

GCP Supporting Document



Pharmaceuticals
Effective

Standard Definition of Last Patient Last Visit (LPLV) and End of Trial

Document Ref.: gcp_spt000215

Valid as of: 30.06.2006 00:00:00

Version No: 1.0

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

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Application Area(s):

ro - pdm

ro - pdms

ro - pdo

ro - pdr

ro - pdq

ro - affiliates

ro - pb

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Reason for signing and Location

Date and Time

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Approval signed in ConDoR

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

Document Objectives:

To provide standard definitions of LPLV and End of Trial that can be applied consistently to Roche sponsored clinical trials.

VIEW ONLY

* BsST = Basel Server Time

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1. Purpose and Scope

The purpose of this document is to provide a standard definition of "Last Patient Last Visit" (LPLV) and "End of Trial", which can be applied consistently to all Roche sponsored Phase I – IV clinical trials conducted by Pharma Development (PD), Pharma Business (PB) and Pharma Affiliates (PA). It is recommended, where possible, that the same definitions also be applied to Roche supported clinical trials. Refer to *Roche Sponsored and Supported Clinical Trials (gcp_pol000020)* for information on Roche sponsored versus supported trials.

2. Supporting Document Details

2.1. Background

The European Union Clinical Trial Directive (EU Directive 2001/20/EC) requires the following in relation to clinical trial completion:

"...within 90 days of the end of a clinical trial, the sponsor shall notify the competent authorities of the Member States or Member States concerned and the Ethics Committee that the clinical trial has ended...."

"Additionally the sponsor needs to provide a summary of the clinical trial report within 1 year of the end of the trial to the authorities in the Member States concerned."

To prevent confusion, or the need to justify a different term to the European Union Clinical Trial Directive, it is recommended that Roche use a standard term globally i.e. for EU and non-EU trials, to define "End of Trial". The standard term that will be used is **LPLV**.

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2.2. Standard Definitions

2.2.1. Standard definition of LPLV

The definition of LPLV has been broadened, such that it also covers the last date at which a data point was received from the last patient (e.g. an analysis result from a central lab). The definition is provided below:

Last Patient Last Visit is **either** the date of the last patient visit of the last patient to complete the study, **or** the date at which the last data point from the last patient, which was required for statistical analysis (i.e. key safety and efficacy results for decision making), was received, whichever is the later date.

Note:

- LPLV includes scheduled follow-up visits, defined in the protocol.
- LPLV can be identified from the schedule of assessments in the protocol. If the assessments include laboratory samples, ECG interpretation etc., the Study Management Team (SMT) should consider LPLV to be the date that these data were received by Roche.

2.2.2. Standard definition of "End of Trial"

SMTs should define "End of Trial" as follows:

End of Trial = LPLV

A definition of "End of Trial" must be provided in the clinical trial protocol regardless of how it is defined and if the definition is not the same as LPLV, justification must be provided.

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Note: According to the definition of LPLV (provided above) it is possible for LPLV to be related to receipt of a data point, which may occur after the date of the last formal visit. Standard protocol text will state that by default, the latest of the 2 time points will be used to define end of trial unless otherwise specified.

2.2.3. Special cases

For some trials, a Health Authority (HA) filing occurs midway through the trial. In this situation, a clinical cut off is defined for filing purposes but the trial continues for a number of months/years afterwards. In this situation, the following approach should be taken:

- The Clinical Trial Application (CTA) submission should clarify plans for providing reports to HA'(s) and Independent Ethics Committee(s) (IEC's).
- The clinical cut off for filing should be clearly stated in the protocol
- An interim Clinical Study Report (CSR) summary can be provided to the HA's after the clinical cut off
- The end of trial should be defined as the **actual** end of trial (=LPLV)
- An end of trial notification will only be sent for the actual end of trial.

3. Definitions

Refer to the *Pharma R&D Glossary*, which can be accessed via the icon on the GCP eSOP Portal.

4. Change History

Version	Reason(s) for Change
1.0	New document.