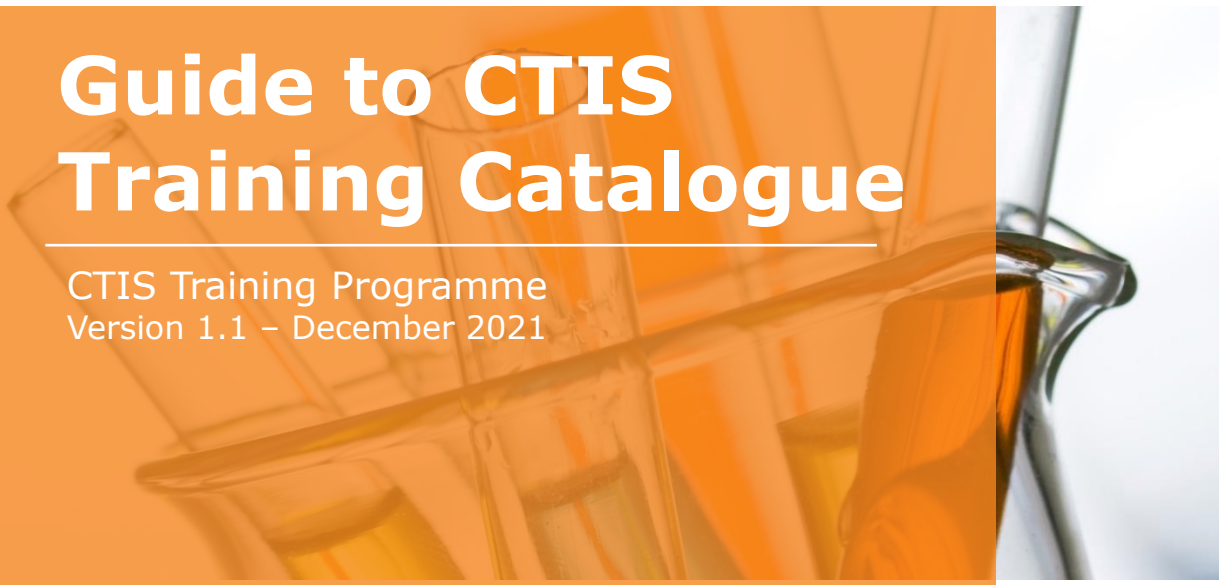
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guide to CTIS Training Catalogue

CTIS Training Programme
Version 1.1 – December 2021



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.

Training Modules

The training programme is divided into **learning modules targeted for the different user groups** involved in CTIS. These modules aim to ensure a clear understanding of the different process of the system.

Please find below the list of modules:

- **Module 1:** Introduction to the Clinical Trials Regulation
- **Module 2:** Overview of CTIS workspaces and common system functionalities
- **Module 3**: User Access Management
- **Module 4:** Support with workload management by workspace
- **Module 5:** How to manage a Clinical Trial *(Notifications, Ad hoc assessment, Corrective measures, and Trial results)*
- **Module 6:** Evaluate a Clinical Trial Application *(Selection of Reporting Member State (RMS) and validation of the clinical trial application)*
- **Module 7:** Management of registered users and role matrix
- **Module 8:** Evaluate a Clinical Trial Application: Assessment and Decision-making
- **Module 9:** How to search, view and download a Clinical Trial and a Clinical Trial Application *(Sponsors)*
- **Module 10:** How to create, submit and withdraw a Clinical Trial Application
- **Module 11:** How to respond to Requests For Information received during the evaluation of a Clinical Trial Application
- **Module 12:** Data protection in CTIS
- **Module 13:** Clinical Study Reports submissions
- **Module 14:** Supervise a Clinical Trial – Corrective measures
- **Module 15:** How to search, view and download a Clinical Trial and a Clinical Trial Application *(Authority)*
- **Module 16:** Supervise a Clinical Trial – Inspection records
- **Module 17:** Supervise a Clinical Trial – Ad hoc assessment *(including safety)*
- **Module 18:** How to submit an Annual Safety Report and respond to related Requests for Information
- **Module 19:** CTIS for SMEs and academia
- **Module 20:** Assess an Annual Safety Report
- **Module 21:** Manage Union Controls
- **Module 22:** Introduction to CTIS for Public Users
- **Module 23:** Transition of trials from EudraCT to CTIS
- **Module 24:** Business Intelligence Reporting

Training Materials

Due to the high volume of end-users, the training programme focuses on **online learning materials.** The materials and tools have been chosen considering the **user groups and learning objectives** involved in each module.

Please find below a summary of each training material:

eLearning

Interactive presentation including a detailed explanation of the process that can be viewed and completed by users at their own pace.

Quick guide

Document that presents key information about specific system functionalities and steps in the system.

Video

Video-clips that show a demonstration step by step of the process.

Step-by-step guide

Document summarising the basic steps of the process.

FAQ's

List of Frequently Asked Questions regarding the information of each module.

Infographic

Visual representation of key information.

Additional support document

Ad hoc documentation to support the dissemination of specific content.

Instructor's guide

How-to guides for Master Trainers to support consistent knowledge dissemination.

CTIS High-level processes

CTIS is the single-entry portal for submitting clinical trials information in the EU. The system supports the **day-to-day business processes of authorities and sponsors** throughout the life-cycle of a clinical trial.

Below, users can find an overview of the main topics of CTIS, as well as the life cycle process flow of a clinical trial and in which module they can find the related information per audiences:

Users

General CTIS information

CTIS introduction
- Module 1
- Module 2
- Module 12

User management
- Module 3
- Module 7

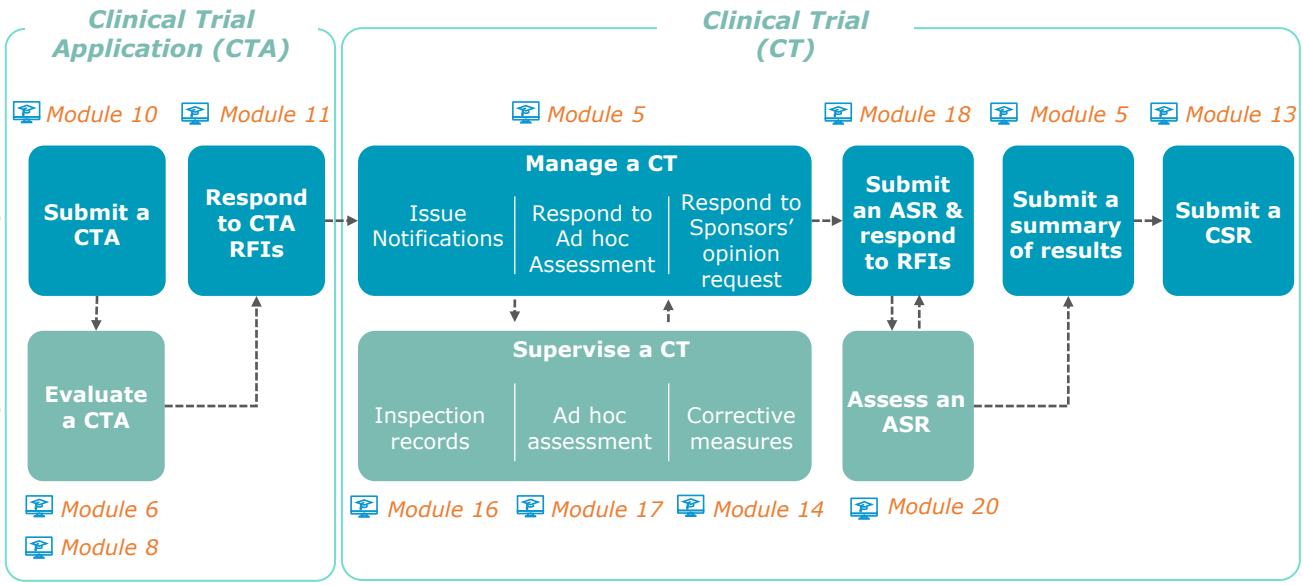
CTIS management
- Module 4
- Module 9
- Module 15
- Module 23

Others (Union Controls & Business Intelligence)
- Module 21
- Module 24

SMEs and academia
- Module 19

Introduction for public users
- Module 22

Clinical trial life cycle in CTIS



User group

Sponsors | Member States | European Commission | Public Users

Note: This is a high-level illustration of the process and does not necessarily apply in the exact same way to every occurrence.

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