19 November 2024
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European Medicines Agency

CTIS newsflash – 19 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 3 December 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. Members States have agreed on an expedited procedure for transitioning trials to the CTR which will be applied whenever 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.

CTIS Vendor Transition in Q4 2024

Following a competitive procurement procedure, we are entering an important transition phase to a new provider in Q4 2024. This phase is designed to streamline the knowledge and documentation transfer to a new provider, setting the stage for the simplification and modernisation of CTIS.

During this period, the primary focus will be on enhancing security and quality code monitoring activities, conducting a thorough CTIS Simplification analysis, and performing essential system stabilisation tasks as needed. Although no new features are planned for this quarter, this strategic pause will ensure a smooth handover and pave the way for future improvements.

We are excited about this transition and confident that it will lead to a more efficient and modern CTIS.

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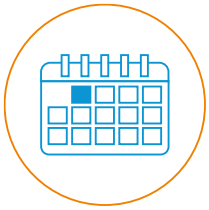
Winter clock stop

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.

Save the date: CTIS walk-in clinic



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.

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 due to a system update that will also delete all data recorded in the system until that date.

Advice for CTIS users

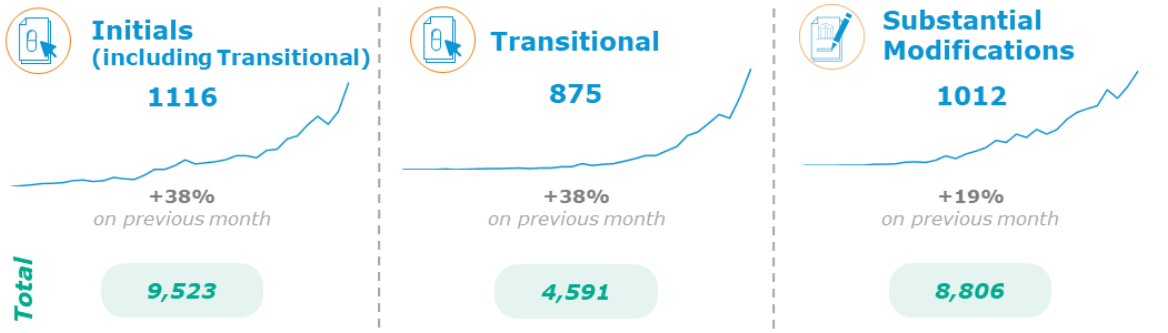
- **System downtime:** In case of downtime outside of the regular maintenance windows, users can consult EMA's User support Service landing page for further information. This is also indicated on the page Website outages and system releases of the CTIS website, under the section "Unplanned system interruptions".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

Current operational experience with CTIS

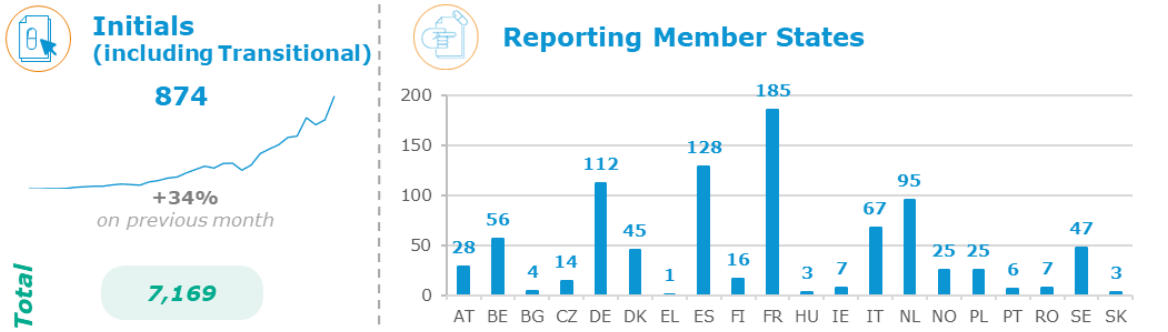
This section on CTIS metrics provides key data and trends.

The data presented below refer to the period from 1 to 31 October 2024.

CTA Submissions



CTAs with a Decision



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.