# EMA Clinical Trials Information System (CTIS) Information Day

**16 November 2022**
**13:30 - 17:30 CET | VIRTUAL Event**

## | PROGRAMME COMMITTEE

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## | FACULTY

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Eli Lilly, IRL

**Spulber Roxana**
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European Medicines Agency, EU

## | OVERVIEW

The Clinical Trials Information System (CTIS) is the single-entry point for clinical trials authorisation and supervision in the EEA. This includes a single clinical trial application dossier, covering clinical trial applications submitted to EU/EEA Member States, including submission to National Competent Authorities (NCAs) and Ethics committees (ECs) and registration of the clinical trial in a public register; all in one integrated submission. CTIS provides harmonised and simplified end-to-end electronic application procedures over the lifecycle of clinical trials across the EU/EEA.

The focus of this virtual information day 9 months after the CTIS launch is to share some practical advice regarding transitioning clinical trials from the Clinical Trials Directive (2001/20/EC) to the Clinical Trial Regulation (536/2014) as well as best practices on user management.

Furthermore, first insights on submissions and assessments of clinical trial applications and system metrics on usage of CTIS will be presented. It will also outline the importance of understanding timelines in CTIS, as will upcoming training opportunities and events.

**Ample time is foreseen for Q&A. The faculty invites participants to submit related questions by 17 October 2022 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 submission and assessment of clinical trial applications
- Timelines in CTIS
- Best practices on user management
- 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 |

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| **13:30** | **WELCOME NOTE**<br>Noémie Manent, European Medicines Agency, EU |
| | SESSION CHAIR: Laura Pioppo, European Medicines Agency, EU |
| 13:35 | **TRANSITION PERIODS FOR CLINICAL TRIALS FROM DIRECTIVE (2001/20/EC) TO REGULATION (536/2014) – REGULATORY CONSIDERATIONS AND PRACTICAL ASPECTS**<br>Maria Elgaard Sørensen, Danish Medicines Agency, DK |
| 13:55 | **INSIGHTS OF SUBMITTING APPLICATIONS IN CTIS – SPONSOR PERSPECTIVE**<br>Marianne Andersson, AstraZeneca, SE |
| 14:10 | **INSIGHTS OF SUBMITTING APPLICATIONS IN CTIS – SPONSOR PERSPECTIVE**<br>Maria Spillane, Eli Lilly, IRL |
| 14:30 | **ASSESSMENT OF CLINICAL TRIAL APPLICATIONS – FIRST INSIGHTS**<br>Outi Konttinen, Tukija, FI & Monique Al, CCMO, NL |
| 15:05 | **TIMELINES AND THEIR IMPACT IN CTIS**<br>Noémie Manent, European Medicines Agency, EU |
| **15:20** | **BREAK** |
| | SESSION CHAIR: Noémie Manent, European Medicines Agency, EU |
| **15:45** | Q&A and panel discussion |
| 16:15 | **SYSTEM METRICS ON CTIS SYSTEM USAGE**<br>Laura Pioppo, European Medicines Agency, EU |
| 16:30 | **BEST PRACTICES FOR SPONSOR USER MANAGEMENT**<br>Gabriella di Matteo, Pfizer, BE |
| 16:45 | **BEST PRACTICES FOR MEMBER STATE USER MANAGEMENT**<br>Marianne Lunzer, AGES, AT |
| 17:00 | Q&A and panel discussion |
| **17:20** | **OUTLOOK OF UPCOMING TRAINING AND EVENT OPPORTUNITIES**<br>Roxana Spulber, European Medicines Agency, EU |
| **17:25** | **WRAP UP and Closing**<br>Noémie Manent, European Medicines Agency, EU |
| **17:25** | **END OF THE INFORMATION DAY** |