22 December 2023
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European Medicines Agency

CTIS newsflash – 22 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 12 January 2024.

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.

Recently published documents

- A list of the official public holidays in European countries for 2024, as recorded in the Clinical Trials Information System (CTIS), has been published on the EMA website.
- The November 2023 report on the implementation of the Clinical Trials Regulation (CTR) is now available on the ACT EU website.

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Transitioning trials to CTR/CTIS

By 30 January 2025, any ongoing trials approved under the Clinical Trials Directive (CTD) will fall under the CTR. Therefore, any ongoing trials will need to be transitioned to CTIS and approved by 30 January 2025.

The provision to submit a substantial amendment to EudraCT for trials authorised under the CTD will cease from 31 January 2025. If an ongoing trial authorised under the CTD is foreseen to continue beyond 30 January 2025, it is mandatory to transition it to CTIS before the end of the transition period. All ongoing trials will have to be exclusively monitored and managed through the CTIS under Clinical Trials Regulation (CTR).

Sponsors have submitted around 580 transitional trials to CTIS, out of an estimated total of 5,000 trials that need to be transitioned.

CTCG has agreed on an **expedited, harmonised Member State evaluation procedure open until 16 October 2024** focussing on the validation of minimum application dossiers restricted to documents already authorised under the CTD. After this date and depending on the MS workload, this expedited procedure may not be available.

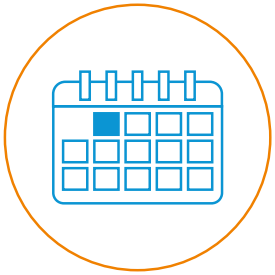
Further resources and guidance from the European Medicines Regulatory Network are available on the CTIS website, in order to support sponsors transitioning their trials to the CTR/CTIS.

Updated guidance on 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 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.

As detailed in section 4 of the updated Q&A document, for initial clinical trials applications sponsors may already follow the principles of the revised CTIS transparency rules. A sponsor may therefore refrain from deferring publication of documents and provide a version 'for publication' and 'not for publication' only for those documents in scope of the revised rules (Annex I of the revised CTIS transparency rules).

Over 590 viewers followed the CTIS Bitesize talk on 29 November 2023. During the event, CTIS experts answered several submitted questions on the CTIS transparency rules and offered clarifications. A video recording of the event will be available on the event page in due course.



Save the date: CTIS Walk-in Clinic

On 24 January 2024, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CET. Participants can submit their questions in advance until 15 January via Slido with the code #clinic241.

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

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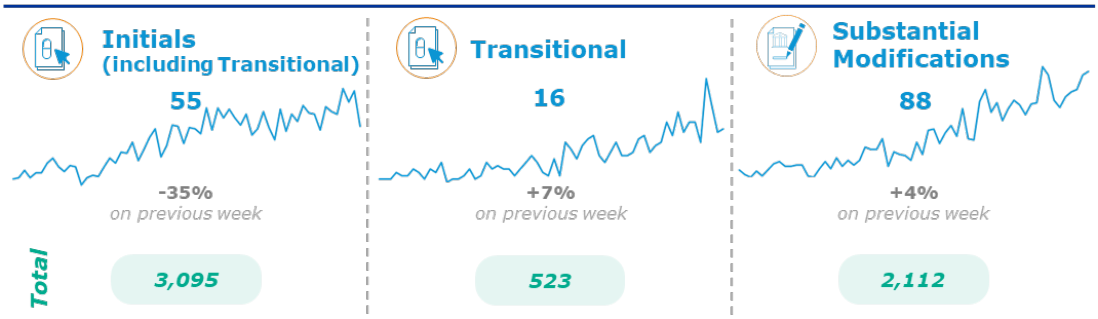
More details on the potential impact of organisation-IDs merges on CTIS users will be published in January 2024 and the CTIS training material will be updated accordingly.

Current operational experience with CTIS

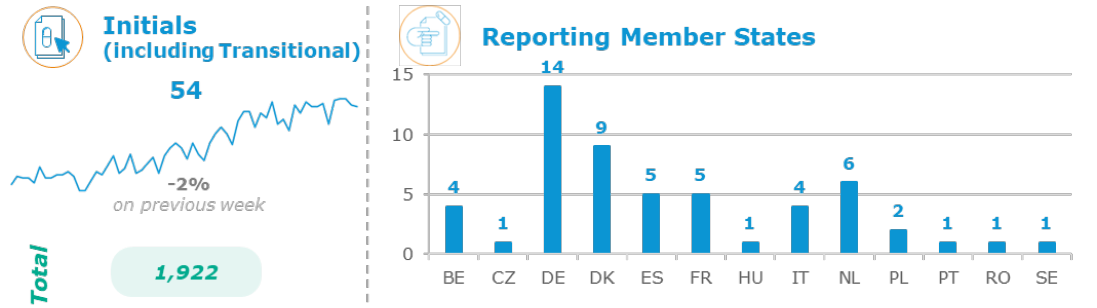
This section on weekly CTIS metrics provides key data and trends compared to the previous week.

The data presented below refer to the period from 5 to 11 December 2023.

CTA Submissions

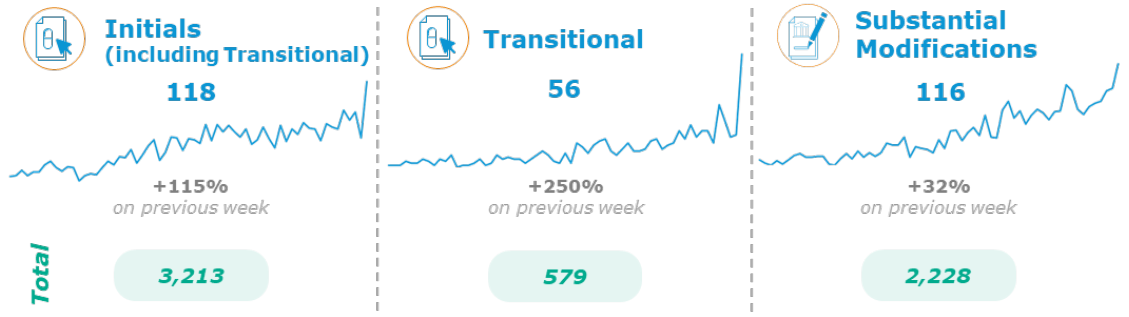


CTAs with a Decision

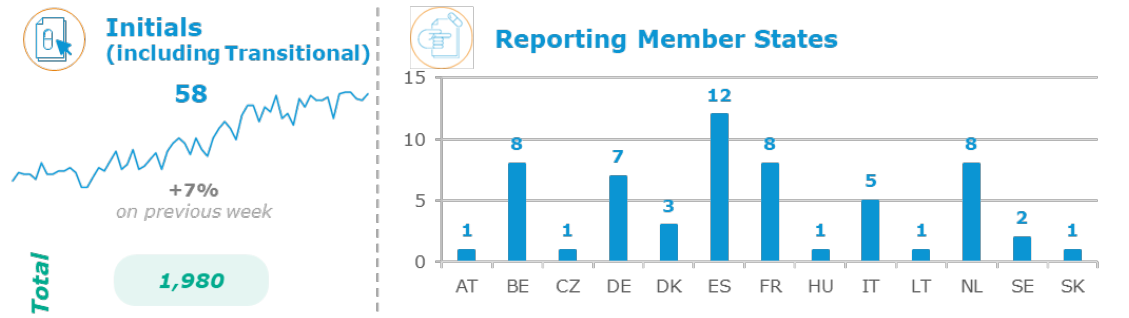


The data presented below refer to the period from 12 to 18 December 2023.

CTA Submissions



CTAs with a Decision



System improvements

The CTIS releases deployed in December 2023 introduced several improvements to enhance user experience:

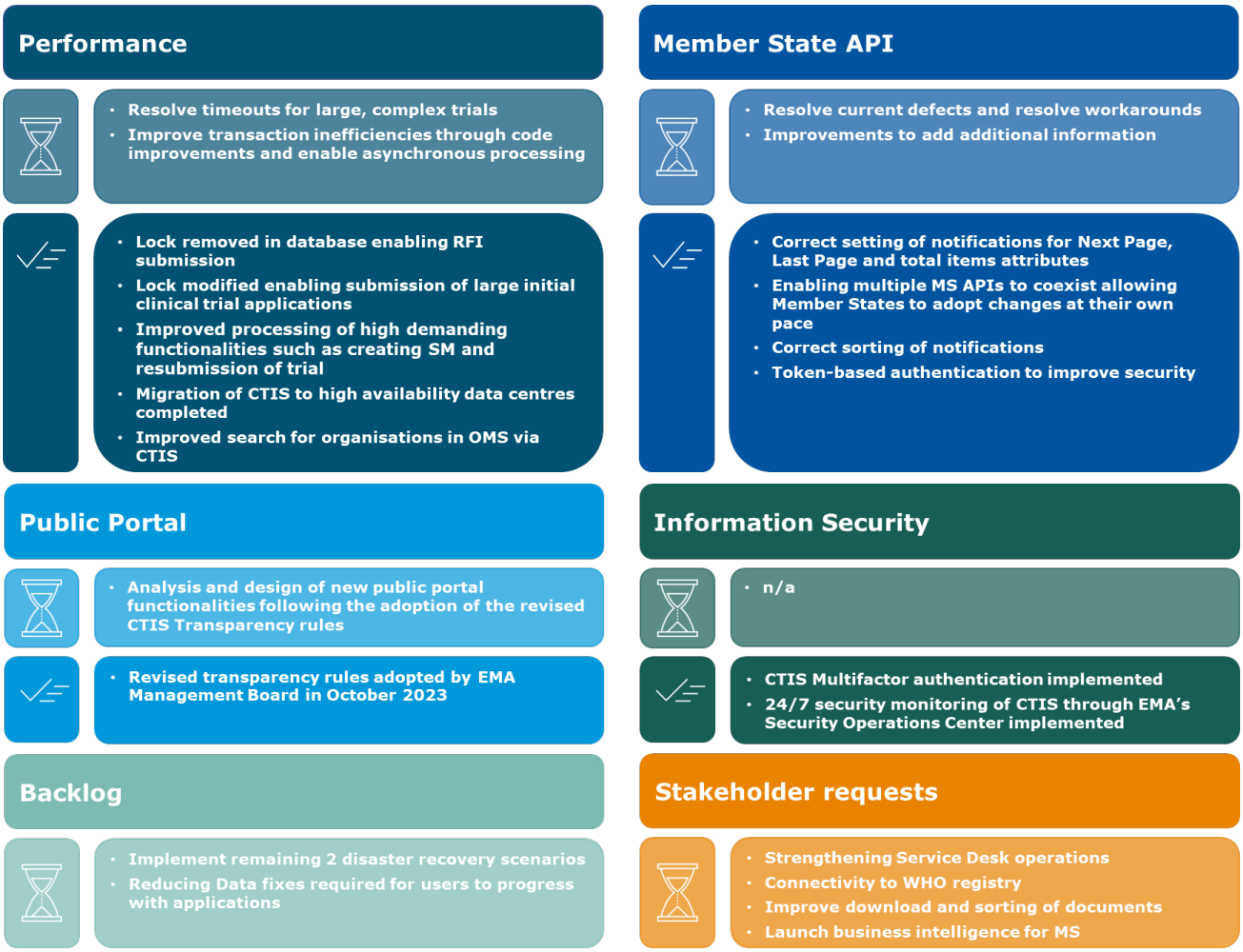
- In an Org-Centric Organisation, a CT Admin user with a "specific clinical trial" scope can now resubmit that specific initial clinical trial application (CTA). Upon resubmitting, the system automatically grants them CT Admin "specific clinical trial" scope to the resubmitted CTA.
- Sponsor users are now able to submit Part II only Substantial Modifications (SMs)/Non-SMs and Additional Member State Concerned (AMSC) applications as well as Assessment Part II Requests for Information (RFIs), even if part I is no longer compliant with business validation rules or if there has been a change of Medicinal Product or Substance EudraVigilance code.
- Sponsor users are now prevented from submitting a Part II for a partially submitted application before the hard task "Submit Part I conclusion" is completed, with only the "Withdraw", "Copy" and "Check" buttons enabled.
- Sponsor users are now able to add, delete, re-add and save translations for existing populated data in draft AMSC applications.
- After the number of subjects is updated in an SM application, the latest authorised information is now displayed in the "Full trial information" tab.
- When responding to RFIs or creating SMs containing Part I, the field "Authorisation number of Manufacturing and Import" in the Medicinal Product section "Compliance with (GMP)" is now editable. In RFI responses, the number previously added in an authorised application is not deleted. Also, highlighted changes do not appear in this field if changes have not been made yet.
- When sponsor users upload supporting documents in response to an RFI, the label for the "not for publication" document in the pop-up window is now correctly displayed.
- When extending the "Start of the recruitment" as approved via SM, the sponsor user is now able to select a date within the extension period until the approved "Anticipated Start of Recruitment Date" and submit the notification within a maximum of 15 days after this extension period.
- Notices and alerts are now generated correctly when a Member State Concerned (MSC) is withdrawn.
- If the AMSC has raised considerations for Part I and the Reporting Member State (RMS) has pending tasks to be completed (Consolidate considerations and/ or Submit RFI tasks) for this Part I, once the "Authorise" task is triggered, a message is displayed to inform the AMSC that there are pending tasks to be completed by the RMS. In this way, the AMSC can then decide whether to wait for the pending tasks to be completed by the RMS or complete the "Authorise" task.
- When submitting applications subsequent to the initial CTA, all tasks are now extended to take into account the winter clock stop.
- In the context of an SM Part I & II, if a MSC is withdrawn after the "Authorise" task is generated, ongoing tasks are now changed to "Cancelled" and future tasks for the withdrawn MSC are not generated. The status also remains "Withdrawn" after the projected due date for the decision has passed.
- When the "Submit Part II conclusion" task expires, the "Conclusion" field now displays "No conclusion". The saved information is no longer visible from the sponsor workspace prior to submission.

- When the "Submit Part I and II conclusion" hard tasks expire, the decision now displays "No conclusion" and any condition added to these task are no longer displayed in the evaluation-assessment overview.
- MS users are now able to generate and download the Part I Draft Assessment Report (DAR) templates.
- In the advance search of the task tab, the use of filters has been improved.
- MS users are now able to view and download documents for trials for which they are not the MSC.
- After an ad hoc assessment is saved and completed, the investigational medicinal product name is now correctly displayed.
- The Annual Safety Report (ASR) search filters in the tasks tab are now working correctly.
- The ASR - safety assessing MS (saMS) selection functionality has been improved:
  - In the "Appoint saMS" task, the MS of the candidate saMS is now correctly displayed in the drop-down menu and the "saMS selection" section is correctly populated in the Authority workspace.
  - In an ASR with multiple MSC if only one MSC expresses willingness via the relevant task ("Express willingness/unwillingness") and the task expires for at least one MSC, the willing MSC automatically becomes saMS (without receiving the task "Appoint saMS") and the normal saMS workflow starts for this MSC.
- MS users are now able to complete the "Authorise" task in an AMSC application of a MS that was previously "Not Authorised" in the initial clinical trial application.
- MS users with a National Organisation Administrator (NOA) Admin role for a "specific clinical trial" and a business role for a different "specific clinical trial" are now able to manage users in line with the scope of their roles.
- The GDPR functionality has been enhanced, enabling users to successfully replace documents while keeping the original metadata.

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.

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.



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.

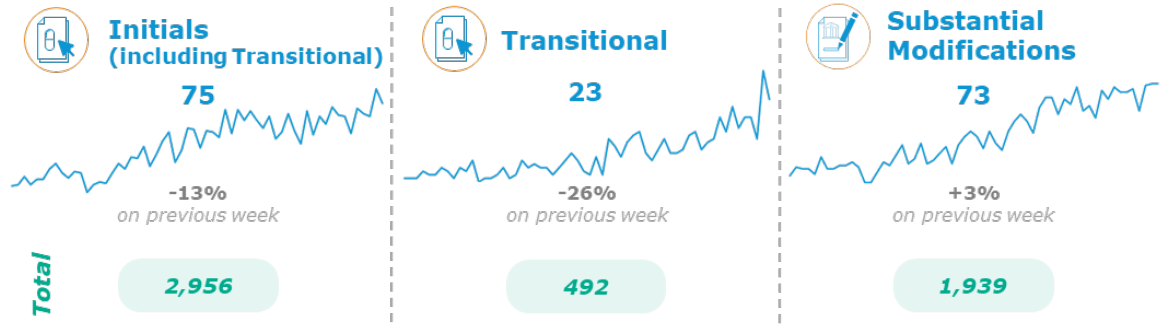
More information

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.

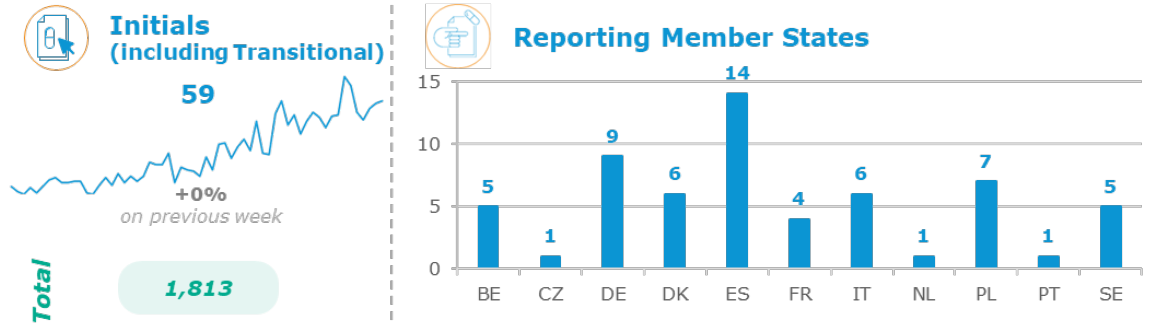
Annex: CTIS operational experience 21 November to 4 December 2023

The data presented below refer to the period from 21 to 27 November 2023.

CTA Submissions

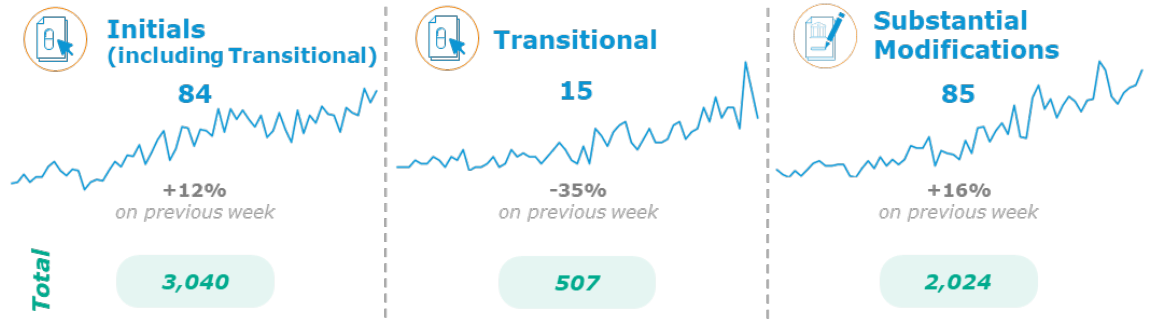


CTAs with a Decision



The data presented below refer to the period from 28 November to 4 December 2023.

CTA Submissions



CTAs with a Decision