14 January 2025
EMA/582910/2024
European Medicines Agency

CTIS newsflash – 14 January 2025

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.

Due to the holiday break, the next issue will be circulated on 28 January 2025.

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 submit any remaining trials for transition as soon as possible.

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

For academia & SMEs: share your clinical trial training needs

The Accelerating Clinical Trials in the EU (ACT EU) initiative aims to deliver a clinical trials training curriculum for different stakeholder groups.

As part of this work, we invite stakeholders from academia or micro, small and medium-sized enterprises (SMEs) involved in the development of medicines to fill in a brief survey with their clinical trial training needs. The survey will be open until 11 February 2025.

The identified training needs will then be matched with available trainings and potential gaps, an overview of which will be published later in 2025.

Recent publications

- The Clinical Trials Coordination Group (CTCG) has published a document on 'Fees for clinical trials submitted under CTR', which provides an overview of fee structures across EEA Member States. The document is available on the CTCG website under the section ' Key documents list'.
- An updated version of the FAQ document on Module 10 of the CTIS Training Programme ("How to create, submit and withdraw a CTA") has been published on the EMA website.

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- The December report "Monitoring the European clinical trials environment" has now been published. All previous issues are available on the ACT EU website.

Thank you for your feedback: survey on EMA support in CTR implementation

More than 55 stakeholders provided valuable feedback on EMA's events, training materials and communications aimed at supporting CTIS users in implementing the Clinical Trials Regulation. Respondents indicated an overall high level of satisfaction while also highlighting areas for further improvement. This input, along with feedback received via other established channels, will be taken into account in the planning of EMA's activities in 2025 and beyond.

Upcoming CTIS event

EMA is hosting a CTIS walk-in clinic on 29 January 2025, 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 22 January 2025 at 12:00, with the code #clinic249.

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

Tip for sponsors: Submitting an SM created before an End of Trial notification

If a Substantial Modification (SM) is created and submitted after an End of Trial notification has been submitted for a particular Member State, that Member State will not be included in the assessment of the SM.

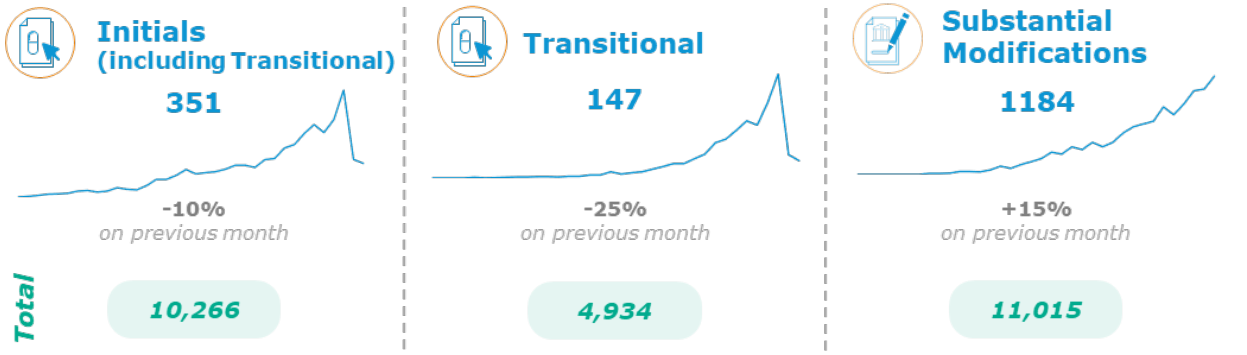
If the SM is created before the End of Trial Notification but submitted after, that Member State will still be included in the SM application. In such cases, it is advised to cancel the draft SM before submitting and create a new SM. This will ensure that the Member State where the trial has ended will not be included in the SM application.

Current operational experience with CTIS

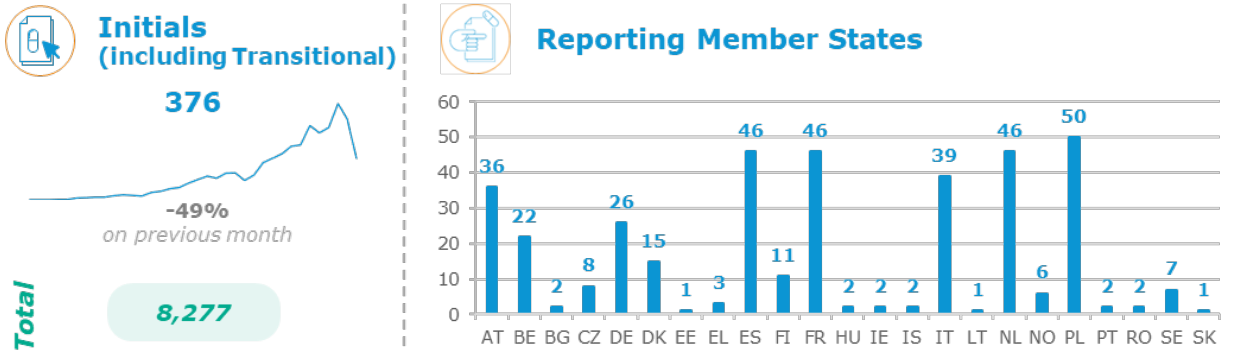
This section on CTIS metrics provides key data and trends.

The data presented below refer to the period from 1 to 31 December 2024. Please note that the data below takes in consideration the Winter Clock stop.

CTA Submissions



CTAs with a Decision



Reminder for sponsors: CTIS timetable

After the submission of an application, CTIS estimates the maximum due dates of tasks related to the validation and assessment by the Member States and of specific sponsor actions (i.e. RFI response) based on the Clinical Trials Regulation. These estimated timelines are illustrated in graph form in the **timetable** feature in CTIS. The document '[CTIS evaluation timelines]' explains in detail how the timelines are calculated and under which circumstances they can be shortened. You can also refer to the [CTIS newsflash of 17 December 2024] for an overview of how the timetable works.