8 April 2022
EMA/207142/2022
European Medicines Agency

CTIS newsflash #10 - 08 April 2022

Introduction

Welcome to the 10th CTIS newsflash. This newsflash provides updates on key facts and figures regarding CTIS usage, as well as links to useful reference materials.

Note on the CTIS newsflash

The weekly CTIS newsflash was created to provide frequent updates about CTIS in the months following CTIS go-live. As of May 2022, the weekly CTIS newsflash will be replaced with a monthly CTIS metrics update. The monthly metrics update will include the key metrics reported via the CTIS newsflash to date, as well as updates about CTIS when relevant.

In addition, the newsflash will not be circulated the week of 11th April due to the Easter break. The 11th and final newsflash will be circulated the week of 18th April.

Key metrics

Metrics reported cover the period 28/03/2022-03/04/2022.

Total number of logins to CTIS: 10,682

- This metric represents the total sum of unique logins by individual users per day at the end of the period

- **Number of draft applications in CTIS:** 305

    - This metric counts the number of applications with status "Draft" in CTIS at the end of the period

- **Number of submitted applications in CTIS:** 26

- **Number of authorised applications in CTIS:** 1

News spotlight

The first clinical trial has been authorised through CTIS. It is a transition trial, i.e. a trial that was ongoing under the Clinical Trials Directive and registered in EudraCT that has been transferred to the

regime of the Clinical Trials Regulation and to CTIS. The Member State concerned in the trial is Sweden.

Details of the trial, including trial objectives, endpoints, protocol, sponsor and medicinal product information can be viewed in the CTIS public database here. This information is open and accessible to all, including patients, healthcare professionals and clinical researchers.

More information about CTIS and the CTIS public search is available at https://euclinicaltrials.eu/home.

Did you know?

CTIS includes a public searchable database where patients, healthcare professionals and the general public can find information on clinical trials. By searching for trials on euclinicaltrials.eu, patients can find clinical trials which are recruiting participants within their country and therapeutic area of interest and can easily find sponsor contact information to request more information about joining specific trials. When trials have ended the sponsor must upload a summary of the results of the trial in lay language, making clinical trial results easily understandable to the public.

Helpful hint

Users are reminded that due dates in CTIS are calculated in line with a timetable, which ensures harmonised timelines for clinical trial assessment across the EU and EEA. Details of how the clinical trial application timetable is calculated in CTIS can be found in the e-learning course within Module 04 – Support with workload management. Please see section 5: Timetable.

- Authority workspace e-learning course
- Sponsor workspace e-learning course

More information

Users can review Module 04 – Support with workload management for more information on the clinical trial assessment timetable in CTIS.

Would you like to unsubscribe from the CTIS newsflash? Please write to CT.NewsletterSubscriptions@ema.europa.eu with the subject line 'Unsubscribe from CTIS newsflash'. This will also unsubscribe you from the Clinical Trials Highlights Newsletter.