23 June 2025
EMA/198062/2025
European Medicines Agency

CTIS newsflash – 24 June 2025

Important Update: Changes to the CTIS Newsflash

Please be informed that from July 2025, the biweekly CTIS Newsflash will be replaced by the Clinical Trials Highlights Newsletter.

For updates on CTIS and other topics related to clinical trials in the EU, we encourage you to subscribe to the Clinical Trials Highlights Newsletter. This newsletter will now be released monthly, offering a more comprehensive overview of clinical trial developments and insights.

👉 Subscribe here to stay updated on the evolving clinical trials landscape in the EU.

CTIS unplanned downtime

On **Thursday 26 June 2025**, the system will be unavailable between 22:00 to 23:00 CET, in addition to the planned downtime during the regular maintenance window from 18:00 to 21:00 CET.

Redesigned sponsor handbook out on 9 July 2025

EMA is redesigning the CTIS training materials for sponsor users, with the aim to improve navigation and ease of use based on stakeholder feedback. A stakeholder focus group, set up under the ACT EU Multi-stakeholder platform, has reviewed and validated the quality of the redesigned materials.

The revised sponsor handbook will be published on the EMA website on 9 July 2025, superseding the existing training modules for sponsors. The handbook will serve as the definitive reference for sponsors using CTIS.

To support sponsors on the new layout, EMA is also hosting a dedicated CTIS bite-size talk on Wednesday 9 July 2025 at 15:30 CEST.

For all CTIS users: notices and alerts to be archived after 90 days

As one of the measures to improve CTIS performance, EMA has decided to migrate and archive all notices and alerts **after 90 calendar days from their generation**. This change is expected to be implemented in late July 2025 - the exact date will be announced in the next CT Highlights newsletter.

For this reason, we encourage users to regularly check their notices and alerts in CTIS, as they will no longer be visible in the system after this 90-day period.

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

© European Medicines Agency, 2025. Reproduction is authorised provided the source is acknowledged.

COMBINE "all-in-one" coordinated assessment pilot: Call open for expressions of interest

The European Commission, participating Member States and EMA are pleased to announce the launch of the COMBINE Project 1 pilot. Phase 1 of this initiative explores the feasibility of a coordinated assessment procedure using CTIS for applications which involve a multinational clinical trial of an investigational medicinal product combined with an interventional clinical performance study of an *in vitro* diagnostic or companion diagnostic medical device, run by the same sponsor.

Sponsors are invited to express their interest by submitting a completed form and a synopsis of proposed combined study via Eudralink to EUcombinepilot@ccmo.nl by 31 August 2025. Further details are available on the dedicated COMBINE programme webpage.

Tips for CTIS users when assigning roles

In CTIS, users can be assigned viewer, preparer or submitter roles. As per page 5 of the summary of the role matrix for the authority workspace and sponsor workspace, these roles are embedded in each other, i.e. 'Preparers' also have 'Viewer' rights and 'Submitters' have both 'Preparer' and 'Viewer' rights.

To avoid system performance issues, administrators are advised to **only assign one role per user**, based on whether the user needs to "view", "prepare" or "submit" information in CTIS. For example, the 'Assessor Part II Submitter' role already includes the permissions of the 'Assessor Part II Preparer' role, so assigning both roles to the same user is unnecessary.