# Updating the International Standards for Clinical Trial Registries

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# Updating the International Standards for Clinical Trial Registries

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## Introduction/Background

World Health Organization's (WHO's) International Clinical Trials Registry Platform (ICTRP) sets international standards and supports a network of national registries representing over 425,000 registered clinical trials.

- Initially minimum data set of 20 prospective items; most clinical trial registries follow this set and lack data fields for results from completed trials.
- Declaration of Helsinki from World Medical Association (2013) endorsed universal prospective trial registration and reporting results at trial completion.
  - May 2017: 20+ large health research funders signed similar position statement.
- May 2017: Primary Registries of the ICTRP met to discuss how trial registry standards might be updated to facilitate clinical trial reporting and increase transparency in clinical trials.

## Problem Statement

New data fields agreed upon by the Primary Registries needed to be translated into an updated standards document for trial registries to guide the international community.

## Methods

- Current International Standards for Clinical Trial Registries (2012) used as a base document.
- Final internal report from May 2017 meeting of Primary Registries guided the development of four new data fields added to the Trial Registry Data Set.
- Supporting information for descriptions and terminology from International Committee of Medical Journal Editors (ICMJE), United Nations, WHO, and the National Institutes of Health (NIH).
- Document also reviewed and edited for accurate description of procedures, clarity, and appropriate external references.
- Document initially drafted internally with assistance from an external consultant, reviewed by the coordinator within the Research, Ethics and Knowledge Management unit at the WHO, then shared with Primary Registries for feedback.

## Results

- Information for the data fields compiled from summarizing notes taken at the May 2017 meeting.
- Clarifying material sourced from official documents within WHO, United Nations, NIH, ICMJE and other international governing bodies.
- Table 1 for a brief overview of the new standard dataset.
  - New prospective fields: ethics review and data sharing plan.
  - Sample size field now includes final enrolment numbers.
  - Post hoc fields: Study completion date and summary results to be reported within 12 months of study completion.

**Table 1. Brief Overview of the Trial Registry Data Set (version 1.3). Items Highlighted in Yellow are New or Updated from version 1.2.1.**

| # | Item/Label |
|---|---|
| 1 | Primary Registry and Trial Identifying Number |
| 2 | Date of Registration in Primary Registry |
| 3 | Secondary Identifying Numbers |
| 4 | Source(s) of Monetary or Material Support |
| 5 | Primary Sponsor |
| 6 | Secondary Sponsor(s) |
| 7 | Contact for public queries |
| 8 | Contact for scientific queries |
| 9 | Public title |
| 10 | Scientific title |
| 11 | Countries of Recruitment |
| 12 | Health condition(s) or problem(s) studied |
| 13 | Interventions |
| 14 | Key Inclusion and Exclusion Criteria |
| 15 | Study type |
| 16 | Date of first enrolment |
| 17 | Sample size |
| 18 | Recruitment status |
| 19 | Primary Outcome(s) |
| 20 | Key Secondary Outcome(s) |
| 21 | Ethics Review |
| 22 | Study Completion Date |
| 23 | Summary Results |
| 24 | Data Sharing Plan |

## Conclusions

- Revised International Standards for Clinical Trial Registries outline four new and one revised data fields for participating clinical trial registries.
  - Compliant with new requirements from the ICMJE going forward.
  - Registries now working to restructure their databases to accommodate these new fields, and many are in the process of collecting a subset of these data.
  - Document will now proceed within the WHO for internal publishing clearance.
- New fields will allow for greater transparency for patients and providers to follow clinical trials, and improve the efficacy of future funding dollars