Policy on Disclosure of Clinical Trial Data

Background

Astellas is committed to increasing transparency and sharing 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 information and disclosure of clinical trial results.

Registration of Clinical Trials

Astellas commits to registering all interventional clinical trials with a medicinal product sponsored by Astellas that seek to evaluate the safety and/or efficacy profile of an Astellas owned or in-licensed product. Clinical trials sponsored by Astellas that are covered under this policy are registered on a publicly accessible clinical trial registry (e.g., www.clinicaltrials.gov). In addition, other Astellas sponsored studies (e.g., non-interventional studies, medical device, early access) are included in national/regional registries, if required by local/regional laws or regulations.

Posting of Clinical Trial Results

Astellas commits to disclosing summary results for all phase 1 to 4 interventional clinical trials with a medicinal product sponsored by Astellas, conducted in the target patient population, with Astellas products that have health authority (HA) approval. In addition, summary results for other Astellas sponsored studies (e.g., non-interventional studies, medical device, early access) are disclosed on national/regional registries, if required by local/regional laws or regulations.

Summary results and a plain language summary are posted on clinical trial results website(s) (www.clinicaltrials.astellas.com and/or www.trialsummaries.com/Home/LandingPage) for clinical trials conducted with medicinal products that receive initial HA approval after January 1, 2014. Summary results are publicly disclosed within 3 months after initial HA approval is granted for studies with an end of study (EOS) clinical study report (CSR) available at the time of the first HA approval, within 30 days of CSR EOS for studies without a EOS CSR at time of HA approval, or within 12 months after trial completion for clinical trials with a medicinal product conducted with product formulations and indications that previously received HA approval. Additionally, summary

results are posted on a publicly accessible clinical trial results website for trials with a medicinal product conducted with products that received initial HA approval from November 1, 2008 through December 31, 2013.

Summary results and a plain language summary are also disclosed on clinical trial results website(s) for clinical trials conducted with medicinal products that are terminated during development after January 1, 2014. Results are disclosed for completed trials within 12 months after medicinal product development is terminated. Results are disclosed within 12 months after trial completion for clinical trials that are ongoing at the time that development of the medicinal product is terminated.

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 (www.Vivli.org) where researchers may request access to participant level data, trial level data and protocols from Astellas sponsored clinical trials with a medicinal product conducted in patients that are completed after January 1, 2010.
Access to this data is granted for medicinal 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 is given by Astellas after review and approval by the Scientific Review Board and execution of a data sharing agreement.

Before participant-level data is shared, it is anonymized to respect the rights of the clinical trial subjects to privacy and to protection of their personal health information in accordance with the applicable laws and regulations.