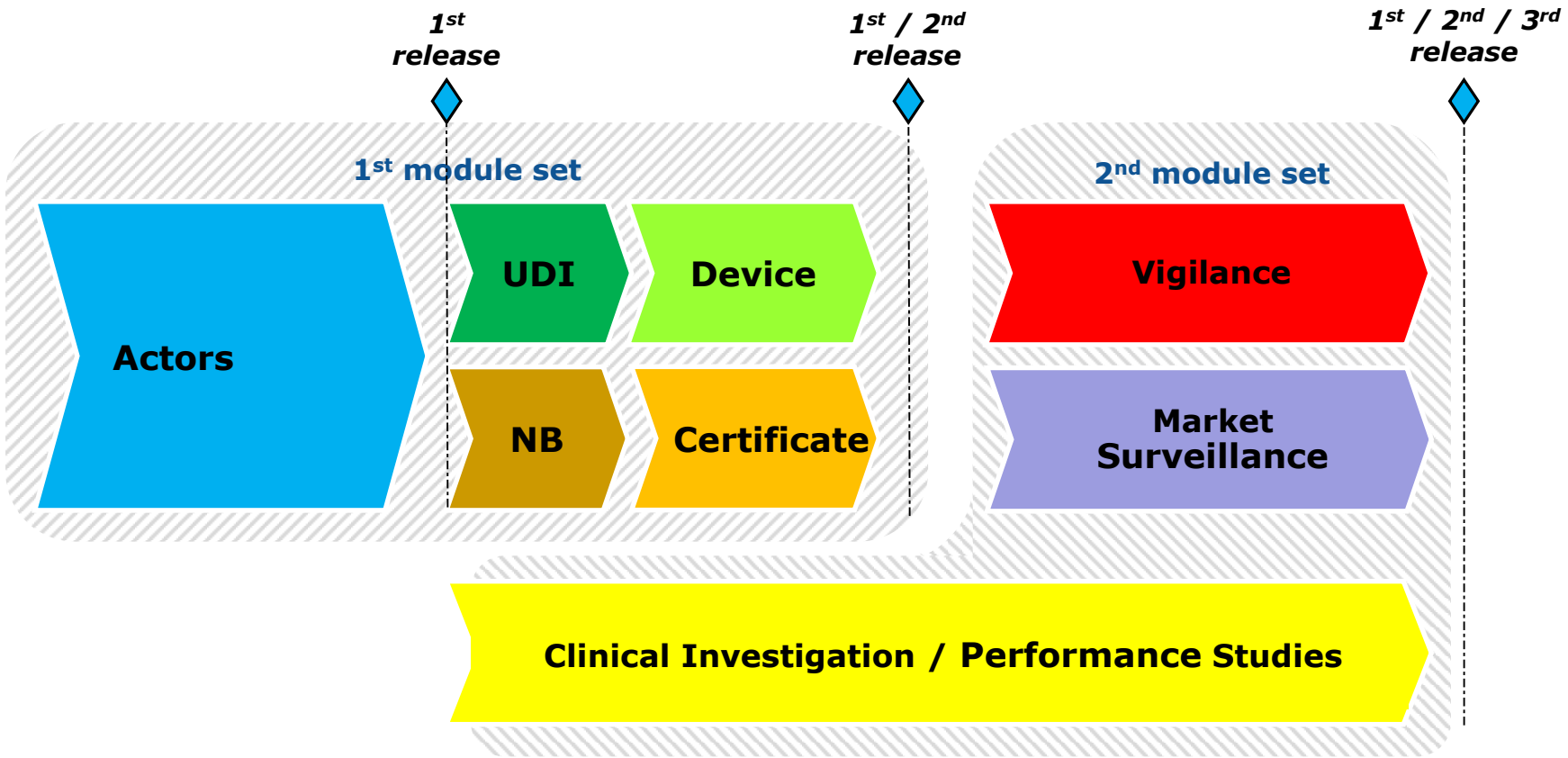
MDR Eudamed Registration WG

Transition period – Roadmaps

20/10/2016

Internal market, Industry, Entrepreneurship and SMEs

- **Article 27 MD/25 IVD - Electronic Systems included in Eudamed**



- **Priority to 1st set of Modules (Actors first) with different possibilities of releases**

Transitional provisions (Art 94/87)

- **Article 94 MD/ 87 IVD - Transitional provisions**
  - NB designations under Directives stop at date of application
  - NBs may be designated, may apply conformity assessments and issue certificates before date of application
  - Certificates under Directives remain valid until certificates end date (max 2 or 4 years after date of application and 5 years period)
  - Devices complying with the Regulations, may be placed on the market before date of application
  - Devices compliant under Directives prior to the date of application may continue to be on the market/put into service until 5 years after that date
  - During the 18 months after date of application/Eudamed application, economic operators and NBs complying with MDR Eudamed registration should be considered compliant with national legislations
  - CI/PS started prior to date of application may continue, but from date of application SAE and device deficiencies to be carried out from Regulations
  - GS1, HIBCC and ICCBBAUDI are designated issuing entities until the Commission has designated the issuing entities

Entry into force and date of application Article 97 MD/ 90 IVD

- Entry into force 20 days after OJ publication
- Date of application 3 (MD)/ 5 (IVD) years after entry into force
- Derogation to date of application:
  - **6 months after entry into force**
    NB designation, CAs designation and set up, MDCG established
  - **12 months after entry into force**
    Cooperation between MS and with the Commission
  - **3 years after entry into force (or later when Eudamed is ready)**
    All obligations/provisions requiring the use of Eudamed, except the following:
  - **18 months after date of application/Eudamed functional**
    Devices and Certificates registrations (+ Importers obligations)

… (labelling, CI/PS in several MS)

Analysis of the issues: Outcome

- SRN not required before Eudamed is functional
- NB designation will take ~ 18 months
- Devices may remain on the market
- UDI not applicable before date of application
- Audit constraint/risk/cost/workload
- Ambition/challenges in implementation of Eudamed are high → complex and high risk
- Interoperability/data exchange should be ready from go-live → fast registration of UDI, Devices and Certificates

Availability of Eudamed: Preference

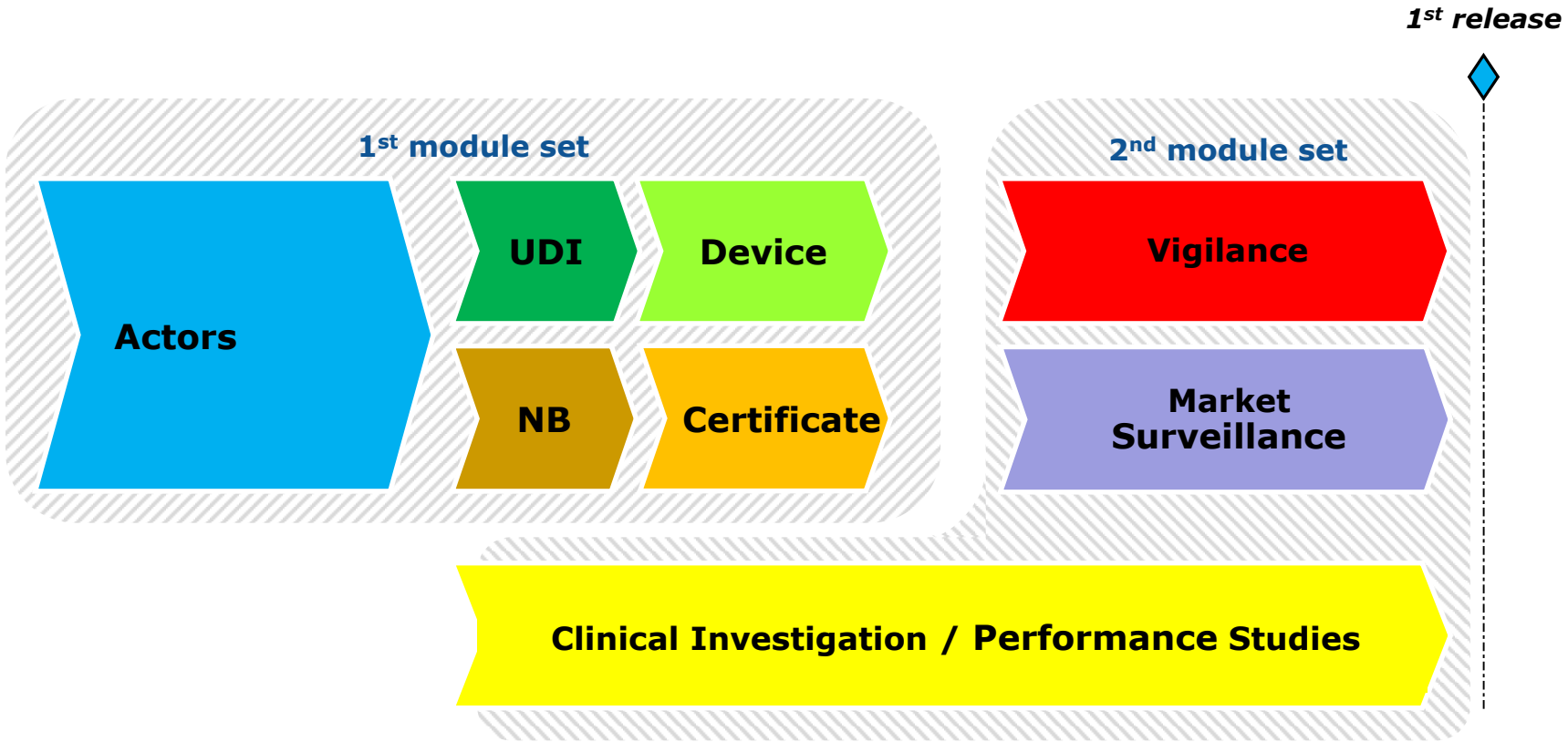
Only **one release** including all modules going life:

- **as soon as possible**
- **Not before 2 years after entry into force**
- **No later than 2 years and 10 months (3 years – 2 months) after entry into force**

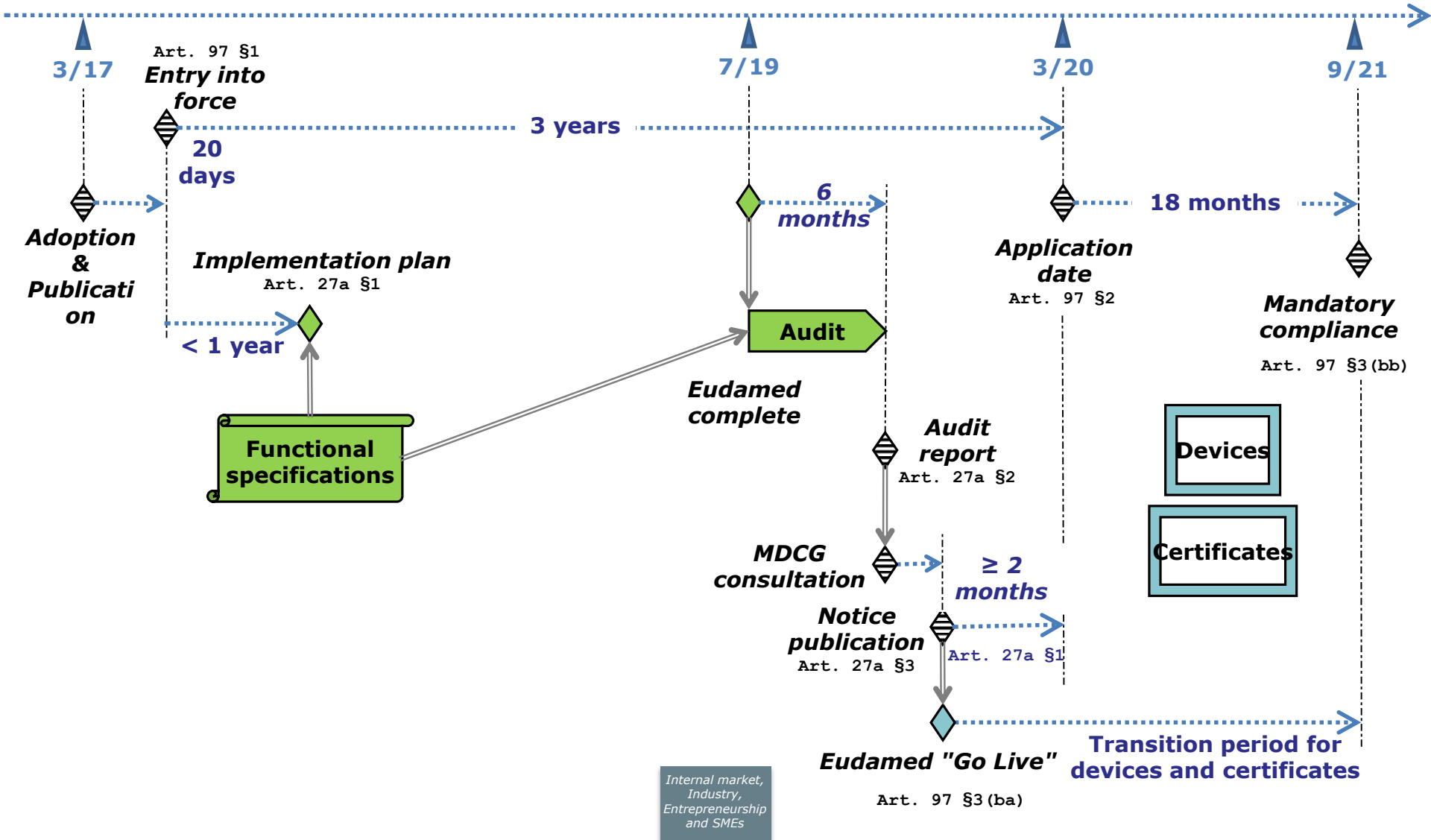
Because

- **As in Regulations with lowest cost (Audit/Support)**
- **No real obligation to have it before (Regulations consider it)**
- **Need time to implement interoperability/data exchange on both sides**
- **Compliance to Eudamed registration is quick compared to other compliances**

• Article 27 MD/25 IVD - Electronic Systems included in Eudamed



• Priority to 1st set of Modules (Actors first) but all available together in first release


3/17
Art. 97 §1
Entry into force
20 days
3 years
7/19
3/20
9/21
Adoption & Publication
Implementation plan
Art. 27a §1
< 1 year
Functional specifications
6 months
Audit
Eudamed complete
Audit report
Art. 27a §2
MDCG consultation
≥ 2 months
Notice publication
Art. 27a §3
Art. 27a §1
Eudamed "Go Live"
Art. 97 §3(ba)
Application date
Art. 97 §2
18 months
Mandatory compliance
Art. 97 §3(bb)
Devices
Certificates
Transition period for devices and certificates