ALK's policy for responsible clinical trial data sharing

Background

ALK aims to improve quality of life for patients suffering from allergy. As a global research-driven pharmaceutical company, ALK believes that sharing of clinical trial information will enable the medical and scientific community in the further understanding of the allergic disease and the treatment for the future benefit of patients. It is ALK's policy to disclose clinical trial results openly and accurately for any ALK sponsored clinical trial regardless of development phase or outcome.

ALK is committed to EFPIA's and PhRMA´s "Principles for Responsible Clinical Trial Data Sharing" guidelines in a manner that safeguards the privacy of patients, respects the integrity of national regulatory systems, and protects proprietary information.

Data sharing with researchers

Upon request from qualified scientific and medical researchers, ALK will share anonymised patient- and study-level clinical trial data and protocols from clinical trials for medicines and indications approved in the European Union (EU) and the United States (US) after 1 January 2014 as necessary for conducting legitimate research.

To obtain access, qualified researchers must submit a request containing the following: the research proposal including objective and rationale, identification of the data requested, the research and analysis plan, the publication plan, and a signed "Data Sharing Agreement". Application forms will be available at ALK's website during 2018. Access to data will be provided following a thorough review of the request by a scientific review board including external independent academic scientists and healthcare professionals. The access will be consistent with the data protection principles, in accordance with the patients' informed consent provided in relation to their participation in the clinical trial and other legal restrictions preventing sharing of the clinical data. In addition, access to data collected in collaboration with third parties may be limited by contractual provisions.

Public access to clinical trial information

In order to help patients and healthcare professionals understand the results of clinical trials and the evidence used to support product approval or new indications for products approved in the EU and US after 1 January 2014, ALK will make publically available the synopses of the trial reports. Trials included are those that are submitted to the Food and Drug Administration, European Medicines Agency, or national competent authorities of EU member states. The information will be available consistent with the need to protect patient privacy, publication rights, and confidential commercial information through appropriate redaction.

ALK discloses company sponsored clinical trial protocol information and results, regardless of outcome, in publicly accessible clinical trial registries, e.g. EudraCT (www.clinicaltrialsregister.eu) or www.clinicaltrials.gov.

Data sharing with patients who participate in clinical trials

Information to clinical trial participants is of importance for ALK. ALK and its industry peers are working with regulators to adopt mechanisms through which companies can share clinical trial information with subjects who participated in a particular clinical trial, consistent with local legislation. At the moment, this information is available through the individual clinical trial investigators.

Publications

ALK encourages publication of the results from clinical trials of its products, irrespective of whether the results are positive or negative, and acknowledges a special obligation to publish data related to patient safety. As a minimum, ALK will submit for publication the results of all ALK sponsored phase III clinical trials and the results of any other clinical trials of significant medical importance, primarily in peer-reviewed journals or as abstracts, posters, or other presentations at scientific meetings. Publication activities will be undertaken responsibly and ethically to ensure that all relevant information is communicated in an accurate, balanced and complete manner.