21 July 2023
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European Medicines Agency

CTIS newsflash – 21 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 4 August 2023.

Spotlight: Move of CTIS User Service to ServiceNow from 31 July

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.

Key updates

- Users of CTIS Business Intelligence (BI) and EudraCT BI are advised that both systems will be unavailable on the weekend of 5-6 August 2023 due to essential maintenance.
- The 15th issue of the Clinical Trials Highlights newsletter is now available. This is the first issue created in Newsroom, a modern and user-friendly platform used by European Institutions and agencies to create and disseminate information online.

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- The final guidance document and related annexes on the protection of personal data and commercially confidential information (CCI) in CTIS have now been published. The documents aim to assist sponsors and authorities in fulfilling the transparency obligations set out in the Clinical Trials Regulation (CTR).
- An open consultation has been launched on the draft WHO guidance on best practices for clinical trials, following the resolution on *Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination* adopted by the 75th World Health Assembly. Stakeholders can provide their comments by 15 September 2023.
- An open consultation has been launched on the ICH reflection paper on proposed international harmonisation of real-world evidence (RWE) terminology and convergence of general principles regarding planning and reporting of studies using real-world data, with a focus on effectiveness of medicines. Stakeholders are invited to provide their comments by 30 September 2023.

Available guidance on transitioning trials to CTIS

Sponsors are already preparing for the next phase of implementation of the CTR. By 30 January 2025, any ongoing trials approved under the Clinical Trials Directive will fall under the CTR. Therefore, any ongoing trials will need to be transitioned to CTIS and approved before 30 January 2025. Sponsors have already submitted over 210 transitional trials to CTIS.

More information on transitional trials is available in the Guidance for the transition of clinical trials published by the European Commission under EudraLex volume 10, the best practice guide for multinational sponsors of transitional trials adopted by CTCG, and under Module 23 of the CTIS online training programme.

Quality improvement of substance data and potential impact on development products

Following the ongoing substance data quality improvement activities taking place in EMA's Substance Management System (SMS), development products registered in the Extended EudraVigilance Medicinal Product Dictionary (xEVMPD) may have been updated and associated to an approved substance data with a new EudraVigilance (EV) code.

If such a development product is updated in xEVMPD and referenced in a clinical trial application in CTIS, an error message appears when submitting a subsequent draft application, when responding to a Request for Information (RFI) with an update to the dossier, or when cancelling the application. This error message reads: "The product(s) information has changed in the xEVMPD. Therefore, please update this application to include the new product information". As a consequence, the sponsor is not able to submit the application or the response to the RFI, nor cancel the application.

In order to resolve the error, the sponsor needs to update the development product record in CTIS. Please note that only the structured data should be updated, while the previously uploaded associated documents will remain in the draft application unless they are proactively deleted by the user.

In order to update the unauthorised product, the sponsor needs to:

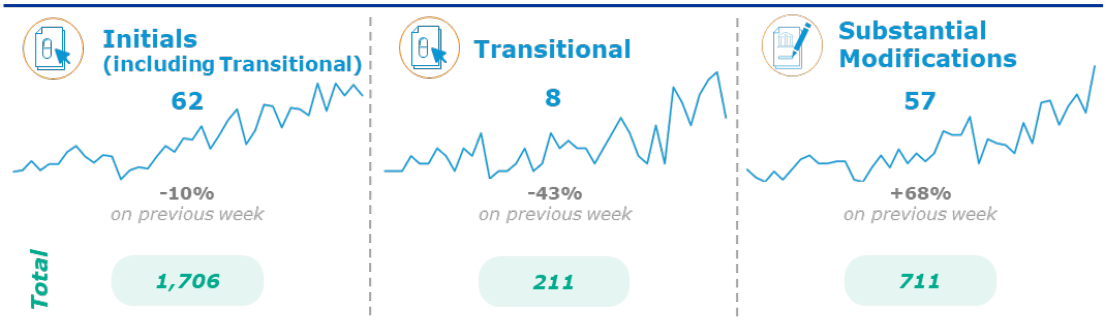
- identify the product requiring update;
- remove the development product (only the structured data);
- search for it using the updated substance EV code; and
- add the product in the application.

Current operational experience with CTIS

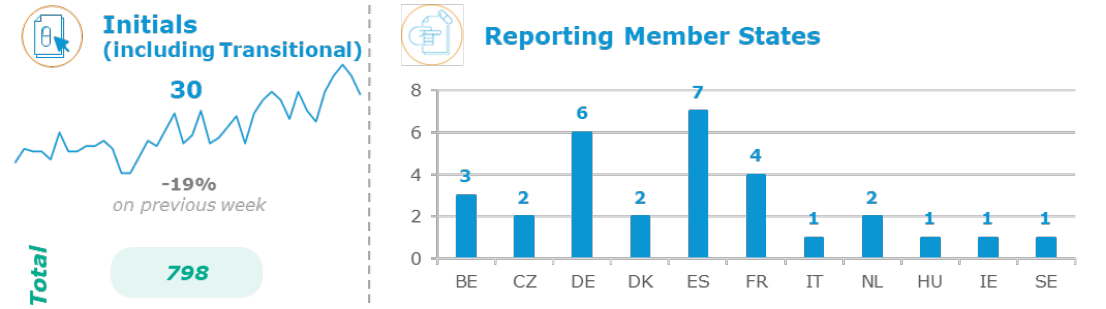
This section on weekly CTIS metrics provides key data and trends compared to the previous week.

The data presented below refer to the period from 4 to 10 July 2023.

CTA Submissions

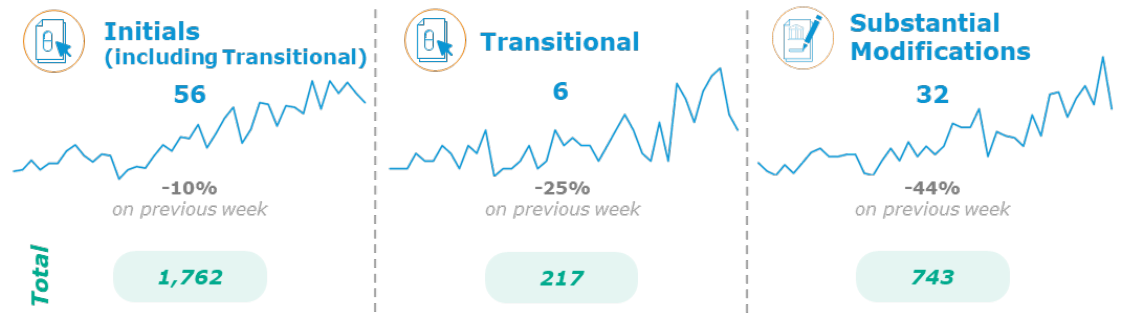


CTAs with a Decision

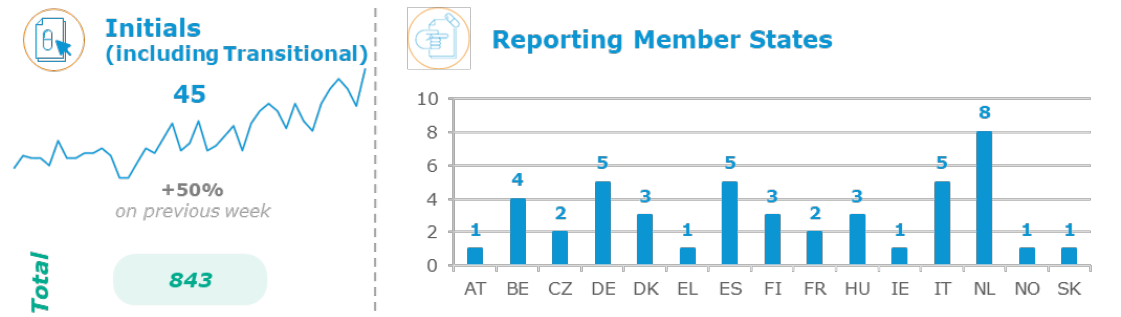


The data presented below refers to the period from 11 to 17 July 2023.

CTA Submissions



CTAs with a Decision



System improvements

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.

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

- 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.
- 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 :