Does the proposed research address a critical need in primary HIV prevention for MATRIX's targeted populations?
  - Does the proposed research develop an original, innovative, potentially game-changing concept or technology?

#### Approach:

- Are the proposed study design, methods, and analyses adequately described and realistic for the time frame of the award?
- Does the application include proper time-bound milestones and benchmarks, including go/no-go criteria at the halfway mark and end of the proposed study?
- Are the timelines and budget appropriate and realistic for the proposed project?
- Will the generated data support the proposed outcomes and identified go/no-go criteria?

- PI's qualifications and mentorship:
  - Does the PI possess, or will he or she gain, the proper training and experience to direct and/or manage the proposed research?
  - Does the assembled team have expertise to complete the proposed work?
  - For young investigators, are the identified mentors appropriate to the proposed research? Does the mentoring plan demonstrate the advantages or training that the awardee will gain?

Note: MATRIX reserves the right to include additional criteria.

#### XII. Terms and conditions of the solicitation

## Notice of nonbinding solicitation

MATRIX and PATH reserve the right to reject any and all applications received in response to this solicitation. MATRIX and PATH are in no way bound to accept any application.

## Confidentiality

All information provided to MATRIX and PATH by the applicant as part of this solicitation will be treated as confidential. If any information is inappropriately released, MATRIX and PATH will seek appropriate remedies as allowed. With the fact-finding questions as an exception, all letters of interest, applications, discussions, and information received in response to this solicitation will be held as strictly confidential within the MATRIX consortium and its partners, except as otherwise noted.

# Conflict of interest (COI) disclosure

Applicants must disclose any actual or potential COIs via email to <a href="MatrixTechAcceleratorRFA@path.org">MatrixTechAcceleratorRFA@path.org</a>. A COI could be present if there is a personal relationship with a MATRIX and/or PATH staff member that constitutes a significant financial interest or if there are board memberships, other employment, or ownership or rights in intellectual property that may be in conflict with the applicant's obligations to MATRIX and/or PATH. When necessary, a management plan that provides mitigation of potential risks presented by the disclosed COI will be created. Not reporting any COI via email indicates that no COIs are present. Failure to disclose any actual or potential COI will result in the application being returned without review.

# **Communication during application process**

All communications regarding this solicitation shall be directed to <a href="MatrixTechAcceleratorRFA@path.org">MatrixTechAcceleratorRFA@path.org</a>. Contacting third parties that are not part of the research team but are involved in MATRIX or operations of TA-D1, the review panel, or any other party may be considered a COI and could result in disqualification of the application.

#### Acceptance

Acceptance of an application for evaluation/review does not imply funding of the application as submitted, nor does it imply acceptance of its terms and conditions. MATRIX and PATH reserve the right to negotiate on the final terms and conditions of the award. MATRIX and PATH additionally reserve the right to modify the substance of the finalist's application, such as milestones and go/no-go criteria, as well as the option to accept partial components of an application, if appropriate. Required flow-down clauses are listed under "Terms and Conditions of the Award" (section XII) of this document and are nonnegotiable.

## **Third-party limitations**

MATRIX and PATH do 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 MATRIX and PATH in any way without our express written consent.

## **Application validity**

Applications submitted under this request shall be valid for 90 days from the date the application is due.

#### Intellectual property

Intellectual property generated under this award will be owned by awardees who are nonfederal entities. USAID can access the intellectual property and may authorize it for US federal purposes. See "Terms and Conditions of the Award" (section XII) of this document for further details.

#### Conflict resolution

The PI is responsible for conducting the research in accordance with the agreed-upon scope of work. Additionally, it is the responsibility of the PI to manage research collaborations and any conflicts that arise within the proposed research team.

Throughout the award period, project teams are expected to meet with an assigned technical liaison to track progress and risks. Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) or any missed milestones or no-go decisions reached will necessitate a meeting with the technical liaison, TA-D1 co-chairs, and the MATRIX leadership to discuss the future of the project. MATRIX leadership will make the final decision on how the project will proceed.

#### Terms and conditions of the award

USAID, the federal awarding agency for this award, specifies the requirements to be placed on all funded research. These terms and conditions are nonnegotiable upon acceptance of the award. Applicable links to 2 CFR 200, 2 CFR 700, and Standard Provisions are included below as a reference:

- 2 CFR 200 applies to US- and non-US-based organizations: https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200?toc=1.
- 2 CFR 700 applies to US- and non-US-based organizations: https://www.ecfr.gov/current/title-2/subtitle-B/chapter-VII/part-700.
- Mandatory Standard Provisions for US-based organizations: https://www.usaid.gov/ads/policy/300/303maa.
- Mandatory Standard Provisions for non-US-based organizations: <a href="https://www.usaid.gov/ads/policy/300/303mab">https://www.usaid.gov/ads/policy/300/303mab</a>.
- Mandatory Standard Provisions for Fixed Amount Awards for US- and non-US-based organizations: <a href="https://www.usaid.gov/ads/policy/300/303mat">https://www.usaid.gov/ads/policy/300/303mat</a>.