



Combating Zika and Future Threats: A Grand Challenge for Development

Addendum 01 to

The USAID Development Innovation Accelerator
Broad Agency Announcement (BAA) for
Global Health Challenges

I. Background

The recent outbreaks of the Zika virus on the heels of the Ebola crisis reveals how vulnerable to the threat of infectious disease we are in this global, interconnected world and reminds us how fast these crises can unfold. Urbanization, migration, and climate change¹ hold the potential to make such outbreaks even more frequent and severe. Whether vector-borne like Zika, which is transmitted by mosquitos, or airborne like SARS, these emerging threats also are both opportunistic and unpredictable, often resulting in a reactive approach to containing the risk they pose and creating little incentive for investment in new tools and approaches, especially those tailored for use in developing world settings. Without sufficient incentive, cutting-edge science, technologies and innovative approaches are not being proactively applied to prepare for these future challenges. The Global Health Security Agenda (GHSA) strives to ensure that we are better prepared to prevent, detect, and respond to disease outbreaks and advance a world safe and secure from infectious disease threats. USAID recognizes that robust investment in innovative tools and approaches must be an integral part of this agenda if we are to close current gaps in our prevention, detection, and response capabilities in developing countries.

II. Solutions Sought

USAID seeks to catalyze development of the most cutting-edge technologies and approaches to ensure we have the best tools available to fight global health security threats today, as we mobilize to address Zika, and tomorrow. The goal of this Grand Challenge is to enhance our prevention, detection, and response capabilities in both the short and long term by sourcing innovations that:

- (1) Mitigate the spread and impact of the Zika virus by filling critical gaps in the pipeline
- (2) Improve our ability to prevent, detect and respond to future infectious disease outbreaks

Through this Addendum, USAID will support the further development/refinement, adaptation, testing, introduction, and scale up of innovative solutions that improve our ability to combat the current Zika

¹ http://www.nytimes.com/2016/04/05/us/politics/climate-change-health-risks.html?_r=0

outbreak and to prevent, detect and respond to future infectious disease outbreaks in the following areas:

PREVENT

- **Vector control:** The growing resistance to insecticides, the increasing occurrence of diseases carried by vectors not susceptible to standard vector control approaches (such as urban, outdoor, daytime biting mosquitoes), and potential for spillover of zoonotic diseases from animal to human populations point to a critical need for new vector control strategies. We seek novel, sustainable, and environment-neutral tools and approaches for reducing and/or eliminating (when appropriate) populations of disease vectors to prevent the spillover, spread, and amplification of vector-borne and other potential zoonotic vector-borne diseases in humans as well as methods to build the capacity of entomologists to identify and respond appropriately to specific vectors.
- **Personal and household protection:** Personal protection products to repel insects and kill viruses currently available in the market require frequent replenishment and/or reapplication and often are unappealing to end users due to factors like smell, skin or eye irritation, and comfort. Given the challenges associated with protecting against urban, daytime, and/or outdoor biting mosquitoes in particular, this paradigm must be shifted and begin to incorporate household-, school- and workplace-level protection in addition to individual-level protection products. Yet keeping predominantly outdoor breeding mosquitoes away from indoor home, school, and work environments also is challenged by the variety of building designs and materials in use and issues of social acceptability of the necessary changes and their cost. We seek rapidly deployable, affordable, scalable, acceptable, and sustainable tools and approaches to enable individuals, households, and communities to prevent and/or reduce indoor and outdoor exposure to disease and protect against transmission.
- **Healthcare worker safety:** As the most recent Ebola outbreak revealed, too often the equipment healthcare workers use to protect themselves from becoming infected is not optimally designed for either the threat at hand or the environment in which it is being used. This can impede healthcare workers from doing their jobs effectively and efficiently and put them at greater risk of infection, both of which ultimately result in lives lost. We seek bold, imaginative, forward-thinking and practical ideas to protect healthcare workers against the myriad of potential disease threats and that address known and unknown shortcomings of standard equipment as well as fill gaps where equipment does not exist yet.

DETECT

- **Surveillance:** Few easy-to-use, field-based tools for rapid, early and accurate identification of disease vectors and infection exist. Compounding this problem is a worldwide shortage of medical entomologists and animal health personnel, including veterinarians. In the absence of such skilled personnel and user-friendly tools to report animal or human morbidity and mortality, potential disease threats often go undetected until an outbreak erupts. In addition, a lack of methods for accurately estimating vector populations impedes understanding of linkages to disease transmission risk. We seek tools and approaches that help detect threats early, particularly those that originate in insects and animals (domestic and wildlife), ensure that they are reported quickly, leverage metadata and enable analysis that facilitates data-driven decision-making.

- **Clinic and laboratory systems:** Many clinics and laboratories lack the basic systems needed to ensure the provision of quality care and quality laboratory testing--they do not have a potable and stable water supply; they do not have proper tools for decontamination and lab waste management and disposal, especially for the proliferation of plastics; they do not have facilities for safe handling of highly infectious/hazardous samples; they do not have environmental control systems needed by many laboratory instruments; and they have little to no inventory management systems in place for infection prevention and control supplies or rely on outdated paper-based systems, resulting in stock-outs of essential supplies, mismanagement of procured commodities, and increased biosecurity risk. We seek simple, user-friendly tools to address these challenges, equip clinics and laboratories to provide quality care on both a routine and emergency basis, and ensure that clinics and labs are well-prepared to respond in times of crisis.
- **Diagnostics:** Existing diagnostics for infectious diseases are highly specialized, dependent upon customized reagents which may be difficult to obtain, rely on electricity or cold chain, many are designed to operate in environmentally controlled spaces and often produce results difficult to interpret by healthcare staff with limited skills, rendering them unsustainable over time. We seek cutting-edge, low-cost diagnostic platforms and technologies that can rapidly, accurately, and simply identify emerging infectious diseases at the point of care as well as contribute to detection and surveillance.
- **Sample transport:** Challenges with transporting samples for surveillance and diagnostic purposes in a timely and quality-assured manner impacts the quality of diagnosis and limits the ability to obtain samples to test from rural areas. This hampers appropriate nationwide surveillance and diagnostic efforts; hinders countries from effectively meeting International Health Regulations (IHR) to confirm a reportable condition; and also disproportionately affects the poorest and more vulnerable who do not have access to services. We seek novel approaches to efficient and appropriate transport, tracking and storage of samples to facilitate timely surveillance and diagnosis of infectious diseases.

RESPOND

- **Community engagement:** Community actions can make or break a disease outbreak response. When effectively recognized, mobilized and incentivized, communities can and will participate eagerly in activities around surveillance, deployment of vector control tools, and personal and household protection, as is needed for Zika, and beyond, as might be needed for other public health threats. Conversely, a lack of meaningful community engagement can lead to distrust of the health system and/or government, the proliferation of inaccurate information, and a population reluctant or unwilling to adopt behaviors that could prevent further disease transmission. We seek out-of-the-box approaches that inform, empower, and motivate communities to prevent disease outbreaks and to identify, report, and control outbreaks when they occur, as well as to support the health system response and enable speedy dissemination of critical information.
- **Healthcare worker tools:** On the frontlines of a disease outbreak, healthcare workers must be swift and precise to save lives and prevent further spread of disease. Yet in environments where electricity is intermittent, infrastructure is weak, essential medicines are in short supply, and both human and financial resources are often scarce, even performing routine care can be

challenging. We seek new tools and approaches that correct for these system-wide problems and enable healthcare workers in the midst of a possible epidemic to do their jobs better, faster, and cheaper.

USAID and its partners seek both innovators with novel solutions and resource partners with the ability to test and scale up innovations. We are particularly interested in resource partners with, but not limited to, the following capabilities:

- Ability to rapidly prototype and produce manufacture-ready products
- Expertise and interest in collaborating to obtain end-user feedback
- Capacity and willingness to partner to test identified solutions
- Ability to deploy solutions in contexts worldwide, particularly Central and South America

WHAT WE ARE LOOKING FOR

Generally we are 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 and appropriate for various developing country settings, particularly those lacking a consistent supply of electricity and facing frequent power outages
- Environmentally-friendly with minimal generation of excess waste material
- Ability to be scaled rapidly
- Strong likelihood of achieving a substantial impact
- Solutions that can be deployed and make significant improvements in the near-term (several months of initial investment) in the response to the current Zika outbreak or longer-term (within one to two years of initial investment) ability to prevent, detect, and respond to known and emerging disease threats.
- To have the greatest impact on future disease threats, we are particularly interested in platform solutions that can address multiple diseases rather than a single disease in isolation

WHAT WE ARE NOT LOOKING FOR

- Research that does not provide a clear path to development and testing of prevention and intervention strategies
- Solutions that are less efficacious than current technologies or approaches
- Proven approaches that are already in use in the field
- Basic research or laboratory-intensive research. Basic research is defined as research directed towards fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind

Awards are planned to be in the range of \$100,000 to \$1M.

III. Submission Instructions

Please submit an expression of interest that clearly describes your idea/approach, what makes it different from and superior to current practice, and how it is relevant to the Solutions Sought; highlights your group's unique capabilities and value to the partnership; and discusses the potential for your idea to transform the way in which the global community prevents, detects, and responds infectious disease threats. For ideas specific to the current Zika response, include a discussion of the potential for and timeframe to impact on the response.

Submitted expressions of interest will:

- Be in English
- Be submitted electronically via the link to the application platform found at [usaid.gov/grandchallenges/zika](https://www.usaid.gov/grandchallenges/zika).
- Be up to 3 pages in length, no smaller than 12 point font;
- Contain a header with the following information (included in the page count):
 - Respondent Name/Group and Contact Information;
 - Response Title;
 - BAA Addendum Name/Number;
- Contain one optional graphic that fits on an 8.5"x11" or A4 piece of paper (included in the page limit);
- Be in .pdf or .docx format

Information Protection

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

Expressions of interest should be free of any intellectual property that the submitter wishes to protect, as the expressions of interest will be shared with USAID partners as part of the selection process. However, once submitters have been invited to engage in further discussions, submitters 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 enhancing our disease prevention, detection, and response capabilities.

IV. Review of Submissions

A. Criteria

The following criteria will be applied to all expressions of interest:

1. **Idea/Approach:** Novelty, creativity and soundness of the idea/approach, its advantages relative to existing practice or products, its relevance to the Solutions Sought (Section II), and its appropriateness for developing country settings.
2. **Organizational Capacity and Value:** Strengths of your organization or consortium, including your capacity to make a unique contribution to the Solutions Sought.
3. **Impact:** The likelihood of generating substantial impact for the current Zika response and/or for improved capacity to prevent, detect, and respond to future disease outbreaks. Zika-focused approaches specifically will be assessed on potential for rapid deployment.

B. Selection Process

USAID and partners will review and select expressions of interest submitted in accordance with the guidelines and criteria set forth in this Addendum. USAID and partners reserve the right to disregard any expressions of interest that do not meet the guidelines. USAID is not obligated to issue a financial instrument or award as a result of this Addendum.

Stage 1: Selected organizations or consortia will be invited, individually or in combination, to discuss their proposals with USAID and its partners, which may result in one or more applicants being invited to submit concept notes.

Stage 2: Concept notes will be submitted to USAID and reviewed for selection. Approved proposals will proceed to an award process.

C. Timing

Zika response-focused submissions should be submitted via the link to the application platform found at [usaid.gov/grandchallenges/zika](https://www.usaid.gov/grandchallenges/zika) by May 20, 2016 at 5:00 p.m. EDT.

All other submissions should be submitted via the link to the application platform found at [usaid.gov/grandchallenges/zika](https://www.usaid.gov/grandchallenges/zika) by June 17, 2016 at 5:00 p.m. EDT.

All submissions will be accepted starting on April 29, 2016.

USAID intends to select apparently successful applicants as quickly as possible.

The USAID Broad Agency Announcement for Global Health Challenges

I. Overview

- A. This Broad Agency Announcement (BAA) seeks opportunities to co-create, co-design, co-invest, and collaborate in the research, development, piloting, testing, and scaling of innovative, practical and cost-effective interventions to address the most pressing problems in global health. The United States Agency for International Development (USAID) invites organizations and companies to participate with USAID, in cooperation with its partners, to generate novel tools and approaches that accelerate and sustain improved health outcomes in developing countries.
- B. Federal Agency Name:
The United States Agency for International Development (USAID)
- C. Opportunity Title:
The USAID Global Health Challenge BAA
- D. Opportunity Number: Broad-Agency-Announcement-GLOBAL-HEALTH-2016
- E. Authority:
This BAA is issued under Federal Acquisition Regulations (FAR) Part 35.016 (c). This is not a FAR Part 15 Procurement.
- F. Catalog of Federal Domestic Assistance (CFDA) Number:
98.001 USAID Foreign Assistance Programs for Overseas

II. Collaboration

The intent of the BAA is to allow co-creation and co-design to the maximum extent to create high quality, effective partnerships with great efficiency in time and resources. The types of collaboration include:

- I. Co-creation. Co-creation occurs after an Expression of Interest is approved, but before the concept is developed. The potential partner, the Government, represented by the Activity Manager, and potentially others work together to write and/or revise the

Concept Paper, and jointly present the Concept Paper to USAID's Peer and Scientific Review Board.

2. Co-design/development. Co-design/development occurs after the Peer and Scientific Review Board recommends the project for further development, and the Contracting Officer or Agreement Officer has determined the proposer to be an Apparently Successful Partner. At this point, the Contracting Officer or Agreement Officer may determine the general nature of the award type or the specific award type, depending on the nature of the project, to facilitate project design. During co-design, the Apparently Successful Partner and the Activity Manager will design the technical approach, general resource requirements, and management control of the project under the guidance of the Contracting Officer/Agreement Officer.
3. Co-invest. Co-invest refers to the Government's strategic aim that the partnerships resulting from the individual BAA awards represent opportunities to achieve mutual or complementary development goals of the Partner, USAID, and potentially other resource partners, and therefore embrace shared responsibility, shared risk, and shared resourcing. Shared resourcing may be accomplished through funding by both parties, either through cash resources or the exchange of other resources, both tangible and intangible, such as in-kind contributions, expertise, intellectual property, brand value, high-value coordination, and access to key people, places, and information. Co-investing does not require equally shared resourcing (such as 1:1 leverage), but rather resource contributions that are appropriate to the specific project's objectives, considering the comparative advantages brought by the participation of each party and the award type.

III. Specific Rights Reserved for the Government under this BAA

The Government reserves specific rights, in addition to rights described elsewhere in this document or by law or regulation, including:

1. The right to award multiple awards, a single award, or no awards.
2. The right to make award without discussions, or to conduct discussions and/or negotiations, whichever is determined to be in the Government's interest.
3. The right to accept proposals in their entirety or to select only portions of proposals for award or co-investment.

4. The right to select for award an instrument type that is appropriate to the specific development context, partner relationship, and proposal 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.
5. The right to co-create projects with one or more proposers under the BAA, when it is in the best interest of the Government.
6. 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.
7. 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.
8. The right to award instruments under this BAA that do not commit or exchange monetary resources.
9. 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.

V. Problem and Challenge Statements

PROBLEM: The global community has made great strides in reducing mortality around the world over the last 50 years, but progress in developing countries lags far behind that seen in developed countries. Every year an estimated 303,000 women die during pregnancy and childbirth, 5.9 million children die, and an even greater number become infected with life-threatening diseases like HIV/AIDS, malaria, diarrhea, pneumonia, and TB, among others. The vast majority of deaths due to these largely preventable causes occur in developing countries where access to health services is often poor. Outbreaks of emerging infectious diseases like Ebola and Zika only serve to further compound these health challenges, taxing already stressed health systems and elevating the risk of disease epidemics of global proportions.

CHALLENGE: Harness the power of science, technology, and innovation to generate new knowledge, tools, and approaches that can reduce developing country mortality down to the levels of more developed countries within a generation. USAID and partners will work to rapidly implement solutions and create an environment for sustainability, scalability, and ultimately health impact.

V. Criteria for Consideration

- A. Initial submissions are not evaluated against other submissions, but solely whether USAID believes that the submitter will be a valuable contributor to the co-creation process. USAID may need to limit the number of initial submissions selected to move forward based on efficiencies.
- B. Concept Papers are not evaluated against other submissions, but solely based on USAID's determination that the Concept Paper will successfully address the Problem and Challenges set forth herein. USAID may need to limit the number of Concept Papers selected to move forward based on efficiencies.
- C. Decisions regarding USAID's pursuit of a particular project, technology or relationship are based on the available evidence, data, and resulting analysis. USAID seeks solutions that have a significant impact (i.e. breakthroughs, not incremental improvements), and can achieve that impact at scale.
- D. The reputations of an organization, its past performance, the managerial and technical ability of the person or team of people engaged in the endeavor are always significant considerations in assessing the potential and the risks associated with each award.
- E. Additional criteria that may be considered under this BAA to indicate that the submission successfully addresses the Problem and Challenges will be specified in each Addendum.

VI. Award Stages

The amount of resources made available under this BAA will depend on the Addenda issued, concepts received, and the availability of funds. Some award types may not include any funding. The award process under this BAA generally has the following steps:

Stage 1

Expression of Interest: Potential partners will submit an Expression of Interest in response to a Global Health Challenge Addendum.

Expressions of Interest must indicate the research or development idea which will work towards discovering potential solutions to the Problem and Challenge Statement(s), by increasing knowledge and understanding of potential solutions, exploiting scientific discoveries or improvements in technology, materials, 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 of an improvement in an existing product or service).

Stage 2

Development of the Concept Paper. For Expressions of Interest which are deemed to have merit by USAID and pass criteria/eligibility stated within the BAA and/or specific addenda, USAID will issue an invitation to collaborate to the potential partner to participate in a co-creation workshop, conference, meeting, or the method designated by USAID to work together with all invitees to further develop the idea presented in the expression of interest.

Note that due to the large number of Expressions of Interest, USAID is unable to provide detailed information to those EOIs that are not selected to move forward.

Working together, USAID and the potential partner will collaborate on a Concept Paper. It is during this phase of co-creation and co-design that the parties will begin to determine additional partners and resources to complement the project. The Concept Paper, generally 5-10 pages, will further detail and explain the project as initially provided in the Expression of Interest.

Additional Partners/Resources. During the project co-creation and co-design, both the Apparently Successful Partner and USAID will identify additional partners and resources, and whether additional mechanisms are necessary to implement the project.

All potential partners may not move forward to Stage 3.

Stage 3

Review by the Peer and Scientific Review Board. Concept Papers developed during Stage 2 will be reviewed by the Peer and Scientific Review Board, comprised of experts from USAID, partners, and/or outside parties. The Peer and Scientific Review Board will review Concept

Papers and recommend which applicants should be considered Apparently Successful Partners. Using its technical expertise, the Peer and Scientific Review Board will recommend whether to move forward with the project including revisions/additions to the project, and potential partners and resources.

All potential partners may not move forward to Stage 4.

Stage 4

Contracting/Agreement Officer Determination. The Contracting/Agreement officer will review the Peer and Scientific Review Board's recommendations and consider other information, such as resource availability, preliminary partner responsibility assessment, and Agency priorities, and will make a determination that the respondent is an Apparently Successful Partner. The Contracting/Agreement Officer may also make or narrow down the anticipated instrument type to facilitate project design.

Request for Additional Information. USAID will work with partners identified by the Peer and Scientific Review Board, and co-design the project and assist the partner to provide additional information with respect to the proposer's technical approach, capacity, management and organization, past performance, and budget, as well as representations and certifications, as needed.

Final Review and Negotiation. The USAID Contract/ Agreement Officer will engage in final review, negotiation, and determinations of instrument type, responsibility cost reasonableness, etc., and will craft an award instrument with the Apparently Successful Partner. If the Apparently Successful Applicant and USAID cannot arrive at a mutually agreeable arrangement, the Contract/ Agreement Officer will cancel the project at no cost to the Government.

Award. Where USAID determines that the award of an instrument is appropriate, the USAID Contract/ Agreement Officer will award the instrument.

VII. Award Information

Number of awards could vary and may not mirror the number of expressions of interests or invitees to co-creation.

- A. Awards under this BAA will be made to Apparently Successful Partners on the basis of their ability to further USAID's goals of accelerating progress in global health. USAID is seeking new applications of science, innovations, and partnerships that provide the best

value to the Government and have the potential to substantially contribute to these goals.

- B. Proposals identified for negotiation may result in a contract, grant, cooperative agreement, Global Development Alliance agreement, Development Innovation Agreement, Inter-Agency Agreement, Government to Government Agreement, Donor to Donor Agreement, Memorandum of Understanding or alternative agreement type, depending upon the nature of the work proposed, the required degree of Government involvement, and other factors. The Government Contracting/Agreement Officer will determine award instrument type and negotiate instrument terms and conditions with selectees. USAID may select the award instruments it deems appropriate.
- C. Eligibility Information. Public, private, for-profit, and nonprofit organizations, as well as institutions of higher education, public international organizations, non-governmental organizations, U.S. and non-U.S. governmental organizations, multilateral and international donor organizations are eligible under this BAA. All organizations must be determined to be responsive to the BAA and sufficiently responsible to perform or participate in the final award type.
- D. Standard Clauses and Provisions of Award. The standard clauses or provisions for awards are generally prescribed by law and regulation and will vary considerably by award type. Information regarding clauses and provisions will be offered to the proposer when the award type is identified.
- E. Organizations are encouraged to consider providing reasonable cost sharing, leverage, or other exchange of resource arrangements, and are encouraged to suggest creative approaches to resourcing projects.

VIII. Information Protection:

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

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

Therefore, organizations making submissions under this BAA grant to 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. 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 this BAA are free of any third party proprietary data rights that would impact the license granted to USAID herein.