

Policy on Publications

Background

In the best interests of patients, the medical and scientific community, and the public at large, Astellas is committed to increasing transparency by making our important study findings widely available, regardless of whether they are positive or negative, in a timely manner. Publications are credible, evidence-based ways for Astellas to communicate the research results for our investigational and marketed products to the medical and scientific community. This policy is our roadmap to ensure that publications on these products are developed in co-operation with external investigators in a transparent, accurate, balanced, and timely manner.

This policy adheres to Good Publication Practices (GPP), International Committee of Medical Journal Editors (ICJME), International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Pharmaceutical Research and Manufactures of America (PhRMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA) principles on the conduct of clinical trials and communication of clinical trial results.

Policy

The results of Astellas' clinical trials are made publicly available through both peer-reviewed publications (journal articles or scientific presentations) and by disclosing results on public registries or websites. At a minimum and regardless of trial outcome, Astellas strives to submit a manuscript for all interventional clinical trials at phase 3 and beyond, for publication in a peer-reviewed journal. In addition, Astellas strives to submit a manuscript for Astellas sponsored research assessed as having significant scientific or medical relevance, including results from research of compounds whose development has been discontinued. Results should be submitted as a manuscript for publication, wherever possible, within 12 months and no later than 18 months of Last Subject Last Visit (LSLV) unless otherwise defined in the protocol for marketed products or regulatory approval or decision to discontinue development for new investigational products. Astellas encourages the submission of all manuscripts based on Astellas-sponsored research to journals that offer public availability via Open Access.

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