AVANTYO
INSTITUTE OF CLINICAL RESEARCH

INNOVATION IN EDUCATION

"Stay Ahead of the Game:
Transformation in Clinical Trials
in the Age of Artificial Intelligence."

ANNUAL CLINICAL TRIALS SYMPOSIUM

November 8th, 2024

EUCROF
European CRO Federation

Clinical Trials Symposium Romania

"Stay Ahead of the Game: Transformation in Clinical Trials in the Age of Artificial Intelligence"

November 8th, 2024, Bucharest

Message from EUCROF

Dr. Martine Dehlinger-Kremer

President, EUCROF & VP Scientific Affairs, ICON Plc

The European Clinical Trials Landscape

The European clinical trial ecosystem is critical to patients, healthcare systems and society:

- For **patients**,

clinical trials offer early access to innovative medicines, and for rare disease patients, trials can be the only treatment option

- For **health systems**,

clinical trials bring revenue, cost-savings, clinical skills, and staff satisfaction

- For **society**,

clinical trials bring economic investment and GDP benefits, valued at multi-billion Euros

Recent European level and member state policy initiatives have attempted to **increase the capabilities and attractiveness** of the clinical trial ecosystem

EU Clinical Trials Regulation (CTR) aimed to **harmonize** clinical trial capabilities across Europe, and make multi -country applications more streamlined, with the goal of **boosting** Europe's competitiveness in attracting clinical trials

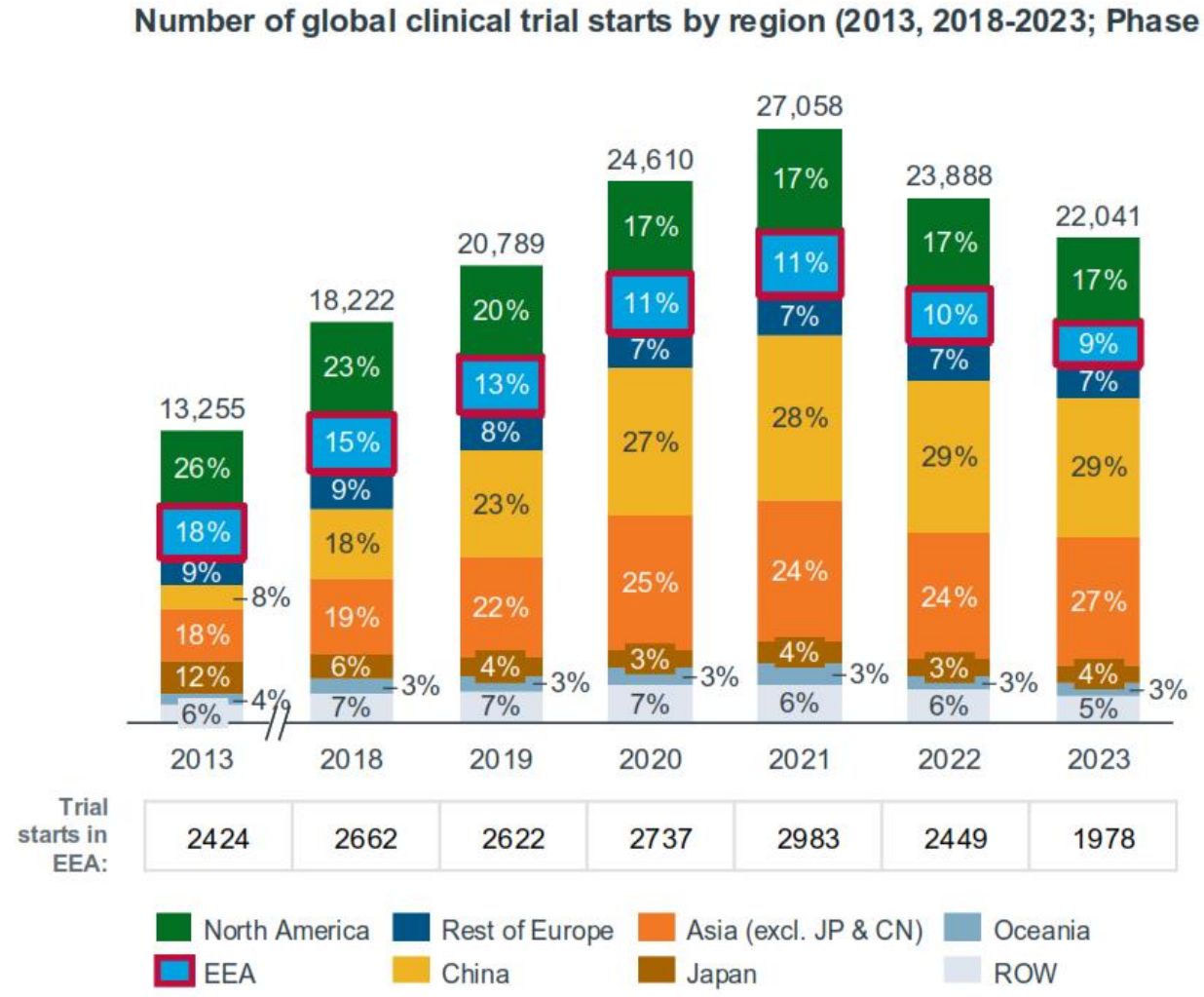
This goal has not yet been met.

At best,

Europe has held, but not yet improved its position

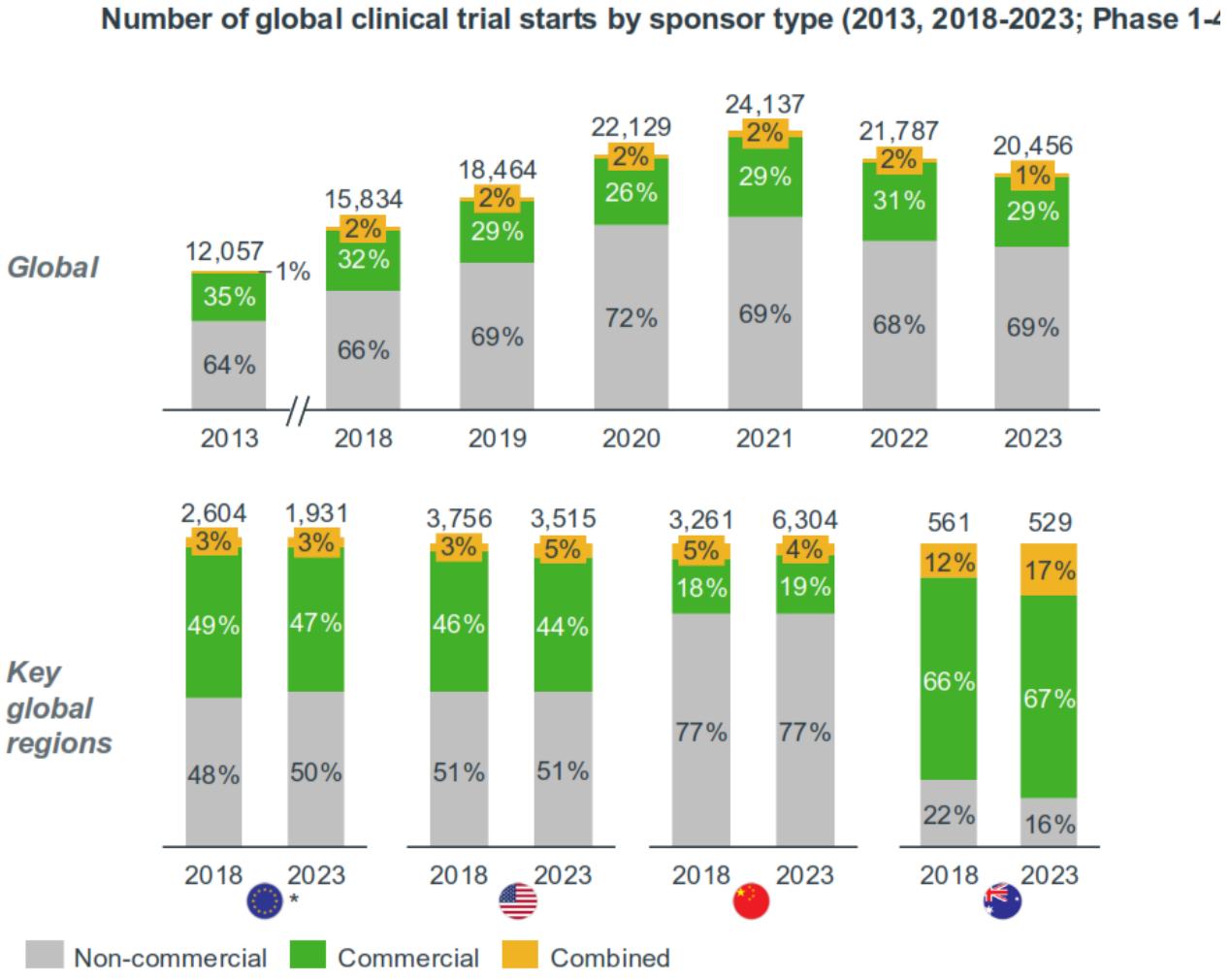
Source: IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | Final Report | October 2024

Evolving Global Clinical Trial Ecosystem: Declining European Share and Rising Asian Influence for new Clinical Trial Starts



Source: IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | Final Report | October 2024

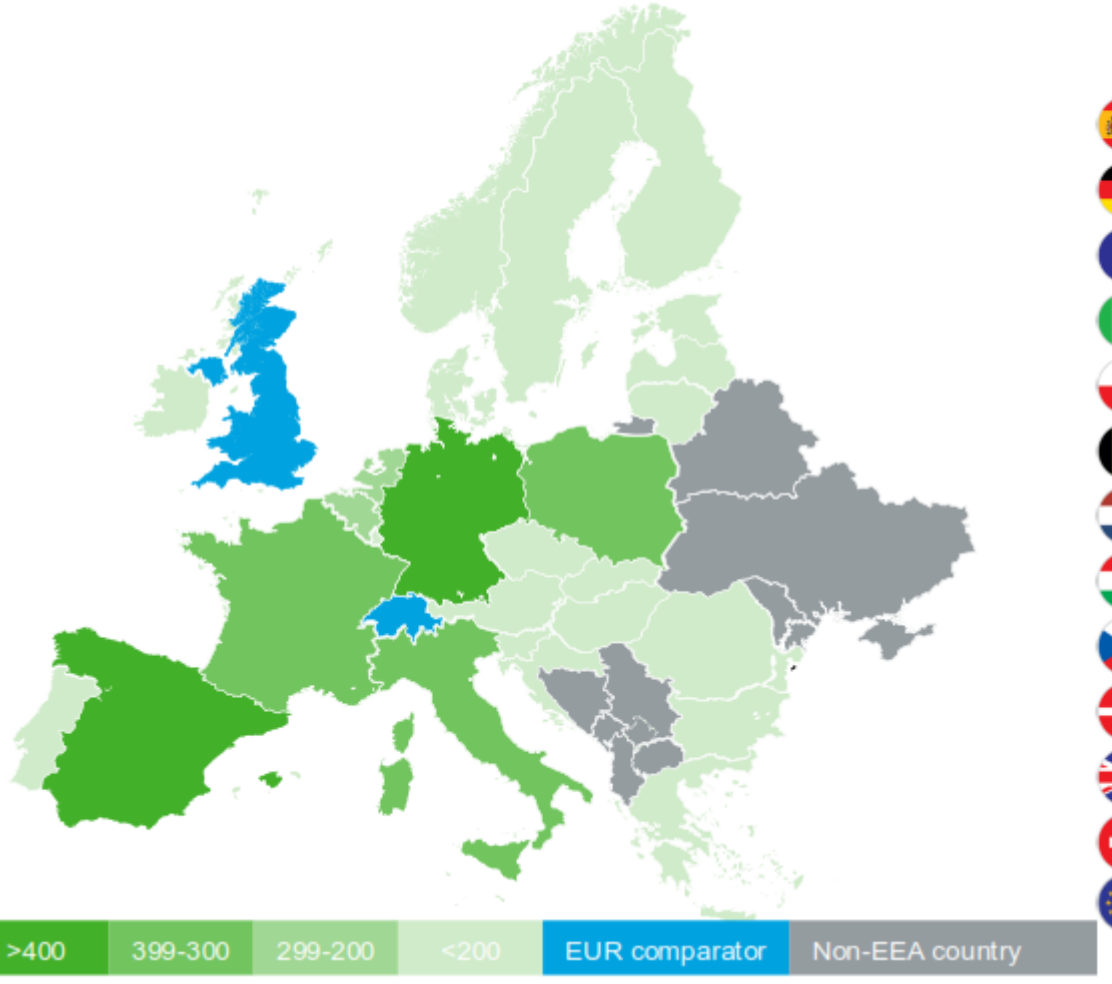
Balanced Split Between Commercial and Non-Commercial Trials in EEA, with a Slight Declining Commercial Share Since 2018 in EEA and US



Source: IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | Final Report | October 2024

Variability in EEA Commercial Trials Performance - Recently Spain Surpasses Germany in Clinical Trial Starts

Number of EEA commercial clinical trial starts in 2018 and 2023, top 10 countries



	2018	2023	CAGR
	491	**485**	-0.2%
	618	**417**	-7.6%
	439	**389**	-2.4%
	378	**343**	-1.9%
	332	**300**	-2.0%
	305	**218**	-6.5%
	282	**210**	-5.7%
	205	**161**	-4.7%
	199	**147**	-5.9%
	156	**118**	-5.4%
	573	**439**	-5.0%
	120	**107**	-2.3%
	1253	**920**	-6.0%

Source: IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | Final Report | October 2024

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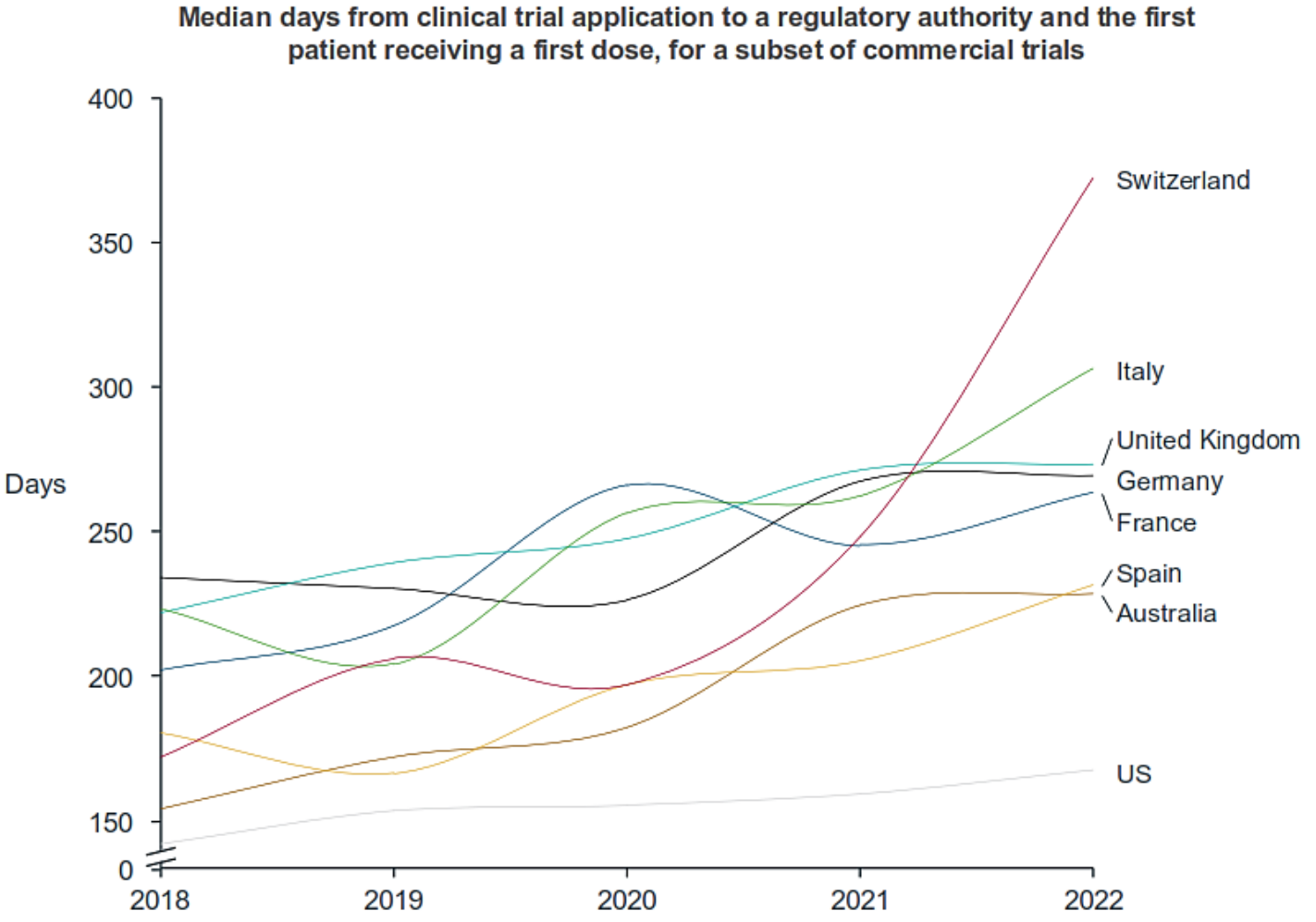
Slowdown in Trial Setup and Recruitment in Western Countries including the US: The Potential Impact of Increased Trial Complexity



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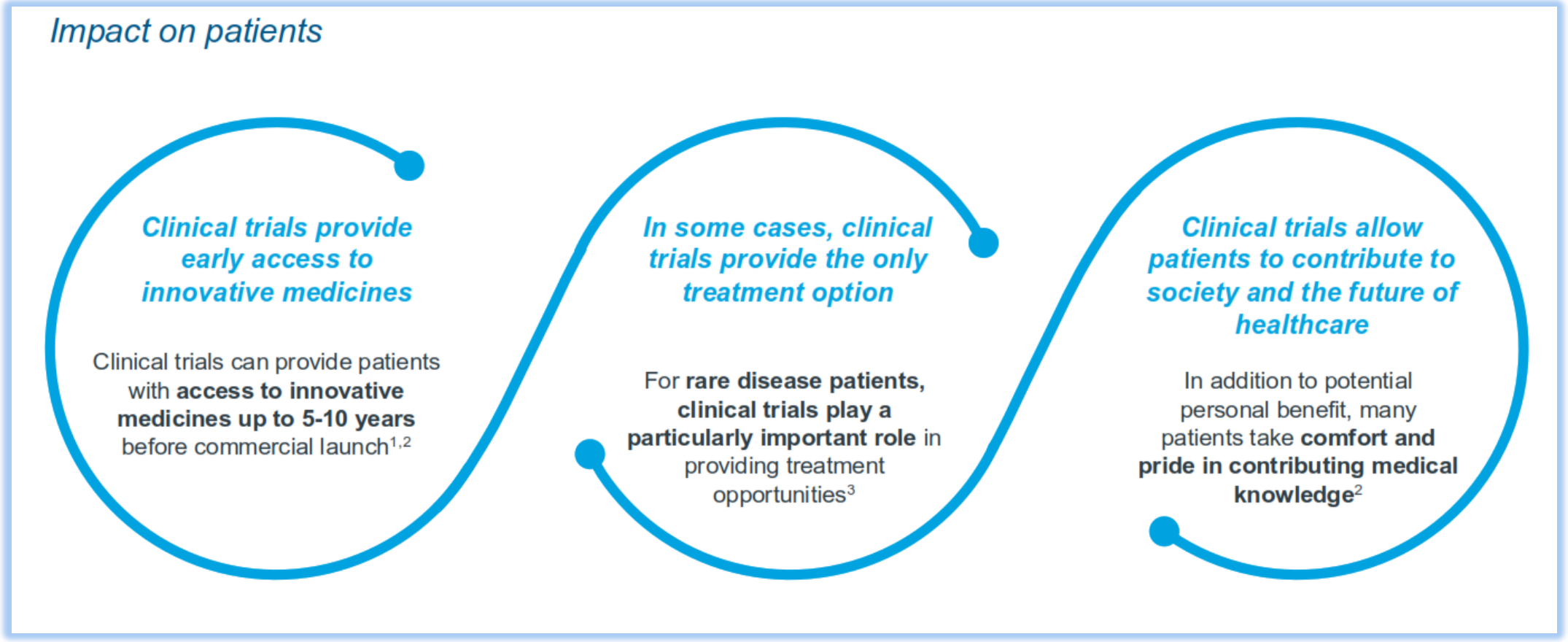
Source: IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | Final Report | October 2024

The Value of Clinical Trials to Patients: Early Access to Medicines and the Opportunity to Advancing Scientific Knowledge



Source: 1. CRUK, 2. NIH 3. NORD
IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | Final Report | October 2024

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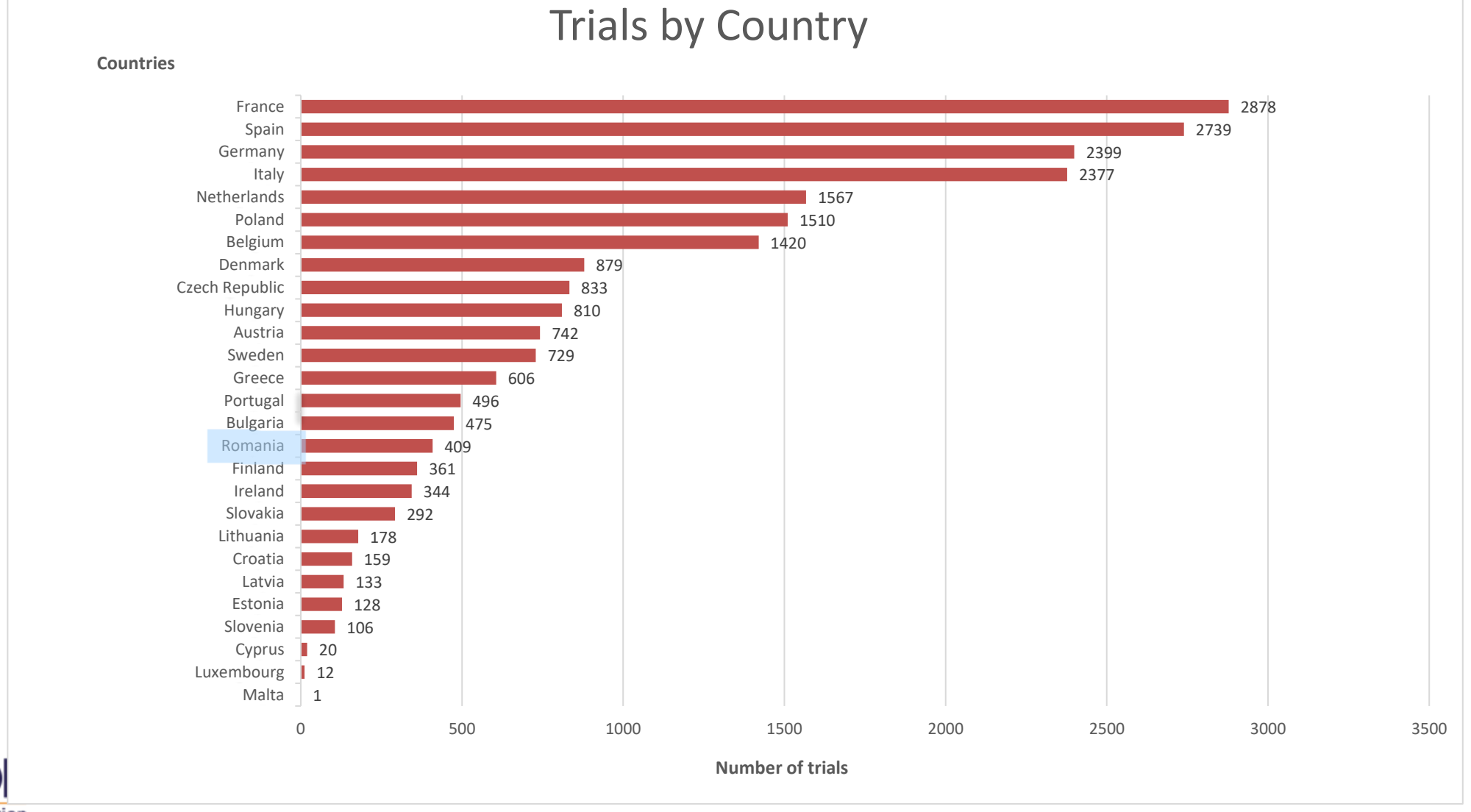
Ongoing Clinical Trials in the EU

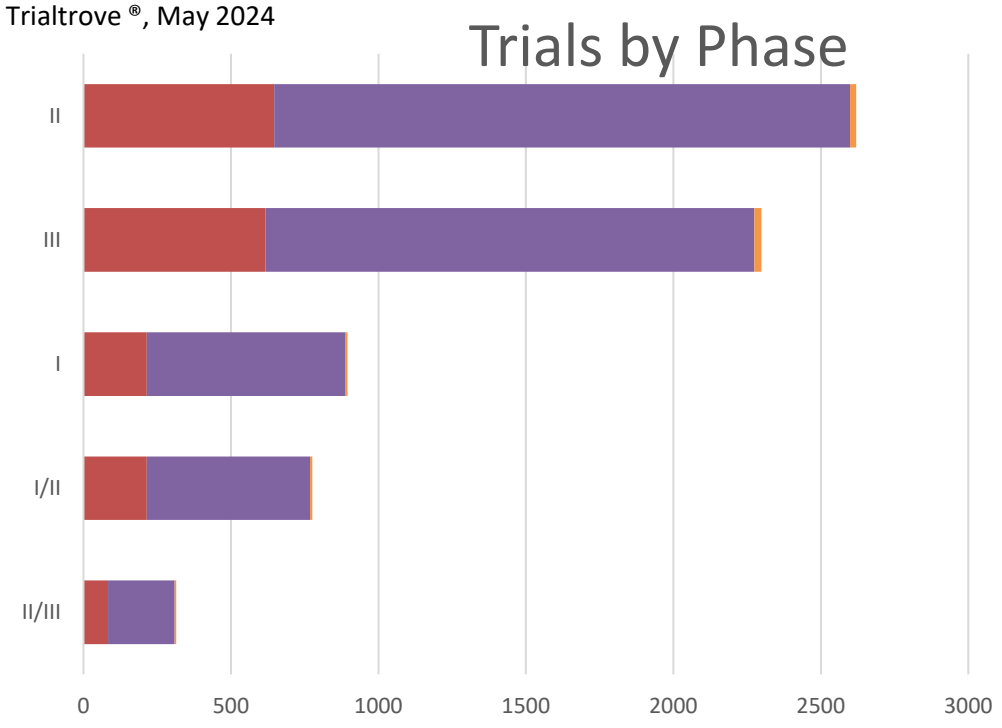
Trialtrove ®, May 2024

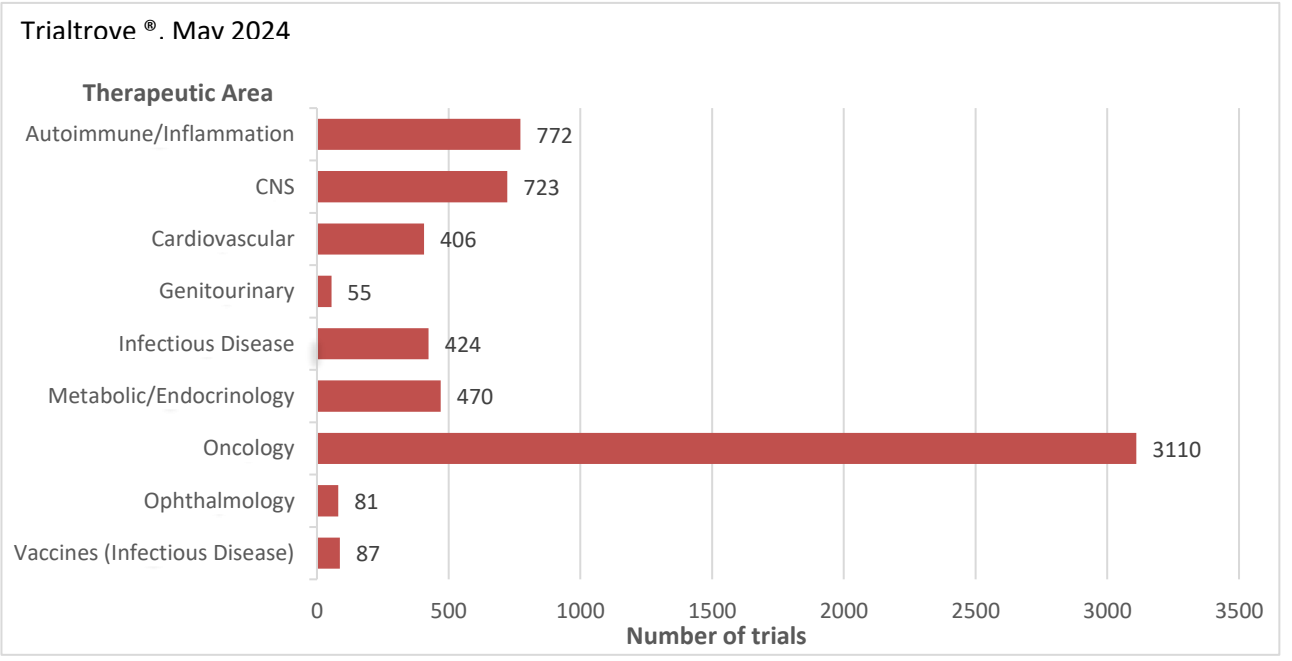


Source: Citeline Trialtrove 30 May 2024 / 6903 trials

Phases of the Ongoing Clinical Trials in the EU

Trialtrove ®, May 2024





Source: Citeline Trialtrove 30 May 2024

Accelerating Clinical Trials in the European Union - ACT EU

ACT EU INITIATIVE TO SUPPORT SMARTER CLINICAL TRIALS THROUGH REGULATORY, TECHNOLOGICAL AND PROCESS INNOVATION

BETTER, FASTER, OPTIMISED CLINICAL TRIALS

IMPROVING THE CLINICAL TRIALS ENVIRONMENT IN THE EUROPEAN UNION THROUGH HARMONISATION, INNOVATION AND COLLABORATION WITH STAKEHOLDERS

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The Work of ACT EU

Clinical trials analytics

Clinical trials in public health emergencies

Clinical trials methodologies

Clinical trials safety

Clinical trials training curriculum

Good clinical practice modernisation

Implementation of the Clinical Trials Regulation

Mapping & governance

Multinational clinical trials by non-commercial sponsors

HIGHLIGHTED

Multi-stakeholder platform

Scientific advice

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Consolidated Pilots on Scientific and Regulatory Advice

The Accelerating Clinical Trials in the EU (ACT EU) launched **two advice pilots**

The pilots
- enhance the **coordination within the EMRN**
- to offer sponsors/applicants **harmonised advice** on
- how to improve the quality of their applications for **clinical trial application** and **marketing authorisation**.

I Pilot: SAWP-CTCG

II Pilot: Pre-CTA Advice

Pilots started officially on **June 10th**

Supported by training Webinars
for Applicants (recorded)
for Assessors
Published Guidance documents on ACT EU website

List of MS participating in the pilot projects:
Member States participating in ACT EU pilots on consolidated advice (europa.eu)

Context:
Up to date **mapped information on current voluntary advice procedures** available from EU regulators on Medicines for human use

Source: EMA, CTIS Forum, 24 October 2024
EMRN = European medicines regulatory network

EUCROF - Mission

- EUCROF is a legal non-profit entity founded in 2005 and representing the interests of CROs towards
  - Regulatory bodies
  - Pharmaceutical, biotech, medical device industry
  - Healthcare related industry within the field of clinical research
  - Patients' associations

- EUCROF's goal is to promote Clinical Research by improving the knowledge, competence and skills of CROs

EUCROF – An International Representative Organisation

MEMBERS : National Associations

1. ACCSCR	Romania	17
2. ACRO-CZ	Czech Republic	16
3. ACROA	Albania	3
4. ACRON	The Netherlands	41
5. AECIC	Spain	29
6. AFCROs	France	100
7. AICRO	Italy	30
8. ASCRO	Sweden	17
9. BeCRO	Belgium	52
10. BVMA	Germany	46
11. CCRA	United Kingdom	28
12. GCP&RA	Lithuania	5
13. HACRO	Greece	16
14. POLCRO	Poland	15
15. SACROP	Slovakia	16
16. SAKDER	Turkey	24

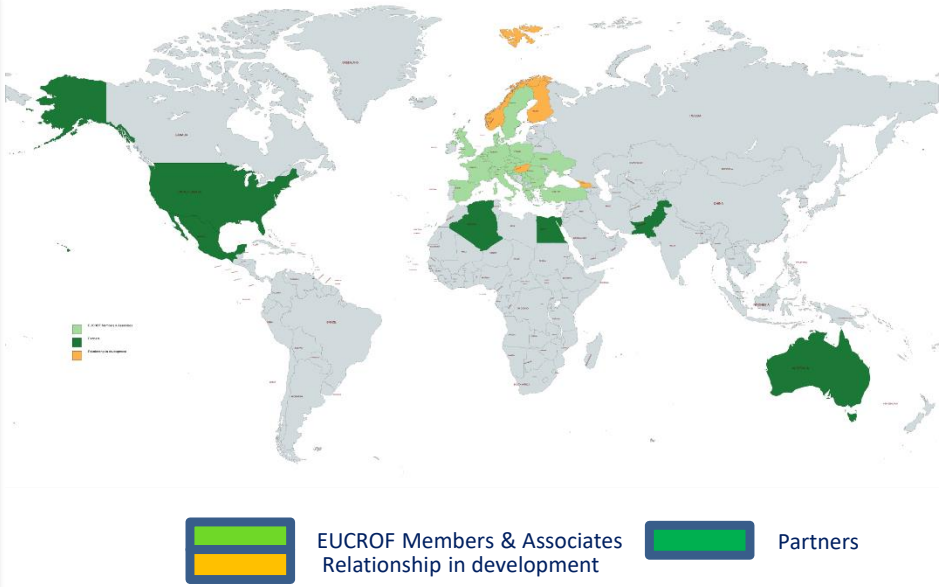
- **Members & Associate Mbs: legal entities registered in Europe**
- **Partners: legal entities registered outside Europe**

Associate Members

1. Bulgaria
2. Croatia
3. Denmark
4. Georgia
5. Latvia
6. Portugal
7. Slovenia
8. Spain
9. Switzerland (3)
10. Ukraine
11. United Kingdom (1)

Partner Members

1. Algeria
2. Australia
3. Egypt
4. Israel
5. Mexico
6. Pakistan
7. USA



- 450+ Affiliated CROs
- 33 Countries
- 300 CROs are SMEs

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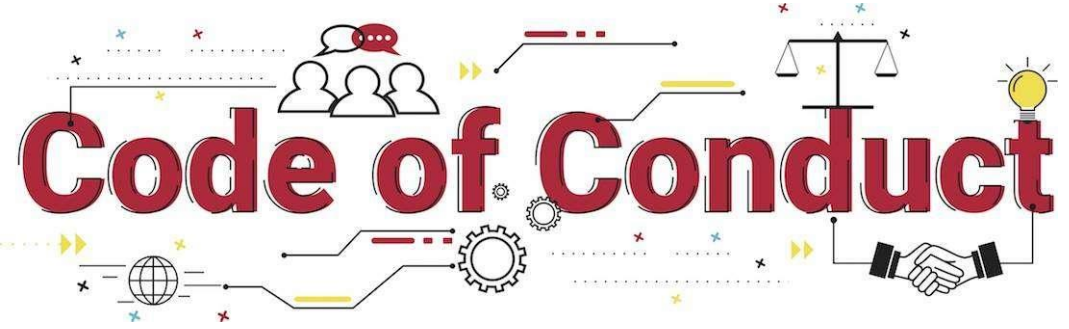
Ongoing Initiatives and some recent Accomplishments

- **Active Stakeholder of the EMA**
  - EU Clinical Trial Information System (CTIS), involved since 2014
  - Member of Industry Stakeholders, Quarterly meetings
  - ACT EU
    - Member of ACT EU Multi-Stakeholder Platform
    - Member Ad Hoc MSP Advisory Group
- **Specific positions with the EMA**
  - Member European Network of Centres forPharmacoepidemiology and Pharmacovigilance (ENCePP) WG2, since February 2018
  - Observer Member Coordinating Group of European Network of Paediatric Research at EMA (Enpr-EMA) since April 2018
- **EU CRO Benchmarking -** Position of CROs in clinical research environment
  - Article published in 2022
  - Presentation results 2023 at ISPOR Conference in Nov 2024 in Barcelona, Spain

EUCROF GDPR Code of Conduct for CROs – Approved!

- Approval by the European Data Protection Board (EDPB) on June 18th 2024 and by the CNIL's (French data protection authority) resolution on 12th Sept. 2024
- Code is for **Service Providers** for clinical research acting as a **Data Processor** for the research/study sponsor in the frame of a **Service Contract**
- **Covers** 23 classes of services that a CRO can deliver as well as Patients & healthcare professionals Data
- More information under: https://www.eucrof.eu/gdpr-code-of-conduct
- Registration under: https://cro.eucrof.eu/eucrof-code-public-registry
- First adherence decisions expected in Q1 2025
- First submissions considered first



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EUCROF25

2-4 FEBRUARY | COPENHAGEN

EUCROF25 Conference

Europe continues to be a key player in the global clinical trials landscape, with numerous strengths to leverage for future growth

Together, we can drive improvements

THANK YOU FOR YOUR ATTENTION

Wishing you an excellent Symposium

EUCROF - Working Groups

Working Group	Chair
Clinical Trial Centres	Antoinette van Dijk
Clinical Trials Legislation	Dagmar Chase
Clinical Trials Logistics	Michael Shumilin
Communication	Christophe Golenvaux
Early Phase	Ana Maria Iancu
Events and Training	Donato Bonifazi
Innovative Medicines	Dolores Pérez Méndez
Medical Devices	Şebnem Yaşaroğulları
New Technologies	Fiona Maini
Paediatrics	Martine Dehlinger-Kremer
Patients' Associations	Jean-Sébastien Gosuin/Manika Kreka
Pharmacovigilance	Marco Anelli
Real World Data & Digital Health	Alexandre Malouvier

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