12 July 2024
EMA/303545/2024
European Medicines Agency

CTIS newsflash – 12 July 2024

Introduction

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

The next issue will be circulated on 26 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.

Sponsors can consult CTCG's recently updated best practice guide on transition, Annex I: Cover letter template, and the newly published Annex II: Fees for transitional trials in EU/EEA Member States. Further resources to support sponsors transitioning trials are available on the CTIS website.

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

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.

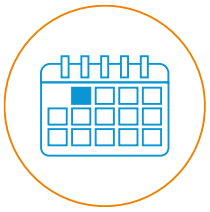
For support in the implementation of the revised rules, sponsors can consult the updated quick guide for users, guidance, annex I and Q&A document on the protection of personal data and CCI in CTIS.

The latest quick guide for users and Q&A (question 1.9) include details on cases where only 'track-changes' versions of certain documents, which are no longer subject to publication, are present in the CTIS workspaces.

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: Upcoming events



On 16 July 2024, EMA is organising a LinkedIn live discussion about the Accelerating clinical trials in the EU (ACT EU) initiative with Peter Arlett, Head of Data Analytics and Methods Task Force, and Marianne Lunzer, chair of the Heads of Medicines Agencies (HMA) Clinical Trials Coordination Group (CTCG) and member of the Austrian Agency for Health and Food Safety. We invite you to post your questions for our two speakers via the comment section, either in advance or during the LinkedIn event. Interested participants can follow the interview on the event page from 12:00 to 12:30 CEST.

On 17 July 2024, EMA is hosting a webinar on the newly launched ACT EU consolidated advice pilots (SAWP-CTCG and pre-CTA), outlining their scope and benefits. The pilots aim to improve the quality of applications for clinical trials and/or marketing authorisation. The event will take place from 15:00 to 17:00 CEST. Participants can submit questions via Slido, using the code #pilotsCA.

System improvements

The CTIS release on 4 July 2024 introduced several improvements:

- Sponsors can now only submit a later staggered Part II trial application once they have submitted a Part I conclusion.
- When sponsors create a new Substantial Modification (SM), the system now correctly displays the latest authorised number of subjects in the Member State Concerned (MSC) section.
- Sponsors can now create any type of application (SM all types, Non-Substantial Modification all types, and Additional MSC) on top of an initial application which was previously withdrawn, then resubmitted and authorised.
- During the validation check, if the mandatory field "Plan to share IPD" has been left blank, the system now highlights the sub-section "Trial information" in Part I, so users can visually identify the section where information is missing.
- When authority users save the Part II conclusion without submitting it, if the task "Submit part II conclusion" expires, the conclusion field now displays "No conclusion".
- Sponsors navigating to the Notifications tab within a clinical trial with sites outside the European Economic Area (EEA) are now able to see the "Submit Global End" button, complete the notification and submit, if:
  - The MSC Trial Status is ended for all Member States Concerned;
  - The MSC Trial Status is ended for at least one Member State and the rest are in status Withdrawn, Not authorized, Lapsed, Revoked and/or Expired.
- Each authority user is now only able to see, assign and complete tasks for their MSC.
- When a Member State that did not authorise the Initial Application is later added through an Additional MSC application, this Member State is now able to successfully submit a Part II Request for Information (RFI) in Substantial Modifications Part I&II.
- During the Part II assessment of a Substantial Modification Part I&II or Part II only, sponsors can now see any Part II assessment RFI(s) and related information (including considerations) submitted by a MSC that did not authorise the Initial Application or was withdrawn and added later through an Additional MSC application, if the SM was created after the addition of this MSC.

- For new applications submitted after the revised transparency rules became applicable, the warning message displayed in the pop-up window "Submit Application Confirmation" has been updated:
  - In the section with the statement from the sponsor, a new item is displayed: "6. Personal data and commercially confidential information were protected in those data and documents, that will be subject to publication";
  - The "Confirm submission" of the application message now reads: "Upon confirmation, this application will be sent to the EU Member State(s) selected for assessment as per Regulation (EU) No. 536/2014. Please note that you may only and notification date of the decision on trial. Your application will be subject to revised publication rules. Before clicking on 'confirm', please ensure that protection of personal data and commercially confidential information is applied: see Annex I of the relevant Guidance."

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.

Recent publications

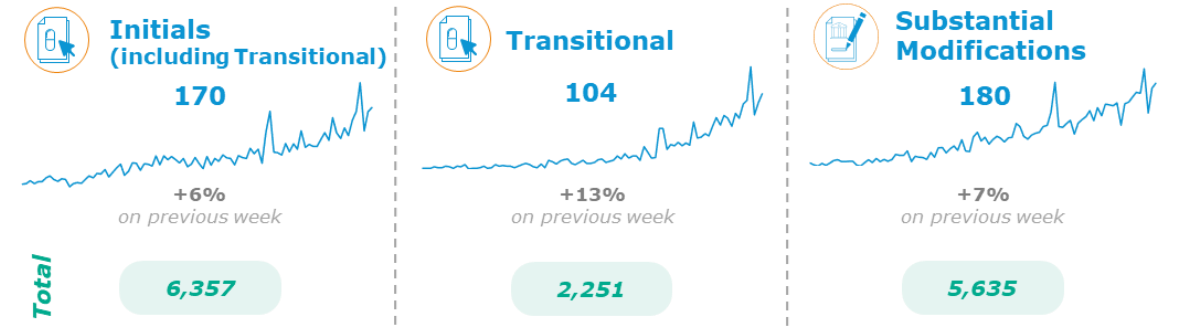
A targeted survey in September – October 2023 collected feedback from clinical trial sponsors on their experience with the implementation of the CTR and the use of CTIS. A summary report of the survey has been published.

Current operational experience with CTIS

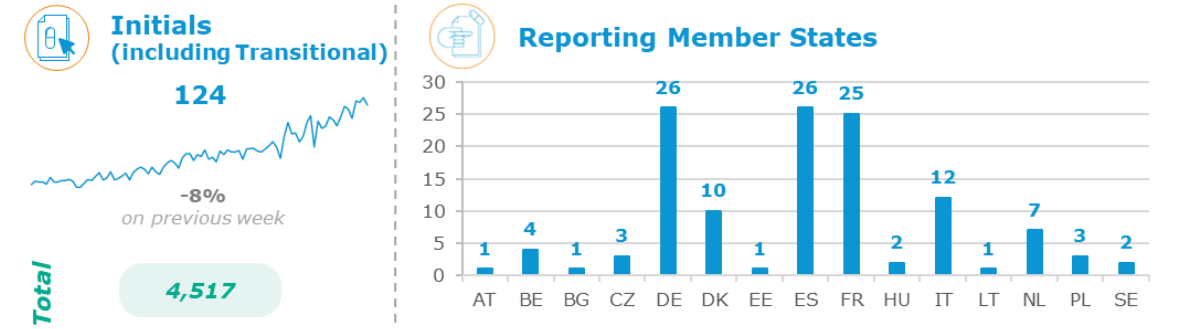
This section on weekly CTIS metrics provides key data and trends.

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

CTA Submissions

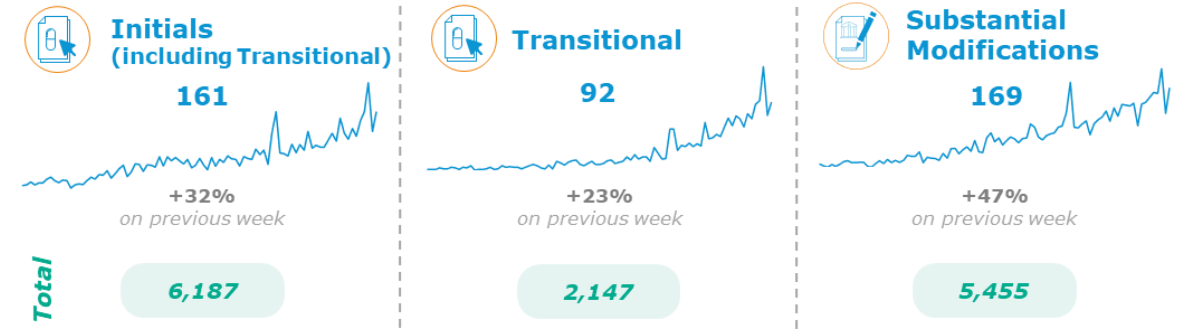


CTAs with a Decision

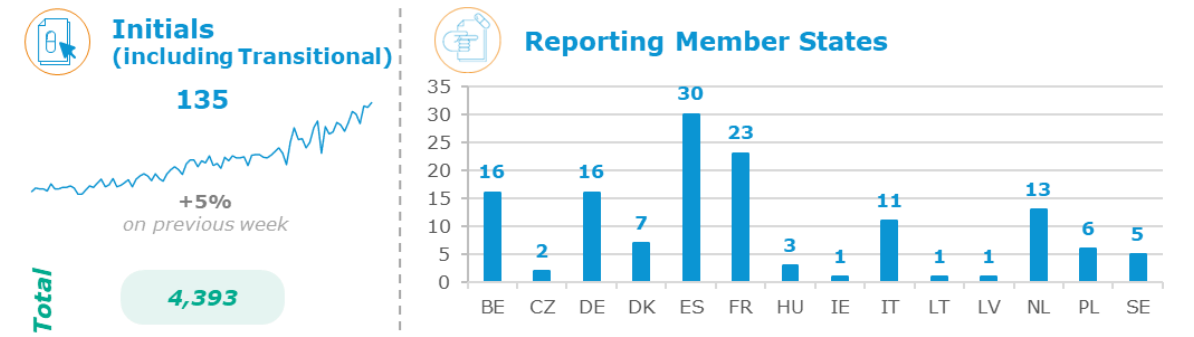


The data presented below refer to the period from 25 June to 1 July 2024.

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 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.