13 October 2023
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European Medicines Agency

CTIS newsflash – 13 October 2023

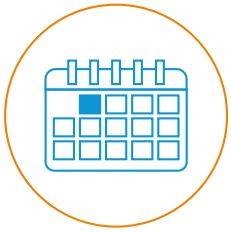
Introduction

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

The next issue will be circulated on 27 October 2023.

Key updates

- During its October meeting, the Management Board adopted **revised transparency rules** for publication of information on clinical trials submitted in the system, following a public consultation earlier this year. More details about the revised transparency rules can be found in the news announcement published on EMA's website.
- The monthly KPI reports on the implementation of the CTR, as well as the final guidance document, annexes and Q&A on the protection of personal data and commercially confidential information in CTIS can now be found on the ACT EU website, under the webpage Implementation of the Clinical Trials Regulation.



Upcoming CTIS events

Interested participants can register for the virtual CTIS Info day planned on 17 October at 13:30-17:30 CEST. The virtual event aims to support sponsors of clinical trials in preparing and proceeding with the transition to meet the deadline of 30 January 2025.

On 15 November 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CET. Participants are able to submit their questions in advance starting 1 November via Slido with the code #clinic2311.

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

Current operational experience with CTIS

This section on weekly CTIS metrics provides key data and trends compared to the previous week.

The data presented below refer to the period from 26 September to 2 October 2023.

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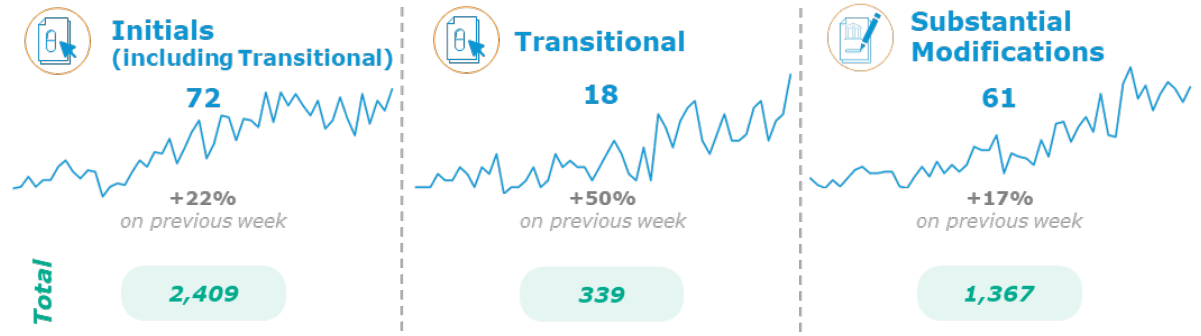
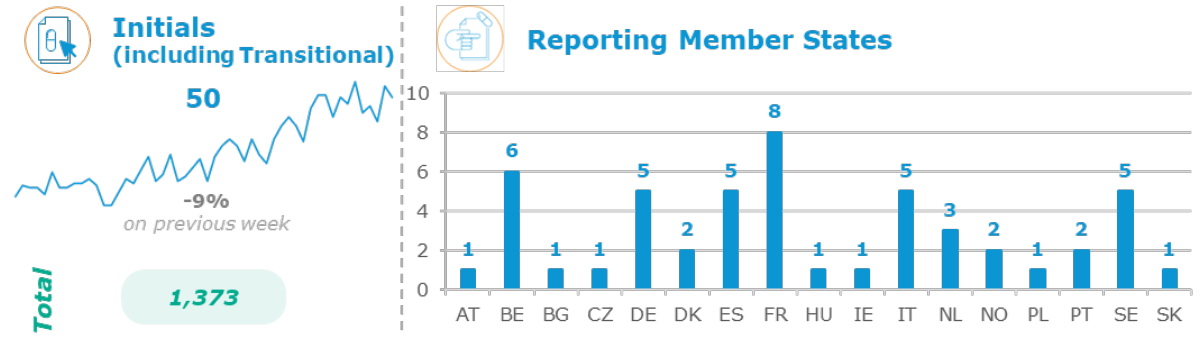
CTA Submissions



CTAs with a Decision



The data presented below refers to the period from 3 to 9 October 2023.

CTA Submissions

CTAs with a Decision

System improvements

More 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.

EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

The dashboard below summarises the main improvement areas of focus for 2023 and the improvements implemented.

Reminder: Access to 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. Due to limited capacity, access to eligible users is provided for a limited period of time. In addition, access is prioritised for users/organisations with no previous access in the system.

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 new 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.