Clinical Trial Regulation Information Day for CEE Countries

18 September 2020 | VIRTUAL EVENT

PROGRAMME ADVISOR

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PROGRAMME COMMITTEE

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Stefan Strasser - Head of Clinical Trials, Institute Surveillance AGES, Austria

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Ekaterina Borcheva-Dancheva - Assoc. Director Regulatory Affairs, PPDI, Bulgaria

Vojtech Kvita -Former Head of Clinical Trials Unit, PrimeVigilance, Czech Republic

Karol Szczukiewicz - Board member at Association for Good Clinical Practice in Poland

Piotr Iwanowski - Board Member, Polish Association for Good Clinical Practice (GCPpl) / Vice President Clinical Research Europe, Wockhardt Bio AG, Assoc., Poland

Overview

This Clinical Trial Regulation Information Day provides a forum to prepare stakeholders from Central and Eastern European Countries for the implementation and launch of the new EU Clinical Trial Regulation (536/2014) which will replace the European Clinical Trials Directive (2001/20/EC). The Information Day will focus on the differences between the present and new requirements for managing clinical trials in the face of forthcoming changes. It further aims to provide a platform for discussion about the compliance with the new Regulation and associated implementing acts in the region. You will hear from experts in the field and regulators from various Member States about their preparedness status for the new legislation and how the new rules will impact clinical trials run in the EU.

Key Objectives

- Clinical Trials Regulation objectives and why the replacement of EU Directive is needed
- Clinical Trial Regulation Overview and Latest Status
- Key changes from Directive to Regulation and associated challenges
- Procedure for Initial Authorization and Substantial Modifications Mono and Multinational CTs
- Submission of application dossier
  - o Part I common scientific documents
  - o Part II the national documents
- New Process for Clinical Trial Registration and EU CT number application
- Transition from the Directive to the Regulation
- Implementation and readiness status at the local level in Central and Easter European countries
- Competent authorities and Ethics Committees perspectives
- Update on the CT Information System (CTIS) formally “EU Portal and Database”
- Clinical Trials Regulation related guidelines

Who Should Attend

- Regulatory agencies: assessors, reviewers, inspectors
- The pharmaceutical industry and contract research organisations, including:
  - o Regulatory affairs personnel in clinical research
  - o Professionals in charge of clinical trial strategy
  - o Regulatory intelligence and policy professionals
  - o Change managers for clinical trials business processes
  - o Clinical research professionals working with submission, data, information sharing
  - o Clinical safety professionals

Please check our website on how to register online!

AGENDA - TIMING IN CEST

08:30 LOG IN TO THE VIRTUAL CONFERENCE

09:00 WELCOME AND KEYNOTE

Radoslaw Sierpinski, Acting President, Medical Research Agency, Poland

09:30 SESSION 1

CLINICAL TRIALS REGULATION OVERVIEW, OBJECTIVES AND WHY THE REPLACEMENT OF EU DIRECTIVE IS NEEDED

Session chair:
Steffen Thirstrup, Director, NDA Regulatory Advisory Board, NDA Advisory Services Ltd, UK

Key Changes from Directive to Regulation and Associated Challenges
Massimiliano Sarra, CTFG Secretary, Italian Medicine Agency (AIFA), Italy
- Transition from the Directive to the Regulation
- Overview of the Changes
- Safety

10:30 COFFEE BREAK

11:00 SESSION 2

PROCEDURE FOR INITIAL AUTHORIZATION AND SUBSTANTIAL MODIFICATIONS

Session chair:
Massimiliano Sarra, CTFG Secretary, Italian Medicine Agency (AIFA), Italy

Submission of application dossier
- Part I common scientific documents
- Part II the national documents

Stefan Strasser, Head of Clinical Trials, Institute Surveillance, AGES, Austria

11:45 SESSION 3

INDUSTRY PREPAREDNESS AND VIEW: PANEL DISCUSSION

Session chair:
Mihaela David, Director Regulatory Affairs, PSI CRO AG, Romania

Panel Discussion:

Czech Republic
Vojtech Kvita, Former Head of Clinical Trials Unit PrimeVigilance, Czech Republic

Poland
Karol Szczukiewicz, Board member at Association for Good Clinical Practice in Poland, Head of Training Section; Clinical Trial Manager at DOCS International / Janssen-Cilag (a company of Johnson & Johnson), Poland

Bulgaria
Ekaterina Borcheva-Dancheva, Assoc. Director Regulatory Affairs, PPDI, Bulgaria

Romania
Mihaela David, Director Regulatory Affairs, PSI CRO AG, Romania

13:00 LUNCH BREAK

14:00 SESSION 4

IMPLEMENTATION AND READINESS STATUS AT THE LOCAL LEVEL MEMBER STATES AND ETHIC COMMITTEES

Session Chair:
Stefan Strasser, Head of Clinical Trials, Institute Surveillance AGES, Austria

Status of Implementation in European Member States from CTFG Point of View
Massimiliano Sarra, CTFG Secretary, Italian Medicine Agency (AIFA), Italy

Panel Discussion Focusing on Challenges and Solutions with Competent Authorities and Ethic Committees from:

Poland
Ewa Ołdak, Director, Department for Clinical Trial of Medicinal Products, The Office for Medicinal Product, Medical Devices and Biocidal Products, Poland
Eunika Ksiazkiewicz, Legal specialist for scientific projects, Medical Reasearch Agency, Poland
Piotr Iwanowski, Board Member, Polish Association for Good Clinical Practice (GCPpl) / Vice President Clinical Research Europe, Wockhardt Bio AG, Assoc., Poland

Austria
Stefan Strasser, Head of Clinical Trials, Institute Surveillance, AGES, Austria

Romania
Mirela Vita, Head of Clinical Trial Department, National Agency for Medicines and Medical Devices, Romania

Slovakia
Katarina Kovacova, Clinical Trial Expert Consultant, Ministry of Health, Institute for Research and Development/BioHub, Slovakia

15:45 COFFEE BREAK

16:15 SESSION 5

OVERVIEW AND UPDATE ON THE CLINICAL TRIAL INFORMATION SYSTEM (CTIS)

OVERVIEW OF EU REGULATION RELATED GUIDELINES

Session Chair:
Mihaela David, Director Regulatory Affairs, PSI CRO AG, Romania

Overview and Update on the CTIS
Fia Westerholm, Programme Assurance Manager, Clinical Trials Information System (CTIS) Programme, European Medicines Agency, The Netherlands

Overview of EU Regulation Related Guidelines
Steffen Thirstrup, Director, NDA Regulatory Advisory Board, NDA Advisory Services Ltd, UK

17:30 SPEED NETWORKING

Further your engagement by meeting your peers in a quick and easy format designed for fun and speed! Click here to Register

18:30 END OF THE INFORMATION DAY

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