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European Medicines Agency

CTIS newsflash – 24 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 CTIS website.

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

The revised Questions and Answers document for the Clinical Trials Regulation (EU) No 536/2014 published on 17 February 2023 by the European Commission in EudraLex Volume 10 provides guidance on how a third party, other than the sponsor, can submit in CTIS the quality section of the Investigational Medicinal Product Dossier (IMPD-Q). The revised Q&A also includes an update to Annex II (language requirements for part I documents) following amendments by France and Norway in the relevant table.

Key Updates

EMA has initiated the process to register CTIS as a WHO data provider. Once the registration process is completed, CTIS data will be included in WHO's International Clinical Trials Registry Platform (ICTRP) Search Portal. Further updates will be provided in future issues of this Newsflash.

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

Current operational experience with CTIS

With the aim to enhance transparency on system use, 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 14 to 20 February 2023.

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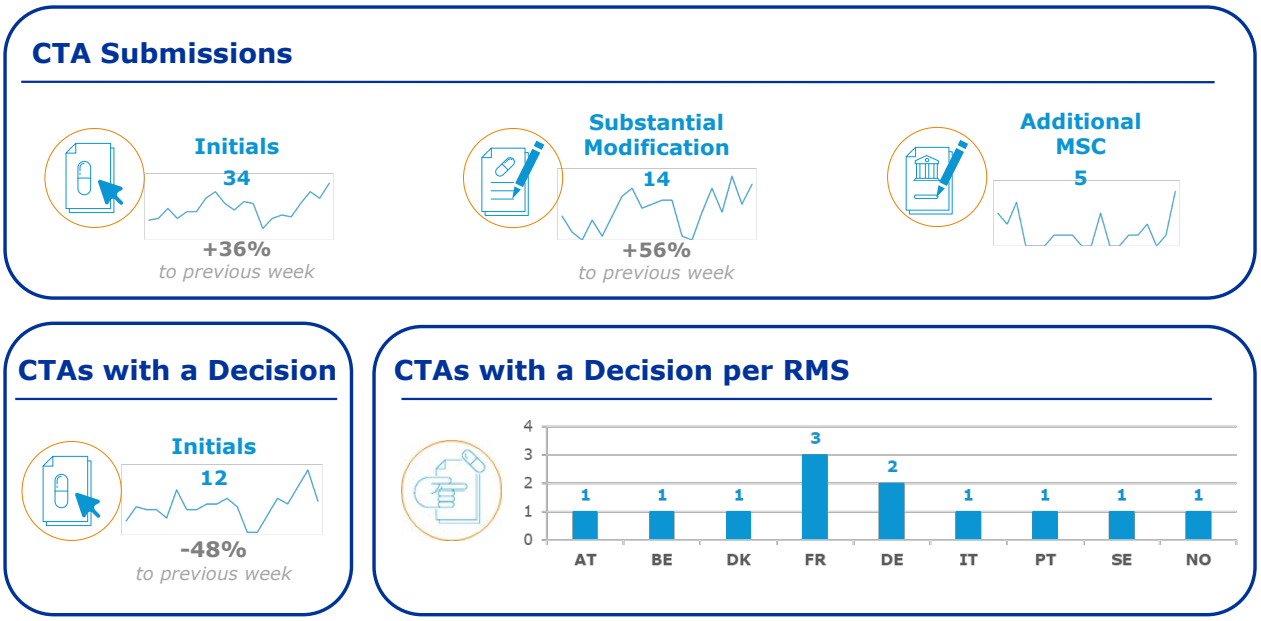


System improvements

A CTIS "Hotfix" which was implemented on 20 February 2023 has enabled a group of sponsors to change an application through the response to a Request for Information (RFI) by resolving database locks that had occurred in a small number of trials.

Due to the need for extended testing, the next CTIS release is now foreseen to take place next week. This release 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 auxiliary medicinal products (AxMP)-related documents will be resolved.
- The downloaded PDF documents related to sections "IMPD-Q" and "sponsor contact point for the Union" will include the latest information displayed in the user interface.
- 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.
- When trying to submit an RFI response, an error message will no longer appear.

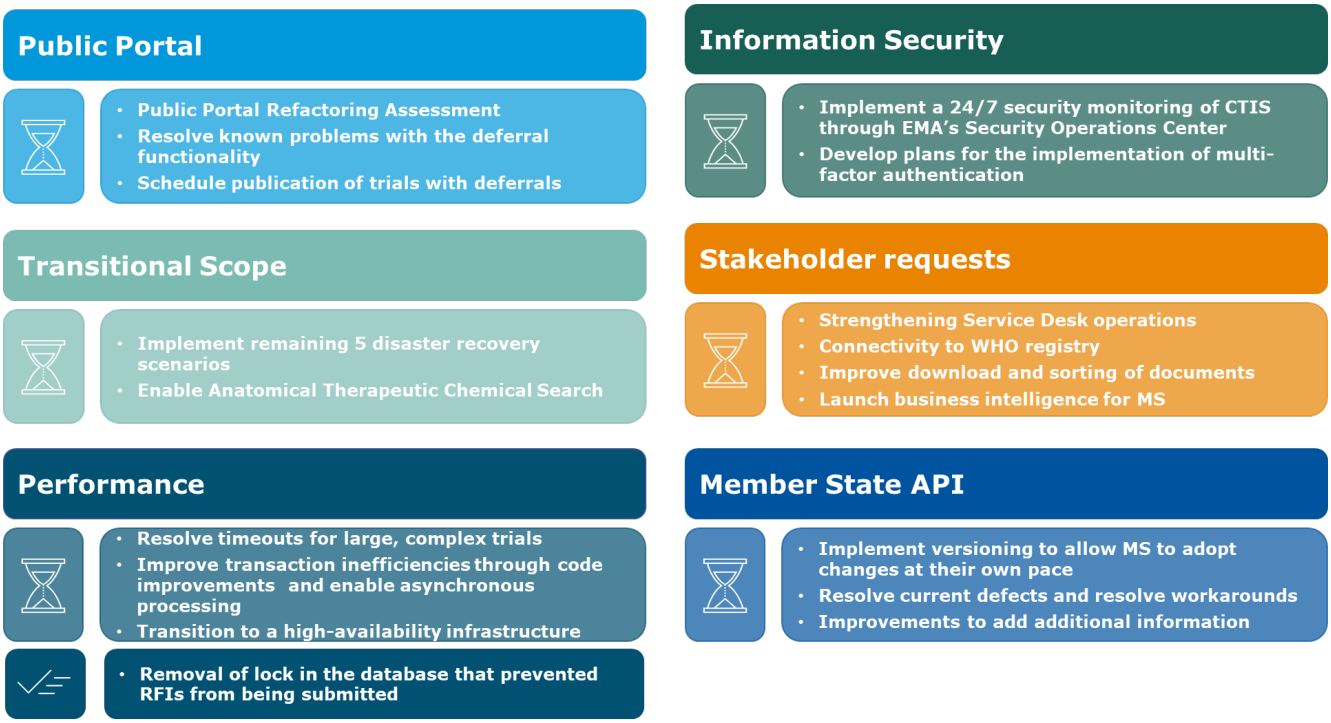
In addition to the above functional improvements, several technical improvements are also foreseen to be implemented in the same release:

- 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.

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.



Initial launch of CTIS Business Intelligence system

Following the initial launch of the CTIS Business Intelligence (BI) system, EMA hosted a full-day training for Member State-nominated experts on 21 February 2023. The CTIS BI system enables Member State users to run faster, bespoke queries in a user-friendly dashboard, also allowing them to customise and save queries for future use. As more Member States start using the CTIS BI system - which is distinct from core CTIS - query load in the core of CTIS will be reduced, therefore improving overall performance to the benefit of all users.

Training material and guidance for SMEs & Academia users of CTIS

With the aim to support SMEs and Academia conducting clinical research using CTIS, EMA has published dedicated training and guidance material adapted to these users' needs. The community can consult the online training module 19 for SME/Academia, the recordings of CTIS webinars targeted to SME & Academia and the infographic Sponsor Quick Guide to CTIS. EMA also regularly publishes a newsletter for SMEs with key updates on the European regulatory environment.

Reminder: Personal information in document properties

When uploading documents in CTIS, personal information may be contained in the document properties. It is the responsibility of sponsor or Member States users to ensure that personal information is removed from the document properties before submitting any data to CTIS. Users are encouraged to review the training documentation and in particular the Guide on CTIS Common features of module 02, which includes instructions on removing personal information from document properties.

Under the Joint Controllership Arrangement (JCA) for CTIS, users share responsibility in protecting personal data when uploading data and documents during the trial life cycle. For further information on the JCA, users may consult the related Q&A document.

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.