



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](#)

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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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.

- First Substantial Modification (SM): document requirements after a trial dossier is transitioned from the Clinical Trials Directive to the Clinical Trials Regulation
 - [CTCG Best Practice Guide to sponsors updating the application dossier Part I after CTR transition vs 2.0](#)
 - [Annex I Cover letter template First SM after vs 2.0](#)
 - [Annex II Substantial modification template First SM after transition vs 2.0](#)

- [Annex III First SM Part II after transition vs. 1.0](#)
- [Guidance for the transition of clinical trials](#) published by the European Commission under EudraLex volume 10
- CTEG'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](#)
- 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](#)
- Walk in clinic: [Responding to questions dedicated to transition](#)

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