

Joint DIA/IFAPP Pharmaceutical Policy Forum

(including 11th IFAPP European Conference)

Event #10102

February 4-5, 2010

Hotel Hilton London Canary Wharf, London, UK



Programme Chairperson

Norbert Clemens

Head Clinical Development, CRS Clinical Research Services Mannheim GmbH, Germany, representing DIA and IFAPP

Programme Committee

Domenico Criscuolo

Chief Executive Officer, Genovax, Italy, representing IFAPP

Brenton James

Strategic Consultant Regulatory Affairs in the European Union, London

Truus Janse-de Hoog

Staff member MEB, Chair CMD(h)
Medicines Evaluation Board, The Netherlands

Peter Schulz

Vice President Global Safety, ii4sm, Switzerland

Detlef Niese

Head, Development External Affairs, Novartis Pharma AG, Switzerland

BENEFIT FROM PRACTICAL INDUSTRY CASE STUDIES!

Programme Overview

This Forum will highlight current and upcoming global pharmaceutical development hot topics from various viewpoints. Experts from Regulatory Authorities, Industry and Contract Research Organisations will present and discuss emerging issues. This Forum offers an excellent networking opportunity.

Topics Will Include

- Transparency - EMEA transparency policy
- Future of Clinical Trial Legislation (Drugs and Devices)
- Intersection between pharmaceutical/device industry and healthcare
- Fraud and misconduct
- Globalisation - co-operation FDA and EMEA
- Standardisation of investigational site qualification

Learning Objectives

At the end of this conference participants should be able to:

- Anticipate upcoming modifications of legislation
- Identify pre-cursors of fraud and misconduct
- Optimise investigational site selection
- Familiarise with EMEA and FDA working environments

Who Should Attend

Professionals working in the following areas:

- Clinical Development
- Regulatory Affairs
- Quality Assurance
- Project Management
- Legal Departments

IFAPP - INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS

The Federation is a non-profit organisation and has existed since 1975. The aim of IFAPP is to act as an international forum for all the organisations of Pharmaceutical Physicians world-wide by dealing with matters suggested by its 30 National Member Associations, representing more than 8000 pharmaceutical professionals. IFAPP fosters the development and international recognition of Pharmaceutical Medicine as a medical specialty and the development of training and continuing education programmes in pharmaceutical medicine. It stimulates a closer relationship between the Member Associations and an improved understanding between the Associations and the medical and allied professionals, regulatory authorities and health care providers. Every two years a National Member Association organises the International Conference on Pharmaceutical Medicine (ICPM).

About the Drug Information Association (DIA)

DIA serves more than 30,000 biopharmaceutical professionals from industry, academia and regulatory agencies worldwide. Through its domestic and international meetings, training courses, workshops and webinars, DIA provides a neutral global forum for the exchange of information critical to the advancement of the drug discovery and lifecycle management processes.

Headquartered in Horsham, PA, USA, and with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China, the Association is led by its volunteer-based Board of Directors and executive management team. For more information, visit www.diahome.org or call DIA in Europe +41 61 225 51 51.

Conference starts at 09:00 on February 4th
and ends at 17:00 on February 5th



THURSDAY | FEBRUARY 4, 2010

08:00 Conference Registration and Welcome Coffee**09:00 Session 1****TRANSPARENCY**

Session Co-Chairs:

Truus Janse-de Hoog, Staff member MEB, Chair CMD(h), Medicines Evaluation Board, The Netherlands

Arielle North, Scientific Administrator, Directorate, EMEA, EU

The European Medicines Agency (EMA) released for public consultation their draft Transparency policy that sets out how the Agency intends to increase transparency and openness in all areas of its operation.

In this session the objectives of the EMA Transparency policy will be explained. Strengthening of the interaction with stakeholders is one of the objectives of the EMA. Different stakeholders: a healthcare representative and industry representative will give their views on the proposals for more transparency. The EMA and Heads of National Agencies work together in the European Network in order to achieve a common approach on Transparency issues. As an example of this common approach the handling of requests for safety information will be discussed.

Transparency Policy of EMA

Valentina Stamouli, Scientific Administrator, EMA, EU

What Do Doctors Want to Know?

Speaker invited

A Company's View

Speaker invited

Handling of Requests for Safety Information

Truus Janse-de Hoog, Staff member MEB, Chair CMD(h), Medicines Evaluation Board, The Netherlands

Arielle North, Scientific Administrator, Directorate, EMA, EU

Panel discussion with session speakers and Fergus Sweeney, Head of Sector, Inspections, EMA, EU

11:00 Coffee Break**11:30 Session 2 - Part 1****FUTURE OF CLINICAL TRIAL LEGISLATION**

Session Chairperson:

Domenico Criscuolo, Chief Executive Officer, Genovax, Italy

The European Directive on Clinical Trials was a remarkable effort to standardise and harmonise all the procedures to activate clinical trials in the European Union. Since its publication however the EU expanded, reaching the present number of 27 Member States: in addition some weaknesses were identified, which need to be addressed in order to safeguard the EU role in the clinical development of new drugs. This session will address these issues and will provide an up-to-date state of the art.

Clinical Trial Directive - Progress

Hartmut Krafft, Head, Section Clinical Trials, Paul Ehrlich Institute, Germany

Clinical Trials in the EU - Better Quality Standards

Fergus Sweeney, Head of Sector, Inspections, EMA

12:30 Lunch Break**14:00 Session 2 - Part 2****Italian Law on the Minimal Requirements for CRO Personnel - a case study**

Speaker invited

The European Directive on Clinical Trials was a remarkable effort to standardise and harmonise procedures to conduct clinical trials in the European Union (EU). Since it came into effect however, the EU has expanded, reaching the present number of 27 Member States. In addition, some weaknesses were identified which needs to be addressed in order to safeguard the EU's role in the clinical development of new drugs. This session will address these issues and provide an update on the subject.

Panel discussion with session speakers

15:00 Coffee Break**15:30 Session 3****INTERSECTION BETWEEN PHARMACEUTICAL/DEVICE INDUSTRY AND HEALTHCARE**

Session Chairperson:

Peter Schulz, Vice President Global Safety, ii4sm, Switzerland

The scientific, economic, regulatory and reimbursement framework of the pharmaceutical industry is changing very rapidly, leading to the development of more specialised medicines in smaller populations, ultimately paving the way to personalised medicine. The associated development strategies need to take this change into account and drive a much closer collaboration between the pharmaceutical industry and the healthcare sector. This session evaluates the opportunities of this collaboration, the recent progress in the standards community and technologies that support the collaboration and looks at a case study of clinical development in the healthcare environment.

Clinical Development in a Healthcare Setting

Judith Kramer, Executive Director, The Clinical Trials Transformation Initiative (CTTI), USA

Enabling Technology and Standards

Charles Mead, Chief Technology Officer, National Cancer Institute (NCI), France

Case Study of Clinical Development in the UK NHS

Louise Woods, Head of Innovation & Industry R&D Relations, Department of Health, UK

Economic and Reimbursement Drivers for Pharma/Healthcare Collaboration

Rob Thwaites, Senior Executive Director - Europe, United BioSource Corporation, UK

Panel discussion with session speakers

17:30 Reception

The Drug Information Association (DIA) has been approved as an 'Authorized Provider' by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102.

DIA is authorised by IACET to offer **1.2 CEUs** for this programme.

If you would like to receive a statement of credit, you must attend the programme, return your evaluation form and complete the online credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request.

Disclosure Policy

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

FRIDAY | FEBRUARY 5, 2010

08:30 Welcome Coffee**09:00 Session 4****FRAUD AND MISCONDUCT**

Session Chairperson:

Jane Barrett, The Barrett Consultancy, UK

This session is currently in development

Please visit www.diahome.org > click on Conferences / Meetings > Find a Meeting > enter Keyword: 10102**11:00 Coffee Break****11:30 Session 5 - Part 1****GLOBALISATION**

Session Chairperson:

Brenton James, Strategic Consultant Regulatory Affairs in the European Union, London

The Confidentiality Agreement between the European Commission, European Medicines Agency and the US FDA is of major interest to stakeholders, and its current status will be discussed.

GMP inspections of Active Pharmaceutical Ingredients are taking place as part of a pilot project between EU, the TGA of Australia and the USA FDA. The Global Pharmaceutical Industry is conducting more and more clinical studies in the developing world and GCP Inspections for applications for Marketing Authorisations in the Centralised Procedure have increased. These topics will be presented and discussed in this session.

12:30 Lunch Break**13:30 Session 5 - Part 2****GLOBALISATION**

Session Chairperson:

Brenton James, Strategic Consultant Regulatory Affairs in the European Union, London

This session is currently in development

Please visit www.diahome.org > click on Conferences / Meetings > Find a Meeting > enter Keyword: 10102**14:30 Coffee Break****15:00 Session 6****STANDARDISATION OF INVESTIGATIONAL SITE QUALIFICATION**

Session Chairperson:

Norbert Clemens, Head Clinical Development, CRS Clinical Research Services Mannheim GmbH, Germany

Investigational Site Qualification in view of the EU Clinical Trial Directive is mainly focussed on investigator qualifications. Investigators should be able to critically evaluate study proposals, to conduct studies according to Good Clinical Practice (GCP), and to conclude and report valid data as rapid and safe as possible. The way to achieve this is through education and training, but on a global scale harmonisation is not yet completed. This session will present established trainings and will provide an investigator perspective.

APPI Qualification/Certification Trainings for Investigators

Greg Koski, The Academy of Pharmaceutical Physicians and Investigators (APPI) Past President, Partners, USA

eCLIN Qualification/Certification Trainings for Investigators

Jean-Paul Deslypere, CEPM chair IFAPP, SGS Testing & Control Services Singapore Pte. Ltd., Singapore

Investigator Perspective - Case Study

Bettina Bergtholdt, emovis GmbH, Germany

Panel discussion with session speakers

17:00 End of Conference

Hotel Information

The DIA has blocked a number of rooms at the:

Hilton London Canary Wharf Hotel

South Quay Marsh Wall

London E14 9SH

United Kingdom

www.hilton.co.uk/canarywharf

Tel: +44 (20) 3002 2300

Fax: +44 (20) 3002 2350

at the special rate of:

£159.00 per single standard room inclusive of English Breakfast, excluding VAT

Travel to the Hilton London Canary Wharf hotel, 15 minutes by taxi from London City Airport in the bustling commercial district. The hotel is within easy reach of Greenwich and the West End, on London's river taxi network. The nearest underground station is Canary Wharf on the Jubilee line or South Quay station on the Docklands Light Railway.

Please make your reservation online at:<http://www.hilton.com/en/hi/groups/personalized/LONCWHI-ADIA-20100201/index.jhtml>**Important:**

Please complete your reservations by January 5, 2010. A credit card is required to guarantee your reservation.

Cancellation Policy:**Free cancellation can be made up to 16.00 PM (UK time) on the day of arrival. The full accommodation will be charged when cancellations are received after this deadline or in case of no show.**

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 Drug Information Association.

Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

REGISTRATION FORM

Joint DIA/IFAPP Pharmaceutical Policy Forum (including 11th IFAPP European Conference)

February 4-5, 2010 - Hotel Hilton London Canary Wharf, London, UK

ID# 10102



If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Early-Bird rates available for Members: Deadline on or before December 23, 2009

Join DIA now to qualify for the early-bird member fee! To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. **Does not apply to government/academia/non-profit members**

Early-Bird Fee (on or before December 23, 2009)	FEE
Join DIA now to qualify for the Early-Bird Rate	€ 115.00 <input type="checkbox"/>
Early-Bird Industry (DIA and IFAPP)	€ 1'000.00 <input type="checkbox"/>

Category	Member Fee (after December 23, 2009) FEE	Category	Non-Member Fee FEE
Industry	€ 1'200.00 <input type="checkbox"/>	Industry	€ 1'315.00 <input type="checkbox"/>
Charitable/Non-profit/Academia (Full-Time)	€ 900.00 <input type="checkbox"/>	Charitable/Non-profit/Academia (Full-Time)	€ 1'015.00 <input type="checkbox"/>
Government (Full-Time)	€ 600.00 <input type="checkbox"/>	Government (Full-Time)	€ 715.00 <input type="checkbox"/>

In case you are member of one of the national member associations of IFAPP please tick the box. In that case you will pay the reduced DIA member fee

A one-year membership to DIA is available to those paying a non-member registration. If paying a non-member fee, please indicate if you do, or do not wish to become a member: YES___ NO___

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the event

STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT DIA FOR MORE INFORMATION.

[10102DIAWEB](#)

REGISTRANT

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

Prof. Dr. Ms. Mr.

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

Please indicate your professional category: Academia Government
 Industry Contract Service Organisation

PAYMENT METHODS - Credit cards are our preferred payment method.

Please charge my credit card - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

VISA MC AMEX

Card Number

Exp. Date

Cardholder's Name

Date Cardholder's Signature

Cheques should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:

D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

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." including your name, company, Meeting ID# 10102 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.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

All cancellations must be in writing and received at the DIA office by 17:00 CET on January 27, 2010

Cancellations received by the date above are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/non-member) = € 200.00 Government/Academia/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Transfer Policy

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

IMPORTANT: Hotel and travel reservations should be made **ONLY** after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org

Fax +41 61 225 51 52

Email diaeurope@diaeurope.org

Mail DIA European Office
Postfach, 4002 Basel, Switzerland