



# COVAX: THE VACCINES PILLAR OF THE ACCESS TO COVID-19 TOOLS ACCELERATOR STRUCTURE AND PRINCIPLES

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**What is the COVAX Structure & Principles document?** This document outlines the working structure and guiding principles for collaboration of COVAX, the Vaccines pillar of the Access to COVID-19 Tools Accelerator (ACT-A). The working structure of COVAX continues to adapt to emerging needs and the changing trajectory of the pandemic. Some components of the pandemic response capabilities united under COVAX may eventually be integrated into regional, national and sub-national health systems, routine immunization programmes and future global pandemic preparedness and response (PPR) structures. Therefore, the working structures outlined in this document continue to evolve and the document provides a snapshot of the COVAX ways of working in the first half of 2022.

**Disclaimer:** The work of COVAX covers a range of complex matters and variables that continually change with the evolving trajectory of the COVID-19 pandemic and new developments in the global pandemic response. As a result, this document—including specific details on membership, composition and responsibilities of various groups, as well as the stakeholders who are involved in COVAX operations—should be taken as indicative as of the date of publication. It is an update of the document previously published on 17 March 2021.

# 1. INTRODUCTION

## 1.1 WHAT IS COVAX?

COVAX is a global, multilateral initiative aimed at making COVID-19 vaccines available equitably and to those who need them. COVAX also serves as the vaccine pillar of ACT-A, which was subsequently set up in April 2020 as a global initiative to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

The objective of COVAX is to ensure that COVID-19 vaccines are rapidly available to and affordable for all countries around the world, regardless of income level. COVAX was able to make COVID-19 vaccines available to lower-income countries just 39 days after the global rollout began. As of October 2022, 63% of the world's population had been vaccinated with the primary series of COVID-19 vaccines, including 51% in AMC92 countries. Since the beginning of the pandemic, COVAX has delivered more than 1.8 billion doses to 146 economies, with more than 90% of these going to people in lower income countries.

COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO) – working in partnership with developed and developing country vaccine manufacturers, Pan American Health Organization (PAHO), the World Bank, and others.

COVAX is an end-to-end partnership and has dedicated groups working along the vaccination value chain: from accelerating the development and manufacturing of COVID-19 vaccines, promoting fair and equitable access for every country in the world, assisting countries with rolling out vaccination programmes to strengthening in-country delivery systems.

While COVAX is a new construct specifically set up to effectively respond to the COVID-19 pandemic, collaboration between its partners has been longstanding through the Gavi Vaccine Alliance and other initiatives.

For COVAX, each partner brings different but complementary expertise and capabilities to the table:

**CEPI** is leading on the [COVAX vaccine research and development portfolio](#), investing in R&D across a variety of promising candidates, with the goal to support development of safe and effective vaccines which can be made available to COVAX participants. As part of this work, CEPI has secured first right of refusal for the COVAX Facility to access doses of multiple vaccines, and made strategic investments in vaccine manufacturing, which includes reserving capacity to manufacture doses of COVAX vaccines at a network of facilities. CEPI is also investing in 'next generation' and 'variant-proof' vaccine candidates, which will give the world additional options to control COVID-19 in the future.

Building on more than two decades of experience reaching nearly half the world's children with essential childhood vaccines, shaping vaccine markets to support access in lower-income countries, and fighting outbreaks by maintaining global vaccine stockpiles and supporting response activities, **Gavi, the Vaccine Alliance**, through the COVAX Facility, leads global procurement and delivery at scale for COVAX. Gavi designed and manages the [COVAX Facility](#), COVAX's global risk sharing and pooled procurement mechanism, as well as the [Gavi COVAX Advance Market Commitment \(AMC\)](#). Gavi hosts the Office of the COVAX Facility, coordinating the day-to-day operation and governance of COVAX, and manages financial and legal relationships with COVAX participants and donors. Gavi also secures doses for COVAX: managing the COVAX portfolio by negotiating advance purchase agreements (APAs) with manufacturers and designing and coordinating the COVAX dose sharing mechanism.

As part of its role coordinating design, operationalization and fundraising for the Gavi COVAX AMC, Gavi has raised more than US\$ 12 billion in donor funding to ensure that the doses it secures for COVAX through APAs and dose donations are provided free-of-cost to 92 lower-income participants. Gavi funds UNICEF and PAHO procurement and shipment of vaccines to AMC participants, and plays a key role coordinating and supporting delivery of COVID-19 vaccines – with nearly \$1.5 billion in COVID-19 Delivery Support funding made available to AMC participants. Gavi also co-designed, raises funds

for and supports the operationalization of the [AMC's no-fault compensation mechanism](#) as well as the [COVAX Humanitarian Buffer](#).

**UNICEF** is leveraging its experience as the largest single vaccine buyer in the world and working with manufacturers and partners on the procurement of COVID-19 vaccine doses, as well as their freight, global logistics and storage. UNICEF already procures more than 2 billion doses of vaccines annually for routine immunisation and outbreak response on behalf of nearly 100 countries. In collaboration with the [PAHO Revolving Fund](#), UNICEF is leading efforts to procure and supply doses of COVID-19 vaccines, safe injection equipment and cold chain equipment for COVAX. In addition, UNICEF in close collaboration with WHO is supporting governments with funding, technical assistance and political advocacy to support the delivery of vaccines to high risk communities. UNICEF is also playing a lead role at the global and country level to foster trust in vaccines, delivering vaccine confidence communications and tracking and addressing misinformation around the world.

**WHO** has multiple roles within [COVAX](#), with the organization providing normative guidance on vaccine policy, regulation, safety, R&D, allocation, and country readiness and delivery. The Strategic Advisory Group of Experts ([SAGE](#)) on Immunization develops evidence-based immunization policy recommendations. WHO's [Global COVID-19 Vaccination Strategy](#) outlines the guiding global targets of vaccinating 100% of health care workers and 100% of the highest risk populations, alongside reaching 70% population coverage.

Its Emergency Use Listing (EUL) / prequalification programmes ensure the harmonized regulatory review and authorization of vaccines across Member States. WHO provides global coordination and Member State support on vaccine safety monitoring. WHO also developed the target product profiles for COVID-19 vaccines and provides R&D technical coordination. WHO, together with UNICEF, provides support to countries as they prepare to receive and administer vaccines. On behalf of the COVAX Partners, WHO developed a No-Fault Compensation Program.

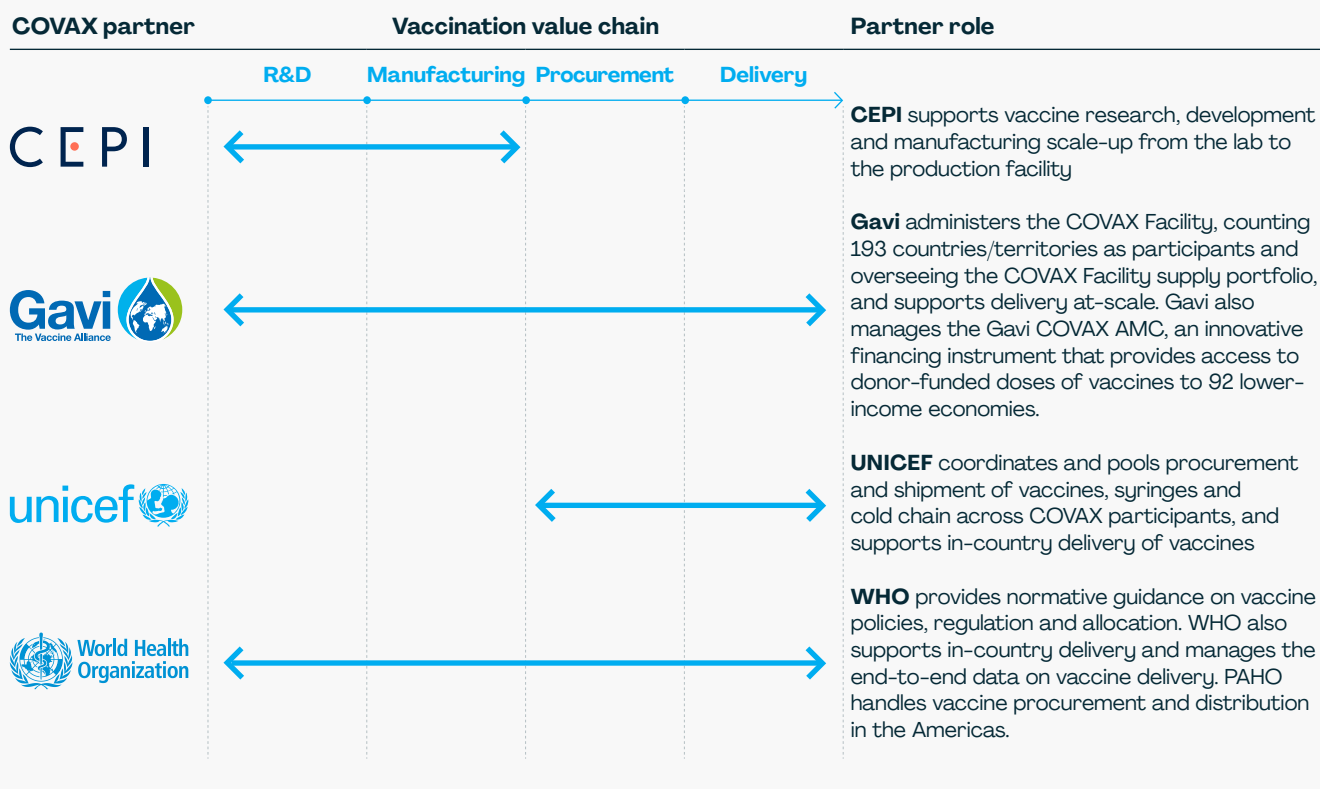
In January 2022, WHO, UNICEF and Gavi established the COVID-19 Vaccine Delivery Partnership (CoVDP) to support vaccine roll out in the 92 AMC countries. It specifically provides urgent operational support to the 34 countries that were at or below 10% primary series vaccination coverage in January 2022 to progress towards national and global targets. The work of CoVDP has been built upon the functions and structures of the country readiness and delivery (CRD) workstream, leveraging the capabilities of the WHO and UNICEF Regional and Country Offices and Gavi Senior Country Managers (SCMs). Aligned with the SAGE roadmap, countries are supported to focus on their priority populations – older adults, healthcare workers, and persons with co-morbidities including immunocompromised persons.



Figure 1

## COVAX is a robust partnership, with each partner playing a crucial role across the vaccination value chain

In addition to the four core partners, COVAX works with Civil Society Organisations (CSO), manufacturers, multilateral development banks, regional alliances, national/subnational implementing partners, beneficiary governments, donors and funders.



## 1.2 COVAX OPERATING STRUCTURE

COVAX is an end-to-end partnership covering R&D, Procurement and Delivery. The aim is to:

1. Support a timely, reliable portfolio and pipeline of effective, affordable and scalable vaccines through interventions in the field of R&D, regulatory, manufacturing, and procurement
2. Advance equitable access and fair allocation in a dynamic environment
3. Work to support countries' needs and ambitions to control the disease and reopen society, contributing to the achievement of global and country-level vaccination coverage targets, also recognizing the revised WHO targets: 100% of health workers, 100% of the highest risk populations and 70% of populations
4. Support governments to reach their national COVID-19 vaccination targets by provision of technical assistance, funding and political advocacy

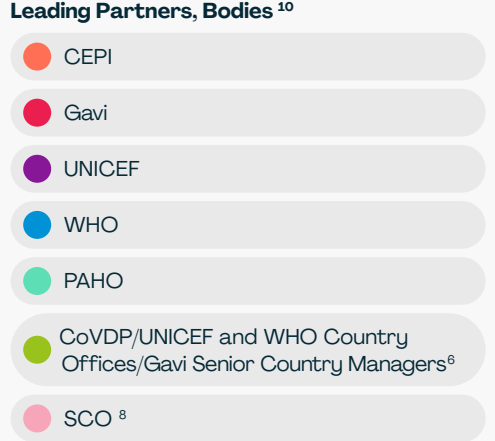
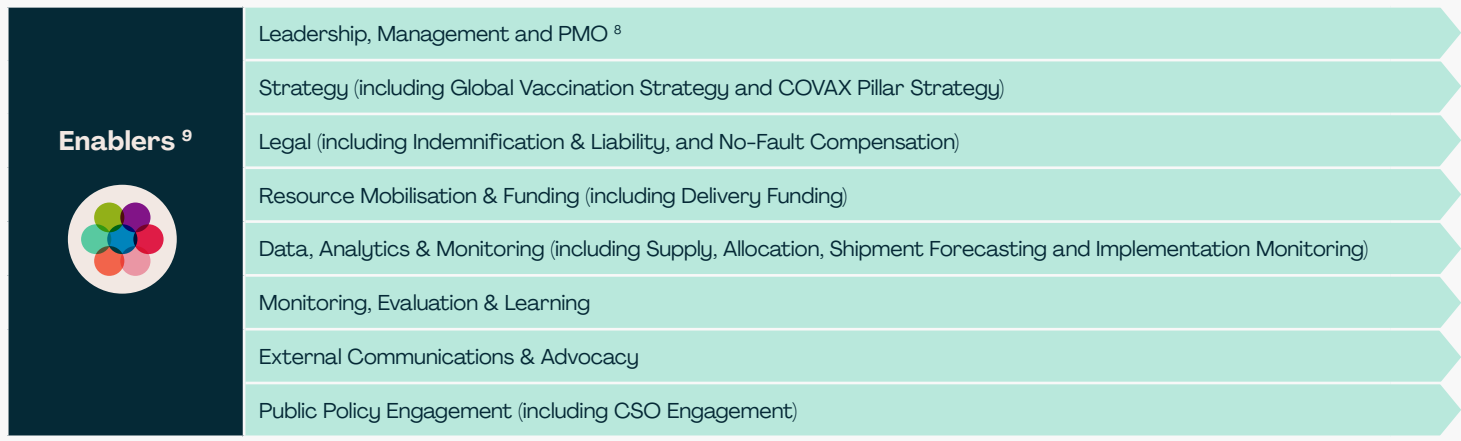
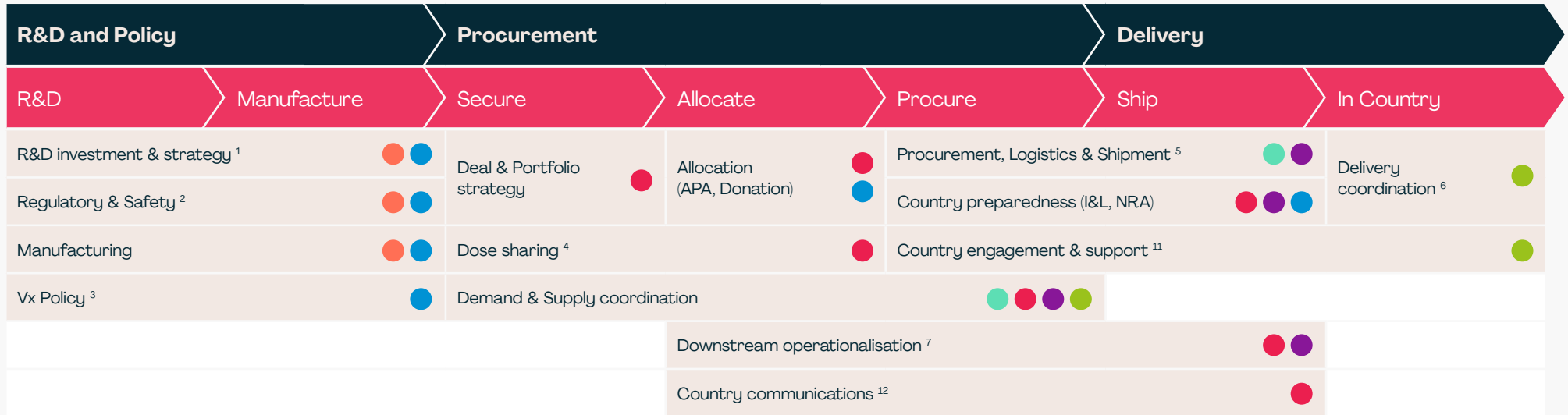
5. Support countries in integrating COVID-19 vaccination into routine immunization and primary healthcare systems

COVAX draws on the experience and pre-existing capabilities of its partners, which are leading global health organisations and trusted pioneers in their areas of expertise. In this way, COVAX builds on the existing operational capabilities of its constituent organisations and enables these organisations to work together in the joint COVID-19 response.

The following sections of this document describe the key Workstreams, Enabling Capabilities and Coordination Bodies as shown in Figure 2. It provides a brief overview of key activities undertaken by each work unit, along with governance and oversight mechanisms, principles that guide the conduct of the work, and interlinkages with other areas of work, working groups or governance and coordination bodies.

# Figure 2 COVAX Operating Model: Workstreams, Enabling Capabilities and Leading Partner Organizations

Partners that lead the specific workstreams ○ and enabling capabilities ● are shown with the indicated colours.



1. Including activities around vaccine development and optimization, and variants

2. WHO Pre-qualification

3. WHO SAGE and Post-implementation safety monitoring group

4. Includes donor engagement, supply confirmation with manufacturers, country acceptance and signature of tripartite agreements with donors, recipients and manufacturers

5. Handled jointly by UNICEF Supply Division and PAHO Procurement Coordination Team

6. In close collaboration with governments and local stakeholders, in-country delivery support is provided to all AMC 92 countries through Gavi Senior Country Managers, and the WHO and UNICEF country offices. CoVDP is providing targeted supported to 34 out of the 92 countries with vaccination coverage rates at or below 10% in January 2022.

7. Includes Product Managers from UNICEF and Gavi, and SCO Product Focal Points, who support the end-to-end coordination of a product's life cycle from APA signature to shipment

8. Strategic Coordination Office (SCO), coordinates COVAX's governance, cross-pillar Project Management and Pillar Leadership engagement activities

9. In addition to the enabling activities, there are COVAX Programmes, such as the COVAX Humanitarian Buffer Programme and the COVAX Facility Cost Sharing Programme

10. The coloured dots on the diagram indicate partner organizations that lead each workstream. In addition to leading partner organizations, there are cross-partner engagement structures in place that draw input and insight from other COVAX partners to conduct above COVAX workstream activities in a collaborative spirit

11. Gavi, UNICEF and WHO. CoVDP is providing targeted support to the 34 AMC countries with the lowest vaccination coverage rates (at or below 10% in Jan 2022). The remaining AMC countries are supported by Gavi, UNICEF and WHO.

12. The Country Communications Team is the information and coordination hub for COVAX country communications and acts as a liaison point for COVAX country-facing staff across Gavi, UNICEF, and WHO.

## 2. COVAX GOVERNANCE AND COORDINATION

COVAX is responsible for the end-to-end vaccine COVID-19 emergency response led by the four COVAX partners (CEPI, Gavi, UNICEF and WHO).

Technical teams across partners join their capabilities in dedicated COVAX workstreams and coordination mechanisms, such as the COVAX Coordination Meeting (CCM), Pillar Leadership Team (PLT) and Workstream Conveners (WSC) to enable technical and leadership groups to align on common issues, priorities and risks that affect the whole COVAX partnership. In addition, coordination between COVAX technical teams and other ACT-A pillars facilitate cross-pillar collaboration.

The COVAX Strategic Coordination Office (SCO) is the cross-partner secretariat that aligns the Leadership, Management and Project Management Offices across the COVAX partnership. The

COVAX Operational SWAT facilitates alignment across technical teams that work on activities leading up to the shipment of vaccines to countries, and CoVDP/CRD coordinates operational teams working with countries on COVID-19 vaccine delivery at country level.

In addition to the dedicated, cross-partner coordination bodies and COVAX workstreams, each partner organization has their own governance structures and protocols in place, which provide guidance and oversight on COVAX.

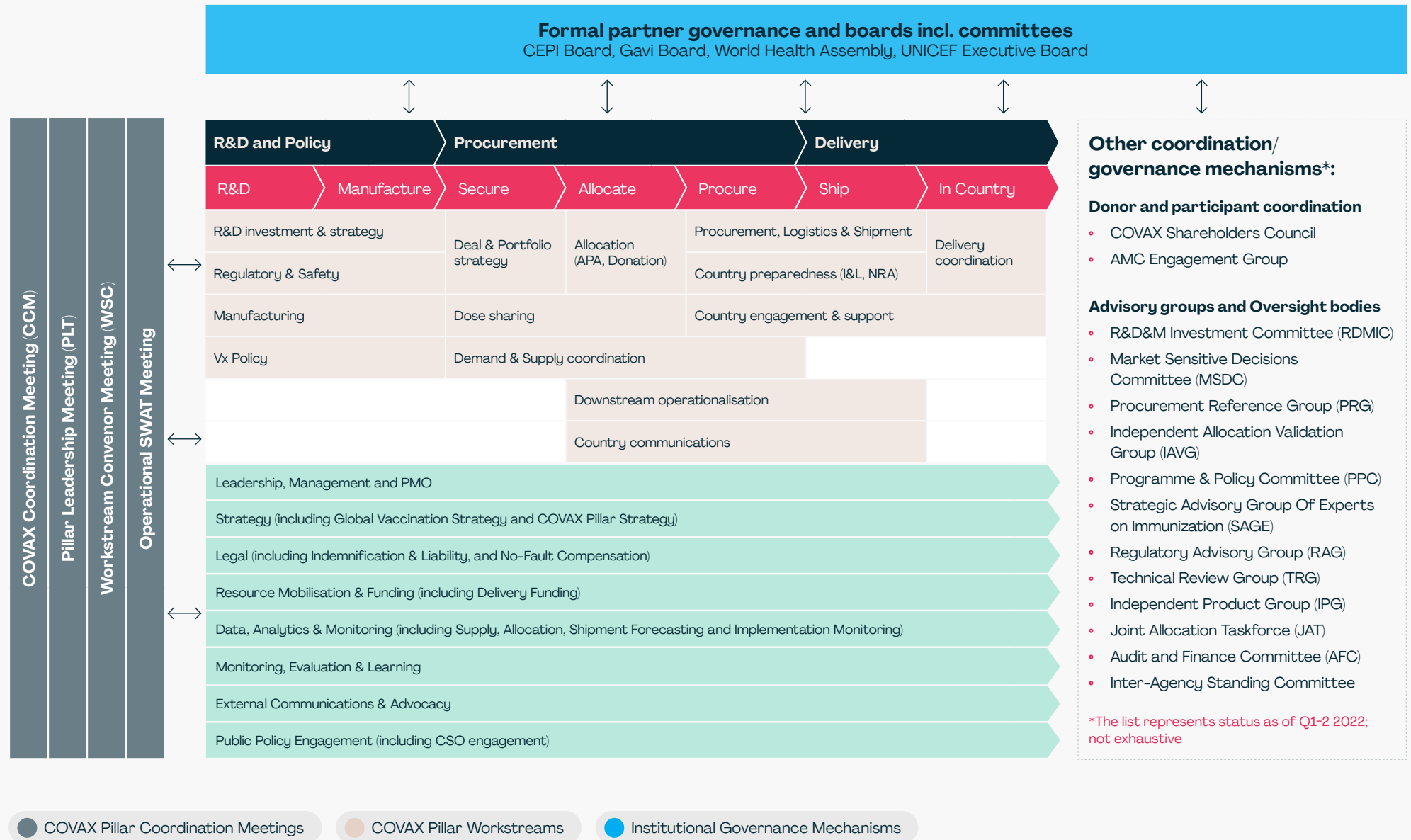
The figure below outlines the key workstreams and coordination mechanisms of the COVAX partnership, along with a list of partner-specific governance structures that take decisions or make recommendations to guide the joint COVID-19 response of the four COVAX partners.





Figure 3

# Overview of the COVAX Coordination and Governance Ecosystem



COVAX workstreams and enabling capabilities are further detailed in the following sections, along with select “Other coordination/ governance mechanisms” that are relevant to the oversight and management of the COVAX workstreams listed in the figure above.

Key inter-agency COVAX coordination meetings, fora and bodies include:

## 2.1 COVAX COORDINATION MEETING (CCM)

CCM is the Strategic Steering & Advisory Committee of the COVAX partnership. CCM is COVAX’s strategic advisory body and focuses on identifying risks and mitigations on issues pertaining to COVAX’s governance, strategy, policy and reputation.

CCM includes the highest-level representatives from the extended COVAX ecosystem, including vaccine manufacturers (the International Federation of Pharmaceutical Manufacturers & Associations, IFPMA, and the Developing Countries Vaccine Manufacturers Network, DCVMN), the World Bank, CSO representatives, executives of core COVAX partners (CEPI, Gavi, UNICEF, WHO) and leads of the ACT-A hub and [CoVDP](#) (3.3).

CCM is co-chaired by the Board Chairs of CEPI and Gavi and is convened monthly by the COVAX [Strategic Coordination Office](#) (SCO) (2.5).

The functions of the CCM are to:

- Discuss major strategic questions and provide direction on critical policy, political and reputational issues as well as create effective mechanisms for advocacy
- Provide external partners (industry, CSO, Multilateral Development Banks (MDBs)) with visibility on COVAX’s progress and key challenges and possible mitigations
- Ensure alignment and coordination between the extended COVAX partnership and the wider ACT-Accelerator

## 2.2 COVAX PILLAR LEADERSHIP TEAM (PLT)

The PLT is the cross-partner strategic decision-making body of the COVAX partnership, overseeing strategic and broader operational

questions, external communications and advocacy, risk and issue mitigation.

The PLT provides oversight on the development and execution of COVAX strategy, strategic guidance on policy, funding, supply, demand and allocation issues, the COVAX operating model and sign off on new or evolving COVAX processes.

The core members of PLT include executive officers of the COVAX partners (CEPI, Gavi, UNICEF Supply Division and WHO), as well as the CoVDP lead. The workstream conveners of each partner attend the PLT meetings. In addition, experts, technical workstream leads, and the ACT-A lead are invited to the forum as needed.

The PLT is convened weekly by the COVAX [Strategic Coordination Office](#) (2.5), or more often if needed.

The function of the PLT is to:

- Provide guidance and take decisions on COVAX strategy, operations, policy and communication/advocacy
- Address or mitigate urgent issues and risks that implicate COVAX’s reputation and success
- Monitor progress of COVAX’s strategic milestones and plan
- Provide a forum for cross-partner alignment on COVAX matters, in conjunction with formal governance mechanisms of the partners
- Ensure alignment with broader ACT-A strategy, plan, and reporting

## 2.3 COVAX WORKSTREAM CONVENORS (WSC)

WSC is COVAX’s strategic operational decision-making mechanism providing oversight across all workstreams and tracking progress against COVAX’s plan. WSC provides oversight of COVAX working groups and time-sensitive cross-partner initiatives.

The core members of WSC include the COVID-19 programme leads from each of the COVAX partners (CEPI, Gavi, UNICEF and WHO), as well as representatives from the CoVDP. Additional technical experts are invited to the forum as needed.

WSC is convened weekly by the COVAX [Strategic Coordination Office](#) (2.5), or more often if needed.

The function of the WSC is to:

- Make decisions and provide technical guidance on key operational matters to COVAX workstreams
- Provide cross-partner alignment on operational and technical questions
- Monitor progress and de-bottleneck issues raised via workstreams and COVAX Operational SWAT
- Escalate strategic risks and issues of operational matters to PLT

## 2.4 COVAX OPERATIONAL SWAT FORUM

### Overview

COVAX Operational SWAT provides coordination and oversight of the end-to-end COVAX Operations Process (Demand and Supply Planning through to Shipment). It acts as a consultative forum for cross-functional teams to monitor progress, de-bottleneck day-to-day challenges and develop options for solutions. It is a decision-making triage forum that escalates policy and strategic recommendations on supply, demand, allocation and shipment. It executes delegated operational decisions made by decision-making bodies such as [Workstream Convenors](#) (WSC) (2.3) and [Pillar Leadership](#) (PLT) (2.2).

### Key activities

Operational leads from Gavi, UNICEF, WHO, PAHO Revolving Fund and representatives from CoVDP meet weekly. The group is convened by the COVAX Strategic Coordination Office (SCO) Operations Lead. If updates to operational processes are needed, the group forms a joint recommendation that is then escalated to either WSC or PLT for approval.

### Objectives

- Monitor progress of operational activities ([Demand Planning](#) (3.2.2), [Supply Planning](#), [Allocations](#) (3.2.3), [Downstream Tracking](#) (3.2.6), [Shipment](#) (3.2.5))
- Discuss and de-bottleneck any operational issues
- Regular reviews of operational processes; recommend updates where necessary

### Principles

1. Transparency – monitoring progress and raising operational issues in a forum in which all COVAX partners are represented
2. Collaboration – provides oversight of operational processes

### Interlinkages with other areas of work

1. Close coordination with operational teams (e.g., Supply Team, [Demand Planning Team](#) (3.2.2), [allocation teams](#) (3.2.3), Downstream Team, Product Teams, [Resource Mobilization](#) (4.2), [Dose Sharing](#) (3.2.4))
2. Linkages to decision making bodies such as One Deal Team, Allocation Leadership Group
3. Escalates operational recommendations for approval by COVAX Pillar Leadership (WSC, PLT)

## 2.5 COVAX STRATEGIC COORDINATION OFFICE (SCO)

### Overview

The COVAX Strategic Coordination Office (SCO) is the strategic coordination and programme management office of the COVAX partnership. CEPI, Gavi, UNICEF and WHO have each seconded dedicated staff to the SCO. The SCO is intentionally set up as a neutral, intra-partner team with its staff supporting the COVAX mission and strategy overall rather than supporting individual partner objectives. It is sometimes described as the “mortar between the bricks” of the COVAX partnership.

The SCO convenes all COVAX coordination meetings ([CCM](#) (2.1), [PLT](#) (2.2), [WSC](#) (2.3), [SWAT](#) (2.4)), coordinates and supports cross-partner technical working groups, and supports strategic and operational topics along the COVAX value chain (i.e., [R&D/Policy](#) (3.1), [Procurement/Logistics](#) (3.2), [Delivery](#) (3.3), and enabling capabilities, such as [External Communications](#) (4.5), [Resource Mobilization](#) (4.2), [Data and Analytics](#) (4.3), etc.). The SCO is also regularly tasked with solving time-critical issues that require cross-partner engagement.

The SCO maintains relationships across the COVAX ecosystem, incl. ACT-A, industry, CSOs, MDBs and over a hundred technical workstream members across the COVAX partners.

## Key activities

### Governance and Coordination

- In collaboration with the Chiefs of Staff and Programme Managers of the partner organizations, determine key strategic and operational priorities of COVAX and facilitate stakeholder engagement and alignment leading to key strategic decisions
- Lead the planning, convening and follow up of the COVAX Leadership meetings (CCM, PLT, WSC, SWAT), both in-person and virtual, and ensure two-way information flow between the COVAX Leadership and workstreams
- Provide project management and convening support to select workstreams where tight and strategic cross-partner coordination is needed, such as COVAX Pillar Strategy, Manufacturing and Supply Chain Taskforce, External Communications and Advocacy, Resource Mobilization, One Deal Team and COVAX input to ACT-A Quarterly reports
- Provide strategic coordination and design support to flagship projects such as strategic priorities setting, the COVAX transition and others
- Proactive and continuous stakeholder engagement across all levels of the partnership to pre-empt and resolve issues

### Operations

- Provide day to day project management, analytics and convening support for operational activities that happen before vaccine shipments take place, such as but not limited to coordinating demand, supply, country-facing and manufacturer/ donor-facing teams

### Other

- Bring together existing analytical capabilities of the partners to create demand, supply, allocation and administration forecast for internal planning and target setting
- As needed, provide time-limited surge support for strategic projects with specific deliverables

## Governance and oversight

The COVAX PLT is ultimately responsible for the SCO, with operational oversight coming from the COVAX Workstream Conveners (WSC)

## Principles

- Creating a neutral coordination space and enabling cross-partner collaboration to achieve COVAX's strategy and objectives

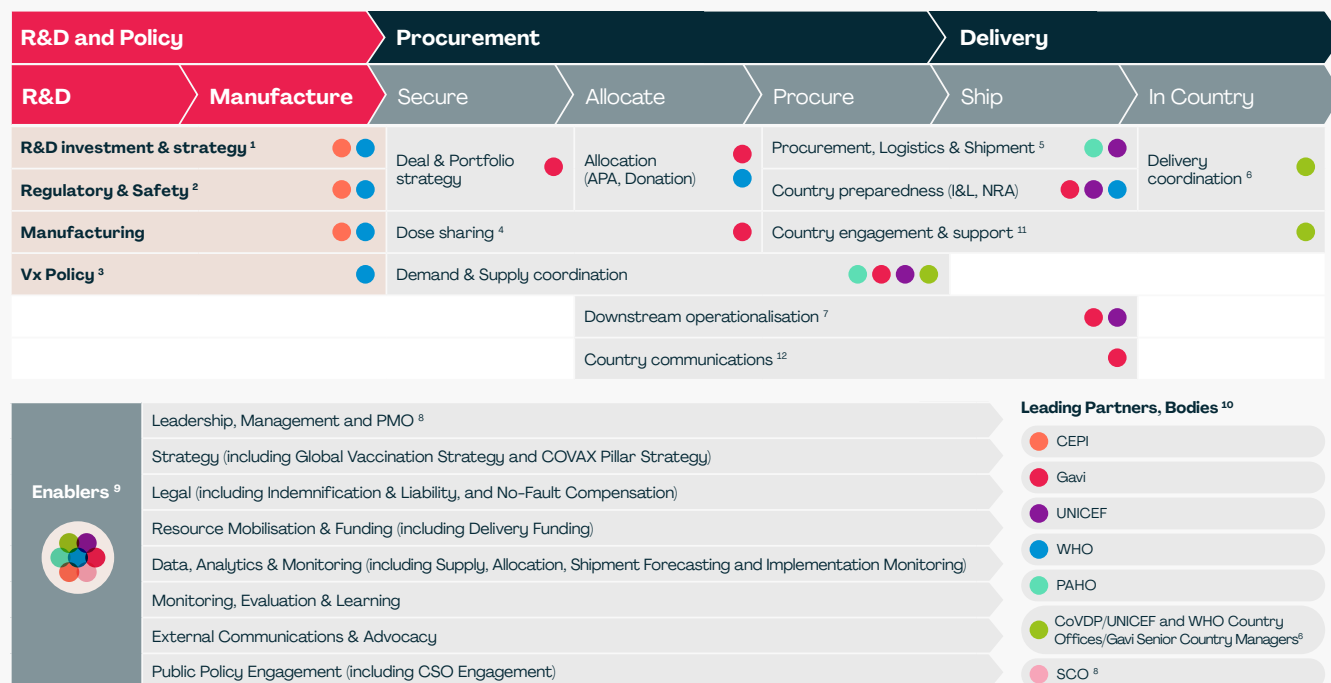
## Interlinkages with other areas of work

- Executive, Project Management and Coordination Offices of CEPI, Gavi, WHO, UNICEF, CoVDP, ACT-A



# 3. COVAX WORKSTREAMS

## 3.1 R&D, POLICY AND MANUFACTURING



- Including activities around vaccine development and optimization, and variants
- WHO Pre-qualification
- WHO SAGE and Post-implementation safety monitoring group
- Includes donor engagement, supply confirmation with manufacturers, country acceptance and signature of tripartite agreements with donors, recipients and manufacturers
- Handled jointly by UNICEF Supply Division and PAHO Procurement Coordination Team
- In close collaboration with governments and local stakeholders, in-country delivery support is provided to all AMC 92 countries through Gavi Senior Country Managers, and the WHO and UNICEF country offices. CoVDP is providing targeted support to 34 out of the 92 countries with vaccination coverage rates at or below 10% in January 2022.
- Includes Product Managers from UNICEF and Gavi, and SCO Product Focal Points, who support the end-to-end coordination of a product's life cycle from APA signature to shipment

- Strategic Coordination Office (SCO), coordinates COVAX's governance, cross-pillar Project Management and Pillar Leadership engagement activities
- In addition to the enabling activities, there are COVAX Programmes, such as the COVAX Humanitarian Buffer Programme and the COVAX Facility Cost Sharing Programme
- The coloured dots on the diagram indicate partner organizations that lead each workstream. In addition to leading partner organizations, there are cross-partner engagement structures in place that draw input and insight from other COVAX partners to conduct above COVAX workstream activities in a collaborative spirit
- Gavi, UNICEF and WHO. CoVDP is providing targeted support to the 34 AMC countries with the lowest vaccination coverage rates (at or below 10% in Jan 2022). The remaining AMC countries are supported by Gavi, UNICEF and WHO.
- The Country Communications Team is the information and coordination hub for COVAX country communications and acts as a liaison point for COVAX country-facing staff across Gavi, UNICEF, and WHO.

### 3.1.1 R&D OPERATIONS AND COVAX PRODUCT PORTFOLIO INVESTMENTS

#### Overview

#### Research and Development (R&D):

WHO develops normative guidance, convenes and coordinates stakeholders to align on research needs, drive strategic alignment, and helps accelerate and fund priority research to curtail the COVID-19 pandemic. In the early days of the pandemic, WHO activated the R&D Blueprint for COVID-19, which is a global strategy and preparedness plan that enables the rapid

activation of R&D activities during epidemics. WHO also plays a critical role in aligning the regulatory pathway for products, across regulators and engaging with manufacturers on consultations to clarify and facilitate regulatory harmonization and pathways with appropriate specification of norms and standards. The COVID-19 R&D Roadmap was developed, target product profiles (TPPs) for COVID-19 vaccines were prepared, and national regulatory and ethics bodies were supported. In addition, WHO continues to lead the Solidarity Trial, an international, multi vaccine, adaptive clinical trial that evaluates the efficacy and safety of promising new and second-generation COVID-19 vaccines.

CEPI provides technical, financial, and strategic support throughout the development cycle of candidate vaccines in the CEPI Portfolio, from preclinical R&D activities to licensure, including at-risk scale up of manufacturing capacity. CEPI also funds the research and development of second-generation and broadly protective betacoronavirus vaccines. In addition to vaccine development, CEPI supports clinical research activities in low- and middle-income countries and funds studies to close real-world effectiveness data gaps and generate evidence on COVID-19 vaccination strategies (e.g., heterologous priming, fractional dosing, etc.). Finally, CEPI creates a neutral platform for collaboration and problem-solving for COVID-19 vaccine developers and manufacturers via the Clinical, Enabling Sciences, and Manufacturing SWAT teams co-convened with WHO & Bill and Melinda Gates Foundation (BMGF) with representatives from industry and global R&D experts, as well as the Regulatory Advisory Group (RAG) co-convened by CEPI and WHO.

Gavi monitors emerging data and research by WHO and CEPI relevant for products in the COVAX Facility Portfolio as well as cross-cutting issues (e.g., variants, second-generation vaccines, safety profiles, etc.), and any potential implications on the COVAX Facility Product Portfolio. For more information, please see the section on [Deal and Portfolio Strategy](#). (3.2.1.1)

### **Product Portfolio Investments:**

CEPI funds the research, development, and manufacturing of a diverse set of candidate COVID-19 vaccines and vaccine platform technologies. The Research and Development and Manufacturing Investment Committee (RDMIC) governs CEPI investments in COVID-19 vaccine research and development and enabling projects. The Technical Review Group (TRG) makes recommendations to the RDMIC regarding the technical performance and probability of technical and regulatory success of potential CEPI investments and maintains oversight of risks identified. Advanced candidate COVID-19 vaccines supported by CEPI are considered, among others, for inclusion in the COVAX Facility Product Portfolio.

Gavi leads the Office of the COVAX Facility, which is the entity responsible for selecting and financing vaccines for inclusion in the COVAX Product Portfolio. The Independent Product Group (IPG) provides independent scientific and technical advice to the Office of the COVAX Facility regarding the suitability of vaccine candidates for prioritization or inclusion in COVAX Product Portfolio. Following the IPG's recommendation, vaccine candidates are reviewed

by the Procurement Reference Group (PRG), which provides independent technical advice on procurement strategy. Finally, the Market Sensitive Decisions Committee (MSDC) is responsible for financially binding agreements with manufacturers and decides the terms of proposed COVAX APAs.

## **Governance and oversight**

### **Technical Review Group (TRG)**

*Mandate:*

- Assess the technical merit of projects considered for CEPI investment

*Composition:*

- Participation of CEPI, Gavi, BMGF, and WHO members

*Key activities:*

- Provide end-to-end oversight of project execution, including review and monitoring of Vaccine Teams' progress, milestones, and budgets
- Review significant deviations in projects (scope, time, or budget) and approve extensions or escalate to the Research and Development and Manufacturing Investment Committee (RDMIC)
- Recommend project selection based on technical review and approve investment decisions less than US\$ 5 million (e.g., new project selections, stage gate reviews, change requests, etc.)
- Provide scientific, technical, and operational review of projects and risks for Vaccine Teams
- Raise challenges or issues from Vaccine Teams to SWAT teams
- Make recommendations to the Research and Development and Manufacturing Investment Committee (RDMIC) across different stages of the investment decision pipeline

### **The Research and Development and Manufacturing Investment Committee (RDMIC)**

*Mandate:*

- Selection of candidates and projects for CEPI Investment

*Composition:*

- CEPI, Gavi, BMGF, industry experts, and senior global public health leaders

*Key activities:*

- Drive portfolio strategy and investment decision recommendations in line with COVAX strategic objectives

- Define the target composition, diversity, investment allocation, and risk profile of the portfolio, including COVAX-funded vaccine candidate projects and cross-cutting enabling projects
- Recommend project selection and investment decisions greater than US\$5 million (e.g., new project selections, stage gate reviews, portfolio reviews, major change requests, etc.)
- Oversee progress of COVAX-funded vaccine candidate projects and cross-cutting enabling projects
- Identify and address cross-portfolio challenges and interdependencies

### Independent Product Group (IPG)

#### Mandate:

- Assessment of eligibility and evaluation for inclusion of product candidates in the COVAX portfolio

#### Key activities:

- Evaluate product candidates for inclusion in the COVAX portfolio
- Assess the comparative advantage of each candidate and overall portfolio balance (e.g., considerations on attributes, access & delivery, diversification)
- Provide advice (for PRG and MSDC) on candidates to be included in the COVAX portfolio
- Regularly review the status of the COVAX portfolio based on clinical, manufacturing and supply information

### Product Reference Group (PRG)

#### Mandate:

- Advise on procurement strategy implementation

#### Composition:

- UNICEF and Gavi jointly determine the composition of the PRG (~7 members)
- A chairperson is appointed by UNICEF and Gavi from among the members of the PRG

#### Observers:

- UNICEF, Gavi, PAHO, and WHO are observers of the PRG

#### Key activities:

- Review commercial terms of a deal, taking into account risk tolerance and broader market conditions

- Recommend deal terms of APAs in advance of negotiation with manufacturers

### Market-Sensitive Decisions Committee (MSDC)

#### Mandate:

- Approval of binding agreements with manufacturers for the COVAX Facility portfolio

#### Composition:

- 14 members, including representatives from Gavi, WHO, UNICEF, World Bank, BMGF, representatives of donor country governments, and CSOs

#### Key activities:

- Review business terms of proposed COVAX volume guarantee agreements
- Approve financially binding agreements with manufacturers

### Interlinkages with other areas of work

- [Manufacturing](#) (3.1.3)

- CEPI and WHO also support vaccine manufacturing, via the Manufacturing and Supply Chain Taskforce

- [Policy](#) (3.1.4)

## 3.1.2 REGULATORY AND SAFETY

### Overview

The WHO Prequalification of Medical Products team (WHO PQ) sets the global regulatory standards and guidelines and leads the quality, safety and efficacy assessments for EUL of candidate COVID-19 vaccines. WHO also provides support to all Member State regulatory authorities for their reviews and reliance on EUL assessments, and establishes the mechanisms for reliance.

CEPI supports the development of regulatory strategies for COVID-19 vaccines in the CEPI portfolio. In addition, CEPI collates insights on common regulatory issues faced by vaccine developers and manufacturers.

Together, WHO PQ and CEPI lead the Regulatory Advisory Group (RAG), a neutral and inclusive forum where regional and national regulatory agencies can discuss and align on common regulatory issues and challenges faced by vaccine developers, manufacturers, and regulators.

## Key bodies

### Regulatory Advisory Group (RAG)

#### Mandate:

- Support and promote regulatory planning among COVID-19 vaccine developers to ensure access when scientifically appropriate
- Inform Regulatory Agencies of the questions and challenges faced by vaccine developers in the development of COVID-19 vaccines (e.g., batch release, enriching and dynamic expiry date, immuno-bridging, etc.)
- Address regulatory science questions raised by Clinical Development and Operations, Enabling Sciences, and the Manufacturing SWATs led by CEPI

#### Composition:

- RAG is co-led by WHO (regulatory & prequalification department) and CEPI
- Members from Regulatory Agencies, including Argentina, Australia, Brazil, Canada, EU (European Medicines Agency (EMA) & European Directorate for the Quality of Medicines & Health Care (EDQM)), Ghana, India, Japan, Singapore, Republic of Korea, UK, China, and the USA

## Key activities

- Discuss (product agnostic) regulatory science questions from COVAX SWAT teams
- Respond to COVAX SWAT teams and publish Technical Briefs on the WHO website. For more information, please view [RAG Technical Briefs](#)
- Conduct closed discussions and information sharing between Regulatory Agencies

## Principles

- A safe platform: Support open exchange of perspectives, problems faced, and lessons learned
- Global representation: RAG brings the regulatory expertise of the world together across all income levels and world regions
- Fostering common understanding and collaboration: RAG brings both the perspectives of developers and regulators to the table

## Interlinkages with other areas of work

- RAG briefings and discussions feed into other regulator forums, such as the Cluster Meetings which include Health Canada, EMA, US Food and Drug Administration (FDA) and WHO (as an observer) and the International Coalition of Medicines Regulatory Authorities (ICMRA, which includes 40+ agencies)
- COVID-19 Regulatory activities led by the WHO and CEPI have strong linkages with other WHO technical groups:
  - [SAGE](#) (Strategic Advisory Group of Experts on Immunization) (3.1.4)
  - [GACVS \(Global Advisory Committee on Vaccine Safety\)](#)
  - Technical Advisory Group on COVID-19 Vaccine Composition ([TAG-CO-VAC](#))
  - [WHO R&D Blueprint](#)
  - [WHO Target Product Profiles](#) (TPP)
- RAG also has links to the Clinical Development and Operations, Enabling Sciences, and Manufacturing SWATs led by CEPI

## 3.1.3 MANUFACTURING

### Overview

The COVAX Supply Chain & Manufacturing Taskforce (MFTF) was established in May 2021 to strengthen coordination and alignment on vaccine manufacturing and to address the short, medium and long-term hurdles facing sustainable manufacturing and supply chain resilience (see the *Info Box at the end of the section*). The objectives of the Manufacturing Taskforce were:

- Creating transparency on input supply, accelerating select export permits, and facilitating fill-finish matchmaking
- Enhancing visibility of existing and mid-term deployable capabilities
- Expanding the capabilities of manufacturers in LMICs

Co-led by WHO and CEPI, MFTF efforts were distributed into four workstreams<sup>1</sup>:

1. UNICEF was a contributor to all workstreams and part of the MFTF Leadership Team.



1. Immediate COVAX Response: led by CEPI and designed to enhance visibility on input supplies, accelerate export permits and custom clearance for critical raw materials, expand fill and finish match-making mechanisms.
2. Mid-Term COVAX Response: co-led by CEPI and Gavi. It strove to create an overview of global manufacturing capacities, better utilize existing capabilities, and develop regulatory and manufacturing workforces.
3. Long-Term Sustainable Manufacturing: led by WHO and Medicines Patent Pool (MPP) with the objective to expand the capabilities of existing manufacturers in LMICs, grow existing capabilities and strengthen the know-how of existing manufacturers. Combined, these activities established sustainable capacity in regions with low capacity.
4. Taskforce Coordination Office: led by the [COVAX SCO](#) (2.5) with the aim to provide coordination support between the Manufacturing Taskforce workstreams and the COVAX governance structure as well as the Vaccine Manufacturing Working Group (VMWG). It also provided visibility and coordinating support among workstreams and partners and overall project management support.

The MFTF concluded in February 2022, with on-going activities transitioning to business-as-usual within CEPI and WHO.

### Governance and oversight

- The MFTF Leadership team met biweekly to advise and guide the Taskforce. The leadership team was made-up of partners, industry representatives and CSO representatives
- The MFTF referred to the PLT for governance and decision-making when needed and to the CCM for strategic guidance
- The Taskforce was advised by the Vaccine Manufacturing Working Group (VMWG). The VMWG was established to eliminate or mitigate political issues associated with vaccine trade and manufacturing. The VMWG culminated in October 2021 with a [report to the G20](#). The membership of the VMWG consisted of senior representatives from participating countries including USA, Japan, Brazil, and South Africa.

## 3.1.4 VACCINE POLICY

### Overview

The WHO Strategic Advisory Group of Experts on Immunization (SAGE) advises on overall global policies and strategies on vaccines and immunization, including on COVID-19 immunization. COVAX adopts WHO SAGE policy recommendations and structures its immunization programme around SAGE guidelines.

### Key bodies

#### Strategic Advisory Group of Experts on Immunisation (SAGE)

*Mandate:*

- Continuous monitoring of *candidate* COVID-19 vaccine progress against SAGE recommendation requirements
- Systematic assessment of *candidate* COVID-19 vaccine safety, efficacy, and effectiveness
- Development of timely COVID-19 immunization policy recommendations, which includes interim policy recommendations on the use of *emergency-licensed* COVID-19 vaccines
- Development of statements, guidelines, and roadmaps on cross-cutting immunization issues, such as, but not limited to, the public health goals of COVID-19 immunization; hybrid immunity; seroprevalence; vaccination schedules and boosters; prioritization of high-risk groups; paediatric immunization; and variant-containing vaccines
- Review of strategy approaches and development of strategic documents to advance optimum impact from the vaccines, such as developing the Ethics Framework and the Prioritization Roadmap

*Key activities:*

The SAGE Secretariat established a dedicated COVID-19 Working Group in summer 2020, with members selected via public call for nominations. The SAGE COVID-19 Working Group (WG) works on the public health objectives of COVID-19 immunization programmes, evidence gathering, and modelling. An illustrative SAGE workflow includes the following steps and follows WHO procedures for development of norms and standards:

- SAGE Working Groups carry out detailed technical evidence reviews and develop draft recommendations for consideration and finalization by SAGE. Recommendations from SAGE are offered for consideration by the WHO Director General to establish WHO policies and positions. WG reviews the evidence based on existing literature and direct consultations with investigators or companies
- Based on evidence reviewed, the WG prepares draft recommendation on pertinent policy questions
- SAGE deliberates on the summary of evidence provided by the WG and concludes with recommendations based on consensus view. SAGE is ordinarily convened twice a year but for COVID-19 (or other health emergencies) additional meetings are exceptionally convened to address pressing policy issues. Final SAGE recommendations are presented to the WHO Director-General (DG) for approval
- SAGE recommendations approved by WHO DG become official WHO policy
- COVAX partners follow official WHO SAGE policy recommendations and develop joint stances on key immunization questions

#### *Composition and Membership:*

- SAGE members are recruited and selected from among global experts in the fields of epidemiology, public health, vaccinology, paediatrics, internal medicine, infectious diseases, immunology, drug regulation, programme management, immunization delivery, health-care administration, health economics, and vaccine safety using WHO policies and processes for convening external expert groups
- The Working Group included Regional Immunisation Technical Advisory Group (RITAG) chairs as observers, along with the chairs of other relevant WHO advisory bodies (e.g. vaccine safety) to facilitate the alignment, rapid development and roll-out of COVID-19 vaccine related policies

## Principles

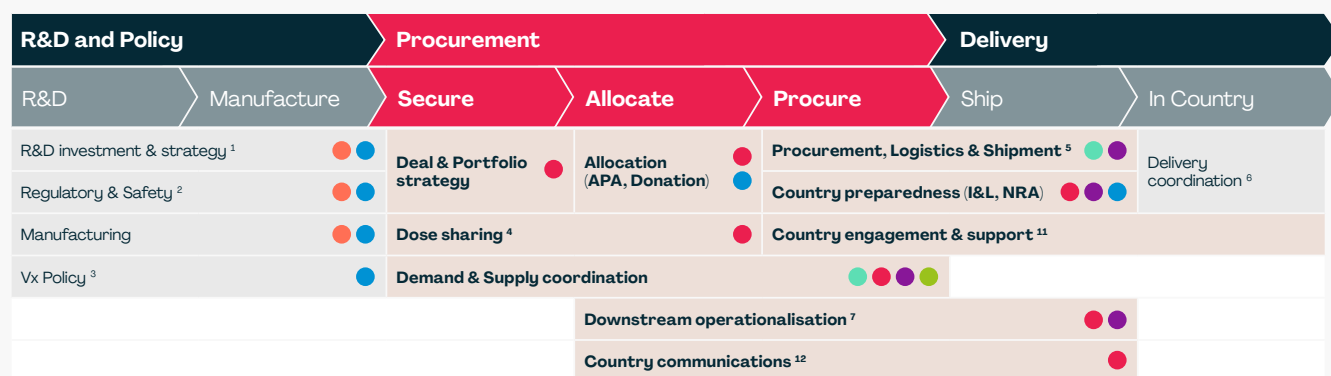
- *Accountability and transparency:* All the evidence accompanying a policy recommendation, along with the process to grade the quality of evidence and any supporting analyses conducted to reach policy decisions, are published online on the [WHO SAGE website](#)
- *Consultation:* SAGE meetings are open to observers from technical, policy and other relevant stakeholders. Key representatives include the six Chairs of the Regional Immunization Technical Advisory Groups, representatives of National Immunization Technical Advisory Groups, UNICEF, Gavi, CSO constituency, vaccine manufacturers, and many other stakeholders
- *Public health impact:* SAGE follows a framework that systematically evaluates and incorporates the public health impact of any new vaccine product or vaccination strategy to its recommendations. For more information, please refer to the [framework](#)

## Interlinkages with other COVAX areas of work

- WHO Safety and the Committee on Post-Implementation Vaccine Effectiveness Monitoring
- [WHO Pre-qualification](#) (SAGE workplans are synchronized with the WHO Emergency Use Listing process)
- The SAGE Secretariat is consulted on [WHO COVID-19 vaccine composition recommendations](#) (3.2.1.1)

*SAGE provides updates to interim policy recommendations as more safety and effectiveness data becomes available from sub-populations (pregnant women, adolescent and paediatrics, etc.). While SAGE follows the same procedures and protocols for gathering and evaluating evidence for all vaccine-preventable diseases, the evidence streams, and the frequency of updates may differ for COVID-19 vaccine products given “real-time” evolution of literature. For more information, please visit the [SAGE webpage](#) and the [Working Group webpage](#)*

## 3.2 PROCUREMENT AND SHIPMENT OPERATIONS



- Including activities around vaccine development and optimization, and variants
- WHO Pre-qualification
- WHO SAGE and Post-implementation safety monitoring group
- Includes donor engagement, supply confirmation with manufacturers, country acceptance and signature of tripartite agreements with donors, recipients and manufacturers
- Handled jointly by UNICEF Supply Division and PAHO Procurement Coordination Team
- In close collaboration with governments and local stakeholders, in-country delivery support is provided to all AMC 92 countries through Gavi Senior Country Managers, and the WHO and UNICEF country offices. CoVDP is providing targeted support to 34 out of the 92 countries with vaccination coverage rates at or below 10% in January 2022.
- Includes Product Managers from UNICEF and Gavi, and SCO Product Focal Points, who support the end-to-end coordination of a product's life cycle from APA signature to shipment
- Strategic Coordination Office (SCO), coordinates COVAX's governance, cross-pillar Project Management and Pillar Leadership engagement activities
- In addition to the enabling activities, there are COVAX Programmes, such as the COVAX Humanitarian Buffer Programme and the COVAX Facility Cost Sharing Programme
- The coloured dots on the diagram indicate partner organizations that lead each workstream. In addition to leading partner organizations, there are cross-partner engagement structures in place that draw input and insight from other COVAX partners to conduct above COVAX workstream activities in a collaborative spirit
- Gavi, UNICEF and WHO. CoVDP is providing targeted support to the 34 AMC countries with the lowest vaccination coverage rates (at or below 10% in Jan 2022). The remaining AMC countries are supported by Gavi, UNICEF and WHO.
- The Country Communications Team is the information and coordination hub for COVAX country communications and acts as a liaison point for COVAX country-facing staff across Gavi, UNICEF, and WHO.

### 3.2.1 COVAX FACILITY

#### Overview

The COVAX Facility (The Facility) global procurement mechanism is coordinated and legally administered by Gavi. In this role, Gavi established the Office of the COVAX Facility within the Gavi Secretariat in the second half of 2020, with a dedicated team supporting Facility operations.

The Facility makes investments across a broad portfolio of promising vaccine candidates (including those being supported by CEPI) and signs APAs for selected candidate vaccines. The Facility then accesses the COVID-19 vaccine doses following regulatory approval, subject to demand. Guided by a fair [allocation framework](#) (3.2.3) developed with WHO in consultation with Member States, Gavi and other stakeholders, the joint Facility-WHO allocation working group equitably distributes these doses to help protect the most at-risk groups in all participating countries.

#### Key activities

The Office of the COVAX Facility is responsible for design, coordination, market-shaping activities, COVID-19 vaccine portfolio management, and overall country engagement strategy and policies. It is comprised of the following three teams:

##### 1. Design and Operationalisation (D&O)

The D&O team designs and operationalizes processes and develops policies that enable the deployment of COVID-19 vaccines, monitors and advises on COVID-19 vaccine policy developments, and provides coordination and project management for the COVAX Facility. The D&O team also houses the [Humanitarian Buffer](#) (5.3) team.

##### 2. Deal and Portfolio Strategy Team

[The Deal and Portfolio Strategy](#) (3.2.1.1) team builds and manages the COVAX vaccine portfolio, ensures that the COVAX portfolio's supply meets country needs and optimally uses

available funds to procure vaccine supply. APAs are agreements with vaccine manufacturers negotiated by Gavi on behalf of participants (countries) to secure access to a certain quantity of vaccine doses at the best possible terms, including pricing.

### 3. Country Engagement

The Country Engagement team manages the COVAX Facility's engagement and communications with countries (in collaboration with partners' country and regional offices) and provides coordination across COVAX teams to enable countries to reach their vaccination goals. The Country Engagement team also supports country data management and tracking.

## Governance and oversight

### COVAX Facility AMC Engagement Group

This Group was established by the Gavi Board to convene representatives from implementing countries, donors and other parties engaged in the financing and operation of the AMC portion of the Facility, with the aim of providing strategic guidance and advice to the Facility on operational aspects.

The Group is open to all implementing countries, donors and other partners engaged in financing and operations of the AMC portion of the Facility. A representative from WHO, PAHO, UNICEF, the World Bank, and CSOs each have permanent observer seats.

### COVAX Shareholder Council

The Council was established by the Gavi Board to convene Self-Financing Participants (SFPs) and solicit their strategic guidance. Similar to the AMC Engagement Group, the Council also receives regular updates from the Facility, including reports on allocation decisions and overall activities, and decisions or recommendations made by technical bodies (MSDC, Independent Product Group, Procurement Reference Group and Independent Allocation Validation Group) and the Board.

The Council is open to all SFPs. A representative from WHO, PAHO, UNICEF, the World Bank, CSOs and the AMC92 Group each have permanent observer seats.

### Gavi Board

The Board of Gavi, the Vaccine Alliance (The Board) is responsible for overseeing the role of the Gavi Secretariat and the Alliance in the COVAX Facility. It therefore has ultimate responsibility for decisions and the effective implementation of the COVAX

Facility. To support this role, the Audit and Finance Committee (AFC), a Board subcommittee, oversees the Facility's financial management, risk and control framework, (including internal and external audit), and adherence to appropriate standards of good practices and ethics. The AFC undertakes this function due to Gavi's role as the legal administrator of the COVAX Facility.

### Market-Sensitive Decisions Committee (MSDC)

A Board subcommittee, the MSDC provides oversight and makes decisions that are market and/or commercially sensitive. The MSDC is responsible for reviewing business terms of proposed COVAX agreements with manufacturers to ensure: (i) reasonableness of terms and acceptable level of reputational risks; and (ii) availability of resources to back proposed agreements.

## Principles

The COVAX Facility aspires to be a flexible global instrument, urgently meeting the immediate needs of countries and providing resilience as the pandemic evolves. The vision is composed of:

- Urgently building the foundations of COVID-19 protection, with a focus on lower income countries and the most in need. Recognising the continued global toll of the pandemic, persistent inequitable access, and the emergence of other procurement mechanisms, COVAX continues to provide critical supply of COVID-19 vaccine to support countries' coverage ambitions on an urgent timeline and is sharpening its focus on those who most need supply and where that supply will have the most impact (i.e., high-risk populations)
- Deploying a flexible, reliable portfolio of COVID-19 vaccine to manage uncertainty and anticipate risk. As seen in 2021, a diverse, actively managed portfolio is important in the context of the rapidly evolving pandemic and global environment. Looking ahead, this flexibility remains critical in light of continued uncertainties (e.g., need for boosters, emergence of new variants)

## Interlinkages

Given the nature of the COVAX Facility's central role in maximising access to COVID-19 vaccines by contracting for and distributing vaccines through UNICEF and PAHO among other things; the Facility hosts and/or interacts with all COVAX functions across the value chain.

### 3.2.1.1 DEAL & PORTFOLIO STRATEGY

#### Overview

The objective of Facility's Deal Team is to build a resilient COVAX portfolio of COVID-19 vaccines that can fulfil both current and future anticipated country needs. As of writing, COVAX has the world's largest vaccine portfolio with access to 11 vaccine candidates across several vaccine platforms.

The team monitors country demand, epidemiological trends, [WHO SAGE guidance](#) (3.1.4) and the development of new products and adjusts its portfolio strategy and manufacturer negotiations accordingly.

Strategic inputs from COVAX partners on the portfolio are sought through the PLT, WSC, the Allocation workstream and the "One Deal Team", composed of CEPI, Gavi and UNICEF.

COVAX also receives large volumes of [vaccine donations](#) (3.2.4) which complement the portfolio of APA doses.

#### Key activities

- Negotiating and signing APAs with manufacturers to secure access to COVID-19 vaccines
- Leveraging country-level demand forecasting to understand evolving volume needs and product preferences, particularly in light of evolving epidemiology (waves of transmission, emergence of new variants, etc.)
- Monitoring [WHO policies and guidance](#) (3.1.4) to understand potential implications for country demand and likely vaccine requests to COVAX
- Monitoring the research and development landscape to understand the pipeline of potential COVID-19 products and innovations that may be requested by countries
- Monitoring the supply landscape and adjusting COVAX portfolio strategy in response (e.g., regulatory risks, manufacturing risks, export controls)
- Negotiating with manufacturers and donors to align incoming supply of vaccines with [country demand](#) (3.2.2) (volume, timing, product type)

#### Governance and oversight

- Gavi's [MSDC](#) (3.1.1) is responsible for approving deal terms

- Partner input on portfolio matters is captured through regular "One Deal Team" meetings between CEPI, Gavi and UNICEF

#### Principles

The COVAX portfolio was built in line with several principles and based on a set of assumptions to ensure country demands could be met, while ensuring suitable mitigation against potential risks (regulatory, manufacturing, export, demand):

- Benefits of the vaccine candidates: clinical differentiation; breadth of indication; ease of implementation
- Suitability to the COVAX portfolio: price/affordability; time to market; geographic distribution; supplier readiness to scale; country preference

*For more information on the principles, please refer to the [Portfolio Principles for New Candidates](#).*

#### Interlinkages with other areas of work

- CEPI – supports monitoring of R&D landscape and assessment of development risks
- IPG – provides guidance on suitability of vaccines from a technical perspective
- PRG – provides guidance on commercial terms of deals, particularly with a view of the overall portfolio
- WHO – provides policy recommendations that guide country programme design
- UNICEF / Gavi – provide forecasts of, and insights into, country demand

### 3.2.1.2 SELF-FINANCING PARTICIPANTS (SFP) TO THE COVAX FACILITY

#### Overview

SFPs are participants procuring COVID-19 vaccines from the COVAX Facility based on domestic funding. While the Facility provides vaccines to 92 low- and middle-income countries (AMC92) based on funding made available by the AMC donors, SFPs not eligible for donor-funded supply can purchase vaccines from the COVAX Facility (these are Self-Financing Participants, or SFPs).

The Facility has historically provided all participants access to the same vaccine candidates, on the same accelerated timeline in an effort to end the COVID-19 pandemic as quickly as possible. Upon joining the Facility, an SFP is requested to indicate the number of vaccine doses it would like to procure through the Facility. Going forward, SFPs are expected to have minimal need to continue procuring through COVAX (given the improved global supply situation). There is currently no down payment for doses, and SFPs are offered a decision window to choose to opt-into specific deals.

SFPs do not need to procure doses in order to participate in the Facility in 2022; COVAX Facility provides regular updates, dialogue, idea generation, and best practices at subject-specific

workshops to all its participating economies regardless of their purchase history.

### SFP 1.0 and SFP 2.0

SFP 1.0 was the first iteration of SFPs joining the Facility to procure under COVAX. In June 2021, the Gavi Board tasked the Facility with designing a new model for SFP engagement in 2022 based on the principles of simplifying the operations of the Facility, mitigating the financial risk to Gavi, and inclusivity. SFP 2.0 was launched in November 2021. SFP 2.0 allows SFPs to join as procuring or non-procuring participants. If SFPs wish to join as non-procuring, they can remain as part of the Facility with access to the Shareholder’s Council and receive donations. The key differences between SFP 1.0 vs 2.0 are summarized in the table below.

SFP 1.0	SFP 2.0
Two purchase models - Committed and Optional Purchasers	Single purchase model for procuring participants
Down Payment required	No down payment required, only the fulfillment of the operational fee for procuring participants
Minimum and maximum percentage of coverage that can be requested by participants	No minimum or maximum number of doses required
Opt-out model for deals for optional purchasers	Switch to opt-in model
2 decision windows in the Optional Purchase model	1 decision window
Full payment at Window 2 for optional purchasers	Full payment at opt-in (after signing the Confirmation Agreement)
SFPs are procuring	Can join as procuring vs non procuring

### Key activities

- Supply Offering: COVAX facilitates a supply offering. SFPs communicate how many doses they would like to purchase of each vaccine on offer
- Purchase of Doses: SFPs sign a legally and financially binding Confirmation Agreement(s), detailing the exact number of doses and price per dose
- Financial Commitment: SFPs must submit the full financial commitment for confirmed doses (e.g., Letter of Credit or Cash)
- Exercise Doses: COVAX enters into agreement(s) with manufacturers for the committed doses (options or APAs)
- Shipment: SFPs can procure through UNICEF/ PAHO or can procure independently. Upon the release of the purchase order, payment is fulfilled. Doses are shipped as they become available
- Joining SFP 2.0: For procuring: Sign a framework agreement indicating the number of doses participant wishes to procure from COVAX; pay operational fee. For non-procuring: SFPs automatically join after fully closing out of 1.0

## Governance and oversight

- Gavi Executive Office – Countersigning framework agreements; Managing Director of the COVAX Facility – countersigning Confirmation Agreements; Director of Country Engagement – signing supply notice and final supply offer
- Gavi Board & Audit and Finance Committee: Changes to operational design (i.e., changes from 1.0 to 2.0)
- Shareholder’s Council: Mechanism for SFPs to participate in the Facility to hear updates and be involved in discussion

## Principles

1. Purchase of vaccines is voluntary.
2. SFPs cannot receive access to pricing information until they sign a framework agreement.
3. Once an SFP signs a confirmation agreement, the commitment is binding.
4. SFPs can transition from non-procuring to procuring at any time.

*These are the principles guiding the SFP 2.0 design. The Principles that guided the SFP 1.0 operations are available on request.*

## Interlinkages with other areas of work

1. Country Engagement
2. Legal
3. Finance
4. [Deal and Portfolio Strategy](#) (3.2.1.1)

## 3.2.2 DEMAND PLANNING

### Overview

The COVAX Demand Planning Team is composed of representatives of Gavi, UNICEF, WHO/PAHO and is chaired by a nominated lead from UNICEF and Gavi. The team meets to coordinate cross-partner demand planning activities to triangulate data on Covid-19 vaccine needs and to understand the demand for doses provided through COVAX. These

estimates are important inputs for the COVAX Deal and Portfolio strategy/market shaping and allocation decisions.

The demand planning leverages two approaches – a global top-down model based on country realities and projections as well as a bottom-up demand planning exercise undertaken with all AMC91 countries (AMC92 countries except India).

Since Q2 2022, COVAX has delinked the demand forecasting process from the allocation process and as of Q3 2022, [Rolling Allocations](#) (3.2.3) have been implemented, processing ad-hoc requests for vaccines from Participants on an instant basis.

### Key activities

Demand Planning occurs on an as-needs basis, as follows:

- Gather demand from countries via standard demand planning template (three times in 2022)
- Move to integrate the demand planning process into routine planning processes managed by PAHO and UNICEF
- Consolidation and analysis of responses
- Management and regular review of the global demand model
- Provision of a consolidated and triangulated demand planning scenarios into the procurement process

The scope of urgent demand activity is similar but sees a faster turnaround, with demand matched to available supply and approved via the [Allocation Leadership](#). (3.2.3)

### Principles

- Representation or consultation of all relevant COVAX partners
- Gathering information from countries directly when appropriate
- Leveraging capacities and experience in demand forecasting of PAHO and UNICEF country teams in country as interlocutors
- Integration into routine demand planning processes

## Interlinkages with other areas of work

- Until Allocation Round 16 (May/June 2022), demand planning exercises provided a direct input into the [COVAX allocation process](#) (3.2.3)
- Close consultation with supply planning teams liaising with manufacturers and donors on required vaccine volumes (informed by country demand)

### 3.2.3 ALLOCATIONS

#### Overview

The COVAX Joint Allocation Taskforce (JAT) is composed of representatives of the two partners involved in allocation of vaccines: Gavi and WHO. It also consults closely with UNICEF and PAHO in the process. The team meets regularly to oversee the allocation of vaccine doses to countries, specifically the preparation, processing and communication of COVAX Allocation rounds.

#### Key activities

The majority of COVAX-allocated doses have been processed via allocation ‘rounds’; this took place in the context of constrained supply, insufficient to meet demand. Under exceptional circumstances, if countries urgently required doses earlier than the standard allocation process allowed, doses were allocated under an urgent allocation process. As of Q3 2022, following a shift from supply constraint, Rolling Allocations that are demand driven have now been implemented, processing requests for vaccines from participants as they are received.

#### Objectives

- Support all countries’ ambitions to control the disease. Contribute to countries’ vaccination coverage goals, in view of the [WHO Global Vaccine Strategy](#), and in consideration of supply beyond COVAX
- Allocate vaccine doses in a way that minimizes inequalities of access to vaccines

#### Principles

- Allocation processes were designed in accordance with the overarching principles of equitable access and fair allocation of COVID-19 health products. See section in the [Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility](#) document for details

## Interlinkages with other areas of work

- The allocation process requires input from both the supply and demand planning teams
- The output of the allocation process feeds all downstream activity, including country preparedness, regulatory approvals, purchase orders and shipments

### 3.2.4 DOSE DONATIONS

#### Overview

To mobilise urgent additional supply, the COVAX Facility established a [dose sharing mechanism in 2021](#). Dose sharing encompasses several different modalities, including dose donations from bilateral agreements between donors and manufacturers, donations by SFP countries of doses available pursuant to their [SFP Commitment Agreement](#) (3.2.1.2), and in some cases the donation of doses already under title and possession of a donor country. By September 2022, over half a billion donated doses had been shipped to over 100 countries.

Several teams within Gavi carry out roles to ensure the operationalization of the dose donation portfolio. These include [Resource Mobilization](#) (4.2), Country Engagement, Product managers, Country programmes, [COVAX Design & Operationalization](#) (3.2.1), Finance and Legal. In addition, Gavi teams work closely with partner teams across COVAX in the allocation and shipment of donated doses.

#### Key activities

1. Gavi engages with the donor to discuss offer details and legal aspects
2. In collaboration with the donor, Gavi engages with manufacturers to discuss logistics and payment
3. The donor, Gavi, and the manufacturer sign a tripartite agreement creating a framework for how doses will be transferred to COVAX from the donor and the terms which will apply to a donation
4. Gavi provides a Gavi Shared Doses Acceptance Notice to the donor confirming the acceptance of the offer



5. [COVAX allocation team](#) (3.2.3) runs the allocation to decide which country the doses will be allocated to. The urgent and rolling allocation processes allow countries to request doses which fall outside the timing of an allocation round, within parameters of volume and supply availability
6. Downstream dose sharing team works with in-country colleagues to obtain necessary approvals & waivers from participants
7. UNICEF Supply Division/PAHO or SFPs issue a [Purchase Order](#) (3.2.5) to the manufacturer under the supply agreements of the Gavi Advance Purchase Agreement or provides instruction to donors in case of TAP (Tripartite Agreement) doses
8. UNICEF Supply Division/PAHO & in-country teams mobilize [logistics](#) (3.2.5) to facilitate shipment

*Steps 5-8 are standard procedures to all doses and are not unique to dose sharing.*

## Oversight

The Broader COVAX partner governance and coordination mechanisms including the [Gavi Board](#) (3.2.1) and [COVAX PLT](#) (2.2) provide oversight to the Dose Donations workstream.

## Principles

Decisions on whether to accept donations are guided by numerous principles that are aligned with the overall objectives of COVAX to ensure safe and equitable access to vaccines by all countries

- Ensuring safe, effective, rapidly deployable and flexible vaccine supply
- Supply visibility
- Cost effectiveness of operations

*Please see: [Published dose sharing principles](#) (The original principles were published in December 2020 and updated in February 2022)*

## Interlinkages with areas of work

- WHO [Regulatory Team](#) (3.1.2)
- [Joint Allocation Team](#) (3.2.3)
- UNICEF SD/PAHO for [shipment logistics](#) (3.2.5)

- UNICEF/WHO Country-facing staff
- Gavi [Country Communications](#) (3.2.7)
- [Shareholder's Council](#) (3.2.1)
- [AMC Engagement Group](#) (3.2.1)

## 3.2.5 PROCUREMENT, SHIPMENT AND LOGISTICS

### Overview

UNICEF, in collaboration with the [PAHO Revolving Fund](#), leads efforts to procure and supply doses of COVID-19 vaccines, cold chain equipment and corresponding devices on behalf of COVAX for 92 low- and lower middle-income countries, implementing COVAX commitments with suppliers under Advance Purchase Agreements. This includes coordinating international freight and logistics for these supplies as well. The purchase of these supplies is supported financially by the mechanism through the [Gavi COVAX AMC](#) (3.2.1). When necessary, buffer doses for humanitarian emergencies (see *the section on [Humanitarian Buffer](#)* (5.3)) are deployed as a last resort to secure access. UNICEF also serves as procurement coordinator to support procurement by 80 higher-income economies, who finance the vaccines in the COVAX Portfolio from their own public finance budgets (see *the section on [SFP](#)* (3.2.1.2)).

UNICEF also designed, established and maintains the COVAX Procurement Portal (CPP), which is the online portal maintaining operational information relating to shipments. This enables all parties to keep up-to-date and work collaboratively. This portal is accessible to authorized users across the COVAX partnership.

Lastly, UNICEF conducts regular assessments on the health and evolution of the vaccines and devices markets and maintains the publicly available [COVID-19 Vaccine Market Dashboard](#).

### Key activities

UNICEF, in collaboration with PAHO, leads the following key activities for the procurement, logistical planning and shipment of COVID-19 Vaccines in the [COVAX Portfolio](#) (3.2.1.1):

#### Procurement coordination

- Liaise with vaccine manufacturers on supply availability

- Inform the [JAT](#) (3.2.3) on supply availability before each vaccine allocation round, and with the implementation of the Rolling Allocation, provide ongoing supply updates
- Communicate confirmed allocation volumes and shipment sequencing to vaccine manufacturers
- Coordinate with the Devices Departments of the UNICEF Supply Division for the timely shipment of syringes, safety boxes and cold chain equipment for each vaccine allocation
- Manage allocation rejections and requests for shipment delays in coordination with countries and manufacturers
- Co-lead the generation of country forecasts to inform suppliers, enable planning, and guide relevant decision making
- Manage all operational information concerning vaccines, injection devices and cold chain equipment across the COVAX Portfolio, and make it available in the COVAX Procurement Portal for utilization across partners

### Procurement agency operations

Issue tenders guiding later stage APAs signed between Gavi and manufacturers. Operationalize Gavi APAs into Long-term Agreements (LTA) (*Please note that the deliveries of vaccine candidates with UNICEF LTAs are contingent upon [WHO Emergency Use License authorizations](#)*).

- Ensure that recipient countries have import authorization licenses, which are required for the entry of vaccine shipments to the country
- Work with governments to ensure that countries are ready to receive vaccine shipments, with appropriate cold chain equipment in place and health workers trained to dispense them (these activities are also referred to as *country readiness and preparedness*)
- Coordinate the completion of documents that are required to place Vaccine Purchase Orders, such as the Indemnification & Liability and National Emergency Use Authorization documents, which are processes led by Gavi and WHO, respectively
- Issue Vaccine Purchase Orders
- Plan shipment schedules with manufacturers and donors (in case of TAP doses)
- Coordinate the shipment of vaccine products from the supplier to the port of entry
- After the shipment of Vaccine Purchase Orders to countries, follow up on vaccine and cold chain capacity utilization

UNICEF also established dedicated COVAX Logistics and COVAX Devices teams to streamline and accelerate the shipment activities UNICEF Supply Division conducts for COVID-19 vaccines (considering the fact that business-as-usual timelines for other Routine Immunization Programmes are longer).

### Governance and oversight

Procurement, logistics and shipment activities, which UNICEF leads on behalf of COVAX, follow the established public procurement principles, governance structures, contracting rules and regulations, and standard operating procedures of UNICEF Supply Division (e.g., tendering, Contracts Review Committee approval of contract awards, long-term supply arrangements, and issuance of purchase orders). However, these have been adapted to the dynamics of the COVID-19 emergency situation and the pre-selection of vaccine candidates by the COVAX Facility for inclusion in the COVAX Portfolio (*see the section on [Vaccine Portfolio Investments](#) (3.2.1.1)*).

### Principles

- UNICEF follows the common guidelines for procurement by organizations in the UN System. The UNICEF Procurement Policy ensures fairness, integrity and transparency through competition and securing the best value for money
- Guiding principles of the PAHO Revolving Fund, which are quality, transparency, solidarity and equity

### Interlinkages with other areas of work

- The [JAT](#) (3.2.3) decides on the volume and sequence of shipments to recipient countries when vaccine supply is limited
- Gavi and UNICEF jointly provide funding and technical assistance to countries for the procurement, installation and effective utilization of ultra-cold chain capacity
- UNICEF procurement coordinators work closely with the Gavi [Resource Mobilization teams](#) (4.2) for the effective shipment, planning, and delivery of dose donations

- UNICEF co-leads with Gavi the [Demand Forecasting team](#) (3.2.2) and works closely with the Delivery team in this regard
- UNICEF collects, stores and provides access to critical data for the execution of the [No-Fault Compensation Program](#) (5.2), which is jointly run by Gavi and WHO. It tracks other data to ensure real-time monitoring of progress towards key COVAX deliverables

### 3.2.6 DOWNSTREAM PROCESSES (RESPONSE, PREPAREDNESS, PURCHASING AND SHIPMENT COORDINATION)

#### Overview

COVAX ensures that vaccine doses are shipped to participants only when all critical preparedness and readiness requirements are met, including regulatory, contractual, and other critical programmatic components. The portfolio has included to date 11 products, all with WHO EUL as was specified in the design of the COVAX Facility. COVAX has shipped these to 146 participants (91 AMC and 59 SFP).

The COVAX Operations end to end process includes downstream steps that start once allocation letters are sent to in-country teams and end upon shipment. The participant response step is managed by Gavi Senior Country Managers (SCMs). SCMs ensure that allocated doses are formally accepted, partially accepted, or rejected. Gavi, UNICEF, and WHO oversee the preparedness step of this process, ensuring the regulatory, import, and liability requirements are tracked and logged. Specifically, Product Focal Points, the Downstream Team, and PAHO are responsible for this step. The same team also manages the readiness step, making sure that participants have the supporting equipment (e.g. cold chain facilities and syringes) in place.

Triggers for issuance of purchase orders are monitored by UNICEF and PAHO and implemented by UNICEF Supply Division and PAHO. This team ensures that all purchase orders have been placed for the correct quantity of doses after preparedness and readiness requirements have been met.

The shipment step is managed by UNICEF, PAHO, and Pfizer\*, where the team makes sure that

doses are shipped and delivered to participants, and with UNICEF capturing data across all deliveries including Self-Financing Participants to provide real-time ability to monitor progress towards COVAX key indicators. *\*Pfizer uses its own freight forwarders to ship doses to participants. They inform COVAX of the status of shipment.*

#### Key activities

- Tracking or entering participant's formal response to allocated doses
- Tracking status of regulatory, import, and insurance requirements
- Tracking status of country readiness (e.g., availability of syringes, availability of cold chain capacity)
- Issuing purchase orders
- Tracking and shipping doses to participants
- Support countries to complete readiness and preparedness steps
- De-bottleneck issues

#### Governance and oversight

Each workstream/team has nominated leads from responsible COVAX partners who oversee activities. Key metrics are reported to leadership teams within each partner on a regular basis.

#### Principles

- Putting Countries First – providing support to make sure that participants are able receive the doses they need
- By shipping allocated doses, the downstream processes follow the upstream allocation process principles

#### Interlinkages with other areas of work

- Downstream processes depend on [COVAX allocation](#) (3.2.3) decisions made by 'upstream' operational teams
- Data tracked and entered during Downstream Processes, including [regulatory status](#) (3.1.2), [shipment arrival](#) (3.2.5), etc., feed into [COVAX Data & Analytics](#) (4.3)

## 3.2.7 COUNTRY COMMUNICATIONS

### Overview

The Gavi Country Communications Team (CCT) coordinates country engagement and support activities across the COVAX Partnership, working closely with colleagues in WHO and UNICEF Country Offices and Programme in close coordination with the Office of the [COVAX Facility](#). (3.2.1) The CCT collaborates with COVAX technical teams across Gavi, UNICEF, and PAHO to ensure that communication products are strategic, centralized, consistent, and stakeholder-driven.

The CCT coordinates COVAX activity to meet country information needs, such as keeping participating economies informed and engaged on [supply and demand](#) (3.2.2), [shipments](#) (3.2.5), and other important information, including updates to COVAX vaccine policy or funding support.

### Key activities

The primary stakeholders of the country communications workstream are teams within Ministries of Health that are involved in the planning and service delivery of COVID-19 vaccines. The Gavi CCT coordinates country engagement and supports activities across the COVAX Partnership through the following activities and coordination meetings.

#### External engagement and support

- Monthly COVAX Participant and Country-Facing Staff Briefings (multiple language interpretations available)
- Ad hoc briefings (e.g., COVID Delivery and Systems Strengthening (CDS), demand forecasting information sessions)
- Coordination of communications to countries on technical matters
- Preparing and publishing Country Delivery Stories (collecting and highlighting COVAX achievements and challenges, in alignment with the AMC engagement group)
- Providing inputs into the COVID-19 Delivery Partnership Situation Report
- Consulting with countries on building and maintaining effective strategies for participant engagement, primarily via the WHO Regional Office and UNICEF Country Office staff

#### Internal engagement and support

- Coordination and collaboration on country communication among CoVDP and COVAX teams
- Preparing and maintaining country-facing communications, workplans and SOPs
- Development of country-facing talking points
- Coordinating with [External Communications](#) (4.5) teams across partners

### Governance and oversight

- The Country Communications Liaison Group convenes fortnightly meetings with representation across the COVAX pillar partners. The group ensures coordination across partners and oversight of communications to countries
- The Gavi CCT also participates in [SWAT](#) (2.4)

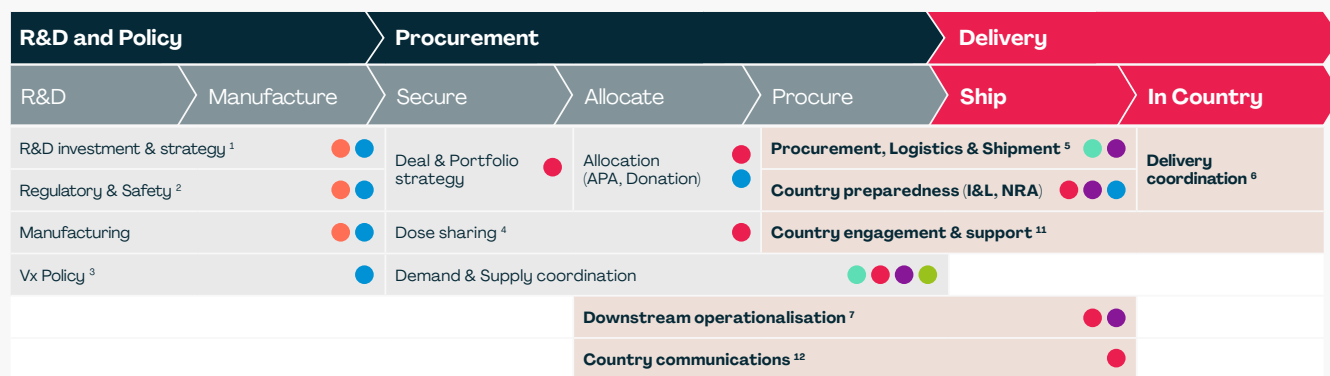
### Principles

- Serving as an information and coordination hub for country communications and as a liaison point for COVAX country-facing staff
- Ensuring country information needs drive communication planning, and the utilisation of appropriate channels at the appropriate time
- Promoting a culture of transparency amidst uncertainties, providing information and reassurance where possible
- Prioritizing clear messaging over quantity of information, and promoting consistent messaging across partners
- Proactively identifying and mapping country information needs
- Aligning communication approaches across COVAX country-facing partners (WHO, PAHO, UNICEF) and [CoVDP](#) (3.3)
- Facilitating a steady flow of COVID-19 delivery success stories/challenges to support external communications and knowledge sharing amongst participants as well as strategic partner/donor engagement

### Interlinkages with other areas of work

- Allocation and other associated teams, such as the [Joint Allocation Task Force](#) (JAT) (3.2.3), [Demand Planning](#) (3.2.2), [Downstream Dose-Sharing Team](#) (DDST) (3.2.4), and Country Support, including funding streams (e.g. Gavi CDS).

### 3.3 COVID-19 VACCINE DELIVERY SUPPORT



- Including activities around vaccine development and optimization, and variants
- WHO Pre-qualification
- WHO SAGE and Post-implementation safety monitoring group
- Includes donor engagement, supply confirmation with manufacturers, country acceptance and signature of tripartite agreements with donors, recipients and manufacturers
- Handled jointly by UNICEF Supply Division and PAHO Procurement Coordination Team
- In close collaboration with governments and local stakeholders, in-country delivery support is provided to all AMC 92 countries through Gavi Senior Country Managers, and the WHO and UNICEF country offices. CoVDP is providing targeted support to 34 out of the 92 countries with vaccination coverage rates at or below 10% in January 2022.
- Includes Product Managers from UNICEF and Gavi, and SCO Product Focal Points, who support the end-to-end coordination of a product's life cycle from APA signature to shipment
- Strategic Coordination Office (SCO), coordinates COVAX's governance, cross-pillar Project Management and Pillar Leadership engagement activities
- In addition to the enabling activities, there are COVAX Programmes, such as the COVAX Humanitarian Buffer Programme and the COVAX Facility Cost Sharing Programme
- The coloured dots on the diagram indicate partner organizations that lead each workstream. In addition to leading partner organizations, there are cross-partner engagement structures in place that draw input and insight from other COVAX partners to conduct above COVAX workstream activities in a collaborative spirit
- Gavi, UNICEF and WHO. CoVDP is providing targeted support to the 34 AMC countries with the lowest vaccination coverage rates (at or below 10% in Jan 2022). The remaining AMC countries are supported by Gavi, UNICEF and WHO.
- The Country Communications Team is the information and coordination hub for COVAX country communications and acts as a liaison point for COVAX country-facing staff across Gavi, UNICEF, and WHO.

#### Overview

Acknowledging that countries shoulder primary responsibility to plan, organize, administer and finance the delivery of COVID-19 vaccines, COVAX partners' role in COVID-19 vaccine delivery has focused on providing guidance, training, coordination, funding, planning and political advocacy support, as well as broader technical assistance (TA).

WHO, UNICEF and other Gavi Vaccine Alliance partners have dedicated staff on the ground, leveraging existing emergency coordination mechanisms, and streamlining decision-making and administrative processes to rapidly scale-up support to countries. Areas of support have included: microplanning, human resources, mass vaccination sites, in-country logistics and vaccine management.

Throughout the pandemic, vaccine delivery in the 92 "Advanced Market Commitment" (AMC92)

countries has been supported through the multi-agency Country, Readiness and Delivery (CRD) workstream. To provide more intensive operational support to the 34 countries with vaccination rates below 10%, at the beginning of 2022, Gavi, UNICEF and WHO launched the COVID-19 Vaccine Delivery Partnership (CoVDP). CoVDP is expected to continue through Q2 2023. At the time of writing, the future delivery support model is in development and will leverage both the ongoing CRD workstream as well as other existing country teams (e.g. Gavi SCMs, WHO and UNICEF regional and country offices).

CoVDP implements its work through four main levers: country engagement, delivery funding, demand planning, and technical assistance (including data support). CoVDP's objective is to support countries in rolling out primary series coverage with a focus on high-priority groups – older adults, health care workers, and persons with co-morbidities including immunocompromised persons.

## Areas of work

**Country engagement** supports countries to implement and monitor their COVID-19 vaccination programmes, through support for receiving COVAX funded doses, technical assistance and delivery funding. COVAX relies on national leadership and national covid vaccination working groups led by national governments and including the WHO and UNICEF Country offices as well as other key stakeholders.

Since the launch of COVAX, Gavi SCMs have played a critical operational role as the interface between COVAX supply teams and countries, working closely with WHO and UNICEF country and regional teams on the ground. Support has included helping countries understand and execute on all administrative readiness requirements (e.g., Indemnity & Liabilities agreements, regulatory clearance, import/export licenses), and providing or clarifying communications on supply and delivery support available.

Gavi SCMs, UNICEF and WHO Country Offices work closely with national COVID-19 vaccination leadership to develop their COVID-19 vaccination scale-up plans and articulate corresponding funding needs. They also work closely with countries to minimize disruption of routine immunisation and to prioritize restoring routine immunisation when there has been backsliding. In addition, monitoring progress on delivery, identifying bottlenecks early-on, and supporting countries to identify solutions were critical as COVID-19 vaccinations scaled up.

CoVDP follows a “One Team, One Plan and One Budget” approach (see *the Information Box at the end of the section*). This provides a high-level of coordination among the partners necessary to resolve critical bottlenecks in vaccine delivery at the global and country levels. The One Country Team, composed of all key partners involved in vaccine delivery in-country, acts as the main coordination mechanism under the leadership of government, through which operational, financial and political bottlenecks are surfaced, prioritized, actioned and resolved.

### Key activities

- The WHO and UNICEF Regional Offices organized coordination committees and working groups to support countries in developing and updating their National Deployment and Vaccination Plans (NDVPs), the initial version of which had to be approved for countries to receive shipments from COVAX

- The regional working groups identified implementation bottlenecks and ensured a coordinated approach between partners, shared lessons learnt and documented best practices
- The regional working groups also organized joint missions to provide surge support and technical assistance to countries and implemented a series of inter-action reviews (IARs) across most countries
- CoVDP conducts global-level intensification which works in concert with country and regional-level activities that are ongoing and will remain once the CoVDP surge effort concludes. Since January 2022, CoVDP has supported regional and country-level political engagement, including high-level country missions to garner political support around the One Team, One Plan and One Budget concept. Each mission has resulted in concerted actions that the One Team has been implementing, leveraging the comparative advantage of the various partners on the ground
- CoVDP is supporting countries to develop One Plans and One Budgets, that are key documents used to create greater coherence in the deployment of vaccines and transparency for funding priorities across the agencies, e.g. develop Gavi Country Delivery Support (CDS) applications and to align with funding from the ACDC SLL project and UNICEF HAC and WHO SPRP funding. WHO and UNICEF provided over USD 1B of delivery funding jointly in 2022
- CoVDP organizes weekly country support calls with a rotating focus on one or two countries, gathering key partners to provide an overview of countries’ experience in vaccine delivery, identify bottlenecks and discuss/prioritize solutions
- CoVDP has also launched a series of south-to-south knowledge sharing events where countries recount best practices and lay out the success factors that have enabled them to successfully deploy vaccines

**Political advocacy** is a key component of country, regional and global engagement that aims at mobilizing the highest level of decision-makers within government and key regional and global public health institutions to maintain COVID-19 vaccinations as a key health priority within countries and the global public health agenda.

*Key activities*

- CoVDP conducts high-level missions to countries with very low vaccination rates and to those that have progressed, where there is an opportunity to build on the momentum. These high-level political missions are designed to engage the highest level of government (Head of State and Minister of Health) to catalyze political support and buy-in for COVID-19 vaccinations and mobilize technical partners (UN agencies other than WHO and UNICEF, NGOs, CSOs and bilaterals).
- CoVDP leverages high-level political fora to ensure that COVID-19 vaccine delivery remains on top of the global public health agenda. CoVDP actively engaged Health Ministers and Ministries during the 2022 World Health Assembly, provided an update and call to action to members of the UN Security Council, updated partners at key international events such as the US Government's Global Action Plan (GAP) convenings, the Partnership for Maternal, Neonatal and Child Health (PMNCH), NGO and CSO convenings and through government and parliamentary briefings with key bilateral partners such as Germany and Japan.
- CoVDP also proactively engages with global and regional funding partners, the humanitarian cluster, the Health Systems and Response Connector (HSRC) and other strategic partners to ensure strategic and political alignment and coordinated action. There are other custom-built mechanisms used for enhancing partner coordination and information exchange, such as the Funders Forum, the Implementers' Forum, and the Immunization Partners call. These mechanisms were initiated in 2021 and have continued to be used as key mechanisms of engagement during this intensified era of operational support.

**Delivery funding** provided by COVAX partners is meant to complement countries' domestic funding to support key activities required to scale up COVID-19 vaccines. Specific attention is given to ensure a greater level of visibility on available funding sources from various partners.

In the 34 countries prioritised by CoVDP, with enhanced partner coordination, CoVDP aims to improve the matching of available funding sources with the short-term, urgent funding needs of countries, as well as the medium and longer-term financial needs that enable countries to deploy vaccines in a steady and reliable manner

beyond mass vaccination campaigns. The issue encountered was that donors requested countries to submit a variety of different budgets and funding requests using different costing categories. This made it difficult to align and compare budgets across donors and to identify funding gaps or duplication of funding. To overcome this, CoVDP worked with key donors to align on standardised budgeting categories that could be used by all donors. The next step was to encourage and support countries to use these budgeting categories to develop comprehensive and operational One Budgets that allowed donors to align their funding. In addition, it provided clarity at the country level on 'who funds what and when'.

*Key activities*

- Since late 2020, Gavi has mobilised a total of ~US\$ 1.6 billion for COVID-19 vaccine delivery to support the AMC92 countries of which ~US\$ 800 million has been programmed, disbursed or fully committed under Gavi's leadership based on country needs.
  - Before vaccine delivery started, the Gavi Board approved an envelope of US\$ 150 million for Technical Assistance ('COVAX TA') and Cold Chain Equipment (CCE) support to countries' preparedness, which has supported >400 UNICEF and WHO in-country short-term positions and has provided 5,900 vaccine fridges and freezers, 180 walk-in cold rooms and 150,000 passive transport devices.
  - Following Gavi Board approval in June 2021, substantial delivery support – US\$822 million – has been added which includes dedicated support for technical assistance in specific areas identified as particular risks such as vaccine confidence, management capacity, and stock management; and support for ultra-cold chain (UCC). It also included a COVID-19 Delivery Support (CDS) early access window of approximately US\$270 million which was launched on 5 July 2021. CDS was supplanted by a needs-based window of US\$ 330-400 million which was initiated in Oct 2021, as countries had time to plan more definitively.
  - Finally, a third CDS window of an additional US\$600 was made available to support countries in June 2022 following successful fundraising in April 2022. 32 countries have submitted their CDS3 applications by September 30th and 13 countries have submitted after this date.

- UNICEF developed a global COVID-19 vaccine delivery funding tracker that tracks funds across 28 different funding sources and donors across 133 countries and is the most comprehensive overview of funding available. UNICEF has to date provided US\$817.6 million in funding for delivery activities, of which the full amount has been committed and disbursed.
- UNICEF and partners have developed and published the global COVID Vaccine Delivery Costing tool that has been used to quantify delivery funding needs which have been included in the ACT-A and the AMC fundraising event.
- WHO has provided a total of US\$610,840,641 in funding for delivery activities of which US\$457,348,139 have been fully committed or disbursed (as of October 2022).
- CoVDP has provided technical assistance for the development of “One Budgets” which enables governments to create a comprehensive and realistic view of funding needs for C-19 vaccine delivery, aligned across all partners, against which they can identify gaps and target their financial support more accurately. To date, 10 countries have received technical assistance to develop “One Budgets.” 1 country has completed One Budget development, 7 countries have drafts currently being refined before finalization, and an additional 5 countries are in the process of developing drafts. One Budgets are live documents, so completed budgets need to be maintained and updated as campaigns are executed and funding sources change.
- The Funders Forum, initiated by the CRD workstream and co-convened by USAID since its inception has been a channel for CoVDP to regularly gather key donors to discuss implementation and funding related issues and helped to garner political support from donors

#### Key activities

- Until May, COVAX conducted monthly demand planning exercises, collecting relevant data from Ministries of Health to understand product preferences, needs and expected volumes of demand to better coordinate the phasing and shipment with available supplies from COVAX.

Finally, CoVDP’s **technical assistance** lever provides tailored support to address the operational bottlenecks faced by countries and

that hamper the effective implementation of vaccine delivery on the ground, including support on the implementation of guidelines, the capturing and sharing of good practices and lessons learnt, the mobilization of humanitarian partners and support for the tailoring of vaccine delivery strategies to humanitarian contexts, as well as data systems support.

#### Key activities

- Since early 2022, 34 countries have been supported through a dedicated Desk Officer<sup>2</sup> whose role is to ensure strong coordination at global and regional levels and with the Country Team, to reduce countries’ transactional costs and respond to their needs and help countries to efficiently distribute and use their vaccine doses, overcome delivery bottlenecks to achieve their One Plan and accelerate vaccination to achieve their vaccination targets, in close collaboration with Gavi Senior Country Managers (SCMs) and UNICEF and WHO in-country focal points and regional teams.
- WHO and UNICEF conduct technical missions to countries that are designed to provide timely and targeted support to resolve key operational bottlenecks and technical assistance for microplanning or intra-action reviews of the COVID-19 vaccine roll-out. As COVID-19 vaccination scales up, Gavi SCMs and Alliance partners also play an important role in monitoring progress on delivery, identifying operational bottlenecks early on and supporting countries to identify solutions.
- CoVDP coordinated the COVAX Demand Planning Working Group that implemented bottom-up, country- and data-driven demand planning for 92 low- and middle-income countries to effectively match demand with supply, reduce dose expiry risk, and ensure doses get to where they are needed the most.
- CoVDP collects, analyses and disseminates delivery data for 92 low- and middle-income countries to track progress towards agreed targets, identify and close funding gaps quickly, increase the transparency of funding flows, and provide viable estimates of delivery costs to government and funding partners.
- CoVDP also works closely with humanitarian partners, specifically the health cluster and partner NGOs and UN agencies, to map

2. The CoVDP desk officers were appointed in early 2022, seconded by the CoVDP core partners (Gavi, UNICEF and WHO). There are a total of eight desk officers, covering 4-5 countries each.



out humanitarian populations not reached through NVDPs, identify bottlenecks specific to humanitarian settings and identify and work with humanitarian partners – building on their in-country expertise and capacities – to enhance outreach and access to vaccines for humanitarian populations.

## Governance and oversight

- Since January 2022, the CoVDP reports to the Principals of WHO, UNICEF and Gavi on a monthly basis, in addition to the COVID-19 Vaccination Delivery Support Steering Committee, which was established by the Gavi Board. During the Steering Committee sessions, the Global Lead Coordinator and the Gavi Director of COVID-19 Vaccine Delivery, Coordination and Integration provide an update on progress against national and global targets and receives guidance and support from the Steering Committee members.
- The Global Lead Coordinator role was established at the Assistant Secretary-General level through the UNICEF Executive Board decision 2022/3 at the First Regular Session on 11 February 2022. CoVDP reports to the UNICEF Executive Board twice a year.
- The Gavi Alliance Programme and Policy Committee (PPC) and the Gavi Alliance Board

are charged with oversight of the investments made through Gavi funding. The Gavi Board and PPC are updated on an at minimum bi-annual basis covering decisions on CDS funding and related matters.

## Operating principles

- National ownership and centrality of countries to define and manage bottlenecks
- Focus on countries with the greatest vaccine equity gap for immediate concerted support
- One Team, One Plan, One Budget – reducing duplications, enhancing coordination and leveraging each partners' competitive strength
- Ensure vaccine delivery investments strengthen routine immunization and primary health care systems

## Interlinkages with other areas of work

1. Country engagement
2. Delivery funding
3. [Demand planning](#) (3.2.2)
4. Technical Assistance
5. [Data & Analytics](#) (4.3)
6. Health Systems and Response Connector Pillar

CoVDP is an intensified operational phase of the Country Readiness and Delivery (CRD) workstream, co-led by WHO, UNICEF and the Gavi Secretariat. It was set up in January 2022 to respond to an urgent need to boost vaccination uptake in the face of an increasingly stable supply picture, but low uptake by many middle- and low income countries. The three co-leading agencies of the CRD workstream intensified work under the title of the COVID-19 Vaccine Delivery Partnership (CoVDP) to differentiate and launch this accelerated phase.

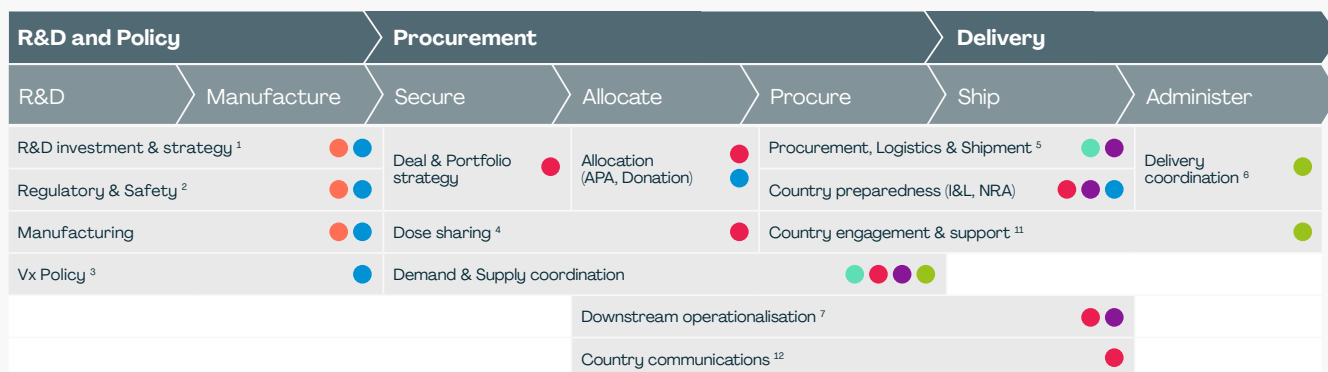
CoVDP leverages the existing resources and partnerships of Gavi, WHO and UNICEF at country, regional, and global levels to accelerate support to 34 AMC prioritised countries, strengthen coordination of partners, and improve delivery data reporting and monitoring.

CoVDP works with partners based on a 'One Country Team', 'One Plan', and 'One Budget' approach:

1. One Team – One Team of in-country partners at the centre of all national, regional and global-level planning and support activities
2. One Plan – One joint operational plan, incl. vaccine implementation bottlenecks and areas for support
3. One Budget – One joint view of funding available from all funding sources (incl. bilateral funding) and funding needs to support COVID-19 vaccination

CoVDP puts countries at the centre of its operations and engages with countries identified for immediate support weekly. CoVDP Desk Officers contribute to weekly coordination calls with the One Country Teams, led by the national governments. Ministries of Health, country-level UNICEF and WHO health leads are invited on a rotating basis to present deep dives into their respective country experiences, discuss and problem-solve operational, financial and political bottlenecks.

# 4. COVAX ENABLING CAPABILITIES



- Including activities around vaccine development and optimization, and variants
- WHO Pre-qualification
- WHO SAGE and Post-implementation safety monitoring group
- Includes donor engagement, supply confirmation with manufacturers, country acceptance and signature of tripartite agreements with donors, recipients and manufacturers
- Handled jointly by UNICEF Supply Division and PAHO Procurement Coordination Team
- In close collaboration with governments and local stakeholders, in-country delivery support is provided to all AMC 92 countries through Gavi Senior Country Managers, and the WHO and UNICEF country offices. CoVDP is providing targeted support to 34 out of the 92 countries with vaccination coverage rates below 10% in January 2022.
- Includes Product Managers from UNICEF and Gavi, and SCO Product Focal Points, who support the end-to-end coordination of a product's life cycle from APA signature to shipment
- Strategic Coordination Office (SCO), coordinates cross-pillar Project Management and Pillar Leadership engagement activities
- In addition to the enabling activities, there are COVAX Programmes, such as the COVAX Humanitarian Buffer Programme and the COVAX Facility Cost Sharing Programme
- The colorful dots on the diagram indicate partner organizations that lead each workstream. In addition to leading partner organizations, there are cross-partner engagement structures in place that draw input and insight from other COVAX partners to conduct above COVAX workstream activities in a collaborative spirit
- Gavi, UNICEF and WHO. CoVDP is leading and providing targeted support to the 34 AMC countries with the lowest vaccination coverage rates (below 10% in Jan 2022). The remaining AMC countries are supported by Gavi, UNICEF and WHO.
- The Country Communications Team is the information and coordination hub for COVAX country communications and acts as a liaison point for COVAX country-facing staff across Gavi, UNICEF, and WHO.

## 4.1 COVAX STRATEGY

### Overview

COVAX first articulated a strategic vision in 2020. This provided the impetus for the follow-on activity that was delivered through the rest of that year and into 2021. By mid-2021, the pandemic had evolved and the operating environment for COVAX had changed. New stakeholders had emerged, successful vaccine products were being deployed around the world, and the epidemiology had continued to evolve.

In light of these changes and building on WHO's COVID-19 Global Vaccination Strategic Vision exercise, COVAX revisited its [strategy and updated it for the period October 2021 to September 2022](#).

The objectives of the 2021-22 Strategy for COVAX were:

- Clarify the Pillar's objectives, role, and value proposition
- Help delineate the role of each of the partners

- Provide a cohesive foundation upon which each partner organisation can plan and structure
- Support internal Pillar coordination and effectiveness, but also define externally what COVAX stands for and what COVAX seeks to offer to the world

### Key activities

- As required, a COVAX Strategy Working Group meets to coordinate strategy development on all areas of the value chain for the agreed period.
- Sections are developed with close involvement of technical leads from partners. A combination of working sessions and 1-2-1 engagement was used to gather the necessary input.
- For 2021-22, the development of the COVAX strategy was closely synced with that of the wider [ACT-A Strategy](#), both completed in October 2021.

### Interlinkages with other areas of work

The COVAX strategy has been the foundation for the subsequent activities of all COVAX workstreams. There has been a particularly strong link to the [Resource Mobilization](#) (4.2) workstream, reflecting how important funding has been to supporting the success of COVAX's strategic objectives, and the [External Communications](#) workstream (4.5).

## 4.2. RESOURCE MOBILIZATION

### Overview

To coordinate Resource Mobilization (RM) activities, COVAX established a cross-partner Resource Mobilization Working Group. During the peak periods of RM activity, this group met frequently to coordinate activity, share progress updates and address any challenges collaboratively. Throughout the pandemic RM activities have been undertaken and driven by partner teams, not through any centralised function.

Each COVAX partner has a Resource Mobilization (RM) team focused on raising the necessary funds to support the core activities of COVAX.

The Gavi resource mobilization team, for instance, ensures that the COVAX Facility and partners receive required financial resources. It is responsible for preparing the Gavi COVAX AMC Investment

Opportunity, as well as organizing COVAX AMC pledging events and summits. The team works on innovative financial instruments, such as International Finance Facility for Immunisation (IFFIm), US International Development Finance Corporation (DFC) and European Investment Bank (EIB) partnerships, to allow frontloading of resources. It also oversees relationships with donors and plays a critical role in the dose sharing mechanism to secure a supply of donated doses.

### Key activities

- To identify funding needs for the successful delivery of COVAX overall.
- To agree areas of RM responsibility between partners to ensure coverage across all needs and avoid duplication.
- To coordinate activity between partners, especially during busy periods.
- To align on overall figures to be communicated externally by COVAX / ACT-A.

### Governance and Oversight

The COVAX partner RM teams are collaborating closely, and overseen by partner-internal governance structures. The RM teams report on a regular basis to the COVAX PLT and ACT-A for broader RM coordination.

### Interlinkages with other areas of work

RM is a critical enabler for much of COVAX's work. Key interlinkages include [COVAX Strategy](#) (4.1), [External Communication](#) (4.5), and [Dose donations](#) (3.2.4).

## 4.3. DATA AND ANALYTICS

### Overview

COVAX operational data are owned by WHO, PAHO, UNICEF, and Gavi and shared amongst all of the COVAX partners. There are three platforms/portals that are used by COVAX partners and participants, and even more tools published for the general public with related data and information.

### COVAX Platforms/Portals:

- The COVAX Collaboration Platform (CCP) – hosted by Gavi, is external, COVAX-participant-facing. It contains data related to allocations, shipments, vaccine preferences, cold chain capacity, etc.

Participants use this tool to view country-specific data and to take actions when necessary.

- The COVID-19 Procurement Portal (CPP) – hosted by UNICEF, contains data related to allocations, shipment arrivals, forecasted shipments, regulatory, I&L, Import Authorizations etc. Users access this portal to get the latest data related to what has arrived in country, as well as information about planned deliveries.
- The WHO Allocation Portal – hosted by WHO, is COVAX internal with restricted access for partners. It contains data related to vaccine allocations, etc.

In addition to these core tools, COVAX partners maintain a range of tools and platforms that provide support to different teams both in their own organisations and across the partnership.

### COVAX Analytics:

Analytics based on available data are regularly made available to internal governance bodies as well as the COVAX Coordinating Meeting. Each partner may also generate analyses for internal purposes. COVAX partners produce analyses and related outputs that fit into six categories: Supply, Demand, Allocation, Shipment, Vaccine Administration, and Vaccine Wastage/Expiry. Supply data is led by Gavi, while Demand data is managed by Gavi, UNICEF, and PAHO. Both Gavi and WHO manage Allocation data. Shipment data is overseen by UNICEF and PAHO, while CoVDP cross-partner teams monitor data on both vaccination coverage and wastage/expiry.

### Key activities

- Collect and maintain COVID-19 vaccine data, focused, but not limited to, COVAX
- Develop and maintain platforms and portals for both internal and external usage
- Generate key analytics and metrics to drive decision-making and communications
- Provide key analytics and metrics to internal and external stakeholders on an as-needed basis

### Governance and oversight

- Data owners report into their respective leadership teams for guidance and approval
- [COVAX Pillar Leadership Team \(LT\)](#) (2.2) is the governance body responsible for COVAX-specific data and analytics

## Principles

- Inclusive – Data and metrics are solicited from all COVAX partners along the operational end-to-end process
- Efficient – Existing data and metrics are utilized, where possible, and identification of new key data or metrics are the responsibility of the COVAX business or technical teams
- Open – Data and metrics are shared equally with all COVAX partners

## Interlinkages with other areas of work

COVAX data and analytics are critical to every workstreams in the operational end-to-end process. Analytics are presented to the [SWAT](#) (2.4) and [COVAX PLT](#) (2.2) on a regular and as needed basis.

## 4.4. MONITORING, EVALUATION AND LEARNING (MEL)

### Overview

COVAX has ambitious goals and objectives. It presents many challenges, new ways of working and opportunities for all stakeholders involved. As such, there is a strong desire and commitment to maximise learning from COVAX, from its design through to innovations, challenges, results and impact. Each organization is contributing towards a robust monitoring, evaluation and learning approach, which must remain agile and responsive to the realities of operating in a still evolving landscape with associated uncertainties.

### Key activities

- Development of a holistic theory of change that documents key intended results, risks and assumptions
- Monitoring reports that compile key results and learning
- Development and tracking of Key Performance Indicators (KPIs) to monitor results across the entire results chain, from inputs through to impact
- Multi-stage evaluation approaches, beginning with evaluability and baseline assessments
- Coordination across partners of ongoing and future evaluation activities to share learnings and avoid duplicative efforts

- Maintenance of the COVAX Collaboration Platform to facilitate the monitoring of key interactions with COVAX, such as allocation decisions and history, delivery data and dose sharing
- Generation of learnings and synthesis of key COVAX learnings and lessons

## Principles

Key inputs and regular exchanges across partners are critical to ensure alignment across the COVAX Pillar and to maximise efficiencies (for example – through minimizing duplication of efforts). MEL activities aim to generate robust, timely and well-informed evidence and learning to inform decision-making and policy.

## Governance and oversight

- The work of the Cepi, Gavi, UNICEF and WHO MEL teams is overseen by each partner's internal governance process.
- In addition, outputs from the teams' work is presented to and discussed at COVAX Workstream Convenors and Pillar Leadership Team meetings.

## 4.5. EXTERNAL COMMUNICATIONS

### Overview

The COVAX External Communications and Advocacy Team is composed of representatives of each core partner's and ACT-A's external communications teams, including CEPI, Gavi, UNICEF, WHO, as well as the [COVID-19 Delivery Partnership](#) (CoVDP) (3.3) and Access to COVID-19 Tools Accelerator (ACT-A).

A regular meeting is held between the partners to align on COVAX-related strategic messaging and advocacy positions, create visibility of media requests, co-design proactive campaigns and content, set-up a joint assets base of talking points and media resources, organise media engagements and advise on and escalate strategic communications risks and issues to the COVAX PLT where necessary. The [COVAX SCO](#) (2.5) convenes the external communication meeting and supports urgent and ad hoc requests.

Once a month, the team is joined by communications leaders from the broader COVAX ecosystem. This includes communication

and advocacy representatives from the vaccine industry (IFPMA and the Developing Countries Vaccine Manufactures Network (DVCMN)), World Bank, Bill and Melinda Gates Foundation, and regional COVAX partners. The objective of this meeting is to create visibility of communication and advocacy priorities regarding topics of shared strategic importance.

Overall, the objectives of the COVAX External Communications Core and Extended Group meetings include:

- Alignment with ACT-A communication and advocacy strategy and plans
- Ensuring COVAX partners' alignment on COVAX external messaging and advocacy including briefings, press releases, statements and participant briefings
- Reaching consensus around the high-level joint messaging strategy on topical issues that affect the whole of COVAX partnership now or in the future
- Providing a platform for the core and external teams to share updates on agencies' advocacy and communications, to ensure external communications activities are tracked
- Aligning on engagement of forums, such as the World Health Assembly (WHA), G7, G20, African Union and United Nations General Assembly

### Key activities

- Aligning on COVAX advocacy positions and tactics
- Synchronizing messaging and leadership speaking engagements across COVAX agencies for key external events (e.g. World Health Assembly, UNGA, G7, G20, one-off events, such as the Ports to Arms Conference)
- Preparing talking points and joint statements as required (e.g. to respond to matters of public interest or commemorate COVAX milestones)
- Sharing information about media engagement opportunities, interview requests, and coverage of COVAX and related topics in the media
- Identifying opportunities for collaboration around routine communication (e.g. coordinating routine press briefings, sharing social media content)

## Principles

The team works to ensure that COVAX partnership communicates information that is accurate and reliable while acknowledging complexity, uncertainty, and risks involved as transparently as possible, in consultation with all COVAX partners and ACT-A in a timely manner.

### Interlinkages with other areas of work

- The COVAX external communications and advocacy team reports to the [COVAX Workstream Convenors](#) (WSC) (2.3) and the [Pillar Leadership Team](#) (PLT) (2.2) for strategic guidance and resolution of issues
- In addition, external communications processes are closely linked with the ACT-A Hub, [Country communications](#) (3.2.7) and [COVAX Operational SWAT](#) (2.4) – on an ad-hoc basis as required

## 4.6 CSO ENGAGEMENT

### Overview

Civil Society Organizations (CSOs) have been progressively engaged since the start of COVAX through a variety of mechanisms. This includes consultations with the focal points for CSO engagement at the lead agencies, monthly/bimonthly dialogue calls, CSO participation on Gavi/CEPI governance bodies, CSO representation on COVAX workstreams and multiple informal interactions with the COVAX Pillar lead organisations on joint coordination and planning.

The first dialogue webinar took place in July 2020 and was followed by the appointment of 10 CSO representatives to various COVAX workstreams and working groups in October 2020.

In addition to CSO contributions to key workstreams, COVAX, together with CSO focal points, hosts monthly/bi-monthly dialogues. This is a forum to exchange updates and learnings, which is attended by COVAX leads as well as over 150 CSOs and community-based organisations. In addition, regular coordination meetings are held with COVAX partner CSO focal points and appointed CSO focal points. Moreover, three deep-dive discussions have been arranged focusing on Manufacturing, Supply and Allocation and the Humanitarian Buffer.

Specifically, CSO Engagement has the following objectives:

- Ensure CSO representation and participation in COVAX operations and strategic decisions and leverage the expertise and insights of the CSO community
- Enhance constructive relationships and stimulate advocacy collaboration between CSOs and COVAX
- Build aligned agendas given COVAX evolving priorities (e.g., Delivery, HB, supply, demand/uptake, manufacturing)

### Key activities

#### CSO Representation on COVAX Workstreams

CSOs were engaged across COVAX, with CSO representatives contributing to COVAX workstreams. Examples from different stages across the COVAX lifespan:

- COVAX Coordination Meetings (Save the Children)
- Allocation (Save the Children)
- Steering committee of the COVID-19 Vaccine Delivery Partnership (ISGlobal)
- CoVDP Implementers' Forum (Open Invitation to CSOs)
- Immunisation Partners Call (Open Invitation to CSOs)
- Clinical Development and Operations SWAT (Aga Khan Foundation)
- Manufacturing SWAT (Médecins Sans Frontières)
- Enabling Science SWAT (Safari Doctors)
- Humanitarian Buffer (International Council of Voluntary Agencies)
- Manufacturing Task Force (Médecins Sans Frontières)
- Country Readiness & Delivery (American Red Cross)
- RDMIC Technical Advisory Group, Open Sessions (Médecins Sans Frontières)

### COVAX CSO Dialogues

Forum for exchange across CSO efforts, with presentations from COVAX partner leads and CSO representatives. Held regular webinars attended by over 200 CSOs. Jointly organised between COVAX partners and CSO representatives. To date, 16 dialogue meetings have been co-hosted.

### Deep Dive Meetings

Ad-hoc deep-dive discussions on specific issues. To date, 3 deep-dive sessions have been hosted with several in planning.

### Bilateral Exchanges

Ongoing dialogue between COVAX partners and CSO representatives on key topics and to trouble-shoot/ brainstorm ideas on advocacy opportunities and other technical areas, including through bimonthly meetings.

### Advocacy planning

Ad-hoc collaboration between CSOs on potential advocacy for COVAX, including supporting bilateral

engagement, incorporating COVAX messages in various global and regional documents on COVID-19 vaccines, and participation in key events.

### ACT-A collaboration

CSO focal points and CSO partners also collaborate with the ACT-A CSO hub, and the equivalent representatives and focal points across the other pillars. This is through monthly calls to share information and ways of working, aiming to focus on areas of cross-pillar relevance.

### Governance and oversight

CSO Engagement was overseen and operationalized by focal points from CEPI, Gavi, and WHO, in coordination with COVAX CSOs (Frontline Aids, CORE group, Aga Khan Foundation, American Red Cross, International Council of Voluntary Agencies, International Federation on Aging, ISGlobal, Médecins Sans Frontières, Safari Doctors, Save the Children, Village Reach, World Vision).



# 5. COVAX PROGRAMMES

## 5.1 COST-SHARING PROGRAMME

### Overview

Cost sharing was created as a voluntary mechanism for AMC countries to purchase additional doses as a “top up” to doses received through round allocations. Through this mechanism, countries can reach their own national targets faster by purchasing additional doses on top of the free doses provided through the Gavi COVAX AMC. The cost sharing mechanism is managed by the [Gavi COVAX Facility](#) (3.2.1). In this process, the Facility works closely with the AMC country government for supply offers and requests, and with the Multilateral Development Banks (MDBs) for the financing of the deals. UNICEF developed specific Procurement Service Agreements to manage the financing from MDBs for countries towards the placement of orders. Upon allocation of doses by the COVAX Facility and confirmation of such, UNICEF will issue a cost estimate to the AMC country.

### Key Activities

1. Supply Offering & Selection – led by COVAX Facility
2. Signing for Purchase of Doses – led by the country
3. Procurement – led by UNICEF/ PAHO
4. Financing – facilitated between the country, Gavi, UNICEF/ PAHO, and in some cases, MDBs
5. Allocation – led by Gavi, WHO
6. Purchase Orders – led by UNICEF/ PAHO

### Governance and Oversight

1. Strategy development, offer creation, escalation of issues to UNICEF/PAHO co-led by Resource Mobilization and Country Engagement
2. Manage MDB partnership, escalate issues to MDBs, exceptions to supply terms requiring AFC or MSDC – lead by Resource Mobilization

3. Support for demand and pipeline planning, defining offers, finalizing paperwork – led by Country Engagement

### Interlinkages with other areas of work

1. Several teams within Gavi carry out roles to ensure the operationalization of the cost share portfolio. These include: Country Engagement, [Deals](#) (3.2.1.1), [Legal, Resource Mobilization](#) (4.2), Country Support/SCMs, Finance
2. [Allocations](#) (3.2.3)
3. [UNICEF/PAHO procure](#) (3.2.5) the vaccines and facilitate [transport and logistics](#) (3.2.5) from manufacturer to countries

## 5.2 NO-FAULT COMPENSATION PROGRAM

### Overview

The COVAX No-Fault Compensation Program for AMC Eligible Economies (the “Program”) provides fair, no-fault, lump sum compensation to eligible individuals in the [92 low and middle income economies covered by the COVAX Advance Market Commitment \(AMC 92\)](#) who suffer a serious adverse event resulting in permanent impairment or death associated with a COVID-19 vaccine received through the [COVAX Facility](#) (3.2.1) or the administration of such a vaccine.

WHO is acting as the contracting party for the Program, for COVAX and for the benefit of Gavi, CEPI and WHO as the organizations co-leading COVAX. As such, WHO has entered into a Service Agreement with the Program's independent claims administrator (ESIS, Inc., the “Administrator”) and concluded an agreement with the Program's lead insurer, Chubb. The Program has been operational since 31 March 2021 and applications are received through a user friendly [web portal](#).

The Program is financed through Gavi, based on a donor-funded levy on vaccines procured or delivered through the COVAX Facility for use in AMC eligible economies.



WHO and Gavi work together to highlight the benefits and encourage the use of the Program in the AMC92. In addition, WHO, Gavi and CEPI consult with each other on needed revisions or adaptations of the Program.

*\*The Program covers vaccines that have been earmarked for delivery through the COVAX Facility to an AMC eligible economy, or to a Humanitarian Agency for use in an AMC eligible economy, up to and inclusive of 30 June 2023 (in accordance with the terms of the [Program's Protocol](#)).*

## Key activities

- WHO provides ESIS with the information needed to support the effective implementation of the Program. This includes [safety](#) (3.1.2) data of COVID-19 vaccines to guide the determination of claims under the Program in accordance with the terms of the Program's Protocol. In addition, based on information provided by Gavi, WHO also provides continuous information to ESIS on the vaccines distributed through the COVAX Facility to the AMC92 and [Humanitarian Agencies](#). (5.3)
- The Program's Protocol and other documentation are adapted and updated by WHO as needed, including to account for [SAGE recommendations](#) (3.1.4) and reflect the extension of the date by which vaccines can be earmarked for delivery through the COVAX Facility to AMC92 countries, for coverage under the Program.
- WHO further supports the roll-out of the Program in AMC92 countries, through briefings for national and regional stakeholders, developing communications materials on the Program, exchanging information on the Program with UNICEF, PAHO and other stakeholders, and holding continuous discussions with the Administrator and the insurers regarding Protocol revisions/updates.
- The Program's independent claims Administrator is responsible for reviewing applications for compensation under the Program, which includes:
  - Review of Applications for Receivability
  - Review of Receivable Claims (by a central review panel of nurses, and where relevant, an appeals panel of nurses and physicians, appointed by ESIS)
  - Payment of Compensation

- Information exchange with applicants

## Governance and oversight

- Decisions on material issues regarding the Program are taken by the [COVAX Pillar Leadership Team](#) (PLT) (2.2), following consultation with the [COVAX Coordination Meeting](#) (CCM) (2.1).
  - WHO senior management, including WHO's Chief Scientist, the Assistant Director-General for Access to Medicines and Health Products and the Director of Immunization, Vaccines and Biologicals are consulted on material issues prior to PLT and CCM meetings.
  - Where decisions regarding the Program (as taken by the PLT), require financing, or additional financing, for the Program, such financing is first discussed and agreed between Gavi and WHO, and then submitted by Gavi for approval to the [COVAX Facility AMC Engagement Group](#) (3.2.1), the [Gavi Audit and Finance Committee](#) (3.2.1) and the Gavi Executive Office.

## Principles

- *Fairness and Equity:* The Program is designed to be fair and equitable, and includes due appeals processes. Applicants are not charged any fees by the Administrator and the compensation amount is calculated taking into account the GDP per capita of the country where the Claimant is resident in order to ensure equitable compensation across the 92 AMC economies (taking into account differences in cost of living across countries) and is aimed at providing a fair level of compensation.
- *Transparency:* All information about the Program's application and review process, as well as the methodology for calculating compensation payments is publicly available on the Program web portal. Applicants are also informed of the reasons as to why claims are deemed not receivable or non-compensable.
- *Efficiency and Speed:* The Program is designed to be fast and efficient. The Administrator (ESIS) has defined timelines in which it is required to respond to each applicant, making the process for access to compensation faster. In addition, the Administrator offers help to applicants in multiple languages through global and regional helplines.

## Linkages with other areas of work

- WHO/Access to Medicines and Health Products
- [Allocation](#) (3.2.3)
- WHO/Immunization, Vaccines and Biologicals (IVB)
- [Regulation and Prequalification](#) (including Pharmacovigilance) (3.1.2)
- COVAX Facility
- COVAX Humanitarian Buffer.

Following accelerated development, the delivery of COVID-19 vaccines in hundreds of countries and territories in a matter of months is the fastest and the largest deployment of a vaccine in history. All vaccines made available or procured through the COVAX Facility have received regulatory approval or an emergency use authorization to confirm their safety and efficacy. However, even under normal circumstances, vaccines that are approved for general use may nevertheless, in rare cases, cause injuries to some individuals. Given the unprecedented speed and scale of the development, manufacture and distribution of COVID-19 vaccines, traditional risk transfer solutions are not available to manufacturers from the outset. This is why all countries receiving their COVID-19 vaccines through the COVAX Facility are required to indemnify manufacturers and other stakeholders against any losses they incur from the deployment and use of these vaccines.

COVAX wishes to ensure that those that may suffer Serious Adverse Events (SAE) associated with the vaccines procured or distributed through the COVAX Facility, or their administration, will have access to a fast and fair mechanism to provide compensation.

The establishment of the Program is designed to contribute to the supply of life-saving COVID-19 vaccines in the most resource-constrained economies around the world and ensure that eligible individuals in these economies can receive compensation in an equitable, transparent and timely manner, if they suffer serious injuries following vaccination with a COVAX-distributed vaccine.

The Program is designed to be fast, robust and transparent, making it easier for any affected, eligible individual to get fair compensation without having to go through a lengthy and expensive legal process. The Program also reduces the financial burden to which the AMC92 may be exposed in the event of such injuries.

## 5.3 COVAX HUMANITARIAN BUFFER PROGRAMME

### Overview

The COVAX Humanitarian Buffer (HB) is a mechanism established within the [COVAX Facility](#) (3.2.1) to serve as a flexible safety net to ensure access to COVID-19 vaccines for the hardest-to-reach populations in humanitarian settings. It was set up on the backbone of the COVAX partnership's mandate of guaranteeing fair and equitable access to COVID-19 vaccines.

The HB is intended to be used where there are unavoidable, persistent or unforeseen gaps in coverage in national vaccination plans and micro-plans. Populations of concern in humanitarian settings may include:

- Those living under the state-like control of non-state armed groups

- Populations in conflict settings
- Those affected by humanitarian emergencies or those in need of humanitarian assistance, including but not limited to refugees, asylum seekers, stateless persons, internally displaced persons, minorities, detainees and vulnerable migrants irrespective of their legal status.

COVAX Humanitarian Buffer applications are for doses, devices and delivery funding, as required. In March 2021, the Gavi Board approved the reservation of up to 5% of Gavi COVAX AMC funding for doses to be deployed via the Humanitarian Buffer.

### Key activities

Gavi, WHO and UNICEF colleagues work collaboratively across the HB application fulfillment process, each with clear responsibilities based on their respective organizational roles:

- Gavi works on the policy, project management, design and operationalization and reporting of the HB process.
- WHO manages the regulatory approval process, with Global Health Cluster Leads supporting discussions with in-country partners.
- Gavi and WHO each provide a representative to serve the Secretariat function to the Inter-Agency Standing Committee Decision Group (IASC DG).
- The HB Secretariat (led by Gavi and WHO) processes applications, interfaces with applicants and coordinates review processes.
- Gavi processes approved applications
- UNICEF handles procurement, transport and logistics for the shipment of doses and delivery of operational funding.
- Legal and formal COVAX communications are led by Gavi

COVAX partners in addition work with governments, humanitarian agencies, non-governmental and CSOs.

## Governance and oversight

A Decision Body established under the IASC Emergency Directors Groups is responsible for decision making on issues related to the Humanitarian Buffer. This process has been designed to ensure that humanitarian experts are involved in decision-making, guided by the principles of COVAX, the HB and the humanitarian principles, as well as to ensure judgements on the feasibility of delivery to populations of concern are made by those with experience of vaccination campaigns in humanitarian settings.

### IASC DG (Inter-Agency Standing Committee Decision Group)

#### Overview

A Decision Group comprising experts from IASC entities has been established to take decisions on allocations to the Buffer and will report to the IASC EDG. The Decision Group will decide by consensus, based on the information provided. If, in exceptional circumstances, the Decision Group cannot reach consensus, it may refer the request to the Emergency Directors' Group (EDG) for input

before deciding. The final decision remains with the Decision Group. Applications will be received on a rolling basis. Decision-making will be guided by the humanitarian principles of neutrality, impartiality, independence, and humanity.

The Decision Group reports to the IASC EDG. The Decision Group will provide the Gavi Board with twice yearly reporting on the allocations through the Humanitarian Buffer.

#### Objectives

Decision making on Humanitarian Buffer applications

#### Composition

- IASC DG
- WHO, UNICEF, UN Office for the Coordination of Humanitarian Affairs (OCHA), International Organisation for Migration (IOM), UN Refugee Agency (UNHCR), International Committee of the Red Cross (ICRC), IFRC, MSF and ICVA.
- Gavi is an observer and WHO is the chair of the Decision Group.

*In cases where exception financial approval is required for COVAX to finance an approved Humanitarian Buffer application, the Funding Review Panel is notified of the need, volume and cost, and makes a determination as to whether COVAX funds can be used.*

*The Board approvals that created the Humanitarian Buffer also requested the feedback and reporting mechanism on operationalisation, inter alia, key performance metrics, the number of requests received and approved and the timeliness of that approval, the number of Humanitarian Buffer doses allocated and delivery support funding.*

## Principles

- Equitable access
- Targeted deployment
- Measure of last resort
- Contextual parity
- Alignment with overarching principles of ACT-A COVAX Pillar
- Adherence to humanitarian principles

## Interlinkages with other areas of work

- [Joint Allocation Taskforce](#) (3.2.3): to ensure doses are available to the Buffer
- Humanitarian Agencies: to understand in-country partner needs and demand
- Gavi Country Programmes: receive feedback and support from SCMs
- Vaccine manufacturers: I&L waivers and agreements for shipments to Humanitarian Agencies
- UN Country teams: check-ins with Resident Coordinators and Humanitarian Coordinators
- IASC COVID-19 Working Group: expert design and review of Buffer process



# 6. ANNEX

## 6.1 GLOSSARY

<b>ACT-A</b>	Access to COVID-19 Tools Accelerator
<b>AFC</b>	Audit and Finance Committee
<b>AMC</b>	Advanced Market Commitment
<b>APA</b>	Advance Purchase Agreement
<b>BMGF</b>	Bill and Melinda Gates Foundation
<b>CCM</b>	COVAX Coordination Meeting
<b>CCP</b>	COVAX Collaboration Platform
<b>CCT</b>	Country Communications Team
<b>CDC</b>	United States Centers for Disease Control and Prevention
<b>CDS</b>	COVID Delivery and Systems Strengthening
<b>CEPI</b>	Coalition for Epidemic Preparedness Innovations
<b>CPP</b>	COVAX Procurement Portal
<b>CRD</b>	COVAX Country Readiness and Delivery
<b>CSO</b>	Civil Society Organization
<b>DDST</b>	Downstream Dose-Sharing Team
<b>DG</b>	Director General
<b>DVCMN</b>	Developing Countries Vaccine Manufacturers Network
<b>EDQM</b>	European Directorate for the Quality of Medicines & HealthCare
<b>EMA</b>	European Medicines Agency
<b>EU</b>	European Union
<b>EUL</b>	Emergency Use Listing
<b>FDA</b>	United States Food and Drug Administration
<b>GACVS</b>	Global Advisory Committee on Vaccine Safety
<b>HSRC</b>	The Health Systems and Response Connector
<b>ICMRA</b>	International Coalition of Medicines Regulatory Authorities
<b>IFPMA</b>	International Federation of Pharmaceutical Manufacturers & Associations
<b>IPG</b>	Independent Product Group

<b>JAT</b>	Joint Allocation Taskforce
<b>LT</b>	Leadership Team
<b>LTA</b>	Long-Term Purchase Agreements
<b>MDB</b>	Multilateral Development Banks
<b>MFTF</b>	COVAX Supply Chain & Manufacturing Taskforce
<b>MPP</b>	Medicines Patent Pool
<b>MSDC</b>	Market Sensitive Decisions Committee
<b>NFC</b>	COVAX No Fault Compensation Program for AMC Eligible Economies
<b>PAHO</b>	Pan American Health Organization
<b>PLT</b>	Pillar Leadership Team
<b>PO</b>	Purchase Order
<b>PRG</b>	Procurement Reference Group
<b>RAG</b>	Regulatory Advisory Group
<b>RDMIC</b>	Research and Development and Manufacturing Investment Committee
<b>RITAG</b>	Regional Immunisation Technical Advisory Group
<b>RM</b>	Resource Mobilisation
<b>SAGE</b>	Strategic Advisory Group of Experts
<b>SCO</b>	Strategic Coordination Office
<b>SD</b>	Supply Division
<b>SFP</b>	Self-Financing Participants
<b>TAG-CO-VAC</b>	Technical Advisory Group on COVID-19 Vaccine Composition
<b>TPP</b>	Target Product Profiles
<b>TRG</b>	Technical Review Group
<b>UN</b>	United Nations
<b>UNICEF</b>	United Nations Children's Fund
<b>USAID</b>	United States Agency for International Development
<b>VMWG</b>	Vaccine Manufacturing Working Group
<b>WG</b>	Working Group
<b>WHA</b>	World Health Assembly
<b>WHO-PQ</b>	WHO Prequalification of Medical Products team
<b>WSC</b>	Workstream Convenors