3 December 2024
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European Medicines Agency

CTIS newsflash – 3 December 2024

Introduction

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

Previous issues of the CTIS Newsflash are available on the EMA website. The next issue will be circulated on 17 December 2024.

Reminder: Winter clock stop

All timers within the evaluation of a clinical trial application will stop on 22 December 2024 at 23:59:59 CET and resume on 8 January 2025 at 00:00:01 CET.

Due to this winter clock stop, the timelines for the applications may be affected. More information is available in the CTIS evaluation timelines document.

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

Sponsors are advised to transition any clinical trial 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. This means sponsors should submit trials for transition as soon as possible.

Sponsors can consult CTCG's best practice guide on transition, Annex I: Cover letter template, and the newly published Annex II: Fees for transitional trials in EU/EEA Member States. Further resources to support sponsors' transitioning trials are available on the CTIS website.

Tips for CTIS users

- **System downtime:** The regular maintenance window for CTIS on Thursdays (18:00-21:00 CET) is not planned to be used from 13 to 31 December 2024. Therefore, CTIS can be used as usual during these hours. Please note that the planned maintenance window on Tuesdays (18:00-21:00 CET) may still be used.
- **Known issues:** Updated lists of known issues in CTIS for sponsors and Member State users have been published on the CTIS website: Website outages and system releases.
- **Notices & alerts (submission due):** CTIS automatically generates an alert when a due date to submit the Start of Recruitment or Summary of Results is approaching. These alerts are meant as

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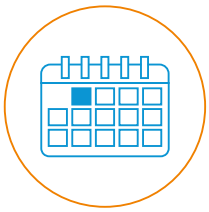
general reminders and are generated irrespective of the current status of the trial lifecycle. As such, an alert for Start of Recruitment due will be generated even if the Start/End of Recruitment date has already been submitted. In such cases, the alert can be ignored providing the Start of Recruitment has been correctly submitted.

- **Opening a ticket:** Before raising a ticket with the CTIS User Support Service (ServiceNow), users are advised to consult the list of frequent reported issues and some useful tips, available on the CTIS website: Tips for users reporting issues to CTIS User Support Service.

Register now: workshop on ICH E6 R3



The EU Network is hosting a workshop on ICH E6 R3 (principles and Annex 1) on 19-20 February 2025, as part of the Accelerating Clinical Trials in the EU (ACT EU) initiative's activities to support the modernisation of good clinical practice.

The workshop aims to provide an overview of major changes in the guideline and engage all relevant stakeholders to discuss the guideline's implementation.

Register here by 10 December 2024 to attend.

CTIS Training Environment: update and data wipe-out in December

Users should note that the CTIS Training Environment will be unavailable on 18 December 2024 due to a system update that will also delete all data recorded in the system until that date.

The training environment is a simulation of CTIS used in production and allows users to get familiar with system functionalities. Sponsors can express their interest in gaining access to the CTIS Training Environment via the survey.

System improvements

The CTIS release on 21 November 2024 introduced several improvements.

For sponsors:

- For trials where a sponsor has received an extension for the "Start of Recruitment" beyond 2 years and 15 days via a Substantial Modification (SM), the trials now remain authorised once the extended due date plus 15 days arrives. Trials only expire if the "Start of Recruitment" document is not submitted within 15 days after the extended due date and if no additional SM requesting a new extension has been authorised.
- For halted trials, sponsors can now submit the "Restart trial" notification when the current date is equal to the "Restart date" in the selected SM application by the relevant Member State Concerned (MSC) plus 15 days.
- For initial clinical trial applications that are partially submitted for all or some of the MSCs, sponsors can now change the application and submit a validation response to a Request for Information (RFI) without receiving an error message due to the Part II not being submitted.
- When the due date for the "Submit Part I conclusion" task has been extended as part of a trial including an advanced therapy medicinal product (ATMP) and the sponsor has replied to a Part I RFI previously submitted on the extended due date of this task, the MS can no longer raise a second Part I RFI on that date.

For Member States:

- When a MS user reverts the MSC evaluation decision, the updated reverted version is now correctly displayed in the "Assessment Overview" section within the Evaluation folder, along with any conditions if applicable.
- When a Reporting Member State (RMS) submits Part I and/or Part II Conclusion tasks as "Acceptable with conditions" or "Acceptable" but the authorise task remains pending, the decision section under the "+" button for the RMS row in the "Assessment Overview" table no longer displays any decision information or assessment conditions.
- When a MS involved in a trial is withdrawn and then re-added through an Additional Member State application, notices and alerts are now correctly generated and displayed for that Member State for all application types.
- After the safety MS (saMS) circulates the draft Annual Safety Report (ASR), if there is no pending RFIs awaiting response from the sponsor on the due date of the "Review ASR" task, the saMS can now complete the "Finalise Assessment" task without facing any error message. The status of the ASR is also correctly displayed in the sponsor workspace as "Finalised".
- MS users who have some roles with a scope of "all trials" and other roles with a "specific trial"-scope can now search and retrieve all clinical trials according to their role scope, without encountering the "Permission Denied" error message.

More information on the latest system improvements is available in the published release notes.