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CTIS newsflash #06 - 11 March 2022

Introduction

Welcome to the sixth 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 28/02/2022-6/03/2022.

Total number of logins to CTIS: 5,000

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

- **Number of draft applications in CTIS:** 208
  - This metric counts the number of applications with status "Draft" in CTIS at the end of the period
- **Number of submitted applications in CTIS:** 11

News spotlight

Over 10 clinical trial applications have been submitted for assessment in CTIS by the relevant regulatory authorities. The majority of applications were submitted by academic sponsors, while a significant number are also submitted by pharmaceutical companies.

Did you know?

CTIS contains various user roles to enable organisations to manage access to data according to their needs, and to build the profiles of users based on the actions they need to take in CTIS.

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Organisations can choose to give users roles which allow access to different parts of the clinical trial, such as Part I and Part II. In addition, organisations can choose between 'Viewer' roles, which allow users to see relevant data, 'Preparer' roles which allow for the input of data, and 'Submitter' roles which allow for the submission of data for review by the relevant regulatory authorities. You can also choose to grant roles with the scope 'all trials' to those who should be able to view or take actions for all trials in your organisation, or 'specific trials' when more narrow access to individual trials is appropriate.

Helpful hint

The European Commission provides templates for Part II clinical trial application documents, including for the Investigator *Curriculum Vitae* (CV), site suitability form and informed consent document. Sponsors can use these templates to draft their documents in a way that is Clinical Trials Regulation-compliant, which supports efficient and streamlined assessment by the Member States. The document templates can be found in Chapter I of Eudralex Volume 10.

More information

Users can review Module 07 – Management of registered users and role matrix for more information on the user roles available in CTIS. Users can also review the CTIS sponsor user personas and sponsor organisation modelling documents for guides on how to build the profiles of users to perform different clinical trial processes in CTIS. Users can consult the European Commission's Eudralex Volume 10 for a variety of useful document templates and guidance on interpretation of the Clinical Trials Regulation.

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