EMA CTIS SPONSOR USER TRAINING PROGRAMME

The New Way of Submitting, Managing and Supervising a clinical trial via the Clinical Trial Information System

Blended training course including on-demand and live virtual components

| DATES & TIME

23-26 September 2024 (#24523)
09:00-13:30 CET

28-31 October 2024 (#24527)
14:00-18:30 CET

25-28 November 2024 (#24528)
09:00-13:30 CET

| 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
CEO, PVPharm, ES

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

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).

| OVERVIEW

European Medicines Agency (EMA) has developed this 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

Section I - These topics are offered on demand and should be completed before joining the live course:

- 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

Section II - These topics are offered in a live virtual course:

- 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 and download a Clinical Trial and Clinical Trial Application (CTA)
- Create and submit an Annual Safety Report and respond to related RFIs
- Clinical Study Reports (CSR) submissions

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

AGENDA | SECTION I -ON DEMAND COMPONENTS TO BE COMPLETED BEFORE THE LIVE EVENT

95 MIN **CLINICAL TRIAL REGULATION (CTR) AND WHAT IS CHANGING IN PRACTICE (CTTM01)**
European Commission, DG Sante, BE

35 MIN **TRANSPARENCY-PUBLICATION OF CLINICAL TRIAL INFORMATION CONTAINED IN CTIS**
European Medicines Agency, TDA EMA, EU

35 MIN **DATA PROTECTION IN CTIS**
European Medicines Agency, TDA EMA, EU

20 MIN **CTIS SPONSOR USER PERSONAS**
European Medicines Agency, TDA EMA, EU

25 MIN **TRANSITIONING TRIALS FROM EUDRACT TO CTIS – PRINCIPLES AND GUIDANCE**
European Medicines Agency, TDA EMA, EU

AGENDA | SECTION II - VIRTUAL LIVE TRAINING COURSE

Please note that timings refer to either morning **or** afternoon course. All times are in CET/CEST

DAY 1 – START AT 09:00 FOR MORNING OR AT 14:00 FOR AFTERNOON OFFERING

09:00 | 14:00 **Welcome & Introduction**

SESSION 1 – OVERVIEW OF CTIS COMPONENTS AND SYSTEM FUNCTIONALITIES (CTTM02)
Theoretical part

SESSION 2 – SPONSOR USER ACCESS MANAGEMENT (CTTM03)
Theoretical part

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

11:15 | 16:15 **SESSION 3 – MANAGEMENT OF REGISTERED USERS (CTTM07)**
Sponsor Roles and Permission in CTIS (ROLE MATRIX)
Theoretical part, Live demo

SESSION 4 - CREATE, SUBMIT AND WITHDRAW AN INITIAL APPLICATION (CTTM10)
Theoretical part, Live demo

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**
- **Check and request roles**
- **Update the full trial title and add a translation**

13:00 | 18:00 **Q&A**
13:30 | 18:30 **END OF DAY 1**

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.

AGENDA | SECTION II - VIRTUAL LIVE TRAINING COURSE

Please note that timings refer to either morning **or** afternoon course. All times are in CET/CEST

DAY 2- START AT 09:00 FOR MORNING OR AT 14:00 FOR AFTERNOON OFFERING

09:00 | 14:00 LOG IN & WELCOME

SESSION 4 - CREATE, SUBMIT AND WITHDRAW AN INITIAL APPLICATION (CTTM10) Continued - Theoretical part, Live demo & practical exercises

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
- which user roles can create, submit, and withdraw an Initial CTA
- timelines of evaluation that impact the sponsor

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 - RFI FUNCTIONALITIES: RESPOND TO REQUEST FOR INFORMATION (RFI) RECEIVED DURING THE EVALUATION OF A CTA (CTTM11)**
Theoretical part and Live demo

This session will focus on

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

13:00 | 18:00 Q&A

13:30 | 18:30 END OF DAY 2

Please note that timings refer to either morning **or** afternoon course. All times are in CET/CEST

DAY 3- START AT 09:00 FOR MORNING OR AT 14:00 FOR AFTERNOON OFFERING

09:00 | 14:00 LOG IN & WELCOME

SESSION 6 - UPDATE OF AN INITIAL APPLICATION cont. (CTTM10) SUBSTANTIAL MODIFICATIONS, ADDITIONAL MSC APPLICATION, USE OF NON-SUBSTANTIAL MODIFICATION
Theoretical part and Live demo

10:45 | 15:45 BREAK

AGENDA | SECTION II - VIRTUAL LIVE TRAINING COURSE

11:15 | 16:15 **SESSION 7 - MANAGE A CLINICAL TRIAL THROUGH CTIS (CTTM05)**
Theoretical part and Live demo

This session will focus on

- the use of notifications
- the processes 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 | 18:30 Q&A
13:30 | 18:30 **END OF DAY 3**

DAY 4- START AT 09:00 FOR MORNING OR AT 14:00 FOR AFTERNOON OFFERING

09:00 | 14:00 LOG IN & WELCOME

SESSION 8 - MANAGE A CLINICAL TRIAL THROUGH CTIS – CONTINUED (CTTM05)
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 - CLINICAL STUDY REPORTS (CSR) SUBMISSIONS (CTTM13)
Theoretical part and Live demo

This session will focus on

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

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

10:45 | 15:45 **SESSION 10 - SPONSOR SEARCH, VIEW AND DOWNLOAD INFORMATION ON CLINICAL TRIALS AND CLINICAL TRIAL APPLICATIONS (CTTM09)**
Theoretical part and Live demo

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 - CREATE & SUBMIT AN ANNUAL SAFETY REPORT AND RESPOND TO RELATED RFIS (CTTM18)
Theoretical part and Live demo

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 AND LOCATION OF CTIS TRAINING MATERIAL AND SUPPORT**

12:30 | 17:30 Q&A
13:30 | 18:30 **END OF SECTION II**