Roche Global Policy on Sharing of Clinical Study Information

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This policy outlines Roche's position on sharing clinical study information.

Roche's position

Roche shares information about its clinical studies, including study results and data, to help patients, physicians, and other healthcare providers to make informed treatment decisions, and support researchers to advance scientific knowledge. Roche makes its clinical study information available, given that patient privacy and commercial confidential information are protected. By sharing clinical study information, Roche strives to maximise the value of its clinical studies to the benefit of public health.

Key principles

1. Roche is committed to ensure that the information generated in its 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, Roche`s 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 its commercial confidential information or that of third parties with whom Roche has contractual obligations.
5. Roche aligns with industry standards of clinical trial data sharing such as the EFPIA-PhRMA principles of Responsible Clinical Trial Data Sharing [1] and BIO Principles on Clinical Trial Data Sharing[2].

Roche focuses on finding new medicines and diagnostics to evolve the practice of medicine and help patients live longer, better lives. The applicable regulatory requirements for the development of medicinal products and medical devices (including in vitro diagnostics) differ. Therefore, Roche's approach for sharing respective clinical study information is slightly different for these two categories as described below.

[1] *https://phrma.org/clinical-trials/phrma-principles-for-clinical-trial-data-sharing*

[2] *https://archive.bio.org/articles/bio-principles-clinical-trial-data-sharing*

Roche's approach to sharing information on clinical studies with MEDICINAL PRODUCTS

Roche seeks to share clinical study information concerning medicinal products in multiple ways as outlined below. For the purpose of this section, clinical studies are differentiated between clinical trials (also known as interventional studies) and non-interventional studies (also known as observational studies).

1. Roche discloses information from protocols and clinical study results

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 summaries of results once available.

Roche commits to post all Roche-sponsored phase 2-4 clinical trials and safety and efficacy non-interventional studies in patients on recognised public registries as applicable (such as ClinicalTrials.gov, EU CTIS, ENCePP EU PAS Register, EUDAMED, and ISRCTN[3]). Roche further discloses phase 1 clinical trials, though some may not appear in the registry if there are legitimate reasons to exclude them. Roche works to do this in a timely manner and shares information irrespective of study outcome as per below criteria:

- The clinical study registration is completed according to the registry guideline (e.g. before the first patient is enrolled).
- The clinical study results summary is reported within one year after primary outcome completion and/or study completion date and within 6 months of study completion date for paediatric studies.
- For complex clinical trials, Roche strives to disclose the results of individual sub-protocols/treatment arms following their completion, unless it interferes with the trial integrity.
- Some clinical study information may not appear in the registry if a deferral process is applicable and there is a legitimate reason to defer.

2. Roche discloses information from protocols and clinical study results in lay language

Providing information about clinical trial results and a summary of clinical trial protocol in lay language is important for patients, their family members, caregivers or doctors who are looking for information about Roche-sponsored clinical trials in clear, easily understood plain language. Roche's ForPatients Platform (www.forpatients.roche.com) provides publicly accessible information about our clinical trials in lay language. Roche also makes this information available on clinical trials registries as applicable. Roche is committed to provide a protocol synopsis in lay language for all applicable clinical trials, however, some may not appear if there are legitimate reasons to exclude them.

[3] *US National Institutes of Health's website (ClinicalTrials.gov), The European Union Clinical Trials Information System (EU CTIS), European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) / EU electronic Register of Post-Authorisation Studies (EU PAS Register), EUropean DAtabase on MEdical Devices (EUDAMED), International Standard Randomised Controlled Trial Number (ISRCTN) Registry*

Roche is also committed to make clinical trial results summaries from phase 1-4 clinical trials available in lay language at the end of the study. However, some clinical trial results summaries may not appear if there are legitimate reasons to exclude them (e.g. phase 1 clinical trials).

Roche may also develop a summary of interim results for clinical trials that have a long follow up or for multi-arm trials where treatment arms may close in advance of overall trial closure.

For complex clinical trials, Roche strives to develop clinical trial results summaries of individual sub-protocols/treatment arms following their completion, unless it interferes with the trial integrity.

3. Roche discloses 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 regardless of study outcome, as long as patient privacy is safeguarded and commercial confidential information is redacted.

Upon request, Roche provides access to redacted clinical study reports and redacted protocols for Roche-sponsored trials conducted for regulatory purposes. Requests to access study information that falls outside this scope will be considered on a case-by-case basis.

Clinical study documentation can be requested using the form accessible via this link: https://www.roche.com/innovation/process/clinical-trials/data-sharing/

Additionally, public access to study documentation is made available by some national health authorities (e.g. Health Canada[4] and the European Medicines Agency (EMA)[5]) at completion of the regulatory review process for a submission.

4. Roche publishes clinical study results in peer-reviewed journals and shares data in scientific meetings

Peer-reviewed publications and scientific meeting presentations are the main channels through which Roche`s study outcomes are shared.

Roche commits to submit the Roche-sponsored Phase 2-4 primary clinical trial results for publication in a peer-reviewed journal in a timely, objective and clinically meaningful manner regardless of whether the findings are positive or negative, unless there is a legitimate reason why publication is not appropriate. This commitment also pertains to development programs that have been discontinued. Roche also strives to publish phase 1 clinical trials and non-interventional studies, however, not all studies produce data which are publishable (e.g., when the data are of limited scientific or clinical value or in the case of multiple journal or conference rejections).

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[4] *https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/profile-public-release-clinical-information-guidance/document.html*

[5] *https://www.ema.europa.eu/en/about-us/contacts/send-question-european-medicines-agency*

For complex clinical trials, Roche seeks to publish clinically and scientifically meaningful data from closed treatment arms prior to study completion through either a peer-reviewed journal publication or presentation at a medical/scientific congress, unless it interferes with the trial integrity.

For investigational products for which a marketing authorisation has already been granted in any country, Roche strives to submit primary clinical trial results to a peer-reviewed journal within 18 months of study completion. For investigational products for which a marketing authorisation has not been granted in any country, Roche strives to submit primary clinical trial results to a peer-reviewed journal within 12 months after product approval or 18 months after development program discontinuation (for all indications).

To increase transparency and enable access to publication for everyone, Roche aims to publish with open access.

5. Roche provides qualified researchers access to individual patient data

Recognising that clinical trial 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 clinical trials 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 https://vivli.org. This platform was designed to enable the sharing of datasets from multiple organisations through a single request process. Full details of the approach to sharing individual patient data can be found on https://vivli.org/ourmember/roche/

Subject to applicable local laws and patient's rights, Roche shares data sets from Phase 2 and 3 clinical trials, and Phase 4 clinical trials that were used as part of a regulatory submission. Roche may also share clinical trial datasets beyond this (e.g. if the development program for all indications has discontinued). To safeguard patient privacy, data is anonymised prior to sharing.

Requests for access are assessed by an Independent Review Panel managed by Vivli. Information regarding panel membership is available at https://vivli.org/about/independent-review-panel/. The panel considers the scientific merit of each application. This independent group then decides whether the data should be provided or not. Once approved, data is available for a minimum of 12 months.

Datasets from clinical trials can be requested 18 months[6] after a clinical study report has been completed and, as applicable, 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.

[6] *This timing is also the case for clinical trials that have multiple reporting events and clinical study reports.*

Roche's approach to sharing information on clinical studies with MEDICAL DEVICES (MDs) (including in vitro diagnostics)

Roche shares information from its sponsored clinical MD studies in multiple ways as outlined below. The term MD clinical study[7] in this section refers to a study leveraging human participants to evaluate biomedical or health-related outcomes. These studies include those conducted for the purpose of gaining market approval, as well as those conducted following market approval.

1. Roche discloses information from clinical study protocols and clinical study results on clinical study registries / databases as applicable

Clinical study 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 study registries also help physicians and patients access summaries of results once available.

Roche commits to post all Roche sponsored MD clinical studies on recognised public registries as applicable to the country specific laws and regulations (such as WHO registry network, ClinicalTrials.gov, EUDAMED and ISRCTN[8]). This includes in particular all interventional studies according to the Applicable Clinical Trial (ACT)[9] FDA definition (including all paediatric post-market surveillance studies). This commitment may not apply to some studies if there are legitimate reasons to exclude them.

Roche shares this information irrespective of study outcome as outlined below:

- The clinical study registration is completed according to the registry guideline (e.g. no later than 21 calendar days after the first patient is enrolled for clinicaltrials.gov).
- The clinical study results summary is generally reported within one year after study completion or within 6 months of study completion date for paediatric studies.
- Some clinical study information may not appear in the registry if a deferral process is applicable and there is a legitimate reason to defer.

2. Roche discloses clinical study documentation

Clinical study documentation can provide valuable information for fellow researchers who are interested in assessing and comparing research findings.

For all Roche sponsored clinical device studies outlined in item 1 above:

- Roche supports the release of clinical study documents regardless of study outcome, as long as patient privacy and commercial confidential information are safeguarded.

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[7] *Includes clinical performance studies and clinical investigations*

[8] *US National Institutes of Health's web site ClinicalTrials.gov (https://clinicaltrials.gov), EUropean DAtabase on MEdical Devices (EUDAMED), International Standard Randomised Controlled Trial Number (ISRCTN) Registry*

[9] *According to FDAAA 801 and the United States (US) 42 Code of Federal Regulation (CFR) Part 11, an applicable device clinical trial means (I) a prospective study of health outcomes comparing an intervention with a device against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and (II) a paediatric post-market surveillance (https://classic.clinicaltrials.gov/ct2/manage-recs/fdaaa)*

- Upon request, Roche provides access to redacted clinical study reports and redacted protocols for applicable studies conducted for regulatory purposes. Requests to access study information that falls outside this scope will be considered on a case-by-case basis.
- Related redacted clinical study documentation can be requested via Dia.DataSharing@roche.com

3. Roche provides qualified researchers access to individual patient data

Recognising that MD clinical study 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 the studies described in item 1 above as long as data privacy is safeguarded and commercial confidential information is redacted.

Datasets can be requested via Dia.DataSharing@roche.com as early as 18 months after an MD clinical study report has been completed and, as applicable, once the regulatory review has completed (whichever is later). This timeframe is used to enable the original study investigators to complete the data analysis and publish the results.

Roche first established its Global Policy on Sharing of Clinical Study Information June 2013
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