10 November 2023
EMA/486111/2023
European Medicines Agency

CTIS newsflash – 10 November 2023

Introduction

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

The next issue will be circulated on 24 November 2023.

Previous issues of the CTIS Newsflash are available on the EMA website.

Update on CTIS downtime - 8 November 2023

CTIS was briefly unavailable on the afternoon of 8 November 2023. The downtime, now confirmed to have been caused by human error, was resolved later the same day.

We recommend that users check if all changes made on 8 November 2023 are still correctly reflected in CTIS. If needed, please reach out to CTIS service desk for support.

We acknowledge the inconvenience to users and assure you that further safeguards have been put in place to prevent such incidents in the future.

Winter clock stop

All timers within the evaluation of a clinical trial application will stop on 22 December 2023 at 23:59:59 CET and resume on 8 January 2024 at 00:00:01 CET. Due to this winter clock stop, the timelines for the applications may be affected. More information is available in the CTIS evaluation timelines document.

Expedited procedure for transitioning trials to CTIS

By 30 January 2025, any ongoing trials approved under the Clinical Trials Directive (CTD) 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 420 transitional trials to CTIS, out of an estimated total of 5,000 trials that need to be transitioned.

CTCG has agreed on an **expedited, harmonised Member State evaluation procedure open until 16 October 2024** focussing on the validation of minimum application dossiers restricted to documents already authorised under the CTD. After this date and depending on the MS workload, this expedited procedure may not be available.

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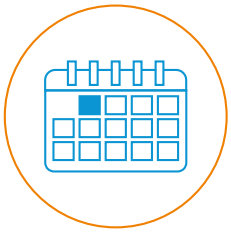
Further resources and guidance from the European Medicines Regulatory Network are available on the CTIS website, in order to support sponsors transitioning their trials to the CTR/CTIS.



Save the date: CTIS events in 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.

The last CTIS Bitesize talk of the year will take place on 29 November 2023, at 15:30 – 17:00 CET. The focus of this session will be on training materials, CTIS pre-requisites and an update on transparency rules. Participants are able to submit their questions in advance until 21 November via Slido with the code #bt29nov.

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

Quality improvement of substance data and impact in CTIS applications

Following the ongoing substance data quality improvement activities taking place in EMA's Substance Management System (SMS), development products registered in the Extended EudraVigilance Medicinal Product Dictionary (xEVMPD) may have been updated and associated to an approved substance data with a new EudraVigilance (EV) code.

If such a development product is updated in xEVMPD and referenced in a clinical trial application in CTIS, an error message appears when submitting a subsequent draft application, when responding to a Request for Information (RFI) with an update to the dossier, or when cancelling the application. This error message reads: "*The product(s) information has changed in the xEVMPD. Therefore, please update this application to include the new product information*". As a consequence, the sponsor is not able to submit the application or the response to the RFI, nor cancel the application.

In order to progress with submission, the sponsor needs to update the development product record in CTIS. Please note that only the structured data should be updated, while the previously uploaded associated documents will remain in the draft application unless they are proactively deleted by the user.

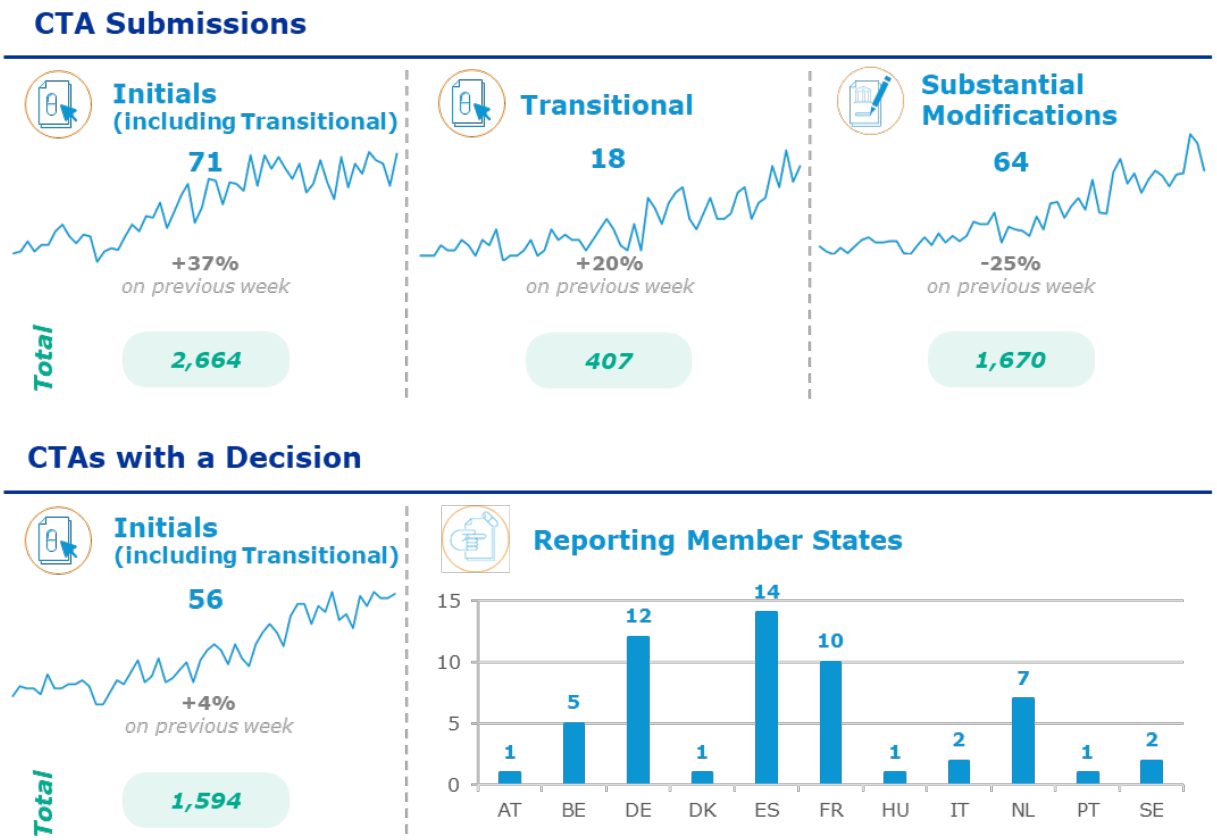
In order to update the unauthorised product, the sponsor needs to:

- identify the product requiring an update;
- remove the development product (only the structured data);
- search for it using the updated substance EV code; and
- add the product in the application.

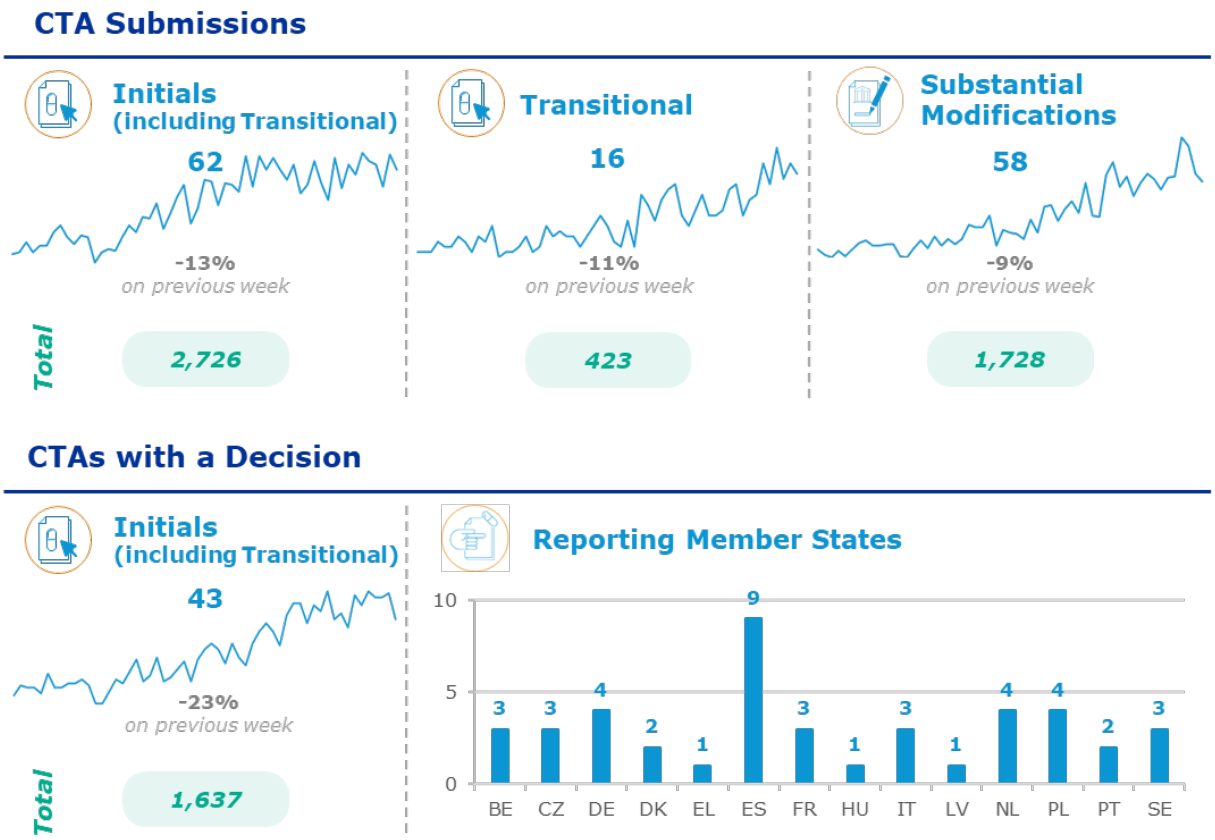
Current operational experience with CTIS

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 24 to 30 October 2023.



The data presented below refers to the period from 31 October to 6 November 2023.



System improvements

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.

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.

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.