



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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CTIS newsflash – 3 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](#).

Key Updates

On 23 February 2023, over 400 viewers followed the CTIS Bitesize talk on Document and Personal data in CTIS. The event provided an opportunity for sponsors to learn how to use the 'Publication' and 'Not for publication' requests and remove personal data from Document properties. CTIS experts answered related questions submitted via Slido. A video recording will be made available on the [event page](#) in due course.

EMA has initiated the process to register CTIS as a WHO data provider. Once the registration process is completed, all CTIS data will be included in WHO's [International Clinical Trials Registry Platform \(ICTRP\) Search Portal](#). This will apply to all future clinical trial data published in CTIS in addition to all data published in CTIS since the launch of the system on 31 January 2022. Further updates will be provided in upcoming issues of this Newsflash.

The latest issue of the [CT Highlights newsletter](#) is now available on the EMA website, including updates on milestones, upcoming activities, and new developments related to CTIS and the ACT EU initiative.

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 21 to 27 February 2023.

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CTA Submissions



Initials

33

-3%

to previous week



Substantial Modification

10

-29%

to previous week



Additional MSC

0

CTAs with a Decision



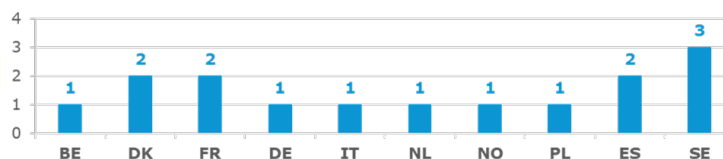
Initials

15

+25%

to previous week

CTAs with a Decision per RMS



System improvements

The CTIS release deployed on 1 March 2023 implemented several improvements to enhance user experience:

- When an initial clinical trial application (CTA) is withdrawn in all Member States, alerts for such CTA are no longer generated.
- The search functionality has been improved in the following instances:
 - retrieving medicinal products with more than 35 substances
 - adding a product using the ATC code
- Issues with duplication of IMP and auxiliary medicinal products (AxMP)-related documents have been resolved.
- The downloaded PDF documents related to sections “IMPD-Q”, “IMPD Safety and Efficacy” and “sponsor contact point for the Union” include the latest information displayed in the user interface.
- User profiles with combined roles of Member State Admin and National Organisation Admin only manage users (assign/ revoke/ amend) affiliated with the Member State Admin organisation.

In addition to the above functional improvements, several technical improvements have been implemented:

- Disaster recovery scenarios related to Timetable and Restart of Trial.
- WHO API basic setup.
- The Member State API (Application Programming Interface) was improved:
 - Correct setting of notifications in MS API for Next Page or Last Page and total items attributes.
 - Enabling multiple versions of the MS APIs to coexist, allowing Member States to adopt changes at their own pace.

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](#).

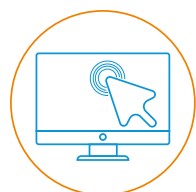
The work continues in close collaboration with our stakeholders to deliver further system improvements and enhance the user experience. The dashboard below summarises the main improvement areas of focus for 2023 and improvements implemented.

<h3>Performance</h3> <ul style="list-style-type: none"> Resolve timeouts for large, complex trials Improve transaction inefficiencies through code improvements and enable asynchronous processing Transition to a high-availability infrastructure <ul style="list-style-type: none"> Lock removed in database enabling RFI submission 	<h3>Member State API</h3> <ul style="list-style-type: none"> Implement versioning to allow MS to adopt changes at their own pace Resolve current defects and resolve workarounds Improvements to add additional information <ul style="list-style-type: none"> Correct setting of notifications for NextPage, LastPage and total items attributes Enabling multiple MS APIs to coexist allowing Member States to adopt changes at their own pace
<h3>Public Portal</h3> <ul style="list-style-type: none"> Public Portal Refactoring Assessment Resolve known problems with the deferral functionality Schedule publication of trials with deferrals 	<h3>Information Security</h3> <ul style="list-style-type: none"> Implement a 24/7 security monitoring of CTIS through EMA's Security Operations Center Develop plans for the implementation of multi-factor authentication
<h3>Transitional Scope</h3> <ul style="list-style-type: none"> Implement remaining 5 disaster recovery scenarios Enable Anatomical Therapeutic Chemical Search <ul style="list-style-type: none"> 3 out of 5 disaster recovery scenarios implemented Anatomical Therapeutic Chemical Search enabled 	<h3>Stakeholder requests</h3> <ul style="list-style-type: none"> Strengthening Service Desk operations Connectivity to WHO registry Improve download and sorting of documents Launch business intelligence for MS <ul style="list-style-type: none"> Process initiated for CTIS to become a WHO data provider



Save the date: 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.