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Addendum Number: No. 02

The Simplification of Linkage to and Delivery of Antiretroviral Therapy in USAID/PEPFAR Supported Programs
Addendum No. 02
To
The USAID Development Innovation Accelerator
Broad Agency Announcement for Global Health Challenges

SECTION A. BAA OVERVIEW

1) This Broad Agency Announcement (BAA) seeks opportunities to co-create, co-design, co- invest, and collaborate in the development, testing, and scaling of innovative approaches that address critical global health challenges. The United States Agency for International Development (USAID) invites organizations and companies to participate with USAID, in cooperation with its partners, in response to a Global Health Challenge Addenda issued under this BAA, as described below, to provide innovative interventions and technologies that further the U.S. Government's commitment to prevent and manage critical global health challenges.

2) Federal Agency Name:
The United States Agency for International Development (USAID), and administered through the Global Health Bureau.

3) Opportunity Title:
The USAID Global Health Development Innovation Accelerator BAA

4) Announcement Type:
This BAA serves to inform the public of the opportunity for funding from USAID, in cooperation with its partners, to address pressing global health challenges. Actual opportunities for funding and partnering will be issued as Global Health Challenge Addenda to this BAA. The terms of this BAA apply to each Global Health Challenge Addendum. Individual Global Health Challenge Addenda may have specific requirements for evaluation criteria and administrative information, such as the requirements for expressions of interest, concept papers, and response deadlines.

5) Opportunity Number:
BAA-GLOBAL HEALTH-2015

6) Authority:
   This BAA is issued under Federal Acquisition Regulations (FAR) Part 35.016(c). This is not a FAR Part 15 procurement.

7) Catalog of Federal Domestic Assistance (CFDA) Number:
   98.001, USAID Foreign Assistance for Programs Overseas.

8) Response Date:
   The response date, as well as instructions to responders, is established by individual Addenda to this BAA.

Overall Purpose and Specific Rights Reserved for the Government under this BAA

1) This BAA is a competitive approach to consider proposals that harness scientific research and innovation to help prevent and manage critical global health challenges, allowing USAID and other funding Partners to:
   a) Reach out to potential partners with recognized expertise in relevant areas, and
   b) Co-create, co-design, co-invest, and collaborate with partners.

2) Multiple awards are anticipated. The amount of resources made available under this BAA will depend on the concepts received and the availability of funds. Some award types may not include any funding.

3) This BAA reserves specific rights for the Government, in addition to rights described elsewhere in this document or by law or regulation, including:
   a) The right to select for negotiation and award all, some, one, or none of the proposals received in response to this solicitation.
   b) The right to make awards without discussions, or to conduct discussions and/or negotiations, whichever is determined to be in the Government's interest.
   c) The right to accept proposals in their entirety or to select only portions of proposals for award or co-investment.
   d) The right to select for award an instrument type that is appropriate to the specific development context, partner relationship, and concept selected for award. Instruments types include but are not limited to contracts, grants, cooperative agreements, Global Development Alliance agreements, Development Innovation Agreements, Inter Agency Agreements, Government to Government Agreements, Donor to Donor Agreements, and Memorandums of Understanding. In addition, the Government may craft a new instrument type to meet the needs of a specific relationship.
   e) The right to co-create projects with one or more submitter under this BAA, when it is in the best interest of the Government.
   f) The right to request any additional, necessary documentation upon initial review. Such additional information may include, but is not limited to, a further detailed proposal, budget, and representations and certifications.
   g) The right to fund or co-invest in proposals in phases, with options for continued work at the end of one or more of the phases.
   h) The right to remove proposers from award consideration should the parties fail to reach agreement on award terms, conditions, and cost/price within a reasonable time, the

proposer fails to timely provide requested additional information, or the Government believes it is in its best interest.

SECTION B. BAA ADDENDUM No. 02 -PROGRAM DESCRIPTION

Program Summary

Under this Broad Agency Announcement (BAA) and in support of the United States Agency for International Development's (USAID) objective to co-create, co-design, co-invest, and collaborate in the development, testing, and scaling of innovative approaches that address critical global health challenges, this addendum (Addendum No. 02) will provide innovative interventions and technologies that further the U.S. Government's (USG) commitment to prevent and manage a critical global health challenge; the treatment of HIV positive people.

This Addendum supports the overall purpose and specific rights reserved for the Government under this BAA.

Problem Statement

The USG has made an historical commitment in its support of an AIDS free generation through the President's Emergency Plan for AIDS Relief (PEPFAR). Under PEPFAR 3.0 which emphasizes control of the epidemic, PEPFAR is committed to supporting the achievement of the Joint United Nations Programme on HIV/AIDS' (UNAID) fast track treatment goals (see the following link for additional information about PEPFAR 3.0 - http://www.pepfar.gov/documents/organization/234744.pdf). To do so and in light of reduced budgets that will continue to contract over time, sustainable, simpler, and less expensive ways of delivering successful Anti-Retroviral Therapy (ART) programs must be better understood and brought to scale. New ART regimens are also on the horizon that could substantially reduce the cost and complexity of ART implementation. ART, when initiated according to scientifically based recommendations and adhered to over time, has a definitive impact for the health of an individual and for reduction of transmission of HIV. Overall, there are a number of emerging technological and programmatic innovations which are potentially synergistic with one another and have great promise to facilitate ART expansion and improve outcomes.

What We Are Looking For

USAID is looking for Expressions of Interest that clearly demonstrate the following attributes:

- Innovation, including creativity of the given approach and clear differentiation from existing approaches;
- Low-cost or highly cost-effective;
- Strong likelihood of achieving a substantial impact;
- Scalable in resource-poor settings; and
- Ability to be monitored, measured, and evaluated.

Solutions Sought

To maintain the enormous gains made in lives saved by ART, expand coverage and strengthen retention of patients on ART, USAID specifically seeks solutions that will bring together promising and proven technologies, innovations, and approaches in the following interrelated areas:

1) Alternative modes of ART delivery such as, but not limited to, community based distribution, technology assisted distribution, and other optimized drug distribution to individuals and the cost-effectiveness of these models
2) Innovative approaches and more effective technologies for viral load monitoring including rapid cost-effective scale up methods for programs which lead to greater efficiencies in training, sample transport, result returns, and quality assurance
3) Use of technology and innovative programmatic strategies to enable more effective linkage activities from diagnosis to treatment, adherence and retention, using community and facility collaboration models for HIV and HIV/TB co-infected individuals
4) Successful care and treatment approaches that directly respond to the needs of key populations as measured by increases in the number of HIV+ individuals in key population groups that are on treatment and retained in care.
5) Promising "Test and Treat" strategies and the cost-effectiveness of models used, as they are brought to scale globally
6) Exploration of new antiretroviral drug regimens that are simpler to use, have a more robust resistance barrier, are less expensive to manufacture, and have other beneficial characteristics to meet the needs of populations in low-income countries, including women and children

This Addendum will be funded with both headquarters' Office of HIV/AIDS (OHA) and USAID field mission funds. As such, activities (co-created by implementing partners) supported by the Addendum will be driven by joint planning and management by both OHA and field mission teams.

Partners

This Addendum seeks to bring together a collaboration of willing partners with complementary skill sets to address the historic public health challenge of scaling up ART to tens of millions of additional people over the coming decade. Particularly desired are foreign organizations, as defined in 2 CFR 200.47, that are NGOs or academic institutions in high prevalence countries in Africa who have a proven track record in leading highly successful and innovative programs in HIV-related groundbreaking science, technology, ART delivery, and the monitoring of patient outcomes in both the general, key, and priority populations.

Other desired partners are ~~generic~~ pharmaceutical companies that have the capacity to develop, test, manufacture, register, and introduce new and improved ARV regimens for patients in low and middle-income countries; companies with other technological capacity or products related to diagnostics or information technology that could soon be deployed to make substantial improvements in ART delivery; and private sector groups with expertise in re-design of medical interventions and systems to better meet end-user needs and preferences.

Multi-national organizations, academic institutions, private sector, and NGOs that have capacity to add value to a global effort to support and facilitate multi-country coordination and cross-fertilization related to ART simplification may also be useful in such efforts, though it is expected that foreign organizations will lead in-country implementation arising out of future collaborations.

The intent of this Addendum is to bring outcome driven, cost-effective approaches and models to scale. While ongoing quantified monitoring and measurement are implicit, this addendum will focus on service delivery and implementation, not on research. Evaluation may be conducted at determined intervals by an independent entity.

SECTION C: SUBMISSION GUIDELINES AND INSTRUCTIONS

Submission Overview and Timeline

Expressions of Interest (EOIs) must indicate the development idea that will serve to advance potential solutions, as outlined under the Solutions Sought section above. Applicants should elaborate on how these solutions will be implemented at scale, by utilizing scientific discoveries or advancements in technology, processes, methods, devices, or techniques, advancing the state of the art, or using scientific and technical knowledge in the design, development, testing, or evaluation of a potential new product or service (or improvement of an existing product or service). Organizations are encouraged to consider collaborating with peer organizations that bring differing perspectives and/or comparative advantages.

USAID will review and select EOIs submitted in accordance with the guidelines and criteria set forth in this Addendum. USAID reserves the right to disregard any EOIs that do not meet the guidelines.

Please submit your Expression of Interest in English to HIVTreatmentSubmissions@usaid.gov**, no later than 11:59 pm EST, June 22, 2015**.

Selected Applicants will be invited to join the co-design process which will consist of a co-creation workshop(s) in Washington, DC, where USAID, partners, and selected groups will gather to collaboratively develop the program(s). This will result in one or more concept papers of 5-7 pages each, outlining the concrete programmatic plan, focus areas, goals, timelines, etc.

There is no guarantee that participation in the co-creation workshop will lead to an award from USAID. This is a collaborative process and the outcome may be that all, some, or none of the workshop participants will be engaged in the final project. The co-creation workshop is an opportunity to team up, brainstorm, and prepare the skeleton for a research or applied research proposal that USAID may or may not fund.

Final concept papers will be submitted to USAID's Internal Review Board. Approved concept papers for programs will be further refined (co-design) and potentially implemented.

USAID is not obligated to issue a financial instrument or award as a result of this Addendum.

Unsuccessful Projects: Applicants with unsuccessful Expressions of Interest will receive notice that they were not selected.

Information Protection

USAID's goal is to facilitate the development that is required to lead to innovative and potentially commercially viable, solutions. Understanding the sensitive nature of Applicants' information, USAID will work with organizations to protect intellectual property.

EOIs should be free of any intellectual property that the Applicant wishes to protect, as the EOIs will be shared with USAID partners as part of the selection process. However, once Applicants have been invited to engage in further discussions, applicants will work with USAID to identify proprietary information that requires protection.

Therefore, organizations making submissions under this BAA Addendum hereby grant USAID a royalty-free, nonexclusive, and irrevocable right to use, disclose, reproduce, and prepare derivative works, and to have or permit others to do so to any information contained in the expressions of interest submitted under the BAA Addendum. If USAID engages with the organization regarding its submission, the parties can negotiate further intellectual property protection for the organization's intellectual property. Organizations must ensure that any submissions under the Addendum are free of any third party proprietary data rights that would impact the license granted to USAID herein. This Addendum falls under the Development Innovation Accelerator Broad Agency Announcement for Global Health Challenges. Specifically, this Addendum is focused on monitoring, evaluation, research and learning.

Submission Instructions

Submitted Expressions of Interest (EOIs) will:

- Not exceed 1000 words, excluding header and optional graphics
- Contain a header with the following information, not included in word count:
    - Applicant Name/Group and Contact Information
    - Response Title
    - BAA Addendum Name/Number
    - The solution (i.e., #1-6 as described under "Solutions Sought") that the EOI is addressing; EOIs may address multiple solutions and/or applicants can submit multiple EOIs that each respond to a unique solution
- Be in .pdf or .docx format
- Contain the following:
    - Idea/approach to this Addendum, including brief identification/summary of supporting evidence (the evidence itself does not have to be submitted, but should be made available to USAID if requested)
    - Talent and other resources the Applicant is willing to dedicate to this collaboration
    - The Applicant's unique perspectives and capabilities as it relates to responding to the problem statement above, as well as abilities to harness the comparative advantages of other parties

Evaluation Criteria

The Addendum will respond to PEPFAR 3.0 strategic priorities, including program and patient outcomes and impact that can be quantified, analyzed, and brought to scale. In addition, the Addendum will be in USAID's and Global Health's strategic interest. The following criteria also will be used to determine eligibility for consideration.

1) Applicants that have experience in at least three of the six above solutions
2) Organizations that have a proven track record of success in the provision of HIV care and treatment services demonstrated by: support to high volume sites, large cohorts of over 100,000 HIV+ individuals across all age groups, and measured improvements in retention of patients over time
3) Organizations that have evidence based results in working with host country national and sub-national government's care and treatment programs
4) Preference will be given to organizations that meet the USAID Forward criteria for local organizations with experience working in geographic regions with high HIV prevalence and burden
5) Given the burden and indigenous management of the epidemic, preference will be given to African organizations
6) Preference will be given to organizations that have a documented history of peer reviewed and regionally or internationally recognized HIV related basic or applied research
7) Demonstrated experience in developing innovative approaches along the continuum of care from patient identification to long term retention in care
8) ~~Generic~~ Pharmaceutical companies and other organizations with evidence based, promising, new and innovative approaches regarding development, testing, manufacturing, registering, and introducing new and improved ARV regimens, are also eligible and only need experience with solution six (above).

Partners will be encouraged to work together when advantageous for program outcomes. This Addendum is expected to result in two or more implementing mechanisms.