5 May 2023
EMA/186032/2023
European Medicines Agency

CTIS newsflash – 5 May 2023

Introduction

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

Spotlight: Updates on CTIS transparency rules

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.

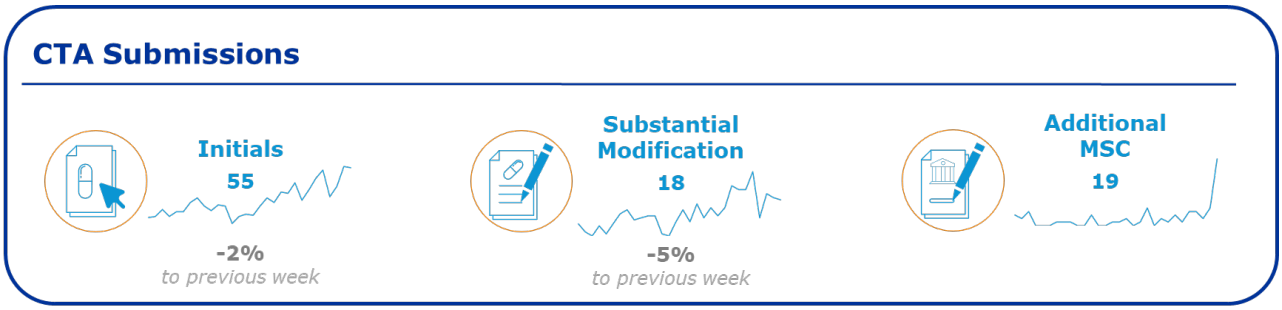
Current operational experience with CTIS

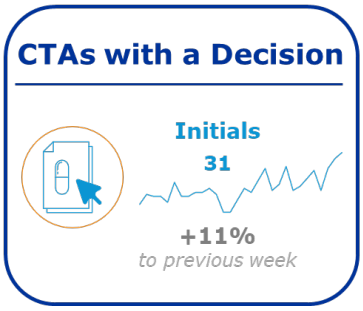
This section on weekly CTIS metrics provides key data and trends compared to the previous week.

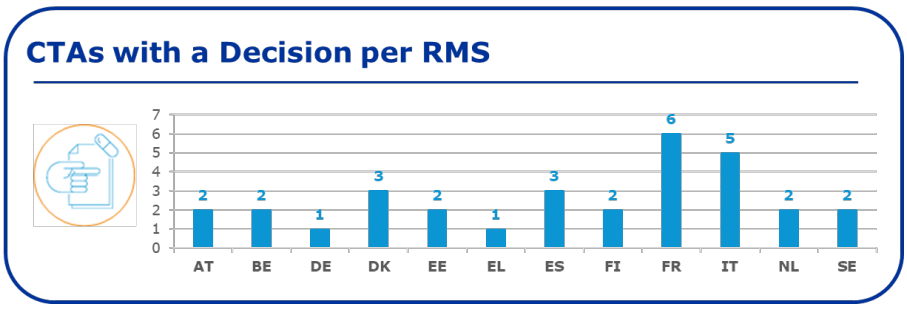
Over 500 clinical trials with a decision issued under the CTR are now available in CTIS.

The data presented below refers to the period from 25 April to 1 May 2023.

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



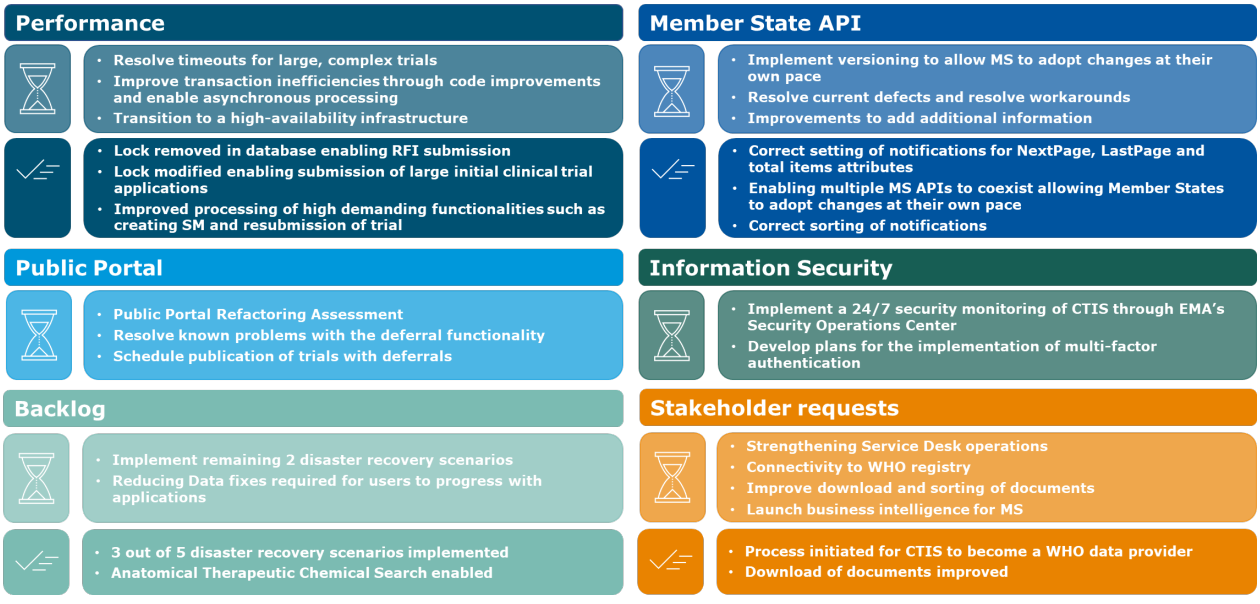




System improvements

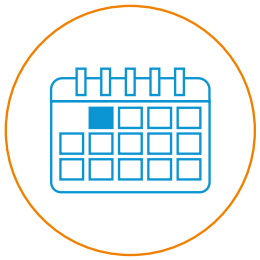
EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

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



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.

Save the date: CTIS Bitesize talk 10 May 2023 – IMPD-Q only submission



On 10 May 2023 EMA is hosting a CTIS Bitesize talk at 15:30-17:00 CEST. The talk will focus on part I-only submission of the investigational medicinal product dossier on quality (IMPD-Q), and related scenarios. Participants will be able to submit their questions in advance (starting 26 April) or during the event via Slido with the event code #bt10may.

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

Reminders

- 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.
- Resubscribe here to receive future issues of the Clinical Trials Highlights newsletter, which provides overview of milestones, developments and events related to CTIS and the ACT EU initiative.
- During the upcoming May holidays, the CTIS User Support Service will be providing service limited to critical or blocking issues: 9 May, 18 May, 19 May, 29 May.
- 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.
- The training environment will be unavailable on 10 May 2023 from 8:00 till 17:00 (CEST), due to maintenance operations and users will not be able to log in the system during that time window. The training environment will be accessible again for users to resume any activities after 17:00 (CEST).
- EMA has published a document with all official EU/EEA Member State public holidays for the year 2023 as recorded in CTIS.
- Since 24 April 2023, the regular **maintenance windows** in CTIS have been amended with the aim to limit downtime due to planned system interruptions. Users are advised to avoid using CTIS during the following times:
  - Tuesdays and Thursdays, from 18:00 to 21:00 Amsterdam time
  - Each first Saturday of the month, from 10:00 to 14:00 Amsterdam time

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.