

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 25 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 tranching, upfront or through reimbursement of the costs?

[FIND RESPONSE]: *The payments will be tranching 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.