

RVMC

Regionalized Vaccine
Manufacturing Collaborative

Strategy

2024-2027

www.rvmc.net



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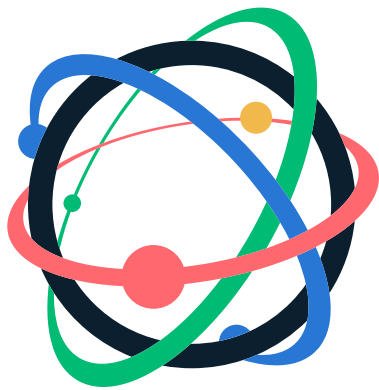


01. Introduction

The stark disparities in vaccine access during the COVID-19 pandemic underscored the urgency of developing regional vaccine manufacturing networks to support vaccine self-sufficiency. Countries rightfully want to have greater health security and control over vaccine manufacturing within their borders. However, consolidating

this approach at regional level is more likely to achieve the necessary scale of demand, investment, and capability to maintain viable and sustainable vaccine production.

The Regionalized Vaccine Manufacturing Collaborative (RVMC) was set up in 2022 to meet this challenge.



RVMC

Regionalized Vaccine
Manufacturing Collaborative



02.

Vision

Our vision is a world where vaccine equity and health security are created for countries in all regions of the world.

Mission

We aim to achieve this vision through the establishment of regional vaccine manufacturing and supply chain networks capable of producing vaccines for routine use in a sustainable manner, with readiness for outbreak manufacturing.

03. How we got here

For decades, vaccine access in most low-and-middle-income countries lagged significantly behind high-income countries. The cost of vaccines was one of the biggest barriers for lower income countries.

GAVI, the Vaccine Alliance, industry, UNICEF, the World Bank, the World Health Organization and the Bill & Melinda Gates Foundation came together in 2000 with the aim of ensuring sustainable, healthy market dynamics for immunization-related product, incentivizing innovation, and encouraging manufacturers to lower vaccine prices for the poorest countries in return for long-term, high-volume and predictable demand from those

countries, backed by assured finance. Their efforts transformed access to vaccine around the world.

Gavi, the Vaccine Alliance now provide affordable and quality assured vaccines to vaccination programmes for more than half of the world's children, and through its market shaping has increased the number of manufacturers supplying prequalified Gavi-supported vaccines from 5 in 2001 to 19 in 2022 (with more than half based in low - and middle-income countries).

However, the pandemic demonstrated that the global system that has been built for routine immunization is unable to deliver vaccine equity during health emergencies.





Almost a year after the first COVID vaccine was approved for use, high-income countries had achieved a twofold higher vaccination rate than middle-income countries, and 20-fold higher rate than lower-income countries. This gap in access was driven by unequal sovereign purchasing power, delays in the provision of surge financing, the concentration of manufacturing capacity and capability in a small handful of countries and companies, export bans and logistical challenges in the supply chain. Voluntary efforts were undertaken to try and set up local manufacturing of COVID vaccines but came late and were hampered by weak demand.

[Vaccine inequity prolonged the pandemic](#), contributing to over [7 million confirmed deaths](#) (as of June 2024), and an estimated \$14—28 trillion of economic damage globally.

As a result of the experience during the pandemic, countries, manufacturers and regional health institutions are now calling for regional diversification of vaccine manufacturing (and R&D) capabilities and platform technology to support greater self-sufficiency and supply security for routine immunization and epidemic/pandemic response vaccines. The two go hand-in-hand – developing viable regional markets for routine immunization provides the ecosystem and sustainability required to create readiness for outbreak manufacturing.

04. Time for change

Many political leaders have responded to vaccine inequity and weak health security by committing to build their own capacity and capabilities as one key element towards securing future equitable access. Established manufacturers have made pledges to contribute to a more distributed network of manufacturing sites, and development banks have begun to look at how they might support these efforts.

Alongside specific vaccine related responses, there has also been a wider movement towards regionalization.

The Lusaka Agenda (a multi-stakeholder backed movement) includes as one of its top recommendations the need for “coordinated approaches to products, research and development (R&D), and regional manufacturing to address market and policy failures in global health”. Similarly, the host of the G20 in 2024, Brazil, has proposed as one of its five health priorities “Prevention, Preparedness, and Response to Pandemics, with a focus on local and regional production of medicines, vaccines, and strategic health supplies”.



05. An opportunity

Regionalization of manufacturing represents a shift in the current global vaccine system: a shift that is already underway. With equity and health security at the core of their thinking, regions have decided that they want to take greater control over the production and supply of vaccine to meet their needs.

This shift represents an opportunity for all stakeholders. New developments in vaccine technology and know-how will contribute to an acceleration and expansion of the future global vaccine market.

Regionalization is one component of this changing vaccine landscape. For example, we are now beginning to see the introduction of adult vaccinations programmes, and countries are seeing the potential to eliminate HPV related diseases through vaccination. We have the capabilities to build targeted and personalised vaccines for cancer that are therapeutic rather than protective. Such innovations in platform and manufacturing technologies are likely to continue in the coming decade.

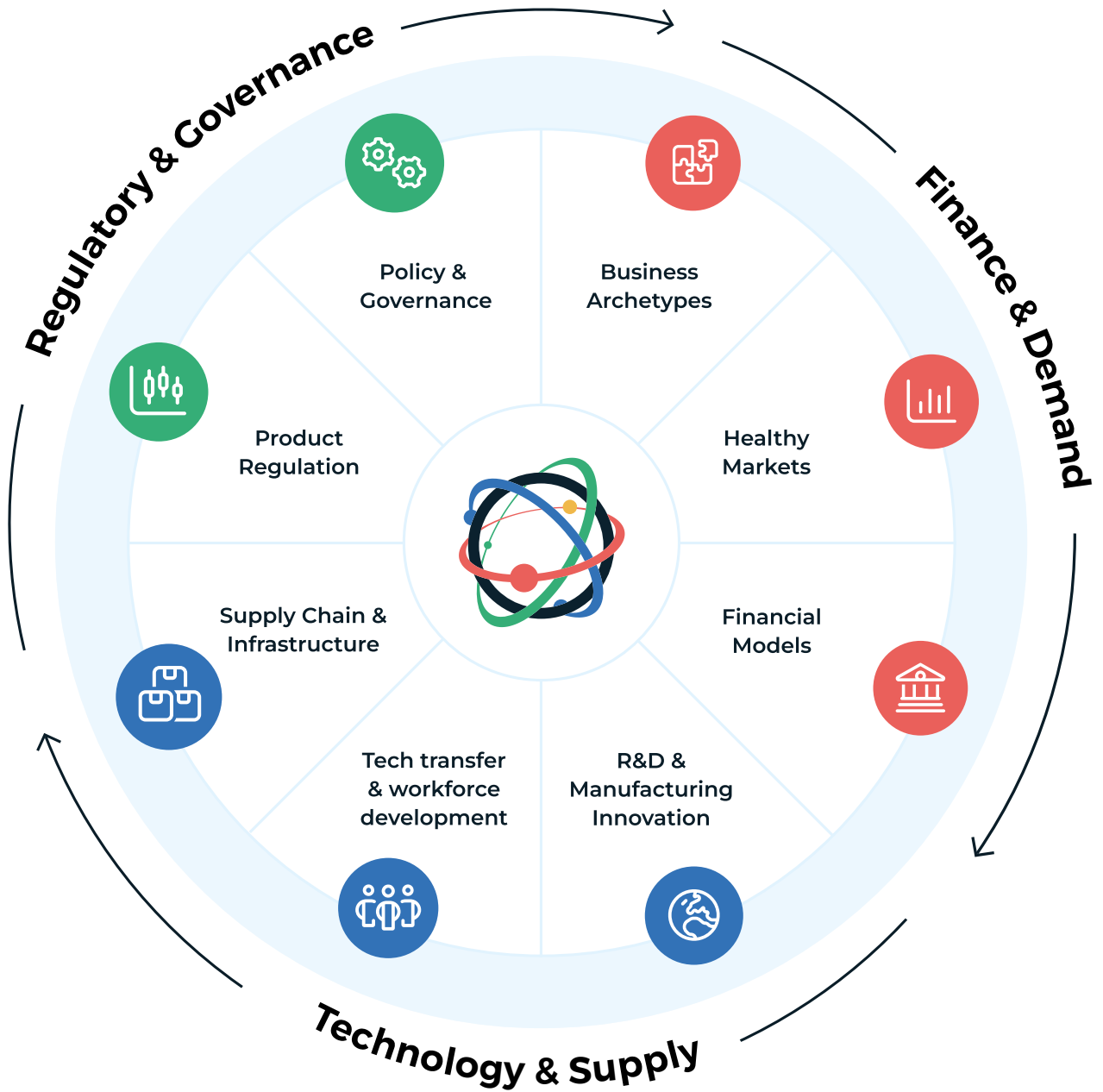
Global and regional vaccine markets will also be impacted by changing health needs in countries. Stakeholders at all levels (national, regional and global) will need to plan their responses and contributions to these changes.

RVMC is focused on accelerating this shift already underway, supporting initiatives to ensure that regionalized vaccine manufacturing is economically sustainable and contributes to a growing global demand for vaccines.

06. Looking forward

In January 2024, we launched the RVMC Framework Report, that sets out in detail what needs to be addressed if regional vaccine manufacturing is to become a reality.

Following consultation with dozens of subject matter experts and policy-makers around the world, our report lists eight areas where focus and development is needed:



**DOWNLOAD OUR
FRAMEWORK REPORT**

Business Archetypes

Sustainable commercial and public sector business models need to be developed

Healthy Markets

Additional and pooled capital needs to be incentivized to flow toward regional manufacturing in a sustainable manner, for both routine and emergency production, and reliable demand forecasting and generation is required

Financial Models

The cost of capital needs to be lowered to attract sustained investment through the life cycle of a manufacturing facility and financing provided to lower risk around the supply and uptake of regionally made vaccines

R&D and Manufacturing Innovation

Manufacturing technology capabilities need to be developed, advanced and linked to product innovation that is responsive to regional needs

Technology Transfer & Workforce Development

Incentives need to be in place to train and retain a qualified local workforce for right-sized manufacturing operations

Supply Chain and Infrastructure

Networked regional vaccine supply chains need to be created close to points of need among countries that are mutually dependent

Product Regulation

Faster access needs to be enabled to markets for vaccine manufacturers through mutual recognition and shared submission procedures

Policy & Governance

Collaborative regional policy frameworks are needed to address cross-border challenges and opportunities

Successful implementation of the Framework requires comprehensive action across multiple stakeholder groups, and ownership and leadership by each region. RVMC recognises that the causes of vaccine inequity vary around the world, so implementation priorities will vary in nature between regions.

Through our 2024-27 implementation period, we will primarily focus our efforts on the African, Latin American and Southeast Asian Regions.

07. Challenges to implementation

Since the pandemic, a multitude of initiatives have been launched across the globe with the common aim to support establishing local and regional vaccine manufacturing capacities and capabilities.

For example: the African Union has launched the Platform for Harmonized African Health Products Manufacturing, and Africa CDC has announced its intention to operate a pooled procurement mechanism; GAVI has launched a new instrument designed to support the sustainable growth of Africa's manufacturing base; PAHO is hosting a platform to advance manufacturing of vaccines and other health technologies in the Americas; ASEAN has established its Vaccine Security and Self Reliance project (AVSSR); WHO is implementing its mRNA technology transfer hub that reaches across regions; and UNICEF has extended its partnership with Africa CDC to strengthen supply chain management, pooled procurement and local manufacturing among other things.

These initiatives are important and show the current interest in vaccine equity, but on their own cannot fully deliver sustainable regional vaccine manufacturing. More resources, more collaboration, more alignment and more agreement is needed.

Challenges to implementation of the eight areas exist across all levels of the vaccine manufacturing ecosystem.

Here they are summarized in three core problems:

Lack of consensus of vision

There is a clear lack of consensus about exactly what the vision for regionalized vaccine manufacturing looks like, and especially what needs to be done to realize this vision. At the global level, this is complicated by differing national and regional interests, and at the regional level is exacerbated by competing country interests.

Insufficient coordination of initiatives

There is insufficient coordination within and between various regional initiatives, as well as among manufacturers. Varying levels of project maturity and local development make it difficult, along with complex and inconsistent regulatory environments.

Components missing

Efforts to build new capacity and capabilities (technology transfer, production, supply chain, workforce training) are not yet attracting the resources they will need to sustain them. The pooling of demand and funding is not secured (will countries prioritise local vaccines over cheaper overseas alternatives or more advanced presentations, and over what timeframe?), and a small number of countries and companies currently manage resources and technology for manufacturing.

08. RVMC's Approach

In response to these core problems, RVMC's approach will encompass four cross-cutting roles that recognise RVMC's position in the space between

regions, aggregating regional developments and understanding how these interplay with the evolving global system.





Advocating for change

RVMC will make the case for regionalized vaccine manufacturing, setting out the global vision for the regionalization agenda and helping others to define and implement their regional approach.

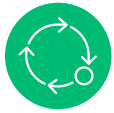
Through advocacy RVMC will build consensus around what is meant by regionalized vaccine manufacturing (its objectives, what a future state looks like, and cost implications for domestic, regional and global levels) and establish policy positions and access to data to inform how best it can be realised. Raising awareness and engagement with a global vision should foster a common approach between partners. Thought leadership and evidence generation will be key enablers for this work.



Aligning partners for impact

RVMC will facilitate discussions within and between regions and stakeholders, and work to align their projects to common objectives and regional priorities.

Convening partners around a unified vision will ensure that the resources available to invest in regionalized vaccine manufacturing are used efficiently, and in a coordinated and coherent manner. Better coordination should generate more impact and encourage further investment in the regionalization agenda, thereby improving the economic sustainability of vaccine manufacturing. Independent convening, match-making and facilitating dialogue will be key enablers of this work.



Advising on sustainable approaches

RVMC will provide independent trusted advice to stakeholders, focusing on expanding the current fact base for current global and regional capacity, capabilities and coverage.

We will champion existing data providers (recognizing the excellent work that has already been done) and identify additional data needs. At the moment it is not clear what manufacturing capacity is already in place around the world, and what kind of additional resources are actually needed to realise the regionalized manufacturing vision.

Publishing this position together with perspectives on what else is therefore required to achieve a sustainable regional manufacturing ecosystem will help manufacturers trying to construct viable business models, funders seeking to support regional supply chains, and stakeholders working on the creation of healthy markets. Analytical tools and tailored recommendations to stakeholders will be key enablers of this work.



Accounting for progress

As the author of the Framework for regionalized vaccine manufacturing, RVMC will observe and report on progress across the eight areas.

Reporting will enable all the stakeholders involved in the collaborative (and other interested parties) to see the whole picture and help the Secretariat to see what may need more attention from itself or other partners.

This will feed into the ongoing Advocacy role and could also provide useful insights and encouragement for attracting sustainable investment in the right areas. Stakeholder mapping, trend analysis and simple metrics will be enablers of this work.

How we will deliver

Delivery principles

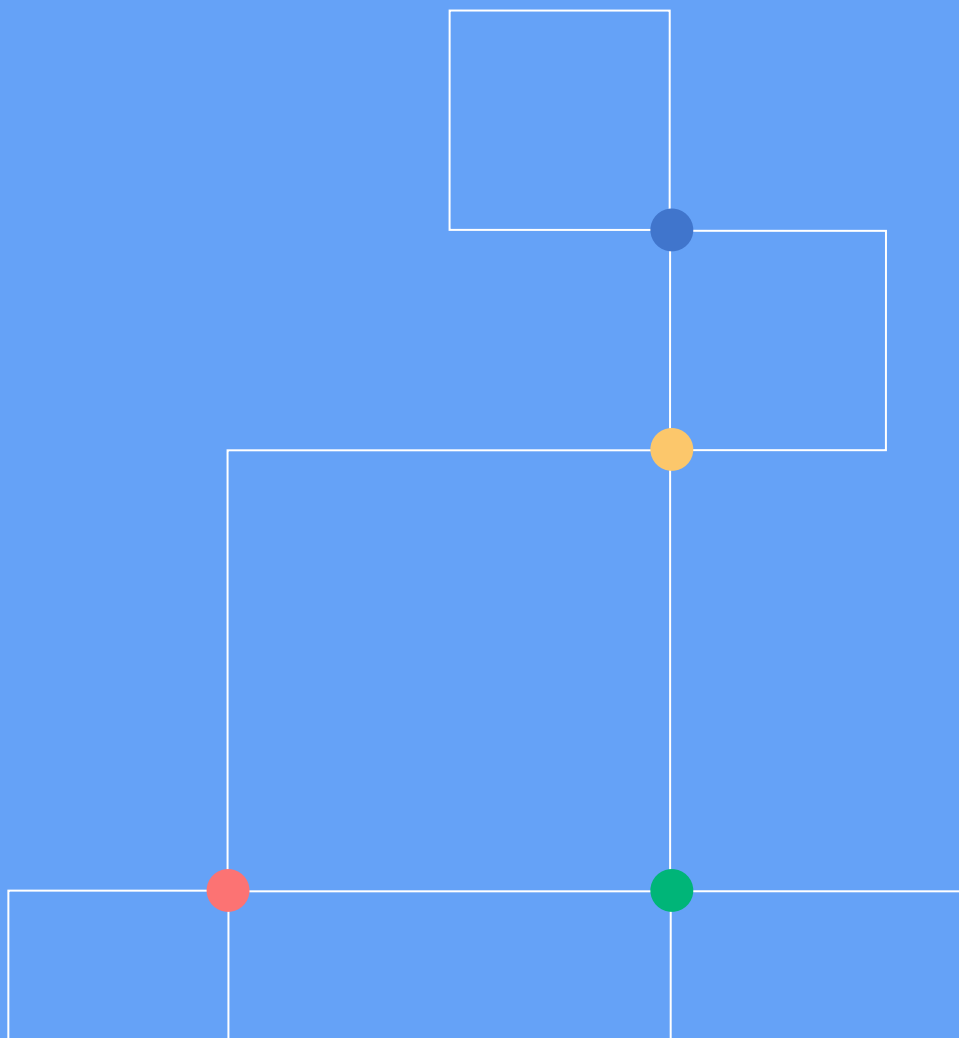
RVMC is a collaborative. We are a group of stakeholders with a big vision. The Secretariat will deliver impact by sticking to some simple delivery principles:

- We'll ensure that **regional leaders** are front and centre throughout our work
- We will **elevate the existing work** of our partners, while complementing it with what more is needed
- We'll prioritise **collaboration** in our work, and expect to deliver much of our impact through inspiring the actions of others
- We'll build partnerships with **existing organisations** in each region
- We'll provide partners with **access to technical experts** in support of their projects
- We'll protect our **independence** in order to play a trusted adviser role
- We'll **present the facts** and will also **advocate** for specific approaches to implementation when we think that the facts suggest clear gaps and pathways
- We'll remain a **small** staff team, focusing our time and skills on where we can be most catalytic
- We'll **focus** our funding on our Advocate, Align, Advise and Account roles. We won't be providing direct funding to manufacturing projects
- We'll be **flexible and agile** when considering what shape our support will take, because we know the challenges are different around the world
- We'll remain a **time-bound initiative**, with an initial timeframe of 2024-2027

As a time-limited entity we expect to complete our work by 2027 or as decided by the RVMC Executive Committee. Recognising that the journey to sustainable regionalized vaccine manufacturing will take much longer, we will work closely with our regional and global partners over this three-year strategy period to ensure that the right organisations are ready to take this work forward. During 2026 we will review with our Executive Committee whether any significant tasks remain that may require a time-limited extension.

09.

Our strategic goals



Goal 01



Advocating for change

Sustained political, financial and industrial support for the Regionalization Agenda

The window of opportunity to shift the vaccine manufacturing system towards a regionalized approach is beginning to close. Political attention is moving away from health security in the face of geo-political conflict, and industry commitment is wavering. Our goal is to build support across stakeholders for sustaining interest and investment in the regionalization agenda.

To achieve this

RVMC will set out a clear and compelling global vision for regionalization, to create consensus across stakeholders on what it looks like and what needs to be done.

Our aim is to bring all partners towards a common approach. To be launched at Davos 2025 - and using the Framework as the foundation - we will develop a document that makes a persuasive case for staying the course on regionalization, for the mutual benefits of this approach, for the risks of not delivering the agenda fully and in true collaboration between stakeholders. This goal is at the core of delivering the other three goals.

We will also provide thought leadership in the form of policy positions, data analysis and modelling advice to help guide and inform partners with their plans.

Together with the global vision, these products will be used to advocate – to secure and sustain political, financial and industrial support.

To succeed

We will develop an advocacy plan covering our engagement with regional and global political forums, multi-lateral public health initiatives, industry representative bodies, leading manufacturers, supply chain providers and procurers, and the media.

By the end of Year 1 we will have:

- Published our global vision document
- Secured regionalized manufacturing as an issue on G20 and regional political agendas for 2025
- Support packages to two regions in place
- Delivered three significant advocacy and thought leadership interventions

Our long term goal

For the regionalization agenda to remain a priority for global and regional leaders, and for the different parts of the agenda to be owned by a coalition of organizations.

Goal 02



Aligning partners for impact

Complementary regional initiatives provide global vaccine coverage

Existing efforts to generate regional self-sufficiency in vaccine manufacturing have operated largely independently from one another, with loose ties. Projects will, of course, look different from region to region based on differing levels of maturity across their vaccine ecosystem. But there is a growing need for partners to better understand one another's aims and objectives, and to come together to collaborate. If existing resources are to generate maximum impact and play a catalytic role in attracting further resources to the regionalization agenda, then more focus is needed on aligning all stakeholders to a common approach and directing resources to the highest priority (most impactful) projects.

To achieve this

RVMC will provide independent convening capacity and capabilities, working closely with partners to identify the critical gaps where constructive dialogue and aligning is required. We initially expect to play a convening role within and between regions on sustainable markets, and help promote regional supply chain convenings with a particular focus on Latin America to begin with.

We will also map funders' interests and provide a platform for aligning funding streams, and use our network intelligence to act as a connector between new entrants and existing projects, in order to reduce duplication. In other areas (such as the innovation ecosystem) our plan is to support others who are already leading the convening.

Our aim is to increase the opportunities for quality information and learning exchange within and between stakeholders and regions.

To succeed

We will develop internal convening capacity and identify a small number of opportunities where our independent convening and connecting services can deliver high impact. Together with our thought leadership and evidence generation capabilities (compiling existing evidence and building on this where there are gaps), we are well placed to serve and support partners to join the dots between regional efforts and ensure that they are pulling in the same direction. By not directly funding manufacturing projects we can ensure we remain an independent convenor and connector, and thereby more effective at delivering trusted advice to partners looking to invest or for investment.

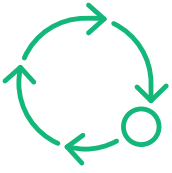
By the end of Year 1 we will have:

- **Built the foundations for a first sustainable markets global gathering**
- **Worked with partners to understand their preferences for an inter-regional supply chain convening mechanism**
- **Mapped funders' interests**

Our long term goal

For regional priorities to be clear in each region and aligned between regions through ongoing liaison, and sustainable market and supply chain convenings to be embedded in the regional and global level annual calendars.

Goal 03



Advising on sustainable approaches

Long-term sustainability and self-sufficiency in vaccine manufacturing & distribution

Global vaccine manufacturing currently lacks a centralized, comprehensive database that includes detailed information on manufacturing capacity, technology transfer status, product registration, and operational metrics. This lack of aggregated data creates challenges for partners considering if / how to contribute to the regionalisation agenda. For resources to be committed in the right places, for the right products in the right way, requires knowledge of what already exists (both locally and globally).

If supply side partners are to succeed in creating economically sustainable business models, and demand side partners are to succeed in creating healthy markets, then we need: reliable information on global vaccine manufacturing capacity; and assessments of how many manufacturers and which products and platforms are needed to deliver regional vaccine equity and health security.

To achieve this

RVMC will work with partners to bring existing market analyses together and present the global fact base, including insights on building financial models for regional vaccine manufacturing that are sustainable. Our aim is to build on existing frameworks and data points created by our partners and bring together additional data from the wider network of RVMC stakeholders, to compile a more complete view across the vaccine manufacturing ecosystem.

We will consult with other sectors and data transparency initiatives to inform our thinking around what is feasible,

cost effective and delivers value to all stakeholders. Considerations will include the level of data that can be reliably accessed, to what degree this can be automated, and how complete a picture can be provided. Our intention is to highlight the work already done by partners, identify additional data needs, and provide a platform for data sharing along with tools to analyse the data that support better decision-making among current actors and new entrants to the regional vaccine manufacturing ecosystem.

To succeed

We will leverage existing frameworks, and data points developed by key partners will be used as the foundation for this work. And we will develop incentives for the sharing of proprietary data, so that all stakeholders are clear how they will benefit from access to the complete data set and analysis and recommendations that will flow from that.

Together with the RVMC Framework and our global vision, this single source of truth about global capacity and regional needs will act as a comprehensive resource to inform and guide decision-making among stakeholders on which opportunities they / growing coalitions should pursue.

By the end of Year 1 we will have:

- Launched an initial market capacity analysis alongside our global vision
- Completed financial mapping on viable business models

Our long term goal

For regions to have measurably and sustainably increased production capacity, capability and supply chain resilience, and for locally manufactured vaccine to account for a significant percentage of total procurement in the region.

Goal 04



Accounting for progress

Real-time view of progress across the Framework

Sustaining commitments, building momentum, improving efficiency and highlighting the real gaps should all create positive impact. Knowing if they are requires us to observe and record what is happening. To achieve our vision of a world where vaccine equity and health security are created for countries in regions left behind in the COVID-19 pandemic, we need to monitor the impact of our actions.

To achieve this

RVMC will work with partners to develop a set of targets that will be applied to the RVMC framework, and a monitoring process. Our aim is to develop a simple, effective approach that can be used by governments, public health institutions, investors, industry and the media to understand how far we are towards securing sustainable regional vaccine manufacturing.

The findings will, in turn, inform and shape our advocacy priorities and show us what tweaks might be needed to the global vision.

To succeed

We will keep the monitoring and reporting requirements light-touch, and deliver reporting formats that are useable, engaging and tell a story. Together with our global vision and fact-base, we will use the progress report to advocate for additional commitments and the direction of resources within the Framework to the highest priority areas.

By the end of Year 1 we will have:

- Agree metrics and methodology for monitoring and reporting with partners
- Developed a publicly accessible dashboard for reporting
- Published our first (baseline) report

Our long term goal

Ongoing analysis and reporting of the global and regional vaccine ecosystem drives the prioritization of resources to most needed areas.

Contact

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