



4 February 2022  
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European Medicines Agency

## CTIS newsflash 4 February 2022

### Introduction

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Welcome to the first CTIS newsflash. CTIS went live on 31 January 2022 and sponsors across Europe are beginning to use the system to compile and submit clinical trial applications. In addition, Member States are working in CTIS to prepare for the evaluation and supervision of clinical trials and to evaluate the first submissions. In these early days of CTIS, this newsflash will provide regular updates on interesting facts and figures regarding CTIS usage, as well as links to useful reference materials.

### Key metrics

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Metrics reported cover the period 31/01/2022-03/02/2022.

- **Total number of logins to CTIS:** 1,260
  - This metric represents the sum of unique logins by individual users per day
- **Number of draft applications in CTIS:** 53
  - This metric counts the number of applications with status: Draft in CTIS
- **Number of submitted applications in CTIS:** 1

### News spotlight

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The first clinical trial has been submitted by a sponsor in CTIS. This trial was submitted by an academic sponsor and is now ready for review by the relevant regulatory authority.

### Did you know?

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CTIS harmonises submission and assessment processes for clinical trials. Prior to CTIS, sponsors had to submit clinical trial applications separately to national competent authorities (NCAs) and ethics committees in each country to gain regulatory approval to run a clinical trial, and registration and posting of results were also separate processes.

CTIS enables sponsors to submit one online application via a single online platform for approval to run a clinical trial in several European countries, covering NCA and ethic committee assessments as well as



registration of the trial in a public searchable database, once the application has been decided on by the Member States.

### **Helpful hint**

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To access CTIS, users must register for a user account via [EMA Account Management](#). Users with an account that has been inactive for more than 6 months will need to re-activate their account by clicking on 'Forgot Password' on the secure workspace login page (found [here](#) for the sponsor workspace and [here](#) for the authority workspace) and resetting their password.

### **CTIS scheduled maintenance windows for system improvements**

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For the first six months following go-live, EMA will perform regular system updates to CTIS to ensure smooth operation for users. To facilitate this, CTIS 'maintenance windows' will be in place.

During maintenance windows, EMA may perform updates to CTIS which affect system usage, meaning that CTIS may be intermittently unavailable or not work optimally. It is advised that CTIS users avoid accessing the system at these times. Users who choose to access the system at these times are advised to save their work regularly to avoid data loss.

The CTIS maintenance windows are as follows:

- Each **Tuesday and Thursday from 18:00 to 21:00 CET.**
- **The first Saturday** of each month **from 10:00 to 14:00 CET.**

### **More information**

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Users can review [Module 05 – Manage a clinical trial through CTIS](#) for more information on the clinical trial submission process in CTIS, and [Module 03 – User access management](#) for more information on user account registration.