26th Annual

EuroMeeting Vienna 2014

Early-bird rate for DIA Members – register by Tuesday, 11 February 2014 and save €150!

25-27 March 2014
ACV, Vienna, Austria

Advance Programme

FIFTY YEARS 1964-2014 DIA®
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Continuing Professional Development Credits

DIA meetings are accredited by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine). All participants are eligible for these credits and certificates are available on request from the registration desk.

The 26th Annual EuroMeeting is expected to be awarded up to 14 CPD credits from the Faculty of Pharmaceutical Medicine (FPM) of the Royal College of Physicians (RCP) of the UK. Medical practitioners who are eligible for credits can click on http://www.fpm.org.uk/cpd/registration for more information. If you are already a CPD member, please go directly to http://cpd.fpm.org.uk to claim your credits.

EuroMeeting Quick Facts

- Neutral, global forum featuring over 110 sessions attracting more than 3,000 professionals involved in the development of medicines from more than 50 countries
- Speakers from the European Medicines Agency, the European Commission, the FDA and other regulatory agencies from European countries and other regions of the world
- More than 170 exhibitors on one of the largest exhibition floors in Europe
- Unparalleled multi-disciplinary networking opportunities
- Student and professional poster sessions
- Active involvement of patient organisations
- Pre-conference tutorials led by expert faculty
- Hot topics

Disclosure Statement

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of DIA Europe. Speakers and agenda are subject to change without notice.

Recording of any DIA Europe tutorial/workshop/session information in any type of media is prohibited without prior written consent from DIA Europe.

Programme Advisors

Emer Cooke, Head of International Affairs, European Medicines Agency, EU
Craig Johnson, Senior Director, Global Regulatory Affairs, GlaxoSmithKline, UK
Stefano Marino, Head of Sector, Legal Services, European Medicines Agency, EU
Maria Mavris, Director Therapeutic Development, EURORDIS, France
Detlef Nehrdich, Senior Associate, Waife and Associates Inc., Germany
Ilona Reischl, Head of Division, Austrian Medicines and Medical Devices Agency (AGES), Austria
Alexander Roediger, Director European Union Affairs, Merck, Sharp and Dohme, Belgium
Ad Schuurman, Head of Reimbursement Department, Health Care Insurance Board (CVZ) Chair of MEDEV, the Netherlands
Eva-Maria Zebedin-Brandl, Institute for Pharmacology, Medical University of Vienna, Austria
Pēteris Zilgalvis, Head of Unit, Health and Well Being, Directorate General Communications Networks, Content and Technology. European Commission, EU
EuropaBio Association, Topic Group, Belgium
EU Regulatory Intelligence Network Group (EU RING)

Welcome from the EuroMeeting 2014 Co-Chairs

Dear Participant,

We are excited to welcome you to the DIA EuroMeeting 2014 in Vienna. Located right in the geographical centre of the European Union, Vienna is an ideal place to come together to discuss and reflect on different perspectives from north to south and east to west.

Vienna is a city that relishes its past, and it has the attractions to prove it. There is a long tradition of classical music performed every day in the opera houses and concert halls. Vienna's rich history of art, from the fine arts to great architecture, such as the "Hundertwasserhaus", is visible all over the city to inspire your mind. In addition to its beautiful surroundings, Vienna offers many culinary delights and places to enjoy good food and wine. This welcoming atmosphere will pleasantly enhance your unique DIA Euromeeting experience.

This meeting's motif is 'Different perspectives – one vision: Better healthcare for patients'. We are putting patients' rights in the centre of our discussions and broadly encourage their contribution to all themes. Better healthcare for patients is our common goal. Although you may hold your own views on the current issues linked to your specific role in the system, the meeting will offer a special opportunity to actively listen to other stakeholders' perspectives and enlarge your own horizon. We strongly believe that as the complexity of the issues has dramatically increased, and everyone needs to know what is happening in other areas or disciplines to better anticipate potential impacts of decisions down the line. This cross-fertilisation and inclusiveness of the debates will hopefully generate better understanding of each other's perspectives and allow the generation of new ideas to achieve our common goal. As such, this can be our contribution to innovation in healthcare.

Over the years, this conference has become a real centre of attention for regulatory professionals and related life science experts. We are proud to have attracted a number of very high level speakers from institutions including the European Commission, Heads of National Regulatory Agencies and the European Medicines Agency. Furthermore, we are delighted to have attracted additional views from outside Europe including international speakers from the agencies in the US and Japan.

We truly believe that anyone who wants to understand the trends of the healthcare and regulatory environment for medical products and medical devices will be fascinated to listen to and engage in the discussions.

We are looking forward to warmly welcoming you to Vienna.

Angelika Joos and Christa Wirthumer-Hoche

PROGRAMME CO-CHAIRS

Angelika Joos

Head Regulatory Policy EU and Most of World, Merck Sharp and Dohme, Belgium

Angelika Joos is a licensed pharmacist. Since 2001, she is responsible for regulatory policy issues at Merck Sharp & Dohme's Regulatory Affairs department in Brussels. Over the past 17 years, Angelika has gained strategic as well as operational experience with all regulatory procedures and various products in different therapeutic areas.

In her current position as Head Regulatory Policy EU & Most of World she has been responsible for monitoring and implementing regulatory policies and procedures and advising the company on regulatory strategies. She represents MSD in the EFPIA Scientific Regulatory and Manufacturing Policy Committee and in the IFPMA Regulatory Policy Committee. Her main interests are related to clinical trials, pharmacovigilance, HTA and paediatrics.

She has been a member of the DIA Advisory Council Europe since 2008 and has been involved in the organisation of several DIA Forums as well as two DIA EuroMeetings.

Christa Wirthumer-Hoche

Head of Austrian Medicines and Medical Devices Agency, Austria

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 then joined the Austrian National Institute for Quality Control of Drugs in 1983, focusing on the assessment of quality documentation. From June 1998 until December 2005 she was the 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 1 January 2006 her position is Head of Institute for Marketing Authorisation and Lifecycle Management of Medicinal Products and she was appointed Head of the Austrian Medicines and Medical Devices Agency on 1 October 2013.

Dr. Wirthumer-Hoche has also 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, in the PERF project). In Dec.1999 she was appointed by the European Commission as Co-ordinator for the CTD Implementation in Europe (ICH-IWG). She is the Austrian Delegate in the Coordination Group for Mutual Recognition and Decentralised Procedures for human MPs (CMD-h) and chair of the Joint Working Group on ASMF-procedures.

Anna Bucsics
Department Head, Department of Pharmaceuticals Affairs, Main Association of Austrian Social Security Institutions, Austria

Salah-Dine Chibout
Head of Exploratory Development Europe, Global Head Investigative Toxicology, Novartis, Switzerland

Graham Cook
Senior Director, Process Knowledge/ Quality by Design, Global Quality Strategy, Pfizer, UK

Judith Creba
Head EU Liaison & Policy, Novartis Pharma, Switzerland

Christopher Foreman
Senior Director Legal Affairs, Scandinavia & Baltic, Merck Sharp and Dohme, Belgium

Hans-Georg Eichler
Senior Medical Officer, European Medicines Agency, EU

Shayesteh Fürst-Ladani
Managing Director, SFL Regulatory Affairs and Scientific Communication, Switzerland

Jan Geissler
Director, The European Patients' Academy on Therapeutic Innovation (EUPATI)
Belgium

Clara Heering
Vice President Clinical Risk Management, ICON Clinical Research, Belgium

Peter Høngaard Andersen
Senior Vice President, H. Lundbeck, Denmark

Wills Hughes-Wilson
Vice President External Affairs, Chief Patient Access Officer, Sobi, Sweden

Tim Kievits
Director Healthcare Innovation, Vitromics Healthcare, the Netherlands

Vesna Koblar
Director, Pharmaceutical Regulatory Affairs Consulting and Education (raPHARM), Slovenia

Marianne Köhne
Global Regulatory Affairs/RCC Coordinator, Boehringer Ingelheim, Germany

Geneviève Michaux
of Counsel, Hunton & Williams Belgium

Carl Naraynassamy
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Senior Director, Policy and Intelligence, Europe and International Regulatory Policy, Intelligence, AstraZeneca, UK

Terje Peetso
Policy Officer, Directorate General Communications Networks, Content and Technology, European Commission, EU

Lembit Rägo
Coordinator, Quality Assurance and Safety for Medicines, Essential Medicines and Health Products, WHO, Switzerland

Kristin Raudsepp
Director General of State Agency for Medicines, Estonia

Tomas Salmonson
Chair Committee for Medicinal Products for Human Use (CHMP), Senior Scientific Advisor, Medical Products Agency (MPA) Sweden

Valerie Simmons
EU QPPV, Global Patient Safety, Eli Lilly & Company, UK

Peter Stokman
Head Global Data Management & Standards Oss, Merck Sharpe and Dohme, the Netherlands

Nick Sykes
Senior Director
Worldwide Safety and Regulatory, Pfizer, UK

Hans van Bruggen
Director, eCTDConsultancy, the Netherlands

Christa Wirthumer-Hoche
Head of Austrian Medicines and Medical Devices Agency, Austria

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26TH ANNUAL

EUROMEETING VIENNA 2014

SCHEDULE AT A GLANCE

MONDAY, 24 MARCH 2014

Registration Hours:

09:00-18:00	Exhibitor Registration and Set-up
15:00-18:00	Attendee and Speaker Registration
	Avoid the rush on Tuesday by picking up your badge and conference material on Monday afternoon
17:30-18:30	Students and Young Professionals Welcome Reception

TUESDAY, 25 MARCH 2014

Registration Hours:

08:00-17:30	Attendee, Speaker and Exhibitor Registration
07:30-11:00	Exhibitor Set-up

Schedule:

09:00-12:30	Pre-Conference Tutorials* - Choose from 13 Tutorials
09:00-12:30	Student Tutorial
09:00-12:30	Young Professional Tutorial
10:30-11:00	Pre-Conference Tutorials Coffee Break
12:00-14:00	Lunch in the Exhibition Hall
12:00-19:00	Conference and Exhibition Open
12:45-13:45	Patient Representatives Lunch
14:00-17:15	Opening Plenary Session
15:00-15:45	Coffee Break in the Exhibition Hall
17:30-19:00	Welcome Reception in the Exhibition Hall

**Space is limited for pre-conference tutorials, therefore pre-registration is strongly recommended*

EXHIBITION HALL HOURS

Tuesday, 25 March 2014
12:00 – 19:00
Wednesday, 26 March 2014
09:00 – 18:30 | Exhibition Guest Passes 14:00 – 15:30
Thursday, 27 March 2014
09:00 – 16:00

WEDNESDAY, 26 MARCH 2014

Registration Hours:

08:00-17:30	Attendee, Speaker and Exhibitor Registration

Schedule:

08:00-09:00	Welcome Coffee
09:00-18:30	Exhibition Open
09:00-10:30	Session 1 - Choose from Parallel Sessions
10:15-11:00	Coffee Break in the Exhibition Hall
11:00-12:30	Session 2 - Choose from Parallel Sessions
12:00-14:00	Lunch in the Exhibition Hall
12:30-13:15	DIA Communities - Meet and Eat
13:30-14:00	Speed Networking
14:00-15:30	Session 3 - Choose from Parallel Sessions
14:00-15:30	Exhibition Guest Passes
15:15-16:00	Coffee Break in the Exhibition Hall
16:00-17:30	Session 4 - Choose from Parallel Sessions
17:30-18:30	The Wednesday Reception in the Exhibition Hall
17:45-18:15	Student Poster Award Ceremony at the DIA Booth

THURSDAY, 27 MARCH 2014

Registration Hours:

08:00-16:00	Attendee, Speaker and Exhibitor Registration

Schedule:

08:00-09:00	Welcome Coffee
09:00-16:00	Exhibition Open
09:00-10:30	Session 5 - Choose from Parallel Sessions
10:15-11:00	Coffee Break in the Exhibition Hall
11:00-12:30	Session 6 - Choose from Parallel Sessions
12:00-14:00	Lunch in the Exhibition Hall
14:00-15:30	Session 7 - Choose from Parallel Sessions
15:15-16:00	Coffee Break in the Exhibition Hall
16:00-17:30	Session 8 - Choose from Parallel Sessions
17:30	End of Conference

Preliminary Schedule Status October 2013 - Subject to change

VIENNA 2014

OPENING PLENARY

TUESDAY | 25 MARCH 2014 | 14:00 – 17:15

Keynote address

Ilona Kickbusch, Director of the Global Health Programmme at the Graduate Institute of International and Development Studies, Switzerland

Panel Discussion

Sustainable Healthcare Systems - Did we think about the citizen?

There will be debate around economic constraints, health equities, importance of health literacy, patient involvement in decision making, responsible consumer demands.

Panel

Anna Bucsics, Department Head, Department of Pharmaceuticals Affairs, Main Association of Austrian Social Security Institutions, Austria
Nicola Bedlington, Executive Director, European Patients Forum, Belgium
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU
Mike Rosenblatt, Executive Vice President and Chief Medical Officer, Merck & Co., USA
Andrzej Rys, Director of Health Systems and Products, European Commission, EU

Closing Remarks

Ilona Kickbusch, Director of the Global Health Programmme at the Graduate Institute of International and Development Studies, Switzerland

The DIA Award Ceremony will take place during the Opening Plenary.

REGULATORY TOWN HALL MEETING

Session 0103 | Wednesday, 26 March, 14:00-15:30

REGULATORY TOWN HALL MEETING

Session Co-Chairs:
Guido Rasi, Executive Director, European Medicines Agency, EU
Christa Wirthumer-Hoche, Head of Austrian Medicines and Medical Devices Agency, Austria

At the Town Hall Meeting attendees can put burning questions to expert regulators about these topics:

- Transparency
- Implementation of the Pharmacovigilance Legislation
- Latest Changes to the Clinical Trial legislation
- Innovation - products in the pipeline
- EU Telematics
- EU-enlargement with Croatia

Aginus Kalis, Chair HMA, Executive Director, Medicines Evaluation Board, the Netherlands
June Raine, Chair PRAC, Vigilance and Risk Management of Medicines Division, MHRA, UK
Andrzej Rys, Director of Health Systems and Products, European Commission, EU
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, Medical Products Agency (MPA) Sweden
Viola Macolic Sarinic, Head of Agency, Agency for Medicinal Products and Medical Devices (HALMED), Croatia

JAPANESE REGULATORY SESSION/PMDA UPDATE

Session 1706 | Thursday, 27 March, 11:00-12:30

Session Chair:
Nobumasa Nakashima, Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The PMDA will explain its current services and the Japanese drug regulation and answer questions on these and PMDA's future initiative / challenges for faster review and better life cycle management of drugs.

Tatsuya Kondo, Pharmaceuticals and Medical Devices Agency, Chief Executive Officer, Japan

Hideo Utsumi, Executive Director, Pharmaceuticals and Medical Devices Agency, Japan

Hiroshi Yamamoto, Chief Safety Officer, Pharmaceuticals and Medical Devices Agency, Japan

AUSTRIAN SATELLITE MEETING

Session 1900 | Tuesday, 25 March, 11:00-12:30

REQUIREMENTS FOR AN ATTRACTIVE AUSTRIAN RESEARCH AND INDUSTRIAL PHARMA LOCATION

Cooperation and interaction between the Austrian Medicines and Medical Devices Agency, Academia and the Austrian Pharma Industry will be topics for discussion.

Positioning of the Austrian Medicines and Medical Devices Agency in the EU Network
Speaker invited

Business Environment - What does the Industry need?
Jan Oliver Huber, General Secretary, Austrian Pharmaceutical Industry Association (PHARMIG)

OKids – Austrian Paediatric Research Network
Christoph Male, Medical University of Vienna (invited)

Panel discussion

AGES Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH

PHARMIG

CALL FOR STUDENT POSTER ABSTRACTS

Submission Deadline: 15 November 2013

DIA welcomes abstract submissions for the Student Poster Programme at the EuroMeeting.
The Student Poster Programme is an opportunity for you to present your research results to a diverse group of scientific professionals who are actively involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and healthcare related products.

A maximum of 20 abstracts will be selected for the 2014 EuroMeeting based on the following criteria:
- Bona fide research project
- Specific objectives
- Clear methods
- Analysis of actual data and results
- Conclusion

SELECTED STUDENT POSTER PRESENTERS WILL RECEIVE

- One complimentary meeting registration to attend the DIA EuroMeeting 2014
- Maximum of three night's hotel accommodation at the DIA assigned hotel
- One return economy trip, airline/train to Vienna, Austria
- One year complimentary DIA student membership
- Accepted abstracts will be printed in the EuroMeeting Final Programme and posted on the DIA website prior to the EuroMeeting
- Prizes for three winning posters

  Title and author of accepted abstracts will be printed in a DIA publication/Journal.

STUDENT ELIGIBILITY

- Individuals must be full-time undergraduate students on 25 March 2014
- One author only will be fully supported to attend the EuroMeeting
- Past DIA EuroMeeting or Annual US meeting student poster presenters are not eligible
- All submitting authors must complete and return the student verification form and send to Maureen.McGahan@diaeurope.org as part of their application
- Applications received without verification of full-time student status will not be considered

GENERAL SUBMISSION REQUIREMENTS

- Abstracts must be submitted through the DIA website www.diahome.org/EM2014) by 15 November 2013
- A student may submit only one abstract
- Abstracts may not refer to specific brand names
- Abstracts will be reviewed and authors notified of results by the week of 2 December 2013
- Submissions must include complete contact information
- If an abstract is accepted, one author must attend the EuroMeeting 2014 to present the abstract

For further information and to download an application form, please visit www.diahome.org/EM2014 and click on "Students & Professional Posters".

EuroMeeting Amsterdam 2013 Student Poster Presenters

EuroMeeting Amsterdam 2013 Student Poster Winners

Please check back for regular programme updates

CALL FOR PROFESSIONAL POSTER ABSTRACTS

Submission Deadline: 20 January 2014

Professional individuals are invited to submit a poster for display at the 26th Annual EuroMeeting. The professional poster programme is an opportunity to present your research to a diverse group of scientific professionals who are actively involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and health care related products.

POSTER PRESENTERS BENEFITS

- Designated poster area and poster board to display poster and network with attendees at the meeting
- Accepted abstracts will be posted on the DIA 2014 Annual EuroMeeting website prior to the meeting
- Abstract title and lead author will be printed in the final programme that is distributed to EuroMeeting attendees
- Title and author of accepted abstracts will be printed in an edition of the *DIA Global Forum* digital association news magazine

GENERAL SUBMISSION REQUIREMENTS

- Abstracts must be submitted online through the DIA website www.diahome.org/EM2014 by 20 January 2014
- Abstracts may not refer to specific brand names, products or services and must be limited to generic names, including poster titles and or handouts
- All poster presentations must be non-commercial and scientific in nature and may not be used as a marketing opportunity
- Posters must include data, i.e., objectives, methods, research results and conclusion
- Submissions must include complete contact information

ONSITE REQUIREMENTS

If an abstract is accepted, the primary author is required to pay the applicable meeting registration fee and related expenses and must be onsite in Vienna at the EuroMeeting

- To confirm participation, complete the registration online at www.diahome.org/EM2014 before Friday, 7 February 2014
- Accepted abstracts **are not transferable** to exhibitors, speakers, session chairs or young professional fellows
- Please note that an author cannot present more than one poster
- Co-authors who would like to attend the EuroMeeting as well must register and pay the applicable meeting fee before the deadline
- If none of the authors are able to attend the meeting, the poster will be withdrawn from the programme
- Presenters are liable for their own shipping and transportation costs

If registration deadlines are not met, poster and author information will not be published in the onsite Final Programme

EUROMEETING FELLOWSHIP PROGRAMMES

PATIENT FELLOWSHIP | Application Deadline: Friday, 8 November 2013

The DIA Patient Fellowship, now in its ninth successful year, is a programme to promote the participation of representatives of patient organisations at the EuroMeeting.
DIA fully supports 15 patient representatives, covering their complete travel and accommodation costs plus complimentary admission to the EuroMeeting, and is offering 15 additional patient representatives complimentary registration for the meeting.

BENEFITS

- Complimentary admission to the conference and to one optional pre-conference tutorial of choice
- Travel costs and maximum three nights' hotel accommodation covered for 15 patient representatives
- A dedicated *DIA Patient Fellowship Booth* which will act both as a centre for patient activities and also as a source of information for EuroMeeting attendees
- Patient Poster Session where patient representatives can display information about their organisations
- Patient Representative networking lunch
- Feedback session

A Patient Representatives Lunch will take place on Tuesday, 25 March 2014 from 12:45-13:45

STUDENT FELLOWSHIP | Application Deadline: 17 January 2014

DIA Europe promotes the participation of students in the 26th Annual EuroMeeting by offering up to 20 complimentary registrations to full time students. DIA Europe will waive the registration fee. Selected students are expected to bear their own travel and accommodation costs.

An exclusive student tutorial on the morning of Tuesday, 24 March 2014 will enable you to get the most out of the conference.

YOUNG PROFESSIONAL FELLOWSHIP | 17 January 2014

DIA Europe promotes the participation of young professionals in the EuroMeeting by offering up to 15 complimentary registrations for professionals under the age of 30 currently working in the pharmaceutical sector. DIA Europe will waive the registration fee. Selected young professionals are expected to bear their own travel and accommodation costs.

A Student and Young Professional Networking evening reception will take place on Monday, 24 March 2014 from 17:30-18:30

PRE-CONFERENCE TUTORIALS
TUESDAY, 25 MARCH 2014 | 09:00-12:30

Tutorial 1

INTRODUCTION TO EU PHARMACEUTICAL LAW AND CURRENT DEVELOPMENTS

John Lisman, Lawyer, Lisman Legal Life Sciences, Netherlands
Paul Van Dongen, Lawyer, NautaDutilh, Netherlands

Pharmaceutical law is of utmost importance for lawyers, regulators and pharmaceutical industry: it is the basis for daily business in the sector. In the last few years many developments have occurred in the field of pharmaceutical law as well as in the marketing authorisation practice. This tutorial brings you up to date in respect to:

- Marketing Authorisation for Biosimilars
- Paediatric Regulation
- Advanced Therapy Medicinal Products Regulation
- Pharmaceutical Package
- Pharmacovigilance Legislation
- Directive on Falsified Medicines
- Proposed Legislation on Information to Patients
- New Guidelines and Notes for Guidance
- Revision of Clinical Trials Legislation

For each of the topics the most relevant highlights will be presented in an interactive manner.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:

- Discuss new and amended legislation in the EU
- Understand the implementation of this legislation and future developments

Target Audience
Professionals in regulatory affairs and lawyers, who have basic knowledge of the changing legal environment, but want to complete the picture. By following the tutorial they will be provided with enough information to participate actively in all sessions where pharmaceutical law is concerned.

Tutorial 2

IMPLEMENTATION OF THE PHARMACOVIGILANCE LEGISLATION IN THE EU - ACHIEVEMENTS, LESSONS LEARNED AND NEXT STEPS

Sabine Brosch, Business Lead EudraVigilance and International Standardisation in Pharmacovigilance and Risk Management Sector, European Medicines Agency, EU
Gaby Danan, Hepatologist, Pharmacovigilance Expert, France

Specific topics will be elaborated on with main focus on Good Pharmacovigilance Practices (GVP) module VI, the implementation of the new ISO ICSR/ICH E2B(R3) standard as well as coding and data retrieval principles in relation to medication errors. In addition, an update will be provided on the latest development on quality control and maintenance of Article 57(2) data and the business process for notifications of market cessations and medicinal product withdrawals.

This tutorial will provide a forum for stakeholders to obtain an overview of the overall achievements and lessons learned regarding the implementation of the new pharmacovigilance legislation.

Learning Objectives
At the conclusion of this tutorial, participants will be able to:

- Share knowledge about the new pharmacovigilance legislation, overall achievements and lessons learned
- Discuss key areas of the new pharmacovigilance legislation and further developments
- Understand the preparation for the implementation of the new ISO ICSR/ICH E2B(R3) and IDMP standards with main focus on EU specific requirements
- Discuss recent changes and frequently asked questions in relation to GVP module VI

Target Audience
Qualified Persons for Pharmacovigilance (QPPVs) and persons involved in:

- Pharmacovigilance
- Clinical Development
- Information Management
- Safety databases

Tutorial 3

PRACTICAL TOOLS FOR SIGNAL MANAGEMENT SYSTEMS: HOW DO YOU OVERCOME CHALLENGES AND MEET THE NEEDS OF NEW PHARMACO-VIGILANCE LEGISLATION? IS DATA QUALITY IMPORTANT?

Shelley Gandhi, Director, Pharmacovigilance, Drug and Safety, NDA Group, UK

The tutorial will discuss sources of signals from clinical trials to any post authorisation data such as world-wide literature, spontaneous data, post-authorisation safety studies, periodic benefit/risk evaluation reports (PBRER), variations, data from other regulatory bodies such as WHO, EudraVigilance and US FDA AERs. The advantages and disadvantages of methodologies used in signal detection and whether data mining tools really help? How analysis and prioritisation could be carried out and tools which are helpful. We will also consider the impact of communicating these potential safety signals. Finally we will look at database requirements which ensure data quality and minimise the generation of false signals focusing on solutions for large, medium and small enterprises.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:

- Examine the relationship between data quality and signal detection process
- Discover the rationale for introducing automated signal detection
- Learn about pitfalls in manual signal management systems and best practices for recording and reporting outcomes

Target Audience

- Pharmacovigilance professionals
- Statisticians
- QPPVs and deputy QPPVs
- Medical Affairs
- Clinical safety

PRE-CONFERENCE TUTORIALS
TUESDAY, 25 MARCH 2014 | 09:00-12:30

Tutorial 4

ANALYSIS OF SAFETY DATA FROM CLINICAL TRIALS

Joachim Vollmar, International Clinical Development Consultants, LLC, USA
Jürgen Kübler, Global Head, Clinical Design, Analysis and Reporting, CSL Behring 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 tutorial is to provide a basic understanding of the underlying methodology and the current guidelines on safety data. Aspects of the planning of clinical trials as well as the problems and pitfalls during the analysis of safety data will be presented. Opportunities for prospective planning of safety analysis at the project level will be discussed. The presentations will also include case studies.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Examine relevant guidelines and regulatory requirements for clinical trials
- Recognise how to contribute to safety analysis plans
- Assess statistical safety analysis and identify pitfalls in safety analysis
- Recognise the impact of benefit/risk assessment in safety data

Target Audience
This tutorial is designed for biostatisticians, medical writers, clinical researchers, drug safety specialists, project managers, and investigators.

Tutorial 5

NON-CLINICAL SAFETY FOR NON-EXPERTS: WHAT IS IMPORTANT FOR YOUR SUBMISSIONS?

Klaus Olejniczak, Non-clinical Regulatory Consultant, Germany
Gerd Bode, Lecturer, University of Göttingen, Essen, Lyon, Bonn and Consultant, Germany

This tutorial identifies the challenges and solutions for integrating all sources of toxicological data involved and helps to understand the non-clinical development and strategies of drug toxicity or safety assessments. The international state of the art of non-clinical evaluation of pharmaceuticals, the interpretation of toxicological data and the acceptability or unacceptability of toxicological risks (benefit/risk assessments) for pharmaceuticals will be discussed.

This tutorial should attract everybody who is interested in or responsible for non-clinical (toxicological) data. This tutorial does not require specialist knowledge in this area.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise the principles, objectives and strategies of non-clinical safety evaluation of pharmaceuticals
- Identify the need of interactive discussion of quality, non-clinical and clinical data in drug development
- Interest in selection and performing of important non-clinical data for submission of pharmaceuticals

Target Audience
Non-specialists in toxicology, regulatory affairs personnel, clinical colleagues, project team leaders and members

Tutorial 6

BIOSIMILAR DEVELOPMENT - WHAT ARE THE CURRENT CHALLENGES?

Sundar Ramanan, Director, Global Biosimilars Policy, Amgen, USA

This interactive tutorial will provide an overview of the key steps required for developing a biosimilar, the differences between biosimilars and non comparable biologics and worldwide guidelines for and regulation of biosimilars. It will provide an in-depth understanding of the key principles for evaluating biosimilars, and give examples that highlight the importance of clinical trials for detecting clinically meaningful differences. The tutorial will explain the need for a separate biosimilars' pathway to the generics pathway as well as the importance of unique naming for biosimilars.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Describe the differences between biosimilars and non comparable biologics
- Describe the key worldwide regulations and guidelines for biosimilars
- Describe the key principles for evaluating biosimilars
- Discuss the different risk management needs between biosimilars and generics

Target Audience
Professionals involved in the development of Biosimilars.

Tutorial 7

INTRODUCTION TO MEDICAL DEVICES (AND WHAT IS COMING NEXT)

Sabina Hoekstra-van den Bosch, Senior Manager, Standards & Regulations, Philips Healthcare - Global Quality & Regulatory, Netherlands
Erik Vollebregt, Attorney, Axon Lawyers, the Netherlands

This tutorial will give a condensed overview of the EU device legislative system and the principles and philosophy behind it. It will explain the definition of a medical device and subsequently the delineation between medical devices and pharmaceuticals and the provisions on combination products will be explained. The characteristics and the organisational structure of the medical device sector and the role of the various stakeholders in it will be highlighted. It will explain the concept of risk classification of medical devices and the relationship between risk classification and conformity assessment procedures. It will highlight the role of the Notified Bodies in the system and the main provisions on clinical evaluation and clinical investigation. It will discuss the headlines of the EU regulation of In-Vitro Diagnostics, with a focus on the differences with the medical device regulation. The theoretical concepts will be illustrated with practical examples.
The tutorial will include a look ahead regarding the biggest changes that will be brought about by the revision of the Medical Device and IVD Regulations by the European Union, based on the stage of the legislative process at the time of the conference.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Understand the main characteristics of the EU Medical Device regulatory system, including the provisions on risk classification, conformity assessment, Notified Bodies, clinical evaluation and clinical investigation
- Understand the delineation between pharmaceutical and medical devices

Target Audience
Professionals in the pharmaceutical area (e.g. regulatory affairs, clinical development), who either are involved in the development and marketing of drug device combinations or who would like to obtain a condensed overview of the EU Medical Device regulatory system.

PRE-CONFERENCE TUTORIALS
TUESDAY, 25 MARCH 2014 | 09:00-12:30

Tutorial 8

THE PAEDIATRIC REGULATION STEP BY STEP - FROM THE PIP TO THE REWARD

Daniel Brasseur, Immediate Past PDCO Chairman, General Directorate Medicine, Federal Ministry of Public Health (AFMPS), Belgium
Geneviève Michaux, of Counsel, Hunton & Williams, Belgium

The tutorial analyses each relevant step of the Paediatric Regulation, from the PIP to the reward. It teaches to the participants (i) to assess whether a PIP is needed and, if so, to prepare a PIP proposal which is consistent with the EMA's new policies, (ii) to best use the paediatric procedures to secure acceptable paediatric studies, (iii) to determine the impact of the paediatric requirements on the (successive) regulatory approval(s) of the product, and (iv) to predict the eligibility for the reward(s) and the steps to undertake to secure their granting.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Analyse each relevant aspect of the Paediatric Regulation and their interactions
- Assess how the Paediatric Regulation will or may affect the development of their products
- Adapt development plans accordingly and to anticipate possible issues

Target Audience
Professionals in the pharmaceutical area involved in regulatory, legal and clinical research.

Tutorial 9

EARLY ACCESS SCHEMES: CONSIDERATIONS FOR DEVELOPING REGULATORY STRATEGIES

Nick Sykes, Senior Director, Worldwide Safety and Regulatory, Pfizer, UK

Patients are waiting to obtain access to novel medicines. Regulatory processes exist that may aid faster access for patients. However, not every approach is applicable for all circumstances. Additionally, other approaches are being developed that could help to speed up the regulatory review process while maintaining the robust assessment of benefits and risk. Strategic considerations need to be taken into account when determining which approach to follow. The different processes will be outlined and, using different situations, participants will be asked to discuss the most important strategic aspects before embarking on a particular pathway.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Distinguish and compare the options available for faster regulatory approval in the major global regions.
- Assess the merits of each option to evaluate the best strategic course of action

Target Audience
Medical affairs, regulatory and all other industry experts who want to understand how different regulatory approaches can help contribute to getting innovative medicines to patients faster.

Tutorial 10

IS HTA LIKE HTA? WHAT HIDES BEHIND A CONCEPT WHICH INCREASINGLY IMPACTS INNOVATION AND ACCESS TO MEDICINES?

Edith Frenoy, EFPIA, Belgium

Publicly funded healthcare systems in European countries base their decisions on access to medicines on evidences and Health Technology Assessment (HTA) is used to prepare and present this evidence. But HTA means different things in different countries, and HTA processes, methodologies and impact on decisions differ. We will outline market access processes for medicines in BE, FR, DE, IT, NL, PL, SE, England/Wales and also the US, to identify where HTA fits in these systems and what type of HTA is used. We will describe in detail the types of HTA used in FR, DE, England/Wales, PL, and the type of evidence requested from manufacturers across the medicines' life-cycle. We will describe the differences between regulatory requirements and HTA clinical evidence requirements, and economic evaluation requirements. In practical exercises, participants will get a better understanding of the underlying assumptions behind HTA requirements. Based on this review and on participants' knowledge of development, regulatory and market access processes, we will discuss how regulatory assessment and HTA could be streamlined, and which assessment elements could be shared between countries. We will compare these findings with current policy discussions in Europe.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Identify the differences and similarities in objectives, procedures and methodologies of existing HTA systems
- Manage internal company processes to optimally contribute to HTA submissions early in the process
- Influence internal and external policy discussions on regulatory-HTA interactions and on European collaboration on HTA with their specific knowledge and experience

Target Audience
- Medical affairs, regulatory and all other industry experts who want to understand why their market access colleagues ask them for additional evidence for 'HTA'; and market access experts who want to hear their colleagues' point of view.
- Representatives from regulatory and HTA authorities who are asked to align their pre- and post-approval evidence requirements.

Tutorial 11

HOW TO REGISTER DRUGS WITH MEDICAL DEVICES (COMBINATION PRODUCTS) AND IN-VITRO DIAGNOSTICS (COMPANION DIAGNOSTICS): CURRENT AND FURTURE REGULATORY FRAMEWORK AND STRATEGIES FOR A SUCCESSFUL DEVELOPMENT

Magali Gibou, Senior Regulatory Affairs Manager, Transgene, France
Sabine Ohse, Head of Medical Devices Certification, BSI Group, Germany

This tutorial will give a condensed overview of the medical device and in -vitro diagnostics legislative systems, including the classification rules, the requirements for clinical investigations and the role of competent authorities and notified bodies at the development stage and for the conformity assessment. It will describe the current regulations with a focus on the differences with the coming new regulations on medical devices and in vitro diagnostics that are currently discussed at the European parliament. It will highlight potential challenges of the co-development of drug/medical device and drug/companion diagnostic products, illustrated with practical examples. Finally, some example of successful co-developments will be summarised with a focus on recently marketed drug/companion diagnostic products.

PRE-CONFERENCE TUTORIALS
TUESDAY, 25 MARCH 2014 | 09:00-12:30

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Understand the coming regulatory framework for drug/medical devices and drug/IVDs registration
- Estimate how the changes in the forthcoming regulations will impact current development projects in your company
- Implement good development practices in favour of a successful combination product/companion diagnostics development

Target Audience
Professionals in the pharmaceutical area (regulatory affairs, clinical development) who are involved in the development and marketing of drug/medical device combinations or drug/companion diagnostics.

Tutorial 12

CLINICAL TRIALS IN EMERGING MARKETS: FOSTERING STRATEGIC RELATIONSHIPS, BUILDING CAPACITY AND ENHANCING CAPABILITY

Nadina José, Managing Director, Anidan Group Pte. Ltd., Singapore
Joao Massud Filho, Trials Consulting, Brazil

Asia, being the biggest continent in the world, presents a variety of opportunities for the clinical trial enterprise. In the past 10 years countries like Korea, Singapore, Taiwan, Hong Kong have distinguished themselves as the more mature markets for companies to conduct both early phase and late-phase studies. Equally active in the Latin America region: Brazil, Argentina and Mexico are the top three clinical trial arenas impacting the global pharmaceutical and biotech industry.

By having a better understanding of the scientific, moral and business drivers that serve as pillars for conducting clinical trials in both Asia and Latin America; companies need to become more operationally sound and better prepared to meet both the challenges and successes of its projects in these emerging and developing regions. It is also incumbent upon the companies that choose to venture into Asia and Latin America to expect that the industry in these regions are primarily and similarly based on building and maintaining relationships to ensure sustainability and building capacity. With these factors in mind, optimising the integration of sponsor-CRO-site functions rests on each stakeholder's ability to thoroughly recognise each other's needs and manage each other's expectations.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Identify strategies for building and sustaining Sponsor-CRO-Site partnerships in Asia/Latin America
- Assess the impact of global economics on clinical operations and development
- Apply best practices in choosing the best fitted service provider or functional partner
- Formulate streamlined processes in conjunction with developing a quality oversight plan for identifying risks and tracking issues until resolution

Target Audience
Programme Leads, Project Leads, Project managers, Heads of Clinical Operations, Client Relations, Site Directors, Study and Project team members.

Tutorial 13

AN INSIDER'S LOOK AT THE EMA: COMMITTEE INTERACTION

Anthony Humphreys, Head of Regulatory, Procedural and Committee Support, European Medicines Agency, EU

DIA is pleased to offer this brand new topic which is currently in development. Please check our website for details as they develop.

YOUNG PROFESSIONAL TUTORIAL

Tuesday, 25 March 2014 | 09:00– 12:30

PLAN YOUR CAREER IN PHARMA OR ASSOCIATED INDUSTRIES

Sonja Pumplün, Actelion, Vice President Head, Global Drug Regulatory Affairs, Actelion, Switzerland
Annette Mollet, Head of Education & Training, ECPM Institute of Pharmaceutical Medicine, University of Basel, Switzerland

The tutorial will highlight key decisions and planning steps for career paths. Options and strategies how to find the way in the health care system will be discussed. Different players in the system will be introduced.
The tutorial will also talk about the importance of soft skills. An interactive case study on soft skills will be presented, examples how to acquire them and how to best apply them, are discussed.

Part 1 | Career path examples;
Speakers will discuss their career path being in different departments/ organisations, including smaller companies and large pharmaceutical organisations. The speakers will outline the following:

- How did they enter the pharmaceutical industry or associated organisations?
- How did they move between departments and responsibilities as well as companies, how did they get these opportunities (where to look, network etc)?
- Why did they choose a certain way, what motivated them?
- Did size make a difference: which risk from their perspective did they take moving to a small pharmaceutical company or national association?
- Did they experience mergers and what was positive about it?

At the end of the presentation there will be a round table discussion with guidance provided

Part 2 | The Power of Soft Skills;
2 case studies with short introductory presentations, followed by a round table discussion focusing on the following questions

- Which soft skills are most relevant for the different career paths?
- How can these soft skills be strengthened in advance? What is available in the media?

Target Audience
Young professionals that are interested in further insights about planning their next career steps and learning more about the importance of soft skills.

STUDENT TUTORIAL

Tuesday, 25 March 2014 | 09:00– 12:30

THE IMPORTANCE OF EMOTIONAL INTELLIGENCE IN ACHIEVING SUCCESS AT JOB INTERVIEWS AND IN DEVELOPING YOUR FUTURE CAREER PATH

Judy Churchill, Director, Language Consulting Services, UK
Alexandra Marques, Past Chairperson of Media and Publications, International Pharmaceutical Students' Federation (IPSF), the Netherlands

Understand the soft skills that recruiters and pharmaceutical companies require from a job applicant. Learn how to improve or acquire these Emotional Intelligence skills. Understand the 'what, why and how' of Emotional Intelligence (E.I.) in career development and why it is essential for success and career mobility.

Participate in practical hands-on Emotional Intelligence exercises.

The tutorial will be divided into two main chapters containing sub-parts.

Chapter 1 will focus on the soft skills required for job interviews:
Part 1 - What is your Emotional Intelligence Quotient (E.Q.)?
Part 2 - E.Q., and recruiters.
Part 3 - Improve your E.Q.
Part 4 - Frequently asked questions

Chapter 2 will examine the importance of emotional intelligence (E.I.) in developing your career.
Part 1 - Why is E.I., so important when working in a company and building a team?
Part 2 - What do you need to do to maintain and build E.I.?
Part 3 - How to continually assess your E.I., and improve in the workplace

Both chapters will end with practical exercises.

Target Audience
Students

Please check back for regular programme updates

Registration Opens October 2013

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Theme 1 | Regulatory Science

Nick Sykes, Senior Director, Worldwide Safety and Regulatory, Pfizer, UK

Christa Wirthumer-Hoche, Head of Austrian Medicines and Medical Devices Agency, Austria

This theme will consider how the regulatory environment should evolve to meet the needs of the future. The individual sessions will facilitate discussions on the business needs for change, the barriers and challenges (and options available to overcome them) and the enablers that need to be fostered. Discussion topics include redesigning regulatory approval processes to foster rapid patient access to new medicines and the impact that these may have on the development processes, specific regulatory considerations for novel types of products (biosimilars, personalised medicines, advanced therapy medicinal products), new EU legislation governing medicinal products and the issues they present, adapting the label for a digital age, and a Town Hall of EU regulators.

Session 0101/0301 | Wednesday, 26 March, 09:00-10:30

MAKING THE PHARMACOVIGILANCE LEGISLATION WORK – A TEMPERATURE CHECK

Session Chair:

Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance, AbbVie Ltd., UK

Sabine Straus, Head of Pharmacovigilance, Medicines Evaluation Board, the Netherlands

Theo Radnor, Professor of Pharmacy Practice, School of Healthcare, University of Leeds, UK

This session is currently in development.

Session 0102 | Wednesday, 26 March, 11:00-12:30

HURDLES TO OVERCOME TO ENSURE REGULATORY SUCCESS FOR THE NEXT GENERATION OF PRODUCTS

Session Chair:

Susan Forda, Vice President, Global Regulatory Affairs, International, Eli Lilly & Co., UK

One of industry's key responses to the EU's Horizon 2020 programme is to initiate a series of work streams to investigate new models for R&D. The aim is to ensure that the development and regulatory models of the future meet the needs of all stakeholders and continue to get innovative products to patients as quickly as possible. This session will outline the business needs for change within both industry and at the regulator level and will explore what needs to be done to ensure a successful evolution.

The Business Need for Changing the R&D Model
Speaker invited

The Role of the 21st Century Regulator
Ian Hudson, Chief Executive, MHRA, UK

Achievable Efficiencies within the EU Regulatory System
Speaker invited

Session 0103 | Wednesday, 26 March, 14:00-15:30

REGULATORY TOWN HALL MEETING

Session Co-Chairs:

Guido Rasi, Executive Director, European Medicines Agency, EU

Christa Wirthumer-Hoche, Head of Austrian Medicines and Medical Devices Agency, Austria

At the Town Hall Meeting attendees can put burning questions to expert regulators about these topics:

- Transparency
- Implementation of the Pharmacovigilance Legislation
- Latest Changes to the Clinical Trial legislation
- Innovation - products in the pipeline
- EU Telematics
- EU-enlargement with Croatia

Aginus Kalis, Chair HMA, Executive Director, Medicines Evaluation Board, the Netherlands
Marcus Müllner, Chair, Telematics Support Group; Head, Austrian Medicines and Medical Devices Agency (AGES), Austria
June Raine, Chair PRAC, Vigilance and Risk Management of Medicines Division, MHRA, UK
Andrzej Rys, Director of Health Systems and Products, European Commission, EU
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, Medical Products Agency (MPA) Sweden
Viola Macolic Sarinic, Head of Agency, Agency for Medicinal Products and Medical Devices (HALMED), Croatia

Session 0104 | Wednesday, 26 March, 16:00-17:30

HOW TO GET READY FOR THE NEW CLINICAL TRIALS LEGISLATION

Session Chair:

Sabine Atzor, Head of EU Regulatory Policies, F. Hoffmann-La Roche, Switzerland

The new Clinical Trials Regulation is likely to be adopted in 2014 and will become applicable two years thereafter. The new legislation is expected to bring significant improvements with a single submission to the EU database, a single (joint) assessment by all concerned Member States and a single decision by each Member State within competitive timelines. Member States decide how they organise the work between competent authorities and ethics committees. To gain experience, pilots have been conducted by Member States with a coordinated integrated assessment process involving competent authorities and ethics committees through the Voluntary Harmonisation Procedure as "VHP +". As a trade-off for competitive assessment timelines, companies are expected to prepare complete submissions as not to risk the withdrawal of a submission.

Session 0105 | Thursday, 27 March, 09:00-10:30

BIOSIMILARS - BUILDING ON EUROPEAN FOUNDATIONS TO ACHIEVE GLOBAL HARMONISATION

Session Chair:

Judith McDonald, Senior Director, Global Regulatory Lead, Pfizer Biosimilars, Pfizer, UK

The session will review the fundamental tenets of the biosimilar concept as pioneered by the European regulators and why upholding these is of central importance in view of the fact that these concepts are sometimes misunderstood by stakeholders. We will review the challenges faced by companies in applying these concepts in a global setting and will conclude with a discussion on stakeholder education followed by a panel discussion.

I. Keynote Address

European Regulation of Biosimilars - past, present and future
Speaker invited

II. Upholding the Biosimilar Concept as Pioneered in the EU: Challenges in applying this globally

The Role of Analytics and Clinical Studies in the Development of Biosimilars
Joerg Windisch, Chief Science Officer, Sandoz Biopharmaceuticals, Austria

Overview of Regulatory Challenges in Applying the Biosimilar Concept Globally
Judith McDonald, Senior Director, Global Regulatory Lead, Pfizer Biosimilars, Pfizer, UK

Education of Stakeholders on biosimilar concepts - why does it matter globally?
Virginia Acha, Director, Regulatory Affairs - R&D Policy, Amgen, UK

Session 0107 | Thursday, 27 March, 14:00-15:30

OPTIMISING REGULATORY OPERATIONS THROUGH USE OF INFORMATION TECHNOLOGY

Session Chair:
John Kiser, Senior Director, Regulatory Operations, AbbVie, USA

This session will present information on how the regulatory environment can evolve by embracing a new paradigm for worldwide regulatory submissions enabled by information technology, what are the business drivers, what are the perceived cost and business benefits, what are the major barriers and enablers. In the regulatory environment, balancing the need to be product focused while meeting the needs of all national regulators is key, the process for prioritising and producing and customising dossiers needs to be reconsidered, access to the company systems and the company knowledge base may change and maintaining validated business processes and technology systems can be seen as a major challenge.

Globally Integrated Operations: How to develop a new regulatory model that reduces cost of operations and enables regulatory strategists to focus on product strategy, compliance and regulators
Katy Page, Senior Director Submissions and Operations Support, Pfizer, UK

Using a Hub and Spoke Model to Drive Efficiency and Cost-Effectiveness in the Global Regulatory Process
Peter Lassoff, Vice President and Head of Global Regulatory Affairs, Quintiles, UK

Regulator Evolution - Impact of technological change on the development and approval process, covering EU Telematics Roadmap, what this means for organisations, status with e-submissions around the globe and how this enables regulator evolution
Luc Verhelst, Head Information Technology Division, European Medicines Agency, EU

Session 0108 | Thursday, 27 March 16:00-17:30

CHALLENGES AND OPPORTUNITIES IN THE IMPLEMENTATION OF THE FALSIFIED MEDICINES DIRECTIVE

Session Chair:
Maren von Fritschen, Managing Partner, Director Regulatory Affairs, PharmaLex, Germany

A falsified medicine is any medicinal product with a false/fake representation of its identity, source or history. The Falsified Medicines Directive, FMD (Dir 2011/62/EU) substantially changes the European framework for the supply of medicines.

The issues relating to the implementation of the FMD will be considered from the perspective of EU regulators, inspectorates and industry. This will include a review of the current status, practical aspects and options and effectiveness of required changes to further protecting patients from the scourge of fake medicines.

A panel discussion will give room for consideration of the perspectives of all involved parties.

Challenges and Opportunities in the Implementation of the Falsified Medicine Directive from the Perspective of EU Regulators and Inspectorates
Gerald Heddell, Director, Inspection Enforcements and Standards Division, MHRA, UK

Optimising Labelling for a Digital Age
Petra Wiesinger, Clinical Assessor and Qualified Person for Regulatory Affairs, Member of the QRD Working Group, Austrian Medicines and Medical Devices Agency (AGES), Austria

Challenges and Opportunities in the Implementation of the Falsified Medicine Directive from Industry's Perspective
Alexander Natz, Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Belgium

Theme 2 | HTA/Regulatory Interface

Wills Hughes-Wilson, Vice President External Affairs, Chief Patient Access Officer, Sobi, Sweden
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU

The traditional regulatory pathway has changed considerably in recent years, particularly in supporting the interface between HTA bodies and regulators. This theme will look into the effect of these changes, whether they are delivering to those responsible for paying for drugs and services and ensuring that the right treatments reach patients in a timely manner. Participants will discuss what still needs to change to smooth the pathway from drug development to patient access, by providing the data required along that process. The theme will explore whether it is possible to create a continuous dialogue and an integrated approach to a post-marketing evidence-generation plan.

Session 0201 | Wednesday, 26 March, 09:00-10:30

CREATING AN ADAPTIVE PATHWAY FOR MEDICINES TO PATIENTS - COULD THIS BE AN APPROACH THAT FULFILLS THE NEEDS OF ALL DECISION MAKERS? A ROUNDTABLE DISCUSSION

Session Chair:
Andrzej Rys, Director of Health Systems and Products, European Commission, EU

Would a move away from having the Marketing Authorisation as a "magic moment" create an environment that meets the needs of all stakeholders in the drug development process? In other words, would "staggered", "progressive", or "adaptive" approaches, allowing authorisations for use in a defined patient population in certain situations, be one way to allow access to treatment early on in the process, while still allowing regulators, treaters, HTAs and payers the data that they need on an on-going basis. What would be the real-world benefits, barriers and enablers of such an approach? And what needs to change – if anything – to make this possible?

Regulator Perspective
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU

HTA Perspective
Jürgen Windeler, Director, IQWiG, Germany

The Agency Perspective – European and national
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, Medical Products Agency (MPA) Sweden

HTA Perspective
Carole Longson, Director, Centre for Health Technology Evaluation, National Institute for Health & Care Excellence (NICE), UK

Patient Perspective
John Kell, Policy Manager, Motor Neurone Disease Association, UK

Industry / Company Perspective
Anton Hoos, Senior Vice President, European Medical & Acting Head of Rare Diseases, GlaxoSmithKline, UK

Session 0202 | Thursday, 27 March, 11:00-12:30

HOW DO PAYERS VIEW CURRENT DEVELOPMENTS IN THE HTA AND REGULATORY ENVIRONMENT?

Session Chair:
Anna Bucsics, Department Head, Department of Pharmaceuticals Affairs, Main Association of Austrian Social Security Institutions, Austria

A variety of collaborative efforts have been undertaken in recent years to support the interface between HTA bodies and regulators. How are these interfaces delivering to those that are responsible for paying for drugs and services? And, if Health Technology Assessments (HTAs) are carried out to support the decision-making process for payers, how useful are these assessments in reality and how are they used by payers when deciding whether or not to reimburse a product? Payers will be asked what they do with HTAs and how they include such assessments in their decision making.

Andrew Donald, Chief Officer, Stafford and Surrounds and Cannock Chase Clinical Commissioning Groups, UK

Barbara Wójcik-Klikiewicz, Director of Drug Management Department, Narodowy Fundusz Zdrowia (NFZ) (National Health Fund), Poland

Session 0203 | Wednesday, 26 March, 14:00-15:30

ESTABLISHED INTERACTIONS THROUGHOUT THE REGISTRATION PATHWAY: WHAT EXISTS AND WHAT IS MISSING?

Session Chair:
Andrew Donald, Chief Officer, Stafford and Surrounds and Cannock Chase Clinical Commissioning Groups, UK

There are multiple opportunities for interactions at different stages during the lifecycle of a drug. These are tending to start earlier and should continue through post-marketing data generation. Are these interactions worthwhile and for whom? How can these interactions be improved? Who should be the players? What should be their role?

Experience with HTA Authority Interactions throughout the Registration Pathway: An industry perspective
Jens Grueger, Head Global Pricing & Market Access, Pharma Division, Roche Pharmaceuticals, Switzerland

HTA and EMA working Together: 20 parallel scientific advice procedures later, what have we learnt?
Spiros Vamvakas, Head of Scientific Advice, European Medicines Agency, EU

Parallel scientific advice – a national perspective
Niklas Hedberg, Head of Department, the Dental and Pharmaceutical Benefits Agency (TLV), Sweden

Session 0204 | Thursday, 27 March, 16:00-17:30

DATABASES, REGISTRIES AND OTHER DATA CAPTURE TOOLS: HOW CAN WE AVOID MULTIPLICITY AND CREAT AN INTEGRATED DATA-CAPTURE APPROACH ALONG THE PRODUCT DEVELOPMENT CYCLE?

Session Chair
Jens Grueger, Head Global Pricing & Market Access, Pharma Division, Roche Pharmaceuticals, Switzerland

Various data capture tools are being developed to address different needs at different stages of the product lifecycle. These include initiatives at national level – such as coverage with evidence development schemes – and at European level, for example the EUnetHTA EVIDENT database, the EMA's data collection tools to support Post-Authorisation Efficacy Studies (PAES) and Post-Authorisation Safety Studies (PASS) and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). There is the possibility to create a wealth of data with these different tools, but how can these individual systems be integrated to create a data continuum that supports informed decision-making by all actors and to avoid duplication? And are we missing opportunities provided by new technologies such as eHealth?

Integrating our Data Capture Tools – the regulatory perspective
Peter Arlett, Head of Pharmacovigilance & Risk Management, Patient Health Protection, European Medicines Agency, EU

Integrating our Data Capture Tools – the HTA perspective
Finn Børlum Kristensen, Director, EUnetHTA, Denmark

Integrating Data Capture Tools to Make the Most of Data – the patient perspective
Speaker invited

Session 0205 | Wednesday, 26 March, 09:00-10:30

MARKETING AUTHORISATION AND BEYOND: MOVING FROM EARLY DIALOGUE TO CONTINUOUS DIALOGUE – CREATING AN INTEGRATED RESEARCH AND DEVELOPMENT PATHWAY: PROVIDING A 'ONE-STOP SHOP' FOR INDUSTRY?

Session Chair:
Jérôme Boehm, Team Leader, e-Health and Health Technology Assessment, DG SanCo, European Commission, EU

Is it possible to develop a system of integrated, comprehensive Scientific Advice that brings together early and late dialogue, to inform the lifecycle of drug development, not just what is required to secure a marketing authorisation, but also to address the evidence required in support of value proposition and access? This could include scientific advice at phase 2, at the point of marketing authorisation and during post-marketing authorisation evidence generation. Would this, in fact, enable sponsors to have just one integrated research pathway, rather than generating different data for regulators, HTA bodies and payers throughout the product lifecycle? And could this be provided by an EU-wide "one-stop shop"?

How Can the EMA Contribute to a One-Stop Shop?
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU

An Integrated Pathway in Practice – a national perspective
Paolo Siviero, Head of Office, Italian Medicines Agency (AIFA), Italy

How will Industry Contribute to Making Increased Collaboration Deliver Value to Society and Patients?
Birgitte Volck, Chief Medical Officer, Sobi, Sweden

Session 0207 | Thursday, 27 March, 14:00-15:30

HOW DO WE BRING THE PATIENT'S VOICE INTO THE DISCUSSION? HOW DO WE ENSURE THAT ALL THE RIGHT VOICES ARE HEARD?

Session Chair:
Josie Godfrey, Associate Director – Highly Specialised Technologies, National Institute for Health and Care Excellence (NICE), UK

What is the reaction from stakeholders to the idea of an integrated research pathway? Will this simplify the drug development and post-marketing authorisation process, rather than continuing with the "silo'ed" approach? How will such a process work in practice and how do we ensure that the right people are involved at the right time, including the patients? What is the potential future role of patients in the drug review process?

Societal Decisions and the Patient's Voice
Mary Baker, President, European Brain Council, UK

Measuring the Burden of Not Being Treated – the BUR-QOL study
Panos Kanavos, Deputy Director, LSE Health, London School of Economics (LSE), UK

Conjoint Analysis Research – a scientific methodology to bring patient values into the process
Maarten J. IJzerman, Chair Dept. Health Technology & Services Research, University of Twente, the Netherlands

Session 0208 | Thursday, 27 March 16:00-17:30

ARE OUR HEALTHCARE SYSTEMS READY TO SUPPORT THESE APPROACHES? WHAT – IF ANYTHING – NEEDS TO CHANGE? A ROUNDTABLE DISCUSSION

Session Chair:
Wills Hughes-Wilson, Vice President External Affairs, Chief Patient Access Officer, Sobi, Sweden

If the systems are being developed to ensure that a dialogue is possible to create target populations that are agreed by all stakeholders in the development lifecycle, what impact will that have on the practice of medicine? Are we ready to work in an integrated way and, if not, what needs to change?

Patient Perspective
Christoph Thalheim, Vice CEO & Director External Affairs, European Multiple Sclerosis Platform (EMSP), Belgium

Industry Perspective
Richard Bergström, Director General, EFPIA, Belgium

Authority / Ministry Perspective
Hugo Hurts, Director Pharmaceutical Affairs & Medical Technology, Ministry of Health, Welfare & Sports, the Netherlands

The Future Policy Perspective
Speaker invited

A Payer Perspective
Klaus Klaushofer, Professor, Ludwig Boltzmann-Institute of Osteology at the Hanusch-Hospital of WGKK and AUVA Trauma Centre Meidling, Austria

Theme 3 | Benefit/Risk Management and Lifecycle Approach

Valerie Simmons, EU QPPV, Global Patient Safety, Eli Lilly & Company, UK
Tomas Salmonson, Chair Committee for Medicinal Products for Human Use (CHMP), Senior Scientific Advisor, Medical Products Agency (MPA) Sweden

European Pharmacovigilance Legislation is one of many stimuli shaping a new paradigm in benefit/risk management throughout the lifecycle of a medicine. There is more emphasis on the key drivers of a product`s benefits and risks, how to study these parameters in a real world setting, how to evaluate and re-evaluate changes throughout development and how to effectively communicate what can be complex concepts to all stakeholders in an increasingly transparent global environment. This approach has prompted fundamentally new ways of working, the need for new skill sets and closer interactions across functional boundaries not usual in traditional organisational models. This theme will explore various aspects of this Brave New World, and examine the extent to which it has met its objectives in promoting patient safety.

Session 0101/0301 | Wednesday, 26 March, 09:00-10:30

MAKING THE PHARMACOVIGILANCE LEGISLATION WORK – A TEMPERATURE CHECK

Session Chair:
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance, AbbVie Ltd., UK

Sabine Straus, Head of Pharmacovigilance, Medicines Evaluation Board, the Netherlands

Theo Radnor, Professor of Pharmacy Practice, School of Healthcare, University of Leeds, UK

Session 0302 | Wednesday, 26 March, 11:00-12:30

THINKING BEYOND OLD PHARMACOVIGILANCE BOUNDARIES

Session Chair:
John Ayres, Senior Director, Product Safety Assessment, Eli Lilly & Co., USA

The session will explore opportunities where pharmacovigilance scientists might bring their expertise into the drug development design space. Incorporating the voice of the patient into safety study design and identifying benefit/risk attributes early in development will be discussed.

A Framework and Minimum Dataset for Patient-Reported Outcomes in Adverse Event Reporting (PRO-AEs)
Swapu Banerjee, Deputy Managing Director, Pope Woodhead & Associates Ltd, UK

Implementation of a Structured B/R Profile Approach into Drug Development
Isabelle Stöckert, Head Global Regulatory Affairs Europe/Canada, Bayer Pharmaceuticals, Germany

Linking Critical Quality Attributes (CQAs) to the Benefit/Risk Calculus
John Ayres, Senior Director, Product Safety Assessment, Eli Lilly & Co., USA

Session 0304 | Wednesday, 26 March, 16:00-17:30

CURRENT INDUSTRY PRACTICE FOR BENEFIT/RISK GOVERNANCE
Session Chair:
Anne Bouvier, Director and Head of Benefit Risk Management and Process Innovation, UCB Pharma, Belgium

A case study will be used to illustrate changes made to a company's existing safety risk governance model to include expanded functional stakeholders necessary to align on a comprehensive benefit/risk characterisation. The session will also review the ongoing debate regarding the qualitative vs. quantitative methods used for benefit/risk evaluations and the importance of standardised process. Finally, an approach for achieving an integrated lifecycle approach to benefit/risk evaluation and the current industry practices in operationally addressing new requirements will be explored. Industry benchmarking data will be referenced to characterise current practices in organisation & governance, benefit/risk assessment processes, benefit/risk source data and the challenging areas for development.

A Case Study to Illustrate the Benefit/Risk Evaluation Process and Governance
Anne Bouvier, Director and Head of Benefit Risk Management and Process Innovation, UCB Pharma, Belgium

Evaluation of Qualitative Benefit/Risk Assessment Methods
Berit Nautrup Andersen, Head of Safety Operations and Risk Management, ALK, Denmark

Current Industry Best Practices and Achieving Lifecycle Integration
Sharmila Sabaratnam, Senior Consultant, WCI Consulting, Ltd., UK

Session 0305 | Thursday, 27 March, 09:00-10:30

TRANSPARENCY IN THE PHARMACEUTICAL SECTOR – WHAT HAVE WE LEARNED?
Session Chair:
Ragnar Lofstedt, Professor of Risk Management, Kings College, UK

Carmen R. Bozic, Senior Vice President, Global Head, Safety and Benefit/Risk Management, Biogen Idec, USA

Aginus Kalis, Chair HMA, Executive Director, Medicines Evaluation Board, the Netherlands

Session 0306 | Thursday, 27 March, 11:00-12:30

MOVING FROM RISK MANAGEMENT TO BENEFIT/RISK MANAGEMENT PLANNING
Session Chair:
Susana Perez-Gutthann, Vice President, Global Head Epidemiology, RTI Health Solutions, Spain

This session is currently in development.

Session 0307 | Thursday, 27 March, 14:00-15:30

PERIODIC BENEFIT RISK EVALUATION REPORTING – HAS IT ACHIEVED WHAT IT SET OUT TO DO?
Session Chair:
Craig Hartford, Vice President, Safety Surveillance and Risk Management, Worldwide Safety Strategy, Pfizer Medical, UK

The Periodic Benefit Risk Evaluation Report ICH E2C (R2) Guidance reached Step 4 of the ICH process in November 2012. In this session we evaluate, based on experience to date, whether the main objective of the PBRER is being met viz. to present a comprehensive, concise, and critical analysis of new or emerging information on the risks of the medicinal product, and on its benefit in approved indications, to enable an appraisal of the product's overall benefit-risk profile.

A Regulatory Perspective on the Achievement of PBRER Objectives
Almath Spooner, Vice-Chair, PRAC, Pharmacovigilance and Risk Management Lead, Irish Medicines Board (IMB), Ireland

A Pharmaceutical Industry Perspective on the Achievement of PBRER Objectives
Barbara de Bernardi, Deputy QP, Pfizer, UK

Panel Discussion- Periodic Benefit/Risk Evaluation - has it achieve what it set out to do?
This panel will include industry and regulator subject matter experts including session speakers and
Valerie Simmons, EU QPPV, Global Patient Safety, Eli Lilly & Company, UK

Additional panelists invited

Session 0308 | Thursday, 27 March 16:00-17:30

RISK MINIMISATION AND ITS EFFECTIVENESS – WHAT IS STATE OF THE ART AND WHAT IS REALISTIC?
Session Chair:
Stephen Heaton, Head of Safety Risk Management Planning and Coordination, Bayer Healthcare, Germany

This session is currently in development. Please check the online programme for details.

Theme 4 | Special Populations

Judith Creba, Head EU Liaison & Policy, Novartis Pharma, Switzerland

Special populations such as children and the elderly require particular attention during drug development. The Paediatric Regulation has slowly started to deliver better and more data for medicines used in children, with the European Commission's conclusions after 5 years of experience eagerly awaited and still to be discussed. The latest developments in paediatrics from the perspective of all stakeholders will be covered.

The changing demographics and aging of populations are increasing the need to provide safe and effective medicines for the older population. This theme will explore the various initiatives and strategies to address specific issues in developing medicinal products for use in older people.

Session 0401 | Wednesday, 26 March, 09:00-10:30

PAEDIATRIC REWARDS - WHERE DO WE STAND? WHAT ARE THE OBSTACLES, AND HOW COULD THE SYSTEM BE IMPROVED?
Session Chair:
Geneviève Michaux, of Counsel, Hunton & Williams, Belgium

The session discusses the difficulties faced by the industry for being rewarded for their paediatric development and examines the possible solutions.

SPC Extensions – What are national patent offices demanding?
Lawrence Cullen, Deputy Director (Biotechnology, Pharmaceuticals & Organic Chemistry), Intellectual Property Office, UK

Orphans – Where are the rewards?
Emmanuelle Lecomte-Brisset, Senior Director, Head of European Regulatory Affairs, Shire, Switzerland

PUMA – Could it be worthwhile?
John Watson, Senior Director Regulatory Affairs Europe, ViroPharma, UK

Session 0402 | Wednesday, 26 March, 11:00-12:30

LATEST DEVELOPMENTS IN PAEDIATRICS

Session Chair:
Christina Bucci-Rechtweg, Head, Pediatric & Maternal Health Policy, Global Drug Regulatory Affairs, Novartis Pharmaceuticals, USA

The Paediatric Regulation has set the stage to advance the development of better medicines for children within the broader global regulatory environment. A PDCO representative will provide his vision for the future of pediatric drug development in the EU. A representative from the EMA and an industry representative will provide their perspectives on new developments related to paediatrics, and provide an outlook on opportunities and challenges that lie ahead.

The PDCO Chairman's Perspective: 2014 and Beyond
Speaker invited

Opportunities and Challenges: An EMA perspective
Paolo Tomasi, Head of Paediatric Medicines, European Medicines Agency

Opportunities and Challenges: An industry perspective
Speaker invited

Session 0403 | Wednesday, 26 March, 14:00-15:30

DEVELOPING MEDICINAL PRODUCTS FOR OLDER PEOPLE - GETTING ON TRACK

Session Chair:
Markku Toivonen, NDA Advisory Board - Scientific Director, NDA Group, UK

Rational pharmacotherapy in the older population requires fit-for-purpose data for benefit risk assessment at the time of marketing application. Specific, early attention is required in designing clinical programs and in providing regulatory input.

EMA Geriatric Strategy – What is it and how is it delivering?
Paolo Tomasi, Head of Paediatric Medicines, European Medicines Agency, EU

Optimising Clinical Trial Design and Conduct to Support Benefit/Risk Assessment in Older Patients
Florian von Raison, Senior Global Program Head and Chairman Geriatric Medicine Working Party/ EFGCP, Novartis, Switzerland

Benefit/Risk Assessment in Older Patients in the Pre- and Post-Authorisation
Andrea Laslop, Head of Scientific Office, Austrian Medicines and Medical Devices Agency (AGES), Austria

Theme 5 | Personalised Medicine: Drug-companion diagnostics combinations

Tim Kievits, Director Healthcare Innovation, Vitromics Healthcare, the Netherlands
Anna Bucsics, Department Head, Department of Pharmaceuticals Affairs, Main Association of Austrian Social Security Institutions, Austria

Personalised medicine refers to the strategy of trying to identify responders to a specific treatment before initiating therapy. The FDA and EMA already encourage the inclusion of companion diagnostics during development of medicines and in the market. However, co-development and assessment of therapies and associated diagnostics, also called companion diagnostics, is challenging. The pharmaceutical industry and payers, such as national healthcare services or health insurers, for different reasons, worry about the business and economic consequences of developing therapies for small groups of patients. Furthermore personalised medicine currently seems to be a mostly technology driven topic while other equally important aspects such as socio-ethical, organisational and educational/training challenges are not yet adequately addressed.

This complex and unresolved situation will be discussed in the Personalised Medicine Theme covering:
- A description of the current status and latest developments
- Discussion of bottlenecks and visions on how to implementation of personalised medicine
- Next steps on a practical basis for healthcare professional

Session 0501 | Wednesday, 26 March, 09:00-10:30

TRANSLATION OF PERSONALISED MEDICINE CONCEPTS

Session Chair:
Michael Zühlsdorf, Senior Director Oncology, Global Head Translational and Biomarker Research, Merck Serono Global Research and Early Development, Merck KGaA, Germany

This session addresses the latest scientific developments driving personalised medicine, adaptive trial concepts supportive of personalised medicine and early scientific advice for the development of personalised medicine from regulators, HTA bodies and payers.

Latest Scientific Developments/New Biomarker Technologies
Giulio Superti-Furga, Scientific Director, Research Center for Molecular Medicine of the Austrian Academy of Sciences, Austria

Scientific Advice from Regulators
Spiros Vamvakas, Head of Scientific Advice, European Medicines Agency, EU

Adaptive Enrichment Design - A case study
Zoran Antonijevic, Senior Director, Strategic Consulting and Adaptive Implementation, Cytel, USA

Session 0502 | Wednesday, 26 March, 11:00-12:30

FROM BIOMARKERS TO COMPANION DIAGNOSTICS

Session Chair:
James Creeden, Chief Medical Officer, Roche Professional Diagnostics, Switzerland

This session will cover validation and regulation of drug-diagnostics combinations, introduction of personalised medicine innovations in clinical practice, corporate and governmental pharmaceutical and diagnostic coordination, and introduction of personalised medicine in to clinical practice.

Current Regulation and Challenges for Biomarker and Companion IVD Development – Focus on biotech products
Jörg Engelbergs, Scientific Expert Antibody Therapeutics, Paul-Ehrlich-Institut, Germany

Developments in Companion Diagnostics/PHC
Rainer Metzger, Vice President Global Business Development Pharma, Qiagen, Germany

Validation of the diagnostic component
Speaker invited

Introduction Therapy/Test Combination in Clinical Practice
Robert Mader, Director of Translational Research, Medical University Clinics – Vienna General Hospital, Austria

Session 0503 | Wednesday, 26 March, 14:00-15:30

HEALTH ECONOMIC ASPECTS OF PERSONALISED MEDICINES

Session Chair:
Sabine Vogler, Head of Pharma Team, PPRI Project Manager, Austrian Health Institute (Gesundheit Österreich Gmbh), Austria

Personalised medicine approaches aim at assuring optimal use of healthcare budgets by only providing a therapy to those patients that benefit from the treatment. However this approach drives towards many different and often more expensive treatments. This session will address the question: How to make personalised medicine affordable?

Pre-empting Problems for Personalise Medicine Adoption in the Market
Brian Godman, Senior Researcher, Karolinska Institute, Division of Clinical Pharmacology, Karolinska University Hospital, Sweden

European Payers Overview on Reimbursement
Claudia Habl, Head of Austrian Pharmaceutical Price Information (PPI-Service), Austrian Health Institute (Gesundheit Österreich Gmbh), Austria

Need for Valuing of Diagnostics Essential for Success of Personalised Medicine
James Creeden, Chief Medical Officer, Roche Professional Diagnostics, Switzerland

Market (easy?) Access for PM
Speaker invited

Session 0504 | Wednesday, 26 March, 16:00-17:30

THE SOCIETAL PERSPECTIVE ON PERSONALISED MEDICINE - MANAGING THE PARADIGM SHIFT

Session Chair:
Brian Godman, Senior Researcher, Karolinska Institute, Division of Clinical Pharmacology, Karolinska University Hospital, Sweden

The introduction of personalised medicine asks for adoptions of many stakeholders. How are we going to manage the paradigm shift in the healthcare sector to assure fast adoption of personalised medicine?

Can Society Afford Personalised Medicine?
Claudia Wild, Director, Ludwig Boltzmann Institute for Health Technology Assessment, Austria

Patient Representative's View on Personalised Medicine
Speaker invited

Industry-Society Interactions are Essential to Make Promises of Personalised Medicine Come True
Alexander Roediger, Director European Union Affairs, Merck Sharpe and Dohme, Belgium

Introduction of Personalised Medicine in East European Economies
Judit Molnar Maria, Vice Rector, Semmelweiss University, Professor of Genomic Medicine and Rare Diseases, Hungary

Theme 6 | Clinical Research

Clara Heering, Vice President Clinical Risk Management, ICON Clinical Research, Belgium
Carl Naraynassamy, Director, Explicator, Ltd., UK

Draft risk-based monitoring (RBM) regulations, new technologies organising aggregated sources of digital data, as well as advances in behavioural sciences provide new responses to the industry's search for optimised clinical research paradigms. We need to ascertain that the paradigm shifts are founded on robust assessments of risk and evidence of qualitative and effective processes, verify that investigators, monitors and project managers are empowered in their decision making and satisfy ourselves that the greater reliance on digital data enhances patient safety and ethical conduct of clinical research. What are the lessons learned and benchmarks to date in this new era of clinical research?

Session 0601 | Wednesday, 26 March, 09:00-10:30

THE IMPORTANCE FOR ALL TO ADOPT RISK- BASED MONITORING TODAY: INTRODUCTORY SESSION

Session Chair:
Clara Heering, Vice President Clinical Risk Management, ICON Clinical Research, Belgium

Attendees will be brought to speed on the various pan-industry initiatives over RBM. The speakers will situate RBM in the context of optimising drug development, the regulatory framework for conducting research and its impact on study participants.

Industry Perspective
Jessica Holthuizen, Clinical Operations Head CVM, Janssen Pharmaceuticals, Belgium (representing TransCelerate BioPharma Inc.)

Patient Perspective
Speaker invited

EMA Perspective
Ana Rodriguez, Head of Clinical and Non-clinical Compliance, European Medicines Agency, EU

Session 0603 | Wednesday, 26 March, 14:00-15:30

RISK- BASED MONITORING: THE CASE FOR DEVELOPING NEW ROLES, SKILLS AND COMPETENCIES

Session Chair:
Carl Naraynassamy, Director, Explicator, Ltd., UK

The presenters will discuss how the changes in monitoring practices call for adapted competencies in those who work closely on the collection of study data.The debate will focus on ways and means to maximise the acquisition of these adapted competencies.

Evolution of the Project Manager
Brendon Binneman, Senior Director, Pfizer, USA

Evolution of the Monitor Role

Albrecht de Vries, Global Quality and Compliance Head, Janssen R&D, the Netherlands

Evolution of the Investigator and Team
Karolinien de Roeck, Associate Clinical Director, AbbVie, Belgium

Debate: How to diminish resistance to change and engage the full clinical research team

Session 0604 | Wednesday, 26 March, 16:00-17:30

RISK- BASED MONITORING: WHICH INFRACTURIAL AND BUSINESS RELATIONSHIP CHANGES DO WE NEED TO CONSIDER?

Session Chair:
Beat Widler, Managing Partner, Widler & Schiemann, Switzerland

The presenters will consider changes required to the established infrastructure for providing clinical research services in order to accommodate risk based monitoring. The evolution in the business relationships over outsourcing will be specially considered.

New Landscape: CRO and biopharma partnerships in RBM
Regina Freunscht, Vice President, Global Research & Development Quality Assurance, Merck Serono, Germany

Infrastructure Changes Required for RbM and their Change Management Implications
Beat Widler, Managing Partner, Widler & Schiemann, Switzerland

Performance and Quality Monitoring Systems
Speaker invited

Debate: Old versus New: Opportunities and challenges of both systems

Session 0605 | Thursday, 27 March, 09:00-10:30

INNOVATIVE METHODOLOGIES USED IN ENHANCING QUALITY

Session Chair:
Chair invited

In this session, the speakers focus on specific novel methodologies which improve quality to improve three aspects of drug development which prove always to be challenging.

Use of Virtual Population Simulation to Improve Protocol Design and Amendment Management
Badri Rengarajan, Medical Director, Archimedes Inc., USA

Incorporating Risk-Based Monitoring Strategies: Challenges and Implementation from industry and regulators
Sherri A. Hubby, Director, US Quality Assurance, Premier Research Group, USA

Identifying Patients at Risk in Clinical Trials Using Data Mining and Data Visualisation Technologies
Robbert van Manen, Sales Consultant, Oracle Health Sciences, the Netherlands

Session 0606 | Thursday, 27 March, 11:00-12:30

SYSTEMATIC APPROACHES TO DELIVER QUALITY: LEARN FROM THE EXPERTS!

Session Chair:
Brian Edwards, Principal Consultant Pharmacovigilance and Drug Safety, NDA Regulatory Science, UK

In this session, three experts reflect on practical ways to achieve quality.

Risk Assessment Trends
Speaker invited

Realising Time and Cost Savings through Protocol Design Planning Improvements
Stella Stergiopoulos, Project Manager, Tufts Center for the Study of Drug Development, USA

What Can Safety Engineering Teach Us about Better Controlling Clinical Safety and Managing Risk?
Brian Edwards, Principal Consultant Pharmacovigilance and Drug Safety, NDA Regulatory Science, UK

Session 0607 | Thursday, 27 March, 14:00-15:30

RISK-BASED MONITORING: STAKEHOLDER PERSPECTIVES FOR A RATIONAL PROCESS

Session Co-Chairs:
Peter Stokman, Head Global Data Management & Standards Oss, Merck Sharpe and Dohme, the Netherlands
Clara Heering, Vice President Clinical Risk Management, ICON Clinical Research, Belgium

In the first part, the speakers focus on the rationale and applicability of prioritising limited resources to crucial sectors. Key regulatory documents are analysed and drivers such as 'proportionality' are reviewed. In the second part, 'complicating factors' are discussed in small groups. This is a challenge to the audience to think freely on how to break away from company culture and thinking, and to provide and justify ideas for reconfiguring the current process. The complicated factors covered are: the fragmentation of responsibilities linked to the specialisation of service providers; risk aversion and the reluctance to change current practices; business practices which stifle innovation; misconstrued and over-interpreted regulatory requirements which lead to perverse results.

This session will have break-out discussions followed by review of overall findings.

Current Pharma Solutions to Address Protocol Data Relevance
Ken Getz, Director of Sponsored Research Programs, Associate Professor, CSDD, Tufts University School of Medicine, USA

Data-Driven Clinical Development: A means by which the pharmaceutical industry can improve its productivity and efficiency
Sarah Athey, Director, European Consulting, Quintiles, UK

Additional speaker invited

Session 0608 | Thursday, 27 March 16:00-17:30

THE BRAVE NEW WORLD OF DIGITAL DATA: WHAT ARE THE NEW LEGAL AND ETHICAL QUESTIONS?

Session Chair:
Chair invited

The session addresses some ethical and legal repercussions of collecting patients' data digitally. The potential impact on data privacy is covered as well as the likely education that subjects will need to enable them to make informed decisions on the release of their personal data.

Lack of Reproducibility or Why Most Published Research Findings Are False
Joachim Vollmar, Executive Consultant, International Clinical Development Consultants LLC, USA

Patient and Data Privacy in a Digital World
Speaker invited

Debate: What will it mean for patient education?
Panel with all speakers and Geneviève Michaux, Counsel, Hunton & Williams, Belgium

Theme 7 | eClinical: Reaching Out

Peter Stokman, Head Global Data Management & Standards Oss, Merck Sharpe and Dohme, the Netherlands

Over the last decade, 'Clinical' took a giant leap to become 'eClinical'. This greatly increased the possibilities for speeding up, increasing quality, performing new types of studies and analyses, streamlining the data flow, and in general taking clinical development to the next level. During this session the added value, implications and future perspectives of eClinical will be presented in an understandable way to the various (non-technical) disciplines involved in pharmaceutical development.

Session 0701 | Wednesday, 26 March, 09:00-10:30

eTRIAL MASTER FILE (eTMF)

Session Chair:
Peter Stokman, Head Global Data Management & Standards Oss, Merck Sharpe and Dohme, the Netherlands

Over the last couple of years, the greatest advances in eClinical have been made in the data collection arena. The 'next big thing' for many companies is the leap to full electronic storage of the clinical documentation required to ensure regulatory compliance. During this session, the need, the issues and the benefits will be addressed, including how 'The Cloud' can be leveraged as data repository.

Horses for Courses - Is the eTMF really a document management problem?
Jonathan Burd, Solution Director, GxPi, UK

eTMF in Clinical Trial Management - Improve your clinical operations efficiency
Speaker invited

Cloud Computing Solutions for the Clinical Environment
William O'Mara, Manager, Clinical Data Management, DATATRAK International, USA

Session 0702 | Wednesday, 26 March, 11:00-12:30

eCLINICAL TRIALS

Session Chair:
Isabelle de Zegher, Worldwide Senior Director, Clinical Data Standards, Perceptive Informatics, Belgium

Increased efficiency in clinical trial execution remains a key target. This session will explore more particularly three aspects: faster system set-up, increased compliance of investigators and opportunities for improved monitoring by CRA.

Implementation of eProtocol BRIDG Structure toward Increased Efficiency in Data Collection, Submission and Data Integration
Isabelle de Zegher, Worldwide Senior Director, Clinical Data Standards, Perceptive Informatics, Belgium

Using Gamification to Incentivise Sites
Niki Kutac, Product Manager, DATATRAK International, USA

Trends in Global Clinical Research Monitoring: A Perspective from the field, Annual Survey on the State of the Industry
Scott Freedman, President, MonitorForHire.com, USA

Session 0703 | Wednesday, 26 March, 14:00-15:30

eCLINICAL STRATEGY

Session Chair:
Detlef Nehrdich, Senior Associate, Waife and Associates Inc., Germany

This session will focus on the strategical aspects eClinical solutions. Examples of ePRO, EDC and a clinical portal will be used to describe how to prepare organisations strategically for the implementation of different eClinical solutions.

How to Implement an ePRO Strategy: A best practices guide
Frans Wald, Head Clinical Trials Support, Boehringer-Ingelheim, Germany

Successful Usage of Cloud-Based Clinical Portals both with CROs, Investigators and Internally
John Aggerholm, Project Director, HERAX, Denmark

EDC for Small to Mid-Size Companies
Bernard Brandewiede, Managing Director, AMEDON, Germany

Session 0704 | Wednesday, 26 March, 16:00-17:30

DATA INTEGRATION

Session Chair:
Philippe Verplancke, Managing Director, XClinical, Germany

The Future for Clinical Trials
Serge Van der Geyten, Associate Director Global Regulatory Affairs – Neuroscience, Janssen Research and Development, Belgium

Making it Work: Bringing technology together to produce useful data
Carmen Weese, Associate Director, Data Management, INC Research, USA

Advantages of a Real End-to-End Approach with CDISC Standards
Philippe Verplancke, Managing Director, XClinical, Germany

Theme 8 | eHealth - Innovation in Healthcare and its Impact for Industry

Hans van Bruggen, Director, eCTDConsultancy, the Netherlands
Terje Peetso, Policy Officer, Unit H1 - Health and wellbeing, Directorate General Communications Networks, Content and Technology (DG CONNECT), European Commission, EU

Efficient and sustainable healthcare systems, such as eHealth, are needed to maintain and improve overall public health. eHealth includes efficient exchange of clinical trial data, eHealth Records and ePrescriptions across the IT systems. This requires interoperable systems for healthcare professionals, patients/citizens, epidemiologists and pharmaceutical industry. Remote access and interoperability allows for mobile health, including smart phones/tablets and social media apps. The use of smart mobile devices will increase the amount of electronically available information and improve therapy compliance. The use of social media augments the power of the public on how therapies are perceived. All these support patient empowerment.

Session 0805 | Thursday, 27 March, 09:00-10:30

EUROPEAN COMMISSION'S eHEALTH ACTION PLAN 2012-2020

Session Chair:
Terje Peetso, Policy Officer, Unit H1 - Health and wellbeing, Directorate General Communications Networks, Content and Technology (DG CONNECT), European Commission, EU

The 'eHealth Action Plan 2012- 2020, Innovative Healthcare for the 21st Century' aims at utilising eHealth to address current healthcare challenges. The activities can be largely divided into four groups: 1. Achieve wider interoperability in eHealth services; 2. Support research, development, innovation and competitiveness in eHealth; 3. Facilitate uptake and ensure wider deployment of eHealth and 4. Promote policy dialogue and international cooperation at global level. The action plan emphasises activities at the EU level, but it encourages all stakeholders such as national and regional authorities, health and social care providers, professional organisations, researchers and patients being active in this area and working closely together.

Introduction to the eHealth Action Plan
Paul Timmers, Director ICT addressing Societal Challenges, Directorate General Information Society and Media, European Commission, EU

eHealth, mHealth and Apps
Erik Vollebregt, Partner, AXON Lawyers, the Netherlands

Innovation Partnership on Active and Healthy Ageing
Elena Mancini, Product Manager, Daiichi Sankyo Italia, Italy

Session 0806 | Thursday, 27 March, 11:00-12:30

INTEROPERABILITY FOR HEALTHCARE PROVIDERS ACROSS THE EU

Session Chair:
Terje Peetso, Policy Officer, Directorate General Communications Networks, Content and Technology, European Commission, EU

Interoperability of ICT-enabled solutions and of data exchange is the precondition for better coordination and integration across the entire chain of healthcare delivery and health data exchange. Equally important are the following four aspects of the interoperability: legal, organisational, semantic and technical.

Interoperability
Scott Adams, Practice Lead- Interoperability, Global Health Portfolio & Practices, BT Global Services, UK

epSOS: Interoperability in respect to the eHR and ePrescription
Marcello Malgara, LIspa c/o Health Information System and International Health Projects, Lombardy Region, Regional Government, Health Ministry, Italy

Additional speaker invited

Session 0807 | Thursday, 27 March, 14:00-15:30

BIG DATA, eHEALTH RECORDS AND TAXONOMY

Session Chair:
Hans van Bruggen, Director, eCTDConsultancy, the Netherlands

The goal of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is to further strengthen the post-authorisation monitoring of medicinal products in Europe by facilitating the conduct of multi-centre, independent, post-authorisation studies focusing on safety and on benefit/risk, using available expertise and research experience across Europe. Gathering this kind of data in ONE taxonomy database leads to greater interoperability between pharmaceutical industry, healthcare professionals and patients. However, until now there has been a shortage of fully integrated informatics solutions that can handle data from multiple sources. Integration of these multiple platforms might achieve personalised medicine in the future.

ENCePP and eHRs
Peter Arlett, Pharmacovigilance Department, European Medicines Agency, EU

Tracing Adverse Drug Reactions (ADRs) to eHR – Bridging the interoperability gap
Ola Strandberg, Chief Product Officer, Uppsala Monitoring Center, Sweden

Big Data: The promise and challenge for personalised medicine
Joel Haspel, Director Healthcare Strategy, Oracle Health Sciences, UK

Session 0808 | Thursday, 27 March 16:00-17:30

THE ROLE OF SOCIAL MEDIA IN HEALTHCARE

Session Chair:
Hans van Bruggen, Director, eCTDConsultancy, the Netherlands

Social media typically consists of four characteristics that have changed the nature of interactions among people and organisations: user generated content, community, rapid distribution, and open, two-way dialogue. This change in nature of the interactions does not only impact the communication in people's social life, but also the communication between patients and healthcare providers and between healthcare providers and industry.
This session focuses on the patients view on social media in healthcare, as well as the role of the users in the development of social media and its impact on industry.

Patient View on the Role of Social Media in Healthcare
Anders Olauson, President, European Patients' Forum, Sweden

Role of Various End-Users in the Development of Social Media
Tim Pellens, Managing Partner, Value Proof, the Netherlands

Social Media – Changing landscape and impact
Murali Parthasarathy, Managing Director, Saaraa Medical Solutions, USA

Theme 9 | Involving and Informing Patients

Jan Geissler, Project Director EUPATI

Well informed patients and patient advocates have a key role to play in the implementation of patient-centred clinical research strategies and approval processes, access to treatments and treatment optimisation approaches. In an era of growing demand and emphasis on both quality and sustainability of healthcare, it is critical to involve patients in the R&D process.

In many disease areas, patients are already actively engaging in the many processes involved in the development of new treatments today - from contributing to protocol design, informed consent and ethical review to the overall medicines development process, marketing authorisation and healthcare policy. Involving patients can accelerate research and make it more effective.

This theme will look into examples of what patients need to know about clinical trials, how to turn informed consent into an opportunity, best practice how patient advocates are involved in clinical research today, how to effectively use social media and mobile devices to work with patients, and how to train patient advocates to be knowledgeable partners in clinical research.

Session 0901 | Wednesday, 26 March, 09:00-10:30

PATIENTS AS PARTNERS IN CLINICAL RESEARCH

Session Chair:
Jan Geissler, EUPATI, Leukemia Patient Advocates Foundation

Increasing Health Literacy and Making Doctor-Patient Communication More Effective
Kay Parkinson, Chief Executive Officer, Alstrom Syndrome, UK

Communicating Clinical Trials: Combining regulatory obligations and patient recruitment
Holger Maria Rohde, Medical Operations Officer, TEVA Pharma, Germany

Empowering and Educating Patients in Medicines R&D
Maria Mavris, Director Therapeutic Development, EURORDIS, France

Session 0902 | Wednesday, 26 March, 11:00-12:30

PATIENT EMPOWERMENT: OPPORTUNITIES AND CHALLENGES

Session Chair:
Gerard Nguyen, Hôpital Avicenne Aphp/Rett Syndrome Europe, France

Six Proven Strategies to Advocacy Engagement for Clinical Trials
Aaron Fleishman, Social Innovation, BBK Worldwide, USA

Focus on the Patient: An industry players perspective on collaboration and patient empowerment
Kay Warner, Project Manager "Focus on the Patient", Global Medical Platforms & Capabilities, GlaxoSmithKline, UK

Patient Viewpoint on Patient Empowerment: Concepts, misconception, use and misuse
Gerard Nguyen, Hôpital Avicenne Aphp/Rett Syndrome Europe, France

Session 0904 | Wednesday, 26 March, 16:00-17:30

EFFICIENT USE OF SOCIAL MEDIA TO WORK WITH e-PATIENTS

Session Chair:
Chair invited

Patient-Centric Engagement in Clinical Trials and the Digital Age
Kai Langel, Principal Consultant, eClinical Health, Belgium

Collaborating with Patient Organisations via Social Media to Optimise Drug Development
Stella Stergiopoulos, Tufts Center for the Study of Drug Development, USA

The Power of Patient-Driven Communities and their Role in Research: The RareConnect example
Rob Pleticha, RareConnect Project Manager, EURORDIS, France

Theme 10 | Globalisation/Inspections

Estelle Michael, Senior Director, Policy and Intelligence, Europe and International Regulatory Policy, Intelligence, AstraZeneca, UK
Lembit Rägo, Coordinator, Quality Assurance and Safety for Medicines, Essential Medicines and Health Products, WHO, Switzerland

Globalisation continues to grow and evolve in a number of areas of interest to the pharmaceutical industry. Indeed, if time permitted a whole conference could be dedicated to this topic! In lieu of such luxury the focus of this theme will be:

- Regulatory harmonisation initiatives – from EU accession to global networking
- Market access – regulatory and cultural challenges and opportunities, e.g. impact of new science on concepts such as ethnicity
- Challenges of developing global regulatory strategies in light of innovation and emerging diseases
- Managing and working around complexity of supply chain in face of increasing regulatory scrutiny
- Mutual recognition and sharing of resource, particularly with regard to GxP inspections
- Future regulatory framework – what will the landscape look like in 10-20 years from now?

Session 1001 | Wednesday, 26 March, 09:00-10:30

REGULATORY HARMONISATION AND REGULATORY CONVERGANCE - AN UPDATE

Session Chair:
Lembit Rägo, Coordinator, Quality Assurance and Safety for Medicines, Essential Medicines and Health Products, WHO, Switzerland

Current Status and Challenges of Bilateral/Multilateral Meetings
Nobumasa Nakashima, Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Experience of Accession
Viola Macolic Sarinic, Head of Agency, Agency for Medicinal Products and Medical Devices (HALMED), Croatia

Session 1002 | Wednesday, 26 March, 11:00-12:30

SURVIVING SAFETY AND QUALITY INSPECTIONS IN THE ERA OF GLOBALISATION: HARMONISING SYSTEMS AND PROCESSES ACROSS COMPANY UNITS

Session Chair:
Ambrish Mathur, Vice President, Strategic Development, Aris Global, USA

With the global market reach of most large Pharma, together with their widely distributed business and manufacturing centres, companies are challenged with implementing efficient workflows and quality processes that ensure global regulatory compliance and inspection readiness. This session looks at case studies from large Pharma on implementing processes for monitoring and ensuring compliance with safety submissions globally.

Surviving Safety and Quality Inspections in the Era of Globalisation: Harmonising systems and processes across company units
Ambrish Mathur, Vice President, Strategic Development, Aris Global, USA

Achieving Excellence in Pharmacovigilance Inspection Preparedness for Global Environments
Global Head Safety Operations
Leann Fieldstad, Global Head Safety Operations, Genentech, USA

Herding a Flock – Global adverse event submission
Martin Henzl, Director, Pharmacovigilance Technology, Baxter, Austria

Session 1003 | Wednesday, 26 March, 14:00-15:30

GLOBAL DEVELOPMENT AND SUPPLY

Session Chair:
Chair invited

Effects of Complex Supply Chains on the Regulatory Strategy for Emerging Markets
Kirsten Jacobs, Head of Regulatory Submissions/Operations, Pharmalex, Germany

Additional speakers invited

Session 1004 | Wednesday, 26 March, 16:00-17:30

GXP INSPECTIONS – FOCUS ON HAMONISATION EFFORTS

Session Chair:
Ana Rodriguez, Head of Clinical and Non-clinical Compliance, European Medicines Agency, EU

This session is currently in development.

Session 1005 | Thursday, 27 March, 09:00-10:30

GLOBAL SUBMISSION AND REVIEW STRATEGY - HOW RAPIDLY INNOVATION CAN REACH GLOBAL MARKETS

Session Chair:
Joseph Scheeren, Senior Vice President, Head Global Regulatory Affairs, Bayer Pharmaceuticals, Germany

This session will discuss how to optimise global regulatory submissions and review for timely patient access to innovative medicines as well as the challenges beyond (ICH) harmonisation.

Perspective from Regulator: Good review practice
Speaker invited

Achieving Convergence in Global Regulatory Approvals and Market Access for True Innovation
Alberto Grignolo, Corporate Vice President, Global Strategy, PAREXEL Consulting, USA

Perspective from Industry: How to develop and manage global regulatory submission, from pre-filing strategy to handling multiple, cross-regional questions from authorities during assessment
Speaker invited

Session 1006 | Thursday, 27 March, 11:00-12:30

REGULATION 2025 – STAKEHOLDER VISION FOR THE FUTURE OF THE GLOBAL REGULATORY FRAMWORK BETWEEN NO AND 2025

Session Chair:
Richard Barker, Director, Centre for the Advancement of Sustainable Medical Innovation (CASMI), UK

This session is currently in development.

Session 1007 | Thursday, 27 March, 14:00-15:30

CURRENT STATUS AND FUTURE CHALLENGES OF ASIAN REGULATORY ENVIRONMENT

Session Chair:
Nobumasa Nakashima, Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The Asian region is becoming a pharmaceutical manufacturing hub as well as a key market. This session will clarify current issues and discuss future direction in promoting regulatory harmonisation in Asia, focusing on ICH, APEC and ASEAN.

Speakers to be announced

Session 1008 | Thursday, 27 March 16:00-17:30

REGULATORY SIMPLIFICATION: VISION, OXYMORON, OR 'MISSION IMPOSSIBLE'?

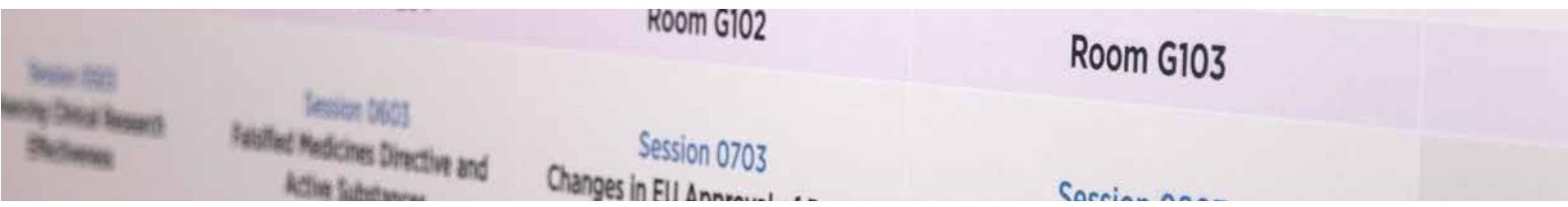
Session Chair:
Markus Hartmann, Principal Consultant, European Consulting & Contracting in Oncology, Germany

Regulatory simplification is more than a buzzword: it reflects concerns from many stakeholders that future clinical R&D will face serious problems if no adequate equilibrium between best-harmonised public supervision and self-regulation can be established. This session will look at how new forms of and initiatives for self-regulation could contribute to a future, simplified regulatory framework urgently required for the efficient conduct of global clinical trials.

Heteronomy versus Autonomy: The normative context for regulatory simplification
Nicola Stingelin, Ethics Expert to the European Commission, Basel University Hospital, Institute for Biomedical Ethics, Switzerland

Self-Regulation in the Clinical Development Process: Pros and cons. An industry perspective
Surendra Gokhale, Head of EU/ROW CT Regulatory Management, F. Hoffmann-La Roche, Switzerland

Alliance for Clinical Research Excellence and Safety (ACRES): An initiative to build a globally-shared system infrastructure for clinical research based on standardised operating policies
Beat Widler, Managing Partner, Widler & Schiemann Ltd., Switzerland



Theme 11 | Regulation of Medical Devices and Combination Products

Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs and Scientific Communication, Switzerland

This theme will outline major changes in the forthcoming EU Regulations on medical devices and IVDs and how they impact drug/device combination products and companion diagnostics. It will also describe what to expect from regulators and notified bodies when applying for and conducting clinical trials for combination products. Further, this theme aims to shed some clarity on the rules as well as to look at the latest IT-based method of communicating instructions for use to users.

Session 1106 | Thursday, 27 March, 11:00-12:30

THE NEW REGULATORY OUTLOOK FOR DEVICES, IVDs AND COMBINATION PRODUCTS

Session Chair:
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs and Scientific Communication, Switzerland

This session will outline major changes in the forthcoming EU Regulations on medical devices and IVDs and how they impact drug/device combination products and companion diagnostics. It will summarise the latest developments at a critical time in the history of medical device regulation.

Forthcoming Major Changes to the New EU Medical Device Regulation
Erik Hansson, Deputy Head of Unit, Health and Consumers Directorate General European Commission, EU

How the Regulation of Drug/Device Combinations will Change under the New Medical Device Regulation
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs and Scientific Communication, Switzerland

Notified Bodies' Perspective on the Revision of Medtech Regulation
Theresa Jeary, Technical Manager- Medical Devices, LRQA, UK

Session 1107 | Thursday, 27 March, 14:00-15:30

KEY CONSIDERATIONS FOR DEVELOPMENT AND APPROVAL OF COMPANION DIAGNOSTICS

Session Chair:
Shuna Mason, Partner, Head of Regulatory, CMS Cameron McKenna LLP, UK

An overview of the current and prospective EU regulatory frameworks for companion diagnostics including CE marking requirements and the parties and regulatory authorities involved. The session will include analysis of the significance of the proposed changes for manufacturers of companion diagnostics and associated pharmaceutical companies looking at the EU legal and patient access frameworks and challenges. The regulators' perspective will also be covered in the form of a notified body's view of the likely impact of the new regulatory framework upon the relationship between companion diagnostics manufacturers and their notified bodies.

Development of EU Regulatory Framework for Companion Diagnostics
Shuna Mason, Partner, Head of Regulatory, CMS Cameron McKenna LLP, UK

Companion Diagnostics – Reimbursement and market access
Rebecca Jundwirth, Government Affairs Manager, F. Hoffmann-La Roche, Switzerland

Companion Diagnostics - A Notified Body's view
Sabine Ohse, Head of Medical Devices Certification, BSI, Germany

Session 1108 | Thursday, 27 March 16:00-17:30

CLINICAL INVESTIGATIONS FOR COMBINATION PRODUCTS

Session Chair:
Ilona Reischl, Head of Division, Austrian Medicines and Medical Devices Agency (AGES), Austria

Clinical investigations of medical devices and combination products will be the focus of this session. Regulatory and scientific requirements will be presented and discussed, with particular emphasis on specific issues at the intersection of the medicinal product and medical device frameworks.

Authority's Requirements for Clinical Investigations for Medical Devices and Combination Products
Ilona Reischl, Head of Division, Austrian Medicines and Medical Devices Agency (AGES), Austria

Post-Marketing Studies with Medical Devices in Europe
Erdmann Johannes Zippel, Senior Clinical Operations Director, Aptiv Solutions, Germany

Notified Body's Requirements for Clinical Investigations for Devices and Combination Products
Gert Bos, Head of Regulatory and Clinical Affairs, BSI, UK

Theme 12 | Pharmaceutical Quality in the 21st Century

Graham Cook, Senior Director, Process Knowledge/Quality by Design, Global Quality Strategy, Pfizer, UK

What are the quality-CMC initiatives that will improve the delivery of medicines to patients? Are we at a crossroad on the journey for the adoption of the New Quality Paradigm, also known as Quality by Design (QbD)? The opportunities to enhance quality approaches in pharmaceutical/biopharmaceutical development and manufacturing across the product lifecycle, and support them through the EU and global regulatory framework, will be explored by considering some current hot topics and future challenges for pharmaceutical quality in the 21st century.

Session 1205 | Thursday, 27 March, 09:00-10:30

QUALITY BY DESIGN (QBD) AND INNOVATION IN DEVELOPMENT AND MANUFACTURING

Session Chair:
Graham Cook, Senior Director, Process Knowledge/Quality by Design, Global Quality Strategy, Pfizer, UK

QbD Approach and Regulatory Challenges in Japan
Yoshihiro Matsuda, Deputy Director, Division of Pharmacopeia and Standards for Drugs, Office of Standards and Guidelines Development, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

QbD approach and Regulatory Challenges in Europe
Peter Richardson, Head of Quality, European Medicines Agency, EU

QbD: Where next? – industry experience and perspective
Speaker invited

Panel discussion

Session 1206 | Thursday, 27 March, 11:00-12:30

EXPERIENCE WITH IMPLEMENTATION OF THE LIFECYCLE APPROACH
Session Chair:
Michael James, Director of CMC Regulatory Advocacy, Policy and Intelligence, Global Regulatory Affairs, GlaxoSmithKline R&D, UK

Opportunities from the Variations Regulations
Speaker invited

Experiences with the Review/Approval of Post-Approval Protocols in Vaccines/Biopharmaceuticals
Speaker invited

Industry Experiences with Post-Approval Protocols
Speaker invited

Panel discussion

Session 1208 | Thursday, 27 March 16:00-17:30

CHALLENGES AND OPPORTUNITIES FOR PHARMACEUTICAL QUALITY
Session Chair:
Gerd Fischer, Quality Manager, Boehinger-Ingelheim, Germany

After a decade with multiple iniatives and the advancement of science- and risk based quality concepts, where stands the pharmaceutical sector today, and what are the new challenges and opportunities ahead? The session will stimulate discussion on what these challenges and opportunities are and offer perspectives on how these could potentially be addressed.

This session is under development. Please check back for details.

Theme 13 | Legal: The role of ethics and transparency in the European regulatory environment

Geneviève Michaux, of Counsel, Hunton & Williams Belgium
Christopher Foreman, Senior Director Legal Affairs, Scandinavia & Baltic, Merck Sharp and Dohme, Belgium

The theme is dedicated to 'hot' legal topics, in particular disclosure of data by regulators. The first session will generally discuss transparency. Why must data be disclosed and are the current disclosure obligations suited to that objective? The second and third sessions examine in more detail disclosure of clinical data and safety data. Both categories of data are important but they raise different issues and carry different risks. The fourth session analyses the possible impact of data disclosure on patentability, approval of medicinal products outside of Europe and publication in medical journals as well as the safeguards needed to avoid such negative impacts. The fifth session concerns transparency of payments made by pharmaceutical and medical devices companies to the healthcare sector. European 'Sunshine' will change how the health industry interacts with the healthcare sector. The sixth session examines early access to medicinal products, through compassionate use or named patient programs or due to off-label uses. The seventh session discusses product liability in relation to off-label use and the content of the patient information leaflet.

Session 1301 | Wednesday, 26 March, 09:00-10:30

TRANSPARENCY – IS CLEARING THE PAST OPAQUING THE FUTURE?
Session Chair:
Christopher Foreman, Senior Director Legal Affairs, Scandinavia & Baltic, Merck Sharp and Dohme, Belgium

Richard Bergström, Director General, EFPIA, Belgium

This session is under development. Please check back for details.

Session 1302 | Wednesday, 26 March, 11:00-12:30

DISCLOSURE OF CLINICAL TRIAL DATA - WHAT DOES THE FUTURE HOLD?
Session Chair:
Peter Bogaert, Partner, Covington & Burling LLP, Belgium

This session will review the legal principles that govern the release of clinical trial data to third parties, such as researchers but also to the public in general. The principles governing reactive and proactive will be discussed, as well as the latest status of the new Clinical Trials Regulation and its potential impact on transparency.

EMA View on the Legal Aspects of Access to Clinical Trial Data
EMA speaker invited

Industry View on the Legal Aspects of Access to Clinical Trial Data
Victoria Kitcatt, Assistant General Counsel, European Regulatory Law, Pfizer, UK

Update on the Legal Situation and Pending Cases before the EU Court
Peter Bogaert, Partner, Covington & Burling LLP, Belgium

Session 1303 | Wednesday, 26 March, 14:00-15:30

EARLY ACCESS TO MEDICINES
Session Chair:
Koosje Van Lessen Kloeke, Life Sciences Lawyer – Partner, Leijnse Artz, the Netherlands

This session is under development. Please check back for details.

Session 1304 | Wednesday, 26 March, 16:00-17:30

UNINTENDED IMPLICATIONS OF TRANSPARENCY: PATENTABILITY, USE OF COMPETITORS BY EX-EU AND MEDICAL JOURNALS
Session Chair:
Lenita Lindström-Gommers, Senior Policy Officer, European Commission Health and Consumers Directorate-General, EU

Session 1305 | Thursday, 27 March, 09:00-10:30

TRANSPARENCY OF PAYMENTS TO THE HEALTHCARE SECTOR
Session Chair:
Samantha Regenthal, Attorney at Law, SFL Regulatory Affairs & Scientific Communication, Switzerland

Richard Bergström, Director General, EFPIA, Belgium

Blandine Fauran, Legal Director, Leem, France

Session 1306 | Thursday, 27 March, 11:00-12:30

DISCLOSURE OF SAFETY DATA: CAN PRAC, PATIENTS AND INDUSTRY PERSPECTIVES BY RECONCILED?
Session Chair:
Joyce Ter Heerdt, Assistant General Counsel, Johnson & Johnson, Belgium

June Raine, Chair PRAC, Vigilance and Risk Management of Medicines Division, MHRA, UK

This session is under development. Please check back for details.

Session 1307 | Thursday, 27 March, 14:00-15:30

PRODUCT LIABILITY, OFF-LABEL USE AND PATIENT INFORMATION LEAFLETS
Session Chair:
Karina Hellbert, Lawyer, Fiebinger Polak Leon, Austria

Ina Brock, Partner, Hogan Lovells, Germany

This session is currently in development.

Theme 14 | Innovation

Salah-Dine Chibout, Head of Exploratory Development Europe, Global Head Investigative Toxicology, Novartis, Switzerland
Peter Høngaard Andersen, Senior Vice President, H. Lundbeck, Denmark

Efficient and commercially attractive innovation is critical for companies to achieve high quality products. Concepts of innovation in various areas and practices of pharmaceutical research, in discovery and safety research, clinical trial design as well as in drug delivery systems, biomarkers and strategies for patient stratification will be addressed. Innovation opportunities through collaborations with single external partners and extending into large public private partnerships will be discussed.

Session 1402 | Wednesday, 26 March, 11:00-12:30

INNOVATION THROUGH PUBLIC-PRIVATE PARTNERSHIP COLLABORATIONS

Session Chair:
Salah-Dine Chibout, Head of Exploratory Development Europe, Global Head Investigative Toxicology, Novartis, Switzerland

Modern information and communication technologies are reinforcing and expanding PPPs beyond all previous limitations and boundaries. Together with the insight that certain innovations are unfeasible without inter-organisational collaboration today PPP programs hold a great promise. Outcomes of the largest EU PPP program, IMI, will be discussed. In addition, legal, IP and collaboration management aspects within such large scale PPPs will be addressed.

Achievements and Outlook of IMI
Michel Goldman, Executive Director, Innovative Medicines Initative (IMI), Belgium

Initiatives and Challenges for Creating Innovative Drugs
Nobumasa Nakashima, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Biomarker Development
Thomas Joos, Deputy Managing Director, NMI Natural and Medical Sciences Institute at the University of Tübingen, Germany

Session 1403 | Wednesday, 26 March, 14:00-15:30

INNOVATION IN BIOMARKERS AND DISEASE STRATIFICATION

Session Chair:
Neil Weir, Senior Vice President, Global Research, UCB, Belgium

Genomic and epigenetic biomarkers offer great promise in refining the development and clinical application of new and existing medicines as well as for assessing disease risk. The use and impact of innovative pharmacogenomic biomarkers in several areas of medicine will be addressed with case studies as well as highlighting the latest advancements in the molecular diagnostics field.

This session is currently in development.

Session 1404 | Wednesday, 26 March, 16:00-17:30

INNOVATION IN CLINICAL TRIAL DESIGN AND EVALUATION

Session Chair:
Mats Sundgren, Principal Scientist, Clinical Information Strategy, Global Clinical Development, AstraZeneca, Sweden

Research on clinical trial design and evaluation needs to be so seamlessly woven into clinical practice, that the delivery of care also is generating new knowledge and thus enables innovation. Clinical research will be addressed from the perspective of enhancing study design methodologies and transparency combined with a continuous learning loop to provide the best personalised patient care possible.

Real-Life Data in Drug Development: Perspectives on R&D, market authorisation and HTA (IMI Get Real)
Diederick Grobee, Professor, Utrecht University Medical Centre, the Netherlands

Predictive Analytic Modelling Operational Characteristics at Design and Monitoring Clinical Trials
Vladimir Anisimov, Senior Strategic Biostatistics Director, Quintiles, UK

Common Study Design Language/Syntax
Norbert Bleich, Senior Project Manager Clinical Science, F. Hoffmann-La Roche, Switzerland

Gathering and Leveraging Quality-Centric Metadata in Clinical Trials
Aaron Gadberry, Director Software Architecture, DATATRAK International, USA

Session 1405 | Thursday, 27 March, 09:00-10:30

INNOVATION IN DRUG DELIVERY SYSTEMS AND COMPLIANCE

Session Chair:
Kenny Simmen, Johnson & Johnson Pharmaceutical Research & Development, UK

Innovative drug targeting, topical administration, in situ forming systems as well as new biomaterials will be discussed. The important role of the patient in the development of drug delivery systems to create innovative solutions and innovative ways to improve patient compliance with treatments will be addressed.

Oral-Timed Drug Delivery Affords Chronotherapeutic Benefit in Patients
Howard Stevens, Emeritus Professor, University of Strathclyde, Strathclyde Institute of Pharmacy and Biomedical Sciences, UK

Novel Drug and Vaccine Delivery Technologies – from the bench to the patient
Henderik W. Frijlink, Department of Pharmaceutical Technology and Biopharmacy, University of Groningen, the Netherlands

Improvement of Convenience for the Patient by Designing the Delivery Form
Lieven Baert, Managing Director, Jalima Pharma, Belgium

Session 1406 | Thursday, 27 March, 11:00-12:30

INNOVATION IN PRE-CLINICAL AND CLINICAL SAFETY SCIENCES

Session Chair:
Jonathan Moggs, Global Head of Molecular Toxicology, Novartis Institutes for Biomedical Research, Novartis, Switzerland

The poor prediction of toxicity during early drug development is a major challenge to bringing more effective medicines to patients. Key opportunities for enhancing safety sciences include improved characterisation of molecular, biochemical and cellular pathways of toxicity, together with the development of predictive tools, models and translational safety biomarkers that allow discovery researchers and clinicians to anticipate and mitigate safety issues. A safe harbor approach for amassing pre-clinical/clinical safety data and exploring chemotype-toxicity relationships is essential for an improved information flow between bedside and bench.

Integrated Approach in Assessing Carcinogenicity Potential to Reduce Animal Testing
Jan Willem van der Laan, Medicines Evaluation Board, Utrecht, the Netherlands

Predictability of Non-Clinical Safety Models, Present and Future in Debate
Beatriz Silva Lima Silva Lima, Professor of Pharmacology at University of Lisbon, Portugal

Novel Insight into Drug Hypersensitivity Mechanisms through Integration of Immunogenetics, Metabolism, Biochemistry and Preclinical Models
Kevin Park, MRC Centre for Drug Safety Science, University of Liverpool, UK

Session 1407 | Thursday, 27 March, 14:00-15:30

NON-CLINICAL DEVELOPMENT STRATEGIES FOR BIOSIMILAR MONOCLONAL ANTIBODIES

Session Chair:
Guenter Waxenecker, Expert Biologics, Austrian Medicines and Medical Devices Agency (AGES), Austria

This session will provide a reflection on the need for innovative methods for non-clinical assessment of biosimilar monoclonal antibodies from a regulators and industry perspective and finally gives a view on globalised development strategies.

Non-Clinical Development Paradigms for Biosimilar Monoclonal Antibodies from a Regulators Perspective
Guenter Waxenecker, Expert Biologics, Austrian Medicines and Medical Devices Agency (AGES), Austria

The Challenges in the Non-Clinical Development of Biosimilar Monoclonal Antibodies from an Industry Perspective
Speaker invited

Aiming Globalised Development
Jennifer Sims, President, Integrated Biologix, Switzerland

Session 1408 | Thursday, 27 March 16:00-17:30

PHARMA INDUSTRY INCENTIVE SYSTEMS

Session Chair:
Peter Høngaard Andersen, Senior Vice President, H. Lundbeck, Denmark

Science brings us towards a world of personalised medicines. However, current incentive systems punish companies targeting specific patient groups enriched with responders and thus prevent translation of science to medical innovation.

Wim Vanhaverbeke, professor Innovation Management & Strategy at the Hasselt University, founder Exnovate, Belgium

Chas Buantra, Chief Scientist, Structural Genomics Consortium, UK

Peter Høngaard Andersen, Senior Vice President, H. Lundbeck, Denmark

Theme 15 | Known Active Substances – Harmonised understanding and regulatory implications

Vesna Koblar, Director, Pharmaceutical Regulatory Affairs Consulting and Education (raPHARM), Slovenia
Kristin Raudsepp, Director General of State Agency for Medicines, Estonia

EU pharmaceutical legislation follows the understanding that the extent of regulatory burden is to be linked to the risk associated with use of medicinal product. Medicines with known active substances have a more advanced safety profile due to more informational input. Regulatory optimisation is possible in this highly regulated area only if based on risk-informed decisions.

Four sessions offer different views on the understanding of a known active substance, advantages and disadvantages, particularly for biosimilars, discussion on possible regulatory optimisation, and on risk management from the point of view of different interest groups as well as possible impact of new directive on falsified medicines on accessibility of medicines with known active substances.

Session 1505 | Thursday, 27 March, 09:00-10:30

NEW ACTIVE SUBSTANCES AND KNOWN ACTIVE SUBSTANCES – DESIGNATION, IMPLICATIONS

Session Chair:
Carla Schoonderbeek, Partner, Hoyng Monegier LLP, the Netherlands

The subject for the session is Regulatory Data Protection (RDP) for New Active Substances (NAS), Known Active Substances (NAS) and combination products. As these issues usually concern matters of both law and science, the session will focus both on the application of the law and the application of the relevant scientific tests. The session aims to address the issues from a legal, regulatory and public policy perspective in an interactive manner. The speakers will make presentations focusing on the relevant legal provisions as well as the guidance, application in practice and as yet unresolved issues. This will be followed by a panel discussion between the audience and the speakers.

NAS: Designation and Consequences (legal aspects)
Carla Schoonderbeek, Partner, Hoyng Monegier LLP, the Netherlands

NAS: Designation and Consequences (regulatory aspects)
Henk Schuring, Group Vice President Regulatory Affairs - Europe , Genzyme Europe B.V., the Netherlands

KAS: Fresh Periods of RDP for Known Active Substances and RDP for Combination Products
Barbara Lange, Senior Regulatory Legal Counsel, Novartis, Switzerland

Decision Makers and Unresolved Issues
Lidia Retkowska-Mika, Director, Legal Department, Office for Registration of Medicinal Products, Medical Devices and Biocides, Poland

Session 1506 | Thursday, 27 March, 11:00-12:30

HOW TO REALISE BIOSIMILARS' FULL POTENTIAL

Session Chair:
Sundar Ramanan, Strategic Planning & Operations Director, R&D, Amgen, USA

The increasing uptake of existing biosimilars has generated considerable interest and debate about the future potential of the biosimilars space but despite the widespread optimism, a number of key challenges relating to the known active substance remain – pharmacovigilance, naming and traceability – which if not adequately addressed, can limit the potential of biosimilars before it is fully realised. This session will review these three independent but interlinked challenges, providing case studies and examples to illustrate key points and reflect on what needs to be done to ensure the conversation remains focused on patient safety first.

EGA Point of View
Martin Schiestl, Scientific and Regulatory Advisor, Sandoz, Austria

EFPIA Point of View
Sundar Ramanan, Strategic Planning & Operations Director, R&D, Amgen, USA

Regulator's Point of View
Peter Richardson, Head of Quality, European Medicines Agency, EU

Session 1507 | Thursday, 27 March, 14:00-15:30

HOW TO OVERCOME THE OBSTACLES IN PATIENTS' ACCESS

Session Chair:
Kristin Raudsepp, Director General of State Agency for Medicines, Estonia

The session will look at the availability and accessibility of medicinal products. We try to find out if there is a favourable environment for all stakeholders, especially patients. The session will explore the possible hurdles for patients' access to known active substances and look at the ongoing developments to accelerate the start of the marketing of generics in Europe, e.g., new transparency directive. Attention will be paid to the price pressure on generics. The experience will be given about the implications of the new directive on falsified medicines from the viewpoint of access to known active substances. We will discuss if the patent regulation and data exclusivity are fully in the interest of a patient and where is the best balance for new and known active substances. We will discuss the scientific development, including "repurposing" known products to more targeted populations with improving the safety profile or enhancing the efficacy. The session will explore the opinions of the industry, of the agency and of patients about the known active substances, including biosimilars and interchangeability.

Off-Patent Medicines - More valuable than ever
Richard Bergström, Director General, EFPIA, Belgium

Does the Current Regulatory Framework Constitute a Threat to a Long-Term Access to Generic Medicines?
Beata Stepniewska, Deputy Director, Eurpean Genrics Association (EGA), Belgium

Partners and Competitors in Ensuring Availability and Access
Kristin Raudsepp, Director General,State Agency for Medicines, Estonia

The panel will be joined by representatives of Patients' Organisations.

Session 1508 | Thursday, 27 March 16:00-17:30

RISK PERCEPTION, RISK ACCEPTANCE AND KNOWN ACTIVE SUBSTANCES

Session Chair:
Vesna Koblar, Director, Pharmaceutical Regulatory Affairs Consulting and Education (raPHARM), Slovenia

Our decisions, although based on the same safety information on medicines, show diversity that implies. Our risk perception and risk acceptability differs across the EU depending on interested groups, cultural background and tradition. We will discuss the risk perception and risk acceptability from a National Competent Authority (NCA), a patient and industry point of view and try to find common points of understanding of risk acceptance and consequences in practice linked mostly to medicines with known active substances.

Risk Perception, Risk Acceptance and Known Active Substances – NCA point of view
Aginus Kalis, Chair HMA, Executive Director, Medicines Evaluation Board, the Netherlands

Patient Awareness of Off-Label Use of Know Active Substances and Risk Acceptability in Rare Paediatric Diseases
Tsveta Schyns-Liharska, PDCO Member, Representative, European Network for Research on Alternating Hemiplegia (ENRAH), Belgium

Benefit-Risk Assessment of Established Substance
Hubertus Cranz, Director General, AESGP, Belgium

Theme 16 | Knowledge Management and Regulatory/Competitive Intelligence in Drug Development

Marianne Köhne, Global Regulatory Affairs/RCC Coordinator, Boehringer Ingelheim, Germany

Knowledge Management and Regulatory / Competitive Intelligence (RI/CI) are disciplines which help manage the flood of information in the rapidly changing regulatory environment and its increasing complexity and transparency in a global environment. Adding business value by gathering and analysing this information to provide targeted input along the drug development process and into regulatory strategies and decision making is the leading objective of an RI function. This goes along with safeguarding regulatory compliance and making efficient use of the increasing amount of regulatory information available on authority websites. RI experts will share their experiences and provide practical examples.

Session 1601 | Wednesday, 26 March, 09:00-10:30

WHAT CAN REGULATORY INTELLIGENCE GROUPS LEARN FROM EXPERTS IN KNOWLEDGE MANAGEMENT?

Session Chair:
Carolyn Hynes, Director, GlaxoSmithKline, UK

Core functions of regulatory intelligence groups are closely related to the process of knowledge management. This session examines current practices and tools and novel approaches for future consideration

Sharing Regulatory Intelligence: Best Practices and Case Studies
Carolyn Hynes, Senior Director, Global Regulatory Intelligence, GlaxoSmithKline, UK

Knowledge Management in Regulatory Strategy: The importance of Regulatory Intelligence
João da Silva Duarte, Regulatory Intelligence & Policy Manager, H. Lundbeck, France

Knowledge Management and Regulatory Intelligence
Rob Van der Spek, Director Knowledge Management Advisory Services, DNV GL, the Netherlands

Session 1602 | Wednesday, 26 March, 11:00-12:30

THE PRACTICAL ASPECTS OF THE REGULATORY INTELLIGENCE FUNCTION – ORGANISATION AND PROCESSES

Session Chair:
Linda Bowen, Head of US Regulatory Policy and Intelligence, Sanofi, USA

This session will focus on the who, what and how of the Regulatory Intelligence function including expected deliverables, measurable metrics, and the active role RI plays in influencing the regulatory environment.

How to Successfully Implement and Leverage the Regulatory Intelligence Function
Speaker invited

The Journey from Consultation to Compliance
Deborah Henderson, Executive Director, Global Regulatory Policy, Merck, USA

Experiences from Building and Maintaining a Regulatory Lessons-Learned Database
Åsa Rembratt, Senior Regulatory Intelligence Manager, Novo Nordisk, Denmark

Session 1603 | Wednesday, 26 March, 14:00-15:30

RI INPUT INTO STRATEGIES
Session Chair:
Christine Mayer-Nicolai, Merck KGaA, Germany

This session will provide insights into how regulatory intelligence can provide a deeper understanding and valuable metrics as a sound basis for product development and regulatory strategies. Different perspectives of involved parties like the scientific Escher project, a consultant and a pharmaceutical company will be presented.

Scientific approach: Regulatory Science and Methods: How to generate tangible results
Jean Philippe de Jong, Project manager,The Escher Project, the Netherlands

Synergies of Public Affairs and Regulatory Affairs Functions – How to maximise internal coordination and external impact?
Anna Hallersten, Public Affairs Director, SFL Regulatory Affairs & Scientific Communication, Switzerland

Industry point of view: Regulatory Intelligence input for development and regulatory strategy
Claire Lavery, Director, Global Regulatory Policy and Intelligence, Janssen Research and Development, UK

Session 1604 | Wednesday, 26 March, 16:00-17:30

REGULATORY INTELLIGENCE IN PRACTICE – HOW REGULATORY AUTHORITIES INFORM ABOUT DECISION MAKING
Session Chair:
Birgit Wolf, Regulatory Intelligence Manager, Bayer Pharma, Germany

This session will outline the current and potential future approach on how regulatory authorities inform about decision making - what kind of information is available on the website, how can stakeholders use this information? The session will have a detailed look at differences between agencies in different regions - EU (EMA, National Agencies, HMA harmonisation initiative), US, Canada and others.

National Agencies View and Harmonisation Initiatives at HMA level
Truus Janse-deHoog, Staff Member European Cluster, Medicines Evaluation Board (MEB, the Netherlands

EMA Perspective
Melanie Carr, Head of Small and Medium-sized Enterprise Office, European Medicines Agency, EU

Transparency and Access to Information in the US, Canada and Australia: A case study
Linda Bowen, Head of US Regulatory Policy and Intelligence Sanofi, USA

STAND-ALONE/HOT TOPIC SESSIONS

Session 1705 | Thursday, 27 March, 09:00-10:30

PRESENTATION OF THE NEW STRUCTURE OF THE EUROPEAN MEDICINES AGENCY
Session Chair:
Melanie Carr, Head of Small and Medium-sized Enterprise Office, European Medicines Agency, EU

This session is currently under development

Session 1706 | Thursday, 27 March, 11:00-12:30

JAPANESE REGULATORY SESSION /PMDA UPDATE
Session Chair:
Nobumasa Nakashima, Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The PMDA will explain its current services and the Japanese drug regulation and answer questions on these and PMDA's future initiative / challenges for faster review and better life cycle management of drugs.

Tatsuya Kondo, Pharmaceuticals and Medical Devices Agency, Chief Executive Officer, Japan

Hideo Utsumi, Executive Director, Pharmaceuticals and Medical Devices Agency, Japan

Hiroshi Yamamoto, Chief Safety Officer, Pharmaceuticals and Medical Devices Agency, Japan

Session 1707 | Thursday, 27 March, 14:00-15:30

GCP HOT TOPIC 1
Session Chair:
Beat Widler, Managing Partner, Widler & Schiemann Ltd., Switzerland

Quality Risk Management, Quality by Design and Risk-Based Monitoring are seen by sponsors and regulators as ways to make the clinical trials process more efficient while ensuring even better patient protection and data quality. However, the implementation of such an approach requires a careful assessment of processes involved, of the understanding of its requirements by stakeholders involved, and also of the acceptability of methodologies applied by independent ethics committees and regulators. These challenges will be debated by speakers from health authorities, sponsors and other competent parties.

Gabriele Schwarz, Head GCP Inspectorate, BfArM, Germany

Rebecca Stanbrook, Group Manager Inspections, MHRA, UK

Anne-Marie Vangsted, Head of Division, Danish Health and Medicines Authority, Denmark

Session 1708 | Thursday, 27 March 16:00-17:30

GCP HOT TOPIC 2
Session Chair:
Ana Rodriguez, Head of Clinical and Non-clinical Compliance, European Medicines Agency, EU

This session builds on the successful "Inspectors' Roundtable" tutorial of past EuroMeetings. Inspectors from health authorities will debate questions submitted by participants and the GCP and QRM DIA Communities.

This session is currently in development.

FOCUS ON NON-CLINICAL

Tutorial 5 | Tuesday, 25 March, 09:00-12:30

NON-CLINICAL SAFETY FOR NON-EXPERTS: WHAT IS IMPORTANT FOR YOUR SUBMISSIONS?

Klaus Olejniczak, Non-clinical Regulatory Consultant, Germany
Gerd Bode, Lecturer, University of Göttingen, Essen, Lyon, Bonn and Consultant, Germany

This tutorial identifies the challenges and solutions for integrating all sources of toxicological data involved and helps to understand the non-clinical development and strategies of drug toxicity or safety assessments. The international state of the art of non-clinical evaluation of pharmaceuticals, the interpretation of toxicological data and the acceptability or unacceptability of toxicological risks (benefit/risk assessments) for pharmaceuticals will be discussed.

See page 11 for details

Tutorials are not included in your registration but can be added for an additional fee.

Session 1406 | Wednesday, 26 March, 11:00-12:30

INNOVATION IN PRE-CLINICAL AND CLINICAL SAFETY SCIENCES

Session Chair:
Jonathan Moggs, Global Head of Molecular Toxicology, Novartis Institutes for Biomedical Research, Novartis, Switzerland

The poor prediction of toxicity during early drug development is a major challenge to bringing more effective medicines to patients. Key opportunities for enhancing safety sciences include improved characterisation of molecular, biochemical and cellular pathways of toxicity, together with the development of predictive tools, models and translational safety biomarkers that allow discovery researchers and clinicians to anticipate and mitigate safety issues. A safe harbour approach for amassing preclinical/clinical safety data and exploring chemotype-toxicity relationships is essential for an improved information flow between bedside and bench.

See page 30 for details

Session 1407 | Thursday, 27 March, 14:00-15:30

NON-CLINICAL DEVELOPMENT STRATEGIES FOR BIOSIMILAR MONOCLONAL ANTIBODIES

Session Chair:
Guenter Waxenecker, Expert Biologics, Austrian Medicines and Medical Devices Agency (AGES), Austria

This session will provide a reflection on the need for innovative methods for non-clinical assessment of biosimilar monoclonal antibodies from a regulators and industry perspective and finally gives a view on globalised development strategies.

See page 31 for details

FOCUS ON BIOSIMILARS

Tutorial 6 | Tuesday, 25 March, 09:00-12:30

BIOSIMILAR DEVELOPMENT - WHAT ARE THE CURRENT CHALLENGES?

Sundar Ramanan, Director, Global Biosimilars Policy, Amgen, USA

This interactive tutorial will provide an overview of the key steps required for developing a biosimilar, the differences between biosimilars and non comparable biologics and worldwide guidelines for and regulation of biosimilars. It will provide an in depth understanding of the key principles for evaluating biosimilars, and give examples that highlight the importance of clinical trials for detecting clinically meaningful differences. The tutorial will explain the need for a separate biosimilars' pathway to the generics pathway as well as the importance of unique naming for biosimilars.

See page 11 for details

Tutorials are not included in your registration but can be added for an additional fee.

Session 0105 | Wednesday, 26 March, 09:00-10:30

BIOSIMILARS - BUILDING ON EUROPEAN FOUNDATIONS TO ACHIEVE GLOBAL HARMONISATION

Session Chair:
Judith McDonald, Senior Director, Global Regulatory Lead, Pfizer Biosimilars, Pfizer, UK

The session will review the fundamental tenets of the biosimilar concept as pioneered by the European regulators and why upholding these is of central importance in view of the fact that these concepts are sometimes misunderstood by stakeholders. We will review the challenges faced by companies in applying these concepts in a global setting and will conclude with a discussion on stakeholder education followed by a panel discussion.

See page 16 for details

Session 1506 | Thursday, 26 March, 11:00-12:30

HOW TO REALISE BIOSIMILARS' FULL POTENTIAL

Session Chair:
Sundar Ramanan, Strategic Planning & Operations Director, R&D, Amgen, USA

See page 32 for details

Session 1407 | Thursday, 27 March, 14:00-15:30

NON-CLINICAL DEVELOPMENT STRATEGIES FOR BIOSIMILAR MONOCLONAL ANTIBODIES

Session Chair:
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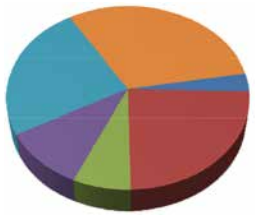
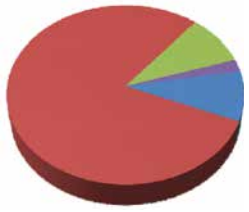
See page 31 for details

ATTENDEE LEVELS OF RESPONSIBILITY



- 3% CEO, President
- 24% Director
- 7% Vice President
- 11% Senior Level Executive
- 24% Manager
- 31% Other

ATTENDEE WORK SETTING



- 9% Government
- 80% Industry
- 9% Academia
- 2% Student

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NON-MEMBER ACADEMIA/GOVERNMENT (FULL-TIME)	€ 1'070.00
ONE DAY MEMBER	€ 1'075.00
ONE DAY NONMEMBER	€ 1'195.00
EXHIBITION HALL ONLY PASS ONE DAY*	€ 150.00
EXHIBITION HALL ONLY PASS TWO DAYS*	€ 250.00

* Includes refreshments, lunch and reception

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"DIA EuroMeeting is a great forum for continual learning and networking for clinical research professionals"

EUROMEETING 2014 VENUE INFORMATION

The EuroMeeting will take place at the Austria Center Vienna (ACV) from Tuesday, 25 March to Thursday 27 March 2014.

Austria Center Vienna (ACV)
Bruno-Kreisky-Platz 1
A-1220 Wien

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Connect with pharmaceutical, medical device and related companies as they showcase the hottest products that foster innovation to improve health and well-being worldwide.

WHY EXHIBIT AT THE EUROMEETING?

The Annual EuroMeeting brings together more than 3,000 biopharmaceutical, contract service organisation, academic research centre, and regulatory affairs professionals from more than 50 countries, making it Europe's largest and most respected industry event of its kind. DIA Europe's annual flagship event offers timely and relevant session topics, continuing education, networking opportunities, and access to one of the largest exhibition floors in Europe.

HIGHLIGHTS FROM THE EUROMEETING EXHIBITION

- Anticipated EuroMeeting attendance of more than 3,000
- Join more than 170 exhibitors to connect with attendees from more than 50 countries
- Explore the latest technologies and services, all under one roof

INCREASE YOUR EXPOSURE IN VIENNA!

Exciting marketing and hosting opportunities will ensure that you stand out from the crowd at the EuroMeeting in Vienna. More information on marketing and hosting opportunities will be available soon.

Booth space is sold on a first come first served basis.

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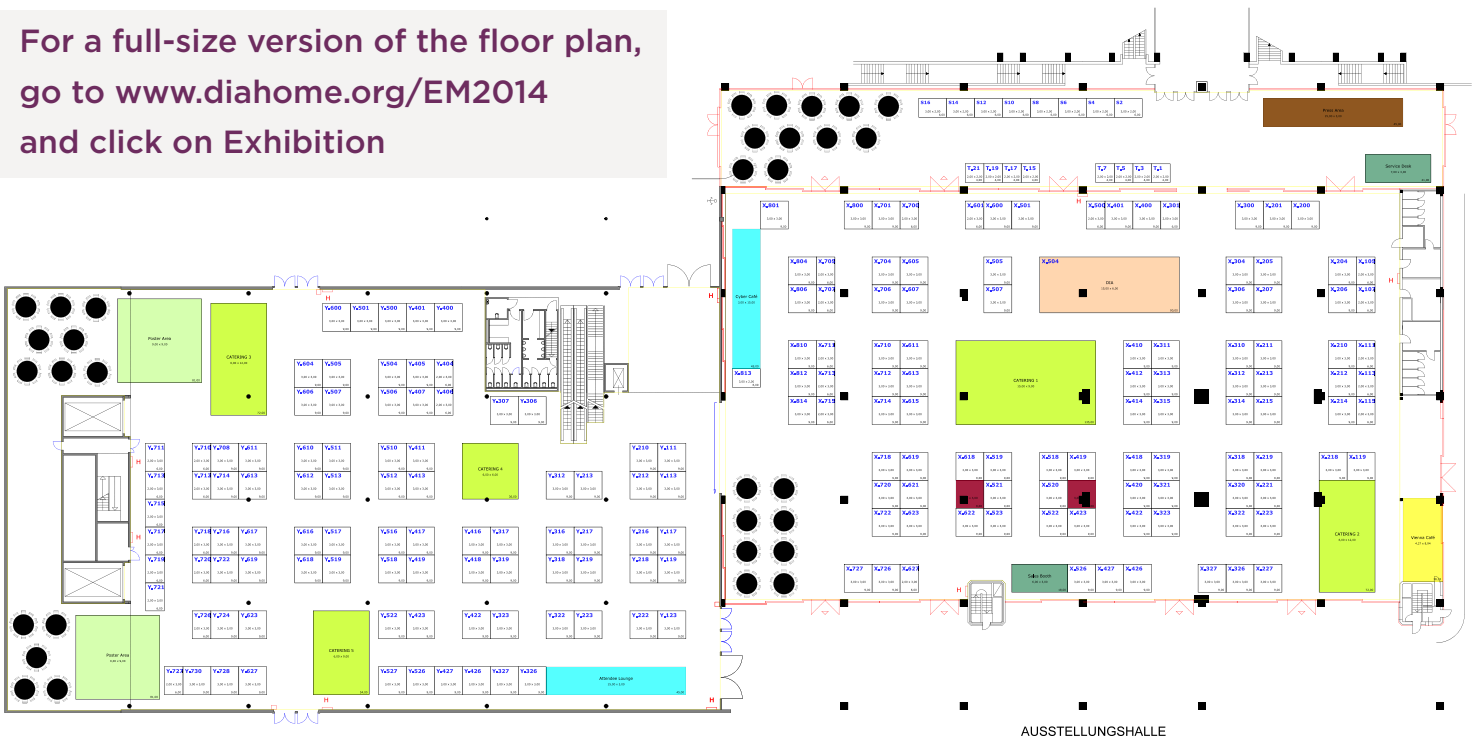
Please check back for regular programme updates

EXHIBITING COMPANIES AS OF 10 OCTOBER 2013

Accenture	United Kingdom	NDA Group	Sweden
Applied Clinical Trials	United States	NNIT A/S	Denmark
Arriello Group	Ireland	nSpire Health, Inc.	United States
AXPHARMA SAS	France	Online Business Applications	United States
BASECON A/S	Denmark	Pharmalink Consulting Ltd	United Kingdom
Cardiocore	United States	PHT Corporation	United States
CCRA	United Kingdom	Pope Woodhead and Associates Ltd	United Kingdom
CMIC Holdings Co., Ltd	Japan	ProductLife Group	France
CTC Clinical Trial Consulting	Switzerland	Proswell Medical Company	China
DATATRAK	United States	Quality and Compliance Consulting, Inc.	United States
DIA	Switzerland	Quintiles	United States
DIA Patient Fellowship	Switzerland	Real Regulatory Limited	Ireland
DIA Student Corner	Switzerland	Regulatory Pharma Net s.r.l.	Italy
ERT Inc.	United States	RJR Consulting Inc.	United States
EUDRAC Ltd	United Kingdom	RWS Group	United Kingdom
European Pharminvent Services Ltd	Czech Republic	SanaClis s.r.o.	Slovakia
Eurotrials	Portugal	Schlafender Hase GmbH	Germany
EXTEDO GmbH	Germany	syneed medidata GmbH	Germany
Foresight Group International	United States	Tarius	Denmark
Keyrus Biopharma SA	Belgium	the Uppsala Monitoring Centre	Sweden
LA-SER ANALYTICA	United Kingdom	Thomson Reuters	United States
Lindeq	Norway	TransPerfect	United Kingdom
LIQUENT, A PAREXEL Company	United States	Trilogy Writing and Consulting GmbH	Germany
LORENZ Life Sciences Group	Germany	United BioSource Corporation	United States
MedDRA MSSO	United States	Veeva Systems	United Kingdom
MEDICADEMY	Denmark	Viedoc	Sweden
Medidata Solutions Worldwide	United Kingdom	XClinical GmbH	Germany
Moravia IT as	Czech Republic		

For a full-size version of the floor plan, go to www.diahome.org/EM2014 and click on Exhibition



NETWORKING EVENTS
ALL INCLUDED IN YOUR REGISTRATION FEE!

Networking is an integral part of the EuroMeeting. Past attendees tell us that the networking opportunities presented by the EuroMeeting are one of the key reasons for attending. Each year, the EuroMeeting offers numerous opportunities to catch up with existing contacts and to make new ones in a relaxing setting. All networking events at the EuroMeeting are included in the registration fee.

EuroMeeting Grand Opening Reception

Tuesday, 25 March 2014 | 17:30-19:00 in the Exhibition Hall

Join us at the Grand Opening Networking Reception for an excellent opportunity to renew your existing contacts and to make new ones. It is exclusive to registered EuroMeeting attendees and will take place in the Exhibition Hall.

Patient Fellowship Networking Lunch

Tuesday, 25 March 2014 | 12:45-13:45

Patient Representatives and Patient Speakers only

Student and Young Professional Networking Reception

Monday, 24 March 2014 | 17:30 - 18:30

The Student and Young Professionals Reception is an opportunity to get to know each other better before the conference begins.

Student Poster Award Ceremony at the DIA Booth on the Exhibition Floor

Wednesday, 26 March 2014 | 17:45

DIA Communities – Meet and Eat

Wednesday, 26 March 2014 | 12:30-13:15

An opportunity for all Community members – and those interested in joining one – to get together for networking at lunchtime.

Speed Networking Session

Wednesday, 26 March 2014 | 13:30-14:00

The EuroMeeting is used as a networking opportunity by all participants. However, it is not easy to walk right up to someone, introduce yourself and have a conversation. The EuroMeeting Speed Networking session aims to make this process a lot easier.

Speed networking, which is actually based on the original concept of speed dating, brings together individuals who are attending a conference. It will help you to make new contacts and intensify your networking experiences. The goal is to ensure that each participant will make at least six new professional contacts during the speed networking sessions.

Wednesday Reception

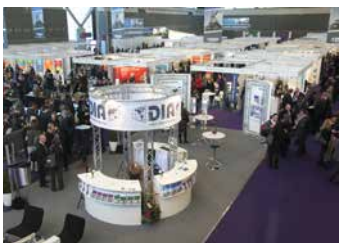
Wednesday, 26 March 2014 | 17:30-18:30

Wednesday's networking reception takes place in the Exhibition Hall. Drinks and snacks are included. It is open to all registered attendees.

Network on the Exhibition Floor

All refreshments will be served in the Exhibition Hall, making it the ideal place to meet the people you want to meet. There will be an internet café and attendee lounge as well as a seating area.



Please check back for regular programme updates

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You will be able to find out further details such as pricing and proximity to the ACV, Vienna, where the EuroMeeting will take place.

Please be advised that DIA has only one contracted and exclusive hotel agent for the EuroMeeting 2014: K.I.T. Group GmbH

DIA works with one agent to ensure that:
- Your hotel reservations are officially part of the EuroMeeting
- The hotels rates have been individually negotiated for the EuroMeeting and are exclusive to EuroMeeting participants
- Your hotel reservations, privacy and personal data are completely secure

EuroMeeting 2014 Conference Hotels in Vienna

- 25hours Hotel
- Arcotel Kaiserwasser
- Artis Hotel Vienna
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- Donauzentrum
- Europa
- Grand Hotel Wien
- Ibis Budget Wien Messe
- Ibis Wien Messe
- Imlauer
- Lassalle
- Le Meridien Vienna
- Mercure Secession
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- Egyptair
- Ethiopian Air
- LOT Polish Airlines
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Registered participants plus one accompanying person travelling to the event can qualify for a discount of up to 20%, depending on fare and class of travel booked. Discounts are offered on international flights on most published business and economy class fares, excluding website/internet fares, senior and youth fares, group fares and Round the World fares. When making your travel plans please be able to present confirmation of your registration or proof of attendance for the EuroMeeting.

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ABOUT THE DIA EUROMEETING

DIA's Annual EuroMeeting is global in scope and attracts well over 3,000 attendees from over 50 countries. It brings together professionals from the biopharmaceutical industry, contract research and service organisations, academic research centres, regulatory agencies and health ministries as well as delegates from patient organisations. This convergence affords participants the opportunity to network with professional colleagues from around the world.

DIA is a global association of approximately 16,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal. DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow DIA to organise conferences, workshops and training courses and provide educational publications.

ABOUT VIENNA

Vienna is the capital and the largest city of Austria, and one of the nine states of Austria. Vienna is Austria's primary city, with a population of about 1.7 million and is by far the largest city in Austria, as well as its cultural, economic, and political centre. It is the 9th-largest city by population in the European Union. Until the beginning of the 20th century it was the largest German-speaking city in the world. Vienna is host to many major international organisations, including the United Nations and OPEC. The city lies in the east of Austria and is close to the borders of the Czech Republic, Slovakia, and Hungary. These regions work together in a European Centrope border region. Along with nearby Bratislava, Vienna forms a metropolitan region with 3 million inhabitants. In 2001, the city centre was designated a UNESCO World Heritage Site.

Apart from being regarded as "The City of Music", because of its musical legacy, Vienna is also said to be "The City of Dreams" because it was home to the world's first psycho-analyst - Sigmund Freud. The city's roots lie in early Celtic and Roman settlements that transformed into a Medieval and Baroque city, the capital of the Austro-Hungarian Empire. It is well known for playing an essential role as a leading European Music Centre, from the great age of Viennese Classicism through the early part of the 20th century. The Historic centre of Vienna is rich in architectural ensembles, including Baroque castles and gardens, as well as the late-19th-century Ringstrasse lined with grand buildings, monuments and parks.

In a 2005 study of 127 world cities, the Economist Intelligence Unit ranked the city first (in a tie with Vancouver, Canada) for the world's most livable cities (in the 2012 survey of 140 cities Vienna was ranked number two, behind Melbourne).

The city was ranked first globally for its culture of innovation in 2007 and 2008, and fifth globally (out of 256 cities) in the 2011 Innovation Cities Index, which analysed 162 indicators in covering three areas: culture, infrastructure and markets. Vienna regularly hosts urban planning conferences and is often used as a case study by urban planners.

Each year since 2005, Vienna has been the world's number one destination for international congresses and conventions. Vienna attracts about five million tourists a year.

More information on Vienna can be found at: http://www.vienna.convention.at

EUROMEETING 2014 GLOSSARY OF TERMS

ADR	Adverse Drug Reaction
AR	Assessment Report
ASMF	Active Substance Master File
ATMP	Advanced Therapy Medicinal Product
BSWP	Biostatistics Working Party
CAT	Committee for Advanced Therapies
CDASH	Clinical Data Acquisition Standards Harmonisation
CDISC	Clinical Data Interchange Standards Consortium
CDM	Clinical Data Management
CHMP	Committee for Medicinal Products for Human Use
CMC	Chemistry, Manufacturing & Controls
COMP	Committee for Orphan Medicinal Products
CP	Centralised Procedure
CRF	Case Report Form
CRO	Clinical Research Organisation
DCP	Decentralised Procedure
eCTD	Electronic Common Technical Document
EDC	Electronic Data Capture
EVMPD	EudraVigilance Medical Product Dictionary
EHR	Electronic Health Record
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
ePRO	Electronic Patient Reported Outcomes
EUnetHTA	European network for Health Technology Assessment
GCP	Good Clinical Practice
GHTF	Global Harmonisation Task Force
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GXP	Good Practice
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HTA	Health Technology Assessment
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	Individual Case Safety Report
IDMP	Identification of Medicinal Products
IMI	Innovative Medicines Initiative
ISO	International Organization for Standardization
ISO IDMP	International Organization for Standardization Identification of Medicinal Products
IVDD	In-Vitro Diagnostics Directive
MA	Marketing Authorisation
MedDRA	Medical Dictionary for Regulatory Activities
MRP	Mutual Recognition Procedure
NBCD	Non-Biological Complex Drugs
PAR	Public Assessment Report
PASS	Post-Authorisation Safety Study
PIP	Paediatric Investigation Plan
PDCO	Paediatric Committee
PRAC	Pharmacovigilance Risk Assessment Committee
PRO	Patient Reported Outcomes
PSUR	Periodic Safety Update Report
QbD	Quality by Design
RPS	Regulated Product Submission
QPPV	Qualified Person for Pharmacovigilance
SAWP	Scientific Advice Working Party
SDTM	Study Data Tabulation Model
SME	Small and Medium-sized Enterprises
SMQ	Standardised MedDRA Query
RPS	Regulated Product Submission
XEVPRM	eXtended EudraVigilance Product Report Message

Tuesday, 25 March 2014

09:00-12:30 Pre-conference Tutorials

11:00-12:30 Austria Satellite Meeting

14:00-17:15 Plenary

17:30-19:00 EuroMeeting Grand Opening Reception

	Theme 1	Theme 2	Theme 3	Theme 4
	Regulatory Science	HTA/Regulatory Interface	Benefit/Risk Management and Lifecycle Approach	Special Populations

Wednesday, 26 March 2014

Session 1 09:00-10:30	Session 0101/0301 Making the Pharmacovigilance Legislation Work – a temperature check	Session 0201 Creating an Adaptive Pathway for Medicines to Patients	Session 0101/0301 Making the Pharmacovigilance Legislation Work – a temperature check	Session 0401 Paediatric Rewards- Where do we Stand?
Coffee Break				
Session 2 11:00-12:30	Session 0102 Hurdles to Overcome to Ensure Regulatory Success for the Next Generation of Products	Session 0202 How do Payers View Current Developments in the HTA and Regulatory Environment?	Session 0302 Thinking Beyond Old Pharmacovigilance Boundaries	Session 0402 Latest Developments in Pediatrics
Lunch				
Session 3 14:00-15:30	Session 0103 Regulatory Town Hall Meeting	Session 0203 Established Interactions throughout the Registration Pathway		Session 0403 Developing Medicinal Products for Older People –getting on track
Coffee Break				
Session 4 16:00-17:30	Session 0104 How to Get Ready for the New Clinical Trials Legislation	Session 0204 Databases, Registries and other Data Capture Tools	Session 0304 Current Industry Practice for Benefit Risk Governance	

17:30-18:30 Networking Reception in the Exhibition Hall

Thursday, 27 March 2014

	Theme 1	Theme 2	Theme 3	Theme 8
	Regulatory Science	HTA/Regulatory Interface	Benefit/Risk Management and Lifecycle Approach	eHealth- Innovation in Healthcare

Session 5 09:00-10:30	Session 0105 Biosimilars- building in European foundations to achieve Global Harmonisation	Session 0205 Marketing Authorisation and Beyond	Session 0305 Transparency in the Pharmaceutical Sector – what have we learned?	Session 0805 European Commission's eHealth Action Plan 2012-2020
Coffee Break				
Session 6 11:00-12:30			Session 0306 Moving from Risk Management to Benefit/Risk Management Planning	Session 0806 Interoperability for Healthcare Providers across the EU
Lunch				
Session 7 14:00-15:30	Session 0107 Optimising Regulatory Operations through Use of Information Technology	Session 0207 How Do We Bring the Patient's Voice into the Discussion? How do we ensure that all the right voices are heard?	Session 0307 Periodic Benefit/Risk Evaluation Reporting – Has it achieved what it set out to do?	Session 0807 Big Data, eHealth and Taxonomy
Coffee Break				
Session 8 16:00-17:30	Session 0108 Challenges and Opportunities in the Implementation of the Falsified Medicines Directive	Session 0208 Are Our Healthcare Systems Ready to Support These Approaches?	Session 0308 Risk Minimisation and its Effectiveness – what is state of the art and what is realistic?	Session 0808 The Role of Social Media in Healthcare

End of Conference

Tuesday, 25 March 2014

09:00-12:30 Pre-conference Tutorials

11:00-12:30 Austria Satellite Meeting

14:00-17:15 Plenary

17:30-19:00 EuroMeeting Grand Opening Reception

Theme 5	Theme 6	Theme 7	Theme 9
Personalised Medicines	Clinical Research	eClinical: Reaching Out	Involving and Informing Patients

Wednesday, 26 March 2014

Session 0501 Translation of Personalised Medicine Concepts	Session 0601 The Importance for All to Adopt Risk- Based Monitoring Today: Introductory session	Session 0701 eTrial Master File (eTMF)	Session 0901 Patients as Partners in Clinical Research
Coffee Break			
Session 0502 From Biomarkers to Companion Diagnostics		Session 0702 eClinical Trials	Session 0902 Patient Empowerment: Opportunities and challenges
Lunch			
Session 0503 Health Economic Aspects of Personalised Medicine	Session 0603 Risk- Based Monitoring: The case for developing new roles, skills and competencies	Session 0703 eClinical Strategy	
Coffee Break			
Session 0504 The Societal Perspective on Personalised Medicine	Session 0604 Risk- Based Monitoring: Which infracturial and Business relationship Changes do we need to consider?	Session 0704 Data Integration	Session 0904 Efficient Use of Social Media to Work with e-Patients
17:30-18:30 Networking Reception in the Exhibition Hall			

Thursday, 27 March 2014

Theme 11	Theme 6	Theme 12	Theme 15
Regulation of Medical Devices and Combination Products	Clinical Research	Pharmaceutical Quality in the 21st Century	Known Active Substances
	Session 0605 Innovative Methodologies Used in Enhancing Quality	Session 1205 Quality by Design (QbD) and Innovation in Development and Manufacturing	Session 1505 New Active Substances and Known Active Substances – designation, implications
Coffee Break			
Session 1106 The New Regulatory Outlook for Devices, IVDs and Combination Products	Session 0606 Systematic Approaches to Deliver Quality: Learn from the Experts!	Session 1206 Experience with Implementation of the Lifecycle Approach	Session 1506 How to Realise Biosimilars' Full Potential
Lunch			
Session 1107 Key Considerations for Development and Approval of Companion Diagnostics	Session 0607 Risk-Based Monitoring: Stakeholder perspectives for a rational process		Session 1507 How to Overcome the Obstacles in Patients' Access
Coffee Break			
Session 1108 Clinical Investigations for Combination Products	Session 0608 The Brave New World of Digital Data: What are the new ethical and legal questions?	Session 1208 Challenges and Opportunities for Pharmaceutical Quality	Session 1508 Risk Perception, Risk Management and Known Active Substances
End of Conference			

Tuesday, 25 March 2014

09:00-12:30 Pre-conference Tutorials

11:00-12:30 Austria Satellite Meeting

14:00-17:15 Plenary

17:30-19:00 EuroMeeting Grand Opening Reception

Theme 10	Theme 13	Theme 14	Theme 16
Globalisation/ Inspections	Legal : The role of ethics and transparency	Innovation	Knowledge Management

Wednesday, 26 March 2014

Session 1001 Regulatory Harmonisation and Regulatory Convergance- an update	Session 1301 Transparency – is Clearing the past opaquing the future?		Session 1601 What Can Regulatory Intelligence Groups Learn from Experts in Knowledge Management?
	Coffee Break		
Session 1002 Surviving Safety and Quality Inspections in the Era of Globalisation	Session 1302 Disclosure of Clinical Trial Data- what does the future hold?	Session 1402 Innovation through Public Private Partnership Collaborations	Session 1602 The Practical Aspects of the Regulatory Intelligence Function-Organisation and Processes
	Lunch		
Session 1003 Global Development and Supply	Session 1303 Early Access to Medicines	Session 1403 Innovation in Biomarkers and Disease Stratification	Session 1603 Regulatory Intelligence Input into Strategies
	Coffee Break		
Session 1004 GXP Inspections – focus on hamonisation effort	Session 1304 Unintended Implications of Transparency	Session 1404 Innovation in Clinical Trial Design and Evaluation	Session 1604 Regulatory Intelligence in Practice - access to information and decision making

17:30-18:30 Networking Reception in the Exhibition Hall

Thursday, 27 March 2014

Theme 10	Theme 13	Theme 14	
Globalisation/ Inspections	Legal : The role of ethics and transparency	Innovation	Stand-Alone Hot topics
Session 1005 Global submission and review strategy - how rapidly innovation can reach global markets	Session 1305 Transparency of Payments to the Healthcare Sector	Session 1405 Innovation in Drug Delivery Systems and Compliance	Session 1705 Presentation of the New Structure of the European Medicines Agency
Coffee Break			
Session 1006 Regulation 2025 – stakeholder vision for the future of the global regulatory framwork between now and 2025	Session 1306 Diclosure of Safety Data: Can PRAC, patients and industry perspective be reconciled?	Session 1406 Innovation in Preclinical and Clinical Safety Sciences	Session 1706 Japanese Regulatory Session: PMDA Update
Lunch			
Session 1007 Current Status and Future Challenges of the Asian Regulatory Environment	Session 1307 Product Liability, Off-Label Use and Patient Information Leaflets	Session 1407 Non-Clinical Development Strategies for Biosimilar Monoclonal Antibodies	Session 1707 GCP Hot Topic 1
Coffee Break			
Session 1008 Regulatory simplification: vision, oxymoron, or 'mission impossible'?		Session 1408 Pharma Industry Incentive Systems	Session 1708 GCP Hot Topic 2

End of Conference

EuroMeeting Key Contacts

Go to the EuroMeeting website www.diahome.org/EM2014 for up-to-the-minute information, to register for the EuroMeeting or for a pre-conference tutorial, to download the programme and to book hotel rooms.

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

Exhibitors
Enquiries from exhibiting companies or enquiries regarding hosting opportunities, company summary book, exhibitor kiosk and/or hospitality suites should be directed to exhibition@diaeurope.org

Press Passes/Press List/Press Release Programme
All enquiries regarding press passes and/or press lists should be directed to Talana Bertschi at talana.bertschi@diaeurope.org or +41 61 225 51 74

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

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

General Queries
For all other queries or for unresolved issues, please contact Natacha Scholl at natacha.scholl@diaeurope.org or +41 61 225 51 59

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- Updates on the conference networking events, hotels, travel and transport information

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Tuesday, 25 March 2014

Tutorial (1-13) € 400.00 ❑

Please indicate which Tutorial you wish to attend: _____

(See pages 10 to 14 of the advance programme for full description of Tutorials)

TOTAL AMOUNT DUE: € _____

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

ATTENDEE DETAILS

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

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All cancellations must be in writing and received at the DIA Europe office by 17:00 CET on 17 March 2014 and will be subject to an administrative fee:

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For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee.

DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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

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The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52 **Web** www.diaeurope.org **Mail** DIA Europe, Postfach, 4002 Basel, Switzerland

All registrations received at DIA Europe Office by 18:00 CET on 21 February 2014, will be included in the Attendee List.