22 October 2024
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European Medicines Agency

CTIS newsflash – 22 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 5 November 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 the 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.

CTIS unplanned downtime

- **23rd October**: From approximately 18:30-19:00 CET users may experience some disruption but there will be no downtime. In cases of interruptions, please try refreshing the page.
- **4th November**: From approximately 08:00 CET there will be additional downtime for a period of 30 minutes. CTIS is expected to be available again from 08:30 CET.

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

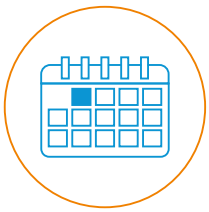
Advice for CTIS users

- **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.
- **Application Assessment Status**: In some cases, when clicking on the + INFO button of an application, an authorisation date will be shown for a Member State even though the Part II assessment has not been completed. This is incorrect date in the + INFO screen. The application status is still correctly reflected as "Under evaluation" and the Part II assessment will still be shown as pending. Also, the final decision will be shown as pending in the downloaded PDF. Please always ensure all assessments (i.e. Part I and/or Part II) are completed and that the authorisation status is also reflected in the downloaded pdf file before starting any recruitment.
- **Expiration of the clinical trial authorisation**: According to article 8.9 of the CTR, the clinical trial authorisation expires in a Member State Concerned (MSC), if no subject has been included in that MSC within two years from the authorisation date, unless an extension via a Substantial Modification (SM) has been authorised. From the date the initial clinical trial application (CTA) is authorised or authorised with conditions in an MSC, the 'first visit of the first subject' in that MSC must be within 2 years. The sponsor notifies the 'First visit of the first subject' with the 'Start recruitment' notification, where the 'Start of recruitment date' entered must be within the 2-year timeline, while the notification can be submitted within 2 years plus 15 additional days. Failure to notify the 'Start recruitment' within the timeline will change the trial authorisation status in that MSC to 'Expired'.
  If needed, Sponsors can request an extension to start the recruitment beyond 2 years via a Substantial Modification (SM) Part I & II or via SM Part II. Note, that an SM Part I-only cannot be used to request the extension of start of recruitment.

  In the 'Form' section of this SM Sponsors must select "Extension to start trial recruitment beyond 2 years" as the reason for the SM and must enter the anticipated extended deadline in the field "Recruitment start date".

  According to the CTR the SM must be authorised or authorised with conditions in that MSC within the 2 year timeline. The trial will remain 'Authorised' in that MSC allowing the sponsor to submit the 'First visit of first subject' with the 'Start recruitment' notification, where the 'Start of recruitment date' entered in the notification must be within the extended recruitment start timeline authorised in the SM, while the notification can be submitted within the extension period granted plus additional 15 days.

Save the date: upcoming events



Clinical Data Publication webinar: Registration is now open for EMA's webinar on the next step in the resumption of Clinical Data Publication (CDP).

At this webinar on 14 November 2024, aimed at consulting industry stakeholders including small and medium-sized enterprises, EMA will present its plans on the proposed extension of activities related to Policy 0070, the handling of legacy procedures and on the updated guidance for applicants preparing submissions. Participants will have the opportunity to ask questions.

Please register before 14th November 2024 on the following link: https://ema-europa.webex.com/weblink/register/r1ce35f3be44a2971963a62e2c05940da

For more information visit the Clinical Data Publication section on the EMA website.

EMA is 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

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.

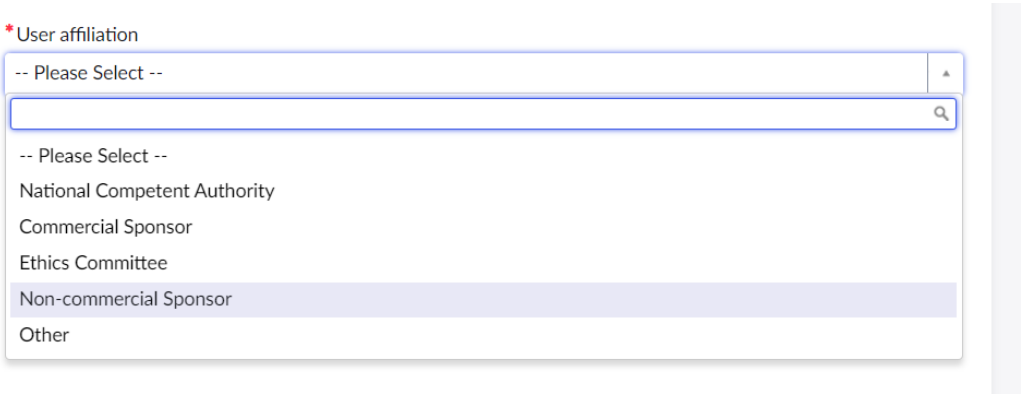
Reminder: Helpdesk for non-commercial sponsors

The Accelerating clinical trials in the EU (ACT EU) initiative has established a dedicated helpdesk, which employs additional 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 questions 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



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.