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**BUSINESS  
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# TGA update: Regulatory insights and what's ahead

Tracey Duffy

First Assistant Secretary

Medical Device and Product Quality Division

Therapeutic Goods Administration

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## Australia's regulatory environment

### A complex landscape, shaped by engagement

- Rapid technological change, particularly software, AI and personalised devices
- Global regulatory reform and system pressures
- Increasing expectations of transparency, evidence and lifecycle accountability
- A consultative, risk-based regulatory approach

## Major reforms now embedded

### A stronger regulatory foundation

- Application Audit Framework
- Unique Device Identification (UDI)
- Mandatory adverse event reporting (healthcare facilities)
- Recalls framework reform

### What this has delivered

- Greater predictability in pre-market assessment
- Improved post-market signal detection
- Increased alignment with comparable overseas regulators
- Better visibility of devices across the lifecycle

## Looking ahead: emerging priorities and regulatory signals

### **Evolving expectations and emerging priorities**

- Stronger expectations on evidence quality, transparency and lifecycle responsibility
- Increased focus on software, AI and controlled change over time
- Growing attention on personalised, point-of-care and boundary devices
- Continued alignment with international frameworks and risk-based regulation

### **Opportunities to shape future reforms**

- Targeted public consultations
- Continued use of working groups and co-design
- Early engagement emphasised over late remediation

## Sponsor readiness: what will matter most

### What you can do

- Engage early with the TGA
- Be clear on intended purpose and classification
- Demonstrate clinical benefit and manage change
- Plan for post-market responsibilities
- Design for transparency and traceability

## TGA Website and Guidance updates

### UDI Hub and AusUDID

- Updates to the [UDI Hub](#), including revised UDI guidance, release notes, and technical documentation.
- Enhancements to [AusUDID](#) usability, system performance, HL7 SPL interfaces, and extension of the data-entry grace period to support sponsor readiness.

### Post-Market Review (PMR) compliance portal

- [PMR compliance portal](#) updated to allow sponsors (including those supplying exempt devices) to view and respond to post-market review notifications online, supported by updated [web guidance](#).

### Application Audit Framework

- [Understanding selection criteria for medical device application audits](#)
- [Understanding the medical device application audit process](#)

### Surgical Loan Kits

- [Manufacturing and supplying surgical loan kits to Australian hospitals](#)

### Consultation outcome publications

- [UDI Consent to Supply approach and fees](#)
- [Proposed changes to the IVD medical device classifications and definitions](#)

## Regulatory Changes

### IVD companion diagnostics

Amendments to the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) extended the transitional arrangement for in-vitro diagnostic (IVD) companion diagnostics until 31 December 2028. These changes took effect from 1 October 2025, aligning Australia's timelines with the European Union's extended transition period for class 3 IVD medical devices.

### Recognition of UK Approved Bodies as Comparable Overseas Regulators

Amendments to the [Therapeutic Goods \(Overseas Regulators\) Determination 2018](#) and [Therapeutic Goods \(Medical Devices—Information that Must Accompany Application for Inclusion\) Determination 2018](#) recognise UK approved bodies (UKCA bodies') under our comparable overseas regulator arrangements and the related preliminary assessment requirements. They commenced from 1 December 2025.

### Boundary products

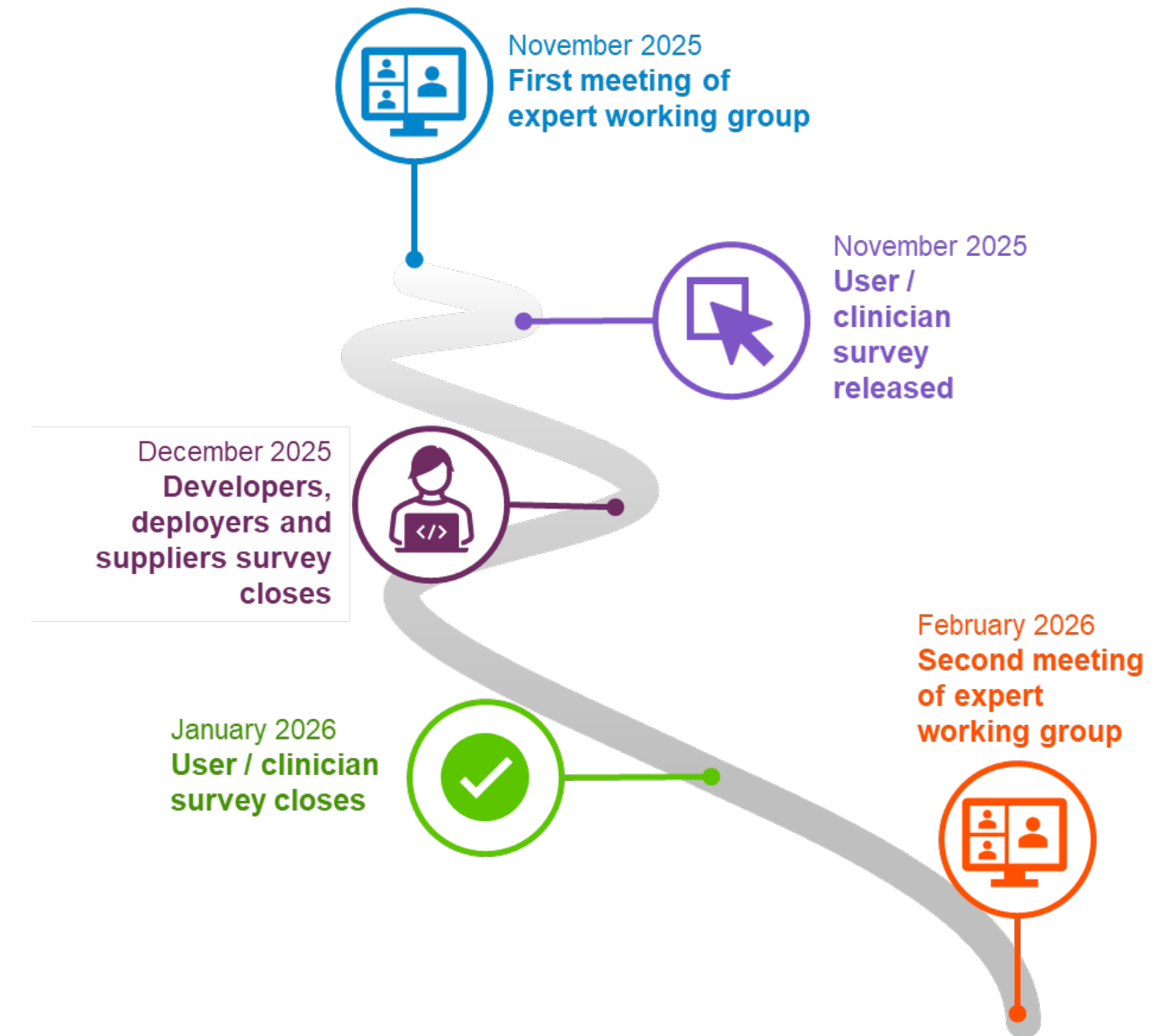
Amendments to the [Therapeutic Goods \(Medical Devices—Specified Articles\) Instrument 2020](#) and [Therapeutic Goods \(Articles that are Not Medical Devices\) Declaration 2023](#) clarify whether certain products are medical devices based on their principal intended action. They commenced on 1 January 2026.

### Emergency access to overseas medical devices

The [Therapeutic Goods \(Medical Devices—Foreign Countries\) Amendment Determination 2026](#) expands the Secretary's approval powers under section 41HD for the importation and/or supply of specified overseas medical devices during emergencies, subject to preconditions.






## Digital Mental Health Tools (DMHT) – Key issues and Review

<b>What are DMHTs?</b>	Digital services, web-based tools, and apps for screening, assessment, diagnosis, or therapy; used with or without clinical oversight.
<b>Current Position</b>	Conditionally excluded from TGA regulatory framework if based on established clinical practice guidelines that are reviewable by the user; very few tools identified as meeting criteria.
<b>Why Review Now?</b>	Growing functionality (analytics, AI), increased consumer use without oversight, and 62% of stakeholders say exclusion is no longer appropriate.
<b>What We Are Doing</b>	Surveys of developers, clinicians, and users; Expert Advisory Group established; data analysis, consultation, and advice to Government in 2026.



## SaMD and AI Regulation Review – Outcomes

Five strategic priority areas emerged from the Review – commenced work on these

 <p>Priority Area 1 <b>Supporting stakeholders</b></p>	<p>Providing clear information and guidance explaining regulatory requirements to support compliance.</p>	<ul style="list-style-type: none"> <li>• Multiple channels for communication</li> <li>• Targeted support for specific sectors</li> </ul>
 <p>Priority Area 2 <b>Robust regulation</b></p>	<p>Refining regulation to ensure risks associated with therapeutic goods continue to be appropriately mitigated throughout their lifecycle</p>	<ul style="list-style-type: none"> <li>• Medical Devices Regulations 2002</li> <li>• Excluded Goods Determination 2018</li> <li>• Pharmaceutical Inspection Co-operation Scheme (PIC/S)</li> </ul>
 <p>Priority Area 3 <b>Reinforce roles &amp; responsibilities</b></p>	<p>Ensuring language in our legislative framework (the Act) captures responsibility appropriately</p>	<ul style="list-style-type: none"> <li>• Mapping emerging terminology to existing definitions</li> <li>• Introducing new definitions where needed</li> </ul>
 <p>Priority Area 4 <b>Improve transparency of AI use</b></p>	<p>Facilitating access to information and support for stakeholders to understand how AI is used in the goods they access and how it is regulated.</p>	<ul style="list-style-type: none"> <li>• Explore levers for improving transparency of AI use</li> </ul>
 <p>Priority Area 5 <b>Conducting compliance</b></p>	<p>Pragmatic and timely compliance activities to ensure the policy outcomes</p>	<ul style="list-style-type: none"> <li>• Ongoing compliance</li> </ul>

## Digital Scribes – Compliance Review – Goals

### Education



#### Clarify the rules

When digital scribes become medical devices

Advertising code and medical devices

### Scoping



#### Market research

Identify current suppliers

Identify current functionality

### Compliance - for medical device digital scribes



#### Voluntary compliance

Remove or disable functionality  
OR  
cease supply



#### Enforced compliance

Interrupt supply of non-compliant products through regulatory powers.



#### Review applications for inclusion

Ensure products with medical device functionality are included in the Register and comply with regulatory requirements.

## Digital Scribes – Compliance Review – Timelines



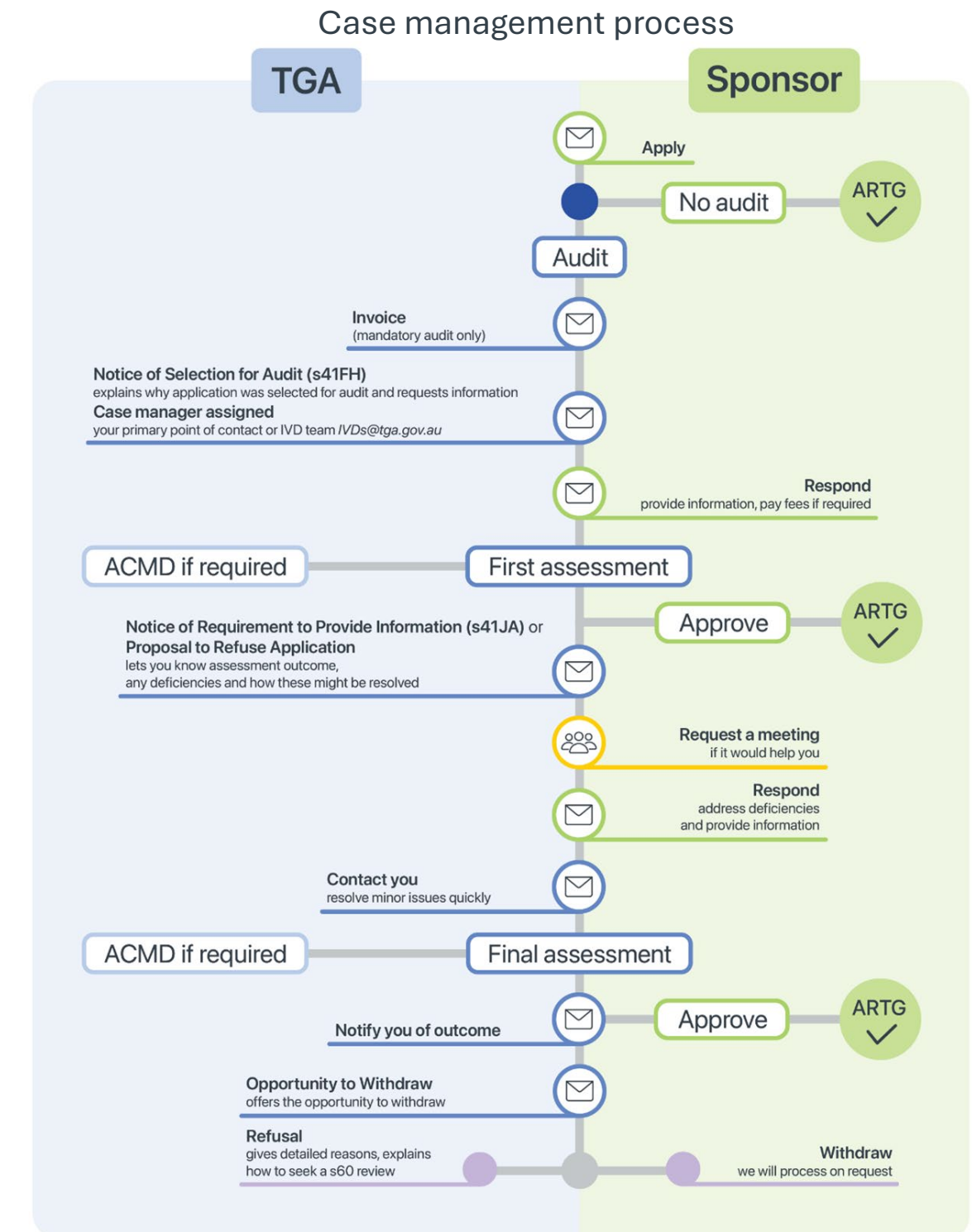
## Application Audit Framework

### Framework formalised and embedded

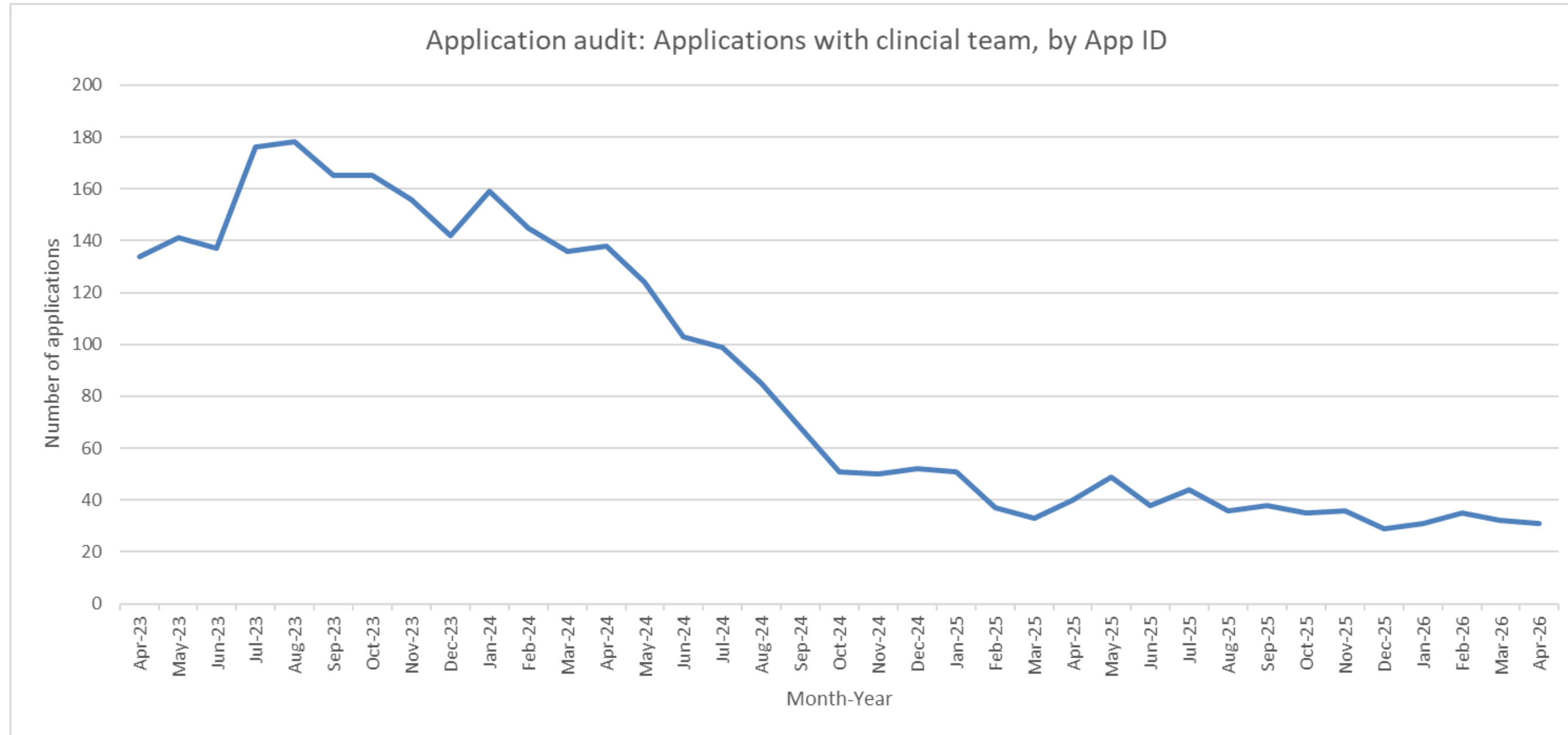
- Dynamic risk-based selection criteria for application audits
  - [Criterion 1: Aspects related to the application and the device](#)
  - [Criterion 2: Kinds of devices subject to regulatory reforms](#)
  - [Criterion 3: Post market signals](#)
  - [Criterion 4: Factors related to the sponsor or manufacturer](#)
- Better case management and communication for applications selected for audit
- Improvements to clinical assessment processes and timelines
  - Shortened timelines for clinical assessments
  - More targeted, risk-based clinical assessments
  - Enhanced regulatory engagement meetings including pre-submission advice to support application compliance
  - Clinical assessment reports provided directly to sponsors

### Primary drivers for application audits

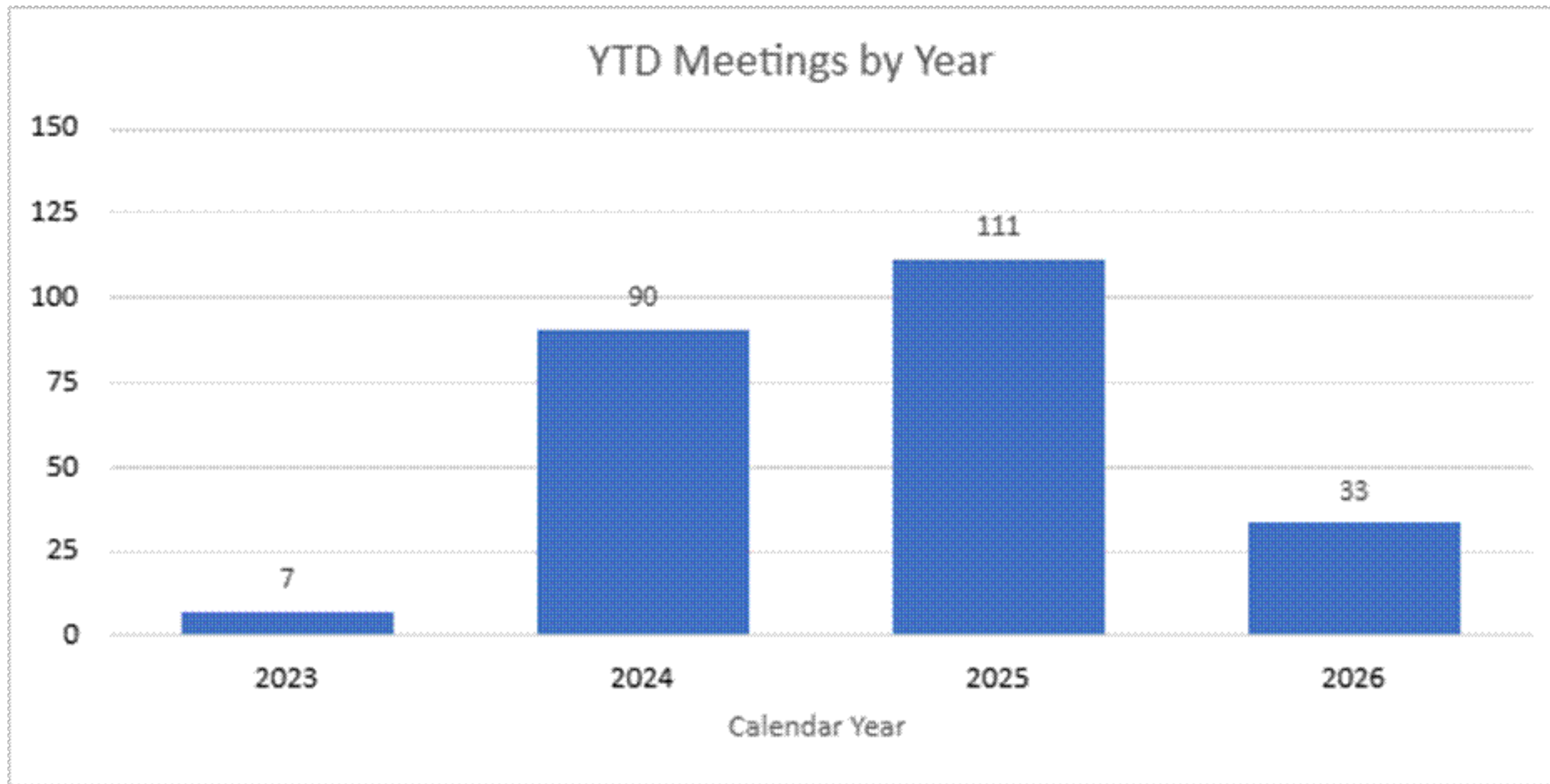
- Clarification of information in the application (79%)
- Medical device software and artificial intelligence (AI) (13%)



## Clinical assessment wait times for application audits (2023-2026)

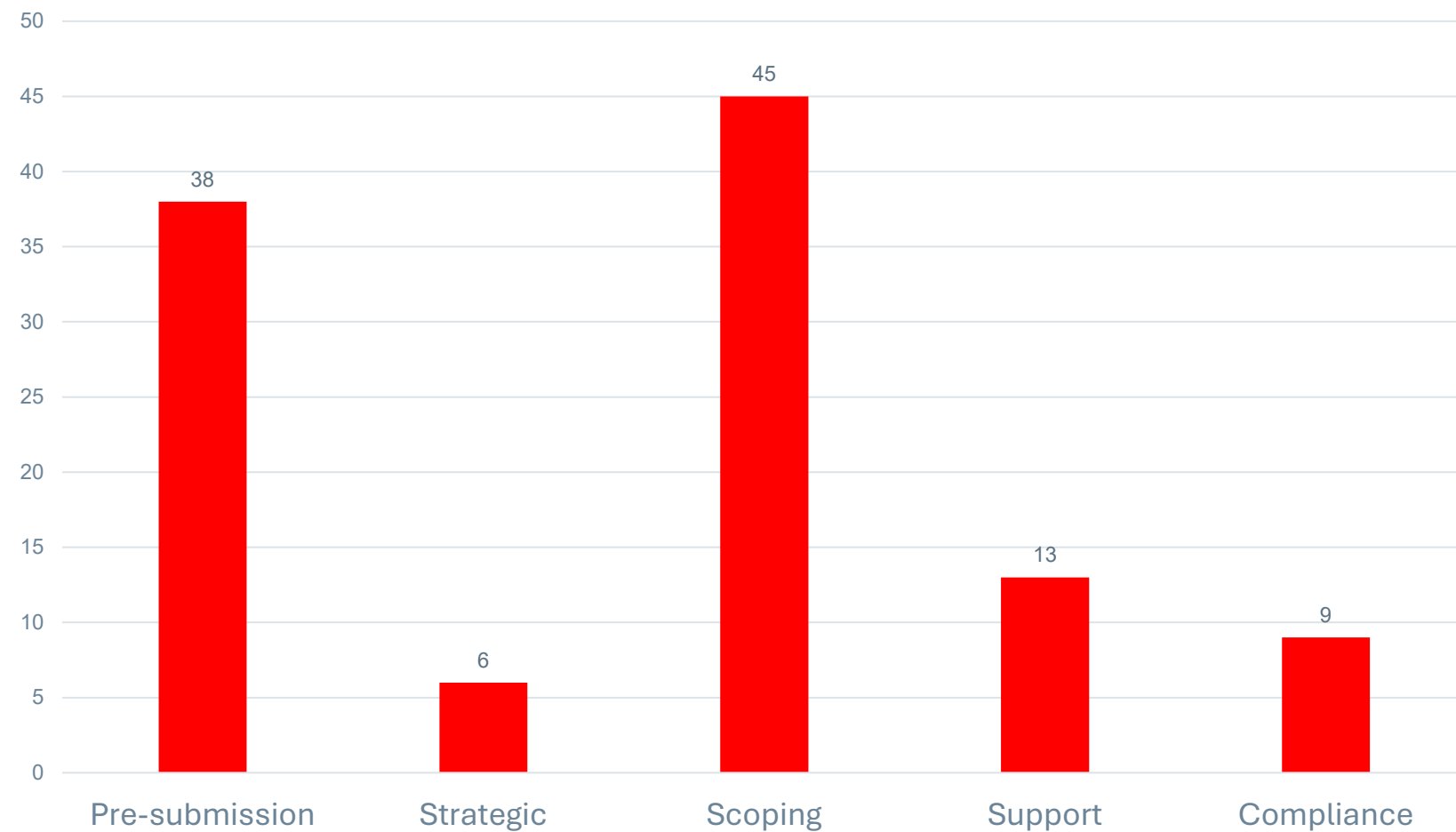


## Regulatory Engagement - Statistics

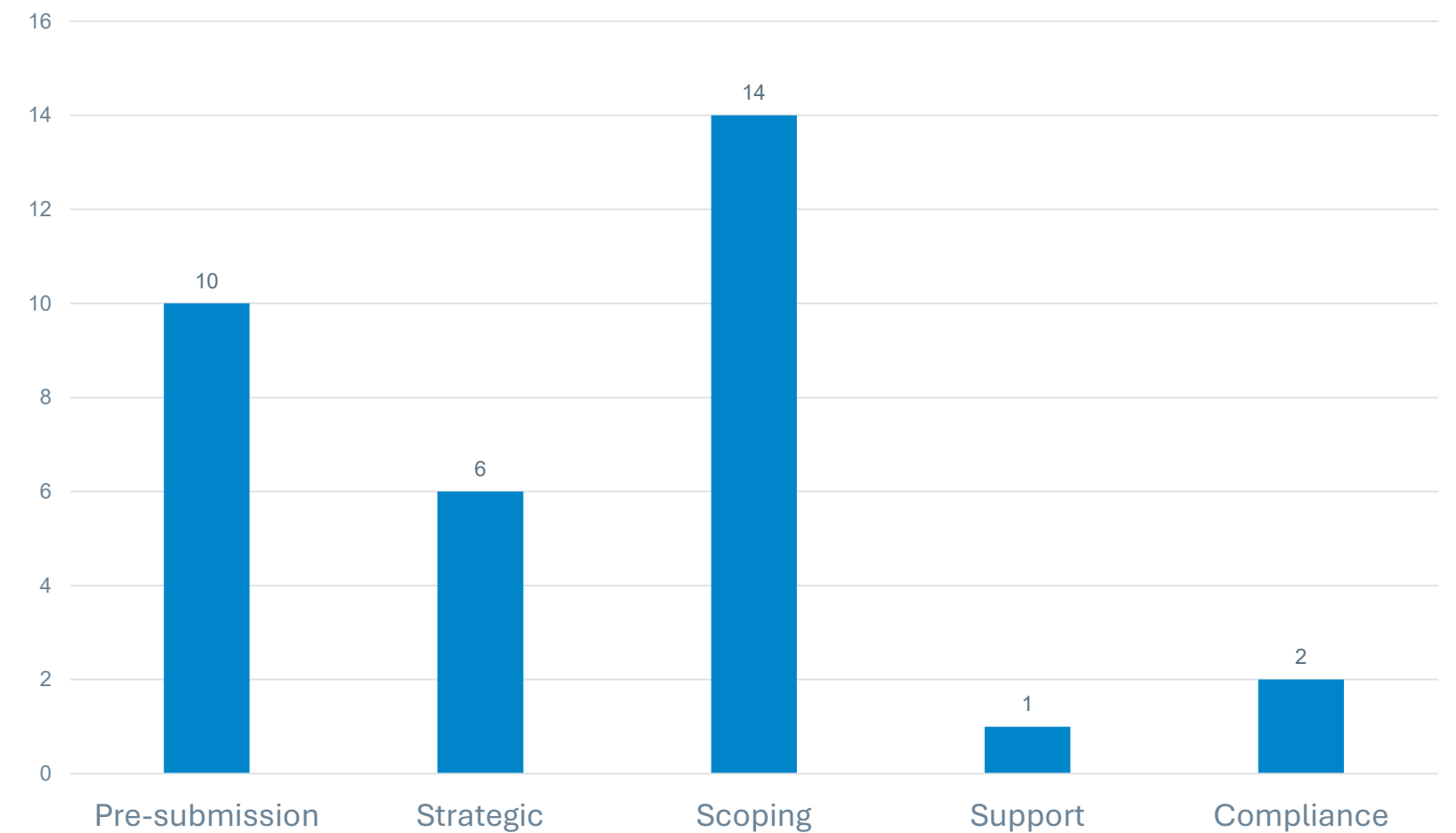


## Regulatory Engagement – meeting types

Meeting Types – 2025 Calendar Year

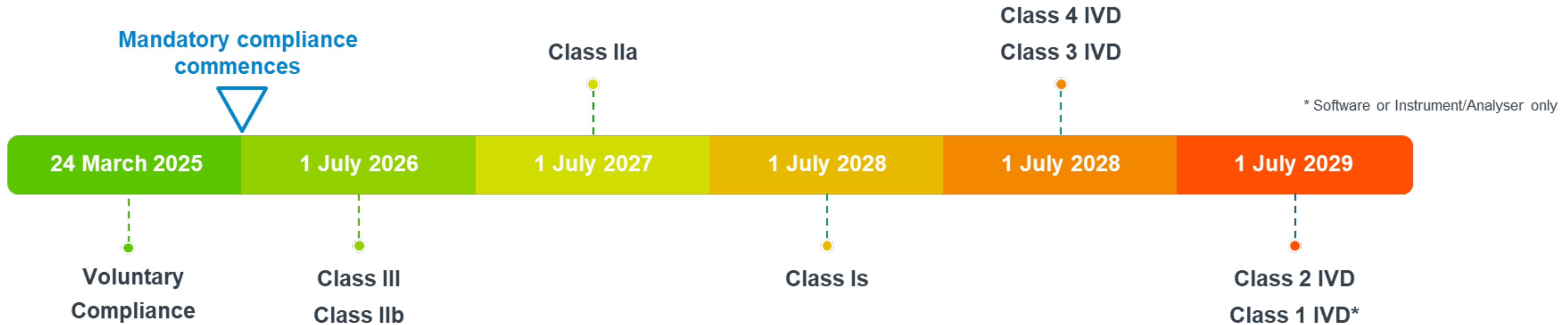


Meeting Types – 2026 Calendar year



## Unique Device Identification (UDI) – commencing 1 July 2026

- Phased implementation: high-risk devices from 1 July 2026



## Unique Device Identification (UDI)

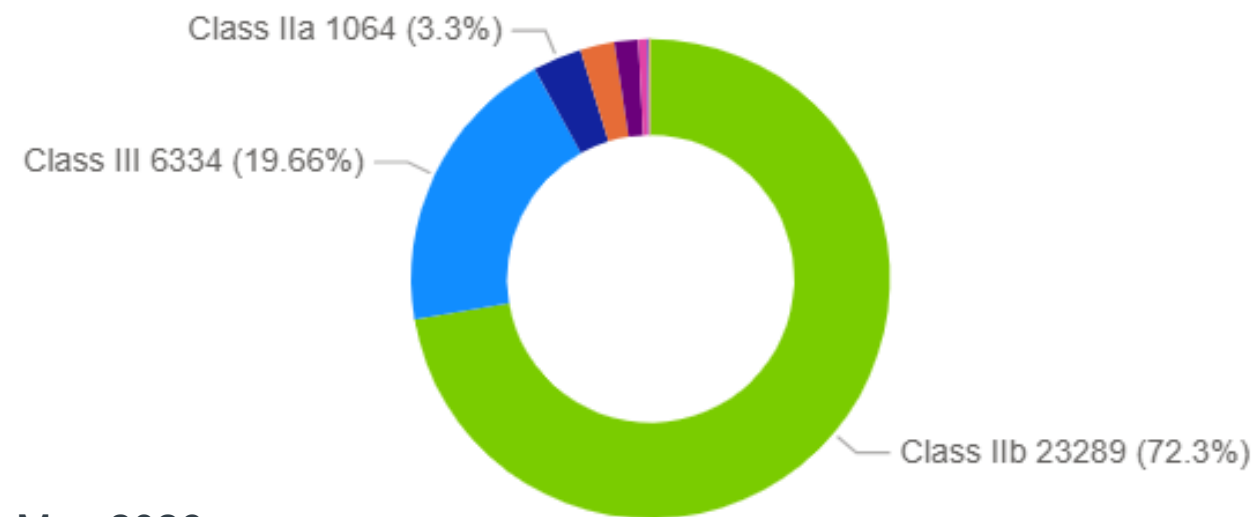
- 3 Issuing Agencies – GS1, HIBCC, ICCBBA
- Australia will accept labels with UDI Carriers that meet US and EU requirements for UDI
- Selected device classes

	Medical devices	Invitro diagnostic devices
<p>UDI</p> <p>✓</p>	<ul style="list-style-type: none"> <li>• Class III</li> <li>• Class IIb</li> <li>• Class IIa</li> <li>• Class I – supplied sterile</li> </ul>	<ul style="list-style-type: none"> <li>• Class 4</li> <li>• Class 3</li> <li>• Class 2</li> <li>• Class 1 (Software IVDs or Instrument/Analyser IVDs only)</li> </ul>
<p>UDI</p> <p>✗</p>	<ul style="list-style-type: none"> <li>• Class I - measuring</li> <li>• Class I</li> <li>• Class 1 IVD (remainder)</li> <li>• In house IVDs</li> </ul>	<ul style="list-style-type: none"> <li>• Devices not included on the ARTG</li> <li>• Patient-matched medical devices with a volume of 5 or less supplied each financial year</li> <li>• Medical devices exempt under Special Access Scheme (SAS) or Authorised Prescriber (AP) Scheme</li> </ul>

## Unique Device Identification (UDI)

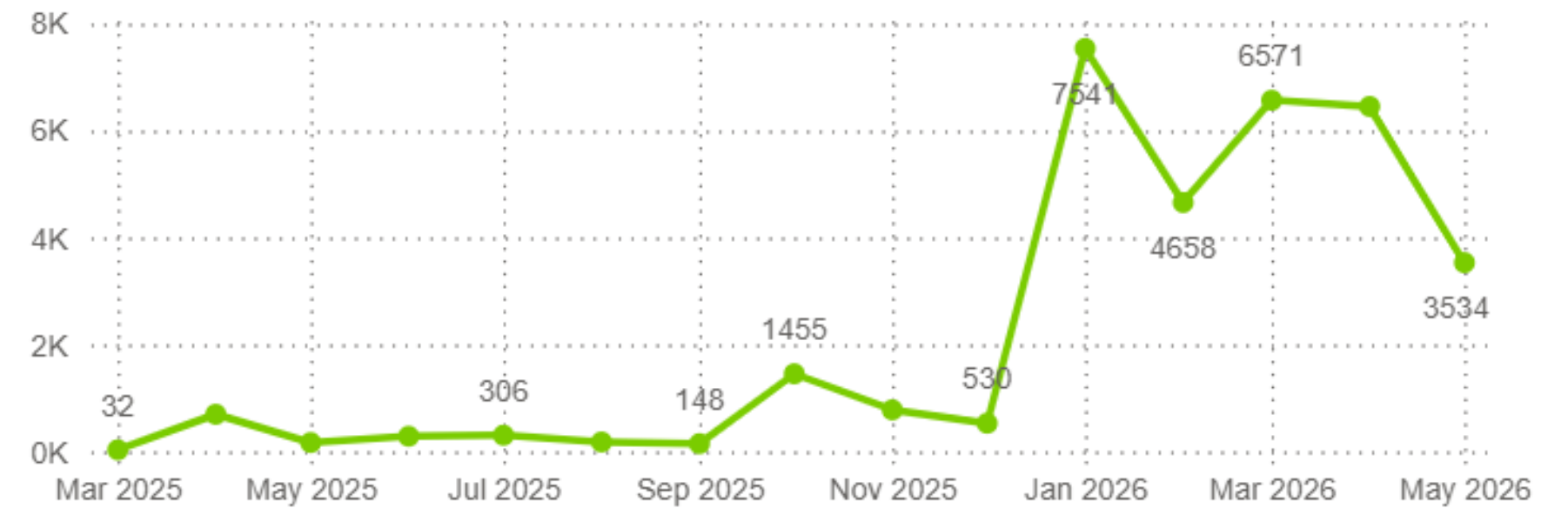
- Industry has been actively adding UDI data for Class III and Class IIb devices
- With sponsors and their data providers confirming the readiness of their machine to machine solutions, the number of records is expected to jump in weeks leading up to 1 July

Active published UDI records by ARTG Device Class



\* As at 10 May 2026

Active published UDI records



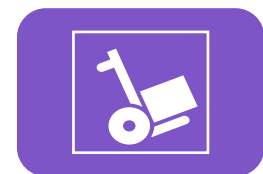
## Unique Device Identification (UDI) – adoption in healthcare

TGA will continue to promote UDI adoption within healthcare organisations

UDI can enable healthcare benefits through:



Increased time for patient care  
Improved patient outcomes  
More insightful performance analysis of devices








Decreased costs through effective inventory management  
Improved data linkages



Ease of actioning recalls  
Simplified adverse event reporting

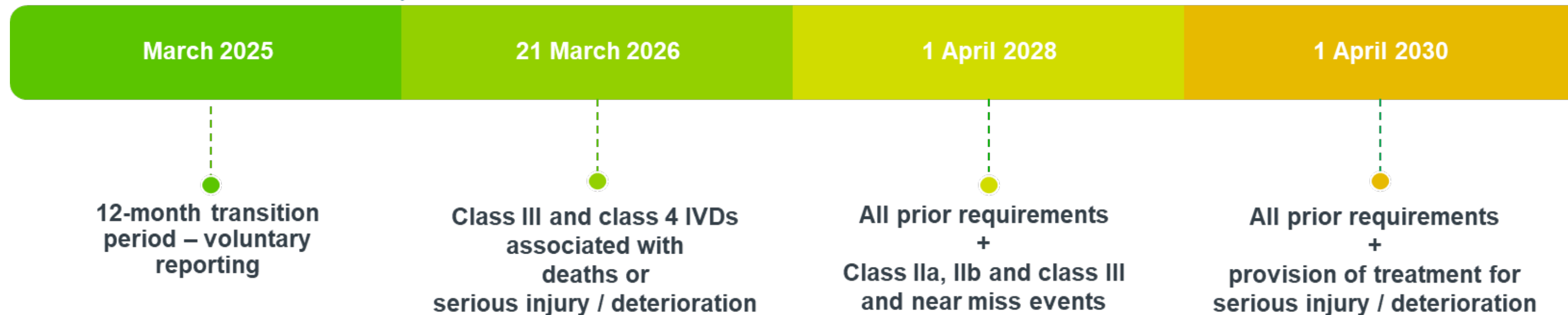
## Unique Device Identification (UDI) – Consent to Supply

 <p><b>Prepare</b></p>	<p><b>Prepare</b> your UDI Consent to Supply Application</p>	<ul style="list-style-type: none"> <li>The UDI-specific Consent to Supply User Guide will give you wording and suggestions to help you streamline drafting of your application</li> </ul>
 <p><b>Submit</b> No earlier than 1 July 2026</p>	<p><b>Submit</b> your UDI Consent to Supply Application</p>	<ul style="list-style-type: none"> <li>Reduced fees for UDI Consent to Supply come into effect from 1 July</li> <li>No refunds will be provided for application fees paid before 1 July 2026</li> </ul>
 <p><b>Pay</b></p>	<p><b>Pay</b> the invoiced amount</p>	<ul style="list-style-type: none"> <li>After submission, the TGA will issue you an invoice based on the selected Essential Principles and the number of ARTG entries</li> </ul>
 <p><b>Review</b></p>	<p><b>TGA review</b></p>	<ul style="list-style-type: none"> <li>Following payment, the TGA will review your application and you will be notified of the outcome</li> </ul>
 <p><b>Close</b></p>	<p><b>Close</b> out your application by submitting evidence of compliance</p>	<ul style="list-style-type: none"> <li>Within the period of consent, provide evidence of EP compliance</li> </ul>

## Mandatory Reporting of Medical Device Related Adverse Events by Healthcare Facilities

- Mandatory reporting requirements commenced on 21 March 2026 for all public, private and day hospitals in Australia
- Reporting requirements expand over three stages based upon the risk classification of the medical device and the nature of the adverse event

Commencement of mandatory reporting  
by healthcare facilities



## Other Medical Device Reforms

Medical Device Reform	Status
Clinical Decision Support System (CDSS)	Regulatory amendments to refine exemption requirements are expected to be in place in June 2026 to
Electronic Instructions for Use (eIFU)	Regulatory amendments to allow eIFUs where appropriate are expected to be in place in June 2026
Exempt medical devices	Preparing second consultation
Combination products	Continue internal review of processes
Conformity Assessment Procedures	Reviewing consultation submissions
Essential Principles	Reviewing consultation submissions
IVD definitions and classifications	Preparing legislative amendments
Medical device vigilance program	Reviewing pilot program
Mandatory adverse reporting exemption rules	Reviewing current exemptions

## Recent, current and upcoming public consultations

Consultation Topic	Consultation Intent	Dates
Information sharing	Consultation for proposed amendments relating to transparency of disruptions to supply of a medical device.	Closed 20 Feb 2026
Variations to ARTG entries	Consultation on refining the current framework, including fees, for varying ARTG entries	Q2/3 2026
Boundary Products	Consultation on clarifying the regulatory categories of additional boundary products, and guidance	Q2/3 2026
Information sharing	Consultation on proposals to refine TGA's information sharing arrangements for post market reviews	Q2/3 2026
Exempt Devices and Other Therapeutic Goods	A second consultation to refine the regulatory requirements for medical devices and other therapeutic goods that are exempt from certain premarket requirements including a model of notifications.	Q2/3 2026
Patient-matched medical devices	Consultation on proposed refinements to the regulation of personalised medical devices, specifically for patient-matched medical devices including those manufactured at the point-of-care. We will also conduct a consumer survey seeking feedback from people who have experience with personalised devices.	Q2/3 2026
Adverse event reporting forms	Targeted consultation to require adverse event reports submitted by medical device sponsors be provided in a specified form	Q2/3 2026
Conformity Assessment Procedures	A second consultation on clarifying post-market requirements under conformity assessment procedures	Q3 2026
Digital mental health tools	Consultation on proposed amendments to the way we regulate digital mental health tools (DMHTs) including consideration of the current DMHT exclusion	Q3 2026
Regulatory pathways for innovative medical devices	Consultation on options to improve the regulatory pathway for innovative medical devices, including the priority pathway	Q3 2026
Adverse Event reporting requirements	Targeted consultation to require sponsors to provide IMDRF codes in their submissions	TBA
In-house IVD arrangements	Seeking feedback on the regulatory framework for in-house IVDs to verify whether it continues to be fit for purpose	TBA
Disinfectants	Conduct targeted and public consultation on the regulation of disinfectant products to refine the current arrangements and to align more closely with international risk classifications	TBA
Medical device vigilance program	Consultation on proposed options to implement an ongoing medical device vigilance program	TBA
Software and Artificial Intelligence	Conduct targeted and public consultations on proposed refinements to the current arrangements for the regulation of software and AI.	TBA
Clinical Trials	Consultation on legislative amendments to allow flexibility in administrative arrangements	TBA

## Thank You

Therapeutic Goods Administration (TGA)

Medical Devices Information Unit

Email [devices@tga.gov.au](mailto:devices@tga.gov.au)

Phone 1800 141 144