



Frequently Asked Questions

Laboratory and Field Evaluations of Advanced Technologies for Diagnostics in Low-Resource Settings

Q. I was wondering if further information was available regarding the solicitation announcement for POC diagnostic technologies for LRS, specifically regarding the method of detection employed. A prior solicitation from the GHDx requests technologies exploiting NAT themes only, is this solicitation similarly limited in its scope as well?

A. This solicitation is not limited to nucleic acid-based diagnostic tests. We are open to any chemistry/platforms that meet the specifications described in this RFA.

Q. What is relationship of your center with Genomic Health Inc, which is also called GHDX. Thank you for your answer.

A. We are not affiliated with Genomic Health, Inc.

Q. Please comment on what level of user expertise is acceptable for laboratory and field trial evaluation phases.

A. The ultimate goal of this RFA is to support technologies for non-expert users in low-resource setting in the developing world. However, we do understand that products are continually refined during the R&D process. For the laboratory evaluation phase, we are open to technologies with greater complexity and numbers of assay steps. However, to be eligible for the field evaluation, there must be a time-limited and clearly defined pathway for simplification of all procedures.

Q. Should a project get funded, is there precedent for company scientists spending time at the start of the trials working with PATH scientists in the laboratory in Seattle?

A. Yes.

Q. Part of the rationale for laboratory and field trials is to obtain user feedback and identify weaknesses in the system. This is critical for product development but is not something we would typically share with the “outside world” during development. How confidential are study results? Note that this is not an intellectual property question but instead is a confidential outcomes question.

A. No publication of any results will occur without the agreement of both the grantee and the GHDx Center; however, public disseminations in a timely fashion of both lab and field results that are deemed appropriate by both parties are a desirable outcome to the GHDx Center and NIBIB/NIH. The GHDx Center regularly enters into CDAs and nondisclosure agreements with partners as necessary.

Q. Please comment on how you expect system improvements to be handled during the grant term.

A. This will be addressed on a case-by-case basis. The GHDx Center acknowledges that the R&D process is iterative and that multiple generations may be necessary to achieve project goals.

Similarly, is it expected that successful technologies will progress from initial laboratory-based testing to later field testing in resource poor regions?

A. Yes, technologies that successfully perform in laboratory evaluation will be eligible for field evaluation in low resource settings in the developing world.

Q. Please comment on the PATH's relationship or experience with companies entering parallel FDA clinical trials.

A. We welcome the opportunity to work with companies that are engaged in parallel FDA clinical trial tracks. However, the scope of this RFA is to evaluate technologies for low-resource settings for global health.

Q. What other items does PATH anticipate seeing on budgets? Are there direct costs specifically excluded?

A. Budgets must account for all direct and indirect costs anticipated by the applicant. A line item budget is not required for the LOI submittal. If invited to submit a full proposal, applicants will be required provide a detailed budget and narrative, organized around the categories provided.

All awards are subject to NIH terms of agreement, regulations, assurances, and guidelines, including cost principles. Links to relevant NIH references are provided in the solicitation instructions.

Q. Diseases in low-resource settings cover a broad range of potential targets, such as TB, HIV, malaria, and Chagas. The corresponding variety of sample types is also large. Will the field trials be able to handle this wide potential variety of sample types and infectious hazard, or are specific targets recommended?

A. The GHDx Center has extensive experience in evaluating diagnostic technologies for a wide range of diseases that require varying specimen collection, handling, and disposal procedures. We will be able to accommodate a wide variety of sample types. There are no specific targets recommended.

Q. Does "have a viable pathway to commercialization" mean that commercialization partners must be already in place or are preceding stages, i.e., en route to identify partners, acceptable?

A. Being in the preceding stages or in a clear pathway to identifying partners is acceptable.

Q. Can reaching "pilot scale manufacture" status be part of the proposal, or does the technology have to be at that stage already?

A. We are not requiring that applicant technologies be at a specific stage at the beginning of collaboration. However, the applicant must be capable of reliably producing hundreds to thousands of tests for laboratory and field evaluations.

Q. In pathogen detection, is there a list of preferred pathogens? For example, does GHDx Center prefer pathogens that occur in both developed and developing countries, or does LRS pertain to developing countries exclusively, or are communities in rural USA considered LRS?

A. We do not have a preferred list of pathogens. Equal consideration will be given to pathogens that occur in LRS in developing and/or developed countries.

Q. What does “dynamic ranges of detection for a model, or clinically useful, analyte system” mean? (Instructions_GHDx_20090206.pdf)

A. We define “dynamic ranges of detection for a model, or clinically useful, analyte system” as the demonstrated range of the technology from the lowest quantity or concentration to the highest quantity or concentration of a pathogen or analyte detected, specific to a disease or condition that is relevant to an individual’s health status.

Q. What are “Proposed collaborators?” (LOI_Form_GHDx_20090206.doc)

A. Proposed collaborators would be other individuals or institutions that will contribute to carrying out the scope of work proposed. However, please note that subcontracts by the recipient to a second party are not allowable under this award.