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, HGCO19 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 t**ake 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.