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CTIS newsflash – 11 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 25 March 2025.

For sponsors: reminder to keep trial information up-to-date

With the launch of the Trial Map on 3 March 2025, patients and healthcare professionals can even more easily access information on clinical trials of interest in their area via the CTIS public portal.

In order to ensure the accuracy of information that is available to the public, sponsors are reminded to keep CTIS up-to-date, in compliance with articles 36, 37 and 38 of the Clinical Trials Regulation. This is especially important for the recruiting status and contact details of investigators.

By ensuring public access to accurate information, we can facilitate recruitment and ultimately accelerate the conduct of clinical trials in the EU / EEA.

Key updates

- On 7 March 2025, around 800 participants followed the public webinar on the ACT EU Trial Map, which demonstrated how to use the features of the newly launched tool. A video recording will be available soon on the event page.
- Almost 2,000 people from 50 different countries followed the two-day workshop on the ICH E6 R3 guideline on good clinical practice (GCP) on 19-20 February 2025. The high level of engagement highlights the importance of GCP modernisation. The video recordings and presentations are available on the event page.

For sponsors: update to CTIS training materials

EMA has published an updated Frequently Asked Questions (FAQ) for CTIS online training module 10 "How to create, submit and withdraw a CTA". The FAQ for module 18 "How to submit an annual safety report and respond to related RFIs" has also been updated to add question "2.18 What can I do if I cannot find the sponsor in the Sponsor Information (Step 1) section?".

The full catalogue of CTIS online training modules is available on the EMA website.

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

Upcoming CTIS training for sponsors

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).

Current operational experience with CTIS

This section on CTIS metrics provides key data and trends.

The data presented below refer to the period from 1 to 28 February 2025.