



Roche Global Policy on Publication and Data Disclosure

Executive Summary

Roche is dedicated to transparency in the communication and dissemination of information about clinical trials and other research and development activities for the lifecycle of all Roche products. This information should be disclosed in a timely, objective, and clinically meaningful manner that is consistent with good science.

The company adheres to the principles of Good Clinical Practice and the Declaration of Helsinki, and follows clear guidelines to ensure this policy.

Global Policy

The purpose of this global policy is to describe the principles that govern:

- (a) the posting of Roche-sponsored trial information and tabular study results on the National Institutes of Health's ClinicalTrials.gov website (CTg)
- (b) publication planning and other activities related to non-promotional, peer reviewed publications to ensure the scientific integrity and credibility of publication activities performed by, or on behalf of, Roche.

Clinical Trial Registration and Results Posting

Regardless of the outcome of a trial, Roche is dedicated to providing balanced information on the trial to healthcare professionals and to the public. Roche posts information on CTg for all Roche-sponsored Phase I clinical trials in patients, all Phase II-IV interventional and observational clinical trials, and all interventional trials using advanced and launched diagnostic products¹.

Roche posts tabular results on CTg for all Roche-sponsored clinical trials that are applicable under the FDA Amendments Act of 2007 and/or Maine's Prescription Drug Clinical Trial Reporting Regulations. Roche provides hyperlinks from trial records on CTg to results summaries for all Roche-sponsored Phase I clinical trials (in patients) to Phase IV interventional and observational trials completed for marketed products and all diagnostic interventional trials using launched diagnostic products.

Roche Affiliates may maintain their own trial websites as long as the content is aligned with the information provided on CTg and reflected in Roche CTMS systems. Affiliates should not post records on CTg for Roche-sponsored trials.

Roche-supported trials are not posted by Roche on CTg. For supported trials, posting is the responsibility of the investigator or cooperative group and the agreement with the sponsor must specify the details of the site on which the trial will be posted, and the personnel responsible for the posting.

Publication and Data Disclosure

Roche is also committed to disclosing any financial contributions made by the Company related to a clinical trial, any publication assistance provided by the Company to the author(s) (financial or otherwise), and any other disclosures required by the applicable journal or congress or local regulations.

Authorship – Authorship criteria for all publications of Roche-sponsored clinical trials are based on International Committee of Medical Journal Editors (ICMJE) “Uniform Requirements for Manuscripts Submitted to Biomedical Journals.” Authorship credit can be granted only to those who make substantial contributions to the publication, including, but not limited to ALL of the following criteria:

- (i) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of the data;
- (ii) Drafting or revision of the abstract/manuscript for important intellectual content, and;
- (iii) Approval of the final version to be published.

Author Access to Data - Databases from a Roche-sponsored study are considered confidential and proprietary information and the sole property of Roche. Roche will ensure however, that all non-Roche authors (both Investigators and other experts directly involved in the study) will have access to the appropriate study protocol, case report forms (CRFs), the statistical analysis plan, results of statistical analyses and the Clinical Study Report (CSR).

Alignment with External Standards - Roche conducts publication activities in alignment with international regulations and industry guidelines [e.g., Good Publications Practice (GPP), Consolidated Standards of Reporting Trials (CONSORT statement), International Committee of Medical Journal Editors Uniform Requirements for Manuscripts (URM)].

¹ Healthy volunteer and non-interventional biomarker trials are not required to be posted on CTg.

Entry into Force

This policy was adopted on December 10, 2010 and entered into force the same day.