FAQs

Overview of CTIS workspaces and common system functionalities

CTIS Training Programme – Module 2

Version 1.2 – January 2022

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FAQs

In this document, we list common questions regarding *Module 2: Overview of CTIS workspaces, public website, and common system functionalities.* They are categorised in questions of a general nature and questions related to the common functionalities of the two workspaces presented in this module. These functionalities correspond to the following tabs: 'Clinical Trials', 'Notices & alerts', 'User administration', and 'Annual safety reporting'. The specific learning objectives of this module are:

1. Understand what CTIS is, its two workspaces, and the public website it is composed of.

2. Understand the databases and systems that CTIS interacts with.

3. Remember CTIS functionalities which are common in both workspaces.

4. Remember the main CTIS functionalities specific for each workspace.

5. Understand the goals of the public website and what public users will find there.

We encourage you to read these questions and answers carefully. If you have any questions which are not covered in this document, please contact the Service Desk. This document will be progressively enriched with the input of the experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

1. General

1.1 What is CTIS?

From the entry into application of Regulation (EU) No 536/2014 (Clinical Trials Regulation), CTIS is the single entry portal for submitting clinical trials information in the EU with the highest standards of safety for participants since 31/01/2022. It supports the day-to-day business processes of authorities and sponsors throughout the life-cycle of a clinical trial through collaboration and communication tools between sponsors and authorities and among authorities; workflow capabilities, and document management and reporting capabilities. CTIS also supports the transparency of data regarding clinical trials conducted in the EU for the general public through a public website.

CTIS is structured in **two restricted and secured workspaces**, only accessible to registered users, and a **website openly accessible to the general public**:

- The **sponsor workspace**, is accessible to commercial and non-commercial sponsors. It supports the preparation, compilation and submission of clinical trial data for its assessment by Member States.
    - Access: *https://euclinicaltrials.eu/ct-sponsor-services/login*

- The **authority workspace**, is accessible to national competent authorities, ethics committees, the European Commission, and the European Medicines Agency (EMA). It supports the activities of Member States and the European Commission in assessing and overseeing clinical trials.
    - Access: *https://euclinicaltrials.eu/ct-authority-services/login*

- The **public website**, is accessible to patients, healthcare professionals, scientists, clinical research associations, media, and members of the public. It supports the open access to clinical trials' data in the European Union, in line with the transparency goal set out in Regulation (EU) No 536/2014 (Clinical Trials Regulation).
    - Access: *https://euclinicaltrials.eu/search-for-clinical-trials*

Additionally, all this information can be accessible from the **Clinical Trials website.**
    - Access: *https://euclinicaltrials.eu/home*

1.2 What categories of data are stored in CTIS?

CTIS stores different categories of data to support the activities of users in both workspaces. These data include:

Self-populated data by users: data populated in the system when completing or assessing a clinical trial dossier, as well as documents **uploaded** as attachments in certain parts of an application or dossier (e.g. cover letter, protocol information, product information such as IMPD Quality, Safety and Efficacy, paediatric investigational plan, proof of payment fee, informed consent form, annual safety reports, document of considerations for RFI, etc.).

Data retrieved from other databases that interact with CTIS, such as:

- Data on medicinal products pulled from EudraVigilance medicinal product dictionary

(XEVMPD)

- User data (such as first name, last name, email or user ID) pulled from IAM

- Organisations' data (e.g. name, address) pulled from OMS

For more information on these databases and systems, see question 1.3.

1.3   Where does the data in CTIS come from?

CTIS interacts with other databases and systems. These provide relevant data to CTIS, such as user credentials, medicinal products and organisation information details that are requested for completing a clinical trial dossier, and well as storage capabilities. The main databases and systems are:

- **Identity Access Management** (IAM): IAM is a central EMA login system enabling access to CTIS and other EMA-managed systems and applications. All users need to be registered with IAM prior to being granted access to CTIS. IAM provides user-relevant data information, such as first name, last name, email, or user ID to CTIS. *For more information, refer to [Step-by-step guide (high-level CTIS administrator)](#) of Module 7.*

- **SharePoint**: Serves as a central repository for documents recorded by users in CTIS and allows them to view and download documents.

- **EudraVigilance medicinal product dictionary** (XEVMPD): Stores and provides quality data on authorised or investigational medicinal products to CTIS. This information is requested to sponsors when filling out a clinical trial dossier/application. *For more information, refer to the [EMA EudraVigilance Homepage](#) and [CTIS Sponsor Handbook](#).*

- **Organisation Management Services** (OMS): Provides a central dictionary of organisation data, such as organisation names and location address details. CTIS pulls data from this database for its user organisations. CTIS can also push information to this database when new organisations are created directly in CTIS. *For more information, refer to the [Quick guide (OMS)](#) of Module 3.*

1.4   When/how are data categories updated in CTIS?

The data pulled from other databases and systems is copied in CTIS at the moment it is pulled from the databases. This data is not automatically updated in CTIS when changes are made to the source database. This is so due to legal security grounds, to ensure that CTIS reflects the data as it was when the application was submitted by the sponsor or when it was assessed by a Member State.

Data self-populated and submitted by the sponsor when filling out a clinical trial application can be later updated in the context of an RFI, a substantial or a non-substantial modification.

1.5 What type of reports can the user retrieve/generate with the BI reporting tool?

The BI reporting tool will allows Member State users to access standard reports about clinical trials recorded in CTIS, and will generate reports on the basis of a set of parameters. Examples of available reports include: report to retrieve information on Responsible Member States' workshare, applications submitted for clinical trials over time, reports on the medicinal products used in clinical trials, etc.

1.6 How was CTIS developed?

A group of representative users from Member States, sponsors, and the European Commission have participated in the development of the system since March 2019, and provided regular feedback to the releases to ensure that the system meets the requirements of the Clinical Trials Regulation while meeting the business process needs of both the regulatory authorities and the industry.

1.7 If CTIS is not working properly, who should the user contact to get assistance?

A maintenance team takes care of the assistance requests, communicated via a Service Desk, as in other systems managed by EMA. EMA's general Service Desk is available at:

https://servicedesk.ema.europa.eu/jira/servicedesk/customer/user/login?nokerberos&destination=portals.

1.8 In which languages is CTIS available?

CTIS is available in all the EU official languages, as per requirement in Article 81(8) of the Clinical Trials Regulation: '*The user interface of the EU database shall be available in all official languages of the Union*'[1].

1.9 How can users access CTIS?

Users can access the CTIS interface through two workspaces:

- Authority: https://euclinicaltrials.eu/ct-authority-services/login

- Sponsor: https://euclinicaltrials.eu/ct-sponsor-services/login

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[1] Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, *EU Official Journal* L158. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

Once they are in the corresponding workspace, they can populate the fields 'username' and 'password' with their user credentials. After users have populated both fields, they can click on the button 'Login'.

1.10 How can users recover their passwords?

If users forget their passwords, they can access the corresponding workspace and click on 'forgot password?' button in order to reset it.

1.11 Which browsers and Internet connection are recommended?

Users can use modern browsers such us Chrome 88, Edge, Firefox to navigate through CTIS, however, Chrome is the most recommended. For acceptable user experience, the Internet connection should support at least 3MBps download and 1MBps upload transfer rates. Higher network transfer rates are recommended for optimal user experience.

1.12 What is the session timeout limit?

If users stay more than 45 minutes idle, they will be logged out automatically.

2. Overview of clinical trials

2.1. Does CTIS display the same search results for the users of the sponsor and the authority workspace?

Users in both workspaces are able to see the clinical trial applications in which they have a role. However, the users of the different workspaces do not see exactly the same information at the same time. For instance:

- Authority users are not able to see draft clinical trial applications that are being prepared by sponsors – they only see them once they have been submitted to the Member States concerned for assessment. For more information, refer to the Frequently asked questions of *Module 15: Search, view and download a clinical trial and a clinical trial application – Authority workspace.*

- Sponsor users are not able to see an assessment that is being conducted by the Member State concerned - they only see the final assessment report. For more information, refer to the Frequently asked questions of *Module 9: Search, view and download a clinical trial and a clinical trial application – Sponsor workspace.*

The same principle applies to other clinical trials data prepared and submitted within CTIS by both the sponsors and the authorities.

2.2. Do users retrieve different results depending on the advanced search they apply?

CTIS offers two advanced search options: one is trial-centric and the other one is application-centric:

- **Trials Advanced Search**: returns a list of clinical trials that match a set of entered parameters, such as the Member State(s) concerned (MSC), the medicinal product being tested, the trial start and end dates, the protocol code, or the recruitment status.

- **Application Advanced search**: returns a list of clinical trials which contain application(s) that match the entered search parameters, such as the application type (i.e. initial, substantial modification or additional MSC), the status of the application (e.g. lapsed, authorised, withdrawn, not authorised, etc.), the Responsible Member State (RMS), the evaluation process within the application (i.e. validation, assessment part I, assessment part II and decision), or the submission, decision, and validation dates.

Both search functionalities share several search parameters (e.g. overall trial status, therapeutic area, active substance, product name, or Member State(s) concerned). However, the Trial Advanced search includes specific parameters to search clinical trials and the Application Advanced search includes specific search parameters to look for clinical trial applications.

2.3. How many clinical trials can users search?

The search functionality retrieves a maximum of 200 results per search, due to the system performance (speed, responsiveness, etc.). If the user does not find the clinical trial that he/she is looking for, they must narrow down the search.

The results page can display a maximum of 100 results per page. The user can indicate how many results they want to see per page (10, 20, 50, or 100).

Users are also able to download in a CSV format the list of clinical trials appearing in a single results page by clicking on 'download trials'. Users can select from this list the ones in which they are interested and then proceed to 'start download'.

These principles are applicable to the search results of all the tabs within CTIS ('Notices & alerts', 'Tasks', 'RFI', etc.).

2.4. How can users check the status of a clinical trial or a clinical trial application?

Users can view the overall status of a clinical trial (i.e. authorised, under evaluation, halted, etc.) on the summary page of the clinical trial.

OVERALL TRIAL STATUS

Member State	Overall Trial Status	First decision date	Start of trial	End of trial	Recruitment start date
AT	Authorised ⓘ	12/05/2020	12/05/2020		
DE	Authorised ⓘ	12/05/2020	12/05/2020		

Moreover, users can view the status of an application in each Member State concerned by clicking on '+ Info', on the 'Application and Non-substantial modification' subsection, at the bottom part of the summary page of a clinical trial.

APPLICATION AND NON-SUBSTANTIAL MODIFICATION

Type	ID	Parts	MSCs	Submission date	Decision date	
Initial	IN	Part I Part II	AT (Authorised) DE (Authorised)	15/05/2020	15/05/2020	+ INFO

Application Details ✕
EU CT number: 2020-500279-59-00   **ID:** 337   **Type:** Initial (Part I, Part II)
Submission Date: 15/05/2020

MSCs	Validation	Assessment Part I	Assessment Part II	Decision
AUSTRIA			Acceptable (15/05/2020)	Authorised (15/05/2020)
GERMANY RMS	Valid (15/05/2020)	Acceptable (15/05/2020)	Acceptable (15/05/2020)	Authorised (15/05/2020)

Users can also view and download a graphical summary of the detailed status of a clinical trial application in the 'Timetable' section inside the application. This summary provides detailed information on the status and phases of the application assessment.

MSCs
Part I
Part II
Evaluation
Timetable

Timetable

- All tasks / events are shown in European Central Time (CET).
- Please note that the due dates for tasks in the future are indicative and might get updated.
- After the RMS has been selected, all projected tasks / events will be updated based on the RMS calendar.
- Part II assessment project timeline is based on each respective MSC calendar

Legend		Filter	
Concerns MSC			
Concerns RMS		Time Filter	Monthly
Concerns sponsor			
Weekends			
Winter clock stop days		Including Validation Phase RFI: ☐	Including Assessment Phase RFI: ☑
Today's date			

⌄ Application submission
⌄ Validation
⌄ Part I
⌄ Part II
⌄ Decision

⬆ Download ⤢ 🔍 🔍

3. Notices & alerts

3.1   What are notices and alerts?

Notices and alerts are messages automatically triggered by the system that enable users to monitor the events that occurred during the lifecycle of a clinical trial, either with an informative purpose or with an actionable purpose. Notices and alerts inform the user of the events occurring during the clinical trial application and the clinical trial itself (including notifications, corrective measures, ad hoc assessment, etc.). Notices and alerts can be distinguished as follows:

- Notices are messages that aim to inform the user of an event. Examples: task completed by an MS, Part I and Part II or Part I (only) or Part II (only) submitted, etc.

- Alerts are messages indicating an action that needs to be performed by the user. Examples: serious breach submitted by the sponsor, consideration has been shared, etc. CTIS includes a sub-type of alerts ('alert reminders') which are specifically aimed at reminding sponsor and authority users of actions or tasks, respectively, which are about to expire.

For more information, refer to [Frequently asked questions](#) of *Module 4: Support with workload management by workspace.*

3.2   What is the difference between 'notices' and 'notifications'?

Notices are messages automatically triggered by the system to inform users of an event that occurs during the life cycle of a clinical trial, in which such users have a role. These can be found under the 'Notices & alerts' tab.
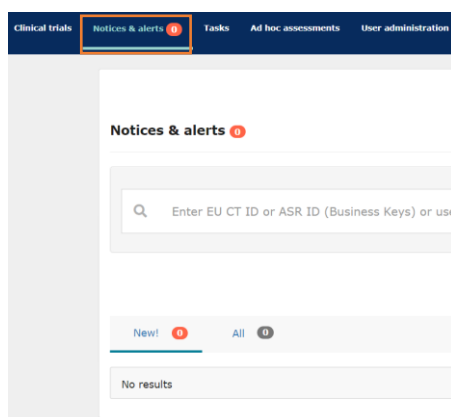
Notifications are events that occur only after a clinical trial application has been authorised. These are actively reported by the sponsors into the system through the notifications sub-tab of a clinical trial. Examples of notifications submitted by the sponsors are the recruitment of patients, notification of an unexpected event, a serious breach, or an urgent safety measure.

AK testing

thorised 2020-500323-32-00 **RMS:** France

| Summary | Full Trial Information | Notifications | Trial results | Corrective measures | Ad hoc assessments | Users | Amend | Inspections |

3.3 Do all users of the same organisation receive the same notices & alerts?

Users only receive the notices and alerts relating to the clinical trial/s of their organisation or Member State, as applicable, to which they have been given access and a specific role in CTIS. Users with the same role regarding a given clinical trial will receive the same notices and alerts.

3.4 Is there an option to turn off/re-direct notices and alerts?

There is not an option for redirecting notices and alerts to another user. All users who are registered in the system with a certain role will continue to receive notices and alerts based on their profile for the whole duration of the role authorization period.

4. User administration

4.1 Which users can assign a role?

Only users with administrator permissions can assign roles through the 'User administration' tab by clicking on 'assign a role'. The administrator must introduce the relevant data (such as user ID, EU CT number of a clinical trial, role, date, etc.) to assign a role to a user. CTIS provides a predefined drop-down list of roles that the user administrator can select from.

For more information, refer to the Frequently asked questions of *Module 7: Management of roles and permissions.*

4.2 How are administrator roles assigned?

There are two types of administrator roles: high-level and medium-level administrators. EMA is responsible for validating the first request of users to become CTIS high-level administrators of an organisation of sponsors (Sponsor Admin), Member States (MS Admin) and the European Commission (EC Admin). There is no limitation to the number of high-level administrators an organisation or a Member State can have, but they all need to be appointed in IAM. EMA manages requests of users only if the organisations/Member State/European Commission have no CTIS high-level Administrator. Any new requests will then be managed by the existing Administrator(s) of the organisation.

High-level Administrators can assign other high-level administrators or delegate user administration permissions to medium-level administrators in CTIS.

For more information, refer to the Frequently asked questions of *Module 7: Management of roles and permissions.*

4.3 Where can users view their roles?

Users can view their roles by clicking on their username button at the top-right corner of the CTIS interface and then on 'My roles'. There, users can view the role(s) they have been assigned by an administrator user. Roles can be sorted by alphabetical order, user ID, email, employer, organisation name, organisation ID, role type, scope, EU CT number, creation date, assessment date, status, authorised from, or authorised to (dates).

4.4 How can the sponsor administrator view the requests for a role of other users from the same organisation?

In the sponsor workspace, Administrators can approve or request a role from the 'User administration' tab. No notices and alerts are generated in this respect. Admin users can view the requests for roles by using the 'Requested' value in the status field.

4.5 Can a Member State user request a role?

No. Only sponsor users can request a role. Authority users can only have a role if the authority administrator assigns one to them using the 'User administration' tab.

4.6 Can any role be revoked?

In both workspaces, any role can be revoked except for high-level administrator roles (i.e. Member States administrator, sponsor administrator, Marketing Authorisation Applications (MAA) administrator, European Commission administrator, and EMA administrator). These roles are managed through IAM and cannot be revoked through CTIS.

5. Annual Safety Reporting

5.1. Who can submit an annual safety report (ASR)?

In the sponsor workspace only users with the role 'ASR submitter' can submit ASRs for a clinical trial. Additionally, only users with ASR related roles can see the 'Annual safety reporting' tab.

For more information, refer to the [Frequently asked questions](#) of *Module 18: How to submit an annual safety report and respond to related RFIs.*

5.2. Who can assess and submit a decision regarding an ASR?

In the authority workspace only users with the roles 'ASR assessor' and 'ASR decision maker-submitter' can assess and submit (respectively) the decisions regarding the ASRs submitted by sponsors.

For more information, refer to the [Frequently asked questions](#) of *Module 20: Assess an annual safety report.*

5.3. Can any user view an ASR?

No. CTIS is a role-based system. In both workspaces (Sponsors and Member states), users can only see the ASRs related to clinical trials for which they have been given an ASR related role.

5.4. How can users search for an ASR?

Users can search ASRs by entering the EU CT number or ASR ID (only the number of the code without the 'ASR' or the 'CT' at the beginning), or use the 'Advanced search' with specific parameters. Once the specific ASR is retrieved, authority users can select it and view the ASR submission and the assessment data on CTIS or download the ASR submission and assessment documents.