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


General useful information

- [Training module 02](https://www.ema.europa.eu/en/medicines/products): high-level overview of CTIS workspaces and common system functionalities
- [Set of documents applicable to trials authorised under Regulation EU No 536/2014](https://www.ema.europa.eu/en/medicines/products), 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:

  - How to create a CT: [Clinical Trial centric approach vs organisation centric approach](https://www.ema.europa.eu/en/medicines/products)
  - 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

• 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 and cover letter template for sponsors of transitional trials

• Module 23 of the CTIS online training programme

• Bitesize talk: How to submit a transitional trial in CTIS (including presentation)

• Bitesize talk: Transitional trials and additional Member State concerned (MSC) application (including presentation)

• Clinical Trials Information System Webinar: Second Year of Transition (including presentation)
In case of technical issues encountered during the submission of a transitional trial application, sponsors should raise a ticket on ServiceNow.