

Policy on Disclosure of Clinical Trial Data

Background

Astellas is committed to increasing transparency and sharing of clinical trial data. Realizing the full value of clinical trial data, such as scientific advancement and increasing innovation, requires that the data be appropriately accessible to the research community and others who might be able to use it. We recognize that making this clinical trial data accessible to researchers, healthcare professionals, patients, and interested members of the public will benefit public health.

Policy

Astellas complies with relevant laws, regulatory requirements and industry guidance for registration of clinical trials, posting of clinical trial results, and publication of Astellas sponsored trials.

Registration of Clinical Trials

Astellas commits to registering the existence of all Astellas sponsored phase 1 to phase 4 interventional trials, in patients, that seek to evaluate the safety and efficacy profile of an Astellas owned or in-licensed product. When required by local laws or regulations, noninterventional studies are registered. Trials sponsored by Astellas that are covered under this policy are registered on a publicly accessible clinical trials registry (e.g., <http://www.clinicaltrials.gov/>). Trials are also registered on national registries, if required by local laws or regulations.

Posting of Clinical Trial Results

Astellas commits to disclosing summary results of certain Astellas sponsored clinical trials. This policy applies to products that receive initial regulatory approval after January 1, 2014 consistent with the European Federation of Pharmaceutical Industries and Associations (EFPIA)/the Pharmaceutical Research and Manufacturers of America (PhRMA) principles for responsible clinical trial data sharing dated July 18, 2013, and includes the summary results for trials covered under this policy or included in the application to support regulatory approval. Summary results for trials completed after January 1, 2014 with product indications and formulations that received regulatory approval before this date are also disclosed on a publicly accessible clinical trial results database. Summary results are posted on national clinical trial databases as and when required by local law or regulation.

Astellas discloses summary results for studies conducted with compounds that are discontinued during development after confirming there is no intent for future collaboration, out-licensing or development of the molecule.

Astellas is working to provide a layperson summary of clinical trial results for studies within the scope of the policy that are conducted with Astellas products that have regulatory approval.

Publication of Astellas Sponsored Trials

Astellas seeks to have clinical trial data of its sponsored trials presented and published, regardless of their outcome, at scientific congresses and in peer-reviewed journals.

Scientific Community Access to Study Data

Subject to compliance with the applicable laws and regulations relevant to protection of personal data, Astellas provides a platform where researchers may request access to patient level data, study level data and protocols from Astellas sponsored clinical trials conducted in patients that are completed after January 1, 2010.

Access to this data may be granted for products and indications approved in any country after the request has been reviewed and approved by an independent panel of experts (“Scientific Review Board”) based on scientific merit and the qualifications of the researcher. Access will be given by Astellas after review and approval by the Scientific Review Board and execution of a data -sharing agreement.

Before patient-level data is shared, it will be anonymized to respect the rights of the clinical trial subjects to privacy and to protection of their personal health information.