

CCMO

Centrale Commissie Mensgebonden Onderzoek Dutch Committee for Human Research

Sipko Müller
Algemeen Secretaris / Directeur CCMO

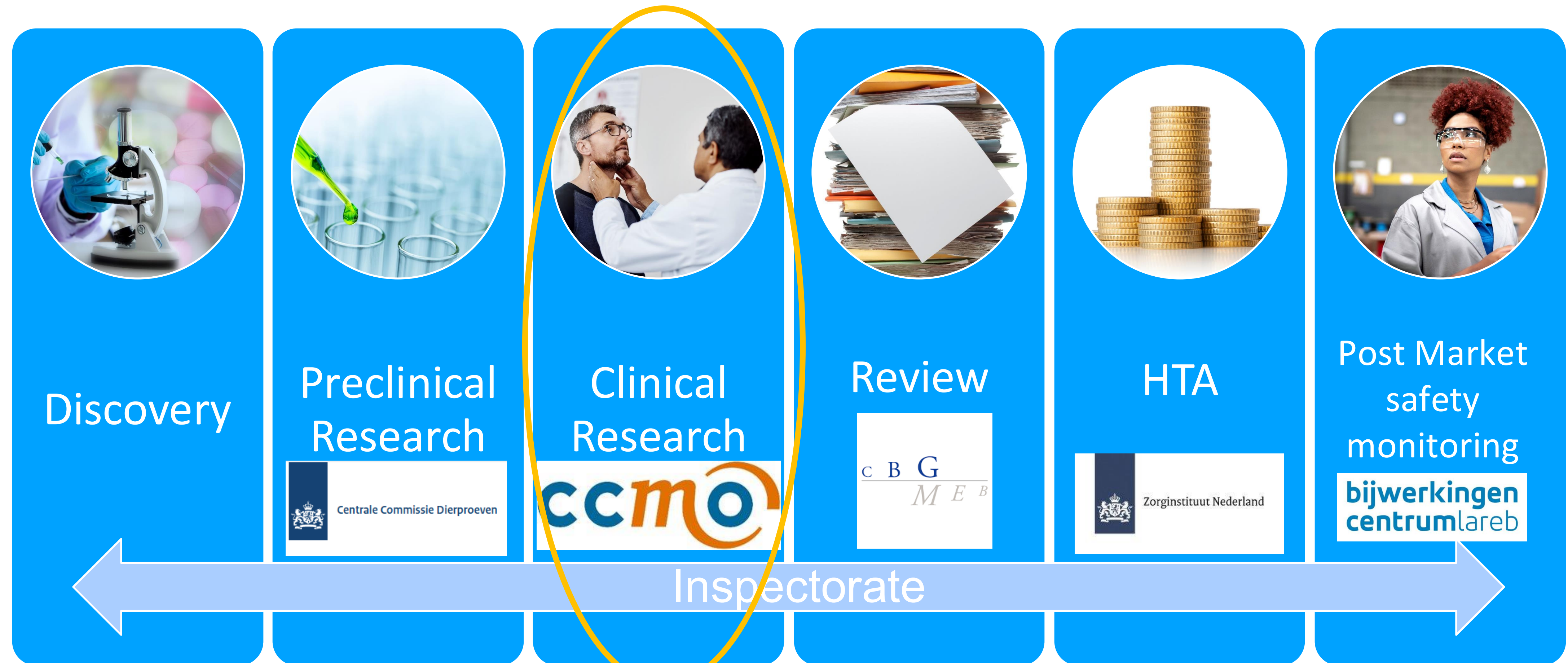
Disclosure of speaker's interests

- Sipko Mülder
 - Algemeen Secretaris / Directeur CCMO
 - October 2026
-
- **(Potential) conflict of interest : NONE**
 - **Potentially relevant company relationships in connection with event : NONE**



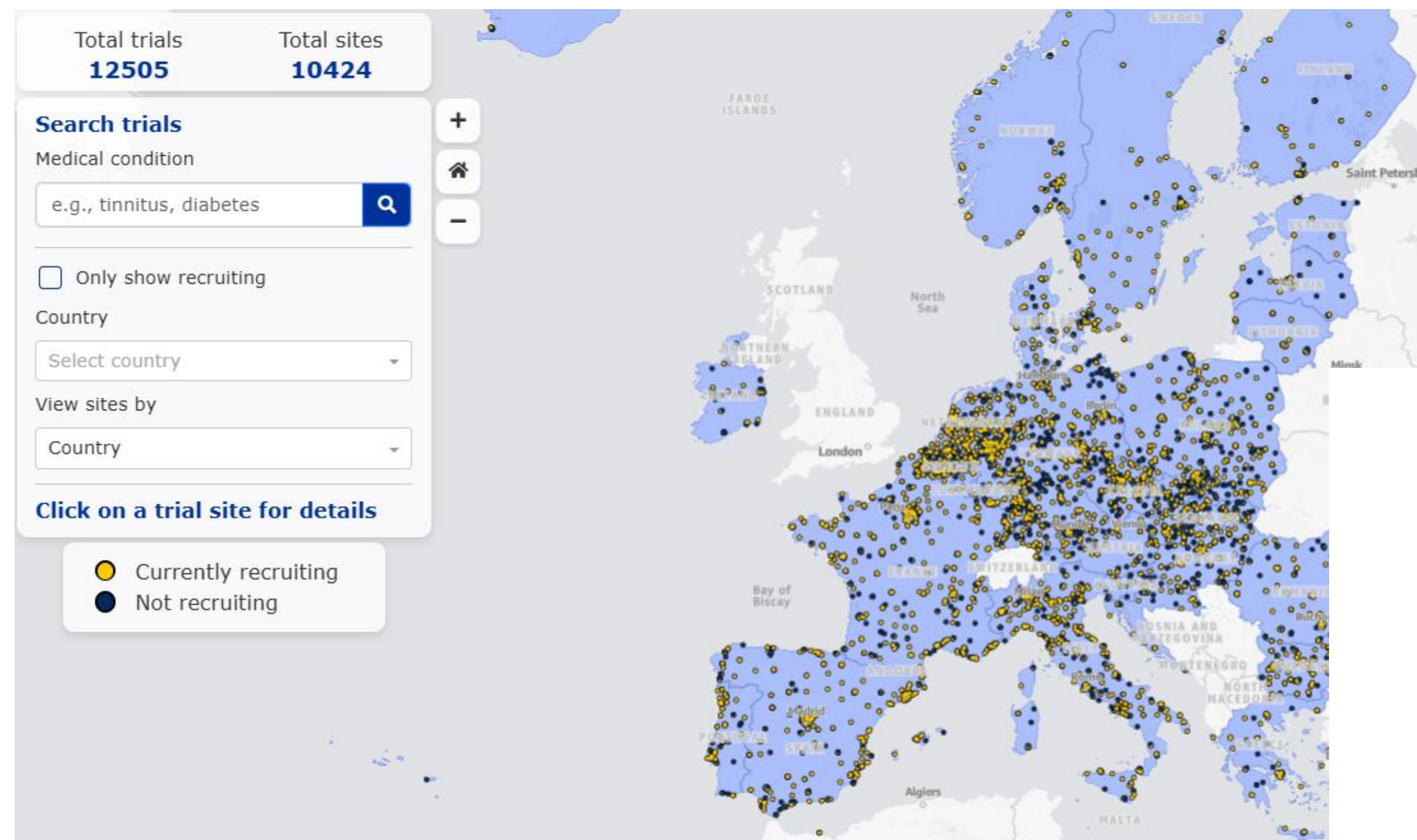
Dutch Committee for Human Research
Bezuidenhoutseweg 30 Den Haag

Drug Development Process and Regulatory Authorities in the Netherlands



Inspectie Gezondheidszorg en Jeugd
Ministerie van Volksgezondheid,
Welzijn en Sport

European Landscape



Number of ongoing clinical trials (CTR) in Europe at 29 September 2026
[Search for clinical trials - EMA](#)

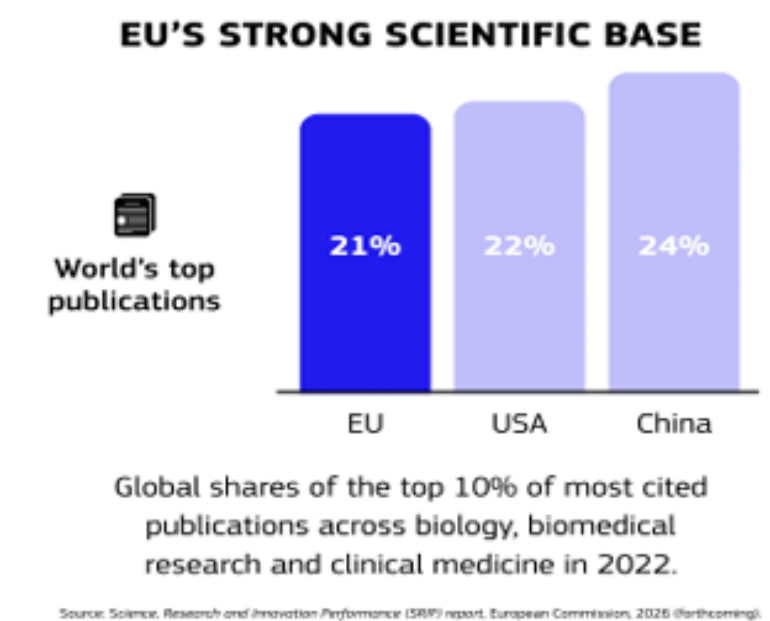


Figure 1: Top tier life science publications of the EU compared to the USA and China
[ec1475b7-e3f9-409e-b927-fc7e69306a8c_en](#)

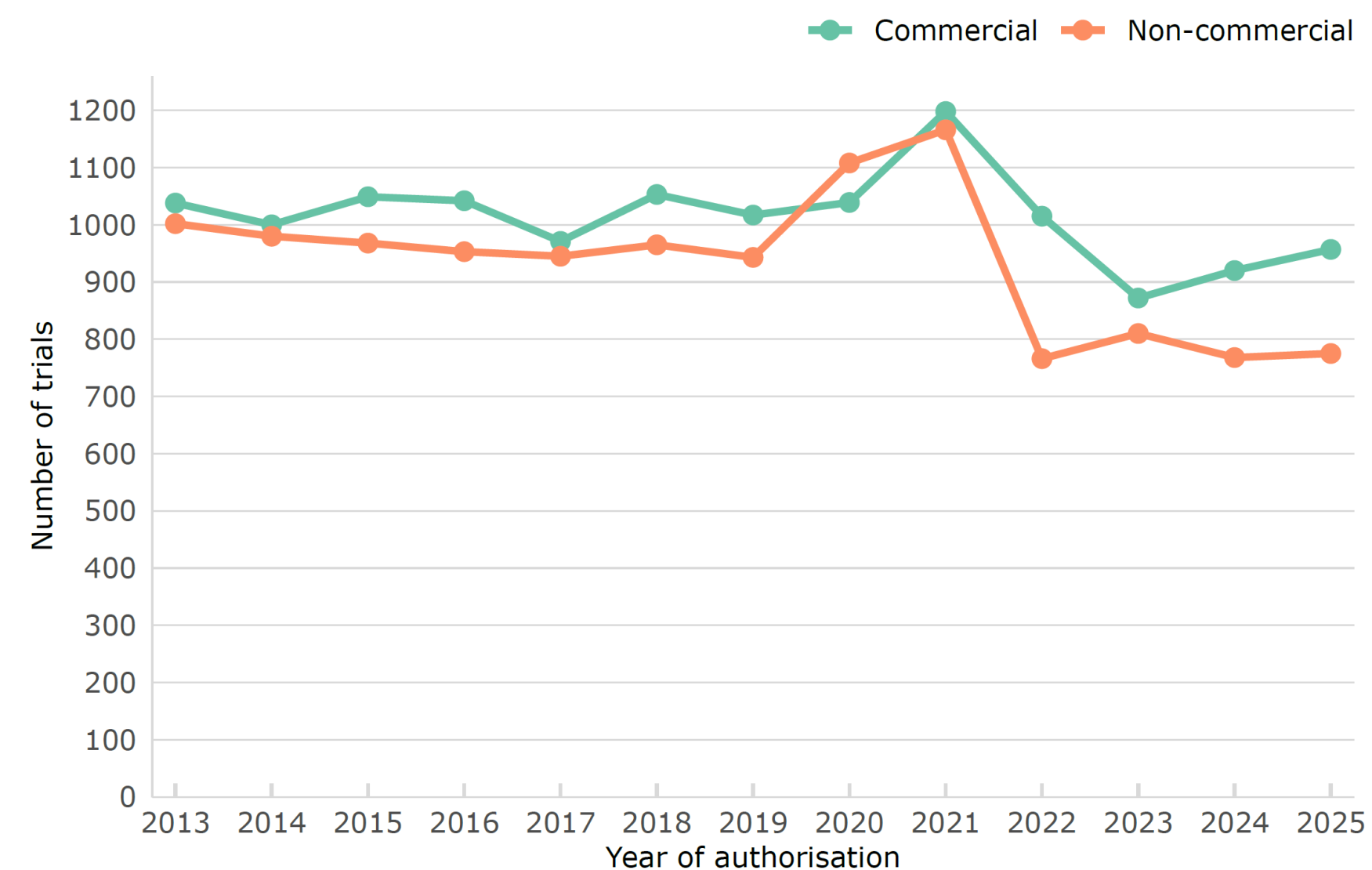
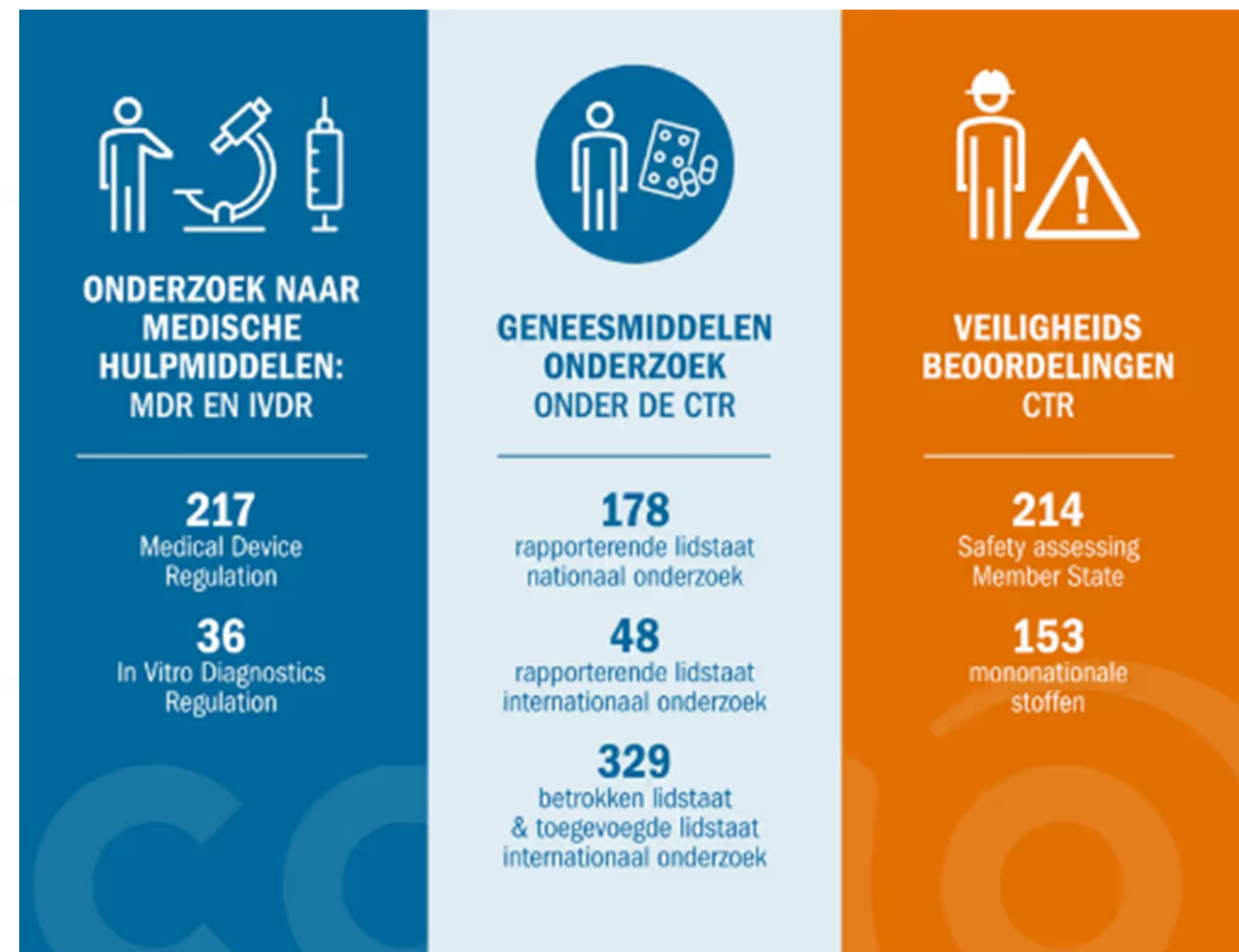
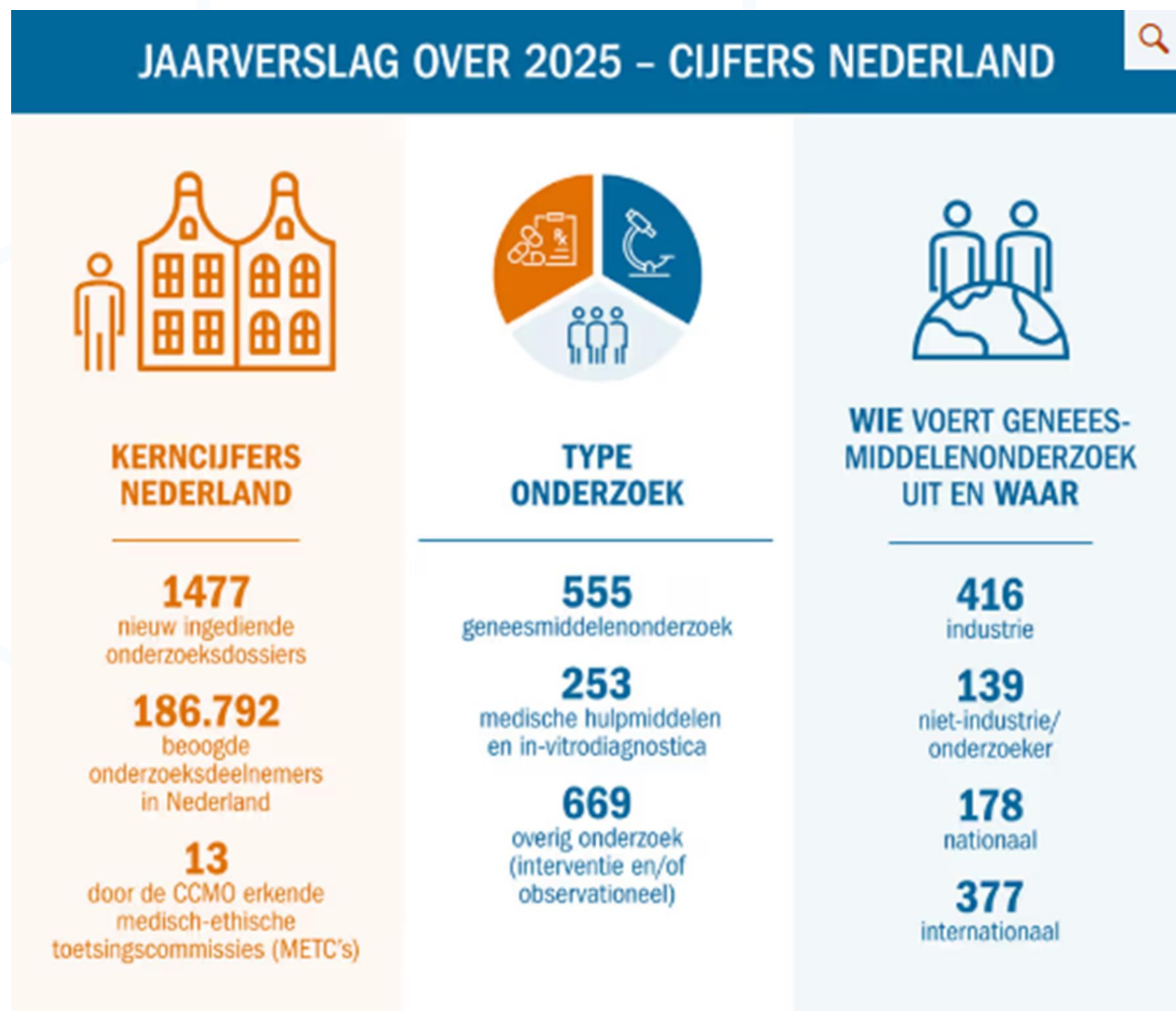


Fig. 4: Annual number of authorised clinical trials in the EU/EEA per sponsor type, 2013–2025, excluding adult phase I trials. Data exclude trials conducted exclusively in the UK and adult phase I trials.

[Clinical trials on medicinal products in the EU/EEA, 2013–2025: a cross-sectional analysis of CTIS and EudraCT data - ScienceDirect](#)

Numbers clinical trial in the NL 2025





Mission

The CCMO ensures that medical research involving humans in the Netherlands is carefully reviewed in advance. This protects participants and helps research contribute to better care.

CCMO

**6 April 1999 – Medical Research Involving Human Subjects Act (WMO)
Establishment of the Central Committee on Research Involving Human Subjects (CCMO)**



Els Borst

Applicable Laws



Legislation

- Clinical Trials Regulation (CTR) → medicines
- Medical Device Regulation (MDR)
- Substances of Human Origin (SoHO)
- Dutch Medical Research with Human Subjects Law (WMO)
- Embryo Law

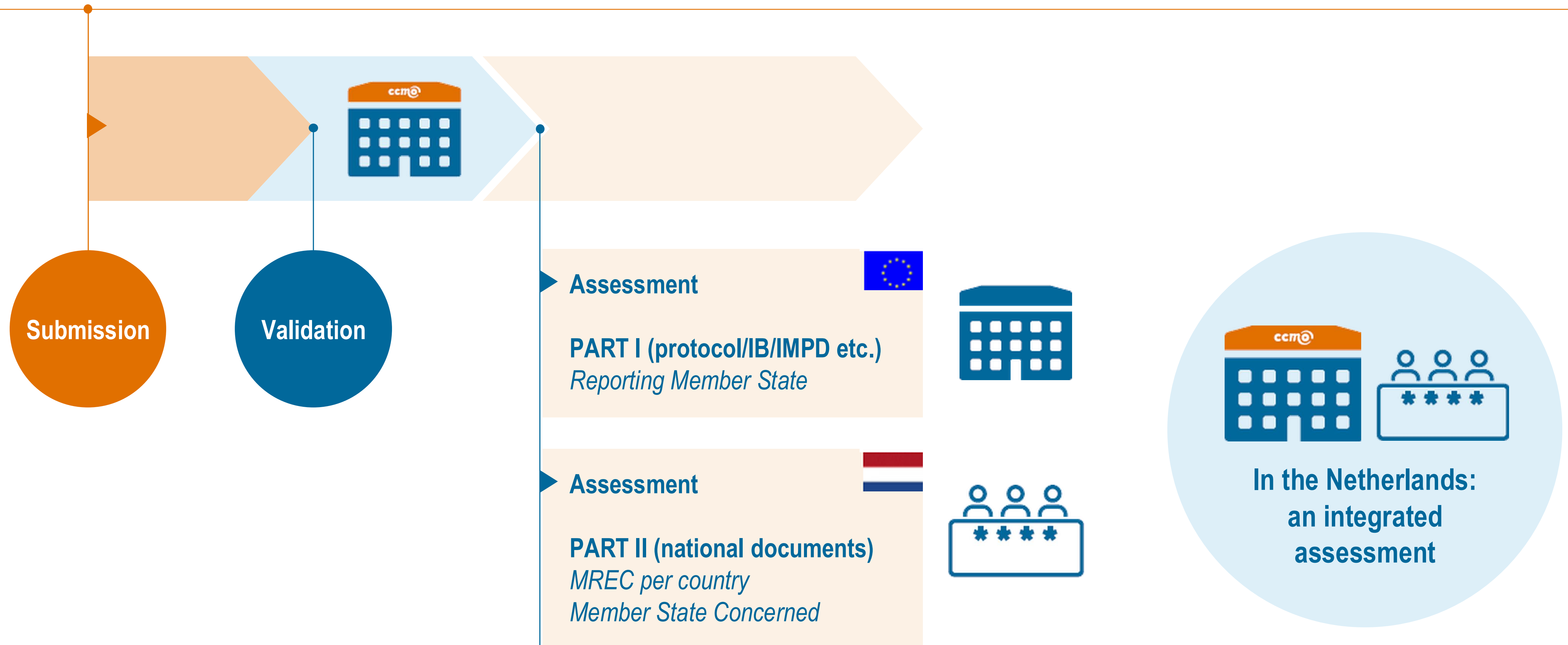


Scope of medical ethical review

- Medicines
- Devices
- Diagnostics
- Other research (comparison of care, new surgical methods, large-scale health surveys, etc.)

Assessment of CTR Studies in the Netherlands

ASSESSMENT OF CLINICAL TRIALS



Overseeing the operations of the accredited medical research ethics committees (MRECs)

10 METC's

- ▶ METC NedMec+ (Amsterdam, Utrecht)
- METC LDD (Leiden)
- METC UMCG (Groningen)
- Stichting BEBO (Assen)
- METC azM/UM (Maastricht)
- METC Erasmus (Rotterdam)
- METC Zuyd-Máx (Veldhoven, Geleen)
- METC Oost-Nederland (Nijmegen)
- MEC-U (Nieuwegein)
- CCMO (Den Haag)**



What is the problem with the current review system?

- **Lack of harmonisation:** Similar studies may be assessed differently by different MRECs. This creates uncertainty and unpredictability for researchers.
- **High administrative burden:** Submitting and amending research dossiers requires significant time and resources.
- **Insufficient proportionality:** The level of review is not always perceived as proportionate to the risks associated with the research. In particular, low-risk studies are considered to be subject to disproportionate review requirements.
- **Barriers to research:** The length and complexity of the review process can hinder research, including innovative and international studies.

Reviews in the Future (Toekomst van toetsing)

A package of measures focusing on:

- Compliance with legal requirements
- Greater harmonisation within the review system and increased predictability of the process
- Greater efficiency and shorter review timelines
- Clear and optimal allocation of responsibilities and roles between the CCMO and MRECs
- Sound financial management
- Mergers of MRECs

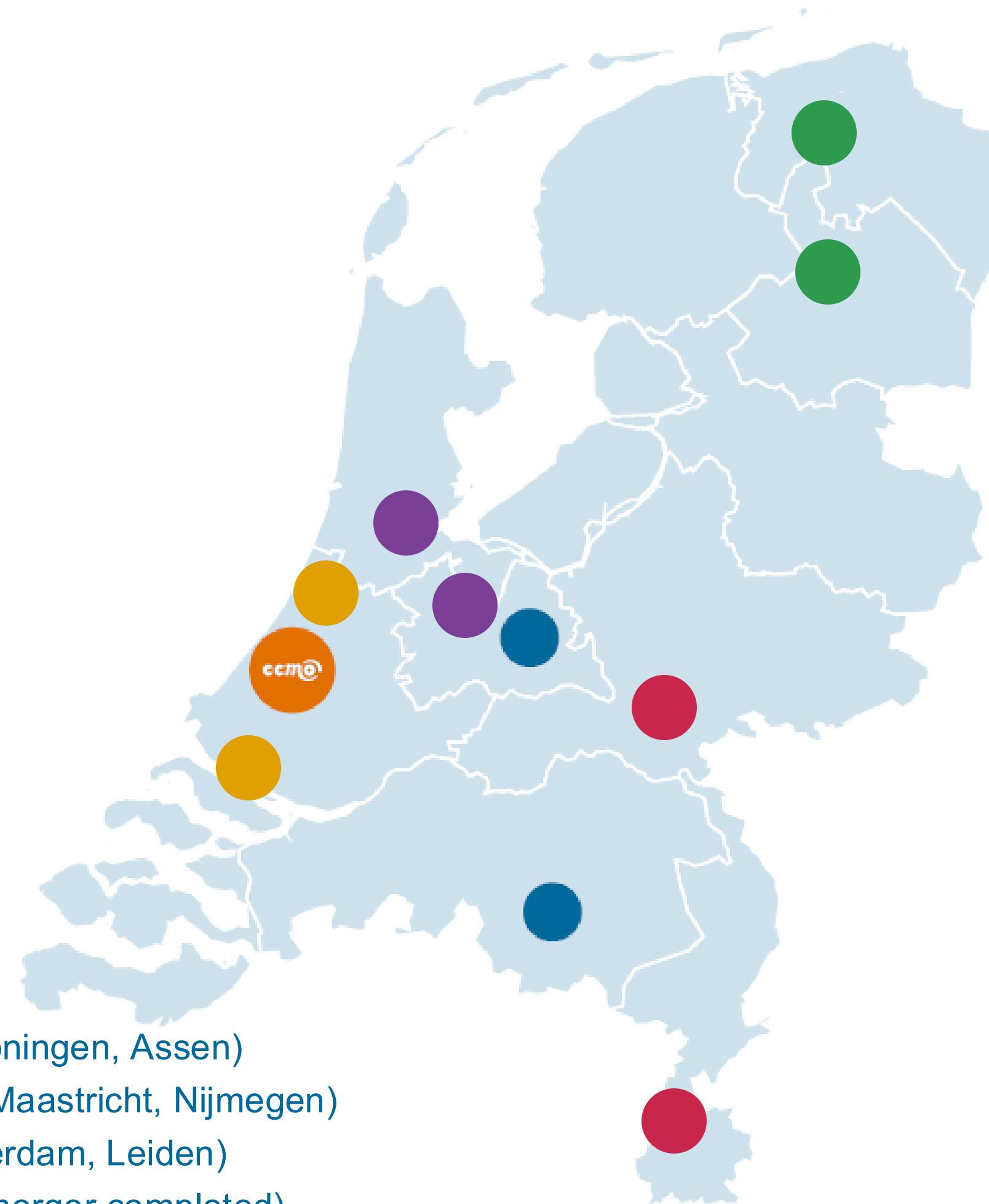
Overseeing the operations of the accredited medical research ethics committees (MRECs)

10 METC's

- ▶ METC NedMec+ (Amsterdam, Utrecht)
- METC LDD (Leiden)
- METC UMCG (Groningen)
- Stichting BEBO (Assen)
- METC azM/UM (Maastricht)
- METC Erasmus (Rotterdam)
- METC Zuyd-Máx (Veldhoven, Geleen)
- METC Oost-Nederland (Nijmegen)
- MEC-U (Nieuwegein)
- CCMO (Den Haag)**

Fusies

- METC UMCG + Stichting BEBO (Groningen, Assen)
- METC azM/UM + METC Oost-Nederland (Maastricht, Nijmegen)
- METC Erasmus + METC LDD (Rotterdam, Leiden)
- METC NedMec+ (Amsterdam, Utrecht; merger completed)



Aim – new Information Sheet Research Participant

- **Accessible** and **inclusive** information on medical scientific research.
- Informed decision making for potential participation with equal opportunities and rights to participate
- Harmonize & simplify



Result: new template

55% reduction of words: 4639 -> 2085 words

Elimination duplicates

Shorter sentences

Rewrite sections (insurance, data)

General information -> website CCMO

All text: language proficiency level B1

tested by multiple language ambassadors

Cover page!!!



IRP Template: FINAL Version - ~~EMBARGO~~ - English translation
Date: 19 March 2026

In short: Information about taking part in research
Complete: Clear title of the research

 **What are we asking you?**

- We are asking if you are willing to take part in research.
- Read the information sheet carefully and ask any questions you may have.
- If you wish to take part, you can complete the consent form at the end of the sheet.

 **Reason for this research**

- This research looks at how [briefly state the reason, as also indicated in the information sheet].

 **How does participation work?**

- The research lasts [X].
- You will come [Y] times to [Institution/ hospital] for the research study.
- [Type of measurements/tests] will be carried out.

 **What are the side effects and risks?**

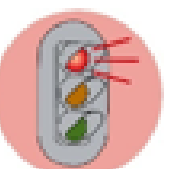
- These are the three main side effects:
- [...]
- See Appendix B for more information about side effects.

 **What happens to your data and <if applicable> bodily material?**

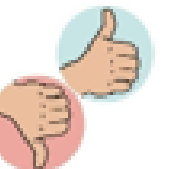
- The researchers store your data securely.
- Appendix C explains how the researchers do this.
- The researchers handle your data securely.

 **About insurance, reimbursements and compensation**

- You will receive [no reimbursement/ X] for taking part in the research.
- <if applicable> You will be reimbursed for travel and parking costs.
- <if applicable> We have arranged [insurance cover] for you for participating in the research.

 **About stopping your participation**

- [The research ends after [X months/ years]]
- You can stop your participation in the research study at any time.

 **What are the benefits and disadvantages?**

- By taking part in this research, you help us learn more about how [X] can be treated.
- See Appendix B for more information about complaints, and the benefits and disadvantages of the research.

Study code: [XXX], version [nr.] Page 4 of 38

Political context: Biotechnology is a hot and rapidly evolving field.

De Nationale Technologiestrategie

Bouwstenen voor strategisch technologiebeleid



Kabinetsvisie op
Biotechnologie
2025 - 2040



RAPPORT WENNINK

**DE ROUTE NAAR
TOEKOMSTIGE WELVAART**

Een sterk Nederland in een relevant Europa

The Draghi and Wennink reports



The Future of European Competitiveness: Mario Draghi 2024:

“The innovative pharmaceutical industry is a critical pillar of the European economy, yet its position as a global leader is precarious as investors increasingly look elsewhere.”



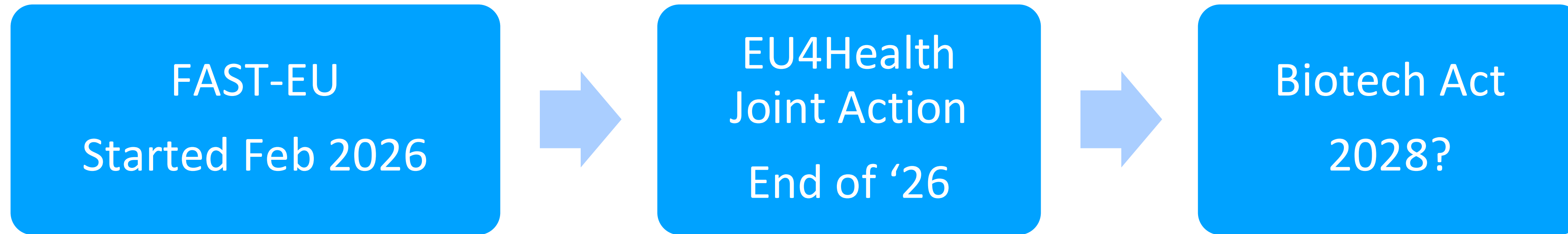
Investing in the earning capacity of the Netherlands: Peter Wennink 2025:

“Life sciences and biotechnology are crucial for the Netherlands’ future earning capacity and for maintaining a sustainable healthcare system.”

EU Biotech Act

- Proposal by European Commission from Dec 2025
- Extensive package of measures to strengthen European Biotech sector
- Affects much existing legislation, including EU Clinical Trials Regulation
- Implementation date unknown, rough estimate first half of 2028

Applying accelerated timelines in the meantime



FAST-EU: limited pilot using the BTA timeline

- 2-4 trials per month – only multinational trials, prioritised by impact
- Almost all MS participate, in NL all MRECs participate
- Monthly slot to submit expression of interest. Sponsor Guide: [CTCG website](#)



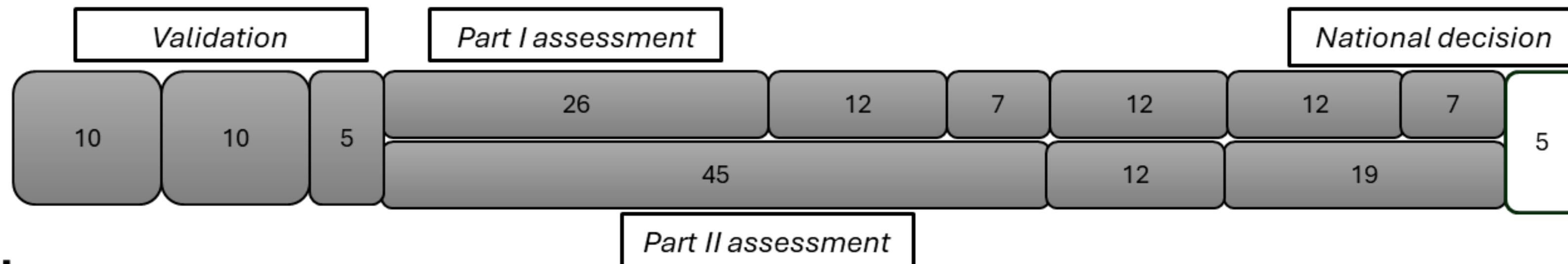
EU4Health Joint Action:

EU funding to apply BTA timeline on a larger scale, and to prepare for BTA implementation

- Expected to start end of 2026, replaces FAST-EU
- NL: CCMO and all MRECs

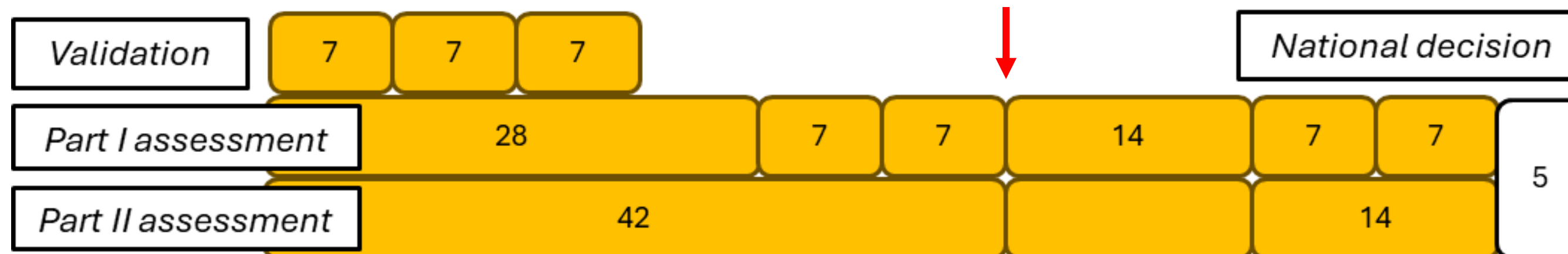
FAST-EU: shorter timelines, same standards

Today – sequential validation and assessment



~ 113 days

FAST-EU

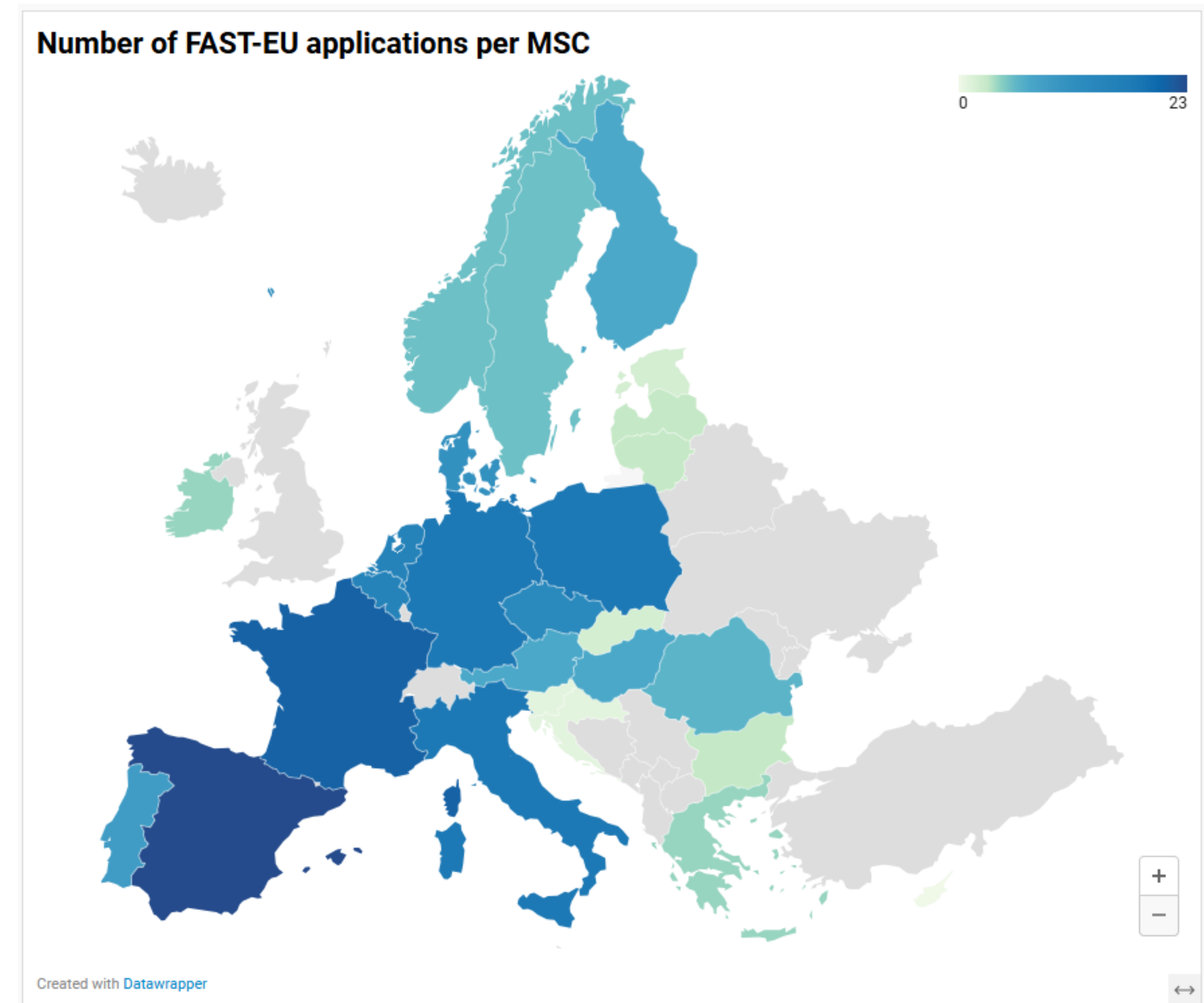


70 + 5 days

- Predictable timelines
- Validation and assessment run in parallel
- Shorter assessment time for authorities
- Longer response time for applicants (requires CTIS update)
- Same scientific and ethical standards

Trials going in FAST-EU*

- **125** expressions of interest
→ 15-20 per month
- **30** procedures selected
→ 4 per round
- **19** RMS countries and **26** sponsors
- Average of **7.4 MSCs per trial (2-22)**
- All development phases, commercial and non-commercial sponsors, diverse products, paediatric trials (4) and orphan products (7).



*Cut off point 07.09.2026

Because in the end, it's all about:

The Patient — our ultimate purpose.

The Healthcare System — our shared responsibility.

Innovation — our driving force.



Thank you / Dank u