DIA

Clinical Trial Regulation Information Day for CEE Countries

31 March 2020 | Novotel | Warsaw, Poland

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

CTFG
Member Invited

Steffen Thirstrup
Director, NDA Regulatory Advisory Board NDA Advisory Services Ltd, UK

FACULTY

Medical Research Agency, Poland - Representative Invited

The Office for Medicinal Product, Medical Devices and Biocidal Products, Poland - Representative Invited

Katarina Kovacova - Former Head of Clinical Trial Department, State Institute for Drug Control, Slovakia

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

SUKL, Czech Republic - Representative Invited

European Medicines Agency - Speaker Invited

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

Karol Szczukiewicz, GCP Association, Poland

Additional Faculty Members from EC and Patient Representatives Invited

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

Location

Novotel Center, Warsaw
Marszałkowska 94
00-510 Poland

AGENDA

08:30 REGISTRATION

09:00 WELCOME AND KEYNOTE

DIA and Representative of Polish Agency

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
CTFG representative Invited

- 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: TBC

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 Discussants:

Czech Republic
Representative Invited

Poland
Karol Szczukiewicz, GCP Association, Poland

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

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

13:15 LUNCH

14:15 SESSION 4

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

Session Chair: TBC

Status of Implementation in European Member States from CTFG Point of View
CTFG Representative Invited

Panel Discussion Focus on Challenges and Solutions with Invited Discussants Competent Authorities and Ethic Committees from:

Poland
Representative Invited

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

Czech Republic
Representative Invited

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

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

17:30 NETWORKING RECEPTION

18:30 END OF THE INFORMATION DAY

| Disclosure Policy

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The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

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