31 May 2024
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European Medicines Agency

CTIS newsflash – 31 May 2024

Introduction

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

The next issue will be circulated on 14 June 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. Members States have agreed on an expedited procedure for transitioning trials to the CTR which will be applied whenever possible.

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

Spotlight: 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 Please note that existing CTIS documents of these trials will not be published.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.

[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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In the interim period until 18 June 2024, sponsors may already follow the principles of the revised CTIS transparency rules, as defined in section 4 of the ACT EU Q&A.

More information and resources are available on the ACT EU website and on the CTIS website.

Save the date: Upcoming events

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

On 20 June 2024, EMA is hosting a CTIS Bitesize talk on the revised transparency rules and the new version of the CTIS public portal at 15:30-17:00 CEST. Participants can submit their questions in advance from 20 May until 13 June via Slido with the code #bt20jun. More information is available on the event page.

The next CTIS Walk-in Clinic will take place on 10 July 2024 at 16:00 – 17:00 CEST. Participants are able to submit their questions via Slido from 10 June to 3 July 2024, with the code #clinic246. More information is available on the event page.

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 21 to 27 May 2024.

CTA Submissions

Initials (including Transitional)

112

-13%
on previous week

Total: 5,377

Transitional

70

-9%
on previous week

1,654

Substantial Modifications

150

+8%
on previous week

4,642

CTAs with a Decision

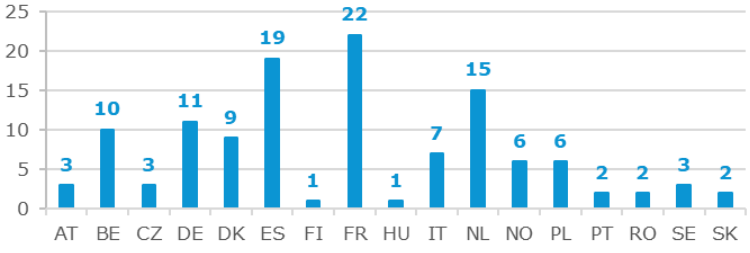
Initials (including Transitional)

122

+15%
on previous week

Total: 3,778

Reporting Member States



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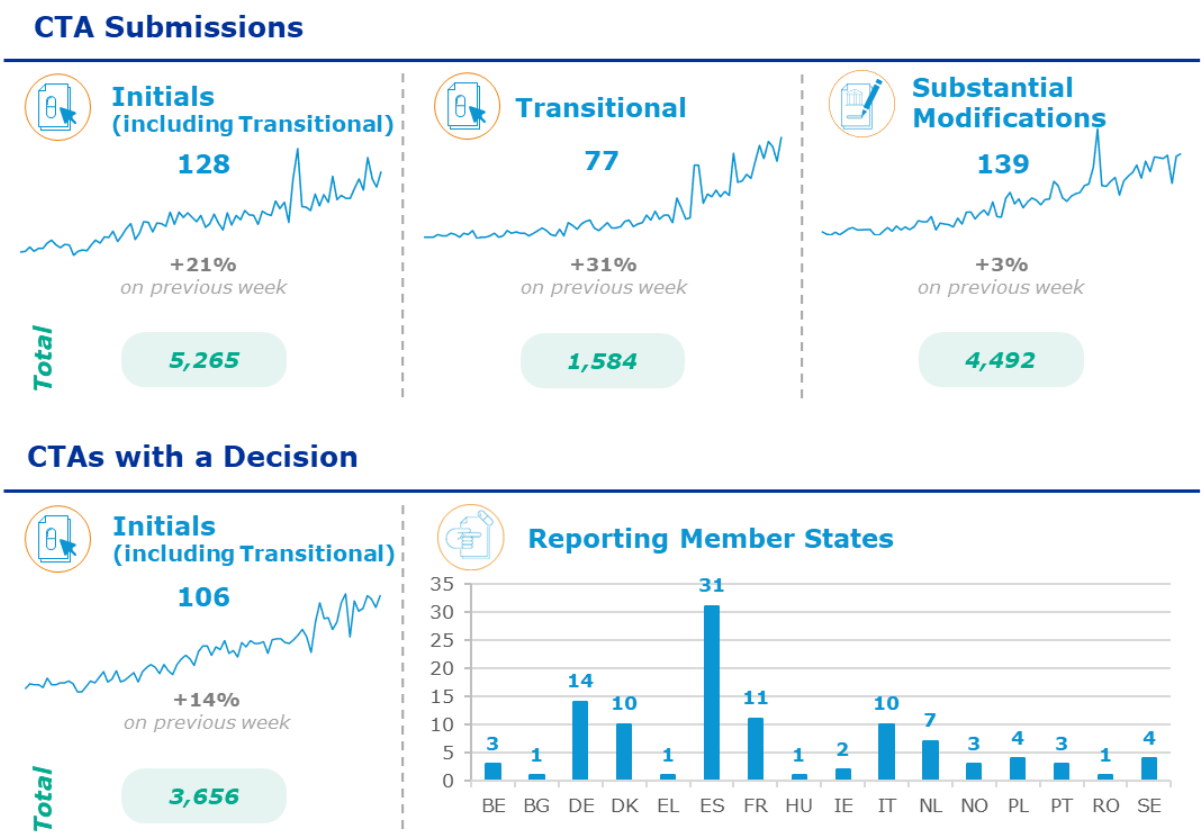
The data presented below refer to the period from 14 to 20 May 2024.



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 latest 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.

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.

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