10 September 2024
EMA/374537/2024
European Medicines Agency

CTIS newsflash – 10 September 2024

Introduction

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

The next issue will be circulated on 24 September 2024.

Previous issues of the CTIS Newsflash are available on the EMA website.

Advice for CTIS users

- **Notices & Alerts**: For an overview of open tasks and required actions, CTIS users are advised to regularly consult the tabs "Tasks" and/or "Requests for Information (RFI)" instead of relying solely on the notices and alerts.
- **Timetable**: During the assessment of a clinical trial application, a timetable is available to help sponsors plan their work in CTIS. Users are advised that this timetable is intended as a visual support tool and should always be consulted in parallel with the actual due dates - compliant with the Clinical Trials Regulation -as recorded in the individual tasks and RFIs. In case of occasional discrepancies in the timetable information, this does not impact the workflow and the actual due dates of tasks and RFIs.

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 take into account the time necessary for completion of the Member State(s) evaluation procedure, which can take up to 3 months. Members States have agreed on an expedited procedure for transitioning trials to the CTR which will be applied whenever possible.

Sponsors can consult CTCG's recently updated 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

CTIS public portal: new features available soon

On 20 September 2024, additional features are foreseen to be implemented on the CTIS public portal. The new features will allow users to perform advanced searches, subscribe to an RSS feed and download their search results and clinical trial information. Following a thorough consultation of stakeholders, especially patients, several changes to the interface will also be implemented to improve the overall user experience. Updated search tips will be made available, along with explanatory documents for each section.

Save the date: upcoming events

- CTCG, with support from ACT EU, is hosting a stakeholder meeting of the CTR Collaborate initiative on 11 September 2024. The open session will be live-streamed, sharing insights from the work of CTR Collaborate.
- EMA is hosting a CTIS Walk-in Clinic on 18 September 2024 dedicated to answering users' questions on the transition of trials from the Clinical Trials Directive to the Clinical Trials Regulation. Participants will be able to submit their questions in advance until September 2024.
- On 20 September 2024, EMA is hosting a webinar on new functionalities of EMA's Account Management portal. Industry and national competent authorities can learn more about access-management aspects and procedures for requesting and managing access to EMA applications, including CTIS.
- Sponsors can register to the upcoming CTIS user training on 23-26 September 2024, 09:00-13:30 CEST.
- On 17 October 2024, CTIS users can attend the CTIS Info day, which will include updates on transitioning trials and the implementation of the revised transparency rules.

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

Issue with ASR submissions

When preparing to submit an Annual Safety Report (ASR), CTIS users with a trial-specific role are currently unable to find a clinical trial in the system. A technical solution is being developed and expected to be deployed in the release planned for October 2024. In the meantime, impacted users are advised to request the role of ASR submitter with access to 'All trials' to proceed with the submission.

For ASR submissions with a due date before October 2024 where users can in no way be granted access to 'All Trials', an extension of the due date may be granted until the issue is resolved. In these cases, users are requested to inform the Reporting Member State (RMS) of the delay by email; please note that this delay in the ASR submission will not shift the due date for the ASR submission the following year. Any new critical safety issue uncovered during the preparation of the ASR is expected to be handled with appropriate risk mitigation.

System improvements

The CTIS release on 27 August 2024 introduced several improvements:

- When creating a new application (all type), sponsors now receive the warning message: "Do not create a draft application if the same part of the dossier is currently under evaluation. Any changes in the ongoing application will NOT be included in this draft".

- In applications to change the sponsor Org-ID through a Substantial Modification (SM) for "Part I only – Change of Sponsor":
  - When all Member States Concerned (MSCs) have not yet authorised the SM, the tab 'Full Trial Information' still displays the old sponsor Org-ID;
  - While the SM application is in draft, all clinical trial information is still visible to the old sponsor and the new sponsor cannot see any information. If the draft SM application is copied, the clinical trial section in Part I of the newly created clinical trial still displays the old sponsor Org-ID.
- In the 'Submit confirmation' pop-up window related to the revised transparency rules, the hyperlinks now open the related documents in a new tab.
- After an initial application with no conclusion in the assessment phase nor a tacit decision, the status of Part II-only SMs is now correctly set to 'tacitly authorised' when the Part II conclusion is acceptable and the 'Authorise' task has expired.
- In multinational clinical trials involving many Member States, when creating an SM (all types), Non-SM or Additional MSC applications, the system no longer displays a timeout error related to the number of documents.
- In the notices and alerts tab, when searching for notices/alerts with the character "," in the name of the notice/alert, the name is now correctly displayed.
- In SMs Part I and II where Part II is submitted only to some MSCs, the expiration of the 'Authorise' task now correctly triggers tacit authorisation.
- In Additional MSC applications, authority users from a MSC that was lapsed in the initial application can now complete the soft task 'Consolidate considerations'.

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 for sponsors and for Member State users.

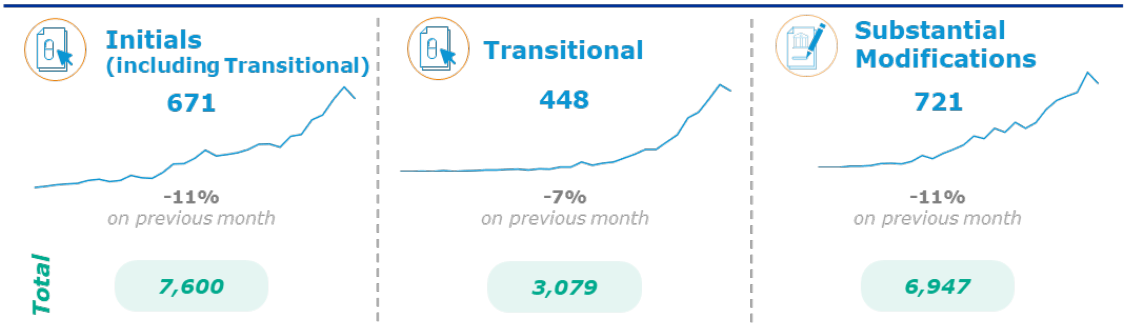
EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

Current operational experience with CTIS

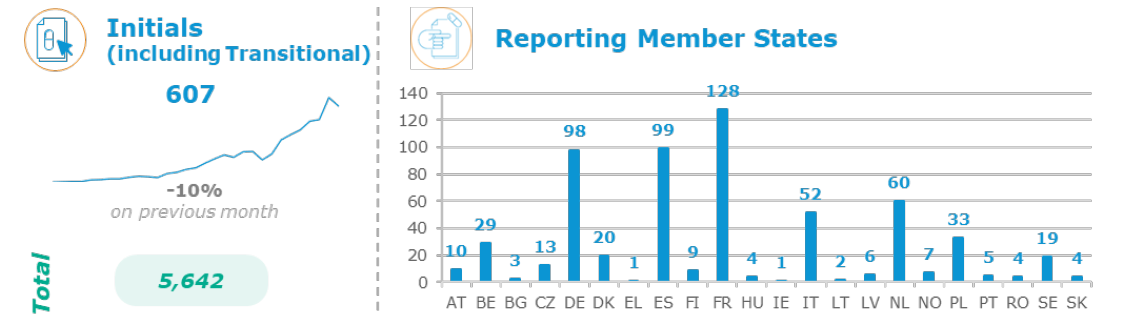
This section on monthly CTIS metrics provides key data and trends.

The data presented below refer to the period from 1 to 31 August 2024.

CTA Submissions

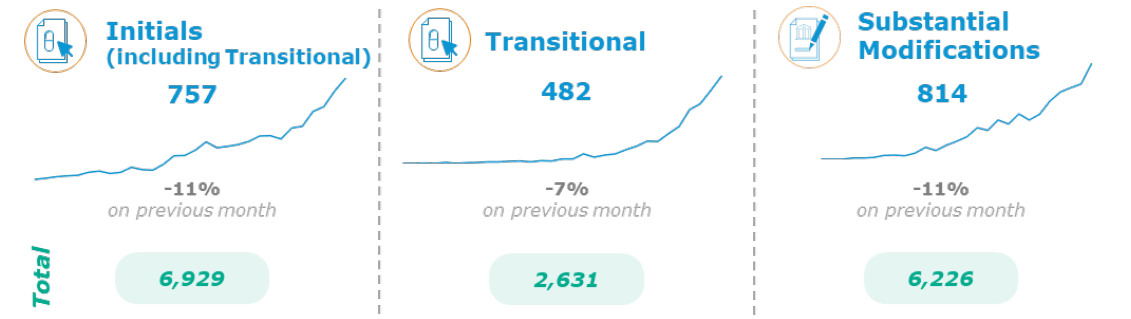


CTAs with a Decision

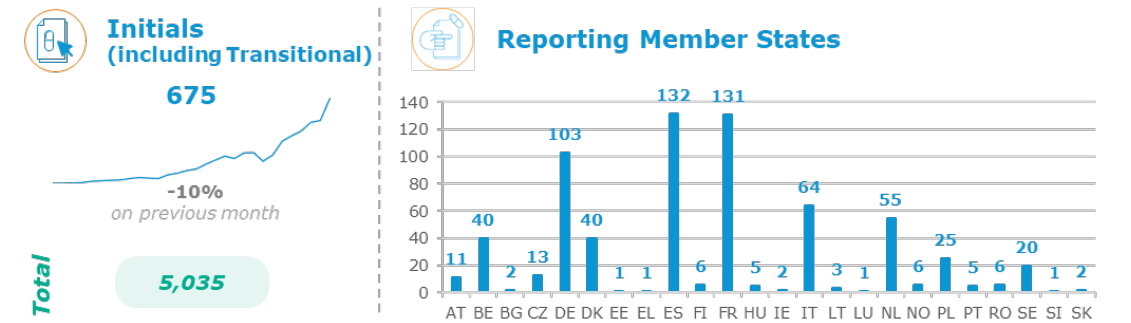


For reference, please find below the date referring to the period from 1 to 31 July 2024.

CTA Submissions



CTAs with a Decision



Revised CTIS transparency rules: resources for sponsors

With the successful launch of a new version of the CTIS public portal on 18 June 2024, the revised CTIS transparency rules are now applicable.

For support in the implementation of the revised rules, sponsors can consult the updated quick guide for users, guidance, annex I and Q&A document on the protection of personal data and CCI in CTIS.

The latest quick guide for users and Q&A (question 1.9) include details on cases where only 'track-changes' versions of certain documents, which are no longer subject to publication, are present in the CTIS workspaces.

All documents are available under the "Transparency in CTIS" section of the ACT EU website.

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.

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 latest 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.

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 for sponsors and for Member State users. Resources to support sponsors transitioning trials from the Clinical Trials Directive (CTD) to the CTR are available on the CTIS website.