Astellas conducts research on human subjects, and obtains and conducts research on specimens derived from humans, after appropriately obtaining the consent of the trial subjects in accordance with the Declaration of Helsinki* as well as the laws, regulations and guidelines of relevant countries.

In Japan, Astellas provides training for researchers in areas such as bioethics, genomic research and related clinical studies, based on a strong commitment to respecting the human rights of research subjects, protecting the privacy and confidentiality of their personal information, and assuring the reliability of the research. The Astellas Research Ethics Committee has been established to determine the ethical acceptability and scientific propriety of research plans in a fair and impartial manner, taking account of information on potential conflicts of interest involving research institutions, researchers and other parties. In fiscal 2016, this committee met 12 times, deliberated on 31 issues, and conducted 179 brief reviews.

Astellas has established a Global Policy for Animal Care and Use, and conducts animal testing based on this policy. We have established the Corporate Institutional Animal Care and Use Committee, in which outside members also participate as committee members, at our animal testing facilities.

Astellas’ initiatives in animal testing are recognized by AAALAC International*. As a result, all of our animal testing facilities have acquired accreditation from AAALAC International.

Astellas performs experiments using genetically modified organisms, or materials containing pathogens, under the World Health Organization Laboratory Biosafety Manual*1 and the Centers for Disease Control (CDC) and Prevention / National Institute of Health Biosafety in Microbiological and Biomedical Laboratories*2, as well as the laws of individual countries.

In Japan, Astellas has established biosafety management rules in compliance with the Cartagena Act*3 and related ministerial ordinances, and has detailed procedures in place for handling experimental materials. In addition, we have set up the Biosafety Committee at each facility as a body to review whether the experiments meet the standards required by these rules.

In addition, laboratory personnel receive regular training courses once a year, in order to rigorously enforce safe and proper biosafety management and use of these organisms and suchlike. 1,010 participants received the training in fiscal 2016. In the U.S., we use such experimental materials based on the rules established by the occupational health and safety authorities.

Appropriate protection of intellectual property is critical to Astellas in order to address unmet medical needs and maintain a competitive advantage. Astellas has established a Policy on Intellectual Property. In view of the importance of improving people’s access to healthcare, we are committed to not filing or enforcing patents in countries facing significant economic challenges. These select countries are decided by referring to those designated as Least Developed Countries (LDCs) defined by the United Nations or Low Income Countries (LICs) defined by the World Bank.
Clinical Development

Protection of Human Rights, Privacy and Confidentiality of Personal Information of Research Subjects, and Assurance of Reliability in Clinical Trials

In clinical trials, we investigate new drug candidates developed through drug discovery research in further detail, and assess the efficacy and safety of the new drug candidates in patients.

Under the Declaration of Helsinki, clinical trials must be ethically planned and safely conducted with full consideration to protecting the human rights and privacy of clinical trial subjects. Astellas ensures full compliance with Good Clinical Practice (GCP) and all relevant laws and regulations so that new drug candidates are developed into drugs that can be used confidently by patients. Plans for clinical trials conducted by Astellas are evaluated and approved for ethical acceptability and scientific validity by internal and external committees.

In conducting clinical trials, Astellas confirms that clinical trial subjects have provided informed consent, having received a full explanation of the purpose and methods of the trial, its expected benefits and disadvantages, matters related to compensation for health impairment and other details. Moreover, we implement education and training for any employees or staff members involved in clinical trials, and monitor medical institutions that perform clinical trials to ensure full GCP compliance.

In addition, we manage trial data appropriately to protect the privacy of clinical trial subjects. Periodic assessments are also made to check that any outsourced clinical trials are conducted in accordance with the same standards.

Disclosure of Information on Clinical Trials and Their Results

Astellas has formulated a global policy on the disclosure of clinical trial data and results to enhance the transparency of information gained from clinical studies while maximizing its value, and to ensure this leads to the advancement of science and the promotion of innovation.

Specifically, Astellas provides patient-level data that have been anonymized in accordance with applicable laws and regulations through an external website*1 to those scientists and healthcare professionals requesting it. Doctors and the public can access summaries of clinical trial findings via the Astellas website. We are also developing a website to give patients access to special summaries of study results prepared for non-experts*2.

*1 Patient-level data are provided through the following website: http://www.clinicalstudydatarequest.com
*2 Results of the clinical trials are provided through the following website: http://www.astellasclinicalstudyresults.com/Welcome.aspx

Patient Centricity in Drug Development

Real-world considerations in clinical trials are increasingly important in ensuring that our studies are aligned with current medical practices and patient needs.

We are trying to incorporate insights from real-world data into our clinical trials by understanding how healthcare is provided to patients.

Patient centricity is now a focus for regulatory authorities and the pharmaceutical industry. The patient-centric approach is being discussed at all points in the drug development value chain, from discovery through commercialization. Efforts are being made to include patient input in how to optimally design trials, recruit participants, and identify relevant endpoints that patients care most about.

Astellas employs various methods to incorporate patient-centric approaches into clinical programs. For example, we use patient-reported outcomes (PROs) such as questionnaires and patient diaries to assess patients’ health conditions. In addition, we use real-world data for estimation of target population based on the morbidity rate or ineligible cases in screening, and feasibility of studies in clinical trial facilities. Also, patient input is used to assess feasibility of clinical trials. Through these activities, we try to improve recruitment, retention and relevance of data. We are also working with patient advocacy organizations where appropriate to assess protocol feasibility including frequency of visits, procedures and PRO elements.

Disclosure of Information on Clinical Trials and Their Results

Please refer to the following URL for information about related CSR activities in research and development.

- Ethical Considerations in Stem Cell Research and Development
- Expanded Access to Investigational Medicines


Please refer to the following URL for information about our policies & position statements.

https://www.astellas.com/en/about/policies-and-position-statements/