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European Medicines Agency

CTIS newsflash – 6 January 2023

Introduction

With the aim to enhance communication with the CTIS user community, as of December 2022 EMA has reinstated the regular 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.

The next CTIS newsflash will be circulated on 13 January 2023.

Spotlight: Start date of mandatory CTIS use

CTIS was launched on 31 January 2022, starting the clock for the one-year transition time for 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.

The last date for sponsors to submit initial Clinical Trial Applications under the Clinical Trials Directive is 30 January 2023. Starting from 31 January 2023, the use of CTIS will be mandatory for all initial clinical trial applications in the EU. For trials authorised under the Clinical Trial Directive, sponsors can continue to submit substantial amendments under the regime of the Clinical Trial Directive until the end of the transition period on 30 January 2025.

Key Updates

A CTIS "Hotfix" went live on 22 December 2022 and on 5 January 2023 with the following improvements:

- Documents will no longer be inadvertently removed from the original clinical trial application when deleted in a copied clinical trial application.
- Sponsor will be able to submit a response to a RFI with a change application without documents being lost in part I.

More information is available in the latest published release notes as well as in List of known issues and proposed workarounds.

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The latest version of the Sponsor Handbook was published on 20 December 2022. The aim of the handbook is to provide sponsors with the information they need to navigate CTIS to create and submit clinical trial information to the member states of the European Union as required by the Clinical Trial Regulation [CTR: Regulation (EU) No 536/2014].

Furthermore, please note that the European Commission published in December 2022 an updated version of the Questions and Answers document for the Clinical Trials Regulation (EU) No 536/2014.

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.

Winter Clock stop

A winter clock stop is in place for all clinical trial applications (CTAs) that are under evaluation in CTIS, meaning that timers within the evaluation of a CTA have stopped on 22 December 2022 at 23:59:59 CET and will resume on 8 January 2023 at 00:00:01 CET. The due dates for any tasks will automatically fall on dates after this winter clock stop.

Site registration in CTIS

The CTIS release on 12 December 2022 enabled the creation of organisations locally in CTIS, without the need to register them in OMS, in the following five areas of the system:

- Part I: Sponsor section- "Third-party organisations"
- Part II: "Trial sites"
- Serious Breach Notification: "Details of the site where the serious breach occurred"
- Third Country Inspectorate Notification: "Third country inspection site"
- MS Inspections: "Inspected site"

Organisations created locally in CTIS behave and function in the same way as the ones sourced from OMS and can be searched and selected once they have been registered in CTIS and validated by OMS team.

For clinical trial sites, this new feature replaces the temporary process which had been in place since 3 November 2022, enabling users to record organisations in OMS which were not registered in any public national business registry by attaching a CT registration headed letter to their OMS request. Now that the new functionality is in place to allow direct recording of organisations in CTIS, the temporary process 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. Importantly, draft clinical trial applications created with the OMS trial sites (those created with the headed letter) can be submitted: The removal from OMS of the trial sites temporarily created with the procedure of the headed letter, does not change the draft applications created.

Step-by-step instructions on how to register sites in CTIS have been circulated to all users. The CTIS training material will be revised accordingly, and updates will be provided in future issues of this Newsflash.

Save the date: CTIS Event on 20 January 2023

A public CTIS Event on Readiness for mandatory use of the Clinical Trials Regulation from 31 January 2023 is taking place on Friday, 20 January 2023 from 10:00–13:00 CET.

Stakeholders are invited to raise questions in advance of the event, starting on 9 January to 16 January 2023, via the interaction tool Slido. Please go to www.sli.do and enter the event code "CTIS2023".

Reminder: 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 training 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'.

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