4th MDR Eudamed UDI & Devices ad hoc WG Meeting

Planning - Roadmap

01/03/2018

Meetings

Planned Meetings:

- 22/03/18 – 4th UDI and Device WG
- 19/04/18 – 2nd CI/PS WG
- 26/04/18 – 2nd Vigilance WG
- 23/05/18 – 3rd Data Exchange WG
- 23/08/18 – 8th Actor Registration WG
- 13/09/18 – 5th NB & Certificates WG
- 27/09/18 – 5th UDI & Device WG
- 04/10/18 – 3rd Vigilance WG
- 18/10/18 – 3rd CI/PS WG
- 25/10/18 – 2nd Market Surveillance WG
- 21/11/18 – 4th Data Exchange WG
- 13/12/18 – Steering Committee

Implementation plan

Objectives

- Ensure Eudamed achieves full functionality (all the must-haves) on time
- Ensure Eudamed meets the functional specifications
- Prioritisation
- Communicate timing
- Progress tracking

Implementation plan

Project milestones

- Eudamed Go Live before 26/03/2020 (to comply with article 34)
- Eudamed functionally complete before Audit start – 09/2019
- Finalise functional specifications, process descriptions, data models and business rules by 10/2018 – to allow stakeholders to prepare their own systems (e.g. for data exchange)
- Plan for the implementation of functional specifications by 26 May 2018

Implementation plan

Project deliverables

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

- User guide
- Technical documentation
- Training material
- Technical support

- Reports on data analytics (priority to be considered)

Implementation plan

Working documents

- Functional Specifications document contains
  - Legal requirements
  - Functional specifications
  - Non-functional specifications
- Wireframes / Mock-ups
- Business rules
- Data models
- Process overviews
- Implementation plan with scope for 1st release

Implementation plan

For UDI/Device:

- Functional Specifications document
  - Comments from WG Members and if necessary new FS by 12/04/2018
- 2 weeks for feedback on the following draft documents provided by COM:
  - Wireframes / Mock-ups from May 2018
  - Business rules from May 2018

- Process overviews provided as from May 2018
- Data models as from May 2018
- Implementation plan for first release as from 29/03/18
- Have review iterations on these documents with the aim to finalise in June 2018 (for UDI/Device)

Implementation plan

For UDI/Device:

- Implementation order:
  1. UDI registration for MF and non-EU MF (with prevention of duplicates) with exception of systems and procedure packs
  2. Device registration for MF and non-EU MF
  3. Search and view UDI-DI and Device data
  4. UDI update
  5. Device update
  6. Systems and procedure packs

Implementation plan

7. Enable NB to manage the information on certificate ID in device data (confirm, reject or enter/update)
8. Enable NB to upload the SS(C)P and enter related meta-data to device data already provided by a manufacturer
9. Register specific device types requiring specific rules
10. (Relabelling/repackaging done by distributors/importers (Art 16(2 to 4)) (new, not in functional specification yet)
11. Enable an AR to indicate its disagreement with information related to a Basic UDI-DI / UDI / Device information referencing this AR
12. Enable Importers to associate their details to manufacturers (and possibly their specific devices)
13. Device Nomenclature data management (depending on decision for Device Nomenclature)
14. Search and view Device Nomenclature data

Acceptance process

- Based on functional specifications
- Regular testing by WG members or delegates when functionality has been implemented
    1. Testing separate modules
    2. Testing integration between modules
- On-line, test scenarios provided
- Feedback will be done through wiki
- Feedback will be analysed and used to improve the system, in line with functional specifications
- Audit before Go-Live

- User testing UDI / Device in September 2018

Risks

European Commission

Main Risks

- *Schedule imposed by the Medical Device Regulation for the delivery of Eudamed is not met*
- *Delays because Stakeholders/MS might take time or not reach a consensus on the rules/specifications to be implemented*
- *Eudamed too complex or inappropriate to be useful, workable, performant and/or user friendly*

Issue

New rules on Basic UDI-DI

- *Basic UDI-DI rules in relation with device data (How to deal with Part A section 2?)*
  - ✓ **Previously, Part A Section 2 was entirely related to Basic UDI-DI (unique identifier of a device in Eudamed)**
  - ❖ **Now, Part A Section on device data are associated to either Basic UDI-DI or UDI-DI**

    Basic UDI-DI not any more the unique identifier of a device in Eudamed, it is now more the UDI-DI(s).

    Device from Eudamed perspective is something hybrid → Registration more complex/less clear

Questions?

European Commission