5 April 2024
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European Medicines Agency

CTIS newsflash – 5 April 2024

Introduction

This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

The next issue will be circulated on 19 April 2024.

Previous issues of the CTIS Newsflash are available on the EMA website.

Reminder: Transition ongoing trials from CTD to the Clinical Trials Regulation

Sponsors are advised to transition any trials that are expected to continue after 30 January 2025 from the Clinical Trials Directive (CTD) to the Clinical Trials Regulation (CTR).

Sponsors should take into account the time necessary for completion of the Member State(s) evaluation procedure, which can take up to 3 months. When possible, Members States have agreed on an expedited procedure for transitioning trials to the CTR.

Further resources to support sponsors transitioning trials are available on the CTIS website.

Key updates

- CTCG has published a best practice guide for sponsors updating Part I documents in line with the CTR at the time of the first Substantial Modification (SM) Part I for trials transitioned from the Clinical Trials Directive. Templates for the cover letter and description of the first SM are also available.
- On 25 March 2024, over 1800 viewers followed the online CTIS webinar on the final year of transition to the CTR. The video recording will soon be available on the event page.
- Due to the planned downtime of several EMA systems including SPOR (Substance, Product, Organisation & Referentials), CTIS users will not be able to register new organisations or trial sites in OMS from Thursday 11 April 2024 at 18:00 CEST to Monday 15 April 2024 end-of-business. Users are, therefore, advised to take this into account when planning new registrations to OMS.
- An updated version of the quick guide for CTIS users on the revised transparency rules is now available on the ACT EU website.

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Save the date: Upcoming events

The EU Innovation Network, in conjunction with the Accelerating Clinical Trials in the EU (ACT EU) initiative, is organising an information and training webinar on Simultaneous National Scientific Advice (SNSA) on 19th April 2024. The SNSA pilot focuses specifically on scientific advice to facilitate clinical trials within the EU. Participants can submit questions in advance via Slido until 12 April 2024, using the code #SNSAwebinarApril.

On 24 April 2024, EMA is hosting a CTIS Bitesize talk on alternate Investigational Medicinal Product Dossier – Quality (IMPD-Q) and new guidance on Auxiliary Medicinal Products (AxMP) at 15:30-17:00 CEST. Participants can submit their questions in advance until 17 April via Slido with the code #bt24apr.

Sponsors can already register to the upcoming CTIS user training on 10-13 June 2024, 09:00-13:30 CEST.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu).

System improvements

A CTIS release on 4 April 2024 introduced several improvements:

- The buttons for the soft tasks "Assign", "Assign to me" and "Create sub task" are now available for users of Members States added via an Additional Member State Concerned application, even if the trial is suspended or halted for that Additional Member State.
- After creating, sharing and searching for an Ad-hoc assessment, Member State users are now able to update it and save it with no error message displayed.
- The task "Submit RFI" (Request for information) is now generated in the task list for the Reporting Member State in the following scenarios:
  - After sharing consolidated Part I considerations in Additional Member State Concerned applications, when an RFI is created in Part II before creating and sharing the Part I considerations;
  - After sharing consolidated Part II considerations in Substantial Modifications Part I & II, when an RFI is submitted for Part I before submission of the documentation of Part II considerations.
- In the evaluation section, the "Validation conclusion" information saved in the authority workspace is only displayed to sponsor users after the Member State Concerned submits the validation decision.
- Users are now able to submit Annual Safety Reports (ASRs) for clinical trials linked to Investigational medicinal products (IMPs) containing more than 23 substances.
- Trial sites in saved and/or submitted clinical trial applications are now displayed and can be downloaded by users in both the sponsor and authority workspaces.

More information on the latest system improvements is available in the published release notes as well as in the Lists of known issues and proposed workarounds for sponsors and for Member State users.

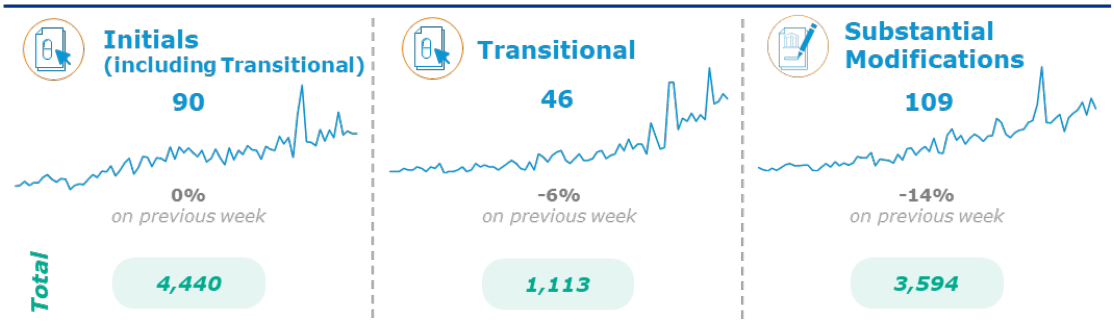
EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

Current operational experience with CTIS

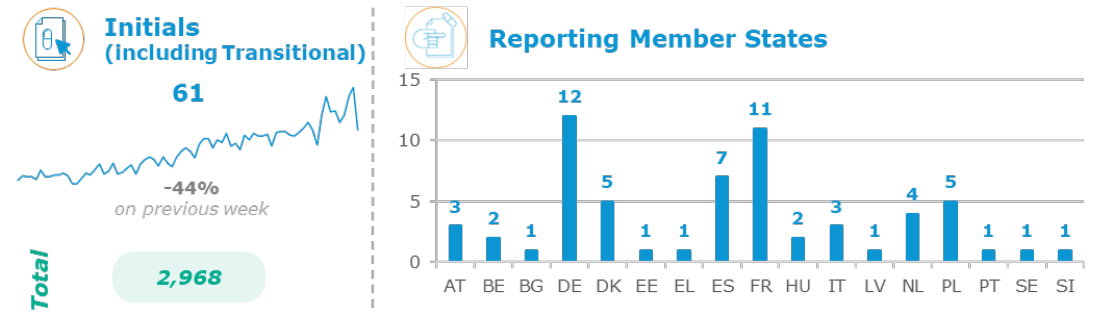
This section on weekly CTIS metrics provides key data and trends.

The data presented below refer to the period from 26 March to 1 April 2024.

CTA Submissions

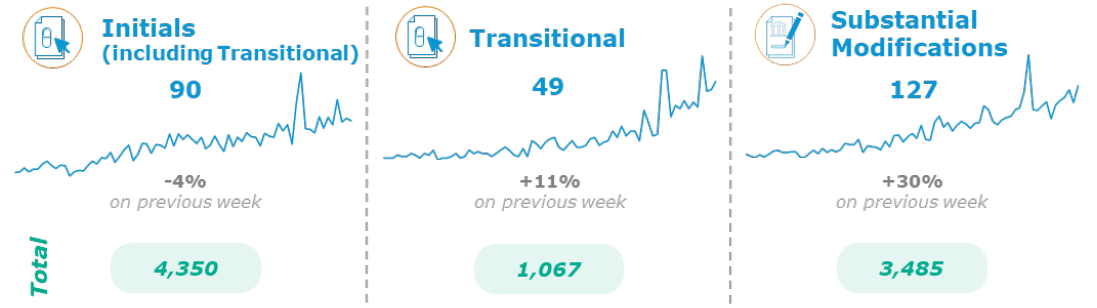


CTAs with a Decision

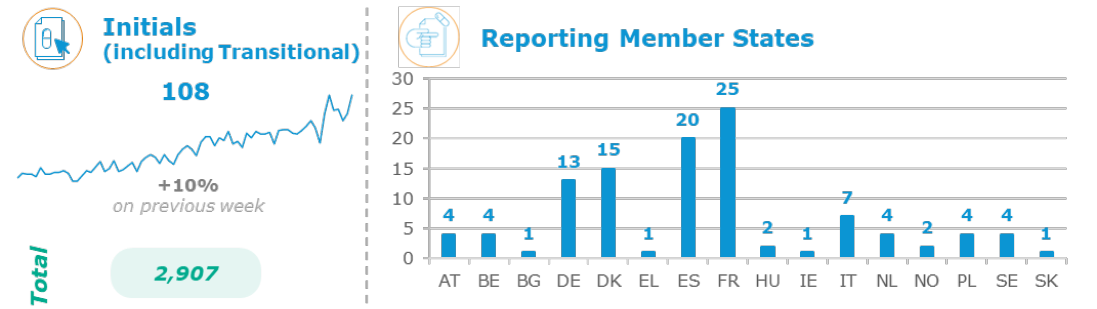


The data presented below refer to the period from 19 to 25 March 2024.

CTA Submissions



CTAs with a Decision



Requesting access to the CTIS Training Environment

Sponsors can express their interest in gaining access to the CTIS Training Environment by filling in the ongoing survey. The training environment is a simulation of CTIS used in production and allows users to get familiar with system functionalities.

More information

Are you a sponsor user starting out with CTIS? Please consult the 'Sponsor quick guide: Getting started with CTIS' or refer to the CTIS training material, including the new version of the 'CTIS Handbook for clinical trial sponsors'. The handbook provides useful information on how sponsors can navigate CTIS to create and submit clinical trial information to the member states of the European Union as required by the Clinical Trial Regulation (EU) No 536/2014.

Resources to support sponsors transitioning trials from the Clinical Trials Directive (CTD) to the CTR are available on the CTIS website.