Clinical Trial Regulation Workshop

Organised adjunct to the Clinical Trial Disclosure & Data Transparency Workshop

6-7 December 2016
Amba Hotel Marble Arch, London, United Kingdom

PROGRAMME CHAIR

Nick Sykes
Senior Director, Worldwide Safety & Regulatory, Pfizer Inc., UK

PROGRAMME COMMITTEE

Surendra Gokhale
Head of Clinical Trial Regulatory Management, F. Hoffmann-La Roche Ltd, Switzerland

Elke Stahl
Clinical Trial Unit, BfArM, Germany

OVERVIEW

While publication of the Clinical Trial Database is delayed, the endorsement of the Clinical Trial Regulation is moving forward in other areas. The Clinical Trials Forum will focus on the differences between, the present and new requirements on managing clinical trials in the face of forthcoming changes.

This 2-day workshop will provide a forum for **information exchange** on both **conceptual** and **practical** questions of:

- How will the new legislation change the **processes and the format of the trial application**?
- What are the impacts on how a clinical trial is managed after approval has been granted?
- What are the **critical issues affecting sponsors and Member States** as they consider changes needed to implement the regulation?
- How will the new provisions for public access to an EU Clinical Trials Database enforce disclosure of clinical trial data and information?

Attendees will participate in the collaborative discussions through lectures, panel discussions and interactive sessions.

KEY TOPICS

- Learnings from the first pilots under the new Regulation
- Member States preparedness for the regulation, including plans for co-operation between agencies and ethics committees and coordinated assessment
- Considerations for the preparation of applications and notifications by sponsors
- Development of the EU clinical trials portal and database
- Impact of new requirements for disclosure and transparency of data from clinical trials

OBJECTIVES

- Understand the new requirements along with the practical and operational considerations for implementation by authorities and clinical trial sponsors
- Identify the key challenges and opportunities of the new requirements and policies
- Leverage insights on how companies and research institutions are fine-tuning and optimising processes to meet the requirements of the Clinical Trials Regulation
- Exchange views between regulators, clinical trial sponsors, patients, and other stakeholders

This programme is in development. For more information contact: Inka Heikkinen at Inka.Heikkinen@DIAGlobal.org

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REGISTRATION FORM

Clinical Trial Regulation Workshop | ID#16111
6-7 December 2016 | Amba Hotel Marble Arch, London, United Kingdom

DIA DEVELOP INNOVATE ADVANCE

Early-bird discount available for members: Register by 25 October 2016

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.
Early-bird fee applies to industry members only. **€ 1'230.00** ❑

CATEGORY (AFTER 25 OCTOBER 2016)	Member *	Non-Member*
Industry	€ 1'430.00 ❑	€ 1'585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 715.00 ❑	€ 870.00 ❑
Upgrade and **add a third day** of the adjacent **"Clinical Trial Disclosure & Data Transparency" Workshop** for a special fee:		
Industry	€ 585.00 ❑	
Government/Charitable/Non-profit/Academia (Full-Time)	€ 293.00 ❑	

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Exhibition hall only passes available. Please contact DIA EMEA for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

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Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00
Academia/Charitable/Government /Non-profit (Member/Non-member) = € 100.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

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Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and

The DIA Europe, Middle East & Africa Contact Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

Email emea@DIAglobal.org
Tel. +41 61 225 51 51
Fax +41 61 225 51 52
Web www.DIAglobal.org
Mail DIA EMEA, Kuechengasse 16, 4051 Basel, Switzerland