28 June 2024
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European Medicines Agency

CTIS newsflash – 28 June 2024

Introduction

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

The next issue will be circulated on 12 July 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.

EMA is also hosting a CTIS Walk-in Clinic dedicated to answering users' questions on the transition. The event is planned on 18 September 2024 and more details will follow in due course.

Revised CTIS transparency rules: resources for sponsors

With the successful launch of a new version of the CTIS public portal on 18 June 2024, the revised CTIS transparency rules are now applicable.

For support in the implementation of the revised rules, sponsors can consult the updated quick guide for users, guidance, annex I and Q&A document on the protection of personal data and CCI in CTIS. All documents are available under the "Transparency in CTIS" section of the ACT EU website.

Additionally, modules 02, 07, 10 and 11 of the CTIS online training programme have been updated to reflect the changes introduced by the revised CTIS transparency rules and the new version of the public portal.

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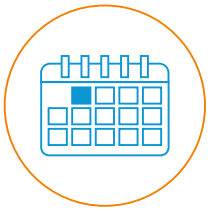
Key updates

- A fix was implemented in CTIS in May 2024 to improve user experience and unblock users during the creation of Substantial Modifications (SMs) for very large trials involving many Member States. Since then, monitoring of the system has shown a sixfold improvement in average performance and a 100% success rate in creating SMs.
- The May 2024 report on the implementation of the Clinical Trials Regulation (CTR) is now available on the ACT EU website.
- CTCG published a new document on safety, which clarifies topics in addition to section 7 of the Q&A in EudraLex Vol.10 regarding the annual safety report, safety-relevant notifications, reference safety information and requests for information sent within the 'adhoc' workflow which is used for supervision of clinical trials.



Save the date: Upcoming events

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 until 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).

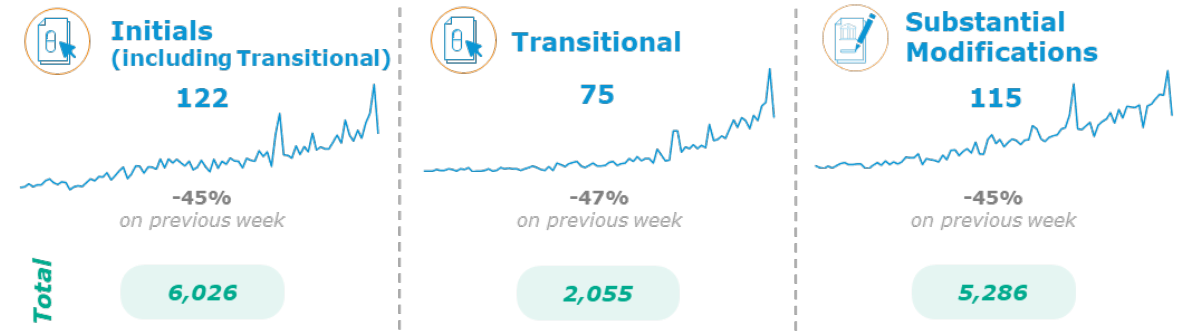
On 17 July 2024, EMA is hosting a webinar on the newly launched consolidated advice pilots, outlining their scope and benefits. The pilots aim to improve the quality of applications for clinical trials and/or marketing authorisation. Participants can submit questions between 24 June to 10 July 2024 via Slido, using the code #pilotsCA.

Current operational experience with CTIS

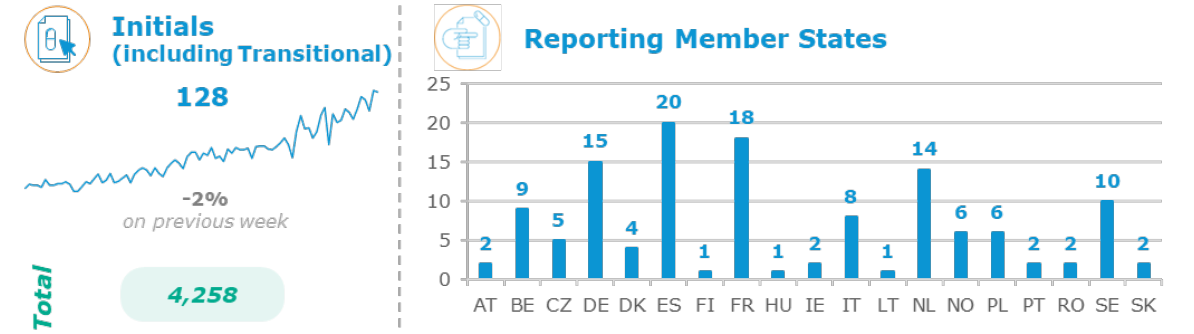
This section on weekly CTIS metrics provides key data and trends.

The data presented below refer to the period from 18 to 24 June 2024.

CTA Submissions

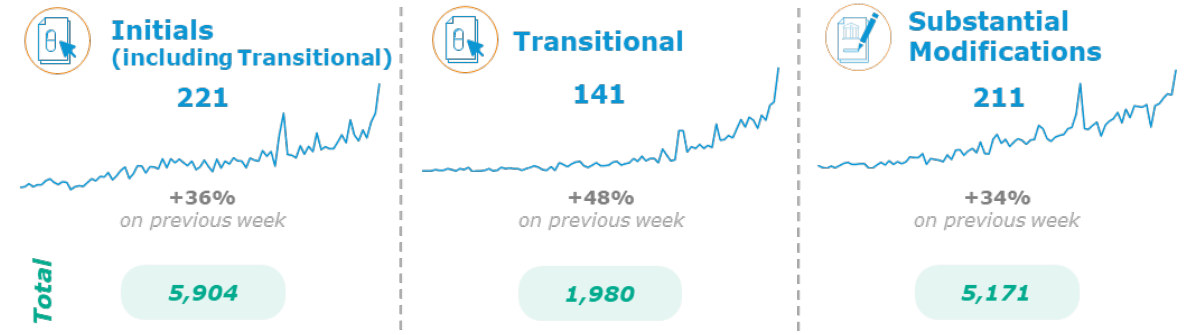


CTAs with a Decision



The data presented below refer to the period from 11 to 17 June 2024.

CTA Submissions



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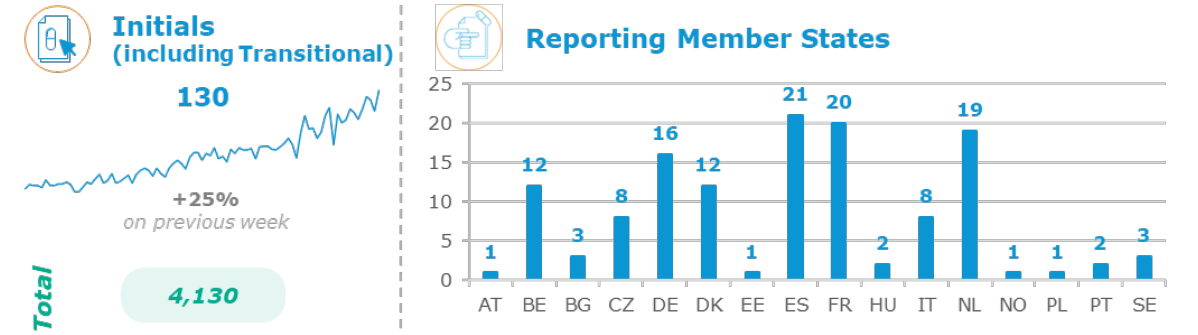

Information on the latest system improvements is available in the published release notes as well as in the Lists of known issues and proposed workarounds for sponsors and for Member State users.

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.