Welcome

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

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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

sponsor workspace
authority workspace
public website

EU Portal

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

2021

2022

2023

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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