MDR Eudamed
2nd Vigilance ad hoc WG Meeting

Planning - Roadmap

26/04/2018

Meetings

Planned Meetings:

- 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 before 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

Implementation plan

Working documents

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

Implementation plan

For VIG:

- Functional Specifications document
  - Comments from WG Members by 14/05/2018
- 2 weeks for feedback on the following draft documents provided by COM:
  - Vigilance Process overview: first draft provided today
  - Data models:
    - First draft of logical data model for those parts for which we have received input: from end of July 2018 (input needed from WG)
    - Business rules: together with data model
  - Additional Wireframes / Mock-ups from August 2018
- Have review iterations on these documents with the aim to finalise in October 2018 (for VIG)

Input from WG

- Input from the workgroup :
  - 1st draft of forms (point 6 on agenda)
    - Field Safety Corrective Action (FSCA)
    - Periodic Summary Report (PSR)
    - Trend Report (TR)
    - Field Safety Notice (FSN)
    - Periodic Safety Update Reports (PSUR)
    - Feedback on Manufacturer Incident Report (MIR)
  - Updates and final version expected until September 2018

Implementation plan

For VIG:

- Implementation order:
  1. Manage serious incidents reports (submission and assessment)
  2. Manage FSCAs (submission and assessment)
  3. Manage FSN
  4. Manage Trend Reports (submission and assessment)
  5. Manage PSRs
  6. Coordinated assessment procedure implementation
  7. Manage PSUR (submission and evaluation)
  - Horizontal activities: Search and view information; Notifications
  - M2M implementation will follow the above order

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

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*

Main Risks

- *Disclosure of non-public data: An incorrect implementation might result in the disclosure of confidential data or personal data to non-authorised persons*

Questions?

European Commission