8 March 2024
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European Medicines Agency

CTIS newsflash – 8 March 2024

Introduction

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

The next issue will be circulated on 22 March 2024.

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

Key updates

- An new version of the CTIS Evaluation Timelines is available, including additional clarifications on the tasks "Assess Part II" and "Substantial Modification (SM) Submit decision" for SM Part II only; clarifications regarding earlier completion of tasks/actions; and examples of calculations of timelines in the Annex.
- Several guidance documents have been updated:
  - The European Commission's Questions and Answers document on the Clinical Trials Regulation has been updated to version 6.8.
  - The European Commission's Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation.
  - The Clinical Trials Coordination and Advisory Group (CTAG)'s Recommendations on the use of Auxiliary Medicinal Products (AxMP) in Clinical Trials.
- 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 is now available on the event page.
- 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.

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Save the date: Upcoming CTIS events

The second CTIS Walk-in Clinic of the year will take place on 12 March 2024 at 16:00 – 17:00 CET. Participants were able to submit their questions via Slido from 23 February to 6 March. More information is available 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 via 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:

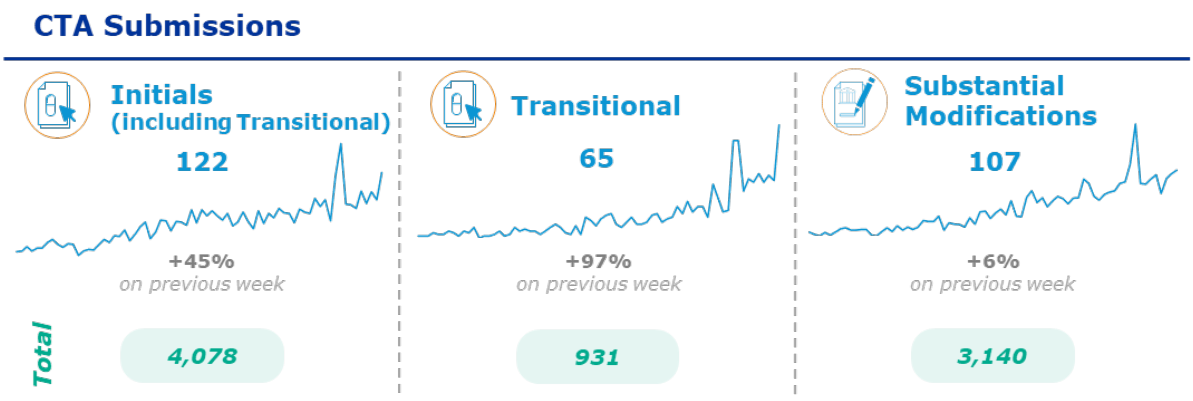
- 8-11 April 2024, 14:00-18:30 CEST
- 10-13 June 2024, 09:00-13:30 CEST

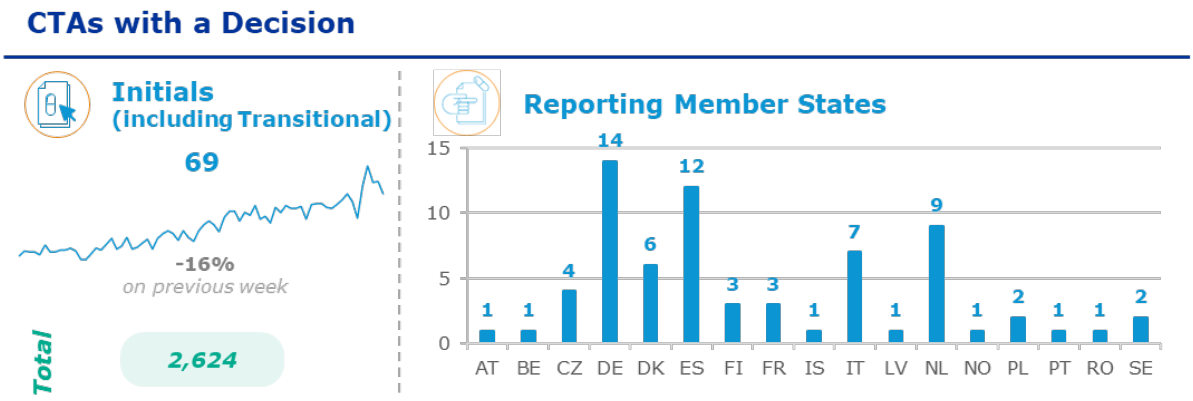
For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu).

Current operational experience with CTIS

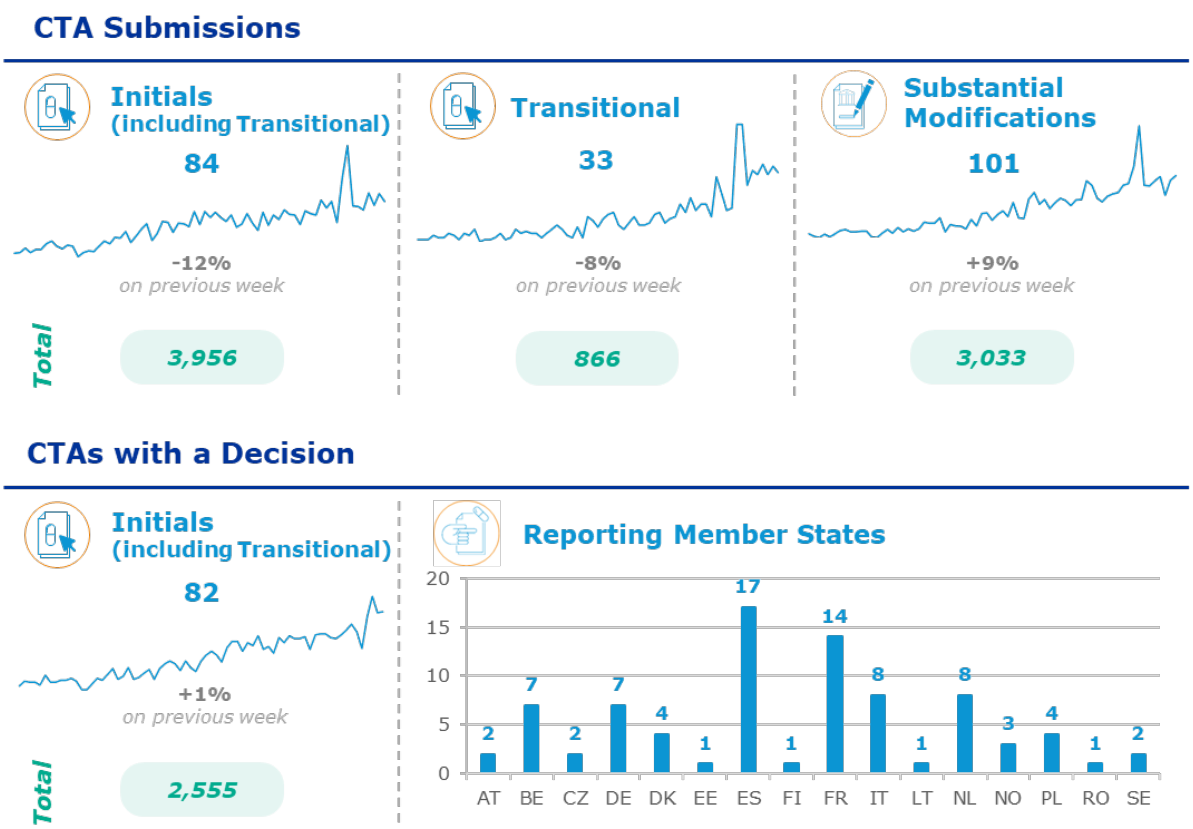
This section on weekly CTIS metrics provides key data and trends.

The data presented below refer to the period from 27 February to 4 March 2024.





The data presented below refer to the period from 20 to 26 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.

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.

Resources to support sponsors transitioning trials from the Clinical Trials Directive (CTD) to the CTR are available on the CTIS website.