24 March 2023
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European Medicines Agency

CTIS newsflash – 24 March 2023

Introduction

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

A status update highlighting the start of CTIS mandatory use is available on the CTIS website.

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 14 to 20 March 2023.

CTA Submissions

Initials
36

+33%
to previous week

Substantial Modification
23

-8%
to previous week

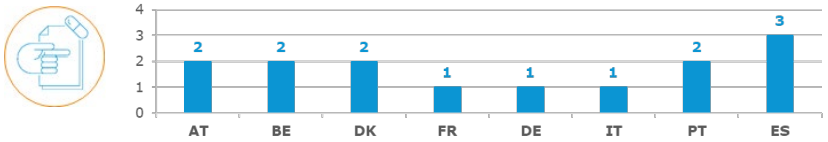
Additional MSC
3


CTAs with a Decision

Initials
14

+17%
to previous week

CTAs with a Decision per RMS



System improvements

The CTIS release deployed on 23 March 2023 implemented several improvements to enhance user experience:

- When a sponsor user removes a product and saves the application, the change is reflected in the section "all documents".

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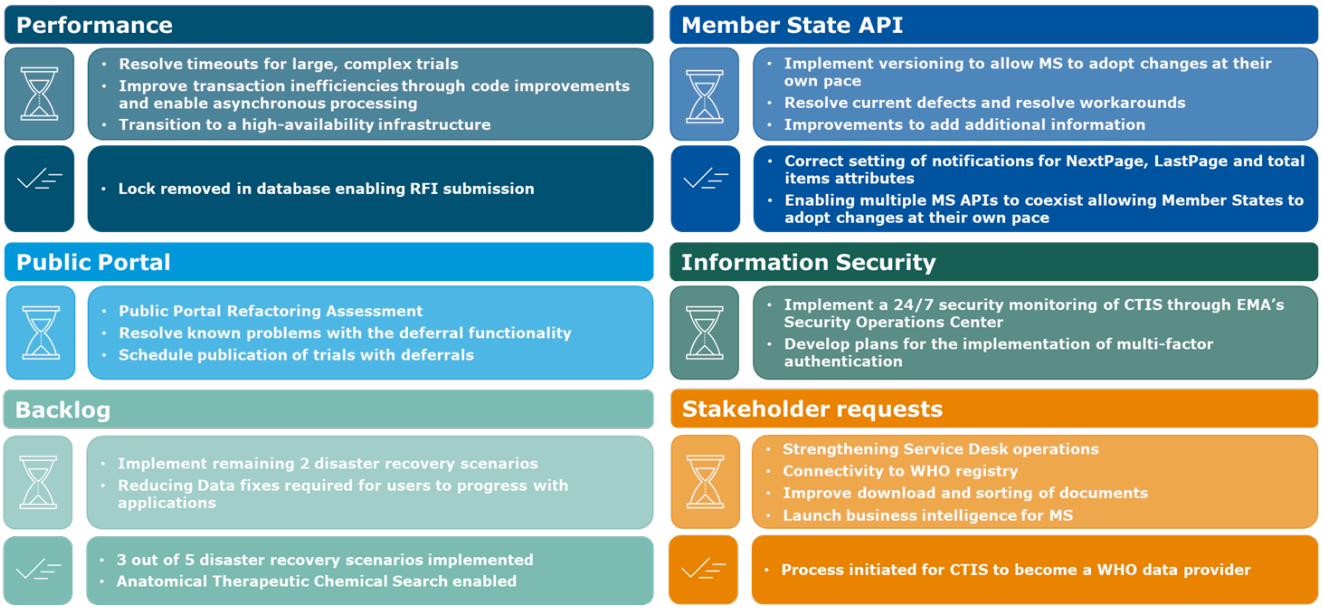
- The due date of the "Submit validation decision" task is now correctly displayed for all Substantial Modification application types in the Validation phase.
- Completion of the "Submit Part II Conclusion" task is now enabled for a Member State Concerned (MSC) that was re-added via an Additional MSC application and did not previously authorise the trial.
- In Additional MSC applications, the "Authorise" task is now extended when a Request for Information has been issued for Part I after completion of the "Submit part II conclusion" task.
- Member State validator and assessor preparer roles with quality restricted rights are now able to create, edit and delete quality "Part I considerations" that are not related to IMPDQ (Investigational Medicinal Product Dossier - Quality).

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.

The work continues in close 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.



Reminders

- The time zone used in CTIS is Central European Time (CET). All due dates and deadlines are displayed in CET despite the daylight-saving time change taking place in Europe on 26 March 2023.
- 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.