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A path toward health equity

Equitable access to vaccines through regionalized manufacturing

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Executive summary and RVMC framework

The COVID-19 pandemic exposed a number of inequities regarding the ways that health care is delivered around the world, particularly related to vaccines. In the year after the first Emergency Use Authorization was granted by the UK's Medicines & Healthcare Products Regulatory Agency for the Pfizer-BioNTech COVID-19 vaccine, high-income countries achieved a vaccination rate twice that of lower-middle-income countries and 20 times that of lower-income countries.[1] It was clear vaccine equity could be improved with better distributed vaccine manufacturing capacity.

Deloitte is committed to helping address inequities such as this, most recently by working with the World Economic Forum (the Forum) in support of its Regionalized Vaccine Manufacturing Collaborative (RVMC). The Forum joined forces with the National Academy of Medicine (NAM) and the Coalition for Epidemic Preparedness Innovations (CEPI) to launch RVMC in May 2022. RVMC brought together private and public sector organizations to develop a roadmap for establishing and expanding regional vaccine manufacturing capacity and ecosystems that can complement existing global networks.[2]

The impact of regional vaccine manufacturing ecosystems

Global vaccine manufacturing has traditionally relied on a "hub-and-spoke" model with centralized production facilities in a few locations and well-developed distribution networks. However, this model can 1) contribute to inequitable vaccine distribution and 2) create brittle supply chains that are susceptible to single-point-of-failure disruption. Both of these challenges were witnessed throughout 2021 and 2022 with the COVID-19 vaccines.

While a straightforward solution may seem to be for each country to foster its own vaccine manufacturing ecosystem of private and public sector participants, few possess the necessary scale of demand, capital, and/or technical capabilities to sustain production. Regional scale vaccine manufacturing networks could change this dynamic. Once established, these networks could produce enough vaccines for regional self-sufficiency during both routine periods and pandemics. A recent analysis revealed that the benefit-cost ratio of vaccine manufacturing investments increases by up to six times when delivered regionally rather than in individual nation markets.[3]

Regional coalitions that bring together nations with similar disease targets, health needs, and governance priorities could benefit from coordinating a cross-border vaccine manufacturing ecosystem. Creating a common regional vaccine market by pooling demand and manufacturing capacity could enable regional initiatives to achieve a sustainable scale. Effectively functioning regions could also simplify decision-making and speed responses to health emergencies.

The RVMC framework

This report summarizes the RVMC Framework launched at the World Economic Forum's Annual Meeting in January 2024. It provides a framework (figure 1) to advise regional groups on how to scale production and distribution of vaccines in an economically viable and sustainable manner. The framework consists of eight pillars aligned to three broad areas: financing and demand; technology and supply; and regulatory and governance.

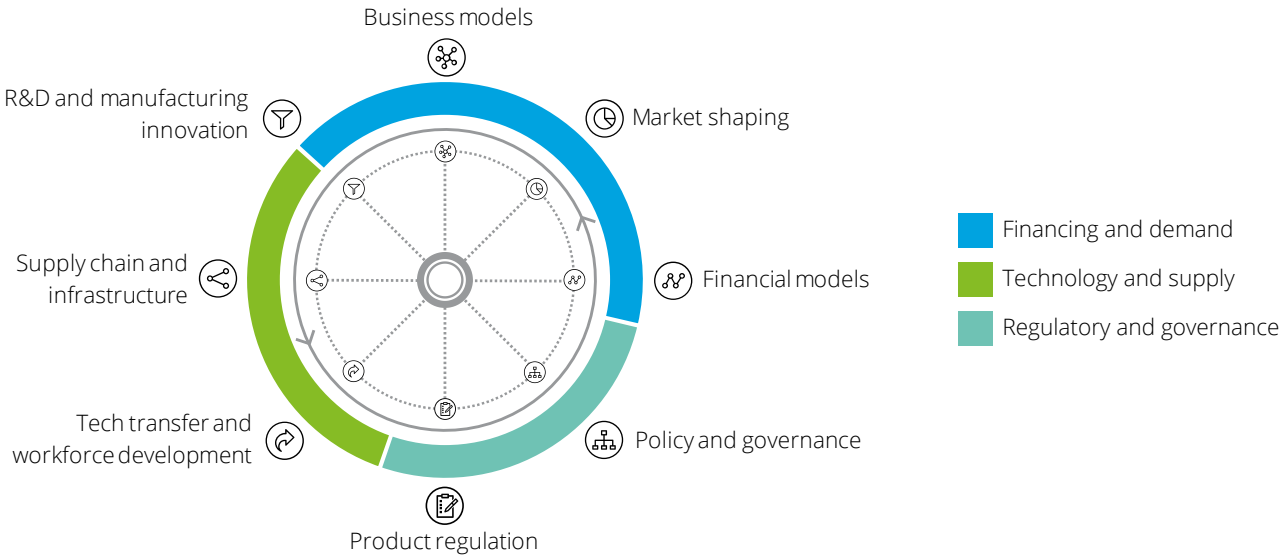
The framework's eight pillars are the building blocks of a regional implementation plan, designed to frame the challenges and opportunities regions may face. Multiple paths may exist for regions to develop and expand vaccine manufacturing capabilities. These paths can largely be driven by each region's need to develop or acquire expertise in each pillar and its ability to gain regional stakeholders' consensus.

While identifying implementation steps or key components for each pillar, the plans should be adapted to reflect region-specific challenges, needs, and resources. The size, complexity, and scope of regional initiatives will vary according to the needs of the countries in the region.

Regardless of the starting point and development path, the general goal of each pillar is the same across regions.

- **Pillar 1: Selecting business archetypes.** Develop sustainable commercial and public sector business operations for regionally scaled vaccine manufacturing ecosystems.
- **Pillar 2: Developing healthy regional markets.** Create incentives to direct the flow of capital toward uptake of regional manufacturing capacity and achieve an efficient, unified regional market that is scaled, sustainable, and transparent during both routine and high-volume production times.
- **Pillar 3: Deploying financial models.** De-risk financing and structure an ecosystem that attracts sustained private, donor, and public partnership investment throughout the life cycle of the ecosystem.
- **Pillar 4: Committing to research and development (R&D) and manufacturing innovation.** Manage the portfolio of basic, clinical, and applied manufacturing and translational research required to help integrate processes, continuously improve yields, assure quality, and promote innovation to achieve the regional vaccine platform coverage, scale, compliance, and optimization necessary to be competitive.
- **Pillar 5: Supporting technology transfer and workforce development.** Efficiently, effectively, and repeatably enable regions to introduce and operate right-sized vaccine manufacturing capacity at scale. To compete, regions will need to have incentive structures in place for retention of a qualified workforce so that vaccine manufacturers can train and deploy the local workforce. Intellectual property (IP) holders should develop repeatable, foundational tech-transfer programs that are appropriate to the skills and goals of the regional workforce. IP licensing contracts should incorporate transfer protections for the licensor and training and communications provisions to help employees of the receiving organization receive the tech transfer.
- **Pillar 6: Building sustainable supply chains and infrastructure.** Efficiently operate a resilient, responsive, and equitable vaccine manufacturing and supply chain ecosystem that is regionalized, end-to-end, and meets normal and high-volume vaccine demand.

Figure 1. Eight-pillar RVMC Framework



Source: "Regionalized Vaccine Manufacturing Collaborative Framework: A Framework for Enhancing Vaccine Access Through Regionalized Manufacturing Ecosystems," World Economic Forum, January 2024

- **Pillar 7: Harmonizing vaccine safety and quality regulations.** Enable faster access to markets for vaccine manufacturers through mutual recognition and shared submission procedures without compromising quality, safety, or efficacy of vaccines.
- **Pillar 8: Setting policy and governance strategy.** Lead and implement cross-border mechanisms to address challenges and opportunities through a collaborative regional policy framework.

Regional networks can avoid both the disadvantages of relying upon global systems too inflexible to ramp up manufacturing and the duplication and inconsistencies that are inherent in reliance upon uncoordinated multiple local manufacturing systems. The framework and implementation practices outlined here provide actionable starting points for regional manufacturing ecosystems that can help improve vaccine access equity and lay a foundation for sustainable economic development in adjacent sectors.

Pillar 1: Selecting business archetypes

A key observation of the COVID-19 pandemic response was that vaccine production is scaled and configured for either global or national supply chains, not regional production. Yet regional networks have distinct benefits. Consequently, to achieve viable regional production, business models and operations should be right-sized. The effort involves two main implementation steps:

- Step 1: Select a business archetype and positioning strategy
- Step 2: Assemble, test, and scale minimum viable business models

Step 1: Select a business archetype and positioning strategy

Regions should evaluate the feasibility of various business archetypes and develop strategies that combine several of these archetypes to create sustainable models. The primary archetypes in pharmaceutical manufacturing and their relative strategic advantages include (figure 2):

Figure 2. Business archetypes for select capabilities and functions

Archetype	Role	Strategic advantages to regions
Contract manufacturing organizations (CMOs)	Producers acting as contractors and manufacturing vaccines developed by larger pharmaceutical firms that provide the IP and protocols for a set cost.	Maintains low-cost manufacturing and workforce as well as direct control over manufacturing and quality operations. This avoids R&D, clinical trials, and B2C marketing expenses.
Contract development manufacturing organizations (CDMOs)	Essentially, a CMO plus limited late-stage development research capabilities, such as developing second-generation products or being contracted for R&D tasks by larger pharmaceutical firms. Can include revenue-sharing.	Has access to clinical patient populations for more-efficient clinical trials and regulatory approvals. May offer preferential access to regional markets.
Locally/regionally focused biopharma	Biopharmas that concentrate on developing and commercializing niche vaccines or ingredients to address specific diseases and priorities of regional markets.	Can achieve profitability even with lower manufacturing volumes by targeting regional patient populations and avoid competing with entrenched manufacturers.
Biosimilars	Companies can specialize in biosimilars at lower costs than existing branded vaccines. Companies can obtain licenses from the National Institutes of Health (NIH) or similar agencies and further develop vaccines to commercialization.	Avoids marketing and R&D costs and leverages established processes and low-cost scaled supply chains as well as reduces regulatory burdens.
Ancillary products and services	Producers of raw materials, excipients, and adjuvants using locally sourced and more secure and responsive supply chains.	Has high enough demand for regionally sourced raw materials to garner priority access to markets.

Source: "Regionalized Vaccine Manufacturing Collaborative Framework: A Framework for Enhancing Vaccine Access Through Regionalized Manufacturing Ecosystems," World Economic Forum and Deloitte, January 2024

Step 2: Assemble, test, and scale minimum viable business models

A minimum viable business is designed to go to market as quickly as possible with the minimum amount of investment. To launch a minimum viable business, a region should:

A. **Select critical business archetype components.** Business archetype components include how personnel, processes, tools, and technologies function as well as the ability to achieve key operating metrics and goals.

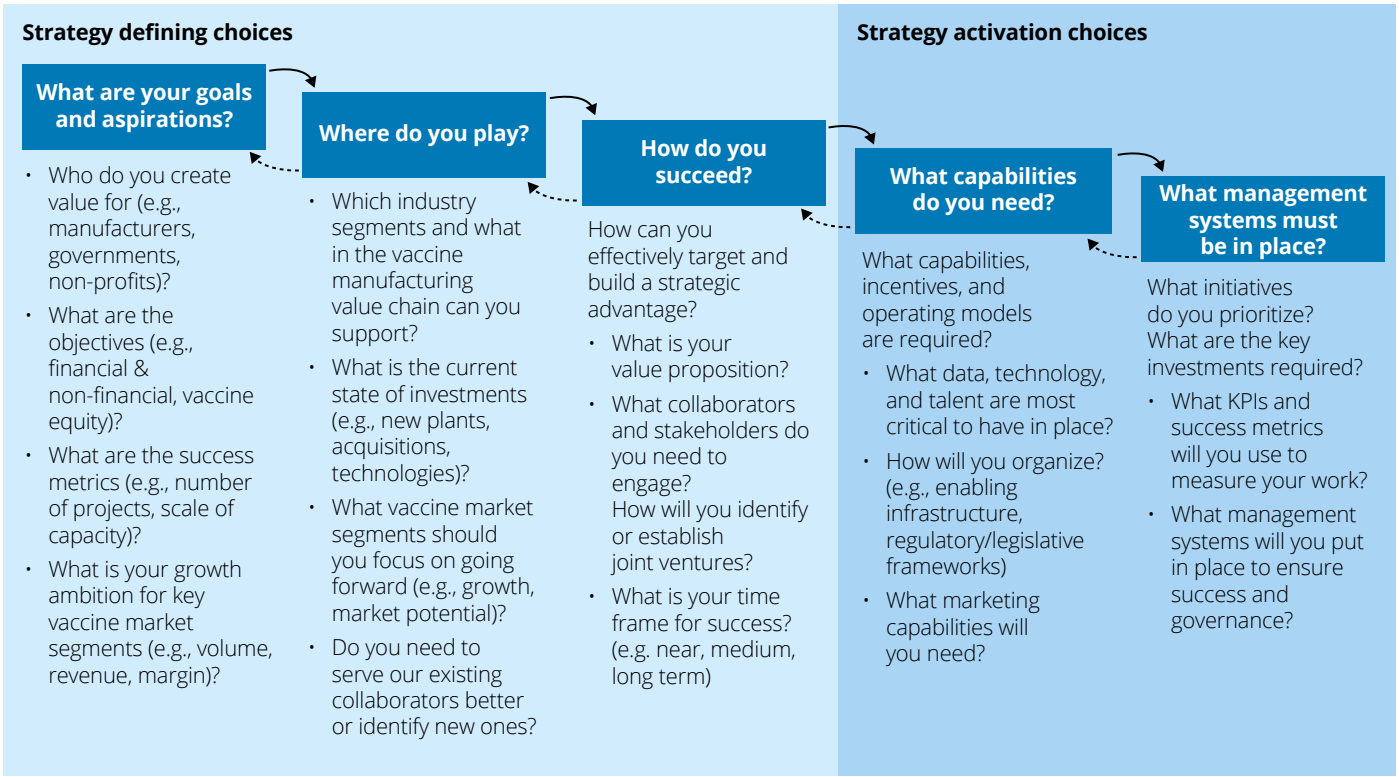
B. **Assess, right-size, and integrate components into the core archetype.** Assess each component's ability to support the core manufacturing archetypes. A regional feasibility assessment could include proposed manufacturing technologies, local capabilities, market dynamics, funding sources, and strategic alliances—all of which should be integrated into the core business model.

Regional public and private sectors should coordinate to develop components that support a variety of business archetypes, which can evolve with the business's roadmap, shifting technology, markets, and competitor landscape. This approach can help ensure a healthy balance of competition and differentiation as well as equitable and affordable regional access to vaccines.

A strategic choice cascade to develop realistic and implementable strategies

Strategy and choice go hand in hand. Organizations should make a series of interconnected choices to define their aspirations, the markets they serve, how they will achieve their objectives, their core capabilities, and their management systems. These choices serve as the scaffolding upon which regions' strategies and implementation roadmaps can be built. An example of a choice cascade that can help regions, markets, or manufacturers identify and develop the strategies that leverage their strengths to achieve their goals is presented below (figure 3):

Figure 3. Vaccine manufacturing investment strategy



Source: Deloitte analysis

Pillar 2: Developing healthy regional markets

Regional markets offer potential advantages to drug manufacturers and public health systems in that they can help scale efficiencies, lower manufacturing costs, reduce regulatory risks, and help produce faster responses to infectious diseases, including diseases that have disproportionate impacts on regionalized populations. Developing a regional market involves four implementation steps:

- Step 1: Aggregate demand
- Step 2: Attract supply
- Step 3: Build and shape healthy markets
- Step 4: Optimize and sustain regional markets

Step 1: Aggregate demand

Regions can streamline demand management processes from product selection and procurement to post purchase quality assurance processes. Demand aggregation includes key sub-steps, including:

- **Building a coalition of stakeholders.** The coalition should be grounded in shared proximity, similar health systems, disease prevalence and vaccine needs, and aligned legal or regulatory systems. Once empaneled, a shared vision as well as objectives, roles, and decision-making processes can be articulated.
- **Selecting vaccine portfolio, aggregating current and potential vaccine demand, and generating forecasts.** Solid demand forecasting can attract better-qualified vaccine suppliers, enhance pricing and priority access throughout longer periods, facilitate advanced purchase agreements, and improve equitable access to vaccines.
- **Qualifying suppliers and coordinating and pooling financing and procurement.** Centralizing and making transparent funding, product specifications, and supply mechanisms can help enable regions to avoid the high cost of managing extensive product offerings and supplier networks.

Step 2: Attract supply

Regions should attract multiple vaccine suppliers to compete in the marketplace to help ensure supply security. Both single supplier monopolies and supplier oversaturation can increase cost and complexity. Regions could consider inviting a limited number of manufacturers to supply the market, together with alternative secondary suppliers, adapting that number as needed to maintain capacity. Supply attraction also includes these key factors:

- Developing transparent, objective vendor qualification programs
- Promoting market competition, including technology transfer, to enhance quality, supply, and affordability
- Requiring uniform product specs and labeling throughout the region to prevent variations in product quality
- Using regional supply infrastructure to standardize service levels, manufacturing quality, and vaccine availability
- Obtaining sustainable public/private procurement financing that supports long-term purchase agreements to de-risk capacity expansion involving new suppliers

Step 3: Build and shape markets

Gavi's Healthy Markets Framework provides a good template for how regions can shape their own markets. In particular, regions can strive for the following:

- **Minimize trade barriers,** including tariffs, quotas, and nontariff barriers that hinder the movement of vaccines, personnel, data, and capital throughout the region, while adhering to local laws and regulations including those related to confidentiality and privacy.
- **Create regulatory pathways to accelerate entry to market,** minimizing time lags between submission, review, approval of the application dossier, and ultimately access to product.
- **Drive and maintain predictable pooled demand** that's aligned with health policies, disease monitoring, and pandemic response plans relevant to each region as appropriate.

- **Establish transparent procurement operations to help secure an equitable and reliable supply**, including qualifying suppliers and buyers, making evidence-based decisions, and disclosing contracts and prices.
- **Negotiate sustainable and competitive pricing** that considers costs across the value chain, from R&D to measuring the public health impact of vaccines. Surge capacity programs can also improve responsiveness during disease outbreaks.
- **Share market information.** For the market to be efficient, real-time demand data from relevant health systems should be matched with supplier-demand forecasting and sales-and-operations planning systems.
- **Promote public awareness and education** about the potential benefits of vaccinations to build trust.

Step 4: Optimize and sustain regional markets

Over the long term, an effective regional vaccine manufacturing ecosystem could cultivate diverse suppliers and regionally pertinent vaccine R&D portfolios. It can also balance economic sustainability with production scale while avoiding anticompetitive behavior. To achieve this result, the following should be done:

- **Develop market-shaping roadmaps**. This includes the development of production goals, demand projections and supply curves as well as the targeting of supply-and-demand balance.
- **Deploy market-shaping toolsets to increase equitable market access.** These could include advanced and long-term purchase and capacity reservation agreements, vaccine allocation frameworks, and differentiated or tiered pricing models.
- **Optimize and actively monitor markets to improve forecasting.** Actions include using market monitoring to proactively manage risk and course correct manufacturing, if needed. Market monitoring entails surveying or collecting data about general health, epidemiology, suppliers, or health systems as well as using artificial intelligence or advanced decision support systems to run a range of disease-related scenarios.

Establishing "rules of the road" for regional markets can help ensure long-term sustainability and meet vaccine demands.

Solutions that aggregate demand increase negotiating strength

Online pooled procurement platforms at a major global fund helped to aggregate order volumes on behalf of participating grant implementers. This created more leverage when negotiating with manufacturers regarding prices and delivery conditions. Users could place orders for quality-assured products used by programs to fight HIV, tuberculosis, malaria, and COVID-19 (figure 4).

Figure 4. Market shaping: Analyze, design, deploy

Market analysis

- Primary and secondary research and subsequent analysis to gain insights on current market access landscape
- Development of market archetypes for geographies in scope, country mapping based on current state assessment, and translation of potential market opportunities and focus areas

Contract life cycle management

- Contract request and creation using preauthorized templates and clauses
- Execution and archival with automated multi-party workflow for signature approvals and enterprise-wide repositories
- Data management of a central contract repository including contract metadata
- Compliance and performance monitoring

Pooled procurement mechanism

- Detailed analysis for current vaccine programs in place and how they are procured and governed
- Identifying potential global pooling providers, initiate a more detailed analysis with regards to cost saving impact and present to client
- Develop a pooled procurement mechanism for countries, NGOs, donors, etc. to fund bulk purchases

Supplier negotiation

- Negotiation documentation for global and local suppliers, including market research, should cost models, total cost of ownership models, and tailored negotiation strategies with savings targets for each supplier
- Tiered supplier strategies with training and step-by-step playbooks
- Tracking, reporting, and management of cost savings opportunities

Source: Deloitte analysis

Pillar 3: Deploying financial models

Funding for the expansion of regional vaccine manufacturing capacity is typically available from public, private, and donor organizations. Accessing these funds can require the following actions:

- Step 1: Conduct project feasibility studies to make strong business cases
- Step 2: De-risk financial projections for public and private investors
- Step 3: Develop targeted financial instruments

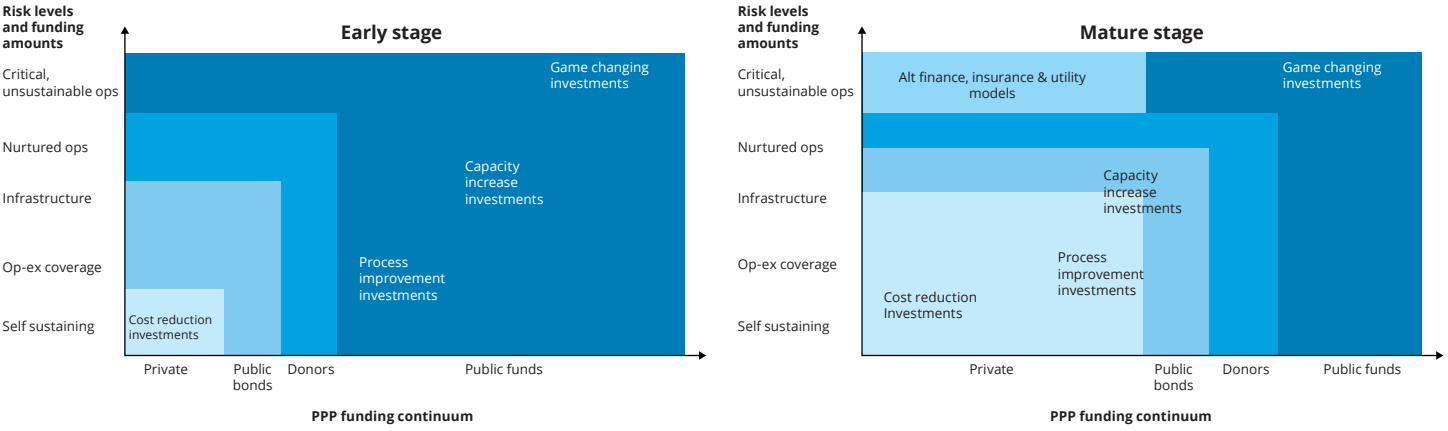
Step 1: Conduct project feasibility studies to make strong business cases

Financiers need comprehensive feasibility studies to evaluate funding requests. Third-party validation by credible subject matter specialists (for example, in product development, regulatory, or acquisition) is essential. Objective risk analyses and due diligence that reflect local context and perspectives can strengthen a business case for investors. Because proposed projects may have drastically different financing needs, regions should have a system for evaluating a variety of projects.

Step 2: De-risk financial projections for public and private investors

Private institutions seek to mitigate investment risk, which means that manufacturers should understand financiers' investment parameters. By understanding financiers' typical risk matrices and parameters, manufacturers can adjust their business plans (including execution plans, capital, and operational expenditures, etc.) to show how they plan to optimize the cost of capital and funding. A robust business case is critical for manufacturers and lead investors to mobilize funding and to evolve funding models over time. As an example, public-private partnerships (PPPs) can provide multiple funding streams early in the development of a project when the cost-benefit analysis is not favorable. As the ecosystem matures and the cost-benefit analysis comes more in line with private funding parameters, PPPs can make way for more private sector participation. PPPs evolve—for example, with heavy, bond-financed, initial public investment in infrastructure—giving way to smaller, privately funded investments as bonds or loans mature. Public and donor support helps de-risk private financing, helping increase project viability and improving the path to profitability. The optimal blend of funding is expected to vary across a PPP continuum as depicted below (figure 5).

Figure 5. Evolution of risk levels, funding amounts, and participants



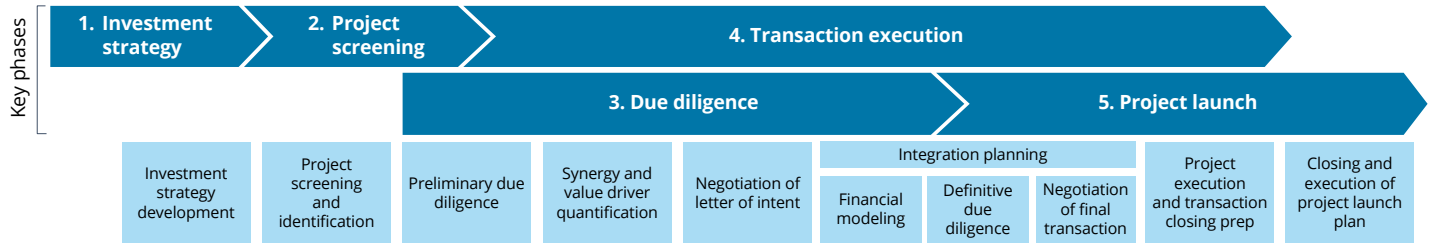
Source: Deloitte US analysis

Step 3: Develop targeted financial instruments and oversight

Different technologies and business models have a range of financing needs. A mix of traditional and innovative financial instruments can incentivize both public and private sector participation. A consortium of regional leaders and non-governmental organizations (NGOs) can coordinate funding with private financiers to avoid duplication and backstop specialized instruments, speeding the availability of private funding.

There are many routes to expanding vaccine production capacity, including engaging in strategic alliances and collaborations. To maximize the efficiency and cost-effectiveness of activities, organizations operating regionally should conduct end-to-end due diligence from investment strategy to project launch (figure 6).

Figure 6. End-to-end set of due diligence from investment strategy to project launch



1. Investment strategy	2. Project screening	3. Due diligence	4. Transaction execution	5. Project launch
Development and validation of investment strategy and growth goals • Develop plan for overall business unit portfolio • Determine and develop internal investment capability • Develop long-term investment goals and objectives	**Identification and screening of targets** • Assess projects based on decision criteria • Develop project profile and investment thesis/valuation • Project investment path analysis • Project leadership engagement	**Identification and assessment of deal-specific opportunities and risks/issues** • Financial, commercial, operations, IT, HR and risk management analysis • Evaluate quality of historical/projected cash flows, earnings, capital expenditures and assets • Identify hidden costs, contingencies and commitments	**Planning and management of key pre-Day 1 activities** • Negotiate appropriate deal structure to align with synergy targets and strategic considerations • Develop Day 1 project launch plan • Develop transaction agreements and transition services agreements if applicable in a buyout • Finalize post-due diligence project valuation and investment requirements	**Planning and management of Day 1 plan and post-Day 1 project execution** • Develop and execute Day 1 plan • Execute post-launch management of communications, IT systems, HR, and other critical functions • Monitor and report KPIs for value creation and synergies realization

Source: Deloitte analysis

Pillar 4: Committing to R&D and manufacturing innovation

Ongoing innovation is needed to develop fit-for-purpose technologies suited to meet the needs and ambitions in a particular region. Accordingly, regional programs must manage and coordinate a portfolio of technologies to ensure sufficient coverage of requisite capabilities within the region. Doing so involves three steps:

- Step 1: Establish a multipronged, regional, vaccine manufacturing innovation strategy
- Step 2: Prioritize and fund a portfolio of technologies
- Step 3: Create and execute innovation programs

Step 1: Establish a multipronged, regional, vaccine manufacturing innovation strategy

To support innovation, regions can foster a collaborative ecosystem that coordinates the activities of regional teams, identifies R&D opportunities, pools critical resources, and enables appropriate data-sharing. Once these elements are in place, regions can target their manufacturing innovation investments, particularly in applied and clinical development programs initially. Platforms require dramatically different capital investments, technical expertise, and timelines. Accordingly, it is critical to diversify R&D and manufacturing to sustain ongoing innovation. Regions can prioritize their innovation investments across applied and translational, clinical development, and discovery or basic research programs depending on needs and goals.

Applied innovation programs

When resources are constrained, regions can prioritize their innovation budgets to develop and scale technologies with immediate applications, such as vaccine delivery technologies (nasal, micro-array patches, etc.) that can be readily administered without significant training, multi-valent single dose technologies that reduce logistics and patient monitoring requirements, and ambient temperature technologies that minimize or eliminate the need for cold-chains. By focusing investments initially on readily applicable innovations, regions can realize immediate returns that can then be used to support basic research programs.

Clinical development programs

Focused and targeted clinical trials coupled with standardized regulatory data management and dossier submissions will be critical in accelerating a vaccine's time to market, with post-market surveillance to report and manage adverse events. Regions can begin by backing ongoing research and pipelines, and collaborate with regulators at local, regional, and global levels to enhance trial design, study implementation, and data management at study sites, thereby easing the process of regional product approvals. For novel vaccines, regions will need the capabilities to conduct clinical trials, which includes staffing clinical investigators and maintaining facilities.

Basic research programs

Regions can develop basic research programs to address scientific questions of most relevance in addressing disease vectors of interest. Leveraging GenAI capabilities and high-throughput screening, facilities can accelerate detection and optimization of vaccine prototypes for these diseases. One possible model of collaboration is for independent and university labs to conduct the basic research and discovery and partner with manufacturers or contracted researchers with facilities in compliance with Good Laboratory Practices.

Step 2: Prioritize and resource a portfolio of technologies

Regional teams can use data and risk-reward criteria to manage technology portfolios and make investment decisions that align to applied innovation, clinical development, and basic research programs. An example would be the Cystic Fibrosis Foundation, which invests in a range of complementary therapies focused on the goal of improving health outcomes for people with a specific disease.

Step 3: Create and execute innovation programs

The pathway to a diversified portfolio will be specific to each region, based upon starting points, technology and disease selection, risk acceptance levels, resources, capabilities, and priorities. To manage the risks of innovation, it is vital that regions build the necessary capabilities including skills, facilities, and research capacity necessary to conduct vaccine R&D.

Pooling staff and equipment can help reduce costs, and regions can secure funding through public bonds, grants, donors, and pharmaceutical companies. Many international organizations, such as the National Institute of Health (NIH), fund research outside their home countries, the United States in this case. Securing that funding often requires that regions share knowledge, resources, and data to demonstrate why and how selected R&D warrants attention and funding.

BioNTech jumpstarts manufacturing capacity and capability-building in Rwanda

BioNTech's initial BioNTainer vaccine factory was housed in six 40-foot shipping containers. Despite its unorthodox beginning, the facility greatly enhanced the country's production capacity, and enabled technology transfer and workforce development. In collaboration with its German sites, BioNTech will expedite the training of about 100 Rwandan personnel who will oversee on-site production, laboratory operations, and quality assurance tasks at the facility. As countries mature in their R&D and manufacturing capabilities, there will be a growing need to embed digital solutions in every facet of business and facility operations.[4]

R&D and manufacturing organizations will need a breadth of digital and functional capabilities (figure 7) to help sustain regional vaccine manufacturing over the long term.

Figure 7. R&D capabilities

R&D strategy			
R&D productivity and capital allocation	Operating model transformation	Portfolio choice, governance, & valuation	Real world evidence
Clinical	**Regulatory**	**Safety**	**Medical affairs**
Clinical analytics	Automated authoring	Analytics & cognitive automation	Medical information management
	Regulatory intelligence	Transformation strategy	Medical science liaison analytics & insights
Functional process efficiency & intelligent automation	Optimized labeling		Publications planning
	RIM/IDMP	Business model transformation	Med affairs org transformation
New clinical trial paradigms (digital/virtual/patient centric)	Regulatory transformation	Safety technology services	Manage investigator initiated trials
Medical technology			

Source: Deloitte analysis

Pillar 5: Technology transfer and workforce development

To be cost competitive, regional vaccine manufacturing facilities should employ a trained and efficient local workforce. Using external workforces can make final products more expensive and unprofitable to sell at local vaccine market prices. Similarly, without sufficient technology transfer, new regional vaccine production will either be reliant on generic technologies with expired patents or will be waiting for domestic regional manufacturers to develop new proprietary methods.

To develop the necessary workforce and secure efficient, repeatable tech transfer, regional manufacturers can take the following steps:

- Step 1: Contextualize and customize the tech-transfer process for the region's capabilities
- Step 2: Train the local manufacturing workforce to receive and use the technology

Step 1: Contextualize and customize the tech-transfer process for the region's capabilities

IP holders must develop repeatable, foundational tech-transfer programs that are appropriate to the skills and goals of the regional workforce. Transferring vaccine manufacturing technology platforms to a new, local workforce is a complex process. IP licensing contracts should incorporate transfer protections for the licensor *and* training and communications provisions to help employees of the receiving organization.

IP holders should offer the following to establish effective tech-transfer programs:

- **Detailed standard operating procedures (SOPs) for all manufacturing processes**. SOPs should be clear and as simple as possible to understand and transfer.
- **Customized training programs.** Develop comprehensive, modular training programs that cover the process and support systems end to end.
- **Multimedia learning management systems and infrastructure.** This should include classroom, remote, digital, on-the-job, and real-time training as well as assessment and feedback activities.
- **Ongoing evaluations of workforce capability and tech-transfer uptake**. Update training based on feedback and new developments, regulations, teaching methods, and manufacturing practices.

Manufacturers should offer IP holders the following support to protect their brand and rights while training the new workforce and improving success and efficiency:

- **Facility assessments and workforce evaluation.** This includes assessing existing infrastructure, inputs, equipment, systems, and regulatory compliance levels. Workers' baseline capabilities should be measured for manufacturing operations, regulatory compliance, and safety protocols.
- **Facility-level training that reflects workforce-specific skill levels and knowledge gaps.** Employ long-term expert instructors and mentors, and design train-the-trainer programs so that the existing workforce can train employees, lowering costs and increasing training frequency.
- **Ongoing technical support and guidance throughout the tech-transfer process**. This can include having experienced technicians and experts from the IP owner's organization work closely with the local team to encourage both knowledge exchange and continuous improvement.
- **Understanding of and compliance with regional regulatory requirements**. This would include working with local authorities as well as conducting process and operator training, completing qualifications documentation, and ensuring compliance.

Step 2: Train the local manufacturing workforce to receive and use the technology

Regions and facilities receiving technologies should consider their workforces' skill and the ease of manufacturing technology transfer within their business models, technology platforms, and site-selection criteria. A workforce dominated by local workers is best for long-term sustainability and cost competitiveness. Partnering with local universities and trade schools, manufacturers can create tailored training, internships, and accreditation programs to build a pipeline of workers. An internal cross-functional leadership team can oversee and assess the workforce development process and impact.

Regionally relevant programs and access to online and in-person training for trainers are also vital and can be developed in collaboration with regional academic institutes, industry, clinical research organizations, and international technical partners. One example is The World Health Organization's (WHO) work with the Republic of Korea to host the Global Training Hub-Biomanufacturing.[5]

PAVM works to transfer vaccine technology and intellectual property

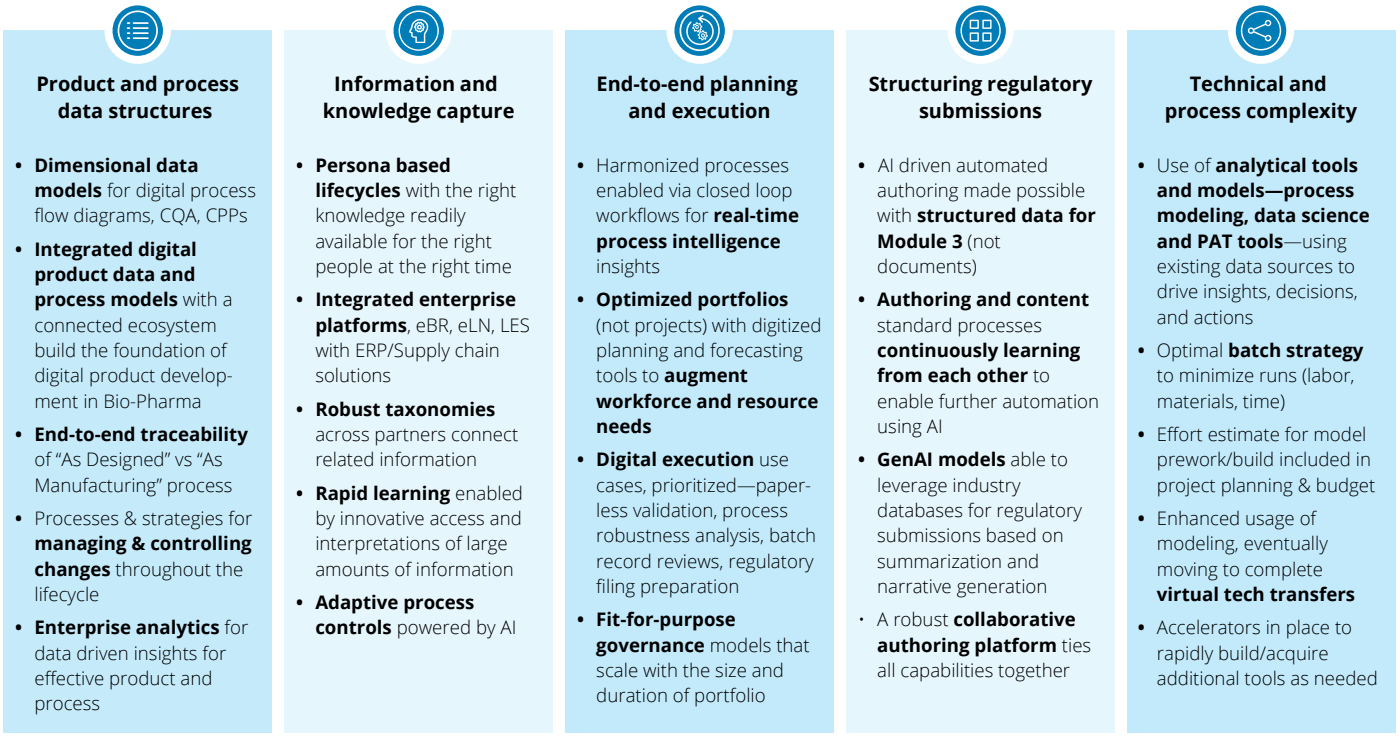
Some regions are already progressing with technology and intellectual property transfers. The enablement unit of the Partnership for African Vaccine Manufacturing (PAVM) will accelerate successful transfers by addressing barriers such as the following:

- Lack of capacity, capability, and resources required for technology transfers among African companies.
- Absence of clear incentives for technology providers to transfer their technologies to African vaccine manufacturing companies.
- Limited visibility and understanding of different national regulatory agencies' requirements, leading to delays in launch preparations and transfer rollouts.

The enablement unit both accelerates technology transfers already in the pipeline (as needed) and creates an environment for additional transfers, all in support of the goal of achieving local manufacturing by 2040. The enablement unit will help local manufacturers to be "transfer ready" and will also facilitate manufacturer-to-manufacturer transfers by sharing best practices and lessons learned. It will also coordinate access to technical expertise, partnerships, funding, talent, research, and manufacturing capacity, and it will enable regulatory alignment.

Organizations will need foundational capabilities, enhanced by well-defined methodologies and tools to optimize technical and product transfers. These capabilities include data structures, knowledge management systems, planning and execution, structured regulatory submissions, and analytical tools to handle technical and process complexity (figure 8).

Figure 8. Tech-transfer capabilities
Foundational capabilities, enhanced by well-defined methodologies and NextGen tools will enable optimization of technical and product transfers



Source: Deloitte analysis

Pillar 6: Building sustainable supply chains and infrastructure

Right-sizing, integrating, and optimizing regional vaccine end-to-end supply chain infrastructure requires a real-time network with the capabilities to coordinate planning, procurement, manufacturing operations, sales, warehousing, distribution, quality assurance, and regulatory compliance. Ideally, regionalized supply chains will be a web of mutually dependent nodes that extend across the member states.

Building this kind of supply chain and infrastructure can be achieved in five steps:

- Step 1: Design end-to-end vaccine supply chains right-sized to the regional market
- Step 2: Diversify vaccine manufacturing operations
- Step 3: Establish inbound supply chains and logistics
- Step 4: Establish outbound supply chain distribution networks
- Step 5: Implement end-to-end supply chain information systems, data integration, and digital automation

Step 1: Design end-to-end vaccine supply chains right-sized to the regional market

Regions must take the following steps to create robust supply chains and support infrastructure:

- **Map states' existing end-to-end supply chains.** Document the current and planned supply, manufacturing, and distribution capabilities of vaccines, both regionally and locally.
- **Simulate the current and envisioned supply chain.** Outbreak and manufacturing response simulations will identify risks and vulnerabilities in routine and pandemic supply chains.
- **Identify critical points of supply chain failure.** Gaps, overlaps, imbalances, and bottlenecks in the current supply chain and infrastructure will need to be mitigated by incorporating geospatial data and scenario models with regional partners.
- **Integrate regional pandemic preparedness and response plans.** Document strategies to mitigate risks such as shortages of raw materials, transportation stoppages, disease outbreaks, geopolitical disruptions, workforce illness, financing constraints, natural disasters, vaccine hoarding or hesitancy, and production delays.
- **Develop end-to-end integration plans.** Coordinate with manufacturers, health systems, and markets at country, regional, and global levels to ensure the appropriate balance of supply and demand. Engage with international organizations for technical support and guidance to integrate nodes effectively.
- **Monitor continuously.** Regular risk assessments, simulations, and stress tests will identify vulnerabilities in the supply chain as the region rolls out and adjusts the supply chain strategy.

Step 2: Diversify vaccine manufacturing operations

Regions will need a wide range of manufacturing facilities to create a sustainable manufacturing ecosystem. Similarly, using diversified supply networks at every stage—from raw materials to patient administration—will reduce risk.

Step 3: Establish inbound supply chains and logistics

Inbound supply chains and logistics involve the coordination of raw-material suppliers, transport, storage, and utility systems to produce finished goods. For agile, efficient inbound logistics, manufacturers should do the following:

- **Develop strategic sourcing strategies.** This includes building relationships and qualifying suppliers in order to lower material costs, accelerate innovation, comply with regulations and quality standards, and reduce working-capital requirements.
- **Diversify the supplier base.** Diversifying suppliers of critical components and materials can improve negotiating power and minimize the impact of supply chain disruptions.
- **Create supply chain redundancy and resilience.** Mapping critical pinch points and creating supply chain redundancies will improve resilience and reduce vulnerabilities during emergencies.
- **Manage supplier quality.** Quality control processes and the tracking of ingredients and batch lots can generate supplier quality ratings and ensure suppliers meet reporting and audit requirements.
- **Collaborate with infrastructure providers.** New or updated requirements for key regional raw materials (e.g., refrigeration) must be coordinated with the relevant suppliers, including warehouse, transport, waste management, and laboratory providers.

Step 4: Establish outbound supply chain distribution networks

Outbound supply chains include the storage and shipment of final vaccine products through regional and extra-regional logistics networks to supply the intended market. To prevent outbound disruptions, regions should create cross-border supply chains as well as transport, warehouse, and vaccine-administration infrastructure. Effective outbound networks require continuous

forecasting of demand, as well as management of logistics, warehousing, and inventory.

Leading practices in forecasting and sales and operations planning include the following:

- **Work from a single plan.** When each node of the regional network shares data, responds to the same supply-and-demand signals, and knows how much material is in the system, the downstream supply chain can plan and operate at maximum efficiency, improving equitable access to vaccines.
- **Monitor plan accuracy.** Communicate plans across supply, manufacturing, and distribution hubs to optimize production, allocate resources efficiently, and prevent overproduction or underproduction.
- **Plan surge capacity**. Develop plans for scaling up production, stockpiling, and distribution during emergencies or other times of increased demand, such as a pandemic.

Leading practices in managing transport logistics, warehousing, and inventory include the following:

- **Eliminate infrastructure pinch points.** Arranging distribution hubs and nodes into networks, strengthening weak links, and investing in infrastructure can boost coverage and speed delivery.
- **Diversify warehousing and transportation options.** A range of warehouse capabilities, logistics modes, and transport routes throughout the region—from production facilities to vaccination centers—will help prevent single points of failure from taking down the entire network.
- **Optimize geographic distribution network coverage.** Regional demand and health allocation needs during routine and pandemic times should determine the capacity and placement of manufacturing and distribution hubs.
- **Invest in support infrastructure and technology.** Governments and donors can assist regional manufacturers and suppliers by investing in roads, electricity, telecoms, and IT.
- **Track vaccine lots from "factory to arm."** Real-time tracking can monitor inventory levels and ensure timely replenishment.
- **Optimize warehousing, stock levels, and batch-run quantities.** Dynamic inventory strategies reduce storage costs and waste while increasing turnover. Safety stock and buffer strategies can meet demand surges, and economic order calculations can maximize batch run efficiencies.
- **Upgrade environmental monitoring and cold chain infrastructure.** Environmental monitoring technologies are needed to track cold chain excursions. Additionally, regions should invest in cold chain infrastructure, including refrigerated trucks, storage, and vaccination facilities.

Step 5: Implement end-to-end supply chain information systems, data integration, and digital automation

Collecting information at nodes throughout the supply chain can generate a single source of truth that, in turn, improves manufacturing and supply chain operations, supply and demand forecasting accuracy, and risk-mitigation activities. Data integration and automation are critical to generating a comprehensive, credible picture of supply chain operations that can respond to the needs of regional member states, increase equitable vaccine access, and improve public health outcomes.

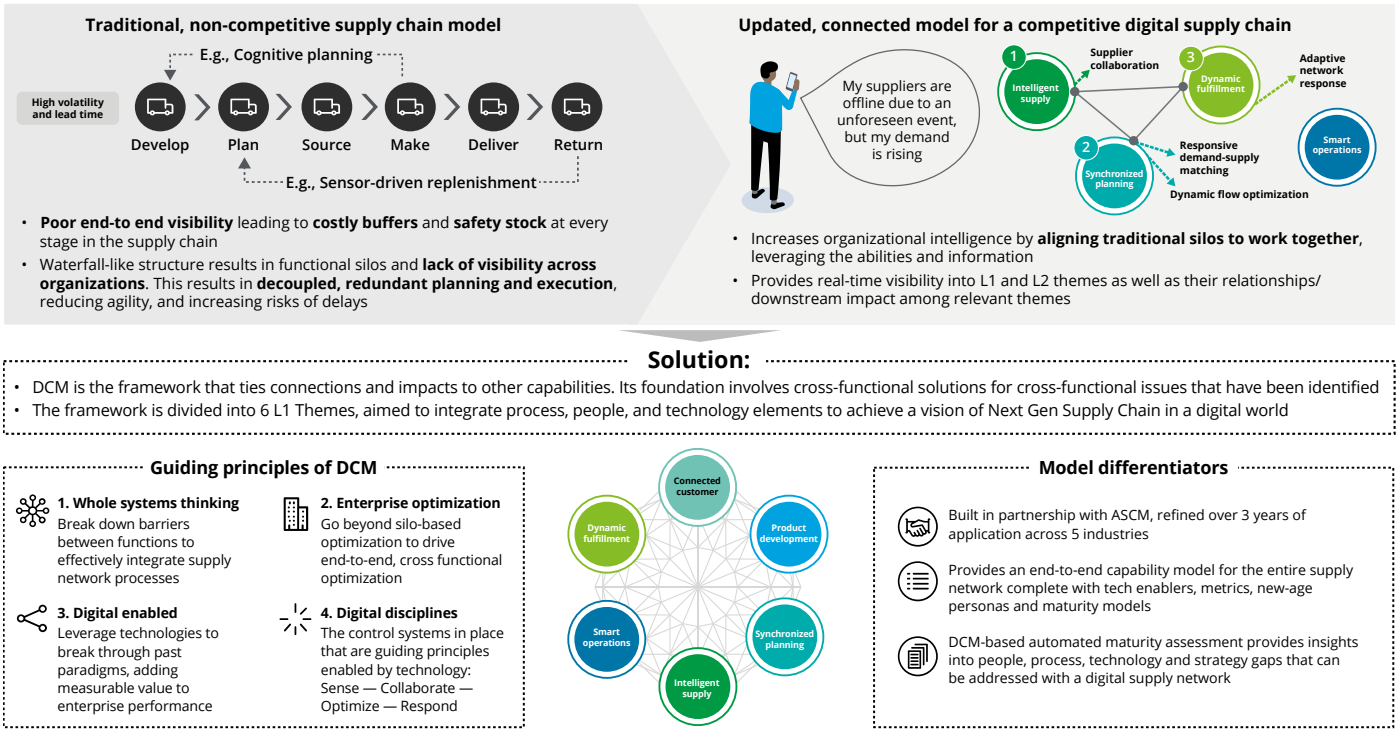
USAID Bureau for Global Health builds a next-gen supply chain control tower

USAID Global Health has embarked on a multiyear effort to optimize their flagship supply chain programs. The initiative aims to prevent maternal and child deaths and combat infectious diseases—including HIV/AIDS, malaria, and tuberculosis—across 65-plus countries.

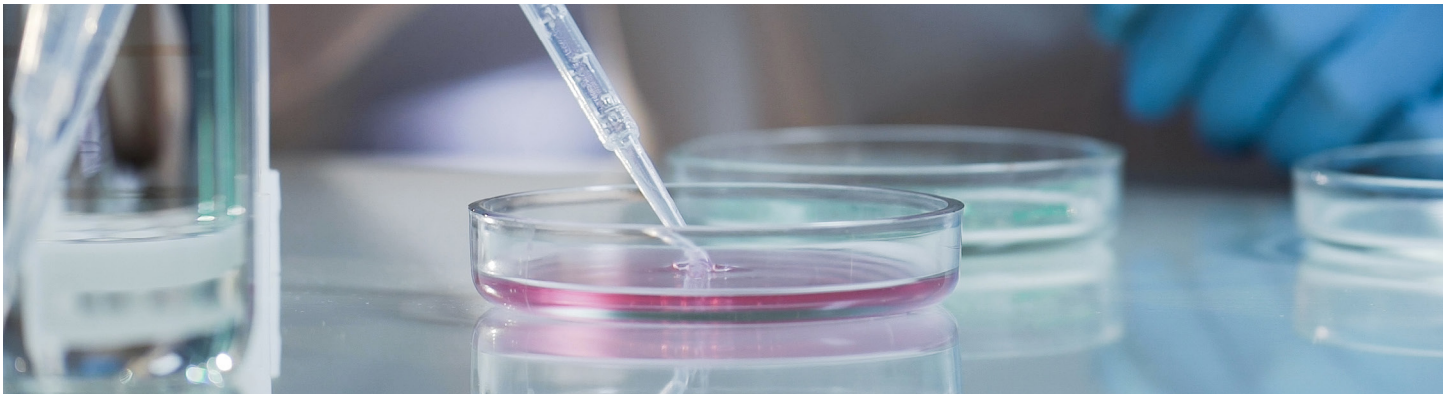
Applying leading practices in supply chain and AI solutions will improve multiple operational processes and empower USAID to do the following (figure 10):

- Provide end-to-end supply chain visibility into order management as well as inventory management and transportation, generating a single source of the truth.
- Facilitate information sharing and collaboration across the full next-gen suite of contracts.
- Enable enhanced USAID management oversight across the suite of programs.
- Enhance the effectiveness of decision-making to manage and improve supply chain efficiency.

Figure 9. Next generation supply chain model



Source: Deloitte analysis



Pillar 7: Harmonizing vaccine safety and quality regulations

Manufacturers must navigate regulatory approval processes when bringing a vaccine to market. Achieving this on a regional basis requires harmonizing approvals across multiple countries to allow for single submission, joint review, and shared recommendations. These processes can reduce the time and cost to manufacturers, thereby motivating further investment in the region's manufacturing and supply chain. Focusing on the primary and secondary laws governing vaccines—and not on regulations to cover all medicines—will increase the likelihood of consensus and success. Existing regulatory frameworks of successful regions, such as the EU (see sidebar), or in-progress frameworks from the African Medicines Agency can provide starting points.

Best practices when designing regional regulatory frameworks

Regions should consider the following practices to accelerate access to vaccines, ensure safety standards, and lower costs and barriers to market entry without compromising safety or quality:

- **Joint review process.** To minimize approval times and costs, the region must develop a unified, harmonized approach with single dossier submission, review, and approval processes.
- **Reliance and mutual recognition.** Member state authorities should identify states whose market authorizations, trade policies, and compliance standards they will accept and recognize.
- **Flexibility.** Regions must develop benefit-risk criteria for vaccines both in development and already in market that reflect the health needs and vaccine production capabilities of the region. This includes the establishment of fast-track approval processes, emergency response protocols, and emergency use authorizations (EUAs) to inject needed flexibility into regional regulatory frameworks.
- **Quality control and compliance.** Ensure rigorous quality control measures and compliance with international regulatory standards.

Achieving a minimum-viable regional regulatory framework

Gaining complete member state alignment across all regulatory areas may not be feasible initially. Instead, regions can select the critical areas of common interest. At a minimum, member nations should reach agreement and harmonize regulations in the following areas:

- **Manufacturing and distribution quality standards** to ensure consistent vaccine product quality.
- **Marketing authorization** that empowers vaccine agencies to implement single submission, review, and approval processes and allows scaled operations to produce to standard all labels and claims across regional common markets.
- **Pharmacovigilance processes** to report adverse events associated with vaccines, ensuring safety is maintained after approval.
- **Batch release** of manufactured vaccines and lot testing at a qualified regional laboratory before entering the market. For example, a model for sharing resources and reliance for vaccines and biologicals across competent WHO-recognized labs has now been proposed for Africa.
- **Regional access** that ensures member states have identical product specifications and labels for authorized vaccines to overcome complexities posed by country-specific product registrations.

The European Union: A proven regulatory foundation

Regions can look to EU regulations as they develop their own frameworks. These are the key components:

- **Vaccine-specific regulations** regarding the manufacture, authorization, marketing, and distribution of products, including provisions that mirror WHO maturity and quality standards
- **Pharmacovigilance regulations** to govern the collection, assessment, and monitoring of adverse drug reactions and safety data for vaccine products
- **Good manufacturing and distribution practices (GMPs and GDPs)** to ensure adherence to strict quality standards in the production and distribution of medicinal products
- **Human clinical trial regulations** to harmonize, simplify, streamline, and mutually recognize the approval process for new vaccine products and aid in conducting multi-country trials
- **Data-sharing regulations** and surveillance protocols to monitor vaccine safety and efficacy
- **Pediatric vaccine** regulations to address the development and authorization of safe childhood vaccines[6]

Some regulations may initially remain with individual member states, although doing so has drawbacks, including:

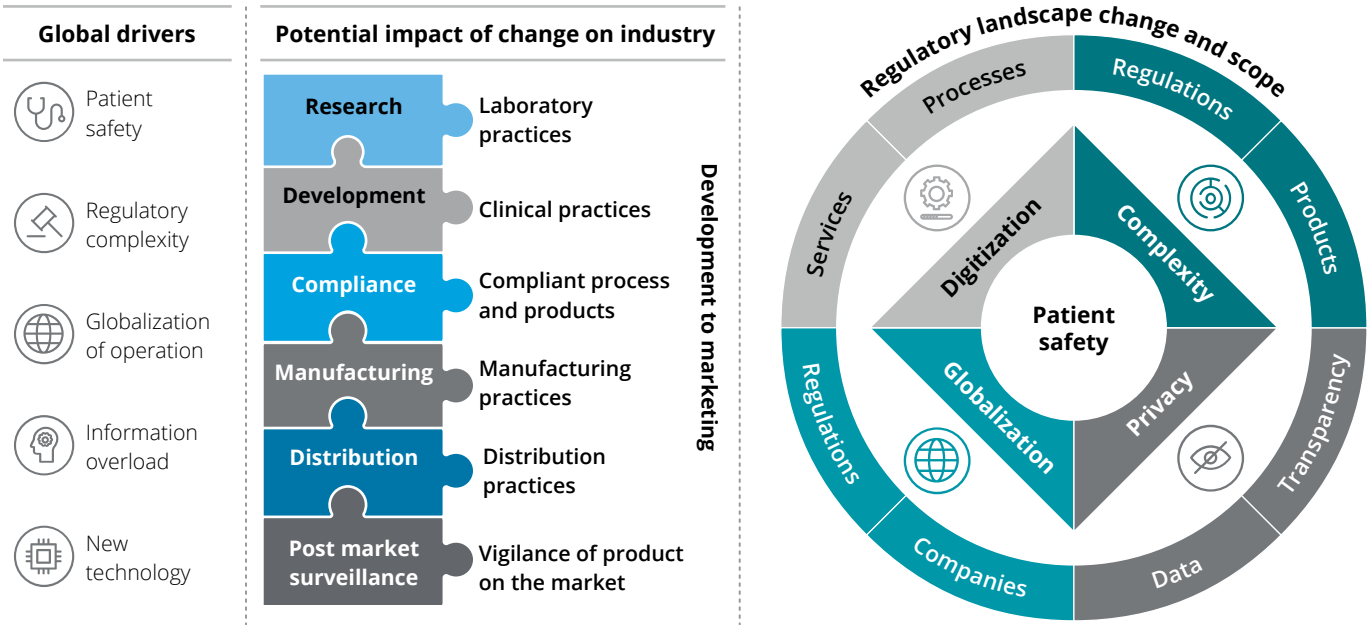
- **Pricing and reimbursement.** Each country may negotiate prices and reimbursement policies separately, potentially leading to differences in access and affordability.
- **Vaccine distribution and administration.** Operations can differ between member states but that could also affect the availability and accessibility of vaccines.
- **Vaccination schedules and policies.** These may vary based on members' health care priorities and epidemiological situations.
- **Data protection and privacy regulations.** Variance here may have an impact on how vaccine products and patient data are managed.

Regions should work during non-pandemic times to ensure that regulatory standards are harmonized, good governance structures are in place, and workforces are trained and qualified to meet vaccine safety and quality regulatory requirements.

Global regulatory intelligence

Anticipating and clearing regulatory hurdles and vaccine development go hand in hand and can consume an inordinate amount of resources if the right capabilities and action plans are not in place. Leading global health care regulators can benefit from real-time tracking and analysis of changing regulations on vaccine manufacturing and supply chains. For example, the use of both advanced supply chain modeling and regulatory intelligence helped a major federal drug agency through mission-critical situations such as supply chain disruptions and drug shortages caused by COVID-19 and natural disasters. The figure below illustrates the interplay between changing regulatory landscapes and the impact on industry.

Figure 10. Global regulatory intelligence



Pillar 8: Setting policy and governance strategy

Regional markets need strong governance and shared policies to be effective and improve access and health equity in the long term. To achieve these ends, regional members states will need to do the following:

- Step 1: Set governance strategy and establish regional initiatives
- Step 2: Implement regional policy frameworks

Step 1: Set governance strategy and establish regional initiatives

Regions may establish or leverage a regional governing body that oversees multilateral agreements with donor organizations, NGOs, and member states' health systems; technology licensing agreements; common market regulations; and the mutual recognition and harmonization of product approvals. This new body could be hosted at a permanent institution in the region and run by a secretariat structure as, for example, the Africa Centres for Disease Control (AfCDC) hosts the Partnership for African Vaccine Manufacturing (PAVM). Alternatively, where no such permanent regional institution exists, a secretariat could be hosted at a country institute or through a rotating arrangement among member countries.

Creating Free Trade Zones in Africa

Recently, the African Continental Free Trade Area (AfCFTA) Secretariat and the World Economic Forum co-created *An Action Plan to Accelerate Global Business and Investment in Africa*,[7] presenting goals and initiatives to integrate Africa into a single market. The action plan, with commitments from industry leaders across automotive, agriculture and agro-processing, pharmaceuticals, and transport and logistics, represents a clear signal to investors that Africa is open for business.

Whichever approach is used, countries will need to empower the assigned leaders with clear roles and responsibilities. Regions must decide which areas of governance can be resolved by collectively recognizing member state decisions and which areas may need a legal process framework or a new regional agency. Governance institutions must delineate processes that address subjects such as who can raise issues and which governance processes and institutions are responsible for resolving them.

Gaining consensus on governance strategy requires skillful diplomacy, knowledge of laws and policies, and the discipline to maintain a singular focus on regional vaccine manufacturing.

Step 2: Implement regional policy frameworks

Regions must establish primary and secondary laws that serve the minimum viable regulatory framework necessary to promote the free movement of vaccine goods, services, capital, and people among member states. To implement common market regulations across member states, regions can use regional authority agreements, rulings, and precedent to create seamless economic spaces that eliminate trade barriers and safeguard fair competition.

The specific regulations needed to create and shape a common market vary depending on the level of product harmonization and mutual procurement that's desired across the market. To begin, regions could use pillar-based initiatives that help ensure their framework is managed in a consistent way through regional governance processes, working toward their policy objectives as the initiative matures.

Concluding thoughts

Equitable access to vaccines would be a significant step toward achieving health equity. Among the many lessons of the COVID-19 pandemic, a particularly heartbreaking one was that inequitable access to vaccines—in Africa, some parts of South America, and many rural areas worldwide—resulted in countless unnecessary deaths. Needless to say, the world must be prepared next time.

As a path forward, the RVMC Framework summarized in this document provides a way for regions to frame challenges and opportunities, including the capabilities necessary to help prevent an inequitable response in the future. A key focus is how regions can use their resources and outside expertise to expand vaccine manufacturing capacity. Expertise in supply chain management, health care systems, innovation financing, digital transformation, human capital management, and workforce development are all relevant to the eight pillars presented here as the foundation of regional vaccine manufacturing networks.

Regions have an opportunity to fundamentally shift how organizations support the health and welfare of societies across the globe. We know that it will require one of the most significant transformations ever in health care—and we believe that there are multiple paths to success. Working alongside other passionate leaders and global organizations, regions can make the transformation a reality.

Just as Deloitte assisted in developing this report of the RVMC for the World Economic Forum, we will continue working to realize our vision that true health equity means that no region or country should be without life-saving vaccines. Our hope is that what began as an effort to provide regional self-sufficiency for pandemic response scenarios can evolve to improve health outcomes more generally, accelerate the availability and acceptance of new technology platforms, and, ultimately, lay the foundation for sustainable economic development.

My co-authors and colleagues Joe and Zubair join me in gratitude to the World Economic Forum, the RVMC Co-Chairs and Secretariat, and other contributors for their collaboration and leadership on this important initiative. Please reach out with any questions.

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