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European Medicines Agency

CTIS newsflash – 5 December 2022

Introduction

With the aim to enhance communication with the CTIS user community, EMA is reinstating the weekly CTIS newsflash, providing key updates on CTIS, as well as links to useful reference materials.

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

Key Updates

Applications through CTIS are steadily increasing. Ninety-nine (99) initial clinical trial applications were submitted to CTIS in November 2022, compared to sixty-one (61) in October 2022.

A new CTIS release went live on 23 November 2022, implementing functional improvements, including:

- increased maximum upload size to 50 MB per document
- added active substance name field in the summary tab for unauthorised products
- improved subtasks assignment from the CT Coordinator to other users
- optimised search results for organisation names with special characters
- defined permissions for trial creation by the CT Admin user role

More information is available in the latest published release notes.

EMA continues proactive support to sponsor users with RFIs due to expire, and further improvements to the module are planned in upcoming releases.

The CTIS public portal migration to the Angular platform was successfully completed, resolving 3 related issues.

The next release is currently under validation by the CTIS Business Team, planned to be delivered on 6 December 2022. Release notes will be available on the dedicated webpage.

Some users have experienced problems with the system. 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 for no blocking issues in the core CTIS processes. The Agency has invested additional resources to achieve this goal.

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Update on issues with RFI due dates for Member States

Following the email communication to all users, the root cause of the issues has been identified. Development and testing is being planned with the highest priority. We are doing all we can to go live with a definitive fix for these problems in the week beginning 12 December. In the interim, we acknowledge the inconvenience these issues are causing some users and we remain committed to supporting the workarounds that are in place. More information will follow in the next weekly newsflash.

Extended maintenance windows

We are in a period of rapid system improvement to prepare for compulsory use on 31 January 2022. In order to accommodate increased delivery of problem-fix releases, EMA is extending planned maintenance windows from twice to five times a week, on Monday to Friday between 18:00 – 21:00 Amsterdam time. Maintenance also continues on the first Saturday of each month, from 10:00 – 14:00 Amsterdam time. Users are advised to avoid using CTIS or the website search during these times. Information on planned and unplanned disruptions are available on the Website outages and system releases page of the CTIS public portal.

CTIS Sponsor handbook version 3.0 now published

EMA is pleased to announce that a new version of the 'CTIS Handbook for clinical trial sponsors' is available on our website. The Handbook provides guidance to clinical trial sponsors to prepare for using CTIS, covering priority topics with references and links to further supporting materials. We recommend that sponsors use it as a starting point when reviewing the available training material ahead of any clinical trial application submission.

New processes for registration in OMS

Since 3 November 2022 a new process is in place, enabling any Sponsor not registered in a national business registry to request their registration in the Organisation Management Service (OMS). In their request to OMS, Sponsors should attach a CT registration headed letter (a template is available in OMS portal).

Additionally, as a temporary process, clinical trial sites not registered in a national business registry can register in OMS following a similar process. In their request to OMS, Sponsors/CT sites should submit a change request to register the CT site directly to OMS including the CT registration headed letter available in the OMS portal. The above process is valid only until a planned change is implemented in CTIS to allow recording of sites, not registered in OMS, directly into the clinical trial application.

News Spotlight

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 CET.

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.