EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CTIS key benefits

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EMA Clinical trial sponsor training for SME and academia

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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.

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency

Increased Transparency

Enhanced Patient Safety

Support to Innovation & Research

- Unique digital tool for harmonised submission, evaluation and supervision and storage of structured data and documents on clinical trials in the European Union.
- End-to-end fully electronic process over the life-cycle of a clinical trial.
- Member States benefit from tools for collaboration and coordination.
- Clinical trial sponsors can submit, manage and report on a trial in one single place throughout the lifecycle of this trial. CTIS allows flexibility to submit dossiers in parts.
- Easy access to structured data and documents on clinical trials for patients, healthcare professionals, scientists and the general public.

Clinical Trials Information System - CTIS

Digitalisation & Improved Efficiency

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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

CTIS – three-year transition period

Year 1, starting from launch of CTIS

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

CTIS - User groups have dedicated work spaces

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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

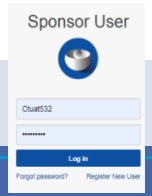
secure access

open access

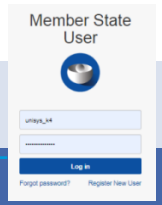
sponsor workspace

authority workspace

public website



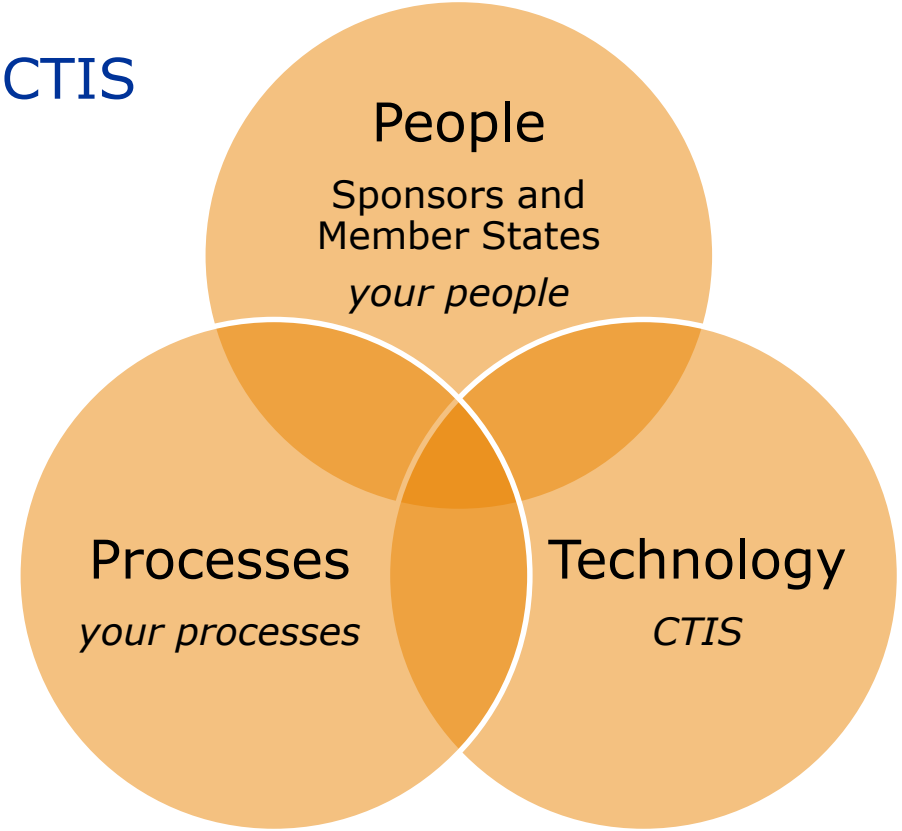
EU Portal



EU CT Database

Data accessible to the public

Preparing for CTIS



CTIS – next steps

- *Focus: Put effort now into preparing for CTIS GoLive*
- *Get ready: Define functions and processes embedding CTIS, define the form of your organisation, choose the people to work with CTIS, train the people*

Any questions?

Further information

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