Medicines & Healthcare products Regulatory Agency

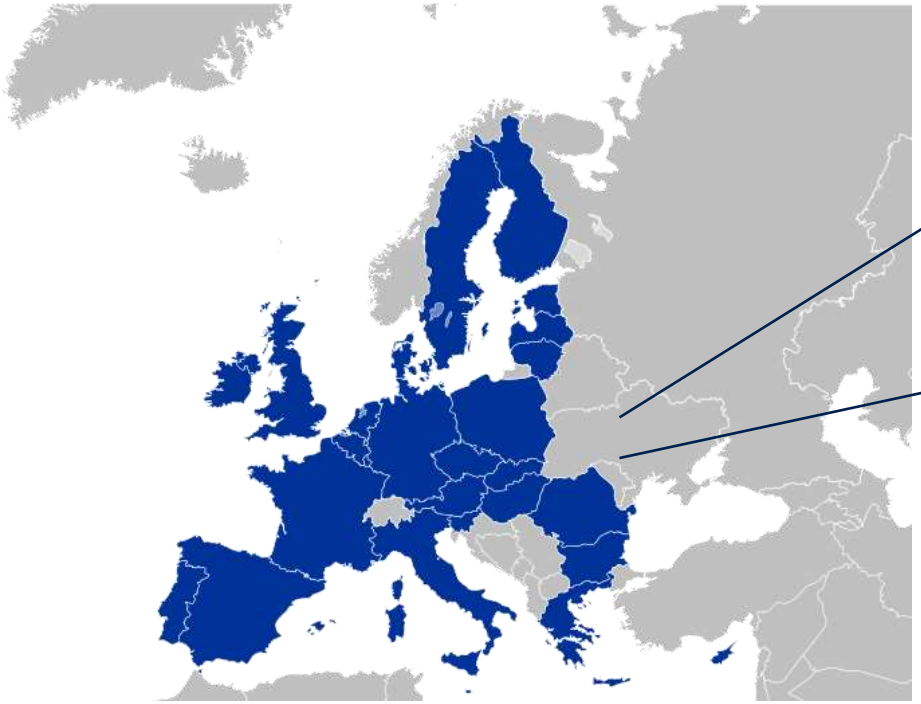
Use of Real World Evidence under European MDR

Japan-US Harmonization by Doing East 2017 Think Tank meeting
Tokyo - 7 December 2017
Andy Crosbie – Manager, Post Market Surveillance Strategy - MHRA

CPRD NIBSC MHRA

New European medical device regulations

New medical device regulations
Two EU Regulations - May 2017



MDR - Regulation (EU) 2017/745 – published 5 May 2017

Medical Devices Regulations

in-Vitro Diagnostic Devices Regulations

IVDR - Regulation (EU) 2017/746 – published 5 May 2017

New European Regulations: major upgrade

Council Directive 93/42/EEC - 14 June 1993	Regulation (EU) 2017/745 – 5 May 2017
60 pages	175 pages
23 Articles	123 Articles
12 Annexes	17 Annexes

Major upgrade of the MDR/IVDR

Headline measures:

- strengthening of the requirements for clinical investigation of medical devices (clinical trials)
- promoting European cooperation in the control and monitoring of devices (notified bodies)
- promoting transparency and traceability (includes mandatory Unique Device Identification)

Recording of UDIs will be mandatory

Manufacturers, importers, distributors and hospitals must store and keep UDIs by electronic means

UDI improves post-market safety

Using Unique Device Identification (UDI) will facilitate real world data collection/use and enhances device safety:

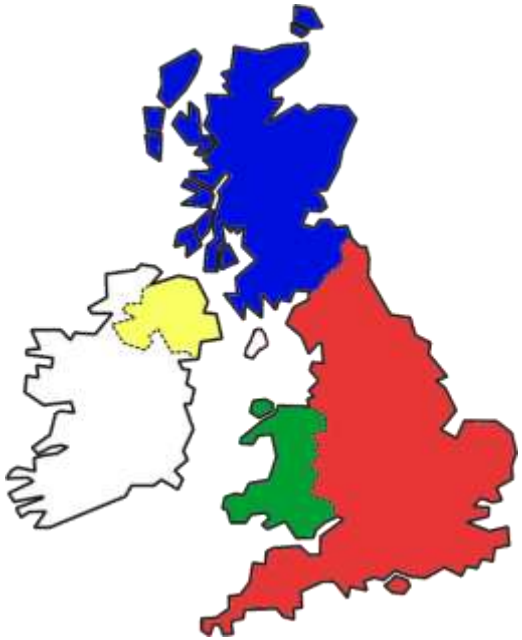
- improved incident reporting
- ➢better targeting of recalls
- better monitoring by competent authorities
- reduced medical errors
- helps fight against counterfeit devices
- as well as improving purchase-policy and stock-management by hospitals

** Regulation (EU) 2017/745: Recital 41*

UDI with a GTIN, Expiry and Serial Number

SCAN4SAFETY

Patient, Product, Place, Process.



Scan4Safety programme – Vision

UK ***Scan4Safety*** programme – Implementation of GS1 *core enablers*

Deliverables– Initial Core Enablers

Location Identification

- Implementing **GLNs**, a global standard for location identification

Unique Location Identification

Patient Identification

- Wristbands **GSRN** compliant can be scanned by patient systems

Unique Patient Identification

Catalogue Management

- All relevant processes use the **GTIN** as the primary product identifier

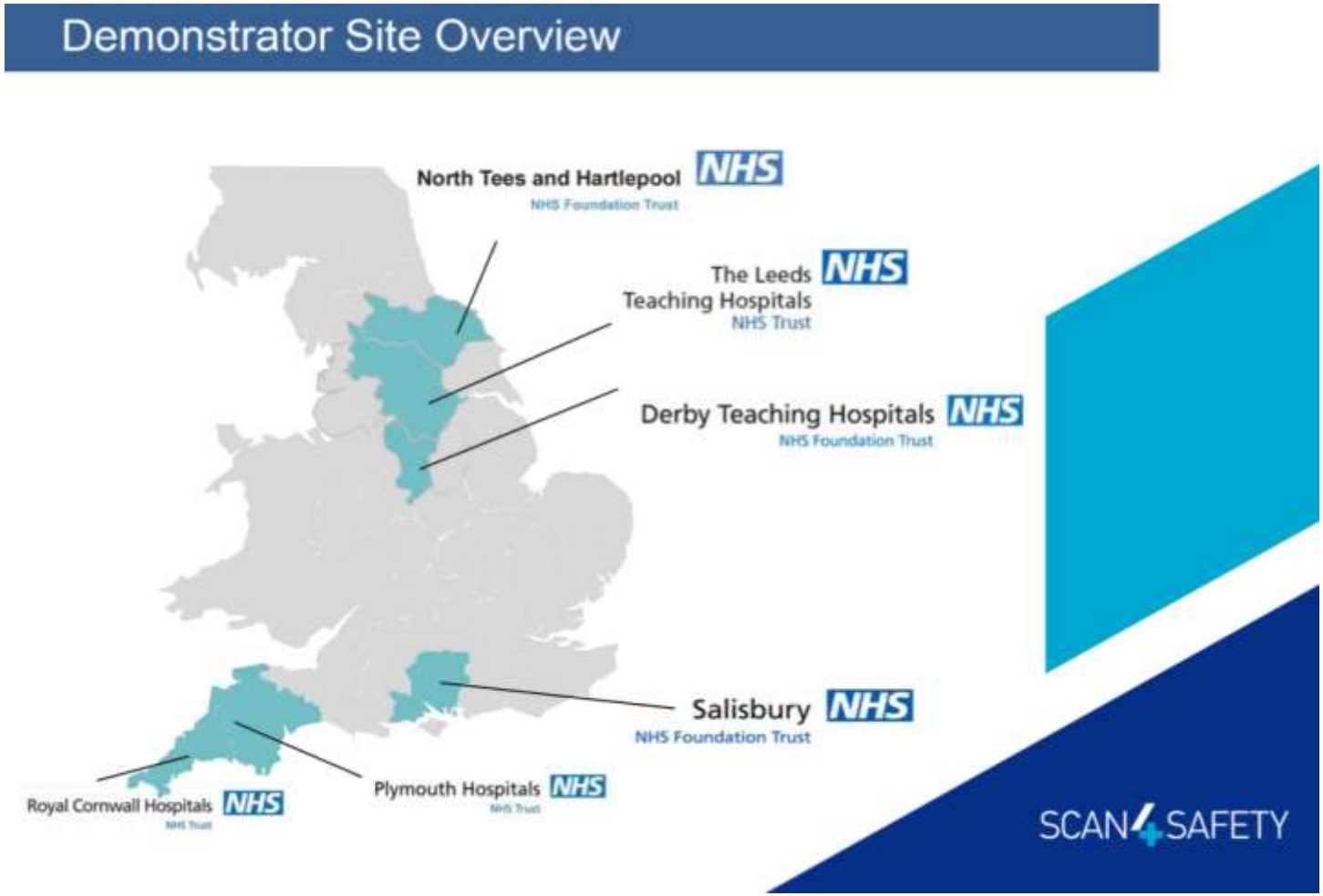
Unique Device Identification

SCAN4SAFETY

Scan4Safety programme – Demonstrator sites

Established January 2016

Aim to complete first wave of work by December 2017



Scan4Safety – initial successes

Scan4Safety – some of the wins so far:

- Improved control of internal supply chain – cut waste
- Facilitate recalls
- Location of patients and equipment
- Reducing occurrence of critical medical errors - “never events”
- Better information re. operation efficiency

** Regulation (EU) 2017/745: Recital 41*

Using UDI / GS1 standards will help to improve patient safety – implant tracking and surveillance

+ convergence with registries / real world data collection

- Implant / patient track-&-trace
- Post-market safety monitoring

More accurate and convenient registry and real world data collection

Thank you

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www.scan4safety.nhs.uk