

Guidelines for Publication of Clinical Trials in the Scientific Literature

Our Company Philosophy

We strive to discover and develop breakthrough medicines and vaccines for unmet medical needs, for patients around the world. We conduct clinical studies in an ethical and rigorously scientific manner, collaborating with leading experts in the field, to clearly demonstrate the benefits, risks, and value of our medicines to physicians and to the patients who take them. We accept the obligation to facilitate publication of medically important clinical data in a timely, objective, accurate, and balanced manner, regardless of the outcome of a trial. At the same time, our company is a publicly held corporation with an obligation to protect its proprietary information and its intellectual property. These considerations do not in any way affect our long-standing practice of making information public that relates to either the efficacy or the safe use of our products by physicians and patients.

We have developed guidelines to give investigators, physicians, and patients — as well as the editors and readers of medical journals to which we submit our data — confidence that we are reporting complete, balanced and accurate information about our studies. The aim of these guidelines is to ensure that we consistently produce publications in a responsible and ethical manner. These guidelines are designed to be applied in conjunction with those from the International Committee of Medical Journal Editors,¹ the CONSORT (Consolidated Standards of Reporting Trials) group,^{2,3} Good Publication Practice,⁴ and the individual journals.

Scope of the Guidelines

These guidelines apply to the publication of results from interventional clinical trials in patients involving a Company product and from preventive interventional trials in healthy subjects involving a Company product (e.g., vaccine trials) that are sponsored and monitored by Merck & Co, Inc. and that list Company personnel as authors or as contributors. Studies initiated and conducted by external investigators or by commercial or academic collaborators for which the company only provides drug supplies and/or financial support are not covered by these guidelines, although we share them with our collaborators for their consideration when developing publications from these clinical trials.

Our Guiding Principles

- **What we publish:** Regardless of trial outcome, we commit to submit for publication in the scientific literature the results of our Phase 3 interventional clinical trials involving a Company product and the results of any interventional clinical trial in patients (or preventive interventional trial in healthy subjects) of significant medical importance, according to the pre-specified plans for data analysis. We do not intend to publish in the scientific literature results of trials that did not complete as planned (e.g., trials terminated early due to low enrollment or trials where the data collected are not valid due to data collection errors) or from trials of limited therapeutic interest (e.g., results from small or early-phase trials). In these latter cases, a posting of the results for registered trials on a clinical trials website such as www.clinicaltrials.gov, <https://eudract.ema.europa.eu/>, or www.merck.com/clinical-trials will substitute for a peer-reviewed publication. [Our Company policies for the registration of clinical trials and posting of results are addressed at www.merck.com/clinical-trials].
- **When we publish:** For registered clinical trials as described above, a manuscript will be submitted within 18 months after the last patient's last visit occurs or the last data available, whichever is later.
- **How we publish:** We often work with external investigators for our clinical trials to produce high-quality manuscripts for publication. When collaborators or others external to the Company conduct analyses of Company-sponsored study data or develop other works that use our data, we maintain the right to be informed of any plans for publication and to *review* any resulting works, including abstracts, presentations, or manuscripts, before they are submitted. We will return our comments to the authors in a timely manner so that they may submit the work for publication.
- **Data access and analysis:**

Plans for data analysis by Company biostatisticians are always part of the study protocol. To support a planned publication, all authors — internal and external — are provided with the plans for statistical analysis and the complete statistical report. For primary reports of randomized clinical trials, this includes a full accounting of patient disposition, per CONSORT guidelines.³ We will allow investigators to review the

complete study database at our facility, on request. We provide a copy of clinical trial protocols and plans for statistical analysis to a medical journal when a submitted manuscript is being considered for publication, with the understanding that the documents are not to be disclosed without our prior written approval. If the manuscript is accepted for publication, we will allow the journal to post on its website, at the time of publication, the key sections of the protocol that are relevant to evaluating the study, specifically those sections describing the study objectives and hypotheses, the patient inclusion and exclusion criteria, the study design and procedures, the efficacy and safety measures, the statistical analysis plan, and any amendments relating to those sections. We reserve the right to redact proprietary information. We will also allow a medical journal editor to review the complete study database at our facility, on request. Our policy for access to the clinical trial database by independent researchers is described at <http://www.merck.com/clinical-trials/policies-perspectives.html>.

- **Authorship and accountability:** Per ICMJE recommendations¹, an author is generally considered to be anyone who provides substantive intellectual contributions to a publication. Specifically, authorship credit should be based on 1. substantial contributions to study conception and design, or acquisition, analysis and interpretation of data, *and* 2. drafting the article or revising it critically for important intellectual content, *and* 3. final approval of the version to be published, *and* 4. agreement to be accountable for all aspects of the work to ensure its accuracy and integrity. *All four conditions should be met.* Conversely, individuals who do not contribute in this manner do not warrant named authorship. Individuals who do not meet criteria for authorship but who contributed materially to the manuscript will be recognized in acknowledgments when the manuscript is published. In some cases, journals recognize contributors rather than authors; we will comply with the journal policy for publications targeted for those journals. Subject to journal policy, we will list the names of all investigators at the end of a clinical study manuscript.
- Company staff or contract writers hired by the Company may facilitate the development of a manuscript when the lead author provides oversight and direction; the efforts of such writers will be acknowledged in the publication.

References

- 1 International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals. [Accessed September 17, 2013]. Available at <http://www.icmje.org/>.
- 2 Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996;276(8):637-639. doi: 10.1001/jama.1996.03540080059030. Available at: <http://www.consort-statement.org/consort-statement/>
- 3 Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Ann Intern Med* 2010;152(11):726-732. doi:10.7326/0003-4819-152-11-201006010-00232. Available at <http://www.annals.org/content/early/2010/03/18/0003-4819-152-11-201006010-00232.full.pdf+html> and <http://www.consort-statement.org>.
- 4 Battisti WP, Wager E, Baltzer L, et al. Good Publication Practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med* 2015;163(6):461-464. doi: 10.7326/M15-0288.

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