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CTIS newsflash #09 - 01 April 2022

Introduction

Welcome to the ninth 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 21/03/2022-27/03/2022.

Total number of logins to CTIS: 9,164

- 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:** 278
  - This metric counts the number of applications with status "Draft" in CTIS at the end of the period
- **Number of submitted applications in CTIS:** 20

Did you know?

CTIS provides flexible options for the submission of quality documentation for investigational medicinal product dossier (IMPD-Q) documents. Sponsors can upload IMPD-Q documents directly to CTIS with the user role CT Admin or Q-IMPD Preparer, or they can cross-reference to an existing clinical trial where the IMPD-Q information can be reviewed by the Member State concerned. Due to the commercially sensitive nature of the IMPD-Q, sponsors may decide to assign CT Admin roles to people within their company, or to ensure confidentiality arrangements are in place if they delegate the CT Admin role to a CRO. More information about the possibilities for submission of and access to quality documentation in CTIS can be found in the sponsor organisation modelling document and Module 10 – Create, submit and withdraw a clinical trial in the training material.

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Helpful hint

Users are reminded to consult the known issues and workarounds document on the Clinical Trials website to understand possible issues they could encounter when using CTIS and how to complete key processes when such issues are encountered.

CTIS bitesize recording available and next event

The recording of the first CTIS bitesize talk is now available on the EMA website. The next CTIS bitesize talk is on 28 April 2022 at 14:00 CET.

CTIS walk-in clinics update

The first CTIS walk-in clinic was held on Monday 28 March 2022 at 16:00 CET with approximately 200 attendees. The walk-in clinics provide an opportunity for sponsors to receive practical advice about any CTIS functionality by asking questions to CTIS experts. The next walk-in clinics are scheduled for 4 April and 22 April.

Reporting safety information on clinical trials

A new webpage has been added to the EMA website to explain the obligations of clinical trial sponsors for reporting suspected unexpected adverse reactions (SUSARs) and other safety information. This page can be used as a simple guide to the information that must be reported to EudraVigilance, and the information which must be reported to CTIS for trials authorised under the Clinical Trials Regulation.

More information

Users can review Module 10 – Create, submit and withdraw a clinical trial for more information on the clinical trial application submission process including IMPD-Q submission. Users can also consult the Sponsor organisation modelling document for further explanation of the possibilities for IMPD-Q submission.

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