



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

Updated November 10, 2009 (with minor revisions as of January 15, 2018)

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 sponsor 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 clinical trials³ in patients conducted on a medicinal product 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 US (www.clinicaltrials.gov), the ISRCTN Registry (www.isrctn.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 to track the trial through multiple databases, including clinical trial results databases.

³ For purposes of this Position, a « clinical trial » means an interventional trial involving human subjects from Phase 1 and beyond. For example, the term does not include the use of a medicinal product in the normal course of medical practice or non-clinical laboratory studies.

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 clinical trials⁴ in patients 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

⁴ For purposes of this Position, a « clinical trial » means an interventional trial involving human subjects from Phase 1 and beyond. For example, the term does not include the use of a medicinal product in the normal course of medical practice or non-clinical laboratory studies.

Library of Medicine in the USA (www.clinicaltrials.gov), the company databases, and the Japan Pharmaceutical Information Center database (www.clinicaltrials.jp/user/ctrSearch_e.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

- This Joint Position supersedes the November 18, 2008 Joint Position.
- Additional trials that fall within the scope of this revised Joint Position and are initiated 6 months after the publication date of this Joint Position should be included in a public clinical trial registry.
- 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.

ANNEX

WHO Trial Registration Data Set (TRDS)⁵ – Updated November 2017

	Item		Item
1.	Primary Registry and Trial ID#	13.	Intervention(s)
2.	Date of Registration in Primary Registry	14.	Key Inclusion and Exclusion Criteria
3.	Secondary ID#s	15.	Study Type
4.	Source(s) of Monetary or Material Support	16.	Date of First Enrollment
5.	Primary Sponsor	17.	Sample Size
6.	Secondary Sponsor(s)	18.	Recruitment Status
7.	Contact for Public Queries	19.	Primary Outcome(s)
8.	Contact for Scientific Queries	20.	Key Secondary Outcomes
9.	Public Title	21.	Ethics Review
10.	Scientific Title	22.	Completion Date
11.	Countries of Recruitment	23.	Summary Results
12.	Health condition(s) or Problem(s) Studied	24.	IPD Sharing Statement

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.

⁵ who.int/ictpr/network/trds/en/ - Accessed January 2018. Original WHO Policy announced on May 19, 2006.

- 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.