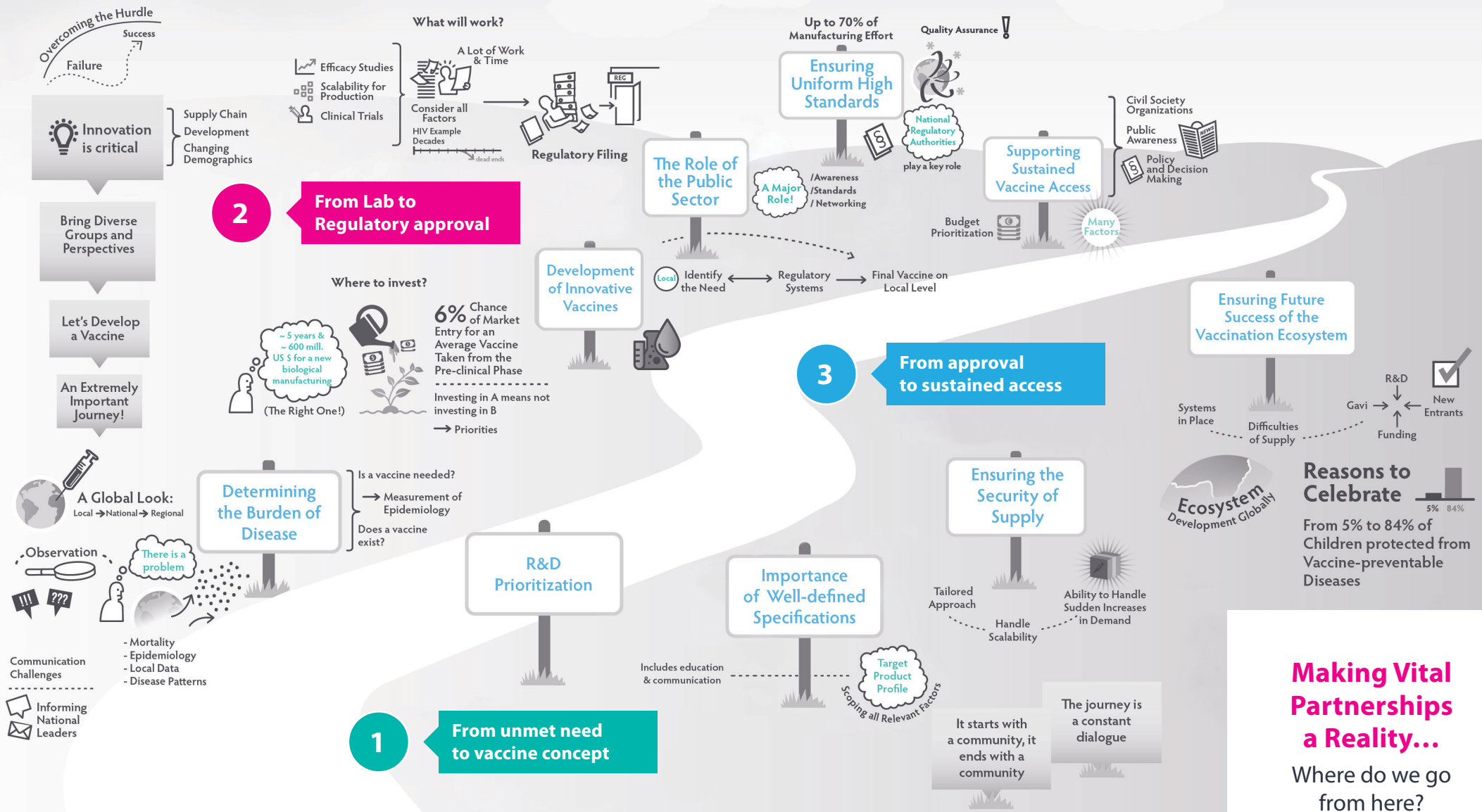


SECURING SUPPLY THROUGH SHARED UNDERSTANDING

The Exciting Journey of Vaccines





R&D



APPROVED

Safe & effective by a regulatory authority.

THE COMPLEX JOURNEY OF A VACCINE

MANUFACTURING CHAIN



DAY "0"

Vaccine manufacturing involves **6 basic steps**. Each step can be performed in different sites situated in different countries.



Quality Control represents up to **70%** of manufacturing time.



A vaccine typically travels through **several different sites** before being ready for shipment.



A vaccine undergoes up to **several hundred quality control tests** during its manufacturing journey.



SHIPMENT



DISTRIBUTION

1



RAW MATERIAL RECEPTION

All incoming raw materials are checked for conformance with the quality specifications.

2



BULK ANTIGEN MANUFACTURING

The active ingredient of the vaccine is manufactured. This is the most critical step in the production of high quality, safe and efficacious vaccines.

3



FORMULATION

The active ingredient is mixed with other ingredients to enhance the immune response and ensure product stability.

4



FILLING

The vaccine is filled into the final container. This could be a vial or a prefilled syringe.

5



PACKAGING

The vaccine in the final container is labeled in accordance with regulatory requirements and packed, ready for shipping to the customer.

6



LOT RELEASE

Quality assurance confirms the product has been manufactured and tested in accordance with the correct procedures. The national regulatory authority gives final authorization to distribute the vaccine.



+/- 24 MONTHS
Vaccine of consistent quality.

- Testing done by the **manufacturer**
- Testing done by the **exporting country**
- ▲ Testing done by the **importing country**

Leaving no-one behind with immunization is a shared goal of Gavi, the Vaccine Alliance, IFPMA*, and DCVMN* and contributes to the advancement of Sustainable Development Goals.

Member companies are proud to contribute to Gavi's vision 2025 by ensuring that timely demands for life-saving vaccines are met for Gavi-eligible countries, as it is a critical enabler of success.

We recognize the important work Gavi has done to move towards greater demand visibility, however there remain a number of aspects that still contribute to uncertainty:

- Vaccine manufacturing is a challenging, specialized process, with inherent variability;
- Vaccines require a long lead time due to stringent quality control, taking from several months up to 3 years from the time production is initiated;
- Vaccine manufacturing is capital intensive. It can take up to 5-10 years for new facilities to be built and certified, with upfront financial investment of \$10 to \$100 million, or more;

- Highly skilled and trained personnel are essential to ensure a consistent manufacturing process;
- Compliance with diverging local and international regulations. For example, post marketing approvals can take up to 2-4 years to process and can cause further delays.

*IFPMA: International Federation of Pharmaceutical Manufacturers and Associations

*DCVMN: Developing Countries Vaccine Manufacturers Network

SECURING SUPPLY THROUGH SHARED UNDERSTANDING

- Foster and sustain early dialogue with manufacturers to help align Gavi's goals with industry strategic planning.
- Ensure we can anticipate policy changes together to ensure supply.
- Support prioritization of future vaccine innovations with significant public health impact.
- Ensure sustainability and diversity of vaccines supply within healthy market framework.