Novartis Guidelines for the Publication of Results from Novartis-Sponsored Research

January 2018

Introduction

Novartis is committed to following and applying high ethical standards, and supports the industry standards for publications as outlined in the British Medical Journal's (BMJ) *Good publication practice for communicating company sponsored medical research: the GPP2 guidelines*, (BMJ 2009;339:b4330) and the International Committee of Medical Journal Editors' (ICMJE) *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*, (www.icmje.org). The scope of this guideline covers the principles and practice (i.e., authorship, disclosure of conflict of interest, etc.) for publications from Novartis-sponsored research across all divisions. Novartis-sponsored research includes studies where Novartis takes responsibility for the initiation, management and/or financing of the study. Studies that are initiated by a third-party sponsor and are merely 'supported' by Novartis (being strictly limited to the provision of funds and/or drug supply upon unsolicited request by third-party sponsor) are qualified as independent third-party sponsored investigator-initiated trials (IITs). As such, publication of results from IITs is the responsibility of the third-party sponsor. Therefore, the guidelines described in this document are out-of-scope for third party sponsored investigator initiated trials (IITs).

Within this guideline, "publications" are defined as abstracts, posters or oral presentations at scientific congresses, and articles in scientific or medical journals.

Publication Practice: Key Principles

The key principles that will be followed for Novartis-sponsored, research-related publications are:

- Novartis supports the publication of study results for its innovative medicines in a timely manner, whatever their outcome. Novartis policy is not to withhold, veto or suppress data. However, due consideration must be given to the rights of Novartis to protect confidential and/or patentable information, and to the protection of personal information, in particular patient privacy.
- Review by Novartis of draft publications by clinical investigators in advance[1] of submission/presentation of publication is designed to:
    - Confirm the accuracy of the data
    - Verify that proprietary information is not being inadvertently disclosed
    - Secure intellectual property rights, as needed
    - Provide any relevant supplementary information
- Publication of partial data (unless planned in the protocol) is discouraged. As a matter of scientific rigor and fairness to all investigators involved in a clinical study, and in accordance with the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature, issued by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Japan Pharmaceutical Manufacturers Association (JPMA), and Pharmaceutical Research and Manufacturers of America (PhRMA), it is Novartis policy for multicenter clinical studies that:
    - The first publication in journal, or presentation at a congress, be based on consolidated data from all centers, analyzed as stipulated by the protocol and agreed upon by investigators before trial initiation.

[1] At least 15 business days for review of an abstract, poster or oral presentation, and 30 business days for that of a journal submission. In a few instances, and where the planned publication contains potentially patentable subject matter, additional time of up to four months may be required for preparation and filing of patent applications.

    - Multicenter trials are designed to take full account of data accumulated from all centers (sample sized, powered with appropriate error rates), and Novartis discourages presenting or publishing data gathered from a single, or small group of centers, unless agreed to by study investigators (e.g., Study Steering Committee) and Novartis. Center-specific analyses have greater variability and lead to exaggerated observed-treatment effects that are inherently less reliable. Valid conclusions regarding the primary endpoint of a clinical trial can only be based on the analyses predefined by the protocol.
- Study results should be published according to the contracted protocol agreements.
- Marketing (i.e. non-Sales) associates may participate in the annual publication-planning process with the purpose of providing input into the development of publication plans; however, they may not manage, facilitate, control or otherwise influence the development, drafting, review or editing of the content of a scientific publication or public disclosure. Sales associates cannot participate in any part of study disclosure, publication planning or development process.

Authorship of Publications

Novartis follows the ICMJE authorship guidelines (www.icmje.org). Authors (including Novartis associates who may qualify for authorship), must therefore satisfy all of the following ICMJE authorship criteria:

1. Substantial contributions to conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work 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 in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Acquisition of funding, data collection, general supervision of the research group, or overseeing the conduct of the study alone does not justify authorship.

All authors must fulfill all four ICMJE authorship criteria during publication development to be included as authors on the publication.
Selection of authors and the position of their names in the publication should be discussed and aligned with the study committee/team members, prior to the start of the publication. The authors must respect the guidelines of the journal or congress to which the publication is to be submitted. Authors will not receive remuneration for their writing of a publication, either directly from Novartis or through the professional medical writing agency.

Professional medical writers may play an important role in assisting authors with publication development. Upon agreement from the authors, medical writing/editorial assistance may be provided by a professional medical writer, which may be funded by Novartis, consistent with industry standards. Such assistance may involve drafting/editing the publication under the authors' guidance, and other general editorial or administrative support (e.g., help with publication submission) as needed. Authors retain control over the publication content and decisions associated with publishing (e.g., journal or congress selection, type of publication, etc.). In such instances where medical writing/editorial assistance is provided, there must be a formal acknowledgment of a medical writer or editor and his/her professional affiliation within the publication, as well as disclosure of funding of the medical writing/editorial support.

Possible differing views may be voiced during the course of the preparation of a publication, e.g., in the analyses/interpretation of the data and the preparation of the publication. These views should be acknowledged and dealt with in a transparent manner. Ideally, they should be

reconciled through dialogue respectful of the differing opinions and expertise of all those involved in this joint research effort (i.e., the investigators/researchers and the Novartis research team). Where opinions continue to diverge despite mediation efforts, authors ultimately have authority over the content of their publications, but Novartis non-authors may independently present their views.

Disclosure of Possible Conflicts of Interest

Novartis will disclose/report any payments or transfer of value made to healthcare professionals and/or their institutions for research studies and third-party medical writing support for publications, according to industry code, and country laws and regulations.

As part of its commitment to full transparency in publications, Novartis supports the full disclosure of any actual and potential conflicts of interest of financial and non-financial nature by all authors, writers, and other contributors to publications that could be perceived to bias their work or inappropriately influence their professional judgment. Such conflicts of interest can include, but are not limited to:

- Any financial ties, obligation, or personal relationships (including those of immediate family members) to the research sponsor or other companies such as contractual relations, consultancy fees for scientific, government, or legal services, funding of professional medical writing/editorial assistance, or equity in the company.

In case of actual conflicts of interest, Novartis believes that these conflicts should be managed appropriately to ensure data integrity, so as not to compromise the safety or the well-being of patients. In addition, the role of Novartis in the scientific research must also be disclosed. Novartis recommends that these disclosures are made public in all articles published in peer-reviewed journals as well as in abstracts (where space allows), posters and oral presentations at congresses, regardless of whether disclosure is requested by the journal or congress.

Privacy

Novartis respects individuals' rights to the privacy and the confidentiality of their personal information, including those of its scientific partners and of individuals enrolled in Novartis-sponsored clinical studies in accordance with applicable laws and regulations.

Novartis is committed to implementing the necessary safeguards to ensure that the personal information gathered by Novartis, with the knowledge and expressed consent of the individuals concerned, is adequately protected.

Novartis keeps this information accurate, complete and up-to-date, in accordance with the purposes for which it was collected. It must be retained for only as long as needed to meet the legitimate purposes for which it was collected and in compliance with Novartis data retention policies and legal requirements.

Access to Data for Innovative Medicines

Participating study investigators
Novartis supports the publication of scientifically rigorous analysis that is relevant to patient care, regardless of a positive or negative outcome. To facilitate interpretation and publication of data from Novartis-sponsored studies, Novartis will ensure that authors of the study publication have access to the study results and analyses for planned publication.

Independent external researchers
Qualified external researchers can request access to anonymized patient-level data, respecting patient informed consent, through the following web portal: www.clinicalstudydatarequest.com.

This commitment commences with innovative medicines approved by regulators in the United States (US) and European Union (EU) in 2014 (for a new medicine or a new indication), while maintaining the ability to publish the relevant clinical trial results in scientific journals. Novartis will:

- Provide access to anonymized, patient-level, analyzable data sets from clinical trials (that meet eligibility criteria as noted on www.clinicalstudydatarequest.com) to qualified external researchers upon submission of a research proposal, approval by an external Independent Review Panel (IRP), and a signed data-sharing agreement. The signed data-sharing agreement will include the researcher's agreement to share results of their research analyses with Novartis and, if these results have implications for public health, with regulatory authorities prior to any publication. To promote objectivity and scientific rigor, an IRP comprising of independent global experts external to Novartis will assess the merit and value of all research proposals. The IRP will consider, among other factors, whether the research question is clearly defined and whether there is a well-documented Statistical Analysis Plan. The IRP will be the final decision-maker on the availability of data to a researcher.
- Release patient-level data beginning with innovative medicines that received regulatory approval in both the EU and US on January 1st, 2014 and onwards, unless approval is only sought in either the EU or the US. Data-sharing requests for clinical trial data for EU/US-approved drugs before January 1, 2014 will be considered on a case-by-case basis by the Data Sharing Portfolio Review Committee, and data provided if materially possible (e.g., it may not be possible to provide data from studies that are more than 10 years old, or if patient informed consent does not allow data sharing). The requested clinical studies must support the approved indication and must have been accepted for journal publication.

Journals

- Upon journal request, in cases where the redacted protocol and analysis plan have not been publicly disclosed, Novartis may provide a copy of the protocol and pre-specified data analysis plan.
- Upon journal request, Novartis may provide anonymized patient-level data for re-analysis/verification