EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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CTIS newsflash – 12 December 2022

Introduction

With the aim to enhance communication with the CTIS user community, as of December 2022 EMA has reinstated the weekly CTIS newsflash, providing key updates on CTIS and links to useful reference materials.

A status update on the implementation of the Clinical Trials Regulation is also available on the CTIS public portal.

Spotlight: Start date of mandatory CTIS use

CTIS was launched on 31 January 2022, starting the clock for the one-year transition time for all sponsors of clinical trials. During the first year of the transition period, clinical trial sponsors can choose whether to submit an initial clinical trial application in line with the Clinical Trials Directive or under the Clinical Trials Regulation, via CTIS.

Starting from 31 January 2023, the use of CTIS will be mandatory for all initial clinical trial application in the EU. For trials authorised under the Clinical Trial Directive, sponsors can continue to submit substantial amendment following the principles of the Clinical Trial Directive until the end of the transition period on 31 January 2025.

Key Updates

A CTIS release went live on 6 December 2022, implementing functional improvements, including:

- Adding an option for sponsors to record whether they are a commercial or non-commercial entity in the clinical trial application
- Simplified user role assignment across organisations with the same name
- Improved role assignment to users with trial-specific roles
- Improved notices to users, including visibility of the "response to RFI responses submitted" notice
- Improved automated validation rules pertaining to the clinical trial application when responding to an RFI
- Enhanced task visibility for MS users
- Enhanced interface with WHO International Clinical Trial Registry Platform
- Strengthened deferral functionality to be applicable throughout the life cycle of the trial

More information is available in the latest published release notes.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

EMA continues to provide proactive support to sponsor users with requests for information (RFIs) due to expire. Further improvements to the RFI functionality are planned in upcoming releases.

EMA continues to work closely with Member States, the European Commission, and stakeholders to improve the CTIS user experience. By the time the use of the system becomes mandatory for all new applications (31 January 2023), the aim is to have no blocking issues in the core CTIS processes. The Agency has invested additional resources to achieve this goal.

Upcoming Improvements

The next CTIS release is planned to go live on the evening of 12 December 2022 and will include several improvements:

- Resolving the issues with RMS/MSC raising RFIs on due dates of tasks and the extension of response due dates for sponsors, thus alleviating the need to use workarounds
- Allowing trial sites which cannot be registered in OMS (i.e. not registered in a national business registry) to be recorded directly into CTIS
- Enhancing the lock mechanism feature allowing multiple users to work on a clinical trial application
- Ensuring visibility of documents "Agreement from another Sponsor" and "PIP Opinion" in the MS workspace following upload by Sponsor
- Improving the MS API to display conditions provided in Part II conclusion

Further instructions on how to register investigational sites in CTIS will be shared with all users after the release is deployed.

Amendment to CTR Annex on labelling rules

The labelling rules on unauthorised investigational and unauthorised auxiliary medicinal products used in clinical trials have been reviewed. The revised rules eliminate the obligation to include an expiry date on the immediate packaging of unauthorised medicinal products used in clinical trials in specific circumstances (e.g. on syringes). The aim is to prevent additional safety and quality risks associated with the re-labelling procedure and the need for more frequent re-supply, which may lead to delays in clinical trials.

Access to Sandbox

Sponsor users who want to be trained on CTIS have the opportunity to express their interest in gaining access to the CTIS Training Environment (Sandbox), by filling in the ongoing survey.

CTIS Sandbox is a simulation of CTIS used in production and allows users to get familiar with system functionalities in a safe environment.

Reminder: Maintenance windows

EMA regularly upgrades CTIS to improve user experience and deploy enhancements during dedicated time windows. Users are advised to avoid using CTIS or the website search during the maintenance windows:

- Mondays to Fridays between 18:00 – 21:00 Amsterdam time
- Every first Saturday of the month between 10:00 – 14:00 Amsterdam time

Information on planned and unplanned disruptions is available on the Website outages and system releases page of the CTIS public portal.

Reminder: CTIS training event

Participants can already submit their questions via Slido for the CTIS Bitesize talk on Annual Safety Reports (ASR) scheduled for 15 December 2022 at 16:30-18:00 CEST.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu)

More information

Are you a sponsor user starting out with CTIS? Please consult the Sponsor quick guide: Getting started with CTIS or refer to the CTIS training material, including the new version of the 'CTIS Handbook for clinical trial sponsors'.