

(\*) In context of recent Pandemic, discuss the various steps to deal with challenges involved in conduct of clinical trials for vaccination.

Clinical trials are research performed in people that are aimed at evaluating a medical, surgical or behavioural intervention, to find out if new drug is safe & effective in people

⇒ Challenges :-

- Some research might cause rumor pain, discomfort, uneasiness from medical procedures as well as side effects from drugs
- Participation might cause emotional and mental stress which could be transitory or permanent in nature
- To address conflicts of interest to guide investigators for ethical ramifications & change in approach.
- Medical management during adverse events and compensation must be considered.

## ⇒ Steps to deal with challenges :-

- Permitting post risk benefit analysis favouring participating patients
- Creating faith who volunteer for trial with respect & justice.
- Providing autonomy to choose, discontinue or withdraw without loss of any benefits
- Ensuring informed consent obtained without coercion.
- Making new information on drugs available to patients
- Mitigating conflicts of interest by disclosing information on risks
- Working with globally accepted guidelines and adoption of fair practice
- Improving quality of data with more transparency.
- making trial information available to public.

At times, there may not be a single solution for all types of research, the ethical committees shall have dialogue with all stakeholders to get maximum possible results for participants.