

Summary of Bristol-Myers Squibb Company Policy on Scientific Publications

Purpose

The purpose of this Policy is to establish the principles and expectations for the ethical and transparent development of and support for Scientific Publications at Bristol-Myers Squibb (BMS) Company.

Guiding Principles

Commitment to Publish

In alignment with the PhRMA /EFPIA Principles for Responsible Clinical Trial Data Sharing, all company-sponsored clinical trials will be considered for publication in scientific literature irrespective of whether the Clinical Trial results are positive or negative. At a minimum, we expect results from all phase 3 Clinical Trials and any Clinical Trial results of significant medical importance to be submitted for publication. This commitment to publish includes investigational medicines whose development programs have been discontinued.

Good Publication Practices

BMS is committed to developing Scientific Publications based upon our data, assets or research in order to communicate accurate, timely, transparent and scientifically objective information to the scientific community and healthcare providers. BMS adheres to the tenets of Good Publication Practice Guidelines (GPP; www.ismpp.org) and International Committee of Medical Journal Editors Recommendations (ICMJE; www.icmje.org).

BMS Scientific Publications must:

- address a meaningful scientific hypothesis, disclose scientific observations or address a knowledge gap
- interpret data results in a scientifically objective and unbiased manner that enriches scientific understanding
- reflect complete, accurate and scientifically objective data
- not be influenced by commercial or promotional objectives

Authorship

Selection of authors is based on substantial intellectual contributions to the work as described by ICMJE criterion #1. Authors of a BMS Scientific Publication must meet all four of the following ICMJE criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; and
2. Drafting the work or revising it critically for important intellectual content; and
3. Final approval of the version to be published; and
4. Agreement to be held accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Authors must take responsibility for the integrity and accuracy of the data presented in Scientific Publications. Individuals who do not meet authorship criteria but provide substantive assistance should be acknowledged for their contribution in the Scientific Publication (with their permission).

BMS may provide writing and editorial assistance by a professional medical writer to support authors in the development of BMS Scientific Publications. BMS does not provide writing and editorial assistance support for independent publications where BMS did not sponsor the study.

BMS does not use Scientific Publications or the activities related to them to influence or reward the prescribing practices of authors or healthcare providers.

BMS does not provide payment to authors for any aspect of the development of a Scientific Publication, or for preparation or presentation of BMS data at a Scientific Congress.

Access to Data

To support the development of a Scientific Publication, BMS will provide authors access to relevant and applicable BMS research or study data. BMS must have confidentiality disclosure agreements (CDA) in place with all authors before providing access to BMS confidential information.

BMS Review

Scientific Publications must undergo appropriate review for medical accuracy and protection of intellectual property.

Disclosure of Potential Conflicts of Interest

BMS supports the full disclosure of any actual and potential conflicts of interest of financial and non-financial nature by authors to the relevant journals/congresses. All BMS financial or non-financial support or assistance for a study and/or publication must be disclosed, including such services as professional medical writing assistance and data analysis.

Publication Rights of Investigators

BMS does not prohibit investigators from publishing clinical study results, regardless of outcome. The investigator clinical trial or research agreement stipulates that institutions or investigators may publish their site-specific results after the results of a multi-center BMS-sponsored clinical trial have been published and that BMS must review the publication prior to submission or presentation

Financial Transparency

BMS adheres to laws and industry standards for financial transparency reporting (e.g. US Sunshine Act, EFPIA Code). BMS reports funding for medical writing, editorial assistance, and payment of congress or journal fees.

Privacy

BMS adheres to applicable laws and regulations (eg, EU General Data Protection Regulation [GDPR]) and respects authors' rights to the privacy and confidentiality of their personal information.

Date: December 2018