European Commission

Medical Device Coordination Group

EUDAMED State of Play

DG SANTE Unit R4, IT Systems

3 April, 2025

Agenda

1. Planned Releases
2. Upcoming Development Priorities
3. EUDAMED Audit update
4. 2025 Key Focus areas

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Planned Releases

PG 3.11.0 (mid-April)

Content of the Release	
Actors & User Registration • Bug Fixes & Useability improvements **Devices Module** • Master UDI-DI registration process enhancements • Public API • Bug Fixes & Useability improvements **NB & Certificates Module** • Bug Fixes & Useability improvements	**Market Surveillance Module** • Bug Fixes & Useability improvements **Vigilance Module** • DTX Upload (Create and Update) & Download MIR, FSCA, FSN, NCAR • DTX Download for MTR, PSUR • Improved search functionality in application • Bug Fixes & Useability improvements

Feedback Period Timeline to be defined

nonDTX Functionalities and Public API possibly same as usual, around 4-5 weeks
Longer period for Vigilance DTX Functionalities

Upcoming Development priorities

Next development priorities is a combination of functionalities coming from the prioritized list of Functional specifications (for mandatory use) and User feedback suggestions/ improvements received during the previous Playground Releases to ensure the best user experience using EUDAMED.

Among others:

- ✓ M2M Upload functionality for Notified Bodies
- ✓ M2M Upload of Market Surveillance data from MS national databases
- ✓ Clinical Evaluation Consultation Procedure Outside of EUDAMED and Mechanism for Scrutiny inside of EUDAMED
- ✓ Authorized Representative receives notification when new Basic UDI-DI is submitted
- ✓ User Experience enhancement in Market Surveillance Module
- ✓ Certificate Notifications full implementation
- ✓ Versioning of EMDN and IMDRF Codes
- ✓ Initial certificate may have other status than Issued
- ✓ Mergers & Acquisitions

& MANY more
(analysis ongoing)

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EUDAMED Audit update

*The overall status of the Project – **GREEN**

In total more than 940 Test Cases created/ executed

**Source: Audit bi-weekly reporting meeting*

Actor/ Devices/ Certificates

- Core test execution completed (pass rate above 98%)
- Regression testing for Actor completed; Certificates in Progress
- M2M testing completed except for NB
- **Next Steps**: API testing & M2M download for NB

Market Surveillance

- Core testing and Regression testing completed
- M2M testing completed except for NB
- **Next Steps** – M2M download for NB

Vigilance

- Initial Review of the module conducted

- The Review of Actor/ Devices/ Certificates/ MSU to be finalized by end of April with Final Audit Report to be published around May 2025
- The Audit for Vigilance will continue till October with Vigilance Audit report to be finalized possibly by end October/ November 2025

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2025 Key Focus Areas

First 4 Modules

- Fix all audit findings to finalize Minimum Viable Product (MVP)
- Additional Stabilization & Scalability of first 4 modules (including Security, Vulnerability and Performance testing)
- Initiate prioritized development of nonMVP but for Mandatory Use

Vigilance

- Finalize MVP Development & implement recommendations from CA Vigilance Oversight Board (i.e. DTX/ M2M; Search and View)
- Fix all audit findings to finalize Minimum Viable Product
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- DTX WG took place on 6 March 2025

Onboarding activities

- Technical documentation update and user guides revision ongoing
- Translation of User Guides planned and User interface translation started (with initially focus on first 4 modules to go live)
- Onboarding Workshops: **Stuttgart** May 2025, **Rome** October 2025, **Brussels** December 2025
- Medical devices related events reach out
- Call for expression of interest for train the trainer sent to CAs and Stakeholders
- Trainings (module and actor specific)

2025 Key Focus Areas

First 4 Modules – Actor, Devices, Certificates, Market Surveillance

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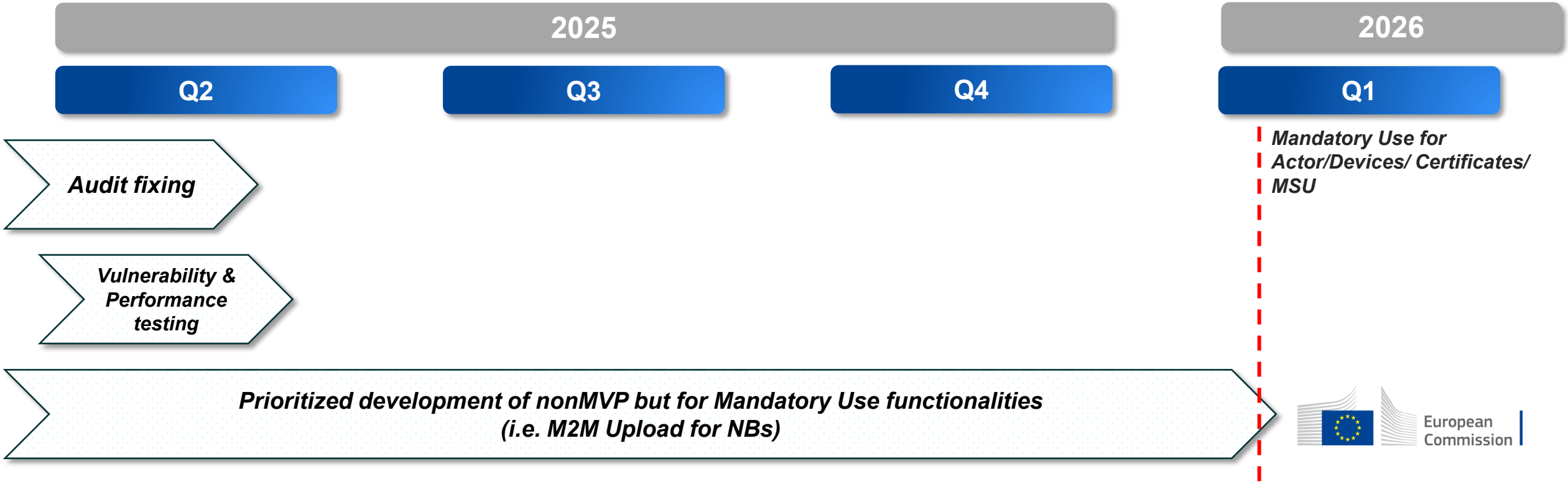

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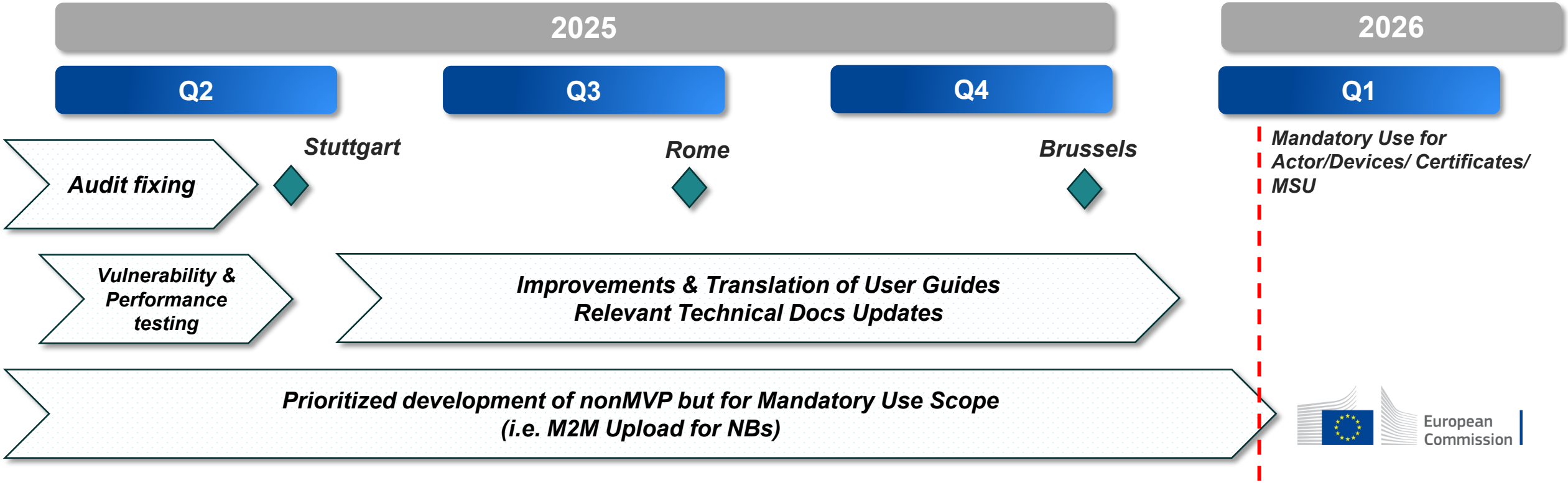

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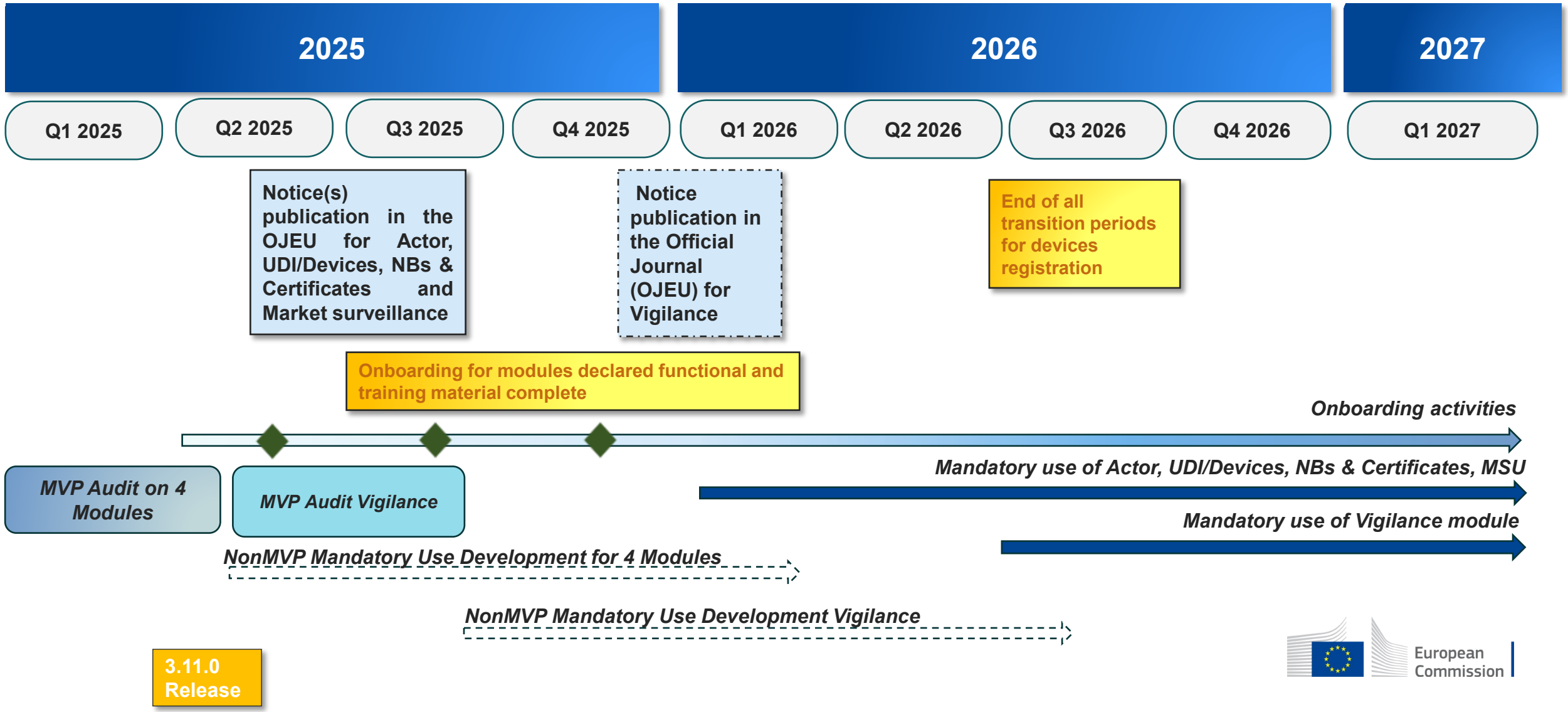
Current planning for gradual roll out and modules' functionality view

Face-to-Face events in specific locations



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Thank you – Questions?

Keep in Touch

EUDAMED Support email address: SANTE-EUDAMED-SUPPORT@ec.europa.eu

EUDAMED Information Centre on Production

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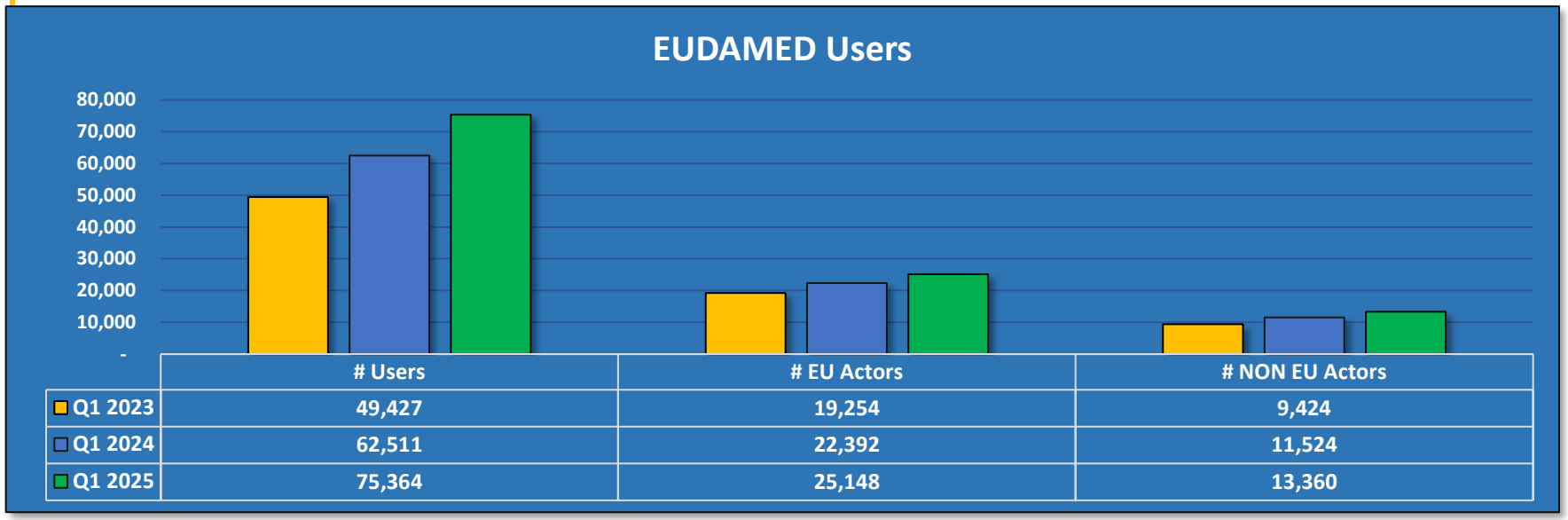
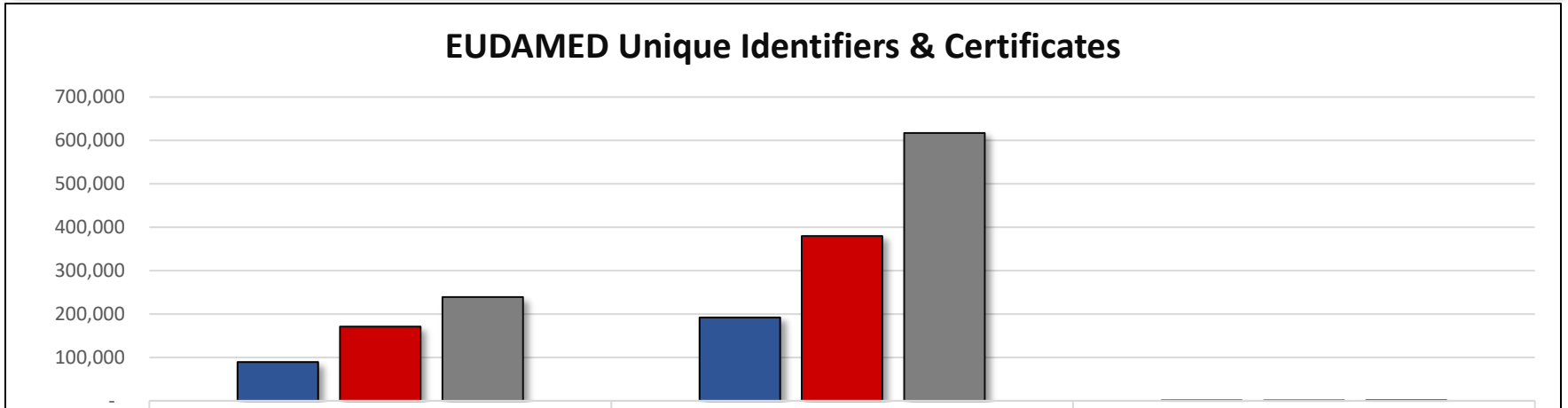
EUDAMED Production Statistics



	# Users	# EU Actors	# NON EU Actors
Q1 2023	49,427	19,254	9,424
Q1 2024	62,511	22,392	11,524
Q1 2025	75,364	25,148	13,360



	# BUDI	# UDI	# Certificates
Q1 2023	89,287	192,288	184
Q1 2024	171,376	379,974	586
Q1 2025	239,254	617,080	1,329

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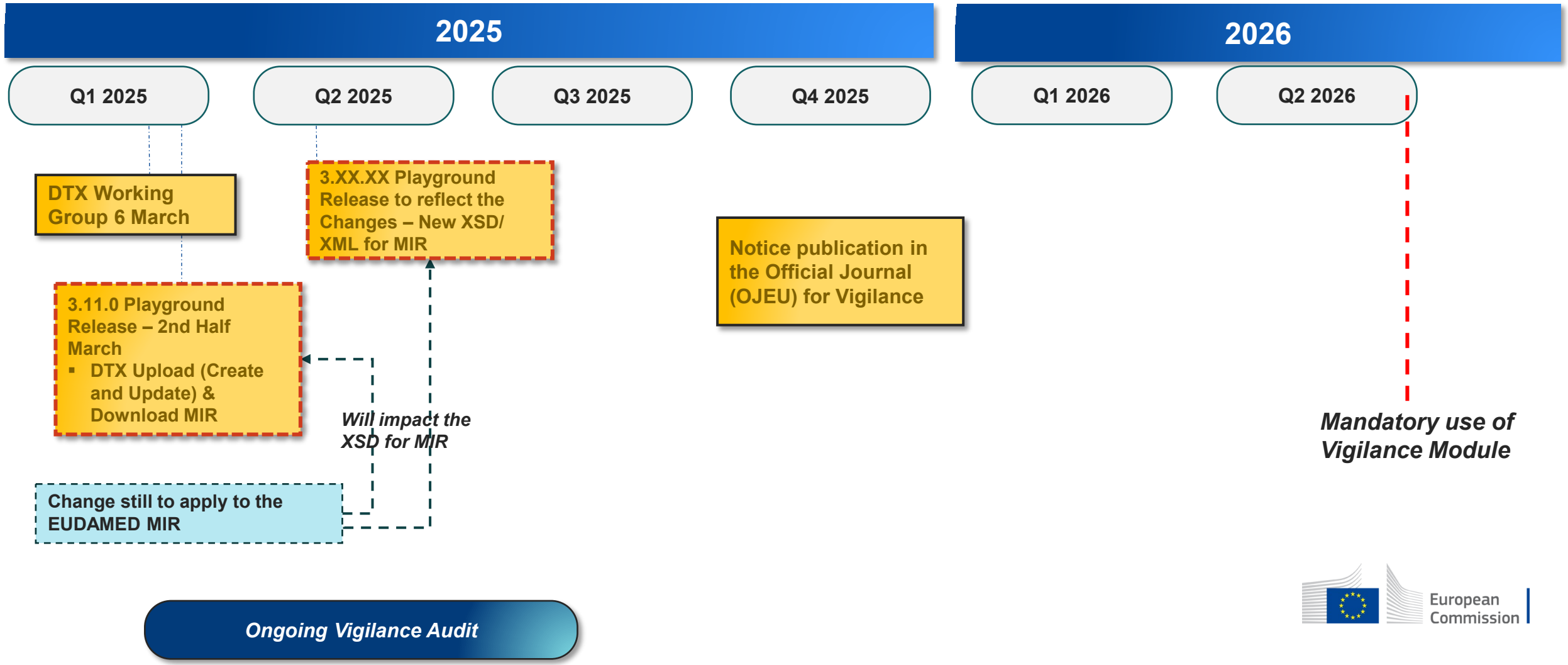
EUDAMED High Level Timeline

DTX MIR Implementation



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