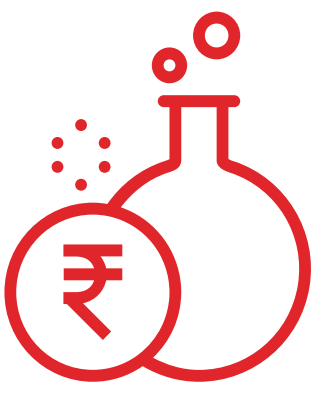
Behind Vaccine Development: The Clinical Trial Process

Vaccine commercialization is a lengthy process that may often take **10 years or longer.**[1]

Developing vaccines requires special consideration because vaccines:[2]

- Are given to healthy individuals to help prevent disease and contribute to the health and well-being of society as a whole[3]
- Demand a high safety threshold to achieve regulatory authority approval
- Are highly complex substances often derived from living materials that require specific manufacturing processes
- Require specialized testing to help assure quality and safety of all vaccines distributed



How Are New Vaccines Developed?

The research and development cycle of a vaccine includes: [4]

- Exploratory stage
- Pre-clinical stage
- Clinical development (Phases 1-3)
- Regulatory review and approval
- Long-term clinical development (Phase 4)
- Manufacturing
- Quality control

What Are Clinical Trials?

Clinical trials are research studies involving human volunteers that often evaluate the **safety and efficacy** of preventative measures or treatment products such as vaccines, medicines or medical devices.[5]

Clinical Trials Also:

- Provide important insight into diseases and how they may be prevented or treated [5]
- Are a critical step to support the approval of vaccines or medicines and medical devices by regulatory bodies[6]

How Are Trials Designed?

In order to produce the required data, clinical trials need to be designed based on clear protocols for the conduct of the trial. [5,6]

Studies vary in their endpoints, the number of participants involved, and the study design, however, all clinical studies follow criteria to protect the participants and ensure proper evaluation of the investigational product.[7]

Certain types of human biases have been shown to influence trial outcomes, and the goal of randomizing and blinding is to minimize this influence.[8]

Double-blinding: [5]

A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental vaccine and which are receiving a placebo or another therapy.

Randomization: [5]

A method based on chance by which study participants are assigned to different treatment groups.

Randomization avoids bias and allows researchers to compare different treatments in similar groups.

What Happens During Clinical Trials?

Clinical development, in general, is a three-phase process:

PHASE 1

First safety studies are completed in small groups of healthy volunteers.[5]

PHASE 2

Study size is expanded and vaccine is tested for safety and immunogenicity in people with characteristics (such as age and physical health) similar to those for whom the vaccine is intended.[5]

PHASE 3

Vaccine is given to thousands of people and often tested for safety and efficacy.[5]

Many vaccines also undergo long-term studies (Phase 4) after the vaccine is licensed for ongoing monitoring of safety and effectiveness.[2,5]

A Leader In Vaccine Development

For more than 70 years, Takeda has supplied routine vaccines to help protect the health of the people of Japan. Today, Takeda is expanding our global vaccine business by relying on innovation to tackle some of the world's most challenging infectious diseases, such as dengue, COVID-19 and pandemic influenza.

Our mission is to develop and deliver innovative vaccines that tackle some of the most challenging problems in public health and help protect the health of people around the world.[9]

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