EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CTIS: harmonising the submission, authorisation and supervision of clinical trials

CTIS July Info Event

Presented by Pieter Vankeerberghen on 29th July 2021

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

EUROPEAN MEDICINES AGENCY

Sponsors: industry and academia

Marketing authorisation applicants

Member States *NCAs and ethics committees

European Commission

European Medicines Agency

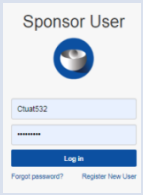
General public

*National competent authorities

secure access

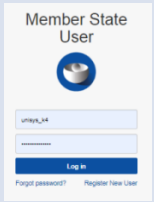
open access

sponsor workspace



EU Portal

authority workspace



public website

EU CT Database

Data accessible to the public

CTIS: harmonising the authorisation and supervision of clinical trials

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.

CTIS: harmonising the authorisation and supervision of clinical trials

CTIS Benefits

With CTIS sponsors can:

- Apply for a clinical trial in up to 30 EU/EEA countries with a **single application**
- Facilitate involvement of trial participants by allowing **easy expansion of trials to other EU/EEA countries**
- **Collaborate across borders** for better results and knowledge sharing
- Ensure the EU/EEA remains an attractive location for **clinical research investment**
- Fulfil all **clinical trial publication requirements** with no additional effort

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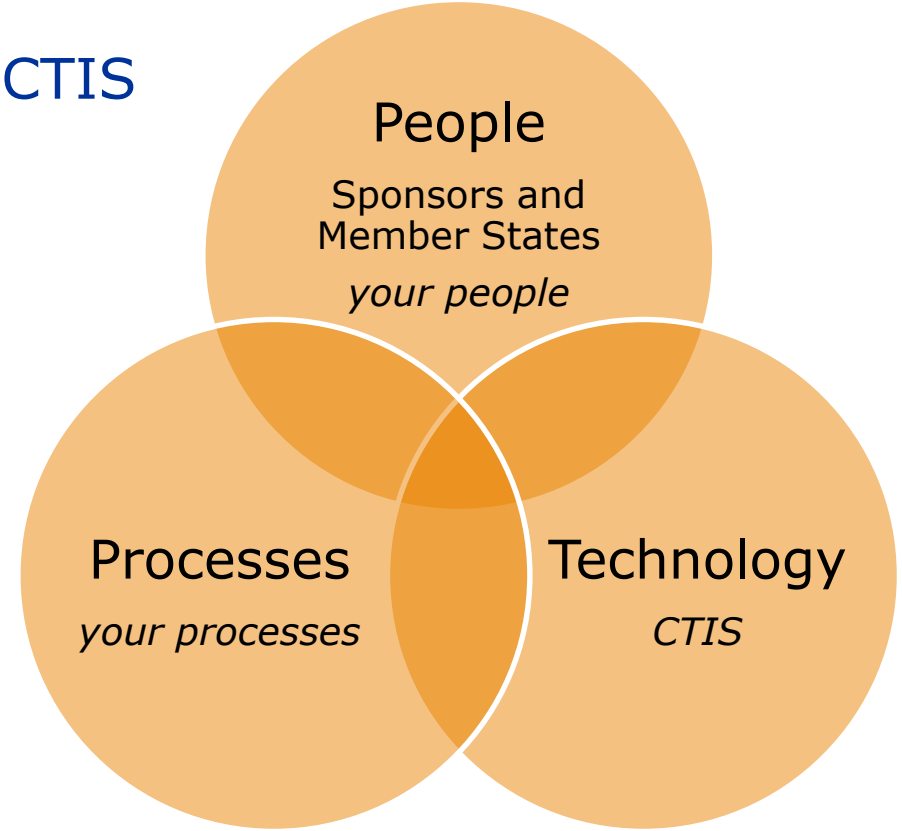
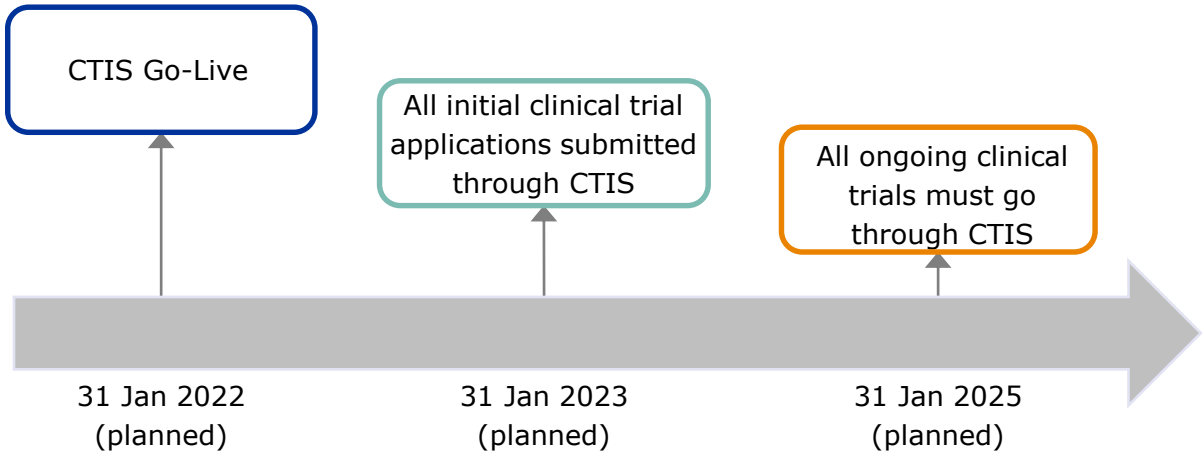
Preparing for CTIS



CTIS Go-Live timeline

Now is the time to **prepare for CTIS Go-Live**.



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Any questions?

Further information

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