

AstraZeneca

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Approvals

Approval Reason

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GLOBAL STANDARD Publications

KEY PRINCIPLES

We commit to publishing results from our studies involving human subjects in peer-reviewed journals in a timely way to demonstrate transparency.

We commit to publishing results from human studies, even if they are unfavourable to us.

We follow ICMJE Recommendations and Good Publication Practice guidelines in sharing objective and meaningful scientific information about our studies without compromising our intellectual property.

WHY IT MATTERS

Science is at the core of everything we do, and our company reputation is often judged by the integrity of our publications. Publications are important to the practice of medicine in supporting diagnosis, treatment, and health care policy decisions. Because published information from our research can change standards of care, it is important that we gather and publish our scientific, clinical, and real-world study data, as well as related information, in an unbiased, objective, transparent, and ethical manner.

WHAT YOU NEED TO KNOW

- We publish clinical study, real-world evidence (RWE) and other medically or scientifically important research results, whether positive, negative or inconclusive, while protecting patient confidentiality.
- We ensure that our publications are fair balanced, truthful, accurate, and not misleading and that they are never intended for purposes of off-label or pre-approval promotion.
- We provide authors with access to relevant study data.
- We issue author agreements that clearly articulate authorship responsibilities and obligations to abide by the principles of Good Publication Practice and the International Committee of Medical Journal Editors (ICMJE) criteria.
- Our publications acknowledge non-author contributors, including professional writers.
- Our publications disclose authorship affiliations and any personal or financial relationship that could be seen as having the potential to bias an author's work.
- Our publications acknowledge all financial support for publications and funding sources for the research being reported.
- We do not financially compensate authors for publication authorship.
- We document all other payments, reimbursements, and transfers of value relevant to the publication in accordance with regulatory requirements.
- We ensure that AstraZeneca publications from all functional areas undergo appropriate review and Publications Sign-Off (PSO) to confirm medical and scientific accuracy and to safeguard our intellectual property.

PUBLICATION OF RESULTS FROM HUMAN STUDIES

- We make good-faith efforts to publish results from all research involving humans (clinical and RWE) or human data in a timely manner, regardless of whether the study outcome was positive or negative.
 - At a minimum, clinical study results from phase 3 onward and RWE, in addition to any research results of significant medical importance, will be submitted to a peer-reviewed journal. This includes investigational clinical products from discontinued programmes and post-hoc analyses of medical importance.
 - We also will publish results from phase 1 and 2 clinical studies for products that achieve market approval in one or more countries.
 - We will publish negative or neutral studies as a citable peer-reviewed journal article and not only as a congress abstract submission or clinical trial website entry.
 - We submit primary manuscripts for studies from phase 3 onwards within 12 months of study completion, which is defined as last subject, last visit for clinical studies, last patient observation for non-interventional studies, and completion of data analyses for retrospective database or registry analyses.
- We give authors, upon request, access to copies of documentation related to the research, such as the study report, final protocol, statistical tables, and figures, as well as individual-level study data under conditions that protect patient confidentiality and intellectual property.
 - We provide a redacted copy of the protocol and the statistical analysis plan with intellectual property and personally identifiable information redacted in accordance with the AZ redaction guidelines, when requested by a journal considering a submitted manuscript for publication. Redactions should be completed in compliance with Global Guideline for Redaction of Clinical-Regulatory Documentation AZDoc0004788
- We include the unique trial identifier in all publications and website postings of clinical studies.

PUBLICATION OF RESULTS FROM NONHUMAN STUDIES

- In the interest of transparency, we will publish scientifically meaningful results, following external publications guidelines and best practices, for the benefit of the wider scientific community.
- We commit to publishing all results from nonhuman studies where patient safety is a consideration.
- We ensure that all publications from nonhuman studies undergo mandatory PSO to confirm scientific accuracy and safeguard our intellectual property and patents.

PUBLICATION PLANNING

- We develop publication plans to meet specific educational, scientific or data dissemination objectives. Publication plans are not developed with the intent to promote off-label use of a product or to unduly influence prescribers.

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- These plans are developed and approved in advance of starting work on the publications and they are reviewed at least annually in accordance with appropriate global, local or functional governance processes.
 - All planned publications related to an AstraZeneca product will be communicated to the relevant Publications Lead/Team for that product before being written so that they can be considered in context with the approved publication plan.
 - Marketing companies will share their product or therapy area publication plans with the Global Publications Lead/Team quarterly and prior to starting work on proposed publications, to ensure global alignment and to reduce the chance of delays during PSO.
 - We avoid developing publications using data from patients enrolled in Early Access Programs or other small patient populations as there is the potential to compromise patient privacy and to overstep any regulatory restrictions of the program.

GENERAL AUTHORSHIP REQUIREMENTS

- We follow the criteria set forth by ICMJE for authorship selection to ensure that named authors have provided substantive intellectual contributions to the research work and related publication and that “guest authors” are not included on our publications. To meet these criteria, authors will:
 - provide substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work;
 - draft the work or revise it critically for important intellectual content;
 - approve the final version to be published; and
 - agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved.
- Authorship is granted based on the level of intellectual contribution to our research and the related publication.
 - We do not offer authorship as an incentive or reward for services rendered, such as patient enrolment, technical assistance or routine operational support for the study.
 - We also do not offer “guest authorship” to individuals who did not provide substantive intellectual contributions to the design, conduct, analysis, or interpretation of the research to be published.
- We make a good-faith effort to include appropriate external clinical investigators as authors on publications involving clinical trial data to ensure that analysis and interpretation of our study data benefit from contributors having direct and recent experience with clinical practice and patient care.
- We avoid having excessive numbers of authors on our publications to ensure that each named author can make a substantial intellectual contribution. Contributors who do not qualify for authorship (ie, who meet fewer than all four of the ICMJE criteria) are acknowledged as non-author contributors or collaborators.
- We apply the ICMJE authorship requirements to both external investigators and internal company contributors.
- We work only with those health care professionals who remain in good standing in their medical practices. We further ensure that US health care professionals have not been debarred or suspended from participating in US Federal health programs before inviting them to participate in a

publication, as these individuals must not be engaged as authors for AZ-supported publications.

- For employees leaving AstraZeneca, authorship on publications from the research they have contributed to will depend on their ability to meet all ICMJE authorship recommendations and any other conditions relating to confidentiality and conflict of interest.
 - Continued authorship roles of departing employees are agreed upon through discussions with their project leaders, line managers, and publications teams before they leave the company and are documented in writing by the line manager.
 - In the event of changes to aspects of the design, concept, analysis, or interpretation of a study or project, a former employee may still qualify for authorship if all ICMJE criteria are fulfilled.
 - We list former employees in the author list with their affiliations listed as AstraZeneca to indicate where the research was conducted. Their current affiliation is listed as a footnote or in the Acknowledgments unless journal guidelines state otherwise.

AUTHOR AGREEMENTS

- We issue author agreements to external authors prior to initiating work on AstraZeneca-sponsored publications, in line with Good Publication Practice.
 - It is good practice to issue these author-specific agreements even if publication policy principles have been included in their clinical study or research agreement, as they provide a more comprehensive description of author requirements
 - Author agreements should also be provided to AstraZeneca authors who leave the company and who are no longer covered by our policies and standards.
- We may, under a service agreement at fair market value rates, pay an author fees for non-author services associated with publication development, such as statistical analysis. Any fee for service must be disclosed in the publication.
- We may reimburse reasonable travel and registration expenses for presenter attendance at scientific meetings.

USE OF PROFESSIONAL WRITERS

- We may employ professional medical writers (company employees, external consultants, or communication agencies) to assist in developing publications and presentations.
- We ensure that collaboration between professional medical writers and authors adheres to ethical publication practice, as follows:
 - authors must agree to the medical writer's involvement,
 - authors provide input and approve the general content and direction of the article before it is written and through all stages of development,
 - authors are responsible for data interpretation and for providing opinion on the significance of the data,
 - authors approve the final version of the article before it is submitted to a journal and retain full responsibility for the article's content, and
 - contribution of professional writers and their funding by AstraZeneca must be fully acknowledged in the publication

in line with their level of contribution.

- Medical writers from communication agencies generally do not meet accepted authorship criteria, but there may be exceptions (for example, if they contribute substantially to a review article). If writers qualify for authorship they should be listed as authors and their financial relationship with AstraZeneca should be disclosed.
- We share this publication standard with professional writers or external independent communications agencies working with us, and they will acknowledge in writing that this standard has been read and understood.

PUBLICATION REVIEW AND SIGN-OFF PROCESS

- We review and sign-off on publications sponsored by AstraZeneca prior to submission to a journal or congress, using the PSO process. Failure to submit publications for PSO represents a compliance violation subject to auditing and reporting to Compliance.
 - PSO is also required for all publications related to external collaborations where an AstraZeneca employee serves as author.
 - PSO is not required for publications related to research done by an employee at a previous institution or company. For these publications, AstraZeneca authors should list their affiliation as the institution or company where the research was performed and indicate that they are currently employed by AstraZeneca in the Acknowledgments or Disclosures section.
- We conduct PSO without influencing the opinions of investigators or authors, acknowledging that authors are publicly accountable for work they publish and have the right to make decisions on content as long as scientific accuracy, intellectual property, and patient privacy concerns have been addressed.
- Company personnel in commercial roles will not participate in publication content development, review, or sign-off processes, although they may be involved in publication strategy development as part of a multidisciplinary publication planning team.
 - Exceptions to this restriction will be made for Global Product Leads or personnel in Commercial functions that conduct publishable research.

PRIOR AND DUPLICATE PUBLICATION

- Publication of a primary manuscript (first publication of primary endpoints) in a peer-reviewed journal is the most important communication of our study results. We ensure that the primary publication is not compromised by prior inappropriate communication activities, including case study and data subset reporting from individual sites.

Abstracts, posters, oral presentations, and posting of clinical trial results and plain language summaries on public trial registries or trialsummary.com does not constitute prior publication and will not compromise publication in a peer-reviewed journal. Posting of congress presentations (oral and poster) on the congress or QR-code websites should not jeopardize journal publication, but such postings should be considered on a case-by-case basis.

- Press releases reporting on abstracts, posters, and oral presentations do not constitute prior publication as long as they are not disseminated promotionally or supplemented with additional data beyond that contained in the abstract or

congress presentation.

- We generally do not submit duplicate publications to separate journals or congresses, although this sometimes may be acceptable with permission of the primary journal or congress in order to publish a translated version or present an 'encore' abstract, providing that the original publication is cited. Such publications will reference all potentially duplicative submissions and previous communications of the same or similar work.
 - We abide by the rules of scientific congresses regarding encore presentations. Most congresses do not accept duplicate presentations, but 'encore' presentations can be justified when permitted by a congress and the attendee demographics differ from the initial congress (eg, different discipline or geographical variation).
 - Encore abstracts should not be submitted to a congress if the data has already been published in a peer-reviewed journal.
 - Posting of manuscripts to preprint servers (e.g, BioRxiv, ChemRxiv, MedRxiv) prior to submission to a peer-reviewed journal is becoming more commonplace, and a growing number of journals now consider this acceptable. Policies of targeted peer-reviewed journals regarding this practice should be reviewed in advance of posting to a preprint server.
- Multiple publications arising from a single study will include the unique trial identifier, when available, and cite the primary publication.
- The Clinical Trial Transparency Registries Team and Study Manager will be notified of all upcoming publications in peer-reviewed journals related to clinical and RWE studies so that regulatory and results posting requirements can be satisfied.
- We do not engage in plagiarism, even if it is from the author's previous work (self-plagiarism). We will obtain copyright permission and will provide appropriate citation to reuse copyrighted work.

AUTHOR DISCLOSURES

- We require all authors to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work.
- AstraZeneca authors will disclose that they are employees of AstraZeneca and that they have ownership, options, and/or interests in AstraZeneca stock, if applicable.

PREDATORY PUBLISHERS

- In alignment with ICMJE recommendations, we will not submit publications to known predatory journals or congresses that use an exploitive business model involving charging publication fees without providing the standard editorial, peer review, and publishing services.

DIGITAL PUBLICATIONS AND SUPPLEMENTAL MATERIALS

- It is acceptable to develop supplemental digital content (eg, slide presentations or audio abstracts) to accompany a published manuscript or

congress presentation when such content is a standard offering of the journal or congress.

- It is also acceptable to make congress presentations available digitally through the use of QR codes when allowed by the congress and local regulatory guidelines
- We ensure that AstraZeneca-sponsored supplementary/enhanced content is submitted for PSO before it is provided to a journal or other external party for publication.