



## **ISMPP Issues and Actions Committee The Rationale and Value of Medical Publications**

There is a significant investment in ongoing medical research in the United States (US) and worldwide. The number of studies conducted each year is staggering, with nearly \$59 billion invested annually in research and development by biopharmaceutical companies in the US alone.<sup>1</sup> Publishing all of the data generated by these studies is an important but challenging task that provides a tremendous growth in our understanding and knowledge about diseases and their treatment. Each year approximately 800,000 published articles are added to PubMed, the comprehensive database of medical articles compiled by the US National Library of Medicine.

To translate this data in a meaningful way, it must be analyzed, put into the context of existing care paradigms, and made accessible to physicians and other healthcare professionals. The medical data emerging from this effort can directly impact decisions about patient diagnosis and treatment, and the rapid, accurate, and clear communication of this data is critical to advancing the knowledge of clinicians. Medical publications represent the tangible result of this effort, providing a valuable and lasting legacy of our advances in health care.

The process of conducting medical research is highly regulated and undergoes tremendous scrutiny, and that is also true of the process of publishing medical information. Peer-reviewed medical journals are an important, established, and credible means of communicating clinical trial results and other relevant scientific information to the medical community. They provide a searchable base of literature on which the current and future understanding of medical research is based. As the principal source of medical publications, the purpose of medical journals is to educate and inform a wide variety of healthcare professionals who must routinely and efficiently identify and deliver the most effective treatment for their patients.

All major medical journals rely on the peer-review process to assure that manuscripts submitted for publication are scientifically sound and that the information is correct and relevant to clinical practice. Peer review involves independent and unbiased medical experts, with no conflicts or ties to the study, who review and critique the paper and recommend that the article be either accepted or rejected for publication. This is a critical step in the process, as it introduces expert third parties to critically evaluate a paper and determine its value to the medical community.

Other steps are also in place to ensure accuracy and transparency in medical publications. Guidelines have been established by the Food and Drug Administration (FDA) and other organizations (IFPMA, EFPIA, PhRMA and JPMA) to ensure that all clinical study results are made publicly available, regardless of the results of the study.<sup>2,3</sup> These guidelines require that applicable clinical studies be registered on a publically accessible web site prior to the study's start in order to be considered for subsequent publication in a peer-review journal. They also specify that results be published in a relatively short period of time after the study is completed. Medical publications must also include a disclosure of all financial support or other potential source of bias that may be associated with the article or those involved in its development. With approximately 70% of the funding for clinical drug trials coming from private industry, this disclosure is important to address the potential bias that could occur. All individuals contributing to a publication must also be disclosed, including the involvement of professional medical writers, which is a clear and acceptable practice, and eliminating the involvement of "ghostwriters", or undisclosed contributors. All of these steps are taken to enhance the validity and credibility of medical publications, and to provide the reader with the information needed to judge to value of the publication to their own medical practice.

The scientific frontiers of medicine are constantly evolving. Individuals who choose the medical profession make a commitment to lifelong learning and service to their patients. Professional schools (medical, nursing, pharmacy, etc) and post-graduate training are merely the entry point. Information communicated in medical research publications are a major means by which professionals in the healthcare field keep abreast of new developments that will ensure the best possible care for the patients they treat.

## References

1. Pharmaceutical Research and Manufacturers of America. R&D Spending by U.S. Biopharmaceutical Companies Reaches Record \$58.8 Billion in 2007. Available at: <http://www.pfma.org/media/releases/record-number-new-medicines-heart-disease-stroke-now-development>
2. Food and Drug Administration Amendments Act (FDAAA) of 2007. Available at: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SigificantAmendmentsstotheFDCA/FoodandDrugAdministrationAmendmentsActof2007/default.htm>
3. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. Updated October 2008. Available at: <http://www.icmje.org>