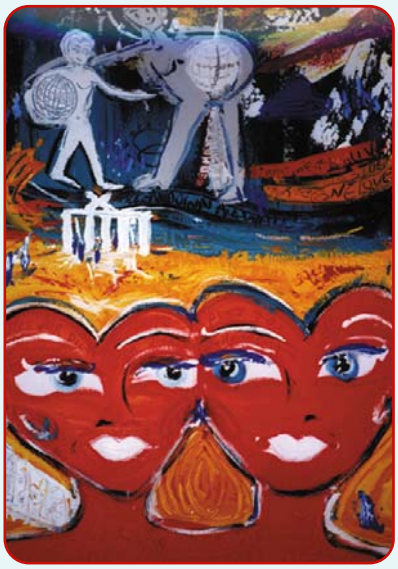
EuroMeeting 2009 Cover Image



2009 is a special year to be in Berlin, marking the 20th anniversary of the fall of the Berlin Wall. After The Wall was opened in 1989, hundreds of artists from all over the world gathered and transformed the East Side Gallery, a 1.3km-long section of the wall near the centre of Berlin in celebration and reflection of this freedom achieved. Approximately 106 paintings by artists from all over the world cover this memorial for freedom and make it the largest open air gallery in the world. With the recognition of its special connection to the past and the present, an artists' initiative was formed to preserve this "gallery" and later won Historical Monument status. To support the East Side Gallery, please visit: www.eastsidegallery.com.

The EuroMeeting cover image chosen for Berlin 2009 reflects the global, diverse ethos of the DIA itself. It is of a East Side Gallery mural by artist Kiddy Citny. Kiddy Citny is a musician and fine artist, born in Stuttgart in 1957. He grew up in Bremen, moved to West Berlin in 1977, lived in Amsterdam and London (1979), in Zurich (1980), Bern (1989/90), Los Angeles (1993/94), and also used a studio in Munich until 2000. Citny is a famous Berlin Wall graffiti artist who began playing cat and mouse with German border guards back in 1985. His work features the themes of love and mutuality, peace and freedom, sensitivity and tenderness, willpower and responsibility. Kiddy Citny communicates complex issues with simple metaphors: "Herzgesichter" (heart-shaped faces), "Welt im Arm" (the world in your arms), "Königskinder" (royal children).

EuroMeeting Key Contacts

Go to the EuroMeeting website (www.diahome.org and click on the EuroMeeting icon) for up-to-the-minute information, to register for the EuroMeeting or for a pre-conference tutorial, to download the programme and to book hotel rooms and tours.

Accounting Queries
For accounting inquiries please contact Suzanne de Zilva at suzanne.dezilva@diaeurope.org or +41 61 225 51 50

Advertising Opportunites
Enquiries should be directed to Frank Vivian at fvivian@ki-lipton.com or +1 267 893 56 75

Exhibitors
Enquiries from exhibiting companies or enquiries regarding the product locator, company summary book, exhibitor mailings, exhibitor kiosk and/or hospitality suites should be directed to Phyllis Suter at phyllis.Suter@diaeurope.org or +41 61 225 51 54

Press Passes/Press List/Press Release Programme
All enquiries regarding press passes and/or press lists should be directed to Talana Bertschi at talana.bertschi@diaeurope.org or +41 61 225 51 49

Registration Queries
For attendees with last names A-M please contact Roxann Schumacher at roxann.schumacher@diaeurope.org or +41 61 225 51 38

For attendees with last names N-Z please contact Simona Ponzer at simona.ponzer@diaeurope.org or +41 61 225 51 69

Speakers/Session Chairs
Enquiries from speakers should be directed to Sharon Evans Schuler at sharon.evans@diaeurope.org or +41 61 225 51 44

Poster Presenters and DIA EuroMeeting Fellowships
Further information is available from Maureen McGahan at maureen.mcgahan@diaeurope.org or +41 61 225 51 60

For all other queries or for unresolved issues, please contact Dermot Ryan, Senior Event Manager (EuroMeeting) at dermot.ryan@diaeurope.org or +41 61 225 51 32

FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52

FOR ONE ATTENDEE ONLY - The DIA Customer Services Team in Europe 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, or email diaeurope@diaeurope.org

DRUG INFORMATION ASSOCIATION

REGISTRATION FORM - ID# 09101

21ST ANNUAL EUROMEETING - MARCH 23-25, 2009 - INTERNATIONALES CONGRESS CENTRUM, BERLIN, GERMANY

Join the DIA now to qualify for the early-bird member rate! ***Please mark the box indicated below if you wish to take this option.***
To qualify for the early-bird discount, registration form and accompanying payment must be received by the date below.
The early-bird rate does not apply to government, student or academia/nonprofit attendees.

+ MEMBERSHIP
❑ € 130.00

EARLY-BIRD DEADLINE On or before JANUARY 23, 2009	MEMBER FEE	MEMBER VAT 19%	MEMBER TOTAL	NON-MEMBER (with optional membership) FEE	NON-MEMBER VAT 19%	NON-MEMBER MEMBERSHIP	NON-MEMBER TOTAL	NON-MEMBER (without optional membership) FEE	NON-MEMBER VAT 19%	NON-MEMBER TOTAL
Early-bird Industry	**€ 1'545.00**	€ 293.55	**€ 1'838.55** ❑	EARLY-BIRD NOT AVAILABLE				EARLY-BIRD NOT AVAILABLE		
Industry	**€ 1'695.00**	€ 322.05	**€ 2'017.05** ❑	**€ 1'695.00**	€ 322.05	€ 130.00	**€ 2'147.05** ❑	**€ 1'825.00**	€ 346.75	**€ 2'171.75** ❑
Charitable/Non-profit/ Academia (Full-Time)	**€ 1'271.25**	€ 241.54	**€ 1'512.79** ❑	**€ 1'271.25**	€ 241.54	€ 130.00	**€ 1'642.79** ❑	**€ 1'401.25**	€ 266.24	**€ 1'667.49** ❑
Government (Full-Time)	**€ 847.50**	€ 161.03	**€ 1'008.53** ❑	**€ 847.50**	€ 161.03	€ 130.00	**€ 1'138.53** ❑	**€ 977.50**	€ 185.73	**€ 1'163.23** ❑
Student (Full-Time)	**€ 100.00**	€ 19.00	**€ 119.00** ❑	**€ 100.00**	€ 19.00	€ 34.50	**€ 153.50** ❑	**€ 134.50**	€ 25.56	**€ 160.06** ❑
Tutorials	**€ 350.00**	€ 66.50	**€ 416.50** ❑							

Monday, March 23, 2009

Please indicate the tutorial number you wish to attend (see page 7 for full description of the tutorials) : _____

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

GROUP DISCOUNTS AVAILABLE! PLEASE CONTACT US FOR MORE INFORMATION. **09101DIAWEB**

REGISTRANT

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code

City

Country

Telephone

Telefax (Required for confirmation)

Email (Required for confirmation)

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

PAYMENT METHODS

❑ **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: Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA, 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. Payment should be in EURO and your name and company, as well as the Meeting ID# 09101 and invoice number, must be included on the transfer document to ensure correct allocation of your payment. **Payments must be net of all charges and bank charges must be borne by the payee. Bank transfers will only be accepted until February 13, 2009.**

Persons under 18 are not allowed to attend DIA meetings.

TO MAKE REGISTRATION EVEN SIMPLER, PLEASE ATTACH THE REGISTRANT'S BUSINESS CARD HERE

CANCELLATION POLICY

All cancellations must be in writing and be received at the DIA office by 17:00 CET on March 13, 2009

Cancellations received in writing on or before March 13, 2009 – An Administrative fee that will be deducted from fee: Full Meeting Cancellation: Member/Nonmember = EUR 200.00 Government/Academia/Nonprofit (Member/Nonmember) = EUR 100.00. 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 Europe reserves the right to alter the venue if necessary.

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

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

HOW TO REGISTER

Online	By Fax	Email	Mail
www.diahome.org	+41 61 225 51 52	diaeurope@diaeurope.org	DIA European Office Postfach, 4002 Basel, Switzerland

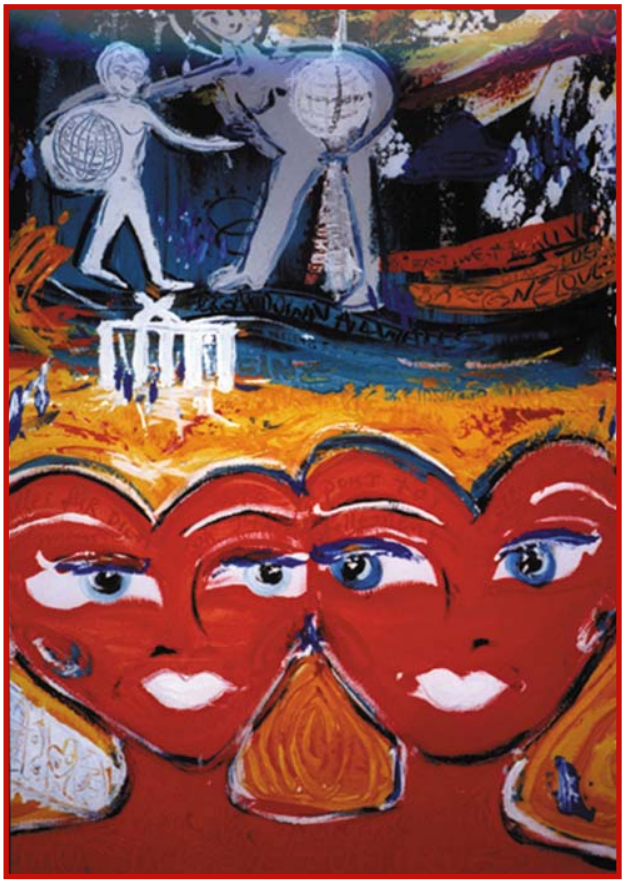
All registrations received at the DIA European Office by 18:00 CET on February 20, 2009, will be included in the EuroMeeting Attendee List.

DRUG INFORMATION ASSOCIATION

21st Annual

EuroMeeting Berlin 2009

Advance Programme



March 23-25, 2009

Internationales Congress Centrum

Berlin, Germany

DIA's 21st Annual EuroMeeting - a neutral global forum for industry, academia and regulatory professionals from over 50 countries

- The largest event of its kind in Europe
- Choose from over 125 sessions in 16 themes
- Attend presentations by more than 350 speakers
- Hear representatives from the EMEA, FDA and regulatory agencies throughout Europe
- Attend one of the 21 pre-conference tutorials
- Visit student and professional poster sessions
- Take advantage of excellent multidisciplinary networking opportunities
- Join over 240 exhibitors on one of the largest exhibition floors in Europe to showcase your company, products and services
- Return of the popular Japanese Regulatory Session
- Hot Topic sessions

Special early-bird registration fees until January 23, 2009

Register NOW and save €150.00!

Welcome from the EuroMeeting 2009 Co-Chairs - Barry Burnstead and Susanne Keitel

Dear Colleague,

We were delighted to be invited by the DIA to chair the 2009 EuroMeeting and particularly enthused by the location selected, Berlin. Delight turned to apprehension as the responsibilities associated with co-chairing became clear. Nevertheless, our resolve is firm and our determination to build upon the success of 2008 unquestioned. The theme approach was very well received in Barcelona and will be retained in Berlin. Certain refinements around the theme sessions have been identified that will support the quest to have all disciplines interacting at our event.

Alongside the traditional areas of drug development, regulation and patient safety, our desire is to broaden the appeal of the EuroMeeting by introducing complementary topics. Information technology has established itself in a role that is unquestionable, central to all our activities, and this is reflected as a prominent theme in the programme. The vital importance of appreciating the patient's perspective on drug information features strongly and the connection between the worlds of drugs and medical devices is strengthened by once more tackling the challenging subject of combination products.

The key to a successful event is for the organising committee to construct a programme that truly represents our members' interests. This year's organising committee has performed impressively and has demonstrated commitment complemented by high levels of expertise.

Our sights are firmly focused on Berlin in March 2009 with the clear target of delivering an event that not only fulfils but actually exceeds your expectations.

See you there.

Barry Burnstead **-** Consultant, SelectCRO, UK

Barry Burnstead has worked in the pharmaceutical industry for 35 years. Formative years were spent in chemistry, formulation sciences, project management and biometrics at SmithKline Beecham. He entered the CRO world in 1991, and a year later with ex-SB colleagues founded a CRO in Germany and established CRUs in Sweden and the UK.

In 1999, he decided to concentrate on consulting and joined Domain Pharma. When Phase Forward acquired Domain, he became global Head of Programme Management and latterly held responsibility for product commercialisation. Barry joined i3 Statprobe in August 2006 as Director of Project Management and subsequently moved to a central role leading standards implementation. Since August 2008, Barry has been working as a consultant at SelectCRO.

Susanne Keitel **-** Director, European Directorate of the Quality of Medicines and Healthcare (EDQM), EU

Susanne Keitel joined BfArM in 1997 after ten years in pharmaceutical development in industry. In the following ten years with BfArM, she held, amongst others, the positions of Head of Pharmaceutical Quality and Head of EU, International Affairs. She has been a member of various EU working parties, including QWP, PEG, NtA, and, on an international level, ICH Expert Groups. Since October 2007, Susanne has been Director of the Council of Europe's European Directorate for the Quality of Medicines and HealthCare (EDQM).

About the DIA EuroMeeting

The Drug Information Association's Annual EuroMeeting is global in scope, attracting well over 3,000 professionals from over 50 countries. It brings together professionals from the biopharmaceutical industry, contract service organisations, academic research centres, regulatory agencies, health ministries, patients' organisations and trade associations. This convergence affords attendees the opportunity to network with professional colleagues from around the world.

About the Drug Information Association

The DIA is a financially independent non-profit organisation that funds itself from meeting and membership fees. To preserve its neutrality, the DIA does not accept any form of sponsorship.

The DIA is a professional association of approximately 18,000 members worldwide who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. We are committed to the broad dissemination of information on the development of new medicines or generics and biosimilars, with continuously improved professional practice as the goal. The DIA is a financially independent non-profit organisation that funds itself from meeting and membership fees. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications at reasonable, competitive costs. Go to www.diahome.org to find out more about the benefits of becoming a DIA member.

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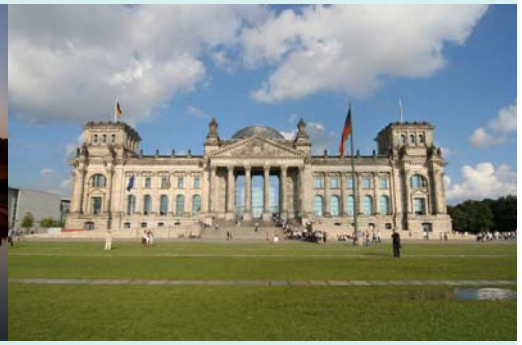

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Theme Leaders

The EuroMeeting 2009 is structured around 16 broad themes, each of which focuses on a pivotal aspect of healthcare or drug development, led by a group of dedicated and highly qualified theme leaders

Valdo Arnera
General Manager - Europe,
PHT Corporation, Switzerland

Sabina Hoekstra-van den Bosch
Senior Advisor, Ministry of Health, Welfare and Sport, The Netherlands

Monika Pietrek
Drug Development and Safety Expert, Germany

Peter Bachmann
Senior Expert European Affairs, BfArM, Germany

Wills Hughes-Wilson
Director Health Policy Europe, Genzyme, Belgium

Jean-Louis Robert
Head, Department of Medicines Control Laboratory, National Health Laboratory, Luxembourg

Norbert Clemens
Head Clinical Development, CRS Mannheim GmbH, Germany

Alar Irs
Deputy Director General, State Agency Medicine, Estonia

Gabriele Schwarz
Head, GCP Inspection Services, BfArM, Germany

Ros Coulson
PhC, MSc, FR, PharmS, UK

Michael J. James, Head of CMC Regulatory Advocacy and Intelligence, Global Regulatory Affairs, GlaxoSmithKline, UK

Dagmar Stará
Head of the EU Affairs Coordination Unit, State Institute for Drug Control, Slovak Republic

Suzy De Cordt
Group Leader, Senior Project Manager, Merck Serono, Switzerland

Suzette Kox
Senior Director, Scientific Affairs, EGA, Belgium

Barbara Sickmüller
Deputy Director General, German Pharmaceutical Industry Association (BPI), Germany

Nikos Dedes
Co-chair, Patients' and Consumers' Working Party (PCWP), EMEA, EU

Jürgen Kübler
Global Head, Statistical Safety Sciences, Novartis Pharma AG, Switzerland

Peter Stokman
Senior Director Clinical Data Management, Organon Schering-Plough, The Netherlands

Kerstin Franzén
Senior Director Worldwide Regulatory Policy and Intelligence, Pfizer AB, Sweden

Yann Le Cam
CEO, EURORDIS, France

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Director Health Economics and Outcomes, i3 Innovus, Germany

John Wise
Senior Director, Informatics, Daiichi Sankyo, UK

Robert Hemmings
Statistics Unit Manager, MHRA, UK and CHMP

Klaus Olejniczak
Scientific Director, BfArM, Germany

Michael Zuehlsdorf
Biomarker Development Global Head, Novartis Pharma AG, Switzerland

Programme Advisors

Christelle Anquez-Traxler
Regulatory and Scientific Affairs Manager, AESGP, Belgium

Christer Backman
EU Coordinator, Senior Expert, MPA Sweden

Gerd Bode
Lecturer, University of Göttingen and Consultant, Germany

Klaus Cichutek
Head, Department of Medical Biotechnology, Paul-Ehrlich-Institute, Germany

Hazel Collie
Global Head, Project Management, Gruenenthal GmbH, Germany

Joseph DeGeorge
Vice President Safety Assessment, Merck & Co, USA

Hans-Georg Eichler
Senior Medical Officer, EMEA, EU

Ralf Eulentrop
Head of Project Leadership Training, Merck Serono, Germany

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Staff Member European Cluster, Medicines Evaluation Board, The Netherlands

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Ingrid Klingmann
President, Pharmaplex, Belgium

Jos Kraus
Senior Inspector, Health Care Inspectorate, The Netherlands

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Deputy Head of Sector, Safety and Efficacy of Medicines, EMEA, EU

Francesco Pignatti
Scientific Administrator, Safety and Efficacy of Medicines, EMEA, EU

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Per Spindler
Director, BioLogue, University of Copenhagen, Denmark

Ursula Streicher-Saied
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Fergus Sweeney
Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, EMEA, EU

Joachim Vollmar
Executive Consultant, International Clinical Development Consultants, USA

Ralph White
Director, PPMLD Ltd., UK

Beat Widler
Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Matthias Wilken
Head of Drug Regulatory Affairs Europe, German Pharmaceutical Industry Association (BPI), Germany

Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The American Medical Association has determined that physicians not licensed in the US who participate in this CME activity are eligible for AMA PRA category 1 credit.

Select sessions may offer AMA RA Category 1 Credits and will be clearly identified in the final programme

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.

The DIA is authorised by IACET to offer 1.5 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 programme 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.

Plan Your EuroMeeting Experience

- Knowledge
- Networking
- EuroMeeting Information

Sunday, March 22, 2009

15:00-17:00	Conference Registration/Information Open. Avoid the rush on Monday by picking up your badge on Sunday afternoon.
18:30-19:30	DIA Reception for representatives of Patients' Organisations - Patients Only

Monday, March 23, 2009

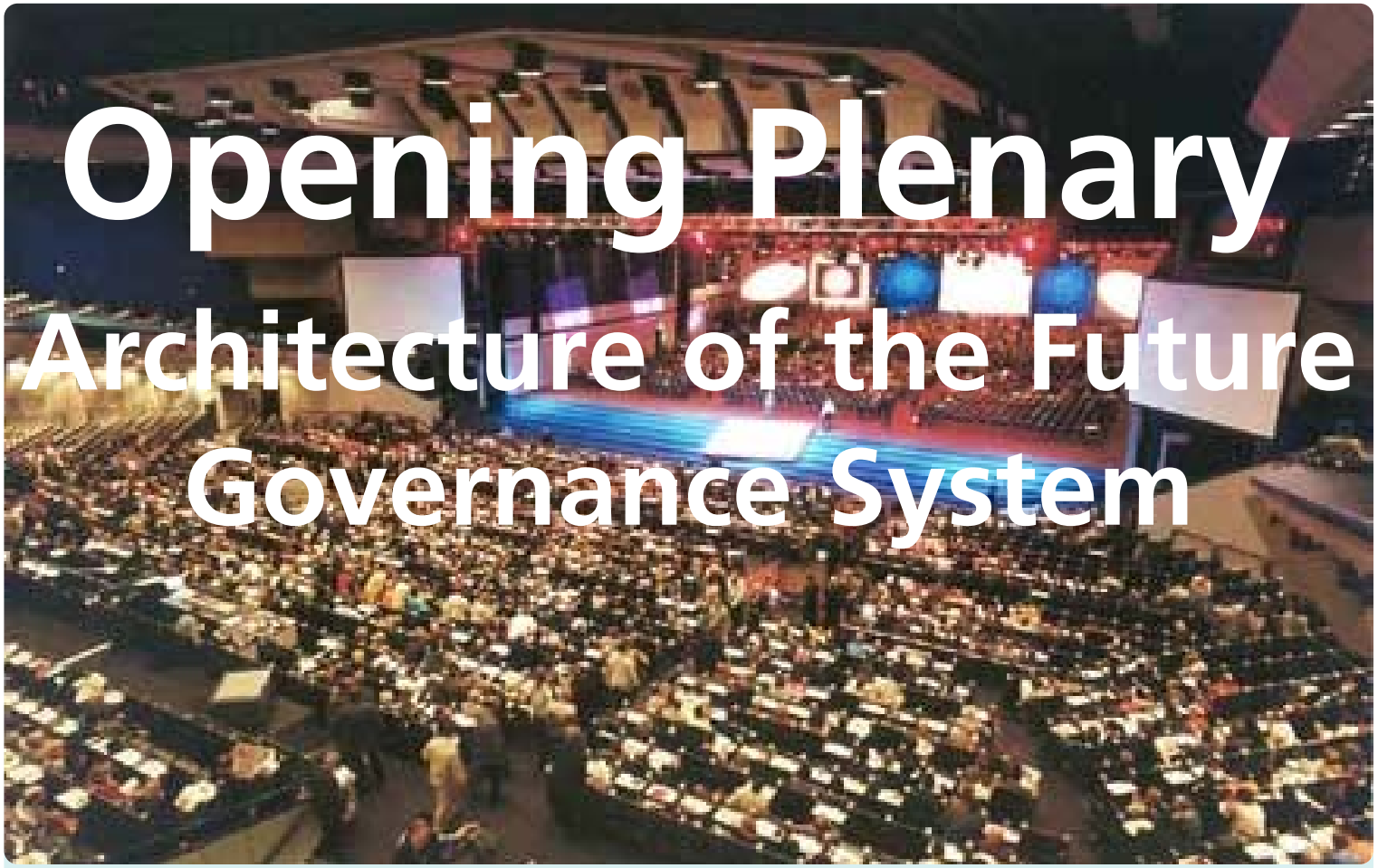
07:30-19:00	Conference Registration/Information Open
08:30-09:00	Patients' Representatives Briefing - Patients Only
08:30-09:00	Students Briefing – Students Only
09:00-12:30	21 Pre-Conference Tutorials
09:00-10:30	Student Session (in partnership with the European Pharmaceutical Students Association)
11:00-12:30	Emerging Professionals Session
12:30-13:30	Students/Young Professionals Networking Lunch
12:30-13:30	Regulators and Patients Reception: An opportunity for patients and regulators to come together - Invitation Only.
12:30-14:00	Lunch
12:30-18:00	Exhibition Opens
CONFERENCE OPENS	
14:00-17:30	Opening Plenary Session
17:30-20:00	Jitterbug Networking Reception at the Palast am Funkturm with food, drink and entertainment

Tuesday, March 24 2009

07:30-18:30	Conference Registration/Information Open
08:00-09:00	Welcome Coffee
08:00-18:30	Exhibition Open
08:30-09:00	Patients' Representatives Briefing – Patients Only
08:30-09:00	Students Briefing – Students Only
09:00-10:30	Session 1 (17 parallel sessions)
10:30-11:00	Coffee Break
11:00-12:30	Session 2 (17 parallel sessions)
11:00-12:30	Japanese Regulatory Session
12:30-14:00	DIA Special Interest Area Communities (SIACs) – Meet and Eat
12:30-14:00	Lunch
14:00-15:30	Session 3 (17 parallel sessions)
15:30-16:00	Coffee Break
16:00-17:30	Session 4 (17 parallel sessions)
17:30-18:30	The Tuesday Reception: Drinks Reception with entertainment on the Exhibition Floor
18:00-19:30	German Satellite Session

Wednesday, March 25 2009

08:00-18:00	Conference Registration/Information Open
08:00-16:00	Exhibition Open
08:00-09:00	Welcome Coffee
08:30-09:00	Patients' Representatives Briefing – Patients Only
08:30-09:00	Students Briefing – Students Only
09:00-10:30	Session 5 (15 parallel sessions)
10:30-11:00	Coffee Break
11:00-12:30	Session 6 (15 parallel sessions)
12:30-14:00	Lunch
14:00-15:30	Session 7 (13 parallel sessions)
15:30-16:00	Coffee Break
16:00-17:30	Sessions 8 (14 parallel session)



Opening Plenary
Architecture of the Future Governance System

The 21st Annual EuroMeeting will officially start on **Monday, March 23, 2009 at 14:00** in the Auditorium of the ICC Convention Centre and will run for three and a half hours, including a refreshment/networking break on the conference exhibition floor.

The title of the opening plenary is **Architecture of the Future Governance System**. The debate will be strategic and will enable the distinguished panel to set forth their vision for the next five years. Topics to be discussed will be broad and far-ranging, and will include the evolution of the European Regulatory Network and the contribution of the National Competent Authorities, changes in pharmacovigilance legislation, market access and what Member States will pay for new products, and the impact of counterfeit medicines. Panellists who are opinion leaders in their organisations will be invited.

Confirmed panel participants:

- **Christina R. Åkerman**, Director General, Medical Products Agency, Sweden
- **Daan J. A. Crommelin**, Scientific Director, Top Institute Pharma - TI Pharma, Netherlands
- **Alastair Kent**, Director, Genetic Interest Group, and President EGAN, UK and EU
- **Thomas Lönngren**, Executive Director, EMEA, EU
- **Martin Terberger**, Head of Unit, European Commission, Enterprise and Industry DG Pharmaceutical Unit, EU
- **Lisette Tiddens-Engwirda**, Secretary General, Standing Committee of European Doctors, EU
- **Floortje van Nooten**, Senior Research Associate – Health Economics, Health Care Analytics Group, United BioSource Corporation, Belgium

The plenary will also feature the DIA Awards session, which recognises the contributions of several distinguished award winners to the development of the Drug Information Association in Europe.

Opening Plenary Musical Highlight

The opening plenary session of the EuroMeeting attempts to give attendees a taste of the EuroMeeting host city. This year's musical highlight will feature a short performance by the Berlin Children's Choir. Founded over 60 years ago, the choir continues to delight audiences at home and abroad. Led by its artistic director, Veronica Pietsch, the Berlin Children's Choir is made up of approximately 60 children.

Special Sessions

Emerging Professionals Session

Monday, March 23, 2009, 11:00-12:30

YOUR FUTURE IN THE WORLD OF THE PHARMACEUTICAL INDUSTRY AND HEALTHCARE SYSTEM

Session Chair:
Sonja Pumplün, Head Global Drug Regulatory Affairs, Actelion Pharmaceuticals, Switzerland

The Emerging Professionals Session is for those who are new to the pharmaceutical profession and for students who are interested in finding a way into the profession. Discuss issues of interest with different key players in the pharmaceutical industry and healthcare system. Learn about different job profiles and opportunities to enter the pharmaceutical industry or healthcare system.

Finding the Right Job in the Pharmaceutical Industry
Detlef Niese, Head External Affairs, Novartis Pharma A.G., Switzerland.

Job Opportunities at the Health Authority
EMEA Speaker invited

How to Best Present Myself: the View of Human Resources
Alex Khatuntsev, Human Resources Director, Actelion Pharmeceuticals Ltd., Switzerland

Japanese Regulatory Session

Wednesday, March 25, 2009, 11:00-12:30

PMDA UPDATE: INITIATIVES AND CHALLENGES FOR PROMOTING GLOBAL DRUG DEVELOPMENT INCLUDING JAPAN

Session Chair:
Kyoichi Tadano, Director, International Affairs Division, PMDA, Japan

In this session, the Pharmaceuticals and Medical Devices Agency (PMDA) will explain the current PMDA/Japanese drug regulatory environment and present PMDA perspectives for successful global drug development including Japan.

Future Directions of PMDA
Tatsuya Kondo, Chief Executive, PMDA, Japan

PMDA Perspectives and Challenges to Promote Global Drug Development
Satoshi Toyoshima, Executive Director and Director, Center for Product Evaluation, PMDA, Japan

Current Projects for Promoting Global Drug Development including Japan
Yoshiaki Uyama, Review Director, Office of New Drugs III, PMDA, Japan

Student Session

in partnership with the European Pharmaceutical Students Association (EPSA)

Monday, March 23, 2009, 09:00-10:30

EUROPEAN HIGHER EDUCATION: CURRICULA FOR THE PHARMACEUTICAL WORLD

Participants will learn in an informal atmosphere about the education students need to lead them into the pharmaceutical world. They will hear what students themselves all over Europe think about their curricula (EPSA European research project) and will have the opportunity to put questions to and exchange opinions with industry professionals and academia.

This session is being developed by the EPSA with the support of the DIA.
The EPSA represents over 120,000 pharmacy students in 32 European countries. The objective of EPSA is to develop the interests and opinions of European pharmacy students and to encourage contact and co-operation between them.

German Satellite Session

Tuesday, March 24, 2009, 18:00-19:30

THE MARKETING AUTHORISATION AND SUPERVISION OF MEDICINAL PRODUCTS AND PATIENTS, DOCTORS AND INDUSTRY EXPECTATIONS

This session will discuss the tasks, duties and cooperation of the regulatory agencies in Germany, the Federal Institute for Drugs and Medical Devices and the Paul-Ehrlich-Institute, in a changing scientific environment.

Session Co-Chairs:
Birka Lehmann, Director and Professor, Head of Licencing Division 3, BfArM
Christian Schneider, Acting Head, Division EU Cooperation/Microbiology and Acting Head, Section EU Cooperation Biomedicinal Products, Paul-Ehrlich-Institute

Global Challenges, European Adaptation and National Transformation
Harald Enzmann, Director and Professor, Head of Licencing Division 2, BfArM
Klaus Cichutek, Vice- President and Professor, Department of Medical, Biotechnology,Paul-Ehrlich-Institute

The Concept of Benefit-Risk Evaluation
Karl Broich: Director and Professor, Head of Licencing Division 4, BfArM

Paediatric Population and Medicinal Products
Dirk Mentzer, Head, Department of Pharmacoviglance 1, Paul-Ehrlich-Institute

Advanced Therapies
Klaus Cichutek, Vice- President and Professor, Head, Department of Medical Biotechnology, Paul-Ehrlich-Institute

Pharmacovigilance
Brigitte Keller-Stanislawski, Director and Professor, Head of Department Safety of Medicinal Products and Medicinal Devices, Paul-Ehrlich-Institut
Ulrich Hagemann, Director and Professor, Head of Department Safety of Medicinal Products and Medicinal Devices, BfArM

DIA EuroMeeting Fellowships

Would you like to receive complimentary admission to the 21st Annual EuroMeeting in Berlin, March 23-25, 2009, featuring approximately 130 sessions, over 350 speakers and numerous networking opportunities?

DIA Young Professional Fellowship:
Application Deadline December 1, 2008
DIA welcomes the involvement of young professionals in the EuroMeeting and is providing complimentary admission to the EuroMeeting for 15 young professionals in full-time employment under the age of 30.

DIA Student Fellowship:
Application Deadline December 1, 2008
DIA welcomes the involvement of students in the EuroMeeting and is providing complimentary admission to the EuroMeeting for 15 students in full-time education.

DIA Patient Fellowship:
Application Deadline December 1, 2008
The DIA Patient Fellowship, now in its fourth successful year, is a programme to promote the participation of patients' organisation representatives in the EuroMeeting. In 2009, the DIA in Europe will support 22 patients' representatives' participation in the EuroMeeting by covering their complete travel and accommodation costs plus complimentary admission to the EuroMeeting in Berlin and is offering 25 additional patients' representatives complimentary registration for the EuroMeeting, thus enabling a total of 47 patients' representatives to actively participate in the EuroMeeting in Berlin.

- Complimentary admission to conference and pre-conference tutorial of choice
- Specific DIA Patient Fellowship Booth to act as a focal point to network and to distribute information
- Travel costs covered
- Up to 3 nights complimentary hotel accommodation provided
- Patient Fellowship Reception on Sunday evening and daily briefings to encourage information and skills sharing

Fellowship Application Process:
Application packs for all three fellowships can be obtained by contacting Maureen McGahan: maureen.mcgahan@diaeurope.org or by calling +41 61 225 51 60 or by going to www.diahome.org and clicking on the EuroMeeting icon.

EuroMeeting 2009 Student/Young Professional Guidance Scheme

Purpose and Benefits
The DIA is committed to the active participation of students and emerging professionals in the EuroMeeting and to maximising the quality of their experience while attending. Targeted activities at the EuroMeeting have been increasing over a number of years. The EuroMeeting Student/Young Professional Guidance Scheme is the latest step in increasing the value of the EuroMeeting for students and emerging professionals. It will complement existing activities planned for the 21st Annual EuroMeeting. These include:

- Fully supported packages for up to 20 student poster presenters
- Student Fellowship offering 15 complimentary registrations
- Student/Emerging Professional Reception
- Daily Student Orientation Briefing
- Special Student and Emerging Professional sessions
- DIA Young Professional Fellowship offering 15 complimentary registrations

Benefits for the student/young professional include

- An opportunity to learn from an experienced professional
- Guidance in choosing which EuroMeeting sessions to attend
- Discussion and feedback on sessions attended
- Insight into the pharmaceutical world from the perspective of a senior professional
- Advice on potential career paths
- Advice on skills required for career development
- Advice on improving professional and personal networks

Benefits for the experienced professional include

- An opportunity to share experience and expertise
- A sense of personal satisfaction in helping to contribute to the professional development of somebody just starting their career
- Being exposed to a fresh or different perspective

Please contact Maureen McGahan in the EuroMeeting team for further information about how you can get involved: maureen.mcgahan@diaeurope.org or call +41 61 225 51 60.

Volunteers Sought for Student/ Young Professional Guidance Scheme

Are you an experienced professional and willing to spare a couple of hours to offer guidance to a student or young professional during the EuroMeeting? If the answer is yes, then the EuroMeeting team would love to hear from you. The time commitment will be as much as you are able to offer, but a minimum of two hours contact with a student/young professional would be appreciated. It could involve activities such as attending the special networking lunchtime reception on Monday, March 23, 2009, spending some time reviewing the programme and perhaps attending a session together and discussing the content afterwards. This is a great opportunity to invest in the future of the pharmaceutical profession by sharing your expertise and experience. Please contact Maureen McGahan in the EuroMeeting team for further information about how you can get involved: maureen.mcgahan@diaeurope.org or call +41 61 225 5160.

Student Poster Abstracts/Professional Poster Abstracts

Call for Student Poster Abstracts: Deadline November 21, 2008

Chair of EuroMeeting 2009 Poster Committee:
Rolf Bass, Professor for Pharmacology and Toxicology, Charité - University Hospital Berlin

Full-time university students, residents and fellows are invited to submit abstracts for the Student Poster Session which will take place on Tuesday, March 24, 2009 at the EuroMeeting in Berlin. A maximum of 20 abstracts will be selected for the student poster presentation.

A total of EUR 1,800 in prize money will be awarded to student winners based on the following criteria:

- Bona fide research project
- Specific objectives and hypothesis
- Clear methods
- Analysis of actual data and results
- Conclusion

Eligibility:

Full-time students, residents or fellows at the time of the presentation. One author or the author's designee must attend the EuroMeeting.

Benefits:

- One fully supported registration for the EuroMeeting to include: return flight to Berlin, three nights hotel accommodation and complimentary registration for the EuroMeeting
- A second complimentary EuroMeeting registration for an accompanying co-author/professor
- Accepted abstracts will be printed in an early 2009 issue of the *Drug Information Journal*
- A total of EUR1,800 in prize money

Abstracts:

- All poster abstracts must be received by Friday, November 21, 2008. Submit your abstract online by going to www.diahome.org and clicking on the EuroMeeting icon.
- Abstracts are limited to 100 words
- A student may submit only one abstract
- Abstracts may not refer to specific brand names
- Abstracts should follow a structured format including all of the following: objectives, methods, results, conclusions
- Submissions must include complete contact information
- Abstracts will be reviewed and authors notified of results by Friday, December 12, 2008

Call for Professional Poster Abstracts: Deadline November 21, 2008

A maximum of 40 abstracts from full-time professionals will be selected for the professional poster presentations to be held on Tuesday, March 24, 2009.
Selected professional poster presenters will be required to pay the applicable meeting registration fee and will be responsible for all other meeting expenses.

Abstracts:

- All poster abstracts must be received by Friday, November 21, 2008. Submit your abstract online by going to www.diahome.org and clicking on the EuroMeeting icon.
- Abstracts are limited to 100 words
- Abstracts may not refer to specific brand names
- Abstracts should follow a structured format including all of the following: objectives, methods, results, conclusions
- Submissions must include complete contact information
- Abstracts will be reviewed and authors notified of results by Friday, December 12, 2008

If you require further information about Student or Professional Posters, please contact Maureen McGahan in the DIA European office: maureen.mcgahan@diaeurope.org or call +41 61 225 51 60.

Session Topics in Specific Interest Areas

Please consult pages 20-53 for details of sessions and page 62-64 for the EuroMeeting 2009 session matrix

Clinical Development and Research

- Paediatric Trials - Better Medicines for Children with Regulatory Efforts
- Patient-Reported Outcomes
- Infectious Diseases
- First-in-Man: Clinical Trials Issues
- Patient Recruitment
- Novel Approaches in Clinical Research
- Multinational Trials in China, Africa and South America
- Strategy of Clinical Development
- Safety Planning in Drug Development - Real Improvement or Yet Another Document?
- Addressing Key Safety Challenges in Clinical Drug Development: Signal Detection and Continuous Risk Assessment
- Statistics for Biomarkers and "Omics"– Anything New?
- Getting the Dose Right - Dose Finding and Exposure Response
- Building Health Technology Assessments into Product Development for Success
- Clinical Trials - The Start not the End. Building Integrated Data Sets in a European Context to Meet the Needs
- Project Management Tools, Processes and Organisation
- Is There Mistrust in Drug Research?
- Optimising the Dilemma of the Informed Consent Process Between Ethical Requirements and Organisational Burden
- Society, Patients and Advanced Therapy
- Can We Draw a New Social Contract in Drug Development?
- Are Benefits of eClinical Methods in Step with Regulations and Recent EMEA Guidance?
- Added Therapeutic Value - Are Common Criteria for Effectiveness Assessment Possible? What are the Discussions at the European Level?
- Advanced Therapies Implementation - Recent Developments and Open Questions
- New and Updated Regulations: How Do They Affect the Interface between Drugs and Devices?
- Roundtable: The Spirit of One Team Created from Two Worlds – the Key to Successful Development of Devices/Drug Combination Products
- Communicating Benefit – Risk to the Public: 12 Years after the Erice Declaration, How much Progress Has Been Made?
- Clinical Trials with Biological – IMPD Requirements

Generics

- Safeguarding Public Health: Balancing Early Access with Safety and Affordability Aspects
- Regulatory Implications of Outsourcing Clinical Development to Emerging Markets
- Ways to Improve the Current Regulatory System for Assessment of Medicinal Products with Known Active Substances
- Drug Counterfeiting in Europe: Trends and New Initiatives
- Implementation of ICH in Non-ICH countries: Where Are We Now and What Will Happen in the Future?
- Known Active Substances and Bibliographic Applications - Current Problems, Possibilities and Solutions

GCP

- Regulatory Implications of Outsourcing Clinical Development to Emerging Markets
- Paediatric Trials - Better Medicines for Children with Regulatory Efforts
- Strategy of Clinical Development
- Novel Approaches in Clinical Research
- Performance and Quality Control in Pharmacovigilance and Risk Management – Too Much or Too Little? What is the Impact on Public Health?
- Safety Surveillance Plans: Strategies for Monitoring Safety during the Development Lifecycle
- The Spirit of One Team Created from Two Worlds – the Key to Successful Development of Devices/Drug Combination Products
- Inspection Findings on Investigational Sites and at the Sponsor of Drug Device Combination Trials
- The Transparency Imperative
- Optimising The Dilemma of the Informed Consent Process Between Ethical Requirements and Organisational Burden
- Integrating Different eClinical Data Streams: Needs and Benefits
- Advanced Therapies Implementation - Recent Developments and Open Questions
- Implementation of ICH in Non-ICH countries: Where Are We Now and What Will Be in the Future?
- International GCP Inspection Experiences
- Serious GCP Breaches Including Falsification and Fraud

IT, eClinical and Data Management

- Integrating Different eClinical Data Streams: Needs and Benefits
- Are Benefits of eClinical Methods in Step with Regulations and Recent EMEA Guidance?
- Technology & Standards…How about the Process?
- The Loose Ends in EDC and How to Address Them
- A Look into the Future: What Is on the Horizon after We Have Managed EDC Properly?
- Experience with CDISC Standards
- CDISC End-to-End: To What Extent?
- CDISC as an Avenue to Process Improvement
- The 'Electronic-Only' Centralised Procedure - Now a Reality
- Towards 'Electronic-Only' Mutual Recognition, Decentralised and National Procedures
- Product Information Management (PIM) - Towards Full Implementation
- Product Partnering: The Effective Management of Information Assets
- Risk Management and Pharmacovigilance - Between a Regulatory Rock and the Litigation Hard Place
- Project Management Applied in Functional Areas – Is PM the New Middle Management?
- Drug Safety Personnel – Which Qualification and How Much Education is Needed? Where do Regulators and Industry Find Talent?
- Audits and Inspections on e-CRFs and e-Source Data
- Hot Topic in Telematics

Session Topics in Specific Interest Areas

Manufacturing and GMP

- Advanced Therapies Implementation - Recent Developments and Open Questions
- Regulatory Implications of Outsourcing Clinical Development to Emerging Markets
- Quality Assurance Systems for Drug Device Combination Manufacturers: Experiences of QA Manager and Auditors
- Special Requirements for the Safety of Biologicals and Biosimilars
- Expanding our Regulatory Horizon to Deliver Device and Drug Combination Products Successfully to Market: Where Could Drugs and Devices Meet?
- Drug Counterfeiting in Europe: Trends and New Initiatives
- Implementation of ICH in non-ICH countries: Where Are We Now and What Will Be in the Future?
- Sourcing of API in a Globalised Environment
- Innovative Technologies in Drug Development and Manufacture

Medical Devices

- New and Updated Regulations: How Do They Affect the Interface between Drugs and Devices?
- Quality Assurance Systems for Drug Device Combination Manufacturers: Experiences of QA Manager and Auditors
- Expanding our Regulatory Horizon to Deliver Device and Drug Combination Products Successfully to Market: Where Could Drugs and Devices Meet?
- Roundtable: The Spirit of One Team Created from Two Worlds – the Key to Successful Development of Devices/Drug Combination Products
- Borderlines between Devices and Other Product Categories: Opportunity or Mystery?
- Medical Assessments and Safety-Evaluations for Medical Devices, Drugs and their Combinations
- Inspection Findings on Investigational Sites and at the Sponsor of Drug Device Combination Trials
- New Developments in Drugs and Devices: Therapeutic Shift or Synergy?

Non-Clinical Development

- Use of Imaging in Non-Clinical Toxicity Testing: What Is its Value? What about Regulatory Acceptance?
- Non-Clinical Evaluation of Hepatotoxicity: Where do We Stand? How Sceptical is the Pharmaceutical Industry?
- Non-Clinical Support for First-in-Man Studies
- Update on Anti-cancer Drug Guideline ICH9
- Update on ICH S6 Non-Clinical Safety Testing of Biotechnology-Derived Products: Part 1
- Update on ICH S6 Non-Clinical Safety Testing of Biotechnology-Derived Products: Part 2
- New Concepts in the Assessment of Genotoxicity
- Update on the Use of Juvenile Animal Studies for Paediatric Drug Development
- Translating siRNA to Medicines
- Safety Surveillance Plans: Strategies for Monitoring Safety during the Development Lifecycle

Patient Representation

- Benefit–Risk
- What Does the User Consider Value? Including the Patients' Voice in Assessments
- Patient Recruitment
- The Transparency Imperative
- Optimising The Dilemma of the Informed Consent Process Between Ethical Requirements and Organisational Burden
- Communicating Benefit – Risk to the Public: 12 Years after the Erice Declaration, How much Progress Has Been Made?
- Can We Draw a New Social Contract in Drug Development?

Pharmacovigilance and Safety

- Surveillance: Diseases and Pharmacovigilance – How Good are our Baseline Data?
- Safety Surveillance Plans: Strategies for Monitoring Safety during the Development Lifecycle
- Special Requirements for the Safety of Biologicals and Biosimilars
- Performance and Quality Control in Pharmacovigilance and Risk Management – Too Much or Too Little? What is the Impact on Public Health?
- EU-Harmonised Pharmacovigilance Requirements versus Global Pharmacovigilance – Supplement or Contradiction?
- Safety Decision Making – How much Science is Deployed? An update on Methodology
- Drug Safety Personnel – Which Qualification and How much Education is Needed? Where do Regulators and Industry Find Talent?
- Post-Marketing Studies – Commitments and Reality
- Safety Planning in Drug Development - Real Improvement or yet Another Document?
- Addressing Key Safety Challenges in Clinical Drug Development: Signal Detection and Continuous Risk Assessment
- Optimising The Dilemma of the Informed Consent Process Between Ethical Requirements and Organisational Burden
- Communicating Benefit – Risk to the Public: 12 Years after the Erice Declaration, How much Progress Has Been Made?
- Safeguarding Public Health: Balancing Early Access with Safety and Affordability Aspects
- Benefit–Risk
- Key Initatives in Drug Development Optimisation
- Risk Management and Pharmacovigilance - Between a Regulatory Rock and the Litigation Hard Place
- New and Updated Regulations: How Do They Affect the Interface between Drugs and Devices?
- Medical Assessments and Safety-Evaluations for Medical Devices, Drugs and their Combinations
- Optimising The Dilemma of the Informed Consent Process Between Ethical Requirements and Organisational Burden
- Introduction of Biosimilar Medicines into Clinical Practice
- Audits and Inspections on Pharmacovigilance
- Quality Risk Management and Risk Detection

Session Topics in Specific Interest Areas

Regulatory

- Safeguarding Public Health: Balancing Early Access with Safety and Affordability Aspects
- Benefit – Risk
- Applications of Novel Pharmacometric Approaches for Internal Decision Making and Regulatory Submission
- How Can Regulators Engage in Novel Drug Development? Revisiting the Regulator – Industry Dialogue
- Building HTA into the Process: Meeting the Needs of Licensing Authorities, Payers and Patients
- Enabling Early Access
- Communicating Benefit – Risk to the Public: 12 Years after the Erice Declaration, How much Progress Has Been Made?
- Regulatory Implications of Outsourcing Clinical Development to Emerging Markets
- Optimising The Dilemma of the Informed Consent Process Between Ethical Requirements and Organisational Burden
- Incremental Research - Important Benefits, Neglected in European Law?
- Drug Counterfeiting in Europe: Trends and New Initiatives
- Implementation of ICH in Non-ICH countries: Where Are We Now and What Will Be in the Future?
- Ways to Improve the Current Regulatory System for Assessment of Medicinal Products with Known Active Substances
- Known Active Substances and Bibliographic Applications - Actual Problems, Possibilities and Solutions
- "Smart Regulation" for Non-Prescription Medicines
- News on Rx to OTC Switch
- Patents and the EU Regulatory Systems
- The Transparency Imperative
- Society, Patients and Advanced Therapy
- The 'Informed Patient' - A Controversial Goal
- The Electronic-Only Centralised Procedure - Now a Reality
- Hot Topic in Telematics
- Harnessing Industry and Authority Experience: Working Together to Achieve Effective Guidelines
- EU Agreement: Administrative Regulatory Simplification – The Next Phase?
- International GCP Inspection Experiences
- Towards Electronic-only Mutual Recognition, Decentralised and National Procedures
- Regulatory Guidelines Compared to Medical Practice Guidelines: Their Places in Personalised Medicine
- Personalised Medicine: A Challenge for Drug Development?
- From Populations to Individuals: Industry Tools and Assessment of Benefit/Risk Balance
- Implementation of the New ICH Quality Paradigm
- Pharmacopoeias – Do They Have a Place in a Quality-by-Design Environment?
- The Paediatric Regulation – An Easy Way to Age-Appropriate Formulations?
- Revision of the Variations Regulations: An Update
- What's New in the Quality Arena?

Research and Development

- Paediatric Trials - Better Medicines for Children with Regulatory Efforts
- Strategy of Clinical Development
- Infectious Diseases
- The EU Landscape
- The Electronic-Only Centralised Procedure - Now a Reality
- Towards Electronic-only Mutual Recognition, Decentralised and National Procedures
- Product Information Management (PIM) - Towards Full Implementation
- Product Partnering: The Effective Management of Information Assets
- Knowledge Management & Innovation
- Project Management Tools, Processes and Organisation
- Key Success Factors for Portfolio and Project Management
- Demonstrating Cost-Effectiveness in Challenging Situations and When Data is Limited
- Building Health Technology Assessments into Product Development for Success
- Clinical Trials - The Start not the End. Building Integrated Data Sets in a European Context to Meet the Needs
- Personalised Medicine: A Challenge for Drug Development?

Statistics

- Surveillance: Diseases and Pharmacovigilance – How Good are our Baseline Data?
- EU-Harmonised Pharmacovigilance Requirements versus Global Pharmacovigilance – Supplement or Contradiction?
- Performance and Quality Control in Pharmacovigilance and Risk Management – Too Much or Too Little? What is the Impact on Public Health?
- Medical Assessments and Safety Evaluations for Medical Devices, Drugs and their Combinations
- Adaptive Designs – From Statistical Science to Regulatory Guidance
- Adaptive Designs – A Discussion with Stakeholders
- Safety Planning in Drug Development - Real Improvement or yet Another Document?
- Addressing Key Safety Challenges in Clinical Drug Development: Signal Detection and Continuous Risk Assessment
- Statistics for Biomarkers and "Omics"– Anything New?
- Getting the Dose Right - Dose Finding and Exposure Response
- Beyond Trial Design and Sample Size Estimation - The Utility of Clinical Scenario Assessments
- 'Missing Data' for Your 'Quantitative Benefit-Risk' Assessment Supporting 'Conditional Marketing Authorisation'? Where Next for Regulatory Guidance?

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Pre-Conference Tutorials 09:00-12:30

TUTORIAL 1

DETAILED DESCRIPTION OF PHARMACOVIGILANCE SYSTEMS FOR MEDICINAL PRODUCTS FOR HUMAN USE: VOL. 9A AND EU REGULATORY REQUIREMENTS

Sabine Brosch, Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA, EU
Gaby Danan, Senior Director, Expert in Pharmacovigilance, Global Pharmacovigilance and Epidemiology, sanofi-aventis, France

This tutorial will allow attendees to discuss the regulatory requirements with regard to the Chapter of Volume 9A on the 'Description of Pharmacovigilance Systems for Medicinal Products for Human Use' also referred to as DDPS. It must be supplied with the application dossier and as part of supporting documentation that the Applicant must maintain and supply to the Competent Authorities on request.
Emphasis will be put on the main elements of the DDPS such as the role and responsibilities of the Qualified Person Responsible for Pharmacovigilance (QPPV), an outline of the pharmacovigilance procedures and the pharmacovigilance database(s) as well as methods for updating the DDPS and points to consider for preparation of inspections.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Interpret the potential implications of the requirements on pharmaceutical companies' business processes
- Share knowledge on how to prepare DDPS
- Adhere to the requirements for updating a DDPS
- Share knowledge on how to prepare for an inspection in relation to the DDPS and the pharmacovigilance systems

Target Audience
This tutorial is designed for:
- Qualified Persons Responsible for Pharmacovigilance
- Persons in charge of pharmacovigilance systems
- Experts in Regulatory Affairs
- Persons in charge of Quality and Compliance
- Sponsors of clinical trials

TUTORIAL 2

PAEDIATRIC DEVELOPMENT AND INNOVATIVE ASPECTS OF PAEDIATRIC TRIALS

Agnès Saint Raymond, Head of Sector Scientific Advice and Orphan Drugs, EMEA, EU

Paediatric development and innovative aspects of paediatric trials are hot topics for agencies, industry and academia. Industry will need new skills at early phase development steps and academia will have to include more and more paediatric clinical trials as part of their activities. Families and patient groups will be key partners in this new process. New methodological approaches are needed.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise the need to include paediatric development in early R&D and lifecycle management of medicinal products
- Identify requirements for success in submission of PIP, waivers or deferrals
- Use innovative aspects and new methodological approaches for setting paediatric trial protocols

Target Audience
R&D, regulatory, biometry, formulation, strategic planning, regulatory agency personnel and experts, and patients' associations.

TUTORIAL 3

RISK MANAGEMENT: TURN PLANS INTO PRACTICE

Rosalind Coulson, PhC, MSc, FR, PharmS, UK
Andrzej Czarnecki, Director, Deputy Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK
Monika Pietrek, Drug and Safety Expert, Germany

The New Medicines Legislation has provided a formal framework for risk management activities. Risk management plans need to be submitted within a marketing authorisation application or in response to a newly identified safety concern for a marketed product. Following discussions with regulatory authorities, such plans may require modification before risk management programmes can be fully or partially executed. Programmes have to be regularly evaluated and reported. This tutorial will focus on the principles of risk assessment and risk management, presenting examples of plans, investigations and minimisation. Special attention will be paid to the critical success factors of risk management programmes.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Summarise the New Medicines Legislation framework for risk management
- Discuss any risk management plan modifications that may be required
- List critical success factors of risk management programmes

Target Audience
This tutorial is designed for drug safety and clinical development professionals, with functional emphasis on medical directors, pharmacists, statisticians and epidemiologists.

TUTORIAL 4

THE PSUR: A PHARMACOVIGILANCE AND MEDICAL WRITING VIEW WITH EMPHASIS ON PRACTICAL SOLUTIONS TO THE PITFALLS AND GREY AREAS

Giovanni Furlan, Head, Global Product Safety Analysis & Evaluation, Bracco Imaging SpA, Italy
Alison Rapley, Director, Medical Writing Services Europe, PAREXEL International Ltd, UK

This tutorial critically examines PSUR content and process from the pharmacovigilance and medical writing perspectives. The first half of the tutorial will review the source and content of the different PSUR sections. It will provide an overview of the relevant guidance documents, discuss the limitations of the PSUR basic components and explain, providing practical examples, how the content and data of a good PSUR should vary depending on the drug's characteristics. The second half of the tutorial will look at PSUR practical implications of pitfalls and grey areas and suggest possible solutions. The overlap and cross-link between PSURs and other regulatory documents will be highlighted. Differences between the issues of innovative vs generic drug PSURs will also be presented.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Explain why and how to prepare a PSUR
- Describe the content of each PSUR section and recognise how the content, presentation and analysis of the data should differ depending on the time since drug approval, the volume of data and the type of drug
- Recognise the PSUR pitfalls and grey areas and how they could be overcome
- Identify the links and partial overlap between PSURs and other pharmacovigilance/drug safety documents
- Discuss how a signal can be identified and analysed in the context of a PSUR

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Pre-Conference Tutorials 09:00-12:30

Target Audience
- Medical writers and pharmacovigilance personnel relatively new to PSURs and those with some experience in writing, contributing to and/or analysing PSUR data
- Regulatory affairs professionals may also benefit from the tutorial

It is recommended that attendees with no previous PSUR experience read the ICH E2C guideline and 'Volume IXa of the Rules Governing Medicinal Products in the EU' before the tutorial.

TUTORIAL 5

ANALYSIS OF SAFETY DATA FROM CLINICAL TRIALS

Jürgen Kübler, Global Head, Statistical Safety Sciences, Novartis Pharma AG, Switzerland
Joachim Vollmar, Executive Consultant, International Clinical Development Consultants, USA

This tutorial is a combination of theory, guidelines, practical considerations and real-life solutions for those working in the clinical development environment (pharmaceutical, biotech industry or CRO). The aim of this course is to provide a basic understanding of the underlying methodology and the current guidelines on safety data. Aspects regarding the planning of clinical trials as well as the problems and pitfalls during the analysis of safety data will be presented. The presentations will also include case studies.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Understand relevant guidelines and regulatory requirements
- Contribute to safety analysis plans
- Assess statistical safety analyses
- Identify pitfalls in safety analyses

Target Audience
Clinical researchers, drug safety specialists, medical writers, investigators, biostatisticians and project managers

TUTORIAL 6

OPERATION OF EUROPEAN REGISTRATION PROCEDURES: CENTRALISED, MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

Truus Janse-de Hoog, Staff Member European Cluster, Medicines Evaluation Board, The Netherlands, Chair CMD(h)
Anu Tummavuori-Liemann, Associate Director European Regulatory Liaison Celgene International Sarl, Switzerland
EMEA representative invited

Presented by representatives from a national authority, EMEA and industry, this tutorial will provide a pragmatic view on how EU registration procedures work. The basic principles of the centralised, mutual recognition and decentralised procedures will be explained. Hints and tips will be given how to avoid delays in the procedures and how to prepare for submissions of applications that can involve 30 Member States.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Discuss the basic principles of centralised and mutual recognition procedures
- Recognise the difficulties that can be experienced during the operation of these procedures and apply practical solutions
- Describe the changes in the procedures as a consequence of new legislation

Target Audience
Regulatory affairs, pharmaceutical industry personnel and students

TUTORIAL 7

INTERACTIONS BETWEEN THE REGULATORY REGIME AND THE LEGAL PRINCIPLES GOVERNING INTELLECTUAL PROPERTY, COMPETITION, AND PRODUCT LIABILITY FOR NON-LAWYERS

Geneviève Michaux, Special Counsel, Covington & Burling, Belgium

Interactions between, on the one hand, the regulatory regime and, on the other hand, intellectual property, competition, and product liability rules are increasing. As a result, those matters can no longer be approached in isolation, and a more comprehensive perspective is required when addressing regulatory issues. The tutorial will explain key concepts of the laws governing intellectual property, competition, and product liability and discuss how they relate to the regulatory pharmaceutical regime. The tutorial is designed for non-lawyers with considerable regulatory experience and for regulatory lawyers who want to learn the basics of intellectual property, competition, and product liability rules as they apply in the pharmaceutical sector.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Explain and discuss the basics of intellectual property, competition and product liability rules applicable to medicinal products
- Identify and better address the regulatory issues that present an intellectual property, competition or product liability aspect

Target Audience
All persons involved in regulatory affairs and in-house regulatory lawyers.

TUTORIAL 8

QUALIFIED PERSON FOR PHARMACOVIGILANCE: WHAT DO YOU NEED TO KNOW?

Brian Edwards, Director Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK
Keith Wimbley, NDA Regulatory Science Ltd., UK

Recent European legislation, as well as Volume 9A, requires all marketing authorisation holders to have one qualified person for pharmacovigilance (QPPV) with responsibility for establishing and maintaining all aspects of the company's global pharmacovigilance system. Although acknowledged to be a vital function, there is little practical guidance on how QP responsibilities should best be conducted, while maintaining compliance with regulatory requirements. The jurisdiction of the QPPV stretches to wherever there is an active licence for a product authorised in the EU. Thus the role in many companies has a global impact. During this tutorial we will discuss and advise on current practice to help address issues such as:

- What does being qualified mean in practice for the QPPV and the organisation?
- What are appropriate contractual obligations and job descriptions to cover points such as 24-hour availability, workload, personal indemnity, delegation and adequate back-up?
- How QPPV activities should be documented to allow adequate quality assurance
- How inspectors and regulatory authorities regard the EU QPPV role and expectations for involvement in the entire PV system
- How to make the QPPV role work in practice using examples from both large and small companies, including CROs
- How to optimise interactions between the company as a whole and the QPPV to obtain adequate mutual oversight and support
- What should be QPPV input into post-authorisation commitments and risk management plans
- How should the interface between the QPPV and quality function work in practice
- How the QPPV function relates to national nominated individuals for safety

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Pre-Conference Tutorials 09:00-12:30

The speakers will also update the audience about whether there should be an appropriate forum to allow QPPVs across the industry to interact and share best practice to the mutual benefit of both public health and industry alike.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Explain legal, regulatory and business implications surrounding the QPPV function to permit effective implementation of this role
- Describe the range of expectations to have about a QPPV
- Understand the different approaches taken by other companies
- Better understand the expectations of regulators and inspectors

Target Audience
Professionals in companies who will shortly be setting up pharmacovigilance operations in Europe or with experience in post-marketing clinical safety and who are involved in:
- Pharmacovigilance
- Clinical Research
- Risk Management
- Medical product safety assessment
- Data analysis
- Epidemiology
- Labelling
- Quality Assurance/Quality Control
- Compliance
- Qualified persons for pharmacovigilance (QPPV)
- Deputy QPPVs
- Contract research organisations and consultants

TUTORIAL 9

HEALTH ECONOMICS AND HTA – HOW TO DEMONSTRATE PRODUCT VALUE

Carolin Miltenburger, Director Health Economics and Outcomes, i3 Innovus, Germany
Linus Jönsson, Vice President, i3 Innovus, Germany

This tutorial is a combination of concepts, guidelines, methods and case studies for those working in the clinical development and regulatory environment (industry, agency, CRO). The aim is to provide a basic understanding of the methods and standards in health economics and outcomes research such as study designs, modelling, and observational studies and retrospective database analysis.

- Economic modelling
- Retrospective database analysis
- Patient-reported outcomes
- Observational studies

Learning Objectives
At the conclusion of this tutorial, participants will be able to:
- Understand different types of economic analysis and the principles of health economic simulation models.
- Understand how data from different sources are integrated in a framework of costs and benefits based on a range of different data sources presented.

For patient reported outcomes, participants should have a good basic understanding of concepts and methodologies to quantify subjective assessment of health by patients. The use of health economics in development and commercialisation of health technologies will be presented from a practical perspective.

Target Audience
Clinical development, regulatory affairs, medical affairs, pharmacovigilance/drug safety, corporate or government affairs, health policy

TUTORIAL 10

MEDICAL DEVICE LEGISLATION FROM A PHARMACEUTICAL POINT OF VIEW: RECOGNISE THE DIFFERENCES AND THE ADVANTAGES

Jos Kraus, Senior Inspector, Health Care Inspectorate, The Netherlands
Waldo Weijers, Coordinator Consultation Procedures for Medicated Medicinal Devices, Medicines Evaluation Board, The Netherlands

In this tutorial the Medical Device Directive (92/42 upgraded with 2007/47) will be explained from a pharmaceutical point of view, with special focus on the following issues:
- How to overcome the hurdles of putting a combination product on the market
- The role of the Notified Body and Medicinal Product Agency in the design-to-market process
- The best strategy for combination products containing new chemical entities and for combination products with marketed pharmaceutical substances
- How to collect clinical data without performing clinical studies

Learning Objectives
At the conclusion of this tutorial, participants will be able to:
- Identify the main characteristics of the European Medical Device regulatory system
- Identify the main topics of the EU Medical Device Directive (Directive 93/42 as amended by Directive 2007/47), including the provisions on risk classification, combination products and delineation with pharmaceutical products
- Define how the system of conformity assessment by Notified Bodies works
- Identify the roles of Competent Authorities for Medical Devices and for Medicinal Product Agencies
- Set up a list of criteria for selection of a Notified Body

Target Audience
- All those who are new to or not familiar with medical device legislation and who would like to have a condensed overview
- Trained professionals in pharmaceutical legislation, who are not familiar with the medical device legislation for combination products (medical device/medicinal product/biological)

TUTORIAL 11

EUROPEAN PHARMA LAW FOR NON-LAWYERS: PRINCIPLES OF PHARMACEUTICAL LEGISLATION AND CASE LAW

John A. Lisman, Senior Associate, NautaDutilh N.V., The Netherlands
Peter Bogaert, Partner, Covington & Burling LLP, Belgium

The pharmaceutical industry and competent authorities work in a legal environment, but many workers in regulatory affairs are non-lawyers. In this tutorial, the legal background of regulatory affairs will be explained and discussed. The tutorial will address the sources of law and the main legal topics: patents, data exclusivity, parallel import, etc. Furthermore, the European procedures for Marketing Authorisations will be discussed in a legal context.

Learning Objectives
At the conclusion of this tutorial, participants will be able to:
- Explain the sources of law in the European Union
- Describe the key legal topics in relation to pharmaceutical legislation
- Analyse legal aspects of the marketing authorisaton procedures in the EU

Target Audience
This tutorial is designed for non-lawyers with an interest in European Union law related to regulatory affairs.

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Pre-Conference Tutorials 09:00-12:30

TUTORIAL 12

FROM CREATION TO VARIATION: SUCCESSFUL ECTD COMPILATION

Olaf Schoepke, Managing Director, Extedo Limited, UK

During the tutorial, participants will be guided through the process of creating eCTD-ready documents, assembling these in an eCTD submission, and how to validate and publish eCTDs effectively. The process will focus on submissions in the EU with regional differences and expectations. Once submitted, the audience will learn how agencies validate and review their applications, from first submission to eCTD lifecycle.

Learning Objectives
The objective of this tutorial is to explain and demonstrate to the audience a clear path of how an eCTD is assembled, from document creation to eCTD variation.

Target Audience
Regulatory, IT, publisher, submission manager, document management

TUTORIAL 13

COMMON SENSE COMPUTER COMPLIANCE PRACTICES FOR MEDICAL SITES AND CROS PERFORMING CLINICAL TRIALS

Teri Stokes, Director, GXP International, USA

This tutorial will provide answers to the following questions:
- Without being computer professionals, how do we identify those systems at our medical site that are subject to GCP/21 CFR Part 11 regulations?
- How do we perform a risk analysis and document the current compliance status of the GCP systems identified at our site for a specific trial and across trials?
- What support should we get from any study sponsor for the EDC technology they provide for a trial? (eCRF, IVRS, E-Diary, E-Device)
- Without being computer professionals, how can we prepare an Electronic Data Quality Plan for a specific trial at our site?
- How do we prepare for and host audits and inspections of computer systems at our site?

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Identify and perform a risk analysis for computerised systems at their site that are subject to GCP/21CRF Part 11 regulations
- Document the current compliance status of GCP systems identified for a specific trial at a site
- Prepare an Electronic Data Quality Plan for a specific clinical trial at a site without being computer professionals
- Better host audits and inspections of site computer systems for site qualification or study inspection purposes

Target Audience
CRAs and monitors from industry and CROs, QA professionals, GCP/Part 11 Auditors and Inspectors, study site coordinators and clinical investigators, CRO and medical site IT practitioners

TUTORIAL 14

SIGNAL DETECTION METHODS FOR BEGINNERS – OVERVIEW AND CASE STUDIES

Stephen Jolley, Vice President, Pharmacovigilance, Patni Life Sciences, USA
David Olaleye, Senior Analytical Consultant, SAS Institute Inc., USA
William Smedley, Associate Director, PV Operations, Shire Pharmaceuticals, USA

This tutorial will provide a theoretical and methodological review of the application of signal detection and data mining techniques to safety surveillance. An overview of strategies and specific situation applications will be presented.

Highlights
- Recommended approach to signal detection and use of data mining techniques
- Use of visualisation tools to enhance signal detection
- Comparison of approaches for a large and a small company

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise the basic concepts of data mining and principles of signal detection
- Outline how to apply these techniques within their company
- Discuss data mining techniques to analyse large volumes of adverse event report data

Target Audience
Clinical safety professionals involved in:
- Pharmacovigilance
- Pharmacoepidemiology
- Regulatory affairs
- Quality assurance
- Medical product safety assessment
- Labelling

TUTORIAL 15

THE "QUALITY-BY-DESIGN" INITIATIVE – A LOOK INSIDE FROM MULTIPLE ANGLES

Gert Thurau, Associate Director, Merck & Co., Inc., USA

Quality-by-Design (QbD) is a concept that has the potential for introducing transformational changes to the way pharmaceutical products are developed, registered and manufactured. With the regulatory aspect of QbD anchored around the ICH guidelines ICH Q8, Q9 and Q10, industry has embraced QbD as beneficial for both the patient and their business processes in R&D and manufacturing. On the technical level QbD supports concepts like risk management, continuous improvement and the overall modernisation of pharmaceutical manufacturing. This new concept is also expected to be implemented into the EU Variations framework via the revised legislation. A reality check of the much described vision will be performed, based on recent implementation of QbD concepts into practice by several pharmaceutical companies both in newly developed and in line products. This tutorial will give an introduction to the overall framework of QbD as well as provide an overview of regulatory and technical approaches currently discussed and utilised to push the envelope beyond the previously accepted boundaries, including the utilisation of enablers like risk management and Process Analytical Technology (PAT). Both of these previously existing approaches have been recognised as core tools for QbD practitioners, leading to true benefits like continuous improvement or real time product release testing. Presentations on both industry and regulatory interpretations and expectations will be combined with an overview of currently available guidance and interpretation. Finally, real life examples of QbD will help to illustrate what opportunities QbD is opening up

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and where its real potential lies for the enhancement of the post approval framework to ensure the safety and benefit of patients.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Identify and analyse Quality by Design (QbD) approaches to product and process development
- Assess the current regulatory positions on QbD
- Define how the concept could be used in their own work to further patient safety and benefits.

Target Audience
- Physicians, pharmacist and pharmaceutical scientists involved in product (synthesis and formulation) and manufacturing process development
- Regulatory personnel involved in drug registration (CMC)
- Manufacturing personnel with innovation needs
- Regulators with interest in real life QbD examples

TUTORIAL 16

NEW STRATEGIES IN NON-CLINICAL SAFETY TESTING

Gerd Bode, Lecturer, University of Göttingen and Consultant, Germany
Klaus Olejniczak, Scientific Director, BfArM, Germany

Relevant guidelines and new trends will be addressed. The focus will also be on the new draft ICH guidelines. The speakers share with you their proposals for improving strategies in the preclinical development phase. They give advice based on their long-term experience as topic leaders in the International Conferences on Harmonisation. Attendees will be updated in regulatory guidances and their interpretations.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise objectives and strategies in toxicology
- Improve the use of preclinical safety data
- Understand better the agencies' requirements for safety.

Target Audience
Non-toxicologists or beginners in toxicology, regulatory affairs personnel, clinical colleagues, project team leaders and members.

TUTORIAL 17

ADVANCED THERAPIES – A NEW LEGISLATIVE FRAMEWORK FOR CELL-BASED MEDICINAL PRODUCTS

Christa Schröder, Scientific and Regulatory Advisor, Paul-Ehrlich-Institute, Germany
Barbara Sickmueller, Deputy Director General, German Pharmaceutical Industry Association (BPI), Germany
Matthias Wilken, Head of Drug Regulatory Affairs Europe, German Pharmaceutical Industry Association (BPI), Germany

This tutorial will provide an overview of the new legislative framework regarding advanced therapy medicinal products (somatic cell therapy, gene therapy, tissue engineering): the new Regulation (EC) 1394/2007, Annex I to Directive 2001/83/EC, Guidelines of CHMP Working Parties. The established system regarding GMP, GCP and pharmacovigilance has to be adapted to these new products. In the context of medical device regulations the requirements of the Advanced Therapy Regulation will be discussed. Pros and cons of the European system for SME's (provisions for certification of quality and non-clinical data for small and medium-sized enterprises (SMEs), pursuant to Article 18 of Regulation (EC) No 1394/2007, fees, etc.) will be considered. The tutorial will give a brief overview for people with basic knowledge in this field. For people with advanced knowledge, a session on Advanced Therapies has been organised.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Understand the new legislative framework regarding cell-based medicinal products
- Describe the implications of both Regulation (EC) 1394/2007 on Advanced Therapies Medicinal Products and Directive 2004/23/EC (European Cell and Tissue Directive)
- Identify key aspects of the new regulatory framework and put the new framework in the context of existing legislations and soft-law (e. g. GCP, GMP)

Target Audience
R&D, regulatory affairs, strategic planning, regulatory agency personnel, all participants interested in gaining an overview in the emerging field of somatic cell therapy, gene therapy and tissue engineering

TUTORIAL 18

ADAPTIVE DESIGNS FOR CONFIRMATORY CLINICAL TRIALS

Norbert Benda, Statistical Methodologist, Novartis Pharma AG, Switzerland
Heinz Schmidli, Statistical Methodologist, Novartis Pharma AG, Switzerland

This tutorial will give an introduction to the theory and practice of adaptive designs for pivotal clinical trials. Adaptive designs allow for mid-course design modifications such as the adjustment of sample size, the dropping of treatment arms or the selection of a subpopulation. We will review and discuss statistical methodology that allows such adaptations without compromising the overall type I error rate. All methods will be illustrated by examples. Several case studies will be presented, explaining in detail both methodological and practical issues which arise in designing and analysing an adaptive clinical trial.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Understand the principles, opportunities and challenges for adaptive designs
- Understand operational considerations

Target Audience
Clinical project team members within drug development.

TUTORIAL 19

CAN EUROPEAN HERBAL MEDICINES BECOME AMERICAN BOTANICAL DRUGS? THE RISING GLOBAL MARKET OPPORTUNITY OF COMPLEMENTARY MEDICINE

Nadina C. José, Clinical Site Network Manager, Medicus Research LLC, USA
Jay Udani, CEO and Medical Director, Medicus Research LLC, USA

European Herbal Medicines continue to experience growth with expansion into the Eastern European markets. Part of this rising trend is the movement towards harmonising systems of training, registration and the practice of complementary medicine in the European Union. This surge has still to make its way to a larger untapped opportunity which exists in the US. This tutorial will compare and contrast the regulatory, marketing, manufacturing and clinical development pathways of dietary supplements, medical foods and botanical drugs with those of Drugs/Devices and with European Herbal Medicines. Detailed knowledge, planning and experience are required to navigate the regulatory and marketing waters of dietary supplements, medical foods, herbal medicines and botanical drugs. Participants will be better prepared to formulate and evaluate their own global expansion plans with the knowledge acquired during this tutorial. An overview will be given of the current environment for

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complementary/integrative medicine, followed by a presentation on the development cycle, regulatory pathway/or registration, marketing of herbal medicines/botanicals vs. drugs vs. biotech globally and, then concluding the tutorial, an interactive Q & A session.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Identify and describe the clinical development path required to maximise the dietary supplement, medical food, and/or botanical drug markets
- Compare and contrast the market opportunities for Herbal Medicines in Europe with dietary supplements, medical foods, and botanical drugs in the US
- Assess the current increase in the use of "alternative/complementary" (EU) or "integrative" (US) therapies in the global medical practice arena
- Differentiate the regulatory, manufacturing, and marketing requirements of dietary supplements, medical foods, and botanical drugs in the US market from those of Herbal Medicines in Europe

Target Audience
- Scientific, Marketing, and Strategic executives of European Herbal Medicine companies who are considering global expansion of their market.
- Pharmaceutical and biotech project team members about to conduct clinical trials on herbal/botanical products

TUTORIAL 20

CLINICAL STATISTICS FOR NON-STATISTICIANS

Kerry Gordon, Senior Director, Biostatistics, Quintiles Ltd., UK

This short course is designed to be an introduction of basic statistical concepts fundamental to clinical research, for professionals who have regular exposure to statistics either through studies or professional experience. The material is roughly equivalent to an introductory statistics course. While it includes a few formulae for individuals who are interested in computational details, the course emphasizes the application of statistical concepts to clinical investigation.

Learning Objectives
At the conclusion of this course, participants should be able to:
- Discuss basic statistical concepts such as variability, confidence intervals, hypotheses testing and p-values
- Distinguish various study designs and identify techniques to avoid bias
- Understand the difference between superiority, equivalence and non-inferiority objectives
- Interpret some common statistics regularly used in clinical trials

Target Audience
This course will particularly benefit professionals who must understand and work with statistical concepts related to clinical research. It assumes a basic understanding of statistics (either through professional experience or studies) roughly equivalent to an introductory statistics course.

TUTORIAL 21

REFERRALS TO CHMP- ALL YOU WANT TO KNOW

Marisa Papaluca Amati, Deputy Head of Sector, Safety and Efficacy of Medicines, EMEA
Zaide Frias, Scientific Administrator, Legal/Regulatory Affairs, EMEA, EU
Thomas Larsson, EMEA, EU
Mats Marfalt, Cardiovascular Portfolio Leader, European Regulatory Affairs, AstraZeneca, Sweden

This tutorial is designed to increase the understanding of referrals procedure, promote available tools to reduce the likelihood of a referral and improve transparency in this field. Topics to be covered will include:
- Referrals: The Regulatory Context
- Art 29 & 30: How CHMP reconciles areas of technical disagreement/benefits of referrals
- Art 31 Referrals: A Case Study
- Referrals: Industry Experience

Learning Objectives
At the conclusion of this course, participants should be able to:
- Understand the referrals procedure
- Identify available tools to reduce the likelihood of a referral
- Identify ways to improve transparency in this field

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 1
Audits and Inspections – The Evolution of GCP into a Holistic Approach to Quality Management

Theme Leaders:
Gabriele Schwarz, Head, GCP Inspection Services BfArM, Germany
Helena Van den Dungen, Head Country Management CQA, Novartis Pharma AG, Switzerland

Sponsors of clinical trials as well as their contractual partners are forced to implement effective quality assurance and quality control arrangements in order to meet the growing expectations regarding the quality of clinical trials and products. These arrangements need to cover a wide range of facilities, functions and processes. In the theme "Audit and Inspections", experiences of specific topics such as audits and inspections of e-CRFS and e-source data, data analysis, pharmacovigilance and quality aspects of Advanced Therapy Products will be shared. The presentations will also cover challenges related to the delegation of sponsor functions to CROs and other third parties, quality risk management tools and issue escalation. As more and more products are developed and marketed in a global setting, ethical and quality standards need to be harmonised to enable the effective planning and execution of clinical trials, audits and inspections. Representatives from EU, US and other Third Country Regulatory Authorities will discuss their international GCP inspection programmes, procedures and experiences. Over the last few years, European Competent Authorities have obtained increasing information about serious GCP breaches, including falsification and fraud. One session will discuss sponsor, investigator and patient responsibilities and how to detect, report and avoid those cases.

Tuesday, March 24, 2009

09:00 **Session 1**

INTERNATIONAL GCP INSPECTION EXPERIENCES
Session Co-Chairs:
Gabriele Schwarz, Head, GCP Inspection Services BfArM, Germany
Fergus Sweeney, Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, EMEA, EU

This session will provide insight into clinical trial regulations in place in various regions such as the US, the EU and the Far East. It will be discussed how and to what extent data generated during clinical trials conducted in foreign countries/regions will be accepted. Furthermore the mechanisms of conducting GCP inspection in foreign countries/regions will be presented from the various authorities' point of view. The overall goal of the session will be to contribute to the harmonisation process of globally aligning the regulatory requirements on clinical trials that are subject to filing for marketing authorisations at any authority.

Yuichi Kato, Director, Office of Conformity Audit, PMDA, Japan

David Lepay, Senior Advisor for Clinical Science, Science and Health Coordination, OC, FDA, USA

11:00 **Session 2**

THE DRUG SAFETY SYSTEM: CHALLENGES AND OPPORTUNITIES
Session Chair:
Helen Motamen, Associate Director GCS&P Quality Assurance, UCB, UK

Regulatory authorities throughout the world heavily regulate activities of drug safety and pharmacovigilance. As a consequence of recent drug safety-related regulatory actions and revision of the Rules Governing Medicinal Products in the European Union, regulatory agencies have substantially increased their focus and investment for drug safety surveillance activities – not only of internal processes, but also in regard to supervision of industry. Failure to comply with these requirements may result in significant negative regulatory, legal, and public opinion impact.

Creating Pharmacovigilance Quality Assurance
Helen Motamen, Associate Director GCS&P Quality Assurance, UCB, UK

The Drug Safety System: Challenges and Opportunities for Small/Start-Up Companies
Thierry Hamard, Director, PV Focus, France

Safety Management during Clinical Trials: Challenges from a Regulator's Perspective
Emmanuelle Pinès, PV Inspector, Afssaps, France

14:00 **Session 3**

AUDITS AND INSPECTIONS ON e-CRFS AND e-SOURCE DATA
Session Chair:
Teri E. Stokes, Director, GXP International, USA

Computers are a necessary part of every clinical trial today and the role of Inspectors and Auditors has refocused from verifying paper CRFs, paper patient diaries, and other paper medical records to verifying e-CRFs, e-diaries, e-medical records, and a variety of other electronic source data.
Speakers in this session will share their experiences with auditing electronic source data and the EU GCP Inspectors' white paper on the inspection process for e-source data in clinical trials.

Detecting Fraud in E-Source Data - A CRO Auditor's View
Sabine Brunschoen-Harti, Associate Director Quality, Process & Training, Clinical Operations Central Europe, PAREXEL International GmbH, Berlin, Germany

Electronic Source Documents in Clinical Trials - Inspection Issues
Lisbeth Bregnhøf, Medicines Inspector, Danish Medicines Agency, Denmark

Electronic Data Quality: Challenges and Opportunity for CRA's and Study Teams
Teri E. Stokes, Director, GXP International, USA

16:00 **Session 4**

DELEGATION OF SPONSOR FUNCTIONS TO CROS AND OTHER THIRD PARTIES – HOW TO STAY ON TOP OF THINGS
Session Chair:
Ferdinand Hundt, Director, Clinical Operations, sanofi-aventis Deutschland GmbH, Germany

The session will discuss needs and expectations of sponsors in selecting suppliers and will cover the practicalities of getting things started. This will include topics like preferred providers, project progress, how changes are reflected and performance measured. Finally the collaboration between sponsor and vendors before, during and after audits will be discussed, focusing on how to audit processes to detect, correct and prevent failures.

A Risk-Based Approach to Supplier Selection
Siegfried Schmitt, Principal Consultant, PAREXEL, UK

What is Expected from Contracts and Technical Agreements?
Liz Hilton, Head of GCP Study Audit Management Africa/Middle East/Asia, Bayer, UK

How to Audit the Role of the Vendor in the Conduct of Outsourced Studies
Kristel van der Voorde, Director WW Regulatory Compliance – Europe, Bristol-Myers Squibb, Belgium

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Wednesday, March 25, 2009

09:00 **Session 5**

SERIOUS GCP BREACHES INCLUDING FALSIFICATION AND FRAUD – HOW TO DETECT, COMMUNICATE AND AVOID THEM

Session Chair:
Helena Van den Dungen, Global Head Country Management CQA, Novartis Pharma AG, Switzerland

The discovery of a serious GCP breach in the conduct of a clincal trial results in an often highly difficult and complex situation for both the sponsor as well as for the Regulatory Authorities. In such a situation, ensuring patient protection and safety is of prime importance. Likewise, it is important to assess the implication for the quality and trustworthiness of the clinical trial data at the site as well as for the whole trial. To contain the problem, evaluate its impact on patients and trial data and to secure as much of the trial data are equally challenging. How can sponsor companies and Regulatory Authorities work best together to limit the damage to patients and clinical trial data.

Serious GCP Breaches: How Can We Deal with the Situation?
Helena Van den Dungen, Global Head Country Management CQA, Novartis Pharma AG, Switzerland

Auditing In Third World Countries
Alec Deighton, Senior Director, QA & Compliance, PharmaNet, UK

Misconduct in Clinical Trials: The French Experience
Pierre-Henri Bertoye, Inspectorate and Companies Associate Director, Afssaps, France

11:00 **Session 6**

NEW APPROACHES TO QUALITY RISK MANAGEMENT AND RISK DETECTION

Session Chair:
Beat Widler, Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche AG, Switzerland

This session will consider recurrence of critical inspection or audit findings even when established systems and processes are used or when processes are managed by experienced stakeholders; evidence that quality cannot be effectively ensured through auditing and other compliance activities. The session will review how FMEA methodology combined with 'intel-ligent' data mining allows for a proactive and systematic oversight of processes and data.

Quality Risk Management - A Novel Concept for Quality Management
Peter Schiemann, Quality Risk Management Project Leader, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Mining Study Clinical Data for Knowledge-Based Audit Planning
Grant Simmons, Head, CQA Operations, Novartis Pharmaceuticals Corporation, USA

Dynamic Auditing
Robrecht Tistaert, Associate Director CQA, PPD International, Belgium

14:00 **Session 7**

THE QUALITY OF ADVANCE THERAPY PRODUCTS- REGULATORY AND PRACTICAL CHALLENGES

Session Chair:
Margarida Menezes Ferreira, R & D Coodinator, INFARMED, I.P., Portugal; Biologicals Working Party and Cell Products Working Party Member, EMEA

Advanced therapy medicinal products such as cell-based therapies, gene therapy and tissue engineering have particular features related to the highly complex nature of the active substance and final product, their manufacturing process and to the delivery to the patient. For these highly diverse medicines EU legislation introduces a risk-based approach to building development, marketing authorisation documentation and risk management. The quality requirements for marketing authorisation of these products as ultimate goal will be addressed with special focus on cell-based products. Process validation for the clinical development of the now well-established biological products will be presented to provide a platform for the discussion on validation challenges and GMP issues for the advanced therapy products where existing concepts can be built upon to accommodate the challenges of process validation associated with advanced therapies.

Harmony in Diversity-Regulatory Challenges with the Quality of Advanced Therapies
Margarida Menezes Ferreira, R & D Coodinator, INFARMED, I.P., Portugal; Biologicals Working Party and Cell Products Working Party Member, EMEA

Process Validation During Clinical Development of Biological Medicinal Products
Cecil Nick, Vice President (Biotechnology), PAREXEL Consulting, Uxbridge UK

Common Issues Raised During the Inspection of Advanced Therapy Medicinal Product Manufacturing Sites - An Inspector's Viewpoint
Kevin Page, Medicines Inspector, GMP Inspections Team, MHRA, UK

16:00 Session 8

AUDITS AND INSPECTIONS OF DATA MANAGEMENT AND ANALYSIS

Session Chair:
Ursula Streicher-Saied, Head of Global R & D Quality, Bayer Schering Pharma, Germany

The session will address an approach to auditing the data management function/procedures in a globally acting company. It will also give an insight in best practice observed in conducting data center audits and provide a checklist for conducting such audits in future. Furthermore, it will consider the inspector's perspective with regard to challenges and pitfalls in data analysis.

Data Management System Audit - Experiences and Lessons Learned
Evelin Hänisch, Senior Global System Auditor, Bayer Schering Pharma AG, Germany

Auditing Data Centers and Formal Testing Practices
Teri E. Stokes, Director, GXP International, USA

Challenges and Pitfalls in Data Analysis from an Inspector's Perspective
Katharina Kurpanek, GCP Inspector, GCP Inspection Services BfArM, Germany

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 2
Regulatory Challenges and Controversies - Balancing Access with Safety and Affordability Aspects

Theme Leaders:
Kerstin Franzén, Senior Director Worldwide Regulatory Policy & Intelligence, Pfizer AB, Sweden
Dagmar Stará, Head of the EU Affairs Coordination Unit, State Institute for Drug Control, Slovak Republic

Efforts are being made today to bring new treatments to the market in a timely manner, especially in areas where there are no or insufficient treatments available. At the same time, safety awareness is key and increasingly of importance. Another factor to consider is the affordability of medical treatments. The early access to new treatments must be sensibly balanced with safety considerations and affordability aspects in order to safeguard public health. This is the vision for the theme as these aspects have important implications for the regulatory environment and impact the regulatory process. The sessions will discuss different factors playing into this equation, such as new pharmacometric approaches and the related regulatory dialogue; the benefit–risk aspects and how to communicate this in a way that can be understood by the lay people; cost aspects. The regulatory challenges connected with this will be highlighted.

Tuesday, March 24, 2009

09:00 **Session 1**

SAFEGUARDING PUBLIC HEALTH: BALANCING ACCESS WITH SAFETY AND AFFORDABILITY ASPECTS
Session Co-Chairs:
Hans-Georg Eichler, Senior Medical Officer, EMEA, EU
Kerstin Franzén, Senior Director Worldwide Regulatory Policy & Intelligence, Pfizer AB, Sweden

Timing for access to market for new medicines is an act of balancing the need for early access for patients with the need for adequate information and data on safety. Access by patients is increasingly driven by considerations of affordability. Safety awareness has increased over the past few years but must be weighed against the efficacy; there may be risks associated with the disease if medical treatment is not used or is not available. In this session it will be discussed how this balance can be approached in a sensible way, seen from the perspective of different stakeholders.

Role, Responsibility and Duty of the Payer to the Public
Ann-Christin Tauberman, Director General, The Dental and Pharmaceutical Benefits Agency (TLV), Sweden

How Can the European Commission Ensure Equitable Access to Drugs?
Martin Terberger, Head of Pharmaceuticals Unit, DG Enterprise and Industry, European Commission, EU

How Can the Pharmaceutical Industry Contribute to a Reasonable Balance?
Susan Forda, Vice President, Regulatory Affairs, Eli Lilly & Company Ltd., UK

11:00 **Session 2**

THE CHANGING PERCEPTIONS OF THE BENEFIT/RISK BALANCE
Session Chair:
Eric Abadie, Chairman, CHMP, EMEA, EU, General Directorate, Afssaps, France

The benefit–risk balance concept is evolving and CHMP has announced that they will look at how the balance might be viewed in a quantitative way. The balance might also be viewed differently depending on who the stakeholder is and whether risk is perceived the same way by all. These questions will be discussed in the session where some perhaps provocative views will be presented.

Patients' Perception of Benefit / Risk - Does It Make Any Difference?
Mary Baker, President, European Parkinson's Disease Association (EPDA), UK

Regulators' Assessment of Benefit and Risk: Between Realism and Protection
Bruno Flamion, Chair Scientific Advice Working Party, CHMP, Professor Clinical Pharmacology, University of Namur, Belgium

Perception of Benefit and of Risk at Different Stages of a Product Lifecycle and its Consequences
Paul Coplan, Senior Director, Risk Management, Global Safety Surveillance, Epidemiology and Labelling, Wyeth Research, USA

14:00 **Session 3**

APPLICATIONS OF NOVEL PHARMACOMETRIC APPROACHES FOR INTERNAL DECISION MAKING AND REGULATORY SUBMISSION
Session Chair:
Robert Hemmings, Statistics Unit Manager, MHRA, UK and CHMP

The session will focus on how new pharmacometric approaches can bring value to drug development and to the regulatory process. What is the current experience within the industry and in which areas will these methods prove most fruitful in the future? How will agencies receive these novel approaches and what is the procedure for 'qualification' of these methods? The pros and cons of use for decision making will be brought out through consideration of case studies.

Pharmacometric Approaches to Drug Development in Paediatrics
Gerard Pons, Vice-Chair Paediatric Committee (PDCO), Head Clinical Pharmacology, University René Descartes, France

Modelling and Simulation for Decision-Making – PK / PD modelling
Peter Milligan, Head of Clinical Pharmacometrics, Pfizer Global Research & Development, UK

PK/PD Modelling to Inform Dose-Selection Trial with an Adaptive Design
Amy Racine, Biostatistician, Novartis Pharma AG, Switzerland

16:00 **Session 4**

HOW CAN REGULATORS ENGAGE IN NOVEL DRUG DEVELOPMENT? REVISITING THE REGULATOR – INDUSTRY DIALOGUE
Session Chair:
Per Nilsson, Head of Strategic Clinical Development, Actelion Pharmaceuticals Ltd., Switzerland

The biomarker qualification process will be covered, how and when could it contribute to early, and safe, access. What would be the perceived benefit for patients? Would an EU-US cluster on biomarkers be an advantage? Should Japan be involved? What is the value of the different regulator meetings for the development process; briefing meetings SAWP, joint SA, etc.? Could there be any potential conflict of interest? There will be an update from PSTC.

Qualifications of Biomarkers - A Model for the Way Forward?
Spiros Vamvakas, Acting Deputy Head of Sector, Scientific Advice and Orphan Drugs, EMEA, EU

Biomarkers and Other Topics for Early Meeting. Is there a Value and Who Should You Ask?
Bertil Jonsson, Senior Expert, MPA, Sweden

Scientific Advice for Innovative Approaches to Therapy: How to Make Most Out of It
Andrea Stefanie Braun-Scherhaug, Head of Regulatory Affairs, Roche Pharma AG, Germany

Early SA: What Are Companies Actually Doing and Why (Not)? From SME to Large Pharma - The Consultant's View
Olof Tydén, Associate Professor, Partner, Eureda, Sweden

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Wednesday, March 25, 2009

09:00 **Session 5**

BUILDING HTA INTO THE PROCESS: MEETING THE NEEDS OF LICENSING AUTHORITIES, PAYERS AND PATIENTS

Session Co-Chairs:
Dagmar Stará, Head of Registration Unit, State Institute for Drug Control, Slovak Republic
Clare McGrath, Senior Director Evidence Based Strategies, Medical Division, Pfizer Ltd., UK

This session will clarify the distinction between licensing and purchasing decision making. It will also explore whether there are opportunities for these distinct systems to learn from each other, methods and processes that might address some of their current issues and optimise public health in the EU including access to medicines. What has already been learned from the development of the licensing processes in terms of scientific standards and processes? What are the specific needs of purchasers and patients? Can all of these requirements be anticipated for a drug development programme that needs to think 15 years down the line?
The session will be organised in the form of a mini-panel with short presentations followed by a discussion.

Marketing Authorisation and HTA: Purposes, Scientific Standards and Opportunities to Progress
Hans-Georg Eichler, Senior Medical Officer, EMEA, EU

Meeting the Needs of the Payer Community in EU Countries
Ad R. Schuurman, Head of Reimbursement Department, the Health Care Insurance Board (CVZ), Chair MEDEV, The Netherlands

Health Technology Assessment and Regulatory Review of a Product - What Are the Proper Legal Criteria?
Peter Bogaert, Partner, Covington & Burling LLP, Belgium

Challenges and Opportunities in Meeting the Needs of Reimbursement and Licensing Authorities in the Development Process
Clare McGrath, Senior Director Evidence Based Strategies, Medical Division, Pfizer Ltd., UK

Key Success Factors for an EU Cooperation on HTA
Jérôme Boehm, Head of Pharmaceuticals Sector, Health and Consumers Directorate General, European Commission, EU

11:00 **Session 6**

ENABLING EARLY ACCESS

Session Chair:
Mike Doherty, Global Head, Pharma Regulatory Affairs, F. Hoffmann-La Roche AG, Switzerland

Conditional approvals, as well as accelerated assessment, are to be to be covered. If CA and AA will become used more often, do we need more specified treatment criteria, more narrow patient subpopulations? How would an extended use of CA and AA affect patient affordability? Across MSs? Who is the beneficiary: industry, patients or payers? What are the implications for the reimbursement evaluation; how can this be managed? Orphan drugs are of specific interest here; what is the use of the early approval if reimbursement is subsequently denied? The Nexium approach (few indications initially) or the Glivec approach (several indications initially); what might be the most suitable?

Earlier Access to New Medicines - Myth or Reality?
Angelika Joos, Regulatory Policy Europe, Merck Sharp & Dohme (Europe) Inc., Belgium

Conditional marketing Authorisations: Regulatory Opportunities and Challenges
Silvia Chioato, Director, Regulatory Strategy, Pfizer Italia SRL, Italy

Too Early Approval?
Bertil Jonsson, Senior Expert, MPA, Sweden

Panel with Franceso Pignatti, Scientific Administrator, Safety and Efficacy of Medicines, EMEA, EU

14:00 **Session 7 - In cooperation with Themes 4 and 8**

COMMUNICATING BENEFIT – RISK TO THE PUBLIC: 12 YEARS AFTER THE ERICE DECLARATION, HOW MUCH PROGRESS HAS BEEN MADE?: A PANEL DISCUSSION

Session Chair Co-Chairs:
Ragnar Löfstedt, Professor, Director of King's Centre for Risk Management, King's College, UK
June Raine, Director, Division of Vigilance Risk Management of Medicines, MHRA, UK and Chair of Pharmacovigilance Working Party

Patients and the public rightly demand to know more about their medicines. The session will discuss how to communicate not only the risks connected to a medicine but also the effects? Can patients be educated to absorb and understand the information? Risk management including post-marketing activities is now an important part of the lifecycle management. Are the commitments of value for public health protection, or do we risk requesting commitments for academic purposes? What is the true benefit for the patient and how should we communicate this? Is there impact on the cost for a medicine?

June Raine, Director, Division of Vigilance Risk Management of Medicines, MHRA, UK and Chair of Pharmacovigilance Working Party

Tony Whitehead, UK Medical Director, sanofi-aventis, UK

François Houÿez, Health Policy Officer, EURORDIS, France

16:00 **Session 8**

REGULATORY IMPLICATIONS OF OUTSOURCING CLINICAL DEVELOPMENT TO EMERGING MARKETS

Session Chair:
David Verbraska, Vice President, Worldwide Regulatory Policy & Intelligence, Pfizer, Inc, USA.

This session will explore the regulatory challenges and opportunities related to the pharmaceutical industry's external sourcing of aspects of clinical trials in emerging markets. The speakers from a regulatory agency, third party sourcing company and industry will discuss the issues from their perspectives.

A Regulator's View
Alar Irs, Deputy Director General, State Agency Medicine, Estonia

Challenges, Risks and Benefits of Conducting Clinical Trials in Developing Regions
Graciela Racaro, Senior Director, Study Start-Up, The Americas, PAREXEL International, LLC, USA

Clinical Development in New Territories – Expected and Unexpected Challenges
Per Nilsson, Head of Strategic Clinical Development, Actelion Pharmaceuticals Ltd., Switzerland

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Theme 3
Clinical Research – Increased Complexity by Integration of Real Life Settings

Theme Leaders:
Norbert Clemens, Head Clinical Development, CRS Mannheim GmbH, Germany
Alar Irs, Deputy Director General, State Agency Medicine, Estonia

Everybody has to focus on relevant patient data today, as these are the driving forces for licensing, treatment and reimbursement decisions. Randomised clinical trials of good quality represent the most scientifically valid study design for evaluating the safety and efficacy of new medical treatments. However, for patient-relevant data, the usual pivotal clinical trial in its current form may not always represent the most appropriate tool for generating information on the safety and cost-related issues of medical treatments. Recently a patients' group started an open and non-blinded, patient-driven trial, and an approach that has amazing potential, but increased risks. Another hot topic is the first-in-man studies with biologicals post TGN1412. Considerable effort has been put into providing guidance, which now needs to be transferred into practice. The requirements for paediatric studies have not completely arrived at the operational level of clinical development. The sessions of this theme will discuss these and other topics of current interest in the clinical field and will provide up-to-date guidance on future clinical research.

Tuesday, March 24, 2009

09:00 **Session 1**

PAEDIATRIC TRIALS- BETTER MEDICINES FOR CHILDREN THROUGH REGULATORY EFFORTS

Session Chair:
Holger Maria Rohde, Head of Preclinical & Medical Affairs, PharmaLex GmbH, Germany

Better medicines for children are reaching a global dimension. Since January 2007, when the paediatric regulation came into force in the EU, paediatric drug development statements are obligatory for any marketing authorisation in the EU. Regulatory and clinical experts take the challenge to meet European requirements with clinical trial development plans and practical paediatric protocol planning in compliance with current legal demands. This session will cover the major issues from a regulatory affairs as well as from the clinical perspective, including aspects for waiver, referral, informed consent, patient recruitmentand the ethics of paediatric trials and will provide insights into how the regulatory framework translates into practice.

Better Medicines for Children: A Dialogue Reaching Global Dimensions
Klaus Rose, Head Paediatrics, F. Hoffmann-La Roche, Switzerland

Clinical Trials in the Paediatric Population
Susannah Lyon, Regulatory Associate, PRA International, UK

Practical Paediatric Protocol Planning to Prevent Your Company Losing Time and Money
Jane Lamprill, Paediatric Research Consultant/Specialist Paediatric Medical Writer, Paediatric Research Consultancy, UK

EMEA Experiences
EMEA speaker to be confirmed

11:00 **Session 2**

PATIENT REPORTED OUTCOMES

Session Chair:
Heike Schön, Managing Director, CSG, Germany

Patient reported outcomes data are gaining an increasing importance in drug development, market authorisation and in real life evaluations. The session will consider the regulatory perspective and the integration of PROs into the different stages of drug development and lifecycle management. This conceptual approach will be taken further, Looking at the use of ePROs and their acceptance by the regulatory agencies.

Patient Reported Outcomes - A Regulatory Perspective for Europe
Mira Pavlovic, Head of Scientific Advice Unit, Afssaps, France

Integrating PRO into Clinical, Non-Interventional and Health Economic Studies
Peter K. Schädlich, Department Head Health Economics and Outcomes Research, IGES Institut GmbH, Germany

ePRO Soup to Nuts: The Application of ePRO in Clinical Trials
Keith W. Wenzel, Product Director, ePRO, Perceptive Informatics, USA

14:00 **Session 3**

INFECTIOUS DISEASES

Session Chair:
Irja Lutsar, Professor in Clinical Microbiology, Tartu University, Estonia

Challenges in antibacterial and antiretroviral drug development will be discussed. Special attention will be paid to the most recent changes in guidelines on antibacterial agents. The pros and cons of conducting placebo-controlled trials in patients with respiratory tract infections will be critically analysed.

Challenges in the Development of HIV Products - Case Study: Maraviroc, A Novel CCR5 Antagonist for the Treatment of HIV-1
Elna van der Ryst, Senior Director, Clinical R&D, Pfizer Global Research and Development, UK

Important Issues to Be Considered in the Revision of the CHMP Guideline on Antibacterial Agents
Mair Powell, Senior Clinical Assessor, MHRA, UK

Placebo-Controlled Studies and Non-Inferiority Design in Respiratory Tract Infections
Ian Friedland, Chief Medical Officer, Calixa Pharmaceuticals Inc., USA

16:00 **Session 4**

FIRST-IN-MAN: CLINICAL TRIALS ISSUES

Session Chair:
Walter Haefeli, Medical Director, University of Heidelberg, Germany

First-in-Man applications of potential high-risk medicinal products are strictly regulated. In this environment the planning and conduct of studies, especially with biologicals is a complex and costly enterprise. This session will elaborate on innovative strategies for First-in-Man applications, on the regulatory view and on practical issues of these trials.

Innovative Strategies to Accelerate Early Clinical Proof of Concept
Robert Butz, Vice President Medical & Scientific Affairs, BioVail Technologies Ltd., USA

Safety Protocols in Practice and the Consequences for First-in-Man Studies with Biologicals
Walter Haefeli, Medical Director University of Heidelberg, Germany

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Wednesday, March 25, 2009

09:00 **Session 5**

PATIENT RECRUITMENT

Session Chair:
Andreas Reimann, CEO, Cystic Fibrosis Association, Germany

Recruiting patients is one of the most critical success factors for running clinical trials efficiently. Different ways of attracting, recruiting and retaining patients have been successfully used. The session will provide an overview on these approaches. Participants will benefit from the expertise and different perspectives of the speakers from industry, a CRO and a non-for-profit network. After having attended this workshop, participants will be enabled to use up-to-date techniques in patient recruitment and retention when tackling day-to-day business.

Improving Patient Retention and Compliance on Clinical Trials through Patient Support Programmes
Radzhika Raizada, Senior Consultant, Infosys Technologies, UK

Global Patient Recruitment and Retention
Janet Jones, Senior Director, Strategic Patient Access, Kendle, UK

Accessing Patients through Disease-Specific Networks
Andreas Reimann, CEO, Cystic Fibrosis Association, Germany

11:00 **Session 6**

NOVEL APPROACHES IN CLINICAL RESEARCH

Session Chair:
Khazal Paradis, Senior Vice President Clinical Research, Genzyme Europe BV, The Netherlands

This session will give an overview of the trends that have been observed in clinical research; that clinical trials are becoming more complex both for the sponsors and the investigators, ultimately leading to increased resources and costs. In addition to looking at what can be done to decrease the burden of clinical trials, new developmental tools will be presented that can enhance the quality and reliability of the data that are obtained.

Protocol Design Trends and Their Impact on Clinical Trial Performance
Kenneth A. Getz, Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP, USA

Wireless Transmission of Spirometric Measurements to ePRO Devices Used by Subjects With Asthma
Stephan Raymond, Chief Scientific Officer and Quality Officer, PHT Corporation, USA

Drug Telemonitoring for Compliance and Pharmacodiligence
Barbara Rapchak, CEO, Leap of Faith Technologies, Inc., USA

14:00 **Session 7**

MULTINATIONAL TRIALS IN CHINA, AFRICA AND SOUTH AMERICA

Session Co-Chairs:
Jean-Paul Deslypere, Business Development Manager, Life Sciences - Asia Pacific, Singapore
Fergus Sweeney, Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, EMEA, EU

Currently only a small percentage of clinical trials are conducted in the emerging markets, but year to year growth rates are higher than in the US or Europe. There are many good reasons to conduct clinical trials in Africa, Asia and Latin America but on the other hand one should only start working in these continents well prepared. Doing clinical trials in these countries has its pitfalls and particularities, which will be presented and discussed in this session.

The Importance of a Contract Research Organisation (CRO) in Latin America: Professional Services for Partnering Solutions to the Pharmaceutical, Biotechnology and Healthcare Industries
Marlene Llopiz-Aviles, Regional Director for Latin America, Venn Life Sciences Clinical Research de Mexico, S.A. de C.V., Mexico

The Role and Responsibility of a CRA in China
James Fan, Associate Medical Director, Asia Pacific Region, ICON Clinical Research Ltd., Singapore

The Added Value of Including Emerging Markets in Global Clinical Trials
Renée Moore, President Global Operations, Progenitor International Research, Germany

16:00 **Session 8**

STRATEGY OF CLINICAL DEVELOPMENT

Session Chair:
Christoph Gleiter, Director Coordination Centre for Clinical Trials, CenTrial GmbH, Germany

Guidelines provide a framework for the conduct of clinical trials but are subject to interpretation by their users. At the same time scientific facts have to be incorporated in the strategic planning of the development of a new entity. The session will focus on the implementation and interpretation of the regulatory framework and its adaptation to the scientific goals of a series of clinical trials during clinical development.

Mapping the Shift from Transactional to Partner Based Outsourcing
Kenneth A. Getz, Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP, USA

Global Oncology Product Development: Strategies for Successful Selection of Patient Populations and Study Endpoints in Early to Late Phase Clinical Development
Marga Oortgiesen, Senior Director, Integrated Drug Development, Cato Research, Ltd., USA

Executing Phase IV Studies - Operational Challenges
Hugo Stephenson, President Strategic Research and Safety, Quintiles Transnational, USA

Academic Trials in Oncology Drug Development
Francesco Pignatti, Scientific Administrator, Safety and Efficacy of Medicines, EMEA, EU

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 4
Safety throughout the Product Lifecycle: Strategies to Better Protect Public Health

Theme Leaders:
Monika Pietrek, Drug and Safety Expert, Germany
Rosalind Coulson, PhC, MSc, FR, PharmS, UK

In December 2007 the European Commission launched a public consultation on a strategy to better protect public health by strengthening and rationalising EU Pharmacovigilance. This is the latest of several regulatory initiatives to improve the safety of medicinal products. Both health authorities and the pharmaceutical industry are endeavouring to regain the confidence of the patients as well as the public. The different aspects identified should contribute to safer products: better understanding of disease mechanisms is aimed at the development of personalised medicines, specific risk minimisation activities and increased scrutiny of post-authorisation commitments additionally will support the protection of patients and consumers. The the role of consumer reports has also been recognised in the EU, and this may provide further insight into the effects of medicinal products when exposed to large populations.

While industry and regulators are implementing the new regulatory requirements, globalisation and exploding costs of drug development and health care are the other major forces requiring pharmaceutical and biotechnology companies to re-adjust their working practices. Off-shore working, outsourcing and new technologies are considered to provide adequate solutions to such challenges. However, the impact of these changes will only be measurable after a number of years of experience. Therefore, it is important that the major stakeholders agree on common objectives to support public health. In particular, societies need to determine which treatments should be provided, and how benefits, risks and costs should be balanced.

Though public health and the availability of medicinal products remain a national responsibility, the safety of medicinal products is determined globally through e.g. clinical development, manufacturing, marketing and surveillance. The regulators in the US and the EU have acknowledged the need for harmonisation and simplification. The progress, however, will depend on the scope of such efforts and the time frame for implementation as well as on the involvement of health authorities in other jurisdictions, the involvement of other stakeholders and ultimately on effective communication.

Tuesday, March 24, 2009

09:00 **Session 1**

SURVEILLANCE: DISEASES AND PHARMACOVIGILANCE - HOW GOOD ARE OUR BASELINE DATA?

Session Chair:
Susana Perez Gutthann, Vice President, Global Head Epidemiology, RTI Health Solutions, Spain

The development, safety and risk management of therapeutics, particularly those for complex, chronic diseases requires strong information on the natural history of disease, patient and treatments characterisation, and background incidence rates of events occurring during the course of the disease. While general disease frequencies are often available, there is scarce information at the levels of granularity and quality required for decision making. The session will cover:

- An introduction to the current situation, and key challenges with examples
- A presentation for the newly set up European Centre for Disease Prevention and Control (ECDC) to describe the European-wide surveillance system for infectious diseases. This is of relevance, due to the Vol 9A 5.9. requirement to handle case reports on infections as serious adverse events.
- An overview of the sources of data with focus on Europe. What are the options, including population disease statistics, population databases, cohorts/registries, case-control network?

Challenges when Baseline Disease Epidemiology is Required
Marie-Ann Wallander, Senior Epidemiologist, Bayer Schering Pharma AG, Germany

The ECDC: Overview and Contributions to Infectious Disease in Risk Management
Piotr Kramarz, Deputy Head of Scientific Advice Unit, European Centre for Disease Prevention and Control (ECDC), Sweden

Sources of Disease Epidemiology in Europe
Susana Perez Gutthann, Vice President, Global Head, RTI Health Solutions, Spain

11:00 **Session 2**

SAFETY SURVEILLANCE PLANS: STRATEGIES FOR MONITORING SAFETY DURING THE DEVELOPMENT LIFECYCLE

Session Chair:
Andrzej Czarnecki, Director, Deputy Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

Surveillance plans are strongly associated with the pharmacovigilance plans compiled for risk management programmes (RMP). They should be well implemented during drug development as part of developmental RMP (DRMP) and later in the post-marketing RMPs. Drug safety during the product lifecycle as a concept was introduced over 20 years ago. It took some time to incorporate it into everyday practice of industry and regulators. This session will present, from different perspectives, views on monitoring safety during the product lifecycle and its impact on handling of safety.

Safe Use: Improving the Safety of Medicines
Nancy Smith, Director, Office of Training and Communications, FDA, USA

Adopting a Lifecycle Approach to Safety Risk Management
Christoph Hofmann, Drug Safety Officer, Bayer Schering Pharma AG, Germany

Interim Epidemiological Analyses of Selected Endpoints: A Way to Detect and Anticipate Potential Safety Issues
Alejandro Arana, Partner, Risk Management Resources España, SL, Spain

14:00 **Session 3**

SPECIAL REQUIREMENTS FOR THE SAFETY OF BIOLOGICALS AND BIOSIMILARS

Session Chair:
Glyn Belcher, Vice President Drug Safety and Risk Management International, Biogen Idec Ltd., UK

Of newly approved medicinal products, an increasing number are biologics. In addition, biosimilars have now been approved in the EU and the FDA is consulting concerning its approach to licensing biosimilar products. This session will discuss safety issues specific to biological products both in the clinical development phase and the post marketing phase and including risk management for such products. The session will seek to address the different safety aspects of relevance to innovative products and to biosimilars.

Investigation of Post-Marketing Safety Issues with a Biologic and Recommendations for Post-Marketing Safety Monitoring of Biosimilars
Alexander Berghout, Head Global Clinical Research & Development, Sandoz Biopharmaceuticals, Hexall AG, Germany

Biosimilars - How to Manage Risks
Lia McLean, Practice Head, Process Design and Implementation, PopeWoodhead and Associates, UK

Specific Safety Issues to Be Considered During Clinical Development and Marketing of Biologics
Christian Schneider, Acting Head of Division EU Cooperation/Microbiology, Chairman Biosimilars Working Party, Paul-Ehrlich-Institute, Germany

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

16:00 **Session 4**

PERFORMANCE AND QUALITY CONTROL IN PHARMACOVIGILANCE AND RISK MANAGEMENT – TOO MUCH OR TOO LITTLE? WHAT IS THE IMPACT ON PUBLIC HEALTH?
Session Chair:
Sarah Daniels, S Daniels Consulting, Ltd. UK

This session will examine performance and quality control (QC) in pharmacovigilance and risk management from three perspectives: Firstly, the role of QC, and how much is optimal in the interests of public health. Secondly which performance indicators really play a part in ensuring public health? Finally, a thought-provoking look at the airline industry, drawing parallels with the pharma industry and considering what, if anything, the pharma industry could learn.

Applying QA/QC to PV from a Holistic Perspective: Focusing on the Critical
Nigel Cryer, Interim Head of Global Quality Manufacturing & Supply Chain, Norgine Pharmaceuticals, UK

The Human Element: Asset or Liability? The Limitations We Pose on Complex Systems
Tor Krokstad, Senior Consultant, HUCON, Norway

Monitoring Quality throughout the Lifecycle: Signal Detection, Safety Risk Management and Benefit-Risk Assessment
Philippe van der Auwera, Global Head of Drug Safety and EU QPPV, F. Hoffmann-La Roche Ltd, Switzerland

Wednesday, March 25, 2009

09:00 **Session 5**

EU-HARMONISED PHARMACOVIGILANCE REQUIREMENTS VERSUS GLOBAL PHARMACOVIGILANCE – SUPPLEMENT OR CONTRADICTION?
Session Chair:
Vicki Edwards, Senior Director European Pharmacovigilance, Abbott Laboratories Ltd., UK

The session will aim to provide an industry and regulatory view of:
- Which initiatives are working well in the interests of harmonisation
- Which impediments exist for further harmonisation
- Why have ICH initiatives not solved the problem?
- What is different about the current EU legislative proposals that will secure success this time?

Harmonisation in Pharmacovigilance - an Industry Perspective
Karen Pattenden, Senior Director, Gilead Sciences International Ltd., UK

Current Status of International Harmonisation and Collaboration in Pharmacovigilance
Peter Arlett, Head of Sector for Pharmacovigilance and Risk Management, EMEA, EU

Challenges for the Industry
Vicki Edwards, Senior Director European Pharmacovigilance, Abbott Laboratories Ltd., UK

11:00 **Session 6**

SAFETY DECISION MAKING – HOW MUCH SCIENCE IS DEPLOYED? AN UPDATE ON METHODOLOGY
Session Chair:
Rosalind Coulson, PhC, MSc, FR, PharmS, UK

One of the key factors for achieving a successful outcome to the application for a marketing application and to the continuance of the product on the market is the decision process associated with the safety assessment of benefit-risk. The importance of this process cannot be underestimated both to the benefit of public health and the innovator of the product and yet there is currently no agreed approach on a methodology to quantify the overall benefit-risk balance to aid more accurate decision making. This session will discuss both the current position and thinking and explore potential methodology to improve consistency and transparency in the decision-making process.

The Regulatory Challenges in Identifying a Changing Benefit-Risk Balance in the Post-Marketing Phase of the Product Lifecycle: Consistency, Transparency and Communication of the Benefit-Risk Decision
June Raine, Director, Division of Vigilance Risk Management of Medicines, MHRA, UK and Chair of Pharmacovigilance Working Party

When Are Observational Studies Good for Decision-Making?
Nancy Dreyer, Senior Vice President, Chief Scientific Affairs, Outcome, USA

Optimal Methodology both to Establish and Support Continuous Evaluation of the Benefit-Risk Balance: A Dream or Reality?
Speaker invited

14:00 **Session 7**

DRUG SAFETY PERSONNEL – WHAT QUALIFICATION AND HOW MUCH EDUCATION ARE NEEDED? WHERE DO REGULATORS AND INDUSTRY FIND TALENT?
Session Chair:
Monika Pietrek, Drug Development and Safety Expert, Germany

The steep increase in workload, enhanced risk management requirements and the evolving challenges associated with more complex biological compounds have triggered a great demand for suitably qualified drug safety personnel. However, no international curriculum of drug safety qualifications and training exists. This session will focus on the needs, both current and future, and the opportunities for drug safety staff, describe a drug safety training programme and provide recommendations for successful recruitment.

Drug Safety Personnel - Trends in Industry and at Regulatory Authorities
Arthur Meiners, Senior Medical Advisor, Benefit & Risk Management Services, Inc., A Division of Janssen Pharmaceutica NV, Belgium

Drug Safety Training and Professional Education – A Perspective
Monika Pietrek, Drug Development and Safety Expert, Germany

The Successful Placement of Drug Safety Personnel
Carl Metzdorff, Partner, ACES Healthcare, Belgium

16:00 **Session 8**

POST-MARKETING STUDIES – COMMITMENTS AND REALITY
Session Chair:
Nancy Dreyer, Senior Vice President, Chief Scientific Affairs, Outcome, USA

Post-Authorisation Safety Studies (PASS) to identify and quantify safety risks for marketed products offer a strong approach to enhancing drug safety through systematic signal detection/investigation, but they also present an administrative nightmare for businesses. Population studies for PASS commitments can be an important resource that, with careful stewardship, is useful for safety and other business needs. This session will describe tools and resources, experience to date, including differences between EU and US approaches, and some controversies.

Practical Aspects: An Investigator's Perspective
Saad Shakir, Director, Drug Safety Research Unit, UK

Generating Evidence in the EU and US
Annalisa Rubino, Director of Pharmacoepidemiologic Research, Outcome Sciences Inc., UK

A Regulator's Perspective
Peter Arlett, Head of Sector for Pharmacovigilance and Risk Management, EMEA, EU

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Theme 5
Knowledge Management – The Key to Inexpensive, Timely, Safe and Effective Drug Development and Approval

Theme Leader:
John Wise, Head of Informatics, Daiichi Sankyo, UK

This theme, broad in scope, will consider knowledge management (KM) across the pharma R&D value chain from clinical candidate selection through to dossier submission and review. It sets out to provide value for senior management wishing to catch the key strengths and concerns of the discipline while providing KM practitioners with a state-of-the-art update on the status of their discipline, its opportunities and future direction.

Key topics will be covered ranging from a review of current standards appropriate to KM and their near-term evolution, to mandatory and desirable "electronic" procedures with the EMEA and European National Competent Authorities, including a detailed assessment of the status and use of the eCTD and PIM. The urgent need better to integrate and mine phenotypic and genotypic information during drug development will be addressed. The potential for exploitation of KM to optimise the myriad processes supporting product cross-licensing will be examined by industry experts. The challenge of exploiting knowledge throughout the drug development lifecycle to support the construction of drug risk management plans - now an essential part of a marketing application – will be covered, leading up to a tour d'horizon of how effective innovation – so sorely needed in today's hard-pressed biopharmaceutical industry - can be encouraged, initiated and enabled by KM. The theme will culminate in a key-note concluding address challenging the participants to consider the validity of the cry "the Chief Information Officer is dead, long live the Chief Knowledge Officer!"

Tuesday, March 24, 2009

09:00 **Session 1**

THE EU LANDSCAPE
Session Chair:
Rene Ziegler, Strategic IT Projects, Novartis International AG, Switzerland

This is a scene-setting session describing the landscape of working groups (industry, industry/agency, agency) on KM-related topics including emerging standards and a more in-depth review of the significance of ICH eCTD and the RPS.

Using KM to Spark Innovation and Raise Its Value
Steve Gardner, Senior Consultant, BioLauncher Ltd., UK

The Evolving Face of Electronic Interchange in the Regulatory Arena: Where Are We Heading and Why?
Andrew Marr, Director, Global eRegulatory Development, Global Regulatory Operations, GlaxoSmithKline, UK

From Data to Evidence and Knowledge Creation: Are the Regulators More Innovative than Pharma?
Isabelle de Zegher, Belgium

11:00 **Session 2**

THE "ELECTRONIC-ONLY" CENTRALISED PROCEDURE - NOW A REALITY
Session Chair:
Andrew Marr, Director, Global eRegulatory Development, Global Regulatory Operations, GlaxoSmithKline, UK

In February 2008, the EMEA announced its plan to implement the electronic-only submission of information in support of marketing authorisation applications in the centralised procedure by January 2009 and the use of the Electronic Common Technical Document (eCTD) as the required format by July 2009.

Towards the Paperless Centralised Procedure: Now a Reality
Claire Holmes, Project Management, Communications and Networking, PIM Project Manager, EMEA, EU

Transitioning to an e-only Centralised Procedure. A Case Study from a Larger Company
Adam Aparacio, Head, Global Regulatory Operations, Merck Serono, Germany

Transitioning to an e-only Centralised Procedure. A Case Study from a Smaller Company
Glynis Archibold, Head, Regulatory Operations, Norgine, UK
Ruth Stone, Director, Comply Services, UK

14:00 **Session 3**

TOWARDS "ELECTRONIC-ONLY" MUTUAL RECOGNITION, DECENTRALISED AND NATIONAL PROCEDURES.
Session Chair:
Geoffrey Williams, Site Head of Regulatory Operations, Roche Products Ltd., UK.

Progress towards implementation of electronic-only submissions in procedures other than the Centralised Procedure has been limited in most Member States. Experience from a Member State that has progressed significantly will be reported, together with that from a Member State at the initiation of transition. Experience of running a multi-state procedure such as an eCTD and the challenges and opportunities that it provides will be shared.

Towards the "Electronic-Only" MRP, DCP and National Procedures – An Agency Viewpoint
Christa Wirthumer-Hoche, Head, Unit for Marketing Authorisation and Lifecycle Mgt of Medicinal Products, AGES PharmMed, Austria

Transitioning to Electronic-Only Submissions in the MRP, DCP and National Procedures: A Case Study for a Large Pharma Company
Alastair Nixon, GlaxoSmithKline

Transitioning to Electronic-Only Submissions in the MRP, DCP and National Procedures: A Case Study for a Small Company Working with a Services Organisaton
Sibylle Teuchmann, Managing Director, Exalon GmbH, Germany

16:00 **Session 4**

PRODUCT INFORMATION MANAGEMENT (PIM) - TOWARDS FULL IMPLEMENTATION
Session Chair:
Stephen Hasler, Vice President, Global Regulatory Operations, GlaxoSmithKline, UK

The objective of PIM is to increase the efficiency of the management and exchange of product information (Summary of Product Characteristics, package leaflet and labelling) by all parties involved in the evaluation process. Where are we with respect to the Centralised Procedure and where are we going with the Decentralised, Mutual Recognition and National Procedures?

Full Implementation of PIM: Progress and Plans from an Agency Perspective
Timothy Buxton, Head of Sector, Project Management, Communications and Networking Unit, EMEA, EU

Experience of PIM as an Applicant: What is Needed for Full Implementation?
Leigh Sandwell, Associate Director, E-Regulatory, Pfizer Worldwide Regulatory Operations, UK

Challenges to Overcome: A Software Vendor's Perspective
Andy Glemser, Chief Technology Officer, Glemser Technologies, USA

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Wednesday, March 25, 2009

09:00 **Session 5**

KEY INITATIVES IN DRUG DEVELOPMENT OPTIMISATION

Session Chair:
John Wise, Head of Informatics, Daiichi Sankyo, UK

Much needs to be accomplished to make clinical development quicker and cheaper. Integrating the electronic Health Record with EDC, merging phenotypic information with genotypic information and the use of modelling and simulation techniques can all contribute to optimising key processes within this much challenged domain.

Timely, High Quality Electronic Data in Clinical Trials - From Fiction to Reality
Gudrun Zahlmann, Director Imaging for Pharma, Siemens AG, Healthcare Sector Image and Knowledge Management – IKM, Germany

Modelling & Simulation - a Key Discipline to Quicker, Better, Cheaper Drug Development
Ferdinand Rombout, Director Modelling and Simulation, Daiichi Sankyo Development, Ltd.

Pharmacogenomics - a Non-Discretionary Discipline in Tomorrow's Drug Development
Lloyd Curtis, Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline, UK

11:00 **Session 6**

RISK MANAGEMENT AND PHARMACOVIGILANCE - BETWEEN A REGULATORY ROCK AND THE LITIGATION HARD PLACE

Session Chair:
Uwe Trinks, Chief Information Officer, Sentrx, USA

Volume 9A of the Rules Governing Medicinal Products in the European Union: "Guidelines on Pharmacovigilance for Medicinal Products for Human Use" is demanding and in significant part requires support from knowledge management and its associated technologies deployed in a regulatory-compliant manner. From the transaction processing and reporting of Individual Case Safety Reports, through signal detection, to the support of the product risk management plan (RMP), KM needs to be involved and exploited.

The Challenge to Create a Global Regulatory Tracking Tool and Managing an Intelligence Database
Sharon Kinning, CTrack Manager, Quintiles, UK

Knowledge Management: Can We Improve the Signal Detection and Evaluation Processes
Trevor Gibbs, Executive Vice President, Chief Medical Officer, ii4sm, Switzerland

The Regulatory Framework for Risk Management - From the European PASS to the FDA REMS
Uwe Trinks, Chief Information Officer, Sentrx, USA

14:00 **Session 7**

PRODUCT PARTNERING: THE EFFECTIVE MANAGEMENT OF INFORMATION ASSETS

Session Chair:
Eldin Rammell, Managing Director & Principal Consultant, Rammell Consulting Limited, UK

Product cross-licensing provides a very significant contribution to R&D productivity. Fundamental knowledge management processes are essential to the success of this activity, including the optimal presentation of intellectual business assets to a prospective purchaser, enabling electronic due diligence and the effective management of business assets – in a regulatory compliant manner - as a multiplicity of partners contribute to the development of a compound.

Critical Success Factors for the Management of Corporate Intellectual Property to Support Acquisition and In-Licensing Activities
Frank Hultschig, Information and Records Management Site Lead, Pfizer Ltd., UK

Effective Use of Technology for Knowledge Management
Chris Beckmann, Director, International DataSite, Merrill Corporation, Germany

Pitfalls to Avoid – Is This Your Experience with Product Licensing?
Jean Samuel, Director, STEP-IN Management Ltd., UK, 1996 RMS Records Manager of the Year

16:00 **Session 8**

KNOWLEDGE MANAGEMENT & INNOVATION

Session Chair:
Sue Jackson, Vice President, Business Development, Versant EuroVentures, UK

Innovation is much needed in the sorely pressed R&D domain. Many imaginative uses of KM are being deployed to support and create innovation in R&D and some key examples will be presented, including coverage of the important Innovative Medicines Initiative (IMI) created by the partnership of the European Community and EFPIA. A challenge will be offered to CIOs to re-invent themselves as CKOs – Chief Knowledge Officers.

Open Innovation in the Contemporary Biopharmaceutical Industry
Speaker invited

From CIO through CKO back to CIO - But the Last "I" stands for "Innovation"!
Guy Henninger, Senior Vice President, Business Development, Vertical*i, USA

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 6
Medical Device Drug Combination: The Medical Opportunities and Regulatory Challenges of the 21st Century

Theme Leaders:
Andreas Grund, General Manager, GCP-Service, Germany
Sabina Hoekstra-van den Bosch, Senior Advisor, Ministry of Health, Welfare and Sport, The Netherlands

The pharmaceutical and medical devices sectors could be considered as two separate sectors, which differ in history, culture, organisational structure, legislation and even in language. However, since the traditional boundaries between medical devices and drugs are blurring, there is a need for improvement in communication between the two sectors. Nowadays, the pharmaceutical and the device worlds meet each other in the combination products of drugs and devices and in the so-called 'borderline products'.
This theme will analyse the current similarities and differences between the drug and the device regulatory system and will focus on possibilities for working together on both the operational and regulatory levels, e.g. in clinical research, in adverse event reporting and in market access. This theme will also reflect the most recent developments in device regulation, such as the changes resulting from EU-Directive 2007/47 and from more recent initiatives. New and emerging technologies will have a huge impact on product development in both the pharmaceutical and the device sector and will result in many new products, some of which will be difficult to characterise as either a pharmaceutical or a medical device. New and emerging technologies could result in a 'therapeutic shift' from drugs to devices and vice versa. This theme will highlight some interesting developments. We will also proactively consider what efforts need to be made to harmonise the sectors and how the future regulation of pharmaceuticals and devices could be developed in order to offer the best of both worlds to both pharmaceuticals and medical devices.

Tuesday, March 24, 2009

09:00 **Session 1**

NEW AND UPDATED REGULATIONS: HOW DO THEY AFFECT THE INTERFACE BETWEEN DRUGS AND DEVICES?

Session Chair:
Hugo Hurts, Director of Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport, The Netherlands

This session will highlight the implications of the recent Review of the European Medical Device Directives, resulting in Directive 2007/47, for the interface between drugs and devices. Furthermore, in view of the announced recast of the Medical Device Directives, prospects for the (near) future of the drug-device interface will be explored.

The Recast of the Medical Device Directives and the Interface between Drugs and Devices
Georgette Lalis, Director ENTR/F, European Commission, EU

European Medical Device Regulation on the Move?
John Wilkinson, Chief Executive, Eucomed, Belgium

Global Developments in Drug and Device Regulation
David Feigal, Vice President, Global Regulatory Affairs, Amgen, USA

11:00 **Session 2**

QUALITY ASSURANCE SYSTEMS FOR DRUG DEVICE COMBINATION MANUFACTURERS: EXPERIENCES OF QA MANAGER AND AUDITORS

Session Chair:
Haydar Jaafar, General Devices Group Manager, BSI Group, UK

Is a single Quality System (QS) approach for the manufacturing of combination products possible? Medical Device Quality System (EN ISO 13485) and Current Good Manufacturing Practice (CGMP) regulations overlap considerably in content and intent. Many facilities operate under just one of the relevant quality systems since compliance with both sets of regulations can be generally be achieved by either means. In this session we will show how medical devices manufacturers of combination products can demonstrate compliance with the applicable requirements under the Medical Devices Directive 93/42/EEC. A representative from a Notified Body will outline the challenges facing the QS of combination products, followed by a manufacturer's successful experience in this field. The last speaker, a medical device assessor, working for a Notified Body, will give an overview of auditing manufacturers of combination products.

Quality Challenges for Combination Products - A Notified Body Viewpoint
Gert Bos, Principal Certification Manager for Medical Devices, KEMA Quality B.V, The Netherlands

The Experience of a Medical Device Manufacturer of Operating a Quality Management System for Device Drug Combination Products
John Wilkins, Quality & Regulatory Affairs Manager, Insense Ltd., UK

Prospective Auditing Manufacturing Processes of a Device/Drug Combination Product Manufacturer
Stewart Brain, Principal Microbiologist/Team Manager, Healthcare, BSI Group, UK

14:00 **Session 3**

EXPANDING OUR REGULATORY HORIZON TO DELIVER DEVICE AND DRUG COMBINATION PRODUCTS SUCCESSFULLY TO MARKET: WHERE COULD DRUGS AND DEVICES MEET?

Session Chair:
Sabina Hoekstra-van den Bosch, Senior Advisor, Ministry of Health, Welfare and Sport, The Netherlands

Combination products are subject to quality requirements from both the pharmaceutical and medical device regulatory regimens and could benefit from better coherence between these regimens. This session will analyse the existing regulatory approaches for quality in both the pharmaceutical and the medical device regulatory systems, compare these approaches and identify common elements. Possibilities to use these common elements as a starting point for improving coherence between both regulatory systems will also be explored.

The Pharmaceutical Approach: ICH Q8, Q9, Q10 and Quality-by-Design
Jacqueline Schumacher, Research Fellow, Global CMC, Pfizer, USA

ICH and GHTF: Does Freedom Oblige?
Michael Gropp, Vice President, Global Regulatory Strategy, Medtronic Inc., USA

ICH and ISO: Same Game, Different Rules
Jos Kraus, Senior Inspector, Health Care Inspectorate, The Netherlands

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16:00 **Session 4**

ROUNDTABLE: THE SPIRIT OF ONE TEAM CREATED FROM TWO WORLDS - THE KEY TO SUCCESSFUL DEVELOPMENT OF DEVICES/DRUG COMBINATION PRODUCTS.
Session Chair:
Dario Pirovano, Consultant - Regulatory and Technical Affairs, EUCOMED, Brussels, Belgium

Health technology is moving fast towards products which benefit from the innovations introduced both in the medical technology and in the medicinal product sectors. This development demands urgently a comprehensive, and possibly global, regulatory model which will allow the timely availability for patients of products in line with the scientific developments. In order to do so, the benefits from the consolidated regulatory regimes for devices and medicinal products shall be used as a solid basis for developing an appropriate combination product regulatory regime, which takes into account the differences between the "two worlds". This session will explore the current work ongoing in this direction.

Recent Developments: GHTF and European Plans
Brian R. Matthews, Senior Director, EC Registration, Alcon Laboratories Ltd., UK

BfArM Experience with the Consultation Procedure and Implementation Plan for Directive 2007/47/EC
Dirk Wetzel, Head, Medical Devices Division, BfArM, Germany

Wednesday, March 25, 2009

09:00 **Session 5**

BORDERLINES BETWEEN DEVICES AND OTHER PRODUCT CATEGORIES: OPPORTUNITY OR MYSTERY?
Session Chair:
Dr. Luisa Carvalho, Director, Infarmed, Portugal

The medical device world is one of fast innovation and development. The rules applied should be able to cope with regulators, industry and patients' needs. Discussing the borderline issues is essential to ensure the quality, efficacy, safety and availability of medical devices. In this session, borderlines of medical devices with adjacent product categories, such as pharmaceuticals, cosmetics, biocides and other healthcare-regulated products will be explained and discussed.

Borderlines: Don't Fence Me In
Peter M. Lassoff, Vice President Europe, PAREXEL Consulting, UK

Are Boundaries Clear Enough? The System Explained
David Jefferys, Vice President, Global Regulatory, Eisai Europe Ltd., UK

Aesthetic Implants - Towards a New Legal Regime?
Geneviève Michaux, Of Counsel, Covington & Burling LLP, Belgium

11:00 **Session 6**

MEDICAL ASSESSMENTS AND SAFETY-EVALUATIONS FOR MEDICAL DEVICES, DRUGS AND THEIR COMBINATIONS
Session Chair:
Leonardo Ebeling, General Manager, Dr. Ebeling & Assoc. GmbH, Germany

Assessments, Conformity and Vigilance for Medical Devices and Borderline Products
Reinhard Berger, Head of Unit, AGES PharmMed, Austria

Vigilance for Drug-Device Combination Products in a Pharmaceutical Company - Challenges and Possible Solutions
Christine Benert, PV Contract Management, Bayer Schering Pharma AG, Germany

[Pharmaco] Vigilance systems - Consultation versus Outsourcing
Eva Thiemann, Pharmacovigilance Advisor, Medical Science & Affairs, Dr. Ebeling & Assoc. GmbH, Germany

14:00 **Session 7**

INSPECTION FINDINGS AT INVESTIGATION SITES AND THE SPONSOR OF DRUG DEVICE COMBINATION TRIALS
Session Chair:
Helena Van den Dungen, Global Head Country Management CQA, Novartis Pharma AG, Switzerland

This session will be evaluating the recent developments in this new area of clinical trials with medical devices. The development of the regulations and their impact on clinical research and the complexities related to drug-device combination trials will be discussed. Initial inspection findings will be explored from the inspector as well as from the viewpoint of those inspected.

Medical Devices and Drug Device Combinations
Esther Gil, Regulatory Director, PAREXEL International, Spain

Inspection of Clinical Trials on Medical Devices: French and European Context, Feedback of Experience
Pierre Henri Bertoye, Inspectorate and Companies Associate Director, Afssaps, France

Compliance Issues from Audits of Medical Device Clinical Trials: Over Thirteen years Experience from Cardiovascular Trials
Herman Pieterse, Head, Profess Medical Consultancy BV, The Netherlands

16:00 **Session 8**

NEW DEVELOPMENTS IN DRUGS AND DEVICES: THERAPEUTIC SHIFT OR SYNERGY?
Session Chair:
Lennart Philipson, Director of Medical Devices, MPA, Sweden

New and emerging technologies will have a huge impact on product development in both the pharmaceutical and device sectors and could even result in a therapeutic shift from drugs to devices and vice versa. This session will give a broad overview of new developments in medical technology and will highlight two developments, in which convergence of different technology areas could directly benefit patients: artificial organs and theranostics.

Overview of New Developments in Medical Technology
Dario Pirovano, Consultant - Regulatory and Technical Affairs, EUCOMED, Brussels, Belgium

Converging Technologies in Drugs and Devices: Artificial Organs as a Case Study
Robert Geertsma, Senior Scientist/Project Leader, RIVM, The Netherlands

Theranostics: Is there a Benefit for Individual Patients in Diagnostic Therapy?
Richard Moore, Manager for Nanomedicines and Life Sciences, Institute of Nanotechnology, UK

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Theme 7
Project Management in a Changing Environment

Theme Leader:
Suzy De Cordt, Group Leader, Senior Project Manager, Merck Serono, Switzerland

Driving drug development projects forward is at the heart of a pharma/biotech company, and it is a challenge in a world where the only constant is change. Project Management (PM) is a key success factor. The key is to rigorously plan and monitor timelines, and budget and coordinate the wide cross-functional scope of expertise, whilst staying lean, fast, agile and strategically focused. This theme will offer a forum to exchange views on PM tools, processes, organisations, management of projects and portfolio, applying PM in functions and partnerships.

Tuesday, March 24, 2009

09:00 **Session 1**

PROJECT MANAGEMENT TOOLS, PROCESSES AND ORGANISATION

Session Chair:
Suzy De Cordt, Group Leader, Senior Project Manager, Merck Serono, Switzerland

The session takes a broad-scope view on tools, processes and organisation of projects and portfolio management.

- How do different methods perform when applied to evaluating pharma R&D projects?
- How can process optimisation increase speed and quality and how does it relate to organisational change?
  Why do drug development projects differ from business change projects and how can they be put to work together successfully?
- Why do drug development projects differ from business change projects and how can they be put to work together successfully?

Application of Evaluating Methods in Pharmaceutical Research and Development Projects: A Case Study
Iris Ye Mao, Medical Information Associate, AstraZeneca, China

Benchmarking as a Companion of Process Optimisation: A Case Study
Birgit Schümmer, Junior Performance Manager, Gruenenthal, GmbH, Germany

Drug Development Projects are from Mars, Business Change Projects Are from Venus: A Practical Guide for Improving Communication and Getting what You Want
David Bridges, Director, eChange Solutions Ltd., Ireland

11:00 **Session 2**

KEY SUCCESS FACTORS FOR PORTFOLIO AND PROJECT MANAGEMENT

Session Chair:
Ralf Eulentrop, Head of Project Leadership Training, Merck KGaA, Germany

Portfolio and project management organisations and processes are widely established in pharma companies. However there is often disappointment about the implementation of portfolio and project management processes. The session will focus on the factors, that are seen as key, ensuring portfolio and project management contribution to the company's success. Special focus will be on people working in the matrix organisation and their development, implementation of the right processes and the contribution of project management to the matrix organisation.

Portfolio Management – Time to Up the Game
Stephen Allport, Managing Director, SWA Consulting Ltd., UK

Recipe for Success: Add Management to your Project and Assure Quality
Nancy Meyerson-Hess, Senior Vice President Project Management International, Omnicare Clinical Research GmbH & Co. KG, Germany

The Role of Project Management in the Matrix Pharmaceutical Organisation
Isabel Saez-Pujol, Associate Director, Informatics, Daiichi Sankyo Ltd., UK

14:00 **Session 3**

PROJECT MANAGEMENT APPLIED IN FUNCTIONAL AREAS – IS PM THE NEW MIDDLE MANAGEMENT?

Session Chair:
Hazel Collie, Head Global Project Management & Global Biometrics, Gruenenthal GmbH, Germany

Project management is increasingly being applied in a variety of functional areas and the need for people with good project management skills is growing. In this session we hear of project management principles being applied in three very different functional areas and ask ourselves the question: Is PM the new middle management?

Submission Management: Achieving the Optimum Result
James Reilly, Consultant Software Implementation, Octagon Research Solutions, Inc., USA

Adopting EDC - The Importance of Project Management
Laurence Charonnat, Principal Project Manager, Phase Forward, France

Doing the Project Planning for Large Multinational Clinical Trials
Diego Martin Glancszpigel, Vice President Latin America, PAREXEL, Argentina

16:00 **Session 4**

ROLE OF PROJECT MANAGEMENT IN PARTNERSHIPS

Session Chair:
Ralph White, Director, PPMLD Ltd., UK

Long gone are the days when a company could support all the functions needed for product development: much more reliance is now placed on external providers. In these three interrelated talks, the evolution of the service provider into successful partner is studied alongside the project leadership skills needed for it to thrive.

Cardiac Safety Core Lab Collaborations - From the Individual Project to a Successful Collaboration
Jeffrey Heilbraun, Senior Director, Business Development, Medifacts International, USA

Project Management Excellence: Balancing Art and Science
Rajeev Vasudeva, Director, Deloitte Consulting, USA

Will Strong Project Leaders Be Needed in the Future? An Einsteinian View!
John Faulkes, Consultant, TeamCommunications Development, UK

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December 5, 2008 | LONDON, UK

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
December 8-10, 2008 | PARIS, FRANCE ID# 08552

8th Middle East Regulatory Conference (MERC 2009)
January 20-21, 2009 | MANAMA, BAHRAIN ID# 09107

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
February 9-13, 2009 | PARIS, FRANCE ID# 09526

Essentials of Clinical Study Management
February 18-20, 2009 | SPAIN ID# 09528

Qualified Person for Pharmacovigilance (QPPV) Forum
April 29-30, 2009 | LONDON, UK

Medical Approach in Diagnosis and Management of ADRs
September 17-18, 2009 | PARIS, FRANCE ID# 09532

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
October 12-16, 2009 | BERLIN, GERMANY ID# 09527

US Regulatory Affairs
October 19-22, 2009 | BASEL, SWITZERLAND ID# 09525

3rd Annual Clinical Forum
October 19-22, 2009 | NICE, FRANCE ID# 09103

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DIA® DRUG INFORMATION ASSOCIATION

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 8
Media, Society and Research

Theme Leaders:
Nikos Dedes, Co-chair, Patients' and Consumers' Working Party (PCWP), EMEA, EU
Yann Le Cam, CEO, EURORDIS, France

This theme aims to discuss society's perceptions and the role of media in research and drug development. It will analyse the needed paradigm shift in communication, the need for better information among the stakeholders, what is accurate information and who is responsible for delivering this information.

Erosion of public trust in drug research has been observed, often tarnishing the image of researchers, industry and regulatory agencies. The media plays an important role and can have a huge impact on the public. How can researchers, industry, regulators and legislators better work with the media? Is transparency on drug research and results a way to solve mistrust? What is the role of industry and regulators in educating patients and empowering them regarding their choice for potential treatments and getting involved in clinical trials taking into account legal and ethical obligations? How can we effectively communicate on the risk-related to drug and innovative therapies?

Through the sessions, we will attempt to identify possible ways to address these issues from the perspectives of patients, health professionals, industry and regulators.

Tuesday, March 24, 2009

09:00 **Session 1**

IS THERE MISTRUST IN DRUG RESEARCH?
Session Chair:
Nikos Dedes, Co-Chair, Patients' and Consumers' Working Party (PCWP), EMEA, EU

The session will describe the erosion of public trust in drug research, whether it be directed towards the researchers, the industry or the regulators who supervise. It will seek the causes and contributing factors and address the perceptions and attitudes of the public.

Public Perceptions and Confidence in Clinical Research
Kenneth A. Getz, Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP, USA

Asbestos, Tobacco and the Pharmaceutical Industry: Where Did It Go Wrong and How Can This Image Be Turned Around?
Beat Wilder, Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd

Trust and Distrust in the Regulatory Process – A Legal Viewpoint
Geneviève Michaux, Of Counsel, Covington & Burling LLP, Belgium

11:00 **Session 2**

MEDIA COVERAGE OF CLINICAL RESEARCH
Session Chair:
Sarah Boseley, Health Editor, *The Guardian*, UK

Media coverage of medical research has often been accused of sensationalism. Can the press and media help to educate and inform the public without being alarmist? Could it do more to monitor the practices of researchers, industry, regulators and legislators and hold them better to account?

Media and Science - Who Manipulates Whom?
Gordon McVie, Professor, Cancer Research Campaign, UK

14:00 **Session 3**

THE TRANSPARENCY IMPERATIVE
Session Chair:
Georgette Lalis, Director ENTR/F, European Commission, EU

In previous sessions we described the causes and contributing factors of the tarnished image of researchers, industry and the regulatory agencies. Is transparency across the board part of the solution? Clinical trial registries, publication of trial results, public access to data, clear definition of commercially sensitive information, elimination of ghost writing, full disclosure of funding relations between industry and researchers have all begun to be addressed more proactively. What more must we do?

Increasing Transparency towards the Public: What's Next for the Competent Authorities?
Johannes Löwer, President, Paul-Ehrlich-Institut, Germany

Chris Strutt, Vice President, European and Corporate Government Affairs, GlaxoSmithKline, UK

What Do Patient and Consumer Groups Expect?
Nikos Dedes, Co-Chair, Patients' and Consumers' Working Party, EMEA, EU

16:00 **Session 4**

THE 'INFORMED PATIENT' - A CONTROVERSIAL GOAL
Session Chair:
Monika Kosinska, Secretary General, European Public Health Alliance (EPHA), EU

Better informed patients benefit all, and yet recent policy developments at European level are fraught with controversy. How can they overcome the barriers, empower themselves and gain access to the information they need? Who is responsible for informing the patient? What role should regulators, industry and health professionals play in moving towards better informed patients and offering more information about their choices.

Changing Patient Behaviour: The Role of Information
Robert Horne, Professor of Behavioural Medicine, The School of Pharmacy, University of London, UK

Information to Patients
Irene Sacristan-Sanchez, Administrator, DG Enterprise, European Commission, EU

Information to Patients: The Pharmaceutical Industry's Perspective
Paul Woods, Global Compliance Policy Director in AstraZeneca and Chairman of EFPIA's "Informed Patient"

The Informed Patient: Do Consumers Have the Tools To Make Healthcare Decisions?
Ilaria Passarani, Health Policy Officer, BEUC, Belgium

Wednesday, March 25, 2009

09:00 **Session 5**

OPTIMISING THE DILEMMA OF THE INFORMED CONSENT PROCESS BETWEEN ETHICAL REQUIREMENTS AND ORGANISATIONAL BURDEN
Session Chair:
Ingrid Klingmann, President, Pharmaplex, Belgium

There is no clinical trial without the participation of patients or healthy volunteers. Their voluntary contribution means – hopefully – a chance to get better treatment or to contribute to better treatments in the future. But it also means acceptance of additional risk as well as often additional physical, organisational and financial burden. Study participants need to be fully informed to be able to make the decision on their participation. In everyday medical practice, however, there is limited time available to present and discuss the lengthy patient information sheet so that the patient understands fully and

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appropriate reflection can be ensured. Sponsors, ethics committees and investigators need to find ways to handle this process more efficiently in the interest of the patient and the fulfillment of their legal, ethical and moral obligations.

The Ethical Aspects of the Informed Consent Process: From the Regulations and Guidelines to the Real World
Silvia Zieher, Director, Clinical Operations, Head, Latin America Resourcing Solutions, MDS Pharma Services, Argentina

Testing and Improving Readability of Clinical Trial Patient Information Sheets by User Testing
Peter Knapp, Senior Lecturer, School of Healthcare, University of Leeds & LUTO Research Ltd., UK

Patient Information in Cancer Trials: Experiences from CancerHelp
Liz Woolf, Head of CancerHelp, Cancer Research, UK

11:00 **Session 6**

SOCIETY, PATIENTS AND ADVANCED THERAPY
Session Chair:
Fergus Sweeney, Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, EMEA, EU

This topic is at the forefront of controversies capturing all aspects of this theme: a political session on research and therapy opportunities vs. the debate in society, the current state of legislation in the EU and the US and the current state of mind of public opinions, the civil society and policy makers.

Christian Schneider, Acting Head of Division EU Cooperation/Microbiology, Chairman Biosimilars Working Party, Paul-Ehrlich-Institute, Germany

Speakers invited

14:00 **Session 7 - In cooperation with Themes 2 and 4**

COMMUNICATING BENEFIT – RISK TO THE PUBLIC: 12 YEARS AFTER THE ERICE DECLARATION, HOW MUCH PROGRESS HAS BEEN MADE? : A PANEL DISCUSSION
Session Co-Chairs:
Ragnar Löfstedt, Professor of Risk Management and the Director of King's Centre for Risk Management, King's College, UK
June Raine, Director, Division of Vigilance Risk Management of Medicines, MHRA, UK and Chair of Pharmacovigilance Working Party

Patients and the public rightly demand to know more about their medicines. The session will discuss how to communicate not only the risks connected to a medicine but also the effects. ? Can patients be educated to be able to absorb and understand the information? Risk management including post-marketing activities are now an important part of the lifecycle management. Are the commitments of value for public health protection, or do we risk requesting commitments for academic purposes? What is the true benefit for the patient and how to communicate this? Is there impact on the cost for a medicine?

June Raine, Director, Division of Vigilance Risk Management of Medicines, MHRA, UK and Chair of Pharmacovigilance Working Party

Tony Whitehead, UK Medical Director, sanofi-aventis, UK

François Houÿez, Health Policy Officer, EURORDIS, France

16:00 **Session 8**

CAN WE DRAW A NEW SOCIAL CONTRACT IN DRUG DEVELOPMENT?
Session Chair:
Yann Le Cam, CEO, EURORDIS, France

Patients with chronic diseases in Europe are faced with growing challenges: huge remaining unmet medical needs, very little true innovation in treatments, a high level of failure in drug development, and an administrative maze for their approval, lack of real patient access to approved medicines and strident tensions in society about the rising prices and affordability of new medicines. Can we build society support for health research innovation? Can we move away from the damaging mirage of a "zero-risk society" to a new paradigm of policies and regulations geared at stimulating drug development for unmet medical needs? Can we reshape the regulatory framework of complex cumulative committees and lengthy procedures toward a system enhancing success rates in drug development and faster availability of drugs? Can we devise a European Medicine Agency that looks beyond quality, safety and efficacy at clinical added value and real-life studies? Can we have future democratic EU health technology assessment in future? Can we have a patient-centred decision-making system where patients and citizens will make decisions based on experts' opinions?

This closing session of the theme on Media, Society and Research is organised with a panel of key speakers from the EuroMeeting who will contrast future options in an open-minded talk.

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Theme 9
Future of Drug Development and Globalisation – Important Trends and Hot Topics

Theme Leaders:
Barbara Sickmüller, Deputy Director General, German Pharmaceutical Industry Association (BPI), Germany
Christine Mayer-Nicolai, Regulatory Coordination Europe and Global Regulatory Intelligence, Merck KGaA, Germany

This theme, broad in scope, will provide you with information about recent developments in the area of drug development and globalisation; taking into regard hot topics like new therapeutic opportunities in the field of therapeutic vaccines and medicinal products in the area of advanced therapies. In addition, the aim of the theme is to discuss possibilities to strengthen incremental research and to give an overview about the current political situation concerning added therapeutic value as well as political activities to fight against counterfeit medicinal products in the supply chain. The roll-out of ICH to non ICH-countries will also be a topic.

Tuesday, March 24, 2009

09:00 **Session 1**

THERAPEUTIC VACCINES - PROMISING NEW CANCER TREATMENT OPTIONS IN NEED OF APPROPRIATE REGULATIONS

Session Chair:
Karl-Jozef Kallen, Biotherapy Development Association, Germany

As therapeutic vaccines become increasingly important and some companies are developing these kinds of products, this is regarded as an important topic.

Immunological Response Parameters: FDA Requirements for Approval
Bharat Joshi, Chemist/Staff Scientist, Office of Cellular, Tissues and Gene Therapies, CBER, FDA, USA

European Perspective on Cancer Vaccines: Does the Present Regulatory Environment Suffice to Give These Promising Approaches a Chance for Approval?
Thomas Hinz, Head of Section Therapeutic Vaccines, Paul-Ehrlich-Institute, Germany

New Data from Relevant Trials and Experiments: Present Regulations Pose a Hurdle for Demonstrating Efficacy
Bernard A. Fox, Chief, Laboratory of Molecular and Tumor Immunology, Robert W. Franz Cancer Research Center in the Earle A. Chiles Research Institute, Providence Health & Services, USA

11:00 **Session 2**

ADDED THERAPEUTIC VALUE - ARE COMMON CRITERIA FOR EFFECTIVENESS ASSESSMENT POSSIBLE? WHAT ARE THE DISCUSSIONS AT THE EUROPEAN LEVEL?

Session Chair:
Barbara Sickmüller, Deputy Director General, German Pharmaceutical Industry Association (BPI), Germany

Effectiveness assessment is done in nearly all European Member States by different institutions. We will look at the latest developments at European Level to achieve common positions on how the criteria for such an assessment should be laid down. What will the next steps be and what are the scientific discussions?

Appraisal of Health Care from Patients' Value to Societies' Benefit
Franz Porszolt, Klinische Ökonomik, Universitätsklinikum Ulm, Germany

Deliverables on the Relative Effectiveness Working Group of the Pharmaceutical Forum and their Implementation
Jérôme Boehm, Head of Pharmaceuticals Sector, Health and Consumers Directorate General, European Commission, EU

Relative Effectiveness Assessment – Development at European Level and Industry's Position
Markus Frick, Manager, Market Access and Reimbursement, sanofi-aventis GmbH, Germany

14:00 **Session 3**

INCREMENTAL RESEARCH - IMPORTANT BENEFITS, NEGLECTED IN EUROPEAN LAW?

Session Chair:
Michael Popp, CEO, Bionorica AG, Germany

Incremental research with known active substances leads to important benefits for patients, but is often neglected in companies and politics. Coming from the current legislative framework it can be shown that there are manifold approaches to find new indications for known substances although the possibilities to protect the collected data are limited. What could be done in future to promote incremental research by setting adequate incentives will be discussed.

Value of Research with Known Active Substances – Access to Innovation for Patients / Regulatory Data Protection for Industry
Burkhard Sträter, Lawyer, Kanzlei Sträter, Germany

Research and Clinical Evidence with Herbal Medicinal Products – Interesting Approaches and Missing Incentives
Michael Heinrich, Centre for Pharmacognosy and Phytotherapy, The School of Pharmacy, University of London, UK

Incremental Research with Known Active Substances – Current Legislative Framework and Commission's Viewpoint for Future Developments
European Commission speaker invited

16:00 **Session 4**

ADVANCED THERAPIES IMPLEMENTATION - RECENT DEVELOPMENTS AND OPEN QUESTIONS

Session Chair:
Klaus Cichutek, Head, Department of Medical Biotechnology, Paul-Ehrlich-Institute, Germany

Advanced Therapy Medicinal Products are regulated by pharmaceutical law, but need special regulations due to their specific characteristics. Regulation (EC) 1394/2007 lays down these specific requirements. What are the latest developments in relation to the implementation of this Regulation at EMEA? What are the latest developments concerning further technical requirements and guidance for these products? And what is Industry's perspective? These questions will be discussed within the session.

Implementation of Advanced Therapies Regulation at the EMEA – Latest Developments and Open Questions
Patrick Celis, Scientific Administrator, EMEA, EU

Advanced Therapies – Technical Requirements for Quality, Safety and Efficacy for Cell-Based Products in Relation to Existing Rules and Guidance
Paula Salmikangas, Senior Researcher, National Agency for Medicines, Finland

Gene Therapy Medicinal Products – Latest Developments and Special Requirements
Valerie Pimpaneau, Project Director, Voisin Consulting, France

Cell-Based Medicinal Products – Latest Developments and Special Requirements
Andreas Emmendörffer, Managing Director, EuroDerm, Germany

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Wednesday, March 25, 2009

09:00 **Session 5**

IMPLEMENTATION OF ICH IN NON-ICH COUNTRIES: WHERE ARE WE NOW AND WHAT WILL HAPPEN IN THE FUTURE?
Session Chair:
Yves Juillet, Senior Advisor, LEEM, France

The aim of harmonisation is to avoid duplication of studies for ethical and economic reasons and to allow quicker access to new treatments. One of the main difficulties is the extrapolation of clinical trial results in new regions/countries. In this session we will consider how implementation is addressed at the ICH level and how industry and regulators are moving forward particularly in Asia.

Implementation of ICH Guidelines in Non-ICH Countries: The Way Forward
Kohei Wada, General Manager, Asia Clinical Development Department, Daiichi Sankyo Co. Ltd., Japan

Experiences in East Asia: Impact on Global Development
Joseph Scheeren, Senior Vice President, Head Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals, USA

Global Development: How to Move Forward – Joint Initiative of Japan, China and Korea
Yoshiaki Uyama, Review Director, Office of New Drugs III, PMDA, Japan

Discussion: ICH Roll-out in India & China: Challenges of an Emerging Healthcare Environment
Nermeen Varawalla, President & CEO, ECCRO, UK

11:00 **Session 6**

DRUG COUNTERFEITING IN EUROPE: TRENDS AND NEW INITIATIVES
Session Co-Chairs:
Yves Juillet, Senior Advisor, LEEM, France
Thomas Zimmer, Head, CD Safety, Quality and Environmental Protection, Boehringer-Ingelheim GmbH, Germany

Drug counterfeiting is an increasing risk in Europe, depriving patients of effective treatment and possessing direct safety consequences. It has led the European Commission to take some initiatives which will be presented and discussed. The objective of the session is to update participants on the current situation, identifying in particular the channels used by counterfeiters to inform and exchange about the different initiatives taken.

Counterfeiting in Europe: Commission Activities to Combat Counterfeit
Sabine Atzor, Principal Administrator, European Commission, EU

Distribution and Wholesaling: How to Secure the Chain
Monika Derecque-Pois, Director General, GIRP, Belgium

Initiatives Taken by the Council of Europe: The Way Forward
Sabine Walser, Administrative Officer, Council of Europe, EDQM, EU

Discussion with Thomas Zimmer, Head, CD Safety, Quality and Environmental Protection, Boehringer-Ingelheim GmbH, Germany

Thank You!

The DIA would like to express its sincere gratitude to the EuroMeeting 2009 Co-Chairs, Theme Leaders, Advisors and Session Chairs who have made this EuroMeeting possible – a truly comprehensive, neutral platform for the exchange of information and knowledge.

All are volunteers who have dedicated considerable time and energy to putting together this scientific programme.

Thank you!

DIA® DRUG INFORMATION ASSOCIATION

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 10
Impact of Technology and Standards on Drug Development: Now Better, Safer and Faster?

Theme Leaders:
Peter Stokman, Senior Director Clinical Data Management, Organon Schering-Plough, The Netherlands
Valdo Arnera, General Manager - Europe, PHT Corporation, Switzerland

Over the last few years, electronic data capture (eCRF, ePRO, IVRS/IWRS, etc.) has rapidly and dramatically changed clinical drug development. At the current speed of EDC adoption, by the end of this decade the paper trial may have become extinct. However, neither the loose ends in EDC nor the interfacing of the many systems involved yet make for an optimal process, which impedes the leap from 'using EDC' to true eClinical. Rigorous standardisation is one of the answers. The various CDISC models offer an end-to-end solution in which the use of standards can bring an unprecedented streamlining of data flows, encompassing the healthcare community, investigational sites, pharma companies and regulators. Although most companies are able to provide regulators with data in SDTM format, the tremendous improvements offered by the various CDISC models remain largely untapped. Both EDC and CDISC are causing a paradigm shift regarding efficiency and quality in clinical development. This theme will give us a sense of where we are, and a vision of where we are headed.

Tuesday, March 24, 2009

09:00 **Session 1**

INTEGRATING DIFFERENT ECLINICAL DATA STREAMS: NEEDS AND BENEFITS

Session Chair:
Valdo Arnera, General Manager - Europe, PHT Corporation, Switzerland

With the ever increasing use of electronic means of collecting data during clinical trials, it is becoming tempting to integrate all these data streams as soon as possible. But how feasible and how useful is it, and in which circumstances? This session will explore some answers to these questions presenting today's solutions and exploring what the future could look like. We will also learn from a case study that both the technology and the human aspects of a programme of change projects must be addressed to ensure the success of the rationalisation and streamlining of data flows within the clinical value chain.

Integration of Technology – Today's Fad or Tomorrow's Standard?
Bill Byrom, Vice President, Product Strategy, Perceptive Informatics, UK

A Process Approach to Integration of the Clinical Trial Value Chain
Mike Bartlett, Technical Architect - eClinical Programme, H. Lundbeck A/S, Denmark

Integration: a Case Study
Inge Hansen, Section Head/Change Project Manager Lündbeck, Denmark

11:00 **Session 2**

ARE BENEFITS OF ECLINICAL METHODS IN STEP WITH REGULATIONS AND RECENT EMEA GUIDANCE?

Session Chair:
Steve Raymond, Chief Scientific Officer and Quality Officer, PHT Corporation, USA

There are many advantages in efficiency, cost and data quality when eSource data are captured directly from electronic health records and from eRecords completed directly by subjects in clinical studies. This session takes the view that useful advances make sense even when they challenge regulatory guidance, and that familiar approaches that fall within current regulations (isolated trials performed in sequence with paper methods) do not meet the test of better, safer, or faster. Speakers directly engaged in conducting, planning, reviewing or enabling clinical trials that rely on eSource documents will consider the promise of eSource and the challenges to its optimum adoption that lurk in regulations developed during the age of paper methods.

Regulating eDiaries – From Planning to Retention of Archival eSource Records
Steve Raymond, Chief Scientific Officer and Quality Officer, PHT Corporation, USA

eSource, EHR, Metadata Standards - A Road to Better, Safer, Faster
Isabelle de Zegher, Belgium

Achieving the Benefits of Electronic Methods under EMEA Regulatory Guidance
Fergus Sweeney, Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, EMEA, EU

14:00 **Session 3**

TECHNOLOGY & STANDARDS... HOW ABOUT THE PROCESS?

Session Chair:
Peter Stokman, Senior Director Clinical Data Management, Organon Schering-Plough, The Netherlands

Initially, adoption of a new technology will typically lead to continuation along the old lines of thinking. In the last couple of years a lot of new technology has become available in clinical development. Did that just improve the old process or are we defining new concepts? Nick Lucas will evaluate where we are as an industry, and contrast with best practices in other lines of business, Martin Semrau will give an example of how new thinking can change the way we utilise technology and Joe Anderson will stretch it further and help us envision an optimised picture based on people, process and current technologies.

An Honest Look at the eClinical Process: How We Can Learn from Best Practices Outside the Industry
Nick Lucas, Vice President, Global Data Management, INC Research, UK

Service Oriented Clinical Trials
Martin Semrau, Enterprise Architect, Novartis Pharma AG, Switzerland

We're Halfway There: Making Full Use of EDC
Joseph Anderson, Principal Associate, Waife & Associates, Inc., USA

16:00 **Session 4**

THE LOOSE ENDS IN EDC AND HOW TO ADDRESS THEM

Session Chair:
Johann Proeve, Global Head, Data Management, Bayer Schering Pharma, Germany

This session is taking a closer look at the non-core areas of EDC that, however, add value once the users go beyond the basic features of EDC. You will learn about the interfacing from EDC to the pharmacovigilance database, about external data to be made available in EDC and about the usefulness of edit checks in EDC. Overall, the audience will get a good overview of the value-added features of EDC.

SAE Reporting from EDC Data - A Seamless Flow of Information?
Jens Knoesel, eClinical Project Manager, Metronomia Clinical Research GmbH, Germany

Integrating External Data into EDC for Better, Safer, and Faster Online Adjudication
Vincent Cabane, Clinical Director, Kika Medical, France

EDC and Edit Checks: How Far Can We Go?
Ricky Dolphin, Professional Services Consultant, eResearchTechnology, UK

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Wednesday, March 25, 2009

09:00 **Session 5**

A LOOK INTO THE FUTURE: WHAT IS ON THE HORIZON AFTER WE HAVE MANAGED EDC PROPERLY?

Session Chair:
Massimo Raineri, Head of System Development, Biometry, Actelion, Italy

A few years ago EDC was perceived as being "the future". Now EDC is real and solid; it is our present, but we still face a lot of challenges: adding integration, simplicity and intuitive user interface to existing applications in order to obtain next generation systems. The session will analyse and discuss emerging trends which might design the new future of the EDC world.

The Next Generation of EDC Integration
David Stein, Vice President, Product Management, Perceptive Informatics, USA

Removing the Boundaries between the Worlds of Data, Trial and Safety Management through EDC
Simon Neville Hawken, Director, Business Development, eResearch Technology Inc., USA

The Digital Pen and Paper Technology in Clinical Trials Data Collection: Transforming Paper into an Easy and Smart Interface to Collect Patients' Data
Massimo Raineri, Head of System Development – Biometry, Actelion, Italy

11:00 **Session 6**

EXPERIENCE WITH CDISC STANDARDS

Session Chair:
David Iberson-Hurst, Vice President, Technical Strategy, CDISC, UK

This session will look in detail at the use of the CDISC standards and provide the audience with detailed practical experiences of how the standards have performed and the issues raised.

Using ODM Standard to Gain Efficiency in the Management of Hybrid Trials
Gilles Rondeau, System Architect, eclinical Solutions, Canada

Integration of Direct Data Capture, ePRO and EDC Data via CDISC ODM
Wolfgang Summa, Vice President Europe & Asia Pacific, invivodata, inc., UK

Use of Standards to Automate the Creation of CDISC ADaM Data Structures and Metadata
Jon Roth, Director, S-Cubed ApS, Sweden

14:00 **Session 7**

CDISC END-TO-END: TO WHAT EXTENT?

Session Chair:
Stephane Rouault, Global Head, Data Management Services, F. Hoffmann-La Roche Ltd., Switzerland

Currently clinical care and clinical research organisations are two totally separate worlds from an electronic perspective, still both striving towards standards. Connecting patients, healthcare providers and medical research sponsors is opening a totally new world of possibilities and opportunities. The interoperability afforded by CDISC and HL7 standards is providing the capability of integrating patient care, clinical research and safety assessments. The following presentations will provide some further insights.

Electronic Health Records - Practical Experiences
Stephane Rouault, Global Head, Data Management Services, F. Hoffmann-La Roche Ltd., Switzerland

CDISC End-to-End: To What Extent Do the CDISC Standards Achieve Information System Independence?
Ricky Dolphin, Professional Services Consultant, eResearchTechnology, UK

Standardisation of Basic Data Collection Standards - An Idea Whose Time Has Come
Rhonda Facile, CDASH Project Director, CDISC, USA

16:00 **Session 8**

CDISC AS AN AVENUE TO PROCESS IMPROVEMENT

Session Chair:
John Aggerholm, eClinical Senior Project Manager, NNIT A/S, Denmark

When optimising processes today with the support of integrated IT systems, it is important to use standards. This session will show the benefits of using CDISC, both in the processes themselves, and for integration both internally and externally. The benefits of the use of EDC, metadata respositories and the business as a whole will be demonstrated in the presentations.

CDISC Standards, EDC Libraries, and Integrations are Key Drivers for Process Improvement and Innovation
Ward Lemaire, Senior Manager Biometrics, Data Management, Tibotec, Belgium
Metadata Repository Use in an End-to-End, CDISC Standards-Based, Clinical Data Lifecycle
Barry Cohen, Senior Director, Clinical Data Strategies, Octagon Research Solutions, USA

How to Use an eClinical CDISC-based Business Architecture to Optimise R&D
John Aggerholm, eClinical Senior Project Manager, NNIT A/S, Denmark

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Theme 11
Optimising Drug Development through Sound Methodology

Theme Leaders:
Jürgen Kübler, Global Head, Statistical Safety Sciences, Novartis Pharma AG, Switzerland
Robert Hemmings, Statistics Unit Manager, MHRA, UK and CHMP

The current R&D process is facing significant challenges: there is a need to develop efficacious and acceptably safe drugs more efficiently, and to improve in the early identification of drugs that will ultimately fail to prove a favourable profile of benefits and risks. Sound quantitative methods can play a major role in optimising drug development in terms of both design and conduct of an individual study, and design and decision making across a development programme. The theme will explore statistical approaches to improve the efficiency with which medicines are developed. This includes a thorough discussion of how to optimise implementation of established and new methodology and their applicability in a highly regulated environment. The theme aims to provide a forum for discussion between industry, academic and regulatory thought-leaders. Relevant experience will be shared and discussed, reflecting on lessons learned. By investigating the underlying processes, recommendations for best practice will be developed.

Tuesday, March 24, 2009

09:00 **Session 1**

ADAPTIVE DESIGNS - FROM STATISTICAL SCIENCE TO REGULATORY GUIDANCE

Session Chair:
Armin Koch, Biostatistician, BfArM, Germany
Joachim Vollmar, Executive Consultant, International Clinical Development Consultants, USA

For over 15 years, the concept of flexible trial designs has been a focus of statistical and regulatory research. Adaptive (flexible) trial designs allow redesigning the study (e.g. sample size, randomisation ratio, number of treatment arms) based on the results of interim analyses. The statistical theory underlying these trial designs and the availability of appropriate software allow for controlling the overall type I error probability (significance level) precisely. The regulatory impact of and view on adaptations midstream of a study are dealt with in the EMEA's Reflection Paper (2007) and FDA's draft guidance (2009) on methodological issues in confirmatory clinical trials with flexible design and analysis plan. This session includes the statistical background and the current view of the European and US regulators with a discussion on the general methodological issues and regulatory principles.

Statistical Principles of Flexible Designs – an Overview
Peter Bauer, Professor, University of Vienna, Austria

European Regulatory Perspective - EMEA Reflection Paper
Armin Koch, Biostatistician, BfArM, Germany

US Regulatory Perspective - Draft FDA Guidance
Robert T. O'Neill, Director, Office of Biostatistics, CDER, FDA, USA

Discussion with Joachim Röhmel, Department of Biostatistics and Clinical Epidemiology, Charité University, Germany
Michael Branson, Global Head, Clinical Advanced Statistical Solutions, Novartis Pharma AG, Switzerland

11:00 **Session 2**

ADAPTIVE DESIGNS – A DISCUSSION WITH STAKEHOLDERS

Co-Chairs:
Armin Koch, Biostatistician, BfArM, Germany
Joachim Vollmar, Executive Consultant, International Clinical Development Consultants, USA

This session presents practical experience when employing adaptive designs. Benefits (including acceleration of the clinical trial process, enhancement of trial efficiency and improvements in patient safety) and risks (lack of integrated technologies for patient allocation, drug supply, data management, study monitoring and statistics) as well as the success factors of adaptive trials will be intensively discussed through various scenarios.

Examples from SAWP/CHMP
Robert Hemmings, Statistics Unit Manager, MHRA, UK and CHMP

Pushing the Boundaries for Adaptive Phase III Trial Designs
Brenda Gaydos, Research Advisor, Center for Applied Statistical Expertise, Eli Lilly and Company, USA

Practical Experience of a Sponsor with Adaptive Designs During Drug Development
Ralf Müller, Manager Clinical Research & Development, Dr. Falk Pharma GmbH, Germany

14:00 **Session 3**

SAFETY PLANNING IN DRUG DEVELOPMENT - REAL IMPROVEMENT OR YET ANOTHER DOCUMENT?

Session Chair:
Jürgen Kübler, Global Head, Statistical Safety Sciences, Novartis Pharma AG, Switzerland

The session will present and discuss recent recommendations of PhRMA's Safety Planning, Evaluation and Reporting Team (SPERT). The goal of SPERT was to recommend an industry standard for safety planning, data collection, evaluation and reporting. SPERT's recommendations are based on our review of relevant literature and on consensus reached in our discussions, although we recognise that there might be other valid approaches.

Safety Planning - An Overview
Jürgen Kübler, Global Head, Statistical Safety Sciences, Novartis Pharma AG, Switzerland

Planning for the Identification, Data Collection, and Integration of Adverse Events of Special Interest (AESI)
Manfred Oster, Deputy Head Clinical Safety Pharmacovigilance Unit, sanofi-aventis, USA

Approaching a Safety Analysis Plan to Address Adverse Events of Special Interest
George Rochester, Lead Mathematical Statistician, Drug Safety, Office of Biostatistics, CDER, FDA, USA

16:00 **Session 4**

BEYOND TRIAL DESIGN AND SAMPLE SIZE ESTIMATION - THE UTILITY OF CLINICAL SCENARIO ASSESSMENTS

Session Co-Chairs:
Michael Branson, Global Head, Clinical Advanced Statistical Solutions, Novartis Pharma AG, Switzerland

Modern drug development is demanding more efficient approaches to develop new therapeutics, balancing the requirements of many stakeholders: patients, payors, regulators, etc. The aspect of leveraging scientific innovation through the use of novel trial designs and analysis techniques should be considered within an overarching framework of improved efficiency for the clinical program. In this session, we describe a framework that considers the planning of a clinical development strategy taking the contributions of quantitative statistical scientists beyond the usual trial design and sample size calculation. This framework is illustrated with case study discussions.

Aspects of Modernising Drug Development Using Scenario Planning and Evaluation
Norbert Benda, Statistical Methodology, Novartis Pharma AG, Switzerland

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Use of Trial Simulation to Optimise Trial Design and Analysis Strategies
Brenda Gaydos, Research Advisor, Center for Applied Statistical Expertise, Eli Lilly and Company, USA

Regulatory Agency Panel :
Robert T. O'Neill, Director, Office of Biostatistics, CDER, FDA, USA
Robert Hemmings, Statistics Unit Manager, MHRA, UK

Wednesday, March 25, 2009

09:00 **Session 5**

STATISTICS FOR BIOMARKERS AND "OMICS"– ANYTHING NEW?

Session Chair:
Richardus Vonk, Head of Drug Discovery Statistics, Bayer Schering Pharma AG, Germany

The statistical challenges around "omics" and biomarker data are well discussed. How is statistical science progressing in this field? As the use of biomarkers, and in particular omics-data is slowly gaining importance in the pharmaceutical industry (again), this session will provide a brief overview of recent developments in statistical approaches towards such data.

Selecting Promising New Compounds Earlier by Tapping into Modern Safety and Pharmacological Mechanism in Early Exploratory Clinical Research
Matthias Grossman, Vice President and Principal Consultant, PAREXEL International, USA

Weibull Failure-Time Mixture Models for Evaluating Efficacy in the Presence of a Biomarker
Kallappa M. Koti, Division of Biometrics, FDA, USA

Choice of Reference Genes for RT-PCR Normalisation
Susanne Schwenke, Director Non-Clinical Statistics, Bayer Schering Pharma AG, Germany

11:00 **Session 6**

GETTING THE DOSE RIGHT - DOSE FINDING AND EXPOSURE REPONSE

Session Chair:
Mike K. Smith, Director Pharmacometrics, Pfizer, UK

Selecting the right dose for confirmatory studies and regulatory submission involves characterising the relationships between dose, exposure, efficacy and safety balancing sufficient to effect an acceptable level of risk due to safety or tolerability issues. The choice should be based on the synthesis of all information, including prior information, knowledge of disease progression and physiological processes, previous experience with this drug and other similar compounds. The choice becomes more difficult in the case of special populations such as paediatrics – currently an important topic of discussion between the industry and regulatory agencies. We should aim to run efficient trials which optimise our learning and give us the best chance of getting the dose right for the majority of patients.

Impact of Dose Selection Strategies on the Probability of Success in Phase III
Zoran Antonijevic, Senior Director, Strategic Development, Biostatistics, Quintiles, USA

Leveraging Prior Quantitative Knowledge in Guiding Paediatric Drug Development: A Case Study
FDA speaker invited

Case Study: Dose-Finding for Maraviroc Anti-Retroviral Therapy
Lynn Mc Fadyen, Pharmacometrician, Pfizer Ltd., UK

14:00 **Session 7**

ADDRESSING KEY SAFETY CHALLENGES IN CLINICAL DRUG DEVELOPMENT: SIGNAL DETECTION AND CONTINUOUS RISK ASSESSMENT

Session Co-Chairs:
Joachim Vollmar, Executive Consultant, International Clinical Development Consultants, USA
Trevor Gibbs, Executive Vice President, Chief Medical Officer, ii4sm, Switzerland

Drug safety signal detection and continuous risk assessment throughout the lifecycle of a medicinal product are highly multi-disciplinary processes involving experts from pharmacovigilance, data management, statistics and epidemiology. The implications of these tasks and the day-to-day problems will be presented by specialists having hands-on experience in this field. A panel will address the challenges of detecting drug safety risks early in the pre-marketing and later in the post-marketing drug life cycle sooner by employing appropriate methodologies.

Quantitative Signal Detection and Assessment of Safety Signals
Stephen Evans, Professor, The London School of Hygiene & Tropical Medicine, UK

Signal Detection from Clinical databases – The Pitfalls and the Pointers
Michael K. Williams, Principal Statistician, Biostatistics and Programming Development Partners, GlaxoSmithKline, UK

Risk Management Plans - Practical Implications
Stella Blackburn, Principal Scientific Administrator, EMEA, EU

Panel with George Rochester, Lead Mathematical Statistician, Drug Safety, Office of Biostatistics, CDER, FDA, USA

16:00 **Session 8**

'MISSING DATA' FOR YOUR 'QUANTITATIVE BENEFIT-RISK' ASSESSMENT SUPPORTING 'CONDITIONAL MARKETING AUTHORISATION'? WHERE NEXT FOR REGULATORY GUIDANCE?

Session Chair:
Robert Hemmings, Statistics Unit Manager, MHRA, UK

EU regulators have, through CHMP, written and published guidance documents to set out and, hopefully, to agree standards and expectations for drug development programmes. This session looks at ongoing regulatory activities in the areas of conditional approval, handling of missing data and improving the quantification and transparent communication of benefit-risk assessments. Speakers will outline ongoing activities and try to promote discussion to shape future guidance.

Methodological Guidance and Practical Implementation of Conditional Approval
Robert Hemmings, Statistics Unit Manager, MHRA, UK

Methods for Quantification of Benefit: Risk
Jeff Kirsch, Director, Strategic Health Outcomes, Global Health Outcomes, GlaxoSmithKline, UK

Updates on Regulatory Requirements for Missing Data
Ferran Torres, Clinical Pharmacologist, Statistician, Hospital Clinic de Barcelona, Spain

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Theme 12
Health Economics and Health Technology Assessments – Supporting Sustainable, Socially Acceptable and Equitable Access to Innovation

Theme Leaders:
Wills Hughes-Wilson, Director Health Policy Europe, Genzyme, Belgium
Carolin Miltenburger, Director Health Economics & Outcomes, i3 Innovus, Germany

Growing budget constraints in healthcare worldwide increasingly determine market access and new medical technologies. Evidence of product value is critical to meet the requirements of reimbursement agencies, clinical guideline committees but also the expectations of patients and physicians. Product value goals are therefore essential development objectives, equal in importance to safety, efficacy and quality. Ten years after the introduction of NICE into the European landscape almost all EU countries have established processes and standards for HTA and economic appraisal. This theme will explore the European health policy environment and the various methodologies used to build a product value platform as part of drug development. The theme aims to cover different phases of the product lifecycle, different perspectives and novel approaches. The theme aims to be a forum to exchange and discuss experience and to participate in the search for best practice.

Tuesday, March 24, 2009

09:00 **Session 1**

DEMONSTRATING COST-EFFECTIVENESS IN CHALLENGING SITUATIONS AND WHEN DATA IS LIMITED

Session Chair:
Jeremy Chancellor, Director, Health Economics & Outcomes Research, i3 innovus, UK

Health Technology Assessment and Health Economics rely on data to allow decisions to be taken. But what happens when, due to the very nature of the treatment in question, the data are not available? Our regulatory approval systems have evolved to take account of urgent, unmet medical needs, of rare diseases and other treatment needs requiring a special approach. But what happens after these products are approved? Are the reimbursement systems as understanding as the regulatory systems? And, if not, what needs to change?

HTA and Economics: When and How Can We Make Reasonable Assessments Earlier in the Lifecycle?
Jeremy Chancellor, Director, Health Economics & Outcomes Research, i3 innovus, UK

Orphan Medicinal Products – How to Ensure Patients Get Access to Treatment While at the Same Time Developing the Data that Health Technology Assessors and Health Economists Need?
Aline Gauthier, PhD Programme, University of Glasgow, UK

Approval under Exceptional Circumstances - Does It Mean Reimbursement in Exceptional Circumstances? How to Bridge the Gap?
Mark Rothera, European and Regional Sales & Marketing Director, Shire HGT, UK

11:00 **Session 2**

MARKET ACCESS IN EUROPE: HOW DOES INNOVATION GET TO THE PATIENTS?

Session Chair:
Andrea Rappagliosi, Vice President, Health Policy & Market Access, Merck Serono, Switzerland

Access to innovation is a key element of getting the newest and, arguably, most effective treatment to patients. But the situation across Europe is not uniform in the evaluation of what constitutes value. This session seeks to explore the current situation in several key therapeutic areas and provide insight into which factors influence decisions on value, pricing & reimbursement.

Access to Treatment in Europe – Challenges in Getting Innovation to Patients in Key Indications?
Catherine Steele, International Head Public Policy, F. Hoffman-La Roche Ltd., Switzerland

Value-Based Pricing – How Do We Get a Good Idea about the Value of a Product? What Role for Risk-Sharing?
Adrian Towse, Director, Office of Health Economics, UK

Innovative Oncology Treatments – The Role of HTA in the Assessment of Value
Carole Longson, Director, Centre for Health Technology Evaluation, National Institute for Clinical Excellence (NICE), UK

14:00 **Session 3**

WHAT DOES THE USER CONSIDER VALUE? INCLUDING THE PATIENTS' VOICE IN ASSESSMENTS

Session Chair:
Mary Baker, President, European Parkinson's Disease Association (EPDA), UK

Decisions are taken by various agencies on whether a treatment gets onto the reimbursement lists or not. Arguably, the payers are the customers. But the real customers – the ones that stand to benefit, or not – from treatments are the patients themselves. So how can we include their voice, their assessment and view in the overall Health Technology Assessment? Is it ever appropriate to not include them? And if so, when?

Structures for Including the Patients' Voice Early On in the Decision-Making Process. Where (Not) To Include the Patients' Voice in HTA
Mattias Neyt, Economic Analysis Expert, KCE – Belgian Health Care Knowledge Centre, Belgium

Patient-Reported Outcomes in Multinational Clinical Trials – Status in 2009 & Beyond?
Ingela Wiklund, Gothenburg University, Former Director Patient-Reported Outcomes, GlaxoSmithKline, UK

Patient-Reported Outcomes – Methodologies for Studies and Real Life
Thomas Kohlmann, Professor, Ernst Moritz Arndt University of Greifswald, Germany

16:00 **Session 4**

CLINICAL TRIALS - THE START NOT THE END. BUILDING INTEGRATED DATA SETS IN A EUROPEAN CONTEXT TO MEET NEEDS

Session Chair:
Stefan Willich, Director, Institute for Social Medicine, Epidemiology & Health Economics, Charité University Medical Center, Germany

Health Technology Assessment agencies and reimbursement authorities want data on which to base their evaluations. And sometimes that data is not there. Or is it? Research is happening all the time, but are we making the best use of it? This session aims to investigate if and how the data developed in other circumstances can be used to fill the gaps.

Patient-Registries and Databases – A Road to Understanding Effectiveness?
Bernd Brüggenjürgen, Coordinator Health Care System Research, Charité University, Germany

Sharing Data from Clinical Trials - How to Make the Most of It?
Martin Daumer, Scientific Director, Sylvia Lawry Centre for Multiple Sclerosis Research, Germany

Observational Trials - The Opportunity to Move from Efficacy to Effectiveness Evaluation?
Andrea Spannheimer, Vice President Late Phase International, i3 Innovus Late Phase Research, Germany

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Wednesday, March 25, 2009

09:00 **Session 5**

HEALTH ECONOMICS AND HEALTH TECHNOLOGY ASSESSMENT IN 2009 – A MORE DIVERSE OR MORE UNIFORM LANDSCAPE?

Session Chair:
Bengt Jönsson, Professor Health Economics, Stockholm School of Economics, Sweden

Much has happened over the past 10 years in the field of Health Economics & Health Technology Assessment. More countries are using the approach before granting reimbursement and patient access and agencies are increasingly working together. So where do we stand? Is there convergence in terms of methodologies used and, if so, is there best practice that should be shared? And how wide are the remaining differences, 10 years after NICE was established? How do newer EU Member States address public health challenges? This session will set out a "state of the nation" overview of where we stand with HTA and Health Economics in 2009.

Cooperation Between Agencies: How Do the Leading Agencies such as HAS, IQWIG & NICE Cooperate?
Thomas Lönngren, Executive Director, EMEA, EU

NICE 10 Years On – What Will the Next 10 Years Hold?
Andrew Dillon, Chief Executive Officer, National Institute for Clinical Excellence (NICE), UK

The Newer EU Member States: HTA and Public Health Challenges. Are They Compatible?
László Gulácsi, Professor, Corvinus University, Hungary

11:00 **Session 6**

BUILDING HEALTH TECHNOLOGY ASSESSMENTS INTO PRODUCT DEVELOPMENT FOR SUCCESS

Session Chair:
Carolin Miltenburger, Director Health Economics & Outcomes, i3 Innovus, Germany

How can developers use study design to create endpoints that produce the most effective data for both authorisation and reimbursement? And if the companies organise themselves internally to meet this challenge, can the Agencies cooperate in the same way? How should the process work? What will scientific advice look like in the future? And how can one ensure that the data-set developed is respected?

Using Study Design to Create End-Points that Produce the Most Effective Dataset
Anita Burrell, Associate Vice President, Health Economics & Reimbursement (HERA), sanofi aventis, France

Clinical Development and Health Economics Working Together in the Company. Can It Be Successful?
Clare McGrath, Senior Director Evidence Based Strategies, Medical Division, Pfizer Ltd., UK

Designing Trials to Deliver Payer-Relevant Clinical and Economic Evidence. Can Scientific Advice Be Binding?
Jens Grueger, Head Global Pricing & Reimbursement, Global Marketing & Sales, Novartis Pharma AG, Switzerland

14:00 **Session 7**

MEDICINES ARE ABOUT MORE THAN MONEY. BUILDING SOCIAL VALUES INTO HEALTH ECONOMICS

Session Chair:
Yann Le Cam, CEO, EURORDIS, France

We are repeatedly told that healthcare budgets are restricted, but how do we decide how the money is to be spent? Non-reimbursement decisions are often challenged in a public arena after the fact. So how can we ensure that Health Technology Assessments include the values of the society that is ultimately paying the bill?

Advisory Committees – Can Multi-Stakeholder Groups Ensure that Decisions Reflect Society's Wishes?
Hubert G.M. Leufkens, Division of Pharmacoepidemiology & Pharmacotherapy, Faculty of Science, Utrecht University, Utrecht Institute for Pharmaceutical Sciences (UIPS), The Netherlands

Can More Public Discussions Ensure the Right Outcomes for Society?
James Whale, Chairman, James Whale Fund for Kidney Cancer, UK

Challenging the System in Challenging Cases
Gabrielle Silver, CNS Director, Esai, Ltd., UK

16:00 **Session 8**

ACCESS TO INNOVATION: A ROLE FOR NEW APPROACHES?

Session Chair:
Ann-Christin Tauberman, General Director, The Dental and Pharmaceutical Benefits Agency (TLV), Sweden

The old ways might not necessarily work for new products. Indeed, according to many stakeholders, the old systems are not working. Several companies have tried collaborative approaches with different parts of the decision-making chain. In this session, we will hear from the trail-blazers themselves on these new, innovative approaches to getting innovative treatments to patients.

Is There a Role for Registries in the Health Economics and Clinical Added Value Assessment of Orphan Drugs?
Erik Tambuyzer, Senior Vice President, Corporate Affairs Europe and International, Genzyme, Belgium

Risk-Sharing Schemes – The Way Forward?
Martin Price, Head of Market Access, Janssen-Cilag Ltd., UK

Working with Agencies – A Shared Approach. First Feedback from Industry-Agency Cooperation in Development Co-Design – Speaking from Experience
Jens Grueger, Head Global Pricing & Reimbursement, Global Marketing & Sales, Novartis Pharma AG, Switzerland

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 13
Pre-Clinical/Clinical Interface: How to Improve Success in Developing Innovative Medicines

Theme Leaders:
Bert Haenen, Toxicologist, Schering-Plough, The Netherlands
Klaus Olejniczak, Scientific Director, BfArM, Germany

Pre-Clinical studies are generally used to explore the initial safety, pharmacology and pharmacokinetic behavior of new medicinal products before entering clinical studies. Even after reaching the clinical stage of development, preclinical testing continues. In pre-clinical R&D, researchers are continuously searching for new techniques, targets, safety endpoints, animal models etc. to improve the predictability of animal studies for the clinical situation. A session chaired by Beatriz Silva Lima, chairperson of EMEA-SWP focuses on juvenile animal studies for first in children trials. Another focuses on the safety and efficacy of the new emerging area of RNAi therapeutics.

Tuesday, March 24, 2009

09:00 **Session 1**

USE OF IMAGING IN NON-CLINICAL TOXICITY TESTING: WHAT IS ITS VALUE? WHAT ABOUT REGULATORY ACCEPTANCE?

Session Chair:
Thomas Monticello, Executive Director Toxicological Sciences Safety Assessment, Merck Research Laboratories, USA

Imaging technologies are widely used in clinical practice and are emerging as an important tool in efficacy assessment in clinical trials. Unfortunately, they have found limited use in preclinical settings and in toxicological research for various reasons. The growing promise of these technologies that will facilitate greater information sharing in the globalised non-clinical development of drugs, their promise to reduce the number of animals used in routine testing and their potential direct translation to clinical safety biomarkers will be discussed. In the presentations and discussions we will look at the implications for and regulatory acceptance of such methodologies for incorporation in routine non-clinical development of pharmaceuticals. This is a current challenge that needs to be addressed from a determination of what is raw data in the imaging world to the validation of the technologies.

Use of MicroCT in Reproductive and Developmental Toxicity Studies
Chris Winkelmann, Imaging Research, Merck and Company Inc., USA

Computer-Assisted Pathology Use in General Toxicology for Pharmaceutical Development
Stephen J. Potts, Global Director of Biotechnology and Pharmaceuticals, Aperio Technologies, USA

Development of PET Imaging Probes for Use in General Toxicology - The New Biomarker
William Slikker, Center Director, National Center for Toxicological Research, FDA, USA

11:00 **Session 2**

NON-CLINICAL EVALUATION OF HEPATOTOXICITY: WHERE DO WE STAND? HOW SCEPTICAL IS THE PHARMACEUTICAL INDUSTRY?

Session Chair:
Bert Haenen, Toxicologist, Schering-Plough, The Netherlands

Drug-induced liver injury is one of the major causes for market withdrawal of an approved medicinal product. Pharmaceutical industry is well aware of this issue and is searching for new strategies to improve signaling for hepatotoxic compounds. In addition, both EMEA and FDA have issued guidelines for evaluation of (pre) clinical hepatotoxicity. The EMEA guideline was received particularly with scepticism by the pharmaceutical industry. In this session both EMEA and FDA guidelines will be discussed. In addition, a contemporary approach to assessing the potential clinical relevance of hepatotoxic signals by new drug candidates will be presented, as well as the search for new hepatotoxic biomarkers from using an integrated "omics" approach.

The EMEA and FDA Hepatotoxicity Guideline
Gerd Bode, Lecturer, University of Göttingen and Consultant, Germany

Current Industry Approach to Filter Potentially Livertoxic Compounds
Colin Fish, Director, Non Clinical Safety Projects, GlaxoSmithKline, UK

New Biomarkers for Hepatotoxicity: An Integrated Omics Approach
Kirstin Meyer, Non-Clinical Drug Safety, Bayer Schering Pharma AG, Germany

14:00 **Session 3**

NON-CLINICAL SUPPORT FOR FIRST-IN-MAN STUDIES

Session Chair:
David R. Jones, Expert Scientific Officer, Pharmacotoxicologist, MHRA, UK

It is recognised that in some cases insight on human physiology/pharmacology, knowledge of drug candidate characteristics and therapeutic target relevance to disease are benefited by earlier access to human data. Streamlined early exploratory approaches can accomplish this end. Exploratory Clinical Studies (ECS) for the purpose of this guidance are those intended to be conducted early in Phase 1, involve limited human exposure, have no therapeutic or diagnostic intent, and are not intended to examine maximum tolerated dose. They can be used to investigate a variety of parameters such as pharmacokinetics, pharmacodynamics and other biomarkers, which could include PET receptor binding and displacement.

Non-Clinical Support for First-in-Human Studies
Paul Baldrick, Head of Regulatory Affairs, Covance Laboratories Ltd., UK

Exploratory Clinical Studies - Why, When and How?
Phil Wilcox, Vice President, World-Wide Non-Clinical Safety Projects Safety Assessment, GlaxoSmithKline, UK

First-in-Human Studies - An EU Regulatory Perspective
David R. Jones, Expert Scientific Officer, Pharmacotoxicologist, MHRA, UK

16:00 **Session 4**

UPDATE ON ANTI-CANCER DRUG GUIDELINE ICH9

Session Chair:
Klaus Olejniczak, Scientific Director, BfArM, Germany

There have been no internationally accepted objectives or recommendations on the design and conduct of non-clinical studies to support the development of anti-cancer drugs. The purpose of this session is to provide information to assist in the design of an appropriate program of non-clinical studies for the development of anti-cancer drugs.

Update on Anti-Cancer Drug Guideline ICH S9
Klaus Olejniczak, Scientific Director, BfArM, Germany

Industry Experience with Non-Clinical Development of Anti-cancer Drugs
Hermann Schweinfurth, Head of Non-Clinical Drug Safety, Bayer Schering Pharma AG, Germany

Cancer Research UK Experience with Non-Clinical Development of Anti-Cancer Drugs
Robert Williams, Head of Drug Development Projects & Non-Clinical Development, Cancer Research UK

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Wednesday, March 25, 2009

09:00 **Session 5**

UPDATE ON ICH S6 NON-CLINICAL SAFETY TESTING OF BIOTECHNOLOGY-DERIVED PRODUCTS: PART 1

Jennifer Sims, Director, Head NBx Translational Sciences & Safety, Novartis Biologics, Switzerland

In June 2008 it was decided by ICH that the S6 Guideline will be updated with a focus on a few topics. Over two sessions the topics will be highlighted and followed by a panel discussion of several members of the Expert Working Group dealing with these topics.

Update of S6 Guideline: Reprotox of Homologue Monoclonals: Is it Useful?
Jan Willem Van der Laan, Senior Assessor Section on Safety of Medicines and Teratology Centre for Biological Medicines & Medical Technology, RIVM, The Netherlands

Reproductive Toxicity Testing of Monoclonals
Jane Stewart, Reproductive Toxicology, AstraZeneca, UK

Immunogenicity
Jeanine Bussiere, Executive Director of Toxicology, Amgen Inc., USA

Selection of the Right Species
Marguerite Dempster, Safety Assessment, GlaxoSmithKline Research and Development Ltd., UK

11:00 **Session 6**

UPDATE ON ICH S6 NON-CLINICAL SAFETY TESTING OF BIOTECHNOLOGY-DERIVED PRODUCTS: PART 2

Session Chair:
Jan Willem Van der Laan, Senior Assessor Section on Safety of Medicines and Teratology Centre for Biological Medicines & Medical Technology, RIVM, The Netherlands

In addition to the topics in Part 1, Part 2 will discuss Study Design Issues followed by a panel discussion of several members of the Expert Working Group dealing with these topics.

Study Design Issues 1 PKPD
Peter Lloyd, Head of PKPD Biologics, Novartis Horsham Research Centre, UK

Study Design Issues 2
FDA speaker invited

Panel discussion with speakers and Beatriz Silva Lima, Professor, Pharmacology, iMED, University of Lisbon, INFARMED, Portugal

14:00 **Session 7**

NEW CONCEPTS IN THE ASSESSMENT OF GENOTOXICITY

Session Chair:
Peter Kasper, Scientific Director, BfArM, Germany

The current revision of the ICH S2 genotoxicity guideline and a recent CHMP Q&A document on genotoxic impurities have provided several new recommendations for genotoxicity assessment. This session presents an overview of the key changes in these areas and highlights some of the challenges from industry perspective; in particular in relation to the integration of genotoxicity measurement into general toxicity studies and the controlling of genotoxic impurities during early drug development.

Revision of the ICH S2 Genotoxicity Guideline: What's New?
Regulation of Genotoxic Impurities: Supplementary Advice from a CHMP Q&A Document
Peter Kasper, Scientific Director, BfArM, Germany

Genetic Toxicology – Moving from Stand-Alone to Integrated Testing
Andreas Rothfuss, Genetic Toxicology, Bayer Schering Pharma AG, Germany

Strategies for Managing Genotoxic Impurities During Preclinical and Clinical Development
Bernard Leblanc, Director, Regulatory Submissions & External Relations Safety Sciences, Pfizer, France

16:00 **Session 8**

UPDATE ON THE USE OF JUVENILE ANIMAL STUDIES FOR PAEDIATRIC DRUG DEVELOPMENT

Session Chair:
Beatriz Silva Lima, Professor, Pharmacology, iMED, University of Lisbon, INFARMED, Portugal

An update on the current discussions regarding non-clinical development plan of paediatric drugs, the role of juvenile animal studies and the approaches in place in the European and US context, taking into consideration the recently approved regional guidelines, will be addressed by EU and US Regulators and by an industry representative.

The European Situation with Several Case Studies
Beatriz Silva Lima, Professor, Pharmacology, iMED, University of Lisbon, INFARMED, Portugal

FDA Experience of the Request for Juvenile Animal Studies and Guideline Management
FDA speaker invited

The Industry Experience Including the Highlight of Aspects Needing Harmonisation between Regions
Mark Hurtt, Head, Global Developmental and Reproductive Toxicology, Pfizer, USA

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 14
Personalised Medicine in Drug Development: Adding Value with New Tools - Biomarkers, Diagnostics and Health Economics

Theme Leaders:
Michael Zuehlsdorf, Biomarker Development Global Head, Novartis Pharma AG, Switzerland
Linda Surh, Director, CEDD Global Regulatory Affairs, Neurology and Pharmacogenetics, GlaxoSmithKline, UK

Improved understanding of diseases, mechanisms of drug action, and human genome sequencing have raised public expectations for modern targeted medicines towards a personalised medicine approach. A doctor prescribing a medicine to a patient might say she/he already practices 'personalised medicine', so this term may be just a 'buzz' word for them. A payer reimbursing the patient's medicine might say that the economic pressures within the healthcare system must drive the future pharmaceutical market towards individualised treatment to improve efficacy, value and safety. Yet how does anyone (whether regulator, industry researcher or medical practitioner) convert complex population data gathered over decades for one new drug into prescriber decisions and actions that tailor treatment for an individual? This theme covers key new tools in drug development, from emerging biomarkers to health economics, with a focus on how these may be expected to meet the demands of the personalised medicine field. In turn, we will show how this creates specific challenges in the project management of a new drug by following benefit-risk assessments, moving through specific regulatory environments such as drug-diagnostic co-development, health economic evaluations and effective integration of biomarkers that need clinical validation.

Tuesday, March 24, 2009

09:00 **Session 1**

PERSONALISED MEDICINE: BEYOND THE BUZZ WORD

Session Chair:
Michael Zuehlsdorf, Biomarker Development Global Head, Novartis Pharma AG, Switzerland

Today, 'Personalised Medicine' is one of the most used buzzwords in healthcare. Each stakeholder has a different understanding of the term. This session will open the topic with specialists from the pharmaceutical industry, medical practice and health economics who will point out their views on the promises and problems. Topics covered include the understanding of individual responses to disease (prognosis) and drug (prediction) with value assessments optimising the rationalised use of limited resources in today's healthcare systems.

Industry View (Rx and Dx)
Jean-Jacques Garaud, Global Head Pharma Development, F. Hoffmann-La Roche AG, Switzerland

Clinician View
Munir Pirmohamed, Senior Lecturer, Dept of Pharmacology, University of Liverpool, UK

Economics View
Adrian Towse, Director, Office of Health Economics, UK

11:00 **Session 2**

FROM POPULATIONS TO INDIVIDUALS: INDUSTRY TOOLS AND ASSESSMENT OF BENEFIT/RISK BALANCE

Session Chair:
Lawrence J. Lesko, Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA, USA

The session deals with two basic building blocks of Personalised Medicine: Biomarkers and Value (defined as quality/cost) assessment for an individualised therapy and/or labelling for a given drug. Key discussion topics will be the longitudinal translation and validation of biomarkers to "fit for purpose"; stratified development and labelling to reach regulatory approval, and payer reimbursement. The concluding panel discussion will be a forum to discuss the strategies, positive impact, and global challenges of Personalised Medicine with regulators from Europe, US, and Japan.

Established Biomarkers and How Much Time towards Medical Meaningfulness
Lawrence J. Lesko, Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA, USA

Fitting Biomarkers for Purpose in Drug Development
Erik Tambuyzer, Senior Vice President, Corporate Affairs Europe and International, Genzyme, Belgium

Panel: Benefit Risk Assessment: How to Integrate the New Tools for Better Decision Making
Yoshiaki Uyama, Review Director, Office of New Drugs III, PMDA, Japan and Bruno Flamion, Chair Scientific Advice Working Party, CHMP, Professor Clinical Pharmacology, University of Namur, Belgium

14:00 **Session 3**

PERSONALISED MEDICINE: THINKING OUT OF THE BOX

Session Chair:
Marisa Papaluca Amati, Deputy Head of Sector, Safety and Efficacy of Medicines, EMEA, EU

Early integration of PM concepts (i.e., targeted therapies) in development is a decision with far-reaching consequences not only for the pharmaceutical and diagnostic industry but also for the regulatory environment. What will be the challenges for today's drug development and regulatory framework, and tomorrow's need for regulatory evolution? Does the scientific and regulatory complexity of Personalised Medicine require new ways of interaction among stakeholders including learning from each other, or is there not so much 'new' here? This session will try to give a potential outlook on the recommendation of future drug development geared to individualised medicines based on the experiences of the past and of today.

Impact of Personalised Medicine on the Regulatory Framework Marisa Papaluca Amati, Deputy Head of Sector, Safety and Efficacy of Medicines, EMEA, EU

Diagnostic Challenges: Interaction with Regulators, Pharma and Users
Ron Lagerquist, Director, Regulatory Affairs and Quality Assurance, Dako North America, Inc. USA

Personalised Medicine and Orphan Drug Designation – Commonalities and Differences
Tim Coté, Director, Office of Orphan Products Development, FDA, USA

Q&A Panel: What to do Next beyond Regulations?

16:00 **Session 4**

REGULATORY GUIDELINES COMPARED TO MEDICAL PRACTICE GUIDELINES: THEIR PLACES IN PERSONALISED MEDICINE

Session Chair:
Linda Surh, Director, CEDD Global Regulatory Affairs, Neurology and Pharmacogenetics, GlaxoSmithKline, UK

In this session, we focus on the frontline involvement of medical practitioners, government regulators, and industry researchers in drug development. For Personalised Medicine on a medicine label, complex population data will need to be converted into predefined cut-offs for stratification of patients and yet still enable decisions and actions for an individual prescriber and patient. An expert panel will discuss via brief highlights and audience Q&A on how innovations in understanding new genomic factors and other non-genomic covariates can be used to tailor treatment for a patient subgroup in drug development to maximise the probability of a positive drug response for an individual in medical practice.

How Does a Medicine Label Influence Medical Practice: Advise vs. Drive?
Munir Pirmohamed, Senior Lecturer, Dept of Pharmacology, University of Liverpool, UK

How Much Clinical Difference by an Emerging Biomarker Is Needed to Make a Difference to Alter Label and/or Medical Practice?
Bruno Flamion, Chair Scientific Advice Working Party, CHMP, Professor Clinical Pharmacology, University of Namur, Belgium

Lawrence J. Lesko, Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA, USA

Yoshiaki Uyama, Review Director, Office of New Drugs III, PMDA, Japan

How does Drug Development Incorporate Innovation like Personalised Medicine with Medical Practice and Regulation?
Oscar Della Pasqua, Director of Clinical Pharmacology, GlaxoSmithKline, UK

Wednesday, March 25, 2009

09:00 **Session 5**

HOT TOPIC:
MAJOR PLAYERS IN PERSONALISED MEDICINE: EXPECTATIONS AND SPECIFIC NEEDS IN ONGOING EDUCATION
Session Chair:
Michael Zuehlsdorf, Biomarker Development Global Head, Novartis Pharma AG, Switzerland

The application and development of Personalised Medicine approaches is dependent on biomedical progress and the application of newest medical and clinical pharmacological research data to drug development and medical practice. As the speed of biomedical research and diagnostics tools are increasing the need of ongoing education of all involved partners in Personalised Medicine will be a major challenge and prerequisite of appropriate applications. Speakers from academia, pharmaceutical industry, regulators and patient representation will discuss the educations needs from their specific point of views and how offer ideas on how these needs can be met.

Clinician's View
Matthias Schwab, Professor and Chair of Clinical Pharmacology, Dr. Margarete Fischer-Bosch Institute, Department Clinical Pharmacology, University Hospital Tuebingen, Germany

Pharma View
Ansar Jawaid, Global Skills Group Leader Statistical Genetics, Research & Development Genetics, AstraZeneca, UK

Patient's View
David Haerry, Representative, European AIDS Treatment Group, Belgium

Regulator's View
Bruno Flamion, Chair Scientific Advice Working Party, CHMP, Professor Clinical Pharmacology, University of Namur, Belgium

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Theme 15
Regulatory Developments and Availability of Biosimilar, Generic, and Self-Care Medicines

Theme Leaders:
Suzette Kox, Senior Director, Scientific Affairs, EGA, Belgium
Peter Bachmann, Senior Expert European Affairs, BfArM, Germany

The regulatory environment is constantly evolving, bringing new opportunities but also new challenges that enhance the need for ongoing dialogue and adaptation by the regulatory authorities and industry.
The sessions in this theme will discuss how industry and regulators can meet these various new challenges and improve the efficiency of the current regulatory system in order to increase the availability of biosimilar, generic and self-care medicines for the benefit of the patients. The individual sessions will particularly discuss the current initiatives to optimise the use of resources at the level of the national competent authorities and the pharmaceutical industry, the issues surrounding the introduction of biosimilar products into high-prescribing areas, the feasibility of a global development programme for biosimilar medicines, the scientific and regulatory perspective regarding second generation biosimilar products and patent linkage in the EU regulatory systems. The sessions on self-care will reflect on how access to non-prescription medicines, whether of chemical or herbal origin, may be improved by a better regulatory system taking into account the characteristics of these medicines.

Tuesday, March 24, 2009

09:00 **Session 1**

WAYS TO IMPROVE THE CURRENT REGULATORY SYSTEM FOR ASSESSMENT OF MEDICINAL PRODUCTS WITH KNOWN ACTIVE SUBSTANCES

Session Chair:
Beata Stepniewska, Director Regulatory Affairs, EGA, Belgium

The purpose of this session is to discuss current initiatives to optimise the use of resources at the level of the national competent authorities and the pharmaceutical industry to improve the efficiency of the current regulatory system. The cooperation of the European network, sharing the workload among authorities in the assessment of new applications, variations, PSUR etc. will be discussed in particular. The outcome of on-going discussions at the HMA and CMD(h) level will be presented and supplemented with ideas from the industry side.

Heads of Medicines Agencies' Strategy to Improve Efficiency of the EU Regulatory System
Jean Marimbert, Director General, Afssaps, France

CMD(h) Initiative to Increase Access to DCP/MRP Procedures
Peter Bachmann, Senior Expert European Affairs, BfArM, Germany

Industry Contribution
Beata Stepniewska, Director Regulatory Affairs, EGA, Belgium

11:00 **Session 2**

INTRODUCTION OF BIOSIMILAR MEDICINES INTO CLINICAL PRACTICE

Session Chair:
Sandy Eisen, Chief Medical Officer, TEVA Europe, UK

The EU is leading worldwide in providing a legal framework for biosimilar medicines. This session will discuss the issues surrounding the introduction of biosimilar products into high-prescribing areas as well as the prescribing and pharmacovigilance practices in place in various Member States.

Update on Current EU Clinical Issues for European Biosimilar Medicines
Sandy Eisen, Chief Medical Officer, TEVA Europe, UK

Introduction of Biosimilars into Clinical Practice: A Company's Perspective and Experience
Michael Muenzberg, Global Head Medical Affairs Biopharmaceuticals, Sandoz, Germany

Ex-Regulator Point of View
Frits Lekkerkerker, Advisor MEB, Member NDA Advisory Board, NDA Regulatory Science Ltd, UK

14:00 **Session 3**

KNOWN ACTIVE SUBSTANCES AND BIBLIOGRAPHIC APPLICATIONS - CURRENT PROBLEMS, POSSIBILITIES AND SOLUTIONS

Session Chair:
Peter Bachmann, Senior Expert European Affairs, BfArM, Germany

The legal basis, the bibliographic application (Article 10 (a) of Directive 2001/83/EC, as amended) for known active substances with well established use is currently at the centre of various legal and procedural discussions in the European Community. One of the fundamental questions is the extent/quality of the bibliography and the degree of scientific interest which has to be provided by the applicant in such a case.

A Company's Perspective
Speaker to be confirmed

The European Commission Perspective
Irene Sacristan-Sanchez, Administrator, DG Enterprise, European Commission, EU

A Regulator's Perspective
Peter Bachmann, Senior Expert European Affairs, BfArM, Germany

16:00 **Session 4**

A GLOBAL PROGRAMME FOR THE NEXT GENERATION IN BIOSIMILARS

Session Chair:
Cecil Nick, Vice President (Biotechnology), PAREXEL Consulting, Uxbridge UK

The biosimilar approach is controversial for more complex biologicals such as monoclonals and vaccines. Furthermore, no clear pathway exists for approval of biosimilars in many regions outside Europe. The aim of this session is to explore how best to navigate the global regulatory environment to bring affordable high quality similar biologicals to the world markets. Both the simple and more complex proteins will be considered.

Challenges in Formulating a Global Biosimilar Development Program
Akundi Sriram, Scientific Manager, Research and Development (Biologicals), Biocon Ltd., India

Developing the Next Generation of Biosimilars
Brian Kim, Vice President of QA and Regulatory Compliance, Celltrion Inc., South Korea

Rising to the Future Challenges Faced by EU Regulators
Christian Schneider, Acting Head of Division EU Cooperation/Microbiology, Chairman Biosimilars Working Party, Paul-Ehrlich-Institute, Germany

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Wednesday, March 25, 2009

09:00 **Session 5**

"SMART REGULATION" FOR NON-PRESCRIPTION MEDICINES

Session Chair:
Helen Darracott, Director of Legal and Regulatory Affairs, PAGB, UK

The session will reflect on how 'the better regulation principles' have so far been beneficial for the non-prescription sector at both EU and national levels and what remains to be done. Proposals for an adequate future regulatory environment are outlined in the AESGP document "Smart Regulation 2015". This builds on recent successful national initiatives such as the German synchronisation of PSURs which inspired a similar EU initiative or the Better Regulation of Over-the-Counter Medicines Initiative (BROMI) in the UK.

Update on BROMI
Helen Darracott, Director of Legal and Regulatory Affairs, PAGB, UK

AESGP Vision for the Future of Non-Prescriptive Medicines-Smart Regulation
Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, AESGP

Better Regulation in Practice: Example of the BfArM Initiative
Michael Horn, Head of Division 'Licensing 1: Validation, Simplified Procedures, Parallel Import', BfArM, Germany.

11:00 **Session 6**

PATENTS AND THE EU REGULATORY SYSTEMS

Session Chair:
Elke Grooten, Director Pharmaceutical Policy, EGA, Belgium

According to EU legislation, there is no linkage of the application or granting marketing authorisation to a generic medicine with the patent situation of the reference product. However there are various moves to patent linkage at the level of registration, pricing & reimbursement in some Member States. This session will provide an overview of patent linkage since the implementation of the pharmaceutical legislation (DIR 2001/83) in 2004 in the 27 Member States, and will explore the impact of patent linkage on the availability of generic medicines at patent expiry.

Overview of the Patent Linkage Situation in the EU
Elke Grooten, Director Pharmaceutical Policy, EGA, Belgium

Litigation Based on Patent Linkage in Different Member States
Kristof Roox, IP Partner, Crowell and Moring, Brussels Bar Association, Belgium

A Member State's Perspective
Speaker to be confirmed

14:00 **Session 7**

NEWS ON RX TO OTC SWITCH

Session Chair:
Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, AESGP, Belgium

This session will strive to provide a comprehensive overview on changing the legal status of a medicine from prescription to non-prescription by answering the following questions: Which factors are necessary to make a switch successful? What incentives can a country provide to increase switches? Which procedures need to be followed? What lessons can be learned from the latest switches?

EMEA Experience to Date
Zaide Frias, Scientific Administrator, Legal/Regulatory Affairs, EMEA, EU

Role of Pharmacists Pre- and Post-Switch
John Chave, Secretary General, PGEU, EU

The Calcipotriol Case Study
Bernd Eberwein, Executive Director, BAH, Germany

16:00 **Session 8**

IMPROVED MARKET ACCESS TO HERBAL MEDICINAL PRODUCTS

Session Chair:
Bernd Eberwein, Executive Director, BAH, Germany

Four years after the implementation of the directive on traditional herbal medicinal products, the session will review the progress made by the EMEA Herbal Medicinal Products Committee (HMPC) on the development of the monographs and list entries and the practical impact this had on the market for traditional and well-known herbal medicines in Europe. Based on practical experience gained, and taking into account the report of the European Commission, implementation issues and possible solutions aiming at facilitating the registration and authorisation of phyto-medicines in Europe will be discussed.

Regulatory Background and Practical Implementation in Europe: The Role of the HMPC
Werner Knöss, Head of Department for Herbal Medicines, Homeopathics and Anthroposophics, BfArM, Germany

Registration and Marketing Authorisation of Herbal Medicinal Products: Practical Experiences and Viewpoint of Industry
Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, AESGP, Belgium

Toxicological Assessment of Herbal and Traditional Herbal Medicinal Products: New Developments
Olaf Kelber, Steigerwald GmbH, Germany

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Theme 16
Preparing for the Future – Challenges in Pharmaceutical Quality

Theme Leaders:
Michael J. James, Head of CMC Regulatory Advocacy and Intelligence, Global Regulatory Affairs, GlaxoSmithKline, UK
Jean-Louis Robert, Head, Department of Medicines Control Laboratory, National Health Laboratory, Luxembourg

It is foreseen that a number of important topics in the Quality area which have and continue to influence our current thinking will be addressed. The discussion at the ICH level on Pharmaceutical Development, Quality Risk Management and Pharmaceutical Quality System has provided new opportunities for development and manufacturing of medicinal products and aims at facilitating the introduction of innovative technologies. The possible impact of this new paradigm on pharmacopoeias and on lifecycle management of medicinal products will be addressed. In addition, other quality topics will cover the problem of API sourcing in a global pharmaceutical environment, the quality challenges in relation to paediatric formulations and the investigational medicinal product requirements for biological products.

Tuesday, March 24, 2009

09:00 **Session 1**

IMPLEMENTATION OF THE NEW ICH QUALITY PARADIGM
Session Chair:
Jean-Louis Robert, Head, Department of Medicines Control Laboratory, National Health Laboratory, Luxembourg

Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), Q10 (Pharmaceutical Quality System) have reached broad consensus among the ICH partners. The devil is in the detail: how can these three complementary guidelines be effectively implemented by industry and acknowledged by regulators, so that full benefit can be gained? This session will present the work currently performed in the ICH Q8, 9, 10 Implementation Working Group and the challenges encountered. It will come up with some preliminary answers.

General Considerations in Implementation of Q8, Q9 and Q10
Jean-Louis Robert, Head, Department of Medicines Control Laboratory, National Health Laboratory, Luxembourg

GMP Inspections of the Future: Role of Inspector and Assessor
Jacques Morenas, Associate Director, Inspection and Companies Department, Chairman of PIC/S, Afssaps, France

How Can Industry Convince the Regulators?
Georges France, Vice President, Quality & Compliance Europe, Middle East, Africa, Wyeth Europe Ltd., UK

11:00 **Session 2**

INNOVATIVE TECHNOLOGIES IN DRUG DEVELOPMENT AND MANUFACTURE
Session Chair:
Gordon Muirhead, Vice President and Dose Form Leader, Global Manufacturing and Supply, GlaxoSmithKline, UK

Compared with other industrial sectors, such as the aerospace and electronics industries, the pharmaceutical industry has historically been slow to adopt modern process design principles. However this situation is changing rapidly and there many drivers for this; alongside the adoption of ICH Q8, Q9 and Q10 recognition, there is a need to improve manufacturing efficiencies, as well as the requirement to meet patient needs for personalised medicines. Whilst this presents many opportunities and potential benefits for the pharmaceutical industry, it also presents a number of challenges. This session will provide a unique opportunity for industry and regulatory experts to present on the development, manufacturing, and regulatory challenges and opportunities associated with implementing such innovative technologies.

Innovative Technologies in Drug Development and Manufacture
Gert Ragnarsson, Scientific Director, MPA, Sweden

Using Innovative Technology Platforms to Customise Medicines for the Future
Patrick Crowley, USA

The Application of Innovative Technologies in Dosage Form Design and Drug Product Development
Alastair Coupe, Senior Director, WorldWide Pharmaceutical Sciences, Pfizer Global R&D, UK

14:00 **Session 3**

PHARMACOPOEIAS - DO THEY HAVE A PLACE IN A "QUALITY-BY-DESIGN" ENVIRONMENT?
Session Chair:
Susanne Keitel, Director, EDQM, EU

Pharmacopoeias define standards that are binding for the pharmaceutical industry. Recent developments in quality guidelines at an ICH level have seen a change in paradigm by the introduction of notions such as "quality-by-design" and "flexible regulatory approaches". How will pharmaopoeias fit into this changed environment? Is there still a need for legally binding standards? Is there a potential risk by hindering innovative approaches by industry? The session will discuss the present and future role of pharmacopoeias, focusing on expectations of industry from an API, excipient and finished-product point of view.

The Future Role of Pharmacopoeias in a "Quality-by-Design" Environment
Susanne Keitel, Director, EDQM, EU

"Quality-by-Design" and Pharmacopoeial Standards – A Contradiction?
Seppe de Gelas, Head of Regulatory Affairs & Quality Assurance Lonza Braine SA, Belgium

Can the Pharmacopoeias Have a Role in Fostering Innovation?
Janeen Skutnik, Director Quality & Regulatory Policy - Global Regulatory CMC, Pfizer Inc., Belgium

16:00 **Session 4**

THE PAEDIATRIC REGULATION - AN EASY WAY TO AGE-APPROPRIATE FORMULATIONS?
Session Chair:
Diana van Riet-Nales, Coordinator, Regulatory Affairs, RIVM, The Netherlands

Recently the EU Paediatric Regulation entered into the force with the aim of facilitating the development and availability of paediatric machines. The regulation compels the pharmaceutical industry to provide the results of studies conducted in children when applying for a Marketing Authorisation for medicines containing a new active substance, or when adding a new indication, pharmaceutical form or route of administration to an existing medicine. These studies have to be conducted according to an approved Paediatric Investigation Plan and implicate the development of age-appropriate paediatric formulations. But what is an age appropriate formulation? And what should Regulatory Authorities consider appropriate?

Experiences and Recommendations from a Hospital Pharmacy
Françoise Brion, Director, Pharmacy Service, Department of Pharmacy, Hôpital Robert Debré AP-HP, France

The Challenge of Deciding on Acceptable and Unacceptable Age Appropriate Formulations
Diana van Riet-Nales, Coordinator, Regulatory Affairs, RIVM, The Netherlands

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

Opportunities and Challenges from an Industry Perspective when Developing a Paediatric Formulation
Julie Williams, Executive Director, Global Chemistry, Manufacturing and Control (CMC), Pfizer Global Research and Development, UK

Discussion with George Wade, Scientific Administrator, EMEA, EU

Wednesday, March 25, 2009

09:00 **Session 5**

CLINICAL TRIALS WITH BIOLOGICAL - IMPD REQUIREMENTS

Session Chair:
Brigitte Brake, Head of Unit Pharmaceutical Biotechnology, Biologics, Inspections, BfArM, Germany

Approval of clinical trials is the responsibility of individual EU Member States, which evaluate the products used in clinical studies. In view of the current lack of common reference guidance on which to base the assessment of quality of biological clinical trial material and the difference in experience among sponsors and competent authorities, there is a need to promote a harmonised approach throughout the European Union and facilitate multi-centre clinical trials in particular. The progress in drafting a guidance in this area will be discussed by regulators and industry. Views, experience and expectations of a regulator and representatives from industry will be shared.

Filing an IMPD for Biologics in Europe Strategy, Experiences and Problems
Jason Hampson, Senior Manager, European Regulatory Affairs, Amgen Ltd., UK

Chemical, Pharmaceutical & Biological Requirements for Biotechnology-derived Investigational Medicinal Products: Consolidated EFPIA & EBE Industry Perspective on the Content of the Future Guideline
Jens Schletter, Director, Regulatory Affairs, Human Genome Sciences Europe GmbH, Germany

Quality Requirements for a Biological Investigational Medicinal Product Experiences and Expectations-A Regulator's View
Brigitte Brake, Head of Unit Pharmaceutical Biotechnology, Biologics, Inspections, BfArM, Germany

11:00 **Session 6**

REVISION OF THE VARIATIONS REGULATIONS: AN UPDATE

Session Chair:
Michael J. James, Head of CMC Regulatory Advocacy and Intelligence, Global Regulatory Affairs, GlaxoSmithKline, UK

The European Commission launched the revision of the Variation Regulations in 2006, as part of the "Better Regulation" initiative. Its overall objectives were a clearer, simpler and more flexible system, a reduction in administration burden, adoption of ICH quality concepts, and further harmonisation. This session will provide an opportunity for industry and regulatory experts to present an update on the status of the overall legislative process, as well on the various implementation initiatives. Particular emphasis will be given to a discussion on the Commission's procedural and classification guidelines.

Revision of the Variations Regulations – Present Status and Further Steps
Hilde Boone, Scientific Administrator - Regulatory Affairs and Organisational Support, EMEA, EU

Revision to EU Variations - An Opportunity to Move to a Science and Risk-Based Approach?
Michael J. James, Head of CMC Regulatory Advocacy and Intelligence, GlaxoSmithKline, UK

The UK Experience
Keith Pugh, Senior Assessor and Chair of the EMEA PAT Group, MHRA, UK

14:00 **Session 7**

SOURCING OF API IN A GLOBALISED ENVIRONMENT

Session Chair:
Nigel Hamilton, Quality Director, Industrial Quality and Compliance, sanofi-aventis, France

This session discusses the opportunities and challenges facing the pharmaceutical industry and regulatory agencies in the context of global API sourcing.

Sabine Atzor, Principal Administrator, European Commission, EU

API Inspections in the Framework of the Certification Scheme- The EDQM Experience
Thomas Hecker, Inspector, EDQM, France

Risk-Based Approach for Sourcing of API's
Hanno Binder, Head Quality Management, Sandoz, Austria

16:00 Session 8

WHAT'S NEW IN THE QUALITY ARENA?

Session Co-Chairs:
Michael J. James, Head of CMC Regulatory Advocacy and Intelligence, Global Regulatory Affairs, GlaxoSmithKline, UK
Jean-Louis Robert, Head, Department of Medicines Control Laboratory, National Health Laboratory, Luxembourg

The session will provide an update of the key quality initiatives in EU, and will reflect the higher-priority topics and activities of both the CHMP Quality Working Party and EFPIA Quality Ad Hoc Group. The following topics are foreseen, but may be revised due to future developments:

Setting Specifications in the Future
Genotoxic impurities
Analytical methods: new paradigms in the future?

This will be a joint presentation, providing both an industry and EU regulatory agency perspective. It is envisaged that this will be an interactive session, and audience participation will be actively encouraged.

Regulator's Point of View
Jean-Louis Robert, Head, Department of Medicines Control Laboratory, National Health Laboratory, Luxembourg

EFPIA's Point of View
Michael J. James, Head of CMC Regulatory Advocacy and Intelligence, Global

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Tuesday, March 24, 2009

09:00 **Session 1**

UPDATE ON REGULATORY PHARMACOVIGILANCE

Session Chair:
Noël Wathion, Head of Unit, Post-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

Pharmacovigilance and safety of medicines continue to be a priority for the EMEA in 2009. Various activities will be undertaken in line with the rolling Work Plan for the European Risk Management Strategy (ERMS), a joint initiative between the EMEA and Heads of Medicines Agencies (HMA). This session will focus on several initiatives important for both regulators and pharmaceutical industry, and will provide a status report on major progress made in 2008 and important work planned for 2009.

Update on EU Risk Management Plans
Stella Blackburn, EMEA Risk Management Coordinator, EMEA, EU

Signal Management in the EU
Xavier Kurz, Principal Administrator, EMEA, EU

ENCePP: Current Status and Next Steps
Henry Fitt, Specialised Group Leader ONC/CVS, EMEA, EU

Panel with Peter Arlett, Head of Sector for Pharmacovigilance and Risk Management, EMEA, EU

11:00 **Session 2**

HOT TOPIC IN TELEMATICS

Session Chair:
Timothy Buxton, Head of Sector, Project Management, Communications and Networking Unit, EMEA, EU

The Annual DIA EuroMeeting provides the forum for a status review of key European pharmaceutical industry information initiatives. This Telematics "Hot Topics" session will assess where we are with the implementation of the telematics strategy and describe what we should expect in 2009/2010.

The EU telematics strategy supports the strategic objectives of the EU for the implementation of key information systems as required by various Directives and Regulations issued since 2001. The telematics management structure is putting into place a number systems that implement these requirements of the legislation including EudraVigilance, EudraCT, EUDRApharm, EudraGMP and EudraNet.

14:00 **Session 3**

HARNESSING INDUSTRY AND AUTHORITY EXPERIENCE: WORKING TOGETHER TO ACHIEVE EFFECTIVE GUIDELINES

Session Co-Chairs:
Gesine Bejeuhr, VFA German Association of Research-Based Pharm Co., Germany
Marianne Koehne, Head of Regulatory Intelligence Office, Boehringer Ingelheim GmbH, Germany

This session will address experiences in commenting on draft guidelines from an industry point of view, to focus on practical aspects in order to "break down the walls" between different business functions. Furthermore what happens behind the scenes of industry associations when compiling the final industry position will be outlined. And finally, an EMEA representative will illustrate the process of drafting a new guideline as well as experiences with the EMEA "Guideline on Guidelines", published in June 2005.

Knowledge Exchange in the Development of Guidelines
Julie Doel, Manager, Regulatory Intelligence (Europe), GlaxoSmithKline, UK

Contribution of Industry Associations in the Development of Guidelines
Gesine Bejeuhr, Regulatory & Safety Intelligence, Gruenenthal GmbH, Germany

Working towards Better Legislation in Practice
Hans-Georg Eichler, Senior Medical Officer, EMEA, EU

16:00 **Session 4**

TRANSLATING SIRNA TO MEDICINES

Session Chair:
Gunther Hartmann, Director Department of Clinical Pharmacology, University Hospital Bonn, Germany

There is a recent debate on whether siRNA should be developed under the regulations of gene therapy, and there is great concern that this would slow down this innovative and promising new class of drugs on its way to the patient. This session will view the clinical development of siRNA from three different angles: regulatory agency, academia and industry.

Gene Therapy and siRNA: Why Apply the Same Regulations?
Harn Hermsen, Assessor, Member Gene therapy Working Party EMEA, RIVM, The Netherlands

Dedicated Phase I Unit in the University Hospital
Gunther Hartmann, Director Department of Clinical Pharmacology, University Hospital Bonn, Germany

Clinical Development of siRNA: The Practical Experience
Rachel Myers, Director of Research, Alnylam Pharmaceuticals, USA

Wednesday, March 25, 2009

09:00 **Session 5**

THE PHARMACEUTICAL PACKAGE- RECENT DEVELOPMENT AND POSITIONS OF DIFFERENT STAKEHOLDERS

Session Chair:
Barbara Sickmüller, Deputy Director General, German Pharmaceutical Industry Association (BPI), Germany

The so-called Pharmaceutical Package is one of the last legislative activities of the current European Commission in the pharmaceutical field. It consists of a bundle of legal proposals in the fields of Pharmacovigilance, Counterfeiting and Patient Information. What are the main proposals within the Pharmaceutical package? How is the Package discussed at a European level? What are the views of different stakeholders? The session will bring together expertise taking into regard the view of the European Parliament and Council as well as industry representatives. The timeframe for the package will look like and what amendments might be needed in order to achieve a positive vote in Parliament and Council.

The Pharmaceutical Package - Main Topics Regarding Pharmacovigilance and Patient Information and Industry Position

The Pharmaceutical Package - Main Topics Regarding Counterfeiting and Industry Position

Overview about the Discussions in the European Parliament Regarding the Pharmaceutical Package

The Pharmaceutical Package from the perspective of the Council

09:00 **Session 5**

UPDATE IN ADVANCED THERAPIES

Session Chair:
John Purves, Head of Sector, Quality of Medicines, EMEA, EU

The European Unions's Regulation 1394/2207 on advanced therapy medicinal products (ATMP) came into force on the 30th December 2008.
During 2007-2008, EMEA and Commission worked closely together in planning and executing the implementation of this new Regulation. The EMEA established an internal Task Force, to co-ordinate the work it had to do to assist in the implementation exercise. This involved contributions to technical

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requirements and the development of a number of procedures and guidelines, including for example Annex I revision, CAT Rules of Procedure, guidelines on Classification, Certification, Traceability, GMP and GCP.
The objective of this session is to update colleagues on the most current positions for the topics cited in the programme and to facilitate the introduction of the new procedures and guidelines in a transparent manner, the review of dossiers and, thus, the availability of ATMPs for patients in Europe.

Update on Advanced Therapies Regulation Implementation and Quality and Non-Clinical Certification
Patrick Celis, Scientific Administrator, EMEA, EU

Review Process of Advanced Therapy Products: from Scientific Advice to CAT CHMP Opinion
Marie-Helene Pinheiro, EMEA, EU

Risk Management of Advanced Therapy Products
Jan Petracek, Risk Management Team, Sector Pharmacovigilance, Safety & Efficacy of Human Medicines, EMEA, EU

Panel with:
Christian Schneider, Acting Head, Division EU Cooperation/Microbiology and Acting Head, Section EU Cooperation Biomedicinal Products, Paul-Ehrlich-Institute

11:00 **Session 6**

FDA'S PRO GUIDANCE AND EMEA'S HRQL REFLACTION PAPER- 3 YEARS ON

Session Chair:
Laurie Burke, Director Study Endpoints and Label Development, FDA, USA

The FDA's draft Guidance for Industry 'Patient-Reported Outcome Measures: Use in medical product development to support labeling claims' and the EMEA's 'Reflection Paper on the Regulatory Guidance for the Use of Health-Related Quality of Life (HRQL) Measures in the Evaluation of Medicinal Products' were both published over three years ago. This session will compare and contrast the principles set forth in the two documents and will look at the impact they have had on clinical programs and international medical product development.

PRO Measurement: FDA Regulatory Concerns
Laurie Burke, Director Study Endpoints and Label Development, FDA, USA

Comparing FDA and EMEA Regulatory Concerns
Olivier Chassany, Medical Head, Clinical Head Research and Development Department, Assistance Publique – Hopitaux de Paris, Medical Unversity Paris, France

Harmonising PRO Measurement Standards: EMEA Regulatory Perspective
Mira Pavlovic, Vice-Chair Scientific Working Party (EMEA) and Head of Scientific Advice Unit, Affsaps, France

11:00 **Session 6**

MOVING TOWARDS GREATER OPENNESS ON REGULATORY ACTIVITIES: THE NEW EMEA TRANSPARENCY POLICY

Session Chair:
Noël Wathion, Head of Unit, Post-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

One of the EMEA priorities for 2009 is to further increase transparency of operation. Building on the initiatives already taken in the past the EMEA will explore in 2009 how it can further improve in this field. This should result in the availability of an EMEA Transparency Policy in Autumn 2009. The EMEA will launch a public consultation on its proposals. This session will provide an opportunity to discuss with stakeholders the key principles of the proposed Transparency Policy.

The Key Principles of the Proposed EMEA Transparency Policy
Valentina Stamouli, Scientific Administrator-Regulatory Affairs, EMEA, EU

The Transparency Challenge
Vincenzo Salvatore, Head of Legal Sector, EMEA, EU

What Level of Transparency Does Civil Society Expect from Regulatory Authorities?

11:00 **Session 6**

JAPANESE REGULATORY SESSION
PMDA UPDATE: INITIATIVES AND CHALLENGES FOR PROMOTING GLOBAL DRUG DEVELOPMENT INCLUDING JAPAN

Session Chair:
Kyoichi Tadano, Director, International Affairs Division, PMDA, Japan

In this session, the Pharmaceuticals and Medical Devices Agency (PMDA) will explain the current PMDA/Japanese drug regulatory environment and present PMDA perspectives for successful global drug development, including Japan.

Since 2004, the Pharmaceuticals and Medical Devices Agency (PMDA), the Japanese regulatory agency, has provided more efficient regulatory reviews of new drug applications (NDAs). The timing of new drug approval in Japan, however, is still longer than in US by approximately 2.5 years. To reduce this lag, shortening the review time and drug development period are major areas for improvement. In FY 2007, the PMDA announced a new plan to strengthen the review system in which the total time clock for drug approval (from a NDA submission to approval) will be decreased from approximately 24 months to 12 months. To achieve this, the PMDA has been introducing many new initiatives, including a new reviewer recruitment plan, a new project management system, a new training system and a new IND (investigational new drug) consultation system, etc. Regarding the number of reviewers, the PMDA will hire new 236 reviewers within 3 years starting from FY 2007. On the other hand, the PMDA has encouraged the inclusion of Japan in global drug development for synchronising the drug development period in Japan with that in US/EU. In the PMDA's IND consultations, numbers of cases focusing on issues in global drug development have been rapidly increasing since 2004. On September 2007, MHLW/PMDA published a paper entitled "Basic Principles of Global Clinical Trials" for promoting global drug development including Japan. In this session, the PMDA will explain current PMDA/Japanese drug regulatory environment and present the brief outlines of the next 5-year (FY2009-2013) mid-term plan and PMDA perspectives for successful global drug development including Japan.

Future Directions of the PMDA
Tatsuya Kondo, Chief Executive, PMDA, Japan

PMDA Perspectives and Challenges to Promote Global Drug Development
Satoshi Toyoshima, Executive Director and Director, Center for Product Evaluation, PMDA, Japan

Current Projects for Promoting Global Drug Development including Japan
Yoshiaki Uyama, Review Director, Office of New Drug III, PMDA, Japan

14:00 **Session 7**

THE PHARMACEUTICAL SECTOR INQUIRY

Session Chair:
Bertold Bär-Bouyssère, Partner EU & Competition, DLA Piper UK LLP, Belgium

The European Commission launched a Sector Inquiry in January 2008 to follow up on indications that competition in the EU's pharmaceutical market may not be working well, with fewer new medicines being brought to market and the entry of generics in some cases being delayed. A preliminary report was published in November 2008 for a two-month public consultation. This session will discuss the different positions of industry organisations and different scenarios of possible impact of the final report expected in the spring/summer of 2009.

The Pharma Sector Inquiry: The Role of Patients and Competition
Fabio Domanico, Case Handler, Pharmaceuticals Sector Task Force, European Commission, EU

This is a preliminary programme. New speakers and sessions will be added. Visit www.diahome.org for the most recent additions to the programme.

How to Enhance Innovation so that Patients Can Continue to Access Life-Saving Medicines
EFPIA representative invited

How to Ensure Immediate Patient Access to Affordable Generic Medicines a Day on after Patent Expiry
Elke Grooten, Director Pharmaceutical Policy, EGA, Belgium

Competition Rules and their Impact on Current and Future Rules in the Pharmaceutical Sector
Bertold Bär-Bouyssère, Partner EU & Competition, DLA Piper UK LLP, Belgium

14:00 **Session 7**

DO WE ALWAYS NEED TO PERFORM EFFICACY TRIALS WITH CHILDREN?

Session Chair:
Agnès Saint Raymond, Head of Sector Scientific Advice and Orphan Drugs, EMEA, EU

Paediatric investigation plans and paediatric development should avoid unnecessary trials. This session will investigate what can be done, and how data should be used to maximise the use of existing data in adults, in older children or from various sources.

Extrapolation of Efficacy from Adults to Children
FDA speaker invited

Using Available Published Data and Systemic Review
Speaker invited

Extrapolation of Efficacy in Paediatric Cardiovascular Diseases
Speaker invited

14:00 **Session 7**

EU AGREEMENT: ADMINISTRATIVE REGULATORY SIMPLIFICATION – THE NEXT PHASE?

Session Co-Chairs:
Marie A. Dray, President, International Regulatory Affairs Group, LLC, USA
Brenton E. James, Strategic Regulatory Affairs in the European Union, Consultant, UK

Since the establishment of the US-EU Confidential Arrangements to Exchange Information in 2004, reports on progress with exchanges of personnel and documents have been provided publicly via DIA Annual Meetings. This session will update the audience, to the extent not limited by confidentiality of sponsors' applications, on the current status of bilateral discussions under this arrangement. In addition, speakers will present the latest information on the newest US-EU dialogue, being conducted under the auspices of the Transatlantic Economic Integration project, whereby parties are implementing a roadmap for US-EU regulatory cooperation and transparency, to address simplification of regulatory processes.

EMEA Perspective
Thomas Lönngren, Executive Director, EMEA, EU

Regulatory Simplification – The Next Steps Forward
Murray Lumpkin, Deputy Commissioner, International and Special Programs, OC, FDA, USA

Industry Perspective
Graham C Higson, Vice President & Head of Global Regulatory Affairs, AstraZeneca, UK

14:00 **Session 7**

GLOBAL STRATEGY ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

Session Chair:
Kees de Joncheere, Regional Advisor, Health Technologies and Pharmaceuticals, Regional Office for Europe, WHO, Denmark

The World Health Assembly 2008 adopted resolution 61.21 including a global strategy and plan of action aimed at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area. The report was based on the recommendations of the WHO Commission on Intellectual Property Rights, Innovation and Public Health. The session will discuss the strategy and the perspectives from different partners.

A Global Strategy for Public Health, Innovation and Intellectual Property
Bart Wijnberg, Senior Advisor, International Strategy, Ministry of Health, Welfare and Sport, The Netherlands

Innovative Approaches for Medicines Innovation for Developing Countries
Michelle Childs, Director Policy Advocacy, Médecins sans Frontières, France

How Industry Supports Innovation for Diseases Affecting the Poor in the World
Brendan Barnes, Director, Multilateral Issues & Health Policy, EFPIA , Belgium

16:00 **Session 8**

SUMMARY OF THE ROUNDTABLE/WORKSHOP ON GCP INSPECTION AND AUDIT FINDINGS

Session Co-Chairs
Fergus Sweeney, Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, EMEA, EU
Beat Widler, Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche AG, Switzerland

The session will present an overview of current issues being raised during inspection and audit. In particular the panel will focus on presenting feedback from discussions during a closed "Inspection Roundtable" (which will take place on Sunday, March 23, 2009), providing an overview of the key findings discussed, their impact and potential solutions. The panel will also highlight key developments in GCP compliance.

Leslie Ball, Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA, USA

Pierre-Henri Bertoye, Head, Department of Inspection of Clinical & Non-Clinical Trials, Afssaps, France

David A. Lepay, Senior Advisor for Clinical Science, Science and Health Coordination, OC, FDA, USA

Gabriele Schwarz, Head, GCP Inspection Services, BfArM, Germany

Sunday, March 22, 2009, 14:00-17:00

CLOSED SESSION – Invitation Only

GCP INSPECTION AND AUDIT FINDINGS - ROUNDTABLE DISCUSSION

Session Co-Chairs:
Fergus Sweeney, Principal Scientific Administrator, GCP & Pharmacovigilance Inspector, EMEA, EU
Beat Widler, Global Head of Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

During the course of GCP Inspections some important themes are identified by the inspectors as being common to multiple inspections. In a similar way GCP auditors working for industry identify key issues of concern. This round table provides an opportunity to identify and discuss some of these key findings with a panel of GCP inspection experts from regulatory authorities and GCP audit experts from industry/academia.

Leslie Ball, Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA, USA
Pierre-Henri Bertoye, Head, Department of Inspection of Clinical & Non-Clinical Trials, Afssaps, France
David A. Lepay, Senior Advisor for Clinical Science, Science and Health Coordination, OC, FDA, USA
Gabriele Schwarz, Head, GCP Inspection Services, BfArM, Germany

Greening the EuroMeeting: Towards an Environmentally-Friendly Conference

The DIA in Europe is committed to ensuring that it minimises the affect that the EuroMeeting has on the environment and is taking proactive steps in Berlin 2009 to ensure that this happens. We know from participant feedback that greening the EuroMeeting is also something that our attendees want to see as well and we are confident that working together we can reduce our environmental impact.

- Berlin has an excellent public transport system and the convention centre is easily accessible by metro, suburban trains and public buses. The DIA in Europe encourages participants to use public transport during the EuroMeeting
- The DIA in Europe is reducing its carbon footprint by offsetting the airmiles of staff travelling to the EuroMeeting. We offset our miles with a Swiss non-profit foundation, myclimate – The Climate Protection Partnership, at www.myclimate.org. We encourage all our participants travelling by air to the EuroMeting to consider offsetting their miles
- All plastic names badge holders will be recycled
- Participants will be offered the choice of a regular conference bag, an environmentally-friendly bag or no bag, as they wish
- Conference bags will be recyled at the end of the EuroMeeting
- The paper used in all DIA's EuroMeeting publications is FSC-certified. The Forest Stewarship Council (FSC) is an independent, non-governmental, not-for-profit organisation established to promote the responsible management of the world's forests. FSC's standards are the highest social and environmental requirements in the forestry sector and they have proven to work across continents, forest types, sizes and ownership

FSC Mixed Sources
Product group from well-managed forest, controlled sources and recycled wood or fibre
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- Attendees can receive a reusable water bottle from the DIA booth to use during the conference and water coolers will be placed around the convention centre
- Increased food options so that participants have the possibility to eat as low on the food chain as possible (e.g. more vegetarian options)
- No styrofoam, paper or plastic cups, plates or cutlery will be be used for catering during the EuroMeeting
- The EuroMeeting Exhibitor Kit will be available online, signficantly reducing paper waste
- Exhibitors will be encouraged to use lead retrival to send virtual brochures to attendees and to provide environmentally-friendly giveaways
- Recycling facilities will be provided for participants, exhibitors and conference contractors for paper/cardboard, glass, plastic, packaging and wood. Recycling will be carried out a by a registered recycling company to the standards of ISO 900. Transportation to the recycling centre will be in vehicles with low emission levels
- Organic cleaning chemicals and recycled water will be used to clean the Convention Centre

Exhibiting Companies as of October 13, 2008

AbCRO Inc, United States
Accovion GmbH, Germany
AKOS, United Kingdom
Almac, United States
Applied Clinical Trials, United States
Aris Global LLC, United Kingdom
Asian Clinical Trials, India
Averion International Corp., United States
B&C Group, Belgium
Basecon AS, Denmark
Berzelius Clinical Research Center, Sweden
Bio-Kinetic Europe Ltd., United Kingdom
Biomedical Systems, Belgium
Bioskin GmbH, Germany
BioStorage Technologies, Germany
BT Global Services, Germany
C3i, Inc., United States
Cardinal Health Research Services, United States
Cardiocore, United States
CCRA, United Kingdom
CDISC, United States
CEMO S.A., France
Charles River Clinical Research, United States
Chiltern International, United Kingdom
Cirion Clinical Trial Services Inc., United States
CitySprint Medical Express, United Kingdom
Clinical Research Services Andernach GmbH, Germany
Clinical Trial EndPoint Ltd., Ireland
clinIT AG, Germany
ClinPhone, United Kingdom
Clinsys Clinical Research, United States
Comply Services, Belgium
Covance, United Kingdom
CRF Inc., United States
Crom Sl, Italy
CROS NT, Italy
Crown CRO Oy, Finland
Datatrial Limited, United States
DIA Patient Fellowship, Switzerland
Diapharm International, Germany
DOCS International, Ireland
Dora Wirth (Languages) Ltd., United Kingdom
Drug Safety Research Unit, United Kingdom
Eclinso, Switzerland
EMEA (European Medicines Agency), EU
Ennov/Clinsight, France
entimo AG, Germany
eResearchTechnology, United States
EuroTrials Scientific Consultants, Portugal
Extedo GmbH, Germany
fme AG, Germany
Fraunhofer Item, Germany
Global Clinical Trials, United States
Globex Couriers GmbH, Germany
Hays Pharma, United Kingdom
i3, United States
Image Solutions, Germany
Imperial Clinical Research Services, United States
INTERLAB central lab services – worldwide, Germany
IRL Pvt, Ltd., India
Kinapse Ltd., United Kingdom
Levy Associates Ltd., United Kingdom
Lionbridge Technologies, Inc., United States
LORENZ Life Sciences Group, Germany
Macron, Poland
MDS Pharma Services, United States
Meda Manufacturing GmbH, Germany
MedDRA MSSO, United States
Medicademy, Denmark
Medical Research Network Ltd., United Kingdom
Medidata Solutions Worldwide, United States
Medifacts International, United States
Medikala Oy MedFiles, Finland
Metronomia Clinical Research, Germany
MNX Global Lifesciences, UK
MSOURCE, Belgium
NDA Regulatory Science Ltd., United Kingdom
Online Business Applications, United States
Oracle, United States
Outcome, United States
PAREXEL International, United States
Perceptives Informatics, United States
PFC Pharma Focus, Switzerland
PharmaForms GmbH, Germany
PharmaNet, United Kingdom
Phase Forward, United Kingdom
PHT, United States
PMDA, Japan
PRA International, United States
Premier Research Group plc, United Kingdom
Quadratek Data Solutions Ltd., United Kingdom
Quality Compliance Consulting, United States
QuickSTAT, United States
Quintiles, United Kingdom
Regulatory Pharma Net, Italy
Regulatory Resources Group Ltd., United Kingdom
Relsys International, United States
RSA, United Kingdom
S-Clinica, Belgium
SGS Life Science Services, France
Tarius, Denmark
TFS Trial Form Support, Sweden
the Uppsala Monitoring Centre, Sweden
Theradex (Europe) Ltd., United Kingdom
Thomson Reuters, United States
TOPRA, United Kingdom
TransPerfect Translations Ltd., United Kingdom
United BioSource Corporation, United States
Virtify Inc., United States
Vitalograph, United Kingdom
WCI Consulting Limited, United Kingdom
Woodley Equipment Company Ltd., United Kingdom
World Courier, Belgium
Xclinical GmbH, Germany

Berlin – A Great City For Conference Attendees

At the very heart of Europe, Berlin is a bridge between east and west and over the last few years has evolved into a major platform for communication and knowledge transfer.

Berlin is ranked first among Germany's best conference locations and is in the international top five. Easily accessible, Berlin has three airports providing flight connections to the whole world, with 91 airlines operating flights to Berlin from 157 cities in 49 countries. When in Berlin, one of the most extensive underground and regional train systems of any major city in the world as well as over 1,000 buses and trams will help you get around. If that's not enough, over 7,000 taxi cabs will take you wherever and whenever you want to go.

Berlin can boast an outstanding selection of hotels, with more than 600 available across all categories, offering one of the largest and most modern selections of accommodation in Europe. Nearly all the major international hotel chains are represented.

Berlin is cosmopolitan and open 24 hours a day, 7 days a week. About 1,700 events every day entertain people from all over the world. A variety of restaurants from all different kinds of cultures and countries, as colourful and diverse as the city itself, are on offer. Every district, every street corner offers something new and exciting.

One thing is certain: Berlin is always changing and it is this dynamism that gives Berlin its special appeal. For more information go to **www.visitBerlin.de**. DIA Berlin tours are a great way to see the city and to meet other conference participants. **Tours** can be booked by going to www.diahome.org and clicking on the EuroMeeting icon.

INTERNATIONALES CONGRESS CENTRUM (ICC) BERLIN

ICC Berlin ranks among the biggest, most advanced and most successful congress venues in the world. It was designed by architects Ralf Schüler and Ursulina Schüler-Witte.

The ICC Berlin is a landmark of postwar German architecture and the model for many new congress centres all over the world. With its 80 halls and rooms seating between 20 and 9,100, its versatile facilities, superb technical installations and comprehensive range of services, ICC Berlin is the perfect choice for any convention.

Special Hotel Rates for your EuroMeeting 2009
Accommodation in Berlin

Hotel Name	Single Room incl. Breakfast	Double Room for single use incl. Breakfast	Double Room incl. Breakfast
5-Star Hotels			
Concorde Berlin		200.00	220.00
Kempinski Bristol		190.00	215.00
Palace Berlin	195.00	195.00	215.00
Steigenberger Berlin		235.00	255.00
Intercontinental Berlin		210.00	230.00
		237.00	257.00
The Westin Grand		268.00	337.00
		298.00	367.00
4-Star Hotels			
California Hotel		135.00	150.00
Crowne Plaza Berlin City Centre		210.00	230.00
Ellington Hotel		135.00	162.00
Golden Tuilp Hotel Hamburg		150.00	180.00
Hecker's Hotel	146.00	166.00	182.00
Hollywood Media Hotel	140.00	150.00	160.00
Maritim proArte		211.00	244.00
		227.00	260.00
Melia Berlin		197.00	219.00
NH Berlin Kurfürstendamm		197.00	215.00
NH Jolly Berlin Friedrichstrasse		208.00	227.00
Novotel Tiefgarten		199.00	232.00
Park Inn Berlin	136.00	136.00	163.00
Seehof		210.00	250.00
3-Star Hotels			
Art'hotel Kudamm		130.00	145.00
Berlin Plaza Hotel	89.00	109.00	126.00
Concorde am Studio		95.00	115.00
Ku'damm 101	87.00	105.00	105.00
Mark Apart Hotel		110.00	130.00
Mark Hotel Berlin		110.00	140.00
Sylter Hof	90.00	112.00	134.00
2-Star Hotels			
Ibis Messe		99.50	129.00
Headquarter Hotels			
Hilton Berlin (HQ Central)		228.00	272.00
Pullmann Schweizerhof (HQ West)		200.00	220.00

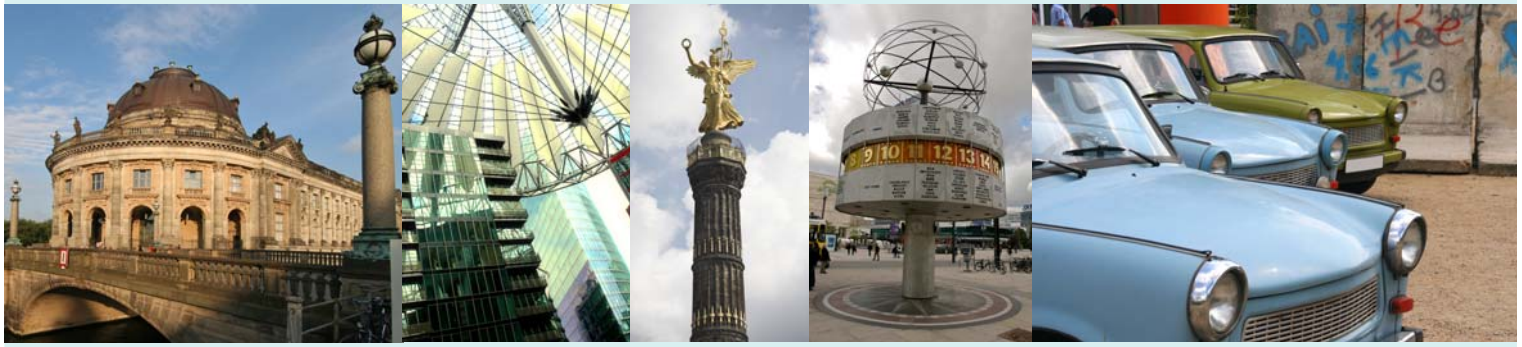
The DIA's accommodation agency in Berlin, KIT, has negotiated special rates exclusively for EuroMeeting 2009 participants. Download a hotel location map and book hotel rooms online by going to www.diahome.org and clicking on the EuroMeeting icon. All enquiries regarding room reservations should be directed to Kirstin Leifels at K.I.T. GmbH Berlin at +49 30 24 60 3226 or dia2009-hotel@kit-group.org.

Make the most of your stay in Berlin and meet other EuroMeeting participants by reserving a place on one of our city tours. There are four tours to choose from: two on Sunday and one each on Tuesday and Wednesday.

Tours can be booked online by going to www.diahome.org and clicking on the EuroMeeting icon. Enquiries should be directed to Stephanie Kiewitz (K.I.T.) at dia2009tours@kit-group.org.

1) Orientation Tour through Berlin's architecture

Sunday, March 22, 2009, 9:00-13:00
EUR 27 per person



The reunified city of Berlin offers a kaleidoscope of all the most important trends in the recent history of architecture: from Neo-Classical to Post Modern, from Neo-Gothic to Bauhaus, from Socialist to the American 1950s, without forgetting the German Art Nouveau.

This tour will show you some of the best examples of all these sources of inspiration:
Alexanderplatz, Gendarmenmarkt, Unter den Linden, Karl-Marx Allee and of course what we commonly now call the "New Berlin" designed since the fall of the Wall by world-famous architects like IM Pei, Jean Nouvel, Daniel Libeskind, Frank O. Gehry and Renzo Piano.

2) Jewish Life in Berlin

Sunday, March 22, 2009, 13:00-17:30
EUR 36 per person including guided visit of the Jewish Museum

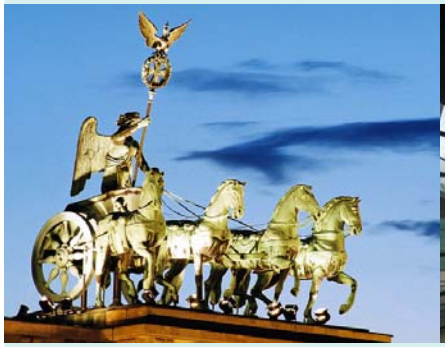
The tour focuses on the Jewish past and present in Berlin. We will first go to the Jewish Museum housed in one of the most spectacular buildings erected in Berlin since the Second World War. The plan of Daniel Libeskind's building is interpreted as an exploded Star of David.

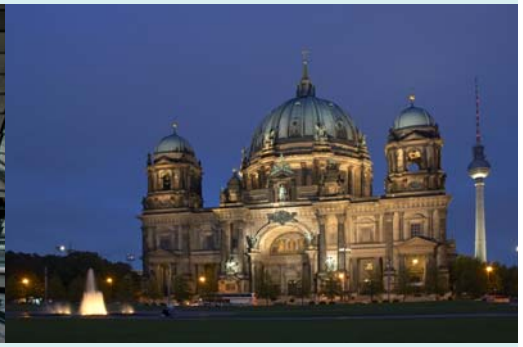
Participants will then continue the tour in the "Scheunenviertel" where the Jewish community lived before the war. There are few traces of the Jewish residents of this quarter except for a few reopened restaurants and, of course, the beautifully restored synagogue in the Oranienburgerstrasse.

Lastly, we will have a look at the huge memorial for the victims of the Holocaust situated close to the Brandenburg Gate.

3) Berlin Panoramic Tour

Tuesday, March 24, 2009, 13:00-16:00
EUR 22 per person





The goal of this tour is to show visitors the sights of Berlin that are most closely connected to its history of change, including the following:

Charlottenburger Schloss - a jewel of baroque art and the favourite retreat of Queen Sophie Charlotte, wife of Frederick I
Kurfürstendamm - the longest shopping street in town, with its famous KaDeWe, the largest department store in Europe
Philharmonie - the famous concert hall designed by Sharoun, where Herbert von Karajan was once conductor
Potsdamer Platz - the new and old heart of Berlin was the most crowded square of the Golden 1920s and has been brought back to life out of a no man's land
Schloss Bellevue - built as a summer residence for Prince August Ferdinand, it is now the official residence of the German Federal President
Siegessäule - built from 1865 to 1873 to commemorate the Prussian campaigns against France, Austria and Denmark
Reichstag - the seat of the Bundestag (parliament) since May 1999
Bundeskanzleramt - the new headquartesr, as well as private residence, of the German Chancellor
Brandenburger Tor - the landmark of Berlin was built for King Frederick William II between 1788 to 1791 and has become, with the Quadriga on top, the strongest symbol of German unity
Gendarmenmarkt - the most beautiful square in Berlin and one of the most beautiful squares in Europe, is bordered by two churches - the Französischer Dom and the Deutscher Dom; the Schauspielhaus is the central building of the square
Unter den Linden – The most beautiful boulevard in the German capital
Berliner Dom - with the Hohenzollern tombs below - built at the end of the 15th century and completed in 1905, this church, in Italian Renaissance style, was destroyed during the Second World War and was beautifully restored afterwards
Alexander Platz - centre of the former East Berlin with the Fernsehturm and the Rote Rathaus, today the official office of the mayor of Berlin
Checkpoint Charlie - the former famous border crossing for diplomats, Allied military and foreigners; some parts of the Berlin Wall can still be seen

4) The Government Quarter

Wednesday, March 25, 2009, 09:00-13:00
EUR 27 per person



This tour focuses on the government buildings beginning at Pariser Platz. There we find the French, the English and the American embassies all surrounding the Brandenburg Gate. The next stop is the Reichstag, the home of the German parliament. Burned and bombed in World War II, it has been completely renovated with a new glass dome giving visitors an amazing view over Berlin. On to the Chancellery, which serves as both office and private residence of the German Chancellor. You will also see Schloss Bellevue, residence of the German President, as well as many embassies in the area.

Networking Opportunities

There have never been more ways to network at the EuroMeeting!

Networking is an integral part of the EuroMeeting. Attendees tell us that the networking opportunities presented by the EuroMeeting are one of the key reasons for attending. Each year, the EuroMeeting offers numerous opportunities to catch up with existing contacts and to make new ones in a relaxing setting.
ALL NETWORKING EVENTS AT THE EUROMEETING ARE INCLUDED IN THE REGISTRATION FEE.

Speed Networking Sessions – New at the EuroMeeting for 2009
Dates and times to be confirmed

All participants in the EuroMeeting try to use it as an opportunity to network. It is not easy to walk right up to someone, introduce yourself and have a conversation. The EuroMeeting Speed Networking sessions aim to make this process a lot easier.

Speed networking, which is based on the original concept of speed dating, brings together individuals who are attending a conference. It will help you to make new contacts and intensify your networking experiences. The goal is to ensure that each participant will make at least six new professional contacts during the speed networking sessions.

Please check the EuroMeeting website for updates and further information or contact Dermot Ryan in DIA European office at dermot.ryan@diaeurope.org or +41 61 225 51 32.

SIAC Knowledge Cafés - New at the EuroMeeting for 2009
Tuesday, March 24 and Wednesday, March 25, 2009 – Times to be confirmed

The Drug Information Association's Special Interest Area Communities (SIACs) are just one of the many benefits that DIA offers. Each SIAC provides a discipline-specific, global community where members can share common experience and knowledge and connect with others in their particular field. SIACs provide a forum for volunteers to network and exchange information. Further information about SIACs can be found on DIA's website at: http://www.diahome.org/DIAHOME/Membership/SIAC.aspx

What is a Knowledge Café?
Everybody gets a coffee and sits in groups of about 6 in a circle of chairs. The facilitator then introduces the café topic and poses one or two open-ended questions which the group discuss. At the end the participants reflect on the group discussions.

Some SIACs will be running Knowledge Cafés at the 21st Annual EuroMeeting, which provide an excellent opportunity to discuss topics of mutual interest while expanding your professional contacts at the same time. Watch the EuroMeeting website for updates or contact the DIA Volunteer Services Coordinator in Europe, Sarah Schuppener, on +41 61 225 51 62.

Jitterbug Reception
Monday, March 23, 2009, 18:00-20:00 at the Palast am Funktum (beside the ICC)

Monday evening will see DIA rocking and rolling at a networking banquet reception at the Palais Am Funkturm. The Palais is one of the largest and most beautiful ballrooms in Berlin and is a premiere venue for social functions. Located just a short walk from the Convention Centre, it is the perfect choice for Monday's reception. In a well-preserved 1950s interior, from the gilded ceiling to the elegant staircase to the panoramic bay windows, the Palais Am Funkturm cannot fail to impress. The theme of the reception will be the 1950s, with music and dance to fit the theme. At 18:15 there will be a Jitterbug dance performance by three couples. The Palais am Funkturm is beside the famous Berlin Funkturm (Radio Tower), completed in 1926.

A special "Berlin" menu will be served

Cold
Slices of beetroot with a sauce of green horseradish and young pees
Marinated asparagus tips with Neuenhagen smoked ham
Tiny meatballs on a salad of Teltow turnips and white beans
Salad of Kenya Beans with cauliflower marinated in walnut oil and young thyme
Fried Havel zander fillet on a sweetcorn and chicory salad
Vegetarian Crêpes with Vegetables, sprouts and fresh Cheese with chive
A selection of green salads with different dressings

Soup
Vegetarian Potato soup

Warm
Potato boulangère with brisket of beef and horseradish sauce
Gratinated pumpkin with slices of green asparagus
Poached Salmon on creamy spinach with horseradish and coconut
Different kind of fresh vegetables gratinated with manchego cheese
Selection of market cheeses with 10 different types of bread

Dessert
"Berliner Luft" and Berliner Donuts
Garden-fresh fruit salad with lemon balm
Home-made red berry compote with vanilla sauce

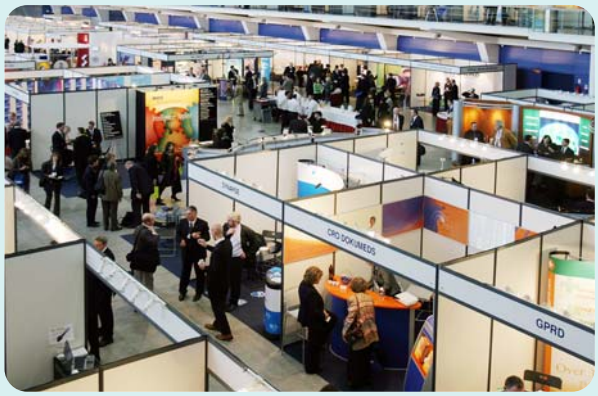
The Tuesday Reception
Tuesday, March 24, 2009, 17:30-18:30 on the Exhibition Floor

A drinks reception will take place on Tuesday on the Exhibition Floor. Entertainment will be provided.

DIA Special Interest Area Communities (SIACs) – Meet and Eat
Wednesday, March 25, 2009, 12:30-14:00

An opportunity for all SIAC members – and those interested in joining one – to get together for a networking lunch. The DIA Volunteer Service Coordinator in Europe will be on hand to answer any questions.

Network on the Exhibiton Floor



In response to attendee feedback, the Exhibition Floor is open even longer for the EuroMeeting 2009 in Berlin. Attendees now have the opportunity to visit the Exhbition Floor before sessions start with the door opening at 08:00 on Tuesday and Wednesday. All refreshements will be served on the Exhibition Floor, making it the ideal place to meet the people you want to meet.

Special Targeted Networking Activities

The DIA in Europe has developed a programme of activities to facilitate networking for patients representatives, students, emerging professionals, regulators and industry leaders.

Patients
Sunday, March 22, 2009
DIA Reception for representatives of Patients' Organisations – Patients Only

Monday, March 23, 2009, 12:30-13:30
Regulators and Patients Reception – An opportunity for patients and regulators to come together. Regulators and patients only

Students/Young Professionals
Monday, March 23, 2009, 12:30-13:30
Students/Young Professionals Networking Lunch at the ICC Convention Centre

Regulators from the EMEA and national regulatory authrorities
Monday, March 23, 2009, 12:30-13:30
Regulators and Patients Reception – An opportunity for patients and regulators to come together. Regulators and patients only

Industry Leader Reception
Wednesday, March 25, 2009, 11:00-12:00
Industry Leader Reception – Invitation Only

If you require further information about at of the above receptions, please contact Dermot Ryan at dermot.ryan@diaeurope.org or call +41 61 225 5132

DIA 21st Annual EuroMeeting 2009 at a Glance

Monday, March 23, 2009

09:00-12:30						
12:30						
14:00-17:30						
17:30-20:00						Jitterbug Networking
	Theme 1	**Theme 2**	**Theme 3**	**Theme 4**	**Theme 5**	
	Audits and Inspections – The Evolution of GCP into a Holistic Approach to Quality Management	**Regulatory Challenges and Controversies – Balancing Early Access with Safety and Affordability Aspects**	**Clinical Research: Increased Complexity by Integration of Real Life Settings**	**Safety throughout the Product Lifecycle: Strategies to Better Protect Public Health**	**Knowledge Management – The Key to Inexpensive, Timely, Safe and Effective Drug Development and Approval**	

Tuesday, March 24, 2009

Session 1 09:00-10:30	International GCP Inspection Experiences	Safeguarding Public Health: Balancing Early Access with Safety and Affordability Aspects	Paediatric Trials - Better Medicines through Regulatory Efforts	Surveillance: Diseases and Pharmacovigilance – How Good are our Baseline Data?	The EU Landscape	
Session 2 11:00-12:30	Audits and Inspections on Pharmacovigilance	Benefit – Risk	Patient Reported Outcomes	Safety Surveillance Plans: Strategies for Monitoring Safety during the Development Life Cycle	The "Electronic-only" Centralised Procedure - Now a Reality	
Session 3 14:00-15:30	Audits and Inspections on e-CRFs and e-Source Data	Novel Pharmacometric Approaches	Infectious Diseases	Special Requirements for the Safety of Biologicals and Biosimilars	Towards "Electronic-only" Mutual Recognition, Decentralised and National Procedures	
Session 4 16:00-17:30	Delegation of Sponsor Functions to CROs and other Third Parties	How Can Regulators Engage in Novel Drug Development? Revisiting the Regulator – Industry Dialogue	First- in-Man: Clinical Trials Issues	Performance and Quality Control in Pharmacovigilance and Risk Management – Too Much or too Little? What is the Impact on Public Health?	Product Information Management (PIM)- Towards Full Implementation	
17:30-18:30						The Blechharmonike
18:00-19:30						

Wednesday, March 25, 2009

Session 5 09:00-10:30	Serious GCP Breaches Including Falsification and Fraud	Building HTA into the Process: Meeting the Needs of Licensing Authorities, Payers and Patients	Patient Recruitment	EU- Harmonised Pharmacovigilance Requirements versus Global Pharmacovigilance – Supplement or Contradiction?	Key Initatives in Drug Development Optimisation	
Session 6 11:00-12:30	Quality Risk Management and Risk Detection	Enabling Early Access	Novel Approaches in Clinical Research	Safety Decision-Making – How Much Science is Deployed? An Update on Methodology	Product Partnering: The Effective Management of Information Assets	
Session 7 14:00-15:30	Audits and Inspections of Quality Aspects of Advanced Therapy Products	Communicating Benefit – Risk to the Public: 12 Years after the Erice Declaration, How much Progress Has Been Made	Multinational Trials in China, Africa and South America	Drug Safety Personnel – What Qualification and How much Education ares Needed? Where do Regulators and Industry Find Talent?	Risk Management & Pharmacovigilance - Between a Regulatory Rock and the Litigation Hard Place	
Session 8 16:00-17:30	Audits and Inspections of Data Analysis	Regulatory Implications of Outsourcing Clinical Development to Emerging Markets	Strategy of Clinical Development	Post-Marketing Studies – Commitments and Reality	Knowledge Management & Innovation	

Half-Day Tutorials

Exhibit Hall Opening

Plenary Session

Reception at the Palast am Funkturm with food, drink and entertainment

Theme 6	Theme 7	Theme 8	Theme 9	Theme 10	Theme 11	
Medical Device Drug Combination: The Medical Opportunities and Regulatory Challenges of the 21st Century	**Project Management in a Changing Environment**	**Media, Society and Research**	**Future of Drug Development and Globalisation – Important Trends and Hot Topics**	**Impact of Technology and Standards on Drug Development: Now Better, Safer and Faster?**	**Optimising Drug Development through Sound Methodology**	**H T**
ew and Updated Regulations: How Do They Effect Medical Device Drug Combinations?	Project Management Tools, Processes and Organisation	Is There Mistrust in Drug Research?	Therapeutic Vaccines – Promising New Cancer Treatment Options in Need of Appropriate Regulations	Integrating Different eClinical Data Streams: Needs and Benefits	Adaptive Designs - From Statistical Science to Regulatory Guidance	
uality Assurance Systems for Drug Device Combination Manufacturers: Experiences of QA Manager and Auditors	Key Success Factors for Portfolio and Project Management	Media Coverage of Clinical Research	Added Therapeutic Value- Are Common Criteria for Effectiveness Assessment Possible? What are the Discussions at the European Level?	Are the Benefits of eClinical Methods in Step with Regulations and Recent EMEA Guidance?	Adaptive Designs - A Discussion with Stakeholders	
Expanding our Regulatory Horizon to Deliver Device and Drug Combination Products uccessfully to Market: Where uld Drugs and Devices Meet?	Project Management Applied in Functional Areas – is PM the New Middle Management?	The Transparency Imperative	Incremental Research - Important Benefits, Neglected in European Law?	Technology & Standards… How about the Process?	Safety Planning in Drug Development - Real Improvement or yet Another Document?	V V
oundtable: The Spirit of One am Created from Two Worlds – the Key to Successful evelopment of Devices/Drug Combination Products.	Role of Project Management in Partnerships	The 'Informed Patient' - A Controversial Goal	Advanced Therapies Implementation- Recent Developments and Open Questions	The Loose Ends in EDC and How to Address Them	Beyond Trial Design and Sample Size Estimation - The Utility of Clinical Scenario Assessments	Cl E S

r Reception: Drinks Reception with entertainment on the Exhibition Floor

German Satellite Session

Borderlines between Devices nd Other Product Categories: Opportunity or Mystery?		Optimising The Dilemma of the Informed Consent Process Between Ethical Requirements and Organisational Burden	Implementation of ICH in non-ICH countries: Where Are We Now and What Will Happen in the Future?	A Look into the Future: What Is on the Horizon after We Have Managed EDC Properly?	Statistics for Biomarkers and 'Omics' - Anything New?	Te
Medical Assessments and afety Evaluations for Medical Devices, Drugs and their Combinations		Society, Patients and Advanced Therapy	Drug Counterfeiting in Europe: Trends and New Initiatives	Experience with CDISC Standards	Getting the Dose Right- Dose Finding and Exposure Reponse	
Inspection Findings at Investigation Sites and the Sponsor of Drug Device Combination Trials		Communicating Benefit – Risk to the Public: 12 Years after the Erice Declaration, How much Progress Has Been Made? See Theme 2		CDISC End-to-End: To What Extent?	Addressing Key Safety Challenges in Clinical Drug Development: Signal Detection and Continuous Risk Assessment	M M
New Developments in Drugs and Devices : Therapeutic Shift or Synergy?		Can We Draw a New Social Contract in Drug Development?		CDISC as an Avenue to Process Improvement	'Missing Data' for Your 'Quantitative Benefit-Risk' Assessment Supporting 'Conditional Marketing Authorisation'? Where Next for Regulatory Guidance?	A

Theme 12	Theme 13	Theme 14	Theme 15	Theme 16	
ealth Economics & Health echnology Assessments – Supporting Sustainable, Socially Acceptable and Equitable Access to Innovation	**Pre-Clinical/Clinical Interface: How to Improve Success in Developing Innovative Medicines**	**Personalised Medicine in Drug Development: Adding Value with New Tools - Biomarkers, Health Economics and Diagnostics**	**Regulatory Developments and Availability of Biosimilar, Generic and Self-Care Medicines**	**Preparing for the Future – Challenges in Pharmaceutical Quality**	**Hot Topics and Stand Alone Sessions**
Demonstrating Cost-Effectiveness in Challenging Situations and when Data is Limited	Use of Imaging in Non-Clinical Toxicity Testing: What Is its Value? What about Regulatory Acceptance?	Personalised Medicine: Beyond the Buzzword	Ways to Improve the Current Regulatory System for Assessment of Medicinal Products with Known Active Substances	Implementation of the New ICH Quality Paradigm	Update on Regulatory Pharmacovigilance
Market Access in Europe: How Does Innovation Get to the Patients?	Non-Clinical Evaluation of Hepatotoxicity: Where do We Stand? How Sceptical is the Pharmaceutical Industry?	From Populations to Individuals: Industry Tools and Assessment of Benefit/Risk Balance	Introduction of Biosimilar Medicines into Clinical Practice	Innovative Technologies in Drug Development and Manufacture	Hot Topic in Telematics
Vhat Does the User Consider alue? Including the Patients' Voice in Assessments	Non-Clinical Support for First-in-Man Studies	Personalised Medicine: A Challenge for Drug Development?	Known Active Substances and Bibliographic Applications - Current Problems, Possibilities and Solutions	Pharmacopoeias – Do They Have a Place in a "Quality-by-Design" Environment?	Harnessing Industry and Authority Experience: Working Together to Achieve Effective Guidelines
inical Trials - the Start not the nd. Building Integrated Data ets in a European Context to Meet Needs	Update on Anti-Cancer Drug Guideline ICH9	Regulatory Guidelines Compared to Medical Practice Guidelines: Their Places in Personalised Medicine	A Global Programme for the Next Generation in Biosimilars	The Paediatric Regulation – An Easy Way to Age - Appropriate Formulations?	Translating siRNA to Medicines
Health Economics and Health chnology Assessment in 2009 – a More Diverse or More Uniform Landscape?	Update on ICH S6 Non-Clinical Safety Testing of Biotechnology-Derived Products: Part 1	Major Players in Personalised Medicine: Expectations and Specific Needs in Outgoing Education	"Smart Regulation" for Non-Prescription Medicines	Clinical Trials with Biological – IMPD Requirements	Update on Advanced Therapies
Building Health Technology Assessments into Product Development for Success	Update on ICH S6 Non-Clinical Safety Testing of Biotechnology-Derived Products: Part 2		Patents and the EU Regulatory Systems	Revision of the Variations Regulations: An Update	Japanese Regulatory Session: PMDA Update ? Initiatives and Challenges for Promoting Global Drug Development including Japan
edicines Are about More than Money. Building Social Values into Health Economics	New Concepts in the Assessment of Genotoxicity		News on Rx to OTC Switch	Sourcing of API in a Globalised Environment	EU Agreement: Administrative Regulatory Simplification – The Next Phase?
Access to Innovation: A Role for New Approaches?	Update on the Use of Juvenile Animal Studies for Paediatric Drug Development		Improved Market Access to Herbal Medicinal Products	What's New in the Quality Arena?	Summary of the Roundtable/Workshop on GCP Inspection and Audit Findings