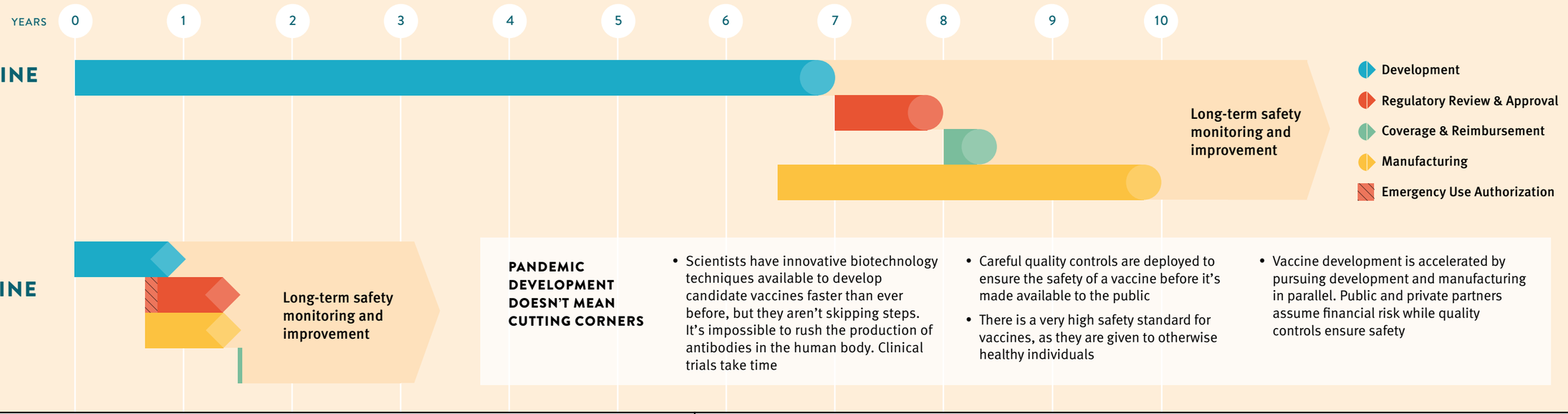
From Lab to Jab Accelerating safe vaccine development to prevent COVID-19



Standard Vaccine Development

10-20 years

DEVELOPMENT (UP TO 12 YEARS)

Developing a vaccine takes years to ensure it is safe and effective, and will remain so over time

- Exploratory stage: Research and discovery
- Pre-clinical stage: Test tube and animal studies
- Clinical trials: Ensuring safety and effectiveness in healthy human participants
  1. Phase 1: tens of volunteers
  2. Phase 2: hundreds of volunteers
  3. Phase 3: tens of thousands of volunteers

REGULATORY REVIEW AND APPROVAL [8 (PRIORITY) TO 12 MONTHS (STANDARD)]

A vaccine candidate must undergo regulatory review and be approved by the Food and Drug Administration (FDA) before it can be made available for broad distribution to patients

- The FDA conducts in-depth evaluations of safety and effectiveness to make sure benefits outweigh potential risks
- The Vaccine Adverse Event Reporting System (VAERS) and other safety systems continuously monitor safety to reveal any potential rare side effects

COVERAGE AND REIMBURSEMENT (6-12 MONTHS)

The U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends optimal timing and population for vaccination based on scientific evidence. Their recommendations impact how vaccines are covered by both commercial and government insurance programs

MANUFACTURING (6-36 MONTHS)

Vaccines may be manufactured at facilities around the country or world

- Each vaccine batch is tested and re-tested to ensure quality and consistency between batches
- Growing cells and viruses can take two days to three months
- It can take years of research to safely inactivate a virus that causes disease but provides immunity
- There are multiple phases of transportation and storage to ensure safe delivery

Emerging Pandemic Vaccine Development Goal of 12-18 months

As a matter of urgency, a robust global collaboration of scientists, and public and private partners are developing a safe vaccine that meets all vaccine development criteria

DEVELOPMENT (UP TO 12 MONTHS)

In accelerating vaccine development, scientists carefully balance speed and safety

- Pre-clinical stage
- Clinical trials: Ensuring safety and effectiveness in healthy human participants is done in parallel, while maintaining trial size, quality, approval of regulatory trials, and ability to scale up
  - Initial results can modify the existing trial as it moves forward

REGULATORY REVIEW AND APPROVAL (8-12 MONTHS)

- There is continuous and early collaboration with federal agencies (FDA, CDC, HHS) to ensure a rapid and appropriate approval process
- If a vaccine candidate indicates a positive immune response, preliminary evidence of efficacy, and an adequate safety profile, approval could be considered early for emergency use, first in high-risk populations such as healthcare workers, the elderly and those with pre-existing conditions*
- FDA, CDC and private partners comprehensively monitor safety after the public begins using the vaccine

MANUFACTURING

In a global emergency, widespread manufacturing of a vaccine can be scaled up to commercial levels before clinical trials are complete. Each vaccine batch is still tested and re-tested to ensure quality and consistency between batches

COVERAGE AND REIMBURSEMENT (14 DAYS)

Coverage of vaccines will be available in both public and private markets. Vaccine distribution is unique during a pandemic, and federal response is done in coordination with state administered response

**Emergency Use Authorizations (EUA) are not the same as product approvals, and are only utilized when there are no adequate approved and available alternatives. Manufacturers will continue to seek full regulatory approval for products that receive EUA.*

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