GUIDELINES FOR PUBLICATION OF CLINICAL TRIALS IN THE SCIENTIFIC LITERATURE

Our Company Philosophy

At Merck Sharp & Dohme LLC, Rahway, NJ., USA (the "Company"), 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] Good Publication Practice,[3] and the individual journals.

Scope of the Guidelines

These guidelines apply to the publication of results from interventional clinical trials in participants involving a Company product and from preventive interventional trials in healthy participants involving a Company product (e.g., vaccine trials) that are sponsored and monitored by the Company 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.

- **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 participants (or preventive interventional trial in healthy participants) 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 ClinicalTrials.gov, EudraCT, Clinical Trial Information System (CTIS) , or https://www.msd.com/research/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 https://www.msd.com/research/clinical-trials/].

- **When we publish:** For registered clinical trials as described above, a manuscript will be submitted within 18 months after the last participant'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.[2] We will allow investigators to review the complete study database at our facility, on request. 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 https://trialstransparency.msdclinicaltrials.com/policies-perspectives.aspx

- **Authorship and accountability:** Per ICMJE recommendations,[1] 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. Shulz 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.

3. DeTora LMF, Toroser D, Sykes A, et al. Good Publication Practice (GPP) Guidelines for Company-Sponsored Biomedical Research: 2022 Update. Ann Intern Med 2022;175:1298-1304.