Frequently Asked Questions:
Questions about Clinical Trials Registration:

Will the ICMJE consider clinical trial results posted at ClinicalTrials.gov in compliance with the Food and Drug Administration Amendments Act of 2007 to be prior publication?

It is important to note that the ICMJE clinical trial registration policy requires prospective registration of all interventional clinical studies, but does not require results reporting for registered trials. While the ICMJE recognizes the potential problems associated with posting preliminary research results that have not yet undergone an independent peer-review process, it acknowledges that the Food and Drug Administration Amendments Act of 2007 (FDAAA; U.S. Public Law 110-85, Title VIII), mandates the posting of summary results data for certain trials in ClinicalTrials.gov. Thus, the ICMJE will not consider results data posted in the tabular format required by ClinicalTrials.gov to be prior publication. However, editors of journals that follow the ICMJE recommendations may consider posting of more detailed descriptions of trial results beyond those included in ClinicalTrials.gov to be prior publication. The ICMJE anticipates that the climate for reporting results for registered trials will change dramatically over coming years and the ICMJE may need to amend these recommendations as additional agencies institute other mandates related to results reporting.

Does the ICMJE require registration of clinical trials of devices? What if I register my device trial in ClinicalTrials.gov and it is covered by the delayed posting (“ lock box” ) provision of Food and Drug Administration Amendments Act of 2007 (FDAAA), meaning that the registered information is not publicly accessible immediately following registration?

The ICMJE does require public, prospective registration of clinical trials of all interventions, including devices. Two options are available to investigators who are conducting trials covered by the FDAAA lock box provision and seeking consideration for publication in ICMJE journals:

If you wish for the information to be made available to the public in accordance with the ICMJE clinical trials registration policy, do not answer the optional question, “ Delayed Posting?

(Y/N)," during the registration process that results in the placement of device trial registration in the lock box.

Alternatively, you may wish to register the trial in another acceptable registry, in addition to ClinicalTrials.gov. Although the ICMJE believes that dual registration should be avoided in most situations, it is, however, another mechanism around the ClinicalTrials.gov device trial lock box problem. Note that each registration should cross-reference the unique registration identification number (e.g., NCT number for ClinicalTrials.gov) issued by the other registry to ensure recognition that both registrations present information about a single device trial.)

Do trials that began before July 1, 2005 need to be enrolled before September 13, 2005 in order to be eligible for consideration at an ICMJE journal?

Trials that began before July 1, 2005:

Investigators should register trials that began enrolling patients any time before July 1, 2005 as soon as possible if they wish to submit them to a journal that follows the ICMJE policy. While the ICMJE hoped that all such trials would be registered by September 13, 2005, the committee understands that the policy statement was not entirely clear. Thus, ICMJE journals will consider trials that began before July 1, 2005 that were not registered prior to September 13, 2005. However, beginning on September 13, 2005, ICMJE journals will consider such trials only if they were adequately registered before journal submission. The ICMJE journals will accept "retrospective registration" of trials that began before July 1, 2005 (retrospective meaning registration occurs after patient enrollment begins).

Trials that began after July 1, 2005:

ICMJE journals will consider trials beginning on or after July 1, 2005 only if registration occurred before the first patient was enrolled (" prospective registration" ).

What is the ICMJE definition of an " ongoing" trial?

The ICMJE considers trials that began enrollment before July 1, 2005 to be " ongoing" if the investigators were still collecting, cleaning, or analyzing data as of July 1, 2005. Ongoing trials require registration before submission to a journal.

What is the ICMJE definition of a clinical trial?

The most recent editorial on trails registration at www.icmje.org discusses the evolution of the ICMJE definition of clinical trials. In June 2007 the ICMJE adopted the WHO' s definition of clinical trial: " 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." Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and

adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. The ICMJE member journals will start to implement the expanded definition of clinically directive trials for all trials that begin enrollment on or after 1 July 2008. Those who are uncertain whether their trial meets the expanded ICMJE definition should err on the side of registration if they wish to seek publication in an ICMJE journal. The ICMJE secretariat office is unable to review specific studies to determine whether registration is necessary. If researchers or others have questions about the need to register a specific study, they should err on the side of registration or consult the editorial office of the journal they wish to publish the study in.

What is the relationship between the ICMJE trials registration policy and the ongoing WHO trials registry effort?

In September 2005, the ICMJE implemented a policy that requires registration of clinically directive trials. The WHO is also working towards the implementation of an international trials registration process. Although several editors of ICMJE journals are independently involved as advisors to the WHO process, the two efforts are separate. The ICMJE welcomes the WHO initiative and is following its progress closely. When the final WHO policy is available, the ICMJE will determine whether to revise the ICMJE requirements to correspond to the WHO requirements. At present, the ICMJE expects investigators who wish to publish in ICMJE journals to adhere to the current ICMJE trials registry policy as documented on this web site (see May 2005 editorial and Frequently Asked Questions for details of the current ICMJE policy including the definition of applicable trials, acceptable registries, timing of registration, and required data items).

Which trials registries are acceptable to the ICMJE?

The ICMJE accepts registration in the following registries:

http://www.anzctr.org.au/

http://www.clinicaltrials.gov/

http://www.isrctn.org/

www.umin.ac.jp/ctr/index/htm

http://www.trialregister.nl/

In addition to the above registries, starting in June 2007 the ICMJE will also accept registration in any of the primary registries that participate in the WHO International Clinical Trials Portal (see http://www.who.int/ictrp/network/primary/en/index.html). Because it is critical that trial registries are independent of for-profit interests, the ICMJE policy requires registration in a WHO primary registry rather than solely in an associate registry, since for-profit entities manage some associate registries. Trial registration with missing or uninformative fields for the minimum data elements is inadequate even if the registration is in an acceptable registry.

What should trial registries that wish to be ICMJE-acceptable registries do?

The ICMJE is no longer the entity that reviews registries for acceptability. Registries should consult the WHO International Clinical Trials Registry Platform. Registries that the WHO designates as primary registries will be acceptable to the ICMJE.

Where can I get information about how to register a trial?

Please refer to the registry that you choose to register in for instructions about the registration process for that specific registry.

I'm having trouble registering my trial in ClinicalTrials.gov or believe that my trial is not eligible for registration in that registry... What now?

Send an email to register@clinicaltrials.gov with your question or explaining the problems you are encountering.

Are clinical trials registries in languages other than English acceptable to meet the ICMJE's trials registration policy?

The ICMJE is cooperating with the WHO effort and will adopt WHO policy with respect to registry language. However, until the WHO has a mechanism in place to solve the problems of searching across registries in different languages, the ICMJE feels that the minimal data items need to be registered in English as well as in the native language of the registry.

Do I need to register a trial if the subjects were health care providers and not patients?

Some trials assign health care providers, rather than patients, to intervention and comparison/control groups. If the purpose of the trial is to examine the effect of the provider intervention on the health outcomes of the providers' patients, then investigators should register the trial. If the purpose is to examine the effect only on the providers (for example, provider knowledge or attitudes), then registration is not necessary.

# Frequently Asked Questions



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