



# EUDAMED

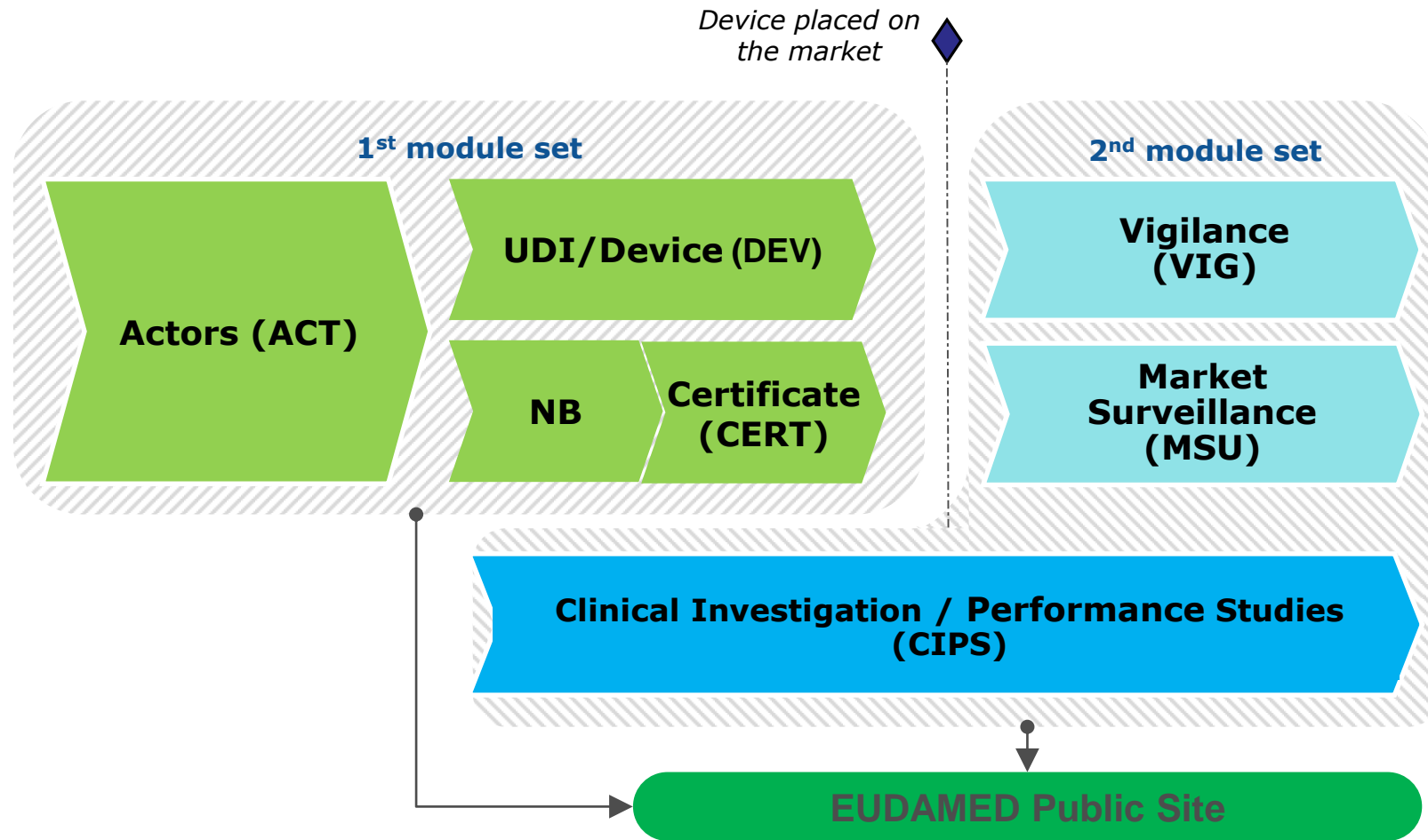
MDCG EUDAMED Subgroup meeting  
EUDAMED State of Play and Roadmap

*28 April 2022*

# Content

- State of play
- EUDAMED in numbers
- Delivery roadmap
- EUDAMED Customer Service
- Next steps

# State of play – EUDAMED modules



Light green = in production  
Dark green = in production for first 3 modules  
Light blue = first delivery in playground  
Dark blue = under development

# State of play – application

- ACT – CERT – DEV: New release delivered in Production
  - Fixes and improvements
  - Updated documentation
- VIG – CIPS – MSU:
  - 1st release for VIG & MSU delivered in Playground
  - 1st Playground release for CIPS planned mid-May
- Discussion on some requirements still open for releases after Q1 (e.g. Data exchange). **Clarify requirements as soon as possible!**

# State of play – Baseline requirements MVP

Module	Baseline requirements	Implementation
Actors	Stable	90%
Certificates	Stable	85%
Devices	Stable	85%
Vigilance (exc. DTX)	80% stable	50%
Market surveillance (exc. DTX)	95% stable	20%
Clinical investigations / Performance studies (exc. DTX)	90% stable	25%
Vigilance – DTX	Still to be discussed	Pending
Market surveillance – DTX	Still to be discussed	Pending
Clinical investigations / Performance studies – DTX	Still to be discussed	Pending

**Note:** Changes / change requests are a normal part of the process but should be limited

# State of play – Baseline requirements MVP

- In the effort to deliver the Minimum Viable Product (MVP), we are taking out of the work scope any subject that does not clearly fit the MVP context
- During the evaluation of feedback, we give priority to possible bugs followed by essential changes
- Any non essential changes and bugs may be addressed with lower priority or will be planned for implementation after the MVP

# EUDAMED in numbers\*

- 13 527 Manufactures (7518 EU, 6009 non EU)
- 1 417 Authorized Representatives
- 3 812 Importers
- 482 System and Procedure Pack Producers
- 33 150 Users
- 22 527 Basic UDI-DIs
- 58 348 UDI-DIs
- 7 Certificates (only QMS)

\* Reflects all non-draft data as of 21/04/2022

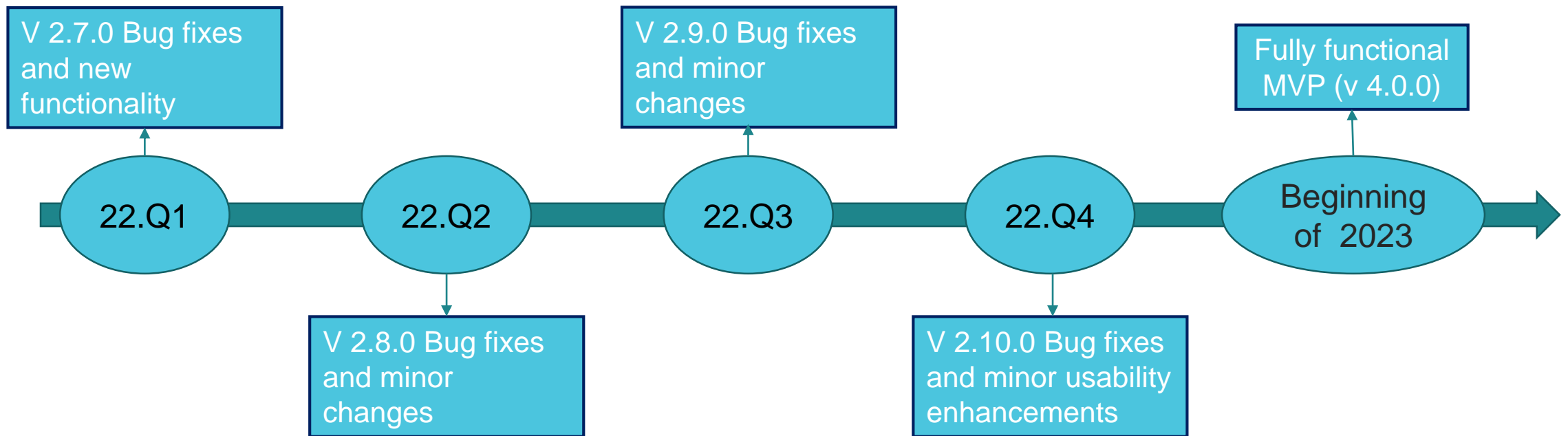
# Delivery Roadmap - Planning

- Release to playground once a quarter. Scope and content will be communicated early enough to stakeholders, so that they can prepare
- Each release is the result of 4 internal development cycles (Sprints), all of which deliver working products and are thoroughly tested by SANTE
- The final Sprint for each release has the primarily focus on QA / Stakeholder feedback
- At any one time we have 90-100% clarity on the next 2 sprints and a more high level plan for the 2 following sprints
- We are focusing our work on delivering fully working functionalities that need also be audit ready



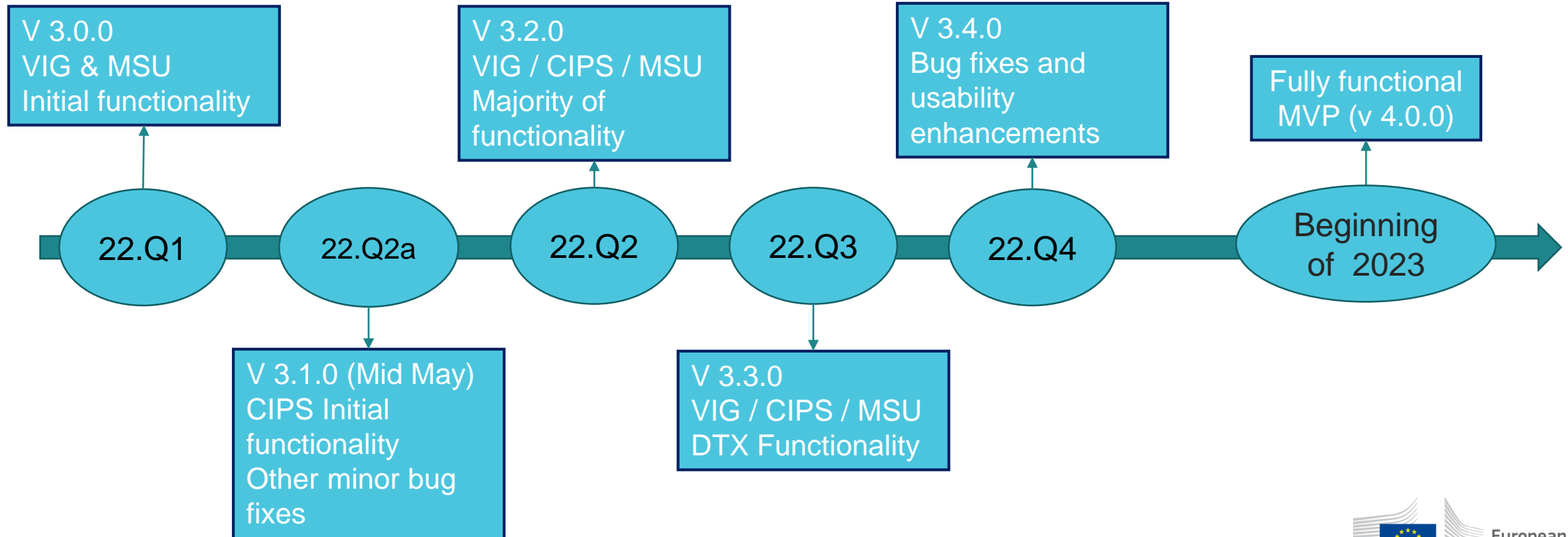
# Delivery Roadmap - Production

- Production releases will be mainly bug fixes, but will also contain changes and enhanced functionality



# Delivery Roadmap - Playground

- Playground releases will include all Production enhancements
- Stakeholders will get a defined period after each release to provide feedback



# What's next?

- Release once per quarter to playground at a minimum
- More frequent fixes to be delivered in production if required
- Focus on closing entire use cases in order to trace audit readiness against functional specification
- Please provide your Playground feedback for first VIG and MSU release by 10/05/2022
- EUDAMED Data Exchange Working group meeting planned for 12/05/2022
- Set up of a EUDAMED Wiki for communication and addressing user needs

# EUDAMED Customer Service

[SANTE-EUDAMED-SUPPORT@ec.europa.eu](mailto:SANTE-EUDAMED-SUPPORT@ec.europa.eu)

- EUDAMED Support Team:
  - Treats users request by email on a daily basis for both PROD and PG environments
  - Operates from Monday to Friday, 8:00 to 17:00 CET
  - Treats approx. 200 to 250 new user requests per week (info April 2022)
  - Facilitates users in providing feedback by questionnaires in specific forms:
    - Feedback for PG
    - Error / bug reporting for Production
  - Provides the following customer service scope:
    - Actors, Devices, Certificates, Data exchange, horizontal questions, Vigilance (PG), Market surveillance (PG)
- Under preparation: EUDAMED Wiki to serve better and in a more user friendly way users' needs.

# Your contribution and collaboration

- Added value of the feedback provided by CAs, Industry stakeholders, NBs
- Collaboration in testing new Playground releases is really appreciated and encouraged
- We count on your support during the next releases to help us deliver a stable and performing MVP

Thank you – Questions?