

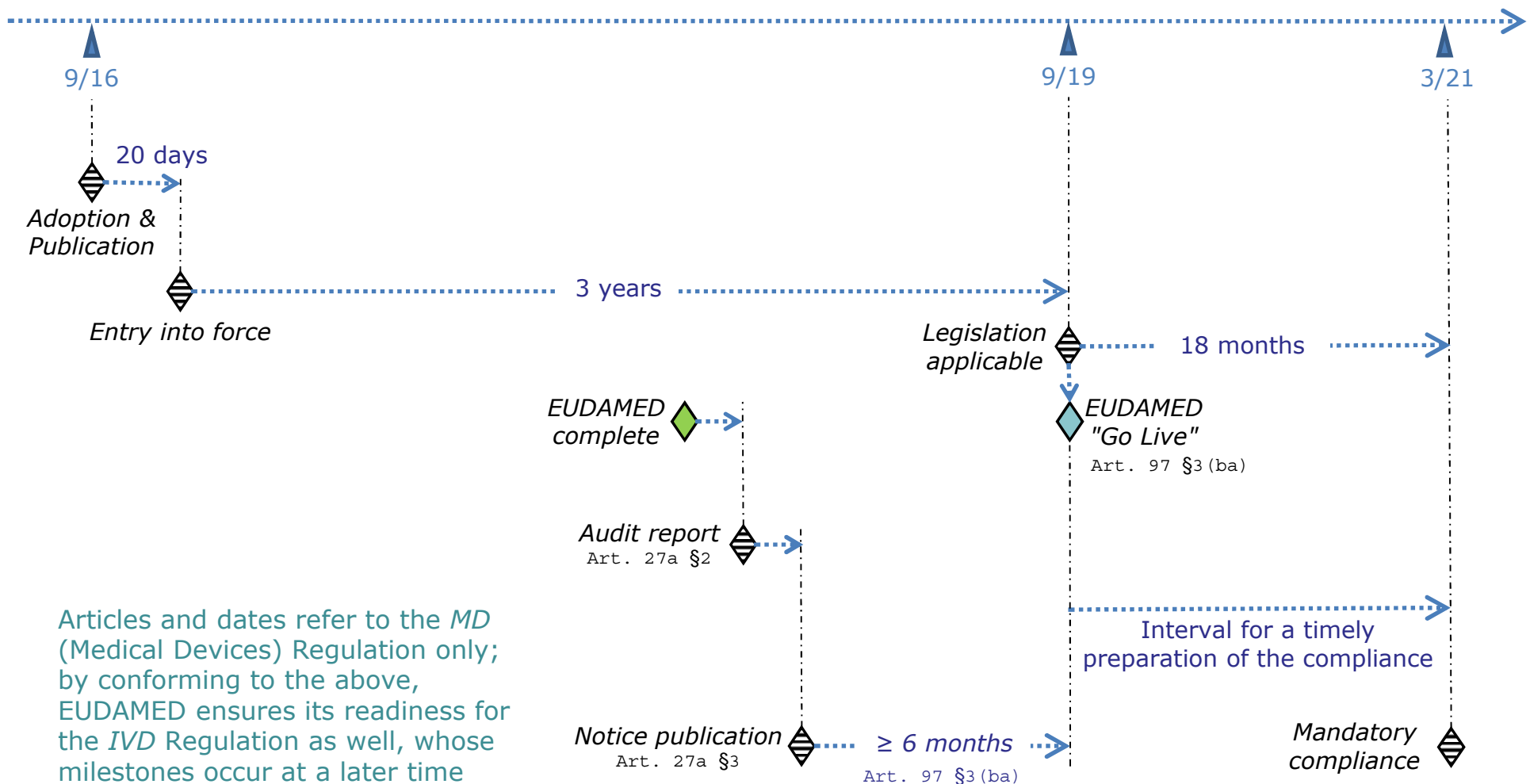


Roadmap

MDR EUDAMED

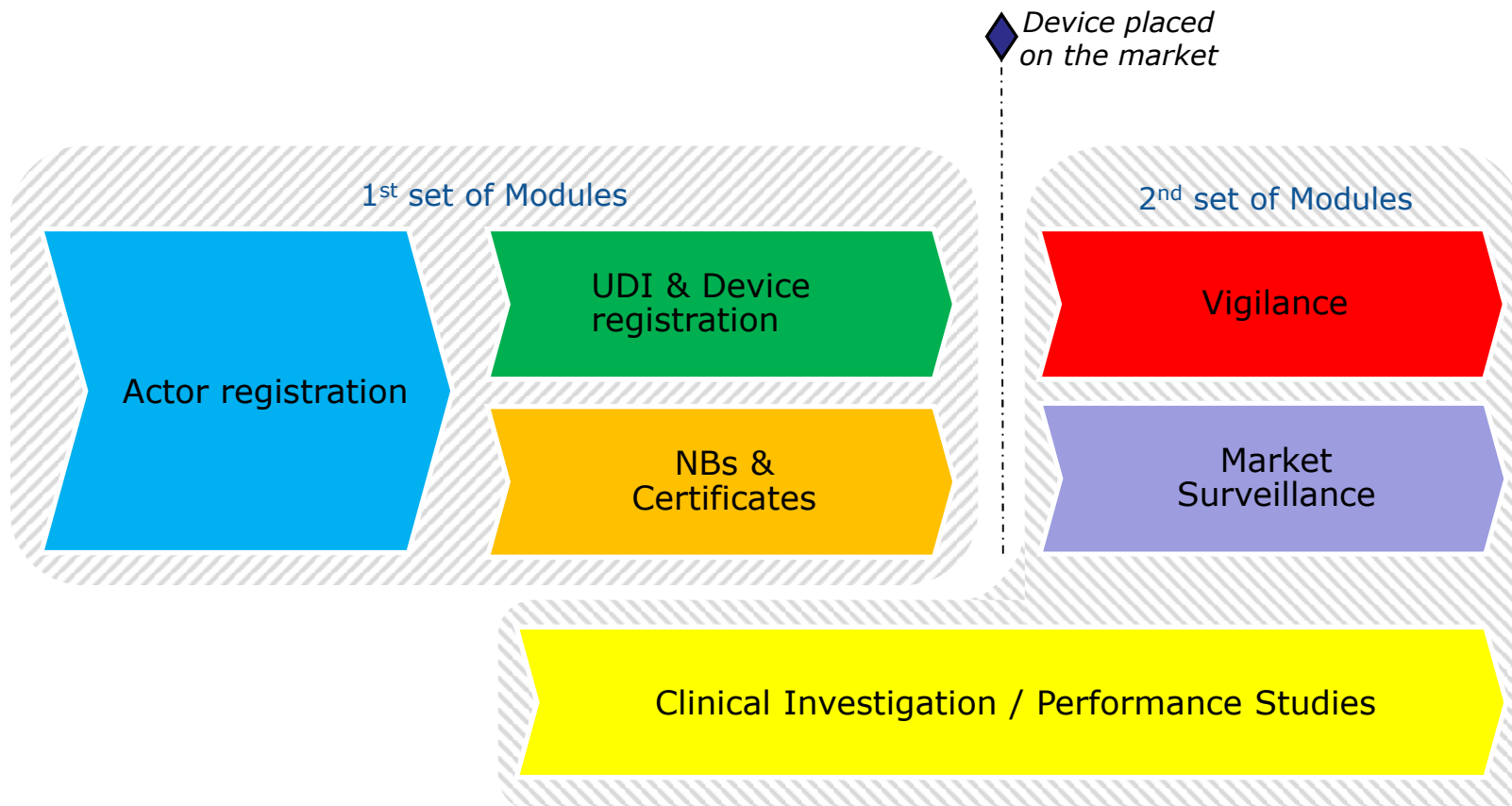


Scheduled legal milestones





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 Role and Access rights**

1st set

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

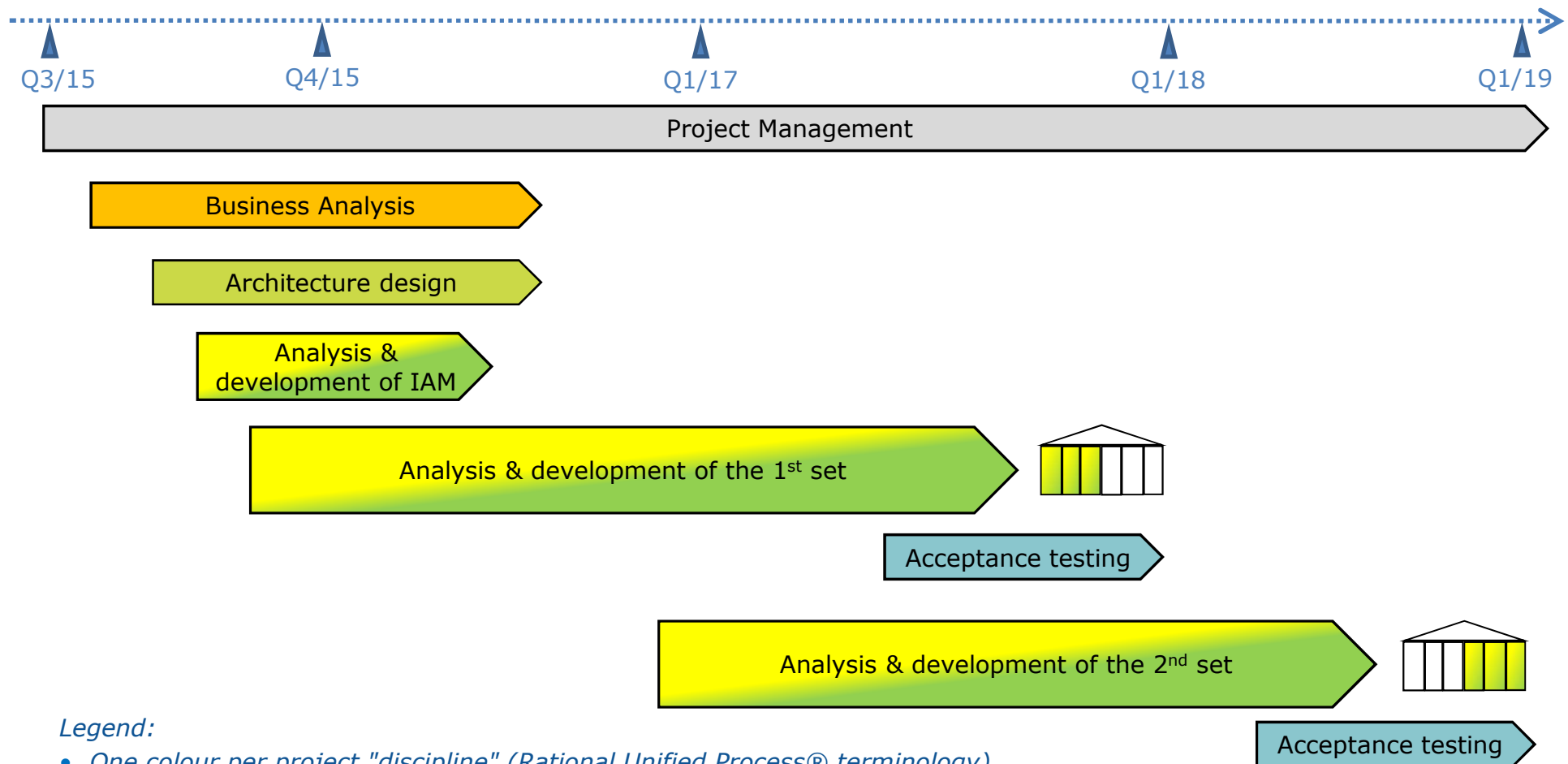
2nd set

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





Global planning: "Best scenario"

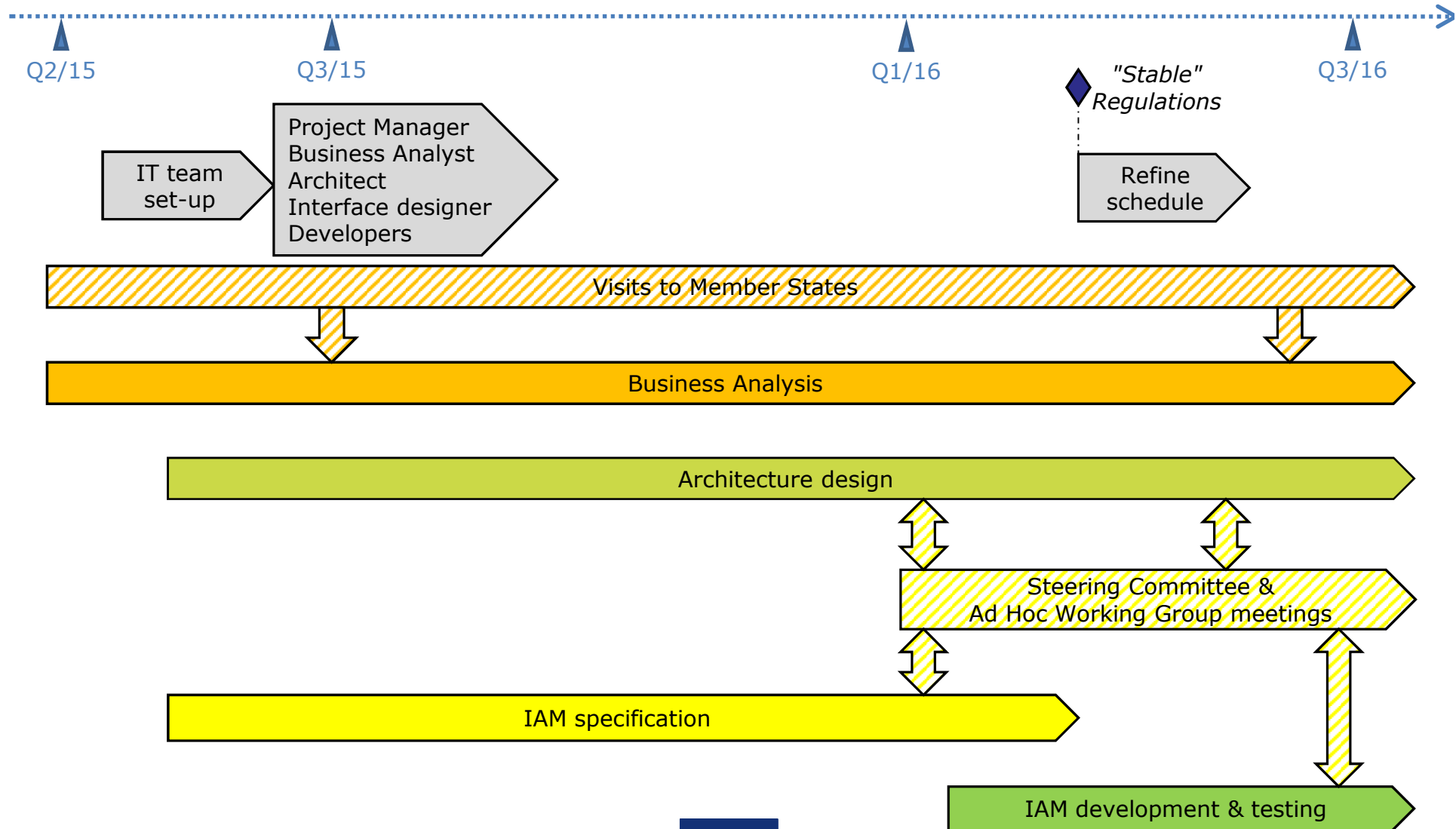


Legend:

- One colour per project "discipline" (Rational Unified Process® terminology)
- Hashed background used for activities involving both EC and external stakeholders

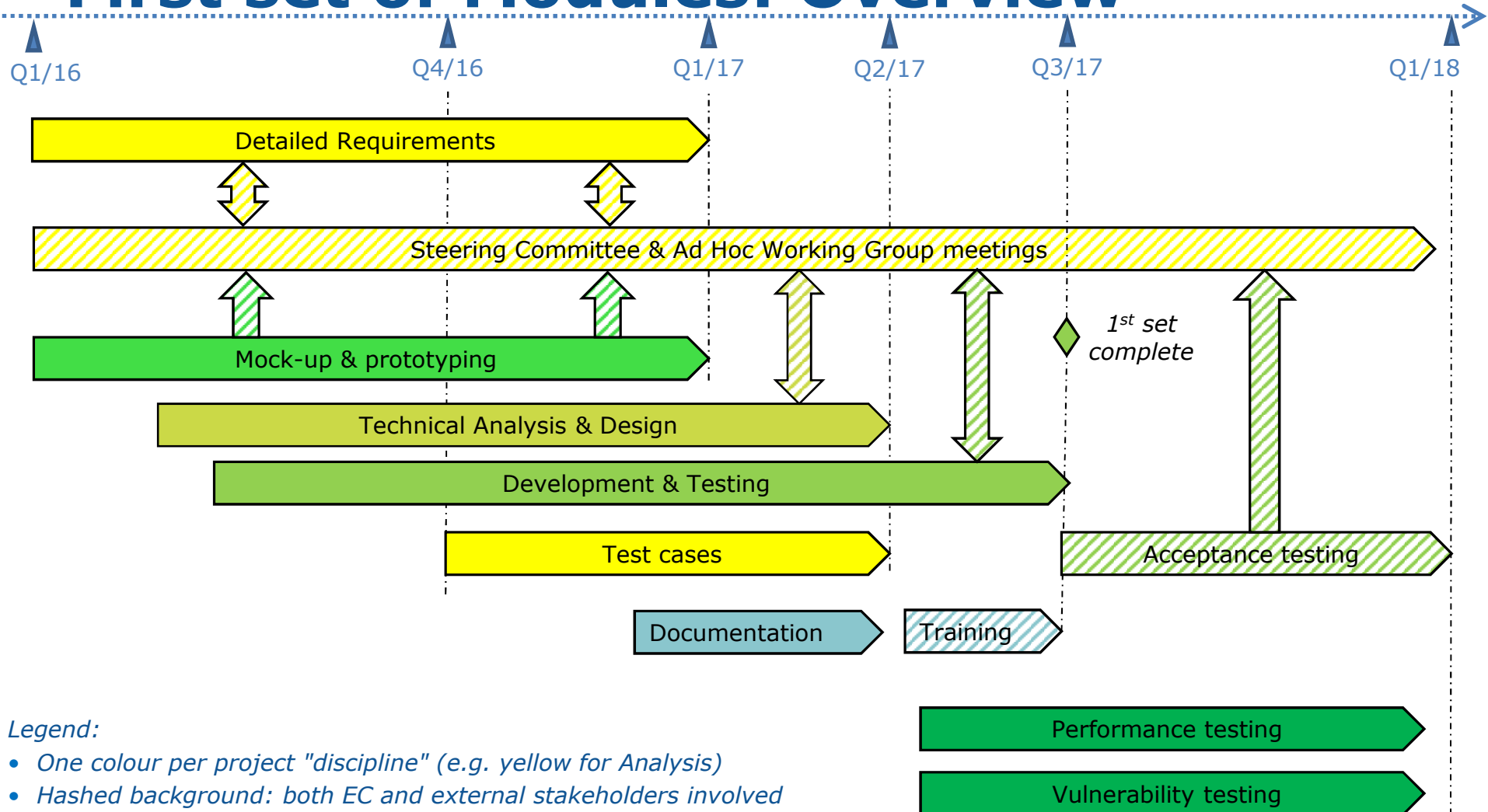


Architecture & IAM



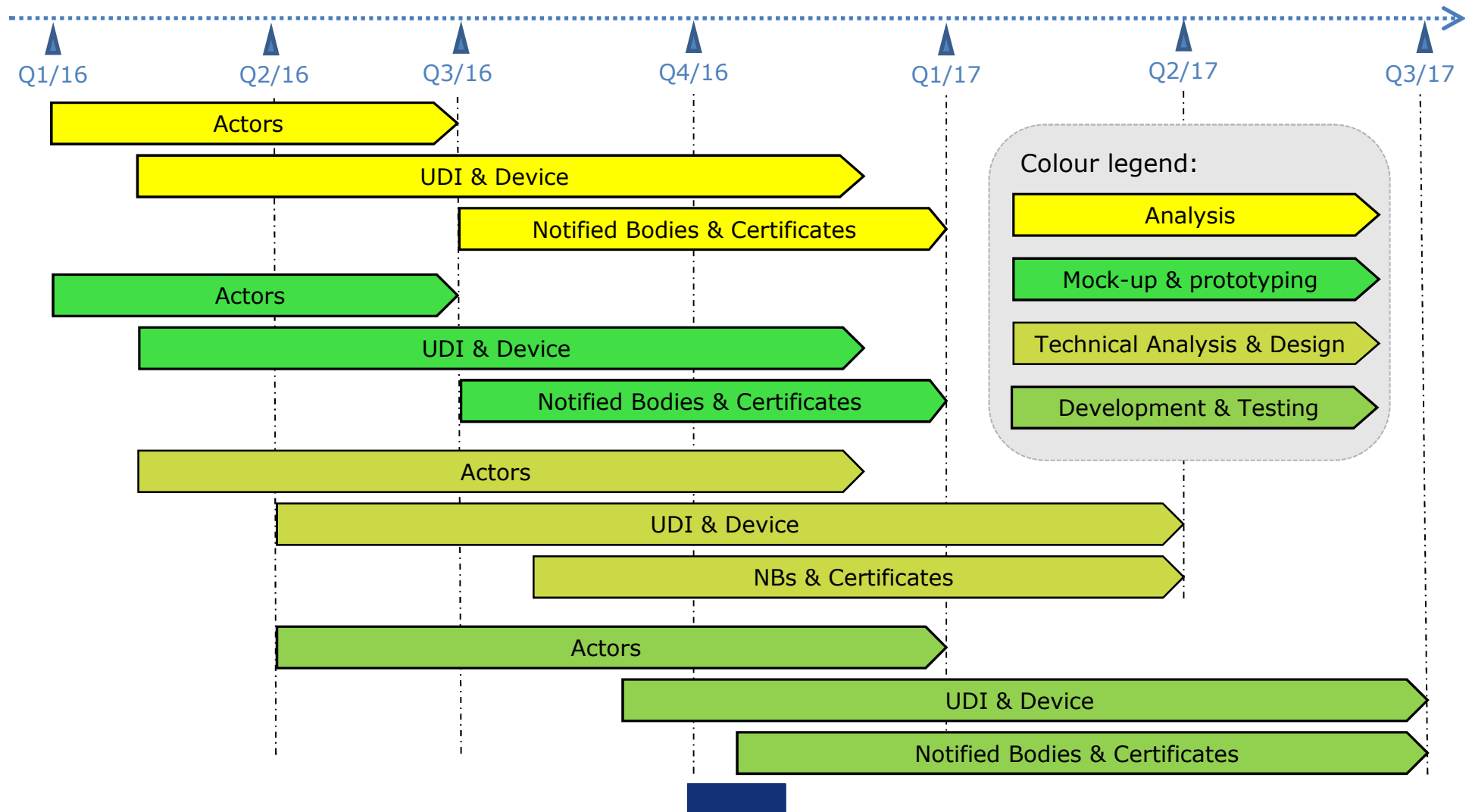


First set of Modules: Overview



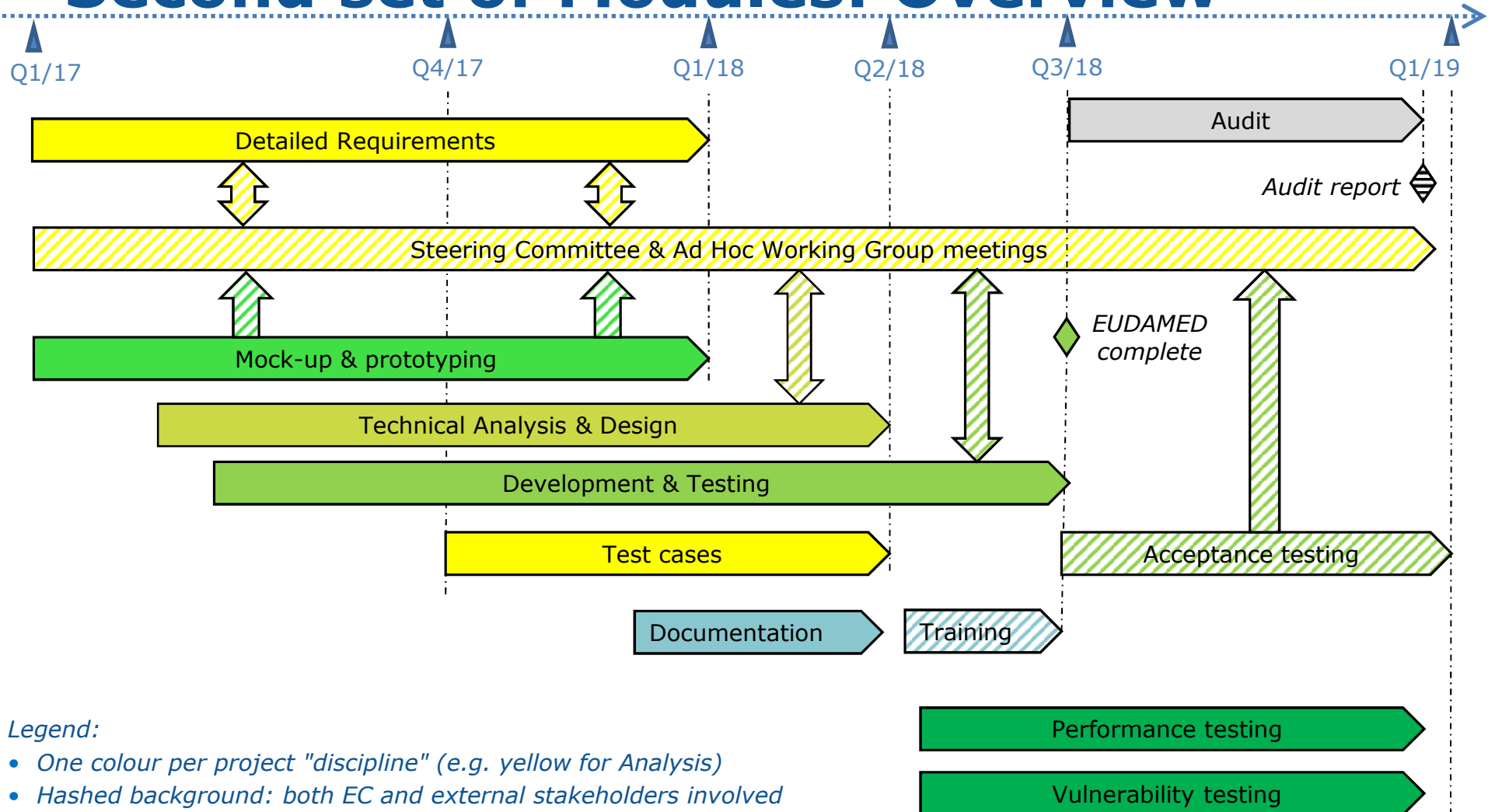


First set of Modules: Breakdown



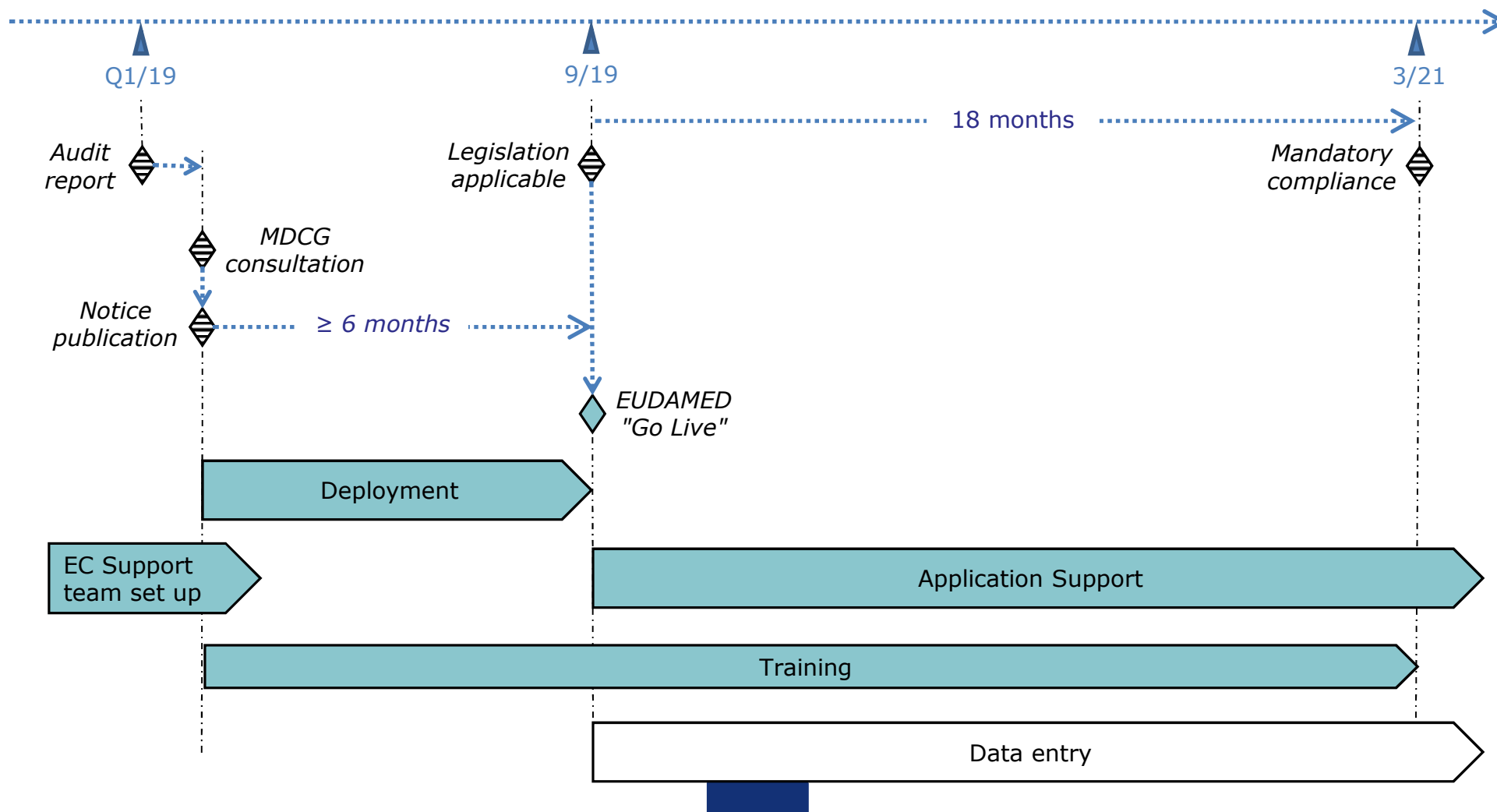


Second set of Modules: Overview





Deployment & Use





Conclusion

Planning

- Commitment of resources for a timely completion
- EUDAMED "Go Live" driven by the Adoption Date

Functionality

- Requirements depend on final content of Regulations

Architecture

- Tailored to the needs of the project
- Based on proven solutions

Success relies on cooperation among Stakeholders

Thank you in advance!

