

# **MDR Eudamed Data exchange WG**

## **Roadmap and deliverables**

15/11/2017

# Contents

- Deliverables
- Roadmap
- Communication channels
- Q&A

# Deliverables

For each module:

- Clear needs for data exchange
  - -> list of needs per Actor Role with priorities
  - -> Define features of the data exchange based on needs list
  - -> identify limitations to be imposed on data exchange
  - -> Deliverable: Business requirements Specifications + scope statement
- Elicit requirements covering the needs
  - -> identify functional requirements
  - -> identify non-functional requirements (usability, reliability, performance, scalability, supportability,...)
  - -> model usage scenarios (message exchange scenarios)
  - -> deliverable: Requirements Specifications

# Deliverables

Based on the requirements:

- Prepare Test Cases for UAT and System Test
  - -> Write business scenario test cases for User Acceptance Test and System Test
  - -> Create the requirement validation matrix
  - -> Deliverable: Test Strategy containing test scenarios

# Deliverables

For the different types of needs:

- Elaborate use of standards and protocols for data exchange
- COM selects technology platform(s)
- Deliverable: data exchange architecture overview document
- Defining service interfaces for data exchange
  - Based on usage models
  - Based on data models
  - -> Deliverable: definitions of schemas and operations
- Based on technology platforms
  - Defining the authentication and authorisation processes
  - -> Deliverable: authentication and authorisation processes description

# Deliverables

- Implementation and testing
  - Implementing solution in development environment and do initial testing
  - Write technical guidance documents for Data Exchange Clients ( + write test client)
  - Deploy solution in acceptance environment
  - Have solution tested by Data Exchange Clients
  - Correct and improve solution
  - Perform performance and vulnerability testing
- Deployment
  - Prepare deployment environment
  - Deploy data exchange solution(s)
  - Create end user support material
  - Open the solution for use

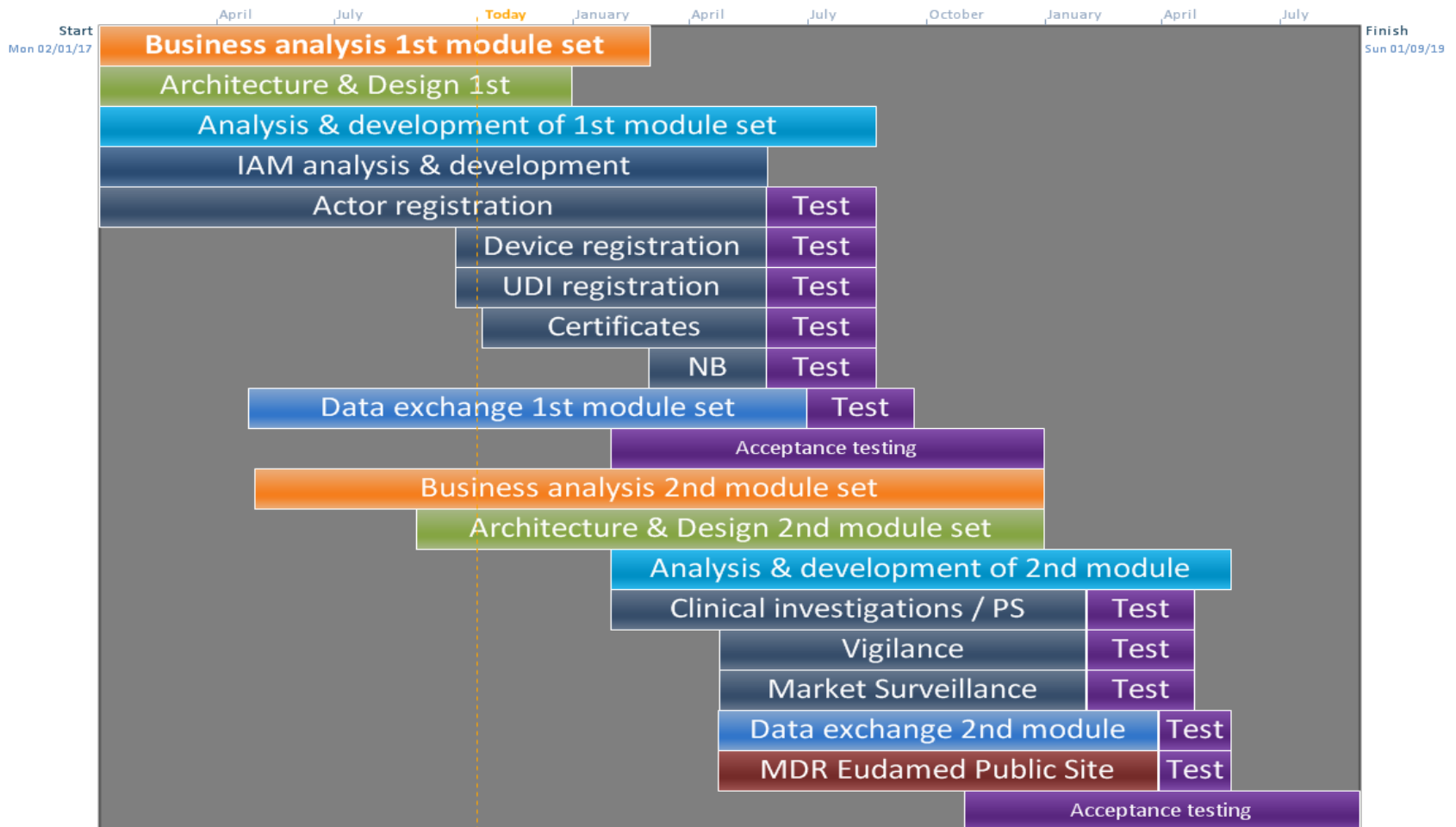
# Roadmap

- Business requirements Specifications + scope statement = Needs, for first set of modules: review until end of 2017
- Draft Requirements specifications : in February 2018 for first set of modules, soon after, second set of modules, to be finalised by May at the latest for the MDCG
- Division by 1st and 2nd module set
- Schemas to be developed in line with the requirements for the different modules, as soon as possible, based on input from relevant working groups

# Roadmap

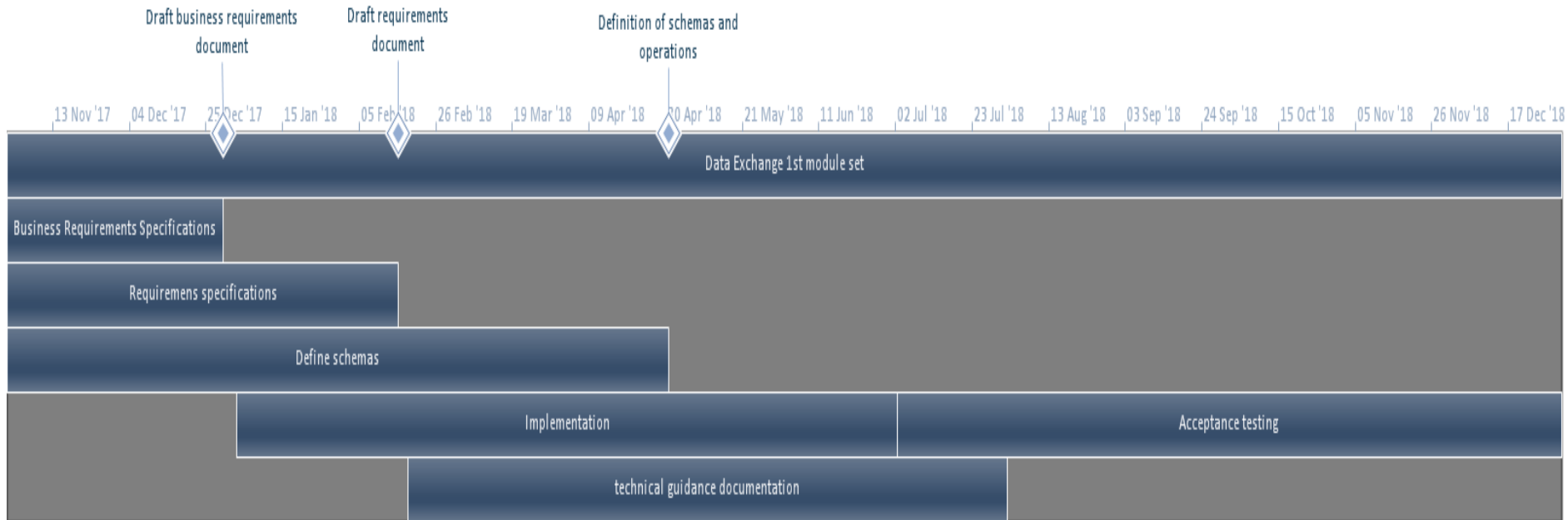
- Implementation of data exchange in parallel with the GUI, to be delivered soon after the GUI
  - 1<sup>st</sup> Actors – only download by MS (needs to be clarified)
  - 2<sup>nd</sup> UDI - Upload
  - 3<sup>rd</sup> Device – Certificates –Upload
  - 4<sup>th</sup> UDI, Device – Certificates Download for MS
  - ...
- Prepare for acceptance testing
- Deployment: only at the end, after the audit

# Overall Roadmap



# Data Exchange Roadmap

For 1<sup>st</sup> set of modules



# Communication Channels

Wiki – being set up – CIRCABC – Functional mailbox

- Foster close collaboration and receive early feedback
- Only for members of the Eudamed working groups

Use of the Wiki

- Questions and issues will be placed by COM on the wiki
- Feedback on acceptance testing will be gathered via the wiki
- Documents from outside will be handled as before by using the functional mailbox
- Supporting/Working documents will be stored on CIRCABC

WG Members invited to provide comments and input

# Q&A