



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guide to CTIS Training Catalogue

CTIS Training Programme
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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 (*To be developed*)

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:



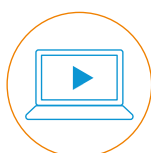
eLearning

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.



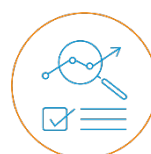
Step-by-step guide

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.

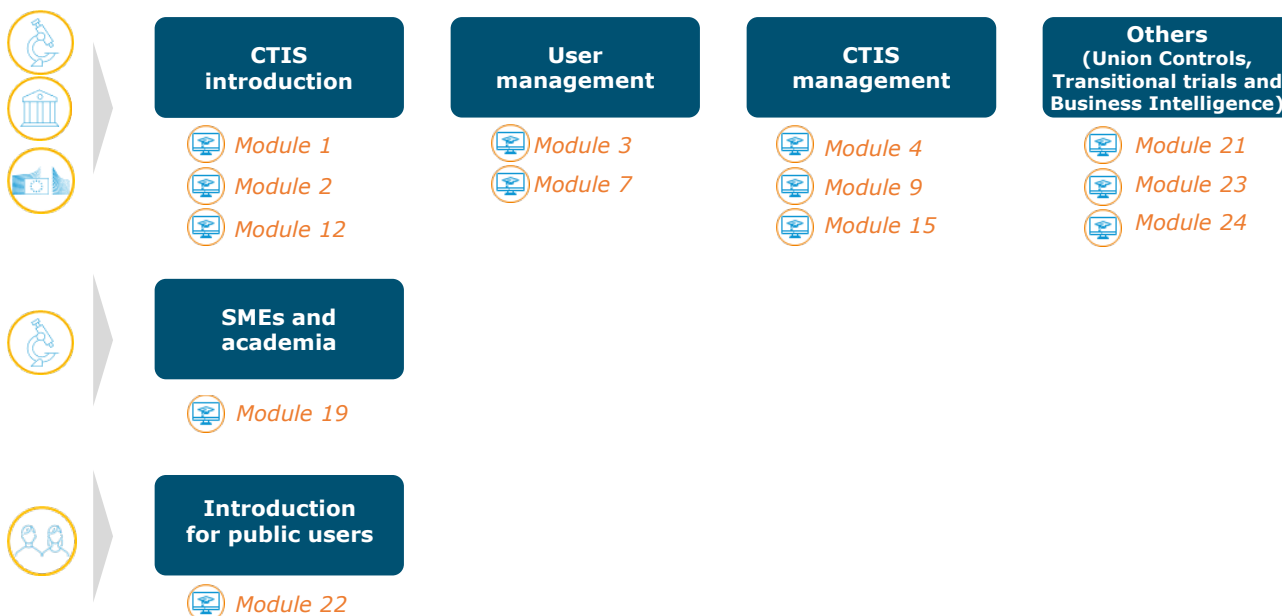
CTIS High-level processes

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.

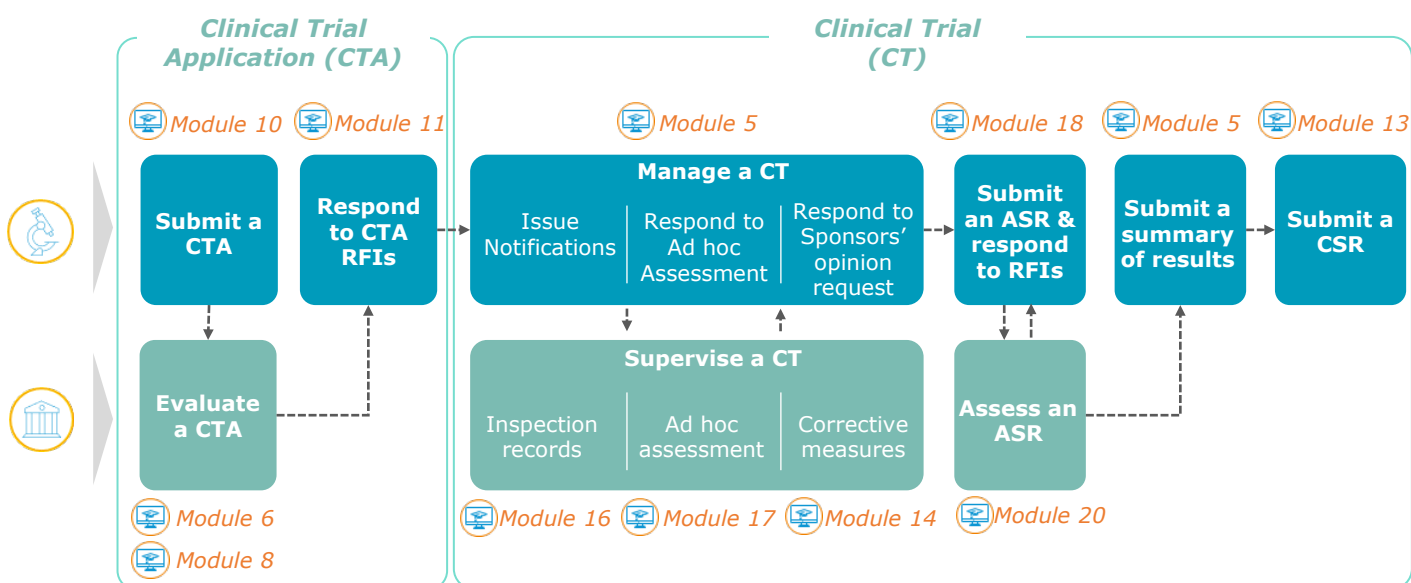
Below, users can find an overview of the main topics of CTIS, as well as the life cycle process flow of a clinical trial and in which module they can find the related information per audiences:

Users

General CTIS information



Clinical trial life cycle in CTIS



Click on the icon to see the training materials

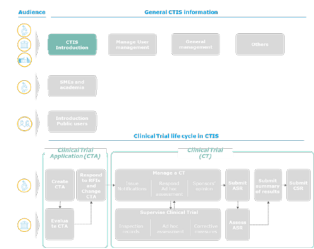
Click here to access the materials on the EMA website

User group





CTIS INTRODUCTION



Module 1: Introduction to the Clinical Trials Regulation

Learning objectives:

- Understand the scope and objectives of the Clinical Trials Regulation.
- Understand the key changes and new elements of the Clinical Trials Regulation compared to Directive 2001/20/EC (the Clinical Trials Directive).
- Understand the transition period from the Clinical Trials Directive to the Clinical Trials Regulation.
- Remember the actors targeted by the Clinical Trials Regulation and its benefits for each of them.



eLearning

Interactive presentation to convey more detailed information on the Clinical Trials Regulation.



Infographic

Brief document that visually summarises the key elements of the Clinical Trials Regulation.



FAQ's

List of Frequently Asked Questions on the key elements of the Clinical Trials Regulation covered in Module 1.



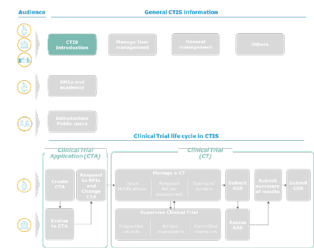
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 1.





CTIS INTRODUCTION



Module 2:

Overview of CTIS workspaces and common system functionalities

Learning objectives:

- Understand what CTIS is, its two workspaces, and the public website it is composed of.
- Understand the databases and systems that CTIS interacts with.
- Remember CTIS functionalities which are common in both workspaces.
- Remember the main CTIS functionalities specific for each workspace.
- Understand the goals of the public website and what public users will find there.



eLearning

Interactive presentation to familiarise the user with CTIS workspaces and the common functionalities in both workspaces. Additionally, the eLearning provides a short introduction to the public website.



Video – clips

- Clip 1:** [CTIS technical environment](#)
- Clip 2:** [CTIS common functionalities, Part A](#)
- Clip 3:** [CTIS common functionalities, Part B](#)
- Clip 4:** [CTIS specific functionalities](#)
- Clip 5:** [CTIS public website](#)



Quick guide

Brief and practical guide with system screenshots to show users how to use CTIS functionalities which are common in both workspaces.



FAQ's

In this document, we list common questions regarding Module 2. They are categorised in questions of a general nature and questions related to the common functionalities of the two workspaces presented in this module.



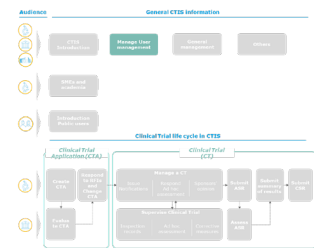
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 2. A specific activity is proposed to support users understanding the information.





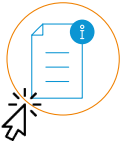
USER MANAGEMENT



Module 3: User Access Management

Learning objectives:

- Understand the process of self-registration in CTIS through EMA's Account Management Portal.
- Remember how to log into CTIS and access the landing page
- Understand the basic roles and permissions in CTIS
- Understand how the user profile management functionality works



Quick guide

Brief and practical guide with system screenshots to show users how to create an account in EMA Account Management system in order to obtain user credentials for CTIS, how to log into CTIS, an introduction to the roles and permissions available in CTIS, and how to navigate through the user profile functionalities.



Quick guide (OMS)

Brief and practical guide with system screenshots to show users how to search, create and update an organisation in OMS.



Video – clips

- **Clip 1:** [Registration of a new CTIS user](#)
- **Clip 2:** [Registration of a new organisation in CTIS](#)
- **Clip 3:** [CTIS password recovery and User profile functionalities](#)



FAQ's

List of the most common questions regarding to the process of self-registration in CTIS via EMA's Account Management system; the process of login to CTIS and accessing the landing page; the basic roles and permissions in CTIS; and user profile management.



Step-by-step guide

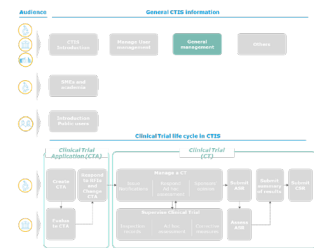
Brief guide to show users how to register in EMA's Account Management system and how to log in and manage a user profile.



Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 3.





Module 4:

Support with workload management in the sponsor and authority workspace

Learning objectives:

- Remember the main system functionalities enabling efficient workload management in the sponsor 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 Sponsor



eLearning Authority

Interactive presentations to familiarise the users with CTIS' functionalities that support the workload management in the Sponsor and Authority workspaces and highlight the commonalities and specificities of each workspace, as well as those which are found in both workspaces.



Video – clips

Clip 1: [How to manage the workload in CTIS - Tasks tab \(authority workspace\)](#)

Clip 2: [How to manage the workload in CTIS - RFI tab \(sponsor workspace\)](#)

Clip 3: [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 - Sponsor



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).



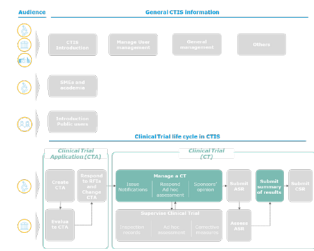
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 4.





MANAGE A CLINICAL TRIAL AND SUBMIT A SUMMARY OF RESULTS



Module 5:

How to manage a Clinical Trial (Notifications, Ad hoc assessment, Corrective measures, and Trial results)

Learning objectives:

- Remember the responsibilities of the sponsors from the submission of a clinical trial application until the submission of the clinical trial summary of results.
- Understand the use of Notifications.
- Understand the processes of ad hoc assessments and corrective measures and how to address requests for information regarding to them.
- Understand how to prepare and submit clinical trial results.



eLearning

An interactive presentation that present the key system functionalities and processes enabling sponsors to fulfil their obligations after the authorisation of a clinical trial (Notifications; RFIs addressed as part of an Ad Hoc assessment and opinion requests before a corrective measure is applied).



Quick guide

Practical and simple guide with system screenshots that provides a basic introduction to understand how to submit clinical trial results.



FAQ's

Compilation of a list of common questions about requests for information (RFIs) raised as part of an ad hoc assessment; questions about RFIs raised before a corrective measure is applied by a Member State Concerned (MSC); and questions about Trial results' submission.



Video – clips

- **Clip 1:** [Trial and recruitment periods notifications](#)
- **Clip 2:** [Other notifications](#)



Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 5. A specific activity is proposed to support users' understanding the process.



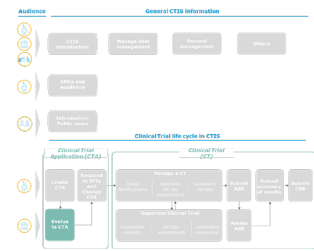
Step-by-step guide

Brief and practical guide with system screenshots to show users how to manage the events that might occur during the conduct of a clinical trial.





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 with the RMS selection process and examples of possible scenarios.



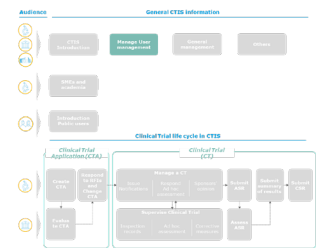
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 6. A specific activity is proposed to support end-users' understanding of the RMS selection process.





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.



eLearning

An interactive presentation to familiarise users with the purpose and main types of roles and permissions in CTIS, the two user management approaches, and the hierarchy to assign roles, as well as the main user groups interacting with the system and the roles that each of them can be assigned.



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.



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.



Video – clips

- **Clip 1:** [Creating a clinical trial: Clinical trial centric approach vs organisation centric approach](#)
- **Clip 2:** [How to request roles and how to assign roles to registered users in CTIS](#)
- **Clip 3:** [How to amend and revoke roles of registered users in CTIS](#)
- **Clip 4:** [How to request the CTIS high level Administrator role via IAM](#)
- **Clip 5:** [How to approve requests for CTIS Administrator role and how to remove CTIS Admin role](#)



Step-by-step guide

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



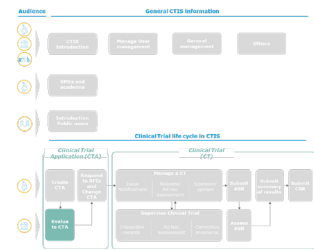
Supporting documents

- [Member States Processes and Roles](#)
- [Member States Roles and Permissions matrix](#)
- [Sponsor Processes and Roles](#)
- [Sponsor Roles and Permissions matrix](#)
- [Notices and Alerts per role](#)





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:

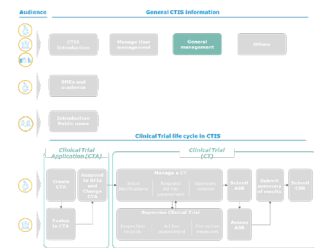
- How to evaluate an Additional Member state concerned clinical trial application
- How to evaluate a Substantial modification clinical trial application



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.



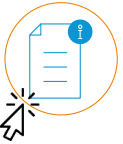


Module 9:

How to search, view and download a Clinical Trial and a Clinical Trial Application

Learning objectives:

- Remember how to search for a Clinical trial and a Clinical Trial Application.
- Understand the information displayed while navigating through a Clinical trial and a Clinical Trial Application.
- Understand how to download information and associated documents.
- Understand which user roles can access and download specific information related to a Clinical trial and a Clinical Trial Application.



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 clinical trial in the CTIS sponsor workspace](#)
- **Clip 2:** [How to view and download clinical trial information](#)



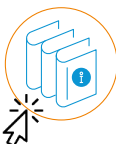
FAQ's

List of Frequently Asked Questions regarding the following aspects: Search functionalities available in CTIS, how to view CTs and CTAs information, and how to download CT and CTAs and available formats.



Step-by-step guide

Brief and practical guide with system screenshots to show users how to search, view and download a CT and a CTA.



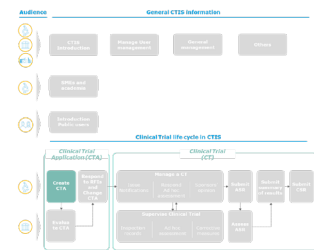
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 9.





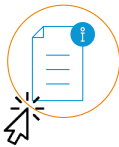
CREATE A CLINICAL TRIAL APPLICATION



Module 10: Create, submit and withdraw a CTA

Learning objectives:

- Understand the different types of Clinical Trial Applications (CTAs) and Non-substantial modifications.
- Understand the process of creating, submitting, and cancelling an Initial Clinical Trial Application (CTA).
- Understand the process of withdrawing a CTA.
- Understand the key differences regarding the creation, submission, and withdrawal process of other types of applications (Additional MSC application and Substantial modification), compared to an Initial CTA.
- Remember the evaluation process of a CTA and how to view and respond to Requests for Information (RFIs) received during the validation and/or the assessment phases.



eLearning

Interactive presentation as the main reference material that aims to present an overview of the all types of CTAs and non-SM; and how to create, populate, submit, copy and withdraw a CTA.



FAQ's

Compilation of a list of common questions regarding the different types of applications, and their creation, population, submission, copy and withdrawal.



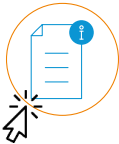
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 10. It includes an exercise to help participants understand the sequence of the process of submission of an Initial CTA.



Video – clips

- **Clip 1:** [Create a CT: Form and MSC sections](#)
- **Clip 2:** [Part I section](#)
- **Clip 2a:** [Part I Trial details](#)
- **Clip 2b:** [Part I - Sponsors](#)
- **Clip 2c:** [Part I - Products](#)
- **Clip 3:** [Part II section](#)
- **Clip 4:** [Submit a substantial modification CTA](#)
- **Clip 5:** [Submit an Additional MSC CTA](#)



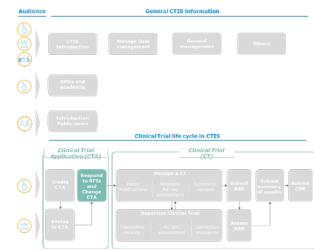
Step-by-step guide

Brief and practical guide with system screenshots to show users the main steps for create, submit and withdraw a clinical trial application and non-substantial modifications.





RESPOND TO CTA RFIs



Module 11:

How to respond to Requests For Information (RFI) received during the evaluation of a Clinical Trial Application (CTA)

Learning objectives:

- Remember the phases and associated timelines for the evaluation of a CTA.
- Understand what an RFI is and the different types of RFIs that can be sent by MSC during the evaluation of a CTA.
- Remember how to search and view an RFI received during the evaluation of a CTA.
- Understand how to create and submit an RFI response, including changes to an existing application.
- Understand the roles and permissions involved in the management of an RFI.



eLearning

An interactive presentation that provide a detailed explanation of the processes for responding to Requests for Information (RFIs) received during the evaluation of a Clinical Trial Application (CTA).



Video – clips

- **Clip 1:** [How to access and view an RFI in CTIS](#)
- **Clip 2:** [How to change a Clinical Trial Application as part of an RFI response](#)
- **Clip 3:** [How to respond to RFI considerations and submit an RFI response](#)



FAQ's

List of Frequently Asked Questions regarding the evaluation process of an application, how to view and access RFIs; create an RFI response with or without changes to the CTA, and submit an RFI response.



Step-by-step guide

Brief and practical guide with system screenshots to show users how CTIS supports sponsor users to view and access RFI raised by Member States Concerned (MSCs) during the validation and assessment phases of the evaluation of a CTA, as well as how to create and submit the responses, and how to modify an existing CTA as part of the response.



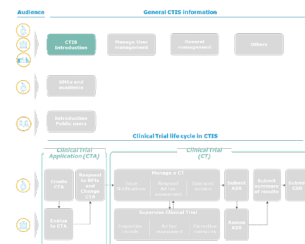
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 11. This guide includes an exercise to help participants to understand the process of RFIs.





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

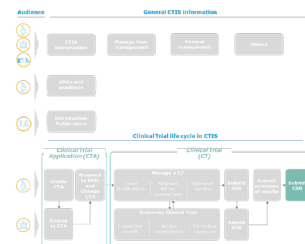
Interactive presentation to explain the user on how CTIS supports compliance with the GDPR/EUPDR.



Video – clips

Clip 1: [Data protection in CTIS](#)





Module 13: Clinical study reports submissions

Learning objectives:

- Remember what a Clinical Study Report (CSR) is.
- Understand how to prepare and submit a CSR.
- Understand how to view, download, update and withdraw a CSR.
- Understand the roles and permissions involved in managing a CSR.



Quick guide

A quick guide document to explain in detail how to create, submit, update, download, and withdraw a CSR.



Step-by-step guide

Document summarising the main steps to submit and update a CSR.



FAQ's

List of Frequently Asked Questions regarding information and timelines of CSR; the management of CSR; the publication of CSR; and the roles and permissions involved in CSRs.



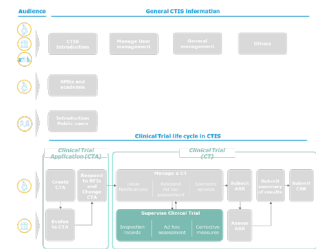
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 13. A specific activity is proposed to support users' understanding the information.





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

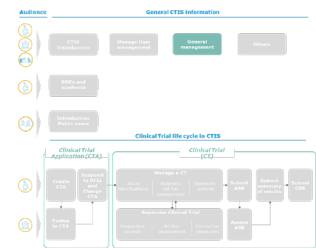
Short step by step document to show the users how to create, submit, update and revert a corrective measure.



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.





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

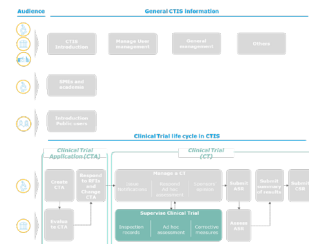
Short and practical document that includes the most relevant steps of the processes described in the module



Instructor's guide

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





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](#)



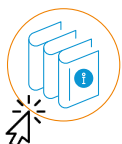
FAQ's

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

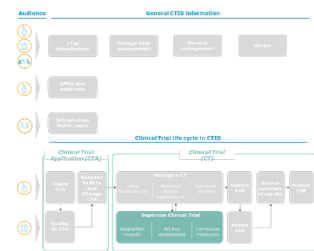
Document summarising the basic steps of the inspection record process.



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.





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.



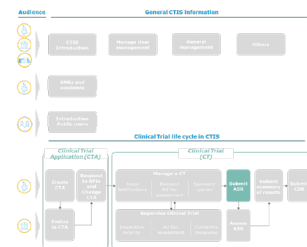
Instructor's guide

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





SUBMIT AN ASR & RESPOND TO RFIS



Module 18:

How to submit an annual safety report and respond to related RFIs

Learning objectives:

- Remember what an annual safety report (ASR) is and when a sponsor can create one.
- Understand how to create, cancel, and submit the ASR submission form.
- Remember the phases and associated timelines for the assessment of an ASR.
- Understand how to respond to RFIs received during the assessment of an ASR.
- Understand how to search, view, and download an ASR.
- Understand the roles and permissions involved in the ASR process.




eLearning

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



Video – clips

- **Clip 1:** [How to create, cancel or clear, and submit an annual safety report](#)
 - **Clip 2:** [How to search and view an annual safety report \(ASR\), and respond to requests for information \(RFIs\) received during the ASR evaluation](#)
- 



FAQ's

List of Frequently Asked Questions including general questions on ASR, the process of submitting, the phases of assessment, the process of responding to 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 create an ASR submission form and how to submit it, as well as how to respond to related Requests for Information (RFIs).



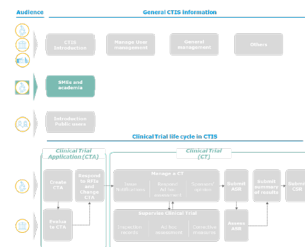
Instructor's guide

Guide supporting Master Trainers to disseminate the content of Module 18. A specific activity is proposed to support users' understanding the information.





SMEs AND ACADEMIA



Module 19: CTIS for SMEs and Academia

Learning objectives:

- Understand user access management and user administration approaches.
- Remember CTIS main functionalities for the sponsor workspace.
- Understand how to search, view, and download a clinical trial and a clinical trial application
- Understand how to submit the different types of clinical trial applications and non-substantial modifications.
- Understand how to create and submit an RFI response, including changes to an existing application
- Understand how to manage a clinical trial.
- Understand how to submit an annual safety report and how to respond to related RFIs.



Step-by-step guide

Step-by-step 1: [User access management and user administration](#)

Step-by-step 2: [CTIS workload functionalities](#)

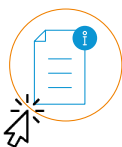
Step-by-step 3: [Search, view and download a CT and a CTA](#)

Step-by-step 4: [Submit CTAs and non-SMs](#)

Step-by-step 5: [Submit an RFI response](#)

Step-by-step 6: [Manage a CT](#)

Step-by-step 7: [Submit an ASR and respond to RFIs](#))



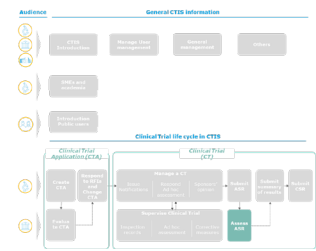
Quick guide

Short and practical document that remember the steps of main processes related to the Sponsors activities in CTIS and the roles and permissions involved





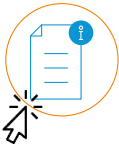
ASSESS AN ASR



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

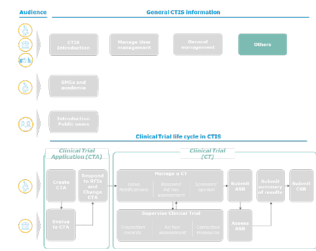
Guide supporting Master Trainers to disseminate the content of Module 20. A specific activity is proposed to support users' understanding the information.





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

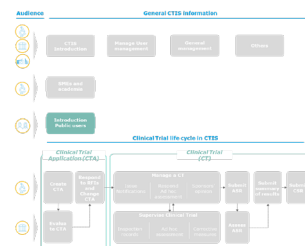
List of Frequently Asked Questions regarding the processes of creating and sharing the Plans/Programmes for Union Controls, and creating and submitting Union Controls reports.



Step-by-step guide

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





Module 22: Introduction for public users

Learning objectives:

- Remember what the CTIS public website is.
- Understand how users can search for a Clinical Trial (CT).
- Understand how to view and download the information displayed in a CT.
- Understand how to remove information from the public website.
- Remember how users can view union control reports.



Quick guide

Practical and simple guide with system screenshots that provides a basic introduction for the use of the CTIS Public Website for the general public.



FAQ's

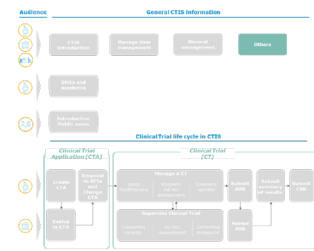
List of Frequently Asked Questions regarding the different public website search functionalities, the available information of CTs and CTAs in the public website and how to remove it, the downloading structured data and documents and questions regarding union controls.





OTHERS

(Union Controls, Transitional trials & Business Intelligence)



Module 23: Transition of trials from EudraCT to CTIS

Learning objectives:

- Remember what a Transitional trial is (common in both workspaces).
- Understand how to submit a Transitional trial in the sponsor workspace.
- Understand how to evaluate a Transitional trial in the authority workspace.
- Understand how to submit notifications and clinical trial results for a Transitional trial (available for sponsor users).
- Understand the roles and permissions involved (available for sponsor users).



Quick guide (Sponsor users)

Practical and simple guide with system screenshots that provides a basic introduction for Transitional trial: creation and submission of Transitional trials, creation and submission of notifications for Transitional trial and submission of the summary of results.



Quick guide (Member state users)

Practical and simple guide with system screenshots that provides a basic introduction for Transitional trial: management of Transitional trials and evaluation of them.



FAQ's

List of Frequently Asked Questions regarding an overview of Transitional trials (creation, submission, notifications associated and evaluation).



European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Telephone +31 (0)88 781 6000

Send a question

www.ema.europa.eu/contact

Clinical Trials Information System (CTIS)

Guide to CTIS Training Catalogue

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