30 April 2025
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European Medicines Agency

CTIS newsflash – 16 May 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 27 May 2025.

CTIS downtime

On 12 May some CTIS users experienced issues when trying to perform tasks in the system, most notably the system was slow to respond, and documents and tasks did not load correctly. EMA has implemented changes in the system and following these changes there has been a marked improvement in CTIS performance. The issue is now considered to be resolved.

If you experience issues with CTIS, please contact the ServiceDesk.

Key updates

- 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.
- EMA is redesigning the CTIS training materials for sponsor users, with the aim to improve navigation and ease of use based on stakeholder feedback. A stakeholder focus group was set up under the ACT EU Multi-stakeholder platform to validate the quality of the redesigned materials, expected to be published from June 2025. The exact launch dates will be announced in upcoming issues of this newsflash.

Current operational experience with CTIS

This section on CTIS metrics provides key data and trends.

After a significant increase driven by the transition period deadline at the end of January 2025, the volume of initial applications submitted, as well as the corresponding decisions, is now showing signs of stabilisation.

The data presented below refer to the period from 1 to 30 April 2025.

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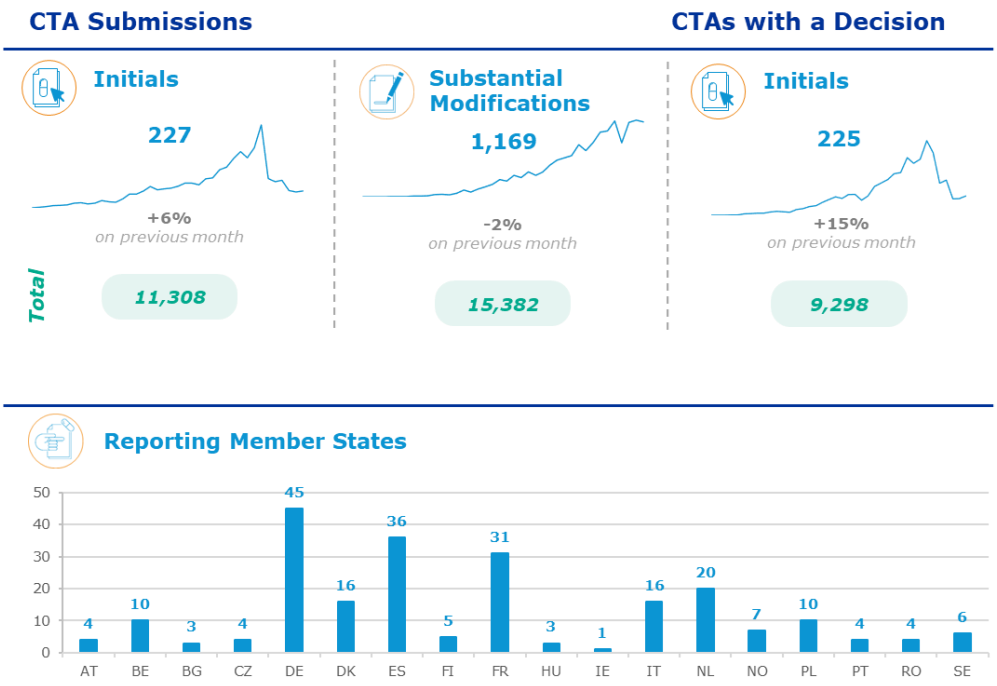

Reminder for EMA account users:

Since the beginning of 2025, CTIS users using a legacy username (i.e. username@id.ema.europa.eu) have been requested to convert their email authentication method so that they can login with their own email address.

CTIS users that had not yet converted their account were sent an email and all accounts have now been converted. As such, all users should now be able to login in with their own email address rather than username@id.ema.europa.eu.

In case you do experience any issues when logging into CTIS, please open a ServiceDesk ticket.

Safe-CT Project Extension

The Safety Assessment Cooperation and Facilitated Conduct of Clinical Trials (SAFE CT) Steering Committee are delighted to announce the extension of the project for 1 year, from April 2025 **to April 2026**. The amendment to extend the project duration was approved by the European Commission on (24th April 2025). The project will continue to support the objectives of Joint Action (JA)12 in fostering cooperation and harmonisation of safety assessment for clinical trials within the European Union.

The Clinical Trial Regulation and Implementing regulation which became applicable on 31 January 2022 introduced the concept of safety cooperation and work-sharing among Member States.

Joint Action (JA) 12 of the EU4Health Safety Assessment Cooperation and Facilitated Conduct of Clinical Trials (SAFE CT) supports these new concepts through provision of additional resources and expertise necessary to implement the new regulation.

The goal of this JA is to establish and maintain cooperation in safety data assessment in clinical trials via building capacities and performing training activities in the participating Member States. The experience gained during the JA will be used to update and improve the procedures on cooperation and training in safety surveillance in clinical trials.