EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trial Regulation and Clinical Trials Information System (CTIS) - what changes in 2022

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Disclaimer

The presenter does not have any conflict of interests.

The views expressed are those of the presenter.

The Clinical Trial Regulation: *where we come from*

…Before May 2004

National rules, different processes/requirements for authorisation in each EU Member States

…resulted in delays and complications

…Directive 2001/20/EC

(since 1 May 2004)

First step to harmonise processes and requirements for clinical trial authorisations

Introduction of e-application form

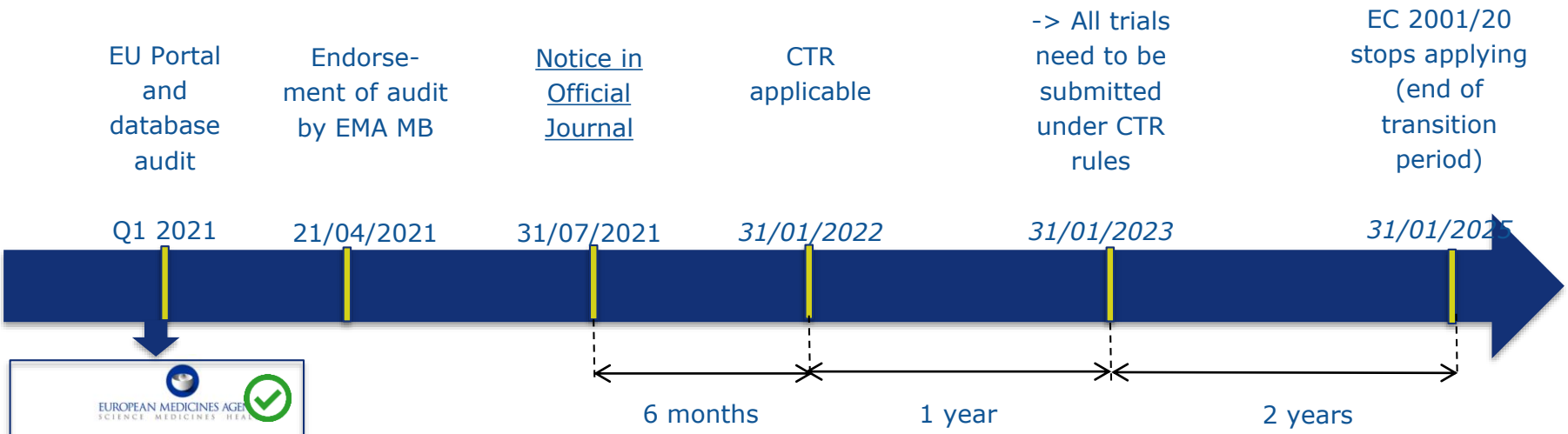
…Regulation (EU) No. 536/2014

(published May 2014)

Full harmonisation and combined assessment of multinational trials (after full functionality of the EU portal and EU database)

e-submission

Timeline for the CTR



- EMA MB endorsement of full functionality is a condition for the publication of the notice in the official journal and was confirmed on 21/04/2021. 6 months later, the CTR starts to apply
- The date of application is January 31, 2022

Why CTIS?

CTIS is the business tool of the **Clinical Trials Regulation**.
CTIS **harmonises the submission, assessment and supervision of clinical trials**.

Public health

Facilitates large-scale trials to address key health issues (COVID, EU Beating Cancer plan…)

Research and innovation

Enables knowledge sharing and expert collaboration.

Investment in research

Ensures the EU/EEA remains an attractive clinical research hub globally.

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency

Increased Transparency

Enhanced Patient Safety

Support to Innovation & Research

- The **single EU entry point** for clinical trial application submissions for sponsors (e-dossier)
  A single application and maintenance process, dossier and timeline; covering clinical trial application to NCA, submission to ethics committee and registration of the clinical trial in a public register; all in one integrated submission
- Harmonised and simplified **end-to-end electronic application procedures** over the life-cycle of clinical trials across the EU
- Collaboration and **coordination in evaluation and supervision of clinical trials** for Member States
- Fully **electronic exchange** of information between sponsors and Member States
- Digital secured **archive** of documents, decisions and information on a clinical trial

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency | *Increased Transparency* | *Enhanced Patient Safety* | *Support to Innovation & Research*

- Offers searchable **clinical trial information** to the patient, the healthcare professional and the general public
- Clinical trial **results available in lay language**
- Information can be retrieved for the life-cycle of a **clinical trial or investigational medicinal product** across trials

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency

Increased Transparency

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Support to Innovation & Research

- Patient safety is enhanced in clinical trials as CTIS provides an end-to-end electronic solution for safety reporting of trials
- CTIS facilitates a harmonised assessment in Europe, supported by agreed assessment report templates
- The clinical trial module of EudraVigilance is updated for the electronic reporting of SUSARs by sponsors and re-routing to Member States
- CTIS provides for one single decision per Member State Concerned
- CTIS delivers an electronic Annual safety reports (ASRs) repository

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency

Increased Transparency

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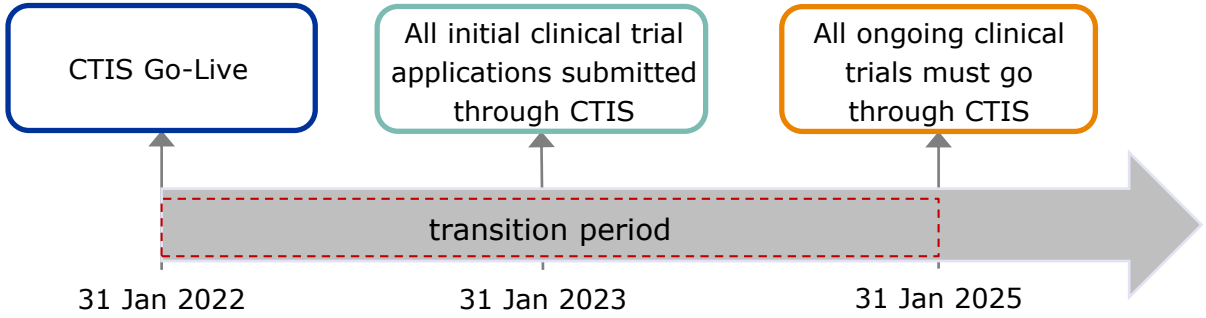
Support to Innovation & Research

- CTIS is a unique intuitive tool that facilitates submission of clinical trial applications including those for trials across borders and for investigation of rare diseases. It thereby also supports academic innovative work.
- CTIS offers structured data to allow efficient reporting for scientists
- A clinical trial can be extended to more Member States e.g. to enhance recruitment rates without resubmission/reassessment of the clinical trial application. The implemented CTIS timelines can be shortened.

CTIS Go-Live 31 January 2022

After Go-Live Member States will use CTIS from the start while sponsors can make use of a transition period.

The volume of **publicly available data in CTIS will gradually start to accumulate**.



Clinical Trials Information System - CTIS

- *Focus:*
  - *Ensure quality and stability of CTIS*
  - *Deliver CTIS for go-live*
  - *Put effort now into preparing for CTIS Go Live*
- *Get ready:*
  - *Define functions and processes embedding CTIS*
  - *Nominate the Administrator (if applicable)*
  - *Define the form of your organisations*
  - *Choose the people to work with CTIS, train the people implement the processes*
- *Countdown has started:*
  - ***Go Live 31 January 2022***

Thank you for your attention

Further information

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