

POLICY SCIENTIFIC PUBLICATIONS

OBJECTIVE

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

SCOPE AND APPLICABILITY

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

Publications originating from research initiated and conducted by external investigators or commercial partners for which Actelion only provides drug supply and / or financial support are not covered by this policy. However, Actelion will provide and encourage the use of this policy in these situations, communicating Actelion'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 Actelion employees, and as appropriate, to those parties with whom Actelion 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.).

REVIEW AND APPROVAL

Corporate Affairs and Compliance 06-Jan-10 signed ¹
Global Medical Communication 06-Jan-10 signed ²
CEO 06-Jan-10 signed ³

¹ Author, signs for correctness and completeness

² (Only if applicable) Reviewer, signs for control of correctness and completeness

³ Approver, signs for the release of this document

CONTENT

COMMITMENT TO PUBLICATION

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

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

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

AUTHORSHIP

Actelion 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 Actelion employees or contractors hired by Actelion.

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.

Actelion staff or contractors hired by Actelion, 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 Actelion-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, Actelion 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 Actelion following the article's publication.

USE OF PROFESSIONAL MEDICAL WRITERS

Actelion 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 Actelion for conducting clinical or non-clinical research but no authorship compensation is made for publishing the results of such research. Actelion also does not compensate for authorship of review articles.

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

DISCLOSURES

Actelion 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 Actelion and describe the role of Actelion, if any, in the design, conduct and analysis of the research, and the decision to submit the research for publication. If Actelion had no such involvement, the authors should state so.

GLOSSARY

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

Actelion-supported - Actelion 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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Actelion Pharmaceuticals Ltd is a global biopharmaceutical company headquartered in Allschwil/Basel, Switzerland. Actelion concentrates on discovering, developing and marketing innovative drugs for high unmet medical needs. The company is quoted on the SIX Swiss Exchange (tickersymbol: ATLN).