

POLICY – SCIENTIFIC PUBLICATIONS

Objective

This document defines Idorsia's policy for the development of publications related to Idorsia-sponsored non-clinical and clinical research and/or publications supported by Idorsia.

Scope and Applicability

The Idorsia Policy for Scientific Publications is applicable to all scientific, technical and medical publications supported by Idorsia and/or related to Idorsia-sponsored non-clinical and clinical research.

Publications originating from research initiated and conducted by external investigators or commercial partners for which Idorsia only provides drug supply and / or financial support are not covered by this policy. However, Idorsia will provide and encourage the use of this policy in these situations, communicating Idorsia's commitment to transparency, openness, and ethical publication to these external partners, as appropriate.

Publications are defined as (1) contributions to print and electronic scientific and biomedical journals or (2) oral/audiovisual or written presentations at scientific and medical meetings. This policy covers peer-reviewed publications (e.g. original research articles, case reports, review articles) and non-peer-reviewed publications (e.g. abstracts, posters, lectures, book chapters, journal supplements and conference proceedings).

This policy is applicable to all Idorsia employees, and as appropriate, to those parties with whom Idorsia contracts (e.g., clinical research organizations, medical writing agencies or consultants) who are involved in generating scientific, technical & medical publications covered under this policy.

This policy is designed to be applied in conjunction with guidelines from the International Committee of Medical Journal Editors (ICMJE), internationally recognized reporting guidelines (CONSORT, STROBE, MOOSE, PRISMA, etc.), individual journal guidelines, and good publication practice guidelines, such as Good Publication Practice (GPP); and position statements from the European Medical Writers Association (EMWA), American Medical Writers Association (AMWA) and International Society for Medical Publication Professionals (ISMPP), etc.).

Content

Commitment to publication

Idorsia supports the timely publication by its researchers and clinical trial investigators of Idorsia-sponsored non-clinical and clinical research that is of scientific or medical importance. For Idorsia-sponsored clinical trials, the timing of publications is further described in Idorsia's Policy on the public disclosure of clinical research information.

Non-clinical and clinical research results should be reported in an objective, accurate, balanced and complete manner, with a discussion of the strengths and limitations of the research, as outlined in several guidance documents.

Idorsia reserves the right to review any publications or other public disclosures relating to Idorsia-sponsored research before they are submitted for publication or otherwise publicly disclosed by external researchers or study investigators. Idorsia is committed to responding in a timely manner. Idorsia does not suppress or veto publications or other appropriate public disclosures of Idorsia-sponsored research; however, in rare cases, it may be necessary to delay publication or other public disclosures for a short time to allow Idorsia to seek intellectual property protection.

In the case of conflicts arising due to differing opinions or concerning data interpretation, Idorsia will mediate and help resolve any and all issues through objective scientific discussion and with deference toward ensuring patient welfare.

Authorship

Idorsia endorses the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE) and adopted by the Pharmaceutical Research and Manufacturers of America (PhRMA). Authorship credit should be based on substantial contributions to 1) conception and design, 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. Authors should meet all three conditions. However, some journals may have a more narrow definition of authorship. If so, this convention is to be followed for such journals.

Pursuant to the ICMJE criteria, general supervision of the research group is not sufficient for authorship. Similarly, participation solely in the acquisition of funding or collection of data does not qualify for authorship.

Authorship criteria apply equally to external investigators and to Idorsia employees or contractors hired by Idorsia.

When feasible, authorship should be discussed and agreed at the outset of a research project to avoid later misunderstandings and conflicts. Each author must consent to have their name included in the list of authors. The named corresponding author must take responsibility for leading the overall content development and working closely with co-authors. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Idorsia staff or contractors hired by Idorsia, such as medical writers or project coordinators, may facilitate the development of publications. Such supporting personnel must act in collaboration with the authors. Their contributions should be recognized appropriately in resulting publications - either as a named author, a contributor, or in acknowledgments, depending on their level of contribution.

Data Access

All authors of a publication relating to Idorsia-sponsored research are provided with the relevant documentation that is needed to support the planned publication. For clinical trials, authors will be provided with the final protocol, summary results of the overall trial, statistical tables and figures.

Upon request, Idorsia will provide a copy of the relevant final protocol to any journal considering publication of a submitted manuscript, subject to the condition that such information is kept confidential and returned to Idorsia following the article's publication.

Use of Professional Medical Writers

Idorsia may offer authors the assistance of professional medical writers to facilitate the development of publications. Such collaborations must follow ethically acceptable practice, as outlined in several internationally recognized guidance documents (GPP; EMWA; AMWA; ISMPP).

The named author(s) must determine the content of the publication and retain overall responsibility for it throughout the publication development:

- the medical writer should begin drafting the publication only after consultation and discussion with the named author(s)
- the named author(s) should comment on all versions of the publication and approve the final version before it is submitted to a journal
- the contribution of the medical writer must be recognized in any resulting publication in line with their level of contribution and the funding source for their assistance disclosed

Payments

External researchers and investigators are compensated by Idorsia for conducting clinical or non-clinical research but no authorship compensation is made for publishing the results of such research. Idorsia also does not compensate for authorship of review articles.

In the case of congress contributions (e.g. posters or oral presentations), Idorsia may reimburse the presenting author for travel, lodging, and expenses.

Disclosures

Idorsia fully supports openness and transparency in any publication covered in this policy.

Authors should disclose any potential conflicts of interest including any financial or personal relationships that might be perceived to bias their work.

Authors should acknowledge the contributions by individuals who have supported the development of the publication (e.g. medical writers) and disclose the funding source for such support. Authors should also disclose the fact that research was sponsored by Idorsia and describe the role of Idorsia, if any, in the design, conduct and analysis of the research, and the decision to submit the research for publication. If Idorsia had no such involvement, the authors should state so.

Glossary

Idorsia -sponsored - Idorsia acts as Sponsor and assumes all the responsibilities of a Sponsor.

Idorsia -supported - Idorsia supports financially and/or through the supply of drug, but does not act as Sponsor.

Clinical research - Clinical trials (phase I-IV) and other types of clinical research, such as prospective observational research.

Clinical trial - Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Investigator-initiated study - A study where the investigator initiates and conducts the study and acts as the sponsor. The responsibilities include both those applicable to an investigator and a sponsor.

Observational research - Epidemiological study that does not involve any intervention, experimental or otherwise. Such a study may be one in which nature is allowed to take its course, with changes in one characteristic being studied in relation to other characteristics.

Sponsor - An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial and non-clinical research projects.

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Idorsia is an independent biopharmaceutical company based on science and innovation. The company is specialized in the discovery and development of small molecules, to transform the horizon of therapeutic options. It is headquartered in Allschwil/Basel, Switzerland and is quoted on the SIX Swiss Exchange (tickersymbol: IDIA). All trademarks are legally protected by their respective owners.

Disclaimer: This fact sheet has the sole purpose to provide members of the public with general information about the activities of Idorsia. The forward-looking statements in this fact sheet are based on current expectations and belief of company management, which are subject to numerous risks and uncertainties.

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