Geneva, 30 September 2016

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Outline

- Background
- The Registry Network
- WHO position on results disclosure

What is ICTRP?

- **The International Clinical Trials Registry Platform (ICTRP) is a global initiative** that aims to make information about all clinical trials involving human beings publicly available.

Since 2006…

- It was established in 2006 in response to demand from countries through the World Health Assembly resolution that called for:
  - *"a voluntary platform to link clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials with a view to enhancing access to information by patients, families, patient groups and others"*

ICTRP Values

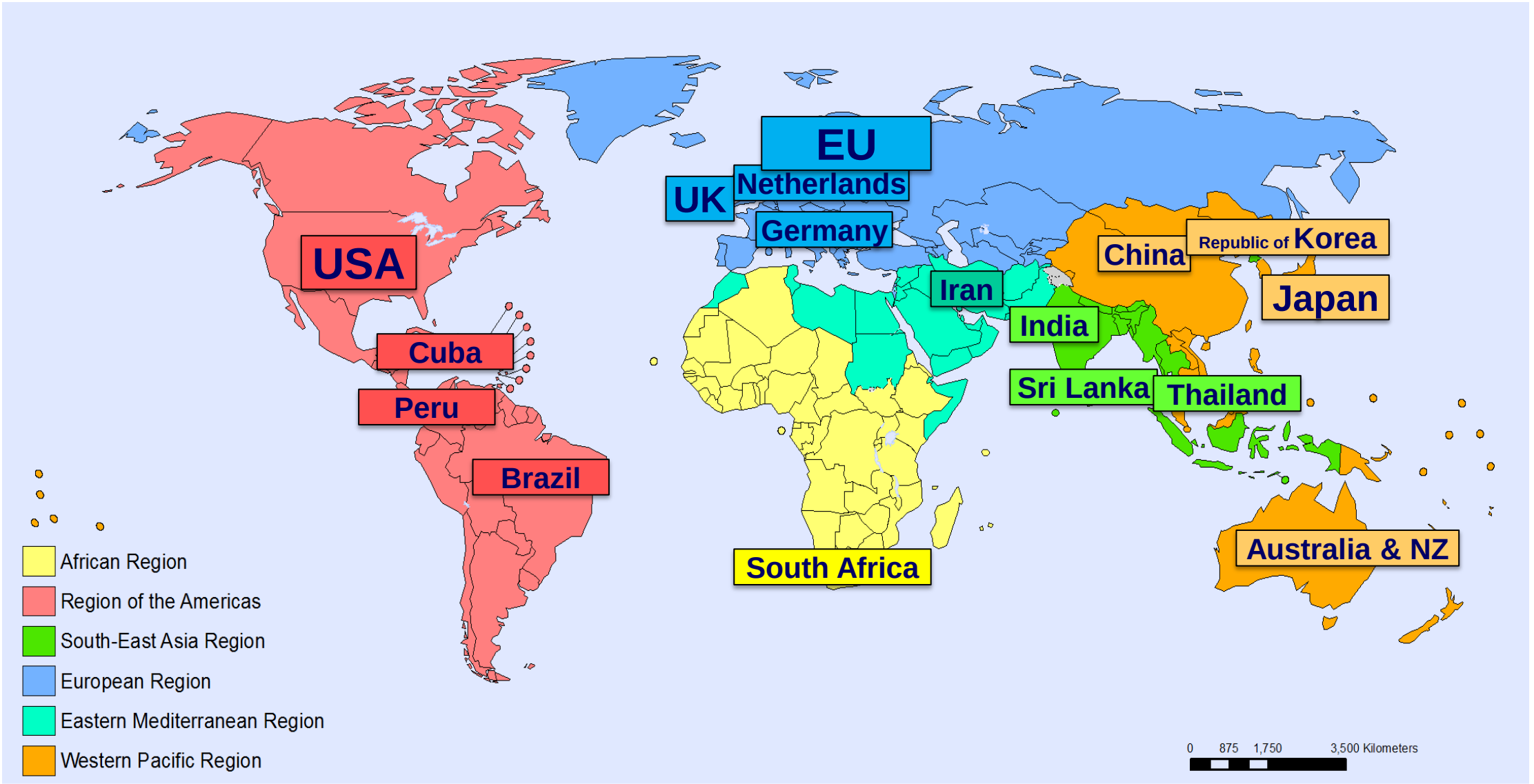
- It is the position of the ICTRP that the registration of all interventional trials is a scientific and ethical responsibility.
  - No position on Observational trials.

- Clinical trials must be registered in order to:
  - improve transparency
  - ensure greater accountability
  - meet ethical obligations
  - improve public trust
  - prevent publication bias and selective reporting
  - identify gaps in research
  - facilitate the building of research infrastructure and capacity
  - improve trial design, conduct and reporting
  - prevent unnecessary duplication and encourage necessary replication
  - **improve health**

Main functions

- **The ICTRP:**
  - **Publishes the ICTRP Search Portal**
    - a web site and database that makes it is possible for anyone in the world to search, for free, data provided by clinical trial registries around the world that meet WHO criteria for content and quality
  - **Supports the WHO Registry Network**
    - a forum for Registries to exchange information and work together to establish international standards for clinical trial registration
  - **Supports countries and regions**
    - wanting to establish clinical trial registries or policies on trial registration. In some cases, these registries will be a catalyst for other capacity-building activity in clinical trial conduct and oversight - particularly ethical and regulatory oversight

The Registry Network



World Health Organization

What is a Primary Registry?

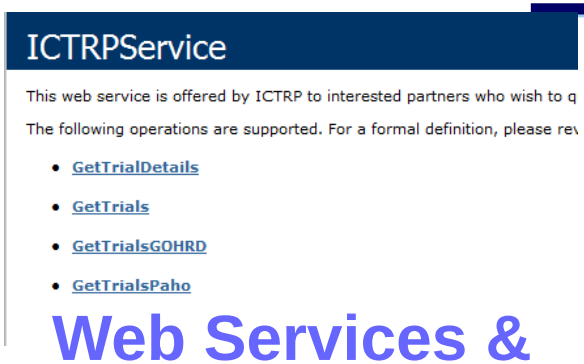
- **Meet criteria for**
  1. **Content (prospective, TRDS 20 items)**
  2. Quality and Validity (SOP, public audit trail)
  3. Accessibility (24/7 registration and search, local language)
  4. Unambiguous Identification (use sec ids for bridging)
  5. **Technical Capacity (xml transfer, IT)**
  6. Administration & Governance (national remit, Not-for profit)
- **Managed by a not-for-profit agency**
- **Have the support of government within the country/region for the proposed Primary Registry to act as the Primary Registry for the country/region**
- **Have the support of the International Committee of Medical Journal Editors (ICMJE)**

http://www.who.int/trialsearch

Trial Registration Data Set - TRDS

1. Primary registry / Trial ID
2. Date of registration
3. Secondary ID
4. Source of support
5. Primary sponsor
6. Secondary sponsor
7. Contact (public)
8. Contact (scientific)
9. Public Title
10. Scientific Title
11. Countries of recruitment
12. Health Conditions
13. Interventions
14. Inclusion/Exclusion criteria
15. Study type
16. Date of first enrolment
17. Target sample size
18. Recruitment status
19. Primary outcomes
20. Secondary outcomes

ICTRP Data Model



Web Services & Crawling Services

Central Database

UMLS

Search Portal

WHO Trial Registration Data Set

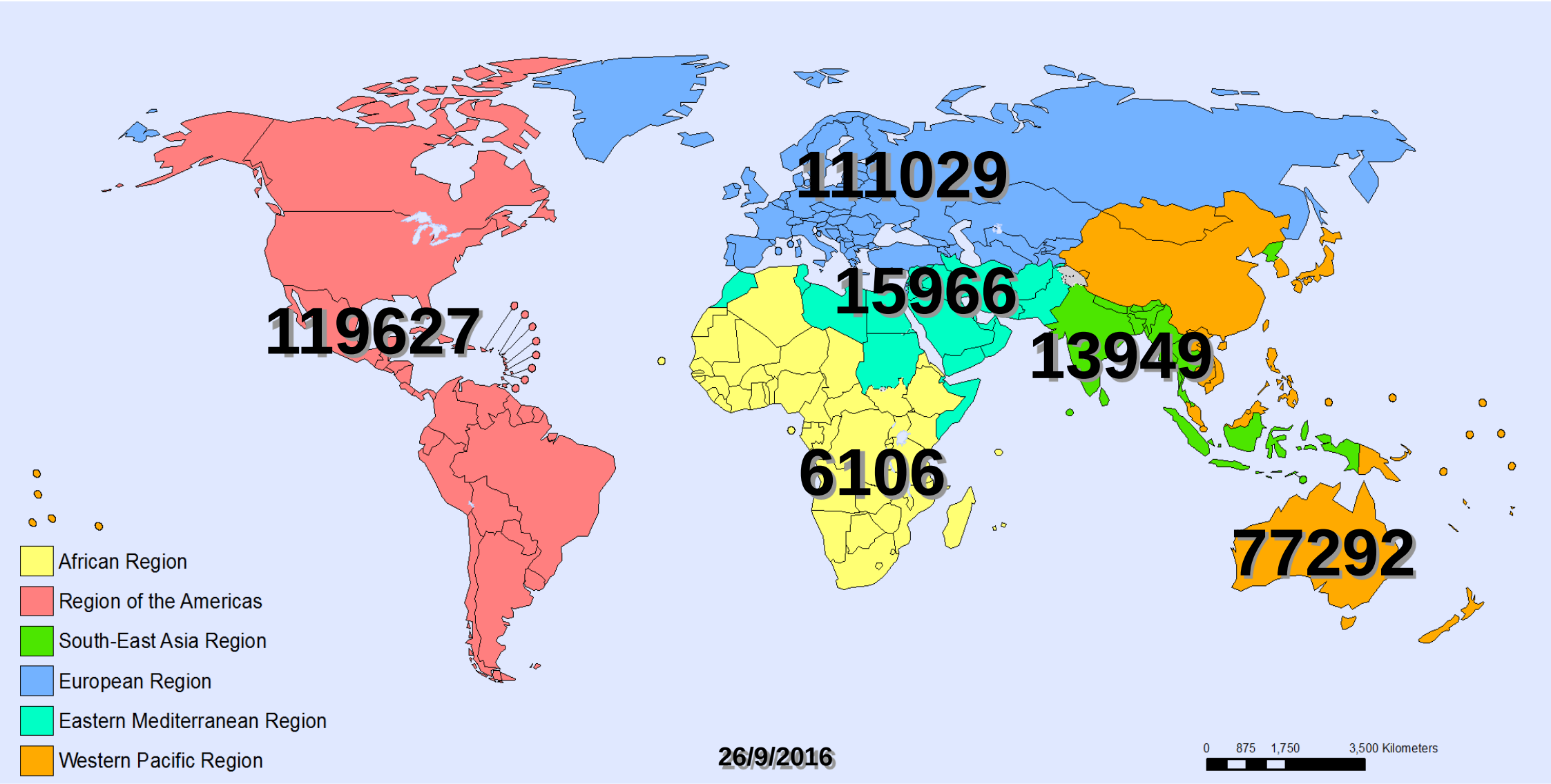
DTD, XML

Primary Registries and Data providers

Partner registries

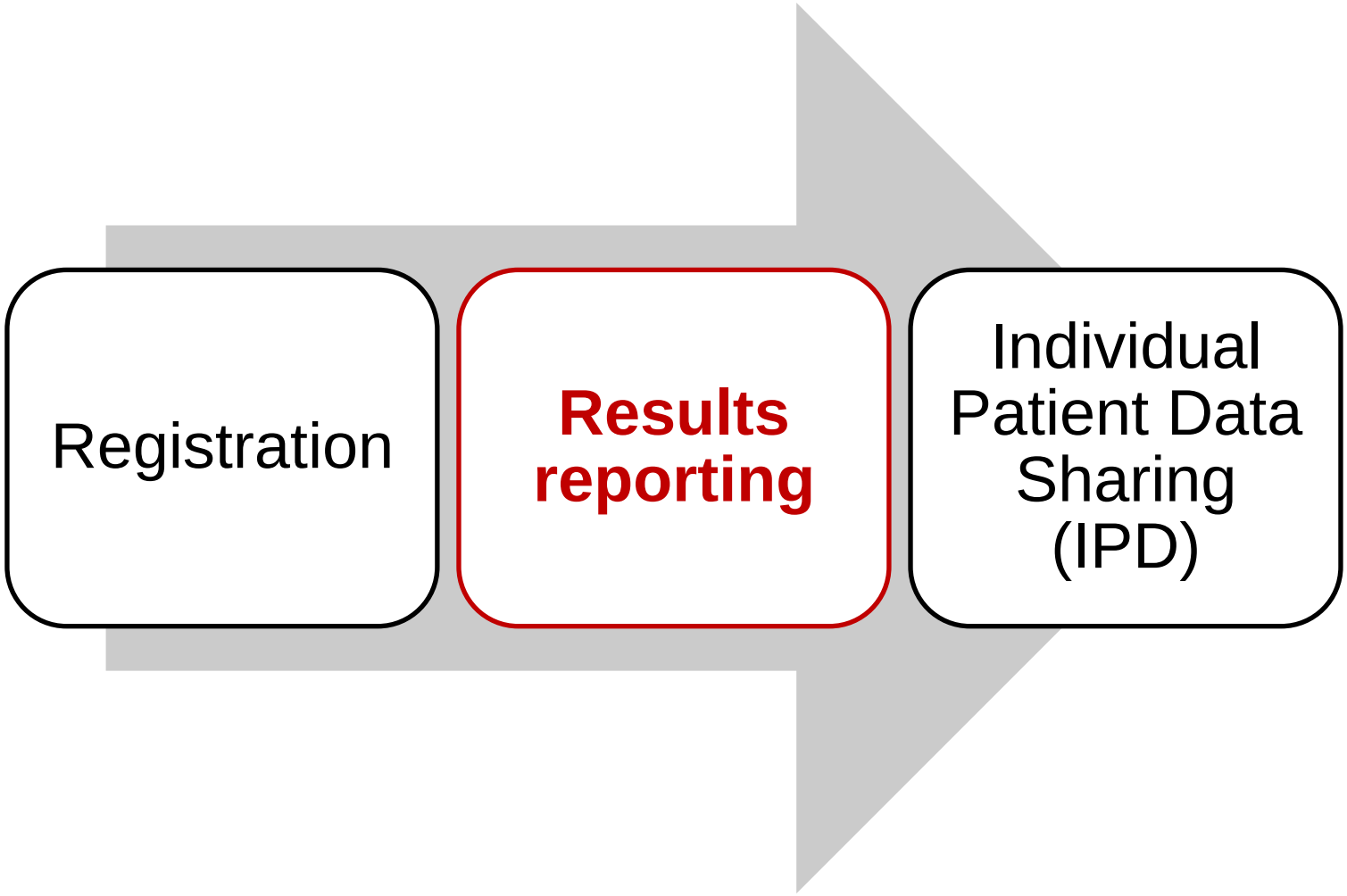
World Health Organization

ICTRP Data by country of recruitment



World Health Organization

CT Transparency Flow



WHO position on results disclosure

- A statement calling for public disclosure of CT results was prepared in October 2014.

- Main points:
  1. The need to register CTs and to update registries was reiterated.
  2. Following study completion, results are to be published in an open access, peer reviewed journal and in a primary clinical trial registry
  3. Trial ID to be included in all publications and abstracts

→ the draft was submitted to public consultation

Final WHO statement

- Timeframe for disclosure of CT findings was reduced:

	Draft	Final Statement
In peer reviewed journal		
Submission	18	12
Publication	30	24
In primary CT registry		
Posting	30	12

- Call for disclosure of past trials in registries and in peer reviewed journals.

WHO statement on results disclosure

WHO calls for increased transparency in medical research

Note for the media

14 APRIL 2015 | GENEVA - WHO today issued a public statement calling for the disclosure of results from clinical trials for medical products, whatever the result. The move aims to ensure that decisions related to the safety and efficacy of vaccines, drugs and medical devices for use by populations are supported by the bes evidence.

"Our intention is to promote the sharing of scientific knowledge in order to a public health," said Dr Marie-Paule Kieny, WHO Assistant Director-Genera Systems and Innovation. "It underpins the principal goal of medical researc the betterment of humanity."

"Failure to publicly disclose trial results engenders misinformation, leading priorities for both R&D and public health interventions," said Dr Kieny. "It cr indirect costs for public and private entities, including patients themselves, for suboptimal or harmful treatments."

Unreported trials lead to misinformation

For example, in a study that analysed reporting from large clinical trials (mo 500 participants) registered on ClinicalTrials.gov and completed by 2009, 23% had no results reported. These unreported trials included nearly 300 000 participants. Among clinical trials of vaccines against 5 diseases registered in a variety of databases between 2006-2012, only 29% had been published in a peer-reviewed journal by the WHO recommended deadline of 24 months following study completion.

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ESSAY

Rationale for WHO's New Position Calling for Prompt Reporting and Public Disclosure of Interventional Clinical Trial Results

Vasee S. Moorthy, Ghassan Karam, Kirsten S. Vannice, Marie-Paule Kieny

Published: April 14, 2015 • DOI: 10.1371/journal.pmed.1001819

ICTRP aspirational milestones

- A significant reduction in the gap between what we do and do not know about clinical trials, particularly those conducted in low and middle income countries.
- 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 in the WHO Registry Network
- An improvement in the quality of registered data
- Clinical Trials results database

Thank you

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http://www.who.int/ictrp

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