29 September 2023
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European Medicines Agency

# CTIS newsflash – 29 September 2023

## Introduction

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

The next issue will be circulated on 13 October 2023.

## Tip for CTIS users: Consult the lists of known issues

Before submitting a ticket with the CTIS User Support Service, users are advised to consult the latest lists of known issues for sponsors or Member States published on Website outages and system releases. These documents outline the issues that sponsor and authority users may encounter when using the CTIS secure workspaces, with possible workarounds.

## Key updates

- The September issue of the Clinical Trials Highlights is now available, with updates on clinical trials topics, including ACT EU and CTIS. Subscribe to receive future issues.
- The latest monthly report on the implementation of the Clinical Trials Regulation (CTR) is now available on the ACT EU website. The revised report includes Key Performance Indicators (KPIs) on clinical trials (CTs) transitioned from the Clinical Trials Directive to the CTR. Data on the EudraCT database, which is no longer in use for submitting new CT applications, is no longer be reported. EudraCT remains in use for ongoing CTs and posting of results.
- Previous editions of the monthly KPI report on the implementation of the CTR, as well as the final guidance document, annexes and Q&A on the protection of personal data and commercially confidential information in CTIS can now be found on the ACT EU website, under the webpage Implementation of the Clinical Trials Regulation.
- The European Commission has published a new version of the CTR Quick Guide for sponsors. This revised version includes clarifications on how to submit the IMPD-Q on the manufacturing of the Investigational Medicinal Product in case this is done at a decentral point of care, at one of the clinical trial sites in the additional Member State.

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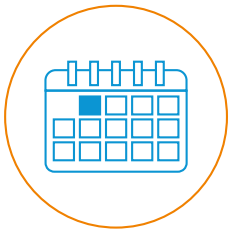
## Transitioning trials to CTIS

By 30 January 2025, any ongoing trials approved under the Clinical Trials Directive will fall under the CTR. Therefore, any ongoing trials will need to be transitioned to CTIS and approved by 30 January 2025. Sponsors have submitted around 320 transitional trials to CTIS, out of an estimated total of 4,000-6,000 trials that need to be transitioned.

Guidance for sponsors transitioning trials from the Clinical Trials Directive to the CTR/CTIS is available:

- in the Guidance for the transition of clinical trials published by the European Commission under EudraLex volume 10;
- in the CTCG's best practice guide and cover letter template for sponsors of transitional trials;
- under Module 23 of the CTIS online training programme.

National Competent Authorities of the EU/EEA Member States remain responsible for keeping the information on the trial status in EudraCT up to date, including inserting the end of trial date once notified by the sponsor.



## Upcoming CTIS trainings and events

Registrations are open for the CTIS sponsor end user training course on 10-13 October 2023, 09:00-13:30 CEST. The course is addressed to commercial and non-commercial sponsors and Contract Research Organisations (CROs).

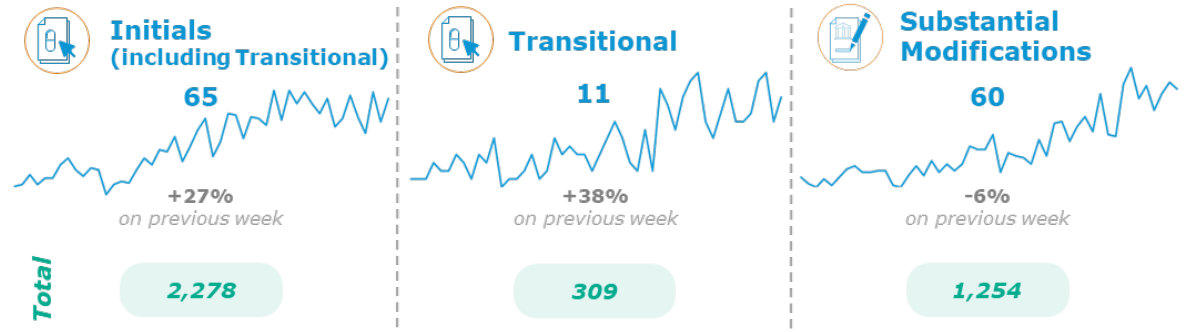
Interested participants can also register for the virtual CTIS Info day planned on 17 October at 13:30-17:30 CEST. Questions may be submitted in advance by 3 October 2023.

## Current operational experience with CTIS

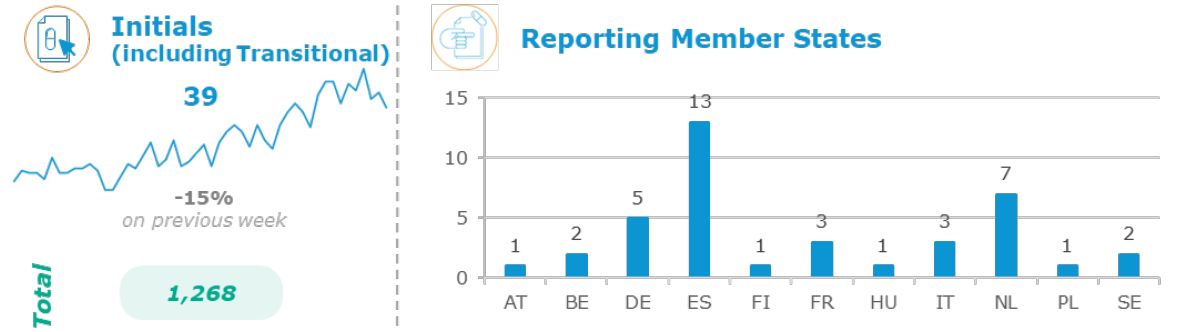
This section on weekly CTIS metrics provides key data and trends compared to the previous week.

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

## CTA Submissions



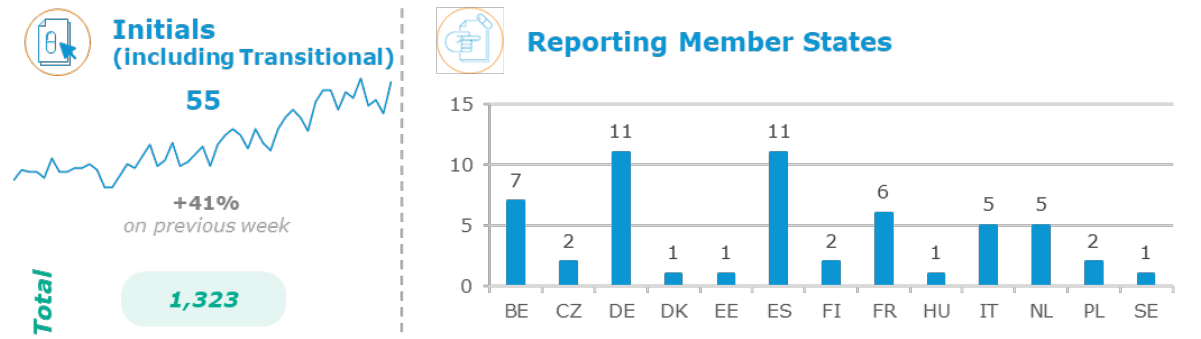

## CTAs with a Decision




The data presented below refers to the period from 19 to 25 September 2023.

## CTA Submissions


## CTAs with a Decision



## System improvements

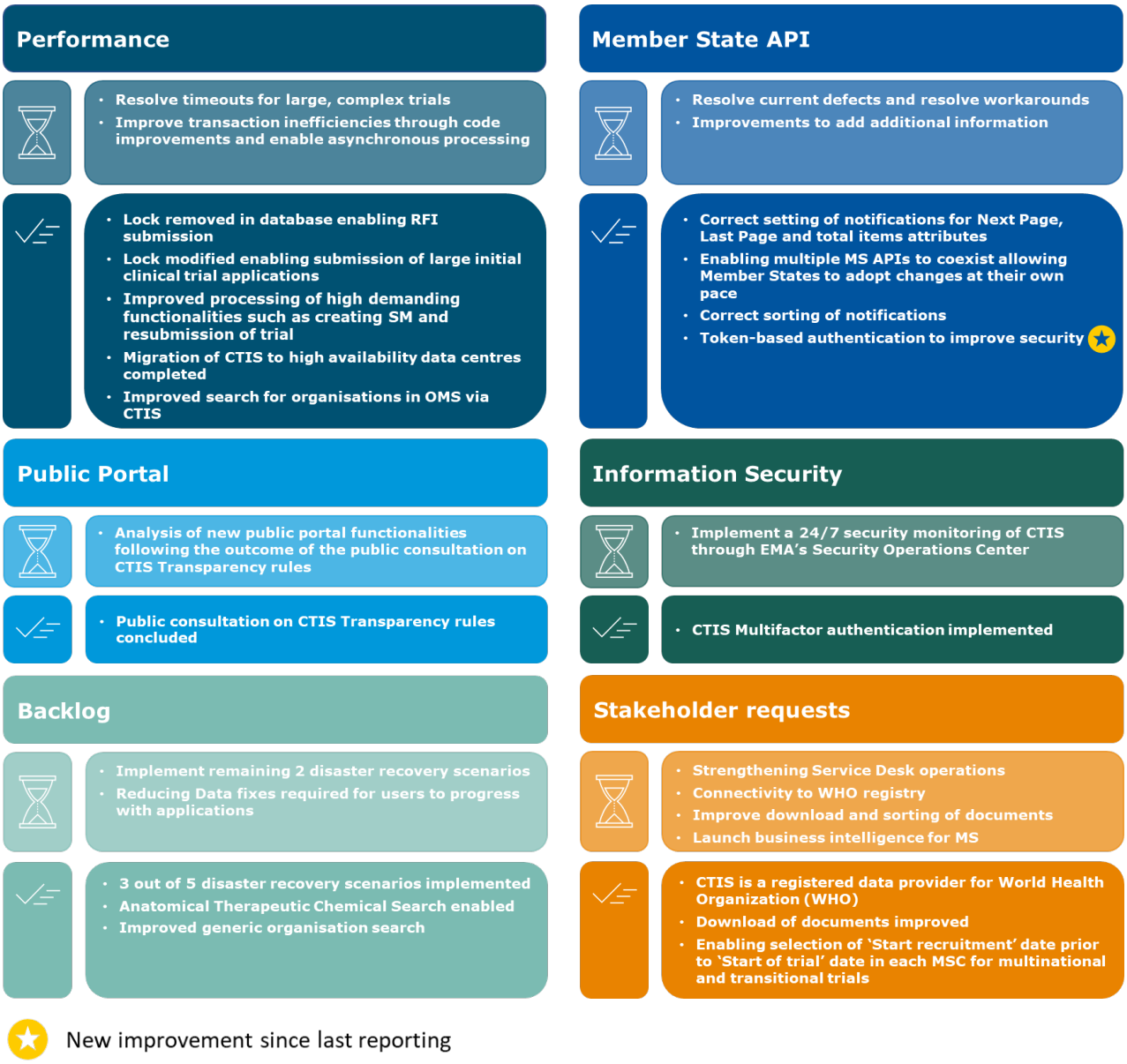
A CTIS release was deployed on 21 September 2023, introducing several improvements to enhance user experience:

- Sponsors transitioning trials from EudraCT to CTIS are now able to find and select a clinical trial available in EudraCT when searching by EudraCT number in the "Form" section.
- When adding translations in Part I, users are now able to save translations with up to 4,000 characters for the fields "Full title", "Public title", "Medical condition", "Main objective", "Secondary objective", "Principal inclusion criteria", and "Principal exclusion criteria" and 500 characters for the field "Primary and Secondary endpoints".
- When downloading the "Decision" and "Evaluation" documents:
  - The "Submission date" in the "Disagreement with Part I" section is now only populated when the MSC has disagreed with Part I.
  - The "Reporting date" has been renamed to "Decision date" in the Decision document and "Conclusion reporting date" in the Evaluation document for Part I and II.
  - When there is "No conclusion" in a Member State Concerned, the correct "no conclusion" date is populated in the "Conclusion" field.
- In Additional Member State (AMS) applications where a Request for Information (RFI) is raised in Part I, the "Authorise" task is now extended correctly, even if the "Submit Part II Conclusion" task has already been completed.
- AMS applications now only lapse when the Sponsor does not respond to a Part I or Part II RFI by the due date deadline.
- In cases where an extension of the "Start of Recruitment" has been authorised via Substantial Modification, sponsors are now able to select a start of recruitment date during the extension period.
- The date picker in different applications and phases of the "RFI response" is now improved.
- Authority users with the Validator Part II submitter role are now able to consolidate considerations and send RFIs in the Validation phase of a Substantial Modification (SM) part II-only application.
- Users now receive a role confirmation email when a role is assigned, revoked, rejected or amended.
- User permissions for the re-submission of clinical trial applications (CTAs) are now improved:
  - In an Organisation-Centric approach, the CT Admin with scope for a "specific CT" is now able to resubmit the initial application for that trial, and automatically gets the same role and scope for the resubmitted CTA;
  - In either an Organisation-centric or Clinical Trial-Centric approach, the Application Submitter cannot resubmit an initial CTA, regardless of the role scope i.e. "Specific CT" or "All trials".

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: Access to 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.