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# CTIS newsflash – 3 February 2023

## Introduction

With the aim to enhance communication with the CTIS user community, this regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

## Spotlight: CTIS now mandatory for initial Clinical Trial Applications

**Since 31 January 2023, the use of CTIS is mandatory** for all initial clinical trial applications in the EU/EEA. **Therefore, sponsors can no longer submit initial EU/EEA Clinical Trial Applications under the Clinical Trials Directive.**

For trials submitted to the National Competent Authorities (NCAs) before 31 January 2023 under the Clinical Trial Directive (CTD), sponsors can continue to submit any amendments under the regime of the CTD until the end of the transition period on 30 January 2025, including requests for the NCAs to update their trials' status. EudraCT trial results need to be submitted through the EudraCT database, even after the end of the transition period, as applicable, unless the trial was transitioned to CTIS.

The EudraCT website has been updated accordingly and is therefore to be used only for the purposes of:

- updating information on EudraCT trials submitted until 30 January 2023, under the Directive (CTA amendments, status updates, results submission)
- creating and submitting third country files of Paediatric Investigation Plans (PIP)/Art 46 trials conducted exclusively in third countries (outside of the EU/EEA)

Additional information on the topic can be found in the EudraCT FAQs (questions 98-114).

## Recent Improvements

The work to improve the CTIS user experience continues. A CTIS release went live on 1 February 2023, delivering further system improvements and enhancing the user experience:

- The following 'Alerts' will no longer be displayed:
  - "There are 2 days remaining to submit a decision on the trial" once a decision has been issued for a trial.

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  - "Express willingness/unwillingness task due" after willingness/unwillingness has been expressed.
  - "Assess Part I. 12 days after circulating end date passed for application" as it is not applicable.
  - "Considerations due (Validation)" for non-Member States Concerned.
- Documents uploaded by sponsors will be immediately saved in the system when responding to RFIs. This will enable another user from the same organisation, with the proper roles and permissions, to see the changes in draft.
- Sponsors will be able to submit the trial period notifications after a non-substantial modification has been submitted.
- Updated clinical trial titles will be correctly displayed following a Substantial or Non-Substantial Modification in the Sponsor and Authority Workspace as well as in the Public Portal.
- Sponsors with a CT admin-specific trial will be able to assign roles to another user for the trials in their scope.
- Users will no longer be logged-out when facing an internal server error, due to slow response time.

More information on the latest system improvements is available in the published release notes as well as in the Lists of known issues and proposed workarounds.

EMA continues to work closely with Member States, the European Commission, and stakeholders to improve the CTIS user experience and support sponsors in the transition to mandatory CTIS use.

## Key updates

The recording and supporting slide deck for the CTIS public event "Readiness for mandatory use of the Clinical Trials Regulation from 31 January 2023" held on 20 January 2023 have been published on the dedicated event page.

EMA has published the latest report with metrics on the implementation of the CTR and the use of CTIS, as well as a Q&A document providing preliminary guidance to CTIS users on how to protect personal data and commercially confidential information (CCI) in CTIS. Further information on the protection of personal data and CCI in CTIS is available on the EMA website.

## How to search and create organisations in CTIS

New training material has been added to Module 03 of the CTIS training material catalogue. The Step-by-Step guide describes how users can search for organisations, retrieve them from OMS/CTIS, and insert them in their trials in CTIS, as well as how they can create organisations (i.e. third parties, clinical trial sites, etc.) locally in CTIS.

Now that the new functionality is in place to allow direct recording of organisations that are not registered in any public national business in CTIS, the temporary process of recording organisations in OMS via the submission of a headed letter is discontinued. Trial sites created in OMS under the temporary process will be removed from OMS. Sponsor users have to create these trial sites in CTIS under the new process.

## CTIS User Support Service

EMA is monitoring tickets daily and continuously working on strengthening the CTIS User Support Service to provide quicker, better and more efficient support to CTIS users, to address issues raised in a shorter time period and ensure that disruptions to CTIS use are limited. EMA welcomes users' feedback on their experience with the service desk via the available survey, which can be found in the automatic email sent to users to confirm their ticket has been closed.

## CTR Quick guide for sponsors

The European Commission published a Quick guide on the rules and procedures of the EU Clinical Trial Regulation drawn up by the Clinical Trials Coordination and Advisory Group (CTAG). The guide, available under 'Chapter V – Additional document' of EudraLex - Volume 10 (europa.eu), provides a useful overview for sponsors who wish to conduct clinical trials (national and multinational) in the European Union (EU) / European Economic Area (EEA) or have ongoing clinical trials in this region.

## Last chance to register: CTIS Sponsor end user training course 7-10 February 2023

EMA offers a virtual training course, organised by DIA, to support sponsor user preparedness for CTIS and the new way of submitting a clinical trial application and managing the lifecycle of a clinical trial. A hands-on approach is taken to explaining and demonstrating the functionalities of the system, such as user management, how to submit an initial application as well as modifications, both substantial and non-substantial. In addition, how to manage the lifecycle of a Clinical Trial, how to apply Deferral rules and how to respond to an RFI will be addressed. Further information is available on the event page.

## New format: CTIS Walk-in Clinics

As of February 2023, the CTIS walk-in clinics will continue in a new monthly format. Participants are invited to submit their questions via www.sli.do until 15 February 2023 using the code **#clinic232**. CTIS experts will then review and select the 30 most relevant questions, and provide answers in writing via Slido, by the end of the month. The Slido channel will remain visible for 1 year, enabling users to consult previously provided answers during this period.

## Reminder: Access to CTIS Training Environment

Sponsor users who want to be trained on CTIS have the opportunity to express their interest in gaining access to the CTIS Training Environment, by filling in the ongoing survey. The training environment is a simulation of CTIS used in production and allows users to get familiar with system functionalities in a safe environment.

## 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'. The handbook provides useful information on how sponsors can navigate CTIS to create and submit clinical trial information to the member states of the European Union as required by the Clinical Trial Regulation (EU) No 536/2014.