Edition 1

Brazilian Health Surveillance Agency

MANUAL FOR THE SUBMISSION OF CLINICAL TRIAL START AND END FORMS AND FOLLOW-UP REPORTS

General Management of Medicines - GGMED

Coordination of Clinical Research in Medicines

and Biological Products - COPEC

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DRUGS

MANUAL FOR THE SUBMISSION OF CLINICAL TRIAL START AND END FORMS AND FOLLOW-UP REPORTS

This Manual aims to guide professionals in the area with information on how to apply Resolution RDC/Anvisa No. 9 of February 20th, 2015, contributing to the development of safe actions, in addition to providing relevant and updated information that can be better clarified through the Manual instrument.

The Manual does not create new obligations, and should be used by public and private agents as a reference for compliance with the existing legislation.

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1. ACRONYMS

DDCM - Clinical Drug Development Dossier
ICH - International Conference on Harmonization
RDC - Collegiate Board Resolution

2. INTRODUCTION

The publication of the regulation on clinical trials with medicines in Brazil makes it mandatory to submit the follow-up reports of clinical trial protocols and forms informing the start and end date of a clinical trial in Brazil. This manual is intended to provide guidance for the sponsor, sponsor-investigator, or CRO to properly submit these reports and forms.

It is a non-binding regulatory measure adopted as a complement to health legislation, with the educational purpose of providing guidance on routines and procedures for complying with the legislation, not intended to expand or restrict established technical or administrative requirements.

3. LEGAL BACKGROUNDS

Anvisa Resolution - RDC No. 9, of February 20th, 2015, which provides for the regulation for conducting clinical trials with medicines in Brazil.

4. OBJECTIVE

With no prejudice to the provisions contained in legal instruments, this manual aims to guide the submission of follow-up reports of clinical trial protocols and clinical trial start and end date forms, described in chapters III and VII of RDC No. 09/ 2015. We recommend that the format be standardized in terms of order and content in order to facilitate assessment.

5. FOLLOW-UP REPORTS OF CLINICAL TRIAL PROTOCOLS

It is the sponsor's responsibility to submit to Anvisa annual and final follow-up reports containing information exclusively from Brazilian centers, in a tabulated form, for each clinical trial protocol.

a) For regulatory submission purposes, the annual and final reports must be secondary electronic petitions linked to the process number of the respective clinical trials consent.
b) The linking of secondary petitions to the corresponding processes is essential for their analysis and traceability in Anvisa's electronic systems.
c) The following petition subjects should be used: 1391 – CLINICAL TRIALS – Annual Clinical Trial Protocol Follow-up Report and 1392 - CLINICAL TRIALS – Final Clinical Trial Protocol Follow-up Report.
d) All non-substantial amendments shall be included in the Annual Clinical Trial Protocol Follow-up Reports.
e) The annual and final reports, for each clinical protocol, must contain the minimum requirements established in Art. 68, for the annual report, and Art. 69, for the final report, of RDC No. 09/2015, or they may be presented in ICH E3 format.
f) Annual reports must be cumulative.
g) The annual report must be filed within a maximum period of 60 (sixty) calendar days having the starting date of the clinical trial in Brazil as reference for annuality.
h) The final report must be filed within 12 (twelve) months from the end of the clinical trial.

6. CLINICAL TRIAL START AND END DATE FORMS

Anvisa must be informed of the start and end date of each clinical trial included in the DDCM, in accordance with RDC No. 09/2015. For this, the sponsor must file the forms of clinical trial start and end date in Brazil.

a) The forms must be secondary electronic petitions linked to the specific dossier process number for each clinical trial.

b) The forms must be filed within 30 (thirty) calendar days after each start and end date of the clinical trial through the subjects: 10480 - CLINICAL TRIALS - Notification of Clinical Trial Start in Brazil and 10481 - CLINICAL TRIALS - Notification of End of Clinical Trial in Brazil, respectively.
c) The forms described in this item are available on Anvisa Website > Medicines > Clinical Research > Forms.

7. GLOSSARY

I. Clinical Trial Start Date - corresponds to the date when the first subject was included in the clinical trial worldwide;

II. Clinical Trial Start Date in Brazil - corresponds to the date when the first subject was included in the clinical trial in Brazil;

III. Inclusion date: Date of randomization or another sponsor definition expressly stated in this document or in the specific clinical trial protocol.

IV. Clinical Trial End Date - corresponds to the date of the last subject's last visit in the clinical trial worldwide or another sponsor definition, expressly determined in the specific clinical trial protocol;

V. Clinical Trial End Date in Brazil - corresponds to the date of the last subject's last visit in the clinical trial in Brazil or another sponsor definition, expressly determined in the specific clinical trial protocol;

VI. Clinical Drug Development Dossier (DDCM) - compiled of documents to be submitted to Anvisa with the purpose of evaluating the steps involved in the development of an experimental drug in order to obtain information to support the registration or post-registration changes of that product;

VII. Clinical Trial-Specific Dossier - compiled of documents to be submitted to Anvisa in order to obtain information regarding the clinical trials to be conducted in Brazil, which are part of the Experimental Drug Development Plan;

VIII. Clinical trial - research conducted in human beings with the purpose of discovering or confirming the clinical and/or pharmacological effects and/or any other pharmacodynamic effect of the experimental drug and/or identifying any adverse reaction to the experimental drug and/or studying the absorption, distribution, metabolism and excretion of the investigational drug to verify its safety and/or efficacy;

IX. Experimental drug - test pharmaceutical product, object of the DDCM, to be used in the clinical trial, in order to obtain information for its registration or post-registration;

X. Investigational product - experimental drug, placebo, active comparator or any other product to be used in the clinical trial;

XI. Clinical Trial Protocol - document that describes the objectives, design, methodology, statistical considerations, and organization of the trial. It also provides the context and rationale for the clinical trial;

XII. Annual report - an annual document containing specific information on the conduction of a given clinical trial in centers in Brazil, in accordance with the clinical protocol and the GCP.

XIII. Final report - document containing specific information about the conduct of a given clinical trial in all centers participating in the study, in accordance with the clinical protocol and the GCP.

8. REFERENCES

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9. HISTORY OF CHANGES

Version	Changes made	Explanation and Rationale
1st Edition	Initial version.	