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

2026 DATES & TIME (CET)

- 19 - 22 Oct - 09:00-13:30, # 26522

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
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José Ortiz
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Ruediger Pankow
Regulatory Affairs Expert, DE
CTIS Sponsor Subject Matter Expert representing Industry & Academia

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
INTRODUCTION TO CTIS AND SYSTEM PREPARATORY STEPS

This session will focus on

- how CTIS interacts with other EMA databases and different workspaces
- preparatory steps before accessing CTIS (EMA account, sponsor organisation and product (XEVMPD) registration)
- CTIS sponsor workspace

SESSION 2 | Theoretical part
SPONSOR USER MANAGEMENT AND ROLE MATRIX

This session will focus on

- the different types of roles available
- the key concepts related to CTIS user management
- how to register a CTIS sponsor administrator

11:00 | 16:00 BREAK

11:30 | 16:30

SESSION 3 | Theoretical part, Live demo & practical exercise
INITIAL APPLICATION

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

- Login to CTIS training environment
- Update your employer information

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 3 continued | Live demo & practical exercises
INITIAL APPLICATION Continued

This session will focus on demonstrating CTIS and performing practical exercises

PRACTICAL EXERCISES

- Create a draft application
- Check and request roles
- Update the full trial title and add a translation
- 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 4 | Theoretical part and Live demo
RESPOND TO REQUEST FOR INFORMATION (RFI)

This session will focus on:

- the phases & associated timelines for the CTA evaluation
- the RFI response timelines for validation & assessment
- the RFIs types 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 5 | Theoretical part, Live demo
SUBSTANTIAL AND NON-SUBSTANTIAL MODIFICATIONS ADDITIONAL MSC APPLICATION

The session will focus on:

- the process of submitting a substantial and non-substantial modification
- the process of adding an additional MSC

10:45 | 15:45 BREAK

11:15 | 16:15
SESSION 6 | Theoretical part and Live demo
NOTIFICATIONS AND AD HOC RFIs

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 7 | 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

SESSION 8 | Theoretical part and Live demo
SUBMISSION OF RESULTS

This session will focus on:

- how to prepare and submit clinical trial results (intermediate and final)
- which user roles can submit summary of results

10:15 | 15:15 BREAK

DAY 4 - continuation

10:45 | 15:45
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

SESSION 10 | Theoretical part, Live demo
SPONSOR DOWNLOAD OPTIONS

This session will focus on:

- 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
AVAILABILITY & LOCATION OF CTIS TRAINING MATERIAL AND SUPPORT

12:00 | 17:00 Q & A

12:30 | 17:30 END OF THIS TRAINING COURSE

* 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.