EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MS Master Trainers – December 2020 Training event

Introduction to the Clinical Trials Regulation & the Clinical Trials Information System

07/12/2020

Content

- Welcome and introduction to the session (*10 min*)
- Practicalities about the training session (*5 min*)
- Recap on User Confluence page (*10 min*)
- Training material available and selection (10 min)
- Key concepts covered in Module 01 – Introduction to new CTR (*30 min*)
  - *Introductory slides*
  - *Group exercise*
  - *Training catalogue materials*
- **Break (*15 min*)**
- Key concepts covered in Modules 02 – Overview of main CTIS components and system functionalities (*60 min*)
  - *Introductory slides*
  - *Demo (20')*
  - *Group exercise*
  - *Training catalogue materials*
- **Q&A (*30 min*)**
- Update on Training Programme & next steps (*10 min*)

Welcome and introduction to the session

*Welcome to the **first training session for the MS Master Trainers of CTIS**. Your role is key in the dissemination of CTIS knowledge to end-users. For this reason, it is important that you get acquainted with the training materials developed so far to get you up-to-speed as soon as possible.*

Objectives of this session

- Highlight **key information** about the **Clinical Trials Regulation**
- Introduce you to CTIS: **workspaces** and **public website**
- Show the **common system functionalities** of both workspaces in CTIS and highlight most important elements.
- **Address your questions** to the materials.

Key considerations

- *The focus of this Programme is to **train users on CTIS, not on the CT Regulation**, which falls under the responsibility of the Commission. Still we have included a **general module** as background material.*
- *This is an **introductory session assuming the majority of you do not have previous knowledge of CTIS**. We will have dedicated sessions in 2021 to go in-depth on the functionalities presented today.*

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Practicalities about the training session

To maximise this engagement and minimise technical challenges, let's first review the main session technicalities.

Session plan

- The session will be a mix of **material presentation**, practical **demos** and **group exercises**.
- We have **reviewed the input** sent by some of you in advance and have taken it into account when preparing this session.
- We have foreseen a **dedicated Q&A at the end** of the session, but feel free to stop us if you have an immediate question.
- We foresee a **15-minute break** in the middle.

Bear-in-mind practicalities

- **Mute yourself** while not speaking to avoid background noises.
- Use the **hand raise symbol** to request the floor. After your intervention, please clear the status. You may also **use the chat** to post your questions.
- You will need **two devices** for the participatory activities we have foreseen: a laptop and a mobile phone or tablet.
- If you have any technical issue during the session, please write to VirtualMeetings@ema.europa.eu.

Practicalities about the training session

Available statuses

Muting and unmuting yourself

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Recap on CTIS User Community Confluence page

It is important that you are familiar with the Confluence page as main source for training materials and events overview. Click on 'watch' page on top to receive notifications any time there are updates on the page.

Confluence page

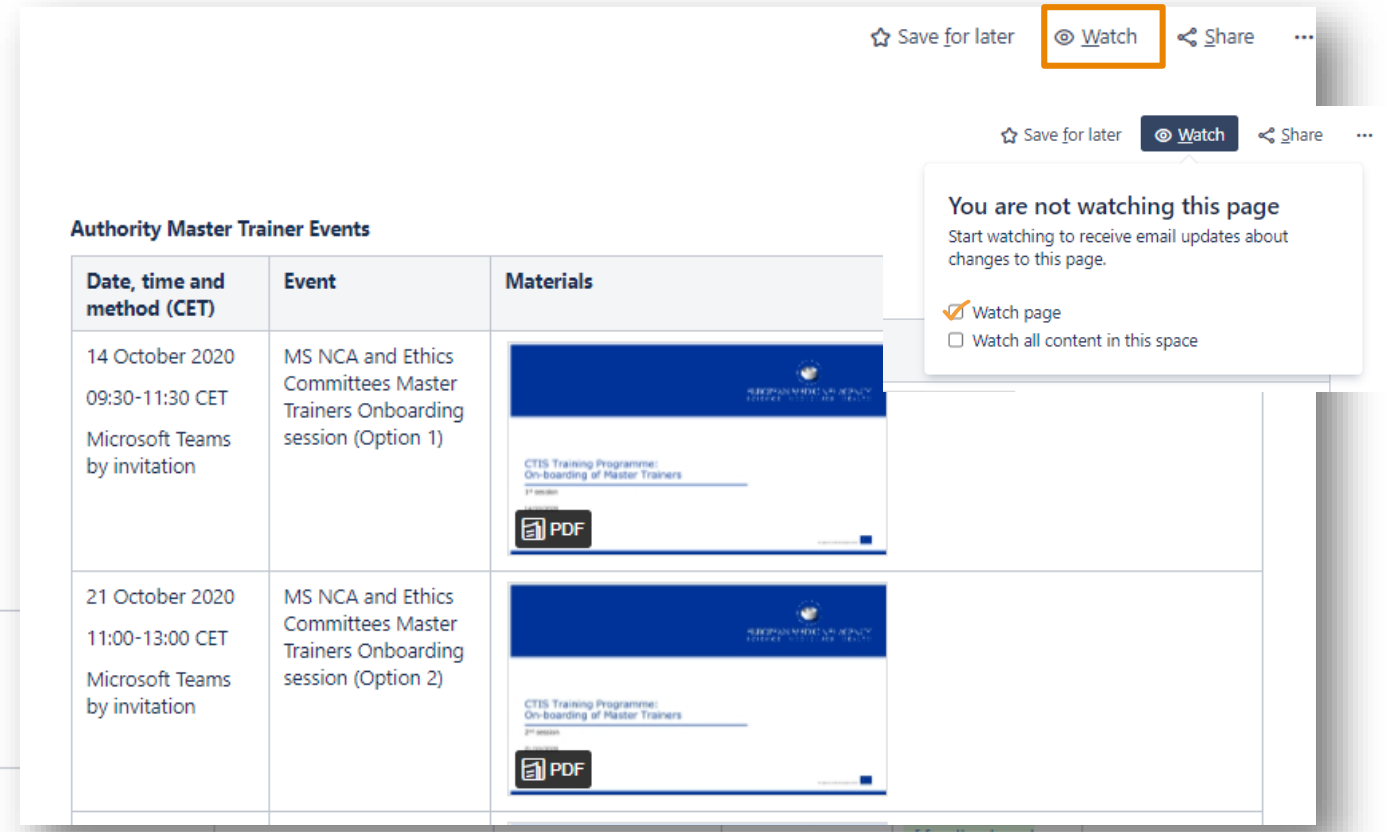
- **Page structure & info available:**
  - **Landing page**: Information about CTIS Training Programme
  - **Catalogue**: Ready to disseminate materials
  - **Master Trainers page**: planned training events & activities

Can you confirm you can all access it? Contact MSMasterTrainer@ema.europa.eu in case of issues

Recap on CTIS User Community Confluence page

Updates on the page

For any updates made on the page you will receive an email indicating what changed (highlighted in green)



CTTM08	Module 8: Evaluate a CTA - Assessment and decision-making Member States						
CTTM09	Module 9: Sponsor search, view and download a Clinical Trial Sponsors						
CTTM10	Module 10: Create, submit and withdraw a Clinical Trial and address responses to Requests For Information Sponsors						CTTM10 - Proposed design - overview of feedback and outcome.pdf

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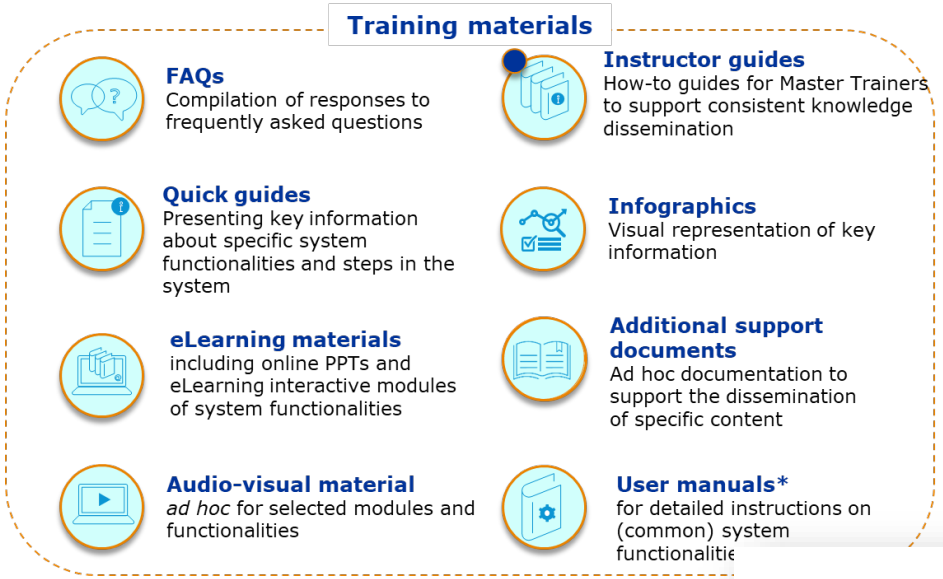
Training material available and selection

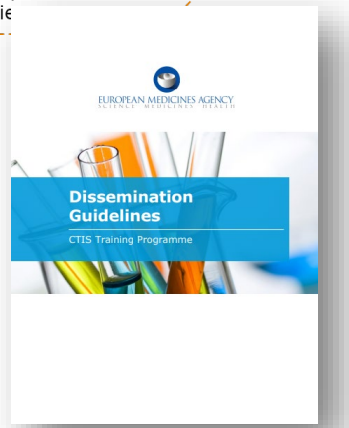
CTIS Training Team has a catalogue of materials to choose from. For each module, an assessment is made in the design phase on the best mix, considering the content complexity and the resources available. Additional materials may be added in the revision phase, in which updates to existing materials are also expected (from 05/21).

Training material selection

- The team works with a catalogue of **6 types of materials**, plus ad hoc support materials
- The specific materials to be prepared **are chosen for each module** depending on the content to be covered
- **Specific material for MTs**:
  - Instructor Guides
  - General dissemination guidelines



General dissemination guidelines



Learning scope of today

*The **training catalogue** comprises **21 modules.** In this session we will cover the first two introductory modules. Please note that the functionalities presented today in high-level will be covered in more detail in future modules.*

Introductory modules	Modules targeted to Member States	Modules targeted to Sponsors	Common modules for MS/EC and Sponsors	Other audience-specific modules
Introduction to new Clinical Trials Regulation	BI reporting (*also the European Commission*)	How to manage a CT *(trial results, notifications, ad hoc assessment & CMs)*	Support with workload management *(tasks, notices & alerts, RFI list & timetable)*	Manage Union Controls (European Commission)
Overview of main CTIS components and system functionalities (high level)	Evaluate an initial CTA *(application types, evaluation overview, RMS selection & validation)*	Create, submit and withdraw a CTA	User Access Management (self-registration, login & user profile)	Clinical Study Reports submissions (Marketing Authorisation Applicant)
	Evaluate an initial CTA *(assessment and decision-making)*	How to search, view and download a CT and a CTA in the sponsor workspace	Management of registered users & role matrix	Supervise a CT – Inspection records (MS inspectors)
	Supervise CT – Ad hoc assessment (incl. safety)	Respond to RFIs received during the evaluation of a CTA		Introduction to CTIS for Public Users
	Supervise CT – additional information assessment (safety related)	Create and submit an Annual Safety Report and respond to related RFIs		
	How to search, view and download a CT and a CTA in the authority workspace			
	Supervise a CT – Corrective measures			
	Assess an Annual Safety Report			

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Key contents covered in training Module 1: The Clinical Trials Regulation

- *The CT Directive vs the CT Regulation*
- *The CT Regulation scope*
- *Main benefits*
- *Actors targeted*
- *The CT Regulation and CTIS*
- *Application and transitional period*

CT Directive vs CT Regulation

*The Regulation (EU) No 536/2014 (**the CT Regulation**) was published in the EU Official Journal on 27 May 2014. From its application, it will replace the existing CT Directive and become applicable across the EU. This will occur as soon as the EU Clinical Trials Portal and Database (CTIS) is fully functional.*

Limitations of the CT Directive

- Highly complex regulatory framework for submission of clinical trial data
- Fragmented assessment process of multinational clinical trials applications
- Limited data available to the public for clinical trials applications and results

Improvements with the CT Regulation

- Simplify and harmonise the procedures for the submission of clinical trial applications
- Facilitate and harmonise the assessment of multinational clinical trials applications
- Improve public data availability concerning clinical trials applications and results

*The CT Regulation aims to **make the EU attractive for scientific research and innovation** by simplifying the clinical trial application process, in particular for multinational trials.*

The CT Regulation scope

*The CT Regulation applies to **interventional trials with medicinal products for human use**, including **low-interventional trials**. It does not apply to non-interventional studies or to trials not involving medicinal products.*

In the scope

- Interventional trials with medicinal products for human use conducted in the European Union
- Also low-interventional trials *(trials with authorised medicinal products, used in accordance with the marketing authorisation, and additional diagnostic and monitoring procedures not posing additional risk or burden to patients' safety compared to normal practice in MSC)*

Outside the scope

- Non-interventional studies
- Trials without medicinal products (e.g. devices, surgery, etc.)

See Articles 1 and 2(2) of the CTR

Benefits of the CT Regulation

*The **CT Regulation** aims at creating an environment that is favorable for conducting clinical trials (**CTs**) in the EU with the **highest standards of safety for participants** and increased **transparency** of CTs information.*

Main benefits of the CT Regulation

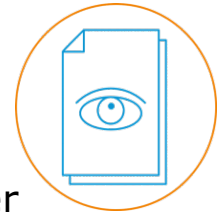
Higher safety standards

Efficient submission & assessment

Transparent clinical trials' data

Clear rules for participants' consent

Harmonised authorisation through one application dossier



Reinforced supervision by the European Commission

Flexible risk-based rules for low-risk trials

Improved cooperation among actors

Common provisions governing CTs

Actors targeted by the CT Regulation

*Similarly to the existing **CT Directive**, the **CT Regulation** targets **all actors** involved in the clinical trial lifecycle. Additionally, the CT Regulation increases transparency of information on clinical trials conducted in the EU, thereby benefiting in particular the **general public**.*

Authorities

National competent authorities, ethics committees, the European Commission and the European Medicines Agency

Sponsors

Commercial organisations, non-commercial organisations and academia

General public

Patients, healthcare professionals, clinical research associations, media, members of the public, etc.

Main outcome of the CT Regulation

*The rules established in the CT Regulation will be implemented through a **dedicated EU Portal and Database** (the Clinical Trials Information System or CTIS), currently under development and expected to go live by end 2021.*

Article 80

EU portal

The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a portal at Union level as a single entry point for the submission of data and information relating to clinical trials in accordance with this Regulation. The EU portal shall be technically advanced and user-friendly so as to avoid unnecessary work.

Article 81

EU database

1. The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a EU database at Union level. The Agency shall be considered to be the controller of the EU database and shall be responsible for avoiding unnecessary duplication between the EU database and the EudraCT and Eudravigilance databases.

The EU database shall contain the data and information submitted in accordance with this Regulation.

The EU database shall identify each clinical trial by a unique EU trial number. The sponsor shall refer to this EU trial number in any subsequent submission relating or referring to that clinical trial.

Article 82

Functionality of the EU portal and the EU database

1. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the EU portal and the EU database, together with the time frame for their implementation.

2. The Management Board of the Agency shall, on the basis of an independent audit report, inform the Commission when it has verified that the EU portal and the EU database have achieved full functionality and the systems meet the functional specifications drawn up pursuant to paragraph 1.

3. The Commission shall, when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the *Official Journal of the European Union*.

CTIS

Application and Transition period

Application

- The CT Regulation will become applicable **six months after** the publication by the Commission of a notice in the EU Official Journal stating that **CTIS has achieved full functionality**.
- EMA's MB will inform the Commission that the system has reached this status following the results of **independent audit report**, expected by spring 2021.

Transition

- A **3-year transition period** is foreseen from the application date of the CTR in which the Directive will also apply.
  - In the **1st year of application** sponsors will be able to **choose**
  - In the **2nd year initial CTAs must be submitted under CTR** and previously submitted CTAs will remain under CT Directive
  - At the **end of the 3rd year all CTAs will have to switch to CTR regime**

Group exercise

EUROPEAN MEDICINES AGENCY

The Clinical Trials Regulation

Increasing transparency, efficiency and cooperation on clinical trials information in the EU

What is it?

Regulation (EU) No 536/2017 (the Clinical Trials Regulation) aims at creating an environment that is favourable for **conducting clinical trials (CTs) in the EU** with the highest standards of **safety** for participants and increased **transparency** of CTs **information**. It will replace and expand the scope of the existing EU Clinical Trials Directive 2001/20/EC.

What will the Clinical Trials Regulation do?

- Ensure the highest **safety** standards for all participants in CTs
- Strengthen reliability, robustness, and **transparency** of patients' data in the European Union
- Increase the **efficiency** for the **submission** and **assessment** of CTs applications within established deadlines
- **Harmonise** the **authorisation** process of CTs, resulting in a single decision for all Member States concerned.
- Provide **tailored-made provisions** governing CTs in different Member States
- Improve the **cooperation** between Member States and sponsors, and among Member States in the assessment of a CT application
- Establish clear **rules** at EU level for unbiased and **informed consent** of participants in CTs including for those who are unable to provide said consent
- Introduce a **risk-adapted approach** with more stringent rules for those trials conducted with authorised medicines and low-risk CTs
- Reinforce **supervision** of CTs by introducing Union Controls to ensure compliance with the Clinical Trials Regulation

Who will the Clinical Trials Regulation benefit?

Authorities
Member States national competent authorities, ethics committees, European Commission and EMA

Sponsors
Academia

General Public
Patients, scientists, healthcare professionals, clinical research associations, media, citizens

The implementation of the Clinical Trials Regulation will be supported by...

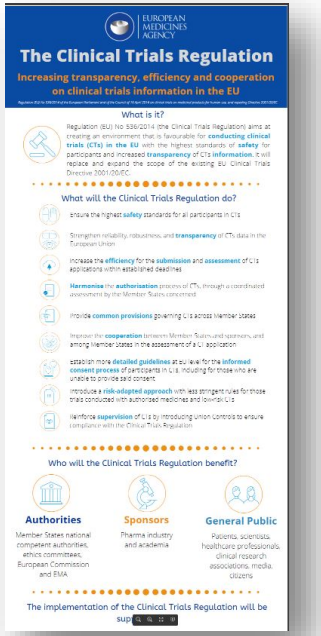
The Clinical Trials Information System (CTIS)

The rules established in the Regulation will be supported through a dedicated EU Portal and Database (the Clinical Trials Information System) that will become the **single entry point** for submitting CTs information in the EU and will support the **daily business processes** of Member States and sponsors throughout the life cycle of their CTs.

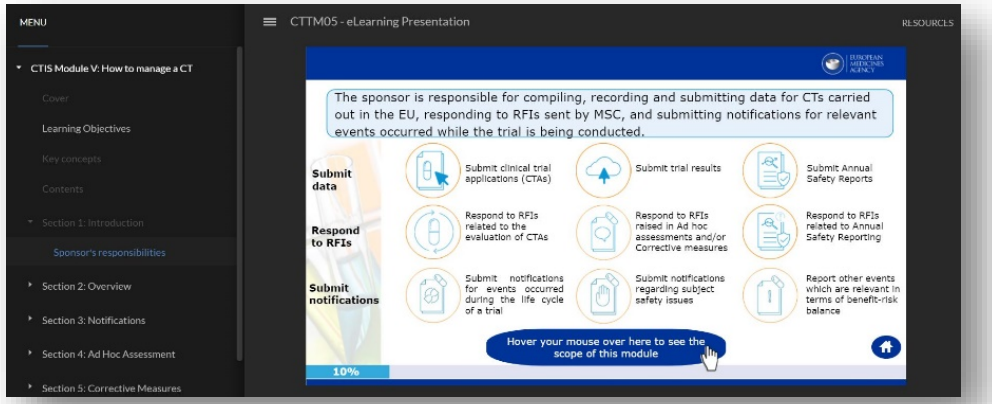
"Spot-the-mistakes" exercise:

1. There are **six mistakes** in the areas marked in yellow
2. You will be displayed each of these areas individually and be given a few seconds to reflect on what seems odd
3. Error types: missing words or incorrect words/numbers
4. You will need to identify the error and propose a correct phrasing
5. How? Go to www.menti.com with your mobile phone or tablet and **enter the code** that will be provided to you

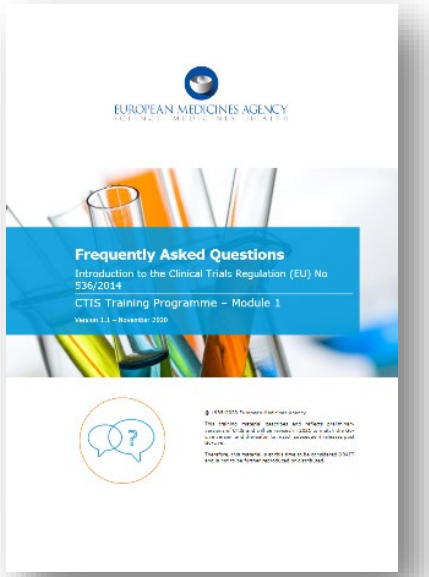
Training materials available



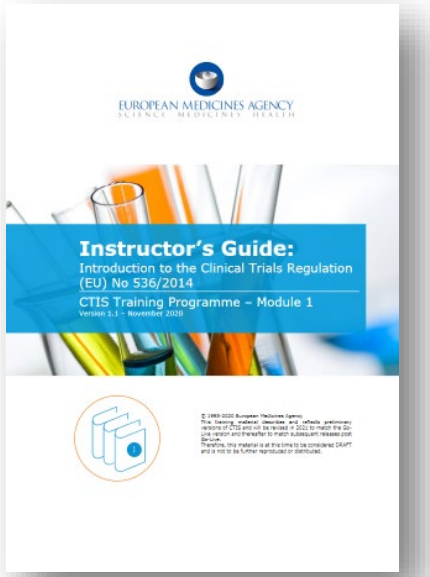
Infographic



eLearning material



FAQs document



Instructor Guide

15-minute break!

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Key contents covered in Module 2: Overview of CTIS workspaces and common system functionalities

- *Introduction to CTIS and its two workspaces*
- *Databases and systems interacting with CTIS*
- *Overview of clinical trials & search functionality*
- *Notices & alerts*
- *User administration*
- *Annual Safety Reporting*

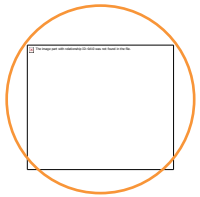
What is CTIS?

*CTIS is the system implementing the requirements set out in the Clinical Trials Regulation. It is referred to in Article 80 and 81 of the CTR as and **EU portal and database** for the submission and storage of clinical trials data and information.*

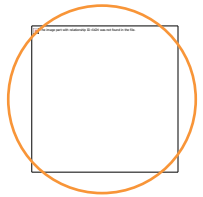
CTIS will become the **single entry point for clinical trials data in the EU** and will support the **harmonisation of the submission and assessment processes** of clinical trials conducted in the EU.

CTIS will have multiple features enabling the **harmonisation** of the submission and assessment processes of clinical trials conducted in the EU. Most of these features are already implemented with a need for further development to meet full functionality and user acceptance. **CTIS will offer the following features:**

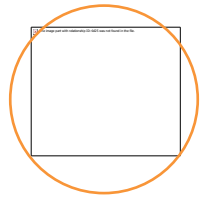
Collaboration tools for information exchange between the actors



Workflow capabilities in line with the timelines defined in CTR



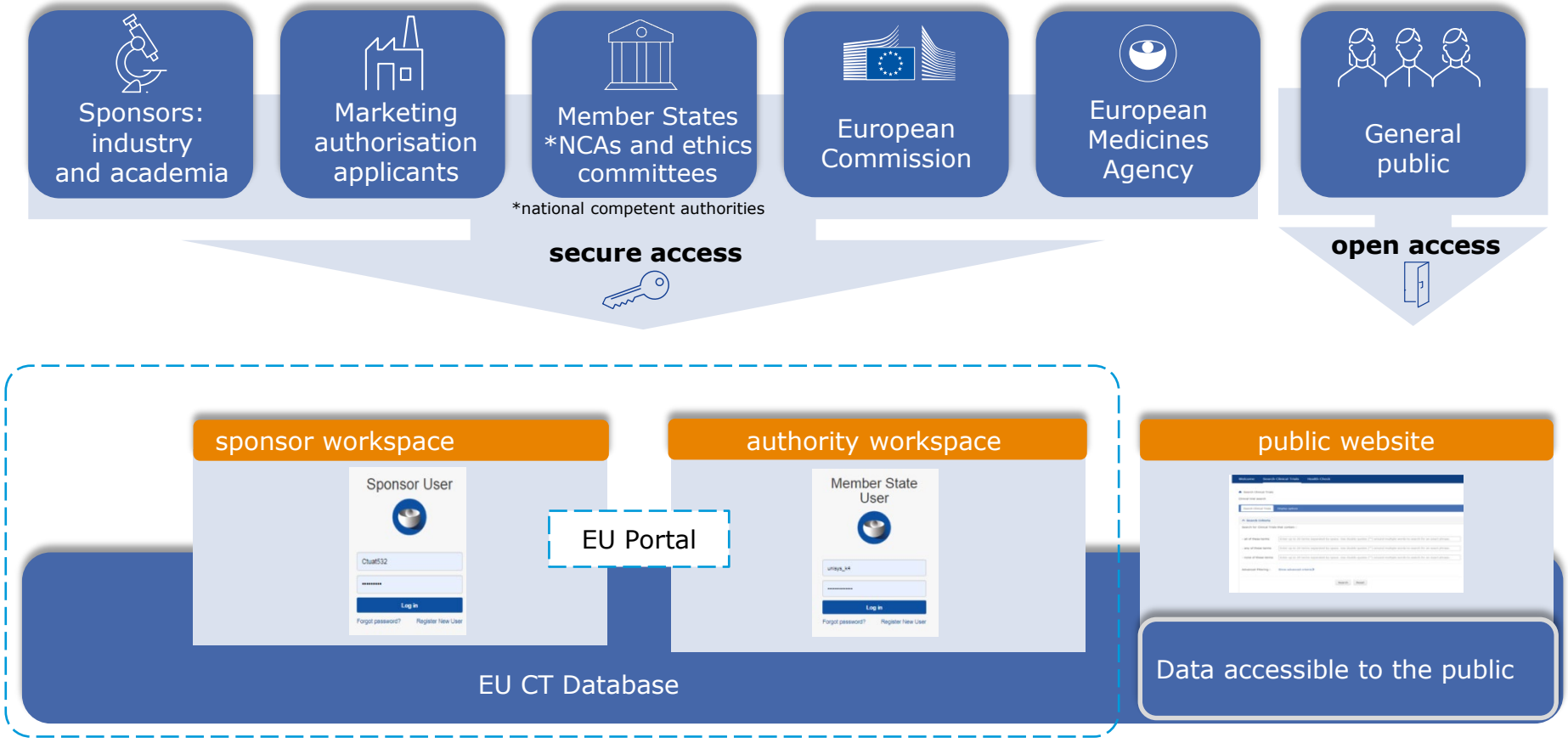
User management functionalities for assigning roles & permissions to the users



Document management and reporting through a common repository and standard reports

Introduction to CTIS workspaces and public website

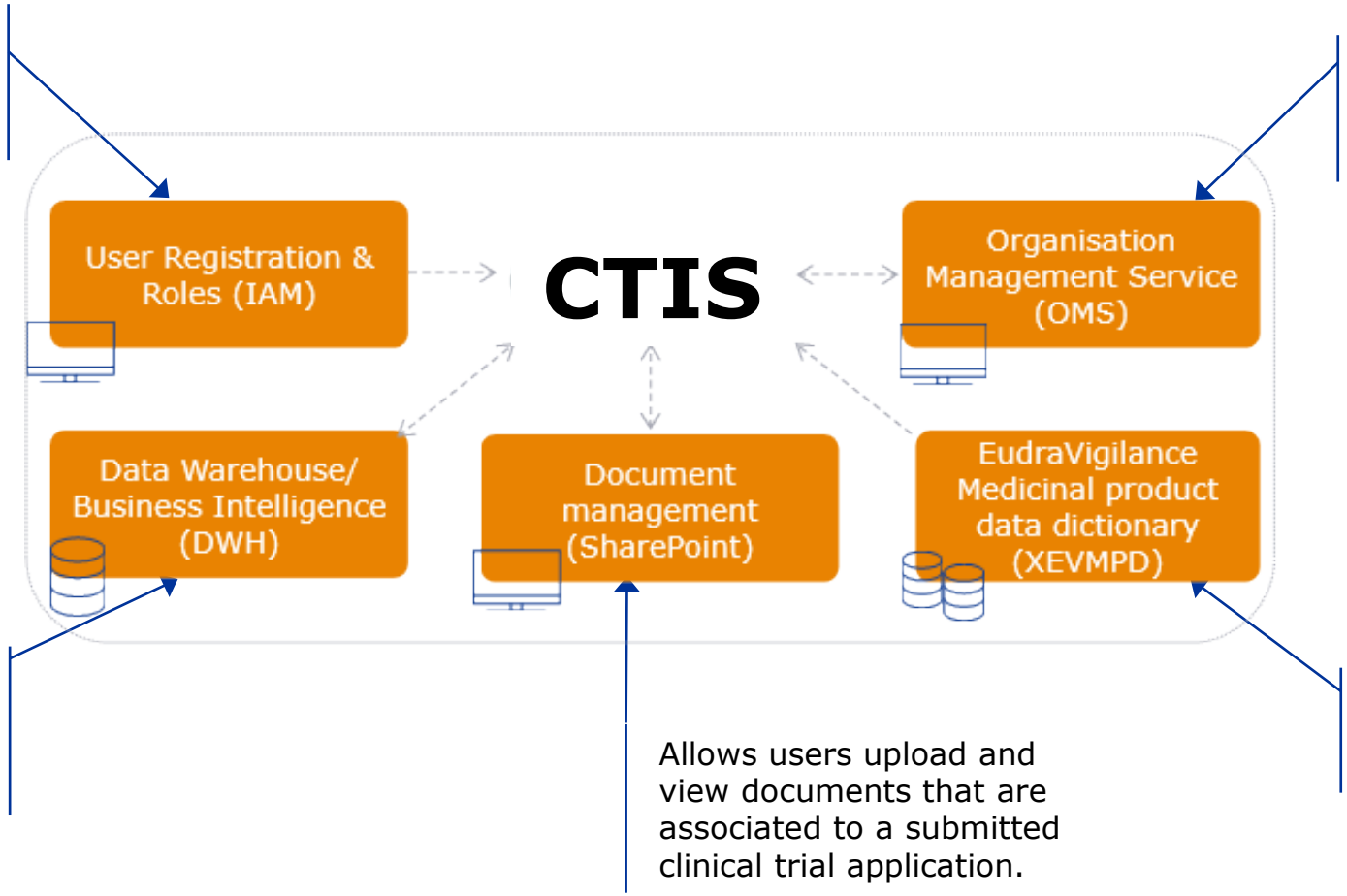
*CTIS is composed of **two workspaces** with secured and restricted access for sponsors and authorities, and a **public website** openly accessible to the general public.*



Interaction of CTIS with other systems and databases

CTIS interacts with several databases and systems. These allow to register users, search information on organisations and medicinal products, or store data and documents provided to CTIS. All these databases and systems are managed by EMA.

Provides users with access to CTIS applications that are managed by EMA. It also records roles and permissions for admin users.



Provides organisation data to CTIS (organisation name, address, location)

Allows users to obtain reports and statistics based on the clinical trial data contained in CTIS.

Allows users upload and view documents that are associated to a submitted clinical trial application.

Provides information on medicinal products to CTIS.

Introduction to the common functionalities

CTIS offers four common functionalities for the two main user groups (i.e. sponsors and authorities). These are: Overview of CTs (search functionality), Notices & alerts, User administration and Annual Safety Reporting.

*This is an **introduction** to these functionalities. There are dedicated modules on each of them in the Catalogue, except for ASR, which is a functionality still in development.*

Overview of Clinical Trials

Allows users to search, select and view a clinical trial, and to monitor the status and information of the clinical trials that are stored in the EU Clinical Trials' Database.

Notices & Alerts

Allows users to monitor the messages triggered by events that have occurred during the lifecycle of a clinical trial in which they are involved.

User administration

Allows users with an administrator role to manage the roles and permissions of the registered users within their organisation or Member State.

Annual Safety Reporting

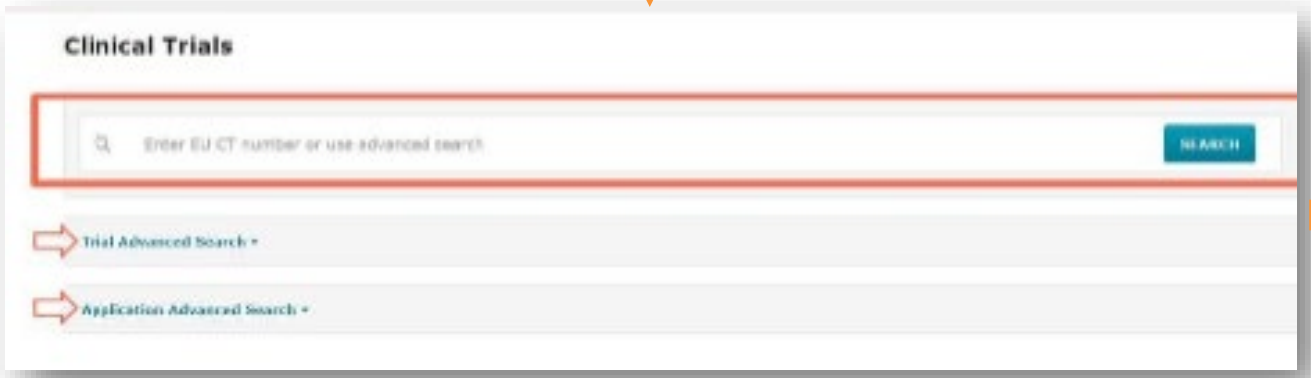
Allows sponsors with certain permissions to submit the ASR on the safety status of their trials and to have them assessed by authority users with certain permissions.

Overview of clinical trials & searches

*In the overview of clinical trials, users can retrieve information on clinical trials through CTIS. This is enabled through a **basic search functionality** and **two advanced search functionalities** that retrieve trial-relevant information.*

Sponsor users will not be able to see an ongoing assessment done by the Member State - only the final outcome.

Member State users will not be able to see draft clinical trial applications until they are submitted.



Search types

- **Basic search**: Allows the user to look for a specific clinical trial by entering its EU CT number. Predictive feature available.
- **Advanced searches**: Useful for organisations or users managing numerous trial and willing to monitor specific criteria.
    - **Trial Advanced search**: Allows the user to search for clinical trials that match a set of specified parameters.
    - **Application Advanced search**: Allows the user to retrieve clinical trials which contain application(s) that match the specified search parameters.

*Both advanced searches **share several search criteria**, but the trial advanced search includes **additional criteria** to look for CTs, while the application advanced search has specific criteria to look for CTAs.*

Common & specific search criteria in advanced searches

	Trial advanced search	Application advanced search
Common criteria (11)	• Overall trial status • Trial title • Protocol code • Condition • Sponsor • Active substance • Product name • Route of administration • Therapeutic area • Member states concerned • Reporting member state	
Specific criteria	• MSC trial status • EU MP number • Has serious breach(es) (Y/N) • Summary of results • Trial start date • End of trial date • Global end of trial date • Recruitment status	• Application status • Evaluation process • Submission date • Validation date • Reporting date • Decision date • Application type • Part II conclusion date • Has disagreement (Y/N)

Notices & alerts

Users can monitor the messages triggered by the system following the occurrence of events during the lifecycle of a clinical trial (i.e. from the creation and submission to the reporting of results of a clinical trial).

Notices are messages that aim to inform the user of an event.
Alerts are messages of an action required to be performed by the user.

Examples:

Sponsors workspace

- **Notice**: a decision has been submitted by a MS
- **Alert**: a corrective measure has been made by a MS

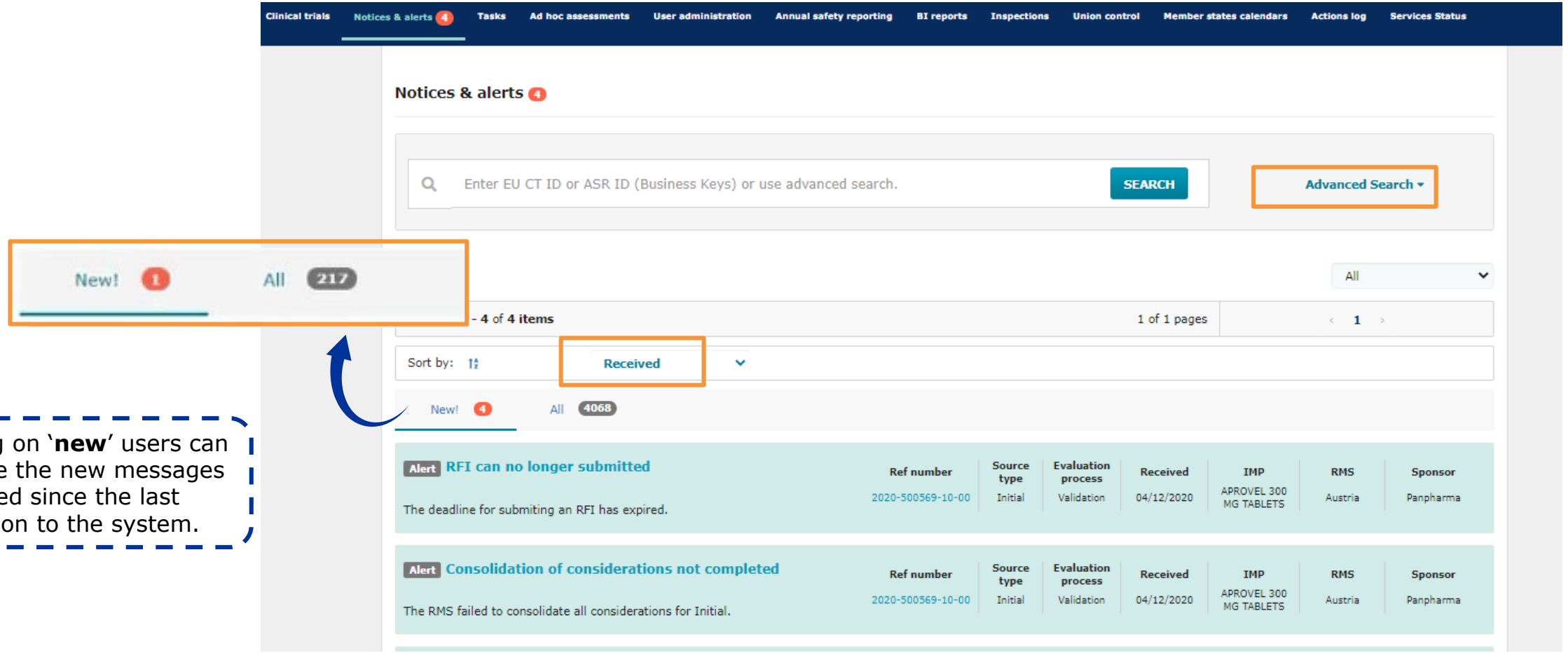
Authority workspace

- **Notice**: task completed by a MS
- **Alert**: serious breach submitted by the sponsor

In both workspaces, users will only receive messages related to the clinical trials(s) they are involved in.

Notices & alerts

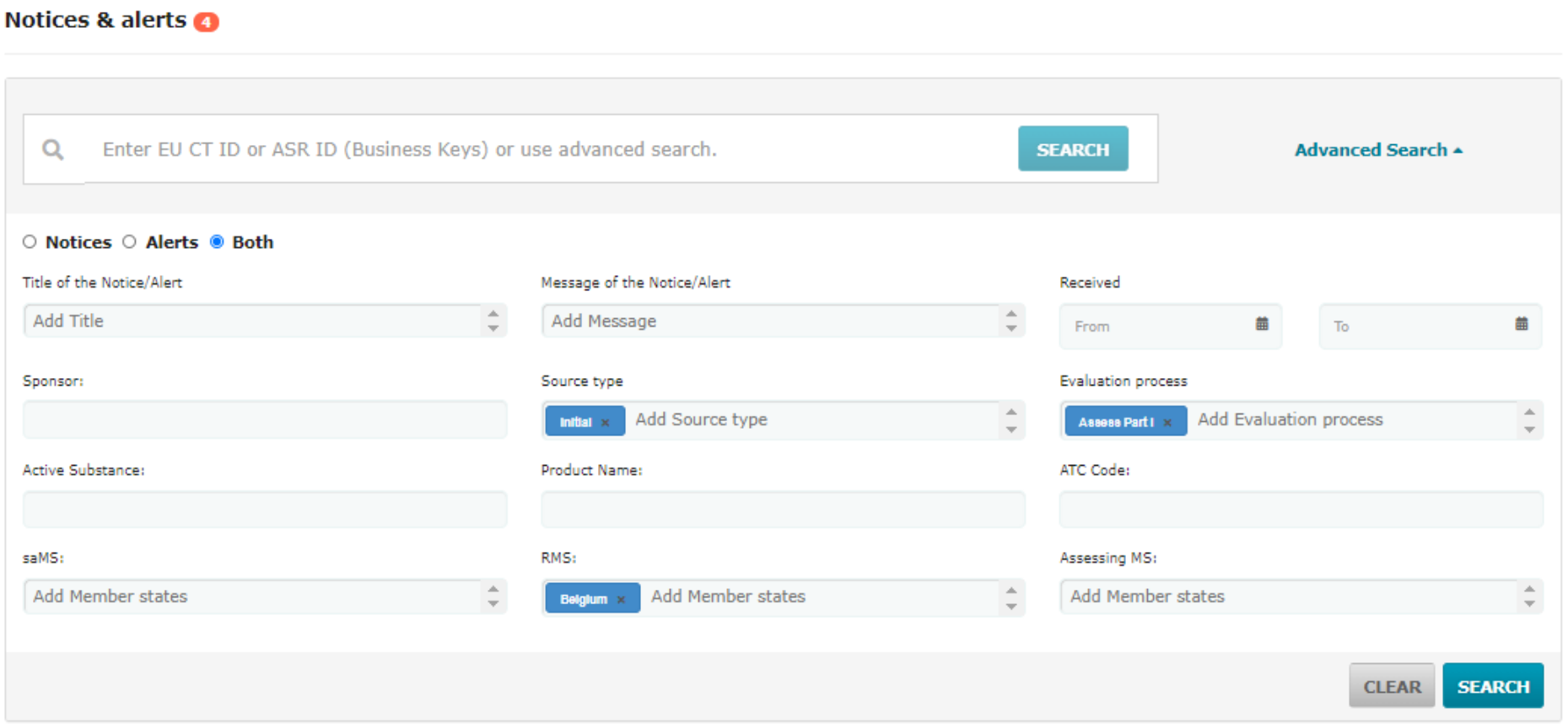
*Users can **sort** the messaged by several parameters (e.g. reception date, EU CT number, evaluation process, etc.). They can also use the **advanced search** to look for notices and/or alerts after specifying several criteria (e.g. reception date, sponsor, source type, active substance, RMS, etc.).*



Bly clicking on '**new**' users can quickly see the new messages received since the last connection to the system.

Notices & alerts

*The **search functionality** is available across the various tabs in CTIS and works in a similar way. There is a basic search and an advanced search. When multiple values are specified within one search parameter, the system interprets this as an 'OR' operator, while when each search parameter only includes one value, the system interprets it as an 'AND' operator. By adding multiple values in one parameter, a wider search is obtained.*

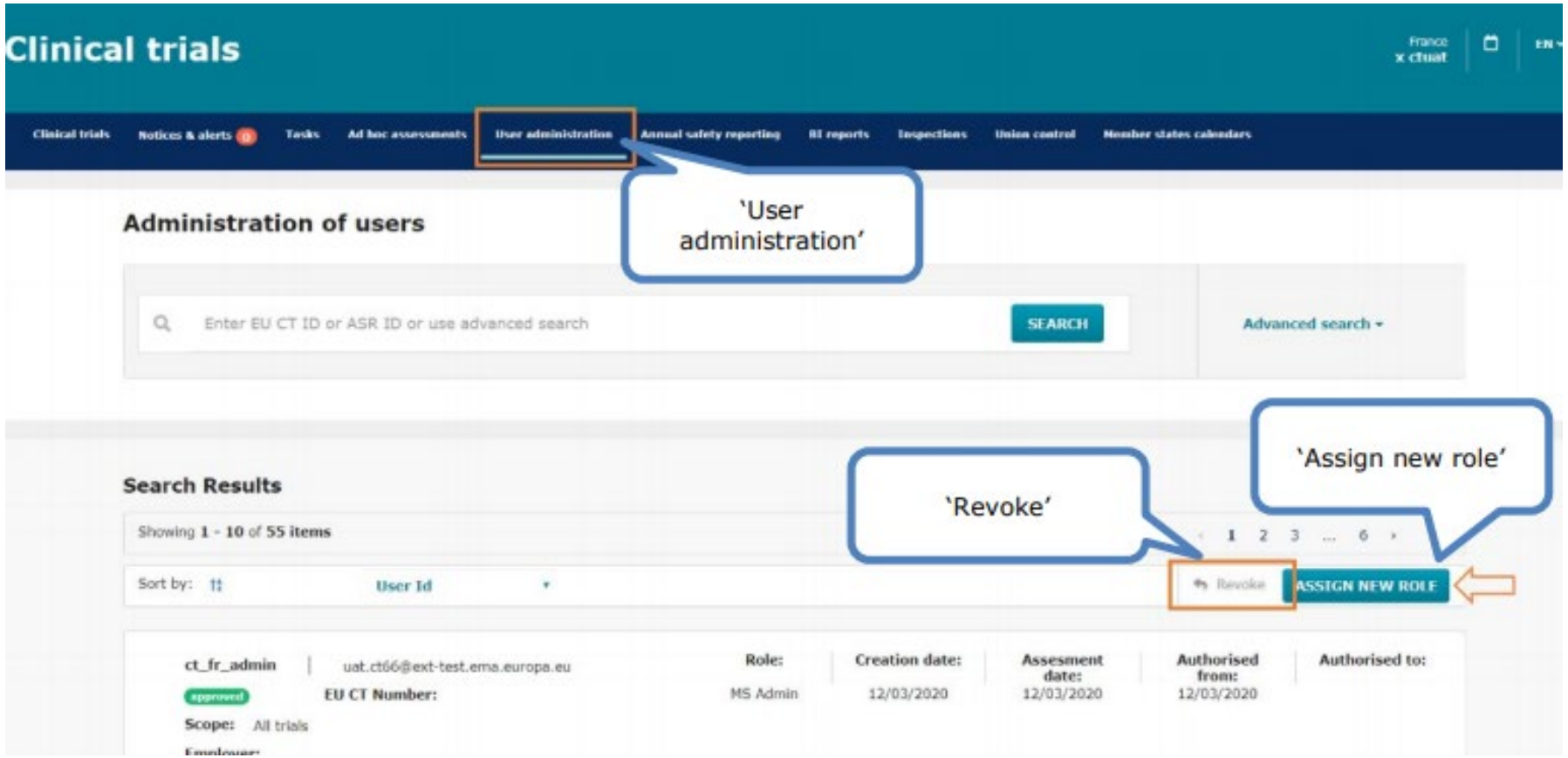


User administration

*The user administration tab allows users with an administrator role to manage users and **assign roles and permissions** to users registered in the system that belong to their organisation or Member State. When assigning a role to a user, they can determine the **scope** (all trials or a specific one) and the **duration** of the authorisation.*

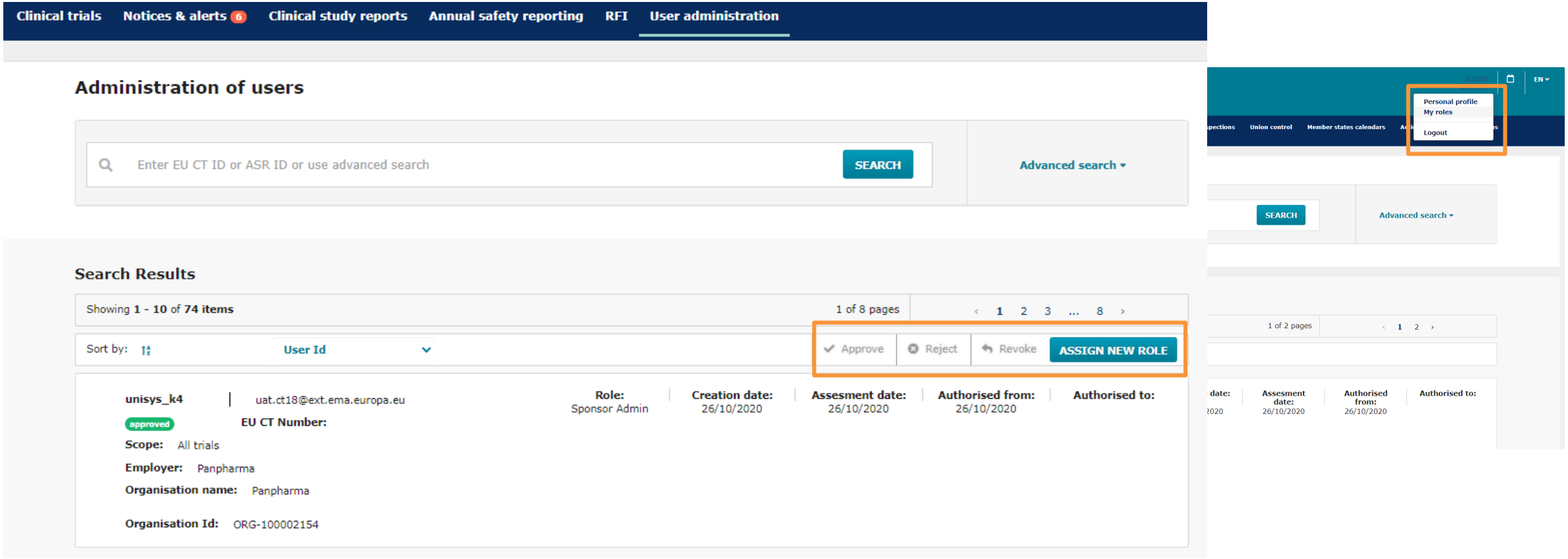
This functionality is only available to **users with an administrator role** in either of the workspace.

*Admin users may **assign** a role to users within their organisation or Member State, as well as **revoke** and **amend** existing roles.*



User administration

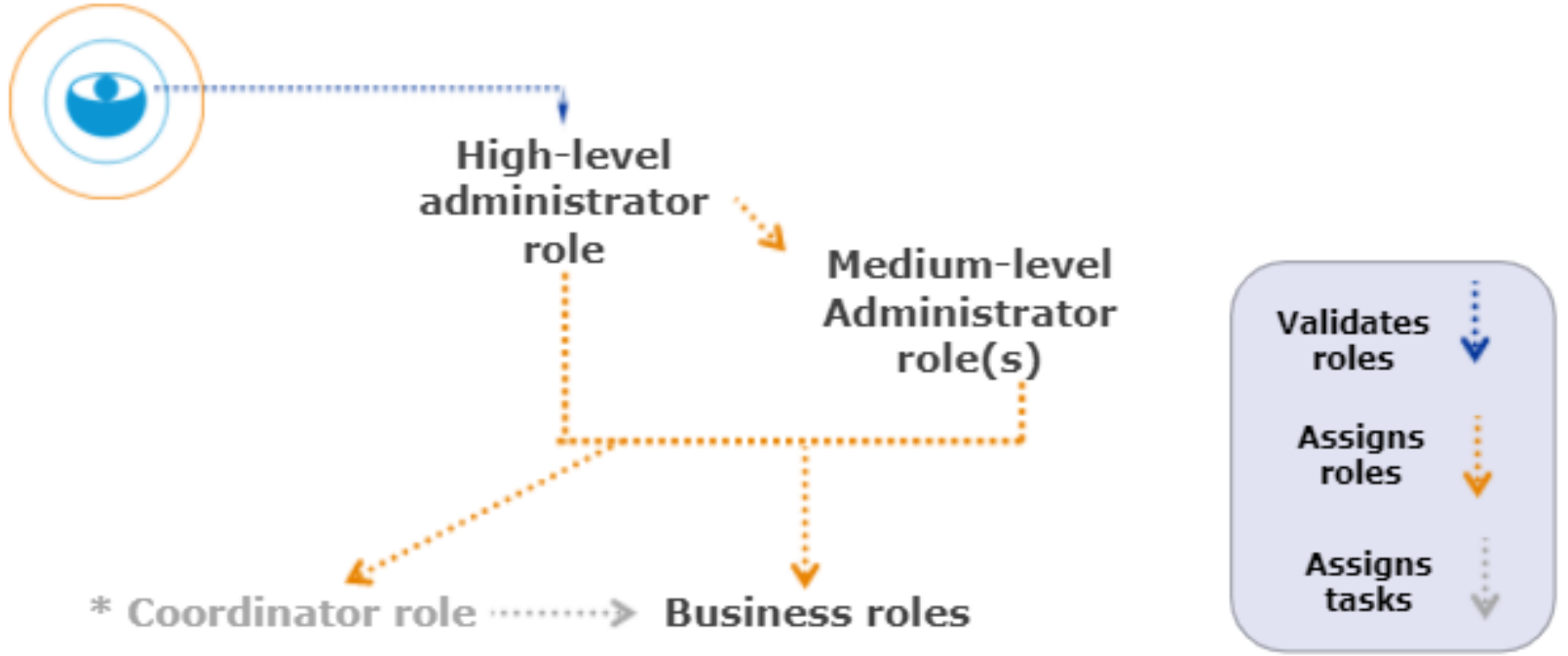
*Users from both workspaces can view the roles they have been assigned by clicking on their **profile** and then on 'my roles'. In addition, sponsor users can **proactively request a role** from an administrator user from their organisation via '**my roles**'. In the authority workspace this only works by invitation. This is why additional buttons are displayed to admin users in the sponsor workspace to approve or reject incoming requests.*



User administration

*CTIS foresees **high-level** and **medium level administrators** for each Member State or organisation. High-level administrators (MS Admin and Sponsor Admin) are appointed in IAM following a specific validation procedure. High-level administrators can then delegate user management permissions to medium-level admins (NOAs in the MS workspace). There is no limitation on the number of admin users an organisation can have.*

NOAs can only assign to users from their organisation based on their own profile.

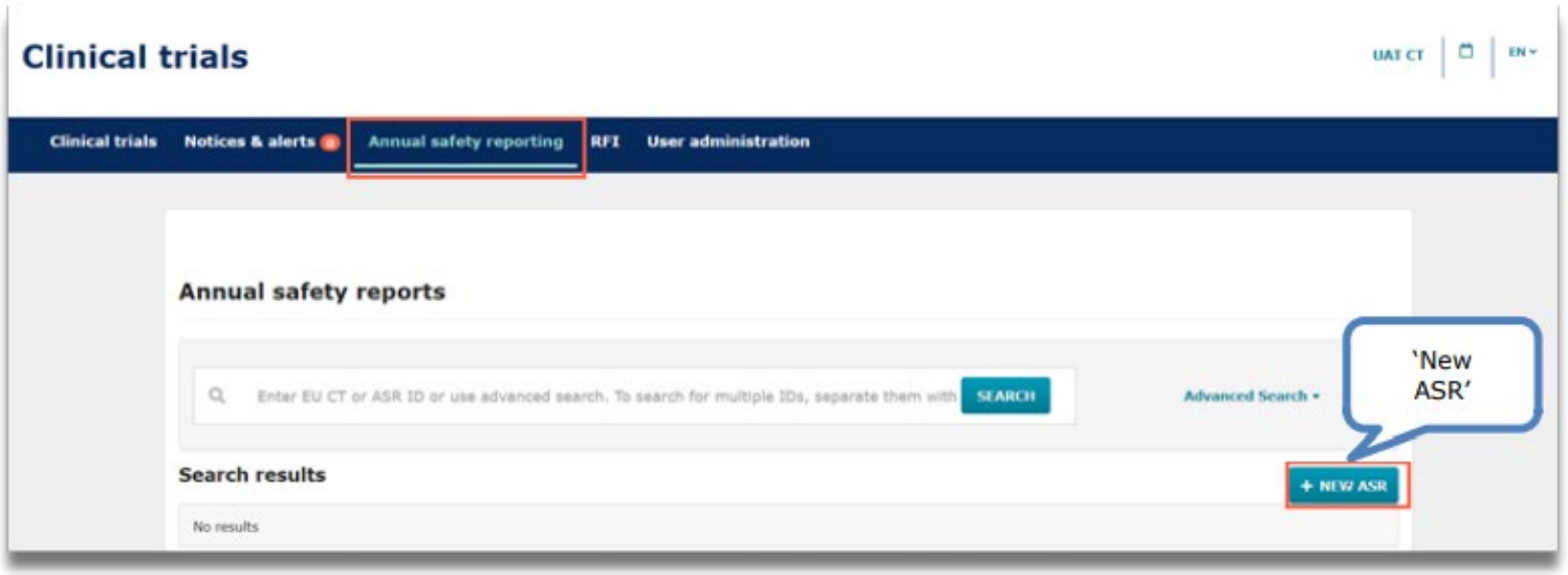


More details in Module 7

Annual Safety Reporting

The Annual Safety Reporting tab allows sponsors to submit the annual reports on the safety status of investigational medicinal product used in a trial, and Member States to assess the content of the ASR and adequately monitor the safety profile of the investigational drug.

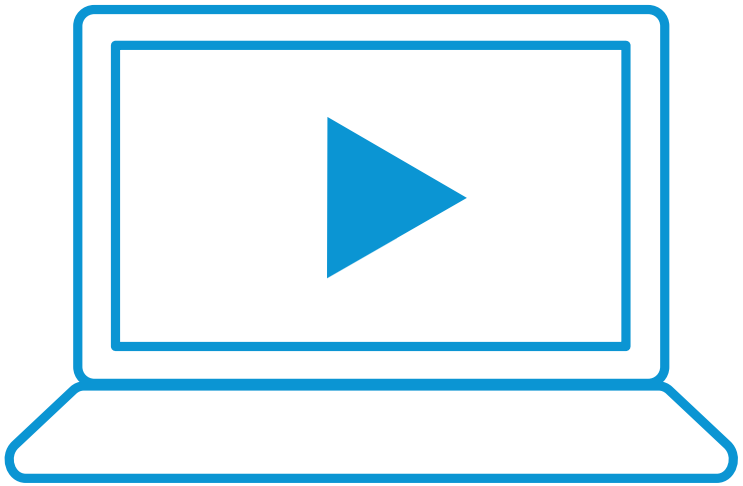
Only users with certain roles can assess and submit a decision regarding ASRs, but users can view ASRs for the CTs they are involved in.



Functionality under development, to be explained in another module

Demo

20’

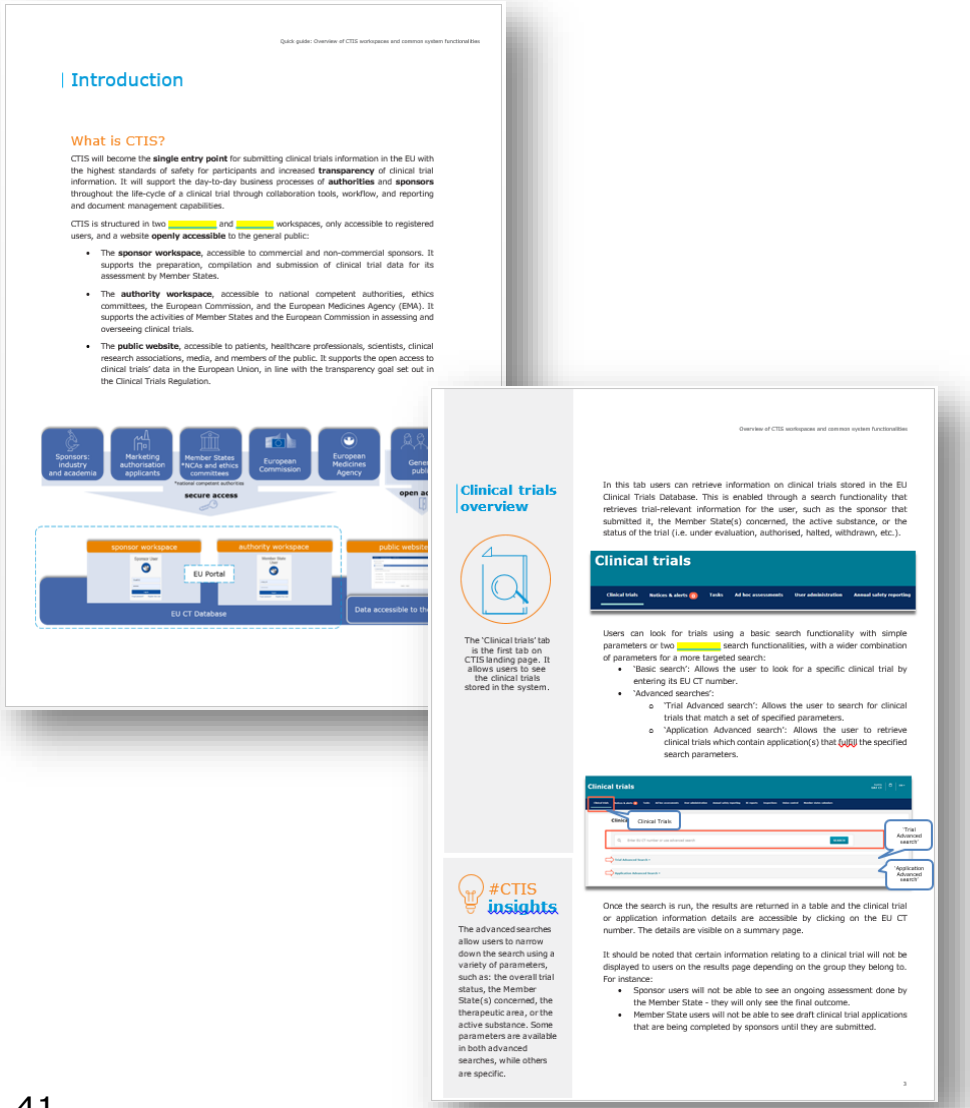


*In line with your requests in the survey, we are proposing you a **short demo** on CTIS landing page and 2 basic functionalities:*

- *CT/CTA search*
- *User administration*

Note that each these functionalities will be covered in detail in future modules.
We kindly ask you to keep your questions for the end.

Group exercise



"Fill-in-the-gaps" exercise:

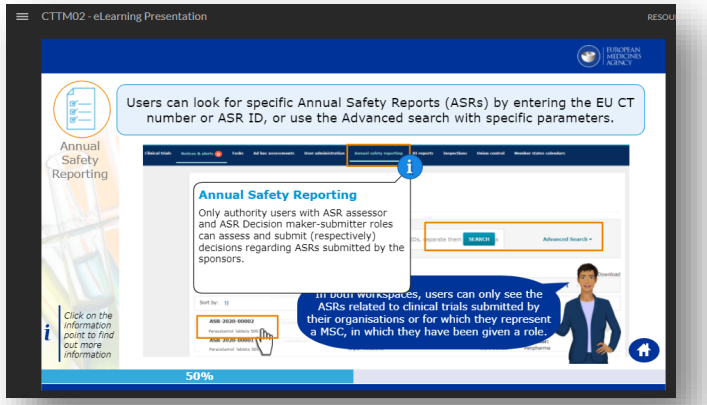
1. There are **7 missing highlighted elements** in this document (one word per blank space);

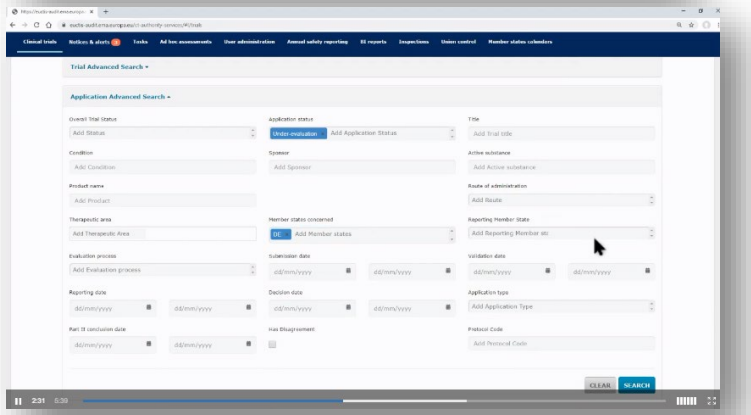
2. You will be displayed each of the paragraphs and given time to reflect on **what seems missing** (one word per blank space);

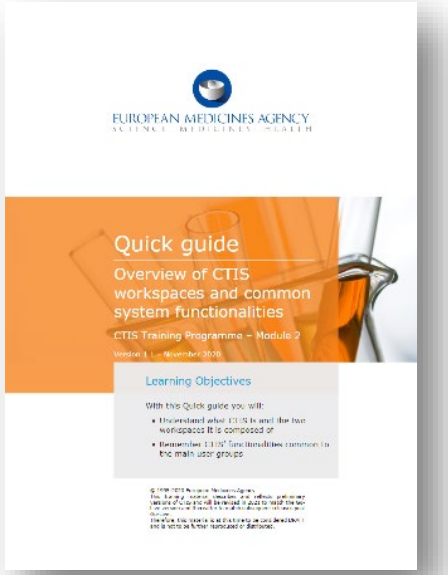
3. You need to find out and share what word(s) are missing;

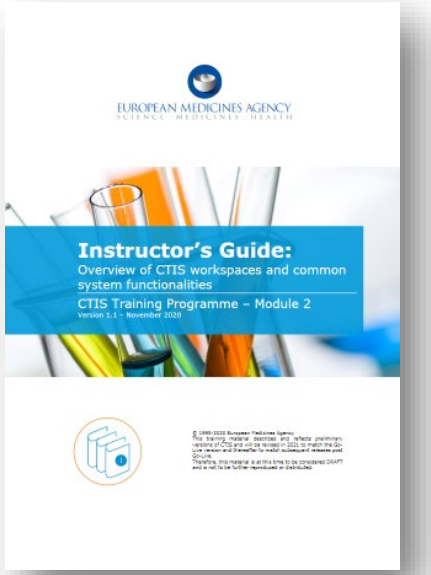
4. How? Go to www.menti.com with your mobile phone or tablet and **enter the code** that will be provided to you.

Training materials available









eLearning material

5 demo video clips

Quick Guide

FAQs document

Instructor Guide

Content

- Welcome and introduction to the session (*10 min*)
- Practicalities about the training session (*5 min*)
- Recap on User Confluence page (*10 min*)
- Training material available and selection (10 min)
- Key concepts covered in Module 01 – Introduction to new CTR (*30 min*)
  - *Introductory slides*
  - *Group exercise*
  - *Training catalogue materials*
- **Break (*15 min*)**
- Key concepts covered in Modules 02 – Overview of main CTIS components and system functionalities (*60 min*)
  - *Introductory slides*
  - *Demo (20')*
  - *Group exercise*
  - *Training catalogue materials*
- **Q&A (*30 min*)**
- Update on Training Programme & next steps (*10 min*)

Any questions?

If you have any question/s after this session, please contact:

CT.MSMasterTrainer@ema.europa.eu

Questions received in advance on the materials (1)

*"Where can I find a **full list of roles** with descriptions?"*

*"What is the **procedure for registering organisations and users** with the system? When is it anticipated to start?"*

*"To better understand the **modules distribution**, why is the **ASR included** in this module as will be further described in later ones?"*

*"A NOA can have all CT or specific trials- if specific trial, can the **scope be amended** to add additional CT? Or only to extend dates? This question applies other to other roles."*

*"Are organisations free to organise who will have **administrator roles** in their organisation? Can an existing admin assign another admin in its own organisation, or should all be **requested centrally**?"*

*"I would like to know more about **Member States Calendars tab.** Does this mean that all other MS involved need to comply with RMS`s bank holidays etc. on evaluation timelines?"*

*"Can users with different role receive a different **set of notices**?"*

*"Could you explain the **meaning of different colours** in alerts and notices?"*

Questions received in advance on the materials (2)

*"The **scope** "all trial" or "1 specific trial" …can be for 3 specific trials?"*

*"Regarding data publication: will **Informed Consent Forms be published too**?"*

*"What are the "**prioritised " notices and alerts**? Based on what criteria these are prioritised?"*

*"Not clear the difference between **Trial Advanced search** and **application advanced search**"*

*"Users with administrator roles can search for the user involved in a specific clinical trial. But how can **a user with no administrative role look for the users** that are acting in the different sections of a clinical trial?"*

*"How can we **change the role** of a user?"*

Clarification questions and system design questions

*"Difference for **business permissions** and **access permissions** not clear"*

*"What is the **rational behind** the fact that **only sponsor users can request a role** in CTIS? Why this is not like this in the authority workspace?"*

*"NOA **will only be able to assign roles that have been previously assigned to them** (not others) not clear in the training"*

*"No **notification or alert** – when a user request a role (for the sponsor administrative role) . **Why is that**? He should be alerted that roles requested are pending to be acted upon."*

*"Users receive **notice and alerts** based on the group they belong and only on the CT they are provided . Not clear if different roles receive different set of notices …please show a clear example."*

*"Do you plan **more exercises and examples** about user management and administration?"*

*"It says that **graphical summary** of the CT application in the timetable section can be downloaded"*

*"In addition to the common functionalities, each workspace has its **own specific functionalities** that are not linked to the roles and responsibilities that are <u>not</u> expected to each user group…. Not clear what is the meaning of this sentence. Please clarify."*

Content

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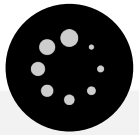
Update on CTIS Training Programme

Ongoing



- Production team currently **developing the materials of Module 10** (*Create, submit and withdraw a CTA*)
- Session validation with training experts on 17/12.
- **Batch 2 materials** (Modules 8-10) available on Training Catalogue in early January 2021.

Coming up

- **Lessons' learned session** with all experts who have participated in the training programme so far on 15 Jan to review training catalogue and standard materials
- **Batch 3** starting in January until March 2021:
  - *Respond to RFIs received during the evaluation of a CTA*
  - *Clinical Study Reports submissions*
  - *Supervise a CT – Corrective measures*
  - *MS search, view & download a CT*

CTIS Training Catalogue progress status

The training catalogue comprises 21 modules. A session is foreseen with training experts in mid-January 2021 to review and adjust the catalogue in view of recent developments in the system.

Introductory modules	Modules targeted to Member States	Modules targeted to Sponsors	Common modules for MS/EC and Sponsors	Other audience-specific modules
Introduction to new Clinical Trials Regulation	BI reporting (*also the European Commission*)	How to manage a CT (*Notifications, Ad hoc assessment, Corrective measures and Trial results*)	Support with workload management *(tasks, notices & alerts, RFI list& timetable)*	Manage Union Controls *(European Commission)*
Overview of main CTIS components and system functionalities (high level)	Evaluate a CTA – Step 1 *(application types, evaluation overview, RMS selection & validation)*	Create, submit and withdraw a CTA	User Access Management *(self-registration, login & user profile)*	Clinical Study Reports submissions (*Marketing Authorisation Applicant*)
	Evaluate an initial CTA – Step 2 (*assessment and decision*)	How to search, view and download a CT and a CTA in the sponsor workspace	Management of registered users & role matrix	Supervise a CT – Inspection records *(MS inspectors)*
	Supervise CT – Ad hoc assessment *(including safety)*	Respond to RFIs received during the evaluation of a CTA		Introduction to CTIS for Public Users
	How to search, view and download a CT and a CTA in the authority workspace	Create and submit an Annual Safety Report and respond to related RFIs		
	Supervise a CT – Corrective measures			
	Assess an Annual Safety Report			

Catalogue completion

Batch 0 (2nd Q 2020)	10%
Batch 1 (3rd Q 2020)	33%
Batch 2 (4th Q 2020)	47%
Batch 3 (1st Q 2021)	67%
Forthcoming batches	100%

Next steps for Master Trainers Programme

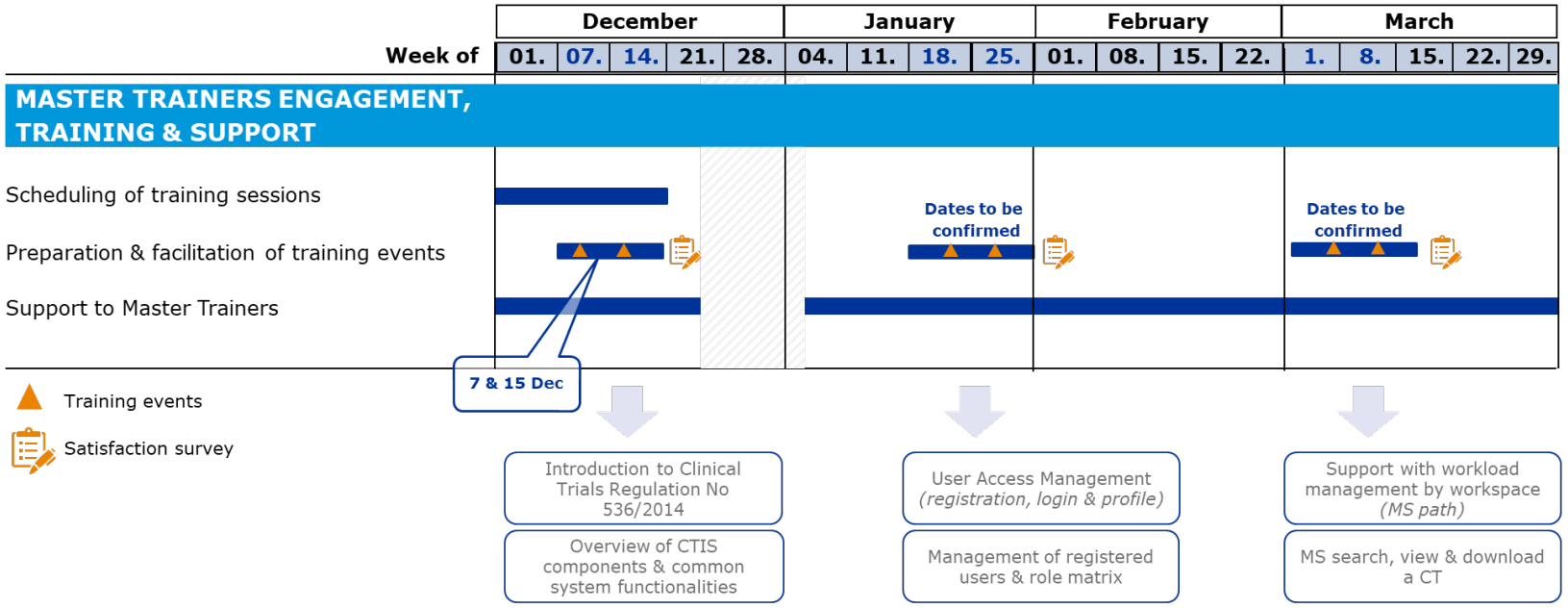
The team will schedule the training events until March 2021 included and will work on a reporting strategy to evaluate impact of Training Programme towards both MTs and end-users, to be presented in early 2021.

Feedback survey to be completed *by 9/12 COB*

Proposed dates for next training sessions (Group A):

- 21/01 *9.30-13 CET*
- 03/03 *9.30-13 CET*

Tentative **an ad hoc session on dissemination tips** on 15/02 (2h duration)



Further information

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