21 April 2023
EMA/171343/2023
European Medicines Agency

CTIS newsflash – 21 April 2023

Introduction

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

Key Updates

- EMA has published a document with all official EU/EEA Member State public holidays for the year 2023 as recorded in CTIS. The document is available under the section "Reference materials for clinical trials sponsors" of the EMA website.
- Starting 24 April 2023, the regular **maintenance windows** in CTIS will be 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

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 11 April to 17 April 2023. It should be noted that due to Easter, the previous week (comparator week) was shorter, likely explaining the important increases seen.

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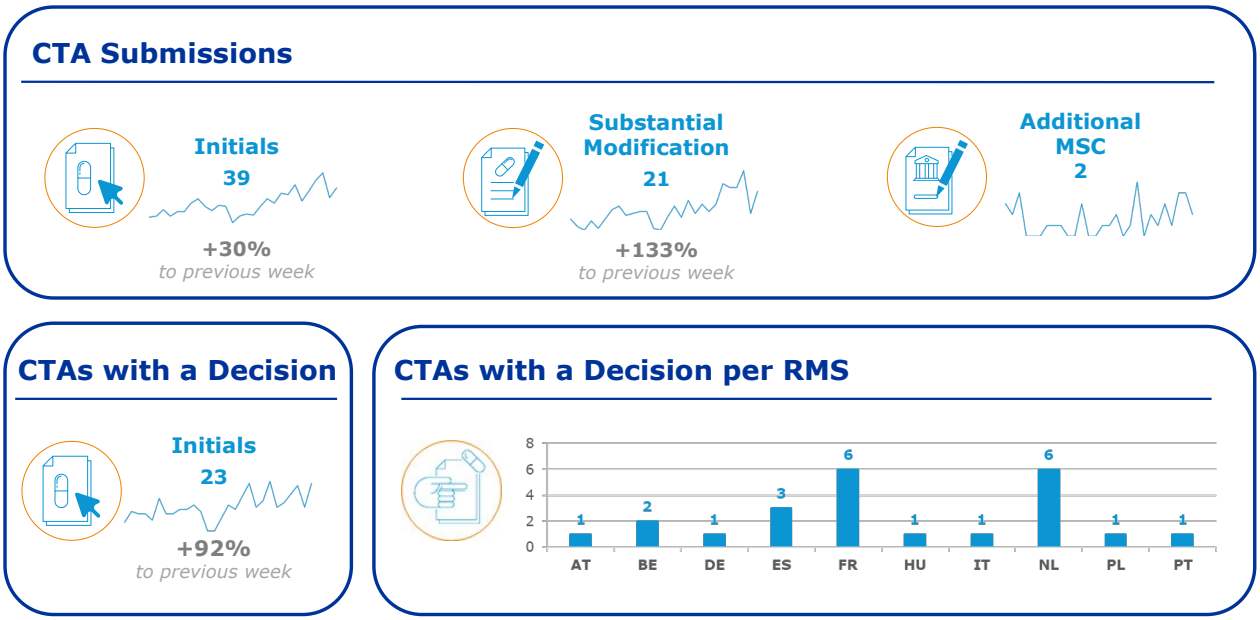
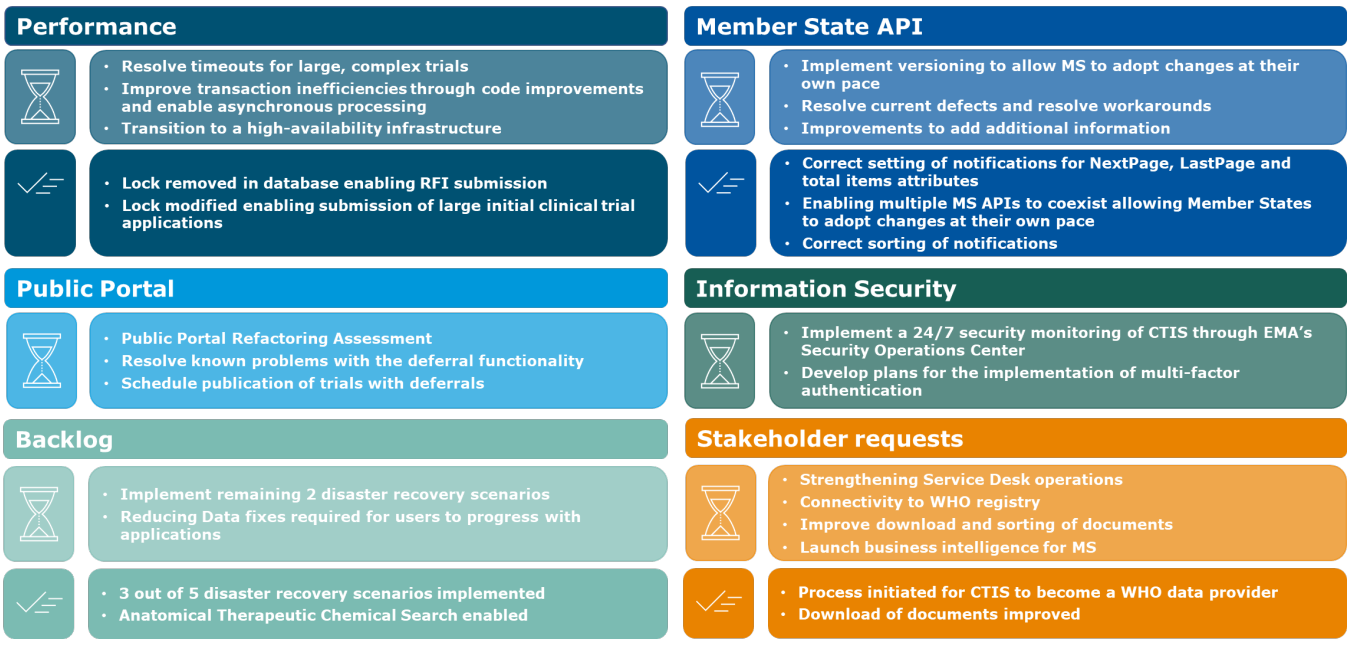


Some users have been experiencing issues with system performance. EMA is investigating the issue to identify a solution and providing ad hoc support to affected users.

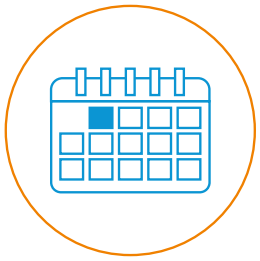
System improvements

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 (starting 26 April) 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.

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.

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.