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European Medicines Agency

CTIS newsflash – 24 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 8 October 2024.

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

New version of the CTIS public portal

New features were introduced on the CTIS public portal as of 20 September 2024, following a thorough consultation with stakeholders, including patients and healthcare professionals. Users can now:

- perform an advanced search, including searching per recruitment status in a specific country;
- download the full list of search results for a performed search;
- download all published information and documents for a specific clinical trial;
- subscribe to a certain search via RSS feed.

In addition, several changes to the interface have also been implemented to improve the overall user experience. The list of search results is now translated in every European language and clearly displays the most important information, including the recruitment status and locations for each trial. Moreover, every trial page now displays:

- a dedicated section on 'Locations and contact points', for anyone who wishes to get in touch with the trial locations or with the sponsor;
- more extensive information in the 'Summary' page, such as the main objective of the trial and its estimated duration;
- a dedicated section with all available trial documents;
- a section with the 'Full trial information' which is easier to consult;
- documents with layperson explanations of the fields in each section.

The pages Search tips and What to search for have been updated accordingly.

Currently, information and documents on over 6000 trials are publicly available on CTIS, with more added every day. The improvements to the public portal aim to benefit the public, including patients,

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healthcare professionals and researchers, by making it easier to search for publicly available information on clinical trials in the EU and EEA.

Advice for CTIS users

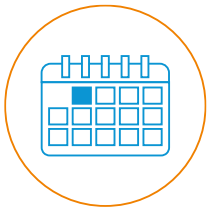
- **Notices & Alerts**: For an overview of open tasks and required actions, CTIS users are advised to regularly consult the tabs "Tasks" and/or "Requests for Information (RFI)" instead of relying solely on the notices and alerts.
- **Timetable**: During the assessment of a clinical trial application, 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.



Save the date: upcoming events

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.

EMA is also hosting a CTIS walk-in clinic on 20 November 2024, where sponsors can raise questions about any CTIS functionality and receive advice from CTIS experts. CTIS users can submit and upvote questions in advance via Slido from 23 October 2024 to 13 November 2024 at 12:00, with the code #clinic248.

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 10 September 2024 introduced several improvements:

- When sponsors create a Substantial Modification (SM) application Part I&II or Part I-only, the SM no longer includes Member States Concerned (MSCs) where the status of the clinical trial application is "Ended" and these MSCs do not receive any related tasks.
- When sponsors create a new clinical trial, the optional field "Plan description" is no longer highlighted after validation of the application via the "Check" button.

- The field "Authorisation number of manufacturing and import" is now displayed correctly, with a different number per document and per section.
- When downloading the PDF file of a Corrective measure, the file now correctly displays the field "Anticipated date of summary of result from revocation".
- For trials created prior to the implementation of the revised transparency rules, sponsors are able to save a draft application or draft response to a Request for Information (RFI) with no error message displayed.
- Once an SM "Part I only – Change of Sponsor" is tacitly authorised, the sponsor of the trial is now correctly changed to the new one.
- In trials temporarily halted for benefit/risk or other reasons, sponsors are now able to link an "authorised" SM to restart the halted trial during the extension period.
- When the "Authorise" task expires after the submission of an acceptable "Validation Decision" and "Part II Conclusion", the SM Part II-only application status correctly displays "Authorised" instead of "Under Evaluation" in the Sponsor workspace.
- When sponsors update the field "Authorisation number of manufacturing and import" in response to a Validation/Part I assessment RFI, the field is shown as updated (highlighted), in both workspaces, only for the updated product.
- Once an SM Part II-only is authorised, the "Authorise" task in the Authority workspace now only displays the "Part II conclusion".
- Administrator users with "Trial specific" scope now cannot assign roles with a scope for "All trials".
- When creating a new clinical study report (CSR), the search under the CSR tab displays all available clinical trials, including trials with NSM in draft status or cancelled.
- Sponsors are now able to revoke a role via the "User administration" tab with no error message displayed.
- When the "Submit Validation" task expires in an SM Part II-only application, the application is tacitly validated and the assessment workflow continues.

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.

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.