



## EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

22 May 2023  
EMA/238430/2023  
European Medicines Agency

# CTIS newsflash – 23 June 2023

## Introduction

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

The next issue will be circulated on 7 July 2023.



### Move of CTIS User Service to ServiceNow platform

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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**.

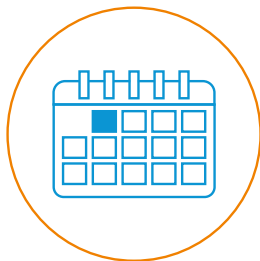
As of 31 July 2023, Jira will no longer be available to raise requests or incidents in CTIS and the CTIS Training Environment. Existing data related to CTIS USS tickets opened prior to this date will remain available in JIRA until the tickets are resolved.

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](mailto:ServiceNow@ema.europa.eu) for support.



### Save the date: CTIS Info Event on Transitional Trials – 4 July 2023

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Sponsors are preparing for the next phase of implementation of the Clinical Trials Regulation (CTR). By 30 January 2025, any ongoing trials approved under the Clinical Trials Directive will fall under the CTR. Therefore, any trials will need to be transferred to CTIS and approved before 30 January 2025 if they are ongoing. Sponsors have already submitted over 185 transitional trials to CTIS.

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EMA is organising an Info event on transitional trials – 4 July 2023, 13:00 – 17:30 CET [Clinical Trials Information System Webinar: Second Year of Transition | European Medicines Agency \(europa.eu\)](#)

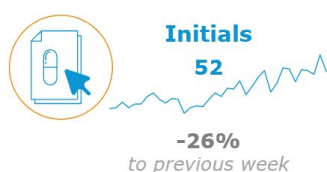
More information on transitional trials is available under Module 23 of the [CTIS online training programme](#) and the CTCTG's [best practice guide](#) for multinational sponsors of transitional trials.

## 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 6 to 12 June 2023.

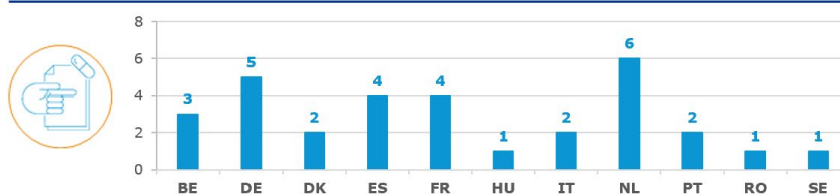
### CTA Submissions



### CTAs with a Decision

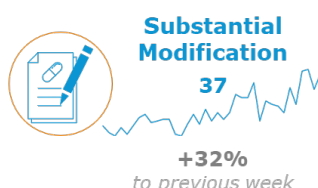
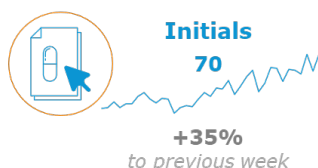


### CTAs with a Decision per RMS

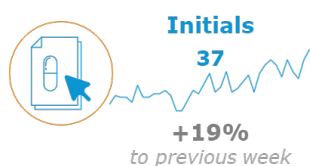


The data presented below refers to the period from 13 to 19 June 2023.

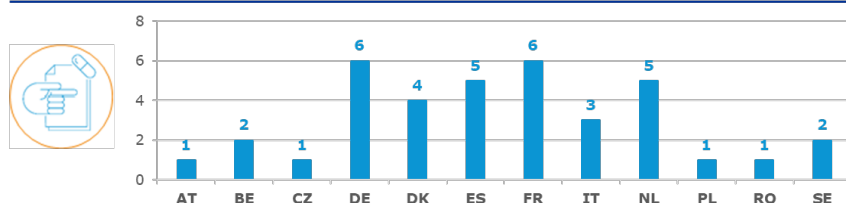
### CTA Submissions



### CTAs with a Decision



### CTAs with a Decision per RMS



## System improvements

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Two CTIS releases were deployed on 13 and 15 Jun 2023, introducing several improvements to enhance user experience:

- The "All documents" list now correctly displays the submission date of the clinical trial application in which they were submitted.
- In the context of an SM Part I and II, no empty error message appears when expanding the "All documents" section and the documents are correctly displayed in both sponsor and authority workspace.
- When trying to submit a subsequent application, the sponsor user will be informed if the information of an unauthorized product included in a previous application has changed or does not exist in xEVMPD anymore, guiding the user on the need to update the product information to allow its submission.
- The sponsor user will be able to submit the part II for the MSC for which partial submission was done only once the 'submit part I' hard task is completed and not before.
- The sponsor user will be able to submit the part II for the MSC for which partial submission was done, even if the "estimated start of recruitment" date has passed, without triggering an error.
- The sponsor user will be able to find and select a clinical trial available in EudraCT when searching with its EudraCT number in the Form section.
- In the case of halted trials, if the authorised trial is not started/restarted within 2 years and 15 days the status now changes correctly to expired.
- Users can see the publication timepoint for "RFIs sent to Sponsor" and for "Assessment Reports and conditions" in the Decision section of the Assessment Overview under the Evaluation area in line with the selection done by the MSC/RMS when completing the decision task. Also, on the download data, the deferrals recorded from the MSC/RMS are now displayed.
- If the Part II submission task expires, the conclusion field displays correctly now "no conclusion" in those cases where a conclusion was saved but never submitted.
- Saved but not submitted Part I and/or II conclusions (i.e. 'Acceptable with condition' or 'Not acceptable') by authority users are not visible now from the sponsor workspace.

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.

<b>Performance</b> <ul style="list-style-type: none"> <li>Resolve timeouts for large, complex trials</li> <li>Improve transaction inefficiencies through code improvements and enable asynchronous processing</li> <li>Transition to a high-availability infrastructure</li> <li>Lock removed in database enabling RFI submission</li> <li>Lock modified enabling submission of large initial clinical trial applications</li> <li>Improved processing of high demanding functionalities such as creating SM and resubmission of trial</li> </ul>	<b>Member State API</b> <ul style="list-style-type: none"> <li>Implement versioning to allow MS to adopt changes at their own pace</li> <li>Resolve current defects and resolve workarounds</li> <li>Improvements to add additional information</li> <li>Correct setting of notifications for Next Page, Last Page and total items attributes</li> <li>Enabling multiple MS APIs to coexist allowing Member States to adopt changes at their own pace</li> <li>Correct sorting of notifications</li> </ul>
<b>Public Portal</b> <ul style="list-style-type: none"> <li>Public Portal Refactoring Assessment</li> <li>Resolve known problems with the deferral functionality</li> <li>Schedule publication of trials with deferrals</li> <li>Public consultation on CTIS Transparency rules launched</li> </ul>	<b>Information Security</b> <ul style="list-style-type: none"> <li>Implement a 24/7 security monitoring of CTIS through EMA's Security Operations Center</li> <li>Develop plans for the implementation of multi-factor authentication</li> <li>CTIS Multifactor authentication implemented</li> <li>Migration of CTIS to high availability data centres completed</li> </ul>
<b>Backlog</b> <ul style="list-style-type: none"> <li>Implement remaining 2 disaster recovery scenarios</li> <li>Reducing Data fixes required for users to progress with applications</li> <li>3 out of 5 disaster recovery scenarios implemented</li> <li>Anatomical Therapeutic Chemical Search enabled</li> <li>Improved generic organisation search</li> </ul>	<b>Stakeholder requests</b> <ul style="list-style-type: none"> <li>Strengthening Service Desk operations</li> <li>Connectivity to WHO registry</li> <li>Improve download and sorting of documents</li> <li>Launch business intelligence for MS</li> <li>CTIS is a registered data provider for World Health Organization (WHO)</li> <li>Download of documents improved</li> <li>Enabling selection of 'Start recruitment' date prior to 'Start of trial' date in each MSC for multinational and transitional trials</li> </ul>

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](#).

## Reminders

- Resubscribe [here](#) to receive the Clinical Trials Highlights Newsletter and newsflash. The next newsletter issue will be circulated in mid-July 2023.
- Due to planned maintenance for infrastructure upgrade of the SPOR application, users are advised to take note of the downtime window:
  - Saturday 24 June and Sunday 25 June 2023 from 07.00 to 11.00 and 8:00 to 13:00 CEST respectively, organisation and product search functionalities will be intermittently unavailable in the CTIS website.
- Due to the planned migration of EMA applications to high availability data centres, users are advised to take note of below downtime windows which may impact their use of the system:
  - On Saturday 24 June 2023 from 08.00 to 12.00 CEST, users will be unable to search and select authorised or not-authorised medicinal products, ACT codes or active substances in the CTIS website and CTIS training environment.

- A **public consultation on the CTIS transparency rules** has been launched on the [EMA website](#). The review aims at simplification to improve user experience while also reducing the risk of data breaches and maintaining high levels of transparency. Stakeholders are invited to provide their comments by **28 June 2023**.
- An [interim guidance document \(and its annex\)](#) on the current transparency rules has also been published. The documents are intended for CTIS users and have been revised following the public consultation.
- The CTIS Multi-factor authentication was successfully implemented is enabling a better and more secure log in process to CTIS enabling better protection of the clinical trial information.
- 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.
- The maximum limit of documents that can be uploaded **in one batch** in the system is 25.
- 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.

### More information

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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

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QR code for Android :



QR code for iOS :

