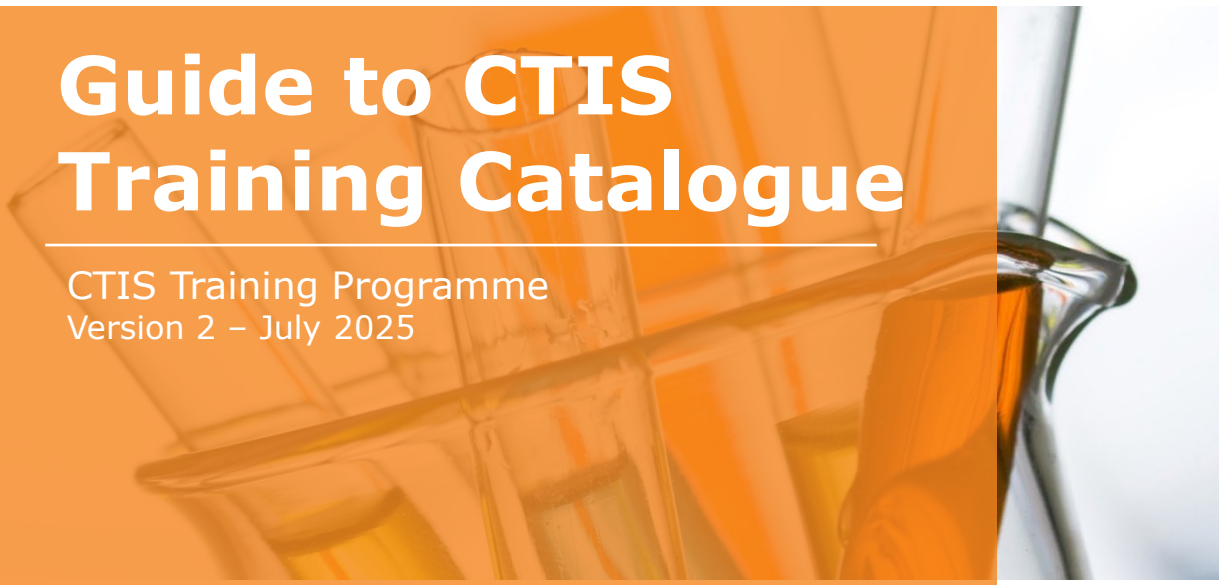
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guide to CTIS Training Catalogue

CTIS Training Programme
Version 2 – July 2025



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.

Record of updated versions

Version	Version description	Date
2	Update of the catalogue to replace the sponsor facing documents with the Sponsor handbook references	July 2025
1.3	Module 12 – 'Data protection in CTIS' video link *updated*	August 2024
1.2	Training material version published at CTIS go-live.	January 2022

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Training Materials

The training materials are **targeted for the different user groups** involved in CTIS. These training documents aim to ensure a clear understanding of the different process of the system.

Please find below the structure of the training material for sponsors:

Sponsor users should refer to this page for all sponsor facing training materials

Sponsor workspace

- **Sponsor Handbook:**

1. **Pre-submission steps:** Covers the foundational setup before submitting a clinical trial application
    - Gain access to EMA systems (CTIS, OMS, EV, XEVMPD).
    - Register sponsor organisations and medicinal products.
    - Assign user roles and manage access in CTIS.
2. **Apply for a CT authorisation:** Guidance on submitting a new clinical trial application
    - Understand publication rules.
    - Complete required data fields and documents.
    - Submit, track, and manage the Initial Application (IN).
3. **Evaluation Phase:** Follow the assessment process
    - Monitor evaluation steps and timelines.
    - Respond to any Requests for Information (RFIs).
4. **Conduct a clinical trial:** Manage the trial lifecycle
    - Notify authorities of key events.
    - Submit and manage modifications (AM, SM, NSM).
    - Handle safety reporting and inspections.
5. **End of the Clinical Trial & submit results:** Steps to close the trial and report outcomes
    - End-of-trial notification.
    - Submit results, summaries, and the Clinical Study Report (CSR).
6. **CTIS training and support:** Resources for users
    - Release notes and known issues.
    - Training materials.
    - Helpdesk contact.

Training Materials

The training materials are **targeted for the different user groups** involved in CTIS. These training documents aim to ensure a clear understanding of the different process of the system.

Note: *Authority users should refer to the **Sponsor handbook** for an introduction and overview of CTIS workspaces, and the technical requirements for optimal use*

Please find below the list of documents:

Authority users should refer to this page for all sponsor facing training materials

Authority workspace

- **Module 4:** Support with workload management *(Authority)*
- **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 *(Authority)*
- **Module 8:** Evaluate a Clinical Trial Application: Assessment and Decision-making
- **Module 12:** Data protection in CTIS
- **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 20:** Assess an Annual Safety Report
- **Module 21:** Manage Union Controls
- **Module 24:** Business Intelligence Reporting

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 what training material they can find the related information per audiences:

Users

General CTIS information

CTIS introduction
- Sponsor Handbook
- Module 12 (Authority)

User management
- Sponsor Handbook
- Module 7 (Authority)

CTIS management
- Sponsor Handbook
- Module 4 (Authority)
- Module 15 (Authority)

Others (Union Controls, and Business Intelligence)
- Module 21 (Authority)
- Module 24

SMEs and academia
- Sponsor Handbook

Introduction for public users
- Sponsor Handbook

Clinical trial life cycle in CTIS

Clinical Trial Application (CTA)

Sponsor Handbook

- **Submit a CTA**
- **Respond to CTA RFIs**
- **Evaluate a CTA**

Module 6
Module 8

Clinical Trial (CT)

Sponsor Handbook

- **Manage a CT**: Issue Notifications | Respond to Ad hoc Assessment | Respond to Sponsors' opinion request
- **Supervise a CT**: Inspection records | Ad hoc assessment | Corrective measures
- **Submit an ASR & respond to RFIs**
- **Assess an ASR**
- **Submit a summary of results**
- **Submit a CSR**

Module 16 | Module 17 | Module 14 | Module 20

Click on the icon to see the training materials

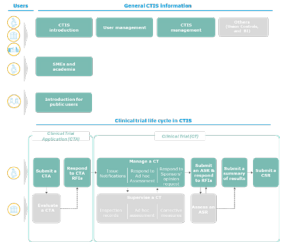
Click here to access the materials for authority users and here for the materials for sponsor users

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.

SPONSOR WORKSPACE



Sponsor Handbook

Learning objectives:

- Learn how to navigate the Clinical Trials Information System (CTIS) from pre-submission steps through trial conduct, modifications, and result submissions.
- Gain knowledge of the legal, procedural, and technical requirements for sponsor registration, user role assignment, and data protection obligations under the Clinical Trial Regulation (EU) No 536/2014.
- Learn how to submit substantial and non-substantial modifications, handle safety-related events (e.g., SUSARs, ASRs), and respond to Requests for Information (RFIs) from Member States.

Clickable Table of Contents

Interactive navigation to quickly access specific sections of the trial lifecycle and system functionalities.

Step-by-Step Procedural Guides

Detailed walkthroughs for tasks such as submitting applications, responding to RFIs, and managing user roles

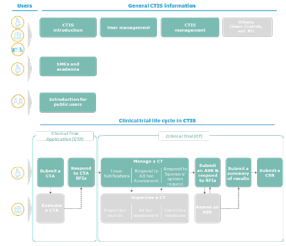
Embedded Video Tutorials and event recordings

Links to EMA-hosted videos demonstrating CTIS functionalities, including user access, application submission, and safety reporting.

Annexes

Includes acronyms, regulatory definitions, and links to external resources like EudraLex and CTCG guidelines.

This handbook consolidates and replaces all content from the former Sponsor Workspace training modules, offering a single, comprehensive reference for navigating CTIS.

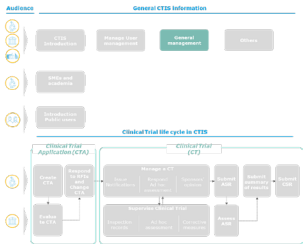


SPONSOR WORKSPACE

Sponsor Handbook – snapshot of structure

Clickable table of contents

AUTHORITY WORKSPACE - CTIS MANAGEMENT



Module 4:

Support with workload management in the authority workspace

Learning objectives:

- Remember the main system functionalities enabling efficient workload management in the authority workspace.
- Understand the use of the Requests for information (RFI) list functionality.
- Remember the use of the Notices & Alerts functionality.
- Understand the use of the Timetable supporting the monitoring of a specific clinical trial application.

eLearning Authority

Interactive presentations to familiarise the users with CTIS' functionalities that support the workload management in the Authority workspace and highlight the specificities of the workspace.

Video – clips

Clip 1: How to manage the workload in CTIS - Tasks tab (authority workspace)
Clip 2: How to manage the workload in CTIS - Timetable

FAQ's

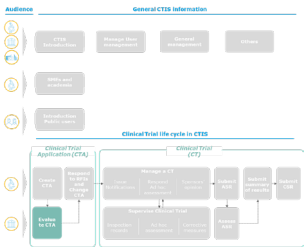
List of common questions and answers related to each of the main system functionalities enabling efficient workload management in CTIS, including the Tasks, the Request for Information (RFI), the Notices & Alerts and the Timetable.

Step-by-step guide - Authority

Short step by step documents of the basic processes described in the module (one for sponsors and another one for authority users).

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE - EVALUATE A CLINICAL TRIAL APPLICATION



Module 6:

Evaluate a clinical trial application (Selection of Reporting Member State (RMS) and validation of the clinical trial application)

Learning objectives:

- Understand the different types of Clinical Trials Applications (CTAs).
- Understand the evaluation process of an initial CTA and the common aspects in the different types of CTAs.
- Understand the Reporting Member State (RMS) selection process for a multinational CTA.
- Understand the validation phase for an initial application.

eLearning

An interactive presentation providing an overview of the evaluation process and the types of CTAs; the RMS selection process and the validation of an initial multinational CTA.

Video – clips

- **Clip 1:** RMS Selection
- **Clip 2**: Validation – Document considerations
- **Clip 3:** Validation – RFI and issue validation decision

FAQ's

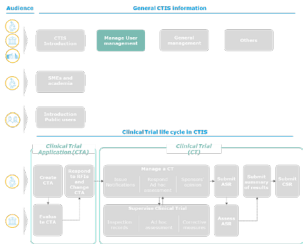
Compilation of a list of common questions about the different types of Clinical Trials Applications (CTAs) that are provided for in the CT Regulation; questions about the evaluation phases; questions about the RMS selection, and questions about the validation phase of an initial application.

Step-by-step guide

Brief and practical guide with system screenshots to show users the different scenarios withing the RMS selection process and examples of possible scenarios.

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE – USER MANAGEMENT



Module 7:
Management of roles and permissions

Learning objectives:

- Remember the basic principles of user management in CTIS.
- Understand the roles and permissions and their hierarchy in CTIS.
- Understand the permissions linked to the roles and their implications to perform actions in CTIS.
- Remember how administrators can manage users in CTIS.
- Remember how roles can be viewed and managed in CTIS.

FAQ's

List of common questions and answers about roles and permissions; the two user management approaches available in CTIS; user profile and user administration functionalities and types of roles.

Video – clips

- **Clip 1:** How to request roles and how to assign roles to registered users in CTIS
- **Clip 2:** How to amend and revoke roles of registered users in CTIS

Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 7. Specific activities are proposed to support users' understanding of the process.

Step-by-step guide

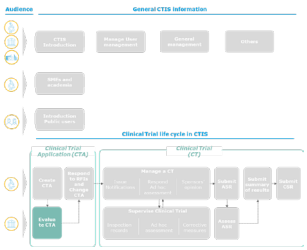
Brief and practical guide with system screenshots to show users how to request the High-level Administrator role for CTIS.

Supporting documents

- Member States Processes and Roles
- Member States Roles and Permissions matrix
- Notices and Alerts per role

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE - EVALUATE A CLINICAL TRIAL APPLICATION



Module 8:

How to evaluate an Initial Clinical Trial Application: Assessment and Decision

Learning objectives:

- Remember the phases and associated timelines for evaluating an initial Clinical trial application (CTA).
- Understand the process and the user roles involved in the Assessment of Part I II of an initial CTA as a Reporting Member State (RMS) and as a Member State Concerned (MSC).
- Understand the process and the user roles involved in the Assessment of Part I II of an initial CTA as an MSC.
- Understand the process and the user roles involved in the Decision regarding the authorisation of an initial CTA.
- Remember the workload functionalities in CTIS that allow users to monitor their tasks during the evaluation of an initial CTA.

Quick guide

Introduction: CTTM08 - Quick Guide - Introduction (europa.eu)
Part I: CTTM08 - Quick Guide - Part I (europa.eu)
Part II: CTTM08 - Quick Guide - Part II (europa.eu)
Decision: CTTM08 - Quick Guide - Decision (europa.eu)

Video – clips

- **Clip 1:** How to assess an initial clinical trial application in CTIS – Part I
- **Clip 2**: How to assess an initial clinical trial application in CTIS – Part II
- **Clip 3:** How to submit the final decision on the clinical trial application in CTIS (Authority)

FAQ's

List of Frequently Asked Questions regarding the assessment and decision of a CTA.

Step-by-step guide – Add MSC

Step-by-step guide - SM

Short step by step documents of two basic processes described in the module:

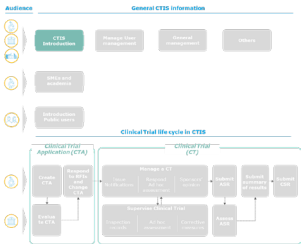
- How to evaluate an Additional Member state concerned clinical trial application
- How to evaluate a Substantial modification clinical trial application

Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 8. A specific activity is proposed to support users' understanding the information.

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE - CTIS INTRODUCTION



Module 12:

Overview of CTIS workspaces and common system functionalities

Learning objectives:

- Remember the basic principles of the EU data protection framework.
- Remember the implications of data protection law for all the actors involved in the operation of CTIS.
- Understand the processing activities for each user group and the related responsibilities.
- Understand how CTIS supports compliance with data protection obligations.

eLearning

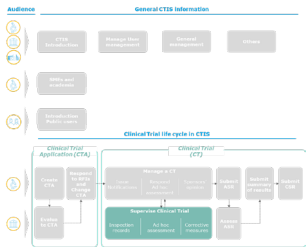
Interactive presentation to explain the user on how CTIS supports compliance with the GDPR/EUPDR.

Video – clips

Clip 1: Data protection in CTIS

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE - SUPERVISE A CLINICAL TRIAL



Module 14:

Supervise a clinical trial: Corrective measures

Learning objectives:

- Understand what a corrective measure is, when can be created and the types.
- Understand how to create and cancel a corrective measure.
- Understand how to consult other MSCs on an intended corrective measure.
- Understand how to request the sponsor's opinion.
- Understand how to apply a corrective measure and how to update and revert an existing one.
- Understand the roles and permissions involved in the corrective measure functionality

eLearning

An interactive presentation that provides a detailed explanation of the corrective measure process during the supervision phase of a Clinical Trial (CT).

Video – clips

- **Clip 1**: How to create and cancel a Corrective Measure (Authority)
- **Clip 2**: How to submit, update and revert a Corrective Measure (Authority)

FAQ's

List of Frequently Asked Questions regarding the creation, consultation with other MSCs, request for sponsors' opinion, submission and roles and permission involved in the management of the corrective measure.

Step-by-step guide

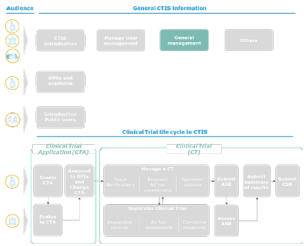
Short step by step document to show the users how to create, submit, update and revert a corrective measure.

Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 14. A specific activity is proposed to support users' understanding the information.

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE - CTIS MANAGEMENT



Module 15:

How to search, view and download a CT and a CTA (Authority)

Learning objectives:

- Remember how to search for a clinical trial (CT) and a clinical trial application (CTA).
- Understand how to view the information displayed in a CT and a CTA.
- Understand how to download information and associated documents.
- Understand which user roles can view and download specific CT/CTA information.

Quick guide

Practical and simple guide with system screenshots to show users how to search for a CT and a CTA, the information displayed in the clinical trial page sub-tabs and clinical trial application page sections, and the information and formats available for download.

Video – clips

- **Clip 1:** How to search for a CTs in the authority workspace
- **Clip 2:** How to view and download CTs in the authority workspace

FAQ's

List of Frequently Asked Questions regarding the search functionalities available in CTIS, how to view CTs and CTAs information, and how to download CT and CTAs and available file types.

Step-by-step guide

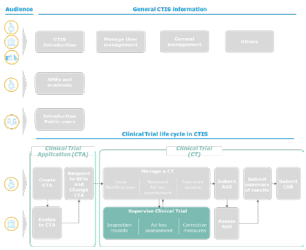
Short and practical document that includes the most relevant steps of the processes described in the module

Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 15.

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE - SUPERVISE A CLINICAL TRIAL



Module 16:

Supervise a clinical trial: Inspection record

Learning objectives:

- Remember what an inspection record is and when an MSC can create one.
- Understand how to create and submit an inspection record.
- Understand how to search, view, update and cancel an inspection record.
- Understand which user roles are involved in the inspection record process

eLearning

An interactive presentation that provides a detailed explanation on how to complete the inspection record form in CTIS when an inspection is requested as part of the supervision of a Clinical Trial (CT).

Video – clips

- **Clip** 1: How to create an inspection record and how to populate the General information section
- **Clip 2**: How to populate the Inspections section
- **Clip 3**: How to populate the overall inspection outcome and update and cancel an inspection record

FAQ's

List of Frequently Asked Questions regarding the following aspects: General information, creation and submission, search and update of the inspection records, inspection outcomes and reports; and Roles and permissions.

Step-by-step guide

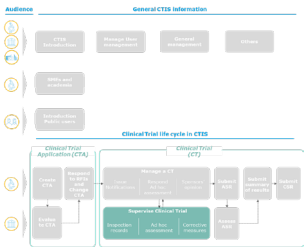
Document summarising the basic steps of the inspection record process.

Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 16. A specific activity is proposed to support end-users' understanding of process.

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE - SUPERVISE A CLINICAL TRIAL



Module 17:

Supervise a clinical trial: Ad hoc assessment

Learning objectives:

- Remember what an ad hoc assessment is and when an MS can create one.
- Understand how to create, cancel, save, and share an ad hoc assessment.
- Understand how to raise an RFI, consult with other MSs, update and complete an ad hoc assessment.
- Understand how to search, view, and download an ad hoc assessment.
- Understand which user roles are involved in the ad hoc assessment process.

eLearning

An interactive presentation is an adequate format to present the information regarding the ad hoc assessment due to the complexity of the content, as well to present the steps that users need to follow to complete the process.

Video – clips

- **Clip 1**: How to create an Ad hoc assessment - CT selection and assessment details
- **Clip 2**: How to create an Ad hoc assessment - Discussion with MSs and create Requests for Information
- **Clip 3**: How to update and complete an Ad hoc assessment

FAQ's

List of Frequently Asked Questions regarding general information of an ad hoc assessment, the creation, update and completion of an ad hoc assessment, the request for information and consultation with other MSs, the search, view and download of an ad hoc assessment; and roles and permissions.

Step-by-step guide

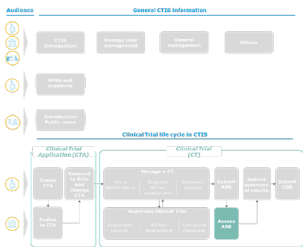
Short step by step document to show the users how to create, complete, search and view an ad hoc assessment.

Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 17. A specific activity is proposed to support users' understanding of the process.

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE - ASSESS AN ASR



Module 20:
Assess an Annual Safety Report

Learning objectives:

- Remember what an Annual Safety Report (ASR) is and when a sponsor can submit one.
- Understand the phases of the assessment of an ASR.
- Understand how to search, view, and download an ASR.
- Understand how to assess an ASR.
- Understand how to request additional information to the sponsor.
- Understand the roles and permissions involved in the ASR process.

eLearning

Interactive presentation that provide a detailed explanation of the ASR assessment process and the steps that users need to follow.

Video – clips

- **Clip 1**: Search and view an ASR and saMS selection
- **Clip 2**: Circulate draft ASR - AR, create and consolidate consideration
- **Clip 3:** Submit ASR RFIs, assess RFI responses, and finalise ASR assessment

FAQ's

List of Frequently Asked Questions including general questions on ASR, the process of assessing an ASR, the process of creating a Request for Information (RFI) related to an ASR, and the ASR roles and permissions.

Step-by-step guide

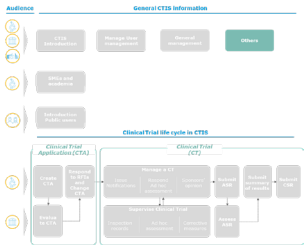
Short step by step document to show the users how to assess an ASR (from the point of view of the saMS), and how to create an RFI as part of the assessment of an ASR.

Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 20. A specific activity is proposed to support users' understanding the information.

Click on the icons or links to see the training materials

AUTHORITY WORKSPACE – OTHERS (Union Controls, Transitional trials & Business Intelligence)



Module 21:
Manage Union Controls

Learning objectives:

- Remember what a Union Control is and when a European Commission user can create one.
- Understand how to create and submit a Union Control report.
- Understand how to view, download, update and withdraw a Union Control report.
- Understand the roles and permissions involved in the Union Controls process.

eLearning

An interactive presentation to familiarise users with the plan/programmes for Union Controls, the creation, viewing, downloading and updating of Union Controls and the roles and permissions involved in the process.

FAQ's

List of Frequently Asked Questions regarding the processes of creating and sharing the Plans/Programmes for Union Controls, and creating and submitting Union Controls reports.

Step-by-step guide

Brief and practical guide with system screenshots to show users the main steps of the Union Control process.

Click on the icons or links to see the training materials

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Clinical Trials Information System (CTIS)
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