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European Medicines Agency

CTIS newsflash #05 - 4 March 2022

Introduction

Welcome to the fifth CTIS newsflash. This newsflash provides updates on key facts and figures regarding CTIS usage, as well as links to useful reference materials.

Key metrics

Metrics reported cover the period 21/02/2022-27/02/2022.

Total number of logins to CTIS: 3,846

- This metric represents the total sum of unique logins by individual users per day during the period
- **Number of draft applications in CTIS: 185**
 - This metric counts the number of applications with status "Draft" in CTIS at the end of the period
- **Number of submitted applications in CTIS: 7**

News spotlight

Three submitted clinical trial applications have passed validation by the relevant regulatory authorities.

Did you know?

Validation is the first step in the clinical trial application evaluation process in CTIS. The validation phase ensures that the clinical trial application falls under the scope of the Clinical Trials Regulation and that the application dossier documentation is complete. It is also the phase in which the selection of the Reporting Member State (RMS) occurs for multinational trials. During validation, the RMS may send requests for information (RFIs) to the sponsor if necessary.



Helpful hint

If you are transitioning a trial from the Clinical Trials Directive to the Clinical Trials Regulation by submitting the trial to CTIS, you must indicate this in the clinical trial application.

When creating a new initial clinical trial application in CTIS, by clicking on the 'New trial' button, a pop-up window will open. Users will have to populate the trial title field, select the sponsor organisation and then must click on the 'Transition trial' checkbox followed by the 'Create' button to create a draft transition trial. Clicking the tick box on 'Transition trial' will ensure that the application is clearly marked in the system as a trial that is being transitioned.

Clicking 'Transition trial' when creating the initial clinical trial application enables a new field in the 'Form' section that allows users to link the EudraCT number to the trial. If users do not select the checkbox at the time of creation of the initial application, they need to cancel the clinical trial application and create a new one. If you selected 'Transition trial' in error when creating the application, you can turn off this label in the 'Form' section of the application.

OMS and RMS webinars

On 10 March 2022, EMA will host an [introduction to Organisation Management Service \(OMS\) and Referentials Management Service \(RMS\) services and activities](#) Industry webinar. This webinar will provide an introduction to OMS and RMS services and activities for industry users.

On 18 March 2022, EMA will host a webinar on [requesting access to and using EMA's substance, product, organisation and referential \(SPOR\) application programming interface \(API\)](#). This webinar is aimed at industry and national competent authority technical audiences that wish to integrate with OMS and RMS to achieve more automated processes and consume data directly from the SPOR API.

A video recording will be made available following each webinar.

CTIS and related systems maintenance: update

CTIS has regular maintenance windows to ensure technical updates to the system can be implemented in a timely manner. Systems that CTIS interacts with also undergo regular and ad-hoc maintenance which may affect CTIS usage. Please find below updates on the regular CTIS maintenance windows, and scheduled maintenance of OMS and EudraCT which will affect CTIS usage for a limited period of time. These updates will be reflected shortly on the [Website outages and system releases page](#) on the Clinical Trials website.

Each Tuesday: 18:00 – 21:00 Amsterdam time

During this maintenance period, CTIS may be intermittently unavailable.

In addition, EMA's Organisation Management System (OMS) undergoes weekly maintenance in the same period. During the OMS maintenance, CTIS users cannot perform the below actions. Error messages will be displayed for many of these actions indicating that OMS is not available.

- User administration:
 - Updating your employer data
 - Assigning or requesting a role
 - Assigning a role to a Member State National Organisation Administrator (NOA)

- Clinical trial application:
 - Creating a new clinical trial initial application
 - Adding a sponsor to a clinical trial initial application
 - Adding a contact point for Scientific Advice, or as a Legal Representative or Third Party
 - Adding a trial site to part II of the application
- Other:
 - Adding a site to an inspection
 - Creating a new Annual Safety Report

Each Thursday: 18:00 – 21:00 Amsterdam time

During this maintenance period, CTIS may be intermittently unavailable.

Each first Saturday of the month, starting in March, from 10:00 – 14:00 Amsterdam time

During this maintenance period, CTIS may be intermittently unavailable.

Friday 4 March 18:00-Saturday 5 March 12:30 Amsterdam time

During this maintenance period, EudraCT will undergo scheduled maintenance. During this maintenance period, CTIS users cannot perform the below actions in CTIS. No error message will be displayed in CTIS for these actions.

- Linking the EudraCT clinical trial application to the clinical trial application in CTIS in the case of transition trials
- Adding EudraCT trials using the associated clinical trials functionality, in the CTIS clinical trial application

[More information](#)

Users can review [Module 06 – Evaluate a clinical trial application: Selection of RMS and validation of a clinical trial application](#) for more information on the validation of clinical trial applications in CTIS. Users can also consult [Module 23 – Transitional trials](#) for further information on transitioning trials to CTIS.

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