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European Medicines Agency

CTIS newsflash #07 - 18 March 2022

Introduction

Welcome to the seventh 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 07/03/2022-13/03/2022.

Total number of logins to CTIS: 6,369

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

- **Number of draft applications in CTIS:** 221

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

- **Number of submitted applications in CTIS:** 14

Did you know?

The requests for information (RFI) functionality in CTIS allows Member States to request further information from sponsors to assist in the assessment of clinical trial applications within a single, online platform. With the CTIS RFI functionality, requests for information are centralised and deadlines for replying to RFIs are easy to track. CTIS provides reminders to sponsors via the 'Notices and alerts' tab when the due date for an RFI response is approaching.

Helpful hint

EMA has published a CTIS Technical requirements for optimal use document on the CTIS training and support page. This document outlines the technical aspects users can consider to ensure the best experience when using CTIS, covering items such as internet connectivity and preferred browsers.

CTIS walk-in clinics

EMA offers walk-in clinics to provide an opportunity for sponsors to receive practical advice about any CTIS functionality by asking questions to CTIS experts.

EMA plans to hold two walk-in clinics a month, with the first clinic on 28 March 2022 at 16:00 CET. Questions about the interpretation of the Clinical Trial Regulation and/or national processes are out of the scope of the walk-in clinics. It is highly recommended to first consult the available online CTIS training and support materials prior to attending the CTIS walk-in clinics.

In addition to the walk-in clinics, EMA holds CTIS bitesize functionality talks once a month, focussing on a specific CTIS functionality and including a live demonstration by CTIS experts and an opportunity for users to ask questions. The next CTIS bitesize talk is on 23 March 2022 at 14:00 CET and will focus on creating an initial clinical trial application.

More information

Users can review Module 11 - Respond to requests for information received during the evaluation of a clinical trial application for more information on the RFI functionality in CTIS. Users can also consult the CTIS training and information events section of the CTIS training and support page for the latest information on CTIS events.

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