Project Information Document/ Identification/Concept Stage (PID)

Concept Stage | Date Prepared/Updated: 08-Dec-2021 | Report No: PIDC250510

BASIC INFORMATION

A. Basic Project Data

Project ID	Parent Project ID (if any)	Environmental and Social Risk Classification	Project Name
P177439		Low	Accelerating Genomics-based Surveillance for COVID-19 Response in South Africa
Region	**Country**	**Date PID Prepared**	**Estimated Date of Approval**
AFRICA EAST	South Africa	08-Dec-2021	10-Dec-2021
Financing Instrument	**Borrower(s)**	**Implementing Agency**	
Investment Project Financing	National Treasury	Stellenbosch University	

PROJECT FINANCING DATA (US$, Millions)

SUMMARY

Total Project Cost	5.00
Total Financing	5.00
Financing Gap	0.00

DETAILS

Non-World Bank Group Financing

Trust Funds	5.00
Health Emergency Preparedness and Response Multi-Donor Trust	5.00

B. Introduction and Context

Country Context

South Africa (SA) is one of the largest economies in Africa and their populations have been seriously affected by the COVID- 19 pandemic. As of mid-October 2021, SA reported almost 3 million cases of COVID-19 infections and 90,000 deaths. SA accounts for about 50 percent of the total confirmed cases of COVID-19 and 60 percent of deaths in Sub-Saharan Africa. The number of people with compromised immunity due to the high prevalence of HIV/AIDS makes SA more vulnerable to the COVID-19 pandemic. The first two waves of the pandemic in SA were dominated by novel variants of severe acute respiratory syndrome coronavirus 2

(SARS-CoV-2), B.1.351 (501Y.V2) and B.1.525, whereas the third wave was dominated by the Delta variant. These variants have also spread widely to neighboring countries and may evolve further and affect diagnostics and vaccines.

In June 2020, SA established a network for genomic surveillance (NGS-SA), funded by the Department of Science & Innovation (DSI) and the South African Medical Research Council (SAMRC), to monitor genetic changes that impact pathogenicity, diagnostics and therapeutics and vaccines. This network combines five of the largest laboratories in the country and their associated academic institutions in five major SA cities. Since then, the network has expanded to also include private diagnostic laboratories and other academic institutions in and outside SA.

Since September 2020, SA has served as one of the few hubs for the entire Africa region to reinforce genome sequencing of the SARS-CoV-2. By the end of 2020, SA has carried out most of the total 4,948 sequences completed in the region and has identified 35 SARS-CoV-2 lineages.

In recognition, the WHO selected the South African National Bioinformatics Institute (SANBI) and Kwazulu-Natal Research Innovation and Sequencing Platform (KRISP) as their reference laboratories for genomic sequencing. Further, the Centre for Epidemic Response and Innovation (CERI) has been established at Stellenbosch University to expand the efforts of KRISP. The other reference laboratory is the African Center of Excellence for Genomics of Infectious Diseases (ACEGID), at Redeemer's University in Ede, Nigeria.

Many LMICs do not have the strong health systems and genomic sequencing infrastructure (instruments and properly trained personnel) needed to underpin a good genomic surveillance system, that could in turn report to regional/continental systems and/or global systems. Outside of the HICs (High Income Countries), Sub-Saharan Africa and LAC (Latin America and Caribbean) regions seem to have better regionally coordinated sequencing [ac1] and surveillance reporting systems. Despite this apparent success, gaps still exist in these and other regions.

Sectoral and Institutional Context

The COVID-19 pandemic is one of the greatest challenges that humankind has faced in generations. It has already cost almost five million lives globally, sickened nearly 250 million people around the world, upended countless livelihoods, and caused substantial economic loss. Despite advances in the development and rollout of vaccines as well as in the clinical management of patients with COVID-19, the end of the worst public-health crisis in a century is not yet in sight as new variants that decrease the effectiveness of the public health interventions and vaccines are emerging.

The evolution of SARS-CoV-2 has generated viral variants that differ in their genetic sequence from the original strain detected in Wuhan in December 2019 and pose a great risk to public health. Some of these variants are less sensitive to neutralization by convalescent sera or vaccine-induced neutralizing antibody responses, raising concerns about its negative impact on vaccine effectiveness. It is expected that SARS-CoV-2 will continue to mutate. There is a high risk not only for vaccine and immune escape variant to emerge, but also for loss of sensitivity of molecular and antigen capture tests. Thus, continued generation, analysis and sharing of virus genomes in real-time will be important to monitor the expected efficacy and sensitivity of different vaccines and nucleic acid tests across the continent.

The generation of near-real time genomic surveillance data and analyses has already proven useful in responding to COVID-19 outbreaks by producing actionable information for public health officials and policymakers. Genomic surveillance integrates clinical, epidemiological, genomic, and phenotypic data to track changes in virus transmission, virulence, and effectiveness of medical countermeasures. Recent advances in next-generation sequencing make it possible to quickly and cost-effectively sequence a large number of SARS-CoV-2-positive cases. Parallel advances in bioinformatics, computational biology, and molecular virology make it possible to analyze the virus in context to assess risk in close to real-time. Near-real time open-source sharing of viral genome sequences have facilitated near real-time detection, comparison, and tracking of evolving SARS-CoV-2 variants that can inform public health efforts to control the pandemic.

The rise of new SARS-CoV-2 variants have highlighted the need for partnerships at multiple levels and across institutions for detection and surveillance. Building a strong and resilient global sequencing network can maximize the public health impact of sequencing, not only for SARS-CoV-2 but also for future emerging pathogens. Various pathogen-specific laboratory networks have invested in sequencing capacity as part of their surveillance activities. As the costs of sequencing are substantial and many parts of the sequencing workstream can be used for various pathogens and sequencing objectives, national and regional collaborations are encouraged to ensure optimal use of existing capacity.

The World Bank Group mounted the largest and fastest crisis response in its history when COVID-19 emerged as a global threat, has committed over US$ 157 billion in grants and financing to help the countries mitigate the health, social, and economic impacts of COVID-19, boost countries' preparedness and ability to respond to the pandemic, deliver COVID-19 tools (vaccines, therapeutics, and diagnostics), protect the most vulnerable people from its critical shocks, and help countries strengthen health systems that are prepared for future disease outbreaks.

The proposed project is aligned with World Bank Group (WBG) strategic priorities, particularly the WBG's support to achieving Universal Health Coverage and the Sustainable Development Goals (SDGs) by 2030, as well as national plans and global commitments to strengthening pandemic preparedness. In addition, with its focus on health preparedness, it will directly complement other initiatives in promoting health security and building a resilient health system.

Relationship to CPF

The proposed project is aligned with the WBG Country Partnership Framework for the period FY22 - FY26. It will contribute to Cross-cutting Theme 3: Governance primarily through objective 3.3.6: Maintaining and Deepening the Knowledge Agenda.

Specifically, this project will expand the capacity of South Africa and the region to produce more than 20,000 SARS-CoV-2 genomes in a two-year period (September 2021 and September 2023) by investing in Center for Epidemic Response and Innovation (CERI) in South Africa – one of the two most well-known sequencing groups in Africa. Genomics surveillance aims to transform public health interventions by monitoring genetic changes that impact pathogenicity, diagnostics, therapeutics and vaccines. It will facilitate knowledge exchange between academic institutions on the African continent and build capacity on genomic sequencing that will inform the health response to COVID-19 by governments.

C. Project Development Objective(s)

Proposed Development Objective(s)

The project development objective (PDO) is to improve genomic surveillance of SARS-CoV-2 capacities of South Africa and the African region.

Key Results

This project is expected to yield the following main outcomes: (a) capacity of genomic sequencing in South Africa and the region is improved by upgrading CERI genomics laboratories and training sequencing staff and scientists; (b) an effective system to evaluate diagnostics and vaccine effectiveness against SARS-CoV-2 variants in South Africa is established; and (c) the data system/ platform for sharing and analyzing sequencing data is strengthened.

Key PDO indicators are: (a) number of sequences produced in South Africa; and (b) number of staff who are able to analyze COVID-19 variants.

D. Preliminary Description

Activities/Components

This project will expand the capacity of South Africa and the region to produce more than 20,000 SARS-CoV-2 genomes in a two-year period (November 2021 and November 2023) by investing in CERI and other regional laboratories. Genomics surveillance aims to transform public health interventions by monitoring genetic changes that impact pathogenicity, diagnostics, therapeutics and vaccines. Therefore, this funding will not only help fight COVID-19, but also represent a unique opportunity to expand the genomics

infrastructure that can be used for endemic diseases such as AIDS, tuberculosis, malaria, cholera, and other infectious diseases in South Africa and the continent. Furthermore, such genomics infrastructure could also be used to support Africa's preparedness for future epidemics and pandemic responses.

Activity 1:

Expanding the NGS-SA network and training sequencing staff and scientists. One of the concerns of the WHO is the time that it takes to produce sequence data to identify and control outbreaks. To detect an established local transmission cluster, whole genome sequencing is essential and should preferably be performed close to sample collection. The proposed project will enable viral genomes of patients with COVID-19 to be analyzed quickly with the application of standardized sequencing and bioinformatics pipelines. In order to do so, the project will support CERI and ACEGID to carry out sequencing of approximately 20,000 COVID-19 more samples identified in South Africa, Nigeria and the region. This will add to the 12,000 genomes that have already been produced in Africa. This will allow researchers to understand how SARS-CoV-2 is currently spreading and evolving as vaccines are rolled out in Africa. Specifically, the project will help CERI:

- expand the NGS-SA network to include sequencing laboratories and genomics and bioinformatics experts to share expertise, data and resources. The NGS-SA would serve as an integrated hub with sample collection taking place at multiple laboratories among the network member countries.
- organize monthly meetings between the CERI and the national, regional laboratories that are generating genomic data in South Africa, and the region. This will allow close collaboration between African scientists and will provide training and capacity building to other researchers on SARS-CoV-2 genomic data generation and data analysis.

Activity 2

Establishing an effective system to evaluate diagnostics and vaccine effectiveness against the variants in Africa. The proposed project will allow for surge support to the operationalization of national sequencing protocols/ plans to quickly identify and share data on COVID-19 variants. Specifically, the project will support:

- CERI to procure additional equipment and test essays, and hire staff to conduct analysis aiming to assess changes in vaccine effectiveness and diagnostic testing. It will also help CERI and ACEGID to establish an operational protocol to ensure adequate representations from member countries within the region regarding ethical regulations, laboratory and data safety measures and capacity strengthening.
- countries with limited laboratory and sequencing capacity to establish a mechanism for COVID-19 samples (both vaccinated and unvaccinated samples) to be sent to the regional laboratories in SA. A protocol must be in place to ensure rapid transportation of samples, ideally with a target of 48-hours from sample collection to analysis.

Genomic data collected at CERI and other laboratories should be analyzed, ideally weekly, focusing on: (a) local transmission versus imported cases; (b) chains of transmission; (c) rates of epidemic growth, including cases and deaths; (d) genetic changes; and (e) identification of genomic changes potentially impacting on therapeutic and vaccine effectiveness. For example, a fully vaccinated individual becoming sick and hospitalized with COVID-19 would be the first sign that variant viruses are becoming resistant to vaccine-induced immunity.

Activity 3

Strengthening the data systems to share and analyze sequencing data in near-real time. Rapid sequencing of virus genomes is now achievable in varied settings, and analyses of SARS-CoV-2 genomic sequences have a huge potential for informing public health efforts surrounding COVID-19. The rapid generation and global sharing of virus genomic sequences provides information that will contribute to the understanding of transmission and the design of clinical and epidemiological mitigation strategies. To enhance the value of genomic sequencing data, proper sequencing data tools must be used and should be linking with patient's epidemiological, clinical and vaccination data.

The rapid sharing of pathogen genome sequence data, together with the relevant anonymized epidemiological and clinical metadata will maximize the impact of genomic sequencing in the public health response. Such data, generated during an outbreak, should be shared with the global community as rapidly as possible, to ensure maximum usefulness in improving public health. The proposed project will support CERI to establish a data platform and train experts in the network to be able to analyze genomic sequencing data.

Environmental and Social Standards Relevance

E. Relevant Standards

ESS Standards		Relevance
ESS 1	Assessment and Management of Environmental and Social Risks and Impacts	Relevant
ESS 10	Stakeholder Engagement and Information Disclosure	Relevant
ESS 2	Labor and Working Conditions	Relevant
ESS 3	Resource Efficiency and Pollution Prevention and Management	Relevant
ESS 4	Community Health and Safety	Relevant
ESS 5	Land Acquisition, Restrictions on Land Use and Involuntary Resettlement	Not Currently Relevant

ESS 6	Biodiversity Conservation and Sustainable Management of Living Natural Resources	Not Currently Relevant
ESS 7	Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities	Not Currently Relevant
ESS 8	Cultural Heritage	Not Currently Relevant
ESS 9	Financial Intermediaries	Not Currently Relevant

Legal Operational Policies

Safeguard Policies	Triggered	Explanation (Optional)
Projects on International Waterways OP 7.50	No	
Projects in Disputed Areas OP 7.60	No	

Summary of Screening of Environmental and Social Risks and Impacts

The environmental risk classification for the project is Low with main environmental risks related to: (a) environment, health, and safety risks due to the generation of biohazard/health care wastes emanating from increased capacity in testing at the laboratory; (b) healthcare and chemical wastes management related to the handling, transportation, and disposal of hazardous virus sample and infectious health care waste; (c) occupational health and safety-related to minor refurbishment and the implementation of laboratory activities; and (d) community health and safety issues also related to the handling, transportation, and disposal of hazardous virus sample and infectious health care waste. The social risk classification for the project is low based on the nature of the activities which mainly involves capacity building and procurement of equipment to strengthen the CERI laboratory in South Africa. The project is expected to have positive social impacts by contributing to an improvement in genomic surveillance and pandemic preparedness and response at both the national and regional levels. The Project will not include any civil works and any direct interaction with communities is expected to be limited. The main inherent social risk is rated minimal and include: (a) inadequate or conflictual public engagement and lack of trusted and adequate consultation could negatively influence sequencing activity and reduce the program effectiveness; (b) occupational health and safety (OHS) related risks to health and laboratory workers; (c) fraud, corruption of procurement activities of sequencing equipment and supplies; (d) use of security personnel - the risk from use of government security personnel for transport, distribution and/or safeguarding of genomes and genomic data. Engagement will be required with other professional agencies including the World Bank, NIH, WHO, African CDC to ensure successful implementation of the project. Due to the likely nature and scale of the workforce issues related to labor and working conditions that are anticipated to be negligible but will be addressed through the requirement of the national law and requirements as will be outlined under the Environmental and Social Commitment Plan (ESCP). Sexual Exploitation and Abuse/Sexual Harassment (SEA/SH) Risk Rating is Low. The Project will not include any civil works and/or any direct interaction with communities is expected to be limited and as such the risk of SEA involving community members is expected to be low. The project mainly focuses on Capacity Building activities including training and purchasing of genomic sequencing equipment. The risk of SEA/SH involving workers at these events is also considered to be low, although such risks may be present in workplaces around the world. Whereas SEA/SH risk is considered low at this stage, minimum

requirements will need to be considered such as the signing of a Code of Conduct (CoC) by each of the project workers and development/inclusion in the national institutions a Grievance Redress Mechanism (GRMs) sensitive to Gender, GBV/SEA/SH potential risks and impacts. The required measures will be determined based on further analysis during project preparation. The GBV risk assessment tool will be applied to the project and its results included in the Project Appraisal Document. This project is not expected to involve any land acquisition or restrictions to land use. Renovation required at the designated laboratories to accommodate additional capacity for genomic sequencing will be done within existing structures and facilities. Appropriate proper training on the environmental and social risk management procedures including OHS measures will be provided by the project?s environmental and social focal points for the project workers to ensure they fully understand the Covid-19 protocols and principles for face to face events and appropriate biohazard disposal. The project will appoint an environmental and social focal point to provide oversight and technical support to ensure that environmental and social risk management, especially on managing infectious disease transmission risk and taking the necessary OHS measures are adequately integrated into the project design through the Terms of References (ToRs) for the focal points. The ToRs for the Focal Points will be prepared by ESCA-HC and approved by the World Bank. The management of biohazard sample waste will be implemented through infection control and solid waste plan that will be required for all project locations or events. Given the short duration of the project, no long-term or irreversible adverse risks related to environmental or social risk management are anticipated.

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