



International
Federation of
Pharmaceutical
Manufacturers &
Associations



European Federation of Pharmaceutical
Industries and Associations



Japan
Pharmaceutical
Manufacturers
Association



Joint Position on the Publication of Clinical Trial Results in the Scientific Literature

The innovative pharmaceutical industry¹ is committed to the transparency of clinical trials that are sponsored by its member companies.

We recognize that there are important public health benefits associated with making clinical trial results widely available to healthcare practitioners, patients, and others. IFPMA, EFPIA, JPMA and PhRMA and their member companies have already committed to registering all clinical trials conducted in patients on a public registry and disclosing the results of industry-sponsored clinical trials in patients, through public databases as detailed in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases.²

In addition, we commit to the following principles regarding the publication of results from industry-sponsored clinical trials in the scientific literature, and we encourage the sponsors of all trials to follow these principles.

Such publication, 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.

¹ 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).

² *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases* available online at www.ifpma.org/clinicaltrials

PUBLICATION IN THE SCIENTIFIC LITERATURE

We recognize the importance of seeking to publish results of clinical trials in the peer-reviewed scientific literature as discussed below. Our approach is described in this Joint Position paper which for convenience is organized by “Which Trials”, “When Submitted”, “Where Submitted”, “What information”.

WHICH TRIALS:

All industry-sponsored³ clinical trials⁴ should be considered for publication in the scientific literature irrespective of whether the results of the sponsors’ medicine(s) are positive or negative. At a minimum, results from all phase 3⁵ clinical trials and any clinical trial results of significant medical importance should be submitted for publication. This includes investigational clinical products whose development programs are discontinued.

WHEN SUBMITTED:

Submissions for publication of applicable clinical trials in the scientific literature should take place in a timely manner. Industry sponsors should prioritize clinical trials for submission where the results are of high medical or scientific importance. The results of completed clinical trials described above should be submitted for publication wherever possible within 12 months and no later than 18 months of:

- In the case of already marketed medicinal products, the completion of clinical trials;
- In the case of investigational medicinal products:
 - › The regulatory approval of the new medicine; or
 - › The decision to discontinue development.

Primary publication(s)⁶ (i.e. the results from all centers) should be published before, or in parallel with, any secondary publications (such as sub-group analyses or results from individual centers). For a multi-site clinical trial, analyses based on single-site data usually have significant statistical limitations, and frequently do not provide meaningful information for health care professionals or patients.

³ See ICH E6 1.53; 21 C.F.R. 312.3(b).

⁴ 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 drug in the normal course of medical practice or non-clinical laboratory studies. Clinical trials “in patients” are those that test a medicine on subjects who actually require medical care.

⁵ See ICH E8 3.1.3.3.

⁶ The first publication that is based on consolidated data from all centres, analysed as stipulated in the research protocol and agreed upon by investigators before trial initiation.

WHERE SUBMITTED:

It should be the intention to submit clinical trial results for publication as manuscripts in peer-reviewed journals. Whenever possible, these clinical trial results should be submitted to journals indexed by online bibliographic databases (e.g. Medline).

WHAT INFORMATION:

Authorship and Acknowledgements

Authorship and acknowledgements for scientific publications from industry-sponsored clinical trials should be consistent with the principles embodied in the ICMJE Uniform Requirements for Manuscripts. Specifically, authorship credit should be based on meeting all three of the following criteria:

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content;
3. Final approval of the version to be published.

Some journals may employ a more narrow definition of authorship, which should be respected in such cases. All individuals who qualify according to the authorship criteria should be listed on the publication.

The ICMJE guidelines do not provide clear guidance in determining the order in which authors are listed, so this should be agreed by the authors.

Where medical writers, statisticians or others help to develop publications but do not meet authorship criteria, their involvement should be appropriately acknowledged and their identities, affiliations, source of funding and any other potential competing interests stated.

All other sources of support and/or assistance should be acknowledged.

Disclosure

Companies should disclose their involvement in both the research and the development of publications. Sponsors should also encourage external authors to meet their responsibilities in disclosing all relevant competing interests when submitting a publication or making a presentation. Examples include, but are not limited to, disclosure of an author's receipt of research grants, author's receipt of payments for consultant or speaker services, and/or author's ownership of stock.

We support the adoption by journals of a uniform format to collect and publish author information, including potential conflicts. Consistent presentation of this information, both within and across journals, is crucial to establish the trust and integrity of authors and sponsor.

Content

The primary publication for the study should provide an accurate report of the clinical trial findings, including adverse events. This should include primary efficacy analyses, safety results with relevance for patient care and, when informative (and within the space constraints for abstracts), secondary and exploratory analyses. Post-hoc analyses should be clearly described as such. Journal articles should include sufficient details of the methods so that readers may judge the validity and generalizability of the results. There should also be a discussion of the strengths and limitations of the study.

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.

CONCLUSION

This joint position from the innovative pharmaceutical industry recognizes the important public health benefits associated with making clinical trial results widely available through submission for publication and demonstrates a commitment to the transparency of clinical trials that are sponsored by its member companies.

Announced on June, 10, 2010