

GCP Supporting Document



Clinical Trial Protocol Registry and Results Database - FAQ

Document Ref.: **gcp_spt000444**

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

Version No: **1.0**

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

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Application Area(s):

ro - pd

ro - pb

ro - affiliates

Prepared by

Karol Cheryl

Organisational Group

ro - pdqe

Electronic Signatures for Approval

Name Firstname

Reason for signing and Location

Date and Time

Wright Louise
Widler Beat E.

QA Approval signed in ConDoR
Approval signed in ConDoR

DD.MM.YYYY hh:mi:ss (BsST*)
27.11.2006 03:29:13
27.11.2006 07:24:18

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

gcp_spt000215

Document Objectives:

To provide responses to Frequently Asked Questions (FAQs) regarding the Roche Clinical Trial Protocol Registry and Results Database.



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Pharmaceuticals
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Referenced document(s):

Roche: Clinical Trial Protocol Registry and Results Database

VIEW ONLY

* BsST = Basel Server Time

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Procedures/tasks described in Supporting Documents are intended to eliminate excessive detail from a Policy/SOP. Therefore, in most cases, they are "binding" by default as they represent an extension of a Policy/SOP. If applicable, any "non-binding" elements in the following document are explicitly identified as "recommendations" or prefaced with terms such as "should" or "may".

1. Purpose and Scope

The purpose of this document is to support the Roche Global Policy, *Roche Clinical Trial Protocol Registry and Results Database (gcp_pol000027)* by providing responses to Frequently Asked Questions (FAQs).

This document is applicable to Roche sponsored clinical trials conducted by Pharma Development (PD), Pharma Business (PB) and Pharma Affiliates (PA).

2. Supporting Document Details

2.1. Where is information disclosed?

Roche has established a publicly available website, www.roche-trials.com, that is hosted by an independent, neutral entity, to disclose information about new studies at or before their inception i.e. **Clinical Trial Protocol Registry**, and to publish key clinical trial results i.e. **Clinical Trial Results Database** on these trials. All eligible clinical trial results will be published in this results database, whether there is a publication of the study results in the scientific literature or not. Clinical trial results will also continue to be published through peer-reviewed medical journals, subject to the discretion of the journal editors. References (and links when available) will be provided in the clinical trial results database for study results disclosed in the scientific literature.

2.2. What information is disclosed?

The Clinical Trial Protocol Registry provides basic information about available Roche sponsored, interventional clinical trials in patients. A description of the trial design, methodology and locations in which the trial will be conducted, is included for each study.

The Clinical Trials Results Database displays the clinical trial results (in summary form)

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of the primary and secondary outcome measures as specified in the study protocol, in addition to safety results. This applies in all cases, whether there is a publication of the trial results in the scientific literature or not.

2.3. When is information disclosed?

For any trial in patients, regardless of the phase of the trial, the results will be disclosed within one year of the time that a drug or new indication is first approved in any market or within one year from when a product is permanently discontinued from further development. For trials conducted after approval, the results will be disclosed within one year after the trial has been completed [defined as "Last Patient, Last Visit". Refer to *Standard Definition of Last Patient Last Visit (LPLV) and End of Trial (gcp_spt000215)*].

If a study is under review by a peer-reviewed journal that prohibits pre-publication of results, the results will be posted at the time of the journal publication. An explanation will be placed in the database, in accordance with the timelines stated in the preceding paragraph, while publication of the manuscript is pending. In addition, in some instances, there may be a delay in posting complete trial summaries due to the need to seek intellectual-property protection or to comply with confidentiality provisions in agreements with other parties. In such cases, an explanation will be placed in the results database.

2.4. How is disclosure verified?

Adherence to the Roche Global Policy, *Roche Clinical Trial Protocol Registry and Results Database (gcp_pol000027)* is audited periodically by our internal auditing group Pharma Development Quality Auditing (PDQA). This occurs as a matter of course as clinical trials are audited. In addition, other audits specifically address the registration of trials, prior to or at the time of initiation, and the subsequent publication of data once each listed trial has been completed and the results analyzed.

2.5. How are the protocol registry and results database cross-referenced?

For each trial posted in the clinical trial protocol registry there is a link to the corresponding listing within the clinical trial results database. Roche will also update the clinical trial protocol registry to reflect when and where the results are published.

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2.6. Are there any circumstances in which results of clinical trials covered by the Roche policy would not be published?

There are certain situations in which it would be improper to publish clinical trial results. One example would be the case of a study that ended prematurely where no conclusions can reasonably be drawn due to insufficient data. Another example would be a case where the study results were found to be invalid. This could be due to a flaw in the study design, or in the data itself, possibly connected to improper collection of data, storage or shipping conditions of samples, lab error, etc. In these and other circumstances, where it is not appropriate to publish the data, the reason(s) for this decision will be detailed in the results database.

2.7. What is the effective date for implementation?

Results from any trial posted in the protocol registry will be published on www.roche-trials.com / www.centerwatch.com according to the timelines defined in Section 2.3 of this document.

Roche has committed to **register and enter results** for:

- Phase II-IV interventional clinical trials completed after October 1, 2004
- Phase I trials conducted in patients (Effective 01 July 2006)

In addition, **results have been entered** retrospectively for all:

- Phase II-IV trials for products "first marketed" October 1, 2002 - October 1, 2004
- Phase II-IV trials completed October 1, 2002 - October 1, 2004

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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 definitions.

Term	Definition
First marketed	First marketed is defined as approval for the first indication in the first market.

4. Change History

Version	Location in document	Comment/Description of Change
1.0	NA	New document. Content previously documented within the <i>Roche Global Policy on Clinical Trial Protocol Registries and Clinical Trial Results Databases (gcp_pol000027)</i> . Text here has been revised to ensure alignment with version 3.0 of the Policy. See below for major change.
	2.7	Revision of text to indicate status of implementation for the different trials types e.g. effective 01 July 2006, all phase I trials conducted in patients are also published."