1 September 2023
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European Medicines Agency

CTIS newsflash – 1 September 2023

Introduction

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

The next issue will be circulated on 15 September 2023.

Tip for CTIS users: Consult the lists of known issues

Before submitting a ticket with the CTIS User Support Service, users are advised to consult the latest lists of known issues for sponsors or Member States published on Website outages and system releases. These documents outline the issues that sponsor and authority users may encounter when using the CTIS secure workspaces, with possible workarounds.

Transitioning trials to CTIS

By 30 January 2025, any ongoing trials approved under the Clinical Trials Directive will fall under the Clinical Trials Regulation (CTR). Therefore, any ongoing trials will need to be transitioned to CTIS and approved before 30 January 2025. Sponsors have already submitted over 270 transitional trials to CTIS.

Guidance for sponsors transitioning trials from the Clinical Trials Directive to the CTR/CTIS is available:

- in the Guidance for the transition of clinical trials published by the European Commission under EudraLex volume 10;
- in the best practice guide for multinational sponsors of transitional trials adopted by CTCG;
- under Module 23 of the CTIS online training programme.

Sponsors are advised to raise a ticket with the CTIS User Support Service if they cannot find the trial they wish to transition in CTIS when searching by EudraCT number.

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Save the date: CTIS Walk-in Clinic on 20 September 2023

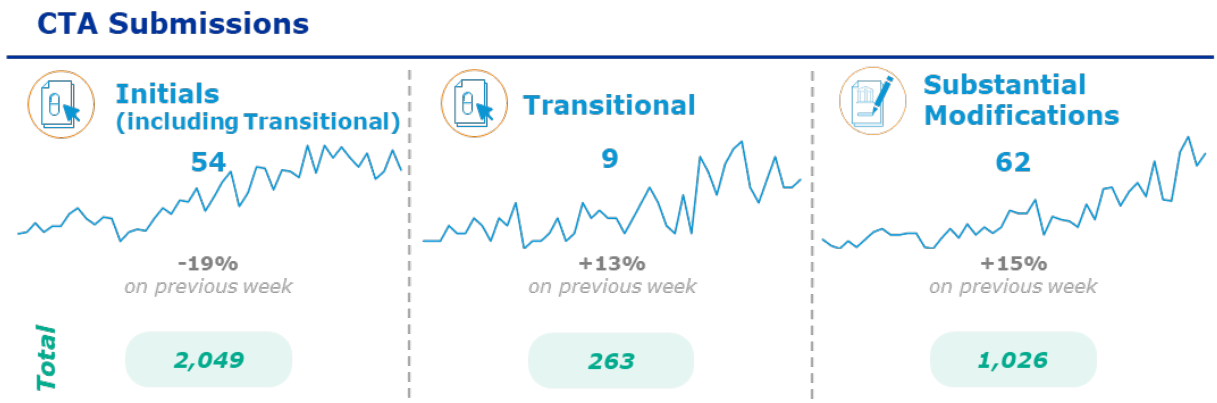
On 20 September 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CEST. Participants will be able to submit their questions in advance starting 6 September or during the event via Slido with the code #clinic239.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu)

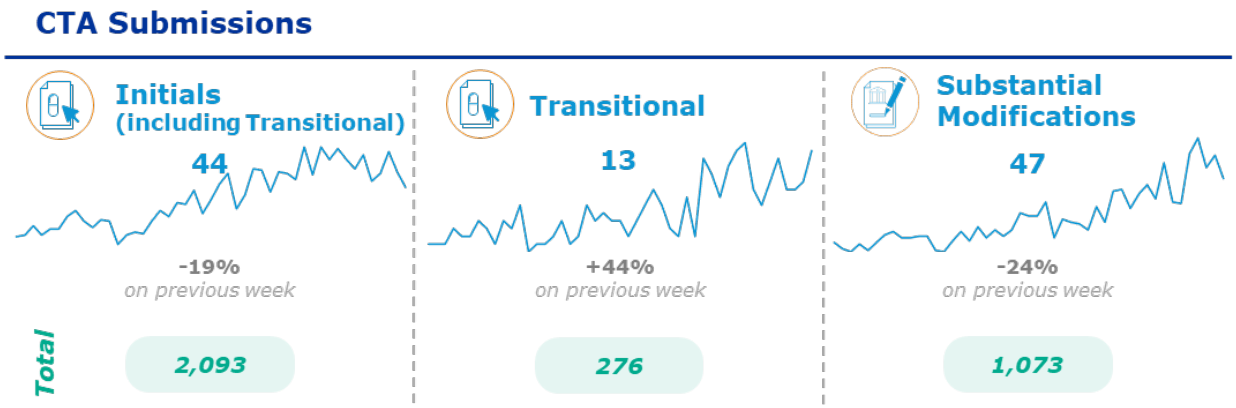
Current operational experience with CTIS

This section on weekly CTIS metrics provides key data and trends compared to the previous week.

The data presented below refer to the period from 15 to 21 August 2023.



The data presented below refers to the period from 22 to 28 August 2023.

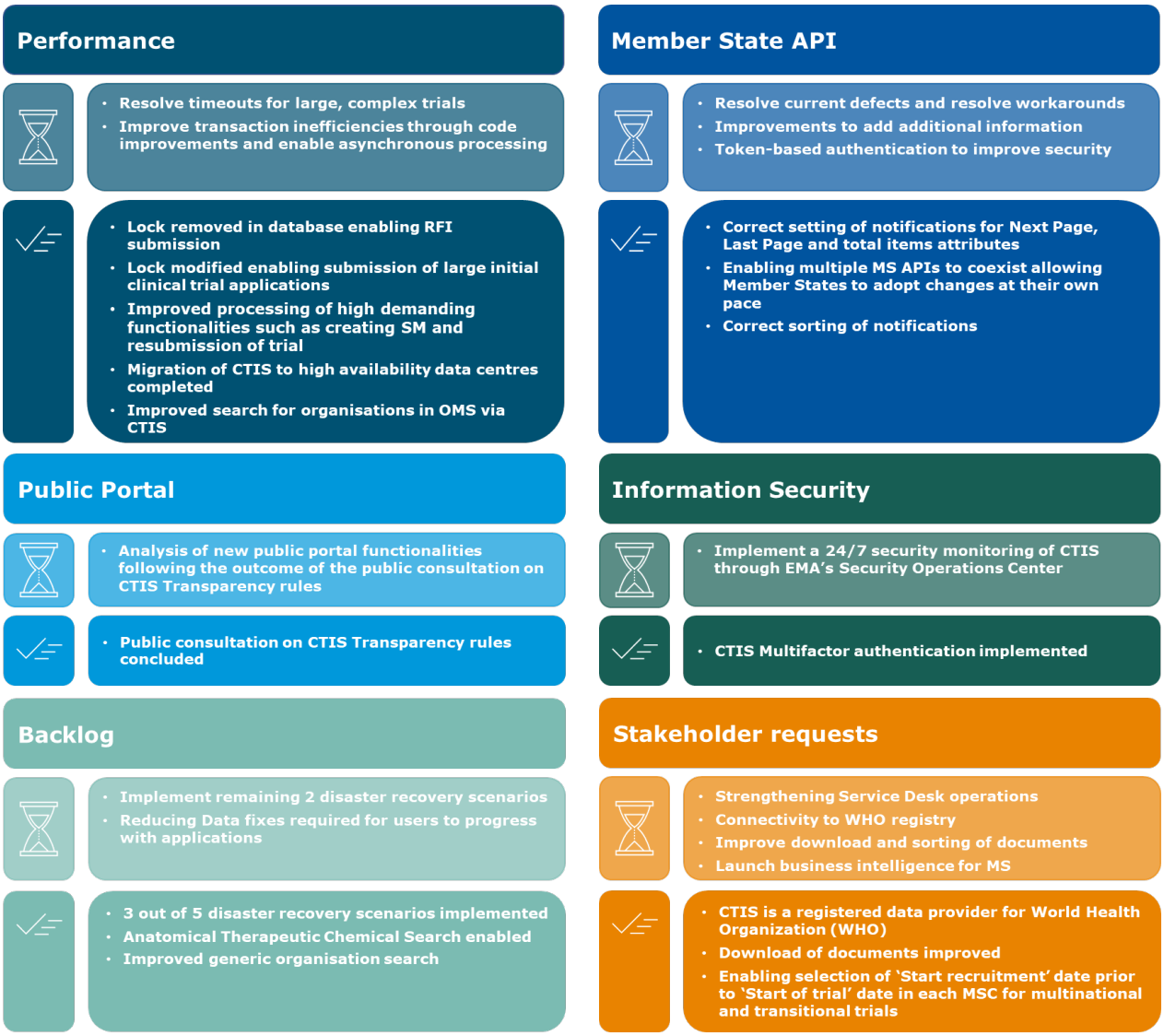


The data on CTAs with a decision for the period from 15 to 28 August 2023 will be provided in the next issue of this newsflash.

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 the 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.

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. Due to limited capacity, access to eligible users is provided for a limited period of time. In addition, access is prioritised for users/organisations with no previous access in the system.

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.