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European Medicines Agency

CTIS newsflash #03 - 18 February 2022

Introduction

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

Key metrics

Metrics reported cover the period 31/01/2022-13/02/2022.

Total number of logins to CTIS: 2,440

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

- **Number of draft applications in CTIS:** 116

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

- **Number of submitted applications in CTIS:** 3 on 13/02/2022

Did you know?

CTIS provides flexible features and functionality to suit all kinds of clinical trial sponsors, from large pharmaceutical companies to small investigator-led research groups. CTIS has two user management approaches to cater to the different needs of sponsors:

- the organisation management approach, which allows for the administration of user roles at the organisation level for sponsors with many trials and users; and

- the trial-centric approach, suitable for sponsors who will run one or a small number of clinical trials to easily manage user roles at the level of an individual clinical trial.

Helpful hint

Clinical trial application evaluation in CTIS is based on a set of timers, which ensure streamlined and harmonised timelines for clinical trial assessment across the EU and EEA. The timers provide strict deadlines for the various steps of Member State evaluation of a clinical trial, as well as sponsor actions during the evaluation, such as responding to RFIs. Details about the timers in CTIS and the rules for their calculation are available 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](#)

CTIS bitesize talk: first event reminder

The first open CTIS bitesize talk will take place on 24 February 2022, offered by EMA. The CTIS bitesize talks allow sponsors to learn about a dedicated CTIS functionality, while also providing time to ask practical questions. The first talk covers the user access and role management functionality in CTIS. More information is available [here](#).

More information

Users can review [Module 07 – Management of registered users and role matrix](#) to learn more about user management approaches in CTIS, and the e-learning and FAQs in [Module 04 – Support with workload management](#) for more information on timers in CTIS.

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