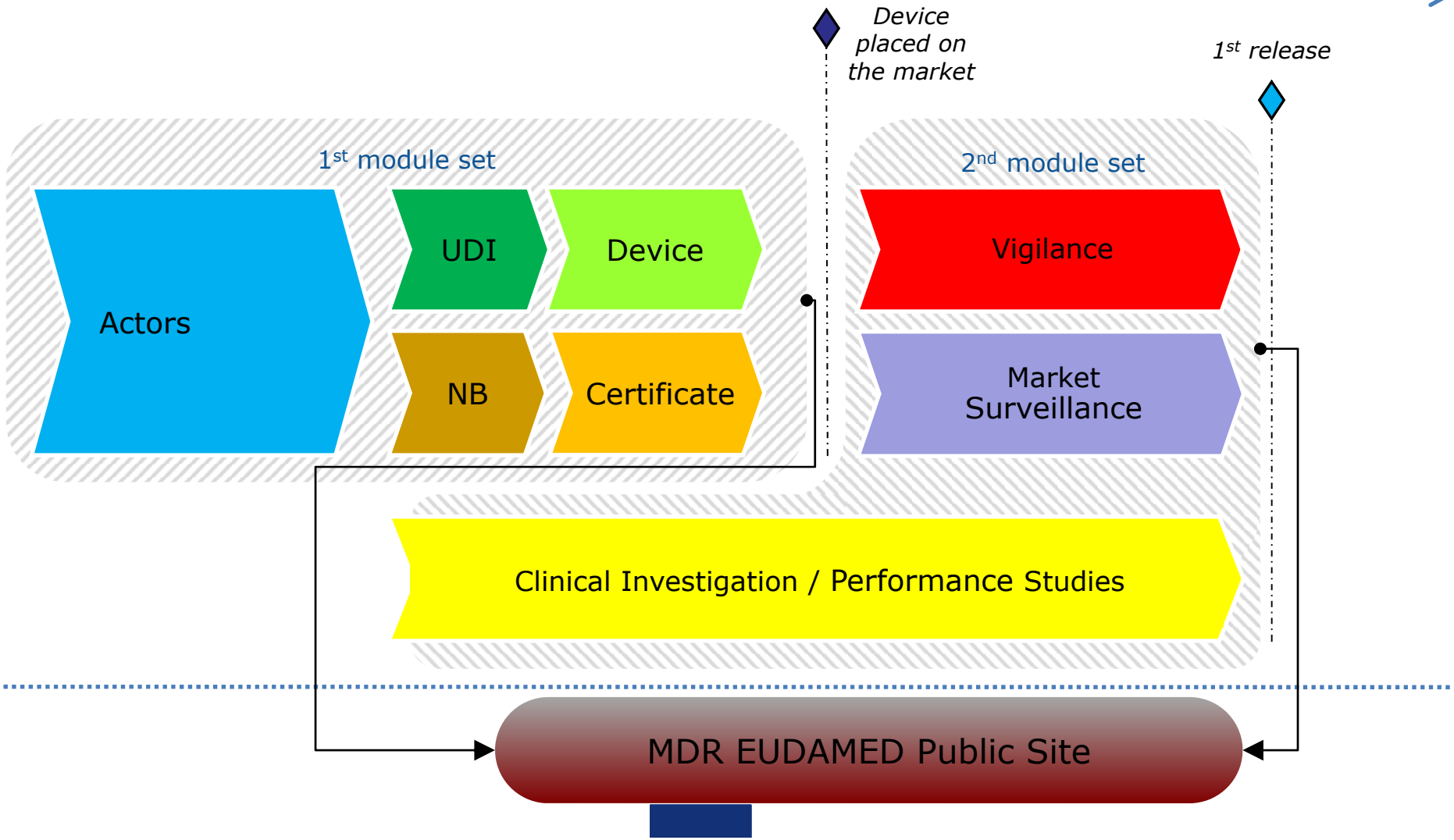
MDR Eudamed 1st Vigilance WG Meeting

Planning - Roadmap

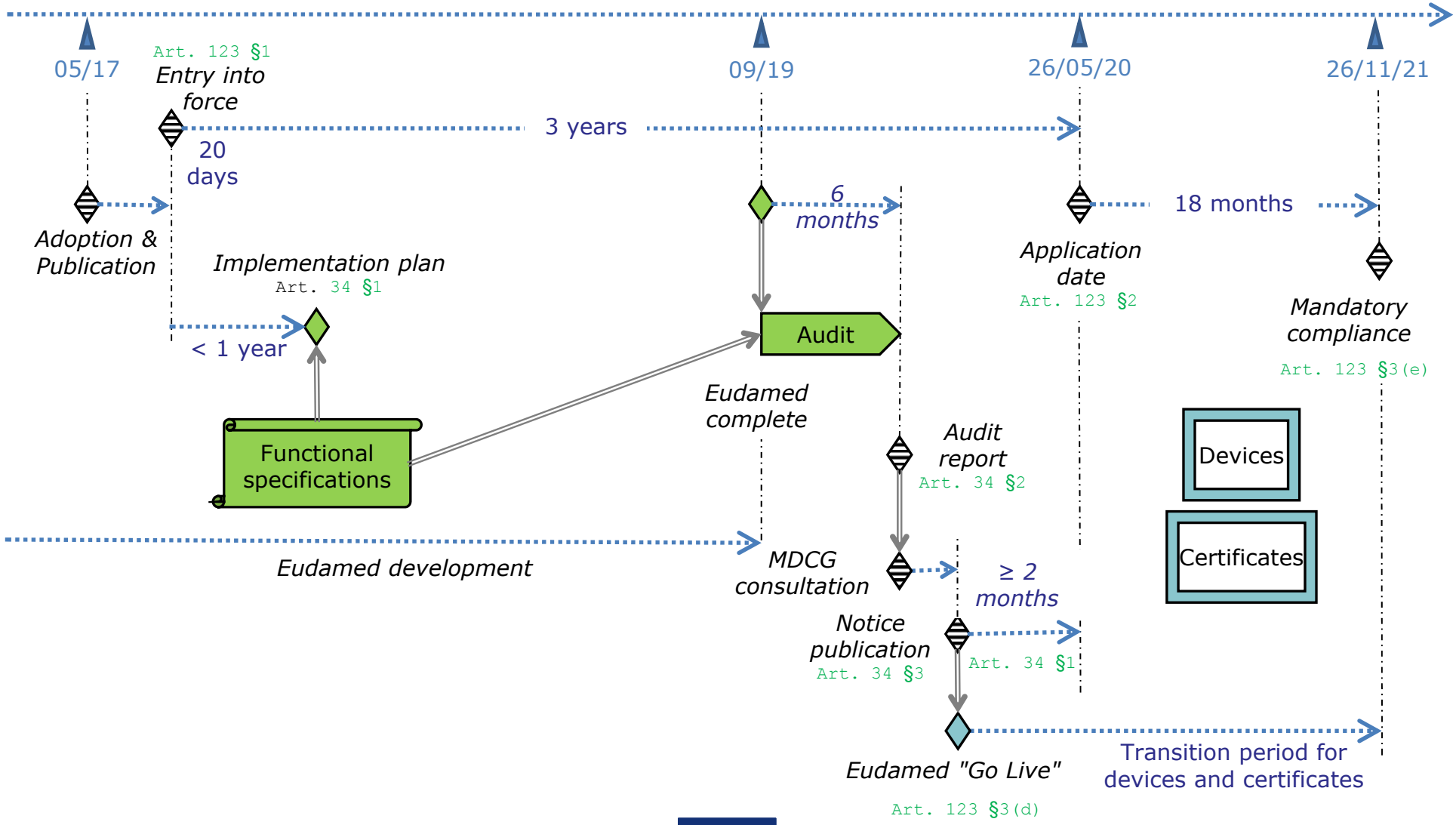
24/01/2018

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

Deliverables

- **Implementation Plan**
- **Functional Specifications**
  - **Legal requirements**
  - **Needs (feedback from WGs)**
  - **High-level requirements**
  - **Scope**
  - **Architecture overview of Eudamed**
  - **Actors**

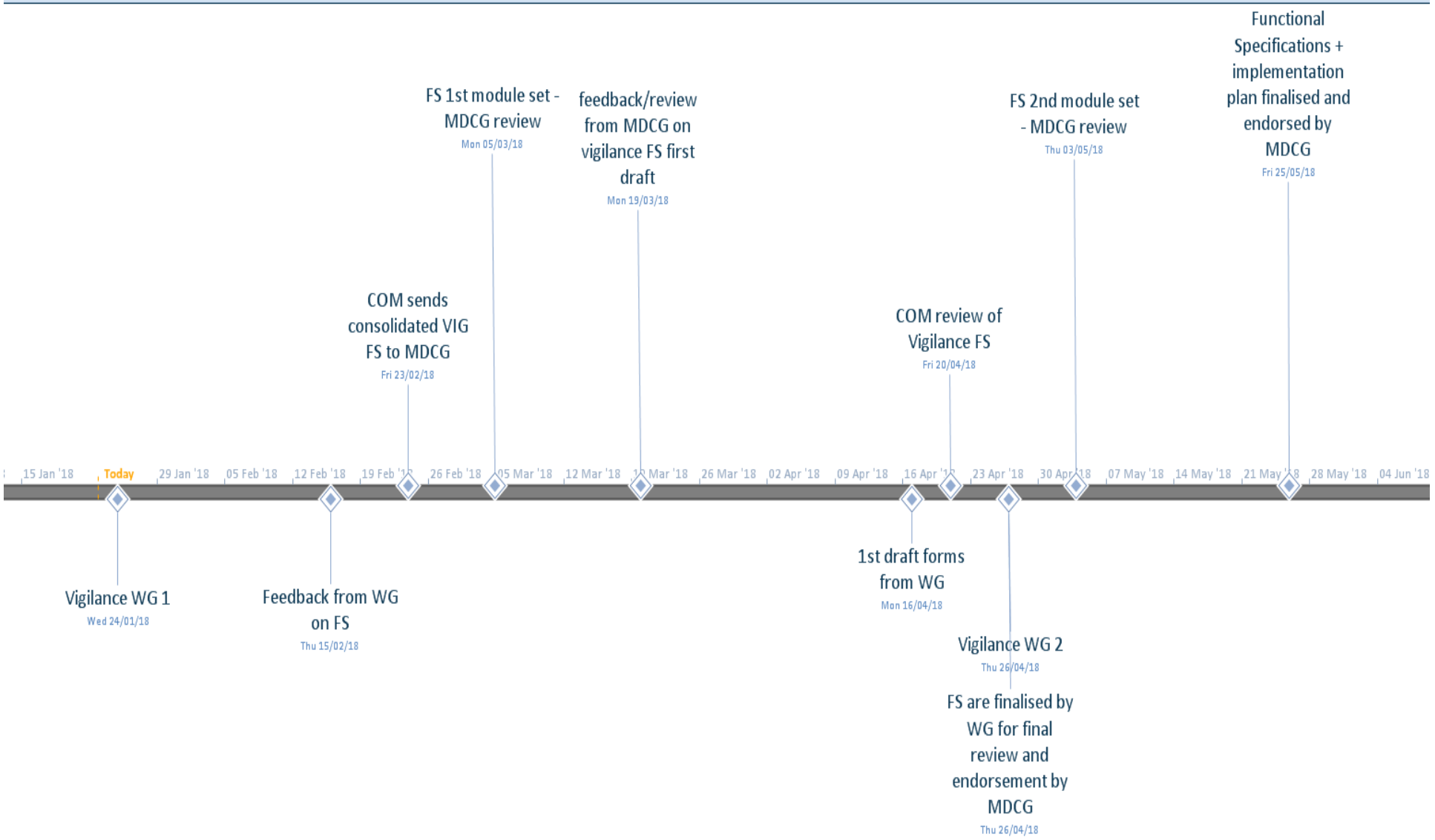
WG Collaboration

- **Workgroup Collaboration based on:**
  - **Wireframes**
  - **Epics**
  - **Processes**
  - **Logical Data Models + Constraints**
  - **Roles and grants**

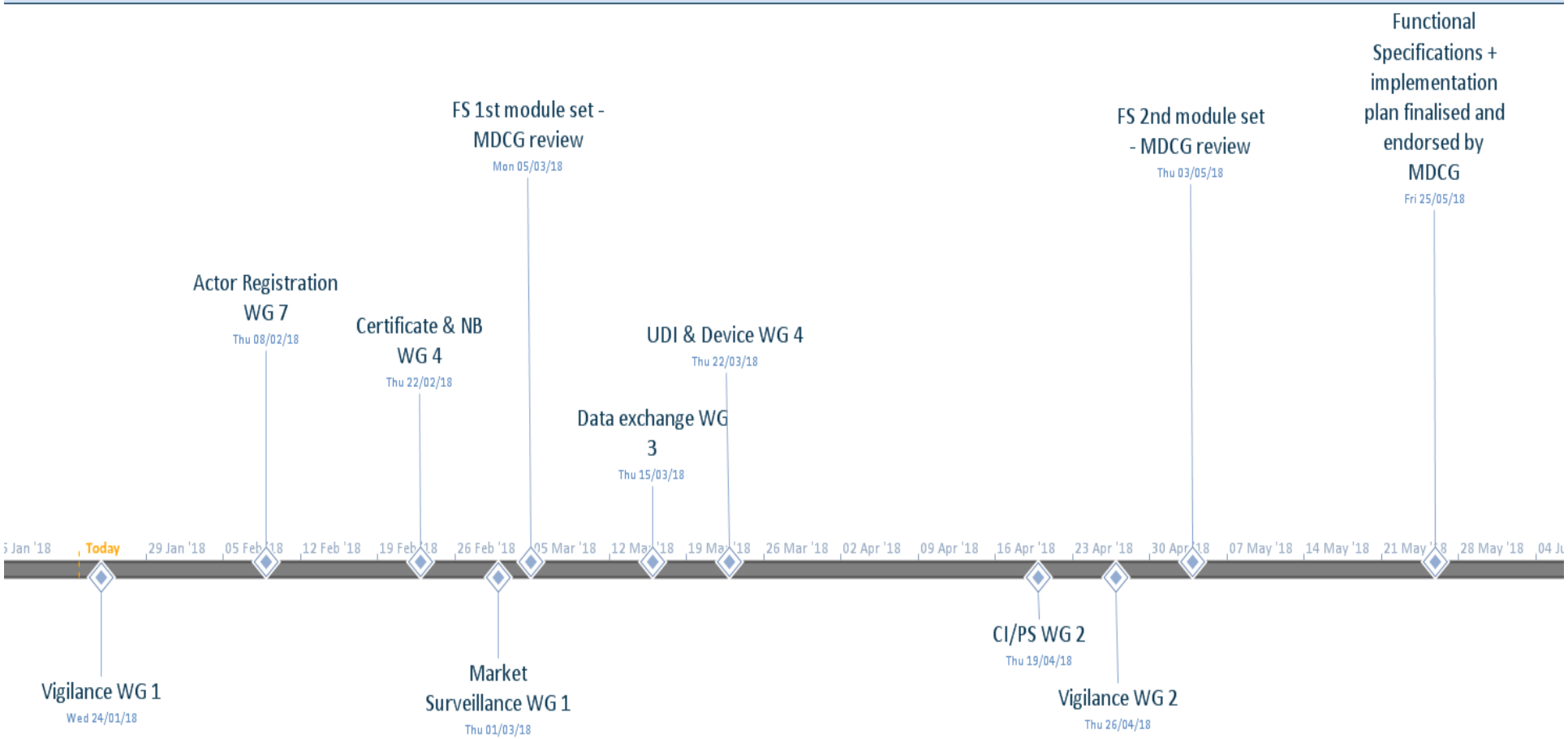
Input from WG

- **Following input is expected from the workgroup :**
  - **By 15/02/18: Feedback on functional specs**
    - **This allows COM to send consolidated Vigilance functional specs to MDCG by 23/02/18**
  - **1st draft of forms asap and by 16/04**
    - **Field Safety Corrective Action (FSCA)**
    - **Periodic Summary Report (PSR)**
    - **Trend Report (TR)**
    - **Field Safety Notice (FSN)**
    - **Periodic Safety Update Reports (PSUR)**

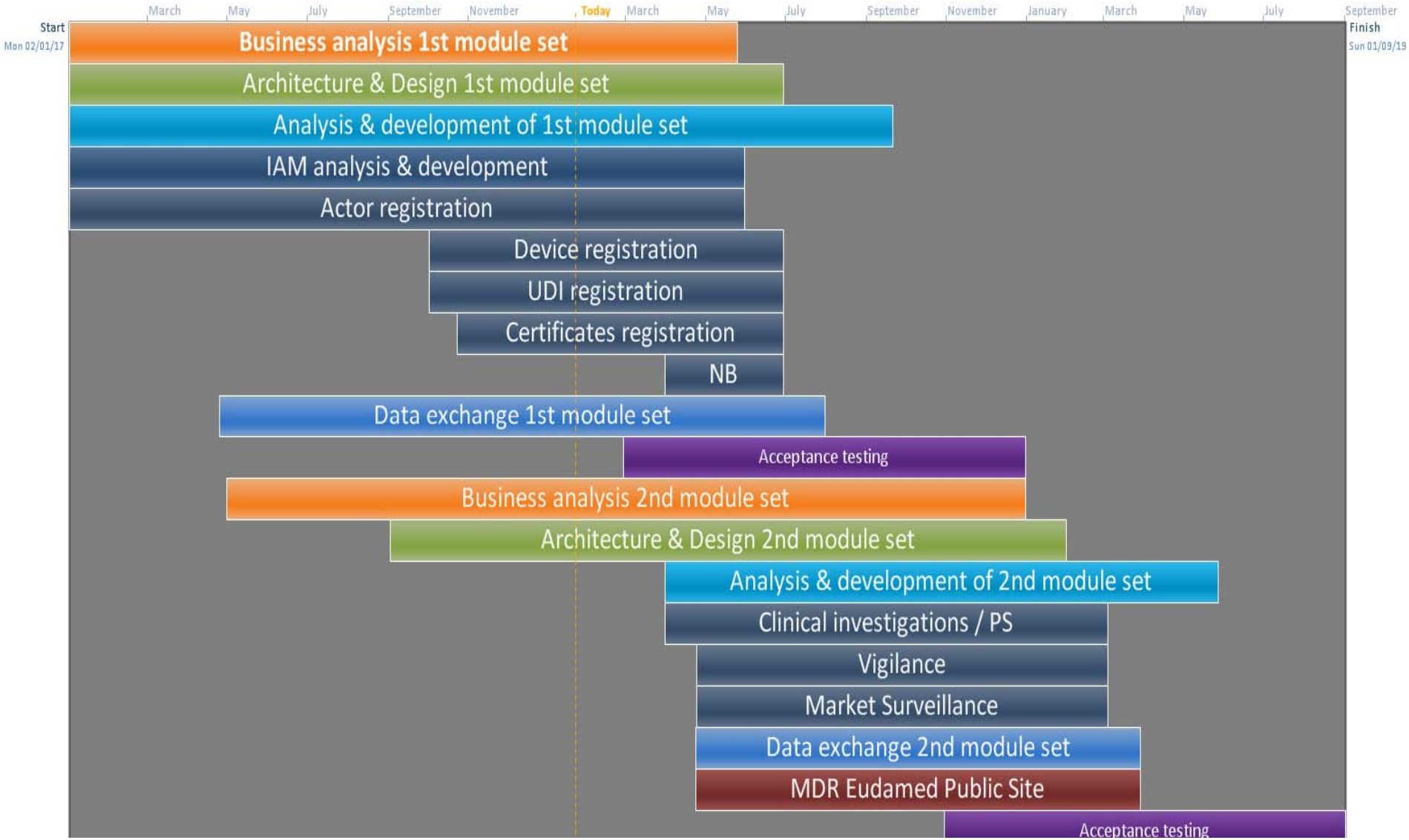
Planning


Functional Specifications + implementation plan finalised and endorsed by MDCG
Fri 25/05/18
FS 2nd module set - MDCG review
Thu 03/05/18
FS 1st module set - MDCG review
Mon 05/03/18
feedback/review from MDCG on vigilance FS first draft
Mon 19/03/18
COM sends consolidated VIG FS to MDCG
Fri 23/02/18
COM review of Vigilance FS
Fri 20/04/18
15 Jan '18
Today
29 Jan '18
05 Feb '18
12 Feb '18
19 Feb '18
26 Feb '18
05 Mar '18
12 Mar '18
19 Mar '18
26 Mar '18
02 Apr '18
09 Apr '18
16 Apr '18
23 Apr '18
30 Apr '18
07 May '18
14 May '18
21 May '18
28 May '18
04 Jun '18
Vigilance WG 1
Wed 24/01/18
Feedback from WG on FS
Thu 15/02/18
1st draft forms from WG
Mon 16/04/18
Vigilance WG 2
Thu 26/04/18
FS are finalised by WG for final review and endorsement by MDCG
Thu 26/04/18

Planning


Functional Specifications + implementation plan finalised and endorsed by MDCG
Fri 25/05/18
FS 2nd module set - MDCG review
Thu 03/05/18
FS 1st module set - MDCG review
Mon 05/03/18
Actor Registration WG 7
Thu 08/02/18
Certificate & NB WG 4
Thu 22/02/18
UDI & Device WG 4
Thu 22/03/18
Data exchange WG 3
Thu 15/03/18
Today
29 Jan '18
05 Feb '18
12 Feb '18
19 Feb '18
26 Feb '18
05 Mar '18
12 Mar '18
19 Mar '18
26 Mar '18
02 Apr '18
09 Apr '18
16 Apr '18
23 Apr '18
30 Apr '18
07 May '18
14 May '18
21 May '18
28 May '18
Vigilance WG 1
Wed 24/01/18
Market Surveillance WG 1
Thu 01/03/18
CI/PS WG 2
Thu 19/04/18
Vigilance WG 2
Thu 26/04/18

Overall Roadmap



Conclusion Roadmap

Planning

- Commitment of resources for timely deliveries
- Progress based on reviews of mock-up and/or prototypes
- Only 1 Audit on final release including all modules and functionalities (no partial go-live)
- Implementation Plan for functional specifications
- Acceptance testing as soon as modules / functionalities are ready
- Derogation applied as long as MDR Eudamed is not functional

Content

- WG feedback should result in user-friendly functionality

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**

  E.g.
  - **Specifications for PSR and TR**

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