

## 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](#)

