Updates to the CTN form and first-in-human high-risk implantable or cardiac invasive medical device clinical trials

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14 March 2024

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

Welcome

Housekeeping

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- Live Poll (use survey tab when prompted)

Using the QR code

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Session outline

- Background (5 min)
- CTN form updates (15 min)
- Proactive monitoring of medical device clinical trials (15 min)
- Q&A (10 min)

Background

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 **(webinar 2)**

Mar 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)

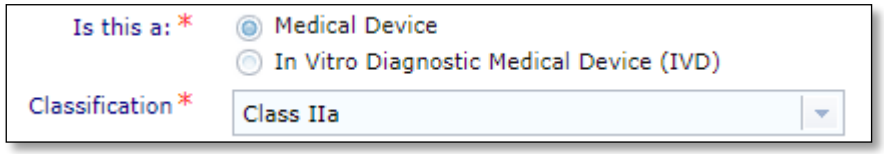
- IB review

CTN form updates

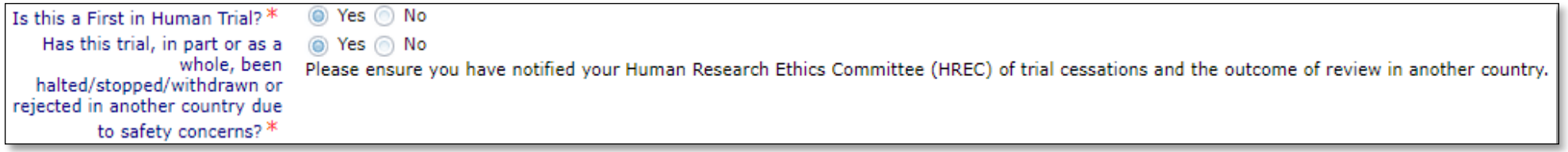
Erin Andrew
Assistant Director
Risk Management Section
Medicines Regulation Division, TGA

14 March 2024

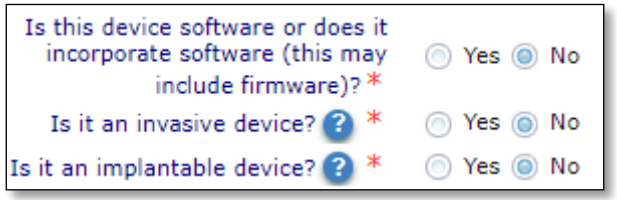
Additional fields and mandatory information



Device Classification and Biological Classification fields are now mandatory

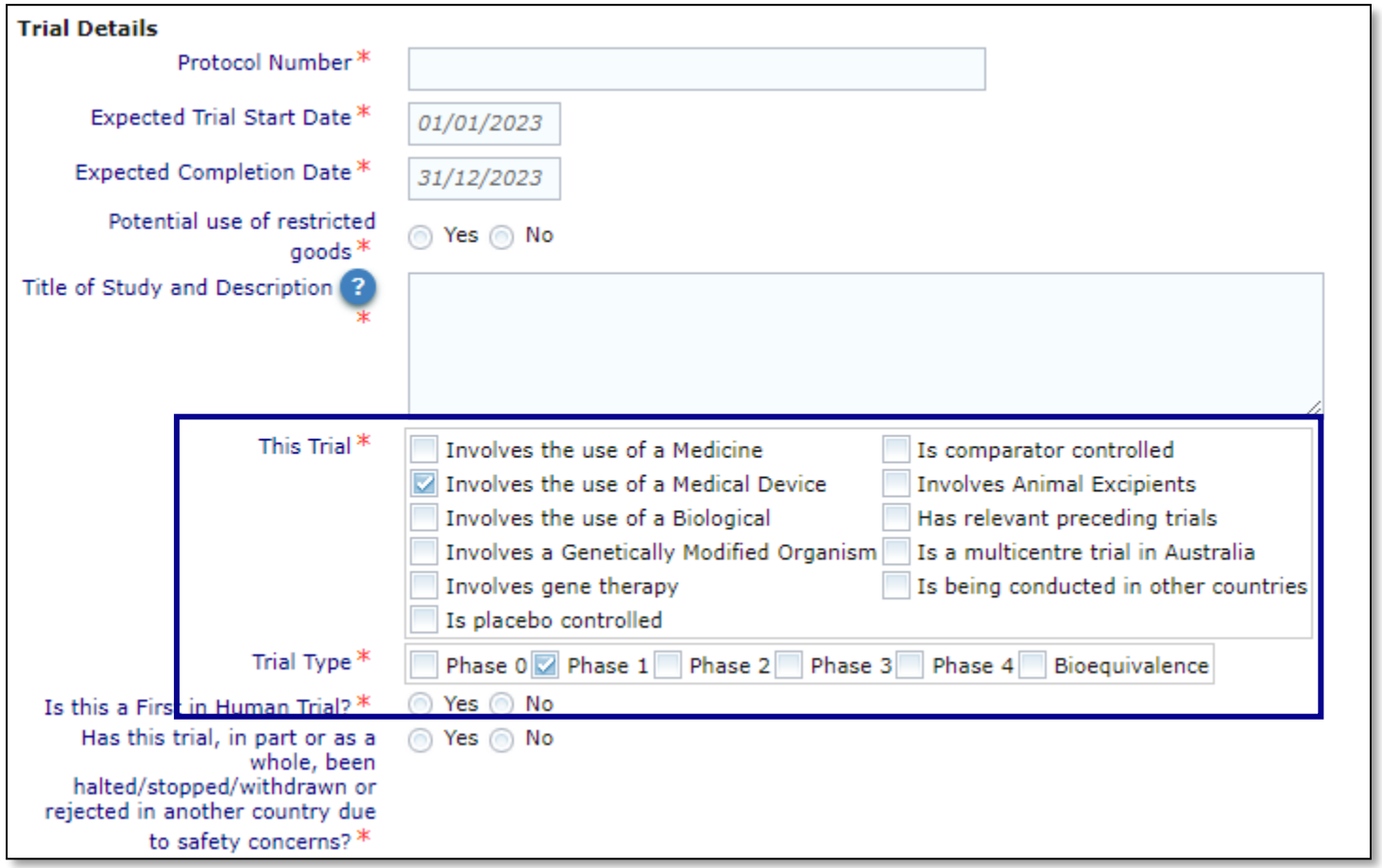


Two new mandatory questions to identify First in Human trials and trials ceased overseas



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

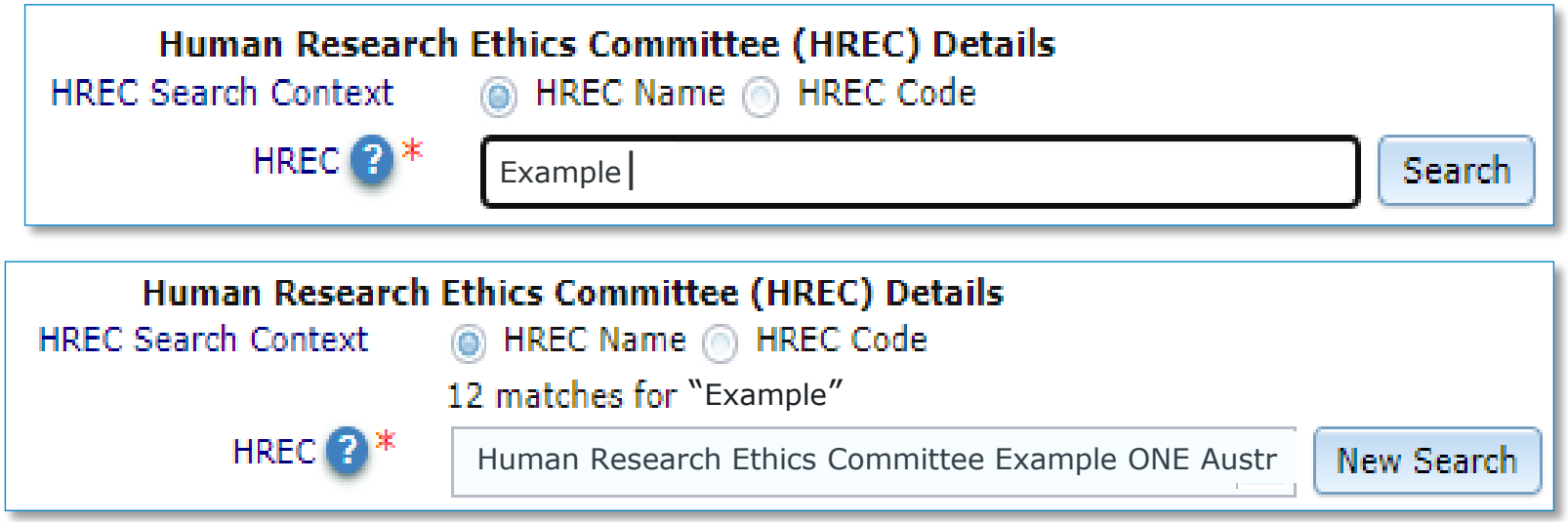
Trial phases for medical device clinical trials



Trial classification and categories have been separated from trial type and phase selection. This will now allow for medical device clinical trials to provide the trial phase.

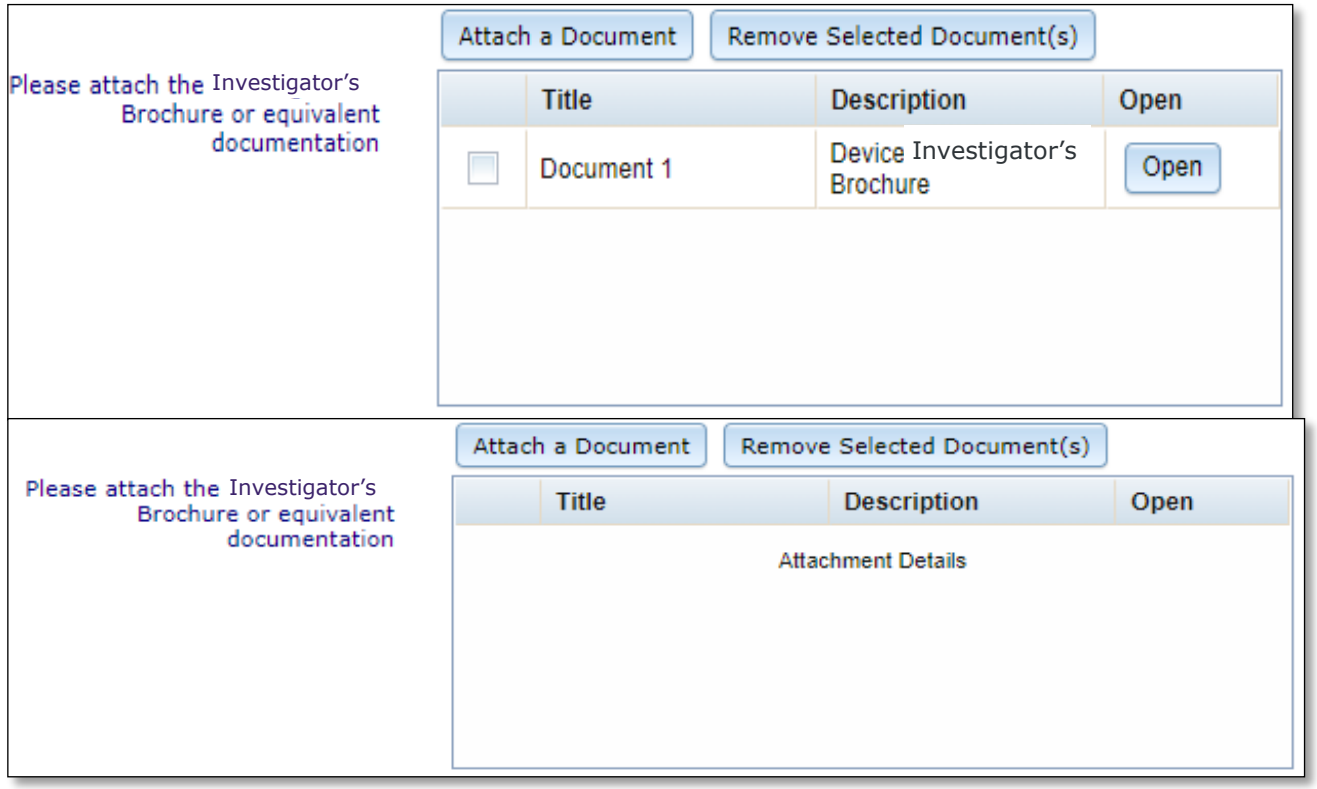
Q & A

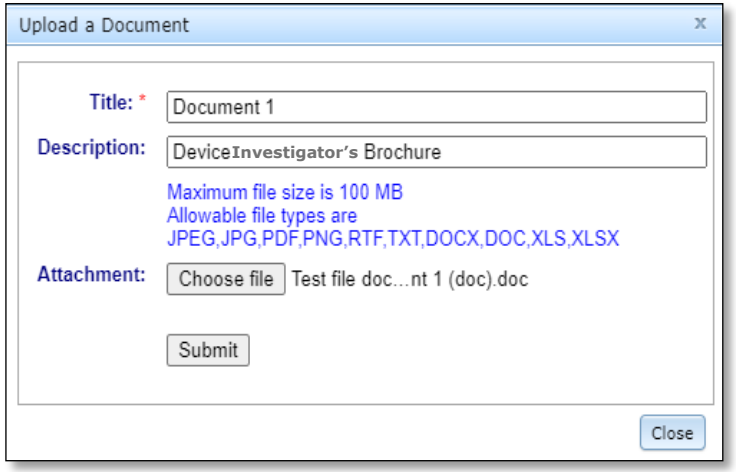
HREC autofill and searchability



HREC names and HREC Codes will now be a search field with drop-down option. After typing a relevant HREC name or HREC code in the search field, a drop-down list will appear with options to select.

Attachment upload function

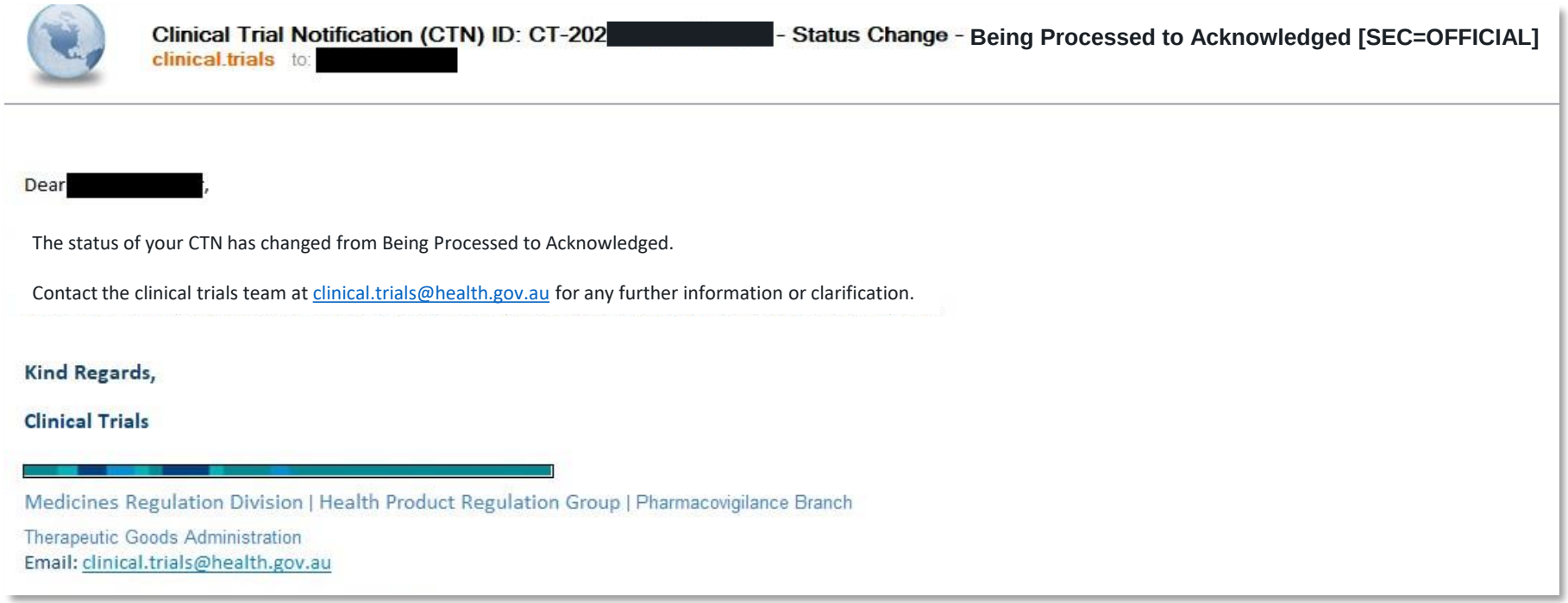




The CTN form will now include an upload function for the inclusion of additional documentation related to Devices, Medicines, and Biologicals (for example, the Investigator's Brochure)

Q & A

Automatic email notifications of your CTN



Clinical Trial Notification (CTN) ID: CT-202[redacted] - Status Change - Being Processed to Acknowledged [SEC=OFFICIAL]
clinical.trials to: [redacted]

Dear [redacted],

The status of your CTN has changed from Being Processed to Acknowledged.

Contact the clinical trials team at clinical.trials@health.gov.au for any further information or clarification.

Kind Regards,

Clinical Trials

[redacted]

Medicines Regulation Division | Health Product Regulation Group | Pharmacovigilance Branch

Therapeutic Goods Administration

Email: clinical.trials@health.gov.au

When the status of a CTN changes the sponsor primary contact and alternate contact will automatically receive an email when the status of a CTN changes.

Improved layout for printing of CTN information

Sites	
Site Name	**Site 1 Amended**
Site Physical Location	site location 1243
State / Territory	Northern Territory
Expected Site Start Date	06/04/2024
Principal Investigator Name	PI Name Amended
Principal Investigator Contact Phone	0410000000
Principal Investigator Contact Email	john@smith.com
HREC Name and Code	Human Research Ethics Committee Example ONE Australia (EC
HREC Contact Officer	HREC Officer
HREC Contact Position	HREC Position
HREC Contact Phone	0410000000
HREC Contact Email	john@smith.com
Name of Approving Authority	Approving Authority 1
Approving Authority Contact Officer	AA Officer
Approving Authority Contact Position	AA Position
Approving Authority Contact Phone	0410000000
Approving Authority Contact Email	john@smith.com

Biological	
Trade/Product/Code Name	**Biological 1**
Is this a combination product	No
Product Description	Biological 1 Description
Class of Biological	Class 1
Type of Container	Other Container
Type of Container Other Description	Other container Description
Dosage Form	Capsule, hard

Changes

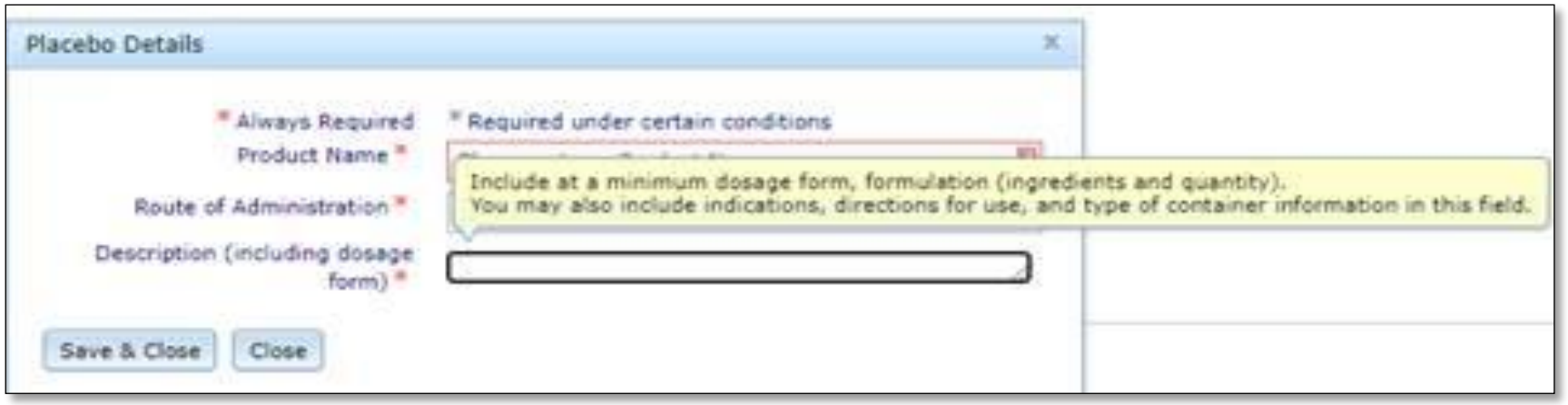
No.	Change
1	Site - Site 1 Amended: Site Name has been altered from 'Site 1' to 'Site 1 Amended'
2	Site - Site 1 Amended: Principal Investigator Name has been altered from 'PI Name' to 'PI Name Amended'
3	Site - Site 1 Amended: HREC Name has been altered from 'Human Research Ethics Committee Example ONE Australia (ECXXX)' to 'Human Research
4	Site - Site 1 Amended: HREC Code has been altered from 'ECXXX' to 'EC001'
5	Medical Device - Device 1: Is it an implantable medical device has been altered from 'Yes' to 'No'
6	Medical Device - Device 1: Is this an invasive medical device has been altered from 'Yes' to 'No'
7	Medical Device - Device 1: Is this device software or does it incorporate software (this may include firmware)? has been altered from 'Yes' to 'No'

Changes have been made to the formatting of the print design/layout of the CTN acknowledgement and CTN variations.

These changes will make it easier for the Sponsor to read and review.

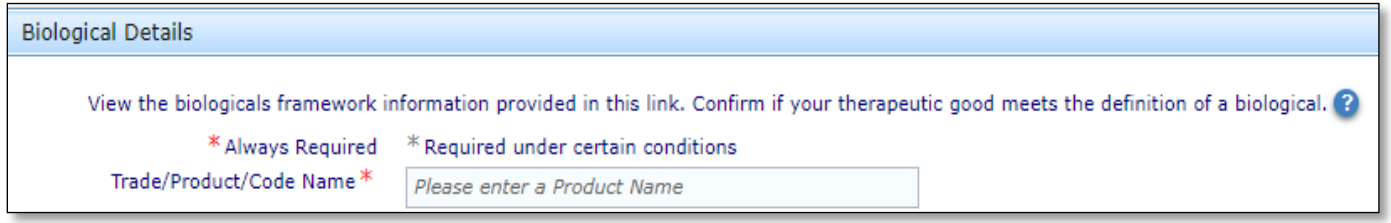
Q & A

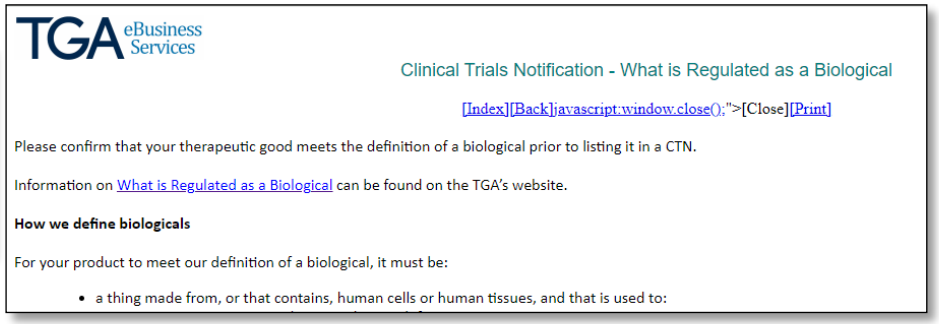
Instructional text, guidance and info tools



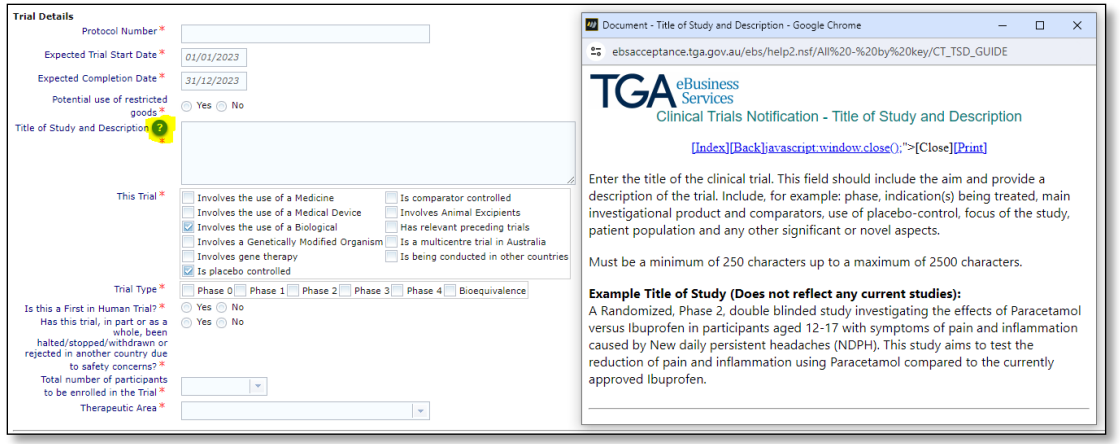
Hover text has been included so that it is clear to the user what information needs to be supplied in this field.

Instructional text, guidance and info tools





Guidance and tool tips have been added to multiple fields across the CTN form, containing field instructions and examples.



The CTN form has been updated to incorporate links to:

- the CTN form user guide
- the Clinical trials handbook
- guidance on the TGA website

Q & A

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

Edwina Chan
Medical Adviser
Devices Clinical Evaluation Section
Medical Devices and Product Quality Division, TGA

14 March 2024

Objective

To ensure the safety and wellbeing of medical device trial participants

- By assessing potential risks and ensuring appropriate mitigation strategies are in place

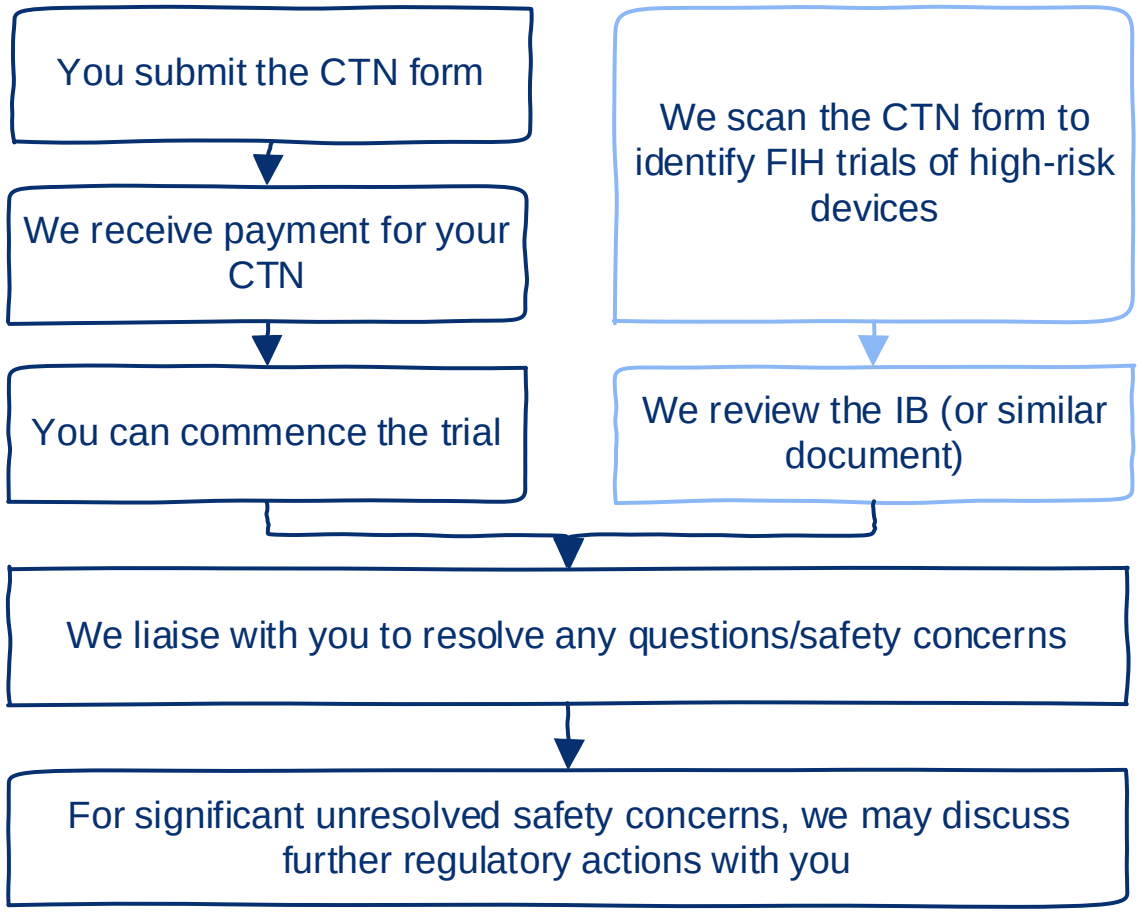
Scope

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

- 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

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

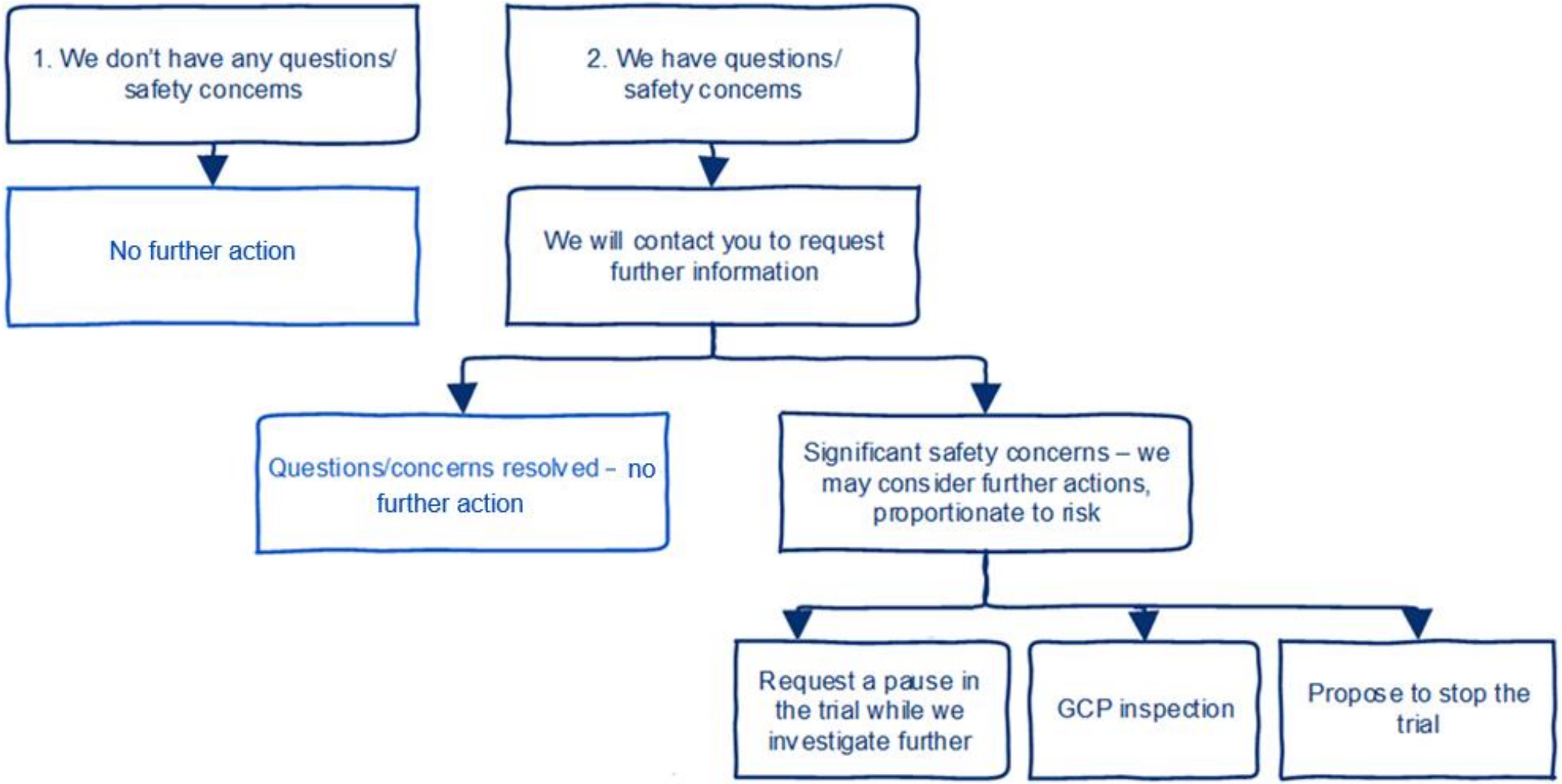
Coming soon: guidance on review of high-risk medical device trials

What we review

- Device description/operation
- Pre-clinical and clinical data on the investigational device
  - Bench and animal testing (engineering, biomaterials, sterility, toxicology)
  - Existing clinical data
- Risk management documentation

Coming soon: guidance on IBs for medical device clinical trials
(aligns with ISO 14155:2020)

Review outcomes



Take home messages

- There will be no changes to the CTN/CTA pathways
- The CTN form and associated guidance will be updated to improve data quality
- The TGA will start 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

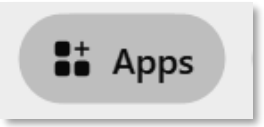
Q & A

Upcoming guidance and webinars

1. CTN user guide – March 2024
2. Review of high-risk medical device clinical trials – March/April 2024
3. Investigator’s brochures for medical device clinical trials – March/April 2024
4. GCP inspections for medical device trials – May/June 2024

How did we go?

Take a moment to complete our survey

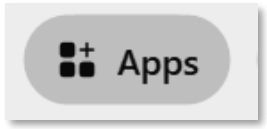


Use the app in Webex

Use the QR code

Questions?

As us through Slido



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TGA

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Assistant Director
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Medicines Regulation Division,
TGA

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
Consultation on proposed regulatory changes for clinical trials of medical devices I TGA	https://www.tga.gov.au/sites/default/files/2022-08/consultation-proposed-regulatory-changes-clinical-trials-medical-devices.pdf
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

Contact us

Clinical trials

clinical.trials@health.gov.au

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