

How to access CTIS training materials and support

Clinical Trials Information System (CTIS) Virtual information day: The future user perspective

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CTIS training and support page



Available on www.ema.europa.eu

20 Online training modules and more to come e-learning, FAQs, videoclips, quick guides, step-by-step guides Essential: Guide to CTIS training material catalogue

CTIS Sponsor Handbook for clinical trial sponsors

Summary information, links, references

Reference materials for clinical trial sponsors

Sponsor user personas, organisation models, structured data forms

Reference materials for authorities

Member State user personas

Training and information events

Recordings of previous events; see also **EMA** general events page

URL QR code:



CTIS training environment and User Support Service



The CTIS training environment is an important component of CTIS Go-Live plan. User support will be available at Go-Live

Purpose of the CTIS Training environment

- Available for users and their organisations for training
 - to explore user configuration & CTIS functionalities before and after go-live date
 - enable MS to explore authority workspace in steps of an application
 - enable sponsors to create an application in sponsor workspace
- Limited interaction using a copy of the system

Controlled access in waves to dedicated workspaces

- For users who are already trained on the system, through the CTIS Training Programme
- First access to MS and Sponsor Master Trainers, who can leverage their access to support the preparedness of the users in their organisation
- Access based on need and urgency

User Support Service

- A dedicated support desk is available for training environment users
- The main service desk opens when CTIS goes live

Stay up to date: <u>CTIS Highlights Newsletter</u>

Access to CTIS training environment (CTIS Sandbox)



A phased rollout of the CTIS training environment will be provided in waves to defined CTIS end-user groups to enable knowledge transfer.

15 Oct 2021 Wave 1

Member States Master Trainers and related users

From mid-Nov 2021 Wave 2

Sponsor Master Trainers and related users

Access based on completion of Sponsor Master Trainer programme

In phases, timing tbd

Wave 3

Sponsor users/organisations (if no Master Trainer)

Access based on guided sponsor self-assessment of need and urgency, EMA to evaluate

How to perform self-assessment of need and urgency?:

A survey is open until 31 October 2021

Further information

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