gavi.org



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Foreword from Gavi's CEO and CERCO



David Marlow
Chief Executive Officer (Interim)

I am pleased to present the Annual Risk and Assurance Report 2023.

In today's dynamic and uncertain political context and environment, understanding and managing risks are critical to the success and sustainability of our Alliance.

This Annual Report is designed to offer an overview of our Top risk landscape considering our mission and strategic goals (5.1). It is emphasizing our commitment to transparency and the safeguarding of our stakeholders' interests. The report also reflects the Alliance dedication to risk management. It serves as a structured platform for the Board, through the Audit Finance Committee and the Programme and Policy Committee to discuss how we continually assess our strategic choices, collaborate and adapt to changing contexts and conditions.

Risk management is a critical tool to ensure responsible and effective use of the Alliance funds in the context of delivering on the defined strategic goals and the Alliance mission now and in the long-term future.

"Understanding and managing risks are critical to the success and sustainability of our Alliance"



Maria Thestrup
Chief Ethics, Risk and Compliance Officer

As Chief Ethics, Risk and Compliance Officer, it is my responsibility to provide you with a comprehensive overview of the Top risks faced by the Alliance and the response strategies, activities and projects we are implementing to manage and mitigate these risks effectively. Monitoring the health of our risk mitigation strategies is an essential component of our risk management activities.

As a new element in the Annual Report, we have included select key risk indicators, where available. In combination with our mitigation strategies, these are tracked regularly (as part of the Gavi Balanced Scorecard "GBS") to gauge the effectiveness of our risk mitigation efforts. We have also listed the Gavi Secretariat risk coordinator (per Department) responsible for coordinating mitigation activities.

Risk Management is about providing value to the Alliance, and it is considered an integral component of good governance.

"Risk Management is about providing value to the Alliance"



The Report

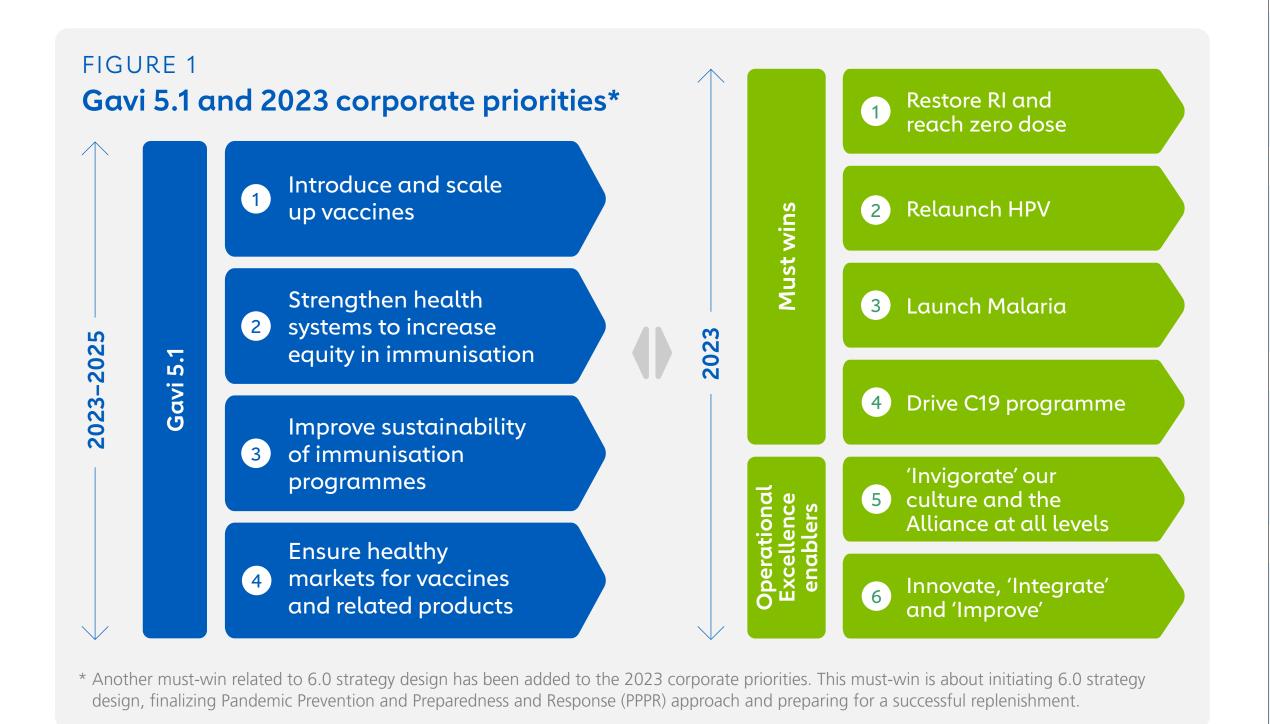


1.1 Introduction

Effectively managing risks is critical to achieving our strategic goals, delivering on our mission and creating value for our stakeholders and the globe at large. Gavi Alliance 5.1 strategy creates both opportunities and risks.

Our Risk Management approach is designed to generate a holistic view of Top risks for the Gavi Alliance. It serves to better understand our risk

exposure by providing increased transparency on the evolution of risks (year to year) and the related effectiveness of our mitigating actions. The annual Risk assessment and the 2023 Risk and Assurance Report is intended to help our Board and senior management focus on Top risks, align our strategy with risk exposure and oversee the effectiveness of our ability to mitigate risks.



Risks are grouped into 5 dimensions:



Programmatic

Risks directly associated with programmatic activities



Strategic

Risks associated with current and future plans and strategies



Financial

Risks associated with potential fiduciary issues and/or financial opportunity cost



Engagement with partners

Risks associated with our engagement with Alliance and local partners



Organizational

Risks associated with business activities and operations, procedures, people and systems Risks are rated on a five-point scale – very high, high, medium, low and very low – based on their likelihood and potential impact. More information about the scales and methodology can be found in Annex 1.

Following a well-defined Top risk selection process, we are providing a full overview of the Gavi Alliance 10 Top risks and a summary of additional 10 risks (among the Top 20) which are considered relevant for the Board to execute its oversight mandate.

Based on the approach taken in 2022, three top risks have been assessed as being outside of the Board's approved risk appetite statement (i.e. the amount of risk that the Alliance is willing to take or accept to achieve its strategic goals): Country Management Capacity, Vaccine-Preventable Disease (VPD) Outbreaks and Limited introduction of vaccines.

A review of the June 2021 Board-approved Gavi's Risk Appetite Statement is planned for 2024 and is expected to improve the ability of the Secretariat to determine risk appetite levels against individual risks identified.

1.2 Executive summary

Doc 08 - Annex A

1.2 Executive summary

This year's report details 10 top risks, i.e. risks that could potentially have an impact on the ability of the Alliance to achieve its mission and deliver on its strategic goals. It shows that Gavi's overall risk profile has changed, with six top risks increasing and two top risks decreasing (as illustrated in next page). The report also highlights 10 other relevant risks to be monitored during 2024.

The key drivers of the changes to Gavi's risk profile are linked to the current environment (macroeconomic factors), development in global health, developments within Gavi and the COVID-19 epidemiological evolution.



Summary of 2023 Top Risks across five dimensions



Programmatic

Five programmatic risks have been selected among our Top 10:

- VPD outbreaks risk has the most noticeable increase from high to very high, bringing the risk outside of Gavi's risk appetite.
- With a very high-risk level, Country Management Capacity remains the most elevated risk and is outside of Gavi's risk appetite.
- Risk of supply shortages, disruption and stockouts has slightly increased driven by increase in demand, production issues and product preferences.
- Risk related to Sustainability transition and backsliding has decreased from Very High to High.
- Risk related to limited introduction of vaccines remains Very High and is currently outside of risk appetite, driven by outbreaks and external factors.

Three other programmatic risks related to Health System Strengthening (HSS), data quality and availability and suboptimal campaigns are among Top 20 and rated as high.



Strategic

A new risk related to adverse events of vaccines and Alliance reputation is among our Top 20. Despite low likelihood, the risk could have a severe reputational impact on the work of the Alliance should it materialize.



Financial challenges

Two risks have been selected among the Top 10:

- Despite remaining High, the risk likelihood of misuse of funds has increased due to the increase in the value and concentration of cash grants in countries with weak financial and assurance systems.
- While the residual risk level remains High, the risk of decreased donor funding is increasing due the competitive donation landscape, rising number and complexity of donor requirements.

Three other risks are considered relevant to monitor (among Top 20): Finance operations challenges (High), SFP close-out (Medium) and Treasury risks (Medium).



Engagement with Partners

The risk related to engagement with CSOs and local Partners* is among our Top 10 and remains High. Our increased use of CSOs comes with increased legal, financial and reputational risks, as well as transaction costs.

The risk related to degraded Alliance health and insufficient Alliance capacities and capabilities is rated as Medium. The risk has a decreasing trend due to proactive mitigations by Gavi and Alliance Partners and is among our Top 20.



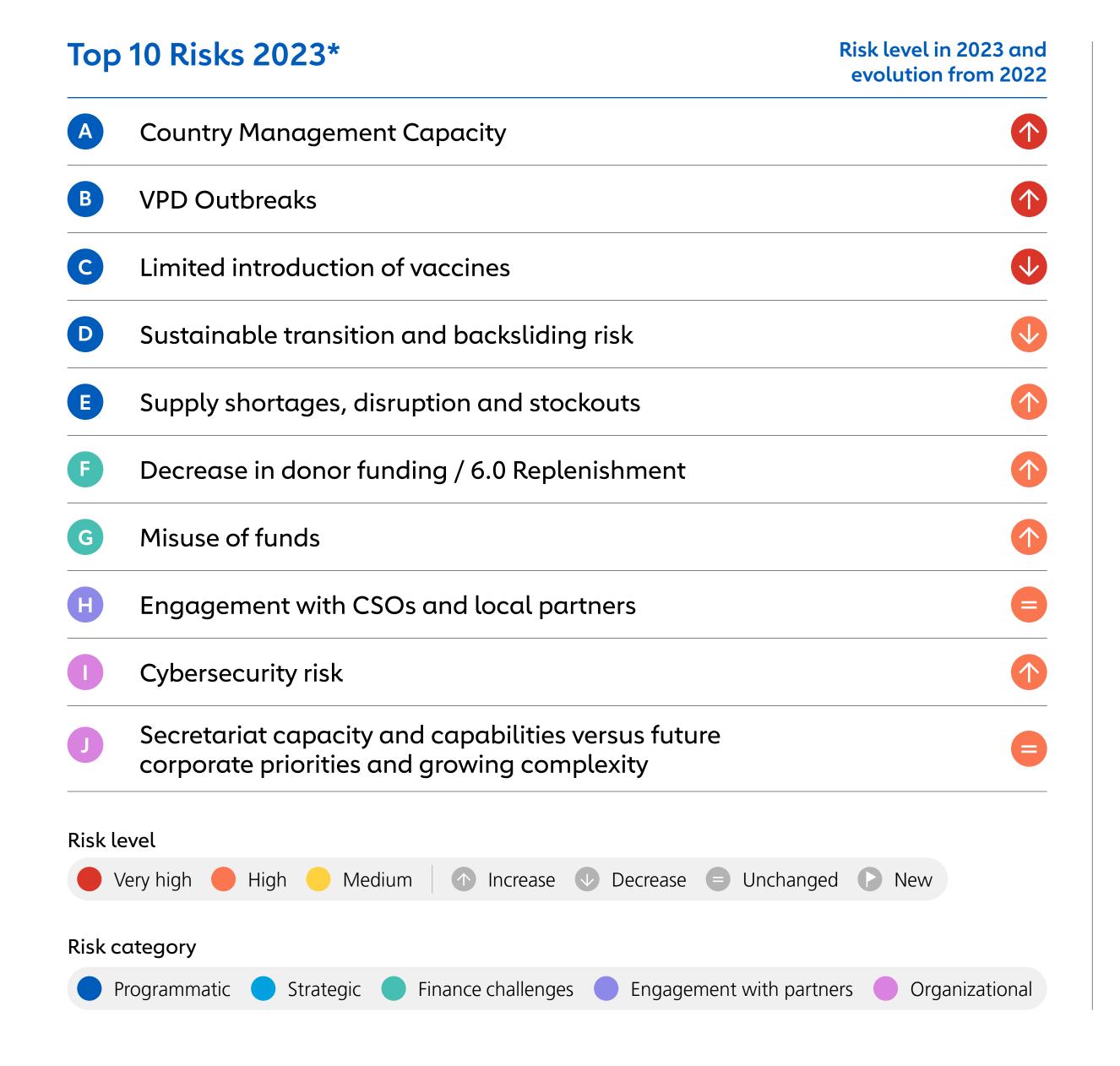
Organizational

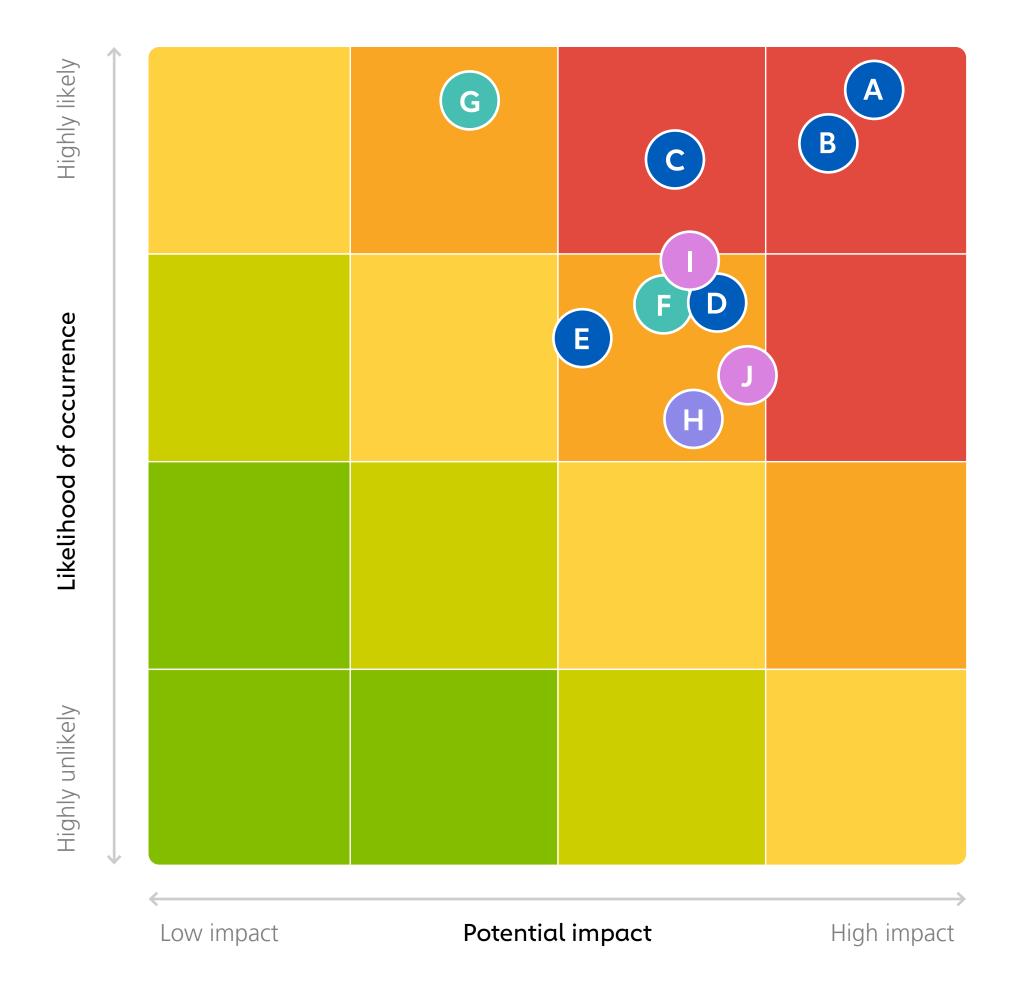
The risk that Secretariat capacity, capabilities and processes may be inadequate to deliver on future corporate priorities remains High and is among our Top 10. The risk is mainly driven by complexity of Secretariat operations, increasing oversight responsibilities, capacity and capabilities gap, changing organizational environment and staff attrition.

The risk of cybersecurity remains High mainly driven by rise in cyber-attacks globally and a substantial increase in Gavi financial resources.

Two other organizational risks related to culture and conduct (new), and to Secretariat disruption are rated respectively as High and Medium (among Top 20).

1.2 Executive summary



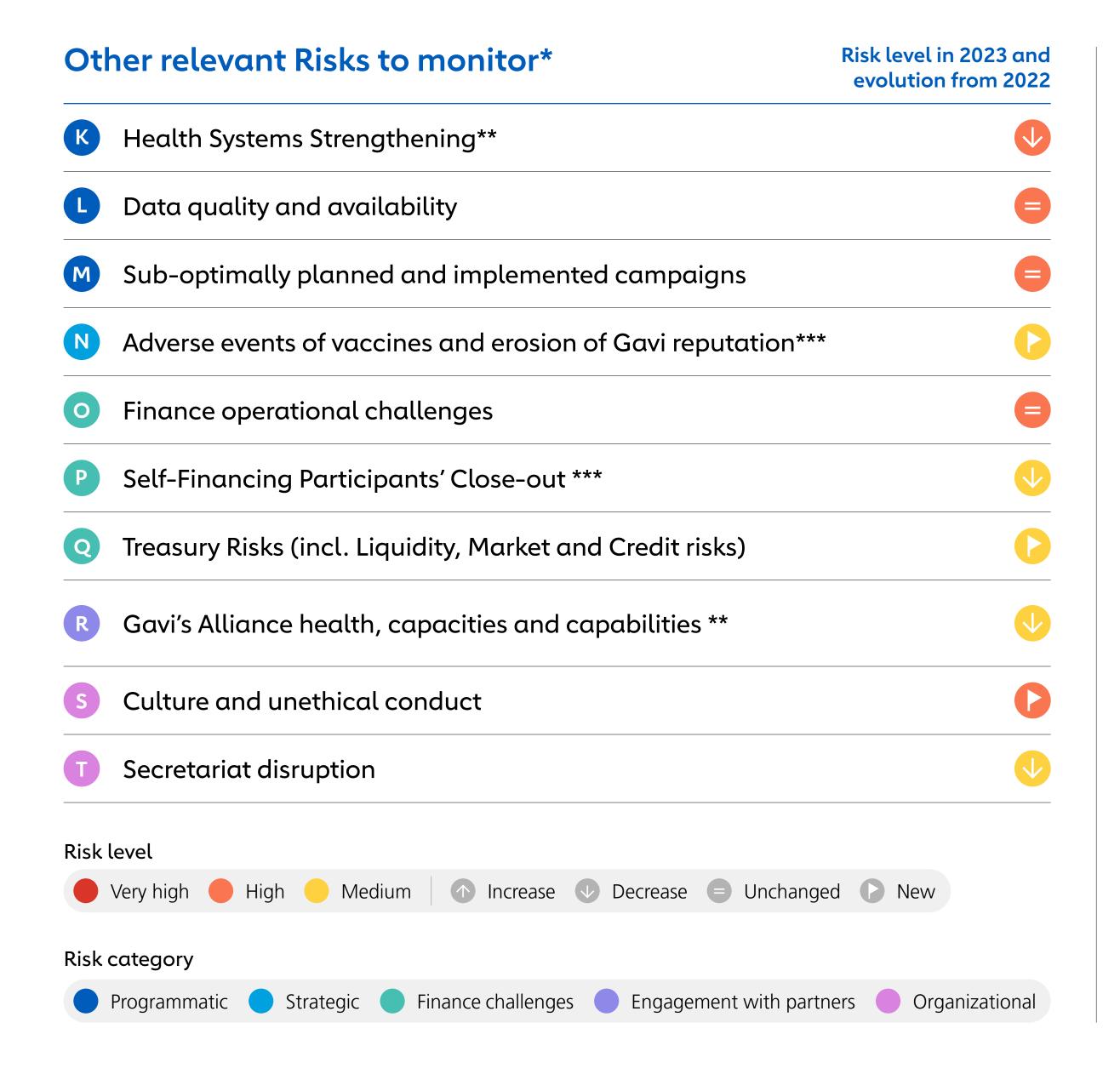


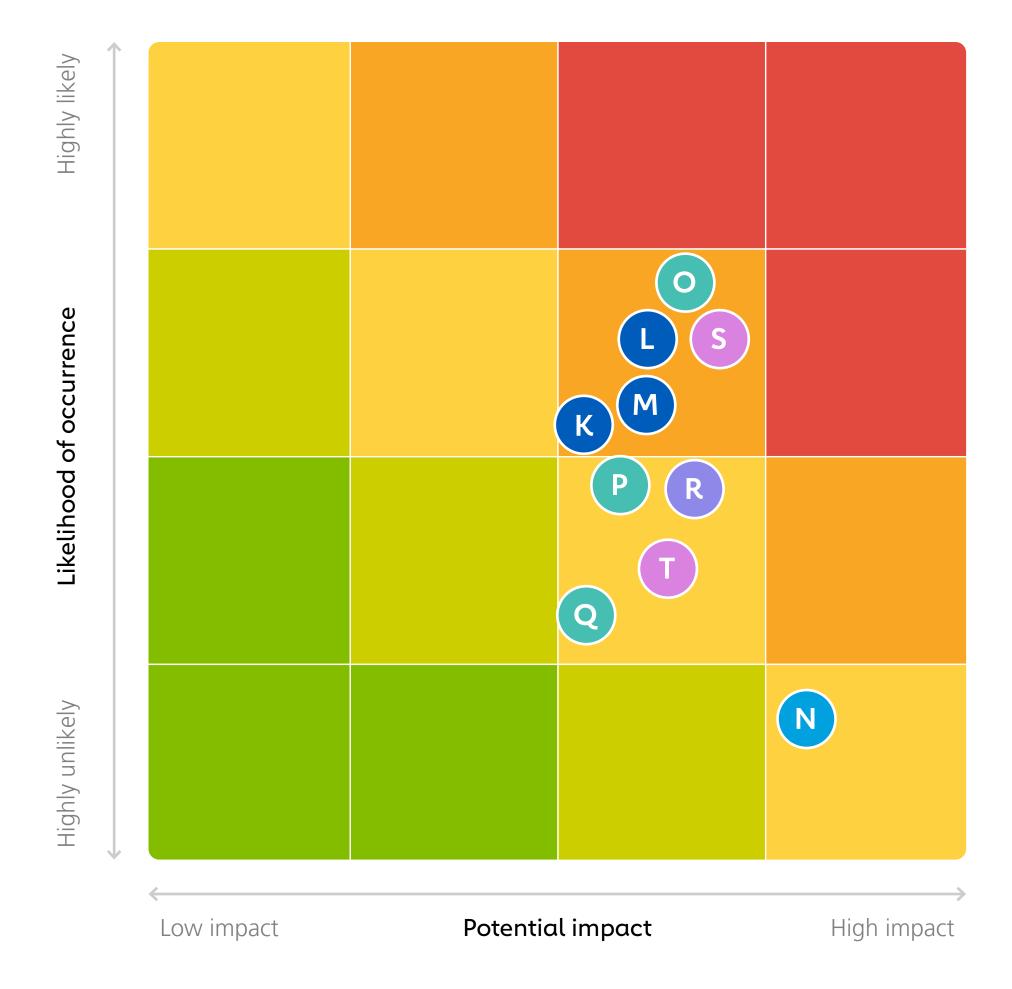
Likelihood of occurrence, given preventive mitigation in place to address the potential causes **Potential impact** on the ability of the Alliance to achieve the Gavi mission, given reactive mitigation in place to address the potential consequences once the risk materialises

^{*} Note that the Top risks are not ranked based on relevance and importance. They are grouped per dimension. For information, there is no relationship between letters assigned to risks in this report and letters assigned to risks in the 2022 Annual Risk and Assurance Report.

2023 Annual Risk and Assurance Report

1.2 Executive summary





Likelihood of occurrence, given preventive mitigation in place to address the potential causes **Potential impact** on the ability of the Alliance to achieve the Gavi mission, given reactive mitigation in place to address the potential consequences once the risk materialises

^{*} Note that other relevant risks are not ranked based on relevance and importance. They are grouped per dimension. For information, there is no relationship between letters assigned to risks in this report and letters assigned to risks in the 2022 Annual Risk and Assurance Report. ** Risks that are within Gavi's Risk Appetite. *** Risks whose risk appetite shall be defined.

1.3 General Context



Macroeconomic factors

The Alliance continues to operate in a volatile global environment and is exposed to continuously changing exogenous factors which could affect Gavi's risk profile. The economic aftereffects of COVID-19 and the war in Ukraine have resulted in skyrocketing inflation, a rapid normalization of monetary policies and started a low-growth, low-investment era*. Global economic activity is experiencing a broad-based and sharper-than-expected slowdown, with inflation higher than seen in several decades. The cost-ofliving crisis and tightening financial conditions in most regions, also weigh heavily on 2023 macroeconomic picture. This macro-economic context sharply constrains donors' and implementing countries' fiscal spaces, potentially leading to decreasing donor funding and immunization co-financing levers.



Key developments in global health

Unprecedented disruptions caused by the COVID-19 pandemic, followed by social, economic, geopolitical and environmental challenges, continue to place complex and interconnected threats on population health, especially impacting vulnerable populations, and increased strains on healthcare systems, particularly healthcare workers and supply of essential health products**.

On May 5th, 2023, the World Health Organisation (WHO) lifted the Public Health Emergency of International Concern (PHEIC) status for COVID-19. The change in PHEIC status and updated WHO guidance to deprioritize C-19 vaccination for pediatrics and adolescents is likely to result in the de-prioritisation of COVID-19 activities, further decreases in demand and limited or time-lagged COVID-19 data. The updated PHEIC status also means that WHO will no longer accept new regulatory filings for Emergency Use Listing (EUL), with countries unclear about the longer lead times for vaccine approval through Pre-qualification (PQ).



1.3 General context

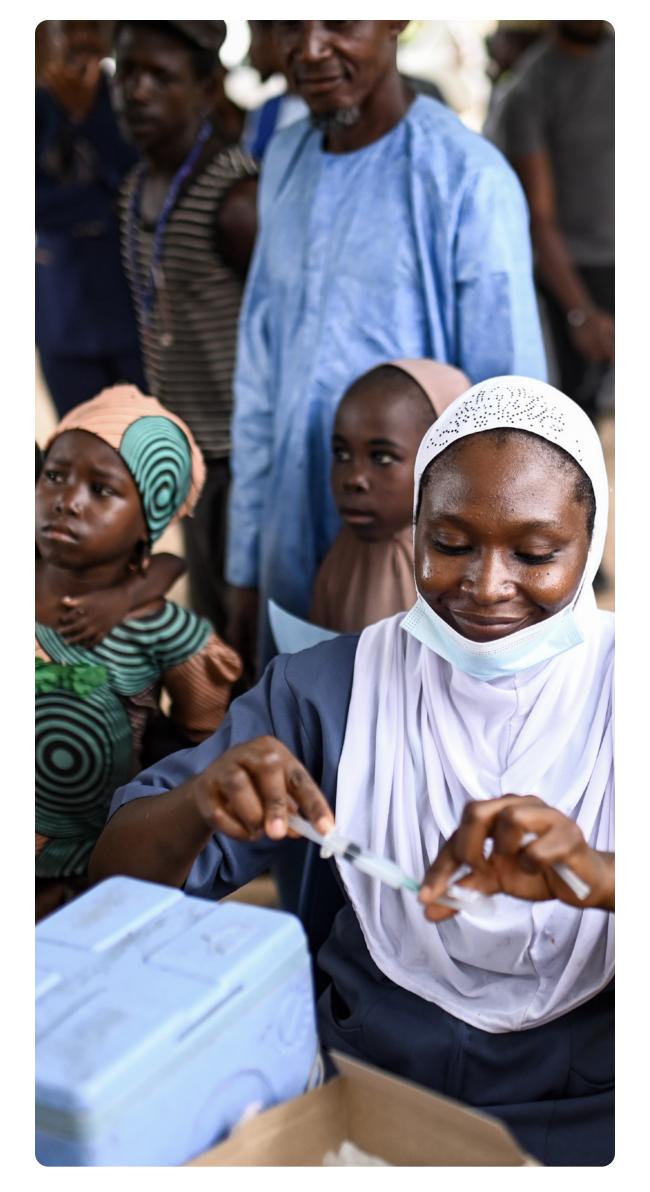
Key developments in Gavi

The Alliance remains on-track to reach the majority of mission indicator targets by the end of the Gavi 5.0/5.1 period. Progress in introducing and scaling up vaccines has continued with breadth of protection in Gavi-supported countries now higher than in the rest of the world. However, whilst WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) data also confirms signs of recovery in routine immunization across Gavi-supported countries, the impact of pandemic-related disruptions continues to be felt. This is particularly evident in the continued high number of vaccine-preventable disease (VPD) outbreaks. A key focus continues to be reaching zero-dose children and missed communities. Alliance partners have launched the 'Big Catch-Up'

to help restore immunization coverage and catch-up children missed during the pandemic.

Implementation of the Secretariat's ambitious Operational Excellence (OE) agenda is underway to ensure the successful delivery of Gavi 5.0/5.1 and prepare for Gavi 6.0. While a portion of the OE initiatives focuses on supporting processes and functions aiming to increase the effectiveness and efficiency of the Secretariat overall, some have more direct programmatic relevance. Among those are the EVOLVE initiative, COVAX integration, an initiative on Alliance ways of working as well as the implementation of recommendations from the Independent Review Committee evaluation. The integration of COVAX, managing the transfer into a regular C19 programme while safeguarding critical elements such as Gavi's work on Global Health Security, will conclude this year, with integration finalized in the beginning of 2024.

The Secretariat has implemented a One Gavi approach supporting a more integrated leadership team to design the future whilst staying focused on execution and prioritization. This streamlining of leadership reporting lines enables the new interim CEO to be fully dedicated to his new role and to rely on a stronger leadership team with clear roles and responsibilities. This enables the overall leadership transition process as Gavi is currently recruiting a new CEO to join the organization in 2024.



- * World Economic Forum Report 2023
- ** World Economic Forum Global Health and Healthcare Strategic Outlook



Gavi's Risk Landscape in 2023



2.1 The Alliance Top Risks

Country Management Capacity

Risk that many countries may have insufficient resilient Expanded Programme on Immunisation (EPI) capacity and capabilities to maintain, restore and strengthen immunization programmes and reach Zero-dose communities.

In-country interventions have contributed to help advance EPI capacities during the pandemic along with support from the Alliance on the ground. However, countries continue to have difficulties managing competing priorities. Weak EPI capacity in areas such as leadership, management, coordination, financial management and programme implementation are barriers to programme delivery especially in fragile countries. This is notably due to factors outside of Gavi's control such as insufficient human resources, retention challenges and external programme disruptions caused by instability, shocks or political change, natural disasters and more recently – the COVID-19 pandemic and the roll-out of COVID-19 vaccines. The risk that this will affect the Alliance's ability to reach zero-dose communities is therefore **VERY HIGH** and is assessed as outside of Gavi's risk appetite (BALANCED). The inherent risk is likely to increase with COVAX integration given limited know/ how and capacity of countries to integrate COVID-19 vaccination into their routine immunization programmes.



Root Causes

- A selection of Gavi countries' EPI units have weak management capacity due to insufficient human resources, retention challenges and competency gaps.
- Existing capacity in Gavi's countries especially in fragile countries may be disrupted or diverted due to external factors such as: political and social instability, shocks or change, lingering effects of Covid-19 pandemic and increasing trend in Vaccine Preventable Diseases (VPD) outbreaks.
- Low prioritization of health and immunization in public budgets due to constrained fiscal budgets and competing governmental priorities affect Gavi-countries management capacity.
- Natural disasters due to climate change are becoming more frequent with most countries having weak management capacity to respond to emergencies.

Ongoing Mitigating Actions



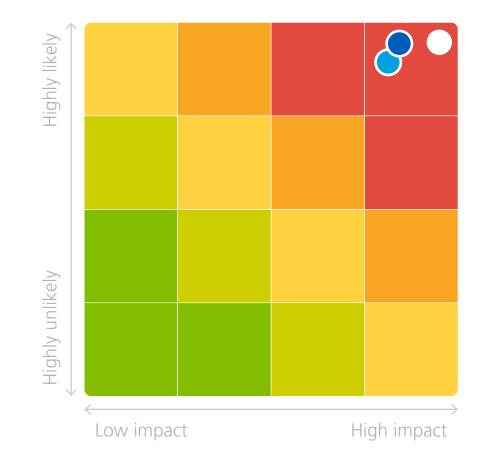
On track Delays/challenges

- The Secretariat is actively streamlining and simplifying application process to facilitate access to funding by reducing average length of Full Portfolio Planning (FPP) and redesigning the grant management process (also known as "EVOLVE project").
- The Secretariat's Programme Leadership Team is focusing on strengthening country ability in the following areas:
- Planning and prioritization by developing one plan per country and country heat maps for prioritization;
- Coordination by providing surge capacity e.g., additional Leadership, Management and Coordination (LMC) capacity, especially at subnational level;
- Timely execution by developing solutionfocused action plans to increase absorption capacity; and
- Review and reporting by conducting periodic country reviews to monitor progress against targets.

Risk Coordinator

Country Programmes Delivery

Residual risk level	VERY HIGH
Outlook	1
Level of external influence	HIGH









2023

Key Risk Indicators Indicators H1 2023 Target Campaigns achieving target coverage TBD N/A Co-financing fulfilment 100% 30% Primary Healthcare Expenditures >80% (Baseline 2022) 82% (2020) Cash going through government systems (Core) 41% (2021-2022) ≥29% (Baseline) Significant delays/challenges No target/TBD Delays/challenges

Potential impact of the risk on strategic goals and corporate priorities * **5.1 Strategic Goals 2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria **4** Drive C19 programme Improve sustainability of immunisation programmes 5 Invigorate our culture and the Alliance Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1

- The Partners' Engagement Framework (PEF) envelope (through Targeted Country Assistance (TCA), Foundational Support (FS) and Strategic Focus Areas (SFA)) has increased from \$694m in Gavi 4.0 to \$926m in Gavi 5.0/5.1, resulting in support targeted at country management and capacity. Enhanced Technical Assistance has notably been provided through PEF TCA & FS to support revitalisation of the HPV programme, which is a top priority for the Alliance in Gavi 5.1.
- The Secretariat operationalized the MICs approach to mitigate and prevent backsliding in routine immunisation programmes in former-Gavi countries, with a number of former-Gavi benefiting from targeted interventions support. In addition, MICs facing challenges like fragility, emergencies, and displaced population can access MICs Fragility support. This type of time-limited support has been provided to Venezuela and Lebanon. An application from Sri Lanka, a former-Gavi country, is also under review. Lastly, discussions continue with Ukraine.

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Planned Mitigating Actions

• Assessment of the development of a holistic Health Systems Strengthening (HSS) strategy as part of the overall Gavi 6.0 strategy.

Observations

Despite planned and ongoing mitigation (on track), the risk remains outside of Gavi's Board approved Risk Appetite statement. Given the documented impact on Gavi's strategic goals 5.1 and corporate priorities, the Alliance continues to allocate resources to proactively support country management capacity. The pipeline of potential future vaccines will be targeted at new populations beyond infants, therefore requiring new strategies, partnerships, and investments. Developing sufficient and resilient national and subnational capacity is crucial for countries to maintain or improve immunisation coverage levels also in the context of increasing birth cohorts, notably in Africa. Continued close monitoring by the Secretariat's SLT of the evolution of the risk is recommended.



Vaccine-Preventable Diseases (VPD) Outbreaks

Risk of sizeable outbreaks of vaccine-preventable diseases in some Gavisupported countries which cause cases, disability and death and can disrupt immunization programmes

Since mid-2021, there has been an increasing trend in the overall number of VPD outbreaks, driven primarily by Measles and Cholera outbreaks and to a lesser extent Yellow Fever, with countries facing challenges in timely detection and response. There has also been an upsurge of outbreaks caused by other VPDs without Gavi-specific established mechanisms for outbreak response for some of these diseases. As an example, Nigeria is experiencing a large, disruptive diphtheria outbreak with a risk of further spread in bordering countries. Furthermore, some countries have experienced concurrent outbreaks aggravated by natural disasters. Coordination and logistics of multi-crises responses have been challenging in a context of post-pandemic weakened health systems and exhausted health staff, who are faced with addressing multiple public health priorities. There is therefore a VERY HIGH risk of VPD outbreaks in some Gavi-supported countries falling outside of Gavi's current risk appetite (BALANCED). Should the trend observed continue to increase, it may lead to a drastic increase in morbidity and mortality of children caused by devastating but preventable diseases and therefore reduce significantly the impact of the Alliance immunization programmes overall.



Root Causes

- Millions of children are at risk from devastating preventable diseases, due to combined factors such as lingering effects of COVID-19 pandemic on Routine Immunization (RI), preventive campaigns disruptions, chronic gaps in immunization coverage, weak health systems, lack of capacities to detect, prevent and respond to outbreaks, vaccine hesitancy, external programme disruptions caused by conflicts and natural disasters, as well as logistics issues leading to delays in shipments.
- **Cholera outbreak** The lifting of COVID-19 control measures have paved the way for a new 7th cholera pandemic wave across several geographies such as South Asia, Middle East, Southern, Central and Eastern Africa and Haiti, exacerbated in some locations by extreme weather events linked to climate change (e.g. floods in Pakistan and Southern African and droughts in Eastern African). This rise in Cholera outbreaks resulted in a surge in demand for Oral Cholera Vaccine (OCV) and created a gap in supply for planned preventative campaigns in 2022.
- **Measles outbreak** Despite doubling of planned preventative Measles / Measles Rubella (M/MR) campaigns from seven in 2021 to 14 in 2022, significant immunity gaps for Measles persist, largely due to a decline in routine immunisation coverage, delays in conducting campaigns during and after the COVID-19 pandemic and failure to improve quality and effectiveness of and evaluate outcome of campaigns.
- **Yellow Fever outbreaks** trends have been mainly driven by disruptions in routine vaccination, chronic gaps in immunization coverage and delayed implementation of the planned preventive mass vaccination campaigns.

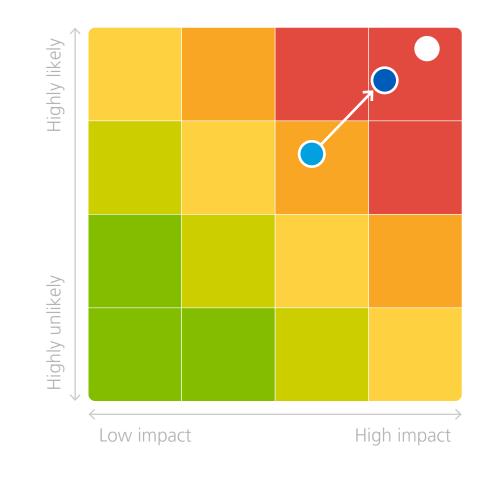


- Monitoring of outbreak signals and timely outbreak response through VPD surveillance including timely, continuous and systematic collection, analysis and interpretation of health-related data needed for planning, implementation and evaluation.
- Removal of requirement to demonstrate DTP3 coverage of 70% for MR introductions from the Vaccine Funding Guidelines to help accelerate closure of the MR immunity gap in the midlonger term. Of 15 countries that have not yet introduced rubella-containing vaccine, seven have become eligible to apply for MR vaccine introduction with the removal of the DTP3 filter.
- To mitigate the increasing risk of Cholera Outbreaks:
- Launch of Gavi application window for preventative Cholera campaigns in January 2023, with countries encouraged and supported to apply without delay with comprehensive long-term Cholera control plans.
- Tender run by UNICEF in Q2 2023, giving Oral Cholera Vaccine (OCV) manufacturers the opportunity to request special contracting terms to mitigate residual demand uncertainty and to help accelerate scale-up and market entry.

Risk Coordinator

Vaccine Programmes

Residual risk level	VERY HIGH
Outlook	^
Level of external influence	MEDIUM







2023 Gross Risk Leve

Key Risk Indicators Indicators Baseline (2019) H1 2023 Target Timely outbreak detection +50% by 2025 25% 18% (2022) Measles campaign coverage 25% 70.2% (2022) 50% by 2025 Approved measles applications 100% N/A upon first IRC No target/TBD Delays/challenges Significant delays/challenges

Potential impact of the risk on strategic goals and corporate priorities * 5.1 Strategic Goals **2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria **4** Drive C19 programme Improve sustainability of immunisation programmes 5 Invigorate our culture and the Alliance N/A Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve N/A Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1



Ongoing Mitigating Actions

On track Delays/challenges

- To decrease the risk of large disruptive outbreaks through timely preventive campaigns, the Secretariat and partners propose decreasing VPD outbreaks risk appetite from balanced to low. If this amendment of the June 2021 Risk Appetite Statement is approved by the Audit and Finance Committee (AFC) and the Board, the Secretariat together with the Alliance partners will further reflect and align on its effective operationalization in the mid-term.
- To further support countries address their growing Measles immunity gaps:
 - The Secretariat is exploring process improvements to accelerate the pathway for approval to ensure timely Measles / Measles Rubella (M/MR) preventative campaigns.
 - There are also ongoing efforts across the Alliance to strengthen timely and quality preventative campaign planning, applications and implementation, including through the work of the Health Campaign Effectiveness Coalition (HCE).
- The Secretariat is requesting partners' support for timely implementation of Post Campaign Coverage Surveys (PCCS) to ensure more robust assessment of the performance of campaign outcomes.
- To reduce the risk of Yellow Fever Outbreaks:
 - A comprehensive global strategy to eliminate yellow fever epidemics (EYE) is being implemented by a coalition of partners (Gavi, UNICEF and WHO) to face yellow fever's changing epidemiology, resurgence of mosquitoes, and the increased risk of urban outbreaks and international spread.

- Gavi Risk Committee has been closely following the risk of supply disruptions of Yellow Fever vaccines related to one of the major suppliers and provided guidance on mitigations such as suppliers diversification, which are currently being pursued.
- The Alliance is supporting countries to develop catch-up plans, building on existing catch-up activities through reallocating Health Systems Strengthening (HSS), Equity Accelerator Funding (EAF) and Country Delivery Support (CDS) funds. Moreover, approvals of country applications are being fast tracked to ensure timely implementation of the Big Catch-up – a targeted global effort to boost vaccination among children following declines driven by the COVID-19 pandemic.



Planned Mitigating Actions

• The Secretariat is planning to develop Standard Operating Procedure (SOP) to have predictable answer when VPD outbreak is detected and include this as part of the Funding Policy Review.

Observations

Despite significant efforts to reduce VPD outbreaks risk through a combination of timely preventive campaigns, fast-tracked grant application and enhanced routine immunization services, more can be done to prevent the accumulation of susceptible children and thus reduce the risk of disease outbreaks. Given the devastating impact of VPD outbreaks on morbidity and mortality, the Secretariat and partners shall pursue their deliberate efforts to reduce the risk to an acceptable level.

Limited introduction of vaccines

Challenging introduction of vaccines due to external programme disruption, poor country management capacities and commitment, leading to insufficient immunization coverage

Despite a decreasing trend, the risk related to limited introduction of vaccines by countries remains **VERY HIGH** and outside of Gavi's current risk appetite (LOW). While the Alliance was on track with its 5.1 target for routine vaccine introductions in 2022, there is a risk of falling behind in 2023. In 2022, Gavi supported 16 routine introductions across seven vaccines, exceeding the number of planned introductions for 2022 (15). In 2023, out of 21 targeted routine introductions, only 6 had occurred by September 2023, with a risk that the target is not fully met. The risk has experienced an increase in likelihood driven by numerous concurrent factors including increasing Vaccine-Preventable Diseases (VPD) outbreaks, the lingering effects of COVID-19 pandemic and external factors such as the war in Ukraine and climate change. Some reluctance to introduce new vaccines such as Rotavirus vaccine, Pneumococcal Conjugate Vaccine (PCV), Human Papillomavirus (HPV) vaccine was identified in Middle-Income Countries (MICs), in particular for countries with existing coverage issues not previously under Gavi support. While the likelihood has increased, the risk impact has decreased thanks to strong ongoing mitigations.



Root Causes

- The lingering effect of COVID-19 pandemic is a key risk contributor. All Gavi-supported countries have introduced the first dose of Inactivated polio vaccine (IPV) into their routine schedules, reaching 80% coverage in 2022. However, due to COVID-19 related disruptions, switches to IPV2 are delayed with 24 countries not yet having applied for IPV2 support.
- Another factor is the increasing number of outbreaks diverting from routine immunization strengthening. The number of outbreaks has increased year-on-year since 2020, rising beyond pre-pandemic baseline levels in 2022. Measles and cholera outbreaks continue to be the key driver of increased outbreaks with countries facing challenges in early detection and timely responses
- Other risk contributors include poor country management capacity, sub-optimal technical assistance, lack of political support for HPV relaunch due to ideological opposition against the HPV vaccine
- External factors such as climate change implications and global impact of war in Ukraine on fiscal spaces are also risk contributors.



Ongoing Mitigating Actions

On track Delays/challenges

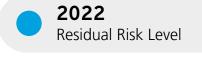
- Gavi continues to work with countries as well as through the Global Polio Eradication Initiative (GPEI) to advocate for IPV2 switches, particularly in countries impacted by poliovirus transmission.
- The Alliance has been supporting countries to develop catch-up plans, building on existing catch-up activities through reallocating Health Systems Strengthening (HSS), Equity Accelerator Funding (EAF) and Country Delivery Support (CDS) funds. Moreover, approvals of country applications are being fast tracked to ensure timely implementation of the Big Catch-up – a targeted global effort to boost vaccination among children following declines driven by the COVID-19 pandemic.
- The Secretariat is strengthening country capacities by providing surge capacity e.g., additional Leadership, Management and Coordination (LMC) capacity, especially at subnational level.
- The MICs approach has been operationalized and is currently providing in-country catalytic support for vaccine introduction in formerand never-Gavi countries.
- Operationalization of Gavi's Fragility, Emergencies and Displaced Populations (FED) Policy is supporting countries affected by chronic fragility, acute emergencies and hosting large numbers of displaced population in immunization coverage strengthening.

Risk Coordinator

Country Programmes Delivery

Residual risk level	VERY HIGH
Outlook	↓
Level of external influence	HIGH









Key Risk Indicators Indicators H1 2023 Target New vaccine introductions N/A Campaigns achieving target coverage TBD N/A Vaccination campaigns conducted 15 9 MICs countries engaged with introducing 10% / 76% (2022) 80% new vaccines / mitigating backsliding Significant delays/challenges No target/TBD Delays/challenges

Potential impact of the risk on strategic goals and corporate priorities * **5.1 Strategic Goals 2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria Improve sustainability of immunisation programmes **4** Drive C19 programme 5 Invigorate our culture and the Alliance Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1



Planned Mitigating Actions

- HPV revitalization involving strengthening program delivery and ensuring quality vaccine introductions continues to be a priority. Looking ahead, four routine introductions and five multi-age cohort (MAC) vaccination launches are anticipated between now and the end of 2023 with two routine introductions and four MAC launches to come in the first half of 2024. This will contribute to reach the target of 86 million girls by the end of Gavi 5.0/5.1 and to further increase coverage in coming years.
- The Alliance plans is rapidly accelerating the operationalization of technical assistance platforms at regional level to support MICs with applications for New Vaccine Introduction (NVI).
- The Alliance plans to further operationalize the FED policy
- The Pandemic Prevention Preparedness and Response (PPPR) initiative approved by the Board will contribute to strengthen health systems in readiness for a major epidemic threat and working towards equitable access to outbreak and pandemic vaccines.

Observations

Despite a decreasing trend, the risk remains Very High due to concurrent factors such as surge in VPD outbreaks and lingering effects of COVID-19 pandemic. Given the severe impact that such a risk might have on immunization coverage, ERCO recommends to pursue deliberate efforts to reduce the risk level and close monitoring of the risk and mitigating actions progress.

Sustainable transition and backsliding risk

Risk that some countries may fail to successfully transition out of Gavi support or see their immunisation programmes backslide after transition

The risk that some countries may fail to successfully transition out of Gavi support or see their immunisation programmes backslide after transition has decreased from VERY HIGH to **HIGH**. The risk's decreasing trend is supported by positive indicators such as: (i) a record US\$ 162 million in domestic resources for co-financing of Gavi-supported countries in 2022; (ii) an increased coverage of Gavi-supported vaccines costs by countries (from 10% a decade ago to 21% now); (iii) improved timeliness of co-financing payments especially in larger countries; (iv) a positive trend of successful transitions; (v) post-transition support having been rolled-out as part of the Middle Income Countries (MICs) strategy for former-Gavi countries; and (vi) an increased focus on programmatic sustainability under Gavi 5.0. However, the risk remains HIGH due to serious macro-fiscal challenges, including the impact of COVID-19, high inflation, local currency depreciation combined with high debt levels, and the economic uncertainty related to the Russia-Ukraine war. These challenges are likely to affect fiscal space and transition trajectories of Gavi-supported countries and could induce backsliding risk in already transitioned countries which is already high.



Root Causes

- The lingering impact of COVID-19, combined with high inflation, interest rate rises, high debt levels, and economic uncertainty related to the Russia-Ukraine crisis, has significant impact on macro-economic and fiscal stability in Gavi-supported countries and is likely to affect countries' fiscal space for domestic financing, their transition trajectories, and backsliding in already transitioned countries.
- Gavi-supported countries entering or currently in Accelerated Transition (AT) are facing some unprecedented challenges and transition risks as their transition occurs in a period of considerable economic uncertainty. Board-approved transition extensions have been given to Papua New Guinea (PNG) and Nigeria, with PNG continuing to experience significant challenges. In light of the continued fallout from pandemic and deeper system issues the PPC is being requested to recommend an approval of a no cost extension for Gavi support to two countries in accelerated transition (PNG and Timor-Leste). As of 2022, eight former Gavi-supported MICs maintained or increased DTP3 coverage compared to 2019, while nine countries did not maintain or increase DTP3 coverage.
- Other key risk contributors are country management capacity issues, their limited access to global markets as well as political conflicts and wars notably in fragile context.



- Contracting of a firm to work with local Civil Society Organizations (CSOs) to carry out budget advocacy in selected countries;
- Approval of Accelerated Transition (AT)
 extension from five to eight years by the
 Board in December 2022 to support countries
 in smoothing the co-financing trajectory
 and provide additional time to address
 programmatic issues.

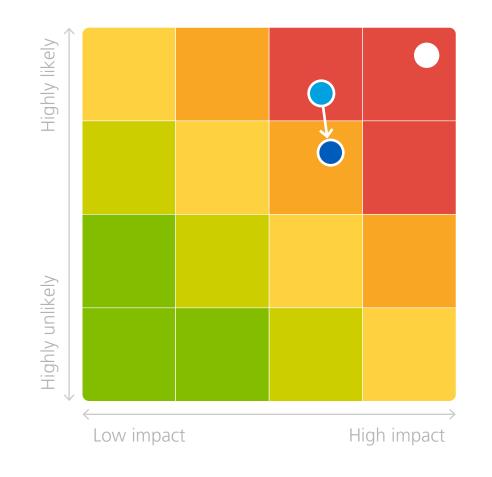


- Gavi is having closer collaboration with the World Bank and the International Monetary Fund (IMF) and is working with partners through the Alliance Technical Team (ATT) and the Sustainable Financing for Health Accelerator (SFHA).
- The Alliance is developing "transition roadmaps" for the Accelerated Transition (AT) countries.
- To offset backsliding risk, the Middle-Income Country's (MICs) approach and corresponding budget envelope has been operationalized to help sustain routine immunisation programmes in former-Gavi countries and help both former-Gavi and never-Gavi countries to sustainably introduce new high impact vaccines.

Risk Coordinator

Immunization financing and sustainability

Residual risk level	HIGH
Outlook	\downarrow
Level of external influence	MEDIUM





Key Risk Indicators Indicators H1 2023 Target Co-financing fulfilment 30% TBU MICs countries engaged with introducing new vaccines / mitigating backsliding 10% / 76% (2022) 80% On track Delays/challenges Significant delays/challenges No target/TBD

Potential impact of the risk on strategic goals and corporate priorities * 5.1 Strategic Goals **2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria Improve sustainability of immunisation programmes **4** Drive C19 programme 5 Invigorate our culture and the Alliance Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1

- US\$ 27 million funding for regional and globallevel technical assistance for WHO and UNICEF has been approved until end 2025 to support countries prevent backsliding of vaccine coverage and drive sustainable introductions of key missing vaccines.
- The Alliance is implementing MICs Targeted Interventions for former Gavi-supported countries backsliding.

Planned Mitigating Actions

- The Alliance is planning to increase advocacy efforts and high-level engagement with countries to improve domestic financing for health.
- The Alliance is also addressing backsliding in countries that struggle to recover and have limited Zero-dose.



Observations

The risk decreasing trend is promising.
However, given persistent barriers such as impact of Covid-19, reduced fiscal spaces, macroeconomic challenges as well as political instability, ERCO recommends to pursue deliberate efforts to support countries which are at high risk of not being ready for transition or of backsliding.



Shortages in the global vaccine supply affecting Gavi-supported countries

The risk of supply shortages remains **HIGH**, with a slight increase in risk likelihood driven by challenges identified in four vaccine markets. UNICEF Supply Division is collaborating on a new Oral Cholera Vaccine (OCV) tender to address risks around demand uncertainty. Supply disruptions affected all three Gavisupported rotavirus vaccines during 2021-2023, with Gavi working with manufacturers to help countries to switch to an alternative rotavirus vaccine. For HPV, a new market shaping roadmap is on track, with Alliance partners aligning on strategies to manage the market's demand imbalance and uncertainties regarding the uptake of one-dose schedules. The first malaria market shaping roadmap was published in January 2023 with the goals of ramping up supply and supporting price reductions following the approval of a second malaria vaccine. A series of proactive and strong mitigations have been put in place to limit potential programmatic and reputational impacts of the risk.



Root Causes

- Supply insecurity may occur if vaccine manufacturers lack adequate capacity to meet demand or choose to exit certain markets due to declining commercial interest, price evolution or demand unpredictability.
- Gavi may not be able to meet country presentation preferences if demand exceeds available supply. An example is when the supply is disrupted by external factors: epidemiological, political or technical.
- The emergence of new variants of C19 could require the development of Variant Containing Vaccines (VCVs) if previous vaccine supply is no longer effective.



Ongoing Mitigating Actions



On track Delays/challenges

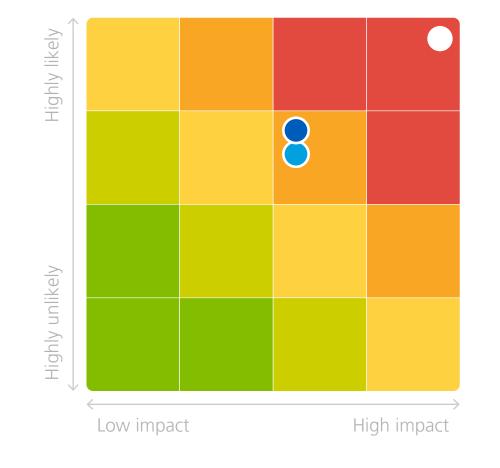
- Proactive engagement has been established with pipeline manufacturers to enter market and inject supply security and competition into at-risk vaccine categories.
- Supplier planning and stocks are being closely monitored through monthly and year end stock counts is conducted in partnership with UNICEF.
- Engagement with Partners is ongoing to ensure that there is equitable access to malaria vaccines.
- Alliance-wide Rotavirus vaccine switch guidance is being updated. Additionally, an easier-to-deliver liquid Rotavirus vaccine is being introduced.



Risk Coordinator

Market Shaping

Residual risk level	HIGH
Outlook	
_evel of external influence	HIGH









Indicators Indicators H1 2023 Target Antigens stockouts (Core) 1 (June 2023) N/A Sufficient and uninterrupted availability of vaccine products that adequately meet programmatic needs On track Delays/challenges Significant delays/challenges No target/TBD

Potential impact of the risk on strategic goals and corporate priorities * 5.1 Strategic Goals **2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria Improve sustainability of immunisation programmes 4 Drive C19 programme 5 Invigorate our culture and the Alliance Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1



Planned Mitigating Actions

- The African Vaccine Manufacturing Accelerator (AVMA) is being proposed to create a sustainable African vaccine manufacturing base, contributing to global healthy markets and an improved African pandemic and outbreak vaccine supply resilience.
- A new approach is to be developed to enable timely and accelerated country switching if supply shocks were to occur.
- The "Big catch-up" recovery effort to reach unvaccinated children is completing a review of low stock levels.
- Activities in the Malaria and OCV roadmaps are to be implemented.



Observations

Despite numerous ongoing mitigations, the risk remains high. Managing this risk is critical to the success of many of Gavi's 5.1 strategic goals and 2023 priorities, and it will continue to be a key for the success of Gavi's 6.0 strategy. Close monitoring by the Secretariat's Senior Leadership Team of the evolution of the risk is therefore recommended.



Decrease in donor funding / 6.0 Replenishment

Risk of decreased donor support during the replenishment for Gavi's 6.0 strategy, leading to insufficient funding, potential disruption of immunization programmes and challenges to implement new initiatives.

Gavi is defining its 6.0 strategy for 2026-2030 and donor support is crucial to the upcoming replenishment scheduled for second half of 2024. However, economic uncertainty and slowing of the global economy, the war in Ukraine and emerging changes in global power dynamics, competing priorities in international cooperation and aid, as well as leadership transition in some donor countries may result in reduced funding. Should the risk materialize, this could lead to severe disruption of countries' programmes, limit the Alliance capacity to overcome a resurgence of Covid-19 pandemic and hinder Gavi's efforts to achieve its 6.0 strategy objectives or launch new initiatives. Despite remaining **HIGH**, the residual risk is slightly increasing due to the timing of the next replenishment, the competitive donation landscape and the complexity and rising number of donor requirements. The risk will be reassessed closer to the replenishment.



Root Causes

- Donor fatigue or diversion of interest may occur due to geopolitical developments with competing fundraising needs, such as climate change, ongoing wars and refugee crises.
- Political instability, upcoming elections or fiscal constraints may impact donor priorities.
- Fundraising efforts may be impacted by limited appetite for new Gavi initiatives, such as African Manufacturing.
- Insufficient or delayed conversion of donors' pledges might lead to potential disruption of immunization programmes and challenges to implement new initiatives.
- The remaining earmarked funds from COVAX might also discourage some donors from further contributing for 6.0 replenishment.
- Political risk resulting from some donors not being part of Gavi's Board might also affect Gavi's engagement with donors and ultimately their contributions.



Completed Mitigating Actions

Strong Moderate Weak

- Implementation of market specific strategies including bipartisan engagement, proactive outreach to political leadership, creation of an expansive network of supporters in civil society and media, close work with G7 and G20, as well as private sector champions in key markets.
- Proactive monitoring and engagement with donors ahead of the 6.0 replenishment focusing on extending private sector outreach and amplifying existing partnerships.
- Reinforcement of donor trust and confidence during the June 2023 Mid-Term Review (MTR) by providing evidence of progress in delivering on majority of key Gavi 5.0/5.1 commitments made to donors during the 2020 replenishment.
- Proactive engagement with other Global Health organizations such as the Global Fund to coordinate replenishment timelines, develop a shared narrative and collaborate on the Future of Global Health Initiatives.



Ongoing Mitigating Actions

Delays/challenges

 The Alliance has made significant efforts in diversifying and broadening its donors base – with the number of sovereign donors growing from 29 in Gavi 4.0 to 34 in Gavi 5.0.

Risk Coordinator

Resource Mobilization Department

Residual risk level HIGH Outlook Level of external influence **MEDIUM**









* Assumptions for impact assessment are available in Section 3.1

Key Risk Indicators Indicators H1 2023 Target Resources received vs. forecast (Core) 97% 100% Resources received vs. forecast (COVAX) 108% TBU Liquidity in months forecast expenditure 13.8 9+ Resource signed vs. pledged 100% 88% (5.0/5.1) Delays/challenges No target/TBD Significant delays/challenges

5.1 Strategic Goals 2023 Corporate Priorities Restore RI and reach ZD N/A Introduce and scale up vaccines 2 Relaunch HPV N/A Strengthen health systems to increase equity in immunisation 3 Launch Malaria N/A **4** Drive C19 programme Improve sustainability of N/A immunisation programmes 5 Invigorate our culture and the Alliance N/A Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve N/A Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable

Potential impact of the risk on strategic goals and corporate priorities *

- The Alliance is also ensuring that donors' needs are met, including with financial instruments tailored to donors' budgetary processes and requirements.
- Refinement of Gavi's campaign and narrative is ongoing for the 6.0 replenishment to foster continued trust and support. Significant efforts are made to diversify private sector partners, including at regional level.
- The Alliance is engaging with donors to develop options for the Pandemic Vaccine Pool (PVP), including support for COVID 19 2024/2025 programme and adapting grant agreements.
- The Alliance is pursuing its engagement with G7 and G20 countries and actively contribute to global fora such as UN General Assembly and World Health Summit to emphasize Gavi's critical role in Pandemic Prevention Preparedness and Response (PPPR) and routine immunization.

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Planned Mitigating Actions

- The Alliance is planning to develop a Donor Compliance Framework in 2024 to clarify internal roles and responsibilities as well as processes to address and comply with increasingly complex donors' requirements.
- Other initiatives include the development of a new multilateral development bank (MDB) strategy and creation of a strong value case for African Vaccine Manufacturing Accelerator (AVMA).

 Work on a clear positioning, agreed within the Alliance to donors on the complementarity of approaches and the overall increased value.

Observations

Despite mitigation activities (on track), the risk remains high. Given the potential impact on effective implementation of Gavi 6.0 strategic goals for the period 2026-2030, close monitoring by the Secretariat's SLT of the evolution of the risk is recommended.



Misuse of Funds

Improper use or mismanagement of Gavi support or funding within Gavi-supported countries.

Some Gavi-supported countries have weak systems, low capacity, weak programme design, prevailing corruption or poor governance and management. This environment exposes the Alliance to the risk of its support being misused or inadequately accounted for with unsupported or ineligible expenditures, whether done deliberately or in error. The risk is therefore **HIGH**. Despite strong mitigations in place and evolving situation, the risk likelihood has increased due to the increase in the value and concentration of cash grants in countries with weak financial and assurance systems. Gavi remains a high-profile organization and target for fraud, and the risk has materialized recently with fraud attempts and incidents having been identified.



Root Causes

- Over-disbursement and idle funds create an opportunity for misuse in countries with weak institutions and systems.
- The presence of weak controls, limited monitoring or poor reporting compliance along the funding journey impacts the ability to attest where Gavi's funds have been spent, potentially masking incidents of misuse.
- Internal or third-party actors may also seek to obtain funds for personal gain through fraudulent means, such as hacking or phishing attempts, declaration of ineligible expenditures or as part of a culture of gifts or corruption.
- Increased attrition of personnel in ministries during the COVID-19 pandemic has resulted in competency gaps for oversight and monitoring.

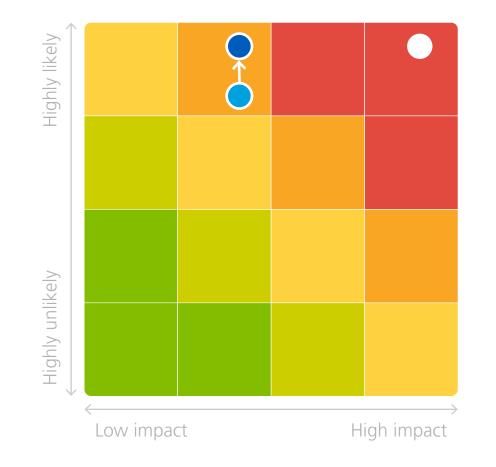


- Review of cash balances in-country, monitoring of cash usage and assessment of government systems, prior to disbursements.
- IT security initiatives to limit cyber-attacks including trainings to increase user cybersecurity awareness and implementation of email security settings such as the Domain-based Message Authentication, Reporting, and Conformance (DMARC) authentication protocol.
- Processes strengthening in 2020 following SAP implementation and control reviews conducted by Kroll.
- Review and implementation of in-country assurance options conducted by monitoring agents, internal and external auditors with the option of using an Alliance partner if needed. Audit concluded that key controls are adequately designed and implemented, with further recommendations on sourcing, contract management, performance evaluation and reporting.
- Close monitoring of effective reimbursement of misuse by countries.

Risk Coordinator

Portfolio Financial Management

Residual risk level	HIGH
Outlook	^
Level of external influence	MEDIUM





Key Risk Indicators Indicators H1 2023 Target \$564M USD (2022) Country Cash Balance TBD Cash Utilization vs. Disbursement 90% (2022) TBD Cash Disbursement vs. Forecast 108% 100% Cash going through government systems (Core) 41% (2021/2022) ≥29% (Baseline) No target/TBD Delays/challenges Significant delays/challenges

Potential impact of the risk on strategic goals and corporate priorities * **5.1 Strategic Goals 2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria Improve sustainability of immunisation programmes **4** Drive C19 programme 5 Invigorate our culture and the Alliance Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1



Ongoing Mitigating Actions

On track Delays/challenges

- With significant CDS and HSIS resources remaining available to countries for the rest of Gavi 5.1, additional measures have been identified to help countries accelerate absorption of cash grants. These include design of plans for increasing cash absorption in 12 countries with highest balances, providing surge leadership and management capacity support to several countries and the extension of CDS implementation from 2023 through 2025 to enable countries to phase CDS absorption over time.
- New agreements with expanded partners are being designed, which will contain robust provisions about performance management, audit and misuse.
- Assessment of relevant controls is ongoing, with implementation of technical controls to further lower the risk profile. The fiduciary risk mechanism is being reinforced across term of references, mandate, reporting and oversight.



Planned Mitigating Actions

• The Secretariat is planning to leverage programme audit's lessons and Operational Excellence initiatives related to assurance and Three Lines of defense (3LOD) to link misuse data with assurance mechanisms.

Observations

A country-level fraud incident that occurred in 2023 was related to idle funds and was detected by an assurance provider. Controls at the Secretariat-level appear effective, as evidenced by the successful prevention of a banking fraud attempt in 2023. While immediate action is not required in the shortterm, mitigations need to be continually reviewed and improved given the size and nature of the risk.

Engagement with Civil Society Organizations (CSOs) and local partners

Challenges in engagement with local partners and CSOs leading to sub-optimal delivery of immunization programmes

Civil Society Organisations (CSOs) and local partners are complementing on-the-ground activities and advocating for financial sustainability and domestic funding. Overall, they play an increasingly critical role in the Alliance's ability to deliver on its mission and strategy. At country-level, the Civil Society and Community Engagement (CSCE) Approach approved by the Board in 2021 aims to commit at least 10% of Gavi funding across funding levers to CSOs and local partners. This broader engagement comes with increased operational complexity of vetting and managing new partners at country levels, including increased transaction costs (programmes design and contracting) and broader risk management. Furthermore, CSOs and local partners, despite having critical context-specific expertise and ability to reach zero-dose children in humanitarian and conflict areas, may not be able to access Gavi funding as existing processes and systems for accessing funding and reporting are complex and developed for a different type of partners. If not well managed, the risk related to engagement with CSOs and local partners could ultimately lead to sub-optimal delivery of immunization programmes and heightened reputational risks for the Alliance. The risk is assessed as **HIGH**.



Root Causes

- When selecting new local partners and CSOs, there may be risks related to quality of services, financial viability, regulatory and reputational issues.
- CSOs and local partners may not always be able to access Gavi funding due to complicated engagement processes
- Accountability and performance, coordination and measurability of cross-cutting Technical Assistance
 (TA) priorities like equity are more complex to manage in a broader partnership with CSOs and other local
 institutions and in absence of automated data collection systems.
- Existing partner organizations are still affected by the lingering effects of Covid-19 pandemic.
- Limited internal capacities and capabilities dedicated to CSOs and local partners undermining the effective implementation of the CSCE approach.
- Pushback from countries and partners due to lack of clarity about Gavi's evolving priorities affecting our engagement with local partners.

Completed Mitigating Actions Strong Moderate Weak

- Creation of a dedicated CSO and Local Partner Engagement team responsible for: (i) defining and driving implementation of Gavi's CSO engagement work at national level, (ii) operationalizing the CSCE Approach approved by the Gavi Board in 2021 as a new strategic vision to deepen and expand partnerships with CSOs and local partners, (iii) strengthening Gavi's funding model related to CSO and local partner engagement.
- Streamlining of grant processes adapted to CSOs and introduction of complementary funding channel for CSO engagement by outsourcing the E2E contract/grant management process.
- Active engagement of Public Policy Engagement team with CSOs that are influential in the advocacy space at the global level and invitation of CSOs to join Gavi's CSO community.

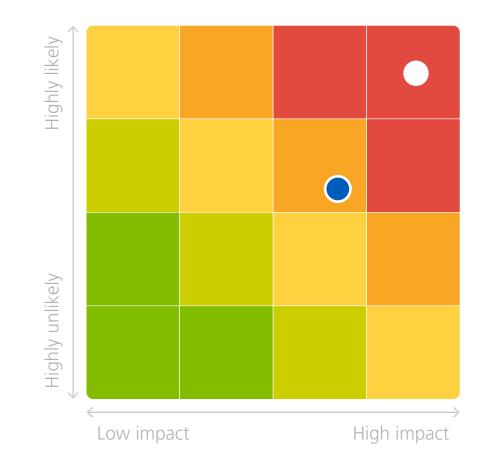
Ongoing Mitigating Actions On track Delays/challenges

• The Secretariat is implementing an exhaustive strategic and operational framework for CSOs and local partners that includes an Operational Plan, a Risk Management Strategy, a Communications Strategy, a Monitoring & Learning framework, a Localisation approach and a Gender Strategy.

Risk Coordinator

Country Programme Delivery Programme Support Team

Residual risk level	HIGH
Outlook	=
Level of external influence	LOW





Key Risk Indicators Indicators H1 2023 Target HSS, EAF & TCA allocated to CSOs 17.5% (1-6/2023) 10% % countries adhere to Board decision 78% (2022-2023) 100% % allocation to global CSOs 10% (1-6/2023) % allocation to local CSOs 90% (1-6/2023) No target/TBD Delays/challenges Significant delays/challenges

Potential impact of the risk on strategic goals and corporate priorities * **5.1 Strategic Goals 2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria **4** Drive C19 programme Improve sustainability of immunisation programmes 5 Invigorate our culture and the Alliance N/A Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1

- The Secretariat is optimizing internal processes for effective CSO engagement, including creating a new outsourced fund management mechanism which should help reduce the administrative burden for the Secretariat as they engage an increased number of CSOs and local partners. The Secretariat is in the process of finalizing the contracts for the selected CSO and Local Partner Fund Managers.
- Implementation of the Civil Society and Community Engagement (CSCE) approach has gained traction since establishment of a dedicated team to drive the agenda, with the majority of countries adhering to the Board decision to allocate at least 10% of combined Health System Strengthening (HSS), Equity Accelerator Funding (EAF) and TCA ceilings for CSO implementation.
- The Secretariat is working with the concerned countries to better understand the structure and the financing mechanisms of different community health actors and identify potential gaps.
- With the help of the catalytic CSCE Strategic Initiative funding, Gavi is tailoring its processes to the needs of CSOs and local partners and strengthen impact at the local and community level.
- The Secretariat is working to strengthen engagement with the CSO Steering Committee and wider CSO constituency, as part of wider Partner Engagement.

Observations

Despite existing mitigations, the risk of operational complexity, legal, reputational and financial risks, in engaging and managing CSOs and local partners remain high. Given the important role of CSOs and local partners in the Alliance ability to deliver its mission in-country, there is an opportunity to further reduce risks in the short-term through acceleration of implementation of the strategic and operational frameworks, structured knowledge sharing and collaboration with other organizations like the Global Fund.



Cybersecurity Risk

Risk that large cyber-attack or breach of data privacy significantly compromises critical information systems or data

The Secretariat increasingly makes use of IT systems, software applications and centralized cloud-based data repositories to support collaboration and maximize work efficiency. While the increasing reliance on technology mitigates risks related to human error and process delays, it also exposes the Secretariat to cybersecurity risk. A large cyber-attack, phishing and malware could lead to theft of sensitive or confidential data. This could also lead to business disruption, interrupting the Alliance's operations for a prolonged period, due to inability to maintain communications and coordination internally and externally, inability to complete disbursements to countries, partners or employees, or inability to approve, manage, and monitor grants. That risk could also have financial, legal and reputational impacts. Despite strong mitigating actions implemented, with many external factors beyond Gavi's control, the risk level remains HIGH due to increasing number of cyber-attacks and to a substantial increase in Gavi's financial resources.



Root Causes

- Vulnerabilities within Gavi's internal systems, data and processes contribute to the risk of a cyber-attack or data breach, including end-user behaviour related to remote working.
- Increases in the amount and accessibility of shared sensitive information, such as the use of cloud computing, raise the risk exposure.
- The level of cyber-attacks' sophistication as well as the ease of access to critical IT systems and data are increasing due to the weaponization of generative AI technology.
- Globally, we see an increasing number of phishing, malware and ransomware.
- Gavi's risk exposure is increased due to its profile and mandate (international profile and financial resources). The organization is increasingly a target for cybercrime and espionage. Gavi's risk exposure is further increasing use of external suppliers.



Completed Mitigating Actions

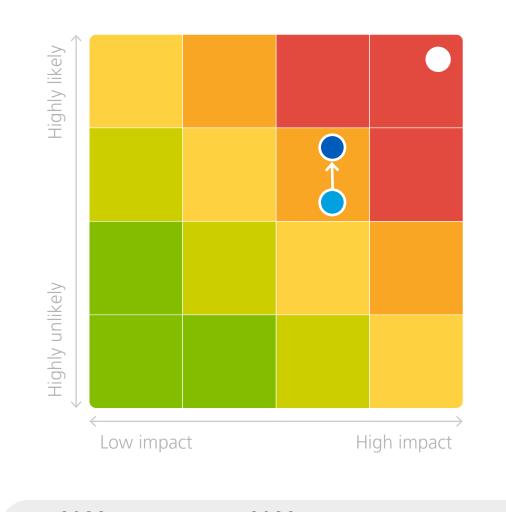
Strong Moderate Weak

- More efficient, effective and systematic controls have been implemented for an improved monitoring of Gavi's IT systems
- Additional cybersecurity initiatives such as mailbox protections have led to a substantial reduction in the amount of malicious and bulk inbound emails.
- Initiatives to increase user awareness include mandatory trainings and frequent engagement through different communication channels. Several phishing campaigns have been launched, with non-compliant users required to attend an awareness session.
- In case of supplier interruption or other data incident, a data back-up has been created to limit the impact on Gavi's operations.
- Business impact analysis was completed in October 2022 to identify impact of IT systems disruption on business operations. In the event of an incident, clear response plans have been developed across potential scenarios.
- Gavi has achieved compliance with ISO 27001, the international standard to manage information security. Ten new controls have been implemented as part of ongoing alignment with new requirements.
- A dedicated insurance has been subscribed to cover legal liability for potential financial losses resulting from violation of personal rights caused by breaches of data protection regulations.

Risk Coordinator

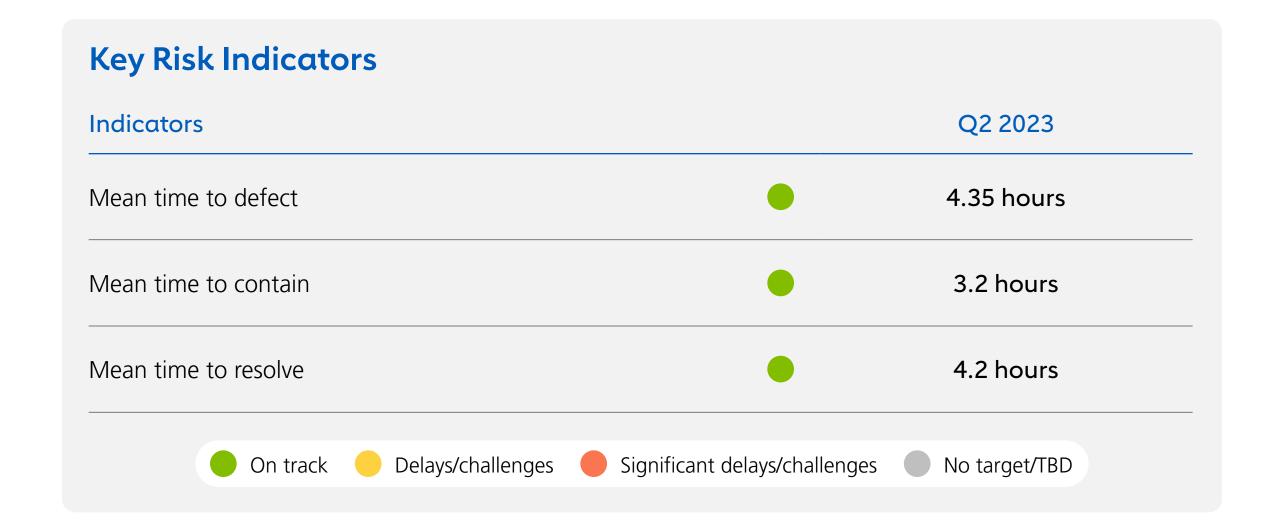
Public Engagement and Information Services Knowledge Management and Technology Solutions

Residual risk level HIGH Outlook Level of external influence **MEDIUM**





2023 Gross Risk Level



Potential impact of the risk on strategic goals and corporate priorities * 5.1 Strategic Goals **2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria Improve sustainability of immunisation programmes **4** Drive C19 programme 5 Invigorate our culture and the Alliance Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1



Ongoing Mitigating Actions

On track Delays/challenges

• Significant efforts involving multiple stakeholders across the organization (such as Legal, Risk and KMTS teams) are ongoing to review and update Gavi policies related to cybersecurity and data (e.g. Security policy, Data classification and retention).



Planned Mitigating Actions

 As part of continuing alignment with ISO 27001, work is planned to ensure that the Washington DC new premises meet the standards.



Observations

Despite strong mitigations implemented to reduce the risk of cybersecurity, the risk likelihood requires close monitoring due to a rise in cyber-attacks globally and a substantial increase in the Alliance financial resources. To further mitigate this risk, additional security enhancements shall continue to be delivered as part of the Cybersecurity programme overseen by the Cybersecurity Steering Committee.

Secretariat capacity and capabilities versus future corporate priorities and growing complexity

Secretariat capacity, capabilities and processes may be inadequate to deliver on future corporate priorities in an increasingly complex environment

The risk that Gavi's current operating model (designed to fit its original more simple business activities with high reliance on Alliance partners), including competencies, processes and resourcing across the Alliance, will not be fit for delivering on future priorities remains **HIGH** due to complexity of Secretariat operations, increasing oversight responsibilities from Secretariat, increased volume of work, more complex sustainable coverage and equity objectives, changing organizational environment and staff attrition. The risk may have significant organizational impacts such as staff health and wellbeing issues, staff demotivation, loss of knowledge and can ultimately lead to organizational ineffectiveness and delays in corporate priorities.



Root Causes

- Current risk contributors include a heightened workload across the Secretariat to accelerate the zero-dose agenda, and to continue to support the delivery of COVID-19 vaccines and integration of the COVAX Facility into Gavi core.
- Gavi's current systems have become complex with laboursome processes and approvals combined with multiple funding levers and funding buckets and not always clear roles and responsibilities. Over the years, the model of a lean Secretariat – that has been very efficient in the past for quick decision-making, does no longer fit Gavi's evolved mandate and strategy, growing programmes and increasingly complex processes and operations.
- Multiple leadership and team transitions as well as departure of key staff from the organization for voluntary or unvoluntary reason including resignation, termination, retirement are other risk contributors that might lead to disruptions and loss of institutional knowledge. For instance, there is a risk of losing key staff to complete COVAX work in 2023 and maintain preparedness for future pandemics.
- Vulnerabilities within Gavi's organizational culture also contribute to the risk.

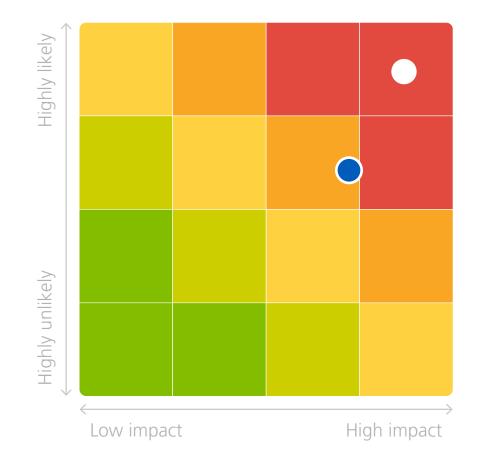


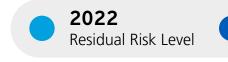
- Strong and frequent engagement between the Senior Leadership Team and Interim CEO to discuss secretariat capacity and capabilities in light of corporate priorities.
- Implementation of a Health and Wellbeing Committee to raise awareness and accelerate leadership actions for staff health and wellbeing.
- Streamlining of senior leadership reporting lines as part of the One Gavi approach with clear roles and responsibilities across the Senior Leadership Team.
- Evaluation of support needed by Country Programmes Delivery team for the Covid-19 programme resulting from COVAX integration into Gavi core.
- Work prioritization by Country Programmes
 Delivery teams with a focus on countries with lowest coverage and highest programmatic need.

Risk Coordinator

Human Resources

Residual risk level	HIGH
Outlook	=
Level of external influence	LOW









Key Risk Indicators Indicators H1 2023 **Target** COVAX COVAX Gavi core Gavi core Filled roles vs. approved resource 90% envelope (staff & consultant) 87% 94% Voluntary attrition rate of staff 5% TBD Net Promoter Score 74% (2022) 80% Delays/challenges Significant delays/challenges No target/TBD

Potential impact of the risk on strategic goals and corporate priorities * **5.1 Strategic Goals 2023 Corporate Priorities** Restore RI and reach ZD Introduce and scale up vaccines 2 Relaunch HPV Strengthen health systems to increase equity in immunisation 3 Launch Malaria **4** Drive C19 programme Improve sustainability of immunisation programmes 5 Invigorate our culture and the Alliance Ensure healthy markets for vaccines and related products 6 Innovate, Integrate and Improve Negligible impact Mild impact Moderate impact Significant impact Severe impact NA Not applicable * Assumptions for impact assessment are available in Section 3.1

Ongoing Mitigating Actions

On track Delays/challenges

- Gavi's Operational Excellence (OE) focuses on organizational improvements and innovations and is playing a central role in the optimisation of organisational design, structure, culture, business processes, and operational effectiveness.
- A multi-year EVOLVE programme is being implemented to engineer simpler and integrated country programme portfolio management processes and improve grant application and approval, as well as disbursement processes.
- Human Resources team in collaboration with business teams are managing retention issues and COVAX integration impact on the organization.
- The organization is also accelerating recruitments to fill in vacant positions including at senior leadership levels. Recruitments for future CEO and General Counsel have been launched.
- Some of Gavi's teams are being restructured with clarification of roles and responsibilities to seamlessly execute and enable improved prioritization.
- Human Resources are prioritizing understanding and improvement of organizational culture building on recent staff survey on organizational culture.
- To reduce institutional knowledge loss, learnings and knowledge are being documented to extent possible.

Observations

Despite mitigations implemented, risk related to secretariat capacity and capabilities remain high. Given the significant impact the risk might have on the Alliance ability to deliver on its corporate priorities and strategic goals, close monitoring of successful implementation of transformational projects (mitigating actions) will be necessary.

2.2 Other relevant Risks to monitor

Health Systems Strengthening (HSS)

Risk Coordinator

Health Systems & Immunization Strengthening Team

Residual risk level HIGH Outlook Level of external influence **MEDIUM**

- The risk that Health Systems Investments do not materially improve programmatic outcomes remains HIGH despite a decreasing trend as countries pivot back to routine immunisation. HSS risk could significantly affect the achievement of quality, efficiency and equity of immunization programmes.
- Major disruptions caused by COVID-19 pandemic and other events (e.g. internal conflicts) in several larger Gavisupported countries have resulted in significant delays in programming of new Gavi support for health systems as well as slowed down implementation of existing grants. The COVID-19 pandemic has also resulted in backsliding of immunisation coverage in many countries, that need to catch-up those children missed during the pandemic as well as working to reach zero-dose children within their available resource envelopes.
- However, 2023 is on track to be a record year for new HSS and EAF applications, with around half of countries developing HSS/EAF grants in 2023 and approximately 45% of HSS/EAF investments focused on ZD.

Although disbursement and utilisation of Gavi cash grants are at record highs in absolute terms, there is a risk that countries are unable to absorb all HSIS and COVID-19 Delivery Support (CDS) resources.

Mitigating Actions

- The Secretariat has designed plans for increasing cash absorption and providing surge leadership and management capacity (LMC) support to several countries. Furthermore, an extension of CDS implementation until 2025 was approved at the June 2023 Board meeting, facilitating more deliberate alignment between CDS and HSS resources. LMC and FPP surge support and Zero-Dose technical assistance have also been launched to address stretched EPI and workforce capacities.
- As part of Gavi 6.0 strategy, Gavi is planning to develop an HSS Strategy to align with the Board, Alliance, and key stakeholders on the vision, objectives, approach and measurement for Gavi's investments in HSS. Moreover, HSS application requirements are to be reviewed to simplify the application process.
- HSS efforts should continue to be prioritized to support the Alliance efforts in improving immunization coverage.

Data quality and availability

Risk Coordinator

Measurement, Evaluation and Learning Team

Residual risk level	HIGH
Outlook	=
Level of external influence	MEDIUM

- The risk that poor or lack of data may affect the ability of the Alliance to identify and reach ZD children, implement effective interventions and demonstrate impact remains HIGH as long as strong mitigations are still ongoing. The Alliance face risks associated with working in settings with relatively weak data systems, particularly in very poor or fragile countries.
- Analysis of data needs required in Gavi 5.0 had identified significant gaps in the data required for identification of missed communities such as uncoordinated data tools and systems as well as limited, incomplete or outdated data.
- The Alliance poor culture around effective review, sharing and use of data impacts its ability to make best datadriven decisions to influence immunization programmes. Notable gaps include the lack of centralized mechanism to collect data sets in standardized formats and inefficiencies in existing data systems and processes.
- The materialization of the risk may affect the ability of the Alliance to identify, characterize, and reach unvaccinated populations and translate data into targeted and tailored strategies. The risk can also negatively impact Gavi's ability to execute core financing business, including contract

processing as well as tracking and reporting on investment portfolios.

 More granular, sub-national, geospatial, qualitative and timely data are required to improve monitoring and evaluation of immunization programmes and make relevant data-driven decisions.

- The Measurement, Evaluation and Learning (MEL) team has contributed to grant management efforts (EVOLVE) as well as SAP implementation. It has also leveraged existing fora, processes and leadership support to promote use and learning from data as part of the operationalization of the Learning System Strategy. MEL and KMTS teams have been brought together under the Chief Engagement & Information Officer to ensure a streamlined approach to the OE initiative of Data & Analytics.
- The Monitoring and Performance Management (MPM) dashboard has improved access and use of programmatic data, and the new Gavi Balanced Scorecard facilitates regular holistic reviews by senior leadership and governance committees. A letter co-signed by Gavi Secretariat, WHO and UNICEF is being sent to countries in September 2023 requesting that they submit timely data on outbreaks, monthly immunisation coverage, and monthly vaccine stock to WHO or UNICEF. Additionally, a provider will be contracted to conduct Post Campaign Coverage Surveys.













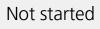














Sub-optimally planned and implemented campaigns

Risk Coordinator

Vaccine Programmes

Residual risk level	HIGH
Outlook	=
Level of external influence	MEDIUM

- The risk that sub-optimally planned and implemented vaccine campaigns undermine the capacity to manage and deliver routine health and immunisation **services is rated as HIGH**. While the risk level remains High, attention has been brought to the need to prioritize Measles campaigns given the current immunity gap.
- The lingering impact of C19 along with competing priorities at country level have affected countries' ability to implement high quality campaigns. Pressure to implement quickly may result in insufficient consideration on effective integration or focus on reaching missed and zero-dose communities. The diversion of management capacity, front line workers and infrastructure (e.g., supply chain, transport) to implement campaigns are other risk drivers. This is to recognize that some countries would have to focus on implementing timely and quality campaigns to effectively reduce the number of suscepttibles and avoid large outbreaks.
- Poor planning and management undermine quality campaigns, which could result in low coverage or delay and reduce the impact campaigns related to HPV, malaria, and other diseases. In the past 12 months, 32 Gavisupported countries experienced large and disruptive measles outbreaks, almost twice the number in the preceding 12-month period.

Mitigating Actions

- Country-tailored strategies have been implemented, such as the Periodic Intensification of Routine Immunization (PIRI). Other mitigations include improved integration including co-delivery of multiple antigens and health interventions (e.g. HSS support), when feasible, into one campaign and leveraging country-level insights from monitoring agents.
- The Alliance has begun to operationalize support for timely preventative Measles campaigns to mitigate the risk of outbreaks. The Secretariat and Alliance Partners will reflect and align on the redesign and redefinition of quality preventative campaigns. Other planned mitigations include the timely approval and disbursement of funds and providing technical assistance to countries. Further collaboration with the Health Campaign Effectiveness (HCE) Coalition is planned.
- The risk requires close monitoring by the M&RP and Alliance partners given the strategy to address measles outbreaks and the revision of the risk appetite of VPD outbreaks from Balanced to Low. (See Risk Number 2 for further details on very high risk of VPD outbreaks)

Adverse events of vaccines and erosion of Gavi reputation

Risk Coordinator

Vaccine Markets and Health Safety

Residual risk level	MEDIUM
Outlook	
Level of external influence	MEDIUM

- The risk that adverse events following immunisation (AEFIs) may negatively impact Gavi's reputation, trust in the immunization system leading to decrease vaccine demand is rated as MEDIUM. While the risk appetite for this new risk is not yet defined, the appetite for risks affecting Gavi's image and confidence of its stakeholders is rated as Balanced, which is in-line with the residual risk level.
- Vaccines that cause adverse events following immunisation (AEFIs) may impact Gavi's ability to deliver on its mission and vaccination objectives. AEFIs are more likely to occur if used prior to regulatory approval, when limited safety data is available or contain manufacturing errors. Media coverage or the spread of misinformation can amplify level of impact to Gavi.
- The risk is seen as very low in terms of likelihood, and in 2023 no major AEFI occurrences have been reported. The impact has been assessed as severe as the materialization of the risk could lead to a large reduction in demand, reputational damage or financial liability. Gavi may be impacted regardless of whether the concerned vaccine is part of Gavi's existing portfolio given its position within the GH landscape.

- For routine immunization (RI) vaccines, active AEFI surveillance practices at the country level and AEFI reporting and response have been implemented to identify and escalate incidents. For COVAX, an innovative No Fault Compensation (NFC) Programme was designed. The NFC Programme was the first global vaccine injury compensation mechanism, providing a lump sum compensation to any individual in the COVAX AMC who suffers a serious adverse event.
- The third window of CDS, which has been extended until the end of 2025, contains strengthening AEFI surveillance and monitoring as part of its objectives.
- Despite the low likelihood, the risk requires close monitoring given the potential severity if it were to materialize. Further analysis is required to determine the associated risk appetite and whether additional mitigation measures are required.







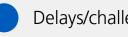






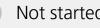












Finance operations challenges

Risk Coordinator

Finance

Residual risk level	HIGH
Outlook	=
Level of external influence	LOW

- The risk of operational limitations or failures resulting from inadequate or failed internal processes, people and systems is HIGH. Operational challenges resulting from inadequate or failed internal processes, people and systems can undermine Gavi's financial operations and ultimately lead to financial losses. Issues related to Gavi's financial platform (SAP) accessibility, functioning and security could prevent or delay payments to countries, third parties and secretariat staff. Moreover, finance staff turnover and limited capacity to address increasing stakeholder requirements could lead to operational overload. Insufficient automation of financial systems is likely to increase financial mistakes and erroneous data.
- If operational failures do occur, it may prevent Gavi from meeting its statutory reporting requirements or lead to inaccurate forecasts or grant allocation. Despite existing mitigations, potential risk impact has been assessed as significant and likelihood of the risk materializing has been assessed as probable given insufficient automation and complexity of financial processes as well as capacity issues in Finance team.

Mitigating Actions

- Given the importance of accurate financial data and reporting, a Risk and Controls Matrix is used to monitor existing controls and review control evidence. Other mitigations include business continuity plans, systems run on the cloud to enable data restoration, internal rotation for critical activities, analytical reviews to mitigate large unexplained variances and an SAP continuous improvement approach.
- Formalized succession plans are to be created within the Finance department. Finance also plans to invest in new system and process developments that will simplify work and provide team confidence that workload will improve.
- Further process and control improvements are recommended in addition to current mitigations. Automating or streamlining manual processes and controls should be prioritized to reduce the risk of human error.

Self-Financing Participants' Close-out

Risk Coordinator

Vaccine Market and Health Security Management

Residual risk level	MEDIUM
Outlook	V
Level of external influence	MEDIUM

- Risk related to unilateral close-out by SFP countries that could lead to legal, reputational and financial challenges is rated as MEDIUM.
- While there is no defined risk appetite for this risk, its level of uncertainty has been reduced following the closure of the COVAX Facility in September 2023. At that time, 10 SFP countries had not signed a Termination Agreement and were unilaterally closed-out. The amount of SFP liabilities associated with these countries is 66.4M USD.
- Unilateral close-outs by SFP countries might also lead to legal and reputational risks in case of SFP countries' disagreement with the terms of unilateral close out and willingness to recover amounts retained by Gavi. Knowing that Gavi will only be responsible to pay a country its associated liability in case of successful legal challenge, the legal risk is considered low based on ongoing engagement with SFP countries and strength of Gavi's legal arguments. However, the reputational risk is considered as medium in case of legal challenges.

- A proactive engagement approach was taken with SFP countries, including involvement at the Gavi leadership level. Prior to closure, Termination Notices were sent to SFPs who had not yet signed a Termination Agreement. A media management plan on the SFP Close-out process was implemented. To address HR risks, a COVAX HR action plan was created, and a list of open positions was shared. Cash held on hand on behalf of SFPs exceeds liabilities and includes sufficient funds to absorb losses if there are successful legal challenges.
- A comprehensive approach has been taken to understand and assess the risks that Gavi faces from the ending of the COVAX Facility and the impact of potential unilateral SFP close-outs. The risk continues to be monitored by the SFP, Legal, Risk, Finance and Communications teams as the risk exposure remains post the closure of the COVAX Facility.
- Although the risk is tied to the COVAX Facility which is about to be integrated into Gavi core, it should be closely monitored in case of new developments and given its reputational, financial and legal impacts.









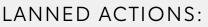














Treasury Risks (including Liquidity, Market and Credit risks)

Risk Coordinator

Finance

Residual risk level	MEDIUM
Outlook	
Level of external influence	MEDIUM

- The risk that liquidity, credit and market risks could negatively impact cash flows and ultimately Gavi's operations, activities and programmes is **MEDIUM** despite strong implemented mitigations
- The main risk drivers are external risk factors such as counterparty downgrades, banking failures and global economic trends that may create market, interest rate and Foreign Exchange (FX) rate volatility. Internal risk factors include Treasury team capacity overload, operational and oversight failures or weaknesses in controls, processes and policies.
- Should the risk materialize, there may be uncertain or reduced cash flows to finance Gavi's operations, activities and programmes (e.g. disruption in fund disbursements). This could lead to reputational damage and loss of confidence from partners and donors.

Mitigating Actions

- For credit risks, bank credit ratings are reviewed at least 💨 on a monthly basis. The Treasury policies that provide a framework for risk management (credit, liquidity and market risks) monitored on a monthly basis by the Treasury Risk Management Committee. For market risks, hedging instruments have been used on the majority of Gavi 5.0 funds. Diversification of financing and investment sources and market monitoring are other key mitigations. Governance mechanisms such as the Treasury policies and the Treasury Risk Management Committee have been implemented. Treasury policies are updated on a regular basis and address monitoring, reporting and decision processes.
- A Risk Committee was held in 2023 in response to turmoil in the banking industry. The Treasury team continues to monitor this risk and ensure that counterparty exposure and diversification are appropriately maintained.
- While the mitigations in place are strong, the risk shall be closely monitored given the potential for significant financial, reputational and programmatic impacts.

Gavi's Alliance health, capacities and capabilities

Risk Coordinator

Country Programmes Delivery

Residual risk level	MEDIUM
Outlook	V
Level of external influence	MEDIUM

- The risk of degraded Alliance health and insufficient Alliance capacities and capabilities is rated as **MEDIUM.** The risk has a decreasing trend due to proactive mitigations by Gavi and amongst Alliance Partners.
- Fragmentation and competition within the Global Health (GH) landscape and a lack of clarity on roles and responsibilities are key risk drivers. The creation of initiatives such as COVAX, Pandemic Prevention Preparedness and Response (PPPR) and Global Virtual Pooled Inventories (GVPI) also contribute to the complexity of Alliance dynamics. Other challenges include differing priorities, competing funding needs and potentially disruptive collaboration opportunities.
- The materialization of the risk may result in reduced trust, disagreements, weakened relationships and competition between Alliance Partners. Duplication of efforts between Partners could lead to ineffective Alliance interventions. Gavi's influence or credibility within the GH landscape and with other external stakeholders may be impacted and ultimately lead to loss of trust and confidence from donors and immunization community.

- An Alliance Leaders Group was launched between the Secretariat, WHO, UNICEF and World Bank which included discussions on Alliance ways of working and an agreement on operating principles. Gavi also signed a Memorandum of Understanding (MoU) for closer collaboration with African Union Commission. The Partners' Engagement Framework (PEF) model has focused on delivering more partner capacity directly to countries through increased PEF Targeted Country Assistance (TCA) funding in Gavi 5.0/5.1. PEF has further enhanced the effectiveness, efficiency and transparency of collaboration with core Partners (WHO, UNICEF, WB and CDC). In addition, the Partnerships Team and the High-Level Review Panel (HLRP) were merged into the Alliance Partnership and Performance Team (APPT).
- The Programme Support Team is to relaunch an Alliance Health survey to drive new actions to improve the health of the Alliance. Public Policy Engagement (PPE) is hiring a consultant on the global health architecture to further support engagement. Opportunities are being explored to enable Partners to present their work directly to the Gavi Board and Committees.
- The risk should be monitored closely as it might significantly affect the purpose, strategy and cohesion of the Alliance.

























Culture and unethical conduct

Risk Coordinator

Ethics, Risk and Compliance Office

Residual risk level		
Outlook		
Level of external influence	LOW	

- The risk of unethical behavior that can damage Gavi's reputation and result in loss of trust from donors, countries and the Alliance is rated HIGH. This new risk is being proactively addressed through organizational changes, policies and new mitigations.
- Factors that contribute to this risk are weak prevention strategies, unclear governance on ethics and compliance, capacity and weak speak-up culture. Organisational leadership transition, workforce planning and perceived employment uncertainties may elevate the risk further.
- Unethical behavior can damage Gavi's reputation and result in loss of trust from donors, countries and the Alliance. Absence of a culture of integrity may lead to operational inefficiencies, including higher turnover rates, challenges in attracting talents, increased HR and legal costs, and a lack of alignment with strategic objectives. The materialization of the risk can have long-lasting financial consequences as donors are increasingly focused on ensuring that Gavi maintains a healthy culture that aligns with legal and ethical standards. It can also impair Gavi's ability to function effectively and achieve its goals.

Mitigating Actions

- The Ethics, Risk and Compliance Office (ERCO) was established in 2023, and the position Chief Ethics, Risk and Compliance Office (CERCO) was created. An ERC Strategy has been developed, and a new ERC Charter outlining the mandate, terms of references and roles and responsibilities of the Gavi Alliance with respect to ERC has been recommended for approval to the Board. Human Resources (HR) team conducted Organizational Culture Inventory survey to identify behavioral norms and expectations and current strengths and challenges.
- A roadmap on ERC upcoming objectives will be prepared with each activity assigned an owner. The Ethics and Compliance program is to be launched as per the ERC Charter. The Donor Compliance Policy and Protection against Sexual Exploitation Abuse and Harassment (PSEAH) Action Plan and Policy are to be drafted and operationalized. Review of the Code of Conduct, Restrictive measures (Sanctions) Policy and whistleblower program are also part of ERCO objectives for 2024.
- While the risk is currently High, the range of activities planned for 2024 should help to further mitigate this risk.

Secretariat disruption

Risk Coordinator

Operations

Residual risk level	MEDIUM
Outlook	↓
Level of external influence	MEDIUM

- The risk of significant disruption of Secretariat operations due to unexpected events, incidents or crisis is MEDIUM. Despite its decreasing trend driven by strong mitigations such as ongoing building and implementation of crisis management framework, that risk requires a close monitoring given its huge potential impacts on the Alliance operations.
- The likelihood of an extreme event such as incident or loss of life during travel, force majeure situations (war, conflicts, pandemic) that may disrupt Gavi's operations is rated as possible. However, should the risk materialize, the impact would be severe and may hinder Gavi from delivering on its mission. Depending on the nature of the disruption, there could also be financial losses, recovery costs, interrupted assurance activities and the loss of donor and partner confidence.

- A full externally management test of cybersecurity response has been launched. Other completed mitigations include an ISO 27001 audit on security compliance, travel security trainings and further engagements between Senior Country Managers (SCMs) and the Security Team to understand better travel security issues. Capacity building efforts have also been made to upskill and support knowledge sharing across permanent resources.
- A Crisis Management Framework including a Policy, a Crisis Management Plan, Incident Response Plans (IRPs) and Business Continuity Plans is being established. Work is ongoing to further develop the IRPs and a readiness assessment and to deliver team trainings and IRP testing. A crisis management statement is also planned. Automated processes are being developed in light of increased security risks with travel related to the Zero-dose agenda. The Secretariat is also planning to apply for an ISO certification to recognize the quality of its crisis management framework.























2.3 ERCO achievements in 2023

During the transition period*, the Risk function has continued to deliver on its objectives. Despite reduced capacities, the Ethics, Risk and Compliance Office continued to engage actively with the business, identify and frame new risks, maintain awareness of existing risks, ensure adequate risk monitoring and follow up progress in mitigations.

Engagement on Gavi core

The Ethics, Risk and Compliance Office (ERCO) has strengthened collaboration with the Country Programmes Delivery (CPD) team on closer engagement for an improved monitoring of programmatic risks. This will include monthly updates on programmatic risks with each CPD director and quarterly touchpoints with CPD management team on country risk profile with a focus on the eighteen countries of concern. Moreover, the development of a risk management dashboard to monitor programmatic risks through the Secretariat's Monitoring and Performance Management (MPM) tool is progressing. ERCO has continued to support EVOLVE risk management efforts with the creation of a project risk register. As next steps, it will identify and monitor potential risks generated by EVOLVE at grant management and organization levels. Furthermore, the Ethics, Risk and Compliance Office has provided guidance and feedback on the development of a CSOs risk management strategy, as well as a risk

register to be used to assess CSO specific risks such as Sexual, Exploitation, Abuse and Harassment (SEAH) risks. Meanwhile, Ethics, Risk and Compliance Office has led Gavi's participation to SEAH workshop gathering public health partners.

ERCO has been working with the Finance team to monitor closely credit, liquidity, and market risks, review its Finance Risk and Control Matrix – which defines key internal controls in finance operations, and update its Treasury Policies. ERCO is also a member of the standing Treasury risk committee.

ERCO has engaged with the Audit & Investigations teams on the advisory on COVAX integration and on thematic internal audits, including on risk aware culture and on SEAH. As a member of the Crisis Management Team, Ethics, Risk and Compliance Office has also been reviewing Gavi's Incident Response Plans.

Finally, it has provided insightful updates and information on Gavi's risk management approach as part of the Multilateral Organisation Performance Assessment Network (MOPAN) and the UK Foreign, Commonwealth & Development Office (FCDO) evaluations.

Engagement on COVAX

ERCO is routinely participating in COVAX Facility Leadership Team (FLT) meetings to provide bi-monthly reviews of the dynamically evolving COVAX risk profile. In addition to the FLT, regular touchpoints have been organised to monitor closely COVAX financial risks (e.g. cost-sharing, SFP close-outs). ERCO has also provided guidance to the Delivery team and supported Portfolio Financial Management (PFM) team on the creation and onboarding of a new Monitoring Agents (MAs) risk assessment tool, designed to streamline, standardize and leverage COVAX risks identified by MAs for an improved monitoring of COVAX fiduciary risks. Furthermore, ERCO continues to be engaged in discussions on a potential Pandemic Prevention Preparedness and Response (PPPR) mechanism, drawing on learnings from the COVAX Facility from a risk management and a risk sharing perspective.

Updates on Risk Team and clarity on Mandate

A newly elevated Chief Ethics, Risk and Compliance Officer (CERCO) position was created, with the new CERCO being onboarded mid-May 2023. Accountability for implementation and integration of Gavi's Ethics, Risk and Compliance programmes rests with Gavi's Chief Executive Officer, Chief Operating Officer, and the senior leadership team (SLT). The CERCO is, inter alia, accountable for increasing transparency around key risks across the Alliance and the Secretariat, enable cross-enterprise collaboration to mitigate risks and prioritize resources effectively, and to support management in effectively mitigating strategic, financial, operational and programme risks. In addition, building the risk team is a key priority. To this end, two new full-time positions have been approved and recruitments are completed.

The increased capacity will enable ERCO to address growing demands from the business, identify new risks early-on, increase understanding and awareness about risks in the organization, and operationalize the Board approved risk appetite statement.

^{*} The transition period has started since the departure of the former Head of Risk in December 2022 and ended with the onboarding of the new Chief Ethics, Risk and Compliance Officer from May 2023.

Annexes



Doc 08 - Annex A

3.1 Methodology

This year's report is based on a **bottom-up risk assessment using multiple quantitative and qualitative data** from selected internal and external sources. This approach serves to identify the Alliance most critical risks, assess effectiveness of existing mitigations and determine further actions needed to improve risk management across the Alliance.

FIGURE 2

Risk Assessment Sources

Stakeholders' consultation

32

Teams have identified

153 risks related to
their team priorities



Gavi leadership members have been consulted



Desk Review

90

Documents with qualitative and quantitative data have been reviewed



The Alliance risk assessment is:



Inclusive – with several rounds of consultations with Secretariat Departments and Gavi's Leadership Teams.



Methodical – Our risk selection and assessment is based on a 3-steps selection process to filter top risks for Board oversight.



Reliable Assumptions – The basis of our risk assessment is done in close consultations with Risk Owners and the Senior Leadership Team.



Trackable – Data and processes supporting our risk assessment outcome are well documented and recorded for sake of audit trail.

FIGURE 3

Bottom-up Risk Identification and Assessment



Board discussion – Gavi's AFC and Board

Oversees the top risks and Senior Leadership actions/decisions based on presented risk information.



Leadership review – Gavi's Senior Leadership Team

Reviews, discusses and approves the selection of the top 10-20 risk and/or risk updates, approves assessment of mitigation effectiveness and initiates actions/activities based on risk information as required.



Risk Selection - ERCO

Reviews and consolidates identified risks based on top risks definition and criteria. ERCO selects 10 to 15 top risks*, assesses effectiveness of mitigating actions and determines further actions needed.



Risk Identification – Gavi's Teams / Departments

Identify, assess and report risks related to their 2023 team priorities and risks related to Gavi's strategic ambitions and goals.

* In 2023 the total number of risks reported was 193 - prior to risks reconciliation between TPM and other sources.

Key Changes in the 2023 Annual Risk and Assurance Report



Standardized annual risk reporting process involving active engagement with Risk Owners and Alliance Partners and in-depth analysis of qualitative and quantitative data to identify top risks.





Risk assessment methodology –

Assessment criteria for risk impact and likelihood have been redefined to align with Gavi's context (see next page):

- The risk level represents the **residual exposure**, taking into account the effectiveness of existing mitigation strategies to prevent risks from occurring (thereby reducing the likelihood), as well as to detect and be prepared to react once/if they materialise (thereby reducing the potential impact).
- Each level of risk likelihood (i.e. unlikely, possible, probable and very likely) corresponds to a specific range of occurrence probability.
- Overall risk impact is calculated based on the weighted average of four criteria relevant to Gavi's business model: programmatic, financial, reputational and organizational impacts. The weight of each criteria depends on the type of risk and has been validated and reviewed by the ERCO and risk coordinators.







Weighted average of:

- Programmatic impacts
- Reputational impacts
- Financial impacts
- Organizational impacts



Selection of top risks: Following consultations with Gavi's senior leaders, review of TPM risk catalogue and other relevant documentation, SLT together with ERCO has selected the top risks using the following criteria:

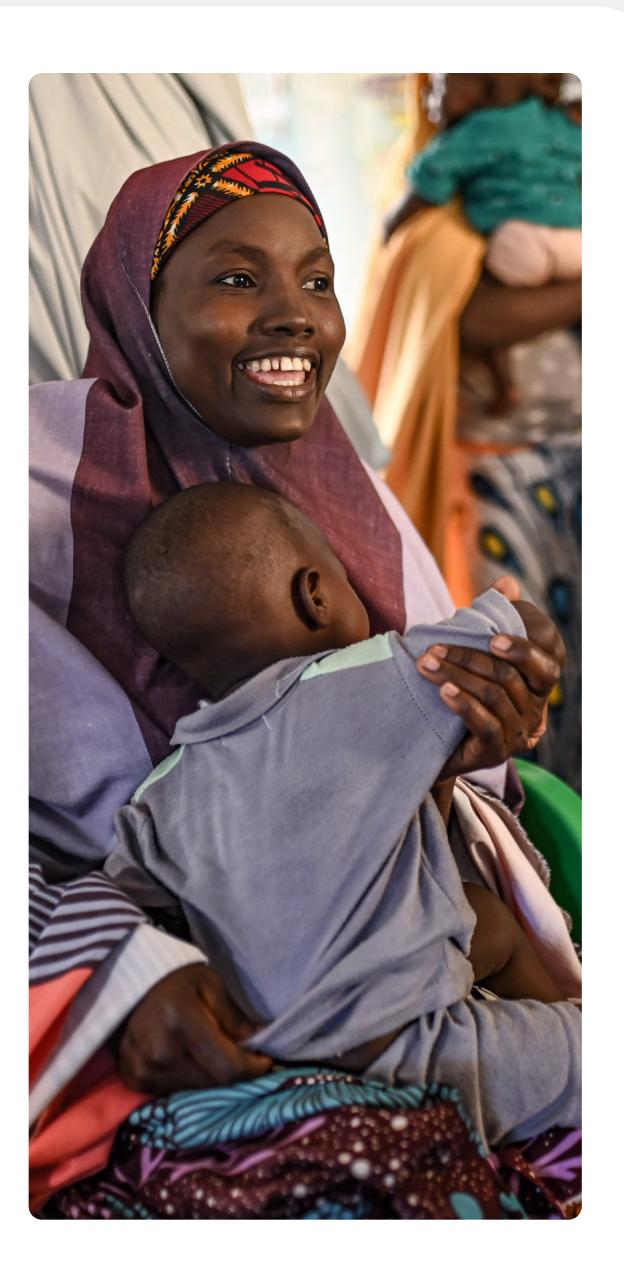
- Residual risk level,
- External trends and related influence on risk level,
- Impact of the risk on ability to achieve strategic goals and corporate priorities,
- Effectiveness of mitigating measures.



A report focused on Top 10 risks that could potentially have an impact on the ability of the Alliance to achieve its mission and strategic goals and Top **20** risks that are considered relevant to monitor, using the selection criteria listed above.



A report reviewed and signed off by the Senior Leadership Team, CERCO and **CEO**.



2023 Annual Risk and Assurance Report 3.1 Methodology

* The weight of each criteria depends on the type of risk and has been validated and reviewed by ERCO and risk owners

Assumptions for Risk Assessment

RISK LEVEL



LIKELIHOOD



IMPACT

Doc 08 - Annex A

Likelihood	Occurrence Probability
Unlikely	≤10%
Possible	11-49%
Likely	50-80%
Very Likely	≥81%

	WEIGHTED AVERAGE OF			
Impact	Programmatic *	Financial *	Reputational*	Organizational*
Mild	Mild programmatic impact with almost no effect on programme delivery, timeliness and quality, on coverage and on VFM	Minor exposure inferior to 5 m EUR	Short-term local or national adverse media attention, not requiring a reactive statement	Minor impact on our organizational capacity and capabilities to deliver on our objectives (Capacities issues that remain manageable at team's level)
Moderate	Moderate programmatic impact affecting programme delivery, timeliness and quality, immunisation coverage and VFM to a manageable extent.	Moderate exposure between 5 m EUR and 10 m EUR	 Longer-term national or short-term regional adverse media attention potentially requiring a reactive statement Relationships with governments, key stakeholders 	Moderate impact on our organizations capacity and capabilities to deliver on our objectives (e.g. Limited capacities leading to reorganization of several teams and to manageable delays in work delivery)
Significant	Significant impact drastically limiting programme delivery, timeliness and quality, and leading to insufficient immunisation coverage and poor VFM.	Major exposure above 10 m EUR to 25 m EUR	 Longer-term regional adverse media attention, requiring a statement and an issue management plan Negative reaction from regional or national authorities and officials Relationships with stakeholders affected, namely donors Relationships with potential donors / investors affected 	Major impact on our organizational capacity and capabilities to deliver on our objectives (e.g loss of HR resources leading to stretched capacities, overloasignificant delays in work delivery and massive teams' reorganization)
Severe	Severe programmatic impact leading to impossibility to deliver our immunisation programmes with the quality required and on a timely manner (unrecoverable deadlines)	Extreme exposure above 25 m EUR	 International adverse media attention, requiring active issue management Negative reaction from authorities and high-ranking officials across multiple countries Relationships with and/or attractiveness of donors affected significantly 	Extreme impact on our organizational capacity and capabilities to deliver on our objectives (e.g. Secretariat's activities disruptions affecting drastically our programmes delivery)

Top Risks Selection Criteria



Residual Risk Level The residual risk level is the risk exposure after considering the effectiveness of existing mitigation strategies to prevent the risks from occurring (thereby reducing the likelihood), as well as to detect and be prepared to react once or if they materialise (thereby reducing the potential impact).



Level of external influence / trends*

The level of external factors or circumstances that impact the risk level rated on a three-.point scale: Low, Medium or High. Low level of impact of external factors may be less resource heavy or faster to mitigate, and high level of external influence may be longer and require more resources or strong and sustained long term mitigation strategies.



Impact on strategic goals*

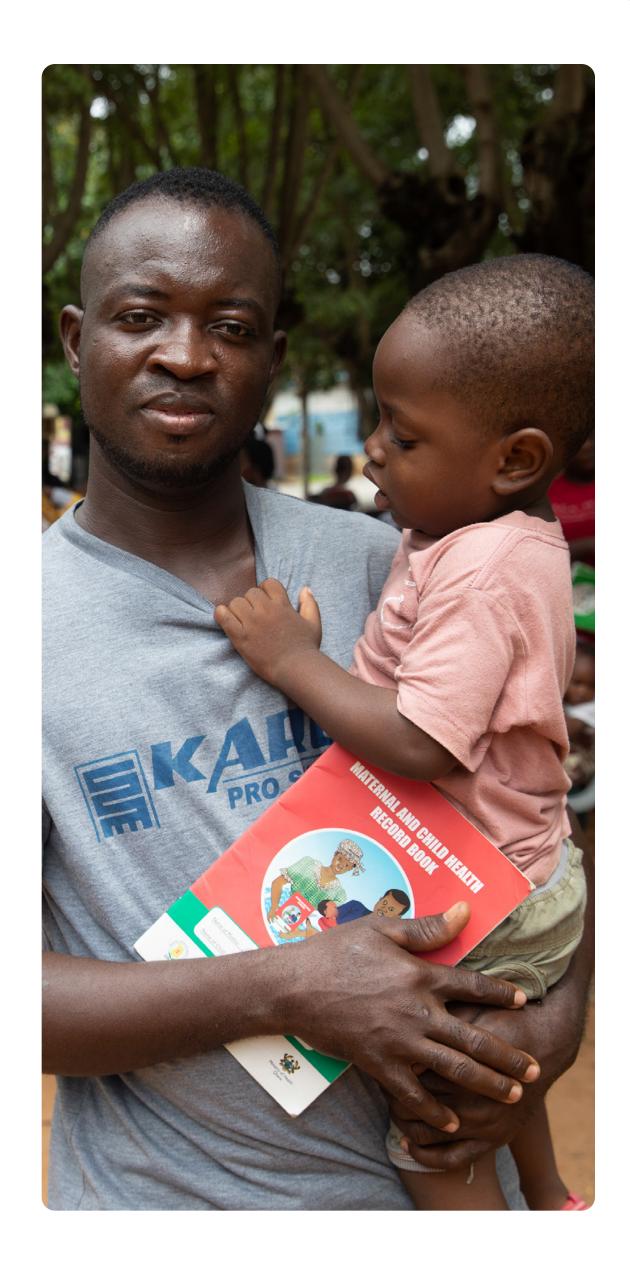
The extent to which a risk affects the Alliance's ability to deliver on its strategic goals and corporate priorities is a key selection criteria. This helps determine the amount of efforts and the level of urgency in addressing the risks.



Mitigating actions

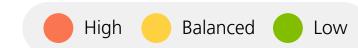
Mitigations are split into three categories: completed mitigations (i.e. already implemented), ongoing mitigations (i.e. not ended) and planned mitigations (i.e. not started).

Mitigation effectiveness is assessed based on the impact that the mitigation has in reducing the risk. It is a three-points scale (Weak, Medium and Strong) assessed only for completed mitigations. Ongoing mitigations can either be on track or delayed in case of challenges in their implementation.



Doc 08 - Annex A

3.2 Gavi's Risk Appetite Statement approved by the Board in 2021



The amount of risk the Alliance is willing to take, accept, or tolerate to achieve its goals

The Alliance is accepting to face risks required to achieve its goals, enabled by robust risk management to ensure these stay within the Board-approved risk appetite

Mission

- The Alliance embraces the need to take risk to achieve its ambitious mission of leaving no-one behind with immunisation in the world's poorest countries
- It acknowledges risks inherent in its operating model relying on many partners and in its business model requiring country ownership
- It acknowledges that during the COVID-19 crisis risks may increasingly materialise, and is willing to take risk needed to respond flexibly and timely to special needs
- It understands that operating the COVAX Facility carries risks worth taking, and seeks to find the right balance to minimise risks to core resources and programmes

Strategic Goals

The Alliance adopts an overall high risk appetite to achieve its strategic goals, acknowledging the aspirational ambition of the Gavi 5.0 strategy, requiring more and novel support to countries to reach missed communities and zero-dose children in hard-to-reach areas and challenging operating environments

1

INTRODUCE AND SCALE UP VACCINES

- Risks required to introduce and scale up coverage in fragile/emergency settings
- Risks required for equitable allocation and timely delivery of COVID-19 vaccines
- Vaccine-preventable disease outbreaks
- Vaccine introduction decisions exacerbating inequities or affecting sustainability
- Campaigns undermining routine immunisation or being of low quality

2 STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION

- Risks required to strengthen health systems and increase equity
- Risks of working with new partners
- Risks of exploring innovative strategies
- Building immunisation-critical management capacity in-country
- Improving data quality to find and target zero-dose children
- COVID19 roll-out adversely affecting routine immunisation or missed opportunities for synergies
- Fraudulent misuse of Gavi support
- Drop or insufficient increase in vaccine demand and confidence
- Weak systems jeopardising vaccine and immunisation safety

3 IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES

- Countries transitioning without sufficient financial and programmatic capacity
- Significant reduction in performance post-transition
- Drop in political will and social commitment for immunisation
- Countries defaulting on co-financing obligations

4 ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS

- Risks required to transform markets
- Risks required to incentivise innovation for vaccine development and scale up of related products
- Supply shortages impacting existing programmes
- Risks required for securing access to and sufficient supply of safe and efficacious COVID-19 vaccines

Organisation

The Alliance has overall a lower appetite for organisational risks that could impede its ability to deliver on the mission, while recognising the risks inherent in having a lean Secretariat without in-country presence and reliance on many partners

OPERATIONAL RISK

- Quality and robustness of Secretariat processes, facilities and business continuity
- Critical information systems or data being compromised
- Risks related to staff health and safety, engagement and capacity, including harassment and exclusion

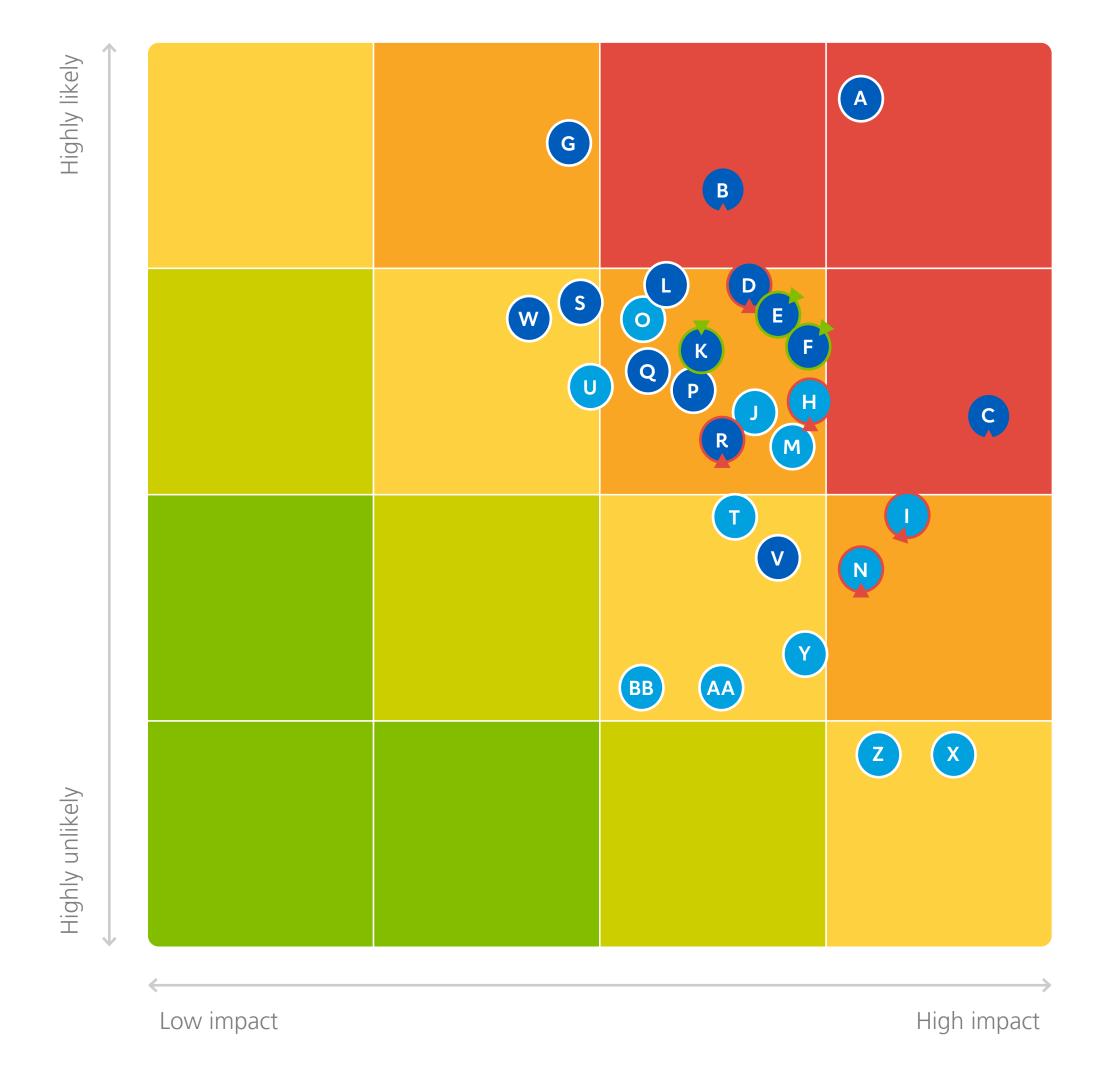
PERFORMANCE RISK AND OVERSIGHT

- Risks related to the capacity and performance of Alliance partners
- Risks related to the increasing complexity of managing many partners at country level
- Risks related to grant performance in-country
- Risks undermining accountability and transparency

REPUTATIONAL, FUNDING AND FINANCIAL RISK

- Risks required for attracting new donors
- Risks affecting Gavi's image and confidence of its stakeholders
- Immunisation becoming a lower priority on policy agendas
- Risks affecting the sustainability of donor funding
- Risks affecting Gavi's finances (accounting, foreign exchange, credit, liquidity, financial market and internal fraud risk)
- Forecasting variability reducing manufacturer or donor confidence

3.3 Last year's Top Risk Profile



A	Country management capacity			
В	Sustainable transition			
С	Insufficient demand			
HIC	GH RISKS			
D	VPD outbreaks			
E	COVAX delivery			
F	COVAX supply			
G	Misuse by countries			
Н	Secretariat capacity			
ı	Secretariat disruption			
J	Cyber-attack			
K	Data on zero-dose			
L	Polio immunisation			
M	Partner capacity			
N	Donor support			

0	Forecasting variability
P	Sub-optimally planned campaigns
Q	Global supply shortages
R	Health systems strengthening
MEI	DIUM RISKS
S	External programme disruption
Т	Conflicting Board priorities
U	Expanding partnership complexity
V	Unresolved co-financing default
W	Closed vial wastage
X	Board confidence
Y	Misuse by partner
Z	Misuse by Secretariat
AA	Leadership succession
BB	Donor grant fulfilment

Programmatic risk Corporate risk Recent evolution

Likelihood of occurrence, given preventive mitigation in place to address the potential causes

Potential impact on the ability of the Alliance to achieve the Gavi mission, given reactive mitigation in place to address the potential consequences once the risk materialises

3.4 Acronyms

3LOD	Three Lines of Defense
AEFI	Adverse Event Following Immunization
AFC	Audit and Finance Committee
Al	Artificial Intelligence
AMC	Advance Market Commitment
APPT	Alliance Partnerships and Performance Team
AT	Accelerated Transition
	_
ATT	Alliance Technical Team
AVMA	African Vaccine Manufacturing Accelerator
C19	Coronavirus Disease 2019
CDC	Centers for Disease Control and Prevention
CDS	Country Delivery Support
CEO	Chief Executive Officer
CERCO	Chief Ethics, Risk and Compliance Officer
COVAX	COVID-19 Vaccines Global Access
COVID-19	Coronavirus Disease 2019

CPD	Country Programmes Delivery
CSCE	Civil Society and Community Engagement
CSO	Civil Society Organizations
DMARC	Domain-based Message Authentication, Reporting and Conformance
DTP3	Diphtheria Tetanus Toxoid and Pertussis
EAF	Equity Accelerator Funding
EPI	Expanded Program on Immunization
ERC	Ethics, Risk and Compliance
ERCO	Ethics, Risk and Compliance Office
EUL	Emergency Use Listing
EUR	Euro
EYE	Eliminate Yellow Fever Epidemics
FED	Fragility, Emergencies and Displaced Populations
FLT	Facility Leadership Team
FPP	Full Portfolio Planning
FS	Foundational Support

FX	Foreign Exchange
G20	Group of 20
G7	Group of 7
GH	Global Health
GPEI	Global Polio Eradication Initiative
GVPI	Global Virtual Pooled Inventories
HCE	Health Campaign Effectiveness
HLRP	High-Level Review Panel
HPV	Human Papillomavirus
HR	Human Resources
HSIS	Health Systems and Immunization Strengthening
HSS	Health Systems Strengthening
IMF	International Monetary Fund
IPV	Inactivated Polio Vaccine
IRC	Independent Review Committee
IRP	Incidence Response Plan

ISO	International Organization for Standardization
IT	Information Technology
KMTS	Knowledge Management & Technology Solutions
LMC	Leadership, Management and Coordination
M/MR	Measles / Measles Rubella
MA	Monitoring Agents
MAC	Multi-Age Cohort
MDB	Multilateral Development Bank
MEL	Measurement, Evaluation and Learning
MICs	Middle Income Countries
MoU	Memorandum of Understanding
MPM	Monitoring and Performance Management
MTR	Mid-Term Review
N/A	Not Available
NFC	No Fault Compensation
NVI	New Vaccine Introduction
OCV	Oral Cholera Vaccine
OE	Operational Excellence

PCCS	Post Campaign Coverage Surveys
PCV	Pneumococcal Conjugate Vaccine
PEF	Partners Engagement Framework
PFM	Portfolio Financial Management
PHEIC	Public Health Emergency of International Concern
PNG	Papua New Guinea
PPDS	Programme Design and Delivery Support
PPE	Public Policy Engagement
PPPR	Pandemic Prevention Preparedness and Response
PQ	Pre-qualification
PQ PSEAH	Pre-qualification Prevention of Sexual Exploitation, Abuse and Harassment
PQ PSEAH PVP	
	Prevention of Sexual Exploitation, Abuse and Harassment
PVP	Prevention of Sexual Exploitation, Abuse and Harassment Pandemic Vaccine Pool
PVP	Prevention of Sexual Exploitation, Abuse and Harassment Pandemic Vaccine Pool Routine Immunization SAP Software (System Applications and
PVP RI SAP	Prevention of Sexual Exploitation, Abuse and Harassment Pandemic Vaccine Pool Routine Immunization SAP Software (System Applications and Products in Data Processing)
PVP RI SAP SCM	Prevention of Sexual Exploitation, Abuse and Harassment Pandemic Vaccine Pool Routine Immunization SAP Software (System Applications and Products in Data Processing) Senior Country Manager

SFP	Self-Financing Participants
SLT	Senior Leadership Team
SOP	Standard Operating Procedure
TA	Technical Assistance
TBD	To Be Determined
TCA	Targeted Country Assistance
TPM	Team Performance Metrics
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
USD	United States Dollar
VCV	Variant Containing Vaccines
VFM	Value For Money
VPD	Vaccine Preventable Diseases
WB	World Bank
WHO	World Health Organization
WUENIC	WHO/UNICEF Estimates of National Immunization Coverage
ZD	Zero-Dose