22 April 2024
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European Medicines Agency

CTIS newsflash – 22 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 3 May 2024.

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

Launch of revised CTIS transparency rules on 18 June 2024

The revised CTIS transparency rules will become applicable on 18 June 2024, with the launch of an updated version of the CTIS public portal. Sponsors are advised to adapt their business processes accordingly, and can refer to the quick guide for users for an overview of the changes.

For all clinical trial applications submitted on or after 18 June 2024:

- it will no longer be possible to defer the publication of data and documents;
- data and documents will be published according to the established timelines for the trial category, population age and trial phase;
- publication of documents will be focused on key documents of interest.

Data on all clinical trial applications submitted before 18 June 2024 will be made publicly available in line with the principles and timelines defined in the revised transparency rules. Please note that documents of these trials will not be published. Documents included in subsequent applications of these trials submitted after 18 June 2024 will be published in line with the revised rules[1]; more details are available in the quick guide for users.

In the interim period until 18 June 2024, sponsors may already follow the principles of the revised CTIS transparency rules.

A CTIS Bitesize talk on the topic is planned on 20 June 2024, to further support sponsors in adapting their business processes accordingly. The event page will be shared in upcoming issues of this newsflash.

The Guidance and Q&As section of the CTIS website as well as the ACT EU website on Implementation of the Clinical Trials Regulation include all resources and support materials on transparency in CTIS.

[1] This applies to documents of all types of applications, with the exception of part I documents of Non Substantial Modifications and Additional Member State applications.

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More information is available on the news item: Launch of revised CTIS transparency rules.

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.

Save the date: Upcoming events and trainings

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.

The next CTIS walk-in clinic will take place on 15 May 2024 at 16:00 – 17:00 CEST. Participants can submit their questions via Slido until 8 May 2024, with the code #clinic245.

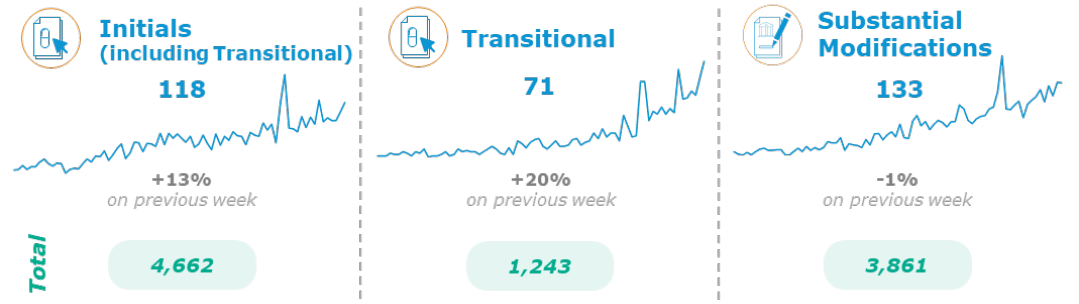
Sponsors can already register to the upcoming CTIS user training on 10-13 June 2024, 09:00-13:30 CEST. For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu).

Current operational experience with CTIS

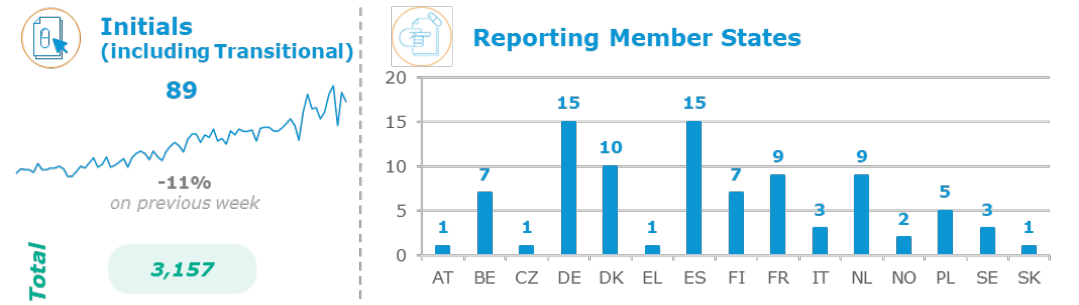
This section on weekly CTIS metrics provides key data and trends.

The data presented below refer to the period from 9 to 15 April 2024.

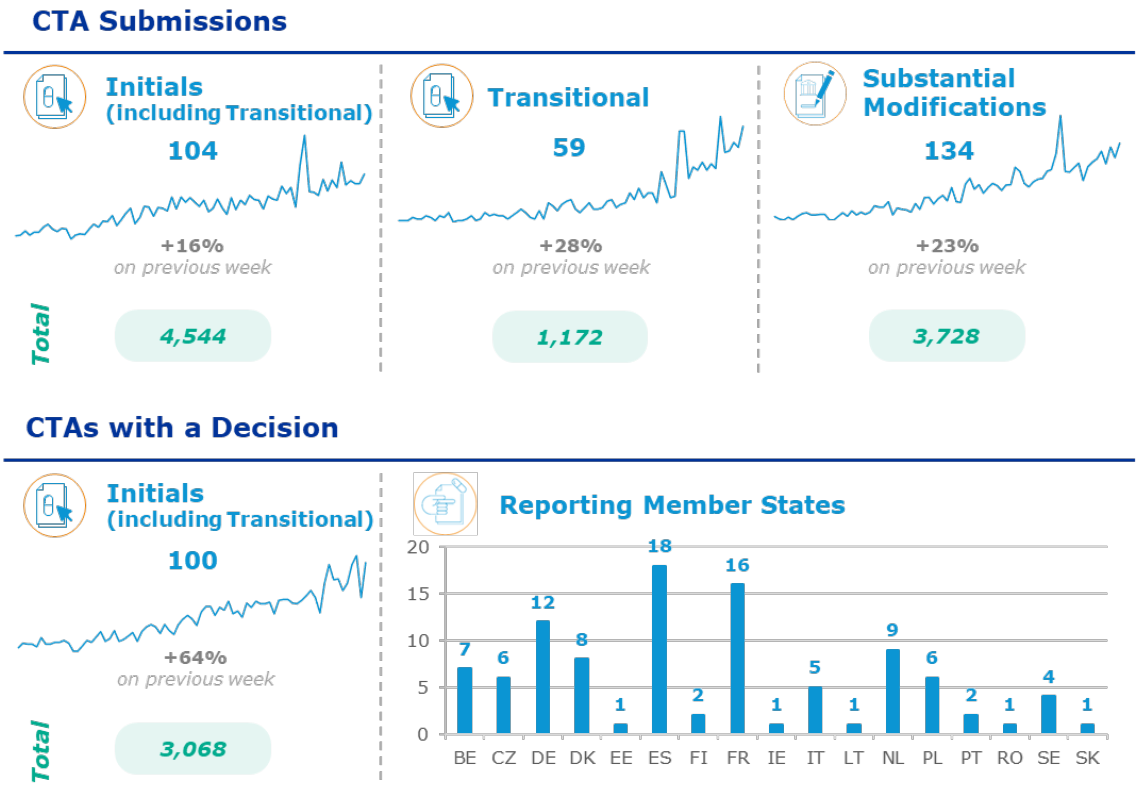
CTA Submissions



CTAs with a Decision



The data presented below refer to the period from 2 to 8 April 2024.



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.

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.