GLOBAL GS1
HEALTHCARE CONFERENCE

Copenhagen Denmark
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UNIQUE DEVICE IDENTIFICATION

Situation in the International Medical Device Regulators Forum (IMDRF)

and in the European Union

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EUROPEAN COMMISSION - Health and Consumers DG

Health and Consumers

European Commission

CONTENT OF THE PRESENTATION

1. **UDI: an IMDRF Work Item**

2. **Achievement: the IMDRF Guidance on UDI**

3. **Extension work on UDI Databases (UDIDs)**

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4. **EU activities on UDI and Traceability**

5. **Outlook for the future**

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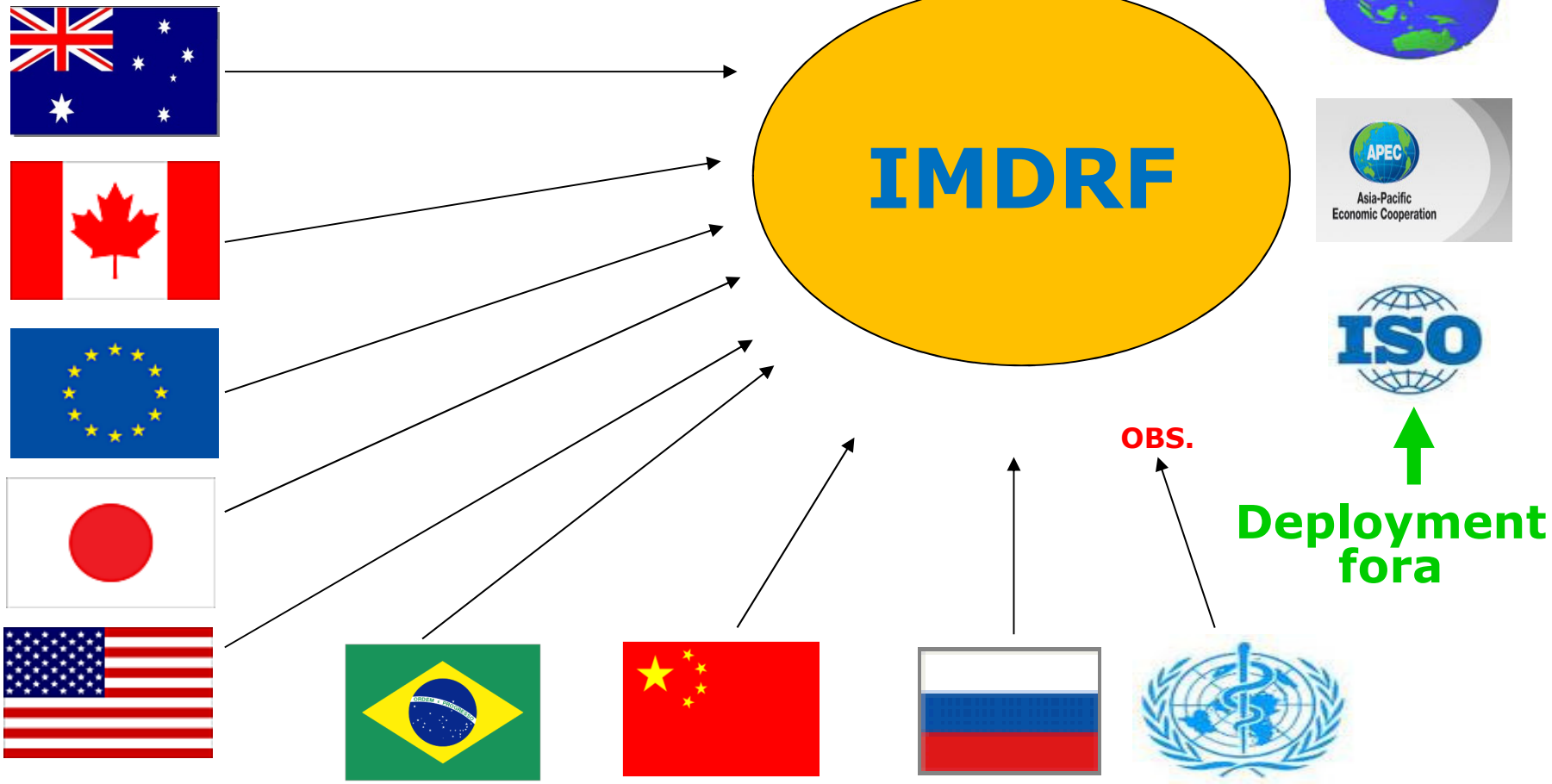
Aspiration to convergence



International Medical Device Regulators' Forum (IMDRF)

Australia, Therapeutic Goods Administration
Brazil, National Health Surveillance Agency (ANVISA)
Canada, Health Canada
China, China Food and Drug Administration
European Union, European Commission DG Health and Consumers
Japan, Ministry of Health, Labour and Welfare with Pharmaceuticals and Medical Devices Agency
Russian Federation, Russian Ministry of Health
United States of America, US Food and Drug Administration

+ Observers (**WHO**) , Affiliates (**AHWP, APEC**)

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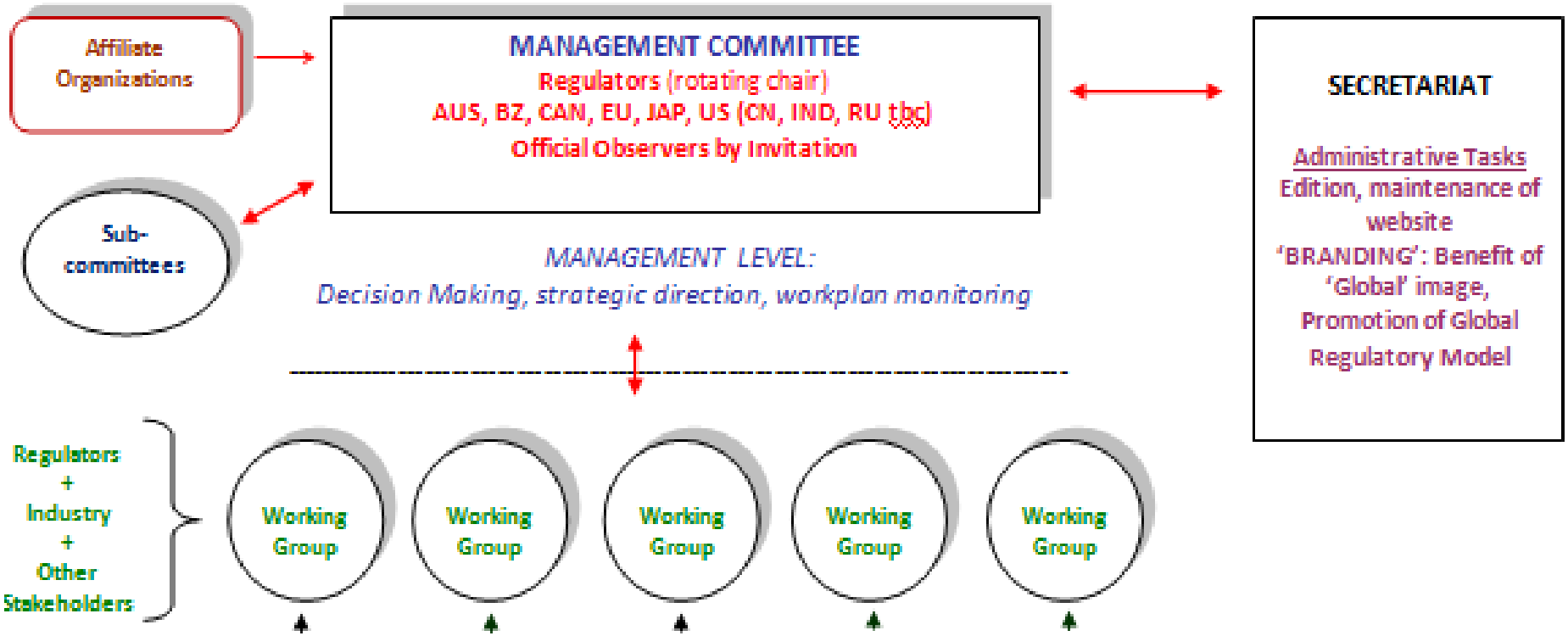
INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM



IMDRF International Medical Device Regulators Forum

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IMDRF Work Item: UDI
Roadmap for implementation

European Commission

2012-2013

UDI Work Group

- US-FDA
- CHINA CFDA
- EU DG SANCO
- JAPAN PMDA
- ADVAMED
- HEALTH CANADA
- EUCOMED /EDMA
- DITTA
- JFMDA/JIRA
- AHWP
- ANVISA

…With some invited observers.

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UDI SYSTEM

European Commission

Bar-coding
for every Medical Device

(01) 1 4987578 12345 0 (17) 251210 (10) ABC12345

DI
Device Information
- Company
- Product ID

PI
Production Information
-Life
-Serial or Lot Information

UDID
Database
For DI part Only

DI
-Company Name
Address
-Product Name
.
-GMDN
-code
-term
.
. etc

IMDRF UDI Guidance

The IMDRF UDI Guidance was adopted as a final document (IMDRF/WG/N7:2013) by the Management Committee on 15 November 2013.

IMDRF International Medical Device Regulators Forum

Final Document

Title: UDI Guidance
Unique Device Identification (UDI) of Medical Devices

Authoring Group: IMDRF UDI Working Group

Date: 9 December 2013

Despina Spanou, IMDRF Chair

Summary table- UDI - AIDC Marking / Placing Rules

Category	Unpacked UoU → direct marking	Base Package	Bulk Package (higher pack. config)	Remarks
Single-use MDs				
• IMDRF class A (low-risk)	-	-	DI + PI*	• *PI not required by the US FDA
• IMDRF class B (medium-r.)	-	-	DI + PI	
• IMDRF classes C+D (high-r.)	-	DI + PI	DI + PI	
Re-usable MDs				Require reprocessing between uses
• all risk-classes	DI + PI	DI + PI	DI + PI	• not all package levels necessarily exist • surgical instruments, IV pumps, etc
Implantable MDs				PI = serial number for active implants
• sterile	-	DI + PI	DI + PI	• usually single packed (1 piece)
• non-sterile	must be identifiable	DI + PI	DI + PI	• often multiple packed (‚n' pieces) • not necessarily DPM, other tech. options allowed to identify the unpacked MD
Others				
• Kits (IVD / non-IVD)	-	DI + PI	DI + PI	• concerns the kit package itself
• Standalone Software	DI + PI	DI + PI	-	• must not necessarly be packed
• config. MD Systems	DI + PI	-		• AIDC carrier to be placed on a ‚main part' (primary mode of action)
• OTC exclusively	-	-	DI (linear bar code)	• Point-of-Sale scanners can't work with PI
• OTC + other channels	-	-	DI + PI (non-concatenated)	• PI should be presented in a separate AIDC carrier due to Point-of-Sale scanners

DIVERGENCES BETWEEN THE FDA UDI RULE AND THE IMDRF UDI DRAFT GUIDANCE…?

- **NOTHING SIGNIFICANT…** **(Examples)**
- **ALIGNMENT** **(Fair…)**

The UDI Challenge

Manufacturers DBs

FDA UDID

EU UDID

China UDID

Japan UDID

UTOPIA … One Global UDID

Deployment of a small number of regional UDIDs

European Commission

Extension of the UDI Work Item

UDI Guidance adopted by IMDRF-4 not sufficient?

—

IMDRF MC Decision: A joint "RPS + UDI" subcommittee to capture regulatory life-cycle aspects.

RPS= Regulated Product Submission,

now extended to Common Data Elements for regulatory life-cycle

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PROPOSED EXTENSION OF IMDRF UDI Work item in 2014

2013	2014-2015
GUIDANCE IMDRF/WG/N7FINAL:2013	HARMONIZED DATA SETS (UDI DATABASES) Part of RPS Extension "Common Data Elements"

European Commission

Proposed "RPS + UDI" Extension:

DATA FIELDS AND DATA SETS:

CLEAR STANDARDIZED RULES ON RIGHTS

TO ACCESS, READ, WRITE OR CORRECT DATA

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I. E.

level of identification, verification, validation of data

same/similar mechanism to keep data in the UDID up-to-date

standardized structures

standardized (secured and legally correct) protocols for data exchange

technical minimum hardware requirements to enable the interaction and communication between UDIDs

standardized field names, etc

(UDIDs challenges ahead)

RPS/UDI extension Work plan approved on 30 June 2014

With strong involvment of IT/database experts

Open to all IMDRF jurisdictions

Aiming at ensuring the alignment with the GUDID Data Sets Formats

With MC consent, constitution of WG in progress

European Commission

Benefits expected: Paving the way…

For the IMDRF "Regulators":

towards future international traceability.

For Industry:

towards less burdensome UDID entries

THE EU AGENDA 2020

European Commission

EU political strategy for the globalisation phenomenon.

"The Council of the EU invites the European Commission:

- to take the following considerations into account in the course of its future legislative work (…),

as the medical device sector is a global one, a stronger coordination with international partners is desirable

in order to ensure that medical devices are manufactured according to high safety requirements worldwide" **(OJ C202/7 of 8.7.2011).**

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EU AGENDA 2020

European Commission

EU Internal Market

↓

EU 'Regulation'

International Trade

↓

Global 'Regulation'

Two sides of the same medal

→ INTERNATIONAL REGULATORY CONVERGENCE!

CHAPTER III: Identification and traceability

(MDs) Article 23, 24, 25 and 27
(IVDs) Article 22, 23, 24 and 26

- Identification within the supply chain

- Unique device identification system

- Electronic system on registration of devices and economic operators

- European databank (EUDAMED)

European Commission

Identification within the supply chain

"Economic operators shall be able to identify:

(a) any economic operator to whom they have supplied a device;

(b) any economic operator who has supplied them with a device;

(c) any health institution or healthcare professional to whom they have supplied a device.

Upon request, they shall inform the competent authorities thereof."

In the EU

UDI System's EU Proposals for MD/IVDs Regulations

Provisions on the future EU UDI System define:

- **The general framework of the System,**
- **The objectives of the System,**
- **The powers delegated to the Commission,**
- **UDI Electronic System Data Elements,**
- **Accreditation system (UDI issuing entities)**

European UDI System

- A system for Unique Device Identification shall be put in place in the EU;

- A UDI system for identification and traceability of devices consisting of:
  - *(a) production of a UDI (DI+PI),*
  - *(b) placement of the UDI on the label of the device,*
  - *(c) storage of UDI by economic operators and the health institutions through electronic means,*
  - *(d) establishment of an electronic system on UDI.*

- Entities designated for the assignment of UDIs according to international standards.

…i.e. IMDRF

European Commission

UDI System

- The UDI shall be used for reporting serious incidents and field safety corrective actions;

- Economic operators and health institutions shall store and keep both DI and PI;

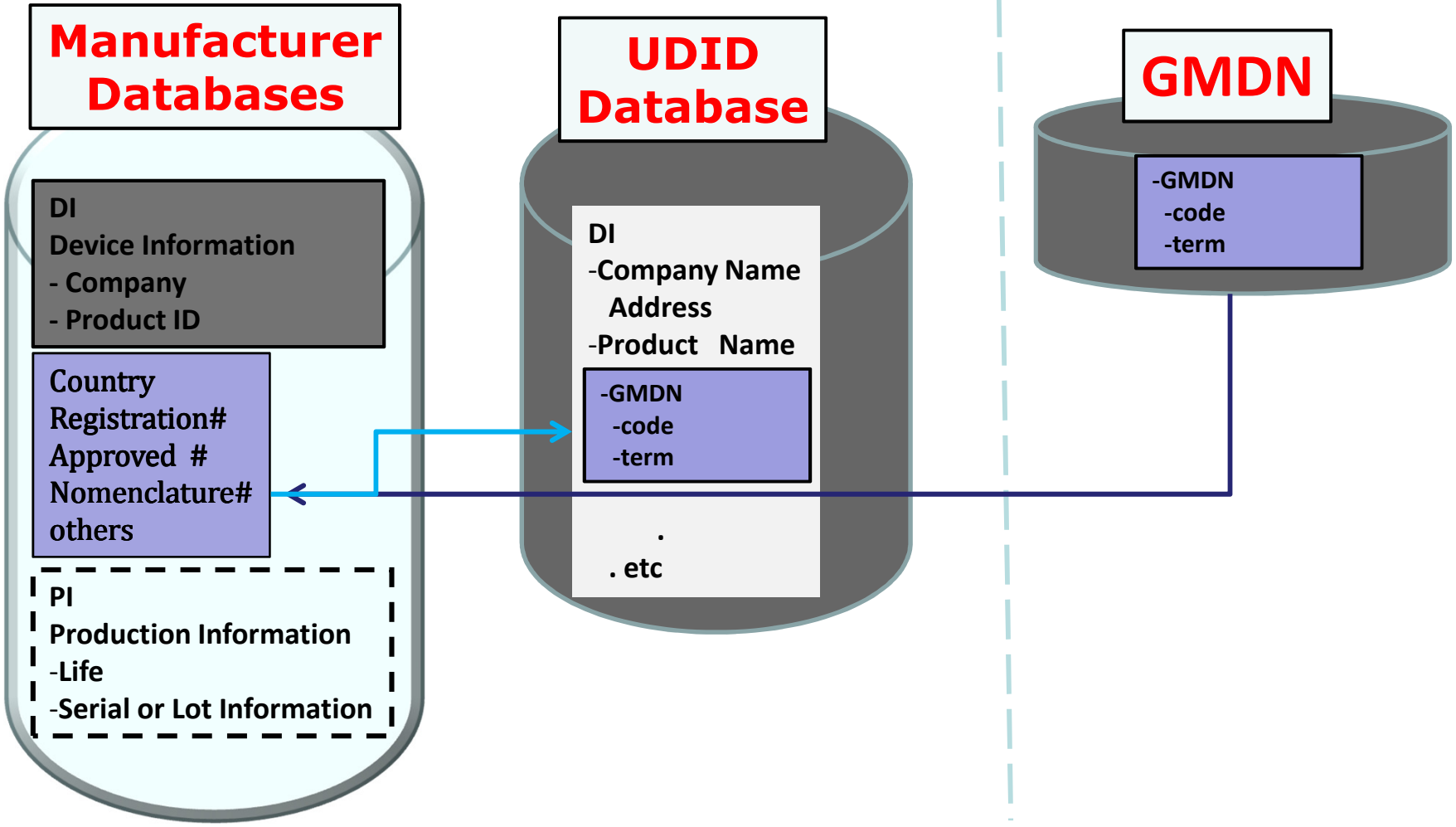
- The Commission shall be empowered to adopt delegated acts to specify:
  - *the devices, categories or groups of devices, whose identification shall be based on the UDI system,*
  - *the timelines for implementing the system (risk-based approach),*
  - *the data to be included in the production identifier (risk-based approach),*
  - *the obligations of economic operators, of health institutions and of professional users*

TRANSPARENCY

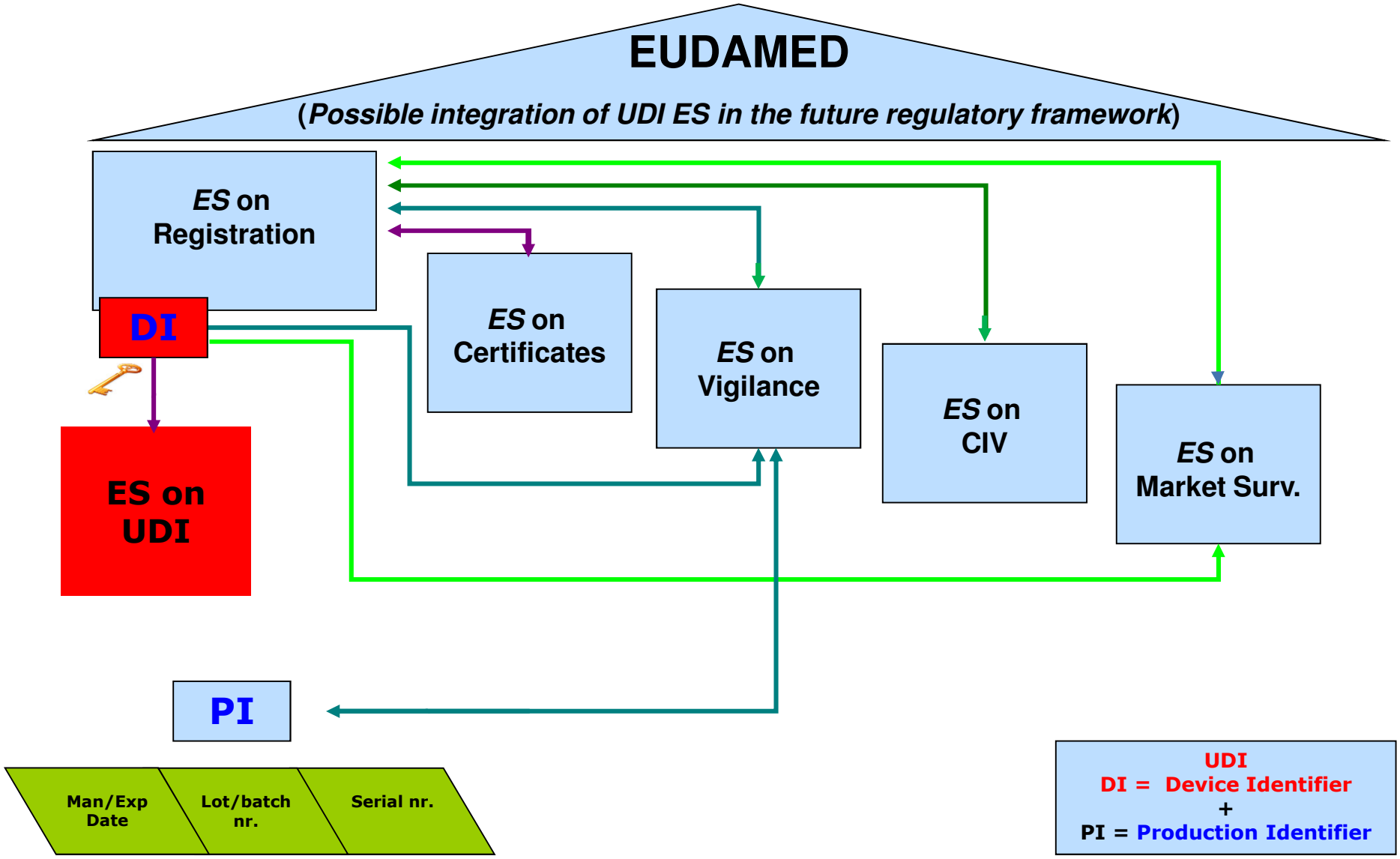
Publicly available information in EUDAMED regarding:

- Devices on the EU market,
- Summary of Safety and Clinical Performance Data for high risk devices,
- Manufacturers, authorized representatives and importers,
- Certificates issued by notified bodies,
- Clinical investigations / clinical performance studies,
- Field safety notices.

DIFFERENT TYPES… of DATABASES



IN THE EU: UDI in EUDAMED



DEVELOPMENT OF THE EU UDI DATABASE WILL BE KEY

Outlook

UDI: EU Implementation

Revision proposals

(26th September 2012)

Recommendation a common UDI System in the EU

(March 2013)

Ordinary legislative procedure

(2 to 3 years)

Adoption of the New REGULATIONS

(2015?)

Preparation of delegated acts (UDI and traceability requirements)

(End 2015 or 2016?)