25 February 2022
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European Medicines Agency

CTIS newsflash #04 - 25 February 2022

Introduction

Welcome to the fourth 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 14/02/2022-20/02/2022.

Total number of logins to CTIS: 3,113

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

- **Number of draft applications in CTIS:** 151

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

- **Number of submitted applications in CTIS:** 5

News spotlight

The first clinical trial application submitted by a large pharmaceutical company has been received in CTIS.

Did you know?

CTIS provides workload management tools so that sponsors and regulatory authorities can easily keep track of their clinical trial applications and tasks in CTIS.

Sponsors can use the 'Notices and alerts' tab to see information such as when the validation of the clinical trial application has been completed by the Reporting Member State (RMS) and when requests

for information (RFIs) are due. Sponsors can also use the 'RFI' tab to keep track of all RFIs to be completed.

Regulatory authorities can use the 'Notices and alerts' and 'Tasks' tab to stay up to date on when their inputs are needed to e.g. to express willingness/unwillingness to be the RMS.

Helpful hint

When using the EMA Service Desk to get help with a CTIS issue, describing your issue accurately ensures the fastest solution. In Service Desk, there are three options:

- Ask a question: use this option when you need to discuss or clarify any general subject.

- Request a service: use this option if you need a standard service e.g. password reset, in the case where the user cannot reset using the standard 'Forgot password' process from the CTIS workspace login page.

- Report an issue: use this option when you are prevented from completing a task with CTIS due to a problem with the system.

Please ensure you give a clear and detailed description of your question, request or issue, attaching screenshots of the relevant sections of CTIS where possible.

Sponsor end user training programme: reminder

EMA offers a virtual training programme, with organisational support from DIA, to support sponsor users in learning how to use CTIS to submit clinical trial applications and manage clinical trials throughout their life cycle. The planned dates for the upcoming end user training programmes are:

- March course 01/03/2022 to 04/03/2022

- April course 05/04/2022 to 08/04/2022

- May course 10/05/2022 to 13/05/2022

- June course 20/06/2022 to 23/06/2022

More information

Users can review Module 04 – Support with workload management for more information on workflow tools within CTIS, and the notices and alerts per role document in Module 07 – Management of registered users and role matrix for more further detail on the notices and alerts visible for each user role.