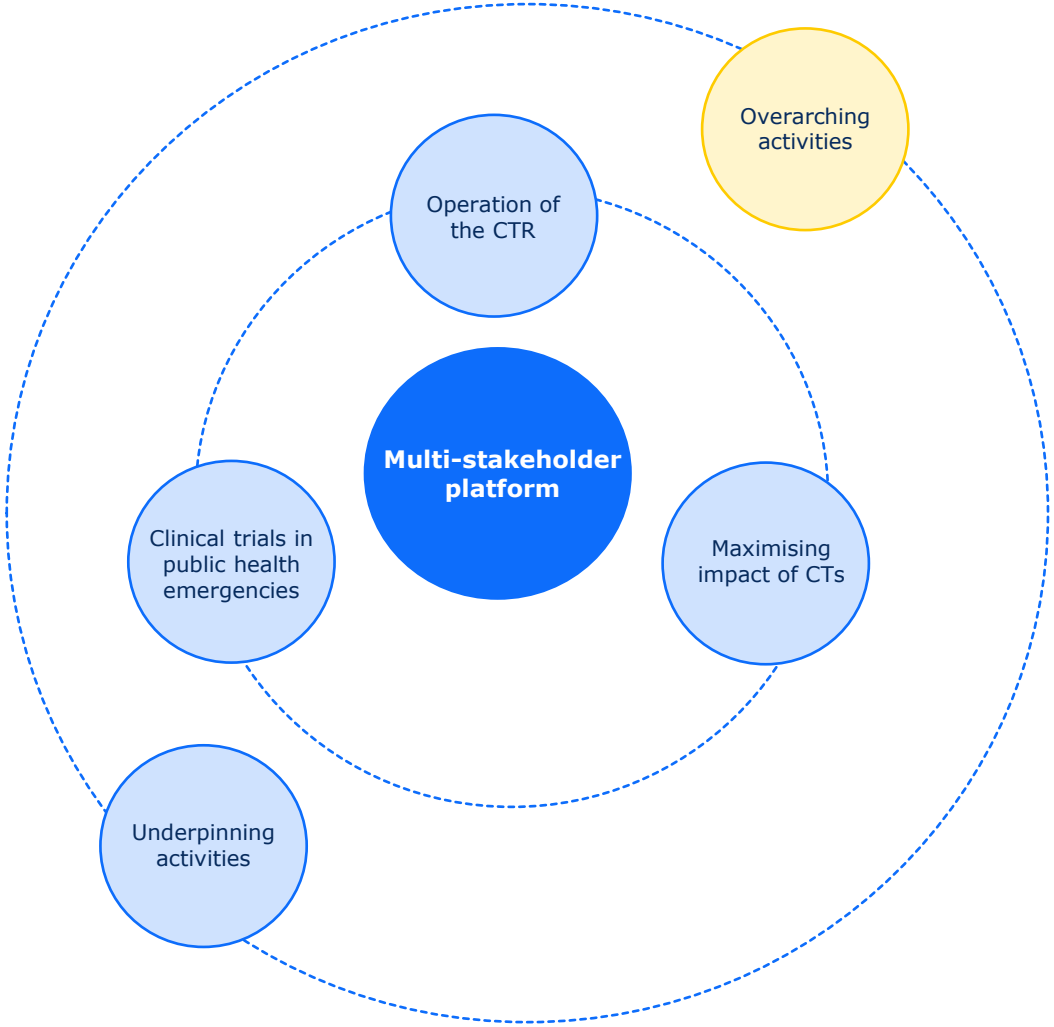
ACT EU: Collaboration with Enpr-EMA

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 **workplan** 2025/2026 will be updated at the end of the year

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

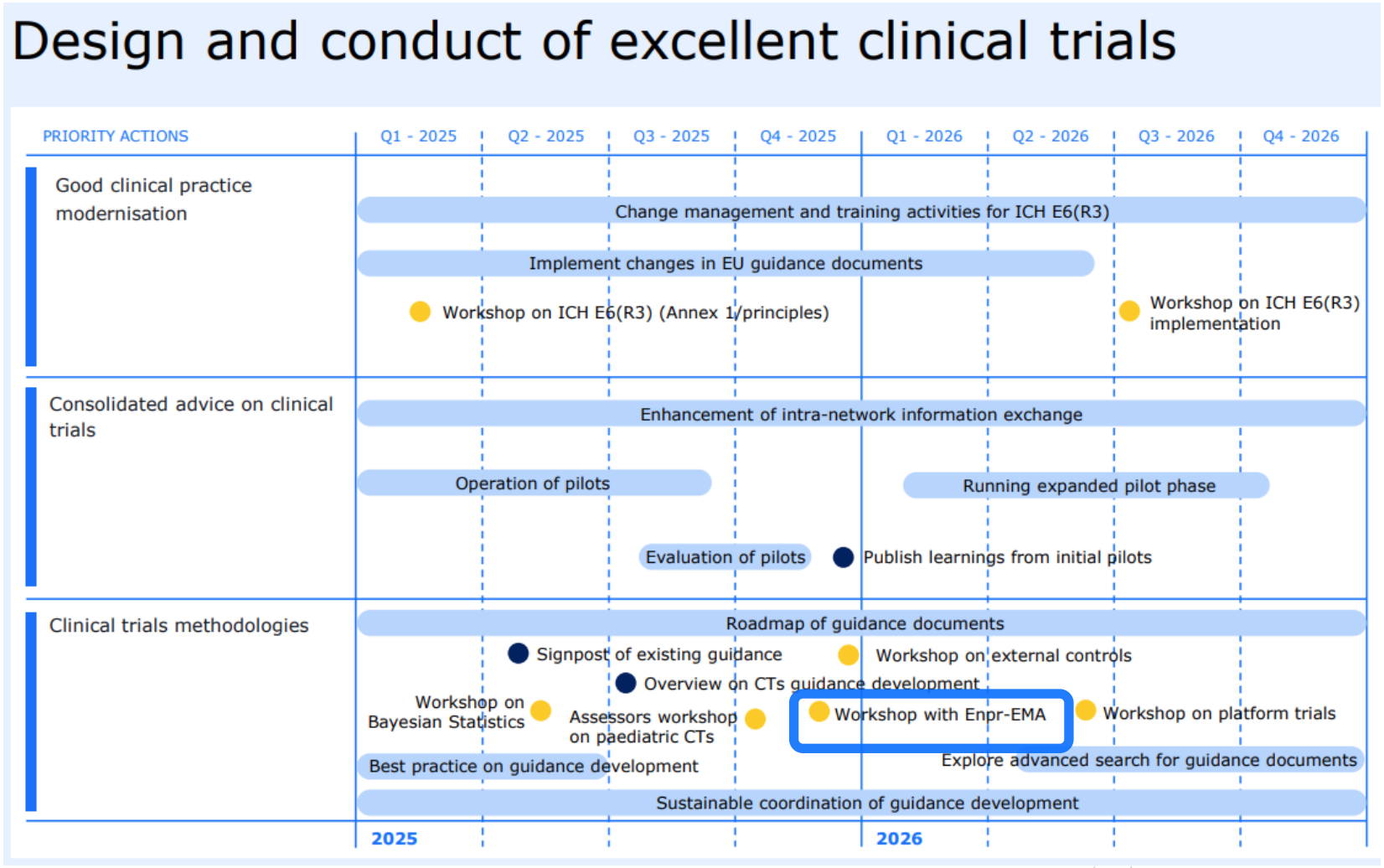
Maximising impact of clinical trials – design and conduct of excellent clinical trials:

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

Underpinning activities:

- Communication
- Clinical trials analytics
- Clinical trials training

Methodologies



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

- Dedicated multi stakeholders ACT EU/Enpr-EMA workshop planned in Q1 2026, one day, F2F at EMA (hybrid)
- Regulators and stakeholders (industry/academia/patients' rep/HCP/funders)
- Focus on clinical trials in paediatric population
- A workshop for clinical assessors has already taken place in July and the meeting report has been published recently on the ACT EU website
- The outcome of the assessors' workshop can set the foundation for the multi stakeholders ACT EU/Enpr-EMA workshop

Outcome of assessors' workshop

- Main points identified during the workshop are:
  - Differences in interpretation of Article 32 of CTR and variability in how Member States assess paediatric clinical trials
  - Interplay between PIPs (if agreed) and CTA assessment
  - Revised Declaration of Helsinki (DoH) aim at facilitating involvement of paediatric population not to exacerbate disparities in opportunities offered
  - Extrapolation of data from others (eg adult) populations as appropriate to avoid unnecessary trials in paediatric population and to make the best use of existing evidence
  - Greater involvement of patients in trial planning, regulatory and ethical discussions is needed
  - Justice and equitable access to research must be central to a scientific and ethical review.

Outcome of assessors' workshop

- Actions discussed at the assessors' workshop include:
  - Calling for a decision-making framework supporting the assessment of paediatric trials.
  - Consider **updating** the recommendation paper on ethical considerations in clinical trials with minors.
  - Considering developing a **sponsor guidance** on what to include in a paediatric CTA, including full PIP Decision, including its Annexes, if available.
  - Need for further **regulatory training** on how to apply e.g. use of extrapolation.
- Survey on national laws (TBC)
- Based on the above, the objective of the **ACT EU/Enpr-EMA workshop** would be to define concrete actions to support the dialogue between regulators, sponsors and patients' representatives on clinical trials in paediatric population.
- Programme committee to be set up, define meeting objective, define meeting date

Thank you