Covid-19 Pathogen Genomic Sequencing (PGS) in Africa Rules & Guidelines

Applications due no later than Thursday May 13th, 2021 12:00pm, U.S. Pacific Time

Background

The COVID-19 pandemic has brought unprecedented challenges for Africa, with every country potentially at risk for unmitigated spread of SARS-CoV-2. Like most health systems in the world, there is a significant risk for current levels of care to be overwhelmed by sheer volume of patients requiring intensive care and ventilatory support. In addition, health care workers are at risk of acquiring SARS-CoV-2 and given limited infection control practices in many settings, there is also risk of nosocomial transmission of SARS-CoV-2 among patients.

The emergence of new SARS-CoV-2 variants is further raising concerns of the possibility of reinfection among those previously infected with the 'wild type' virus. A recent survey conducted by the African Academy of Sciences Scientific Priority setting initiative found that the most important questions that African scientists, health care workers and public health officials should study included the detailed epidemiology and transmission dynamics in African settings, as well as infection prevention and control for health care workers. These are questions that are widely applicable across the continent yet require local context and expertise to address in a timely and effective manner.

Pathogen genomic sequencing (PGS) has been increasingly used in wealthy countries to help respond to outbreaks of infectious diseases, from MDR bacteria to Ebola to Yellow Fever, Measles, and Polio. Already, PGS has been shown to be important in understanding the transmission dynamics and epidemiology of SARS-CoV-2 in the US, Europe, and China. PGS has been used for outbreak size estimation based on phylodynamic analyses and to identify and characterize new variants.

The emergence of new SARS-CoV-2 variants in multiple locations across the world, including in Africa, has highlighted the need for genomic sequencing in surveillance and epidemiology. PGS has enabled the identification of emergent strains and provided the ability to monitor their spread. Genomic data has allowed for characterization of mutations, providing insights into possible mechanistic changes and biological implications. These insights provide the first clue of potential impact on the effectiveness of therapeutics, such as monoclonal antibodies, and vaccines that may warrant further investigation. Furthermore, the ability for genomic sequencing to differentiate which SARS-CoV-2 variant someone has been infected with, makes PGS an important tool for aiding in the investigation of changes to transmissibility and impact on clinical outcomes of new variants.

Genomic sequencing of SARS-CoV-2 can also help in effectively managing and controlling the epidemic in the continent by providing information to allow a precise identification of transmission clusters and of mutations of the virus. The information obtained can also help in tailoring new vaccine and/or treatment efforts within Africa by for example combining genetic, clinical, and epidemiological data.

Contrary to initial models and forecasts, the reported number of cases and mortality rates reflect a markedly less severe epidemiologic picture of COVID-19 in Africa. Consequently, SARS-CoV-2 sequencing (COVID-19 genomics) may also shed some light on the underlying factors possibly explaining these differences between Africa and those other parts of the world. It is important to note that human genomics will not be covered by this call. Furthermore, sequencing can help to monitor and characterize the changes to the genetic epidemiology of the COVID-19 pandemic after vaccine introduction. Unfortunately, PGS is not in widespread use in Africa. A rapid introduction of PGS in Africa will help in the fight to control SARS-CoV-2 and help prepare the continent for the next epidemic not yet identified.

Over the past three years, the Africa CDC has established expertise in PGS. In 2020 along with partners, Africa CDC launched the Africa Pathogen Genomics Initiative, which will include many activities to strengthen the capacity for and public health use of PGS in Africa. One such activity is the development of a continental laboratory network that will eventually have advanced sequencing capacity at national public health institutes across at least 20 African countries. Africa CDC has the mandate and vision to bring together African thought leaders in PGS in a coherent and sustainable peer network through the pan-continent Africa Pathogen Genomics Initiative. The challenge will support the parallel development of a cadre of African scientists and public laboratories who can contribute substantively to this initiative.

The Challenge

Grand Challenges Africa, in partnership with the Bill & Melinda Gates Foundation ("Gates Foundation") and the Swedish International Development Cooperation Agency (SIDA) invites proposals that will primarily support public-health-use cases of PGS in African settings to respond to the Covid-19 pandemic. Grand Challenges Africa (GC Africa) is a program that seeks to promote Africa-led scientific innovations to help countries better achieve the Sustainable Development Goals by awarding seed and full grants to the continent's most impressive solutions and has covered topics such as Data Science Approaches to Improve Maternal and Child Health in Africa, Innovation for WASH (Water, Sanitation, and Hygiene) in Urban Settings, & Drug Discovery. Through this partnership, we seek to make awards that will support increased understanding of SARS-CoV-2 in Africa for use in public health decision making.

Specifically, the **objectives** of the challenge will be:

- 1. Use of PGS to establish routine genomic surveillance and understand the epidemiology and transmission of SARS-CoV-2
- 2. Use of PGS in public health field epidemiology response for SARS-CoV-2 to investigate new virus variants and their impact on the epidemiology of Covid-19
- 3. Use of PGS to monitor the impact of vaccine introduction on the epidemiology of SARS-CoV-2 in terms of transmission dynamics and/or incidence of virus variants.
- 4. Use PGS to inform the development of diagnostics and/or therapeutics and/or monitor the impact of new product introduction.

Projects addressing more than one challenge (e.g., clinical and field epidemiology) are encouraged. In some geographies many of these challenges exist simultaneously, at different times for different populations; in other geographies only one or two of these challenges predominate. Applications should clearly state which of these challenges is being targeted and provide clear rationale for why the project is likely to address the challenge.

Applications should also state how the knowledge generated from their proposal would be produced in a timely manner in order to inform public health decision making. We expect that PGS data on SARS-CoV-2 will be shared immediately with local government health officials as well as uploaded to a standard repository for genetic data such as GISAID, NCBI or ENA, all in compliance with applicable data protection laws. Such sharing is important for the public health response locally but also globally.

Responding to the above challenges requires a multidisciplinary approach. Thus, collaborative work is highly encouraged.

What We Are Looking For:

We will highly preference funding for projects in national public health institutes or other public laboratories with links to the public health systems that focus on pathogen genomic sequencing.

All applications should:

- Describe how laboratory and staff can immediately put to use PGS technology at your site to respond to at least one of the challenges listed above.
- Describe how the data generated from your project will be used to inform public health decision making in your country and/or region in a timely manner. How will you communicate your findings and engage with stakeholders to ensure uptake and use of your findings for these public health purposes?
- Given the fast-moving nature of the research field into SARS-CoV-2, how will you ensure that the results that your work produces are timely, and the question being addressed is still relevant at the time when the results are available.
- Describe the sampling approach for obtaining specimens for genomic sequencing and how the sampling approach will be optimized to answer at least one of the challenges outlined above. In addition, describe how metadata and clinical, epidemiological or other data will be collected and combined with the PGS data to answer at least one of the challenges listed above.
- Articulate how the capacity built through the proposed project will strengthen your institute's approach to using PGS for surveillance beyond the covid-19 pandemic.

A few of the many options we will consider include (but are not limited to) support for:

- Laboratory equipment, supplies and reagents needed for next generation pathogen genomic sequencing (PGS). Centers with Sanger sequencing capabilities can also apply.
- Field supplies for sample collection, transportation, storage and preparation.
- Collection of linked epidemiological data and meta-data.
- Laptop or computer with appropriate software for the analysis; high speed internet access and cloud compute time, if not provided through the Africa CDC lab network.
- Salary for personnel (including for example laboratory personnel, epidemiologist, field staff to collect samples).
- Training specific for PGS technology or bioinformatics, either online or in person.
- Travel to Africa CDC to support network development or to present findings at an international conference.
- Costs for high performance computing, where applicable.

We will not consider funding for projects that do not primarily respond to SARS-CoV-2 public health response. Human genomics will not be covered by this call.

Supporting Materials

- 1) Full RFP Covid-19 Pathogen Genomic Sequencing (PGS) in Africa
- 2) Application Instructions
- 3) Budget Template and Narrative
- 4) Frequently Asked Questions

Application Instructions

Key dates and deadlines

Key Dates	Event
Tuesday April 20, 2021	Application period opens
Thursday May 13, 2021 12:00pm, US Pacific Time/ 8:00pm West Africa Time	Application period closes, deadline to submit
Spring/Summer 2021	Target grant start date, announcements made
November 2021	Finalists participate in Grand Challenges Annual Meeting

*Note, any changes to the Key Dates or Events, to include the request for additional information, will be directly communicated to invited applicants.

How to Apply

Please note, applications for this RFP will be accepted by invitation only. This invitation is transferrable and collaborations are encouraged. If you believe another person within your institution would be better suited than you to respond to the RFP, or, if you want to invite coapplicants iointly submit а proposal with vou, please email to us at grandchallenges@gatesfoundation.org. We can assist in providing these applicants with access to our system.

Changes to the Rules and Guidelines and to the <u>frequently asked questions (FAQ) document</u> will be posted periodically, including any changes to the dates listed above. Please read the FAQ document before submitting any questions or concerns. Your proposal package will consist of:

- (1) Applicant profile and information completed via our application portal.
- (2) Your Proposal (3 pages maximum) uploaded as a Microsoft Word® or Adobe® PDF file.
- (3) Budget table and narrative (1 page, use <u>template provided</u>) uploaded as a Microsoft Word® or Adobe® PDF file.

We will consider proposals for awards of up to USD \$150,000 plus associated indirect costs permitted under our <u>Indirect Cost Policy</u> for implementation of up to 12 months. If you are selected to receive a grant, your organization will be required to agree to the terms and conditions governing the grant award.

For detailed information application instructions, please see the <u>application instructions</u> <u>document</u>.

Proposal Format – 3 pages maximum

We encourage you to reference the request for proposals document along with the application instructions document to ensure that your proposal responds to the challenge. You are required to submit either a Microsoft Word® or PDF® document; no more than 3 pages in length describing your project as well as a one-page budget table and narrative. Please do not include a cover sheet with your proposal. A cover sheet will be automatically generated from your registration data.

(Indicated page limits are guidelines only for individual sections.)

Section I: What is your idea and how will you test your hypothesis? (2 1/2 pages)

- 1. Describe how your laboratory and staff can immediately put to use PGS technology at the site to respond to at least one of the challenges listed above.
- 2. Given the fast-moving nature of the research field into SARS-CoV-2, how will you ensure that the results that your work produces are timely, and question being addressed is still relevant at the time when the results are available.
- 3. Work plan: Describe the sampling approach for obtaining specimens for genomic sequencing and how the sampling approach will be optimized to answer at least one of the challenges outlined above. In addition, describe how metadata and clinical, epidemiological or other data will be collected and combined with the PGS data to answer at least one of the challenges listed above.
- 4. Describe how the data generated from your project will be used to inform public health decision making in your country and/or region in a timely manner. How will you communicate your findings and engage with stakeholders to ensure uptake and use of your findings for these public health purposes?
- 5. Articulate how the capacity built through the proposed project will strengthen your institutions approach to using PGS for surveillance beyond the covid-pandemic.

Section II: Scaling Innovations through Partnerships (1/2 page)

We seek to encourage intra-Africa relationships across the continent. Use this section to describe how your project will either build on an existing partnership or start a new one.

Budget Table and Narrative – 1 page maximum

Please use the <u>budget template</u> (linked and on the application portal) to include a breakdown of allowable direct costs under the following categories.

- Personnel
- Subcontracts
- Subgrants
- Capital Assets/Equipment
- Travel
- Supplies
- Other Expenses
- Indirect Costs (please review the <u>Indirect Cost Policy</u>)

Proposals must be submitted prior to the deadline of Thursday May 13, 2021 12:00pm, U.S. Pacific Time

Awards

The funding level for the Covid-19 Pathogen Genomic Sequencing (PGS) in Africa Project is **a grant of up to \$150,000 USD, provided to the organization,** with a term of up to twelve (12) months. Application budgets should be commensurate with the scope of work proposed. Indirect costs will be considered in addition to the \$150,000 award. (subject to the <u>Bill & Melinda Gates</u> Foundation's indirect cost policy).

Please note:

During the application process you will be required to confirm that you have read and understood the <u>Website Terms of Use and Privacy Policy</u>, and these Rules and Guidelines, and acknowledge that any information that you provide to us (either orally or in writing) will be subject to and handled in accordance with such provisions.

Subject to the Foundation's <u>Privacy Policy</u>, the Foundation may share <u>information you and your</u> <u>host organization provide to us (either orally or in writing)</u> with third parties, including external reviewers, key partners and potential co-funders. This document is subject to the Foundation's <u>Terms of Use</u>.

Eligibility Criteria

This initiative is open to Africa-based organizations that have been invited to apply, including nonprofit organizations, government agencies, and academic institutions We will highly preference funding for projects in national public health institutes or other public laboratories with links to the public health systems. Individuals and organization classified as individuals for U.S. tax purposes are not eligible to receive an award from the foundation as part of this initiative. All grant funds would need to be awarded directly to organizations located in Africa.

Sequencing data will be made publicly available in a timely manner in compliance with applicable data protection laws and in accordance with our <u>Open Access Policy</u>. If an applicant is not willing or able to do so, they will not be eligible to apply for this opportunity.

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.

Please review the include additional instructions regarding specific limitations regarding eligibility for this initiative.

Review Process

Handling of Applications

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 Foundation's Privacy Policy, 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.

Additionally, the foundation is required by the IRS to publish a list of its grants. The foundation also provides general descriptions of its grants on its web sites, in press releases, and in other marketing materials. These Rules and Guidelines are subject to these <u>Terms of Use</u>.

Review of Applications

The Grand Challenges application review process is executed in four steps:

- 1. The first step consists of screening applications to evaluate whether proposals address the key needs described in the topic. We screen for responses that are completely unrelated or specifically excluded in the topic description. Excluded responses encompass ideas related to the topic but that, for strategic reasons, we are not funding under the Grand Challenges initiative. In addition, we exclude proposals considered incremental advances, appropriate responses that are similar to work in which the foundation or other Grand Challenges programs are already investing, or avenues of inquiry we deem ill-suited to the Grand Challenges initiative. Applicants with proposals removed from consideration during the screening process will be notified that their proposals were declined but will not receive specific feedback.
- 2. In the second step, reviews are chaired or co-chaired by technical leads from the foundation and, in some cases, other funding partners and are conducted by reviewers both outside and within the foundation. Reviewers are selected from the world's leading researchers and comprise both experts in the topic area and experts in complementary areas. Not all reviewers have deep expertise in the topic; please consider this information when drafting your proposal.

The criteria considered in these reviews are:

- Potential to lead to solutions with substantial impact related to the specific topic
- Scientific and technical excellence & innovation, including:
 - creativity of the project's approach and clear differentiation from existing approaches
 - o a clear and rigorous conceptual framework for the activities
- Project Plan, including:
 - o investigator and organization capabilities and potential for collaboration
 - value in terms of appropriateness of the budget and timeline relative to project complexity, risk, and potential impact
 - Applicant's capability to execute the work, and the appropriateness of the budget request.
- 3. The third step is the validation and final selection of the proposals to be funded by the Executive Committee. The Executive Committee may recommend the proposal be funded, subject to specific modifications which will be negotiated as part of the award process.
- 4. The fourth and final step is a due diligence review and to directly discuss and negotiate any adjustments to the proposed project recommended by the Executive Committee. Investigators will be contacted as part of the due diligence review.

Management of Conflict of Interest

To identify and avoid conflicts of interest among application reviewers, such reviewers will not be permitted to review proposals from organizations with which the reviewer has self-identified conflicts of interest.

Eligibility and Notifications

A. Allowable Costs

Grant funds may be used for the following costs: personnel, necessary travel, supplies, contracted services, sub-grants, and consultants. Partial or full support for equipment may be requested subject to the circumstances described below. Please provide budget estimates according to these categories. The foundation provides a limited amount of indirect costs based on the nature of the applicant organization.

B. Privacy Notice

To help foundation staff in their evaluation and analysis of projects, all documents, communications and associated materials submitted to the foundation (collectively, "Submission Materials") will become the property of the foundation and may be subject to external review by independent subject matter experts in addition to analysis by foundation employees, contingent workers and/or consultants. Please consider carefully the information included in the Submission Materials. If you have any doubt about whether to disclose confidential or proprietary information, the foundation recommends you consult with your legal counsel. You may wish to consider whether such information is critical for evaluating the submission, and whether more general, non-confidential information we receive. Nonetheless, notwithstanding your characterization of any information as being confidential, the foundation may disclose all information contained in Submission Materials to the extent it determines is necessary to evaluate them and the manner and scope of potential funding and as may be required by law.

C. Disclaimer

Neither these Rules & Guidelines nor the associated invitation constitute an offer to contract or award grant funds. The foundation assumes no responsibility for the applicants' cost to respond to this these invitations.

D. Release and Verification

In exchange for the opportunity to be considered for a grant, contract or program-related investment (PRI) (per the relevant challenge call), the applicant agrees that the foundation may, in its sole discretion: (1) amend or cancel any challenge calls, in whole or in part, at any time; (2) extend the deadline for submitting responses; (3) determine whether a response does or does not substantially comply with the requirements of the challenge call and/or these Rules & Guidelines; (4) waive any minor irregularity, informality or nonconformance with the provisions or procedures of the challenge call and/or these Rules & Guidelines; (5) issue multiple awards; (6) share responses generated by the challenge call and/or these Rules & Guidelines with foundation staff, consultants, contingent workers, subject matter experts, and potential co-funders; and (7) copy the responses.

Applicant agrees not to bring a legal challenge of any kind against the foundation relating to the foundation's selection and award of any grant, contract or award arising from these Rules & Guidelines and the associated challenge calls.

E. Warranty

By providing any Submission Materials, the sender(s) and applicant warrant to the foundation that they have the right to provide the information submitted and that such information is accurate. Any material misrepresentation, including omissions, may disqualify Submission Materials from consideration for a grant, contract or PRI award. Applicants with questions concerning the contents of their Submission Materials may contact the foundation at: grandchallenges@gatesfoundation.org.

F. Intellectual Property (IP)

Since the output of this program may lead to innovative technologies, techniques and/or products that will result in improved health and development-related products for those in greatest need in the developing world, the successful development of these high priority products may require substantial involvement and support of private sector industries as sub-contractors, and may also involve collaborations with multiple organizations, including academic and/or non-profit research institutions.

It is the intent of this program to support the formation of appropriate public-private partnerships that are essential to meet urgent global health and global development needs. IP rights and the management of IP rights are likely to play an important role in achieving the goals of this program. To this end, the foundation requires that, even at the LOI application stage, all applicants seriously consider their willingness to submit a full proposal in compliance with the foundation's proposal guidelines, a portion of which asks for certain information and intentions regarding intellectual property and global access concerns. Specifically, the foundation requires that you agree to use good faith efforts to conduct and manage the research, technologies, information and innovations involved in the Project in a manner that enables (a) the knowledge and information gained during the Project to be promptly and broadly disseminated, and (b) the intended product(s) to be made available and accessible at an affordable price to people most in need in the developing countries of the world. The foundation refers to this as "Global Access."

As part of the foundation's review and evaluation of each full proposal, due diligence will be conducted with respect to each participant's ability and commitment to manage intellectual property in a manner consistent with the stated scientific and charitable goals of the foundation. Due diligence activities may include inquiry into an applicant's: (1) Freedom to operate (FTO) and ability to freely use and acquire needed background technology; and (2) Commitment to promote the utilization, commercialization, and availability of inventions for public benefit in, or the benefit of, developing countries. In order to facilitate this due diligence process applicants are encouraged to provide information with respect to the items above in their Submission Materials.

Applicants are also expected to make new information and materials known to the research and/or medical communities in a timely manner through publications, web announcements, progress reports to the foundation, and other appropriate mechanisms. These concepts may be discussed at some length with the applicants invited to submit full proposals and will be addressed (to the extent appropriate) within each final grant agreement. The Global Access Strategy, developed in connection with each grant awarded to each applicant who submits a successful proposal, will also include provisions defining these concepts.

G. Compliance with Laws and Other Requirements

- 1. Compliance with Laws. In carrying out the individual project, you will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property, privacy, or publicity rights of any third party.
- 2. Compliance with Requirements. You will conduct, control, manage, and monitor the individual project in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards ("Requirements"). You will obtain and maintain all necessary approvals, consents, and reviews before conducting the applicable activity. As a part of your annual progress report to the foundation, you must report whether the individual project activities were conducted in compliance with all Requirements.

If the project involves:

- a. any protected information (including personally identifiable, protected health, or third-party confidential), you will not disclose this information to the foundation without obtaining the foundation's prior written approval and all necessary consents to disclose such information;
- b. children or vulnerable subjects, you will obtain any necessary consents and approvals unique to these subjects; and/or
- c. any trial involving human subjects, you will adhere to current Good Clinical Practice as defined by the International Council on Harmonization (ICH) E-6 Standards (or local regulations if more stringent) and will obtain applicable trial insurance.

Any activities by the foundation in reviewing documents and providing input or funding does not modify your responsibility for determining and complying with all Requirements for the project.

- 3. Indemnification. If the project involves clinical trials, trials involving human subjects, postapproval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services ("Indemnified Activities"), you will indemnify, defend, and hold harmless the foundation and its trustees, employees, and agents ("Indemnified Parties") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "Claims") arising out of or relating to the acts or omissions, actual or alleged, of you or your employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with respect to the Indemnified Activities. You agree that any activities by the foundation in connection with the project, such as its review or proposal of suggested modifications to the project, will not modify or waive the foundation's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Your indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this agreement will constitute an express or implied waiver of your governmental and sovereign immunities, if any.
- 4. **Insurance.** You will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the project in accordance with generally accepted industry standards and as required by law. You will ensure your subgrantees and subcontractors maintain insurance coverage consistent with this section.

Privacy Notice and Terms of Use

Our full privacy policy and terms of use are located at Privacy and Terms of Use.

Representation: By providing any Submission Materials, the sender represents to the Bill & Melinda Gates Foundation that he/she (i) has the authority to bind the named Applicant to the terms set forth above, without amendment, (ii) agrees to be bound by such terms; and (iii) has the right to provide the information submitted.

Frequently Asked Questions

Answers to many application questions can be found on the <u>frequently asked questions</u> <u>document</u>.

Inquiries

Please direct all questions about this initiative, selection criteria or application instructions by email to the following address: grandchallenges@gatesfoundation.org.