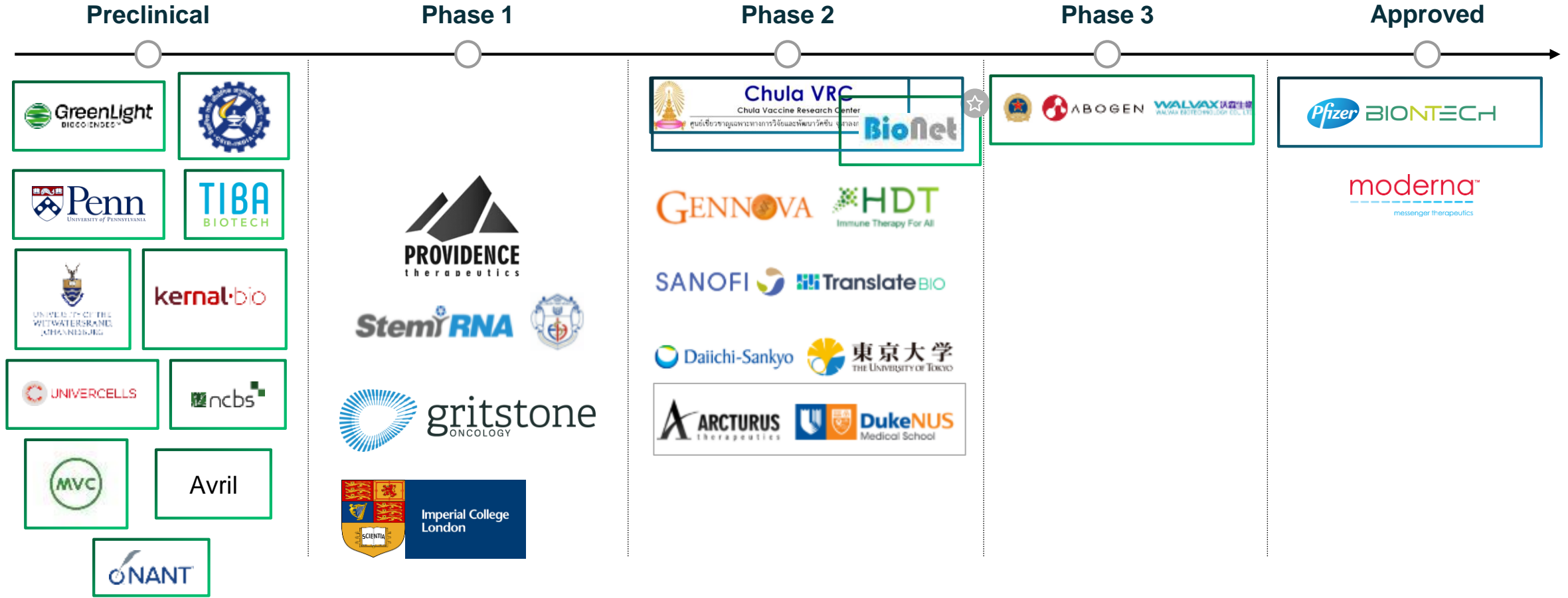


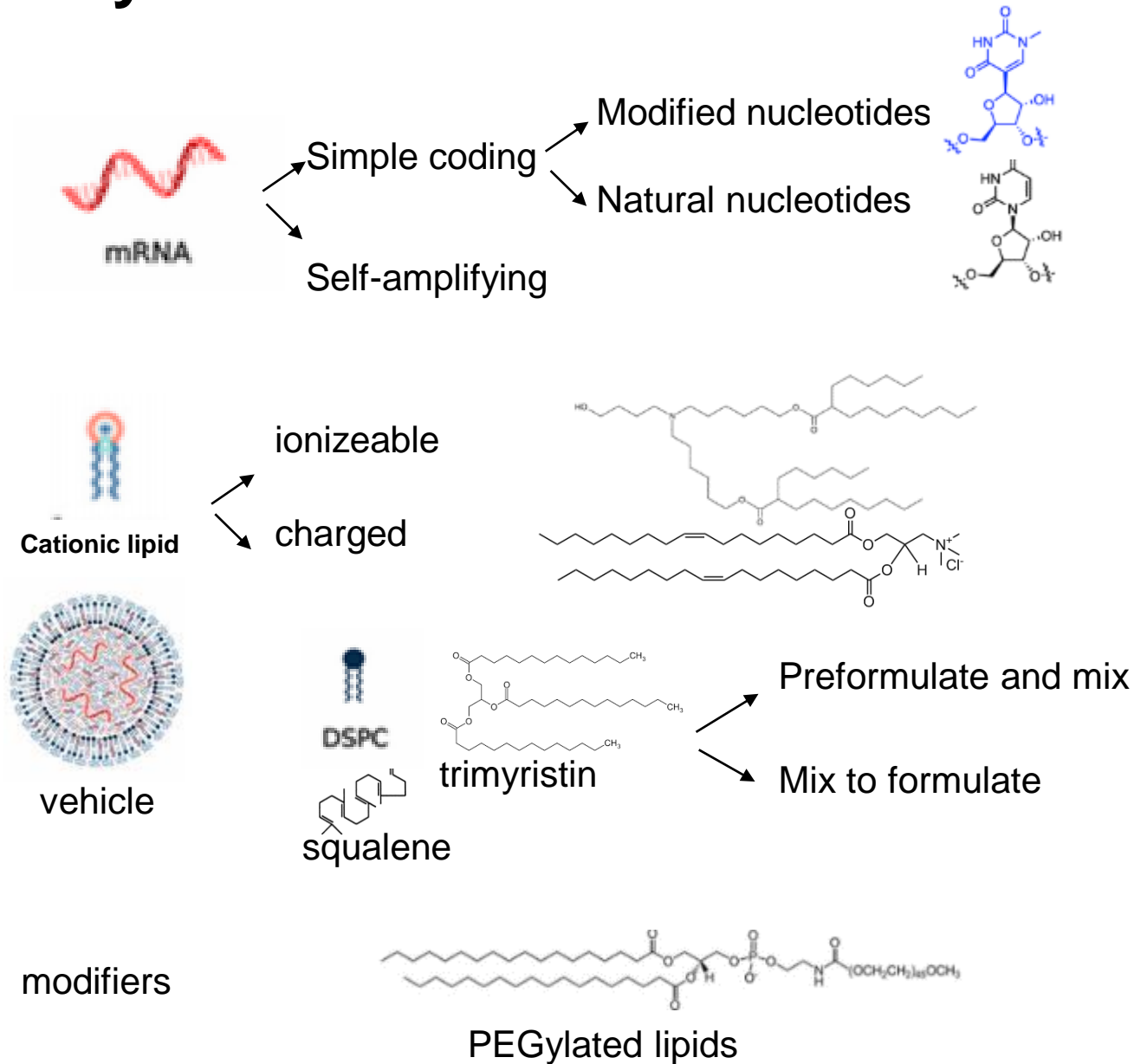
# **mRNA Vaccines expanding capacity in LMICs**

## **Covax manufacturing task force**

# mRNA Technology Landscape: lots of players catching up with the leaders – some improved 2<sup>nd</sup> generation technologies



# Many variations on a theme



immunogenicity

efficacy

reactogenicity

thermostability

cost

Patents: what, where ?

Know-how ?

# The problem...

A fantastic technology in a very limited number of hands

Requests from all regions, especially Africa, Middle East, SE Asia, Western Pacific, Latin America for access to know-how and manufacturing capacity

How to facilitate this ?

# COVAX Manufacturing Taskforce was structured around three workstreams, addressing different needs

## Workstream 0



### Shared Fact Base / Task Force Coordination Office

- Create aligned supply baseline
- Conduct supply and manufacturer ecosystem mapping
- Document and share lessons learned across focus areas



## Workstream 1



### Immediate COVAX Response

- Create voluntary input supply visibility partnership
- Accelerate export permits/custom clearance for critical SKUs



## Workstream 2



### Short- and Mid-Term COVAX Response

- Expand fill & finish match making mechanisms
- Create overview of global manufacturing capacities
- Better utilize existing capacities, e.g., voluntary bilateral tech transfer
- Develop regulatory & manufacturing workforce



## Workstream 3



### New & expanded sustainable capacity in LMICs

- Expand capabilities of existing manufacturers in LMICs
- Establish sustainable capacity in regions with no significant capacity
- Enablers: Develop normative policy frameworks, stimulate manufacturing innovations & investments

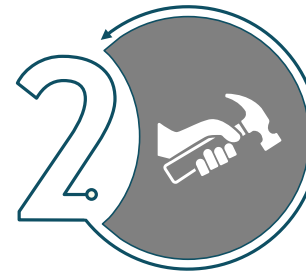


**Workstream 3  
ambition is to  
improve long-  
term LMIC  
health security  
via two key  
objectives and  
enablers**



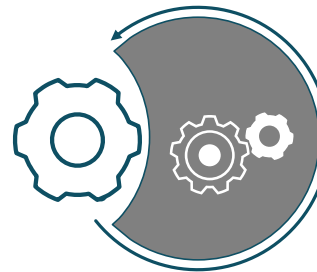
**Objective 1**

Expand capabilities of existing manufacturers in LMICs



**Objective 2**

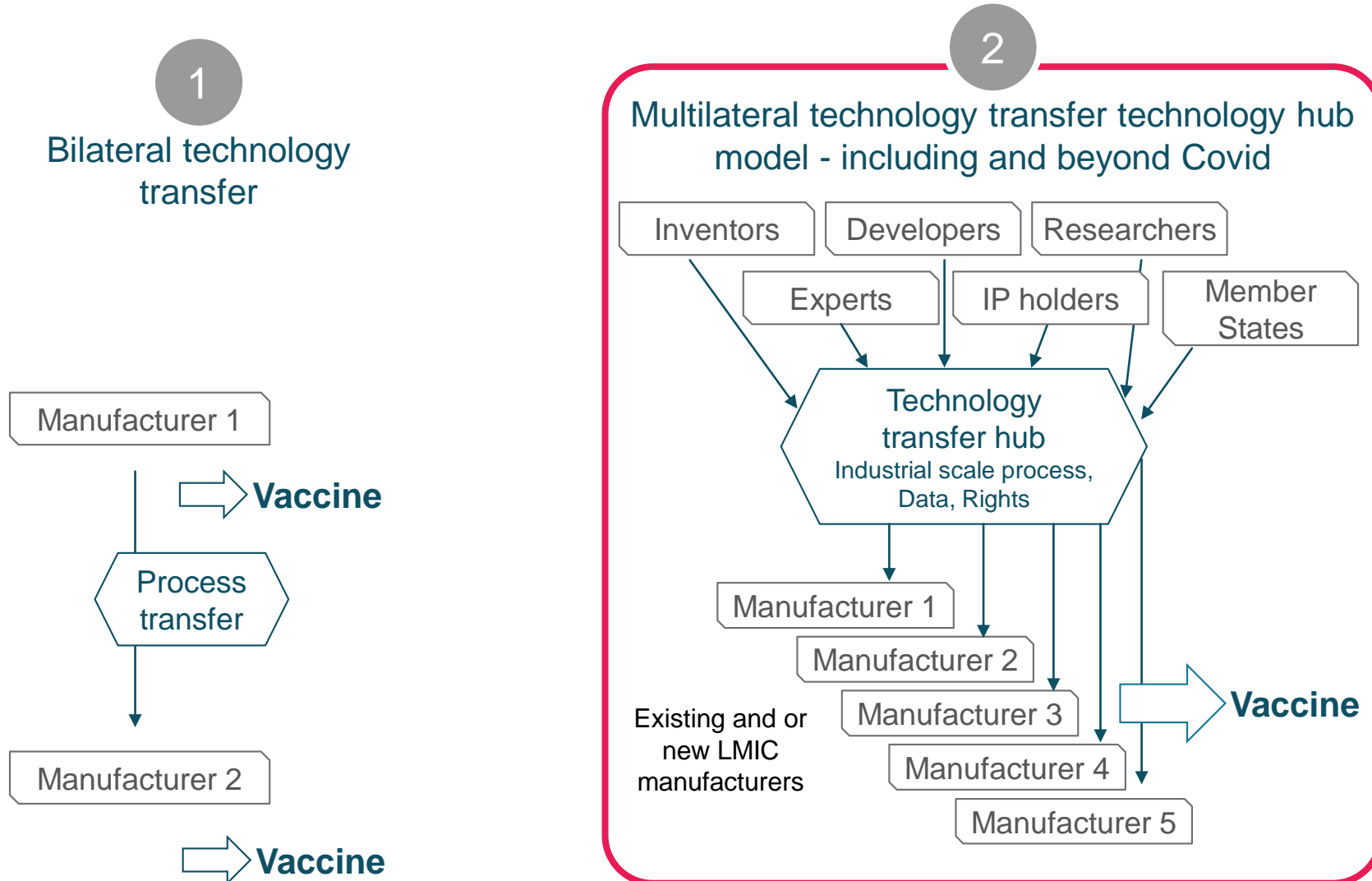
Establish sustainable capacity in regions with no significant capacity



**Enablers**

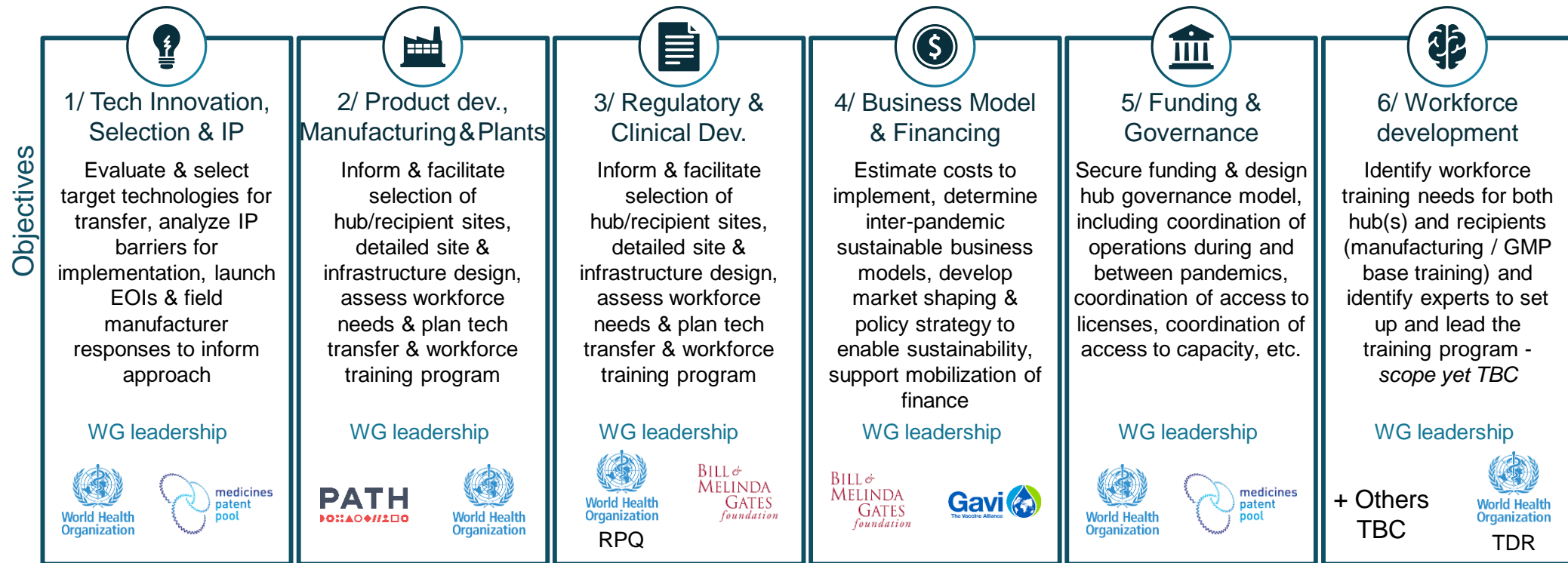
Identify & implement innovations and develop normative frameworks

## 2 potential approaches for increasing capacity and supply



# Project is structured around six Working Groups

## Workstream 3



Cross-WG team (including South African partners) focusing on SA hub / recipient support

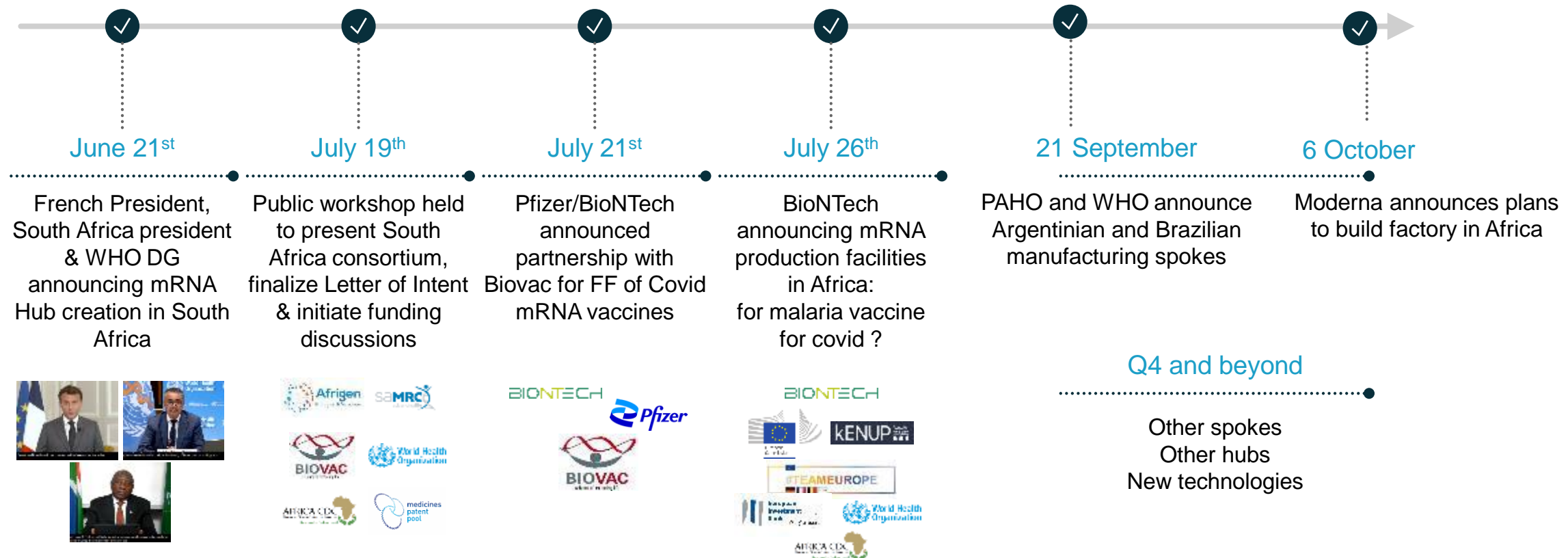


+ others as needed

Note: In addition, Technical Advisory Panel (PDVAC) with expertise across topics areas (from industry, academia, etc.) reviews workstream proposals and provide input and recommendations to shape final solution on hubs / recipients network



# Technology Transfer Hub and spokes and related activities



# Role of PDVAC in hub governance

- Provide TECHNICAL evaluation of proposals /expressions of interest
  - Hubs (training centres) – next call for other technologies eg viral vectors
  - Recipients of tech transfer (ie future manufacturers)
    - Technical/infrastructure/HR capacity to receive the technology
    - Likelihood of bringing manufacture to approval
    - National regulatory agency maturity (ML3 for PQ in x years)
    - Addressing inequity : what is capacity in region/subregion/country
      - Expect proposals from: Indonesia, Vietnam, Malaysia, Philippines, Pakistan, Bangladesh, Iran, Egypt, Tunisia, Morocco, Nigeria, Ghana, Senegal, Rwanda, Ukraine, Serbia, Turkey,...
- Advise secretariat on whether a technology is appropriate

# Challenges and Opportunities

- How many facilities need to be built in Africa ?
  - Impact of bilateral plans (Biontech, Moderna) ?
- What about rest of LMIC world ?
- Which technology ?
  - Most appropriate for LMIC use - low COG, thermostable ?
- What will these facilities do once covid vaccines no longer needed ?
  - What are the real benefits of mRNA over other platforms?
    - Speed from concept to clinic ☒
    - Immunogenicity – high antibody and CD4 / CD8, probably useable repeatedly
- Some opportunities
  - Pandemic influenza preparedness – and seasonal influenza ??
  - TB, HIV ? But Ad5/Ad26 didn't work ?
  - RSV, Dengue,...



## PDVAC Meeting

05 November 2021

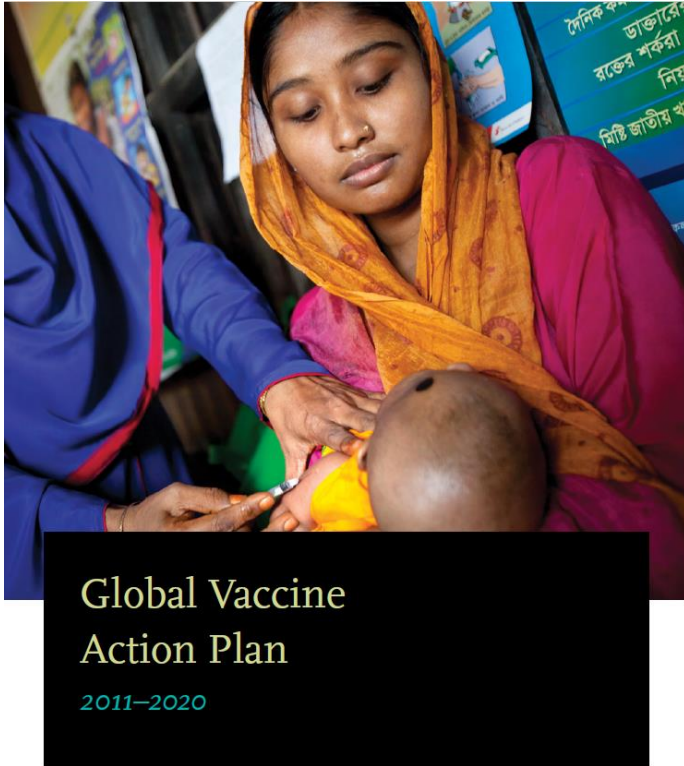
Immunization reaches more people than any other health or social service and is a vital component of primary health care.

# PDVAC Meeting 05 November 2021

## Session outline

Topic	
1	IA2030 and IA2030 SP7 WG introduction
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# IA2030: Built from lessons learned from GVAP; not simply more of the same



- Cooperative design from bottom up
- Tailored to national context
- Adaptable to changing needs
- Targeted ways to reduce inequity
- Life-course approach
- Accelerating innovation (*not just new vaccines, but also to increase reach and impact of immunization*)
- ....



<https://www.immunizationagenda2030.org/>



# AT A GLANCE

## Vision



A world where everyone,  
everywhere, at every age...

... fully benefits from  
vaccines...

... for good health  
and well-being

## Impact goals

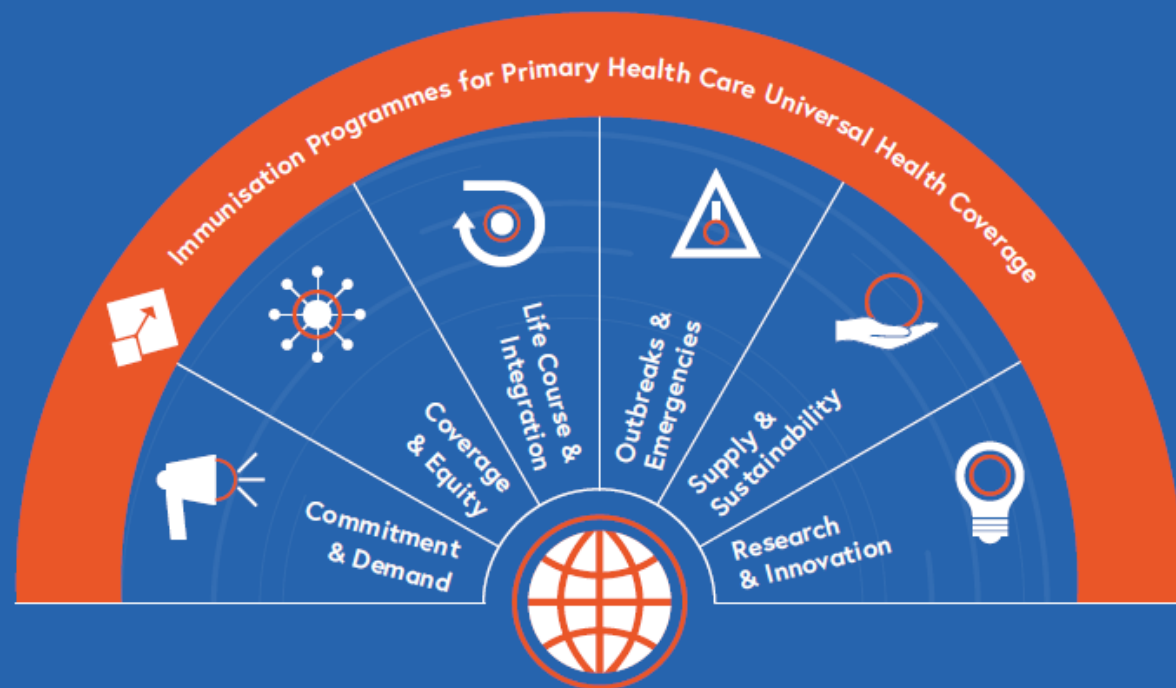


Reduce mortality and morbidity from vaccine-preventable diseases for everyone throughout the life course.

Leave non one behind, by increasing equitable access and use of new and existing vaccines.

Ensure good health and well-being for everyone by strengthening immunisation within primary health care and contributing to universal health coverage and sustainable development.

## Strategic priorities



## Core principles



People  
Centred



Country  
Owned



Partnership  
Based



Data  
Guided

# STRATEGIC PRIORITY 7.

## Research & innovation

**Goal** Innovations to increase the reach and impact of immunization programmes are rapidly made available to all countries and communities.

---

- Objectives**
- Establish and strengthen capacity at all levels to identify priorities for innovation, and to create and manage innovation.
  - Develop new vaccines and technologies, and improve existing products and services for immunization programmes.
  - Evaluate promising innovations and scale up innovations, as appropriate, on the basis of the best available evidence.
-



# STRATEGIC PRIORITY 7.

## Key areas of focus

**Needs-based innovation:** Strengthen mechanisms to identify vaccine-related research and priorities for innovation according to community needs, particularly for underserved populations, and ensure that the priorities inform innovations in immunization products, services and practices.

**New and improved products, services and practices:** Accelerate the development of new vaccines, technologies and improved products, services and practices, while ensuring continued progress in the development of vaccines for priority targets, including HIV, TB, malaria and emerging infectious diseases.

**Evidence for Implementation:** Shorten the path to maximum vaccine impact by implementation and operational research and through evidence-informed decisions on policy and implementation based on sound evidence of needs, benefits and risks.

**Local innovation:** Build local capacity to address programme challenges and maximize impact by cooperative creation, sourcing, adopting and scaling-up of innovations.

The background is a solid blue color with several faint, concentric white circles centered on the right side of the image, creating a subtle ripple effect.

# **OPERATIONALIZATION**

# PDVAC Meeting 05 November 2021

## Session outline

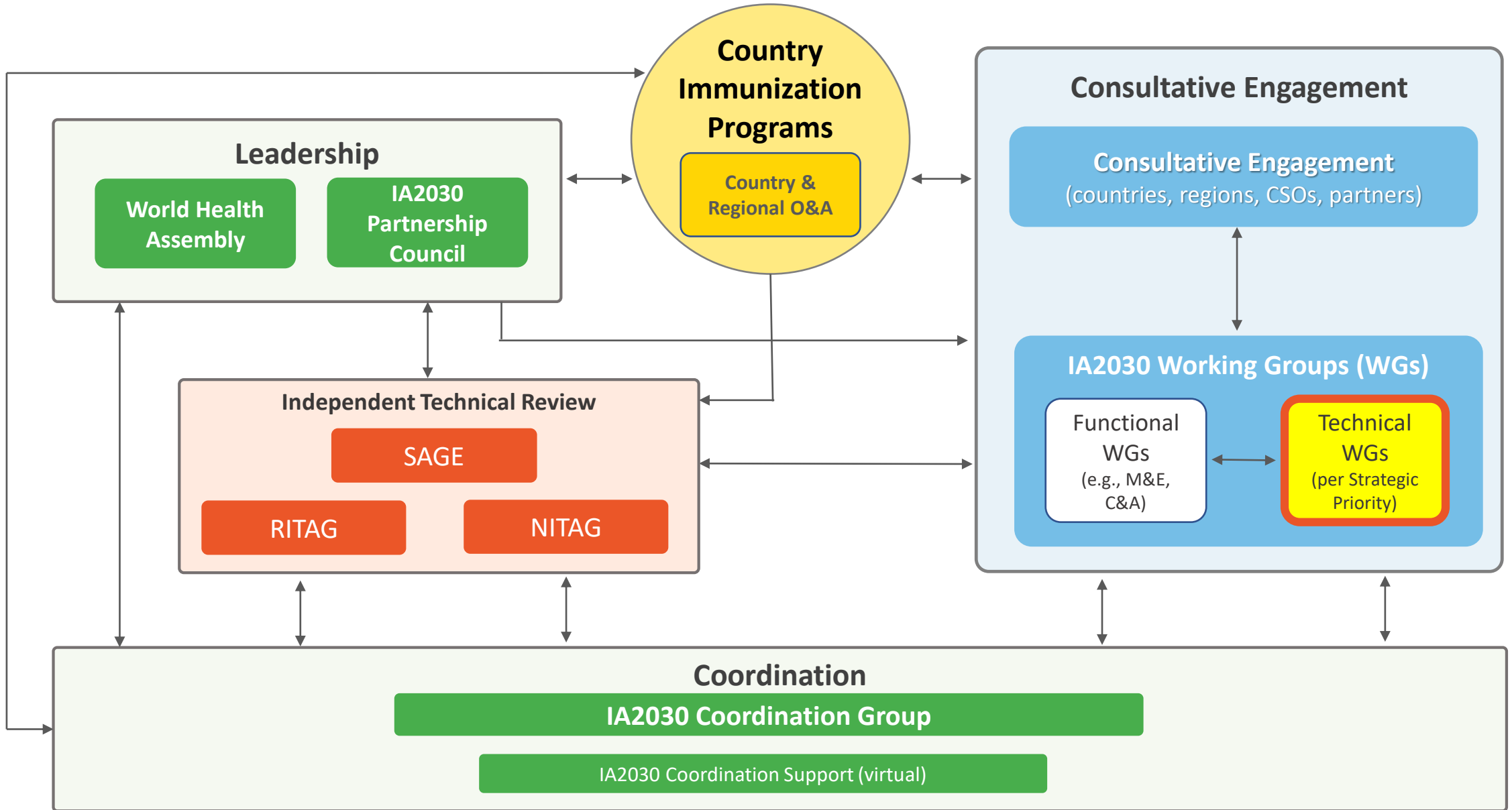
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Focus Area	Lead Partner
SP1: PHC/UHC	USAID
SP2: Commitment and Demand	WHO/JSI
SP3: Coverage and Equity	WHO
SP4: Lifecourse and Integration	CDC
SP5: Outbreaks	IFRC
SP5: Emergencies	WHO
SP6: Supply Security	UNICEF
SP6: Financial Sustainability	WB
SP7: Research and Innovation	PATH
Middle - income countries	WHO
Data strengthening and use	WHO/Gavi
Disease Specific Initiatives	WHO/UNICEF
Measles & Rubella	WHO
Monitoring & Evaluation	CDC
Comms & Advocacy	WHO/UNICEF
Resource Mobilization	tbd

## IA2030 Working Groups

- 13 '**Technical**' Working Groups
- 3 '**Functional/Cross Cutting**' Working Groups
- Each Working Group to have a **global-level partner responsible for leading** coordination and functioning of the group.
- Working Groups to have **balanced representation**: North/South, country/region/global, gender, CSOs, 'free thinkers'.
- Commit to at least one **consultative engagement** with broad stakeholder participation per year
- Drive **M&E cycles** and provide **technical guidance** to drive immunization programmes and learning agendas

# IA2030 global-level partnership



## IA2030 Working Group for SP7 Research & Innovation

2021 – 2023

Terms of Reference [*Annotated outline*]

Higher-level, longer term (e.g., 2025 and 2030) objectives for SP7 include to:

- Establish and strengthen capacity at all levels, to identify priorities for innovation and to create and manage innovation.
- Develop new vaccines and technologies; and, improve existing products and services for immunization programs.
- Evaluate promising innovations, and scale-up innovations as appropriate based on the best available evidence



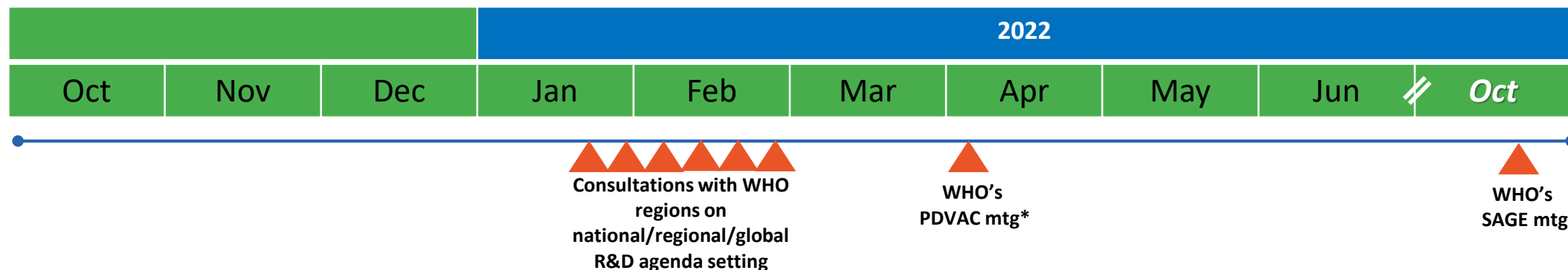
The SP7 Working Group will ensure integration of the 2025 and 2030 objectives with the following initiatives:

- **Gavi 5.0, VIPS** (Vaccine Innovation Prioritisation Strategy), and **VIS** (Gavi Vaccine Investment Strategy renewals)
- **CEPI 2.0**
- **WHO CAPACITI** (Country-led Assessment for Prioritization in Immunization Decision-support Framework)
- **COVAX** and its successor, if any, post-pandemic
- **GVIRF** (Global Vaccine and Immunization Research Fora)
- **WHO AMR VAF** (Anti-Microbial Resistance Value Attribution Framework)
- **WHO R&D Blueprint**

# **OPERATIONALIZATION**

**???COVID-19???**

# IA2030 SP7 Working Group



## Key Focus Areas and Deliverables 2021-2022

- Accelerate and expand the COVAX R&D agenda, including COVAX MTF efforts and variant- and programmatically-optimized vaccines;
- Support LMICs in expanding, strengthening, and/or establishing local and regional capacities for immunization research and innovation (Obj 7.1 indicator: No. of countries with national agenda for research on immunization);
- Develop a mechanism to align country, regional and global level stakeholders on priority diseases for which new vaccines are needed (Obj 7.2 indicator: “short list” of global targets will be developed by WHO and endorsed by SAGE in October 2022);
- Establish 2025 and 2030 IA2030 SP7 Working Group objectives to sustain progress, based on country-led R&D priorities.

## Membership

- SP7 Co-lead actively being recruited from AFRO region; will be a joint appoint to PDVAC & IA2030 SP7 WG
- Up to **18 members**, with up to **12 independent** members (approx. 2 members / WHO region), and up to **6 ex officio** members from the core IA2030 partners (e.g., WHO, Gavi, CEPI, UNICEF, NIH, Wellcome Trust)

\* WHO's Product Development for Vaccines Advisory Committee: <https://www.who.int/groups/product-development-for-vaccines-advisory-committee>

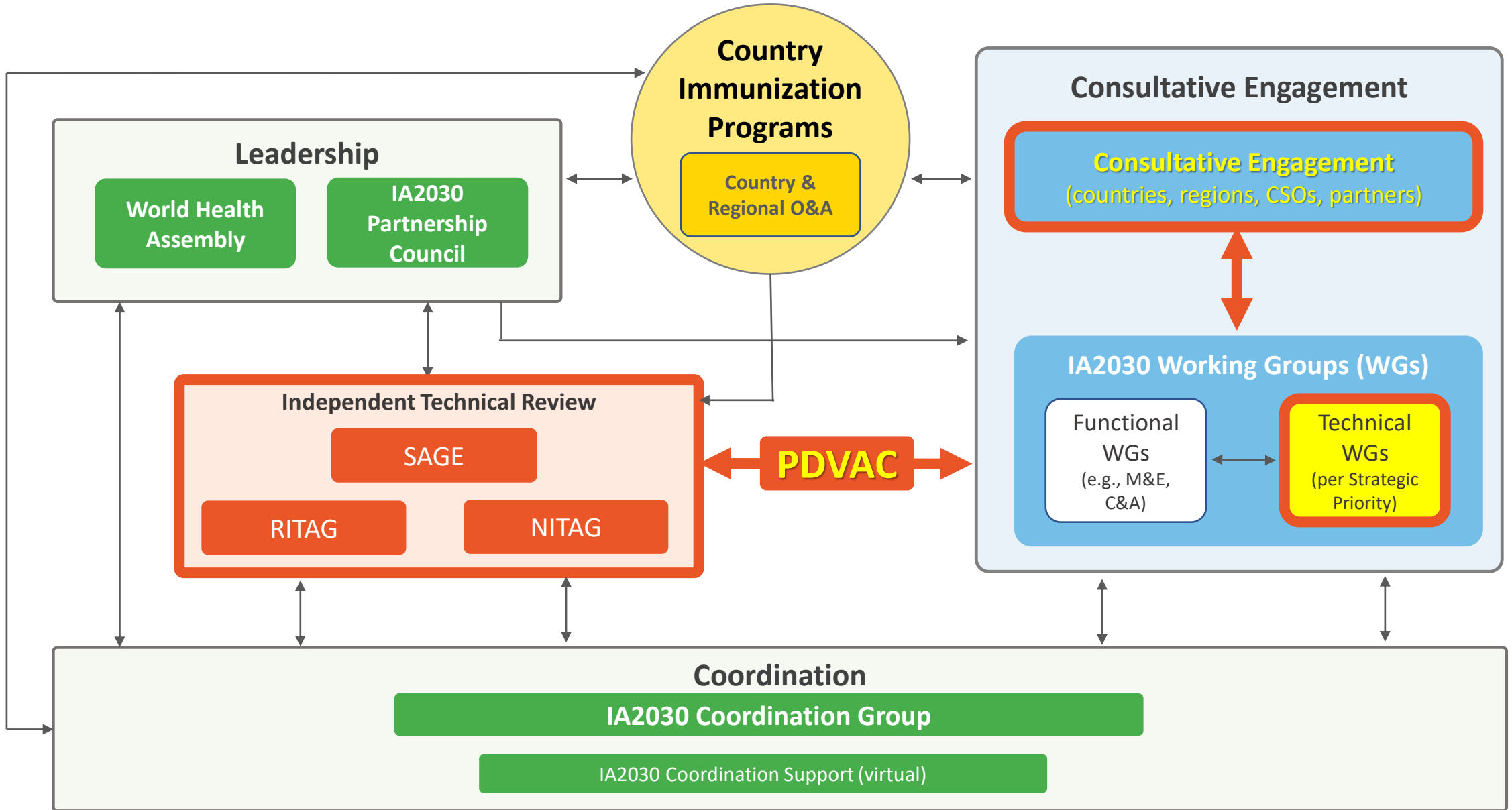


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# IA2030 global-level partnership



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# Role of PDVAC in IA2030?

**PDVAC** reviews the annual IA2030 M&E report and provide feedback on in-depth assessments of specific topics conducted by the IA2030 Strategic Priority 7 Working Groups:

1. **Contribute to assessment of progress** in achieving specific IA2030 Strategic Priority 7 area goals and objectives and highlight areas of concern
2. **Provide technical feedback** on topics elevated to PDVAC by IA2030 SP7 Working Groups or requested by the Coordination Group on behalf of the IAPC

PDVAC findings could be included in the feedback to:

- **IA2030 SP7 Working Group** to highlight specific areas of importance and areas of focus for consultative engagements
- **Regional and National Immunization Technical Advisory Groups** to align on priority areas and R&D agendas
- **SAGE** reporting from IA2030 SP7 WG on IA2030 implementation progress
- **IA2030 Coordination Group** on potential areas for process improvement

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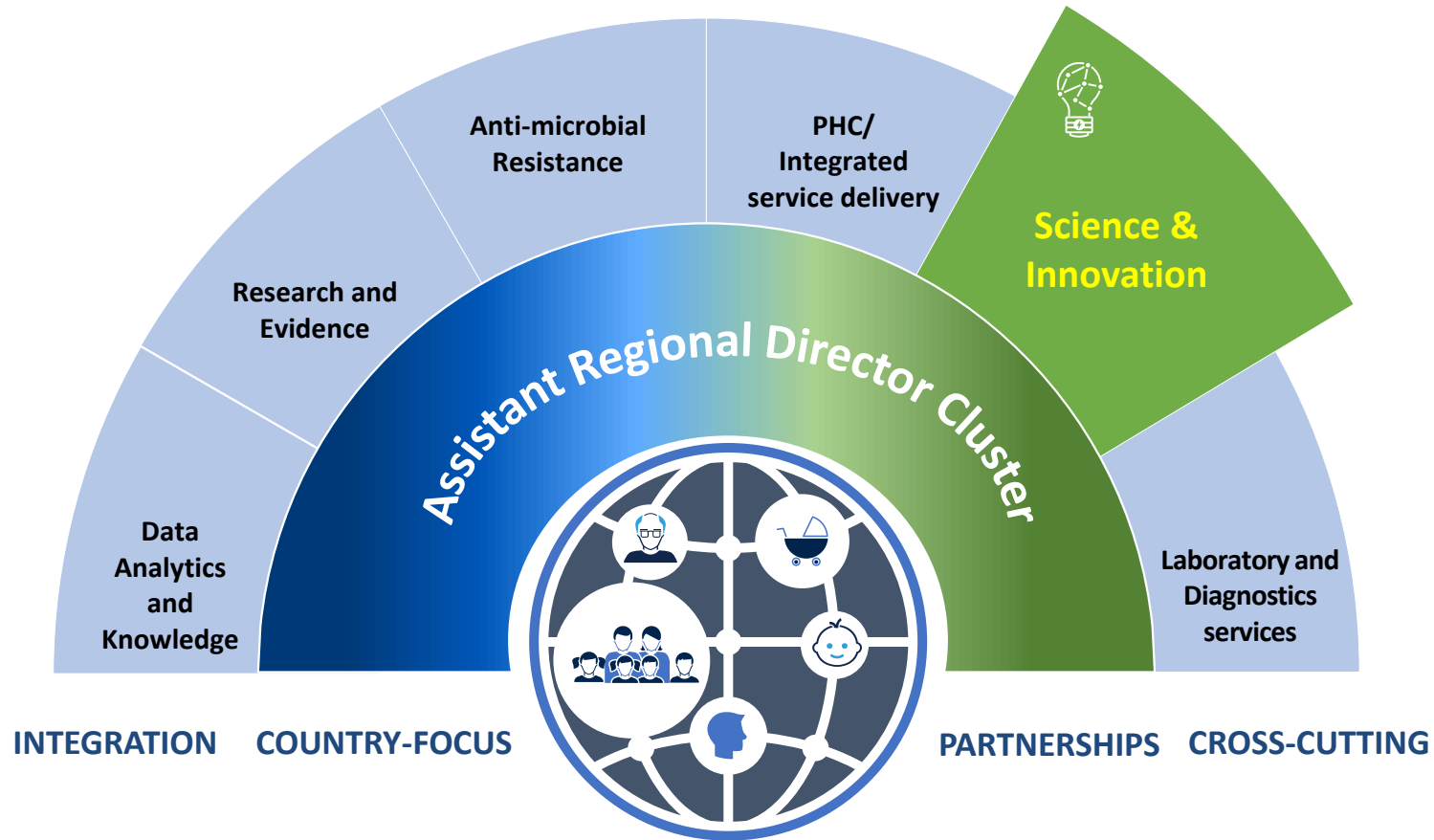
# SCIENCE AND INNOVATION OFFICE

## WHO Regional Office for Africa



**OFFICE OF THE ASSISTANT REGIONAL DIRECTOR**  
**Dr Lindiwe Makubalo**

# WHO AFRO strategic priorities for vaccine development and production



## Assistant Regional Director's Cluster

# TOWARDS PROMOTING ACCESS TO QUALITY ASSURED VACCINES FOR SUSTAINABLE IMPACT IN AFRICA

**1**



**Foster and strengthen  
quality and sustainable  
local production of  
vaccines**

**2**



**Market shaping:  
Procurement, Supply  
Management, and  
Vaccine Delivery**

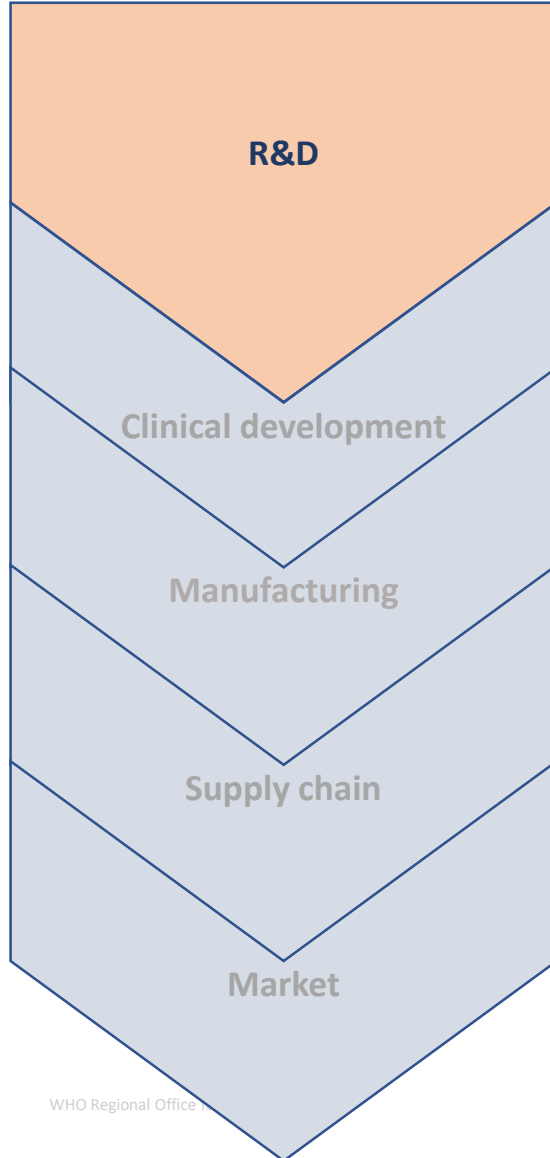
**3**



**Support strengthening  
of country and  
regional regulatory  
systems**



# PROMOTING R&D TO BOOST QUALITY AND SUSTAINABLE LOCAL PRODUCTION OF VACCINES



**Burden of vaccine preventable diseases to inform targeted R&D efforts**

**Mapping out regional capabilities for developing product candidates for therapeutic application, raw materials and reagents**

**Setting up of technology transfer hubs- mRNA hub in South Africa**

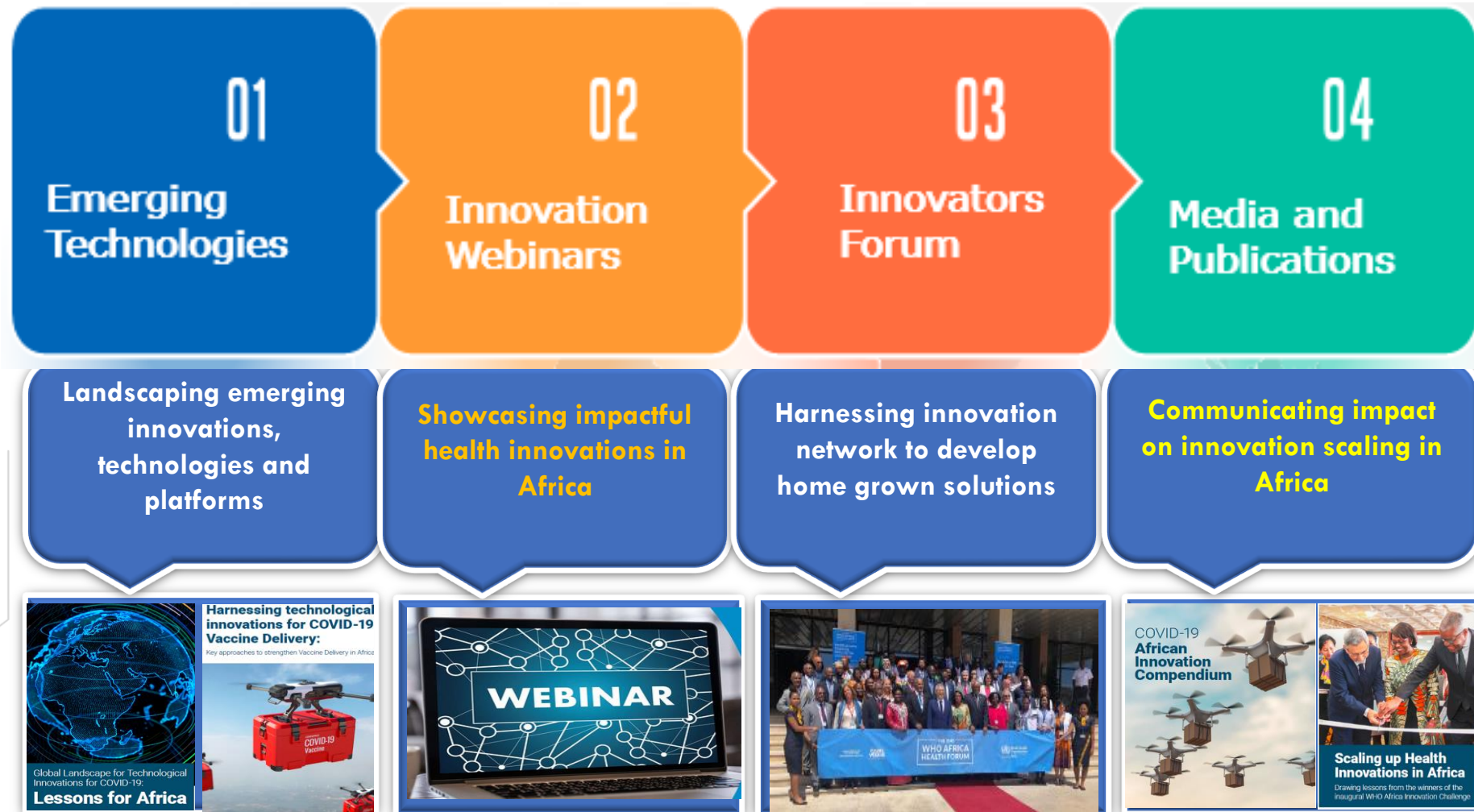
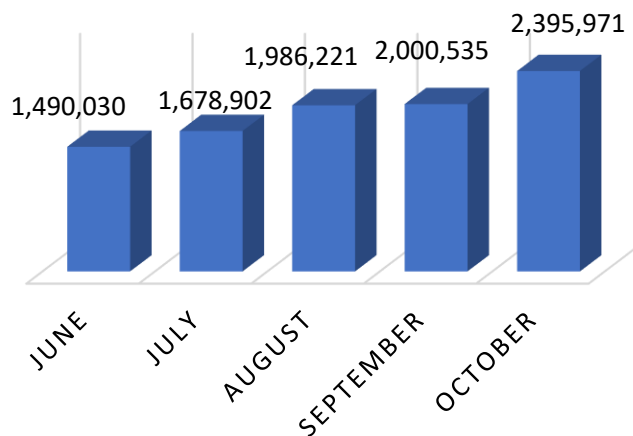
**Strengthen national innovation ecosystems to boost local production**

**Implement institutional oversight mechanisms that set local innovation and research priorities**

**Develop a regional database and knowledge hub for emerging products, technologies and platforms**

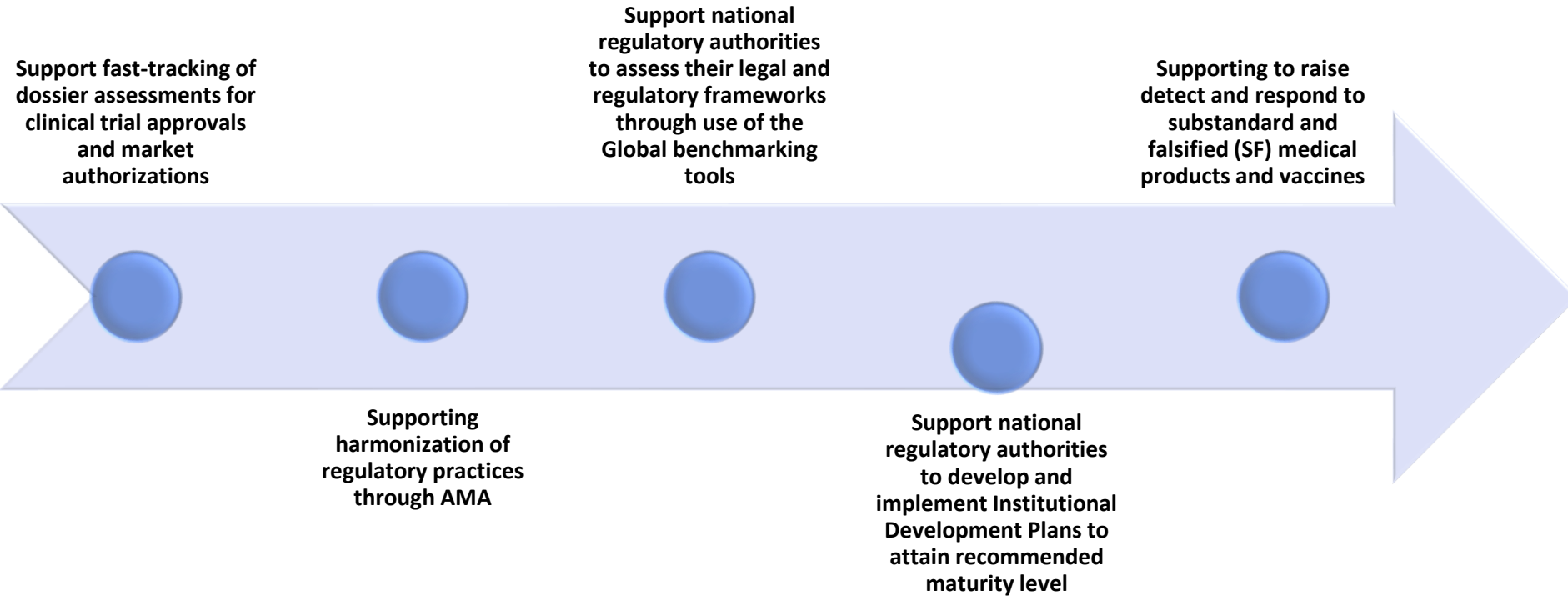
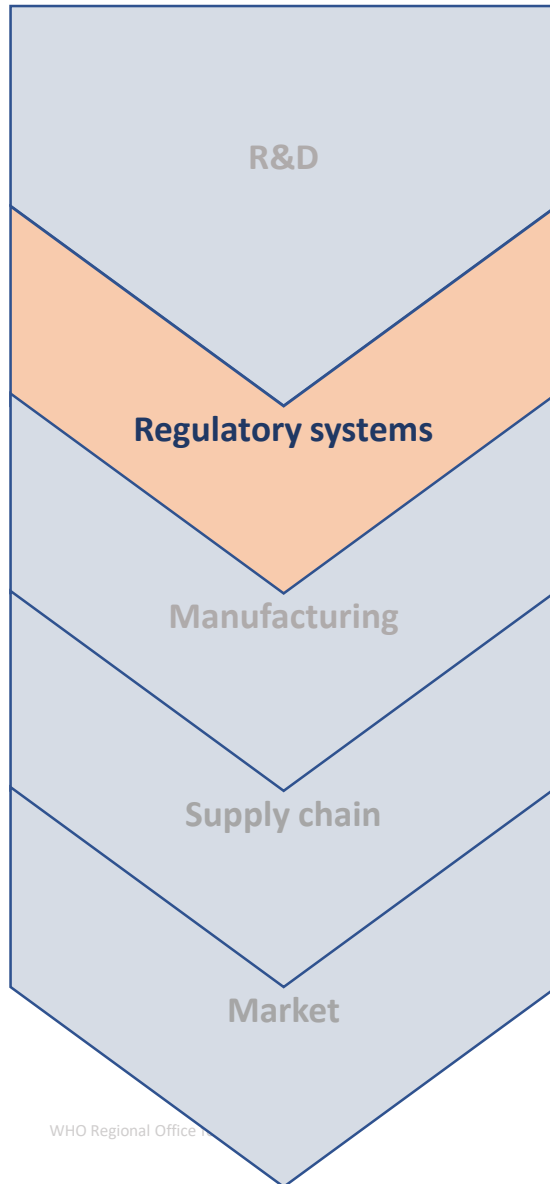
# WHO-AFRO INNOVATIONS MARKET PLATFORM HITS 2.5 MILLION SUBSCRIBERS

**WHO AFRO INNOVATION MARKET PLACE 2021 MONTHLY TRAFFIC**

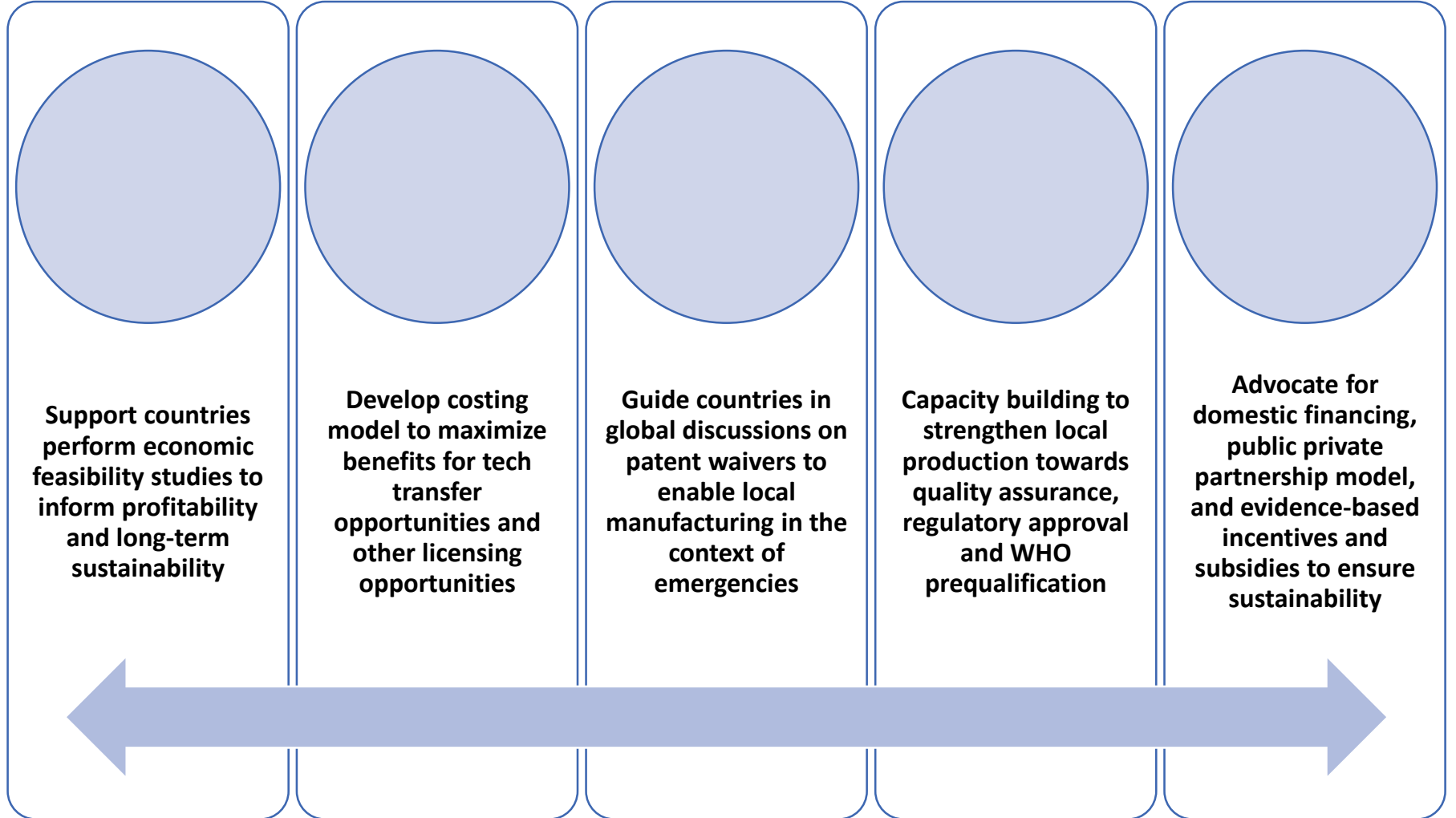
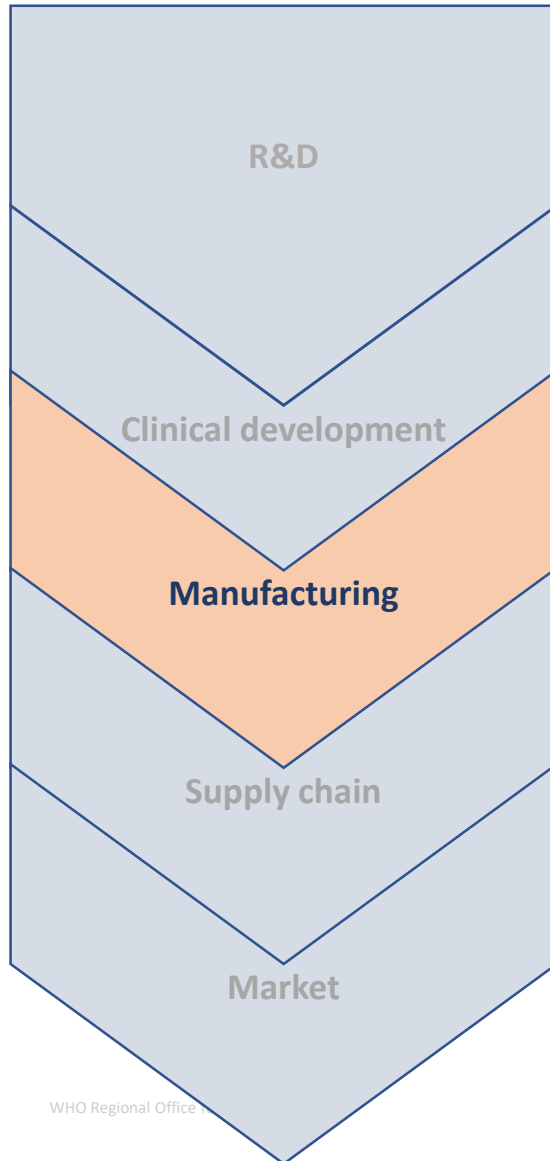


<https://innov.afro.who.int/>

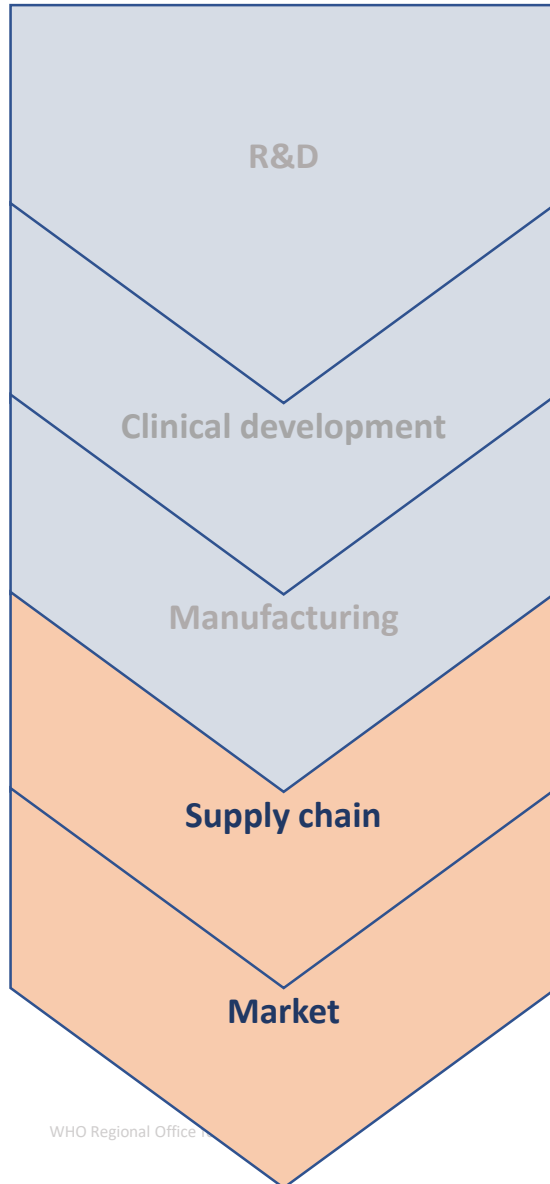
# SUPPORT COUNTRIES TO STRENGTHEN THEIR COUNTRY AND REGIONAL REGULATORY SYSTEMS



# FOSTER AND STRENGTHEN QUALITY AND SUSTAINABLE LOCAL PRODUCTION OF VACCINES



# MARKET SHAPING: PROCUREMENT, SUPPLY CHAIN MANAGEMENT AND DELIVERY OF VACCINES



Engage countries for political commitment for regional alignment on the procurement of vaccines in the context of regional health security

Support countries in forecasting their needs, consolidating the demand for essentials supplies including in the context of emergencies

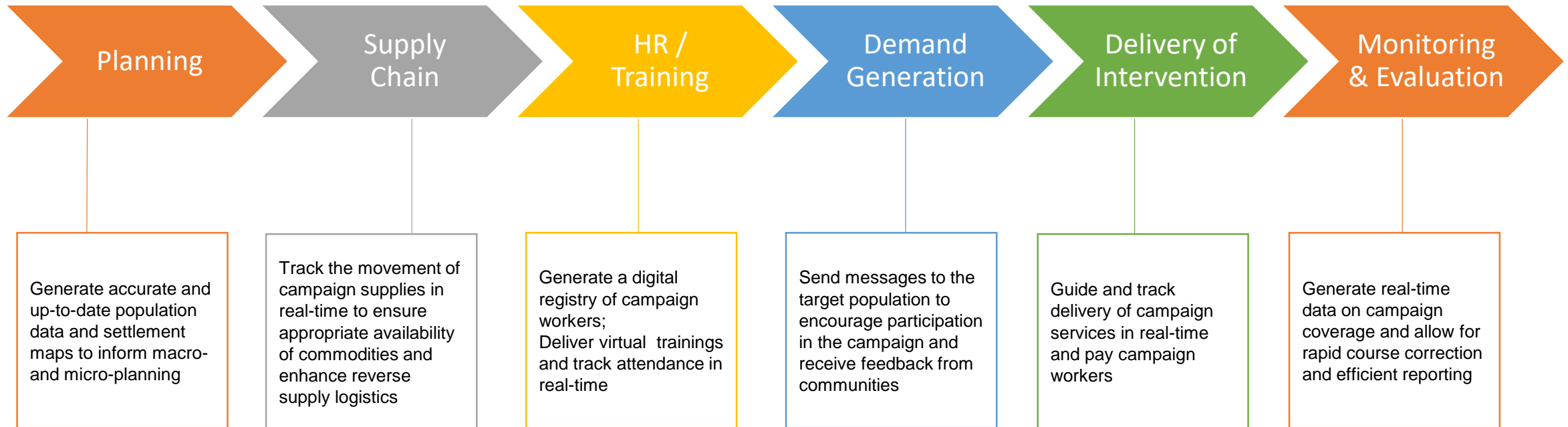
Ensuring that immunization programmes are integrated into broader health budgeting and financing processes

Support harmonization of procurement and supply management practices and operationalization of pooled procurement initiatives

Strengthening national decision-making capacity and the ability to set evidence-based policies and priorities for immunization

Use of innovations to solve programmatic challenges leveraging the power of technologies, e.g digitization of vaccination campaigns

WHO AFRO working with CHAI and ministries of health, other relevant government departments, and partners to introduce digital tools and platforms for integrated campaigns



***THANK YOU***

