



Questions and Answers on the Call for Letters of Interest Announced December 8, 2009

- Q1. The solicitation states that the GHDx Center will “fund projects to the stage of early development prototypes.” If a technology is already past the prototype development stage and has demonstrated that it can meet the technical requirements, will such a technology be eligible for funding?**
- A.** Yes, such a technology would be eligible for funding if the proposed scope of work is to develop a novel component of the technology, which is to date not funded, and would align a current prototype more with the intent of this solicitation.
- Q2. If a technology has demonstrated feasibility to meet the analytical requirements and prototypes are already available, can investigators propose pre-clinical field testing of such prototypes to validate its analytical performance?**
- A.** Pre-clinical field evaluation of a developed prototype **on its own** is unlikely to be competitive under this solicitation. The Center does fund this kind of activity under another mechanism, announced by our Prototype Testing core activity.
- Q3. If a technology has demonstrated feasibility to meet or exceed a portion of the requirements (e.g. test sensitivity, dynamic range, turnaround time, precision, applicability to LRS) but not others (e.g. cost of goods sold and stability at elevated temperature), can investigators propose development specifically designed to adapt the technology to meet the not-yet-met requirements (e.g., manufacturability and cost reduction activities)?**
- A.** Any proposal that furthers the field of the development low cost viral load testing platforms, closer to the patient, is responsive. Proposals addressing any component or aspect required to achieve this is responsive, so, yes.
- Q4. The solicitation states that rapid test results are desired. What turnaround time would be considered applicable to LRS for such a HIV viral load test?**
- A.** Cost and enhanced proximity to the patient (even if to a district hospital level facility) are the highest priority to the Center. With regards turnaround time, for a series of practical reasons, tests requiring more than five hours for the full process are unlikely to be responsive.
- Q5. The solicitation states that “single-use or low throughput platforms that can perform 6-20 specimens or more per run” would be desirable. Turnaround time and throughput together determined the number of tests that can be run in a set period of time. What is the GHDx Center requirement on numbers of runs that can be completed in a given 8 hour period? Is there a preference for rapid time-to-result or parallel processing for multiple samples?**

A. The GHDx Center recognizes that different throughputs and turnaround times address different niches in the diversity of settings that constitute LRS so no preference is stated. For single use throughput devices we would expect a fast turnaround time (significantly less than one hour), where as for higher throughput platforms we would tolerate a wider turnaround time (up to six hours for the complete process).

Q6. Cost of goods sold (COGS) targets are given in the solicitation. As COGS are tied intimately to production volumes, what is the assumed annual production volume for reagents/consumable and instrumentation at which COGS targets are expected to be met?

A. The applicants should provide estimates of the annual production volume which would allow them to meet the target COGS. These target COGS are guideline COGS, applications with credible target COG estimates will be reviewed more favorably than applications with unlikely COG estimates.

Q7. Our institute is not US-based, are we eligible for this funding opportunity?

A. Yes, all institutions, both private and public sector are eligible to compete. Applicants must be able to meet the terms of agreement and funding for the solicitation (see solicitation description).

Additional questions previously asked

Q8. May venture-backed companies participate in this grant, regardless of the level of venture investment?

A. Yes.

Q9. 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. While support from the GHDx Center should not be assumed, nor requested in the LOI or Full application, 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 specific 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.

Q10. 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.

Q11. 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.