17 February 2023
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European Medicines Agency

CTIS newsflash – 17 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.

A status update highlighting the start of CTIS mandatory use is available on the CTIS website.

Current operational experience with CTIS

With the aim to enhance transparency on system use, this section on weekly CTIS metrics provides key data and trends compared to the previous week. The data presented below refers to the period from 7 to 13 February 2023.

CTA Submissions

Initials
25
-14%
to previous week

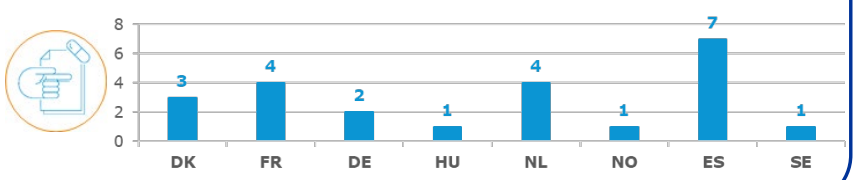
Substantial Modification
9
-44%
to previous week

Additional MSC
1

CTAs with a Decision

Initials*
23
+35%
to previous week

CTAs with a Decision per RMS in the last week



* Please note there were 17 initial CTAs with a decision for the period from 31 January to 6 February 2023, and not 22 as reported last week.

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System improvements

A CTIS "Hotfix" is scheduled to take place next week, to enable a small group of sponsors to change an application through a Request for Information (RFI) and Member States to respond to RFIs by resolving database locks that have occurred in a small number of trials.

Additionally, the next CTIS release, foreseen to take place on the week of 20 February 2023, will implement several improvements to enhance user experience:

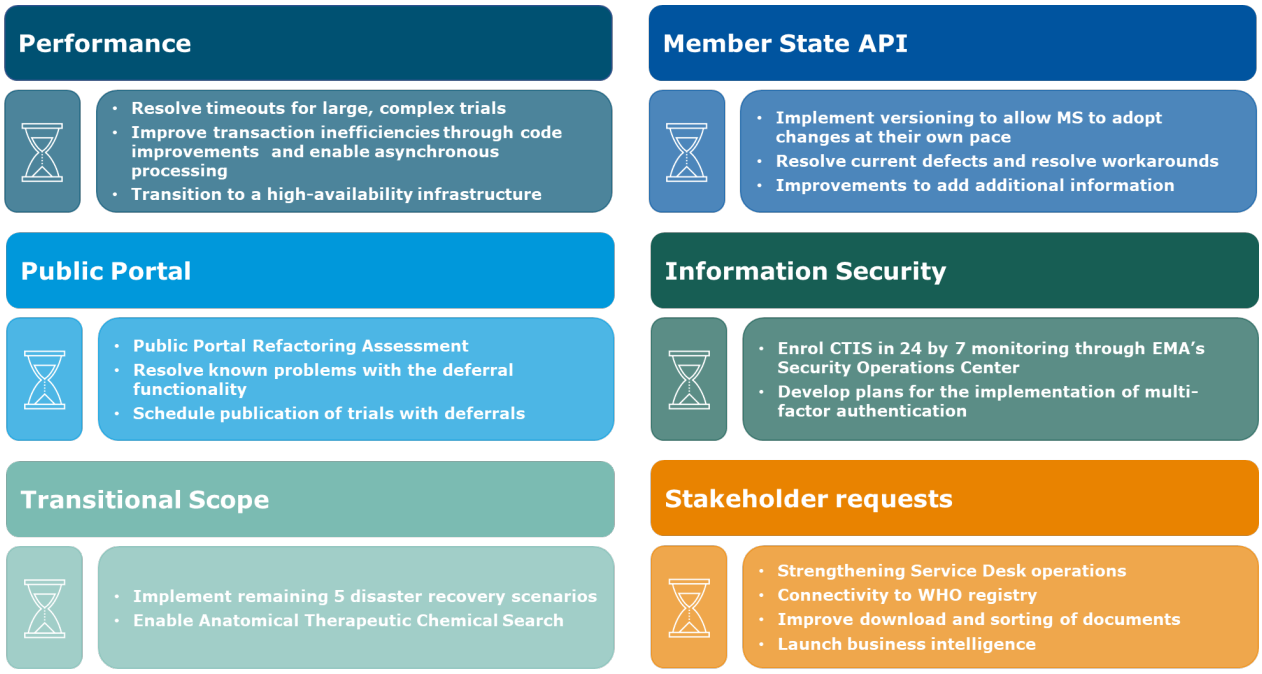
- Notices and Alerts will be displayed to users with Union Controller roles and EMA Admin, as applicable.
- Alerts that are no longer applicable when a clinical trial application (CTAs) is withdrawn will be removed.
- The search functionality will be improved in the following instances:
    - retrieving medicinal products with more than 35 substances
    - Member States Concerned retrieving partially submitted CTAs
    - adding a product using the ATC code
- Issues with duplication of IMP and auxiliary medicinal products (AxMP)-related documents will be resolved.
- The structured data present in the PDF downloaded related to sections "IMPD-Q" and "sponsor contact point for the Union" will show the most updated information displayed in the user interface.
- User profiles with combined roles of Member State Admin and National Organization Admin will only manage users (assign/ revoke/ amend) affiliated with the Member State Admin organization.
- When trying to submit an RFI response, an error message will no longer appear.

In addition to the above functional improvements, several technical improvements are also foreseen to be implemented in the same release:

- Disaster recovery scenarios related to Timetable and Restart of Trial.
- WHO API basic setup.
- Improved performance of Substantial Modification detail review process.
- Ensuring data download includes the latest entries.

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.

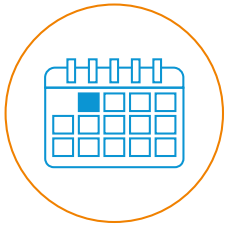
The work continues in close collaboration with our stakeholders to deliver further system improvements and enhance the user experience. The dashboard below summarises the main improvement areas of focus for 2023.



Publication of the Query Management Working Group Q&A

The Questions and Answers document prepared by the Query Management Working Group on CTIS and the CTR has been published on the EMA website.

The Q&A provides answers by the Working Group to questions that were raised by sponsor associations. To help the user, the questions are grouped by topics, and the answers include references to useful sources for a better understanding of the regulation and the use of CTIS.



Save the date: CTIS Bitesize talk on 23 February 2023

On 23 February 2023, EMA is hosting a CTIS Bitesize talk on Document and personal data in CTIS at 14:30-16:00 CET. Participants can already submit their questions via Slido with the event code #bt23feb.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support.

Reminder: 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 earlier 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).

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.