JOINT POSITION ON THE
DISCLOSURE OF CLINICAL TRIAL INFORMATION VIA CLINICAL TRIAL REGISTRIES AND DATABASES[1]

The innovative pharmaceutical industry, which is represented worldwide 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), is committed to increasing the transparency of the clinical trials our member companies sponsor. 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 the regulations in relevant countries. We thus 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.

Clinical Trial Registry

A clinical trial registry serves as a repository for information on ongoing clinical trials. The innovative pharmaceutical industry commits to make the following information available on ongoing clinical trials we sponsor involving pharmaceutical products:

- All clinical trials, other than exploratory trials,[2] should be submitted for listing in a free, publicly accessible clinical trial registry within 21 days of the initiation of patient enrollment, unless there are alternative national requirements.
- The registry should contain basic information about each trial sufficient to inform interested subjects (and their healthcare practitioners) how to enroll in the trial. This 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., drug, vaccine); condition or disease; key eligibility criteria, including gender and age; the location of the trial and contact information. Industry is also prepared to explore the concept of placing additional protocol information in a secure, non-public third party electronic repository[3] for subsequent disclosure to medical journals when publication is sought.

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[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 studies, and 'database' for the results of completed clinical studies. However, the term 'database' has been applied elsewhere for information on ongoing clinical studies, and the term 'register' for the results of completed clinical studies.

[2] Throughout this document the phrase "all clinical trials, other than exploratory trials" is intended to have the same meaning as the terms "hypothesis-testing clinical trials," also known as "confirmatory clinical trials" as defined in the ICH Harmonised Tripartite Guideline E9. Statistical Principles for Clinical Trials. Stats Med 1999; 18:1905-42. Whereas exploratory trials serve to set direction (i.e., to generate hypotheses) for possible future studies, "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.

[3] An example exists in Europe where recent legislation set up a database, "EudraCT," containing information on all interventional clinical trials of medicines initiated in the Community from 1 May 2004. "EudraCT" is accessible to

- Each trial listed in the registry should be given a unique identifier to ensure transparency of clinical trial results. The unique identifier should permit registry users to track the trial through multiple databases, including clinical trial results databases.
- Registration of clinical trials on any one of a number of internet-based registries may achieve these objectives. The clinical trial registry maintained by the National Library of Medicine in the US at www.clinicaltrials.gov is already in place and can be used for this purpose, regardless of where the trial is conducted.

Clinical Trial Results Database

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:

- The results of all clinical trials, other than exploratory trials,[2] conducted on a drug that is approved for marketing and is commercially available in at least one country should be publicly disclosed on a free, publicly accessible, clinical trial results database, regardless of outcome. Trial results from exploratory trials also should be publicly disclosed if they are deemed to have significant medical importance and may have an impact on a marketed product's labeling.
- This disclosure policy applies to drug 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. In all cases disclosure should be undertaken in a manner consistent with applicable local laws.
- If trial results are published in a peer-reviewed medical journal, the database should include a citation to 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 trials results are not published in a journal, the results should be posted on the database in the ICH E-3 summary format.
- The results should include the unique identifier used to register the trial at inception.
- The results generally should be posted within one year after the drug is first approved and commercially available in any country or, for trials completed after this initial approval, within one year of trial completion, unless such posting would compromise publication in a peer-reviewed medical journal or contravene national laws or regulations.
- Publication of clinical trials on any one of a number of internet-based databases may achieve these objectives. We also support the use of an industry-wide clinical trial results database, including to the extent appropriate and feasible, the PhRMA Clinical Study

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European Regulatory Authorities from the time of data submission (i..e., trial initiation). Some data fields will subsequently be made publicly accessible once the product is approved.

Results Database available at www.clinicalstudyresults.org, as well as company-specific databases.

Implementation Dates

- Trials initiated on or after July 1, 2005, and meeting the above requirements should be included in a clinical trial registry.
- Ongoing clinical trials meeting the above requirements should be included in a clinical trial registry by September 13, 2005.
- With respect to the posting of clinical trial results, this proposal applies to clinical trials meeting the above requirements that have been completed since the publication date of this joint position statement.

Compliance

- Companies subscribing to the joint position should establish a process of verification for both the clinical trial registry and the clinical trial database. Companies are encouraged to make public how they will adhere to these standards.