29 April 2025
EMA/124649/2025
European Medicines Agency

CTIS newsflash – 29 April 2025

Introduction

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

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

The next issue will be circulated on 13 May 2025.

Key updates

- Due to the power outage in Portugal and Spain, all deadlines in CTIS with a due date on Monday 28 April 2025 have been exceptionally extended by 24 hours to 29 April 2025. We advise users to double check the due dates in CTIS and contact the Service Desk for any additional support.
- EMA is hosting a CTIS Info day on 22 May 2025. The half-day informational webinar aims to provide an overview of CTIS, its optimisations, best practices, and upcoming developments.
- The quarterly report monitoring the EU clinical trials environment for January – March 2025 has been published on the ACT EU website.
- CTCG has published an updated cover letter template for the submission of initial clinical trial applications in CTIS. High-quality cover letters facilitate validation and assessment.

Tip for sponsors: merging identical organisations in OMS

When two Sponsor organisations merge, this needs to be correctly reflected in Organisation Management Service (OMS) and Clinical Trials Information System (CTIS). Following the 'Data quality standard in OMS' guidelines (document available on the OMS document repository of SPOR portal), the OMS team merges organisations that have been identified to be identical and deletes the organisation-IDs (ORG-ID) of duplicate organisation(s).

In CTIS, this may affect trials registered under the deleted organisation-ID. CTIS users may encounter issues during the submission of Annual Safety Reports (ASR) for trials under deleted organisation-IDs (see also FAQ sheet (Q2.18) of CTIS Training Module 18). In addition, administrators cannot assign new CTIS business roles under the deleted organisation-IDs. The change does 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 are not affected.

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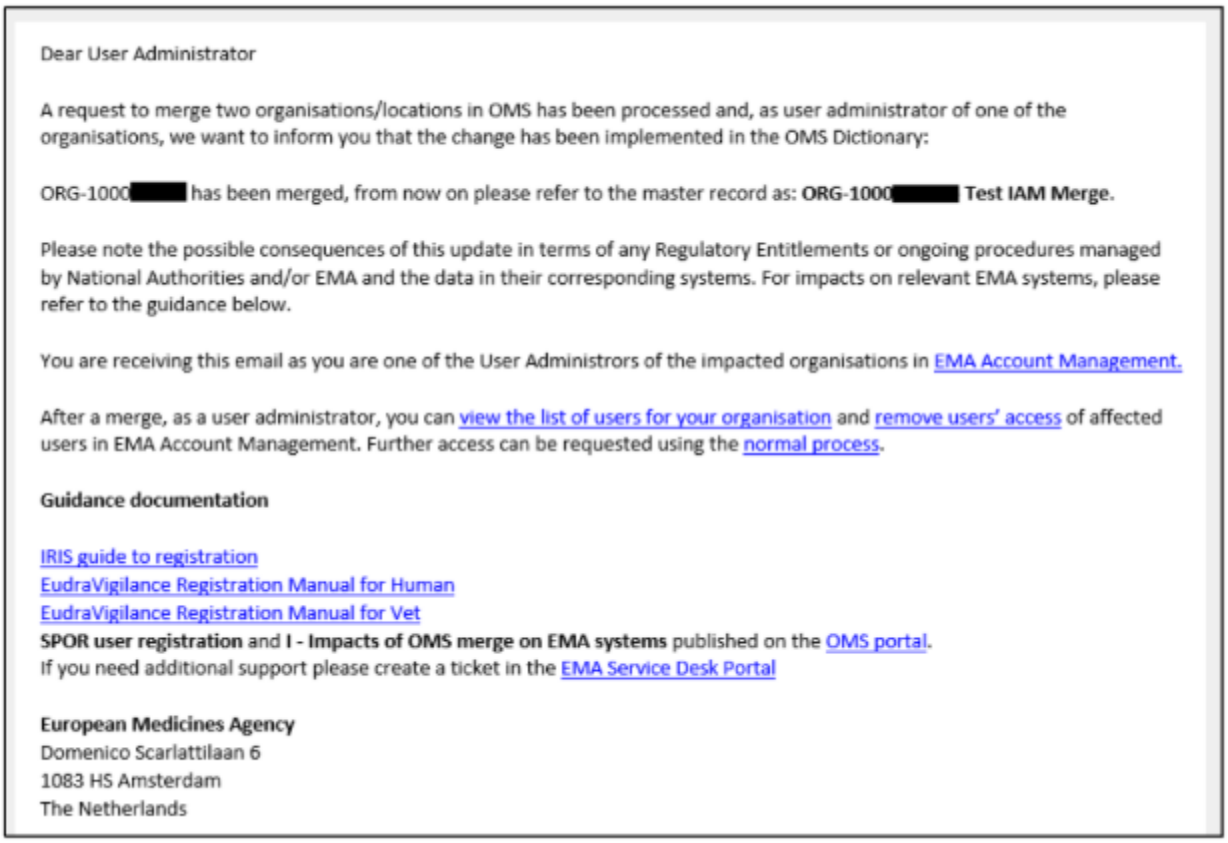
Since December 2023, users that hold Administrator roles in EMA Account Management (i.e. **CTIS Sponsor Admins**, or Admin role for other EMA applications) have been receiving email notifications if their organisation had been merged. Users that receive such notifications (see screenshot below) must check whether the deleted organisation-ID had been used in any of their trials. For trials being conducted under the deleted sponsor organisation-ID, users are advised to submit a Substantial Modification (SM) 'Part I – Change of Sponsor' type, to avoid any of the abovementioned problems.



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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Guidelines on how to submit an SM to change the sponsor of a trial have been published in the CTIS newsflash of 26 July 2024, and in relevant guidelines (in 'Key documents' section), hosted on the HMA CTCG webpage.

Similar issues regarding ASR submission, or role management may appear for trials registered under sponsor organisations that start from 'OR**Q**-' and were created locally in CTIS (instead of 'OR**G**-', as the ones validated and approved in OMS). If the request submitted in OMS (with the creation of the sponsor organisation locally in CTIS) is not approved, an SM 'Part I – Change of Sponsor' type is needed to change the sponsor to a valid ID. If the request in OMS is approved, the sponsor users could easily update the organisation ID to the valid one (starting from 'OR**G**-') with the submission of a non-SM, following the guidelines published on the CTIS newsflash of 30 May 2024.

As mentioned in the guidelines, after the authorisation of the SM – Change of Sponsor by all Member States Concerned, all the roles with scope the concerned trial under the old org-ID are automatically revoked. If the new sponsor organisation follows the CT-centric approach (i.e. no Sponsor Admin has been delegated), the initial sponsor users will be informed accordingly, when they try to submit the SM - Change of sponsor. Users with the revoked CT Admin role (due to authorisation of the SM) need to contact the EMA CTIS Service Desk and request that the CT Admin role is assigned to a user that represents the new sponsor organisation.

All the above aspects were presented in the recent CTIS bitesize talk event on 5 March 2025.

System improvements

The CTIS release on 24 April 2025 introduced several improvements.

For all users:

- When assigning or revoking a role, the EMA address and phone number in outgoing emails to the impacted users have been updated to reflect the current details instead of the old UK details.
- The status of withdrawn substantial modification applications (SMs) now correctly appears as "Withdrawn" instead of "Under evaluation", as was sometimes the case.
- The overall trial status is now correctly reflected for multinational trials in the following scenarios:
  - When the trial is lapsed in one Member State Concerned (MSC), not authorised in another MSC and withdrawn in the third MSC, the overall trial status now appears as "Lapsed" instead of "Not Authorised".
  - When a trial is under evaluation in one MSC, not authorised in another MSC, and withdrawn in the third MSC, the overall trial status is now "Under Evaluation" instead of "Not Authorised".
- The banners on the publication rules displayed in the Authority and Sponsor workspaces have been updated according to the revised CTIS Transparency Rules.
- After an MSC reverts a decision on a clinical trial application, the date of the first "Not authorised" decision is no longer updated with the revert decision date.

For authority users:

- When a "Revert" decision occurs in an SM, the new decision now correctly appears in the Authority Workspace under the evaluation tab. The conditions and documents added in the "Revert decision" pop-up are now correctly displayed in the Assessment overview table - Supporting documents section.

More information on the latest system improvements is available in the published release notes.