

TECHNICAL NOTE No. 74/2026/SEI/COPEC/DIRE2/ANVISA

Case No. 25351.941297/2019-24

	ICH GUIDE IMPLEMENTATION PLAN E8(R1) ON GENERAL CONSIDERATIONS FOR CLINICAL STUDIES AND ICH GUIDELINES E6(R3) - PRINCIPLES AND ANNEX 1 - ABOUT GOOD CLINICAL PRACTICES (GCP)
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1. Introduction

The ICH (International Council for Harmonisation of Technical Requirements for Medicinal Products for Human Use) is an international organisation that brings together regulatory authorities and the pharmaceutical industry to develop harmonised scientific and technical guidelines. Its aim is to promote greater uniformity in the requirements for the development and registration of medicines among countries, and its mission is to contribute to public health by ensuring that safe, effective and high-quality medicines are developed and made available more efficiently.

The main ICH guidelines for planning and conducting clinical trials are guidelines E8, which deals with General Considerations for Clinical Studies, and E6, which deals with Good Clinical Practice (GCP). Other relevant ICH guidelines can be found on the ICH website .

The E8(R1) guideline was revised and published by the ICH on October 6, 2021. The ICH published the E6(R3) guideline - Principles and Annex 1 on January 6, 2025. From then on, each ICH member adopted its own strategies for implementing these guidelines in its region.

On May 19, 2026, Anvisa held the 1st Workshop on GMP Inspections, in partnership with the Pharmaceutical Products Industry Union (Sindusfarma), with the central topic of the event being to discuss and evaluate the impact of the implementation of ICH E8(R1) and E6(R3) guidelines in Brazil.

Considering the substantial changes to both the E8(R1) and E6(R3) guidelines and evaluating the opinions collected during the aforementioned event, Anvisa proposes this plan for the implementation of the ICH E8(R1) and E6(R3) guidelines in Brazil.

2. Implementation Plan for the Guidelines

The proposed plan aims to prepare those involved in clinical research for a gradual and organized implementation of the ICH E8(R1) and E6(R3) guidelines. To this end, Anvisa will establish a working group (WG) to coordinate training and internalization actions for the guidelines in Brazil.

The working group will have the support of the Department of Science and Technology of the Ministry of Health. (DECIT/MS) for the development of materials and training, in addition to the participation of representatives from clinical trial centers, clinical research professionals, sponsor and Representative Clinical Research Organizations (RCOs) through

associations/institutions related to these actors.

Activity schedule:

Term	Activity	Responsible
Until October 2026	Publication of the Implementation Plan for the Guidelines ICH E8(R1) and E6(R3) - Principles and Annex 1	Anvisa
Until November 2026	Establishment of a Working Group (WG) with representatives from Anvisa, Department of Science and Technology of the Ministry of Health (DECIT/MS) and regulated sector to assist in the development of training, webinars and a Questions and Answers document	Anvisa, DECIT/MS and regulated sector
Until December 2026	Development of the GT's activity plan and commencement of activities.	Anvisa, DECIT and the regulated sector
	Publication of the guides in Portuguese on the website of Anvisa	Anvisa
Until July 2027	Publication of training materials and other resources developed by the Working Group.	Anvisa, DECIT and the regulated sector
	Update of guides 35 and 36/2020	Anvisa
	Evaluate processes that may be impacted by E8(R1) and E6(R3) and update them.	All
	Training for those involved in clinical research in Brazil: Materials from the ICH and the Working Group	All
	Inspection reports for GPC conducted in 2027 will reference both E6(R2) and E6(R3) for training purposes.	Anvisa
01/08/2027	Implementation of guidelines E8(R1) and E6(R3) (Principles and Annex 1) in Brazil	All

It should be noted that the implementation plan for Annex 2 of the ICH E6(R3) Guideline will be published at a later date.

From August 2027, Anvisa will base its Good Clinical Practice inspections on the ICH E8(R1) and E6(R3) guidelines. However, this does not prevent those involved in clinical research from already following the guidelines of this version in their activities before this date.



This document was electronically signed by **Claudiosvam Martins Alves de Sousa, Coordinator of Clinical Research in Medicines and Biological Products**, on October 1, 2026, at 9:04 AM, Brasília time, pursuant to § 3 of Article 4 of Decree No. 10,543, of November 13, 2020 http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm.



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