FIND
Diagnosis for all

Request for Proposals - FAQ

Seeking manufacturers of true point-of-care molecular tests for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* to accelerate product development/evaluation and market entry in low- and middle-income countries.

Frequently Asked Questions (version 30 April 2024)

this FAQ will be updated until the 29th of April, 5pm CET

1. For products at TRL4, would the scope of the RFP only cover product development activities, or could FIND extend this to product optimization and even evaluation activities?

[FIND RESPONSE]: For products at TRL4-6, FIND intends to support primarily product development and optimization activities. Given the early stage of these technologies, a field evaluation likely cannot be carried out within the timeline of the project and most likely cannot be funded by FIND within the current timeline of this project.

2. Is there an indicative cost per project that FIND has allocated per project that we could keep in mind? Or any other criteria that we are expected to follow that could help us define a project scope?

[FIND RESPONSE]: For products at TRL4-6, we ask applicants to submit a product development plan, including a timeline and budget, that would enable the product to reach a

technology level appropriate for independent field evaluations (i.e. to reach TRL7). In other words, the project plan must cover the necessary product development and V&V activities to reach TRL7. As these activities will take time, a field evaluation for these early-stage products is most likely not possible within the timeline of the project. The product development plan must state the level of funding requested to FIND vs the level of co-funding provided by the applicant.

3. How do you intend to proceed with the payment of the project costs to the awardees? Would it be tranched, upfront or through reimbursement of the costs?

[FIND RESPONSE]: The payments will be tranched by deliverables.

4. Could you please confirm what type of samples are used? Are you interested in the assay or the final point of care product for this evaluation?

[*FIND RESPONSE*]: *FIND is interested in the full product solution, meaning the combination of the point-of-care device and the molecular assay to enable the dual detection of NG/CT by molecular means. The sample types are:*

Minimal: vaginal swabs for women, and urine for men. Alternatively, urethral swab for men although urine is preferred. The applicant can propose product optimization activities to adapt their device to new, not-yet validated specimen types on their device.

Optimal: vaginal swabs and urine for women. Urine, urethral/rectal/pharyngeal swabs for men.

5. We are unsure of our eligibility due to a difference in the TRL of our assay and that of our POC platform. Our assay is being developed in the lab (for running on our POC system) and we have data points that can be shared in the application, we believe this is at TRL4. Our POC technology is currently being upgraded to an enhanced version of our currently commercially available previous model. We are expecting to have first units in early Summer. It is with this device that we will be running the proposed CT/NG assay but we will not have data that we can share from this device at this time. Can you please advise if the TRL of the assay would be sufficient for inclusion or would we need to have both assay and device at TRL4 to be considered.

[*FIND RESPONSE]: Given that your assay is developed in the laboratory, we understand that you are using laboratory models and methods, which corresponds to a TRL3 based on FIND's definition. However, given that a POC device is already commercially available, and a new generation is reaching the end of its development soon, the full solution seems well advanced. Therefore, FIND is willing to consider your assay and device for review in such a scenario. However, the submission will be scored according to the level of risk and technology value proposition among other selection criteria.*

6. While there seems to be no specific cap on the budget, is there a specific format you would like us to use? Should we provide a budget justification as well?

[FIND RESPONSE]: We ask applicants to provide an R&D plan to bring their technology to TRL7. This plan must present R&D activities to modify/upgrade existing design specifications and components to meet the true POC requirements and reach TRL7 by end 2025/early 2026. For example, the applicant is expected to provide: (i) A list of activities that will be performed if awarded, (ii) A timeline of key deliverables and milestones, and (iii) An overall budget, with indications of co-funding (if any) and how much is requested from FIND. The plan can be presented in the powerpoint presentation of the applicant. FIND will review the plan based on the following questions: (i) Is the overall funding and support ask reasonable in light of the expected activities and impact (e.g. platform, assay, etc)? (ii) How feasible is the proposed R&D plan to meet the proposed design specifications? (iii) How feasible is the proposed timeline to meet key milestones?

7. We saw the Assessment Matrix, PowerPoint presentation, and Self-Declaration Form templates. Is there a format for a proposal narrative? Would that be uploaded under Other supporting documents?

[*FIND RESPONSE]: FIND is not asking for a proposal narrative. However, the applicant can use the PowerPoint presentation to describe its technology, product as well as the R&D plan.*

8. I'm writing to see if biosensor-based diagnostic tests to detect CT/NG would be eligible for R&D funding. Our question is whether biosensor-based assays would be eligible for R&D funding from FIND under this RFP?

[*FIND RESPONSE]: Yes, any POC technology that aims to test for CT/NG by detecting nucleic acids and targets or already meets the key product requirements is within the scope of this RFP, irrespective of the amplification and detection strategy.*

9. We would like to understand the whole picture and potential next steps assuming validation in LMIC setting is successful, in preparation for mass production. Mass production in such volumes with target price as set in program conditions will require significant financing and we would like to understand how FIND and your partners have envisaged next steps. Could it be for example solid order and prepayment (10M units on 10 USD price condition, to be delivered in 12-18 months) from FIND, BMGF or other institution for LMIC countries, that can be used to seek external funds to finance such mass production?

[*FIND RESPONSE]: Downstream funding opportunities will depend, among others, upon test performance, COGS, and company sustainability. During development and/or field evaluation FIND will work with internal teams and external stakeholders to develop roadmaps and provide support for e.g. regulatory approval, gathering market information and identifying potential*

countries and global buyers for the assay. FIND is working with other stakeholders to define a go to market strategy that supports the successful roll out of the test in key countries.

10. What are your expectations regarding the development/optimization work-package in terms of budget and length?

[*FIND RESPONSE]: FIND intends to start R&D activities to optimize/develop the tPOC MDx assay by October 2024 and complete these by end 2025/early 2026.*

For indicative purposes, awards to successful applicants are estimated between USD 200,000 and 1 Mio depending on the TLR level and how well the proposal meets the requirements of the RFP.

11. Would you consider R&D activities targeting cost-reduction and/or adaptation for additional sample types (such as extragenital) eligible?

[*FIND RESPONSE]: Yes, FIND is willing to fund R&D activities with the aim that the product can meet key minimal or optimal product requirements such as price or additional sample types.*

12. Would you agree to consider within this project male and female CT/NG tests due to different sample collection procedure as separate products.

[*FIND RESPONSE]: For this RFP FIND is looking to evaluate dual NG/CT tPOC MDx tests in LMICs sites and/or support the development/optimization of tPOC MDx tests for dual NG/CT detection which as a result of the funded activities funded or before should meet the minimum requirements for sample type, i.e. female vaginal swab and male urine (alternative urethral swab). Products must ultimately meet the minimal specifications to be considered for funding.*

13. In the course of R&D activities, is the applicant required to complete a clinical performance evaluation? Or is clinical performance evaluation conducted at the LMIC site through FIND's support during the independent performance evaluation process?

[*FIND RESPONSE]: We are accepting applicants from TRL 4 and therefore accepting applicants who have not done clinical performance evaluation yet. Applicants who have done clinical performance evaluation are requested to share their documentation, however, FIND* may *still perform an independent evaluation in LMIC sites to assess the performance of TRL7 or above technologies against reference standards in target populations and different specimen types in LMICs.*