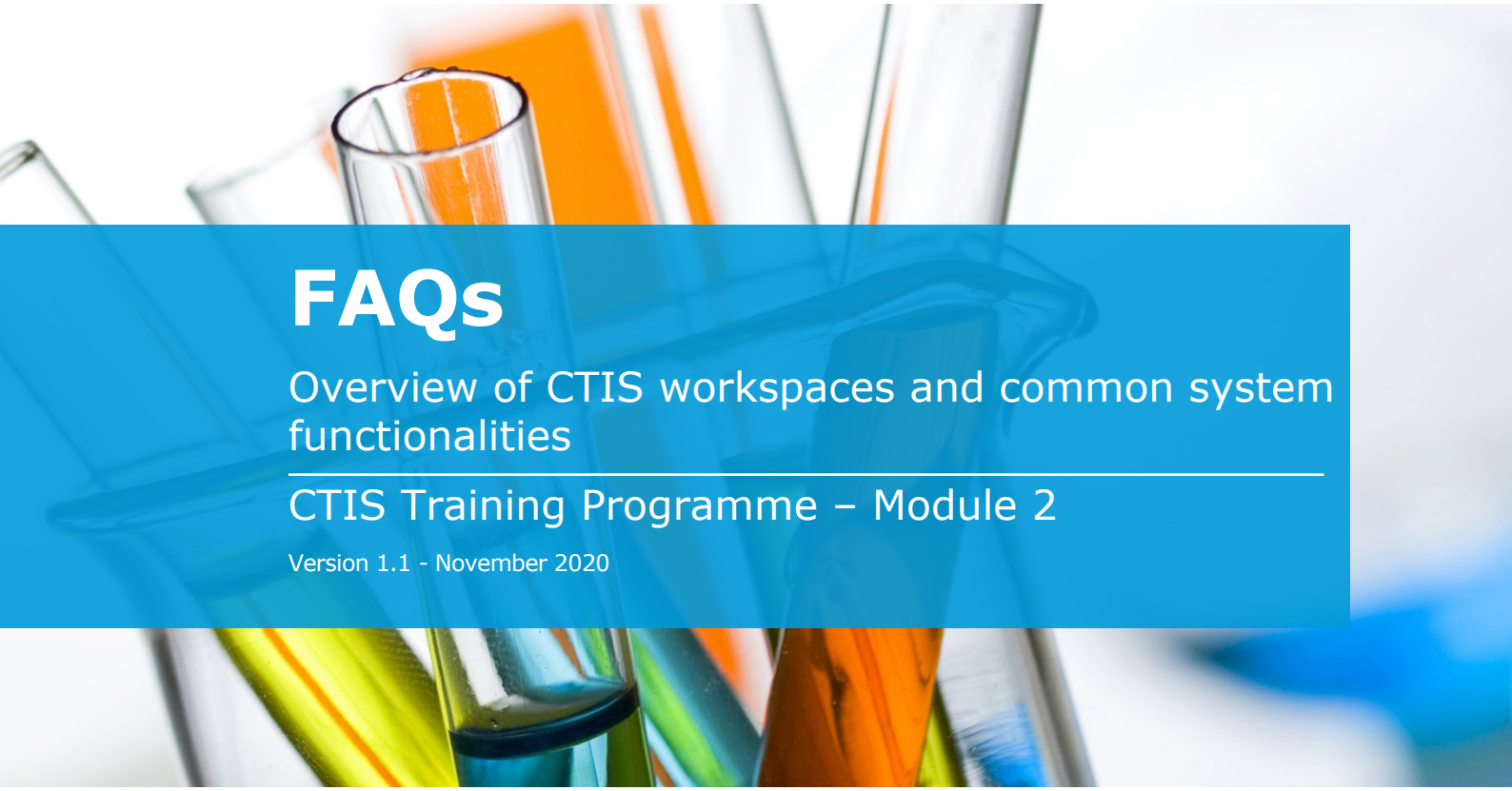
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



FAQs

Overview of CTIS workspaces and common system functionalities

CTIS Training Programme – Module 2

Version 1.1 - November 2020

This training material describes and reflects preliminary versions of CTIS and will be revised in 2021 to match the Go-Live version and thereafter to match subsequent releases post Go-Live.

Therefore, this material is at this time to be considered DRAFT and is not to be further reproduced or distributed.

Table of Contents

General 4

1.1. What is CTIS? 4

1.2. What categories of data are stored in CTIS? 4

1.3. Where does the data in CTIS come from? 5

1.4. When/how are data categories updated in CTIS? 5

1.5. What type of reports can the user retrieve/generate with the BI reporting tool? 6

1.6. How is CTIS being developed? Is it possible to see future development plans? 6

1.7. If CTIS is not working properly, who should the user contact to get assistance? 6

1.8. In which languages is CTIS available? 6

1.9. How do users access the system? How do users recover their password? 6

Overview of clinical trials 7

2.1. Does CTIS display the same search results for the users of the sponsor and the authority workspace? 7

2.2. Do users retrieve different results depending on the advanced search they apply? 7

2.3. How many clinical trials can a user look for? 7

2.4. How can the user check the status of a clinical trial application? And of a trial? 8

Notices and alerts 9

3.1. What are notices? 9

3.2. What are alerts? 9

3.3. What is the difference between 'notices' and 'notifications'? 9

3.4. Do all users of the same organisation receive the same notices & alerts? 10

User administrator 10

4.1. How many user administrators can each organisations/Member State have? 10

4.2. How can a user administrator assign a role within his/her organisation? 10

4.3. Can users be assigned multiple roles? Is there any limit? 11

4.4. Where can users see their roles? 11

4.5. Where does the sponsor administrator receive the requests for a role of other users from the same organisation? 11

4.6. Can a Member State user request a role? 11

4.7. Can any role or permission be revoked? 11

Annual Safety Reporting 12

5.1. Who can submit an annual safety report (ASR)? Who can assess and submit a decision regarding an ASR? 12

5.2. Can any user view an ASR? 12

5.3. Can a user save a draft of the annual safety report before submitting it to CTIS? 12

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'.

We encourage you to read these questions and answers carefully. If you have any questions which are not covered in this document, please contact us at CT.Training@ema.europa.eu so that we can update this document accordingly. 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 will be the single entry portal for submitting clinical trials information in the EU with the highest standards of safety for participants. It will support 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 will also support the transparency of data regarding clinical trials conducted in the EU for the general public through a public website.

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. All these databases and systems are managed by the EMA. These 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.
- **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.
- **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.

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 allows Member State users to access standard reports about clinical trials recorded in CTIS, and to 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 is CTIS being developed? Is it possible to see future development plans?

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

General information about the status of the development of CTIS is available at EMA's website: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation.

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

Once the system goes live, a maintenance team will be set up to take care of the assistance requests. These will be 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?

When the system goes live, CTIS will be 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 do users access the system? How do users recover their password?

For users to gain access to CTIS they first need to request an account in IAM, EMA's centralised user account management. To do so, users need to register first at CTIS login page by clicking on 'Register New Users'. The fields to be populated are the first name, last name, email, password, and mobile phone (optional). The information will be saved in IAM. The user will receive a confirmation of successful registration and an activation link with the username. If the

[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

user forgets his/her password, they can click on 'forgot password?' and be able to reset it. Users will only be able to navigate the system once they have been given a role by a user with administrator credentials.

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.

- 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.

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 a user look for?

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.

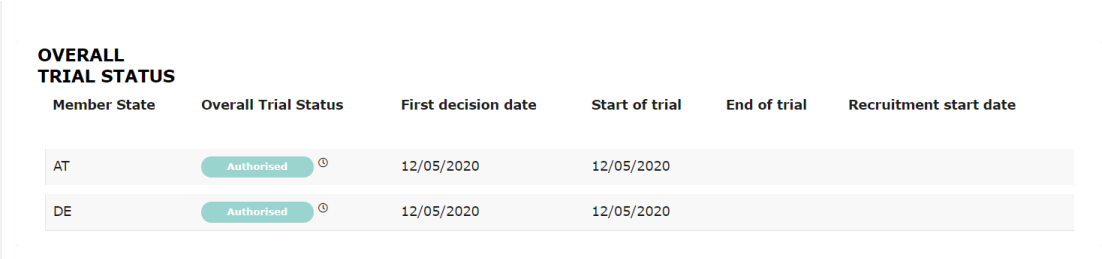
The results page can display a maximum of 100 results per page. The user can indicate how many results they want to see per page (10, 20, 50, or 100).

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 the user check the status of a clinical trial application? And of a trial?

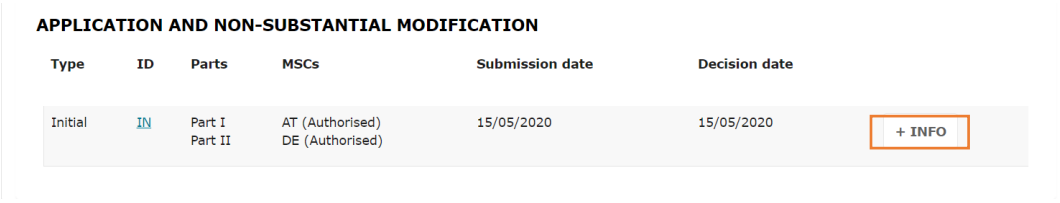
The user can view the overall status of a clinical trial (i.e. authorised, under evaluation, halted, etc.) on the summary page of the clinical trial.



OVERALL TRIAL STATUS

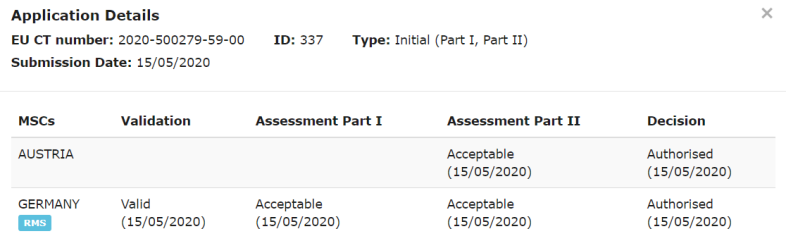
Member State	Overall Trial Status	First decision date	Start of trial	End of trial	Recruitment start date
AT	Authorised	12/05/2020	12/05/2020		
DE	Authorised	12/05/2020	12/05/2020		

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

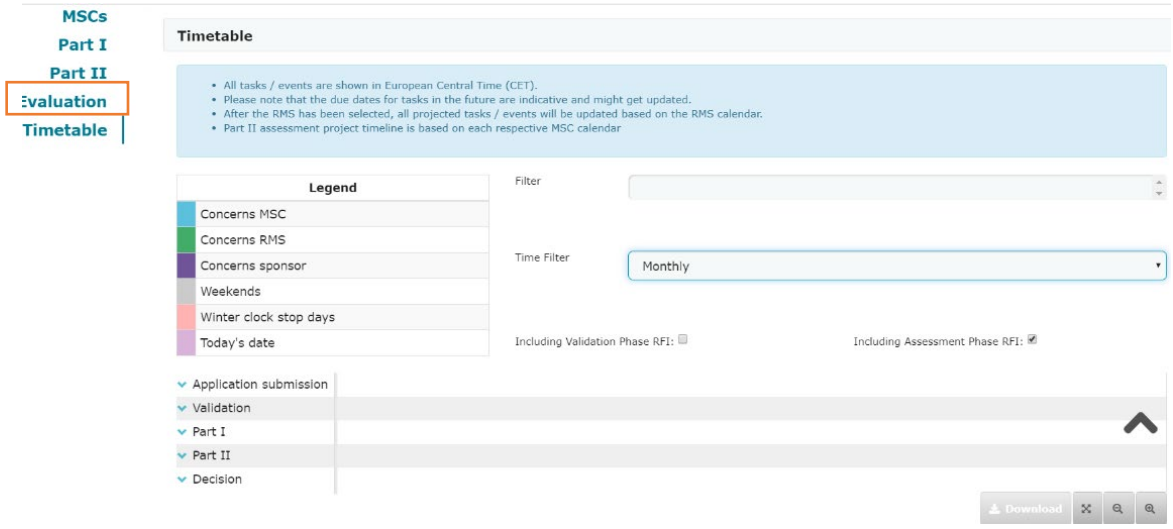


Application Details

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.



3. Notices & alerts

3.1. What are notices?

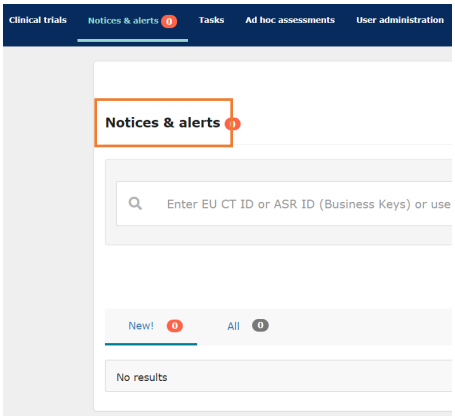
Notices are messages to inform users of an event that occurs during the life cycle of a clinical trial for which they have been given a role (e.g. 'initial application has been submitted', 'serious breach notification has been submitted', 'decision has been submitted', etc.).

3.2. What are alerts?

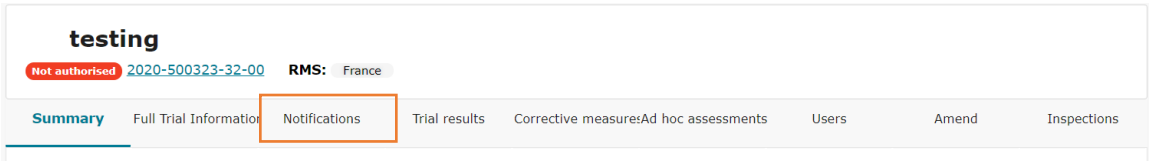
Alerts are messages informing users of an action that needs to be taken by them regarding a clinical trial for which they have been given a role (e.g. 'a corrective measure has been made', 'considerations are due', 'no MSC willing', 'RFI sent to sponsor', 'response to RFI due').

3.3. 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.



3.4. 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 trial will receive the same notices and alerts.

4. User administration

4.1. How many user administrators can each organisations/Member State have?

There is no limit to the number of user administrator that an organisation or Member State can have.

In the case of the authority workspace, Member State administrators can also delegate user management permissions to national organisation administrators (NOAs), which may be national competent authorities or ethics committees. NOAs will only be able to assign roles and permissions within their own organisation.

Similarly for the sponsor workspace, sponsor administrators can assign the role of 'Clinical Trial administrator' to users within their organisation or working on behalf of such organisation.

4.2. How can a user administrator assign a role within his/her organisation?

User administrator roles such as Member State admin or sponsor administrator need to be set

up in IAM. All other roles (including NOA and CT admin described in question 4.1 above) are allocated by users with administrator permissions directly in CTIS.

A user with administrator permissions can assign roles within his/her organisation 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 identify the user to whom he/she wishes to give a new role. CTIS provides a predefined drop-down list of roles that the user administrator can select from.

4.3. Can users be assigned multiple roles? Is there any limit?

Yes, users can be assigned multiple roles within an organisation or Member State. There is no limitation of roles to be given to a user other than the total number of roles available in the system, which are predefined.

4.4. Where can users see their roles?

Users can see their roles by clicking on their profile on the top-right part of the CTIS interface and then on 'My roles'.

4.5. Where does the sponsor administrator receive the requests for a role of other users from the same organisation?

When a sponsor user requests a role, the request will appear in the 'User administration' tab where the sponsor administrator can approve or reject it. No notices and alerts are generated in this respect.

4.6. Can a Member State user request a role?

No. Only sponsor users can request a role within their organisations.

Authority users can only have a role if the authority administrator assigns one to them using the 'User administration' tab.

4.7. Can any role or permission be revoked?

In both workspaces, any role can be revoked except for user 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)? Who can assess and submit a decision regarding an ASR?

In the sponsor workspace only users with the role 'ASR submitter' can submit ASRs for a clinical trial.

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.

5.2. Can any user view an ASR?

No. CTIS is a role-based system. Therefore: In the sponsor workspace, users can only see the ASRs related to clinical trials submitted by their organisations for which they have been given a role. In the authority workspace, users can only see the ASRs related to clinical trials for which they represent a Member State concerned.

5.3. Can a user save a draft of the annual safety report before submitting it to CTIS?

No. CTIS does not include a save button for ASR. All relevant fields need to be populated at once for submitting the ASR.

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Frequently Asked Questions
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