23 February 2024
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European Medicines Agency

CTIS newsflash – 23 February 2024

Introduction

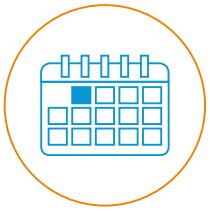
This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

The next issue will be circulated on 8 March 2024.

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

Key updates

- In case of unexpected downtime or issues with the system, users are advised to check the landing page of the CTIS User Support Service for announcements or details.
- New CTIS users can consult the recently published document which includes details on transitioning trials: CTIS: how to get started and how to transition a trial.
- On 9 February 2024, over 1850 viewers followed the online CTIS training event for non-commercial sponsors transitioning clinical trials to the Clinical Trials Regulation. The video recording will soon be available on the event page.



Save the date: Upcoming CTIS events

On 29 February 2024, EMA is hosting a CTIS Bitesize talk at 16.30-18:00 CET. The focus of this session will be on how to submit a transitional trial in CTIS.

The second CTIS Walk-in Clinic of the year will take place on 12 March 2024 at 16:00 – 17:00 CET. Participants can send their questions via Slido from 23 February to 6 March, at noon, using the event code #clinic243. Find out more on the event page.

The next CTIS informational webinar, focused on transitioning trials to the CTR, is planned on 25 March 2024 at 13.00 CET. Participants can provide their questions from 4 to 18 March in slido with the event code #infomarch2024. More information is available on the event page.

Sponsors can already register to the upcoming CTIS user trainings on:

- 8-11 April 2024, 14:00-18:30 CEST
- 10-13 June 2024, 09:00-13:30 CEST

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 creating and submitting IMPD-Q only applications

When sponsor users **create** an application for Investigational Medicinal product Dossier – Quality (IMPD-Q) only, they receive an error message that Part II documents are missing. As a temporary workaround in these cases, users are advised to enter mock data/documents to all (mandatory) structured data fields and document placeholders for Part II in ALL Member States Concerned (MSC). Users should ensure that all MSC Part IIs are populated to prevent similar issues later on, when responding to validation Requests for Information.

When **submitting** the application, users should only select the checkbox for Part I and should leave blank the checkbox for Part II.

Submitting transitional trials in CTIS

Any trials expected to continue after 30 January 2025 must be transitioned from the Clinical Trials Directive (CTD) to the CTR. Sponsors are encouraged to register these trials under CTIS at their earliest convenience, taking into account the time needed for Member States to complete the authorisation procedure, which can take up to three months. Resources to support sponsors transitioning trials are available on the CTIS website.

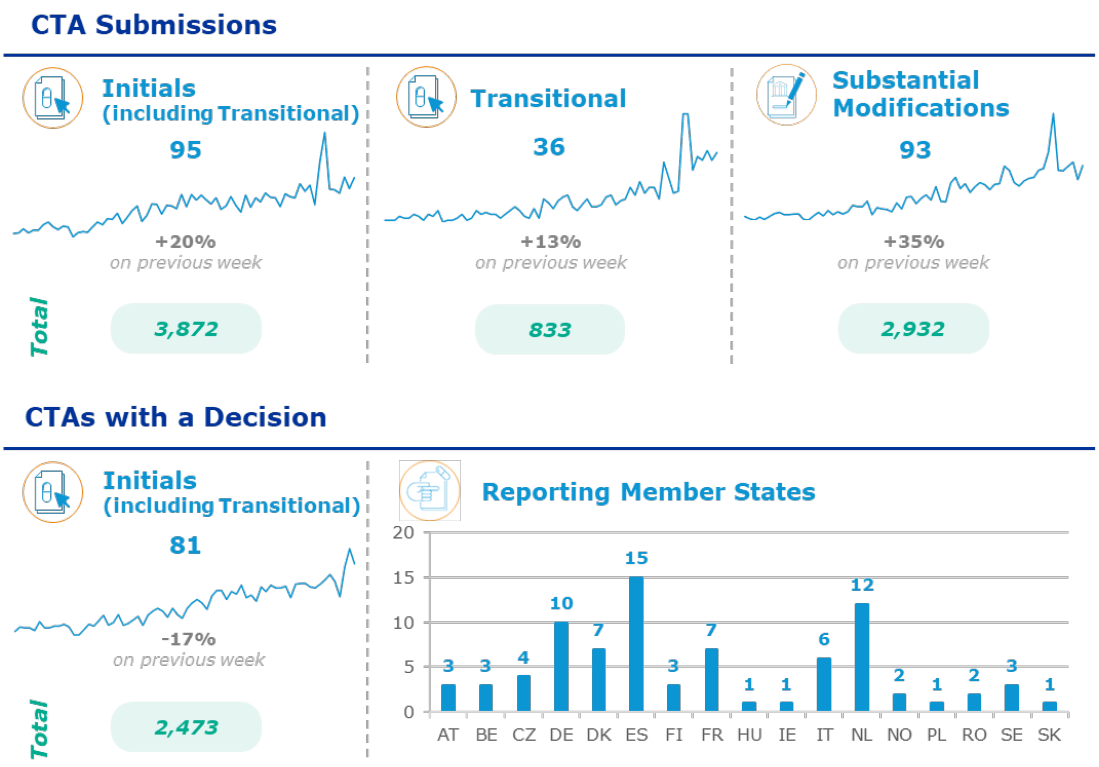
Below are some additional tips to support CTIS users during submission of their transitional trials:

- If a sponsor forgets to tick the checkbox 'Transitional trial' when submitting their application, the user needs to withdraw the application, then submit a Service desk ticket asking for a fix to enable selection of the 'Transitional trial' checkbox. After the Service desk implements the fix and selects the 'Transitional trial' checkbox, the sponsor can resubmit the application.
- After withdrawing a clinical trial application which was marked as transitional, at the time of resubmission the sponsor will not be able to select the 'Transitional trial' checkbox, as it will not be visible due to the current system configuration. In such cases, the sponsor should proceed with the resubmission, although the application will no longer be marked as transitional. In the cover letter, the sponsor should mention that the resubmitted application concerns a transitional trial.
- When sponsors create a CT centric application for a transitional trial, due to the current system configuration the 'Transitional trial' checkbox is not visible. In such cases, sponsors are advised to first create a "dummy" non-transitional clinical trial application. Once the CT Admin role for that specific clinical trial is granted to the creator of the application, the user should log out and log back in. The system will then enable the 'Transitional trial' checkbox for this user which will enable the creation of a CT centric application for a transitional trial. The "dummy" non-transitional clinical trial application can be cancelled afterwards.

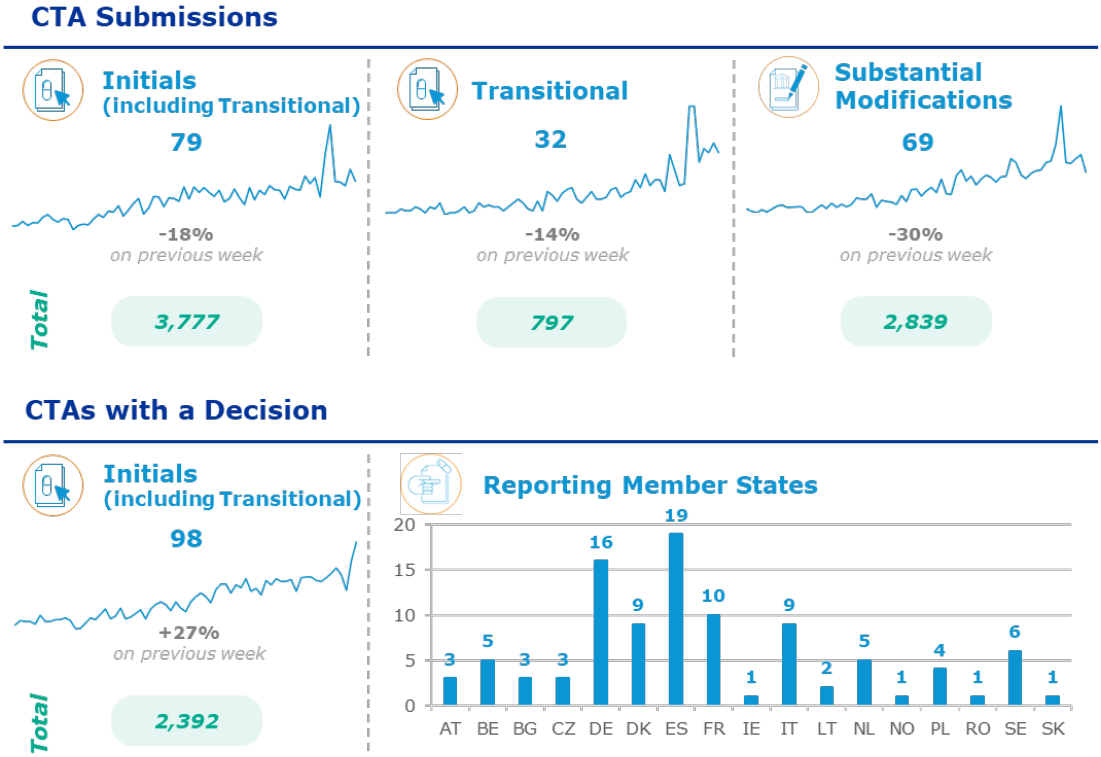
Current operational experience with CTIS

This section on weekly CTIS metrics provides key data and trends.

The data presented below refer to the period from 13 to 19 February 2024.



The data presented below refer to the period from 6 to 12 February 2024.



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 for sponsors and for Member State users.

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

Requesting access to the CTIS Training Environment

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 six months. In addition, access is prioritised for users/organisations with no previous access in the system.

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.