DRUG INFORMATION ASSOCIATION

19TH ANNUAL EUROMEETING VIENNA 2007

MARCH 26-28, 2007

AUSTRIA CENTER, VIENNA, AUSTRIA

DIA's 19th 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 130 sessions in 24 tracks*
- *Attend presentations by more than 400 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 200 exhibitors on one of the largest exhibition floors in Europe to showcase your company, products and services*

Special early-bird registration fees until January 12, 2007

Register NOW and save € 150.00!

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Dear Friends and Colleagues,

We would like to welcome you to the Drug Information Association's 19th Annual EuroMeeting in Vienna, where you will join your colleagues from regulatory agencies, academia and industry.

In Europe, drug development is becoming more complex. Similarly, the development of pharmaceutical compounds and their regulation is constantly being challenged. We are hopeful, however, that, by stimulating the research and development of innovative medicines, we can improve R&D processes, design new paradigms and remove obstacles. To this end, the EuroMeeting will provide the latest information on important European initiatives, including paediatrics, advanced therapies, the technology platform, pharmacogenomics, pharmacovigilance, risk management planning and more.

More than four hundred speakers will discuss best practices and strategies for the research and development of new chemical entities, biotechnology-derived compounds, vaccines and generics.

The Plenary Session on Monday, 26 March, will be a truly European event with the focus on Europe. There will be European keynote speakers and other speakers from Europe, as well as from the Austrian agency and pharmaceutical industry.

Tracks and tutorials will cover a variety of topics, and special events will highlight the 2007 EuroMeeting. On Tuesday, 27 March, the Satellite Symposium will present the activities of the Austrian agency. DIA continually strives to enhance the quality of the EuroMeeting's content and to ensure that "hot topics" are considered.

The EuroMeeting, one of the largest events in pharmaceutical medicine, provides myriad networking opportunities. Delegates, like you, are devoted to the research, development and delivery of new, safe and effective medicines. The EuroMeeting brings together, at one event, representatives from the biopharmaceutical industry, contract research organisations, academic research centres and regulatory bodies.

The exhibition hall presents an extraordinary opportunity to meet over 200 providers offering a wide range of services, all in a single location which is a favourite spot for attendees to visit throughout the meeting.

Vienna, the capital of Austria, has a long and exciting history as well as beautiful castles, churches, gardens, and museums. Mozart, Beethoven, Strauss and many other famous personalities are symbols of this lively metropolis in the centre of Europe, which offers many cultural events, beautiful and colourful restaurants and excellent wines that will stimulate your discussions with colleagues.

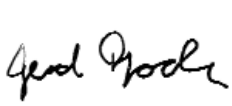
We want to thank the many volunteers devoting their time and energy to making this the best meeting experience for biopharmaceutical, academic and regulatory professionals.

We sincerely thank all of you who have contributed to our programme. In particular, we are grateful to our programme advisors and members who have dedicated their time to this outstanding event.

We look forward to seeing you at the 19th Annual DIA EuroMeeting, in Vienna, from 26-28 March 2007.

Best regards,

Christa Wirthumer-Hoche



Gerd Bode

Programme Co-Chairpersons

CHRISTA WIRTHUMER-HOCHE, PHD, DIPL. ING.

Dr. Christa Wirthumer-Hoche studied biochemistry and graduated from the Technical University, Vienna in 1981. She did her doctoral thesis at the Institute for Medical Physiology, graduating in 1983. She joined the Austrian National Institute for Quality Control of Drugs in 1983 and worked there until May 1998, focusing on the assessment of quality documentation. From June 1998 until December 2005 she was Head of the Licensing Division for Medicinal Products in the Unit for Pharmaceutical Affairs in the Austrian Federal Ministry of Health and Women.

Since the founding of the new Austrian Agency on January 1, 2006 her position has been Head of the Unit for Marketing Authorisation and Lifecycle Management of Medicinal Products at AGES PharmMed. Since 1994 she has been involved in different European committees and working groups (CPMP/CVMP Quality Working Party, the Committee for Proprietary Medicinal Products (CPMP), MRFG, Notice to Applicants Group and the PERF Project).

In December 1999 she was appointed by the European Commission as Co-ordinator for CTD Implementation in Europe. She is a frequent speaker at numerous international and European meetings and particularly at DIA meetings.

GERD BODE, MD, PHD

Gerd Bode, MD, PhD, received his degree in medicine at the University of Goettingen, Germany, working with the university for 12 years and earning board-certified specialisations in Pathology, Legal Medicine, Neuropathology, Pharmacology and Toxicology.

He joined the pharmaceutical industry thereafter and became Head for Toxicology, Pathology and Drug Safety at Boehringer Mannheim. His career then took him to Paris, as Head for Lead Optimisation (all pre-clinical disciplines and Phase I) at Hoechst Marion Roussell/Aventis. Later, he became Head for Pre-clinical Drug Safety at Altana, Hamburg, retiring in 2005.

Currently, Dr. Bode serves as lecturer at the Universities of Goettingen, Bonn and Essen in Germany and at the University of Lyons in France. He served DIA as a speaker, organiser and chairperson for annual meetings and workshops and was part of the Steering Committee for Europe (now the Advisory Council of Europe) for several years. Gerd received the DIA Outstanding Service Award in 2002.

Programme Committee and Advisors

PROGRAMME CO-CHAIRPERSONS

Christa Wirthumer-Hoche
Head of the Unit for Marketing Authorisation and Lifecycle Management of Medicinal Products, AGES PharmMed, Austria

Gerd Bode
Consultant, Germany

PROGRAMME COMMITTEE

Barry Burnstead
Director of Project Management i3 Statprobe, UK

Fritz Erni
Head Technical Liaison, Novartis Pharma AG, Switzerland

Kerstin Franzén
Director Regulatory Policy and Intelligence Pfizer, Sweden

Sören Kristiansen
Director Data Operations, Astellas Pharma GmbH, Germany

Suzette Kox
Managing Director Kox Pharma sprl, Belgium

Klaus Olejniczak
Pre-Clinical Assessor, BfArM, Germany

Sonja Pumplün
Vice President, Head Global Regulatory Affairs, Actelion Pharmaceuticals Ltd., Switzerland

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

Olaf Schoepke
Senior Consultant, Lorenz Life Sciences Ltd., UK

Valerie Simmons
Director, EU Qualified Person for Pharmacovigilance Global Product Safety Eli Lilly & Co. Ltd., UK

Steffen Stuerzebecher
Head of Translational Medicine Support Pre-Clinical Development Schering AG, Germany

Anu Tummavuori
Manager, EU Regulatory Affairs and Liaison International Drug Regulatory Affairs, F. Hoffmann-La Roche Ltd., Switzerland

Milen Vrabevski
Medical Director/CEO, Comac Medical Ltd., Bulgaria

Ralph White
Director, PPMLD Ltd., UK

PROGRAMME ADVISORS

Iman Barilero
Associate Director, European Regulatory Affairs, Global Regulatory Affairs and Quality Assurance, Johnson & Johnson Pharmaceutical Group, UK

Gaby Danan
Expert, Global Pharmacovigilance and Epidemiology, sanofi-aventis, France

Françoise de Crémiers
Associate Professor, Faculty of Pharmacy Paris Sud-Est, France

Marie Dray
President, International Regulatory Affairs Group, USA

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

Yves Juillet
Senior Advisor, Les Entreprises du Médicament, France

Ingrid Klingmann
President, Pharmaplex, Belgium

Yann Le Cam
CEO, EURORDIS, Europe

Murray Lumpkin
Deputy Commissioner for International and Special Programs, Office of the Commissioner, FDA, USA

Jacques Mascaro
Director, European Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

Jean-Louis Robert
Head of Department, Department of Quality Control of Medicines, Laboratoire National de la Santé, Luxembourg

Noël Wathion
Head of Unit Post-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

Plan Your EuroMeeting Experience

	MONDAY, MARCH 26	TUESDAY, MARCH 27	WEDNESDAY, MARCH 28
MORNING	Tutorials (optional) Graduates' Session 09:00 - 12:30	Session 1 & 2 09:00 - 12:30 Exhibits 10:00 - 18:30	Sessions 5 & 6 09:00 -12:30 Japanese Regulatory Session 11:00 - 12.30 Exhibits 10:00 - 16:00
AFTERNOON	Plenary Session 14:00 - 18:00 Exhibits 12:30 - 18:00	Sessions 3 & 4 14:00 - 17:30	Sessions 7 & 8 14:00 - 17:30
EVENING	Viennese Networking Buffet Reception 18:00 - 21:00	Networking Reception 17:30 - 18:30 Austrian Satellite Meeting 18:00 - 19:30	End of Conference 17:30

MONDAY, MARCH 26, 2007

Plenary Session

14:00 – 14:15 **DIA WELCOME AND OPENING**

Brigitte Franke-Bray,
Director, DIA Europe, Switzerland

Cynthia L. Kirk,
DIA President and Global Vice President, Regulatory Affairs, PRA International, USA

David Maola,
DIA Executive Director, USA

Welcome from EuroMeeting 2007 Programme Co-Chairpersons

Christa Wirthumer-Hoche,
Head of the Unit for Marketing Authorisation and Lifecycle Management of Medicinal Products, AGES PharmMED, Austria

Gerd Bode,
Consultant, Germany

14:15 – 16:00 **THE NEW PHARMACEUTICAL LEGAL FRAMEWORK – A STEP IN THE RIGHT DIRECTION FOR EUROPE?**

Keynote Presentations:
Andrew Witty,
President Pharmaceuticals Europe, GlaxoSmithKline, UK

Georgette Lalis,
Director of the Directorate for Consumer Goods European Commission, DG Enterprise and Industry, EU

REGULATORY AGENCIES' PRESENTATIONS

Martin Terberger,
Head of Enterprise and Industry, DG Pharmaceuticals Unit, European Commission, EU

Thomas Lönngren,
Executive Director, EMEA, EU

Jytte Lyngvig,
Chief Executive Officer, Danish Medicines Agency, Chair of HMA Management Group, Denmark

Marcus Müllner,
Director, AGES PharmMED, Austria

16:00 – 16:30 **COFFEE BREAK**

16:30 – 17:15 **TRADE ASSOCIATIONS' PRESENTATIONS**

Brian Ager,
Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Hubertus Cranz,
Director General, AESGP, Belgium

Greg Perry,
Director General, European Generic Medicines Association, Belgium

17:15 – 18:00 **DIA DISTINGUISHED CAREER AND OUTSTANDING SERVICE AWARDS CEREMONY**

followed by
STRING QUARTET CONCERT:

- **KAISERQUARTETT**
  Joseph Haydn
- **EINE KLEINE NACHTMUSIK**
  Wolfgang Amadeus Mozart

18:00 – 21:00 **VIENNESE NETWORKING BUFFET RECEPTION**

Keynote Speaker

ANDREW WITTY

Andrew Witty was named President, Pharmaceuticals Europe for GlaxoSmithKline in January 2003. He is a member of the Corporate Executive Team. Previously, he held the role of Senior Vice President, Asia Pacific, Pharmaceuticals International since January 2001 where he was responsible for the company's operations in Asia Pacific, based in Singapore.

Andrew joined Glaxo UK in 1985. He held various positions in the UK, including Director of Pharmacy and Distribution in Glaxo Pharmaceuticals UK, Director of Business Development for Biocompatibles Limited and International Product Manager for Glaxo Holdings plc. He later served as Managing Director, Glaxo South Africa and subsequent promotion to Area Director for South and East Africa. More recently, he was Vice President and General Manager, Marketing for Glaxo Wellcome Inc., the company's US subsidiary, with responsibility for strategy development, marketing execution and new product positioning.

Andrew served as Economic Adviser to the Governor of Guangzhou, China from 2000 to 2002. He is a board member of the Singapore Economic Development Board, a member of the Economic Development Board audit committee as well as a board member of the Singapore Land Authority Board under the Ministry of Law, during 2002 and 2003.

Andrew has a BA in Economics from Nottingham University in the UK.

Continuing Education Overview

This programme is designed for the full continuum of disciplines in the pharmaceutical and related industries to improve your understanding and skills as related to issues and solutions for a variety of pharmaceutical development interest areas.

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 Drug Information Association designates this educational activity for a maximum of 3.00 AMA PRA Category 1 Credit(s)™ . Physicians should only claim credit commensurate with the extent of their participation in the activity.
(The maximum number of credits noted above includes attendance at tutorials only; tutorials offering these credits are clearly identified in this programme)

Select sessions may offer category 1 credits and will be clearly identified in the final programme.

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 1.5 continuing education units (CEUs) to participants who successfully complete this programme and tutorial.

The DIA has awarded up to 0.3 IACET CEUs for each tutorial and a maximum of 1.2 IACET CEUs for the whole programme. IACET CEUs are not offered for the plenary session on Monday afternoon.

If you would like to receive a statement of credit, you must attend the programme (and tutorial, if applicable), 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. My Transcript will be available for credit requests on Thursday, March 29, 2007.

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 unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

POSTERS

Poster Sessions for Students
Awards

A total of EUR 3,000 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
- Conclusions

A maximum of 20 abstracts from full-time university students, university residents and university fellows will be selected for the student poster presentations to be held on Tuesday, March 27, 2007. To qualify as a student poster presenter, you must be a full-time student, resident, or fellow at the time of the presentation. Selected student poster presenters will receive complimentary meeting registration for two people.

Poster Sessions for Professionals

A maximum of 40 abstracts from full-time professionals will be selected for the professional poster presentation.
Selected professional poster presenters will be required to pay the applicable meeting registration fee and will be responsible for all other expenses.

More detailed information will be provided upon acceptance. All abstracts must be received by December 1, 2006. Please submit all poster abstracts by email to: euromeeting2007@diaeurope.org
Submission requirements are available from the EuroMeeting website at www.diahome.org.

GRADUATES' SESSION

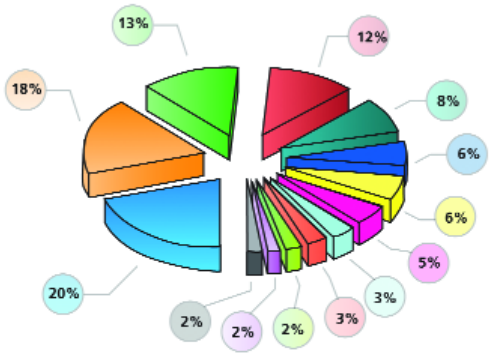
Monday, March 26, 2007, 09:00 – 12:30

Speakers from industry and academia will discuss:
- Drug development and registration process
- Global DIA activity
- Career development and opportunities

All DIA members and volunteers are invited to join both the welcome breakfast and the closing round-table.

Session Co-Chairpersons:
Professor **Charlotte Dupont**, France
Timothée Fraisse, Hôpitaux Universitaires de Genève, Switzerland

2006 DIA EUROMEETING ATTENDEES BY COUNTRY

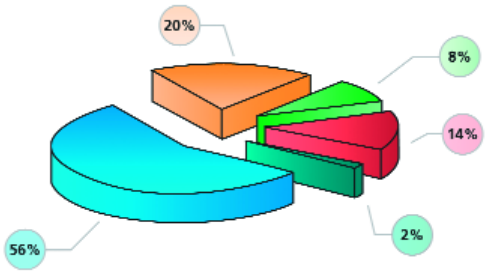


- France
- Germany
- United Kingdom
- United States
- Switzerland
- Denmark
- Belgium
- Sweden
- Netherlands
- Italy
- Spain
- Finland
- Turkey

> *"Wonderful opportunity for exhibitors to meet people who are working in drugs and disease areas and so aid in understanding needs and processes of potential customers."*
>
> Training Manager, International scientific and health publisher

> *"DIA events attract the widest spectrum of delegates, from academia to authorities to pharma companies – due to the excellent sessions available offering exhibitors the premier showcase for their products and services."*
>
> Corporate Marketing Manager, International drug safety software firm

PROFESSIONAL CATEGORY

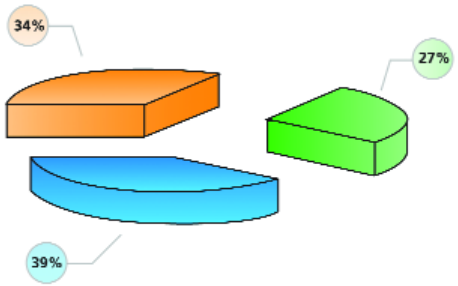


- Academic Institutions
- Government
- HealthCare Delivery - Other
- Industry
- Support Services or Products - Staffing

> *"Excellently organised ... It is THE event of the year!"*

> *"Excellent presentations on current hot topics – very valuable – didn't just 'cut and paste' from guidelines and drafts – really shared key critical information... very provocative, thought–provoking material."*

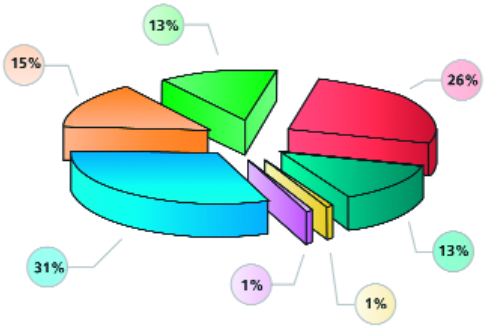
LEVEL OF ORGANISATIONAL RESPONSIBILITY



- Responsible for overall organisation functions
- Responsible for departmental, divisional or group functions
- Responsible for specialised function or a job within a group or division

> *"Visionary! Keep up the good work and congrats for great achievements so far."*

DEGREES HELD



- Doctorate
- MD
- PharmD
- Masters
- Bachelors
- Associates
- Technical Specialty Training

> *"Very valuable forum for meeting prospective customers and solidifying relationships with existing customers ... Offers access to key decision makers."*

The exhibit hall at the DIA EuroMeeting has grown each year, adding to its value as an international industry venue for exhibitors, from CROs and technology vendors to site research centers, academia and many others. In 2007, over 200 exhibitors will be present, offering one of the largest exhibit floors in Europe yielding increased networking opportunities for attendees. Limited exhibiting opportunities are still available. To secure your company's presence at the DIA 19th Annual EuroMeeting, please call Phyllis Suter on +41 61 225 51 54 or email: phyllis.suter@diaeurope.org. For a full list of confirmed exhibitors, see page 46.

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

Half-Day Tutorials

Enhance your EuroMeeting experience by attending one of the 21 half-day pre-conference tutorials. All tutorials will take place on Monday, March 26, 2006 from 09:00 - 12:30 and cost EUR 350 plus VAT. Most tutorials offer continuing education credit. On-site registration may not be guaranteed. Tutorial instructors are subject to change. For more information, please visit www.diahome.org

TUTORIAL 1 **09:00 – 12:30**

Volume. 9A and EU Regulatory Requirements: Pharmacovigilance in the Post-Authoriasation Phase and e-reporting

CME CREDITS OFFERED

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

This tutorial will allow attendees to discuss the new regulatory requirements with regard to the EU Guideline on Risk Management Systems for Medicinal Products for human use in line with the new community legislation. Main emphasis will be put on the risk management description and the requirements for applicants and marketing authorisation holders as well as methods of risk minimisation.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Interpret the potential implications of the new requirements on pharmaceutical companies' business processes
- Adhere to the requirements of establishing, where applicable, a risk management system in the EEA
- Share knowledge on how to prepare a pharmacovigilance/ risk management plan
- Explain the requirements with regard to risk communication and the effectiveness of risk minimisation tools

Target Audience
This tutorial is designed for experts in pharmacovigilance, regulatory experts and sponsors of clinical trials.

TUTORIAL 2 **09:00 – 12:30**

Risk Management: Turn Plans into Practice

CME CREDITS OFFERED

Monika Pietrek, Executive Vice President, Global Scientific & Medical Affairs, PRA International, Germany
Andrzej Czarnecki, Director, Deputy EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly & Co. Ltd., UK
Rosalind Coulson, Safety Consultant, PRA International, UK

The New Medicine 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 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 3 **09:00 – 12:30**

Decision-making Using Pharmacogenetic (Pgx) Markers in Drug Development

CME CREDITS OFFERED

Linda Surh, Director, Regulatory Affairs, GlaxoSmithKline, UK
Aiden Flynn, Statistics Department, GlaxoSmithKline, UK

The first part of this session will describe the important factors that influence the outcome of Pharmacogenetic (Pgx) studies. This will be followed by an interactive position where Pgx scenarios within a drug development programme will be defined and discussed. The audience and expert panel will decide on what happens next as the programme progresses.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Discuss the medical, genetic and statistical factors that can impact the outcome of Pgx studies
- Differentiate types of Pgx-based decisions within a "typical" pharmaceutical project team
- Identify some of the clinical, regulatory, statistical and product profile considerations in making drug development decisions using Pgx

Target Audience
This tutorial is designed for scientists in the pharmaceutical industry and academia involved in clinical studies.

TUTORIAL 4 **09:00 – 12:30**

Operational Aspects of Paediatric Clinical Trials

CME CREDITS OFFERED

Klaus Rose, Head Paediatrics, Medical Science (PDM), F. Hoffmann-La Roche Ltd., Switzerland
Anna-Karin Hamberg, Clinical Pharmacologist, F. Hoffmann-La Roche Ltd., Switzerland
Diane McKay, Clinical Science Specialist, Roche Products Ltd., UK

US and EU health authorities are focusing on paediatric drug development (and will continue to do so in the near future) and routine paediatric assessments at an early project stage. Participants in this tutorial will understand the legal framework that intends to facilitate paediatric drug development and will learn about scientific as well as practical aspects of paediatric clinical trials phase I, II and III during preparation and execution. This tutorial will include a hands-on workshop on current method for dose prediction in children and their limitations, including a glimpse into future paths to improve dose predictions for different age groups by using physiologically based pharmacokinetic modelling.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Identify the essentials in the planning phase of a paediatric trial
- Recognise bottlenecks often encountered in paediatric trials
- Discuss challenges of clinical research in different age groups
- Identify key impact factors of EU and US paediatric legislation
- Limitations of body size adjusted dose predictions in children
- Changes in physiological functions during childhood and their influence on drug behaviour (ADME: Absorption, Distribution, Metabolism, Excretion)
- Physiologically based pharmacokinetic (PBPK) models

Target Audience
Registration associates, medical advisors, clinical research associates and physicians, study nurses, project managers, business associates, medical directors and others in academia, pharmaceuticals and CROs as well as Health Authorities who want to expand their background and operational knowledge of paediatric drug development.

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

Half-Day Tutorials

TUTORIAL 5 **09:00 – 12:30**

Pharmaceutical Project Management: How to Ensure Success

Ralph White, Director, PPMLD Ltd, UK
John Faulkes, Director, TeamCommunications, UK

Delegates will experiment with a range of diagnostic questions and analysis models designed to evaluate whether a project is healthy, or whether it is likely to experience avoidable delays, derailment or major disconnects. Technical aspects of the project (target profile, risk identification & contingency planning, etc) and human factors (project leadership, teamwork) will be explored in an interactive session that actively encourages reflection on the state of a project.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Apply a practical set of questions and analysis models to assess the health of a pharmaceutical development project
- Formulate practical ideas in the workplace to enhance project leadership, teamwork and technical excellence

Target Audience
This tutorial is intended for those relatively new to product development – not only project managers, but also functional managers interested to know more about the development process. It will generate practical ideas that can be applied at regular intervals in the workplace including milestone reviews.

This tutorial is endorsed by the Project Management SIAC

TUTORIAL 6 **09:00 – 12:30**

European Pharma Law for Non-Lawyers: Principles of Pharmaceutical Legislation and Case Law

John A. Lisman, Attorney, NautaDutilh, The Netherlands
Peter Bogaert, Partner, Covington & Burling, 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.

TUTORIAL 7 **09:00 – 12:30**

Analysis of Safety Data from Clinical Trials

CME CREDITS OFFERED

Joachim Vollmar, Executive Consultant, International Clinical Development Consultants, USA
Conny Berlin, Statistician, Bayer HealthCare AG, Germany

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:
- 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 8 **09:00 – 12:30**

Vaccine Views and Issues: Preparing to Face the Pandemic

Anne-Marie Georges, Consultant, AMQuid Pharma, Belgium
Wilfried Dalemans, Director Regulatory Strategy and Development, GlaxoSmithKline, Belgium
Roland Dobbelaer, Chairman of EMEA, Vaccines Working Party, Scientific Institute Public Health, Belgium
Daniel Brasseur, Chairman of CHMP, Ministry of Public Health, Belgium
Vincente d'Agosto, Novartis Vaccines and Diagnostics, Italy

This tutorial is dedicated to a human health threat, the emergence of which is unpredictable but real. The mechanism of occurrence of an influenza pandemic, technology as it currently exists, and the anticipated or ongoing developments in the field of influenza vaccines, as well as the specific regulatory provisions set up in the European Union for the development of "prototype" vaccines will be reviewed. Clinical and medical issues related to influenza pandemic vaccines, in particular the strategy for use of pandemic and pre-pandemic vaccines and pharmacovigilance issues, will be addressed.Mathematical modelling of an influenza pandemic will be reviewed.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise the huge issues raised by the emergence of a pandemic situation due to a large mutation of the influenza virus at the worldwide level
- Discuss the possible solutions that would be available in order to contain the pandemic and the timing of action
- Describe the medical, regulatory and technical aspects of development of pandemic vaccines as well as of scientific progress in this matter

Target Audience
Persons involved with vaccines (companies, regulators, health authorities, etc.). Participants interested in public health threats, virology, scientific development.

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

Half-Day Tutorials

TUTORIAL 9 **09:00 – 12:30**

Successful Management of Clinical Trials in Asia

Nadina C. Jose, President, Research Strategies Inc., USA

Emerging markets, such as Asia, are highly attractive to pharmaceutical companies, thanks to patient population availability, leaner operational expenses and better-motivated investigators. But any entity wishing to succeed in Asia must take a number of important aspects into consideration. Among these are finding ways to diminish costs, developing a good grasp of the region and giving the company's presence in the area firm foundations that can stand the test of time. Speeding up time to market and decreasing the costs associated with new drug development, however, involve many important decisions and processes. To maximise what developing regions have to offer, these are needed to ensure that execution strategies are appropriate, well-resourced and properly supported. The goal of this workshop is, therefore, to provide an in-depth look at the way clinical trials are conducted and managed in Asia.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise the impact of change in the clinical trial arena brought about by emerging markets like Asia
- Describe cultural nuances that exist in Asia, understand and assimilate these nuances and create customised, result targeted, centralised operating procedures
- Discuss how to organise and empower the ideal project team

Target Audience
Professionals in clinical trials management and strategic resource management, Asian investigators, project managers and professionals in strategic resource management.

TUTORIAL 10 **09:00 – 12:30**

Comparability of BioPharmaceuticals

Richard Turner, Director of Regulatory Affairs, ERA Consulting Group, UK
Leena Gajjar, Regulatory Affairs Consultant, Austria

Issues surrounding the complex subject of demonstrating comparability of biological and biotechnological medicinal products from a regulatory perspective will be presented. The impact of manufacturing process changes on product quality, safety and clinical efficacy will be analysed. Using case studies, solutions demonstrating comparability of these complex products will be developed.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Identify key aspects of manufacturing processes of biological and biotechnological medicinal products where changes potentially impact product quality, safety and efficacy
- Assess the impact of process manufacturing changes from a regulatory perspective
- Propose strategies to provide effective demonstration of comparability during the biopharmaceutical drug development process

Target Audience
Professionals in biopharmaceutical development, including development managers, research scientists, scientific officers and regulatory affairs professionals.

This tutorial has been organised with the support of the Biotechnology SIAC

TUTORIAL 11 **09:00 – 12:30**

MedDRA in Practice Workshop

CME CREDITS OFFERED

Tomas Moraleda, International Medical Officer, MedDRA MSSO, Spain
Patrick Revelle, MSSO Director, Northrop Grumman/MedDRA MSSO, USA

This tutorial will look at the implications of using MedDRA in pharmacovigilance and clinical safety. It will cover coding conventions, data retrieval and analysis options, including the use of Standardised MedDRA Queries, and the impact on signal detection and labelling.

Learning Objectives
At the conclusion of this tutorial, participants will be able to:
- Describe how coding conventions affect the retrieval and analysis of MedDRA-encoded data
- Discuss the methods of data retrieval and analysis and the role of Standardised MedDRA Queries in signal detection
- Recognise the impact of using MedDRA-encoded data on product labelling

Target Audience
This tutorial is designed for pharmacovigilance professionals, clinical data managers, statisticians, clinical research physicians and regulatory professionals who already have a basic knowledge of MedDRA and wish to explore the implications of its use in the drug safety environment.

TUTORIAL 12 **09:00 – 12:30**

The CDISC Roadmap from eSource to eSubmission

Rebecca Kush, President, CDISC, USA
David Iberson-Hurst, CEO, Assero Ltd., UK.

As we move into a world of Electronic Health Records (EHR) and ePatient Reported Outcomes (ePRO), it is becoming increasingly important to have a) interoperability among systems for clinical research and clinical care; b) an easy way to integrate data; and c) processes that leverage harmonised standards from end to end, from source to reporting, submission and even safety surveillance. The Clinical Data Interchange Standards Consortium (CDISC) has established standards to support the acquisition, exchange, submission and archiving of clinical trial data and metadata. CDISC has a mission to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of health-care. CDISC has been working to harmonise its standards with each other and with healthcare standards (HL7) and there is a CDISC Roadmap that addresses the technical aspects of achieving the mission. This workshop will provide an overview of the CDISC roadmap and an update on the progress towards the CDISC mission. Goals, principles, milestones, updates and examples will be shared.

Learning Objectives
At the conclusion of this tutorial, participants will be able to:
- Describe the CDISC roadmap
- Discuss the goals and principles of CDISC

Target Audience
Anyone who is involved in implementing new technologies and/or data standards to streamline clinical trials, especially project managers, CRAs, data managers and those managing or implementing trials across departments.

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

Half-Day Tutorials

TUTORIAL 13 **09:00 – 12:30**

Active Involvement of Patient Representatives in the Regulatory Process

François Houyez, Health Policy Officer, EURORDIS, France
Isabelle Moulon, Head of Sector Medical Information, EMEA, EU

This tutorial will explain how patient organisations can play a valuable role in the regulatory process at both a national and European level. As part of improving patient safety, the role of patient organisations in helping regulatory bodies collect information is an important one. This tutorial will discuss ways to participate in the process.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Describe how and why to be involved in the regulatory process at the national level
- Recognise their role in the regulatory process at the European level, with special emphasis on product information
- Identify ways to participate in risk communication regarding safety information

Target Audience
Patient representatives with little or no experience in pharmaceutical products regulatory affairs.

TUTORIAL 14 **09:00 – 12:30**

How to Apply Non-Clinical Safety Guidelines in Global Drug Development

CME CREDITS OFFERED

Gerd Bode, Consultant, Germany
Klaus Olejniczak, Pre-clinical Assesor, BfArM, Germany

The speakers have gained long-term experience as topic leaders in the International Conferences of Harmonisation and would like to share their experience with you. All guidelines concerning safety will be addressed, from single dose to carcinogenicity, including safety pharmacology, immunotoxicology, M3 and common technical document.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise objectives and strategies in toxicology
- Describe improved use of preclinical safety data
- Describe the requirements for safety by agencies

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

TUTORIAL15 **09:00 – 12:30**

Paediatric Development and Innovative Aspects of Paediatric Trials

Gérard Pons, Head of Perinatal and Pediatric, University René Descartes & Groupe Hospitalier, Cochin/Saint-Vincent de Paul, France
Agnès Saint Raymond, Head of Sector Scientific Advice and Orphan Drugs, EMEA, EU
Daniel Vasmant, Délégué Scientifique - Cancéropôle IdF, Hôpital Saint-Louis, France

Paediatric development and innovative aspects of paediatric trials are hot topics for agency, 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 the 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 16 **09:00 – 12:30**

How to Deal with CP and MRP in an Enlarged EU

Anthony Humphreys, Head of Sector Regulatory Affairs and Organisational Support, EMEA, EU
Truus Janse-de Hoog, Staff Member Chair, Medicines Evaluation Board, The Netherlands, Chair CMD(h)
Sara McLean, Roche Products Ltd., UK
Anu Tummavuori, Manager, EU Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

Presented by representatives from national authorities and industry, this tutorial will provide a pragmatic view of how EU registration procedures work. The consequences of the enlargement of the EU from 15 to 25 member states on May 1st, 2004 for the operation of the procedures will be explained. Furthermore, information will be given on the (future) changes in procedures as a result of implementing new legislation.

Learning Objects
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 and pharmaceutical industry personnel and students.

TUTORIAL 17 **09:00 – 12:30**

PIM Light Authoring Tool

Raun Kupiec, Associate Director, Process Management Regulatory Affairs, Genzyme Europe BV, The Netherlands

PIM is a standard, a process and a set of related systems. Included in this system is a free authoring tool provided by the EMEA to enable applicants to construct a PIM submission – the PIM Light Authoring Tool (LAT). In order to successfully create a PIM submission and utilise the LAT, it is critical to understand certain basic principles. At the heart of PIM is the Data Exchange Standard (DES), a standard which aims to minimise the repeated adjustment of information that is included many times in different locations within the documents provided in support of current processes. The standard utilises XML (Extensible Markup Language) to structure and control the product information being exchanged.
This tutorial will cover key components of the PIM approach, explaining the basic principles of the DES, PIM Review System (PRS) & Light Authoring Tool (LAT) – and their interrelationship. It will demonstrate the use of PIM both within and outside an eCTD submission. This tutorial will use the LAT to show participants the principle of content management & content re-use through an explanation of templates and documents within PIM. Basic introductory instruction will be provided in how to: (1) download and install the LAT, (2) build a PIM submission, (3) comment and reply to regulators within the LAT, (4) construct a multi-lingual PIM submissions. This tutorial will also explore the LAT product library and lifecycle.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Identify what PIM is and what the Data Exchange Standard represents
- Explain the concept of structured data and templates and how these are created and managed using the LAT

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

Half-Day Tutorials

Target Audience
Regulatory affairs professionals involved with product labeling, regulatory operations staff, IT professionals supporting regulatory data systems or structured content editing systems and individuals involved with electronic submission.

TUTORIAL 18 **09:00 – 12:30**

Pharmacoepidemiology: Overview of Prinicples, Study Designs and Applications

Saad Shakir, Director, Drug Safety Research Unit, UK

This tutorial will provide an overview of the principles of pharmacoepidemiology and the study designs in pharmacoepidemiology with examples. Areas covered will include:
- The differences between randomised clinical trials and pharmacoepidemiological studies
- The roles of bias and confounding in pharmacoepidemiological studies
- Descriptions of the basic study designs of cross-sectional studies and case-control studies, as well as cohort studies, including their strengths and weaknesses
- Examples of the use of pharmacoepidemiological studies in safety evaluation and risk management in pharmacovigilance
- Opportunities for interactions will be made available during the course

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise the differences between randomised clinical trials and pharmacoepidemiological studies
- Describe basic study designs
- Discuss safety evaluation and risk management in pharmacovigilance

Target Audience
The course is aimed at those with biomedical backgrounds who do not conduct pharmacoepidemiological studies but have a need to understand the methods of pharmacoepidemiological studies and interpret their results. The course is also a suitable refresher for those who have previous training and awareness of pharmacoepidemiology.

TUTORIAL 19 **09:00 – 12:30**

Integrating Quality into Clinical Development

Alison Roberts, Qualitus, Strasbourg, France

This tutorial will cover:
- History of clinical quality assurance
- Context compared to other types of quality systems
- Role of QA in clinical development
- Audits – types and frequency, including investigator site audits: which, where, when, how, with examples of typical observations and corrective action plans
- Current issues and challenges
- Case study/workshop exercise

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise the role of clinical quality assurance
- Identify how to plan projects to include provision for audits at key steps
- Describe the different types of audits
- Recognise how a typical investigator site audit is conducted
- Discuss the most common audit findings from investigator site audits and how to address/correct them

Target audience
Project managers, clinical trial managers, clinical research associates / monitors, medical advisors, anyone working in clinical research/ development with an interest in quality/audits.

TUTORIAL 20 **09:00 – 12:30**

Experience with Voluntary Genomic Data Submission (VGDS) and Bilateral Cooperation

Felix Früh, Associate Director Genomics, Office of Clinical Pharmacology, CDER/FDA USA
Lawrence J. Lesko, Director, Office of Clinical Pharmacology, CDER/FDA, USA,
Marisa Papaluca Amati, Deputy Head of Sector Safety and Efficacy of Medicines, Pre-Authorisation Unit, EMEA, EU

To date, the FDA has received approximately thirty VGDSs and held close to twenty meetings with VGDS sponsors. Although the complexity of the submissions was initially low, more recent submissions contain large and highly complex data sets. In addition to the expanding scientific focus of these submissions, several sponsors have been using this type of informal interaction with the FDA as a stepping stone to present the same or related data in a regulatory context to the FDA later, e.g. in a Phase 2 meeting or in protocol assessments for Phase 3 studies, etc. Questions such as 'Has the marker been developed appropriately?', 'Were the most critical experimental considerations taken?', 'Is the approach to use the marker in a prospective study appropriate?' are discussed in VGDS meetings. At the FDA, exposure to voluntarily submitted exploratory data allowed us to create not only the necessary infrastructure for reviewing this data, but also to identify the need for additional guidance and policy development (for example, drug-test co-development, adaptive clinical trial designs, etc.). It also created a new, informal way to communicate with sponsors and explore novel approaches to data evaluation and interpretation. More recently, we successfully launched FDA/EMEA bilateral VGDS meetings, which have been extremely valuable to identify commonalities as well as differences between the two regions (US and Europe) in the regulatory approach to pharmacogenomics. The experience gathered so has established an operational tool to further exchange PG information between the two regions and to build consensus on future critical scientific and regulatory aspects that can be associated to this new technology

This tutorial will provide an overview of the programme, describe some of its history and plans for the future. Examples will illustrate what type of data can be and is being submitted and the type of questions that are being discussed.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Describe VGDS and the future plans
- Discuss the type of data submitted and the type of questions raised

Target Audience
People interested in cutting-edge research, pharmacogenomics and regulatory aspects of using exploratory data in this context.

TUTORIAL 21 **09:00 – 12:30**

Pharmacovigilance Inspection Workshop

Thierry Hamard, Director, PV Focus, France
Regulatory Agency representative invited

There are many areas covered during a pharmacovigilance inspection as they are now routinely conducted in Europe. For some of them, the requirements are not very specific and both auditors and inspectors have to establish their own standards. This session will provide a forum to discuss situations that are not clearly addressed by the current regulations and guidelines. A number of selected scenarios will be presented which correspond to a particular set-up for processes covered during pharmacovigilance inspections. A pharmacovigilance inspector will provide his feedback on the scenarios presented and explain why these situations are considered appropriate or not. The inspectors' perspectives on the scenarios presented will help understanding of what regulators expect. This will minimise the risk of inspection findings in the areas selected.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Discuss inspectors' perspectives on a number of scenarios in the set-up of pharmacovigilance and related processes

Target Audience
Quality assurance, clinical quality & compliance, quality systems, clinical quality assurance, clinical research, auditing managers, auditors, pharmacovigilance and other quality management professionals.

2007 DIA Annual EuroMeeting Track Overview

TRACK 1
Adapting to Regulatory Changes

Dagmar Stará, Head of Registration Unit, State Institute for Drug Control, Slovak Republic
Anu Tummavuori, Manager, EU Regulatory Affairs and Liaison International Drug Regulatory Affairs, F. Hoffmann-La Roche Ltd., Switzerland

TRACK 2
Adapting to Regulatory Changes

Truus Janse-de Hoog, Staff Member, Medicines Evaluation Board, The Netherlands, Chair CMD(h)
Kerstin Franzén, Director, Regulatory Policy & Intelligence, Pfizer AB, Sweden

TRACK 3
Reconsider the Non-clinical Testing Strategy

Joseph J. DeGeorge, Vice President, Safety Assessment, Merck & Co., Inc., USA
Klaus Olejniczak, Preclinical Assessor, BfArM, Germany

TRACK 4
"Omics" and Molecular Biomarkers

Chris Chamberlain, Medical Genetics Expert, Roche Products Ltd., UK
Claus-Steffen Stuerzebecher, Head Global Clinical Development, Gruenenthal AG, Germany

TRACK 5
R&D and Innovation

Iman Barilero, Associate Director, European Regulatory Affairs, Global Regulatory Affairs and Quality Assurance, Johnson & Johnson Pharmaceutical Group, UK
Patrick Le Courtois, Head of Unit Pre-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

TRACK 6
Clinical Research

Françoise de Crémiers, Associate Professor, Faculty of Pharmacy Paris Sud-Est, France
Milen Vrabevski, Medical Director/CEO, Comac Medical Ltd., Bulgaria

TRACK 7
Investigational Clinical Research

Timothée Fraisse, Medecin Interne, Hôpitaux Universitaires de Genève, Switzerland
Ingrid Klingmann, President, Pharmaplex, Belgium

TRACK 8
Pharmacovigilance and Risk Management

Andrzej Czarnecki, Director, Deputy EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly & Co. Ltd., UK

TRACK 9
Patient Organisations' Involvement in Medicine Development (Tuesday only)

Yann Le Cam, CEO, EURORDIS, Europe
Isabelle Moulon, Head of Sector Medical Information, EMEA, EU

TRACK 10
Medicines for Children

Khazal Paradis, Vice President, Clinical Research & Therapeutics, Genzyme Europe BV, The Netherlands
Agnès Saint Raymond, Head of Sector Scientific Advice and Orphan Drugs, EMEA, EU

TRACK 11
Quality and Compliance

Fritz Erni, Head Technical Liaison, Novartis Pharma AG, Switzerland
Jean-Louis Robert, Head of Department, Department of Quality Control of Medicines, Laboratoire National de Santé, Luxembourg

TRACK 12
eClinical (Tuesday only)

Valdo Arnera, General Manager, Europe, PHT Corporation, Switzerland
Johann Pröve, Global Head Data Acquisition and Management, Bayer Vital GmbH, Germany

TRACK 13
Data Management (Wednesday only)

Barry Burnstead, Director of Project Management, i3 Statprobe, UK
Suzy De Cordt, Director, Data Management, Serono, Switzerland

TRACK 14
Statistics

Simon Day, Statistical Expert, Roche Products Ltd., UK
Sören Kristiansen, Director, Data Operations, Astellas Pharma GmbH, Germany

TRACK 15/16
Information Technology and Telematics

Olaf Schoepke, Senior Consultant, Lorenz Life Sciences Ltd., UK
Andrew Marr, Director, e-Regulatory Development, European and International Regulatory Affairs, GlaxoSmithKline, UK

TRACK 17
Project Management of Outsourcing and Alliances
(Tuesday only)

Tom Halliwell, Global Project Manager, UK Site Head – Project Management & Procurement, Roche Products Ltd., UK
Ralph White, Director, PPMLD Ltd., UK

TRACK 18
Biosimilars – Current Status and Latest Developments (Wednesday only)

Sonja Pumplün, Vice President, Head Global Regulatory Affairs, Actelion Pharmaceuticals Ltd., Switzerland
Pekka Kurki, Head of Section, Biotechnology, National Agency for Medicines, Finland

TRACK 19
intellectual Property Rights and Related Issues (Tuesday only)

Peter Bogaert, Partner, Covington & Burling, Belgium
John Lisman, Attorney, NautaDutilh, The Netherlands

TRACK 20
Future Perspective For Non-prescription Medicines (Tuesday only)

Hubertus Cranz, Director General, AESGP, Belgium

TRACK 21
Public Policies and Ethics (Wednesday only)

Yves Juillet, Senior Advisor, Les Entreprises du Médicament, France

TRACK 22
Clinical Quality Management, GCP and Inspections

Michaela Rittberger, Managing Director, Averen, Germany
Beat Widler, Global Head of Clinical Quality, Roche Products Ltd., UK

TRACK 23
Generic Medicinal Products (Wednesday only)

Suzette Kox, Managing Director, Kox Pharma sprl, Belgium

TRACK 24
Biologics (Wednesday only)

Iman Barilero, Associate Director, European Regulatory Affairs, Global Regulatory Affairs and Quality Assurance, Johnson & Johnson Pharmaceutical Group, UK
Patrick Le Courtois, Head of Unit Pre-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

EuroMeeting Coffee Breaks

Monday, March 26
16:00 – 16:30 Exhibition Hall
Tuesday, March 27 and Wednesday, March 28
10:30 – 11:00 Exhibition Hall
15:30 – 16:00 Exhibition Hall

Viennese Networking Buffet Reception

Monday, March 26
18:00 – 21:00 Hall D

EuroMeeting Lunches

Tuesday, March 27 and Wednesday, March 28
12:30 – 14:00 Exhibition Hall

Networking Reception

Tuesday, March 27
17:30 – 18:30 Exhibition Hall

Sessions are organised and presented in chronological order with interest area codes, as defined in the chart below. Please note that this programme was printed in early November and changes in the schedule may occur prior to the meeting. A final programme will be printed in February and distributed to attendees onsite.

Interest Area Codes

AD	Advertising
AHC	Academic Health Centers
BT	Biotechnology
CDM	Clinical Data Management
CMC	Chemistry, Manufacturing, and Controls
GMP	Good Manufacturing Practices
CP	Clinical Safety and Pharmacovigilance
CR	Clinical Research and Development
CS	Clinical Supplies
CTM	Clinical Trial Management
DM	Document Management/eSubmissions
EC	eClinical
FI	Finance
GCP	Good Clinical Practice
GE	Generics
IMP	Impact of Medical Products and Therapies
IS	Investigator Sites
IT	Information Technology
MA	Marketing and Advertising
MC	Medical Communications
MW	Medical/Scientific Writing
NC	Non-Clinical Laboratory Safety Assessment
NHP	Natural Health Products
OS	Outsourcing
PM	Project Management
PP	Public Policy/Law
RA	Regulatory Affairs
RD	R&D Strategy

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

Session One

TRACKS 1&2 *RA* **09:00 – 10:30**

The "New" Centralised Procedure: Where Are We Heading?

Session Co-Chairpersons:
Daniel Brasseur, Chairman of the CHMP, Paediatrician, Ministry of Public Health, Belgium
Graham Higson, Vice President and Head of Global Regulatory Affairs, Astra Zeneca, UK

The New Medicines Legislation and EMEA Roadmap 2010 have brought significant changes to the registration of centrally approved products; there is impact on the scope, assessment and procedure. Where are we now with the implementation of the changes? How is the assessment in the new environment and what has been the experience with the new procedures? How will this evolve and what will the future bring?

Progress with the New Centralised Procedure
Noël Wathion, Head of Unit Post-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

Innovative Industry Response
Jacques Mascaro, Director, EU Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

TRACK 3 *NC, CP, CR* **09:00 – 10:30**

Future of Toxicology Testing: What Should it Look Like?

Session Chairperson:
Klaus Olejniczak, Preclinical Assessor, BfArM, Germany

This session will present an overview of new screening systems in drug development:
- EST – a new predictive screening system for hazard assessment with regard to developmental toxicity
- A comprehensive overview of the role of imaging in drug discovery and a discussion of major developments and trends both with regard to technologies and applications
- Humanised mice can provide an in-vivo model for drug testing, act as models for the testing of ADME properties of compounds and they can be used as a rodent model to test the efficacy of therapeutic antibodies against human proteins

Embryonic Stem Cell Culture (EST) to Detect the Embryotoxic Potential Early in Drug Development
Nicole Clemann, Laboratory Head, Reproductive Toxicology, F. Hoffmann-La Roche Ltd., Switzerland

Imaging Modalities in Pharmaceutical Discovery: Applications from the Molecular Level to the Whole Animal
Vivek Kadambi, Director Safety Evaluation, Millennium Pharmaceuticals Inc., USA

Use of Humanised Mice in Drug Research and Development
Nico Scheer, Scientific Program Manager, Artemis Pharmaceuticals GmbH, Germany

TRACK 4 *CR* **09:00 – 10:30**

Critical Review of "Omics" Technology Platforms

Session Chairperson:
Friedrich Lottspeich, Head of Department for Protein Analytics, Max Planck Institute for Biochemistry, Germany

Several "omics" technologies are being used today in an exploratory fashion as part of clinical development programmes on an almost routine basis, e.g. RNA expression profiling. Since the goal of their use is the identification of a selected panel of biomarkers to e.g. differentiate treatment response and non-response, these technologies need to be carefully evaluated with regard to their qualitative and quantitative reliability. This session will review proteomics and expression profiling technology platforms and conclude with a vision of the future contribution of consortial approaches in the field of "omics".

Proteomics, Gold Standards Versus Feasibility
Friedrich Lottspeich, Head of Department for Protein Analytics, Max Planck Institute for Biochemistry, Germany

RNA Expression Profiling: What is the State of the Art?
Scott C. Fogerty, Clinical Market Development Manager, Global Pharmaceutical Accounts, Affymetrix, Inc., USA

"Omics" Consortia: Their Future Contributions
Siegfried Neumann, Senior Consultant R&D, Merck KGaA, Germany

TRACK 5 *RD, CR, RA* **09:00 – 10:30**

Improvement in the R&D Process

Session Chairperson:
Thomas Lönngren, Executive Director, EMEA, EU

There are unique roles regulatory agencies can play in the development and validation of new tools to help make better, more timely decisions during the drug development process. Such tools should help make the development process more resource (human, time and financial) efficient. The EMEA's "Roadmap" and the US FDA's "Critical Path Initiative" are two examples of such regulatory efforts. These initiatives will be discussed and updated information from the EMEA, FDA and EFPIA shared.

EMEA Roadmap
Thomas Lönngren, Executive Director, EMEA, EU

FDA Critical Path Initiative
ShaAvhrée Buckman, Deputy Director, FDA, CBER, Office of Translational Sciences (OTS), USA

Industry Point of View
Brian Ager, General Director, EFPIA, 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.

Session One

TRACKS 6&14 *CR, ST, RA* **09:00 – 10:30**

Clinical Trial Registries and the IFPMA Portal and the Benefits Derived from Clinical Trial Registries – Part I

Session Co-Chairpersons:
Merete Jørgensen, Project Director, Novo Nordisk A/S, Denmark
Yves Juillet, Senior Advisor, Les Entreprises du Médicament, France

The two sessions of Clinical Trial Registries aim at giving a balanced overview of the current situation in clinical trial registration and the benefits these registers and databases of clinical trials serve. The aim is to cover the present state and future development in the area of clinical trial registration, from an industry perspective, and also the status and new development of the EUDRACT database for the benefits and use for clinical trial databases for patients, the impact for healthcare professionals/investigators and for scientific publications in journals, as well as the regulatory perspective. Following the presentations a panel discussion will take place, giving ample opportunity to discuss and ask questions of the different stakeholders.

Benefits and Impact of Clinical Trial Registries and Databases for Healthcare Professionals and Investigators
Jacques Demotes, Coordinator, ECRIN Programme, INSERM, France

The EUDRACT Database and Its Future Developments
Fergus Sweeney, Principal Scientific Administrator, EMEA, EU

The Use and Benefits of Clinical Trial Registries from a Patient Perspective
Ulrica Sterky, Vice-President, Swedish Cystic Fibrosis Association, Sweden

Panel discussion with session speakers

TRACK 7 *CR, RD, RA* **09:00 – 10:30**

The Paradigm Shift in Oncology Drug Development

Session Chairperson:
Barbara van Zwieten-Boot, Chairperson, Efficacy Working Party, Medicines Evaluation Board, The Netherlands

This session will address challenges related to global clinical development for oncology products.

Development of Oncology Products in the EU and US: Can it Be Better and Faster?
Ionel Mitrica, Associate Director Integrated Drug Development, CATO Research Ltd., USA

Downstream Effects: The Paradigm Shift in Oncology Development
Eric van der Putten, Vice President Oncology, INC Research, The Netherlands

Impact on Study Design of Patient Recruitment in Emerging Countries
John J. Borg, CHMP Member, Post-Licensing Director, Medicines Authority, Malta

Panel discussion with session speakers and **Françoise de Crémiers**, Associate Professor, Faculty of Pharmacy, Paris Sud-Est, France and **Barbara van Zwieten-Boot,** Chairperson, Efficacy Working Party, Medicines Evaluation Board, The Netherlands

TRACK 8 *CP, CR, RD* **09:00 – 10:30**

Benefit-Risk Assessment: New Approaches and Interface with Risk Management

Session Chairperson:
Patrizia Cavazzoni, Group Director, Surveillance and Epidemiology, Global Product Safety, Eli Lilly and Company, USA

The first part of this session will review new approaches or methodologies for benefit-risk assessment, and how these can be applied during drug development as well as post-launch. The second part will focus on how benefit-risk assessment can be integrated in risk management and risk minimisation. A panel discussion with audience participation will follow.

Are There New/Better Approaches/Methodologies for Benefit-Risk Assessment?
Filip Mussen, Associate Director, Regulatory Affairs, Merck Sharpe & Dohme, Belgium

How can Benefit-Risk Assessment be Systematically Integrated in Risk Management and Risk Minimisation?
Regulatory Agency representative invited

Panel discussion with session speakers and **Bruno Flamion**, Chairman, EMEA Scientific Advice Working Party, FUNPD, University of Namur, Belgium

TRACK 9 *RA, PP* **09:00 – 10:30**

New Approach to Medicine Information to Patients at EMEA

Session Co-Chairpersons:
Isabelle Moulon, Head of Sector Medical Information, EMEA, EU
Lynn Faulds Wood, President European Cancer Patient Coalition, UK

Increased transparency and provision of high quality information on medicines are two EMEA priorities. In order to better understand the needs and expectations of its stakeholders, the agency is developing frameworks of interaction with its stakeholders. The first one to be published in 2006 was the framework of interaction between the EMEA and patients' and consumers' organisations. This session will first look at the implementation of this framework and its direct consequences on the EMEA transparency and provision of information. It will then explain how the involvement of patients in the EMEA activities contributes to better inform patients and the public.

EMEA Framework: Patients' Involvement in the Provision of Information
Isabelle Moulon, Head of Sector Medical Information, EMEA, EU

Is Readability Detrimental to Quality of Information?
David Haerry, Chair of the European Community Advisory Board, European AIDS Treatment Group (EATG), Belgium

Does the Involvement of Patients Improve the Quality of Information?
Frits Lekkerkerker, Chairman, Medicines Evaluation Board, 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.

Session One

TRACK 10 *RA, CR* **09:00 – 10:30**

Implementation of the Paediatric Regulation

Session Chairperson:
Peter Arlett, Principal Administrator, Enterprise & Industry, European Commission, EU

This session will set the scene for the rest of the day by providing an overview of the key measures in the EU Paediatric Regulation and by summarising the priorities for implementation of the regulation from the perspective of the European Commission and the EMEA. In addition, the session will include a presentation on European Commission funding of studies on off-patent medicines for children.

The Paediatric Regulation: Key Measures and Priorities for Implementation
Peter Arlett, Principal Administrator, Enterprise & Industry, European Commission, EU

Medicines for Children: Implementation of the Paediatric Regulation by the EMEA
Nathalie Seigneuret, Scientific Administrator, Safety and Medicines Sector, Pre-Authorisation Unit, EMEA, EU

European Commission Funding of Studies into Off-Patent Medicines for Children
Fergal Donelly, Scientific Officer, Research Directorate General, European Commission, EU

TRACK 11 *CMC, RA, QC* **09:00 – 10:30**

New Manufacturing Concepts for Drug Substance and Drug Products I: Quality-by-Design, PAT and Design Space

Session Chairperson:
Alastair Coupe, Senior Director, Pfizer, UK

This session will provide a broad overview and a common understanding of the evolving regulatory landscape relating to drug product development from both a regulatory and industry perspective. Emerging manufacturing concepts will be described and examples provided about how the concepts may be used during development to build quality into products through increased process understanding; how they will be incorporated into new drug applications and the implications of these new concepts for industry and regulatory authorities will be discussed.

Implications of ICH Q8 and Design Space from a Regulator's Perspective
Blanka Hirschlerová, Senior Pharmaceutical Assessor, State Institute for Drug Control, Czech Republic

PAT and Relationship to Design Space
Staffan Folestad, Senior Principal Scientist, PAT Centre of Excellence, AstraZeneca R&D, Sweden

Quality-by-Design, Design Space and How It Links to Control Space
Chris Potter, Director External Pharmaceutical Programmes, AstraZeneca R&D, UK

TRACK 12 *EC* **09:00 – 10:30**

eClinical Trials From the Sponsor Perspective

Session Chairperson:
Johann Pröve, Global Head Data Acquisition and Management, Bayer Vital GmbH, Germany

This session will address the impact of eClinical on the users of eSystems, in particular EDC. Presentations will focus on the design of the eCRFs, the implementation philosophy of edit checks, the use of standards in EDC and the overall implementation issues.

EDC: Are We Missing the Boat?
David Dworaczyk, Vice President Clinical Development, King Pharmaceuticals, Inc., USA

eClinical: How to Use Standards and Integration to Optimise R&D
John Aggerholm, eClinical Senior Project Director, Novo Nordisk IT, Denmark

Proper and Efficient Design of eCRFs and Edit-Check Programming
Valerie Williams, Associate Director, Advanced Technology Set-up, PharmaNet, Inc., USA

TRACK 15/16 *IT, DM, RA* **09:00 – 10:30**

Document Chain Management in Pharma R&D

Session Chairperson:
Sven Harmsen, Manager, Document Management System, Astellas Pharma GmbH, Germany

Pharmaceutical companies need to manage an increasing amount of electronic documents, emails, letters, faxes, etc. During this session we will discuss different approaches to control this chain of documents in all phases of product development and maintenance.

Document Chain Management during Drug Development: Regulatory Aspects Focusing on Clinical Study Reports
Alexander Kainz, Senior Manager Regulatory Affairs, Fresenius Biotech GmbH, Germany

The Submission-Ready Document and its Lifecycle
Olaf Schoepke, Senior Consultant, Lorenz Life Sciences Ltd., UK

Keeping Track of Regulatory and Clinical Documents
Sven Harmsen, Manager Document Management Systems, Astellas Pharma GmbH, Germany

TRACK 17 *PM, CR* **09:00 – 10:30**

Effective Alliance Management

Session Chairperson:
Tom Halliwell, Project Manager, UK Site Head, Project Management & Procurement Roche Products, UK

Licensing has emerged as a key value driver and now plays an increasing role in the business model of both pharmaceutical and biotechnology companies. This session will examine some of the key challenges involved in alliance management, such as the factors that determine the success or failure of the collaboration, the pitfalls involved in managing cross-cultural international teams and the mechanisms to both exploit and manage cultural differences.

Alliance Management: How to Achieve a Strategic Fit
Georg Mathis, Head/Project Management, Siegfried Ltd., Switzerland

Clinical Development Projects Involving Companies with Diverse Cultures
Wilhelm Horn, Managing Director, Accovion, Germany

Understanding the Cultural Differences that Affect Alliances and Mechanisms to both Exploit and Manage Them
Michael Schuitevoerder, Medical Informatics Director, Team and Technology Limited, UK

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

Session One

TRACK 19 *PP, RA* **09:00 – 10:30**

Patent Rights and Regulation of Pharmaceuticals

Session Chairperson:
Guido Kucsko, Partner, Schönherr Rechtsanwälte, Austria

This session will discuss certain patent topics that are specific to the pharmaceutical industry. There is increasing interplay between regulatory criteria and procedures and the IP principles – as most recently illustrated by the Paediatrics Regulation – and this will be specifically discussed in the presentations.

SPCs and Paediatric Extensions: Key Issues
Alexa von Uexküll, Partner, Vossius and Partner, Germany

Usage Patents and Specific Regulatory Aspects
Paul Tauchner, Partner, Vossius and Partner, Germany

Regulatory Activity and Patent Rules (Bolar Amendment, MA Application During Patent Life, Generic Substitution Listing)
Peter Bogaert, Partner, Covington & Burling, Belgium

TRACK 20 *RA, MA* **09:00 – 10:30**

Harmonisation of Non-Prescription Medicines

Session Chairperson:
Hubertus Cranz, Director General, AESGP, Belgium

Based on an analysis of the non-prescription medicines market, this session will look at the possibilities resulting from the extension of the centralised procedure to innovative non-prescription medicines. This will include an analysis of the incentives for manufacturers for a European-wide single assessment of non-prescription medicines.

Current Market Situation
Phil Henderson, International Business Analyst, IMS Health, UK

Access to Centralised Procedure
Zaide Frias, Scientific Administrator, Legal/Regulatory Affairs, EMEA, EU

Incentives for Manufacturers
Christelle Anquez-Traxler, Regulatory and Scientific Manager, AESGP, Belgium

TRACK 22 *GCP, CR, RA* **09:00 – 10:30**

Implementation of the Clinical Trials Directive and Update on GCP-Relevant Legislation

Session Chairperson:
Birka Lehmann, Director and Professor, Head of Licencing Division 3, BfArM, Germany

Member states are required to implement the directive in a harmonised manner and in a given timeframe. It is the basic for all follow-up measures and facilitation of clinical trials in Europe. This session will reflect the situation of today and which tools are available to further improve the handling of clinical trials in the community.

Summary: The Clinical Trials Directive, Guidelines and Guidance Harmonising the Requirements for Clinical Trials in Europe
Birka Lehmann, Director and Professor, Head of Licensing Division 3, BfArM, Germany

Industries' Strategies to Work Within the Given Timeframe for Clinical Trials and Possible Short Term and Long Term Improvements
Industry representative invited

Competent Authorities' Strategies to Work Within the Given Timeframe for Clinical Trials and Possible Short Term and Long Term Improvements
European Commission representative invited

Session Two

TRACK 1 *RA* **11:00 – 12:30**

Scientific Advice: Does It Deliver as Expected?

Session Co-Chairpersons:
Bruno Flamion, Chairman, EMEA Scientific Advice Working Party, FUNPD, University of Namur, Belgium
Isabelle Stöckert, Vice President, Head Global Regulatory Affairs Europe & Global Strategy AI/CVRM, Bayer Healthcare AG, Germany

The new Scientific Advice Procedure has been introduced at the EMEA and is applied by an extended Scientific Advice Working Party (SAWP). There is a parallel scientific advice pilot programme ongoing between EMEA and FDA. How are these procedures being used? What is the experience from the users of the new system? Are there initial conclusions on the overall impact for EU assessment of new applications? What is the role of national member states' scientific advice in development?

Scientific Advice: The New Procedures from an Industry Perspective
Mats Marfält, Portfolio Leader CV TA, AstraZeneca, UK

Respective Roles of National and EMEA Scientific Advice
Christine Gispen-de Wied, Clinical Coordinator Pharmacotherapeutical Group, SWAP and Medicines Evaluation Board, The Netherlands

Scientific Advice: The New Procedures and an Update on Assessment of New Applications
Marco Cavaleri, EMEA, EU

EMEA Scientific Advice as a Key Regulatory Component of Clinical Development
Lesley Narburgh, Regulatory Manager European and International Regulatory Affairs Neuroscience Therapeutic Group, GlaxoSmithKline, UK

TRACK 2 *CP, CR, RA, RD* **11:00 – 12:30**

Risk Management in the EU: The Regulatory Perspective

Session Co-Chairpersons:
Martha Brumfield, Senior Vice President, Worldwide Regulatory Affairs & Quality Managmenet, Pfizer, Inc., USA
Noël Wathion, Head of Unit Post-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

Several risk management initiatives have been taken in the EU by regulators. This has resulted in new Community legislation introducing a number of new legal tools, such as risk management plans. In addition, a European Risk Management Strategy (ERMS) has been developed. This Session will provide an update on these initiatives, as well as the pharmaceutical industry's experience to date and its viewpoint on how to further progress.

EU RMP (NCA)
Ingemar Persson, Senior Assessor, Unit of Pharmacovigilance**,** MPA, Sweden

Update on the ERMS Initiative
Noël Wathion, Head of Unit Post-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

Experience and Ideas for Enhancing the Development/Approval Process
Martha Brumfield, Senior Vice President, Worldwide Regulatory Affairs & Quality Managmenet, Pfizer, Inc., 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.

Session Two

TRACK 3 *NC, CP, CR* **11:00 – 12:30**

Carcinogenicity Testing: Is a Breakthrough Possible?

Session Chairperson:
Jan Willem van der Laan, Head, Section on Safety and Teratology of Medicines, RIVM, the Netherlands

Carcinogenicity testing of human pharmaceuticals is still a long and costly process, resulting in a lot of irrelevant findings. This is illustrated by the fact that 50% of all compounds used long-term are reported to be carcinogenic in rodents, while only approximately 20 medicines are evaluated as human carcinogens. Several approaches are being studied to come to better models predicting more accurately the real carcinogenic risks of compounds. This session will give an update and an overview of the current discussions.

Toxicogenomics-Based Classifiers for DNA-Damaged Responses
Bob van de Water, Professor in Drug Safety, Leiden Amsterdam Center for Drug Research, The Netherlands

Evaluation of Chronic Toxicology Studies in Rodents for Prediction of Carcinogenic Risk
Joseph J. DeGeorge, Vice President, Safety Assessment, Merck & Co., Inc., USA

Update of Carcinogenicity Testing: The View from a Regulator
Jan Willem van der Laan, Head, Section on Safety and Teratology of Medicines, RIVM, The Netherlands

TRACKS 4&5 *RD, RA, PP* **11:00 – 12:30**

EU Commission/EFPIA Public-Private Initiative to Support Innovation: The Innovative Medicines Initiative

Session Co-Chairpersons:
Irene Norstedt, Head of Sector, Innovative Medicines, Health Research, European Commission, EU
Ian Ragan, Director, Research, Eli Lilly & Co. Ltd., UK and EFPIA RDG

This session will describe the current state of the Innovative Medicines Initiative. Speakers from the two main organisations proposing the public private partnership – the European Commission and EFPIA – will describe the aspirations of the project and how it will achieve its objectives. A speaker from the public sector, as the main research partner of the pharmaceutical industry in IMI, will describe their involvement while a patient representative will explain how IMI will address patient needs.

EU Commission's Point of View
Irene Norstedt, Head of Sector, Innovative Medicines, Health Research, European Commission, EU

EFPIA RDG's Point of View
Ian Ragan, Director, Research, Eli Lilly & Co. Ltd., UK and EFPIA RDG

Point of View form the Public Sector
Jacques Demotes, Coordinator, ECRIN Programme, INSERM, France

Patient's Point of View
Alistair Newton, Secretary-General, European Federation of Neurological Associations, Department of Pharmacology, University of Florence, Italy

TRACKS 6&14 *CR, ST, RA* **11:00 – 12:30**

Clinical Trial Registries and the IFPMA Portal and the Benefits Derived from Clinical Trial Registries – Part II

Session Co-Chairpersons:
Merete Jørgensen, Project Director, Novo Nordisk A/S, Denmark
Yves Juillet, Senior Advisor, Les Entreprises du Médicament, France

The two sessions of Clinical Trial Registries aim at giving a balanced overview of the current situation in clinical trial registration and the benefits these registers and databases of clinical trials serve. The aim is to cover the present state and future development in the area of clinical trial registration, from an industry perspective and the status and new development of the EUDRACT database. Also the benefits and use for clinical trial databases for patients, the impact for healthcare professionals/investigators and for scientific publications in journals as well as the regulatory perspective. Following the presentations a panel discussion will take place, giving ample opportunity to discuss and ask questions of the different stakeholders.

Benefits and Impact of Clinical Trial Registries and Databases for the Scientific Publications seen from the Editor Perspective
Kamran Abbasi, Editor, Journal of Royal Society of Medicine, UK

The Industry Perspective and the Roche Clinical Trial Registry
Beat Widler, Global Head of Clinical Quality, Roche Products Ltd., UK

Benefits and Impact of Clinical Trial Registries and Databases from a Regulator Perspective
Armin Koch, Biostatistician, BfArM, Germany

Panel discussion with session speakers and **Gabriele Dreier**, Medical Director German Gene Therapy Registry, Director Administration and Finance, University of Freiburg, Germany

TRACK 7 *CR, RD, CTM, RA* **11:00 – 12:30**

Small Populations: EU and FDA Viewpoints

Session Chairperson:
Barbara van Zwieten-Boot, Chairperson, Efficacy Working Party, Medicines Evaluation Board, The Netherlands

This session will discuss issues of clinical trial design, conduct and analysis for small populations. Methods to maximise efficiency and study designs that are particularly suited for trials in small populations are described. The choice of the different methods and the regulatory challenges are described in the context of available guidance.

The FDA Guideline on Small Populations in Clinical Trials
Robert O'Neill, Director, Office of Biostatistics CDER, FDA, USA

The EMEA Guideline on Small Populations in Clinical Trials
Francesco Pignatti, Scientific Administrator, Safety and Efficacy, EMEA, EU

The Challenge of Preparation and Management of Clinical Trials in Small Populations
Johan Frieling, Senior Director of Clinical Research, Genzyme, 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.

Session Two

TRACK 8 *CP, CR, RD* **11:00 – 12:30**

The Future of Pharmacovigilance: Safe Drugs in the 21st Century

Session Chairperson:
Monika Pietrek, Executive Vice President, Global Scientific and Medical Affairs, PRA International, Germany

The thalidomide disaster prompted modern drug legislation more than 40 years ago. During that period, the mainstay of drug safety surveillance has been the collection of spontaneous adverse reaction reports. Although several CIOMS and ICH initiatives have added guidance on the collection, evaluation and reporting of safety data, little progress has occurred in the development of more robust methodologies for monitoring drug safety. The current and future challenges of drug development and drug utilisation require re-thinking the way safety monitoring is conducted.

Some key challenges are:
- How do infectious diseases, vaccine coverage and drug resistance impact pharmacovigilance?
- How to address the safety of new treatments for small target patient populations and long-term benefit/risk
- How to monitor effectively the safety of biosimilars and generic drugs
- Considering the emphasis placed on spontaneous reporting worldwide, the reduplication of resources and the limitations of spontaneous data, how much spontaneous reporting is really needed in future? Where should resources, both human and financial, be concentrated in order to ensure public health and individual patient safety?
  In this session safety experts will provide thought-provoking ideas for new approaches, considering cost-effectiveness as well as the budget and resources constraints of the various stakeholders involved.

Thomas Vertraeten, Director of Worldwide Safety and Regulatory Management, GlaxoSmithKline Biologicals, Belgium

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

Monika Pietrek, Executive Vice President, Global Scientific and Medical Affairs, PRA International, Germany

TRACK 9 *RA, PP* **11:00 – 12:30**

Relationship between National Regulatory Agencies (NCA) and Patient Organisations

Session Co-Chairpersons:
Anne Castot, Head of Risk Management and Information on Medicinal Products Division, Afssaps, France
Peter Streng, European Representative on Research and Drug Development, EAMDA, The Netherlands

Following the EMEA positive initiative, several regulatory authorities have developed policies to involve patients' organisations in their activities. What are the results? What can we learn from these experiences? How can patients and regulators mutually benefit from a close partnership? This session will open the discussion from two different perspectives.

Partnership between Afssaps and Patients' Organisations: A Progressive Change in France
Anne Castot, Head of Risk Management and Information on Medicinal Products Division, Afssaps, France

Partnership between Regulatory Authorities and Patients' Organisations: How Can We Work Together?
Evelyne Le Roux, Clinical Research Officer, French Cystic Fibrosis Association "Vaincre La Mucoviscidose", France

The Empowerment of the Patient: International Community Trends and National Experiences
Doris I. Stenver, Chief Medical Officer, Consumer Safety Department, Danish Medicines Agency, Denmark

TRACK 10 *CR, CTM, RA* **11:00 – 12:30**

Practical Aspects of CTs in Children and Ethics

Session Chairperson:
Ingrid Klingmann, President, Pharmaplex, Belgium

Facilitated by the Clinical Trials Directive and the upcoming paediatric regulation, and encouraged by the increasing public awareness of the need for clinical trials in children a rapid increase in paediatric clinical trials is to be expected. However, the performance of clinical trials in children of different age groups and the ethical aspects involved create new challenges for sponsors, investigators, ethics committees, as well as for the patients and their parents. This session will provide an opportunity for exchange of experience and food for thought for stakeholders.

Practical Problems in Performance of Clinical Trials in Children of Different Age Groups
Gérard Pons, Head of Perinatal and Paediatric, University René Descartes & Groupe Hospitalier - Cochin/Saint-Vincent de Paul, France

New Challenges for Ethics Committees Reviewing Paediatric Trials
Dirk Matthys, Paediatric Department, University Hospital of Gent, Belgium

Informed Consent of Parents and Assent of the Child: Dilemma for Patients and Their Parents
Joseph Irwin, The Jennifer Trust, Leader of the EURORDIS Paediatric Drugs Task Force, UK

TRACK 11 *CMC, RA, QC* **11:00 – 12:30**

New Manufacturing Concepts for Drug Substance and Drug Products II: Impact of ICH Q8, Q9 and Q10 Concepts on Drug Substance and Drug Product Manufacturing

Session Chairperson:
Santiago Alonso, Head of Quality Assurance, Sandoz, Spain

The new ICH Guidelines Q8, Q9 and Q10 have opened new concepts of manufacturing of drug products. Many of these concepts are not limited to the manufacturing of final dosage forms but may be used for manufacturing active drug substance, by chemical synthesis for small molecules and by biotechnology processes for big biomolecules.

Quality of API: Present Difficulties and Future Solutions based on Quality-by-Design
Santiago Alonso, Head of Quality Assurance, Sandoz, Spain

Interaction of Q8, Q9 and Q10 from a Regulatory Perspective
Jean-Louis Robert, Head of Department, Laboratoire National de Santé, Luxembourg

Quality Risk Management: An Important Facilitator of Quality-by-Design
Stephan Roenninger, Global Quality Manager, F. Hoffmann-La Roche Ltd., 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.

Session Two

TRACK 12 *EC, IS* **11:00 – 12:30**

eClinical Trials from the Site Perspective

Session Chairperson:
Valdo Arnera, General Manager Europe, PHT Corporation, Switzerland

As sponsors introduce eclinical technologies, the site environment changes in various ways. This session will describe some effects of the use of eclinical technologies from a site perspective and indicates possible future directions. As it is intended to be a very practical session, the experience of an investigator comparing different EDC systems will help us understand real life at a site, and then the human challenges will be debated. Finally the Global Trial Bank (GTB) initiative will be presented. For both the clinical physician and for the principal investigator, the GTB promises to reduce the burden of trial recruitment, to ease the identification of appropriate trials, and to facilitate access to usable, codified clinical trial information.

EDC: Comparison of Different Systems by an Investigational Site
Fraser Inglis, Consultant Physician, Glasgow Memory Clinic, UK

eOverload: The Human Challenges in Running eClinical Technologies at Investigator Sites
Michael Schuitevoerder, Medical Informatics Director, Team and Technology Ltd., UK

The Principal Investigator Perspective on Clinical Trial Recruitment: Impact of a Global Registry
Charles Jaffe, Senior Global Strategist, Intel, USA

TRACK 15/16 *IT, DM, RA* **11:00 – 12:30**

Electronic Submissions (eCTD) Preparations and Lifecycle Management

Session Chairperson:
Maren von Fritschen, Director Regulatory Affairs, PharmaLex, Germany

The range of preparedness for electronic submission varies largely within the pharmaceutical industry, while the move towards eCTD is driven by the authorities. In this session, practical experiences ranging from the preparation of the first eCTD through eCTD submissions in the decentralised procedure up to the electronic lifecycle management are highlighted by experts from the pharmaceutical industry.

eCTD Submission: Overcoming Initial Hurdles
Jörg Schnitzler, Regulatory Operations Manager, Merck KGaA, Germany

eCTD Submission in the Decentralised Procedures
Maren von Fritschen, Director Regulatory Affairs, PharmaLex GmbH, Germany

eCTD Lifecycle Management: Concepts, Requirements and Business Process Integrations
Kevin Wing, Technical Operations Manager, Johnson & Johnson, UK

TRACK 17 *PM, CR, CTM* **11:00 – 12:30**

Managing Clinical Trials

Session Chairperson:
John Shillingford, President Averion Europe, Averion Inc., Germany

The clinical trial business is truly international, with most projects now being undertaken in several different countries to ensure adherence to project timelines and quality of data. This session will look at aspects of managing international projects, including the tools needed for monitoring project performance, optimising performance with teams of diverse cultures and developing techniques for maximising patient enrolments.

Project Management Across Companies and Cultures
Véronique Larsimont, Director of Clinical Operations, Chiltern International, Germany

Managing Internal and External Alliances for Effective Patient Enrollment
Martin Czakon, MD for Europe, BBK Worldwide, Czech Republic

The Metrics of Success
John Shillingford, President Averion Europe, Averion Inc., Germany

TRACK 19 *PP, GE, RA* **11:00 – 12:30**

Regulatory Protection Mechanisms

Session Chairperson:
Peter Bogaert, Partner, Covington & Burling, Belgium

This session will focus on the specific regulatory protection mechanisms. It will address the core function and nature of data and market exclusivity and examine how the protection operates within a regulatory system that is primarily aiming to protect public health.

The Legal Nature of Data Exclusivity and Market Exclusivity
Peter Bogaert, Partner, Covington & Burling, Belgium

Are the Regulatory Procedures Robust Enough to Handle the Pressure?
Irene Sacristàn Sànchez, Administrator, DG Enterprise and Industry, European Commission, EU

A Generic Industry View on the Nature of Regulatory Exclusivity and How it Should be Applied
Suzette Kox, Senior Director Scientific Affairs, European Generic medicines Association, Belgium

TRACK 20 *RA, NHP, CTM* **11:00 – 12:30**

Future of Herbal Medicines

Session Chairperson:
Heribert Pittner, AGES PharmMed Austria, Vice-chair of the EMEA Herbal Medicinal Products Committee (HMPC)

The Committee for Herbal Medicinal Products (HMPC) took up its work in September 2004, and the first Community Monographs on Herbal Medicinal Products have since been adopted. In this session, both the Chair and the Vice-Chair of the HMPC, together with industry representatives, will highlight the future of herbal medicines in Europe.

Impact of the EMEA Herbal Medicinal Products Committee
Konstantin Keller, Federal Ministry of Health, Germany, Chair of the EMEA Herbal Medicinal Products Committee (HMPC)

Clinical Trial Management of Herbal Medicines
James Fan, Medical Director, Protech Pharma Services, Taiwan

Impact of the Traditional Herbal Medicines Directive
Bernd Eberwein, Executive Director, BAH, 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.

Session Three

TRACK 22 *GCP, CR, RA* **11:00 – 12:30**

Quality Standards for Interventional and Non-Interventional Trials

Session Chairperson:
Michaela Rittberger, Managing Director, Averen, Germany

Interventional studies fall under the provisions of Good Clinical Practice. This embraces ethical and scientific quality requirements for assuring the protection of the rights, safety and well-being of trial subjects and the credibility of clinical trial results. What is the situation like for non-interventional studies?
During this session the impact of non-interventional trials for the assessment of effectiveness and safety of drugs will be discussed, highlighting compliance challenges with respective requirements, quality management and oversight.

Differentiating Interventional and Non-interventional Trials - Compliance and Quality Problems and Challenges
Brian Davis, Clinical Trials Unit Manager, MHRA, UK

Industry Experience with Non-Interventional Trials, including Objectives and Quality Management Aspects
Industry representative to be confirmed

Post-Authorisation Safety Studies - Requirements in Volume 9A
Xavier Kurz, Scientific Administrator, EMEA, EU

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TRACK 1 *RA* **14:00 – 15:30**

Increasing Transparency Towards The Public: Panel Session

Session Co-Chairpersons:
Arielle North, Scientific Administrator, Executive Support, EMEA, EU
Ture Sjöblom, Director European Regulatory Affairs, AstraZeneca, Sweden

Outcome of transparency issues emanating from the NML, with focus on commercially confidential information and with the question, "What should be transparent in authorities' agendas and meeting minutes?"

The View of the Patient Organisation
Jean Georges, Executive Director, European Patients' Forum, Alzheimer Europe, Belgium

The View of National Regulatory Authorities
Milan Smid, Director, State Institute of Drug Control, Czech Republic

The View of the Industry
Ture Sjöblom, Director European Regulatory Affairs, AstraZeneca, Sweden

Panel discussion with session speakers **Beata Stepniewska,** Pharmacist, Regulatory Affairs and EU Affairs, European Generic medicines Association, Belgium and **Eva Lilienberg**, Senior Director, Regulatory Affairs Europe, Merck, Sharp & Dohme (Europe) Inc., Belgium

TRACK 2 *RA* **14:00 – 15:30**

Regulatory Strategy and Opportunities for Exclusivity (Panel Session)

Session Chairperson:
Julian Thompson, Head of EU Regulatory Strategy Group, Pfizer Ltd., UK

Regulatory strategies will impact the availability of the opportunities for exclusivity and should take them into account from the earliest stage. In undertaking regulatory planning and assessing exclusivity opportunities for a particular product or project, some basic questions need to be addressed. The session panelists will discuss some of the key points to consider.

Christa Wirthumer-Hoche, Head of Unit for Marketing Authorisation and Lifecycle Management of Medicinal Products, AGES PharmMed, Austria

Anthony Humphreys, Head of Sector Regulatory Affairs and Organisational Support, EMEA, EU

Irene Sàcristan Sànchez, Administrator, DG Enterprise and Industry, European Commission, EU

Marianne Petersen-Braun, Scientific Head, Bayer AG, Germany

Graham Higson, Vice President and Head of Global Regulatory Affairs, AstraZeneca, UK

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Session Three

TRACK 3 *NC, CP, CR, RA* **14:00 – 15:30**

The Challenging Transition from Pre-Clinical to First-in-Man Trials

Session Co-Chairpersons:
David Jones, Principal Scientific Officer, MHRA, UK
Ingrid Klingmann, President, Pharmaplex, Belgium

First-in-man trials are a particularly critical step in drug development and have always been performed with special caution. However, recent serious events have shown that the risks for healthy volunteers in first-in-man trials are not reliably estimated and minimised. A revision of thinking about the need and predictability of pre-clinical information required for a first administration of a drug to humans is underway and health authorities have drawn their conclusions on the required information for trial authorisation. However, are these requirements comparable? Are we envisaging an over-regulation? This session will provide an understanding of the situation in the UK, France and Germany.

Pre-Clinical Requirements for First-in-Man Trials in the UK and Calculation of the First Dose
David Jones, Principal Scientific Officer, MHRA, UK

Clinical Trial Authorisation in Germany for First-in-Man Trials with NCEs
Thomas Sudhop, Head of the Division for Scientific Services, BfArM, Germany

How and Where Will the Pharmaceutical Industry Perform First-in-Man Trials in Future?
Industry representative invited

TRACK 4 *RA, CR* **14:00 – 15:30**

Regulatory Changes and Challenges in the Triad

Session Chairperson:
Marisa Papaluca Amati, Deputy Head of Sector Safety and Efficacy of Medicines, Pre-Authorisation Unit, EMEA, EU

In the past three years, the involvement of regulatory authorities in the retrospective evaluation of pharmacogenomic studies and in the discussion of new Pgx study concepts has been increasing continuously.

First experiences still based on draft guidances (VGDS) and concept papers (pharmacogenetics briefing meetings) and a constructive dialogue with the sponsors of such studies has helped to shape today's regulatory environment, providing the basis to evaluate options of regulatory-relevant use of Pgx early on in drug development programmes. Past experience and future plans and expectations of the regulators will be shared in this session.

Focus on EMEA Activities in 2007
Marisa Papaluca Amati, Deputy Head of Sector Safety and Efficacy of Medicines, Pre-Authorisation Unit, EMEA, EU

From Experience to New Challenges
Felix Früh, Associate Director, Genomics, Office of Clinical Pharmacology, CDER, FDA, USA

Progress at ICH Level: Future Steps
Yoshiaki Uyama, Deputy Review Director, Office of New Drug III, PMDA, Japan

TRACK 5 *RD, CR, RA* **14:00 – 15:30**

PhRMA Public-Private Initiatives to Support Innovation: Biomarker Consortium with FDA and NIH

Session Co-Chairpersons:
Garry Neil, Group President, Johnson & Johnson PRD, USA
ShaAvhrée Buckman, Deputy Director, FDA, CBER, Office of Translational Sciences (OTS), USA

One of the guiding principles and a central focus of the Critical Path Initiative is the development of biomarkers. The Biomarkers Consortium, a public-private partnership among NIH, FDA, industry and other private sector groups, was formed to promote the discovery, development and qualification of biomarkers. This session will provide an overview of the Biomarkers Consortium, the objectives of the consortium and future plans. Representatives from PhRMA, FDA and NIH will provide updated information on the progress made with this initiative. The EMEA will provide their opinion as observers in this consortium.

Point of View from PhRMA
Garry Neil, Group President, Johnson & Johnson PRD, USA

Point of View from FDA
ShaAvhrée Buckman, Deputy Director, FDA, CBER, Office of Translational Sciences (OTS), USA

Point of View from NIH
Gary Kelloff, Chief of the Chemoprevention Branch, NCI, National Cancer Institute, USA

Panel discussion with session speakers and **Spiros Vamvakas,** Acting Deputy Head of Sector Scientific Advice and Orhpan Drugs, EMEA, EU

TRACK 6 *CR, RA, RD* **14:00 – 15:30**

Clinical Trial and New Product Development in Japan and Issues in Global Study When Japan is Included

Session Chairperson:
Takatoshi Sato, Chairman, HyCLIPS Co., Japan

The status of clinical study in Japan will be presented from the point of view of sponsor, CRO and SMO. The attitude of Japanese regulatory affairs regarding the data/issues will be added. Furthermore, points to consider for clinical development teams in the EU/US when Japan is included in the global development programme will be explained.

Changes of Clinical Programme for Regulatory Submission from Sponsor Point of View Including Response of the PMDA
Noriaki Murao, Representative Director, Schwarz Pharma, Japan

Status of CRO and SMO for Clinical Study in Japan
Takatoshi Sato, Chairperson, HyCLIPS Co., Japan

Points to Consider During Global Clinical Development when Japan is Included in the Development Plan
Stewart Geary, Vice President, Global Safety and Deputy Director, Corporate Regulatory Compliance and Quality Assurance, Eisai, Japan

Research and Development of the Regenerative Medicine Products in Japanese Academic Institutes
Koji Kawakami, Professor, Department of Pharmacoepidemiology, Kyoto University, Japan

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

Session Three

TRACK 7 *CR, RA* **14:00 – 15:30**

Informed Consent: Investigator Obligation and Public Perception

Session Chairperson:
Marie-Laure Fraisse, Clinical Trials Coordinator, Serono, Switzerland

Informed consents have become more inadequate and sometimes counterproductive. This session will address the recruitment process from patients' expectations and needs to the development of comprehensive and ethical tools.

Regulatory Requirements on Subject Information and Consent Procedures
Regina Freunscht, Head of Quality Assurance, Accovion, Germany

Patient Documents to Improve Involvement in Clinical Research
Valérie Salzman, Director, Servier, France

Giving an Informed Consent in a Diagnosis-Related Emotional Stress Situation
David Haerry, Chair of the European Community Advisory Board, European AIDS Treatment Group (EATG), Belgium

TRACK 8 *CP, RA* **14:00 – 15:30**

Risk Management Plans: Practical Applications and Experience

Session Co-Chairpersons:
Valerie Simmons, Director, EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly & Co. Ltd., UK
Noël Wathion, Head of Unit Post-Authorisation Evaluation of Medicines for Human Use, EMEA, EU

The European Guidelines on Risk Management Systems have now been in place since November 2005 and are a critical component for optimising benefit risk for patients and ultimately promoting public health. Whilst the principles of risk management planning are inherently sound, both industry and regulators are now faced with the practical implications of developing risk management programmes which will meet these objectives but at the same time be feasible and yield meaningful and timely results, based on objective and scientific criteria. This session will bring together both regulatory authority and industry experience to date with a view to practical considerations and shared learningt

Xavier Kurz, Scientific Administrator, EMEA, EU

TRACK 9 *CR, RD, PP* **14:00 – 15:30**

Innovative and Strategic Longterm Partnership between Patient Organisations and Industry

Session Co-Chairpersons:
Yann Le Cam, CEO, EURORDIS, Europe
Josephine J. Wood, Director, European Stakeholder and Patient Group Relations, GlaxoSmithKline, UK, EFPIA Think Tank

Pattern for partnership between industries and patient organisations has long been initiated and driven by industry. More recently, new models of partnering have emerged in Europe at the initiative of patient groups or as a joint initiative of all stakeholders. The aim is to enhance collaboration driven by patient needs. Concrete case studies will be presented in this session in the areas of innovative products, rare disease/orphan drugs, cancer and alzheimer. The panel will discuss whether these innovative approaches may have a positive long-term strategic impact for the main interested parties involved.

Benefits and Challenges for Partnering with Industry
Michael Griffith, Chief Executive Officer, Fighting Blindness, Ireland

Long-Term Educational Relationship between Patient Groups and Orphan Drug Companies
Yann Le Cam, CEO, EURORDIS, Europe

Building a Healthy Environment for Constructive Partnerships
Marjorie Johnson, Head of Voluntary Sector Relations, ABPI, UK

TRACK 10 *CR, RA* **14:00 – 15:30**

The PIP Content in the Content of Global Development of Paediatric Medicines

Session Co-Chairpersons:
Khazal Paradis, Vice President, Clinical Research & Therapeutics, Genzyme Europe BV, The Netherlands
Agnés Saint Raymond, Head of Sector Scientific Advice and Orphan Drugs, EMEA, EU

Companies are challenged with developing medicines for children to satisfy both EMEA and FDA requirements. This session will examine how industry is preparing for these challenges, as well as the views from both agencies.

Nathalie Seigneuret, Scientific Administrator, Safety and Medicines Sector, Pre-Authorisation Unit, EMEA, EU

The Paediatric Investigation Plan (PIP) of the EU Paediatric Regulation: Operational and Strategic Challenges
Klaus Rose, Head, Paediatrics, F. Hoffmann-La Roche Ltd., Switzerland

Global Development of Paediatric Medicines: The US Perspective
Dianne Murphy, Director, Office of Paediatric Therapeutics, Office of the Commissioner, FDA, USA

TRACK 11 *CMC, RA* **14:00 – 15:30**

The Role of the Qualified Person for Compliance with Marketing Authorisation/Quality Product Reviews

Session Chairperson:
Emer Cooke, Head of Sector Inspections, EMEA, EU

This session will discuss the role of the qualified person from industry and regulatory perspectives. The background and discussion leading to the publication of the recent EMEA reflection paper and the expected next steps will be discussed.

The EMEA Reflection Paper on Compliance with Requirements of the Marketing Authorisation
Emer Cooke, Head of Sector Inspections, EMEA, EU

An Industry Perspective of the Role of the Qualified Person
John O'Sullivan, Senior Director, Quality Operations Ireland/Singapore/UK, Pfizer, Ireland

QP's Discretion versus Need for a Variation – A Regulator's Point of View
Susanne Keitel, Head of EU, International Affairs, 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.

Session Three

TRACK 12 *EC, RA* **14:00 – 15:30**

eClinical Trials From the Standards/ Regulatory Perspective

Session Chairperson:
Rebecca Kush, President, CDISC, USA

The recently issued FDA Critical Path Opportunities List includes a section entitled, "Streamlining the Clinical Trial Process", with two key opportunities: development of data standards and consensus on standards for a case report form. This session will provide an overview of how standards can streamline the clinical development process from protocol through submission: the business case for adoption standards and the FDA perspective.

CDISC Standards, from Protocol/CRF through BRIDG to Submission
Rebecca Kush, President, CDISC, USA

The Business Case for CDISC Standards
Edward Helton, Chief Strategist, Regulatory and Biomedical Affairs, SAS Institute, USA

A "SciBus" Case for the Science Behind Standards in Regulatory Submissions
FDA representative invited

TRACK 14 *ST* **14:00 – 15:30**

(Not) Clinically Relevant?

Session Chairperson:
Armin Koch, Biostatistician, BfArM, Germany

Biostatisticians are responsible for both the concise planning of clinical trials and the successful interpretation of clinical trial findings. In this context, one major objective is to foresee potential problems by already interpreting significant findings at the planning stage. Recent discussions about the relevance of statistically significant findings can be considered as an indicator for an existing gap between the world of biostatistics and medicine. This gap should be overcome as soon as possible.

The Minimal Clinically Relevant Difference: Where is Consensus?
Joachim Röhmel, Department of Biostatistics and Clinical Epidemiology, Charité University Medicine, Germany

A Note on the Feasibility of Clinical Trials by Incorporating the Concept of Clinical Relevance
Dieter Hauschke, Head of Biometry, ALTANA Pharma AG, Germany

Threshholds for Clinical Relevance
Cornelia Dunger-Baldauf, Expert Statistician, Novartis Pharma AG, Switzerland

TRACK 15/16 *IT, DM, RA* **14:00 – 15:30**

National Experience of EU Submissions and the EU Strategy

Session Chairperson:
Geoffrey Williams, Site Head of Regulatory Operations, Roche Products Ltd, UK

A number of national agencies within Europe have implemented or are implementing e-submission initiatives. In Belgium, e-submissions have been effectively mandated since September 2005, and since February 2006, 95% of submissions are being filed electronically. In the UK, all review is being undertaken electronically, and if paper is submitted it is scanned at the MHRA and made available to reviewers electronically. In the Netherlands, where there is significant experience with receipt and review of eCTDs, guidance is being implemented that makes e-submissions highly recommended. This session will explore the experience by these agencies with uptake of e-submissions by industry, internal agency acceptance of electronic reviews and other practical issues of adoption. Finally, a presentation that places these national initiatives within a European context will be provided by EMEA.

Experience of e-submissions
David Wheeler, Plus Unit Manager, MHRA, UK

Experience of e-submissions
Regulatory Agency representative invited

e-Submissions Strategy: The EMEA Viewpoint
Timothy Buxton, Head of Sector Project Management, EMEA, EU

TRACK 17 *PM, OS, CR* **14:00 – 15:30**

Project Management Across Corporate Boundaries

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

The project management of global clinical trials has matured considerably in recent years, and most, if not all, mainstream pharma and biotech companies rely extensively on the expert contributions of specialist providers to extend their capabilities in this area. This session will hear differing perspectives on the management of outsourcing and alliances from three skilled practitioners in the field, with complementary commentaries on emerging best practices.

Exploring Both Sides of the Perfect CRO/Pharmaceutical Partnership
Bryce Bartruff, Manager, Clinical Infectious Disease Research, sanofi-aventis, USA

Risks and Benefits in Utilisation of the Regional CRO Model when Conducting Global Programmes
Richard Leach, Vice-President, Business Development, Russian Clinical Trials, USA

A Proactive Approach for Effective Project Management
Mark Clegg, Senior Director, Project Manager, INC Research, UK

TRACK 19 *PP, RA* **14:00 – 15:30**

Trademarks and Controls of Invented Names

Session Co-Chairpersons:
Brenton James, Consultant in Strategic Regulatory Affairs in the European Union, UK
Zaide Frias, Scientific Administrator, Legal/Regulatory Affairs, EMEA, EU

Trademarks are of vital importance to the innovative pharmaceutical industry. In this session you will hear of the EMEA review of trademarks by the Invented Name Review Group and one company's experience. The issues surrounding the use of trademarks and parallel imports will be discussed.

Invented Name Review Group (NRG)
Zaide Frias, Scientific Administrator, Legal/Regulatory Affairs, EMEA, EU

How to Solve Issues of Name Rejections by the Invented Name Review Group (NRG)
Anja Manz, Head of Global Trademarks, Domain Names and Copyrights, Novartis, Switzerland

Parallel Imports and Trademarks
Sir Hugh Laddie, Chair in Intellectual Property Law, University College of London Faculty of Laws, UK

TRACK 20 *PP* **14:00 – 15:30**

The Borderline Between Medicine, Food, Medical Devices and Cosmetics

Session Chairperson:
Helen Darracott, Director of Legal & Regulatory Affairs, PAGB, UK

Many discussions are focused on the borderline between different categories of products used in a self-care environment. This session will clarify which legal provisions apply.

Borderline Medicines/Food

Session Four

Ariane Titz, CEO, AESGP, Belgium

Borderline Medicine/Medical Device
Leonardo Ebeling, Managing Director, Dr. Ebeling and Associates GmbH, Germany

Borderline Medicine/Cosmetics
Peter Lassoff, Vice President Europe, PAREXEL International, UK

TRACK 22 *GCP, CR, CTM, RA* **14:00 – 15:30**

Inspections – Audits – Monitoring

Session Chairperson:
Gabriele Schwarz, Head GCP Inspection Services, BfArM, Germany

In recital 15, Directive 2001/20/EU underlines that it is essential to verify compliance with the standards of good clinical practice in order to justify the involvement of human subjects in clinical trials.
Furthermore, regulators as well as patients and prescribers expect approved medicinal products to be effective and that the benefits outweigh the risks. This requires that data derived from clinical trials are reliable.
Considering the international context of clinical research activities on the one hand and the need to develop new medicines within a reasonable time and at acceptable cost on the other hand, compliance with the GCP requirements remains a real challenge. Guidance is needed on developing and establishing an effective and resource-saving approach to inspections, QA and QC activities.
In this session, speakers from EU regulatory bodies, the pharmaceutical industry and CROs will present their prevailing practices and standards in these areas.

Inspection Strategies and Impact: Views of a Member State

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Alexander Hoenel, Head of Inspections Unit, AGES PharmMed, Austria

Monitoring Excellence
Christian Weimar, Head International Operations, ALTANA Pharma AG, Germany

Auditing - A Systematic Approach
Michaela Rittberger, Managing Director, Averen, Germany

TRACK 1 *RA, PP* **16:00 – 17:30**

Assessment in the EU: The Future

Session Co-Chairpersons:
Aginus Kalis, Director, Medicines Evaluation Board, The Netherlands
Jacques Mascaro, Director, EU Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

The EMEA Roadmap 2010: "Preparing the Ground for the Future" and the "HMA Strategy Paper" will have an important impact on how the assessment will be done in the EU. What will be the future of scientific assessment in the EU? What will be the role of the Member States developing an optimal network of resources, and how will the Member States share the assessment work? What will be the role of the Member States in having a full involvement in the system, or in specialising in defined areas, or in electing to have a more modest contribution? What will be the impact of Scientific Advice? What will be the role of the EMEA and how will rapporteurship be distributed? What are the expectations of the industry?

Networking and Optimising Resources in the EU
Kent Woods, Chief Executive, MHRA, UK

Will the New Regulatory Framework Trigger a New Vision for Rapporteurship?
Anthony Humphreys, Head of Sector Regulatory Affairs and Organisational Support, EMEA, EU

Assessment in the EU: Industry View
Jacques Mascaro, Director, EU Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

Panel discussion with session speakers and **Bruno Flamion,** Chairman, EMEA Scientific Advice Working Party, FUNPD, Belgium

TRACK 2 *RA* **16:00 – 17:30**

Challenges in the Final Steps Before Obtaining the Central MA

Session Co-Chairpersons:
Anu Tummavuori, Manager, EU Regulatory Affairs and Liaison International Drug Regulatory Affairs, F. Hoffmann-la Roche, Switzerland
Hilde Boone, Scientific Administrator Regulatory Affairs, EMEA, EU

The final stages of the authorisation procedure between the CHMP opinion and up to the Commission's decision involve many critical steps. There may be several changes to the SmPC and PL that must be rapidly managed. Translation into all EU languages complicates this further and must be adequately handled within a short time with many different players involved. The introduction of PIM will in all probability facilitate the process. Experience with using PIM and its benefits will be discussed as well as how the whole process can be best managed.

Analysis of New DMP (EMEA)
Hilde Boone, Scientific Administrator Regulatory Affairs, EMEA, EU

Moving to PIM – NCA View
Fredrik Hussénius, Pharmacist, Regulatory Administration, MPA, Sweden

Moving to PIM - Industry View
Said Ikazban, Associate Director, Merck, Sharp & Dohme Inc, Belgium

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Session Four

TRACK 3 *NC, CP, CR* **16:00 – 17:30**

Nongenotoxic Carcinogens: Is There a Need for a Mechanistic Update?

Session Chairperson:
Beatriz Silva-Lima, Professor, Pharmacology/Chair, SWPO, INFARMED, Portugal

Nongenotoxic carcinogenesis will be discussed on the basis of emerging cases for which a plausible mechanistic explanation could not be clearly identified or which differs from the most commonly known. Updated strategies for human risk assessment of identified rodent tumorigenesis will be discussed by regulators and representatives from the pharmaceutical industry.

A European Regulatory Perspective
Beatriz Silva-Lima, Prof., Pharmacology/ Chair, SWPO, INFARMED, Portugal

Novel Disease Models to Investigate Non-genotoxic Carcinogenicity
Jürgen Borlak, Director, Fraunhofer Institute of Toxicology and Experimental Medicine, Germany

Novel Mode of Action Assiciated with Induction of Hemangiosarcoma in Mice Treated with Pregabalin
David Pegg, Senior Scientific Advisor, Pfizer Global Research and Development, USA

TRACKS 4&5 *RD, RA, PP* **16:00 – 17:30**

Surrogate and Biomarker Endpoints: Regulatory and Patient Perspectives

Session Chairperson:
Solange Corriol-Rohou, Regulatory Affairs Director, AstraZeneca, UK and EFPIA Efficacy group

Developing the use of relevant surrogate endpoints has the potential to change the way clinical development and approval evaluations are performed, which is recognised to be a challenge for all concerned Biomarkers and surrogate endpoints have the potential to speed up drug development and thereby adding to patient benefit by facilitating quicker access to innovative medicines. This session will provide an update on the current situation and how stakeholders are interacting to define the best scientific and medical practices in this area, to ensure high ethical standards, and to allay concerns over use of surrogate endpoints' data.

EFPIA Position on Surrogate End Points
Solange Corriol-Rohou, Regulatory Affairs Director, AstraZeneca, UK and EFPIA Efficacy group

EMEA Experience from CHMP Scientific Advice
Spiros Vamvakas, Acting Deputy Head of Sector Scientific Advice and Orhpan Drugs, EMEA, EU

Biomarkers in Rare Disease and Paediatric Studies: The Patient's View
Joseph Irwin, The Jennifer Trust, Leader of the EURORDIS Paediatric Drugs Task Force, UK

TRACK 6 *CR, CP, RD* **16:00 – 17:30**

Disaster Prevention in Clinical Research

Session Chairperson:
Milen Vrabevski, Medical Director/CEO, Comac Medical Ltd., Bulgaria

Recently the clinical research environment has been struck by a number of disastrous events that could inevitably jeopardise clinical studies' results. Every professional organisation currently in this field would have to take into account the huge risk of unexpected events of various origins. Information about some recent case studies related to disaster impact, as well as routine and specific disaster prevention measures, will be discussed during this session.

Effects of Natural Disasters on Clinical Trials
Alicia Pouncey, Managing Director, Aureus Research Consultants, LLC, USA

Disaster Prevention in Global Clinical Trials
Nadina José, President/CEO, Research Strategies Inc, USA

Ensuring Reliable Information Flow in Eastern European Clinical Trials
Speaker to be confirmed

TRACK 7 *CR, PP* **16:00 – 17:30**

How to Ensure Independence of the Stakeholders in Clinical Research

Session Chairperson:
Christiane Druml, Member, Ethics Committee, Medical University of Vienna, Austria

The roles and interests of investigators, universities and industry are intimately intertwined in a combination of financial, academic and personal relationships. The issues of academic freedom, research integrity and patient safety are therefore under scrutiny. In this session management and policies to resolve these relationships will be presented.

"Conflict of Interest" from the Ethics Committee Perspective
Ernst Singer, Ethics Committee Chairman, Medical University of Vienna, Austria

Fair Market Value in Clinical Grants
Harold Glass, Professor of Pharmaceutical Business, University of Pennsylvania, Philadelphia, USA

Industrially Sponsored Clinical Trials: Who Should Evaluate the Data?
Marcus Müllner, Director, AGES PharmMED, Austria

TRACKS 8&14 *CP, CR, CDM, ST* **16:00 – 18:00**

Signal Detection Throughout the Product Lifecycle: Time to Think Outside the Box

Session Co-Chairpersons:
Trevor Gibbs, Senior Vice President, Medical Governance & Pharmacovigilance, GlaxoSmithKline R&D, UK
Joachim Vollmar, Consultant, International Clinical Development Consultants, USA

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 and data mining, as well as statistics and epidemiology. The implications of these tasks and the day-to-day problems will be presented by specialists with hands-on experience in this field. A panel will address industry's responsibility to detect signals sooner by employing methodologies appropriate to all available databases.

Overview and Vision of Signal Detection
Trevor Gibbs, Senior Vice President, Medical Governance & Pharmacovigilance, GlaxoSmithKline R&D, UK

Tools for Data Mining and Signal Detection
William Blackwell, Director of Lincoln Technologies, Europe, Belgium

FDA's Perspectives on Quantitative Safety Signals in Clinical Trials
Robert O'Neill, Director, Office of Biostatistics CDER, FDA, USA

Practical Signal Detection from Clinical Trials Databases: The Pitfalls and the Pointers
Michael Williams, Principal Statistician, GlaxoSmithKline, UK

How the EMEA Plans to Use the EudraVigilance Database for Signal Detection
Xavier Kurz, Scientific Administrator, EMEA, EU

Panel discussion with session speakers and **Alan Hochberg,** Vice President, Research, ProSanos Corp., USA to present results of a US phRMA project on signal detection

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

Session Four

TRACK 9 *CR, RD, PP* **16:00 – 17:30**

Collaboration between Industry Sponsors and Patient Groups for Clinical Trials: New Paradigm Based on Experience

Session Co-Chairpersons:
Nikos Dedes, Chairperson, European AIDS Treatment Group (EATG), Belgium
Kenneth Getz, Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University, Chairman, CISCRP, USA

What is changing today in clinical trial collaboration between industry sponsors and patient groups compared to few years ago? European patient groups in AIDS/HIV, rare diseases and cancers, have taken initiatives to promote what they consider to be good practices. The aim is to enhance their interaction all along the drug development process to take into account the patients' perspective, the knowledge of their disease and to save time and resources. This session will look at this new paradigm illustrated by practical case studies followed by an in-depth panel discussion on creating value for all stakeholders.

Building Partnerships with Patients: An Essential Drug Development Success Factor
Kenneth Getz, Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University, Chairman, CISCRP, USA

The Collaboration: When it Works and How it Can Go Wrong
Amanda Leighton-Bellichach, Chairperson of the Society for Fighting Pain, President of the European Pain Network, Israel

Panel discussion with session speakers and
Ingrid Klingmann, President, Pharmaplex, Belgium

TRACK 10 *CR, RA* **16:00 – 17:30**

Preparing For the Paediatric Investigational Plan

Session Chairperson:
Khazal Paradis, Vice President, Clinical Research & Therapeutics, Genzyme Europe BV, The Netherlands

This session will look at

- How industry is preparing PIP
- What paediatricians can expect in the coming years and recommendations on how to prepare
- Any special considerations for smaller companies, biotechnology companies and for orphan products

Preparing for the Paediatric Investigational Plan: An Industry Perspective
Suyash Prasad, Paediatrician and Senior Medical Director, Genzyme, UK

Preparing for the Consideration of Orphan Diseases and Biotech Products
Henk Schuring, Director Regulatory Affairs, Genzyme Europe BV, The Netherlands

Global Development of Paediatric Medicines: The European Perspective
Daniel Brasseur, Chairman of the CHMP, Paediatrician, Ministry of Public Health, Belgium

TRACK 11 *CMC, RA, QC* **16:00 – 17:30**

More Flexibility for Variations

Session Chairperson:
Henk Koops, Senior Director, NV Organon, The Netherlands

In this session the current views and proposed improvements on the European Variations Systems will be presented by the Commission and industry. The European Variation Systems will be put into perspective by presenting change control practices and legislation in other major countries and/or healthcare areas.

Variations on the Theme of Variations
Henk Koops, Head Global Regulatory CMC, NV Organon, The Netherlands

Better Regulation of Pharmaceuticals: The Case of Variations
Nicolas Rossignol, Administrator, DG Enterprise, Pharmaceuticals Unit F/2, European Commission, EU

Variation Regulations: what EFPIA Expects from the Revision
Chris Dafforn, Director CMC Regulatory Affairs, AstraZeneca, UK

TRACK 12 *EC* **16:00 – 17:30**

eClinical Trials From the Patient Perspective

Session Chairperson:
Scottie Kern, Assistant Director – ePRO, Wyeth Research, UK

There is increasing emphasis on the role of the patient in clinical research. There are several reasons for this, among which is the dissemination of medical information through the internet and the increasing importance of the Patient Reported Outcomes in the registration and the lifecycle of new drugs. This session will try to let us listen to what patients say when they use new technologies, but also to demonstrate how and why patients can benefit from new ways of conducting Clinical Trials, and even new ways to treat their diseases.

ePRO: "How Was It For You?" The Real Users Speak...
Scottie Kern, Assistant Director – ePRO, Wyeth Research, UK

Validating ePRO Measures for Use in Clinical Trials
Brian Tiplady, Senior Clinical Scientist, invivodata, inc., UK

Challenges of Data Capture from Obese Patients: Technological Developments for Future Treatment?
Breffni Martin, Director, CanReg (Europe) Ltd., Ireland

TRACK 15/16 *IT, DM, RA* **16:00 – 17:30**

Electronic Submissions Standards: Progress with their Development

Session Chairperson:
Andrew Marr, Director, e-Regulatory Development, European and International Regulatory Affairs, GlaxoSmithKline, UK

Processes are being developed by which in the future ICH will collaborate with Standards Development Organisations for the creation of standards to meet its needs for industry/agency and agency/agency electronic communication. Meanwhile the existing standards have to be maintained and implemented effectively. This session will cover how ICH is progressing with its future processes and how the current eCTD specification and its interpretation are being improved, globally and in Europe.

The New Processes for the Development of ICH Electronic Messaging Standards
Andrew P. Marr, Director, e-Regulatory Development, European and International Regulatory Affairs, GlaxoSmithKline, UK

ICH and EU eCTD Specification Changes and Change Control Process
Geoffrey Williams, Site Head of Regulatory Operations, Roche Products Ltd., UK

ETICS: eCTD Tools Interoperability and Compliance Study
Harv Martens, ICH M2 (ESTRI) Expert Working Group and President INGAmerica Inc., USA

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Session Four

TRACK 17 *PM, OS, CR* **16:00 – 17:30**

Outsourcing of the Project Management Role

Session Chairperson:
Winston Liao, Senior Project Manager, Fulcrum Pharma Development, USA

Project management outsourcing is a dynamic process, involving key decisions from corporate strategic planning, scientific/technical, financial/budgetary and regulatory perspectives, among others. This session will present critical strategic opportunities gained from project management outsourcing and will examine the impact of strategic options on different components of the drug development pathway.

Project Management Outsourcing: Drug Development Management Perspective
Winston Liao, Senior Project Manager, Fulcrum Pharma Development, USA

Project Management Outsourcing: Sponsor's Perspective
Mike Wood, Research Director, Vernalis, UK

Project Management Outsourcing: Medical/Technical Perspective
Robert Miller, Chief Medical Officer, Fulcrum Pharma, PLC, UK

TRACK 19 *PP, RA* **16:00 – 18:00**

IP Rights and Public Interests

Session Chairperson:
Lembit Rägo, Coordinator, Quality, Assurance & Safety Medicines Department of Essential Drugs, WHO, Switzerland

IP rights can have an impact on other areas of society. This session will focus on some of these interactions. The possible conflict of interest between regulatory transparency and data protection with respect to trade secrets will be discussed in the first presentation. The second presenter will go into the interaction between competition law and IP rights. The nice example of this interaction of the AstraZeneca case will be presented. The third and last presentation will discuss the relationship between IP rights and the interests of public health.

Transparency of the Regulatory Process and Protection of Confidential Data
John Lisman, Attorney, NautaDutilh, The Netherlands

Competition Law and IP Rights: Key Principles and the AstraZeneca Case as an Example
Erik Vollebregt, Lawyer, Clifford Chance, The Netherlands

The April 2006 WHO report, Compulsory Licensing – Stagnation or Innovation
Lembit Rägo, Coordinator, Quality, Assurance & Safety Medicines Department of Essential Drugs, WHO, Switzerland

Extended panel discussion on IP rights and other protection rights in the pharmaceutical sector

TRACK 20 *RA, NHP* **16:00 – 17:30**

Homeopathic Medicines on the Way to a European Market

Session Chairperson:
Bernd Eberwein, Executive Director, BAH, Germany

The EU Heads of Medicines Agencies formed a Working Party on homeopathic medicines to discuss ways of harmonising this sector. Achievements so far and problems encountered will be presented.

Achievements of the Heads of Agencies Working Group on Homeopathic Medicines
Speaker to be confirmed

Harmonisation of Manufacturing Methods for the European Pharmacopeia and Safety of Homeopathic Medicines
Irene Chetcuti, Regulatory Affairs Manager, Laboratoires Boiron, France

Harmonisation of Homeopathic Medicinal Products in the EU: from Member States Approach to European Approach
Gesine Klein, International Regulatory, Affairs, DHU Arzneimittel GmbH, Germany

TRACK 22 *GCP, CR* **16:00 – 17:30**

Strategies for an Integrated GCP Compliance Oversight System

Session Chairperson:
Beat Widler, Global Head of Clinical Quality, Roche Products Ltd., UK

Since the inception of GCP audits it has been accepted that an audit provides an assessment at a given point in time of the compliance status and quality of a clinical trial center or through systems' audits of a process or function involved in clinical trial activities. Through sampling techniques auditors have tried to overcome the anecdotal nature of an audit (i.e. overcome the limitations in geographical, process, etc. scope); however the increasing complexity of clincial trial activities (numbers of sites, patients, globalisation, etc.) show the limitations of the traditional approach to auditing. This session will discuss how a quality risk approach can overcome the intrinsic limitations of the auditing approach in providing QA oversight.

Next Generation GCP Quality Risk Management
Matthias Buente, Principal, Booz Allen Hamilton AG, Switzerland

Learning from a Different Industry: Operational Risk Management in Banks
Speaker to be confirmed

Quality Risk Management in GCP: Advantages and First Results
Peter Schiemann, QRM Project Leader, F. Hoffmann-La Roche Ltd., 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.

Session Five

TRACKS 1&2 *RA, GE* **09:00 – 10:30**

The Mutual Recognition and Decentralised Procedure: How is the New Co-ordination Group (CMD) Performing?

Session Co-Chairpersons:
Truus Janse-de Hoog, Staff Member Chair, Medicines Evaluation Board, The Netherlands, Chair CMD(h)
Angelika Joos, Associate Director, Regulatory Policy Europe, Merck Sharp & Dohme Inc., Belgium

In this session experiences with the revised Mutual Recognition Procedure (MRP) and new Decentralised Procedure (DCP) will be discussed. What are the practical experiences with the new Decentralised Procedure? Is it working as expected? The new CMD has a much broader mandate than the old MRFG; if a member state raises a potential serious risk to public health that cannot be resolved during the procedure, it is now the task of the CMD to discuss this in the new 60-day referral discussion with the aim of finding a consensus. How does this function in practice and what is the impact of the guideline defining "potential serious risk to public health?" How are national agencies supporting their CMD members and what is the impact of CMD agreements on national processes?

The New Coordination Group CMD(h)
Truus Janse-de Hoog, Staff Member Chair, Medicines Evaluation Board, The Netherlands, Chair CMD(h)

Experiences with the Revised MRP and DCP
Peter Bachmann, Head of Unit, Mutual Recognition Procedures, CMD(h) member, BfArM, Germany

Industry Experience with the Decentralised Procedure
Caroline Kleinjan, RCC-EU (Regulatory Competence Centre Europe) Head RCC-EU, Sandoz B.V. The Netherlands

TRACK 3 *NC, CP* **09:00 – 10:30**

Animal Model of Disease for Safety Assessment

Session Chairperson:
Per Spindler, Director, BioLogue, University of Copenhagen, Denmark

This session will discuss integrative approaches of animal models of disease for safety assessment before first human dose(s) including insights into the concept of NOAEL. Following the presentations, an interactive discussion between audience and speakers and between speakers will be facilitated.

Setting the Scene for Translating Preclinical Safety Sciences to Clinical Settings
Per Spindler, Director, BioLogue, University of Copenhagen,Denmark

Improving the Predictive Value of Preclinical Studies to Support Clinical Development
Joy Cavagnaro, President, Access BIO, USA

Animal Model of Disease for Safety Assessment- Industry Perspective
Philippe Laroque, Director, Laboratoires MSD Chibret, France

Animal Model of Disease for Safety Assessment -Regulatory Perspective
Beatriz Silva-Lima, Professor, Pharmacology/Chair, SWPO, INFARMED, Portugal

TRACK 4 *CR* **09:00 – 10:30**

The Challenge of "Omics" Standardisation

Session Chairperson:
Hans-Peter Arnold, Senior Director, Business Development & Marketing, Epidauros Biotechnologie AG, Germany

Molecular biomarker analysis is a rapidly evolving field with many new and emerging technologies. The use of these new technologies in clinical drug development requires the definition of common standards before these can be routinely integrated into the drug development process. This session will give examples and highlight current efforts in "Omics" standardisation and the application of these new technologies in drug development and clinical settings.

Development of Standard Controls and Guidelines for Microarray-Based Expression Assays
Janet Warrington, Vice President, Emerging Markets & Molecular Diagnostics, Research & Development, Affymetrix, USA

Pharmacogenetics: From Research to Bedside
Glenn Miller, General Manager, Genzyme Analytical Services, USA

Special Challenges in Multi-Centre Trials
Hans Peter Arnold, Senior Director, Business Development & Marketing, Epidauros Biotechnologie AG, Germany

TRACK 5 *RD, CR, RA, CTM* **09:00 – 10:30**

EMEA/FDA "New Paradigms on Phasing of Clinical Trials"

Session Co-Chairpersons:
Lawrence J. Lesko, Director Office of Clinical Pharmacology, CDER, FDA, USA
Bruno Flamion, Chairman, EMEA Scientific Advice Working Party, FUNPD, University of Namur, Belgium

For decades the pharmaceutical industry and regulators have divided clinical drug development into three major phases (Phase 1-3). What was the genesis of the phase designation, and is the rationale for the categorisation still relevant? While the phase definitions are generally understood by scientists, clinicians and regulators, the question to ask is whether this categorisation stifles innovative thinking. Moreover, there are data suggesting that a substantial amount of time can be spent between the phases, in some cases months. Is this time being used productively to analyse and understand data, or is it only "white space"? More and more novel molecules are entering development, and clinical pharmacology is providing more tools to study these molecules in humans. Is it necessary, therefore, to continue to use the phase categorisation? If not, what is the alternative to the phased approach?

This session will specifically focus on 1) the causes of attrition in drug development, 2) how companies are changing in response to "failures," and 3) what FDA and EMEA are doing to change or encourage change.

Challenging the Current Development Paradigm: A Case for Change
Navjot Singh, Associate Principal, McKinsey & Co. USA

New Approaches to Clinical Development: Wyeth Experience
Charlie Gombar, Vice President, Project Management, Wyeth, USA

Panel discussion wih session speakers on:
Regulatory Perspective on "Phased" Development

FDA Point of View:
Lawrence J. Lesko, Director Office of Clinical Pharmacology, CDER, FDA, USA

EMEA/CHMP Point of View:
Bruno Flamion, Chairman,
EMEA Scientific Advice Working Party, FUNPD, 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.

Session Five

TRACK 6 *CR, CTM, PP* **09:00 – 10:30**

Legal and Insurance Issues in Clinical Trials

Session Chairperson:
John Lisman, Attorney, NautaDutilh, The Netherlands

This session will discuss some of the most important legal and insurance issues with respect to clinical trials. The first two presentations deal with incapacitated adult trial subjects; respectively patients with detoriating competence and patients who are unconscious. The last presentation will deal with the required insurance and will use the experience in Germany as an example.

Clinical Trials on Patients with Deteriorating Competence
Salla Lotjonen, Lecturer in Healthcare Law and Ethics, Centre for Social Ethics and Policy School of Law University of Manchester, UK

Free Informed Consent in Emergency Research – Solutions in Discussion
Academic invited

Experiences in Germany with Insurers and the One German Re-Insurer
Inga Rossion, Clinical Trials Oncology, German Cancer Society, Germany

TRACKS 7&14 *CR, CTM, ST, RD* **09:00 – 10:30**

Adaptive Designs – Trends and Controversies

Session Chairperson:
Carl-Frederik Burman, Statistical Science Director, AstraZeneca, Sweden

Adaptive designs have lately been much discussed in industry, academia and regulatory bodies. There is a strong hope that these designs can considerably increase the efficiency in clinical development. On the other hand, regulators (e.g. new EMEA reflection paper) and researchers have pointed out problems. Can these obstacles be overcome?

Adaptive Trial Designs – Overview and Considerations
Graham Nicholls, Product Manager, Randomisation and Supply Chain Management, ClinPhone plc., UK

Group-Sequential and Flexible Designs
Christian Sonesson, Senior Statistician, AstraZeneca R&D, Sweden

How to Analyse Flexible Trials?
Werner Brannath, Associate Professor, Medical University of Vienna, Austria

Panel discussion with session speakers and **Armin Koch**, Biostatistician, BfArM, Germany

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TRACK 8 *CP, RA* **09:00 – 10:30**

EudraVigilance in Supporting the EU Risk Management Activities in the EEA

Session Co-Chairpersons:
Sabine Brosch, Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA, EU
Gaby Danan, Expert, Global Pharmacovigilance and Epidemiology, sanofi-aventis, France

The objective of this session will be to describe the key activities of the EudraVigilance Expert Working and Steering Committee established to co-ordinate and harmonise the implementation of electronic adverse reaction reporting in the pre- and post-authorisation phase across the EU and the establishment of a fully functioning EudraVigilance system. The features of the EudraVigilance Data Analysis System to support signal detection and the overall EU Risk Management activities will be also discussed.

The EudraVigilance Steering Committee and Expert Working Group: Mandate and Work Programme
Sabine Brosch, Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA, EU

Working Towards EU Harmonisation in Reporting Rules in the Pre- and Post-Authorisation Phase
Sabine Luik, Head Regional Centre Drug Safety Europe, Boehringer Ingelheim GmbH, Germany

The New EudraVigilance Data Analysis System to Support the EU Risk Management Strategy
Stefano Cappe, EudraVigilance Administrator, EMEA, EU

TRACK 10 *CR, RA* **09:00 – 10:30**

Communication on Paediatric Data SmPC – Public Access to Paediatric Information

Session Chairperson:
Yann le Cam, CEO, EURORDIS, Europe

This session will address the two key points related to public access to paediatric information:

- Which information is available today on the ongoing paediatric clinical trials, their protocols and their results? What are the needs and the limits from academia, patients and regulators points of view?
- What is being developed in the context of the new EU Paediatric Regulation?
- Which product information will be available to the public? What will be on the medicine pack? What will be on the product information leaflet? What will be on the EMEA website? How should it be articulated with the SPC?

Public Access to Paediatric Information: Point of View of a National Competent Authority
Regulatory Agency representative invited

Public Access to Paediatric Information: Point of View of a Clinical Investigator with a European Vision and including the Project Teddy
Ian Chi Kei Wong, DH National Public Health Career Scientist and Professor of Paediatric Medicines Research, Centre for Paediatric Pharmacy Research - The School of Pharmacy - University of London, UK

Public Access to Paediatric Information: Transparency of Information – Patients' and Parent of Patients' Experience
Catherine Vergely, CEO, ISIS - Institut Gustave-Roussy, France

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Session Five

TRACK 11 *CMC, RA* **09:00 – 10:30**

EU Directive: GMP For Certain Excipients

Session Chairperson:
Jean-Louis Robert, Head of Department, Laboratoire National de Santé, Luxembourg

The European Commission is working on a Directive on GMP for certain excipients. In this session, a representative from the Directorate General Enterprise and Industry will provide information on the rationale and progress of this directive. A representative from the excipients manufacturers (IPEC) and a representative from the pharmaceutical industry will present their views.

GMP for Excipients: Legal Framework
Sabine Atzor, Administrator GMP, MRA, Counterfeit and Parallel Trade, DG Enterprise, Pharmaceuticals, European Commission, EU

GMP for Excipients: The IPEC Perspective
Kevin J. McGlue, Director Global Quality Assurance, Colorcon, UK

GMP for Excipients: The Pharmaceutical Industry Perspective
Chris Dafforn, Director CMC Regulatory Affairs, AstraZeneca, UK

TRACK 13 *CDM* **09:00 – 10:30**

Data Aggregation and Warehousing

Session Chairperson:
Jens Reinhold, EDC Implementation Manager Global Medical Development, Schering AG, Germany

Medical progress resulting in more complex clinical data and rising regulatory requirements for data quality and availability are the main drivers for pharmaceutical companies to work on integrated clinical data repositories, standardise data interchange and optimise the processes around this. Experts of three different companies will introduce their individual approaches and show how those facilitate study and across-study analyses as well as decision support for medical development.

DAWACS: Empower Analysis by Central Clinical Data Integration
Berthold Traub, Group Manager Clinical Application Programming, ALTANA Pharma AG, Germany

Main Challenges and Possible Solutions When Establishing a Clinical Data Warehosue – Practical Examples
Christian Müller, Global Head of Statistical Reporting – Safety, Novartis Pharma AG, Switzerland

Data on Demand: Outsourced Hosted Solutions Facilitate Decisions by the Global Clinical Development Organisation
John Wise, Senior Director, Informatics DaiichiSankyo Pharma Development, Daiichi Pharmaceuticals UK Ltd., UK

TRACK 15/16 *IT, DM, RA* **09:00 – 10:30**

EU Telematics Strategy: Progress to Date

Session Chairperson:
Hans-Georg Wagner, Head of Unit Communications and Networking, EMEA, EU

The implementation of the EU Telematics Strategy by EMEA is entering its fifth year and almost all systems are in production. It is interesting to review the implementation to date and to examine future plans and issues. As the systems have considerable impact on national competent authorities and the pharmaceutical industry, both will provide their view on the EU Telematics Strategy.

EU Telematics Strategy: Update from the EMEA on Implementation Status and Further Plans
Hans-Georg Wagner, Head of Unit Communications and Networking, EMEA, EU

EU Telematics Strategy: The View from National Regulators
Stanislav Primozi, Director, Agency for Medicinal Products, Slovenia

EU Telematics Strategy: Industry Perception, Expectations and Role
Stephen Hasler, Vice President, Operations & Systems, European Regulatory Affairs, GlaxoSmithKline, UK

TRACK 18 *BT, GE, RA* **09:00 – 10:30**

Current and Future Challenges of Biosimilars: EU and US Situation as Well as Aspects from Other Countries

Session Chairperson:
John Purves, Head of Sector Quality of Medicines, EMEA, EU

Current and Future Challenges of Biosimilars from a Regulator's Point of View
Pekka Kurki, Chairman of the CHMP Similar Biological Medicinal Products Working Party, National Agency for Medicines, Finland

Current and Future Challenges of Biosimilars from a Consultant's Point of View, Covering Experience from the EU, US and Elsewhere
Cecil Nick, Director, Parexel, UK

Current and Future Challenges of Biosimilars: Global Perspectives
Irene Krämer, Director of the Pharmacy Department and Professor of the Pharmacy School, Johannes Gutenberg University Hospital in Mainz, Germany

Panel discussion with session speakers, **Thomas Bols**, Director Government Affairs Europe, Amgen, Belgium, **Ajaz S. Hussain,** Vice President & Global Head of Biopharmaceutical Development, Sandoz, USA and **Nicolas Rossignol,** Administrator, DG Enterprise, Pharmaceuticals Unit F/2, European Commission, EU

TRACK 21 *PP* **09:00 – 10:30**

Access to Controlled Medications: Impact for Millions

Session Chairperson:
Willem Scholten, Technical Officer, WHO, Switzerland

Over 80% of the world population has no proper access to medicines controlled under the drug treaties. Consequences include unnecessary suffering from pain and preventable HIV transmission. Reasons are manifold, but start in all cases with the countries' opioid control policies and also include the knowledge and attitude of healthcare professionals.

The Right to Be Free of Pain: A Fata Morgana?
Frank Laschewski, Head Drug Safety Management Pain, Grünenthal GmbH, Germany

Opioid Agonist Treatment of Opioid Dependence: Beyond Reach...but Why?
Chris Chapleo, Director of Puprenorphine Business, Reckitt Benckiser, UK

Improving Access to Controlled Medications: The Romanian Success Story
Angela Pantea, Director, Romanian Monitoring Centre for Drugs and Drug Addiction, Romania

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

Session Five

TRACK 22 *GCP, CR, CTM* **09:00 – 10:30**

Defining the Role and Responsibilities of DSMBs in Clinical Trials

Session Chairperson:
Juntra Karbwang, Clinical Quality Assurance Coordinator WHO-TDR, Switzerland

This session examines the growing importance of Data & Safety Monitoring Boards (DSMBs) in clinical trials. In recent years DSMBs (also called Data Monitoring Committees [DMCs]) are increasingly employed to oversee safety and efficacy developments in clinical trials, both for the protection of trial participants and the ongoing assurance of the scientific validity of a study. At the same time, a number of questions have arisen regarding the precise role and responsibilities of DSMBs. In order to address these questions, in 2005 the Special Programme for Research and Training in Tropical Diseases, World Health Organisation (WHO-TDR) produced operational guidelines for the establishment and functioning of Data & Safety Monitoring Boards in order to clarify some of the challenges and to provide a handbook for establishing a well-functioning DSMB. This session explores real challenges faced by DSMBs in pivotal studies, while examining how these committees can be integrated into the research process in a more defined way.

Questions and Challenges: Why WHO-TDR Undertook the Development of Guidance for DSMBs
Juntra Karbwang, Clinical Quality Assurance Coordinator WHO-TDR, Switzerland

Experiences of DSMBs in Multi-country Clinical Trials in Developing Countries
Francis P. Crawley, Secretary General & Ethics Officer, European Forum for Good Clinical Practice, Belgium

Examining the Role of a DSMB throughout the Development of a Clinical Trials: From Patient Recruitment to Publicaton
Allan Johansen, Head Pharma Development Quality Audits (PDQA), Asia Pacific & South Africa Roche Products Pty Limited, Australia

Implementing Quality into Ethical Review: The SIDCER Recognition Programme
Cristina E. Torres, Secretariat, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP), Thailand

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TRACK 23 *GE, RA* **09:00 – 10:30**

New Developments in Assessment of Generic Medicinal Products in Europe

Session Chairperson:
Martin Olling, Pharmacokinetic Adviser, Medicines Evaluation Board, The Netherlands

After adopting the revision of the guidelines on Bioavailability and Bioequivalence and the enlargement of the EU, new developments were observed in the assessment of generic medicinal products. The place of generics in the therapeutic field in relation to the requirements for registration was also more challenged.

In this session we will give an overview of these developments and discuss the need for revision of the guidelines with these requirements. In addition to the general requirements on the conduct of bioequivalence studies and the assessment of these studies, we will discuss the role of bioequivalence in relation to the problem of prescribeability/"interchangeability"/substitution of narrow therapeutic index drugs and how this should be harmonised within the EU.

Special attention will be given to the question of substitution of modified release products: are bioequivalence studies of different pharmaceutical forms adequate to justify substitution of the innovator product for the generic without changing the benefit/risk profile of the medicinal product or is there a need for a classification of pharmaceutical forms with respect to bioequivalence and substitution?

The Q and A Document on Bioequivalence Testing – What are the Consequences of Implementation of the Q and A Document on Bioequivalence Testing?
Martin Olling, Pharmacokinetic Adviser, Medicines Evaluation Board, The Netherlands

Are the Requirements in the Bioequivalence Guidelines strict enough to Ascertain Interchangeability with Modified Release Products?
Susana Almeida, Clinical Trial Project Manager and Pharmacokineticist, Grupo Tecnimede, Portugal

Are the Requirements in the Bioequivalence Guidelines strict enough to Ascertain Interchangeability with Narrow Therapeutic Index Drugs?
Steffen Thirstrup, Chief Medical Officer, Licensing Division, Danish Medicines Agency, Denmark

TRACK 24 *CR, BT* **09:00 – 10:30**

Gene Therapy: Clinical Experience and Regulatory Hurdles

Session Chairperson:
Marisa Papaluca Amati, Deputy Head of Sector Safety and Efficacy of Medicines, Pre-Authorisation Unit, EMEA, EU

Gene therapy continues to mature as a field with important research implications and achievements. The session will highlight changes in gene therapy development trends and the progress in clinical applications. The audience will be provided with an update on the ICH discussion and on the recent regulatory and industry priorities in the field.

Update on the EMEA and ICH Activities
Marisa Papaluca Amati, Deputy Head of Sector Safety and Efficacy of Medicines, Pre-Authorisation Unit, EMEA, EU

Progress and Challenges in Gene Therapy
Klaus Cichutek, Head Department of Medical Biotechnology, Paul-Erlich Institute, Germany

Case Study: Interaction with the Regulators
Industry representative invited

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

Session Six

TRACK 1 *RA, PP* **11:00 – 12:30**

HMA Member State Agencies in a Strengthened European Network

Session Co-Chairpersons:
Jean Marimbert, Director, Afssaps, France
Susan Forda, Executive Director, Regulatory Affairs, Eli Lilly & Company Ltd., UK

The present and future of the European Medicines Regulatory Network will be addressed. The Strategy Paper on EMRN has been adopted by the Heads of the EU regulatory agencies as a response to the evolving regulatory environment: the legislative changes brought about by the implementation of the new legislation, changing public health needs, the recent enlargement and a reaction to changes and recent developments in the pharmaceutical industry. In a number of ways, it complements the existing EMEA Roadmap.

Keys issues of the continuous improvement of the network will be discussed, including a regular communication process between HMA and the stakeholders and worksharing within the network. The experience from the Benchmarking of European Medicines Agencies exercise, which aims at identification and sharing of the best practices across the network of EEA medicines agencies, will be presented as well.

HMA Strategy Paper (NCA)
Jean Marimbert, Director, Afssaps, France

Collaboration and Worksharing (NCA)
Johannes Löwer, President, Paul-Ehrlich-Institute, Germany

Industry View
Susan Forda, Executive Director, Regulatory Affairs, Eli Lilly & Company Ltd., UK

TRACK 2 *RA, PP, IMP* **11:00 – 12:30**

Role of Patients in Assessment

Session Co-Chairpersons:
Jean Georges, Executive Director, European Patients' Forum, Alzheimer Europe, Belgium
Yves Juillet, Senior Advisor, Les Entreprises du Médicament, France

Patient involvement in the regulatory process is a relatively new phenomenon. This session will highlight the initiatives of the European Medicines Agency to promote greater involvement of patients and patient organisations in the assessment of new medicines. Case studies of the involvement of AIDS patients and patients with rare diseases will be presented with the aim of discussing, in an interactive session, the different views of patients, regulatory authorities and industry on the role of patients in medicines assessment.

Framework of Interaction between EMEA and Patient Organisations
Isabelle Moulon, Head of Sector Medical Information, EMEA, EU

The Views and Experience of EURORDIS for Greater Patient Involvement in the Assessment of Orphan Drugs
François Houyez, Health Policy Officer, EURORDIS, Europe

AIDS Patients and Their Involvement in Medicines Assessment
Nikos Dedes, Chairperson, European Aids Treatment Group, Belgium

Panel discussion with session speakers and **Anne Castot,** Head of Risk Management and Information on Medicinal Products Division, Afssaps, France

TRACK 3 *NC, CP, CR, RA* **11:00 – 12:30**

Accessible Biomarkers of Toxicity

Session Chairperson:
Joseph J. DeGeorge, Vice President, Safety Assessment, Merck & Co. Inc., USA

Animal toxicology studies that are designed to support the safe conduct of clinical trials for candidate pharmaceuticals, can sometimes present with histopathologic findings with no concurrent alterations in the clinical pathology endpoints that are in common use today. Additional improved accessible biomarkers that bridge from animal to humans are needed to enable clinical investigations by demonstrating that the pathologies identified in such studies are safely monitorable. Advances in the development, collaborative qualification, and path to regulatory acceptance of such improved accessible biomarkers for drug-induced damage to the kidney, the vasculature and to skeletal and cardiac muscle will be presented.

Impact on Drug Development and Regulatory Review of the Qualification of Novel Biomarkers of Nephrotoxicity
Jacky Vonderscher, Vice President, Head of Drug Development, Genomics Institute of the Novartis Research Foundation, USA

Mechanistic Studies and Development of Novel Biomarkers of Drug-Induced Vascular Injury
Stephan Chevalier, Director, Molecular and Cellular Toxicology, Drug Safety R&D, Pfizer Global R&D, France

Development, Qualification and Application of Improved Biomarkers for Skeletal and Cardiac Muscle Toxicities
Warren Glaab, Research Fellow, Merck and Co., Inc., USA

TRACK 4 *CR* **11:00 – 12:30**

Application of Pharmacogenetics in Proof of Concept and Early Clinical Development

Session Chairperson:
Colin Spraggs, Therapeutic Area Advisor, GlaxoSmithKline, UK

After years of exploratory study, pharmacogenetics is translating genomics research into drug development gains by classifying drug response (safety and/or efficacy) variability and leading to reduction in development pipeline attrition and better clinical outcomes. In this session, real clinical examples will be presented to demonstrate that pharmacogenetics is happening now and is being applied to support drug development and therapeutic usage that is ready for clinical practice.

Rosiglitazone in Alzheimer Disease: Example of Phase II Efficacy Pharmacogenetics Reducing Pipeline Attrition
Ann Saunders, Director, Pharmacogenetics, GlaxoSmithKline R&D, USA

Pharmacogenetics-based Therapeutic Recommendations: Ready for Clinical Practice?
Julia Kirchheiner, Professor of Clinical Pharmacology, University of Ulm, Germany

The Application and Challenges of Pharmacogenetics at POC
Albert Seymour, Director Pharmacogenomics, Pfizer Global R&D, 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.

Session Six

TRACK 5 *RD, RA, PP* **11:00 – 12:30**

Advanced Therapy: Regulatory Framework and Development Issues

Session Chairperson:
Wills Hughes-Wilson, Director Health Policy Europe, Genzyme, Belgium and Chair EuropaBio Task Force on Cell Therapy

The draft EU Advanced Therapies Regulation will create a single, unified framework for a new generation of so-called "Advanced Therapies", comprising cell therapy, gene therapy and tissue engineered products. The draft regulation aims to fill the regulatory gap that currently leaves tissue engineered products subject to 25 different authorisation procedures and will also bring cell and gene therapy under the same regime, allowing them to benefit from more tailor-made technical requirements than those in the broader pharmaceutical framework. This session will cover the key technical requirements of the draft Regulation, plus give an overview of the state of play in the European decision-making process on this piece of key legislation.

Industry Position
Wills Hughes-Wilson, Director Health Policy Europe, Genzyme, Belgium and Chair EuropaBio Task Force on Cell Therapy

Regulatory Update on Legislation for Advanced Therapy
Nicolas Rossignol, Administrator, DG Enterprise, Pharmaceuticals Unit F/2, European Commission, EU

Patient Point of View
Fabrizia Bignami, Therapeutic Development Officer, EURORDIS, Europe

TRACK 6 *CR, CTM, CS* **11:00 – 12:30**

Optimised Study Medication Management

Session Chairperson:
Philippe Van der Hofstadt, CEO, B&C Group, Belgium

Despite the fact that the logistics processes of all clinical trial materials are similar if not identical, these processes are still split and scattered around amongst the subcontractors and sponsors of the clinical trials, creating redundancies, extra costs and even confusion at the investigator sites. A decade ago, centralisation of laboratory activities was a new concept that is now seen as a norm in the industry. It seems nowadays that centralisation and integration of the logistics processes will become the norm within a decade. This session will compare the centralisation of logistics with central labs and present future opportunities for innovative logistics processes and supply chains used in other industries, e.g., automotive, computer. They have stripped out unnecessary costs and reduced time to market by streamlining supply chains, manufacturing and internal business processes.

Centralisation of Laboratory Analysis versus Vertical Integration of the Supply Chain in Clinical Research
Philippe Van der Hofstadt, CEO, B&C Group, Belgium

Effectively Manage Your Late-Phase Trials: How can CTM Deliver the Right Drugs in a Timely and Cost Effective Manner
Marty Boom, Senior Managing Consultant, World Class International, UK

Driving Delivery Performance Through the Application of Visual Scheduling
Neil Conroy, Strategic Capacity Manager, Centocor – Johnson & Johnson, The Netherlands

TRACK 7 *CR, CTM, DM, GCP* **11:00 – 12:30**

Good Documentation Practices

Session Chairperson:
Anoop Agarwal, Principal, Institute of Clinical Research, India

Good documentation practices are the key element for quality compliance, audit and success of clinical trials. Standard operating procedures for recruitment, recording and reporting of trial results ensure quality data for regulatory submission. It is believed that what has not been documented has not been done.

Quality Assurance Through Records Management
Anoop Agarwal, Principal, Institute of Clinical Research, India

Development of Data Standards and Consensus for Case Report Forms
Rebecca Kush, President, CDISC, USA

Quality Assurance in Academic Trials: Is There a Different Level of Requirements?
Jean-Marc Husson, Director, EUDIPHARM, France

TRACK 8 *CP, CR* **11:00 – 12:30**

Intelligent Risk Communication

Session Chairperson:
Andrzej Czarnecki, Director, Deputy EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly & Co. Ltd., UK

This session will present and discuss risk communication. Different perspectives from academia, industry and regulatory authorities will address steps forward in achieving more intelligent risk communication to the public to avoid unnecessary concerns of patients, misinterpretations and misuse of such information by media and the legal profession.

Intelligent Risk Communication - The Regulatory Perspective
June Raine, Chair of CHMP Pharmacovigilance Working Party and Director Vigilance and Risk Management, MHRA, UK

Communicating Science Limitations and Opportunites
Saad Shakir, Director, Drug Safety Research Unit, UK

Risk Communication: How Can We Do it Better?
Andrzej Czarnecki, Director, Deputy EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly & Co. Ltd., UK

TRACK 10 *CR, RA, CS* **11:00 – 12:30**

Formulations for Children

Session Co-Chairpersons:
Tony Nunn, Clinical Director of Pharmacy, Royal Liverpool Children's NHS Trust and Associate Director, Medicines for Children Research Network University of Liverpool, UK
Julie Williams, Head of Regulatory CMC, Pfizer Global R&D, UK

This session will introduce the need for paediatric formulations; it will examine what might be required in a paediatric investigation plan (PIP) from a regulatory perspective and will highlight the challenges for industry for aligning paediatric formulation development with the PIP. In addition, global formulation activities (NIH, WHO, Medicines for Children Network) and opportunities for collaboration will be discussed.

Needs for Paediatric Formulations
Tony Nunn, Clinical Director of Pharmacy, Royal Liverpool Children's NHS Trust and Associate Director, Medicines for Children Research Network, University of Liverpool, UK

Regulatory Expectations for Paediatric Formulation Development and Linkage to the Paediatric Investigation Plan
Nathalie Seigneuret, Scientific Administrator Safety and Medicines Sector, Pre-authorisation Unit, EMEA, EU

Pharmaceutical Industry Perspective on Paediatric Formulation Development: Progress and Challenges
Despina Solomonidou, Head Global Technical R&D Project Coordination, Novartis Pharma AG, Switzerland

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Session Six

TRACK 11 *CMC, RA* **11:00 – 12:30**

Quality for Investigational Medicinal Products

Session Chairperson:
Michael James, Head of CMC Regulatory Advocacy and Intelligence, GlaxoSmithKline, UK

The CHMP QWP guideline on the requirements to the Chemical and Pharmaceutical Quality Documentation concerning Investigational Medicinal Products in Clinical Trials was released as a final document in July 2006 and came into operation on 1st October, 2006. This session will summarise and discuss harmonisation efforts leading to the development of the guideline, as well as share experience following implementation, from both a regulatory and industry point of view. In addition, the requirements for an investigational medicinal product dossier for a biological product will be discussed from a regulatory perspective.

The Investigational Medicinal Product Dossier: A Regulatory View
Susanne Keitel, Head of EU, International Affairs, BfArM, Germany

The Investigational Medicinal Product Dossier: An Industry View
Michael James, Head of CMC Regulatory Advocacy and Intelligence, GlaxoSmithKline, UK

The Investigational Medicinal Product Dossier for A Biological Product – A Regulatory View
Brigitte Brake, Head of Unit, BfArM, Germany

TRACK 13 *CDM, OS* **11:00 – 12:30**

Managing Clinical Data Management: A Global Perspective

Session Chairperson:
Suzy De Cordt, Director, Data Management, Serono, Switzerland

This session looks at various management aspects in clinical data management, including technology, re-sourcing (out- and in- sourcing, different models of outsourcing), people management (cross-cultural and cross-functional matrix collaboration, virtual organisations), performance management (objective setting and alignment with overall business strategy, metrics, assessment).

Working in the Middle of a Global Matrix
Caroline Fenning, Global Head Data Management, F. Hoffmann-La Roche Ltd., Switzerland

Alternatives to Traditional Outsourcing, the FSP Model
Susan Bornstein, Vice President, Biopharma, Eliassen Group, Inc/Pfizer, USA
Tom Verish, Site Head CPW, Pfizer, USA

The Challenge of Growing Applied to Data Management
Yves Tellier, Head Clinical Data Management, GlaxoSmithKline Biologicals, Belgium

TRACK 14 *ST, CR* **11:00 – 12:30**

Recruitment Modelling and Prediction in Clinical Trials

Session Chairperson:
Vladimir V. Anisimov, Director, GlaxoSmithKline, UK

Existing techniques for patient recruitment planning and trial design are mainly deterministic and do not account for various uncertainties. The novel statistical techniques, simulation tools and software for modelling and prediction of patient recruitment in multicentre clinical trials will be considered. Developed tools allow predicting in time the number of patients and the recruitment time using enrolment data, simulating patient recruitment for various scenarios and providing recommendations on the adaptive adjustment of the study.

Design of Clinical Trials under Uncertainties in Prior Information
Valerii V. Fedorov, Group Director Research Statistics Unit, GlaxoSmithKline, USA

Predictive Modelling of Recruitment in Multicentre Clinical Trials
Vladimir V. Anisimov, Director, GlaxoSmithKline, UK

Software and Simulation Tool for Modelling and Predicting Multicentre Recruitment
Byron Jones, Senior Director Clinical Research and Development, Pfizer, UK

TRACK 15/16 *IT, DM, RA* **11:00 – 12:30**

Electronic Labelling in the European Union: PIM 2007 and Beyond

Session Chairperson:
Raun Kupiec, Associate Director, Regulatory Affairs, Process Management, Genzyme Europe BV, The Netherlands

The Product Information Management (PIM) system for the exchange and review of labelling within the Centralised Procedure went live for 2006. It represents a fundamental re-thinking of how labelling is submitted, managed and reviewed in the European Union. This session will examine initial experience, challenges, and future plans as PIM is extended to other procedures.

Practical Experience of a PIM Submission
Nilmini Murrell, Global Core Labelling Management, GlaxoSmithKline R&D, UK

Initial Agency Experiences with Implementing PIM Review
Regulator Agency representative invited

Key Issues in the Further Development of PIM
Raun Kupiec, Associate Director, Regulatory Affairs, Process Management, Genzyme Europe BV, The Netherlands

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Session Six

TRACK 18 *BT, GE, RA* **11:00 – 12:30**

Ongoing and Planned BMWP/CHMP/EMEA Activities, Proposals and Viewpoints

Session Chairperson:
Pekka Kurki, Head of Section, Biotechnology, National Agency for Medicines, Finland

The legal basis and overall guidance for similar biological medicinal products are now available and first biosimilar medicinal products have been licensed. New issues will emerge when more products enter clinical development, marketing authorisation and post-marketing phases. This session will focus on the new challenges for the regulators of similar biological products.

Ongoing and Planned BMWP/CHMP/EMEA Activities
Martina Weise, BfArM, Germany, Vice Chair of the CHMP Similar Biological Medicinal Products Working Party

Proposals and Viewpoints from Innovator's Point of View
Jacques Mascaro, Director, EU Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

Proposals and Viewpoints from Biosimilar's Point of View
Sandy Eisen, Chief Medical Officer, TEVA Europe, UK

TRACK 21 *PP* **11:00 – 12:30**

Counterfeit Medicines: How to Protect the Patient in Europe

Session Chairperson:
Martijn ten Ham, Consultant, Chair, Ad Hoc Working Group Counterfeit Drugs, Council of Europe, The Netherlands

At the EuroMeeting in 2006 we reported on some initiatives taken under the umbrella of the Council of Europe. During 2006 several other activities were developed and were reported at a big conference held in September 2006 in Moscow, in close collaboration with the Russian government and the Russian Pharmaceutical Society. One of the Russian organisers of the conference will comment on these presentations and present the situation in his country and explain how the government tries to cope with the problem through legislation, policy, and enforcement procedures. The situation in Eastern European countries also needs more attention. Modalities for collaboration in this area will be discussed.

One of the important projects in this context is the protection of the patient against counterfeit drugs. How can he or she be sure that he or she will receive what he needs in case of illness? The session will also deal with the position of the pharmaceutical industry, and discuss how industry can work together with the other parties concerned. In view of the high relevance of international collaboration, counterfeiting of pharmaceuticals becoming more and more internationally organised, the initiatives of the Council of Europe and the World Health Organisation will also be presented. Particular attention will be given to the IMPACT initiative from the WHO.

Introduction
Martijn ten Ham, Consultant, Chair, Ad Hoc Working Group Counterfeit Drugs, Council of Europe, The Netherlands

The Council of Europe and International Collaboration, in Particular with WHO
Domenico Di Giorgio, Senior Chemist Officer, Ministry of Health, Italy

Counterfeit Drugs: Developments in Eastern Europe
Alexander Bykov, Governmental and Public Affairs Manager, sanofi-aventis, Russia

Viewpoint from the European Pharmaceutical Industry
Thomas Zimmer, Head, CD Safety, Quality and Environmental Protection, Germany

TRACK 22 *GCP, RA* **11:00 – 12:30**

American and European GCP: Inspection Strategies

Session Chairperson:
Fergus Sweeney, Principal Scientific Administrator, EMEA, EU

Speakers from US and EU regulators, and from industry, will present an overview of issues and experiences with GCP inspections. Both EU and US authorities conduct inspections at sites across the world as well as within their respective jurisdictions. They will give their perspectives on GCP compliance and an update on emerging practical and regulatory issues.

European GCP Inspections from a Competent Authority Perspective: Strategies, Interfaces and Consequences
Gabriele Schwarz, Head GCP Inspection Services, BfArM, Germany

GCP at FDA: Metrics, Guidances, Initiatives and Strategies
David A. Lepay, Senior Advisor for Clinical Science, Science/Health Coordination and International Programs, Office of the Commissioner, FDA, USA

GCP Inspections in Europe: Experiences and Challenges – An Industry Perspective
Claire Massiot, Associate Vice President, Clinical Quality & Compliance, sanofi-aventis, France

TRACK 23 *GE, RA* **11:00 – 12:30**

New Pharmaceutical Legislation: Implementation of Key Provisions Related to Generic Medicines in Various EU MSs

Session Chairperson:
Beata Stepniewska, Pharmacist, Regulatory Affairs and EU Affairs, European Generic medicines Association, Belgium

The differences in the implementation of key provisions of the Dir 83/2001 as modified by the Dir 27/2004 related to generic medicines in various EU MSs will be presented. Discussion will focus on Article 10, particularly on the scope of the Bolar provision, implementation of the Global Marketing Authorisation concept and data exclusivity, definition of generic medicinal product etc. The practical impact of these differences on activities of the generic industry and competent authorities will be discussed from the points of view of:

A Legal Expert from the National Authorities
John Lisman, Attorney, NautaDutilh, The Netherlands

The European Commission
Irene Sacristàn Sànchez, Administrator, DG Enterprise and Industry, European Commission, EU

The Generic Industry
Beata Stepniewska, Pharmacist, Regulatory Affairs and EU Affairs, European Generic medicines Association, Belgium

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Session Seven

TRACK 24 *CR, BT* **11:00 – 12:30**

New Delivery Systems for Vaccines

Session Chairperson:
Luciano Nencioni, Head of Regulatory Affairs, Novartis Vaccines and Diagnostics, Italy

Quality Requirements and Regulatory Status in the European Union
Roland Dobbelaer, Chair of EMEA Vaccines Working Party, Scientific Institute Public Health, Belgium

New Developments in Vaccine Delivery
Derek O'Hagan, Director, Vaccine Adjuvants & Delivey Systems, Novartis Vaccines & Diagnostics, USA

Prioritisation of Vaccine Delivery Systems for Developing Country Needs
Martin Friede, Initiative for Vaccine Research, WHO, Switzerland

Panel discussion with session speakers and
Anne-Marie Georges, Consultant, AMQuid Pharma, Belgium

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TRACK 1 *RA, GE* **14:00 – 15:30**

SmPC and Package Leaflet Harmonisation: – A Challenge to Stakeholders

Session Co-Chairpersons:
Rhona Elliott, Worldwide Regulatory Strategy, Europe Strategy Line Manager Infectious Diseases, Pfizer, UK
Dagmar Stará, Head of Registration Unit, State Institute for Drug Control, Slovak Republic

The revised pharmaceutical legislation brought about a new legal framework supporting harmonisation of medicinal product information within the European Union. While ensuring development towards a high level of public health protection and completion of the internal market in pharmaceuticals, new requirements and correspondingly more complex regulatory processes present a challenge to all stakeholders.

Regulators' and industry views on the perspectives of a re-designed approach to SmPC harmonisation will be presented. First experience with the package leaflet harmonisation will be shared and discussed.

Package Leaflet Harmonisation: Background and Experience Gained
Christer Backman, EU Coordinator and Policy Advisor, MPA, Sweden

SmPC Harmonisation: The Regulators' Perspective
Dagmar Stará, Head of Registration Unit, State Institute for Drug Control, Slovak Republic

Harmonisation of SmPCs and PILs: Challenges and Achievements
Rhona Elliott, Director, Worldwide Regulatory Strategy, Europe Strategy Line Manager Infectious Diseases, Pfizer, UK
Mary Smillie, Senior Advisor Regulatory and Legal Affairs, European Generic medicines Association, UK

TRACK 2 *RA, PP* **14:00 – 15:30**

Present and Future: Regulatory Collaboration

Session Co-Chairpersons:
Patrick Le Courtois, Head of Unit Pre-Authorisation Evaluation of Medicines for Human Use, EMEA, EU
Brenton James, Consultant in Strategic Regulatory Affairs in the European Union, UK

Collaboration between regulatory agencies around the world is important for public health and for the development of innovative medicines by the research-based industry. This session will explore the breadth and depth of arrangements between European Agencies and the FDA and other countries and describe the types of exchanges and their frequency, as well as the transparency of exchanges.

Overview of EMEA Agreements with FDA and other Countries (Canada, Japan)
Arielle North, Scientific Administrator, Executive Support, EMEA, EU

Agreement by the Medical Products Agency in Sweden with the FDA
Thomas Kühler, Director of Operations, Medical Products Agency, Sweden

Scientific Discussion Between EMEA and FDA: The Cluster on Oncology Products
Francesco Pignatti, Scientific Administrator, Safety and Efficacy, 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.

Session Seven

TRACKS 3&11 *NC, CP, RA* **14:00 – 15:30**

Genotoxic Impurities

Session Co-Chairpersons:
Peter Kasper, Scientific Director, BfArM, Germany
Fritz Erni, Head Technical Liaison, Novartis Pharma AG, Switzerland

This session will describe the principles and practical implications of the new CHMP Guideline on the Limits of Genotoxic Impurities. The use of (Q)SAR methods in the early process of assessing genotoxicity of impurities as recommended by the guideline will be critically discussed as well as approaches to integrating toxicological and chemical aspects in the evaluation of acceptable levels of impurities.

CHMP Guideline on Limits of Genotoxic Impurities
Peter Kasper, Scientific Director, BfArM, Germany

Use of (Q)SAR Methods for Early Identification of Potentially Genotoxic Impurities
Susanne Glowienke, Senior Fellow, Novartis Pharma AG, Switzerland

Residues of Genotoxic Alkyl Mesylates in Mesylate Salt Drug Substances: Real or Imaginary Problems?
David Snodin, Vice President Non-Clinical, Parexel International Ltd., UK

TRACK 4 *CR* **14:00 – 15:30**

Business Models for Biomarker Development

Session Chairperson:
Amy Brower, Executive Director, Medical Informatics & Genetics, Third Wave Technologies Inc., USA

This session will present the business case for biomarker development, marketing and clinical implementation.

Incentives and Disincentives for Biomarker Development
Amy Brower, Executive Director, Medical Informatics & Genetics, Third Wave Technology, USA

Clinical Validation of Biomarkers
Lawrence Oliver, Scientific Director, Mayo Clinical Trials Services, USA

CDER Perspective and CDER/CDRH Interactions and Initiatives
Lawrence J. Lesko, Director Office of Clinical Pharmacology, CDER/FDA, USA

TRACK 5 *RD, CR, RA* **14:00 – 15:30**

Nanomedicine: Advances and Challenges

Session Chairperson:
Uta Faure, Principle Administration Unit "Nanosciences and Nanotechnologies", DG Research, EuropeanCommission, EU

Nanomedicine, the application of nanotechnology in healthcare, offers numerous very promising possibilities to improve medical diagnosis and therapy significantly, leading to an affordable higher quality of life for everyone. Very early and reliable diagnosis, intelligent drug delivery systems and smart regenerative medicine are key issues in this approach towards an effective treatment of plagues of mankind such as cancer, cardio-vascular diseases, diabetes, Alzheimer's and Parkinson's disease.

The European Technology Platform on Nanomedicine
Uta Faure, Principle Administration Unit "Nanosciences and Nanotechnologies", DG Research, EuropeanCommission, EU

Regulatory Challenges and Future Perspective of Nanomedicines
Marisa Papaluca Amati, Deputy Head of Sector Safety and Efficacy of Medicines, Pre-Authorisation Unit, EMEA, EU

Application of Nanoparticles Against Local Tumors
Andreas Jordan, CEO, Magforce, Germany

TRACK 6 *CR, RD, ST* **14:00 – 15:30**

Good Clinical Planning in the Preparation of Development Plans and Trial Protocols

Session Chairperson:
Sören Kristiansen, Director, Data Operations, Astellas Pharma GmbH, Germany

The clinical development plan outlines a series of clinical trials with the objective of generating data sufficient for the benefit risk assessment of a medicinal product. Based on the clinical development plan, clinical trial protocols are designed to generate data in line with this objective. Subsequently, the statistical analysis plan details the planned analyses outlined in the clinical trial protocol. This session will illustrate strategies of good planning and multi-disciplinary work during the drug development process in order to maximise the evidence generated for the benefit risk assessment of a new medicinal product.

Harnessing Uncertainty, the Importance of Clear Statistical Thinking in the Drug Development Plan
Andrew Stone, Therapeutic Area Statistical Expert Oncology, AstraZeneca, UK

Protocols Can Make or Break Your Clinical Study and Sometimes Your Product
Allen Cato, President, Cato Research, USA

The Role of the Statistical Analysis Plan in the Planning and Conduct of a Clinical Trial
Sören Kristiansen, Director, Data Operations, Astellas Pharma GmbH, Germany

TRACK 7 *CP, CR, GCP* **14:00 – 15:30**

Pharmacovigilance in Academic Trials

Session Chairperson:
Timothée Fraisse, Medecine Interne, Hôpitaux Universitaires de Genève, Switzerland

This session will address key safety and pharmacovigilance issues linked to the conduct of clinical trials within an academic framework. Speakers will primarily focus on practical issues and share their experience on the setting of pharmacovigilance tools in the ever-changing academic and regulatory environment.

Regulatory Requirements for Safety Monitoring in Clinical Trials
Andrzej Czarnecki, Director, Deputy EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly & Company Ltd., UK

Establishment of a Pharmacovigilance System in an Academic Environment
Christoph Gleiter, Head of Department, KKS TU GmbH, Germany

Risk Management in Academic Clinical Trials
Alain Leizorovicz, Director of Research, Université Lyon, France

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Session Seven

TRACK 8 *CP, GE, RA* **14:00 – 15:30**

Debate on The Future of Periodic Reports

Session Co-Chairpersons:
Rosalind Coulson, Safety Consultant, PRA International, UK
Arthur Meiners, Senior Medical Advisor, Johnson & Johnson Benefit Risk Management, The Netherlands

- The good, the bad and the ugly of current PSURs (and other aggregate reports)
- Are the concept and layout of ICH E2C outdated?
- Some suggestions for improvement which could be introduced prior to a full redesign

PSURs for Well-known Products – Now and in the Future
Wendy Huisman, EU QP, Teva Pharmaceuticals Europe

A Regulatory View on Current Practice and Possible Improvements
Sabine M. Straus, Head of Pharmacovigilance, Medicines Evaluation Board, The Netherlands

The CROs' Current and Future Contributions
Rosalind Coulson, Safety Consultant, PRA International, UK

TRACK 10 *CR* **14:00 – 15:30**

Network of Paediatric Research

Session Chairperson:
Gérard Pons, Head of Perinatal and Pediatric, University René Descartes & Groupe Hospitalier, Cochin/Saint-Vincent de Paul, France

- Lessons learned from existing networks (EU and US)
- Patients involvement in research.

Lessons Learned from the PPRU
Robert Ward, Professor of Paediatrics and Pharmacology, University of Utah, USA

Lessons Learned from a European Network
Fred Zepp, Director Paediatric Clinic, Johannes Gutenberg University, Germany

The Future of the European Network
Gérard Pons, Head of Perinatal and Pediatric, University René Descartes & Groupe Hospitalier, Cochin/Saint-Vincent de Paul, France

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TRACK13 *CDM, CP* **14:00 – 15:30**

Safety Data Management: "Working Smarter Together"

Session Chairperson:
Barry Burnstead, Director of Project Management, i3 Statprobe, UK

Pharmacovigilance and clinical data management operations have traditionally established parallel activities around the management of safety data. Consistency has been addressed by performing serious adverse event reconciliation and little else. Advances in technology have provided us with rapid clinical data collection whilst offering tools to improve data quality at source. Today we have the attention of regulators and the general public to protect our patients by improving our safety surveillance in the early phases of clinical development. These trends have resulted in pressure upon both operations to work together and identify more efficient processes so that we "work smarter together." This session will address specific aspects of cooperation in managing and analysing safety data.

Efficiencies Gained from Centralised Coding and Dictionary Management
Jane Knight, Head of Global Thesaurus Management, Roche, UK

Single Source Reporting of SAEs with EDC: Pilot Project Update
Bina Patel, Director Case Management Group, Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline, UK

Specific Requirements for EDC Oncology Trials to meet Clinical, Safety and Regulatory Expectations
Ulrich Räth, Vice President Oncology, i3research-SKM Oncology, Germany

TRACK 14 *ST* **14:00 – 15:30**

Statistical Approaches in Pharmacogenomics: Prediction Revisited

Session Chairperson:
Richardus Vonk, Executive Director, Non-Clinical Statistics, Schering AG, Germany

Within Pharmacogenomics the results of RNA expression profiles are used for the prediction of treatment outcomes and/or the prognosis of disease courses. Examples of statistical methods to support this will be given. Also, the pitfalls of such evaluations will be addressed.

Be Sure to Treat the Responders: Optimisation of Classifiers Towards High Sensitivity
Susanne Schwenke, Director Non-Clinical Statistics, Schering AG, Germany

Using Gene Ontology to Analyse Microarray Data
Jelle Goeman, Medical Statistics, University of Leiden, The Netherlands

Gene Selection for Disease Identification Using Microarrays
Luc Bijnens, Research Fellow, Director Biostatics Europe, Janssen Pharmaceutica NV - JJPRD, Belgium

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Session Seven

TRACK 15/16 *IT, DM, RA* **14:00 – 15:30**

Translation of Product Information and the Value of Translation Memories

Session Chairperson:
Stephen Hasler, Vice President, Operations & Systems, European Regulatory Affairs, GlaxoSmithKline, UK

Translation of product information is on the critical path in the review and approval of new products and is a key element in the lifecycle maintenance of products. Through the use of translation memories it should be possible to increase both the quality and the efficiency of translations and speed up the review process. This session will cover the background to translation processes and a report on a project to make EMEA's translation memories publicly available.

The Potential Benefit of Rolling Translations and the Use of Translation Memories
Matthias Heyn, Vice-President Business Consulting, SDL International, Belgium

Analysis of Approved Translations by the EMEA: The Potential to Establish a Translation Memory
Hans-Georg Wagner, Head of Unit Communications and Networking, EMEA, EU

Progress on a Proposal to Establish a Shared Translation Memory for Regulators and Industry
Robert Vogel, Global Head Regulatory Operations, F. Hoffmann-La Roche Ltd., Switzerland

TRACK 18 *CP, RA* **14:00 – 15:30**

INN/Trade Names of Biosimilars and the Impact on Substitution Therapy

Session Chairperson:
Roger Tredree, Chief Pharmacist, St. George's Healthcare NHS Trust and Visiting Professor at Kingston University, UK

Switching patients between biosimilar medicinal products is not only poor clinical practice for chronically administered drugs, but could also create problems when attributing adverse events. This is especially true with immune responses of biologics because of the significant delay between drug administration and the onset of symptoms. There is a need for unambiguous nomenclature for biosimilars if post-marketing surveillance data are to be meaningful. This session will explore the applicability of the current WHO naming policy to biosimilars to prevent generic substitution and, if not, the feasibility for distinct INNs/trade names for biosimilars to support effective post-marketing pharmacovigilance.

A Different Point of View of Biosimilar Companies
Klaus Martin, Head Clinical Development Biopharmaceuticals, Sandoz, Germany

The Point of View from the WHO Expert Group
Lembit Rägo, Coordinator, Quality, Assurance & Safety Medicines Department of Essential Drugs, WHO, Switzerland

The Point of View from the Healthcare Professionals
Roger Tredree, Chief Pharmacist, St. George's Healthcare NHS Trust and Visiting Professor at Kingston University, UK

Panel discussion with session speakers and **Brigitte Keller-Stanislawski,** Head of Unit, Paul-Ehrlich Institute, Germany and **Thomas Bols**, Director Government Affairs Europe, Amgen, Belgium

TRACK 21 *RA, MA, PP* **14:00 – 15:30**

The Role of Marketing Codes in Regulating Marketing Practices: An Update

Session Chairperson:
Richard Bergström, Managing Director, LIF, Sweden

During the last few years the European industry association, EFPIA, and the international association, IFPMA, have adopted new and stricter self-regulatory codes for marketing practices. The EFPIA Code has been in full force since January 2006 and the new IFPMA Code will be effective from January 1, 2007. The codes are similar in terms of content, but the provisions for complaints and sanctions differ. With its new Code, IFPMA has launched a network of compliance officers from companies and national associations to work on education and prevention of breaches. This session will update participants on the introduction of these codes and to provide a forum for discussion of current topics relating to industry marketing codes.

The New IFPMA Code - Status of Implementation
Frédérique Santerre, Director, IFPMA, Switzerland

How Will the New EFPIA and IFPMA Codes Work in Practice? Will They Have Any Impact?
Richard Bergström, Chair of IFPMA Code Compliance Network, LIF Sweden

The Role of Companies in Implementing Industry-wide Codes of Practice
Paul Woods, Head, Promotional Affairs, AstraZeneca, UK

Panel discussion with session speakers and **Jose Zamarriego,** Director, Farmaindustria, Spain and **Heather Simmonds**, Director, PMCPA, UK

TRACK 22 *GCP, CR, RA* **14:00 – 15:30**

The Use of IMPs and the Impact on Clinical Research

Session Chairperson:
Pierre-Henri Bertoye, Head, Department of Inspection of Clinical & Non-Clinical Trials, Afssaps, France

Quality and traceability of IMPs is of great importance for the safety of the trial subjects and the quality and reliability of data. A common definition of the IMP and common expectations in terms of actors, channels and documentation must be established in this context. This session will explore current difficulties met and possible solutions for overcoming them.

IMP: Definition and Consequences, Expectations Traceability from the Assessor
Pierre-Henri Bertoye, Head, Department of Inspection of Clinical & Non-Clinical Trials, Afssaps, France

Issues for Industry
Nick Sykes, Associate Director, Worldwide Regulatory Affairs and Quality Assurance, Pfizer, UK

Issues for Academic Research
Monique Podoor, Data Center Director, EORTC, 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.

Session Eight

TRACK 24 *CR, BT* **14:00 – 15:30**

Stem Cell Therapy: Clinical, Regulatory and Ethical Challenges

Session Chairperson:
Joy Cavagnaro, President, Access BIO, USA

Over the past five years stem cell technologies have advanced not only into early but also mid-stage clinical trials. Stem cell therapies, however, present unique challenges to ultimate commercialisation. A core set of safeguards has been required to ensure advancement of stem cells in clinical development. These safeguards are derived from a multidisciplinary coordinated approach. Key scientific and regulatory considerations in developing stem cell therapies will be highlighted as they apply to manufacturing, preclinical and clinical development as well as the climate surrounding the ethics of stem cell research. At the conclusion of the session, participants should be able to understand the differences between the various types of stem cells, including the key steps in manufacturing and distribution, approaches to preclinical study design for enabling FIH studies and special considerations in clinical trials design, as well as analysis for later stage trials and the current ethical considerations relating to stem cell research.

Overview of Critical Steps in the Manufacture and Delivery of Stem Cell Therapies
Mahendra Rao, Vice President Research in Regenerative Medicine and Stem Cell Technologies, Invitrogen Corp., USA

Key Considerations in Pre-Clinical and Clinical Development of Stem Cell
Joy Cavagnaro, President, Access BIO, USA

Global Benchmark on the Challenges for Stem Cell Products
Annick Schwebig, Director General, Actelion, France

Panel discussion on **Ethical Concerns in Developing Stem Cell Therapies and the View from the Patient** with session speakers and **Fabrizia Bignami,** Therapeutic Development Officer, EURORDIS, Europe

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TRACK 1 *RA, PP, RD* **16:00 – 17:30**

Assisting SMEs in a Highly Complex EU

Session Co-Chairpersons:
Melanie Carr, SME Office, Scientific Advice and Orphan Drugs Sector, Pre-Authorisation Unit, EMEA, EU
Rosmarie Dick-Gudenus, Vice President Development, Green Hills Biotechnology GmbH, Austria

Promoting innovation and development of new medicinal products by micro-, small- and medium-sized enterprises (SMEs) is an important initiative of the European Commission which is also supported by national and regional efforts. New legislation aimed at promoting innovation and the development of new medicinal products by SMEs entered into force in the EU in December 2005. This session will provide insight into whether the recent EU initiatives and the efforts of the EMEA to address the particular needs of SMEs have improved the situation. The regulatory approval process will be presented from an SME company's perspective, together with practical advice from the SME office on how to access assistance from the EMEA, and an account of the experiences of one of the first SMEs to gain access to the new initiative.

The Centralised Procedure from the Perspective of an SME
Anita Osborne, Director of Regulatory Affairs, Rheoscience, Denmark and Chair of the EBE Regulatory & Technical Affairs Committee

Assistance Available from the SME Office
Melanie Carr, SME Office, Scientific Advice and Orphan Drugs Sector, Pre-Authorisation Unit, EMEA, EU

Industry's Experience with the SME Initiative to Date
Tom Vanthienen, Director Regulatory Affairs Europe, Neurochem, Switzerland

TRACK 2 *RA, PP* **16:00 – 17:30**

EU Enlargement: Viewpoint on the Regulatory Changes brought about by EU Enlargement

Session Chairperson:
Rolf Bass, retired from BfArM, Germany

This session will address the regulatory changes brought about by EU enlargement. EU enlargement is a continuous process, which raised the membership from 6 to 15 States until 1995, then peaked in 2004, and will certainly continue on a rolling basis in the future. This implies that candidate and new member states will have different starting levels of relevant legislation, procedures, and science. While in 1995 and 2004 enlargement and "big" new legislation coincided, this may be different in the future. Whereas both scenarios offer advantages and drawbacks, preparation, training by and collaboration with the EU and especially the most recent new member states is essential.

Viewpoint of a Recent New Member State
Vesna Koblar, Counselor to the Government, Agency for Medicinal Products, Slovenia

Viewpoint of a New Member State
Rodica Badescu, Vice President National Medicines Agency, Romania

Industry Contribution: Lessons Learned and Expectations/Wishes for the Future
Kerstin Franzén, Director Regulatory Policy and Intelligence, Pfizer AB, Sweden

Future Visions and Requirements
Birka Lehmann Director and Professor, Head of Licencing Division 3, BfArM, Germany

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Session Eight

TRACKS 3&11 *NC, CP, RA* **16:00 – 17:30**

Genotoxic Impurities and Residues of Metal Catalysts

Session Co-Chairpersons:
Bernard Leblanc, Director, Regulatory Submissions & External Relations Safety Sciences, Pfizer, France
Jean-Louis Robert, Head of Department, Department of Quality Control of Medicines, Laboratoire National de Santé, Luxembourg

This session will be a continuation of the session on genotoxic impurities. Two speakers will present their perspectives on the final CHMP guideline on genotoxic impurities and the draft CHMP guideline on residues of metal catalysts. The issues raised will be further discussed by a panel comprising the chairs and speakers from both sessions.

Quality Issues of Genotoxic Impurities and Residues of Metal Catalysts: Industry's View
Fritz Erni, Head Technical Liaison, Global Quality Operations, Novartis Pharma AG, Switzerland

Safety Limits for Residues of Metal Catalysts
Bert-Jan Baars, Senior Toxicologist and Risk Assessor, RIVM, The Netherlands

Panel discussion on Genotoxic Impurities and Residues of Metal Catalysts with Session Co-Chairpersons and speakers from Session 7 and 8.

TRACK 4 *CR, CP, NC* **16:00 – 17:30**

Systems Biology and Translational Medicine

Session Chairperson:
Joachim Reischl, Translational Medicine Support, Pharmacogenomics Oncology and CNS, Bayer Schering Pharma AG, Germany

Systems biology aims at overcoming the reductionist approach by integrating information of various data sources (genomics, proteomics, imaging etc.) and seeks to understand and predict the behaviour of complex biological processes. In that respect systems biology might be crucial for translational medicine in both directions from bench to bedside and from bedside to bench.This session will explore to what extent systems biology concepts and tools can be applied to translational medicine in getting a better understanding of disease processes, drug reactions and the predictivity of in vitro and in vivo models.

Adding Meaning to the Flood of Data to Facilitate Translational Medicine
Peter van der Spek, Professor, Erasmus MC, Department of Bioinformatics, The Netherlands

Opportunities for Translational Research for Affective Disorders
Irina Antonijevic, Principal Scientist, Lundbeck Research Inc., USA

Mechanistic PK/PD Modelling and Systems Biology: New Tools for Decision Support in Pharma R&D Projects
Jörg Lippert, Head of Systems Biology, Bayer Technology Services GmbH, Germany

TRACK 5 *RD, CR* **16:00 – 17:30**

Challenges of Antibio-resistance Therapy

Session Chairperson:
Otto Cars, Professor, Uppsala University Hospital, Sweden

This panel will discuss the growing and urgent challenge of antibiotic resistance to human health and to the broader ecology of our environment. The treatment options for many bacterial species are becoming seriously limited, leading to increased morbidity and mortality. From an industry perspective, we will understand the scientific, R&D, and commercialisation challenges that explain the dearth of new antibacterial drugs. We will explore a framework of potential solution paths forward, from public-private partnership arrangements to the handling of intellectual property that responds to these concerns. Suggesting exemplars of how these upstream R&D decisions might affect downstream access would also give important context to these discussions.

The Rising Problem of Antibiotic Resistance and the Need for New Drugs - a Policy Challenge
Otto Cars, Professor, Uppsala University Hospital, Sweden

Scientific and Commercial Hurdles for R&D
David Payne, Director and Head of Microbiology Department GlaxoSmithKline, USA

Innovative Arrangements to Encourage R&D of Antibacterials from a Public Health Perspective
Anthony So, Senior Research Fellow in Public Policy and Law, Director, Program in Global Health and Technology Access, Duke University, USA

TRACK 6 *CR, CTM* **16:00 – 17:30**

Managing the Key Challenges of Running Global Expanded-Access Programmes

Session Chairperson:
Anne-Yvonne Kermabon, Associate Project Director, Parexel, France

There are numerous challenges to be considered when running global expanded-access programme. Major aspects that should be considered are overall program set-up and co-ordination, and medical considerations. If these are implemented correctly, valuable data can be generated.

Opportunities and Challenges of an EAP
Régine Buffels, Associate Director Medical International Affairs, Biogen IDEC, Switzerland

Medical Considerations
Géraldine Honnet, Project Manager Virology, Janssen-Cilag SA, France

Challenges from the Data Point of View: Generating Valuable Data
Beatrix Lutiger, Associate International Medical Leader, F. Hoffmann-La Roche Ltd., 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.

Session Eight

TRACK 7 *CTM, DM, GCP* **16:00 – 17:30**

Regulatory Authorities' Expectations of Quality in Academic Clinical Trials

Session Chairperson:
Fergus Sweeney, Principal Scientific Administration, EMEA, EU

Academic clinical trials with medicinal products are subject to the requirements of the Clinical Trials Directive 2001/20/EC. The sponsors of these trials need to be able to fulfill their responsibilities for the preparation, performance and reporting of their clinical trials, the study medication handling and the documentation. These responsibilities include monitoring and SUSAR reporting. Academic groups conducting trials may not have had the appropriate processes in place. In this session GCP inspectors' expectations will be compared, experiences with inspections presented and recommendations provided on how to efficiently and economically establish GCP-compliant processes for an academic site/sponsor.

Experiences with Inspections of Academic Sites Made in Sweden
Gunnar Danielsson, Pharmaceutical Inspector, MPA, Sweden

Expectations of the Quality of Academic Trials in France
Pierre-Henri Bertoye, Head, Department of Inspection of Clinical & Non-Clinical Trials, Afssaps, France

Challenges and Opportunities for an Academic Site to Establish a Quality Assurance System
Christian Ohmann, Professor, Heinrich-Heine-University, Germany

TRACK 8 *CP, RA* **16:00 – 17:30**

The Role of the EU Qualified Person for Pharmacovigilance

Session Chairperson:
Barry Arnold, Vice President, Clinical Drug Safety, AstraZeneca, UK

This session will review current regulatory expectations with regard to the role of the EU Qualified Person for Pharmacovigilance, as updated with the implementation of Volume IXa of the Notice to Applicant. In addition to defining current regulatory authority expectations, industry speakers will present their personal experiences in meeting such expectations.

The Evolution of the Role of the EEA Qualified Person for Pharmacovigilance
Anya Sookoo, Expert Inspector, GCP & Pharmacovigilance, MHRA, UK

Challenges for a New EU QP in a Non-EU-based Pharmaceutical Company
Vicki Edwards, Director, European Pharmacovigilance, Abbott Laboratories, UK

Challenges of Being the EU QP for Pharmacovigilance in a Middle- Sized Japanese Company
Pauline Gerritsen, European Director, Drug Safety and Pharmacovigilance, Astellas Pharma, Inc., The Netherlands

TRACK 10 *CP, CR, RA* **16:00 – 17:30**

Paediatric Pharmacovigilance

Session Co-Chairpersons:
Gaby Danan, Expert, Global Pharmacovigilance and Epidemiology, sanofi-aventis, France
Dirk Mentzer, Head of Pharmacovigilance Unit, Paul-Ehrlich Institute, Germany

This session will provide highlights on the recently released EMEA guideline on pharmacovigilance in the paediatric population and how Eudravigilance database can be used in this respect. Attention will be given to methods used in pharmacoepidemiology and how they can be applied to signal detection in the paediatric population. Finally the relevant sections of the EU Risk Management Plan will be addressed in order to discuss various situations specific to this population such as off-label use and adverse events that could affect growth and development.

EMEA Guidelines on the Conduct of Pharmacovigilance in the Paediatric Population and Use of the EudraVigilance System
Sabine Brosch, Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA, EU

Paediatric Pharmacovigilance: Challenges for Pharmaceutical Companies
Klaus Rose, Head, Paediatrics, F. Hoffmann-La Roche Ltd., Switzerland

Paediatric Pharmacovigilance Addressed in the EU Risk Management Plan
Dirk Mentzer, Head of Pharmacovigilance Unit, Paul-Ehrlich Institute, Germany

TRACK 13 *CDM, EC, RD* **16:00 – 17:30**

Optimising R&D through System Integration

Session Chairperson:
John Aggerholm, Senior Project Manager, NNIT, Denmark

System integration has always been important, but has been a job for the IT department to initiate and keep track of. Today with eClinical projects requiring a detailed process view – using a Business Architecture as basis – it's the clinical line organisation that is in the lead of requiring and tracking integration. Benefit from the experience of those who have created this insight and used it to create remarkable benefits for the clinical organisation.

Integration of IVRS, EDC, CDMS and CTMS in an eClinical Programme: Case Study
Christian Grøndahl, Project Vice President, Novo Nordisk A/S, Denmark

How to Integrate Clinical Systems to Support a CDW Solution
Mathias Poensgen, Clinical Operations, ALTANA Pharma AG, Germany

Process Optimisation and Systems Integration: A Business Architecture Approach
Michael Bartlett, System Project Manager, H. Lundbeck A/S, Denmark

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

Session Eight

TRACK 14 *ST, CTM* **16:00 – 17:30**

Implementing Adaptive Randomisations for Clinical Trials

Session Chairperson:
Eva Miller, Associate Director, Biostatistics, Almac Clinical Technologies, USA

Probabilistic baseline covariate adaptive randomisation (pBAR) is used to support the statistical methodology of a clinical trial by maintaining balance among treatments for the analysis population and subgroups. With pBAR, individual subject response information is maximised: especially important for rare diseases, medical devices or when enrollment is difficult.

Implementing Adaptive Randomisations for Clinical Trials
Eva Miller, Associate Director, Biostatistics, Almac Clinical Technologies, USA

Evaluation of Minimisation in a Phase IIa Multi-Centre International Clinical Trial
Dan Schnell, Procter & Gamble Pharmaceuticals, Inc., USA

Panel discussion on **Appropriate Scientific and Experimental Justifications for Using Adaptive Trial Designs from a Regulatory Perspective** with session speakers and **Armin Koch,** Biostatistician, BfArM, Germany

TRACK 15/16 *IT, CP, DM, RA* **16:00 – 17:30**

EudraCT, EVMPD, EuroPharm and Security

Session Chairperson:
Timothy Buxton, Head of Sector Project Management, EMEA, EU

EU Telematics applications are involved through the lifecycle of a product. EU Telematics applications have been released as a set of individual systems. The goal of this session is to impart an understanding of the common elements between these systems, where data is re-used, and how common aspects are harmonised in the interests of efficiency and interoperability. The session also considers security across the systems. The presentations conclude with an industry view of the applications, and interaction in their development and implementation.

Pan-European Systems: Communication Essentials
Stefano Cappe, EudraVigilance Administrator, EMEA, EU

EU Telematics: Coherence in Implementation
Timothy Buxton, Head of Sector Project Management, EMEA, EU

EU Telematics: An Industry Perspective
Gerhard W. Schlueter, Head Global Regulatory Operations, Bayer HealthCare AG, Germany, representing EFPIA

TRACK 18 *FI, GE, MA* **16:00 – 17:30**

Increasing Role of Biologicals in Pharmacotherapy: Forecast for Economic Consequences to the Healthcare System: Pricing and Reimbursement

Session Chairperson:
John Lisman, Attorney, NautaDutilh, The Netherlands

This session will focus on the impact of the increasing use of biologicals on healthcare budgets and the healthcare system. Presentations will deal with biosimilars, biological innovation and cost/effectiveness of biologicals.

The Competitive Implications of Biosimilars
Tim Wilsdon, Principal, CRA International, UK

Is Biological Innovation Sustainable within Current Healthcare Budget Restraints?
Raphael de Wilde, Vice President Health Economics and Pricing B.I.O., Johnson and Johnson Pharmaceutical Services, P.a. Janssen Pharmaceutica NV, Belgium

Requirements to Realise the Healthcare Economics Potential of Biosimilars
Tim Oldham, Vice President Strategic Partnerships, Mayne Pharma, UK

TRACK 21 *PP* **16:00 – 17:30**

Added Therapeutic Value and Health Technology Assessment

Session Chairperson:
Richard Bergström, Managing Director, LIF, Sweden

This session will provide an update on the progress at the European level in moving towards a consensus view on the best practices of HTA. Over the last few years various stakeholders have come closer to realising the potential benefits of sound HTA for identifying the best treatment options, taking into account the different roles and needs of stakeholders, including patients, healthcare systems and payers, and the pharmaceutical industry. This session will comprise three presentations and be followed by a discussion involving both the panel and the audience.

The EU High-Level Group Pharmaceutical Forum: Progress of the Working Group on Relative Effectiveness
Speaker to be confirmed

EUnetHTA: Its Role in Sharing Information and Promoting Best Practices in HTA
Finn Borlum Kristensen, Project Leader, European Network for Health Technology Assessment (EUnetHTA), Denmark

Best Practices in Assessing Value and Patient Benefit of New Medicines
Richard Bergström, Managing Director, LIF, Sweden, representing EFPIA

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

Session Eight

TRACK 22 *GCP, CR, RA* **16:00 – 17:30**

Clinical Quality Management for Phase I Clinical Studies: Challenges and Pitfalls

Session Chairperson:
Olivier Le Blaye, Clinical Trial Inspector, Afssaps, France

The quality of phase I trials is of the utmost importance to the sponsors taking stop-or-go decisions on drug development, to the CROs wanting to continue to exist and to gain new clients and to the regulatory authorities who have to protect the subjects participating in the trials and the patients who will eventually receive the products, once they are approved.

Quality Management in Phase I Clinical Trials: A Sponsor's Perspective
Anne-Laure Prieur, Senior Quality Manager, Quality and Compliance, Clinical Domain, sanofi-aventis, France

Quality Management in Phase I Clincial Trials: A CRO's Perspective
Shane Comiskey, QA Manager, MDS PS, UK

Quality Management in Phase I Clinical Trials: An Inspector's Perspective
Olivier Le Blaye, Clinical Trial Inspector, Afssaps, France

TRACK 24 *CR, CP, BT, GE* **16:00 – 17:30**

Progess in Immunogenicity and Risk Management for Biotechnology-Derived Products and Biosimilars

Session Chairperson:
Iman Barilero, Associate Director, European Regulatory Affairs, Global Regulatory Affairs and Quality Assurance, Johnson & Johnson Pharmaceutical Group, UK

Immunogenicity may occur throughout the lifecycle of biological/biotechnology-derived proteins, including biosimilars. The detection and monitoring of immunogenicity are therefore an essential part of the development and post-marketing safety surveillance of biological medicinal products. The assessment of immunogenicity requires an optimal antibody-testing strategy, which is an integral component of the risk management plan. This session will provide a regulatory update on the new EMEA/CHMP guideline on immunogenicity and experience from review of applications. It will provide the opportunity to share the experience with EPREX/ERYPO Prospective Immunogenicity Surveillance (PRIMS) registry, as well as to hear the point of view of a biosimilar company in developing risk management associated with immunogenicity.

CHMP Guideline and Regulatory Experience, Update on Standardisation and Methodology of AB Testing
Jean-Hugues Trouvin, Afssaps, Chair CHMP BWP, France

EPREX/ERYPR Prospective Immugenicity Surveillance (PRIMS) Registry
Els Vercammen, Senior Director, Johnson & Johnson Haematology/Oncology, UK

EU Risk Management Plans for Biosimilar Products
Sandy Eisen, Chief Medical Officer, TEVA Europe, UK

Save the Date!

DIA 43rd Annual Meeting

Atlanta, Georgia, USA

Georgia World Congress Center

June 17-21, 2007

Visit www.diahome.org

DIA
Drug Information Association

Exhibiting companies as of October 27, 2006

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AGES, Austria
Almac Clinical Technologies, United States
Amgen Ltd., United Kingdom
Applied Clinical Trials, United States
ArisGlobal, United Kingdom
ARX (Algorithmic Research), Israel
ASIAN Clinical Trials, India
Averion International Corp., United States
B&C International, Belgium
BaseCon A/S, Denmark
Bassilichi, Italy
Bio-Imaging Technolgoies Inc., United States
BioProof AG, Germany
BioStorage Technologies, United States
Cambridge Cognition Ltd., United Kingdom
Capio Diagnostik, Denmark
Cardiocore, United States
CCL Label, The Netherlands
CentraLabs, United Kingdom
Charles River Laboratories, United Kingdom
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Diapharm Gruppe, Germany
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ECRON, Germany
Elsevier, The Netherlands
EMEA, EU
entimo AG, Germany
eResearch Technology, United States
Esoterix Clinical Trials – A Labcorp Company, Belgium
etrials Worldwide, United States
Eurofins Medinet, The Netherlands
European Pharmaceutical Executive, United Kingdom
Eurotrials, Portugal
Fast Track Systems, United States
Ferraris Respiratory, United States
Fisher Clinical Services, United Kingdom
Galt Associates, Inc., United States
GB Pharma Services Consulting, Italy
Geny Research Group, Inc., United States
Global Clinical Trials, United States
Globex Couriers GmbH, Germany
Global Outsourcing Review (GOR), United Kingdom
Hannover Clinical Trial Center GmbH, Germany
Hertford Cardiology, United Kingdom
HFL Ltd., United Kingdom
i3 StatProbe, United States
IABG Life Sciences Solutions GmbH, Germany
IKP GmbH, Germany
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IMRO TRAMARKO, The Netherlands
INC Research, United States
Infermed Ltd., United Kingdom
INPUT Clinical Research GmbH, Germany
IntraLinks, United States
JWS-Research, Austria
Kelly Scientific Resources, United States
Kendle, Germany
Lambda Therapeutic Research Ltd., Germany
Lorenz Life Sciences Group, Germany
MARKEN, France
MedDRA MSSO, United States
MedFiles, Finland
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MSource, Belgium
NDA Regulatory Science Ltd., United Kingdom
NNIT, Switzerland
Nova Language Services., Spain
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PharmaNet, United Kingdom
Pharmalink Consulting Ltd., United Kingdom
Phase Forward, United Kingdom
PHT Corporation, United States
PRA International, United States
PSI Pharma Support International, Switzerland
Quadramed Ltd., United Kingdom
Quality and Compliance Consulting, Inc., United States
Quest Diagnostic, United States
Quintiles, United Kingdom
QUMAS, Ireland
Regulatory Pharma Net, Italy
Relsys, United States
Remedium Oy Ltd., United Kingdom
RSA, United Kingdom
RWD Technologies, United States
Sequani Clinical, United Kingdom
SGS, Belgium
Simbec Research Limited, United Kingdom
Sparta Systems, Inc., Israel
Statistical Solutions, Ireland
Synarc, United States
Synexus Clinical Research PLC, United Kingdom
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To secure your company's presence at the EuroMeeting exhibition 2007, please contact Phyllis Suter on +41 61 225 51 54 or email: phyllis.suter@diaeurope.org

YOU ARE INVITED TO AN AUSTRIAN SATELLITE MEETING ON:

AUSTRIA – An Important Player in the EU-Network for Pharmaceuticals: Driving Innovations in Austria

Tuesday, March 27, 2007
18:00 to 19:30

Moderator:
Dr. Christa Wirthumer-Hoche, AGES PharmMed

AGES PharmMed
Prof. Dr. Marcus Müllner, Director of AGES PharmMed
The new Austrian Agency for Medicinal Products and Medical Devices
– Mission
– Organisation
– Communication with the stakeholders
– Future strategic targets

Pharmig – Association of the Austrian Pharmaceutical Industry
Dr. Jan Oliver Huber, Secretary General
Austria as an Attractive Pharmaceutical Research Location
– General regulations: health policy, guidelines, legal requirements
– Business environment
– Ensuring access to medical progress for patients
– High level of training facilities – Austrian universities and colleges of higher education offering staff with know-how in new technologies

Intercell AG
Univ. Prof. Dr. Alexander von Gabain, Chief Scientific Officer
Intercell – From Academia to a Listed and International Biotech Player
– Starting up in Austria against all odds
– A mature biotech player with worldwide pharma partners
– The future of biotech/pharma in Europe

Boehringer Ingelheim Austria
Dr. Kurt Konopitzky, Head of Division Biopharmaceuticals and Operations and **Mag. Edeltraud Stiftinger**, Chief Executive Officer, Center for Innovations and Technology
Biopharmaceuticals: Development and Production in the Viennese Environment
– Technological innovations
– State-of-the-art technology
– New pharmaceutical production in Vienna

The Austrian Satellite Meeting is open to everyone, however space is strictly limited. To reserve your place at the Austrian Satellite Meeting, please contact: euromeeting2007@diaeurope.org or visit www.diaeurope.org.

AGES PharmMed:

The authorisation and registration of human and veterinary medicinal products and medical devices in Austria has been reorganised. On January 2, 2006, the responsibility for the following tasks was transferred to the Austrian Federal Agency for Safety in Health Care (BASG) and its operative agency AGES PharmMed (Austrian Medicines and Medical Devices Agency). The duties of the agency include:

- *Assessment of quality, efficacy and safety of medicines and medical devices*
- *Pharmacovigilance*
- *Assessment, authorisation and inspection of clinical trials*
- *Provision of Scientific Advice;*
- *Authorisation and Inspection of manufacturers and marketing authorisation holders*
- *Post-marketing-surveillance and laboratory control (OMCL) to safeguard public health*

Executive Director: Prof.Dr. M.Müllner
Deputy: Dr. Ch. Wirthumer-Hoche

www.ages.at

AGES Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH

PHARMIG

PLEASE JOIN US FOR A JAPANESE REGULATORY SESSION ON:

PMDA Challenges for Global Drug Development including Japan

Wednesday, March 28, 2007
11:00 to 12:30

Moderator:
Prof. Sunshuke Ono, Associate Professor, Graduate School of Pharmaceutical Sciences, The University of Tokyo, Japan

This session highlights recent progress in including Japan in truly global development programmes, including issues in evaluating the acceptability of non-Japanese data in Japanese regulatory submissions, how observations in Asian populations can hold critical information for populations in Europe, issues encountered in the use of pivotal data from Japan in EU submissions and practical issues faced in performing global clinical trials that simultaneously include study sites in Europe and Japan.

Challenges to Promote Global Drug Development Including Japan
Shuuichi Kishida, Senior Executive Director and Chief Safety Officer, Pharmaceuticals and Medical Devices Agency, Japan

Recent Examples of Approved Drugs based on Data from Multi-Regional Clinical Trials
Kazuhiko Mori, Associate Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency, Japan

Perspectives for Global Drug Development Strategy
Yoshiaki Uyama, Deputy Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency, Japan

OFFICIAL TRAVEL AGENCY FOR THE DIA EUROMEETING 2007

Austropa Interconvention
Verkehrsbuero-Ruefa Reisen GmbH
Contact: Manuela Jung
Friedrichstrasse 7, 1010 Vienna, Austria
Tel. +43 1 588 00-512, Fax +43 1 588 00 520
E-mail: dia2007@interconvention.at

Austropa Interconvention has been appointed as the official accommodation agent for the DIA 19th Annual EuroMeeting and has pre-booked rooms in selected hotels in and around the Vienna city centre and the conference venue, in all categories, at the best possible rates. These rooms will be allocated to EuroMeeting delegates free of any handling fee. To book hotel accommodation online, please visit:
http://www.austropa-interconvention.at/congress/dia/index.asp

DEADLINE FOR HOTEL RESERVATION IS FEBRUARY 1, 2007

We recommend that you make your hotel reservation as soon as possible, as rooms will be allocated on a first-come, first-served basis. To secure your room reservation a hotel deposit payment of one night per booked room is required. If the hotel requested is fully booked, Austropa Interconvention will book for you an equivalent accommodation. After February 1, 2007, the availability of rooms and rates cannot be guaranteed.

The rates indicated are in EUR per room, per night, with bath or shower/WC and include breakfast (if not otherwise stated), service charge and local taxes.
The conference venue "Austria Center Vienna" is situated at the underground station U1, "Kaisermühlen – Vienna Int. Centre".

Hotel	Single room	Double room	Underground connection
HOTELS *****			
Grand Hotel Wien*	225,00	266,00	U1 Karlsplatz
Hilton Vienna	195,00	210,00	U4 Landstrasse/Wien Mitte to U1 Schwedenplatz
Hilton Vienna Plaza	195,00	210,00	U2 Schottentor/Universität to U1 Karlsplatz
Intercontinental Wien	195,00	215,00	U4 Stadtpark to U1 Schwedenplatz
Marriott Vienna	189,00	189,00	U3 Stubentor to U1 Stephansplatz
Radisson SAS Palais Hotel	190,00	210,00	U3 Stubentor to U1 Stephansplatz
HOTELS ****			
Austria Trend Hotel Ananas	127,00	172,00	U4 Pilgramgasse to U1 Karlsplatz
City Central	118,00	159,00	U1 Schwedenplatz
Deutschmeister	79,00	98,00	U4 Roßauer Lände to U1 Schwedenplatz
Hotel Donauzentrum	122,00	163,00	U1 Kagran
K+K Maria Theresia	142,00	182,00	U3 Volkstheater to U1 Stephansplatz
K+K Palais Hotel	142,00	182,00	U1 Schwedenplatz
Hotel Lassalle	122,00	163,00	U1 Vorgartenstrasse
Mercure Grand Hotel Biedermeier Wien	143,00	183,00	U3 Rochusgasse to U1 Stephansplatz
Mecure Wien Europaplatz	109,00	143,00	U3 Westbahnhof to U1 Stephansplatz
Mercure Josefshof Wien	134,00	173,00	U2 Rathaus to U1 Karlsplatz
Mercure Secession	134,00	173,00	U1 Karlsplatz
Mercure Wien City	119,00	153,00	U1 Schwedenplatz
Park Inn Vienna	135,00	145,00	walking distance
Stefanie	123,00	167,00	U1 Schwedenplatz
HOTELS ***			
Hotel Beim Theresianum	82,00	112,00	U1 Südtirolerplatz
Capri	90,00	125,00	U1 Nestroyplatz
Carlton Opera	75,00	105,00	U4 Kettenbrückengasse to U1 Karlsplatz
Ibis Wien Mariahilf	77,00	101,00	U3 Westbahnhof to U1 Stephansplatz
Ibis Wien Messe	75,00	99,00	U1 Vorgartenstrasse
Ibis Wien Schönbrunnerstrasse	71,00	95,00	U4 Margaretengürtel to U1 Karlsplatz
Mercure Wien Zentrum	140,00	162,00	U1 Schwedenplatz
Nordbahn	82,00	122,00	U1 Praterstern
Post	70,00	97,00	U1 Schwedenplatz
Suitehotel Wien Messe	103,00	111,00	U1 Vorgartenstrasse
Tabor City-Hotel	79,00	98,00	U1 Schwedenplatz
Wandl	95,00	150,00	U1 Stephansplatz

*) excluding breakfast

For further details and a hotel map, please visit: www.austropa-interconvention.at/congress/dia/index.asp

INDIVIDUAL BOOKINGS

HOTEL DEPOSIT, CONFIRMATION AND RECEIPT

Hotel rooms will be reserved and confirmed upon the receipt of your deposit payment. Austropa Interconvention will send you a written confirmation of reservation. Please keep this confirmation letter (voucher) and present it when checking in. The hotel's final invoice will be based on the number of nights you booked in advance. Final hotel expenses less the pre-paid deposit must be paid directly to the hotel upon check out. The hotel will issue an invoice/receipt.

HOTEL CHANGES AND CANCELLATIONS

Please make changes or cancellations in writing directly to Austropa Interconvention and not to the hotel. If you cancel your hotel reservation before March 1, 2007, you will receive a refund of the deposit after the end of the conference. However, an administration fee of EUR 30 per room will be retained. Unfortunately, no refund of the hotel deposit can be made on cancellations received after March 1, 2007 or for no-shows. In the case of a no-show the hotel reservation will be released after the first night.

COMPANY/GROUP BOOKINGS

For company/group bookings (10 or more rooms) different payment and cancellation terms will apply. Please contact Austropa Interconvention for details on Tel: +43 1 588 00-512, Fax: +43 1588 00 520 or E-mail: dia2007@interconvention.at

OPTIONAL TOURS

Austropa Interconvention offers guided tours for all accompanying persons throughout the conference. The minimum number of persons given for walking tours is 15 and for bus tours 25. Tours will be cancelled if the minimum number is not reached, with a full refund for tours which do not take place. All tours are accompanied by an English-speaking guide and are subject to change. Early booking is recommended as onsite availability cannot be guaranteed. Full payment in advance is required. Confirmation will be sent to you on receipt of your payment. The vouchers and receipt will be given to you at the tourist desk at the Austria Center Vienna.

WALK THROUGH "OLD VIENNA"

TUESDAY, MARCH 27, TIME: **14:00,** DURATION: **2 HOURS**
MEETING POINT: **JOSEFSPLATZ**
PRICE PER PERSON INCL. GUIDE, ADMISSION FEE AND VAT**: EURO 20**

The purpose of this walk is to present parts of old Vienna which cannot be shown to the visitor in the course of a regular sightseeing tour. Starting at Josefsplatz, our walk takes us past the Imperial Palace, the winter residence of the Imperial family. After a walk through the Volksgarten we reach the Beethoven-Pasqualati-House, where the famous composer lived for some time. Here, Beethoven composed his first large work, the opera "Leonore", afterwards renamed "Fidelio". Subsequently, our walk leads us over Herrengasse and Graben to St. Stephen's Cathedral. After a tour through its numerous cultural and historical highlights we lead you through small lanes and yards, which provide us with a genuine impression of the old Vienna.

HISTORICAL VIENNA WITH TOUR OF SCHÖNBRUNN

WEDNESDAY , MARCH 28, TIME: **9:00,** DURATION: **3.5 HOURS**
MEETING POINT: **JOSEFSPLATZ**
PRICE PER PERSON INCL. BUS RIDE, GUIDE, ADMISSION FEE AND VAT**: EURO 35**

To provide you with a first impression of the city, we start our tour at Ringstrasse. This boulevard, with an approximate length of 4 km, was created in the course of the city's first expansion in the middle of the 19th century on the site of the former city fortifications. We will see buildings such as the Museum of Fine Arts, the Museum of Natural History, the City Hall, the Burgtheater, the Parliament, the University and many more. The highlight of our excursion is a tour of Schönbrunn Palace, the summer residence of the former Imperial House of Austria.

Cancellations of tours are to be made in writing to Austropa Interconvention.
Tours cancelled after March 1, 2007, and lost or unused tickets cannot be refunded.

CULTURAL PROGRAMME

Vienna, as a world capital of music, is often high on the performance wish list of music groups and choirs all over the world.
Further information is available at: http://www.info.wien.at

Registration Cancellation Policy for DIA EuroMeeting 2007
All cancellations must be in writing and be received at the DIA office by 17:00 CET on March 19, 2007. Registrants who do not cancel by March 19, 2007 and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own airline and hotel reservations. You may transfer your registration to a colleague at any time. Please notify the DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for the non-member fee, if applicable. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants. Speakers and programme agenda are subject to change. Cancellations received in writing on or before March 19, 2007, will be processed as follows:

Full Meeting Cancellation

Member and Non-member	EUR 200.00 will be deducted from fee paid
Government/Academia/Non-profit (Member/Non-member)	EUR 100.00 will be deducted from fee paid

Tutorial Cancellation

All tutorial registrants	EUR 50.00 will be deducted from fee paid

19th Annual EuroMeeting Vienna 2007 at a Glance

Monday, 26 March 09:00 - 12:30							
12:30							
14:00 - 18:00							
18:00 - 21:00							
	Track 1	**Track 2**	**Track 3**	**Track 4**	**Track 5**	**Track 6**	**Track 7**
Tuesday, 27 March	Adapting to Regulatory Changes	Adapting to Regulatory Changes	Reconsider the Non-Clinical Testing Strategy	"Omics" and Molecular Biomarkers	R&D and Innovation	Clinical Research	Investigational Clinical Research
Session 1 9:00 - 10:30	The "New" Centralised Procedure: Where Are We Heading? *Joint session with Track 2*	The "New" Centralised Procedure: Where Are We Heading? *Joint session with Track 1*	Future of Toxicology Testing: What Should it Look Like?	Critical Review of Omics Technology Platforms	Improvement in R&D Process	Clinical Trial Registries and the IFPMA Portal and the Benefits Derived from Clinical Trial Registries - Part I *Joint session with Track 14*	The Paradigm Shift in Oncology Drug Development
Session 2 11:00 - 12:30	Scientific Advice - Does It Deliver as Expected?	Risk Management in the EU - The Regulatory Perspective *Part II: Track 8, Session 3*	Carcinogenicity: Is a Breakthrough Possible?	EU Commission/EFPIA Public-Private Initiatives to Support Innovation - The Innovative Medicines Initiatives *Joint session with Track 5*	EU Commission/EFPIA Public-Private Initiatives to Support Innovation - The Innovative Medicines Initiatives *Joint session with Track 4*	Clinical Trial Registries and the IFPMA Portal and the Benefits Derived from Clinical Trial Registries - Part II *Joint session with Track 14*	Small Populations: US and EU Viewpoints
Session 3 14:00 - 15:30	Increasing Transparency Towards the Public - A Panel Session	Regulatory Strategies and Opportunities for Exclusivity Panel Session	The Challenging Transition from Pre-clinical to First-in-Man Trials *This session also spans with Clinical Research Track 7*	Regulatory Changes and Challenges in the Triad	PhRMA Public-Private Initiatives to Support Innovation - Biomarker Consortium with FDA and NIH	Clinical Trial and New Product Development in Japan and Issues in Global Study When Japan is Included	Informed Consent – Investigator Obligation and Public Perception
Session 4 16:00 - 17:30	Assessment in the EU: The Future	Challenges in the Final Steps Before Obtaining the Central MA	Nongenotoxic Carcinogens: Is There a Need of Mechanistic Update?	Surrogate and Biomarker Endpoints - Regulatory and Patient Perspective *Joint session with Track 5*	Surrogate and Biomarker Endpoints - Regulatory and Patient Perspective *Joint session with Track 4*	Disaster Prevention in Clinical Research	How to Ensure Independence of the Stakeholders in Clinical Research
17:30 - 18:30 **Reception**							
18:00 - 19:30							
Wednesday 28 March							
Session 5 09:00 - 10:30	Mutual Recognition and Decentralised Procedure How is the New Coordination Group Performing? *Joint session with Track 2*	Mutual Recognition and Decentralised Procedure How is the New Coordination Group Performing? *Joint session with Track 1*	Animal Model of Disease for Safety Assessment	The Challenge of "Omics" Standardisation	EMEA/FDA New Paradigms on Phasing Clinical Trials	Legal and Insurance Issues in Clinical Trials	Adaptive Designs - Trends and Controversies *Joint session with Track 14*
Session 6 11:00 - 12:30	HMA Member State Agencies in a Strenghened European Network	Role of Patients in Assessment	Accessible Biomarker of Toxicity	Application of Pharmacogenetics in Proof of Concept and Early Clinical Development	Advanced Therapy: Regulatory Framework and Development Issues	Optimised Study Medication Management	Good Documentation Practices
Session 7 14:00 - 15:30	SmPC and Package Leaflet Harmonisation - A Challenge to Stakeholders	Present and Future - Regulatory Collaboration	Genotoxic Impurities *Joint session with Track 11*	Business Models for Biomarker Development	Nanomedecine: Advances and Challenges	Good Clinical Planning in the Preparation of Development Plans and Trial Protocols This session spans Clinical Research and Statistics tracks	Pharmacovigilance in Academic Trials
Session 8 16:00 - 17:30	Assisting SMEs in a Highly Complex EU	EU Enlargement: Viewpoints on the Regulatory Changes brought about by EU Enlargement	Genotoxic Impurities and Residues of Metal Catalysts *Joint session with Track 11*	Systems Biology and Translational Medicine	Antibio-resistance Therapy - Challenges	Managing the Key Challenges of Running Global Expanded Access Programmes	Regulatory Authorities' Expectations of Quality in Academic Clinical Trials

Optional Parallel Tutorials and Graduates' Session

Exhibition Opens

Plenary Session: The New Pharmaceutical Legal Framework – A Step in the Right Direction for Europe? Plus DIA Distinguished Career and Outstanding Service Award Ceremo

Viennese Networking Buffet Reception

Track 8	Track 9	Track 10	Track 11	Track 12	Track 13	Track 14	Track 15/16	
Pharmacovigilance and Risk Management	Patient Organisations' Involvement in Medicine Development	Medicines for Children	Quality and Compliance	eClinical	Data Management	Statistics	Information Technology and Telematics	Pro
Benefit-Risk Assessment: New Approaches and Interface with Risk Management	New Approach to Medicine Information to Patients at EMEA	Implementation of the Paediatric Regulation	New Manufacturing Concepts for Drug Substance and Drug Products I: Quality by Design, PAT and Design Space	eClinical Trials from the Sponsor Perspective		Clinical Trial Registries and the IFPMA Portal and the Benefits Derived from Clinical Trial Registries - Part I *Joint session with Track 6*	Document Chain Management in Pharma R&D	E
The Future of Pharmacovigilance - Safe Drugs in the 21st Century	Relation between National Regulatory Agencies (NCA) and Patient Organisations	Practical Aspects of CT's in Children and Ethics	New Manufacturing Concepts for Drug Substance and Drug Prod. II: Impact of ICH Q8, Q9 and Q10 Concepts on Drug Substance and Drug Product Manufacturing	eClinical Trials from the Site Perspective		Clinical Trial Registries and the IFPMA Portal and the Benefits Derived from Clinical Trial Registries - Part II *Joint session with Track 6*	Electronic Submissions (eCDT) Preparation and Lifecycle Management	Man
Risk Management Plans: Practical Applications and Experience *Part I: Track 2, Session 2*	Innovative and Strategic Long-term Partnership between Patient Organisations and Industry	The PIP Content in the Content of Global Development of Paediatric Medicines	The Role of the Qualified Person for Compliance with Marketing Authorisation/Quality Product Reviews	eClinical Trials from the Standards/Regulatory Perspective		(Not) Clinically Relevant?	National Experience of EU Submission and the EU Strategy	Pro A
Signal Detection Throughout the Product Life cycle *joint session with Track 14 This session also spans with CDM*	Collaboration between Industry Sponsors and Patient Groups for Clinical Trials: New Paradigm based on Experience	Preparing for the Paediatric Investigational Plan	More Flexibility for Variations	eClinical Trials from the Patient Perspective		Signal Detection Throughout the Product Life cycle *Joint session with Track 8 This session also spans with CDM*	Electronic Submissions Standard- Progress with Their Development	Outso M
2hr session runs until 18:00						2hr session runs until 18:00		

Austrian Satellite Meeting: Austria – An Important Player in the EU Network for Pharmaceuticals: Driving Innovations in Austria

EudraVigilance in Supporting the EU Risk Management activities in the EEA		Communication on Paediatric Data SmPC - Public Access to Paediatric Information	EU Directive: GMP for Certain Excipients		Data Aggregation and Warehousing	Adaptive Designs - Trends and Controversies *Joint session with Track 7*	EU Telematics Strategy - Progress to Date	
Intelligent Risk Communication		Formulations for Children	Quality for Investigational Medicinal Products		Managing Clinical Data Management - A Global Perspective	Recruitment Modelling and Prediction in Clinical Trials	Electronic Labelling in the European Union: PIM 2007 and Beyond	

11:00 - 12:30 Japanese Regulatory Session: PMDA Challenges for Global Drug Development including Japan

Debate on the Future of Periodic Reports		Network of Paediatric Research	Genotoxic Impurities *Joint session with Track 3*		Safety Data Management - Working Smarter Together	Statistical Approaches in Pharmacogenomics - Prediction Revisited	Translation of Product Information and the Value of Translation Memories	
The Role of the Qualified Person		Paediatric Pharmacovigilance	Genotoxic Impurities and Residues of Metal Catalysts. *Joint session with Track 3*		Optimising R&D through System Integration	Implementing Adaptive Randomisations for Clinical Trials	EudraCT, EVMPD, EuroPharm and Security	

ony

Track 17	Track 18	Track 19	Track 20	Track 21	Track 22	Track 23	Track 24
oject Management of Outsourcing and Alliances	Biosimilars- Current Status and Latest Developments	Intellectual Property Rights and Related Issues	Future Perspectives for Non-Prescription Medicine	Public Policies and Ethics	Clinical Quality Management, GCP & Inspections	Generic Medicinal Products	Biologics
ffective Alliance Management		Patent Rights and Regulation of Pharmaceuticals	Harmonisation of Non-prescription Medicines		Implementation o the Clinical Trial Directive and Update on GCP-relevant Legislation		
aging Clinical Trials		Regulatory Protection Mechanisms	Future of Herbal Medicines		Quality Standards for Interventional and Non-Interventional Trials		
oject Management Across Corporate Boundaries		Trademarks and Controls of Invented Names	The Borderline Between Medicine, Food, Medical Device and Cosmetics		Inspections - Audits - Monitoring		
ourcing of the Project Management Role		IP Rights and Public Interests	Homeopathic Medicines on the Way to a European Market		Strategies for an Integrated GCP Compliance Oversight System		
		2hr session runs until 18:00					
	Current and Future Challenges of Biosimilars (a Global Perspective): EU and US Situation as Well as Aspects from Other Countries			Access to Controlled Medications: Impact for Millions	Ethical Standards for Clinical Trial in Developing Countries	New Developments in Assessment of Generic Medicinal Products in Europe	Gene Therapy - Clinical Experience and Regulatory Hurdles
	Ongoing and Planned BMWP/CHMP/EMEA Activities, Proposals and Viewpoints			Counterfeit Medicines: How to Protect the Patient in Europe	American and European GCP Inspections Strategies	New Pharmaceutical Legislation - Implementation of Key Provisions Related to Generic Medicines in Various EU MSs	New Delivery Systems for Vaccines
	INN/Trade Names of Biosimilars and the Impact on Substitution Therapy			The Role Of Marketing Codes in Regulating Marketing Practices - An Update	The Use of IMPs and the Impact of Clinical Research		Stem Cell Therapy - Clinical, Regulatory and Ethical Challenges
	Increasing Role of Biologicals in the Pharmacotherapy: Forecast for Economic Consequences to the Healthcare System Pricing and Reimbursement			Added Therapeutic Value- and Health Technology Assessment	Clinical Quality Management for Phase I Clinical Studies - Challenges and Pitfalls		Progess in Immunogenicity and Risk Management for Biotechnology Derived Products and Biosimilars

General Information - Enhance your EuroMeeting experience with these Networking Opportunities

The 19th Annual EuroMeeting will will be held at the
Austria Center Vienna
Bruno-Kreisky-Platz 1
1220 Vienna, Austria
Tel.: +43-1- 260 69-0
Fax: +43-1-260 69-303

Graduates' Session
Monday, March 26, 2007, 09:00 – 12:30
With prominent speakers from the DIA, industry and academia to discuss:
– Global DIA activities
– Drug development and registration process
– Job opportunities in the industry & health authorities

Viennese Networking Buffet Reception - Hall D, Austria Center Vienna
Monday, March 26, 2007, 18:00 – 21:00
You are invited to attend a sumptuous buffet reception after Monday's Plenary Sessions and Distinguished Career and Outstanding Awards Ceremony and concert. This upbeat and dynamic networking reception will provide an excellent opportunity to renew your existing contacts and make new ones. Admission to the Plenary Sessions, Award Ceremony and Networking Reception is free of charge to all registered attendees. Please indicate your participation on the registration form on the back of this programme. Tickets for guests and partners may be purchased at the registration desk at the Austria Center Vienna for EUR 55.

Networking Reception
Tuesday, March 27, 2007, 17:30 – 18:30
A second networking reception will be held in the Exhibition area. Explore new technologies and interact with colleges from government, industry and academia. This reception is free-of-charge to all registered attendees.

New Members' Breakfast
Tuesday, March 27, 2007, 08:00 – 08:45
A new members' welcome breakfast will be held at the Austria Center Vienna on Tuesday morning. This breakfast is a unique way to identify people onsite who share the same interests or job responsibility as you. Please join us to share ideas and information over coffee, juice and pastries.

Austrian Satellite Meeting
Tuesday, March 27, 2007, 18:00 – 19:30
AUSTRIA – An Important Player in the EU-Network for Pharmaceuticals: Driving Innovations in Austria
Featuring:
AGES PharmMed
Prof. Dr. Marcus Müllner, Director of AGES PharmMed

Pharmig – Association of the Austrian Pharmaceutical Industry
Dr. Jan Oliver Huber, Secretary General

Intercell AG
Univ. Prof. Dr. Alexander von Gabain, Chief Scientific Officer

Boehringer Ingelheim Austria
Dr. Kurt Konopitzky, Head of Division Biopharmaceuticals and Operations
and Mag. Edeltraud Stiftinger, Chief Executive Officer, Center for Innovations and Technology

Moderator:
Dr. Christa Wirthumer-Hoche, AGES PharmMed.

The Austrian Satellite Meeting is free for all registered attendees of the EuroMeeting, however space is strictly limited. To reserve your place at the Austrian Satellite Meeting, please contact: euromeeting2007@diaeurope.org or visit www.diaeurope.org.

Exhibition

There will be over 200 companies exhibiting in Vienna. The exhibition will be open to all **registered** attendees:
Monday, March 26, from 12:30 until 18:00
Tuesday, March 27, from 10:00 until 18:30
Wednesday, March 28, from 10:00 until 16:00
All coffee breaks, lunches and the networking reception on Tuesday, March 27, 17:30 until 18:30, will take place in the exhibition area. There will be free public access to the exhibition hall on Tuesday, March 27, from 14:00 until 15:30.

Poster Session/Student Poster Session
Tuesday, March 27, 2007, 09:00 – 18:30
Posters selected by the review committee, addressing similar topics to those in the programme, will be on display in the exhibition area. Presenters will make themselves available to discuss their work during the coffee and lunch breaks on Tuesday at the Austria Center Vienna. The poster review committee will select the three best student posters and the winning authors will receive a EuroMeeting Student Poster Prize. The prizes will be awarded at the student poster award ceremony on Tuesday, March 27, at 17:30 in the exhibition area. Please join us for the ceremony to support these emerging professionals.

For further information about SIAC sessions, hospitality lounges, the private social functions policy, press registration policies and procedures and more, please visit www.diahome.org and click on the EuroMeeting 2007 icon.

DRUG INFORMATION ASSOCIATION

Registration Form

07101DIAWEB

19th Annual EuroMeeting, Austria Center, Vienna, Austria - March 26-28, 2007

Meeting I.D. Code #: 07101

NOTE: Payment of registration fees must be received before commencement of the meeting

I am a DIA member

If our database cannot prove your membership, you will be charged non-member rate

☑

Early Bird Discount for registration before January 12th 2007

	Total
Member Industry Only	€ 1'854.00

All fees include 20% VAT charges

Registration fee after January 12th 2007

	Total
Member Industry	€ 2'034.00
Member*Government	€ 1'017.00
Member*Academia	€ 1'525.50

For Student fee please call +41 61 225 51 51

* Full time

I am not a DIA member

☑

Option 1: without membership

	Total
Industry	€ 2'190.00
*Government	€ 1'173.00
*Academia	€ 1'681.50

Option 2: with one year's membership

	Total
Industry	€ 2'034.00
*Government	€ 1'017.00
*Academia	€ 1'525.50
+	
☑ Membership	€ 130.00

* Full time

TUTORIALS

☑ Monday, March 26, 2007, 09:00 – 12:30 - Please select one Tutorial only

- ☐1 Volume 9A & EU Regulatory Requirements: Pharmacovigilancein the Post Authorrisation Phase and e-Reporting
- ☐2 Risk Management: Turn Plans into Practice
- ☐3 Decision Making Using Pharmacogenetic Markers in Drug Dev.
- ☐4 Operational Aspects of Paediatric Clinical Trials
- ☐5 Pharmaceutical Project Management: How to Ensure Success
- ☐6 Europ. Pharma Law for Non-Lawyers: Principles of Pharm. Leg.& Case Law
- ☐7 Analysis of Safety Data from Clinical Trials
- ☐8 Vaccines – Emerging Needs
- ☐9 Successful Management of Clinical Trials in Asia
- ☐10 Comparability of BioPharmaceuticals
- ☐11 MedDRA in Practice Workshop
- ☐12 CDISC Workshop
- ☐13 Advanced Understanding of Scientific and Reg. Drug Evaluation for Patient Representatives
- ☐14 How to Apply Non-Clinical Safety Guidelines in Global Drug Development
- ☐15 Paediatric Development & Innovative Aspects of Paediatric Trials
- ☐16 How to Deal with CP and MRP in an Enlarged EU
- ☐17 PIM Light Authoring Tool
- ☐18 Pharmacoepidemiology: Overview of Principles, study Designs and Applications
- ☐19 Integrating Quality into Clinical Development
- ☐20 Experience with VGDS and Bilateral Cooperation
- ☐21 Pharmacovigilance Inspection Workshop

☐ **TUTORIAL Fees EUR 420.00**

☐ I will also attend the Networking Buffet Reception (free)

TOTAL AMOUNT (including 20% VAT charges) €

How to register:

Online www.diahome.org

By Fax 0041 61 225 51 52

Email diaeurope@diaeurope.org

Mail DIA European Branch Office
Postfach, 4002 Basel

PAYMENT METHODS:

☐ Please charge my credit card

☐ VISA ☐ MC ☐ Amex

Card Number

Exp. Date /

Name

Today's Date

Cardholder's Signature

☐ Cheques:
Mail your cheque together with the registration form to:
DIA, Elisabethenanlage 11,
Postfach, 4002 Basel, Switzerland

After February 23, 2007, only credit cards will be accepted.

☐ Bank transfers:
Please tick if you would like us to send an invoice with bank details.

Payment should be in EURO and our invoice number, as well as the Meeting I.D. # 07101, must be included on the transfer document to ensure payment is allocated correctly.

Registrant

☐ Prof. ☐ Dr. ☐ Ms. ☐ Mr.

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code

City

Country

Telephone

Fax (Required for confirmation)

Email (Required for confirmation)

or attach your business card here

Group Registration: No ☐ Yes * ☐

*If yes, please submit all the registration forms at one time

Fax this registration form to: 0041 61 225 51 52