8 April 2025
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European Medicines Agency

CTIS newsflash – 8 April 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.

Due to the Easter break, the next issue will be circulated on 29 April 2025.

CTIS is now a WHO primary registry

CTIS has been designated as a primary registry by the World Health Organisation (WHO) within the International Clinical Trials Registry Platform (ICTRP). The WHO International Clinical Trials Registry Platform aims to ensure that comprehensive research information is accessible to healthcare decision makers globally.

WHO's primary registries meet the standards set by the International Committee of Medical Journal Editors (ICMJE), which is a prerequisite for clinical trials to be published in general medical journal articles. Read more in the news announcement.

Key updates

- EMA is hosting a CTIS Info day on 22 May 2025. The half-day informational webinar aims to provide an overview of CTIS, its optimisations, best practices, and upcoming developments.
- CTCG has published a Guide for Change of Trial Sponsor, outlining the steps sponsors need to follow and the expedited procedure for changing the sponsor legal entity (Org-ID). This change is a substantial modification per Annex IV of the CTR Q&A at EudraLex Volume 10.

Tips for sponsors

- **'For publication' documents:** Sponsors are reminded that the first document uploaded in CTIS is the one 'for publication', for all those documents subject to publication as per table II of Annex I: Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System (CTIS). Therefore, sponsors should make sure that the first document uploaded in each of the 'for publication' placeholders is redacted of commercially confidential information (CCI) and that personal data are anonymised as per the relevant guidance. If needed, the sponsor can then add 'not for publication' versions, which contain CCI and personal data that are necessary for the Member State(s)

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assessment, by clicking the '+' button in the same placeholders. This process avoids the need to submit subsequent modifications in order to upload the correct documents in the 'for publication' placeholders.

- **Contact details of principal investigators:** Sponsors are reminded to include professional contact details of the principal investigators in their clinical trial applications, i.e. a professional or functional/shared email address and *not* personal contact details, as per the relevant guidance (see page 18). Please note that these details are visible in the CTIS public portal and through the Trial Map.
- Sponsors are advised to **avoid creating draft applications** for Substantial Modifications (SM), Non-Substantial Modifications, or Additional Member State Concerned **not only while a previous application is still under evaluation** (as currently indicated in system warning messages) **but also when a draft already exists,** unless the sponsor understands that these drafts are mutually exclusive. This is because when a draft application is created, it copies the documents and data from the last authorised application. For example, if a draft SM Part I is created when an Additional Member State (AMS) application is already in draft, the AMS application will not include the Part I SM changes. As a consequence, if this AMS is submitted and under evaluation after the SM Part I is authorised, the sponsor will have to withdraw the AMS application, as it will not contain the latest version of Part I introduced with the SM Part I.

For academic and not-for-profit developers: your needs on scientific and regulatory support

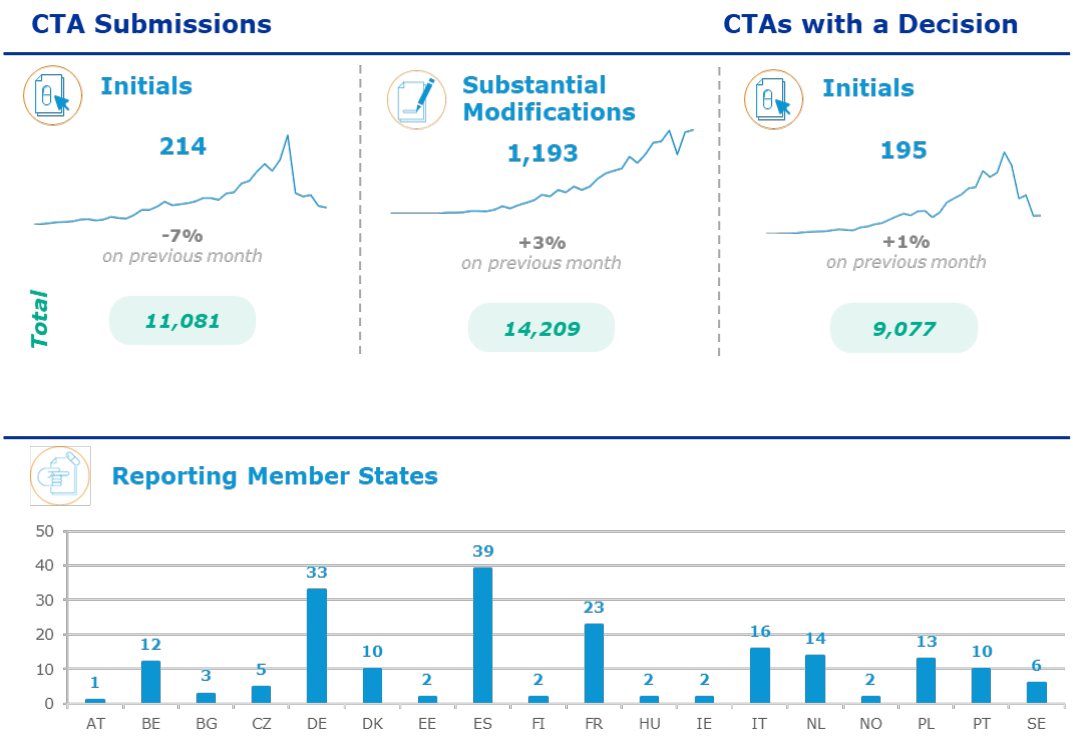
EMA invites developers of medicines and tools for medicine development from academic and not-for-profit organisations to participate in a short survey via this link**.** The survey aims to map academic developments and better understand the needs and experiences of academic developers.

The results of the survey will be used to inform EMA's activities in supporting academic and not-for-profit developers. The survey will be open until 25 April 2025.

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 31 March 2025.



Reminder: send your comments on the revised draft ICH M11 Technical Specification

Stakeholders can provide their feedback on the revised draft ICH M11 Technical Specification until 22 April 2025.

The purpose of this new harmonised guideline is to introduce the clinical protocol template and the technical specification to ensure that protocols are prepared in a consistent fashion and provided in a harmonised data exchange format acceptable to the regulatory authorities.

Stakeholders can send in their comments via email to ich@ema.europa.eu using this template. More information is available on the EMA website.