Webinar for SMEs and Academia on the Clinical Trials Regulation and the Clinical Trials Information System

29 November 2021, 09:00-13:30 CET

Virtual meeting

Background and objectives

The way clinical trials are conducted in the EU will change when the Clinical Trials Regulation (Regulation (EU) No 536/2014) becomes applicable and the Clinical Trials Information System (CTIS) goes live on 31 January 2022.

The EMA is organising a webinar to remind SMEs and academic sponsors of clinical trials of the main changes brought by the Regulation and its impact on their trials-related activities.

The aim of the training is to give an overview of the Regulation and introduce the new process for submitting clinical trials information in the EU/EEA. In addition, it covers the functionalities of the Clinical Trials Information System (CTIS) as well as transparency aspects and safety reporting requirements. Guidance and training material available for sponsors are also presented.

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Introduction

08:30 – 09:00	**Joining and technicalities**	30′
09:00 – 09:10	**Welcome address and opening remarks** *Andrzej Rys (Director for health systems and products, DG SANTE, European Commission)* *Peter Arlett (EMA) and Constantinos Ziogas (EMA)*	10′

Session 1: An overview of the Clinical Trials Regulation

09:10 – 09:30	**Objectives, key changes of the Clinical Trials Regulation and transitional arrangements** *Kristof Bonnarens (DG SANTE, European Commission)*	20′
09:30 – 10:00	**Stakeholders' experience with the Clinical Trials Regulation implementation** *Stephanie Kromar (EORTC)* *Andrea Seidel-Glätzer (University Hospital Heidelberg)* *Julien Romanetto (Transgene)*	30′
10:00 – 10:10	**Q&A**	10′

Session 2: Introduction to the Clinical Trials Information System (CTIS)

10:10 – 10:25	**Access and user management, roles and permissions** *Ana Rodriguez (EMA)*	15′
10:25 – 10:40	**CTIS explained with user personas and organisation models** *Sarah Scales (EMA)*	15′
10:40 – 11:00	**High level overview of CTIS, data protection aspects (joint controllership arrangement) and publication rules** *Laura Pioppo (EMA)*	20′

11:00 – 11:10	**Q&A**	10′
11:10 – 11:20	**Coffee break**	10′

Session 3: The new process for submitting clinical trials information in the EU/EEA

11:20 – 12:15	• **Submission process of information for a clinical trial and authorisation procedure – what is changing?** – Initial clinical trials applications, including selection of the Reporting Member State – Substantial and non-substantial modifications to an application, addition of a new Member State Concerned of a clinical trial – Notifications • **Summary of clinical trials results** • **High level demonstration of CTIS functionalities for sponsors** *Maria Elgaard Sørensen (Danish Medicines Agency, CTIS Member State Product Owner)* *Ruediger Pankow (Parexel International, CTIS Sponsor Product Owner)* *Charalampos Drosos (EMA)*	55′
12:15 – 12:30	**Q&A**	15′

Session 4: Safety reporting in CTIS

12:30 – 12:45	• **Future changes to clinical trial safety reporting** • **Submission of Annual Safety Reports** • **EU Network cooperation** *Marianne Lunzer (AGES, CTIS Member State Product Owner)*	15′
12:45 – 12:55	**Q&A**	10′

Session 5: Guidance and training for SMEs and Academia

12:55 – 13:10	**Overview of guidance and training available for sponsors** *Fia Westerholm (EMA)*	15′
13:10 – 13:20	**Q&A**	10′

Conclusion

13:20 – 13:30	**Concluding remarks** *Peter Arlett (EMA)*	10′