COMBINE programme
ACT EU Multi Stakeholder Platform Advisory Group meeting

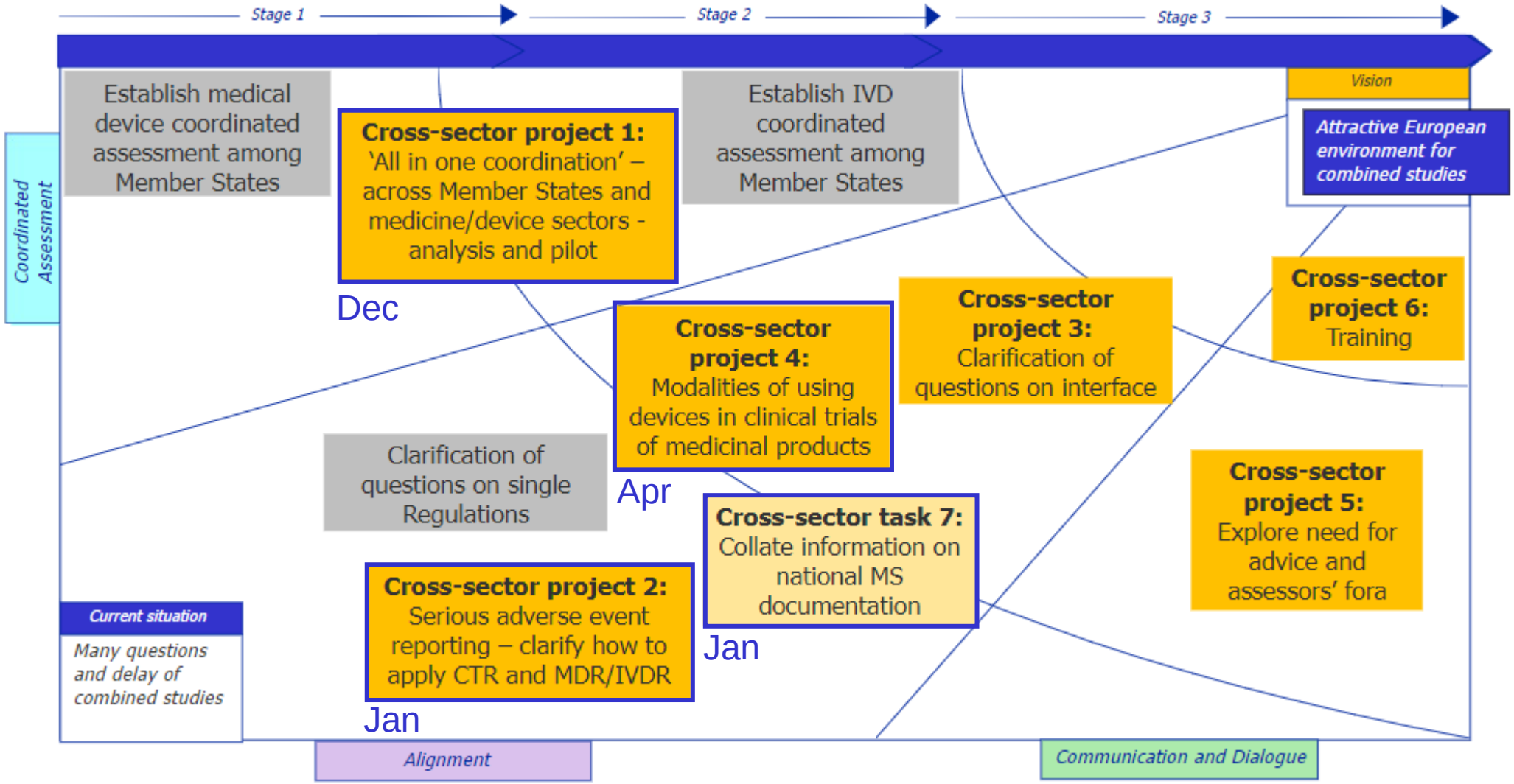
12 March 2025

Isabelle Clamou, Unit D.2 – Medicinal Products : Quality Safety , Innovation
Directorate-General for Health and Food Safety (DG SANTE) European Commission

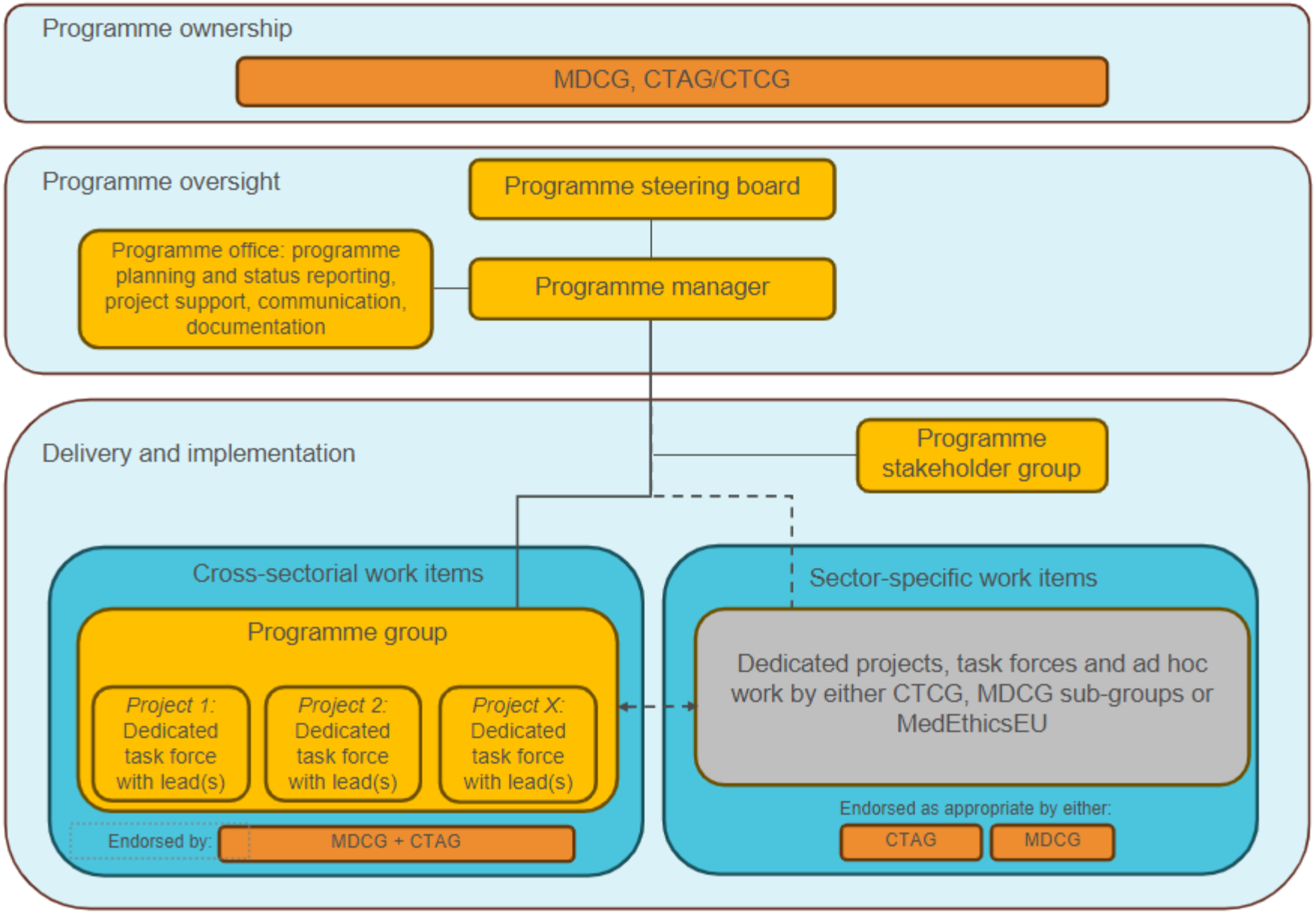
Update since October 2024

- ACT EU MSP workshop October 2024 :
  - From project to programme
  - Presentation of the draft programme strategy
- December 2024:
  - Adoption of the programme strategy by COMBINE governance
  - Kick off of cross functional projects

Transformation diagram – programme overview



Ways of working



CIE/IVD WG, CTCG, MedEthicsEU *review prior MDCG/CTAG endorsement*

Stakeholders *give input to project work as appropriate – meetings or in writing*

Project groups *consists of network representatives from Ethics, CIE/IVD WG, CTCG, EMA, others – propose solutions*

European Commission

Stage 1 projects

European Commission

Project 1: ‘All in one’ assessment under CTR/IVDR/MDR

Cross-sector project 1:
‘All in one coordination’ – across Member States and medicine/device sectors - analysis and pilot

Purpose: to explore coordinating Member State assessments of applications for studies among Member States (including competent authorities and ethics committees) and across the CTR and IVDR or MDR. Focus on CT of a medicinal product combined with PS of a companion diagnostic IVD.

- **Expected deliverables:**
  - Analyse possibilities for a voluntary multi-Member State CT/PS single procedure
  - Propose outline of a single procedure pilot
  - Establish and run pilot
  - Evaluate the results of the pilot and draw up recommendation for a voluntary single procedure for CT/PS and CT/CI combined
  - Convey learnings on IT business procedures

Project group 1 initiated Dec 2024:
14 Member States + EMA
44 participants across Ethics, CA CT/IVD/MD

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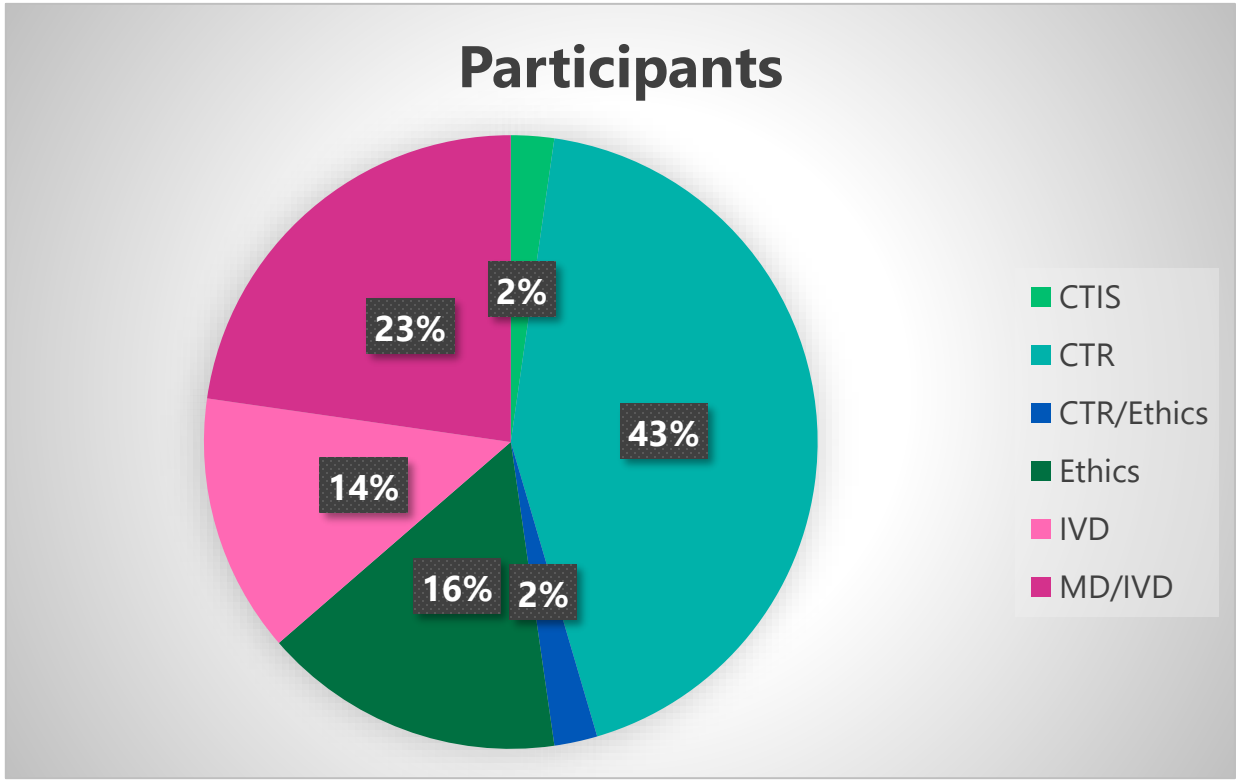
Project 1

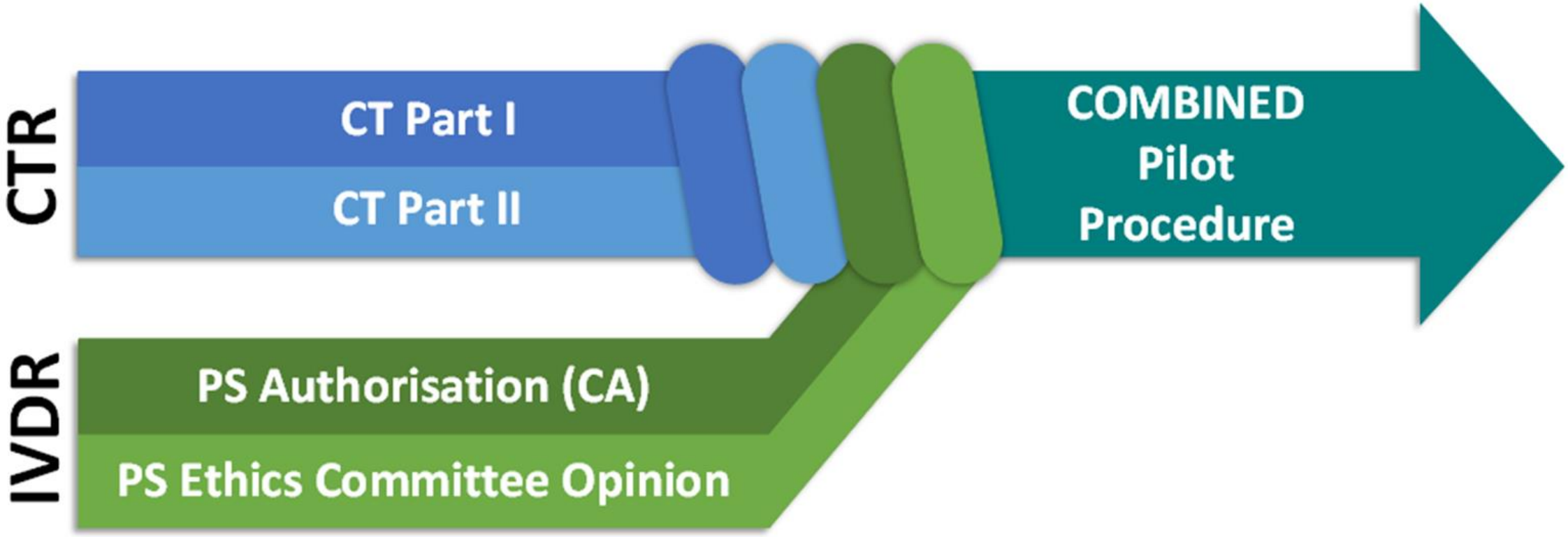
- Launched in December 2024
- Analysis work underway since Q2 2024.
- Discussions to date explored
  - Legal frameworks and current practice for CTR/IVDR
  - Similarities and differences
  - What could a pilot look like?
  - Challenges and aspects for clarification



Project 1 Group as of 24/01/25

- 44 participants
- 14 MS + EMA

Targeted Approach – CT + PS of IVD companion diagnostic



Pilot Key Features

Single submission consisting of a parallel submission of:

CT documentation

PS documentation

EC documentation for the CT

EC documentation for the PS.

Coordinated RFI for CT and PS

Goal: To have questions raised together

Coordinated response from sponsor to the RFI

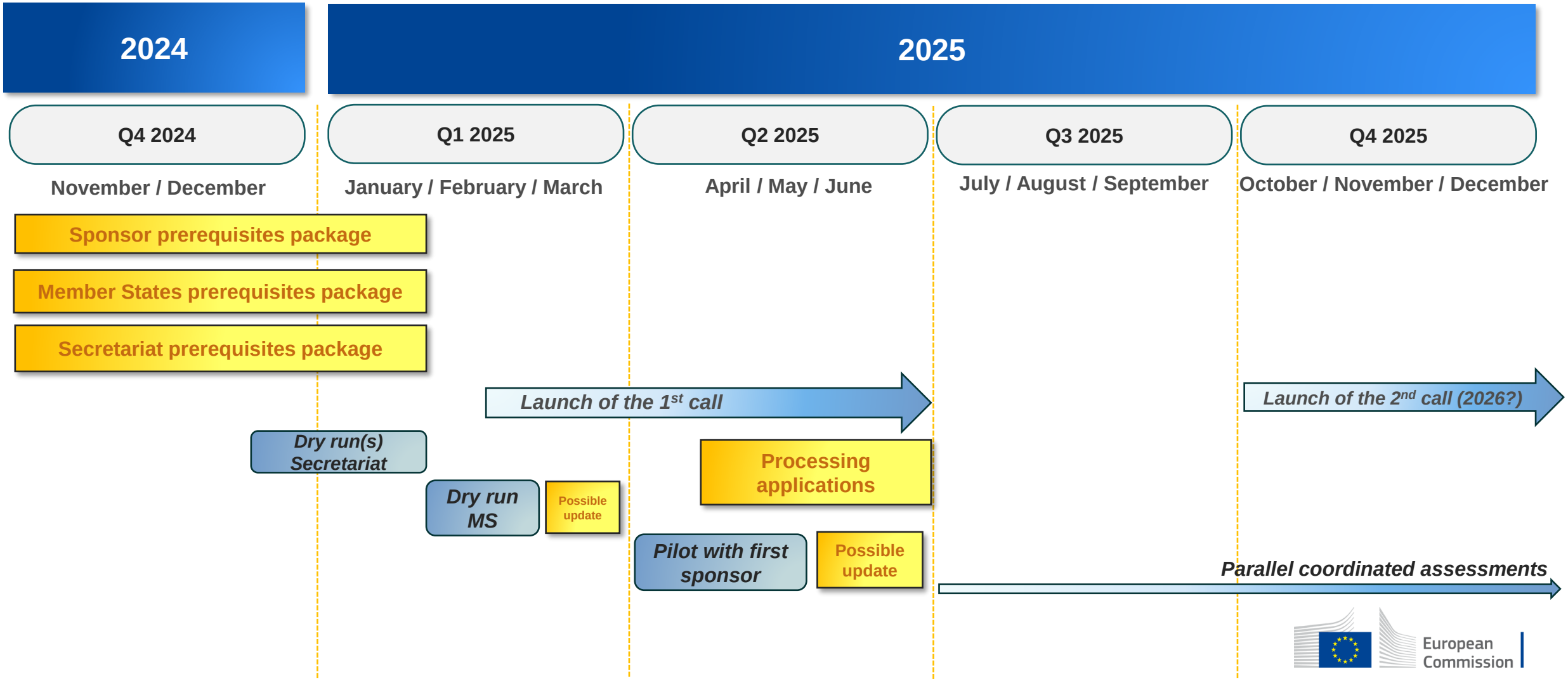
Goal: To have information/ changes to documentation occurring at the same time

Alignment of decisions

Goal: Decisions/ opinions provided together

Medical device clinical investigation coordinated assessment pilot

Establish medical device coordinated assessment among Member States



European Commission

Project 2: ‘Serious adverse event reporting across CTR/IVDR/MDR’

Cross-sector project 2: Serious adverse event reporting – clarify how to apply CTR and MDR/IVDR

Purpose: to clarify how to apply the CTR, MDR and IVDR requirements to serious adverse event reporting in combined studies

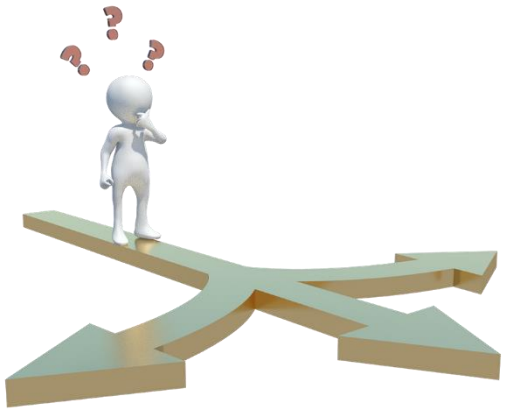
- **Expected deliverables:**
  - Comparison of safety reporting procedures under each of the three legal frameworks and understanding of practical experience from stakeholders.
  - Suggestion for solution of any identified issues e.g. a guidance document text.

Project initiation Feb 2025

European Commission

Project 4: ‘Modalities of using devices in clinical trials of medicinal products’

Cross-sector project 4: Modalities of using devices in clinical trials of medicinal products



Purpose: to explore the **different modalities** of using medical devices and IVDs in clinical trials of medicinal products -> clarify applicable **regulatory context**.

- **Expected deliverables:**
  - A **set of scenarios** for using and/or investigating medical devices and IVDs in clinical trials of medicinal products
  - Clarification of the regulatory framework applicable to each scenario

If appropriate, a guidance document or similar

One possibility is update/expansion of MDCG 2022-10.

Project expected initiated Apr 2025 – stage 1.

European Commission

Task 7: ‘Info on national requirements’

Cross-sector task 7: Collate information on national MS documentation

Purpose: to 1) take stock of feedback from stakeholders on different Member State practices for documentation and 2) facilitate sponsor access to this information.

Expected deliverables:

- Collation and **review of feedback from stakeholders** from analysis phase on different Member State practices on documentation
- Communication to Member States to encourage easy access to information for sponsors (website)
- Collection and publication of a **set of links to national websites** with requirements for combined studies

Task initiated Q1 2025 and performed by Commission.

European Commission

Stage 2 projects

European Commission

Project 3: ‘Questions on interface of CTR, MDR and IVDR’

Cross-sector project 3: Clarification of questions on interface

Purpose: to clarify questions on aligned application of CTR and MDR or IVDR as regards application and/or notification processes for combined studies, for elements that are on the interface of these Regulations.

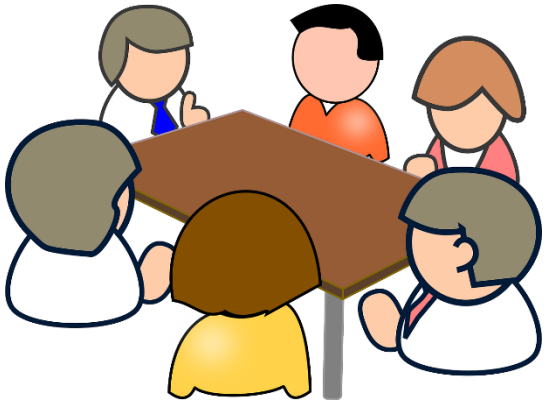
Expected deliverables:

- List of questions that need clarification and assessment of priority
- Guidance text or similar tool to clarify some or all questions

Project to be initiated Q1 2026

Project 5: ‘Explore need for advice and assessors’ fora’

Cross-sector project 5:
Explore need for advice and assessors’ fora



Purpose: to explore needs and opportunities for offering advice to sponsors, and for exchange of best practice among assessors.

Expected deliverables:

- Clarify sponsor needs for advice, assessment of what already exists, and proposals to fill gaps
- Same as above for competent authority and ethics committees’ needs for fora to exchange experience and best practices

Project to be initiated Q3 2025

Stage 3 project

European Commission

Project 6: ‘Training’

Cross-sector project 6:

Training

Purpose: explore the needs for training for sponsors, competent authorities and ethics committees, collect existing training materials or develop new materials as appropriate.

Expected deliverables:

- Identification of training needs
- Collection of existing materials
- Development of a lean training strategy
- Development any necessary new training materials

Project to be initiated in 2027

Outlook - programme approach

- Brings parties together across sectors
- Active participatory roles, intended to address needs
- Aims to facilitate implementation
- Tests new ways of working
- Will inform possible future policy development
- Stage 1 underway with coordinated assessment as centerpiece

More information:

Combined studies - European Commission (europa.eu)

European Commission

Thank you

Any questions?