CTIS newsflash – 4 August 2023

Introduction

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

The next issue will be circulated on 18 August 2023.

Key updates

- Member state 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.

- EMA has launched a public consultation on the draft reflection paper on the use of artificial intelligence (AI) to support the safe and effective development, use and regulation of human and veterinary medicines. Stakeholders are invited to provide their feedback until 31 December 2023. A joint HMA/EMA workshop will take place on 20-21 November 2023 to further discuss the topic. In case of questions on the paper, please contact AIreflectionpaper@ema.europa.eu.

Spotlight: Improved user experience when searching for organisations in OMS via CTIS

In order to add an organisation to a draft application or notification in CTIS, users search for and select the organisation via an interface to the Organisation Management Service (OMS). Heavy overall use of OMS impacts the user experience in CTIS.

With the aim to improve speed and reliability of the search for organisations in CTIS, a new process has been activated to create an 'OMS cache', i.e. a copy of OMS data that will be available locally in the CTIS server.

Under the new process, data is exported from OMS and imported to CTIS daily at 06.00 Amsterdam time. Organisations newly approved in OMS only appear in the CTIS search results one business day after users receive an email confirming the OMS registration.

The OMS cache, activated on 1 August 2023, enables faster, more reliable search for users adding organisations in CTIS.
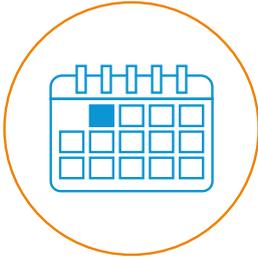
Save the date: CTIS Bitesize talk on 30 August 2023

On 30 August 2023, EMA is hosting a CTIS Bitesize talk at 15:30 – 17:00 CEST. The talk will focus on how sponsors can prepare for the submission of partial initial applications when all Member States Concerned (MSC) receive part I of the dossier and some/none of the MSC receive part II of the dossier.

Participants will be able to submit their questions in advance between 7-22 August or during the event via Slido with the code #bt30aug.
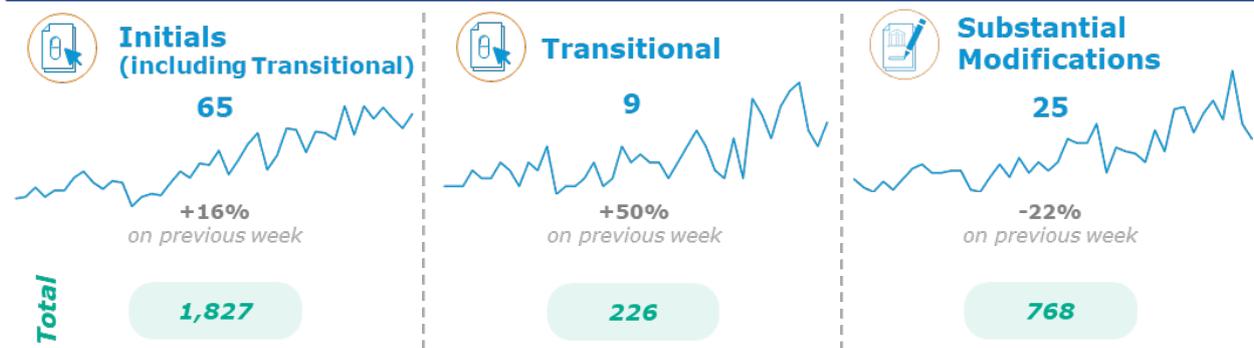
For more information on previous training sessions, including supporting materials, see: Clinical Trials Information System: training and support | European Medicines Agency (europa.eu)
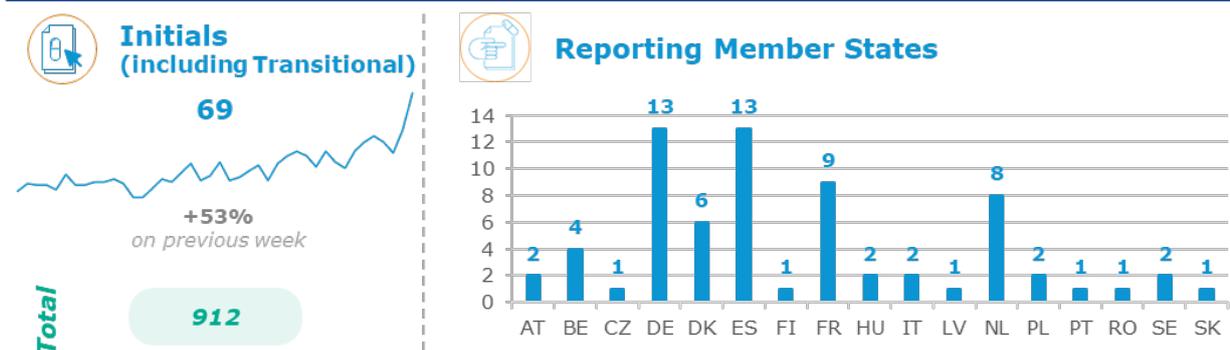
Current operational experience with CTIS

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

The data presented below refer to the period from 18 to 24 July 2023.
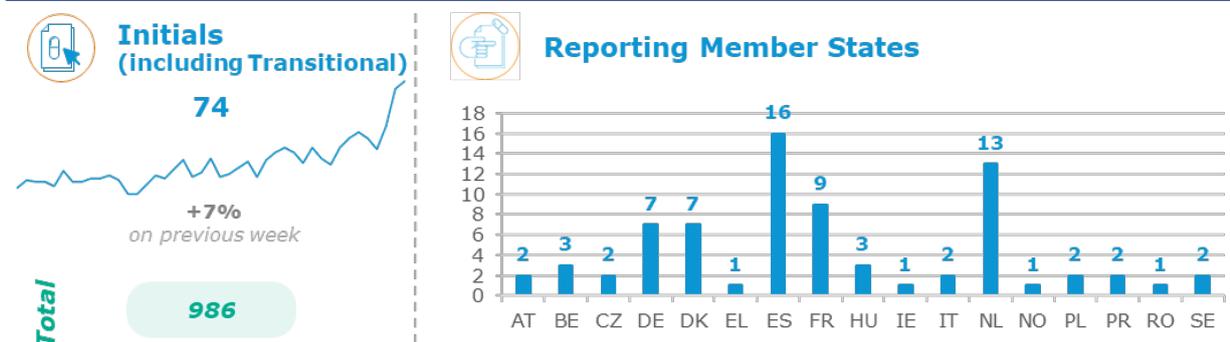
CTA Submissions

Initials (including Transitional)
65
+16%
on previous week
Total: 1,827

Transitional
9
+50%
on previous week
Total: 226

Substantial Modifications
25
-22%
on previous week
Total: 768

CTAs with a Decision

Initials (including Transitional)
69
+53%
on previous week
Total: 912

Reporting Member States

AT	BE	CZ	DE	DK	ES	FI	FR	HU	IT	LV	NL	PL	PT	RO	SE	SK
2	4	1	13	6	13	1	9	2	2	1	8	2	1	1	2	1

The data presented below refers to the period from 25 to 31 July 2023.

CTA Submissions

Initials (including Transitional)

48

-26%
on previous week

Total **1,875**

Transitional

12

+33%
on previous week

Total **238**

Substantial Modifications

42

+68%
on previous week

Total **810**

CTAs with a Decision

Initials (including Transitional)

74

+7%
on previous week

Total **986**

Reporting Member States

AT	BE	CZ	DE	DK	EL	ES	FR	HU	IE	IT	NL	NO	PL	PR	RO	SE
2	3	2	7	7	1	16	9	3	1	2	13	1	2	2	1	2

System improvements

A CTIS release was deployed on 25 July 2023, introducing several improvements to enhance user experience:

- Sponsors are now able to assign the "CT admin" role to a user for two different organisations, i.e. with different organisation IDs, that share the same name, simultaneously or one by one.

- In the Annual Safety Report (ASR), Member States are now able to assess the response to Requests for Information (RFIs) and submit their comments successfully.

- The notice "Considerations due" in the Validation phase is now only received by the Member State Concerned (MSC) that can document considerations.

- In the tasks "Re-express willingness/unwillingness" and "Agree RMS", the system no longer displays "tacit unwilling" for some MSC before the due date.

- The decision drop-down values are now shown correctly in the "Authorise" task of the Additional Member State application, when the Part II conclusion is acceptable with conditions.

- Users from a Member State Concerned where the initial application was lapsed, not authorised or withdrawn are now able to complete the "Authorise" task without issues.

- The "Submit Part I Conclusion" task and "Authorise" task are now generated with the correct creation dates and due dates in cases where there is Consultation with Experts after the RFI creation.

- After an RFI for Part I submission, the due date of the "Submit Part I Conclusion" task is now calculated correctly, taking into account the extension for the Consultation with Experts.

- In the "Supporting information documents" in Substantial Modifications under the "Form" section, the submission date in the "All documents" table is now correctly displayed.

- Under the full trial information, the "Member State" drop-down list now displays all MSC allowing users to select and retrieve the latest authorised MSC information.

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.

Performance

- Resolve timeouts for large, complex trials
- Improve transaction inefficiencies through code improvements and enable asynchronous processing
- Transition to a high-availability infrastructure

- Lock removed in database enabling RFI submission
- Lock modified enabling submission of large initial clinical trial applications
- Improved processing of high demanding functionalities such as creating SM and resubmission of trial
- Migration of CTIS to high availability data centres completed
- Improved search for organizations in OMS via ⭐ CTIS

Member State API

- Implement versioning to allow MS to adopt changes at their own pace
- Resolve current defects and resolve workarounds
- Improvements to add additional information

- Correct setting of notifications for Next Page, Last Page and total items attributes
- Enabling multiple MS APIs to coexist allowing Member States to adopt changes at their own pace
- Correct sorting of notifications

Public Portal

- Analysis of new public portal functionalities following the outcome of the public consultation on CTIS Transparency rules

- Public consultation on CTIS Transparency rules concluded

Information Security

- Implement a 24/7 security monitoring of CTIS through EMA's Security Operations Center
- Develop plans for the implementation of multi-factor authentication

- CTIS Multifactor authentication implemented

Backlog

- Implement remaining 2 disaster recovery scenarios
- Reducing Data fixes required for users to progress with applications

- 3 out of 5 disaster recovery scenarios implemented
- Anatomical Therapeutic Chemical Search enabled
- Improved generic organisation search

Stakeholder requests

- Strengthening Service Desk operations
- Connectivity to WHO registry
- Improve download and sorting of documents
- Launch business intelligence for MS

- CTIS is a registered data provider for World Health Organization (WHO)
- Download of documents improved
- Enabling selection of 'Start recruitment' date prior to 'Start of trial' date in each MSC for multinational and transitional trials

⭐ New improvement since last reporting

Reminders

- Guidance for sponsors transitioning trials from the Clinical Trials Directive to the CTR/CTIS is available:

  - in the Guidance for the transition of clinical trials published by the European Commission under EudraLex volume 10;

  - in the best practice guide for multinational sponsors of transitional trials adopted by CTCG; and

  - under Module 23 of the CTIS online training programme.

- 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. Subscribe to receive future issues.

- 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).

- 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.