Portugal Clinical Trials

*CTIS – Training Guide for contents published by EMA:

The following documents are relevant for Sponsors and Investigators who intend to implement the Clinical Trials Regulation 536/2014 of 16 April, in their training processes and programs:

- The European Medicines Agency (EMA) has published a document intended as a guide for Sponsors to use the new European clinical trial information and submission system – CTIS: Clinical Trial Information System – Sponsor Handbook
- This document will be continuously updated by EMA with new information, so the Sponsors must verify that they are looking at the most recent version, and may also send proposals and comments to the document via a form developed for this purpose: feedback form.
- The European Commission has been approving and making available in volume 10 of Eudralex, a set of documents that are applicable to clinical trials since the respective Regulation came into force. To access the documents applicable to the new Clinical Trials Regulation, see: EudraLex - Volume 10 - Clinical trials guidelines | Public Health (europa.eu)
- Before the CTIS became available, on January 31, 2022, EMA provided training documents on the system for all the stakeholders involved, as well as the respective support material.

- **The resources made available include:**
  - Online training Modules
  - Sponsor Handbook
  - Reference documents for Sponsors and Authorities
  - Master's training program for users
  - Training sessions on CTIS

- **Training sessions on CTIS and respective presentations are available on EMA´s website, with a special focus on training Sponsors and Academy small and medium-sized companies:**

    - Webinar for small and medium-sized enterprises (SMEs) and academia on the Clinical Trials Regulation and the Clinical Trials Information System (CTIS) (29/11/2021) that presents an overview of the CTR, an introduction to the new clinical trial submission process, as well as the CTIS functionalities.
    - SME and academia Clinical Trials Information System (CTIS) two-part training webinar - Day 2 (04/03/202) that presents a generic view of CTIS, user access management (including how to register users), user management by Sponsors and permissions and roles of Sponsors on CTIS.
    - SME and academia Clinical Trials Information System (CTIS) two-part training webinar - Day 1 (22/02/2021) that presents the submission of a new clinical trial application in CTIS, the update of an initial clinical trial application and its substantial modifications as well as the addition of a new involved Member State, the non-substantial modifications and the submission of clinical trial results.

- EMA has also recently organized information sessions on CTIS for all parties involved, with the respective supporting documentation available on the EMA website:
    - Clinical Trials Information System (CTIS): Virtual information day (26/10/2021)
    - Clinical Trials Information System (CTIS) webinar: How sponsor organisations can prepare for CTIS (29/07/2021)
    - EMA Clinical Trial Information System (CTIS) webinar: dynamic demo of sponsor workspace (21/09/2020)

- For additional information regarding CTIS training sessions see the EMA website: CTIS highlights.

Additional information:

EMA provides CTIS user personas to help organizations and individuals, who will work with CTIS, determine who the users will be and their associated tasks.

The first version of the Principles for Sponsor organisation modelling for CTIS was published by EMA. This document is intended to help Sponsors preparing to use the CTIS and provides information and examples of internal organization models for Sponsors and the accesses necessary for using CTIS.

For **small and medium-sized Sponsors companies and academia**, the following modules of the EMA modular online CTIS training program are relevant:

- Module 19 - CTIS for SMEs and academia:

  - ✓ Quick guide - Introduction
  - ✓ Step-by-step guides:
    - Step-by-step guide 1: User access management and user administration
    - Step-by-step guide 2: CTIS workload functionalities for the sponsor workspace
    - Step-by-step guide 3: Search, view and download a CT and a CTA in the sponsor workspace
    - Step-by-step guide 4: Create, submit and withdraw a clinical trial application and nonsubstantial modifications
    - Step-by-step guide 5: Create and submit an RFI response, including changes to an existing application
    - Step-by-step guide 6: How to manage a clinical trial
    - Step-by-step guide 7: Submit an ASR and how to respond to related RFIs

- Module 3– *User access management*

  - ✓ Quick guide
  - ✓ Instructor's guide
  - ✓ Frequently asked questions (FAQs)
  - ✓ Vídeos:
    - Registration of a new CTIS user
    - Registration of a new organisation in CTIS
    - CTIS password recovery and User profile functionalities

- Module 7 – *Management of registered users and role matrix*

  - ✓ e-learning course
  - ✓ Instructor's guide
  - ✓ Step-by-step guide (high-level CTIS administrator)
  - ✓ Frequently asked questions (FAQs)
  - ✓ Supporting materials:
    - Sponsor workspace: summary of roles
    - Sponsor workspace: summary of role permissions
  - ✓ Vídeos:
    - Creating a clinical trial: Clinical trial centric approach vs organisation centric approach
    - How to request roles and how to assign roles to registered users in CTIS
    - How to amend and revoke roles of registered users in CTIS
    - How to request the CTIS high level Administrator role via IAM
    - How to approve requests for CTIS Administrator role and how to remove CTIS Admin role

- Module 10 - Create, submit and withdraw a clinical trial

  - ✓ e-learning course
  - ✓ Instructor's guide
  - ✓ Frequently asked questions (FAQs)
  - ✓ Supporting materials:

    - Process puzzle
    - Checklist of required fields per application type
- ✓ Vídeos:
    - How to submit an initial clinical trial application in CTIS – Fill in the Form and the MSC sections
    - How to submit an initial clinical trial application in CTIS Sponsor workspace – Fill in the Part I section
    - How to submit an initial clinical trial application in CTIS – Fill in the trial details of Part I section
    - How to submit an initial clinical trial application in CTIS – Fill in the Sponsor details of Part I section
    - How to submit an initial clinical trial application in CTIS – Fill in the Product details of Part I section
    - How to submit an initial clinical trial application in CTIS – 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

- Module 11 - Respond to requests for information received during the evaluation of a clinical trial application

- ✓ e-learning course
- ✓ Instructor's guide
- ✓ Frequently asked questions (FAQs)
- ✓ Supporting materials:
    - Process puzzle
- ✓ Videos:
    - How to access and view an RFI in CTIS
    - How to change a Clinical Trial Application as part of an RFI response
    - How to respond to RFI considerations and submit an RFI response