



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.

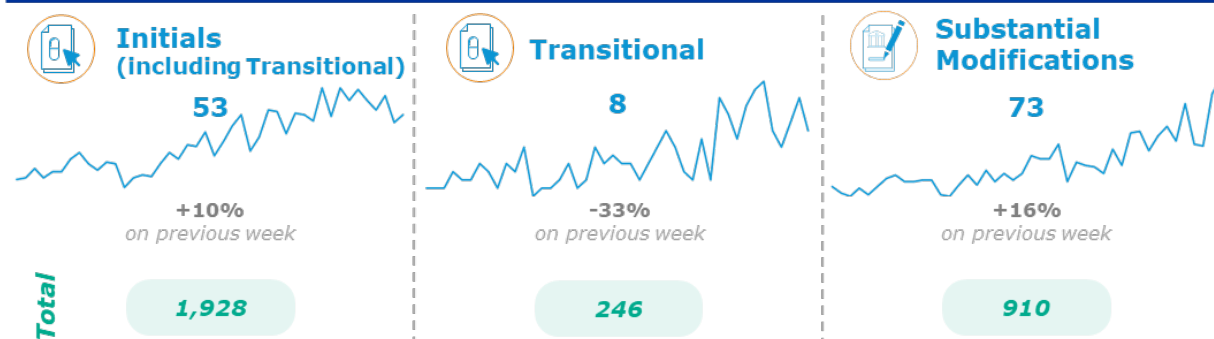
The next issue will be circulated on 1 September 2023.

### Current operational experience with CTIS

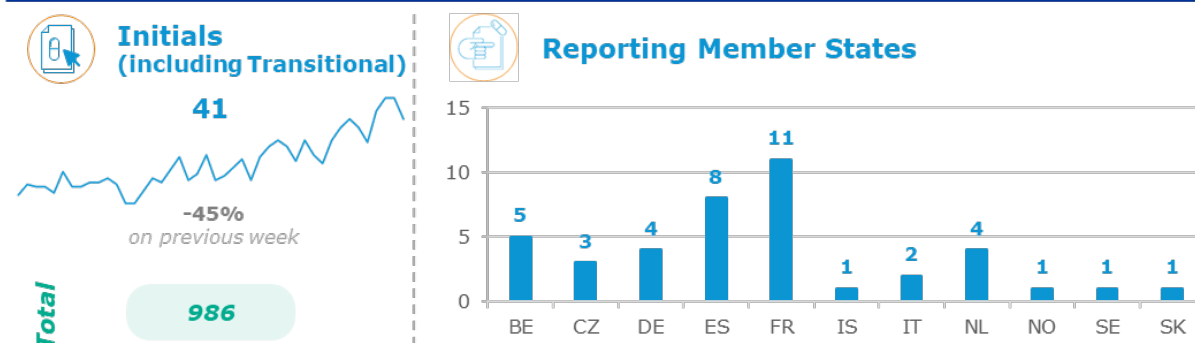
This section on weekly CTIS metrics provides key data and trends compared to the previous week.

The data presented below refer to the period from 1 to 7 August 2023.

#### CTA Submissions



#### CTAs with a Decision



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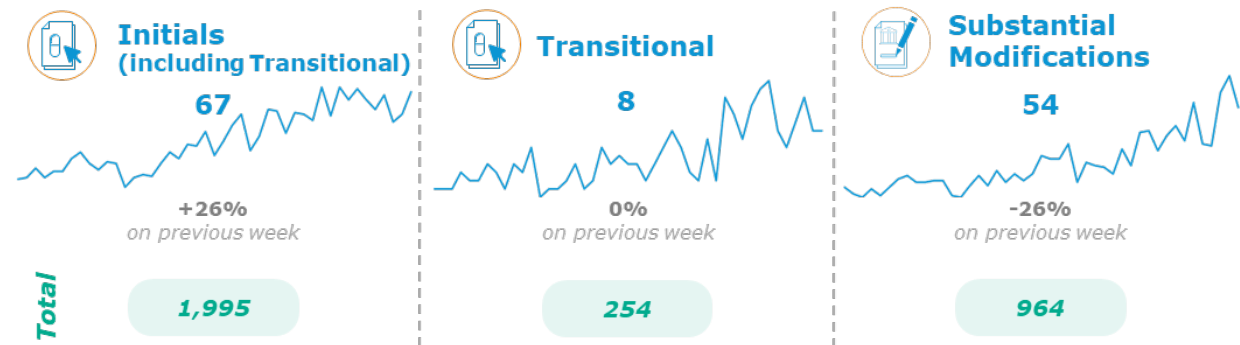
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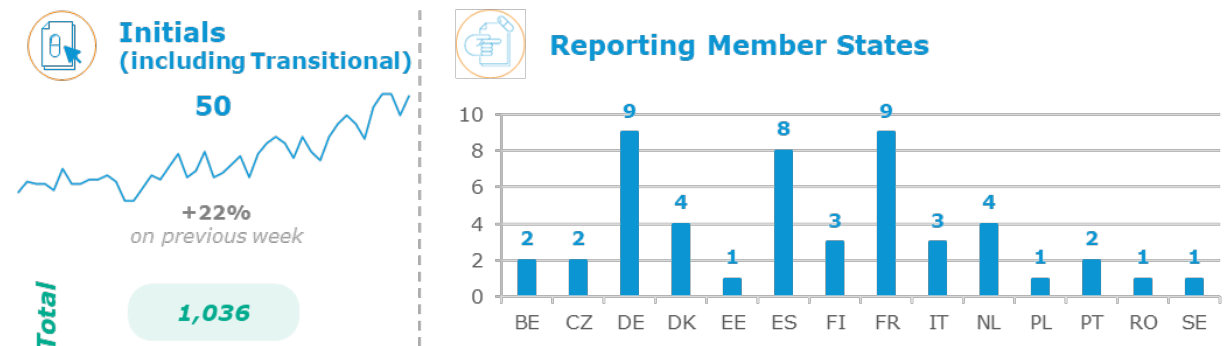


The data presented below refers to the period from 8 to 14 August 2023.

## CTA Submissions



## CTAs with a Decision



## 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.

## Performance



- Resolve timeouts for large, complex trials
- Improve transaction inefficiencies through code improvements and enable asynchronous processing



- 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 organisations in OMS via CTIS

## Member State API



- Resolve current defects and resolve workarounds
- Improvements to add additional information
- Token-based authentication to improve security



- 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



- 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

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 CTG; 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.

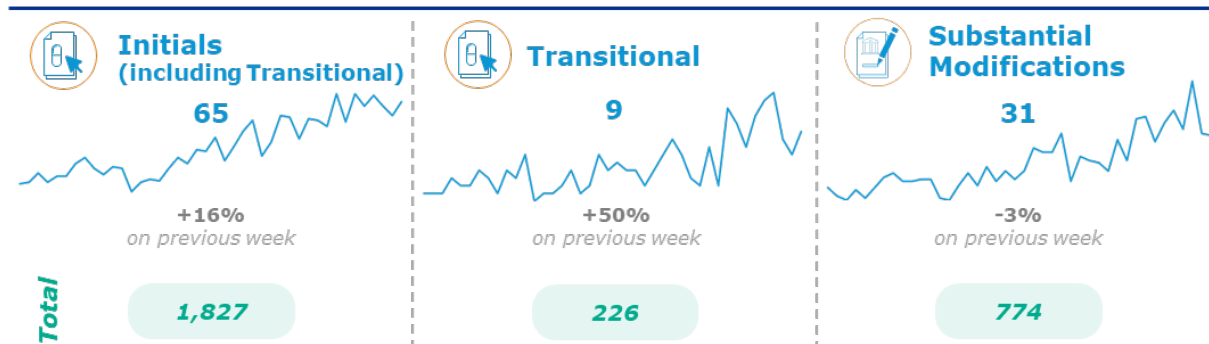
## Annex: Corrected data on CTIS operational experience 18 - 31 July 2023

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.

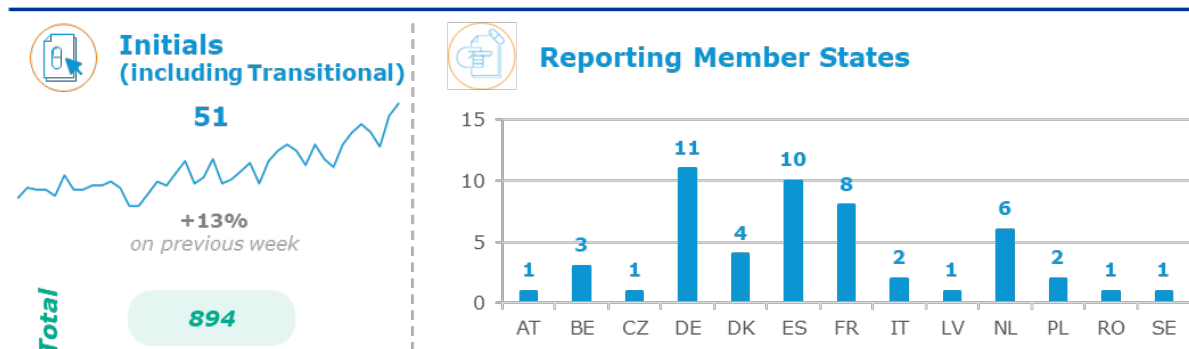
This annex contains the corrected dashboards for reference.

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

### CTA Submissions



### CTAs with a Decision



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

## CTA Submissions



## CTAs with a Decision

