14 April 2023
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European Medicines Agency

CTIS newsflash – 14 April 2023

Introduction

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

Key updates

The revised CTIS Sponsor Handbook has been published on the EMA website. New content includes a section on the multi-factor authentication in CTIS, links to the latest CTIS Bitesize Talks, recent Q&A documents and an updated glossary. A more detailed description of the recent changes can be found in the 'Document evolution' section of the Sponsor Handbook.

Current operational experience with CTIS

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

This issue exceptionally includes metrics from the last two weeks, capturing the operation of CTIS before and during the Easter break. As expected, there was a slight decrease in numbers which is attributed to the holiday period.

The data presented below refers to the period from 28 March to 3 April 2023.

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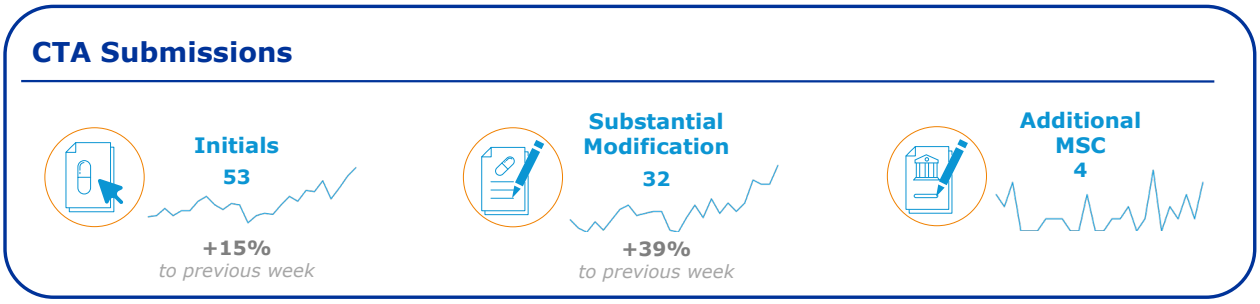
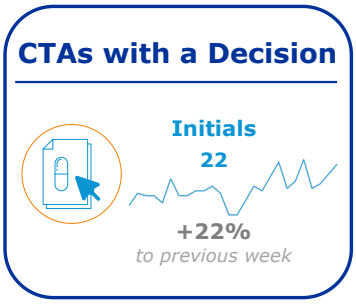
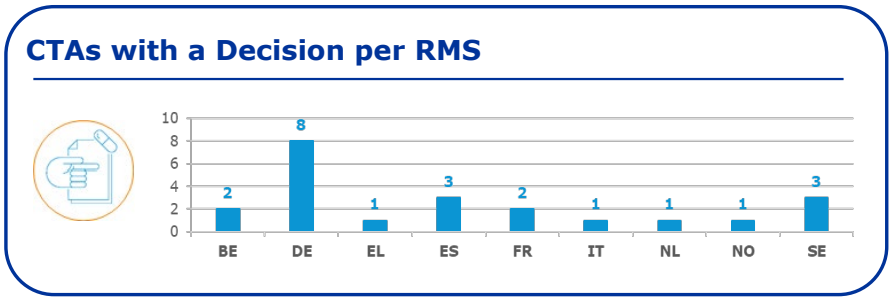
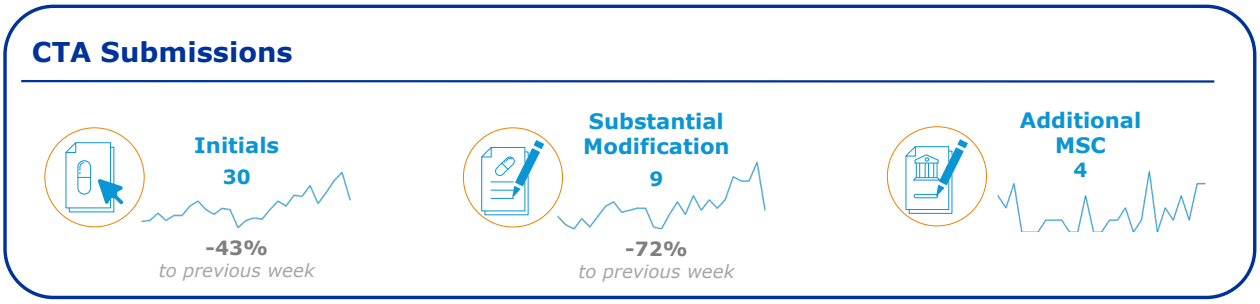
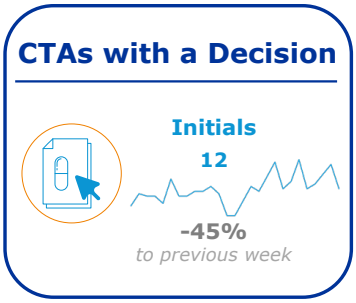


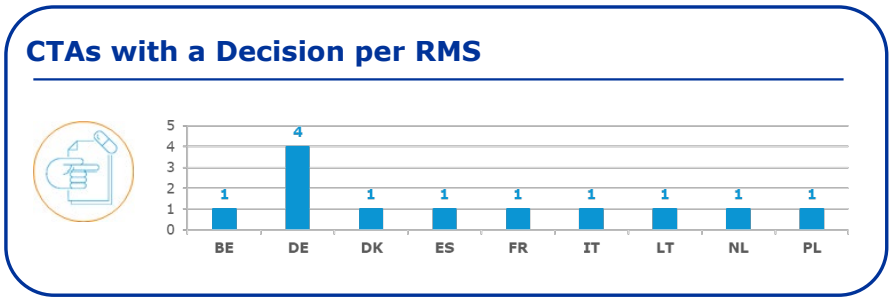




In addition, the data presented below refers to the period from 4 April to 11 April 2023.



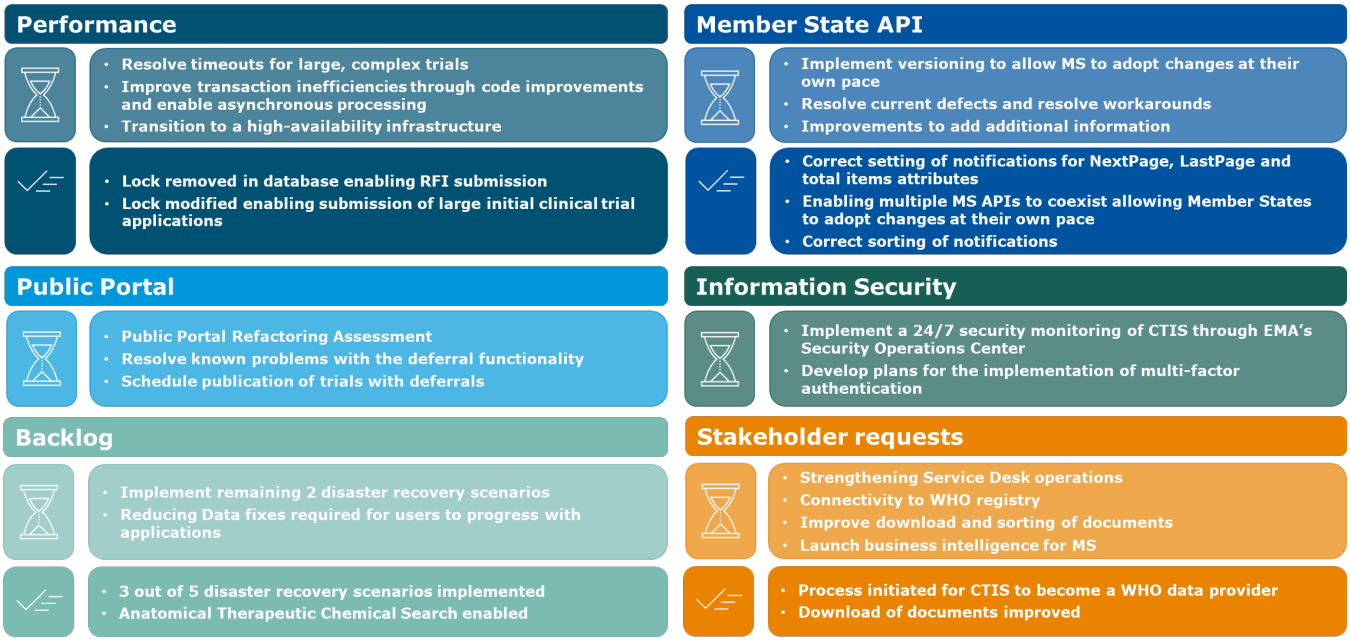




System improvements

With the aim to improve the performance of the system, a release on 11 April 2023 implemented temporary changes to the CTIS loading page, replacing the full-page loading spinner with a loading bar at the top of the webpage.

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 improvements implemented.



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.

Save the date: CTIS Walk-in Clinic 19 April 2023

On 19 April 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CEST. Participants are able to submit their questions in advance or during the event via Slido with the event code #clinic234. For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support.

Reminders

- The time zone used in CTIS is Central European Time (CET). All due dates and deadlines are displayed in CET despite the change to daylight-savings time in Europe since 26 March 2023. Planned maintenance windows for CTIS, published here, refer to Amsterdam time (Central European Summer Time - CEST).
- Multi-factor (MFA) authentication for user logins to CTIS, for both Sponsor and Member State workspaces, will be launched on 1 June 2023. Instructions on setting up the MFA for EMA systems are available here.
- 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.

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.