9 February 2024
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European Medicines Agency

CTIS newsflash – 9 February 2024

Introduction

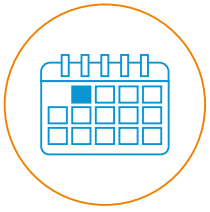
This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

The next issue will be circulated on 23 February 2024.

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

Key updates

- To fix a minor issue with the user rights module, users are advised that CTIS will be briefly unavailable this evening from 18.00 to 20.00 Amsterdam time.
- 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.
- An updated version of the Q&A on protection of confidential information and personal data in CTIS is now available on the ACT EU website, including the new question 3.4 on patient-facing documents disclosure.
- 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.
- Tips for users of the CTIS helpdesk are available on the CTIS website.



Upcoming CTIS events

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).

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Final year of transition to the Clinical Trials Regulation

The Clinical Trials Regulation (CTR) entered into application on 31 January 2022, with a three-year transition period. As the end of this transition period approaches, sponsors are requested to transition any trials that are expected to continue after 30 January 2025 from the Clinical Trials Directive (CTD) to the CTR.

Sponsors should take into account the time necessary for completion of the Member State(s) procedure, which can take up to 3 months. Therefore, to facilitate that process, sponsors are encouraged to register their clinical trials under CTIS at their earliest convenience taking into account the time needed for the approval of the applications: document CTIS: how to get started and how to transition a trial has been published in order to help sponsors in this process.

When possible, Members States have agreed on an expedited procedure for transitioning trials to the CTR. For further information please consult the CTCG Best Practice Guide for sponsors of multinational clinical trials and the Clinical Trial Advisory Group's Guidance for the transition of clinical trials.

Further resources to support sponsors transitioning trials are available on the CTIS website

Clinical trial analytics workshop

Under the ACT EU initiative, EMA hosted a two-day Clinical trial analytics workshop on 25-26 January 2024. Over 200 participants participated in the discussions, which highlighted the desire for improved access to detailed and up-to-date clinical trial data, the importance of patient involvement, standardisation, and identification of the right data sources.

A video recording of the event and speaker presentations will be available on the event page in due course. A report summarising the outcome of the event will be published in March 2024.

Reminder: Generation of draft assessment report in CTIS

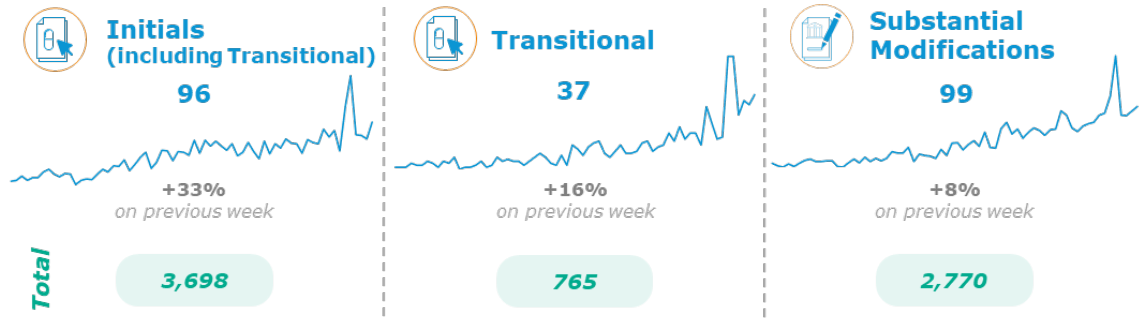
Member State users are reminded that, in accordance with the CTIS system specifications, the draft assessment report (DAR) template should only be generated and available for download once the "Circulate DAR" task is generated. The generation of the "Circulate DAR" task is triggered following the submission of the validation outcome, as described in the first row of the table on page 12 of the published CTIS Evaluation timelines.

Current operational experience with CTIS

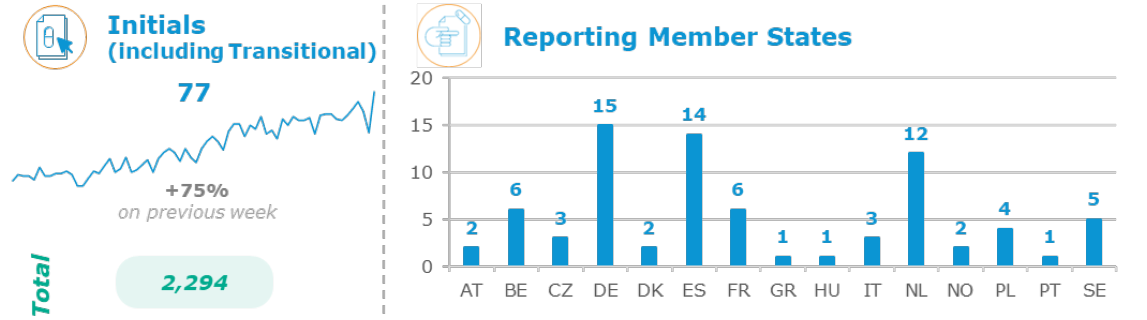
This section on weekly CTIS metrics provides key data and trends.

The data presented below refer to the period from 30 January to 5 February 2024.

CTA Submissions



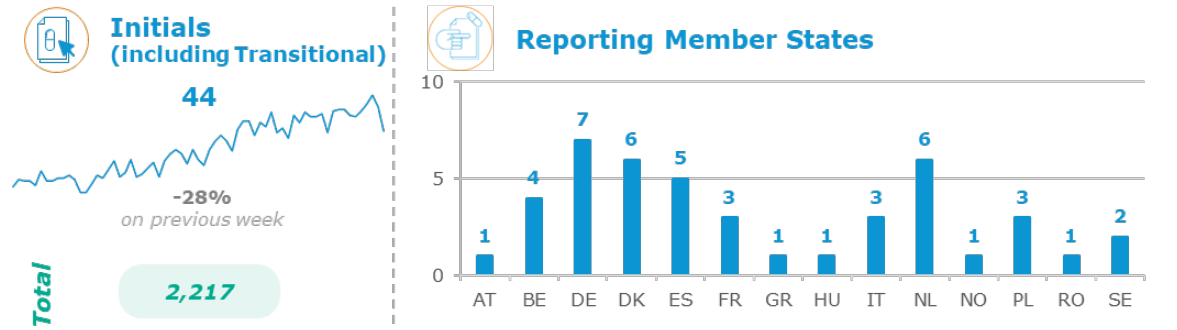
CTAs with a Decision



The data presented below refer to the period from 23 to 29 January 2024.

CTA Submissions

CTAs with a Decision



System improvements

A CTIS release on 8 February 2024 introduced several improvements:

- The search functionality in ad-hoc assessments has been extended to include additional trial statuses (i.e. Not Authorised, Not valid, Lapsed, Expired, Revoked, Withdrawn, Under evaluation), and a new search field "Affected MS" has been added in the advanced search.
- When a user from a Member State Concerned (MSC) raises conditions in Part II, the conditions are no longer displayed in the "Decision" section under the "Evaluation" folder of a different MSC.
- In partial submissions of a Substantial Modification (SM) Part I & II with Part II only submitted to a MSC, when the Reporting Member State accepts the Part I with conditions and claims the "Authorise" task:
  - The conditions added in the "Submit Part I conclusion" task are now displayed in the "Authorise" task under the "Conditions" header for all MSC involved in the trial.
  - The MSC can complete the Authorise task successfully.
  - After the "Authorise" task is completed, previously added conditions remain in the task.

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.

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 time. 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.