14 June 2024
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European Medicines Agency

CTIS newsflash – 14 June 2024

Introduction

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

The next issue will be circulated on 28 June 2024.

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

Spotlight: Launch of revised CTIS transparency rules on 18 June 2024

The revised CTIS transparency rules become applicable on 18 June 2024, with the launch of an updated version of the CTIS public portal. Sponsors can refer to the quick guide for users for an overview of the changes.

Please note that CTIS will be unavailable on Monday 17 June 2024 from 18:00 CEST, due to configuration activities ahead of the go-live. After this downtime window, the revised rules become applicable and for all clinical trial applications submitted:

- it will no longer be possible to defer the publication of data and documents;
- data and documents will be published according to the established timelines for the trial category, population age and trial phase;
- publication of documents will be focused on key documents of interest.

Data on CTIS trials will be made publicly available in line with the principles and timelines defined in the revised transparency rules: more details are available in the quick guide for users. Note that documents of clinical trial applications submitted before 18:00 CEST on 17 June 2024 will not be published. For these trials, only documents provided in subsequent applications will be published; see the quick guide for more information.

As a temporary measure, the publication of the strength fields in the product section has been suspended due to ongoing discussions regarding commercial confidentiality of these data fields. New features will be added to the CTIS public portal over the next few months to improve the overall usability of the system (e.g. advanced search). Additional information will follow in due course.

Resources to support sponsors are available on the ACT EU website and on the CTIS website.

Sponsors can also attend the CTIS Bitesize talk on the revised transparency rules and the new version of the CTIS public portal on 20 June 2024 at 15:30-17:00 CEST.

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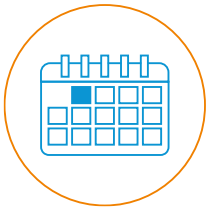
Reminder: Transition ongoing trials from CTD to the Clinical Trials Regulation

Sponsors are advised to transition any trials that are expected to continue after 30 January 2025 from the Clinical Trials Directive (CTD) to the Clinical Trials Regulation (CTR).

Sponsors should take into account the time necessary for completion of the Member State(s) evaluation procedure, which can take up to 3 months. Members States have agreed on an expedited procedure for transitioning trials to the CTR which will be applied whenever possible.

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



Save the date: Upcoming events

The next CTIS Walk-in Clinic will take place on 10 July 2024 at 16:00 – 17:00 CEST. Participants are able to submit their questions via Slido from 10 June to 3 July 2024, with the code #clinic246. More information is available on the event page.

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

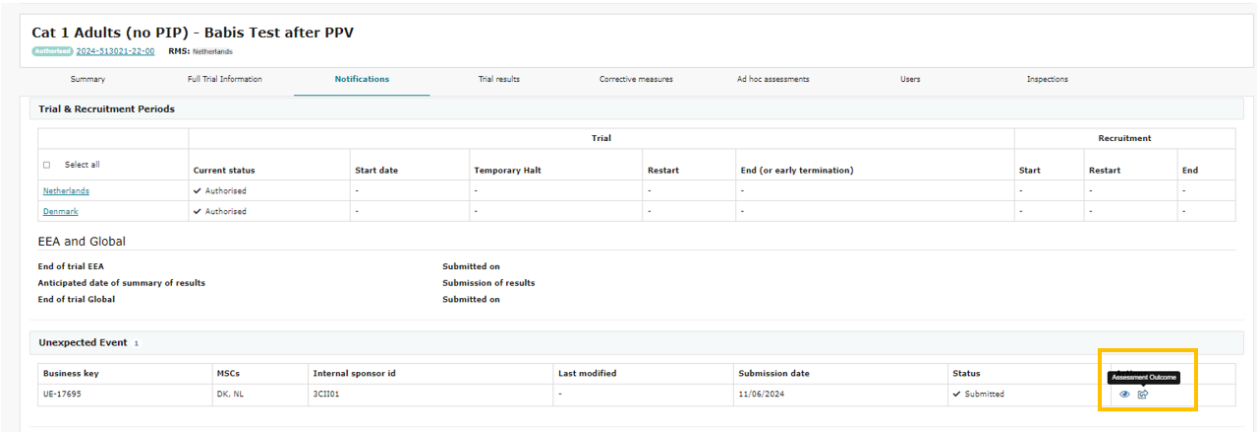
For MS users: Change in publication of Notifications

From 18 June 2024, with the go-live of the new public portal and the implementation of the revised transparency rules in the CTIS workspaces, a change will be introduced in the publication of Notifications.

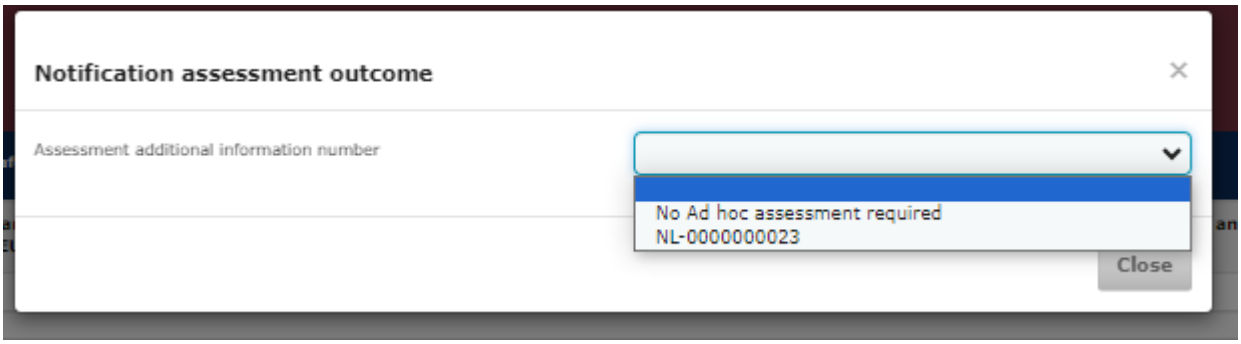
Under the current functionality, MS users, after receiving a Notification, need to start and conclude an ad hoc assessment related to the Notification, to publish its details. As of 18 June 2024, MS users will also be able to publish the details of a Notification without starting an ad hoc assessment.

Step-by-step instructions on how MS users can publish the details of a Notification are provided below.

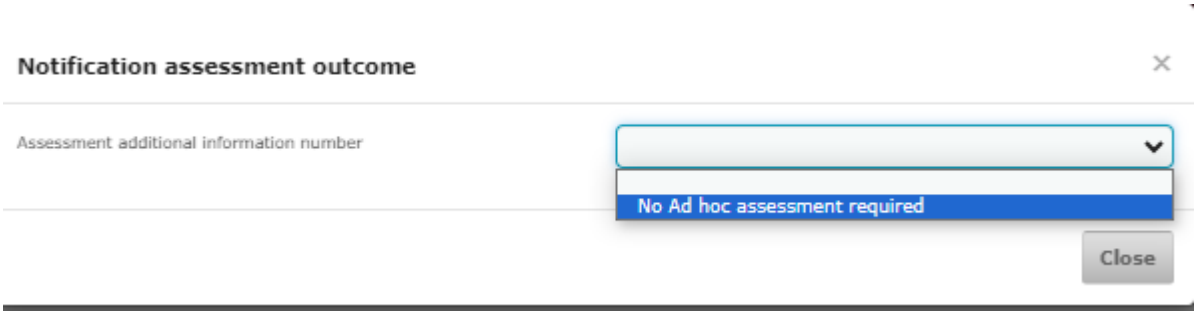
Once MS users are notified of a Notification, they can proceed with its publication. MS users need to open the Notifications subtab, within the trial page.



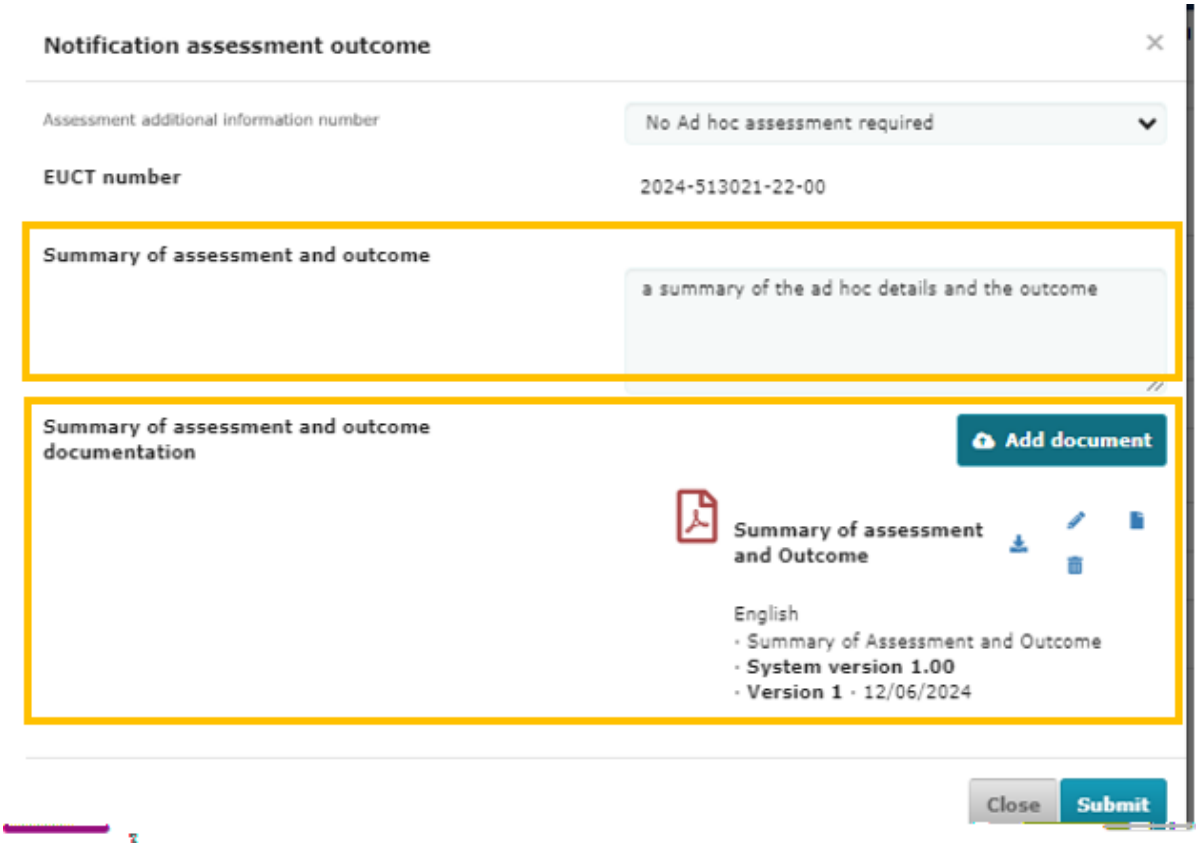
Then they need to use the 'Assessment outcome' button. In the drop-down list of the pop-up window, MS users should indicate if an ad hoc assessment for this Notification has been concluded or if no ad hoc assessment is needed.



Without having linked the ad hoc assessment to the Notification and having concluded it (please see Module 17 of the training material catalogue on how MS users can start and conclude an ad hoc assessment), MS users cannot find the option of the ad hoc assessment on the drop-down list. They will only be able to find the option 'No ad hoc assessment required'.



After the selection, the pop-up window extends, revealing the related EU CT number, a free text field and a document placeholder, which can be used by MS users to add a summary of the assessment and its outcome.



By using the 'Submit' button, MS users publish the Notification details on the public portal.

NOTE: Only the Notification details are published. No information from either the ad hoc assessment or the summary and conclusion will ever be published. Only a message, found at the end of the respective section in the public portal, indicates that the Notification has been assessed by the MS.

The relevant training materials on the publication of Notifications (Module 05 and Module 17) are also being revised to reflect these changes.

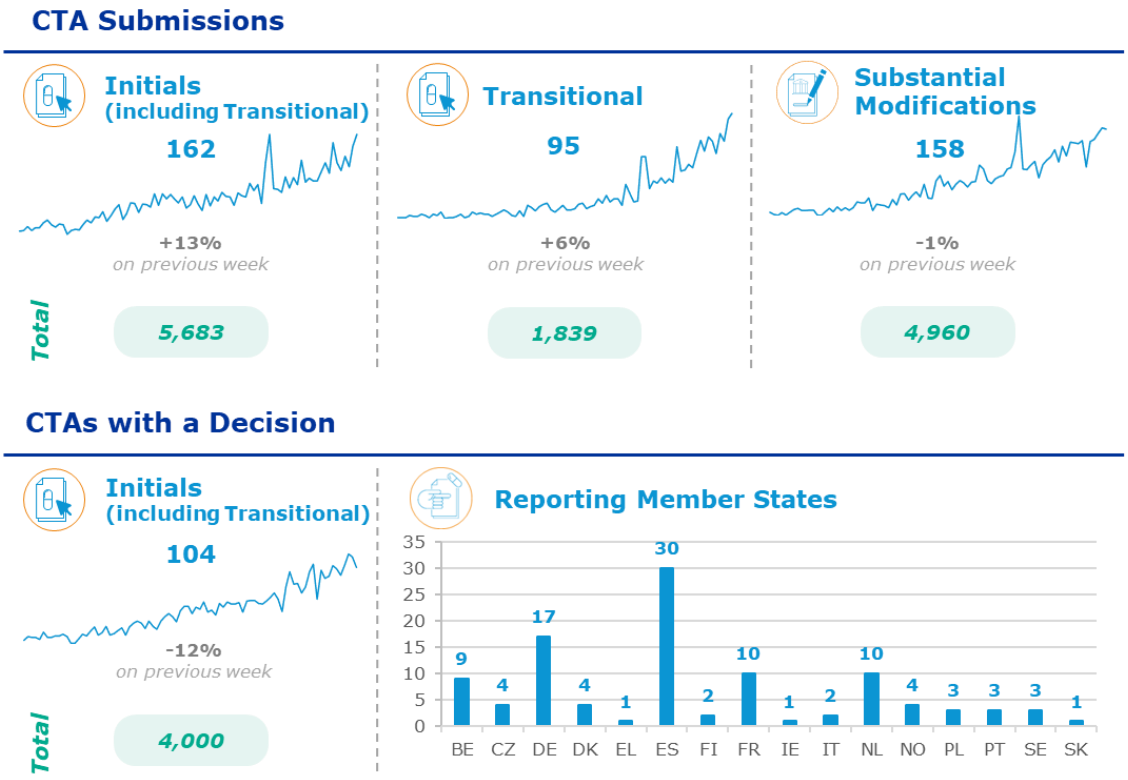
Tips for CTIS users

- When submitting a trial that is being transitioned from EudraCT and the Clinical Trials Directive, users are reminded to select the tick-box for "Transitioning trials" in CTIS. If this tick-box is not selected at the time of creation or drafting of the clinical trial application, the sponsor will have to withdraw and resubmit the application.
- 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.
- After clicking a button in CTIS, e.g. the button 'Change application' under Requests for Information, occasionally the expected page may load a bit slower than normal. If this happens, users are advised to wait for the page to finish loading; a small blue indicator will be visible at the top of the page. Please do not click again until this blue indicator has disappeared.

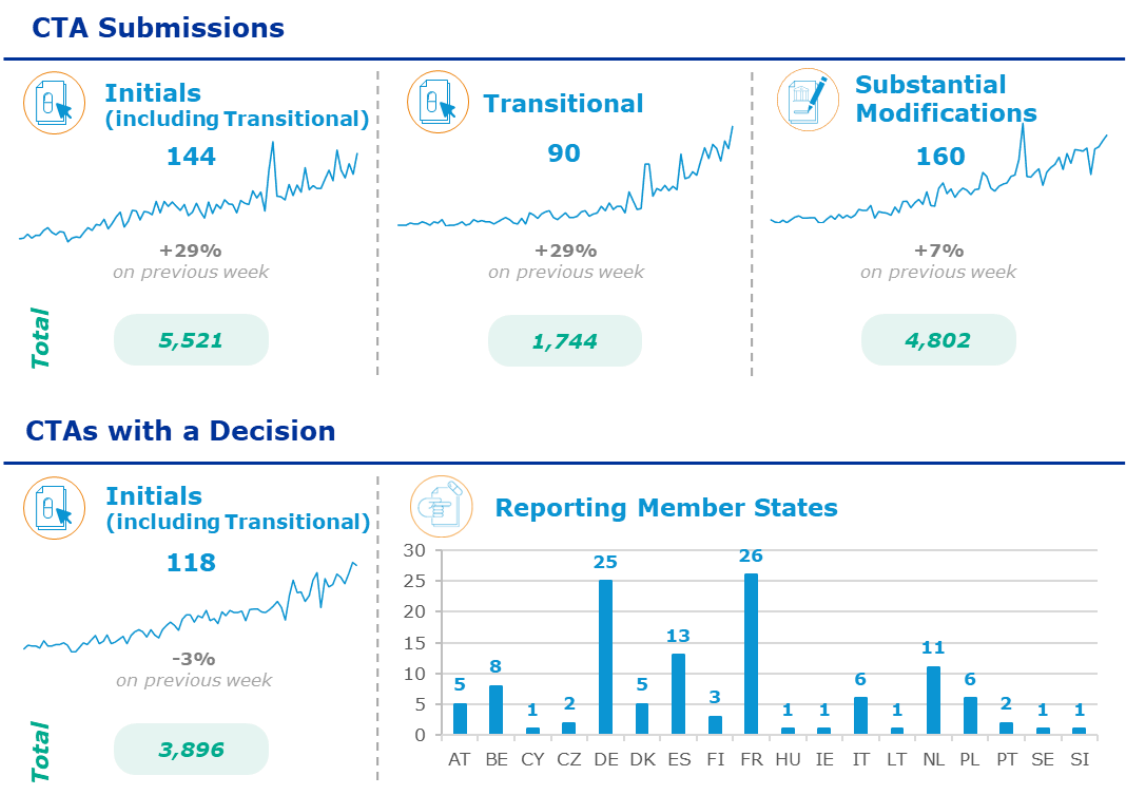
Current operational experience with CTIS

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

The data presented below refer to the period from 4 to 10 June 2024.



The data presented below refer to the period from 28 May to 3 June 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 latest 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.

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.

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