15 September 2023
EMA/397022/2023
European Medicines Agency

CTIS newsflash – 15 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 29 September 2023.

Key updates

- CTIS users are advised that the system will be unavailable on Saturday 16 September 2023 from 08:00 to 12:00 CET.
- The CTCG has published revised versions of the Best Practice Guide and cover letter template for sponsors **transitioning** multi-national **clinical trials to the Clinical Trials Regulation / CTIS.**

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.

Updated CTR Quick guide for sponsors now available

The European Commission has published a new version of the CTR Quick Guide for sponsors. This revised guide includes clarifications on how to submit the IMPD-Q (Investigational Medicinal Product Dossier – Quality) on the manufacturing of the Investigational Medicinal Product at a decentral point of care, at one of the clinical trial sites in the additional Member State.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 were able to submit their questions in advance starting 6 until 14 September 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)

Quality improvement of substance data and potential impact on development products

Following the ongoing substance data quality improvement activities taking place in EMA's Substance Management System (SMS), development products registered in the Extended EudraVigilance Medicinal Product Dictionary (xEVMPD) may have been updated and associated to an approved substance data with a new EudraVigilance (EV) code.

If such a development product is updated in xEVMPD and referenced in a clinical trial application in CTIS, an error message appears when submitting a subsequent draft application, when responding to a Request for Information (RFI) with an update to the dossier, or when cancelling the application. This error message reads: "The product(s) information has changed in the xEVMPD. Therefore, please update this application to include the new product information". As a consequence, the sponsor is not able to submit the application or the response to the RFI, nor cancel the application.

In order to resolve the error, the sponsor needs to update the development product record in CTIS. Please note that only the structured data should be updated, while the previously uploaded associated documents will remain in the draft application unless they are proactively deleted by the user.

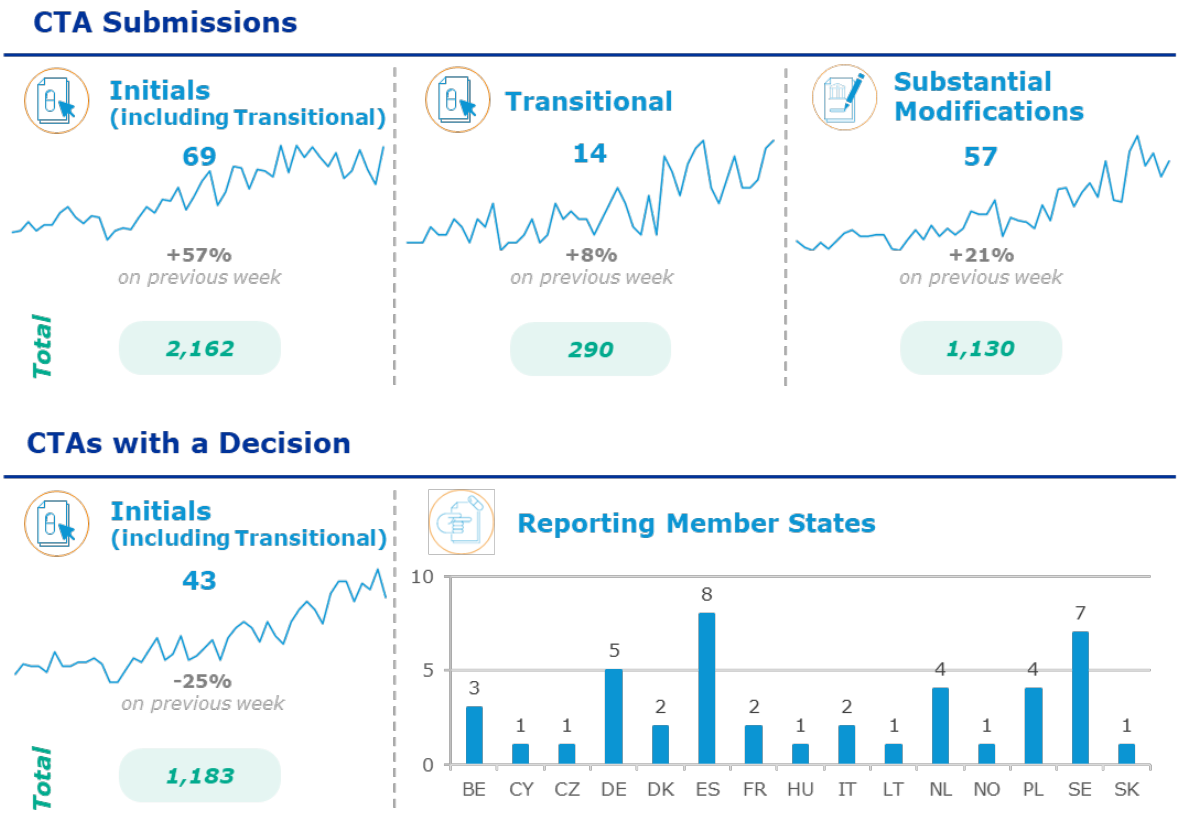
In order to update the unauthorised product, the sponsor needs to:

- identify the product requiring update;
- remove the development product (only the structured data);
- search for it using the updated substance EV code; and
- add the product in the application.

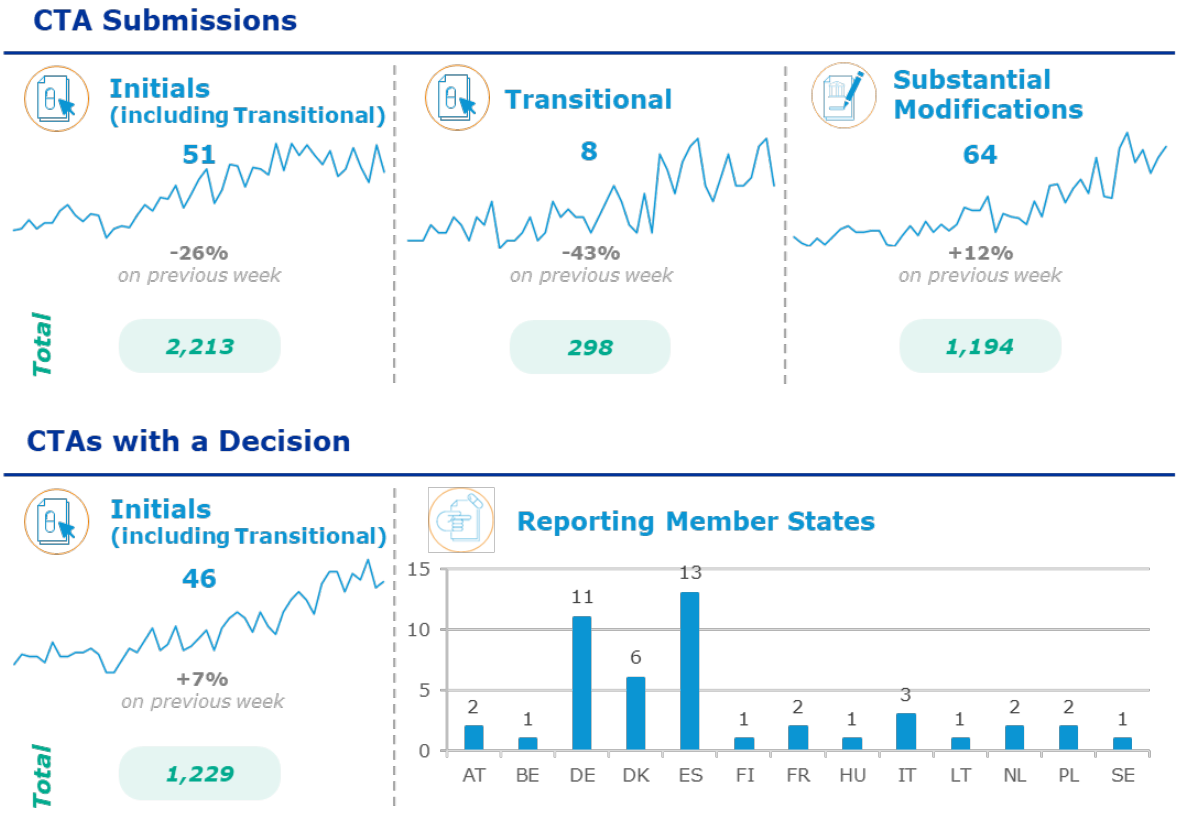
Current operational experience with CTIS

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 29 August to 4 September 2023.



The data presented below refers to the period from 5 to 11 September 2023.



System improvements

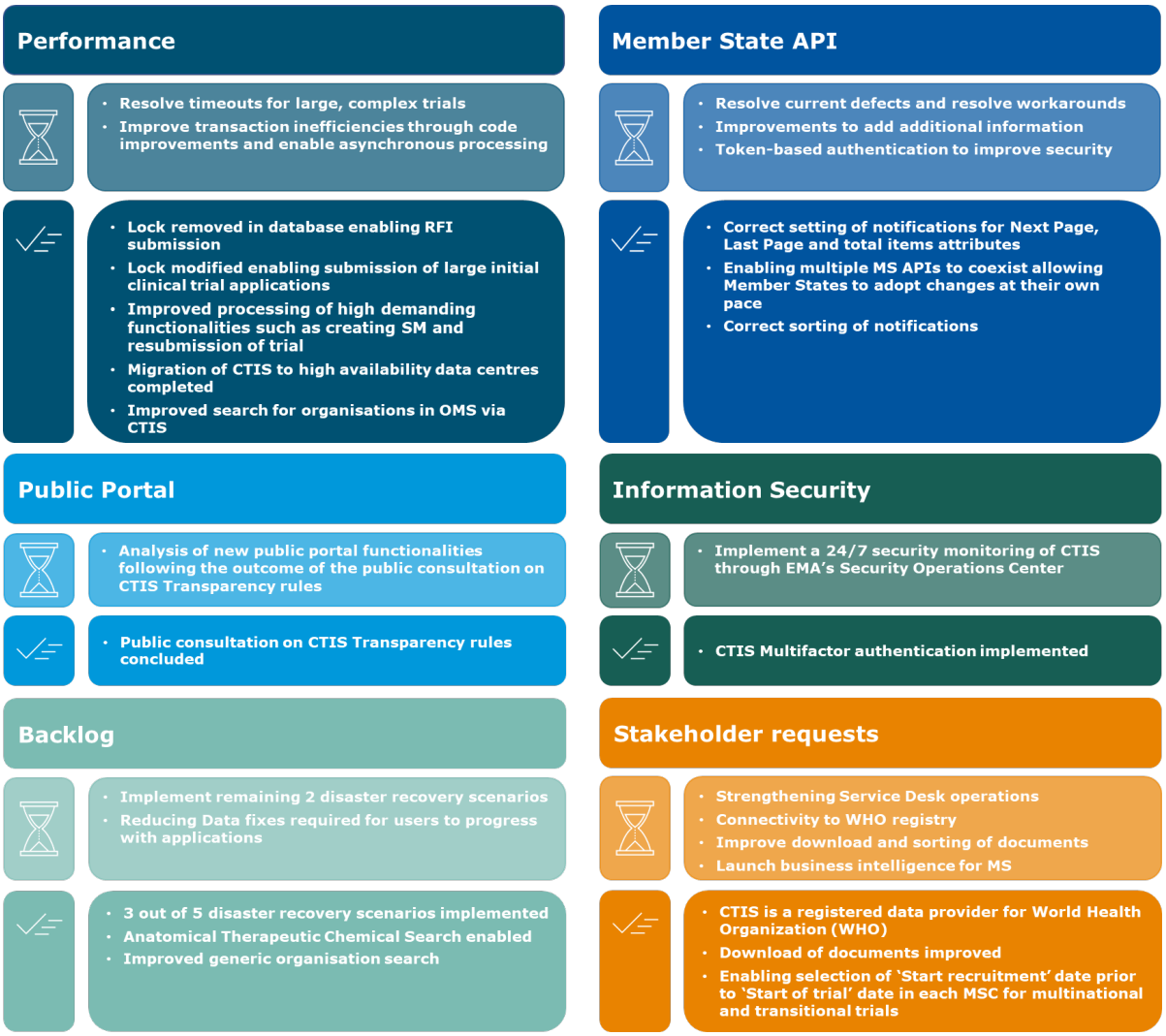
A CTIS release was deployed on 2 September 2023, introducing several improvements to enhance user experience:

- When creating organisations locally in CTIS, sponsors are now able to edit, as required, a previous draft organisation created before submission, and successfully update these local organisations.
- Sponsors with a Q-IMPD (Quality-Investigational Medicinal Product Dossier) preparer role are now able to upload quality documents in a draft clinical trial application without receiving an error message.
- Sponsor users with a CT Admin role for specific trials combined with other non-quality-related business roles for other trials now have access to the Final Assessment Report Part-I Quality only for the specific trial of their CT Admin role.
- Sponsor users are now able to search, select and add organisations located in the United Kingdom (Northern Ireland).
- During the assessment of Part I substantial modification applications, Member States are now able to assess RFI responses until the due date of the related task.
- The impact of the implementation of the two-factor authentication on the Notices and Alerts has been resolved, with Notices and Alerts now appearing correctly.

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 the improvements implemented.



Reminders

- 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.
- Additional 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;
  - under Module 23 of the CTIS online training programme.

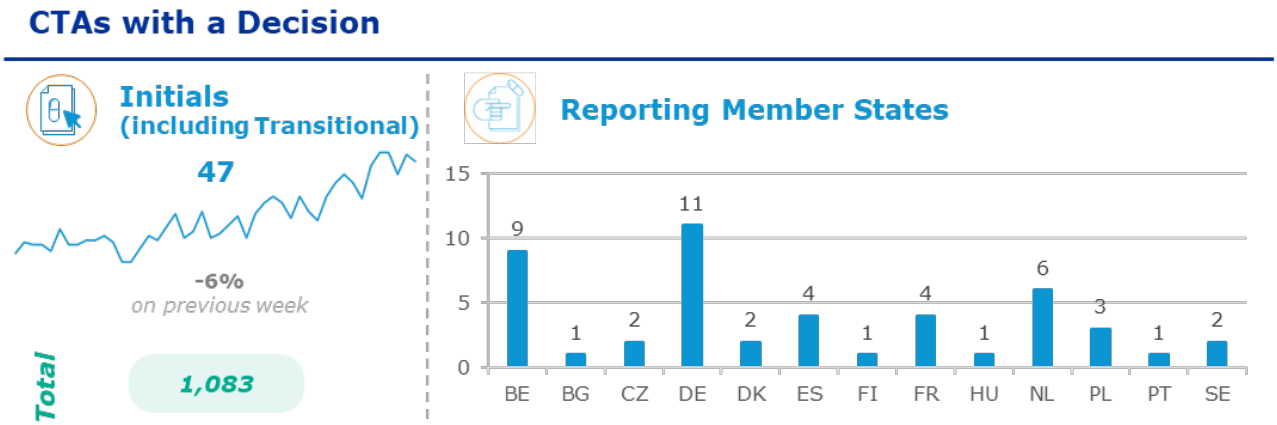
  Sponsors are advised to raise a ticket with the CTIS User Support Service if they cannot find the trial they wish to transition in CTIS when searching by EudraCT number.

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.

Annex: Information on CTAs with a decision 15-28 August 2021

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



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