10 February 2023
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European Medicines Agency

CTIS newsflash – 10 February 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 highlighting the start of CTIS mandatory use is available on the EMA website.

Spotlight: Updated Q&A on IMPD-Q by European Commission

The revised Questions and Answers document for the Clinical Trials Regulation (EU) No 536/2014 published by the European Commission in EudraLex Volume 10 includes a dedicated item to provide guidance on how a third party other than the sponsor can submit a document as part of the Investigational Medicinal Product Dossier (IMPD) in CTIS.

CTIS now mandatory for initial Clinical Trial Applications

Since 31 January 2023, the use of CTIS is mandatory for all initial clinical trial applications in the EU/EEA. **Therefore, sponsors can no longer submit initial EU/EEA Clinical Trial Applications under the Clinical Trials Directive.**

For trials submitted to the National Competent Authorities (NCAs) before 31 January 2023 under the Clinical Trial Directive (CTD), sponsors can continue to submit any amendments under the regime of the CTD until the end of the transition period on 30 January 2025, including requests for the NCAs to update their trials' status. EudraCT trial results need to be submitted through the EudraCT database, even after the end of the transition period, as applicable, unless the trial was transitioned earlier to CTIS.

The EudraCT website has been updated accordingly and is therefore to be used only for the purposes of:

- updating information on EudraCT trials submitted until 30 January 2023, under the Directive (CTA amendments, status updates, results submission)
- creating and submitting third country files of Paediatric Investigation Plans (PIP)/Art 46 trials conducted exclusively in third countries (outside of the EU/EEA)

Additional information on the topic can be found in the EudraCT FAQs (questions 98-114).

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Key Updates: Experience since mandatory use 31 January 2023

With the aim to enhance transparency on system use, we are introducing a section on weekly CTIS metrics to share key data and trends compared to the previous week. The data presented below refers to the period from 31 January to 6 February 2023.

CTA Submissions

Initials
29
+32%
to previous week

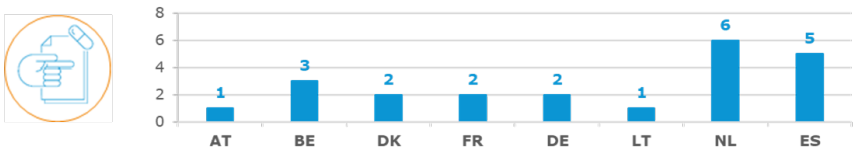
Substantial Modification
16
+129%
to previous week

Additional MSC
None

CTAs with a Decision

Initials
22
+22%
to previous week

CTAs with a Decision per RMS



EMA continues to work closely with Member States, the European Commission, and stakeholders to improve the CTIS user experience and support sponsors.

System improvements

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.

Performance

- Resolve timeouts for large, complex trials
- Improve transaction efficiency through code improvements and asynchronous processing
- Transition to a high-availability infrastructure

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

Public Portal

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

Information Security

- Enrol CTIS in 24 by 7 monitoring through EMA's Security Operations Center
- Develop plans for the implementation of multi-factor authentication

Transitional Scope

- Implement remaining 5 disaster recovery scenarios
- Enable Anatomical Therapeutic Chemical Search

Priority stakeholder requests

- Strengthening Service Desk operations
- Connectivity to WHO registry
- Improve download and sorting of documents
- Launch business intelligence

The next CTIS release is foreseen to take place next week, and will implement several improvements to enhance user experience:

- Notices and Alerts will be displayed to users with Union Controller roles and EMA Admin, as applicable.
- Alerts that are no longer applicable when a clinical trial application (CTAs) is withdrawn will be removed.
- The search functionality will be improved in the following instances:
    - retrieving medicinal products with more than 35 substances
    - Member States Concerned retrieving partially submitted CTAs
    - adding a product using the ATC code
- Issues with duplication of IMP and AxMP-related documents will be resolved.
- The structured data present in the PDF downloaded related to sections "IMPD-Q" and "sponsor contact point for the Union" will show the most updated information displayed in the UI.
- User profiles with combined roles of Member State Admin and National Organization Admin will only manage users (assign/ revoke/ amend) affiliated with the Member State Admin organization.
- Resolving error message when trying to submit an RFI response

In addition to the above functional improvements, several technical improvements are also foreseen to be implemented in the same release:

- Disaster recovery scenarios related to Timetable and Restart of Trial
- WHO API basic setup
- Improved performance of Substantial Modification detail review process
- Ensuring data download includes the latest entries

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.

Training Material on data protection

Users are encouraged to consult the EMA training material on data protection:

- Module 12 of the online training programme "Data Protection in CTIS"
- Question 2.5 of the FAQ on Module 10 "Create, submit and withdraw a clinical trial"
- Q&A document providing preliminary guidance to CTIS users on how to protect personal data and commercially confidential information (CCI) in CTIS

A dedicated section on Transparency, with useful links to reference materials, has been added to the CTIS website: Guidance and Q&As - EMA (euclinicaltrials.eu). Further information on the protection of personal data and CCI in CTIS is also available on the EMA website.

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.