Innovation and Policy Recommendation to ensure Vaccine Impact

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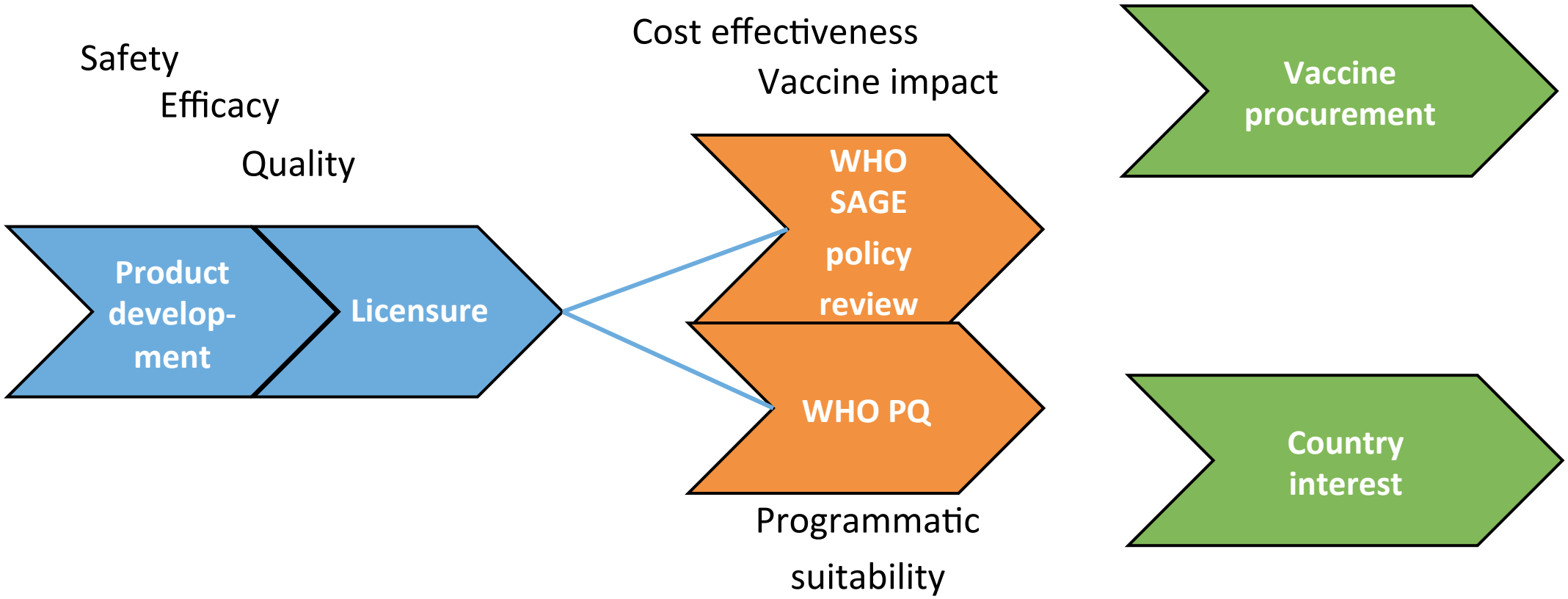
What can WHO's Initiative for Vaccine Research (IVR) do?

- **What is WHO (IVR's) role in advancing vaccine development and impact?**

  Acceleration **of vaccine development and** ***increasing access*** **to vaccines, in low and middle income countries**

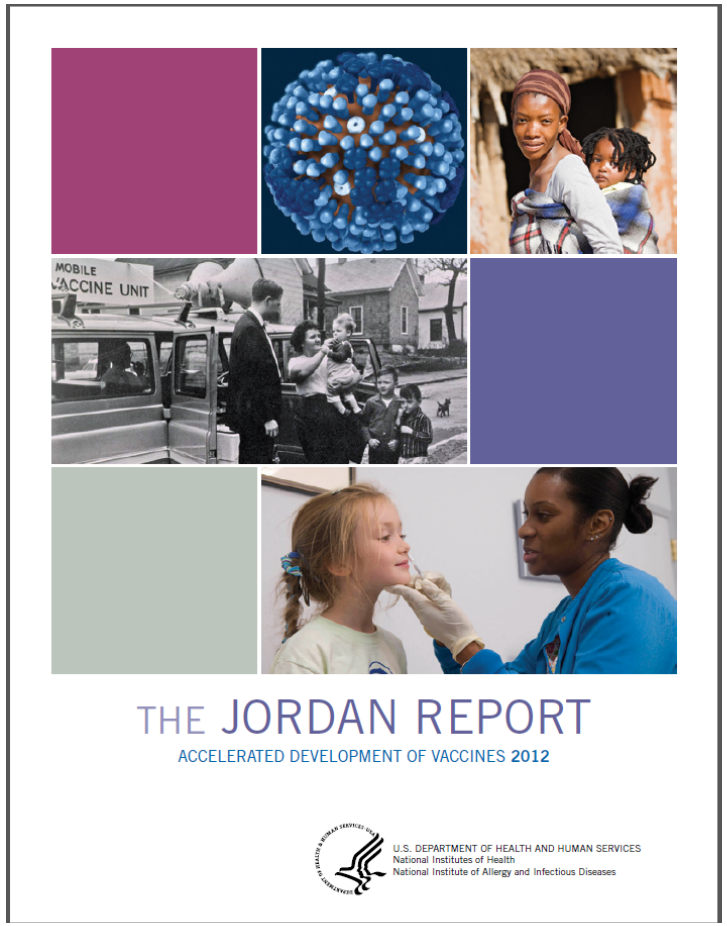
Understand the considerations for PQ and policy recommendation EARLY



Overview of product development focus at IVR

- New vaccines that have a significant burden of disease in LMICs
- Novel vaccine delivery technologies that improve coverage and increase vaccine impact
- Development of new immunization delivery strategies
- Development and evaluation of vaccine technology impact assessment tools
- Establish relevant forums of experts to address product development related issues

New vaccine development: the vaccine development pipeline



Vaccines targeting 110 pathogens

In 2012: 577 approaches in development!

Source: http://www.niaid.nih.gov/topics/vaccines/documents/jordanreport2012.pdf

Challenges of new vaccine product development for LMICs

- Poorly defined disease burden in LMICs
- Vaccine investment is driven by market potential in high income countries
- Different case definitions in high and low income contexts
- Unclear regulatory pathway, and lack of clarity regarding data needs for policy recommendations
- Multiple stakeholders with very different perspectives on public health priorities

WHO's Product Development for Vaccines Advisory Committee (PDVAC)

Identifies areas of focus for IVR

Three "simple" criteria for attention from WHO:

- Unmet public health need focusing on low/middle income country perspective
- Chances of a product emerging from the pipeline
  - Probability of technical and regulatory success
  - Extent of activity/investment in given area
- Added value for WHO engagement in pathogen area

➢ **Since its inception in 2014, PDVAC has evaluated 35 pathogens**

http://www.sciencedirect.com/science/journal/0264410X/34/26

Areas of focus, and ongoing activities in new vaccine development

Respiratory Syncytial Virus (RSV), Group B streptococcus (GBS), ETEC, Shigella, Norovirus, Herpes Simplex Virus (HSV), Tuberculosis, Group A st[illegible]tococcus (GAS)

Ebola, MERS-CoV, Zika….

- **Key endpoints for vaccine evaluation ar[illegible]** through consensus-building on clinical trial progressio[illegible]
- Developing **Preferred Produ[illegible]** (PPCs)
- **Global R&D Roadmar[illegible]**gic goals to articulate priority unmet public health ne[illegible]
- **Linking u[illegible]** with surveillance
- **Value p[illegible]**velopment

Stakeholder consultation

New vaccines spotlight: Respiratory Syncytial Virus (RSV)

Most advanced vaccine candidate for maternal immunization in phase III.

WHO is in active discussions to advance SAGE April 2016 recommendations on RSV vaccines, including:

- RSV surveillance to better characterize **RSV disease burden**
- assessment of the **long term effects of RSV interventions**
- strengthening of the **maternal immunization platform**
- initiate **early discussions with financing bodies**

Challenges of vaccine delivery in resource constrained environments

More than half of the immunization costs are due to vaccine delivery*

*Portnoy, 2015, Vaccine, 33 Suppl 1:A99-108. doi: 10.1016/j

New delivery strategies – Controlled temperature chain (CTC)

What is it?

A set of conditions allowing for a vaccine to be stored and transported outside of the traditional 2° to 8°C cold chain

- One excursion, just prior to administration
- Ambient temperatures up to 40°
- Specifically limited duration (at least 3 days)

What is it used for?

Campaigns and special strategies

- VVM & Peak Threshold Temperature Indicator
- Tested (for safety & stability), Licensed & Prequalified

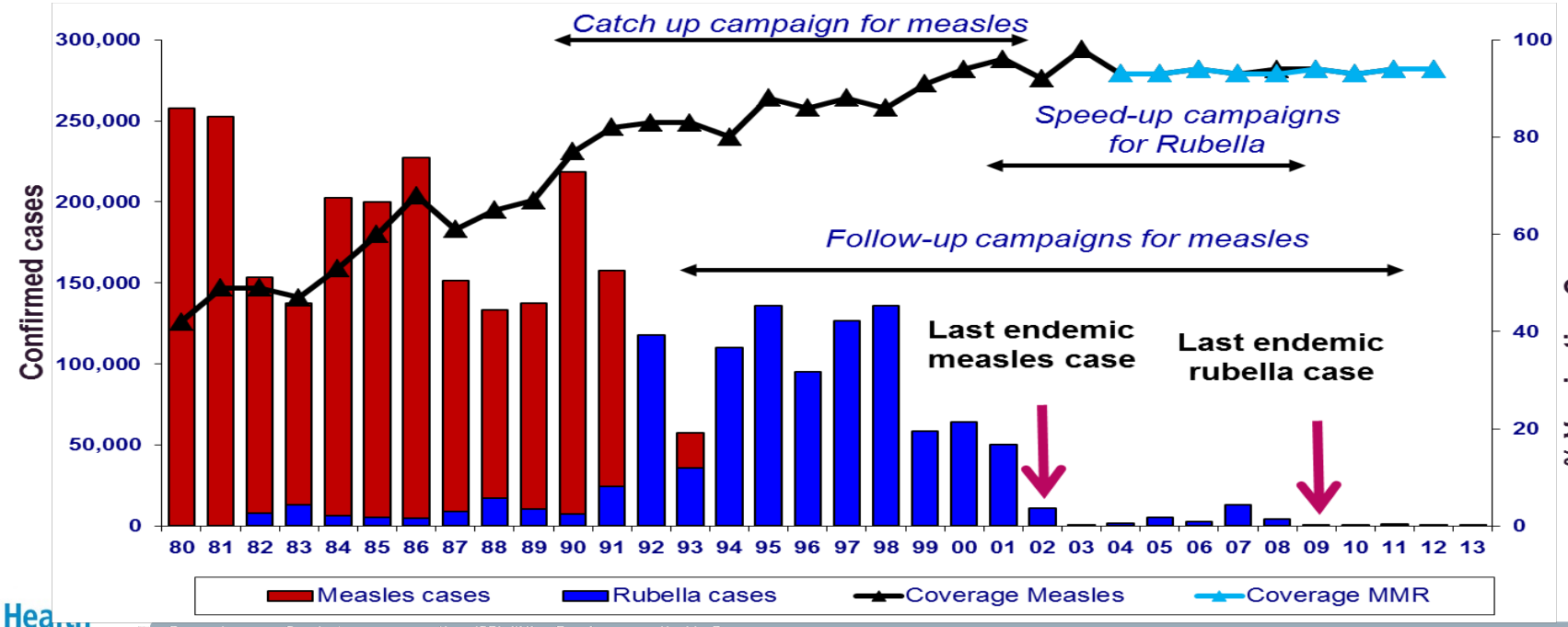
➢ **CTC can save approx. 50% cold chain and associated logistics cost used in campaigns***

*Lydon et al, Bull World Health Organ. 2014 Feb 1;92(2):86-92. doi:

New delivery technologies spotlight: Microarray patches

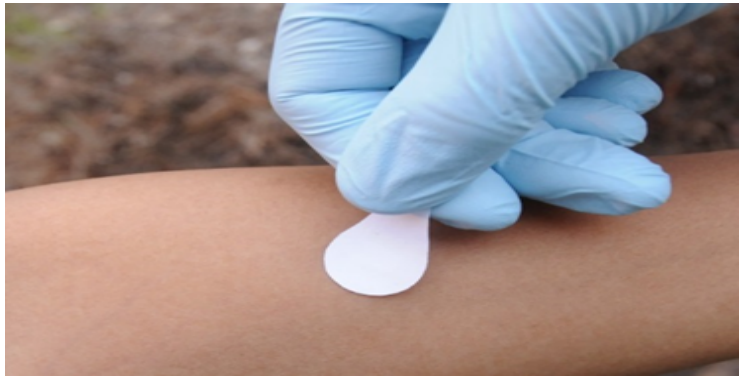
Measles costs 23c per dose. In 2015, it killed 115,000 children

- With high coverage rates, measles eradication is achievable
- The solution must include **new tools and tactics**, combined with stronger programme management and accountability



Spotlight: MR/MAPs as a novel technology to reach the 5th child

Vaccination with the current MR vaccine presentation is **logistically complicated**, requiring a fully trained HCW and **stringent cold chain requirements**



Vaccination with the MAP is **simple**, possible through a **minimally trained volunteer**. MR/MAP may be **thermostable** and as immunogenic as current vaccine

MAPs are **small, lightweight** and generate **minimal waste**

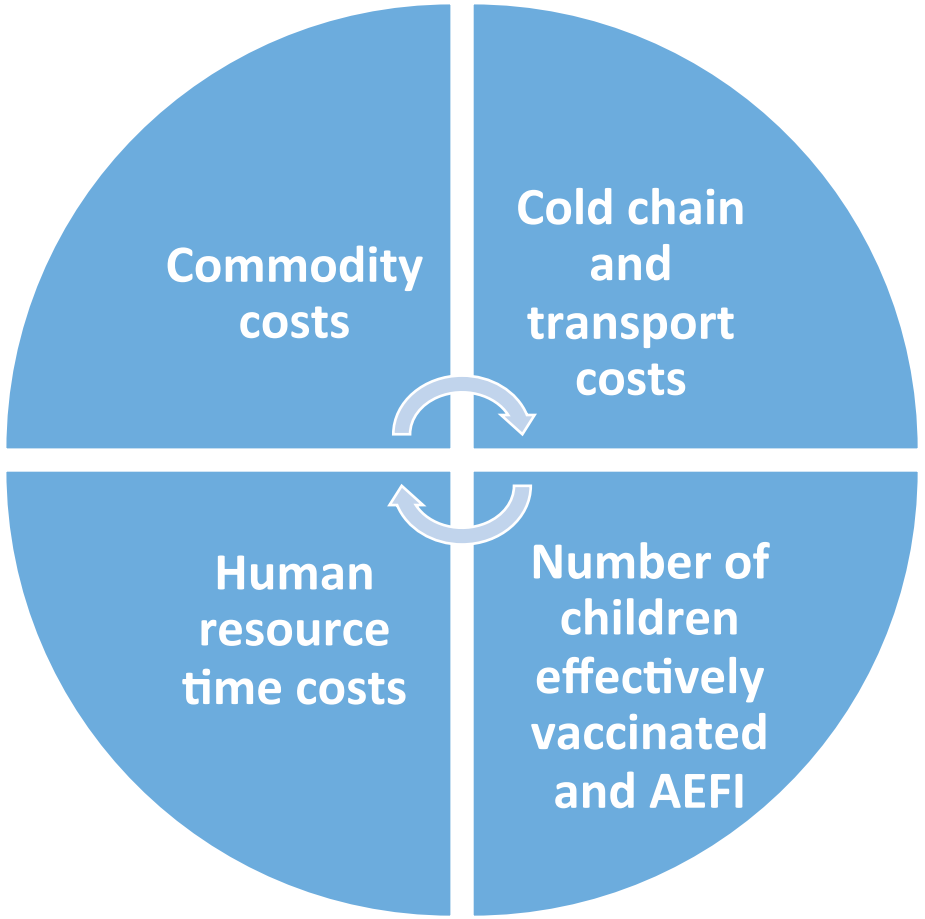
Challenges of developing new vaccines and delivery technologies for LMICs

- Poor investment case if product focused on LMICs
- The cost of goods is likely to be *HIGHER* than existing vaccine delivery technologies – but the total systems cost to vaccinate a child may be lower (over time) – how can we model this?
- Complex partnerships
- Unclear regulatory pathways
- New manufacturing and delivery infrastructure may be required
- Difficulty in getting commitment to develop a disruptive technology, where existing markets are well established

Vaccine Technology Impact Assessment tool to evaluate impact and trade-offs

How do we measure the potential impact of product innovation?

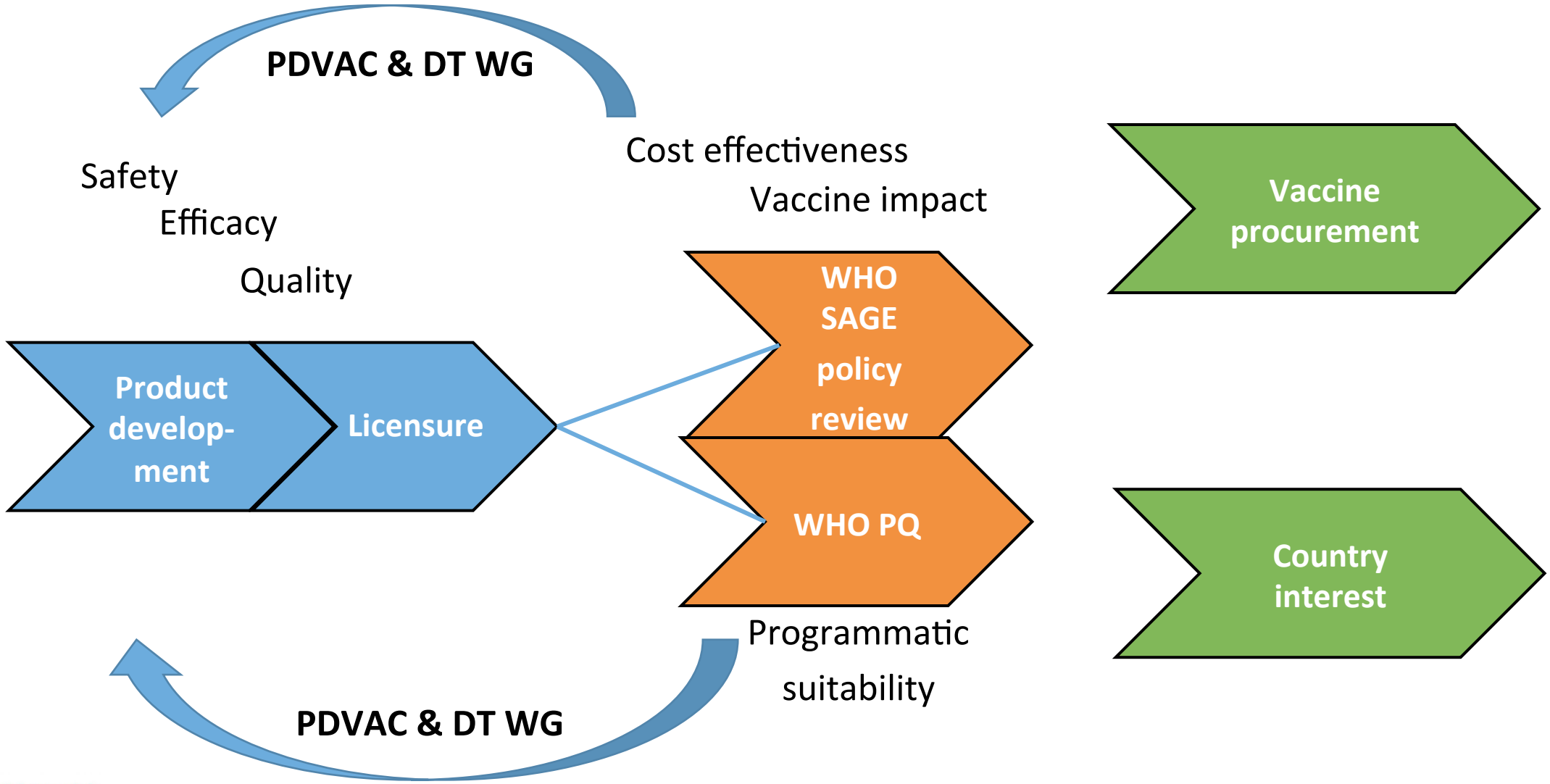
V-TIA is a excel-based model which provides a comparative economic evaluation of the commodity and system costs and health impact for the current vaccine/technology presentation(s) compared to new presentation(s).



Delivery technology working group (DT WG)

- Topic-specific working group within IPAC, co-chaired by PATH and WHO.
- Advocate for LMIC considerations in product development
- Remit to generate/review evidence and develop consensus on recommendations for new delivery technologies and assessment tools
- Understand the potential barriers to delivery technology development

Understand the considerations for PQ and policy recommendation EARLY



So how can IVR assist DCVMN?

- Many technology developers proposing licenses for ‘game-changing’ technologies.
- But, vaccines made with ‘game-changing’ technologies may be difficult to approve, far more costly than existing vaccines and ultimately not be recommended.

IVR can provide neutral evidence on value of the new technologies, and the challenges to be overcome in vaccine approval and recommendation.

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