26 May 2023
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European Medicines Agency

CTIS newsflash – 26 May 2023

Introduction

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

From today, this newsflash will be circulated every two weeks. The next issue is foreseen on Friday 9 June 2023.

Spotlight: CTIS becomes a data provider for WHO

CTIS is now a registered data provider for the World Health Organization (WHO).

Data from authorised trials published on the CTIS website - excluding those with category 1 deferrals of the main characteristics - is now included in the search portal of WHO's International Clinical Trials Registry Platform (ICTRP). This applies to relevant clinical trial data, as required by WHO, which has been published on CTIS since the launch of the system on 31 January 2022.

Publicly accessible registries that are data providers to WHO's ICTRP are accepted by the International Committee of Medical Journal Editors (ICMJE), according to its recommendations.

Sponsors are reminded that clinical trials with any type of deferrals and a decision issued after mid-August 2022 are currently not published on the CTIS website. Therefore, these trials will not be included in WHO's ICTRP.

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. 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. Further instructions on setting up the MFA for EMA systems are available here.

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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. Therefore, all current subscribers are requested to resubscribe using the link above.

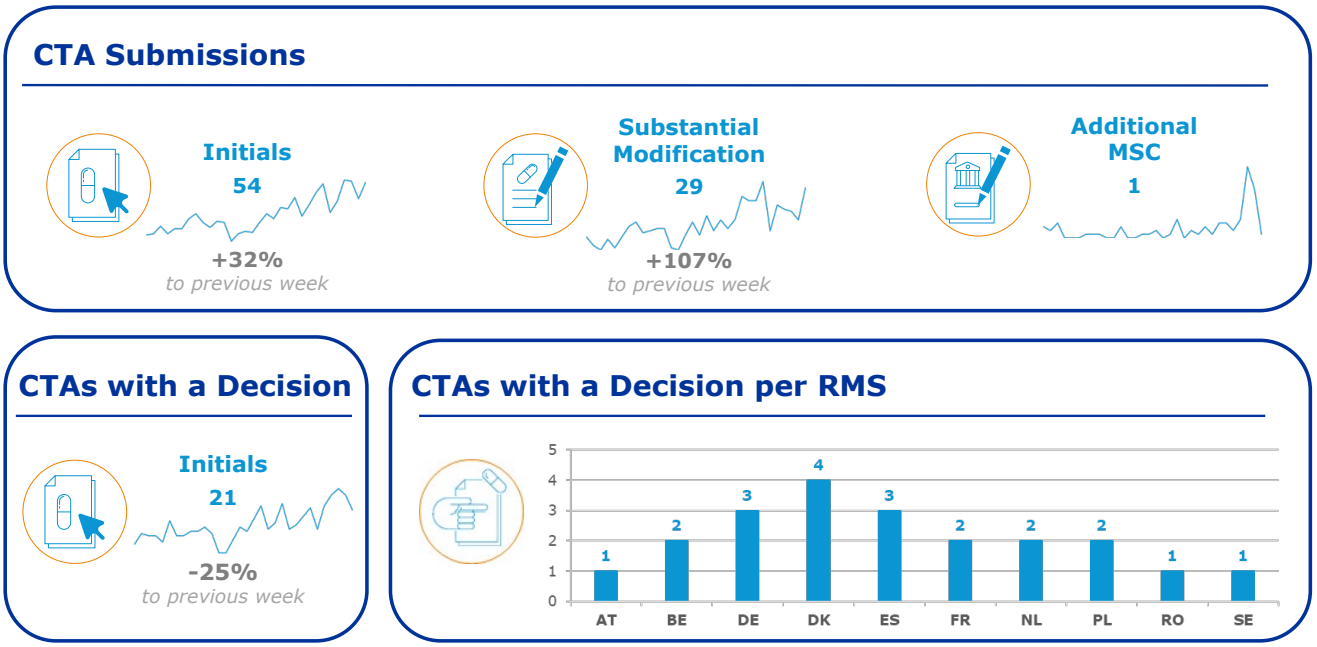
Key updates

- Sponsors are already preparing for the next phase of implementation of the CTR. By 30 January 2025, any ongoing trials approved under the Clinical Trials Directive will fall under the CTR. Therefore, any trials will need to be transferred to CTIS and approved before 30 January 2025 if they are ongoing. As of 25 May 2023, sponsors have already submitted over 143 transitional trials to CTIS. More information on transitional trials is available under Module 23 of the CTIS online training programme and the CTCG's best practice guide for multinational sponsors of transitional trials.
- EMA has published a revised version of the Q&A document providing guidance to users on how to protect personal data and commercially confidential information (CCI) in CTIS, available on the EMA website. The new Q&A item 3.3 clarifies how dose details can be protected from disclosure for certain category 2 clinical trials.
- A very small number of CTIS users have experienced difficulties when trying to create substantial modifications for very large multinational clinical trials, 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 to take note of below downtime windows which may impact their use of the system:
  - On Thursday 8 June 2023 from 08:00-17:00 CEST, the CTIS Training Environment will be unavailable.
  - On Saturday 10 June 2023 from 08.00 to 12.00 CEST, the CTIS website (both the secure workspaces and public search portal) will be unavailable.
  - On Saturday 17 June 2023 from 08.00 to 12.00 CEST, the CTIS website and CTIS MS API will be unavailable.
  - On Saturday 24 June 2023 from 08.00 to 12.00 CEST, users will be unable to search and select authorised or not-authorised medicinal products, ACT codes or active substances in the CTIS website.

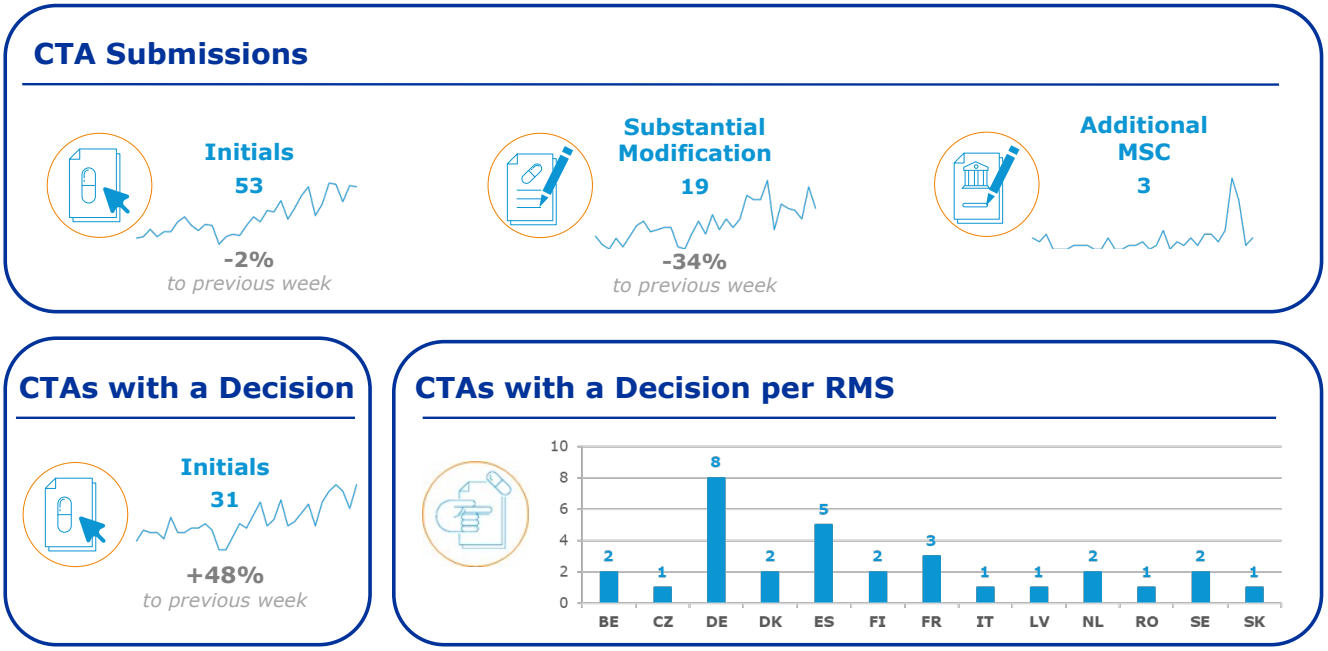
Current operational experience with CTIS

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 9 to 15 May 2023.



The data presented below refers to the period from 16 to 22 May 2023.



System improvements

The CTIS release deployed on 25 May 2023 implemented several improvements to enhance user experience:

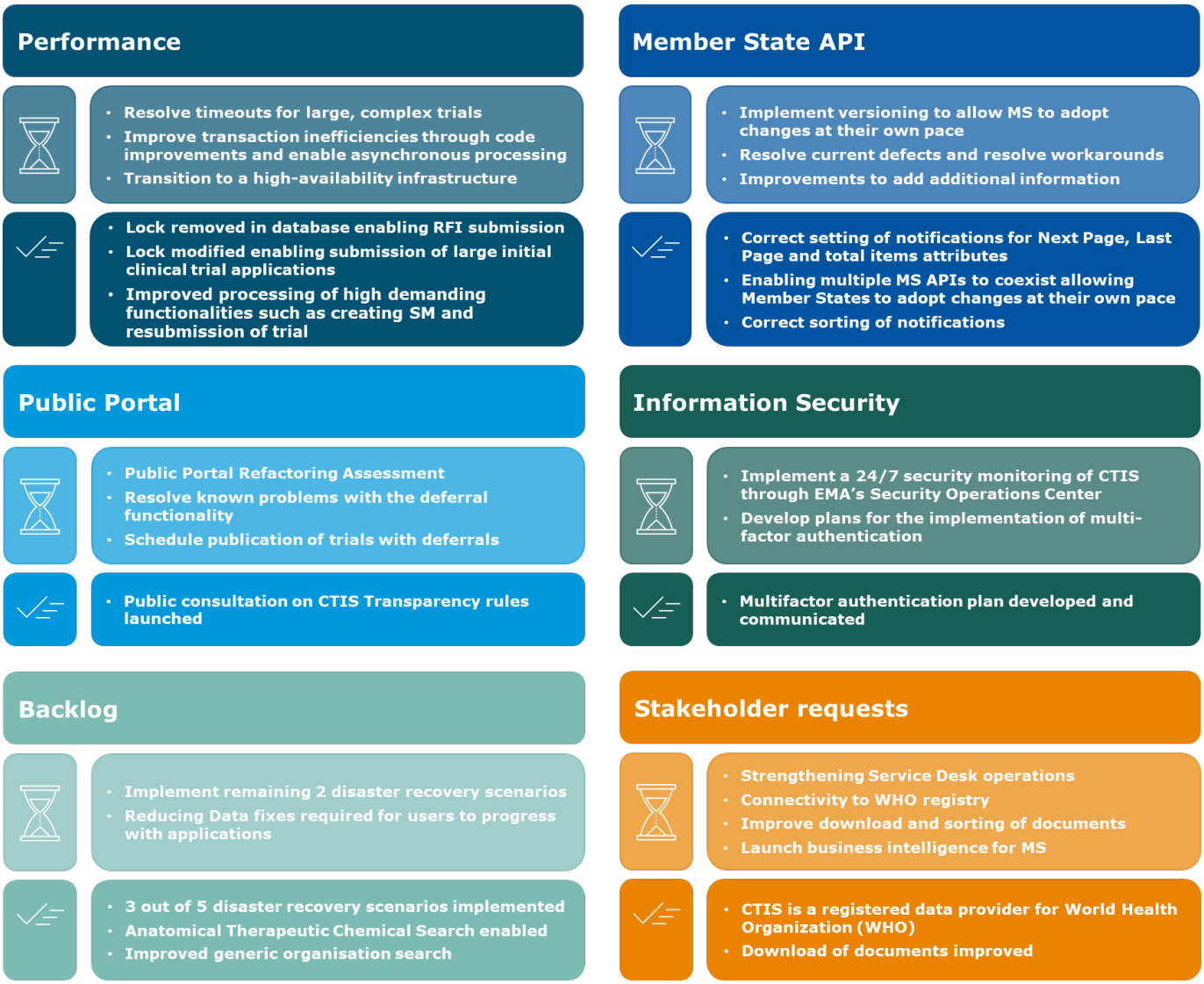
- Improved the "Start of recruitment" notification in both multinational and transitional trials, enabling users to select a "Start of recruitment" date prior to the "Start of trial" date in each Member State Concerned (MSC).
- Assignment of user roles is now enabled in cases where the organisation name selected contains the special characters "&"and "." or Greek letters.

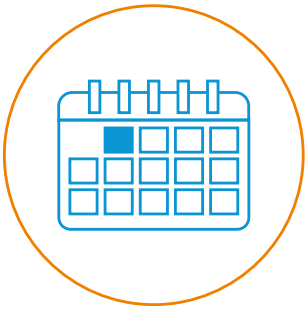
- In initial applications with multiple Part II Requests for Information (RFIs), when users respond to at least one RFI, the rest of the pending RFIs do not expire, avoiding lapse of the application for the MSC.
- When Member State users merge, accept, adapt, or do not include considerations, only the considerations consolidated and selected from the consolidated considerations tab are included in the RFI sent to the sponsor.

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.





Save the date: CTIS events in June

On 14 June 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CEST. Participants are able to submit their questions in advance starting 1 June or during the event via Slido with the event code #clinic236.

On 21 June 2023, a CTIS Bitesize talk is planned at 15:30-17:00 CEST. The talk will focus on transitional trials and the event will be supported by national competent authority and ethics committee representatives. Participants will be able to submit their questions in advance between 1-14 June or during the event via Slido with the event code #bt21jun.

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

Reminders

- During the upcoming holiday on 29 May, the CTIS User Support Service will be providing service limited to critical or blocking issues.
- 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 has also been published. The documents 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.

How to raise a ticket in CTIS User Support Service

Before raising a ticket to the CTIS User Support Service, users are highly advised to review the information available on the Support page of the CTIS website. The page includes links to training and supporting materials on how to use CTIS, questions and answers, and information on website outages, system releases, and lists of known issues.

In cases where the user query is not addressed in the Support page, users can raise a ticket with the User Support Service by following the steps below.

Step 1 – Select the most appropriate option:

- **Request a service:** when a standard service, e.g. a password reset, is required.
- **Report an issue:** when prevented from working by a problem with software/systems.
- **Ask a question:** when information is needed on specific topic.

Step 2 – Under the Summary field, provide the title of the incident. Be specific and if relevant, highlight any deadlines according to the Clinical Trials Regulation.

Step 3 – Under the Description box, provide a detailed description of the issue, including:

- Who you are: sponsor user (e.g. pharmaceutical industry, CRO, academia) or Member State user (NCA, ethics committee, etc.)

- CTIS Role
- EU Trial number/RFI number
- Location (country)
- CTIS Username
- Description of steps taken

Step 4 – Under Attachments, upload any relevant screenshots.

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.