

# **Merck Guidelines for Publication of Clinical Trials and Related Works**

## **Our Philosophy at Merck**

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, Merck 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 Merck consistently produces 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,<sup>1</sup> the CONSORT (Consolidated Standards of Reporting Trials) group,<sup>2,3</sup> and the individual journals.

## ***Scope of the Guidelines***

These guidelines are intended for use by Merck employees who work on clinical trials, related works, and their publication. They apply to the publication and presentation of results from clinical trials sponsored and monitored by Merck — studies in which we collect and analyze data, including observational studies in which medically important results warrant publication.

The guidelines cover publications in biomedical journals — including both traditional print and electronic/online media — and oral or audiovisual presentations at scientific meetings that list Merck personnel as authors or as contributors. They address peer-reviewed publications (e.g., original research papers [primary and secondary analyses], review and other types of articles) and conference abstracts and presentations. Studies initiated and conducted by external

investigators or commercial partners for which Merck only provides drug supplies and/or some degree of financial support are not covered by these guidelines. However, Merck will provide and encourage the use of the guiding principles by the investigators in these situations.

### ***Our Guiding Principles***

- **What we publish:** Regardless of trial outcome, Merck commits to publish the primary and secondary results of its registered trials of marketed products in which treatment is assigned, according to the pre-specified plans for data analysis.\* In addition, Merck seeks to publish the results of other analyses that are important to patients, physicians, and payers. “Publish” refers to peer-reviewed papers; abstracts, posters, or presentations at a scientific meeting; or other communication of study results such as posting on the Internet.

If Merck, together with the investigators, deems certain post-hoc or other exploratory analyses scientifically and medically important, they may be submitted for publication with appropriate caveats for interpreting results. Merck will only publish results of studies in which the data collected are determined to be valid (regardless of study outcome), because the inferences drawn from publications based on invalid data (e.g., erroneous laboratory assay) can be misleading. Merck generally does not support publication of single-center data derived from a multi-center clinical trial, due to the scientific limitations of such analyses.

- **When we publish:** Clinical trial results of marketed products will be disclosed by submitting a synopsis to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) within 30 days after the product is marketed in the United States or within 12 months after the last patient's last visit for the primary outcome occurs, whichever is later.\* In addition, for confirmatory (hypothesis-testing) trials, a manuscript will be submitted to a journal as soon as possible after the last patient's last visit occurs or last data available, whichever is later. Timelines may be longer for trials of product candidates that do not receive regulatory approval.
- **How we publish:** Merck often works with external investigators for its clinical trials to produce high-quality manuscripts for peer-reviewed publication. For studies of limited interest (such as small or early-phase trials), posting a summary online at

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\* Merck policies for the registration and publication of our clinical trials have evolved over time and are addressed at: <http://www.merck.com/research/discovery-and-development/clinical-development/Merck-Perspective-Clinical-Trials.pdf>.

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) may constitute the full extent of disclosure. For analyses of Merck-sponsored studies or other papers that use our data, Merck maintains the right to be informed of any plans for publication and to *review* any resulting abstracts, presentations, or manuscripts before they are submitted. We will return our comments to the external authors in a timely manner so the investigators may submit the abstract or manuscript for publication.

- **Data access and analysis:** The consolidated electronic database of a clinical study is normally created and maintained by Merck. For registration trials (Phases I-III), Merck makes the study electronic database available to regulatory agencies. In some large clinical trial outcomes studies sponsored by Merck, the database may reside either at Merck or at an external Data Coordinating Center. Such studies usually have a Steering Committee that is responsible for the scientific conduct of the trial: investigator access to the data, procedures for data analysis, and roles and responsibilities towards publications are defined in the study protocol and/or contract. Merck retains unlimited access to, and use of, such study databases.

Plans for data analysis by Merck 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.<sup>3</sup> Merck will allow investigators to review the complete study database at our facility, on request. Effective July 1, 2011, Merck will 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 prior written approval of Merck. If the manuscript is accepted for publication, Merck 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. Merck reserves the right to redact proprietary information. Merck will also allow a medical journal editor to review the complete study database at our facility, on request.

- **Authorship and accountability:** Per ICMJE guidelines<sup>1</sup>, an author is generally considered to be anyone who provides substantive intellectual contributions to a published study. Specifically, authorship credit should be based on 1. substantial contributions to study conception and design, or acquisition of data, or 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. *All three 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. Subject to journal policy, we will list the names of all investigators at the end of a manuscript. The lead author is generally responsible for defending the content and the integrity of the manuscript when submitted to a journal.
- Merck staff or contract writers hired by Merck may facilitate the development of a manuscript when the lead author provides oversight and direction; the efforts of the writers should then be acknowledged in the publication.

### ***Communicating Trial Results***

Merck is committed to providing study investigators with the trial results and encourages those investigators to share the results with their patients/volunteers, as appropriate.

### **References**

- 1 Uniform requirements for manuscripts submitted to biomedical journals (and separate statements). International Committee of Medical Journal Editors. *Ann Intern Med* 1997;126:36-47. Updated version (April 2010) is 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;276:637-39.
- 3 Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Ann Intern Med* 2010;1-7. Available at:

<http://www.annals.org/content/early/2010/03/18/0003-4819-152-11-201006010-00232.full.pdf+html> and at: <http://www.consort-statement.org>

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