ASTRAZENECA GLOBAL POLICY

GLOBAL PUBLICATIONS POLICY

1. PURPOSE

This Global Policy applies to all publications originated or sponsored by AstraZeneca and its Group of companies. It is designed to protect the public benefits of transparent, open and unbiased exchange of scientific and biomedical information.

2. AUDIENCE

This Policy applies to all employees engaged in the development or management of publications as defined in this policy. External collaborators, partners or suppliers involved with the company's publications activities shall embrace standards that are consistent with this Policy. Contracts must define the specific expectations with respect to the principles below based on the scope of work being undertaken by the third party.

3. SCOPE

This Policy covers all publications with scientific or medical content, originated or sponsored by AstraZeneca staff from all company divisions and sites. Publications are defined as manuscripts (primary, secondary, reviews, etc), abstracts, slide presentations, posters, journal supplements, letters to editors, books, books chapters, student theses and presentations based on AstraZeneca research, non-peer reviewed product-related trade journal, newspaper or magazine articles, commentaries, in either paper, digital or electronic media formats with medical or other scientific content. Press releases, disclosures made to investors, product promotional materials and contributions to social media are covered under separate AstraZeneca policies. The principles of this publications policy are reflected in author agreements and other external agreements for research and development collaborations.

4. POLICY STATEMENTS

4.1 Key Policy Principles

The advancement of biomedical science is deeply dependent on the open exchange of unbiased scientific, clinical and other research information. This exchange is also relevant to the practice of medicine and forms the basis of treatment and health care policy decisions. Because published information from our research can change standards of care, it is critically important that these data be gathered and published in an objective, transparent and ethical manner.

This Policy is intended to safeguard the integrity of our research and the healthcare community's right to objective and meaningful scientific exchange while protecting patient confidentiality and intellectual property. It does so by ensuring that we:

- Use the principles outlined in the International Committee of Medical Journal Editors (ICMJE) recommendations regarding authorship for

external and internal authors plus criteria for other non-author contributions;

- Fully disclose clinical study and other medically important research results, whether positive, negative or inconclusive, while protecting patient confidentiality;
- Provide authors with complete access to relevant study data;
- Appropriately acknowledge non-author contributors to publications, including professional writers;
- Fully disclose in the publication, authorship affiliations and any relationship that could be seen as having the potential to bias an author's work; Acknowledge all financial support for publications and funding sources for any research being reported
- Document all payments, reimbursements and relevant transfers of value relevant to the publication in accordance with regulatory requirements; and Guarantee that all AstraZeneca-sponsored publications undergo appropriate review to ensure medical and scientific accuracy and protection of our intellectual property, without influencing the opinions of authors.

4.2 Publication of Results from Human Studies

Data Access: Because authors and presenters bear independent responsibility for how biomedical research is interpreted and communicated, they require full access to relevant research and study data. All authors of an AstraZeneca-sponsored publication will be provided, on request, access to the study report, final protocol, statistical tables, figures, and any other reports needed to prepare the planned publication. If requested, authors will also be provided access to patient-level study data under conditions that appropriately protect patient confidentiality and intellectual property.

AstraZeneca will provide a copy (reviewed for intellectual property and personal information) of the study report, protocol, including the statistical analysis plan, to any medical journal considering a submitted manuscript for publication, if requested by the journal. Furthermore, when a manuscript reporting clinical trial or real world evidence results is published in a journal, the protocol for that study is posted publicly on the AstraZeneca clinical trials website.

Data Disclosure*:* AstraZeneca discloses information from its research programmes through presentations at scientific congresses and publication in peer-reviewed journals. AstraZeneca will make good faith efforts to publish the results from all studies conducted in humans or studies involving human data in a timely manner, according to good publication practice guidelines (GPP) and regardless of whether the study outcome was positive,negative or inconclusive. At a minimum, all clinical study results from phase III and onwards plus any research results of significant medical importance will be submitted for publication in a peer review journal. This includes investigational clinical products from discontinued programmes and post hoc analyses of medical importance.
AstraZeneca also registers all clinical trials and posts study results on public websites for all new and ongoing AstraZeneca sponsored clinical trials for products in all phases, including marketed medicines, drugs in development and those drugs whose further development has been discontinued. Results are posted irrespective of whether they are favourable or unfavourable to

AstraZeneca. More information on our clinical trials disclosure policy is available at: http://astrazenecagrouptrials.pharmacm.com/Submission/Disclosure

AstraZeneca includes a unique trial identifier in all publications and website postings of human studies to enhance transparency.

4.3 Authorship:

Requirements for Authors: We use the International Committee of Medical Journal Editors (ICMJE) recommendations regarding authorship.

For publications where a large multicentre group has conducted a study, the group should identify the individuals who accept direct responsibility for the publication. All authors must act as guarantors, and take responsibility for the manuscript. Publication of data subsets from individual institutions participating in multicentre studies should not precede the primary manuscript, and when developed must always reference the primary publication of the entire study.

External authors must enter into an authorship agreement with AstraZeneca in line with good publication practice. AstraZeneca does not compensate authors for authorship of peer-reviewed articles or presentations but may under a service agreement at fair market value rates, pay a fee for services associated with publication development and presentation including reasonable travel and registration expenses to attend such events. Any fee for service must be disclosed in the publication.

Use of Professional Writers*:* AstraZeneca may sometimes employ professional writers (medical or scientific writers) who may be company employees, external consultants or employed by communication agencies to assist in producing publications and presentations. Professional writers are not ghost-writers and their name, involvement and funding is always acknowledged in the publication.

AstraZeneca ensures that collaboration between professional writers and authors adheres to ethically acceptable practice, as follows:

- Authors must agree to the writer's involvement
- Authors will 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 there must be no influence on their opinions;
- Authors must 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 the funding by AstraZeneca must be fully acknowledged in any resulting publication in line with their levels of contribution.

Financial Disclosures: AstraZeneca fully supports openness and transparency and hence the need for all authors of publications (both AstraZeneca employees and external collaborators) to disclose any potential conflicts of interest. This must include any financial or other relationships that might be perceived to bias their work, and any specific disclosure requirement mandated by the institution where they are employed.

4.4 Publication of Results from other Research or Company Activities

Publication of scientific data from preclinical and other research programmes or company activities is essential for providing a deeper understanding of the science behind our products and the methodological approaches used to discover and evaluate medicines in our pipeline.

As with publications of human study data, preclinical and other research publishing must be undertaken in an ethical manner consistent with external guidelines and best practices.

Additionally, it is critical that these publications do not jeopardise our intellectual property rights and company patents. To support these principles, we will ensure that:

- Publications are conducted in accordance with ICMJE recommendations and good publication practice guidelines;
- Publications plans receive appropriate internal review; and
- All publications are reviewed for intellectual property risks; the AstraZeneca Intellectual Property group is accountable for this review.

4.5 Publications Review and Sign-Off Process

AstraZeneca publications undergo a review and sign-off process (The PSO Process) prior to submission to a journal or congress. This process employs the least restrictive means possible, while ensuring scientific and medical accuracy of content, compliance with applicable publication standards, regulatory compliance (for example, avoidance of inappropriate promotional statements) and, protection of intellectual property through patent attorney review.

5. GLOSSARY

Not required.

6. REFERENCES

Not required.