Policy on Public Disclosure

I. Purpose of the Policy

This document relates to Pfizer’s policy on public disclosure or publication of clinical trial results. As a research-based pharmaceutical company, Pfizer recognizes that the availability of clinical trial results is critical to the communication of important new information for the medical profession, patients and the public. Clinical trials may involve already marketed products and/or investigational pharmaceutical products. Pfizer commits to timely communication of meaningful results of controlled clinical trials of marketed products or investigational products that are approved for marketing, regardless of outcome. Communication includes publication of a paper in a peer-reviewed medical journal, abstract submission with a poster or oral presentation at a scientific meeting, or making results public by some other means.

Pfizer designs and conducts clinical trials in an ethical and scientifically rigorous manner to determine the benefits, risks, and value of pharmaceutical products. As sponsors, Pfizer is responsible for receipt and verification of data from all research sites for the studies we conduct; as owners of the data, Pfizer works diligently to ensure the accuracy and integrity of the entire study database.

II. Scope of the Policy

This policy applies globally to public disclosures of clinical trial results of Pfizer sponsored clinical trials and specifically addresses:

- Communication of study results by Pfizer and Investigators
- Authorship of medical articles
- Investigator access to clinical data

Examples of public disclosures include Scientific & Technical Papers, Posters, Book Chapters, Reviews, Manuscripts, Abstracts and Slides or Oral presentations linked to an Abstract.

This policy is intended to supplement other Pfizer interdivisional and/or divisional standard operating procedures, as well as Pfizer policies on business conduct. This policy does not affect Pfizer’s normal reporting requirements to Regulatory Agencies. It also does not address internal review and approval of publications by Pfizer researchers, as this is covered by a separate procedure.

III. Policy

Communication of Results by Pfizer

The following addresses Pfizer’s policy for publications/disclosures to be released from Pfizer Inc.

- Pfizer is committed to communicating or otherwise making available for public disclosure meaningful results of controlled trials of marketed products or investigational products that are approved for marketing regardless of outcome.
- Public disclosure could include peer-reviewed publication, abstract submission with a poster or oral presentation at a scientific meeting, or other means.
- Pfizer reserves the right not to release data until specified milestones, e.g. a final study report is available. This includes providing the interim results from clinical trials, because such results may lead to conclusions that are later shown to be incorrect.
• Pfizer is committed to communication of exploratory studies (early-phase or post-marketing) only if they have scientific or medical importance. Pfizer reserves the right not to release all exploratory study results or to make the designs of these clinical trial protocols available publicly because these are often highly proprietary to Pfizer, and due to their limited statistical power, serve primarily to generate or preliminarily test hypotheses that may be more thoroughly evaluated in future trials.

• In all cases, the study results should be reported in an objective, accurate, balanced and complete manner, with a discussion of the strengths and limitations of the study.

• If requested by a medical journal when reviewing a submitted manuscript for publication, Pfizer will provide via the author, a synopsis of the clinical trial protocol and/or pre-specified plan for data analysis with the understanding that such documents are confidential and should be returned to Pfizer.

Publications by Investigators

• As a general rule, Pfizer will not restrict the ability of an investigator to publish individual site results that are deemed clinically meaningful or significant by the investigator subject to the conditions described below.
  
  o Pfizer reserves the right to ask for deferment of publication of individual site results until after the study report is completed for the study.
  
  o 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 professional or patients and therefore may not be supported by Pfizer. It is Pfizer’s policy, therefore, that such individual reports not precede the study report and should always reference the primary presentation or paper of the entire study.
  
  o Pfizer reserves the right to review any manuscripts, presentations, or abstracts that originate from our studies or that utilize our data before they are submitted for publication or other means of communication. Pfizer commits to respond in a timely manner, and not suppress or veto publications or other appropriate means of communication. In rare cases, it may be necessary to delay publication and/or communication for a short time to protect intellectual property.

• Where differences of opinion or interpretation of data exist, Pfizer will strive to resolve them with the investigator through appropriate scientific debate.

Authorship of Medical Articles

Pfizer adheres to the highest standards of scientific conduct with regard to authorship and content of biomedical publications. Authorship for publications stemming from clinical studies sponsored by Pfizer will be based on the criteria proposed by the International Committee of Medical Journal Editors (ICMJE 1997) and PhRMA Principals on Conduct of Clinical Trials & Communication of Clinical Trial Results.

According to these guidelines, authorship credit is based only on substantial contribution to:

• Concept and design, or analysis and interpretation of the study, and

• Drafting or revising the manuscript for important intellectual content, and

• Approval of the final version to be published

It is Pfizer policy that only those people who meet all the ICMJE Vancouver (triple) criteria should be named as authors on publications of Pfizer sponsored studies. All those who deserve authorship based
on these criteria should be named on the byline and those who do not should be acknowledged elsewhere, if appropriate. Pfizer scientists should be authors if they meet the Vancouver criteria.

Pfizer sometimes employ staff to help analyze and interpret data, and to produce manuscripts and presentations. Such personnel must act in conjunction with the investigator-author. Their contributions should be recognized appropriately in resulting publications – either as a named author, a contributor, or in acknowledgments depending on their level of contribution.

General supervision of the research group that is conducting or supervising a project is not sufficient for authorship. Likewise, participation solely in the acquisition of funding or collection of data does not justify authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

The determination of who obtains authorship credit lies solely with the potential authors. The order of authorship as listed on the byline shall be based on the degree of contribution to the works as determined by the authors. The study authorship group will retain control over the decision to publish. This includes decisions on the specific journal to publish in and the type of publication to prepare (e.g., abstract, letter to the editor, full paper). Once determined, authors should accept responsibility and accountability to ensure compliance with the criteria. Disclosure of compounds in late stage Development must be carefully considered with regard to the contribution of all authors including external authors and/or opinion leaders, and to the appropriate timing of the disclosure.

Where feasible, authorship should be determined upfront. Predetermination of authors may help to determine issues of access to data and communication, as well as to help avoid later potential conflicts.

INVESTIGATOR ACCESS TO DATA AND REVIEW OF RESULTS

As owners of the study database, Pfizer has discretion to determine who will have access to the database. Generally, study databases are only made available to regulatory authorities. Individual investigators in multi-site clinical trials will have their own research participants' data and will be provided, on request, the randomization code after conclusion of the trial. Pfizer will make the summary study results available to the investigators. In addition, Pfizer will permit any investigator who participated in the conduct of a multi-site clinical trial to review relevant statistical tables, figures, and reports for the entire study at a designated Pfizer facility or other mutually agreeable location.

All authors whether from within a sponsoring company or external will be given the relevant statistical tables, figures, and reports needed to support the planned publication.

While Pfizer does not ordinarily provide investigators with the complete study database, we will provide investigators access to relevant data at an agreed location and will respond to reasonable requests for additional analyses.

REFERENCES

In this policy Pfizer acknowledges the following external sources:

- PhRMA Principles on Conduct of Clinical Trials & Communication of Clinical Trial Results
- CONSORT Statement
- Vancouver Criteria (International Committee of Medical Journal Editors “Vancouver criteria” to determine eligibility for authorship)