

WHO Preferred Product Characteristics : Bridging Vaccine R&D with Public Health

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**World Health
Organization**

GVIR

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PPCs will be...

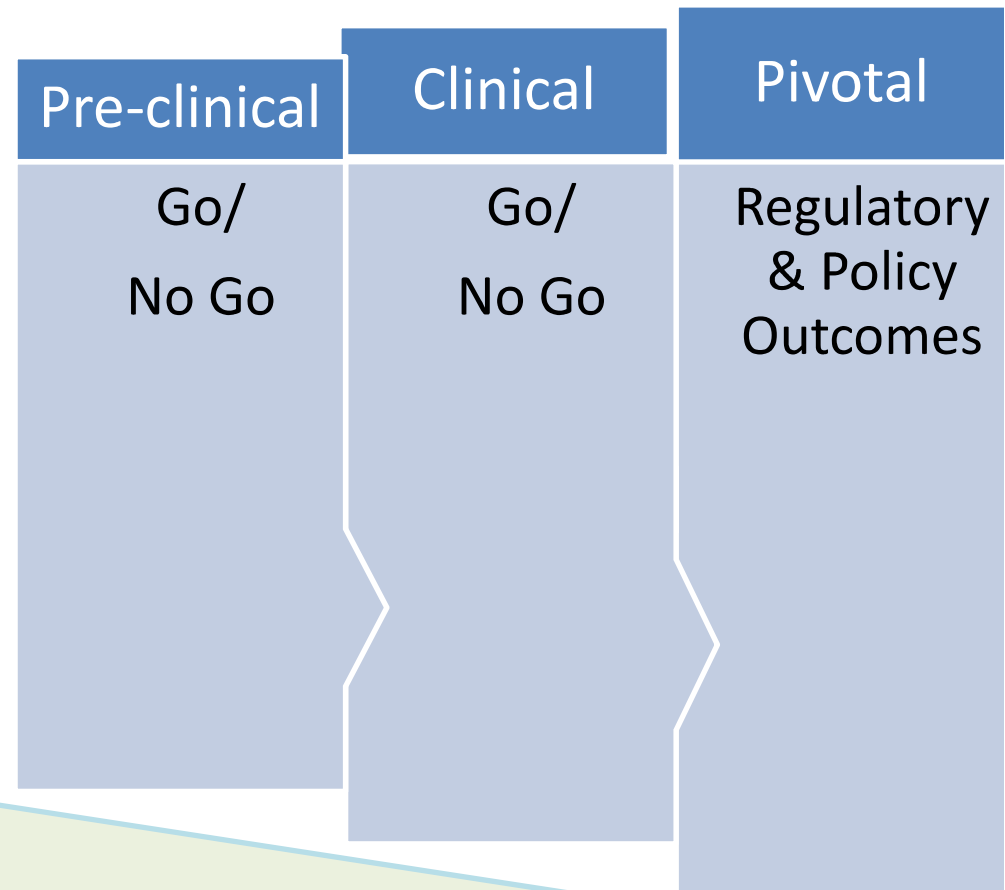
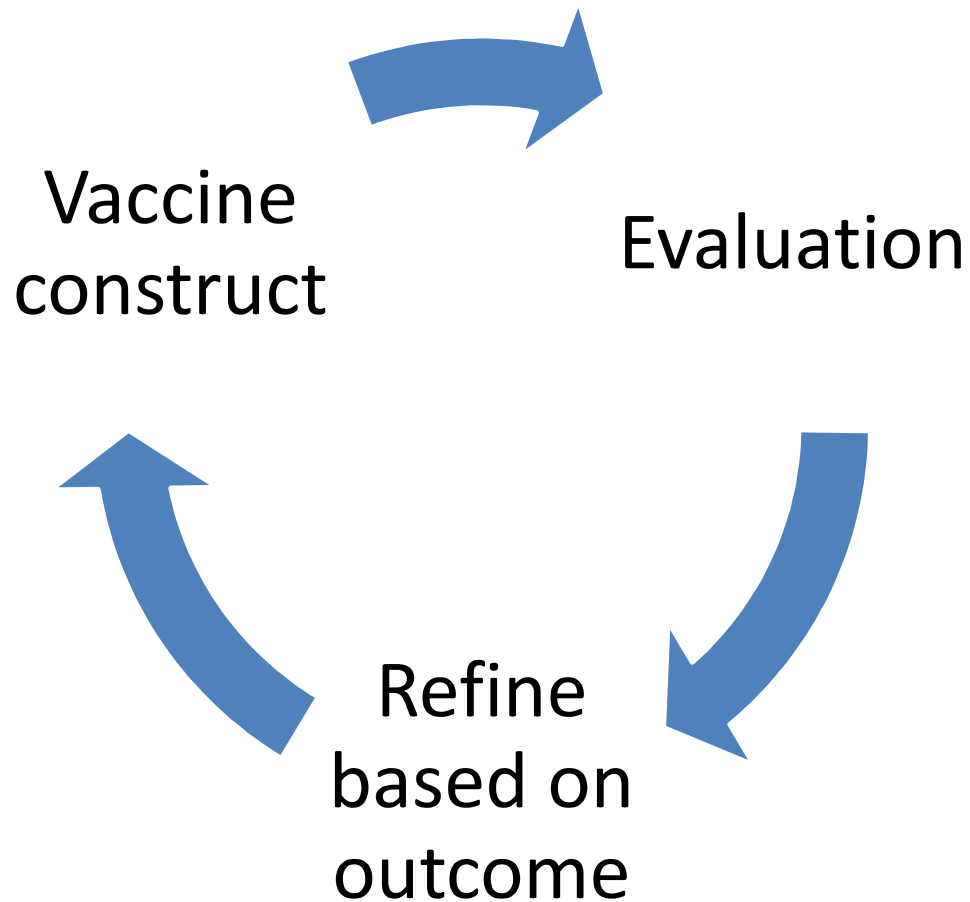
“WHO documents providing guidance for early stage vaccine R&D for products that will meet priority public health needs with a focus on low and middle income countries”



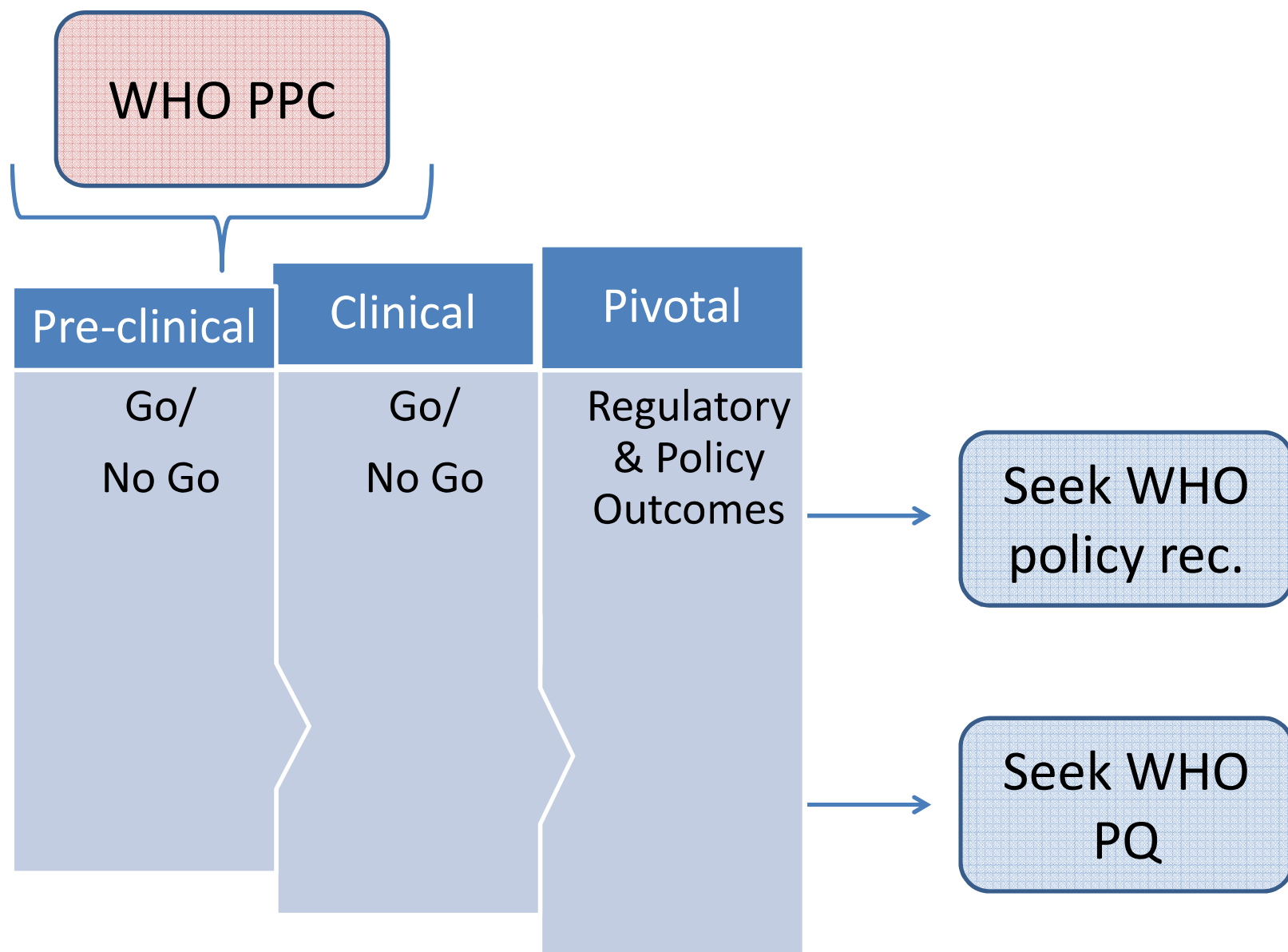
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Organization

Translational Research

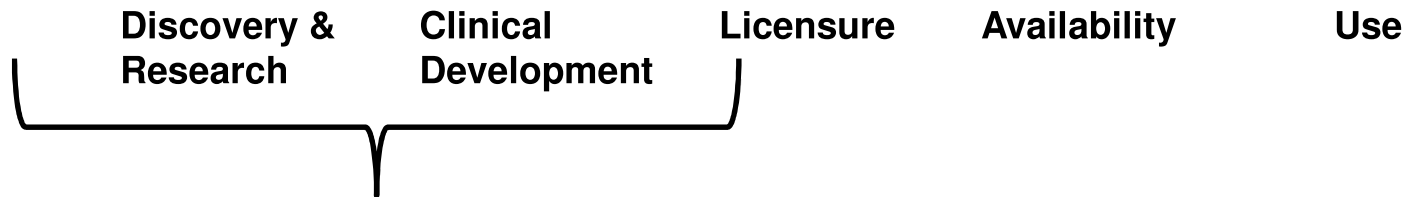
Product Development



Product Development Pathway: LMIC



Vaccine Clinical Development



- Vaccine design based on solid rationale
- Pre-clinical proof-of-concept
- Clinical data on Safety, Efficacy including in target population

- Immunogenicity
- ?Co-administration data
- Duration of protection
- Strain/Clade/Serotype coverage



Potential Brakes on Product Development for LMIC

- Lack of clarity as to whether a product represents a priority unmet public health need
- Uncertainty about clinical data needs to achieve regulatory and policy outcomes
- No established clinical development pathway
- Data generated suitable for high income country indications, where these are not drivers of public health need in LMIC.



Development of WHO Preferred Product Characteristics

- Consensus is obtained about priority unmet public health needs in a given pathogen/disease area
- PPC document confirms WHO's priority interest in a future product meeting the agreed public health need
- The document provides narrative on desired public health applications for such a product if it was developed
 - Geographical distribution of need for vaccine
 - Anticipated target groups and LMIC indications
 - Disease control vs elimination uses
 - Possible immunization strategies
 - Key trial design considerations for generation of safety and efficacy data
 - Guidance on endpoints for proof-of-concept & pivotal trials from policy perspective

Preferred Product Characteristics: What they are & what they are not

What they are

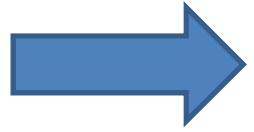
- Guidance from WHO for vaccine developers to take into account when designing vaccines and trials at early stage of vaccine R&D
- Will need to change in line with the scientific state-of-the-art and needs of country programmes (with ongoing review process)

What they are not

- They are not static exit criteria. Innovation is encouraged and harnessed to meet public health needs
- They do not replace standard policy or PQ processes

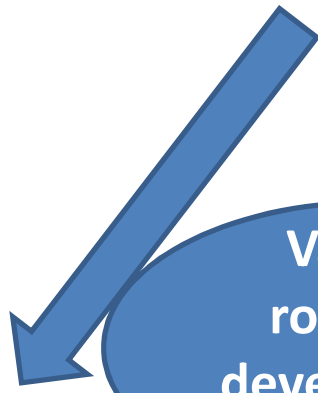
Research for Product Development
Advisory Committee:
Strategic Prioritization
for WHO activities in
early stage vaccine R&D

Proposed criteria for prioritization include disease burden, unmet public health need in LMIC, biological feasibility, technical and regulatory assessments, status of activity, role for WHO



Selection of pathogens for WHO IVR activity

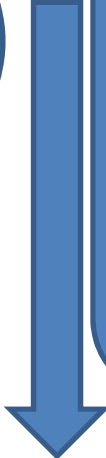
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Vaccine
roadmap
development



Preferred
Product
Characteristics



Clinical Development
Pathways

- Consensus on immunoassays
- Consensus on efficacy endpoints

PPCs relate WHO's core functions to upstream product development

WHO fulfils its objectives through its core functions:

- providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
- shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
- setting norms and standards and promoting and monitoring their implementation;
- articulating ethical and evidence-based policy options;
- providing technical support, catalysing change, and building sustainable institutional capacity; and
- monitoring the health situation and assessing health trends.

