



Questions and Answers on the Funding Opportunity Announced April 8, 2008

- Q1. If a technology does not target nucleic acid markers, but by virtue of its clinical application replaces the need for nucleic acid based tests, would this be acceptable under the current LOI? For example, a POC p24 antigen detection test for early HIV diagnosis could replace the need for NAATs in this context.**
- A. No, we are specifically looking to encourage the development of nucleic acid amplification tests (NAATs) appropriate for uptake in low-resource settings (LRS).
- Q2. May venture-backed companies participate in this grant, regardless of the level of venture investment?**
- A. Yes.
- Q3. If the proposed project does not specifically enhance the possibility to do nucleic acid-based testing at the POC in low-resource settings but does enhance diagnostic testing in LRS, would it be responsive to this solicitation?**
- A. No, we are specifically looking to encourage the development of NAATs appropriate for uptake in low-resource settings.
- Q4. We understand that the GHDx Center will provide technical and commercialization expertise. Please let us know if this would also be available for our research.**
- A. The GHDx Center would like to work with successful awardees to ensure the success of the project. This may be by ensuring that the product is developed towards meeting a clinical need and satisfying the appropriate product specifications. To this end and to the extent where it is possible, constructive, and appropriate, the GHDx Center may provide technical and commercialization expertise. This is NOT a requirement or obligation from either the awardee or the DxCenter. Any parties are welcome and encouraged to seek collaboration with the DxCenter on other relevant funding opportunities.
- Q5. We plan to outsource activities of our scope of work to external parties such as contract research organizations (CROs). Please let us know if this would satisfy the grant's eligibility requirements.**
- A. No, this will not satisfy the grant's eligibility requirements. Awardees will not be allowed to subcontract under the terms of these awards.
- Q6. We are in the process of seeking additional funding through other sources, including foundations, commercial companies, and venture capital funding. Please let us know if there are restrictions on the type of co-funding.**
- A. There are no restrictions on the type of co-funding.

- Q7. Since the instructions state there are no subcontractors allowed, is there any means to share resources among collaborators of co-PIs?**
- A. The Center appreciates that a consortium of collaborators may want to respond to this Solicitation. This is entirely acceptable and will be accommodated. However, funds awarded under this solicitation may not be passed through or subcontracted from the recipient organization or consortium to an organization or individual outside the recipient organization or consortium.
- Q8. Is it possible to have collaborators that are unpaid?**
- A. Yes.
- Q9. Is it possible to hire consultants on this project, or is the consultant considered a subcontractor?**
- A. No. The consultant is considered a subcontractor.
- Q10. We are planning to optimize a current assay and evaluate it in LRS. Is this an appropriate topic for this grant application?**
- A. Adapting existing NAATs for application in LRS is an appropriate topic for this grant. The solicitation is specifically seeking technologies that enable nucleic acid testing to be performed **in primary health care facilities** in low-resource settings.
- Q11. What kind of commercialization potential would you like to see included in the grant proposal?**
- A. The GHDx Center appreciates that at this exploratory phase of development it may be difficult to characterize the commercialization potential of the proposed technology. For these applications, suitability of the technology for adoption in a primary health care facility with limited resources is more important than commercialization potential. Applicants are given an opportunity in the application form to justify this.
- Q12. There are several ways to commercialize our product, i.e., generating a kit, using a fee-for-service approach, or providing the reagents and training for other labs. Does the GHDx Center favor a particular method?**
- A. No.
- Q13. Through other funding sources we have developed workshops to train test users to use our diagnostic test in LRS. We are planning to replicate this model and leverage the tools and skill sets to expand this model to other LRS. Would you consider this a leveraging opportunity?**
- A. This would be considered a leveraging opportunity. It is worth noting, however, that for this exploratory phase funding, the GHDx Center appreciates that significant additional funds may be required to realistically develop even an early prototype technology. Co-funding or leveraging funds that have in the past or will in the future contribute directly to the development of the technology will be favorably considered.

Q14. Is this Solicitation an opportunity to collaborate with PATH?

A. This solicitation is an opportunity to collaborate with PATH. Other opportunities (e.g., NIH awards) can also offer opportunities to collaborate with PATH. PATH and the GHDx Center will work collaboratively with the awardees to ensure the success of their award.

Q15. In Question 10 regarding the Company's unique abilities to achieve the scope of the work, the document will not allow me to input more than 300 characters, but the form indicates a maximum of 600 characters.

A. This was a mistake in the original form. A new form allowing 600 characters for Question 10 has been posted on April 28, 2008.

We have attempted to answer all questions received regarding the request for Letters of Interest for the funding opportunity posted April 8, 2008 by the GHDx Center. If you feel your question has not been responded to or would like further clarification, please contact Dr. Gonzalo Domingo at gdomingo@path.org.