Update on policy development at the EU level

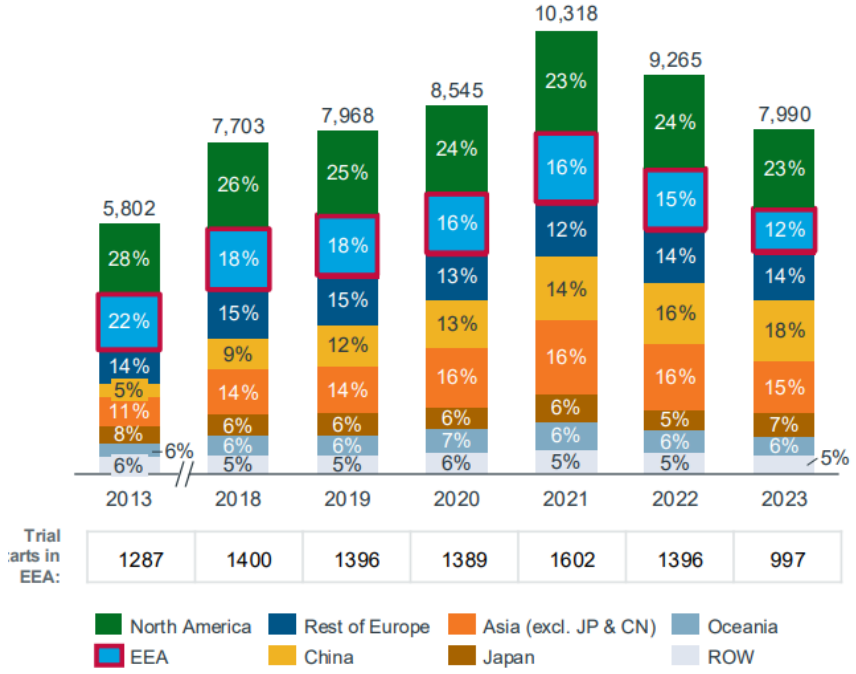
ACT EU Multi-stakeholder Platform Advisory Group

September 18, 2025

Edit Szepessy
European Commission, DG SANTE

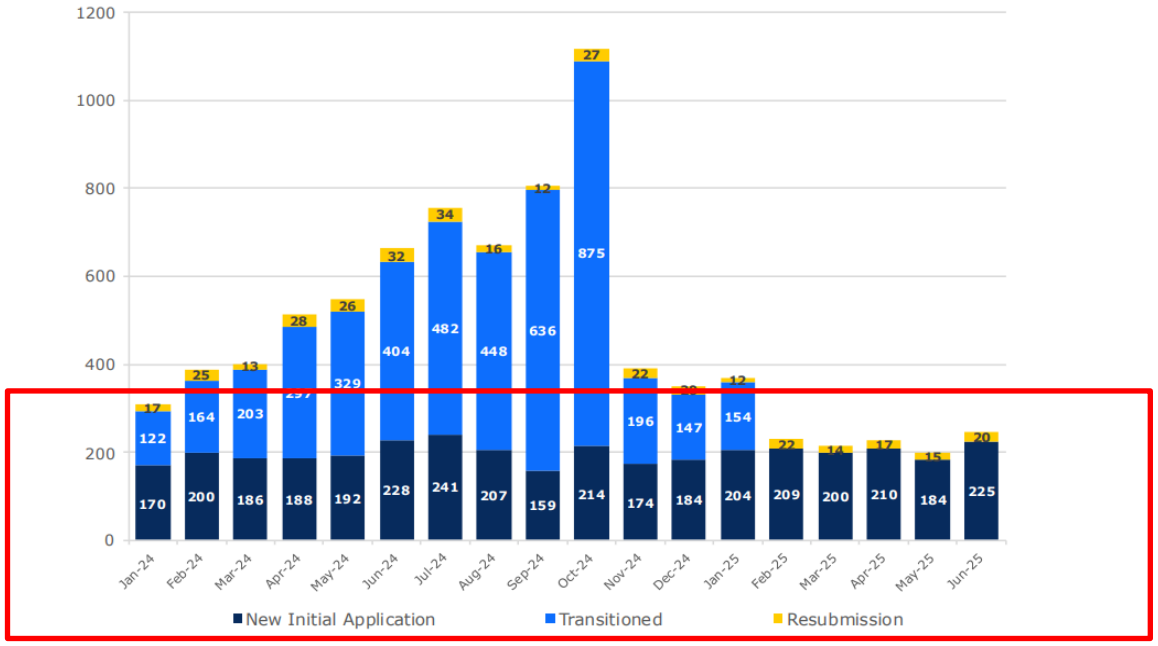
Europe's clinical trials gap (1)

Number of global commercial clinical trial starts by region (2013, 2018-2023; Phase 1-4)



EFPIA / IQVIA report

Number of clinical trial applications in CTIS 01/2024 - 06/2025

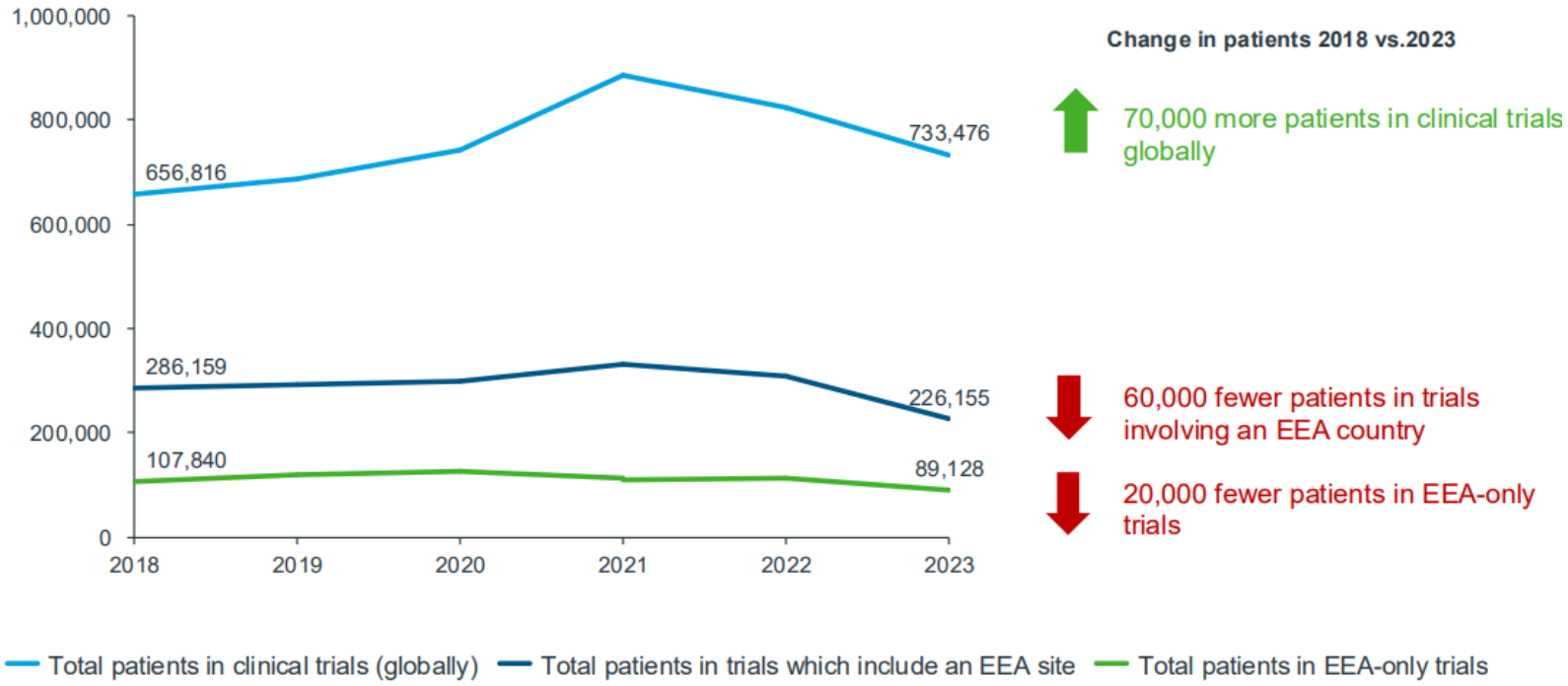


CTIS / KPI report 06/2025

- Broadly stable number of authorised, commercial clinical trials despite the application of the CTR in the EEA
- BUT: EEA's global share of commercial trials decreased from 22% (2013) to 12% (2023)

Europe's clinical trials gap (2)

Total patient numbers enrolled into commercial global clinical trials, EEA-only and EEA-included trials (2018-2023)



EFPIA / IQVIA report

The share of patients in trials with an EEA site, relative to total global clinical trial participants, declined from 43.5% in 2018 to 30% in 2023

European Commission

Biotech Act: preparatory work

General consultations:

Call for evidence: 14 May – 11 June

- 222 valid responses, **14 directly related to clinical trials**
- 148 position papers were submitted by various stakeholders, **12 directly related to clinical trials**

- **Recurrent mentioning of** fragmentation, long and unpredictable delays, duplicative requirements across clinical trials, need for regulatory streamlining and convergence across Member States

Open consultation: ongoing until 10 November

Preparatory studies for the Biotech Act

Analysis of the regulatory framework for biotechnology and biomanufacturing (GROW/SANTE/RTD)

- Assessment of regulatory scenarios through targeted surveys
- Possible policy options in the survey related to:
  - (1) **faster assessments:** shorter timelines, stronger cooperation and reliance across Member States, more streamlined ethics review
  - (2) **additional streamlining:** parallel substantial modifications, reinforced risk adaptations, low intervention trials
  - (3) **harmonised and simplified application dossier**: product based dossier, templates
  - (4) **start of recruitment**
  - (5) **harmonized legal basis for personal data collection and processing**
- Select case studies for further assessments

Preparatory studies for the Biotech Act

‘Landscape analysis’ study for the BTA (SANTE):

Assessment of the Call for Evidence (draft report) // assessment report on the open consultation still TBC

Impact assessment of scenarios for the Biotech Act (SANTE):

Provisional kick-off date early October 2025

Assessment of additional regulatory and non-regulatory options (up to 20 scenarios)

Preparatory studies

	Analysis of the regulatory framework for biotechnology and biomanufacturing	Landscape analysis study	Assessment of scenarios
OBJECTIVES	1. identify challenges/ causes/ consequences in the EU single market in value chains 2. identify areas for action in EU policies and assess their impacts.	1. Identify challenges/ opportunities in the EU 2. Overview of the market 3. Landscape of EU and national measures supporting competitiveness and innovation, their effectiveness and efficiency.	1. identify areas for action in EU policies and assess their impacts.
SCOPE	**Covering: health, agricultural (food and feed) and industrial biotech and marine solutions.** **Not covering: bioenergy.** **EU regulations** **National regulations**	**Non-regulatory policies: access to funding, support for the development, operation and coordination of biotechnology clusters, upskilling and reskilling the workforce, the use of data and AI**	**EU regulations**
SYNERGIES	**Presenting a complementary outlook of today's situation** **Assessing regulatory scenarios**	**Findings of the landscape study will inform the definition of scenarios and the baseline in the 'assessment of scenarios' study**	**Assessing non-regulatory scenarios and some selected regulatory scenarios as needed**

Biotech Act: preparatory work (2)

COM consultation with Member States:

CTAG/CTCG/MedEthicsEU workshop on 30 June and 15 October
MedEthics workshop 22 September
Additional technical workshops (*tbc*)

Simplification Task Force for CTIS

121th HMA meeting: 10-12 September: Optimising the Clinical Trials Regulation to enhance Europe's competitiveness

Informal EPSCO on 16 September: political exchange related to multinational clinical trials

ACT EU MSP meeting on 18 September: shorter timelines and product based application

Draft Council conclusions on Life Sciences Strategy by DK Presidency Biotech Act as an enabler multinational clinical trials

Thank you!