EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Welcome

Clinical Trials Information System (CTIS) Virtual information day: The future user perspective

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The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

# What is CTIS?

- CTIS will be the **single entry point** for clinical trial submission, authorisation and supervision in the EU and the EEA.
- Currently, sponsors submit clinical trial applications to national competent authorities and ethics committees in each EU/EEA country.
- With CTIS, sponsors can apply for clinical trial authorisation in multiple EU/EEA countries with a **single application**.

# CTIS: Two dedicated and secure workspaces and a public portal

Sponsors: industry and academia

Marketing authorisation applicants

Member States NCAs* and ethics committees

European Commission

European Medicines Agency

General public

*National competent authorities

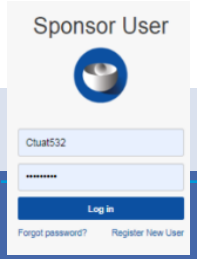
**secure access**

**open access**

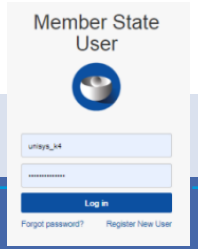
sponsor workspace

authority workspace

public website




**EU Portal**




EU CT Database

Data accessible to the public

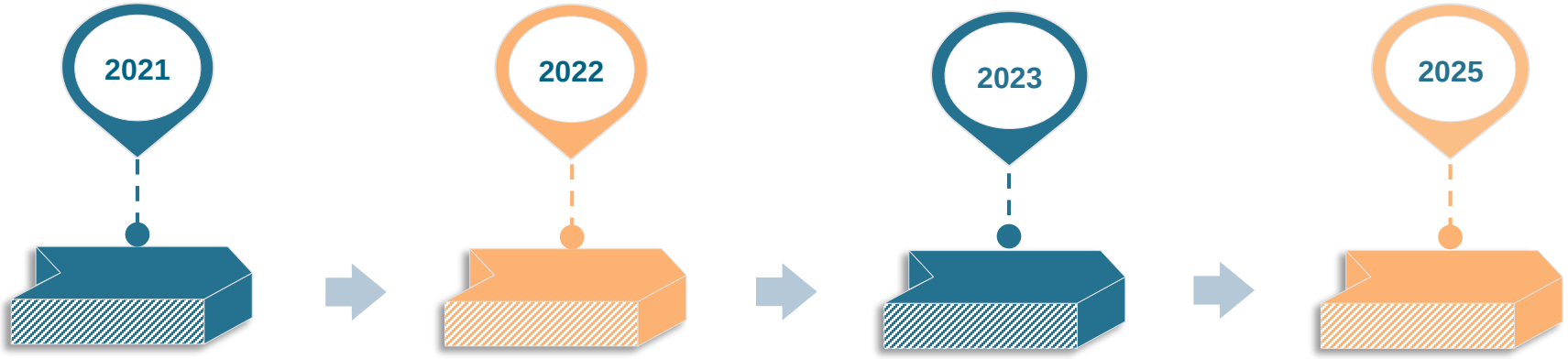
# CTIS Go-Live timeline

Endorsement of CTIS audit by EMA MB

CTR becomes applicable and CTIS go-live **on 31 January 2022**

All initial clinical trial applications submitted through CTIS **by 31 January 2023**

All ongoing clinical trials must go through CTIS **by 31 January 2025**




**3-year transition period**

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

# Why CTIS?

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.

# Preparing for CTIS

**Consider your processes**

- CTIS Sponsor Handbook
- Sponsor organisation modelling

**Review CTIS training resources**

- CTIS online modular training programme
- Training environment

**Prepare for go-live**

- Consider user role configuration and 1st applications in CTIS
- Share knowledge in your organisation

# Further information

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