Presentation 5

Designing UDI into care The NSW Health experience to date

Designing UDI into Care: The NSW Health Experience to date

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10 September 2026

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Acknowledgement of Country and Elders

The CEC acknowledges the people of the many traditional countries and language groups of New South Wales. We acknowledge the knowledge and wisdom of Elders who have passed, those of today and tomorrow and pay respect to Aboriginal communities of the land.



Recognition of living experience

The Clinical Excellence Commission recognises and values consumers, patients, carers, loved ones and staff as partners in healthcare.

The voices of people with living experience are powerful. Their contribution is vital to the work of continuously improving safety and quality in our health system.



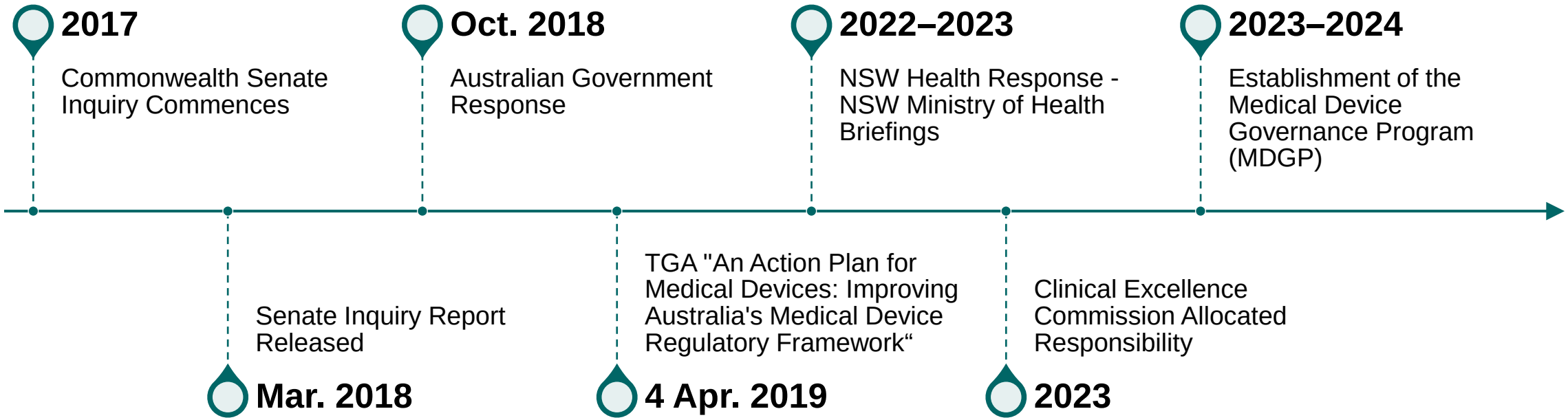
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Context - Why are we doing this work?

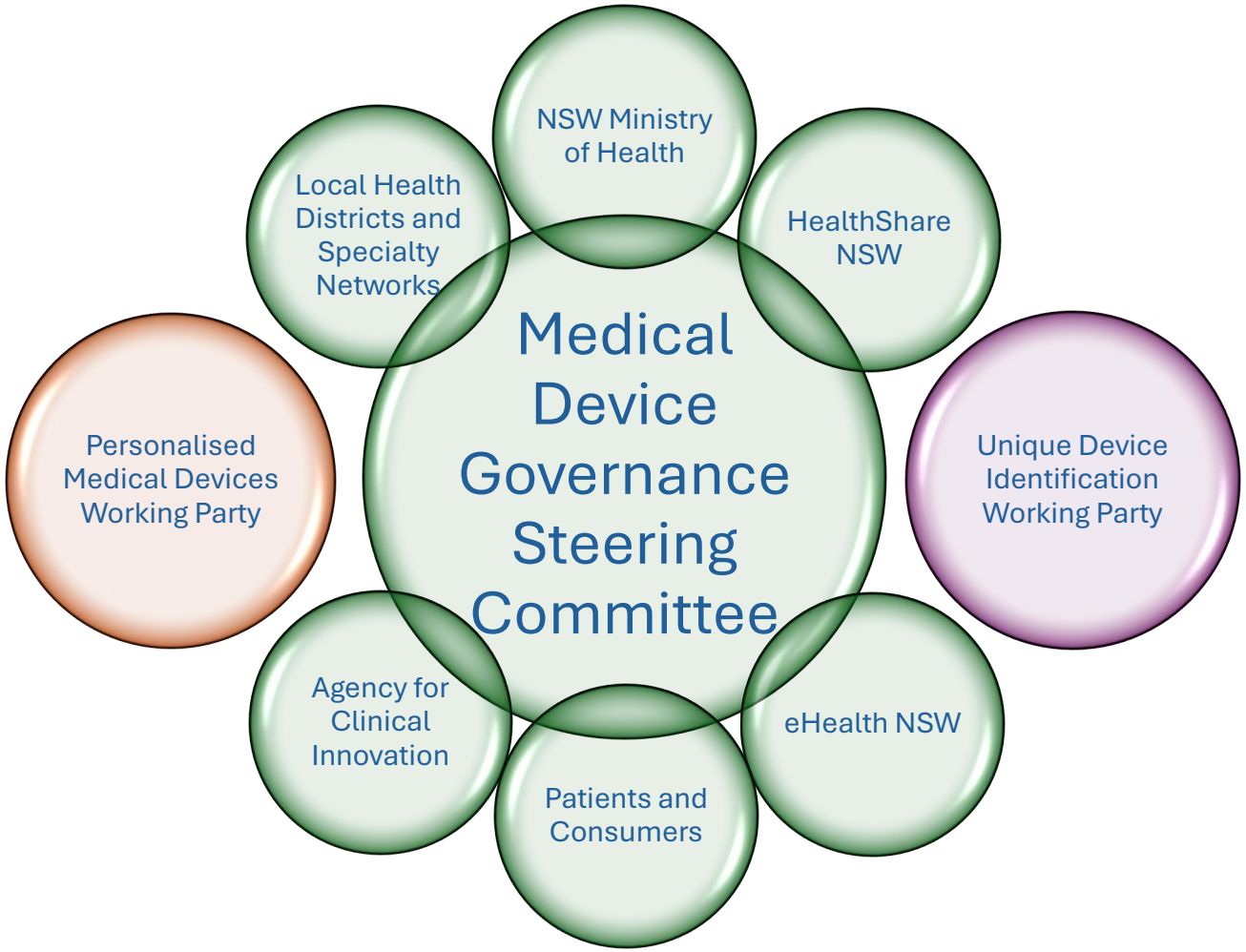
Robyn's Story

Click to view: https://www.youtube.com/watch?v=gZzKX9ka3Ds

Context - Why are we doing this work?



Medical Device Governance Program



UDI Working Party



CEC

- Executive Sponsorship and coordinating role
- Recalls and lookback

HealthShare NSW:

- Sourcing and Contracts
- Procurement and Master Catalogue
- Health Supply Warehouse and Distribution
- Development and Delivery – DeliverEASE, SmartChain, Traceability programs
- Clinical Products Management

eHealth NSW:

- Applications management

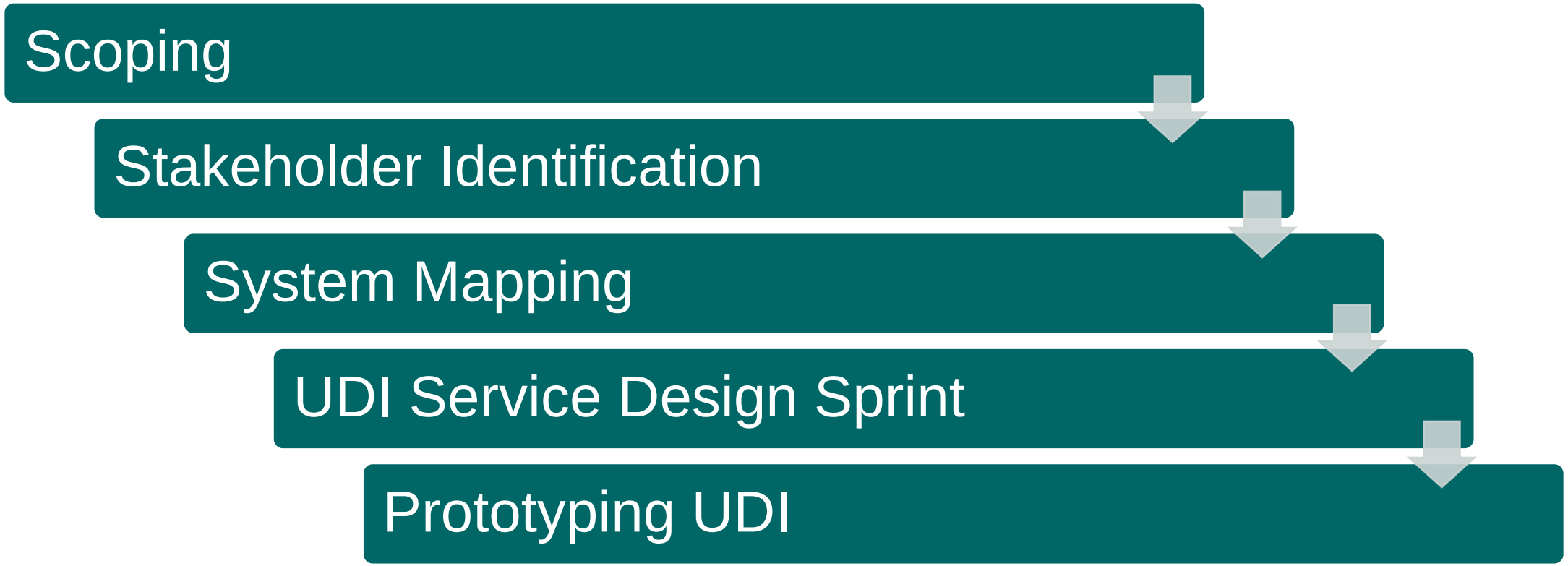
NSW Ministry of Health:

- Strategic Capital Planning and Asset Management

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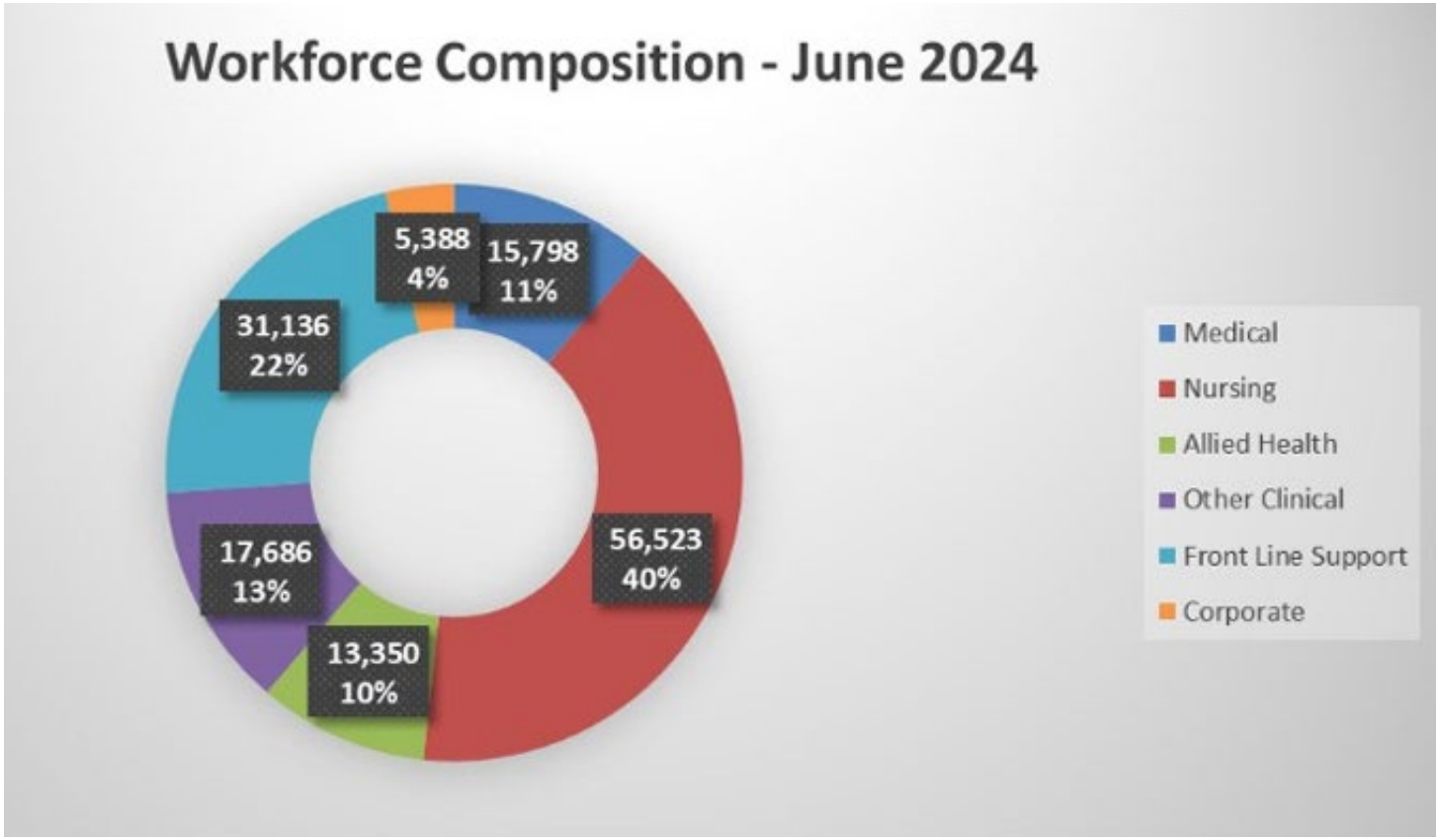
Work to date

Scoping, Stakeholder Identification, System mapping and Service Design Sprint



People affected by UDI

NSW Health Workforce



Source: NSW Health Workforce Data Report (2024)

People affected by UDI

NSW Health Workforce

People	Primary goal	
Sourcing and Contracts	Refer for tender; technical and clinical evaluations; ensure UDI as required for purchased devices	
Master Catalogue Management	UDI capture and alignment with ARTG and AusUDID	
Health Warehouse staff	Manages batch/lot/expiry linkage and stock movements. Picks and delivers ordered items on time.	
Hospital Stores	Receives, verifies and issues UDI labelled items to clinical areas; reconciles discrepancies Picks and delivers ordered items on time	30,000
Clinical Product Managers (State)	System stewardship and management of alternative and substitute clinical products	
Clinical Product Managers (Local)	Local Recalls management and escalation of quality concerns; timely, cost-effective and traceable supply of safe medical devices	
Biomedical Engineers	Ensure device safety, maintenance, and lifecycle tracking	
Medical Device Critical Response	Coordinate state level responses to escalated issues	
Procedural and clinical Staff	Check and prepare the right device for procedures	70,000
CSSD	Reprocess and track re-usable device history	5,000

Systems affected by UDI

Multiple diverse systems in place

MCIS	iProc	hTrak	MaQS	Karisma
Cerner eMR	Surginet	**SmartChain Traceability**	RISPACS	SCIS/HQRS
	ims+	**AFMO**	**SDPR**	

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Current State of UDI capture in NSW Health

BEFORE the NSW Health UDI Service Design Sprint

Current State of UDI Capture In NSW Health

- **Limited end-to-end visibility of how UDI (or equivalent identifiers) is captured** and **maintained**
- **This creates fragmentation across systems and workflows**

Opportunity: Service Design Sprint Blueprinting

- **CEC engaged eHealth NSW Design Health Prototyping Team to facilitate mapping of the end-to-end workflow**
- **Helped identify where to concentrate needs to progressively uplift systems and processes.**

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Blueprints Mapped to UDI

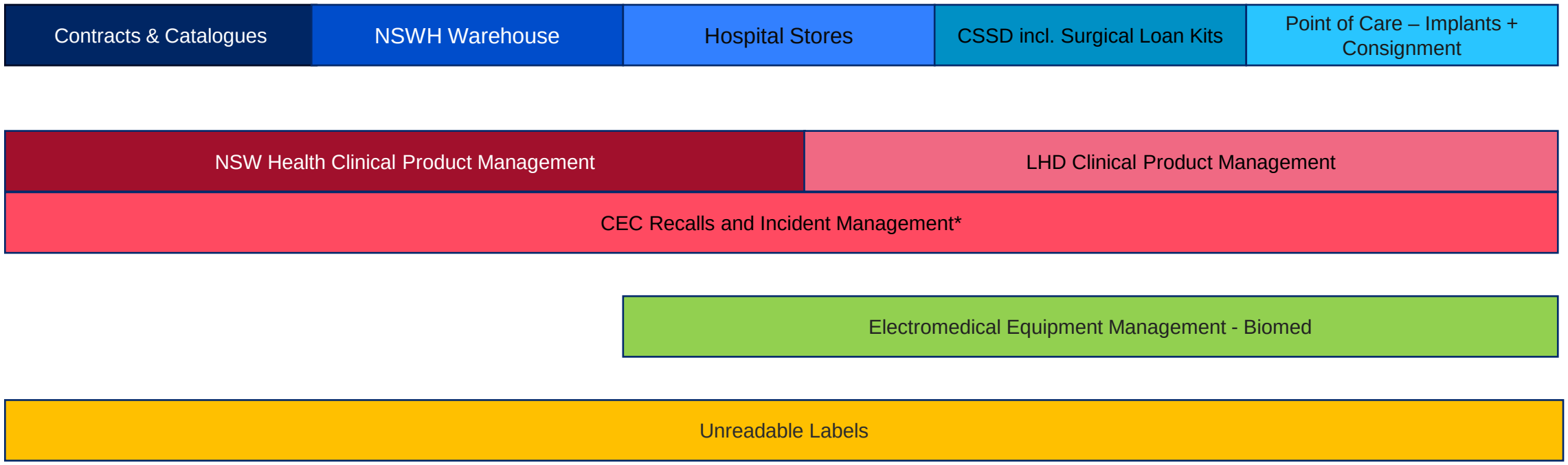
PDF Document

C&C to POC

Recalls & Incidents

Start
Sourcing the Medical Device

End
Medical Device used in/on the patient



Blueprint

NSW Health Unique Device Identifier

Stitched End to End workflow of Implantables and Medical Consumbles

End-to-end workflow of Implantables and Medical Consumables from Sourcing to use on patient





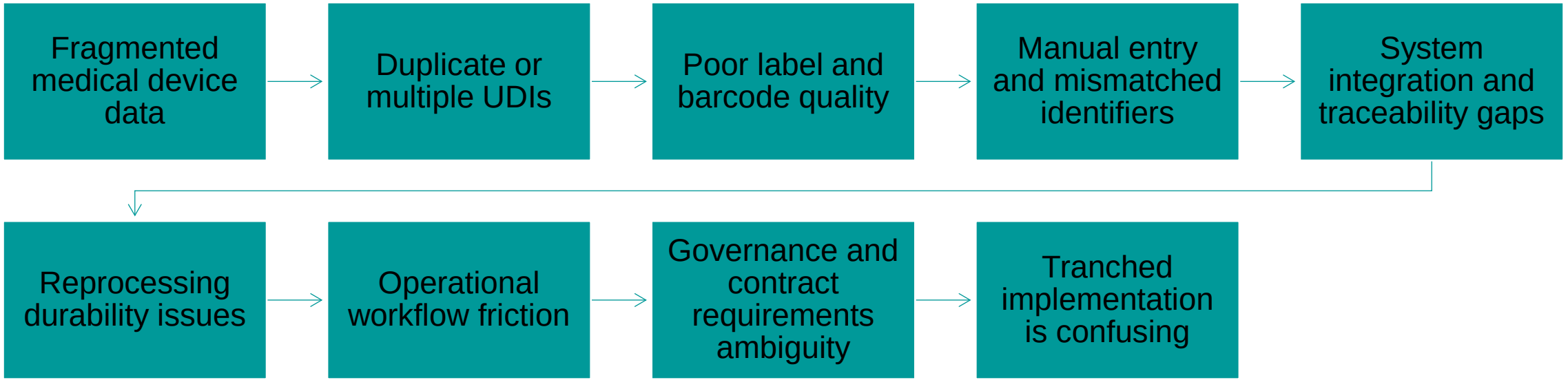


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Challenges and pain points identified

As defined by key stakeholders



UDI Implementation timeline

Unique Device Identification – Legislated commencement dates

general start day, for a UDI medical device, means the following day:

(a) for a Class I medical device that is supplied in a sterile state:
(i) if, on 30 June 2028, an EU certificate is in force covering the medical device—1 January 2029; or
(ii) otherwise—1 July 2028;

(b) for a Class IIa medical device:
(i) if, on 30 June 2027, an EU certificate is in force covering the medical device—1 January 2029; or
(ii) otherwise—1 July 2027;

(c) for a Class IIb medical device that is an implantable medical device:
(i) if, on 30 June 2026, an EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 January 2028—1 July 2029; or
(ii) if, on 30 June 2026, an EU certificate is in force covering the medical device and subparagraph (i) does not apply—1 January 2028; or
(iii) if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 July 2026—1 July 2029; or
(iv) if, on 30 June 2026, no EU certificate is in force covering the medical device and subparagraph (iii) does not apply—1 July 2026;

(d) for a Class IIb medical device that is not an implantable medical device:
(i) if, on 30 June 2026, an EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 January 2029—1 July 2029; or
(ii) if, on 30 June 2026, an EU certificate is in force covering the medical device and subparagraph (i) does not apply—1 January 2029; or
(iii) if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 July 2026—1 July 2029; or
(iv) if, on 30 June 2026, no EU certificate is in force covering the medical device and subparagraph (iii) does not apply—1 July 2026;

(e) for a Class III medical device:
(i) if, on 30 June 2026, an EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 January 2028—1 July 2029; or
(ii) if, on 30 June 2026, an EU certificate is in force covering the medical device and subparagraph (i) does not apply—1 January 2028; or
(iii) if, on 30 June 2026, no EU certificate is in force covering the medical device and the medical device has been manufactured and labelled, but not supplied in Australia, before 1 July 2026—1 July 2029; or
(iv) if, on 30 June 2026, no EU certificate is in force covering the medical device and subparagraph (iii) does not apply—1 July 2026;

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Risks and Patient Safety

- Traceability failure: missing DI/PI prevents accurate identification of affected devices and patients during safety events, delaying mitigation.
- Delayed clinical action: incomplete device data lengthens time to notify clinicians and patients.
- Increased clinical risk: misidentification or incomplete device identification can lead to inappropriate clinical decisions and continued use of affected devices.
- Operational burden and error: manual workarounds for missing device data increase workload and introduces human error into safety processes.
- Weakened surveillance: TGA signal detection and national post-market monitoring are degraded when incident reports lack device identifiers.

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Technical and Operational Complexities

- Identifier heterogeneity: reconciling GTIN, UDI and local catalogues into a single authoritative mapping is non-trivial and requires master data stewardship.
- Label and symbology variability: devices use different barcode symbologies and formats; partial or missing UDI-PI complicates automated capture.
- Direct marking and reprocessing effects: durable marking practices and readability after reprocessing require validation.
- System landscape fragmentation: AFM Online, eMR*, middleware and procurement systems need consistent APIs, agreed data models and robust fallbacks.
- Scale of catalogue remediation: bulk reconciliation needs automated matchings plus manual verification and supplier confirmation.
- Change management: embedding mandatory capture into clinical workflows requires training, local champions and clear exception handling processes.

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*Developing integrations for NSW Health Single Digital Patient Record (SDPR)

Key findings

- **System fragmentation is a dominant barrier.**
- **No standard systems configurations to enable UDI capture and recall.**
- **GTIN is widely captured. UDI is not. (GTIN to UDI transition).**
- **Label quality and reusables medical devices are high-risk operational concerns.**
- **Theatre and CSSD workflows need pragmatic, reliable capture processes.**

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Impact of issues identified

Issue	Impact
Fragmented supplier data and duplicate and multiple UDIs	Ability to verify and reconcile device data
Transition from use of GTIN to UDI	Patient safety and recall delays
Poor barcode/label quality and multiple barcodes and symbologies	ICT requirements; data standards; scan failures, manual entry
UDI-PI not captured at point of care	No persistent link to patient records; manual transcription errors Use of expired stock
Label wear on reusables	Loss of traceability after reprocessing
“Bank” items life cycle monitoring	Use of devices beyond end of life.
Visibility gaps for consignment/loan stock	Untracked stock; billing/traceability issues

Impact across Health processes

Title	Author Branch
Patient Discharge Documentation	System Perfomrance and Support
Implantable Medical Devices	Office of the Chief Health Officer
Nomenclature Standards	Asset Management
Prostheses- Surgically Implanted- Fees Chargeable in Public Health Organisations	Finance
Health Care Records- Documentation and Management	Legal and Regulatory Services
Safety Alert Broadcast System Policy Directive	CEC
Clinical Procedure Safety	CEC
NSW Health Incident Coordination Framework	State Preparedness and Response Branch
Intravascular Devices (IVAD)- Infection Prevention & Control	CEC
Assistive Technology	Health and Social Policy
Incident Management	CEC
NSW Health Foundation Information and Communication Technology (ICT) Services Platforms	eHealth & ICT Strategy Branch
NSW Health Procurement	Strategic Procurement Branch
Software Asset Management	eHealth & ICT Strategy Branch
Asset Management	Asset Management
Accountable items used in Surgery and Other Procedures	CEC
Lookback	CEC
Australian Health Service Safety and Quality Accereditation Scheme in NSW Health Facilities	CEC
Guidelines for Clinical Product Management in NSW Public Health Organisation 2021	NSW Healthshare
User Guide - Supply Chain Information Systems	Strategic Procurement – Catalogue Services
Clinical Handover	Clinical Excellence Commission
Clinical Procedure Safety	CEC
Patient Admission and Discharge to NSW Health Facilities	System Management Branch
System-level patient safety risks: Response co-ordination and communication	CEC
Medical Asset Nomencalture Standards	Strategic Capital Planning and Asset Management

Actions and next steps

Action	Comment
Early UDI capture and verification	Recognised difficulty embedding UDI at sourcing level, with need for GTIN in these processes. AusUDID as managed by the Regulator should be source of truth (advocate for API).
Define GTIN to UDI transition	GTIN is a procurement standard. UDI is the requirement for patient records and mandatory reporting.
Supplier data cleanup	Focus on prostheses and high risk implantables
Automate UDI-DI de-duplication	Mapping/verifying ARTG (and GMDN) – AusUDID – GTIN – HIMF
Improve PoC capture capabilities (UDI-PI)	Recognised difficulty capturing UDI-PI at PoC. Retrospective capture from paper records. Systems continue to mature.
Outline minimum system requirements for 3rd party systems	UDI capture and retrieval is needed to facilitate recalls and lookback.
Develop one page resource for each stakeholders	To outline: How UDI affects you.

Development of Recommendations

Medical Device Governance Steering Committee approval to progress

1: Request AusUDID application programming interface (API) from the TGA.

2: Develop and mandate catalogue data standards to support UDI.

3: Cleanse current contracts and catalogues

4: Deliver middleware and systems integration for legacy systems.

5: Update Asset and Facilities Management On-Line (AFMO) to accept UDI.

6: Define protocols for missing or illegible labels

7: Progress with Human Centred Design process and prototyping.

8: Request application programming interface (API) from HBIC,GS1 (NPC), ICCBA (UDI Issuing Agencies) & GMDN Agency (Global Medical Device Nomenclature). Health Industry Database (HIDL).

Draft 3rd Edition NSQHS Standards

Implications for Medical Device Governance

- Accountability for the safety and performance of medical devices across their lifecycle.
- Traceability requirements for implantable and high-risk devices.
- Governance of device procurement, introduction of new technologies, and monitoring of device performance.
- Requirements for recall management, field safety corrective actions, and post-market surveillance.
- Workforce capability and training relating to medical devices.
- Digital systems and data quality needed to support device traceability and UDI implementation.
- Integration of governance across both clinical and procurement systems.

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Draft 3rd Edition NSQHS Standards

Implications for Medical Device Governance

The draft standards emphasise accessible and integrated care.

Potential implications:

- Ensuring device-related information is accessible, including to consumers.
- Consistent approaches to device information capture and documentation.
- Improved communication during transfers, and between providers and care settings.

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UDI Prototyping

Two main focus areas

Point of Care and post procedure

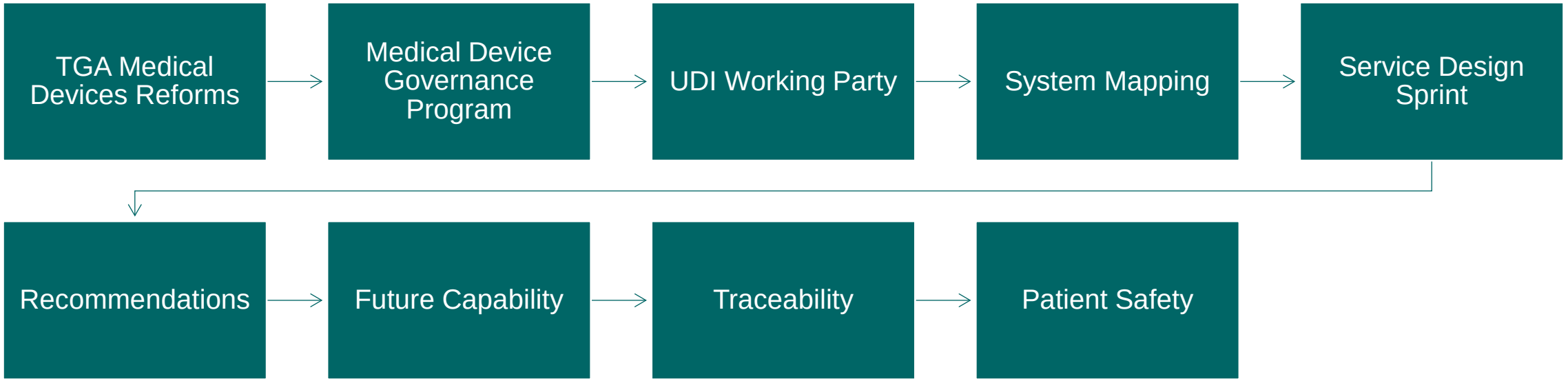
How might we enable accurate and reliable capture of UDI at point of care so that medical devices can be correctly recorded against the patient who received them?

Recalls and Incident Management

How might we enable staff across NSW Health to rapidly identify affected devices and patients during recalls and incident investigations so that appropriate action can be taken quickly and with confidence?

Putting it all together

NSW Health UDI Journey



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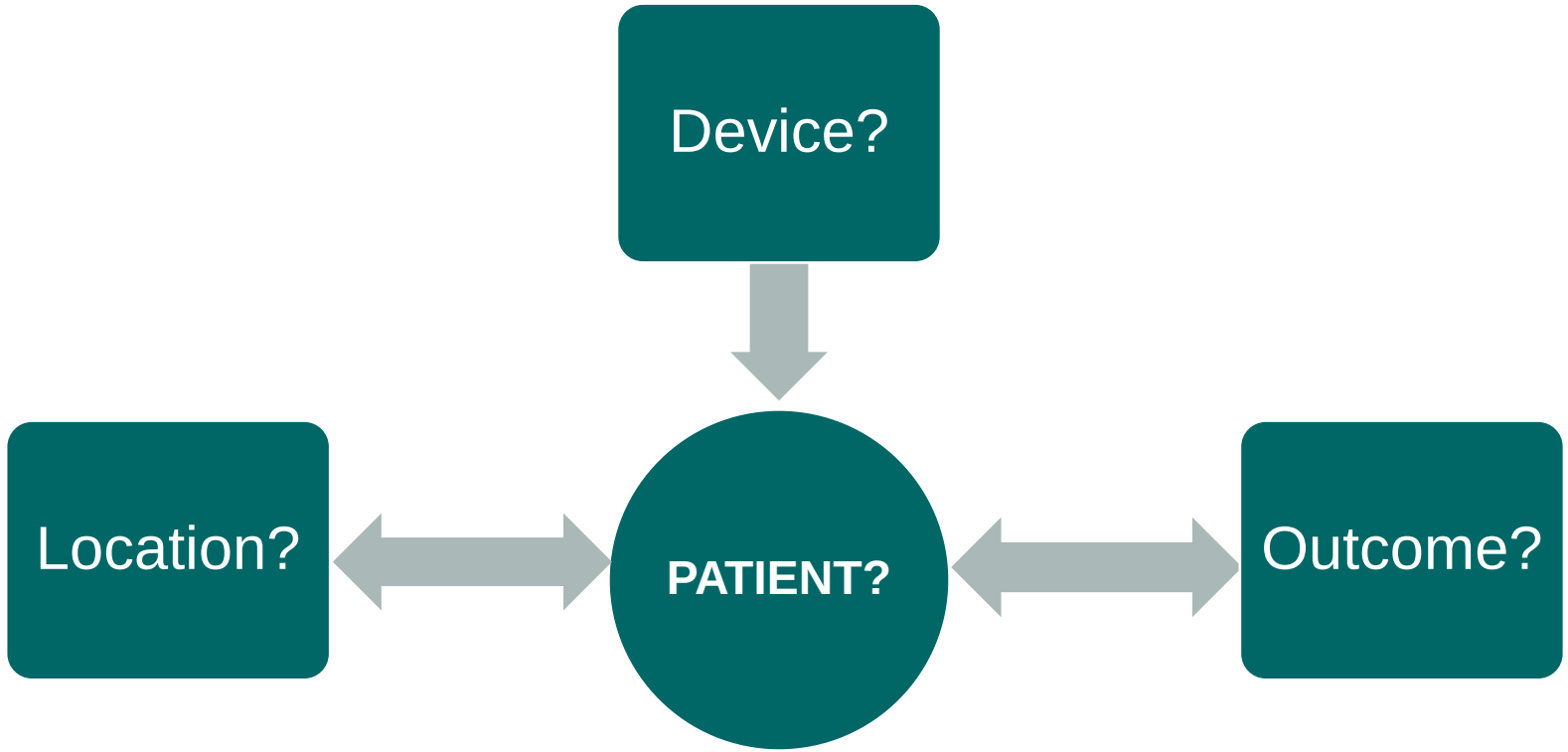
Going Forward

Future planning

- Governance maturation
- UDI roadmap implementation
- Continued prototyping
- API integrations
- Workforce education
- Recalls and lookback uplifts
- SDPR alignment

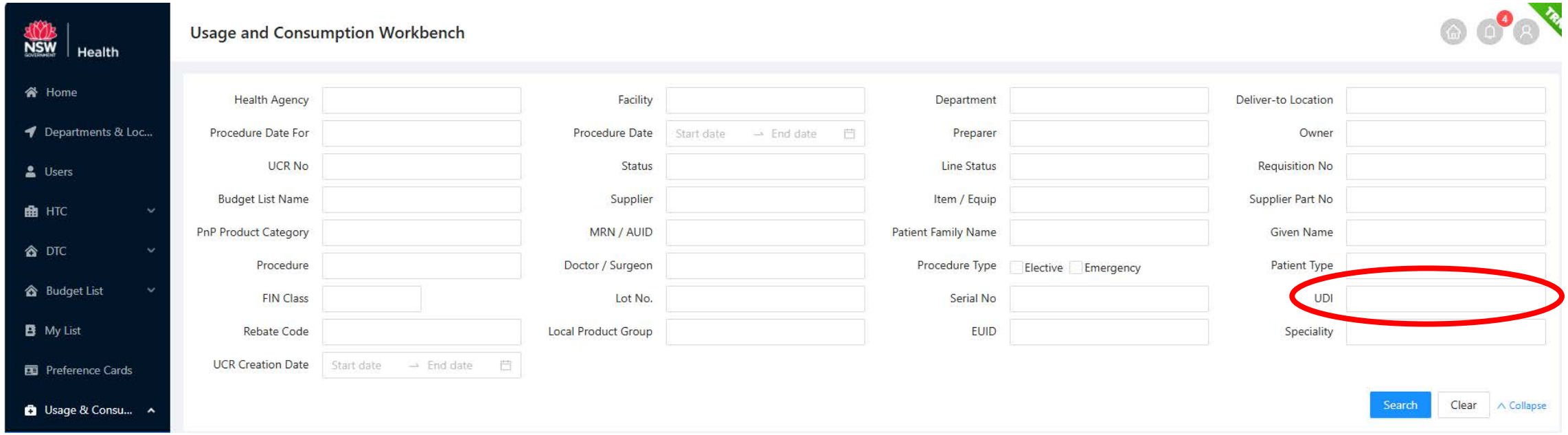
Key Messages

UDI in Healthcare is NOT about identifying devices



Traceability Demonstration

Shane Werner HealthShare NSW



Medical Device Governance Program

NSW CEC Medical Device Governance

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