

# DCVMN

## Roadmap to future vaccines

End-to-end vaccines and vaccination from science to implementation  
from, for and in low- and middle-income countries  
and for the world

# Looking back and currently

← Old vaccine newly made in LMIC →



← New vaccine in LMICs →

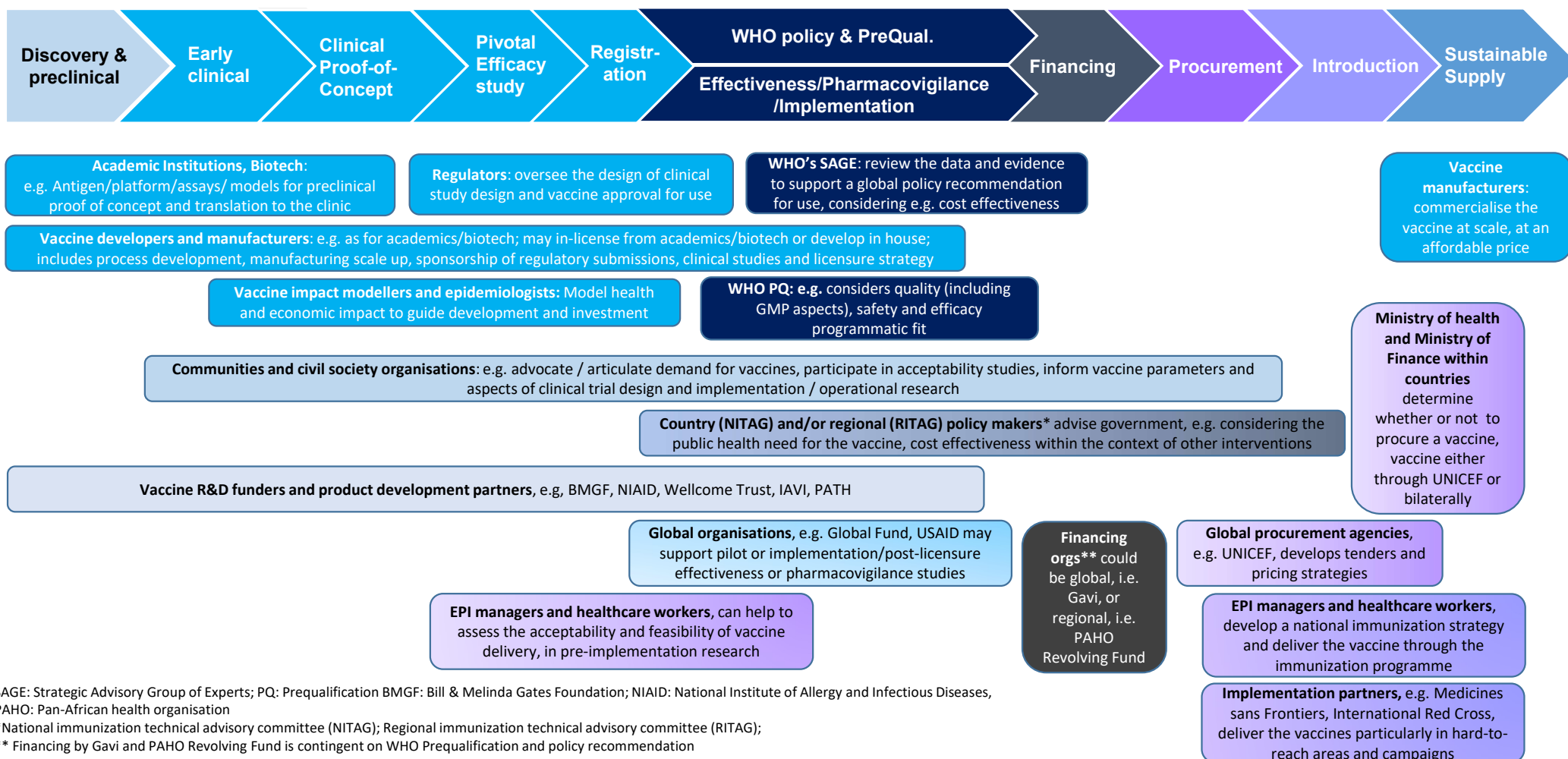
← Licensure to policy and implementation →

Manufacturing capacity moving from the 'global north' to the 'global south', particularly during the pandemic for all platforms other than mRNA

# Stakeholders in the development to uptake continuum

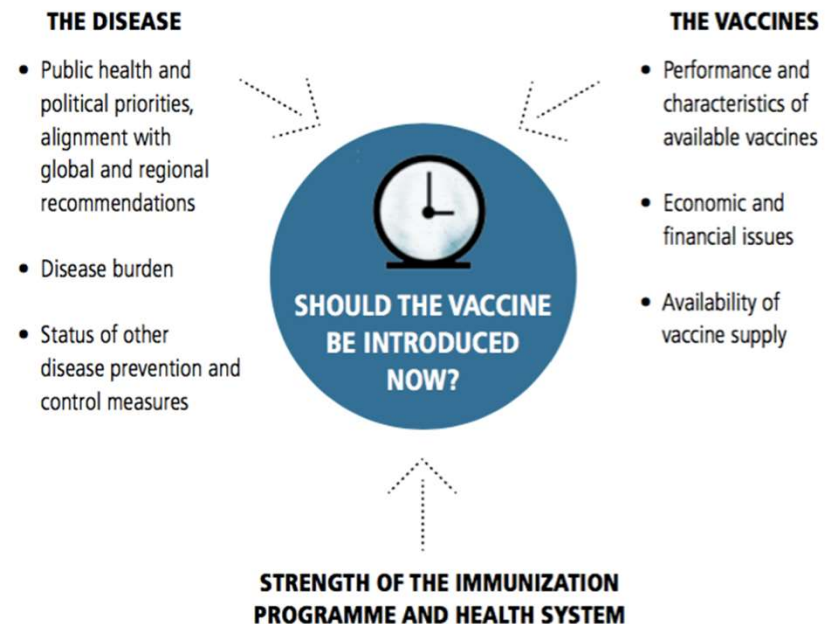
- Developing vaccine candidates-academics, start-ups, vaccine companies
- Supporting the development of vaccine candidates- Funding agencies, government research agencies, funding philanthropies, CEPI
- Burden of disease estimates-academia, public health agencies
- Prioritization, policy- PDVAC, NTAGI, ITAG
- Recommendation-WHO, ITAG, NITAG
- Implementation, including impact/safety-Government and partners

# Outline of a process for new vaccine product development-to-uptake of a vaccine intended for global use



# Which new vaccines need to be developed and deployed?

- At country level-disease burden estimates
- At global level-what is the threat? WHO's R & D Blueprint, CEPI, BARDA, etc
- But implementation in routine immunization and implementation in a pandemic are very different



# Comparing development to uptake for two important diseases

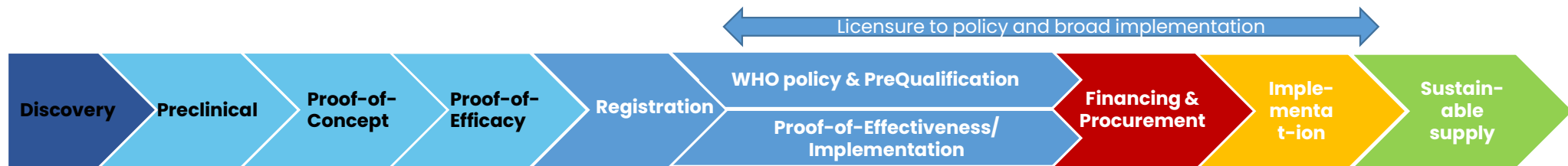
## **COVID-19**

- Global disease burden
- Urgent need for vaccines recognized globally
- Multiple manufacturers, multiple platforms
- Regulatory facilitation
- Rapid clinical trials and EUA/EUL
- Rapid implementation

## **Tuberculosis**

- Unevenly distributed disease burden
- No new product for nearly a century
- Difficulty in identifying manufacturers for potential new candidates
- Standard regulatory pathway but challenges in target populations, outcome definitions in endemic areas
- Clinical trials long
- Implementation?? Given existing vaccine and likely moderate efficacy?

# Context for the need for Evidence Considerations for Vaccine Policy (ECVP)



**Preferred Product Characteristics: (PPC):**  
defines product attributes for LMIC use



**Scientific advice meetings:**  
Data on **safety, quality and efficacy** for licensure

*EVIDENCE CONSIDERATIONS FOR VACCINE POLICY: evidence anticipated to facilitate global policy recommendations developed **before** phase III clinical studies*

Vaccine Product (priority popln)  
Vaccine Delivery  
Vaccination (other target population)  
Regulatory Strategy Considerations to facilitate policy review  
Implementation Considerations (introduction/program implementation, data used in Gavi VIS)



**WHO PQ**

**SAGE Evidence to Recommendation framework**



**WHO Position paper**

The screenshot shows the ScienceDirect interface for the journal 'Vaccine'. It includes the Elsevier logo, the journal title 'Vaccine', and the URL 'journal homepage: www.elsevier.com/locate/vaccine'. Below this, it identifies the document as a 'Conference report' titled 'Building the concept for WHO Evidence Considerations for Vaccine Policy (ECVP): Tuberculosis vaccines intended for adults and adolescents as a test case'. A list of authors is provided, including Sonali Kochhar, Draurio Barreira, Pauline Beattie, Marco Cavaleri, Alejandro Cravioto, Mike W. Frick, Ann M. Ginsberg, Ian Hudson, David C. Kaslow, Sherry Kurtz, Christian Lienhardt, Shahir A. Madhi, Christopher Morgan, Yalda Momeni, Deepali Patel, Helen Rees, Taryn Rogalski-Salter, Alexander Schmidt, Boitumelo Semete-Makokotlela, Gerald Voss, Richard G White, Matteo Zignol, and Birgitte Giersing.

<https://www.sciencedirect.com/science/article/pii/S0264410X21013955?via%3Dihub>

# Summary

- Science has accelerated at a previously unimagined pace
- We have the opportunity to make new vaccines, and manufacturers have demonstrated their ability to scale
- Between science and manufacturing, and manufacturing and implementation are areas where we need to ensure that gaps are identified and have begun to be bridged before the need

Thanks to B. Giersing for the ECVP slides