MDR Eudamed 4th Steering Committee Meeting

Planning - Roadmap

6/04/2017

Regulation milestones

Medical Devices

Entry into force	20 days after publication in the Official Journal	Art. 123 §1
Application	Three years after *Entry into force*	Art. 123 §2

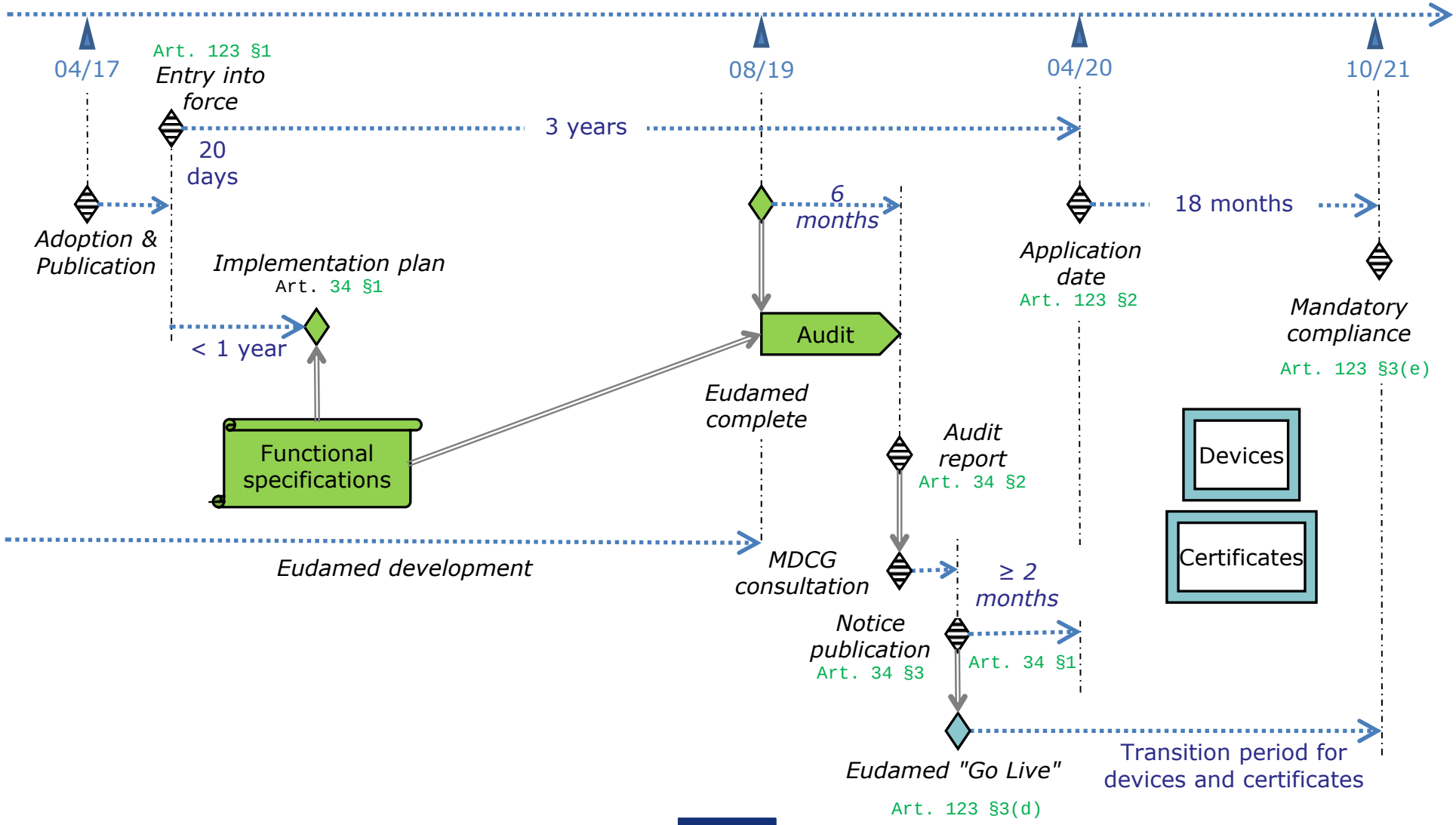
In Vitro Diagnostic Medical Devices

Entry into force	20 days after publication in the Official Journal	Art. 113 §1
Application	Five years after *Entry into force*	Art. 113 §2

Eudamed milestones

Functional specifications	EC to draw up in collaboration with the MDCG	MDR Art. 34 §1
Implementation plan of the *Functional specifications*	EC to draw up at the latest on *Entry into force* + 12 months	
Audit	Independent Auditors to verify compliance with *Functional specifications*	34 §2
Notice in the Official Journal	EC to publish after MDCG consultation at the latest two months before MDR *Application*	34 §1,3
"Go Live"	Eudamed may Go Live only after publication of the *Notice*	34 §1

Deadlines


04/17
Art. 123 §1
Entry into force
08/19
04/20
10/21
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
Eudamed complete
Functional specifications
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

Supervising entity designation

MDR Art. 123 §3(b) states that Articles 35 to 49, 101 and 103 apply from *Entry into force* + 6 months

- **Member States appoint MDCG members** (Art. 103)
- **EC + Member States nominate experts to assess Notified Body designation requests** (Art. 40)
- **Notified Bodies [may] request designation** (Art. 38)

(SRN and UDI not mandatory in Certificates issued before *Application*)

- ...

NB designation under MD Directives becomes void at *Application* date (Art. 120 §1)

Mandatory compliance

Art. 123 §3(d) states that three years after *Entry into force*, [using Eudamed] it shall be mandatory (i.a.) for:

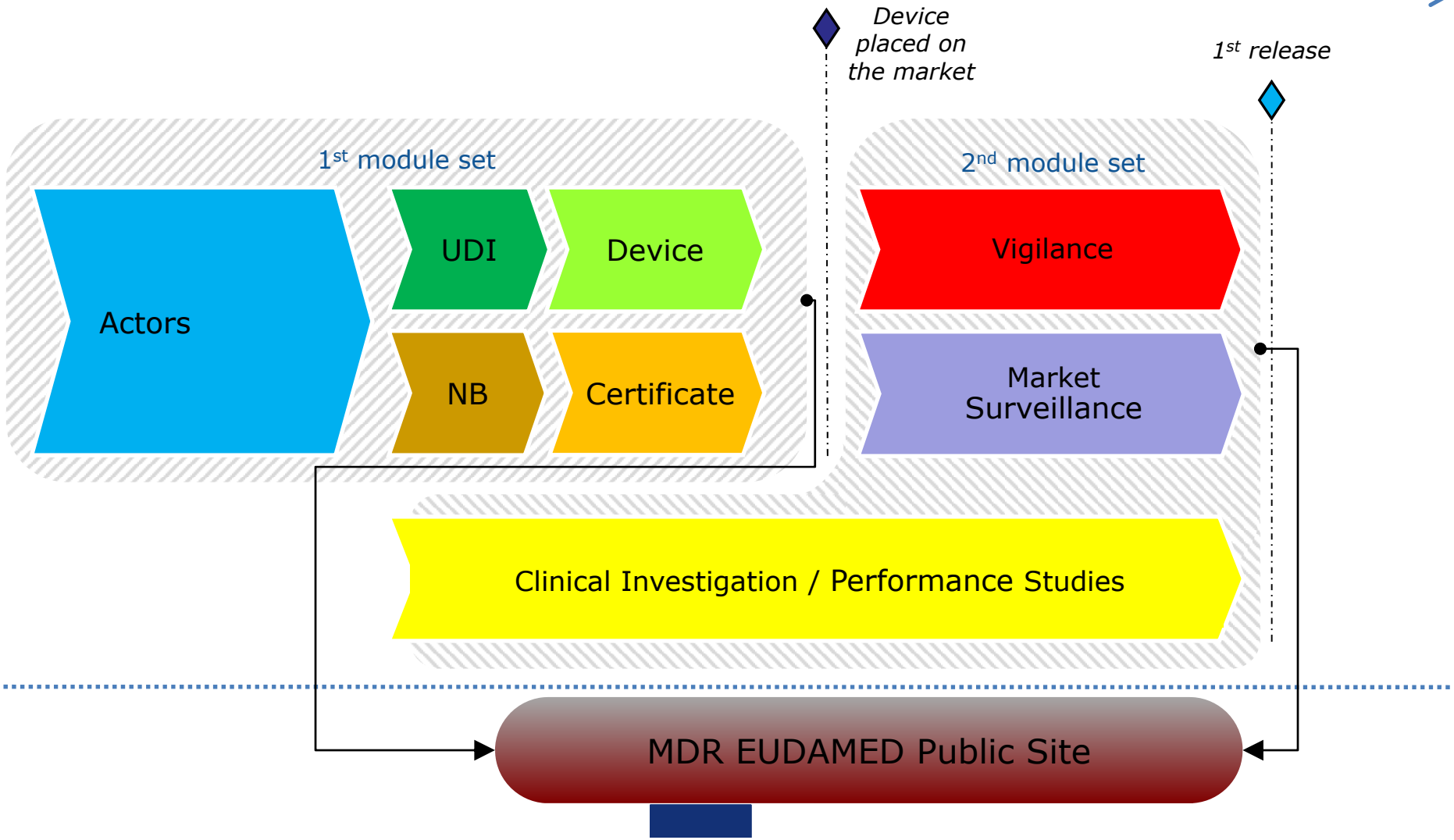
- **Manufacturers to obtain their *SRN***
- **Manufacturers to register the *Basic UDI-DI* of their devices**
- **Manufacturers to report their *Incidents***
- **Competent Authorities to manage their *Market Surveillance* data**
- **Sponsors to introduce *Clinical Investigation / Performance Studies***

Art. 123 §3(e) states that 18 months after date of *Application*, before placing a device on the market, it shall be mandatory for:

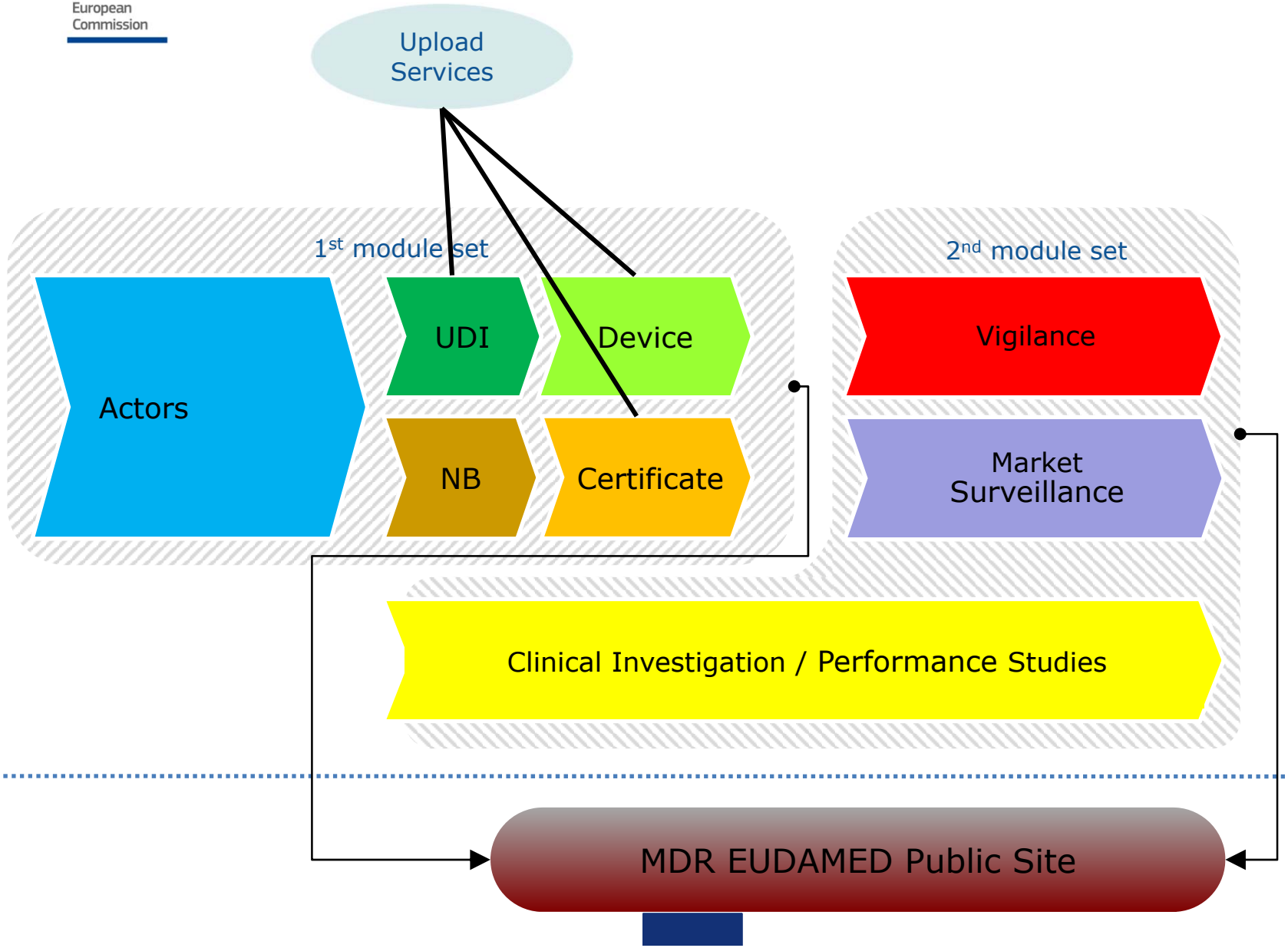
- **Manufacturers to enter *device* data in Eudamed(Art. 29 § 4)**
- **Notified Bodies to enter *Certificate* data in Eudamed (Art. 56 § 5)**

Business processes in Eudamed

- Article 33 MD/30 IVD - Electronic Systems included in Eudamed



Most Important Upload Services



Eudamed module sets

IAM: Identity & Access Management

- Authentication – Authorisation
- User Management

1st module set

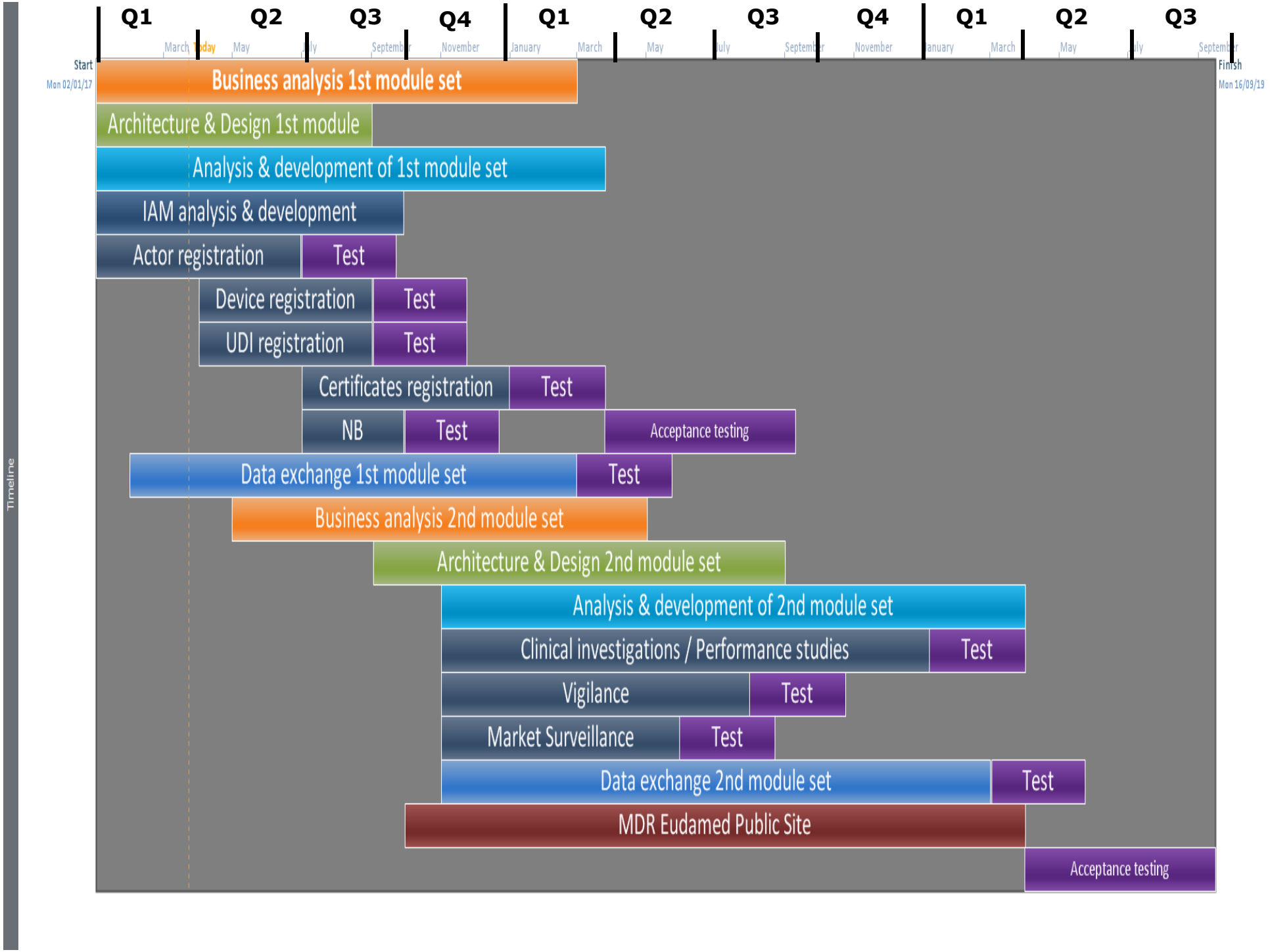
- Actor registration
- UDI
- Device
- Notified Bodies
- Certificates
- Data exchange for 1st module set – Focus on upload functionality for
  - UDI Data
  - Device Data
  - Certificates Data

2nd Module Set

- Clinical Investigations / Performance Studies
- Vigilance – Post-Market Surveillance
- Market Surveillance
- Data exchange for 2nd module set

Public MDR Eudamed site

- Display public data
- Allow for searching of public data


Timeline
Q1
Q2
Q3
Q4
Q1
Q2
Q3
Q4
Q1
Q2
Q3
March
Today
May
July
September
November
January
March
May
July
September
November
January
March
May
July
September
Start
Mon 02/01/17
Finish
Mon 16/09/19
Business analysis 1st module set
Architecture & Design 1st module
Analysis & development of 1st module set
IAM analysis & development
Actor registration
Test
Device registration
Test
UDI registration
Test
Certificates registration
Test
NB
Test
Acceptance testing
Data exchange 1st module set
Test
Business analysis 2nd module set
Architecture & Design 2nd module set
Analysis & development of 2nd module set
Clinical investigations / Performance studies
Test
Vigilance
Test
Market Surveillance
Test
Data exchange 2nd module set
Test
MDR Eudamed Public Site
Acceptance testing

Current work

- **Actor Registration development**
- **Business analysis for NB and Certificates modules**
- **Business and technical analysis for Data Exchange**
- **Graphical design + mockups**
- **Follow up on Basic UDI-DI**
- **Increasing the IT team size**

Starting

- **Business analysis for CIV / PS**
- **Preparing functional specifications and implementation plan**

Conclusion

Planning

- Progress based on reviews of mock-up and/or prototypes
- Acceptance testing as soon as modules / functionalities are ready
- Derogation applied as long as MDR Eudamed is not functional
- Review of plans based on project progress and commitment to achieve deadlines.

Thank you!