IMDRF UDI WG

UNIQUE DEVICE IDENTIFICATION
for medical devices and *in vitro* diagnostics medical devices

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Laurent SELLES
European Commission - DG Health & Consumers
UDI Work Group

...With some invited observers.
UDI SYSTEM

Bar-coding for every Medical Device

UDID Database
For DI part Only

DI
- Company Name
- Address
- Product Name

PI
- Production Information
- Life
- Serial or Lot Information

-GMDN
code
term

etc
The UDI Challenge

Manufacturers DBs

- FDA UDID
- EU UDID
- China UDID
- Japan UDID

Health and Consumers
Best solution: One Global UDID
Deployment of a small number of regional UDIDs
System analysis:

GMDN ↔ UDI ↔ EUDAMED
EUDAMED and UDI

EUDAMED
European Databank on Medical Devices
(as proposed by the European Commission)

Electronic system on Registration
Medical devices / IVDs economic operators, incl. Summary of Safety and Clinical Performance (high risk devices)

Electronic system on UDI
Device Identifier data elements

Electronic system on Certificates
Certificates issued by notified bodies & Information on certificates refused suspended reinstated restricted withdrawn

Electronic system on Vigilance
Serious incidents & Field safety corrective actions & Field safety notices

Electronic system on Market surveillance
Measures taken by Member States re. devices presenting a risk to health & safety preventive health protection measures

Electronic system on Clinical investigations
Sponsors (& manufacturers) description of: investigational device, comparator, purpose of CI, status of CI
EUDAMED

(Possible integration of UDI ES in the future regulatory framework)

ES on Registration

ES on Certificates

ES on Vigilance

ES on CIV

ES on Market Surv.

DI = Device Identifier

PI = Production Identifier
DIFFERENT TYPES... of DATABASES

Manufacturer Databases
- DI
  - Device Information
    - Company
    - Product ID
- Country Registration#
- Approved #
- Nomenclature#
- others

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

GMDN
- GMDN
  - code
  - term
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

Expected application in EU, USA, China, AHWP, Japan, Brazil, Russia, Australia, Canada... +WHO
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

Rules

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

Implementation Guide
(Database (UDID) Design Specs)

Databases Interconnection Specs

Public comments

Revisions → Final

IMDRF revised UDI Guidance
VERS. 2.0

Supplement Implementation Guide

IMDRF-2
27.09.12

IMDRF-3
21.03.13

IMDRF-4
14.11.13

Wash DC
14.12.12

Brasilia
29-31.01.13

Other meetings?

Health and Consumers
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.