EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The Clinical Trials Regulation & its impact on oncology – EMA's perspective

ESMO Public Policy webinar

Presented by Peter Arlett on 12th October 2021
Head of Data and Analytics and Methods Task Force

An agency of the European Union

Disclaimer

The presenter does not have any conflict of interests.

The views expressed are those of the presenter.

The Clinical Trials 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

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 (EU Beating Cancer plan, COVID-19…)

Research and innovation

Enables knowledge sharing and expert collaboration.

Investment in research

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

CTIS: Two dedicated and secure workspaces and a public portal

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Sponsors: industry and academia

Marketing authorisation applicants

Member States *NCAs and ethics committees

European Commission

European Medicines Agency

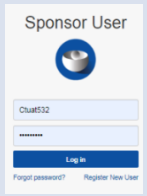
General public

*National competent authorities

secure access

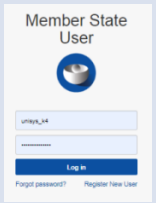
open access

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

CTIS Benefits

- Sponsors can apply for a CT 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

CTIS Go-Live 31 January 2022

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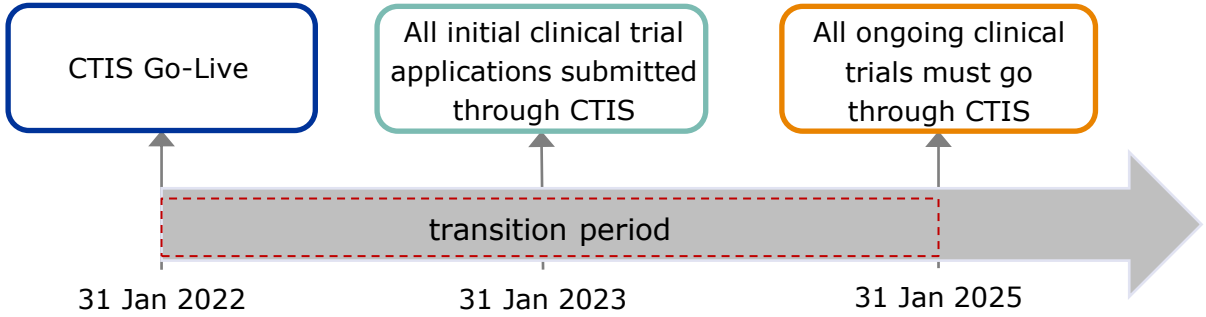
After Go-Live Member States will use CTIS from the start while sponsors can make use of a transition period.

The volume of **publicly available data in CTIS will gradually start to accumulate,** increasing transparency & access to data.



CTR, CTIS & Oncology

- Many trials with patients with a cancer are multi-national,
  thus academic and commercial sponsors will benefit from CTR and CTIS
- Much simplified extension to additional Member States, relevant e.g. for longer-running investigator-initiated trials for cancer treatment optimisation (e.g. ESMO, EHA)
- CTIS can handle master protocols and complex trials
  (may need several EudraCT numbers; in the works: Q&As to facilitate complex trials)
- Trial adaptation(s) if authorised upfront can be implemented by sponsor on its own
- CTIS provides a repository of electronic Annual safety reports (ASRs)

Countdown:

- 111 Days to CTR becoming applicable and CTIS Go Live 31 January 2022

More information and supportive material:

- https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation

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

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CTIS future users

The **future users of CTIS** include:

Sponsors

Commercial: large pharmaceutical companies & CROs, SMEs

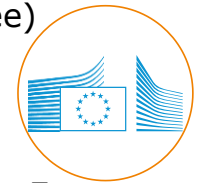
Academia

Will **input clinical trial data** in CTIS

Authorities

Member States (NCA & ethics committee)

EMA



European Commission

Will **review clinical trial data** (MS/EMA) and create **Union Control Reports** (COM)

Public

Public users (Healthcare professionals, patients, other)

Will **search for publicly available clinical trial data** in CTIS