

CTIS HIGHLIGHTS

News, views and interviews for the Clinical Trials Information System (CTIS)

An agency of the European Union



Welcome to CTIS Highlights



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On the 31st of July 2021, a major CTIS milestone has been reached. The coming into application of the Clinical Trials Regulation ([EU\) No 536/2014](#) and therefore the go-live date for CTIS has now been confirmed as **31 January 2022**, meaning the six-month countdown to CTIS has begun. The European Commission has established this through their notice published in the [Official Journal of the European Union](#).

When CTIS goes live, it will harmonise the submission, assessment and supervision of clinical trials in the EU and the EEA.

CTIS will streamline submission processes for commercial, non-commercial and academic clinical trial sponsors. In addition, it will streamline the authorisation and supervision process for the EU/EEA Member States. The European Commission will play a role in the supervision of the implementation of the Regulation.

CTIS go-live date confirmed as 31 January 2022

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On 31st July 2021, the European Commission confirmed the entry into application of the Clinical Trial Regulation ([EU\) No 536/2014](#) by the publication of a notice in the Official Journal of the European Union. As set out in the Regulation, this publication starts the six-month countdown to CTIS go-live and confirms the go-live date for CTIS as **31st January 2022**.

The Clinical Trial Regulation foresees a 3-year transition period to CTIS. Member States will have to work in CTIS immediately from go-live, once applications are submitted. Sponsors will have one year to begin using CTIS,

and can decide whether to submit a new clinical trial application under the Clinical Trial Directive 2001/20/EC or Regulation (EU) No 536/2014 until 31 January 2023.

All new applications for clinical trials must be submitted through CTIS as of 31 January 2023, while all clinical trials must be transferred to CTIS by 31 January 2025, if still ongoing by the end of the transition period.

With 6 months until the system goes live, all future users of CTIS are encouraged to review the available [CTIS training materials](#) and ensure their organisations are prepared for the transition to CTIS.

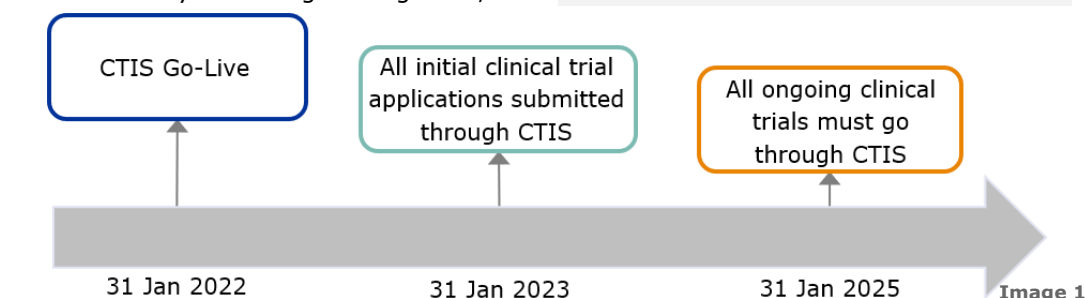


Image 1

CTIS Sponsor Handbook

EMA has published the first version of the [CTIS Sponsor Handbook](#), developed in collaboration with sponsor stakeholders.

The Handbook includes a compilation of key guidance, technical information and references to assist sponsors in preparing for and using CTIS.

It covers topics such as organisation and user registrations for CTIS, key user management concepts, product registration, data transparency, a list of data fields and documents to be submitted by sponsors in CTIS, training and support information.

The Handbook is a living document and will be progressively updated based on sponsor feedback.

The first version of the CTIS Sponsor Handbook was published in July 2021 and can be found [here](#).

Download the CTIS Sponsor Handbook [here](#).

CTIS July Webinar

On July 29th 2021, EMA hosted a webinar on how sponsor organisations can prepare for CTIS.

The webinar was broadcast live and open to sponsor organisations, including pharmaceutical companies, contract research organisations, small and medium-sized enterprises (SMEs) and academia

Speakers representing sponsor organisations, Member States, the European Commission and EMA presented on various topics, including how sponsor organisations are preparing for CTIS, how Member States aim to support sponsor preparedness, the role of the Clinical Trial Regulation and how sponsors can best make use of EMA's [CTIS training materials](#).

Presentations from the event and a video recording will be made available on [the EMA event page](#).

Another webinar is planned on 26th October 2021 on how end users can prepare for CTIS. Information on this event will be shared in future CTIS newsletters and on [the EMA events page](#).

Provide feedback on the CTIS July Webinar [here](#).

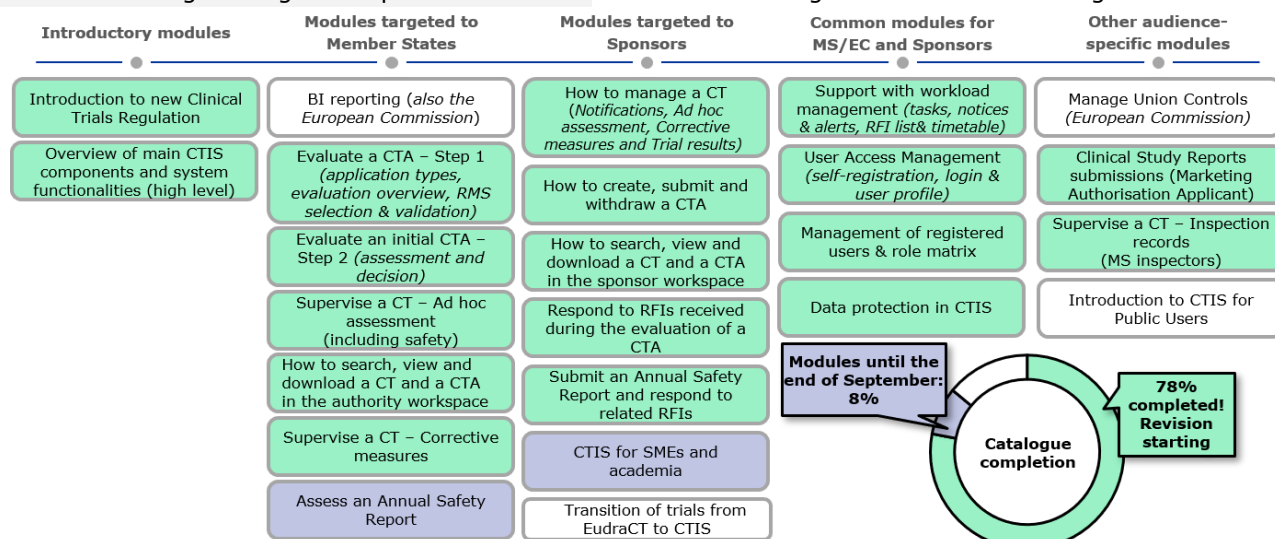
Training programme update

To assist user communities in preparing for CTIS, EMA has prepared an extensive training catalogue. One of the most important documents overarching the training catalogue is the [Guide to CTIS training material catalogue](#) that outlines the life-cycle stages of a [clinical trial](#), with reference to the relevant training modules in each stage.

The CTIS training catalogue comprises several

extensive and detailed modules, covering the life-cycle of a clinical trial and the preparatory actions needed to use CTIS. The CTIS training catalogue is progressively updated on the [CTIS online modular training programme](#) webpage as more modules become available.

Future CTIS users are encouraged to review the training materials available on the CTIS training page and to liaise with their organisations regarding plans for training CTIS users in their organisation.



Registering for CTIS

Before using CTIS, users must register via [EMA Account Management](#). In addition, organisations must register in [EMA's Organisation Management System \(OMS\)](#). The actions to be taken depend on the organisation type (authority or sponsor) and, for sponsors, whether [the trial-centric or organisation-centric approach](#) is chosen.

1. Register for a user account in EMA Account Management (all users)

Before accessing the CTIS secure domain, users who do not yet have an EMA user account must register for an individual account in [EMA Account Management](#). If a user already uses EMA services and systems such as Eudralink, SPOR, EudraCT or IRIS, they have an existing EMA account and do not need to create a new one.

Registration for a new EMA user account can be done by visiting the [EMA Account Management](#) webpage and clicking on 'Create an EMA Account'. Username and password recovery for existing accounts, as well as account re-activation, can also be done via the EMA Account Management webpage.

Having an EMA account with a SPOR user role is a necessary step before registering an organisation in OMS, as described in step 2.

User registration in EMA Account Management can be done at any time, however users will not be able to access CTIS until the system is live.

2. Register an organisation in OMS (for sponsors who have chosen the organisation-centric approach)

Sponsor organisations opting for the [organisation-centric approach](#) in CTIS that are not yet registered in EMA's Organisation Management System (OMS) must do so before using CTIS.

Registration in OMS can be done by visiting the [OMS](#) webpage. An EMA account with a SPOR user role is required in order to register an organisation in OMS. Training materials for OMS can be found on the [OMS webpage](#) on the EMA website. Organisation registration in OMS can be done at any time.

3. Register your high-level administrators (for sponsors who have chosen the organisation-centric approach)

Once registered in OMS, sponsor organisations opting for the organisation-centric approach must register their first high-level administrator, the Sponsor Admin, via [EMA Account Management](#) prior to using CTIS. As explained in the CTIS Newsletter Issue 3, the high-level administrator plays an important role in user management and user role assignment in the organisation-centric approach, as they will be responsible for allocating business roles and permissions to users working for, or on behalf of, their organisation. It is recommended that multiple high-level administrators are registered for an organisation to ensure backup. No limitation on the number of high-level administrators is imposed. The additional high-level administrators can be registered by the first high-level administrator in EMA Account Management.

Registration for high-level administrators is planned to open in **September 2021**. Additional information about the high-level administrator registration process and timelines will be published in future issues of this newsletter and within the [CTIS training programme](#).

All users that do not have an EMA account	Register for an EMA account
Organisation-centric approach, not yet registered in OMS	Register your organisation in OMS
Organisation-centric approach	Register your sponsor administrators

Harmonising clinical trial regulatory submission processes in the EU and EEA

When CTIS goes live, it will harmonise the submission, assessment and supervision of clinical trials in the EU and the EEA. This will generate societal and economic benefits, as shown in the image below.



Public health

Facilitates large-scale trials to address key health issues (COVID, EU Beating Cancer plan...)



Research and innovation

Enables knowledge sharing and expert collaboration.



Investment in research

Ensures the EEA remains an attractive clinical research hub globally.

Image 4

CTIS will streamline submission processes for commercial, non-commercial and academic organisations that act as clinical trial sponsors. It will also streamline and the authorisation and supervision process for the EU/EEA Member States. The European Commission will play a role in the supervision of the implementation of the Regulation.

Sponsors will no longer have to submit clinical trial applications separately in each EU/EEA country. Instead, they will apply through CTIS, the single entry point for clinical trials submissions. In addition, CTIS harmonises submissions to Member State national competent authorities and ethics committees within a single application, and provides public registration of each clinical trial, all within the same process.

CTIS facilitates:

- Authorisation of clinical trials in up to 30 EEA countries with a **single application**
- Involvement of trial participants by allowing **easy expansion of trials to other EU/EEA countries**
- **Collaboration across borders** for better results and knowledge sharing
- **Clinical research investment**, ensuring the EU/EEA remain an attractive location for clinical research
- **Clinical trial publication requirements**, as publication occurs with no additional effort

Read [previous issues of CTIS Highlights](#)

Image 5

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