European Commission

MDR Eudamed
1st CI/PS WG meeting

Scope – Roadmap - Risks

23/11/2017

Scope

We will deal with both CI and PS at the same time.

In scope:

- Implementation of electronic system for collecting and processing of information regarding certain aspects of clinical investigations:
  - Create singe identification numbers of clinical investigation
  - Submission of all applications or notifications for clinical investigations
  - Exchange of information between Member States and between them and the Commission
  - Recording progress and outcome from conducted clinical investigations
  - Reporting on serious adverse events and device deficiencies and related updates

Scope

In scope:

Enable sponsors

- to submit clinical investigation / performance study, application with the single identification number created by the system;
- to submit a multi-sites clinical investigation / performance study, application with a single coordinated application that is transmitted to all concerned Member States by Eudamed;
- to indicate that a clinical investigation / performance study application is withdrawn or that a clinical investigation / performance study is temporarily halted or terminated early;
- to update clinical investigations' / performance studies' information;
- to report serious adverse events and device deficiencies;
- to upload the clinical investigations / performance study report and its summary that will be publicly available through Eudamed.

Scope

In scope:

Enable Competent Authorities to provide:

- their decision on the completeness and applicability of an application for a clinical investigation / performance study;
- their decision with required documents on the authorisation of an application for a clinical investigation / performance study;
- their decision for modification, suspension or termination of a clinical investigation/performance study due to some events.

Foresee interoperability with the EU database for clinical trials on medicinal products for human use as concerns combined clinical investigations of devices with a clinical trial.

Roadmap

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Regulation milestones

Medical Devices

Entry into force	20 days after publication in the Official Journal – 26/05/2017	Art. 123 §1
Application	Three years after *Entry into force* – *26/05/2020*	Art. 123 §2

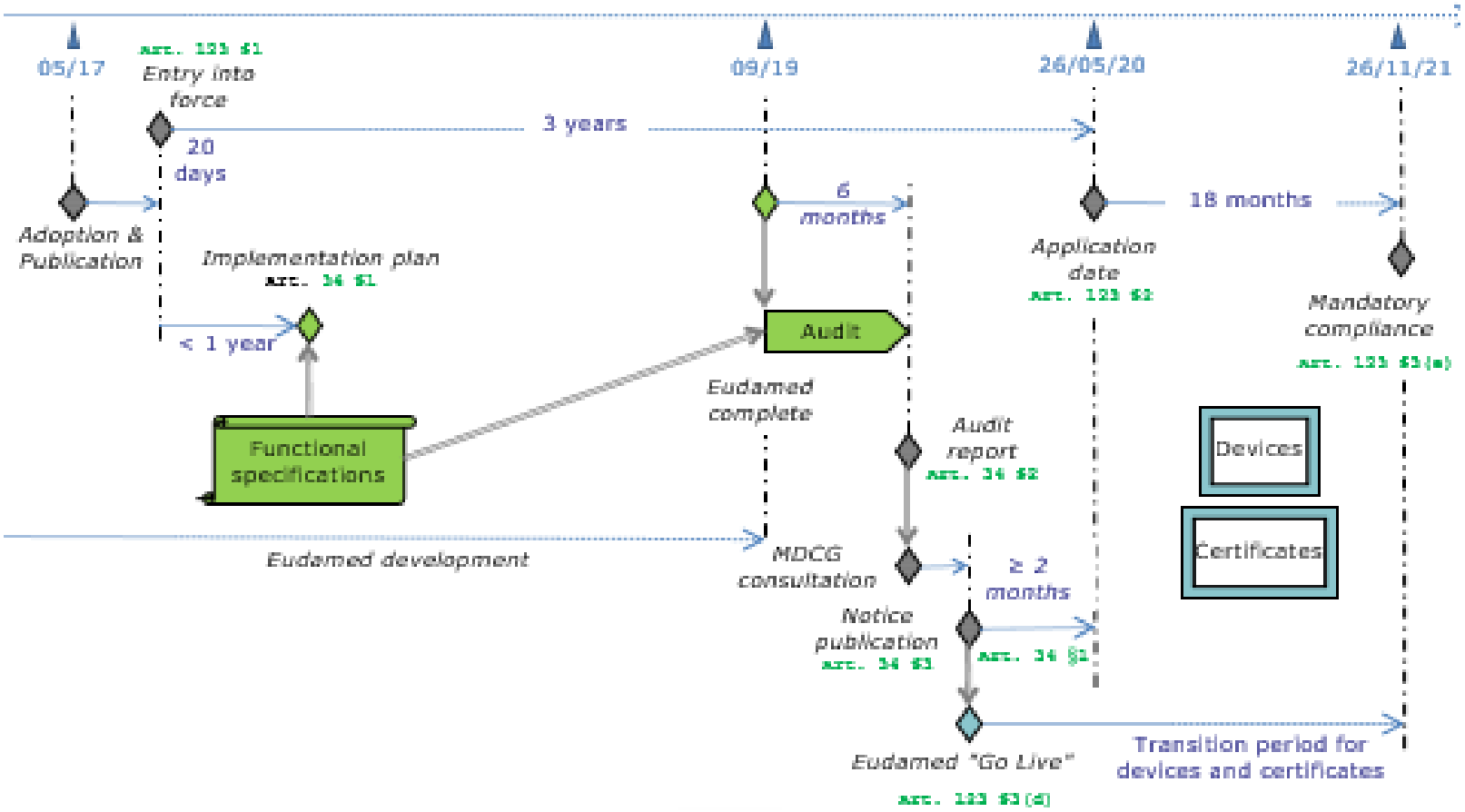
In Vitro Diagnostic Medical Devices

Entry into force	20 days after publication in the Official Journal – 26/05/2017	Art. 113 §1
Application	Five years after *Entry into force* – *26/05/2022*	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 – by 26/05/2018	
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 – by 25 March 2020*	34 §1,3
"Go Live"	Eudamed may Go Live only after publication of the *Notice*	34 §1

Deadlines


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

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***
- **Sponsors to introduce *Clinical Investigation / Performance Studies***
- **Sponsors to report their *Serious Adverse Events and device deficiencies***

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)**

Art. 120 §11 – During transitional period - Serious adverse events and device deficiencies have to be reported in MDR Eudamed also for CI/PS started under the Directives.

Mandatory compliance

Art. 123 §3(h) states that the procedure set out in Article 78 (Coordinated assessment procedure for clinical investigations) shall apply from 26 May 2027, without prejudice to Article 78(14)

Art. 78 §14 : This coordinated assessment procedure shall be applied only by those MS in which the CI is to be conducted which have agreed to apply it. After 27 May 2027, all Member States shall be required to apply that procedure.

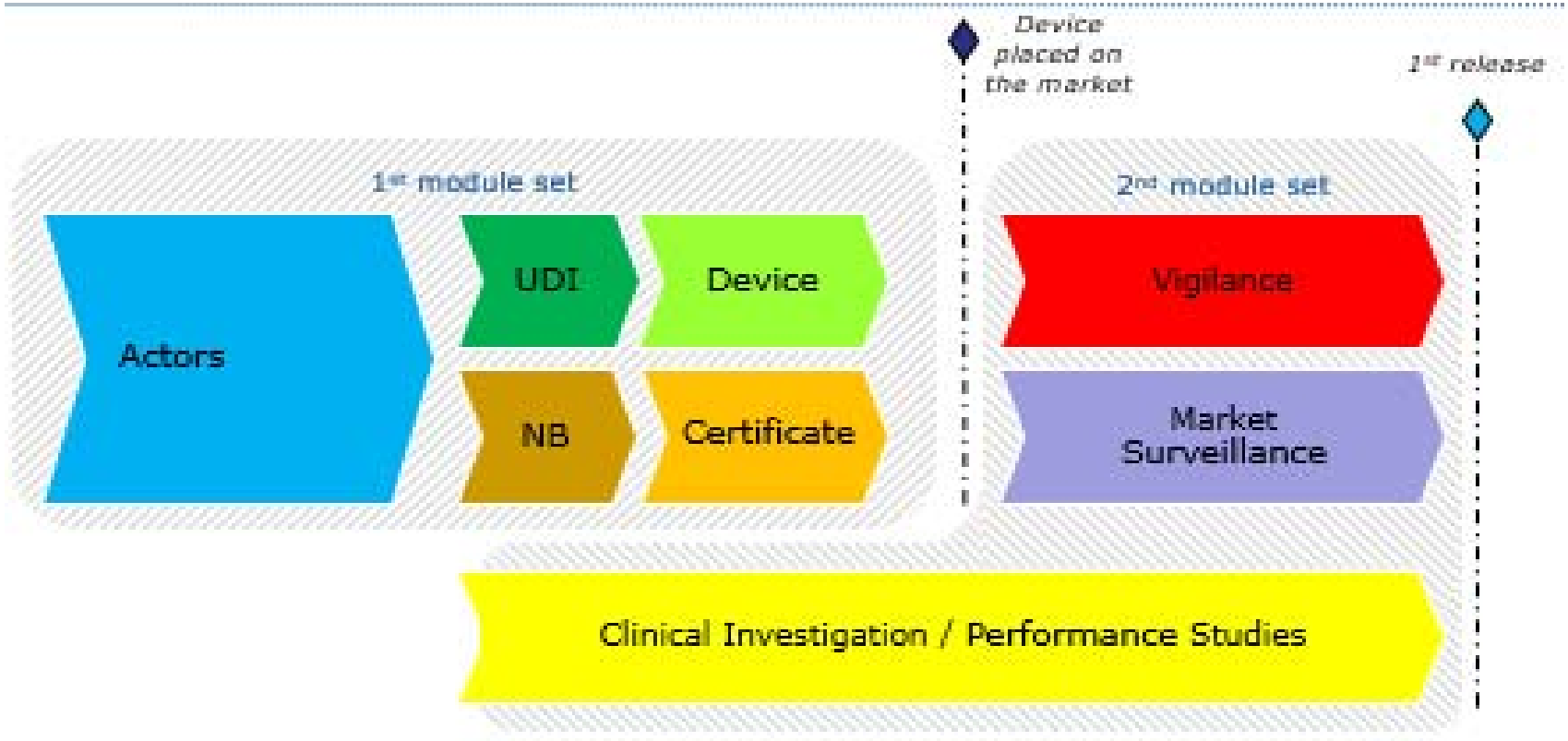
Art. 79 : Review of coordinated assessment procedure by 27/05/2026 – report on experience gained with Coordinated assessment procedure and, if necessary propose a review of Art. 78(14) and Art. 123 (h)

For IVD PS – similar articles but different dates:

- **Art. 113 §3(g) : 26/05/2027**
- **Art. 74 §14 : 27/05/2029**
- **Art. 75: 27/05/2028**

Business processes in Eudamed

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



- Start with 1st set of Modules (Actors first) but all available together in first release

Eudamed module sets

IAM: Identity & Access Management

- Authentication – Authorisation
- User Management

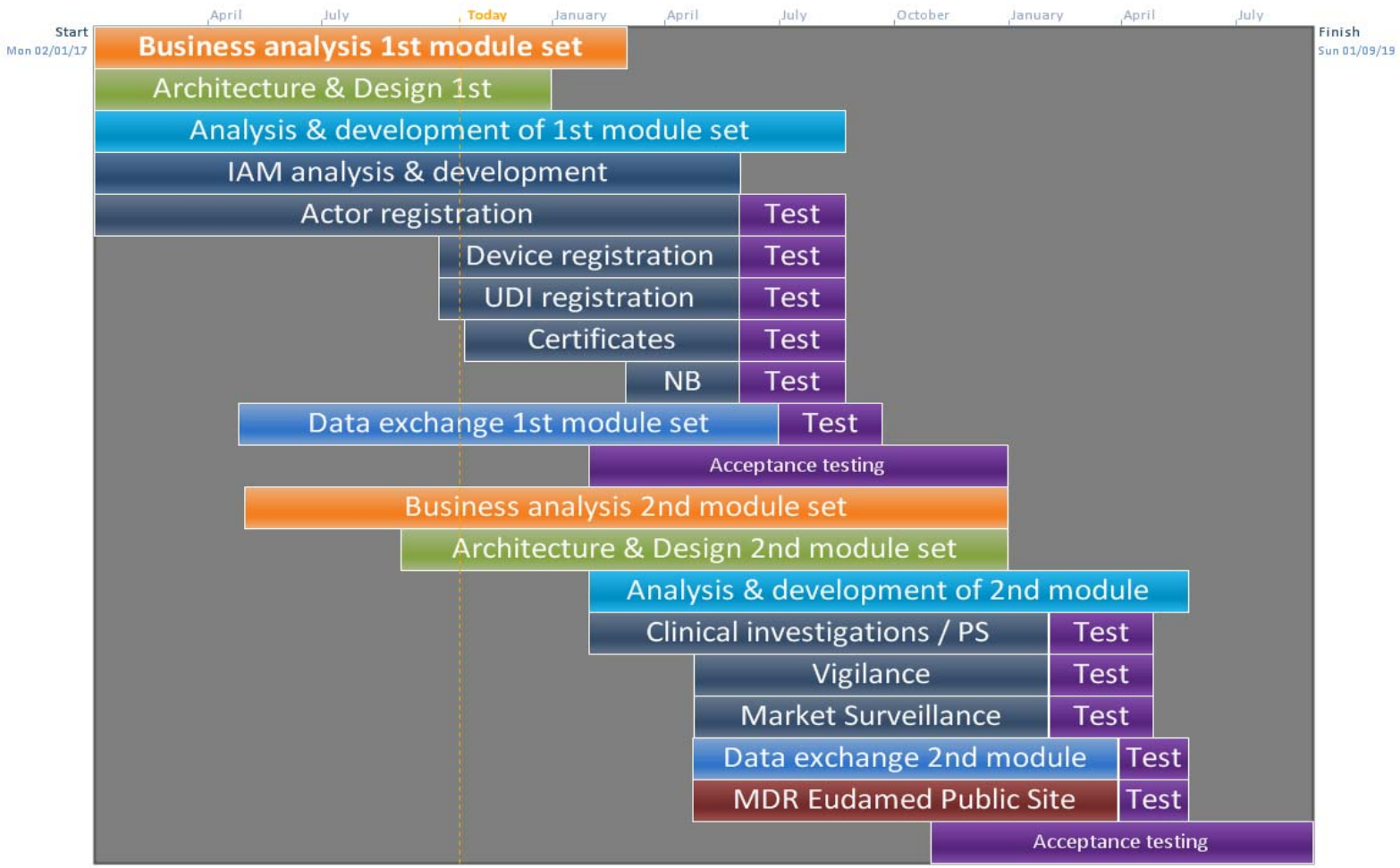
1st module set

- Actor registration
- UDI
- Device
- Notified Bodies
- Certificates
- Data exchange for 1st module set

2nd module set

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

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)
- 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

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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 (majority of 28 MS) + 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
- enable manufacturers to comply with information obligations on **vigilance and post-market surveillance**
- **enable 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
- **enable Sponsors to carry out their tasks and to comply with their obligations** on CI/PS

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 development too long - Audit requirement not met - MDCG satisfaction not met - Implementing acts not done/appropriate - MF cannot comply to their obligations on vigilance and post-market surveillance - Sponsors cannot comply to their obligations	
	Medium			- UDI and traceability not working (Workability)	- CAs and EC cannot carry out their tasks	
	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.
  - **Basic UDI-DI discussion**
  - **Which Nomenclature to be used?**

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 : Medium**
  - **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 sponsors and the public at large*
  - **Probability : Medium**
  - **Impact : High**

IT Risks

Legal Risk

- *Legal risk : users might complain that their entries have been lost. This risk is reduced by keeping all versions of the data, tracing user activity in the application (for non-repudiation purposes) and we'll investigate possibilities for reliable delivery of messages.*
  - **Probability: low**
  - **Impact: low**

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?

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