



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Clinical Trials Schemes

Improved information sharing: understanding the challenges and opportunities around the release and publication of information

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Overview

The Therapeutic Goods Administration (TGA) is seeking feedback on new ways of sharing information under the [Therapeutic Goods Act 1989](#) (the Act). Section 61 of the Act facilitates the release of information in certain circumstances. The proposed amendments will expand our ability to release therapeutic goods information to certain bodies and organisations involved in the [Clinical Trial Notification \(CTN\)](#) and [Clinical Trial Approval \(CTA\)](#) schemes. It would also enable the publication of information about clinical trial sites inspected under the TGA's [Good Clinical Practice \(GCP\) Inspection Program](#), including the names of inspected sites, and whether enforcement was action taken.

Background

As part of the Department of Health, Disability and Ageing, the TGA regulates therapeutic goods, including medicines, biologicals and medical devices. This includes therapeutic goods used in health and medical research.

We receive information about therapeutic goods used in clinical research from a wide range of sources. The primary sources of information we receive are via the CTN and CTA schemes.

We may also receive information from other sources including:

- consumers of therapeutic goods
- stakeholders involved in the manufacture, importation, supply and use of therapeutic goods including health practitioners and healthcare facilities
- other private and Australian government entities in the health, life sciences and clinical trials sectors.

We recognise that transparency helps build trust in regulatory decision-making and helps stakeholders understand regulatory expectations. We are committed to engaging transparently with stakeholders, including reporting [compliance and enforcement](#) outcomes. Transparency of information is also outlined in the World Health Organization's [\(WHO\) Listed Authority \(WLA\) framework](#). The framework is intended to strengthen regulatory systems globally so that medical products are safe, effective, and of assured quality, both before and after they reach the market, whilst also enabling regulatory reliance between countries. The WLA assessment requires that national regulators have robust mechanisms for communicating and being transparent with healthcare professionals and the public.

Releasing Information

Current arrangements

The [Therapeutic Goods \(Clinical Trial Inspections\) Specification \(No. 2\) 2020](#) (Existing Specification) enables the Secretary of the Department of Health, Disability and Ageing to release certain therapeutic goods information about a clinical trial involving therapeutic goods to:

- the approving authority (the body or organisation at whose premises the clinical trial is being conducted)
- the responsible ethics committee (the ethics committee that is responsible for approving the procedural protocol and monitoring the conduct of the clinical trial at each trial site).

The information can only be released for the purpose of ensuring that clinical trials are conducted in a safe and lawful manner, including in accordance with applicable ethics and good clinical practice considerations.

Only information obtained by an authorised officer as part of the [GCP Inspection Program](#) can be released. This includes information related to compliance with the [National Statement on Ethical Conduct in Human Research](#), the [ICH Guideline for Good Clinical Practice](#) and the procedural protocol approved for the trial by the responsible ethics committee.

This information does not ordinarily include personal or sensitive information of trial participants but may include limited personal information of staff involved in the trial (e.g. name, position and qualifications).



The kinds of information the Secretary may choose to release undergoes internal assessment to determine if the TGA can and should release the information.

Changes proposed

We propose to replace the Existing Specification to strengthen regulatory oversight and support the ability of other key stakeholders to perform their relevant functions and duties.

Kinds of information

We propose to enable the Secretary to release the following:

- information collected as part of a GCP inspection
- **NEW:** information collected through the CTN and CTA processes
- **NEW:** information collected in response to requests for information (mandatory and informal)
- **NEW:** information collected through safety reporting
- **NEW:** unsolicited information received by the TGA.

We do not propose to routinely release personal or sensitive information of participants.



Question 1. Do you have any feedback on the different kinds of information we may release?

Kinds of persons, authorities or bodies

We propose to expand the kinds of persons, authorities or bodies to whom the Secretary may release specified therapeutic goods information. We consider release of specified therapeutic goods information to the below entities to be reasonable, necessary and proportionate in the circumstances:

- the responsible ethics committee, because they have an integral role in the scientific and ethical review and monitoring of the trial
- the approving authority, because they are responsible for the governance of the trial (other than in relation to those matters within the remit of the responsible ethics committee)
- **NEW:** the principal investigator, because they are the person in charge of the conduct of the trial
- **NEW:** the persons, authorities or bodies conducting the research, because they take overall responsibility for the trial
- **NEW:** the [National Health and Medical Research Council \(NHMRC\)](#), because they administer the registration scheme for ethics committees
- **NEW:** the [Office of Gene Technology Regulator \(OGTR\)](#), because they regulate genetically modified organisms
- **NEW:** the [Australian Commission on Safety and Quality in Health Care \(ACSQHC\)](#), because they oversee the National Clinical Trials Governance Framework
- **NEW:** State and Territory departments responsible for clinical trials, because they are responsible for administering laws and regulations that govern how research is conducted
- **NEW:** the [Australian Health Practitioner Regulation Agency](#), because they are responsible for regulating the conduct of registered health practitioners.

We have outlined below some examples of when we may release information, and why:

OGTR	During a routine GCP inspection, inspectors noted the licence holder may be operating outside of the conditions of their licence for use of genetically modified organisms. Using the proposed new legislative instrument, we share this information with OGTR.
The responsible ethics committee	In a routine review of high-risk medical devices through the CTN scheme, we identified potential non-compliance with the ethical standards set out in the National Statement on Ethical Conduct in Research Involving Humans. After further correspondence and requests for information, the sponsor is unable to address our concerns. We share the information with the responsible ethics committee to support them to ensure that clinical trials are conducted in a safe and lawful manner.
NHMRC	We receive an enquiry around the ethical conduct and integrity of a HREC. We contact the NHMRC who provide oversight and guidance of HRECs to support them to address any suspected non-compliance issues that have been identified.
State and Territory Government	The TGA received unsolicited information from a consumer raising safety concerns with a trial being conducted in New South Wales. We contact the person conducting the trial to find out more information. We also contact the NSW Department of Health to inform them of the complaint to support them to fulfil their regulatory functions.



Question 2. Do you have any feedback on who we propose to release information to?

Purpose

We propose to broaden the purposes for releasing therapeutic goods information to:

- ensure that clinical trials are conducted in a safe and lawful manner, including in accordance with applicable ethics and good clinical practice considerations
- **NEW:** facilitate the release of information where it is necessary to protect public health and safety.
- **NEW:** facilitate the release of information to persons or bodies responsible for the oversight, regulation, governance, accreditation or quality assurance of clinical trials, health services or health practitioners.
- **NEW:** support regulatory cooperation, compliance, enforcement and public health activities
- **NEW:** promote transparency, accountability and public confidence in the regulation of therapeutic goods and clinical trials.
- **NEW:** protect clinical trial participants and support the identification, investigation and management of safety, compliance or integrity concerns.



Question 3. Do you agree with the proposed purposes for releasing information?

- a. Yes/No/Not sure.
- b. Please provide a reason for your position.

Transparency of GCP enforcement outcomes

Providing information about regulatory activities is an important part of the TGA's commitment to transparency. Making information about GCP inspections publicly available helps the public understanding of the TGA's oversight of clinical trials and supports confidence in the conduct of clinical trials in Australia.

Current arrangements

The TGA currently publishes annual inspection program [metrics reports](#) containing de-identified information on the number and types of inspections conducted, the types of findings identified, and whether those findings have been resolved.

The [Regulatory Compliance Framework](#) sets out the TGA's overall approach to compliance. If an inspection leads to regulatory actions being taken under the Act, information about that action will be published in line with our compliance and enforcement procedures. Such publications can include identification of the parties and offences for more serious contraventions of the Act and/or Regulations. For more information, see [Compliance actions and outcomes](#).

Where the GCP inspection process identifies deficiencies, we work with trial sponsors to address the deficiencies. For example, by providing them with guidance and examples of best practice where available. If necessary, we may take enforcement action, which could include action to stop a trial. To date, no enforcement action has been taken as a result of a GCP inspection.

Changes proposed

The proposed change would involve the routine publication of the names of inspected clinical trial sites together with information on whether enforcement action was taken or no enforcement action was required. This would represent a change from the current approach, where publication is generally limited to cases where enforcement action has been taken.

Your views are sought on this proposal and options to enhance transparency.

The published information would be limited to the:

- clinical trial site name
- location (state/territory)
- inspection date
- type of inspection (routine, re-inspection, for cause)
- clinical trial phase/stage
- enforcement action (yes/no/pending)

The TGA is not proposing to publish confidential or commercially sensitive information. This means that inspection reports or information about clinical trial protocols will not be published as part of this proposal. Enforcement outcomes are distinct from voluntary Corrective and Preventive Action (CAPA) plans. Voluntary CAPA plans are not considered enforcement action and would not be routinely published under the proposed arrangements.

The proposal is intended to apply prospectively only. It would involve publication of the names of inspected clinical trial sites and whether enforcement action was taken, or no enforcement action was required, for GCP inspections completed after commencement of the new arrangements.

Any publication under the proposed arrangements would be **in addition** to the identification of the parties and offences for more serious contraventions of the Act and/or Regulations under the TGA's **existing** regulatory and compliance framework.

If the proposal proceeds, publication of clinical trial site names and whether enforcement action was taken would form part of routine regulatory communication on the TGA website. This means trial site names and enforcement outcomes would be routinely published following completion of the inspection, and sites would be advised at the commencement of the inspection. The TGA is not proposing to seek further approval from clinical trial sites prior to publication.

To enable publication, the TGA proposes to make a legislative instrument under section 61 of the *Therapeutic Goods Act 1989*. The instrument would provide the legal basis for publishing information about clinical trial sites, including the names of inspected sites, and whether enforcement action was taken following a GCP inspection.

Purpose

The purpose of the proposed changes is to:

- Improve transparency of regulatory inspections and promote compliance with GCP requirements
- Enhance public confidence in the conduct and oversight of clinical trials in Australia
- Support the protection of clinical trial participants and the integrity of clinical trial data
- Promote accountability and continuous improvement among sponsors, investigators and trial sites
- Demonstrate the effectiveness of the TGA's regulatory oversight in safeguarding public health and maintaining confidence in Australia's clinical trials ecosystem.



Question 4. Do you support the proposal to publish on the TGA website the names of inspected clinical trial sites and whether enforcement action was taken?

- a. Yes/No.
- b. If no, please explain your reasons.



Question 5. Do you agree with the type of information proposed to be published for each inspected clinical trial site?

- a. Yes/No.
- b. If no, please explain your reasons.



Question 6. Do you think publishing GCP enforcement outcomes will help improve public confidence in the quality of clinical trials in Australia?

- a. Yes/No.
- b. If no, please explain your reasons.

What we invite you to do

This consultation seeks your feedback on the potential impact that the proposed changes to information sharing, including the release or publication of information, will have on you or your organisation.

Your feedback will help inform advice to the Australian Government regarding any proposed changes to the regulatory framework governing use of therapeutic goods under the CTN and CTA schemes. In your submission, we ask you to consider and respond to the questions outlined above and to provide any comments on the proposed changes.

Peak bodies are encouraged to provide a single, consolidated submission on behalf of their members, reflecting the collective views of their membership where possible.

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. Following internal review of feedback received, the consultation outcomes will be published on our website. This is expected to occur by early 2027.

Please contact us at clinical.trials@health.gov.au if you have any questions regarding this consultation.

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