GS1 UK Scan4Safety and UDI forum

Facilitated by:
Chris Florey, engagement manager – healthcare

Wednesday 17 July 2024

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Housekeeping

- This session is being recorded
- Ask any questions via the **Q&A function** on screen
- You can also **upvote questions** using the thumbs up icon to bring the most popular ones to the top
- You can interact and use the **chat function** for anything else

Up first on the agenda

09:00	Welcome	Chris Florey, Engagement manager – healthcare, **GS1 UK**
09:10	An introduction to Global Medical Device Nomenclature (GMDN)	Deniz Bruce, CEO, **GMDN Agency**
09:35	Enhancing healthcare safety: the past, present and future of Scan4Safety in England	Anna Stec, senior project manager - Scan4Safety England, **NHS England**
10:00	NHS Supply Chain: Inventory management systems – a strategic data capture point	Frankie Wallace, data standards engagement manager, **NHS Supply Chain**
10:25	DHSC's MedTech Product Information Management (PIM) database	Jasleen Rehal, senior analyst - medical technology, **DHSC**
10:45	15-minute break	

GMDN INTRODUCTION

GS1 - S4S AND UDI FORUM
17/07/2024

DENIZ BRUCE – CEO

STANDARDISED NOMENCLATURE IS ESSENTIAL FOR MAINTAINING PATIENT SAFETY AND PROMOTING BETTER HEALTHCARE OUTCOMES.

17 JULY 2024

AGENDA - GMDN INTRODUCTION

- What is GMDN?
- GMDN use cases and UDI implementation
- How can it support Global and National public health programmes?
- Q&A

GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN)

A NON-PROFIT, CHARITY

GMDN's history started in 1991 by the European Standards Organisations (CEN) and later supported by the Global Harmonisation Task Force (now the International Medical Device Regulators Forum - IMDRF)

Name and Group All Medical Devices

- ~25,000 GMDN Terms for all medical devices grouped by Categories arranged in a multi-hierarchical structure
- All are systematically named to reduce duplication and ambiguity, representing the current innovation and supply of all medical devices. A dynamic nomenclature updated in real-time
- Term Enquiry service for all users

Access to GMDN

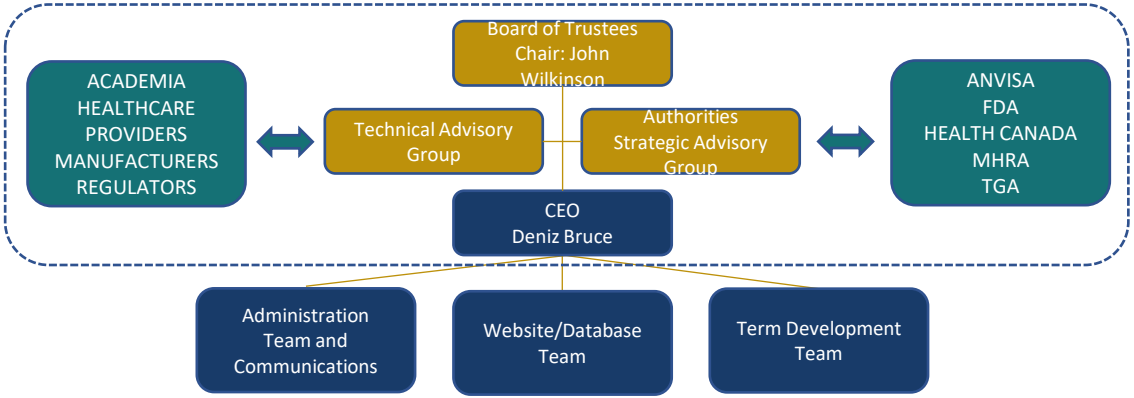
- Register to GMDN, become a Member
- Free access to the complete GMDN Database for all Regulators/Governments, Healthcare Providers/Hospitals, Academia, CABs; and public data sharing via free of charge licence agreement
- Access to all: Membership options (incl. free of charge) are available (https://www.gmdnagency.org)

Globally Recognised and Independent

- ~13,000 users:
  - >70 Regulatory systems,
  - users across >145 countries (Medical Device Manufacturers, CABs, NGOs, Academia, others)
- UDID used since 2013 (FDA's GUDID)
- Self-funded, independent and guided by Regulators

Ref.: https://www.imdrf.org/ghtf/history

THE GOVERNANCE OF GMDN
A NON-PROFIT, CHARITY



Management and maintenance of the GMDN Database is monitored and controlled by an ISO9001 Quality Management System. Our QMS is annually audited by a third-party Certification Body. The GMDN Agency has internal QMS and SOPs regarding Term development, management of GMDN Term Enquiries, translations, stakeholder/Regulator consultation and management of conflicts.

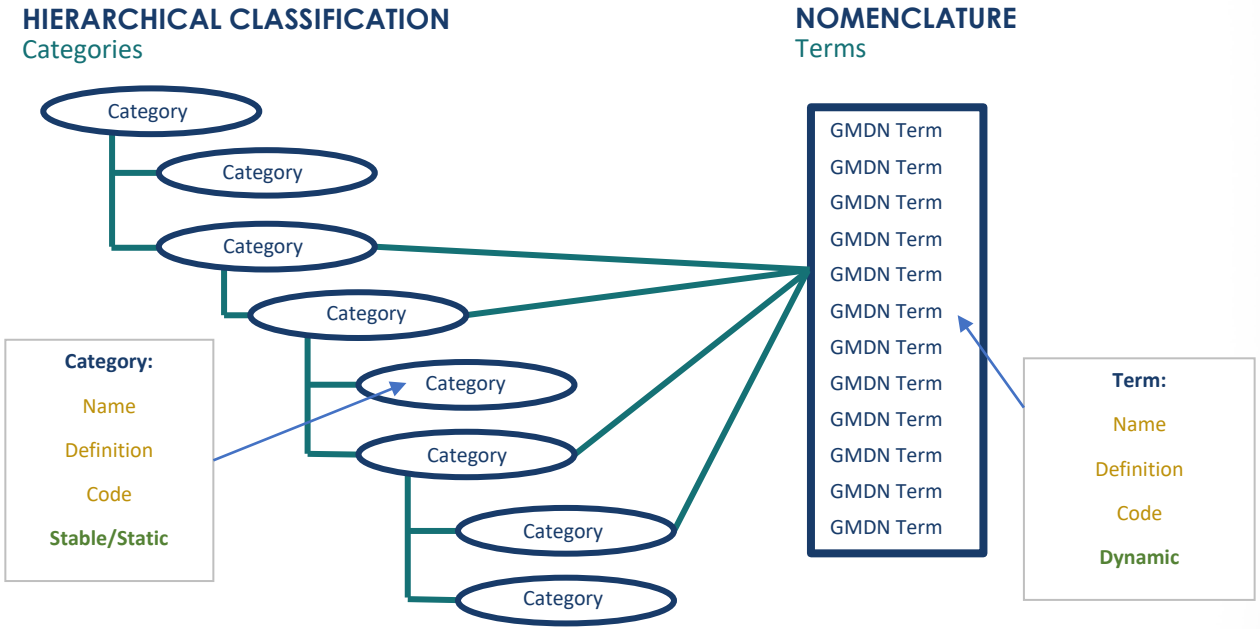
***All Advisory Groups are providing advice to the Board of Trustees, and all members are volunteers and are not funded for activity linked with GMDN Agency governance.**

***GMDN Agency reserves the right to change the organisational structure as needed.**

GMDN DATA STRUCTURE

- GMDN is the nomenclature in **a multi-hierarchical classification** system
- **25,000 Nomenclature Terms** grouped by
- **2,600 Categories** arranged in a multi-hierarchical structure
  - The Categories are grouped under different headers (e.g., Device Function, Anatomical Specialty, Use Frequency, etc.).
    - Under “Device Function”, e.g. there are 22 first-level (highest level) Categories
- This **multi-hierarchical structure of higher-level Categories**, which can group devices based on a range of device attributes (e.g., implantable vs. non-implantable, active vs. non-active), is **a powerful tool for device analysis**

GMDN DATA STRUCTURE



GMDN Terms

Non-proprietary groups are defined by:

- **Name** – Unique and full-descriptive
- **Definition**
  - Scope of devices covered by name, including
    - Intended use
    - Technology/material
    - Form/components
    - Significant attributes (e.g., use-frequency, pharmaceutical inclusion, device power)
- **Code (ID)**

EXAMPLE

GMDN CATEGORIES

- Device Function
  - CT1007 Tissue reparation devices
    - CT2775 Tissue dressing/stabilization devices
      - CT554 Dressings
        - CT2148 Dermal dressings
          - CT1352 Wound-nonadherent dressings
- Anatomical Specialty
  - CT775 Dermatological and soft-tissue reconstructive/cosmetic devices
    - CT2148 Dermal dressings
      - CT1352 Wound-nonadherent dressings
- Names Index
  - CT124 Dressings and associated devices
    - CT554 Dressings
      - CT2148 Dermal dressings
        - CT1352 Wound-nonadherent dressings
- Use Frequency
  - CT981 Single use
- Power
  - CT2986 Non-active
- Featured Attributes
  - CT315 Home-use patient/layperson
  - CT233 Surgical

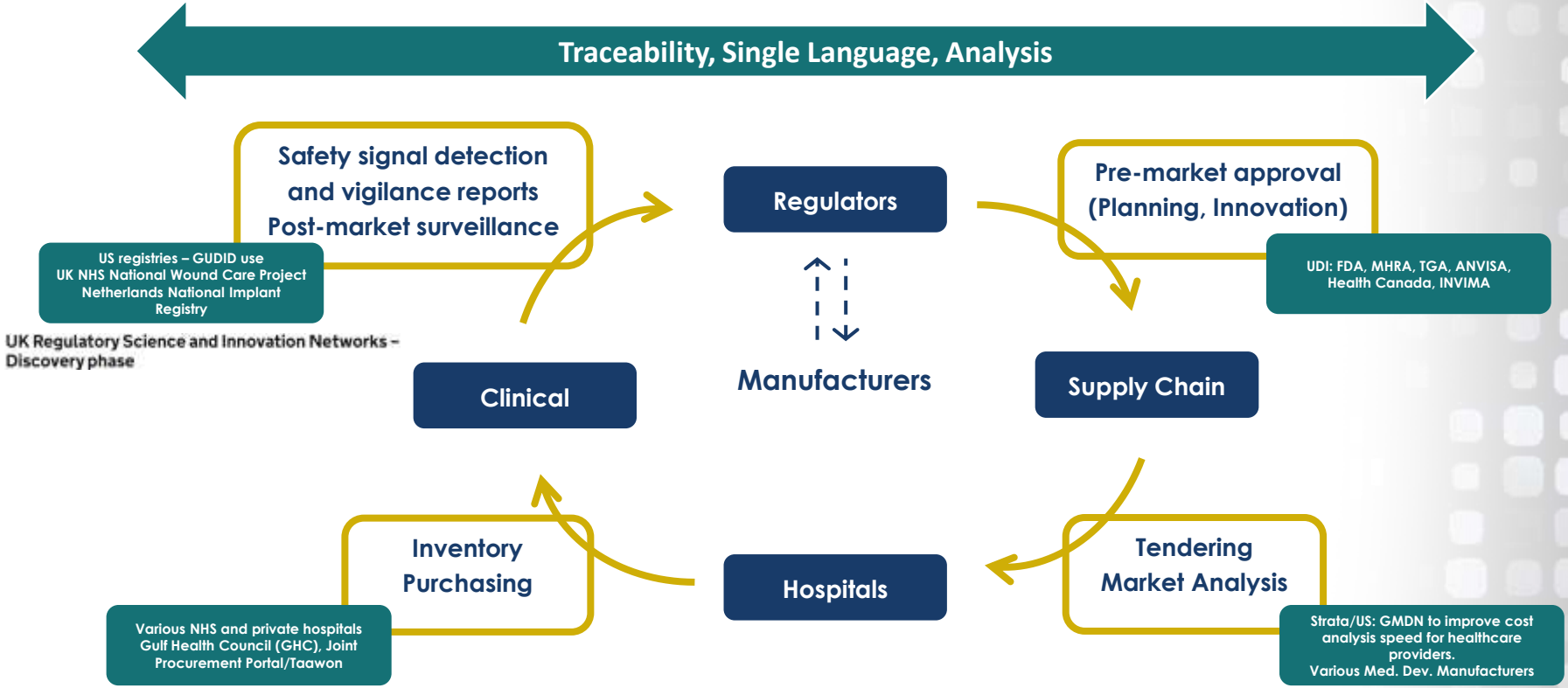
GMDN TERMS

Wound-nonadherent dressing, absorbent, non-antimicrobial
46854

A wound covering typically in the form of a multi-layered pad having a material or substance on its skin-contact surface (e.g., silicone gel), or designed to be soaked in saline prior to application, to prevent adherence to the wound bed thereby decreasing wound trauma potential; it does not contain an antimicrobial agent. It is typically used to absorb wound blood/exudates while protecting the wound from external contamination and maintaining a moist internal environment. It may be used as a primary or secondary dressing to treat chronic and postoperative wounds, burns, ulcers, abrasions, cuts, or puncture sites; it is not a dedicated burn dressing. This is a single-use device.

CT1352: Terms for four different group of devices	Term Code
Wound-nonadherent dressing, absorbent, antimicrobial	47042
Wound-nonadherent dressing, absorbent, non-antimicrobial	46854
Wound-nonadherent dressing, permeable, antimicrobial	47203
Wound-nonadherent dressing, permeable, non-antimicrobial	46855

GMDN* USE CASES



*DAPB4004: Global Medical Device Nomenclature (GMDN)/UK. https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dapb4004-global-medical-device-nomenclature-gmdn. Data Standards and Terminology Standards for Information Submitted to CDRH/USA. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/data-standards-and-terminology-standards-information-submitted-cdrh.

THE UDI/GMDN RELATIONSHIP

Unique Device Identifier (UDI)

GMDN

XYZ Ltd

UDI = 09521234500018

UDI Database

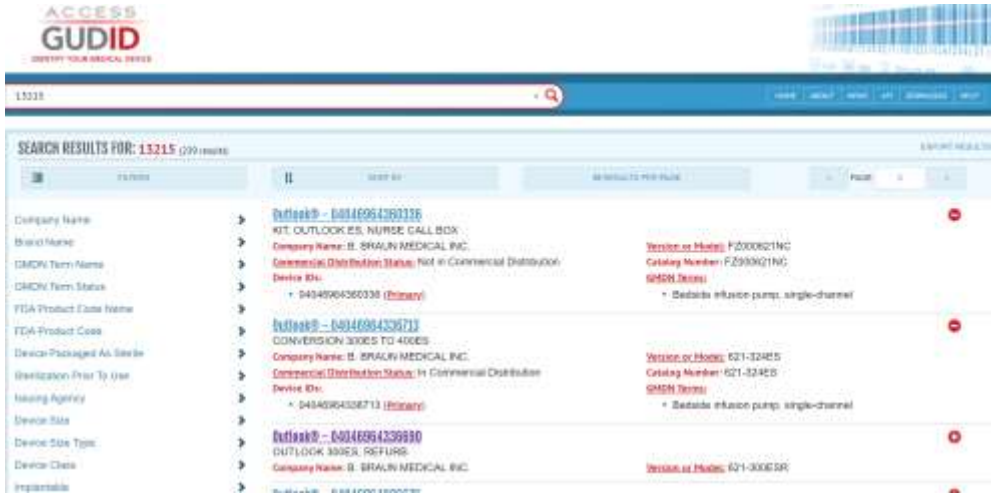
UDI-DI	Manufacturer	Catalogue	GMDN Code	Basic UDI-DI
09521234500018	XYZ Ltd	HDIF-23	17888	95212345AVFCNM
05012345000053	ABC Ltd	GHFKK-345	17888	5012345AAA0002Y
05060989599907	DEF Ltd	CER-BD-15	17888	506098959BBB0155X
09521234500087	XYZ Ltd	HDJUWE-556	17887	95212345MUFCR4
05012345000114	ABC Ltd	30220001	17887	5012345AAA0153D

UDI IMPLEMENTATION & GMDN

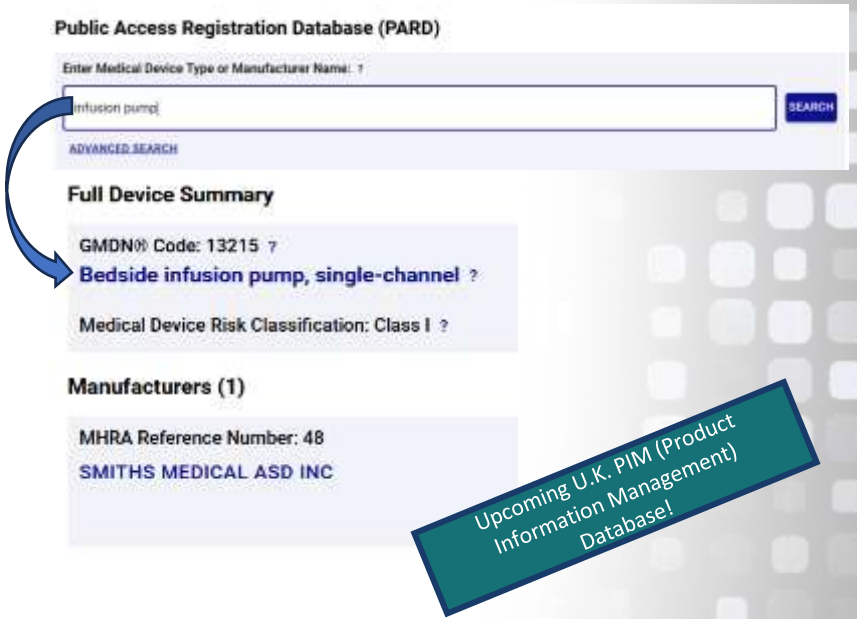
- GMDN collaborates with:
  - FDA
  - MHRA
  - TGA
  - Health Canada
  - ANVISA
  - INVIMA
- Countries working on their UDI implementation have access to the GMDN Database: Japan, Türkiye, Saudi Arabia, Singapore, South Korea, Switzerland, and others
- Some European countries still access and refer to GMDN in different capacities
- GMDN is willing to collaborate with all “Regulators” who wish to utilise GMDN Database

REGULATORY DATABASES (PUBLIC ACCESS)

https://accessgudid.nlm.nih.gov/



https://pard.mhra.gov.uk/



Upcoming U.K. PIM (Product Information Management) Database!

SCAN4SAFETY

HOW CAN GMDN SUPPORT GLOBAL AND NATIONAL PUBLIC HEALTH PROGRAMMES?

Traceability, Single Language, Analysis

GMDN

- Nomenclature in multi-hierarchical classification system
- Mutually-exclusive Terms
- Terms include definitions with intended use and important clinical attributes
- Availability in multiple languages
- Self-funded, independent and guided by Regulators

- **25 years of experience**, reliable editorial rules, internal SOPs and QMS, guided by Regulators
- Embedded in the **regulatory framework**
- A common, **single language to name and group medical devices**
- Represents the **current supply** of all medical devices, captures **innovation**
- Complements UDI:
  - **Traceability** across jurisdictions
  - **Early signal detection** of medical device performance issues (Beyond single device issue detection, capturing proportional reporting ratio within the group of similar devices)
  - Enables **data analysis** - pooling data from pre-market and post-market surveillance programs
  - Enables to **identify the right technology** for the patient
- **Linking medical device data across different healthcare stakeholders**
- Supports **“Harmonisation”**

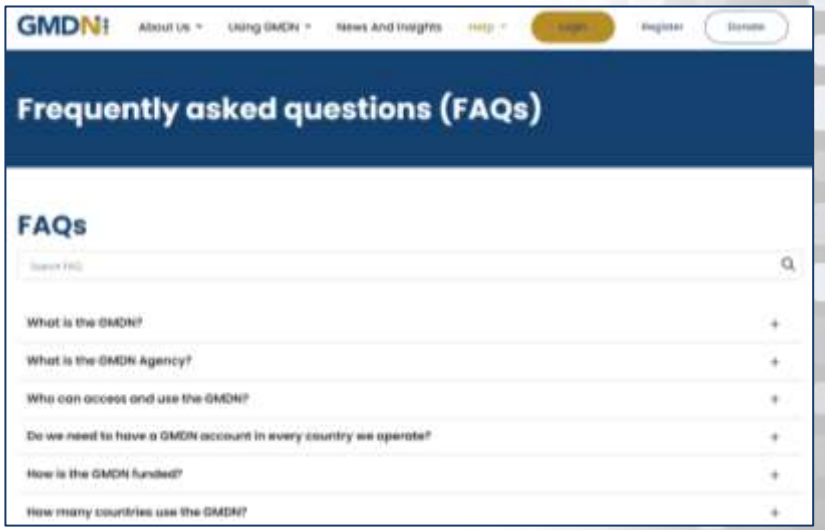
HOW TO ACCESS GMDN

EXAMPLE

- Visit the GMDN website www.gmdnagency.org and select the Register button on the top right of the website
- Complete the member registration form and verify your e-mail address
- The GMDN Agency uses a membership model for access to the GMDN to protect and maintain the integrity of the data, ensuring that any publicly available data is accurate, up to date and supports patient safety

SUPPORT FOR USING GMDN

- The GMDN website www.gmdnagency.org has an FAQ section, Training Videos and User Guides to help you use GMDN
- We also offer one-to-one training sessions for stakeholders
- You can email us at admin@gmdnagency.org to request a session or for any queries



GMDN IS HERE FOR YOU
THANK YOU

BETTER UNDERSTAND YOUR NEEDS

HELP YOU TO GET THE BEST OUT OF GMDN DATA

DEVELOP TOOLS THAT WILL SUPPORT YOUR WORK

Our Website: https://www.gmdnagency.org/
Email Us: admin@gmdnagency.org

Questions

Scan4Safety in England

Overview

UDI Forum – July 2024

Presented by:
Anna Stec

Scan4Safety

Background

Scan4Safety is an initiative implemented in healthcare in the United Kingdom

2016

- Scan4Safety was launched by the Department of Health and Social Care (DHSC) in 2016.
- Initially set up across 6 demonstrator sites:
  - University Hospitals of Derby and Burton NHS FT
  - Leeds Teaching Hospitals NHS Trust
  - North Tees and Hartlepool NHS FT
  - Salisbury NHS FT
  - Royal Cornwall Hospitals NHS Trust
  - University Hospitals Plymouth NHS Trust

  *Hull University Teaching Hospitals NHS Trust
- The pilot demonstrated how the use of barcoding technology in hospitals can **streamline the tracking and management of medical supplies, equipment, and medications.**

Scan4Safety is an initiative implemented in healthcare in the United Kingdom

2020

- Following the Cumberlege report – “First Do No Harm”, the NHS put some central efforts back into Scan4Safety.
- Medical Device Safety Programme and ePOCT project.
- The aim has been to ensure precise tracking of medical instruments and implants.
- Focused on enhancing **patient safety benefits** by implementing comprehensive **scanning procedures in surgical theatres.**

Scan4Safety is an initiative implemented in healthcare in the United Kingdom

2023

- A new mandatory national Medical Device Outcome Registry (MDOR) was launched.
- Aims to collect information on all **high-risk (Class III/IIb) devices**.
- The Government's Mandate to NHS England stipulates that by March 2024, **all NHS trusts must adopt barcode scanning** for high-risk medical devices as part of the broader Scan4Safety program.

Scan4Safety is an initiative implemented in healthcare in the United Kingdom

2023

- **NHS Commercial Strategic Framework** commitments:
- **Promote Scan4Safety as a priority** to improve patient safety, traceability, operational productivity and supply chain efficiency.
- Aligned to Scan4Safety, NHS Supply Chain will accelerate the adoption of integrated inventory management capabilities across providers to deliver demand insight and optimisation, improve operational resilience and reduce patient risk.

Scan4Safety is an initiative implemented in healthcare in the United Kingdom

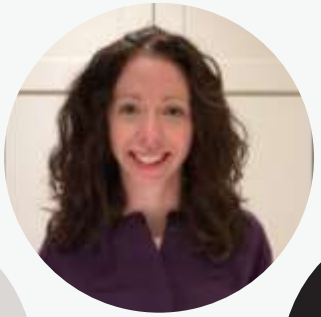
2023

- **NHS Supply Chain – In-Trust Inventory Management Systems (IMS) pilot project.**
- Introduces electronic IMS, point of care and analytics functionality.
- Focused on enables visibility of high value medical devices (Class IIb and III).
- **First entry point enabling Scan4Safety roll out in theatres.**

Scan4Safety

NHS England

National Digital Clinical Safety team - Scan4Safety England



Tracey Herlihey

Deputy Director of Patient Safety, Digital

- PhD in Psychology
- Human Factors and Translational Health Sciences background

Anna Stec

Senior Project Manager

- Registered Clinical Engineer
- Benefits Realisation Manager

Phil Duncan

Senior Programme Manager

- Nursing background
- Quality Improvement expert

Scott Cordon

Business Coordinator

- Data management
- Events coordination

James Nicholls

Project Manager

- Comms and engagement lead

Priorities 2024/2025

Digital Clinical Safety Strategy

Aims for Digital Clinical Safety:

1. To improve the safety of digital technologies in health and care, now and in the future

2. To identify, and promote the use of, digital technologies as solutions to patient safety challenges.

Commitment 4: Accelerate the adoption of digital technologies to record and track implanted medical devices.

Priorities

- Promote Scan4Safety and its benefits.
- Co-ordinate work of Scan4Safety partners.
- Help NHS providers navigate legal and regulatory requirements in relation to barcode scanning and data submission.
- Evaluate and communicate patient safety benefits of scanning solutions.
- Utilise patient safety networks and expertise to support safe implementation of Scan4Safety

Current Scan4Safety initiatives:

- Verification of patient identity via a wristband (HSSIB report on Positive Patient Identification).
- POC scanning to match product data to patient data in the blood transfusion pathways (Infected Blood Enquiry Report).
- Scanning patient's wristbands together with the electronic prescription record (EPR) confirming a match, enabling the introduction of robotic dispensing systems (Closed Loop Medicine Administration).
- Recording implant serial numbers in patient records and central registries (MDOR)
- Working on unified, validated benefits realisation approach for the NHS together with NHS Supply Chain's IMS Pilot Programme.
- Tracking assets and medical devices throughout a network of facilities (DHS PIM programme and NETIS)

We see Scan4Safety as an umbrella term representing the collaborative efforts of multiple national programmes, all working towards common objectives of:
improving patient safety, clinical effectiveness, and operational efficiencies.

Scan4Safety partnership

We have strengthened our partnerships with key organisations such as:

- GS1 UK,
- NHS Supply Chain,
- MHRA,
- DHSC,
- NHSE Commercial,
- Outcomes Registries,

to form a committed team focused on driving and enhancing the Scan4Safety program.

Available resources

Scan4Safety website refresh

https://scan4safety.nhs.uk/

- Information about the Scan4Safety and supporting evidence
- Information about Scan4Safety partners and related programmes
- Guidance for Trusts, Suppliers and Solution Providers

Digital Clinical Safety - NHS Futures Platform: Scan4Safety Page

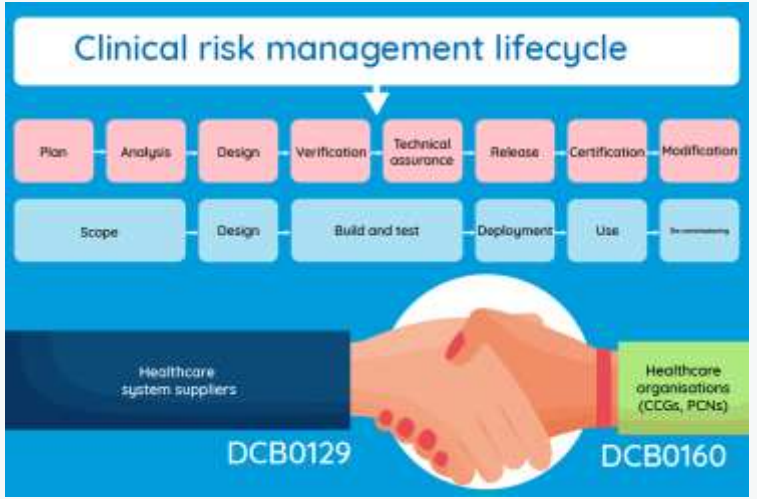
- Documentation and resources for Trusts
- Forum for discussions and networking

Scan4Safety Twitter account

- News related to Scan4Safety from across the system
- Sharing work and successes of our partners, NHS Trusts, etc.

DCB Standards

DCB standards by NHS Digital ensure the safety, quality, and interoperability of UK healthcare information systems.



Full eConsult article available at:
https://econsult.net/blog/dcb0129-dcb0160

DCB0129

Clinical Risk Management: its Application in the Manufacture of Health IT Systems

- It helps manufacturers of health IT systems identify and mitigate risks in system development, ensuring products are safe and reliable.

DCB0160

Application in the Deployment and Use of Health IT Systems

- Focuses on risk management during the deployment and use of health IT systems in healthcare organisations.

*DCB0129/DCB0160 applicability tool: Step by step guidance - NHS England Digital

DCB1077

Automatic Identification and Data Capture for Patient Identification

- Defines how to encode NHS approved patient identifiers into a two-dimensional barcode
- The standard mandates the use of AIDC technologies to accurately capture and verify patient identity. It promotes the standardisation of patient identification methods across healthcare organisations.

Poll

Would you be interested in attending a webinar for a detailed explanation of DCB0160, DCB0129, and DCB1077 standards, including their application, implications, and practicalities, with a Q&A session?

Thank you

anna.stec@nhs.net
digital.clinicalsafety@nhs.net

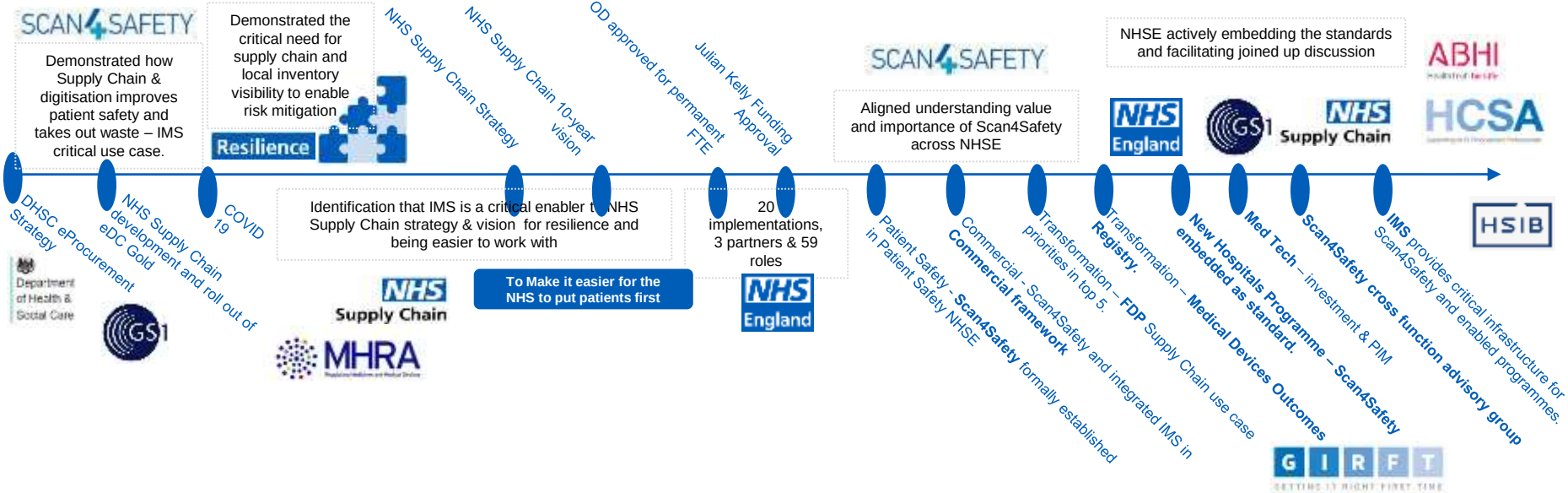
@scan4safety

Questions

Inventory Management Systems – a Strategic Data Capture Point

Frankie Wallace, Data Standards Engagement Manager, NHS Supply Chain

Inventory Management System **I NHS Landscape**



In Hospital Services **I Enabling One NHS**

Our In-Hospital Services has two teams; Deployment and Centre of Excellence who are delivering our vision and outcomes.

Vision

Buy Smart

‘Give trusts practical expert supply chain help beyond the back door’

- Realise inventory benefit with existing infrastructure
- Establish strategy and tools to deliver transformation
- Make changes to best receive our service

Supply Right

Roll out IMS across all trust settings (in and out of hospital)

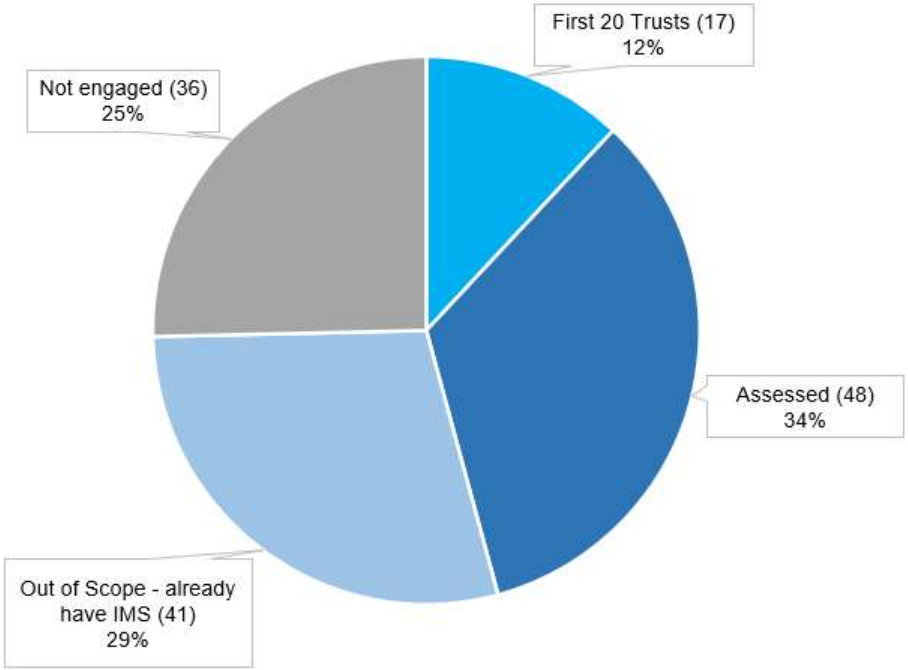
- Savings, improve patient safety and reduce workforce pressures
- Identification and mitigation of risk to drive resilience
- Provide data for multiple NHS strategic programmes

Partner Expertly

Outcomes

Trusts	**Financial and workforce** benefits realised, and **patient safety** improved through matured supply chain and IMS deployment
NHS England	Integrated inventory management - single IMS scan feeds **FDP** and in turn other NHS programmes such as **MDOR** and **Scan4Safety**
NHS Supply Chain	Seamless connectivity and service enablement - Integrates service to **patient and clinicians** through **automated** processes

In Hospital Services **I National Engagement**



Here and now

- 65 trusts engaged to date
- 48 trusts have been assessed
- 35 of which demonstrated high confidence in sponsorship and resource availability and received an on-site assessment
- 17 of which have demonstrated sufficient operational process readiness and change readiness and have been confirmed in the first 20 trusts

Future Facing

- We will be supporting 30 trusts with best practice materials to aid readiness for the next cohort of trusts
- 77 trusts did not seek engagement. NHS Supply Chain's Voice of the Customer team will drive awareness and education of the importance of effective inventory management
- 41 of the 77 trusts have independently implemented IMS. Where these trusts are not realising benefits, NHS Supply Chain's Diagnostics team will provide short-term, practical interventions to maximise local return on investment

IMS and Data Standards **I Patient Safety**

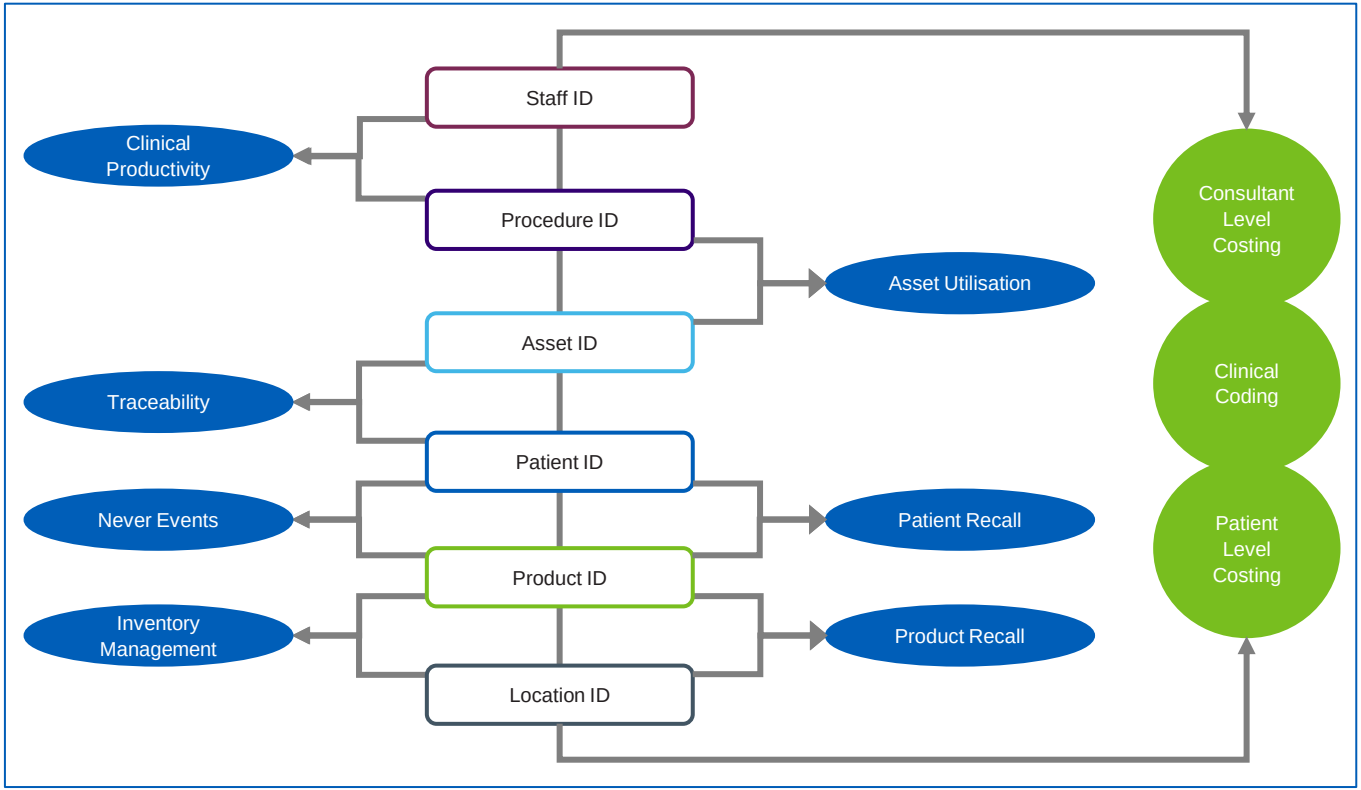
NHS Supply Chain

Scan4Safety enables

- Patient safety
- Clinical productivity
- Supply chain efficiency

Through the capture of

- People
- Product
- Place
- Process



IMS and Point of Care Scanning **I Enabling Patient Benefits**

Through this programme, Inventory Management and Point of Care Scanning can enable NHS England's Scan4Safety programme across three key elements underpinning patient care: **improved patient safety, positive experience** and **better outcomes**

- ✓ Patient-level tracking
- ✓ Prevention of incidents and never-events
- ✓ Key enabler of Scan4Safety
- ✓ GS1 compliance

- ✓ Reduced wait times
- ✓ Reduced appointment and procedure cancellations due to supply or product issues
- ✓ Improved efficiency of clinical services

- ✓ Increased likelihood of treatment success
- ✓ Reduced time in treatment pathways

Data Standards **I Supplier Product Data Standards Policy**

- [NHS Supply Chain Launches Policy on Data Standards for Supplier Product Coding » NHS Supply Chain]
- All our suppliers of all classes of medical devices are to adopt globally recognised coding standards, **preferably the GS1 Global Trade Item Number (GTIN),** for product identification
- Product related data submissions are to include these codes
- For medical devices, Unique Device Identification (UDI) compliant barcode labels are to be carried on the device packaging, meaning the label will carry scannable information relating to the production of the device, e.g. the expiry date and the serial or batch number
- For clinical consumable products, barcode labels are to be carried on the packaging with scannable information relating to the product identifier, preferably the GS1 GTIN
- Timeline for adoption aligned to the EU Medical Device Regulations UDI implementation

IMS **I Strategic Data Capture Point**

NHS Supply Chain

Simple Data Capture

- ✓ **Capture at point of Care**
- ✓ **Value exceeds effort to capture**
- ✓ **One capture point with many uses**

Data IMS Outcomes

Cash Release
- *Waste prevention*
- *Optimised Stock holding*

Patient Safety & Experience
- *Expiry, never event, recall*
- *Release time to care*

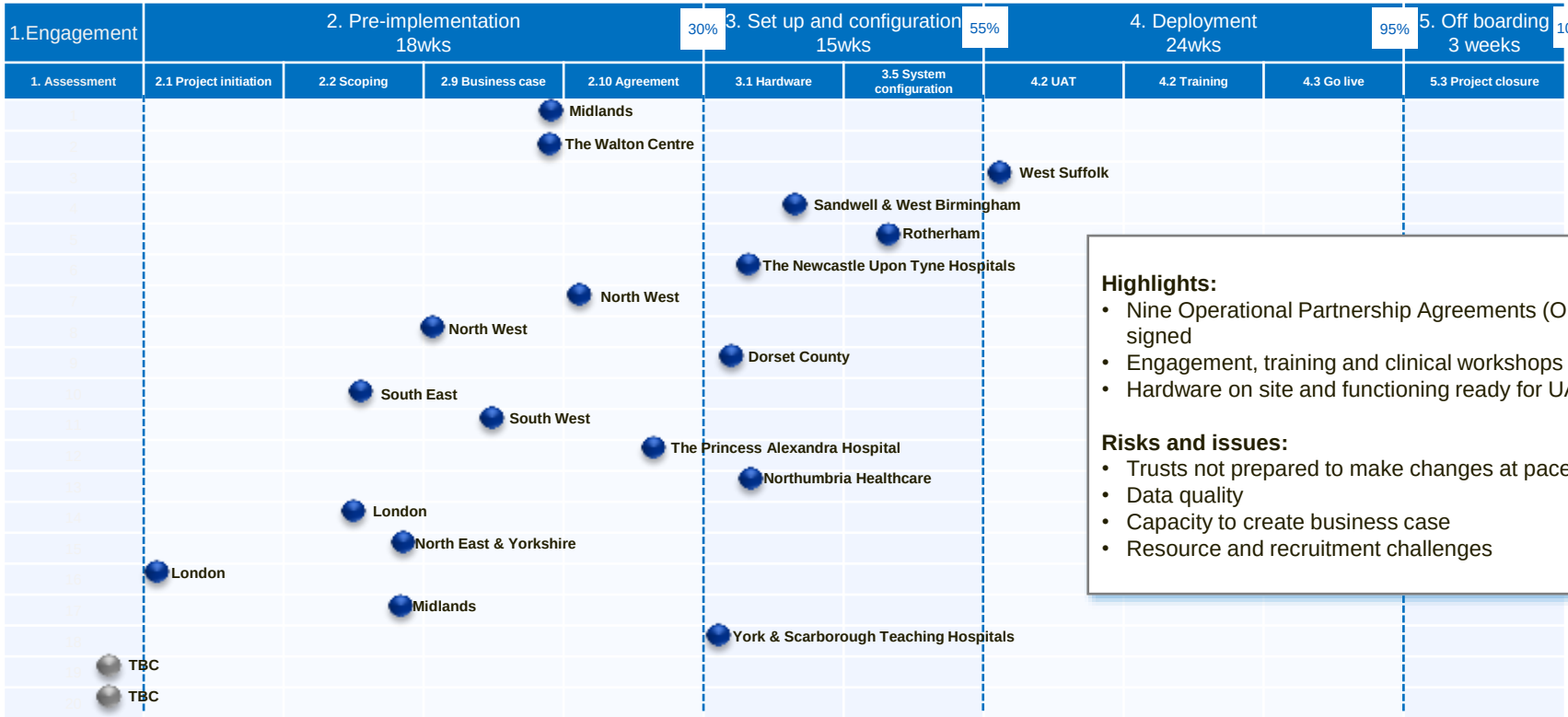
Productivity
- *Automation of process*
- *Simplification of process*

System-wide Resilience
- *Transparency*
- *Safe stock levels*

Consumption of Data

- **MDOR -** *systemised product to patient capture, reducing effort on trust*
- **FDP –** Supply Chain *Combine with other outputs for new capabilities - demand forecasting*
- **Scan4Safety -** *Critical enabling workstream*
- **MHRA -** *Data validation and compliance*
- **PIM** – *Validate data and labelling against data held*
- **ESG** - *Carbon footprint; storage, transport and packaging*

Deployment | **Delivery Status in Top 20 Trusts**



Highlights:

- Nine Operational Partnership Agreements (OPA) signed
- Engagement, training and clinical workshops
- Hardware on site and functioning ready for UAT

Risks and issues:

- Trusts not prepared to make changes at pace
- Data quality
- Capacity to create business case
- Resource and recruitment challenges

Questions

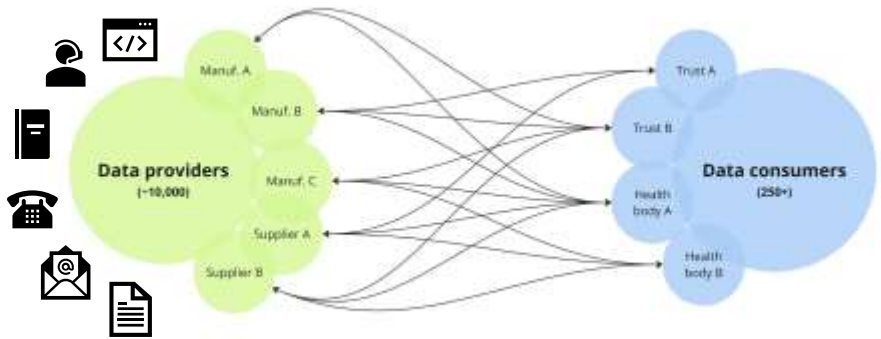
Department of Health & Social Care

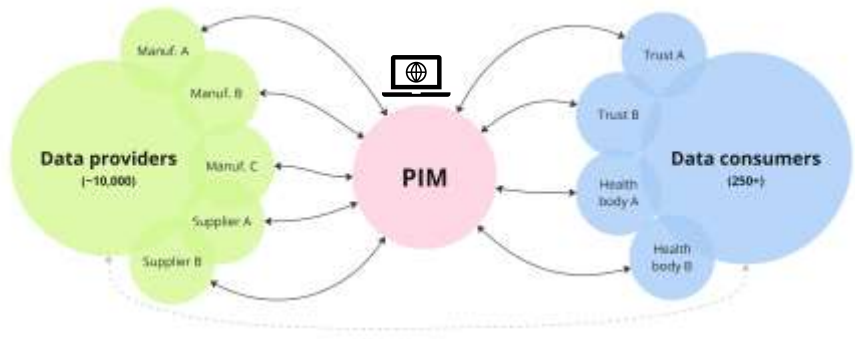
DHSC Product Information Management (PIM) System – Alpha

Scan4Safety and UDI forum 2024

17th July 2024

We are trying to develop a system that helps to streamline the currently inefficient process of requesting and supplying data about medical devices





Current landscape

Future landscape

Discovery

What we knew going into alpha

PIM is a major initiative in DHSC's MedTech Strategy and NHS England's Strategic framework for NHS Commercial

Need	Constraints
It is **time consuming** to **get basic, essential and good quality data** about medical devices for users across the health system.	We want to support the approach of **'collect once, use often'** for data – reusing existing data where possible.
There are **pockets of rich data** that currently exists across the system without a central reference point, or easy way to access or connect these datasets.	Any developed system should be able to embed well into existing systems and recognise the differences in digital maturity across data consumers.
Other **products, platforms and services already exist** that PIM will need to intersect with, depending on the use case.	Data providers would need to have sufficient incentives to engage with any system that requires their input.

Alpha

The purpose of the alpha was to explore assumptions and potential solutions for a system that enables the sharing of medical device data

The alpha focused on 3 core elements:

User research

Conducted user research through a variety of method, engaging with:

- 29 data consumers (12 orgs)
- 15 data providers (8 orgs)
- 1 data standards participant
- 26 wider stakeholders

Data exploration

Reviewed and appraised several data sources against our identified user needs, including:

- MHRA Product Register
- GDSN
- GUDID
- NHS SC Catalogue
- EUDAMED

Content design

Prototyping of the system focused on:

- Finding, requesting and accessing data for consumers.
- Providing data and responding to data requests for providers.

Users we engaged with during the alpha

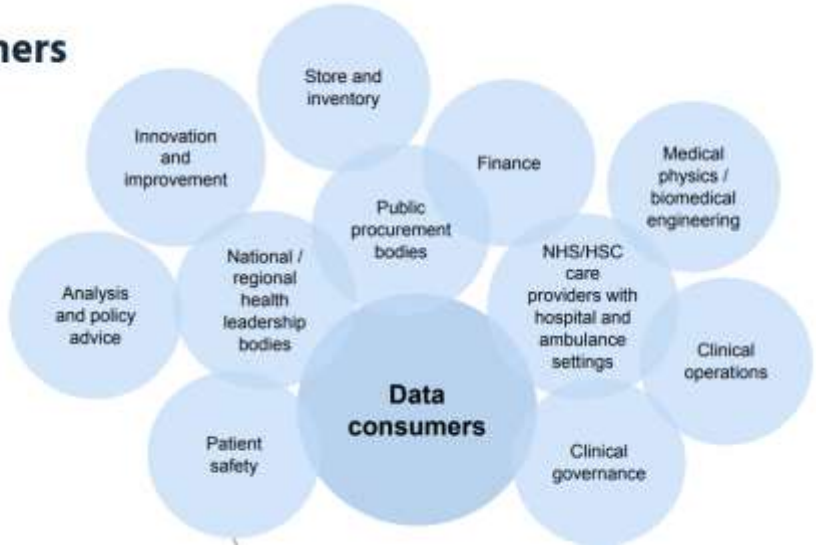
User research

Data consumers

11 data consumer user groups identified.

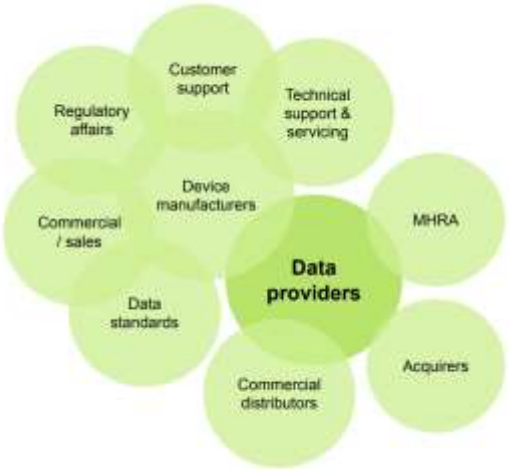
Excluded health organisations:

- Primary care providers
- Local public health bodies
- Local authorities
- Voluntary / private care providers
- Social care providers



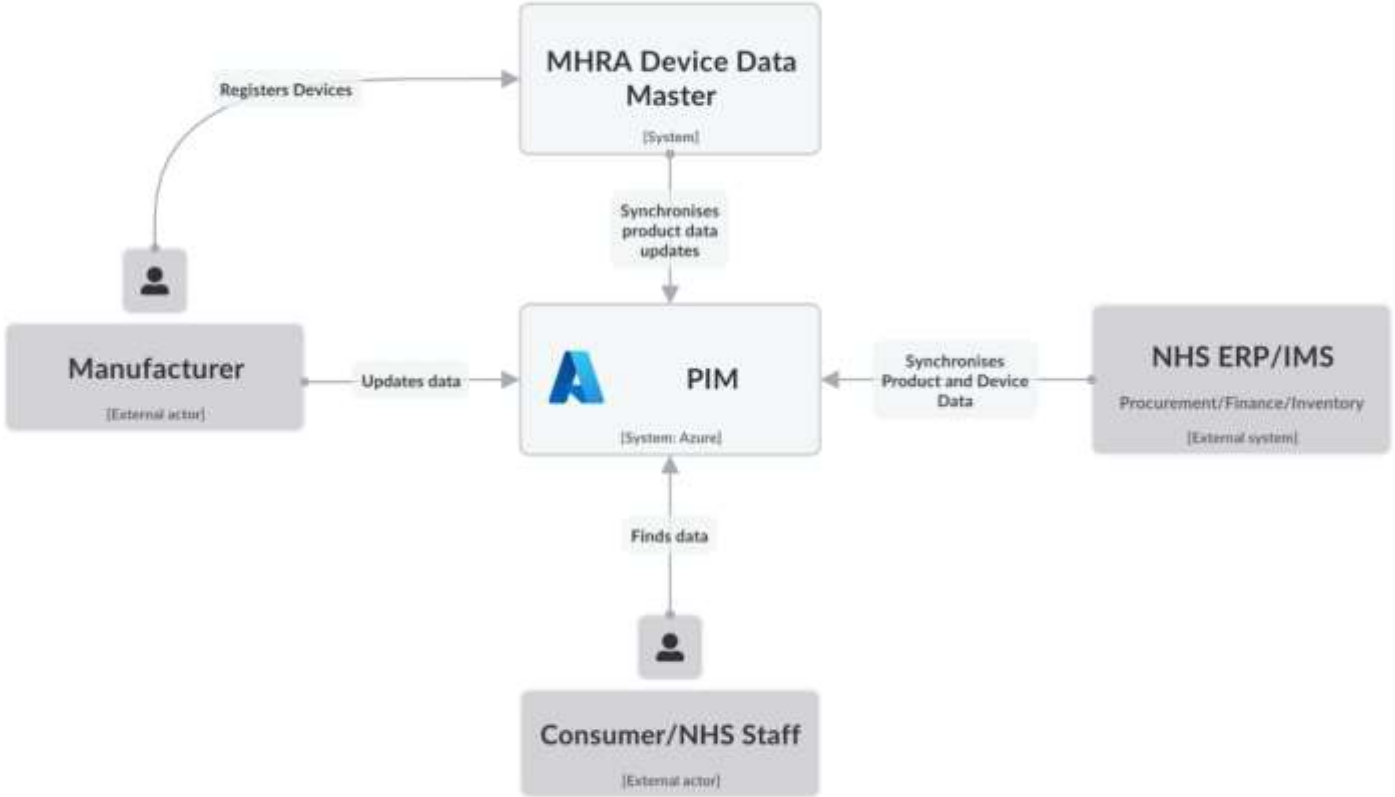
Data providers

9 data provider user groups identified.



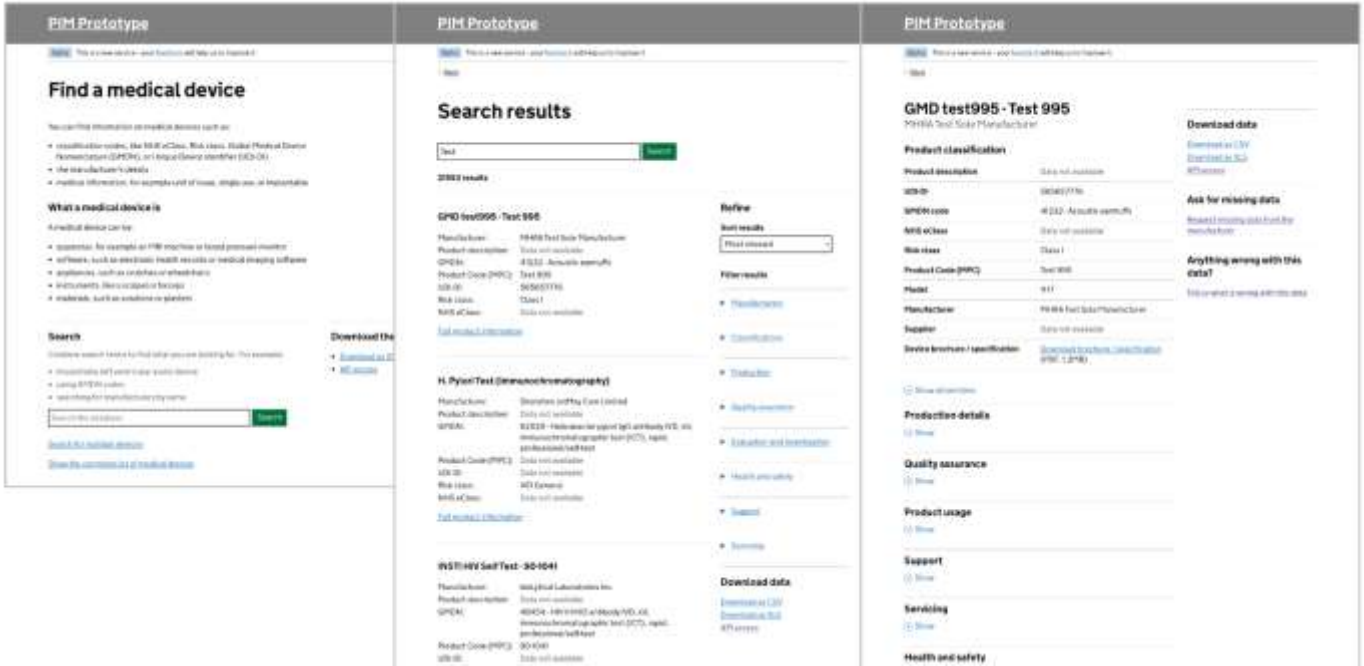
PIM Business Context

Data exploration



Screenshots of the developed dynamic prototype for finding/viewing data

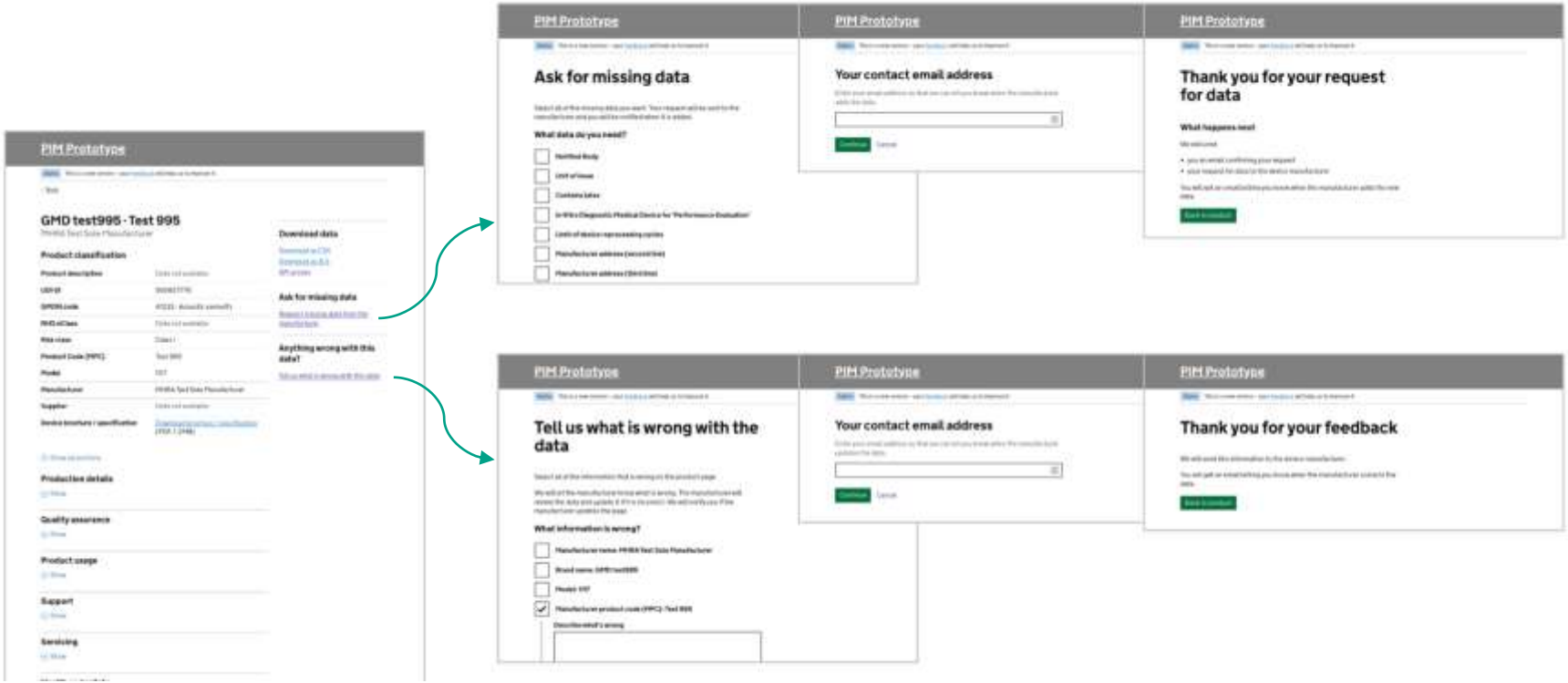
Content Design



Note: the data shown in these screenshots is test

Screenshots of the developed dynamic prototype for requesting/flagging errors

Content Design



Note: the data shown in these screenshots is test

Beta

Key learnings and recommendations from Alpha

The alpha validated user needs for a single source of truth for medical device data. We propose continuing the journey to develop a digital service that collects and provides medical device data.

Aim

To make sharing of medical device data between suppliers and consumers easier, more efficient and more consistent.

Alpha

Through user research with data consumers, data providers and wider stakeholders we developed a more detailed understanding of their data requirements, the existing constraints and received feedback on our prototype.

Learnings

- There are a broad range of potential users with a variety of user needs
- Data and people's information needs both evolve over time
- No existing data set(s) alone/combined meets all identified needs

Beta

Our alpha has validated a proposed approach to deliver the Beta stage.

- PIM should collate medical devices data from multiple sources and collect data itself
- PIM should enable data consumers to access data via a range of means
- PIM should enable data consumers to flag errors and request missing data
- PIM should enable data providers to submit data via a range of means

Beta and beyond

Note: these are the proposed current timelines and may be subject to change

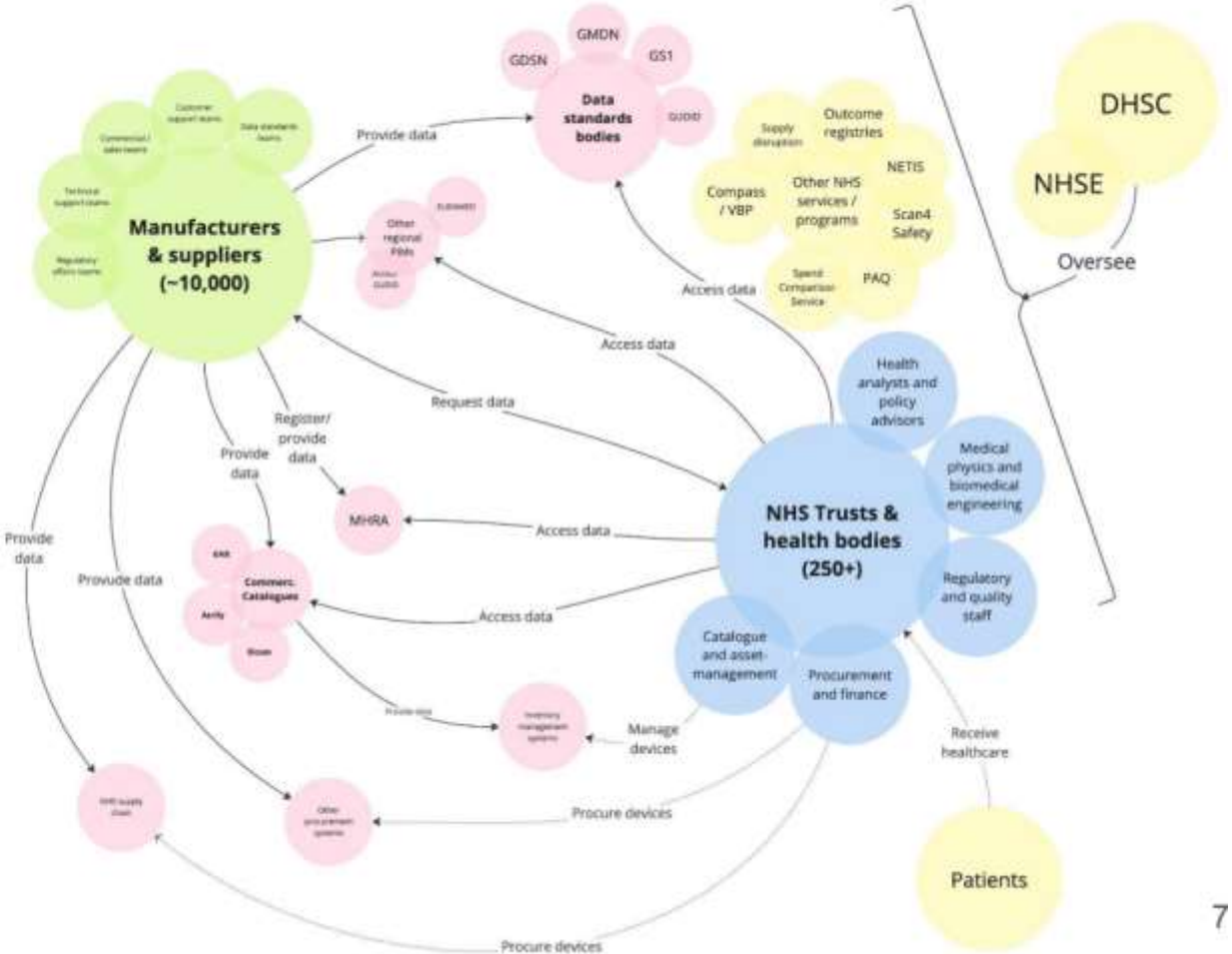
July 24	Nov 24 – April 25	May 25 – Oct 25	Nov 25 +
Finish Alpha	Private Beta Design and develop “MVP.” Build it for real. Test with limited user cohort	Public Beta Open up to all users. Identify and fix problems. Iterate.	Live/continuous improvement Fully functioning live service. Continue to iteratively develop to meet user needs.

Thank you

If you are interested in joining the PIM Stakeholder Group and/or participating in beta, please contact Jasleen.Rehal@dhsc.gov.uk

Questions

Overview of the service: current landscape



Department of Health & Social Care

Key learnings from and for the health system

Data reuse

- Ability and willingness to reuse data varies across trusts.
- Reusing information is not a well-controlled process.
- PIM should help to support the appropriate reuse of data and encourage the validation of data being fit for purpose for its intended use.

Information needs are evolving quickly

- Local trusts may have individual policies so have varying information needs.
- All information needs are not entirely captured by any standardised set of information.
- PIM should not solely rely on existing standards to inform data capture as these may lag behind the needs of users.

PIM

Information needs are being standardised

- Working groups are assessing information needs for certain tasks and setting standards for information that should be requested.
- PIM should use these expert groups and already established standards.

Collaborative maintenance requires incentives

- Manufacturers need to have a reason to want to contribute to PIM.
- PIM may best replace some parts of the existing user journey of obtaining information from manufacturers.

Up next on the agenda

11:00	Supplier snapshot: Preventing the release of harmful anaesthetic gases	Dr Steve Wileman, head of research, **SageTech Medical**
11:15	Trust perspective: Scan4Safety starts with the patient	Mark Songhurst, Scan4Safety programme manager, **LTH NHS Trust**
11:40	Early successes from Scotland's Scan for Safety pilots	Simon White, programme director - Scan for Safety Scotland, **NHS NSS**
12:05	Why now for Scan for Safety in Wales?	Andy Smallwood, assistant director of procurement and SfS lead, **NWSSP**
12:30	GS1's global ambitions@ One product, one barcode	Elisa Zwaneveld, healthcare manager, **GS1 Global Office**
12:50	Closing remarks	Chris Florey, Engagement manager – healthcare, **GS1 UK**

SAGETECH MEDICAL

Leading Sustainable Anaesthesia

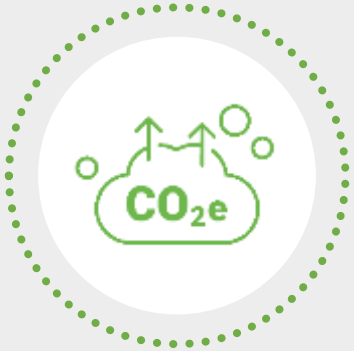
We are proud to play our part in sustaining our planet

The Problem

Environmental Damage

95%

Percentage of anaesthetic agents knowingly released to the atmosphere as waste



4,000,000

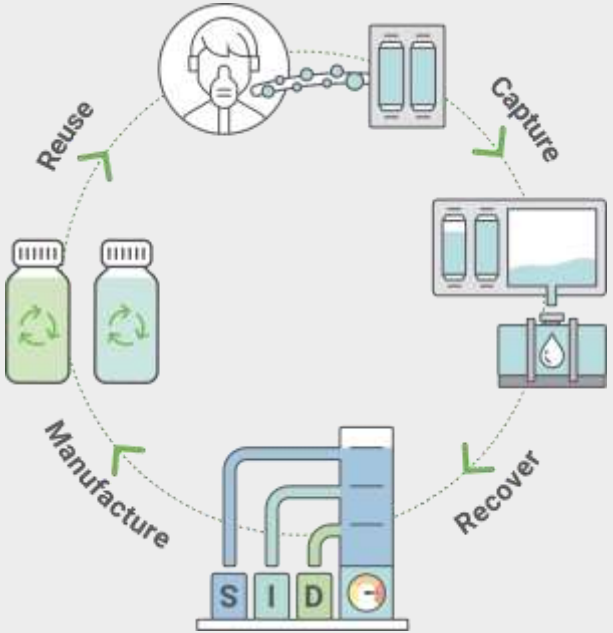
Tonnes of CO_2e (t/CO_2e) released per year from volatile anaesthetic agents globally (human and veterinary healthcare)

20%

Waste anaesthetic proportion of veterinary healthcare's carbon footprint

Circular Economy Solution

SageTech Medical Solutions



Capture
- Reusable capture canisters

Recover
- Local UK canister emptying

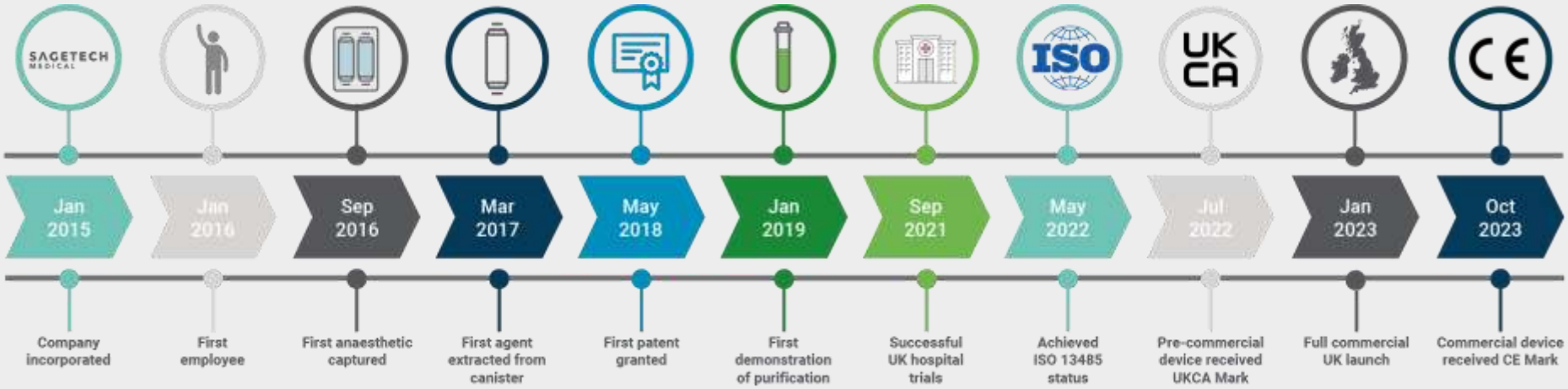
Manufacture
- Purify and recycle waste agent

Reuse
- Reduce raw materials and CO_2e

Human Healthcare Operating Model

Our Journey

Sustainable Innovation By Design



The Solution

VET Dock

VET Can

SID Dock

SID Can

Using GTINs for Traceability

SageTech have unique requirements for traceability

1. Customers require data on site-specific waste capture.
2. The waste is classified as hazardous, which requires full cradle to grave traceability.
3. The waste that SageTech collect becomes the raw material for a pharmaceutical; regulatory agencies require traceability of raw material origin to be acceptable for human use.

Using GTINs for canister traceability

- The canisters use a GS1 GTIN as the unique device identifier.
- Each individual canister is then issued with a serial number to make it globally unique which is critical for traceability.
- The GTIN and the serial number together are captured in a 2D GS1 DataMatrix barcode enabling the canister to be scanned and identified across the supply chain.

Using GTINs for traceability in the waste pathway

The canisters pass through several hands on the logistics pathway

Waste carbon is bulked up at the in-country carbon exchange units

Bulk storage vessels are then transported to a regional waste processing facility

Regional waste processing facilities could be in-country or cross-border

Using GTINs for Traceability

Regulatory environment

EU medical device regulations

GTINs provide a global framework to identify, capture and share medical device product information. GTINs ensure SageTech is compliant with the EU MDR, enabling worldwide implementation for traceability across global supply chains.

Hazardous waste regulations

Hazardous Waste Regulations require full traceability and accountability from waste producer site through to waste processing facility. GTINs are an essential tool in securely meeting this requirement.

European F-gas regulations

New EU F-gas regulations control emissions from fluorinated greenhouse gas sources. Any organisation, must clearly manage and report on their F-gas releases. This will soon become mandatory legislation for hospitals.

NHS Net Zero strategy

The NHS Net Zero Plan define anaesthetic gas emissions as a scope one target. Tracking capture and usage will enable hospitals to report capture volumes as required by the plan.

Using GTINs for Traceability

Traceability is Key

Life Cycle Maintenance

The SID-Dock has a serviceable life of 10 years. The SID-Cans are reusable for many years and are function checked on every cycle of reuse.

SageTech needs to be able to monitor service schedules for routine maintenance.

SageTech needs to keep up to date records of when each SID-Dock was purchased, by who, and when maintenance is due as part of the product lifecycle.

Reporting

Using the GTIN it is possible to track and trace each canister as to where it has been over a particular time period.

It is then possible to measure how much waste is captured at a canister level.

Hospitals can then be provided with a report on what volumes of waste anaesthetic have been captured which in turn allows an accurate estimate of the carbon saving to be made.

Implementation Challenges

Barcode Compliance

We worked with GS1 UK to ensure the device barcodes met requirements for regulatory compliance.

We worked through understanding the options for different barcode types, how the data captured would be structured, and how the human readable text would be displayed.

Using the verification service several editions of the physical barcode label were submitted for review. This enabled us to receive feedback on what changes and improvements were required so both GS1 standards and the highest ISO quality standards were met.

Thanks for listening!

GS1 UK

VET Dock

VET Can

SID Dock

SID Can

Questions

NHS
The Leeds Teaching Hospitals
NHS Trust

#hello my name is…

Mark Songhurst

Programme Manager Scan4Safety
The Leeds Teaching Hospitals NHS Trust

SCAN4SAFETY

NHS
The Leeds Teaching Hospitals
NHS Trust

SCAN4SAFETY

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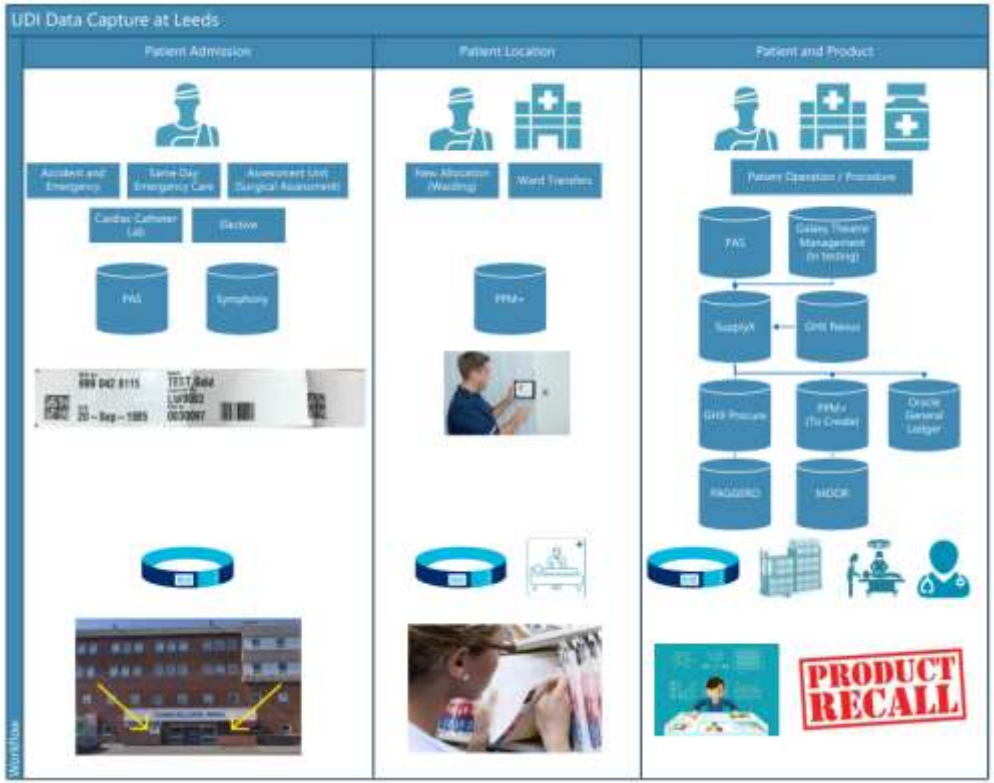
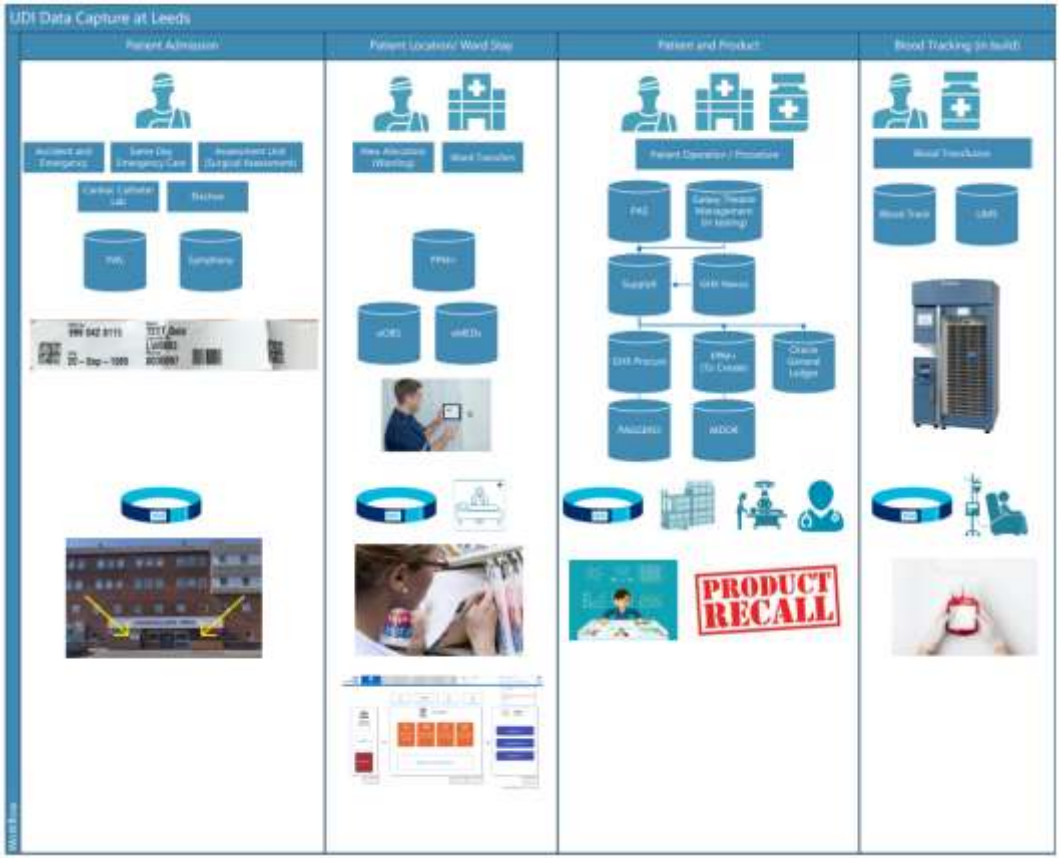
The Leeds Teaching Hospitals
NHS Trust

SCAN4SAFETY



SCAN4SAFETY



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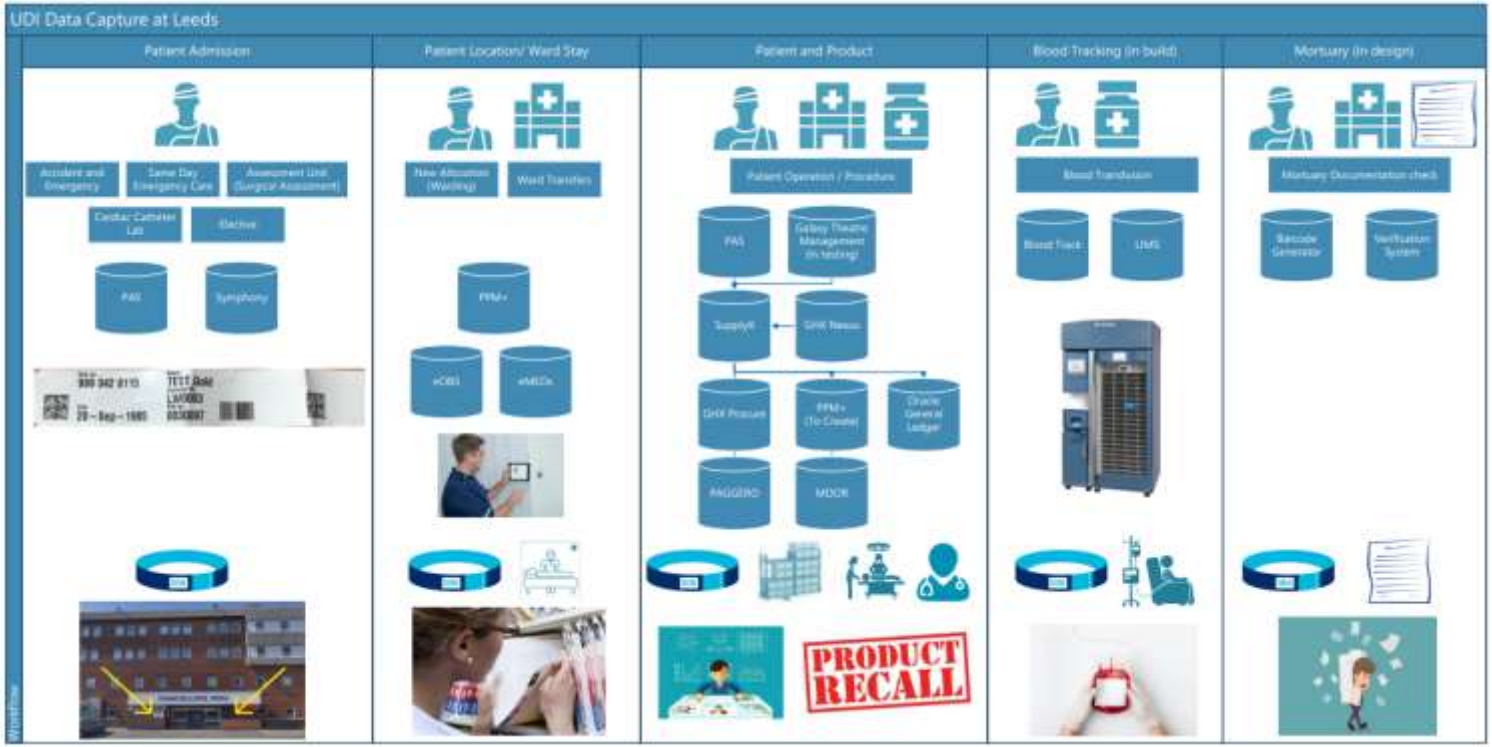


SCAN4SAFETY

NHS
The Leeds Teaching Hospitals
NHS Trust

Conclusion

SCAN4SAFETY

Questions

Scan for Safety

NHS SCOTLAND

NHS Scotland

GS1 UK Scan for Safety and UDI Forum

Simon White
National Programme Director
17 July 2024

Scan for Safety

NHS SCOTLAND

Contents

Scan for Safety

NHS SCOTLAND

Context – National Health Service (NHS) Scotland

- 14 Territorial Boards
- 7 Boards providing “national” support
  1. National Services Scotland (NSS)
  2. NHS Education Scotland (NES)
  3. NHS 24
  4. Scottish Ambulance Service (SAS)
  5. Healthcare Improvement Scotland (HIS)
  6. Golden Jubilee National Hospital (GJNH)
  7. State Hospitals Board
- Serves a population of approximately 5.5 million
- Annual budget of just over £17 billion

Scan for Safety

NHS SCOTLAND

What is Scan for Safety?

Collecting implantable medical device data & linking to individual patients using barcode scanning technology

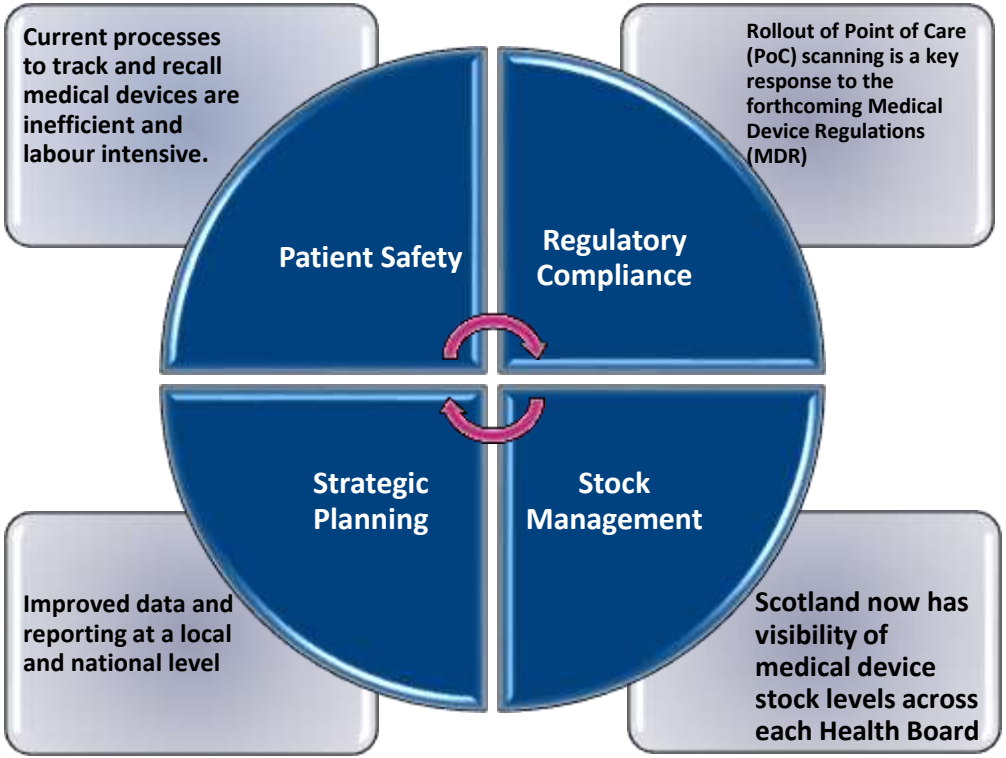
Programme Focus:

- **Acute Care settings in NHS Boards**
- **High Risk Implantable devices – Class IIb and Class III**
- **Four Specialties:**
  1. Orthopaedics
  2. Ophthalmology
  3. Cardiology
  4. Interventional Radiology

Scan for Safety

NHS SCOTLAND

Drivers – Why are we doing this?



Scan for Safety

NHS SCOTLAND

Scan for Safety Vision Statement

Optimising patient safety, clinical effectiveness, and NHS Scotland operational efficiency via ease-of-capture data across the patient journey.

Scanning (GS1 standards)
In-depth data capture from manufacture to point of care - optimising traceability, sustainability, and efficiency advantages for NHS Scotland.

Medical Device Data Hub (MDDH)
Linking data capture across patient, procedure, and medical devices - optimising collective knowledge and insights to further enhance patient-safety and clinical effectiveness.

National Medical Equipment Mgt (NMEMS)
Supporting patient care by facilitating intelligence-led investment in key medical equipment – optimising patient care.

Scan for Safety

NHS SCOTLAND

Scan for Safety Core Dataset – Operating Room

- Product
- Patient
- Practitioner
- Procedure
- Place & Time

Scan for Safety

NHS SCOTLAND

Timeline

2020

Cumberlege Report: First Do No Harm
- Rec 7: Central database linking patients to devices

COVID Pandemic:
- PPE

2021

Genesis Automation:
- Contract signed to implement IMS across NHS Scotland

Medicines & Medical Devices Act:
- Framework Legislation Clause 19 formation of UK MDIS, now referred to as MDOR (Medical Device Outcome Registries)

Scottish Government:
- Development and approval of the Scan for Safety Business Case, approved by SG in October

2022

Inventory Mgt System rollout

NHS National Services Scotland:
- National Programme established to implement Point of Care (PoC) scanning alongside the adoption of GS1 standards

2023

Key Milestones:
- IMS Rollout completed in March 2023
- All Boards in Scotland moved onto NMEMS
- PoC pilots started in August (NHS Lothian)

2024

Point of Care rollout

Key Milestones:
- MDDH capability in place
- Data Reporting Guidance and Framework issued to Health Boards
- PoC implemented across 3 Health Boards (by Dec)

2025

Key Milestones:
- PoC implemented across 6 Health Boards
- Target Operating Model developed and agreed

2026

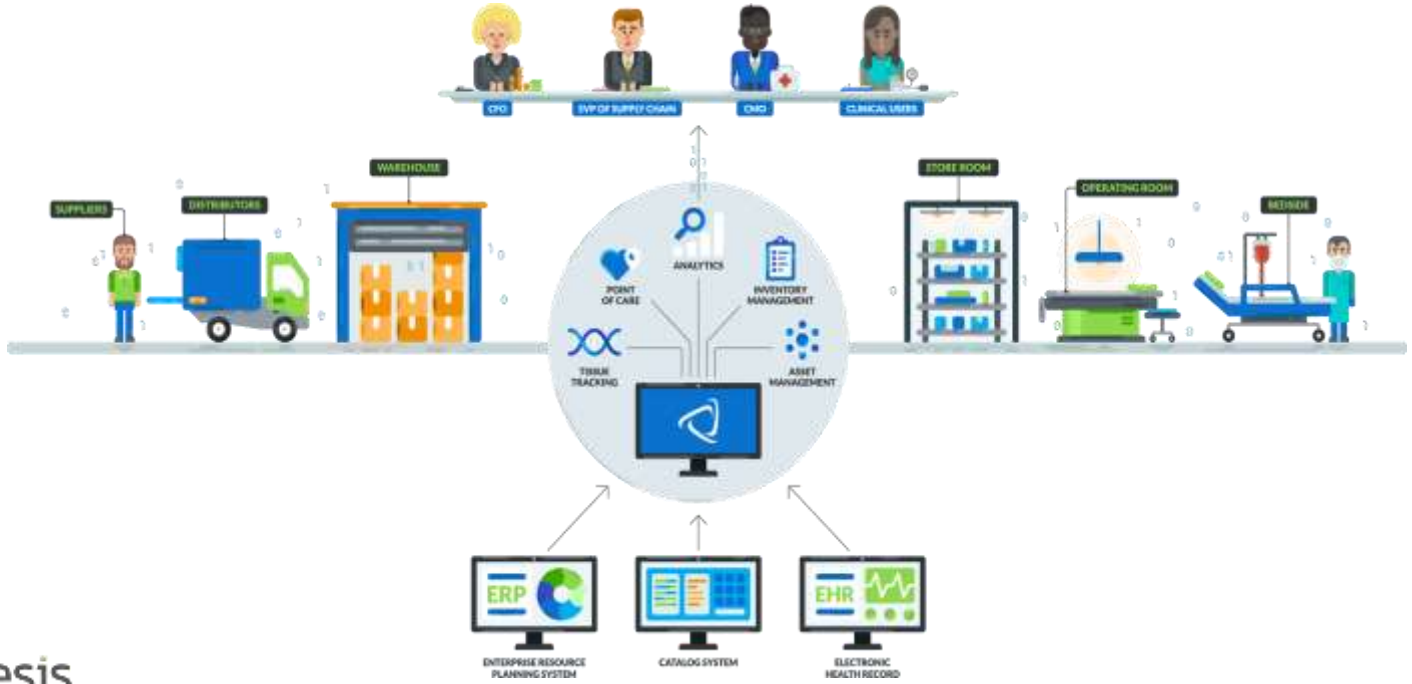
Key Milestones:
- PoC implemented across remaining Health Boards
- Programme closed and handed over to Business as Usual (BaU)

Scan for Safety

National Inventory Management System (IMS)

NHS SCOTLAND

- Implement Genesis Inventory Management, Point of Care and Analytics modules across 18 Health Boards
- Implement Genesis Desktop and Genesis Mobile application
- Roll out integration with Purchase to Pay system (PECOS), catalogue content management system (PCCM) and Finance System (eFinancials)



genesis

Scan for Safety

NHS SCOTLAND

Benefits to Date

Staff Time Saved (Band 4)	Max Stock Level Reduction	Excess Stock Reduction	Stock Expiry and Wastage
NHS Lothian – 1.5hrs per day	NHS Lothian - 16%	NHS Lothian - £60k approx.	NHS Lothian – 0.8% products discarded
GJNH – 1 WTE per day	GJNH - 8%	GJNH - £84k approx.	GJNH – 0.05%

Scan for Safety

NHS SCOTLAND

What else did we do?

Inventory Management System (IMS)
- Implementation completed in March 2023 across all health boards in Scotland

Point of Care Scanning
- PoC scanning started in August 2023 in NHS Lothian (IR)
- Further rollout in GJNH completed by January 2024 across 3 specialties

4 Nations Engagement
- Programme attends regular meetings with other devolved administrations to update on progress, share learning and work collaboratively to address common issues arising

Standards Development
- Standards in place for:
  - Product
  - Place / Location
  - Patient
  - Procedure
  - Clinician

Medical Equipment Management
- eQuip rolled out to all health boards in Scotland, with the exception of one which uses an alternative application

Medical Device Suppliers Guidance
- Developed in 2022 to provide medical device suppliers with guidance on the application of GS1 standards

Scan for Safety

NHS SCOTLAND

Learning to date

- **Executive Engagement** - Senior executive support within each health board is crucial
- **Resourcing** - Local resources must include a dedicated Project Mgt / Coordinating role supported by a local Senior Responsible Officer (SRO) for issue resolution
- **Single plan** - managed locally with support from the national Scan for Safety team and supplier (Genesis)
- **Stakeholder engagement** - Communication activity needs coordinated in terms of those directly impacted

Scan for Safety

NHS SCOTLAND

Challenges

- **Local resource levels** – Skill / knowledge requirement
- **Competing with other initiatives** – all health boards will have their own change portfolios which include local and national programmes of change
- **Time limit** – All health boards to be completed by March 2026
- **Funding** – National programme is expected to run until March 2026, funding only confirmed up to March 2025
- **Expectations beyond the programme** – Further rollout of the technology into other specialties to maximise the return on investment

Scan for Safety

NHS SCOTLAND

Focus for the next year

- **Point of Care** - Continue to work with Health Boards to implement PoC
- **Data Hub** - Deliver the MVP of the Medical Device Data Hub (MDDH) which will enable digital tracking and recall
- **Reporting and Analytics** – build on the framework and engage with stakeholders and governance groups to outline the value this will bring
- **Benefits** – Work with the implemented boards to monitor and deliver the expected benefits which can be shared with other stakeholders
- **Target Operating Model** – Outline the business-as-usual environments which need to be in place after March 2026

Scan for Safety

NHS SCOTLAND

Thank you

scanforsafety.nhs.scot

Get in touch: NSS.ScanForSafetyProgramme@nhs.scot

Questions

Scan for Safety Wales Programme update

Andy Smallwood
Assistant Director of Procurement

July 2024

Adding Value
Through Partnership,
Innovation and Excellence

Scan for Safety Wales Programme

- Background
- Data linkage
- Modernisation
- A look around Wales
- S4S Minimum Viable Product
- Progress to date
- Where to and what next?
- Closing thoughts and questions?

Background to Scan for Safety Wales

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Shared Services Partnership

Scan4Safety

"Patient safety is at the heart of the NHS Wales Scan4Safety programme. The introduction of barcode scanning and the automation of the link between uniquely identified products, places and people, provides real-time data at the point of care and instant traceability of implanted medical devices should a product or patient recall be required. The investment in this Once for Wales initiative will also deliver significant financial savings, improved stock management, removal of time-consuming administrative tasks from clinical staff at the same time as safeguarding our patients from avoidable harm."

Right Patient
Setting standards to make sure we always have the right patient and know **what** product was used with **which** patient, **when**.

Right Product
Setting standards to make sure our staff have **what** they need, **when** they need it.

Right Place
Setting standards to make sure that patients and products are in the right place.

Right Process
Setting standards and implementing common ways of working to deliver better and more easily repeatable patient care.

Adding Value
Through Partnership,
Innovation and Excellence

Where to start?

Base data is fundamental to everything – clean data – automated if possible

Right tools for the job are needed and interoperable

Need to engineer data signals into the system so that the answers to tomorrow's questions are at hand when needed.

Information output needs to be usable and able to inform continuous improvement.

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Shared Services Partnership

Omnicell

ORACLE Applications

AdviseInc

GS1 UK

Adding Value Through Partnership, Innovation and Excellence

Introducing data standards to link information

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Shared Services Partnership

People

Patients
&
Staff

Place

Product

GS1 UK

Procedure

Adding Value
Through Partnership,
Innovation and Excellence

Links with NWSSP logistics modernisation

Significant Investment in NHS Wales-wide logistics operations alongside S4S
Enables supply resilience through visibility of stock across NHS Wales (not just warehouses)
Enhanced system wide tracking of serial, batch number and expiry information
175,309 unique product GTINs loaded in catalogues across NHS Wales

Adding Value
Through Partnership,
Innovation and Excellence

S4S Minimum Viable Product (MVP)

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Shared Services Partnership

Patient safety benefits across each milestone

MVP = Inventory Management Capability SX linking product to place. Expected benefits improving patient safety:

Product recall

Expiry date alerts

Product patient linkage. Individual patients digitally linked to implant. Expected benefit include faster identification and contact of individuals

Patient product data linked to Theatre system and patient record, linkage to LDR and onwards to NDR

Multiple location identifiers

Multiple patient identifiers

Outdated storage

Available budget

Supply Chain Experience

Information Governance

Cyber security

Change management

Clinical Time

Competing local priorities

Dirty data

Varied data structures across systems, Patient, Place, Product, People

Adding Value Through Partnership, Innovation and Excellence

A look around Wales

WAST -Wrexham Make Ready Depot now live with IM

BCUHB - extensive IM spread across >200 locations including wards and theatres

HDDA – IM adopted at over 86 locations. Bronglais Hospital Endoscopy and ICU depts now live with product to patient linkage with their 5 theatres imminent

SBUHB – IM adopted at over 140 locations with 2 catheter labs also live with patient linkage

Powys – IM now in all theatre sites across the org (Brecon and Llandrindod). Patient linkage imminent.

ABUHB – IM adopted at over 80 locations. Product to patient live in Grange catheter labs

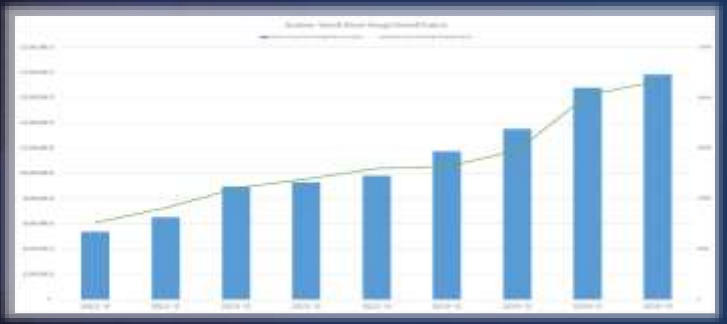
CAV – IM adopted at over 70 locations. Product to patient live in UHW catheter labs

CTM - extensive IM spread across >120 locations

Adding Value Through Partnership, Innovation and Excellence

Progress to date

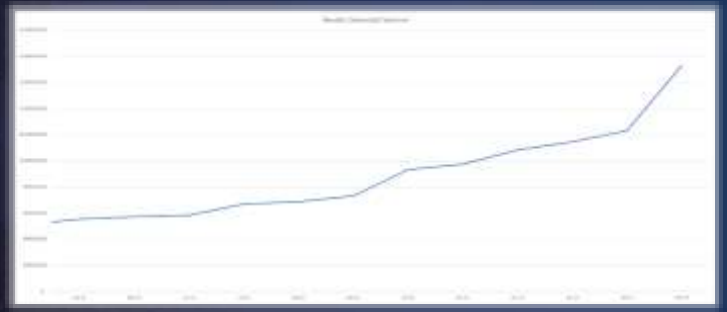
Spread and Scale Trend 2022-March 2024



£55,956,458 total value 2023/24

748,853 total volume 2023/24

Benefits Realisation Trend 2022-March 2024



£1,218,708 benefits realised 2023/24

PTHB Brecon Theatre Store

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Shared Services Partnership

Adding Value Through Partnership, Innovation and Excellence

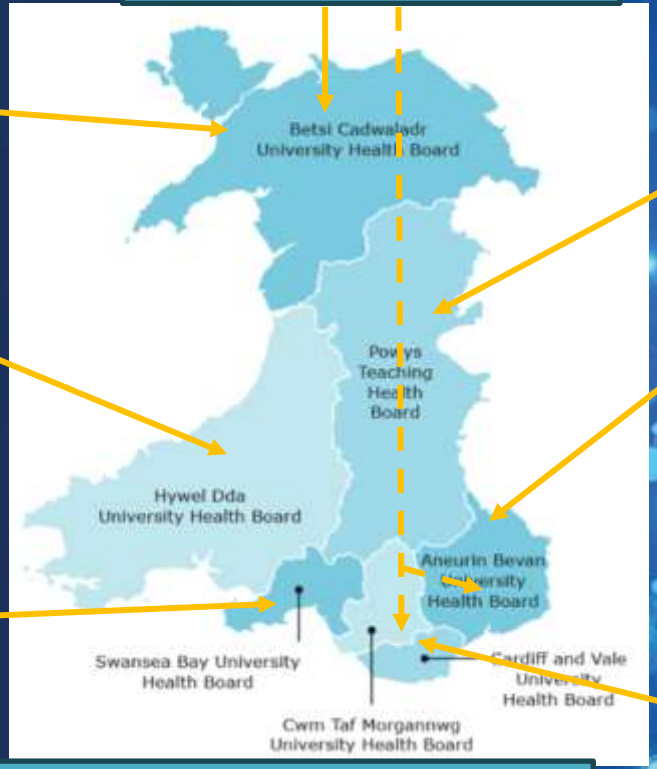
Where to and What next?

WAST -Dobshill N. Wales make Ready Depot to join Wrexham IM capability. Adoption in 3 S. Wales MRDs

BCUHB – progression from IM to patient linkage once IG completed. Catheter labs logical 1st step

HDDA – BGH Theatres to be live with patient linkage then adoption planned for all main hospital sites across the org Prince Philip, Glangwili then finally Withybush

SBUHB –current IM capability that exists across main sites to progress to patient linkage. Completely new areas for implementation Radiology, Lymphoedema and Rehab all being scoped



Powys – Brecon and Llandrindod to progress to patient linkage. All Powys Theatres then live.

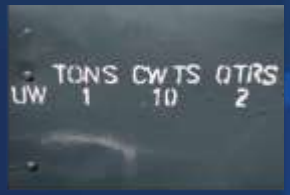
ABUHB – Current IM capability that exists across main sites to progress to patient linkage. Completely new areas for implementation of patient linkage include Endoscopy, Radiology.
Facilities to replace old ADC & Catering to adopt IM

CAV – Patient linkage to progress across theatres with 8 SSSU theatres underway. Significant other IM opportunities identified e.g. EU

CTM - Further IM adoption but patient linkage targeted for catheter labs and Royal Glam Theatres

Closing thoughts

‘if you do nothing else measure, measure, measure!’
Michael Porter



Data standards are key to any measurement

Questions?

Adding Value Through Partnership, Innovation and Excellence

Questions

The Global Language of Business

Scan4Safety and UDI forum

GS1 Healthcare - Better patient outcomes start with accelerated standards adoption and digital transformation

Elisa Zwaneveld – elisa.zwaneveld@gs1.org

17 July 2024

Healthcare Strategy: 7 focus areas

Trends, challenges and opportunities

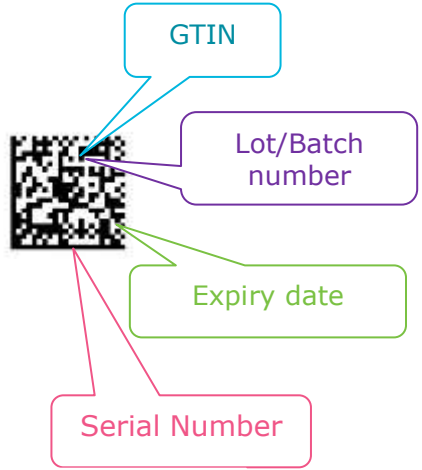
The 2D journey in healthcare: GS1 DataMatrix

- The 2D journey in healthcare started in the early 2000s with a handful of visionary industry leaders whose companies were facing multiple and growing challenges with product identification and regulatory developments.

Supply chain challenges

Regulatory challenges

SOURCE: https://medicfootprints.org/from-doctor-to-health-it-executive-2/

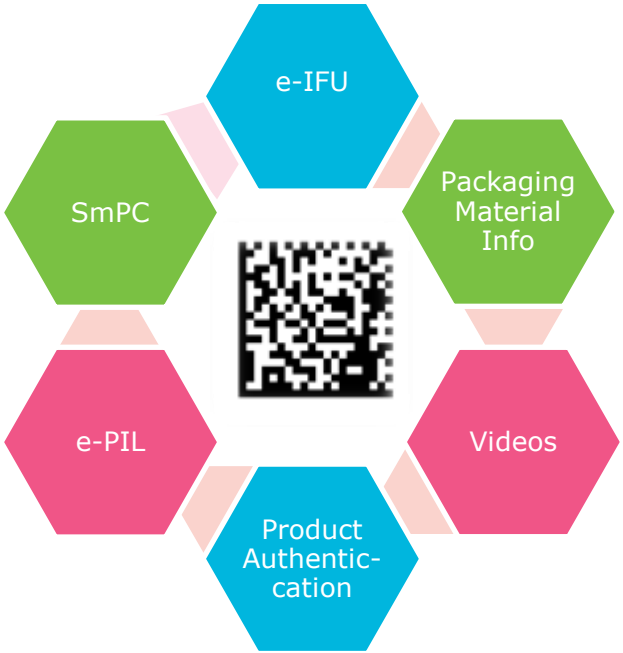


Early 2000s

2005 Launch of GS1 HC

2005 – 2010s and beyond

One product, one barcode… a world of information



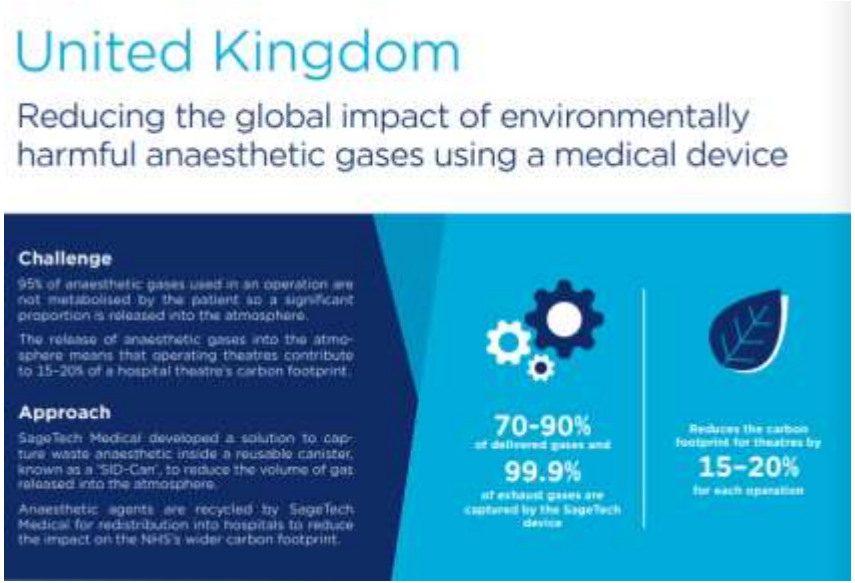
- **Products have a variety of information**
  - Instructions For Use, Product Information Leaflets, packaging material information, videos, etc.

- **Information is**:
  - Created by different functions
  - Stored in different and disconnected source systems
  - Required in multiple languages (EN, FR, JA, RU, CN, KO, etc.)
  - Available in multiple formats (HTML, PDF, audio, video, AR, etc.)

Work ongoing

How standards support more sustainable supply chains

Case studies



https://www.gs1.org/system/files/gs1-denmark_central-denmark-region.pdf
https://www.gs1.org/system/files/gs1seg230313_01_cases_studies_2024_final_.pdf

Visibility in the product’s lifecycle…

… supports sustainability improvements

Exchange product impact data

Inventory management and forecasting

Green procurement

Enable efficient reverse logistics

Automation and digitisation

Access to online product information (eleaflet)

Digital order-to-cash process (EDI)

Medication waste management

Improved stock level data quality because of automatic data capture (barcode)

Primary package identification enables order optimisation and administration of exact treatment quantities

Support proper disposal, recycling, drug return, reallocation, and other processes

Thank you!

Contact details: elisa.zwaneveld@gs1.org

Questions

The GS1 UK healthcare conference returns in 2025

- Save the date: **29–30 April 2025**
- Location: QEII London
- Event partner: BiP Solutions

Scan here to register your interest

Closing remarks

Thank you

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Engagement manager – healthcare

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