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

Presented by Pieter Vankeerberghen on 29th July 2021
© European Medicines Agency, 2021

Reproduction and/or distribution of the content of these training materials for non-commercial or commercial purposes is authorised, provided the European Medicines Agency is acknowledged as the source of the materials.

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.

CTIS: harmonising the authorisation and supervision of clinical trials
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**

**CTIS:** harmonising the authorisation and supervision of clinical trials

- **Open access**
- **Secure access**

- **Sponsor workspace**
- **Authority workspace**
- **Public website**

Data accessible to the public

**EU CT Database**

*NCAs and ethics committees*
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 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

CTIS: harmonising the authorisation and supervision of clinical trials
Preparing for CTIS

People
Sponsors and Member States
your people

Processes
your processes

Technology
CTIS
CTIS Go-Live timeline

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

CTIS Go-Live

31 Jan 2022 (planned)

All initial clinical trial applications submitted through CTIS

31 Jan 2023 (planned)

All ongoing clinical trials must go through CTIS

31 Jan 2025 (planned)
Any questions?

Further information

CT.communication@ema.europa.eu

Official address  Domenico Scarlattilaan 6  •  1083 HS Amsterdam  •  The Netherlands
Telephone  +31 (0)88 781 6000
Send us a question  Go to www.ema.europa.eu/contact

Follow us on  @EMA_News