DIA

Workshop for Excellence in Clinical Development

24-25 October 2017 | Jeddah, Saudi Arabia

PROGRAMME COMMITTEE

Holger G Adelmann
Senior VP and Managing Director, DIA EMEA, Switzerland

Betul Erdogan
Clinical Research Director, GCTO Turkey, Middle East and Egypt, MSD Ilaclari, Turkey

Päivi Itkonen
Managing Director, Crown CRO Oy, Finland

Anoud R. Omer
Chief Medical Writer, KAU Med, Saudi Arabia

OVERVIEW

This workshop will introduce the modern key concepts for preparing and running state-of-the-art clinical trials in humans. A significant part is dedicated to understand the assessment criteria used by Pharma for making partnering decisions and on strategies to increase the attractiveness of clinical trial sites for sponsors. The workshop style will allow in-depth discussions with the expert instructors.

KEY TOPICS

- Get knowledge about the mandatory regional and international guidelines and pre-requisites for clinical investigations in humans.
- Learn the principles of adverse event reporting and the assessment of possible treatment relationship.
- Learn how to interpret and apply modern concepts to govern safe human dose selection and dose escalation via concepts such as MTD (maximum tolerated dose) and MABEL (minimum anticipated biological effect level).
- Choose appropriate endpoints according to the trial purpose.
- Key concepts for data capture, data handling, data interpretation and reporting.
- Understand how Pharma companies assess and select their preferred providers.

OBJECTIVES

This workshop will put you in a position to prepare and run clinical investigations in humans to the highest international standards. You will understand how to attract and build strong business relations with sponsors.

WHO SHOULD ATTEND?

Clinical trial professionals such as medial doctors / investigators, study nurses, clinical research assistants, data managers, clinical project managers, quality leads, clinical trial site managers, clinical supply professionals, clinical pharmacists.

LEARN MORE

Visit **www.DIAglobal.org**
or contact **EMEA@DIAglobal.org** with questions.

Workshop for Excellence in Clinical Development

DAY ONE I TUESDAY, 24 OCT

08:30 REGISTRATION AND WELCOME COFFEE

09:30 SESSION 1

INTERNATIONAL GUIDELINES FOR CLINICAL OPERATIONS & TRIALS IN HUMANS

Moderator: **Päivi Itkonen**, Managing Director, Crown CRO Oy, Finland

- ICH
- Declaration of Helsinki / human research ethics
- Regional guidelines

Speakers:

Medical Products Agency, Sweden, Representative Invited
Hamdi Akan, Professor, Ankara University; Chair of Clinical Research Association, Turkey
Ola Ghaleb Al Ahdab, Pharmaceutical Advisor & CPD-Pharma Program Manager, Drug Department, Public Health Policy & Licensing, Ministry of Health & Prevention, United Arab Emirates
Saudi Food and Drug Authority (SFDA), Representative Invited

11:00 COFFEE BREAK

11:30 SESSION 2

TRIAL DESIGN AND ENDPOINTS

Moderator: **Holger Adelmann**, Senior VP and Managing Director, DIA EMEA, Switzerland

- Right endpoints for different purposes (safety, pharmacodynamics / biomarker, efficacy)
- Volunteer / patient selection & recruitment
- Regional practices
- International practices

Speakers:

Hamdi Akan, Professor, Ankara University; Chair of Clinical Research Association, Turkey
Mutlu Hayran, Professor, Hacettepe University, Cancer Institute, Head of Department of Preventive Oncology, Turkey
Walaaeldin Ahmed, Executive Manager, KAU Med, Saudi Arabia
Holger G Adelmann, Senior VP and Managing Director, DIA EMEA, Switzerland

13:00 LUNCH

14:30 SESSION 3

CLINICAL PROJECT MANAGEMENT & TRIAL CONDUCTION

Moderator: **Päivi Itkonen**, Managing Director, Crown CRO Oy, Finland

- Solutions and best practices
- MABEL and MTD concepts, study termination criteria

Clinical Project Management
Yasser El-Shafei, Clinical Research Manager, Middle East, MSD, Saudi Arabia

Clinical Studies - Saudi Arabia

MABEL and MTD Concepts
Medical Products Agency, Sweden, Representative Invited

16:00 COFFEE BREAK

16:30 SESSION 4

DISCUSSION ON HOT TOPICS WITH ALL ATTENDEES

Moderator: **Holger G Adelmann,** Senior VP and Managing Director, DIA EMEA, Switzerland

17:30 NETWORKING RECEPTION

18:30 END OF DAY 1

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 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

DAY TWO | WEDNESDAY, 25 OCT

08:00 REGISTRATION AND WELCOME COFFEE

09:00 SESSION 5

DATA COLLECTION, DATA MANAGEMENT AND ELECTRONIC DOCUMENT MANAGEMENT

Moderator: **Päivi Itkonen**, Managing Director, Crown CRO Oy, Finland

- Data sources, handling and interpretation of data
- Regional recommendations
- International practices

Speakers:

Alain Zogheib, President, Middle East Clinical Research Association, Lebanon

Academia Representative Invited

10:30 COFFEE BREAK

11:00 SESSION 6

SAFETY AND PHARMACOVIGILANCE

Moderator: **Hamdi Akan**, Professor, Ankara University; Chair of Clinical Research Association, Turkey

- Adverse Event definition & reporting
- Criteria for assessment of treatment relationship

Speakers:

Semra Sardas, Head of the Toxicology Department and Pharmacogenetics and Drug Safety Unit, Marmara University, Turkey

Saudi Food & Drug Authority (SFDA) Representative Invited

12:30 LUNCH

14:00 SESSION 7

PARTNERING WITH THE PHARMA INDUSTRY

Moderator: **Holger Adelmann**, Senior Vice President and Managing Director, DIA Europe, Middle East and Africa

- Assessment criteria used by Pharma
- Strategies to increase attractiveness for sponsors

Speakers:

Betul Erdogan, Clinical Research Director, GCTO Turkey, Middle East and Egypt, MSD Ilaclari, Turkey

Mosaad Morsi, Chairman & CEO, Ray Contract Research Organization, Egypt

15:30 END OF CONFERENCE

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact Zsofia.Molnar@DIAglobal.org for a custom group rate.

NOT TO MISS: COMING UP IN YOUR REGION

Middle East Regulatory Conference (MERC)

21-22 November 2017 | Kuwait City, Kuwait | 17102

This is the 12th DIA Middle East Regulatory Conference (MERC) in partnership with the Middle East Regulatory Network (MERN). The conference will bring together most authorities from the Middle East region and discuss the hot topics in the region, such as serialisation and life cycle management. Recent developments at country-level are also discussed. This conference is one of its kind and takes place on biennially. It has grown rapidly over the past years and early registration is recommended.

http://www.DIAglobal.org/MERC

REGISTRATION FORM | ID# 17121

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Early-bird discount and Advance rate

To qualify for the discount, registration form and accompanying payment must be received by the dates below. Early-bird/Advance rate applies to industry members only.

Early bird discount: register by 1 August 2017 **€ 1'230.00** ❑

Advance rate: register by 12 September 2017 **€ 1'330.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'430.00 ❑	€ 1'585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 715.00 ❑	€ 870.00 ❑

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. Please contact DIA EMEA for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

*All fees are subject to the applicable VAT. 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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Attendee email required to access presentations

Please provide your European VAT number

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID#17121 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here.**

Date	Signature

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.DIAglobal.org and click on Membership for more details.

DIA offers one year complimentary membership against event registration at non-member rate

❑ **I do not want complimentary membership**

TERMS AND CONDITIONS

Cancellations

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (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

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA EMEA office of any such substitutions as soon as possible.

Photography and Video 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 all rights including but not limited to compensation or ownership.

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.

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