



**IMDRF** International Medical  
Device Regulators Forum

**Work Item:**

**Roadmap for Implementation of UDI System**



**Presentation to the Management Committee**

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**Health & Consumer Directorate General**  
**EUROPEAN COMMISSION**



GHTF/AHWG-UDI/N2R3:2011



## FINAL DOCUMENT

### Global Harmonization Task Force

**Title:** Unique Device Identification (UDI) System for Medical Devices

**Authoring Group:** GHTF SC UDI Ad Hoc Working Group

**Endorsed by:** The Global Harmonization Task Force

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Dr. Kazunari Asanuma, GHTF Chair

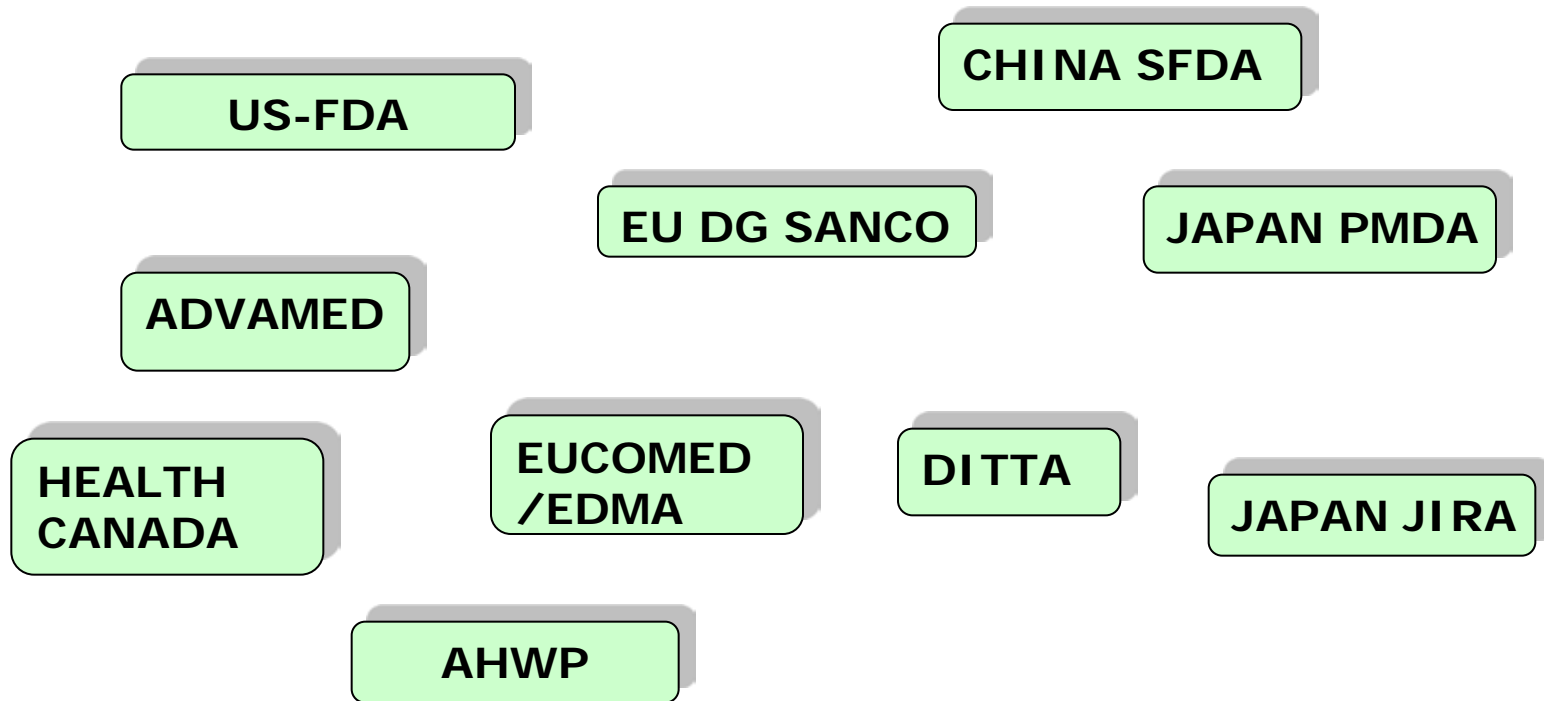
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## The IMDRF UDI Work Group



*...With some invited observers.*



**Caution...**

**Traceability** is key for post market safety

**UDI** is for identification purposes

**Traceability** and **UDI** are 2 different concepts

(General public may confuse the two)



## **What is a "Roadmap"?**

- The identification of all actors/stakeholders*
- A scope of work and planning*
- The identification of risks*
- The issues to be solved prior to implementation*
- An awareness policy*

# IMDRF-2 - Work Item: UDI



# IDENTIFICATION OF STAKEHOLDERS

## Scoping

## landscaping

Country Contact	AUS/NZ	BRAZIL	CANADA T. HAZLE	CHINA L. YAN	EUROPE (27 MS + EEA) L. SELLES M. NEUMANN	INDIA	JAPAN	MEXICO	RUSSIA	SAUDI ARABIA	SOUTH AFRICA	SOUTH KOREA	TAIWAN	USA J. CROWLEY T. REED	SINGAPORE
<b>Stakeholders</b>															
<b>Regulators Competent Authorities</b>	<a href="#">TGA</a>	<a href="#">ANVISA</a>	<a href="#">HC</a>	<a href="#">SFDA</a> <a href="#">AQSIQ</a>	<a href="#">EC DG SANCO</a>	<a href="#">CDSCO CLAA</a>	<a href="#">MHLW</a>	<a href="#">COFEPRIS</a>	<a href="#">Roszdravnadz or</a>	<a href="#">SFDA</a>	<a href="#">DOH</a>	<a href="#">KFDA</a> <a href="#">Ms Hye-Won Roh, Deputy Research Director</a> <a href="#">Mr. Young-Min Kim (UDI)</a>		<a href="#">FDA CDRH</a>	<a href="#">Health Sciences Authority (HSA)</a>
<b>Notified Bodies</b>		<a href="#">ANVISA</a>			<a href="#">Team -NB</a>										N.A. for product registration but 8 certification bodies for dealer's licence's GDPMDS certification: <a href="#">AJA Registrars Pte Ltd</a> <a href="#">Bureau Veritas Certification (Singapore) Pte Ltd</a> <a href="#">Certification International (Singapore) Ltd</a> <a href="#">Det Norske Veritas</a> <a href="#">SGS International Certification Services Singapore Pte Ltd</a> <a href="#">TUV Rheinland Singapore Pte Ltd</a> <a href="#">TUV SUD PSB Pte Ltd</a> <a href="#">DAS Certification Singapore Pte. Ltd.</a>
<b>MD/IVD Manufacturers</b>	<a href="#">MTAA</a> <a href="#">IVD Australia Limited</a> <a href="#">MTANZ</a>	<a href="#">CBDL</a> <a href="#">SBBiotech</a> <a href="#">ABIIMO</a>	<a href="#">MEDEC</a>	<a href="#">CMBI</a>	<a href="#">COCIR EDMA</a> <a href="#">EUCOMED</a>	<a href="#">AIMED</a>	<a href="#">JEMDA</a> <a href="#">JAAME</a> <a href="#">JIRA</a>	<a href="#">Amid</a>			<a href="#">SAMED</a> <a href="#">SALDA</a> <a href="#">MDM</a>	<a href="#">KMDIA</a>		<a href="#">AdvaMed</a> <a href="#">AMDM</a> <a href="#">MDMA</a>	About 100 plus manufacturers in Singapore. Associations: <a href="#">Medical Technology Industry Group (MTIG) in Singapore Manufacturer's Federation (SMa)</a> <a href="#">Association of Medical device Industry (AMDI)</a>
<b>Distributors Third party Logistics Provider</b>		<a href="#">Abimed</a>			<a href="#">EMDDA</a>										About 600 plus distributors in Singapore. Associations: <a href="#">Singapore Manufacturer's Federation (SMa)</a> <a href="#">Association of Medical device Industry (AMDI)</a>





## UDI ROADMAP for IMPLEMENTATION

*Scoping/  
Landscaping*

*Charter*

*Overall Work Plan*

**Purpose**

**Process**

- Rules:**
- 1. Capital equipment
  - 2. IVD Kits
  - 3. Non IVD Kits
  - 4. DPM on implants/surgical
  - 5. Software

**Identification of risks**

*Definition of responsibilities*

**Databases  
Governance**

**Regulators**

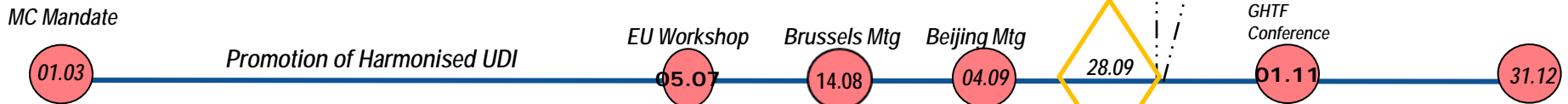
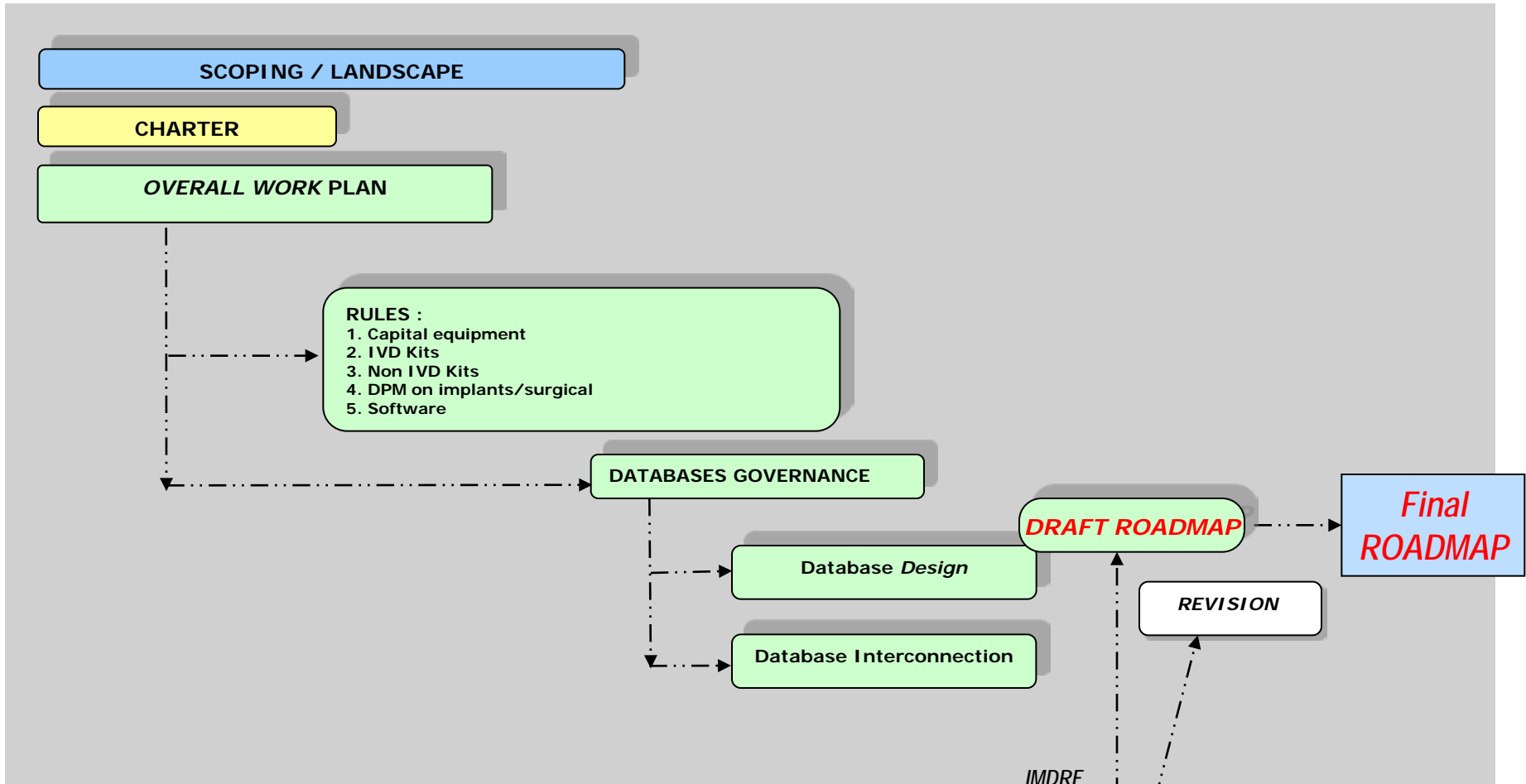
**Users**

**Databases  
Design**

**Databases  
Interconnect.**

**Promotion of  
harmonized UDI System**

MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC







**5 sub-groups  
(topical expertise)**

## **5 Consultations**

- 1. "Capital equipment and other systems (incl. Imaging - refurbished/remanufactured)"***
- 2. "Direct Part Marking (DPM) of Implants and Instruments"***
- 3. "IVD Kits"***
- 4. "Non IVD Kits"***
- 5. "Medical Device Software"***



**Practical aspects of the implementation**

1. When does a device need a new UDI?;
2. Interface with the nomenclature (GMDN application);
3. Reprocessing/reprocessed issues;
4. Which "bits" of a device need a UDI ;
5. UDI placement;
6. UDI on device (DPM) versus UDI on packaging;
7. Are there packaging levels not needing a UDI?;
8. Are there exceptions and alternative placement issues?;
9. Components VS spare parts.

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

Commission

PROMOTION

SCOPING LANDSCAPING

CHARTER

CAPITAL EQUIPMENT

IVD KITS

NON IVD KITS

DIRECT PART MARKING

SOFTWARE

IMDRF revised UDI Guidance  
VERS. 2.0

DATABASES (UDID) DESIGN SPECS

DATABASES INTERCONNECTION SPECS

27.09.12

14.12.12

Wash DC

IMDRF-3

21.03.13

Other Mtgs

IMDRF-4

14.11.13



**IMDRF** International Medical  
Device Regulators Forum

***IMDRF Revised UDI GUIDANCE  
(Vers. 2.0 + Supplement)***