



# **MDR Eudamed 3<sup>rd</sup> Data Exchange WG Meeting**

**Planning - Roadmap**

23/05/2018

## Planned Meetings:

- 23/05/18 – 3rd Data Exchange WG
- 23/08/18 – 8<sup>th</sup> Actor Registration WG
- 13/09/18 – 5<sup>th</sup> NB & Certificates WG
- 27/09/18 – 5<sup>th</sup> UDI & Device WG
- 04/10/18 – 3rd Vigilance WG
- 18/10/18 – 3rd CI/PS WG
- 25/10/18 – 2<sup>nd</sup> 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 1<sup>st</sup> release



# Implementation plan

- Summer 2018: detailed specifications for 1<sup>st</sup> module set (functional specifications, process overviews, data models, business rules)
- October 2018: detailed specifications for 2<sup>nd</sup> module set (functional specifications, process overviews, data models, business rules)

## For Data Exchange 1<sup>st</sup> module set

- Focus on Actor and Actor registration download; UDID upload (MF)/download(CA); CRF upload (NB) /download (CA)
- 16 July 2018:
  - Requirements specifications
  - Use case specifications for data exchange for 1<sup>st</sup> module set
  - Data exchange Architecture overview document

# Implementation plan

For Data Exchange 1<sup>st</sup> module set

- 01 August 2018:
  - XSD for Actors, UDID, CRF
- 31 August 2018: Authentication and authorisation processes description
- 1 October 2018: first version of implementation of Actor Data Exchange Services can be tested
- 5 November 2018: first version of implementation of UDID Data Exchange Services can be tested
- January 2019: first version of implementation of CRF Data Exchange Services can be tested





# 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





# Questions?

