

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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With go-live of CTIS set for 31 January 2022, the date for the launch of CTIS is fast approaching. Future users of CTIS are encouraged to make use of the available CTIS training and support resources to prepare themselves for the new way of working in CTIS. A key sponsor resource to support CTIS preparedness is the CTIS Sponsor Handbook, and many relevant events for sponsors are referenced throughout this newsletter. Member State future users of CTIS are encouraged to liaise with their Master Trainer for training opportunities and consider recommendations by CTFG (the Clinical Trials Facilitation and Coordination Group, a working group of the Heads of Medicines Agencies) on 'best practices' regarding key procedures.

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CTIS information event updates

On **26th October 2021**, EMA will hold a CTIS information day with support from DIA. This event will focus on preparing future users for CTIS go-live. The event will include presentations on the Clinical Trials Regulation and on preparing for CTIS from the perspective of future CTIS users. It will also include a short demo of the CTIS Sponsor and Authority workspaces.

Event attendees will benefit from ample Q&A time, in which they can raise questions about user preparedness for CTIS go-live. A video recording of this event will be made available on the EMA website in December 2021.

On **29th November 2021**, EMA will host a webinar for SMEs and academia on key aspects of the Clinical Trials Regulation and the new processes via CTIS for clinical trial applications submission. Attendance at this tailored event is possible for SMEs registered with EMA, as well as academia contact points.

Other interested parties can follow the event via live broadcast on the EMA website. Video recordings will be made available on the EMA website and YouTube channel after the event.

Find more information about CTIS
Virtual information day
(26th October) [here](#)

Find more information about CTIS
Webinar for SMEs and academia
(29th November) [here](#)

Training environment

A CTIS training environment ("CTIS Sandbox") will be made available progressively to different groups of future CTIS users starting from 15 October 2021.

The goal of the CTIS training environment is to assist future CTIS users and their organisations in exploring user configuration and the steps needed to submit and authorise a clinical trial application, and also to supervise a clinical trial after its authorisation until the submission of summary of results.

Access to the training environment is provided in phases to users who are already trained on CTIS through the CTIS Training Programme. Access will first be provided to Member State and thereafter sponsor Master Trainers, who can leverage their access to support the preparedness of the users in their organisation.

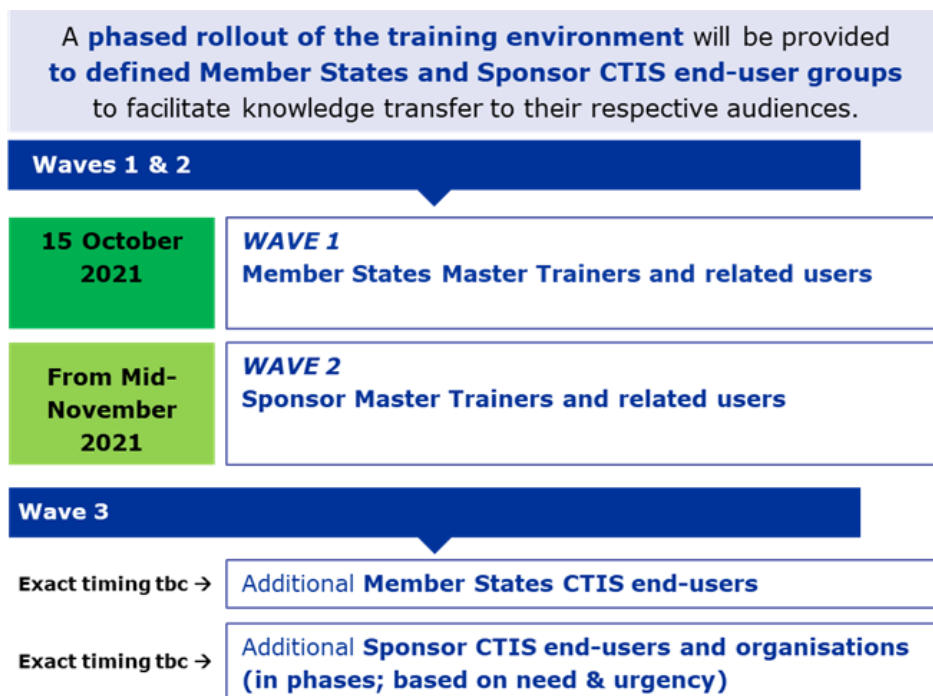


Image 1. Access to CTIS training environment - phases and timings

A phased rollout of the training environment, structured in three waves is foreseen:

- ⇒ **Wave 1 (15 October 2021)**: access provided to **Member State Master Trainers** and their related users
- ⇒ **Wave 2 (Mid-November 2021)**: access provided to **Sponsor Master Trainers** and their related users (Batch 1); access provided to other sponsor representatives who need environment access for organisation planning and user training (Batch 2)
- ⇒ **Wave 3** (timing TBD): access provided to additional Member State and sponsor end-users on the basis of need and urgency. A [survey is available here to provide self-assessment and express interest in access](#).

Subsequent issues of this newsletter will provide updates on training environment access opportunities.

CTIS training and support webpages

The CTIS webpages have been updated on the EMA website to increase the findability of key CTIS documents for users.

A new CTIS [training and support page](#) has been created, which summarises the activities ongoing under the CTIS training and support programme. This page also contains key reference documents which support the preparation for future use of CTIS, such as the [Sponsor Handbook](#).

A dedicated [online modular training programme](#) page has been created to provide easy access to the CTIS online training modules for users. EMA plans to update the Clinical Trials Regulation page in Q4 2021 to ensure it includes the most relevant information as the date of entry into application of the Clinical Trials Regulation approaches. EMA also plans to create a dedicated page on CTIS, which gives an overview of the system. Updates on these pages will be provided in subsequent issues of this newsletter.

SME & academia support

As part of the EMA's efforts to provide support and assist micro, small and medium enterprises (SMEs) and academia with the use of CTIS, a new SME & academia CTIS training module has been published on the [CTIS online modular training programme](#) page on the EMA website. The module consists of a quick guide, which provides a short introduction to CTIS, and a series of step-by-step guides which describe CTIS processes in a simple and concise way. SMEs and academia are encouraged to use this module as a key reference material for using CTIS.

Member State Master Trainers have received training on the SME & academia module to assist them in their national SME and academia support activities. The module will be central to the material presented at the [SME & academia webinar, to be held on 29th November](#).

*Image 2.
Topics covered in the CTIS SME & academia online training module*



Sponsors CTIS processes



Roles and permissions



CTIS's interactions with other databases

Events on related EMA systems

On **21st October 2021** EMA will hold an 'Introduction to Organisation Management Service (OMS) / Referentials Management Service (RMS) services and activities' webinar for industry users. Industry users can sign up at the link below.

Find more information about the Introduction to Organisation Management Service (OMS) / Referentials Management Service (RMS) services and activities webinar [here](#)

On **8th November and 14th December 2021**, EMA will hold extended EudraVigilance medicinal product dictionary (XEVMPPD) training courses for sponsors. The training events are organised in liaison with DIA. The training will focus on how to use XEVMPPD in accordance with the CT-3 detailed guideline on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use. It will also explain the importance of the XEVMPPD to support the submission of clinical trial information in the Clinical Trials Information System (CTIS). Interested sponsors can sign up at the link below.

Find more information about the EudraVigilance medicinal product dictionary (XEVMPPD) training courses for sponsors [here](#)

On **24th November 2021**, the EMA CTIS team will contribute to the EudraVigilance & Signal Management Virtual Information Day. This information day will provide an update on some key elements and activities that will impact EudraVigilance and its stakeholders in the coming years. The information day will also provide information on the impact of the Clinical Trials Regulation (EU) No 536/2014 on safety reporting and will discuss the new Annual Safety Report (ASR) submission processes in CTIS. This information day is hosted with support from DIA, and those interested in attending can find more information via the link below.

Find more information about the EudraVigilance & Signal Management Virtual Information Day [here](#)

CTIS user personas and sponsor organisation modelling

EMA has published CTIS user personas to assist organisations and individuals who will use CTIS in future. User Personas are visual models that describe different types of users in CTIS. They define who will do what in CTIS in different kinds of organisations, including sponsor and Member State organisations. The User Personas also show the possible CTIS user roles each Persona may be given to perform their tasks in CTIS. The sponsor User Personas can be found [here](#) and the Member State user personas can be found [here](#).

EMA has also published the first version of 'Principles for sponsor organisation modelling for CTIS' document to assist sponsors in their preparations for CTIS go-live. The purpose of the document is to outline some examples of how sponsors can manage CTIS access, responsibilities and user roles for different types of clinical trials and in different organisational environments. The types of trials covered include simple arrangements where sponsors work with a small number of CROs, to more complex co-sponsorship arrangements. An academic trial type is also included.

You can read the "Principles for sponsor organisation modelling for CTIS" document [here](#).

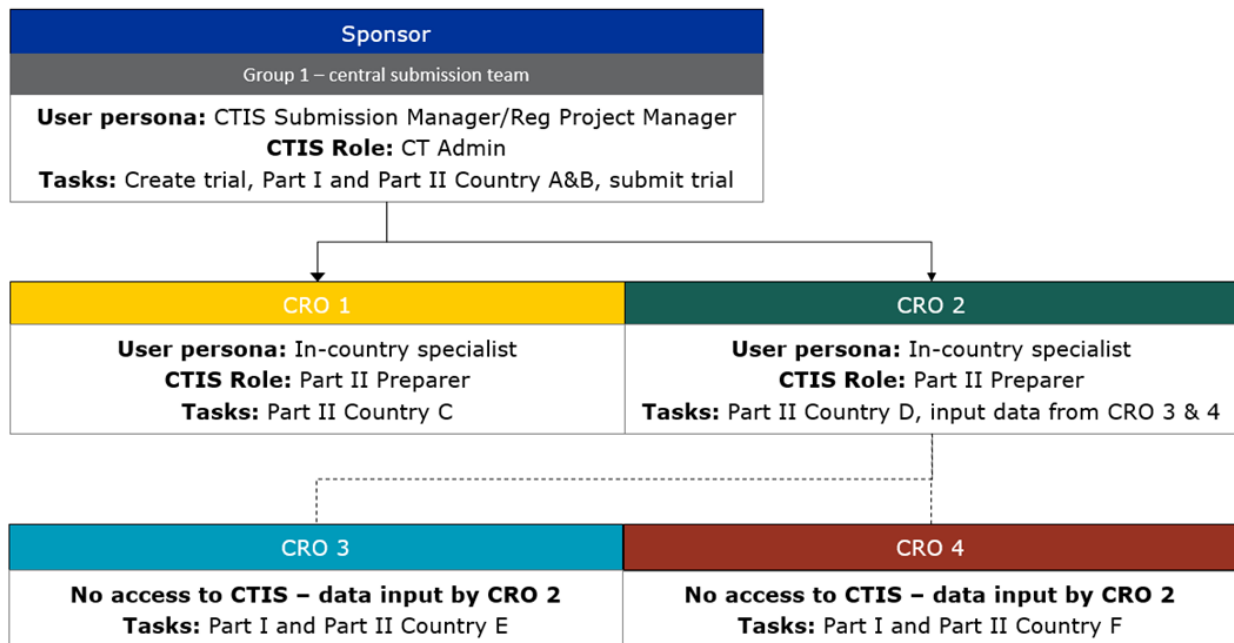


Image 3.
Organisation model example: Sponsor centralised approach

Sponsor high-level administrator registrations now open

Registrations are now open for CTIS Sponsor Administrators. As explained in [CTIS Highlights Issue 4](#), sponsors opting for the [organisation-centric approach](#) in CTIS must register their first Sponsor Admin in EMA Account Management.

When requesting the role of Sponsor Admin in EMA Account Management, the requestor must upload a completed and signed copy of the '[Affiliation Template Letter](#)' as proof of the authority to represent that organisation. This must be on the official company letterhead and signed by someone currently employed by the organisation for which the user will assume the Administrator Role. Please note if no document is attached while requesting the role, the request will be denied by the system. More information on registration can be found on the [EMA Account Management home page](#).

Structured data fields

EMA has published guidance on the data fields that clinical trial sponsors will need to fill in CTIS when submitting a clinical trial application and managing a clinical trial. The structured data forms are available on the [CTIS training and support page](#).

The data forms contain details of the type of data to be entered in each field (e.g. text, numeric, radio button, document upload), whether the fields are mandatory, optional, conditionally required or read only and for document upload fields, the accepted document formats e.g. PDF and Word documents, among other specifications.

Sponsor handbook – call for feedback

At the end of July 2021, EMA published the first version of the CTIS Sponsor Handbook, which is a key document for sponsors that includes a compilation of guidance, technical information and references to assist sponsors in preparing for and using CTIS. EMA is seeking feedback on the sponsor handbook for the purpose of improving the content, adding new chapters, and refining the information for next version of the Handbook.

Please find
the Sponsor Handbook
feedback survey [here](#).

Newsletter – call for feedback

Feedback is sought to ensure the CTIS newsletter is as useful to future CTIS users and other interested parties as possible.

Please find the **CTIS newsletter feedback survey** [here](#).

Read [previous issues of CTIS Highlights](#)

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Send a question via our website www.ema.europa.eu/contact

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