26 maart 2026

Congres Goed Gebruik Geneesmiddelen
‘De Groene Horizon voor Geneesmiddelen’

Sessie 10: Samen sterk in klinisch onderzoek: Nederland in beweging

Voorzitter: Bart Scheerder

ZonMw

Samen sterk in klinisch onderzoek:

Nederland in beweging

Congres Goed Gebruik Geneesmiddelen 2026

26 maart 2026

1931 Congrescentrum Brabanthallen

Disclosure of Interest

- **Potential conflict of interest speakers:**
  - Bart Scheerder: None
  - Laura Pioppo: None
  - Stan van Belkum: None

Dutch Clinical Research Foundation

Programma:

Introductie Programma & DCRF
– Bart Scheerder (UMCG/DCRF)

Important European Developments in Clinical Research
– Laura Pioppo (EMA)

Nationale Ontwikkelingen in Klinisch Onderzoek
– Stan van Belkum (CCMO/DCRF)

Over de Streep
– Nederland in Beweging

DCRF
Dutch Clinical Research Foundation

Dutch Clinical Research Foundation

Platform for Research Networks

Vereniging Innovatieve Geneesmiddelen

ACRON

ccmo

NVMETC

ZonMw

DCRF Dutch Clinical Research Foundation

Bestuur

ACRON
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STZ
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UMCNL
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DCRF
Dutch Clinical Research Foundation

Introductie DCRF – Doelstelling:

De Dutch Clinical Research Foundation, kortweg DCRF, is een stichting die zich ten doel heeft gesteld om medisch-wetenschappelijk onderzoek met mensen (klinisch onderzoek) te faciliteren zodat waardevolle kennis en wetenschap zo snel als mogelijk ten goede komt aan de patiënt.

DCRF
Dutch Clinical Research Foundation

Accelerating Clinical Trials in the EU (ACT EU) initiative: an update

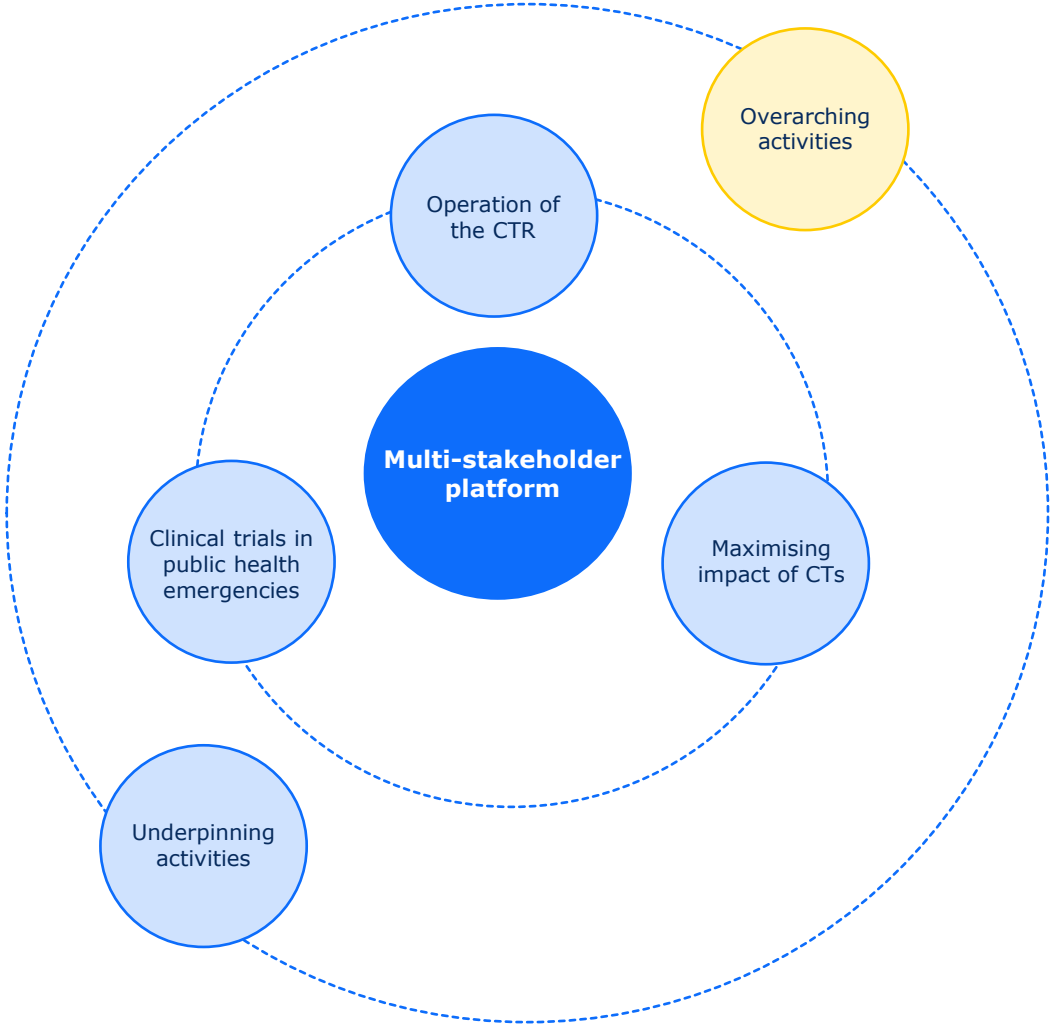
GGG conference, 23 March 2026

Laura Pioppo, ACT EU programme manager
European Medicines Agency

Accelerating Clinical Trials in the EU (ACT EU)

- A joint initiative by the European Commission, Heads of Medicines Agencies and EMA, established in 2022
- Building on the momentum of the implementation of the Clinical Trials Regulation (CTR)
- Our vision is to have **better, faster and smarter clinical trials in the EU**, creating a favourable environment for clinical research

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

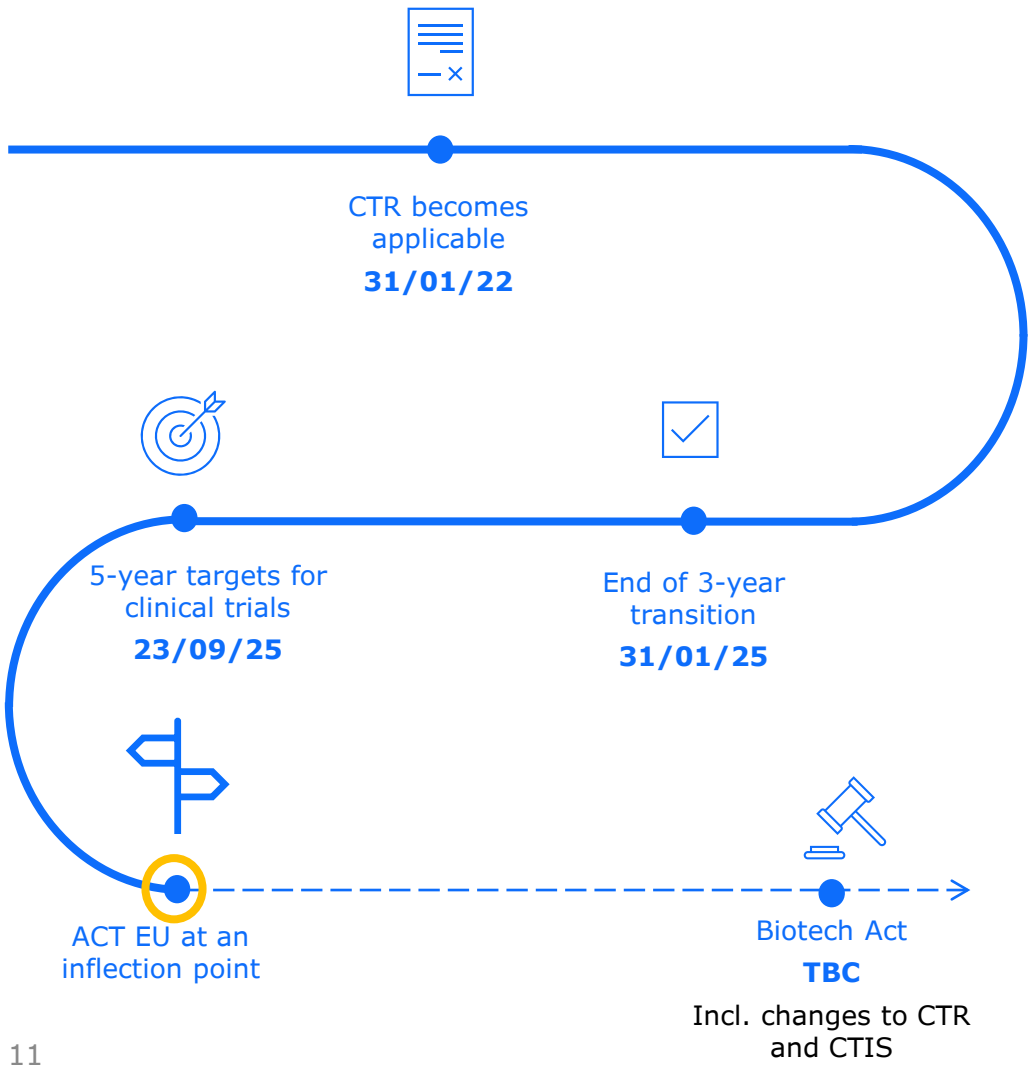
Maximising impact of clinical trials – design and conduct of excellent clinical trials:

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

Underpinning activities:

- Communication
- Clinical trials analytics
- Clinical trials training

A turning point for ACT EU



Since 2022:

- Focused on the implementation of the Clinical Trials Regulation (CTR)
- Successfully supported stakeholders in CTR transition

Now:

- The transition is over but there is still work to do, to fully reap the benefits of the CTR and ensure alignment within the regulatory network and continuous collaboration with stakeholders

Next:

- Working together to address existing & future challenges through the **revised ACT EU objectives and workplan 2026/2027**
- Optimising processes within current legal framework
- Preparing for legislative change

Monitoring the EU clinical trials environment

[New targets for clinical trials in Europe | European Medicines Agency (EMA)]

Increased attractiveness of the EU

Target: 500 more multi-national trials authorised by 2030

Faster access to treatment

Target: 66% of trials start recruitment in under 200 days from application submission

Quarterly progress tracking with publication starting April 2026

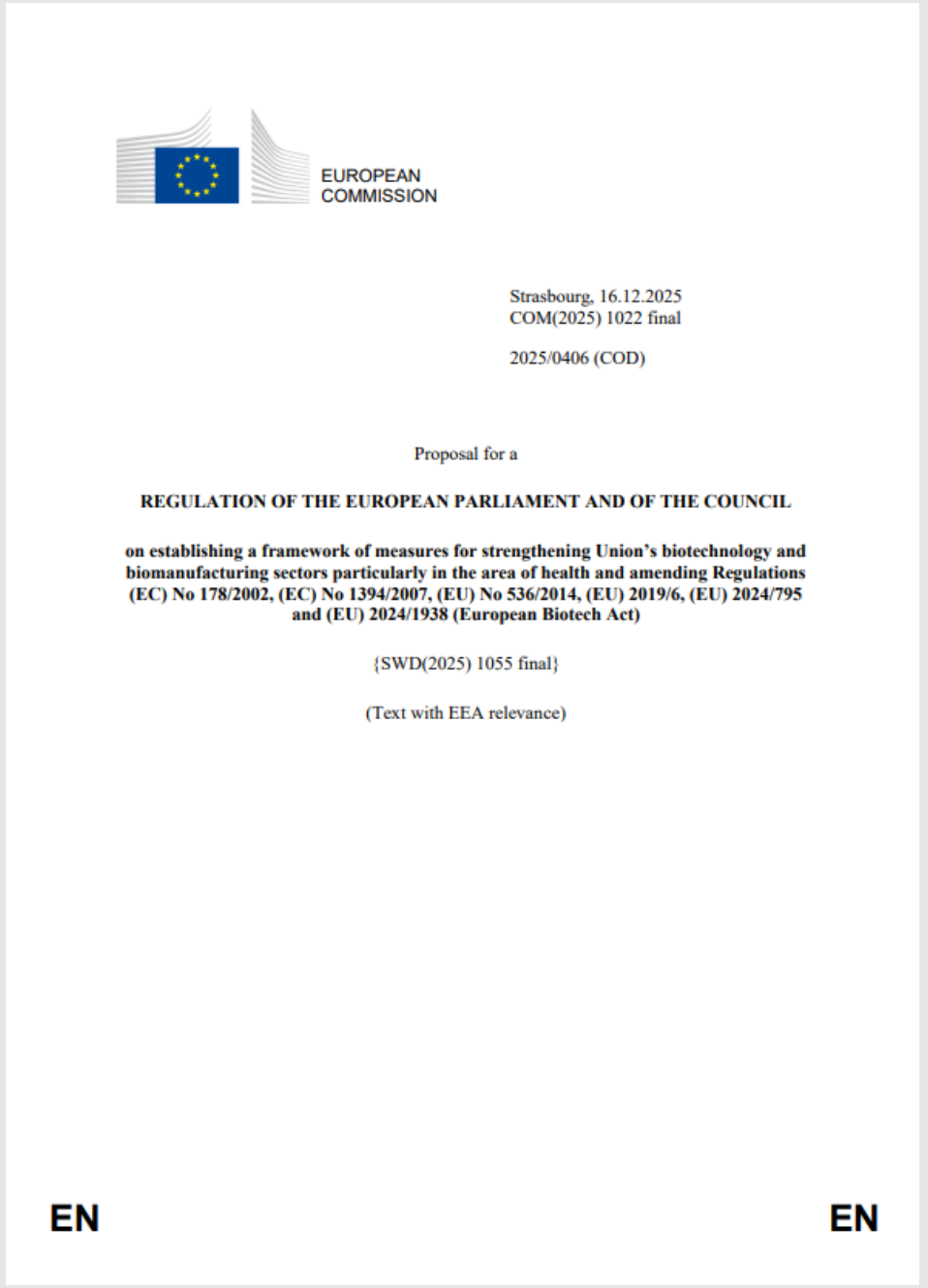
ACT EU priorities in 2026

What does the Biotech Act mean for EU clinical trials?

The new Biotech Act:

- Builds on what already works well under the CTR
- Proposes improvements to the CTR to directly address stakeholders' needs
- Aims to make authorisation of clinical trials faster, simpler and more predictable

ACT EU partners are collaborating closely to prepare for a smooth transition to the new legislative framework



EUROPEAN COMMISSION

Strasbourg, 16.12.2025
COM(2025) 1022 final

2025/0406 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

{SWD(2025) 1055 final}

(Text with EEA relevance)

EN **EN**

Support to non-commercial sponsors

Objectives

- More multinational clinical trials by non-commercial sponsors (NCS) generating **high quality scientific evidence**

Action plan in progress

- A live interactive map of national initiatives on the ACT EU website (*signposting*)
- Optimisation of regulatory helpdesk offering CTR-CTIS support;
- National webinars on fostering clinical research done by NCS
- Exploratory analysis on funding to support academic sponsors to conduct multi-national clinical trials published on ACT EU website
- Involvement of academia in the MSP Advisory Group

Clinical trials analytics

Delivered:

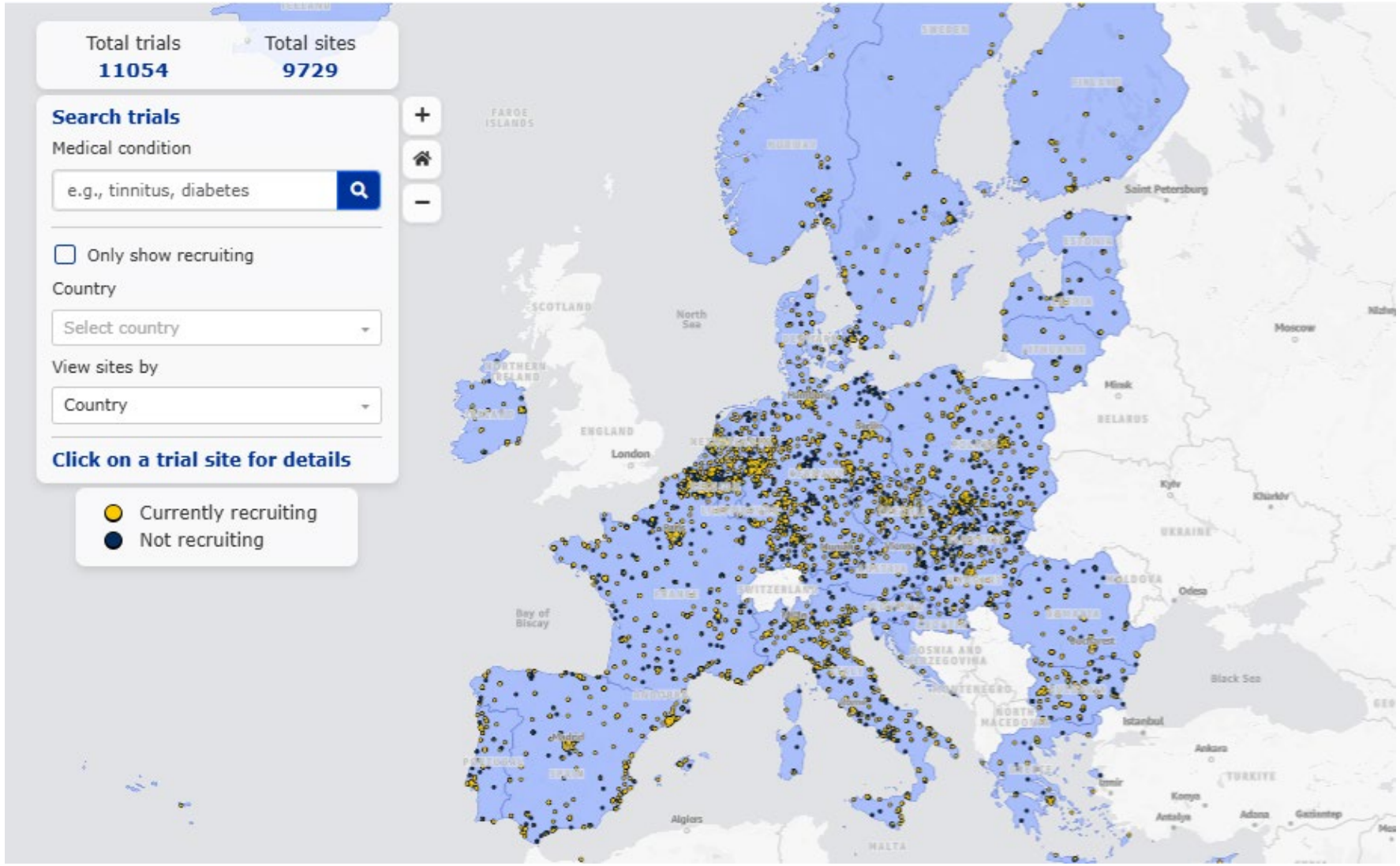
- Launch of Trial Map in 2025 with search available in EU/EEA languages; dedicated demo & materials available on the event page
- Launch of network dashboards to monitor EU clinical trials

Upcoming:

- Publication on research priorities following 2024 workshop (report)
- Publication on clinical trials trends based on EU CTR* and CTIS data
- Establishment of a network of CT data experts (EMA/MSs/EC) looking at analysis of CT data
- Future releases of the Trial Map

**EU Clinical Trials Register (EU CTR)*

Finding clinical trials on the Trial Map



Search for clinical trials – CTIS website

- **Trial Map** developed to empower patients and healthcare professionals
- Integrated with CTIS public portal
- Easy access to information on **more than 10,000 clinical trials** by geographical region and disease area
- Search now available in official EU/EEA languages

Pilots on scientific and regulatory advice

Pilot I: Scientific Advice Working Party (SAWP)-Clinical Trials Coordination Group (CTCG)

14 applications received:
- ✓ 11 concluded
- ⌛ 3 ongoing

Pilot II: Pre-CTA (clinical trial application) advice from CTCG

22 applications received:
- ✓ 18 concluded
- ⌛ 2 ongoing
- ✗ 2 rejected

- Launched by ACT EU in June 2024
- 36 applications received so far
- Interim report published, with very positive feedback from applicants
- Currently exploring if the pilots should be a permanent offering

Clinical trials training

Delivered in 2025:

- Survey of 400 stakeholders to identify training needs of academia & SMEs
- Report of training needs of academia & SMEs published on ACT EU website, outlining key needs, potential gaps and challenges, and suggesting ways to address them

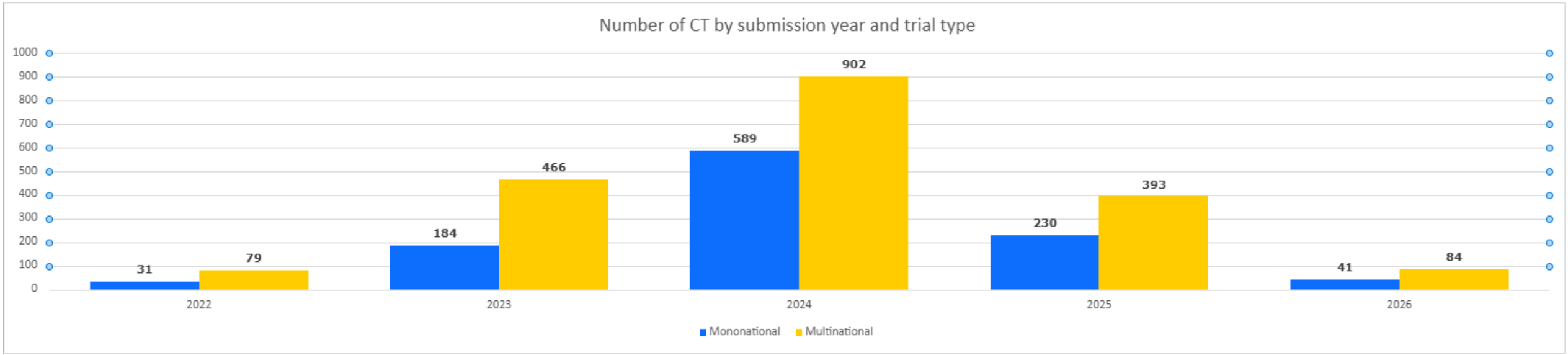
Upcoming:

- Mapping and signposting of available clinical trials trainings
- Contribute to the WHO global action plan on training
- Develop additional trainings covering the main areas identified in the report

Support for clinical trials in public health emergencies (PHE)

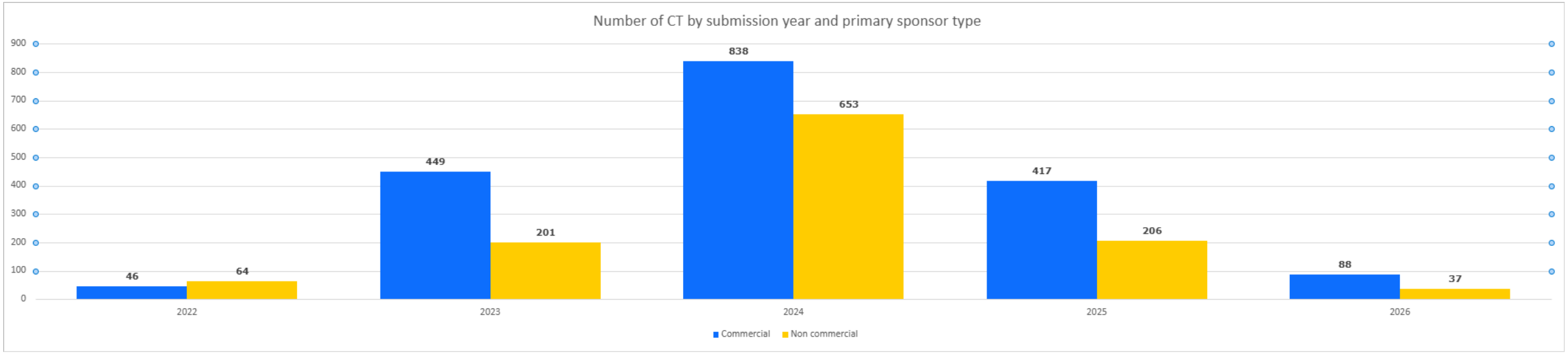
- ACT EU has published a draft guidance document on the conduct of clinical trials in public health emergencies, open for **consultation until 30 April 2026**
- ACT EU has also established a PHE ethics advisory group that joined EMA's Emergency Task Force in providing scientific advice
- Improved advice, with scientific and ethical input, improves clinical trial applications, speeding up authorisation for medicines targeting public health threats

CTs conducted in the Netherlands

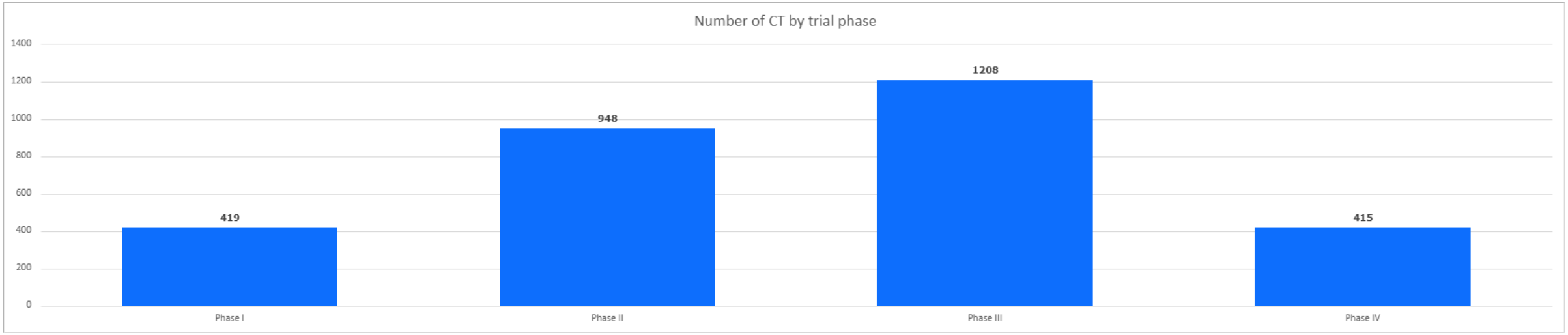


Includes transitional trials

Clinical trials conducted in the Netherlands



Clinical trials conducted in the Netherlands



Looking ahead

- Workshop on contractual agreements, 16 April 2026
- Public consultation of the guidance on conduct of clinical trials in public health emergencies
- Workshop with Enpr-EMA, May 2026
- Publication of revised ACT EU objectives and workplan 2026/2027, May 2026
- Revision of mandate and composition of the ACT EU MSP advisory group, Q3 2026
- Annual meeting of the Multistakeholders platform, Q3 2026

How to stay informed

Subscribe
to the Clinical Trials Highlights newsletter

Follow
the ACT EU website
for updates

Contact
the ACT EU mailbox

Thank you

ACTEU@ema.europa.eu

Centrale Commissie Mensgebonden Onderzoek

CCMO: NL ontwikkelingen

Centrale Commissie Mensgebonden Onderzoek

~~Committee on Research involving Human Subjects~~

Dutch National Committee for Human Research

DATUM EN VERSIE
MAART 2026


BRESSER
Junior


JEANNEKE SCHOLTENS
DE TOEKOMST IS FANTASTISCH
Leer ruimer denken in vier stappen
bot uitgevers


PRECLINICAL
PHASE 0
PHASE I
PHASE II
PHASE III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Is dit jouw eerste GGG-congres?

Kende jij de DCRF al vóór vandaag?

Wie zijn jullie?

Heb jij zelf ooit als onderzoeksdeelnemer meegedaan aan klinisch onderzoek?

Als we niet snel in actie komen, verliest Nederland terrein in klinisch onderzoek.

Wie moet de grootste knelpunten in klinisch onderzoek oplossen: de overheid of het veld?

De DCRF zou richtinggevender en sturender moeten zijn voor het veld.

Een ziekenhuis dat meedoet aan een multicenter studie moet uiterlijk binnen 60 dagen na METC-beoordeling en definitief contract startklaar zijn.

Bij multicenter onderzoek zou één landelijk modelcontract en één landelijke budgetsystematiek het uitgangspunt moeten zijn, ook als instellingen daarmee lokale onderhandelingsruimte verliezen.

Nederland moet bij klinisch onderzoek minder polderen en vaker kiezen voor landelijke standaardisatie, ook als niet iedereen zich daar direct in kan vinden.

In veel klinisch onderzoek wordt de patiënt nog steeds eerder gezien als inclusiedoel dan als partner.

Als patiëntbetrokkenheid het onderzoek aantoonbaar beter maakt, maar ook trager of duurder, dan moet de betrokkenheid toch zwaarder wegen.

Klinisch onderzoek moet in ieder deelnemend ziekenhuis worden gezien als kerntaak en niet als extra activiteit naast de zorg.

Risicomijdend gedrag van bestuurders en ondersteunende afdelingen vertraagt klinisch onderzoek in Nederland meer dan wet- en regelgeving doen.

Als Nederland echt koploper wil blijven in klinisch onderzoek, moeten sommige lokale procedures verdwijnen.

Nederland praat al jaren over samenwerking in klinisch onderzoek, maar zonder meer verplichting en standaardisatie verandert er te weinig.


THANKS
FOR JOINING US