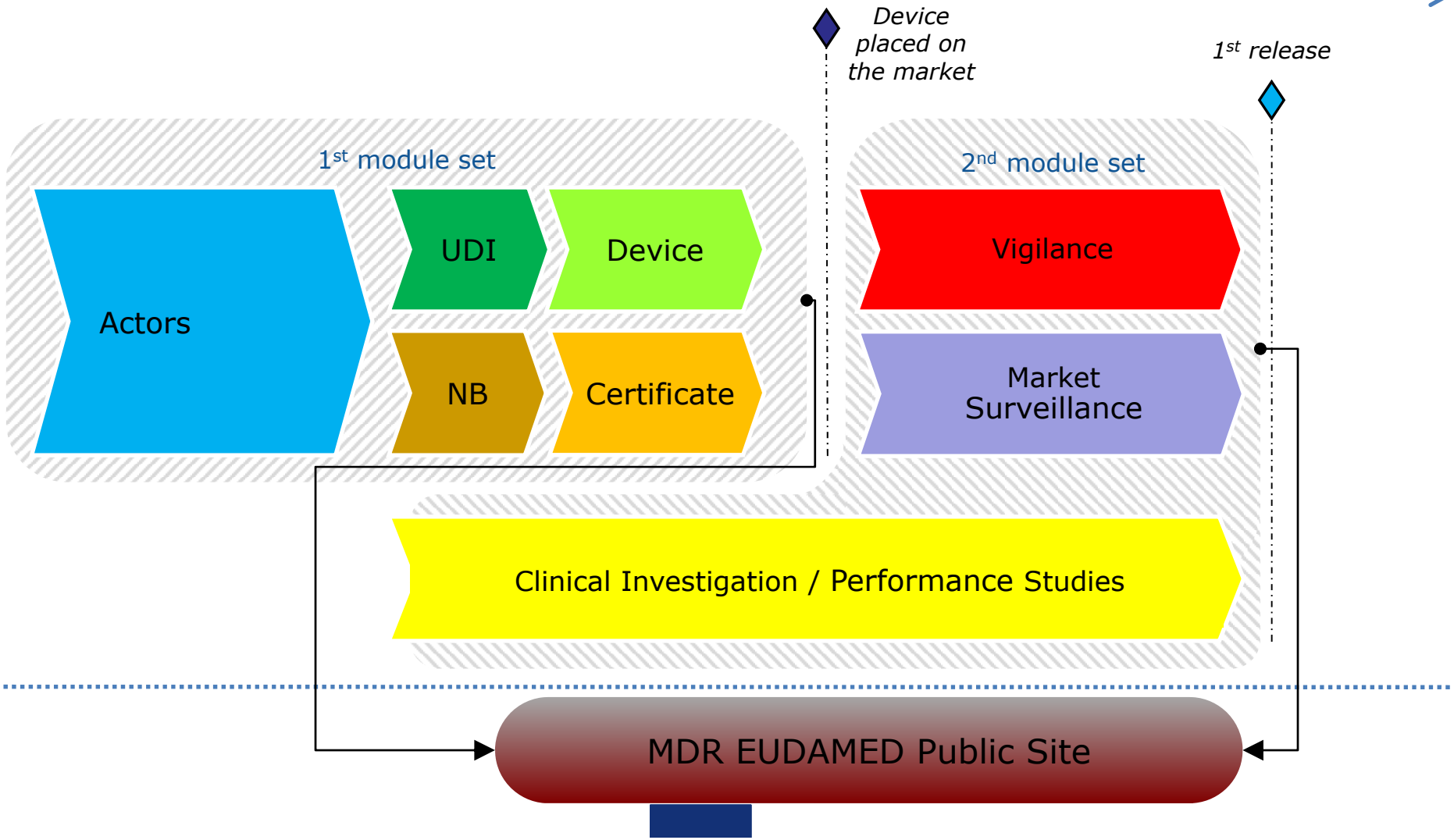
MDR Eudamed
1st Market Surveillance WG Meeting

Planning - Roadmap

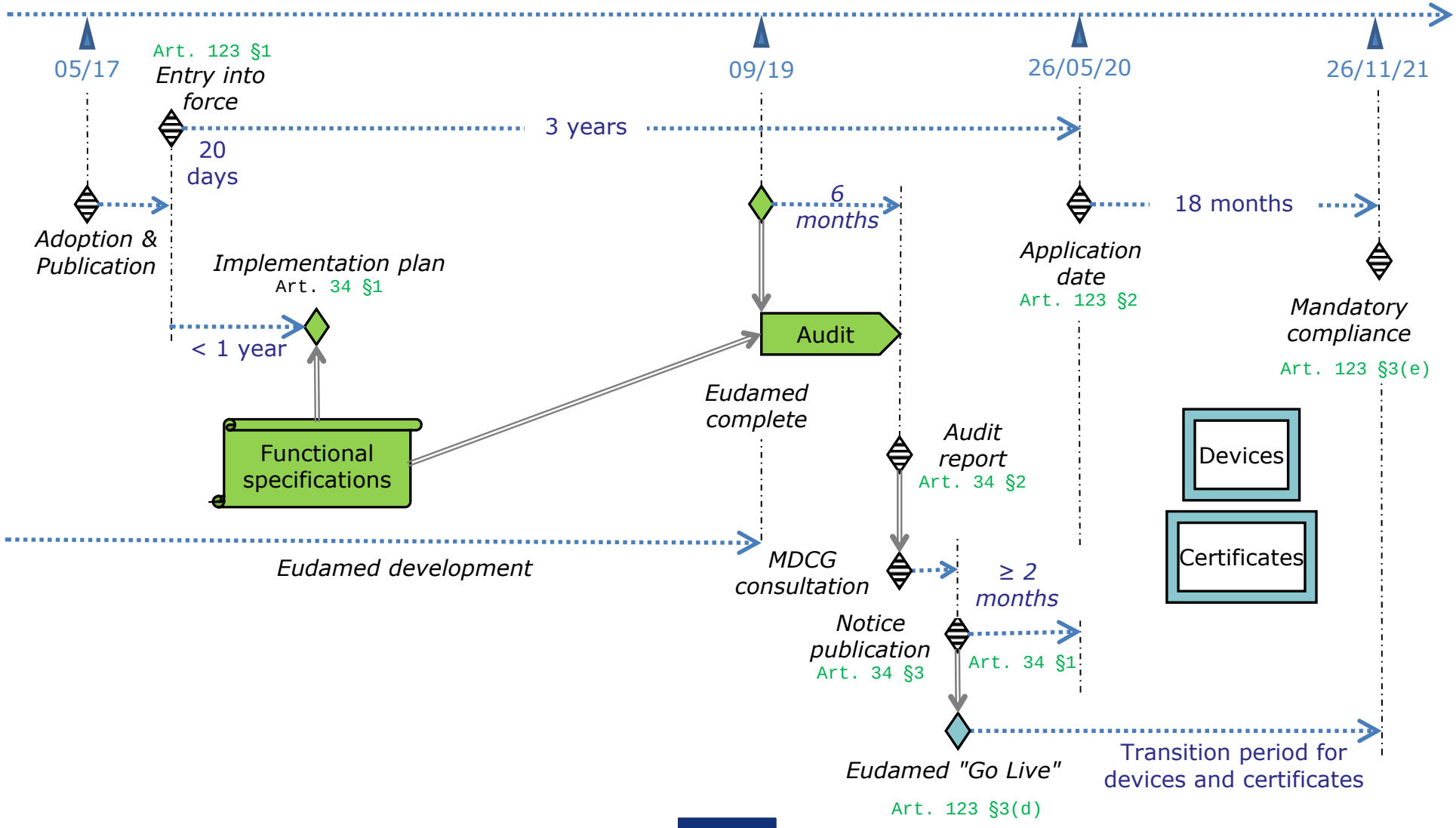
01/03/2018

Modules in Eudamed

- Article 33 MDR/30 IVDR - Electronic Systems included in Eudamed



Deadlines


05/17
Art. 123 §1
Entry into force
09/19
26/05/20
26/11/21
3 years
20 days
Adoption & Publication
6 months
18 months
Application date
Art. 123 §2
Mandatory compliance
Art. 123 §3(e)
Implementation plan
Art. 34 §1
< 1 year
Audit
Functional specifications
Eudamed complete
Audit report
Art. 34 §2
Devices
Certificates
Eudamed development
MDCG consultation
≥ 2 months
Notice publication
Art. 34 §3
Art. 34 §1
Eudamed "Go Live"
Art. 123 §3(d)
Transition period for devices and certificates

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 Market Surveillance:

- Functional Specifications document
  - Comments from WG Members and if necessary new FS by 15/03/18
- 2 weeks for feedback on the following draft documents provided by COM:
  - Wireframes / Mock-ups from end May 2018
  - Business rules from end May 2018

- Process overviews provided as from 19/05/18
- Data models as from end May 2018
- Implementation plan for first release as from 16/04/18
- Have review iterations on these documents with the aim to finalise in October 2018 (for Market Surveillance)

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

Business Risks

Implementation time not respected:

- **MDR Eudamed must be ready enough time before the date of application of the Regulations (deadline)**
- **Art 33(3) – Shall give due consideration to compatibility with national systems**
- **Art 34 – Audit requirement**
- **MDCG satisfaction + Needs for implementing acts (e.g. Art 33(8))**

Legal basis inconsistent and/or incomplete → Implementation difficult/impossible

Purposes not met:

- **unique identification and to facilitate traceability of devices within the internal market**
- **public adequately informed** about **devices** placed on the market, their **certificates** issued by NBs, the relevant **economic operators** and the **CI/PS**
- **manufacturers** to comply with information obligations on **vigilance and post-market surveillance**
- **the CAs and the EC to carry out their tasks relating to this Regulation on a well-informed basis** and to enhance the cooperation between them
- **Sponsors** to carry out their tasks and **to comply with their obligations** on **CI/PS**
- **Notified Bodies** to carry out their tasks and **to comply with their obligations**

Workability/Traceability

- **(Basic) UDI-DI Registration: Primary key in Eudamed to identify the devices in all modules → workability of Eudamed as tool for traceability**
- **Single Identification number for CI/PS**

Business Risks

Business risks – Impact/Probability

Impact/ Probability		Probability				
		Very high	High	Medium	Low	Very low
Impact	Very high					- Health of MD users impacted
	High		- Time for gathering requirements too long - Time for implementation too long	- MF cannot comply to their obligations on vigilance and post-market surveillance	- Audit requirement not met - MDCG satisfaction not met - Implementing acts not done/appropriate	
	Medium			- UDI and traceability not working (Workability) - CAs and EC cannot carry out their tasks and be well informed		
	Low				- Public not adequately informed	
	Very low					

IT Risks

Requirements specification

- *Working group members & Steering Committee together with Commission might not be able to specify the requirements in enough detail or wrongly or differently interpret the regulation which causes delay or incorrect implementation*
  - **Probability : high**
  - **Impact: high**

IT Risks

Requirements specification

- *New requirements might appear after the functional specifications have been agreed on causing scope creep and delays or extra costs; problems to achieve a positive audit report.*
  - **Probability : High**
  - **Impact : High**

IT Risks

Requirements specification

- *Due to excessive requirements the MDR EUDAMED could become too complex and would thus not meet the needs of the national competent authorities, the economic operators and the public at large (including healthcare professionals)*
  - **Probability : Medium**
  - **Impact : High**

IT Risks

Data integrity

- *MDR Eudamed could, e.g. due to an incorrect implementation, contain corrupted data.*
  - **Probability : very low**
  - **Impact : Very High**
  - **thorough testing and secure development practices will lower these risks.**

IT Risks

Disclosure of non-public data

- *An incorrect implementation might result in the disclosure of confidential data or personal data to non-authorised persons*
  - **Probability: Low**
  - **Impact: Very High**
  - **Mitigation: exclude confidential, commercial and personal data if possible; have good authorisation and authentication**

Questions?

European Commission