



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

**Consultation: Proposed TGA Annotations to ICH E6(R3)
Guideline for Good Clinical Practice (GCP): Principles
and Annex I and 12-month Transition Period
August 2025**

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About this consultation

The TGA closely aligns its regulatory approaches to therapeutic products with those of comparable international regulatory counterparts wherever possible. TGA annotations to the ICH E6 Guideline for Good Clinical Practice (GCP) ensures consistency with Australian legislative requirements for clinical trials of [unapproved medicines and biologicals](#) under the Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) schemes.

On 6 January 2025, the International Council for Harmonisation (ICH) endorsed the third revision (R3) of the ICH Guideline for conducting clinical trials titled [ICH E6\(R3\) Guideline for Good Clinical Practice](#). This update addresses changes in trial design and technological innovations, and strengthens a proportionate, risk-based approach to the design and conduct of clinical trials.

This consultation seeks feedback on the [proposed TGA annotations](#) ICH E6(R3) Guideline for GCP: Principles and Annex I and a [12-month transition period](#) to support implementation.

ICH E6(R3) Guideline for GCP: Principles and Annex I with TGA annotations are expected to be adopted in **January 2026**. To support implementation, a 12-month transition period is proposed, allowing sponsors, trials sites and other stakeholders time to meet the updated requirements. The timelines provided are indicative. Following the consultation and consideration of stakeholder feedback, the key adoption and transition dates will be announced on our webpage [ICH Guideline for Good Clinical Practice](#) and promoted on our [social media](#).

Submissions should be made via our [Consultation Hub](#) by close of business **10 October 2025**.

Introduction to TGA annotations

The ICH Guideline for Good Clinical Practice (ICH E6) is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials. The Guideline for Good Clinical Practice is incorporated by reference in the *Therapeutic Goods Regulations 1990*. Compliance with the ICH Guideline for Good Clinical Practice is a condition of approval for the conduct of a clinical trial.

In Australia, the *National Health and Medical Research Council Act 1992* establishes the National Health and Medical Research Council (NHMRC) as a statutory entity to pursue and foster issues relating to public health. The NHMRC is specifically required to issue guidelines for the conduct of medical research and ethical matters related to health. The [National Statement on Ethical Conduct in Human Research](#) (the National Statement) has been produced by the NHMRC as the Australian ethical standard against which all research involving humans, including clinical trials, are reviewed.

The National Statement is incorporated by reference in the *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Medical Devices) Regulations 2002*. Compliance with the National Statement is a condition of approval for the conduct of a clinical trial. If requirements specified in the National Statement appear to differ from those specified in the ICH Guideline for Good Clinical Practice, the TGA recommends compliance with the National Statement.

ICH E6 is referred to as the ICH Guideline for Good Clinical Practice in the TGA's annotations consistent with its title in the *Therapeutic Goods Regulations 1990*.

TGA annotations to the ICH Guideline for Good Clinical Practice are provided to ensure the Guideline is consistent with prevailing legislative requirements in Australia for clinical trials of [unapproved medicines and biologicals](#) under the CTN and CTA schemes.

Scope

This consultation seeks feedback on the [proposed TGA annotations](#). These annotations explain if there are parts of ICH E6(R3) Guideline for GCP: Principles & Annex I that are **not** adopted, or if there are particular considerations that need to be taken into account when applying the guideline in an Australian context.

The annotations provide critical interpretive guidance to align ICH E6(R3) Guideline for GCP with the applicable Australian **legislative framework**. Final TGA annotations are published on the TGA website along with the [ICH E6\(R3\) Guideline for Good Clinical Practice](#) rather than embedded within the legislated guideline itself.

We are seeking feedback on the proposed 12-month transition period for sponsors, trial sites, and other stakeholders to meet the updated requirements.

[ICH E6\(R3\) Guideline for GCP Annex 2](#) is not included in this consultation, and any TGA annotations, if required, will be subject to a separate consultation process.

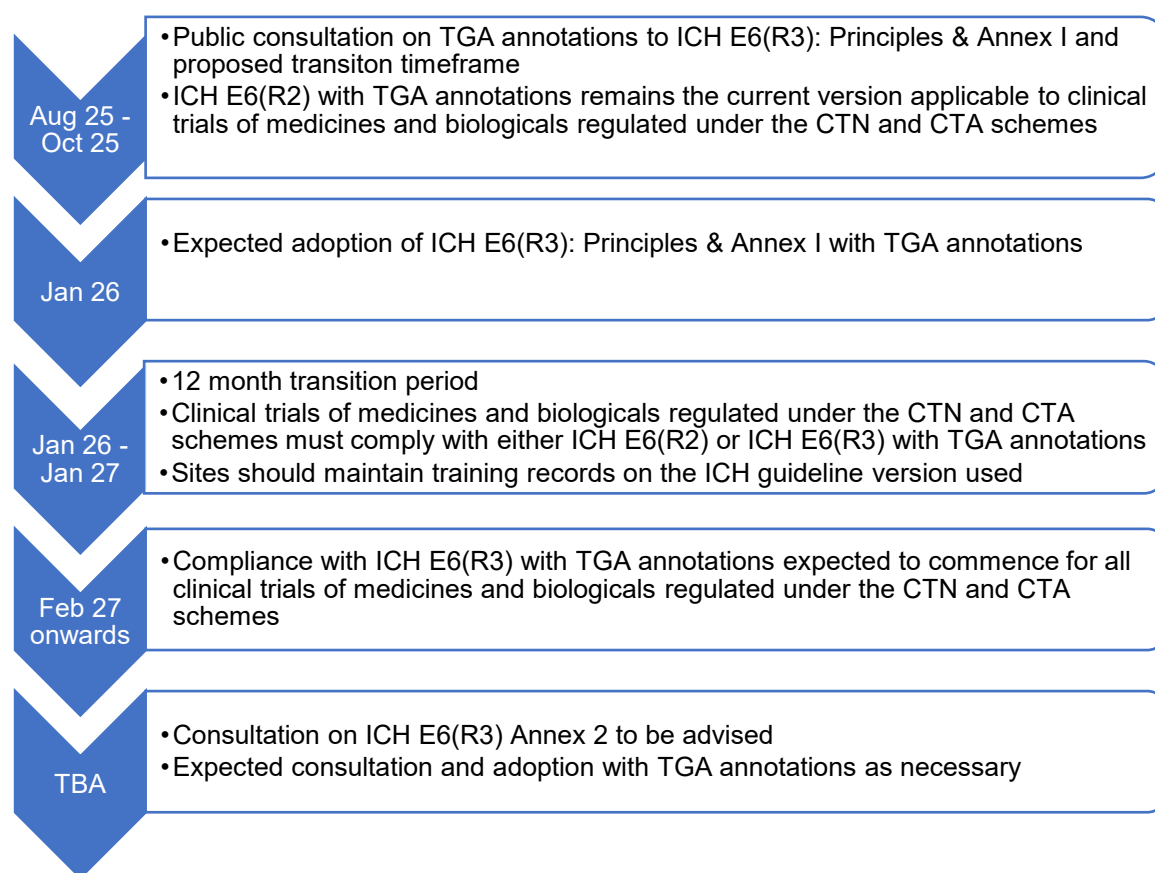
To assist in the review of existing guidance (separate from the TGA annotations) we're inviting input on topics where further guidance may be useful following changes in ICH E6(R3).

How are TGA annotations developed?

Prior to adopting any international guideline, the TGA undertakes an extensive process of internal and external consultations to ensure the guideline is consistent with prevailing legislative requirements in Australia.

As part of this process, we have compared ICH E6(R2) and ICH E6(R3) with a focus on alignment with the Australian legislative framework and identifying new concepts that warrant an updated or new annotation. A 6-week public consultation is currently underway to gather sector wide feedback on the proposed TGA annotations. Consultation outcomes will be published on the [Consultation Hub](#), and the final annotations will be published on the [ICH E6\(R3\) Guideline for Good Clinical Practice](#).

Proposed adoption and transition period



Transition period

The proposed 12-month transition period allows sponsors, trial sites and other stakeholders time to update processes, documentation, and training to meet the updated requirements in ICH E6(R3) with TGA annotations.

If you are running a clinical trial, consider the following in the transition period:

- **Review** ICH E6(R3) Guideline: Principles and Annex I with TGA annotations to understand what's changed. This will help you identify differences between your current practices and the requirements of ICH E6(R3).
- **Develop a plan:** If gaps are identified, develop a plan to meet the updated requirements and document how the review and updates were carried out. Please note that amendments to study documentation approved by the Human Research Ethics Committee (HREC) should be submitted to the HREC for review and, approving authority, or research governance office prior to implementation.
- **Training:** The Principal Investigators (PIs) should be trained on ICH E6(R3), as they are responsible for trial conduct at the site. The PI should ensure that team members receive training on the requirements of ICH E6(R3) suited to their delegated tasks. Keep records of all relevant training completed and which ICH guideline version was used.

If you are planning a new clinical trial during the transition period, you should adhere to the ICH E6(R3) Guideline: Principles and Annex I with TGA annotations.

Note that during the consultation period and prior to adoption, ICH E6(R2) with TGA annotations remains the current version applicable to clinical trials of medicines and biologicals regulated under the CTN and CTA schemes. While we do not provide GCP training or endorse a specific training provider, sponsors and trial sites may choose to undertake training on ICH E6(R3) in anticipation of adoption.

Proposed TGA annotations

Column Number	Relevant section(s) of ICH E6(R3)	TGA comment
1	<ul style="list-style-type: none"> Introduction Principles of ICH GCP 	The TGA has adopted ICH guideline E8 (R1) on general considerations for clinical studies referred within the Guideline for Good Clinical Practice.
2	<ul style="list-style-type: none"> Principle 2 – Informed Consent 	<p>Further information about requirements for obtaining valid consent in special cases can be found in the National Statement.</p> <p>The National Statement explicitly prohibits the use of deferred, delayed, or retrospective consent. These models are not considered ethically acceptable in Australia and must not be used in the design or conduct of human research. Refer to the National Statement for guidance on designing research that considers participants' capacity to receive information, consent to the research, and participate in it.</p>
3	<ul style="list-style-type: none"> Principle 3 - IRB/IEC Review Annex I: Section 1 IRB/IEC Glossary: IRB/IEC 	The <i>Therapeutic Goods Act 1989</i> defines an ethics committee as a committee constituted and operating in accordance with guidelines issued by the NHMRC as in force from time to time; and which has notified its existence to the Australian Health Ethics Committee established under the <i>National Health and Medical Research Council Act 1992</i> . The ethics committee, known in Australia as a Human Research Ethics Committee (HREC), must notify their existence to the NHMRC directly. The responsibilities, composition, function, operations, procedural and record keeping requirements for Human Research Ethics Committees in Australia are set out in the National Statement. To the extent that there is a perceived inconsistency between the National Statement and the ICH Guideline for Good Clinical Practice, the TGA recommends that the National Statement take precedence.

Column Number	Relevant section(s) of ICH E6(R3)	TGA comment
4	<ul style="list-style-type: none"> Principle 11 - Investigational Products Annex I: Section 3.15.2 Manufacturing, Packaging, Labelling and Coding Investigational Product(s) 	The 'applicable GMP' in Australia refers to the PIC/S Guide to Good Manufacturing Practice for Medicinal Products (in particular Annex 13) and the Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products .
5	<ul style="list-style-type: none"> Annex I: Section 3 Sponsor Glossary: Contract Research Organisation See Service Provider 	All clinical trials conducted in Australia must have a trial sponsor that is an Australian entity (an overseas company cannot be the sponsor of a trial in Australia). The Australian trial sponsor retains overall responsibility for the conduct of the trial in Australia.
6	<ul style="list-style-type: none"> Glossary: ADR Annex I: Section 3 Sponsor 	The TGA has adopted ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting in principle, particularly its reporting timeframes. Trial sponsors should refer to the current guidance published by the NHMRC: Safety monitoring and reporting in clinical trials involving therapeutic goods .
7	<ul style="list-style-type: none"> Annex I: Section 3.16.3 Record Keeping and Retention 	The TGA requires records to be retained by the trial sponsor for at least 15 years following the completion of a clinical trial. However, in Australia, the overriding consideration for trial sponsors with respect to record retention is the issue of product liability and the potential need for sponsors of products to produce records at any time during, and possibly beyond, the life of a product in the event of a claim against the sponsor as a result of an adverse outcome associated with the use of the product.
8	<ul style="list-style-type: none"> Annex I: Section: 3.17 Reports 	The National Statement requires researchers to ensure that their trials are registered in a publicly accessible database before recruitment of the first participant. Further information about requirements for dissemination of project outputs and outcomes can be found in the National Statement.

Have your say: questions & how to respond

Consultation Questions

1. Please indicate your level of support for the proposed TGA annotations.

Options:

- support
- partially support
- do not support
- no comments

A short text response field will be provided.

In your response, we encourage you to:

- Reference the relevant section of ICH E6(R3) or column number in the Table of proposed TGA annotations.
- Support your feedback with justification such as references to the legislative framework and relevant examples where possible.

2. Do you have any additional annotations to suggest?

- Yes
- No

An optional short text response field will be provided.

In your response please consider:

- if there are parts of ICH E6(R3) Guideline for GCP: Principles & Annex I that should **not** adopted, or if there are particular considerations that need to be taken into account when applying the guideline in an Australian context
- reference the relevant section of ICH E6(R3).

3. Do you support the 12-month transition period?

Options:

- support
- do not support

A short text response field will be provided for you to share any concerns you may have about meeting the ICH E6(R3) requirements within the proposed 12-month transition period.

4. Are there any topics where additional guidance for future development would be helpful, based on the changes introduced in ICH E6(R3)?

Guidance is separate to the TGA annotations and explains the laws and regulations governing the conduct of clinical trials of medicines and biologicals regulated under the CTN and CTA schemes.

How to respond

Submissions should be provided through our [Consultation Hub](#).

This consultation closes on close of business **10 October 2025**.

Version history

Version	Description of change	Author	Date
V1.0	Original publication	Pharmacovigilance Compliance and Clinical Trials Section (PCCTS), TGA	August 2025

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