Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar 7

Global Manufacturer UDI Learnings

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TGA Health Safety Regulation

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Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- Questions – please use the **Q&A** tool once this function is opened
  - Q&A will occur post presentation in the last 15 minutes
  - Your questions are only visible to the panel
- If you need to contact the moderator – please use the **'Chat'** function ONLY
- Relevant links will be sent to you via the chat function box
- A live poll will be conducted at the end of the presentation.

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OR

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Access code: 2650 466 7077

AGENDA:

- **Invited guest speaker – Debbie Connors, Smith+Nephew**
- TGA project update
- Questions and answers

Guest presenter – Debbie Connors

Senior Director Regulatory Affairs, Smith+Nephew

- Over 30 years of experience in the medical device industry, working in several roles including Product Development, Regulatory Affairs and Regulatory Advocacy and Policy.
- Debbie joined S+N, a leading medical technical company, in 1995, and works within the Regulatory Affairs organisation as Global UDI Program Manager and EUDAMED Business Readiness lead.
- Debbie is currently focusing on implementing Unique Device Identification regulations in the EU and globally. This responsibility includes ensuring that S+N unique device identification strategy meets applicable regulations, strives for global alignment, and meets the needs of the healthcare provider.
- She provides key interface support with the various impacted S+N business teams to implement digital solutions for UDI master data management, business process development and supports organisational change adoption.

Introduction to Smith+Nephew

Smith+Nephew at a glance

Smith+Nephew is a leading portfolio medical technology company, that designs and makes technology that takes the limits off living.

Three global franchises:

- Orthopaedics
- Sports Medicine & ENT
- Advanced Wound Management

18,000

Around 18,000 employees

FTSE100

A constituent of the UK's FTSE100, our shares are traded in London and New York

$4.6bn

Revenue in 2020

Our global footprint and customers

We have a balanced global footprint...

Our customers

- Nurses and nurse specialists
- Healthcare systems and Procurement groups
- Payers and administrators
- Retail consumers and patients
- Physicians and GPs
- Surgeons

Smith+Nephew

Global UDI Program Overview

INTRODUCTION

Global UDI Landscape

OUR APPROACH

S+N Global UDI Strategy

WHERE WE ARE AT

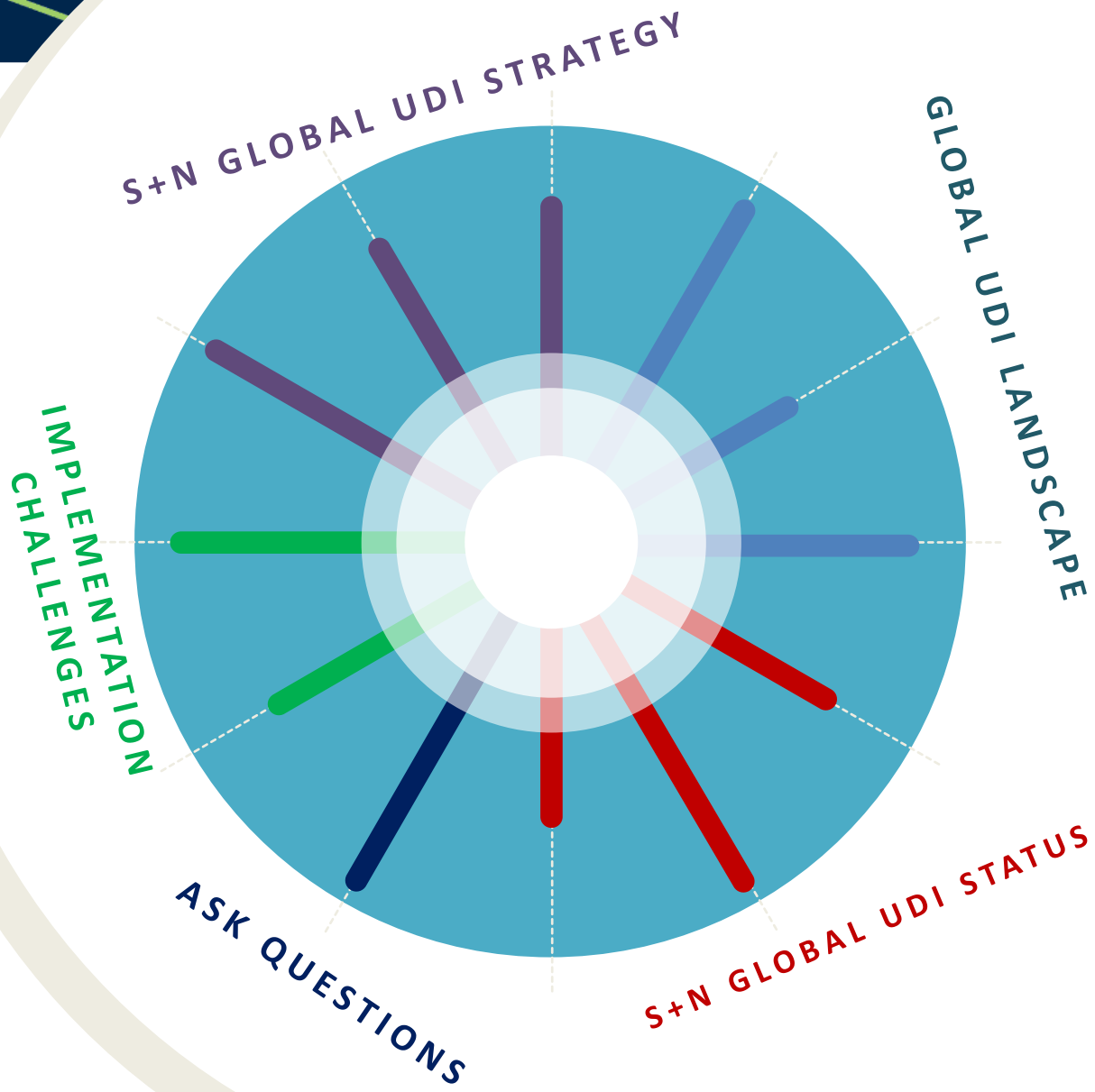
S+N Global UDI Status

ALWAYS LEARNING

Global UDI Implementation Challenges

OPEN TO SHARE

Q&A



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Introduction - Global UDI Landscape

STAGE 1 – Industry Talks

Colombia Ethiopia
India South Africa
UAE

STAGE 2 – Announcements and Discovery –Guidelines and Regulations Under Development; Compliance Dates - TBD

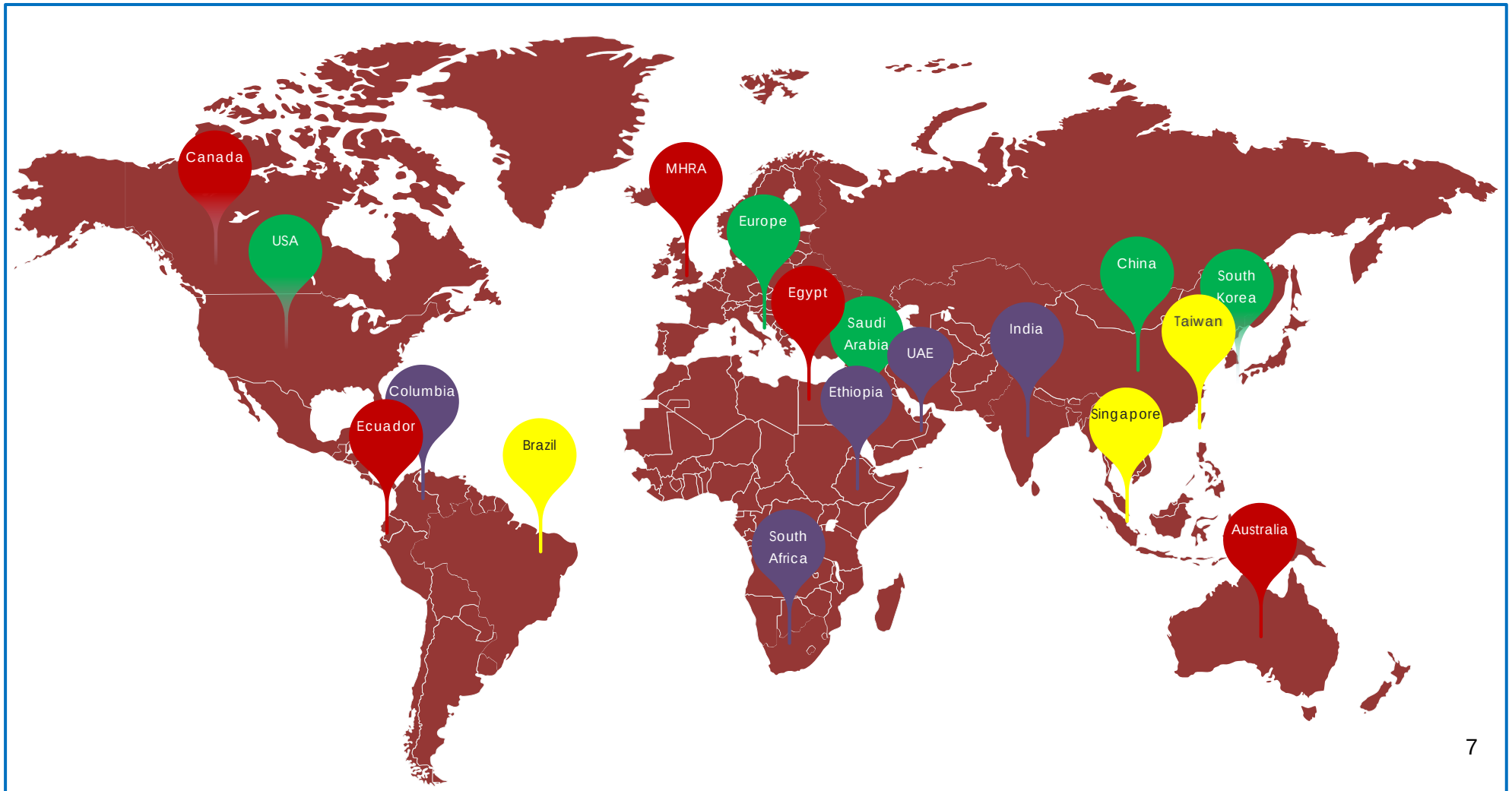
Australia Ecuador
Canada Egypt
MHRA

STAGE 3 - Guidelines and Regulations Published, in implementation.

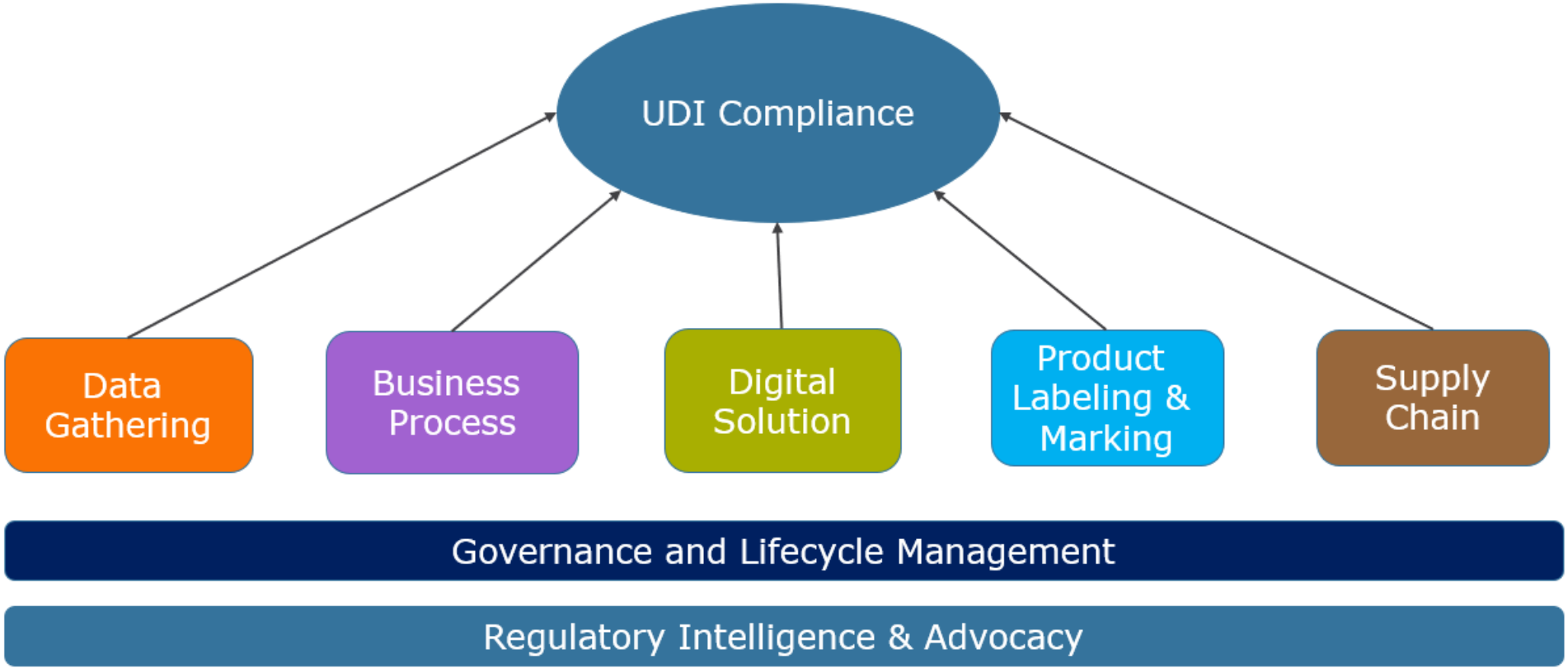
- Taiwan
- Singapore
- Brazil

STAGE 4 – In effect – either fully Live or has multiple compliance Go Live dates

US FDA Europe
South Korea
China
Saudi Arabia



Our Approach - S+N Global UDI Strategy



Our Approach Continued

Global UDI Required Program Stakeholders and What your budget should include

RA Intelligence	Global UDI Project Initiation Approval
	Regulatory Advocacy
Global UDI PMO	Develop Attribute Mapping
	Determine Screen Layout requirements
	Design Extract Report Layout Requirements
	Business Case and CER
	Workstream Management
	Status Reporting
	GS-1 Compliance
	Digital Solution Development & Testing
	Data Collection Tools & Loading
	Business Process Support & Integration
IT	Clone Regulatory Master Table
	Develop New Requirements
	Perform Data Loads
	Generate extraction reports
Operations	Labeling
	Product Marking
	Supply Chain Controls
Local Regulatory	Local Business Process Owners/SMEs
	Data Collection Support/Submission
	Site Integration & Adoption to Local QMS
Commercial	Portfolio Rationalization

Type Of Cost
Global Costs
Global UDI PMO + Global Data Collection
IT
Operations – such as labelling and DPM
Operation – ongoing costs; Such as UDI Solution License
Local Costs
One time Setup – such as local data collection, UDI solution integration and adoption
TOTAL COSTS

Where We are At - Global UDI Status

Data

- As a result of US FDA GUDID, GDSN and EU MDR EUDAMED efforts, we have collected 200+ product attributes for our product portfolio.
- Approximately 80% of the attributes collected are common across geographies including new markets coming into play.
- 20% require data collection efforts by local teams.
- Majority of new attributes are market or region specific

Product

- 98% of our products are physically UDI compliant with the currently live UDI markets, such as US FDA, Europe, China, South Korea, and Saudi Arabia.
- We carry a very small % of S+N products as part of our aging/legacy inventory that predates UDI requirements. Generally, our customers reach out and we are immediately notified when such legacy product is found in global supply chain.

People

- We have a great group of global UDI experts:
- Experts in understanding UDI regulation and its application
- Experts in digital compliance
- Experts in product master data
- Experts in UDI solutions
- Experts in GS1 standards
- Experts in Global Program Management and Business Readiness

Process

- Global Process include identification and collection of UDI attributes as output of our Product Development and Sustaining Programs.
- Site level procedures within local QMS to address labeling and product marking requirements.
- Local market level procedures outlining the UDI registration requirements and submissions processes within impacted markets and regions.

Technology

- We have created the Data Collection Utility that allows us to launch UDI data collection efficiently.
- We have selected the solution provider to establish Global UDI Suite of Tools for Smith+Nephew.
- Where UDI is well established, we have automated submissions to eliminate human errors.
- We have developed Self Serve Product Data Reporting tool for our global colleagues to have visibility to UDI data.

Always Learning - Global UDI Implementation Major Challenges

- **Program Approach Required**
  - Multi-functional; not just a Regulatory activity
  - Multi-faceted; labeling, product, attribution
  - Lifecycle; Not one time and done
  - Set tone from the beginning; Non-Compliance has a direct impact on trading and company reputation
- **Subject Matter Expertise is very niche**;
  - Knowledge in regulatory affairs, supply chain, physical compliance, labeling, and data management systems.
- **Adoption of your Business As Usual Solution**
  - Staff knowledge base is minimal; Why do we need to collect and maintain 200 new attributes?
  - Use of digital solutions is new to many
  - Challenges with implementing standardized process & tools across multiple unique legal manufacturers and Quality Management Systems
  - Adoption is labor intensive for both the program team and endusers

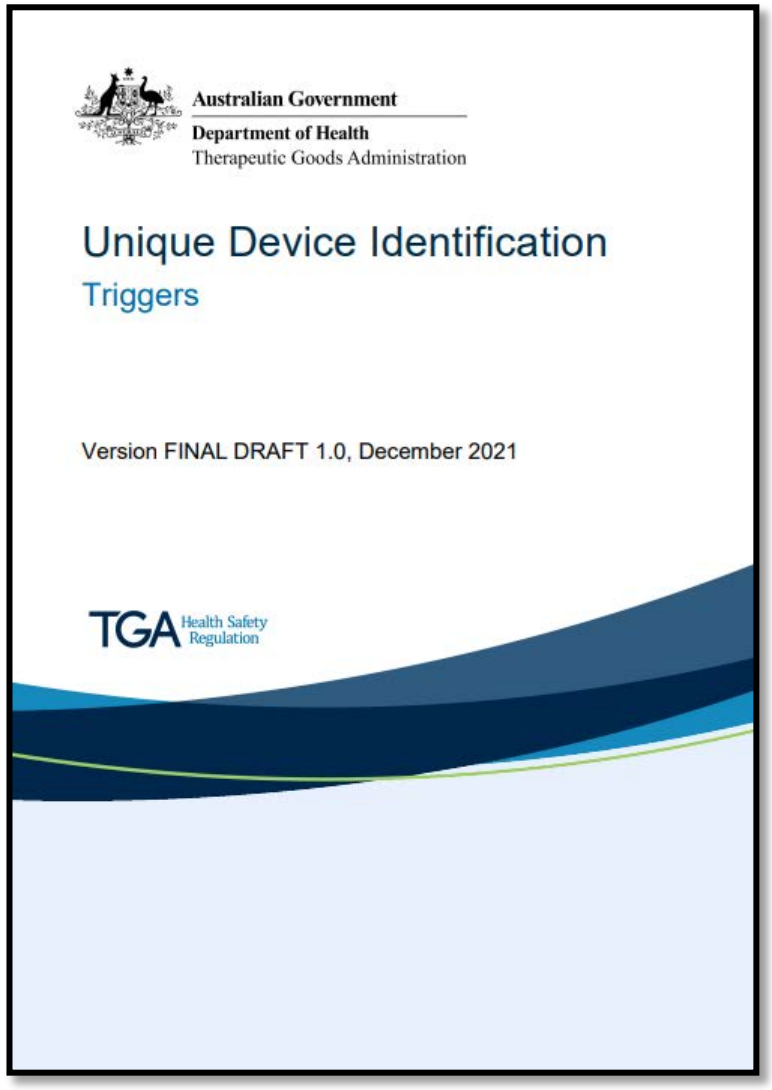
- **Lack of Regulatory Harmonization** pose challenges for Manufacturer implementation and dilutes the value of global UDI. Critical to comment on proposed regulations, drive harmonization.
  - Different attributes by Market
  - Similar Attributes with different definitions
  - Different “Trigger” Attributes
  - Inconsistent database rules for updating records
- **Physical UDI compliance** – label redesign and direct part marking require time, investment and significant testing.
  - Not all products can be direct marked due to size, materials or due to long term safety concerns. Consider how to address in database solution.
- **Lack of off the shelf solutions**
  - Manufacturers develop custom UDI solutions or take a “modular” UDI approach for each market UDI launch; both of which are expensive and resource intensive in the short and longer term.
  - Global UDI regulations are being established faster than the manufacturers or solution providers can launch solutions.

AGENDA:

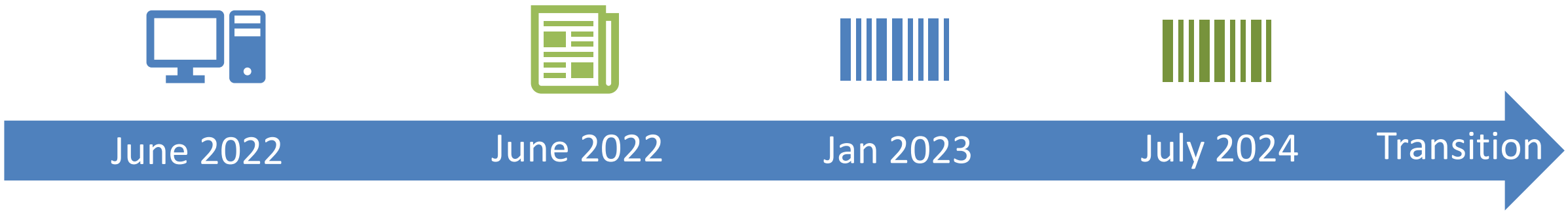
- Invited guest speaker – Debbie Connors, Smith+Nephew
- **TGA project update**
- Questions and answers

Progress Update

- ✓ Triggers Working Group complete and final report produced
- ✓ New GMDN codes updated daily into TGA systems
- Early Adopter Projects
  - Qld Health Early Adopter Project - scoping continues
    Likely to be expanded to include mesh devices (such as hernia mesh)
  - Discussions continue with a second jurisdiction



Implementation Timing (indicative)



Sandpit (beta) version of the Australian UDI database

for general use and testing

Third consultation paper

Voluntary compliance (Regulations in effect)

for high risk devices (Class II, III, AIMD)

Mandatory compliance for implantable devices

allocation of UDIs, UDIs on labelling, and provision of data

New operational support capability

Based on feedback on what worked well in the U.S. a new resource has been moved into the team to design and implement a specific operational support capability within the UDI team:

- ✓Help Desk and phone support
- ✓Self-help (guidance, webinars)
- ✓Connection model and process (machine to machine)
- ✓TGA resourcing
- ✓Technical support

Looking forward

- June sandpit and AusUDID development
- Third consultation
- ARTG/UDI data alignment
- Webinar - guest speakers for April and May (more needed)

AusUDID sandpit (beta)

DRAFT

Early Adopters

- View and download UDI data, full device versions, history and relationships (CSV and M2M (HL7))
- Scan labels and barcodes
- Device data (based on GUDID) to support agreed Projects

Public

- View and download UDI data, full device versions, history and relationships (CSV)
- Scan labels and barcodes

Sponsors and Manufacturers

- Create, update and delete UDI records via the Portal
- Create, update, delete UDI records via M2M (beta NPC and other systems using HL7)
- Bulk upload of new UDI records
- Link UDI to ARTG
- Sponsor access and authentication
- Manufacturer access and authentication
- Attach documents to UDI records
- Support clean-up of ARTG data and alignment / integrity with UDI

TGA

- Manage UDI record and device status
- Verify integrity of UDI data
- TGA Staff Centre (access operational statistics, manage and release reference data)
- Manage reference data sets

AusUDID development

Focus:

- ✓ System to system provision and download of data
- ✓ Connection to beta National Product Catalogue to further explore the benefits for manufacturers/sponsors of using NPC/Global Data Synchronisation Network for the provision of data
- ✓ Preparing for sandpit readiness

Working Group 2 – UDI Technical Working Group

ICT design, interoperability and data exchange between AusUDID and external ICT systems

Topics are expected to include (but not be limited to):

- the AusUDID user experience, user interface design and system flows
- the AusUDID data model and possible sources of UDI data
- the policies for data uptake by the TGA and the use and consumption of AusUDID data by individuals and organisations
- the methods, formats and standards that will apply for data exchange
- business rules and logic being implemented into AusUDID, and
- plans for implementing the AusUDID including stakeholder testing and readiness, and transition planning

- Include representatives who are providers of UDI data (medical device manufacturers and sponsors ranging from small to large, local and international), consumers of UDI data (hospitals, software developers, other healthcare providers and registries) and issuing agencies accredited in other jurisdictions.

- Next meeting Tuesday 29th March 2022 from 10.00-11.00am (AEST) – likely to June

To inform the regulatory framework

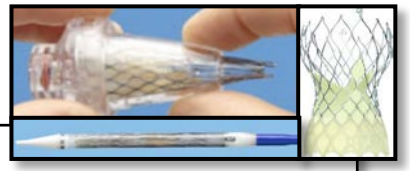
UDI Consultation 3

Focus areas include

- **impacts of accepting both U.S. and EU labels and data**
- **transition approach**

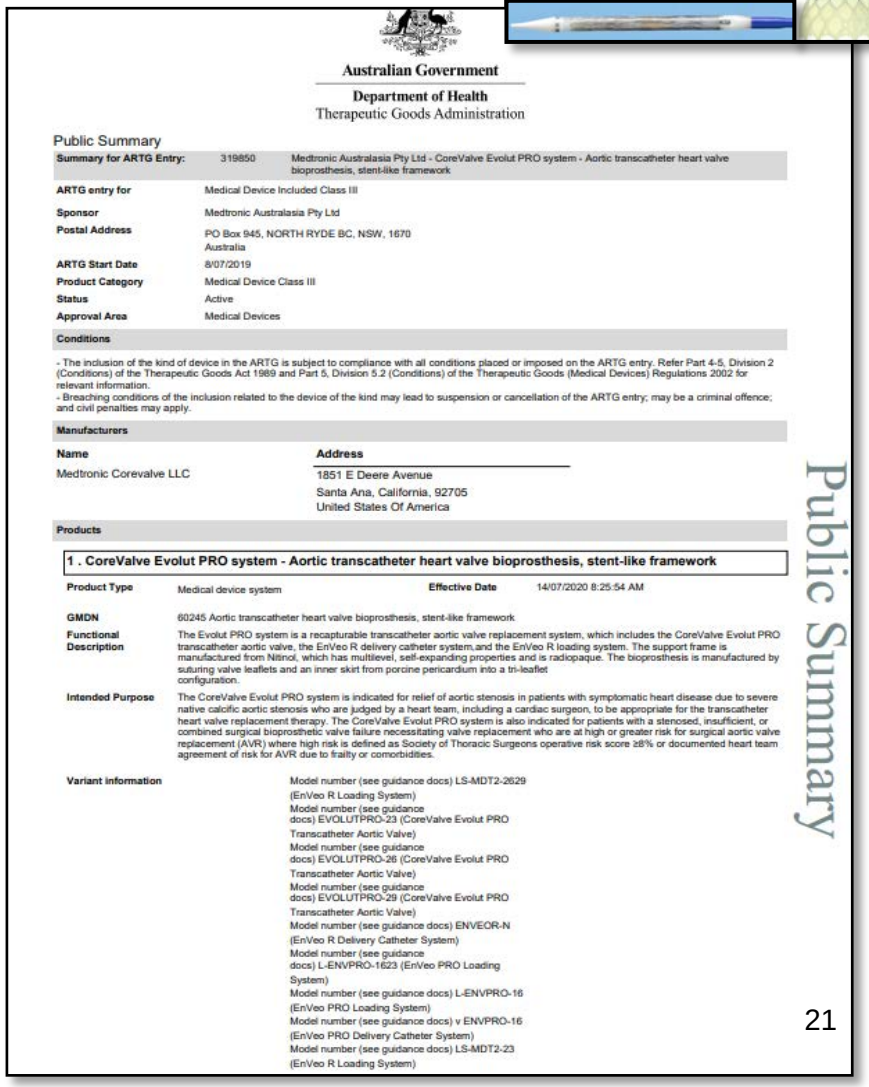
- Likely to be from June 2022
- Using the TGA Consultation Hub
- Notification to existing sponsors and UDI stakeholder list
- udi@health.gov.au

To ensure the success of the UDI implementation



We need to cleanse the ARTG data and better align it to the UDI data

- IT system constraints have prevented the input and ongoing updates to the data
- Manual data entry has introduced errors and inconsistencies in the data
- A number of critical decisions relating to policy and technical challenges ideally need to be resolved as part of the UDI implementation, including:
  - management and alignment of data elements collected at both the inclusion (ARTG) and model of device level (UDI), such as clinically relevant size, supplied sterile, GMDN code
  - breaking down “kind of device” where there is more than one model of device in a single ARTG inclusion, the ability to determine the specific models of devices contained within that ARTG inclusion
  - finding a way for sponsors/manufacturers to update the UDI details as new models are introduced under existing ARTG entries, or models are retired from supply



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Public Summary

Summary for ARTG Entry: 319850 Medtronic Australasia Pty Ltd - CoreValve Evolut PRO system - Aortic transcatheter heart valve bioprosthesis, stent-like framework

ARTG entry for	Medical Device Included Class III
Sponsor	Medtronic Australasia Pty Ltd
Postal Address	PO Box 945, NORTH RYDE BC, NSW, 1670 Australia
ARTG Start Date	8/07/2019
Product Category	Medical Device Class III
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Medtronic Corevalve LLC	1851 E Deere Avenue Santa Ana, California, 92705 United States Of America

Products

1 . CoreValve Evolut PRO system - Aortic transcatheter heart valve bioprosthesis, stent-like framework

Product Type	Medical device system
Effective Date	14/07/2020 8:25:54 AM
GMDN	60245 Aortic transcatheter heart valve bioprosthesis, stent-like framework
Functional Description	The Evolut PRO system is a recapturable transcatheter aortic valve replacement system, which includes the CoreValve Evolut PRO transcatheter aortic valve, the EnVeo R delivery catheter system,and the EnVeo R loading system. The support frame is manufactured from Nitinol, which has multilevel, self-expanding properties and is radiopaque. The bioprosthesis is manufactured by suturing valve leaflets and an inner skirt from porcine pericardium into a tri-leaflet configuration.
Intended Purpose	The CoreValve Evolut PRO system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy. The CoreValve Evolut PRO system is also indicated for patients with a stenosed, insufficient, or combined surgical bioprosthetic valve failure necessitating valve replacement who are at high or greater risk for surgical aortic valve replacement (AVR) where high risk is defined as Society of Thoracic Surgeons operative risk score ≥8% or documented heart team agreement of risk for AVR due to frailty or comorbidities.
Variant information	Model number (see guidance docs) LS-MDT2-2629 (EnVeo R Loading System) Model number (see guidance docs) EVOLUTPRO-23 (CoreValve Evolut PRO Transcatheter Aortic Valve) Model number (see guidance docs) EVOLUTPRO-26 (CoreValve Evolut PRO Transcatheter Aortic Valve) Model number (see guidance docs) EVOLUTPRO-29 (CoreValve Evolut PRO Transcatheter Aortic Valve) Model number (see guidance docs) ENVEOR-N (EnVeo R Delivery Catheter System) Model number (see guidance docs) L-ENVPRO-1623 (EnVeo PRO Loading System) Model number (see guidance docs) L-ENVPRO-16 (EnVeo PRO Loading System) Model number (see guidance docs) v ENVPRO-16 (EnVeo PRO Delivery Catheter System) Model number (see guidance docs) LS-MDT2-23 (EnVeo R Loading System)

Public Summary

The timing is critical to support the UDI implementation

(The alternative is to run two systems and manage the clean up afterwards)

- ✓ The first "clean-up" project – to update the TGA systems with new Global Medical Device Nomenclature (GMDN) Terms on a daily basis - is now successfully completed
- ➢ The Project Plan is being prepared, it will outline the high-level approach, resources, costs, and approach to sponsor engagement
- ➢ Once it is approved, the next phase of work is to undertake detailed analysis on the issues to be addressed and the approach to be taken

We will need support from sponsors

- Identify/review issues and assist us to define the best approach
- Review data and make changes
- No requirement to update GMDN codes (but it may be beneficial)

Considerations

- Regulatory implications and potential burden on sponsors
- Potential changes to scope of inclusions
- TGA Transformation linkages and alignment
- How to best use data analysis technology to reduce/support the manual work that will be needed
- Current fee model
- The UDI data will be collected at the model of device level, whilst the ARTG data is at the ‘kind of device’ level

Website and link references

New UDI hub	https://www.tga.gov.au/unique-device-identification-system
Second UDI consultation paper	https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system
First UDI consultation paper	https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia
Previous webinars	https://www.tga.gov.au/unique-device-identification-system-communications-and-stakeholder-engagement

How did we go?

LIVE POLL

Michelle is currently reading over your submitted questions.

We'll be back shortly for Q&A

TGA Social Media Links

TGA website	https://www.tga.gov.au
TGA Facebook	https://www.facebook.com/TGAgovau/
TGA Twitter	https://twitter.com/TGAgovau
TGA YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
TGA topics blog	https://www.tga.gov.au/blogs/tga-topics
TGA Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
TGA Instagram	https://www.instagram.com/tgagovau/?hl=en

Questions

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