EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trials Regulation – what is changing in practice?

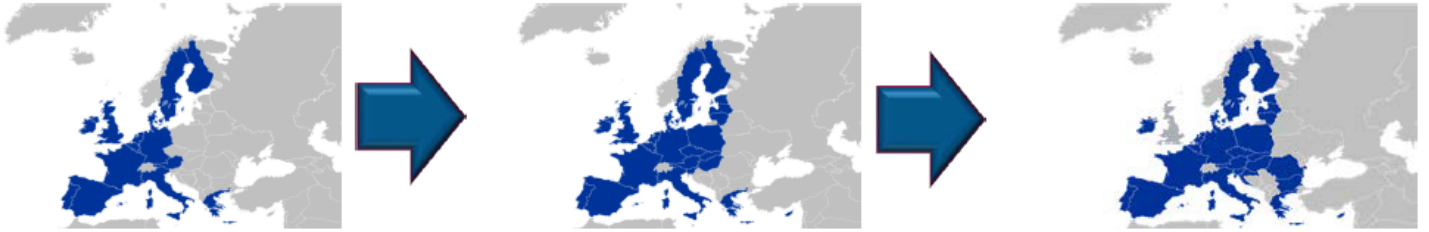
SME and academia Clinical Trials Information System (CTIS) two-part training webinar

Presented by Stéphanie Kromar on 22 February 2021
Sr. Regulatory Affairs Manager, European Organization for research and treatment of Cancer (EORTC)

An agency of the European Union

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.

The CT Regulation: *from where we come?*



...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

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency

Increased Transparency

Enhanced Patient Safety

Support to Innovation & Research

- The **single EU entry point** for clinical trial application submissions for sponsors (e-dossier)
  A single application and maintenance process, dossier and timeline; covering clinical trial application to NCA, submission to ethics committee and registration of the clinical trial in a public register; all in one integrated submission
- Harmonised and simplified **end-to-end electronic application procedures** over the life-cycle of clinical trials across the EU
- Collaboration and **coordination in evaluation and supervision of clinical trials** for Member States
- Fully **electronic exchange** of information between sponsors and Member States
- Digital secured **archive** of documents, decisions and information on a clinical trial

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency | *Increased Transparency* | *Enhanced Patient Safety* | *Support to Innovation & Research*

- Offers searchable **clinical trial information** to the patient, the healthcare professional and the general public
- Clinical trial **results available in lay language**
- Information can be retrieved for the life-cycle of a **clinical trial or investigational medicinal product** across trials

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency

Increased Transparency

Enhanced Patient Safety

Support to Innovation & Research

- Patient safety is enhanced in clinical trials as CTIS provides an end-to-end electronic solution for safety reporting of trials
- CTIS facilitates a harmonised assessment in Europe, supported by agreed assessment report templates
- The clinical trial module of EudraVigilance is updated for the electronic reporting of SUSARs by sponsors and re-routing to Member States
- CTIS provides for one single decision per Member State Concerned
- CTIS delivers an electronic Annual safety reports (ASRs) repository

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency

Increased Transparency

Enhanced Patient Safety

Support to Innovation & Research

- CTIS is a unique intuitive tool that facilitates submission of clinical trial applications including those for trials across borders and for investigation of rare diseases. It thereby also supports academic innovative work.
- CTIS offers structured data to allow efficient reporting for scientists
- A clinical trial can be extended to more Member States e.g. to enhance recruitment rates without resubmission/reassessment of the clinical trial application. The implemented CTIS timelines can be shortened.

Transition period

Year 1

From Go Live

Sponsors may apply for a new trial authorisation under old legislation (EudraCT etc) or new CTR (CTIS) at their own choice.

Member States must all be ready to use CTIS from day 1 (and still run the old process as well).

Year 2 and 3

Clinical trials authorised under the old directive may continue under that directive, but may already switch to the CTIS at sponsor choice

Any new clinical trial application must be submitted and managed via CTIS.

By Dec 2024 at latest all trials authorised under the old directive/legislation must end or have been transferred to CTIS by the sponsor.

Any questions?

Further information

CT.Sponsortraining@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
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