

Policy on Investigator Sponsored Research (ISR)

Background

Astellas is committed to providing benefit to patients, healthcare professionals, and the community through quality research. Astellas recognizes that supporting external medical, scientific, or educational organizations in their research investigations is an important way to understand the needs of patients and to advance knowledge in patient care and improve health. The purpose of this policy is to define the standards that govern the relationship between Astellas and the external Investigators who engage in Investigator Sponsored Research (ISR) aimed at advancing medical and scientific knowledge for Astellas marketed products and in relevant therapeutic areas.

Policy

Astellas principles for support of ISRs include transparent and documented procedures that support compliance with applicable laws, regulations and industry codes. The policy applies to ISRs for both clinical and non-clinical research on products for which Astellas is the marketing authorization holder as well as in associated disease areas.

In alignment with this policy, all ISR concepts and proposals must be unsolicited and originate externally from the Sponsor-Investigator or Institution. The Sponsor-Investigator or Institution assumes full Sponsor responsibilities regardless of the support offered by Astellas. The Sponsor-Investigator or Institution can request drug supply and/or financial support to perform the research.

Astellas Medical Affairs is responsible for supporting ISRs, as well as the internal processes that govern the submission, review and approval of ISRs. ISR submissions are reviewed by a cross-functional scientific review committee. If approved, a fully executed written agreement that specifies the responsibilities of the Sponsor-Investigator or Institution must be in place prior to initiation of the research study. Once an agreement is entered into with a Sponsor-Investigator or Institution, Astellas will periodically communicate with the Sponsor-Investigator or Institution to ensure the study is progressing. Astellas Commercial personnel are prohibited from being involved in ISR activities including the initiation, submission, assessment, approval or ongoing management of ISRs. Astellas will review publications submitted by the Sponsor-Investigator or Institution. The review will be limited to facts related to Astellas products, intellectual property, safety/pharmacovigilance, and proper disclosure of Astellas' support.