



Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases¹

Updated November 2008

The innovative pharmaceutical industry² is committed to the transparency of clinical trials that are sponsored by our member companies.

We recognize that there are important public health benefits associated with making clinical trial information more widely available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protections for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

We therefore commit to the following principles regarding the disclosure of information relating to clinical trials we sponsored and appeal to all sponsors of clinical trials to commit to keeping these registries accurate and up to date.

¹ A number of different terms are in current usage to describe electronic repositories for various types of clinical trial information. This position uses the term 'registry' for information on ongoing clinical trials, and 'database' for the results of completed clinical trials. However, the term 'database' has been applied elsewhere for information on ongoing clinical trials, and the term 'register' for the results of completed clinical trials.

² The Joint Position sets forth the views of the innovative pharmaceutical industry, as represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Clinical Trial Registries

A clinical trial registry serves as a repository for information on new or ongoing clinical trials. The innovative pharmaceutical industry commits to make the following information available on new or ongoing clinical trials of medicinal products it sponsors. For convenience, these are organized by “Which Trials”, “When posted”, “Where Posted” and “What information”.

WHICH TRIALS:

All confirmatory clinical trials³ and all exploratory efficacy trials⁴ at a minimum should be submitted for listing.

In all cases disclosure will be undertaken in a manner consistent with applicable national laws and rules governing protection of intellectual property.

WHEN POSTED:

No later than 21 days after the initiation of patient enrollment, without prejudice to national legal requirements.

WHERE POSTED:

Registration of clinical trials on any one of a number of free, publicly accessible, internet-based registries should achieve the intended objectives. Company clinical trial registries as well as registries such as the National Library of Medicine in the USA (www.clinicaltrials.gov), the UK Current Controlled Trials (www.controlled-trials.com) and the Japan Pharmaceutical Information Center (www.clinicaltrials.jp) can be used for this purpose, regardless of where the trial is conducted.

UNIQUE IDENTIFIER:

Each trial listed in a registry should be given a unique identifier (e.g. a company-assigned study ID) to ensure transparency and avoid multiple postings of the same trial. The unique identifier should permit registry users

³ Throughout this document the phrase “all confirmatory clinical trials” is intended to have the same meaning as the terms “hypothesis-testing clinical trials, as defined in the ICH Harmonised Tripartite Guideline E9. Statistical Principles for Clinical Trials. *Stats Med* 1999; 18:1905-42. “Hypothesis-testing trials” serve to examine pre-stated questions (i.e., to test hypotheses) using statistically valid plans for data analysis and provide firm evidence of safety and/or efficacy to support product claims.

⁴ Exploratory efficacy trials serve primarily to explore therapeutic efficacy in patients. Such trials cannot be the basis of the formal proof of efficacy, although they may contribute to the total body of relevant evidence and they do not include “Phase 1 trials”. ICH Harmonised Tripartite Guideline E8 and E9.

to track the trial through multiple databases, including clinical trial results databases.

WHAT INFORMATION:

- a. The registry should contain basic information about each trial sufficient to: (a) inform interested patients (and their healthcare practitioners) of the existence of a trial and so facilitate participation in a given trial, (b) provide a public reference point to enable trials to be tracked to publication and (c) help reduce unnecessary duplication of trials on marketed medicines.
- b. The registry would include, at a minimum, the following information: brief title; trial description in lay terminology; trial phase; trial type (e.g. interventional); trial status; trial purpose (e.g. treatment, diagnosis, prevention); intervention type (e.g. medicinal product, vaccine); condition or disease; key eligibility criteria, including gender and age; the location of the trial and contact information.
- c. The aim of the registry is to include the Minimum Trial Registration Data Set published by WHO in May 2006 (see Appendix). However, exceptionally, public disclosure of certain data elements could jeopardize the granting of a patent, provide competitive disadvantage among companies, or violate data protection provisions. In such cases, the trial sponsor may reserve the right to delay the disclosure of this information, at the latest, after the medicinal product is first approved in any country for the indication being studied.

One or more of the following fields may be regarded as sensitive for competitive reasons by the sponsor: primary outcome; key secondary outcomes; intervention name; target sample size; and official scientific title of the study. However, it should be noted that disclosure of such sensitive information to regulatory authorities and ethics committees / IRB (as well as providing specific information to patients and investigators participating in clinical trials) will not be delayed.

Clinical Trial Results Databases

A clinical trial results database serves as a repository for the summary results of completed clinical trials. The innovative pharmaceutical industry commits to make the following information available on completed clinical trials. For convenience, and as with the discussion of clinical trials registries (above), these criteria are organized by “Which Results”, “When Posted”, “Where Posted” and “What information”.

WHICH RESULTS:

- a. The results of all confirmatory clinical trials³ and all exploratory efficacy trials⁴ at a minimum, conducted on a medicinal product that has been approved for marketing and is commercially available in at least one country should be publicly disclosed, regardless of outcome.
- b. This disclosure policy applies to medicinal products that have been approved for marketing and are commercially available in at least one country. However, if trial results for an investigational product that has failed in development have significant medical importance, study sponsors are encouraged to post the results if possible.
- c. In all cases disclosure will be undertaken in a manner consistent with applicable national laws and rules governing protection of intellectual property.

WHEN POSTED:

The results should be posted no later than one year after the medicinal product is first approved and commercially available in any country.

For trials completed after this initial approval, results should be posted no later than one year after trial completion. These schedules would be subject to adjustment to comply with national laws or regulations or to avoid compromising publication in a peer-reviewed medical journal.

WHERE POSTED:

Publication of clinical trial results in any free, publicly accessible internet-based clinical trials databases should achieve the intended objectives. Suitable databases include the National Library of Medicine in the USA (www.clinicaltrials.gov), the company databases, the PhRMA Clinical Study Results Database (www.clinicalstudyresults.org) and the Japan Pharmaceutical Information Center database (www.clinicaltrials.jp/result/ctr/ctrSearch.jsp).

UNIQUE IDENTIFIER:

The results should include the unique identifier used to register the trial at inception.

WHAT INFORMATION:

If trial results are published in a peer-reviewed medical journal, the database should include a citation of, or link to the journal article and/or a summary of the results in a standard, non-promotional format, such as the ICH E-3 summary format, that includes a description of the trial design and methodology, results of the primary and secondary outcome measures, and safety results. If trial results are not published in a journal, the results should be posted on the database in the ICH E-3 summary format or in a format in compliance with national requirement.

ADDITIONAL INFORMATION:

To confirm that manuscripts reflect clinical trials as they have been conducted, the industry will, upon request, provide copies of study protocols and amendments to medical journals. Sponsors may enter into confidentiality agreements with medical journals to ensure protection of information in protocols and amendments.

Implementation Dates

- All confirmatory trials initiated on or after July 1, 2005 and meeting the above requirements should be included in a public clinical trial registry.
- Exploratory efficacy trials initiated 6 months prior the publication date of this Joint Position and meeting the above requirements should be included in a public clinical trial registry by September 2009.
- Posting of clinical trial results should occur in compliance with the timelines and conditions defined in this Joint Position.

Compliance

- Companies subscribing to the Joint Position should establish a verification process for both clinical trial registry and clinical trial database information. Companies are encouraged to make public how they will ensure adherence to these standards.

IFPMA Clinical Trial Portal

- IFPMA facilitates transparency and easier access to clinical trial information through a search portal that links to online information on industry-sponsored clinical trials, which exists in a number of registries

and databases. The IFPMA Clinical Trial Portal (www.ifpma.org/clinicaltrials) was launched in September 2005.

- The IFPMA Clinical Trial Portal helps patients, physicians and other stakeholders to access information about ongoing trials as well as the outcome of trials as it searches established clinical trials registries and results databases.
- To facilitate use of the portal by speakers of different languages, user interfaces are provided in English, French, German, Japanese and Spanish.

The November 18, 2008 Joint Position supersedes the January 6, 2005 and the September 5, 2005 Joint Positions.

ANNEX

WHO Policy announced on 19 May 2006

"Minimum 20 items Trial Registration Data Set"

	Item		Item
1.	Primary Register and Trial ID #	11.	Countries of Recruitment
2.	Date of Registration in Primary Register	12.	Health Condition(s) or Problem(s) Studied
3.	Secondary ID#s	13.	Intervention(s)
4.	Source(s) of Monetary or Material Support	14.	Key Inclusion and Exclusion Criteria
5.	Primary Sponsor	15.	Study Type
6.	Secondary Sponsor(s)	16.	Date of First Enrollment
7.	Contact for Public Queries	17.	Target Sample Size
8.	Contact for Scientific Queries	18.	Recruitment Status
9.	Public Title	19.	Primary Outcome(s)
10.	Scientific Title	20.	Key Secondary Outcomes

Annotations by IFPMA

- All minimum data set information should be reported in English.
- All items listed above should be included in the minimum data set on scientific and ethical grounds. Therefore, all fields in the minimum data set should normally be entered into the register at the time of trial registration.
- However, one or more of data items 10, 13, 17, 19, 20 may be regarded as sensitive for competitive reasons by the sponsor who may wish to delay release of the information until possible violations of intellectual property or competitive advantage no longer exist.
- In any event all data items should be made publicly available by agreed dates, and no later than what is stipulated in this declaration.