VIRTUAL EVENT

EMA Clinical Trial Information System Webinar:

Dynamic Demo of Sponsor Workspace

21 September 2020 | 13:00 - 17:30 CEST

PROGRAMME ADVISOR

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

DETAILS OF THIS WEBINAR

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

This webinar provides a demonstration of the current status of the Clinical Trials Information System (CTIS) which is currently under development, combining presentations and discussions on the underlying principles and concepts with demonstrations of specific functionalities.

After a brief introduction and overview of CTIS, the workspace functionalities that are specifically designed for use by clinical trial sponsors, including commercial and non-commercial (academic) sponsors will be demonstrated.

Following, the user roles, their hierarchy, and related permissions as well as access policies of users will be presented and how to manage these in the system. Functionalities for creating and managing a clinical trial application in CTIS will be outlined, and some practical advice as to how the system will be able to support users to manage their daily work and workload planning will be shared.

Presentations will be provided by system experts complemented by pre-recorded demonstrations of the system, and rounded up in a live Q&A.

Key Topics

- Brief introduction to the Clinical Trials Information System (CTIS)
- Access management
- Sponsor user management – principles and concepts
- Role matrix - principles, concepts and sponsor roles
- CTIS Sponsor workspace
  - o General overview
  - o Sponsor user administration in CTIS
  - o Clinical Trial Application management step by step
  - o Tools for user workload overview and management
- Preparations for CTIS Go-Live
- Current status and future master trainer involvement

Who Should Attend

Clinical trial sponsor staff representing commercial sponsors such as pharmaceutical companies and CROs, SMEs, non-commercial sponsors including academia, research institutions. CTIS Stakeholder associations representatives. Expert trainers with an interest in the area of Clinical Trials.

Please check our website on how to register online!

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Disclosure Policy

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

AGENDA

13:00 LOG IN

13:15 HOW TO NAVIGATE THE WEBINAR

Sara Torgal, Scientific Programmes Manager, DIA, Switzerland

13:30 WELCOME AND KEYNOTE

Fergus Sweeney, Head Clinical Studies and Manufacturing, European Medicines Agency, EU

13:45 SESSION 1

INTRODUCTION TO CTIS, USER ACCESS AND MANAGEMENT

Session chair:
Pieter Vankeerberghen, Head of Clinical Trials, European Medicines Agency, EU

Session Overview
Brief introduction to the Clinical Trials Information System (CTIS), User access management, Sponsor user management – principles and concepts, Role matrix - principles, concepts and sponsor roles.

Introduction to the Clinical Trials Information System (CTIS)
Fia Westerholm, Programme Assurance Manager, European Medicines Agency, EU

User access management
Ana Rodriguez Sanchez Beato, CTIS Business Expert, European Medicines Agency, EU

Sponsor user management – principles and concepts
Ana Rodriguez Sanchez Beato, CTIS Business Expert, European Medicines Agency, EU

Role matrix - principles, concepts, and sponsor roles
Ana Rodriguez Sanchez Beato, CTIS Business Expert, European Medicines Agency, EU

Panel discussion with Q&A, with the additional participation of:
Kristof Bonnarens, Policy Officer - Pharmaceuticals, Directorate-General for Health and Food Safety - DG SANTE, European Commission, Belgium
Stéphanie Kromar, Senior Regulatory Affairs Manager & Clinical Trial Sponsor CTIS Product Owner, European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Rüdiger Pankow, Principal Consultant, Parexel International & Clinical Trial Sponsor CTIS Product Owner representing the Association of Clinical Research Organizations (ACRO), Germany

15:15 BREAK

15:30 SESSION 2

CLINICAL TRIAL APPLICATION AND WORKLOAD MANAGEMENT IN CTIS

Session chair:
Gabriella di Matteo, Clinical Trial Submissions Senior Manager, Pfizer

Session Overview
Clinical Trial Application management step by step, tools for user workload overview and management.

Clinical Trial Application management step by step
Laura Pioppo, CTIS Business Expert, European Medicines Agency, EU

Tools for user workload overview and management
Laura Pioppo, CTIS Business Expert, European Medicines Agency, EU

Panel discussion with Q&A, with the additional participation of:
Kristof Bonnarens, Policy Officer - Pharmaceuticals, Directorate-General for Health and Food Safety - DG SANTE, European Commission, Belgium
Stéphanie Kromar, Senior Regulatory Affairs Manager & Clinical Trial Sponsor CTIS Product Owner, European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Rüdiger Pankow, Principal Consultant, Parexel International & Clinical Trial Sponsor CTIS Product Owner representing the Association of Clinical Research Organizations (ACRO), Germany

Preparations for CTIS Go-Live
Pieter Vankeerberghen, Head of Clinical Trials, European Medicines Agency, EU

Future Master Trainer's involvement and Current Status
Sara Torgal, Scientific Programmes Manager, DIA, Switzerland

17:20 WRAP UP

17:30 END OF WEBINAR