EMA Clinical Trials Information System (CTIS) Information Day

17 October 2023
13:30 - 17:30 CET | VIRTUAL Event

| PROGRAMME COMMITTEE

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Roxana Spulber
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Leonard Van den Berg
University Medical Center (UMC)
Utrecht, NL

| OVERVIEW

The Clinical Trials Information System (CTIS) is the backbone of the Clinical Trials Regulation (Regulation (EU) No 536/2014) and acts as a the single-entry point for clinical trials assessment, authorisation and supervision in the EEA.

It also enables the publication and registration of clinical trials in the CTIS public website that is a public register with search and download functionalities.

CTIS provides harmonised and simplified end-to-end electronic application procedures over the lifecycle of clinical trials across the EU/EEA.

Since the launch of CTIS on 31 January 2023, only 15 months remain to transition ongoing trials from the previous legislative framework of the Clinical Trials Directive (2001/20/EC) to the Clinical Trial Regulation (536/2014).

The virtual event aims to support sponsors of clinical trials in preparing and proceeding with the transition to meet the deadline of 30 January 2025. Commercial and non-commercial sponsors with experience in transitioning trials as well as representatives from EMA and EU/EEA member states will share insights and best practices.

Ample time is foreseen for Q&A. The faculty invites participants to submit related questions by 03 October 2023 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
- Insights on preparation for transitioning clinical trials from sponsors' perspective.
- Insights on member states procedures with regard to transitioning of clinical trials.
- CTIS system metrics
- Upcoming training and event opportunities

| 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 2023 | 13:30 – 17:30 CET

13:30 **WELCOME NOTE**
Noémie Manent, EMA, EU

SESSION CHAIRS : Marianne Lunzer, AGES, AT & Noémie Manent, EMA, EU

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

13:50 **Transitioning Clinical Trials - Regulatory Considerations**
Linda Abdelall, European Commission

14:10 **Transitioning Clinical Trials – Considerations From Sponsor Perspective**
Caroline Correas, Bristol Myers Squibb, CH

14:30 **Member States And Ethics Committee Experience And Insights Related To Transitioning Clinical Trials**
Elena García Méndez, Member of the Technical Secretariat of the Ethics Committee , Hospital Universitario La Paz, ES & Laura Lavin de Juan, AEMPS, ES

15:00 **Member States Best Practice Guidance For Sponsors To Transition Clinical Trials**
Monique Al, CTCG Vice-Chair, CCMO, NL

15:20 Q&A and panel discussion

15:45 **BREAK**

16:15 **Practical Insights Of Transitioning Clinical Trials From Industry Sponsor Perspective**
Scott Feiner, AbbVie

16:35 **Practical Insights Of Transitioning Clinical Trials From Academia Sponsor Perspective**
Leonard van den Berg, UMC Utrecht, NL

16:55 Q&A and panel discussion

17:20 **CTIS Key Metrics and WRAP UP**
Marianne Lunzer, AGES, AT
Noémie Manent, European Medicines Agency, EU

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