



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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CTIS newsflash #08 - 25 March 2022

Introduction

Welcome to the eighth 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 14/03/2022-20/03/2022.

Total number of logins to CTIS: 7,757

- 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: 259**
 - This metric counts the number of applications with status "Draft" in CTIS at the end of the period
- **Number of submitted applications in CTIS: 16**

Did you know?

Member States collaborate in the assessment of Part I for multinational clinical trial applications in CTIS and provide a harmonised, single decision on this part of the application. CTIS provides collaboration tools to allow Member States concerned in the application to document their considerations when assessing Part I. The Reporting Member State consolidates these considerations and raises requests for information (RFIs) if needed. The considerations raised by Member States concerned inform the writing of the Final Assessment Report (FAR) and the submission of the conclusion of the Part I assessment by the RMS.

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Helpful hint

The link to access the CTIS Sponsor Workspace is found in the top right corner of the euclinicaltrials.eu website, by clicking on 'CTIS log in' and then 'Sponsor Workspace'. Users can bookmark the [login page link](#) to their internet browser for quick access to this page. Users must register for an EMA account via EMA Account Management to log in to CTIS. If you are the first user in your sponsor organisation to access CTIS, it is recommended that you first consult the [Getting started with CTIS: sponsor quick guide](#) for tips on getting started.

CTIS walk-in clinics and bitesize talks: reminder

The first CTIS walk-in clinic will be held on Monday [28 March 2022 at 16:00 CET](#). The walk-in clinics provide an opportunity for sponsors to receive practical advice about any CTIS functionality by asking questions to CTIS experts.

EMA hosted the second CTIS bitesize functionality talk on the initial clinical trial application on 23 March. Over 1,200 viewers attended the event and received guidance on the initial clinical trial application, as well as answers to attendee questions from CTIS experts. The next CTIS bitesize talk is on [28 April 2022 at 14:00 CET](#).

Questions about the interpretation of the Clinical Trial Regulation and/or national processes are out of the scope of the walk-in clinics and bitesize talks. It is highly recommended to first consult the available online [CTIS training and support materials](#) prior to attending these events.

More information

Users can review [Module 8 - Evaluate a clinical trial application: Assessment and decision-making](#) and [Module 11 - Respond to requests for information received during the evaluation of a clinical trial application](#) for more information on the clinical trial application evaluation process from the perspective of Member States and sponsors in CTIS. Users can also consult the [Getting started with CTIS: sponsor quick guide](#) for information on getting started with CTIS.

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