31 March 2023
EMA/141792/2023
European Medicines Agency

# CTIS newsflash – 31 March 2023

## Introduction

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

Due to the Easter holidays, the next CTIS newsflash will be circulated on 14 April 2023.

## Key updates

EMA has published a revised version of the Q&A document providing preliminary 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 The new Q&A item 1.9 clarifies that documents with track changes can only be submitted in CTIS in the slot 'not for publication'.

The Clinical Trials Coordination Group (CTCG) published a Q&A document on complex clinical trials, to support sponsors submitting or transitioning such trials to CTIS.

The CTIS User Support Service will remain open during the Easter holidays on 6, 7 and 10 April.
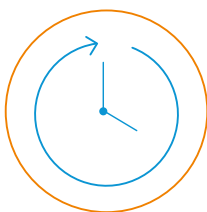
### RFI due dates and timelines

Users are reminded that the due dates for responding to a Request for Information (RFI) in CTIS do not fall on weekends. However, due dates do not take into account Member States' holiday calendars and may fall on a bank holiday of the Reporting Member State (RMS) or Member State Concerned (MSC). Users are advised to consult the published document on CTIS evaluation timelines.

## 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 21 to 27 March 2023.

## CTA Submissions

**Initials**
**46**

+28%
*to previous week*

**Substantial Modification**
**23**

0%
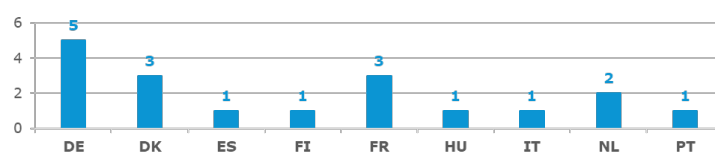*to previous week*

**Additional MSC**
**1**

## CTAs with a Decision

**Initials**
**18**

+29%
*to previous week*

## CTAs with a Decision per RMS

| DE | DK | ES | FI | FR | HU | IT | NL | PT |
|----|----|----|----|----|----|----|----|----|
| 5  | 3  | 1  | 1  | 3  | 1  | 1  | 2  | 1  |

## System improvements

The CTIS release deployed on 30 March 2023 implemented several improvements to enhance user experience:

- During the assessment of a Substantial Modification (SM) Part I & II or SM part II, users can now create a Request for Information for Part II for a Member State Concerned (MSC) that was added after the initial application was lapsed, not-authorised or withdrawn in that MSC.

- Improved search functionality in Annual Safety Reports (ASR):

  – When searching in an ASR by product name, the autosuggestion now lists products that start with/match the name of the product inserted in the search bar.

  – During the creation of a new ASR, sponsor users are able search for and add a valid product ID via the search form.

- Users in the authority workspace with a trial-specific role are now able to view all trials when performing a search in the Clinical Trials tab.

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

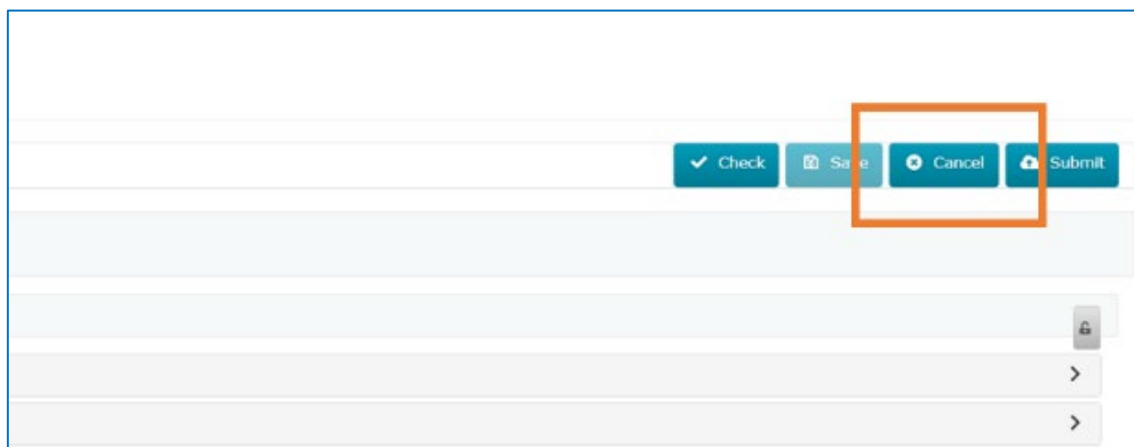## Spotlight for Sponsors: How to avoid cancelling draft applications

The cancellation of a draft clinical trial application (CTA) in CTIS enables users to erase a draft CTA that is no longer of use to the sponsor.
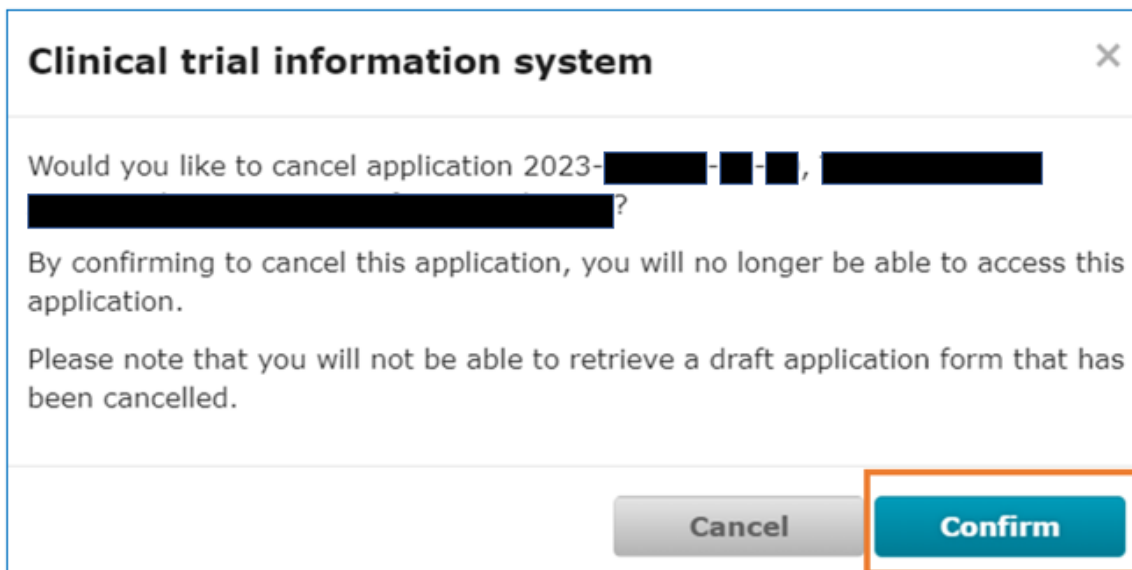
Cancellation of a draft CTA in the sponsor workspace is a two-step process, in order to prevent accidental cancellations. On the upper right corner of their draft CTAs, sponsor users have four control buttons. By using the 'Cancel' button and confirming their action in the ensuing pop-up window, users permanently remove their draft CTA from their sponsor workspace.

Once cancelled, a draft CTA cannot be restored nor retrieved via the search functionality. The EU CT number of a cancelled initial CTA is not retrievable and cannot be used in any subsequent new draft initial CTA.

Sponsors are advised to ensure that the roles 'CT Admin' and 'Application Submitter', which enable the cancellation of draft CTAs in CTIS, are only assigned to users who are familiar with the functionality. More information is available in the Roles and Permission Matrix Summary under Module 7 of the CTIS online training material.

The two steps for cancelling draft CTAs are depicted in the screenshots below.

## Clinical trial information system

Would you like to cancel application 2023-████████-█-█, ████████████
████████████████████████?

By confirming to cancel this application, you will no longer be able to access this application.

Please note that you will not be able to retrieve a draft application form that has been cancelled.

Cancel | **Confirm**

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### Save the date: CTIS Walk-in Clinic 19 April 2023

On 19 April 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CEST. Participants will be able to submit their questions in advance (starting 5 April) or during the event via Slido with the event code #clinic234. For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support.

### Reminders

- The time zone used in CTIS is Central European Time (CET). All due dates and deadlines are displayed in CET despite the change to daylight-savings time in Europe since 26 March 2023. Planned maintenance windows for CTIS, published here, refer to Amsterdam time (Central European Summer Time - CEST).

- 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.

- 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.

### 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.