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Report No: PAD4811

INTERNATIONAL DEVELOPMENT ASSOCIATION

PROJECT PAPER

ON A

PROPOSED ADDITIONAL GRANT

IN THE AMOUNT OF SDR29.3 MILLION
(US\$41 MILLION EQUIVALENT)

TO THE REPUBLIC OF MADAGASCAR

FOR THE
SUPPORT TO COVID-19 VACCINE PURCHASE AND HEALTH SYSTEM STRENGTHENING
PROJECT

December 22, 2021

UNDER THE COVID-19 STRATEGIC PREPAREDNESS AND RESPONSE PROGRAM (SPRP)

USING THE MULTIPHASE PROGRAMMATIC APPROACH (MPA)

WITH A FINANCING ENVELOPE OF

UP TO US\$6 BILLION APPROVED BY THE BOARD ON APRIL 2, 2020, AND

UP TO US\$12 BILLION ADDITIONAL FINANCING APPROVED BY THE BOARD

ON OCTOBER 13, 2020

Health, Nutrition & Population Global Practice
Eastern and Southern Africa Region

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CURRENCY EQUIVALENTS

(Exchange Rate Effective November 30, 2021)

Currency Unit = Malagasy Ariary (MGA)

MGA 3,983.43 = US\$1

US\$1.40 = SDR 1

FISCAL YEAR

January 1 – December 31

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Country Director: Idah Z. Pswarayi-Riddihough

Regional Director: Amit Dar

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Task Team Leader: Maud Juquois

ABBREVIATIONS AND ACRONYMS

AEFI	Adverse Events Following Immunization
AF	Additional Financing
AFEVP	Vice President of the Eastern and Southern Africa Region
APA	Advance Purchase Agreement
AVAT	African Vaccine Acquisition Trust
AU	African Union
AUP	Agreed Upon Procedures
AWPB	Annual Work Plan and Budget
BFP	Bank Facilitated Procurement
CDC	Center for Disease Control and Prevention
CERC	Contingent Emergency Response Component
CPF	Country Partnership Strategy
COVAX Facility	COVID-19 Vaccine Global Access Facility
COVAX AMC	COVID-19 Vaccine Global Access Advance Market Commitment
COVID-19	Coronavirus Disease 2019
DA	Designated Account
DFIL	Disbursement and Financial Information Letter
DHIS2	District Health Information Software 2
E&S	Environmental and Social
ESCP	Environmental and Social Commitment Plan
ESMF	Environmental and Social Management Framework
ESS	Environmental and Social Standards
EUL	WHO Emergency Use Listing
FTCF	Fast Track COVID-19 Facility
FM	Financial Management
GBV	Gender-based Violence
GoM	Government of Madagascar
GRM	Grievance Redress Mechanism
GRS	Grievance Redress Service
GWP	Global Warming Potential
IBRD	International Bank for Reconstruction and Development
IDA	International Development Association
IFR	Interim unaudited Financial Reports
INSTAT	National Institute of Statistics
IPF	Investment Project Financing
IRI	Intermediate Results Indicator
ISR	Implementation Status Report

LMP	Labor Management Procedures
M&E	Monitoring and Evaluation
MoPH	Ministry of Public Health
MPA	Multiphase Programmatic Approach
NFCS	No-Fault Compensation Scheme
NTWG	National Technical Working Group
NVDP	National COVID-19 Vaccination and Deployment Plan
PAD	Project Appraisal Document
PARN	Improving Nutrition Outcomes using the Multiphase Programmatic Approach Project
PCU	Project Coordination Unit
PDO	Project Development Objective
PrDO	Program Development Objective
PID	Personally Identifiable Data
PIM	Project Implementation Manual
PPE	Personal Protective Equipment
PPSD	Project Procurement Strategy for Development
SEA	Sexual Exploitation and Abuse
SH	Sexual Harassment
SEP	Stakeholder Engagement Plan
SPRP	Strategic Preparedness and Response Program
SRA	Stringent Regulatory Authority
STEP	Systematic Tracking of Exchanges in Procurement
UNICEF	United Nations Children's Fund
VAC	World Bank's Vaccine Approval Criteria
VDDM	Vaccine Delivery and Distribution Manual
VIRAT	Vaccine Introduction Readiness Assessment Tool
VRAF	Vaccine Readiness Assessment Framework
WHO	World Health Organization

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BASIC INFORMATION – PARENT (Support to COVID-19 Vaccine Purchase and Health System Strengthening - P176841)

Country	Product Line	Team Leader(s)		
Madagascar	IBRD/IDA	Maud Juquois		
Project ID	Financing Instrument	Resp CC	Req CC	Practice Area (Lead)
P176841	Investment Project Financing	HAEH1 (9316)	AECS2 (5547)	Health, Nutrition & Population

Implementing Agency: Ministry of Public Health

Is this a regionally tagged project?	
No	

Bank/IFC Collaboration	
No	

Approval Date	Closing Date	Expected Guarantee Expiration Date	Environmental and Social Risk Classification
24-Jun-2021	30-Jun-2024		Substantial

Financing & Implementation Modalities

<input checked="" type="checkbox"/> Multiphase Programmatic Approach [MPA]	<input checked="" type="checkbox"/> Contingent Emergency Response Component (CERC)
<input type="checkbox"/> Series of Projects (SOP)	<input type="checkbox"/> Fragile State(s)
<input type="checkbox"/> Performance-Based Conditions (PBCs)	<input type="checkbox"/> Small State(s)
<input type="checkbox"/> Financial Intermediaries (FI)	<input checked="" type="checkbox"/> Fragile within a Non-fragile Country
<input type="checkbox"/> Project-Based Guarantee	<input type="checkbox"/> Conflict
<input type="checkbox"/> Deferred Drawdown	<input checked="" type="checkbox"/> Responding to Natural or Man-made disaster
<input type="checkbox"/> Alternate Procurement Arrangements (APA)	<input type="checkbox"/> Hands-on Expanded Implementation Support (HEIS)

Development Objective(s)



MPA Program Development Objective (PrDO)

The Program Development Objective is to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness

Project Development Objectives (Phase 024)

This Project’s Development Objective is to support the Government of Madagascar to acquire and deploy COVID-19 vaccines, and to strengthen its immunization services.

Ratings (from Parent ISR)

	Latest ISR
	25-Sep-2021
Progress towards achievement of PDO	S
Overall Implementation Progress (IP)	S
Overall ESS Performance	S
Overall Risk	H
Financial Management	S
Project Management	S
Procurement	S
Monitoring and Evaluation	S

BASIC INFORMATION – ADDITIONAL FINANCING (Additional Financing to Support to COVID-19 vaccine purchase and health system strengthening - P178279)

Project ID	Project Name	Additional Financing Type	Urgent Need or Capacity Constraints
P178279	Additional Financing to Support to COVID-19 vaccine purchase and health system strengthening	Scale Up	Yes
Financing instrument	Product line	Approval Date	
Investment Project Financing	IBRD/IDA	30-Dec-2021	



Projected Date of Full Disbursement 30-Oct-2024	Bank/IFC Collaboration No		
Is this a regionally tagged project? No			

Financing & Implementation Modalities

<input checked="" type="checkbox"/> Multiphase Programmatic Approach [MPA]	<input type="checkbox"/> Series of Projects (SOP)
<input type="checkbox"/> Fragile State(s)	<input type="checkbox"/> Performance-Based Conditions (PBCs)
<input type="checkbox"/> Small State(s)	<input type="checkbox"/> Financial Intermediaries (FI)
<input type="checkbox"/> Fragile within a Non-fragile Country	<input type="checkbox"/> Project-Based Guarantee
<input type="checkbox"/> Conflict	<input checked="" type="checkbox"/> Responding to Natural or Man-made disaster
<input type="checkbox"/> Alternate Procurement Arrangements (APA)	<input type="checkbox"/> Hands-on, Enhanced Implementation Support (HEIS)
<input checked="" type="checkbox"/> Contingent Emergency Response Component (CERC)	

Disbursement Summary (from Parent ISR)

Source of Funds	Net Commitments	Total Disbursed	Remaining Balance	Disbursed
IBRD				%
IDA	100.00	11.42	85.46	12 %
Grants				%

MPA Financing Data (US\$, Millions)

MPA Program Financing Envelope	18,000,000,000.00
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MPA FINANCING DETAILS (US\$, Millions)

Board Approved MPA Financing Envelope:	18,000,000,000.00
MPA Program Financing Envelope:	18,000,000,000.00
of which Bank Financing (IBRD):	9,900,000,000.00



of which Bank Financing (IDA):	8,100,000,000.00
of which other financing sources:	0.00

PROJECT FINANCING DATA – ADDITIONAL FINANCING (Additional Financing to Support to COVID-19 vaccine purchase and health system strengthening - P178279)

FINANCING DATA (US\$, Millions)

SUMMARY (Total Financing)

	Current Financing	Proposed Additional Financing	Total Proposed Financing
Total Project Cost	100.00	41.00	141.00
Total Financing	100.00	41.00	141.00
of which IBRD/IDA	100.00	41.00	141.00
Financing Gap	0.00	0.00	0.00

DETAILS - Additional Financing

World Bank Group Financing

International Development Association (IDA)	41.00
IDA Grant	41.00

IDA Resources (in US\$, Millions)

	Credit Amount	Grant Amount	Guarantee Amount	Total Amount
Madagascar	0.00	41.00	0.00	41.00
National PBA	0.00	41.00	0.00	41.00
Total	0.00	41.00	0.00	41.00



COMPLIANCE

Policy

Does the project depart from the CPF in content or in other significant respects?

Yes No

Does the project require any other Policy waiver(s)?

Yes No

Environmental and Social Standards Relevance Given its Context at the Time of Appraisal

E & S Standards	Relevance
Assessment and Management of Environmental and Social Risks and Impacts	Relevant
Stakeholder Engagement and Information Disclosure	Relevant
Labor and Working Conditions	Relevant
Resource Efficiency and Pollution Prevention and Management	Relevant
Community Health and Safety	Relevant
Land Acquisition, Restrictions on Land Use and Involuntary Resettlement	Not Currently Relevant
Biodiversity Conservation and Sustainable Management of Living Natural Resources	Relevant
Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities	Not Currently Relevant
Cultural Heritage	Not Currently Relevant
Financial Intermediaries	Not Currently Relevant

NOTE: For further information regarding the World Bank’s due diligence assessment of the Project’s potential environmental and social risks and impacts, please refer to the Project’s Appraisal Environmental and Social Review Summary (ESRS).

INSTITUTIONAL DATA

Practice Area (Lead)

Health, Nutrition & Population

**Contributing Practice Areas****Climate Change and Disaster Screening**

This operation has been screened for short and long-term climate change and disaster risks

PROJECT TEAM**Bank Staff**

Name	Role	Specialization	Unit
Maud Juquois	Team Leader (ADM Responsible)	Team Leader	HAEH1
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Menezes			
Name	Title	Organization	Location
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Extended Team			
Name	Title	Organization	Location

I. BACKGROUND AND RATIONALE FOR ADDITIONAL FINANCING

A. Introduction

1. **This Project Paper seeks the approval of the World Bank’s Vice President of the Eastern and Southern Africa Region (AFEVP) to provide an additional International Development Association (IDA) grant of US\$41 million equivalent for the Support to COVID-19 Vaccine Purchase and Health System Strengthening Project (P176841).** This project is under the COVID-19¹ Strategic Preparedness and Response Program (SPRP) using the Multiphase Programmatic Approach (MPA), approved by the Board of Executive Directors on April 2, 2020, and the additional financing (AF) to the SPRP approved on October 13, 2020.² The parent project was approved by the AFEVP on June 24, 2021, and became effective on July 26, 2021, with US\$100 million equivalent in financing from the IDA.
2. **The proposed AF will allow the scaling up of the original project to expand the health response to the COVID-19 pandemic in Madagascar.** The project will help maintain the commitment of the Government of Madagascar (GoM) to provide free-of-charge COVID-19 vaccines in public and private health facilities using the national Expanded Program of Immunization (EPI) vaccine delivery system. The proposed AF entails the scaling up of activities under components 1 and 2 in the parent project.
3. **Approval of exception for AF for projects under implementation for less than 12 months.** The parent project has been under implementation for six months. Normally, preparing AF for a project that has not met the requirement of 12 months of implementation would require an exception as per the World Bank Procedure for AF. On October 27, 2020, the World Bank management issued a blanket waiver for AF to well-performing operations—either stand-alone health sector COVID-19 operations or those under the Global COVID-19 SPRP MPA.

B. Consistency with the Country Partnership Framework (CPF)

4. **The proposed AF is aligned with the objectives of the World Bank Group 2017–21 CPF (Report no. 114744-MG), discussed by the Board of Executive Directors’ on May 30, 2017³ and with the GoM’s development plan, the “Initiative Emergence Madagascar” 2019-2023.** Overall, the CPF seeks to increase the resilience of the most vulnerable people and promote inclusive growth, while strengthening national and local institutions to reduce fragility. With an unprecedented health, economic, and social crisis due to COVID-19, the CPF has been adjusted to respond to the COVID-19 crisis. The AF is, therefore, framed within the first focus of the CPF—increase resilience and reduce fragility—which includes investing in human capital, disaster recovery, and disaster risk.

¹ COVID-19 (Coronavirus Disease 2019).

² The World Bank approved a US\$12 billion World Bank Group Fast Track COVID-19 Facility (FTCF or “the Facility”) to assist International Bank for Reconstruction and Development (IBRD) and IDA countries in addressing the global pandemic and its impacts. Of this amount, US\$6 billion came from IBRD/IDA and US\$6 billion from the International Finance Corporation (IFC). The IFC subsequently increased its contribution to US\$8 billion, bringing the FTCF total to US\$14 billion. The additional financing of US\$12 billion (IBRD/IDA) was approved on October 13, 2020, to support the purchase and deployment of COVID-19 vaccines as well as strengthening the related immunization and health care delivery system.

³ Madagascar Performance and Learning Review (P169808) was discussed by the Board on August 26, 2021, Report no. 162157-MG.



C. Project Design and Scope

5. **The Project Development Objective (PDO) of the parent project and this AF** is to support the GoM to acquire and deploy COVID-19 vaccines and strengthen its immunization services. The parent project includes the components as listed below.

Component 1: Acquisition of Vaccines and Medical Supplies. This component supports vaccine acquisition. The acquisition is expected to be implemented through the Africa Union Vaccine Acquisition Task Team (AVATT) and COVID-19 Vaccine Global Access (COVAX) purchasing mechanisms.

Component 2: Strengthening Health System for the Effective Deployment of Vaccines. This component supports the deployment of vaccines (including activities to address vaccine hesitancy) and key investments in the health system that are essential to ensure effective delivery of COVID-19 vaccines and strengthening the health system in the long term (such as strengthening information systems).

Component 3: Contingent Emergency Response (CERC). This component will facilitate access to rapid financing by allowing for the reallocation of uncommitted project funds in the event of a natural disaster, either by a formal declaration of a national emergency or upon a formal request from the government.

This AF scales up existing components. It does not add new activities or components.

D. Project Performance

6. **The project's progress toward achievement of the PDO and overall implementation progress was rated Satisfactory in the last Implementation Status and Results Report (ISR) of September 24, 2021, and the project continues to make good progress.** The project coordination unit (PCU) has been coordinating project planning and procurement effectively. Disbursements started on December 2, 2021 (12 percent), and the project has already begun major procurements, including vaccine doses under the African Vaccine Acquisition Trust (AVAT) through the United Nations Children's Fund (UNICEF). Under component 1, four million doses of the Johnson & Johnson vaccine are being procured (contract amount US\$35.8 million); Madagascar received 302,400 doses on November 14, 2021, and the remaining doses will arrive in batches according to need. Under component 2, procurement for major equipment has been launched and some contracts are already signed (for tents, fridges, personal protection equipment, commodities for vaccination such as cotton swabs and disinfectant products, and so on). With many of the major procurements in the final stages, 25 percent of the parent project funding should be disbursed by the end of 2021 and nearly 50 percent of the funds already committed. A major bottleneck was the opening of the designated bank account—which happened only on December 3, 2021—preventing the project from funding the ongoing vaccination campaign's operational costs (first payments under the project were made before through direct payment).

E. Rationale for Additional Financing

7. **Significant efforts are needed to ensure vaccine availability and to meet the GoM’s target of vaccinating 50.5 percent of the population by the end of FY23.** Madagascar’s strategy is to fully immunize the adult population (not yet those under age 18) according to the National Vaccination and Deployment Plan (NVDP) revised in September 2021. Madagascar’s adult population represents 50.5 percent of the country’s total population. To reach this target, Madagascar will need to vaccinate 14.2 million people over age 18. Madagascar has applied for the COVAX Facility, doses from which should vaccinate 5.6 million people. Via the parent project, it has procured 4 million doses of the Johnson & Johnson (J&J) vaccine through AVAT (and will procure an additional 4 million doses). This AF will cover the acquisition and deployment costs for an additional 1 million doses of the J&J vaccine to reduce the gap in vaccines to cover the population over age 18.

8. **In addition to vaccine acquisition, this AF will support the scaling up of the project’s support to vaccine deployment.** Informed by ongoing analysis of gaps and opportunities for route optimization and outsourcing of last-mile distribution, additional funds will also be used to expand current cold storage capacity, with a focus on the intermediate and health facility levels. This will become increasingly important for the integration of COVID-19 with routine immunization. Together with existing outreach and communication activities, including training and engagement of community health workers, this AF will also be used to strengthen demand promotion (communication at national and local level, involvement of key stakeholders such as artists and religious leaders in the campaign and so on). The project will support vaccine distribution and expansion. The project will ensure coordination at the country level with the work of other development partners (Box 1).

Box 1. Potential Supportive Roles for Partner Agencies in Implementation

Partner Agency	Financing amount (if known)
WHO’s role	
Supporting the GoM via technical support to the National Technical Advisory Group on Immunization (GTCV) under the National Academy of Medicine to inform COVID-19 vaccination policy, strategy, planning and monitoring, vaccine safety, capacity building, surveillance, and advising on vaccine pharmacovigilance.	N/A
UNICEF’ role	
Supporting the development and implementation of the national plan for vaccine deployment, including support for the quantification and forecasting of supply needs, support to procure and install quality cold chain equipment at the national and regional levels, communication and mobilization, and strategies for improved integration of COVID-19 vaccine deployment with routine EPI and other primary health care services.	N/A
Gavi/COVAX’s role	
Providing vaccines to cover the first prioritized 20 percent of the population and beyond, financing to UN and international NGOs for technical assistance and cold chain improvements.	Amount in addition to procurement of vaccines for 20 percent of the population is confirmed. US\$533,106 for the

	deployment of initial 250,000 doses.
Global Fund to fight Acquired immunodeficiency syndrome, tuberculosis and malaria's role	
The GoM has submitted a request under the Accelerated COVID-19 Response Mechanism for the procurement of personal protective equipment (PPE) and COVID-19 testing and treatment.	US\$6,832,072
African Union (AU)-Africa Center for Disease Control and Prevention (CDC)'s role	
<p>The partnership with AU-Africa CDC will be important for some of the components related to information systems and genomic surveillance. The government should leverage harmonized continental digital technologies to respond to COVID-19, with particular attention to digital inclusion, patient empowerment, data privacy and security, legal and ethical issues, and personal data protection, which are values enshrined in the official African Union Trusted Health Framework and its digital archetypes: the Trusted Travel and Trusted Vaccines platforms, provided free of charge to support the digitization of COVID-19 response efforts. Recently, the GoM requested Africa CDC's support to set up a coordinating entity for Africa CDC's activities in Madagascar. The Regional Integrated Surveillance and Laboratory Network (RISLNET) is being deployed as part of the Africa CDC project, and Madagascar's participation is essential in this regard.</p> <p>On genomic surveillance, Africa CDC could build next-generation sequencing capacity by supporting laboratory upgrades (essential diagnostics and equipment, support the deployment of technical staff) and enhancing the technical capacity of laboratory staff through (i) the Institute for Pathogen Genomics, which aims to build a continent-wide functional and operational network of pathogen genomics and bioinformatics, and (ii) regional hubs of laboratories to facilitate coordination as well as training, knowledge sharing, and technical support.</p>	TBC
AVAT's role	
GoM discussed its official application to AVAT at the Council of Ministers on May 6, 2021. Madagascar joined the AVAT initiative on September 15. The procurement of 4 million doses using World Bank funding was processed through AVAT.	

F. National Capacity and COVID-19 Vaccination Plan

Vaccine Readiness Assessment

9. **Madagascar conducted a vaccine readiness assessment in May 2021 to identify gaps and options to address them as well as to estimate the cost of vaccine deployment**, with the support of international organizations including WHO, UNICEF, and Gavi (Table 1). This assessment considered the government's vaccine deployment strategy, described below. Considering the uncertainty surrounding the COVID-19 vaccine market, the assessment will continue to be an evolving process and will be revised and updated as necessary to continue to improve project implementation. The AF will be used to address the identified gaps.



10. **The National Coordination Committee and National Technical Working Group (NTWG) to lead the operational aspects of vaccine introduction are now fully functional**, but the microplanning mechanism requires strengthening at all levels. The AF will contribute to the development of a microplanning framework to be completed by the districts (and readjusted once a month), which will be consolidated at the regional level to improve input requirement forecasting and support vaccine deployment strategies. Health facilities will also conduct microplanning activities to alleviate crowding, optimize vaccine management, and avoid disruption of other activities. Efforts should also be made to actively monitor adverse events following immunization (AEFI) cases. Activities such as the reporting of AEFI cases, identification of possible AEFI clusters, supervision of vaccine pharmacovigilance activities at all levels (regions, districts, and health facilities), and prepositioning of AEFI kits will be planned under this AF. The ability to identify and target priority population groups remains a major challenge. The AF will assist in conducting outreach activities to convince priority targets to receive the COVID-19 vaccine. Community workers will receive training on this outreach; in terms of demand generation and communication, this AF will facilitate the recruitment of a professional communications agency to intensify communication on the safety and efficacy of vaccines to limit misconceptions and distrust.

11. **Vaccine hesitancy is a major challenge in Madagascar.** As of December 13, 2021, 1.9 percent of Madagascar's population was totally vaccinated. The country's adoption of a routine vaccination approach when the second campaign began in August 2021 has resulted in a low daily vaccination rate of just 5,000. During the first campaign during May through June 2021, the country was able to vaccinate 200,000 people in six weeks by using outreach/mobile strategies and setting up vaccination centers ("*vaccinodromes*") in major cities, demonstrating the capacity for vaccine deployment. Several strategies have been discussed and would be implemented with support from the project to overcome the low uptake of vaccinations through diverse approaches (ensure high-level commitment to vaccination, involvement of leaders from various sectors of Malagasy society, private sector, incentives, and so on). Analysis from the November 2021 joint partners' mission⁴ shows that improved coordination and planning, targeted communication campaigns utilizing not only mass media but also key influencers, and motivation of vaccination teams could help Madagascar with vaccine uptake.

⁴ A joint mission of partners took place from November 3–8, 2021, with the involvement of WHO AFRO, UNICEF, GAVI, USAID, and the World Bank. The mission, which included interviews and site visits, aimed to identify bottlenecks and develop a clear roadmap to optimize the deployment of the COVID-19 vaccine in Madagascar.

Table 1. Summary of the Vaccine Introduction Readiness Assessment Tool (VIRAT)/Vaccine Readiness Assessment Framework (VRAF) 2.0⁵

Readiness domain ^a	Readiness of government	Key gaps to address before deployment
Planning and coordination	<ul style="list-style-type: none"> - The National Coordination Committee, as well as a NTWG to lead the operational aspects of vaccine introduction, established and are fully functional. - NTWG subcommittees established/engaged to cover the following workstreams: (1) coordination and finance; (2) service delivery; (3) communication and social-community mobilization; (4) logistics, supply chain, and vaccine forecasting; (5) data management and monitoring and evaluation; and (6) surveillance. - NTWG presents the assessment of COVID-19 vaccination implementation every two weeks. - A NVDP has been developed by the Ministry of Public Health (MoPH), with technical support from partners and based on WHO guidelines. 	All gaps have been addressed.
Budgeting	Budgeted microplans were developed and finalized at the national level, which was key for the initiation of the vaccination program. Guidelines and templates exist for this, but they are not validated or shared at the regional and district levels.	Gaps include: (i) developing budget tracking capacity to monitor COVID-19 program-specific budget execution; and (ii) overall capacity for budgeting and executing national immunization services (still not filled and identified at peripheral levels). The AF will provide support for the development of a budgeted microplanning framework at all levels and support for the monitoring strategy of the implementation of this framework
Regulatory	All necessary regulatory frameworks are in place, including: <ul style="list-style-type: none"> - Emergency authorization procedures for new vaccines at the country level based on the WHO Emergency Use Listing (EUL) - Regulatory procedures for the import of vaccines, including special customs exonerations procedures and inspection procedures for fast processing 	No gaps were identified in the assessment.

⁵ A multipartner effort led by the WHO and UNICEF developed the VIRAT to support countries in developing a roadmap to prepare for vaccine introduction and identify gaps to inform areas for potential support. Building upon the VIRAT, the World Bank developed the VRAF to help countries obtain granular information on gaps and associated costs and program financial resources for vaccine deployment. To minimize duplication, in November 2020, the VIRAT and VRAF tools were consolidated into one comprehensive framework, called VIRAT-VRAF 2.0. The assessment was updated in November 2021.

	<ul style="list-style-type: none"> - Regulatory procedures for the import of supplies related to COVID-19 vaccines 	
Prioritization, targeting, surveillance	<ul style="list-style-type: none"> - Vaccination will follow a three-phase approach. Data on vaccine progress for phase 1 and adherence to priority groups is reviewed daily and shared with all relevant coordination committees. - National COVID-19 disease surveillance groups are coordinating to ensure relevant epidemiological data is collected to inform the planning of subsequent rounds of COVID-19 vaccination, including outbreak responses. 	<p>Gaps include:</p> <p>(i) strengthening the capacity to identify and target the prioritized population groups, in particular, strengthening the ability to identify individuals' comorbidities and other priority-relevant personal information during community outreach and (ii) strengthening capacity for genomic sequencing for better surveillance. This AF will assure community outreach activities will be conducted to identify and convince priority targets to receive the COVID-19 vaccine. Community workers will be oriented for this identification and sensitization</p>
Service delivery	<ul style="list-style-type: none"> - Protocols for infection prevention and control measures have been updated and are being followed. - Protocols for consent to vaccinations are established. - Individual consent form is signed at registration. - The COVID-19 vaccine distribution plan is available. Fixed sites and outreach sites are identified and prepared for mass vaccination efforts. 	All gaps have been addressed.
Training and supervision	<ul style="list-style-type: none"> - A training plan is available, and training modules have been developed using inputs from WHO. - Initial training of trainers, supervisors, and vaccinators took place for the first vaccination phase. - Additional vaccinators will be hired as needed. 	<p>Gaps include:</p> <p>(i) Quantify personnel and training needs as vaccination scales up and (ii) support for covering additional training needs. This will be included in the development of the microplanning framework</p>
Monitoring and evaluation	<ul style="list-style-type: none"> - GoM's health information system is operational to accommodate individual-level tracking of vaccinated persons through the District Health Information Software 2 (DHIS2) tracker. - Currently, information about vaccinated individuals is still collected at the level of the vaccination sites on paper-based tally sheets that are digitalized at the district level on a weekly basis and then sent to the regional level for further aggregation. - A phone hotline with limited bandwidth is in place and is operational for feedback and grievances in relation to the ongoing vaccine effort. - A mechanism for handling rumors has been developed. 	<p>Gaps include:</p> <p>(i) data security audit and (ii) establishing an individual-level digital vaccine registry</p> <p>The AF project will support the functionality of the individual tracking software and enable the availability of digitalized immunization cards</p>

	<ul style="list-style-type: none"> - Measures for data protection and appropriate data governance regulation are being put in place. 	
Vaccine, cold chain, logistics, infrastructure	<ul style="list-style-type: none"> - Key roles and responsibilities needed for vaccine and ancillary products deployment; collect and confirm contact information for key personnel and facilities were mapped. - The national logistics working group with appropriate terms of reference and standard operating procedures to coordinate COVID-19 vaccines and ancillary products deployment established/strengthened. - Dry storage and cold chain capacity and infrastructure needs at all levels with regards to COVID-19 vaccines were assessed and the identified supply and logistics gaps were filled. 	<p>Gaps include: Strengthening the delivery plan for a more efficient distribution system This will be included in the development of the microplanning framework</p>
Safety surveillance	<ul style="list-style-type: none"> - Guidelines, documented procedures, and tools for planning and conducting vaccine pharmacovigilance activities are available. - A technical committee for pharmacovigilance has been established in accordance with the regulation texts and meets regularly to assess recent AEFI. 	<p>Gaps include: (i) additional trained human resources; and (ii) data collection, management, and analysis capacity Throughout its implementation, the project will support capacity building in these specific areas</p>
Demand generation and communication	<ul style="list-style-type: none"> - A national communication and social mobilization strategy for the introduction of the COVID-19 vaccine is being implemented. - Actions have been taken to mobilize public figures, such as local and religious leaders, for communication efforts. 	<p>Gaps include: (i) further strengthening communications and citizen engagement initiatives through data on beliefs, attitudes, rumors, and narratives concerning the COVID-19 vaccine; and (ii) addressing ongoing misinformation and disinformation campaigns This AF will facilitate the recruitment of a professional communications agency to intensify communication on the safety and efficacy of vaccines to limit misconceptions and distrust.</p>

a. As of November 09, 2021.

(ii) National COVID-19 Vaccination and Deployment Plan (NDVP)

12. The GoM revised the NVDP in September 2021 based on the VRAF/VRAT 2.0 assessment findings (further updated in November 2021), gap analysis, and lessons learned from the COVID-19 vaccine acquisition and deployment activities implemented to date. Table 2 details the national vaccine coverage and acquisition plan. The epidemiological evidence on the distribution of the pandemic, burden and morbidity/mortality related to COVID-19, and health system service delivery contexts also guided the NVDP revision. The revised NVDP introduced the following changes after a careful review of local and international evidence and lessons:



- **Changes to the COVID-19 vaccination strategy:** Initially, the strategy was to vaccinate the priority target populations (first during the first immunization campaign) before vaccinating other categories. However, statistics suggested that the populations outside the priority categories were the most active. Therefore, it was decided to open vaccination to people age 18 and over, but to vaccinate the priority targets first at the vaccination sites. This flexibility will be maintained for the rest of the COVID-19 vaccination program, which will now be done in routine mode.
- **Changes to the vaccine deployment strategy:** Basic health facilities with a doctor and a functioning refrigerator (solar or electric) will be identified as vaccination sites. Vaccinations will be carried out closer to the targets by increasing the number of fixed sites, including health centers, and advanced and mobile strategies. The mobile and advanced strategies will be adopted for the vaccination of populations far from fixed sites, particularly in rural areas as well as groups of more than 50 people in urban and periurban areas. The participation of private health facilities contributed to achieving plan objectives during the first vaccination campaign. This good practice will be maintained and further developed.



Table 2. National Vaccine Coverage and Acquisition Plan

[Based on available estimates as of November 26, 2021]

Source of financing	Population		Vaccines				Number of doses needed ^b	Estimated total US\$ (millions)	World Bank's Vaccine Approval Criteria (VAC) status of the vaccine	Contract status	Vaccines already arrived in the country ^c	
	Targeted ^a (out of population of 28,136,681)		Source	Name	Price (US\$/dose)	Shipping (US\$/dose)					Name	Doses
	%	Number										
Stage 1 (3.55%) – 2021: Frontline workers in health care, schools, and other social care services (1%); defense and security forces (0.2%); people over the age of 55 years (1.35%); people under the age of 55 years with underlying conditions that expose them to higher COVID-19 related mortality risk (0.5%); and adults between 18 and 55 years (0.5%).												
COVAX Grant	0.83	234,400	COVAX	Astra Zeneca (AZQ)	0	0	468,800	0.0	Approved	Official request submitted to COVAX March 30, 2021; delivery initiated ^d	AZQ	492,240
COVAX Grant	2.16	608,333	COVAX	Johnson & Johnson (J&J)/Janssen	0	0	608,333	0.0	Approved	Official request submitted to COVAX March 30, 2021; delivery initiated ^e	J&J	638,750
COVAX Grant	0.56	157,267	COVAX	Sinopharm	0	0	314,533	0.0	Approved	Official request submitted to COVAX on March 30, 2021	Sinopharm	468,000
Stage 1 total	3.55	1,000,000					1,391,666	0.0				1,598,990
Stage 2 (30.95%) – 2022: People over age 55 (5.65%); people under age 55 with underlying conditions that expose them to higher COVID-19 related mortality risk (10.5%); and adults between 18 and 55 years (14.8%).												
COVAX Grant	2.7	759,690	COVAX	AZQ	0	0	1,519,380	0.0	Approved	Official request submitted to COVAX March 30, 2021		



COVAX Grant	1.12	315,131	COVAX	J&J	0	0	315,131	0.0	Approved	Official request submitted to COVAX March 30, 2021	J&J	
COVAX Grant	0.23	64,714	COVAX	Sinopharm	0	0	129,428	0.0	Approved	Official request submitted to COVAX March 30, 2021	Sinopharm	
China	0.5	140,683		Sinopharm	0	0	281,366	0.0	Approved	Delivery initiated ^f	Sinopharm	300,000
COVAX Grant	1.4	393,913	COVAX	Pfizer	0	0	787,826	0.0	Approved	Official request submitted to COVAX on March 30, 2021; delivery initiated ^g	Pfizer	398,970
IDA Grant (parent project)	25.0	7,034,170	AVAT/COVAX	J&J	7.4	1.03	7,034,170	62.3	Approved	Official request submitted to AVAT September 15, 2021; delivery initiated ^h Cost-sharing agreement with COVAX/Gavi signed November 26, 2021	J&J	302,400
Stage 2 total	30.95	8,708,302					10,067,301	62.3				1,001,370
Stage 3 (16.0%) – 2023: Adults between 18 and 55 years.												
IDA Grant (parent project and AF)	5.4	1,526,011	AVAT/COVAX	J&J	7.4	1.03	1,526,011	13.5	Approved	Official request submitted to AVAT on September 15, 2021; cost-sharing agreement with GAVI signed November 26, 2021	J&J	



COVAX Grant	10.6	2,974,711	COVAX	TBC; J&J preferred	0	0	2,974,711	0.0				
Stage 3 total	16.0	4,500,722					4,500,722	13.5				
NATIONAL TOTAL	50.5	14,209,024					15,959,689	75.8ⁱ				2,600,360

- a. Fully vaccinated population.
- b. Number of doses needed by type of vaccine to reach the targets. AstraZeneca, Sinopharm, and Pfizer: two doses; Janssen: one dose.
- c. Batch of vaccines partially arrived to date.
- d. 2,076,240 doses of AZQ vaccine are expected to be delivered before the end of the year.
- e. 974,750 doses of J&J vaccine are expected to be delivered before the end of the year.
- f. Grant from China.
- g. 800,000 doses of Pfizer are expected to be delivered
- h. Nine million doses of J&J vaccine are expected to be delivered before the end of 2023 (one million with this AF).
- i. Twenty percent was requested and accepted through the COVAX initiative; the government plans to complete 20 percent; 8 percent will be a combination of AZQ, J&J, and Pfizer; 3 percent to be confirmed.
- j. This amount represents only IDA financing for the national plan. Amounts for other partners are not available.

Box 2. Liability and Indemnification Issues in Vaccine Acquisition

Key Points:

- The rapid development of vaccines increases **manufacturers' potential liability** for adverse effects following immunization.
- Manufacturers want to protect themselves from this risk by including **immunity** from suit and liability clauses, **indemnification** provisions, and other **limitation of liability** clauses in their supply contracts.
- **Contractual provisions and domestic legal frameworks** can all operate to allocate that risk among market participants, but **no mechanism will eliminate this risk entirely**.

For COVAX-financed vaccines:

- COVAX has negotiated model indemnification provisions with manufacturers for vaccines purchased and supplied under the COVAX AMC.
- In providing vaccines through COVAX AMC, COVAX requests that COVAX AMC participants have in place an indemnity agreement directly with manufacturers and the necessary indemnity and liability frameworks for that purpose—either in the form of the COVAX model indemnification arrangements or prior bilateral arrangements with manufacturers.
- The COVAX Facility will have a no-fault compensation scheme (NFCS) for AMC countries as part of its risk mitigation strategy. This will cover vaccines supplied only through COVAX AMC.
- Madagascar will have to consider what it will take to implement these indemnification provisions (including statutory implementation) and how they can avail of the benefits of the no-fault compensation scheme.

For vaccines purchased through AVAT:

- The Advance Purchase Agreement (“APA”) signed on March 28, 2021, by AVAT, Janssen Pharmaceutica NV (“Janssen”), and the African Export-Import Bank (Afreximbank) includes indemnification provisions in favor of Janssen for vaccines purchased and supplied under the APA. Participating countries will assume those indemnification obligations upon execution and delivery of a deed of adherence to the APA.
- As a condition for the delivery of vaccine doses under the APA, participating countries shall also participate in or establish and adequately fund an NFCS in accordance with certain minimum requirements. Participating countries shall either: (i) participate in the NFCS to be established by AVAT, or (ii) establish and maintain their own NFCS. For the avoidance of doubt, AMC countries will not be able to rely on their participation in the COVAX NFCS to meet the conditions under the Janssen APA.
- For vaccines purchased through AVAT, Madagascar will have to consider how to implement the indemnification provisions and NFCS requirements under the APA with Janssen.



For vaccines purchased outside of COVAX and AVAT:

- Madagascar will need to enter direct indemnification arrangements with manufacturers.
- Madagascar does not currently have legislation in place to provide statutory immunity for manufacturers.
- Madagascar has no national NFCS.
- Adoption of any such indemnification provisions or compensation scheme would have to be in accordance with Madagascar’s own national strategy and framework.

Possible World Bank support to Madagascar, depending on needs, may include:

- Information sharing on (i) statutory frameworks in Organization for Economic Cooperation and Development countries and other developing countries; and (ii) overall experience in other countries.

13. The project operational documents (Vaccine Delivery and Distribution Manual, VDDM; Project Implementation Manual, PIM) clarify that Madagascar’s regulatory authority is responsible for assessing COVID-19 vaccine safety and efficacy and is solely responsible for the authorization and deployment of the vaccine in the country.

Vaccines Purchased through AVAT

14. In late 2020, the AU embarked on an ambitious effort to vaccinate at least 60 percent of Africa’s population as quickly as possible through a continental approach. The effort to acquire more vaccines has been led by the AVATT, the AU Special Envoys for COVID-19, Africa CDC, Afreximbank, and the United Nations Economic Commission for Africa. The AU sees this effort as complementary to COVAX, and the World Bank has worked alongside AVATT since January 2021 to inform the design of the AVAT mechanism and to ensure that World Bank financing can be used by participating member countries to purchase vaccine doses.

15. On June 21, 2021, the African Union and the World Bank held a joint meeting with African Ministers of Finance to officially launch the partnership to accelerate vaccination in Africa. AVAT has already successfully negotiated 220 million doses of Johnson & Johnson’s Janssen (J&J/Janssen) COVID-19 vaccine for use by African countries, with an option for 180 million more based on demand. AVAT is negotiating with other suppliers and is expected to secure more doses. World Bank financing and technical assistance are available to help countries obtain vaccines from eligible suppliers through AVAT and deploy them effectively.

16. Madagascar entered into a commitment undertaking with AVAT to purchase eligible vaccines under the mechanism and signed an agreement for US\$35.8 million for four million doses of J&J with UNICEF as the procuring agency on October 5, 2021.

II. DESCRIPTION OF ADDITIONAL FINANCING

A. Proposed Changes

17. **The changes proposed for the AF entail scaling up of activities in the parent project, Madagascar Support to COVID-19 Vaccine Purchase and Health System Strengthening (P176841).** The PDO will remain unchanged. The costs of the existing components 1 and 2 will be revised and are shown in Table 4 below. The content of the components and the Results Framework of the parent project (Annex 3) are adjusted to reflect the new activities proposed under the AF. The Closing Date remains June 30, 2024.

(i) Proposed scaled-up activities

Component 1: Acquisition of Vaccines and Medical Supplies [originally US\$71 million equivalent; with proposed AF, US\$80 million equivalent]

18. **The implementation of the activities under the parent project will continue without any changes.** The project will continue to finance: (i) acquisition of vaccines for priority groups defined in NVDP; and (ii) acquisition of vaccination supplies needed for activities outlined in the VDDM, including diluents, syringes, and medical supplies associated with the vaccination response.

19. **Scale-up:** Under this component, the AF will procure more doses of vaccines. With the parent project, eight million vaccines will be purchased to cover 27 percent of the population (more than initially planned with the allocated budget in as the country opted for single-dose J&J, which costs less than other double doses vaccines). The AF will finance: (i) acquisition of COVID-19 vaccine doses to cover an additional 3 percent of the population, and so the total of 9 million doses purchased by the project will contribute to the government's plan to reach 50.5 percent COVID-19 vaccination coverage by June 2023; and (ii) acquisition of vaccination supplies needed to vaccinate the additional proportion of the population such as diluents, syringes, and all medical supplies associated with vaccination. The country is considering a vaccine purchase via COVAX as the J&J vaccine is now available through the cost-sharing mechanism. The cost-sharing framework agreement was signed on November 26, 2021. World Bank procurement arrangements for vaccines through COVAX are still being finalized.

Component 2: Strengthening Health System for the Effective Deployment of Vaccines [originally US\$29 million equivalent; with proposed AF, US\$61 million equivalent]

20. **The implementation of the activities under the parent project will continue without any changes.** The project will continue to finance (i) strengthening of vaccine logistics system, cold chain, and vaccination sites (storage and transportation); (ii) strengthening surveillance and information systems including vaccine safety and AEFI monitoring; (iii) strengthening planning and coordination capacity including training of health workers/vaccinators and waste management; (iv) communication campaign to address vaccine hesitancy; and (v) operating costs.

21. **Scale-up:** Under this component, the AF will finance activities to scale up (i) deployment of health professionals to deliver additional doses procured (operational costs of vaccination campaigns); (ii) purchase of additional equipment for vaccines distribution (cold chain equipment, vehicles, and motorbikes) and data reporting (tablets and computers); (iii) additional technical assistance for the deployment of vaccines, including for communication and demand creation based on a geographic mapping of pockets of hesitancy and for utilization of drones for vaccines transportation in remote areas. This will be contracted with private operators specialized in drones utilization; and (iv) incentives for community health workers and mobilizers. Incentives to be received by community health workers would be linked to the number of people referred to vaccination sites. An independent organization will be contracted for the payment, and payments will be based on properly validated statements.

22. **The AF will support population groups as summarized in Table 3** (phasing as presented in Table 2 is not fully aligned with the ranking of vulnerable groups; due to vaccine availability and low uptake of vaccines by priority groups, the national strategy is to open vaccination to cover additional groups in phases 1 and 2).

Table 3. Priority Groups for National COVID-19 Vaccination in Madagascar

Ranking of vulnerable groups	Population group	Number of people	Share of population (%)
First	Public and private health workers	27,067	0.10
Second	People greater than 55 years of age	1,907,969	6.78
Third	Vulnerable individuals with comorbidities (hypertension, diabetes, chronic noncommunicable diseases)	3,207,171	11.40
Fourth	Security forces	46,500	0.17
Fifth	Other civil servants and social workers in permanent contact with the population, including community workers	208,211	0.74
	Subtotal of five high-risk priority groups	5,396,918	19.2
Sixth	Other individuals aged 18–54 (excluding high-risk priority groups)	8,812,107	31.3
	TOTAL	14,209,024	50.5

(ii) Financing arrangements

23. The increase in scope will be reflected in an increase in indicative allocation from US\$100 million equivalent to US\$141 million equivalent, with the full amount of the AF being added across the two components (Table 4).

Table 4. Project Cost and Financing

Project Components	Parent Project Cost (US\$ million)	AF Cost (US\$ million)	Parent + AF Cost (US\$ million)	IDA financing (US\$ million)
Component 1: Acquisition of Project COVID-19 vaccines and medical supplies	71.0	9.0	80.0	80.0
Component 2: Strengthening health system for effective deployment of Project COVID-19 Vaccines	29.0	32.0	61.0	61.0
<i>Sub-component 2.1: Strengthening logistics, cold chain, and vaccination sites</i>	14.6	25.0	39.6	39.6
<i>Sub-component 2.2: Strengthening surveillance and information systems</i>	3.2	0.3	3.5	3.5
<i>Sub-component 2.3: Strengthening capacity for managing and implementing immunization campaigns</i>	5.7	5.3	11.0	11.0
<i>Sub-component 2.4: Strengthening communication and addressing vaccine hesitancy</i>	3.0	1.4	4.4	4.4
<i>Sub-component 2.5: Project Implementation and Monitoring</i>	2.5	0.0	2.5	2.5
Component 3: Contingent Emergency Response	0	0	0	0
Total Costs	100.0	41.0	141.0	141.0

Table 5. Summary of COVID-19 Vaccine Sourcing and World Bank Financing

National plan target (population %)	COVAX grant	Source of vaccine financing and population coverage				Specific vaccines and sourcing plans	No. of Doses purchased with World Bank finance (2 doses assumed)	Estimated allocation of World Bank financing
		World Bank-financed			Other *			
		Through COVAX	Through AVAT	Through direct purchase				
Stage 3 – 6% (This AF)	3.0	3.0				World Bank-financed: J&J/ Janssen Non-World Bank-financed: Donations through COVAX	1,000,000	Purchase: US\$9.0 million Deployment: US\$32.0 million

National plan target (population %)	COVAX grant	Source of vaccine financing and population coverage				Other *	Specific vaccines and sourcing plans	No. of Doses purchased with World Bank finance (2 doses assumed)	Estimated allocation of World Bank financing
		World Bank-financed							
		Through COVAX	Through AVAT	Through direct purchase					
						Facility and vaccine type TBC;		Other: US\$0	

National plan target (population %)	COVAX grant	Source of vaccine financing and population coverage				Other*	Specific vaccines and sourcing plans	No. of Doses purchased with World Bank finance (2 doses assumed)	Estimated allocation of World Bank financing
		World Bank-financed							
		Through COVAX	Through AVAT	Through direct purchase					
Stage 1: 3.55% (parent project)	3.55					Non- World Bank-financed: Combination of AstraZeneca, J&J, and Sinopharm through COVAX		Purchase: US\$71 million Deployment: US\$26.5 million Other: US\$2.5 million (project implementation and monitoring)	
Stage 2: 30.95% (parent project)	5.45		25.0		0.5	World Bank-financed: Johnson & Johnson/ Janssen, through AVAT/COVAX (TBC) Non-Bank-financed: Combination of AstraZeneca, J&J, and Pfizer through COVAX, and J&J through AVAT/COVAX Other:	7,400,000	Purchase: US\$71 million Deployment: US\$26.5 million Other: US\$2.5 million (project implementation and monitoring)	

National plan target (population %)	COVAX grant	Source of vaccine financing and population coverage				Specific vaccines and sourcing plans	No. of Doses purchased with World Bank finance (2 doses assumed)	Estimated allocation of World Bank financing
		World Bank-financed			Other*			
		Through COVAX	Through AVAT	Through direct purchase				
						Sinopharm doses donated by China		
Stage 3: 10% (parent project)	8.0		2.0			World Bank-financed: Johnson&Johnson/ Janssen through AVAT/COVAX (TBC) Non-World Bank-financed: Combination of AstraZeneca, J&J, Pfizer	600,000	Purchase: US\$71 million Deployment: US\$26.5 million Other: US\$2.5 million (project implementation and monitoring)
TOTAL	20.0	3.0	27.0		0.5			

Note: *Other includes coverage financed by the government, bilaterally, from other Multilateral Development Banks, and others.

(iii) No change in institutional arrangements

24. There is no change to institutional arrangements, and as in the parent project, United Nations agencies will be contracted (for vaccine acquisition and to support vaccine deployment). No retroactive financing will be requested for this AF since this option already exists in the parent project, which can adequately cover reimbursement for project activities or vaccine acquisition from April 30, 2021, until the signing of the financing agreement on July 21, 2021.

(iv) Changes in the disbursement categories

25. Disbursement categories under the AF will be simplified compared to the parent project: (i) one category for vaccines acquisition (component 1 of the Project); (ii) one for other goods, works, consulting and nonconsulting services, operating costs, and training (component 2); and (iii) for the CERC. Under the parent project, disbursement categories were slightly different to facilitate disbursements before the lifting of disbursement conditions (linked to the disclosure of ESF documents and validation of manuals). Under the parent project, manuals were validated on October 13, 2021, and safeguards documents were validated and disclosed on October 21, 2021, allowing the lifting of the disbursement condition on October 22, 2021.

(v) Results Framework

26. The project’s Results Framework will be modified to include a new intermediate results indicator (IRI) to better capture project performance regarding vaccine administration and deployment. In addition, the end project targets of the PDO indicator and one IRI will be increased to better reflect the additional vaccine doses to be procured and associated logistics.

Table 6. Changes in the Results Framework

Modified indicators	Percentage of the population fully vaccinated: target revised from 40 percent to 50.5 percent (PDO indicator)
	Number of complete doses of eligible COVID-19 vaccine purchased through the project that arrived in the country: target revised from 5,600,000 to 9,000,000 (IRI)
Added indicator	Percentage of doses successfully administered of the total vaccine doses procured by the Project: a new indicator with an end target of 95 percent (IRI)

B. Sustainability

27. There is a strong political commitment in Madagascar from the MoPH to mobilizing resources to ensure rapid vaccination and setting up vaccination capacity in the country. Having the funds through the proposed AF for vaccine purchase and deployment will send a strong message to stakeholders about Madagascar’s commitment to the key priority of vaccination and facilitate an enabling environment for other donors, multilateral development banks, and UN agencies to support efforts in the country. Investments under the parent project and the AF are expected to strengthen Madagascar’s health system, increasing institutional ability to respond to infectious diseases.

III. KEY RISKS

28. **The Overall risk to achieving the PDO with the expanded scale and vaccination through the AF remains High.** The large-scale acquisition and deployment of COVID-19 vaccines entails significant risks. First, global demand for vaccines continues to exceed supply, and vaccines that meet the World Bank’s VAC may not be available in a timely manner. Second, a mass vaccination effort will stretch capacity, particularly in Madagascar’s low capacity, rural, low-population density, low-infrastructure environment. The proposed AF supports the development of vaccination acquisition strategies and invests in deployment system capacity specifically aimed at mitigating these risks. The remaining risk must be considered against the risk of the country having less timely and effective deployment of vaccines, potentially exacerbating development gaps and eroding past development gains.

29. **The Political and Governance risks to the AF remain Substantial.** The risks are related to the authorities’ commitment and ability to ensure appropriate targeting of the AF-supported vaccines to reach the priority populations based on objective public health criteria and their ability to manage public sentiment should there be a gap between vaccine targets and vaccine delivery. These risks will be mitigated through the AF-supported assurance mechanisms, such as the establishment of an acceptable



policy and plan for prioritized intra-country allocation. There are also risks related to the governance of vaccine purchase and deployment, including potential fraud, substandard quality, and fraudulent attempts to gain access to vaccines without following approved protocols for priority populations or for personal gain. This includes the risk of elite capture and corruption in the implementation of the vaccination program. Risks will be mitigated through the application of anticorruption guidelines for vaccine purchase and deployment and robust financial management (FM) oversight of the use of funds, as elaborated in the fiduciary risks below. Proposed mitigation measures under the AF include (i) an expansion of the mandate of the fiduciary agency to validate each expenditure incurred under the project starting from contract signing and (ii) a governance audit of the PCU. Considering these mitigation measures, the AF is not expected to increase the political and governance risks of the parent project.

30. **The risk rating on Technical design of the project remains Substantial** considering global uncertainties around vaccine availability and the GoM's capacity for and experience with large-scale vaccine deployment. The World Bank will work closely with government officials (MoPH) and the UN agencies involved in the pandemic response (WHO and UNICEF) to support GoM's efforts to access the necessary vaccine supply. Vaccine hesitancy is also a major challenge; the in-country vaccination rate is still very low despite the availability of vaccines. The World Bank will also work closely with the MoPH and partners to improve the communication strategy as per the recommendations of the November 2021 joint partners' mission.

31. **Sector strategies and policy risk remains substantial.** Existing health strategies and policies are only partially implemented due to a lack of operationalization plans or realistic budget considering the available financing. This risk will be mitigated by closely monitoring implementation of the NVDP jointly with other partners and ensuring adequate reorientations are integrated based on the context and implementation of the campaign. In that regard, the NVDP has already been revised in October 2021 based on experience from first vaccination campaign.

32. **Institutional capacity risk for vaccine deployment is high. As in the parent project, the AF is designed to address key institutional capacity risks related to vaccine deployment and distribution.** Capacities in logistics, cold-chain, and human resources, information systems capacity are currently inadequate for deployment of the COVID-19 vaccine in Madagascar, especially for the anticipated scale and population group coverage for COVID-19 vaccination. The AF will mitigate this risk through financing additional cold chain equipment, and human resources for vaccine deployment and technical support for immunization system strengthening needs: conducting capacity assessments in coordination with WHO, Gavi, UNICEF, and other partners, and coordinating with other partners in their provision of systems strengthening support. A dedicated unit has been created to monitor the COVID-19 vaccination campaign with support from partners. Thus, the World Bank will continue to provide hands-on technical assistance through that unit and through the weekly strategic group meeting to inform COVID-19 related decision-making process, especially on vaccination campaign

33. **Fiduciary risks associated with the AF remain Substantial.** The procurement and FM risks initially assessed for the parent project cover risks associated with the procurement and distribution of vaccines, including fraud and corruption risks. The same applies to the AF.

- **Procurement:** The main risks in procurement mainly concern (i) market price volatility for imported products, including vaccine and related tools; (ii) the country's dependence on



international trade, especially freight transport; and (iii) delivery delays in the context of the emergency. These risks will be mitigated by an in-depth and contextualized analysis of each acquisition to be made through the Project Procurement Strategy for Development (PPSD) and by setting up a schedule for transmitting needs to the PCU. Overall, training for stakeholders (given by the World Bank) and specific training in contract management will reduce these risks.

- **FM:** The key FM risks relate to (i) untimely funds flow or lack of liquidity given the high requirements to pay manufacturers; (ii) lack of adequate controls over the transparent, prioritized distribution and administration of vaccines, particularly for the most vulnerable population groups the vaccines storage as well as transparent, prioritized distribution and administration of vaccines, particularly for the most vulnerable population groups; (iii) weaknesses of the fixed assets and the stocks management systems; and (iv) risk of fraud and corruption. This AF will use the same options as in the parent project to assess and strengthen control systems, facilitate the timely flow of funds, and ensure adequate liquidity to finance project activities. To further improve the project FM arrangements and reduce the residual FM risk, the following risk mitigating measures were identified:

- The mandate of the fiduciary agency will be expanded to the AF. Given the high risk of fraud and corruption, the fiduciary agency will: validate each expenditure incurred under the vaccine project from the contract's signing; and deploy additional agents in the main departments of the MoPH involved in the vaccination process in order to support the planning and to expedite the disbursement requests.
- The World Bank will require a governance audit of the PCU. The audit will cover all financings managed by the PCU. The terms of reference will be agreed upon by the World Bank, and the involvement of public oversight bodies in this review shall be assessed. The MoPH will consider the outcomes of this audit in the reinforcement of the governance and internal control system of the PCU. The report of will be transmitted to the World Bank no later than March 31, 2022, or a later date agreed with the Bank.

The residual fiduciary risk associated with the AF is Substantial, which is not expected to increase the fiduciary risk for the project.

34. **The anticipated overall environmental and social risks remain Substantial.** The measures to address social and environmental risks in the parent project remain relevant.

- **The environmental risk rating for this AF is Substantial.** Each stage of the vaccine deployment and vaccination process is likely to entail occupational health and safety (OHS), environmental, and social issues. The main environmental risks identified relate to (i) OHS issues, as workers in healthcare facilities and laboratories may be exposed to infectious disease contagion, including the use and disposal of medical supplies and chemicals for cleaning and disinfection; (ii) medical waste management; and (iii) community health and safety-related risks such as increased risk of COVID-19 or other infectious disease transmission. Safety and environmental risks are increased with the utilization of drones for vaccines transportation. Strengthening measures for vaccine transportation and distribution will help mitigate risks and impacts.



- **The social risk rating remains Substantial.** It is expected that AF activities will have essentially positive social impacts by supporting the country's specific needs in preventing the spread of COVID-19 and limiting immediate socioeconomic losses, as well as strengthening public health and essential medical care structures and operations to build resilience and reduce the risk from emerging and re-emerging pathogens. The AF will continue to support activities included in the parent project—mainly purchasing medical equipment and inputs, technical assistance, and capacity building—and will not involve involuntary resettlement or cultural heritage issues. In addition, the AF activities include contracting private drone operators to ensure the effective deployment of vaccines to very remote areas. The key social risk is that vulnerable and high-risk social groups are unable to access the COVID-19 vaccination due to a lack of information, distance from health centers, and possible elite capture. COVID-19 vaccination (safety and efficacy) is still the subject of debate and therefore presents a risk of nonacceptance, which could lead to social unrest and tensions. Given that there is limited experience with the use of drones in-country, especially in hard-to-reach areas, significant efforts will be required to educate communities, especially those within the drone path or corridor, to ensure acceptance. Moreover, sexual exploitation and abuse-sexual harassment (SEA-SH) risks are assessed as moderate since women are given special attention among the priority groups for vaccination and the project may involve a majority of female health workers for vaccine deployment. Project implementation will also involve different types of workers, including PCU staff, health civil servants, local civil society organization staff, and community health workers, which may raise OHS concerns. Finally, the parent project is at a very early stage of implementation and the current PCU has limited capacity and experience in managing social risks under the Environmental and Social Framework (ESF).

35. **Another substantial risk is linked to stakeholders being opposed to vaccination, thus increasing hesitancy of the population for vaccination.** This risk will be mitigated through explicit inclusion in robust stakeholder identification and consultation processes and sharing evidence about efficacy and safety of vaccines. In addition, the GRM required under the ESF should be in place and equipped to address community, worker, and/or individual grievances related to such issues. This includes requirements related to being able to have GRMs in place to address labor and working conditions, and SEA/SH. This AF will further strengthen the approach established in the parent project to engage with stakeholders based upon meaningful consultations and disclosure of appropriate information, considering the specific challenges associated with COVID-19, including the vaccination campaign and sharing evidence about the efficacy and safety of vaccines.

36. **Others. Risks associated with data management and privacy** will continue to be substantial. These include risks of inadequate management and storage of personally identifiable data (PID) and inappropriate sharing of PID in identification systems, health information systems, and other management systems and databases. Mitigation measures may include legal, institutional, and technical measures, as well as investments in data security and training of staff. PID will be available only to trained health professionals duly accredited, password protected on encrypted storage devices, with records of the doses administered using anonymized codes. Given concerns over limited data protection and privacy laws and the data security environment in Madagascar, the project will support required legal and safeguard measures for data privacy.

IV. APPRAISAL SUMMARY



A. Technical, Economic and Financial Analysis

37. **The economic rationale for investment in a COVID-19 vaccine is strong, considering the massive and continuing health and economic losses due to the pandemic.** As of December 2021, more than 273.9 million people were confirmed to have been infected by the virus and over 5.3 million are confirmed to have died. Global economic output is projected to decline by 4.9 percent in 2020, with cumulative losses across 2020 and 2021 exceeding US\$12 trillion. Following an expansion of 4.9 percent in 2019, Madagascar's economy contracted by 4 percent in 2020, a recession comparable to the 2009 constitutional crisis. This was reflected in a sharp contraction in export revenue, particularly from tourism, textiles and apparel, and mining, which were key sources of economic growth and employment before the crisis.

38. The successful development, production, and delivery of a vaccine, however, has the best potential to reverse these trends, generating benefits that will far exceed vaccine-related costs. Indeed, the rapid and well-targeted deployment of the COVID-19 vaccine can help reduce increases in poverty and accelerate economic recovery. Even at levels of imperfect effectiveness, a COVID-19 vaccine that is introduced and deployed effectively to priority populations can assist in significantly reducing mortality and the spread of the coronavirus. It can also accelerate a safe reopening of key impacted sectors and reverse human capital losses by ensuring the reopening of schools. The effective administration of the COVID-19 vaccine also helps to avoid the associated health care costs for potentially millions of additional cases of infection and associated health-related impoverishment. Global experience with immunization against diseases shows that by avoiding these and other health costs, vaccines are one of the best buys in public health. For the most vulnerable population groups, especially in countries without effective universal health coverage, the potential health-related costs of millions of additional cases of COVID-19 infection in the absence of vaccine delivery represent a significant or even catastrophic financial impact and risk of impoverishment. The pandemic is also having dire effects on other non-COVID-19 health outcomes. Increased morbidity and mortality due to interruption of essential services associated with COVID-19 containment measures hinder access to care for other health needs of the population, including maternal and child care services. Routine immunization services have been affected, threatening polio eradication and potentially leading to new outbreaks of preventable diseases, with their own related deaths, illnesses, and long-term costs. Simultaneous epidemics are overwhelming public health systems in different countries that had few resources to begin with, and services needed to address the needs of people with chronic health conditions and mental and substance use disorders have also been disrupted.

39. While uncertainty surrounding the cost and effectiveness of a COVID-19 vaccine makes it difficult to calculate its cost-effectiveness, the effective launch of a COVID-19 vaccine will have direct benefits in terms of averted costs of treatment and disability as well as strengthened health systems. Estimated COVID-19 treatment costs from low- and middle-income countries are US\$50 for a non-severe case and US\$300 for a severe case. This excludes costs of testing of negative cases, as well as the medical costs associated with delayed or forgone care-seeking, which usually results in higher costs. Further, investments in vaccine delivery systems generate health and economic benefits beyond just delivering the COVID-19 vaccine. First, investments in last-mile delivery systems to administer the COVID-19 vaccine to remote communities will require strengthening community health systems, which can have spillover effects to the effective delivery of other services, helping close the significant urban-rural gap. Second, as



the COVID-19 vaccine is introduced and lockdowns and movement restrictions are eased, patients can continue to access care for other conditions. Third, the economic benefits of slowing the economic downturn are likely to significantly exceed the US\$141 million needed to vaccinate 30 percent of the population (parent project and additional financing), leaving aside the immediate health benefits. Given both the economic and health system benefits, an effectively deployed COVID-19 vaccine presents significant benefits.

B. Financial Management

40. In line with the guidelines as stated in the *Financial Management Practices Manual* issued by the FM Sector Board of the World Bank on March 1, 2010, an FM assessment was conducted in November 2021 for the parent project.

41. **The FM arrangements established for the parent project are satisfactory and will be replicated for the proposed AF.** The overall FM arrangements of the parent project that will apply to the AF are assessed to be adequate, provided the recommended risk mitigation measures are implemented. The PCU is implementing the parent project, the Improving Nutrition Outcomes using the Multiphase Programmatic Approach (PARN, P160848), as well as projects funded by other donors. For the parent project, the PIM was approved in October 2021 and covers internal controls in the full cycle of the supply chain of vaccines, acceptance, inventory management, distribution, and physical safeguards. The format of the interim unaudited financial reports (IFR) was agreed upon during the negotiations, and the first report will cover the period ending on December 31, 2021. The additional staff needed for project implementation were recruited in October 2021. The internal audit plan of the PCU was updated to cover the parent project, although no review has been conducted to date and the recruitment of the internal audit firm to support the existing department is delayed. There is also some delay in the recruitment of the external audit firm that will perform two agreed-upon reviews during the first 18 months of implementation in addition to the annual financial audit. These recruitments should have been completed within three months of effectiveness but are planned to be completed by January 31, 2022. Considering the progress made thus far and the first disbursement (on December 3, 2021), the FM performance of the project is rated Moderately Satisfactory. In addition, the mandate of the fiduciary agency currently supporting the PCU and the MoPH in the implementation of the PARN will be extended to the parent project. The fiduciary agency has been recruited to ensure the capacity building of FM staff of each department of the MoPH and to perform a review of transactions prior to payment to ensure their eligibility for financing. Given the increasing financing volume managed by the PCU, particularly since the start of the COVID-19 pandemic, the Bank will require a governance audit of the PCU no later than March 31, 2022, or a later date agreed upon with the Bank. The TOR for this audit will be agreed with the Bank, and the MoPH will consider the result of such audit to improve the governance of the PCU and strengthen the entity's internal control systems.

42. **The AF transactions will be recorded and reported upon using the existing software.** The PCU will prepare consolidated IFRs, and the annual financial statement of the project (including the AF) will be audited annually. The AF funds will be received and managed through the same designated account opened for the parent project. No additional staff will be needed.

C. Procurement



43. **Procurement arrangements remain unchanged from the parent project, and no new measures have been recommended.** Based on the findings of the procurement assessment, the Health PCU has sufficient capacity and prior experience in managing World Bank funds. However, the PCU has limited experience on the New Procurement Framework, particularly for emergency procedures, and therefore gaps will be addressed by training the procurement officers.

44. Procurement under the AF will be carried out in accordance with the World Bank’s Procurement Regulations for Investment Project Financing (IPF) Borrowers for Goods, Works, Non-consulting, and Consulting Services, dated November 2020. As with the parent project, the AF will be subject to the World Bank’s Anticorruption Guidelines, dated October 15, 2006, revised in January 2011, and as of July 1, 2016. The Project will use the World Bank’s online procurement planning and tracking tool, Systematic Tracking of Exchanges in Procurement (STEP), to plan, record, and track procurement transactions.

45. All goods and non-consulting services will be procured in accordance with the requirements set forth or referred to in “Section VI. Approved Selection Methods: Goods, Works and Nonconsulting Services of the Procurement Regulations” mentioned above, and consulting services will be procured in accordance with the requirements set forth or referred to in ‘Section VII. Approved Selection Methods: Consulting Services of the Procurement Regulations’, as well as according to the PPSD and the Procurement Plan approved by the World Bank. For activities specifically identified as emergencies according to the World Bank Guidance definition, the World Bank Guidance on Procurement in Situation of Urgent Need of Assistance or Capacity Constraints of March 2019 will apply.

46. **The PPSD of the parent project will be updated during the first three months after effectiveness** with the concurrence of both the PCU and the technical ministries. World Bank procurement rules and procedures will be applied. The Procurement Plan specifies for each contract (i) a brief description of the activities/contracts; (ii) the selection methods to be applied; (iii) the estimated cost; (iv) time schedules; (v) the World Bank’s review requirements; and (vi) any other relevant procurement information. Any updates of the Procurement Plan and the PPSD will be submitted for the World Bank’s approval. Continuous monitoring and mitigation of any potential risk will be made possible through regular reporting on the progress and implementation of fiduciary activities, regular supervision, and further capacity building, as necessary. Finally, the World Bank will provide additional support and/or training on procurement procedures and STEP for the implementation of the project.

47. All procurement activities under the proposed AF will use STEP to prepare, clear, and update the Procurement Plan and to carry out all procurement transactions.

48. **Madagascar’s national procurement procedures are also used for World Bank-financed projects.** The GoM will include the obligation of suppliers to respect the World Bank’s Anti-Corruption Guidelines (article 4 - III of the National Code) and the right for World Bank audits.

D. Legal Operational Policies

	Triggered?
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Projects on International Waterways OP 7.50	No
Projects in Disputed Areas OP 7.60	No

E. Environmental and Social

49. Activities under the AF, which is a scale-up of the parent project activities, should have positive impacts as it will enable affordable and equitable access to COVID-19 vaccines and play a critical role in further strengthening the health system. However, it could also cause major environmental and social (E&S) risks, including (i) increased risk of COVID-19 transmission (including through inadequate medical waste management), (ii) adverse events following immunization, (iii) social risk of inequity in access to vaccines, and (iv) risks around inadequate or conflictual public engagement and lack of trusted and adequate consultation. The use of drones for vaccine deployment makes Environmental and Social Standard (ESS) 6: Biodiversity Conservation and Sustainable Management of Living Natural Resources relevant in addition to the five (05) standards identified for the parent project: ESS1: Assessment and Management of Environmental and Social Risks and Impacts; ESS2: Labor and Working Conditions; ESS3: Resource Efficiency and Pollution Prevention and Management; ESS4: Community Health and Safety; ESS10: Stakeholder Engagement and Information Disclosure.

50. **Risks will be addressed by updating the E&S instruments developed for the parent project:** the Environmental and Social commitment plan (ESCP) and the Stakeholder Engagement Plan (SEP) were updated and disclosed (published on December 8, 2021, by the World Bank and December 9, 2021, by MoPH); the AF will use the updated National Medical Waste Management Plan (NMWMP) and the Environmental and Social Management Framework (ESMF), which includes a SEA-SH action plan, and the Labor Management Procedures (LMP) will be updated, disclosed, consulted, and adopted as conditions of disbursement. The ESCP could be adjusted during the project life to reflect evolving environmental and social risks and impacts.

51. **Environmental and Social Capacity for ESF instruments implementation.** The AF will be implemented by the current PCU of World Bank-supported health projects within the MoPH. Current E&S staff in the PCU includes one senior E&S specialist, one environmental specialist, one social mobilization and communication specialist, and a MoPH technical team in charge of supervising and monitoring the implementation of waste management measures. The MoPH has more than 15 years of experience working with World Bank safeguards but less experience in ESF implementation. The ESCP provides for the implementation of actions to build the environmental and social capacity of the PCU and project stakeholders.

52. **Resources for implementation.** A sufficient budget and clear institutional responsibilities were prepared for the implementation of E&S measures. The recently-completed workplan takes this into consideration.

Gender Dimensions and Targeting Vulnerable Groups

53. **The pandemic response should be cognizant of the gender-based differences in access to and use of services due to limited mobility and financial capacity.** Support needs to be provided to at-risk



groups such as family caregivers (the majority of whom are women) to reduce their risk of getting ill and passing illness to others.

54. **Pandemics can create or exacerbate the conditions that put women and girls at greater risk of gender-based violence (GBV).** The pandemic response should be cognizant of this risk. Women’s socially ascribed roles in Madagascar restrict their ability to make decisions over household spending, reproductive health, and family planning. Similarly, these norms may restrict women’s access to vaccines as they need to seek their husband’s approval to access health services. Women and girls are at increased risk of violence during the COVID-19 period due to loss of income and limited mobility. A COVID-19 impact evaluation conducted by the United Nations Population Fund (UNFPA) showed an increase in domestic violence during the first wave in 2020, and the number of reported cases reported to the domestic violence hotline increased five-fold by June 2020.

55. **The parent project was designed to close identified gender gaps (including limited access for women to vaccines services and addressing the increase number of GBV cases during COVID-19) and the AF will support several parent project strategies,** including (i) support to community-level vaccination points targeting women; (ii) the inclusion of women who work in informal sectors and as community health workers in applicable priority groups; (iii) provision of vaccines and accurate COVID-19 vaccine information as part of antenatal care and reproductive health services (and other reproductive, maternal, newborn, child, and adolescent health and nutrition services), targeting women and mobile brigades for hard-to-reach and vulnerable populations, including people living with disabilities; and (iv) tailoring communication messages to be gender-sensitive. To address the increasing number of GBV cases during the COVID-19 crisis, health workers will be trained under the parent project and through the AF to prevent, identify, manage, and refer possible cases of GBV. Through this GBV training, the project will support the promotion of awareness and use of GBV services. The project will track the percentage of frontline health care workers with the knowledge to recognize, medically manage, and refer GBV survivors to appropriate services (with a target of 24 percent) in addition to the percentage of women from prioritized populations that are fully vaccinated and female health workers trained in vaccine administration. The ESMF includes a SEA-SH action plan to support monitoring measures contributing to protecting women.

56. The project implementation will ensure appropriate stakeholder engagement, proper awareness-raising, and timely information dissemination. This will help (i) avoid conflicts resulting from false rumors, (ii) ensure equitable access to services for all in need, and (iii) address quarantine-related issues. Standards set out by WHO and other international good practices—including social inclusion and prevention of SEA-SH—will guide these efforts.

F. Climate

57. **The project was screened for short and long-term climate change and disaster risks, and risk to the project was identified as High** due to cyclones, floods caused by storms, extreme rainfall, rising sea levels, and droughts, which in turn have high potential to deliver climate co-benefits. Madagascar is a large island located off the coast of eastern Africa in the Southern Hemisphere. Temperatures are projected to increase between 1.1°C and 2.6°C by 2065, with the highest projections for the southern part of the country. Rainfall is projected to increase for the southern part of the country during January–



April and October–November and decrease during May–September, with greater decreases projected for inland areas. Projections are less certain for the northern area of the country.

58. **Madagascar has one of the highest cyclone risks in Africa**, averaging 3-4 cyclones per year. Cyclones are expected to increase due to rising global temperatures and the resulting increased ocean temperatures. Cyclones bring torrential flooding, which can result in severe damage and cross-sectoral losses (an estimated US\$87 million in losses annually). For example, in 2015, tropical cyclone Chedza caused 68 fatalities and affected an estimated 80,000 people. Additionally, intense rainfall events caused by strong storms and tropical cyclones, as well as rising sea levels, coupled with poor land use practices, weak civil infrastructure, and increasing deforestation, have resulted in significant and damaging floods across the country. In the summer months, heavy rainfall in combination with the lack of efficient rainwater drainage systems often results in intense flooding in densely populated areas like the country's capital, Antananarivo. This can cause extreme road degradation and damage to health facilities, limiting project beneficiary access to immunization and other health services. Flooding increases the incidence of water-borne and diarrheal diseases, including malaria, cholera, typhoid, and rotavirus, which are major causes of morbidity and mortality in Madagascar due to limited availability of clean, potable water. More than 30 floods or heavy rainfall events have affected Madagascar over the past three decades, killing hundreds of people and affecting thousands more. Droughts are also common, particularly in the south of the country where temperatures are highest, leading to food disruptions and interruptions in cold chain logistics for transporting COVID-19 vaccines.

59. **Exacerbating the effects of increased human exposure to climate shocks, the country's infrastructure has not been developed to cope with the effects of current and future climate events, especially in coastal zones and urban areas.** This results in significant impacts on livelihoods, food security, infrastructure, access to safe and potable water, and other sectors related to health and economic development. These hazards also disproportionately impact vulnerable populations, including the 71 percent of the population that lives below the poverty line and 25 percent that are food insecure and highly dependent on climate-sensitive resources for their livelihoods. These populations constitute the poor, elderly, women, and children, some of whom are the project's target beneficiaries. In 2012, as many as 28 percent of the poorest reported being most adversely affected by drought, cyclones, and late rains. The most recently published Demographic and Health Survey (2008–09)⁶ found that 49 percent of households were affected by a cyclone, flood, or drought in the year preceding the survey.

60. **Madagascar has shown its commitment to address climate change, and the climate-related activities for this project align with regional and national climate priorities.** In 2010, the country developed the National Policy to Combat Climate Change to promote and strengthen adaptation activities. The Ministry of Environment, Ecology, Sea, Forests (MEEMF) is responsible for coordinating, implementing, and mainstreaming climate change actions in social and economic sectors. The National Bureau of Climate Change Coordination, within MEEMF, oversees the implementation of all measures in the country's Intended Nationally Determined Contribution. Additionally, on September 21, 2016, Madagascar ratified the Paris Agreement. The climate-related activities outlined in this project align with national and global priorities to address climate change.

⁶ Institut National de la Statistique - INSTAT/Madagascar and ICF Macro. 2010. *Enquête Démographique et de Santé de Madagascar 2008-2009*. Antananarivo, Madagascar: INSTAT and ICF Macro. (National Institute of Statistics- INSTAT/Madagascar and ICF Macro. 2010. *Madagascar Demographic and Health Survey 2008-2009*.)

61. The proposed AF intends to address these vulnerabilities and enhance climate resilience and adaptation through the activities outlined in Table 7.

Table 7. Planned Climate Adaptation Activities

Component/ subcomponent & cost	Climate-related action	Description	How will activity address climate-related vulnerabilities?
Component 2: Strengthening Health System for the Effective Deployment of Vaccines (US\$32 million AF)			
Component 2.1: Strengthening Logistics, Cold Chain, and Vaccination Sites (US\$25million AF)	<ul style="list-style-type: none"> - Mobile outreach to climate-vulnerable groups - Ensuring continuity of vaccination sites during climate shocks 	<ul style="list-style-type: none"> - Expansion of vaccination efforts by including mobile outreach services to reach target beneficiaries, including those most impacted by flooding from heavy rainfall, cyclones, and sea-level rise 	<ul style="list-style-type: none"> - Increasing resilience of groups most heavily impacted by climate shocks - Adapting country's vaccination distribution strategy to climate shocks (cyclones, drought, flooding)
		<ul style="list-style-type: none"> - Purchase reusable tents, tables, chairs, and beds to make vaccination sites resilient to climate risks. This includes using tents to protect vaccination teams from extreme heat and/or including flooding risk in the criteria for positioning vaccination sites to avoid impacts of flooding in flood prone areas 	
	<ul style="list-style-type: none"> - Technical assistance for drones to support use for accessing areas impacted by climate shocks 	<ul style="list-style-type: none"> - Technical assistance for drones will include specific support to use drones to reach areas/populations impacted by climate shocks, particularly cyclones and floods. - The technical assistance will help ensure drones can be used to deliver needed supplies, such as medicines and other emergency supplies, to climate-impacted populations that are otherwise difficult to reach 	<ul style="list-style-type: none"> - Improve resilience to climate shocks
Component 2.2: Strengthening Surveillance and Information Systems (US\$0.3 million AF)	<ul style="list-style-type: none"> - Strengthen monitoring of vaccines for climate-induced diseases 	<ul style="list-style-type: none"> - Support data collection and data infrastructure to improve and monitor vaccines to prevent diseases induced or exacerbated by climate shocks, particularly 	<ul style="list-style-type: none"> - Strengthen vaccine distribution and monitoring of vaccines for climate-induced diseases

		<p>flooding and extreme heat (yellow fever, typhoid, cholera). This will include procurement of data entry devices for use at vaccination sites as well as training of personnel in surveillance of vaccines and data entry.</p>	
<p>Component 2.3: Strengthening Capacities for Managing and Implementing Immunization Campaigns (US\$5.3 million AF)</p>	- Climate vulnerability assessment	- Assessment will be conducted to identify gaps in preparedness for climate-related emergencies, particularly cyclones, sea-level rise, floods, and drought, and opportunities for promoting climate-friendly planning in vaccine deployment and delivery	- Strengthened preparedness and response to the country's climate shocks, particularly cyclones, sea-level rise, floods, and drought
	- Climate-friendly planning of vaccine deployment	- Develop contingency plans for safe vaccine delivery in case of climate emergencies, particularly cyclones, sea-level rise, floods, and drought.	- Strengthen preparedness and response to the country's climate shocks, particularly cyclones, sea-level rise, floods, and drought
	- Preparedness and response to climate shocks	- Provide training and guidelines for health workers' preparedness and response to climate shocks. - Train to include specific modules and materials on preparedness and response to climate shocks, particularly flooding and droughts	- Strengthened preparedness and response to the country's climate shocks
	- Improve medical waste management in flood-prone areas	- Implement guidelines and staff training to strengthen medical waste management in flood-prone areas through proper disposal of medical needles/syringes in syringe boxes and ensuring disposal sites are not in flood plains	- Adapt waste management solutions to consider risks associated with flooding and increased rainfall
<p>Subcomponent 2.4: Strengthening Communication and Addressing Vaccine Hesitancy (US\$1.4 million AF)</p>	- Promote community trust and confidence in vaccines for climate-induced diseases	- Implement a national risk communication plan to promote vaccine uptake and counter vaccine hesitancy and misinformation associated with vaccines for climate-induced diseases, particularly those induced by flooding and extreme heat (ex: cholera, typhoid, and yellow fever)	- Promote uptake of vaccines to combat vaccine-preventable diseases associated with climate-related factors (cholera associated with increased rainfall, flooding)

	- Training and incentives for community health workers to maintain vaccination during climate shocks	- Training and incentives for community health workers, with specific modules on delivering vaccines following and during climate shocks, to reach people impacted by climate shocks	- Increase resilience of groups most heavily impacted by climate shocks
Subcomponent 2.5: Project Implementation and Monitoring (US\$2.5 million, parent project)	- Monitor climate investments	- The project's monitoring component will include monitoring of climate investments	- Monitor implementation of climate investments against plans

62. The project also intends to mitigate against the impacts of climate change through the measures outlined in Table 8.

Table 8. Planned Climate Mitigation Activities

Project Component/Sub-component and Cost	Climate-related action	Description
Component 2: Strengthening Health System for the Effective Deployment of Vaccines		
Component 2.1: Strengthening Logistics, Cold Chain & Vaccination Sites (US\$25 million AF)	- Route Optimization for COVID-19 Vaccine Distribution	- Group shipments, combined deliveries, and structure routes for vaccine delivery to minimize distances traveled and fuel use. Vehicle routes will also be adjusted depending on weather and road conditions to improve fuel mileage and fuel efficiency of the vehicles.
	- Climate-friendly cold chain (US\$6.1 million AF)	- Purchase Solar Direct Drive Refrigerators (US\$6 million AF) - Purchase Energy-efficient positive cold rooms with low global warming potential (GWP) refrigerants (US\$0.1 million AF) - Implement procurement conditions to ensure that only solar direct drive refrigerators and low GWP refrigerators (<150) are used

63. Mechanisms for **citizen engagement**—targeting beneficiaries—to provide ideas and feedback on program delivery help to identify gaps at the point of service delivery (information availability, access to testing and vaccination, access to relevant care, equal treatment, etc.), build community knowledge and confidence, establish trust, ensure governments respond to community needs (including vulnerable groups), and optimize the impact of the COVID-19 emergency response. The following features of the



parent project are also supported through the AF: (i) a citizen-oriented design, with a specific subcomponent (Subcomponent 2.4. Strengthening Communication and Addressing Vaccine Hesitancy), which includes a communications campaign and behavioral change interventions, and (ii) a beneficiary feedback indicator in the Results Framework (Percentage of recorded grievances that are addressed in a timely manner).

64. **Grievance redress mechanism (GRM).** The parent project incorporates a comprehensive project-wide GRM, which enables a broad range of stakeholders to channel concerns, questions, and complaints to the various implementation agencies. At local level, the parent project is building on the GRM set up by the active Madagascar Improving Nutrition Outcomes Project using an MPA (P160848), which was expanded when the latter's CERC was triggered for emergency COVID-19 health response. GRM committees have been set up in each of the 22 regions of Madagascar. They are not yet all fully functional. At central level, the Facebook page from the Ministry of Health has a dedicated space for complaints and questions about COVID-19 vaccination. After four months of implementation, the vaccine project's GRM had recorded 102 complaints mainly at the central level, one-third of which concern the lack of information—more precisely, the inadequacy of clear guidance on the availability of vaccines, the characteristics of these vaccines, and the nearest vaccination site. The project's GRM will be reinforced to be fully functional at all levels and to handle SEA-SH.

V. WORLD BANK GRIEVANCE REDRESS

65. Communities and individuals who believe that they are adversely affected by a World Bank-supported project may submit complaints to existing project-level grievance redress mechanisms or the World Bank's Grievance Redress Service (GRS). The GRS ensures that complaints received are promptly reviewed in order to address project-related concerns. Project-affected communities and individuals may submit their complaints to the World Bank's independent Inspection Panel, which determines whether harm occurred, or could occur, as a result of World Bank noncompliance with its policies and procedures. Complaints may be submitted at any time after concerns have been brought directly to the World Bank's attention, and Bank Management has been given an opportunity to respond. For information on how to submit complaints to the GRS, please visit <https://www.worldbank.org/en/projects-operations/products-and-services/grievance-redress-service>. For information on how to submit complaints to the World Bank Inspection Panel, please visit www.inspectionpanel.org.

VI SUMMARY TABLE OF CHANGES

	Changed	Not Changed
Results Framework	✓	
Components and Cost	✓	
Implementing Agency		✓
Project's Development Objectives		✓
Loan Closing Date(s)		✓
Cancellations Proposed		✓
Reallocation between Disbursement Categories		✓
Disbursements Arrangements		✓
Legal Covenants		✓
Institutional Arrangements		✓
Financial Management		✓
Procurement		✓
Implementation Schedule		✓
Other Change(s)		✓

VII DETAILED CHANGE(S)

MPA PROGRAM DEVELOPMENT OBJECTIVE

Current MPA Program Development Objective

The Program Development Objective is to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness

Proposed New MPA Program Development Objective



EXPECTED MPA PROGRAM RESULTS

Current Expected MPA Results and their Indicators for the MPA Program

Progress towards the achievement of the PDO would be measured by outcome indicators. Individual country-specific projects (or phases) under the MPA Program will identify relevant indicators, including among others:

- Country has activated their public health Emergency Operations Centre or a coordination mechanism for COVID-19;
- Number of designated laboratories with COVID-19 diagnostic equipment, test kits, and reagents;
- Number of acute healthcare facilities with isolation capacity;
- Number of suspected cases of COVID-19 reported and investigated per approved protocol;
- Number of diagnosed cases treated per approved protocol;
- Personal and community non-pharmaceutical interventions adopted by the country (e.g., installation of handwashing facilities, provision of supplies and behavior change campaigns, continuity of water and sanitation service provision in public facilities and households, schools closures, telework and remote meetings, reduce/cancel mass gatherings);
- Policies, regulations, guidelines, or other relevant government strategic documents incorporating a multi-sectoral health approach developed/or revised and adopted;
- Multi-sectoral operational mechanism for coordinated response to outbreaks by human, animal and wildlife sectors in place;
- Coordinated surveillance systems in place in the animal health and public health sectors for zoonotic diseases/pathogens identified as joint priorities; and
- Mechanisms for responding to infectious and potential zoonotic diseases established and functional; and
- Outbreak/pandemic emergency risk communication plan and activities developed and tested

Proposed Expected MPA Results and their Indicators for the MPA Program

COMPONENTS

Current Component Name	Current Cost (US\$, millions)	Action	Proposed Component Name	Proposed Cost (US\$, millions)
1-Acquisition of Project COVID-19 vaccines and	71.00	Revised	1-Acquisition of Project COVID-19 vaccines and	80.00



medical supplies			medical supplies	
2-Strengthening health system for the effective deployment of Project COVID-19 vaccines	29.00	Revised	2-Strengthening health system for the effective deployment of Project COVID-19 vaccines	61.00
3-Contingent Emergency Response	0.00	No Change	3-Contingent Emergency Response	0.00
TOTAL	100.00			141.00

Expected Disbursements (in US\$)

Fiscal Year	Annual	Cumulative
2021	0.00	0.00
2022	50,000,000.00	50,000,000.00
2023	45,000,000.00	95,000,000.00
2024	41,000,000.00	136,000,000.00
2025	5,000,000.00	141,000,000.00

SYSTEMATIC OPERATIONS RISK-RATING TOOL (SORT)

Risk Category	Latest ISR Rating	Current Rating
Political and Governance	● Substantial	● Substantial
Macroeconomic	● Moderate	● Moderate
Sector Strategies and Policies	● Substantial	● Substantial
Technical Design of Project or Program	● Substantial	● Substantial
Institutional Capacity for Implementation and Sustainability	● High	● High
Fiduciary	● Substantial	● Substantial
Environment and Social	● Substantial	● Substantial
Stakeholders	● Substantial	● Substantial
Other	● Substantial	● Substantial
Overall	● High	● High



LEGAL COVENANTS – Additional Financing to Support to COVID-19 vaccine purchase and health system strengthening (P178279)

Sections and Description

Schedule 2, Section 1, A, 3, b :To this end, and without prejudice to paragraph (a) immediately above, or to Section I.3. of Schedule 2 to the Original Financing Agreement, the Recipient shall recruit, by January 31, 2022 or any later date which may be agreed upon in writing between the Recipient, through the PCU, and the Association: (i) an internal auditor, on the basis of terms of reference, qualifications and experience acceptable to the Association; and (ii) an external auditor, in accordance with the Procurement Regulations.

Schedule 2, Section 1, A, 3, e :The Recipient, through the PCU, shall: (i) ensure that the terms of reference of the fiduciary agency for the Project cover this additional Financing, no later than December 31, 2021, or any other date which may be agreed upon in writing between the Recipient, through the PCU, and the Association; (ii) provide the necessary mandate and resources to said fiduciary agency to carry out its duties, including inter alia validation of expenditures and deployment of necessary agents to support disbursement requests, as further set out in the PIM; and (iii) carry out an independent governance audit of the PCU to be transmitted to the Association no later than March 31, 2022, or any other date which may be agreed upon in writing between the Recipient, through the PCU, and the Association, under scope and terms of reference satisfactory to the Association.

Conditions

Type	Financing source	Description
Disbursement	IBRD/IDA	Schedule 2, Section III, B, 1.b. for expenditures under Categories (1) and (2), unless and until the Recipient has prepared, consulted upon, disclosed and adopted the updated ESMF and LMP all in form and substance acceptable to the Association and in accordance with the ESCP.
Disbursement	IBRD/IDA	Schedule 2, Section III, B, 1.c. for Emergency Expenditures under Category (3), unless and until all of the following conditions have been met in respect of said expenditures: (i) (A) the Recipient has determined that an Eligible Crisis or Emergency has occurred, and has furnished to the Association a request to withdraw Financing amounts under Category (3); and (B) the Association has agreed with such determination, accepted said request and notified the Recipient thereof; and (ii) the Recipient has adopted the CERC Manual and Emergency Action Plan, in form and substance acceptable to the Association.



VIII. RESULTS FRAMEWORK AND MONITORING

Results Framework

COUNTRY: Madagascar

Additional Financing to Support to COVID-19 vaccine purchase and health system strengthening

Project Development Objective(s)

This Project’s Development Objective is to support the Government of Madagascar to acquire and deploy COVID-19 vaccines, and to strengthen its immunization services.

Project Development Objective Indicators by Objectives/ Outcomes

Indicator Name	PBC	Baseline	Intermediate Targets				End Target
			1	2	3	4	
Support the Government of Madagascar to acquire and deploy COVID-19 vaccines							
Percentage of the population fully vaccinated, based on prioritized populations as defined in national plan (Percentage)		0.00	3.50	19.00	34.50	50.50	50.50
<i>Action: This indicator has been Revised</i>							
Percentage of females fully vaccinated, based on the prioritized population in the national plan (Percentage)		0.00	50.00	50.00	50.00	50.00	50.00
<i>Action: This indicator has been Revised</i>	<i>Rationale: Addition of intermediate target, no other change</i>						



Intermediate Results Indicators by Components

Indicator Name	PBC	Baseline	Intermediate Targets				End Target
			1	2	3	4	
Acquisition and deployment of Project COVID-19 Vaccines and medical supplies							
Number of complete doses of eligible COVID-19 vaccine purchased through the project that arrived in the country (Number)		0.00	604,800.00	3,177,400.00	5,750,000.00	9,000,000.00	9,000,000.00
<i>Action: This indicator has been Revised</i>							
Strengthening health systems for the effective delivery of Project COVID-19 Vaccines							
Number of sites with functioning refrigerators purchased through the project (Number)		0.00	540.00				540.00
<i>Action: This indicator has been Revised</i>							
<i>Rationale: Addition of intermediate target, no other change</i>							
Number of health workers trained in vaccine administration within the project (Number)		0.00	2,000.00	4,000.00			4,000.00
<i>Action: This indicator has been Revised</i>							
<i>Rationale: Addition of intermediate target, no other change</i>							
Number of female health workers trained in vaccine		0.00	1,100.00	2,200.00			2,200.00



Indicator Name	PBC	Baseline	Intermediate Targets				End Target
			1	2	3	4	
administration within the project (Number)							
Action: This indicator has been Revised	Rationale: Addition of intermediate target, no other change						
Number of vaccination sites that received waste treatment equipment through the project. (Number)	0.00	1,360.00	2,720.00				2,720.00
Action: This indicator has been Revised	Rationale: Addition of intermediate target, no other change						
Proportion of serious adverse events following immunization (AEFI) reported and investigated based on national guidelines (Percentage)	0.00	100.00	100.00	100.00	100.00	100.00	100.00
Action: This indicator has been Revised	Rationale: Addition of intermediate target, no other change						
Percentage of frontline health care workers with the knowledge to recognize, medically manage, and refer GBV survivors to appropriate services (Percentage)	0.00	24.00	24.00	24.00			24.00
Action: This indicator has been Revised	Rationale: Addition of intermediate target, no other change						



Indicator Name	PBC	Baseline	Intermediate Targets				End Target
			1	2	3	4	
Percentage of immunization sites reporting data on time (Percentage)		0.00	80.00	80.00	80.00		80.00
Action: This indicator has been Revised	Rationale: Addition of intermediate target, no other change						
Percentage of recorded grievances that are addressed in a timely manner (Percentage)		0.00	80.00	80.00	80.00		75.00
Action: This indicator has been Revised	Rationale: Addition of intermediate target, no other change						
Percentage of doses successfully administered out of the total vaccine doses procured by the Project (Percentage)		0.00	95.00	95.00	95.00		95.00
Action: This indicator is New	Rationale: The addition of this indicator will better reflect the performance increase in vaccines deployment and administration						

Monitoring & Evaluation Plan: PDO Indicators

Indicator Name	Definition/Description	Frequency	Datasource	Methodology for Data Collection	Responsibility for Data Collection
Percentage of the population fully vaccinated, based on prioritized	Numerator: Number of fully vaccinated persons	Monthly	DHIS2/MoPH	Routine data	PCU/Ministry of Public Health



populations as defined in national plan	(who received the recommended number of doses of COVID-19 vaccine). Denominator: Total number of the population.				
Percentage of females fully vaccinated, based on the prioritized population in the national plan	Numerator: Number of fully vaccinated women. Denominator: Total number of fully vaccinated individuals (who received the recommended number of doses of COVID-19 vaccine).	Monthly	DHIS2/MoPH	Routine data	PCU/Ministry of Public Health

Monitoring & Evaluation Plan: Intermediate Results Indicators

Indicator Name	Definition/Description	Frequency	Datasource	Methodology for Data Collection	Responsibility for Data Collection
Number of complete doses of eligible COVID-19 vaccine purchased through the project that arrived in the country	Number of eligible COVID-19 vaccine full doses purchased through the project that have arrived in the country. A full dose is determined by the number of injection (s) required to fully immunize a person. 2 for AstraZeneca and 1 for Johnson & Johnson.	Monthly	Purchase order and receipts	Project Monitoring	PCU/Ministry of Public Health
Number of sites with functioning refrigerators purchased through the	Number of sites with functioning refrigerators	Quarterly	Installation reports	Project Monitoring	PCU/MoPH department of vaccination



project	acquired through the project. Number does not include existing refrigerators		from the department of vaccination of MoPH		
Number of health workers trained in vaccine administration within the project	Number of health workers trained in administering types of vaccines available. This includes part-time workers.	Quarterly	Vaccination training report	Project Monitoring	PCU/Ministry of Public Health, department of vaccination
Number of female health workers trained in vaccine administration within the project		Quarterly	Vaccination training report	Project Monitoring	PCU/Ministry of Public Health, department of vaccination
Number of vaccination sites that received waste treatment equipment through the project.	Number of health facilities for which the waste treatment equipment acquired under the project is installed and operational.	Quarterly	Environmental safeguard/M&E report of the project	Project Monitoring	PCU
Proportion of serious adverse events following immunization (AEFI) reported and investigated based on national guidelines	Numerator: Number of serious Adverse Post-Injection Events (AEFI) reported and investigated according to country standards. Denominator: Total number of AEFIs reported	Monthly	DHIS2/MoPH	Routine data	PCU/Ministry of Public Health
Percentage of frontline health care workers with the knowledge to recognize, medically manage, and refer GBV survivors to appropriate services	Numerator: number of health workers with the knowledge to recognize, medically manage, and refer GBV survivors to	Quarterly	Vaccination training report	Project Monitoring	PCU/Ministry of Public Health, department of vaccination




	appropriate services Denominator: total number of health workers				
Percentage of immunization sites reporting data on time	Percentage of vaccination sites that report data within the time frame defined by the Ministry of Public Health in DHIS2 of the MoPH	Monthly	DHIS2/MoPH	Routine data	PCU/Ministry of Public Health
Percentage of recorded grievances that are addressed in a timely manner	Numerator: Number of complaints registered in the grievance and redress mechanism that were addressed on time Denominator: Total number of complaints registered	Quarterly	Safeguard report of the project	Project Monitoring	PCU
Percentage of doses successfully administered out of the total vaccine doses procured by the Project	Number of doses administered out of the doses procured under the project (at expiration date).	Quarterly	DHIS2/MoH	Routine data	PIU/MoH



ANNEX 1: LIST OF COVID-19 VACCINES MEETING WORLD BANK APPROVAL CRITERIA

As of November 3, 2021


	Manufacturer/ WHO EUL holder	Name of Vaccine	SRA approval received	WHO EUL ⁷
				Status of assessment
1.	 BioNTech Manufacturing GmbH	BNT162b2/COM IRNATY Tozinameran (INN)	United Kingdom: December 2, 2020 Canada: December 9, 2020 United States: December 11, 2020 European Union: December 21, 2020 Switzerland: December 19, 2020 Australia: January 25, 2021	Finalized: December 31, 2020 Additional sites: <ul style="list-style-type: none"> – Baxter Oncology GmbH Germany (DP). June 30, 2021 – Novartis Switzerland. July 8, 2021 – Mibe (Dermapharm) Germany (DP). July 16, 2021 – Delpharm, Saint-Remy FRANCE (DP). September 17, 2021 Shelf life extension: 9 months at -70 to -90°C. September 20, 2021 <ul style="list-style-type: none"> – Sanofi-Aventis Deutschland GmbH Germany October 6, 2021 Diluent suppliers: <ul style="list-style-type: none"> – Pfizer Perth, Australia Fresenius Kabi, USA June 18, 2021
				Additional sites: <ul style="list-style-type: none"> – Pharmacia & Upjohn, Kalamazoo (DP)PGSMcPherson (DP) July 16, 2021 – Exelead, Inc. Indianapolis, U.S. September 30, 2021

⁷ https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_20Oct2021.pdf



2.	 AstraZeneca, AB	AZD1222 Vaxzevria	UK: December 30, 2020 EU: January 29, 2021 Australia: February 16, 2021 (overseas manufacturing); March 21, 2021 (for local manufacturing by CSL – Seqirus) Canada: February 26, 2021	Core data finalized. April 16, 2021 Additional sites: <ul style="list-style-type: none"> – SK-Catalent – Wuxi (DS). April 16, 2021 – Chemo Spain. April 30, 2021 – Amylin Ohio US (DP). July 23, 2021
				Finalized. Feb 15, 2021
				Finalized. July 9, 2021 Additional site: <ul style="list-style-type: none"> – Nipro Pharma Corporation Ise, Japan. October 11, 2021
				Finalized. July 9, 2021 Additional site: <ul style="list-style-type: none"> – Siam Bioscience Co., Ltd Thailand. October 11, 2021
3.	 Serum Institute of India Pvt. Ltd	Covishield (ChAdOx1 _nCoV-19)		Finalized. Feb 15, 2021
4.		mRNA- 1273	US: December 18, 2020 Canada: December 23, 2020 EU: January 6, 2021 Switzerland: January 12, 2021 UK: January 8, 2021	Finalized. April 30, 2021 Additional Sites. August 6, 2021 <ul style="list-style-type: none"> – ModernaTx. Norwood (DS) – Catalent Indiana, LLC (DP) – Lonza Biologics, Inc. Portsmouth, USA (DS) – Baxter, Bloomington, USA (DP)
5.	 Sinopharm / BIBP¹ Beijing Institute of Biological Products Co., Ltd. (BIBP)	SARS-CoV- 2 Vaccine (Vero Cell), Inactivate d(InCoV)		Finalized. May 7, 2021 <i>2 and 5 dose presentation (new manufacturing site) -- TBC after ongoing inspection</i>



6.	 Sinovac Sinovac Life Sciences Co., Ltd. Sinovac Life Sciences Co., Ltd.	COVID-19 Vaccine (VeroCell), Inactivate d/ Coronavac TM		Finalized. June 1, 2021 2 dose presentation September 30, 2021
7.	 Janssen–Cilag International NV	Ad26.COVS.S	USA: February 27, 2021 Canada: March 5, 2021 EU: March 11, 2021 Switzerland: March 22, 2021 UK: May 28, 2021 Australia: June 25, 2021	Core data finalized (US +NL sites).March 12, 2021 Additional sites: <ul style="list-style-type: none"> – Aspen RSA (DP). June 25, 2021 – Catalent Agnani Italy (DP). July 2, 2021
8.	 Bharat Biotech, India	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN		Finalized. November 3, 2021



ANNEX 2: LATEST COVID-19 SITUATION IN THE COUNTRY

1. Madagascar declared a health state of emergency due to the COVID-19 pandemic (decree 2020-359 of March 21, 2020) and has since repeated declarations and withdrawals of the health emergency declaration. The first health emergency was lifted on October 18, 2020. It was reinstated in early April 2021 due to the second wave (decree 2021-390 of April 3, 2021) and lifted again on September 4, 2021.
2. **A costed emergency contingency plan for COVID-19 was prepared in February 2020 by the GoM with support from development partners.** The World Bank responded swiftly to provide financial support to ensure a strong response to COVID-19 through its CERC Improving Nutrition Outcomes Project Using the Multiphase Programmatic Approach (*Projet d'Amélioration des Résultats Nutritionnels-PARN*, P160848) triggered on April 3, 2020 for US\$20 million, which was replenished in June 2020 with an AF (P173950). The World Bank support and involvement was a catalyst to accelerate the country's preparedness and response.
3. **Due to the increasing needs and financial gaps in the accelerating pandemic, the Government has developed a Multisectoral Social Emergency Plan, validated by the Council of Ministers on July 1, 2020.** The World Bank has allocated US\$169 million to support the Government's health, social, education, water and sanitation plans, and leveraged an additional US\$123 million to finance the Multisectoral Emergency Plan through CERCs of other projects and further mitigate the pandemic's impacts on health, social protection and the private sector⁸. The additional financial support for health response was provided by the Madagascar World Bank portfolio CERC which was triggered on September 3, 2020 and added US\$40 million in financing to the health sector. Main strategies as part of the health response include: (i) coordination; (ii) strengthening disease surveillance system, including at community level, and contact tracing; (iii) developing and strengthening testing capacities (network of laboratories equipped and personnel trained); (iv) ensuring management of positive cases in hospitals and primary health care facilities (training of staff, equipment, oxygen therapy and Personal Protective Equipment) and ensuring continuity of essential health services (such as immunization and safe deliveries); (v) logistical support to social activities (transfers of drugs and inputs, ambulances, waste management, and so on); and (vi) communication at all levels to prevent disease spread.
4. **Since early November 2021, the number of new COVID-19 cases has increased significantly,** rising from an average of 5 cases per day at the end of October 2021 to an average of 142 new cases per day during the week of December 4–10, 2021 (new cases were detected in 17 out of the 22 regions of Madagascar). As of December 10, 2021, Madagascar reported 45,794 cases and 980 official deaths since the start of the outbreak. The first cases (three cases, all imported) were confirmed on March 20, 2020, and a first peak was reached in July/August 2020 (when the number of cases rose fourfold in one month), with the highest number of new cases reaching 360 per day. The capital city of Antananarivo was impacted most, but all of Madagascar's 22 regions were affected. The epidemiological situation worsened during the second

⁸ The Madagascar World Bank portfolio CERC was triggered on September 3, 2020 and an additional US\$123 million was leveraged to finance the urgent gaps in the Multisectoral Emergency Plan and prevent a further deterioration of the crisis. The proposed US\$123 million helped fill part of the financing gap of the Multisectoral Emergency Plan, with a focus on health (US\$40 million), social protection (US\$45 million), private sector mitigation related measures (US\$33 million) and sanitation activities in support of the Antananarivo Municipality (US\$5 million). Through this activation of the IDA Immediate Response Mechanism / CERC in response to COVID-19, the CERC of the P154698 - Sustainable Landscape Management Project was triggered to finance the US\$40 million of the additional health sector response.



wave with the presence of the South African variant that hit Madagascar in March–April 2021, resulting in over 600 new daily cases (and peaking on April 14, 2021, with 854 new cases). The death rate has also increased; it is now estimated at 2.14 percent compared to 1.4 percent in 2020.

5. **As of December 13, 2021, only 1.9 percent of the total population (541,160 individuals) were fully vaccinated.** Vaccine availability is not an issue—out of the 1,898,990 vaccine doses delivered to the country, 742,062 had been administered. Additional dose deliveries are expected over the coming months from COVAX and the AF's parent project, which will be complemented by doses procured under this AF. High levels of vaccine hesitancy and some logistical bottlenecks have prevented an acceleration of vaccine uptake.



ANNEX 3: SUMMARY OF THE PARENT PROJECT COMPONENTS

1. Below is a brief description of each component under the parent project. The PAD of the parent project can be accessed at:

<https://documents1.worldbank.org/curated/en/978101625729383050/pdf/Madagascar-Support-to-COVID-19-Vaccine-Purchase-and-Health-System-Strengthening-Project.pdf>.

2. **Component 1: Acquisition of Project COVID-19 Vaccines and Medical Supplies (US\$71 million equivalent).** In alignment with the revised VAC, the World Bank will provide up to US\$71 million to finance vaccine acquisition. The acquisition is expected to be implemented through the AVAT and COVAX purchasing mechanisms. The vaccines are expected to be AstraZeneca and Johnson & Johnson.⁹ However, depending on the available international supply, other approved vaccines may be procured through the project. The project will fully immunize around 5.6 million people (about 20 percent of Madagascar’s population of 28.1 million). These acquisitions will be complemented by other sources to reach the GoM’s current coverage target of 50.5 percent of the population by June 2023. This percentage corresponds to the entire adult population of Madagascar. This financial support is aligned with the NVDP. In addition to vaccines, this component will finance vaccination supplies needed for vaccine delivery and distribution. These supplies include cotton swabs, needles, syringes, and so on.

3. **Component 2: Strengthening Health System for the Effective Deployment of Project COVID-19 Vaccines (US\$29 million equivalent).** This component will support the deployment of vaccines and key investments in the health system that are essential to ensure the effective delivery of COVID-19 vaccines and strengthen the health system in the long term.

4. **Component 3: Contingent Emergency Response.** This component will facilitate access to rapid financing by allowing for the reallocation of uncommitted project funds in the event of a natural disaster, either by a formal declaration of a national emergency or upon a formal request by the GoM. Following an eligible crisis or emergency, the Government may request that the World Bank reallocate project funds to support emergency response and reconstruction. This component would draw upon uncommitted resources from other project components to cover emergency response. A CERC Manual and an Emergency Action Plan, acceptable to the World Bank, will be prepared and constitute a disbursement condition for this component.