10 February 2025
EMA/37270/2025
European Medicines Agency

CTIS newsflash – 11 February 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 25 February 2025.

Get advice to improve your applications (CTAs and MAAs)

The ACT EU pilots offering scientific and regulatory/technical advice on marketing authorisation and clinical trial applications remain open to applicants.

Developers of medicinal products can request joint scientific advice on their applications for clinical trials and the evidence needed for marketing authorisation applications, provided by the Clinical Trials Coordination Group (CTCG) and EMA's Scientific Advice Working Party (SAWP). Applicants can also ask CTCG for technical and regulatory advice on a clinical trial application before submitting it to CTIS.

Updated guidance for applicants is available on the ACT EU website.

Key updates for sponsors: end of CTR transition

Following the end of the transition period from the Clinical Trial Directive (CTD) to the Clinical Trial Regulation (CTR) on 30 January 2025, the 'Transitional trial' checkbox should no longer be used when submitting new clinical trial applications under the CTR in CTIS. If this checkbox is ticked by mistake, sponsors have the option to withdraw the initial application and resubmit a corrected one (for instructions, see the Annex in CTIS newsflash - 26 July 2024).

CTCG has also published a Best Practice Guide for sponsors who have missed the transition timeline.

Tip for sponsors: End of trial notifications and substantial modifications

Sponsors are advised to carefully plan and submit the End of Trial notification in CTIS within 15 days of the trial's completion, in accordance with the Clinical Trials Regulation. If notified retrospectively or after an application has already been submitted, the assessment of the trial in CTIS will continue in Member States where the trial has ended, causing inefficiencies.

Additionally, if a Substantial Modification (SM) is created and submitted after an End of Trial notification has been submitted for a particular Member State, that Member State will be excluded

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from the assessment of the SM. If the SM is created before the End of Trial Notification but submitted after, that Member State will still be included in the SM application. In such cases, it is advised to cancel the draft SM before submitting and create a new SM. This will ensure that the Member State where the trial has ended will not be included in the SM application.

Save the date: CTIS events in March

- On 5 March 2025 EMA is hosting a CTIS bitesize talk on changing the sponsor of a clinical trial or the sponsor details in CTIS at 15:30-17:00 CET. Participants can submit their questions in advance via Slido with the code #bt5mar until 19 February 2025.
- Sponsors can register to the CTIS end user training programme on 25-28 March 2025. This training programme is open to new sponsor users of the CTIS, commercial and non-commercial, as well as Contract Research Organisations (CROs).

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support (EMA website).

System improvements

The CTIS release on 4 February 2025 introduced several improvements.

For all users:

- If the Reporting Member State (RMS) submits an assessment Part I Request for Information (RFI) in an Additional Member States Concerned (AMS) application submitted after a Substantial Modification (SM), now the AMS application does not lapse on the due date of the Part II conclusion.

For sponsor users:

- Sponsor users who have roles with Part I permissions only can now access an initial application from the summary page in cases where there is a Part II draft response to a Request for Information (RFI).
- Trial sites added in an application containing Part II are now saved automatically. This prevents trial sites from disappearing after submission due to a time out of the user session during the drafting of an application or of an RFI response.
- When a clinical trial application is authorised, sponsors can now submit an "End of Trial" notification without encountering an error message.
- When sponsors include changes in a response to a Validation RFI in an initial application, the "Check" button is now available for sponsors to perform the technical validation for that response.

For Member State users:

- When sponsors submit a Non-Substantial Modification application, the affiliated organisation for MS users with trial-specific roles remains unchanged.
- When an SM Part I or Part I&II is submitted, the due date for the task of "SM document considerations for validations" which is triggered for both the Reporting Member State (RMS) and the Member States Concerned (MSC) is now correctly calculated based on the calendar of the RMS. For SM Part II only, the due date for this task is calculated based on each MSC calendar.

- When a Member State administrator assigns a new role, the field "Organisation name" is now correctly displayed.

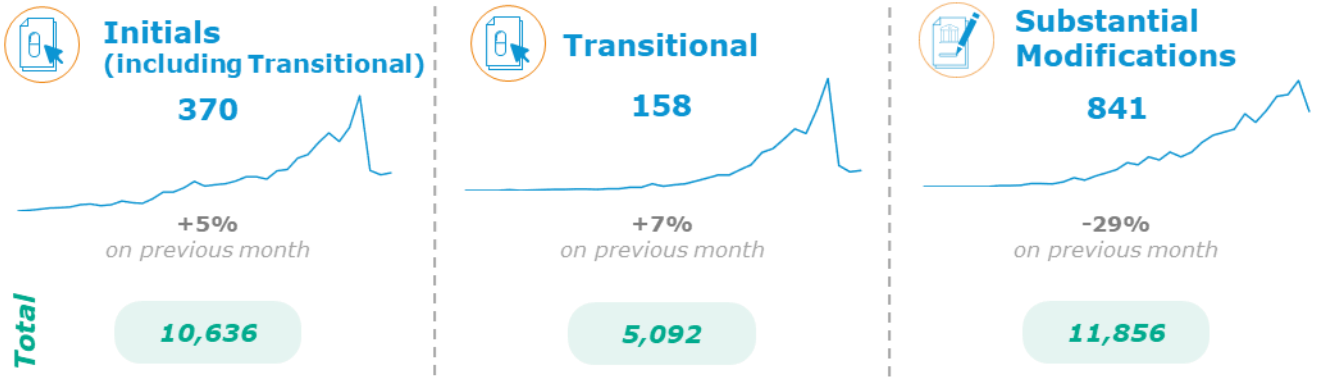
More information on the latest system improvements is available in the published release notes.

Current operational experience with CTIS

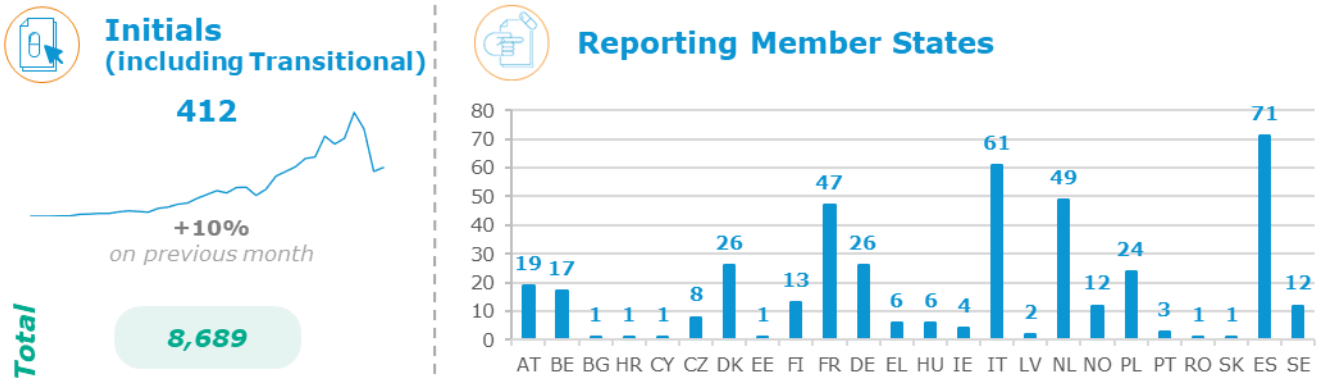
This section on CTIS metrics provides key data and trends.

The data presented below refer to the period from 1 to 31 January 2025.

CTA Submissions



CTAs with a Decision



Reminder for EMA account users: Email authentication to EMA systems

EMA has introduced email address authentication for EMA applications to improve security and usability by removing the need for users to remember their EMA username and password.

Since 30 September 2024, all new self-registered users are automatically set to email authentication. All users not converted to email authentication were requested to opt-in before 20 January 2025.

As of 20 January 2025, EMA has initiated the conversion of all users who did not opt-in to the email authentication, to be completed as follows:

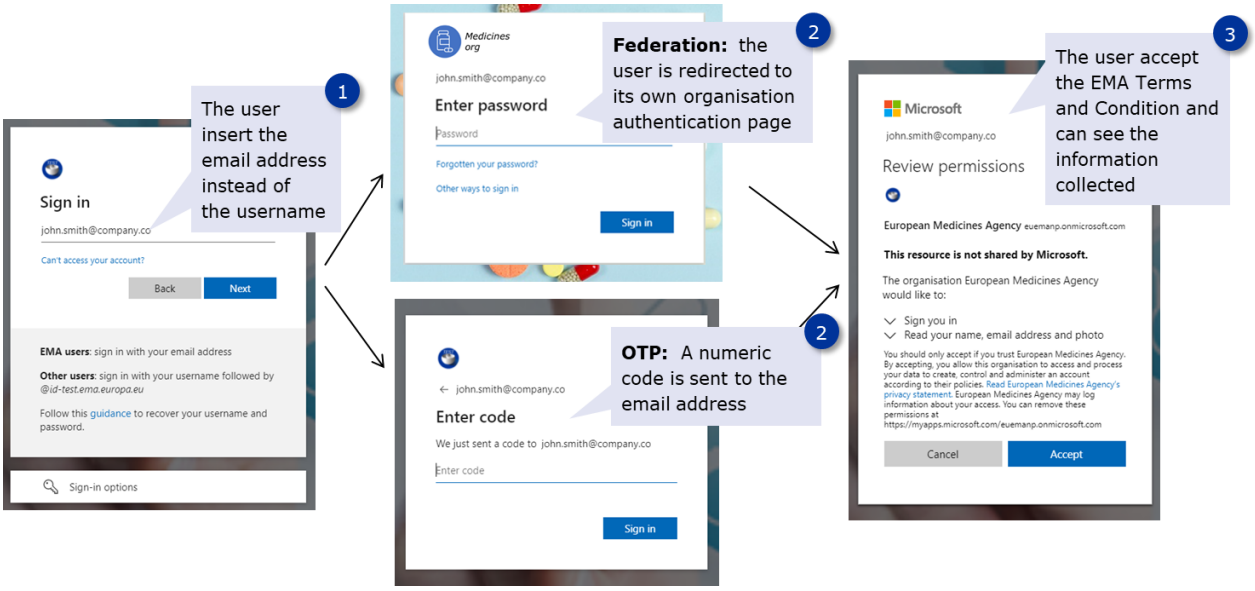
- 20 January 2025: Non-regulatory users without specific application roles;
- 3 February 2025: Non-regulatory users with application roles;

- 3 March 2025: Regulatory users (from the European medicines regulatory network);
- 31 March 2025: All users are converted.

How to opt in

Users are requested to opt-in to email authentication in EMA Account Management, if they have not already done so, at their earliest convenience by following the detailed instructions.

Once converted to email authentication, users can use their email address to authenticate into EMA systems. In this way, as shown in the figure below, and depending on the user domain, they will either be redirected to their authentication page or receive an email with an authentication code.



Useful links

- EMA Account Management home page, section on authentication: Sign In · EMA Account Management (europa.eu)
- Presentation of public systems demo
- EMA Account Management, what's new webinar recording
- Q3 2024 Public system demo recording

Contact

If you cannot find the support you need in the above resources, please contact the EMA Service Desk.

Alternatively, if you are unable to access the EMA Service Desk, please send an email directly to servicenow@ema.europa.eu indicating your name, surname and your unique username.