7 July 2023
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European Medicines Agency

CTIS newsflash – 7 July 2023

Introduction

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

The next issue will be circulated on 21 July 2023.

CTIS Training Environment downtime and data wipe out – 17 July 2023

Due to the deployment of the latest version of the CTIS Training environment on 17 July 2023, users are advised that the system will be unavailable on that date. The deployment will lead to a database wipe out and hence any trials and corresponding recorded data in the system will be wiped out (deleted). Therefore, users are advised to arrange all their training activities taking in consideration the upcoming update on 17 July 2023.

Reminder: Move of CTIS User Service to ServiceNow platform

In alignment with the EMA's information security strategy, a new IT service management solution called ServiceNow will replace the current tool (JIRA) for CTIS User Support Service (USS) requests, with a foreseen launch date of **31 July 2023**.

As of 31 July 2023, Jira will no longer be available to raise requests or incidents in CTIS and the CTIS Training Environment. Existing data related to CTIS USS tickets opened prior to this date will remain available in JIRA until the tickets are resolved.

The move will adapt CTIS processes to the industry best practices and enhance CTIS users' experience, by delivering a more user-oriented service.

The new ServiceNow platform will be accessible via a link and through a mobile app (QR codes for download available in annex). In order to log in, users will need to type in their EMA username followed by @id.ema.europa.eu, e.g. a user with the EMA username "surname_a" should type in surname_a@id.ema.europa.eu.

Training material and more information can be found on a dedicated site of the ServiceNow platform.

In case of issues or difficulties logging in, users can consult the EMA Account Management website or contact ServiceNow@ema.europa.eu for support.

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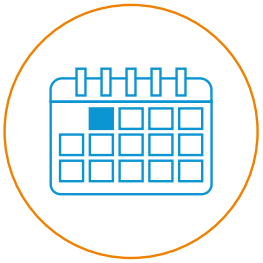
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union



Save the date: CTIS Walk-in Clinic 19 July 2023

On 19 July 2023, EMA is hosting a CTIS Walk-in Clinic at 16:00-17:00 CEST.

Participants are able to submit their questions in advance or during the event via Slido with the event code #clinic237. These walk-in clinics are a series of short, regular events offering CTIS sponsor users the opportunity to consult the Agency's CTIS experts and ask questions about CTIS functionalities in a live forum.

For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu)

Key updates

- CTCG has published a Best Practice Guide and cover letter template for sponsors of multinational clinical trials with different protocol versions approved in different Member States under the Clinical Trials Directive that will transition to the CTR.
- Over 2100 viewers followed the **CTIS informational webinar on the second year of transition** which was held on 4 July 2023. The event provided an update on the current status of CTIS and CTR implementation, and focused on transitional trials and Ethics Committee assessment procedures. The supporting slide deck and video recording will be published on the dedicated event page in due course.
- On 5 July 2023, EMA hosted a workshop on the transition of ongoing trials to the Clinical Trials Regulation (CTR). The event was well attended by representatives of all key stakeholders, ensuring a successful consultation between Member States, the European Commission, EMA, sponsors, patients and healthcare professionals.
- The public consultation on the **CTIS transparency rules** concluded on 28 June 2023. Over 200 responses were submitted, including by CRO (39), Commercial sponsors/SME (77), NCA (20) and Ethics Committees (7), Academia/PI (20), patients organisations (12), health care professionals (5), and other stakeholders. EMA is currently assessing the received feedback. Analysis of the consultation response together with next steps will be shared with stakeholder in due course.

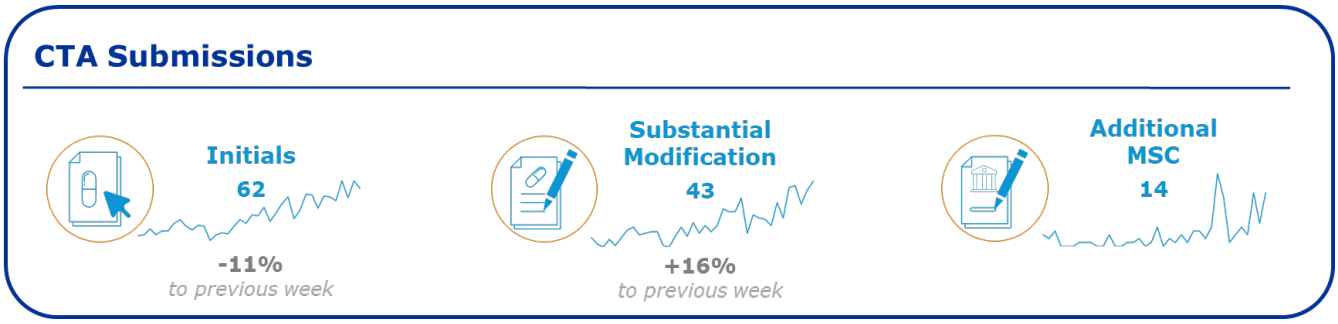
Tips for CTIS users

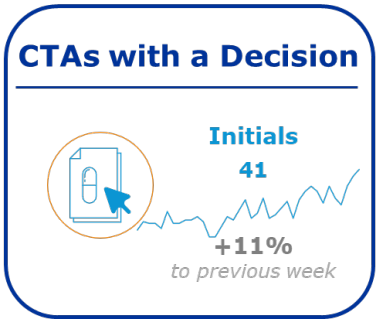
- Sponsors are advised to upload only up to 25 documents in one batch to ensure that the upload is successfully processed in the system.
- During the assessment of a clinical trial application, the timetable may show different due dates/status/information than the actual due dates/status on the Tasks 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 with the individual tasks and RFI.
- When drafting a clinical trial application for a large trial involving several member states, sponsors are recommended to only provide the essential documents required for the assessment and to fulfil the transparency requirement for publication.

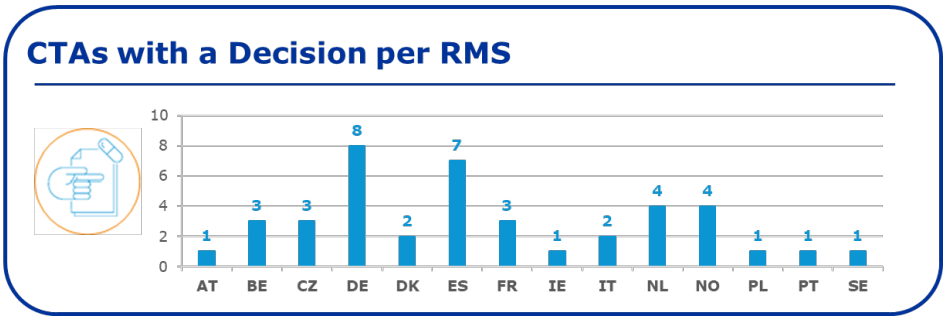
Current operational experience with CTIS

This section on weekly CTIS metrics provides key data and trends compared to the previous week.

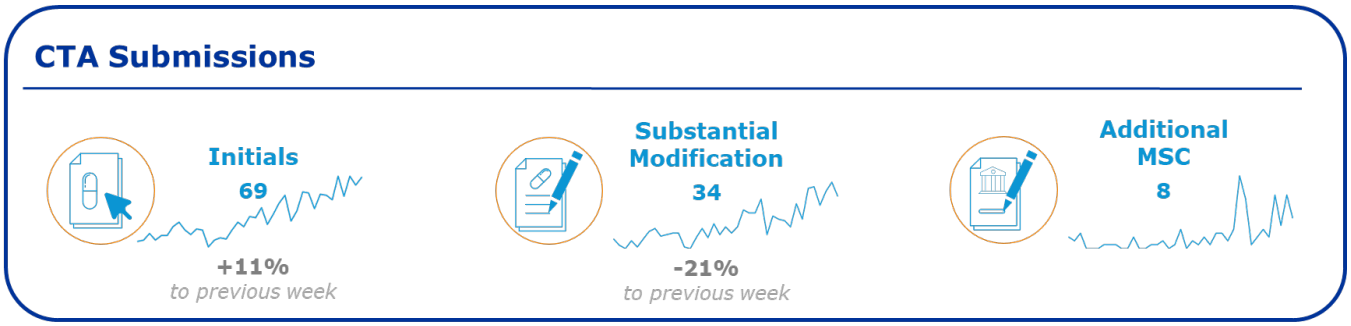
The data presented below refer to the period from 20 to 26 June 2023.

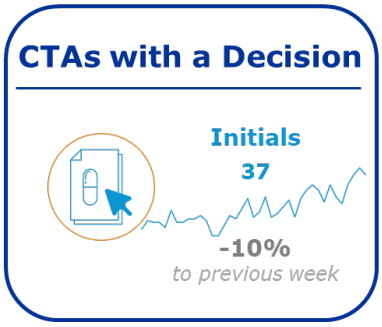


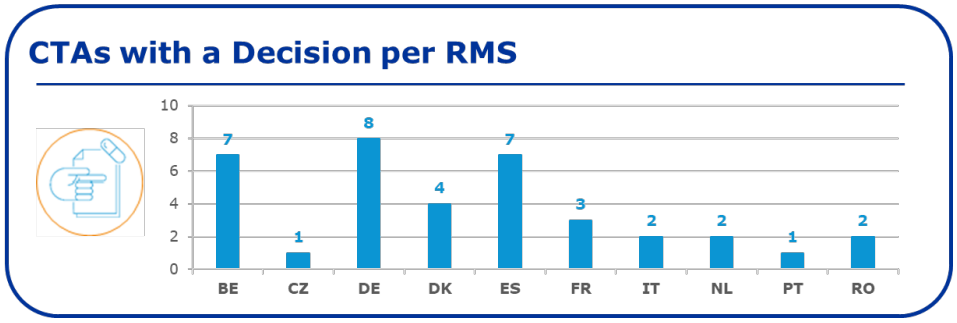




The data presented below refers to the period from 27 June to 3 July 2023.







System improvements

A CTIS release was deployed on 29 June 2023, introducing several improvements to enhance user experience:

- In partial initial applications submission (part I only for at least one MSC) where different documents in the "Form" section are still open for editing after submission, users are now able to

add further documents in the section but cannot remove/edit/update already submitted documents.

- Sponsor users are now able to resubmit a previously withdrawn Additional MSC application containing the proof of payment document without receiving an error message.
- In Assessment Report templates, automatically populated information is now accurate in sections 5.4.15.3 (DSMB), 5.4.15.2 (RSI), 5.4.7 (vulnerable populations), 5.4.5/5.4.6 (Inclusion and exclusion criteria), 5.4.2/5.4.3 (Objectives and endpoints). The versions of documents is also correctly recorded.
- In the consultation with experts after a Part I soft task is complete, Member State users are now able to extend Part I hard task and other soft tasks that are still pending or assigned.
- Users are now able to correctly update notification documents, without the appearance of a red pop-up warning message.
- When a public user downloads data from the CTIS Public Portal, the information of the section "Contact Point for the Union" no longer appears in the downloaded PDF.
- The General Data Protection Regulation (GDPR) functionality was improved:
  - The system now successfully completes the replacement of documents.
  - The "Decision Supporting" document now appears in the list of search results.
  - The sorting and filtering functionality now includes more fields, allowing EMA Admin users with access to this functionality to perform faster and more accurate searches.
- The WHO API (Application Programming Interface) was enhanced to improve the process of data extraction from the CTIS public portal.

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.

The dashboard below summarises the main improvement areas of focus for 2023 and the improvements implemented.

Reminders

- Resubscribe here to receive the Clinical Trials Highlights Newsletter and newsflash. The next newsletter issue will be circulated in mid-July 2023.
- 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 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.

Annex: ServiceNow mobile app QR codes

QR code for Android :

QR code for iOS :