24 November 2023
EMA/513626/2023
European Medicines Agency

CTIS newsflash – 24 November 2023

Introduction

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

The next issue will be circulated on 8 December 2023.

Previous issues of the CTIS Newsflash are available on the EMA website.

Winter clock stop

All timers within the evaluation of a clinical trial application will stop on 22 December 2023 at 23:59:59 CET and resume on 8 January 2024 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.

Tip for CTIS users

In case of unexpected downtime or issues with the system, users are advised to check the landing page of the CTIS User Support Service for announcements or details.

Key updates

- Member State competent authorities for clinical trials and medical devices and the European Commission have published information on the "COMBINE" project, which addresses the challenges at the interface between the regulations on clinical trials of medicinal products, medical devices and in vitro diagnostics.
- The latest KPI report with data from October 2023 on the implementation of the Clinical Trials Regulation has been published on the ACT EU website.

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Save the date: CTIS Bitesize talk on 29 November 2023

The last CTIS Bitesize talk of the year will take place on 29 November 2023, at 15:30 – 17:00 CET. The focus of this session will be on training materials, CTIS pre-requisites and an update on the transparency rules. Participants submitted their questions in advance up to 21 November via Slido with the code #bt29nov.

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

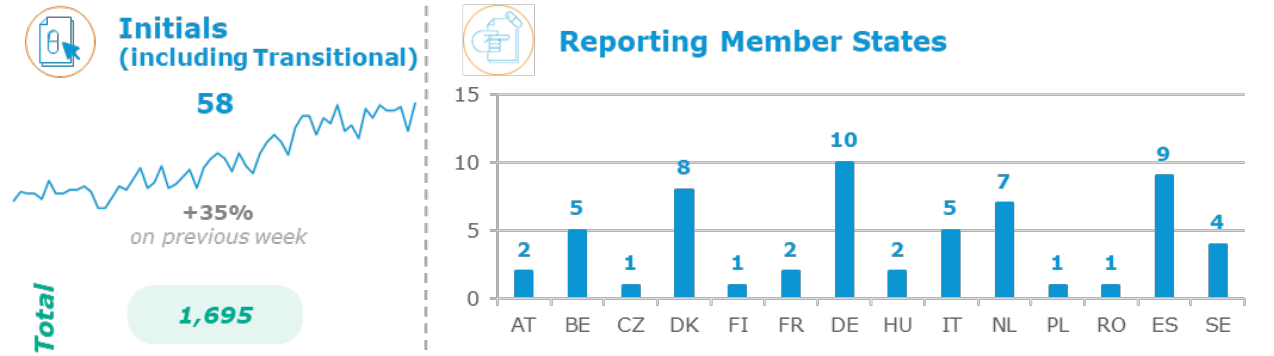
Current operational experience with CTIS

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 7 to 13 November 2023.

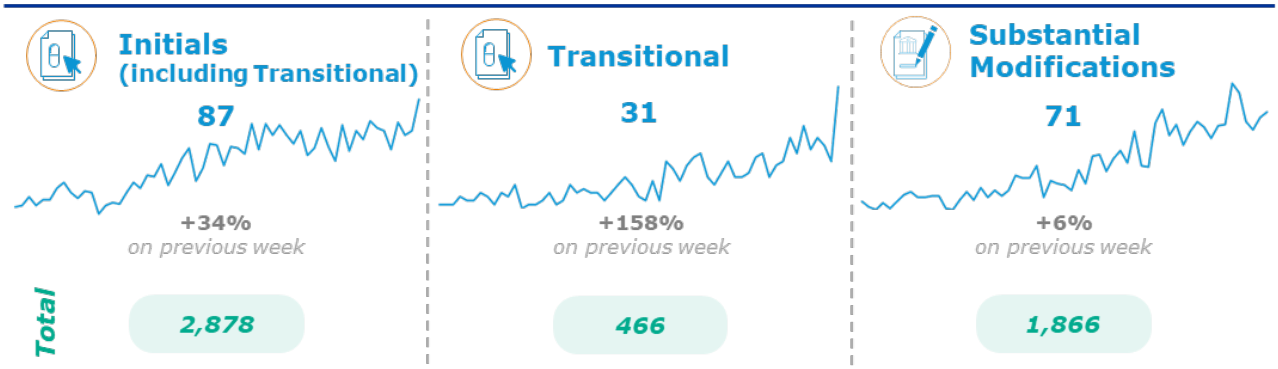
CTA Submissions

CTAs with a Decision

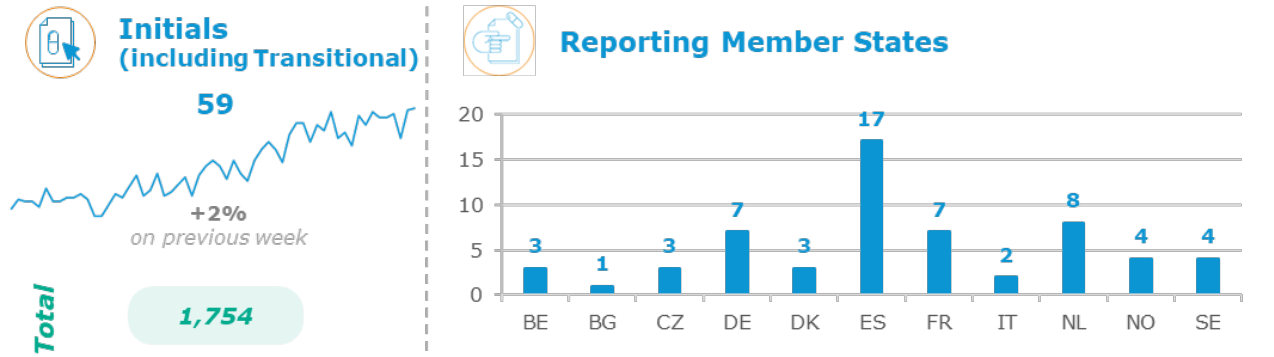


The data presented below refers to the period from 14 to 20 November 2023.

CTA Submissions



CTAs with a Decision

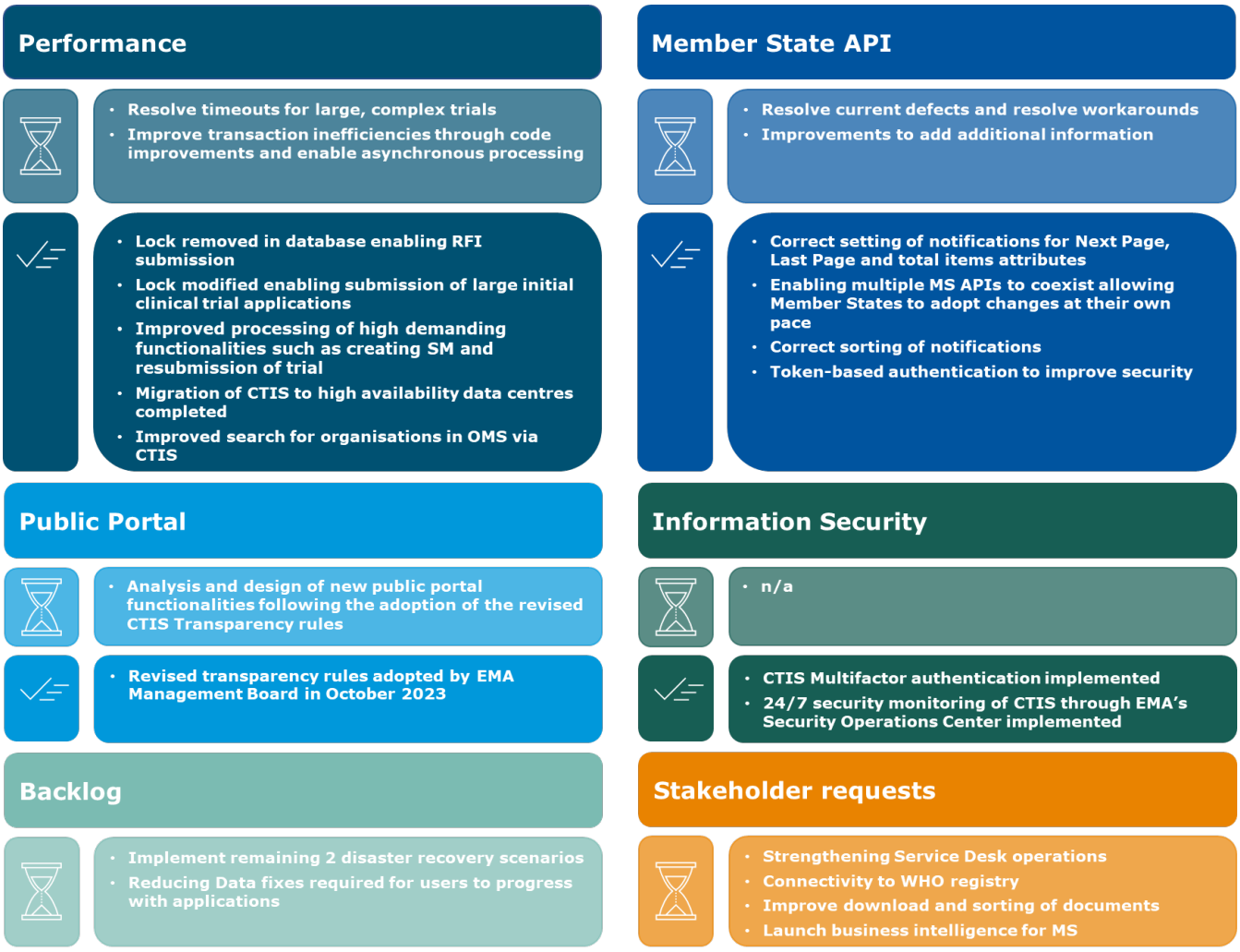


System improvements

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.

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.



Reminders

- 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.
- 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.

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.