The Exciting Journey of Vaccines

1. From unmet need to vaccine concept
   - Overcoming the Hurdle: Failure, Innovation is critical
   - Bringing Diverse Groups and Perspectives
   - Let's Develop a Vaccine: An Extremely Important Journey!
   - A Global Look: Local, National, Regional
   - Observation: There is a problem
   - Determining the Burden of Disease: - Mortality, - Epidemiology, - Local Data, - Disease Patterns
   - Communication Challenges: Informing National Leaders

2. From Lab to Regulatory Approval
   - Supply Chain Development: Changing Demographics
   - What will work: Consider all factors
   - Efficacy Studies: Solvability for Production and Clinical Trials
   - A Lot of Work & Time: Regulatory Filing
   - The Role of the Public Sector: Ensuring Uniform High Standards
   - Development of Innovative Vaccines
   - Where to invest: 6% Chance of Market Entry, 70% Chance of Average Vaccine Taken from the Pre-clinical Phase
   - Identifying the Need for a Vaccine
   - Priorities
   - Regulatory Systems: Final Vaccine on Local Level

3. From approval to sustained access
   - Ensuring Future Success of the Vaccination Ecosystem
   - Ensuring the Security of Supply: Tailored Approach, Handle Scalability, Ability to Handle Sudden Increases in Demand
   - Target Product Profile: It starts with a community, it ends with a community
   - The journey is a constant dialogue

SECURING SUPPLY THROUGH SHARED UNDERSTANDING

Making Vital Partnerships a Reality...

Where do we go from here?
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