

1. Human Challenge Trials

Prelims Syllabus: Medicine and Pharmaceuticals

Mains Syllabus: GS-III Science and Technology - Developments and their Applications and Effects in everyday life Achievements of Indians in Science & Technology; Indigenization of Technology and Developing New Technology.

Why in News:

- Recently, many people have volunteered to take part in the Human Challenge Trials (HCTs). It involves intentionally infecting volunteers with the novel coronavirus, in order to speed up the vaccination development.

About the Vaccine Development:

- Generally, vaccines take several years to develop and their development typically proceeds through three phases of clinical trials.
 1. In Phase 1, a Small Groups of People receive the Trial Vaccine.
 2. In Phase 2, the Clinical study is expanded and the vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended.
 3. In Phase 3, the Vaccine is given to several thousand people and tested for efficacy and safety. During this phase, participants either receive the vaccine or a placebo.
- Its efficacy is determined by comparing the prevalence of infection in the group that was administered the vaccine with the one which received a placebo.
- **Placebo** is anything which looks like real treatment but it is actually not. For example- sugar pills and saline injections.

What is Human Challenge Trials?

- It means the participants of both the vaccine group and placebo group are deliberately exposed to the infection after their consent and thus are challenged by the disease organism. It is not new and they are usually carried out in developing medications for diseases which are considered less lethal and have been better understood by scientists over the years like malaria.
- The scientists have suggested replacing the conventional Phase 3 testing of vaccines by controlled HCTs of Covid-19 (SARS-CoV-2) vaccine which can accelerate the testing and potential rollout of efficacious vaccines.

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- It may reduce many months from the licensure process, making efficacious vaccines available more quickly and will also require significantly less number of people than regular Phase 3 trials.

About the Ethical Concerns of Human Trails:

- The trails for Covid-19 have been questioned by critics because it is a potentially deadly disease for even those who are less at risk, and has not been studied fully yet.
- The World Health Organisation (WHO) emphasised on the ethical framework of the challenge studies and also highlighted the importance of informed consent.
- Human challenge studies should be conducted with abundant forethought, caution, and oversight. The value of the information to be gained should clearly justify the risks to Human subjects.

