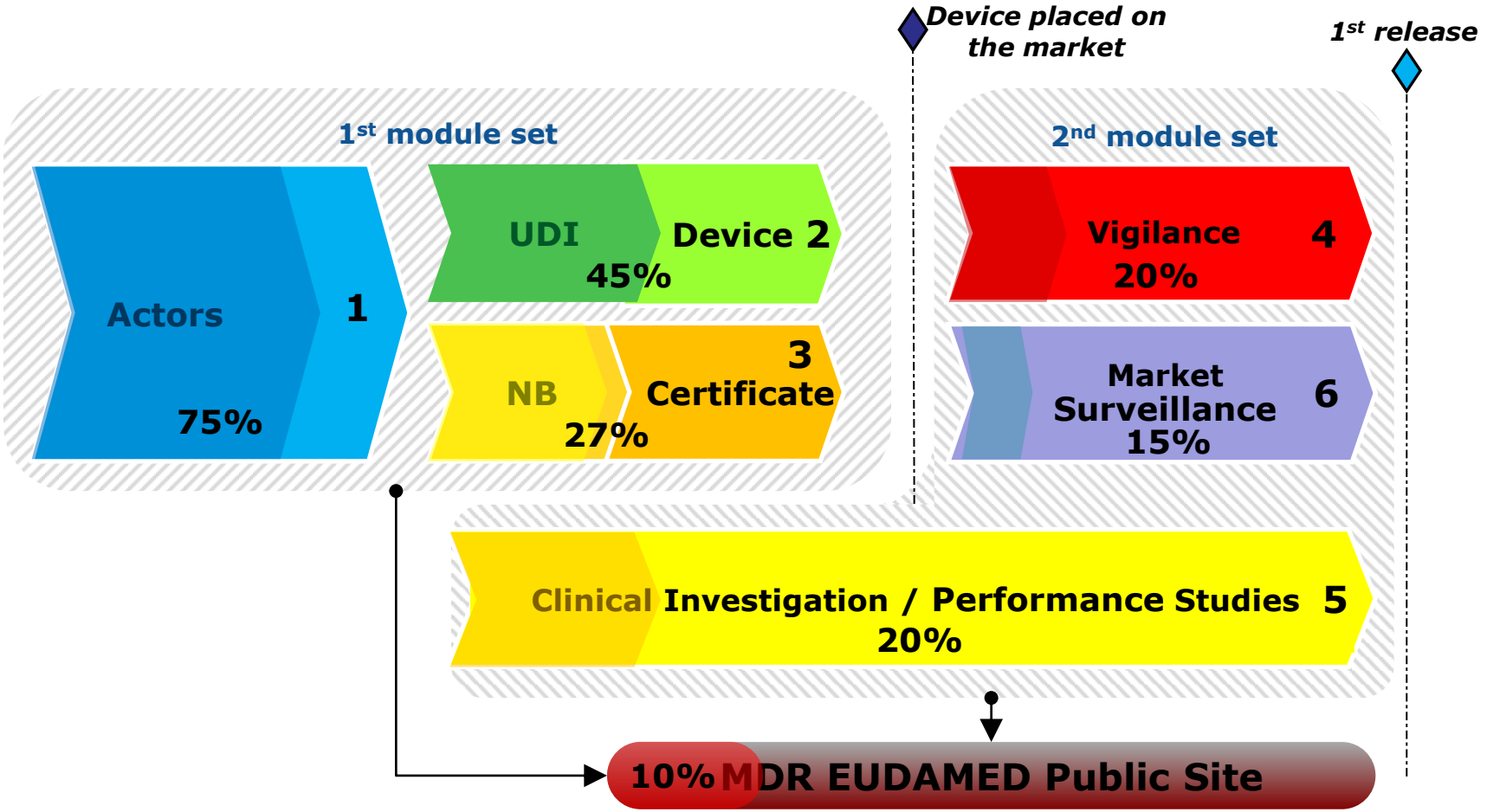
MDR Eudamed – State of play

MDCG 24.9 2018

Health Technology and Cosmetics
DG Internal Market, Industry,
Entrepreneurship and SMEs
European Commission

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



Eudamed content - Actor

- Economic operators (except distributors) and sponsors' Registration with validation (SRN) + CAs, NBs and their users
  - ✓ **75% done (first acceptance testing done)**
  - ✓ **90% done for analysis**
  - ✓ **Entity (data) model (to complement/fine tune) – System/Procedure pack Producer (SPPP) to be added**
  - ✓ **Business rules (to complement/fine tune) – SPPP to be added**
  - ➢ **Data exchange to do – model analysed 90% development started 10%**
  - ➢ **Additional requirements have been identified (SPPP)**
  - ➢ **Sponsor registration validation?**

Eudamed content – UDI/Device

UDI database and Registration of **Devices**

- ✓ **45% done (first acceptance testing planned 09/2018)**
- ✓ **Registration process partially done, new requirements identified (risk classes, certificate info details)**
- ✓ **85% done for analysis**
- ✓ **Entity (data) model to fine tune - finalisation**
- ✓ **Business rules (to complement/fine tune) – 90% (some specific use cases to consider)**
- ➢ **Data exchange – 80% model, validation to be done, development not started yet**

Eudamed content – NB & Certificate (1)

Notified Body:

- NBs and their Designation notifications from NANDO
  - ✓ **70% done for analysis (collaboration with Nando team)**
- NB subsidiaries
  - ➢ **to do (basic) moved to actors – to be analysed**
- List of experts for assessment of Conformity Assessment Bodies
  - ➢ **to do (basic) – analysis is in progress**
- MS annual monitoring summary report on NBs
  - ➢ **to do (basic – medium priority) analysis is in progress**

Eudamed content – NB & Certificate (2)

Certificate/Conformity assessment:

- Withdrawal and refusal of application for conformity assessment
  - ✓ **80% done for analysis**
- Certificate registration (Issued, suspended, withdraw … and Refused)
  - ✓ **85% done for analysis – consultation with the WG on remaining issues**
- Clinical evaluation consultation and mechanism of scrutiny notifications
  - ✓ **75% done for analysis (expert panels issue)**

27% done (NB & Certificate - most of development to do)

Eudamed content – CI/PS

Clinical investigation/Performance studies:

- Applications/Modifications/PMCF with validation and authorisation by CAs and Single ID (with coordinated assessment) + Exchange of information between CAs/COM
  - ✓ **60% analysis done (focus on application without exchange of information)**
  - ✓ **Started wireframe / mock-ups for application form**
- Serious adverse events and device deficiencies reporting
  - ✓ **40% analysis done (close to MIR)**
- Final report and its summary
  - ✓ **35% analysis done**

✓ **20% done** (only analysis)

Eudamed content – Vigilance

Vigilance (and post-market surveillance):

- Serious incidents reporting and Field Safety Corrective Actions (FSCA) with field safety notices + Exchange of information between CAs/COM
  - ✓ **75% done for analysis for incident report (MIR form) and FSN**
  - ➢ **Focus on incident report and FSN**
  - ➢ **30% FSCA – entity model**
- Periodic Summary Reports (PSR)
  - ➢ **To do – in progress 2 teleconferences done**
  - ➢ **PSRIU (new)**
- Trend report by manufacturers
  - ➢ **To do**
- Periodic Safety Update Report (PSUR)
  - ➢ **To do**

20% done (only analysis)

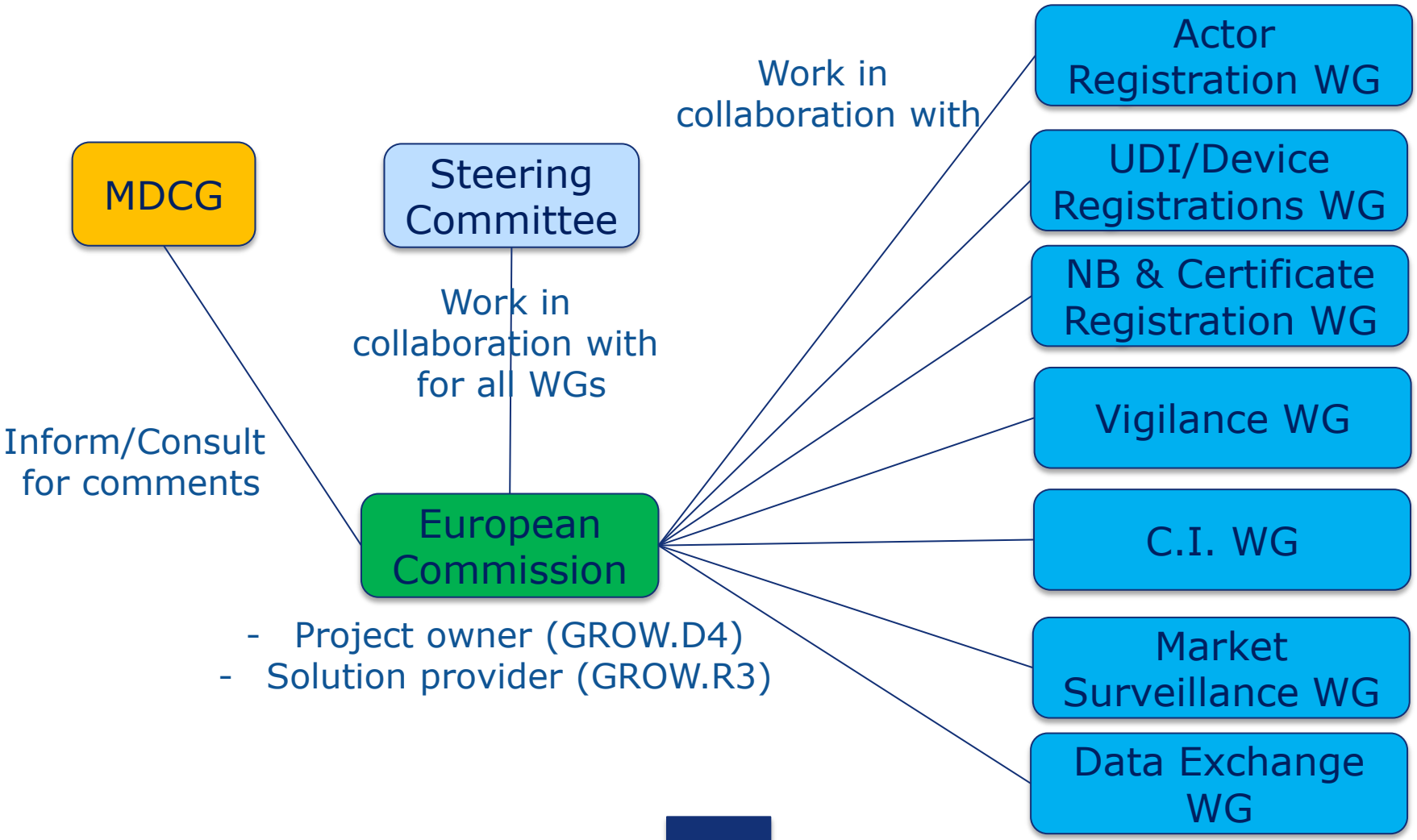
Eudamed content – Market surveillance

Market surveillance:

- Annual Summaries of surveillance activities and final inspection report (**analysis started**)
- Information on devices presenting an unacceptable risk to health and safety, non-compliance of products and on preventive health protection measures (**main part to do**)
- Summaries of the results of the reviews and assessments of the market surveillance activities (every 4 years) (**low priority**)
- Detailed requirements to be aligned with COEN WG – document will be provided – no templates yet provided by stakeholders/business

✓ **15% done** (only analysis)

Working together: Organisation & Means



Eudamed WG meetings:

- 27/09/18 – 5th UDI & Device WG
- 04/10/18 – 3rd CI/PS WG
- 18/10/18 – 3rd Vigilance WG
- 25/10/18 – 2nd Market Surveillance WG
- 21/11/18 – 4th Data Exchange WG
- 13/12/18 – 6th Steering Committee
- 29/01/19 – 9th Actor Registration WG
- 21/02/19 – 6th NB & Certificates WG

In 2018, already 9 WG meetings (15 WG and 5 Steering Committee meetings in previous years)

Implementation plan

Working documents:

For MDCG and Eudamed WGs' members

- Functional Specifications document with Legal requirements and (Non-)Functional specifications
  - ✓ Second version sent end of August 2018
- Implementation plan with scope for 1st and next releases
  - ➢ Second version to come end of October 2018

For Eudamed WGs' members (available to MDCG as well)

- Process overviews (Actors, UDI/Device, NB & Certificate provided, CI/PS and Vigilance soon)
- Data models (Actors, UDI/Device, NB & Certificate provided, CI/PS application and MIR soon)
- Business rules (Actors, UDI/Device, NB & Certificate (to complete) provided, CI/PS application and MIR soon)
- Wireframes / Mock-ups (Actors, UDI/Device, NB & Certificate (to complete) provided, CI/PS application and MIR soon)

Implementation plan

Project Milestones:

- Finalise as much as possible functional specifications, process descriptions, data models and business rules by end October 2018 – to allow stakeholders to prepare their own systems especially for UDI, certificate and serious incident report (e.g. for data exchange)

- Eudamed functionally mostly complete before Audit start – September 2019

- Eudamed Go Live before 26/03/2020 (to comply with article 34)

Main next milestones planned in 2018

- Complete **analysis** on **Actor, UDI, Device and Certificate registrations (end 2018)**
- Finalise **all functional specifications** for all modules (**end 2018**) (not details)
- Do **most of development** of **Actor registration** module, **UDI and Device** module (end 2018) and **NB & certificate** module (March 2019) for acceptance testing **between Q1 and Q2 2019**
- Start prepare **implementing act** and ToR for **audit** (**end 2018 – beginning 2019**)

Main milestones planned in 2019

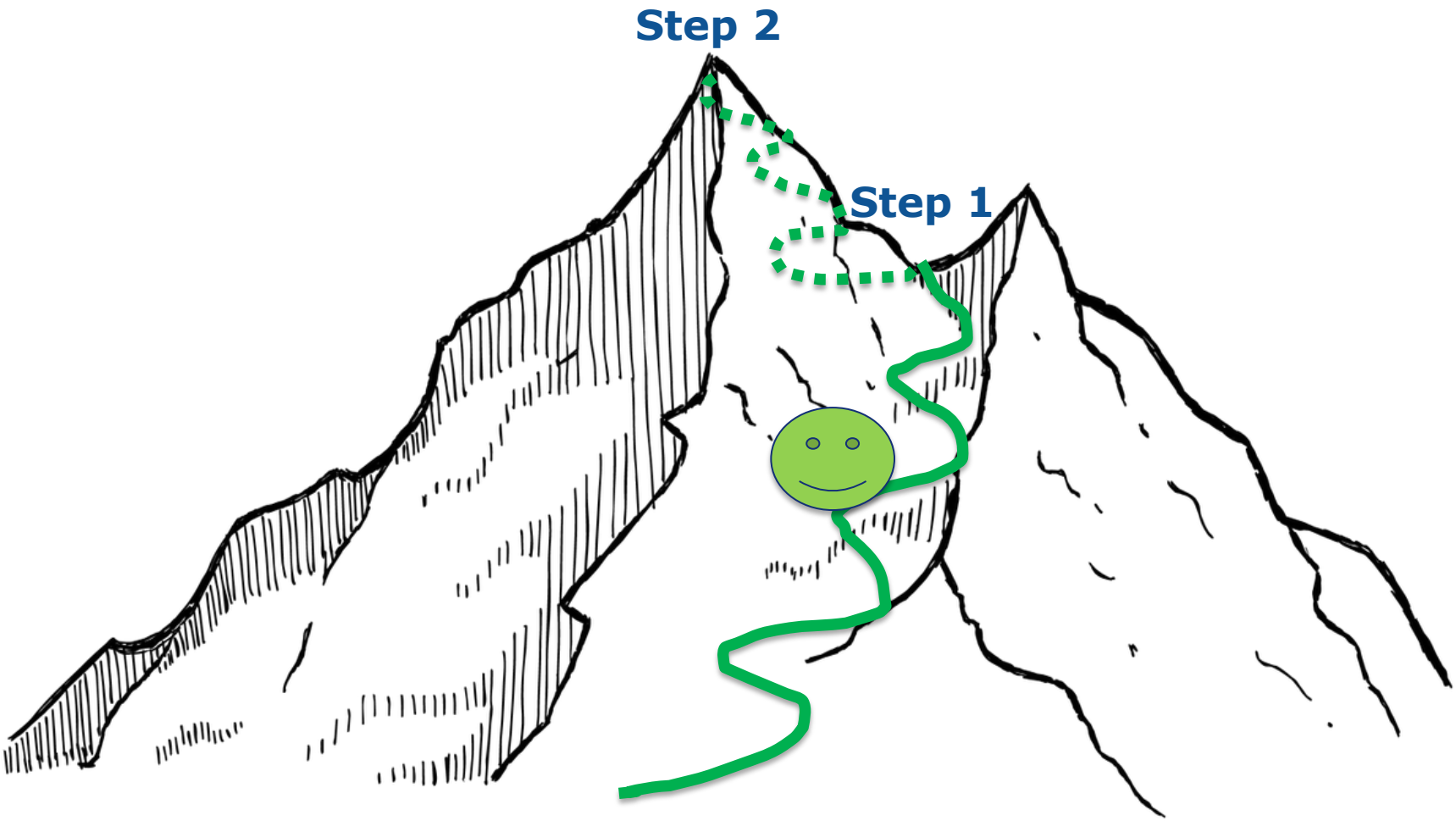
- Fine tuning with more acceptance testing for Actor, UDI and Device and NB & Certificate
  - **Q1 and Q2 2019**
- Implementing act on detailed arrangements necessary for the setting up and maintenance of Eudamed (Art 33(8))
  - **Between Q1 and Q4 2019**
- Development of 2nd set of modules **(Vigilance, CI/PS and Market surveillance)** with acceptance testing
  - **Between Q1 and Q4 2019**
- Development of public web site
  - **Between Q2 and Q4 2019**
- Start audit (Art 34(2)) – **September 2019**

Eudamed prioritisation

- **Now (by March 2020): Deliver what is required by the legislation and absolutely required from day 1**
  - **Mainly provide the tool to register all the required data from day 1**
- **For later: Other features and functions that may come later or that go beyond what is formally required for the application of the legislation**
  - **Mainly features not related to data management like advanced search and reporting capabilities**

European Commission

The Eudamed mountain



Q & A

Thank you for your attention