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CTIS newsflash – 27 January 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 on the implementation of the Clinical Trials Regulation is also available on the CTIS public portal.

Spotlight: Start date of mandatory CTIS use

CTIS was launched on 31 January 2022, starting the clock for the one-year transition time for sponsors of clinical trials. During the first year of the transition period, clinical trial sponsors can choose whether to submit an initial clinical trial application in line with the Clinical Trials Directive or under the Clinical Trials Regulation, via CTIS.

The last date for sponsors to submit initial Clinical Trial Applications under the Clinical Trials Directive is 30 January 2023.

Starting from 31 January 2023, the use of CTIS will be mandatory for all initial clinical trial applications in the EU. For trials authorised under the Clinical Trial Directive, sponsors can continue to submit amendments under the regime of the Clinical Trial Directive until the end of the transition period on 30 January 2025.

Key Updates

On Friday 20 January 2023, over 1900 viewers followed a live broadcast of the CTIS public event on "Readiness for mandatory use of the Clinical Trials Regulation from 31 January 2023". A recording of the broadcast will be made available on the dedicated event page.

A CTIS release went live on 26 January 2023, delivering further system improvements and enhancing the user experience. The improvements include:

- Member States Concerned are able to submit Part I Disagreement for Substantial Modification (SM) part I only or SM part I and II in cases where part II was submitted only to the Reporting Member State (RMS), even if the RMS already issued a decision on the application.

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- The "Authorise" task for Member State users correctly displays conditions for the Part II decision related to the corresponding Member State and will not include conditions of other Member States Concerned (MSC).
- Member States users are able to retrieve the complete list of notifications present in a clinical trial application via the Member State API.
- The display of page entries in the Member State API has been improved.
- The date of a tacit decision is correctly displayed, matching the expiration of the "Authorise" task, i.e. 23.59.59 on the due date.
- The updated information in "number of subjects" created as a response to a Request for Information (RFI) by clicking on "Change application" is only displayed in the authority workspace and Member State API after submission.
- The decision section of an Additional Member State application only includes the Part I disagreement related to that application.
- For authorised medicinal products, the active substance details are correctly retrieved and populated in CTIS.
- The due date of the "Consolidate Considerations" and "Submit RFI" tasks are calculated using Central European Time (CET) instead of Universal Time Coordinated (UTC).
- Behaviour of the Pop-up Cancel Button has been improved to ensure that the user action performed is indeed cancelled.
- The sponsor and Member State users are able to download documents with special characters in the document name.
- When visiting the public portal, users are no longer logged out of the Sponsor or Authority workspace.

The full list of improvements is available in the published release notes. Users are also advised to consult the Lists of known issues and proposed workarounds.

EMA continues to work closely with Member States, the European Commission, and stakeholders to improve the CTIS user experience. By the time the use of the system becomes mandatory for all initial applications on 31 January 2023, we are on track to have no blocking issues in the core CTIS processes. The Agency has invested additional resources to achieve this goal.

How to raise a ticket in CTIS User Support Service

Before raising a ticket to the CTIS User Support Service, users are 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 highlight any deadlines.

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

Step 4 – Under Attachments, upload any relevant screenshots.

EMA is monitoring tickets daily and has reinforced the User Support Service to prepare for 31 January 2023 and the mandatory use of CTIS.

How to remove personal information in document properties

When uploading documents to CTIS, personal information may be contained in the document properties. It is the responsibility of sponsor or member states users submitting data to CTIS to ensure that personal information is not contained in the document properties before upload. Users are encouraged to review the training documentation and in particular the Guide on CTIS Common features, which is being updated to include instructions on removing personal information from document properties.

Reminder: CTIS Sponsor end user training course 7-10 February 2023

EMA offers a virtual training course, organised by DIA, to support sponsor user preparedness for CTIS and the new way of submitting a clinical trial application and managing the lifecycle of a clinical trial. A hands-on approach is taken to explaining and demonstrating the functionalities of the system, such as user management, how to submit an initial application as well as modifications, both substantial and non-substantial. In addition, how to manage the lifecycle of a Clinical Trial, how to apply Deferral rules and how to respond to an RFI will be addressed. Further information is available on the event page.

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.