10 March 2023
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European Medicines Agency

CTIS newsflash – 10 March 2023

Introduction

With the aim to enhance communication with the CTIS user community, 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.

Launch date: Multi-factor authentication in CTIS

A multi-factor (MFA) authentication strategy for user logins to CTIS, for both Sponsor and Member State workspaces, will be launched on 1 June 2023. This strategy will effectively reinforce the security of user accounts. With MFA, users are asked to enter a second factor (besides username and password) when logging into an IT system to verify their identity. This second factor can be:

- A token received in Microsoft Authenticator mobile app, or
- An automated phone call or a text to mobile phone, or
- A call to office phone.

Users may choose their preferred second factor method and amend their choice at any time. 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. Users can already log into the EMA ServiceNow portal to set up their MFA for EMA systems, which will work also for CTIS once deployed and activated.

The MFA for the Member State API will be rolled out at a later date and Member State users will be informed in advance.

Current operational experience with CTIS

With the aim to enhance transparency on system use, 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 28 February to 6 March 2023.

Over 320 clinical trials authorised under the CTR are now available in CTIS.

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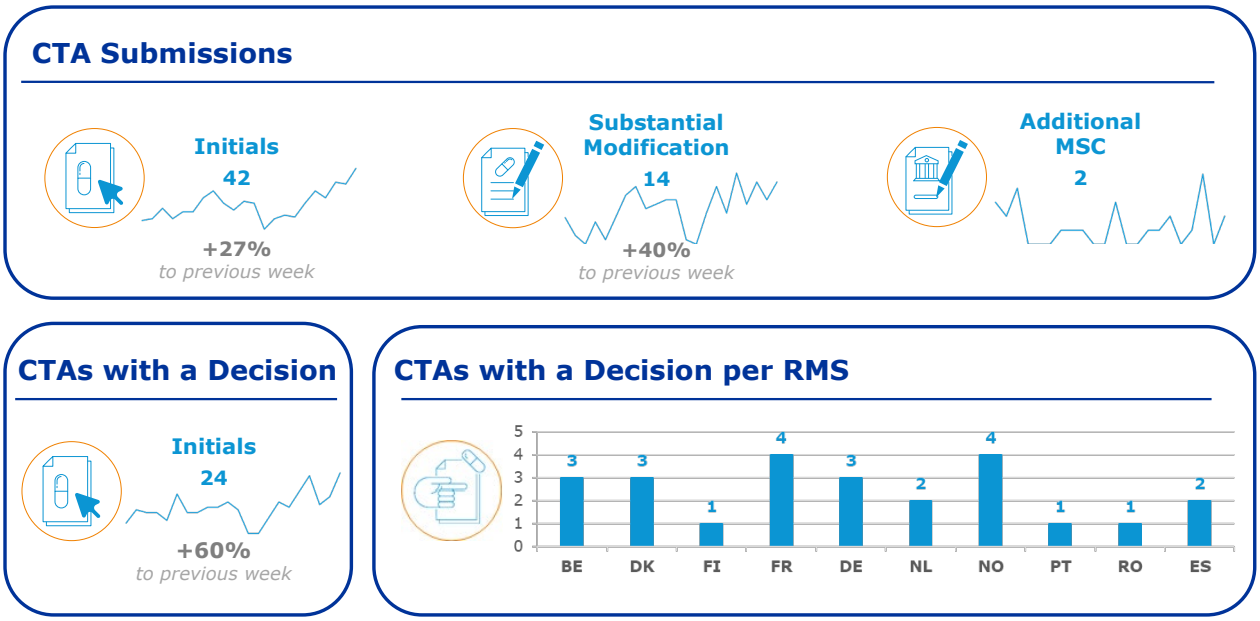
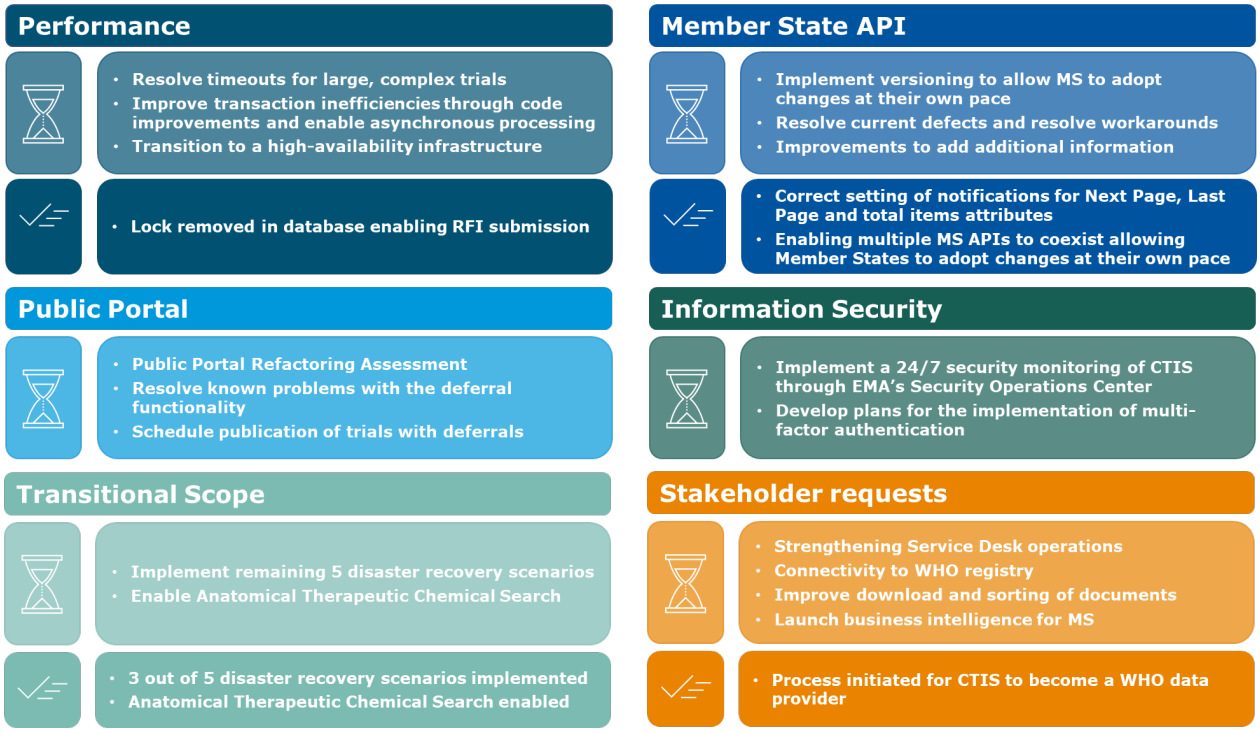


System improvements

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.



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.

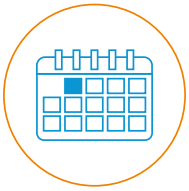
Implementation of the partial initial application (article 11 of the CTR) in CTIS

Based on the currently implemented functionalities in CTIS, sponsors can submit partial initial clinical trial applications, in line with the requirements of Article 11 of the Clinical Trial Regulation (CTR), by submitting an application with part I to all Member States Concerned (MSC) and part II to none or some MSC.

After conclusion on part I is issued, the sponsor has the option to submit the outstanding part II to the MSC, enabling the MSC to issue a decision. A Member State can only issue their decision once Part II has been assessed and concluded. The initial application will remain under evaluation in a Member State from the time the Part I is submitted and until a decision is issued in that Member State or for a period of 2 years, after which the application will lapse.

The submission of further applications, such as substantial modifications - of any type – and/or addition of a MSC, can only occur after **all** MSC have issued a decision, i.e. after all MSC have received both part I and part II of the dossier. In cases where the sponsor needs to submit a substantial modification while some MSC have not yet issued a decision, the sponsor has the option to withdraw the application in those MSC.

EMA is working closely with the European Commission and stakeholders to improve CTIS and ensure the successful implementation of the CTR. Any future changes to the partial initial application functionality in CTIS will have to be compliant with the CTR and will be communicated to users in advance.



Reminder: CTIS Walk-in Clinic on 16 March 2023

On 16 March 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CET. Participants can submit their questions via Slido with the event code #clinic233 until 12 March 2023 or during the event. For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support.

Reminder: Access to CTIS Training Environment

Sponsor users who want to be trained on CTIS have the opportunity to 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 in a safe environment.

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.