Innovations in Cost-Disruptive Tools for Diagnosis and Screening

Grand Challenges

Frequently Asked Questions (FAQ)

Eligibility

Who is eligible for grants?
This initiative is open to research institutes, nonprofit organizations, for-profit companies, international organizations, government agencies, and academic institutions. Please note that all applicants will be expected to comply with the Foundation's global access clause. We encourage applications from projects led by or collaborating with women and/or researchers at institutions based in LMICs. Individuals and organizations classified as individuals for U.S. tax purposes are not eligible to receive an award from the foundation as part of this initiative.

Upon registration, applicants must provide information about the tax status of their organization as different terms and conditions may apply. You should confirm your organization's tax status with the appropriate advisor or entity within your organization such as your grants or contracts department, finance, or office of sponsored research. The foundation may request additional information regarding your tax status. For information about tax statuses, you may check with your own advisors and review information provided on the Internal Revenue Service web site at: www.irs.gov.

Are institutions based in high-income countries eligible to apply? Can a non-LMIC institution serve as the lead applicant?
Yes, this RFP is open globally to research institutes, nonprofit organizations, for-profit companies, international organizations, government agencies, and academic institutions. While we encourage applications from projects led by or collaborating with institutions based in LMICs, it is not a requirement.

Is my specific type of organization eligible to apply?
Any legally registered organization is eligible to apply. However, individuals and organizations classified as individuals for U.S. tax purposes are not eligible to receive an award from the foundation as part of this initiative.

Are startups eligible if legal registration is still in progress?
An organization must be legally registered by the time the application window closes to be eligible to apply.

Is the RFP primarily intended for product developers/manufacturers, or also for implementers and delivery partners?
It is intended for developers/manufacturers. Implementation- or delivery-only projects are out of scope.

Application Process

What must my application include?
Please refer to the Application Instructions document.

Am I able to edit my proposal once submitted?
Yes, you may edit your proposal up until the specified deadline.

What amount of indirect cost is available?
Details of the foundation indirect cost policy guidelines can be found here: Gates Foundation's indirect cost policy.

Can multiple institutions apply jointly as a consortium?
Yes, proposals may be submitted through partnerships and other collaborative arrangements. In such cases, one lead organization must serve as the primary applicant and submit the proposal, with partner organizations included as sub-grantees or informal collaborators.

Is there a limit to the number of international and local partners on an application?
No there is no limit to the number of partners.

Can one organization submit multiple applications across different topic areas?
Yes, an organization may submit more than one project. However, each submission must have a distinct Principal Investigator (PI) and use a unique email address. PIs may serve as collaborators on multiple applications.

If you are proposing a single platform that spans multiple topic areas, please submit one application and clearly outline the relevant topic areas within it. You may include links to additional supporting information if needed.

For this particular RFP, if you have truly distinct projects that apply to different tools and topic areas, you may submit multiple applications under the same PI. Please only do so when the projects are clearly separate in scope and technical approach.

How should we include a letter of support in the application?
Letters of support are not required or expect at this stage and should not be included in your application.

Are graphs allowed in the application proposal?
Yes, you are welcome to include graphs, but they are not expected or required and will count against the 3-page proposal limit.

Given the 3-page limit, what key elements should be included in methods and how detailed should they be?
We created a table that describes the type of evidence that should be included, depending on which Award Option (A, B, C) you are applying for. Please refer to that table when assessing what to emphasize in your proposal.

Option A Typically TRL 2-->TRL 4 (or early five)	Option B Typically late TRL 4-->6	Option C Typically TRL 6-->TRL 7/8

• These are early-stage, high-risk ideas. During the grant period, you would be proving "this could work."
• The expected starting point would be a feasible concept and early lab data
• The expected end point would be a functional prototype with lab data
• We would be looking for:
  ○ A clear technical hypothesis
  ○ A feasible prototype within the grant period
  ○ Early data
 	
Rough credible path to the cost targets
	• These are technologies that already have a prototype and you are proving "this works in practice."
	• The expected starting point would be TRL 4 with an existing lab prototype
	• The expected end point would be TRL 5-6 – the prototype is validated in a relevant real-world setting
	• We would be looking for:
	  ○ A functional prototype
	  ○ Initial performance data
	  ○ Clear path to priority use-case adaptation
	  ○ Early validation plan (but not a full clinical trial)
		• These are technologies that are already working in real settings. During the grant period, you are proving this technology can be used for something else in the priority use cases listed in the RFP.
		• The expected starting point is TRL 5/6: The technology has already been demonstrated for something.
		• The expected end point is a near-final system adapted to a priority use case and ready for validation.
		• We would be looking for:
		  ○ Strong evidence of feasibility already
		  ○ Clear validation pathway
		  ○ Credible deployment + manufacturing plan
		
		Strong alignment with LMIC workflows

Review Process

How does the review process work?
Please refer to the Rules and Guidelines document.

Can I get a list of potential reviewers who might be assigned to my application?
No. We do not make public the roster of reviewers.

Can I request that my application not be reviewed by a specific individual?
No. However, we will ask reviewers to self-identify conflicts of interest and will not assign reviewers with conflicts.

Will I receive specific feedback on my application if it is not selected?
Due to the rapid proposal and review timelines applicable to this RFP, applicants with proposals that are not selected for award may receive a notification of decline without specific feedback.

Award Information

Are grant awards made directly to individuals?
No. All awards are made to the organization where the individual holds their primary appointment. Institutions must agree to the terms and conditions governing each grant award prior to award activation.

How much money will each grant provide?
To accommodate different stages of innovation, this Challenge has multiple award sizes commensurate with technology maturity. For example:

- **Option A:** Smaller proof-of-concept awards (up to five awards of approximately US$300,000, for each selected project, with a grant term of up to 24 months) to support early feasibility and prototyping, inclusive of technically risky, out-of-the-box concepts
- **Option B**: Mid-level awards (up to three awards of approximately US$500,000 for each selected project, with a grant term of up to 24 months) to support product refinement and early validation
- **Option C**: Larger awards (up to two awards of approximately US$1,000,000, for each selected project, with a grant term of up to 36 months) to support mature platforms or advanced adaptation toward verification and field readiness, with commensurate evidence of technical readiness, feasibility, and a clear pathway to validation.

Final award amounts, number of awards at each level, and duration will depend on proposal quality and strategic fit. Applicants should request funding aligned with the scope and maturity of their proposed work and include a clear milestone plan proportionate to the support requested. Indirect costs will be considered and should be included in the budget for up to the grant amount awarded (subject to the Gates Foundation's indirect cost policy).

How much flexibility is there for additional funding beyond the initial award?
Specific plans for additional funding beyond the initial award are not finalized, this will be determined on a case-by-case basis.

What is the expected time horizon from award to product readiness or market entry?
This depends on the starting technology readiness level of the applicant.

Will the foundation support regulatory approval or registration in target countries?
This will be assessed on a case-by-case basis, but generally, yes, we support some parts of these activities. Our goal is to ensure developers get promising technologies to market.

Intellectual Property and Confidentiality

How can applicants protect their ideas and ensure confidentiality when sharing concepts in proposals?
When submitting materials to the Foundation please keep in mind that because we have a focus

on achieving charitable outcomes, we view information that we obtain through our grantmaking as a public good. Subject to the Gates Foundation's Privacy & Cookies Notice, the Foundation may also share information you provide to us (either orally or in writing) with third parties, including external reviewers, consultants, contingent workers, key partners and co-funders. You should assume that nothing will be kept confidential and should not include any information in the proposal, budget, supplemental materials, or reports that you consider proprietary.

Who owns Intellectual Property in funded projects?
Grantees retain ownership of intellectual property (IP) developed through foundation-funded grants. The foundation does, however, require that grant outputs be made widely available to the intended beneficiaries. You can read more here: Gates Foundation Global Access and IP Policy

Scope

Are diagnostics for conditions outside infectious diseases, but relevant to maternal, newborn, or primary care, within scope?
The RFP explicitly includes maternal & newborn health, anemia & women's health, nutrition surveillance, etc., alongside infectious disease areas. Applicants must anchor their work to at least one Table 2 use case and show LMIC fit and a credible path to the $1-class / near-zero incremental-cost objective.

Are diagnostics for latent TB within scope?
Table 2 and the TB background emphasize symptom-agnostic population screening and near-patient diagnosis aligned to WHO TPPs; latent TB is not listed as a separate priority but proposals that credibly map to the TB screening/diagnostic pathways may be considered. See the TB additional information for programmatic rationale.

Are congenital conditions in newborns within scope?
Newborn conditions are in scope when they match the maternal and newborn opportunities in Table 2 (for example, congenital syphilis, neonatal sepsis triage, and NICU outbreak detection). Newborn or congenital proposals should be tied to an explicitly listed use case to be competitive.

Is pneumonia in children within scope?
Table 2 includes syndromic and respiratory multiplex approaches under Emerging Pathogens & Syndromic Testing. A child-pneumonia solution framed as a field-usable respiratory syndromic panel or rapid triage tool would align; a general pneumonia program that doesn't fit those use cases is less clearly in scope.

Are wound or skin infection diagnostics within scope?
Generally no, unless they can be justified under an explicitly listed use case (e.g., a multi-disease, syndromic, or platform-based approach that improves surveillance or primary-care triage).

Must products be strictly limited to the diseases and use cases listed in the RFP, or are multiplex tests and adjacent conditions acceptable if they otherwise meet the criteria?
Multiplex / adjacent-condition / multi-disease platforms are explicitly encouraged, and the broader format often improves economics or deployment value. Just remember every proposal must show how it will be adapted to at least one Table 2 use case.

For screening and diagnostic innovations, is the emphasis more on biomarkers, remote monitoring, or both?
The RFP doesn't favor biomarkers versus remote monitoring. It is technology-agnostic. We welcome traditional biomarker-based assays and non-traditional sensor, software, or AI

approaches (and hybrids) so long as they are transformative, practical for LMIC deployment, and backed by a credible technical and cost pathway to the $1-class/near-zero incremental cost objective. Reviewers will evaluate biomarker proposals on analytical/clinical performance and manufacturability, and sensor/AI proposals on signal validity, algorithm generalizability/robustness, and data governance. In every case LMIC robustness and a clear cost model are mandatory.

Do AI-based tools that rely on symptoms, clinical signals, or sensor outputs rather than lab analytes fit the funding criteria?
Yes. AI-enabled and software-only approaches are within scope if they materially change performance, cost structure, or deployment model for an in-scope use case.

Are logistics-enabling tools, such as sample transport or specimen handling innovations, considered in scope?
The RFP excludes implementation/roll-out projects that lack substantive R&D. However, the application instructions ask teams to address specimen logistics as part of device/system design, so logistics work that is an enabling component of a novel diagnostic can be included.

Would developing low-cost devices to screen for heavy-menstrual bleeding (HMB) and follow response to treatment be within scope?
There are two opportunities related to HMB outlined in Table 2 of the RFP, specifically:

- POC, minimally invasive diagnostic to distinguish iron deficiency anemia from other causes, including for severity testing, repeat testing in ANC and postpartum, for evaluation of heavy menstrual bleeding, and for micronutrient assessment.
- Triage tools for heavy menstrual bleeding (HMB) to rule out structural etiologies and identify ovarian abnormalities (e.g. biomarker panel or AI-enabled tool).

Will zoonoses in LMICs fall under Emerging Pathogens and Syndromic Testing (Section A)?
Possibly. These are most likely to fit within the "Emerging Pathogens and Syndromic Testing" topic area in Table 2. There are four potential opportunities in that section that could apply.

In NTD, is there a priority disease? Are proposals with novel biomarkers and cost-effective translation pathways of interest?
Any of the opportunities in the NTD section of Table 2 are part of our strategy and are priorities. Yes, novel biomarkers are of interest as long as there is an associated platform or test.

For enteric disease (cholera test), do you prefer direct pathogen detection or is immune response detection acceptable?
For cholera, we are specifically seeking a confirmatory test, so the diagnostic accuracy requirements are very stringent. The requirements are outlined in Target Product Profiles (TPPs) listed in the "Additional information: Enteric Diseases" document linked in Table 2. Please determine if your approach can meet the sensitivity and specificity requirements. Gold standard cholera confirmatory tests have historically been molecular tests targeting V. cholerae O1/O139.

Are cancer diagnostics eligible?
Generally, no. High-risk HPV (the causative agent of cervical cancer) is the only cancer-associated test within scope for this Grand Challenge. However, if you have a cancer diagnostics platform, please consider whether it could be adapted for use with one of the use cases outlined in Table 2. We encourage multi-disease and multi-indication platform approaches.

Could refractive error (glasses) be considered for this proposal?
Unfortunately, no. These are not in the scope of this Grand Challenge.

Are low-cost microscopy and sensing tools acceptable for this RFP?
Sensing tools are acceptable. Generally, any approach can be acceptable as long as it addresses one of the use cases in Table 2 and meets performance requirements outlined is the appropriate Target Product Profiles (TPPs), which can often be found in the "Additional Information" documents linked in Table 2. The approach must also meet the other requirements outlined in the RFP (i.e., cost-disruptive, operationally feasible, etc.) Historically, many microscopy-based approaches have not met performance and operational constraints, but we welcome innovation!

Platform fit

If an applicant has a validated platform in one disease area, is it eligible to propose adaptation of that platform to an in-scope disease even without disease-specific data yet?
Yes, we absolutely encourage this, and we see a lot of value in multi-disease platforms. The RFP and supporting notes state applicants are not required to have disease-specific validation yet; what matters is a technically credible adaptation pathway, milestones and LMIC deployment considerations.

Are proposals eligible if they substantially reduce the cost of an existing diagnostic, even if they may not fully achieve the target cost immediately?
Yes, as long as: 1) the applicant can outline a clear and credible path to achieving cost targets, including price break quantities, in their application; and 2) they can make any required technical changes to enable the cost reduction during the grant period.

Are nontraditional formats for diagnostics or screening tools, including low-cost devices, wearables, or integrated sensing systems, allowed?
Yes, these are very strongly encouraged.

How should applicants determine whether their proposal is best suited for Option A, B, or C?
Applicants should self-assess based on the Technology Readiness Level (or TRL) of their technology. If we break that down by award levels:

- Option A: Typically TRL 2-->TRL 4 (or early five)
    - These are early-stage, high-risk ideas. During the grant period, you would be proving "this could work."
    - The expected starting point would be a feasible concept and early lab data
    - The expected end point would be a functional prototype with lab data
    - We would be looking for:
        - A clear technical hypothesis
        - A feasible prototype within the grant period
        - Early data
        - Rough credible path to the cost targets

- Option B: Typically late TRL 4-->6
    - These are technologies that already have a prototype and you are proving "this works in practice."
    - The expected starting point would be TRL 4 with an existing lab prototype
    - The expected end point would be TRL 5-6 – the prototype is validated in a relevant real-world setting

    - We would be looking for:
        - A functional prototype
        - Initial performance data
        - Clear path to priority use-case adaptation
        - Early validation plan (but not a full clinical trial)

- Option C: Typically TRL 6-->TRL 7/8
    - These are technologies that are already working in real settings. During the grant period, you are proving this technology can be used for something else in the priority use cases listed in the RFP.
    - The expected starting point is TRL 5/6: The technology has already been demonstrated for something.
    - The expected end point is a near-final system adapted to a priority use case and ready for validation.
    - We would be looking for:
        - Strong evidence of feasibility already
        - Clear validation pathway
        - Credible deployment + manufacturing plan
        - Strong alignment with LMIC workflows

If we already have an established diagnostic device and would like to validate it, which grant tier or option would you recommend?
It depends on the TRL level and the supporting data, but likely Option B (TRL 4+) or Option C (TRL 6+).

For a short proposal, should applicants emphasize existing platform feasibility data, disease-specific adaptation plans, or implementation design?
Feasibility data and adaptation plans are probably most compelling. Feel free to cite relevant publications with a very brief summary, if available, which may save some space. The goal with the first proposal is to give a clear introduction to the tech and why it would work for one of the use cases. If you move into later stages of the process, there will be opportunities to further shape the proposal.

Are field-readiness projects with implementation partners or government support already in place better suited to a later-stage option?
This really depends on the maturity of the product and the proposal objectives. The RFP excludes implementation/roll-out projects unless they contain substantive R&D. Partnerships are an asset for later-stage validation and scale planning.

Are affordable lab automation solutions acceptable, or must everything be handheld point-of-care?
There are some use cases for which affordable automated solutions would be in scope, as long as the solution would provide a "sample-in, answer-out" workflow. Generally, use cases will specify if they require true point of care deployment and/or how they will be used by programs (e.g., at primary health facilities, in community screening settings, etc.). Please refer to the use cases outlined in Table 2.

Cost, value, and success metrics

How should applicants interpret the "<$1" target: per test, per analyte, per patient screened, or another basis?
This depends on use case. The safest definition is $1 per person tested.

For multiplex tests, how should the cost target be applied?
Apply the cost target to the use case (per person screened or per diagnostic encounter), not necessarily per analyte. Explain how multiplexing improves programmatic value, throughput and the per-person cost.

What are the main success metrics reviewers will use to evaluate proposals?
These expectations are drawn from the "We are looking for…" and "not seeking" sections of the RFP and the application instructions and are echoed in the FAQ. The reviewers evaluate the potential for substantial impact (programmatic fit), technical/scientific excellence and innovation, differentiation from existing approaches, operational/LMIC feasibility, credibility of the cost and manufacturing pathway, quality of the team and milestones, and proportionality of budget to technical maturity.

What are the highest-priority use cases within this call?
The RFP does not rank Table 2 priorities; all listed use cases are eligible. Reviewers will judge on strategic fit, technical strength, transformative potential and the credibility of the cost-disruption and LMIC deployment pathway. For us, the best-case scenario would be that we have even more great options than what we planned to fund. We would work with partners to try to enable any promising technologies.

What are the biggest barriers the foundation sees to implementing sub-$1 diagnostics at scale in primary healthcare settings?
Some of the key barriers include high consumable costs, complex infrastructure needs, operational complexity, cold-chain dependence, limited throughput for mass screening, manufacturing scale and reliability, and ensuring robustness in LMIC environments. Applicants should consider the design criteria in Table 1 and outline realistic mitigation strategies.

How does the foundation view pathways for scaling cost-disruptive tools while maintaining quality and accuracy?
Low cost must be paired with rigorous analytical/clinical validation and regulatory planning. The Foundation expects applicants to demonstrate target performance, alignment to relevant TPPs where applicable, validation milestones, regulatory-readiness planning, and willingness to participate in independent evaluation.

Are you primarily looking for manufacturing progress, clinical validation, or diagnostic performance?
If all of these data are available, they can be compelling evidence and brief summaries of each should be included to strengthen your proposal. However, they are not all required, depending on the funding level requested.

When you ask for use cases, do you require supporting data?
It depends on the situation. If you are applying to Option A, we would like to see bench data. For option B, we would like to see a working prototype. For option C, we are looking for mature devices or tests. However, in all cases, you do not need use-case-specific validation data at this point. If you do not have use-case-specific data yet, please provide a credible hypothesis and clear workplan for generating those data during the grant period.

For early-stage biomarker discovery under Option A, how important is demonstrating a path to $1-class diagnostics versus biological feasibility?
Biomarker discovery is within scope as long as it is associated with a deployable solution (e.g., there should be an associated platform or test). Both biological justification and a path to $1-class

diagnostics should be included. However, feel free to cite any existing publications, if available, and just provide a brief summary of the findings.

Technical Support

I forgot my password. How do I reset my password?
You can request to update your password within the application site. If you continue to have issues, please reach out to grandchallenges@gatesfoundation.org.

How will I know if my application was submitted?
Once an application is submitted, an email confirmation will be sent.

I'm having trouble uploading my application file. What should I do?
If you are having issues submitting your application, we would encourage you to submit from a different browser. If the issue persists, please email the specifics of your problem to grandchallenges@gatesfoundation.org.

How often do you intend to update the Frequently Asked Questions, and do you plan to provide answers to all questions submitted?
We will periodically post answers to questions as they are submitted, but do not have a specific schedule. We will provide answers on this page that are of relevance and of general interest to potential applicants. For answers to specific questions that are not covered here, please email grandchallenges@gatesfoundation.org