



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Consultation: Proposed TGA comments to Annex 2 of ICH E6(R3) Guideline for Good Clinical Practice (GCP)

October 2026

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Contents

Overview	4
Background	4
Proposed TGA comments to Annex 2	5
What we invite you to do	5

Overview

The Therapeutic Goods Administration (TGA) is seeking feedback on proposed TGA comments to Annex 2 of the ICH E6(R3) Guideline for Good Clinical Practice (ICH GCP E6(R3)). TGA comments explain Australian-specific considerations that should be taken into account when applying the guideline.

We are also seeking feedback on the proposal not to provide a transition period for sponsors, trial sites, and other stakeholders, as Annex 2 does not introduce any new requirements, and instead provides additional supporting guidance.

Following consideration of consultation feedback, the TGA intends to adopt the consolidated ICH GCP E6(R3) guideline in **January 2027**.

Background

The TGA is adopting ICH GCP E6(R3) in two stages. The Principles and Annex 1 were adopted on 13 January 2026 with TGA comments and a 12-month transition period to support implementation.

Annex 2 was finalised by the ICH on 3 June 2026. It builds on the foundations established in the Principles and Annex 1 and completes the ICH GCP E6(R3) guideline. While Annex 2 has been made available as a standalone document for the purposes of this consultation (**Attachment A**), the TGA intends to adopt it as part of the consolidated guideline.

TGA comments to Annex 2 will be published on the TGA website alongside the existing comments to the Principles and Annex 1.

Further information, including the published TGA comments to the Principles and Annex 1, is available at [ICH Guideline for Good Clinical Practice](#).

Proposed TGA comments to Annex 2

Annex 2 section	Proposed TGA comments
3.4.2. Consent and Permission Considerations for RWD	Broad consent refers to consent provided by a participant for extended and/or unspecified research. Refer to Chapter 2.2 of the National Statement for more information.

What we invite you to do

This consultation seeks your feedback on proposed TGA comments to Annex 2 of ICH GCP E6(R3). Your feedback will help inform whether any additional Australian-specific considerations should be reflected in the TGA comments to support implementation of the guideline.

In your submission, we ask you to consider and respond to the questions below:



Question 1. Please indicate your level of support for the proposed TGA comments to Annex 2

- support
- partially support
- do not support

An optional short text response field will be provided. We encourage you to support your feedback with relevant justification, such as references to the legislative framework or practical examples, where possible.



Question 2. Do you have any suggestions for additional TGA comments to Annex 2?

- Yes
- No

An optional short text response field will be provided.



Question 3. Annex 2 does not introduce any new requirements beyond those already established in the Principles and Annex 1. Do you support the proposal not to provide a transition period?

- Support
- Do not support

A short text response field will be provided to share any concerns or implementation challenges associated with Annex 2.

We invite comments through the [Consultation Hub](#) by **close of business 20 November 2026**.



The TGA is aware that generative artificial intelligence (AI) may be used to assist in preparing responses to this consultation. It is the respondent's responsibility to ensure the accuracy of their response.

Participation and feedback provided during this consultation is greatly appreciated.

Please contact us at GCP.Inspection@Health.gov.au if you have any questions regarding this consultation.

Version history

Version	Description of change	Author	Date
V1.0	Original publication	Pharmacovigilance Compliance and Clinical Trials Section (PCCTS), TGA	October 2026

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