9 August 2024
EMA/325160/2024
European Medicines Agency

CTIS newsflash – 9 August 2024

Introduction

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

After the summer break, this newsflash will be circulated every two weeks on Tuesdays. The next issue is planned on 10 September 2024.

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

Advice for CTIS users

- Notices & Alerts: For an overview of open tasks and required actions, CTIS users are advised to regularly consult the tabs "Tasks" and/or "Requests for Information (RFI)" instead of relying solely on the notices and alerts.
- Timetable: During the assessment of a clinical trial application, the timetable may show different due dates/status/information than the actual due dates/status on the Tasks page and RFI page. This does not impact the workflow and the actual due date of the task and RFI: users are recommended to comply with the due dates recorded in the individual tasks and RFI.

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.

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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Save the date: events in September 2024

CTCG, with support from ACT EU, is hosting a stakeholder meeting of the CTR Collaborate initiative on 11 September 2024. The open session will be live-streamed, sharing insights from the work of CTR Collaborate. To participate in the closed breakout sessions, stakeholders can pre-register until 30 August 2024.

EMA is hosting a CTIS Walk-in Clinic on 18 September 2024 dedicated to answering users' questions on the transition of trials from the Clinical Trials Directive to the Clinical Trials Regulation. Participants will be able to submit their questions in advance from 18 August to 11 September 2024.

Sponsors can also register to the upcoming CTIS user training on 23-26 September 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).

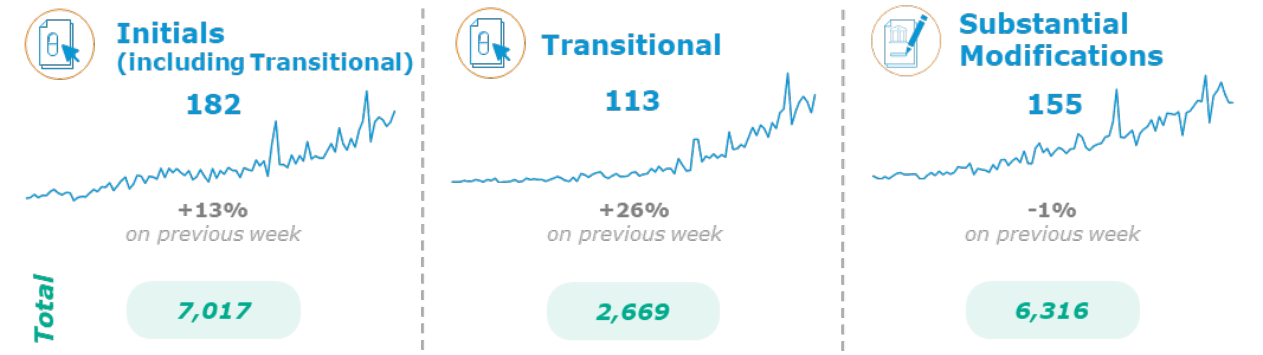
Current operational experience with CTIS

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

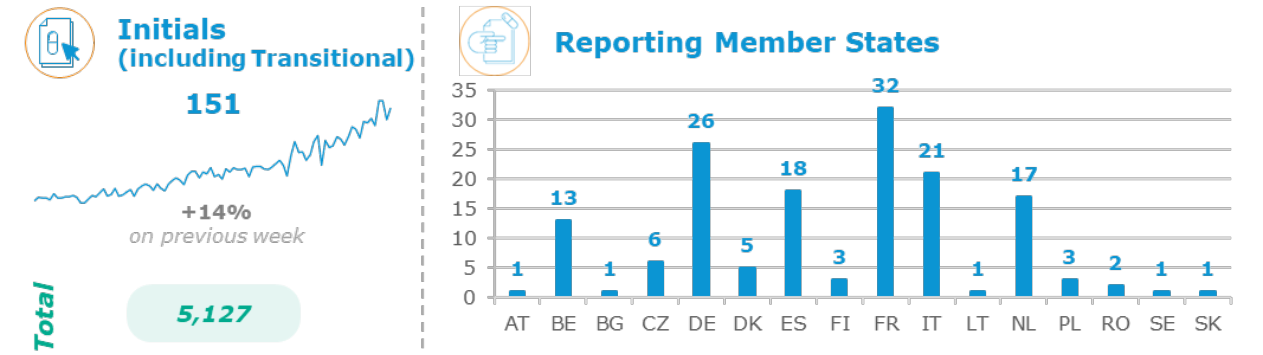
Please note that from September 2024, updates on the CTIS operational experience will be shared on a monthly, rather than weekly, basis.

The data presented below refer to the period from 30 July to 5 August 2024.

CTA Submissions

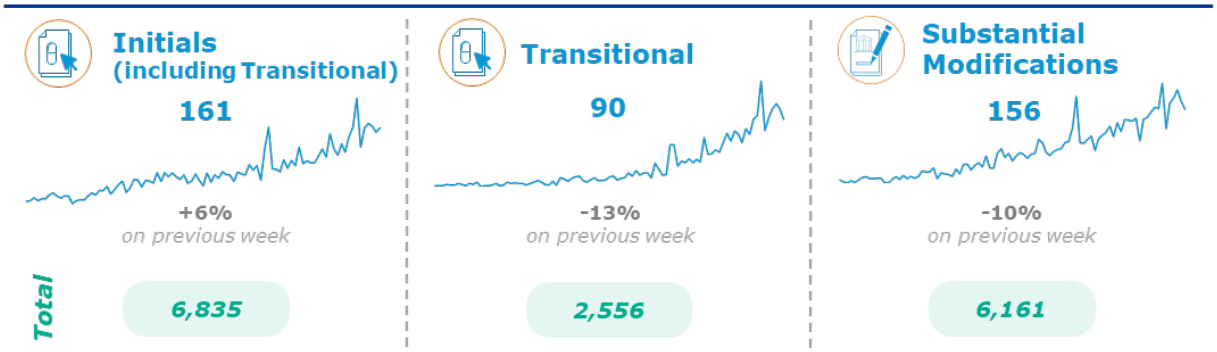


CTAs with a Decision

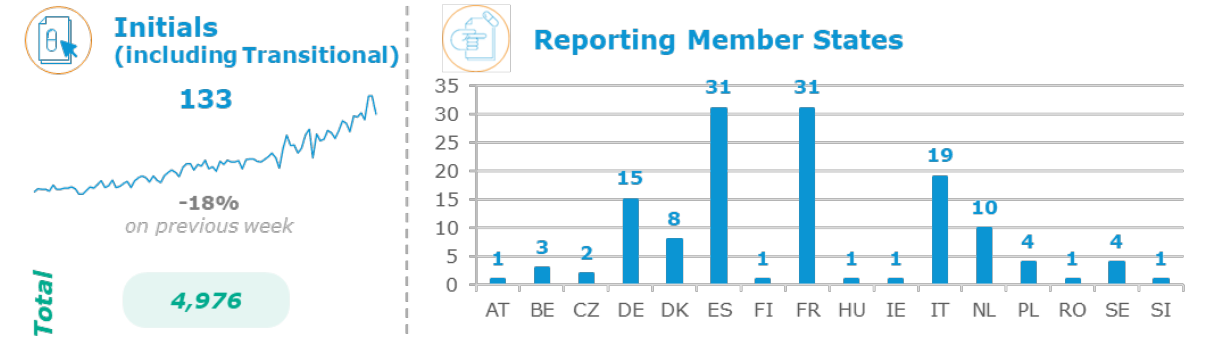


The data presented below refer to the period from 23 to 29 July 2024.

CTA Submissions



CTAs with a Decision



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.