CLINICAL TRIAL REGISTRATION

Punchama Pacharn, MD
What is clinical trial registration?

- An official platform and catalog for registering a clinical trial
- “Clinical Trials.gov” run by the US National Library of Medicine (NLM) is the first online registry and is the largest and most widely used
The International Committee of Medical Journal Editors (ICMJE)

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Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors

Altruism and trust lie at the heart of research on human subjects. Altruistic individuals volunteer for research because they trust that their participation will contribute to improved health for others and that researchers will minimize risks to participants. In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to conduct research ethically and to report it honestly. Honest reporting begins with revealing the existence of all clinical studies, even those that reflect unfavorably on a research sponsor’s product.

Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision-making. Researchers (and journal editors) are generally most enthusiastic about the publication of trials that show either a large effect of a new treatment (positive trials) or equivalencies, other researchers, and experts who write practice guidelines or decide on insurance-coverage policy. If all trials are registered in a public repository at their inception, every trial’s existence is part of the public record and the many stakeholders in clinical research can explore the full range of clinical evidence. We are far from this ideal at present, since trial registration is largely voluntary, registry data sets and public access to them varies, and registries contain only a small proportion of trials. In this editorial, published simultaneously in all member journals, the International Committee of Medical Journal Editors (ICMJE) proposes comprehensive trials registration as a solution to the problem of selective awareness and announces that all eleven ICMJE member journals will adopt a trials-registration policy to promote this goal.
“The International Committee of Medical Journal Editors (ICMJE) decided that from July 1, 2005 no trials will be considered for publication unless they are included on a clinical trials registry”
Which type of clinical trial required registration?

• Any research project that
  - Prospectively assigns human subjects to intervention or comparison groups
  - To study the cause-and-effect relationship between a medical intervention and a health outcome

• Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., phase I trials), would be exempt
Interventions include but are not restricted to

- Drugs, cells and other biological products
- Surgical procedures
- Radiologic procedures
- Devices
- Behavioral treatments
- Process-of-care changes
- Preventive care
Website

- Clinical trial.gov
- The Thai Clinical Trials Registry (TCTR)
How to register?

1) Create username and password email to รศ.พญ. ศิริลักษณ์ สุขสมปอง (sirilak.suk@mahidol.ac.th)
https://register.clinicaltrials.gov/
Create protocol
Create New Protocol Record

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. **Section 801 studies may only be registered by the Responsible Party.** If this is an applicable clinical trial as defined by US Public Law 110-85, Title VIII, Section 801, ensure that your organization is the Responsible Party as defined by the law before registering the study.

2. **IND/IDE studies may only be registered by the IND/IDE holder.** If the study is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE), ensure that your organization is the IND/IDE holder before registering the study.

3. **For NIH-funded studies, coordinate with the relevant Institute or Center.** If this is a US National Institutes of Health (NIH) funded study, registration should be coordinated with the sponsoring NIH Institute or Center to avoid duplicate registration.

4. **Multi-site studies are NOT registered by individual sites.** If this is a multi-site study it must be registered only once, by the sponsor (primary organization that oversees implementation of study and is responsible for data analysis) or its designated principal investigator (PI).

5. **Coordinate with all collaborators before registering.** If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization, as sponsor or its designated PI, is registering the study.

6. **Refer to the ClinicalTrials.gov Review of Protocol Submissions document for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.**

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**Unique Protocol ID:**

**Brief Title:**

*Required by ClinicalTrials.gov
*Required to comply with US Public Law 110-85, Section 801
*May be required to comply with US Public Law 110-85, Section 801
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