EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Strategic Aims of Enpr-EMA 2025-2027

Discussion points for the Coordinating Group and Enpr-EMA new Chair (of networks)

19November2025, Pirkko Lepola

New Coordinating Group 2025-2027

EUROPEAN MEDICINES AGENCY

1. Enpr-EMA Coordinating Group (CG)

- Governing body of Enpr-EMA
- Contributes to short and long-term strategy of Enpr-EMA
- Selects of priority activities – also for Working Groups
- After new EU pharma legislation -> renewal of CG mandate and next CG composition

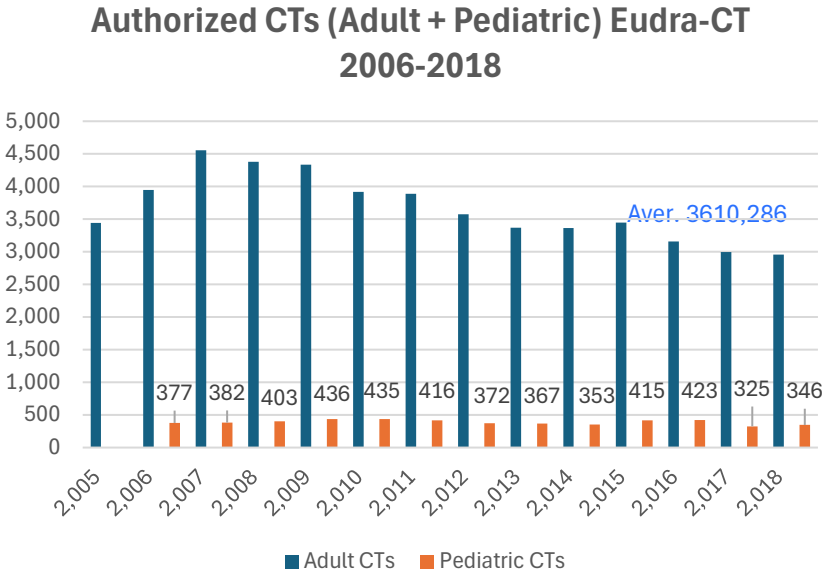
2. New Coordinating Group in March-April 2025 – Term 2025-2027

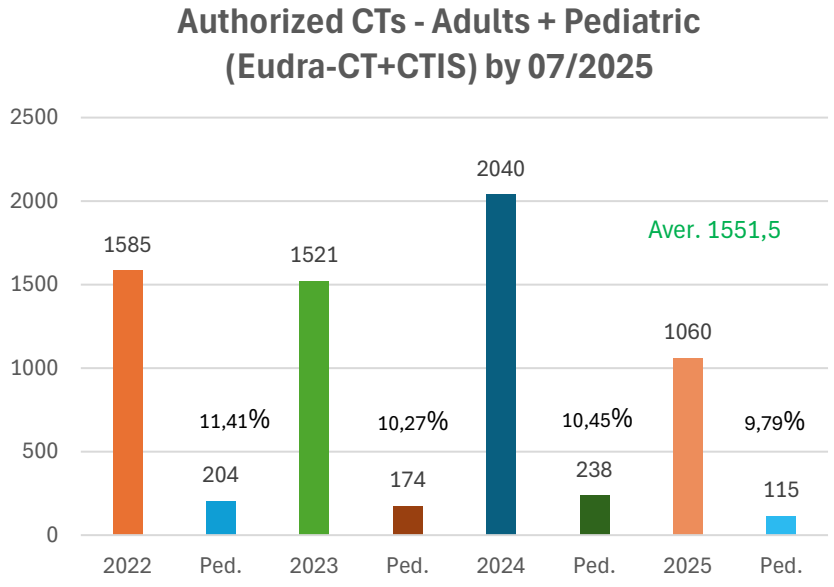
- 11 National and Specialty Networks, 4 Special Activity organizations, 2 PDCO reps., 7 observers (PDCO alternate, industry reps., non-EU networks)
- Election of new Chair (for networks) in Annual meeting 2025

3. Reflections to the EU landscape of product development and clinical trials

- EU to strengthen its competitiveness, crisis preparedness and driving innovation

Paediatric clinical trials in Europe 2006-2025





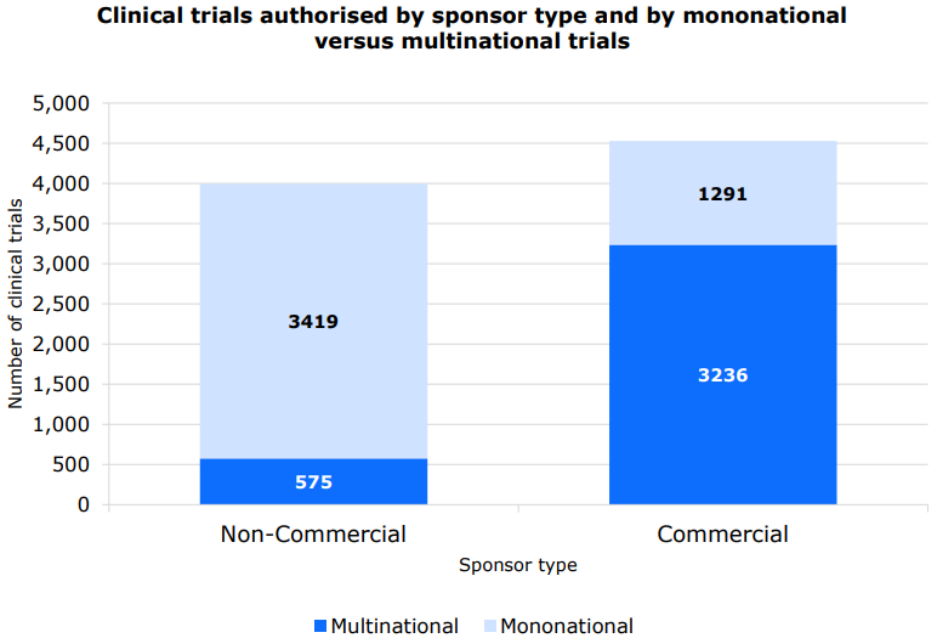
"This report has been generated from the EudraCT Data Warehouse. The information it contains is confidential and should only be distributed to members of the National Competent Authorities, the EMA and the Commission"

The CTR entered into application on 31 January 2022, starting the 3-year transition period. From 31 January 2023 all new clinical trial applications had to be submitted under CTR via CTIS. 30 January 2025 deadline for ongoing trials (under the Directive) to be transitioned to CTR.

Authorised trials 31.1.2022 – 30.1.2025

During the transitional period (3-years), a total of 8,521 initial CT applications were authorised

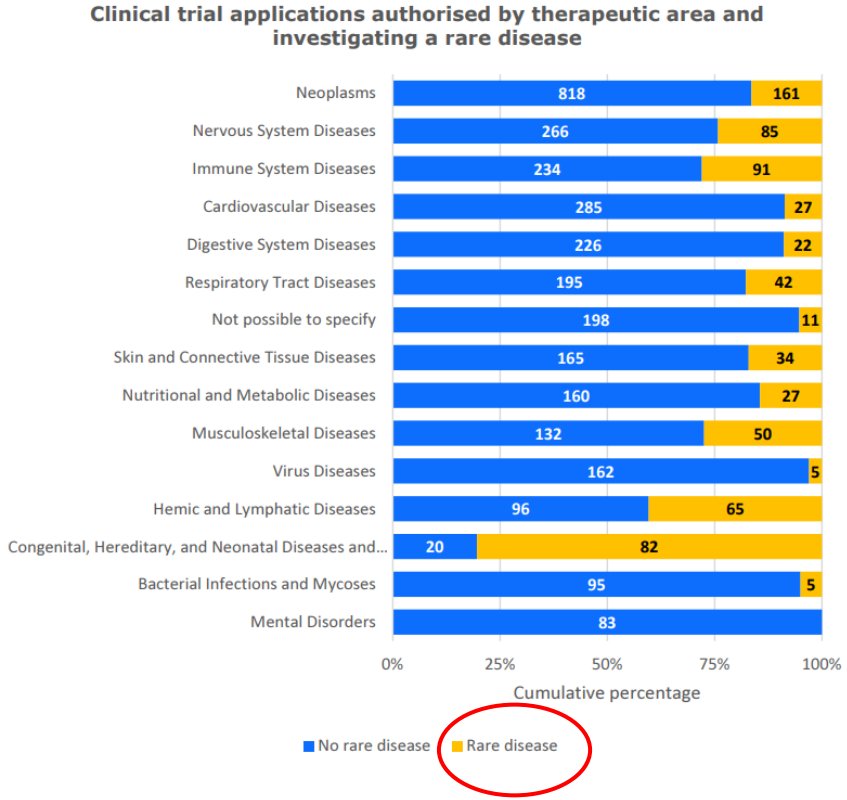
3,811 Multinational	
575 Non-Commercial	**3,236** Commercial
4,710 Mononational	
3,419 Non-Commercial	**1,291** Commercial

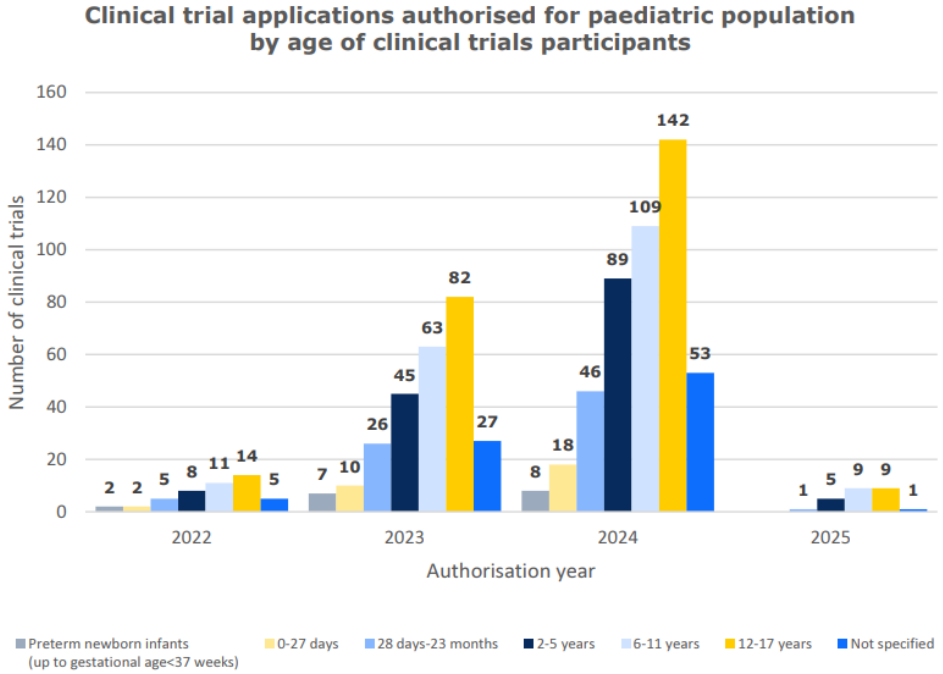


EU clinical trials during the 3-year CTR transition period

Paediatric & Rare Disease Trials 2022-2025

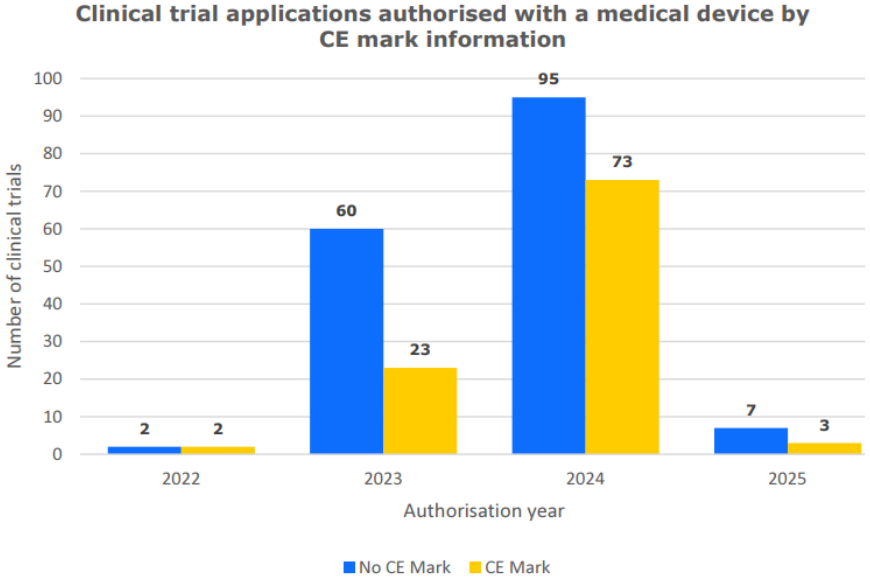
EUROPEAN MEDICINES AGENCY

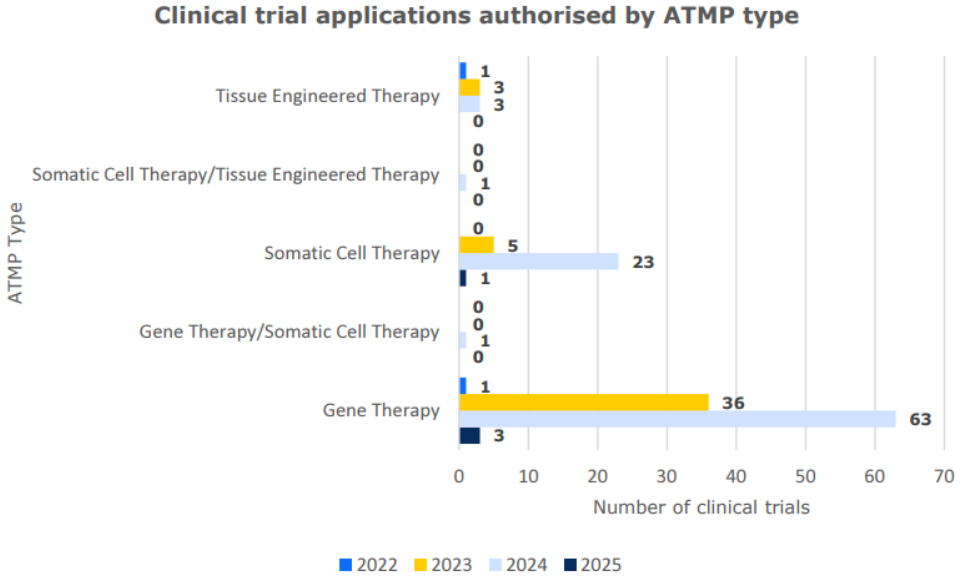




EU clinical trials during the 3-year CTR transition period

CT with MD & ATMPs 2022-2025

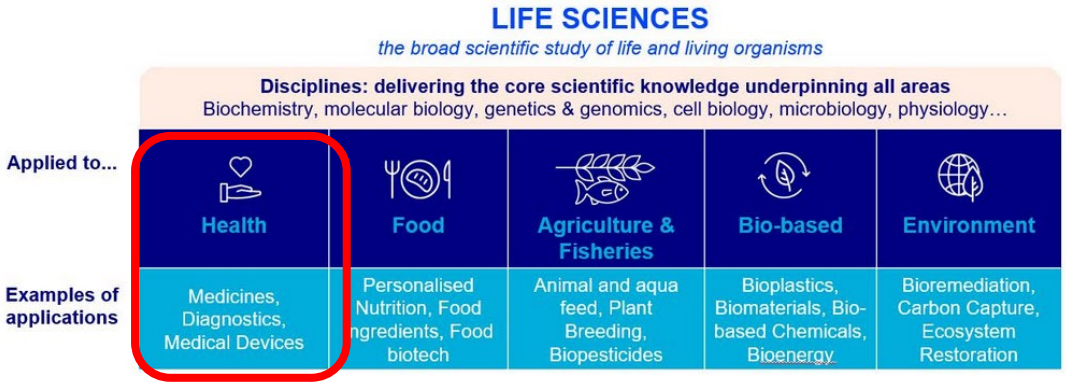




EU clinical trials during the 3-year CTR transition period

Reflections to EU Life Science Strategy 2025-2030*

EUROPEAN MEDICINES AGENCY



1. **Optimizing the R&I ecosystem -> a globally competitive life science sector**
   - Strengthened cooperation, optimized use of resources, promoting a holistic approach…
2. **Ensuring smooth and rapid market access for life science innovations**
   - Innovation friendly regulation, mobilization of private and public investments…
3. **Boosting the uptake and use of life science innovation**
   - Engage with citizens, beat disinformation & build trust, work closer with end-users…

*Strategy for European Life Sciences - Research and innovation, July 2025

EU-LEVEL REFORMS AND PROPOSALS*

EUROPEAN MEDICINES AGENCY

- **Faster authorization of new medicines via centralized MAs;**
  - EMA 180 days (old 210 days) for assessment, Commission 46 days (old 67 days) for authorization
- **New rules for the CTs of medicines of GMOs, likely to facilitate R&D in ATMPs**
- **More effective processes for combination of Med. & MDs, or in vitro diagnostics**
- **HTA Regulation to deliver faster national decisions and access to medicines**
- **EHDS Regulation to ease secondary use of health data for R&I**
- **Use of RWD to streamline patient recruitment and data collection for evidence**
- **Use of AI and machine learning; diagnostics, medicine development**
- **Working through ACT EU to support clinical trials and process innovation**
- **Facilitating multi-country CTs through European partnerships and R&I ecosystems**
- **Over EUR 10 billion EU funding annually to implement the strategy**
  - Horizon, EU4Health, Digital Europe, LIFE, Innovation Fund, Erasmus+

*The Draghi report on EU competitiveness, Part B, September 2024

Supporting various EU-level reforms and activities

EUROPEAN MEDICINES AGENCY

How to do this is practice?	Enpr-EMA support / activities?
- ACT EU	- ACT EU Workshop – methodologies Q1/2026
- MedEthics EU	- MedEthics EU – review of recommendations?
- HTA	- HTA – regulation implementation (role)?
- EHDS	- EHDS – support implementation – data use & share
- Use of RWD and AI	- Use of RWD and AI – participate initiatives?
- Participate ATMP research	- Participate ATMP research – Centres of Excellence
- Increase collaboration and cross-border activities	- Increase collaboration and cross-border activities – also cross-border trials
- Engage with public	- Increase working with PP & YPAG groups

Working Groups in alignment of EU Life Science Strategy?

EU Ped.Reg. and new medicine regulation objectives

EUROPEAN MEDICINES AGENCY

Article 44

1. The Agency shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.

2. The objectives of the European network shall be, inter alia, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population.

Article 95

European network

1. The Agency shall develop a European network of patient representatives, academics, medicines developers, investigators and centres with expertise in the performance of studies in the paediatric population.

2. The objectives of the European network shall be, inter alia, to discuss priorities in the clinical development of medicines for children, in particular in areas of unmet medical need, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population.

➔ **To coordinate** studies
➔ **To build up** scientific & admin. competences
➔ **To discuss** priorities & unmet medical needs
➔ **To avoid** duplication of trials

Enpr-EMA Main Strategic Activities

EUROPEAN MEDICINES AGENCY

PPI & YPAGs collaboration and consultation

Scientific activities

- Reg.Authority collaboration – Pediatric Cluster / EMA
- Scientific advice – by PDCO and EMA committees for protocol development
- WHO, ICH etc. collaboration
- Pre-clinical design and collaboration
- Medical Devices – EMA Advice & opinions from Expert Panels

Administrative level activities

- Prepare for new EU legislation application
- Collaborate with ACT EU & MedEthics EU
- Respond to EU initiatives and consultations
- Review of Enpr-EMA Governance documents
- Share best practices & knowledge – methodological, scientific, clinical…
- Providing publications, guidance & recommendations -> produced by Working Groups
- Enhancing International collaboration
- Increasing Enpr-EMA visibility

Clinical trial activities

- Medicine CTs
- ATMP CTs
- Combination product CTs

https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices

Enpr-EMA members - Individual networks & Experts