



Roche Global Policy on Sharing of Clinical Study Information

This document outlines Roche's position on sharing clinical study information and the steps we are taking to optimise the value our research brings to society.

This policy is in effect since 1 June 2013

Roche's position

Roche shares information about our clinical studies, including study results and data, because this information helps physicians, patients and healthcare providers make informed treatment decisions and advances overall scientific knowledge which benefits society. We endeavour to make our 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.

Key principles

1. Roche is committed to ensuring information generated in our clinical studies is used for the benefit of patients and society.
2. Roche takes all necessary steps to safeguard patient privacy, in compliance with the Roche Privacy Policy, principles of Good Clinical Practice and applicable laws and regulations.
3. Roche respects and supports the role of regulatory authorities in making the benefit-risk decisions that determine access to new products, indications and formulations. As such, our clinical information sharing approach is aligned with the guidelines and requirements of regulatory authorities and other relevant institutions.
4. Roche reserves the right to protect our commercially sensitive information or that of third parties with whom we have contractual obligations.
5. Roche collaborates with a range of organisations and individuals to support and advance the sharing of clinical study information.

Roche's approach to sharing clinical information

We seek to share our clinical study information in four important ways.

1. We disclose information from our protocols and clinical study results information on clinical trial registries

- Clinical trial registries are an important source of information for physicians and patients because they help them to understand if a study is recruiting, ongoing or is completed. Clinical trial registries also help physicians and patients access results once available.

- Roche commits to post all Roche-sponsored safety and efficacy studies in patients on the clinical trial registries of the U.S. National Institutes of Health (NIH) and European Medicines Agency (EMA). Roche works to do this in a timely manner and shares information irrespective of study outcome as per below criteria:
 - *Since 2005, we disclose all required Ph 1-4 interventional and observational studies in patients on global registries, as mandated by applicable regulations.*
 - *The clinical study registration is completed before first patient enrolled.*
 - *The clinical study results summary is reported within one year after primary outcome completion and/or study completion date.*
 - *For clinical studies that qualify for the Delayed Submission of Results with Certification, the results summaries are reported within 30 days of FDA approval or two years after Certification (whichever comes first).*

2. We disclose clinical study documentation

- Clinical study documentation can provide valuable information for fellow researchers who are interested in assessing and comparing research findings.
- Roche supports the release of clinical study documents including study reports, safety reports and clinical summary reports, regardless of study outcome, as long as patient privacy is safeguarded and commercially confidential information is redacted.
- Upon request, we provide redacted clinical study reports (CSRs) for Roche-sponsored trials conducted for regulatory purposes since January 1999. This date was chosen because information prior to 1999 may not be readily accessible due to changes in storage software and hardware. For trials, which were not used for regulatory purposes, we provide CSRs from 1st January 2013.
- Clinical study documentation can be requested via the Roche.com by following the link: https://www.roche.com/research_and_development/who_we_are_how_we_work/clinical_trials/our_commitment_to_data_sharing/clinical_study_documents_request_form.htm

3. We publish in peer-reviewed journals and share data in scientific meetings

- Peer-reviewed publications and scientific meeting presentations are the main channels through which our study outcomes are shared with the medical and scientific community.
- Regardless of outcome, Roche commits to submit the Phase 1-4 primary clinical study results for publication in a peer-reviewed journal in a timely, objective and clinically meaningful manner.
- For investigational products for which a marketing authorization has already been granted in any country, Roche commits to submit a manuscript to a peer-reviewed journal reporting primary clinical trials results within 18 months of the primary completion date for the study.
- For investigational products for which a marketing authorization has not been granted in any country, Roche commits to submit a manuscript to a peer-reviewed journal reporting primary clinical trials results no later than 18 months after the first product approval or decision to discontinue development of the product.
- This commitment will apply to Roche-sponsored trials that were open or active since June 2013 when Roche's first policy on the sharing of clinical information was introduced.
- Roche activities meet international standards including the "Good publication practice for communicating company sponsored medical research" (GPP3), the Consolidated Standards of Reporting Trials (CONSORT statement), and the ICMJE's "Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals".

4. We provide qualified researchers access to individual patient data

- We understand that our data may be of value to other researchers.
- Roche supports qualified investigators engaged in rigorous, independent scientific research by providing access to the data from individual patients participating in studies of products or indications that either (a) are approved by the regulatory authorities, or (b) will not be developed further.
- Access to Roche's patient-level data is facilitated through the cross-industry request site www.clinicalstudydatarequest.com. This platform was designed to enable the sharing of datasets from multiple organisations through a single request process.
- Roche will share data sets from Phase 2 and 3 clinical studies, and Phase 4 studies that were used as part of a regulatory submission, where the first patient was enrolled on or after 01 Jan 1999. Roche will also share datasets if the development program (for all indications) has terminated. Requests to access study information that falls outside this scope will be considered on a case by case basis through enquiries via the www.clinicalstudydatarequest.com site. Further information about trial scope is provided at <http://www.clinicalstudydatarequest.com/Study-Sponsors/Study-Sponsors-Roche.aspx>
- Requests for access are assessed by an Independent Review Panel managed by the Wellcome Trust. The panel considers the scientific merit of each application. This independent group then decides whether or not the data should be provided. Once approved, data are available for up to 24 months.
- Datasets can be requested 18 months after a* clinical study report has been completed and, as appropriate, once the regulatory review of the indication or drug has completed, whichever is later. This timeframe is used to enable the original study investigators to complete the data analysis and publish the results.

*This timing will also be the case for studies that have multiple reporting events and clinical study reports (e.g. oncology studies and studies that include long term follow-up beyond the primary reporting period).