TGA Clinical Trial Initiatives

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TGA Initiatives

- Increased oversight of highest risk device trials
- GCP Inspection Program
- Updates to the CTN submission form
- Safety reporting form
- CTA review
- Educational resources and guidance

Proactive monitoring of highest-risk medical device clinical trials

Proactive monitoring of first-in-human (FIH), highest-risk invasive or cardiac implantable medical device clinical trials

To ensure the safety and wellbeing of medical device trial participants

Apr 2019

Action plan

- The TGA will review the arrangements for medical devices that are used in clinical trials to ensure their use meets community expectations

Aug 2022

Public consultation

- Mandate CTA for certain high-risk medical devices (mixed feedback)
- Include medical device trials in GCPIP (broad support)

Jun 2023

Approved proposal

- No changes to CTN/CTA
- CTN form updates
- Monitoring of high-risk device trials
- Include medical device trials in GCPIP

Nov 2023

Legislative changes

- Enable TGA to require information about devices used in trials
- Enable device trials to be inspected

Apr 2024

CTN form updates

- New mandatory fields for accurate data collection
- Attachment upload function

Apr 2024

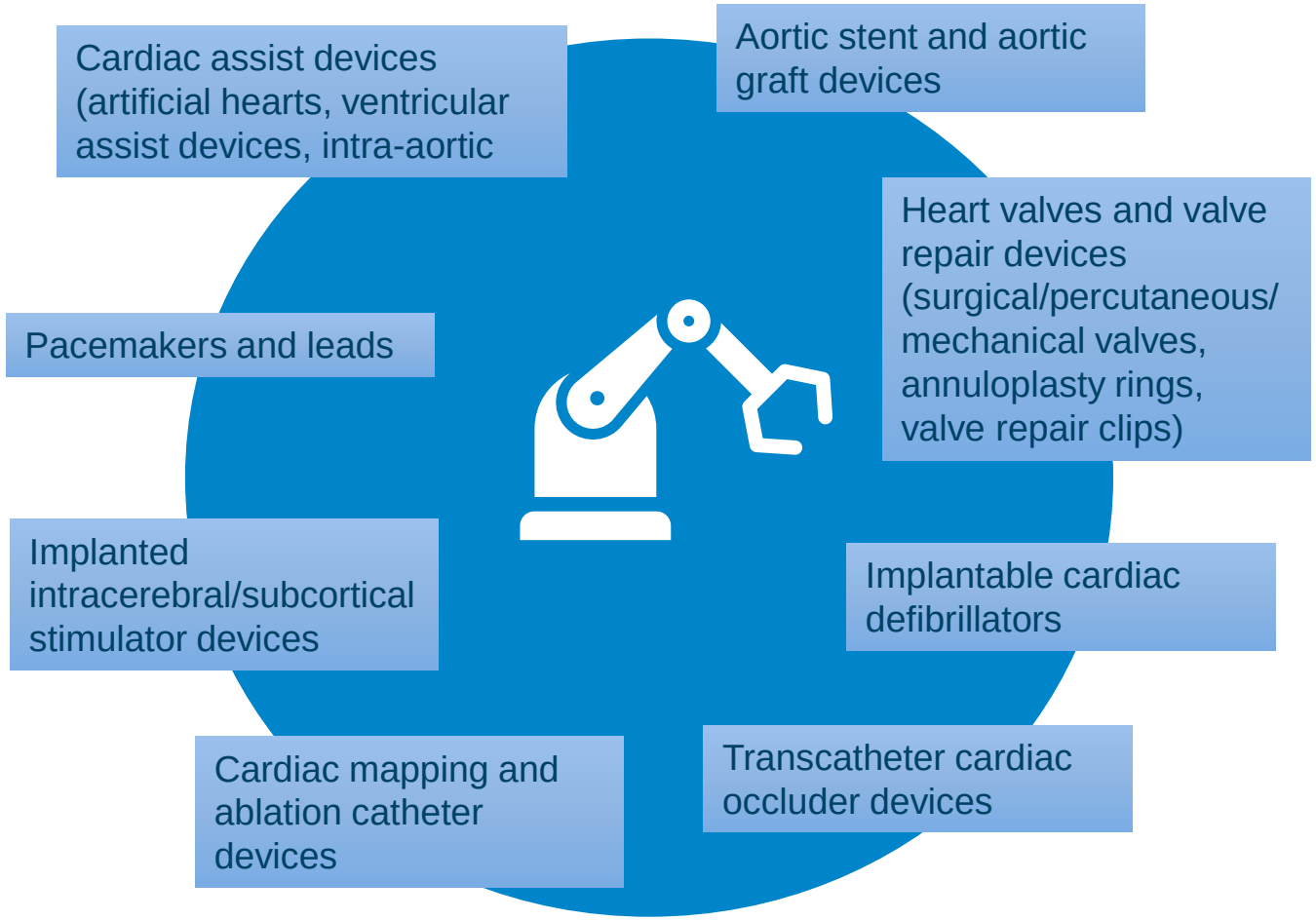
Monitoring of specified high-risk trials (first-in-human, highest risk devices)

- IB review

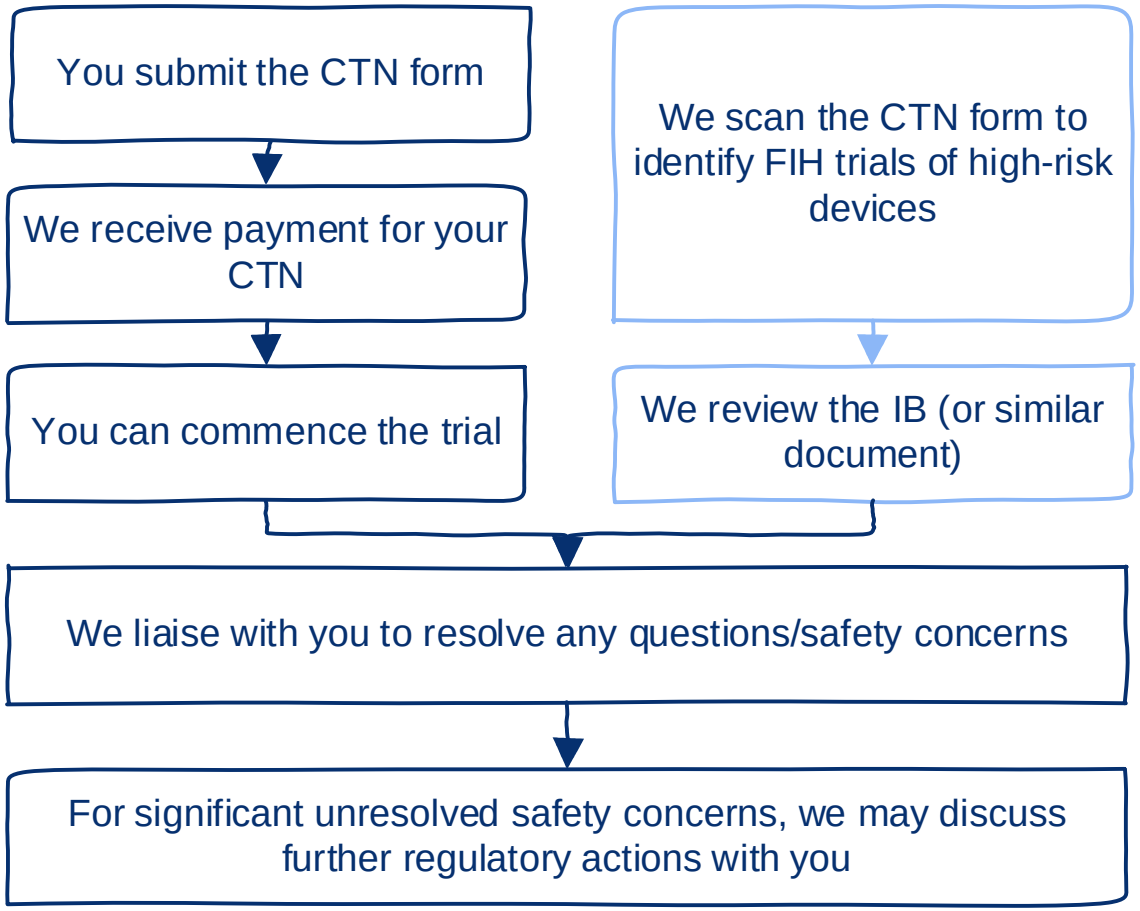
Scope

In-scope: CTNs for first-in-human trials of specified high-risk devices

Out-of-scope: trials of devices that are incremental developments of established devices, CTN variations



Review process



- The review will not affect trial timelines

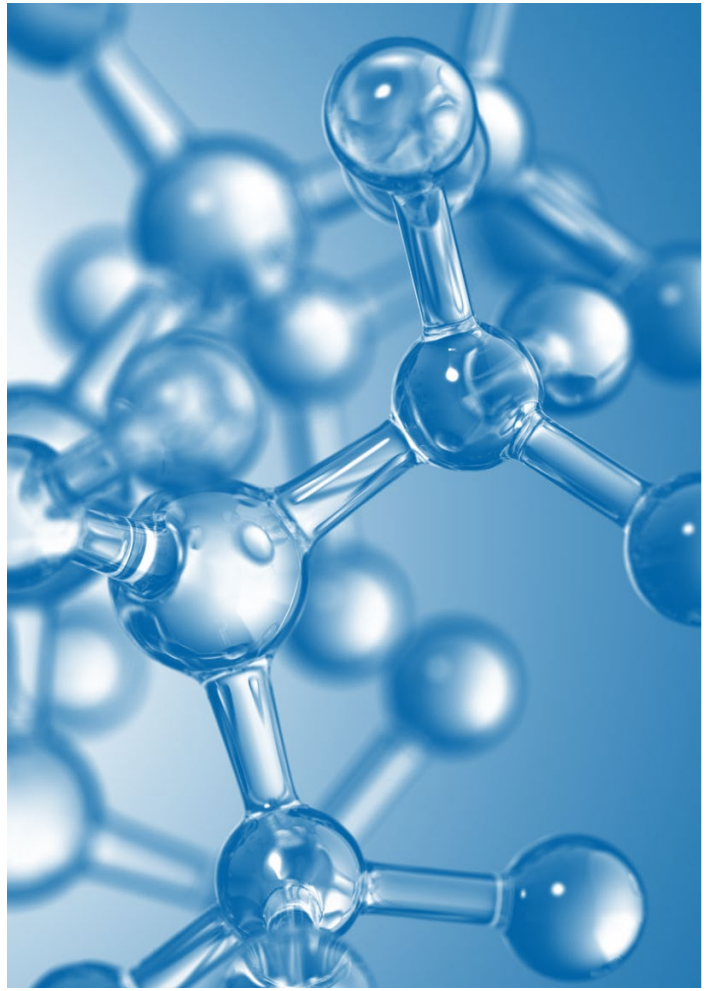
  We encourage you to submit the CTN form as early as possible and to use the attachment upload function to submit the IB (or similar documentation)

- There will be no additional fee if your trial is reviewed
- You won't hear from us unless we have questions or concerns

Just published: guidance on review of high-risk medical device trials

Key features

- There were no changes to the CTN/CTA pathways
- The TGA is reviewing the pre-clinical and clinical data for the highest-risk device trials
  - We encourage you to submit your CTN as early as possible
  - Using the attachment upload function to submit the IB will save later requests for information
  - Familiarise yourself with the general expectations for the contents of an IB



GCP Inspection Program

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials

ICH GCP E6 (R2): International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP E6) with TGA annotations

ISO 14155:2020: International Organisation for Standardisation (ISO) 14155 – Clinical Investigation of Medical Devices for Human Subjects – Good Clinical practice

Medicines & Biologicals

ICH GCP E6 (R2)

Medical Devices

ISO 14155: 2020

Combination Investigational Products

ICH GCP E6 (R2)
ISO 14155: 2020

National Statement on Ethical Conduct in Human Research

Who do we inspect?

- Clinical trials included in the Clinical Trial Notification (CTN) & Clinical Trials Approval (CTA) scheme
  - Investigator site = all locations carrying out clinical trial activity except at patient's homes
  - Risk-based selection of a proportion of eligible clinical trials
- Types of Investigational Products / Therapeutic Goods
  - Medicines
  - Biologicals
  - Medical devices

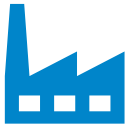
We inspect…

Australian investigator sites including investigator-initiated studies (IIT)

Site-level trial activity contracted to another party

We don’t inspect…

Human Research Ethics Committees (HRECs)



Sponsor

Approving Authority

Inspectors will check your compliance with…

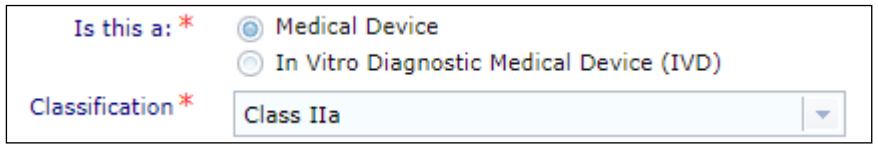
- Therapeutic Goods Act & Regulations
- GCP guidelines(s)
- National Statement
- HREC approved protocol & amendments

Resources to be inspection ready

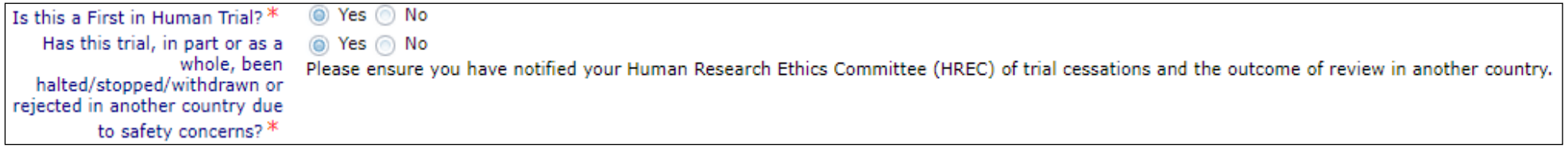
- GCP Inspection Guidance
- Australian Clinical Trials Handbook
- GCP Metrics Report
- National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia

CTN form updates

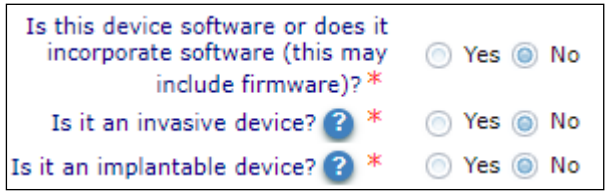
Additional fields and mandatory information



Device Classification and Biological Classification fields are now mandatory



Two new mandatory questions to identify First in Human trials and trials ceased overseas



Three new mandatory questions in the Medical Device Details sub-form to identify devices that incorporate software, invasive devices and implantable devices

Easier to complete notifications

- Trial phases for medical device clinical trials
- HREC autofill and searchability
- Attachment upload function
- Automatic email notification of CTN status change
- Improved layout for printing CTN
- Instructional text within the form
- Updated user guide

New safety reporting form

Safety reporting to the TGA

A new safety reporting form for SSI/USM was published on the TGA website in November last year.

Sponsors must notify the TGA of:

- Significant safety issues (SSI)
- Urgent safety measures (USM)
- Suspected unexpected serious adverse reactions (SUSAR)
- Unanticipated serious adverse device effects (USADE)

Review of the CTA pathway

Objectives of the review

- Streamlined process for CTA applications
- Increased collaboration with HRECs
- Clear guidance, including timeframes and data requirements
- Supports decisions about which pathway to use – CTA vs CTN

Recent targeted consultation with HRECs on the CTA scheme

May 2024: Consultation sent to all HRECs

Received 17 responses from HRECs with various experience with CTA trials

Key response themes:

- Confusion on the TGA CTA process
- TGA approval prior to HREC ethics approval
- Who is responsible for recommending the CTA pathway
- Lack of collaboration between HRECs and the TGA

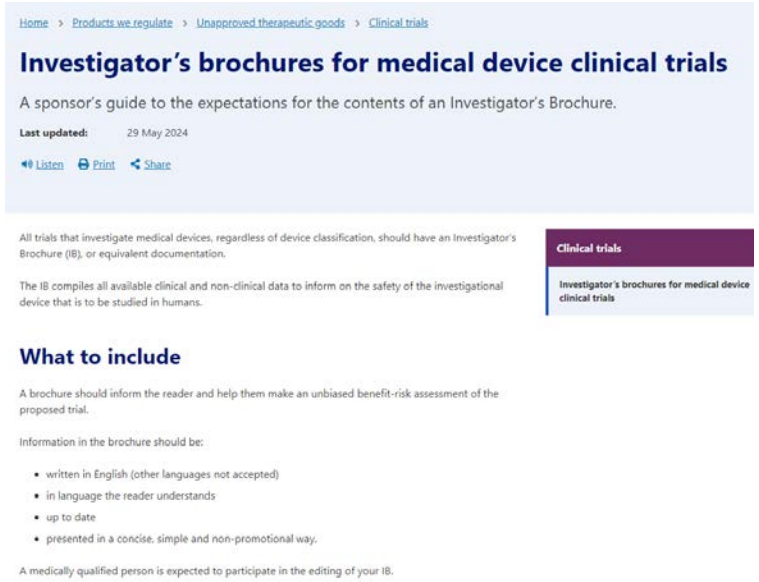
Outcomes:

- Published a page on the TGA website detailing the typical CTA application process
- Also includes updates on the CTA review
- Established the HREC and TGA clinical trials discussion forum

Educational resources and guidance

Education & Collaboration

- Annual metric reports
- Webinars
- eLearning Modules
- Ongoing GCP Inspections
- Seeking feedback from inspectees



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Investigator's brochures for medical device clinical trials

A sponsor's guide to the expectations for the contents of an Investigator's Brochure.

Last updated: 29 May 2024

Listen Print Share

All trials that investigate medical devices, regardless of device classification, should have an Investigator's Brochure (IB), or equivalent documentation.

The IB compiles all available clinical and non-clinical data to inform on the safety of the investigational device that is to be studied in humans.

Clinical trials

Investigator's brochures for medical device clinical trials

What to include

A brochure should inform the reader and help them make an unbiased benefit-risk assessment of the proposed trial.

Information in the brochure should be:

- written in English (other languages not accepted)
- in language the reader understands
- up to date
- presented in a concise, simple and non-promotional way.

A medically qualified person is expected to participate in the editing of your IB.

Guidance updates

- GCP inspection guidance (May 2024)
- Guidance on contents of an Investigator's Brochure for medical devices (May 2024)

Planned publications/updates:

- Guidance on review of high-risk medical device trials
- Australian Clinical Trials Handbook (updates)

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Good Clinical Practice (GCP) inspection program for clinical trials

Guidance for clinical trial investigator sites on what to expect and how to prepare for an inspection

Version 2.0, May 2024

Website and link references

Clinical trials | TGA	https://www.tga.gov.au/clinical-trials
Good Clinical Practice (GCP) inspection program | TGA: guidance and metrics report	https://www.tga.gov.au/resource/good-clinical-practice-gcp-inspection-program
Clinical Trials Toolkit | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/clinical-trials-toolkit
Investigator's brochures for medical device clinical trials	https://www.tga.gov.au/products/unapproved-therapeutic-goods/clinical-trials/investigators-brochures-medical-device-clinical-trials
Learning Modules | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/_files/elearn/index.html
Resources for Clinical Trials in Australia | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/resources-clinical-trials-australia
ICH Guideline for Good Clinical Practice | TGA	https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
About health and medical research in Australia | Department of Health and Aged Care	https://www.health.gov.au/topics/health-data-and-medical-research/about-health-and-medical-research
National Standard Operating Procedures for Clinical Trials | Australian Government Department of Health and Aged Care	https://www.health.gov.au/resources/publications/national-standard-operating-procedures-for-clinical-trials
The National Statement 2018 | National Health and Medical Research Council (NHMRC)	https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC	https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

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