8 December 2023
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European Medicines Agency

CTIS newsflash – 8 December 2023

Introduction

This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

The next issue will be circulated on 22 December 2023.

Previous issues of the CTIS Newsflash are available on the EMA website.

Winter clock stop

All timers within the evaluation of a clinical trial application will stop on 22 December 2023 at 23:59:59 CET and resume on 8 January 2024 at 00:00:01 CET.

Due to this winter clock stop, the timelines for the applications may be affected. More information is available in the CTIS evaluation timelines document.

CTIS User Support Service updates

Improvement of the CTIS User Support Service remains a priority for 2024.

Following the migration of the CTIS User Support Service from JIRA to ServiceNow, all remaining tickets in JIRA will be closed. For issues with significant impact on users, new tickets will be opened by the CTIS team in ServiceNow and users will be provided with the corresponding ticket numbers and links.

As part of the CTIS improvement plan for 2024, to ensure a faster and better response to priority tickets, a limited number of ServiceNow tickets will be closed where they are considered to no longer impact users. If you are informed of a ticket being closed and you consider that the issue continues to have a significant impact on you, then please raise a new ticket in ServiceNow.

Updated guidance for CTIS users

- **CTIS transparency rules:** The Q&A on protection of confidential information and personal data in CTIS has been updated and a quick guide for users has also been published on the ACT EU website. The Q&A now includes a section regarding the interim period until the new rules are in effect and on historical trials (all trials submitted until this date); the quick guide provides a

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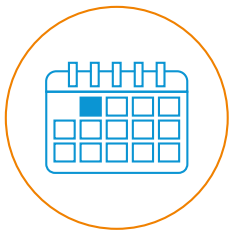
summary of what will be published under the revised rules, the relevant timings of publication, and on the new section of the mentioned Q&A.

- **Transitioning trials to CTR:** The CTCG has published revised versions of the Best Practice Guide and cover letter template for sponsors transitioning multi-national clinical trials to the Clinical Trials Regulation (CTR) and CTIS. The revised guide includes clarifications on background treatment and the status of non–Investigational Medicinal Products in the Clinical Trials Directive (CTD) under the CTR (Investigational Medicinal Product or Auxiliary Medicinal Product). The document also includes recommendations for transitioning clinical trials including such products from the CTD to the CTR.



Save the date: CTIS Walk-in Clinic

On 13 December 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CET. Participants were able to submit their questions in advance until 7 December via Slido with the code #clinic2312.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu).

Changes in OMS and potential impact on CTIS users

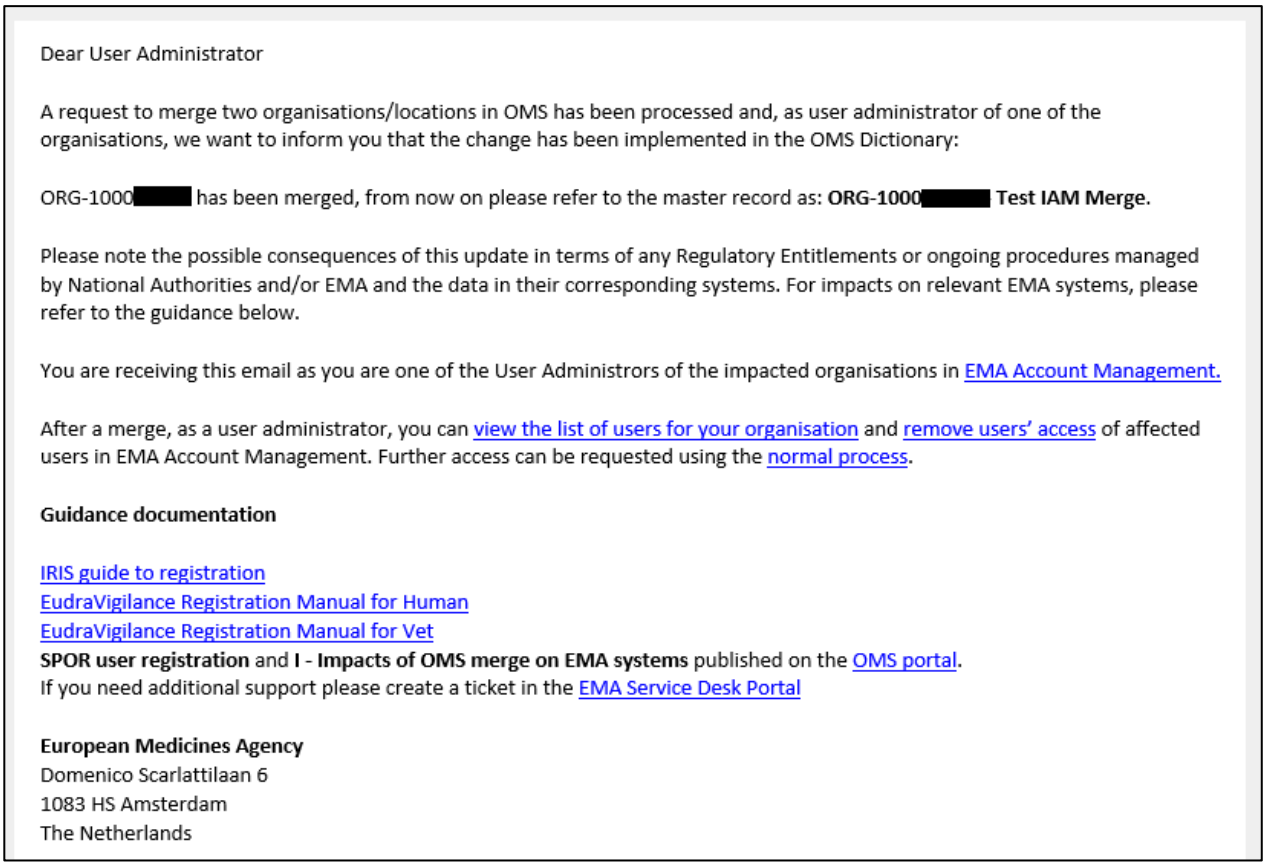
During creation of a new organisation in OMS via CTIS, users need to fill in the "City" field, which is now mandatory. If this field is left blank, users will receive an error message.

Additionally, following the 'Data quality standard in OMS' guidelines (document available on the SPOR portal), the OMS team will be merging organisations that have been identified to be identical and deleting the organisation-IDs of duplicate organisation(s). This may affect trials in CTIS under the deleted organisation-ID. In such cases, CTIS users may encounter issues during the submission of Annual Safety Reports (ASR) for trials under deleted organisation-IDs.

The change will **not** affect users' access nor their ability to submit applications or Request for Information (RFI) responses. Trials that have been submitted under the remaining organisation-ID will **not** be affected.

From mid-December 2023, CTIS users with an Administrator role in EMA Account Management (CTIS Sponsor Admin, External Organisation Administrator or Administrator role for other EMA Applications) will start receiving notifications (via email) if their organisation has been merged. If users receive such notifications and need to submit ASRs for trials under **deleted** organisation-IDs, they will need to contact the EMA User Support Service and raise a ticket to request the migration of the affected trials to the remaining organisation-ID.

An example of such a notification is included below.



Dear User Administrator

A request to merge two organisations/locations in OMS has been processed and, as user administrator of one of the organisations, we want to inform you that the change has been implemented in the OMS Dictionary:

ORG-1000[redacted] has been merged, from now on please refer to the master record as: **ORG-1000[redacted] Test IAM Merge.**

Please note the possible consequences of this update in terms of any Regulatory Entitlements or ongoing procedures managed by National Authorities and/or EMA and the data in their corresponding systems. For impacts on relevant EMA systems, please refer to the guidance below.

You are receiving this email as you are one of the User Administrors of the impacted organisations in EMA Account Management.

After a merge, as a user administrator, you can view the list of users for your organisation and remove users' access of affected users in EMA Account Management. Further access can be requested using the normal process.

Guidance documentation

IRIS guide to registration
EudraVigilance Registration Manual for Human
EudraVigilance Registration Manual for Vet
SPOR user registration and **I - Impacts of OMS merge on EMA systems** published on the OMS portal.
If you need additional support please create a ticket in the EMA Service Desk Portal

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More details on the potential impact of organisation-IDs merges on CTIS users will be published in January 2024 and the CTIS training material will be updated accordingly.

Outcome of the ACT EU multi-stakeholder workshop on methodology guidance

The Accelerating clinical trials in the EU (ACT EU) initiative hosted a multi-stakeholder workshop on clinical trial methodology guidance on 23 November 2023.

Stakeholders and regulators exchanged views on key methodology topics, with a focus on patients' needs. Over 110 participants from key stakeholder groups and the European Medicines Regulatory Network (EMRN) had the opportunity to work together in breakout sessions to identify the main challenges for key topics on clinical trial methodology and to propose the best way forward. The outcome of these discussions will be published in a workshop report on the event page and used to inform future work of the EMRN in methodology guidance development.

Current operational experience with CTIS

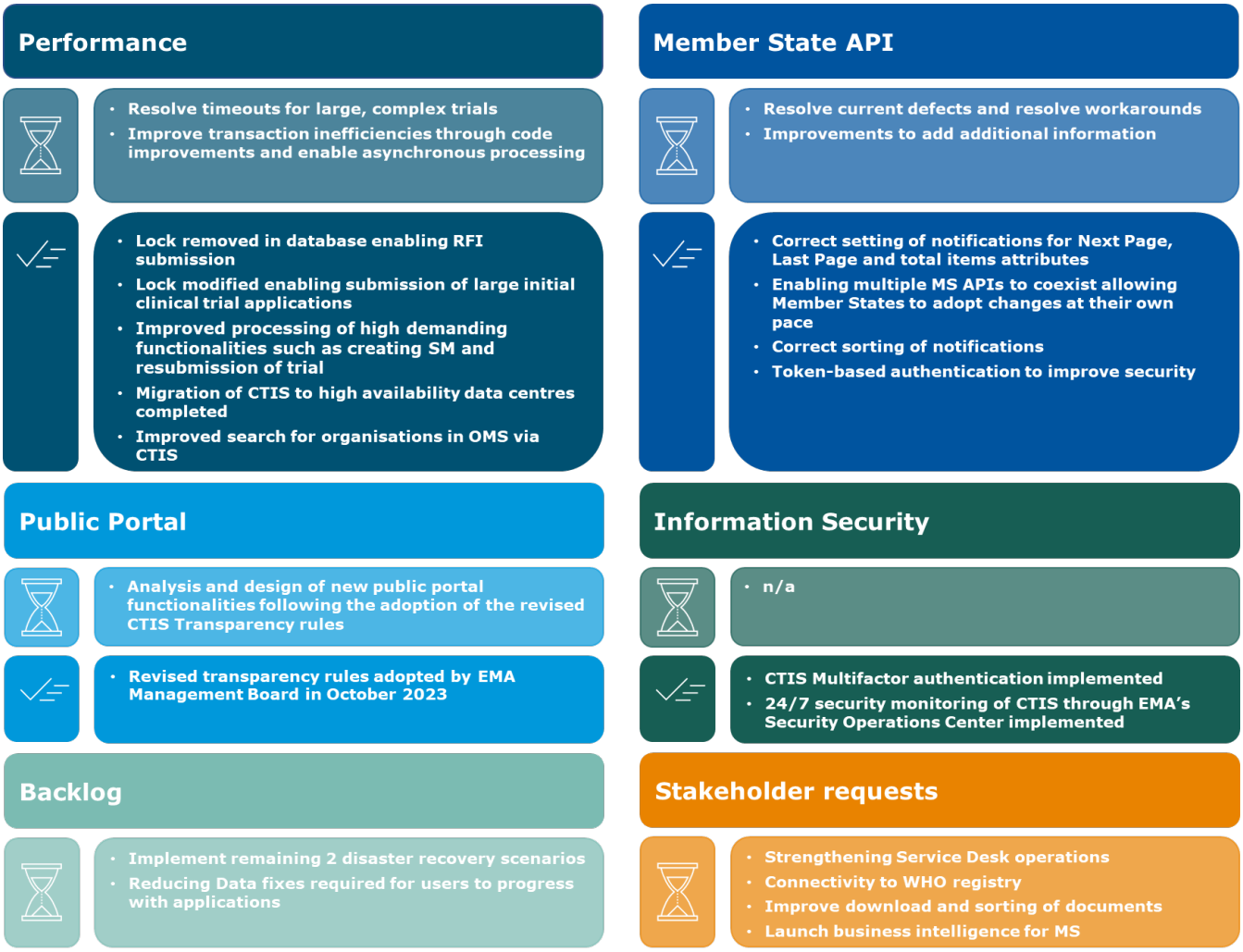
This section on weekly CTIS metrics provides key data and trends compared to the previous week.

Data on the weekly operational experience in CTIS for the period from 21 November to 4 December 2023 will be provided in the next issue of this newsflash.

System improvements

EMA continues to closely monitor user feedback, working in 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 and the improvements implemented.



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.

Reminder: Requesting access to the CTIS Training Environment

Sponsors can 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. Due to limited capacity, access to eligible users is provided for a limited period of time. In addition, access is prioritised for users/organisations with no previous access in the system.

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.