Bayer Corporate Policy:

Global Publications Deriving from Clinical Studies in Humans

Overview

The key aspects of this Global Publication Policy are commitment to publish; consistent application of authorship criteria; transparency; and the disclosure of accurate and balanced information pertaining to the design and results of human clinical studies.

Bayer HealthCare (legal entity Bayer Pharma AG) is a research-based company that endeavors to discover, develop, and manufacture innovative products that will improve human health worldwide. Our products enhance well-being and quality of life by diagnosing, preventing, and treating disease. Bayer HealthCare

- produces and markets its products in more than 100 countries;
- conducts clinical studies to evaluate the safety, efficacy and usability of its products in development and on the market;
- is committed to communicate information on its products and research and development activities in an accurate, objective, and timely fashion.

All scientific communications, including medical publications, are conducted in accordance with current ethical internal and external standards (including evolving national and international statutory requirements) regarding content, development, authorship, transparency, and timeliness. Bayer HealthCare adheres to widely accepted standards for Good Publication Practice. The standards include:

- Good Publication Practice 2 (GPP2) guidelines1; uniform requirements for biomedical journals established by the International Committee of Medical Journal (ICMJE) editors2;
- standards established by the Consolidated Standards of Reporting Trials (CONSORT) Group3 for reporting the results of randomized, controlled clinical trials;
- guidelines established by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) initiative4,5 for reporting the results of observational studies;
- recommendations issued by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Group6 for the optimal reporting of systematic reviews and meta-analyses;
- the Joint Position on the Publication of Clinical Trial Results by IFPMA, EFPIA, JPMA, and PhRMA7 and practices mandated by the US Food and Drug Administration Amendments Act (FDAAA) of 20078.

Furthermore, Bayer HealthCare complies with evolving standards regarding the disclosure of clinical study results and the publication of clinical study results in biomedical journals.

Communication of Clinical Study Results

Bayer HealthCare is committed to transparency and the disclosure of accurate and balanced information pertaining to the design and results of its clinical studies, irrespective of outcome. Bayer HealthCare commits to publishing the primary and key secondary results of clinical studies in humans, in accordance with pre-specified plans for the analysis of data. Bayer HealthCare also strives to publish the results of exploratory and other non–prespecified analyses that are considered important for patients, clinicians, or payers.

Consistent Application of Authorship Criteria

Bayer HealthCare believes that authorship should accurately reflect the contributions made by individuals to the development of publications, as outlined by the ICMJE Authorship Criteria.

All persons designated as authors should have contributed to all three of the following activities:

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

All individuals who qualify as an author based on these criteria should be designated as such. Each author should have access to relevant statistical tables, figures, and reports necessary to support the planned publication, and should have participated sufficiently in the work to take public responsibility for appropriate portions of content. The listing of someone as an author who fails to meet the authorship criteria is prohibited. The acquisition of funding, collection of data, contribution of cases (or samples), or general supervision of the research, of itself, does not justify authorship if the above three criteria are not fulfilled.

Selection of external clinical investigators as authors will not be based on their past prescribing behavior or their potential prescribing ability. Authors should be identified as early as possible in the publication planning process and must be engaged before substantial work begins on the publication.

All individuals or agencies who contribute substantively (e.g., with financial or material support, technical help or assistance in editing) to the development of the publication, but do not qualify as authors, shall be named in the publication as contributors. Bayer HealthCare fully supports the contributions of professional medical writers, provided that their engagement is approved by the authors and their activity is conducted under direction from the authors and in accordance with established guidelines for Good Publication Practice.

A full description of the contribution of all authors and contributors shall be stated, in accordance with journal policies, in the acknowledgements section of the publication.

Transparency and Disclosure

Bayer HealthCare supports transparent communication, independent opinions, and the full disclosure of any potential competing interests by investigators of its clinical studies and authors of its clinical study publications. The nature of Bayer HealthCare's role in the development of the publication will be fully disclosed to the editors of the journal. It is expected and encouraged that authors fully disclose all financial relationships, including material support for research and other potential conflicts of interest related to the publication.

Review

Bayer HealthCare reserves the right to review and comment on any publications pertaining to Bayer HealthCare-sponsored studies or Bayer HealthCare data before they are submitted for presentation, publication, or other public disclosure. This review is necessary in order to ensure that the study results are reported in an objective, accurate, and balanced fashion. Designated Bayer HealthCare personnel with relevant expertise shall review draft publications prior to submission.

Compensation

Bayer HealthCare does not compensate authors for time spent on the preparation of any publication (including time spent meeting and discussing the publication or its presentation with Bayer HealthCare representatives where applicable).

Investigator-Sponsored Studies

This policy does not cover investigator-sponsored studies or the publication of results derived from investigator-sponsored studies. Abstracts, presentations and manuscripts pertaining to investigator-sponsored studies are prepared and submitted by the investigators of the studies according to the terms of relevant research agreements. Authors of investigator-sponsored study-related papers are encouraged to follow prevailing standards for Good Publication Practice. Neither Bayer HealthCare personnel nor contracted parties shall engage in any publication activities directly related to investigator-sponsored studies, unless a prior mutual agreement was made with the principal investigator(s) of an investigator-sponsored study for Bayer HealthCare and/or contracted parties to review draft publications, and to provide editorial and/or writing support for the planned publication.

Prior Publication

Bayer HealthCare is committed to publishing responsibly and, as such, will comply with applicable policies of the appropriate journal and relevant professional and/or regulatory societies regarding the resubmission of data and prior publication.

References

1. Graf C, Battisti WP, Bridges D, et al. Good publication practice for communicating company sponsored medical research: The GPP2 guidelines. Br Med J 2009; 339:b4330.
2. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. Updated April 2010. Available at: http://www.icmje.org/urm_main.html. Accessed September 22, 2011.
3. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. Br Med J 2010;340:698-702.
4. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, for the STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies. Ann Intern Med 2007;147:573-577.
5. Vandenbroucke JP, von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, Poole C, Schlesselman JJ, Egger M for the STROBE initiative. Strengthening the Reporting of

Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. Ann Intern Med 2007;147:W163-W194.

6. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. J Clin Epidemiol 2009;62:1006-1012. http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/20100610_Joint_Position_Publication_10Jun2010.pdf
7. US Food and Drug Administration. Food and Drug Administration Amendments Act (FDAAA) of 2007. Oct 2009. Available at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsAct of2007/default.htm. Accessed September 22, 2011.