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European Medicines Agency

CTIS newsflash – 22 December 2022

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 6 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 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.

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 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 30 January 2025.

Key Updates

A CTIS release went live on 12 December 2022, implementing several functional improvements:

- Resolving the issues with reporting member state (RMS)/concerned member state (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

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An additional release went live on 21 December 2022 with several improvements, including:

- Sponsor user will be able to 'Change application' in a Part II RFI in the context of a multinational clinical trial, regardless of the CTA status in any other MSC.
- An administrator can assign roles to a blank user, regardless of whether this user was previously assigned with roles and further revoked by an administrator of a different organization.
- Responses to RFIs saved but not submitted are not visible by the authority WS/MS API.
- The sponsor user will be able to delete the "for publication" documents when they have a "not for publication" document linked.
- The sponsor user will be able to create a substantial modification (SM) or non-SM and no red pop-up error will be shown.
- Sponsor users will be able to delete the MSC in a CT in draft status albeit the MSC is also involved in a CT under evaluation.
- The field "sponsor type" in the Legal representative section will display a value ('commercial' or 'non-commercial') in all applications.
- The document "proof of payment" will not be lost when the sponsor user performs a "change application" when responding to an RFI in the context of an SM.
- 'Considerations' and 'Consolidated Considerations' sorting mechanism has been improved. The sorting is ascendant or descendant according to (a) arithmetic order when using the number attributed or the date columns and (b) alphabetic order when using wording.
- The GDPR feature can be used now to replace documents uploaded not only by sponsor users but also by Authority users.
- The task 'Submit RFI response' (projected) appears with the correct values in the timetable and there is no gap between 'Submit RFI' (projected) task and 'Submit RFI Response' (projected).

More information is available in the latest published release notes.

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.

An update on the implementation of the Clinical Trials Regulation was shared with the EMA Management Board last week on 15 December 2022. The full MB highlights are published on the Agency's website.

Winter Clock stop

As we approach the holidays, a winter clock stop will be in place for all clinical trial applications (CTAs) that are under evaluation in CTIS. All timers within the evaluation of each CTA will stop 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.

This new feature replaces the temporary process which has 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.

Publication of 12th Issue of the Clinical Trials Highlights newsletter

The latest issue of the CT Highlights newsletter is now available on the EMA website. This newsletter provides updates on ACT EU and CTIS (milestones achieved, activities planned, new developments) on a regular basis to a wide subscriber base, including the European medicines regulatory network, sponsor organisations involved in human medicines such as pharmaceutical companies, CROs, SMEs, academia, and healthcare professionals' and patients' organisations.

Save the date: CTIS Event on 20 January 2023

A public "CTIS Event on Readiness for Mandatory CTR use from 31 January 2023" will be held on Friday, 20 January 2023 from 10:00–13:00 CET. A Programme Committee with representatives from all stakeholder groups has been formed to set the agenda for the discussions. The event will be broadcast, with further details to be provided in the future issues of the newsflash.

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 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'.