21 December 2023
EMA/586501/2023
European Medicines Agency

CTIS newsflash – 12 January 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 January 2024.

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

Key updates

- A list of the official public holidays in European countries for 2024, as recorded in the Clinical Trials Information System (CTIS), has been published on the EMA website.
- The November 2023 report on the implementation of the Clinical Trials Regulation (CTR) is now available on the ACT EU website.
- The European Commission has updated its Guidance for the transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation.
- The European Commission Clinical Trials Regulation Questions & Answers document has been updated to version 6.7 in December 2023.
- The Clinical Trials Regulation Quick Guide for Sponsors was updated to version 4 on 8 December 2023.
- The list of national contact points has also been updated.

Tip for CTIS users

Tickets opened in ServiceNow should be linked to a clinical trial application number in CTIS.

For queries that are not related to any submission in CTIS, users are advised to submit their question via the regular public CTIS events (walk-in clinics or bitesize talks), where CTIS experts can provide guidance and advice and people can learn from each other.

We also advice all users to carefully verify their documents for correctness prior to uploading them in CTIS.

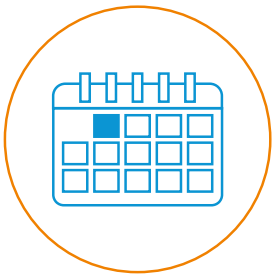
Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Updated guidance on CTIS transparency rules

The Q&A on protection of confidential information and personal data in CTIS has been updated and a quick guide for users has also been published on the ACT EU website. The Q&A now includes a section regarding the **interim period until the new rules are in effect** and on **historical trials (all trials submitted until this date)**; the quick guide provides a summary of what will be published under the revised rules, the relevant timings of publication, and on the new section of the mentioned Q&A.

As detailed in section 4 of the updated Q&A document, for initial clinical trials applications sponsors may already follow the principles of the revised CTIS transparency rules. A sponsor may therefore refrain from deferring publication of documents and provide a version 'for publication' and 'not for publication' only for those documents in scope of the revised rules (Annex I of the revised CTIS transparency rules).

Over 590 viewers followed the CTIS Bitesize talk on 29 November 2023. During the event, CTIS experts answered several submitted questions on the CTIS transparency rules and offered clarifications. A video recording of the event is available on the event page in due course.



Save the date: CTIS Walk-in Clinic

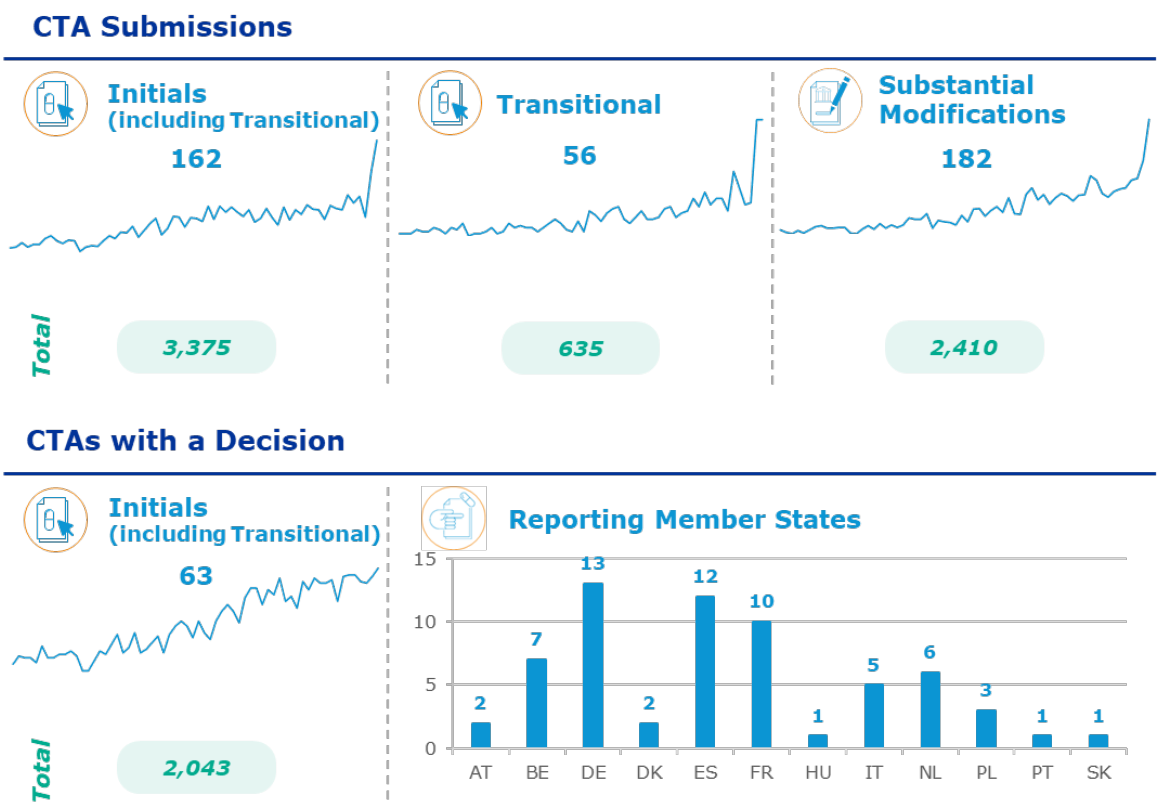
On 24 January 2024, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CET. Participants can submit their questions in advance until 15 January via Slido with the code #clinic241.

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. No comparison with the previous week has been provided due to the Winter clock stop.

The data presented below refer to the period from 19 December 2023 – 8 January 2024. Please note that the data below takes in consideration the Winter Clock stop.



System improvements

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.

EMA continues to closely monitor user feedback, working in collaboration with our stakeholders to deliver further system improvements and enhance the user experience.

Reminder: 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. Due to limited capacity, access to eligible users is provided for a limited period of time. In addition, access is prioritised for users/organisations with no previous access in the system.

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.