

I'm from the government and  
I'm here to help: finding the  
way to the ARTG for medical  
devices

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Medical Devices Branch  
Department of Health, Disability and Ageing, TGA



Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

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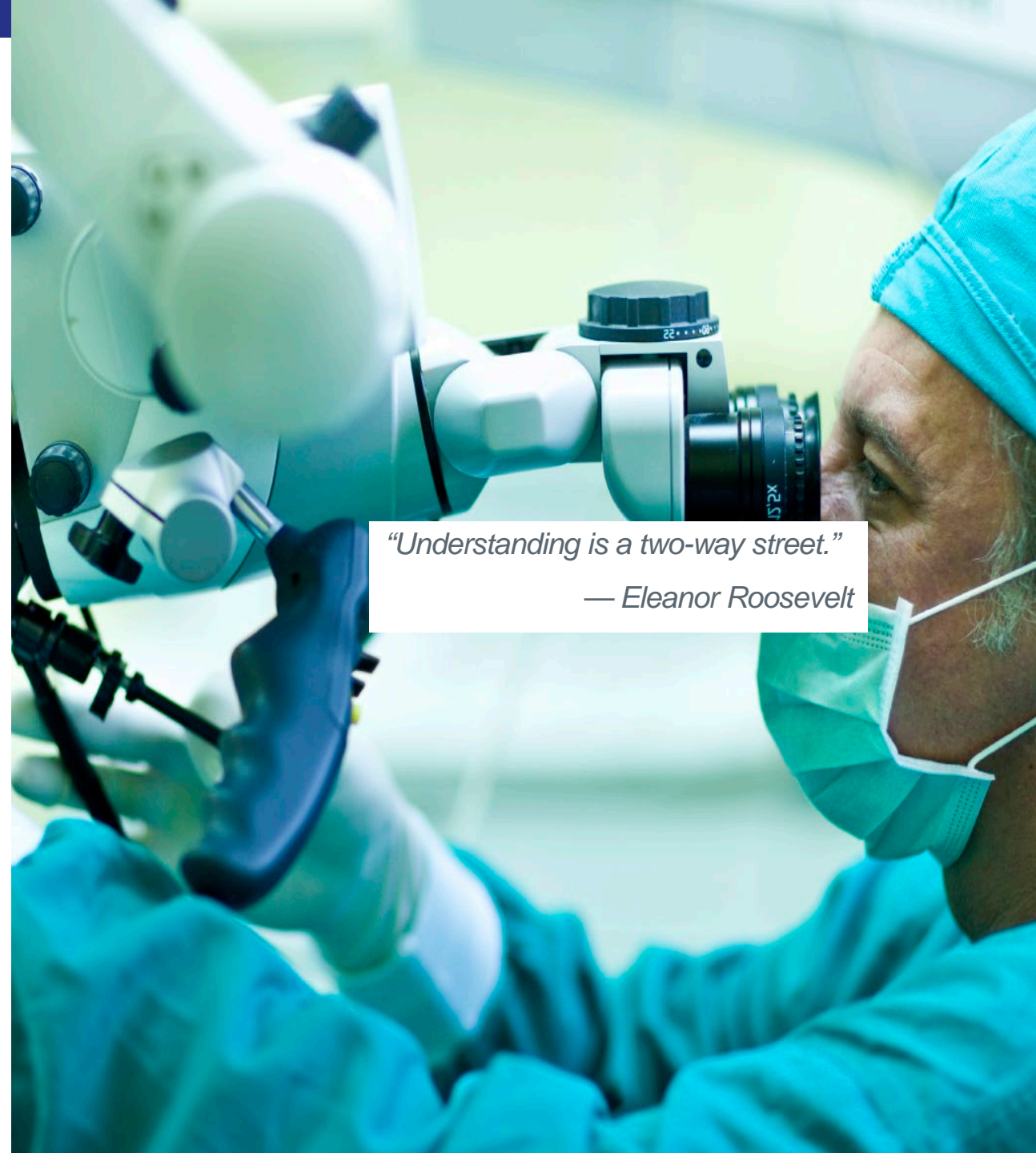
# Session overview

- let's talk  
(yes, really)
- the road to inclusion  
(what you can rely on)
- make us look good  
(by giving us what we need)



## Let's talk

- Regulatory engagement
- Case management



*"Understanding is a two-way street."*

*— Eleanor Roosevelt*

# Regulatory engagement

## Pre-submission meetings

- ✓ specific questions about a product
- ✓ development and preparation for application
- ✓ guidance from TGA specialists
- ✓ based on your briefing package and evidence

## Scoping meetings

- ✓ early stage of development
- ✓ guidance on design process from TGA specialists
- ✓ helps avoid unnecessary data collection
- ✓ expectations of safety and performance evidence

## Out of scope

- x not formal or binding advice
- x does not determine application outcome
- x future applications will be assessed only on information provided with the application
- x no formal advice on appropriate classification
- x TGA does not co-design or co-develop application

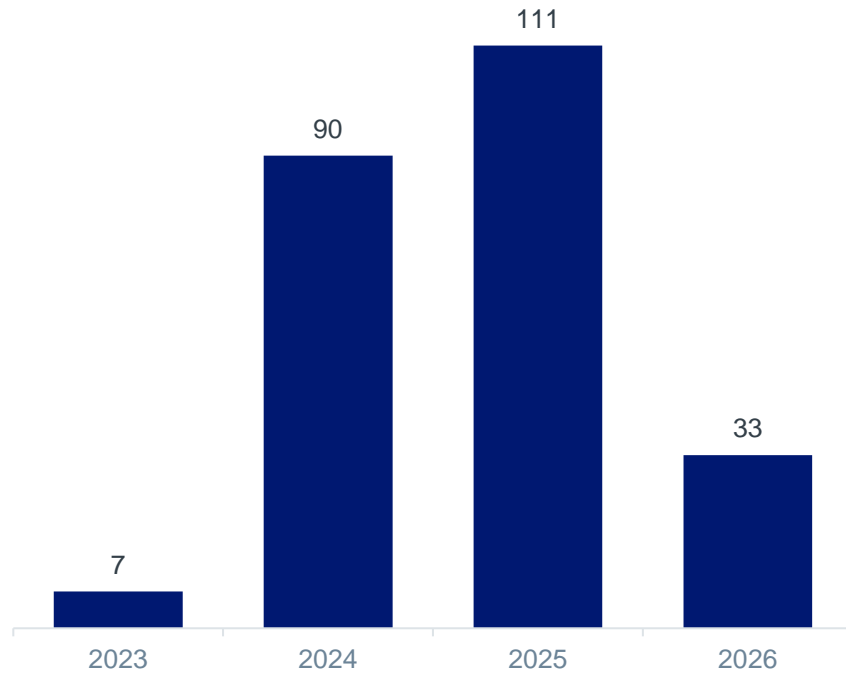
## Contact us

web [Medical device regulatory engagement meetings](#)

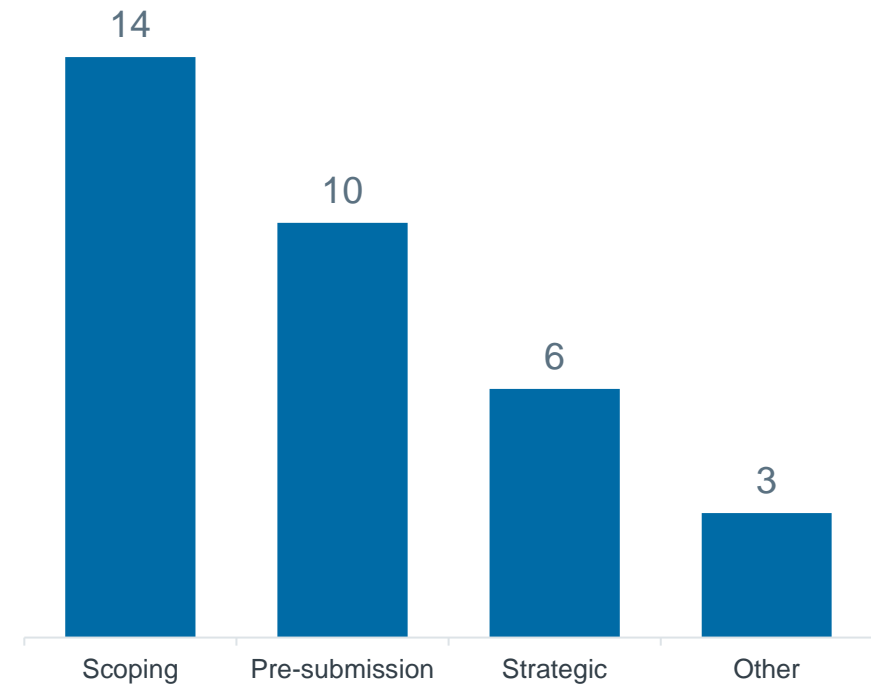
email [DevicesRegulatoryEngagement@health.gov.au](mailto:DevicesRegulatoryEngagement@health.gov.au)

# Regulatory engagement meetings

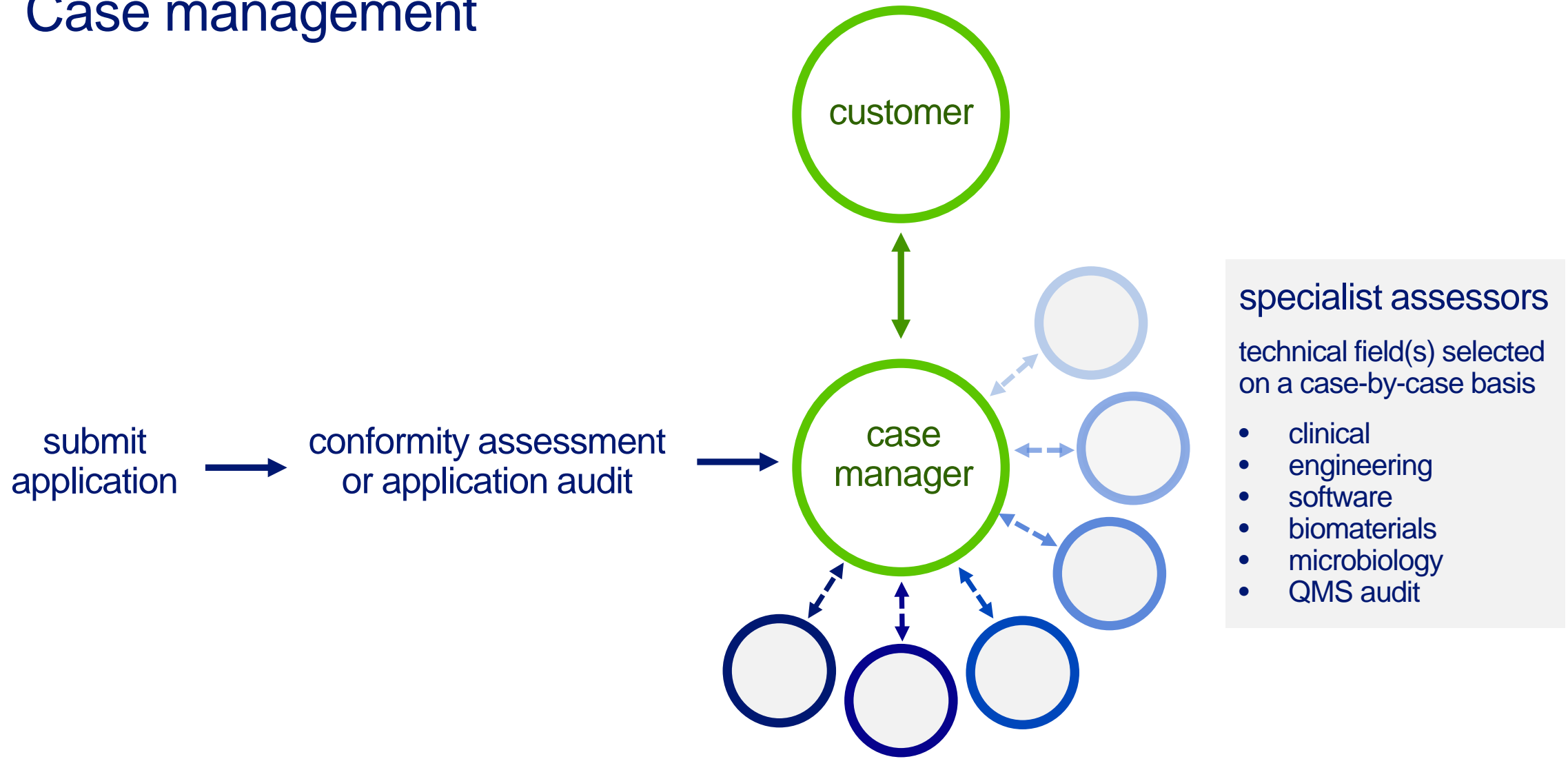
Number of meetings, by year, 2023-26



Type of meeting, 2026



# Case management



# Customer service

## We're here to help

- ✓ case manager contact details
- ✓ single point of contact
- ✓ organise meetings
- ✓ building proactive communication
- ✓ clear written reports
- ✓ monthly status updates (Level 2 audits)
- ✓ improvement based on customer feedback

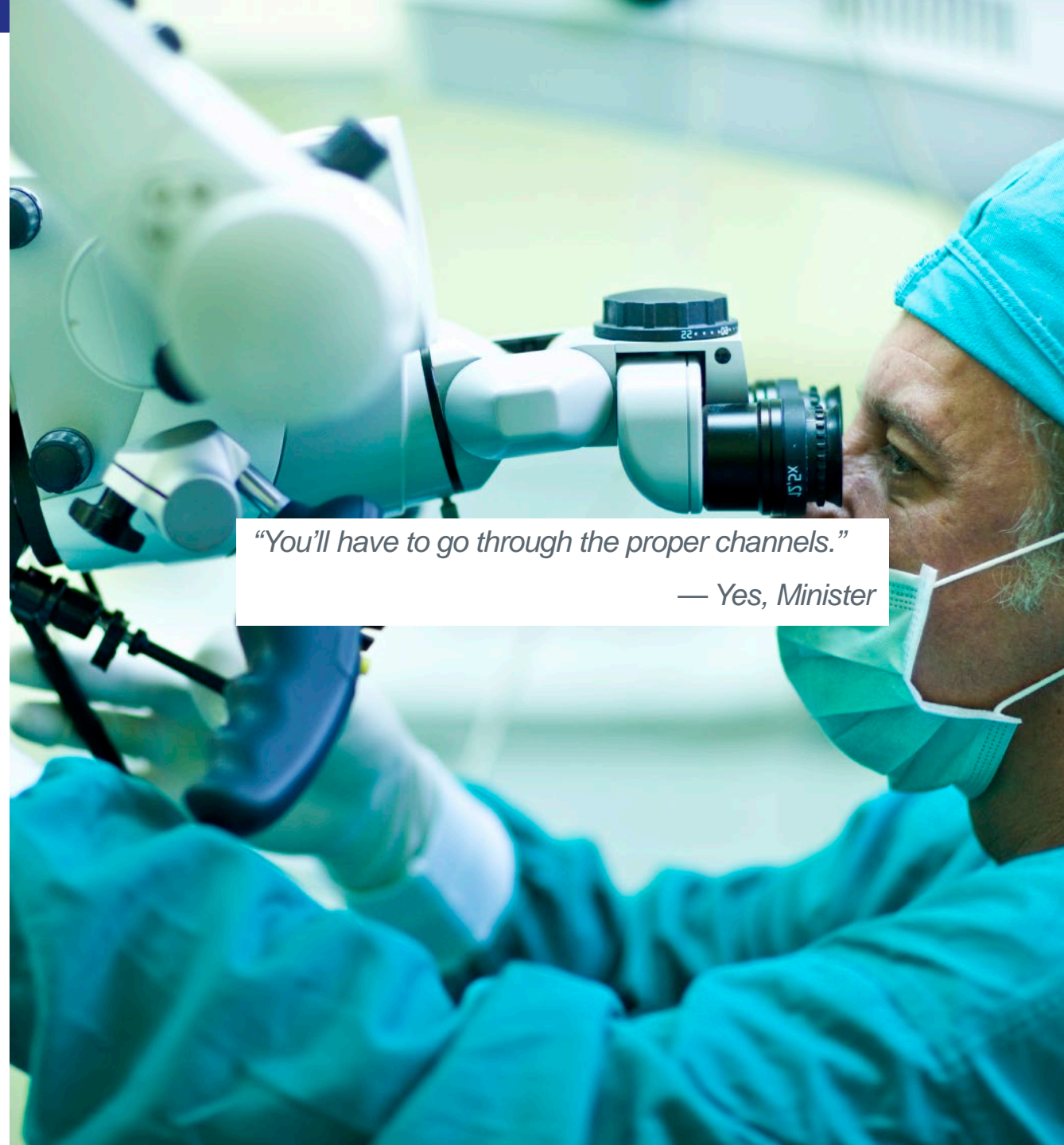
## Contact us

- your case manager
- [devices@health.gov.au](mailto:devices@health.gov.au)
- [Cat.Bruce@health.gov.au](mailto:Cat.Bruce@health.gov.au)



# The road to inclusion

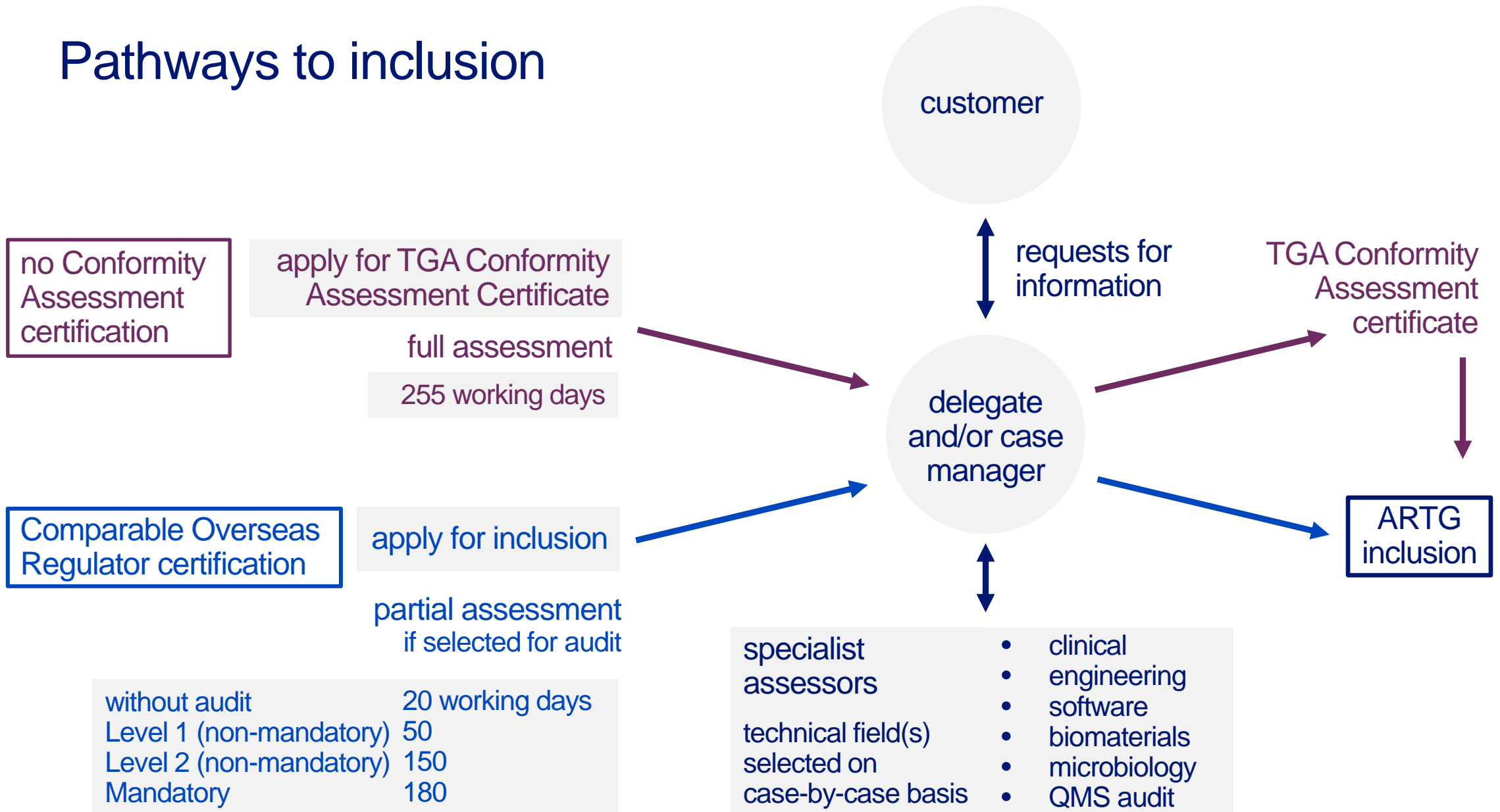
- Pathways to inclusion
- Reliance pathways
- Reforms – what's happening?



*"You'll have to go through the proper channels."*

*— Yes, Minister*

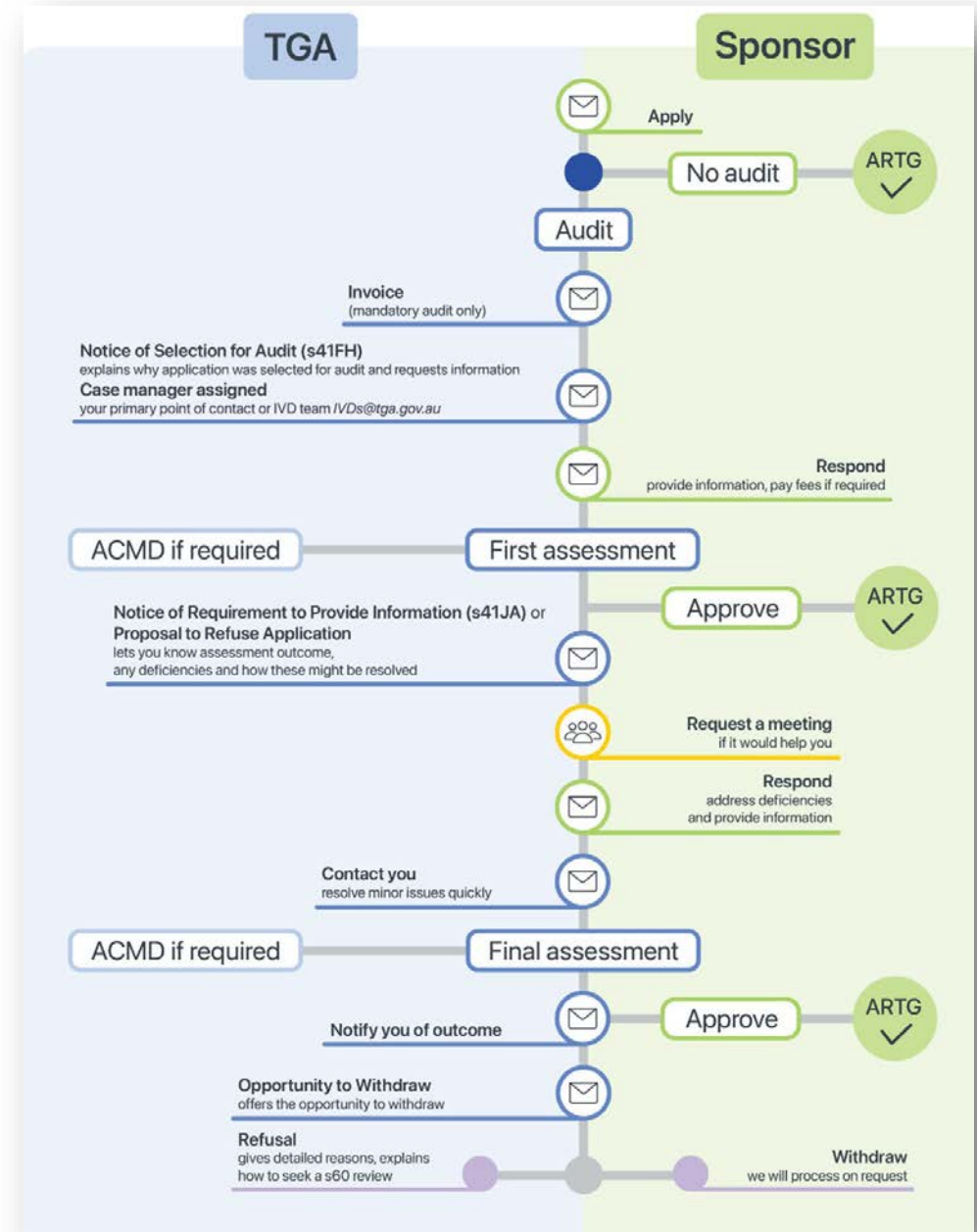
# Pathways to inclusion



# Application Audit Framework

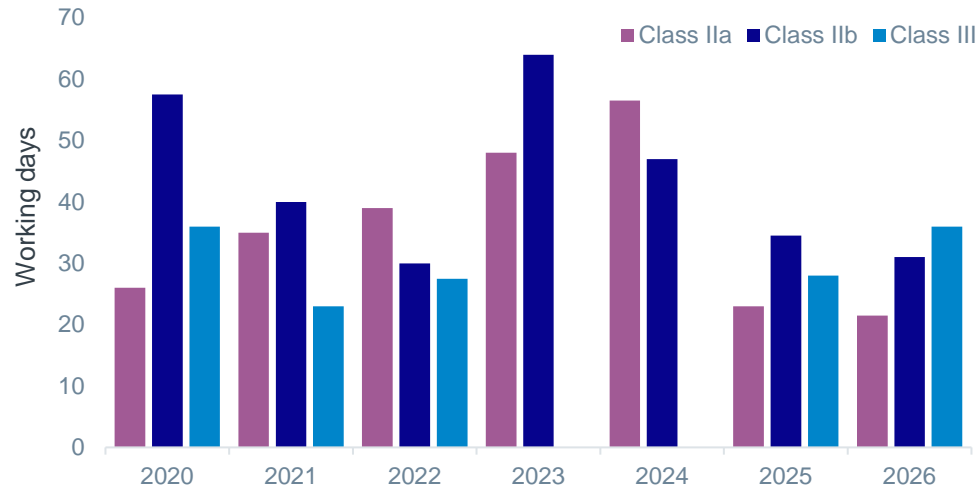
(applies only to non-mandatory audit)

- defined selection criteria
  1. aspects related to the application and the device
  2. kinds of devices subject to regulatory reforms
  3. post-market signals
  4. factors related to the sponsor or manufacturer
- targeted, risk-based assessment
- improved assessment process and timelines
- 3-year review planned

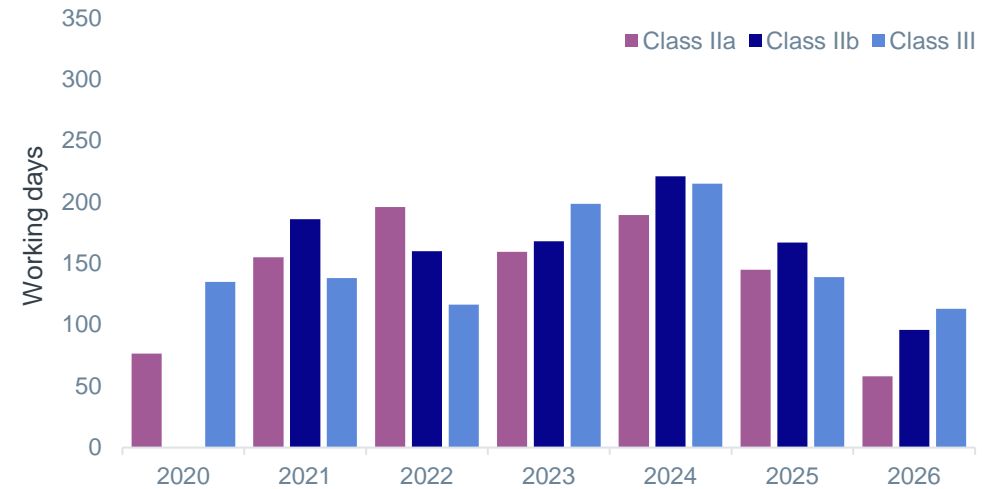


# Application audit timeframes

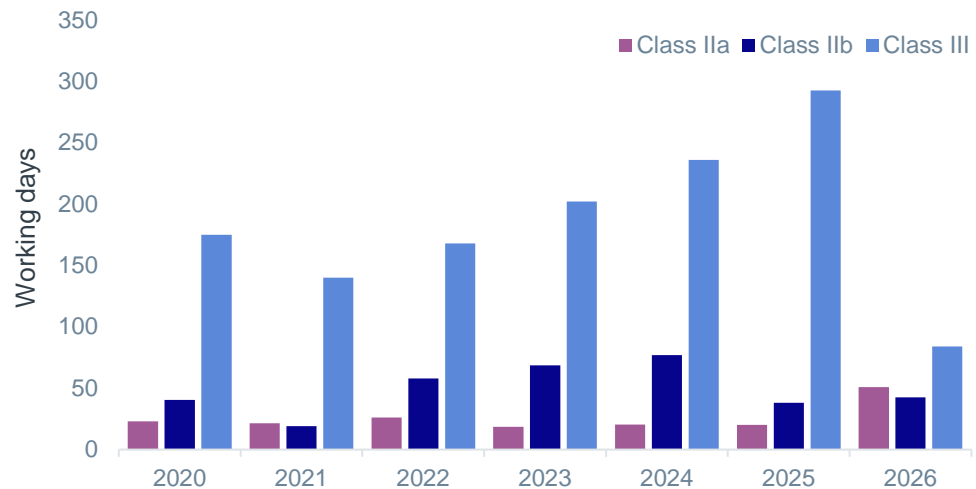
Median working days, **Level 1 non-mandatory audit**, by year finalised



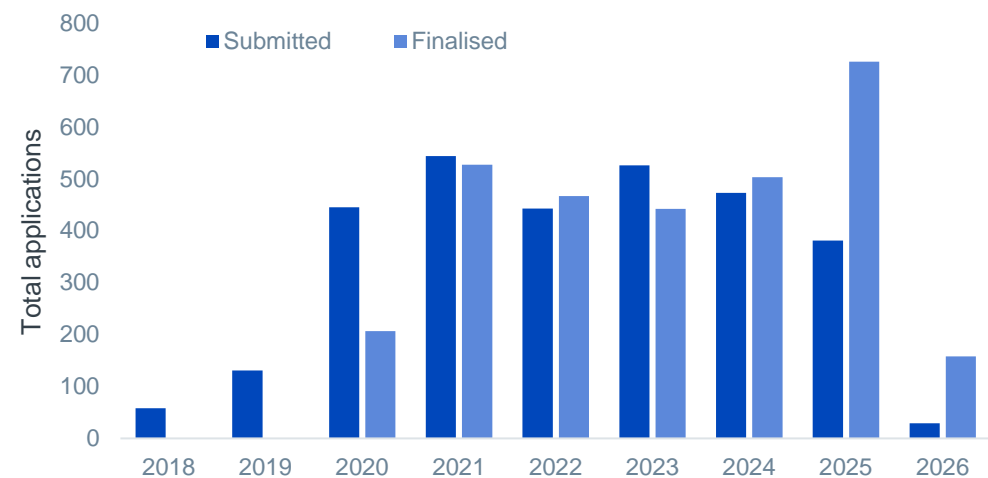
Median working days, **Level 2 non-mandatory audit**, by year finalised



Median working days, **mandatory audit**, by year finalised



Application audits submitted and finalised, by year



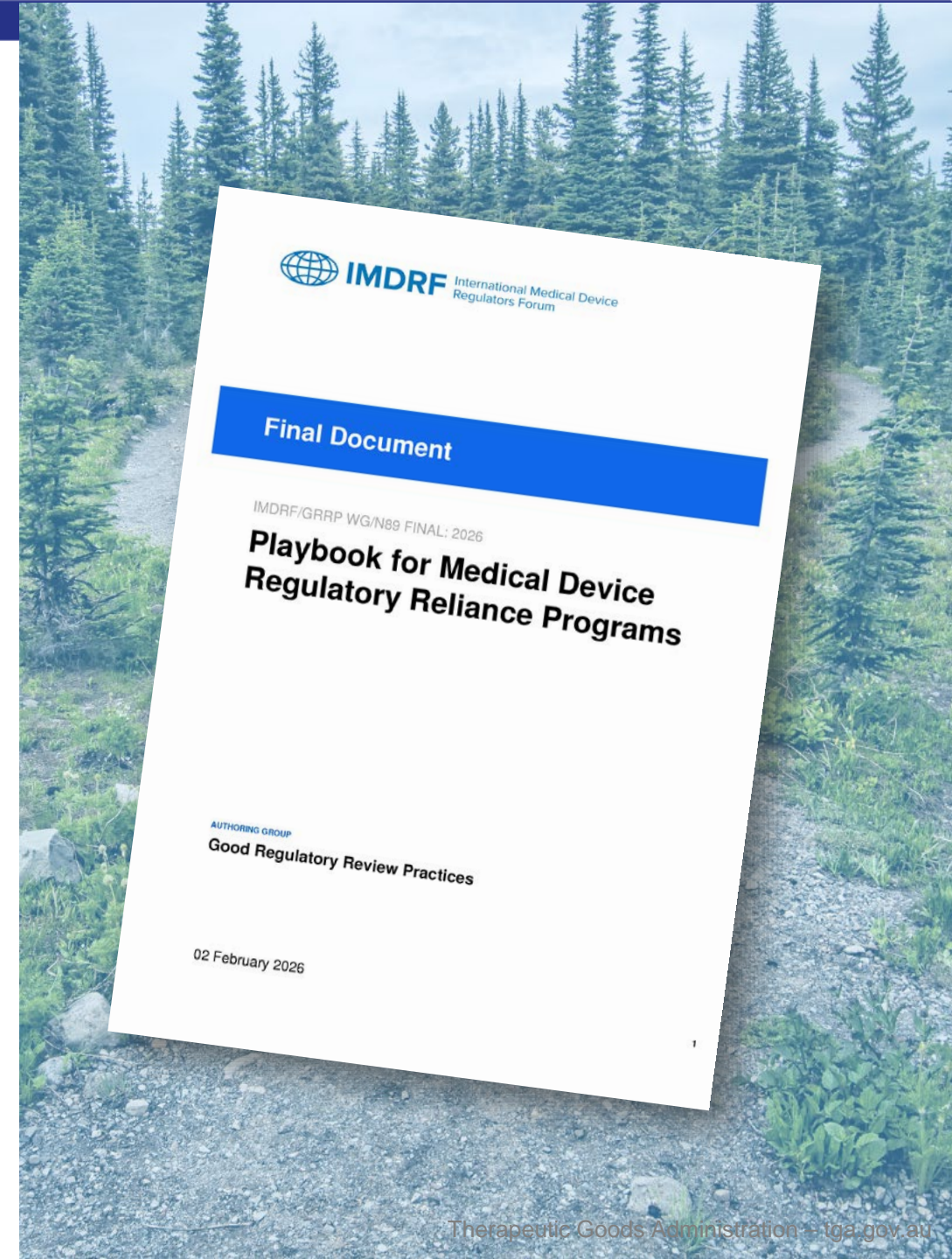
# TGA reliance pathways

## Legislative change

- ✓ work-sharing with other regulators
- ✓ reduce burden to business
- ✓ faster to market

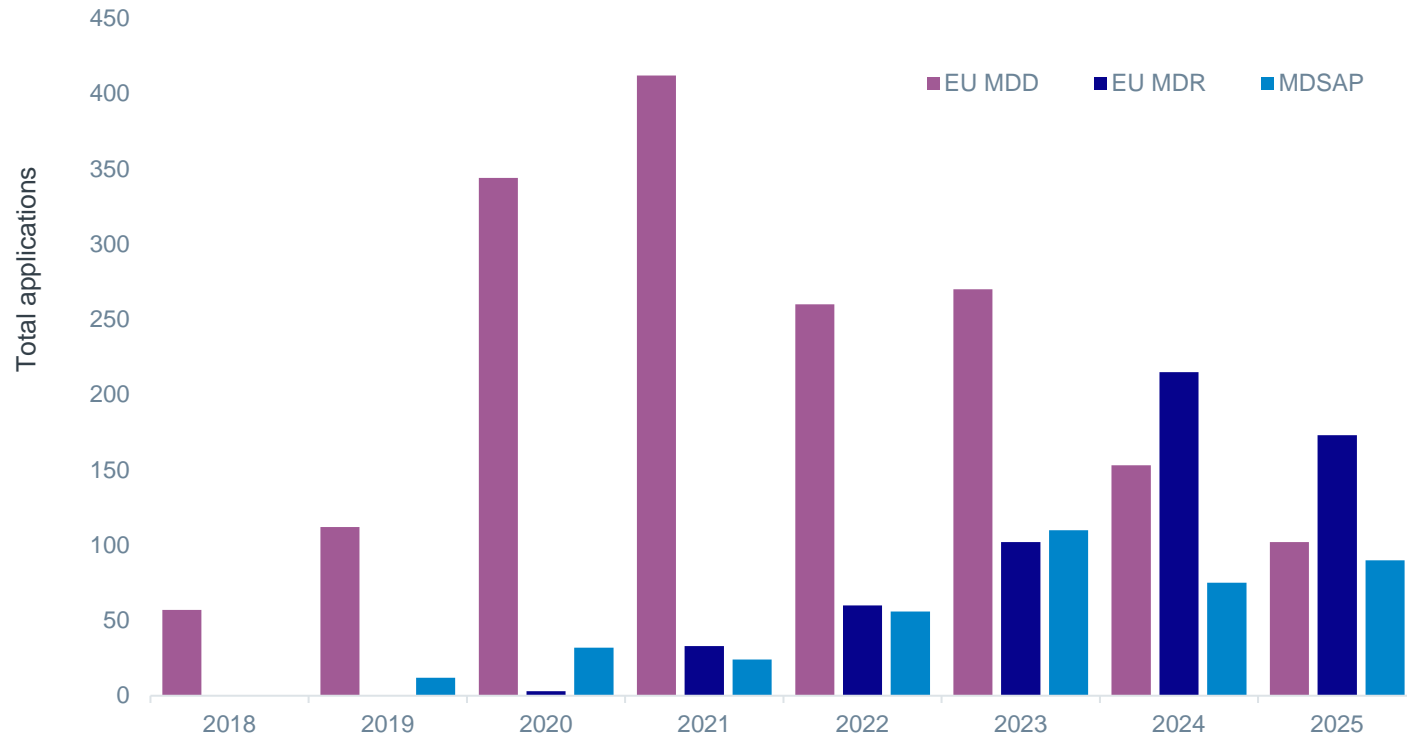
## TGA reliance pathways

1. **Comparable Overseas Regulators or Notified Bodies**  
EU, USFDA, Health Canada, Japan, Health Singapore, UK
2. **Medical Device Single Audit Program (MDSAP) certification**
3. **Mutual Recognised Agreement (MRA) to issue UK Conformity Assessment (UKCA) certification**



# Reliance pathways used

## Applications for inclusion, by year of submission



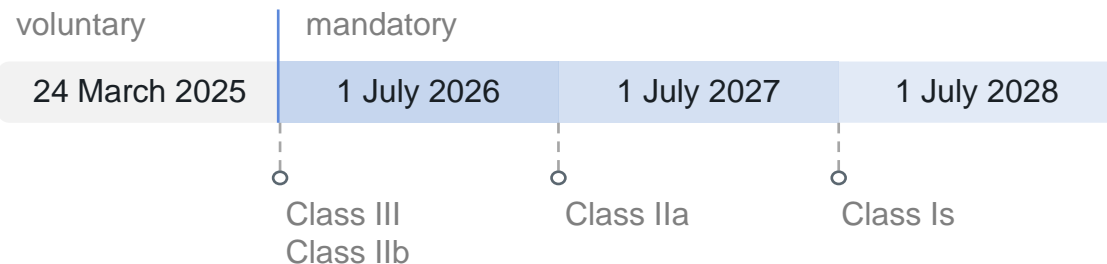
# Reforms

## Emergency access to overseas medical devices

- expanded s41HD powers for import and supply
- specified overseas medical devices

## Unique Device Identification (UDI)

- assign UDI and show on labels of device
- enter into Australian UDI Database (AusUDID)
- link to ARTG entry



## Further reforms

Planned for June 2026

- Electronic Instructions for Use (eIFU)

Review or consultation in progress

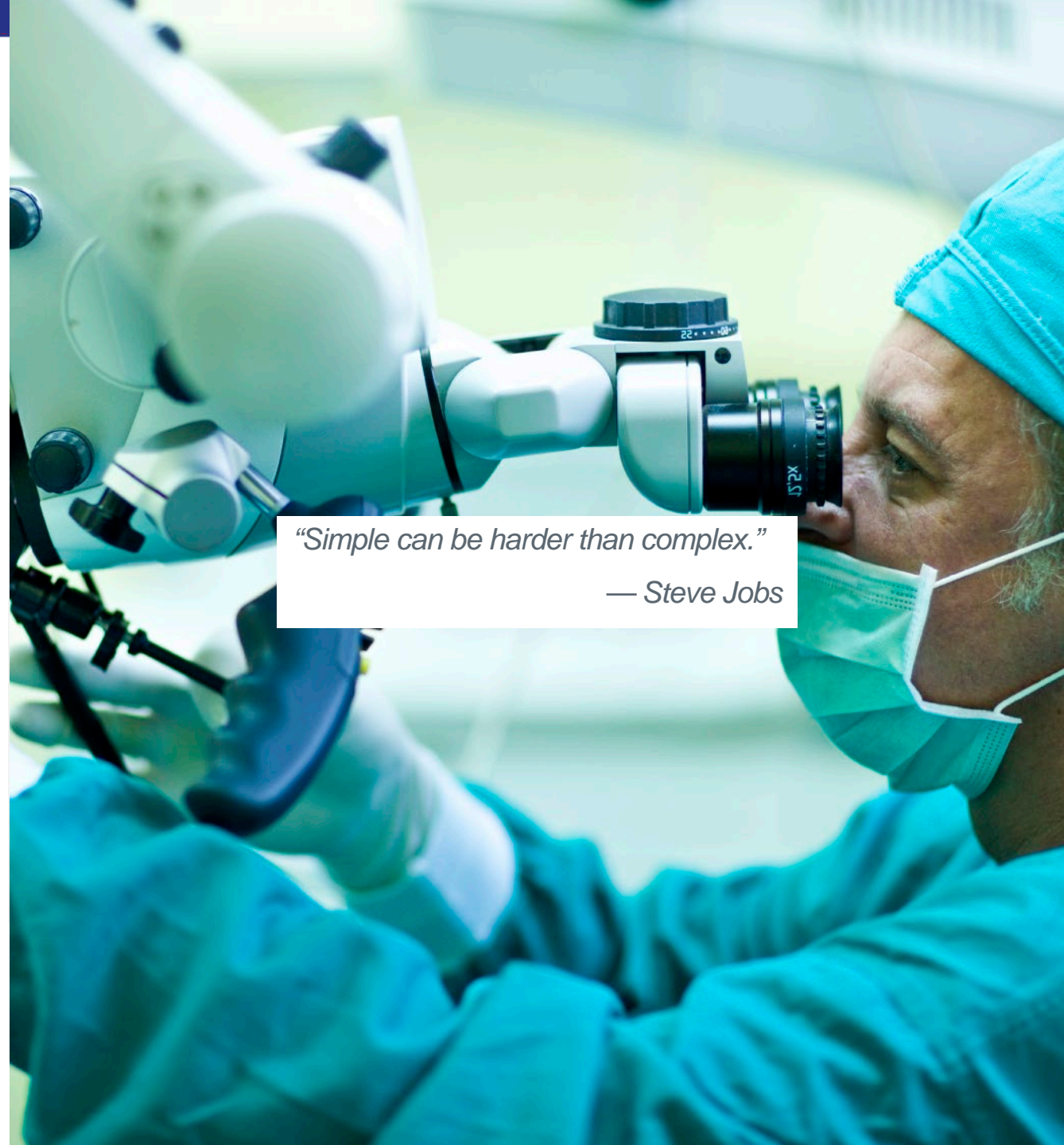
- Conformity Assessment procedures
- Exempt medical devices
- Combination products
- Essential principles

Consultation planned

- Innovative medical device pathways
- Disinfectant reform

# Make us look good

- talk first
- make it easy
- cover letter



*"Simple can be harder than complex."*

*— Steve Jobs*

## Talk to us

- ✓ Regulatory Engagement
- ✓ [devices@health.gov.au](mailto:devices@health.gov.au)
- ✓ your case manager
- ✓ Cat.Bruce@health.gov.au



# Make it easy

## Do

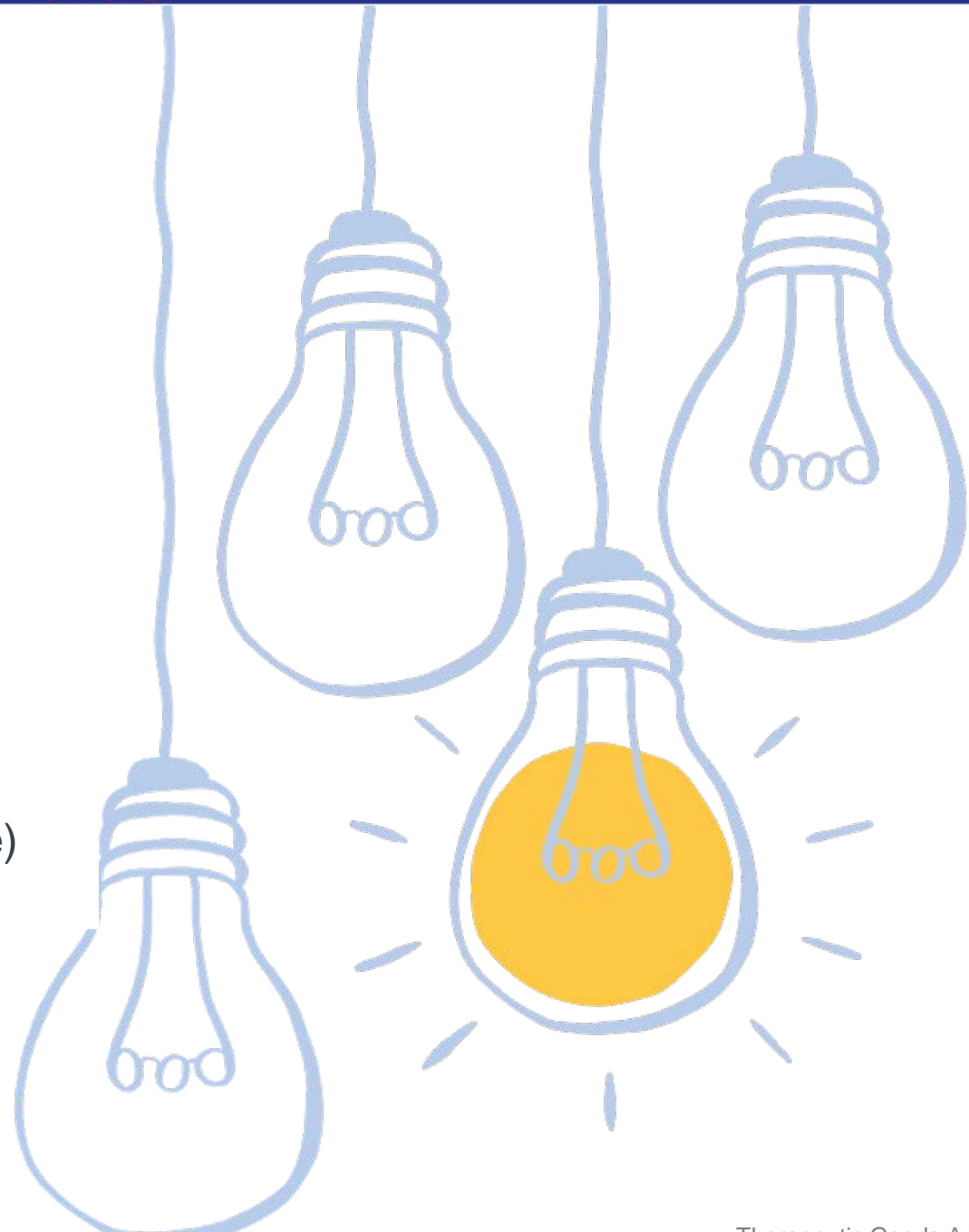
- ✓ be prepared
- ✓ quality evidence
- ✓ clarity of submission
- ✓ respond promptly

## Understand

- application and assessment processes
- audit selection criteria
- essential principles (safety and performance)

## Don't

- x unrealistic timeframes
- x deliberately low classification
- x seek regulatory affairs advice from TGA



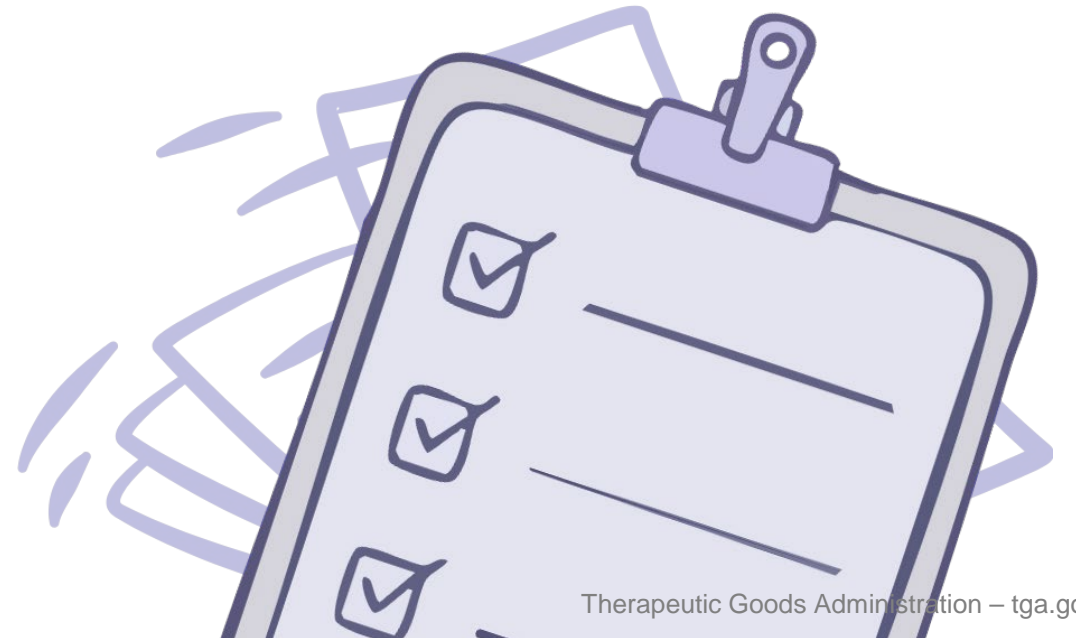
# We encourage cover letters with applications for inclusion

## What's in

- ✓ short and sweet
- ✓ overview of application and documents
- ✓ identify risks (e.g. software, new technologies)
- ✓ specify relevant selection criteria
- ✓ explain classification choice
  
- ✓ explain GMDN choice if unclear
- ✓ explain how conformity assessment covers device
- ✓ regulatory history in Australia and overseas
- ✓ provide Instructions for Use

## What's out

- x too long
- x unclear
- x irrelevant
- x detailed technical analysis
- x does not guarantee outcome



# Summary

- talk to us
- inclusion on the ARTG
- what you can do

What can we do for you?

[devices@health.gov.au](mailto:devices@health.gov.au)

your case manager

[Cat.Bruce@health.gov.au](mailto:Cat.Bruce@health.gov.au)





# Questions?

[www.tga.gov.au](http://www.tga.gov.au)

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