12 May 2023
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European Medicines Agency

CTIS newsflash – 12 May 2023

Introduction

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

Due to the holidays on 18 and 19 May 2023, the next CTIS Newsflash will be circulated on Friday 26 May 2023.

Clinical Trials Highlights Newsletter: Resubscribe here to receive future issues

The Clinical Trials Highlights Newsletter is moving to a new platform, Newsroom, used by European institutions and agencies to create and disseminate information online. Newsroom is a user-friendly tool that will allow more efficient subscriber management. The next issue of the Newsletter, due in July 2023, will only be sent via email to readers who signed up and agreed to the data privacy policy here.

Key updates

- A very small number of CTIS users have experienced difficulties when trying to create substantial modifications to very large multinational clinical trial applications, which include several hundreds of documents. EMA is aware of this and is working intensively to minimise the impact on sponsors.
- Due to the planned migration of EMA applications to high availability data centres, users are advised that both the secure workspaces and public search portal of the CTIS website will be unavailable on:
  - Saturday 13 May 2023 from 08.00 to 10.00 CEST, due to the migration of the EMA Account Management Portal (IAM).
  - Saturday 10 June 2023 from 08.00 to 16.00 CEST, due to the planned migration of CTIS.
- Over 700 viewers followed the CTIS Bitesize Talk on IMPD-Q-only submission, hosted by EMA on 10 May 2023. A recording of the event will be made available on the webpage in due course.

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 2 to 8 May 2023.

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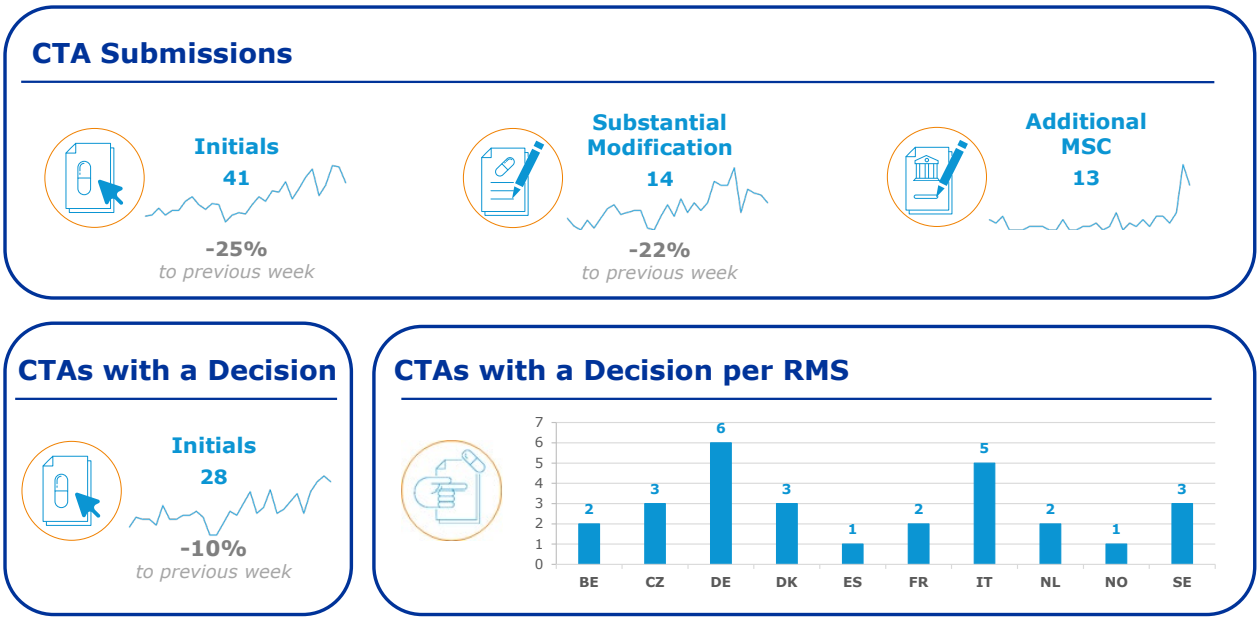


System improvements

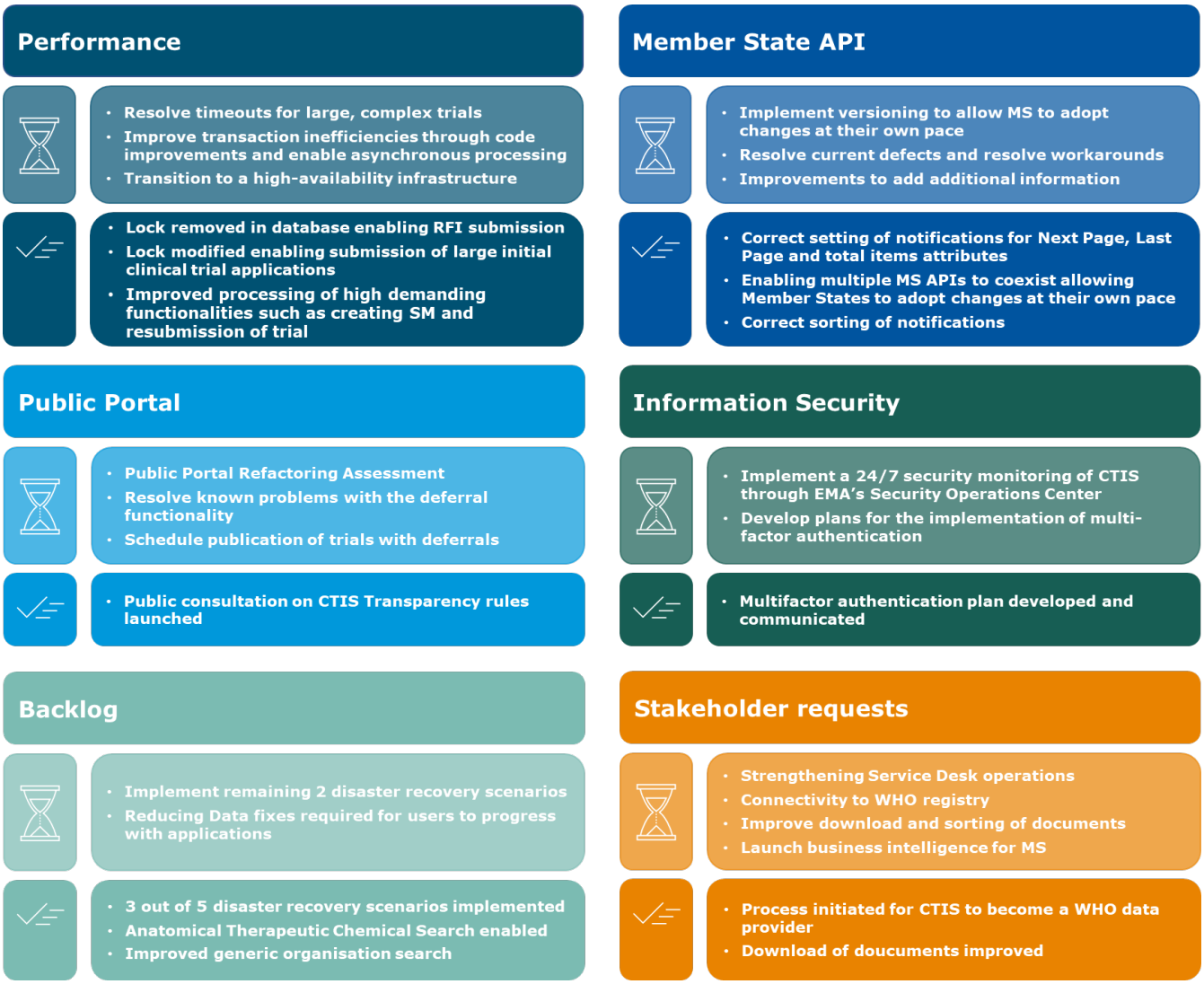
The CTIS release deployed on 11 May 2023 implemented several improvements to enhance user experience:

- In the Evaluation Assessment overview, documents uploaded by authority users per application type (except Substantial Modification Part I only) in the authorise task are now correctly displayed in both sponsor and authority workspaces.
- In Annual Safety Reports, the system now displays 15 items per page in considerations and consolidated considerations.
- Users are now able to create a SM application, Non-Substantial Modification or copy clinical trial application (CTA), following a previously authorised SM application containing documents for publication and not for publication under the Form section.
- The values of age range secondary identifiers are now retained after users save the draft CTA in the system, and are correctly displayed when users download the structured data PDF document.
- When users create/submit a new organisation locally in CTIS, they no longer receive an email confirmation.
- Notices and alerts are now correctly displayed for the roles of EMA admin, European Commission admin, Union controller preparer and Union controller submitter.

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.

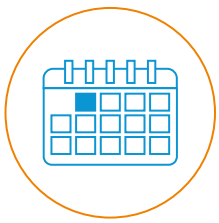
EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

The dashboard below summarises the main improvement areas of focus for 2023 and improvements implemented.



Multi-factor authentication in CTIS from 1 June 2023

Multi-factor (MFA) authentication for user logins to CTIS, for both Sponsor and Member State workspaces, will be launched on 1 June 2023. In preparation for the introduction of MFA, it is recommended that each user is equipped with a mobile or an office phone that can be used for second factor authentication. Further instructions on setting up the MFA for EMA systems are available here.



Save the date: CTIS Walk-in Clinic 17 May 2023

On 17 May 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 #clinic235. These walk-in clinics are a series of short, regular events offering CTIS sponsor users the opportunity to consult the Agency's CTIS experts and ask questions about CTIS functionalities in a live forum.

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

Reminders

- During the upcoming May holidays, the CTIS User Support Service will be providing service limited to critical or blocking issues: 18 May, 19 May, 29 May.
- A public consultation on the CTIS transparency rules has been launched on the EMA website. The review aims at simplification to improve user experience while also reducing the risk of data breaches and maintaining high levels of transparency. Stakeholders are invited to provide their comments by 28 June 2023.
- In addition, to the public consultation, an interim guidance document (and its annex) on the current transparency rules have also been published. The interim guidance document and the annex are intended for CTIS users and have been revised following the public consultation in 2022.
- 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.