



## Solicitation for Proposals

### Emerging Technologies for Point-of-Care Diagnostics for Low-Resource Settings

#### I. Summary of Deadlines

All deadlines are 17:00 Pacific Daylight Time.

Item	Due Date
Request for letters of interest announcement	December 8, 2009
Questions regarding the request for letters of interest	December 17, 2009
Responses to questions published	December 22, 2009
Letters of interest due	January 22, 2010
Initial candidates selected	February 2, 2010
Questions on the solicitation	February 12, 2010
Responses to questions published	February 17, 2010
Full applications due	March 9, 2010
Interviews (optional at the GHDx Center's discretion)	April–May 2010
Estimated award date	June–July 2010

#### II. Project Background and Purpose of Solicitation

##### A. Purpose

The Center for Point-of-Care Diagnostics for Global Health (GHDx Center) announces the availability of funds to support the development of point-of-care diagnostics for low-resource settings (LRS). The GHDx Center is managed by PATH in collaboration with the University of Washington, Departments of Global Health, Laboratory Medicine, and the Division of Infectious Diseases at the School of Medicine. Funding for the GHDx Center is provided by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) (National Institutes of Health [NIH]) as part of the Point-of-Care Technologies Research Network (RFA-EB-06-002).

The mission of the GHDx Center is to identify and catalyze the development of point-of-care diagnostic technologies to meet clinical needs in the developing world and LRS. This will be accomplished through four major activities: (1) assessment of user needs and market research into clinical diagnostic needs in LRS, (2) funding the development of emerging technologies toward applications in point-of-care diagnostics appropriate for uptake in LRS, (3) preclinical laboratory and field evaluation of early stage prototypes of new diagnostic technologies, and (4) a multiphase north-south integrated training program on the clinical realities of designing point-of-care products for LRS.

## Instructions for Responding to the Solicitation

### B. Background

For many reasons, including poverty and lack of sanitation and clean water infrastructure, LRS both in the developing world and the developed world are afflicted the most by infectious diseases. Accurate diagnosis of infectious diseases increases the opportunity for prompt and appropriate treatment of the patient. In LRS, most infectious diseases are managed syndromically, through clinical symptom algorithms which may be sensitive but not very specific. This results in many patients being unnecessarily and incorrectly treated. In addition to poor patient health outcome, these approaches can accelerate drug resistance and are not satisfactory for containment of contagious diseases. There is an urgent clinical and public health need for point-of-care diagnostics appropriate for uptake in LRS.

Effective advancements of diagnostic technologies in LRS are characterized by:

- Enhanced or improved diagnostic practices.
- Low manufacturing costs leading to a low-cost-to-user outcome.
- Low maintenance costs or disposable products.
- Limited environmental impact through chemical and biohazard containment.
- Minimal requirements for external quality control.
- Minimal requirements for end-user training.
- Rapid test results.

The GHDx Center is looking to adapt current technologies or to advance emerging technologies to meet these attributes and enable point-of-care disease testing in LRS.

### C. Funding Objectives

The purpose of this funding opportunity is to support the development of current or emerging technologies and improve point-of-care diagnostics for LRS. This funding opportunity specifically seeks to fund technologies that facilitate quantitative HIV viral load testing for case management of patients on antiretroviral therapy (ART) in LRS. While the global health community has been relatively successful in increasing affordability and access to ART, diagnostic testing for monitoring response to ART has been lagging. Specifically, HIV viral load testing which monitors levels of HIV in the patient's plasma remains expensive, and the technology is inappropriate for resource-limited settings. This solicitation seeks to fund technologies that (1) perform or support viral load testing at point of care and/or secondary healthcare facilities and district hospitals or (2) extend the reach of current centralized quantitative HIV viral load testing to remote/rural populations.

Candidate technologies should address one or more of the following processes in a diagnostic test:

- Sample collection and plasma separation.
- Analytical testing (signal amplification technologies and chemistries).
- Quantitative signal detection.
- Stabilization of internal controls (RNA) up to three months at 45°C.
- Stabilization of quality and quantitative standards (HIV RNA or virions) up to three months at 45°C and a dynamic range of 500 to  $1 \times 10^6$  HIV copies/ml.
- Reagent packaging and stability: up to three months at 45°C.

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- Integrated viral load devices are also applicable; these can be single-use or low-throughput platforms that can perform 6–20 specimens or more per run.

Proposals addressing *exclusively* pre-analytical specimens processing for nucleic acid extraction will not be competitive since the GHDx Center is already funding two projects in this area. Technologies should target a minimum analytical limit of detection of 500 to 1000 HIV copies/ml of plasma from a plasma sample volume of 200 µl and should have an analytical measuring range of 6 logs (up to  $1 \times 10^6$  copies/ml). Better or equivalent performance from equal or smaller volumes of whole blood or plasma is acceptable. Proposals addressing analytical testing, quantitative signal detection or integrated viral load test technologies should be able to detect a fivefold change in RNA copy number with a probability of 0.90. Technologies targeting analytes other than RNA are acceptable but must demonstrate strong correlation with RNA copy numbers. **Low cost and robustness of the technologies are essential features.** The GHDx Center is looking for a final combined cost of goods for reagents and consumables of under US\$5 and instrumentation of under US\$5000. The GHDx Center will fund projects to the stage of early development of prototypes. Projects may involve adapting an existing technology for application to LRS point-of-care diagnostics.

Where appropriate and applicable, the GHDx Center will provide technical and commercialization expertise to assist and monitor selected technologies towards meeting the mission of the GHDx Center, as needed. The assistance and monitoring role of the GHDx Center may be in the form of refining the target specifications of the technology or evaluating the technology as it progresses through development and, as needed, supporting the evaluation of commercial manufacturing options and processes necessary to produce low-cost, rapid diagnostic tests for utilization in LRS. This role or contribution from the GHDx Center is not a requirement.

Investigators with projects that advance to functional prototypes may apply to receive further funding under a separate competitive solicitation process from the GHDx Center for preclinical field testing in LRS. Investigators may also apply separately to the NIH for funding.

### III. Scope of Work and Deliverables

#### A. Scope of Work

The GHDx Center is seeking applications from qualified respondents that describe a technology and the activities that will advance it to an early development prototype stage. Specifically, this requires developing a technology to a stage where:

- Analytical sensitivities, specificities, or dynamic ranges of detection for a model analyte system are determined.
- An estimate of the bill of materials and, preferably, cost of goods can be determined.
- Appropriateness of the technology for uptake in LRS can be accurately assessed.
- Manufacturability of the technology can be assessed.

#### B. Deliverables

Deliverables will be negotiated with applicants prior to the award.

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### IV. Level of Funding

#### A. Level of Funding for the Receiving Institution

Applications submitted under this solicitation should be for work that will be completed in two years or less. It is anticipated that up to two separate grants will be awarded under this proposal. Each grant will not exceed US\$250,000 Total Costs over two years and not more than US\$175,000 for first-year activities. Both Direct and Indirect Costs are included in the Total Costs of the grant. Funds will be awarded on a milestone basis, as negotiated with the recipient prior to award. PATH reserves the option of accepting partial components of an application if appropriate. PATH reserves the right to discontinue funding at negotiated performance milestones. It is expected that the awards under this solicitation will be made late in the third quarter of 2010.

Grant funds may be used to support personnel and purchase equipment, supplies, and services directly related to the project. Overhead costs are allowed, but details of these costs must be provided as part of the budget, with justification of why they are needed to carry out the project.

#### B. Co-Funding

These grants can be used to supplement ongoing grants or other investments supporting the technology development. Respondents should demonstrate how this additional funding is required for this technology development to meet the intent of this solicitation. However, the proposed project should not duplicate substantially similar research that is already supported through other sources.

### V. Eligibility

#### A. Eligible Institutions

- Applications may originate from for-profit and nonprofit organizations; or from public and private institutions, such as universities, colleges, and laboratories; domestic (US) or non-domestic (non-US) entities (foreign organizations); eligible agencies of the federal government; faith-based or community-based organizations; or others within the eligibility guidelines of the NIH.
- Institutions must be willing to and demonstrate the capacity to meet NIH funding requirements. See <http://grants.nih.gov/grants/policy/nihgps%5F2003/>

#### B. Eligible Project Directors/Principal Investigators (PD/PI)

- Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply.

### VI. Application Evaluation Criteria

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Applications that are complete and responsive to this solicitation will be evaluated for scientific and technical merit by a minimum of three external peer reviewers selected in consultation with the NIBIB. Applications will be scored according to the criteria defined below.

The overall application score will be based on review and merit of the individual components as well as the merit of the application taken as a whole. All areas will be considered to have equal importance in the review process. Application components will be evaluated on the following basis:

- Technical merit and feasibility of the scope of work:
  - Consistency with aims and objectives described in this solicitation.
  - Feasibility to complete the scope of work within the requested budget.
  - Strength of the team to successfully complete the proposed scope of work.
  - Soundness of the experimental design and approach and any supporting data to indicate this.
  - Clearly stated objectives.
  - Manufacturability of the eventual product: low cost of goods, manufacture processes, final robustness of technology for use in LRS.
- Appropriateness/specifications of expected final technology to LRS:
  - Expected infrastructure requirements such as water, power, and refrigeration.
  - Expected training requirements for the targeted end users.
  - Instrument maintenance requirements, if any.
  - Improvement of diagnostic result turnaround time for the health care provider, if applicable.
  - Reduction of current testing costs.
  - Applicable to more than one disease or pathogen target of high clinical priority in LRS.
- Other factors that may be considered are:
  - Co-funding or leveraging opportunities of current activities.
  - Direct or indirect involvement and engagement of stakeholders in LRS.
  - Cost to manufacture and perceived future affordability.

### VII. Instructions for Responding

#### A. PATH Contacts

Technical/Program Contact: Gonzalo J. Domingo, PhD, Technical Officer, PATH  
Email address: [dxcenter@path.org](mailto:dxcenter@path.org)

#### B. Applicants

Only applicants who have submitted letters of interest and been invited to submit to this solicitation are eligible to respond. We will not accept applications from entities that were not selected from the letter of interest process that preceded this solicitation.

#### C. Fact-Finding Questions

Review the application form and read this solicitation document in its entirety.

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Questions on this solicitation will be accepted via email to the contact listed above through February 12, 2010. Questions and answers to all questions will be provided to applicants by email by February 17, 2010. Additionally, questions and answers will be posted on the GHDx Center web site as an FAQ. Please note that responses will **not** be confidential except in cases where proprietary information is involved. Inquiries after February 12, 2010 cannot be accommodated.

Send any questions to [dxcenter@path.org](mailto:dxcenter@path.org) prior to the above due date.

### D. Forms and Format

Application form:

Complete the application form and respond to all information requested regarding costs, qualifications, detailed description of the project, and supporting data.

Budget form:

Attach the completed budget form and budget narrative. Provide itemized costs for the total scope of this project based on the scope of work outlined in Section III. The final scope of work may be subject to negotiation. However, awards will be made against the original scope of work. Budgets should include itemized costs for key elements of the scope of work in the following categories:

- **Personnel.** Include the salary rates of key staff and level of effort on the project for each, expressed in percentage of full time effort.
- **Fringe Benefits.** Explain what is included in your fringe benefit costs. Note that leave should be included in Personnel costs.
- **Equipment.** Describe costs and the purpose of equipment required to carry out the scope of work.
- **Supplies.**
- **Travel.** Itemize all anticipated travel (number of trips, travel costs per trip, per diem costs per trip (days x per diem rate), and estimated associated costs.
- **Other Expenses.** Itemize all other expenses not listed in the categories above.
- **Indirect Costs.** Provide the basis for any indirect cost rate, such as summary financial basis or a negotiated indirect cost agreement with a cognizant US agency, if available. Indirect rates are subject to verification prior to award.

### Note:

1. Sub-contracts by the recipient to a second party are not allowable under this award. Collaborations will be accommodated by direct contracts between PATH and each collaborating entity.
2. With the exception of the American University of Beirut and the World Health Organization, full facilities and administrative (F&A) costs will not be allowed for non-US recipients. However, NIH provides limited F&A costs (8% of total direct costs less equipment) to foreign institutions and international organizations to support the cost of compliance with NIH requirements including but not limited to protection of human subjects, animal welfare, and research

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misconduct. NIH will not support the acquisition of, or provide depreciation on, any capital expenditures or support the normal, general operations of foreign and international institutions.

### **E. Attachments to Application Form**

Include all of the following as attachments to the Solicitation Application Form:

- A description of the concrete aims of your proposal (maximum of one page).
- A detailed project description. Use a maximum of 10 pages for this section including any figures and tables. The proposal should be structured as follows:
  - Background.
  - Preliminary data and supporting data.
  - Project design and details.
- A document listing major concrete milestones and timelines that are quantifiable (maximum one page).
- A list of references or citations as cited in the detailed project description in the project.
- The budget form along with a budget narrative for each line item and the indirect costs.
- A letter of support from the leading institution or directorship of the private entity.
- Curriculum vitae (CVs) of all key staff (including the Principal Investigator) from the applicant institution.

Note: All text should be in 11-point type

The GHDx Center will not consider attachments other than those specifically requested in the solicitation. Elaborate materials, artwork, or other information not directly related to the scope of work are discouraged.

### **F. Applications Due: March 9, 2010**

Submit the completed application form, with supporting materials and attachments electronically in a Microsoft document or as a PDF file to [dxcenter@path.org](mailto:dxcenter@path.org) by the above due date.

The subject line of the email should read: "GHDx Application [name of applicant]." We advise that you send files in commonly recognized Microsoft formats or as PDF files. We will not accept responsibility for resolving technical transmission problems associated with applications.

### **G. Selection of Short List**

As part of the selection process, the GHDx Center reserves the option to interview and discuss specific details with those candidates who are on the short list.

### **H. Conclusion of Process**

The anticipated date that applicants will be notified of the GHDx Center's decision is April or May of 2010. The final award is 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.

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### I. Application Checklist

- Complete the application form, including regulatory information and due diligence questions. Do not leave any requests for information blank.
- Submit a description of the concrete aims of your proposal (maximum of one page).
- Submit a detailed project description. The proposal should be structured as follows:
  - a. Background.
  - b. Preliminary data and supporting data.
  - c. Project design and details.Use a maximum of 10 pages for this section including any figures and tables.
- Submit a document listing major concrete milestones and timelines that are quantifiable (maximum one page).
- Submit a list of references or citations as cited in the detailed project description in the project.
- Complete the budget form and provide a budget narrative for each line item and the indirect costs.
- Submit a letter of support from the leading institution or directorship of the private entity.
- Curriculum vitae (CVs) of all key staff (including the Principal Investigator) from the applicant institution.

Note: All text should be in 11-point type

### VIII. PATH Statement of Business

PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being.

Headquartered in Seattle, Washington, PATH has 28 offices in 18 countries. PATH currently works in more than 65 countries in the areas of health technologies, maternal and child health, reproductive health, vaccines and immunization, and emerging and epidemic diseases.

For more information, please visit [www.path.org](http://www.path.org).

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### **IX. Terms and Conditions of the Solicitation**

*As the managing body of the GHDx Center, PATH has set forth the following terms and conditions:*

#### **A. Notice of Nonbinding Solicitation**

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

#### **B. Confidentiality**

All information provided as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed.

Applications, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

All full applications will be submitted to a minimum of three external peer reviewers for review of technical merit and feasibility of scope of work. The final two applications will be selected by the GHDx Center's scientific sub-committee. Applications of finalists selected for funding will be subject to review and approvals by the NIBIB Point-of-Care Centers' Steering Committee.

#### **C. Communication**

All communications regarding this solicitation shall be directed to appropriate parties at PATH. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest, and could result in disqualification of the application.

#### **D. Acceptance**

Award of an application does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the finalists' applications, as well as the option of accepting partial components of an application if appropriate.

#### **E. Right to Final Negotiations**

PATH reserves the option to negotiate on the final costs and final scope of work and also reserves the option to limit or include third parties at PATH's sole and full discretion in such negotiations. PATH reserves the option of accepting partial components of an application if appropriate. PATH reserves the right to discontinue funding at negotiated performance milestones.

#### **F. Third-Party Limitations**

PATH does not represent, warrant, or act as an agent for any third party as a result of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.

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### G. Special Conditions of Agreement

1. Ownership of Confidential Information. Under any Agreement to follow, each Party shall retain ownership of its existing Confidential Information and any new data generated under any Agreement to follow shall be owned by the generating Party provided that the data will be provided to the Other Party for internal use and research and development purposes or for the purposes of publication.
2. Intellectual Property Rights. Intellectual property and technologies existing prior to the effective date of any Agreement to follow shall remain the separate property of the respective Party. Any inventions that arise out of the work to be performed under any Agreement shall be disclosed to the other Party and joint or severable ownership shall be determined by USA laws of invention.
3. Publication. Either Party may publish work performed related to any Agreement to follow except that the non-publishing Party will be given sixty (60) days prior written notice in order to review and comment/approve said publication. Publication may be delayed for a total period not to exceed one hundred and twenty (120) days in order to provide for the filing for patent protection by the applicant Party. PATH may however share results and data from its Project with its Donors without restriction.
4. Independent Contractor. The Parties to any Agreement to follow will act as independent contractors and shall not be deemed to be partners, joint venturers, or each other's agents.
5. Applicable Law. Any Agreement to follow shall be governed by the laws of the State of Washington, USA, exclusive of choice of law provisions.
6. Execution of award. The final approval for funding is subject to the signing of a formal Agreement to be mutually agreed by both Parties.

### H. NIH Terms of Agreement, Regulations, Assurances and Guidelines

All awards are subject to NIH terms of agreement, regulations, assurances and guidelines.

For NIH terms of agreement please review:

<http://grants.nih.gov/grants/policy/nihgps%5F2003>

For NIH requirements involving research using human subjects please review:

<http://grants.nih.gov/grants/policy/hs/index.htm>

For NIH requirements involving the use of vertebrate animals in research please review:

<http://grants.nih.gov/grants/olaw/olaw.htm>

For NIH guidelines involving the use of recombinant DNA for research purposes please review:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html>