



10 June 2025  
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European Medicines Agency

## CTIS newsflash – 10 June 2025

### Important Update: Changes to the CTIS Newsflash

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Please be informed that from July 2025, the biweekly CTIS Newsflash will be replaced by the Clinical Trials Highlights Newsletter. The final issue of the CTIS Newsflash will be released on 24 June 2025.

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.

### Key updates

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- **Open consultation until 15 September 2025:** EMA has released for public consultation a [new guideline](#) providing recommendations on how to include or retain pregnant and breastfeeding people in clinical trials. The goal is to ensure developers generate robust clinical data in those populations, so that these individuals and their healthcare providers can make informed, evidence-based decisions when using medicines. More information on how to provide comments is available in the [news announcement](#).
- María Lamas and Peter Arlett discussed 'Strengthening evidence generation in the EU' in a LinkedIn live event on Tuesday 10 June 2025. The event was inspired by the recent paper: "[Clinical evidence 2030](#)" and a recording is available on [EMA's LinkedIn](#).
- The video recording and presentations from the CTIS Info day on 22 May 2025 are now available on the [event page](#). The event provided an overview of CTIS, its optimisations, best practices, and upcoming developments, and addressed pre-submitted questions from the audience.

### Save the date: COMBINE event 20 June 2025

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The COMBINE PILOT on coordinated assessment is being launched, aiming to **streamline the review** process for **multinational clinical trials with a simultaneous performance study** by synchronizing competent authority and ethics committee reviews.

[Join the webinar](#) on Friday 20 June 2025 at 14:00 to 16:00 CEST to learn about the pilot for the COMBINE 'All-in-One' coordinated procedure for combined studies.

More information on the COMBINE Programme is available on the [European Commission website](#).



## Current operational experience with CTIS

This section on CTIS metrics provides key data and trends.

After a significant increase driven by the transition period deadline at the end of January 2025, the volume of initial applications submitted, as well as the corresponding decisions, is now stabilising.

The data presented below refer to the period from 1 to 31 May 2025.

### CTA Submissions



#### Initials

199

-12%  
on previous month

Total

11,507



#### Substantial Modifications

1,115

-5%  
on previous month

16,497



#### Initials

168

-25%  
on previous month

9,460



### Reporting Member States

