



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Introductory guide

## CTIS for SMEs and Academia

CTIS Training Programme – Module 19  
Version 1.3 – May 2022

### Learning Objective

- Remember the steps of main processes related to the Sponsors activities in CTIS and the roles and permissions involved.

© European Medicines Agency, 2021

Reproduction and/or distribution of the content of these training materials for non-commercial or commercial purposes is authorised, provided the European Medicines Agency is acknowledged as the source of the materials.



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

The table below describes the updated versions after CTIS go-live (January 2022):

Version	Update description	Date
1.3	Links to video recordings of CTIS demonstrations on how to perform the main sponsors functionalities in CTIS, during the life cycle process of a clinical trial.	May 2022
1.2	Links to other modules and databases. Addition of a summary table of the main roles and permissions.	February 2022
1.1	Training material version published at CTIS go-live.	July 2021

# Introductory guide to CTIS for SMEs and Academia

Regulation (EU) No 536/2014 (the Clinical Trials Regulation or CT Regulation) was published in the EU Official Journal on 27 May 2014. From its application, it replaces the existing Clinical Trials Directive (CT Directive) and it becomes applicable across the EU/EEA (for more information, please refer to [Module 1 of the CTIS Training Programme](#)).

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 (CT). CTIS is intended for interventional clinical trials with human medicinal products including low-intervention clinical trials with adapted requirements.

**A 3-year transition period** is foreseen in which the CT Directive will still apply:

- The first year, sponsors are able to choose to submit initial clinical trial applications under the CT Directive regime or under the CT Regulation regime.
- From the second year, initial clinical trial applications must be submitted under the CT Regulation regime. CTs authorised under the CT Directive regime that are still ongoing can remain under that regime over the second and third year of application, unless the sponsor decides to transition those trials to the requirements of the Regulation.
- From the end of the third year of implementation, all clinical trials will have to switch to the CT Regulation regime, regardless of their submission date.

The main objective of Module 19 is to explain in a simple and summarised way all the relevant information for the sponsor workspace, **focusing on SMEs, Academia and CROs**.

To access the **Sponsor workspace**, users can click on <https://euclinicaltrials.eu/ct-sponsor-services/login>.

This guide includes:



## Sponsors CTIS processes

This section outlines the processes that sponsors perform in CTIS. In addition, links to the audiovisual system demonstrations and Step-by-step guides are included.



## Data protection

This section outlines the key information about data protection and confidentiality in CTIS.



## Roles and permissions

This section outlines the roles and permissions for sponsors.



## CTIS's interactions with other databases

This section outlines the interactions with other databases and relevant links with further information.

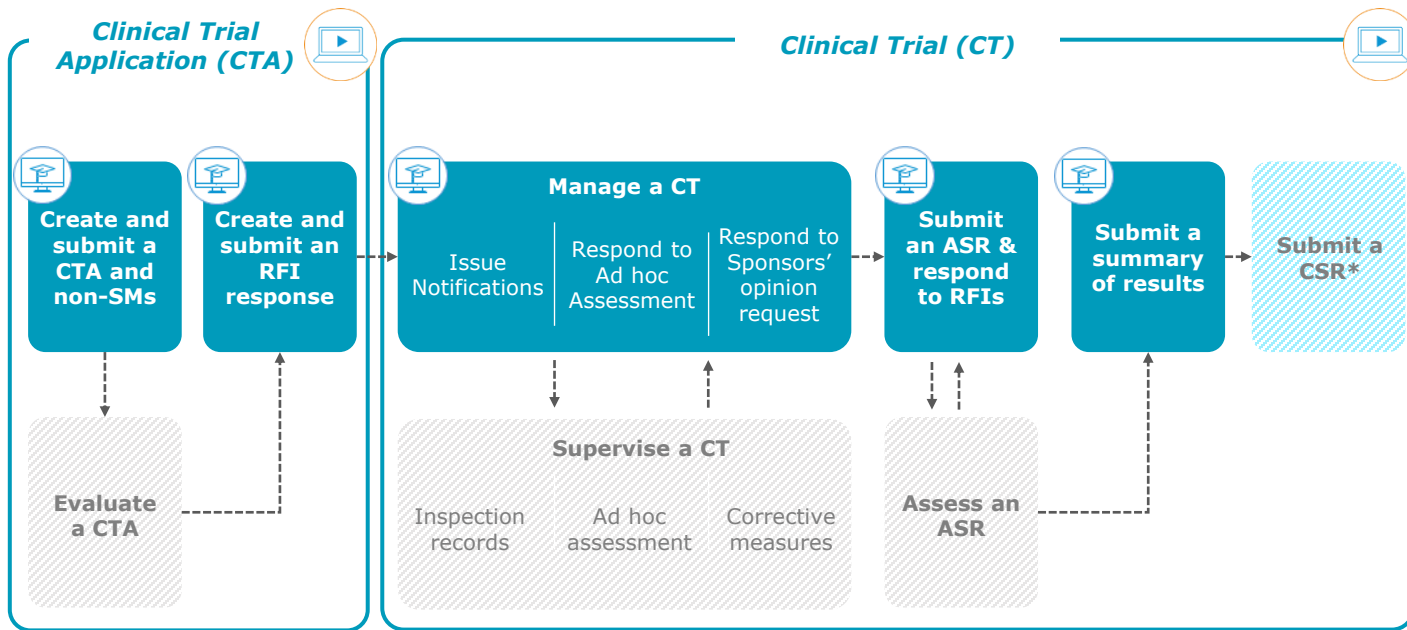
# Sponsors CTIS processes

Below, users can find an **overview of the main sponsors functionalities** in CTIS, during the **life cycle process** of a clinical trial and a link to training materials. Users can also access the [List of acronyms of CTIS](#). Users can click on the **different icons** to see **Step-By-Step (SBS) guides** corresponding to each phase of the clinical trial life-cycle, and **video recordings of system demonstrations**.

## General CTIS information



## Clinical trial life-cycle in CTIS



### Legend

- Focus of this module
- Outside the core process
- Member States Processes



Click on each icon to see the **Step-By-Step (SBS) guide** corresponding to each phase of the clinical trial life-cycle.



Click on each icon to view more details and video recordings of system demonstrations of these processes



[Click here to access to the complete Training Programme.](#)

Note: This is a high-level illustration of the process and does not necessarily apply to every occurrence.  
\*For more information, refer to [Module 13: 'Clinical study reports submission'](#).








## Summary of CTIS demos available

This page offers links to **video recordings** of CTIS demonstrations on how to submit a Clinical Trial Application (CTA) and how to respond to CTA Requests for Information (RFIs). Users can **click on the orange boxes** to access the video or the list below for specific parts.






**New video recordings of system demonstrations** are made available typically up to 60 days after the events organised by EMA where such demonstrations take place. Please subscribe to the [Clinical Trials newsletter](#) for updates on the availability of CTIS event video recordings.

### Clinical Trial Application (CTA)

#### Submit a CTA and non-SMs

-  *Structure of a CTA*
-  *Create a CTA draft*
-  *Populate the MSC section of a CTA*
-  *Populate the Form section of a CTA*
-  *Populate the Part I section of a CTA*
-  *Populate the Part II section of a CTA*
-  *Submit a draft CTA*

#### Respond to CTA RFIs

-  *Access received RFIs*
-  *Overview of an RFI*
-  *Change CTA as part of an RFI response*
-  *Respond to considerations*
-  *Submit an RFI response*



Click on each icon to access the system demonstration specific to that process

# Summary of CTIS demos available


This page offers links to **video recordings** of CTIS demonstrations on how to manage a Clinical Trial (CT), how to submit an ASR and respond to RFIs, how to submit a summary of results, and how to Submit a Clinical Study Report (CSR). Users can **click on the orange boxes** to access the video or the list below for specific parts.

**New video recordings of system demonstrations** are made available typically up to 60 days after the events organised by EMA where such demonstrations take place. Please subscribe to the [Clinical Trials newsletter](#) for updates on the availability of CTIS event video recordings.

## Clinical Trial (CT)

### Manage a CT

Issue Notifications	Respond to Ad hoc Assessment	Respond to Sponsors' opinion request	Submit an ASR & respond to RFIs	Submit a summary of results	Submit a CSR*
<ul style="list-style-type: none"> <li>Types of Notifications</li> <li>Access Notifications</li> <li>Create Trial &amp; Recruitment Periods Notifications</li> <li>Create circumstantial events Notifications</li> </ul>	<ul style="list-style-type: none"> <li>RFI mechanism in ad hoc assessment</li> <li>Make changes to a CTA dossier in the context of an RFI response</li> <li>Respond to considerations</li> <li>Submit an RFI response</li> </ul>		<ul style="list-style-type: none"> <li>Access ASRs</li> <li>Create an ASR</li> <li>Populate the Sponsor Information section</li> <li>Populate the Clinical Trial Detail section</li> <li>Populate the ASR Reporting Period details section</li> <li>Populate the Supporting Documents and Submit section</li> <li>Submit the ASR</li> </ul>	<ul style="list-style-type: none"> <li>Submit Summary of results</li> <li>Submit Lay person summary of results</li> </ul>	<ul style="list-style-type: none"> <li>Submit a CSR</li> </ul>

 Click on each icon to access the system demonstration specific to that process

\* Outside the core processes described in this module. For more information, refer to [Module 13: 'Clinical study reports submission'](#).

## Data protection

The sequence of events occurring during the trial life cycle might require the collection and **processing of personal and non-personal data**. Also, data and documents provided by the users in CTIS might contain information that is considered **commercially confidential**.

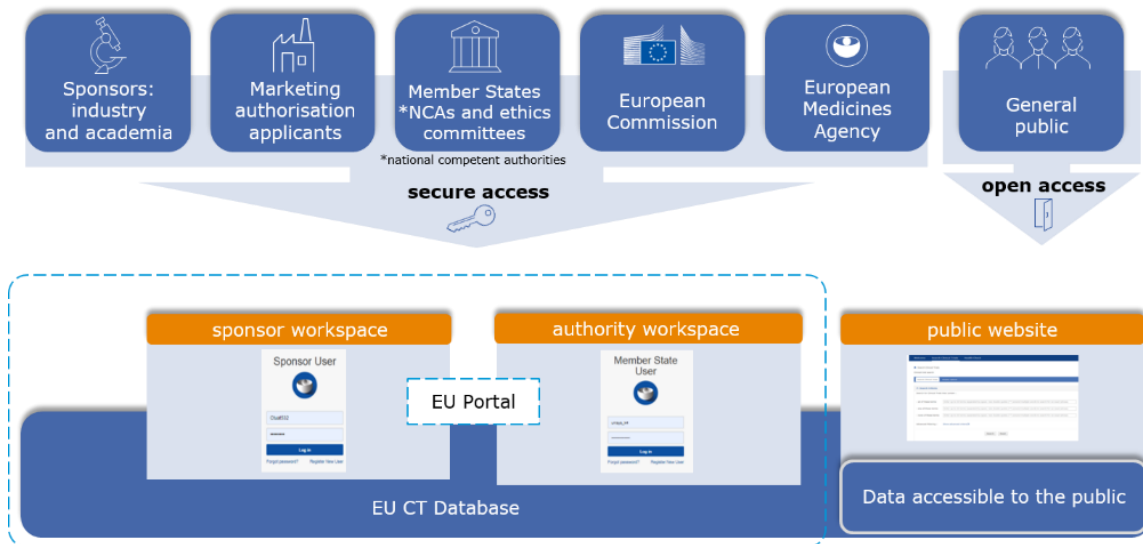
As defined in **Article 81(4)**, both personal data and commercial confidential information are exempted from publication. In order to address this requirement, **CTIS provides several functionalities**:

- Ability to upload documents to specific placeholders that are not **subjected to publication** (e.g. financial arrangements, IMPD-Quality, RFI related to quality).
- Ability to upload alongside a document 'for publication', a version 'not for publication' to **protect personal data** and **Commercially Confidential Information (CCI)**, if the submission is needed for the assessment by the MSC.
- Ability to **defer publication** to protect CCI. This is taking into account the marketing authorisation of a medicinal product and phase of a trial.

Access to data and document in CTIS secure domain is regulated depending on user's profile. Part of the clinical trial information contained in CTIS secure domain will also be made available to the general public, via the public website.

Documents submitted through CTIS will, by default, be published in the public website and should not include personal data. However, certain documents containing personal data may be necessary. To that end, CTIS allows to upload **two versions of a same document**: one for publication and another one not for publication.

This **functionality** is available for documents provided in the CTA dossier, documents provided for an RFI response and documents provided during the life-cycle of a CT. It is also available for the Clinical Study Report of MAH users. *For more information, refer to [Module 12 of the CTIS Training Programme](#).*



The **processing of personal data** in CTIS is necessary to:

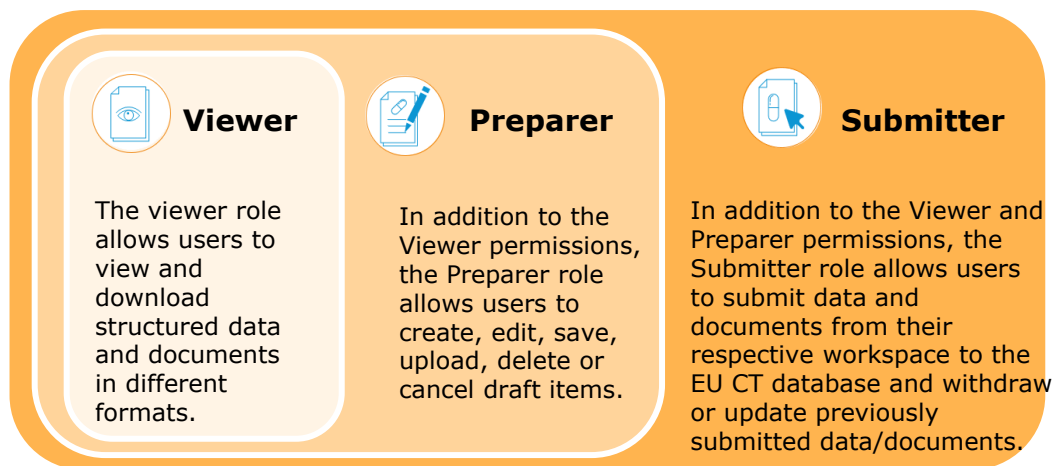
- Ensure that a **public record exists of all clinical trials** conducted in the EU and their outcomes.
- Support **public confidence** in the clinical trial process.
- Provide patients, trial participants, healthcare professionals, the public and academia with **access to information** on CTs in the EU, their results, and the data used to support marketing authorisation decisions.
- Act as a **knowledge management resource** to foster innovation and stimulate further research.
- Sponsor activities are necessary to comply with their legal obligation under the **CT Regulation**.

## Roles and permissions

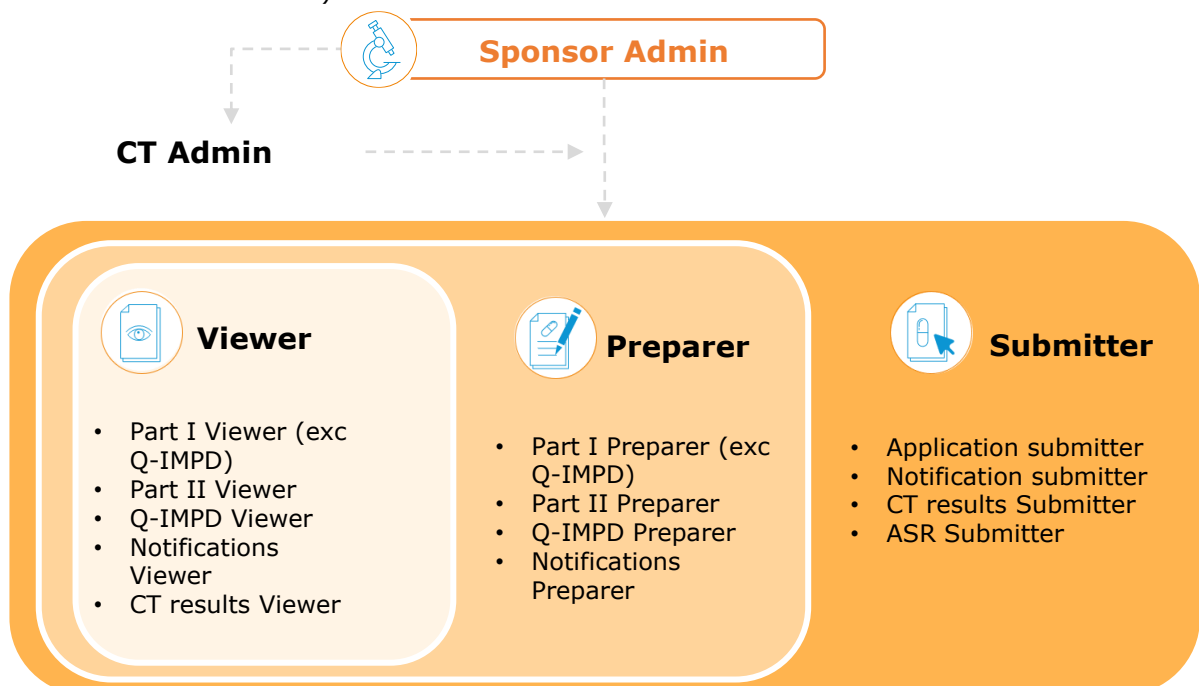
CTIS is a role-based system that enables users to **perform different actions** depending on the permissions assigned to them and their **respective responsibilities** in a clinical trial.

There are two main types of roles in CTIS:

- **Administrator roles:** These roles have the permissions to assign, amend, or revoke roles/CT access to other users to be able to perform actions in CTIS. In the sponsor workspace, administrators can also approve/reject role requests submitted by other users. There are two types of Administrator roles: **high-level and medium-level administrators**. Both can manage user roles, although with different permission limitations. Only the first high-level administration role needs to be validated and assigned by EMA, all the subsequent requests will be managed by the existing high-level admin.
- **Business roles:** they can perform specific activities in CTIS, for a specific CT or for all, within their organisation. They can be grouped according to 3 main set of permissions structured in a cascade approach (i.e. each permission level includes the permissions of the previous levels), as shown in the image below:



The sponsor's roles that can be assigned by sponsor's users comprises 3 administrator roles (including the Sponsor Admin and CT Admin) and 15 business roles\*.



\*Note: CSR users have not been included in this guide that reflects the core process.



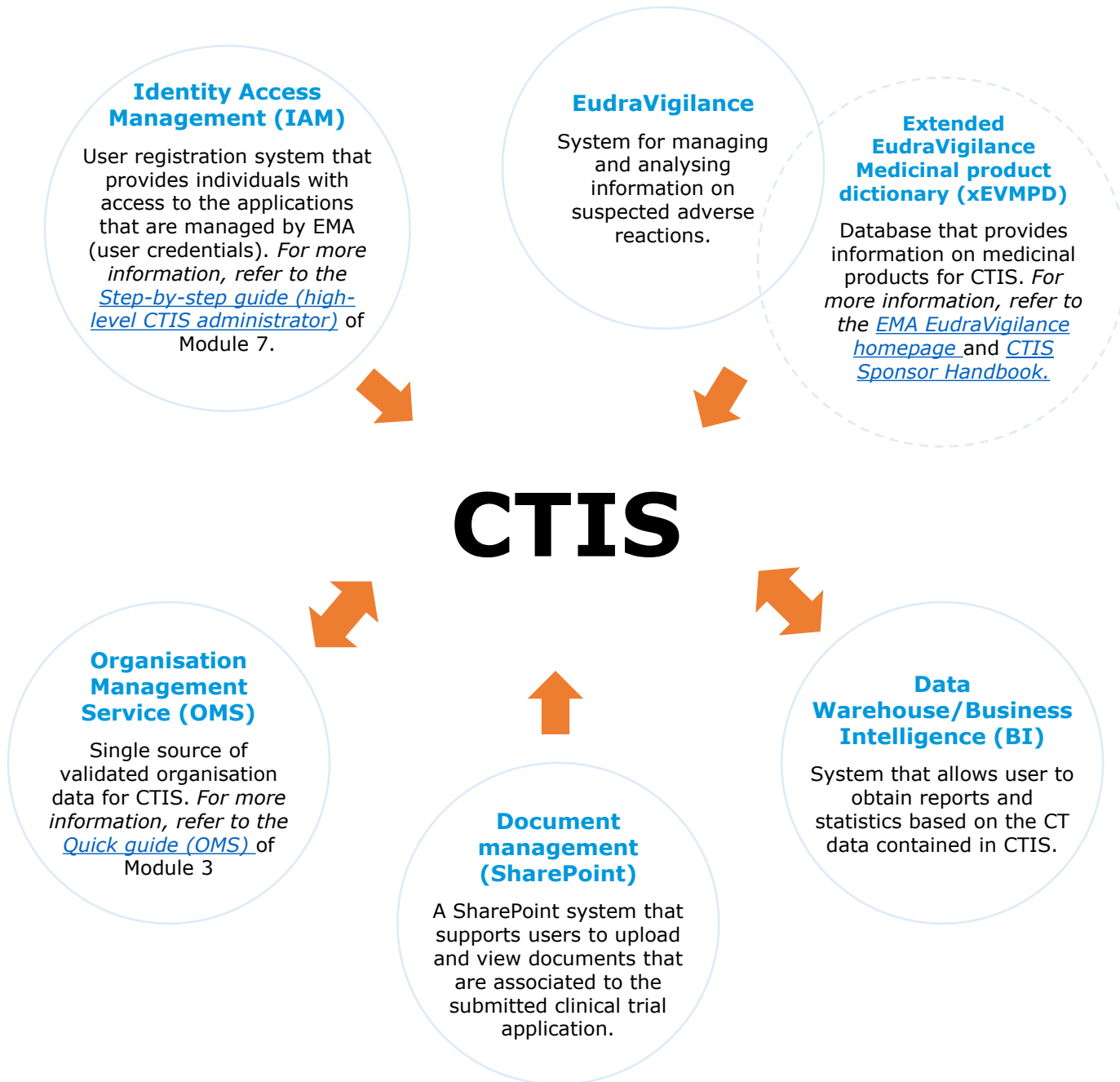
## Roles and permissions

In order to **clearly define each role**, a summary of the main roles is provided below. CT Admin role has all business permissions except those related ASR processes.

Phases	Roles	Sponsor Admin	CT Admin	ASR Submitter
	Permissions			
General	Manage role assignment	●	●	
	View users' roles and requests	●	●	
	Allocate Trials to users	●	●	
Submit a CTA	Create/copy a CT and a CTA		●	
	Edit a CTA		●	
	Submit/ Withdraw a CTA		●	
	Download a CT	●	●	
RFI Response	Create RFI response		●	
	Delete CTA changes or Submit RFI response		●	
	View an RFI		●	
Issue notifications	Create and Delete draft notification		●	
	Submit/ Update/ Withdraw notification		●	
	View notification		●	
Sponsor's opinion	Create opinion		■	
	Submit opinion		■	
	View opinion and request for opinion		■	
ASR	View/Create/ Submit an ASR			●
Summary of results	Submit/ Update/ Withdraw summary of results		●	
	View summary of results		●	

## CTIS's interactions with other databases

CTIS interacts with **different existing databases and systems**. Managed by EMA. These databases allow to register users (IAM), search information on organisations (OMS), medicinal products (xEVMPD), etc.



It is important that the relevant data is pre-registered in those databases interacting with CTIS. Sponsors are responsible to ensure that the appropriate data is registered in advance to the submission of the initial CTA. This data includes:

- **OMS**: information of sponsors organisations, third parties (e.g. CRO), trial sites, etc.
- **xEVMPD**: information on medicinal product (MP) used in the trial (investigational MP or Auxiliary MP) including information for unauthorized MP in the EEA.

## CTIS's interactions with other databases

Find below relevant links for further information on the different databases:

Module / Topic	Material	Source
Introduction to training offering by EMA – Pharmacovigilance (PhV)	<a href="#">PhV – Introduction of EudraVigilance, EVDAS, ADR reporting and signal detection</a>	EMA corporate website
XEVMPD	<a href="#">Extended EudraVigilance medicinal product dictionary (XEVMPD) training</a>	EMA corporate website
EudraVigilance	<a href="#">EudraVigilance training and support page</a>	EMA corporate website
IAM	<a href="#">EMA Account management Guidance documentation</a>	EMA Account management portal
OMS	<a href="#">Organisation Management Service (OMS)</a>	EMA corporate website

**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](http://www.ema.europa.eu/contact)

Clinical Trials Information System (CTIS)

Introductory guide: CTIS for SMEs and Academia

© European Medicines Agency, 2021.

Reproduction is authorised provided the source is acknowledged.