DIA

Clinical Trial Regulation Information Day for CEE Countries

22 October 2019 | Novotel | Bucharest, Romania

PROGRAMME ADVISOR

Elke Stahl
CTFG Co-Chair; Clinical Trial Unit Federal Institute for Drugs and Medical Devices (BfArM), Germany

PROGRAMME COMMITTEE

Mihaela David
Director Regulatory Affairs, PSI CRO AG, Romania
Vojtech Kvita
Associate Director, Pharmacovigilance Head of Clinical Trials Unit PrimeVigilance, Czech Republic
Massimiliano Sarra
CTFG Secretary Italian Medicine Agency (AIFA), Italy
Steffen Thirstrup
Director, NDA Regulatory Advisory Board NDA Advisory Services Ltd, UK
Vladimir Vujovic
Deputy Country Manager Serbia & Regulatory and Safety Manager Optimapharm, Serbia

FACULTY

Ekaterina Borcheva-Dancheva
Assoc. Director Regulatory Affairs, PPDI, Bulgaria
Boyan Dognev
VP, Bulgarian Central Ethics Committee, Bulgaria
Doina Draganescu
Vice-President/Co-chair, Romanian Central Ethics Committee, Romania
Costin Radu Ganescu
Vice President, European Patients Forum (EPF), Romania
Katarina Kovacova
Former Head of clinical trial department, State Institute for Drug Control, Slovakia
Camelia Mihaescu
Scientific Administrator Clinical and Non-Clinical Compliance Committees and Inspections European Medicines Agency, The Netherlands
Wojciech Pilecki
Head Regulatory Affairs, PSI CRO, Poland
Catalina Sarbu
Director Clinical Operations, PAREXEL International Romania Head of the CRO Association in Romania (ASSCRC), Romania
Daniela Stanciu
Regulatory Affairs, Amgen (former Romanian CA's Clinical Trial Department coordinator), Romania
Stefan Strasser
Head of Clinical Trials, Institute Surveillance AGES, Austria

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

DETAILS OF THE INFORMATION DAY

Location:
Novotel Bucharest City Centre
Calea Victoriei 37B Sector 1
Bucharest, Romania 010061

AGENDA

08:00 REGISTRATION

08:15 WELCOME NOTE

Elena Popa, Scientific Programmes Manager, Drug Information Association, Switzerland
Catalina Sarbu, Director Clinical Operations, PAREXEL International Romania Head of the CRO Association in Romania (ASSCRC), Romania

08:45 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

09:30 SESSION 2

INDUSTRY PREPAREDNESS AND VIEW: PANEL DISCUSSION

Session chair:
Catalina Sarbu, Director Clinical Operations, PAREXEL International Romania Head of the CRO Association in Romania (ASSCRC), Romania

Panel Discussion Discussants:

Czech Republic
Vojtech Kvita, Associate Director, Pharmacovigilance Head of Clinical Trials Unit PrimeVigilance, Czech Republic

Poland
Wojciech Pilecki, Head Regulatory Affairs, PSI CRO, Poland

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

Romania
Daniela Stanciu, MD, Regulatory Affairs, Amgen (former Romanian CA's Clinical Trial Department coordinator), Romania

10:30 COFFEE BREAK

11:00 SESSION 3

PROCEDURE FOR INITIAL AUTHORIZATION AND SUBSTANTIAL MODIFICATIONS

Session chair:
Vladimir Vujovic, Deputy Country Manager Serbia & Regulatory and Safety Manager Optimapharm, Serbia

Submission of application dossier

- Part I common scientific documents
- Part II the national documents

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

Reference Safety Information (RSI)
Massimiliano Sarra, CTFG Secretary Italian Medicine Agency (AIFA), Italy

Risk-Based Monitoring - Shaping a New Paradigm
Camelia Mihaescu, Scientific Administrator Clinical and Non-Clinical Compliance Committees and Inspections, European Medicines Agency

12:30 LUNCH

13:30 SESSION 4

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

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

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

Panel Discussion Discussants:

Romania
Anca Budulac, Investigator, National Institute of Infectious Diseases - Prof. Dr. Matei Balș
(on behalf of: Prof. Dr. Adrian Streinu Cercel)
Doina Draganescu, Vice-President/Co-chair, Romanian Central EC
Costin Radu Ganescu, Vice President, European Patients Forum (EPF)
Laurentiu Micu, Investigator, Clinical Institute Fundeni
Vlad Mixich, Board Member of the EU Public Health Alliance, Former VP of Romanian Medicine Agency

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

Bulgaria
Boyan Dognev, VP, Bulgarian Central Ethics Committee

Slovakia
Katarina Kovacova, Former Head of clinical trial department, State Institute for Drug Control Slovakia

14:30 COFFEE BREAK

15:00 SESSION 5

OVERVIEW AND UPDATE ON THE CLINICAL TRIAL INFORMATION SYSTEM (CTIS) FORMALLY "EU PORTAL AND DATABASE"

OVERVIEW OF EU REGULATION RELATED GUIDELINES

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

Overview and Update on the Clinical Trial Information System
Camelia Mihaescu, Scientific Administrator Clinical and Non-Clinical Compliance Committees and Inspections, European Medicines Agency (EMA), The Netherlands

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

17:15 NETWORKING RECEPTION

19:00 END OF THE INFORMATION DAY