

# EMA Clinical Trials Information System (CTIS) Information Day

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

## | PROGRAMME COMMITTEE

### Peter Arlett

Head Data Analytics & Methods Task Force  
European Medicines Agency, EU

### Marianne Lunzer

CTCG Chair  
Assessor, Dept of Clinical Trials  
AGES, AT

### Noémie Manent

Principal Scientific Administrator  
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## | FACULTY

### Linda Abdelall

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### Monique Al

CTCG Vice Chair  
Head of the National Clinical Trial Office  
Central Committee on Research  
Involving Human Subjects (CCMO), NL

### Caroline Correas

Associate Director, Global Regulatory  
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Bristol Myers Squibb, CH

### Elena García Méndez

Member of the Technical Secretariat of  
the Ethics Committee  
Hospital Universitario La Paz, ES

### Scott Feiner

Clinical Records Management  
Strategic Clinical Operations  
AbbVie, US

### Laura Lavin de Juan

Head of Service in the Clinical Trials  
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Spanish Agency for Medicines and  
Medical Devices, AEMPS, ES

### Roxana Spulber

Change Management Officer  
European Medicines Agency, EU

### 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](mailto: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**