17 December 2024
EMA/559561/2024
European Medicines Agency

CTIS newsflash – 17 December 2024

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.

Due to the holiday break, the next issue will be circulated on 14 January 2025.

Spotlight: 10,000 trials submitted in CTIS

Over ten thousand clinical trials have now been submitted in CTIS since its launch in January 2022. These include initial applications for new clinical trials and trials transitioned from the previous legislative framework of the Clinical Trials Directive. Decisions have been issued on over 8,000 of these trials, which are now available on the CTIS public portal.

Reminder: Winter clock stop

All timers within the evaluation of a clinical trial application will stop on 22 December 2024 at 23:59:59 CET and resume on 8 January 2025 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.

Please note that the winter clock stop only applies for due dates related to a clinical trial application. Due dates for Requests for Information (RFIs) in the context of an ad hoc assessment or ASR (Annual Safety Report) assessment can be selected by the Member State Concerned to fall during the winter clock stop; in these cases the concept of "lapse" does not apply.

Reminder: Transition ongoing trials from CTD to the Clinical Trials Regulation

Sponsors are advised to transition any clinical trial expected to continue after 30 January 2025 from the Clinical Trials Directive (CTD) to the Clinical Trials Regulation (CTR).

Sponsors should submit trials for transition as soon as possible.

Sponsors can consult CTCG's best practice guide on transition, Annex I: Cover letter template, and the newly published Annex II: Fees for transitional trials in EU/EEA Member States. Further resources to support sponsors' transitioning trials are available on the CTIS website.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

New features in the CTIS public portal

A release on 10 December 2024 introduced several improvements on the CTIS public portal. The changes aim to enhance the usability of the portal and accessibility of the available clinical trial information to the benefit of patients.

For each trial:

- The 'Full Trial Information' section has been redesigned to improve readability by hiding fields that were previously displayed as empty. Additionally, the outer frames and the 'Product' table have been redesigned.
- In the 'Location and contact points' section, the order of details of the 'contact points' table has been modified to make it easier for patients to find information of interest to them.
- In the 'Trial Results' section, the 'Layperson summary of results' is now displayed above the more detailed 'Summary of results', making it more visible for patients.

In addition, the 'Advanced criteria' menu is now expanded by default, making it easier to view the advanced search option, and specific instructions have been introduced to make the portal more user-friendly.

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.

Read more on how to apply on the ACT EU website. Please note that the evaluation of applications will be paused from 20 December 2024 to 7 January 2025 due to the holiday period.

Tip for sponsors: CTIS timetable

After the submission of an application, CTIS estimates the maximum due dates of tasks related to the validation and assessment by the Member States and of specific sponsor actions (i.e. RFI response) based on the Clinical Trials Regulation. These estimated timelines are illustrated in graph form in the **timetable** feature in CTIS.

The timetable is a dynamic tool that adjusts the timelines if certain tasks/actions are completed earlier. The document 'CTIS evaluation timelines' explains in detail how the timelines are calculated and under which circumstances they can be shortened. The document describes the maximum timelines for each task (per application type) or (sponsor) action.

CTIS calculates the maximum due date of each task based on the rules listed on pages 6-7 of the 'CTIS evaluation timelines' document (stemming from Regulation (EEC, EURATOM) No 1182/71 of the Council of June 1971). The timeline of a task may be prolonged by a few days, e.g. if the due date is to fall on a weekend or on a public holiday. These additional days are taken into account in the estimated timeline of any subsequent task/action which, in turn, may be extended for the same reason.

Consequently, minor extensions of timelines for evaluation-related tasks can lead to an extended overall timeline for the evaluation and authorisation of a clinical trial application. The 106-day timeline

of an (initial) application authorisation is calculated based on no due dates falling on a weekend or a public holiday.

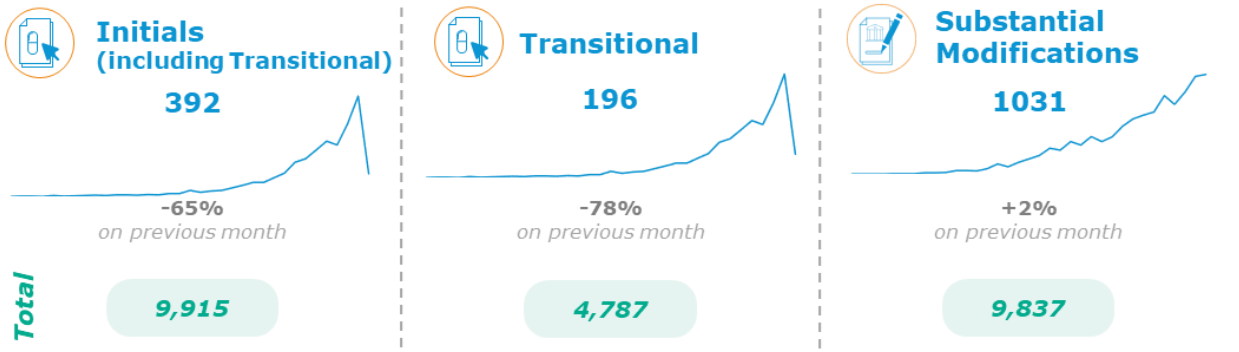
The 'CTIS evaluation timelines' document includes an Annex with practical examples of how the 106-day timeline can be exceeded.

Current operational experience with CTIS

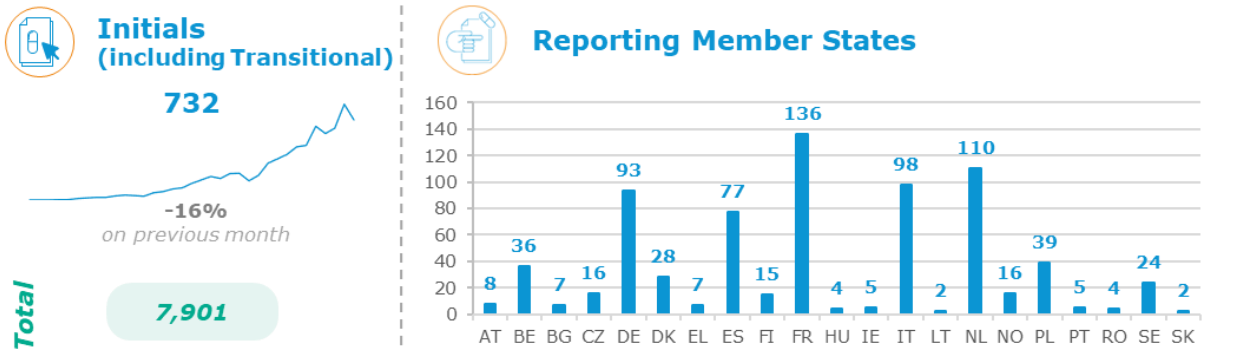
This section on CTIS metrics provides key data and trends.

The data presented below refer to the period from 1 to 30 November 2024. The decrease in submissions this month follows a peak of transitional trial submissions in October 2024, in time for the expedited procedure foreseen by CTCG.

CTA Submissions



CTAs with a Decision



Recent publications

- The November report with metrics monitoring the European clinical trials environment has been published on the ACT EU website.
- Updated versions of the Q&A on protection of Commercially Confidential Information and Personal Data while using CTIS, Annex I table I of Guidance on how to approach protection of personal data and CCI and related quick user guide are now available on the ACT EU website.

Reminders for CTIS users:

- **Update and data wipe-out on CTIS training environment:** Users should note that the CTIS Training Environment will be unavailable on 18 December 2024 due to a system update that will also permanently delete all data recorded in the system until that date. Users will, therefore, need to create new trials for future training purposes.
- **System downtime:** The regular maintenance window for CTIS on Thursdays (18:00-21:00 CET) is not planned to be used from 13 to 31 December 2024. Therefore, CTIS can be used as usual during these hours. Please note that the planned maintenance window on Tuesdays (18:00-21:00 CET) may still be used.
- **Notices & alerts (submission due):** CTIS automatically generates an alert when a due date to submit the Start of Recruitment or Summary of Results is approaching. These alerts are meant as general reminders and are generated irrespective of the current status of the trial lifecycle. As such, an alert for Start of Recruitment due will be generated even if the Start/End of Recruitment date has already been submitted. In such cases, the alert can be ignored providing the Start of Recruitment has been correctly submitted.
- **Opening a ticket:** Before raising a ticket with the CTIS User Support Service (ServiceNow), users are advised to consult the list of frequent reported issues and some useful tips, available on the CTIS website: Tips for users reporting issues to CTIS User Support Service.

Annex: 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 are requested to opt-in before 20 January 2025.

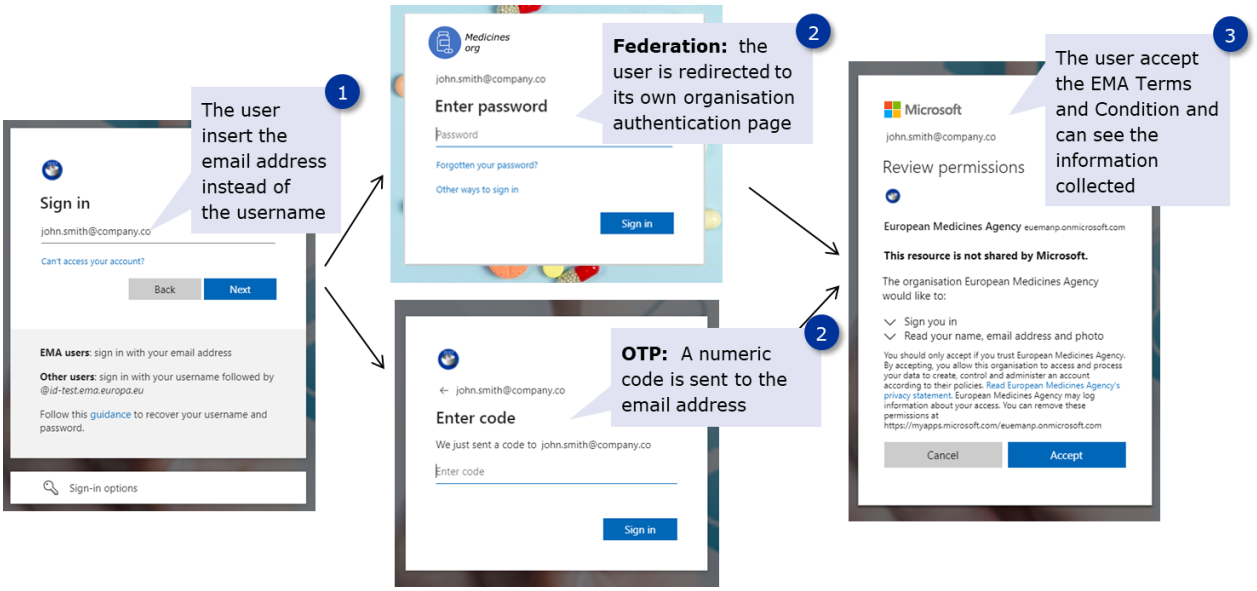
Starting from **20 January 2025** EMA will initiate the conversion of all users that did not opt-in to the email authentication as follows:

- 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 required to opt-in to email authentication in EMA Account Management by following the enclosed detailed instructions. *Please, ensure you opt-in before 20 January 2025.*

Once converted to email authentication, users can use their email address to authenticate into EMA systems, being redirected to their authentication page or by receiving a code in their email address.



Useful links

- EMA Account Management home page, section on authentication: Sign In · EMA Account Management (europa.eu)
- Presentation of public systems demo: presentation-quarterly-system-demo-q3-2024_en.pdf
- EMA Account Management, what's new webinar recording: https://www.youtube.com/watch?v=-1f87bIBei0&t=1930s
- Q3 2024 Public system demo recording: https://www.youtube.com/watch?v=1kllDioAvzc&t=3995s

Contact

If you cannot find the support you need in the guidance documents, 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.

We wish all CTIS users happy holidays and a happy New Year.

Весели празници ❄ Felices fiestas ❄ Šťastné a veselé svátky ❄ Med de bedste ønsker Mit den besten Wünschen ❄ Häid pühi ❄ Χρόνια Πολλά ❄ Season's Greetings Meilleurs Vœux ❄ Beannachtaí na féile ❄ Sretne i ugodne blagdane ❄ Buone feste! Priecīgus svētkus ❄ Linksmų švenčių ❄ Kellemes ünnepeket! ❄ Il-Festi t-tajba Met onze beste wensen ❄ Wesołych Świąt ❄ Boas Festas ❄ Sărbători fericite Šťastné a veselé sviatky ❄ Vesele praznike ❄ Hyvää joulua ❄ God helg