28 April 2023
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European Medicines Agency

CTIS newsflash – 28 April 2023

Introduction

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

Key updates

- The EMA Account Management portal will be unavailable Saturday 29 April 2023 due to essential maintenance. During this period users will not be able to self-register, request and remove access, or approve access to EMA applications. Users will be able to login to other EMA applications. For any questions or concerns, please raise a ticket via the EMA Service Desk.
- During the upcoming May holidays, the CTIS User Support Service will be providing service limited to critical or blocking issues: 9 May, 18 May, 19 May, 29 May.
- A public consultation on the CTIS transparency rules is foreseen to be launched in May 2023 on the EMA website. The review of existing rules aims at simplification to improve user experience while also reducing the risk of data breaches and maintaining high levels of transparency.
- The 14th issue of the Clinical Trials Highlights has been published on the EMA website and provides an overview of milestones, developments and events related to CTIS and the ACT EU initiative. The newsletter is moving to a new user-friendly platform. Resubscribe here to receive future issues.

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 refers to the period from 18 April to 24 April 2023.

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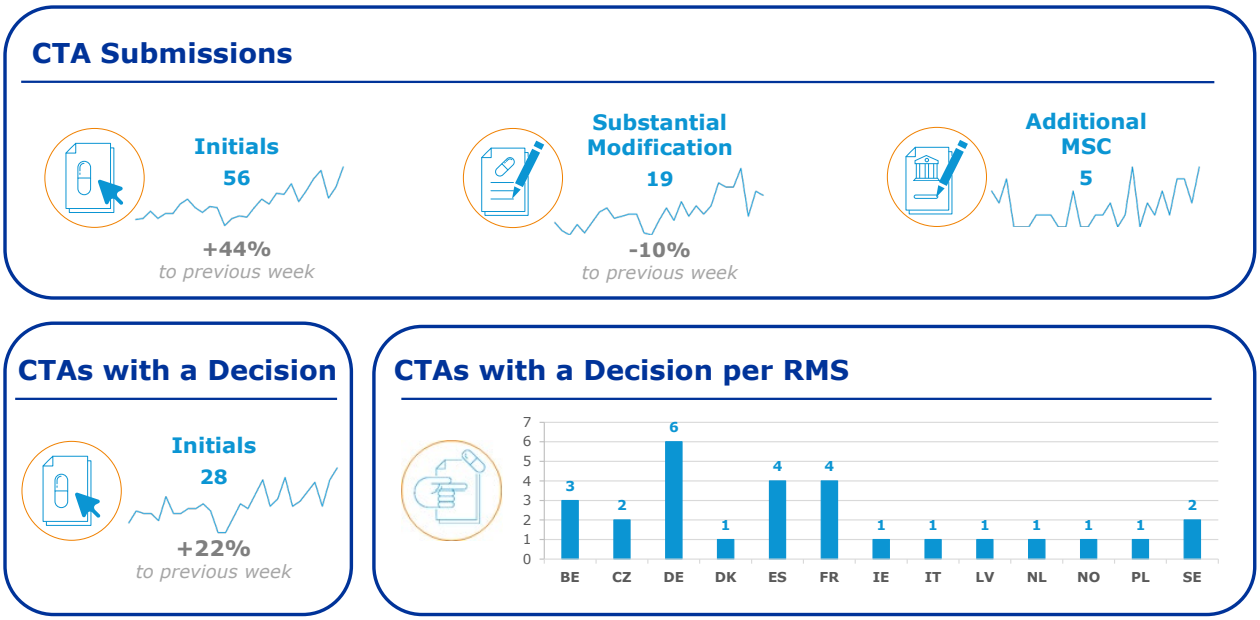
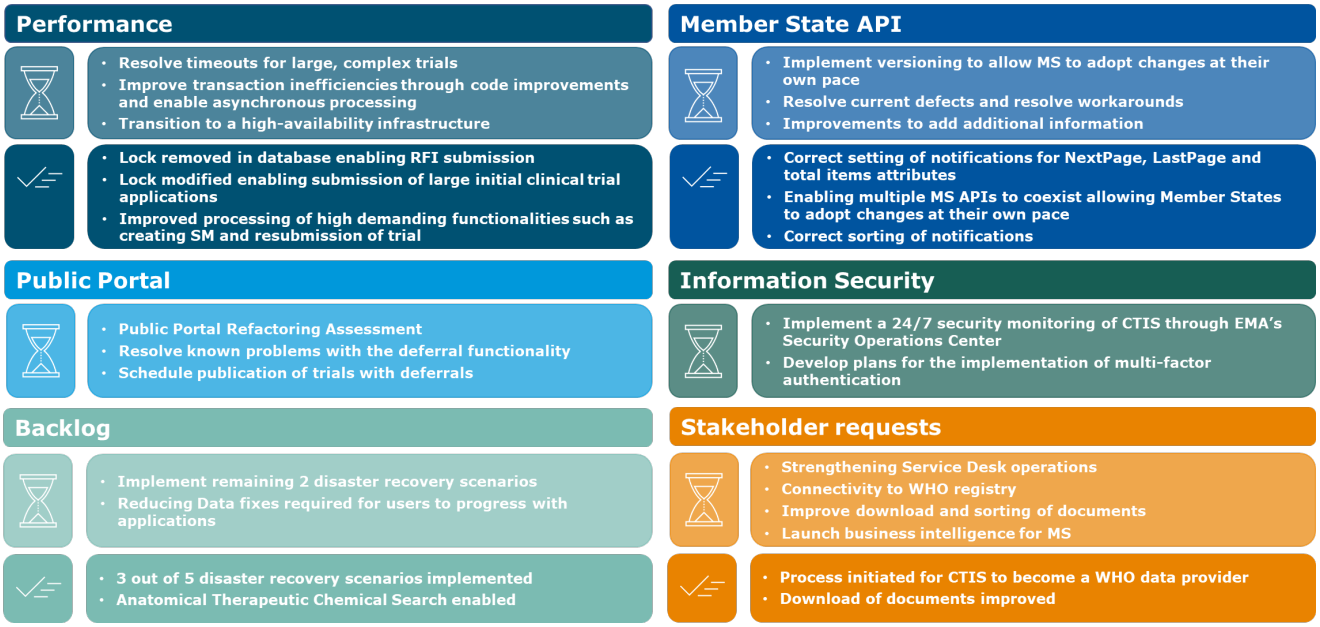


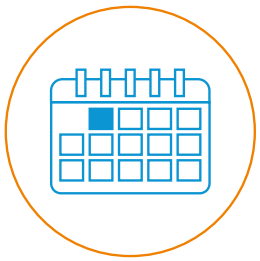
System improvements

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 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 Bitesize talk 10 May 2023 – IMPD-Q only submission

On 10 May 2023 EMA is hosting a CTIS Bitesize talk at 15:30-17:00 CEST. The talk will focus on part I-only submission of the investigational medicinal product dossier on quality (IMPD-Q), and related scenarios. Participants will be able to submit their questions in advance until 4 May or during the event via Slido with the event code #bt10may.

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

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.
- EMA has published a document with all official EU/EEA Member State public holidays for the year 2023 as recorded in CTIS.
- Since 24 April 2023, the regular **maintenance windows** in CTIS have been amended with the aim to limit downtime due to planned system interruptions. Users are advised to avoid using CTIS during the following times:
  - Tuesdays and Thursdays, from 18:00 to 21:00 Amsterdam time
  - Each first Saturday of the month, from 10:00 to 14:00 Amsterdam time

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.