**Review of first-in-human high-risk implantable or cardiac invasive medical device clinical trials**

**Guidance**

The TGA is reviewing safety information supporting notifications of the highest-risk medical devices used in first-in-human clinical trials

**Last updated**

14 Mar 2024

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We have examined and amended the arrangements for medical devices used in clinical trials. This was part of our commitment in the 2019 Action Plan for Medical Devices, and the changes have been made in response to feedback from the consultation on proposed regulatory changes for clinical trials of medical devices.

The following guidance provides a summary of the changes we have implemented and how it impacts stakeholders.

**Changes**

## **CTN form enhancements**

The Clinical Trials Notification (CTN) form will include new mandatory fields to:

1. Better characterise the medical device in the clinical trial, for example:

* risk classification
* intended purpose
* whether it’s an invasive or implantable medical device

1. Identify first-in-human trials and trials halted overseas for safety reasons.

There is also a new attachment upload feature, which sponsors are encouraged to use to upload the Investigator’s Brochure (or another equivalent document) to minimise requests for further information.

These changes come into effect on 20 March 2024.

## **Legislative changes**

Legislative changes have been made to:

1. Enable the TGA to require information about the safety of medical devices used in clinical trials. For example, information regarding materials, engineering and sterility.
2. Enable inspection of medical device trials conducted under a CTN, and the documentation supporting them, to make sure they’re compliant with Good Clinical Practice.

**Impact on trials**

The updated CTN form will help us identify first-in-human trials for the following devices at high risk of immediate, catastrophic consequences if they fail to perform:

* Cardiac assist devices (artificial hearts, ventricular assist devices, intra-aortic balloon pumps, cardiomyoplasty devices)
* Heart valves and valve repair devices (surgical/percutaneous/mechanical valves, annuloplasty rings, valve repair clips)
* Pacemakers and leads
* Implantable cardiac defibrillators
* Transcatheter cardiac occluder devices
* Cardiac mapping and ablation catheter devices
* Implanted intracerebral/subcortical stimulator devices
* Aortic stent and aortic graft devices

For trials involving these devices, we may review the Investigator’s Brochure (or another equivalent document) to assess potential risks to trial participants and make sure appropriate mitigation strategies are in place. Reviews will be performed by TGA clinical assessors and other assessors in relevant disciplines (e.g. engineering, biomaterials, microbiology).

Once you have submitted your notification and payment has been received, you can start the trial. Sometimes the TGA Clinical Trials team will ask you for further information to process the form, separate to this review process. Reviews will not affect trial startup timelines as this is part of the CTN scheme and you will not need to receive an ‘approval’ prior to commencement.

There will be no additional fee for review.

We may contact you if:

* it's not clear what the trial device is
* we would like to review the Investigator’s Brochure but you have not submitted one
* we have uncertainties or concerns about the information in the Investigator’s Brochure

We won't routinely contact you unless we have concerns or questions.

We may take further action if significant safety concerns are found. They will be proportionate to risk, after discussing with you.

This may include:

* Requesting a pause in the trial while we investigate;
* Discussing our concerns with the approving authorities or overseeing HREC;
* GCP inspection;
* Proposing to stop the trial.

**More information**

[LINK] Investigator’s brochures for medical device clinical trials  
[Medical devices reforms: An Action Plan for Medical Devices](https://www.tga.gov.au/resources/publication/publications/medical-devices-reforms-action-plan-medical-devices)  
[Proposed regulatory changes for clinical trials of medical devices](https://consultations.tga.gov.au/tga/proposed-regulatory-changes-for-device-trials/)

New guidance on the inspection process for medical devices will soon be available.

**Topics**Clinical trials