

# February 22, 2021

(Legislative acts)

## REGULATIONS

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 16 April 2014  
on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC  
(Text with EEA relevance)



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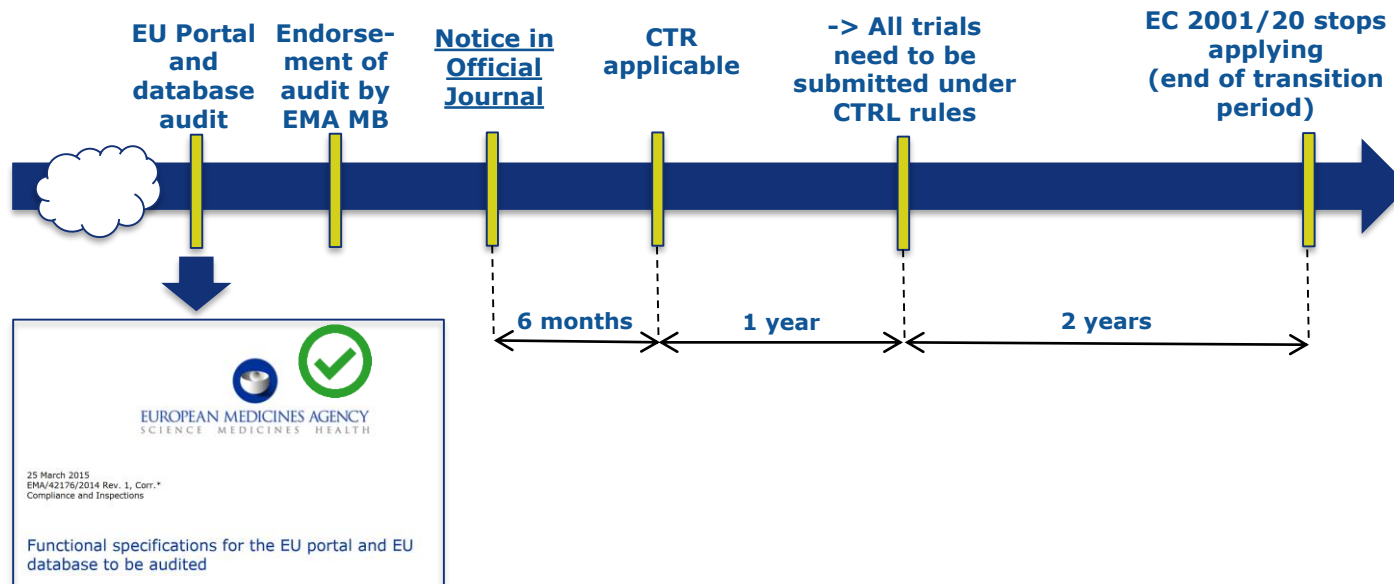
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# Clinical Trials Regulation (CTR)- No 536/2014

- The Regulation was adopted in April 2014 by the **European Parliament** and published in May 2014.
- It is estimated that the Regulation will become applicable at the end of this year.
- The **transition period** for the old and new procedures will be a maximum of **3 years** after the date of application of the Regulation.



# CTIS development



- **MB endorsement of full functionality is a condition for the publication of the notice in the official journal. The publication will set the start of the transition period of 6 months preceding the applicability of the CTR.**

# What is the purpose of the CTR?

- To make Europe **attractive for clinical trials** considering the decline in CTs and number of patients the past years
- **Increased harmonization of a robust and agile approval process** for clinical trials and **close coordination** between Member States for multi-country trials
- **Transparency** of clinical trial data to allow adequate public scrutiny and support improved clinical research efficiency
- To ensure the production of reliable and robust, high-level scientific data, **ensuring high standards in patient safety**

# CTR- EU portal - transparency



- The CTR requires **all** information for the **entire life-cycle** of the trial stored in the database to be publicly available, **unless exempted** under the Regulation to protect:
  - **personal data**
  - **commercially confidential information**
  - **confidential communication between Member States**
  - **supervision of clinical trials by Member States**
- Disclosure rules: EMA/42176/2014

# CTR- safety reporting and assessment



- **Simplified safety reporting**
- **Coordinated assessment** of Suspected Unexpected Serious Adverse Reactions (**SUSARs**) and the Annual Safety Reports (**ASRs**)
  - **harmonised standards of safety for participants and future patients**
  - **improved quality and robustness of safety assessment.**
  - **support by an Implementing Regulation**

# Supporting legislation/Guidance



- Implementing act for coordinated safety assessment
- QnA: safety reporting and assessment, submission and classification of changes to ongoing clinical trials
- QnA: GDPR/CTR (EDPB)
- Guidance: preparation of lay summary, interfacing CTR and IVDR, AxMP, risk proportionality
- Templates: harmonised part II templates



# Interactions with other EU frameworks

## ***Pharmaceutical strategy***

- clinical trials and the regulatory framework for clinical trials are part of the strategy with the aim to build a more patient-centered strategy, which supports innovation, including trials with innovative design, without hindering patients' access to medicines.

## ***Cancer plan***

- Including actions across the entire disease pathway (prevention, diagnosis, treatment).

## ***EU4Health***

- Financial tool to support also increased coordination in clinical research (e.g. coordinated safety assessment) with EU added value

# Thank you for your attention.



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# Any questions?

## Further information

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