GS1 Update and UDI Databases

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22nd Asian Harmonization Working Party, New Delhi, India

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Increasing demands on the Healthcare systems

- Increasing costs for healthcare
- Quality of patient care
- Big data
- Traceability – counterfeiting
- Personalised medicines
- Mobile technologies
- IoT
- Blockchain
- 3D printing

Standards have a role to play

GS1 – a global standard organisation

1 million	150 countries	6 billion	112 MOs
over 1 million companies worldwide use GS1 standards	25 industries served across 150 countries	Barcodes scanned more than 6 billion times per day globally	112 Member Organisations around the world

Our vision in Healthcare

The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders seeking input and direction for global standards in healthcare for

patient safety

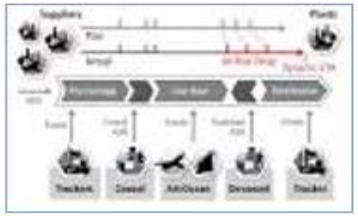
supply chain security & efficiency

traceability

product data

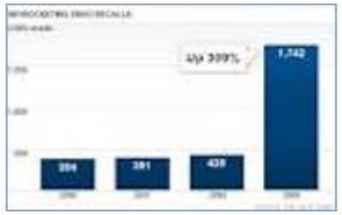
Traceability – important worldwide

Drivers

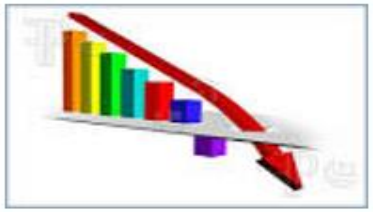


Supply Chain Visibility

Product Protection



Recall Improvement



Returns, Shipment accuracy and efficiency

Reimbursement

Traceability Functions

Identify

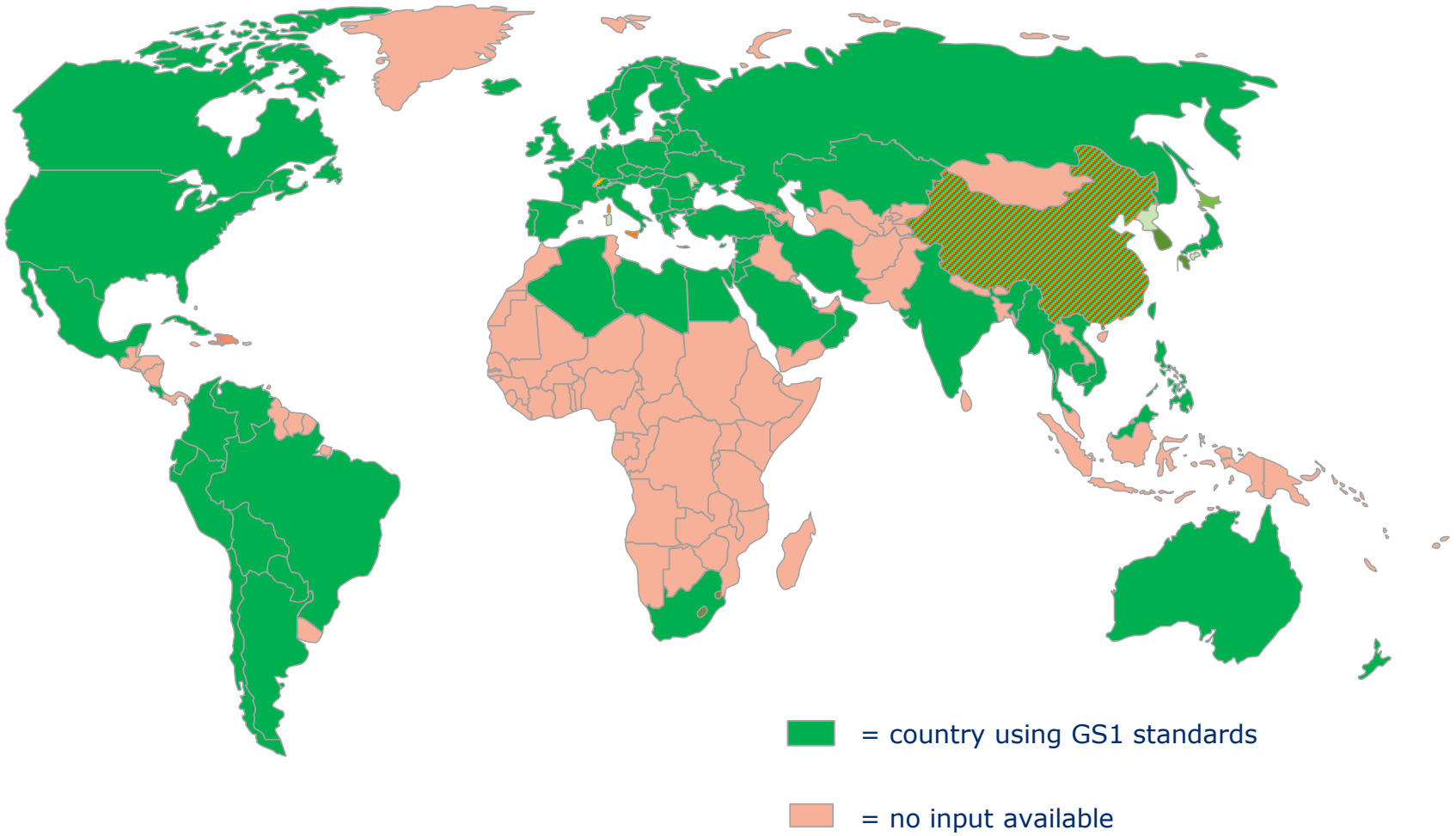
Verify

Track

Trace

Report

Harmonisation around the identification of pharmaceuticals

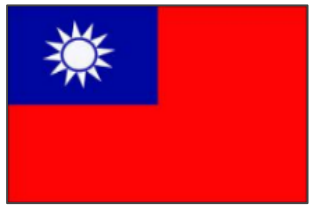


Traceability regulated and implemented







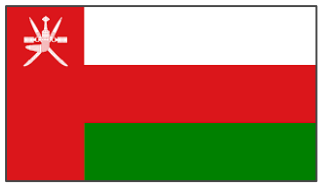
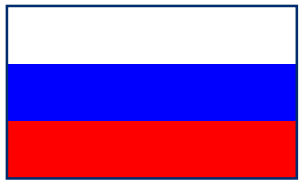












APEC Roadmap for Global Medical Product Integrity and Supply Chain Security

- 5 year project (Jan. 2013 - Dec. 2017)
- 10 work streams, incl. Track & Trace Systems

- Objective:
  - examine current practices and regulatory requirements
  - develop recommendations to regulators
  - develop training programs

- 3 overarching recommendations supporting the APEC goals of regulatory harmonisation and of 10% reduction of supply chain cost:
  - define clear objective to be achieved
  - collaborate with stakeholders
  - recommend the use global data standards (GDS)

APEC Roadmap for Medical Product Quality and Supply Chain Integrity initiative

- APEC Medical Products Supply Chain Security Toolkit went live in March and is housed at the APEC Harmonization Center website http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf

- **APEC Ministerial Meeting (AMM) statement:"** *We commend the progress achieved by APEC members in establishing the Supply Chain Security Toolkit for Medical Products."*

- Establishment of APEC Regulatory Sciences Centers of Excellence (CoEs) at the following institutions: Northeastern University – United States (Biotherapeutics); Peking University - China (MRCT/GCP); PMDA - Japan (MRCT/GCP and Pharmacovigilance & Medical Device Vigilance); Duke/NUS Singapore (MRCT/GCP); Regulatory Affairs Professionals Society of Chinese Taipei, in cooperation with Chinese Taipei FDA (Good Regulatory Management); Korea Institute of Drug Safety and Risk Management (KIDS) (Pharmacovigilance); University of Tennessee (Supply Chain); and US Pharmacopeia (Supply Chain).

Traceability with GS1 standards in Turkey

- The main challenge in Turkey was to ensure and guarantee the reliable supply of drugs to patients
- The solution is **traceability, which is defined as full, end to end, actionable visibility of finished pharmaceuticals in healthcare globally, from point of production to point of use.**
- Results of Turkey's efforts have been tremendous, and in these five areas alone, **the nation is seeing savings of 1 billion US dollars annually.**

Prof. Özkan Ünal,
President of Turkish Medicines and Medical Devices Agency since December 2014.

http://www.gs1.org/sites/default/files/docs/healthcare/gs1_healthcare_reference_book_2015-2016.pdf

Many achievements and benefits

- Safe medicines, prevents counterfeiting
- Prevents resale of medicine
- Expedites recalling of medicine
- Prevents sale of expired medicine
- Preventing drug shortages
- Quality data for insurances
- Provides statistics to develop policies on Rational Medicine Use
- Enables pharmacovigilance and strategic planning

Interagency Supply Chain Group (ISG) Adoption of global GS1 standards

The ISG: **Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO** published a position paper in August 2017 on the **adoption of GS1 standards** committing to the process of transitioning to include established, global data standards as part of their procurement requirements and support country uptake of these standards.

From the Interagency Supply Chain Group:

Visibility for Health Systems: Adoption of Global Data Standards (GS1)

About the ISG

The broad purpose of the Interagency Supply Chain Group (ISG) is to share information and seek greater alignment across supply-chain investments to bring more impact to individual agency supply chain strategies. The group promotes coordination both globally across programs, and locally through national leadership with the overall aim of improving the efficiency and effectiveness of in-country supply chains. The ISG is an informal partnership of 15 major actors involved in providing supply chain support to countries: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.

Boxes of medical supplies are sorted before being distributed among the mobile health brigades at the Chicualacuala District hospital in Maputi, Moramtique, in July 2016. ©UNICEF/Rich.

Background

Medicines supply chain execution and responsiveness require synchronization of supply and demand, as well as the orchestration of three flows of commerce, that are the movement of goods, information and funds, across an increasing number of logistics and trading partners, spanning a wide (if not global geographic) region. Whilst the implementation of traceability systems has been identified by National Regulatory Authorities as a useful and efficient tool to combat falsification and illicit distribution of medical products, only some countries have issued progressive traceability regulation. Many have not, and are still assessing various implementation mechanisms, alternatives or otherwise have not approached this topic at all[1]. The international community has recognized the need to support countries in determining what these best approaches are. Since 2014, the international development community has promoted the use of global data standards (GS1) to provide a wider and harmonized framework for supply chain visibility, strengthening anti-counterfeiting measures and sharing of data between parties. The Interagency Supply Chain Group recognizes the value for advocating for both effective and sustainable solutions to enable traceability and safe passage of medicines through national supply chains and have committed to strengthening this response accordingly.

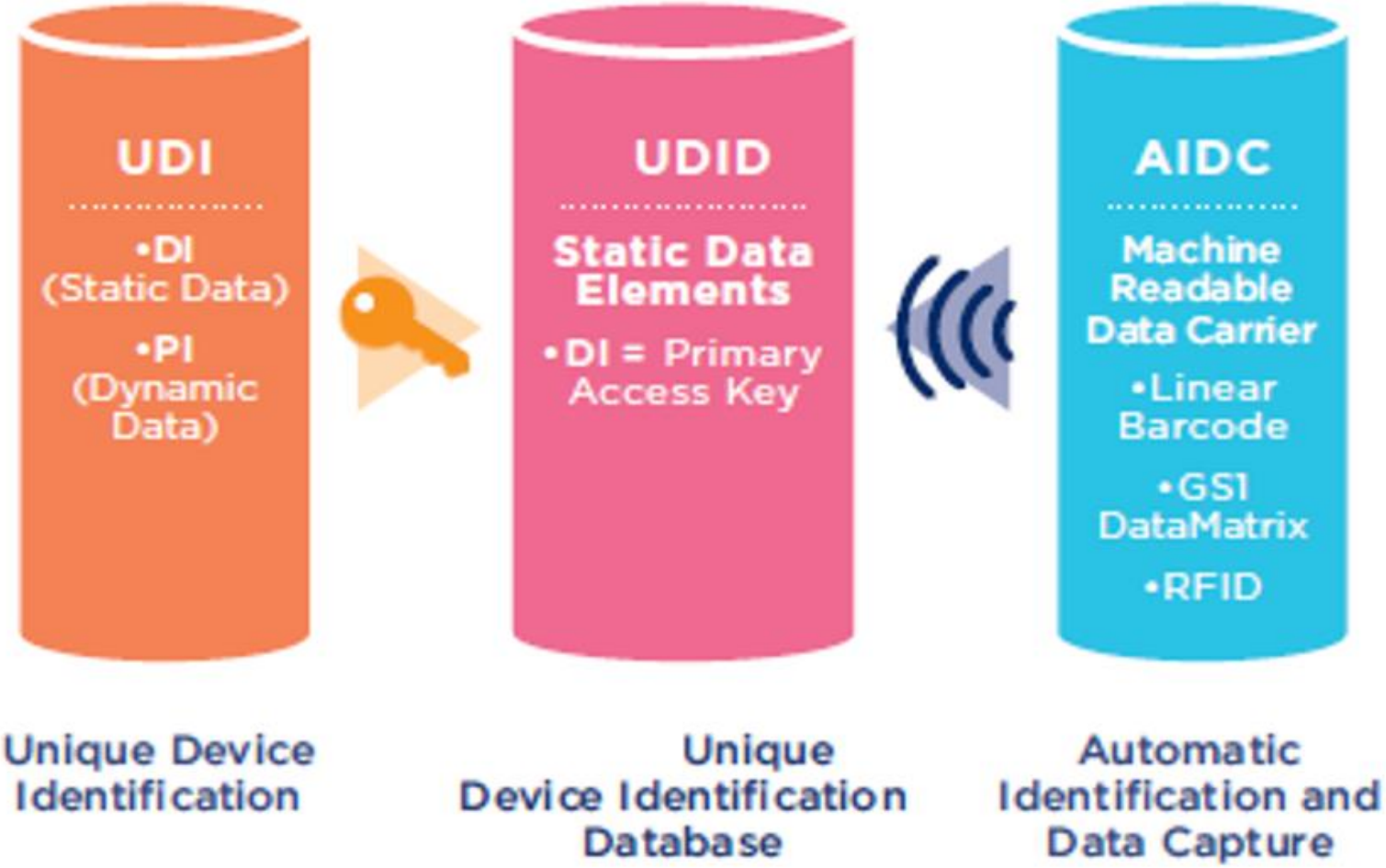
Current activities of the ISG

- Strengthen global and country advocacy for the adoption of GS1 standards and traceability systems with countries, in collaboration with other relevant stakeholders.
- Accelerate the understanding and adoption of an open and global supply chain standard, globally, through technical support, education, and collaboration with manufacturers.
- Collaborate to improve donor procurement guidelines, including the requirement for the use of GS1 standards for identification and barcoding on the different packaging levels, and coordinate with manufacturers on an implementation timeline.
- Develop a roadmap & timeline for the adoption of GS1 standards in labeling all health commodities and products.
- Provide technical assistance to several countries in defining parameters necessary to implement National Traceability Systems. These include development and finance implementation plans for barcoding of health commodities for member states. e.g. support to the Government of Ethiopia to implement a nation-wide adoption of barcoding technology.

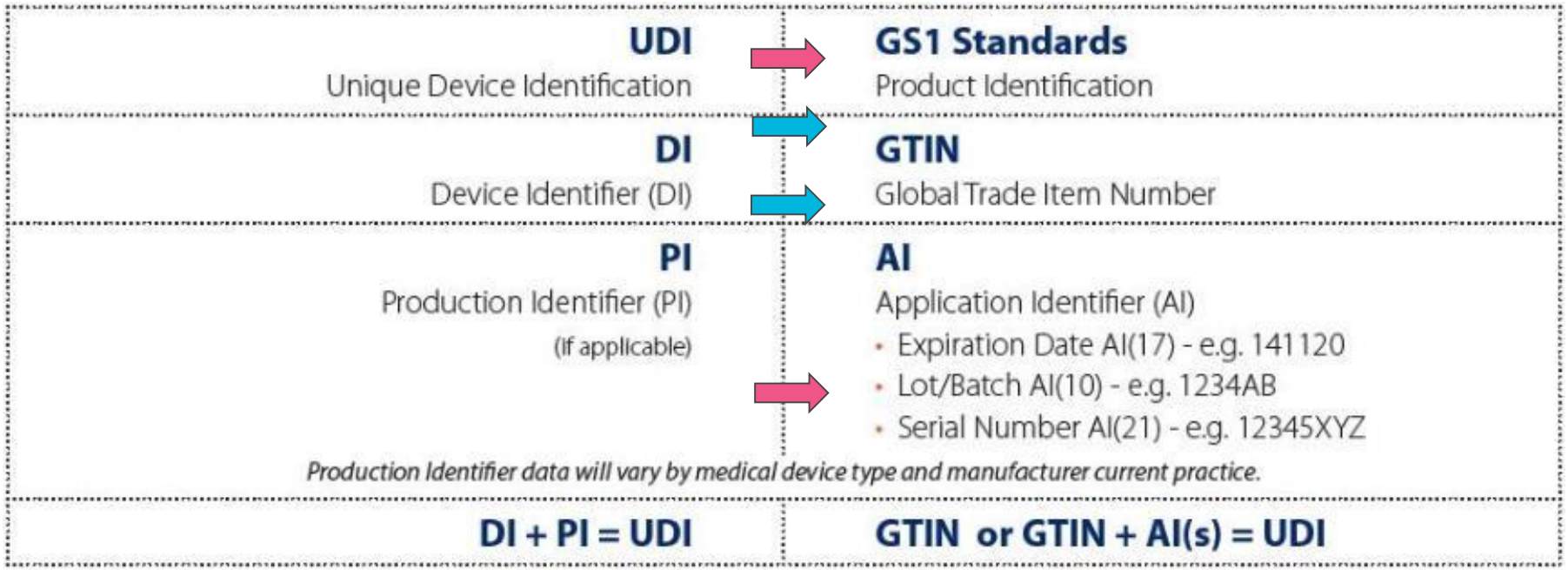
[1] Fourth meeting of the member state mechanism on substandard/spurious/falsely-labelled falsified/counterfeit medical products, 13 November 2015, provisional agenda item 4C. Existing technologies and 'track and trace' models in use and to be developed by member states. Draft document submitted by Argentina.

Requirements for medical devices identification and UDI

The UDI system



UDI in GS1 AIDC terms… identify



The **HRI format** shall follow the rules of the UDI Issuing Agency

GS1 key to implementations on medical devices

Accredited as UDI Issuing Agency by the US FDA

Mandated by ANMAT for traceability of certain devices in Argentina

99% of medical devices identified with GTIN in Japan

MHLW Annual Survey, 2012

£3 million on average saved each year in every NHS hospital in England

Lord Carter interim report, 2015

UDI assigning entities listed in the EU MDR

91,8% of devices identified with GTIN in Turkey

Turkish National Drug and Medical Device Databank (TITUBB)

Device identification system: a UDI system is established

Scope:

- Apply to **all medical devices placed on the market except custom-made devices**

Approach:

- Substantially based on internationally recognised principles and guidance

Use of UDI:

- Basic UDI-DI is the access key for device-related information entered in EUDAMED
- Reference to Basic UDI-DI in key documentation (Declaration of conformity, certificates)
- UDI shall be used for reporting serious incidents and field safety corrective actions
- UDI storage obligations for Class III implantable devices

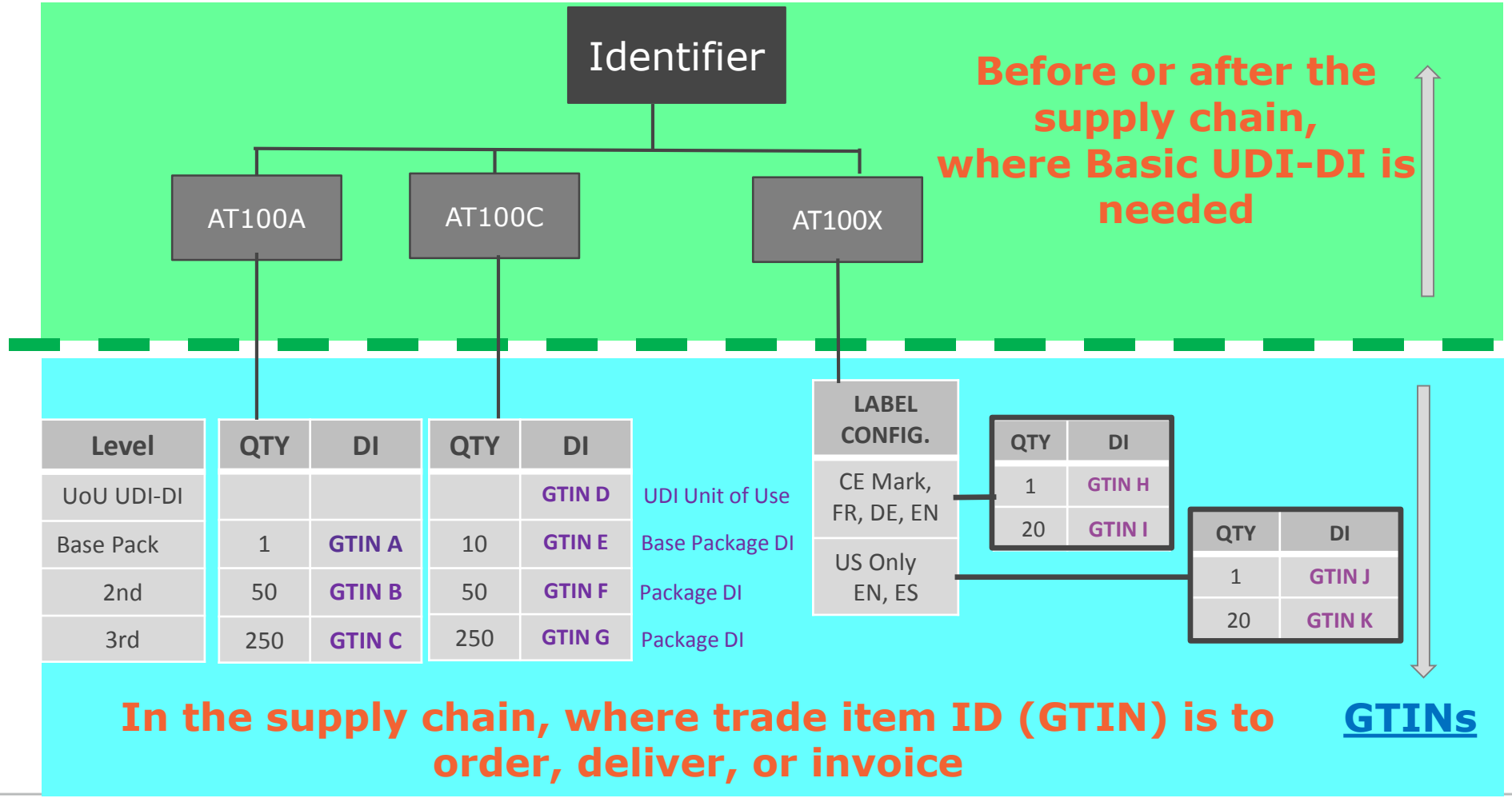
EU “Basic UDI-DI”

The EU Commission definition of “Basic UDI-DI”:

“The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and shall be referenced in relevant certificates and declarations of conformity.”

(MDR as officially adopted, before publication – Annex VI Part C. 1)

EU “Basic UDI-DI”

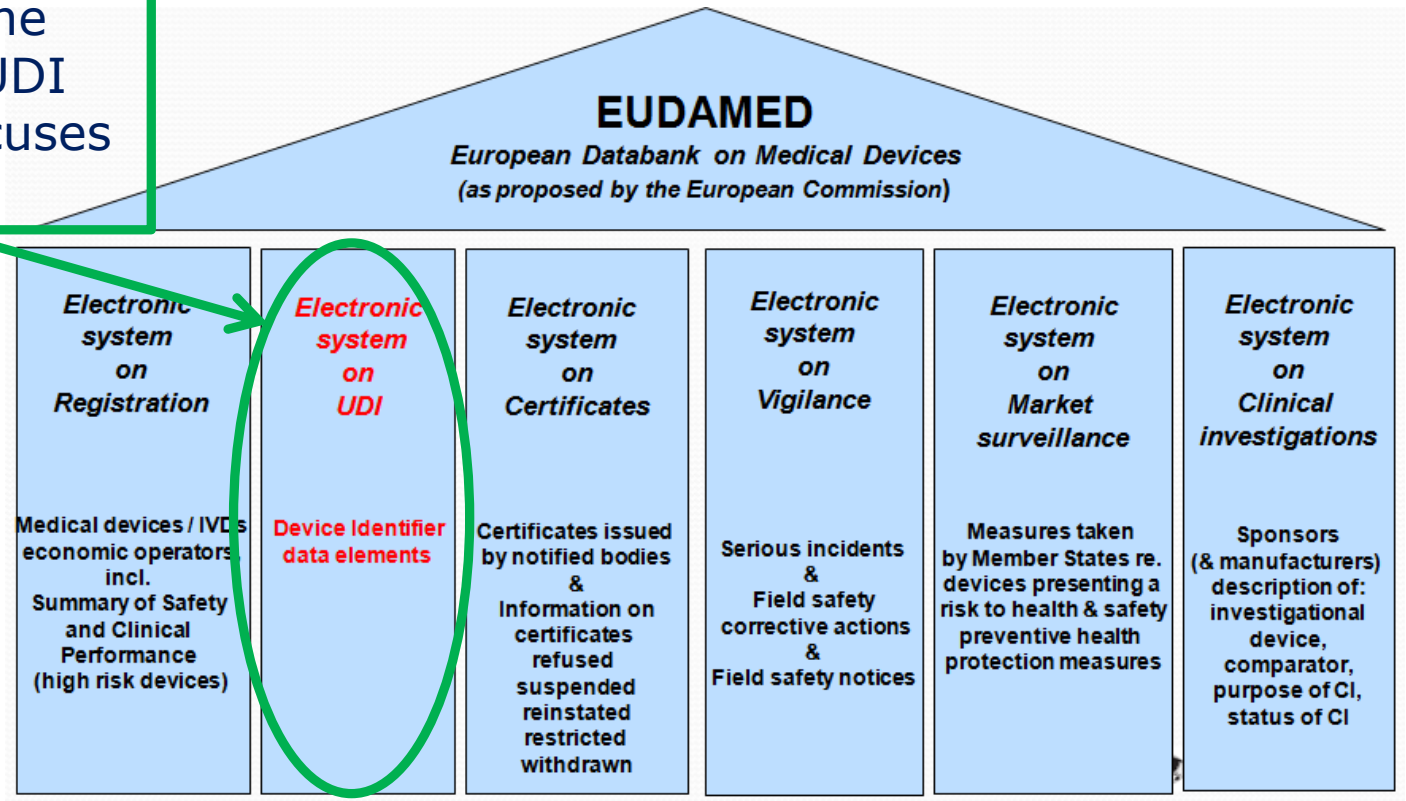


UDI system in EU

- Assignment of a UDI made of a DI and a PI, application of the UDI on the label or the package of the device and higher level of package.
- Data submission in a UDI database (EUDAMED)
- Storage of UDI, *preferably by electronic means*, for class 3 implantable devices and for devices identified via implementing acts by the economic operators, the health institutions and healthcare professionals. **Traceability** by identification of any operator/health institution to whom one has directly supplied a device and any operator who has directly supplied with a device: one-up-one-down traceability model
- The UDI shall be included in the field safety notice for reporting serious incidents and field safety corrective actions.

EUDAMED – a complex database

Part that the U.S. FDA UDI system focuses on today...



- Registration
- UDI database
- Certificates
- Vigilance
- Market surveillance
- Clinical investigations

"**Basic UDI-DI**" is the main key linking device data across Eudamed

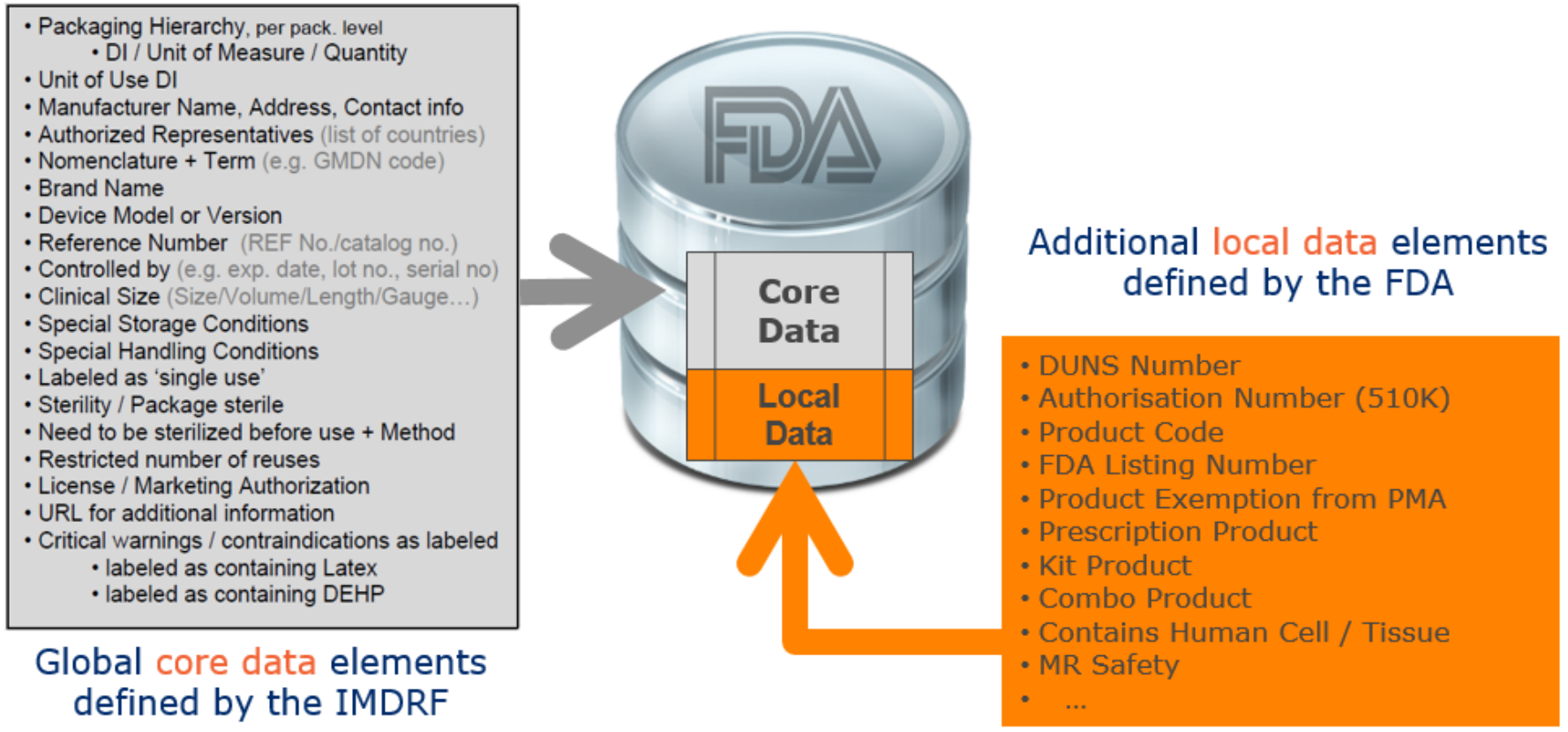
EUDAMED

- Manufacturers can upload the data into EUDAMED via web-portal (manually) or XML (machine-to-machine)
- Divided into **economic operators registration, product registration and UDI registration**
- Delegated/implementing acts to provide more details on implementation

- **Deadline** for implementation should cover all class of MD

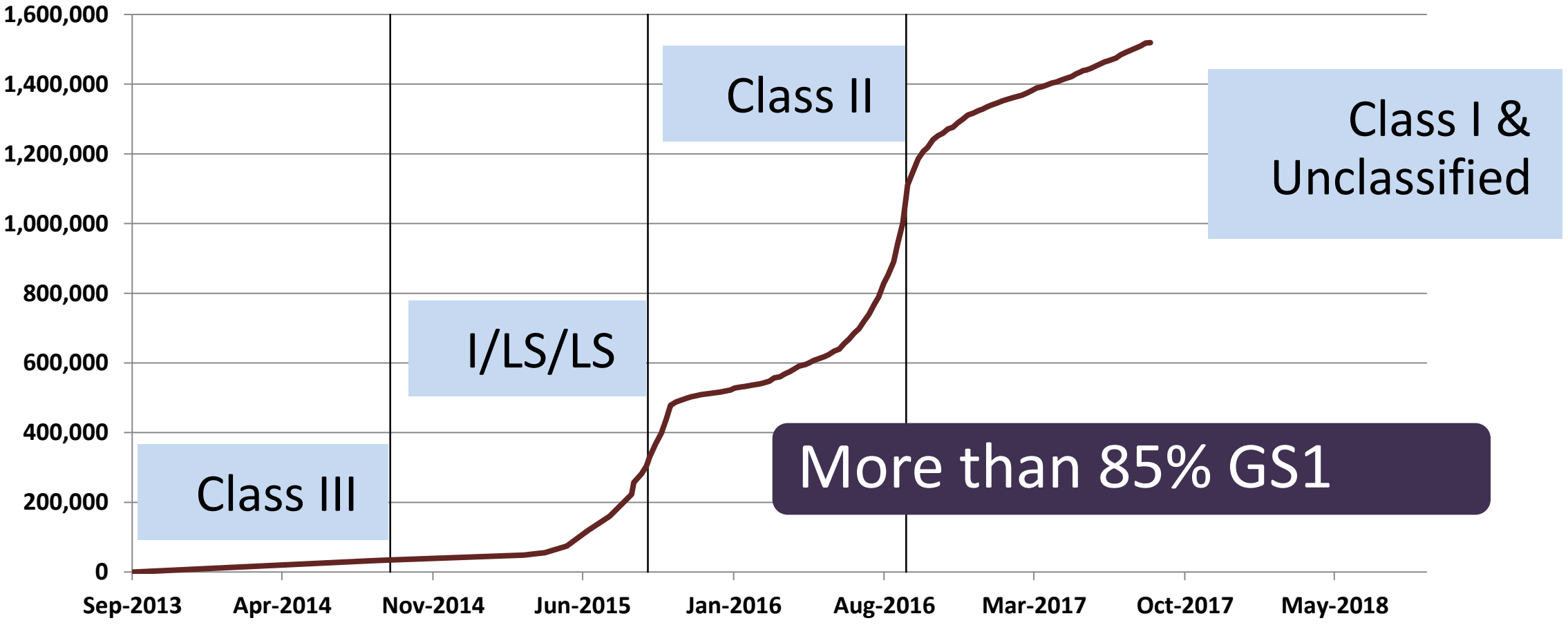
- Open points :
  - Deadline for EUDAMED to be operational?
  - No usage of HL7/SPL – how to map?
  - Nomenclature to be used?

UDI Databases:
Global Core Data + Local Data



GUDID Records and Submission Compliance Deadlines

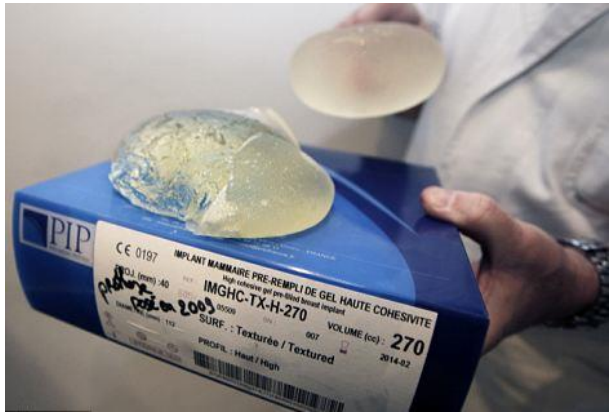
Data Current as of September 5, 2017



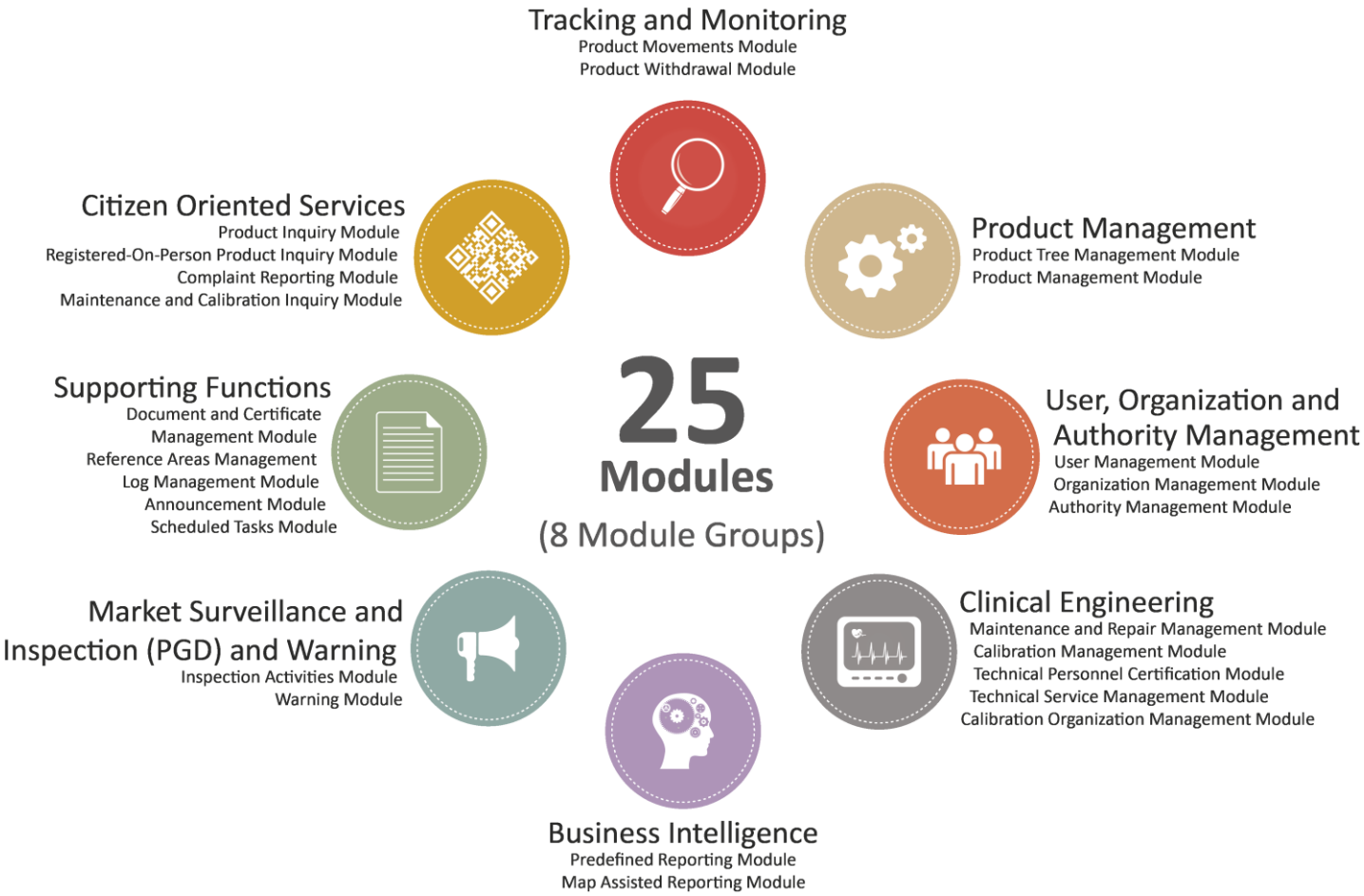
Source: US FDA presentation at GS1 Healthcare conference in Chicago, October 2017

Traceability for patient safety

- In many countries implant registries are being build or already in place
- Data need to be interoperable for the benefit of patients
- Capture data automatically – no manual entries

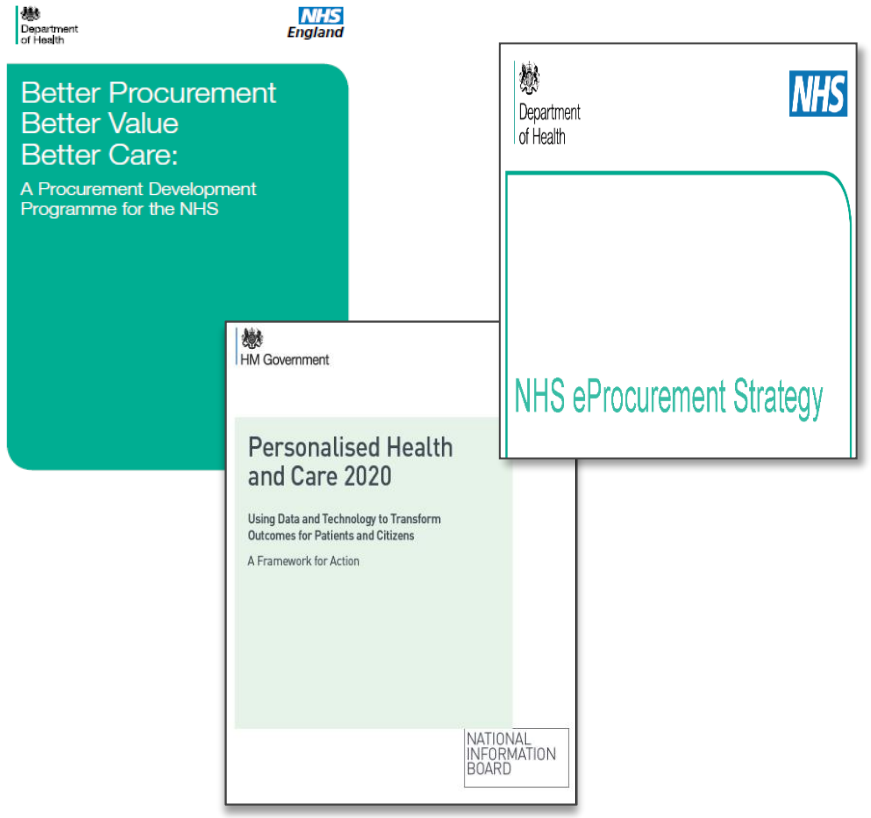


Turkey – new Traceability system



Source: Presentation of Turkish MoH at GS1 Healthcare conference in Chicago, October 2017

England – NHS



Objectives:

- Deliver efficiency and productivity gains
- Improve data, information and transparency
- Re-think clinical engagement in procurement
- Improve trust capabilities in procurement

Actions:

- **Mandate through contracts GS1 standards GTIN, GLN and GDSN**
- **Create a single NHS GS1 data pool**
- Define standards for eProcurement
- Establish standards for datasets/classification
- Put implementation support in place

£6m actual financial benefits realised to end of October 2017 against a forecast of £5.67m.

Scan4Safety at Derby recap: Benefits Delivered

- **£1.2m annual saving in consumption reduction in theatres**
- £360k savings identified in inventory reduction (to be actioned)
- Traceability of implantable products by batch/lot number to patient record
- Auditable evidence – resolution of SUI
- Product standardisation and switching opportunities
- Reduction in clinical time spent on non-clinical activities
- Improved clinical coding
- Ability to analyse clinical variation in practice
- Improved visibility of inventory

Source: Jones & Downs, Derby Teaching Hospital, GS1 Healthcare conference, Chicago

SCAN4SAFETY

Patient care and patient safety Improvement

- Surgical teams now alerted if expired or recalled stock
- 93% of implantable devices accurately tracked to patient
- Significant Clinician Time released back to patient care
- Product recalls now performed in under an hour
- Tracking Provider expertise relative to patient need and quality of care

Source: Anne Snowdon at GS1 Healthcare Conference Chicago 2017

Getting it right !

Source: David Berridge, Medical Director, Leeds Teaching hospital at GS1 Healthcare conference in Chicago

Benefits of UDI

- More accurate reporting, reviewing and analyzing of **adverse event**
- Reducing **medical errors** by providing health care professionals access to information
- Enabling to **document device use** in electronic health records, clinical information systems, claim data sources and registries.
- A more robust **post market surveillance** system
- Manage **product recalls**
- Foundation for a **global, secure distribution chain**, helping to address counterfeiting and diversion and prepare for medical emergencies.

The need to align on a global UDI framework

- UDI is very beneficial - it is crucial that regulators around the world align on the IMDRF Guidelines and ensure consistency when setting-up regional or national UDI system

- This will ensure :
  - highest levels of patient safety beyond borders
  - harmonized identification systems for medical devices globally

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