DIA

Clinical Trial Regulation Information Day for CEE Countries

22 October 2019 | Novotel | Bucharest, Romania

PROGRAMME ADVISOR

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

PROGRAMME COMMITTEE

Mihaela David
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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

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

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

DETAILS OF THE INFORMATION DAY

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

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

AGENDA

08:00 REGISTRATION

08:15 WELCOME NOTE

08:30 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

09:30 SESSION 2

INDUSTRY PREPAREDNESS AND VIEW: PANEL DISCUSSION

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

Discussants:

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

Estonia, Lithuania, Latvia
Päivi Itkonen, Managing Director, Crown CRO Oy

Hungary
Speaker Invited

Bulgaria, Croatia
Speaker Invited

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

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

New Process for Clinical Trial Registration and EU Clinical Trial Number Application
European Medicines Agency Speaker Invited

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 Focus on Challenges and Solutions

| Disclosure Policy

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

Invited Discussants for the Panel Discussion from:

- Romania
- Slovenia
- Bulgaria
- Hungary
- Czech and Slovakia
- Poland

14:30 COFFEE BREAK

15:00 SESSION 5

UPDATE ON THE CT INFORMATION SYSTEM (CTIS) FORMALLY "EU PORTAL AND DATABASE"

OVERVIEW OF EU REGULATION RELATED GUIDELINES

Session Chair:
Mihaela David, Head Regulatory & Matrix Services PSI Pharma Support Romania SRL, Romania

Update on the CT Information System
European Medicines Agency Speaker Invited

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

16:30 WRAP UP AND NEXT STEPS

17:00 END OF THE INFORMATION DAY

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

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.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.

REGISTRATION FORM

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E-MAIL YOUR COMPLETED REGISTRATION FORM TO BUSINESS TRAVEL

Alexandru Popescu – alexandru.popescu@businesstravel.ro or Razvan Toma – Razvan.toma@businesstravel.ro

Registration fees*	Fees
Industry	500.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	180.00 EUR ❑

*Registration fee includes: refreshments, lunch, online access to event presentations as well as online access to certificate of attendance. All fees are subject to the applicable Romanian VAT.

Payment is due 7 days after registration and must be paid in full by commencement of the event.

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Please complete in block capital letters or attach the attendee's business card here.

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The Business Travel Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 18:00 CET.
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