Clinical data transparency

Roche Australia (Pharmaceuticals) Policy Position

Summary

- Roche understands and supports the need for stakeholders to have access to information about our medicines, to inform treatment decisions and advance scientific progress.
- Patient safety along with ensuring that the therapeutic benefits of every medicine outweigh the risks is Roche's highest priority.
- Roche proactively collects and alerts authorities and other health stakeholders to safety information (side effects and adverse events) that may be related to our medicines.
- Roche is committed to making clinical study information available to healthcare professionals, researchers and patients in a variety of appropriate ways.

Background

Having access to clinical data about medicines can help people make informed treatment decisions, and enable researchers to advance scientific progress. Stakeholders get clinical data from a variety of sources, including clinical trial registries (eg. *Australian New Zealand Clinical Trials Registry* and *ClinicalTrials.gov*), publications and government-approved product information documents.

Roche position

Roche understands and supports the need for stakeholders to have access to information about our medicines, including clinical study results. Data transparency, related to both safety and efficacy (how well a medicine works), is a critical part of Roche's approach to ethical and responsible business interactions.

Roche supports the role of regulatory authorities in making the benefit-risk decisions that determine access to new products, indications (uses) and formulations, as well as approving information to be included in product information and consumer medicine information documents.

<u>Patient safety information and reporting</u>

Patient safety along with ensuring that the therapeutic benefits of every medicine outweigh the risks is Roche's highest priority. We are committed to bringing safe, effective medicines of the highest quality to patients. To achieve this, we apply the same rigorous standards wherever a Roche medicine is manufactured or sourced. We collaborate with regulatory authorities, including the Therapeutic Goods Administration (TGA) in Australia, monitor reports of adverse events (side effects) that may be related to our medicines, and communicate on medicine safety, as appropriate, to healthcare professionals, patients/consumers and regulatory stakeholders.

Data transparency

Roche supports the call for greater transparency in access to clinical trial results. In 2013, the company globally implemented a broader data sharing policy, both within the scientific community and the public, and is now at the forefront of the data sharing movement.

Roche endeavours to make clinical study information available to patients, physicians and researchers, subject to the protection of patient privacy and commercial confidentiality. To accomplish this, we collaborate with a range of organisations involved in advancing opportunities for data sharing. We believe that disclosure of our clinical study results and data helps to fully realise the public health benefit of our clinical research.

The company is committed to publishing both positive and negative trial results on a publicly available website to ensure healthcare professionals, academics, patients and their caregivers have ready access to information they need.

Roche registers protocols and posts summary reports for clinical trials involving patients on the US website, *www.ClinicalTrials.gov*, and actively seeks presentation and publication of clinical trial data at scientific congresses and in peer-reviewed journals, respectively. Roche also posts summary data from all clinical trials on *www.roche-trials.com*, a publicly accessible website, and on clinical trial websites launched by health authorities and government organisations.

Clinical Study Reports, Periodic Safety Reports and Summary Reports of clinical data for all licensed, terminated or discontinued medicines are released via regulatory authorities, and the company provides this information on request if it cannot be obtained via regulators directly. Additionally, we also provide access to anonymised patient-level data from trials upon assessment of the scientific merit of such requests (assessment by an independent panel of experts).

Further reference

Roche Position on Clinical Research (Global policy)

Roche Policy on Sharing of Clinical Study Information (Global policy)

This position paper was adopted by the Roche Australia (Pharmaceuticals) Leadership Team on 26 October 2016 and entered into force the same day.