25 March 2025
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European Medicines Agency

CTIS newsflash – 25 March 2025

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.

The next issue will be circulated on 8 April 2025.

Key updates

- Around 800 people followed the live broadcast of the webinar "Finding clinical trials with the ACT EU Trial Map", held on 7 March 2025. The event included a demo and Q&A session. **The video recording** and **presentation** are available on the event page.
- On 5 March 2025, over 200 participants followed the CTIS bitesize talk on making changes to the sponsor section of a clinical trial. The video recording and presentation are available on the event page.

Give your feedback: public consultation on the revised draft ICH M11 Technical Specification

Stakeholders can now provide their feedback on the revised draft ICH M11 Technical Specification.

The purpose of this new harmonised guideline is to introduce the clinical protocol template and the technical specification to ensure that protocols are prepared in a consistent fashion and provided in a harmonised data exchange format acceptable to the regulatory authorities.

Stakeholders can send in their comments via email to ich@ema.europa.eu using this template. The deadline for comments is 22 April 2025. More information is available on the EMA website.

Tip for sponsor users: requesting extensions to start recruitment

From the date the initial clinical trial application (CTA) is authorised or authorised with conditions in a Member State Concerned (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'.

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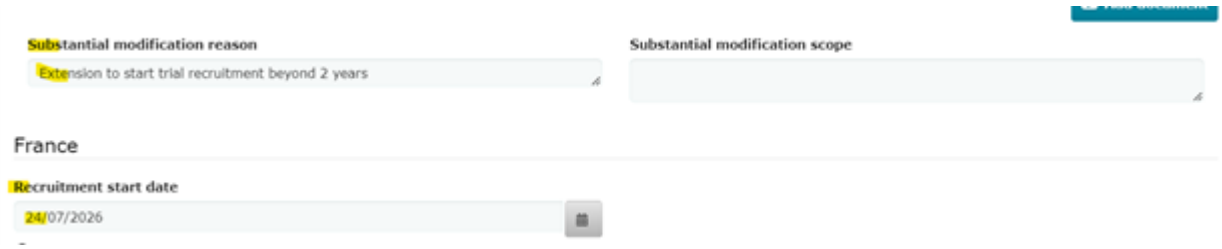
If needed, sponsors can request an extension to start the recruitment beyond 2 years via a Substantial Modification (SM) Part I & II or via SM Part II. Note, that an SM Part I-only cannot be used to request the extension of start of recruitment.

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. The 'Start of recruitment date' entered in this 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.

System improvements

The CTIS release on 18 March 2025 introduced several improvements.

For sponsor users:

- The wording of warning messages related to the CTIS transparency rules have been clarified:
  - In the confirmation message after submitting a response to a Request for Information, the explanatory paragraph at the bottom of the pop-up has been changed to: "Upon confirmation, the response will be sent to the EU Member State(s) as per Regulation (EU) No. 536/2014. CTIS submissions are subject to publication rules: see overview in Annex I of the relevant Guidance."
  - In the section "Trial Category", the warning message in the top right corner has been updated to: "Section Trial Category is already locked by user [username]".
  - In the section "Trial category", the warning message for the "Justification for trial category" field has been updated to read: "Justification for Trial Category may not be null".

For authority users:

- During the authorisation of Initial and Substantial Modifications (Part I and Part I & II) applications, when the Reporting Member State (RMS) has concluded Part I as "Not acceptable", the drop-down list for the "Not Authorised" reasons now includes a new option: "Part I conclusion by RMS: Not acceptable".

More information on the latest system improvements is available in the published release notes.