



Australian Government

Department of Health

Therapeutic Goods Administration

Unique Device Identification Webinar 9

Using UDIs in Healthcare – real world experience



Michelle van Wijk

UDI Project Manager

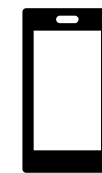
Therapeutic Goods Administration

TGA Health Safety
Regulation

17 May 2022

Welcome

- This webinar is being recorded
- Webinar will be made available in the upcoming weeks
- Any relevant links will be broadcasted via the slido app
- Q&A will open midway in the session – we will be using slido tool
- A live Q&A session will take place after the presentation
- Live poll – please let us know how we went



Difficulties hearing from computer?

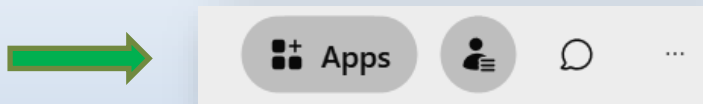
Check your settings located under “**Audio & Video**” tab located top of your screen:

OR

Dial: +61-2-9338-2221 | **Access code:** 2652 449 8142

How to ask Questions...

Slido App



- Click on Apps + icon
- Select “slido”
- Open Q&A tab to ask questions
- Live Poll (use survey tab when prompt to)

OR

Slido QR

Scan the QR
code to access
separately on
your mobile
device

Caretaker mode

We would like to note that the Australian Government is in caretaker mode and in accordance with the caretaker conventions, I will be limiting my statements today to factual issues and matters of administration.

This presentation is for information only and does not constitute legal or formal advice and should not be relied upon for any other purpose than learning.

Agenda:

- **Invited guest speaker – Mark Songhurst, LTHT**
- Invited guest speaker – Kirk Kikirekov, Prospitalia h-trak
- June webinar
- Questions and answers

Mark Songhurst



Mark has been working in the NHS for 23 years, for the last 5 years on the Scan4Safety Team at Leeds Teaching Hospitals NHS Trust.

He is now the Programme Lead, driving further implementation and integration of GS1 standards into the organisation. Having worked for 13 years in Internal Audit he has an in-depth understanding of the processes from across the hospital that go in to delivering good patient care.

Mark is also a Future-Focused Finance ValueMaker and a School of Health and Care Radicals Change Agent. He has a real passion for working with people and understanding how people collaborate across the NHS to make changes that will have a lasting impact on the service we provide to our patients.

Mark was awarded the Future-Focused Finance Award by the HFMA in 2018 in recognition of his work locally, regionally and nationally to improve NHS Finance.

His infectious willingness to accept change, to walk alongside NHS staff of all levels enabling them to engage with change and try something new is helping drive the Scan4Safety project forward at Leeds.

If the last two years in the Healthcare industry have taught us anything it is that we can no longer work alone therefore Mark has been sharing his experience nationally and globally to ensure that the benefits that GS1 standards and Scan4Safety bring can be shared.

hello my name is...

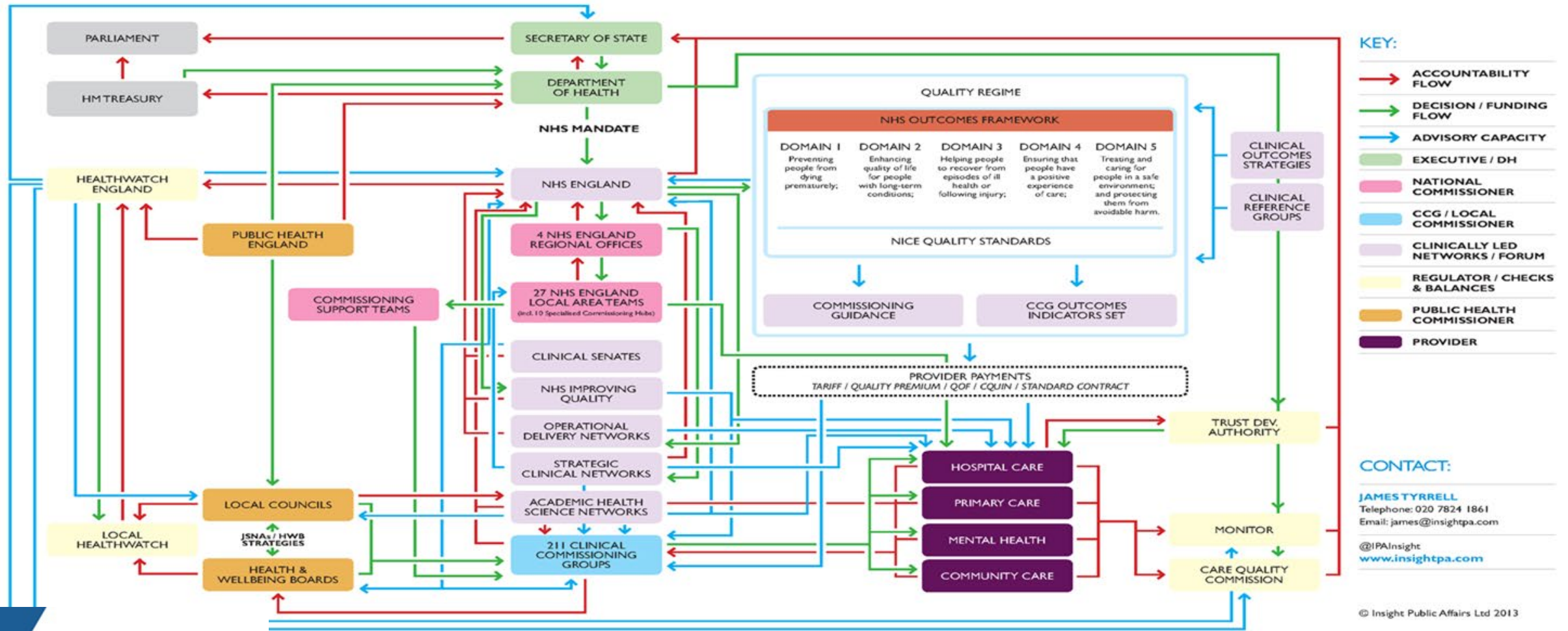


Mark Songhurst

Scan4Safety Programme

The Leeds Teaching Hospitals NHS Trust

Seeing the bigger picture



National Drivers



NHS Procurement Strategy -
published May 2014

GS1 & PEPPOL (Pan-European Public
Procurement Online) - the
mandated standards

Scan4Safety - practical
implementation of
standards

Welcome to Leeds



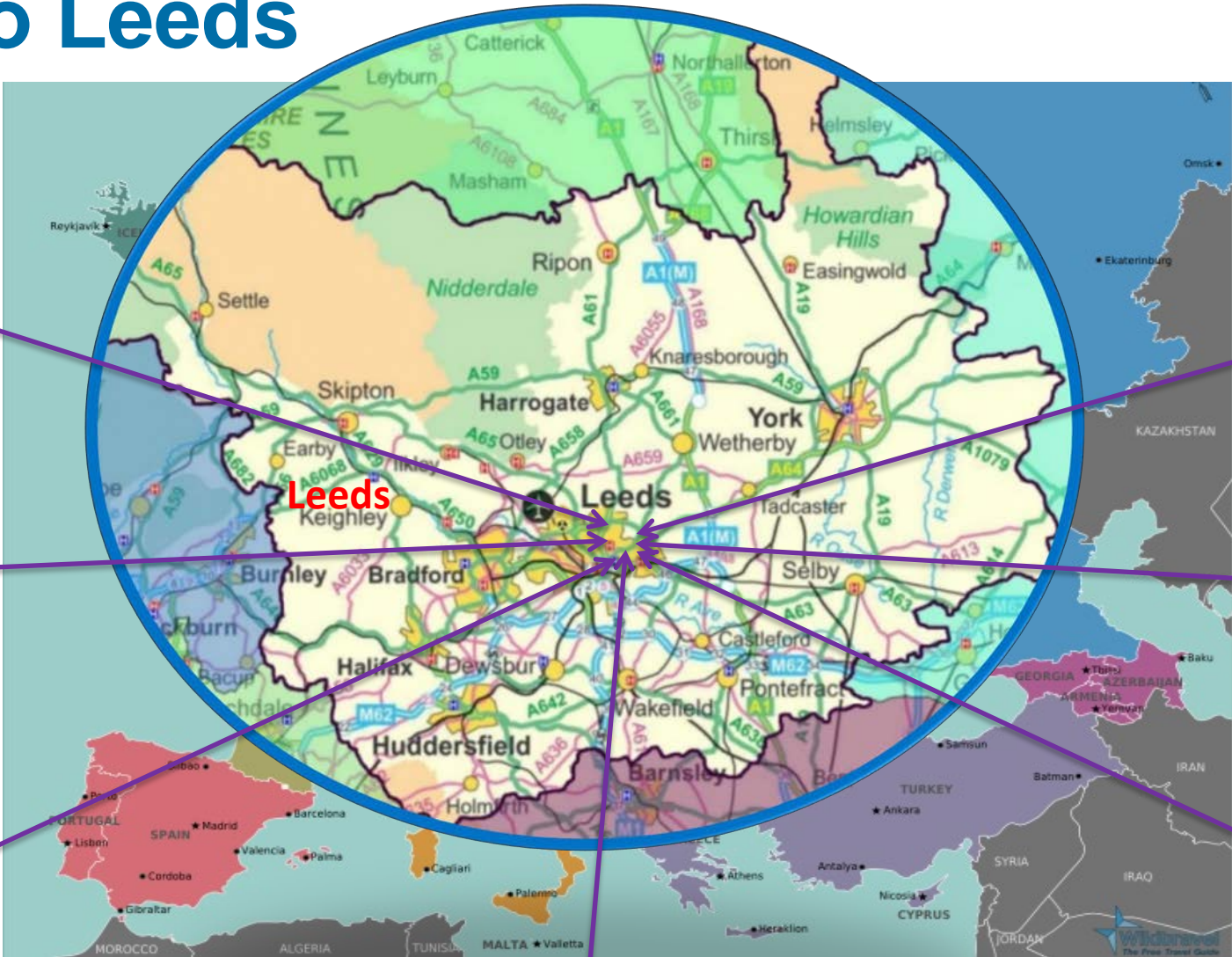
Leeds General Infirmary



Leeds Children's Hospital



Wharfedale Hospital



St. James's
University Hospital



Seacroft Hospital



Leeds Dental Institute



Chapel
Allerton
Hospital

The largest Provider of Specialist Adult and Paediatric Services in England





Our Goals

- The best for patient safety, quality, and experience
- The best place to work
- Seamless integrated care
- Centre of excellence for research, innovation, education, and specialist services
- Financially sustainable

Our Values





Let's pick a product

Possible Names

TAVI

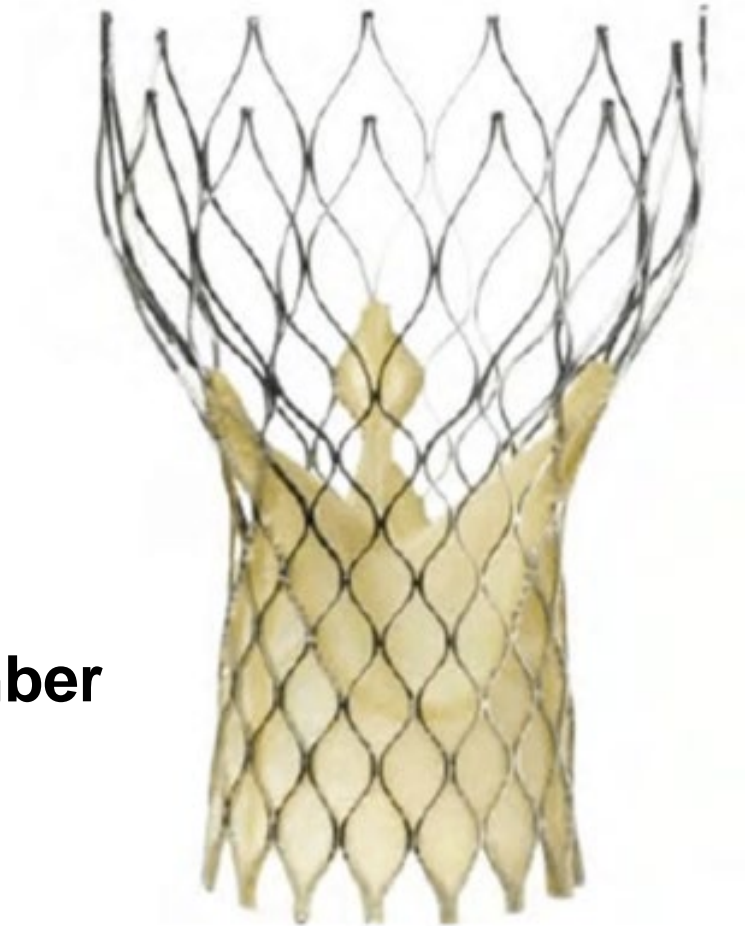
Transcatheter Aortic Value Implantation

Brand Name

Manufactures Product Code

Inventory Management Customer Item Number

**UDI Number (UK GS1 GTIN mandated in
Healthcare)**



What we can do now at Leeds Teaching Hospitals



Clinical Need Identified



Clinical Service Unit Approval



Procurement process



Manufacturer Catalogue and Price List ★



Trust Catalogue ★



Trust Inventory System ★



Trust Financial Enterprise Resource Planning (ERP) ★



Trust PEPPOL Interchange ★



Manufacturer or Distributer Sales ★



Goods Delivered to Hospital ★



Invoice Received and Paid ★



**UDI
Information**

A Patient Journey



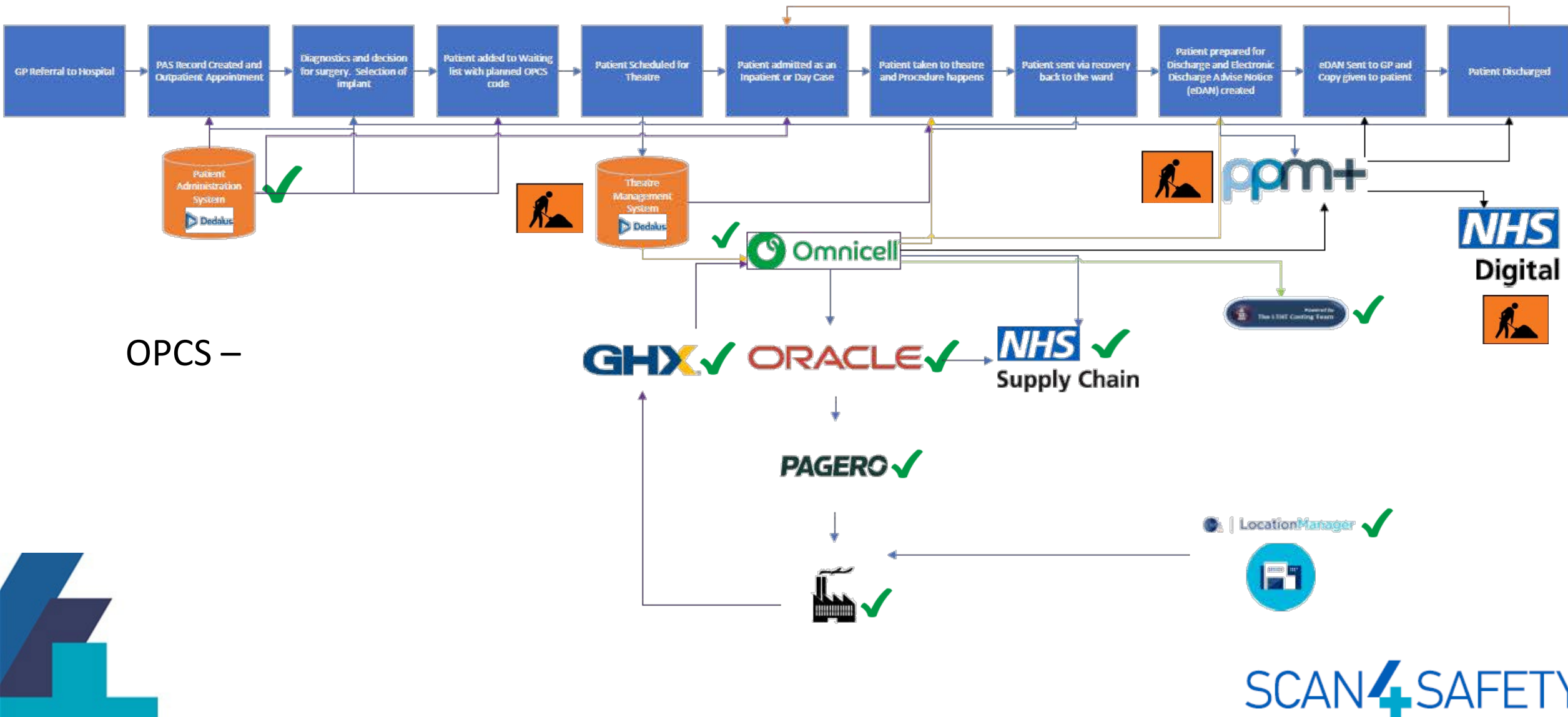
SCAN4SAFETY

Operating Journey



SCAN4SAFETY

What we are aiming for





**Data is useless unless it is turned
into information and information is
useless;
unless it is properly targeted**

Roy Lilly

Benefits

Day to Day



Recall



10:15 – Notification from Medicines & Healthcare Products Regulatory Agency (MHRA) Confirmed in Trust

10:28 – Confirmed we have the product in the Trust and that there will be no use of these products in the coming days

11:42 – Confirmation to Medical Director - Operations that all respective products have been removed from the clinical area and are under the control of the appropriate Inventory Manager.

Financial for Demonstrator Phase

Area	Benefit
Product Recall Staff Time	£84,411
Inventory Reduction	£1,781,634
Returned Stock	£159,082
Efficiency Benefits	£157,645
Tray Rationalisation	£133,564
TOTAL	£2,316,336



A Patient Journey – Building in to the Future



Accountable



Collaborative



Empowered



Fair

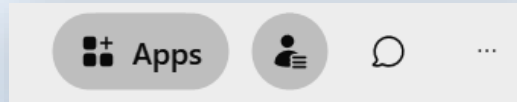
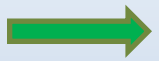


Patient Centred

SCAN  SAFETY

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- Questions and answers

Kirk Kikirekov



Kirk is committed to achieving sustainable health care through digital technologies, and has been dedicated to this cause for two decades.

As the Managing Director of Prospitalia h-trak, he specialises in innovative software solutions for the complex supply chains that exist for Medical Devices.

This includes life-saving and life-enhancing technologies such as implantable prostheses and other medical devices.

His work has contributed to delivering innovative software for patient safety, while also delivering cost savings and efficiency in the supply chain.

He joined the h-trak business soon after the company's establishment in 2002 and has developed the capability of the business to where it is today, with 25% of the Australian acute hospitals using the h-trak software, and its internationalisation with growth in New Zealand, Germany and UK.

About Prospitalia h-trak

- Established in Melbourne in 2002
- Patient-centric system designed for the unique challenges that exist in healthcare around medical devices:
 - Supply chain and product replenishment
 - Prostheses billing
 - Product traceability to patient and documentation in electronic medical record (EMR)
 - Patient safety
- Data capture at the bedside using mobile technology (PDA/Smartphone technology)
- Delivered as software as a service (SaaS) – the most efficient and cost effective means of delivering software
- Product Master Database as core service to customers
- UDI a core design feature from the outset (i.e. for 20 years now)
- Spend analytics at a very granular procedure level
- System integrates within the hospitals ecosystems including Patient administration systems (PAS), EMR, Billing Systems, Enterprise resource planning (ERP) and clinical costing
- System is now used in approx. 20% of the Australian acute hospitals, and growing at a rate of 30% per annum year-on-year
- 50% of Principal referral hospitals in Australia
- Expansion into NZ, UK and Germany
- h-trak system used at Derby and Burton University Hospitals Foundation Trust – the first trust to be accredited for Scan4Safety in 2017





**Inventory
Management**



Reporting



e-Purchasing



**Patient-centric
Model with Data
Capture at the
Point of Care**

Billing



Patient Safety

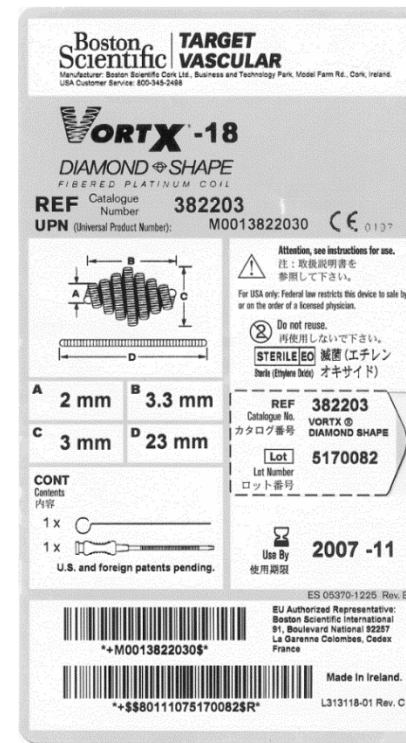


Why is the UDI important?

- Provides certainty in the market (suppliers and providers)
- Guarantees penetration
- Removes inconsistency
- Reduces costs in duplication of effort and costly workarounds
- Provides a consistent and reliable framework for software and systems developers
- Follows the regulations already in place at U.S. FDA and European Commission (EC)
- TGA adopting and managing the UDI is a logical extension



Issued by HIBCC



Issued by GS1



What do we see in practice?

- More than 90% of product data usage captured through h-trak is by scanning manufacturers barcodes
- More than 90% of medical devices by volume are imported into Australia
- The top 20 companies globally represent >70% of all medical devices sold into the Australian market
- There are a few large distributors/importers representing products from many manufacturers overseas (e.g. LifeHealthcare). These companies have little control on what is included on label.
- There are equally a lot of small and medium enterprises (SME) importers of very niche and highly specialised products. These companies have even less influence on manufacturing operations
- Logical for Australia to be in harmony with FDA/EC on UDI

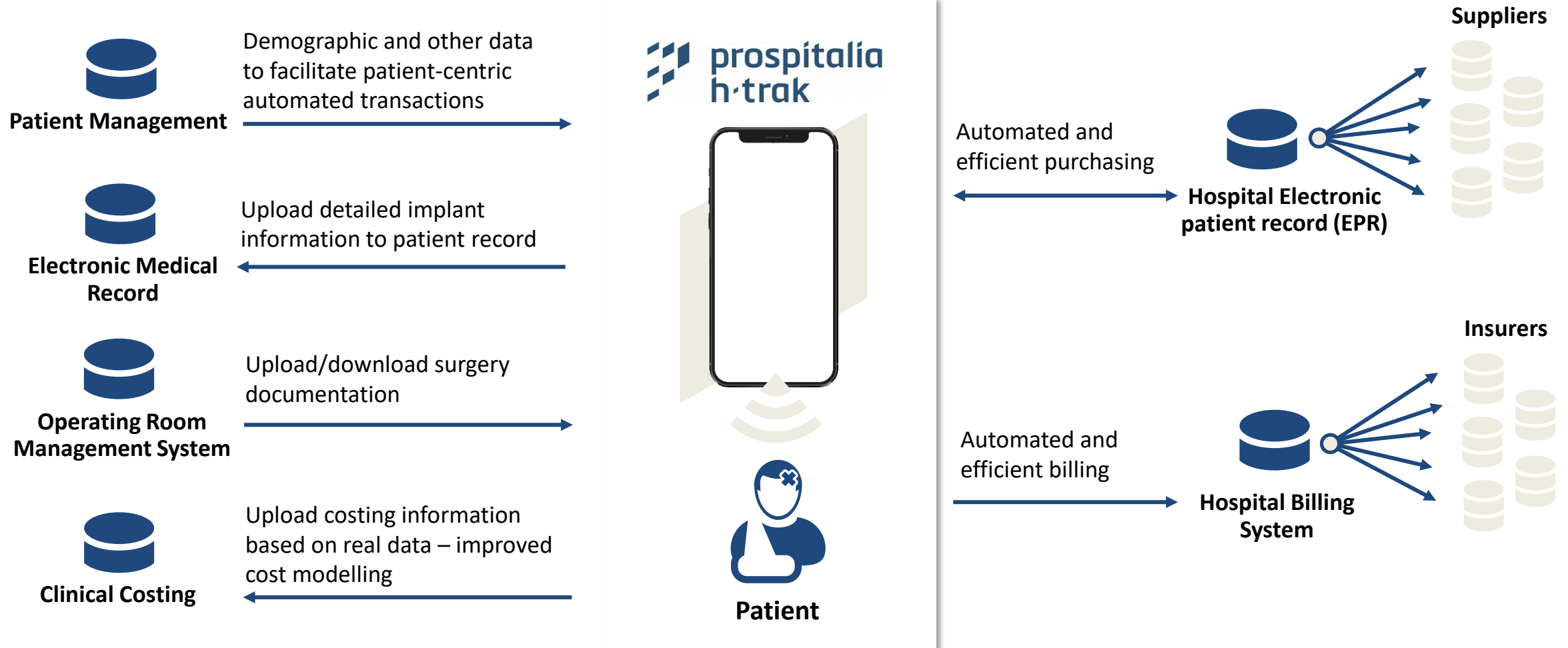


Challenges

- Incorrect application of standards
- Fragment sets (screws, plates etc) used in Trauma/Orthopaedics:
 - Often provided non-sterile (because of surgeon preference and also storage space). Data capture is difficult because there is no product packaging at the point of use (surgery) eg. products provided in caddies.
 - Kits/bundled products. From a traceability standpoint, each product used on the patient needs to be captured. The UDI therefore needs to be applied at the smallest unit (usually the 'each'). This does not always happen, as the Supplier considers the selling unit only.
 - Available real estate on product package.
- Clear definition of use cases, and design of systems to deal with the unique use cases that exist in healthcare
- Stakeholder engagement:
 - Education
 - Communication (at all levels)
 - Change management



Hospital ecosystem



- # HIP FORM

Australian Orthopaedic Association
National Joint Replacement Registry

SIDE 1

Place PATIENT DETAILS label here and/or
If any patient details are not available on the hospital label please complete below

Surname: _____ Female: ☐ Male: ☐
 First Name: _____ Middle Initial: _____
 Address: _____
 Postal Code: _____
 Hospital Patient No: _____ DOB: ____/____/____
 Medicare No: _____ DVA No: _____
(If applicable)

Name of Hospital: _____ State: _____
 Consultant Surgeon Code: _____

Weight (kg) _____ Height (cm) _____ ASA _____

PLEASE COMPLETE THIS SECTION IN FULL
(If an EXTRA use TWO FORMS)

OPERATION DATE ____/____/____ **L** ☐ **R** ☐

OPERATIVE APPROACH (Tick one box only)

Posterior ☐ Lateral ☐ Anterior ☐ Other specify: _____
PRIMARY HIP ☐ **REVISION HIP ☐**

Indicates (Primary Hip) Revision/Transverse Type, Register as T/R
 Indicates revision, exchange or addition of one or more components

DIAGNOSIS **DIAGNOSIS** (Tick more than one box if applicable)

<input type="checkbox"/> Osteoarthritis	<input type="checkbox"/> Loosening
<input type="checkbox"/> Rheumatoid Arthritis	<input type="checkbox"/> Lytic
<input type="checkbox"/> Other Inflammatory Arthritis	<input type="checkbox"/> Dislocation
<input type="checkbox"/> Osteonecrosis/Avascular Necrosis	<input type="checkbox"/> Infection
<input type="checkbox"/> Developmental Dysplasia	<input type="checkbox"/> Implant Breakage
<input type="checkbox"/> Fractured Neck of Femur	<input type="checkbox"/> Stem
<input type="checkbox"/> Tumour specify _____	<input type="checkbox"/> Acetabular
<input type="checkbox"/> Other specify _____	<input type="checkbox"/> Fracture specify _____
	<input type="checkbox"/> Other specify _____

Please return form to: Locked Bag 2, Hutt St Post Office, ADELAIDE SA 5000

ACETABULAR COMPONENTS
(Mark relevant boxes, place company labels on coloured areas or complete details by hand)

NONE ☐ GUN ☐ SHELL ☐ INSERT ☐ BIPOLAR ☐ REINFORCEMENT RING ☐ HSG ☐

Company _____
 Prosthesis Name _____
 Cat/Ref No. _____
 Lot No. _____

Company _____
 Prosthesis Name _____
 Cat/Ref No. _____
 Lot No. _____

Company _____
 Prosthesis Name _____
 Cat/Ref No. _____
 Lot No. _____

ACETABULAR CEMENT NO ☐ YES ☐

See over for cement cement

CEMENT NAME: _____

(Use company label or complete details; if more than one mix is used, use only 1 label)

(Complete by hand, labels not required)

SCREWS: NO ☐ YES ☐ Number used _____

PLEASE COMPLETE SIDE 2

HIP FORM

Australian Orthopaedic Association
National Joint Replacement Registry

SIDE 2

FEMORAL COMPONENTS
(Mark relevant boxes, place company labels on coloured areas or complete details by hand)

NONE ☐ STEM ☐ HEAD ☐ CENTRALISED ☐ INTRA MEDULLARY PLUG ☐

Company _____
 Prosthesis Name _____
 Cat/Ref No. _____
 Lot No. _____

Company _____
 Prosthesis Name _____
 Cat/Ref No. _____
 Lot No. _____

Company _____
 Prosthesis Name _____
 Cat/Ref No. _____
 Lot No. _____

Company _____
 Prosthesis Name _____
 Cat/Ref No. _____
 Lot No. _____

FEMORAL CEMENT NO ☐ YES ☐

See over for cement cement

CEMENT NAME: _____

(Use company label or complete details; if more than one mix is used, use only 1 label)

ADDITIONS
(Use company label for grip and cable and for complete details)

TROCHANTERIC GRIP: NO ☐ YES ☐

Company: _____

CABLE/S: (For multiple cables use 1 label) NO ☐ YES ☐

Number used: _____ **Company:** _____

WIRE: (Complete by hand) NO ☐ YES ☐

TECHNOLOGY ASSISTED tick all that apply

Computer Navigated _____ NO ☐ YES ☐
 System used _____
 Image Derived Instrumentation (IDI) _____ NO ☐ YES ☐
 System used _____
 Robotic Assisted _____ NO ☐ YES ☐
 System used _____
 Acetabular only ☐ Both (Femur and Acetabular) ☐
 Other _____ NO ☐ YES ☐
 System used _____

Affix label here if available:

ADDITIONAL COMMENTS (or Extra Labels)

ALL SECTIONS of this form MUST be COMPLETED

Thank you for completing this form - For further information contact (08) 8128 4280

Completed by _____

Date ____/____/____



Example Case Studies



Customer A

- Prostheses and patient billing – 8 hours reduction in processing time – savings of \$1.2 million per annum
- Pre h-trak 5% slippage on prostheses revenue – current annual prostheses revenue \$37M (four hospitals) ~ \$1.85 million recovered revenue
- Able to provide detailed advice on impact of Prostheses Reforms including mitigation strategy ~ \$6 million impact
- Efficiencies gained with streamlined procurement and payment processing integration with ERP system
- Single Corporate catalogue enabling valuable reporting across all sites

**Massive Operating
Efficiencies**

Customer B

- Revenue for prostheses billing pre h-trak ~ \$3.8 million – post h-trak ~ \$5 million = 30% improvement and counting
- Average spend per procedure pre h-trak = \$1,120 – post h-trak (12 months) = \$964 14% reduction in procedure costs
- Approx 52,000 procedures per year = savings \$8 million per annum
- Efficiencies gained with streamlined procurement and payment processing integration with ERP system
- Single corporate catalogue enabling valuable reporting across all sites
- Return on investment < 6 months

ROI <6 Months

Customer C

- Improved revenue for prostheses billing by \$6 million per annum (\$3m -> \$9m)
- Improved revenue from MBS claims > \$1M pa
- Savings from improved management of consumables and prosthetics ~ \$7 million pa
- Efficiencies gained with streamlined procurement and payment processing integration with ERP system
- Single Corporate catalogue enabling valuable reporting across all sites
- Return on investment < 1 year

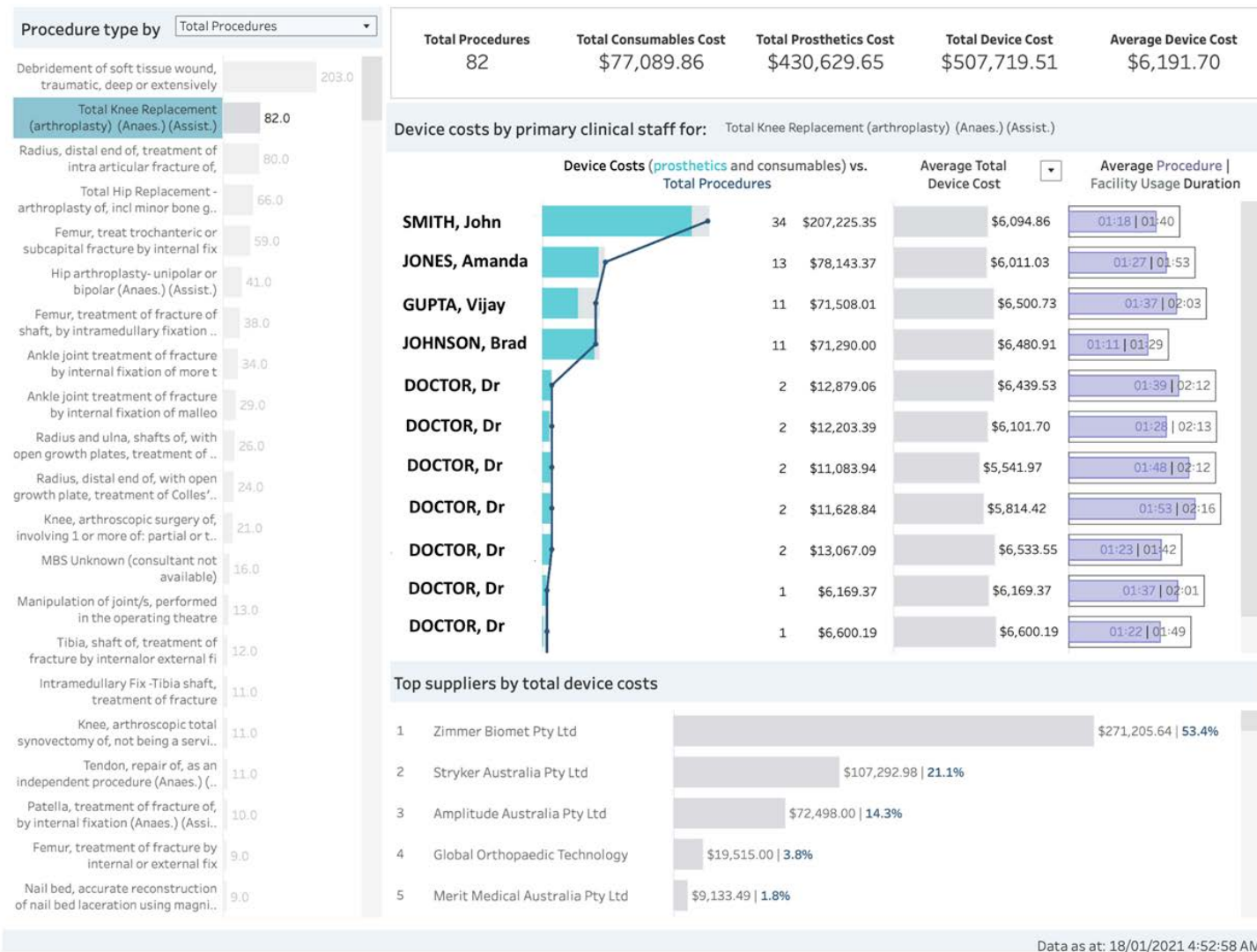
**300% Increase
in revenue**

Analytics

- Total procedures and device costs
- Average device costs
- Breakdown by cost centre
- Month by month fluctuation
- Average procedure duration
- Breakdown by consumables and prostheses



- Total Knee Replacement
- Usage by clinician
- Breakdown by supplier
- Total device costs
- Average device cost per procedure
- Average procedure duration
- Breakdown by consumables and prostheses

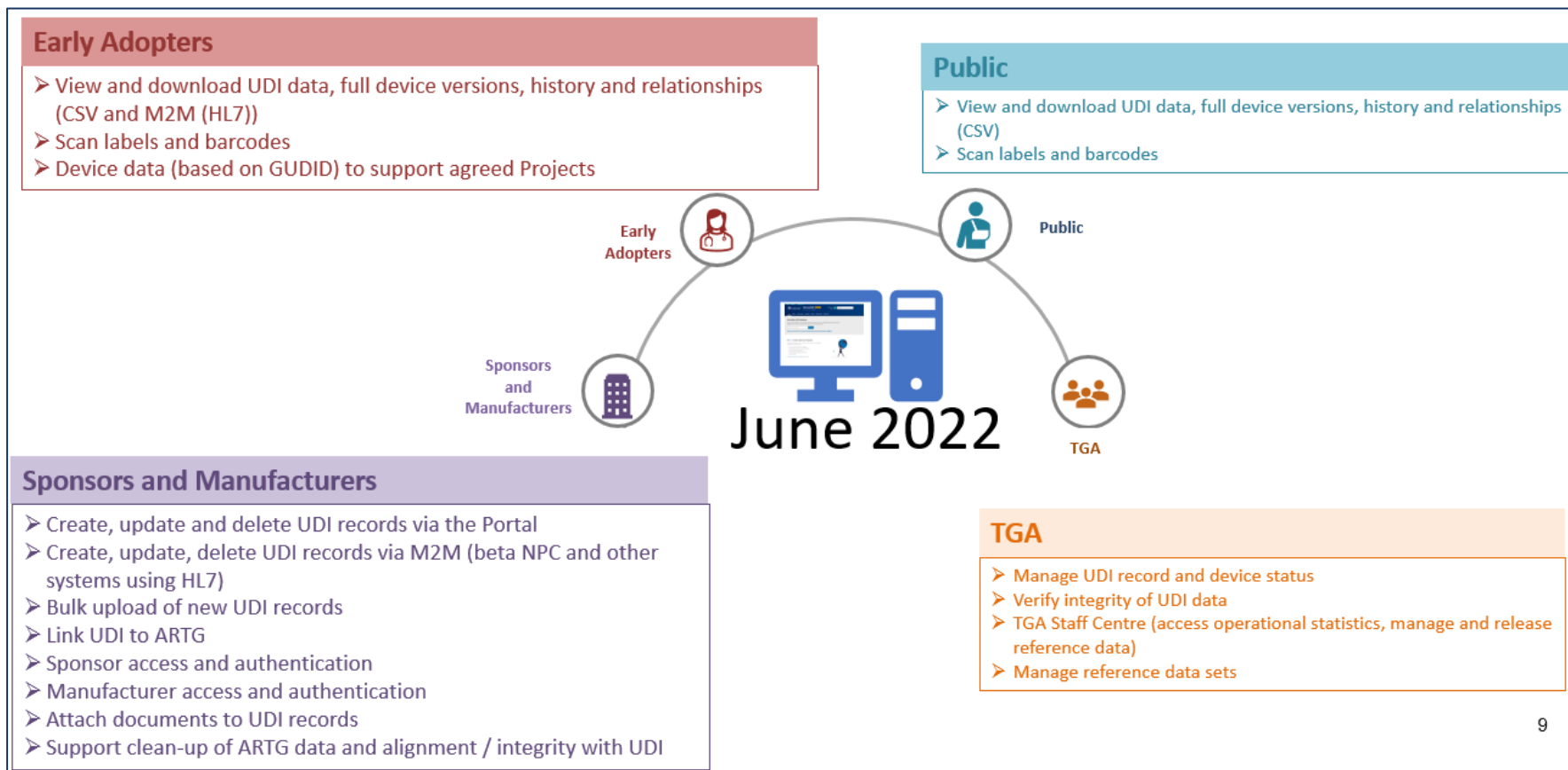


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Next webinar – UDI Sandpit

21 June, 11.30-12.30pm AEST

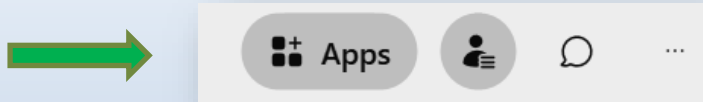


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separately on
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device



How did we go?

LIVE POLL

Michelle is currently reading over your submitted questions.

We'll be back shortly for Q&A



Contact us

UDI Project

udi@health.gov.au

Questions?



Website and link references

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

More information



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TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



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Australian Government

Department of Health
Therapeutic Goods Administration