

GCP Policy



Roche Clinical Trial Protocol Registry and Results Database

Document Ref.: **gcp_pol000027**

Valid as of: **04.12.2006 00:00:00**

Version No: **3.0**

DD.MM.YYYY hh:mi:ss (BsST*)

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Application Area(s):

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ro - pb

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DD.MM.YYYY hh:mi:ss (BsST*)
24.11.2006 14:27:53
30.11.2006 17:08:21

This document replaces:

Reference number(s) of the attached document(s):

gcp_spt000215

gcp_spt000444

Document Objectives:

To outline the key features of the Roche Global Policy on the Roche Clinical Trial Protocol Registry and Results Database.

* BsST = Basel Server Time

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Governing document(s):

Referenced document(s):

Roche: Clinical Trial Protocol Registry and Results Database
Declaration of Helsinki
ICH E6 Guideline for Good Clinical Practice

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Pharmaceuticals
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1. Purpose and Scope

The purpose of this global policy is to outline the key features of the Roche Clinical Trial Protocol Registry and Clinical Trial Results Database.

The scope of this policy is all Roche sponsored clinical trials conducted by Pharma Development (PD), Pharma Business (PB), and Pharma Affiliates (PA). To be considered a Roche sponsored trial, Roche may either act as sole sponsor or as lead sponsor. Refer to *Roche Sponsored and Supported Clinical Trials (gcp_pol000020)* for further detail on "sponsorship".

2. Policy

Roche remains dedicated to transparency in clinical trials. The company adheres to the principles of Good Clinical Practice (GCP) and the Declaration of Helsinki. In order to uphold these principles, and the Roche Policy, clear guidance has been implemented.

Roche has established both a clinical trial protocol registry, to disclose information about new studies at or before their inception, and a clinical trial results database to publish key clinical trial results in English (www.roche-trials.com).

The **Clinical Trial Protocol Registry** consolidates and expands information, which has previously been communicated through local registries and serves as a central global repository for information on ongoing clinical studies conducted in patients. It provides basic study information in language that an educated lay person can understand. The purpose is to inform the public, in particular patients and healthcare professionals, as to each trial's purpose and conditions of participation.

The **Clinical Trial Results Database** ensures that results from Roche sponsored clinical trials, that might "impact the practice of medicine" (see Section 3: Definitions), are reported in a fair and balanced manner. This public database reflects Roche's belief in the ethical obligation to accurately communicate all research results, whether positive or negative.

Both the registry and the database contain information on all interventional Roche

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sponsored clinical trials in patients worldwide. As appropriate, Roche will provide links to its global registry and results database in local registries and databases.

2.1. Clinical Trial Protocol Registry for Disclosure of Information about Ongoing Studies

- A publicly available clinical trial protocol registry provides basic information to inform patients and healthcare workers about available and appropriate clinical trials. This registry contains information on all Roche sponsored clinical trials in patients worldwide and is hosted by an independent, neutral entity. In parallel all Roche sponsored clinical trials in patients worldwide will also be registered in www.clinicaltrials.gov.
- Each clinical trial is labelled with a unique identifier to facilitate cross-reference.
- Information is provided for all interventional, Roche sponsored trials in patients.
- Trial information is included in the registry as soon as the study design has been finalized, and Independent Ethics Committee (IEC)/Institutional Review Board (IRB) or Competent Authority (CA) approval has been obtained, unless local law requires earlier registration. Such registration will always take place at or before inception of the trial.
- Since the goal is to help patients find clinical trials that they might want to join, information is presented in language that an educated lay-person can understand.

2.2. Clinical Trial Results Database for Disclosure of Information about Completed Studies for Marketed Products

- All clinical trials listed in the protocol registry are also listed in the clinical trial results database and cross-referenced to ensure transparency.
- Regardless of outcome, Roche publicly discloses the results of all interventional, Roche sponsored trials in patients on marketed products.
- Since the primary purpose of this database is to provide balanced information to health care professionals, the data is presented in scientific terms.

Refer to *Clinical Trial Protocol Registry and Results Database - FAQ (gcp_spt000444)*, for responses to Frequently Asked Questions.

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3. Definitions

The table below contains definitions specific to this document. Refer to the *Pharma R&D Glossary*, which can be accessed via the icon on the GCP eSOP Portal, for all other definitions.

Term	Definition
Impact on the practice of medicine	Data is of such scientific or medical importance that knowledge of it would influence the decision(s) made by a practicing physician and/or other qualified health care worker(s). The results may influence these decisions with regard to the drug itself, or with regard to drugs in the same class.
Published	If data is of sufficient quality, publication will be pursued in a peer-reviewed journal and/or in abstract form. If not, data will be published on a publicly accessible website.
Roche as Lead Sponsor	In this case, Roche will retain core responsibilities which will be defined in a case-by-case manner for the individual project. The clinical trial partner(s) will assume the remaining responsibilities.
Roche as Sole Sponsor	In this instance, Roche will assume all the responsibilities of a sponsor as defined above.

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4. Change History

Version	Location in document	Comment/Description of Change
1.0	NA	New document.
2.0	NA	Updated Policy: <ul style="list-style-type: none"> - Clarification that only interventional trials will be posted - Roche sponsored phase II-IV, completed after Oct 1 2002 on any approved product will be posted on the results database - Inclusion that all retrospective Roche sponsored phase II-IV trials for compounds that received first approval in first indication after Oct 1 2002 will be posted on the results database
3.0	Table of Contents	Policy written in new GCP Policy Template. Changes as follows: "Scope" changed to "Purpose and Scope" "Policy" sub-headings included "Responsibilities and Procedures" section deleted "Definitions" section added
	Title	Changed from " <i>Roche Global Policy on Clinical Trial Protocol Registries and Results Databases</i> " to " <i>Roche Clinical Trial Protocol Registry and Results Database</i> "
	All sections	Text changed, as appropriate, to indicate that now "All interventional Roche sponsored clinical trials <u>in patients</u> will be available in the registry and the database". Previously restricted to "Roche sponsored <u>phase II – IV</u> interventional clinical trials".
	2.1	New text added to indicate that, "in parallel, all Roche sponsored clinical trials in patients worldwide will also be registered in www.clinicaltrials.gov ."
	FAQ	All FAQ text has been moved to <i>Clinical Trial Protocol Registry and Results Database - FAQ (gcp_spt000444)</i> , which is listed an attachment to this Policy.