EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Useful links and info when creating/transitioning trials in CTIS

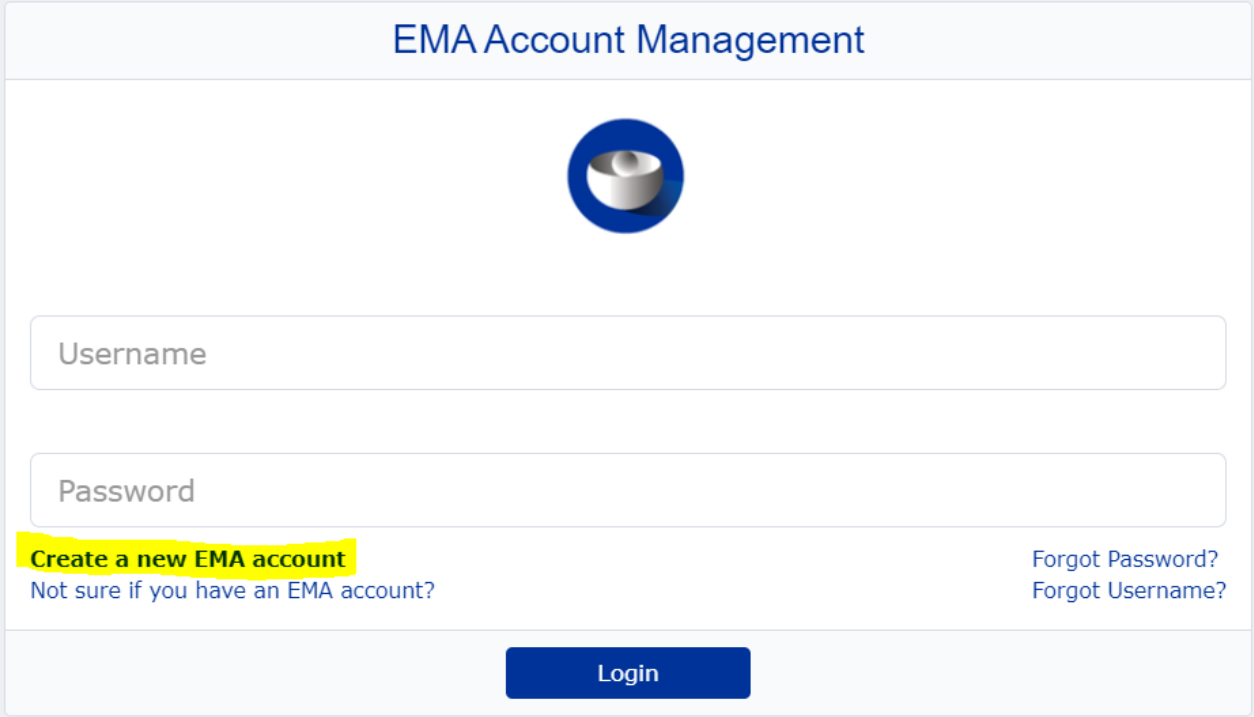
Presented by Ornela Ademi on 09 February 2024
Change Manager
European Medicines Agency

Where to start?

Actions prior to using CTIS

- **EMA account** - any CTIS user needs to have an EMA account
- **Sponsor organisation is registered in OMS** - Log in to OMS with your EMA account
- **Sponsor Administrator is registered in IAM** – request the first Sponsor Administrator role in EMA Account Management
- **Sponsor organisation to register with EudraVigilance** (via Gateway or EudraVigilance (EV) web application (EVWEB)). More information available here.
    - EVWEB enables the submission of a case (i.e., SUSAR) to EudraVigilance. In addition, it allows the registered user(s) to register a new medicinal product in xEVMPD (medicinal product dictionary).
    - For EudraVigilance access, users should log into the EMA Account Management portal and request a 'EudraVigilance role'. For more details, see the Registration manual.

EMA account



Research and development | Marketing authorisation

Herbal products

Organisation Management Service (OMS)

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This content applies to human and veterinary medicines.

The European Medicines Agency (EMA) has launched the Organisation Management Service (OMS) to support regulatory activities throughout the European Union (EU).

The OMS manages one of the four domains of substance, product, organisation and referential (SPOR) master data in pharmaceutical regulatory processes.

Access the OMS on the **SPOR portal** using the button below:

The SPOR portal is compatible with Internet Explorer (version 10 and above) and Chrome (version 58 and above) web browsers.

The OMS service supports the implementation of ISO IDMP standards in the EU.

What the OMS is for

The OMS provides a **single source of validated organisation data** that can be used as a reference to

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SPOR

OMS

Login

Substances | Products | Organisations | Referentials | Help

SPOR data management services

Delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.

The four SPOR data management services are:

- Substance Management Services (SMS)
- Product Management Services (PMS)
- Organisation Management Services (OMS)
- Referentials Management Services (RMS)

OMS and RMS are the first services to go live and they provide the data foundations for PMS and SMS.

SMS and PMS are not currently activated. More information on the implementation of SPOR data management services is available on the EMA corporate website.

The SPOR portal provides users with the following data management services:

- view, search, export SPOR data;

Access to SPOR

Use the links in the navigation panel above to access OMS and RMS.

Please use the menus in the navigation panel to navigate RMS and OMS with 'read-only' access to SPOR.

You will need an EMA account with SPOR user roles to conduct additional tasks, such as requesting changes to data, translating data or managing user preferences.

If you already have an active account for any EMA-hosted website or online application, you should use the same credentials to log in.

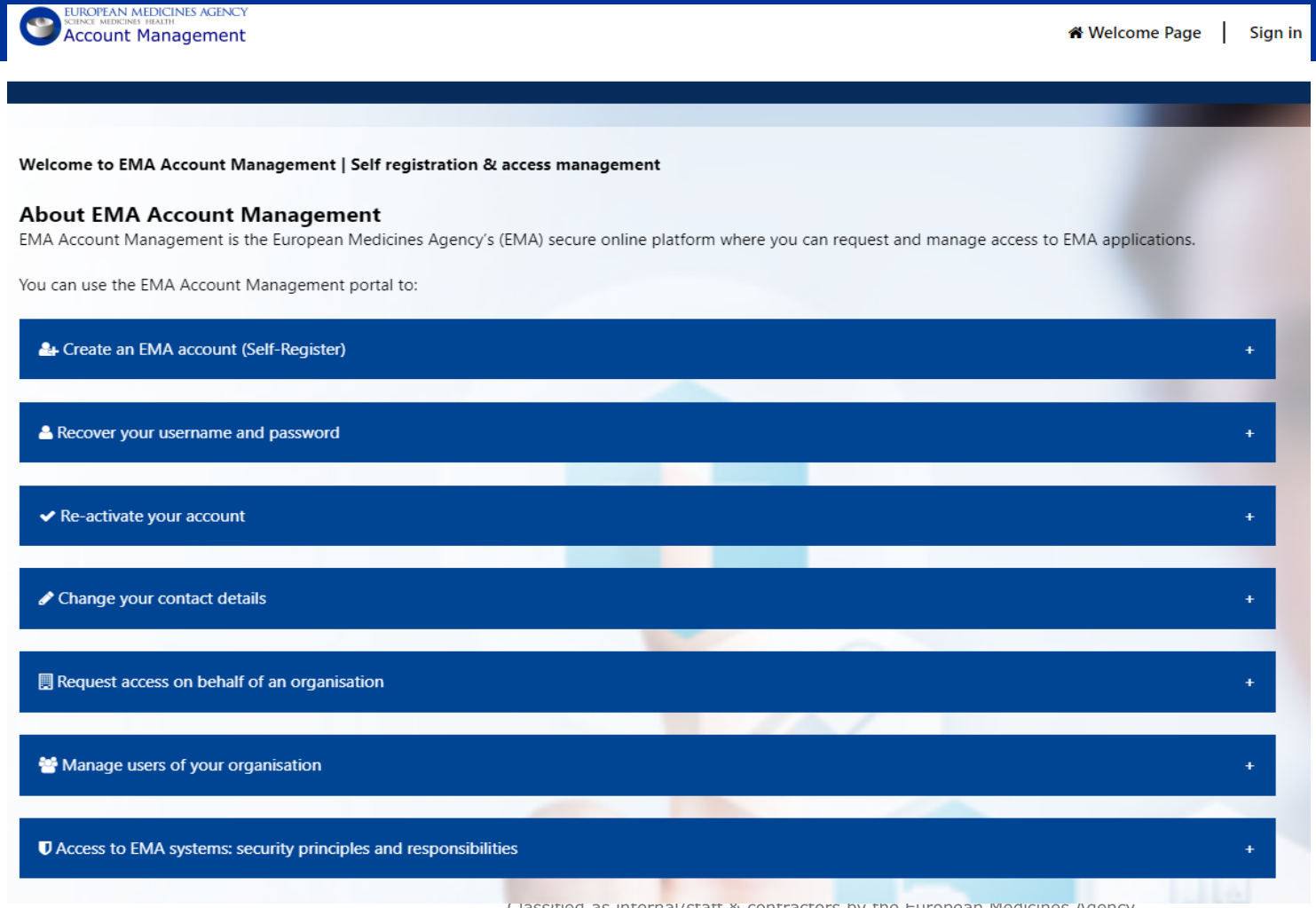
If you do not already have an EMA account, you need to create an EMA account and request the specific SPOR user roles you require.

Please check if you are able to log in before registering as a new user with SPOR.

Create EMA Account

Registered users can log in using the button at the top of the page.

Using SPOR



EMA Account Management

Adaptive pathways
Advanced therapies
Clinical trials
Compassionate use
Compliance
Data on medicines (ISO IDMP standards)
Ethical use of animals
Innovation in medicines
Medicines for older people
Orphan designation
Paediatric medicines
Pharmacovigilance
EudraVigilance
System overview
Registration
Electronic reporting
Access to data

EudraVigilance: how to register

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Pharmaceutical companies holding or applying for a marketing authorisation in the European Economic Area (EEA), sponsors of clinical trials and national competent authorities in the EEA need to register with EudraVigilance for the electronic data interchange of pharmacovigilance information. The registration process is a prerequisite for electronic reporting.

On 26 July 2018, the European Medicines Agency (EMA) integrated the services of EudraVigilance (human) with EMA's Account Management portal and Organisation Management Service (OMS).

All users, including organisations, **need an active EMA account** created through the EMA Account Management portal.

EMA has published a Registration manual a registration frequently asked questions document and has updated this page with new information for companies and users wishing to register with, access or manage their account for EudraVigilance (human) **production environment**. For a quick interactive guide to the revised EudraVigilance registration process, see below:

- Quick interactive guide to EudraVigilance registration process

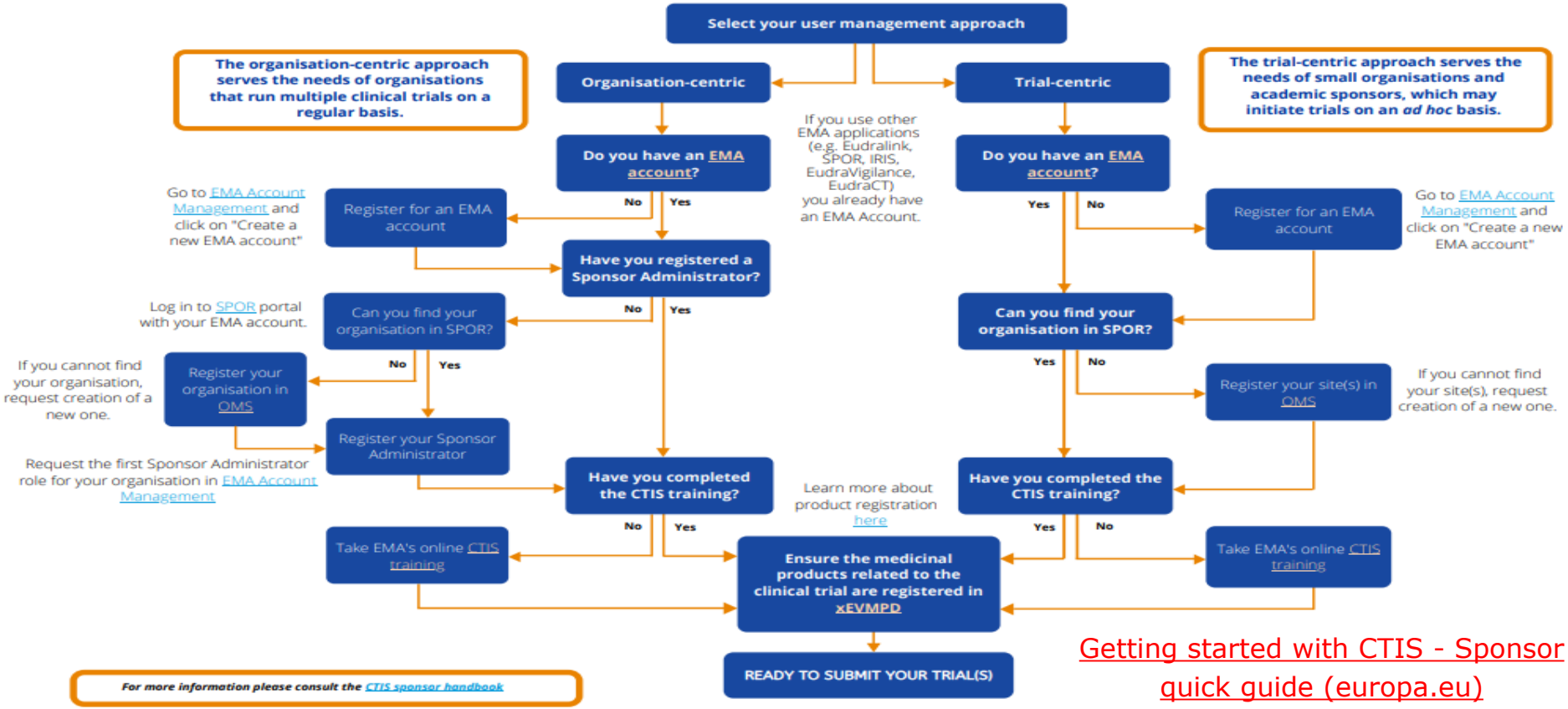
Required actions before EudraVigilance registration

Register with EudraVigilance

EUROPEAN MEDICINES AGENCY

GETTING STARTED WITH CTIS: Sponsor Quickguide

As of GoLive on 31st of January 2022, the Clinical Trials Information System (CTIS) becomes the single-entry portal for submitting clinical trials information in the EU, supporting the day-to-day business processes of authorities and sponsors throughout the life-cycle of a clinical trial.
To get started with CTIS, sponsors must decide their user management approach and complete registrations. A transition period applies for sponsors - Q&A here.



Getting started with CTIS - Sponsor quick guide (europa.eu)

General useful information for sponsors

- CTIS: how to get started and how to transition a trial collection of links for new CTIS users
- Online modular training
  - Overview of the different modules of Online Training: Guidance to CTIS training material catalogue
  - Module 02: High-level overview of CTIS workspaces and common system functionalities
  - Module 19: CTIS for SMEs and Academia
- Sponsor handbook
- CTR Q&A published by the European Commission under EudraLex volume 10
- Quick guide for sponsors - Regulation 536/2014 in practice
- Chapter I - Application and application documents at Set of documents applicable to trials authorised under Regulation EU No 536/2014

Online modular training

Adaptive pathways
Advanced therapies
Clinical trials
Accelerating Clinical Trials in the EU (ACT EU)
Data submission: guidance for sponsors
Reporting safety information during clinical trials
Clinical Trials Regulation
Clinical Trials Information System
Training and support

Clinical Trials Information System (CTIS): online training modules

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EMA provides an online modular training programme to help clinical trial sponsors, national competent authorities, ethics committees, European Commission and EMA staff use the Clinical Trials Information System (CTIS). The programme contains modules and audience-targeted materials covering all clinical trial lifecycle stages, from submission through authorisation to supervision.

The online training modules are all available on this page. EMA regularly updates and enhances its training materials.

Please consult the documents below for:

Guidance to CTIS training material catalogue

Adaptive pathways
Advanced therapies
Clinical trials
Accelerating Clinical Trials in the EU (ACT EU)
Data submission: guidance for sponsors
Reporting safety information during clinical trials
Clinical Trials Regulation
Clinical Trials Information System
Training and support
Online training modules
Compassionate use
Compliance
Data on medicines (ISO IDMP standards)
Ethical use of animals
Innovation in medicines
Medicines for older people
Orphan designation

Clinical Trials Information System (CTIS): online training modules

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The online training modules are all available on this page. EMA regularly updates and enhances its training materials.

Please consult the documents below for:

- a full catalogue of available training modules, organised by clinical trial lifecycle stage;
- the latest new or updated training materials;
- technical system requirements for the best experience with using CTIS.

Guide to CTIS training material catalogue (PDF/1.19 MB)

First published: 23/06/2021
Last updated: 07/02/2022
Version 1.1

CTIS Training materials - Latest updates (PDF/514.23 KB)

First published: 31/05/2021
Last updated: 21/02/2023
Version 1.2 February 2023

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)*

Introduction to CTIS

Expand section | Collapse section

- Introduction to the Clinical Trials Regulation (Regulation (EU) No 536/2014) (Module 01)
- High-level overview of CTIS workspaces and common system functionalities (Module 02)

Sponsor workspace

Expand section | Collapse section

- Create, submit and withdraw a clinical trial (Module 10)
- Respond to requests for information received during the evaluation of a clinical trial application (Module 11)
- Manage a clinical trial through CTIS (Module 05)
- How to create and submit an annual safety report and respond to related requests for information (Module 18)
- Clinical study reports submissions (Module 13)
- Search, view and download information on clinical trials and clinical trial applications (Module 09)
- CTIS for SMEs and Academia (Module 19)

Common functionalities for all registered users

Expand section | Collapse section

- User access management (Module 03)
- Management of registered users and role matrix (Module 07)
- Data protection in CTIS (Module 12)
- Support with workload management (Module 04)
- Transitional trials (Module 23)

Authority workspace

Expand section | Collapse section

- Evaluate a clinical trial application: Selection of reporting Member State (RMS) and validation of the clinical trial application (Module 06)
- Evaluate a clinical trial application: Assessment and decision-making (Module 08)
- Supervise a clinical trial: Ad hoc assessment (Module 17)
- Supervise a clinical trial: Corrective measures (Module 14)
- Supervise a clinical trial: Inspection records (Module 16)
- Assess an Annual Safety Report (Module 20)
- Search, view and download a clinical trial and a clinical trial application (Module 15)
- Union Controls in CTIS (Module 21)

Searching CTIS as a public user

- Introduction to CTIS for public users (Module 22)

Related EU legislation

- Clinical Trial Regulation EU No. 536/2014
- Regulation (EU) 2016/679 (GDPR)
- Regulation (EU) 2018/1725 (EUDPR)

External links

Access the information and secure workspaces in CTIS:

- Clinical Trials website

Related content

- Clinical Trials Regulation
- EMA Clinical Trial Information System (CTIS) webinar: dynamic demo of sponsor workspace(21/09/2020)
- Clinical trials in human medicines
- Support to SMEs
- Academia

Contact point

- High-level overview of CTIS workspaces and common system functionalities (Module 02)

Sponsor workspace

Expand section | Collapse section

- Create, submit and withdraw a clinical trial (Module 10)
- Respond to requests for information received during the evaluation of a clinical trial application (Module 11)
- Manage a clinical trial through CTIS (Module 05)
- How to create and submit an annual safety report and respond to related requests for information (Module 18)
- Clinical study reports submissions (Module 13)
- Search, view and download information on clinical trials and clinical trial applications (Module 09)
- CTIS for SMEs and Academia (Module 19)

Common functionalities for all registered users

Expand section | Collapse section

- User access management (Module 03)
- Management of registered users and role matrix (Module 07)

High-level overview of CTIS workspaces and common system functionalities (Module 02)

Module 02	High-level overview of CTIS workspaces and common system functionalities
Target audience(s)	• Authorities of EU Member States • European Commission • Sponsors • Market authorisation applicants and holders • Members of the public
Topics covered	• What CTIS is • The two individual secure workspaces (i.e. authority and sponsor) in CTIS and their functionalities • The public website which will allow members of the public to access detailed information on all clinical trials conducted in the EU, in all official EU languages • The databases and the systems that feed CTIS with data • CTIS functionalities common to the main user categories, namely sponsors, Member States and the European Commission • Goals of the public website and what information members of the public will be able to access

Learning materials	• e-learning course (use Chrome browser)
	• Quick guide
	• Instructor's guide
	• Frequently asked questions (FAQs)
	• Supporting materials:
	  ◦ Guide on CTIS common features
	  ◦ List of acronyms
	  ◦ Quick guide: Fill in the blanks exercise
	• Videos:
	  ◦ CTIS technical environment
	  ◦ CTIS common functionalities, Part A
	  ◦ CTIS common functionalities, Part B
	  ◦ CTIS specific functionalities
	  ◦ CTIS public website

Guide on CTIS common features

This document outlines the main CTIS common features available across the various tabs in both Authority and Sponsor workspaces. These features enable users to perform actions supporting their day-today business throughout the life cycle of a clinical trial. Users will find a general description of the characteristics of the buttons that support these features and some guidance for the access and navigation in CTIS. Some of the buttons described in this document are in document placeholders and help users to manage the CTA documents. In the last section, users can find some indicative guidelines on how to remove personal information from the properties of documents that upload to their trials in CTIS. The aim of this document is that users can quickly be familiarised with CTIS.

The document is divided in three sections:

Module 02: Online modular trainin

CTIS cross-system buttons

This section outlines the characteristics of cross-system buttons (dependences, users' permissions, similarities, and locations) and the description of the most common buttons.

Access and Practicalities

This section outlines the CTIS access links and some guidelines for a proper use of CTIS.

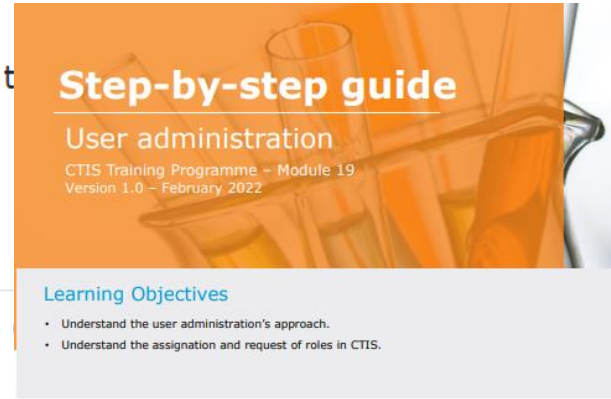
How to remove personal information from properties of CTA documents

This section outlines how users can remove personal information from properties of CTA documents that they upload to their trials in CTIS.

CTIS for SMEs and Academia (Module 19)

Module 19	CTIS for SMEs and academia
Target audience(s)	• Sponsors (SMEs and academia)
Topics covered	• Steps of main processes related to the Sponsors activities in CTIS and the roles and permissions involved • CTIS main functionalities for the sponsor workspace • How to search, view, and download a CT and a CTA • How to submit the different types of clinical trial applications and non-substantial modifications • How to create and submit an RFI response, including changes t application • How to manage a CT • How to submit an ASR and how to respond to related RFIs
Learning materials	• Quick guide - Introduction: CTIS for SMEs and Academia - Programme - Module 19 • Step-by-step guide: User administration - CTIS Training Programme - Module 19

Module 19: CTS for SME and Academia



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6 November 2023

EMA/923413/2022 – v. 3.03

Clinical Trials Information System (CTIS) Programme

Clinical Trials Information System (CTIS) - Sponsor Handbook

A compilation of key guidance, technical information, recommendations, and references for getting ready for the use of CTIS

Executive summary

The aim of the EMA CTIS Sponsor Handbook ('Handbook') is to provide clinical trial (CT) sponsors representing pharmaceutical industry, SME (small and medium-sized enterprises), academia, research organisations and other clinical trial sponsor organisations with the information they need to navigate the Clinical Trials Information System (CTIS) - to create and submit clinical trial information to the member states of the European Union as required by the Clinical Trial Regulation [CTR: Regulation (EU) No 536/2014]. The Regulation harmonises the assessment and supervision processes for clinical trials throughout the EU/EEA, via CTIS. CTIS contains the centralised EU portal and database for clinical trials foreseen by the Regulation.

The Handbook addresses key questions on CTIS and provides a compilation and references to key guidance, technical information, recommendations, training materials, and supportive documentation to facilitate the submission and assessment of CTAs and additional information during the lifecycle of a trial.

It has been developed by the European Medicines Agency (EMA) in collaboration with representatives of industry stakeholders.

The Handbook will be revised as more information becomes available, or system functionalities are updated. It is best used in conjunction with the many references to which it points, for example, Volume 10 of the publication 'The rules governing medicinal products in the European Union' that contains guidance documents applying to clinical trials (EudraLex - Volume 10 - Clinical trials guidelines).

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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Sponsor handbook

CTR Q&A

The rules governing medicinal products in the European Union
VOLUME 10 - Guidance documents applying to clinical trials

CLINICAL TRIALS REGULATION (EU) NO 536/2014

QUESTIONS & ANSWERS

VERSION 6.7

Submitted for discussion to the Expert Group on Clinical Trials and through written procedure to the Clinical Trials Coordination and Advisory Group

Document history:	
Date of discussion by the expert group on Clinical Trials	
Date of discussion by the Clinical Trials Coordination and Advisory Group :	27 November 2023 + written procedure + written requests for changes
Date of publication:	21/12/2023
Supersedes:	6.6
Changes compared to superseded version:	- Review of: 289,294,404 (now numbered 290,295,405). - New Q&A 7.2, 7.41. New point 370 - Annex II: PT (Protocol Synopsis, patient facing documents); EE (patient facing documents). - Annex III: HU (email address for part I-related enquiries); FI (websites) ; SE additional

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Registered uses and role matrix

Module 07 (Online modular training): Management of registered users and role matrix

- Clinical Trial centric approach vs organisation centric approach
- How to request roles and how to assign roles to register users in CTIS

Module 19 (Online Modular training): CTIS for SMEs and Academia

- Quick guide - Introduction
- Step-by-step guide: User administration

Guidance & information on creation of new CTA

Module 10 (Online Modular training): Create, submit, and withdraw a clinical trial

- e-learning course: initial clinical trial applications (use Chrome browser)
- e-learning course: other types of clinical trial applications (use Chrome browser)
- Step-by-step guide
- Instructor's guide
- Frequently asked questions (FAQs)

Supporting materials:

- Process puzzle
- Checklist of required fields per application type

Live demos on creation of new CTA

Bite size talk:

Initial clinical trial application (including presentation)

Video instructions: 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

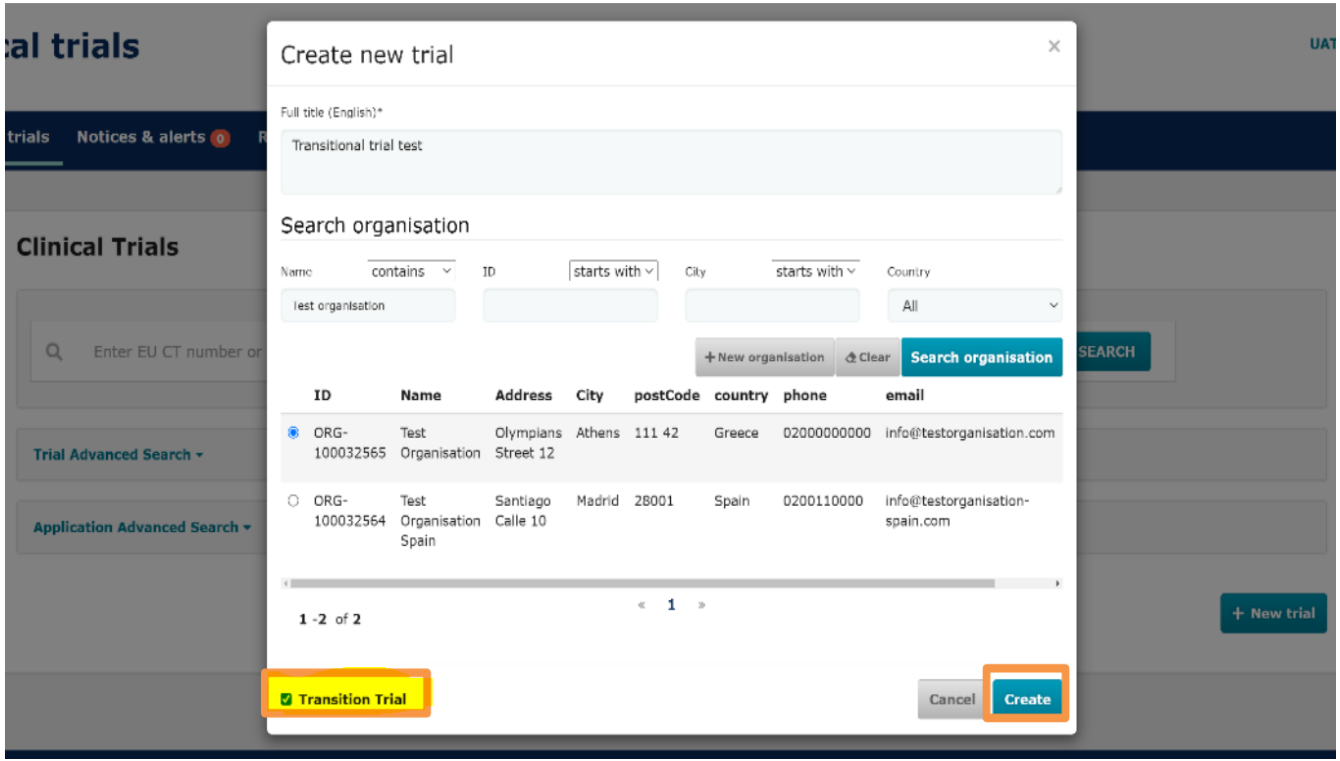
Information on Transitional trials

As of **31 January 2025**, all clinical trials need to be in CTR (CTIS)

Start transition not later than 16 October 2024

- Guidance for the transition of clinical trials published by European Commission under EudraLex vol. 10
- CTCG's best practice guide & 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)

Transitional trials reminder



Remember to tick the box on the application to indicate that the trial is a transitional trial!

If technical issues during the submission of a transitional trial, raise a ticket with ServiceNow.

Additional supporting material

EMA webpage CTIS Training and Support

Regular updates on the CTIS Programme (subscribe): Clinical Trials Highlights

Any questions?

Further information

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