VIRTUAL EVENT

EMA CTIS SPONSOR USER TRAINING PROGRAMME

The New Way of Submitting, Managing and Supervising a Clinical Trial Via the Clinical Trial Information System

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview

European Medicines Agency (EMA) has developed this blended training programme to support sponsor user preparedness concerning the new way of submitting Clinical Trial Applications (CTA) in the EEA via the new Clinical Trial Information System (CTIS) and in compliance with the Clinical Trial Regulation No. 536/2014. This training opportunity is supported by EMA Data Analytics and Methods Task Force (TDA).

A hands-on approach is taken to explain and demonstrate the functionalities of the system, such as user management, how to submit an initial application as well as modifications, both substantial and non-substantial. Also, how to manage the life cycle of a Clinical Trial, how to manage the clinical trial transparency and respond to a Request for Information (RFI) will be addressed.

Furthermore, search and download options will be demonstrated and how CTIS interacts with other EMA systems such as the XEVMPD, EMA account management and OMS. The training programme also includes information on how to submit Annual Safety Reports (ASRs) as well as Clinical Study Reports (CSRs).
A blended learning approach is being used, offering components on-demand, self-paced and live virtual.

Participants receive access to the CTIS training environment and will practice basic functionalities during the live training course.

Key Topics

- Overview of CTIS components and system functionalities
- Sponsor User Access Management
- Management of registered users (Role Matrix)
- Create, submit and withdraw an initial application; Update initial application through other applications (substantial modifications, additional MSC)
- Respond to Request for Information (RFI) received during the evaluation
- Manage a Clinical Trial through CTIS
- Sponsor search, view & download a Clinical Trial & Clinical Trial Application (CTA)
- Create and submit an Annual Safety Report and respond to related RFIs
- Clinical Study Reports (CSR) submissions

On Demand Content

- Introduction to Clinical Trials Regulation (CTR) (EU) No. 536/2014·
- Transparency ·
- Data protection in CTIS
- CTIS Sponsor User Personas
- Transitioning trials from EUDRACT to CTIS – principles and guidance

2026 DATES & TIME (CET)

- 09 - 12 Mar, 09:00 - 13:30, #26520
- 08 - 11 Jun, 14:00-18:30, #26521

TARGET AUDIENCE

This training programme is open to sponsor users of the new CTIS: commercial and non-commercial sponsors as well as Contract Research Organisations (CROs).

INSTRUCTOR POOL

Calin Lungu
CEO, Drug Development Consulting Services S.A. (DDCS), LU

Fatima Pimentel
Director, SSU & Regulatory
Regulatory Advice and Delivery (RAD) Team – SSU Early Engagement
Syneos Health, PT

José Ortiz
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Pierre-Frédéric Omnes
Executive Director, Transperfect, FR
CTIS Lead Product Owner representing Industry & Academia

Ruediger Pankow
Regulatory Affairs Expert
Clinical Trial Sponsor CTIS Product Owner representing the Association of Clinical Research Organizations (ACRO), DE

Vojtech Kvita
Executive Director
NextPV Services, CZ

AGENDA (Timing in CE(S)T)

DAY 1 - VIRTUAL LIVE TRAINING COURSE

Start at 09:00 (morning) or at 14:00 (afternoon).

09:00 | 14:00 **WELCOME & INTRODUCTION**

SESSION 1 | Theoretical part
OVERVIEW OF CTIS COMPONENTS AND SYSTEM FUNCTIONALITIES

SESSION 2 | Theoretical part
SPONSOR USER ACCESS MANAGEMENT

10:45 | 15:45 **BREAK**

11:15 | 16:15
SESSION 3 | Theoretical part, Live demo
MANAGEMENT OF REGISTERED USERS
Sponsor Roles and Permission in CTIS (ROLE MATRIX)

SESSION 4 | Theoretical part, Live demo
CREATE, SUBMIT AND WITHDRAW AN INITIAL APPLICATION
This session will focus on the process of creating an Initial Clinical Trial Application (CTA)

PRACTICAL EXERCISES

- Login to CTIS training environment
- Create a draft application
- Update your employer information demo
- Check and request roles
- Update the full trial title and add a translation

13:00 | 18:00 **Q & A**

13:30 | 18:30 **END OD DAY 1**

DAY 2 - VIRTUAL LIVE TRAINING COURSE

Start at 09:00 (morning) or at 14:00 (afternoon).

09:00 | 14:00 **LOG IN & WELCOME**

SESSION 4 | Theoretical part, Live demo & practical exercises
CREATE, SUBMIT AND WITHDRAW AN INITIAL APPLICATION Continued

This session will focus on:

- the process of creating, submitting, and cancelling an Initial Clinical Trial Application (CTA)
- the process of withdrawing an Initial CTA
- timelines of evaluation that impact the sponsor
- which user roles can create, submit, & withdraw an Initial CTA

PRACTICAL EXERCISES

- Add Member States Concerned in an initial draft application
- Add trial subjects from countries outside of the EEA
- Add scientific and public contact points
- Add a product in an initial draft application
- Add a third party

11:00 | 16:00 **BREAK**

11:30 | 16:30
SESSION 5 | Theoretical part and Live demo
RFI FUNCTIONALITIES: RESPOND TO REQUEST FOR INFORMATION (RFI) RECEIVED DURING THE EVALUATION OF A CTA

This session will focus on:

- the phases & associated timelines for the CTA evaluation
- RFI response timelines for validation & assessment
- types of RFIs that MSC can send during the CTA evaluation
- how to search & view an RFI during the CTA evaluation
- how to create and submit an RFI response, including changes to an existing application
- the roles & permissions involved in the RFI management

13:00 | 18:00 **Q & A**

13:30 | 18:30 **END OD DAY 2**

AGENDA (Timing in CE(S)T)

DAY 3 - VIRTUAL LIVE TRAINING COURSE

Start at 09:00 (morning) or at 14:00 (afternoon).

09:00 | 14:00 **LOG IN & WELCOME**

SESSION 6 | Theoretical part, Live demo | Continued
UPDATE OF AN INITIAL APPLICATION SUBSTANTIAL MODIFICATIONS, ADDITIONAL MSC APPLICATION, USE OF NON-SUBSTANTIAL MODIFICATION

10:45 | 15:45 **BREAK**

11:15 | 16:15
SESSION 7 | Theoretical part and Live demo
MANAGE A CLINICAL TRIAL THROUGH CTIS

The session will focus on:

- the use of notifications
- the process of ad hoc assessments and corrective measures in the sponsor workspace
- which user roles can submit notifications & address RFIs related ad hoc assessments and corrective measures

13:00 | 18:00 **Q & A**

13:30 | 18:30 **END OD DAY 3**

DAY 4 - VIRTUAL LIVE TRAINING COURSE

Start at 09:00 (morning) or at 14:00 (afternoon).

09:00 | 14:00 **LOG IN & WELCOME**

SESSION 8 | Continued
MANAGE A CLINICAL TRIAL THROUGH CTIS
Submission of summary of results (intermediate and final) layperson summary

This session will focus on:

- how to prepare and submit clinical trial results
- which user roles can submit summary of results

SESSION 9 | Theoretical part, Live demo
CLINICAL STUDY REPORTS (CSR) SUBMISSIONS

This session will focus on:

- how to prepare & submit a Clinical Study Report CSR
- how to view, download, update & withdraw a CSR
- which user roles are involved in submission of a CSR

10:15 | 15:15 **BREAK**

DAY 4 - continuation

10:45 | 15:45
SESSION 10 | Theoretical part, Live demo
SPONSOR SEARCH, VIEW AND DOWNLOAD INFORMATION ON CLINICAL TRIALS AND CLINICAL TRIAL APPLICATIONS

This session will focus on:

- search and download options of documents for a Clinical Trial / Clinical Trial Application (CT/CTA)
- how the information is displayed while navigating through a CT/CTA
- which user roles can access and download specific CT/CTA information

SESSION 11 | Theoretical part and Live demo
CREATE & SUBMIT AN ANNUAL SAFETY REPORT AND RESPOND TO RELATED RFIS

This session will focus on:

- the process to create and submit an Annual Safety Report (ASR) form
- how to view and reply to RFIs received during the assessment process of an Annual Safety Report
- which user roles can create and submit an ASR form and respond to related RFIs

12:15 | 17:15
SESSION 12
AVAILABILITY & LOCATION OF CTIS TRAINING MATERIAL AND SUPPORT

12:30 | 17:30 **Q & A**

13:30 | 18:30 **END OD DAY 4**

AGENDA (Timing in CE(S)T)

ON DEMAND COMPONENTS TO BE COMPLETED BEFORE THE LIVE EVENT

- CLINICAL TRIAL REGULATION EU NO 536/2024
- TRANSPARENCY- RULES
- DATA PROTECTION IN CTIS

* Please note that CTIS is an evolving software. The training environment is being used for system demonstrations in this training programme. It is possible that some screenshots in the training material may not match the screen aspect during the live demonstration. The trainers will explain the eventual differences during the training course. Unless otherwise disclosed, DIA acknowledges that the statements made by trainers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Trainers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.