EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Clinical Trial Information System (CTIS)

How to get started and how to transition a trial

1. How to get started

Getting started with CTIS

Prior to starting using CTIS, make sure to have the following**:**

- EMA account
- Sponsor organisation registered in OMS
- Sponsor Administrator registered in IAM
- Sponsor organisation registered with EudraVigilance

Monitor Extended EudraVigilance medicinal product dictionary (XEVMPD) page for 1 day online courses.

For a quick interactive guide, please consult the Sponsor quick guide.

General useful information

- Online modular training and relevant Guidance to CTIS training material catalogue
- Training module 02: high-level overview of CTIS workspaces and common system functionalities
- Sponsor handbook
- Publication rules: quick user guide
- Set of documents applicable to trials authorised under Regulation EU No 536/2014, in particular:
  - Chapter I - Application and application documents
  - Questions and Answers Document - Regulation (EU) 536/2014
  - Quick guide for sponsors - Regulation 536/2014 in practice

Live demo and information on creation of new clinical trial application (CTA) in CTIS:

- Module 07 (Online modular training): Management of registered users and role matrix
  - How to create a CT: Clinical Trial centric approach vs organisation centric approach

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  - How to request roles and how to assign roles to register users in CTIS
- Module 10 (Online modular training): Create, submit, and withdraw a clinical trial: e-learning course: initial clinical trial applications (Chrome browser recommended)
- e-learning course: other types of clinical trial applications (Chrome browser recommended)
- Create, submit and withdraw a clinical trial application and non-substantial modifications:
  - Step-by-step guide
  - Instructor's guide
  - Frequently asked questions (FAQs)
- Video instructions on "How to submit an initial clinical trial application in CTIS":
  - Fill in the Form and the MSC sections
  - Fill in the Part I section
  - Fill in the trial details of Part I section
  - Fill in the Sponsor details of Part I section
  - Fill in the Product details of Part I section
  - Fill in the Part II section
  - How to submit a substantial modification in the CTIS Sponsor workspace
  - How to submit an additional Member State concerned application in the CTIS Sponsor workspace

Supporting materials

- Additional supporting materials are available on the EMA webpage CTIS Training and Support
- For regular updates on the CTIS Programme, subscribe to Clinical Trials Highlights
- Bite size talk: Initial clinical trial application (including presentation)
- Module 19 (Online modular training): CTIS for SMEs and Academia
  - Quick guide - Introduction
  - Step-by-step guide: User administration

2. How to transition a trial

Any clinical trial that is expected to continue after 30 January 2025 needs to be transitioned to CTIS. Please find below a collection of resources to assist sponsors throughout this process.

- Guidance for the transition of clinical trials published by the European Commission under EudraLex volume 10
- CTCG's best practice guide for sponsors of transitional trials, along with Annex I: Cover letter template and Annex II: Fees for transitional trials in EU/EEA Member States
- CTCG's best practice guide for sponsors updating Part I documents at the time of the first Substantial Modification Part I after a trial dossier was transitioned from the Clinical Trials Directive

to the Clinical Trials Regulation, along with the templates for the cover letter and Substantial Modification

- Module 23 of the CTIS online training programme
- Chapter 5 of the CTIS Sponsor Handbook
- Bitesize talk: How to submit a transitional trial in CTIS (including presentation)
- Bitesize talk: How to submit a transitional trial in CTIS
- Bitesize talk: Transitional trials and additional Member State concerned (MSC) application (including presentation)
- Clinical Trials Information System Webinar: Second Year of Transition (including presentation)
- Clinical Trials Information System Webinar: Last year of transition
- Training for non-commercial sponsors: Transitioning trials to the CTR and CTIS

In case of technical issues encountered during the submission of a transitional trial application, sponsors should raise a ticket on ServiceNow.