



5 November 2024
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European Medicines Agency

CTIS newsflash – 5 November 2024

Introduction

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

The next issue will be circulated on 19 November 2024.

Previous issues of the CTIS Newsflash are available on the [EMA website](#).

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, which can take up to 3 months. Member States have agreed on an expedited procedure for transitioning trials to the CTR which will be applied whenever possible.

Sponsors can consult CTICG'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](#).

A few more days to share your feedback

As the end of the CTR transition period approaches, we are inviting stakeholders to share their feedback on events, training materials and communications from EMA that aimed to support them in the implementation of the Clinical Trials Regulation. You can share your views via the [survey](#) by 8 November 2024.

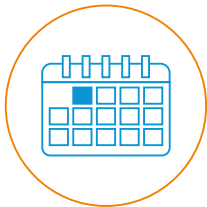
Advice for CTIS users

- **System downtime:** In case of downtime outside of the [regular maintenance windows](#), users can consult [EMA's User support Service](#) landing page for further information. This is also indicated on the page [Website outages and system releases](#) of the CTIS website, under the section "Unplanned system interruptions".
- **Notices & Alerts:** 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.



- **Timetable:** During the assessment of a clinical trial application, a timetable is available to help sponsors plan their work in CTIS. Users are advised that this timetable is intended as a visual support tool and should always be consulted in parallel with the actual due dates - compliant with the Clinical Trials Regulation - as recorded in the individual tasks and RFIs. In case of occasional discrepancies in the timetable information, this does not impact the workflow and the actual due dates of tasks and RFIs.

Save the date: upcoming events



Registration is now open for EMA's webinar on the next step in the resumption of Clinical Data Publication (Policy 0070). Under this policy, EMA publishes clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure. Policy 0070 is independent of the CTIS transparency rules and has a different scope. At the webinar on 14 November 2024, EMA will present its plans and answer questions on the proposed extension of activities related to Policy 0070, the handling of legacy procedures and on the updated guidance for applicants preparing submissions. Participants can register on [Webex](#) until 14 November 2024. For more information visit the [Clinical Data Publication](#) section on the EMA website.

EMA is hosting a [CTIS walk-in clinic on 20 November 2024](#), where sponsors can raise questions about any CTIS functionality and receive advice from CTIS experts. CTIS users can submit and upvote questions in advance via [Slido](#) until 13 November 2024 at 12:00, with the code #clinic248.

For more information on previous training sessions, including supporting materials, see: [Clinical Trials Information System: training and support \(EMA website\)](#).



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.

Users should note that the CTIS Training Environment will be unavailable on 18 December 2024.

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](#).