18 August 2023
EMA/356297/2023
European Medicines Agency

CTIS newsflash – 18 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 1 September 2023.

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 1 to 7 August 2023.

CTA Submissions

Initials (including Transitional)
53
+10%
on previous week
Total 1,928

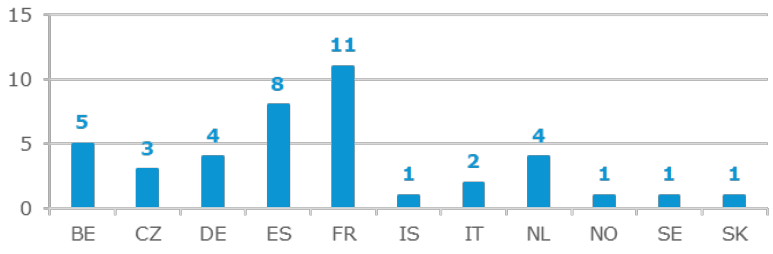
Transitional
8
-33%
on previous week
246

Substantial Modifications
73
+16%
on previous week
910

CTAs with a Decision

Initials (including Transitional)
41
-45%
on previous week
Total 986

Reporting Member States



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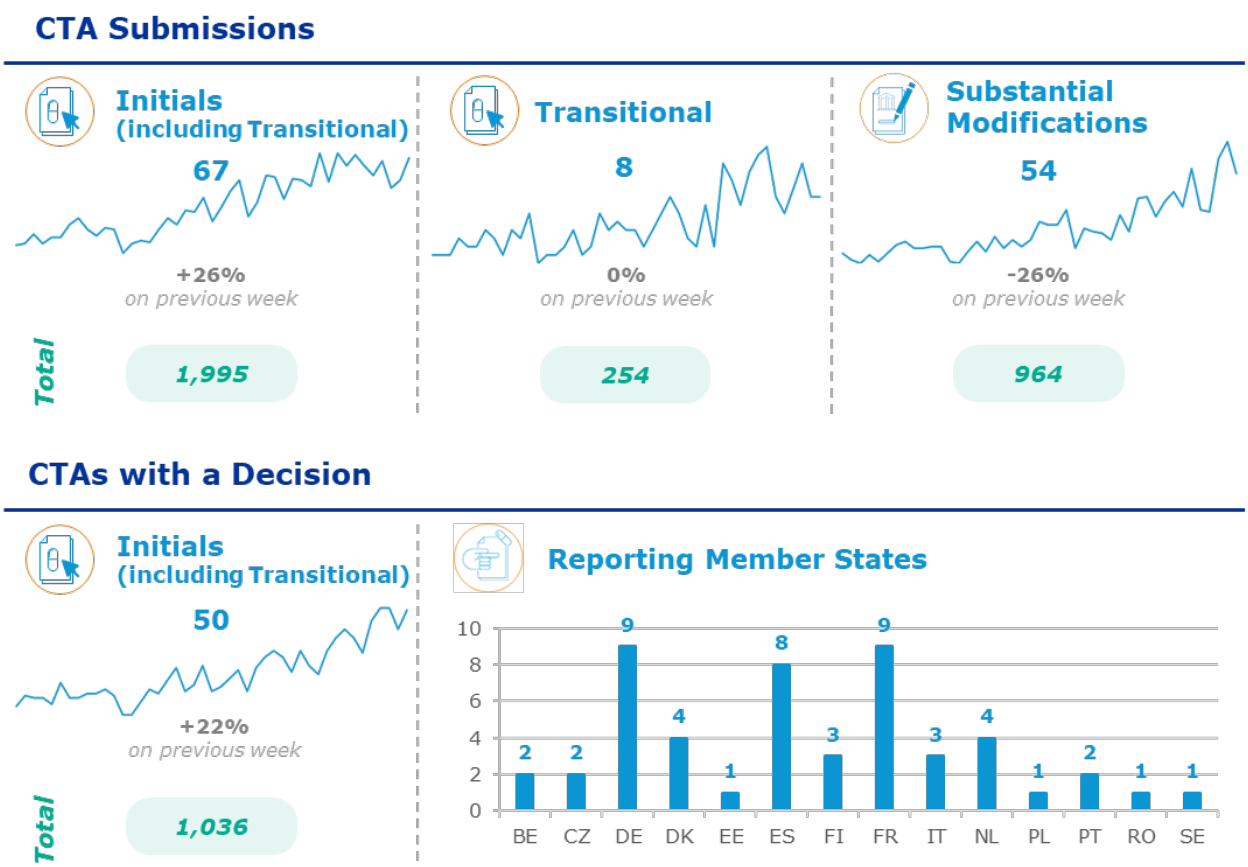
The data presented below refers to the period from 8 to 14 August 2023.

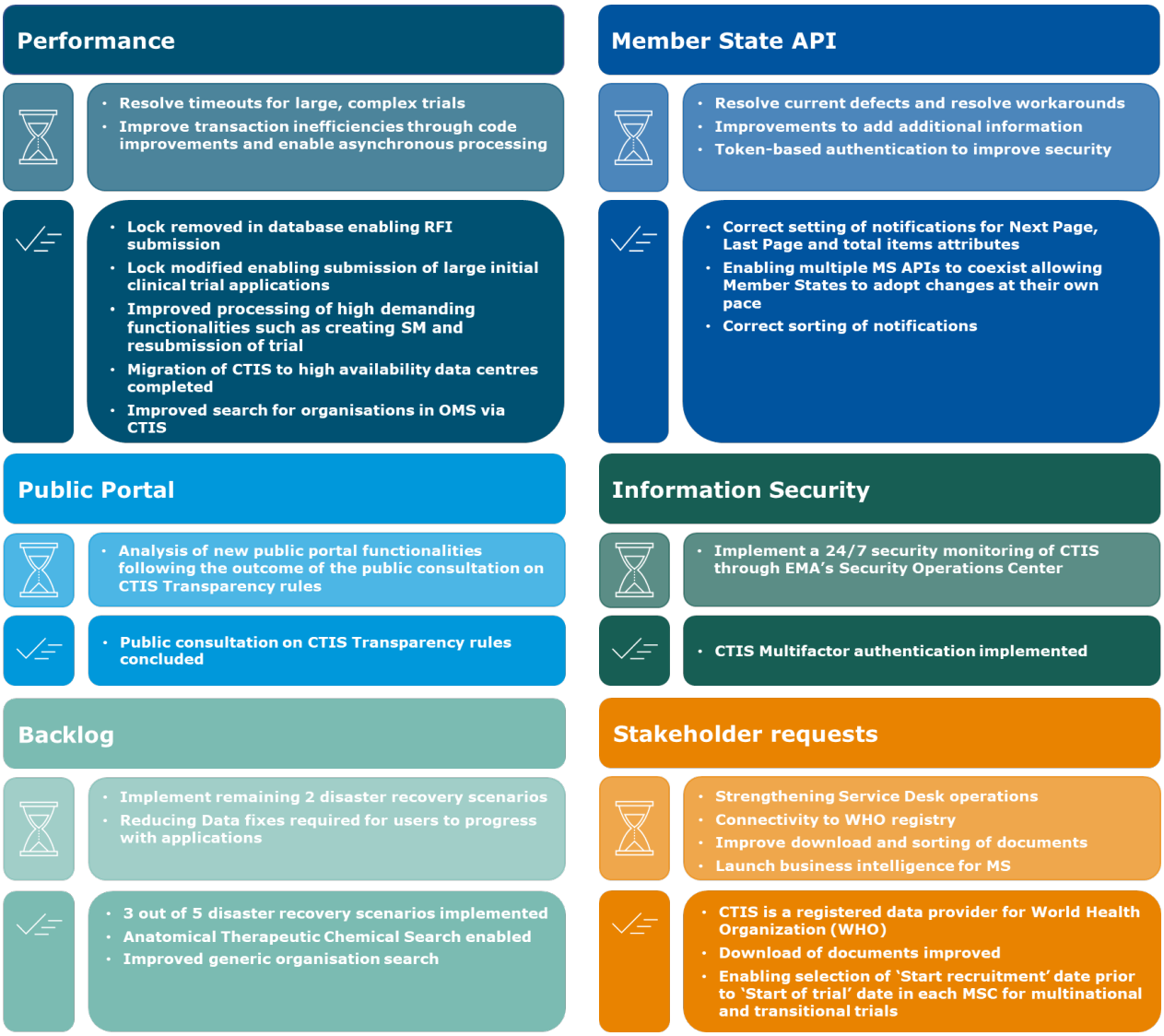


System improvements

Over 1000 clinical trials with a decision under the Clinical Trials Regulation (CTR) are now available in CTIS.

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.



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.

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.
- 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

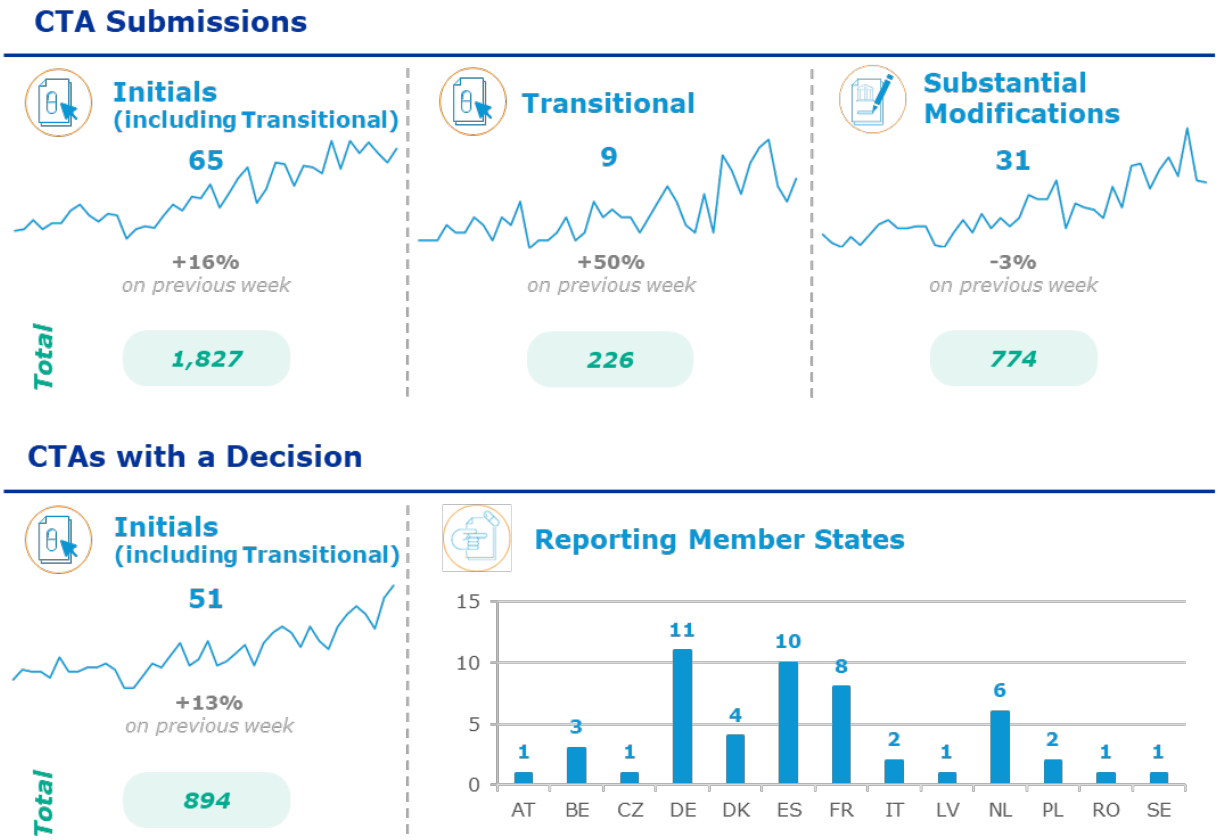
Are you a sponsor user starting out with CTIS? Please consult the 'Sponsor quick guide: Getting started with CTIS' or refer to the CTIS training material, including the new version of the 'CTIS Handbook for clinical trial sponsors'. The handbook provides useful information on how sponsors can navigate 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.

Annex: Corrected data on CTIS operational experience 18 - 31 July 2023

Due to a technical issue with the Business Intelligence tool, there were discrepancies in the data on clinical trials with decisions and substantial modifications published in the previous CTIS Newsflash of 4 August 2023.

This annex contains the corrected dashboards for reference.

The data presented below refers the period from 18 to 24 July 2023.



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

238

Substantial Modifications

63

+103%
on previous week

837

CTAs with a Decision

Initials (including Transitional)

51

0%
on previous week

Total **945**

Reporting Member States