8 October 2024
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European Medicines Agency

CTIS newsflash – 8 October 2024

Introduction

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

The next issue will be circulated on 22 October 2024.

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

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 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.

We want your feedback

As end of the CTR transition period approaches, we are inviting stakeholders to share their feedback on events, training materials and communications from EMA that aimed to support them in the implementation of the Clinical Trials Regulation. You can share your views via the survey by 8 November 2024.

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

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discrepancies in the timetable information, this does not impact the workflow and the actual due dates of tasks and RFIs.

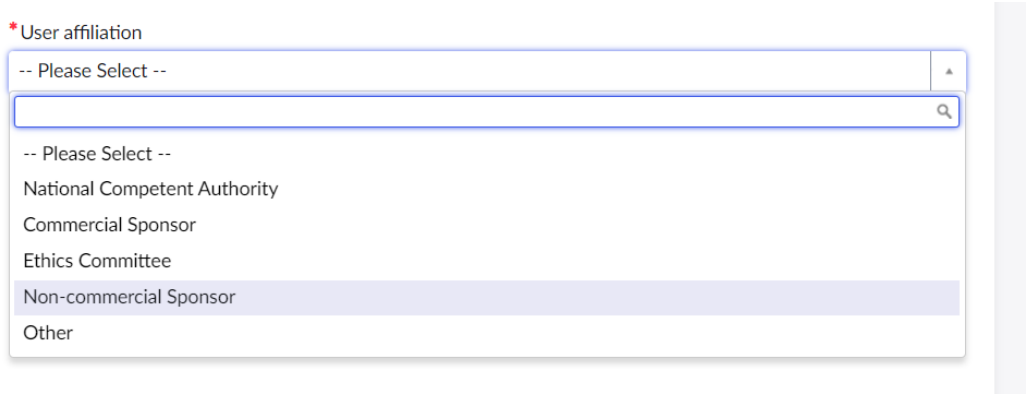
Helpdesk for non-commercial sponsors

The Accelerating clinical trials in the EU (ACT EU) initiative has established a dedicated helpdesk, which employs different measures to support non-commercial sponsors in navigating the clinical trial landscape in the EU.

Currently, the helpdesk offers tailored technical assistance on CTIS functionalities and addresses questions on regulatory requirements related to the clinical trial lifecycle. The helpdesk may also consult National Competent Authorities to provide support on specific cases.

Non-commercial sponsors can submit their question now by raising a ticket in the CTIS Service Desk and indicating their status as a non-commercial sponsor in the mandatory field "User affiliation".

CTIS Service Desk

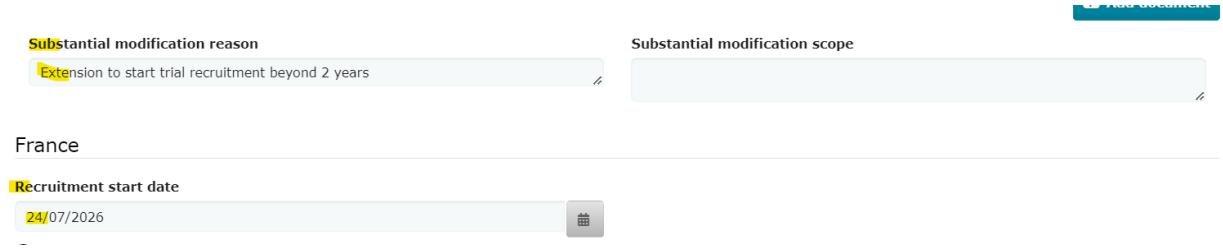


Expiration of trials: a tip for sponsors

Once an initial clinical trial application (CTA) is authorised or authorised with conditions in a Member State Concerned (MSC), the sponsors has 2 years and 15 days from the date of authorisation to start recruitment in that MSC. After this time and if recruitment has not started, the status of the CTA in that MSC changes to 'Expired'.

To prevent the expiration of CTAs, sponsors can request an extension via Substantial Modification (SM) Part I & II or via SM Part II. Sponsors should select "Extension to start trial recruitment beyond 2 years" as a reason for the SM in the Form section and then fill in the "Recruitment start date".

If the SM is authorised or authorised with conditions before deadline of 2 years 15 days, the system will keep the MSC Status as "Authorised" until the Recruitment start date + 15 days.



Please note that SM Part I-only cannot be used to request the extension of start of recruitment.

Save the date: upcoming events

On 16 October 2024, EMA is hosting a CTIS bitesize talk which will focus on the approaching end of the transition period of the Clinical Trials Regulation and provide guidance on transitioning trials and submitting various notifications (e.g. unexpected event reports, urgent safety measures, and serious breaches). Submit and upvote questions via Slido until 9 October 2024, with the code #bt16oct.

Stakeholders are also invited to attend the CTIS Info day on 17 October 2024, which will provide updates on transitioning trials, an overview of the revised transparency rules, as well as a demonstration of the new functionalities of CTIS new public portal.

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).

Current operational experience with CTIS

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

The data presented below refer to the period from 1 to 30 September 2024.

CTA Submissions

Initials (including Transitional)

807

+20%
on previous month

Total **8,407**

Transitional

636

+42%
on previous month

3,716

Substantial Modifications

850

+18%
on previous month

7,796

CTAs with a Decision

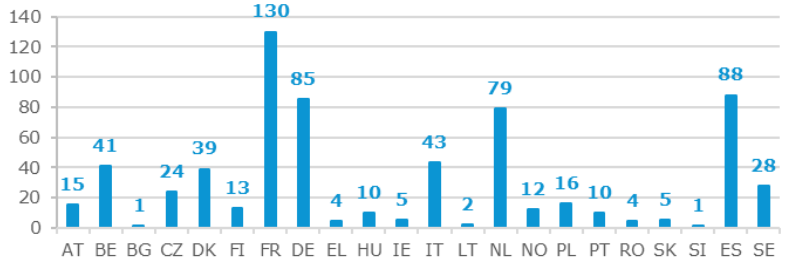
Initials (including Transitional)

655

+8%
on previous month

Total **6,296**

Reporting Member States



System improvements

The CTIS release on 1 October 2024 introduced several improvements:

- When a sponsor creates two or more "Additional Member State Concerned (MSC)" applications and submits at least one of them, the MSCs for the application(s) that remain(s) in draft status no longer receive any Notices & Alerts, nor the task "Assess RFI response," related to the submitted Additional Member State Concerned application.
- When requesting a change of sponsor via Non-Substantial Modification (NSM) application:
  - When NSM applications to change the sponsor's name are submitted while a Request for Information (RFI) for an ad-hoc assessment is pending, the old sponsor's name in that ad-hoc assessment is now retained before and after the submission of the RFI response.
  - When a NSM is submitted to update the sponsor Organisation ID from ORQ (temporary ID provided by OMS) to ORG (final ID provided by OMS), this change is also reflected in the "User Administration" tab. This means that any CT Admin users linked to the "old" ORQ-ID are now linked to the "new" ORG-ID and can assign roles affiliated to the ORG-ID.
  - When copying a clinical trial application where the Organisation ID was updated from ORQ-ID to ORG-ID, the new ORG-ID is also copied and takes effect in the relevant role assignment.
  - When a clinical trial application is copied to create a second application, where the sponsor name is then changed via NSM, the system now links the correct sponsor name to any given clinical trial in the "Associated Clinical Trials" section.
  - When a NSM is submitted to change the sponsor's name, the name of the "Contact point for Union" is automatically updated to the new one.
- When searching for clinical trials to be linked to an Annual Safety Report (ASR) under preparation, the system now returns the clinical trials that match with the provided search criteria.
- Multiple users creating ASRs simultaneously no longer creates duplicate business keys.
- When creating a new ASR, sponsors can populate the field "Organisation responsible for the ASR submission" by selecting one out of all the available addresses that are now displayed under the "Organisation details" in the "Sponsor Information" section.
- Sponsors can now submit Substantial Modification (SM) applications without a time out of the generation of "Notices & Alerts" and "Tasks".
- In Part I Substantial Modifications, when a MSC adds conditions directly in the "Authorise" task and completes it, the conditions are now correctly displayed inside the "Authorise" task and in the MSC "decision" area of the "Assessment Overview" section for both the sponsor and MS workspace.
- When an RFI is submitted by the due date of the extended "Submit Part I conclusion", after the sponsor response to the first RFI, the Reporting Member State is no longer able to select a due date for a second RFI that is equal to or exceeds the "Submit Part I Conclusion" task due date.
- When the due date of the "Submit Part II Conclusion" task is reached, the task expires, the "Assessment Part II" conclusion is set to "No conclusion" and the "Authorise" task is generated for the MSC, allowing it to complete the authorisation process.
- For the existing soft tasks, Member State users can now create and complete a Sub-task without errors.

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.

Reminder: 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. In addition, several changes to the interface have also been implemented to improve the overall user experience. The pages Search tips and What to search for have been updated accordingly.

The full list of new features is available here.

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.