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European Medicines Agency

CTIS newsflash – 13 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

A CTIS release was deployed on 12 January 2023, implementing several functional **improvements**:

- Improved functionality on the submission of an application to add a new Member State Concerned.
- Sponsors are now able to add or remove the Proof of Payment during the response to an RFI in all evaluation phases.
- Sponsors are now able to change an application that is part of the response to an RFI raised in the context of an Additional Member State Concerned application or Substantial Modification.
- Sponsors will be prevented from submitting an initial application that does not contain a valid EudraCT number.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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- Sponsor users will no longer receive a validation error message when users work in parallel in the IMPD-Q and Safety & Efficacy placeholders, ensuring only documents or a justification is included in both.
- Member States are able to retrieve via the Member State API all trial site information and the complete list of age range.
- Member States Concerned now receive the notices "RFI sent to sponsor", "Consolidated consideration shared" and "Response to RFI submitted", in case of submission of partial initial applications (part I only).
- Member State users are able to select all considerations, consolidated considerations and RFI, regardless of the number of pages required to list all of them.

More information on the latest system improvements are available in the published release notes as well as in the Lists of known issues and proposed workarounds.

The European Commission has published an updated version of the Questions and Answers document for the Clinical Trials Regulation (EU) No 536/2014 in December 2022.

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

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

CTIS Walk-in Clinic on 18 January 2023

EMA will host a virtual CTIS Walk-in Clinic on 18 January 2023 from 16:00-17:00 CET. Sponsor users will have the opportunity to raise questions about any CTIS functionality and receive advice from CTIS experts. CTIS users can submit and upvote questions in advance as well as during the live sessions via Slido. Further information is available on the event page.

Save the date: CTIS Event on 20 January 2023

A public "CTIS Event on Readiness for mandatory use of the Clinical Trials Regulation from 31 January 2023" is taking place on Friday, 20 January 2023 from 10:00–13:00 CET. The agenda and further information, including the broadcast link, are available on the dedicated event page.

Stakeholders are invited to raise questions in advance of the event, starting on 6 January to 16 January 2023, via the interaction tool Slido. Please go to www.sli.do and enter the event code "CTIS2023".

Reminder: Access to Sandbox

Sponsor users who want to be trained on CTIS have the opportunity to express their interest in gaining access to the CTIS Training Environment (Sandbox), by filling in the ongoing survey.

CTIS Sandbox 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.