Clinical trial is research involving human volunteers that test the safety and efficacy of preventative measures or treatments such as vaccines, medicines or medical devices.3

For vaccine candidates, clinical trials:1
- Provide important insight into diseases for which vaccines can help prevent
- Are a critical step to support the approval of vaccines by regulatory bodies
- Many vaccines also undergo long-term studies after the vaccine is licensed for ongoing monitoring of safety and efficacy

How Are New Vaccines Developed?

Clinical development, in general, is a three-phase process:3

Phase 1: Preliminary safety studies are done in small groups of healthy volunteers.
Phase 2: Study 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.
Phase 3: Vaccine is given to large number of people and tested for safety and efficacy.

Phase 3 trial has been designed to:
- Investigate the efficacy, safety and immunogenicity of two doses of vaccine against dengue caused by all four virus strains
- Evaluate whether or not they have had previous exposure to dengue virus, including: children and adults, travelers and those living in endemic areas
- Determine whether or not they are protected against future dengue infection
- Determine which study participants are assigned to different treatments
- Double-clicking: A clinical trial design in which the participants individually and the study staff know which participants are receiving the experimental drug or placebo and which are receiving a placebo or another therapy

Randomization: A method (or process by which study participants are assigned to different treatment groups) that provides an allowance for researchers to comparably test vaccines distributed in similar groups

References

Advancing Takeda’s Dengue Vaccine Candidate

Takeda has a long-standing history of conducting clinical trials and bringing products to market across the globe, and more than 70 years. Takeda has produced vaccines to prevent infectious diseases

One vaccine candidate in Takeda’s late-stage pipeline is a dengue vaccine

The development cycle of a vaccine includes:
- Exploratory stage
- Pre-clinical stage
- Clinical development
- Regulatory review and approval
- Manufacturing
- Quality control

Based on Phase 1 and Phase 2 trials, which provided data that support that Takeda’s vaccine candidate is generally safe, well-tolerated and immunogenic, the vaccine has progressed into Phase 3 trials in dengue-endemic Latin American and Asian countries. This marks an important milestone on the journey toward regulatory approval.

Double-blind: A clinical trial design in which neither the participating individuals nor the study staff know which participants are receiving the experimental drug or placebo and which are receiving a placebo or another therapy

Randomization: A method (or process by which study participants are assigned to different treatment groups) that provides an allowance for researchers to comparably test vaccines distributed in similar groups

Takeda is working to provide the necessary evidence to support the development and effective use of its dengue vaccine candidate in people who need it as soon as possible.