The Clinical Trials Registry-India (CTRI)

Why in news?

The speedy approval of Covid-19 vaccines during the SARS-CoV-2 pandemic have raised questions regarding the transparency of the clinical trials and the safety and efficacy of the vaccines.

What is the Clinical Trials Registry-India (CTRI)?

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

- CTRI is a free and online public record system for *registration of clinical trials conducted in India*.
- It is hosted at the Indian Council of Medical Research's National Institute of Medical Statistics.
- Initially it was launched on a voluntary basis in 2007.
- In 2009, the Drugs Controller General of India (DCGI) mandated all trials to be registered in the CTRI.
- CTRI is one of 17 public trial registries under the International Clinical Trials Registry Portal.
- It is one of the 18 primary registries recognized by the *World Health Organization (WHO)*.
- Submission of Ethics approval and DCGI approval is essential for trial registration in the CTRI.

What trials should be registered under the CTRI?

- Any trial involving human participants, of any intervention such as
  - Drugs,
  - Surgical procedures,
  - Preventive measures,
  - Lifestyle modifications,
  - Devices,
  - Educational / behavioral treatment
  - Rehabilitation strategies
  - Trials in the purview of AYUSH

What are the problems with CTRI?

- **Missing data** - The record of enrollment with CTRI are inconsistent with only 281 of 606 (46%) trials being registered.

- **Classification** - Classification of type of study is not defined in CTRI resulted in over 1,000 categories within the registry.
- **Optional** - Classification of study is kept optional by CTRI leading to a large number of trials not providing this information.
- **Variations in names & organisations** - Wrong spelling or different surnames can hinder the process of identifying this important individual.
- **Misleading information** - Wrong data about whether a trial is registered prospectively or retrospectively can be classified as misleading information.

What can be done?

- **Unregistered** – Trials, even though they have an India component, registered in other registries such as US, breaking the mandatory registration.
- CTRI doesn't have the power to make a trialist register but the Central Drugs Standard Control Organisation (CDSCO), can do so.
- **WHO regulations** - Adhering to the WHO requirements can improve the registration of trials. Currently, India ranks 11 out of 18 registries.
- **Permanent body** - Make it a permanent activity with staff on a 5-year contract.
- Currently, the registry is a non-permanent activity of the ICMR with a 'temporary' staff of 15 years.

Other measures

- Registration of trials accurately
- Improving its inner workings for CTRI
- Bringing all the documentation in one platform
- Allow public access to the registry

Quick facts

International Clinical Trials Registry Platform (ICTRP)
• ICTRP facilitates the prospective registration of the WHO Trial Registration Data Set on all clinical trials and the public accessibility of that information. • It is recognized as a primary registry by the World Health Organization. • The CTRI is one of 17 public trial registries under the International Clinical Trials Registry Portal. • In total it recognizes 18 registries with the registry of the U.S., ClinicalTrials.gov (CT.gov), which is recognized only as a data provider.
Central Drugs Standard Control Organization (CDSCO)

• The Central Drugs Standard Control Organisation (CDSCO) is the National Regulatory Authority (NRA) of India.
• It is under Directorate General of Health Services, Ministry of Health & Family Welfare.
• Drugs Controller General of India (DCGI) is the head of department of the Central Drugs Standard Control Organization.
• CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories.
• CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act.
• The functions of CDSCO includes
  - Approval of new drugs and clinical trials,
  - Import registration and licensing of drugs,
  - License approving of blood banks, vaccines and r-DNA products,
  - Banning of drugs and cosmetics,
  - Grant of test license and personal license for drugs export,
  - Testing of new drugs.

References

1. The Hindu | CTRI
2. CDSCO | About CDSCO
3. CTRI | About CTRI
4. ICTRP | About ICTRP