17 March 2023
EMA/114900/2023
European Medicines Agency

CTIS newsflash – 17 March 2023

Introduction

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.

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 7 to 13 March 2023.

CTA Submissions

Initials
27

-36%
to previous week

Substantial Modification
25

+79%
to previous week

Additional MSC
1

CTAs with a Decision

Initials
12

-50%
to previous week

CTAs with a Decision per RMS

BE	DK	ES	FR	PL	SE
3	1	3	1	1	3
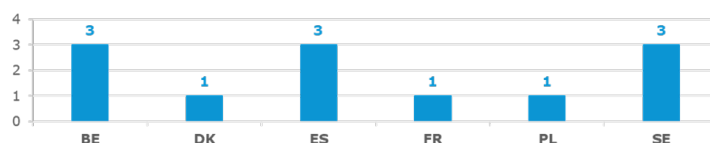
System improvements

The CTIS release deployed on 16 March 2023 implemented several improvements to enhance user experience:

- When submitting a second Request for Information (RFI) in Part II, the user is now able to select the correct dates in the calendar.

- A Member State Concerned (MSC) that is added at a later time through an Additional MSC application and did not authorise the initial clinical trial application, is able to create a corrective measure.

- Users with the role "CT Admin" and/or "Application Submitter" for a specific trial are able to create all types of Substantial Modifications, Non-Substantial Modifications and Additional Member State Concerned applications, regardless of the assignment approach, i.e. Clinical Trial-centric or Organisation-centric.

- The total number of draft Substantial Modifications (SMs) in the system at a time has been changed to allow the creation of one draft SM part I and a maximum of one draft SM part II per Member State Concerned.

- When uploading an Auxiliary Medicinal Product Dossier (AMPD) document, it is labelled as "Not for publication".

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.

Performance
- Resolve timeouts for large, complex trials
- Improve transaction inefficiencies through code improvements and enable asynchronous processing
- Transition to a high-availability infrastructure
- Lock removed in database enabling RFI submission

Member State API
- Implement versioning to allow MS to adopt changes at their own pace
- Resolve current defects and resolve workarounds
- Improvements to add additional information
- 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

Public Portal
- Public Portal Refactoring Assessment
- Resolve known problems with the deferral functionality
- Schedule publication of trials with deferrals

Information Security
- Implement a 24/7 security monitoring of CTIS through EMA's Security Operations Center
- Develop plans for the implementation of multi-factor authentication

Backlog
- Implement remaining 2 disaster recovery scenarios
- Reducing Data fixes required for users to progress with applications
- 3 out of 5 disaster recovery scenarios implemented
- Anatomical Therapeutic Chemical Search enabled

Stakeholder requests
- Strengthening Service Desk operations
- Connectivity to WHO registry
- Improve download and sorting of documents
- Launch business intelligence for MS
- Process initiated for CTIS to become a WHO data provider

Upcoming: Introduction of a full-screen loading spinner in CTIS

With a view to improve user experience and system performance in CTIS, the loading bar at the top of the screen will be replaced by a full-page loading spinner. This means that when users start an operation, such as clicking on the search button, the spinner will appear and the interface will be temporarily inaccessible until the system has completed processing the request. The change, which will enhance the reliability and efficiency of CTIS, is foreseen to go into effect in late March/early April 2023. Further updates will provided in future issues of this Newsflash. A preview of the change is available below.
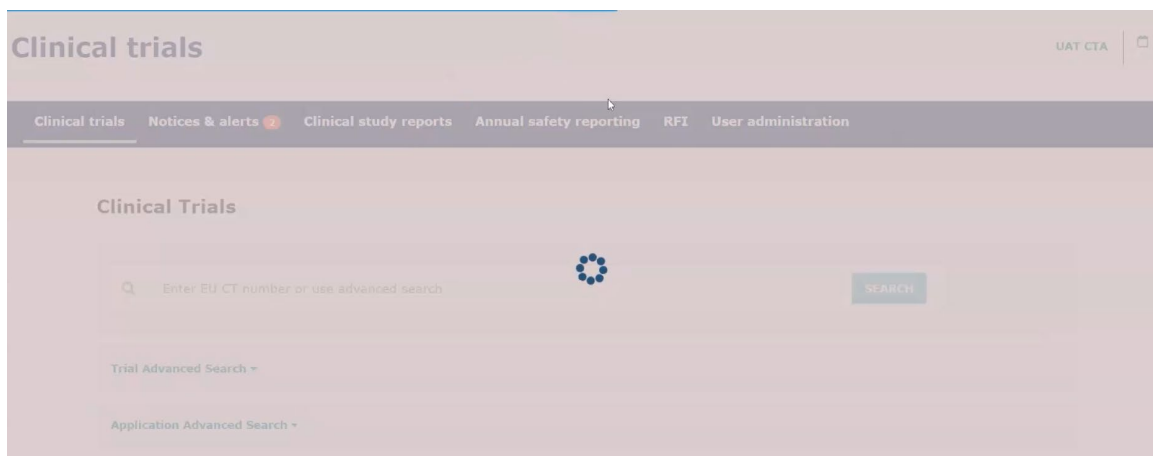
Image 1. Preview of the loading spinner in CTIS

Reminder: CTIS Time zone

CTIS users are reminded that the time zone used in CTIS is Central European Time (CET). All due dates and deadlines are displayed in CET.

Reminder: Multi-factor authentication in CTIS

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.

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.