

# 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