26 January 2024
EMA/20807/2024
European Medicines Agency

CTIS newsflash – 26 January 2024

Introduction

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

The next issue will be circulated on 9 February 2024.

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

Key updates

- CTIS users are asked to note that there may be brief periods of system downtime from Friday 26 January 2024 at 18.00 CET to Monday 29 January 2024 at 07.00 CET.
- The December 2023 report on the implementation of the Clinical Trials Regulation (CTR) is now available on the ACT EU website.
- CTIS was briefly unavailable on Wednesday 24 January 2024 due to a network issue. Service was restored after 1h 15 minutes. We apologise to users for any inconvenience.
- A limited number of CTIS users experienced issues with OMS connectivity starting on Monday 22 January 2024. We can now confirm the issues have been resolved.
- Tips for users of the CTIS helpdesk are now available on the CTIS website.

Final year of transition to the Clinical Trials Regulation

The Clinical Trials Regulation (CTR) foresees a three-year transition period, from 2022 to 2025. Wednesday 31 January 2024 marks the end of the second year of the CTR transition, following the launch of CTIS on 31 January 2022. Over 3500 initial clinical trial applications have been submitted in CTIS, with over 2000 trials authorised.

From 31 January 2025 onwards only the CTR and its Delegated Acts will apply. Sponsors are, therefore, 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

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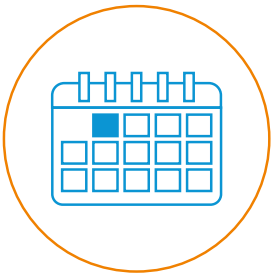
encouraged to register their clinical trials under CTIS at their earliest convenience taking into account the time needed for the approval of the applications.

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.



Save the date: Upcoming CTIS events

On 9 February 2024, EMA is hosting a Training event to support non-commercial sponsors transition trials to CTIS. Participants can already submit their questions via slido with the code #Transitioningtrials.

Additionally, the sponsor end-user training programme continues, with upcoming trainings planned on:

- 12-15 February 2024, 09:00-13:00 CET
- 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).

Update on CTIS transparency rules

EMA is working on the technical implementation of the revised CTIS transparency rules, foreseen for Q2 2024. In the meantime, for initial clinical trials applications sponsors may already follow the principles of the revised CTIS transparency rules. A sponsor may therefore refrain from deferring publication of documents and provide a version 'for publication' and 'not for publication' only for those documents in scope of the revised rules (Annex I of the revised CTIS transparency rules).

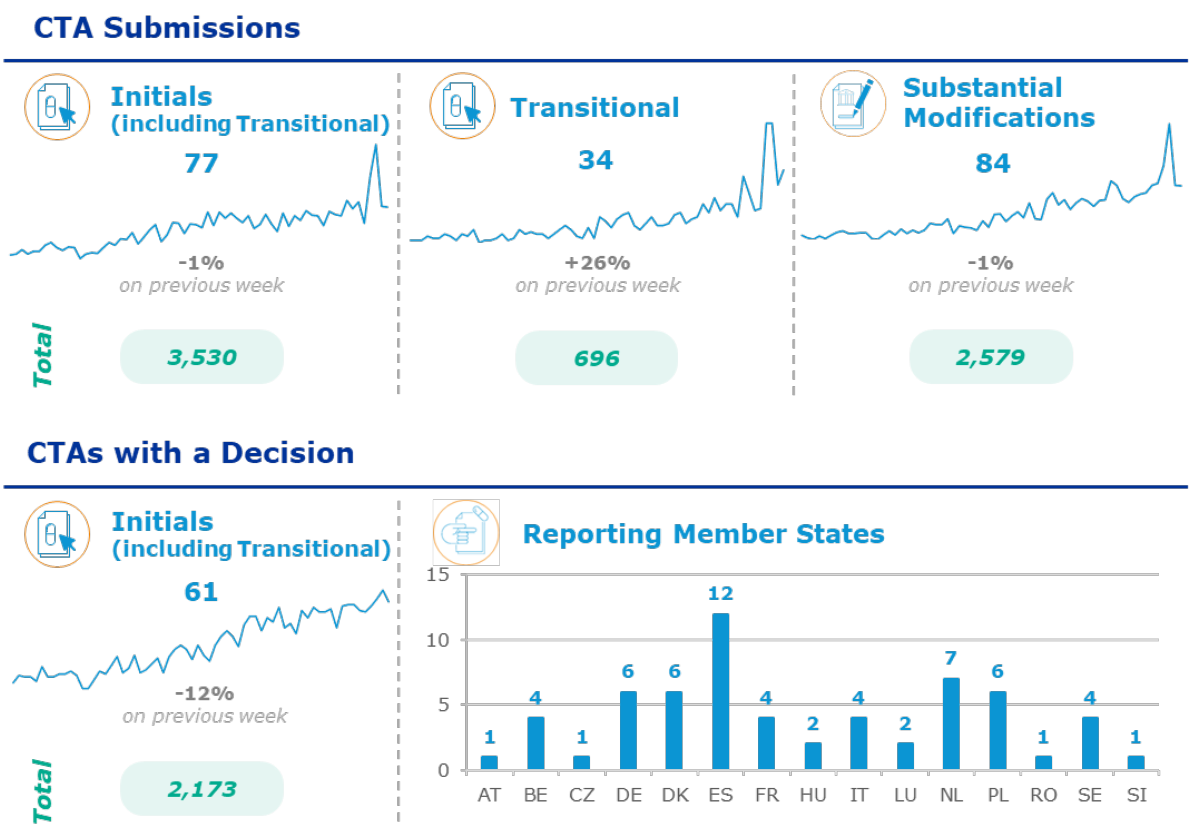
Further information is available:

- In section 4 of the updated Q&A on protection of confidential information and personal data in CTIS which includes information on the interim period until the new rules are in effect and on historical trials (all trials submitted until this date);
- The quick guide for users published on the ACT EU website which provides a summary of what will be published under the revised rules and the relevant timings of publication.
- The video recording and presentation of the CTIS Bitesize talk on 29 November 2023, now available on the event page.

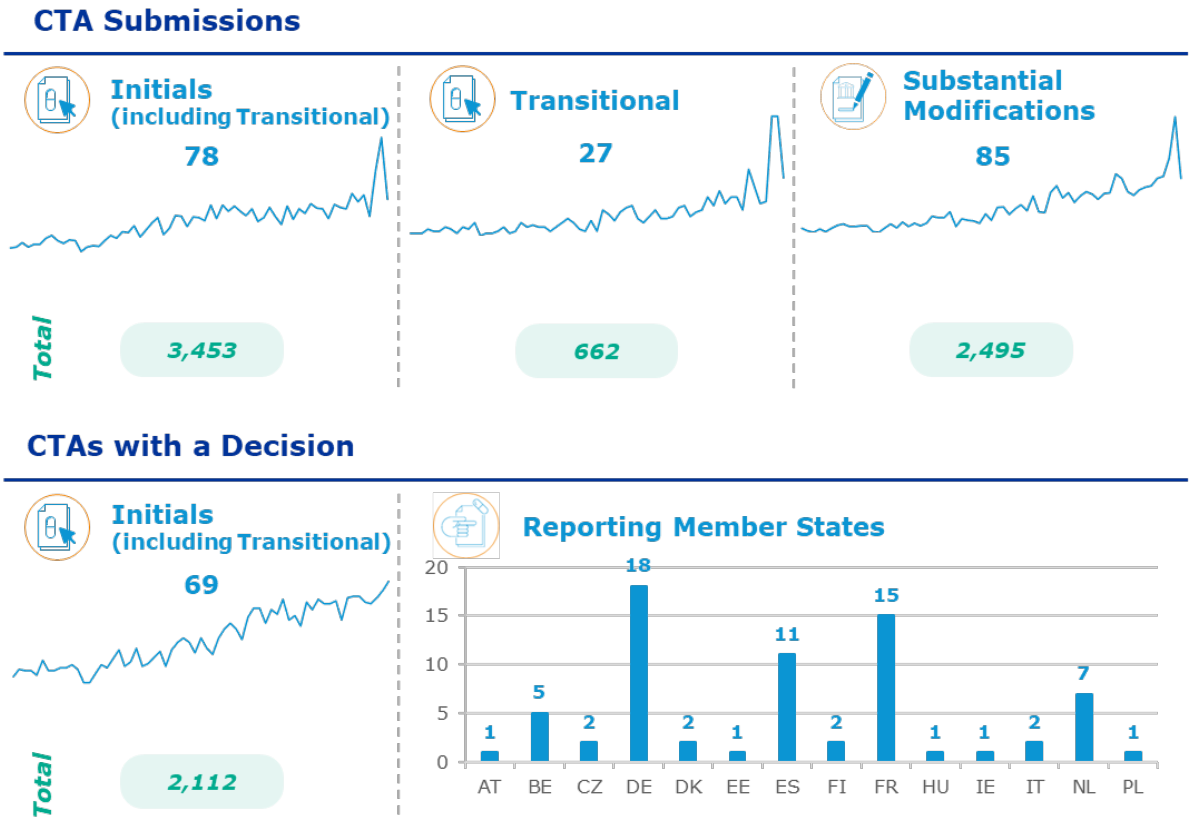
Current operational experience with CTIS

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

The data presented below refer to the period from 16 to 22 January 2024.



The data presented below refer to the period from 9 to 15 January 2024. Please note that due to the Winter Clock stop, this dashboard does not include a comparison with the previous week's data.



System improvements

A CTIS release on 25 January 2024 introduced several improvements:

- When downloading a "Start of Recruitment" notification in both Sponsor and Authority workspaces, the document now includes a new field named "Start of recruitment date", which is populated with this date as entered by the user when creating, editing, submitting or updating the "Start of recruitment" notification.
- The status of a Member State Concerned is now displayed as "Expired" in both Sponsor and Authority workspaces if the "Start of Recruitment" notification is not submitted within 2 years of the authorisation (2 natural calendar years + 15 days), as required by the CTR.
- The tasks "Document considerations'" and "Assess Request for Information (RFI)" are now enabled for a Member State Concerned with the status "Suspended" during the Validation, Assessment part I and Assessment part II phases for Substantial Modification applications Part I & II and Part I only.
- When downloading clinical trial information from the CTIS public portal, the "Start of Recruitment" information is displayed under the "Trial information" section of the Summary document.
- In multinational trials, a Reporting Member State (RMS) that did not authorise the "initial clinical trial application" can now create and share document considerations in the Validation and Assessment Part I for Substantial Modifications Part I & II and Part I only.

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.

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.

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.