22 March 2024
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European Medicines Agency

CTIS newsflash – 22 March 2024

Introduction

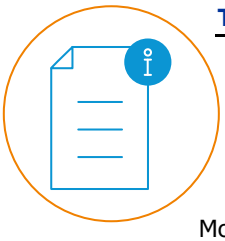
This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

The next issue will be circulated on 5 April 2024.

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

Key updates

- CTCG has updated the best practice guide and cover letter template for sponsors transitioning trials to the Clinical Trials Regulation (CTR).
- CTCG has published a recommendation paper on principles of Good Laboratory Practices (GLP) for clinical trial applications under the CTR. A template table has also been made available for sponsors to use when providing the required information on GLP compliance.



Tips for CTIS users

- For an overview of open tasks and required actions, CTIS users are advised to regularly consult the tabs "Tasks" and/or "Requests for Information (RFI)" instead of relying solely on the notices and alerts.
- 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 include any subsequent information added to the application under evaluation, leading to discrepancies, missing data and manual work for the sponsor.
- Sponsors of clinical trials in CTIS are reminded of their legal obligation, according to Art. 36 of the CTR, to notify the Member State Concerned (MSC) within 15 days of the start of the trial, first-patient-first-visit and end of recruitment. According to Question 10.2 of the European Commission's Q&A on the CTR, "in the current version of CTIS, the date of the first visit of the first subject, as required by article 36(2), should be filled in for each MSC through the "start recruitment" button in the notifications tab of the trial."

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

- 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.

Save the date: Upcoming CTIS events

The next CTIS informational webinar, focused on transitioning trials to the CTR, is planned on 25 March 2024 at 13.00 CET. More information and the link to the live broadcast are available on the event page.

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

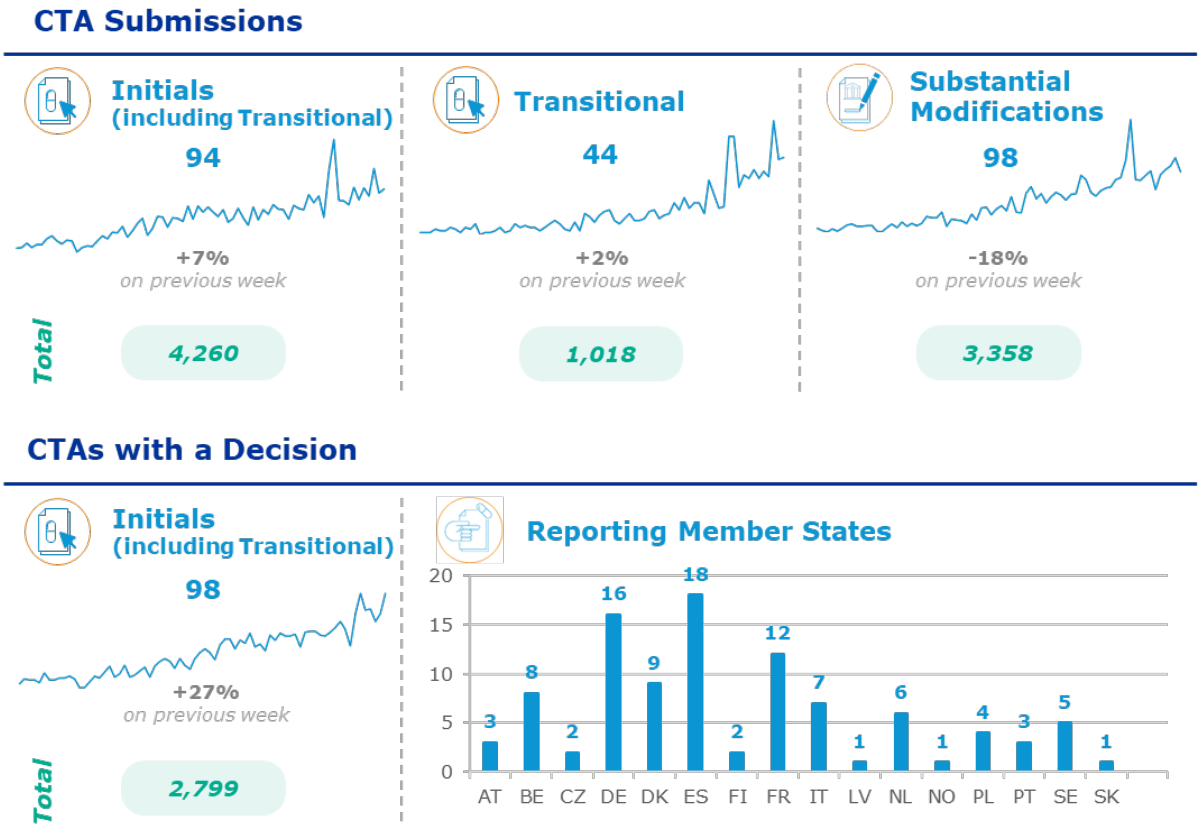
- 8-11 April 2024, 14:00-18:30 CEST
- 10-13 June 2024, 09:00-13:30 CEST

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 12 to 18 March 2024.



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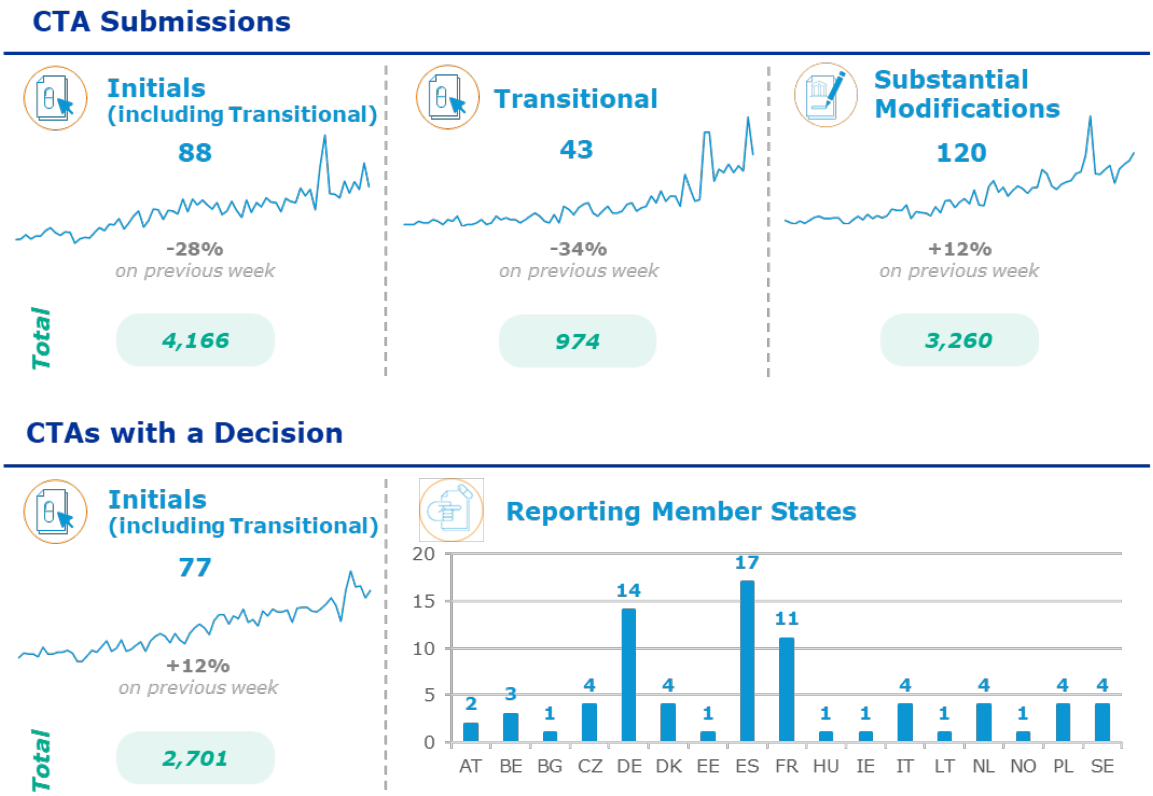
The data presented below refer to the period from 5 to 11 March 2024.



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.