



Medical Device Coordination Group

15 October 2024

Agenda point 7: update on the COMBINE project

SUMMARY OF PROPOSED WORK ITEMS TO ADDRESS ISSUES FOR COMBINED STUDIES.

Group	#	Item
Coordinated Assessment	1.1	CI/PS CA Coordinated Assessment
	1.2	Aligning Ethics Assessment Procedures (MS level)
	1.3	Coordination between CTR & CI/PS CA Assessment (Single Application)
	1.4	IT Infrastructure
Alignment	2.1	Align MS positions
	2.2	Develop Understanding
	2.3	Improve Sponsor awareness
Guidance & Clarity	3.1	IVDR/MDR Topics
	3.2	Common Topics
	3.3	CTR Topics
Communication & Dialogue	4.1	Scientific/Technical Advice
	4.2	Open dialogue/ exchange of best practice
	4.3	Training Initiatives
	4.4	Encourage creation of cross functional national teams at a member state level (CT/CI/PS)

Phase 1 track 4 - proposals

These were ideas for solutions that would address most of identified issues – more than 50 individual actions proposed.

To be addressed **after** the analysis phase:

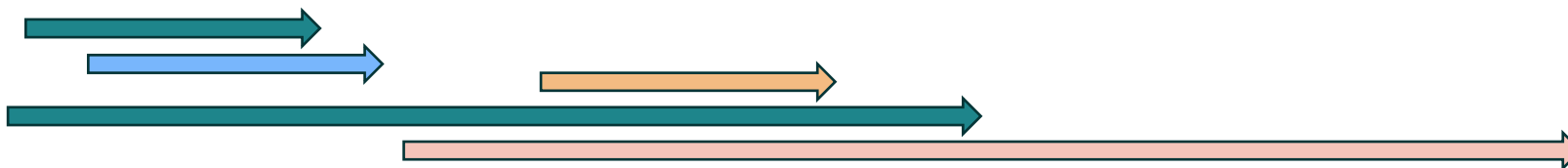
- prioritisation
- concrete plans for implementation

Approach for phase 2: from project to programme



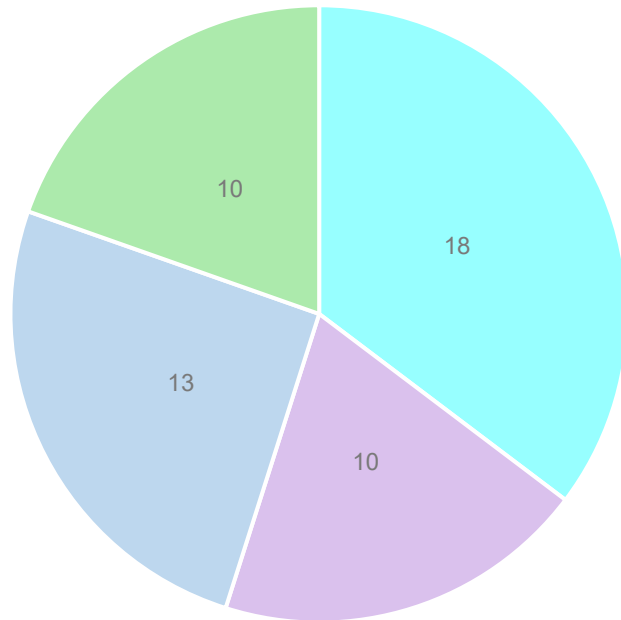
- Working across fields with established groups
- For sector-specific issues relevant to the interface, projects in each respective group
- Projects specific to the interface can be initiated and done jointly
- Stepwise progress, checkpoints and stock-taking together as we go
- Overview of all ongoing work

Inclusive, pragmatic, staggered



From proposed solutions to programme plan

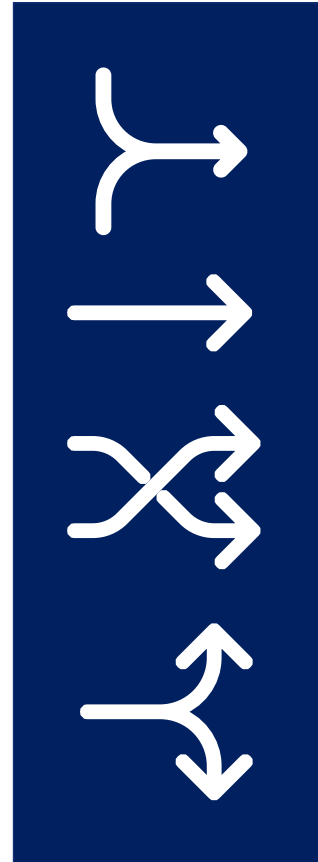
Proposed solutions COMBINE analysis report



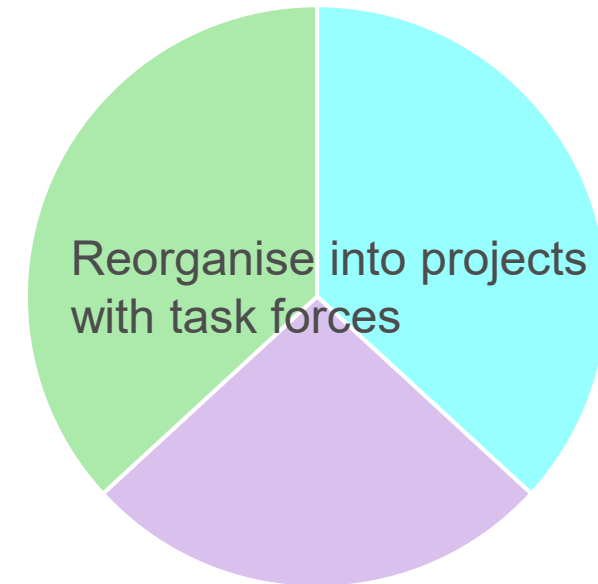
■ Coordinated assessment ■ Alignment ■ Guidance & clarity ■ Communication & dialogue

51 proposed work items

78 issues mapped



Phase 2 actions Programme plan:



■ Coordinated assessment ■ Alignment ■ Communication & dialogue

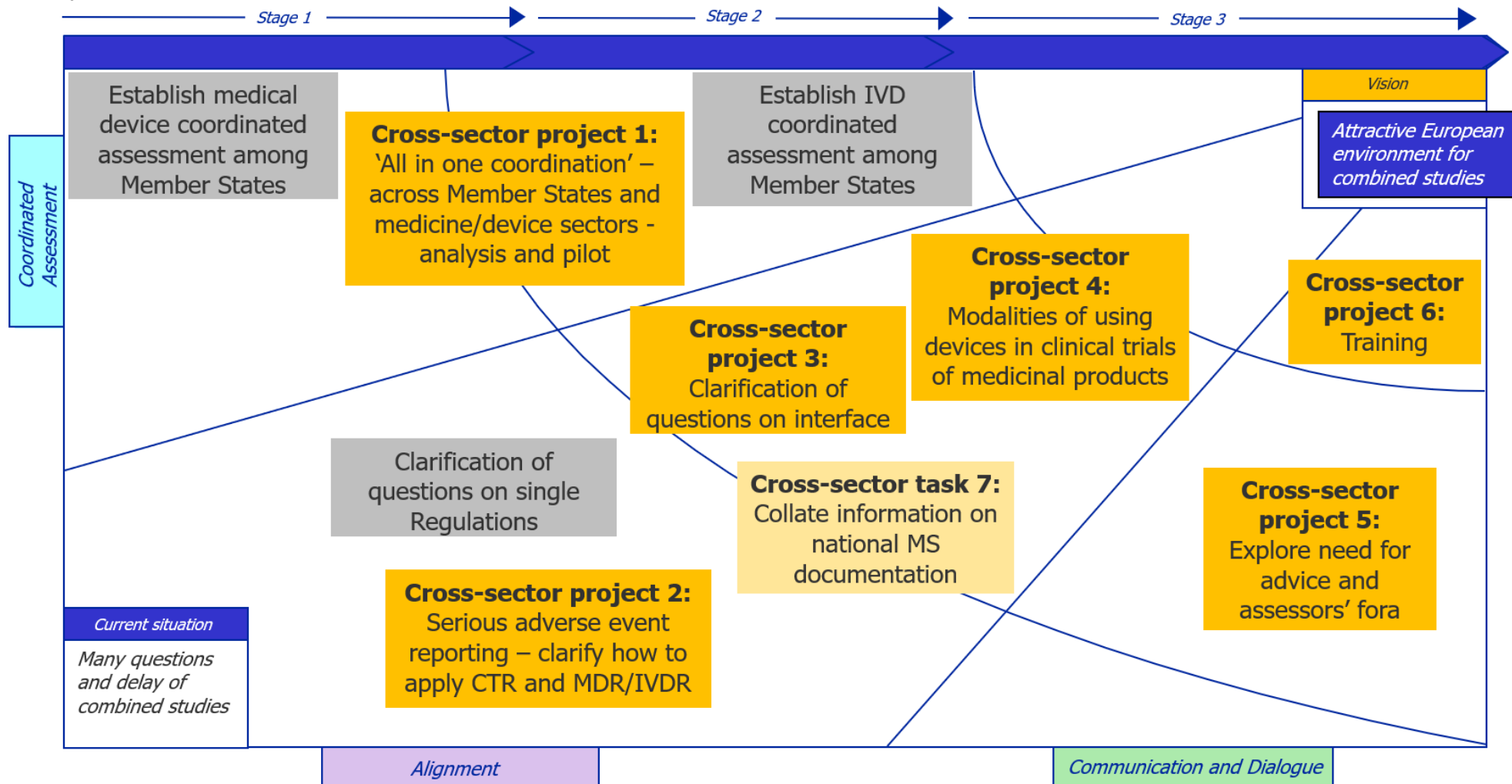
6 cross-sector 'COMBINE' projects and **1** task

Several sector-specific task forces/projects to be mapped and interlinked

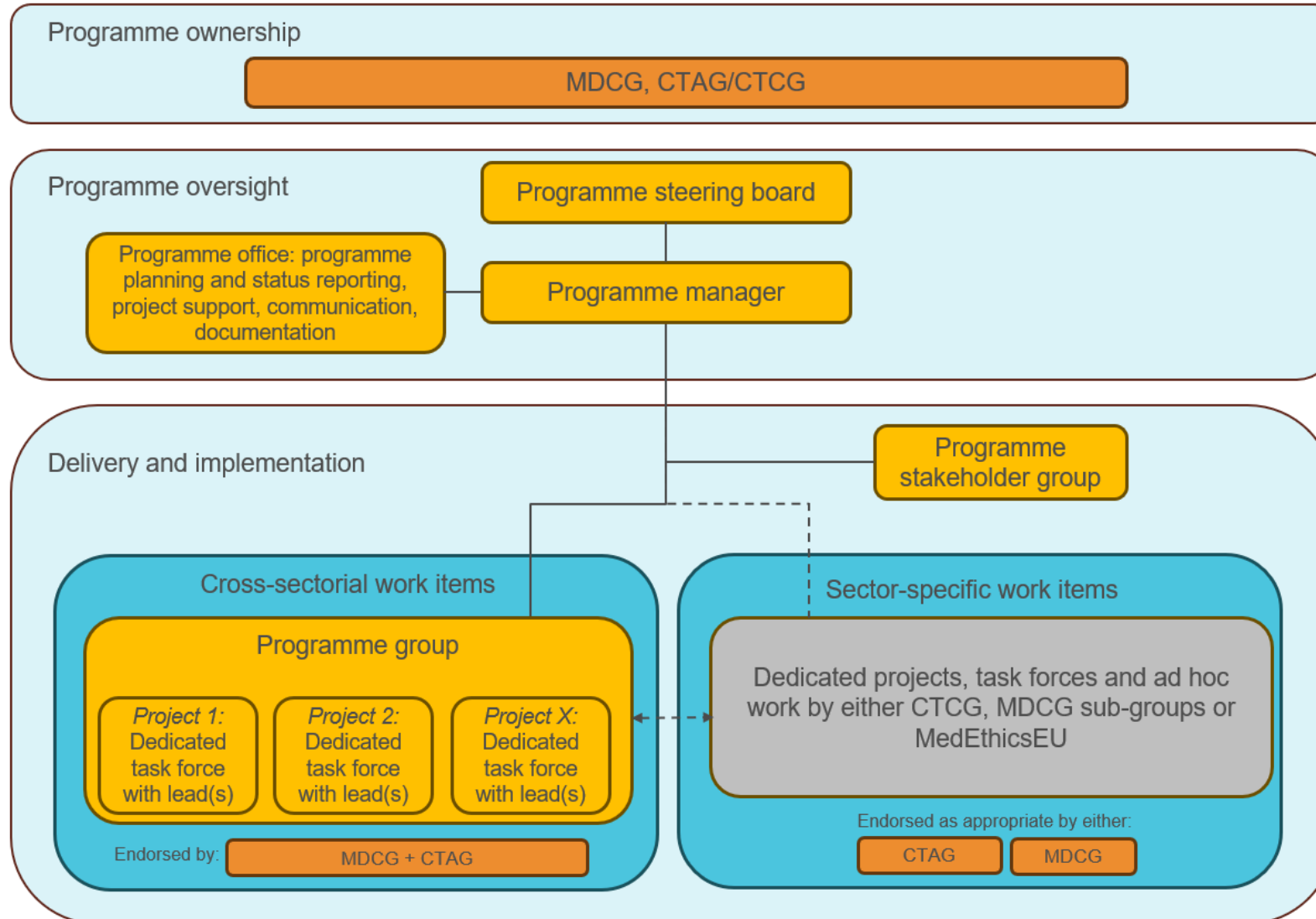
78 issues to be addressed

Summary of proposed programme activities

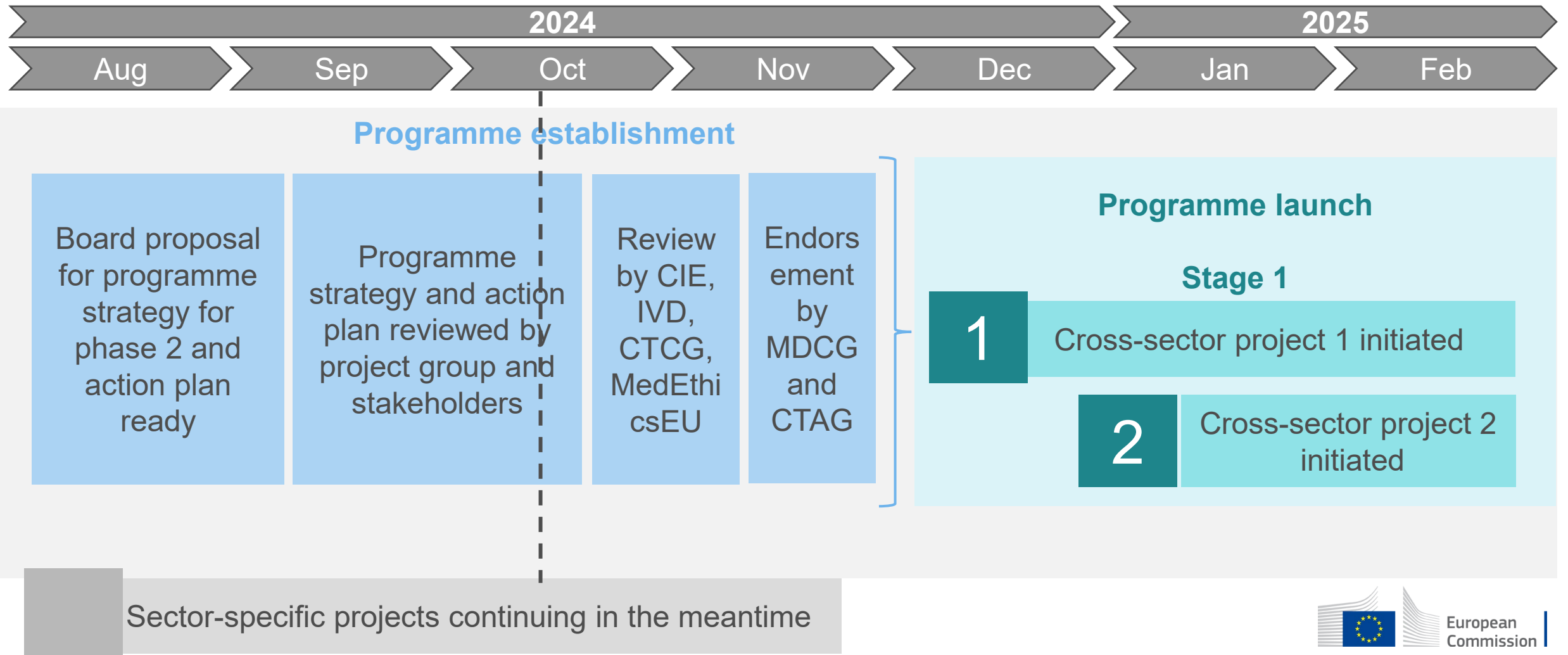
actions already ongoing or indicatively planned to be initiated in **2024 – Q1 2025** to be initiated in Q2 2025 – Q1 2026 to be initiated in Q2 2026 – Q1 2027



Proposed programme governance



High-level timeline for phase 2 – from project to programme





Thank you

Any questions?

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