# IMDRF UDI WG

# UNIQUE DEVICE IDENTIFICATION

## for medical devices and *in vitro* diagnostics medical devices

**Nice, 19 March 2013**

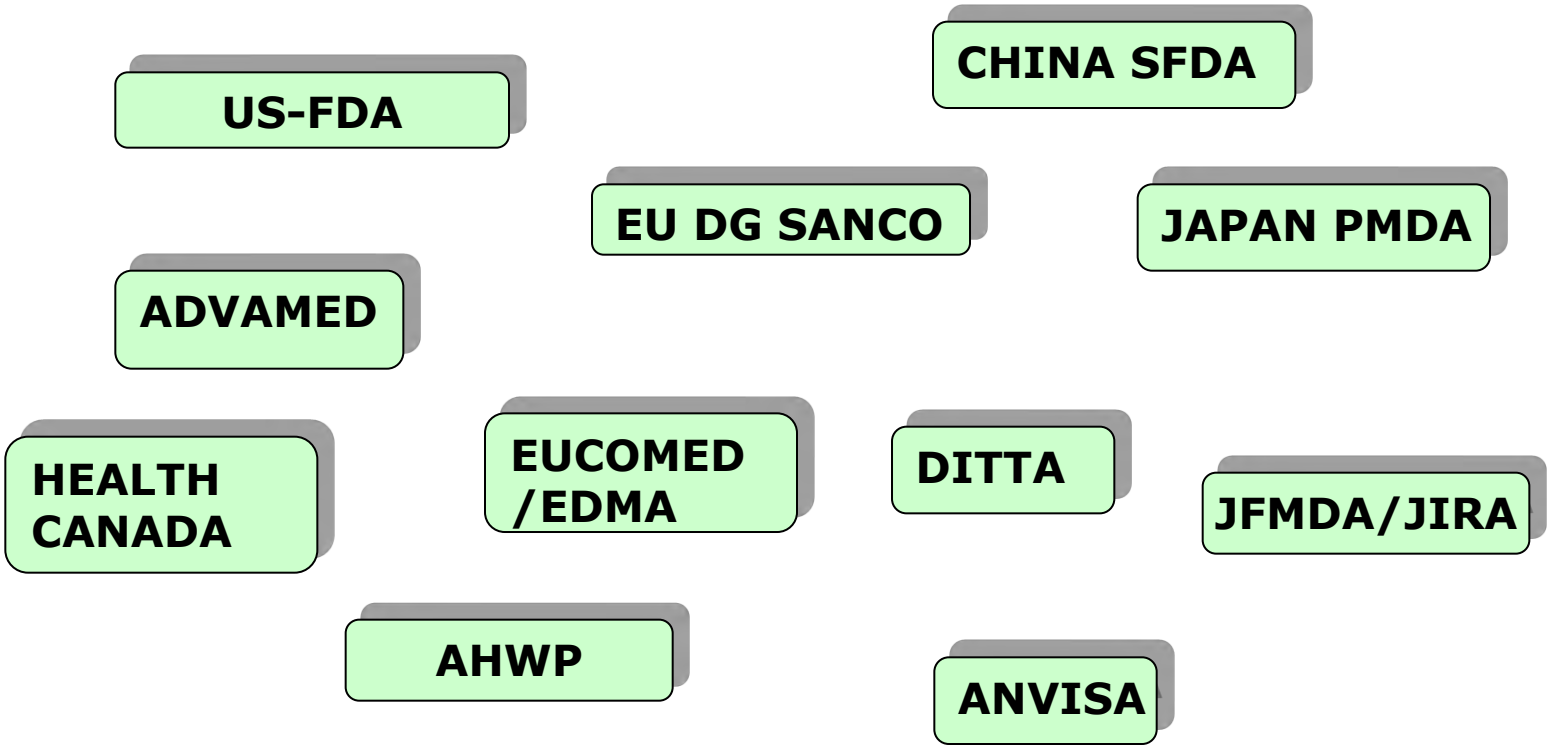
**Laurent SELLES**
**European Commission - DG Health & Consumers**

Health and Consumers

# Presentation to the IMDRF Management Committee
# UDI Work Group – Nice, 19 March 2013

**IMDRF UDI Team in Brasilia 29-31 Jan 2013**

# UDI Work Group




***…With some invited observers.***

# 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

# The UDI Challenge

Manufacturers DBs

FDA UDID

EU UDID

China UDID

Japan UDID

# Best solution: One Global UDID

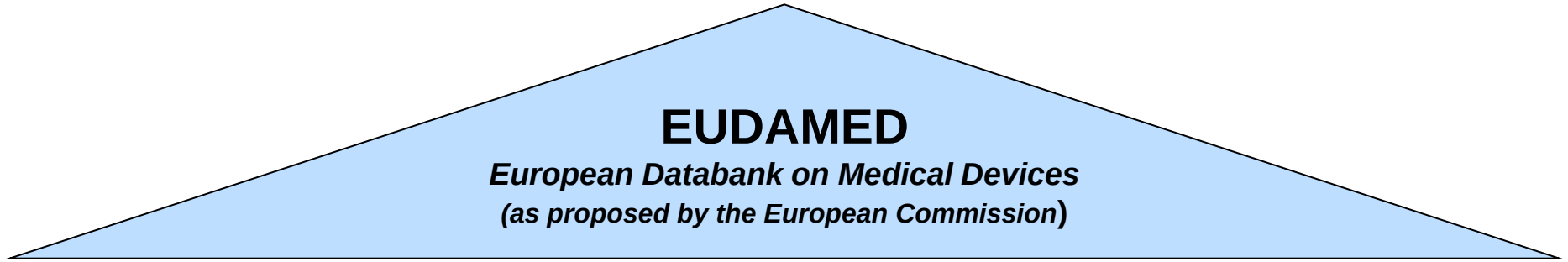
# Deployment of a small number of regional UDIDs




***System analysis:***

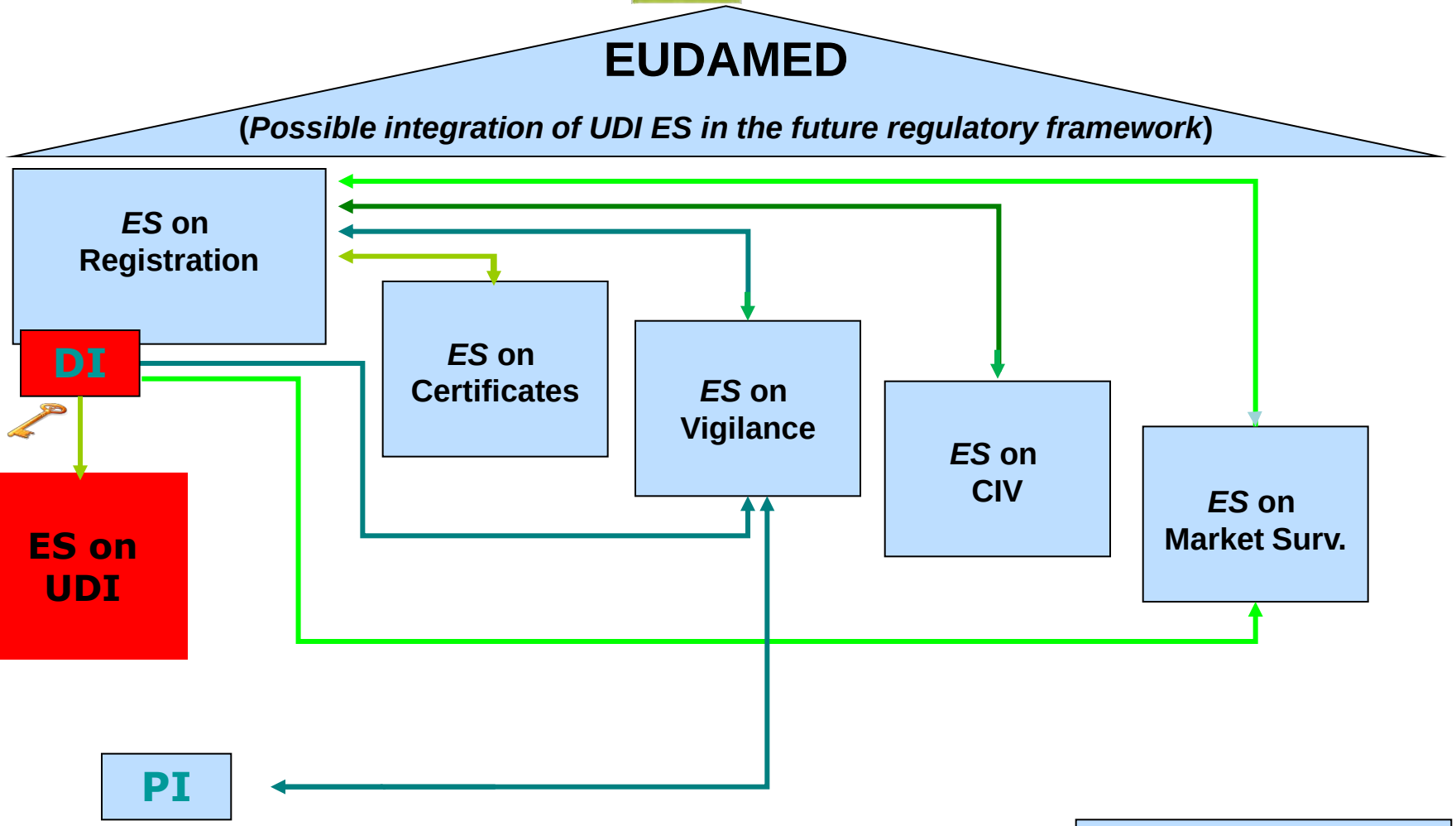
***GMDN ⇔ UDI ⇔ EUDAMED***

# EUDAMED and UDI

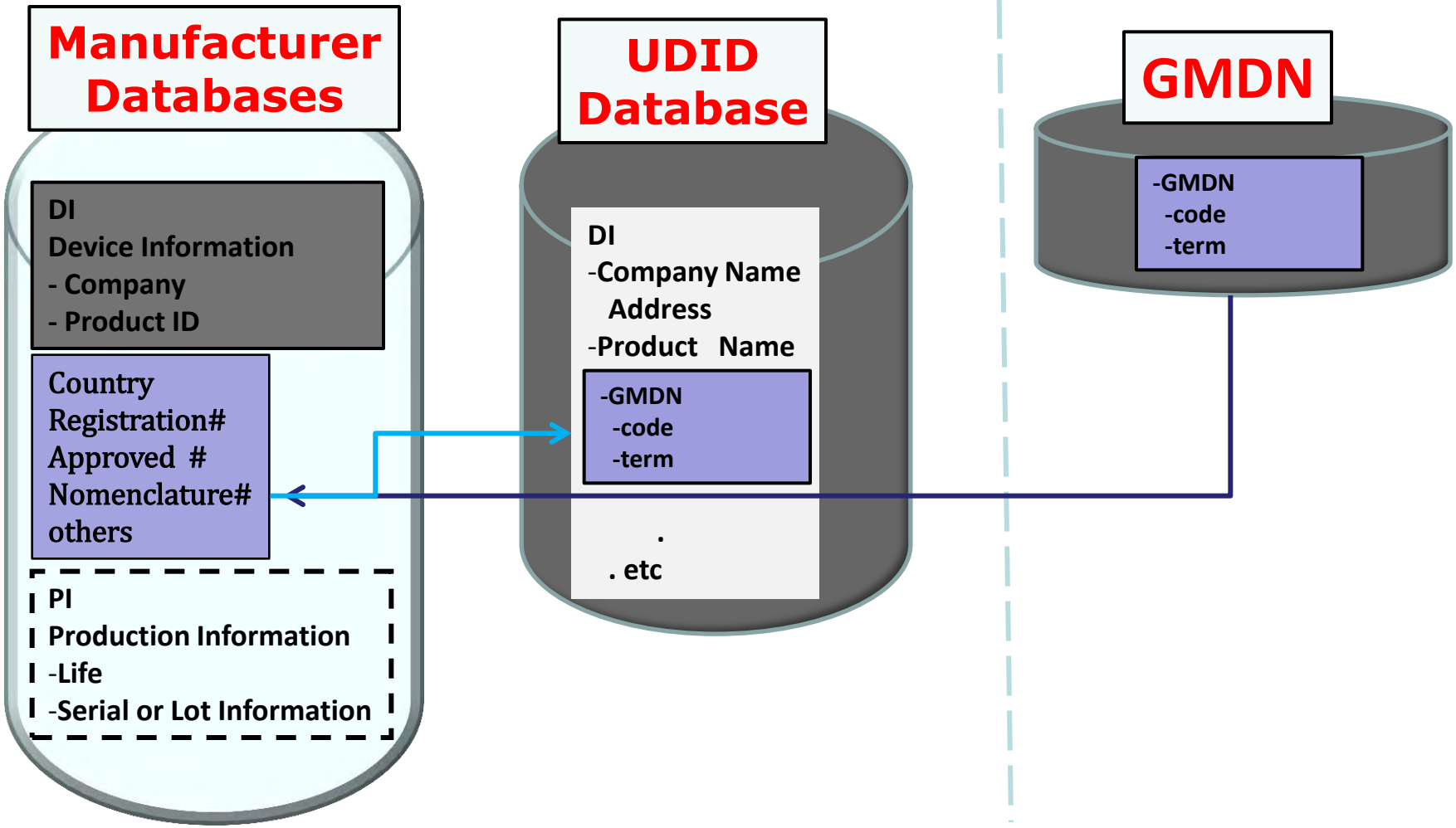



| Electronic system on Registration | Electronic system on UDI | Electronic system on Certificates | Electronic system on Vigilance | Electronic system on Market surveillance | Electronic system on Clinical investigations |
|---|---|---|---|---|---|
| Medical devices / IVDs economic operators, incl. Summary of Safety and Clinical Performance (high risk devices) | Device Identifier data elements | Certificates issued by notified bodies & Information on certificates refused suspended reinstated restricted withdrawn | Serious incidents & Field safety corrective actions & Field safety notices | Measures taken by Member States re. devices presenting a risk to health & safety preventive health protection measures | Sponsors (& manufacturers) description of: investigational device, comparator, purpose of CI, status of CI |

# IN THE EU: UDI in EUDAMED



# DIFFERENT TYPES… of DATABASES



# GMDN

- International nomenclature
- Not for profit organization
- International Board of trustees/Policy Advisers
- Fees?

→ ***Expected application in*** *EU, USA, China, AHWP, Japan, Brazil, Russia, Australia, Canada…*

# UDI

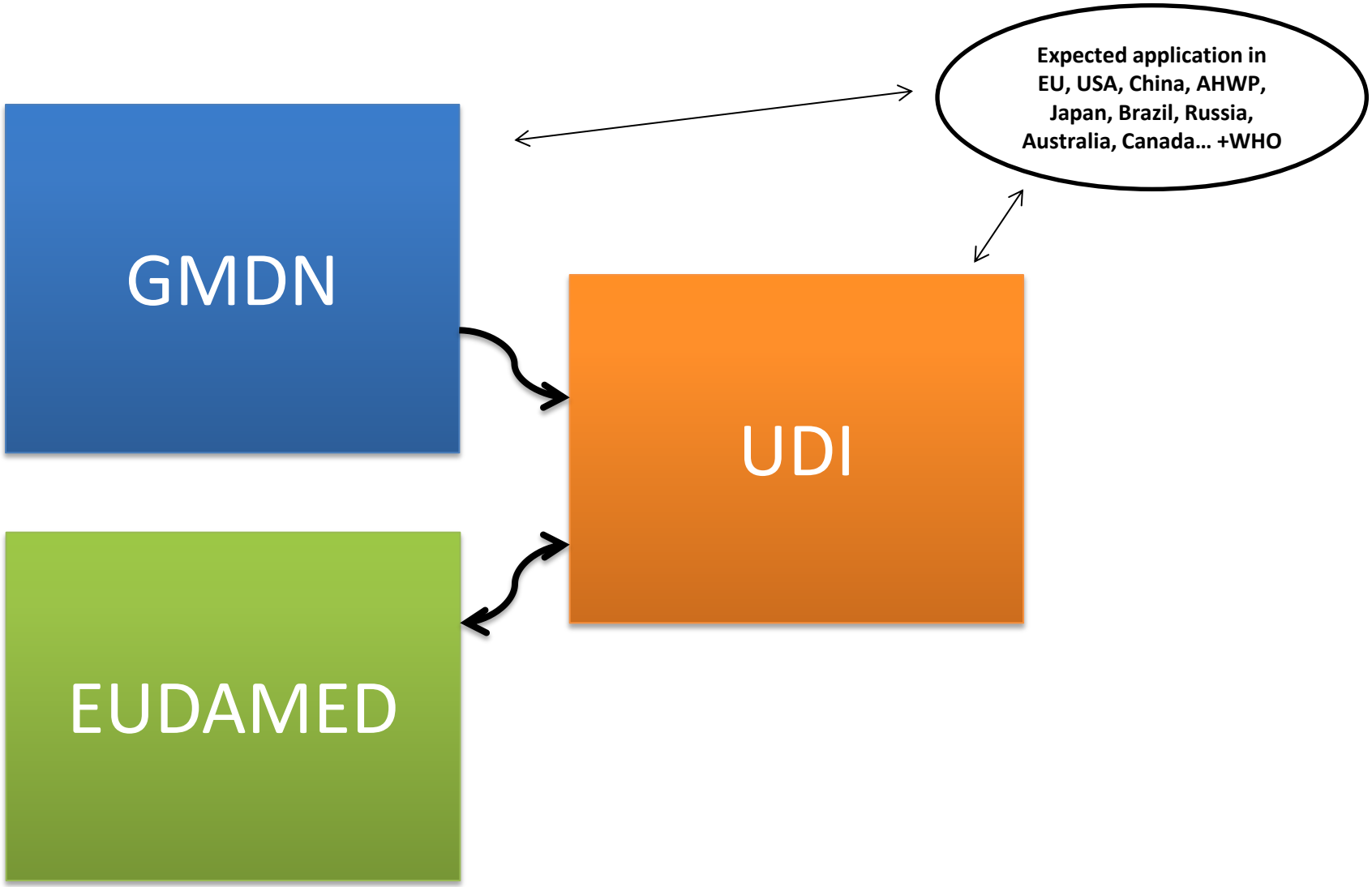
- **Global nature**
- **Identification of devices for Traceability**
- **Recommendation issued end 2012**
- **Manufacturers responsible for the code**
- **Device Id (DI) in the UDID**
- **Production Id (PI) in manufacturers DB**
- **Technology neutral: GS1, HIBCC…**
- **Exchange of data standard: HL7 SPL**
- **Database (UDID): tbd**
- **Interconnectivity of regional UDIDs: tbd**
- **UDID: Publicly available + free of charge**
- **DI contains i.a. GMDN code and term**

→ ***Expected application in*** *EU, USA, China, AHWP, Japan, Brazil, Russia, Australia, Canada…*

# EUDAMED

- European nature
- Centralized registration manufacturers, authorized representatives & devices
- Mandatory 1 May 2011
- Access for Competent Authorities
- Certificates issued, modified, suspended, withdrawn, refused
- Data of clinical investigations
- Central depository for vigilance reports (NCAR)

# RELATIONS BETWEEN EUDAMED, GMDN AND UDI



# UDIDs challenges ahead

- 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
- defined responsibilities of the different actors
- clear and standardized rules on rights to access, read, write or correct data
- rules on ownership of data
- Development of a common web interface

# IMDRF - UDI Roadmap for Implementation

# Proposed Planning of Work Oct 2012 – Dec 2013

OCT NOV DEC JAN FEB MAR APR MAY JUNE JULY AUG SEP OCT NOV DEC

European

**PROMOTION**

**SCOPING LANDSCAPING**

**RULES**

- **CAPITAL EQUIPMENT** — Proposed Draft
- **IVD KITS** — Proposed Draft
- **NON IVD KITS** — Proposed Draft
- **SURGICAL INSTRUMENTS & IMPLANTS (PD)**
- **STANDALONE MD SOFTWARE** — Proposed Draft

Public comments → Revisions → Final → **IMDRF revised UDI Guidance VERS. 2.0**

**IMPLEMENTATION GUIDE (DATABASES (UDID) DESIGN SPECS)**

**DATABASES INTERCONNECTION SPECS** → **Supplement Implementation Guide**

- IMDRF.2 — 27.09.12
- Wash DC — 14.12.12
- Brasilia — 29-31.01.13
- IMDRF-3 — 21.03.13
- Health and Consumers
- Other meetings?
- IMDRF-4 — 14.11.13

# IMDRF UDI WG Presentation to the MC

Nice/Sophia Antipolis 19-21 March 2013

**In short:**

**UDI Labelling Guidance** is drafted and submitted to the MC for consideration and possibly proposed for public comments: April =>31 July 2013

- Analysis of comments: August => September 2013

**Data Base Implementation** will be on a 'Supplement' UDID document:

Lots of challenges ahead (eg. interfacing with GMDN).

Different possible design routes for UDIDs: MC Political guidance is required.

- Prevailing views: A small number of regional UDIDs, same architecture, same format ('clones') ➔Unique IT-language, unique agreed datasets, protocols, validation etc.

**Political support is needed:** MC decision to become policy among IMDRF jurisdictions.

If answer is « yes », UDI WG expansion is needed:

Inclusion of Data Base expertise: Pooling together the designers of the regional UDIDs.

WG expansion in place: May 2013 – Proposal for next meeting June 2013 in USA.