27 October 2023
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European Medicines Agency

CTIS newsflash – 27 October 2023

Introduction

This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

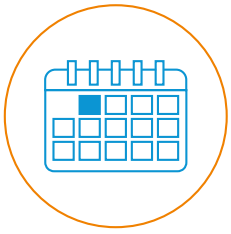
The next issue will be circulated on 10 November 2023.

Reminder: Transitioning trials to CTIS

By 30 January 2025, any ongoing trials approved under the Clinical Trials Directive will fall under the CTR. Therefore, any ongoing trials will need to be transitioned to CTIS and approved by 30 January 2025. Sponsors have submitted around 390 transitional trials to CTIS, out of an estimated total of 4,000-6,000 trials that need to be transitioned.

Further resources and guidance from the European Medicines Regulatory Network are available on the CTIS website, in order to support sponsors transitioning their trials to the CTR/CTIS.

National Competent Authorities of the EU/EEA Member States remain responsible for keeping the information on the trial status in EudraCT up to date, including inserting the end of trial date once notified by the sponsor.



Save the date: CTIS Walk-in clinic on 15 November 2023

On 15 November 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CET. Participants are able to submit their questions in advance starting 1 November via Slido with the code #clinic2311.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu).

Tips for CTIS users

- Sponsors are advised to **avoid creating draft applications** for Substantial Modifications, Non-Substantial Modifications, or Additional Member State Concerned **while the previous application is still under evaluation.** This is due to the fact that after a draft application is created, it will not

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include any subsequent information added to the application under evaluation, leading to discrepancies, missing data and manual work for the sponsor.

- When uploading new versions of documents to their application, e.g. in response to a Request for Information (RFI), sponsors may receive an error message. Before opening a ticket with the CTIS Service desk, sponsors are advised to refresh the webpage and check if their changes are visible.
- In order to prevent applications lapsing, sponsors are advised to **submit responses to RFIs ahead of the due date expiry**. This allows time for the CTIS help desk and technical team to provide support if any issue is highlighted upon submission.
- The vast majority of Substantial Modification (SM) applications submitted in CTIS are processed without any issues. In a small number of SM applications, sponsors may see an error message despite the SM being successfully submitted. Sponsors are, therefore, advised to wait for 10 minutes before reloading the page (logging out and back in to the secure workspace) and checking if their SM submission was successful. If not, sponsors may raise a ticket with the CTIS Service desk which will be able to support you.
- In case of technical issues in completing an action as part of a response to RFI (e.g. uploading a certain document, or updating the Investigational Medicinal Product code in xEVMPD), sponsors are advised to submit the RFI response despite this pending action. Sponsors should then reach out to the Member State Concerned and request for an additional RFI to be raised. This allows more time for the sponsor to coordinate with the CTIS Service desk to resolve the technical issue from the first RFI.

System improvements

A CTIS release was deployed on 12 October 2023, introducing several improvements to enhance user experience:

- Sponsors are now able to select organisations from OMS that contain just the character "-" in their address.
- The information on the strength of a medicinal product is now displayed correctly when expressed as a fraction with a denominator of 1 (e.g. 15mg/1ml instead of 15mg).
- The search functionality for Anatomical Therapeutic Chemical (ATC) codes has been simplified.
- During the resubmission of "Not authorised", "Lapsed" or "Withdrawn" applications, if sponsors click on the resubmit button twice the system now displays the error message "The resubmission is already in progress", ensuring that only one draft resubmitted application is created.
- The Reporting Member State (RMS) is now able to authorise an Additional Member State Concerned (MSC) application after the initial application for that RMS was "Not authorised", "Lapsed" or "Withdrawn". Other MSC are also able to see the tasks of the trial in the related tab.
- When sponsor administrators are amending the "Authorise from" and "Authorise to" dates for user roles under the "User administration tab", clicking on the "Cancel" or "X" to close the pop-up window now correctly discards any changes.
- The creation of an RFI by the RMS has been improved:
  - RMS with status "Lapsed" can create and submit the Part I assessment RFI for an Initial application;

- RMS with status "Not authorised", "Lapsed" or "Withdrawn" can create and submit the Validation or Part I assessment RFI for SM Part I & II, SM Part I only applications and the Part I assessment RFI for Additional Member State (AMS) applications;
- RMS can create and submit the Validation or Part I assessment RFI in the context of partial application submitted to the RMS (i.e. Part II not submitted yet).

- Member States are now able to comment on the RFI response even after the RMS has authorised the application.
- Users are now able to download documents with special characters in the title.
- Users are now able to download and open documents with the part I structured data information which contain the control characters "STX- Start of Text" and "SOH- Start of Heading" in the free text.

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.

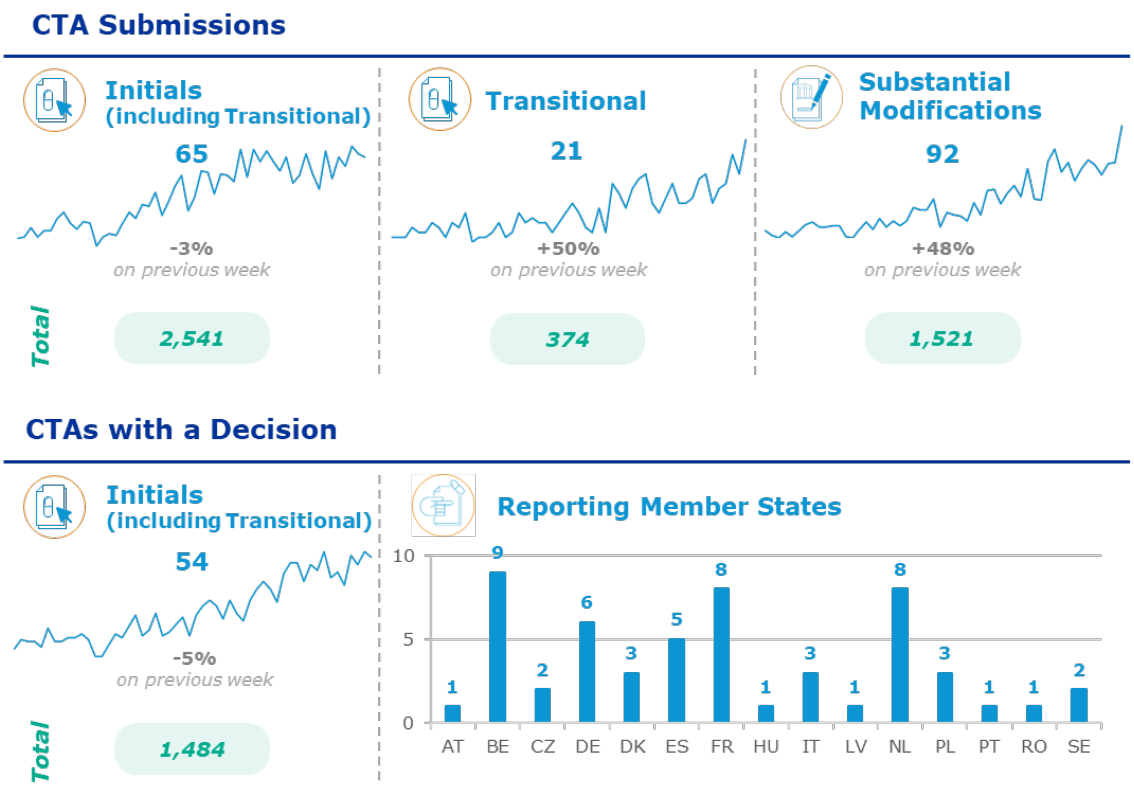
EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

The dashboard below summarises the main improvement areas of focus for 2023 and the improvements implemented.

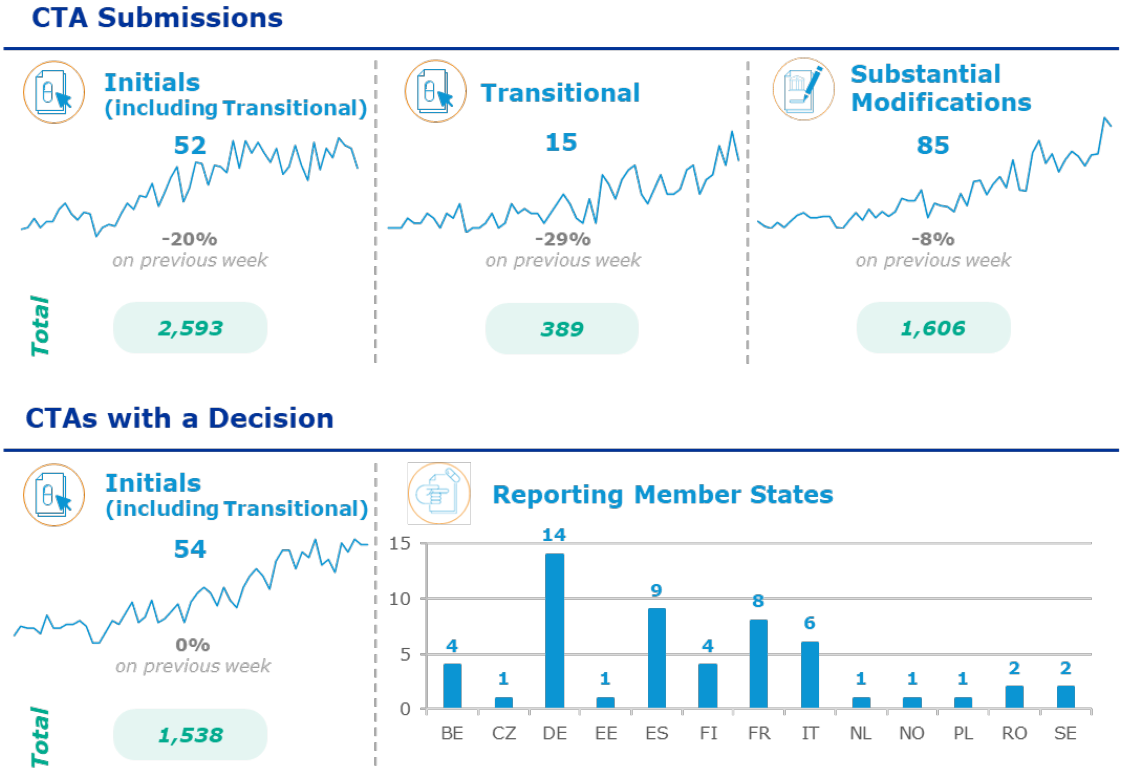
Current operational experience with CTIS

This section on weekly CTIS metrics provides key data and trends compared to the previous week.

The data presented below refer to the period from 10 to 16 October 2023.



The data presented below refers to the period from 17 to 23 October 2023.



Reminders

- Sponsors can 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. Due to limited capacity, access to eligible users is provided for a limited period of time. In addition, access is prioritised for users/organisations with no previous access in the system.
- The monthly KPI reports on the implementation of the CTR, as well as the final guidance document, annexes and Q&A on the protection of personal data and commercially confidential information in CTIS can now be found on the ACT EU website, under the webpage Implementation of the Clinical Trials Regulation.

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.