28 January 2025
EMA/7145/2025
European Medicines Agency

CTIS newsflash – 28 January 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 February 2025.

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 submit any remaining trials for transition as soon as possible.

Sponsors can consult CTCG's best practice guide on transition, Annex I: Cover letter template, and the Annex II: Fees for transitional trials in EU/EEA Member States. Further resources to support sponsors' transitioning trials are available on the CTIS website.

Survey of academia & SMEs: share your clinical trial training needs

The Accelerating Clinical Trials in the EU (ACT EU) initiative aims to deliver a clinical trials training curriculum for different stakeholder groups.

As part of this work, we invite stakeholders from academia or micro, small and medium-sized enterprises (SMEs) involved in the development of medicines to fill in a brief survey with their clinical trial training needs. The survey will be open until 11 February 2025.

The identified training needs will then be matched with available trainings and potential gaps, an overview of which will be published later in 2025.

Resolution of CTIS technical issue on 20 January 2025

On Monday 20 January 2025, CTIS users experienced issues with logging in or searching for trials in the system. The issue was resolved within the same working day and a message was sent to all users to inform them of a 24-hour extension of due dates for RFI responses and hard tasks related to clinical trial applications. We fully acknowledge the disruption this caused some users and would like to assure you that we are working to prevent possible future incidents.

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

Tip for CTIS users: managing your user roles

Users with more than 500 trial-specific roles have reported experiencing long loading times when opening the Requests for Information (RFI) or Tasks tab. To reduce loading times, it is recommended that users actively manage their user roles by removing any roles that are no longer needed.

Save the date: upcoming CTIS events

- EMA is hosting a CTIS walk-in clinic on 29 January 2025, where sponsors can raise questions about any CTIS functionality and receive advice from CTIS experts.
- 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).