ASTRAZENECA STANDARD - PUBLICATIONS

KEY PRINCIPLES

- **We commit to publish results from our research studies in peer-reviewed journals in a timely way, to demonstrate transparency.**
- **We commit to publish irrespective of whether results are positive, negative or inconclusive.**
- **We follow the International Committee of Medical Journal Editors (ICMJE) Recommendations and Good Publication Practice (GPP) guidelines by sharing objective and meaningful scientific information about our studies.**

1. WHY IT MATTERS AND TO WHOM

The AstraZeneca (AZ) Publications Standard sets out the mandatory global publication principles, which are central to the Chief Medical Officer (CMO), supported by AZ's Code of Ethics and governed by the R&D Framework.

This Standard applies to all entities and affiliated companies within the AstraZeneca group of companies. Hence, unless otherwise stated, any reference to "AstraZeneca" or "AZ" herein, shall be deemed to be a reference to all entities within the AstraZeneca group of companies.

Publications are important for the practice of medicine in supporting patient care, diagnosis, treatment, and health care decision making.

Published information and data from our research is an asset that can transform standard of care. Therefore, it is important that we publish our scientific, clinical, and real-world evidence study data in an unbiased, objective, transparent, and ethical manner.

This Standard applies to all AZ employees, including permanent and contract staff and third parties of AZ and affiliate companies, who are responsible for, or involved with, publication development and/or management.

2. WHAT YOU NEED TO KNOW AND WHY

AZ commits to publish Clinical Study, Real-World Evidence (RWE), and other medical or scientifically important research results, whether positive, negative, or inconclusive, while ensuring patient confidentiality/data privacy, in line with local laws and regulations. AZ must ensure that the publications are accurate, fair, and impartial, and that published information and data are never intended to be used in either off-label or for pre-approval promotional purposes.

Publications are defined as manuscripts, abstracts, slide presentations, posters, journal supplements, letters to editors and publication extenders (as defined in Section 3.11), from any source and in any format, covering AZ products, projects, processes and know-how. Further details on definition and scope are available in the publication SOPs – see Reference in Section 5.

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3. REQUIREMENTS

3.1 Publication Principles

AZ commits to follow good publication practice to ensure high ethical standards are maintained in line with relevant publication guidelines and industry standards, including International Committee of Medical Journal Editors (ICMJE), Good Publication Practice (GPP2022) and other internationally recognised reporting guidelines (see References in Section 5), summarised according to the following guiding principles:

- Publications are not developed with the intent to promote off-label use of a product or to unduly influence prescribers.
- Manuscripts are submitted to legitimate peer-reviewed biomedical journals (e.g., indexed in databases such as Pub Med, Embase, Scopus). Likewise, abstracts are only submitted to legitimate scientific congresses. For all activities, we avoid submissions to predatory or fake journals and congresses (as defined in Section 3.10).
- Publications and their supplementary materials should not enable reidentification of study patients or contain data elements which allow direct or indirect identification of an individual. Refer to **"AstraZeneca Global Guideline for Redaction of Clinical-Regulatory Documentation"**– see Reference in Section 5.
- Publications should not be duplicative or redundant with prior publications unless there is a compelling medical/scientific need to reanalyse, reinterpret, or translate the prior publication. Encore congress publications are allowed, see Section 3.8 for guidance.
- AZ provides assigned authors of publications with access, via approved processes, to relevant study data, as well as supporting information, such as protocols, statistical analysis plans (SAPs), and other product information needed to support the development of publications.
- Some documents (e.g., study protocol, statistical analysis plan) may require redactions before release/publication of a manuscript which must be completed in compliance with AZ Guidance **"Redaction of Clinical-Regulatory Documentation"** – see References in Section 5.
- It is best practice to issue author agreements to external authors that clearly outline authorship responsibilities (particularly for Phase 1–3 Publications).
- AZ discloses all non-author contributions, sponsorship and funding for research and publications, plus any author relationships having the potential to bias the work.

AZ does not financially compensate healthcare professionals or patient authors for publication authorship.

AZ ensures that publications from all business units undergo appropriate sign-off, to confirm transparency, medical and scientific accuracy and to protect intellectual property, and are documented and tracked in the publications management system. Please refer to AZ Standard Operating Procedure (SOP) **"AZ Publications Sign-Off (PSO)"**, **the Alexion Publications SOP,** and AZ Standard **"Legal and Intellectual Property (IP)"** – see References in Section 5.

3.2 Publication of Results from Research Studies

AZ commits to publish results from research studies (clinical and non-clinical studies, discovery, research, pre-clinical, translational science, epidemiology, real world evidence, health economics and outcomes research studies) regardless of whether the findings are positive, negative, or inconclusive, or whether the product is investigational, licensed, or has been discontinued or withdrawn from the market. In certain cases, such as where there are few patients or data quality may be insufficient, a clinical trial database disclosure of the study outcome may suffice in lieu of a peer-reviewed publication.

- For the Rare Disease Business Unit (RDU), if a clinical trial database disclosure is used in lieu of a peer-reviewed publication of a Phase 2 or Phase 3 clinical trial, the Senior VP Global Medical Affairs must approve the exception and the exception must be documented by Scientific Communications in the publication management system.

For registration studies, journal submission of primary manuscripts must be within 12 months of study completion (as defined below). For other types of studies and for primary manuscripts of Phase 2 or Phase 3 registration studies from the RDU, this may be extended to 18 months.

For all studies, study completion is defined as the time point where data is available. For clinical studies, this is the availability of primary endpoint data as defined in the protocol.

- For early-phase studies and research studies up to Phase 1 involving investigational products, submission may be delayed to protect intellectual property.
- In the case of discontinued investigational programs, study completion is defined as the time of data availability following termination of the program.

AZ encourages publication in journals that offer open access options. Open access publishing widens the reach and discoverability of the research.

The Standard Data Sharing Statement must be included in manuscripts on AZ-sponsored clinical studies. AZ Data Sharing Guidelines are referenced in Section 5.

3.2.1 Author Access to Data

Where applicable, AZ must provide authors with appropriate access to copies of documentation related to the research, such as the Study Report, Final Protocol, Statistical Analysis Plans, Statistical Tables and Figures, as well as Individual-Level Study Data, under conditions that protect patient confidentiality/privacy and IP. Specific requests for individual patient data should be directed to the Head of Clinical Transparency and Data Sharing.

3.3 Publication Planning

It is best practice to develop Publication Plans to meet specific educational, scientific, and data dissemination objectives, ensuring that clinical research is published and presented in an ethical and timely manner.

The use of Publication Steering Committees (PSCs) aligned with ICMJE and GPP guidance may help the development of Publication Plans in an objective and

transparent manner, through collaboration with study investigators and AZ as the study sponsor. Using PSCs is recommended but not mandated. Publication Plans must be developed in advance of starting work on publications. To ensure that the designated publication is in alignment with the Publication Plan, all planned publications related to an AZ product (including those from country medical affairs and marketing companies) must be communicated to the relevant Product Team Lead.

Company personnel in global or local commercial roles may be involved in publication strategy development as part of a multidisciplinary Publication Planning Team. However, they must not work directly with authors, publication teams, or professional medical writers or participate in publication content development or sign-off processes. Exceptions to this restriction will be considered for Global Product Leads or personnel in global or local commercial functions that conduct publishable research.

With some exceptions as outlined below, it is important to AZ that publications are not developed using data from case reports, or from patients enrolled in Early Access Programmes. This is because there is the potential to compromise patient privacy or to overstep any Early Access Programme governance, and the generalisability of data from such sources is normally limited. Please refer to AZ Standard **"Early Access (EA) to Medicinal Products (MPs)"**– see Reference in Section 5.

- However, for the RDU and Early Oncology, publications may be developed from case reports and early access programmes despite the small numbers of patients involved. Publications from these areas are important in the context of providing information related to the treatment of patients with rare diseases.

3.4 Authorship Principles and Requirements

AZ follows the criteria set forth by ICMJE for authorship selection - see Reference in Section 5. The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement 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 determined based on the level of intellectual contribution to AZ's research and the related publication(s). However, AZ does not allow:

- Authorship as an incentive or reward for services rendered, such as patient enrolment, technical assistance, or routine operational support for the study;
- "Guest authorship" to individuals who do not provide substantive intellectual contributions to the design, conduct, analysis, or interpretation of the research expected to be published; or
- Authorship based on job role or function.

It is important to 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 AZ study data benefits from contributors having direct and recent experience with clinical practice and patient care.

All individuals, including external clinical investigators, who meet the first ICMJE criterion should be considered for authorship. Individuals who do not qualify for authorship, such as those that meet fewer than all four of the ICMJE criteria, are acknowledged for their contributions. Authors should agree to the by-line sequence and the lead author may arbitrate disputes.

While there are no restrictions on the numbers of employees who can author a publication, due consideration should be given to the number of authors needed to take responsibility for the publication which will depend on the scope, breadth, and complexity of the research and the publication.

As recommended by ICMJE, the use of artificial intelligence (AI) technologies in publication development does not meet the criteria for authorship and its use must be disclosed. For guidance on the ethical, safe and secure use of AI by AZ business units refer to **"AZ Employee and Business Use of Generative AI"** – see Reference in Section 5.

It is important to work only with those healthcare professionals (HCPs) who remain in good standing in their medical practices. US HCPs that have been debarred, or suspended from participating in US Federal Health Programs, or have engaged in scientific misconduct must not be engaged as authors for AZ sponsored publications.

For AZ employees who have left the company, authorship on publications must depend on their level of contributions to the research/clinical study and their ability to meet all ICMJE Recommendations and any other conditions related to confidentiality and conflict of interest. Continued authorship of departing employees, or those changing roles internally, are agreed and documented through discussions within the publications or study team responsible for the publication before they leave the company or move departments.

3.5 Author Agreements

It is best practice, prior to working on AZ sponsored publications, for external authors to be issued an Author Agreement, and agree to the principles in this Standard, in line with **"Good Publication Practice (GPP)"** – see Reference in Section 5.

AZ does not pay honoraria or fees for activities related to authorship (writing, editing, reviewing).

Under a Service Agreement at fair market value rate, AZ may pay author fees for non-author services associated with publication development, such as statistical analysis, participation in publication planning and strategy during publication advisory boards and steering committees.

AZ may provide support for medical writing for AZ-sponsored studies or collaborative research as outlined in the contract. Reimbursement for reasonable travel and registration expenses may be paid for presenter attendance at scientific meetings/functions, or expenses related to participation in publication advisory boards or steering committees in line with AZ Business travel policy, under a professional services agreement (PSA) detailing payments in scope.

3.6 Use of Professional Medical Writers

AZ may employ professional medical writers, such as company employees, external consultants, or communication agencies, to assist in the development, review, and submission of publications and presentations.

Collaborations between professional medical writers and authors must adhere to AZ's ethical and transparent publication practices. These include, but are not limited to:

- Authors must agree to the involvement of a professional medical writer;
- Authors provide input and guide the scientific content and overall direction of the publication at initiation, and through all stages of development
- Authors are responsible for data interpretation, and for providing critical review of the data;
- Authors are responsible to ensure data privacy laws are maintained for all study patients as per global legal requirements such as GDPR. This should be achieved through application of the AstraZeneca Global Guideline for **"Redaction of Clinical-Regulatory Documentation"** – see Reference in Section 5.
- Medical writing or editorial support from professional medical writers, and their funding by AZ, must be acknowledged in the publication;
- Professional medical writers generally do not meet accepted authorship criteria, but there may be exceptions, e.g., if they contribute substantially to a manuscript or review article. If writers qualify for authorship, they should be listed as authors and their financial relationship with AZ disclosed; and
- AZ shares this Standard with professional medical writers or external independent communications agencies working with us, and they must acknowledge in writing that this Standard has been read and understood.

3.7 Publication Sign-Off Process

Sign-off is mandatory for publications from all AZ business units, prior to submission or disclosure externally. Failure to submit publications for sign-off represents a compliance breach, that will be subject to compliance reporting and escalation.

- Please refer to the **"AZ Publications Sign-Off (PSO) SOP"**– see Reference in Section 5.

- The RDU will follow the RDU specific sign-off process described in the "**Alexion Publication SOP"** – see Reference in Section 5.

3.8 Prior and Duplicate Publication

AZ must respect all journal and conference embargo guidelines. In general, the primary publication and congress abstract submission must be available before data subsets or individual trial site results are submitted for publication.

- AZ abides by the rules of scientific congresses for encore presentations. Encore presentations are justified when permitted by a congress, when the attendee demographics differ from the initial congress, e.g., a different discipline, language, or geographical location.
- Encore abstracts should not be submitted to a congress if the data have already been published in a peer-reviewed journal.
- AZ does not permit multiple publications of the same manuscript article except for translations to other languages and plain language summaries.

Clinical, RWE or patient-related data should not be posted on preprint servers unless an exception has been approved by the CMO and the target journal allows it. A preprint should not be used as a substitute for a formal peer-reviewed publication, and cannot serve in lieu of a contractual requirement to publish, including externally sponsored research. Preclinical research may be posted on preprint servers where there is a need for early scientific exchange, as long as the materials meet the same ethical and authorship standards as peer-reviewed publications and are reviewed and signed off via the Publication Sign-Off Process (see Section 3.7) prior to posting.

All publications arising from a clinical study should include the unique trial identifier. In addition, once the primary manuscript has been published, all subsequent publications must cite the primary publication.

It is important to not engage in plagiarism, even if it is from the author's previous work (self-plagiarism). AZ must obtain the appropriate copyright permission and must provide appropriate citation to re-use copyrighted work.

3.9 Author Disclosures

All authors are required to disclose any potential conflicts of interest, including any financial or personal affiliations/relationships that might be perceived to bias their work or the publication.

AZ authors must disclose that they are employees of AZ, and that they have ownership, options, and/or interests in AZ stock, if applicable.

3.10 Predatory Publishers

In alignment with ICMJE Recommendations, AZ will not submit publications to known predatory journals or congresses that lack scientific rigour and are based on a model involving charging publication fees without providing robust editorial, peer-review, and publishing services.

3.11 Publication Extenders and Supplemental Materials

Publication extenders are a repackaging of material that is found in the main publication; they do not provide new information. Supplemental material provides additional data or information that cannot be found in the main body of the publication, and it may be in a digital or non-digital format.

The development of publication extenders and supplemental materials to accompany a published manuscript or congress presentation is encouraged when such content is a standard offering of the journal or congress.

It is also acceptable to make congress presentations available digitally using QR codes, when allowed by the congress and local regulatory guidelines. Publication extenders and supplemental materials are considered an important addition to a publication and should be considered alongside other journal selection criteria when choosing a journal.

Development of plain language summaries of manuscripts, abstracts, and poster presentations that contain medically important information relevant for wider dissemination to non-specialist and patient audiences is recommended.

Publication extenders and supplemental materials must be part of the Publication Plan and when included, be agreed to by all authors from the outset of publication development. Where possible, they must be developed in parallel with the main

publication; however, depending on journal requirements, development of publication extenders after the main publication has been published is acceptable.

3.12 Publications and Social Media

The AZ and Alexion Global Social Media Policies provide detailed guidance on the appropriate use of social media **"AZ and Alexion Social Media Policies"** – see Reference in Section 5. Contact your Corporate Affairs partner if you have questions.

3.13 Clinical Trial Results Posting

For information on clinical trial data posting, please refer to the **"AZ Clinical Trial Transparency (CTT)"** – see Reference in Section 5. Data from publications may also be subject to governance under other policies, including but not limited to **"General Data Protection Regulation (GDPR)", "Redaction of Clinical-Regulatory Documentation",** and **"Human Genetic resource (HGr)"** Policies – see References in Section 5.

4. RESPONSIBILITIES AND KEY ACCOUNTABILITIES

Any AZ Employee involved in the Publication process, which includes the Publications Author and Publication Reviewer roles, is responsible to follow the principles set out in this AZ Standard. Publication roles, such as Publication Lead, Scientific Communications Lead (RDU), or designated deputy, are responsible to apply minimum requirements of AZ Publications for the workflow they manage (See Section 3 Key Principles).

5. REFERENCES

Type	Reference/Document Title	Document Number *(if applicable)*
Standard	Legal and Intellectual Property (IP)	Link Here STND-0002068
SOP	AZ Publications Sign-Off (PSO) SOP	Link Here SOP-0036265
Guidance	Redaction of Clinical-Regulatory Documentation	Link Here GUID-0008655
Portal	R&D Process Portal	Link Here
Standard	Early Access (EA) to Medicinal Products (MPs)	Link Here STND-00002305
SOP	Alexion Publications SOP	SOP-0122553
External Source	Good Publication Practice (GPP)	Link Here
Standard	AZ Social Media Policy	Link here STND-0000750
Standard	Alexion Social Media Policy	POL-CA-GL-100
Standard	AZ Employee and Business Use of Generative AI	Link Here
SOP	Human Genetic Resource (HGr)	Link Here SOP-0085533

Standard	AZ Clinical Trial Transparency (CTT)	Link Here STND-0000672
Statement	AZ Data Sharing Statement	Link Here
Standard	External Sharing of Patient Level Data	Link Here STND-0000674
External Source	Good Practice for Conference Abstracts and Presentations (GPCAP)	Link Here
External Source	International Committee of Medical Journal Editors (ICMJE)	Link Here
External Source	International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)	Link Here
External Source	International Society for Medical Publication Professionals (ISMPP) Authorship Task Force Recommendations	Link Here
External Source	General Data Protection Regulation (GDPR)	Link Here
External Source	Consolidated Standards for Reporting Trials (CONSORT)	Link Here
External Source	Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)	Link Here
External Source	Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)	Link Here
External Source	Reporting of In Vivo Experiments (ARRIVE)	Link Here

6. DOCUMENT HISTORY

Version	Description of Change	Effective Date
14.0	AZ Publication Standards and Alexion Publication Policy (POL-GMA-GL-100.2) merged into a single Publication Standard for use across all business units. Includes updated content in line with recent updates to ICMJE and GPP.	Q1 2024
13.0	AZDoc automation - superseded v12.0 to v13.0	12 April 2021
12.0	This Global Standard underpins the Publications Policy and is updated to be applicable to all publications originated by AstraZeneca and its Group of companies.	13 April 2018

7. APPENDIX DEFINITIONS

Author: Any individual included in the author by-line of an article/manuscript, abstract, or oral/poster presentation.

Good Publication Practice (GPP): GPP is a well-recognized and established set of guidelines that describe industry standards for the development of publications from industry-sponsored studies.

International Committee of Medical Journal Editors (ICMJE): (http://www.icmje.org/). The ICMJE "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" are the most widely recognized and established guidelines and standards for ethical practices in scholarly publishing.

Company Sponsored: The GPP guidelines define company-sponsored biomedical research as that which is conducted by or in collaboration with companies or company sponsors.

Publications: Publications are defined as 1) articles in print and/or electronic scientific and biomedical journals and 2) oral/audiovisual or written presentations at scientific and medical meetings. Below are definitions for the most common types of publication:

- **Primary publications:** Primary publications disclose pre-specified primary objectives/endpoints and key secondary endpoints from clinical trials and other types of research including real world evidence. registry, HEOR and preclinical studies.
- **Secondary publications:** Secondary publications may report on methodology, study design, baseline characteristics, and disclose results of exploratory objectives, subgroup analyses, genetic or biomarker data or post hoc analyses.
- **Tertiary publications:** Tertiary publications provide aggregate information from primary and secondary sources (e.g., review articles).
- **Supplements:** Supplements are collections of papers that are related by an overall topic or theme and are published either as a separate or integral component of the issue.

Encore congress abstracts: An encore abstract is a reproduction of an original abstract but may differ due to formatting, word count or other trivial changes.

Plain language summary: A plain language summary describes findings from a medical or scientific publication in everyday language that is understandable to a non-research audience.

Preprints: A preprint is a full-draft research paper that is shared publicly on a preprint server.

Predatory journals: Predatory journals use deceptive practices to actively solicit manuscripts and charge publications fees without providing robust peer review and editorial services.

Predatory Congresses: Predatory conferences are set up to appear as legitimate scientific conferences but do not provide proper editorial control over presentations, and their advertising can include claims of involvement of prominent academics who are uninvolved.

Publication Extenders: Publication extenders, also known as publication enhancements, are a repackaging of material that is found in the main publication and do not provide new information.

Please consult the *AstraZeneca Glossary* for clarity on additional definitions, as needed.