EMA Clinical Trials Information System (CTIS) Information Day

17 October 2024
13:30 - 17:30 CET | VIRTUAL Event

| PROGRAMME COMMITTEE

Ana Zanoletty Perez
Head of Clinical Trials Transformation Workstream
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Francesca Scotti
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European Medicines Agency, EU

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| FACULTY

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Syneos Health, PT

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Ethics Commission
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Lora Killian
Transparency and Disclosure Lead
Pfizer, US

Noémie Manent
Principal Scientific Administrator
European Medicines Agency, EU

Polyana Bastos
Senior Legal Director
Johnson & Johnson, CH

Susanne Lerch
Scientific Officer, PEI, DE

| OVERVIEW

Since 31 January 2023, it has been mandatory for sponsors to submit all initial clinical trial applications via CTIS. In less than 7 months, from 31 January 2025 onwards, sponsors will need to comply with their obligations under the CTR and its Delegated Acts for all clinical trials conducted in the EU/EEA.

Furthermore, the revised transparency rules for the Clinical Trials Information System (CTIS) will become applicable on 18 June 2024, with the launch of a new version of the CTIS public portal.

The virtual event aims to support sponsors of clinical trials in proceeding with the transition to meet the deadline of 31 January 2025. Speakers will share detailed metrics on transitioned clinical trials. In addition, comprehensive guidance and practical examples regarding the following steps in transitioning trials will be presented.

Additionally, during the event representatives from EMA will provide an overview of the revised transparency rules as well as a demonstration of the new functionalities of CTIS new public portal.

Ample time is foreseen for Q&A. The faculty invites participants to submit related questions by 08 October 2024 latest to emaevents@diaglobal.org

| KEY TOPICS

- Transition period from the Clinical Trials Directive (2001/20/EC) to the Clinical Trial Regulation – regulatory and practical aspects
- Overview of the revised transparency rules
- Demonstration of the new functionalities of CTIS new public portal

| TARGET AUDIENCE

This EMA CTIS Virtual Information Day is aimed at CTIS users from:

- Pharmaceutical companies
- Small and medium sized enterprises (SMEs)
- Academic organisations
- Contract Research Organisations (CROs)
- Member State NCAs
- Ethics Committee Members

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AGENDA | 17 October 2024 | 13:30 – 17:30 CET

13:30 **WELCOME NOTE**

Peter Arlett, Head Data Analytics & Methods Task Force, EMA, EU

SESSION 1: TRANSITION PERIODS FOR CLINICAL TRIALS FROM DIRECTIVE (2001/20/EC) TO REGULATION (536/2014)

SESSION CHAIRS: Ana Zanoletty Perez, EMA, EU & Scott Feiner, AbbVie, US

13:40 **Transitioned Clinical Trials – Current Status and Key Metrics**
Noémie Manent, EMA EU

14:00 **Current Status about transitioning Clinical Trials and next steps**
Marianne Lunzer, AGES, AT

14:15 **Follow up on Transitioned Clinical Trials from Sponsors' Perspective**
Scott Feiner, AbbVie, US

14:30 **Follow up on Transitioned Clinical Trials from CROs' Perspective**
Fatima Pimentel, Syneos Health, PT

14:45 **Follow up on Transitioned Clinical Trials from Regulatory Perspective**
Susanne Lerch, PEI, DE

Follow up on Transitioned Clinical Trials from Ethics Committee Perspective
Friederike Heckmann, AEKWL, DE

15:05 Q&A with all speakers

15:30 **BREAK**

SESSION 2: TRANSPARENCY IN CLINICAL TRIALS

SESSION CHAIRS: Francesca Scotti, EMA, EU & Marianne Lunzer, AGES, AT

16:00 **Overview of new Transparency Rules**
Francesca Scotti, EMA, EU

Demonstration of the new Public Portal
Francesca Scotti, EMA, EU

16:30 **New Transparency rules –How to manage from a commercial sponsors' perspective**
Lora Killian, Pfizer, US

New Transparency rules –How to manage from a non-commercial Sponsors' Perspective
Andrea Seidel-Glaetzer; KKS, DE

17:10 **Q&A with all speakers including Polyana Bastos and wrap up**

17:30 **END OF THE INFORMATION DAY**