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CTIS newsflash – 27 May 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 10 June 2025.

Key updates

- CTIS was briefly unavailable between 14:00 to 15:00 CET on Monday 19 May 2025. During the downtime, EMA implemented optimisations to address performance issues. CTIS performance has since markedly improved. If you experience issues with CTIS, please contact the ServiceDesk.
- Updated lists of known issues and proposed workarounds for sponsors and authority users are now available on the CTIS website.
- Over 400 people followed the CTIS Info day on 22 May 2025. The half-day event provided an overview of CTIS, its optimisations, best practices, and upcoming developments, and addressed 25 pre-submitted questions from the audience. The materials and video recording will be available soon on the event page.
- 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, is validating the quality of the redesigned materials, expected to be published from June 2025. The exact launch dates will be announced in upcoming issues of this newsflash.

Joint HMA-EMA LinkedIn live on "Clinical evidence 2030" reflection paper

Peter Arlett and María Lamas will discuss the reflection paper on "Clinical evidence 2030" in a LinkedIn live event on 11 June 2025 at 11:00 CET. The event will be live-streamed on EMA's LinkedIn.

Comments received during ICH M11 consultation

The ICH M11 draft guidelines covers the clinical study protocol template and technical specifications.

Following the end of public consultation on 22 April 2025 on the revised draft ICH M11 Technical Specification, an overview of received comments has now been published on the EMA website.

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The public consultation was part of the ICH Step 2b for the finalisation of the technical specification document by the ICH M11 expert group.

The ICH M11 guideline aims to establish a clinical protocol template and technical specification, ensuring protocols are consistently structured and a harmonised data exchange format is developed to meet regulatory requirements.