A European platform for clinical trials

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CTR, CTIS, ACT EU

- **Update on implementation of Clinical Trials regulation**
- **'Accelerating Clinical Trials in the EU' (ACT-EU)**

The European Clinical Trials Regulation

Before the Clinical Trials Regulation

Clinical trial applications were submitted separately to regulators and ethics committees in each EU Member State

After the Clinical Trials Regulation

Single clinical trial application covering regulatory and ethics submission in up to 27 Member States

Applies as of **31 January 2022**

CTIS is the business tool of the Clinical Trials Regulation

The Clinical Trials Information System (CTIS) is the single submission portal, workspace and public registry which **harmonises the submission, assessment and supervision of clinical trials** in the EU/EEA.

Public health

Facilitates multinational trials to address key health issues, increase transparency & enables patient enrolment

Research and innovation

Enables medical innovation through collaboration and access to clinical research data.

Global hub for clinical trials

Aims to ensure the EU/EEA remains an attractive clinical research hub globally.

CTIS in 2022… and 2023

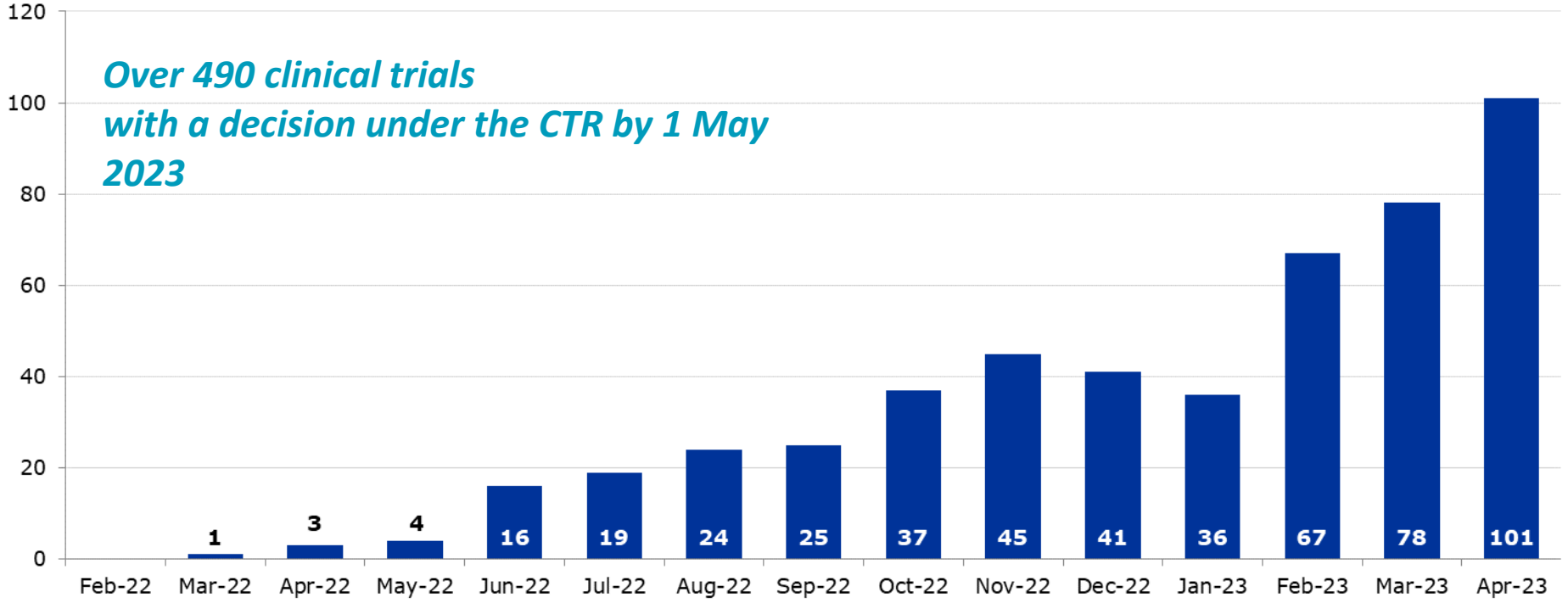
2022

- CTIS went live on 31 January 2022, 1st year of transition of CTR
- 552 initial clinical trial applications submitted in 2022 (201 authorised)
- Intensive collaboration of EMA, Sponsors, MS to resolve technical challenges with some trials

2023

- Since 31 January 2023, CTIS mandatory for all CT applications
- Over 500 initial clinical trial applications submitted since 31 January 2023: submissions increasing (approx. 80% of level under Directive)
- Ongoing collaboration to support users and improve CTIS

Clinical Trials with a decision in CTIS per month



Accelerating Clinical Trials in the EU (ACT EU)

ACT EU is business change initiative to transform the EU clinical research environment in support of medical innovation and better patient outcomes.

- **Builds on the momentum** of the Clinical Trials Regulation and CTIS
- **Driven by** the Network Strategy to 2025 and the EU Pharmaceutical Strategy
- Launched 13 January 2022
- 10 priority actions with a focus on:
  - **enabling clinical trials** (in particular multinational trials)
  - **innovative trial methods**
  - **GCP modernisation**
  - **engaging stakeholders**
- Read the press release and paper

Over the next 4 years ACT EU aims to

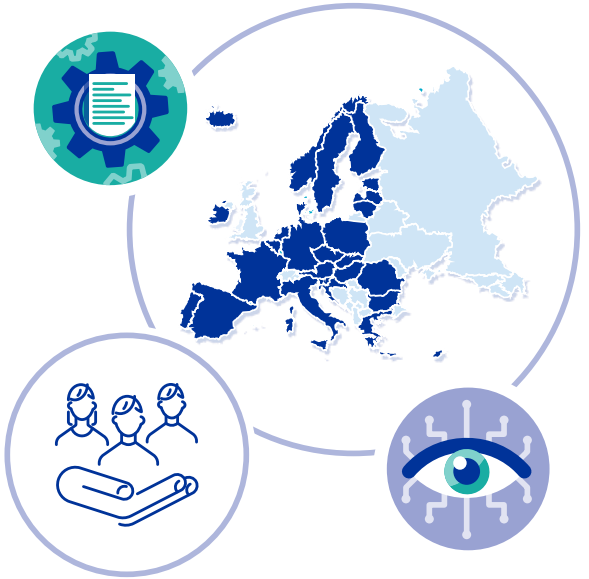
- Ensure **effective** operation of the clinical trials regulation
- **Simplify governance** and align CT approval with scientific advice
- **Support academic sponsors** to conduct impactful clinical trials
- Establish the place of **novel methodologies**
- Enable **decentralised** approaches
- **Training**: create an educational “ecosystem” (leveraging existing initiatives)
- Align internationally (including GCP)
- Optimise the **use of data** about clinical trials for better research and decision-making
- Create a **Multi-Stakeholder Platform**

ACT EU 2023 focus

- Reinforced focus on successful implementation of the Clinical Trials Regulation (CTR), including use of Clinical Trials Information System (CTIS)
- Launch a scheme to support academic sponsors conducting large multi-national clinical trials
- Creation of a Multi-stakeholder platform
  - A sustainable platform that enables all stakeholders to collaborate for better clinical trials.
  - Kick-off meeting: 22-23 June 2023 - link

ACT EU, CTR and CTIS – what this means for patients and R&D in EU

- **ACT EU**:
  - Ensures the voice of patients is heard on clinical trials modernisation
  - Builds engagement with all stakeholders to improve EU as a global centre for clinical trials
  - Addresses health needs by facilitating innovation in CT methods, data insights and large multinational trials
- **The Clinical Trial Regulation and CTIS**:
  - Make it easier to find and potentially join clinical trials
  - Provide clinical trial results in lay language
  - Enable medical innovation and support patient safety



See ACT EU webpage for more information