



Possibility of an ACT EU – Enpr-EMA workshop

Enpr-EMA Coordinating Group and
networks meeting

11 June 2025



Supporting clinical trials in the EU

Supporting the implementation of the [Clinical Trials Regulation](#) and further harmonisation (CTR Collaborate)

Maintaining and improving the Clinical Trials Information System ([CTIS](#)), the IT tool of the CTR

Accelerating Clinical Trials in the EU ([ACT EU](#)) initiative with HMA and EC to deliver [better, faster and smarter clinical trials](#) and support innovation

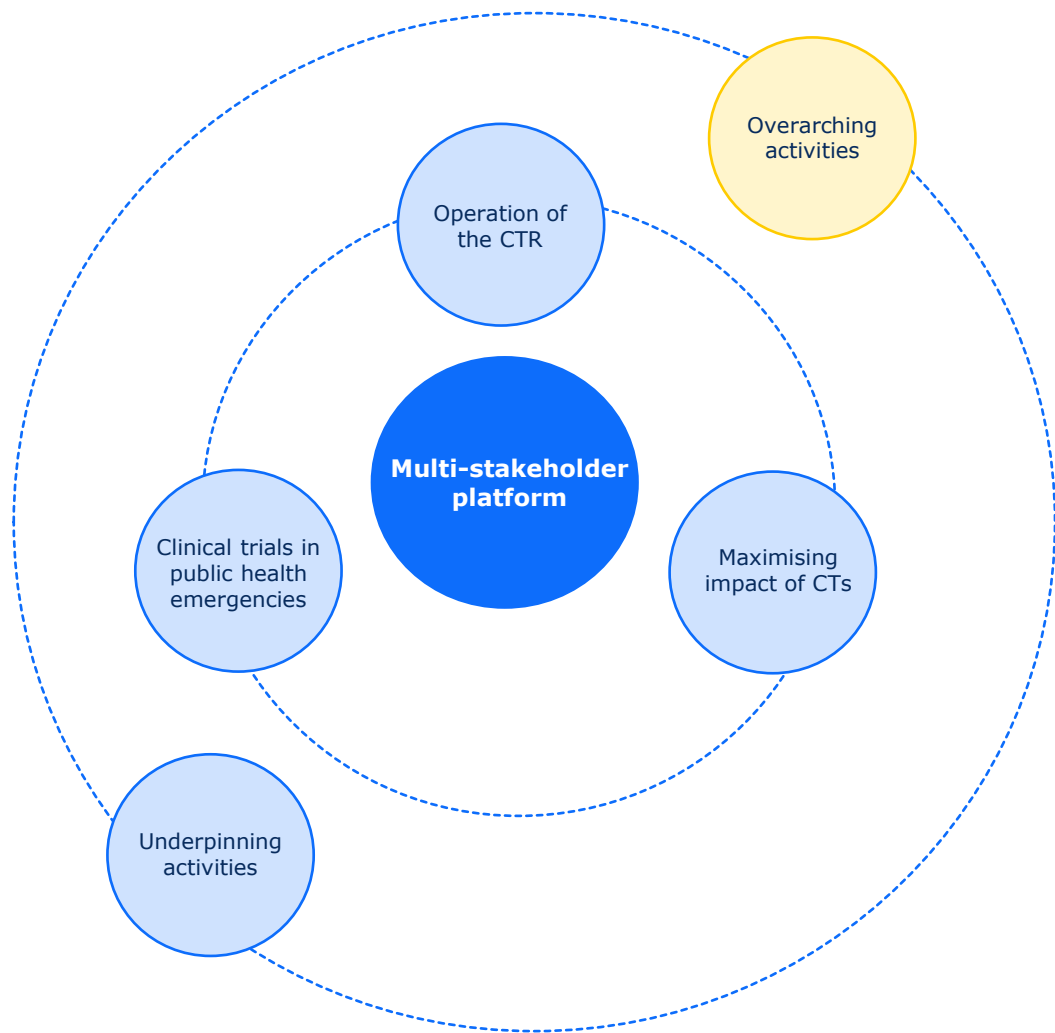
Supporting efforts to streamline trials of medicines & medical devices (COMBINE programme)

ACT EU partners

- A joint initiative by the European Commission, Heads of Medicines Agencies and EMA
- Established in January 2022
- Building on the momentum of the implementation of the Clinical Trials Regulation (CTR)
- An initiative with the vision to have better, faster, smarter clinical trials in the EU



ACT EU focus 2025-2026



Overarching activities:

- ACT EU governance
- Multi-stakeholder Platform

Operation of the Clinical Trials Regulation:

- Implementation of the Clinical Trials Regulation
- Support for non-commercial sponsors
- Clinical trials safety

Maximising impact of clinical trials – design and conduct of excellent clinical trials:

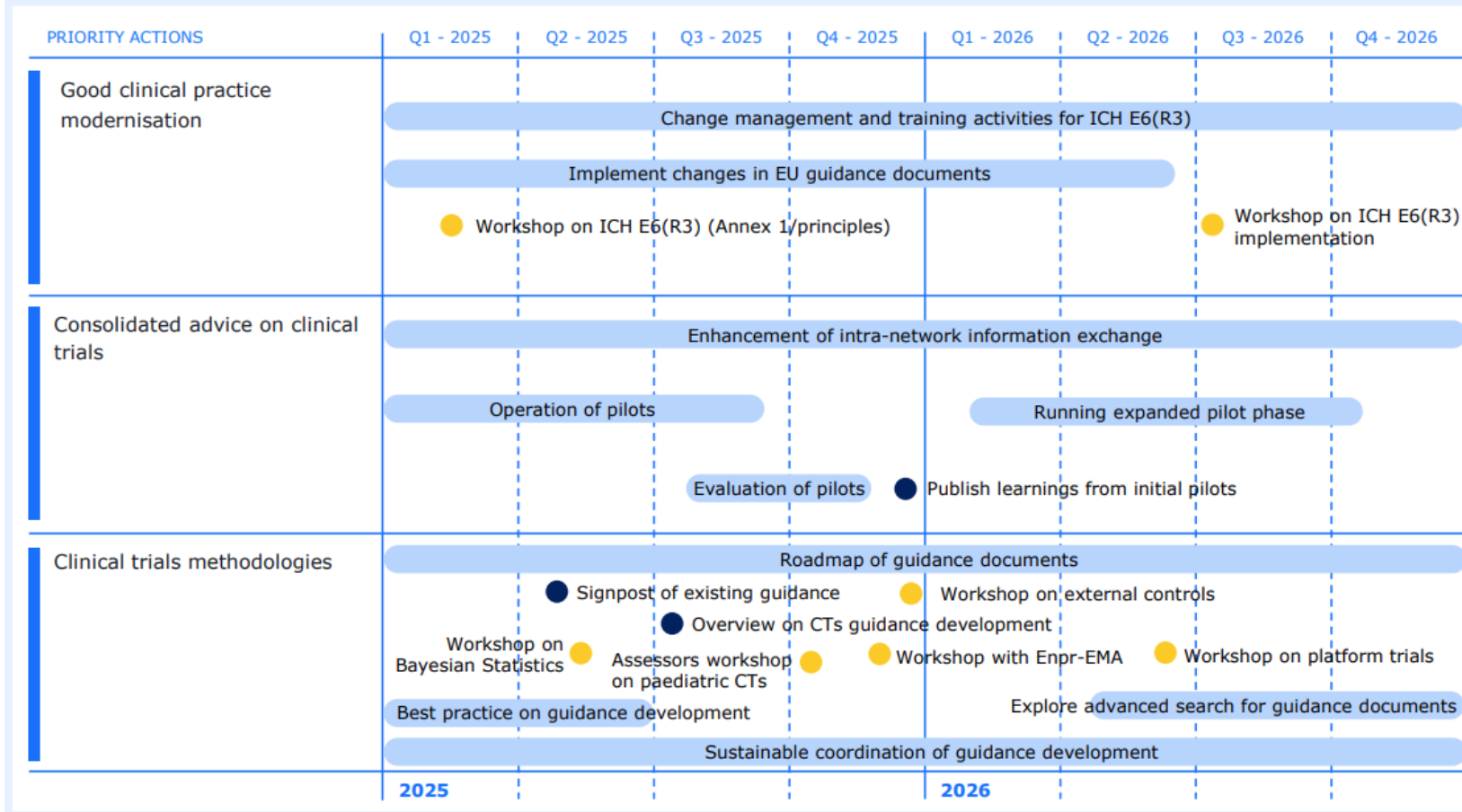
- Good clinical practice modernisation
- Consolidated advice on clinical trials
- Clinical trials methodologies

Underpinning activities:

- Communication
- Clinical trials analytics
- Clinical trials training

Methodologies

Design and conduct of excellent clinical trials



Possibility to have a dedicated ACT EU/Enpr-EMA workshop

- Dedicated ACT EU/Enpr-EMA workshop planned
- Focus on clinical trials aspects for paediatric population
- A workshop for clinical assessors will take place in July where case studies will be discussed
- Topics discussed during the assessors' workshop could be further discussed at the joint ACT EU/Enpr-EMA meeting
- Intention is to focus on topics of interest to support innovation

Thank you

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