

# What are Human clinical trials?

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In news

India's first indigenous mRNA vaccine candidate receives approval to initiate Phase 1 and 2 human clinical trials

## A brief note on novel mRNA vaccine

- The novel mRNA vaccine candidate, HGC019 has been developed by Gennova, Pune and supported with seed grant under the Ind-CEPI mission of the Department of Biotechnology.
- The mRNA vaccines do not use the conventional model to produce immune response.
- Instead, they carry the molecular instructions to make the protein in the body through a synthetic RNA of the virus.
- mRNA-based vaccines are scientifically the ideal choice to address a pandemic because of their rapid developmental timeline.
- The mRNA vaccine is considered safe as is non-infectious, non-integrating in nature, and degraded by standard cellular mechanisms.

## What are clinical trials?

- According to WHO, Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes.
- People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.

- Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials, including children.

### Four phases of clinical trials

There are 4 phases of biomedical clinical trials:

- **Phase I** studies usually **test new drugs** for the first time in a **small group of people** to evaluate a safe dosage range and identify side effects.
- **Phase II** studies test treatments that have been found to be safe in phase I but now need a **larger group of human subjects** to monitor for any adverse effects.
- **Phase III** studies are conducted **on larger populations and in different regions and countries**, and are often the step right before a new treatment is approved.
- **Phase IV** studies **take place after country approval** and there is a need for further testing in a wide population over a **longer timeframe**.

### Clinical trials in India

- Clinical trials in India refers to clinical research in India in which researchers test drugs and other treatments on research participants.
- The New Drugs and Clinical Trials Rules, 2019 and section 3.7.1 to 3.7.3 of ICMR guidelines requires that all researchers conducting a clinical trial must publicly document it in the Clinical Trials Registry India

### Who regulates Human Clinical trials in India?

- The **Drugs Controller General of India grants approval for clinical trials and is the top level authority that specifically oversees clinical trials**
- The **Drugs Controller is a part of the Central Drugs**

**Standard Control Organisation** and answers to that organization.

- Both of those organizations **answer to the Ministry of Health and Family Welfare** as the highest level government agency overseeing everything related to medicine and health.
- **The Indian Council of Medical Research governs the professional and ethical behavior** of the doctors and scientists.
- The **Pharmacovigilance Program of India tracks reports of harm from the use of drugs.**
- Outside of the central government, each state has its own regional regulatory agencies with some input into governing trials.