

Vaccine phase 2

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In News: India to vaccinate citizens above 60 years, comorbid patients above 45 from 1 March

Testing Methods for vaccine and drugs

- There are similarities and differences in the way new drugs and vaccines are tested.
- Broadly both follow a four-stage process when they are tested in people.

Phase-1

- After a drug has proven itself safe in a variety of animals usually mice, rabbits, hamsters and primates that mirror human physiology and by noticing its reactions it enters Phase-1 studies.
- A small group of volunteers is given the drug in small doses and monitored to see if it is safe and well-tolerated.
- In the normal course, those undergoing the trial must report results to the drug regulator which gives the go-ahead for the next stage of trials.

Phase-2-

- It is when a group of volunteers, usually in the hundreds, are selected.
- This is the stage when researchers try to determine what dosage would be required to get the desired response.
- In the case of the COVID-19 vaccine, this is the stage when it's determined if the inoculation had triggered the desired level of antibodies and sufficient cell response in terms of stimulating T-cells that are known to block and neutralise the virus particles respectively. Again, side effects and adverse reactions

are monitored and reported.

Phase-3

- Each of these stages can take several months .
- Such data is again sent to regulators, who, if satisfied, give the green signal for Phase-3.
- In this stage, the drug or vaccine is tested at multiple locations in thousands of volunteers or patients.
- This is the stage when a new drug is compared to the existing standard of care and when it must prove its efficacy.
- A Phase-3 trial is held at multiple locations to capture the demographic variability in the population.
- It is also double-blinded and randomised and may have multiple treatment arms, meaning some participants may get a placebo.
- Some may get lower doses, some higher doses,
- A diverse population group is exposed to a new vaccine, the odds of encountering adverse and the dreaded 'severe adverse reaction' are magnified.
- If severe then, medical researchers have to determine a pattern is apparent, a drug or vaccine can be pulled out.
- Because of the multiple locations and the number of patients that are required, this is also the most expensive stage of a trial.
- Sometimes, phases are combined, given the kind of drug or vaccine and the urgency of the situation.
- Several COVID-19 vaccines are being developed on accelerated time lines.

Phase-4

- A drug or vaccine candidate that clears Phase-3 is usually approved .
- The license and the entire infrastructure of the company is devoted to ramping up production.

- The logistics of storing the drug or vaccine safely is sorted out without degrading or losing potency.
- Phase-4, where all instances of the product's failure and adverse events are recorded.
- Companies are expected to furnish periodic data to the drug regulator.

5 STAGES OF VACCINE DEVELOPMENT

PRECLINICAL TESTING

Vaccine is given to animals such as mice and monkeys to see if it produces an immune response

PHASE I SAFETY TRIALS

Tested on a small number of people for safety and dosage, and to confirm that it stimulates the human immune system

PHASE II EXPANDED TRIALS

Vaccine given to hundreds of people, split into groups by age

PHASE III EFFICACY TRIALS

Testing expanded to thousands of people

APPROVAL

Regulators in each country review the trial results and decide whether to approve the vaccine or not