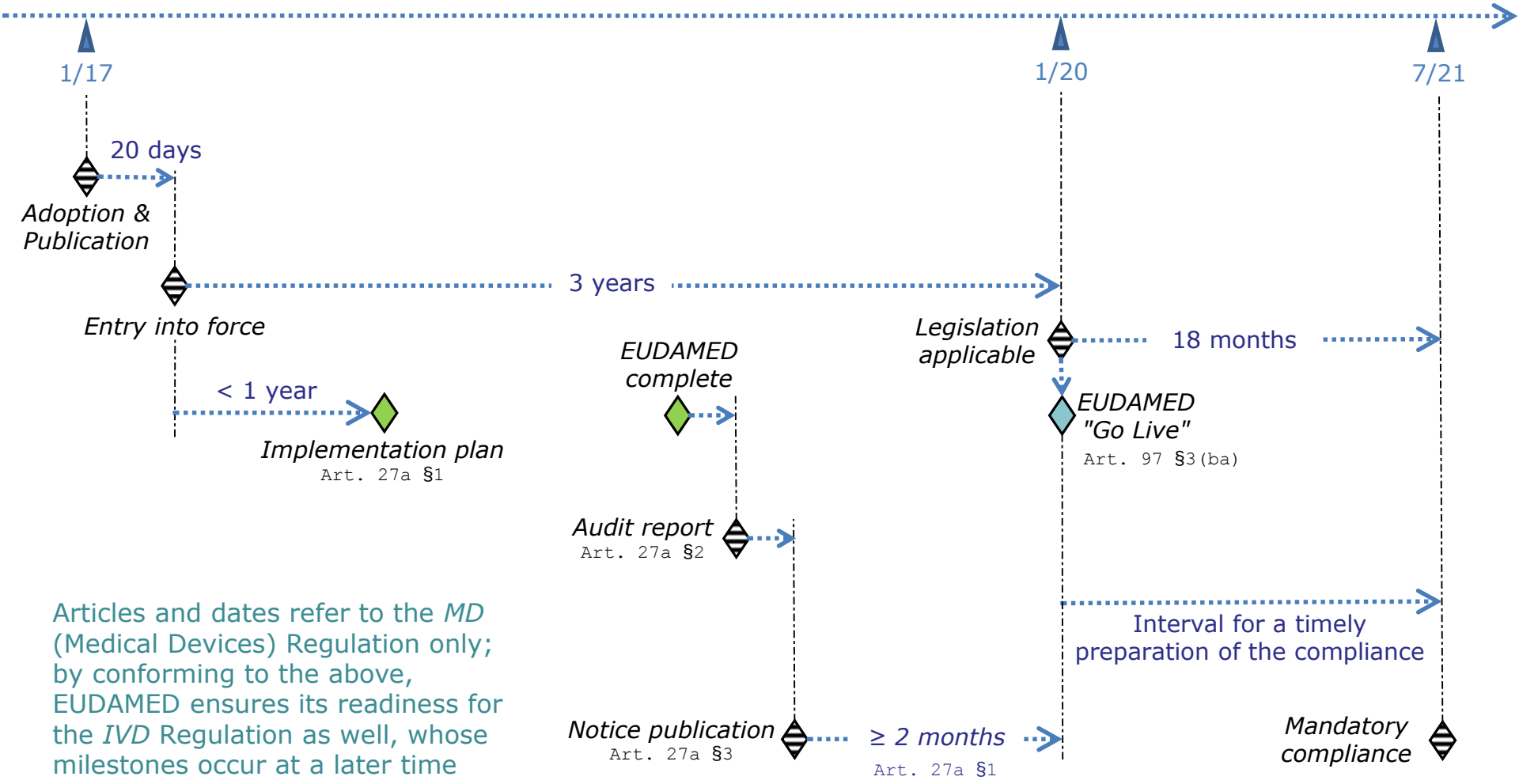
MDR Eudamed
2nd Steering Committee

Planning - Roadmap

05/07/2016

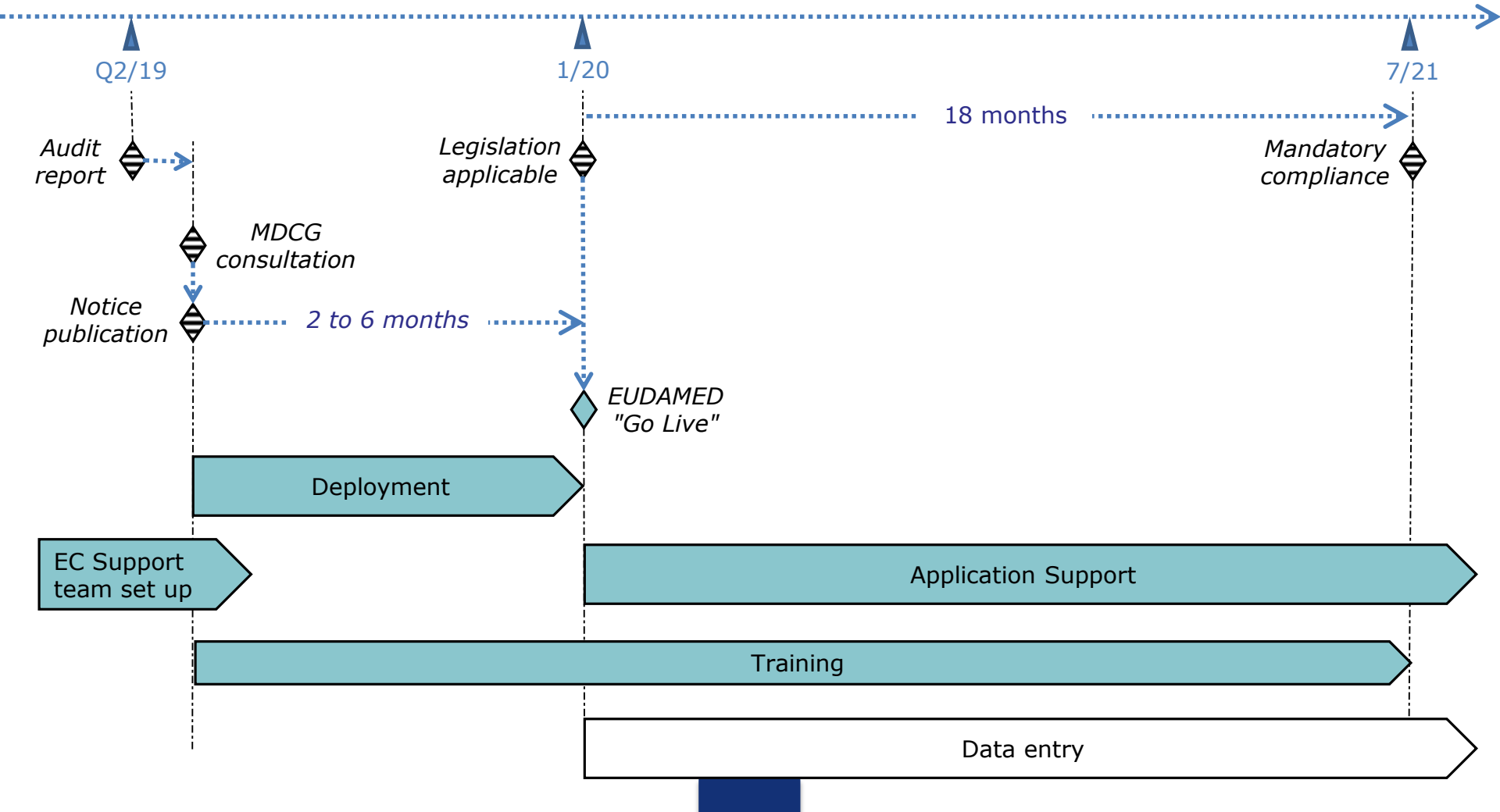
Scheduled legal milestones



Articles and dates refer to the *MD* (Medical Devices) Regulation only; by conforming to the above, EUDAMED ensures its readiness for the *IVD* Regulation as well, whose milestones occur at a later time

European Commission

Deployment & Use

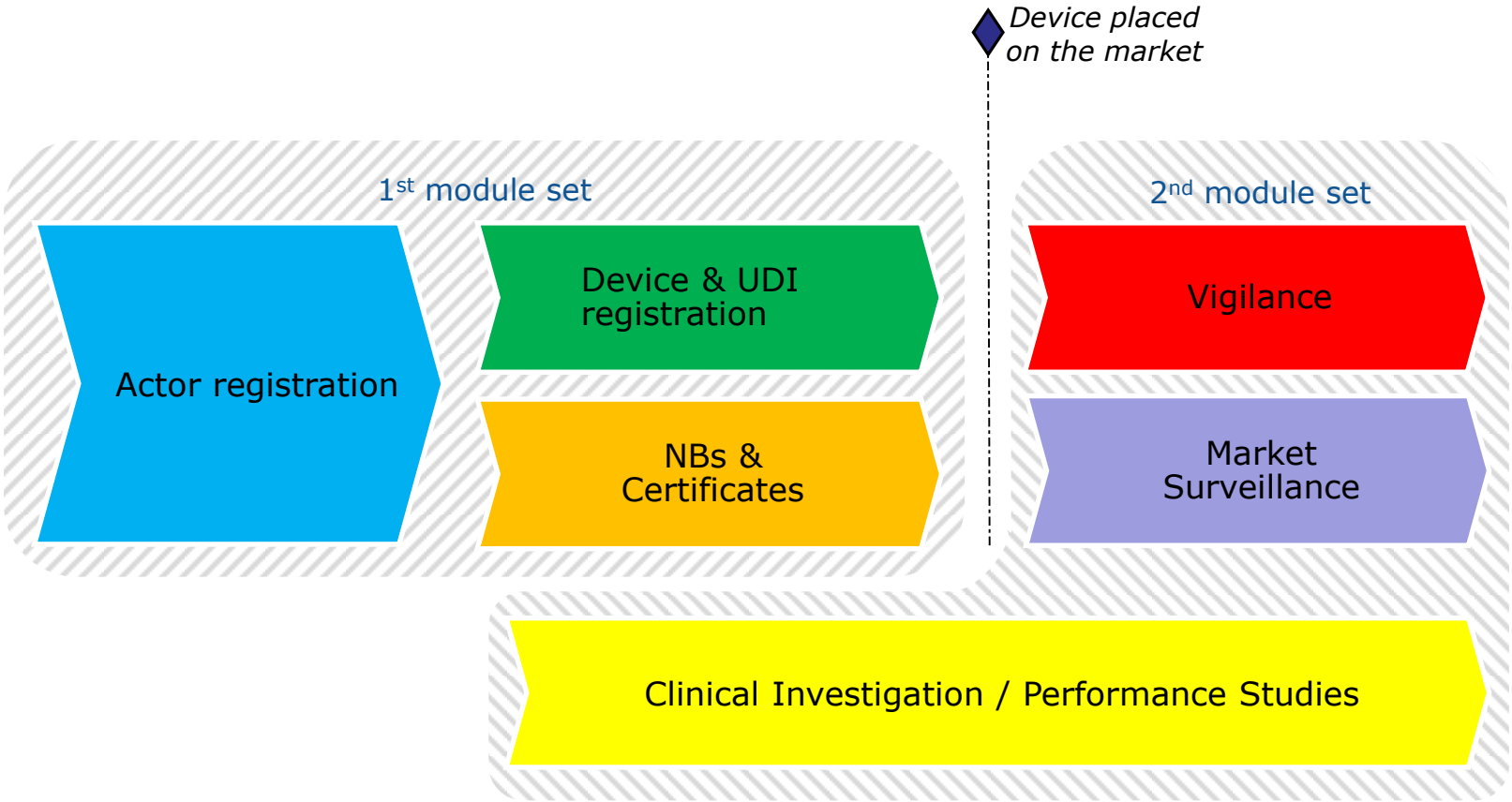


European Commission

Next meetings in 2016

- **UDI WG:** **on 26th of September**
- **Registration WG:** **on 20th of October**
- **Certificates WG:** **on 18th of November**
- **3rd Steering Committee:** **on 14th of December**

Processes of the Device lifecycle



- Each Process managed by one module
- Module deployment optimisation: priority to the 1st set of Modules

EUDAMED modules development

IAM: Identity & Access Management

- Authentication – Authorisation
- User Management

1st module set

- Actor registration
- Device & UDI registration
- Notified Bodies & Certificates

2nd module set

- Clinical Investigation / Performance Studies
- Vigilance – Post-Market Surveillance
- Market Surveillance

Global planning

Project Management

Business Analysis

Architecture design 1st set

Architecture design 2nd set

IAM analysis & development

Analysis & development of the 1st module set

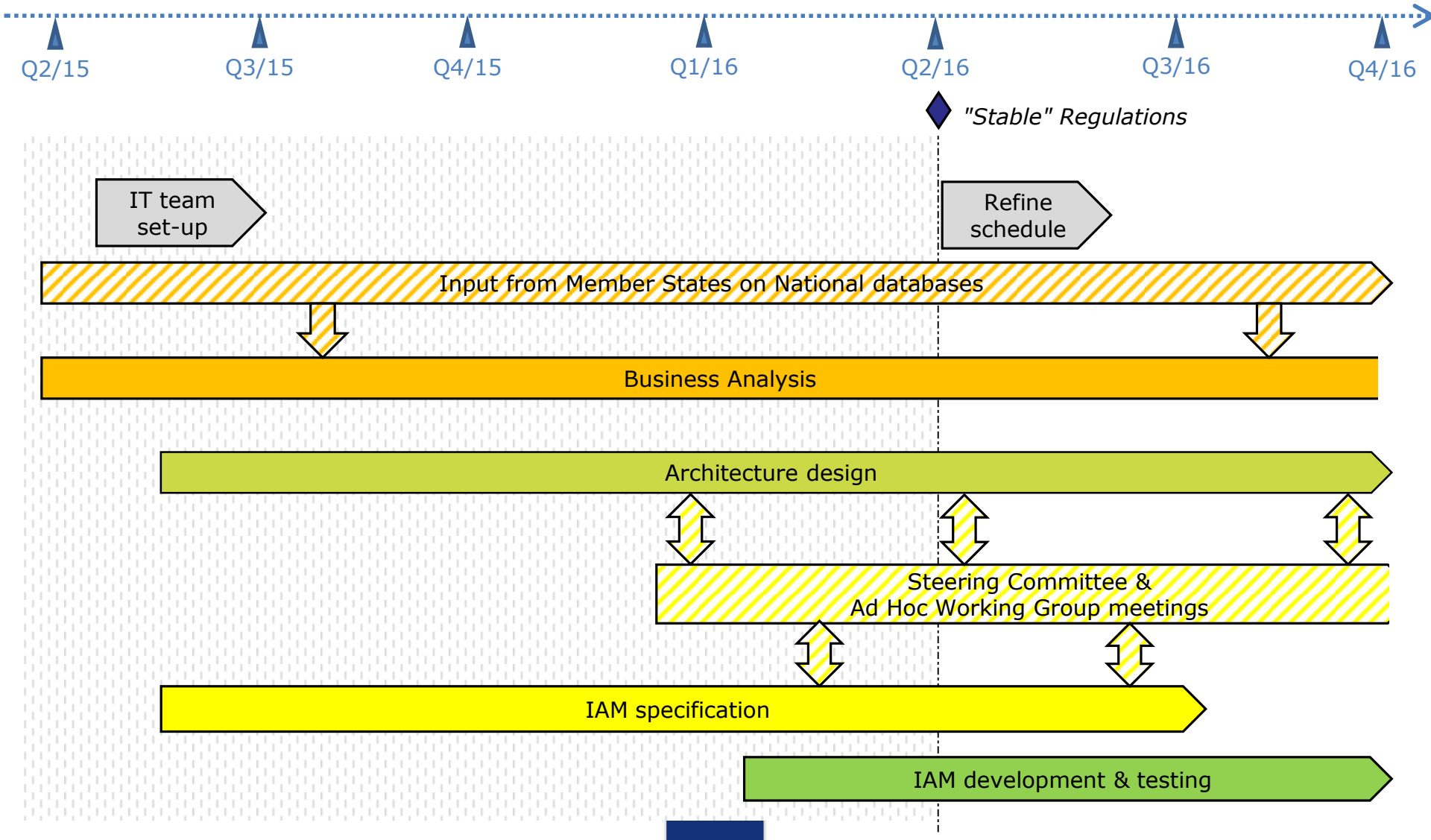
Acceptance testing

Analysis & development of the 2nd module set

Acceptance testing

European Commission

Architecture & IAM



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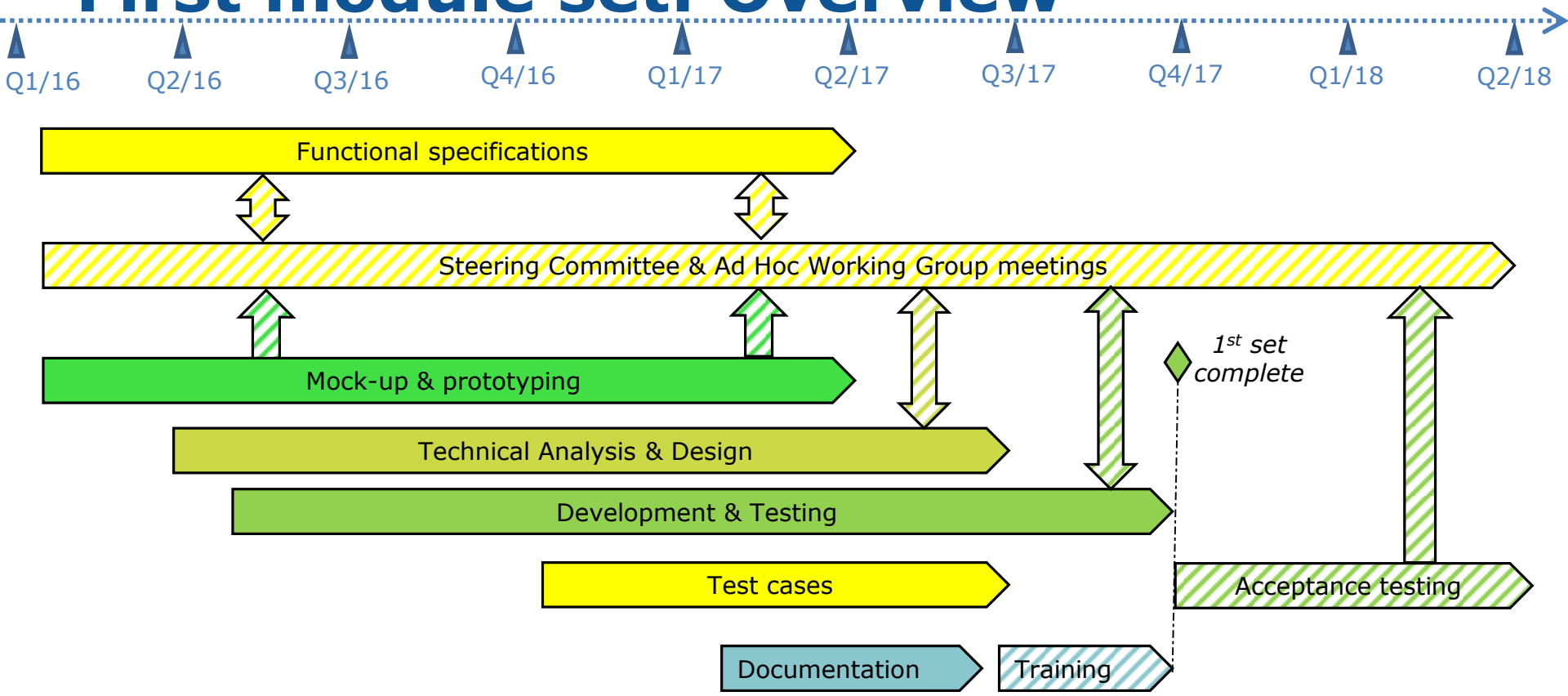
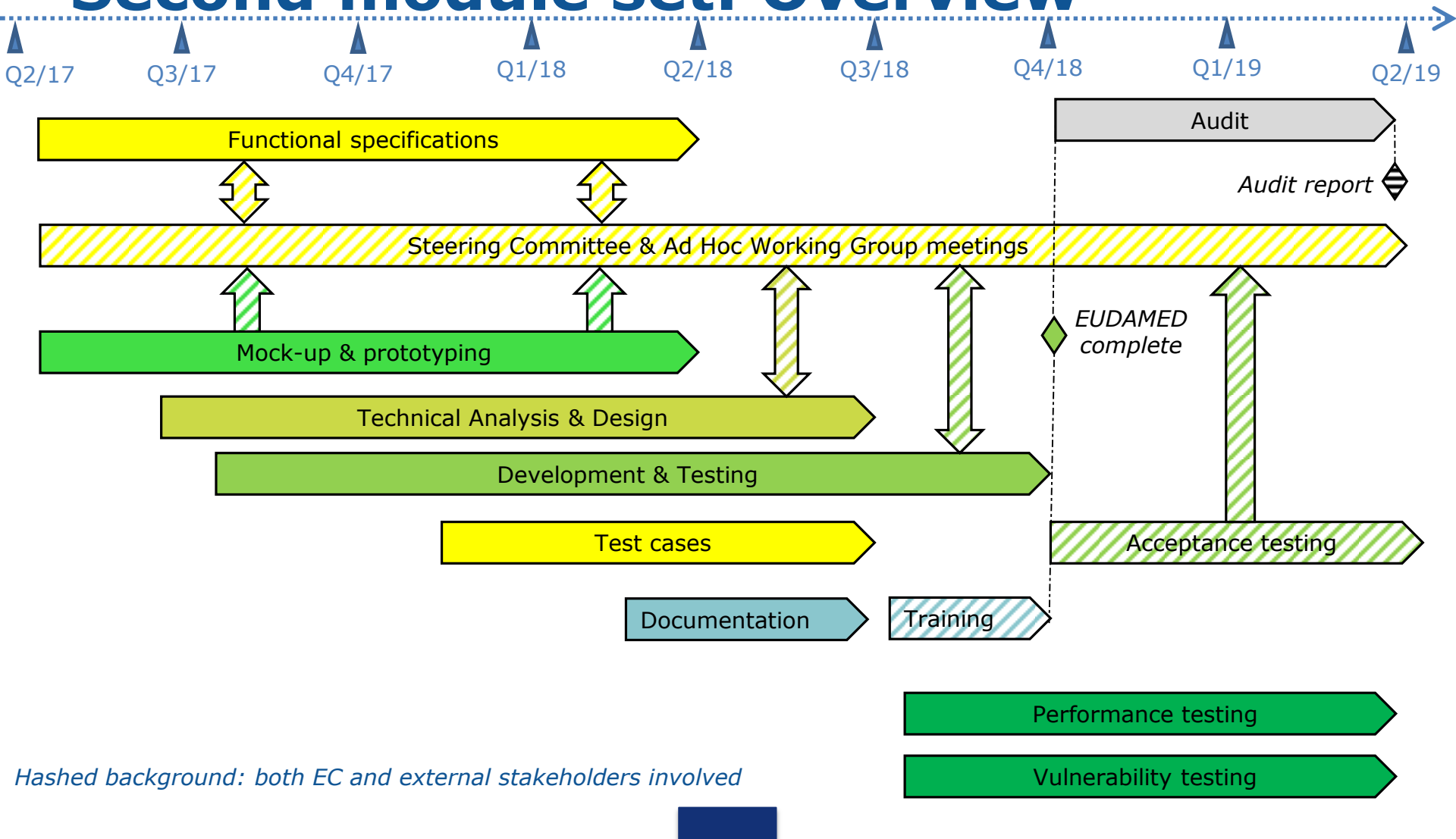
First module set: Overview



Hashed background: both EC and external stakeholders involved

European Commission

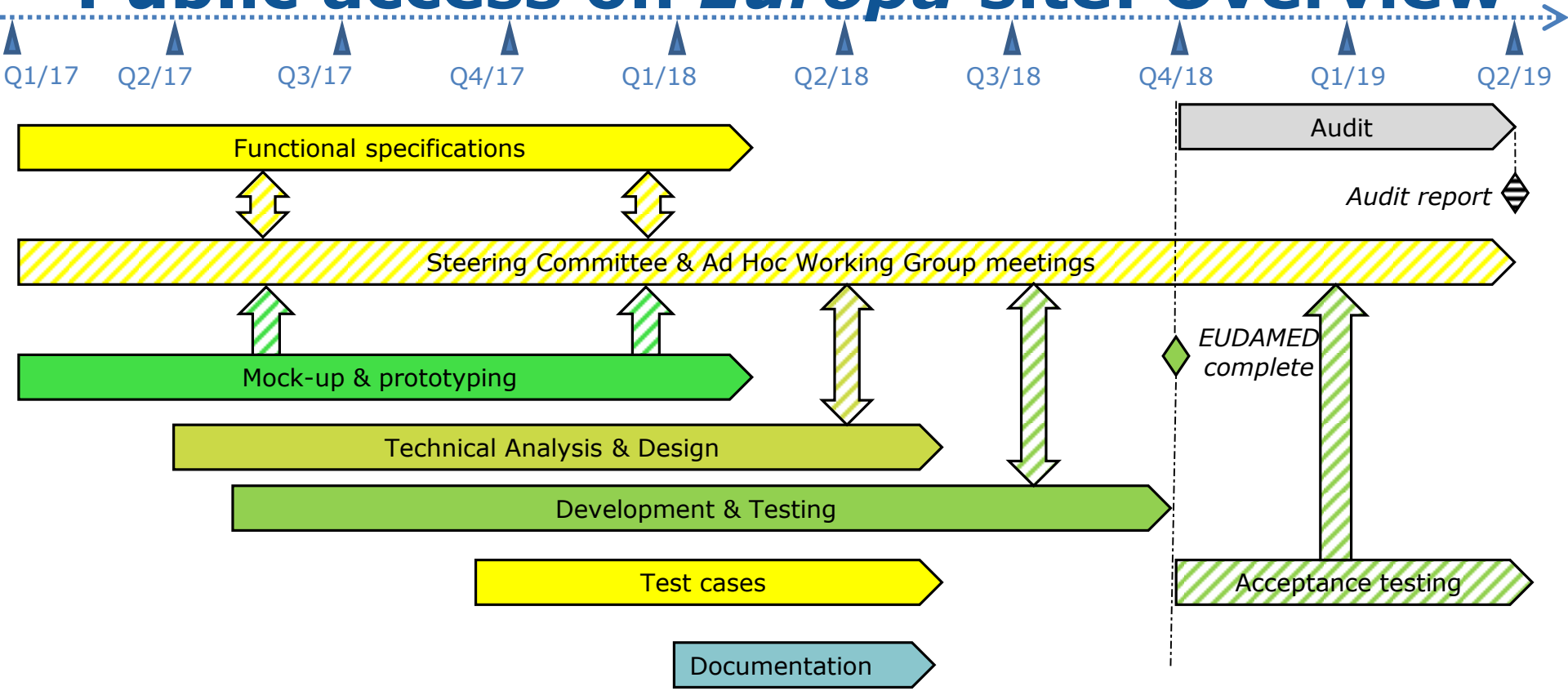
Second module set: Overview



Hashed background: both EC and external stakeholders involved

European Commission

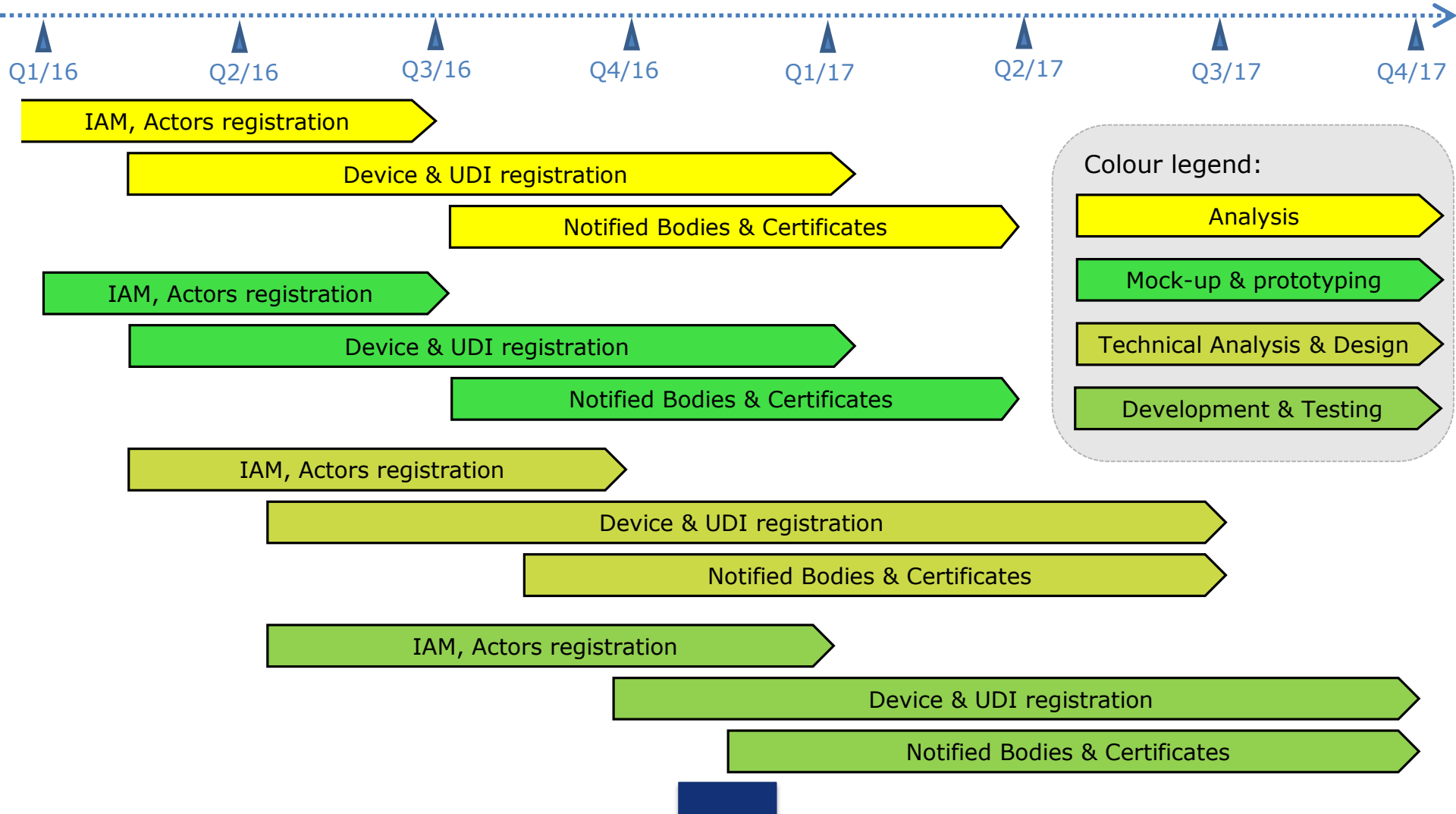
Public access on *Europa* site: Overview



Hashed background: both EC and external stakeholders involved

European Commission

First module set: IT tasks



2016 deliverables

WG meetings | 29-Jun | 26-Sep | 20-Oct | 18-Nov | 14-Dec

User Management

- Prototype v1
- Prototype User administration
- Prototype

Actor registration

- Prototype v1
- Mock-up Non-EU MF
- Prototype v2
- Prototype

UDI – Device registration

- Mock-up Device
- Prototype

Certificates

- Mock-up
- Prototype

European Commission

Conclusion

Planning

- Commitment of resources for timely deliveries
- Progress based on reviews of prototypes
- EUDAMED "Go Live" driven by the Adoption Date (Q1/17)

Content

- Requirements based on consolidated text of Regulations
- WG feedback should result in Business-friendly functionality

Success relies on your collaboration/involvement

Thank you in advance!