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CTIS newsflash – 25 February 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 11 March 2025.

Coming soon to the CTIS website: the ACT EU Trial Map

During the ACT EU Clinical Trials Analytics Workshop in January 2024, stakeholders emphasised the need for a simple, patient-friendly dashboard to help patients and healthcare professionals easily locate clinical trials of interest running in the EU.

In response to this feedback, an interactive map of clinical trials in the EU was developed, integrated in the CTIS public portal. Trial Map will be launched on 3 March 2025.

A public webinar on 7 March 2025 at 13:00 – 14:30 CET will provide a live demonstration of the map's features. Participants will have the opportunity to ask questions during the live Q&A session.

Publication of Updated Data Protection Notice for CTIS

We are pleased to announce the publication of the updated CTIS data protection notice. This update serves as an important opportunity for data subjects, including CTIS registered users, sponsors' staff, and principal investigators, to gain a comprehensive understanding of the personal data processed within the secure domain of CTIS and/or published on the CTIS Public Portal.

For more information, read the Data protection notice regarding personal data processing in the Clinical Trials Information System (CTIS).

Key updates

- CTIS users may experience a brief interruption of the system on 6 March 2025 after 22.00 CET. In case CTIS is unavailable, users are advised to wait 10 minutes and then try again.
- The list of known issues for sponsor users has been updated.
- The European medicines regulatory network's vision for clinical evidence by 2030 has been published, describing six guiding principles for generating excellent clinical evidence. A LinkedIn

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Live session in April will allow experts to dive deeper into what these principles mean. More details will follow in the coming weeks.

Save the date: CTIS events in March

- On 5 March 2025 EMA is hosting a CTIS bitesize talk on changing the sponsor of a clinical trial or the sponsor details in CTIS at 15:30-17:00 CET.
- During the public webinar on 7 March 2025 at 13:00 – 14:30 CET, interested participants can follow a demonstration of the Trial Map and ask questions in the live Q&A session.
- Sponsors can register to the CTIS end user training programme on 25-28 March 2025. This training programme is open to new sponsor users of the CTIS, commercial and non-commercial, as well as Contract Research Organisations (CROs).

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 20 February 2025 introduced several improvements.

For all users:

- In a clinical trial with ongoing Additional Member State Concerned (AMS) applications, if a sponsor creates a new draft subsequent application and goes to Part I, they can now see all Part I translations (data and documents) included in previously authorised AMS applications. Authority users who receive the submission of the subsequent application and go to Part I can also see all the translations.

For sponsor users:

- When a sponsor cancels a draft Substantial Modification or Additional Member States Concerned application under certain circumstances, the draft application (of any type) is now cancelled without any errors.
- When a sponsor uploads a "not for publication" version of a document, it is now correctly listed below the "for publication" document version.

For authority users:

- When a sponsor submits an "End of Trial" notification during the evaluation of a Substantial Modification application, the business workflow now progresses as expected, correctly triggering the “Authorise” task for authority users.
- When a sponsor submits an "End of Trial" notification during the evaluation of a Substantial Modification application, authority users can now submit a Request for Information (RFI) during the assessment phases (Validation, Assessment Part I, and Assessment Part II).

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