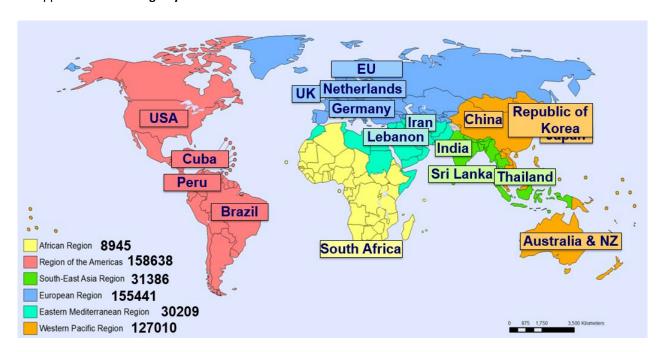


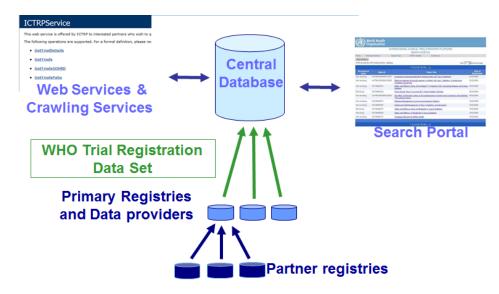


What is ICTRP?

- 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
- It publishes the ICTRP Search Portal (550,000 records as of January 2019)
 - http://www.who.int/trialsearch collecting 24 items per record in English (Trial Registration Data Set)
 - And the website http://www.who.int/ictrp (6 UN languages)
 - It publishes the International Standards for Clinical Trials Registration: Content, Quality and Validity,
 Accessibility, Unambiguous Identification, Technical Capacity, Administration and Governance
- It supports the WHO Registry Network

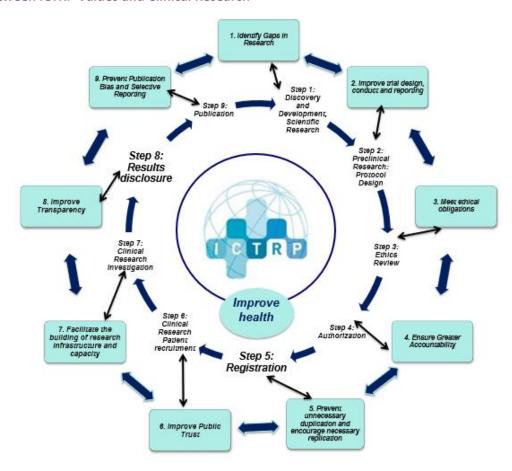


ICTRP data model





Correlation between ICTRP Values and Clinical Research



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 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.

How to become part of the ICTRP 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 to ICTRP
- 5. Successful review by the ICTRP advisory panel & meeting criteria for
 - a) Content (prospective registration, 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, good IT support)
 - f) Administration & Governance (not for profit)