6th MDR Eudamed UDI & Devices WG Meeting

Implementation plan update

14/03/2019
DG GROW

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Meetings

- 14/03/2019 - UDI & Device WG

- 21/03/2019 - Data Exchange WG
- 28/03/2019 – Vigilance WG
- 16/05/2019 – Clinical Investigations WG
- 23/05/2019 – Market Surveillance WG
- 20/06/2019 – NB & Certificates WG

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Project deliverables

- Eudamed information system
  - Restricted site
  - Public site
- Data Exchange solutions

- User guide
- Technical documentation (for Data Exchange)
- Training material
- Application Support
- Demos / Playground

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Working Documents

	Document		Date
1	Functional Specifications	v4.1	7/3/19
2	Business Process	v2.0	5/3/19
3	Entity Model	v2.0	5/3/19
4	Security Matrix	v2.0	7/3/19
5	Business Rules	v2.0	at WG
6	Data Dictionary	v2.0	5/3/19
7	Use Case Register	v2.0	7/3/19
8	Mock-ups	v2.0	at WG
9	Site Maps (restricted, public)		7/3/19
10	Search criteria		7/3/19
11	Implementation Plan (this ppt)	v2.0	at WG

Comments of
WG members
till
29-03-2019

FS-UDID-002.05, FS-UDID-002.08, FS-UDID-002.09

UDI registration for MF and non-EU MF (with prevention of duplicates)

- Analysis completed;
- Implementation of Registration process of Basic UDI-DI and UDI-DI is completed,
- remaining following Use cases: Registration of UDI-DI for existing Basic UDI and Registration of Package Level UDI for existing UDI;

FS-UDID-003.01 Device registration for MF and non-EU MF

- Analysis completed
- Implementation in progress - working now on UC Register Device Data for existing UDI-DI

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FS-UDID-006.01, FS-UDID-006.02

Search, view and download UDI-DI and Device data incl. SS(C)P

- Analysis completed
- Implementation ongoing

FS-UDID-002.06   Basic UDI, UDI-DI update

- Analysis completed
- Implementation ongoing

FS-UDID-003.02 Device data update (except SS(C)P)

- Analysis completed
- Implementation ongoing

FS-UDID-002.01

Registration of Systems and Procedure packs

Analysis completed;

Implementation: Q3 2019;

FS-UDID-002.02

Update System and Procedure packs

Analysis completed;

Implementation: Q3 2019;

FS-UDID-005.01

Enable NB to confirm Device data with related Certificate data

- Analysis started
- Dependency on the implementation on the Certificate Module (Q3 2019)

FS-UDID-009

Enable NB to upload the SS(C)P and enter related meta-data to device data already provided by a manufacturer

- Analysis started

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FS-UDID-001.01

Device Nomenclature data management

FS-UDID-007

Search and view Device Nomenclature data

- Device Nomenclature has been established March 2019 (CND Nomenclature – mapped with GMDN)
- Analysis started

FS-UDID-004   Priority **– Medium**

Enable an AR to indicate its disagreement with information related to a Basic UDI-DI / UDI / Device information referencing this AR

- To be analysed & implemented in a future release

FS-UDID-010   Priority **– Low**

Enable MF to link one of its Basic UDI-DI to another one and give a reason

- To be analysed & implemented in a future release

FS-UDID-008 Upload and Download of Basic UDI, UDI-DI and device data

- **FS-UDID-008.01 : Enable Upload for EU, Non-EU Manufacturers**

  Analysis on-going

  Testing to be planned (not earlier than June 2019)

- **FS-UDID-008.02 : Enable Upload for System/Procedure pack Producers**

  Analysis on-going

  Testing to be planned (not earlier than June 2019)

- **FS-UDID-008.03 : Enable Downloading (not for Sponsor)**

  Analysis on-going

  Testing to be planned (not earlier than June 2019)

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FS-PUB-UDID-001 : Search and view UDI-DI and Device data (including SS(C)P)
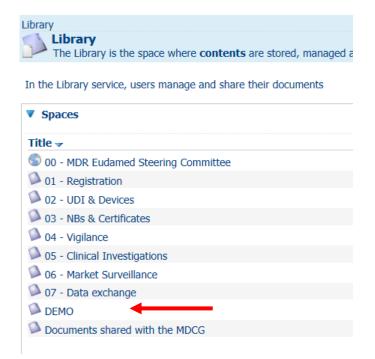
Analysis Started

FS-PUB-UDID-002 : Download UDI-DI and Device data (including SS(C)P)

Analysis to start Q2 2019

Playground and demos

- The Eudamed playground on UDI will be available in Q2. Exact date will be communicated

- The same functional mailbox for questions and comments is valid (GROW EUDAMED SUPPORT)

- Videos/demos will also be available from CIRCABC on the DEMO library

Implementation Plan update

2019   **2020**

MAR ▸ APR ▸ MAY ▸ JUN ▸ JUL ▸ AUG ▸ SEP ▸ OCT ▸ NOV ▸ DEC ▸ JAN ▸ FEB ▸ MAR

◆ Stable Req **80**% of Use Cases

◆ Stable Req **100**% of Use Cases

UDI : Analysis

UDI: Development

Demo

Playground

AUDIT: UDI

1st REL

◆

◆ Final Report

UDI: Fixes, Updates

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