Centrale Commissie Mensgebonden Onderzoek

Lygature Live

‘CCMO in the regulatory field and the added value of the RSNN- Impact for patients’

Thera Max- Mos, Head National Clinical Trial Office CCMO

DATUM EN VERSIE

19 MAR 2025

Centrale Commissie Mensgebonden Onderzoek

Thera Max – Mos
Head National Clinical Trial office
CCMO

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CCMO

6 April 1999 - WMO

The Central Committee of Medical Research with human participants

Els Borst

- Clinical Trial, Medical and In Vitro Diagnostics Regulation (CTR, MDR and IVDR)
- Dutch Medical Research with Human Subjects Law (WMO)
- Embryo Law

Scope: medicines, devices, diagnostics, other research, (secondary) use of biological samples

Mission
Central Committee on Research Involving Human Subjects (CCMO)

The CCMO **protects participants** taking part **in medical research** by reviewing the research on the basis of the statutory provisions laid down for them and **taking into account the interests of scientific progress**.

Drug Development Proces and Regulatory Authorities in the Netherlands

Discovery and Development

Preclinical Research

Centrale Commissie Dierproeven

Clinical Research

ccmo

Review

College ter Beoordeling van Geneesmiddelen
CBG MEB
Medicines Evaluation Board

HTA

Zorginstituut Nederland

Post Market safety monitoring

bijwerkingen centrumlareb

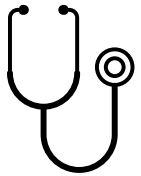
Inspectorate

Inspectie Gezondheidszorg en Jeugd
Ministerie van Volksgezondheid, Welzijn en Sport

ccmo

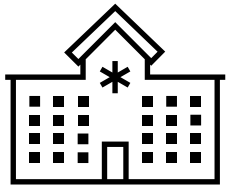
Main stakeholders involved in clinical research

Academia

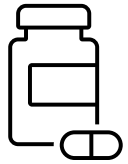


investigators

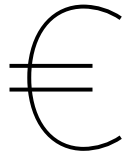
patients



agencies



industry



funding

CCMO member of

Regulatory Science Network Netherlands (RSNN)

network of experts from industry, academia, government bodies and patients

*Our mission is to advance an efficient and effective regulatory system **that supports medicines development**, marketing authorization, access, and appropriate use of medicines.*

10 YEARS RSNN

Why Clinical Research

Clinical research is vital to
continually improve the clinical effectiveness
of medicine and public health measures

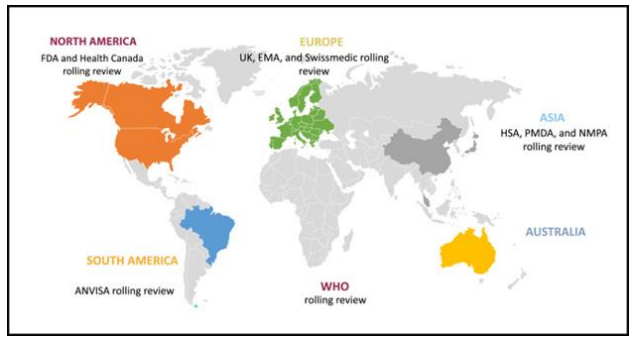
To get better medicines - Data is what we need!

In God We Trust. All Others Must Bring Data.

William Edwards Deming, American statistician and management theorist

Also a common saying at the FDA

Europe and CCMO



Europe

EMA HMA

Evolution of EU clinical trials regulation

Pre 2004: No harmonisation

National rules, different processes in each Member State.
Resulted in **delays** and **complications**

Clinical Trials Directive
(EU 2001/20/EC)

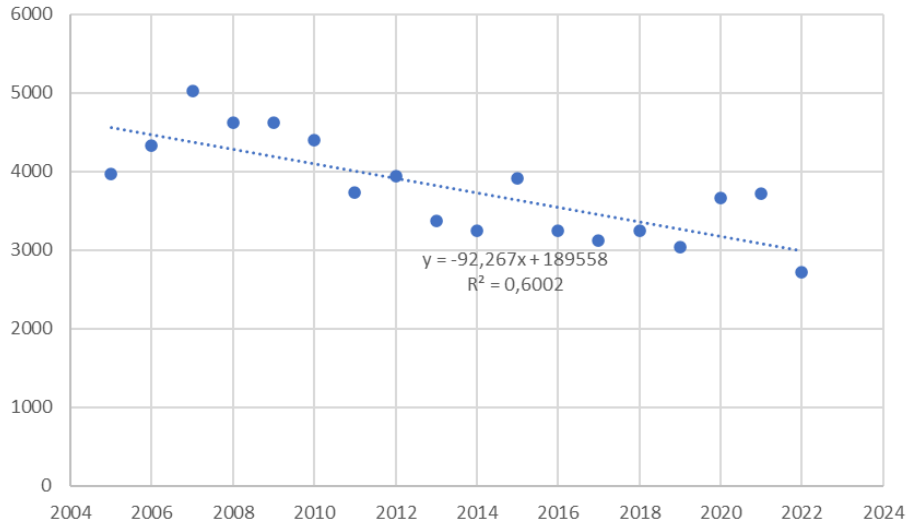
Some harmonisation, but **national systems & processes varied**

Entered into application 1 May 2004

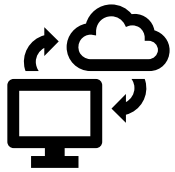
Clinical Trials Regulation
(No.536/2014)

Full harmonisation, collaborative assessment of **multinational trials**, single EU portal & database

Applies as of **31 January 2022**



The CTR aims to ensure greater harmonisation in the EU



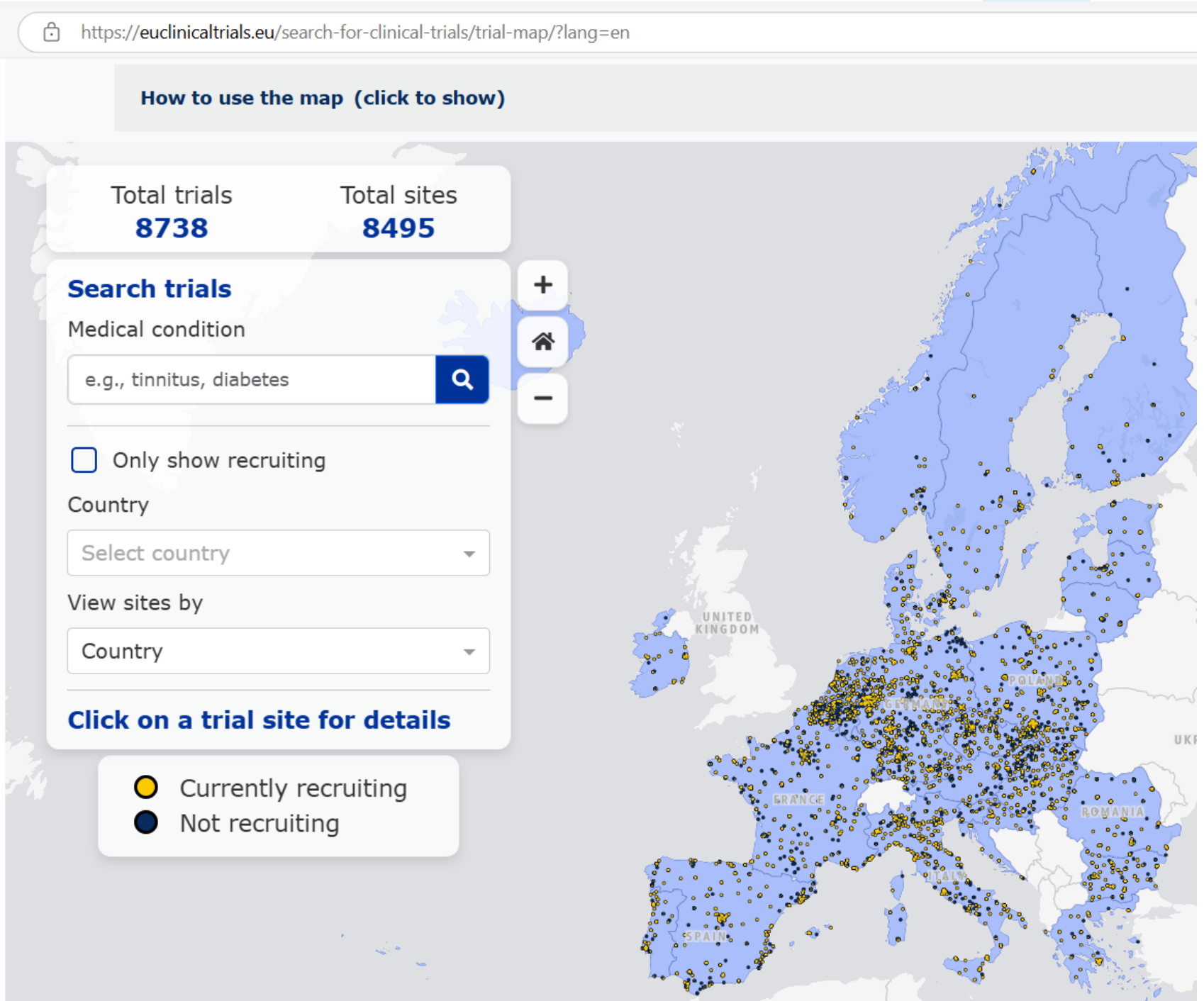
•single-entry point for sponsors and regulators of clinical trials, Clinical Trials Information System (CTIS),

•single authorisation procedure for all clinical trials for faster and better assessment by all EU countries concerned;

•greater transparency for clinical trial data.

Transparancy

Search for clinical trials - EMA (euclinicaltrials.eu)



Registration of medical research with human participants

www.onderzoekmetmensen.nl

Accelerating Clinical Trials-EU ACT- EU

The initiative (europa.eu)/ Priority action areas (europa.eu)

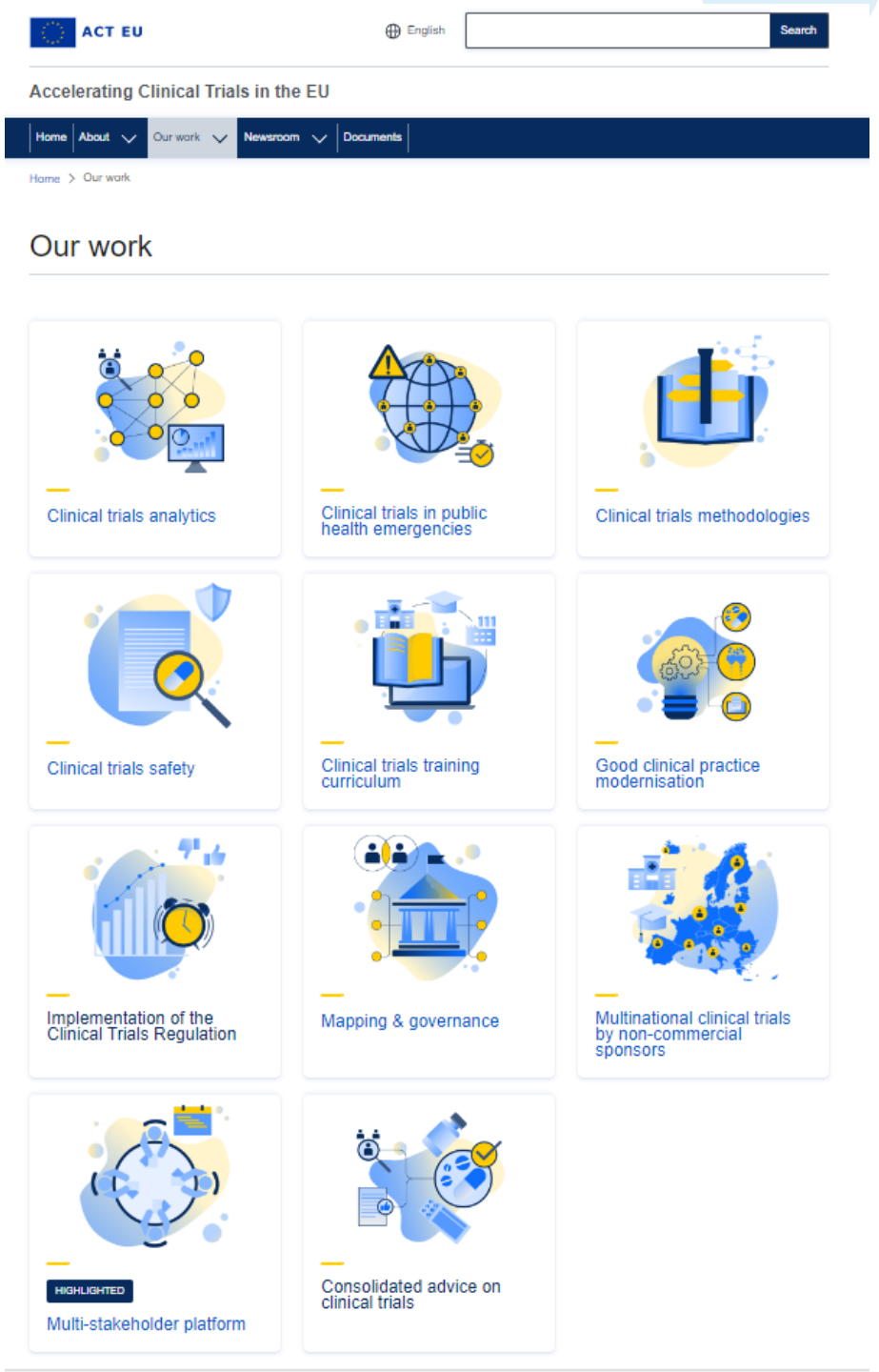
Better, faster, optimised clinical trials

Improving the clinical trials environment in the European Union through harmonisation, innovation and collaboration with stakeholders.

HMA Heads of Medicines Agencies

European Commission

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Impact RSNN

Expert meetings

Clinical Research Climate Netherlands

Implementation of IVDR

RSNN

Make Impact
National Action Plan – Clinical Research

Centrale Commissie Mensgebonden Onderzoek

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Thank you

Questions