



NIH Tech Accelerator Challenge 2020 Guidelines

Please review carefully prior to submitting

[INTRODUCTION](#)

[COMPETITION PRIZES](#)

[ELIGIBILITY REQUIREMENTS](#)

[JUDGING CRITERIA](#)

[SUBMITTING YOUR PROPOSAL](#)

[ADDITIONAL INFORMATION](#)

[CONTACT US](#)

INTRODUCTION

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH) support and encourage the development of new diagnostic technologies important for global health. Through this Challenge, NIBIB will offer \$1,000,000 in prizes to reward and spur the development of platform concepts and prototypes of non-invasive, multiplexed diagnostic technologies for sickle cell disease, malaria and anemia, diseases with high global and public health impact. The Bill & Melinda Gates Foundation (Gates Foundation) shares a commitment to global health and is cooperating with NIBIB to consider additional support for the Challenge winners and honorable mentions. Gates Foundation, separately, will review the Challenge winners and honorable mentions selected by NIBIB for potential follow-on funding and/or in-kind support of up to \$500,000 that can transform design concepts into products for global health on an accelerated timeframe.

Five components of NIH have partnered with NIBIB to contribute to the \$1,000,000 prize purse and will participate in selection of winners and honorable mentions: NIH Office of the Director, National Institute of Allergy and Infectious Disease, National Heart, Lung and Blood Institute, National Institute of Diabetes and Digestive and Kidney Diseases, and the Fogarty International Center.



This Challenge is part of an effort by NIBIB and Gates Foundation to accelerate the development of rapid, non-invasive diagnostic platforms for sickle cell disease, malaria and anemia. NIBIB is offering \$1,000,000 in prizes, with up to \$500,000 for a top finalist and smaller awards to approximately five semi-finalists. NIBIB may recognize additional participants with non-monetary honorable mentions. In partnership with NIBIB, five components of NIH are contributing to the \$1,000,000 prize purse and will participate in selection of winners and honorable mentions: NIH Office of the Director, National Institute of Allergy and Infectious Disease, National Heart, Lung and Blood Institute, National Institute of Diabetes and Digestive and Kidney Diseases, and the Fogarty International Center. All honorable mentions and winners of NIBIB's prizes will be selected by NIBIB and these NIH partners.

Following the NIH selection of winners, Gates Foundation has indicated its intent to separately consider and assess the submissions of the prize winners and honorable mentions for potential additional support from Gates Foundation to develop the proposed technologies for global health applications. If selected by Gates Foundation after the Challenge, follow-on support from Gates Foundation may include grants of up to \$500,000 and in-kind support in the form of consultations and partnerships for clinical data collection, software development, scale-up and manufacturing. The goals of this collaborative effort are to stimulate the design of new diagnostic technologies to transform public and global health and to accelerate the full development of products for use in low-resource settings.

Accessible diagnostic tools are essential for providing treatments and cures for some of the world's highest-burden diseases. While diagnostics currently exist for sickle cell disease, malaria and anemia, they can be challenging to deliver in low-resource settings, particularly at the population level, due to cost, invasiveness and the expertise required to administer the tests. The ready availability of a low cost, rapid, reliable platform for blood-related diseases would enable unprecedented community-level screening, monitoring and treatment. Identification and treatment of these disorders would be especially valuable for reducing the world-wide burden of these diseases.

This Challenge seeks designs for non-invasive technology platforms to diagnose sickle cell disease, malaria, and anemia. While not constrained to any specific technology, the inspiration for this Challenge comes from the widespread availability of mobile phones and the potential for mobile phone-linked sensor technologies to non-invasively detect changes in the blood and vasculature associated with these treatable diseases. Based, for example, on optics and photonics approaches, mobile phone-linked sensors could provide rapid, reliable, low-cost diagnostics and dramatically improve global health.



To be responsive to this Challenge, a Challenge submission should present two focuses: (1) a design with initial feasibility data for a diagnostic platform assessing two diseases in the vasculature, and (2) a robust description of the path for translation of the technology to global health use cases, and how the technology will need to develop further to reduce cost and be suitable for field use.

A strong Challenge submission includes a device design with the following characteristics:

- Technical validity demonstrated by initial feasibility data or references
- Platform potential – potential to adapt or extend the device to at least two relevant diseases/conditions
- At least one target disease should be sickle cell disease, malaria or anemia
- Measures parameters that could be used to track disease state and/or response to therapy
- Uses mobile device or portable attachment to a mobile device
- Non-invasive and does not require blood sampling
- Low-cost and accessible
- Self-contained and highly portable; for example, proposed device does not use biological reagents
- Allows rapid data collection and time to result
- Integrates prior context about the patient and environment into the test result
- Scalable to population delivery

See “Judging Criteria” below for more detail about submission requirements, platform criteria, and additional design considerations specific to diagnostics for sickle cell disease, malaria and anemia.

Additional Partners of NIBIB: NIH OD, NIAID, NHLBI, NIDDK, FIC

Dates:

- Challenge Launch: February 10, 2020
- Submission Start/End : March 2, 2020/June 2, 2020 (***Extended to June 16, 2020.***)
- Judging Start/End: *June/July 2020*
- NIBIB Prize Winners Announced: *August 2020*

COMPETITION PRIZES

Amount of the Prize:



The total prize purse from NIH for this Challenge is up to \$1,000,000. NIBIB will award a top finalist up to \$500,000, with smaller awards to approximately five semi-finalists. NIBIB may recognize additional participants with non-monetary honorable mentions.

Following the selection and awarding of the NIBIB prizes, Gates Foundation has indicated its intent to review the submissions of Challenge winners and honorable mentions by September 2020 with respect to their potential for global impact. The designs deemed by Gates Foundation to be most appropriate for high-priority settings may be eligible for some combination of Gates Foundation grant funding for up to \$500,000 and in-kind support in the form of consultations and partnerships for clinical data collection, software development, scale-up and manufacturing.

Payment of the Prize:

NIBIB prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS/NIH/NIBIB will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

NIBIB reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, or any part of it, for any reason, and/or (b) not award any prizes if no entries are deemed worthy.

Follow-on grant funds or other support offered by Gates Foundation will be provided directly by Gates Foundation, at Gates Foundation's discretion. If Gates Foundation fails to provide any of the funds or other support it has proposed to provide, neither NIH nor NIBIB have the legal authority to provide those funds or support on their behalf. For more information, please contact Gates Foundation.

ELIGIBILITY REQUIREMENTS

Eligibility Rules for Participating in the Challenge:

(1) To be eligible to win an NIBIB prize under this Challenge, a Participant (whether an individual, group of individuals, or entity) —

- a. Shall have registered to participate in the Challenge under the rules promulgated by the NIBIB as published in this announcement;
- b. Shall have complied with all the requirements set forth in this announcement;



c. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States. However, non-U.S. citizens and non-permanent residents can participate as a member of a team that otherwise satisfies the eligibility criteria. Non-U.S. citizens and non-permanent residents are not eligible to win a monetary prize (in whole or in part). Their participation as part of a winning team, if applicable, may be recognized when the results are announced. Teams comprised entirely of non-U.S. citizens and non-permanent residents will be eligible to be recognized with an honorable mention.

d. Shall not be a federal entity or federal employee acting within the scope of their employment;

e. Shall not be an employee of the Department of Health and Human Services (HHS, or any other component of HHS) acting in their personal capacity;

f. Who is employed by a federal agency or entity other than HHS (or any component of HHS), should consult with an agency ethics official to determine whether the federal ethics rules will limit or prohibit the acceptance of a prize under this Challenge;

g. Shall not be a judge of the Challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family of such a party (i.e., spouse, parent, step-parent, child, or step-child).

(2) Federal grantees and recipients of cooperative agreements may not use federal funds to develop their Challenge submissions unless use of such funds is consistent with the purpose of their grant award or agreement. If a grantee or recipient of a cooperative agreement using federal funds wins the competition, the award must be treated as program income for purposes of the original grant or agreement in accordance with applicable Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200).

(3) Federal contractors may not use federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submissions.

(4) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) agrees to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or



consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

(5) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no Participant (whether an individual, group of individuals, or entity) participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

(6) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) agrees to indemnify the federal government against third party claims for damages arising from or related to Challenge activities.

(7) A Participant (whether an individual, group of individuals, or entity) shall not be deemed ineligible because the Participant used federal facilities or consulted with federal employees during the Challenge if the facilities and employees are made available to all Participants participating in the Challenge on an equitable basis.

(8) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) warrants that he, she, or it is the sole author or owner of, or has the right to use, any copyrightable works that the submission comprises, that the works are wholly original with the Participant (or is an improved version of an existing work that the Participant has sufficient rights to use and improve), and that the submission does not infringe any copyright or any other rights of any third party of which the Participant is aware.

(9) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) grants to the NIH an irrevocable, paid-up, royalty-free nonexclusive worldwide license to reproduce, publish, post, link to, share, and display publicly the submission and its contents on the web or elsewhere, and a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the solution throughout the world. Each Participant will retain all other intellectual property rights in their submissions, as applicable. To participate in the Challenge, each Participant must warrant that there are no legal obstacles to providing the above-referenced nonexclusive licenses of the Participant's rights to the federal government. To receive an award, Participants will *not* be required to transfer their intellectual property rights to NIH, but Participants must grant to the federal government the *nonexclusive licenses* recited herein.



(10) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) acknowledges that NIH will provide winning submissions to Gates Foundation.

(11) Each Participant (whether an individual, group of individuals, or entity) agrees to follow all applicable federal, state, and local laws, regulations, and policies.

(12) Each Participant (whether an individual, group of individuals, or entity) participating in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each such Participant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.

JUDGING CRITERIA

Basis Upon Which a Winner Will be Selected.

Participants will present a design and initial feasibility data or references for a non-invasive diagnostic platform to address 2 diseases in the vasculature (at least one of sickle cell, malaria, or anemia). The technology design must describe both the biological principle of the test and measurement approach. Participants may share data collected on prototypes (if available) and up to five pieces of evidence or feasibility data that de-risk elements of the test and the device. To ensure alignment with global health use cases, participants must also submit a robust proposal addressing following questions:

- What changes and further development for hardware, software, or data generation would be required to meet a global health use case?
- What are potential areas for cost reduction and technologies or approaches to achieve the target use case, considering the form factor and capital cost listed in the product requirements below?

The following describe the judging criteria for evaluating submissions for (1) feasibility data demonstrating the utility of the technology across two diseases, and (2) proposals for the utility of the device in global health contexts.

Note: Where appropriate, partial credit may be available against these criteria.

Approach and performance criteria, *for evaluation of feasibility data:*

- **Platform approach.** Proposed device must have a path to use the same underlying technology to address at least two diseases in the vasculature. One disease must be sickle cell, malaria, and / or anemia. Proposals will only be accepted if they describe a way to extend to two diseases on a single platform. Full points require in vivo target accuracy in representative background populations for two diseases, though scoring will be scaled appropriately.
- **Analytic performance.** Proposed device must be relevant for clinical decision-making, with results that are comparable to or improve upon standard practice at a peripheral care setting. The device must have comparable **analytic** sensitivity and specificity to existing tests. The device should be able to incorporate dynamic personal and population priors (e.g. medical history or disease prevalence, respectively) to improve the accuracy of the test result in clinical settings.
 - For **anemia**, in comparison to the reference method, 85% of the results must fall within +1.0g Hb/dL of the reference across a range of Hb concentrations spanning the healthy range and moderate to severe anemia.
- **Clinical utility.** Device must be able to differentiate between relevant strains of the disease, across necessary population age brackets, and over the course of disease progression.
 - For **sickle cell**, the device needs to differentiate sickle cell as early in life as possible, in conjunction with dynamic priors. Ideally, the device should be able to perform with high levels of fetal hemoglobin still present and should be able to differentiate sickle cell disease from sickle cell trait.
 - For **malaria**, the device needs to be able to detect and differentiate various parasite species. Required are *Plasmodium falciparum (Pf)* and / or *Plasmodium vivax (Pv)*; Optimal is all *Plasmodium* species. If all species cannot be differentiated, differentiation between *Pf* and *Pv* is desired.
 - An **anemia** diagnostic must clinically differentiate mild, moderate and severe anemia. In addition, it must have 95% sensitivity and 90% specificity in each trimester of pregnancy at the moderate anemia threshold of 11.0g/dL and the severe anemia threshold point of 7.0g/dL.
- **Detection and interpretation.** Proposed device should measure parameters that could be used to track disease state and/or response to therapy. Results from a test must be interpretable by a machine.
- **Safety.** If used, light sources should be Class 2 or Class 3R with appropriate controls to avoid eye exposure or skin damage. Devices must not trigger crises or significant occlusion events in sickle cell patients.

Intended use, for evaluation of feasibility data (where possible) and use case proposal:

- **Time to results.** Results should be interpretable within 15 minutes.



- **Data capture.** Information should be captured digitally from the device in <10 seconds if handheld, and <60 seconds if wearable. Data should be transferrable to a data system subsequently.
- **Components.** The platform should be either (1) a standalone mobile device or (2) an algorithm on or small attachment to a mobile phone. *Proposals should discuss potential for miniaturization of a prototype to this end state.*
- **Form factor.** The device should be self-contained and highly portable. For example, the devices should not require biological reagents, and a health worker should be able to carry it independently over varied terrain. The participants can determine the appropriate form factor for the intended use case.
- **Cost.** The final cost of the device should be <\$500, not including the cost of the phone. *Proposals should discuss the potential for cost-reduction to meet this target cost.*
- **Target use case.** The device should be intended for use in zero infrastructure conditions including outdoor settings and performed by untrained lay persons.
- **Lifespan of device.** The final device should last at least two years. *Proposal should discuss potential to achieve a two-year lifespan.*
- **Ease of use.** The device should have no user-timed steps; five or fewer user steps, instructions should include diagram of method and results interpretation

SUBMITTING YOUR PROPOSAL

Registration Process:

This Challenge announcement can be found on Challenge.gov and <https://venturewell.org/ntac> websites. A participant or team can submit an entry for the Challenge by registering [here](#) and following the links and instructions to certify that the entry meets all the Challenge rules and to submit the entry.

Submission Requirements:

Submissions to the NIH Technology Accelerator Challenge: Non-invasive Diagnostics for Global Health must follow the Submission Guidelines available at <https://venturewell.org/ntac> . If the Participants will submit as a team, they should identify a Team Leader who will serve as the point of contact and submit the entry to the Challenge on behalf of the team. Only complete submissions that follow the Submission Guidelines will be reviewed. In brief, submissions must:

- Be written in English, observe all page limits, have appropriate page dimensions (8.5 x 11 inches), use a font size of 11 point or greater, and have at least 1-inch margins.



- Include the requested sections and information as listed in the Submission Template: Cover Page, Description of the Submission, Participant Qualifications and References.
- Include the following statement in the Cover Page:
 - *"By submitting this entry to the NIH Technology Accelerator Challenge: Non-invasive Diagnostics for Global Health, I understand and agree that each participant in the Challenge must comply with all terms and conditions of the Challenge rules, and participation in this Challenge constitutes each such participant's full and unconditional agreement to abide by these rules."*
- Be submitted as a single PDF file [here](#) by the submission deadline.
- Format any references according to the [American Psychological Association (APA)] style.

Where applicable, images, videos, webpages and/or YouTube links will be accepted and can be directly entered into the Challenge Application Portal.

Submissions that do not follow the Submission Guidelines may not be considered at NIH's discretion, and any material that exceeds stated page limits will be considered supplemental and will be reviewed and judged at NIH's discretion. Submissions must not include HHS's logo or official seal or the logo of NIH or NIBIB and must not claim federal government endorsement.

ADDITIONAL INFORMATION

Supplemental information: Background detail on disease mechanisms that may be applicable for detection via a non-invasive approach

Note: Background information may not be comprehensive

As mentioned above, the challenge encourages designs for a non-invasive platform device that can diagnose sickle cell disease, malaria, or anemia, and leaves open to the participants the design and approach. There is significant literature on the disease pathophysiology and related properties of the blood that may be amenable to detection with a non-invasive tool. The several examples listed below are intended to demonstrate the potential for such an approach, though should not limit the thinking for disease mechanisms or measurement strategies.

Sickle cell: The underlying cause of sickle cell disease is the de-oxygenation of hemoglobin S that leads to polymerization and the formation of rigid fibers. These fibers reduce the

flexibility of red blood cells, cause the deformed “sickled” shape, and can lead to vaso-occlusion in small vessels.^[i] In a recent publication in *Blood* in 2017, William A. Eaton and H. Franklin Bunn highlight several nuances in fiber assembly kinetics and mechanism, as relevant for sickle cell treatment, that may shed light on the properties that may be observable by a diagnostic tool. Namely, the polymerization of hemoglobin S is dependent on the hemoglobin concentration and oxygen pressure, as well as the microcirculation. Fiber formation occurs if the rate of polymerization is faster than the time through the vasculature and can cause vaso-occlusion if the abnormal red blood cells adhere to the vascular endothelium or leukocytes.^[ii]

Malaria: Malaria causes changes to vascular properties and dynamics by infecting the host’s red blood cells and the release of toxins and byproducts such as hemozoin into the blood when parasites rupture. For *P. falciparum* (distinct from other species), infected red blood cells are in the blood circulation for 24-32 hours, after which the infected cells adhere to endothelial cells and are sequestered in the vasculature. The sequestration (or cytoadherence) can inhibit blood flow and can lead to an immune response. These parasites can remain sequestered for up to 24 hours.^[iii]

While sequestered, mature parasites rupture to yield daughter merozoites into the circulation, in addition to toxins and parasite by-products.^[iv] One of those products, hemozoin (malaria pigment), has been investigated as a potential biomarker for malaria, given its crystalline structure and potential ability to be detected without preparation of an additional sample preparation method. There are several known challenges with identifying hemozoin in the vasculature:

1. In *Pf* infections, hemozoin is encapsulated in RBCs and can only be seen in the peripheral blood stream, when it is difficult to detect.
2. As parasites mature, the concentration of hemozoin increases, though the parasites are sequestered in the microvasculature. Sequestered parasites are localized and do not appear in most blood samples.
3. When the cell ruptures, hemozoin circulates in the blood briefly, though are then quickly taken up by white blood cells. There are few white blood cells circulating early in the infection or at low parasitemia where diagnosis is most critical.^[v]

If non-invasive tools can identify hemozoin throughout the stages of infection, despite the known sequestration process, this could revive interest in taking the marker to field trials.

Anemia: The blood properties and clinical presentation of anemia may lend themselves to diagnosis via a non-invasive tool. There are three primary mechanisms that cause anemia: (1) Loss of blood leading to low iron levels, (2) insufficient red blood cell production due to nutrient and hormone imbalance, and (3) excessive destruction of red blood cells. Anemia is diagnosed today as low hemoglobin levels or low percentage of red blood cells in blood volume.^[vi] In addition to blood properties, anemia can also affect skin color and cause pallor, and has been used as a simple detection mechanism for anemia. In an early study (1999) on using clinical pallor as a screening tool in Nepal and Zanzibar, research found that pallor in the conjunctiva, palm, and nailbed was associated with lower hemoglobin and may be clinically useful in resource-constrained settings, though was insensitive to mild anemia and had varied sensitivity across demographic groups.^[vii]

CONTACT US

For questions about the Challenge:
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[i] [Bunn, H. Franklin, "Pathogenesis and Treatment of Sickle Cell Disease." N Engl J Med 1997; 337:762-769](#)

[DOI: 10.1056/NEJM199709113371107.](#)

[ii] [Eaton WA, Bunn HF. Treating sickle cell disease by targeting HbS polymerization. Blood. 2017;129\(20\):2719-2726. doi:10.1182/blood-2017-02-765891](#)

[iii] [Autino B, Corbett Y, Castelli F, Taramelli D. Pathogenesis of malaria in tissues and blood. Mediterr J Hematol Infect Dis. 2012;4\(1\):e2012061. doi:10.4084/MJHID.2012.061](#)

[iv] [Autino B, Corbett Y, Castelli F, Taramelli D. Pathogenesis of malaria in tissues and blood. Mediterr J Hematol Infect Dis. 2012;4\(1\):e2012061. doi:10.4084/MJHID.2012.061](#)

[v] [Delahunt, C., Horning, M.P., Wilson, B.K. et al. Limitations of haemozoin-based diagnosis of *Plasmodium falciparum* using dark-field microscopy. Malar J **13**, 147 \(2014\) doi:10.1186/1475-2875-13-147](#)

[vi] [Braunstein, Evan., "Overview of Anemia," Merck Manual- Consumer Version, Last updated: February 2019, Accessed November 2019.](#)

[vii] [Stoltzfus, R. J., Edward, A. M., Dreyfuss, M. L., Albonico, M., Montresor, A., Thapa, M. D., ... Tielsch, J. \(1999\). Clinical pallor is useful to detect severe anemia in populations where anemia is prevalent and severe. *Journal of Nutrition*, 129\(9\), 1675-1681.](#)

