WHO/MPP mRNA Technology Transfer Programme

Regulatory Considerations (Expectations and Main Challenges)

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Objectives - mRNA Technology Transfer Programme

1. Establish or enhance sustainable mRNA vaccine manufacturing capacity in regions with no or limited capacity

2. Introduce new technologies in LMICs and promote regional research and development (R&D)

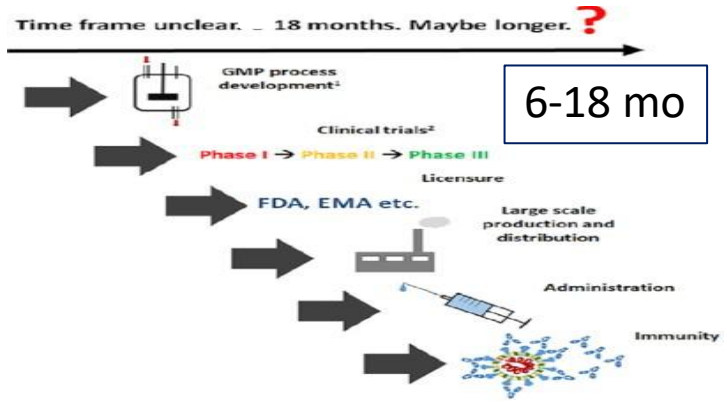
3. Strengthen regional biomanufacturing know-how and workforce development

4. Develop regulatory capabilities and workforce to support and accelerate regional approval and distribution of mRNA vaccines

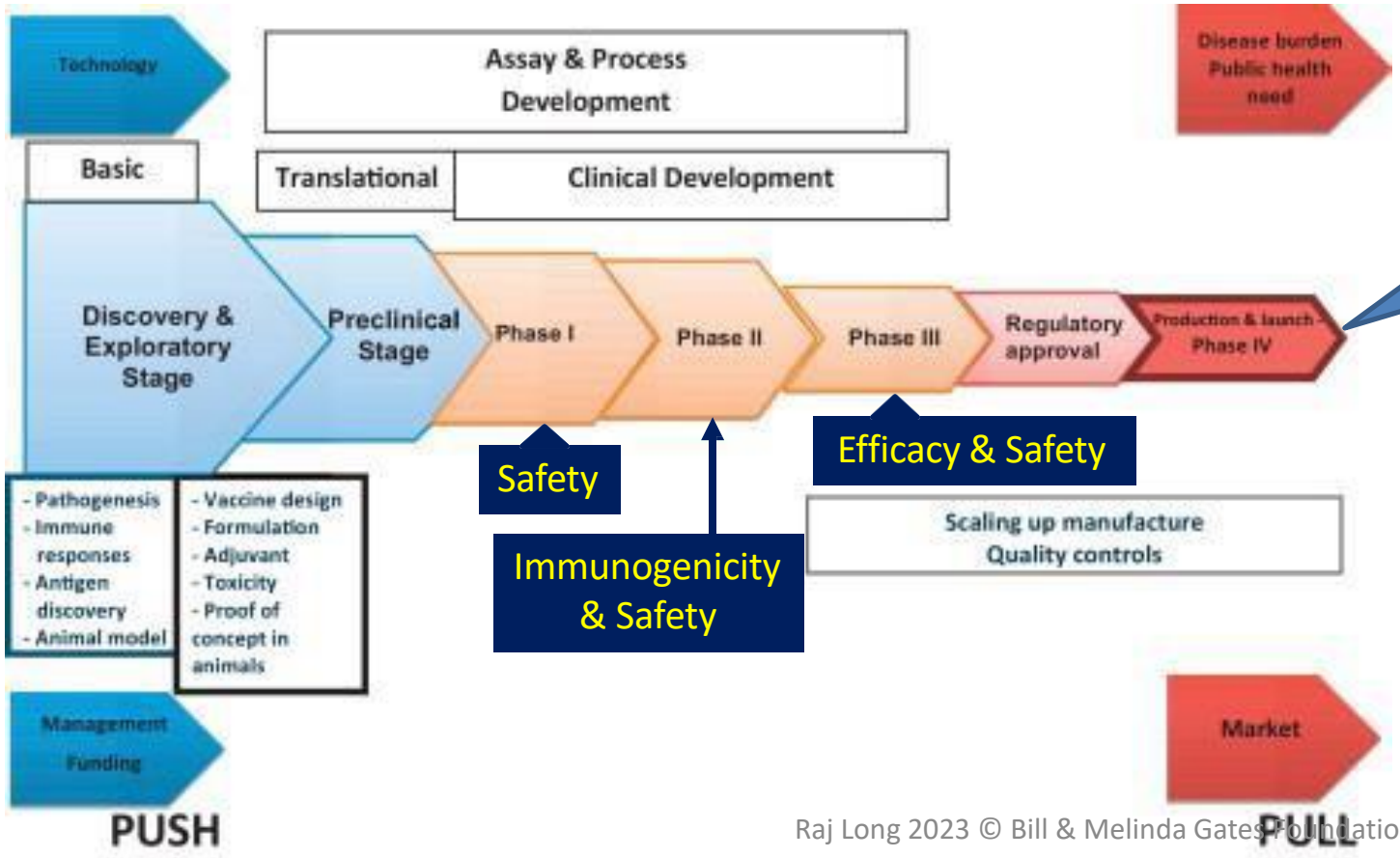
Under normal circumstances it takes 5-10 years to make a vaccine (slide from IVI)

- **COST: USD 500M – 1.5B**
- **FAILURE RATE: 93% (to Market Authorization)**

Accelerated Schedule COVID-19 vaccine



5-10 years



Only 1 in 10 vaccines make it here

Regulatory Considerations for mRNA Technology Transfer Programme

Regulatory considerations for partners will be shaped currently by the following focus:

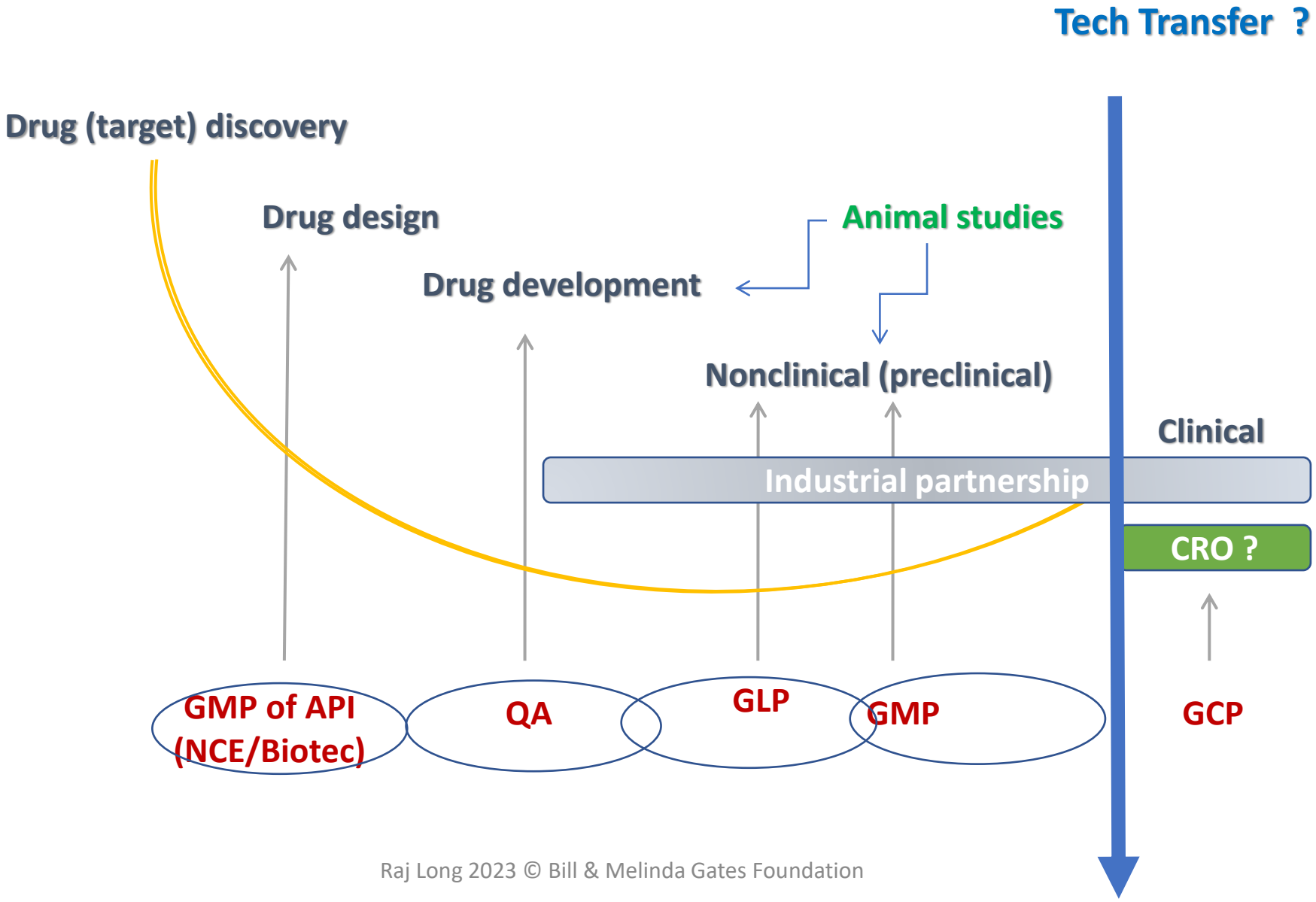
1. **Technology Transfer**

2. **Technology Recipient, Product Development and Launch a Product**

Technology Transfer

Technology transfer in biomedical research and development is the transfer of a medical technology from the originator to a secondary user, allowing that user to manufacture the technology and sell it on usually new markets. It can also include transfer of knowledge, manufacturing practices and intellectual property.

How to proceed from lab to clinic ?

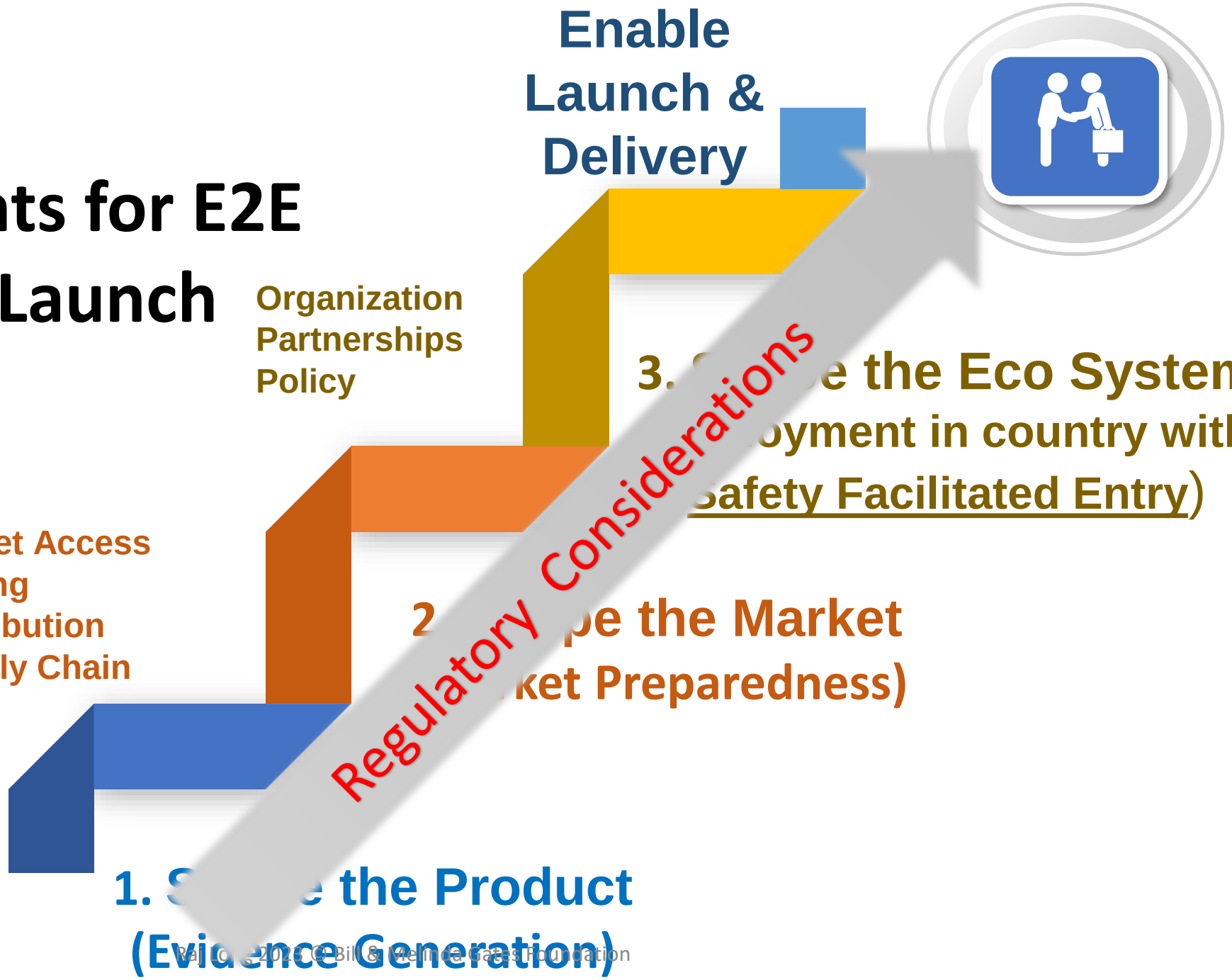


Potential Regulatory Considerations for Tech Transfer

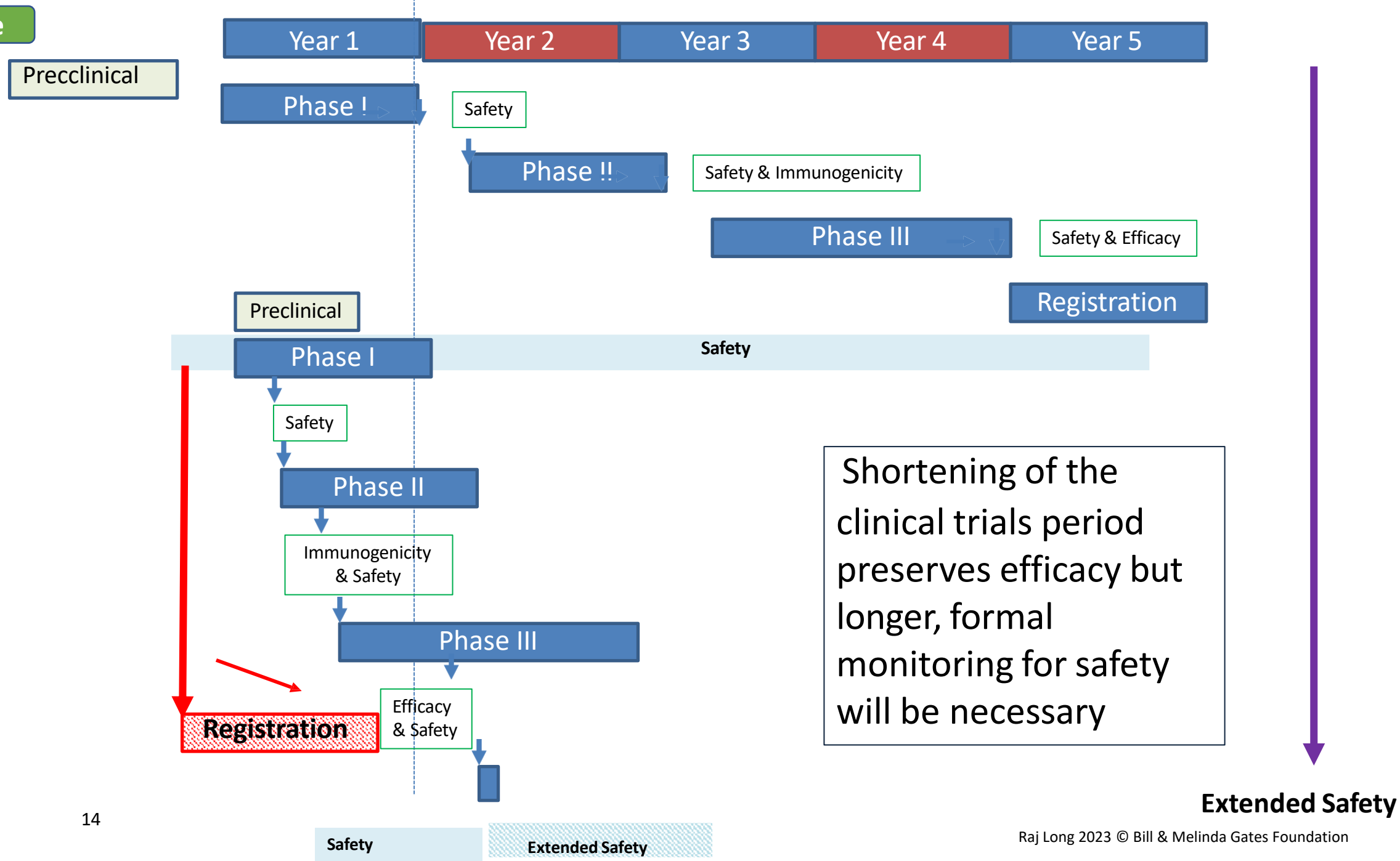
- GMP facility – Vx production
- Pathogenesis
- Immune Responses
- Antigen Discovery
- Animal model
- Vx design and Formulation, PoC in animals etc.
- GMP, GLP, QA

Technology Recipient, Product Development and Launch

Key Elements for E2E Product Launch



IVI slide



Shortening of the clinical trials period preserves efficacy but longer, formal monitoring for safety will be necessary

Extended Safety

Potential Regulatory Considerations - Technology Recipient, Product development and Launch

1. **Scope is very wide (15 countries in Africa, Asia, South America & Europe)**

2. **Very diverse regulatory environment – ranges from strong ML3 regulators to agencies that have evolving**
   - **Opportunity for regional collaboration**

3. **New technology for both regulator and applicant**
   - **Both applicant and regulator will be 'learning by doing' it will be the first for both entities**
   - **Opportunity and Risks**

4. **Regulatory requirements may not be 'universal' to all geographies**

Key Regulatory Considerations - Technology Recipient, Product development and Launch (2)

5. **Evolving mRNA biomanufacturing know-how and workforce development is applicable for the regulator and the applicant**
   - Inspectors, Reviewers - CMC reviewers, Lot release, etc
   - Post licensure - Safety surveillance & RMP (EPI and Regulator interactions)
6. **Focus on accelerated regional approval**
   - How does that translate for the recipient ? Reliance/Reference amongst geographies ?
   - Acquaint yourself what regional pathways are available in your region.
7. **Vaccine TPP - monovalent/bivalent, (? Product),**
   - Regional variant differences , CT design, etc
   - Learning to live with Covid – evolving variants

Regulatory Considerations - Recommendations

- Develop regulatory early strategy – starting with end state in mind . Clear risk plan with mitigations where possible . Regulatory strategy here is not a compilation of the Pre-clinical, Quality and Clinical dossier
- Approach – early and continuous engagement with the regulatory agency. Be transparent to enable predictability. Set mutual expectations to avoid surprises
- Ensure the same understanding of the regulatory requirements for the technology and clinical development as the regulator
- Ensure if you are the recipient that you have access to all of the data/dossier components from the hub/donor as required by YOUR regulator. Licensure is based on the whole Pre-clinical, CMC and Clinical data required in a single dossier
- Post licensure safety – the license holder is legally responsible fro post marketing safety surveillance and safety update. Envisage RMP as a key requirement
- Consider how to initiate collaboration between NRA and EPI or the equivalent vaccine program if at all feasible

An African proverb says

“If you want to walk fast, walk alone - but if you want to walk far, walk together. “

Thank you