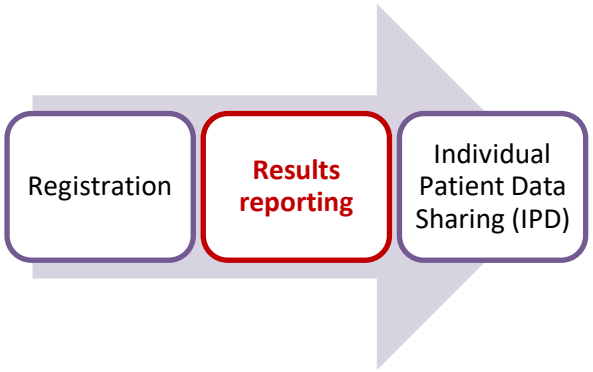
Clinical Trials Transparency Flow



Correlation between ICTRP Values and Steps of Clinical Research

ICTRP Values	Clinical Research
1. Identify Gaps in Research 2. Improve trial design, conduct and reporting 3. Meet ethical obligations 4. Ensure Greater Accountability 5. Prevent unnecessary duplication and encourage necessary replication 6. Improve Public Trust 7. Facilitate the building of research infrastructure and capacity 8. Improve Transparency 9. Prevent Publication Bias and Selective Reporting	Step 1: Discovery and Development, Scientific Research Step 2: Preclinical Research: Protocol Design Step 3: Ethics Review Step 4: Authorization Step 5: Registration Step 6: Clinical Research Patient recruitment Step 7: Clinical Research Investigation Step 8: Results disclosure Step 9: Publication

Website https://www.who.int/ictrp

The ICTRP website contains all the useful information about the ICTRP project

Search portal https://trialsearch.who.int/

The ICTRP Search Portal is the global database to search for free data collected from all the ICTRP registries.

Email ictrpinfo@who.int

Science Division
Research For Health Department
Emerging Technologies, Research Prioritization & Support Unit

World Health Organization

International Clinical Trials Registry Platform

ICTRP

~ Since 2006 ~

"…The registration of all trials is a scientific and ethical responsibility…"

Welcome to the WHO ICTRP
Bienvenue à l'ICTRP de l'OMS
Bienvenido a la ICTRP de la OMS
欢迎访问世卫组织 国际临床试验注册平台
مرحباً بكم في منبر منظمة الصحة العالمية للسجلات الدولية للتجارب السريرية
Добро пожаловать на МПРКИ ВОЗ

What is a clinical trial?

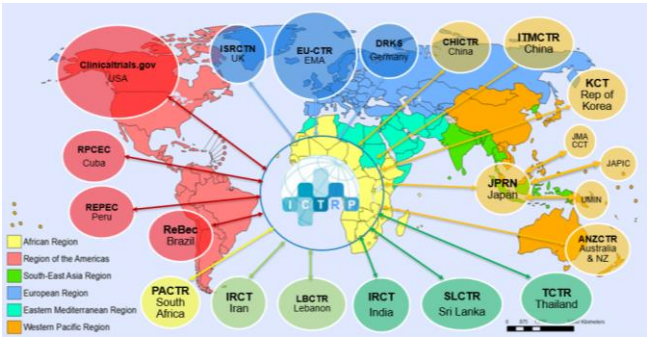
A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. An intervention can be anything that may have an impact on health, ranging from drugs and surgical procedures through to education, diet and exercise.

Clinical trials should be registered in a publicly accessible database before the first participant is recruited. Major scientific journals will no longer publish the findings of a clinical trial unless it was registered before the first participant was recruited in a registry that meets WHO criteria.

What is the International Clinical Trials Registry Platform (ICTRP)?

- **ICTRP is a global initiative** that aims to make information about all clinical trials involving human beings publicly available. It was established in **2006** in response to demand from countries through a World Health Assembly resolution (WHA58.22)
  a) It publishes the ICTRP Search Portal (**850,000 records as of March 2023 including 20,000 COVID-19 studies**)
  b) It publishes International Standards for Clinical Trials Registration
- It allows **patients** to join clinical trials and **researchers** to find out about previous and current research. It helps **policy makers** make better informed decisions.
- It supports the **WHO Registry Network**

Map of Countries in the WHO Registry Network

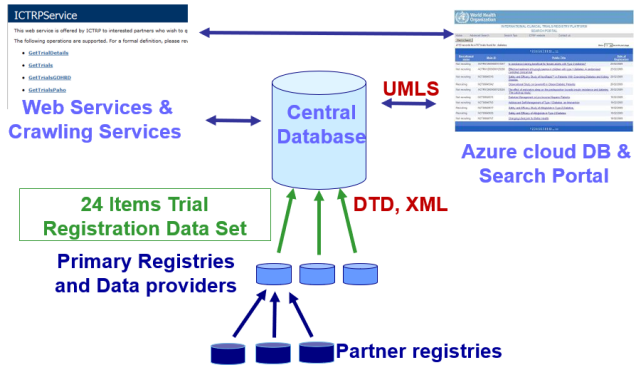


The Trial Registration Data Set (TRDS)

1. Primary registry / Trial ID	13. Interventions
2. Date of registration	14. Inclusion/Exclusion criteria
3. Secondary ID	15. Study type
4. Source of support	16. Date of first enrolment
5. Primary sponsor	17. Target & **final** sample size
6. Secondary sponsor	18. Recruitment status
7. Contact (public)	19. Primary outcomes
8. Contact (scientific)	20. Secondary outcomes
9. Public Title	**21. Ethics approval**
10. Scientific Title	**22. Date of study completion**
11. Countries of recruitment	**23. Summary results**
12. Health Conditions	24. **Individual Patient-Level Data (IPD) sharing**

Items in bold were added in 2017.

ICTRP data model



ICTRP Objectives

- A significant reduction in the gap between trials conducted in High Income countries and in LMIC
- An increase in the number of countries with either their own national clinical trial registry (meeting WHO standards) or an enforceable policy that clinical trials be registered in a Primary Registry of ICTRP
- An improvement in the quality of registered data and the reporting of the results of clinical trials

How to become part of the Registry Network

1. Established national registry (regulated ethics review & clinical trials)
2. Profile form & IT form submitted to ICTRP
3. Letter of support from the Ministry of Health
4. Successful transfer of data in XML to ICTRP
5. Successful review by the ICTRP advisory panel & meet criteria for
   a) Content (prospective, TRDS 24 items)
   b) Quality and Validity (SOP, audit trail)
   c) Accessibility (24/7, local language)
   d) Unambiguous Identification of trials
   e) Technical Capacity (xml transfer, IT)
   f) Administration & Governance (not for profit)