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

08-11 April 2024 (#24521)
14:00-18:30 CEST

10-13 June 2024 (#24522)
09:00-13:30 CEST

| 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

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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**

REGISTRATION FORM

EMA CTIS Sponsor User Training Programme

You can register online at www.diaglobal.org/EMA/course-listing

REGISTRATION FEES

CTIS SPONSOR USER TRAINING PROGRAMME	PRICE IN EURO
Standard fee for Industry/CRO	€ 1'640.00 ❑
Academia/Government	€ 820.00 ❑

All registration fees are subject to VAT, if applicable.

Please enter your Company's European VAT number:_____

A special discount for SMEs on the standard fee is available for a limited number of places.
To proof your status as an SME, a confirmation of the European Medicines Agency is necessary.

Please provide your SME number here : _____

Payment is due 30 days after registration and must be paid in full by commencement of the course.

Please select your preferred dates for the CTIS Sponsor User Programme:

❑ **#24521**: 8-11 April 2024 | 14:00-18:30 CEST - virtual
❑ **#24522**: 10-13 June 2024 | 09:00-13:30 CEST - virtual

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CE(S)T. Tel. :+41 61 225 51 51

Email: Basel@DIAglobal.org
Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel 28 days prior to the event start date and do not attend, you will be responsible for the full registration fee.

Please note that switching from one course date to another is considered a cancellation and the same policy applies.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration - for the same course - to a colleague of the same organisation. Such a transfer is possible until 5 working days before the start of the training course. Please notify the DIA office of such a substitution as soon as possible.

Event Stream and recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/en/about-us/privacy-policy.

ATTENDEE DETAILS:

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Direct email attendee (Required for course material access)

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

- **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature