Towards Regionalised Vaccine Manufacturing

First Status Report

RVMC
Regionalized Vaccine Manufacturing Collaborative

Methodology Document

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1. Introduction and Purpose

Over the past six months, RVMC has developed a Dashboard to assess the current status of Regionalised Vaccine Manufacturing (RVM) across Africa, ASEAN, and Latin America and the Caribbean (LAC) regions. The analytical design was shaped through an iterative, consultative process involving regional and global stakeholders, convened under the Stakeholder Working Group (SWG) and supported by input from subject matter experts. The process prioritised methodological transparency, reproducibility, and comparability across regions to ensure the Dashboard functions as a baseline tool for longitudinal tracking of progress towards regional vaccine self-sufficiency.

The Dashboard presents data drawn primarily from publicly available sources across the eight pillars of RVMC's Framework, which together define the enabling conditions of a sustainable vaccine manufacturing ecosystem. These pillars encompass financial flows, demand sustainability, manufacturing capacity, technology platforms, regulatory performance, and governance mechanisms. Collectively, the data illuminate the systemic enablers of RVM, notably predictable demand, strengthened and harmonised regulatory systems, and diversified technology and supply capacity and highlight interdependencies among these domains that influence regional ecosystem performance.

This report accompanies the RVMC First Status Report (available at www.rvmc.net) to document the methodology used to develop, validate, and interpret the Ecosystem Indicators (ESI) dataset, which underpins the Ecosystem Dashboard and findings presented in the First Status Report. It provides a transparent account of the indicator selection process, data collection methods, analytical frameworks, and quality assurance protocols applied. The methodological approach integrates quantitative and qualitative evidence to produce directional and order-of-magnitude insights that are consistent across regional contexts. By detailing the underlying data construction and validation process, this report aims to provide users with a clear understanding of the evidence base that informs the First Status Report and to ensure the interpretability of resulting trends and findings.

The data collection and analysis covers three regional blocs, Africa, ASEAN, and Latin America and the Caribbean (LAC). The geographic coverage reflects ASEAN membership as of the data cut-off period (September 2025). Timor-Leste, which formally joined ASEAN on 26 October 2025, is therefore not included in this analysis due to timing relative to data closure. However, Timor-Leste will be incorporated in subsequent updates of the ESI dataset and regional analyses beginning with the next reporting cycle. Data reflect the period 2019–2024, representing the most complete multi-year window for which consistent public and partner-sourced information was available. The ESI dataset was designed to enable inter-regional comparability, while recognising variations in institutional maturity, manufacturing capacity, and data disclosure practices across regions.

The analytical foundation of this report is the RVMC Framework, which defines the essential building blocks of a resilient, sustainable vaccine manufacturing ecosystem. The Framework's Eight Pillars, spanning political commitment, predictable demand, financing, innovation, infrastructure, regulatory reliability, workforce capacity, and governance, form the structural logic that guides all indicator design and interpretation. To operationalise the Framework for analysis, the strategy indicators were clustered into **three analytical domains**, reflecting system-level functionality and alignment with the RVMC conceptual model:

1. **Finance & Demand** – encompassing indicators that assess financial commitment, market predictability, and sustainability of vaccine procurement;
2. **Regulatory & Governance** – evaluating the maturity, harmonisation, and efficiency of regulatory systems, as well as the policy environment and regional coordination mechanisms; and
3. **Technology & Supply** – addressing R&D activity, production platforms, technology transfer, and supply chain resilience

These domains collectively form the evidentiary structure of the **RVMC Ecosystem Dashboard**, enabling systematic comparison across regions and over time.

2. Conceptual Framework and Indicator Selection

The indicator design process began by identifying 44 candidate indicators representing the systemic enablers of Regionalised Vaccine Manufacturing (RVM), organised under the eight pillars of the RVMC Framework. These captured the multidimensional nature of manufacturing ecosystems, finance and demand, technology and supply, and regulatory and governance structures, while also aligning with the overarching RVMC mission to strengthen equitable regional vaccine access.

In addition, 16 mission- and vision-oriented indicators were formulated to represent long-term outcomes such as self-sufficiency, innovation capacity, and cross-regional trade in vaccines. For each proposed indicator, a metadata sheet was developed describing:

- The rationale and policy relevance,
- Its alignment with the RVMC Framework pillar(s),
- Formulae or calculation methods,
- Preferred and alternate data sources, and
- Standardised definitions

All definitions were catalogued in a shared metadata repository to ensure traceability and comparability across regions and reporting cycles.

Stakeholder and Expert Review

The preliminary indicator list was reviewed by the Stakeholder Working Group (SWG), a 12-member body of regional and global experts selected to reflect the diverse backgrounds, expertise, and perspectives of the broader RVMC stakeholder community. Each indicator was independently assessed for conceptual clarity, data feasibility, and cross-regional applicability. Structured feedback was incorporated through two iterative consultation rounds (August–September 2025), producing a refined list of technically valid, operationally feasible measures. From the feedback rounds and the data gathering exercise, the 44 candidate indicators were narrowed down to 21 to be included in the first release of the RVMC Ecosystem Dashboard. The remaining indicators were archived in the metadata catalogue and will be reconsidered as data maturity improves. The 16 mission/vision indicators, while conceptually retained, were excluded from initial quantitative reporting due to their long-term and aspirational measurement horizon.

Data Sources, Extraction, and Harmonisation

Data extraction was conducted between August and September 2025, covering reference years 2019–2024. Publicly available datasets formed the primary evidence base. Proprietary partner data were incorporated under formal data-sharing agreements, subject to confidentiality and data-governance standards. Extraction and cleaning for indicators 5.1, 6.1a and 6.1b were performed using the statistical software R, version 4.3.2 . Artificial intelligence–assisted data mining and curation methods were subsequently employed to identify additional relevant sources, enhance dataset completeness, and cross-reference findings across repositories. All AI-derived outputs

were systematically validated against secondary datasets and subjected to manual verification and expert review to ensure methodological integrity, reproducibility, and analytical reliability.

Quality Assurance and Quality Control (QA/QC)

Each indicator underwent a three-tiered QA/QC process:

1. **Technical validation:** verification of computational integrity, reproducibility of calculations, and consistency with metadata definitions.
2. **Contextual validation:** subject-matter experts assessed whether indicator behaviour (directionality, magnitude) aligned with known policy or industry developments.
3. **Data quality scoring matrix:** A formal multi-criteria triage to each of the 21 indicators and scored on a 1–3 ordinal scale across six criteria:
    1. Accuracy – validity of measurement and risk of systematic error;
    2. Accessibility – availability and openness of data sources;
    3. Timeliness – frequency of updates and reporting lag;
    4. Comprehensiveness – coverage across countries/regions;
    5. Validity – conceptual alignment with the indicator's intended construct;
    6. Traceability – ability to verify data lineage and replication.

Scores were added and grouped into a data quality rating, expressed in the Dashboard.

Data Interpretation and Reporting

Preliminary results were compiled into the RVMC Ecosystem Dashboard and accompanied by concise interpretive summaries ("indicator briefs") outlining regional trends, data caveats, and implications. Where gaps were identified, placeholders and recommended data sources were documented to guide future updates.

A second consultation round (August/September 2025) validated final indicator inclusion and interpretation. Consensus was reached through structured discussion.

Limitations and Potential Bias

Several methodological limitations were identified:

1. Data completeness bias: Coverage varied amongst the regions and as a result this may overstate inter-regional disparities.
2. Temporal inconsistency: Indicators vary in reference periods (annual vs triennial), potentially affecting cross-indicator comparisons.
3. Measurement sensitivity: Short-term indicators (e.g., financial disbursements) may fluctuate independently of structural progress.
4. Selection bias: Reliance on public data may under-represent private-sector investments and non-disclosed partnerships.

These components were factored into the Data Quality scoring matrix.

Data Governance and Ethical Considerations

All analyses utilised publicly available or institutionally authorised datasets; no individual-level or personally identifiable information was accessed.

Outcome

This systematic, criteria-based methodology produced a validated, transparent, and reproducible dataset forming the empirical foundation of the RVMC Ecosystem Dashboard. The workflow ensures methodological continuity and provides a replicable model for subsequent editions, enabling longitudinal tracking of RVM ecosystem performance across Africa, ASEAN, and LAC.

3. Glossary

Business archetypes	The classification of vaccine manufacturers based on the portion of the production process involved for each individual vaccine: • Drug Substance-only Manufacturer (focusing only on bulk antigen and drug substance manufacturing); • Drug Product-only Manufacturer (focusing on formulation, fill & finish/packaging, and commercialization/lot release); • Fully Integrated Manufacturer (Bulk antigen manufacturing/drug substance production, drug product formulation, fill & finish/packaging, and performing all production and commercialization steps).
Capabilities relevant for vaccine manufacturing	Scientific & Technical Competencies (e.g., Immunology & Microbiology, Molecular Biology & Biotechnology, Bioprocess Engineering, Analytical Methods, Formulation Science), Regulatory & Quality Competencies (e.g., Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Regulatory Affairs, Quality Control & Quality Assurance, Pharmacovigilance & Safety Monitoring), Operational Competencies (e.g., Facility & Equipment Management, Supply Chain & Cold Chain Management, Automation & Digital Manufacturing, Lean Manufacturing & Six Sigma), Cross-Cutting Professional Competencies (e.g., Project & Program Management, Risk Management, Ethics & Compliance)
Commercialised	A vaccine sold/distributed by a manufacturer in a sufficient number of doses per year (number of doses threshold to be defined)
Disease of specific regional relevance	A vaccine-preventable disease (VPD) with a burden primarily concentrated in the region as defined by the relevant WHO Regional Offices. Both WHO-SEARO and WHO-WPRO priorities have been considered for the ASEAN Member States.
Financial instruments	Contracts or tools that represent an asset to one party and a liability or equity to another. They are used to raise capital, manage risk, or facilitate investment. In the context of establishing vaccine manufacturing facilities, financial instruments serve two primary functions: funding the upfront capital and operating costs, and de-risking investments to attract private and public sector participation. Examples: grant and subsidies, equity investments, concessional loans, advanced market commitments, volume guarantees/offtake agreements, risk-sharing agreements, public-private partnerships, blended finance, etc.
Financial funding sources	The classification of sources of financial funding for announced RVM investments: • Private sector & investors: Funding from market-based actors seeking returns on investment. For example, venture capital, private equity, stock market offerings, pharmaceutical companies, and local/regional manufacturers. • Public & multilateral donors: Funding provided by governments, bilateral aid agencies, and international institutions. For example, development Finance Institutions (DFIs), multilateral organizations (e.g., World Bank, Gavi, CEPI), and bilateral donors (e.g., European Commission). • Domestic government resources: National or regional government allocations from health budgets or broader fiscal commitments. For example, national, regional and local government allocations from health budgets or broader fiscal commitments.

Fully functional (manufacturer)	A manufacturer that has vaccines commercialised of the appropriate quality (stratified based on the maturity level of the NRA under whose jurisdiction the manufacturer operates).
Funder type	Different type of providing of financing to regional manufacturers: stock markets, venture capital, philanthropic, public donors incl DFI, domestic resourcing from recipient country.
Highly qualified vaccine manufacturing position	A professional position that requires advanced education, specialized technical training, and/or extensive experience in disciplines directly supporting the research, development, production, quality control, and release of vaccines. They involve working in regulated environments such as Good Manufacturing Practice (GMP) facilities. They typically require university degree level or higher in fields such as biotechnology, microbiology, pharmaceutical sciences, chemical or biomedical engineering, regulatory affairs, or quality systems, and are critical to the end-to-end vaccine production and quality assurance process. Examples: Process Development Scientist, Bioprocess Engineer, Formulation Scientist, Quality Control (QC) Analyst, Quality Assurance (QA) Specialist, Validation Engineer.
Logistic Performance Index (LPI)	The LPI is a benchmarking tool developed by the World Bank to assess a country's trade logistics performance. It helps governments, investors, and development partners identify the strengths and weaknesses of logistics systems and prioritize reforms. The LPI is based on six key dimensions of trade logistics performance: CUSTOMS (Efficiency of customs and border management clearance); INFRASTRCTURE (Quality of trade and transport infrastructure - e.g., ports, railroads, roads, IT); EASE OF ARRANGING SHIPMENTS (Competence and quality of logistics services) ; LOGISTIC SERVICES QUALITY (Ease of arranging competitively priced shipments); TRACKING AND TRACING (Ability to track and trace consignments); TIMELINESS (Frequency with which shipments reach consignees within expected delivery times). The scores range from 1 (worst) to 5 (best) and are based on surveys of logistics professionals (e.g., freight forwarders and express carriers).
Manufacturer	An operation performing at least one step of the production process – the entity can hold the marketing authorisation for the vaccine produced or produce on behalf of a third party (contract manufacturing)
Marketing authorisation (also Registration, Licensure)	The official approval granted by an NRA that allows a vaccine to be marketed, distributed, and used within a specific jurisdiction. This authorisation confirms that the vaccine has met rigorous quality, safety, and efficacy standards, based on comprehensive data from preclinical studies and clinical trials. It ensures that the benefits of the vaccine outweigh any potential risks when used as intended.
National Health Budget	The portion of a country's overall government budget that is allocated to the health sector. It outlines planned public expenditures for health services, programs, infrastructure, and personnel over a specific fiscal period.
New Vaccine	A vaccine that has received marketing authorisation for the first time globally
Operational regional regulatory body	A supranational regulatory body whose recommendations or authorisation are accepted by National Regional Authorities.
Operationalised policy framework	An approved policy framework that has been approved and whose provisions have started informing / influencing country policies
Originator	A manufacturer that owns intellectual property (IP) and global commercialization rights as well as know-how and seed materials for a vaccine, which it can bestow upon TT partners.

Outbreak and Epidemic-prone diseases	A list of VPDs that can cause Outbreak and Epidemics (list to be defined)
Partnership	A collaborative arrangement between one or more vaccine manufacturers and one or more non-manufacturing organizations aimed at strengthening know-how, technical capacity, or infrastructure in support of vaccine production. Unlike product-specific collaborations, such partnerships focus on building general capabilities rather than developing or producing a particular vaccine
Production process steps	(1) Drug Substance (DS) production - Antigen bulk manufacturing, including the upstream part (cell culture/fermentation, virus propagation where applicable, harvesting) and the downstream part (filtration, inactivation if required, purification) (2) Drug Product (DP) production – formulation, filling & finishing (i.e. visual inspection, packaging and product release). Packaging only operations are not considered Drug Product production. Distribution is not part of the production process.
Regional manufacturer	A manufacturer whose ownership is based in the region in scope and whose manufacturing plants are primarily based in the region in scope.
Regional Policy Framework	Set of shared principles, guidelines, and coordinated strategies developed and adopted by countries within a specific geographic region to support and facilitate local vaccine manufacturing and distribution. This framework helps align efforts across borders and ensures consistency in regulatory, legal, financial, and operational approaches.
Regionally produced	A vaccine for which at least one production process step is completed in the regions in scope.
Regions in scope	• Africa (geographical definition); • Latin America and the Caribbean (geographical definition); • Southeast Asia (ASEAN member states).
Regulatory reliance	The act, governed by a legal agreement, whereby a regulatory authority in one jurisdiction takes into account the scientific assessments and regulatory decisions by another regulatory authority in reaching its own decision. The relying authority remains independent and responsible for its own regulatory decisions.
RVM initiatives	An initiative related to a topic relevant for regionalised vaccine manufacturing (e.g., policy platforms, financing mechanisms, technology transfer programs, coordination efforts). The initiative is originated and lead in one of the regions in scope
Science Based Targets initiative (SBTi)	The Science Based Targets initiative (SBTi) is a globally recognized framework that helps companies set greenhouse gas (GHG) emissions reduction targets in line with the latest climate science and the goals of the Paris Agreement—to limit global warming to well below 2°C, preferably to 1.5°C, above pre-industrial levels. The initiative has been established by the CDP (Carbon Disclosure Project), United Nations Global Compact (UNGC), World Resources Institute (WRI), and World Wide Fund for Nature (WWF).
Sourced	Procured via national public tender or other purchasing agreements or donations directly from the manufacturers (e.g., without the involvement of a distributor)
Supply interruption	Interruption of the flow of goods from the manufacturer to the countries/distributing entity as result of manufacturing-related problems

Targeted Population	The population that can be reached by a specific vaccine based on its approved indications and off-label recommendations (e.g., WHO position papers based on SAGE recommendations)
Technology transfer	The structured process by which the knowledge, methods, protocols, materials, equipment specifications, and quality standards required to produce a vaccine are transferred from one organization (the originator or developer) to another (the recipient or manufacturer). This process enables the recipient to replicate and scale up vaccine production in compliance with regulatory, safety, and quality standards. The transfer can involve different steps of the production process.
Vaccine / immunisation product	Any biologic product, including vaccines and other immunoprophylactic agents such as monoclonal antibodies (mAbs) protecting against a specific disease – all products included irrespective of their manufacturer and product characteristics
Vaccine demand	The willingness and capacity of a country to procure the vaccine doses required to immunize its target populations against specific vaccine-preventable diseases. It is typically measured as Programmatic Dose Requirements: the average estimated number of doses a country must procure to meet its immunization programme needs, including allowances for wastage and buffer stocks. This concept is distinct from population demand for immunization, which refers to the expressed willingness of individuals to receive vaccination.
Vaccine platform	A standardized and adaptable technological framework, process, or system used to develop and produce multiple vaccines. These platforms provide a common foundation for producing different vaccines by utilizing the same core components, processes, or production infrastructure. 1. Whole Pathogen Platforms (Inactivated, Live-attenuated); 2. Subunit Platforms (Inactivate/Toxoid, Polysaccharide, Conjugate, Protein-based, Nanoparticle-based); 3. Genetic Platforms (Nucleic Acid RNA-based, Nucleic Acid DNA-based, Viral vectored).
Vaccine Preventable Diseases (VPDs)	All diseases for which at least one licensed vaccine has received marketing authorisation and is available for use in preventing or reducing disease burden. Diseases – e.g., HIV - for which vaccines are in development but have not yet received marketing authorisation are excluded.
VPDs with Outbreak or Epidemic potential	All diseases that are listed by WHO as having the ability of triggering outbreaks and epidemic

4. Strategy Indicator Methodology

Strategy indicators provide specific implementation metrics organized across the eight RVM pillars that support the mission. These detailed indicators track concrete actions and outcomes that contribute to mission success.

a. Finance & Demand

i. Business Archetypes

1.1 Manufacturing Breadth: Number of fully functional regional manufacturers by business archetype.

Purpose & Definition	Measures the quantity and diversity of business archetypes, which provide preliminary indications of RVM sustainability, with size and differentiation reflecting their effective contribution to regional manufacturing capacity.
Rationale	A progression towards fully integrated regional manufacturers is desired to achieve self-sufficiency and financial sustainability.
Stratification	Regional Fully Integrated (on at least one product) vs Drug Product only
Calculation method	$N_{manufacturers}(r) = \sum_{m \in M_r} 1\left[N_{products}(m) > 0 \; and \; Ownerhip(m) = Regional\right]$ Where: $r = Region$ $m = manufacturer$ $N_{products}(m) = number \; of \; commercialised \; products \; by \; manufacturer \; m$ M_r = set of manufacturers in region r *Results presented as a NUMBER*
Data sources	Desk Review - Status of manufacturer operations, commercialisation, portfolio, export/only domestic and ownership based on multiple individual sources for each manufacturer - **Full list of sources available upon request** Experts' consultation
Data processing & quality assurance	ChatGPT 5.0 has been used to retrieve information but not for its selection and compilation See Data table section for an overview of the intermediate results.
Data reference period	September 2025 (latest year available)
Data caveats/limitations	The data results from a variety of sources and loosely refer to the current year. WHO's MI4A full product list is incomplete (not all manufacturers are included) and not fully up to date (some old products are still listed). It is only used as additional validation source.

2.1 Manufacturing Depth: Number of fully functional regional manufacturers, with a portfolio of 5 or more vaccines which produced >70 million doses/year

Purpose & Definition	Measures the quantity and diversity of business archetypes, which provide preliminary indications of RVM sustainability, with size and differentiation reflecting their effective contribution to regional manufacturing capacity.
Rationale	Sustainability requires for each regional manufacturer a sufficient size both in term of doses produced as well as in number of vaccines produced
Stratification	Regional Domestic only vs Exporting
Calculation method	$N_{manufacturers}(r) = \sum_{m \in M_r} 1\left[N_{products}(m) \geq 5 \; and \; Volume(m) > 70{,}000{,}000 \; and \; Ownership(m) = Regional\right]$ Where: $r = Region$ $m = manufacturer$ $N_{products}(m) = number \; of \; commercialised \; products \; by \; manufacturer \; m$ $Volume(m) = total \; number \; of \; annual \; doses \; produced \; for \; m$ M_r = set of manufacturers in region r *Results presented as a NUMBER*
Data source	Manufacturers included based on indicators 1.1 Desk Review - volumes commercialized, ownership and number of doses commercialised based on multiple individual sources for each manufacturer - **Full list of sources available upon request** Experts' consultation
Data processing & quality assurance	ChatGPT 5.0 has been used to retrieve information but not in their selection and compilation
Data reference period	2022-2023 depending on the manufacturers' information.
Data caveats/limitations	The data results from a variety of sources and refers to different time periods. Number of doses refer to vaccine produced or commercialised depending on the sources.

3.1a Regional Scale (volume): Percentage of regional demand served by fully functional manufacturers from the region / excluded packaging only

Purpose & Definition	Measures the relevance of regional supply sources, confirms demand sustainability, and highlights supply risks.
Rationale	The throughput of a functioning regional vaccine manufacturing ecosystem is capable of serving a relevant share of the vaccine markets, particularly for diseases of regional relevance.
Stratification	Regional
Calculation method	$$Coverage_{2023}(r) = \left(\frac{\sum_{m \in M_r} Volume_{2023}(m)}{Demand_{r,2023}}\right) * 100$$ Where: $r = Region$ $m = manufacturer$ $Volume_{2023}(m) = total\ doses\ commercialised\ by\ RM\ in\ 2023$ $Demand_{r,2023} = total\ estimated\ regional\ demand\ in\ 2023$ M_r = set of manufacturers in region r *Results presented as a* PERCENTAGE
Data source	Based on list of manufacturers defined in 1.1 Volumes commercialised based on WHO Market Study for 2023
Data processing & quality assurance	No data processing Data are considered quality checked at the source
Data reference period	2023
Data caveats/limitations	As per the WHO's market study

3.1b Regional Scale (portfolio): Number of priority diseases for which at least one vaccine is produced by a fully functional regional manufacturer

Purpose & Definition	Measures the relevance of regional supply sources, confirms demand sustainability, and highlights supply risks.
Rationale	The throughput of a functioning regional vaccine manufacturing ecosystem is capable of serving a relevant share of the vaccine markets, particularly for diseases of regional relevance.
Stratification	Regional
Calculation method	$N_{priority\ diseases}(r) = \frac{\sum_{v \in PD_r} 1[vaccine\ v\ is\ unique]}{\sum_{d \in PD_r} 1}$ Where: $r = Region$ $V_{PD,r} =$ set of unique vaccines for priority diseases in region r $PD_r = set\ of\ priority\ diseases\ in\ region\ r$ $1[\cdot]\ equals\ 1\ if\ the\ condition\ is\ true, otherwise\ 0$ *Results presented as a NUMBER*
Data source	List of vaccines commercialised by each manufacturer based on 2.1 Priority diseases based on WHO regional offices official documents: • https://www.who.int/publications/i/item/9789290619697 • https://www.who.int/westernpacific/health-topics/dengue • https://www.who.int/southeastasia/health-topics/immunization • https://www.who.int/southeastasia/activities/rabies • https://www.who.int/southeastasia/activities/immunization-and-vaccine-research-area-priorities-for-strengthening-the-immunization-programmes-in-the-who-south-east-asia-region-%282025-2030%29 • https://www.paho.org/en/documents/regional-immunization-action-plan-americas-2030 • https://www.paho.org/en/topics/yellow-fever • https://www.paho.org/en/topics/arboviral-diseases • https://www.paho.org/en/topics/rabies • https://www.afro.who.int/sites/default/files/2023-09/Ending%20disease%20in%20Africa_ENDISA_ENG_0.pdf • https://www.afro.who.int/health-topics/immunization • https://www.afro.who.int/sites/default/files/2023-09/Ending%20disease%20in%20Africa_ENDISA_ENG_0.pdf
Data processing & quality assurance	ChatGPT 5.0 has been used to retrieve information on vaccine produced but not for its selection and compilation The production steps for the various manufacturers have been checked, where possible, with experts. See Data table section for an overview of the intermediate results.
Data reference period	September 2025 (latest year available)
Data caveats/limitations	The data on vaccine produced by the various manufacturers and the production steps results from a variety of sources.

ii. Healthy Markets

4.1 Distributed manufacturing ecosystem: For regional priority diseases, average proportion of the global doses produced supplied by fully functional regional manufacturers

Purpose & Definition	Measures the relevance of regional supply sources, confirms demand sustainability, and highlights supply risks.
Rationale	Sustainability, health security and equity require a diversified and distributed global vaccine manufacturing ecosystem with regional presence, capable of serving the public health priority of the different regions
Stratification	Regional
Calculation method	$Proportion\ Global\ Doses(r) = \left(\frac{\sum_{v \in PD_r} Volume_{3yr}(m,r)}{\sum_{v \in PD_r} Volume_{3yr}(G)}\right) * 100$ Where: $r = Region$ $m = manufacturer$ $G = global$ $Volume_{3yr}(m,r) = total\ doses\ commercialised\ by\ RM\ in\ last\ 3\ years\ (median)$ $PD_r = set\ of\ priority\ diseases\ in\ region\ r$ *Results presented as a PERCENTAGE*
Data source	Data not available
Data processing & quality assurance	Data not available
Data reference period	Median of the last 3 available years
Data caveats/limitations	Data not available

5.1 Premium vs. Lowest Available Prices: Median price difference between regionally produced vaccines and UNICEF Supply Division price for Gavi

Purpose & Definition	Measures the relevance of regional supply sources, confirms demand sustainability, and highlights supply risks.
Rationale	RVM should be mindful of the lowest prices accessible in the market to avoid countries procuring regionally produced vaccines to have to pay a large premium to contribute to regional supply security
Stratification	Regional
Calculation method	Step 0: Filter WHO MI4A by manufacturer to only include regional manufacturers Step 1: Calculate median prices across countries by procurement mechanism, vaccine, year, manufacturer and region Step 2: Calculate indicator by taking the ratio of self-procured vaccines over UNICEF or PAHO procured vaccines Step 3: Aggregate across manufacturers and regions by taking the median for UNICEF or PAHO procurement ratios $Price\ difference\ (r,y) = Median\left(\left(\frac{Median_{c\in C_r(y)} Price_{c,v,m}^{Region}(y)}{Median_{c\in C_r(y)} Price_{v,m}^{UNICEF\|PAHO}(y)}\right) - 1\right)$ Where: $m = manufacturer\ in\ region\ r$ $v = vaccine\ produced\ by\ m$ $C_r(y) =$ countries in region r with availalable data in year y $\in \{2021,2024\}$ $Price_{c,v,m}^{Region}(y) = price\ of\ vaccine\ v\ from\ manufacturer\ m\ in\ country\ c\ (regionally\ produced)$ $Price_{c,v,m}^{UNICEF\|PAHO}(y) = price\ of\ vaccine\ v\ from\ manufacturer\ m\ (UNICEF\|PAHO\ procurement\ )$ *Results presented as a PERCENTAGE*
Data source	• WHO MI4A - https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a/mi4a-vaccine-purchase-data; • UNICEF Vaccine Pricing Data - https://www.unicef.org/supply/vaccines-pricing-data; • PAHO RF Prices - https://www.paho.org/en/documents/revolving-fund-vaccine-prices-2025 • List of regional manufacturers (20250829 RVMC_ESI, sheet S1.1), as developed in ESI 1.1.
Data processing & quality assurance	***R scripts and output available upon request** • Manufacturers from indicator 1.1 are included to define the prices for vaccines produced in the regions. • Vaccines are included that have price points in the Mi4A dataset for countries where the procurement method is self-procuring to define the prices paid by country that self-procure for vaccine produced by the regional manufacturers. • Corresponding vaccines are retrieved for UNICEF and PAHO RF even if produced by other manufacturers and irrespective of the presentation to define the available lowest price on the market.
Data reference period	2021 and 2024
Data caveats/limitations	Volumes, duration of the contracts and payment terms also play an important role in price and can influence the order of magnitude of the difference. At the same time, they reflect the real-life conditions on which countries operate. The number of datapoints is limited.

6.1a Sustainable demand: Median government vaccine expenditure per surviving infant

Purpose & Definition	Measures the relevance of regional supply sources, confirms demand sustainability, and highlights supply risks.
Rationale	RVM requires sustainable demand to be able to progress
Stratification	Regional
Calculation method	Step 0: Determine country records with complete years of reported values (exclude zeros and missing values) Step 1: Aggregate time period per country by taking the median across selected years Step 2: Aggregate to region level by taking the sum across countries for each region, indicator and time period Step 3: Calculate indicator by dividing the total regional vaccine expenditure by the total number of surviving infants $Vaccine\ expenditure\ per\ infant\ (r,T) = \frac{\sum_{c \in C_r} Median_{y \in T} Expenditure\ _c(y)}{\sum_{c \in C_r} Median_{y \in T} Surviving\ infants_c\ (y)}$ Where: $r = region$ $C_r = set\ of\ countries\ in\ region\ r\ with\ complete\ data$ $T = timeperiod\ in\ T\ \in \{2018-2020; 2021-2023\}$ $Expenditure\ _c(y) =\ annual\ vaccine\ expenditure\ for\ country\ c\ in\ year\ y$ $Surviving\ infants\ _c(y) =\ number\ of\ surviving\ infants\ in\ country\ c\ in\ year\ y$ *Results presented as a NUMBER*
Data source	• WHO vaccine expenditure dataset 2024: https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/planning-and-financing/immunization-financing-indicators • UN World Population Prospects 2024 [File GEN/01/REV1: Demographic indicators by region, subregion and country, annually for 1950-2100]: https://population.un.org/wpp/downloads?folder=Standard%20Projections&group=Most%20used
Data processing & quality assurance	***R scripts and output available upon request** Expenditure Data: Imported from WHO global immunization data (reviewed-jrf-reported-expenditure-data-on-vaccines---december-2024.xlsx) Expenditure data merged with population data by region, ISO country code, and year • Conditional missing value assignment to ensure surviving infant denominators only included for countries with available expenditure data for respective years Data summarized at regional level (or ASEAN level in example implementation) • *Expenditure*: Total across countries • *Population*: Sum of surviving infants • *Indicator*: USD per surviving infant = Expenditure ÷ Surviving Infants
Data reference period	• Period: 2021-2023 • Period: 2018-2020
Data caveats/limitations	Vaccine expenditure includes all vaccines, not only routine vaccines targeting infants. Missing Data Handling: Surviving infants set to missing when corresponding expenditure is unavailable. # of countries with complete data set for analysis: • Africa: 85% - 46 of 54 • ASEAN: 90% - 9 of 10 • LAC: 67% - 22 of 33

6.1b Sustainable demand: Median annual vaccine expenditure from national budget resources as % of total routine immunization expenditure for the country

Purpose & Definition	Measures the relevance of regional supply sources, confirms demand sustainability, and highlights supply risks.
Rationale	RVM requires sustainable demand to be able to progress
Stratification	Regional
Calculation method	Step 0: Determine country records with complete years of reported values (exclude zeros and missing values) Step 1: Aggregate time period per country by taking the median across selected years Step 2: Calculate indicator (sum not meaningful with mixed currencies) Step 3: Aggregate to region level by taking the population weighted mean of the calculated indicator Country-level indicator: $X_c(T) = \frac{Median_{y \in T} Expenditure_c^{GovTot}(y)}{Median_{y \in T} Expenditure_c^{RI}(y)}$ Region-level indicator: $GovShareRIExp(r,T) = \frac{\sum_{c \in C_r} X_c * Pop_{c,2024}}{\sum_{c \in C_r} Pop_{c,2024}}$ Where: $r = region$ $C_r = set\ of\ countries\ in\ region\ r\ with\ complete\ data$ $T = timeperiod\ in\ T\ \in \{2020-2021; 2022-2024\}$ $Expenditure_c^{GovTot}(y) = total\ government\ expenditure\ for\ country\ c\ in\ year\ y$ $Expenditure_c^{RI}(y) = total\ routine\ vaccine\ immunisation\ expenditure\ for\ country\ c\ in\ year\ y$ $Pop_{c,2024} = total\ population\ of\ country\ c\ in\ 2024\ (used\ as\ weight)$ *Results presented as a PERCENTAGE*
Data source	• WHO vaccine expenditure dataset 2025: https://immunizationdata.who.int/global/wiise-detail-page/immunization-expenditure?ISO_3_CODE=&YEAR= • UN World Population Prospects 2024 [File GEN/01/REV1: Demographic indicators by region, subregion and country, annually for 1950-2100]: https://population.un.org/wpp/downloads?folder=Standard%20Projections&group=Most%20used
Data processing & quality assurance	***R scripts and output available upon request**

	• Expenditure Data: Imported from WHO global immunization data (Immunization expenditure 2025-13-09 22-45 UTC.xlsx), Expenditure data on government financing of vaccines and routine immunization were aligned with country and regional identifiers. • Merged by country, region, year. • Derived measures: • Both mean- and median-based aggregated datasets were generated .
Data reference period	• Period: 2022-2024 • Period: 2020-2021
Data caveats/limitations	Outliers removed based on variance and data consistency. # of countries with complete data set (5 years of information) for analysis: • Africa: 30% - 16 of 54 • ASEAN: 10% -1 of 10 (excluded from Dashboard given only 1 country in sample) • LAC: 24% - 8 of 33 Expenditure data used includes mixed currencies.

iii. Financial Models

7.1a Announced investment in manufacturing: Average annual announced investments (in million) in regional vaccine manufacturing initiatives

Purpose & Definition	Measures the level of blended funding (philanthropic, public, and private equity) used to de-risk RMV investments, as well as the extent of the national government's financial commitment through secured domestic resources.
Rationale	Sizeable investments are required for kick-starting a successful RVM ecosystem. The political will behind those investments signals the strategic focus on regional innovation and the momentum behind RVM (e.g. post-COVID donor interest vs sustained local government financing) and the sustainability of the overall strategy.
Stratification	Regional
Calculation method	$Avg\ Announced\ investment_T\ (r) = \frac{\sum_{i \in I_r} Investment_i}{\lvert I_r \rvert}$ Where: $r = region$ $Investment_i = value\ of\ announced\ investment\ i$ $\lvert I_r \rvert = number\ of\ announced\ investments\ in\ region\ r$ *Results presented as a NUMBER*
Data source	CHAI provided dataset (as of August 2025)
Data processing & quality assurance	• Consolidation of individual regional data sets into 1 data set, categorisation into RVMC regions in scope and classification into financial funding source category (private, multi-lateral, domestic)
Data reference period	Period: 2022-2024
Data caveats/limitations	• Represents only publicly announced investments, can not be considered complete • Only data points with all data fields completed were included in the analysis

7.1b Announced investment in manufacturing: Percentage from public & multilateral donors, domestic government resources, and from private sector

Purpose & Definition	Measures the level of blended funding (philanthropic, public, and private equity) used to de-risk RMV investments, as well as the extent of the national government's financial commitment through secured domestic resources.
Rationale	Sizeable investments are required for kick-starting a successful RVM ecosystem. The political will behind those investments signals the strategic focus on regional innovation and the momentum behind RVM (e.g. post-COVID donor interest vs sustained local government financing) and the sustainability of the overall strategy.
Stratification	Regional by funding source
Calculation method	$$Avg\ share\ investments_A(r) = \left(\frac{\frac{\sum_{i \in I_{A,r}} Investment_i}{\lvert I_{A,r} \rvert}}{\frac{\sum_{i \in I_{A,r}} Investment_i}{I_r}} \right) * 100$$ Where: $Avg\ share\ investments_A(r) = Average\ share\ (\%)\ of\ announced\ investment\ from\ funding\ source\ A\ in\ region\ r$ $I_{A,r} = set\ of\ announced\ investments\ in\ region\ r\ from\ funding\ source\ A$ $I_r = set\ of\ all\ announced\ investments\ in\ region\ r$ $Investment_i = value\ of\ announced\ investment\ i$ *Results presented as a PERCENTAGE*
Data source	CHAI provided dataset (as at August 2025
Data processing & quality assurance	Consolidation of individual regional data sets into 1 data set, categorisation into RVMC regions in scope and classification into financial funding source category (private, multi-lateral, domestic)
Data reference period	• Period: 2022-2024
Data caveats/limitations	• Represents only publicly announced investments, can not be considered complete • Only data points with all data fields completed were included in the analysis

b. Regulatory and Governance

iv. Product regulation

8.1a Regulatory strength: Number of vaccines that have achieved WHO PQ

Purpose & Definition	Demonstrates if regional efforts are aligned with global standards and if regulatory systems are becoming more efficient and harmonized.
Rationale	A functioning RVM ecosystem results in manufacturers which can achieve marketing authorisation from fully functional NRAs/WHO PQ for vaccines fully produced locally. This is even more relevant if the manufacturer is also producing bulk.
Stratification	Regional
Calculation method	$N_{PQ}(r) = \sum_{v \in V_r} 1[vaccine\ v\ has\ PQ]$ Where: $N_{PQ}(r) = number\ of\ vaccines\ with\ WHO\ prequalification\ (PQ)\ in\ region\ r$ $V_r = set\ of\ vaccines\ in\ region\ r$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a NUMBER*
Data source	WHO Prequalification website - https://extranet.who.int/prequal/vaccines/prequalified-vaccines
Data processing & quality assurance	No data processing Data are considered quality checked at the source
Data reference period	September 2025 (Latest year available)
Data caveats/limitations	None

8.1b Regulatory strength: Number of vaccines with marketing authorization from a Maturity Level 3 or WHO-listed NRA or PAHO reference NRA

Purpose & Definition	Demonstrates if regional efforts are aligned with global standards and if regulatory systems are becoming more efficient and harmonized.
Rationale	A functioning RVM ecosystem results in manufacturers which can achieve marketing authorisation from fully functional NRAs/WHO PQ for vaccines fully produced locally. This is even more relevant if the manufacturer is also producing bulk.
Stratification	Regional
Calculation method	$N_{Vaccines}^{NRA}(r) = \sum_{v \in V_r} 1[Country\ (v)\ has\ (NRA\ ML3 + or\ is\ WHO\ listed\ NRA\ or\ PAHO\ reference\ NRA)]$ Where: $N_{Vaccines}^{NRA}(r) = number\ of\ vaccines\ in\ region\ r\ whose\ country\ of\ manufacturers\ meets\ regulatory\ authority\ criteria$ $V_r = set\ of\ vaccines\ in\ region\ r$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a NUMBER*
Data source	List of vaccines commercialised based on Indicator 2.1 National Regulatory Authorities maturity level based on WHO Benchmarking tool - https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4 Status of NRA in Latin America in relation to their role as PAHO reference authorities - https://www.paho.org/en/news/11-12-2024-paho-convenes-regulatory-authorities-americas-strengthen-access-health-technologies
Data processing & quality assurance	No data processing Data are considered quality checked at the source
Data reference period	September 2025 (Latest year available)
Data caveats/limitations	None

9.1 Speed of regulatory processes: Number of months between Biologics License Application (BLA) and Marketing Authorisation

Purpose & Definition	Demonstrates if regional efforts are aligned with global standards and if regulatory systems are becoming more efficient and harmonized.
Rationale	Minimisation of the time for regulatory approval while maintaining stringent processes is necessary for regional manufacturers to compete. This requires effective processes both on the developers and the NRA side
Stratification	Regional
Calculation method	$N_{month}(r) = Month(t_{MA}(r) - t_{BLA}(r))$ Where: $N_{month}(r) = number\ of\ months\ between\ BLA\ submission\ and\ MA\ approval\ in\ region\ r$ *Results presented as a NUMBER REPRESENTING TIME DIFFERENCE*
Data source	Desk Review - information collected for individual countries based on public data – this information may refer to target timelines or actual timelines: • https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/appendix-5_target-processing-timeline.pdf • https://doi.org/10.3389/fmed.2021.742200 • https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/DR_And_R_Guidelines/Guidelines-For-Registration-of-Imported-Drugs-Vaccines-IVDs-Under-Collaborative-Registration-Procedure.pdf • https://doi.org/10.1007/s43441-020-00140-4 • https://www.lexology.com/library/detail.aspx?g=89c317e8-cee9-4bf7-8d89-7e79ea5cef77&utm • https://globallawexperts.com/drug-registration-in-vietnam-guide-for-foreign-companies-p2/?utm • https://cms.ipmg-online.com/material/pages/resources/documents/Peraturan%20BPOM%20No.152019%20tentang%20Perubahan%20Atas%20Peraturan%20Kepala%20Badan%20Pengawas%20Obat%20Dan%20Makanan%20Nomor%2024%20Tahun%202017%20Tentang%20Kriteria%20Dan%20Tata%20Laksana%20Registrasi%20Obat.pdf • https://www.questjournals.org/jrbm/papers/vol10-issue4/Ser-3/D10042733.pdf • https://doi.org/10.1007/s43441-020-00169-5 • https://dcvmn.org/wp-content/uploads/2019/10/apresentacao_anvisa_dcvmn_final.pdf • https://www.gov.br/anvisa/pt-br/english/regulation-of-products/drugs?utm • https://globalregulatorypartners.com/registration-of-biologics-in-mexico-frequently-asked-questions • https://doi.10.1016/j.vaccine.2022.07.003
Data processing & quality assurance	ChatGPT 5.0 has been used to retrieve information on timelines but not in their selection and compilation Data analyses separately for targeted and actual timelines
Data reference period	Various years in the period 2017-24
Data caveats/limitations	Based on individual studies, may not include all steps from submission of BLA to effective MA especially for targeted timelines. Target timelines are theoretical. Sample size limited based on public data sources.

v. Governance

10.1 Political action: Proportion of countries that implemented legislation enabling RVM (e.g., procurement, regulatory harmonization, etc.) aligned with a Regional Policy Framework

Purpose & Definition	Measures political action, evidence of enabling infrastructure being put in place, and gives indication of enabling frameworks to allow for operationalization.
Rationale	Political action – like providing sufficient financing and enacting appropriate legislation - is critical to the success of RVM
Stratification	Regional
Calculation method	$LegislationCoverage(r) = \left(\frac{\sum_{c \in C_r} 1[Country\ c\ has\ legislation\ for\ RVM\ and|or\ vaccine\ procurement]}{\sum_{c \in C_r} 1}\right) * 100$ Where: $r = Region$ $C_r = set\ of\ countries\ in\ region\ r$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a PERCENTAGE*
Data source	Data not available
Data processing & quality assurance	Data not available
Data reference period	Data not available
Data caveats/limitations	Data not available

c. Technology and Supply

vi. R&D and Manufacturing Innovation

11.1a New vaccine pipeline to manufacturers: Number of phase III-IV vaccine clinical trials started with at least one regional sponsor

Purpose & Definition	Demonstrates the existence of R&D capabilities, if strategies are targeting newer platforms beyond traditional technologies and if a strategy for regional innovation exists and is being implemented.
Rationale	The initiation of phase III/IV clinical development programs, even if result from tech transfer, co-development agreements or other, is an indication of an ecosystem that is initiating mastering and controlling the pipeline of new products that upon successful MA will translate in locally manufactured products
Stratification	'Regional Main vs Secondary Sponsor Type of Sponsor Site location Vaccine type (C-19 vs not)
Calculation method	$$N_{vaccine\ trials}\ (r) = \sum_{p \in P_r} 1[Phase(p) \in \{III, IV\}\ and\ start\ year\ (p) > 2019\ and\ sponsor_c(p) \in r\ and\ enrolment > 0]$$ Where: $r = region$ $P_r = set\ of\ all\ vaccine\ trials\ associated\ with\ region\ r$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a NUMBER*
Data source	NIH – www.clinicaltrials.gov
Data processing & quality assurance	ChatGPT 5.0 has been used to retrieve information on sponsors and location whose geography or institution type was not specified or known but not in their selection and compilation. **Full list of trials available upon request**
Data reference period	Periods: 2022-2024 and 2019-2021
Data caveats/limitations	Clinical trials not captured in clinicaltrials.gov

11.1b New vaccine pipeline to manufacturers: Percentage of phase III-IV clinical trials started with main sponsor from region

Purpose & Definition	Demonstrates the existence of R&D capabilities, if strategies are targeting newer platforms beyond traditional technologies and if a strategy for regional innovation exists and is being implemented.
Rationale	The initiation of phase III/IV clinical development programs, even if result from tech transfer, co-development agreements or other, is an indication of an ecosystem that is initiating mastering and controlling the pipeline of new products that upon successful MA will translate in locally manufactured products
Stratification	'Regional Main vs Secondary Sponsor Type of Sponsor Site location Vaccine type (C-19 vs not)
Calculation method	$Share\ main\ sponsor\ (r) = \frac{\sum_{p \in P_r} 1[Phase(p) \in \{III, IV\}\ and\ start\ year\ (p) > 2019\ and\ main\ sponsor_c(p) \in r\ and\ enrolment > 0]}{\sum_{p \in P_r} 1[Phase(p) \in \{III, IV\}\ and\ start\ year\ (p) > 2019\ and\ sponsor_c(p) \in r\ and\ enrolment > 0]}$ Where: $r = region$ $P_r = set\ of\ all\ vaccine\ trials\ associated\ with\ region\ r$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a PERCENTAGE*
Data source	NIH – www.clinicaltrials.gov
Data processing & quality assurance	ChatGPT 5.0 has been used to retrieve information on sponsors and location whose geography or institution type was not specified or known but not in their selection and compilation. **Full list of trials available upon request**
Data reference period	Periods: 2022-2024 and 2019-2021
Data caveats/limitations	Clinical trials not captured in clinicaltrials.gov

12.1 Localised manufacturing platforms: Number of operational localised manufacturing platforms

Purpose & Definition	Demonstrates the existence of R&D capabilities, if strategies are targeting newer platforms beyond traditional technologies and if a strategy for regional innovation exists and is being implemented.
Rationale	RVM should target the availability in the regions of different manufacturing platforms to allow production of vaccines relevant for the regions irrespective of the technology requirements. The goal is also to leverage the more modern and financially attractive platforms.
Stratification	Regional
Calculation method	$Integrated\ platform\ share\ (r) = \frac{\sum_{p \in P_r} 1[Platform\ p\ of\ manufacturer\ m\ is\ fully\ integrated\ in\ region\ r\ and\ unique]}{\sum_{p \in P_r} 1}$ Where: $r = region$ $P_r = set\ of\ all\ manufacturer\ platforms\ associated\ with\ region\ r$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a RATIO*
Data source	Based the list of manufacturers defined in indicator 1.1 Based on the list of vaccines defined in indicator 2.1 Desk Review List of platforms as defined by the project - See Data table section
Data processing & quality assurance	ChatGPT 5.0 has been used to retrieve information on selected platforms but not in their selection and compilation.
Data reference period	September 2025
Data caveats/limitations	Same as per sources of indicators 1.1 and 2.1 - information about vaccines commercialised and portion of the manufacturing process performed may be incorrect.

vii. Tech Transfer and workforce development

13.1 Technology Transfers: Number of signed tech transfers by fully functional regional manufacturers

Purpose & Definition	Captures that tech transfers are occurring, and that the workforce is getting trained to support the need of existing and new regional vaccine manufacturers.
Rationale	During the early years of RVM, technology transfers are critical to the development of a functioning RVM ecosystem. Ability of a creating a conducive ecosystem is critical for the further development of RVM
Stratification	'Regional Status (Signed, Completed) Stage (In progress, Paused before Completion, Marketed, Discontinued) Originator type (IFPMA, DCVMV, Other)
Calculation method	$N_{TT}^{Signed}(r,T) = \sum_{t \in TT_r} 1[Signed\ TT(t) = \text{yes} and\ year(t) \in T]$ Where: $N_{TT}^{Signed}(r,T) = number\ of\ signed\ technology\ transfers\ in\ region\ r\ during\ time\ period\ T$ $TT_r = set\ of\ technology\ transfers\ in\ region\ r$ $year(t) = year\ of\ the\ technology\ transfer$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a NUMBER*
Data source	CHAI Tech Transfer Landscape Desk Review – information about time of tech transfers, status and stage based on multiple individual sources for each manufacturer - **Full list of sources available upon request** Expert Input
Data processing & quality assurance	ChatGPT 5.0 has been used to retrieve information but not in their selection and compilation.
Data reference period	Periods : 2022-2024 and 2019-2021
Data caveats/limitations	The data results from a variety of sources with different level of accuracy and precision. CHAI landscape analysis only contains non-confidential information.

14.1 Regional workforce Development: Proportion of highly qualified workforce originating from region

Purpose & Definition	Captures that tech transfers are occurring, and that the workforce is getting trained to support the need of existing and new regional vaccine manufacturers.
Rationale	RVM requires a trained specialised workforce in the various functions . To be sustainable, the workforce employed in the region is ideally trained in or originates from the region.
Stratification	Regional
Calculation method	$RegionalEmployeeShare(r) = \left(\frac{\sum_{e \in E_r} 1[Employee\ e\ originates\ from\ region\ r\ and\ works\ in\ vaccine\ sector]}{\sum_{e \in E_r} 1[Employee\ e\ \ works\ in\ vaccine\ sector]}\right) * 100$ Where: $E_r = set\ of\ highly\ qualified\ employees\ from\ region\ r\ working\ in\ the\ vaccine\ sector$ $E = set\ of\ highly\ qualified\ employees\ working\ in\ the\ vaccine\ sector$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a PERCENTAGE*
Data source	Data not available
Data processing & quality assurance	Data not available
Data reference period	Data not available
Data caveats/limitations	Data not available

viii. Supply Chain and Infrastructure

15.1 Supply interruptions: Number of stockouts classified as supply side (shortages, quality, and procurement delays)

Purpose & Definition	Provides evidence that enabling infrastructure is being put in place, public supply chains are functioning, and manufacturers' supply chains are working effectively.
Rationale	Well functioning supply chains on the manufacturers side results in less supply interruptions and in a more trustworthy RVM impacting positively its sustainability
Stratification	Regional
Calculation method	$N_{stockouts}(r) = \sum_{s \in S_r} 1[Vaccine(s)\ is\ produced\ in\ region\ r\ and\ cause(s) \in \{"Procurement\ delays", "Shortages"\}]$ Where: $S_r = set\ of\ supply\ interruption\ records\ in\ region\ r$ $1[\cdot] = equals\ 1\ if\ condition\ is\ true, otherwise\ 0$ *Results presented as a NUMBER*
Data source	For vaccines produced in the region – Indicator 2.1 For causes of stockouts - WHO eJRF - https://immunizationdata.who.int/global/wiise-detail-page/vaccine-supply-and-logistics?ISO_3_CODE=&YEAR=
Data processing & quality assurance	Incomplete data
Data reference period	Periods : 2022-2024 and 2019-2021
Data caveats/limitations	The data are very partial and the explanations for the causes behind the stock outs mostly incomplete

16.1 Regionally focused procurement: Number of doses (in millions) procured via regional pooled procurement mechanisms

Purpose & Definition	Provides evidence that enabling infrastructure is being put in place, public supply chains are functioning, and manufacturers' supply chains are working effectively.
Rationale	Pooled procurement mechanisms focused on regional needs and with the appropriate set of incentives can support the development of RVM ensuring sizeable and more predictable demand.
Stratification	Regional
Calculation method	$N_{Doses}^{Pooled}(r) = \sum_{v \in V_r} D_v^{Pooled}(r)$ Where: $V_r = set\ of\ vaccines\ procured\ in\ region\ r$ $D_v^{Pooled}\ (r) = number\ of\ doses\ of\ vaccine\ v\ procured\ trhough\ a\ pooled\ procurement\ mechanism\ in\ region\ r$ *Results presented as a NUMBER*
Data source	PAHO: https://www.paho.org/en/news/24-2-2025-over-800-million-vaccines-medicines-and-health-technology-procured-pahos-regional
Data processing & quality assurance	No data processing Data are considered quality checked at the source
Data reference period	2024
Data caveats/limitations	None

d. Key Regional Facts

Number of countries

Purpose & Definition	The number of countries in the regions of scope: Africa (geographical definition), Southeast Asia (ASEAN member states) and LAC (geographic definition)
Stratification	By region
Calculation method	$N_{countries}\,(r) = \sum_{c \in C_r} 1$ Where: $C_r = set\ of\ all\ countries\ in\ region\ r$ *Results presented as a NUMBER*
Data source	Provided by RVMC
Data reference period	Point in time: latest year available = 2024

Population size

Purpose & Definition	The reported population of countries in the regions of scope: Africa (geographical definition), Southeast Asia (ASEAN member states) and LAC (geographic definition)
Stratification	By region
Calculation method	$Population\ (r, y) = \sum_{c \in C_r} Population_c(y)$ Where: $C_r = set\ of\ all\ countries\ in\ region\ r$ $y = year\ of\ interest\ (2024)$ *Results presented as a NUMBER*
Data source	UN World Population Prospects 2024 [File GEN/01/REV1: Demographic indicators by region, subregion and country, annually for 1950-2100] https://population.un.org/wpp/downloads?folder=Standard%20Projections&group=Most%20used
Data processing & quality assurance	Extracted from the UN World Population Prospects 2024 (WPP2024_Demographic_Indicators_Medium.csv), including total population and surviving infants, cleaned and restricted to 2020–2024
Data reference period	Point in time: latest year available = January 2024
Data caveats/limitations	As listed on : https://population.un.org/wpp/downloads?folder=Standard%20Projections&group=Most%20used

Surviving Infants

Purpose & Definition	The reported surviving infant population of countries in the regions of scope: Africa (geographical definition), Southeast Asia (ASEAN member states) and LAC (geographic definition)
Stratification	By region
Calculation method	$Surviving\ infants\ (r, y) = \sum_{c \in C_r} Surviving\ infants_c(y)$ Where: $C_r = set\ of\ all\ countries\ in\ region\ r$ $y = year\ of\ interest\ (2024)$ *Results presented as a NUMBER*
Data source	UN World Population Prospects 2024 [File GEN/01/REV1: Demographic indicators by region, subregion and country, annually for 1950-2100] https://population.un.org/wpp/downloads?folder=Standard%20Projections&group=Most%20used
Data processing & quality assurance	Extracted from the UN World Population Prospects 2024 (WPP2024_Demographic_Indicators_Medium.csv), including total population and surviving infants, cleaned and restricted to 2020–2024
Data reference period	Point in time: latest year available = 2024
Data caveats/limitations	As listed on : https://population.un.org/wpp/downloads?folder=Standard%20Projections&group=Most%20used

5. Data tables used in Strategy Indicators

Indicator 1.1: Manufacturing Breadth : Number of fully functional regional manufacturers by business archetype

region	country	NRA (maturity level as per tab NRA Status)	FULLY FUNCTIONAL RM	Manufacturer name	Ownership	Production Scope	Commercial Geographical Scope	Size	TOTAL COMMERCIALISED
Africa	Egypt	ML3 (producing) / WLA	YES	VACSERA / EGYVAC	REGIONAL	Drug Product only	Domestic	Small (Below 10m)	1
Africa	South Africa	ML3 (producing) / WLA	YES	Aspen Pharmacare	REGIONAL	Drug Product only (C-19 only)	Domestic	Small (Below 10m)	1
Africa	South Africa	ML3 (producing) / WLA	YES	Biovac	REGIONAL	Drug Product only	Domestic	Small (Below 10m)	2
Africa	Senegal	ML3 (producing) / WLA	YES	Institut Pasteur de Dakar	REGIONAL	Fully integrated (<5 Vx)	Export	Small (Below 10m)	1
Africa	Tunisia	Not ML3/ML4/WLA	YES	Institut Pasteur de Tunis	REGIONAL	Fully integrated (<5 Vx)	Domestic	Small (Below 10m)	2
ASEAN	Indonesia	ML3 (producing) / WLA	YES	PT Bio Farma (Persero)	REGIONAL	Fully integrated (>= 5 Vx)	Export	Large (Above 100m)	10
ASEAN	Thailand	ML3 (producing) / WLA	YES	Government Pharmaceutical Organization (GPO)	REGIONAL	Fully integrated (<5 Vx)	Domestic	Small (Below 10m)	4
ASEAN	Thailand	ML3 (producing) / WLA	YES	BioNet-Asia	REGIONAL	Fully integrated (<5 Vx)	Domestic	Small (Below 10m)	4
ASEAN	Thailand	ML3 (producing) / WLA	YES	Queen Saovabha Memorial Institute (QSMI, Thai Red Cross)	REGIONAL	Fully integrated (<5 Vx)	Domestic	Small (Below 10m)	1
ASEAN	Thailand	Not ML3/ML4/WLA	YES	Siam Bioscience	REGIONAL	Drug Product only (C-19 only)	Domestic	Small (Below 10m)	1
ASEAN	Viet Nam	ML3 (producing) / WLA	YES	IVAC (Institute of Vaccines and Medical Biologicals)	REGIONAL	Fully integrated (>= 5 Vx)	Domestic	Small (Below 10m)	6
ASEAN	Viet Nam	ML3 (producing) / WLA	YES	POLYVAC	REGIONAL	Fully integrated (<5 Vx)	Domestic	Small (Below 10m)	3
ASEAN	Viet Nam	ML3 (producing) / WLA	YES	VABIOTECH	REGIONAL	Fully integrated (>= 5 Vx)	Domestic	Small (Below 10m)	5
ASEAN	Malaysia	Not ML3/ML4/WLA	YES	Pharmaniaga LifeScience (PLS)	REGIONAL	Drug Product only (C-19 only)	Domestic	Small (Below 10m)	1
ASEAN	Malaysia	ML3 (producing) / WLA	NO	Substipharm Asia	OUTSIDE (French)	Drug Product only	Export	Small (Below 10m)	1
ASEAN	Singapore	ML4 (non-producing)	NO	GSK (Singapore Vaccines)	OUTSIDE (British))	Drug Substance Only	Export	Large (Above 100m)	0
ASEAN	Myanmar	Not ML3/ML4/WLA	YES	Insein	REGIONAL	Drug Product only (C-19 only)	Domestic	Small (Below 10m)	1
LAC	Brazil	PAHO reference NRA	YES	Instituto Butantan	REGIONAL	Fully integrated (>= 5 Vx)	Domestic	Large (Above 100m)	8
LAC	Brazil	PAHO reference NRA	YES	Bio-Manguinhos/Fiocruz	REGIONAL	Fully integrated (>= 5 Vx)	Export	Large (Above 100m)	12
LAC	Brazil	PAHO reference NRA	YES	Ezequiel Dias Foundation (FUNED)	REGIONAL	Drug Product only	Domestic	Small (Below 10m)	1
LAC	Cuba	PAHO reference NRA	YES	Finlay Vaccine Institute (IFV)	REGIONAL	Fully integrated (>= 5 Vx)	Domestic	Small (Below 10m)	8
LAC	Cuba	PAHO reference NRA	YES	CIGB (Center for Genetic Engineering and Biotechnology)	REGIONAL	Fully integrated (<5 Vx)	Domestic	Small (Below 10m)	3
LAC	Mexico	PAHO reference NRA	NO	Sanofi Pasteur (Ocoyoacac)	OUTSIDE (French)	Fully integrated (<5 Vx)	Export	Large (Above 100m)	0
LAC	Mexico	PAHO reference NRA	YES	Laboratorio Liomont	REGIONAL	Drug Product only (C-19 only)	Domestic	Small (Below 10m)	1
LAC	Argentina	PAHO reference NRA	YES	Sinergium Biotech	REGIONAL	Drug Product only	Export	Small (Below 10m)	3
LAC	Nicaragua	Not ML3/ML4/WLA	YES	Instituto Mechnikov	REGIONAL	Drug Product only	Domestic	Small (Below 10m)	1

Indicator 2.1: Manufacturing Depth: Number of fully functional regional manufacturers, with a portfolio of 5 or more vaccines which produced >70 million doses/year

region	country	FULLY FUNCTIONAL RM	Manufacturer name	BCG	OPV	IPV	MR	MMR	RV	HPV	Leptosp	ViTyphoid	MenACWY	MenACW Conj	MenC	MenBC	Hib	PCV	C-19	Seas. Flu	HepA	HepB	Penta wP	Hexa aP	aP	DTwP	DTaP/TdaP	DT/Td	TT	JEV	OCV	YF	Ebola	Dengue	Rabies
Africa	Egypt	YES	VACSERA / EGYVAC																DP										?						
Africa	South Africa	YES	Aspen Pharmacare																DP																
Africa	South Africa	YES	Biovac																					DP					DP						
Africa	Senegal	YES	Institut Pasteur de Dakar																													FI			
Africa	Tunisia	YES	Institut Pasteur de Tunis	FI																															FI
ASEAN	Indonesia	YES	PT Bio Farma (Persero)	FI	FI	FI	FI												DP	DP		FI	FI					FI	FI						
ASEAN	Thailand	YES	Government Pharmaceutical Organization (GPO)	FI																FI										FI					FI
ASEAN	Thailand	YES	BioNet-Asia																					FI			DP	DP	FI						
ASEAN	Thailand	YES	Queen Saovabha Memorial Institute (QSMI, Thai Red Cross)	FI																															
ASEAN	Thailand	YES	Siam Bioscience																DP																
ASEAN	Viet Nam	YES	IVAC (Institute of Vaccines and Medical Biologicals)	FI																FI						FI		FI	FI	FI					
ASEAN	Viet Nam	YES	POLYVAC		FI		FI		FI																										
ASEAN	Viet Nam	YES	VABIOTECH																DP			FI	DP							FI	FI				
ASEAN	Malaysia	YES	Pharmaniaga LifeScience (PLS)																DP																
ASEAN	Malaysia	NO	Substipharm Asia																											DP					
ASEAN	Singapore	NO	GSK (Singapore Vaccines)																																
ASEAN	Myanmar	YES	Insein	DP																															
LAC	Brazil	YES	Instituto Butantan							DP									DP	FI	FI	FI				FI		FI							FI
LAC	Brazil	YES	Bio-Manguinhos/Fiocruz	FI		DP	FI	FI	DP								DP	DP	FI	DP						FI		FI				FI			
LAC	Brazil	YES	Ezequiel Dias Foundation (FUNED)												DP																				
LAC	Cuba	YES	Finlay Vaccine Institute (IFV)								FI	FI		FI		FI	FI		FI									FI	FI						
LAC	Cuba	YES	CIGB (Center for Genetic Engineering and Biotechnology)																FI			FI	DP												
LAC	Mexico	NO	Sanofi Pasteur (Ocoyoacac)																																
LAC	Mexico	YES	Laboratorio Liomont																DP																
LAC	Argentina	YES	Sinergium Biotech							DP								DP		DP															
LAC	Nicaragua	YES	Instituto Mechnikov																	DP															

Indicator 12.1: 1 Localised manufacturing platforms: Number of operational localised manufacturing platforms

Vaccine Type	Platform	Sub platform	Target/ Tech	Vaccine	Recomb.	Chimeric	Pathogen/Disease	Type
Subunit	Protein-based	Inactivated	surface protein	Acellular Pertussis (PT, FHA, pertactin)			Bordetella pertussis	Bacterial
Whole Cell	Live-Attenuated			BCG (TB)			Mycobacterium bovis	Bacterial
Whole Cell	Live-Attenuated			Cholera (Oral Live-attenuated)			Vibrio cholerae	Bacterial
Whole Cell	Inactivated			Cholera (Oral whole-cell + recombinant protein)	YES		Vibrio cholerae	Bacterial
Whole Cell	Inactivated			Cholera (Oral whole-cell)			Vibrio cholerae	Bacterial
Whole Cell	Inactivated			COVID-19			SARS-CoV-2	Viral
Whole Cell	Live-Attenuated			COVID-19			SARS-CoV-2	Viral
Subunit	Conjugate			COVID-19 (conjugate)			SARS-CoV-2	Viral
Genetic	Nucleic Acid	DNA-based		COVID-19 (DNA)	YES		SARS-CoV-2	Viral
Genetic	Nucleic Acid	RNA-based	mRNA	COVID-19 (mRNA)	YES		SARS-CoV-2	Viral
Subunit	Protein-based	Nanoparticles		COVID-19 (spike nanoparticle)	YES		SARS-CoV-2	Viral
Genetic	Vectored	Viral vectors	Adenovirus	COVID-19 (vector ChAdOx1)			SARS-CoV-2	Viral
Genetic	Vectored	Viral vectors	Adenovirus	COVID-19 (vector: Ad26.COV2.S)			SARS-CoV-2	Viral
Genetic	Vectored	Viral vectors	Adenovirus	COVID-19 (vectors: rAd26 + rAd5)			SARS-CoV-2	Viral
Genetic	Vectored	Viral vectors	DENV-2	Dengue (DENV-2 backbone chimeric)		YES	Dengue virus	Viral
Genetic	Vectored	Viral Vectors	YF	Dengue (Live-attenuated chimeric YF backbone)		YES	Dengue virus	Viral
Subunit	Protein-based	Inactivated	toxoid	Diphtheria			Corynebacterium diphtheriae toxin	Bacterial
Genetic	Vectored	Viral vectors	VSV	Ebola (vector VSV)			Ebola virus	Viral
Whole Cell	Inactivated			Hepatitis A			Hepatitis A virus	Viral

Vaccine Type	Platform	Sub platform	Target/ Tech	Vaccine	Recomb.	Chimeric	Pathogen/Disease	Type
Subunit	Protein-based	Particle-based	VLP	Hepatitis B (HBsAg VLP)	YES		Hepatitis B virus	Viral
Subunit	Conjugate			Hib	YES		Haemophilus influenzae type b	Bacterial
Subunit	Protein-based	Particle-based	VLP	HPV (L1 VLP)	YES		Human papillomavirus	Viral
Whole Cell	Live-Attenuated			Influenza (FluMist, intranasal)			Influenza virus	Viral
Whole Cell	Inactivated			Influenza (inactivated)			Influenza virus	Viral
Subunit	Protein-based	Inactivated	surface protein	Influenza (subunit - HA protein)	YES		Influenza virus	Viral
Whole Cell	Inactivated			Japanese Encephalitis (inactivated)			Japanese encephalitis virus	Viral
Genetic	Vectored	Viral Vectors	YF	Japanese Encephalitis (Live-attenuated chimeric YF backbone)		YES	Japanese encephalitis virus	Viral
Whole Cell	Live-Attenuated			Japanese Encephalitis (live-attenuated. CD_JEV)			Japanese encephalitis virus	Viral
Subunit	Protein-based	Nanoparticles		Malaria (R21/matrix m)	YES		Malaria	Parasitic
Subunit	Protein-based	Particle-based	VLP	Malaria (RTS,S - VLP)	YES		Malaria	Parasitic
Whole Cell	Live-Attenuated			Measles			Measles virus	Viral
Subunit	Conjugate			Meningococcal ACWY - ACWYX - C - BC	YES		Neisseria meningitidis	Bacterial
Subunit	Protein-based	Inactivated	surface protein	Meningococcal B (fHbp)	YES		Neisseria meningitidis	Bacterial
Subunit	Protein-based	Particle-based	OMV	Meningococcal B (OMV)	YES		Neisseria meningitidis	Bacterial
Subunit	Polysaccharide			Meningococcal vaccines			Neisseria meningitidis	Bacterial
Whole Cell	Live-Attenuated			Mumps			Mumps virus	Viral
Subunit	Polysaccharide			Pneumococcal			Streptococcus pneumoniae	Bacterial
Subunit	Conjugate			Pneumococcal	YES		Streptococcus pneumoniae	Bacterial

Vaccine Type	Platform	Sub platform	Target/ Tech	Vaccine	Recomb.	Chimeric	Pathogen/Disease	Type
Whole Cell	Inactivated			Polio (IPV – Salk)			Poliovirus	Viral
Whole Cell	Live-Attenuated			Polio (Oral OPV – Sabin)			Poliovirus	Viral
Whole Cell	Inactivated			Rabies (cell culture)			Rabies virus	Viral
Whole Cell	Live-Attenuated			Rotavirus (Oral)			Rotavirus	Viral
Subunit	Protein-based	Inactivated	surface protein	RSV (F protein)	YES		Respiratory syncytial virus	Viral
Whole Cell	Live-Attenuated			Rubella			Rubella virus	Viral
Subunit	Protein-based	Inactivated	surface protein	Shingles (Herpes Zoster)	YES		Varicella-zoster virus (reactivated)	Viral
Whole Cell	Live-Attenuated			Smallpox / mpox			Smallpox & mpox	Viral
Genetic	Vectored	Viral vectors	Vaccinia	Smallpox / mpox (non replicating Vaccinia)			Smallpox & mpox	Viral
Genetic	Vectored	Viral vectors	Vaccinia	Smallpox / mpox (replicating Vaccinia)			Smallpox & mpox	Viral
Subunit	Protein-based	Inactivated	toxoid	Tetanus			Clostridium tetani toxin	Bacterial
Whole Cell	Inactivated			Tick Borne Encephalitis			Tick Borne Encephalitis	Viral
Whole Cell	Live-Attenuated			Typhoid (Oral Ty21a)			Salmonella Typhi	Bacterial
Subunit	Conjugate			Typhoid (Vi Conj)			Salmonella Typhi	Bacterial
Subunit	Polysaccharide			Typhoid (Vi PS)			Salmonella Typhi	Bacterial
Whole Cell	Live-Attenuated			Varicella			Varicella-zoster virus	Viral
Whole Cell	Inactivated			Whole Cell Pertussis			Bordetella pertussis	Bacterial
Whole Cell	Live-Attenuated			Yellow fever (17D)			Yellow fever virus	Viral

6. Data quality assessment

The quality of each indicator is assessed according to six parameters:

Parameter	Definition	Scoring
Accuracy	The degree to which the indicator's data correctly represents the real-world situation it is intended to measure.	1 – Low: Data are sourced from multiple providers, and/or with no structured process for validation or internal consistency checks. High risk of inconsistencies between sources. 2 – Moderate: Data are sourced from multiple providers, each validated and verified for consistency. Moderate risk of inconsistencies between sources. 3 – High: Data originate from a single authoritative source, routinely validated and verified for internal consistency.
Accessibility	The ease with which users can obtain, interpret, and use the indicator data, including data permissions, formats, and clarity of presentation.	1 – Low: Data are difficult to access (restricted, in non-standard formats, or poorly presented). 2 – Moderate: Data are accessible but require specialized effort or technical skills to retrieve or interpret. 3 – High: Data are easily accessible, well-documented, and supported by a clear and transparent methodology.
Timeliness	The degree to which indicator data is up to date and available within a timeframe that supports effective decision-making and progress monitoring.	1 – Low: Data are not regularly updated. 2 – Moderate: Data are regularly updated and published within 24 months of the closure of the calendar year. 3 – High: Data are regularly updated and published within 12 months of the closure of the calendar year.

Comprehensiveness	The extent to which the indicator captures all relevant countries within the regions in scope.	1 – Low: Data do not cover all countries/manufacturers in scope. 2 – Moderate: Data are available for all countries/manufacturers but may be incomplete for some years. 3 – High: Data are available for all countries/manufacturers and all relevant years.
Validity	The extent to which the indicator accurately measures the concept it is intended to capture.	1 – Low: Indicator is weakly related to the intended concept or relies on poor proxies. 2 – Moderate: Indicator has a reasonable conceptual link to the intended construct but does not fully capture it. 3 – High: Indicator is conceptually sound, methodologically robust, and well aligned with the intended measurement objective.
Traceability	The ability to trace the indicator data back to its original sources, methodologies, and transformations to ensure transparency and reproducibility.	1 – Low: Limited documentation exists; traceability is partial or inconsistent, and results depend heavily on expert judgment or AI-derived estimations. 2 – Moderate: All data sources, collection methods, and processing steps are documented and auditable, but some components (e.g., expert judgment or AI processing) complicate full traceability. 3 – High: All data sources, collection methods, and processing steps are fully documented, auditable, and transparently linked to original data.

a. Summary Score

A total score is calculated for each indicator, with equal weighting that synthesizes the indicators quality. The following indicator composite scoring is adopted:

Composite Score	Quality Category	Interpretation	Dashboard representation
17–18	Very Good Quality	Data are highly reliable, current, comprehensive, and fully traceable. Minimal risk of bias.	
14–16	Good Quality	Minor limitations; data are reliable and broadly suitable for decision-making	
11–13	Moderate Quality	Acceptable for monitoring, but with notable limitations in one or more dimensions.	
8–10	Low Quality	Data present significant quality gaps; interpretation should be cautious.	
6-7	Poor Quality	Data is unreliable or unsuitable for monitoring. Requires major improvement.	

7. General data limitations and caveats

The findings presented in RVMC First Status Report provide a directional, evidence-based assessment of the current status of regional vaccine manufacturing ecosystems, derived from the best publicly available and validated information. As regional data systems evolve and institutional transparency improves, both the RVMC dataset and the corresponding indicator framework will be periodically refined and expanded. RVMC, in collaboration with its partners, will undertake regular methodological reviews of the Dashboard to ensure that it remains fit for purpose, analytically robust, and policy-relevant in guiding regional and global strategies for strengthening vaccine manufacturing capacity.

To support accurate interpretation, all indicator definitions should be read in parallel with the RVMC Framework, which provides the conceptual structure linking each indicator to its underlying pillar and systemic function. Interpreting indicators in this contextual manner ensures alignment with the broader analytical intent of the Framework and prevents reduction of complex interdependencies to single-point observations.

Furthermore, regional variation in data maturity and completeness must be considered when comparing results across regions. More established data infrastructures in some regions yield higher confidence levels than those where institutional data systems are still developing. In addition, COVID-19–era distortions, including exceptional, time-limited funding inflows, atypical technology transfer activity, and temporary fluctuations in procurement and production volumes, have influenced several indicators, particularly during 2020–2022. These factors are explicitly documented in the dataset to safeguard against misinterpretation of pandemic-related anomalies as sustained structural trends.

8. Strategy Indicators - Secondary Indicators

Secondary indicators are presented in the tables below. These measures were identified during the initial "blue-sky" design phase as complementary elements that capture additional dimensions of the regional manufacturing ecosystem. While excluded from the current analysis due to data limitations or inconsistency across sources, they remain methodologically aligned with the RVMC Framework and will be reconsidered for inclusion in future iterations as data systems mature and reporting quality improves.

a. Finance & Demand

Category	Indicator Area	Purpose	Definition	Calculation
Healthy Markets	Market fragmentation	Measures the relevance of regional supply sources, confirms demand sustainability, and highlights supply risks. (Externality monitoring)	For all vaccines where RVM has vaccines commercialised in at least one region: **Average global number of producers per vaccine**	$N^{RVM}_{Mfr/Vx}(r) = \frac{\sum_{m \in M_r} M_m^{Functional}(r)}{\sum_{v \in V_r} V_v^{Commercialised}(r)}$ Where: • M_r = set of regional manufacturers in region *r* • V_r = set of vaccines commercialised in region *r* • $M_m^{Functional}(r)$ = number of fully functional manufacturers *m* in region *r* • $V_v^{Commercialised}(r)$ = number of vaccines *v* for which RVM is commercialising in region *r* *Results presented as a NUMBER*
Healthy Markets	Global vaccine prices	A more fragmented market can result in reduced ability for pooled procurement mechanisms to negotiate low prices. (Externality monitoring)	For all vaccines where RVM has vaccines commercialised in at least one region **Change in price of UNICEF procurement for Gavi (lowest price) and PAHO RF compared to the baseline (pre RVM)**	$\Delta P^{Avg}(r) = \frac{1}{\lvert V_r \rvert} \sum_{v \in V_r} \left(\frac{P_v^Y(r) - P_v^X(r)}{P_v^X(r)} \right)$ Where: • V_r = set of vaccines produced or procured in region *r* • $P_v^Y(r)$ = price of vaccine *v* in year *Y* in region *r* • $P_v^X(r)$ = price of vaccine *v* in year *X* in region *r* • $\lvert V_r \rvert$ = total number of vaccines in the region *r* included in the calculation *Results presented as a PERCENTAGE*

Healthy Markets	Procurement of regional vaccines	Healthy market should translate in countries procuring without any hindrance from regional manufacturers in their region and in the other regions in scope for RVM efforts	For all countries in the regions in scope: **Proportion of countries procuring from fully functional regional manufacturers in their region of origin or across the regions in scope**	$$P_{Proc}^{RVM}(r) = \frac{\sum_{c \in C_r} C_c^{Proc}(r)}{\sum_{c \in C_r} C_c^{Total}(r)}$$ Where: • C_r = set of countries in region *r* • $C_c^{Proc}(r)$ = 1 if country *c* procures vaccines from a regional manufacturer in region *r*, 0 otherwise • $C_c^{Total}(r)$ = total number of countries in region *r* And $$P_{Proc}^{RVM}(R) = \frac{\sum_{r \in R} \sum_{c \in C_r} C_c^{Proc}(r)}{\sum_{r \in R} \sum_{c \in C_r} C_c^{Total}(r)}$$ Where: • R = set of all regions in scope • C_r = set of countries in region *r* • $C_c^{Proc}(r)$ = 1 if country *c* procures vaccines from a regional manufacturer within any of the regions in scope, 0 otherwise • $C_c^{Total}(r)$ = total number of countries in region *r* *Results presented as a PERCENTAGE*
Healthy Markets	Procurement fragmentation	Reduction in the size of the pooled procurement mechanisms is going to impact their attractiveness as source of demand. (Externality monitoring)	For all vaccines (excluded C-19): **Change in average size of the largest 2 pooled procurement mechanisms**	$$\Delta D^{RVM}(r) = \frac{\sum_{v \in V_r} D_v^Y(r) - \sum_{v \in V_r} D_v^X(r)}{\sum_{v \in V_r} D_v^X(r)}$$ Where: • V_r = set of vaccines procured in region *r* • $D_v^Y(r)$ = number of doses of vaccine *v* procured in year *Y* in region *r* • $D_v^X(r)$ = number of doses of vaccine *v* procured in year *X* in region *r* *Results presented as a PERCENTAGE*

Financial Models	Ease of getting credit	Ability of access to credit is necessary for success of manufacturing	For all countries in the regions in scope: **Average rating for the Ease of Credit**	$$R^{Avg}(r) = \frac{1}{\lvert E_r \rvert} \sum_{e \in E_r} R_e(r)$$ Where: • E_r = set of entities (e.g., countries, manufacturers, or indicators) rated in region *r* • $R_e(r)$ = rating value assigned to entity *e* in region *r* • $\lvert E_r \rvert$ = total number of rated entities in region *r* *Results presented as a NUMBER*
Financial Models	Derisking of investments	Clinical development and manufacturing investments are sizeable and risky, in particular for actors of the Global South where the financial sector is less supportive of those enterprises. Success of RVM will require derisking measures to support regional players	For all countries in the regions in scope: **The number of distinct financial instruments deployed that are explicitly designed to reduce financial risk for investments in regional vaccine R&D, clinical development, or manufacturing infrastructure, categorized by type of funder, region, instrument type**	$$N_{Instr}^{Total}(r) = \sum_{i \in I_r} I_i(r)$$ Where: • I_r = set of financial instruments identified in region *r* • $I_i(r)$ = count (or value = 1) of each financial instrument *i* in region *r* *Results presented as a NUMBER*

b. Regulatory and Governance

Category	Indicator Area	Purpose	Definition	Calculation
Product Regulation	Reliance strength	Reliance translates in streamlined regulatory processes across multiple NRAs facilitating Marketing Authorisations (MAs) and Post Approval Changes (PACs)	For all vaccines regionally produced: **Proportion of vaccines that received MA or Post Approval Changes (PAC) by multiple NRAs benefitting from reliance**	$P_{Vx}^{Benefit}(r) = \frac{\sum_{v \in V_r} V_v^{Benefit}(r)}{\sum_{v \in V_r} V_v^{Comm}(r)}$ Where: • V_r = set of vaccines commercialised in region *r* • $V_v^{Benefit}(r)$ = 1 if vaccine *v* benefitted from the intervention or mechanism in region *r*, 0 otherwise • $V_v^{Comm}(r)$ = total number of vaccines commercialised in region *r* *Results presented as a PERCENTAGE*
Product Regulation	Regional regulatory collaborations	Collaboration between NRA will help individual NRAs progressing, enhance reliance and support manufacturers	For the regions in scope: **Number of operational transnational (also outside the regions in scope) collaborative regulatory initiatives**	$N_{Reg}^{Trans}(r) = \sum_{n \in N_r} N_n^{Initiative}(r)$ Where: • N_r = set of transnational (cross-border or multi-country) regulatory initiatives in region *r* • $N_n^{Initiative}(r)$ = count (or value = 1) for each regulatory initiative *n* identified in region *r* *Results presented as a NUMBER*

Product Regulation	Market reach of Marketing Authorisation	Ability of commercialising vaccines in multiple countries leveraging (ideally) a single regulatory process contributes to financial sustainability and reduced time to market	For all vaccines regionally produced: **Average number of countries where the vaccine has received MA and if WHO PQed**	$$P_{MA}^{Vx}(r) = \frac{\sum_{c \in C_r} C_c^{MA}(r)}{\sum_{v \in V_r} V_v^{Total}(r)}$$ Where: • C_r = set of countries in region *r* • V_r = set of vaccines relevant to region *r* • $C_c^{MA}(r)$ = number of countries *c* in region *r* that have granted Marketing Authorisation (MA) for one or more vaccines • $V_v^{Total}(r)$ = total number of vaccines assessed or commercialised in region *r* And $$N_{PQ}^{Vx}(r) = \sum_{v \in V_r} V_v^{PQ}(r)$$ Where: • V_r = set of vaccines in region *r* • $V_v^{PQ}(r)$ = 1 if vaccine *v* has WHO prequalification, 0 otherwise *Results presented as a NUMBER*
Governance	Governance Effectiveness	A strong governance and political system facilitates greatly the progression of RVM with clarity in the rule of law and stable policy framework	For all countries in the regions in scope **Average score for the Governance Effectiveness Index**	$$G_{Eff}^{Avg}(r) = \frac{1}{\lvert C_r \rvert} \sum_{c \in C_r} G_c^{Index}(r)$$ Where: • C_r = set of countries in region *r* • $G_c^{Index}(r)$ = Government Effectiveness Index value for country *c* in region *r* • $\lvert C_r \rvert$ = total number of countries in region *r* *Results presented as a NUMBER*

c. Technology and Supply

Category	Indicator Area	Purpose	Definition	Calculation
R&D & Manufacturing innovation	Transactional research	Translational research capabilities are necessary to promote a well functioning clinical development	For all the regions in scope **Number of institutions specialised in translational research**	$N_{Inst}^{Total}(r) = \sum_{i \in I_r} I_i(r)$ Where: • I_r = set of institutions identified in region *r* • $I_i(r)$ = count (or value = 1) for each institution *i* in region *r* *Results presented as a NUMBER*
R&D & Manufacturing innovation	Intellectual property	Generation of patents in the regions that are embedded in vaccines that are undergoing development is a goal and evidence of an ecosystem progressing towards autonomy in this field	For the regions in scope: **Proportion of clinical trials (all phases) with local intellectual property (IP)**	$P_{Trials}^{IP}(r) = \frac{\sum_{t \in T_r} T_t^{RegIP}(r)}{\sum_{t \in T_r} T_t^{Active}(r)}$ Where: • T_r = set of clinical trials conducted in region *r* • $T_t^{RegIP}(r)$ = 1 if trial *t* involves regional intellectual property (IP) ownership or sponsorship in region *r*, 0 otherwise • $T_t^{Active}(r)$ = total number of active clinical development programs (trials) in region *r* *Results presented as a PERCENTAGE*
R&D & Manufacturing innovation	Clinical trial capabilities	The availability of accredited clinical trial sites is necessary for the vaccine clinical development to be successful in delivering vaccines that can be widely commercialised	For all countries in the regions in scope: **Number of accredited clinical trial sites**	$N_{Sites}^{Accr}(r) = \sum_{s \in S_r} S_s^{Accr}(r)$ Where: • S_r = set of clinical trial sites in region *r* • $S_s^{Accr}(r)$ = 1 if clinical trial site *s* holds formal accreditation, 0 otherwise *Results presented as a NUMBER*
R&D & Manufacturing innovation	Input material for R&D	Access to material required for clinical development and establishment of vaccine manufacturing is necessary for successful RVM	For all countries in the regions in scope: **Volume of pharmaceutical-grade tubing import**	$Q_{Tube}^{Import}(r) = \sum_{i \in I_r} I_i^{Value}(r)$ Where: • I_r = set of pharmaceutical-grade tubing import transactions in region *r* • $I_i^{Value}(r)$ = quantity (in kilograms) or monetary value (in USD) of import *i* in region *r* *Results presented as a NUMBER*

R&D & Manufacturing innovation	Access to adjuvants	With a growing number of vaccines using adjuvant, the ability of accessing those is an indicator of a growing ability of RVM to progress	For all fully functional regional manufacturers in the regions in scope: **Number of deals ensuring access to adjuvants**	$N_{Deals}^{Adj}(r) = \sum_{d \subset D_r} D_d^{Adj}(r)$ Where: • D_r = set of partnership or supply deals in region *r* • $D_d^{Adj}(r)$ = 1 if deal *d* ensures access to adjuvants, 0 otherwise *Results presented as a NUMBER*
R&D & Manufacturing innovation	Collaboration	Collaborative R&D with global partners brings technical know-how, trial design expertise, and pathways for regulatory and commercial advancement. These partnerships are essential for early-stage capacity building, especially in low- and middle-income countries (LMICs).	For all fully functional regional manufacturers in the regions in scope: **Number of transactions in CEPI Market Place**	$N_{Trans}^{CEPI}(r) = \sum_{t \subset T_r} T_t^{CEPI}(r)$ Where: • T_r = set of transactions recorded in the CEPI marketplace for region *r* • $T_t^{CEPI}(r)$ = 1 for each transaction *t* conducted through the CEPI marketplace in region *r* = SUM (Nr. of Transactions) *Results presented as a NUMBER*
Tech transfer & workforce development	Employment growth	A functioning RVM ecosystem will contribute to the growth of employment in the regions	For all the regions in scope: **Growth in the number of individuals gainfully employed in the vaccine manufacturing ecosystem**	$R_{Emp}^{Vx}(r) = \frac{\sum_{e \subset E_r} E_e^Y(r)}{\sum_{e \subset E_r} E_e^X(r)}$ Where: • E_r = set of employees or employment records in the vaccine sector in region *r* • $E_e^Y(r)$ = number of employees in year *Y* in region *r* • $E_e^X(r)$ = number of employees in year *X* in region *r* *Results presented as a PERCENTAGE*

Tech transfer & workforce development	Deficit in workforce	Progression in RVM should be able to rely on a sufficient number of trained personnel. The ecosystem should be able to fill the gaps in a reasonable amount of time to avoid hindering progression	For all fully functional regional manufacturers in the regions in scope: **Proportion of total number of posted vacancies that are open for longer than 6 months for highly qualified vaccine manufacturing positions**	$P_{Vac}^{Long}(r) = \frac{\sum_{v \in V_r} V_v^{>6m}(r)}{\sum_{v \in V_r} V_v^{Total}(r)}$ Where: • V_r = set of vacancies for highly qualified vaccine manufacturing positions in region *r* • $V_v^{>6m}(r)$ = 1 if vacancy *v* remained open for more than six months, 0 otherwise • $V_v^{Total}(r)$ = total number of such vacancies in region *r* *Results presented as a PERCENTAGE or PROPORTION*
Tech transfer & workforce development	**Strength of training programs**	Local training programs capable of training a sufficient number of people on capabilities relevant for vaccine manufacturing is necessary for a functioning RVM ecosystem	For all countries in the regions in scope: **Number and reach of regional educational programs focused on developing relevant capabilities for vaccine manufacturing (this will require a definition of what is included)**	$N_{Edu}^{Vx}(r) = \sum_{p \in P_r} P_p^{Vx}(r)$ Where: • P_r = set of regional education or training programs in region *r* • $P_p^{Vx}(r)$ = 1 if program *p* focuses on developing capacities relevant to vaccine manufacturing, 0 otherwise AND $A_{Edu}^{Yr}(r) = \frac{1}{\lvert P_r \rvert} \sum_{p \in P_r} A_p^{Yr}(r)$ Where: • P_r = same set of regional programs as above • $A_p^{Yr}(r)$ = average yearly number of attendees to program *p* in region *r* • $\lvert P_r \rvert$ = total number of relevant programs in region *r* *Results presented as a NUMBER*

Tech transfer & workforce development	**Regional workforce Development**	A functioning RVM ecosystem is grounded on a trained specialised workforce in the various functions required by vaccine manufacturing. To be sustainable this workforce is ideally trained and employed in the region.	For all fully functional regional vaccine manufacturers in the regions in scope: **Proportion of highly qualified workforce trained/originating from region**	$P_{Work}^{Reg}(r) = \frac{\sum_{w \in W_r} W_w^{Reg}(r)}{\sum_{w \in W_r} W_w^{Total}(r)}$ Where: • W_r = set of highly qualified workforce positions in the vaccine manufacturing sector in region *r* • $W_w^{Reg}(r)$ = 1 if workforce member *w* was trained in or originates from the region *r*, 0 otherwise • $W_w^{Total}(r)$ = total number of highly qualified workforce positions in region *r* *Results presented as a PERCENTAGE*
Supply Chain & Infrastructure	**Critical input availability**	A functioning supply chain relies on availability of critical input produced in the region reducing dependencies on import.	For all fully functioning regional manufacturers in the regions in scope **Value (in USD) of critical inputs (tubing, bioreactor bags, filters, and fill-finish equipment), imported in the regions**	$V_{Input}^{Local}(r) = \sum_{i \in I_r} I_i^{Value}(r)$ Where: • I_r = set of critical input products (e.g., vials, filters, reagents, adjuvants) produced in region *r* • $I_i^{Value}(r)$ = monetary value (in USD or equivalent) of critical input *i* produced within its region of origin *r* *Results presented as a NUMBER*
Supply Chain & Infrastructure	**Transparency**	Transparency in market information is a key contributor to the development of a fully functioning RVM ecosystem	For all fully functioning regional manufacturers in the regions in scope: **Proportion of manufacturers contributing to market information sharing initiatives (e.g., AFRO CDC, PAHO RF, WHO MI4A, UNICEF pricing)**	$P_{Mfr}^{Data}(r) = \frac{\sum_{m \in M_r} M_m^{Share}(r)}{\sum_{m \in M_r} M_m^{Total}(r)}$ Where: • M_r = set of vaccine manufacturers in region *r* • $M_m^{Share}(r)$ = 1 if manufacturer *m* participates in data-sharing initiatives, 0 otherwise • $M_m^{Total}(r)$ = total number of vaccine manufacturers in region *r* *Results presented as a PERCENTAGE OR PROPORTION*

Supply Chain & Infrastructure	**Regional stockpiles**	Regional stockpiles focused on regional needs are in conditions to better support RVM	For all regions in scope: **Number of outbreak-prone diseases served by regional stockpiles or framework firm agreements for the delivery of products and % of the total outbreak-prone VPDs**	$N_{Stock}^{Out}(r) = \sum_{s \subset S_r} S_s^{Out}(r)$ Where: • S_r = set of regional stockpiles in region *r* • $S_s^{Out}(r)$ = 1 if stockpile *s* serves at least one outbreak- or epidemic-prone disease, 0 otherwise AND $P_{Stock}^{Out}(r) = \frac{\sum_{s \subset S_r} S_s^{Out}(r)}{\sum_{d \subset D_r} D_d^{Out}(r)}$ Where: • S_r = set of regional stockpiles in region *r* • D_r = set of outbreak/epidemic-prone diseases in region *r* • $S_s^{Out}(r)$ = number of stockpiles serving outbreak-prone diseases • $D_d^{Out}(r)$ = total number of outbreak/epidemic-prone diseases identified in region *r* *Results presented as a NUMBER & PERCENTAGE*
Supply Chain & Infrastructure	**Quality of Transportation Infrastructure**	A functioning infrastructure is paramount for the success of vaccine manufacturing	For all countries in the regions in scope: **Quality of transportation infrastructure as measured by the Logistic Performance Index of the World Bank**	$LPI^{Avg}(r) = \frac{1}{\lvert C_r \rvert} \sum_{c \subset C_r} LPI_c(r)$ Where: • C_r = set of countries in region *r* • $LPI_c(r)$ = World Bank *Logistics Performance Index* value for country *c* in region *r* • $\lvert C_r \rvert$ = total number of countries in region *r* *Results presented as a NUMBER*

9. Mission Indicators

Mission indicators translate the vision into operational objectives across the vaccine value chain: Development, Production, Procurement, and Distribution. These indicators measure medium-term progress toward achieving the vision.

Category	Indicator / Goal	Rationale	Definition	Formula
Development	**Homegrown vaccine product pipeline**	RVM success in addressing access constraints for relevant VPDs will also depend on the ability of a successful clinical development at that regional level so to ensure independency (from the need of tech transfer) and specificity (to the regional specific need that can be deprioritised especially if relevant disproportionally to low-income populations). At the mission level the focus is on all programs.	For all fully functional regional manufacturers in the regions in scope and for programs that originated in the region **Total count of vaccine in clinical development (all phases, all diseases and diseases of regional relevance)**	$N_{Trials}^{Active}(r) = \sum_{t \in T_r} T_t^{Active}(r)$ Where: • T_r = set of clinical development programs (trials) originated in region *r* • $T_t^{Active}(r)$ = 1 if clinical development program *t* is active (any phase, any disease) in region *r*, 0 otherwise AND $N_{Trials}^{RegDis}(r) = \sum_{t \in T_r} T_t^{RegDis}(r)$ Where: • T_r = set of clinical development programs originated in region *r* • $T_t^{RegDis}(r)$ = 1 if clinical development program *t* addresses a disease of regional relevance, 0 otherwise *Results presented as a NUMBER*

Development	**Regulatory strength**	A functioning RVM ecosystem results in manufacturers which can achieve marketing authorisation from fully functional NRAs/WHO PQ for vaccines fully produced locally. This is even more relevant if the manufacturer also produces bulk.	For all vaccines developed by a fully regional manufacturer in the regions in scope: **Total count of the vaccines that have achieved WHO PQ or marketing authorisation from a ML3 or WLA NRA**	$N_{Vx}^{RegQual}(r) = \sum_{v \in V_r} V_v^{PQ/MA}(r)$ Where: • V_r = set of vaccines developed or produced in region *r* • $V_v^{PQ/MA}(r)$ = 1 if vaccine *v* has achieved **WHO prequalification (PQ)** or **marketing authorisation (MA)** from a **Maturity Level 3 (ML3)** or **WHO-Listed Authority (WLA)** National Regulatory Authority (NRA), 0 otherwise *Results presented as a NUMBER*
Production	**RVM scale**	A functioning regional vaccine manufacturing ecosystem is capable of capturing a relevant share of the vaccine markets for diseases of regional relevance	For all fully functional regional manufacturers in the regions in scope and for all diseases of regional relevance: **Proportion of the market served by regional manufacturers**	$P_{Dose}^{RVM}(r) = \frac{\sum_{d \in D_r} D_d^{RegMfr}(r)}{\sum_{d \in D_r} D_d^{Total}(r)}$ Where: • D_r = set of vaccine doses commercialised in region *r* • $D_d^{RegMfr}(r)$ = number of doses commercialised by **regional manufacturers** in region *r* • $D_d^{Total}(r)$ = total number of vaccine doses commercialised in region *r* *Results presented as a PERCENTAGE OR PROPORTION*
Production	**Distributed manufacturing ecosystem**	Health security and equity will benefit from a diversified and distributed manufacturing ecosystem capable of putting first the public health priorities of the different regions	For all vaccines and all 5 geographical regions: **Number of regions where fully functional vaccine manufacturing is present**	$R_{Active}^{Vx\_RVM} = \frac{1}{\lvert V_{RVM} \rvert} \sum_{v \in V_{RVM}} R_v^{Active}$ Where: • V_{RVM} = set of vaccines produced under Regionalised Vaccine Manufacturing (RVM) initiatives • R_v^{Active} = number of regions with active manufacturing capacity for vaccine *v* • $\lvert V_{RVM} \rvert$ = total number of vaccines under RVM *Results presented as a NUMBER*

Production	**RVM ecosystem sustainability**	Regional manufacturers should be financially and operational viable to be sustainable. An unsustainable ecosystem is likely to result in several market exits with impact on access. A flourishing ecosystem is likely to attract new entrants.	For all fully functional regional manufacturers : **Number of exits and of new entries**	$$N_{Mfr}^{Enter}(r) = \sum_{m \in M_r} M_m^{Enter}(r)$$ Where: • M_r = set of fully functional regional manufacturers in region *r* • $M_m^{Enter}(r)$ = 1 if manufacturer *m* entered (began operations or commercialisation) during the reference period, 0 otherwise AND $$N_{Mfr}^{Exit}(r) = \sum_{m \in M_r} M_m^{Exit}(r)$$ Where: • M_r = set of fully functional regional manufacturers in region *r* • $M_m^{Exit}(r)$ = 1 if manufacturer *m* exited (ceased operations or commercialisation) during the reference period, 0 otherwise *Results presented as a NUMBER*
Procurement	**Financing for vaccine procurement**	Certainty of financing for vaccine procurement is necessary for predictable and sustainable demand that is at the foundation of sustainability of RVM. Since most of vaccines are procured via public tenders, availability of public funding for vaccines is critical to guarantee this certainty.	For all countries in the regions in scope and all vaccines included in the WHO recommended schedule (can be regional specific): **Proportion of the total theoretical funding need based on a 100% coverage assumption covered by domestic funding**	$$F_{Dom}^{Avg}(r) = \frac{1}{\lvert D_r \rvert} \sum_{d \in D_r} \left(\frac{\sum_{s \in S_r} S_s^{Finance}(r)}{\sum_{p \in P_d} (Pop_p^{Target}(r) \times C^{100\%} \times P_v^{Avg}(r))} \right)$$ Where: • D_r = set of vaccine-preventable diseases in region *r* • S_r = set of domestic financing sources in region *r* • $S_s^{Finance}(r)$ = theoretical total domestic financing available for vaccines from source *s* in region *r* • $Pop_p^{Target}(r)$ = target population for disease *d* in region *r* • $C^{100\%}$ = theoretical full vaccination coverage (100%) • $P_v^{Avg}(r)$ = average price per vaccine dose for disease *d* in region *r* • $\lvert D_r \rvert$ = total number of diseases included in the calculation *Results presented as a PERCENTAGE*

Procurement	**Contribution to trade balance**	Increasing the ability of the RVM ecosystem to export vaccine doses contributes to the sustainability and to economic growth of their regions	For all fully functional regional manufacturers in the regions in scope: **Number of doses exported by regional manufacturers**	$N_{Dose}^{Export}(r) = \sum_{d \subset D_r} D_d^{Export}(r)$ Where: • D_r = set of vaccine doses produced by **regional manufacturers** in region *r* • $D_d^{Export}(r)$ = number of doses *d* exported outside region *r* by regional manufacturers *Results presented as a NUMBER*
Distribution	**Effective Vaccine Management**	A well functioning vaccine management system is necessary for an effective flow of goods and reliable demand.	For all countries in the regions in scope: **Average Effective Vaccine Management (EVM2) composite score**	$EVM^{Avg}(r) = \frac{1}{\lvert C_r \rvert} \sum_{c \subset C_r} EVM_c(r)$ Where: • C_r = set of countries in region *r* • $EVM_c(r)$ = *Effective Vaccine Management (EVM) composite score* for country *c* in region *r* • $\lvert C_r \rvert$ = total number of countries in region *r* *Results presented as a NUMBER*

10. Vision Indicators

Vision indicators represent the highest-level goals and long-term desired outcomes of regional vaccine manufacturing initiatives. They focus on long-term impact in three key areas: Vaccine Equity, Health Security, and Sustainable Economic Development.

Subcategory	Indicator / Goal	Rationale	Definition	Formula
Overarching	**Health impact**	Even if a causal link cannot be demonstrated, Improved access to vaccines as result of RVM will have ultimately an impact on mortality and morbidity.	For all VPDs with outbreak potential that have vaccines produced in at least one of the regions in scope **Change in upper range of DALYs for outbreak/epidemic prone diseases** **Note:** The causality link may not be easily defined. Furthermore, changes in DALYs can only be measured ex post after an outbreak and also in those circumstances this is result of modelling exercises. The indicator is not likely to move easily for quite some time	$\Delta DALY(r) = \frac{DALY^{Y}(r) - DALY^{X}(r)}{DALY^{X}(r)}$ Where: • $DALY^{Y}(r)$ = total *Disability-Adjusted Life Years* in year *Y* for region *r* • $DALY^{X}(r)$ = total *Disability-Adjusted Life Years* in year *X* for region *r* *Results presented as a PERCENTAGE*

Vaccine Equity	**Coverage inequities**	Even if a causal link cannot be demonstrated, vaccination coverage in the regions of Africa, Latin America and Southeast Asia, is the targeted equitable outcome. It is assumed that a distributed vaccine production ecosystem closer to the beneficiaries can increase/improve access hence leading to a progressive alignment to global averages	For a basket of vaccines including all those produced in at least one of the regions in scope: **Average across vaccines of the differences between the average coverage of the regions where the vaccines are commercialised and the Global coverage**	$C_{Vx}^{Diff}(r) = \frac{1}{\lvert V_r \rvert} \sum_{v \in V_r} (C_v^{Region}(r) - C_v^{Global})$ Where: • V_r = set of vaccines assessed in region *r* • $C_v^{Region}(r)$ = coverage rate of vaccine *v* in region *r* • C_v^{Global} = global average coverage rate for vaccine *v* • $\lvert V_r \rvert$ = total number of vaccines considered in region *r* *Results presented as a PERCENTAGE*

Vaccine Equity	**Delay in vaccine introduction**	Even if a causal link cannot be demonstrated, the reduction/elimination of the delays in access to vaccines is a primary goal of RVM. It is assumed that more producers closer to the beneficiaries can reduce those delays irrespective if the vaccines are produced in the regions or not but as a result of the overall increase of global capacity and decentralisation	For a basket of vaccines including all those produced in at least one of the regions in scope : **Average regional difference between the vaccine/country years of introduction (of relevant regions where each vaccine is currently produced) and the first introducing HICs**	$\Delta Y_{Intro}^{Avg}(r) = \frac{1}{\lvert V_r \rvert} \sum_{v \subset V_r} \left(Y_v^{Region}(r) - Y_v^{HIC} \right)$ Where: • V_r = set of vaccines introduced in region *r* • $Y_v^{Region}(r)$ = year of first introduction of vaccine *v* in region *r* • Y_v^{HIC} = year of first introduction of the same vaccine *v* in high-income countries (HICs) • $\lvert V_r \rvert$ = total number of vaccines considered in region *r* *Results presented as a NUMBER*

Health Security	**Routine immunisation strengthening**	The availability of regional manufacturing capacity is assumed to increase access to vaccine for all vaccine preventable diseases	For all VPDs with a vaccine available: **Proportion of the consumption and of the theoretical full regional need on a 100% coverage supplied by fully functional regional manufacturers**	$$P_{Dose}^{Source}(r) = \frac{\sum_{v \in V_r} D_v^{RegMfr}(r)}{\sum_{v \in V_r} D_v^{Cons}(r)}$$ Where: • V_r = set of vaccines used or commercialised in region *r* • $D_v^{RegMfr}(r)$ = number of doses of vaccine *v* sourced from **fully functional regional manufacturers** in region *r* • $D_v^{Cons}(r)$ = total number of doses of vaccine *v* **consumed** in region *r* AND $$P_{Dose}^{Need}(r) = \frac{\sum_{v \in V_r} D_v^{RegMfr}(r)}{\sum_{v \in V_r} D_v^{100\%Need}(r)}$$ Where: • V_r = set of vaccines relevant to region *r* • $D_v^{RegMfr}(r)$ = number of doses of vaccine *v* sourced from **fully functional regional manufacturers** in region *r* • $D_v^{100\%Need}(r)$ = total number of doses of vaccine *v* required to meet **theoretical full regional need** assuming **100% population coverage** *Results presented as a PERCENTAGE*

Health Security	**Outbreak response capabilities**	The availability of regional manufacturing capacity is assumed to increase access to vaccine for outbreak-prone vaccines reducing the risk of an access failure	For all VPDs with outbreak/epidemic potential: **Average proportion - across diseases - of the theoretical full regional need to respond to outbreaks that can be supplied by fully functional regional manufacturers - (Targeted population defined by disease)** **Note:** Under the assumption that the whole capacity can be activated resulting in the corresponding availability of vaccine doses all commercialized in the region (e.g., no losses, no exports) It requires the definition of the diseases in scope.	$C_{Avail}^{Avg}(r) = \frac{1}{\lvert D_r \rvert} \sum_{d \subset D_r} \left(\frac{C_d^{RegMfr}(r)}{D_d^{Req}(r)} \right)$ Where: • D_r = set of vaccine-preventable diseases in region *r* • $C_d^{RegMfr}(r)$ = **available regional manufacturing capacity** (in doses) for vaccines targeting disease *d* in region *r* • $D_d^{Req}(r)$ = **total dose requirement** for the targeted population for disease *d* in region *r* • $\lvert D_r \rvert$ = total number of diseases included in the analysis *Results presented as a PERCENTAGE*

Health Security	**Outbreak response capabilities (alternative to level 1 if sufficient data nor available)**	The availability of regional manufacturing capacity is assumed to increase access to vaccine for outbreak-prone vaccines reducing the risk of an access failure	For all VPDs with outbreak/epidemic potential and all regional vaccine manufacturers: **Number of active platforms suitable for quick response (viral vector and nucleic acid)**	$N_{Plat}^{Active}(r) = \sum_{p \subset P_r} P_p^{Quick}(r)$ Where: • P_r = set of vaccine manufacturing platforms in region *r* • $P_p^{Quick}(r)$ = 1 if platform *p* is **active** and **suitable for rapid outbreak or emergency response**, 0 otherwise *Results presented as a NUMBER*

Sustainable Economic Development	**Return on investment into the regional economy**	The investments in RVM will have a positive and sizeable ROI that justifies also from a financial standpoint the overall enterprise	For all investments in vaccine manufacturing in the regions in scope over the last 10 years that have resulted in the commercialisation of products:
			Return on investment generated
			
			Note: This will require modelling efforts.
				$R_{PV}^{ROI}(r) = \frac{PV_{Return}(r)}{PV_{Invest}(r)}$
				Where:
				• $PV_{Return}(r) = \sum_{k \in K_r} R_k^{PV}(r)$ = present value of all **returns** generated in region *r*, including:
				  • $R_k^{Profit}(r)$: company profits
				  • $R_k^{Tax}(r)$: increased tax revenues
				  • $R_k^{HealthSave}(r)$: health expenditure savings
				  • $R_k^{Impact}(r)$: monetised value of health impact (e.g., DALYs averted)
				• $PV_{Invest}(r) = \sum_{i \in I_r} I_i^{PV}(r)$ = present value of total **investments** in region *r*, including:
				  • $I_i^{Capex}(r)$: capital expenditures
				  • $I_i^{TT}(r)$: technology transfers
				  • $I_i^{Infra}(r)$: infrastructure investments
				Results presented as a NUMBER

Sustainable Economic Development	**Dependence on import**	RVM success will result in lower dependency on imports of vaccines at the regional level for those vaccines that are produced in the regions.	For all vaccines (except C-19) used irrespective of their region of origin and for the regional vaccines. **Average proportion of the total vaccine market represented by the vaccine sourced from outside the region:**	$M_{Import}^{Avg}(r) = \frac{1}{\lvert C_r \rvert} \sum_{c \subset C_r} \left(\frac{V_c^{ImpOut}(r)}{V_c^{Total}(r)} \right)$ Where: • C_r = set of countries in region r • $V_c^{ImpOut}(r)$ = **value of imported vaccines** sourced from **outside** the region for country c • $V_c^{Total}(r)$ = **total vaccine market value** (domestic + imported) for country c • $\lvert C_r \rvert$ = total number of countries in region r *Results presented as a PERCENTAGE*

11. Conclusion

This methodology provides a transparent and reproducible foundation for assessing regional vaccine manufacturing ecosystems across Africa, ASEAN, and Latin America and the Caribbean as presented in the RVMC ESI Status Reports. It defines standardized indicators, data sources, and analytical parameters that enable comparability across time and geography. The approach emphasizes triangulation of publicly available data, validation through expert review, and consistency with the RVMC Framework.

While the results represent the best available evidence, they are constrained by varying data maturity across regions and the residual distortions of the COVID-19 era. As reporting systems evolve and new datasets become available, both the indicators and underlying data will be periodically updated to enhance precision and policy relevance.

The methods presented here are intended to guide interpretation of the RVMC First Status Report and Dashboard, ensure reproducibility of analyses, and inform collaborative efforts to strengthen data transparency in regional manufacturing.