NOVARTIS | Reimagining Medicine

Novartis Medical Affairs

Position on Scientific Publications

Introduction

Our purpose at Novartis is to reimagine medicine to improve and extend people's lives.

Our strategy is to deliver high-value medicines that alleviate society's greatest disease burdens through technology, leadership in R&D, and novel access approaches.

A fundamental element of developing new medicines is the collection and analysis of safety and efficacy data through clinical trials and additionally capturing real world data on their use. Scientific publications, (i.e., articles in scientific journals, scientific congress abstracts, and corresponding posters and oral presentations), facilitate sharing and interpretation of these data[1] to help advance treatment, enhance disease knowledge, and support healthcare policy decisions.

Therefore, Novartis commits to ensure scientific publications from our trials and research are developed in an ethical, unbiased, consistent, and transparent manner, upholding the integrity of Novartis, and achieving our vision to become the most trusted medicines company in the world.

Key principles

- We commit to following publication standards, as outlined in the International Committee of Medical Journal Editors (ICMJE) Recommendations[2] and Good Publication Practice (GPP) Guidelines[3].
- We ensure Novartis-sponsored scientific publications are fair-balanced, accurate and non-promotional. We give due consideration to the rights of Novartis (or of third parties with whom Novartis has contractual obligations) to protect confidential and/or patentable information, and to the protection of personal information, in particular, patient privacy.
- We follow established processes and standards to ensure transparency of author interactions, clarity of author responsibilities and publication-related disclosures (e.g., non-author contributions, use of medical writers[4], and funding support).
- We support full disclosure in the publication of any author affiliations and conflicts of interest, including financial or personal relationships that could be perceived to bias their work or inappropriately influence their professional judgement.
- We do not financially compensate for publication authorship.

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Publication of results

- Aligned with Novartis' commitment to clinical study data transparency[1], results from all Novartis-sponsored clinical research are considered for publication in the scientific literature regardless of a positive or negative outcome.
  - At a minimum, results from all Phase 3 clinical trials and any clinical trial results of significant medical importance will be submitted to a peer-reviewed journal, including investigational products for which the development program was discontinued.
- Novartis-sponsored scientific publications undergo appropriate reviews to ensure data accuracy and integrity, and safeguard company intellectual property (IP). The Novartis review of draft scientific publications will take place in advance of author approval and final submission.
- Novartis associates in commercial roles will neither participate in any activities related to tactical planning and implementation, nor in the development, review, or approval of individual publications.

Authorship requirements

What we do	What we don't do

• We adhere to ICMJE authorship criteria to ensure that all named authors have provided a substantial contribution to the research, development, and approval of the scientific publication.
• We have a robust framework that ensures authorship transparency and clarifies responsibilities including:
  ○ Provision of author agreements to clearly define the roles of authors and Novartis in the publication development process.
  ○ The role of medical writers[4].
  ○ Conflict of interest and disclosure requirements.
	• We do not financially compensate for publication authorship.
	• We do not support authorship by any individual who does not meet the ICMJE authorship criteria for a specific scientific publication.
	• We do not approve authorship by any US health care professional who is on the FDA Debarment List and suspended to participate in such activities.

1. Other aspects of data sharing beyond the scope of scientific publications can be found in the Clinical Study Transparency Position Statement, available on Novartis.com.
2. International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Updated January 2024. Accessed at www.icmje.org/recommendations on 6 February 2024.
3. DeTora LM, 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. doi:10.7326/M22-1460.
4. A medical writer is defined by GPP as 'a colleague who supports the work of individual publications; this may be by crafting text, tables, and figures and/or managing the review and approval process.' Authors must agree to medical writer assistance before work begins on the publication, and any assistance is disclosed and acknowledged in the final publication.

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