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

Date: September 16, 2011

Dr. Kazunari Asanuma, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

The IMDRF UDI Work Group

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

...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 / Stakeholders	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
Regulators Competent Authorities	TGA	ANVISA	HC	SFDA AQSIQ	EC DG SANCO	CDSCO CLAA	MHLW	COFEPRIS	Roszdravnadzor	SFDA	DOH	KFDA Ms Hye-Won Roh, Deputy Research Director Mr. Young-Min Kim (UDI)		FDA CDRH	Health Sciences Authority (HSA)
Notified Bodies		ANVISA			Team -NB										N.A. for product registration but 8 certification bodies for dealer's licence's GDPMDS certification: AJA Registrars Pte Ltd Bureau Veritas Certification (Singapore) Pte Ltd Certification International (Singapore) Ltd Det Norske Veritas SGS International Certification Services Singapore Pte Ltd TUV Rheinland Singapore Pte Ltd TUV SUD PSB Pte Ltd DAS Certification Singapore Pte. Ltd.
MD / IVD Manufacturers	MTAA IVD Australia Limited MTANZ	CBDL SBBiotec ABIMO	MEDEC	CMDI	COCIR EDMA EUCOMED	AIMED	JFMDA JAAME JIRA	Amid			SAMED SALDA MDM	KMDIA		AdvaMed AMDM MDMA	About 100 plus manufacturers in Singapore. Associations: Medical Technology Industry Group (MTIG) in Singapore Manufacturer's Federation (SMa) Association of Medical device Industry (AMDI)
Distributors Third party Logistics Provider		Abimed			EMDDA										About 600 plus distributors in Singapore. Associations: Singapore Manufacturer's Federation (SMa) Association of Medical device Industry (AMDI)

IMDRF-2 - Work Item: UDI

WORK BREAKDOWN STRUCTURE (WBS)

UDI ROADMAP for IMPLEMENTATION

Scoping / Landscaping

Charter

Purpose

Process

Identification of risks

Definition of responsibilities

Regulators

Users

Overall Work Plan

Rules:

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

Databases Governance

Databases Design

Databases Interconnect.

Promotion of harmonized UDI System

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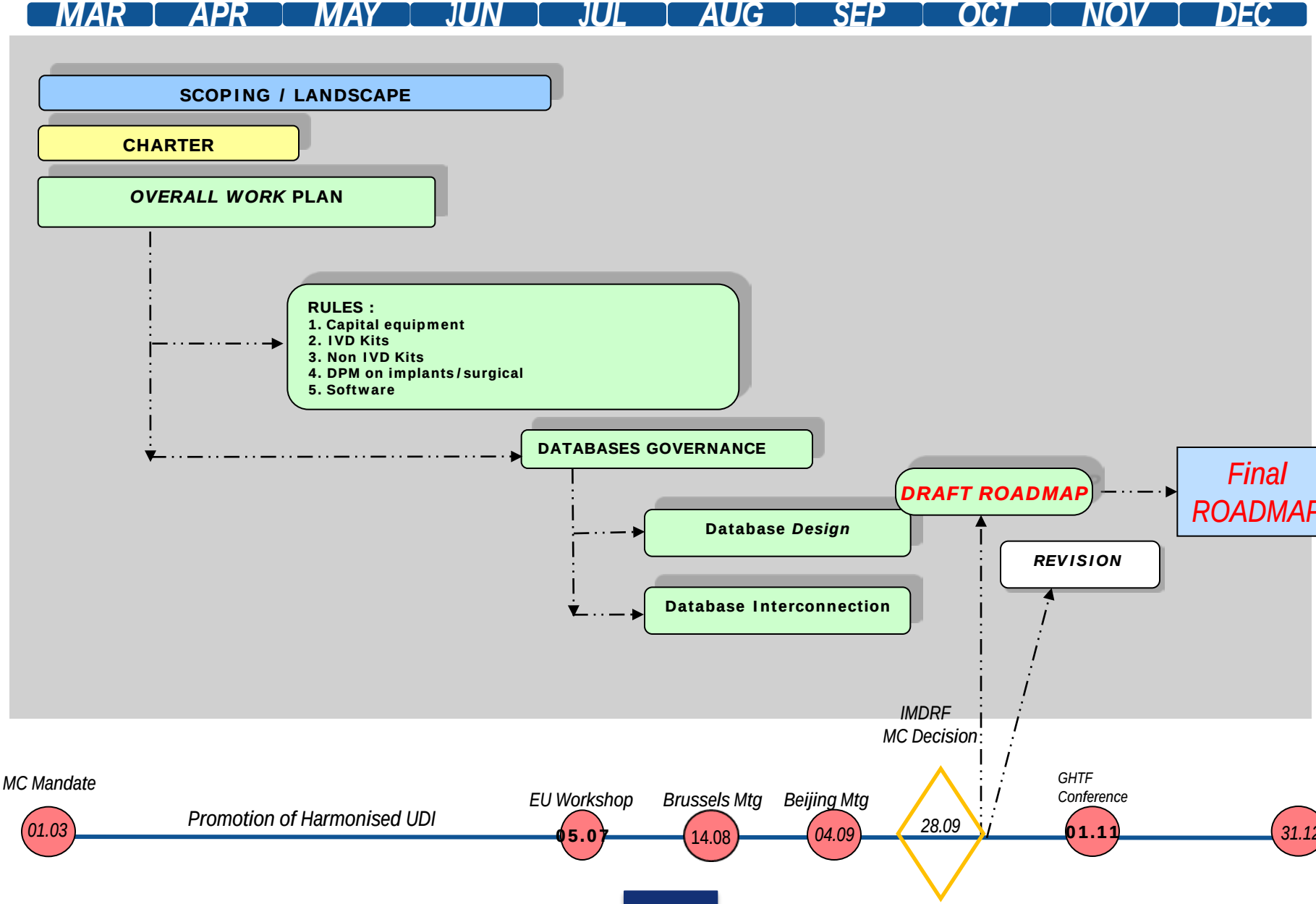
WORK DONE (Mar-Sept 2012)



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.

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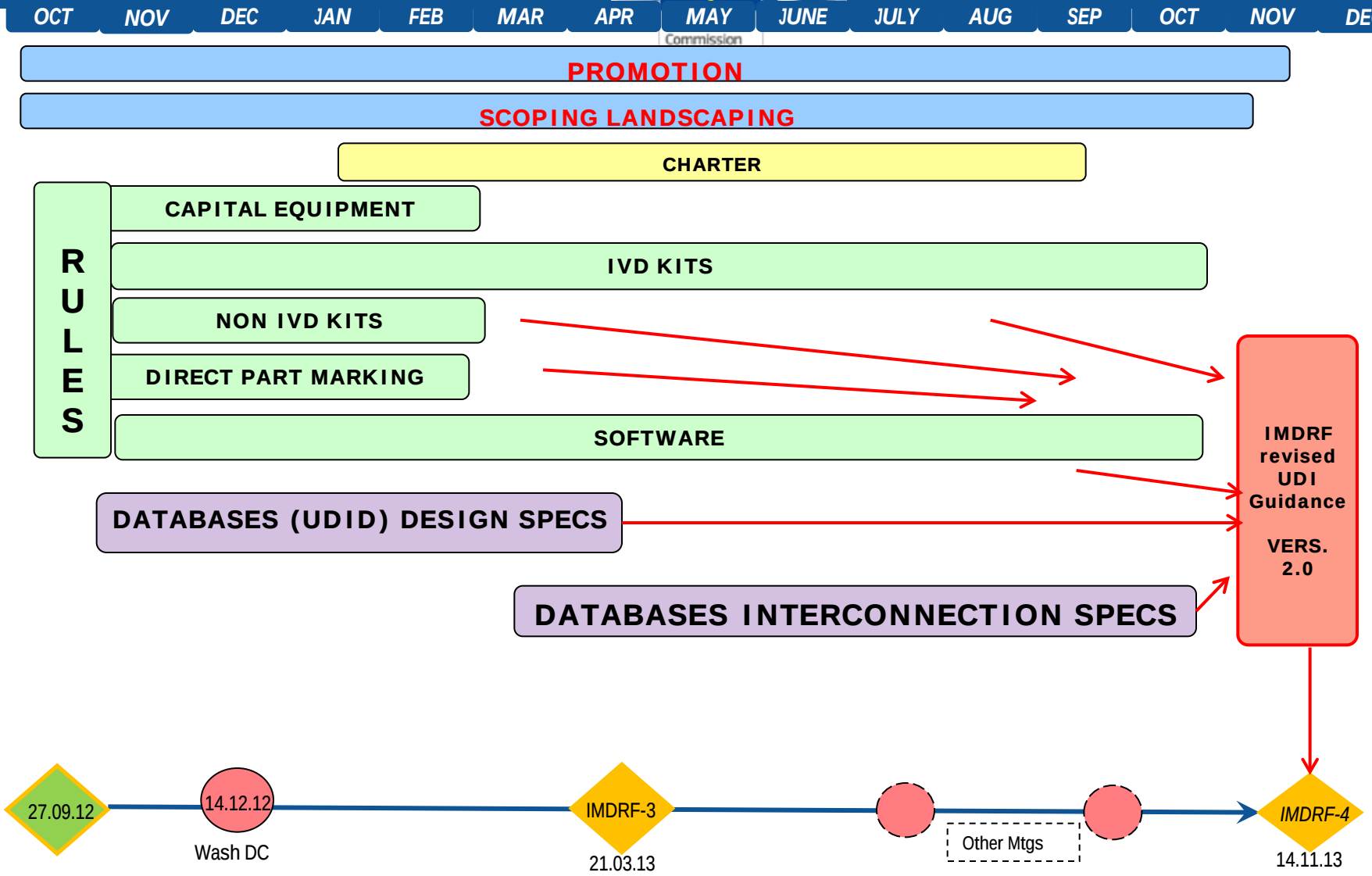
Proposed Planning of Work Oct 2012 – Dec 2013



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IMDRF Revised UDI GUIDANCE
(Vers. 2.0 + Supplement)