EMA Clinical Trials Information System (CTIS): The future user perspective

26 October 2021
13:15 - 17:00 CEST | Virtual Event

PROGAMME COMMITTEE

Charalampos Drosos
CTIS Business Project Officer, European Medicines Agency (EMA), EU

Sarah Scales
CTIS Change Management Officer; European Medicines Agency (EMA), EU

Fia Westerholm
Programme Assurance Manager
European Medicines Agency (EMA), EU

Pieter Vankeerberghen
Head of Clinical Trials
European Medicines Agency (EMA), EU

SPEAKERS & PANNELISTS

Gabriella Di Matteo
Clinical Trial Submissions Senior Manager
Pfizer, BE

Ana Rodriguez Sanchez Beato
CTIS Business Expert
European Medicines Agency (EMA), EU

Stefan Strasser
Head of Clinical Trials
Agency for Health and Food Safety
AGES, AT

DETAILS OF THIS INFORMATION DAY

In this interactive half day webinar both speakers and attendees participate remotely via DIA's digital platform

This event is organised by DIA. For any questions please contact basel@diaglobal.org

| OVERVIEW

The European Commission confirmed 31 January 2022 as the date of entry into application of the Clinical Trials Regulation EU No 536/2014 and the go-live of the Clinical Trial Information System (CTIS).

The objectives of this virtual information day are to help prepare users for the new way of submitting Clinical Trial Applications (CTA) through CTIS.

It will provide –on a high level- an overview of key aspects of CTIS for future users to consider.

Ample time is foreseen for a live demo presenting users an overview of the two restricted workspaces for sponsors and authorities.

Furthermore, current status and experience with sponsor users' preparedness will be shared.

The information day will close with an update on access to CTIS training material and EMA support.

The information day will not cover aspects of the registration process nor user access management in CTIS. More information on those topics can be found on the dedicated EMA CTIS webpages*.

| KEY TOPICS

- The Clinical Trials Regulation and key aspects for users to consider when preparing for CTIS
- CTIS live demo of sponsor and authority workspaces: how to navigate the system
- Sponsor perspective on user preparedness
- Update on Access to CTIS training material and support

| TARGET AUDIENCE

This EMA CTIS Virtual Information Day is aimed at all CTIS users:

- Clinical Trial Sponsors
- CROs
- Member State NCAs
- Ethics Committee Members

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

*https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support#reference-materials-for-clinical-trial-sponsors-section

AGENDA – 26 OCTOBER 2021

13:15 LOG IN & HOW TO NAVIGATE THE VIRTUAL PLATFORM

13:30 WELCOME
Speaker: Pieter Vankeerberghen, European Medicines Agency, EU

13:40 SESSION 1: THE CLINICAL TRIAL REGULATION & CTIS: KEY ASPECTS FOR USERS TO CONSIDER WHEN PREPARING FOR CTIS
Speaker: Stefan Strasser, Agency for Health and Food Safety, AT

- The Clinical Trials Regulation timelines and transition period
- The new submission process in CTIS
- Amendments and notifications
- Transparency

14:25 SESSION 2: TOUR OF CTIS SPONSOR AND AUTHORITY WORKSPACES: (LIVE DEMO)
Speakers: Charalampos Drosos & Ana Rodriguez Sanchez Beato, European Medicines Agency, EU

- Overview of the main tabs in the system: Clinical Trials tab, Notices & Alerts, RFI (for Sponsors) and Tasks (for Member States)
- Presenting the sections of the clinical trial application: Form, MSC, Part I, Part II, Evaluation and Timetable

15:20 COFFEE BREAK

15:40 SESSION 3: HOW TO PREPARE FOR CTIS: A USER PERSPECTIVE
Speaker: Gaby Di Matteo, Pfizer, BE

- Key considerations for users when preparing for CTIS

16:20 SESSION 4: HOW TO ACCESS CTIS TRAINING MATERIALS AND SUPPORT
Speaker: Fia Westerholm, European Medicines Agency, EU

16:35 WRAP UP

16:50 CLOSING
Speaker: Pieter Vankeerberghen, European Medicines Agency, EU

17:00 END OF THE VIRTUAL INFORMATION DAY