DIA 28th Annual EuroMeeting

INnovation • Do You Win by Being IN?

6-8 April 2016 | CCH | Hamburg, Germany

Advance Programme | Discover new opportunities at DIAglobal.org/EM2016
In a world in which new therapies are being developed at a phenomenal rate, is innovation always the answer?

The DIA 28th Annual EuroMeeting brings stakeholders together to collaborate on when, where and how innovation leads to advances in health care product development.

From patient engagement in clinical trials to proactive life-cycle management, the 2016 themes have been designed to inspire breakthroughs in uncovering innovative solutions for patients. EuroMeeting 2016 themes take into account how all players along the product development life cycle, as well as societal needs, impact the development process. Additionally, these themes directly address the interdependencies of how policy decision makers and regulators anticipate, evaluate and adjust guidelines accordingly.

The EuroMeeting provides the premier platform to exchange ideas with thought leaders and to build your professional network.
Dear Colleagues,

We are delighted to announce that the DIA 28th Annual EuroMeeting will be held in Hamburg, on 6-8 April, 2016.

Patients and their families, expect to receive medicinal products, of a high standard, that can make a significant contribution to their health and well-being. The early exchange of information between all key-stakeholders, in a transparent and open fashion, is a key factor in achieving this common goal.

The DIA 2016 28th Annual EuroMeeting in Hamburg, ‘the gateway to the world’, is the perfect place to exchange scientific knowledge. It provides an opportunity for us to learn from each other and to work in partnership to improve the health of society. To this end, we are honored to serve as Program Co-Chairs of this important meeting.

The DIA 2016 28th Annual EuroMeeting will give us the chance to discuss many of the major trends occurring in healthcare. A major focus will be how to involve patients in our activities; on how to provide them with objective and comprehensive information on medicinal products, and also on how to incorporate their perspective into decision making.

The sessions offered this year will cover pharmaceuticals, biotechnology and medical products. It is an opportunity to exchange views and to discuss new technologies, new legislation and their implementation, as well as new information on patient tools in a collegial environment where improving health is the common goal. A wide variety of sessions will be offered, with topics ranging from early development to market access. They include:

• Health technology assessment – more targeted medicines and specialty technologies
• Lifecycle benefit risk management – evidence for market access and efficacy assessments
• Special populations – requirements adapted for pediatrics and geriatrics
• Availability of medicinal products – marketing authorization and drug availability
• Clinical trials – operation of efficacy and personalized medicines
• Medical writing - information to patients – balance between “too long and too short”
• Big data / e-Health – opportunities and challenges of access to patient data
• Medical affairs – better interaction between stakeholders via novel technologies

The DIA Annual EuroMeeting is a forum for you to discuss ideas, challenges and opportunities for therapies in the 21st Century. Together with our DIA colleagues, we hope you will join us in Hamburg. We look forward to meeting you.

Karl Broich
President
BfArM, Germany

Kemal Malik
Member of the Board of Management
Bayer, Germany
Welcome from the EuroMeeting 2016 Co-Chairs & Programme Advisors

Theme 1 | Innovation
Theme 2 | Clinical Research
Theme 3 | Clinical Trials
Theme 4 | Regulatory Science
Theme 5 | Medical Affairs
Theme 6 | Availability of Medicinal Products
Theme 7 | eHealth/Big Data
Theme 8 | Pharmacovigilance
Theme 9 | Lifecycle Benefit-Risk Management
Theme 10 | Globalisation
Theme 11 | Special Populations
Theme 12 | Medical Devices
Theme 13 | HTA
Theme 14 | Medical Writing
Hot Topics and Stand-Alone Sessions
Networking Events
Exhibition
Hotel and Transportation
EuroMeeting Session Plan
Registration Form

Advance Programme status 19 January 2016, subject to change
check back online for regular updates

2015-16 ANNUAL MEETINGS

15-18 November 2015
12th Annual Meeting DIA JAPAN 2015
Tokyo, Japan

6-8 April 2016
28th Annual EuroMeeting
Hamburg, Germany

May 2016
DIA CHINA 2016
8th Annual Meeting

26-30 June 2016
DIA 2016 52nd Annual Meeting
Philadelphia, PA

Visit DIAglobal.org today
EuroMeeting 2016 Programme

THEME LEADERS

Peter Arlett
Head of Pharmacovigilance Department, European Medicines Agency (EMA), EU

Peter Bachmann
Chair CMDh, Senior Expert, European Drug and Regulatory and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Francesca Cerreta
Senior Scientific Officer, European Medicines Agency (EMA), EU

Michael Devoy
Head, Global Medical Affairs & Pharmacovigilance Bayer Pharma, Germany

Petra Dörr
Head of Communication and Networking, Deputy Director, Swissmedic, Switzerland

Emma Du Four
Senior Director Regulatory Policy & Intelligence, Abbvie, UK

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

Edith Frénoy
Director Market Access/HTA, EFPIA, Belgium

Niklas Hedberg
Chief Pharmacist, Dental and Pharmaceutical Benefits Agency (TLV), Sweden

Sabina Hoeckstra-van den Bosch
Global Regulations and Standards, Philips Healthcare, the Netherlands

Maarten Lagendijk
Pharmacovigilance Coordinator, Medicines Evaluation Board (MEB), the Netherlands

Monika Lessl
Head of Innovation Strategy, Bayer, Germany

Sabine Luik
Senior Vice President, Medicine & Regulatory Affairs, Boehringer Ingelheim Pharmaceuticals, USA

Detlef Nehrdich
Senior Associate, Waife and Associates, Germany

Luca Pani
Director General, Italian Medicines Agency (AIFA), Italy

Kristin Raudsepp
Director General, State Agency of Medicines, Estonia
EuroMeeting 2016 Programme

THEME LEADERS

Holger Maria Rohde
Director, Strategy Implementation
Lead, Merck Serono, Germany

Thomas M. Schindler
Head Medical Writing Europe,
Boehringer Ingelheim Pharma,
Germany

Isabelle Stöckert
Vice President, Head Global
Regulatory Affairs EU/CAN, Bayer
Pharma, Germany

Fergus Sweeney
Head of Inspections & Human
Medicines Pharmacovigilance Division,
European Medicines Agency (EMA), EU

Florian von Raison
Senior Global Program Head,
Novartis Pharma, Switzerland

Margaret Walters
Deputy EU Qualified Person for
Pharmacovigilance, MSD, UK

John Wilkinson
Director of Devices, Medicines &
Healthcare Products Regulatory
Agency (MHRA), UK

Milan Zdravkovic
Corporate Project Vice President,
Insulin, Growth Hormone and
Devices, Novo Nordisk, Denmark

I Overall Programme Advisors

Matthias Gottwald
Head R&D Policy and Networking, Bayer Pharma, Germany

Martin Harvey Allchurch
Principal International Affairs Officer, European Medicines Agency (EMA), EU

Alastair Kent
Director, Genetic Alliance UK, UK

Birka Lehmann
Head of EU & International Affairs, BfArM, Germany

Lidia Retkowska-Mika
Director, Legal Department, Office for Registration and Medicinal Products, Poland

I Theme Advisors

Kees de Joncheere
Director of the Essential Medicines and Health Products, WHO, Switzerland

Robert Geertsma
Senior Scientist, National Institute for Public Health and the Environment (RIVM), Netherlands

Christine Bjørn Jensen
Project Director, Novo Nordisk, Denmark

Thomas Lönn gren
Strategic Advisor, NDA Group, UK

Lembit Rägo
Head, Regulation of Medicines and other Health Technologies, WHO, Switzerland

Mary Stewart
Vice President, Medical Documentation, Lundbeck, Denmark

Sabine Straus
Head of Pharmacovigilance, Medicines Evaluation Board, Netherlands

Paolo Tomasi
Head of Paediatric Medicines, European Medicines Agency, EU
The 28th Annual EuroMeeting will take place from 6-8 April 2016 at the:

CCH Congress Center Hamburg
Am Dammtor / Marseiller Strasse
20355 Hamburg
Germany

ABOUT HAMBURG

The Free and Hanseatic City of Hamburg, one of the 16 states of the federation, is the second largest city in Germany with its 1.7 million inhabitants. In this sense, it is a city as well as a state.

Economically and culturally, Hamburg is also the centre of Northern Germany. 3.5 million people live in the 755 square kilometres large metropolitan region of Hamburg - for them, Hamburg is a shopping and cultural metropolis.

With 30 square metres of living space per person, Hamburg has the biggest average living space of all major cities in the world. As much as 14% of the city area is made up of green spaces and recreational areas.

Hamburg has 2,302 bridges - more than Venice and Amsterdam combined. With over 90 consulates, Hamburg is second only to New York City.

As a trade centre, Hamburg has always been outward-looking, that has shaped the mentality of Hamburg’s inhabitants.

Hamburg places second as the largest container harbour in Europe and seventh world-wide. It’s only 120 km away from the high seas and is able to accommodate the largest container ships the world has to offer. Hamburg Harbour is the central hub for trade with Eastern and Northern Europe.

Its inland location and excellent rail, water and motorway connections, make Hamburg very attractive. Trade with the Baltic Sea region alone accounts for 25% of port turnover.

As a trade and transport metropolis, Hamburg has more than 460 companies from Asia have their European headquarters or a branch office in Hamburg. With the HafenCity, an ultra-modern commercial and business district is currently being built directly on the Elbe river.

Hamburg is also a location for highly specialized industries. It is a leader in medical technology and biotechnology and is one of the world centres for aircraft construction: it is here that the wide-bodied A380 is being built.
SCHEDULE AT-A-GLANCE

Tuesday, 5 April 2016
Registration Hours:
15:00-20:00  Exhibitor Registration and Set-up
14:00-18:00  Attendee and Speaker Registration*
17:30-18:30  Students Welcome Reception

* Avoid the rush on Wednesday by picking up your badge and conference material on Tuesday afternoon

Wednesday, 6 April 2016
Registration Hours:
08:00-11:00  Exhibitor Registration and Set-up
08:00-18:00  Attendee, Speaker and Exhibitor Registration

Schedule:
09:00-12:30  Pre-Conference Tutorials and ICH Info Day*
10:30-11:00  Pre-Conference Tutorials Coffee Break
11:00-12:30  German Satellite Session
12:00-18:00  Conference and Exhibition Open
12:30-14:30  Lunch & Innovation Theatre Presentation in the Exhibition Hall
13:30-15:00  Regulatary Town Hall Meeting
15:00-16:00  Extended Refreshment Break in the Exhibition Hall
16:00-17:45  Opening Plenary Session
18:00-20:00  “Welcome to Hamburg” Opening Reception

* Space is limited for Pre-Conference Tutorials and ICH Info Day, therefore pre-registration is strongly recommended. Availability for onsite registration is not guaranteed

Thursday, 7 April 2016
Registration Hours:
08:00-18:30  Attendee, Speaker and Exhibitor Registration

Schedule:
08:00-09:00  Welcome Coffee
08:00-18:30  Exhibition Hall Open
09:00-10:30  Parallel Scientific Sessions - Session 1
09:00-10:30  Choose from Parallel Sessions
10:15-11:00  Coffee Break in the Exhibition Hall
10:15-11:00  Parallel Scientific Sessions - Session 2
10:15-11:00  Choose from Parallel Sessions
11:00-12:30  Parallel Scientific Sessions - Session 3
11:00-12:30  Choose from Parallel Sessions
12:00-12:30  Parallel Scientific Sessions - Session 4
12:00-12:30  Choose from Parallel Sessions
12:30-14:30  Lunch & Innovation Theatre Presentation in the Exhibition Hall
12:30-14:30  Choose from Parallel Sessions
13:00-14:30  Parallel Scientific Sessions - Session 5
13:00-14:30  Choose from Parallel Sessions
14:00-15:30  Parallel Scientific Sessions - Session 6
14:00-15:30  Choose from Parallel Sessions
14:00-15:30  Parallel Scientific Sessions - Session 7
14:00-15:30  Choose from Parallel Sessions
15:15-16:00  Coffee Break in the Exhibition Hall
15:15-16:00  Parallel Scientific Sessions - Session 8
16:00-17:30  Parallel Scientific Sessions - Session 9
16:00-17:30  Choose from Parallel Sessions
17:30-18:30  Networking Reception in the Exhibition Hall
17:30-18:30  Student Poster Award Ceremony at the DIA Booth

Preliminary Schedule, status 12 February 2016
Subject to change
**Tutorial 1 | Wednesday 06 April, 09:00-12:30**

**INTRODUCTION TO THE REGULATION OF MEDICAL DEVICES AND MEDICAL SOFTWARE**

**Sabina Hoekstra-van den Bosch**, Global Regulations and Standards, Philips Healthcare, Netherlands
**Erik Vollebregt**, Attorney, Axon Lawyers, Netherlands

This tutorial will give a condensed overview of the EU device legislative system and the principles and philosophy supporting them. It will also explain the definition of a medical device, the delineation between medical devices and pharmaceuticals and the provisions on combination products. Legal provisions for medical software, regulated as a medical device will be highlighted. The characteristics and the organisational structure of the medical device sector and the role of the various stakeholders will be discussed as well as the concept of risk classification of medical devices and the relationship between risk classification and conformity assessment procedures.

The tutorial will cover the headlines of the EU regulation of in vitro diagnostics, with a focus on the differences to the medical device regulation. Theoretical concepts will be illustrated and supported by practical examples.

Finally, we will look ahead into the main changes resulting from the ongoing revision of the medical device and in vitro diagnostic regulations.

**Learning Objectives**

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

- Understand the main characteristics of the EU medical devices regulatory system, how it operates and how to bring a medical device to market
- Understand the delineation between pharmaceutical and medical devices
- Learn about the regulation of medical software and medical apps
- Discover the main changes resulting from the currently ongoing legislative review process

**Target Audience**

Professionals in the pharmaceutical or medical device area (e.g. regulatory affairs, clinical development), who are:

- Interested in a condensed overview of the EU medical device regulatory system
- Involved in the development and marketing of drug device combinations
- Interested in medical software regulation

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**Tutorial 2 | Wednesday 06 April, 09:00-12:30**

**MOVING FROM RISK MANAGEMENT TO BENEFIT-RISK MANAGEMENT – EMBEDDING PHARMACOVIGILANCE PRINCIPLES INTO THE PRODUCT LIFE CYCLE**

**Shelley Gandhi**, Director Pharmacovigilance and Drug Safety, NDA Group, UK
**William Richardson**, Medical Advisor, NDA Group, UK

Pharmacovigilance, or the activity of monitoring the safety of medicines in clinical use and taking appropriate action to minimise risk, is governed by a range of new EU legislation, a new Pharmacovigilance Risk Assessment Committee (PRAC) and guidance. The value that can be gained from adopting a benefit-risk management system not only addresses known and potential risks to support the current regulatory status of products but also will feed into the further development of a product with regards to new indications and potentially moving from prescription only to over the counter.

This tutorial will discuss how access to robust evidence on emerging risk in post-authorisation phase, good data on how a medicine is used in clinical practice, and data on background rates in the exposed population; gathering evidence throughout the product life cycle will help move companies to a benefit-risk system. The ultimate challenge is working towards an integrated regulatory system, enabling users to query across all information within a company, designing safety studies, monitoring the effectiveness of the risk management systems and gathering robust evidence from clinical practice.

The lessons learned and our experiences so far with post-authorisation commitments (e.g. BRMPs, PASS, PSURs) will be reviewed as will whether these commitments really do support an acceptable benefit-risk profile. This will include the novel approaches to managing benefit-risk to meet the needs of licensing medicines in biotechnology such as advanced therapies. Communicating benefit-risk will also be discussed as the new legislation will push for greater patient involvement within a benefit-risk system. Better methodologies and tools are required to support this integrated approach and adoption of a quality management system across global enterprise could achieve this.

**Learning Objectives**

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

- Learn what are effective strategies and the current thinking on risk mitigation in the context of benefit throughout the product lifecycle
- Access to robust evidence on emerging risk is critical
- Discover what the principles are for proportionate risk based assessment
- Find out about hurdles which get in the way to a systematic approach and how these might be tackled
Target Audience
Professionals in companies or regulatory authorities who are involved in pharmacovigilance operations and with responsibilities for post marketing clinical safety including those who are involved in:
• Pharmacovigilance
• Regulatory
• Clinical research
• Risk management
• Medical product safety assessment
• Data analysis
• Epidemiology
• Labelling
• Quality assurance and compliance

Tutorial 4 | Wednesday 06 April, 09:00-12:30
ANALYSIS OF SAFETY DATA FROM CLINICAL TRIALS
Jürgen Kübler, Global Head, Clinical Design, Analysis and Reporting, CSL Behring GmbH, Germany
Joachim Vollmar, Executive Consultant, International Clinical Development Consultants (ICDC) LLC, USA

This tutorial is a combination of theory, guidelines, practical considerations, and real-life solutions for those working in the clinical development environment (pharmaceutical, biotech industry, or CRO). The aim of this 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 will 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 | Wednesday 06 April, 09:00-12:30
EU RISK MANAGEMENT PLANS: USING (PRE) CLINICAL DATA TO WRITE THE MODULE SVII OF THE RMP PART II – SAFETY SPECIFICATIONS
EMA Representative invited

Risk Management Plans (RMP) are required with every new marketing authorisation application in the European Union. Translating the results of the clinical and pre-clinical development into the safety profile of the product and reflecting the information in the Safety Specifications Module SVII of the RMP can be difficult without proper guidance and experience. This tutorial provides a detailed description of the risk identification principles in the newly revised “Guideline on Good Pharmacovigilance Practices: Module V – risk management systems” and practical exercises on identifying the risks of medicinal products, based on fictive development programme results.

Participants will learn to distinguish between adverse drug reactions (ADRs), risks, and important identified/potential risks and missing information, and be able to identify the data required for an evidence-based risk identification in the RMP. The participants will apply the “RMP template for
the industry” to write a RMP SVII Module by summarising and structuring the available data. The participants will also practice adapting and revising a RMP Module SVII based on results of the most common post-marketing pharmacovigilance activities. The tutorial will provide participants with the context for translating the safety profile of a medicinal product into post-marketing activities, both routine and additional.

Learning Objectives
At the conclusion of this tutorial, participants will be able to:
• Apply the risk definitions in the newly revised GVP Module V to identify the important risks of a medicinal product based on (pre)clinical findings
• Use the RMP template for industry to write an evidence-based Module SVII of the RMP
• Evaluate when the post-marketing safety results enable changes in the RMP

Target Audience
This intermediate/advanced tutorial is designed for industry pharmacovigilance professionals who write or oversee RMPs for products marketed in the European Union, for those responsible for the life cycle management of products and for participants who use post-authorisation safety finding for risk management activities.

Tutorial 6 | Wednesday 06 April, 09:00-12:30
HOT TOPIC IN PHARMACOVIGILANCE AND ADVERSE REACTION REPORTING
Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD, UK
Phil Tregunno, Signal Management & Quality Standards Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

This tutorial will focus on the following key topics: Revision of the EudraVigilance Access Policy, medical literature monitoring by the agency, implementation of the ISO/ICH E2B(R3) ICSR, and FAQs related to GVP Module VI.

Article 24 of Regulation (EC) 726/2004 outlines a new approach for marketing authorisation holders (MAHs) to access EU adverse reaction reports directly in EudraVigilance, following the successful outcome of an audit of the European pharmacovigilance database. In preparation of these changes, the EudraVigilance Access Policy has been revised to define how access will be provided to ICSR in compliance with EU personal data protection legislation.

Following the launch of the new process of monitoring medical literature for selected substances and selected medical literature in line with the provisions set out in Article 27 of Regulation 726/2004, the tutorial will provide the opportunity to discuss experiences and to address specific implementation questions. The implementation of the ISO ICSR/ICH E2B(R3) guideline will be discussed, which requires IT and business changes for which stakeholders need to carefully plan and prepare.

The tutorial will conclude with frequently asked questions with regards to the day-to-day operational aspects of GVP Module VI.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
• Describe the principles of access to EudraVigilance based on the revised policy
• Discuss the implementation experience and FAQs related to the new process for monitoring of medical literature by the EMA
• Address FAQs on GVP Module VI “Management and reporting of adverse reactions to medicinal products” and recent updates
• Describe how to prepare for the ISO/ICH ICSR implementation

Target Audience
This tutorial is designed for Qualified Persons Responsible for Pharmacovigilance (QPPVs) and individuals involved in pharmacovigilance, clinical development, information management, and safety databases.

Wednesday, 6 April 2016
08:00-12:30 ICH INFO-DAY

The ICH Info-day will this year focus on the result of the reform process resulting in the creation of The International Council for Harmonisation (ICH) at the meeting on 23 October 2015.

The reforms build on a 25-year track record of successful delivery of harmonised guidelines for global pharmaceutical development, and their regulation. This info-day will give an update on the reform and the upcoming initiatives.
WEDNESDAY 6 APRIL 2016

SPECIAL SESSIONS

OPENING PLENARY SESSION

WEDNESDAY 6 APRIL
16:00- 17:45

"Innovation – Do you win by being IN? or what is the genuine benefit of innovation and can they be challenged?

Panos Kanavos, Deputy Director LSE Health, London School of Economics, UK

Kemal Malik, Member of the Board of Management, Bayer, Germany

Ritva Halila, Senior Medical Officer, General Secretary National Advisory Board on Social Welfare and Health Care Ethics (ETENE), Ministry of Social Affairs and Health, Finland

Mads Krogsgaard Thomsen, Executive Vice President & Chief Science Officer, Novo Nordisk, Denmark

The debate will be moderated by Barbara Lopez Kunz, Chief Global Executive, DIA

GERMAN SATELLITE SESSION - REGULATORY AND SCIENTIFIC CONTRIBUTIONS OF BFARM AND PEI TO PHARMACEUTICAL INNOVATION

WEDNESDAY 6 APRIL | 11:00-12:30

Innovation and Regulation – Contradiction or Support?

Session Co-Chairs:
Karl Broich, President, Federal Institute for Drugs and Medical Devices (BfArM)
Klaus Cichutek, President, Paul-Ehrlich-Institut (PEI)

Providing patients with safe and effective medicinal products in a timely manner is the main expectation society has of medicines agencies and this is also what defines their mission. The German licensing agencies, BfArM and PEI, operate monitoring systems to continuously assure the safety of medicinal products on the market. They proactively support new developments by giving early scientific advice, supporting the approval of clinical trials and combining research and regulation.

The New Directive and Current Trends in Clinical Trials
Thomas Sudhop, Head Scientific Services Division, Federal Institute for Drugs and Medical Devices (BfArM)

Translation of Basic Research into Product Development
Christoph Conrad, Head DZIF Office for Scientific and Regulatory Advice (DZIF-OSRA), Paul-Ehrlich-Institut (PEI)

Regulatory Expertise through Research - The PEI Model
Klaus Cichutek, President, Paul-Ehrlich-Institut (PEI)

Faster Access to Innovations - Where to Go?
Karl Broich, President, Federal Institute for Drugs and Medical Devices (BfArM)

EUROPEAN REGULATORY TOWN HALL MEETING

WEDNESDAY 6 APRIL | 13:30-15:00

An Interactive Discussion on the EU Medicines Agencies Network Strategy to 2020

Co-Chairs:
Guido Rasi, Executive Director, European Medicines Agency (EMA), EU
Ian Hudson, Chief Executive, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

This interactive European regulatory town hall meeting will focus on the ‘EU Medicines Agencies Network Strategy to 2020’, developed in cooperation with the Heads of Medicines Agency and the European Medicines Agency.

Panellists:
Klaus Cichutek, President, Paul.Ehrlich-Institut (PEI), Germany
Rita Purcell, Acting Chief Executive, Health Products Regulatory Authority (HPRA), Ireland

DIAglobal.org/EM2016
The DIA Patient Advocate Fellowship Programme is designed to do the following:

• Develop, strengthen, and support patient collaborations with policy makers, industry representatives, public health authorities, academia, and other healthcare stakeholders.
• Improve alliances between patient groups and other healthcare stakeholders.
• Increase knowledge and understanding of issues central to the promotion of patient-centred healthcare, biomedical research, and drug development.
• Provide a forum for sharing best practices, stimulating cooperation, and facilitating a two-way dialogue across the entire global healthcare community.
• Enhance the capacity of patient advocates to respond to changes in drug development and health care delivery.
• Integrate the patient voice by attending EuroMeeting program offerings, roundtable discussions, and networking events.

Who should apply?

• Applicant should be affiliated with a patient organisation.
• Demonstrated track record of education and/or advocacy activities.
• Patient engagement in or be familiar with activities related to clinical trials, drug development, HTA, regulatory affairs.
• The business language of the conference is English. Patient Fellows must be able to understand scientific content in English and network with other attendees with ease.

Submission deadline: Monday, 23 November 2015

For more information and to download the application form, please click here.

Or contact EMEA.patients@DIAglobal.org

Students are the future of medicines development and DIA has long recognised this through its Student Poster Programme which is geared to engaging with these key stakeholders as they embark upon their careers. DIA offers you the opportunity to submit a poster for the conference. Successful students receive support to attend the meeting, in addition to being able to showcase their work to professionals coming from across medicines development.

DIA welcomes abstract submissions for the Student Poster Programme at the Annual DIA 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.

Submission deadline: Monday, 30 November 2015

For more information and to download the application form, please click here.

or contact EMEA.students@DIAglobal.org
DIA promotes the participation of young professionals in the EuroMeeting by offering a reduced rate for professionals under the age of 32 currently working in health product development, regulation and related fields. Selected applicants will benefit from a substantially discounted registration fee. A limited number of registrations are available.

The Young Professionals Special Rate is designed to make the EuroMeeting more accessible to talented individuals wanting to improve their professional network and expand their knowledge of the innovation and advancement taking place today, and also to incentivise companies to approve the participation of their junior employees.

In addition to simply giving access to the full meeting programme with all scientific sessions, networking opportunities and the exhibition, a mentoring lunch with leading senior professionals will be held, where Young Professional attendees can discuss issues and trends with industry leaders in their field. Hear directly from experts and learn what core competencies are needed to succeed and progress in this challenging environment.

Who should apply?
Professionals working in health product development, regulation and related fields, under the age of 32 on 13 April 2015, are eligible to apply for the special discounted rate.

Application Deadline: Thursday 24 March 2016 (before 13:00)
Special Rate: €700 (excl. VAT)

For more information and to download the application form, please click here.

or contact EMEA.youngprofessionals@DIAglobal.org

Professional individuals are encouraged to submit a poster for display in the Exhibition Hall. 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 healthcare related products.

General Submission Requirements
Abstracts must be submitted online through the DIA website.

Click here to submit an abstract.

• 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.

Submission deadline: Monday 25 January 2016

For more information, please visit www.DIAglobal.org/EM2016 or contact Sharon.Evans@DIAglobal.org
Recent advances in basic and translational sciences offer the promise to develop new types of treatments, new treatment combinations, new modes of administration, and better patient selection. To translate these innovations in the life sciences into tangible patient benefit will, however, require a parallel track of innovation in the tools and methodologies that inform regulatory, reimbursement and treatment decisions. This theme will explore how the healthcare ecosystem can best support the coevolution of life sciences and methodology innovation.
The Industry View
Anton Hoos, Head of Medical for Europe, Amgen, Switzerland

The Regulator View
Birka Lehmann, Head of EU & International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Session 0104 | Thursday 7 April, 16:00-17:30
START-UPS MEET REGULATORY AND INDUSTRY – HOW CAN IDEAS FROM ACADEMIA BE BEST TRANSLATED TO NOVEL TREATMENT OPTIONS? WHAT KIND OF PARTNERSHIPS ARE REQUIRED?
Session Chair:
Michael Brandkamp, Managing Director, High-Tech Gründerfonds, Germany

Young biotech companies are faced with a plethora of challenges nowadays. Not only do they have to find the money to pursue their research, but also to navigate in an increasingly complex regulatory environment. The panel will discuss what partnerships are required to successfully translate disruptive novel ideas into novel treatment options.

Andreas Schmidt, CEO AYOXXA Biosystems, Germany

New Treatment Paradigms – Regulatory Challenges for SMEs
Christian Schetter, CEO, Rigontec, Germany

The Role of Venture Funds in Enabling Innovation
Frank Kalkbrenner, Corporate Vice President, Bohringer Ingelheim Venture Fund, Germany

The Role of Industry in the Innovation Ecosystem
Joseph Scheeren, Senior Vice President, Head Global Regulatory Affairs, Pharma and Consumer Care, Bayer Consumer Care, Switzerland

Sam Wadsworth, Chief Scientific Officer, Dimension Therapeutics, USA

Session 0106 | Friday 8 April, 11:00-12:30
CUTTING BLOCKBUSTER INDICATIONS INTO ORPHAN-SIZED BITES
Session Chair:
Brigitte Blöchl-Daum, Member COMP and SAWP, Vice Chair, Department of Clinical Pharmacology, Medical University of Vienna, Austria

With the fragmentation of treatment-eligible populations into ever smaller substrata, targeted therapies present new challenges including evaluation of non-RCT data from small populations, regulatory consequences regarding orphan status, issues of pricing and reimbursement and off- (or near-) label use.

Orphans or Orphanisation?
Brigitte Blöchl-Daum, Member COMP and SAWP, Vice Chair, Department of Clinical Pharmacology, Medical University of Vienna, Austria

Standards of Evidence – From Blockbusters to Orphans
Simon Day, Statistical Expert, Regulatory Advisory Board, NDA Group, UK

The End of the Orphan Drug Concept... What’s Next?
Ad Schuurman, Head of Business Contact Center & International Affairs, National Health Care Institute, Netherlands

Panel discussion with Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA), EU

Session 0107 | Friday 8 April, 14:00-15:30
SHAKING THE TOOLBOX: EVOLUTIONS IN APPROACHES IN TRIAL DESIGN
Session Chair:
Robert Hemmings, Statistics Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

The randomised controlled trial (RCT) is alive and kicking for good reason, but conventional design and analysis alone will not serve the future of drug development, licensing and reimbursement. Targeted medicines, orphan conditions and life cycle management call for us to consider other approaches whilst retaining robust methodology. A series of clinical trial designs will be presented and discussed; even the well-established RCT can be improved.

Selecting and Implementing the Right Dose
Frank Bretz, Statistical Methodology and Consulting, Novartis, Switzerland

Ensuring Alignment on What Treatment Effects Are of Interest to be Estimated in Clinical Trials: New ICH Guidance
Chrissie Fletcher, Executive Director Biostatistics, Amgen, UK

Session 0108 | Friday 8 April, 16:00-17:30
BRINGING NGS INTO DRUG DEVELOPMENT: THE IMPACT OF SEQUENCING ON THE FUTURE OF CLINICAL TRIALS AND DRUG REGISTRATION
Session Chair:
Michael Doherty, Global Head - Pharma Regulatory Affairs, F. Hoffmann-La Roche/Genentech, USA

Next-generation sequencing technology (NGS), ‘-omics’, increased computational power and “Big Data” are leading to a world of “precision medicine” in which an individual patient’s genomic/phenotypic profile can be matched to a specific treatment. Trials are already underway to develop this “treatment matching” pathway. Additionally, in clinical practice, many major centres are offering comprehensive molecular diagnostic profiling to patients to augment commercially available panels. It is only a matter of time before it becomes part of standard medical practice. This session aims to discuss the impact on the way clinical trials are designed and the way this approach could drive changes in the regulatory processes.

Panellists:
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA), EU
Jennifer Dudinak, Vice President, Global Regulatory Affairs, GSK, USA
Thorsten Gutjahr, Vice President, Global Head Companion Diagnostics, AstraZeneca, UK

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This theme will look at clinical research from a variety of angles, including the traditional requirements in the development of new medicines, moving into real-world evidence, engaging with patients and other important stakeholders, and discussing how productivity in R&D may be improved.
Session 0207 | Friday 8 April, 14:00-15:30

DEVELOPMENT OF NEW MEDICINES – ENGAGING WITH STAKEHOLDERS
Session Chair:
Wim Leereveld, Founder, Access to Medicine Index, Netherlands

How Can Patients Be More Involved in the Development of New Medicines?
Jan Geissler, Director, EUPATI, Belgium

Clinical Research, Creating Shared Value
Peter Kristensen, Senior Vice President, Head of Global Development, Novo Nordisk, Denmark

How Can the Pharmaceutical Industry Improve Access to Medicines?
Wim Leereveld, CEO, Access to Medicines Index, Netherlands

Session 0208 | Friday 8 April, 16:00-17:30

EXPECT THE UNEXPECTED: CHALLENGES AND OPPORTUNITIES IN THE CLINICAL DEVELOPMENT OF BIOPHARMACEUTICALS
Session Chair:
Diane Seimetz, Co-Founder, Biopharma Excellence, Germany

Industry Perspective on Today’s Challenges and Opportunities in the Clinical Development of Biopharmaceuticals
Nikolai Brun, Vice President Drug Development, Serodus, Norway

Challenges, Opportunities and Mitigation Strategies for Biopharmaceutical Development: Learn from Case Studies across Different Stages of Development
Diane Seimetz, Co-Founder, Biopharma Excellence, Germany

Agency Perspective on the Future Paradigm of an Integrated Clinical Development for Biopharmaceuticals: What Will Be Expected for Approval and Beyond?
Jan Müller-Berghaus, Co-opted CHMP Member, Clinical Assessor, Paul-Ehrlich-Institute (PEI), Germany

2016 CONFERENCES & WORKSHOPS
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25-26 May 2016 | Leiden, the Netherlands | #16110
16th Conference on Electronic Document Management

26-28 May | Edinburgh, UK | #16106
8th European Conference on Rare Disease & Orphan Products (ECRD 2016) - Game Changers in Rare Diseases: Delivering 21st century healthcare to rare disease patients: Together We Can Change the Future!

5-6 Oct | London, UK | #16104
10th Annual Qualified Persons in Pharmacovigilance

3-14 Oct | Düsseldorf, Germany | #16103
9th Annual Clinical Forum and Exhibition

11-12 Oct 2016 | #16107
10th Annual European Medical Information and Communication Conference and Exhibition

9-10 Nov | Brussels, Belgium | #16115
Biosimilars Conference

5-6 Dec | London, UK | #16108
Pharmacovigilance Conference

6-7 Dec | London, UK | #16111
Clinical Trials Workshop

7-8 Dec | London, UK | #16119
Clinical Trial Disclosure and Data Transparency Workshop
Clinical trials at a watershed: New EU Regulation and new ICH E6 GCP addendum – risk proportionate approaches, leveraging new online technology, transparency – supporting the way we drive innovation.

**Session 0301 | Thursday 7 April, 09:00-10:30**

**NEW EUROPEAN CLINICAL TRIAL REGULATION: A NEW PARADIGM WITH MAJOR IMPACT ON CLINICAL TRIAL STAKEHOLDERS**

Session Chair:  
**Elke Stahl**, Chair CTFG, Nonclinical Assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Are stakeholders ready for implementation of the EU Clinical Trial Regulation? Challenges, expectations and progress update by members states, EMA and industry.

**Update on Member State Preparations for Implementing the Clinical Trial Regulation, and Some of the Outstanding Challenges**

Martyn Ward, Head, Group Manager Licensing, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

**Progress Update on the Development of the EU Portal and Database**

EMA representative invited

**How Industry is Adapting Itself to Meet the Requirements of the New Clinical Trial Regulation**

Rose-Marie Swallow, EU Regulatory Policy Manager, Bayer, UK

**Session 0302 | Thursday 7 April, 11:00-12:30**

**ICH E6-GCP ADDENDUM: RISK PROPORTIONATE APPROACHES TO TRIAL DESIGN AND CONDUCT**

Session Chair:  
**Fergus Sweeney**, Head of Inspections & Human Medicines Pharmacovigilance Division, European Medicines Agency (EMA), EU

The ICH E6 Good Clinical Practice addendum sets out to modernise GCP, setting out a clear risk-based approach to quality management and monitoring and embracing new technologies.

**ICH E6 Addendum – Overview and Progress**

Gabriele Schwarz, Head, GCP Inspection Services, Federal Institute for Drugs and Medical Devices (BfArM), Germany

**Session 0303 | Thursday 7 April, 14:00-15:30**

**CLINICAL TRIAL DISCLOSURE**

Session Chair:  
**Craig Johnson**, Senior Director, Regulatory Policy-Europe, GSK, UK

The sharing of patient-level data through voluntary, industry-driven initiatives offers further benefit to patients and society, in addition to the disclosure of clinical reports. This session will examine experiences of current data-sharing initiatives from the perspective of both providers and requesters of data, as well as look forward to the potential for future development of a common, multi-sponsor “portal”.

**Requesting and Using Shared Patient-Level Data – A Researcher’s Experience and Perspective**

Speaker invited

**Providing Access to Patient-Level Data – A Company’s Experience and Perspective**

Rebecca Sudlow, Global Lead Patient-Level Data Sharing, Roche Products, UK

**Development of a Common Portal – Reality or Just a Dream?**

Jennifer O’Callaghan, Clinical Data Sharing Manager, Wellcome Trust, UK
Session 0305 | Friday 8 April, 09:00-10:30
ENHANCING CLINICAL TRIALS EFFICACY: OPERATIONAL EXCELLENCE AND CONTINUOUS IMPROVEMENT OF CLINICAL RESEARCH PROCESSES
Session Chair:
Holger Maria Rohde, Director, Strategy Implementation Lead, Merck Serono, Germany

Can clinical trials efficacy be improved by operational excellence methods such as LEAN and Six Sigma? This session will evaluate their application in clinical trials to remove non-value creating work such as over-processing, waiting times, etc. Needed programme efforts and change management activities will also be discussed.

Best Practices in Protocol Design by Reducing Protocol Amendments
Stella Stergiopoulos, Senior Project Manager, Tufts Center for the Study of Drug Development, USA

Pragmatic Approaches to Improving Productivity in Clinical Development
Ronald S. Waife, President, Waife & Associates, Inc., USA

Are We Making the Wrong Model Efficient? Are Different Modalities Required?
Pete Milligan, Vice President, Clinical Platforms Transformation, GSK, UK

Session 0206/0306 | Friday 8 April, 11:00-12:30
OXFORD DEBATE: ‘THIS HOUSE BELIEVES THAT OVER-ENGINEERED CLINICAL DEVELOPMENT HAS INHIBITED INNOVATION’
Session Chair:
Julianne Hull, CEO, WenStar Enterprises, UK

High-profile representatives from academia, industry, and patient organisations will debate both sides of this controversial hypothesis. Debaters will explore and argue the impact of regulations, budgets, quality, and patient needs.

Debaters:
• Martin Landray, Professor of Medicine & Epidemiology, Nuffield Department of Population Health, University of Oxford, UK
• Thomas Senderovitz, Senior Vice President, Clinical Research Services, PAREXEL, Germany
• Bettina Ryll, Founder, Melanoma Patient Network, Sweden
• Sam Wadsworth, Chief Scientific Officer, Dimension Therapeutics, USA

Session 0308 | Friday 8 April, 16:00-17:30
CHALLENGES FOR ACADEMIC CLINICAL TRIALS
Session Chair:
Jacques Demotes-Mainard, Director General, European Clinical Research Infrastructure Network (ECRIN), France

What challenges and opportunities do the new Clinical Trial Regulation, ICH E6 addendum, and evolving technical and international clinical trial landscape bring for clinical trials sponsored by academia?

Risk-Proportionate Approaches to Trial Design and Conduct – ICH GCP E6 Addendum and Clinical Trial Regulation Provisions
Martin Landray, Professor of Medicine & Epidemiology, Nuffield Department of Population Health, University of Oxford, UK

Data Management in Academic Trials: Data Centre Certification and SaaS / Cloud Solutions for Data Management
Christian Ohmann, European Clinical Research Infrastructures Network (ECRIN), World Package Leader, Heinrich Heine University, Germany

International Cooperation in Academic Clinical Trials
Speaker invited

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THEME 4
REGULATORY SCIENCE

Session 0401 | Thursday 7 April, 09:00-10:30
REGULATORY SCIENCE HAND IN HAND WITH HEALTH TECHNOLOGY ASSESSMENT FOR BETTER OUTCOMES
Session Chair:
Sabine Atzor, Director Regulatory Affairs, European Federation of Industries and Associations (EFPIA), Belgium; on secondment from F. Hoffmänn-La Roche

This session will provide insights from key stakeholders on the impact of regulatory science, pharmaceutical legislation and HTA on the effectiveness of the EU regulatory system’s ability to overcome obstacles and focus on better outcomes for patients’ health.

Is Our Regulatory System Effective? Recent Examples of Applied Regulatory Science
Hugo Hurts, Executive Director, Medicines Evaluation Board (MEB), Netherlands

The Beauty of New Science – What Is Needed to Translate It into Better Outcomes? An Industry Perspective
Richard Bergström, Director General, EFPIA, Belgium

How Does the Regulatory and HTA System Keep Pace with New Science? EU Commission Perspectives on the EU Pharmaceutical Framework and HTA Cooperation
European Commission representative invited

Session 0402/0702 | Thursday 7 April, 11:00-12:30
FAST FORWARD TO THE FUTURE – HOW BIG DATA AND ARTIFICIAL INTELLIGENCE WILL CHANGE OUR REGULATORY ENVIRONMENT
Session Chair:
Joseph Scheeren, Vice President, Head Global Regulatory Affairs, Pharma and Consumer Care, Bayer Consumer Care, Switzerland

The complexity of the regulatory environment is growing rapidly in light of new digital technologies for disease surveillance, diagnostic and medication. This session will focus on future knowledge, artificial intelligence and prediction in intelligence with impact on the regulatory world.

Big Data as Part of European eHealth Policy: Viewpoint of the Regulator
Terje Peetso, Policy Officer, Unit H1 - Health and Wellbeing, Directorate-General Communications Networks, Content and Technology (DG CONNECT), European Commission, EU

What is the Current and Future Status of Big Data in the Health Care Sector: View from the Market
Frank Wartenberg, President Central Europe, IMS Health GmbH & Co. OHG, Germany

Challenges of Big Data in the Regulatory Environment from the Legal Point of View
Peter Bogaert, Partner, Covington & Burling LLP, Belgium

Session 0403 | Thursday 7 April, 14:00-15:30
THE FUTURE OF REGULATORY AFFAIRS IS DIGITAL – KEY SUCCESS FACTORS FOR REGULATORY AFFAIRS IN A RAPIDLY CHANGING ENVIRONMENT
Session Chair:
Georg Neuwirther, IT Director, Agency for Health and Food Safety (AGES), Austria

Regulatory science – the key to the future. This theme aims to open our thinking in exploring and preparing for the future of regulatory affairs in 2020 and beyond. Highlights of topics include: strategic developments in the pre- and post-approval phase, insights and solutions on future plans from the EU Commission and key European regulators, and ideas as to how regulatory science can bring therapeutic innovations to those in need.

How Does Industry Prepare for the Digital Future Along the Value Chain?
Maren von Fritschen, Managing Director, AddOn Pharma, Germany

Peter Bachmann, Chair CMDh, Senior Expert, European Drug and Regulatory and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Isabelle Stöckert, Vice President, Head Global Regulatory Affairs EU/CAN, Bayer Pharma, Germany

Regulatory science – the key to the future. This theme aims to open our thinking in exploring and preparing for the future of regulatory affairs in 2020 and beyond. Highlights of topics include: strategic developments in the pre- and post-approval phase, insights and solutions on future plans from the EU Commission and key European regulators, and ideas as to how regulatory science can bring therapeutic innovations to those in need.
Opportunities and Challenges of ISO-IDMP Implementation
Kevin Horan, Director of ICT and Business Services, Health Products Regulatory Authority (HPRA), Ireland

Session 0404 | Thursday 7 April, 16:00-17:30
ADAPTIVE PATHWAYS AND CONDITIONAL APPROVAL – PANEL DISCUSSION
Session Chair:
Luca Pani, Director General, AIFA, Italy

This panel will outline the opportunities from increasing documentation of real life and post approval data and the incentives provided by regulators to develop new indications.

Panellists:
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA), EU
Susan Forda, Vice President, GRA International, Eli Lilly, UK
Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits Agency (TLV), Sweden
François Houÿez, Treatment Information and Access Director, Health Policy Advisor, EURORDIS, France
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden
EMA representative invited

Session 0405 | Friday 8 April, 09:00-10:30
INNOVATION OF MATURE PRODUCTS – NEW USES FOR OLD PRODUCTS
Session Chair:
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, UK

Multiple challenges exist for the development of products that have been on the market for many years; often these products are operating in a multisource market. Such challenges include the regulatory acceptability of new and existing data, and legal protection for new uses.

Opportunities to Protect Innovation after Expiry of Intellectual Property Rights
Genevieve Michaux, Counsel, Hunton and Williams LLP, Belgium TBC

Challenges to Overcome when Obtaining a New Marketing Authorisation for a Mature Product – A Case Study
Sylvia Lobo, Senior Director, Regulatory - Global Established Products, Pfizer, UK

Regulatory Acceptability of Different Datasets for the Assessment of Novel Uses for Older Products
Speaker invited

Session 0406 | Friday 8 April, 11:00-12:30
EVOLVING AREAS OF REGULATORY SCIENCE
Session Chair:
Beatriz Silva Lima, Professor, University of Lisbon, Portugal

Scientific and technological progress is increasing the need to accommodate science in the regulatory framework. How are regulatory scientists in regulatory agencies, academia and industry balancing science and legislation?

Regulatory Agencies and Regulatory Science
Speaker invited

Regulatory Science and Academia
Per Spindler, Director Biopeople, University of Copenhagen, Denmark

New Development on Environmental Risk Assessments
Jason Snape, Associate Director, SHE Research and Foresight, AstraZeneca, UK

Panel discussion with speakers, Jun Kitahara, Division Director, Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan; EC representative invited

Session 0407 | Friday 8 April, 14:00-15:30
IT’S NEVER TOO SOON – EARLY ACCESS AND EARLY DIALOGUE IN DRUG DEVELOPMENT
Session Chair:
Kate Beaujeux, Senior Regional Regulatory Affairs Director, AstraZeneca, UK

This session will focus on the key contributions of regulatory science in support of timely access to medicines. This includes strategies for consultations with EMA and/or FDA such EMA/HTA joint advice, national advice, new possibilities based on the EMA “PRIME” scheme and how to prepare for compassionate use programmes.

Regulatory Strategies for Early Dialogue: Scientific Advice Including Joint EMA/HTA and National Advice and Pilot Scientific Advice on PASS
Steffen Thirstrup, NDA Group, UK

European Early Stage Innovative Medicines Designation (“PRIME” Scheme)
EMA representative invited

Early Access/Compassionate Use in Europe
Katrin Rupalla, Vice President, Global Regulatory Sciences, BMS, Belgium

Session 0408 | Friday 8 April, 16:00-17:30
WHERE IS THE ORPHAN DRUG JOURNEY GOING?
Session Chair:
Mark Rutter, Director Policy and Intelligence, AbbVie, USA

This session looks at the success of EC Regulation on orphan medicinal products in bringing innovative new therapies to patients with a high unmet medical need. We will explore the upcoming changes in the EU orphan environment and what must be maintained and built upon to further stimulate research in this key research area.

Session in development
Theme 5: Medical Affairs

Session 0501 | Thursday 7 April, 09:00-10:30
Patient-Focused Medicine – To Understand Patients You Must Engage Them
Session Chair: Richard Stephens, Patient Advocate, National Cancer Research Institute (NCRI), UK

The concept of patient-focused medicine is gaining momentum in healthcare. But what does it really mean? And how can an organisation realign itself to be more patient-centric? A multidisciplinary panel will discuss the challenges and opportunities of engaging patients in their own care.

Guy Yeoman, Vice President Patient Centricity, AstraZeneca, UK

EMA/FDA Patient Engagement – Comparing and Sharing
Natalie Bere, European Medicines Agency (EMA), EU

A Meaningful Future of the Patient Information Leaflet in Europe
Aimad Torqui, Merck Sharp & Dohme (Europe), Belgium
Tessa Richards, Assistant Editor, BMJ Publishing Group, UK

Session 0502 | Thursday 07 April, 11:00-12:30
Digital Health: How Digital Technology Is Transforming Health Care
Session Chair: Jessica Federer, Chief Digital Officer, Bayer, Germany

One of the most prominent changes transforming medical care today is the advent of digital technology and social media, which has opened up a world of possibilities for enhancing patient care. Gain unique perspectives on the challenges and opportunities for industry, government, patients, and physicians. Is health care ready for empowered and digitally demanding patients?

Alexia Tonnel, Director of Evidence Resources, National Institute for Health and Care Excellence (NICE), UK

Session 0503 | Thursday 7 April, 14:00-15:30
The Reality of Real-World Evidence (RWE) – How Various Stakeholders Are Working with RWE to Improve Patient Outcomes
Session Chair: June Raine, Chair PRAC, Vigilance and Risk Management of Medicines Division, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

Real-world evidence holds the potential to improve drug discovery and development, speed up access to market, improve patient care and make for more responsive and health care systems. The panel will discuss the progress being made to harness the use of RWE to improve patient outcomes and its practical implications.

Michael Howard, UK Head, IBM Watson Health, UK
Christian Reich, VP RWE Systems, IMS Health; OHDSI, USA

Session 0504 | Thursday 7 April, 16:00-17:30
Physician Engagement, Education and Communication in an Era of Transparency
Session Chair: Michael Devoy, Head, Global Medical Affairs & Pharmacovigilance, Bayer Pharma, Germany

In today’s rapidly changing health care environment, the medical affairs role has become increasingly important in the industry. This session will explore the evolving role of medical affairs and how to build effective, sustainable, transparent and compliant relationships with stakeholders to make a positive impact on patient care.

Gustavo Kesselring, Executive Director, Latin America, VIS Research, Brazil
Otmar Kloiber, Secretary General, World Medical Association, France

Michael Devoy, Head, Global Medical Affairs & Pharmacovigilance, Bayer Pharma, Germany

Health care organisations are challenged by pressures to improve outcomes, reduce costs and be more patient-centric. To stay relevant to their proactive patients, stakeholders have responded by changing philosophies and designing new initiatives to meet patients’ needs. The importance of deep insight from big data, digital technology and scientific dialogue with doctors, patients and the government will only increase as the health care system becomes more sophisticated in its approach to diagnosis, treatment and reimbursement. The time is right for medical affairs organisations to earn their place at the leadership table by creating opportunities to deliver new value for both patients and the health care ecosystem. This theme brings together stakeholders from government, academia, industry, and patient organisations to discuss trends impacting medical practice, present insights, and share practical solutions to create a better health system.
Kristin Raudsepp, Director General, State Agency of Medicines, Estonia

Everybody has experienced the availability problem of a medicinal product, personally or professionally. This theme will bring together all involved stakeholders - the participants will get a good overview about current issues, hear the discussions about possible solutions, understand the latest decisions and have the possibility to give ideas for ways to avoid health threats in the future. Patients, physicians, pharmacists, companies, and regulators are dealing with problems - it is reasonable to strengthen the possibilities and join efforts.
Session 0101/0701/0901/1301 | Thursday 7 April, 09:00-10:30

BENEFIT-RISK MANAGEMENT PLANNING THROUGH THE LIFE CYCLE OF A PRODUCT
Session Chair:
Robert Hemmings, CHMP, SAWP Chair, Statistics Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

This session will aim to introduce and frame not only the subsequent sessions in the Benefit-Risk Management Theme, but also links to the evolutions to be presented and discussed in the Innovation, eHealth/Big Data, and HTA themes. Multiple scientific and policy initiatives have the potential to change the landscape for drug discovery, development, regulation, and reimbursement. The session will present some highlights, with a particular focus on optimising drug development, real-world and ‘big’ data, and multi-stakeholder dialogue, to inform prospective planning for evidence generation across the drug lifecycle.

Initiatives to Enhance the Development and Regulation of Medicines – Before and After Marketing Authorisation
Robert Hemmings, Statistics Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

How Can Real-World Data Support Decisions on Early Reimbursement of New Technologies?
Wim Goettsch, Project Leader EUnetHTA JA2 WP Rapid Assessments, Health Care Insurance Board (CVZ), Netherlands

The Age of Big Data and Better Analytics: How to Achieve Operational and Clinical Gains
Ricky Lakhani, Lead Product Manager, Medidata Solutions Worldwide, UK

Session 0402/0702 | Thursday 7 April, 11:00-12:30

FAST FORWARD TO THE FUTURE – HOW BIG DATA AND ARTIFICIAL INTELLIGENCE WILL CHANGE OUR REGULATORY ENVIRONMENT
Session Chair:
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Terje Peets, Policy Officer, Unit H1 - Health and Wellbeing, Directorate-General Communications Networks, Content and Technology (DG CONNECT), European Commission, EU

What is the Current and Future Status of Big Data in the Health Care Sector: View from the Market
Frank Wartenberg, President Central Europe, IMS Health GmbH & Co. OHG, Germany

Challenges of Big Data in the Regulatory Environment from the Legal Point of View
Peter Bogaert, Partner, Covington & Burling LLP, Belgium

Session 0703 | Thursday 7 April, 14:00-15:30

REAL-WORLD DATA MAKING PERSONALISED MEDICINE A REALITY
Session Chair:
Jacco Keja, Global Head HEOR, IMS Health, UK

The health care informatics revolution allows genetic information to be complemented with patient level outcomes. We will explore how cohort studies and harmonised big data are the foundation for the future of personal medicine.

Evaluation of Modern Data Approaches from an Epidemiologist’s Vantage Point and How to Implement for Achieving Optimal Results
Susan Oliveria, Epidemiologist, Memorial Sloan Kettering Cancer Center; CEO, EpiSource, USA

Population and Census Cohort Approach with Extensive Biobank Information
Ronald Stolk, Chief Scientific Officer, LifeLines, Program Director Research Data & Biobanking, University Medical Center Groningen, Netherlands

Detlef Nehrdich, Senior Associate, Waife and Associates, Germany
Luca Pani, Director General, Italian Medicines Agency (AIFA), Italy

The increasing volume of data collected and the corresponding analytical and logistical challenges around it are the hot topics for the eHealth/Big Data Theme. While the variety of data sources is growing, the current and potential future value of big data and eHealth is not fully understood yet. This session will elaborate on examples of how additional evidence can be generated and how it can be utilised to support risked-based decision making.
Session 0704 | Thursday 7 April, 16:00-17:30
VALUE PROPOSITION, CHALLENGES AND EXAMPLES FOR THE USE OF BIG DATA IN THE PHARMACEUTICAL INDUSTRY
Session Chair:
Duane Schultheiss, Managing Director, Vital Transformation, Belgium
Diederick Grobbee, Professor of Clinical Epidemiology, Utrecht University Center, Netherlands
Protocol Optimisation through Clinical Big Data: Possibilities and Constraints
Isabelle de Zegher, Worldwide Senior Director, Clinical Data Standards, PAREXEL Informatics, Belgium
Analytical Challenges of Big Data
Michael Hennig, Head Biostatistics & Epidemiology, GSK, Germany
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Session 0705 | Friday 8 April, 09:00-10:30
CHALLENGES AND OPPORTUNITIES RELATED TO THE INTEGRATION OF MULTIPLE DATA SOURCES
Session Chair:
Luca Pani, Director General, Italian Medicines Agency (AIFA), Italy
Integrating Safety, Regulatory and Benefit-Risk Functions to Enhance Compliance and Efficiency in Maintaining Marketed Products
Libbie McKenzie, Global Head, Safety Surveillance and Benefit-Risk Management, Quintiles Transnational, USA
Endpoints to Insights: Integrating “External” Data within the Broader eClinical Ecosystem
Nick Neri, ERT Insights Cloud Platform Manager, ERT, USA
Beyond Security: The Growing Need for Data and Privacy Protection
Speaker invited

Session 0707 | Friday 8 April, 14:00-15:30
THE GROWING ROLE AND IMPORTANCE OF INTEROPERABILITY AND STANDARDISATION
Session Chair:
Detlef Nehrdich, Senior Associate, Waife and Associates, Germany
Hear about eHealth interoperability projects on an EU level and how regulatory requirements (e.g. IDMP) can trigger better structure. Understand why standardisation can be a means for better oversight and why it’s a prerequisite for the analysis of big data and corresponding accelerated decision making.
Bringing Structure to Substance Information
Niels Henriksen, Business Consultant, NNIT, Denmark
Interoperability and Standardisation within the Life Sciences: Justification, Mechanisms and Opportunities
Thomas Macfarlane, Director, EU Regulatory Affairs Lead, Accenture, UK

European Commission Perspective
Terje Peetso, Policy Officer, Unit H1 - Health and Wellbeing, Directorate General Communications Networks, Content and Technology (DG CONNECT), European Commission, EU

Session 0708 | Friday 8 April, 16:00-17:30
EXAMPLES OF BIG DATA APPLICATIONS
Session Chair:
Andrew Lawton, Global Head of Clinical Data Management, Boehringer Ingelheim, UK
Andrew Lawton, Global Head of Clinical Data Management, Boehringer Ingelheim, UK
The Estonian Genome Biobank and How it Impacts Clinical Decision Making
Andres Metspalu, Professor of Biotechnology of IMCB, Director of the Estonian Genome Project, University of Tartu
Big Data in Alzheimer Research: Data Integration and Data Mining Challenges
Martin Hofmann-Apitius , Head of the Department of Bioinformatics, Fraunhofer Institute for Algorithms and Scientific Computing (SCAI), Germany

25-26 May 2016
Leiden, Netherlands
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THEME 8
PHARMACOVIGILANCE

Maarten Lagendijk, Pharmacovigilance Coordinator, Medicines Evaluation Board (MEB), Netherlands
Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD, UK

Regulators, health care professionals, patients and speakers from industry will provide the audience with holistic insights and offer solutions to some challenges faced in the ever changing field of pharmacovigilance. This theme will explore several different aspects ranging from innovation in patient reporting, the complexities of medication errors and updates on signal management and effectiveness through to transparency in risk communication and pharmacovigilance for devices.

Session 0801 | Thursday 7 April, 09:00-10:30

INNOVATION FOR PATIENT REPORTING
Session Chair: Phil Tregunno, Signal Management & Quality Standards Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

The session will explore new methods of engaging with patients to maximise the impact of pharmacovigilance activities. It will discuss opportunities and challenges arising from the use of mobile technologies, consider how transparency of information might benefit patient groups and delve into the world of social media for pharmacovigilance purposes.

Launching an App for Patients and Healthcare Professionals in the Netherlands
Linda Härmärk, Head of Innovation and Projects, Netherlands Pharmacovigilance Centre Lereb, Netherlands

How VigiAccess Can Make Global Safety Data Available When and Where it is Needed
Magnus Wallberg, Technology Evangelist, Uppsala Monitoring Centre, Sweden

Understanding Patient and Health Care Professional Motivations for Using an App - What are Patients and Healthcare Professionals Telling Us?
Sieta de Vries, Post-Doc Researcher, University Medical Center Groningen, Netherlands

Everything You Wanted to Know About Social Media and Pharmacovigilance, but Were Afraid to Ask...
Davis Lewis, Global Head of Pharmacovigilance, Novartis, Switzerland

Session 0802 | Thursday 7 April, 11:00-12:30

PERSPECTIVES ON MEDICATION ERRORS
Session Chair: Vicki Edwards, Head of Affiliate Vigilance Excellence and QPPV, Abbvie, UK

Medication errors cause a large number of adverse drug reactions (ADRs) with negative patient health outcomes each year. The new pharmacovigilance legislation expanded the obligations related to medication error which presents some interesting challenges. This session will look at:

- Real experiences from the perspective of a regulatory authority
- Practical challenges for the industry related to coding of medication errors
- Perspectives of patients and healthcare professionals

Medication Errors Provide a Challenge for Pharmacovigilance – Experiences of a Regulatory Authority
Claudia Kayser, Regulatory Affairs Manager, Pharmaceutical Pharmacological Assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Medication Errors – The Perspective of Patients and Healthcare Professionals Relating to Identification of Issues and Collection of Data
Speaker invited

How Do MedDRA Terminology Changes Affect Our Data / Our Interpretation of Verbatims Associated with Medication Errors?
Maren Enssle, MedDRA Specialist, Abbott Laboratories, Germany

Session 0803 | Thursday 7 April, 14:00-15:30

END-TO-END PHARMACOVIGILANCE QUALITY AND COMPLIANCE
Session Chair: Monika Pietrek, Managing Director and Senior Consultant, Pietrek Associates, Germany

A cohesive pharmacovigilance system requires well defined processes which include sufficient quality measures to support patient safety and regulatory compliance. The core pharmacovigilance activities involve several functions of a Marketing Authorisation Holder’s (MAH) affiliates, business partners and service providers beyond the pharmacovigilance department itself. Therefore, the process design has to adequately capture these interfaces to enable appropriate oversight. In addition, the changes prompted by the Clinical Trial Regulation (CTR) will be addressed.

Safety Reporting under the Clinical Trial Regulation
Esteban Herrero-Martinez, Director, Regulatory Intelligence and Policy, Daiichi Sankyo Development, UK
Oversight of Pharmacovigilance Compliance - The Role of Metrics and KPIs
Monika Pietrek, Managing Director and Senior Consultant, Pietrek Associates, Germany

Inspectorate Feedback Regarding the Use of Reference Safety Information
Joanna Harper, Inspector, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

Session 0805/1205 | Friday 8 April, 09:00-10:30
POST-MARKETING SURVEILLANCE AND CE MARKETING
Session Chair:
Reinhard Berger, Head of Department, Medical Device Market Surveillance, Agency for Health and Food Safety (AGES), Austria
This session will focus on vigilance and post-market surveillance in the medical device field. You will learn the principles and methods from various perspectives - manufacturer, user and authorities. Participants will also learn about the different new approach in the medical device arena compared to pharma.

Post-Market Surveillance – A Legal Requirement for Patient Safety and Benefit
Reinhard Berger, Head of Department, Medical Device Market Surveillance, Agency for Health and Food Safety (AGES), Austria
Post Market Surveillance – Compliance, Burden and Benefit with the Legal Requirements from a Manufacturer’s Perspective
Speaker invited
Post Market Surveillance – Product Performance and Quality Aspects Including Reporting from a User’s Perspective
Speaker invited

Session 0806 | Friday 8 April, 11:00-12:30
PLANNING AND OVERSIGHT FOR SUCCESS
Session Chair:
Michael Richardson, International Head GPV&E and EU QPPV, BMS, UK
Planning in 2016 for 2017 Access to EudraVigilance for Industry
EMA representative invited
Towards Implementation – Article 57, IMPD, R3, PSUSA and PSUR Repository
Speaker invited
Use of EU PSMF – Outside the EAA
Speaker invited

Session 0807 | Friday 8 April, 14:00-15:30
EFFECTIVE AND BALANCED RISK COMMUNICATION
Session Chair:
Dolores Montero, Member PRAC, Division Head of Pharmacoepidemiology and Pharmacovigilance, Spanish Medicines Agency, Spain
Risk communication is an essential tool for risk minimisation. This session will provide insight on the patient’s perception, how communication can be tailored to the different audiences and what European countries are doing in order to improve such communications.

Does Transparency in Medicines Information Deliver Benefit to Patients?
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

Different Approaches for Different Audiences
Sabine Straus, Member PRAC, Head of Pharmacovigilance, Medicines Evaluation Board (MEB), Netherlands

Risk Communication in the EU – The SCOPE Joint Action
Dolores Montero, Member PRAC, Division Head of Pharmacoepidemiology and Pharmacovigilance, Spanish Medicines Agency, Spain

Session 0808/0908 | Friday 8 April, 16:00-17:30
IMPACT OF REGULATORY MEASURES TO OPTIMISE BENEFIT-RISK DECISIONS
Session Chair:
June Raine, Chair PRAC, Vigilance and Risk Management of Medicines Division, Medicines & Healthcare Products Regulatory Agency (MHRA), UK
This session will outline approaches for measuring the impact of medicines regulation and of individual regulatory measures. The session will outline how impact measurement is critical to drive process improvement and improve regulatory systems for the benefit of patients. In four short presentations practical examples will be presented and the session will then have a discussion on how to collaborate for better impact measurement.

Why Measure the Impact of Regulatory Action (and How)?
Peter Arlett, Head of Pharmacovigilance, European Medicines Agency (EMA), EU

Measuring Regulation to Drive Process Improvement
Marie Louise (Marieke) De Bruin, Professor, Utrecht Institute for Pharmaceutical Sciences; Medicines Evaluation Board (MEB), Netherlands

Assessment of the Studies Evaluating the Effectiveness of Risk Minimisation Measures in ENCePP e-Register
Vineet Jaiprakash Singh, Medical Evaluator, Global Clinical Safety & Pharmacovigilance, CSL Behring, Germany

Examples of Measuring Impact of Regulatory Action for Marketed Medicines
Martin Huber, Member PRAC; Senior Assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany
This theme will take a holistic look at the elements which contribute to effective and proactive life cycle management of benefit-risk. New approaches to data generation and an increasing recognition of the value to be gained from real-world evidence will be explored, along with some of the practical challenges raised.

**Session 0101/0701/0901/1301 | Thursday 7 April, 09:00-10:30**

**BENEFIT-RISK MANAGEMENT PLANNING THROUGH THE LIFE CYCLE OF A PRODUCT**

Session Chair: Robert Hemmings, CHMP, SAWP Chair, Statistics Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

This session will aim to introduce and frame not only the subsequent sessions in the Benefit-Risk Management Theme, but also links to the evolutions to be presented and discussed in the Innovation, eHealth/Big Data, and HTA themes. Multiple scientific and policy initiatives have the potential to change the landscape for drug discovery, development, regulation, and reimbursement. The session will present some highlights, with a particular focus on optimising drug development, real-world and ‘big’ data, and multi-stakeholder dialogue, to inform prospective planning for evidence generation across the drug lifecycle.

**Initiatives to Enhance the Development and Regulation of Medicines – Before and After Marketing Authorisation**

Robert Hemmings, Statistics Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

**How Can Real-World Data Support Decisions on Early Reimbursement of New Technologies?**

Wim Goettsch, Project Leader EUnetHTA JA2 WP Rapid Assessments, Health Care Insurance Board (CVZ), Netherlands

**The Age of Big Data and Better Analytics: How to Achieve Operational and Clinical Gains**

Ricky Lakhani, Lead Product Manager, Medidata Solutions Worldwide, UK

**Session 0903 | Thursday 7 April, 14:00-15:30**

**ASSESSING THE BENEFITS AND RISKS AS THE BASIS OF BENEFIT-RISK MANAGEMENT**

Session Chair: Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden

An update will be given on benefit-risk management methodologies and approaches along the medicines life cycle including implementation of IMI PROTECT results, advanced therapies, long-term surveillance challenges, benefit-risk management of well-established products, and patients’ perspectives integration.

**Update on Regulatory use of Benefit-Risk Methodologies**

EMA Representative invited

**Advanced Therapies: Planning the Long Term Follow-Up?**

Gopalan Narayanan, Biologics and Advanced Therapies Expert, NDA Group, UK

**Overcoming the Challenges of Benefit-Risk Assessment for Established Products**

Rafael Smets, Head Medical Affairs, SGS Life Science Services, Belgium

**Patient Perspective Elicitation as Integral Part of the Drug Development Dialogue with Regulatory Authorities and Other Decision Makers**

Conny Berlin, Global Head Quantitative Safety & Epidemiology, Novartis Pharma, Switzerland

**Session 0904 | Thursday 7 April, 16:00-17:30**

**POST-AUTHORISATION SAFETY AND EFFICACY STUDIES: SCIENTIFIC CHALLENGES AND FACTORS FOR SUCCESS**

Session Chair: Linda Scarazzini, Vice President Medical Safety Evaluation, Abbvie, USA

The new EU pharmacovigilance legislation increased the focus on scrutiny of post-authorisation activities to assist in the ongoing benefit-risk evaluation of medicines. Post-Authorisation Safety Studies (PASS) play an increasingly important role in characterising and better understanding safety concerns and are now an integral part of understanding the effectiveness of risk minimisation measures. Post-authorisation efficacy study guidance is still under development but it is clear that design of these studies and PASS need to be scientifically robust in order that they achieve the desired objective as described in the legislation. This session will explore the scientific challenges that these requirements pose.

**Scientific Challenges for Post-Authorisation Efficacy Studies**

Speaker invited
Scientific Challenges for Post-Authorisation Safety Studies
Speaker invited

PASS – Is the Ongoing Surveillance a Blessing or a Curse?
Magdalena Matusiak, Manager, Clinical Development, KCR, Poland

Session 0905 | Friday 8 April, 09:00-10:30
POST-AUTHORISATION SAFETY AND EFFICACY STUDIES: OPERATIONAL CHALLENGES AND FACTORS FOR SUCCESS
Session Chair:
EMA representative invited

Session in development

Session 0906 | Friday 8 April, 11:00-12:30
UNDERSTANDING IMPORTANT RISKS AND THE EVOLUTION TO BENEFIT-RISK MANAGEMENT PLANNING
Session Chair:
Maia Uusküla, Member PRAC, Head of the Bureau of Pharmacovigilance, State Agency of Medicines, Estonia

This session will discuss the revised EU benefit-risk management planning good pharmacovigilance practice (GVP) and the expectations of regulators, industry and users of medicines. It will cover what is and is not an important risk and provide case studies and examples.

New Approaches to Benefit-Risk Management Planning in the EU
Sabine Straus, Member PRAC, Head of Pharmacovigilance, Medicines Evaluation Board (MEB), Netherlands

Innovative Industry Experience since 2012 and Reflections on New EU Guidance
Val Simmons, EU QPPV, Global Patient Safety, Eli Lilly and Company, UK

Generics Industry Experience since 2012 and Reflections on New EU Guidance
Katarina Nedog, Safety and Regulatory Manager, European Generic and Biosimilar Medicines Association (EGA)
Panel discussion speakers and June Raine, Chair PRAC, Vigilance and Risk Management of Medicines Division, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

Session 0808/0908 | Friday 8 April, 16:00-17:30
IMPACT OF REGULATORY MEASURES TO OPTIMISE BENEFIT-RISK DECISIONS
Session Chair:
June Raine, Chair PRAC, Vigilance and Risk Management of Medicines Division, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

This session will outline approaches for measuring the impact of medicines regulation and of individual regulatory measures. The session will outline how impact measurement is critical to drive process improvement and improve regulatory systems for the benefit of patients. In four short presentations practical examples will be presented and the session will then have a discussion on how to collaborate for better impact measurement.

Why Measure the Impact of Regulatory Action (and How)?
Peter Ariett, Head of Pharmacovigilance, European Medicines Agency (EMA), EU

Measuring Regulation to Drive Process Improvement
Marie Louise (Marieke) De Bruin, Professor, Utrecht Institute for Pharmaceutical Sciences: Medicines Evaluation Board (MEB), Netherlands

Assessment of the Studies Evaluating Risk Minimisation Measures in ENCePP e-Register - A Review
Vineet Jaiprakash Singh, Bayer Pharma, Germany

Examples of Measuring Impact of Regulatory Action for Marketed Medicines
Martin Huber, Member PRAC; Senior Assessor, Federal Institute for Drugs and Medical Products (BfArM), Germany

DIAglobal.org/EM2016
WHAT HAPPENS IN AND AROUND EUROPE – BEYOND THE EUROPEAN UNION?
Session Chair: Eyal Schwartzberg, Head of Pharmaceuticals Unit, Ministry of Health, Israel

This session will gather speakers and panellists from countries surrounding the European Union: Israel, Russia, Serbia and Turkey. Those countries’ perspectives on achievements and challenges will be shared, leaving sufficient time for discussion and questions from participants.

Closing the Regulation Gap – Overcoming the Challenge of Medicines Regulation in a Non-EU Agency in a Global Environment
Eyal Schwartzberg, Head of Pharmaceuticals Unit, Ministry of Health, Israel

Management Systems Integration – An Approach to Improve Regulatory Performance
Gordana Pejovic, Quality Manager, Medicines and Medical Devices Agency, Serbia

Turkey: The Country of Challenges and Opportunities
Tahsin Yuksel, General Manager, TEVA Pharmaceuticals, Turkey

STRENGTHENING OF REGULATORY SYSTEMS: HOW IS IT ACHIEVED AND WHEN?
Session Chair: Lembit Rägo, Head, Regulation of Medicines and other Health Technologies, World Health Organization (WHO), Switzerland

National competent authorities (NCAs) play a vital role in the health care system by providing regulatory oversight of all health medical products. Helping NCAs fulfill their mandate in an effective, efficient, predictable and transparent manner is therefore of critical importance in ensuring the quality, safety and efficacy of health products in an increasingly complex global environment.

This session examines some of the key considerations and developments associated with building capacity and cooperative approaches to regulation, in line with the World Health Assembly (WHA) Resolution 67.20 on regulatory system strengthening for medical products.

Why is Regulatory System Strengthening Important?
Lembit Rägo, Head, Regulation of Medicines and other Health Technologies, World Health Organization (WHO), Switzerland

Telematics Goes Global – How Can Technology Strengthen Regulatory Systems?
Klaus Menges, Project Manager, Federal Institute for Drugs and Medical Devices (BfArM), Germany

The International Coalition of Medicines Regulatory Authorities (ICMRA) Role in Capacity Building: Where Are the Gaps and Overlaps?
Toshiyoshi Tominaga, Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Regulating Medical Devices: Bridging Gaps on a Global Scale
Josee Hansen, Senior Advisor, World Health Organization (WHO), Switzerland

SECURING THE SUPPLY CHAIN: HOW TO TACKLE THE CHALLENGES
Session Chair: Chair invited

This session will look into the status and next steps with regard to the implementation of the EU Falsified Medicines Directive with a focus on the new rules on safety features, which should be published in early 2016. Participants will also hear about the challenges the implementation poses to industry, and how they may be addressed. Work within the EU is complemented by projects and initiatives at the EDQM, with an aim to secure medicinal product quality and supply chains.

The Implementation of the Falsified Medicines Directive – What’s New?
Patrizia Tosetti, Policy Officer, DG Health and Consumers, European Commission, EU

Globalisation has changed and is still changing the way medicines are developed, approved and supplied to patients. How are the resulting challenges addressed and how can countries learn from each other?

Public health crises like the recent outbreak of Ebola in western Africa and the growing threat from SSFFC medical products show the weaknesses of the health systems. They pose the question of responsibility for players in the developed world to support the strengthening health systems. What is Europe’s contribution to these activities?
Stephan Rönninger, Director, External Affairs/International Quality, Amgen (Europe), Switzerland

The Holistic Strategy of the EDQM to Secure the Supply of Medicines to Patients
Susanne Keitel, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), EU

Session 1004 | Thursday 7 April, 16:00-17:30
JAPANESE REGULATORY SESSION: PMDA UPDATE
Session Chair:
Toshiyoshi Tominaga, Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PMDA has announced “PMDA International Strategic Plan 2015” which outlines the international activities that will be conducted in the period defined in the 3rd and 4th Mid-Term Plans. The progress of the plan will be presented with Q&A.

New Regulations in Japan and Future Direction of PMDA
Takao Yamori, Director of Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Science-Based Initiatives of PMDA
Kazuhiro Shigeto, Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

New Streams of Risk Management
Tomiko Tawaragi, Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 1005 | Friday 8 April, 09:00-10:30
IMPROVING GLOBAL HEALTH: HOW CAN REGULATORS HELP?
Session Chair:
Emer Cooke, Head of International Affairs, European Medicines Agency (EMA), EU

Regulators play an important role in the protection and promotion of public health. Regardless of where they are in the world, they face similar challenges, but not all are equipped or resourced to respond in the same way.

This session will explore various global and regional initiatives that aim to strengthen and build regulatory capabilities through benchmarking and establishing good regulatory practices: Using EMA Article 58 procedure not only to give scientific assessments but also as a tool for capacity building and training; and increasing harmonisation between regulators to increase collaboration and reliance.

Helping Regulators Help Patients
Lembit Rägo, Head, Regulation of Medicines and other Health Technologies, World Health Organization (WHO), Switzerland

Helping to Provide Scientific Assessment and Building Capacity outside the EU (Collaboration with WHO and EMA Article 58)
Emer Cooke, Head of International Affairs, European Medicines Agency (EMA), EU

Reinforcing Common Standards: International Harmonisation, Collaboration and Reliance Initiatives
Petra Dörr, Deputy Executive Director and Head of Communication and Networking, Swissmedic, Switzerland

Session 1006 | Friday 8 April, 11:00-12:30
NEW APPROACHES TO THE APPROVAL OF INNOVATIVE MEDICINES: DO THEY KEEP THEIR PROMISE?
Session Chair:
David Jefferys, Senior Vice President, Eisai Europe, UK

EMA, FDA and PMDA have introduced or are planning to introduce facilitated regulatory pathways aimed at encouraging the development and authorisation of innovative medicines. This session will provide information on these approaches, compare their characteristics and look into their benefits for patients and for industry.

New Approaches to the Approval of Innovative Medicines: The EMA Perspective
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden

PMDA’s Approaches to the Approval of Innovative Medicines: How Does Sakigake Work?
Toshiyoshi Tominaga, Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Comparing the Characteristics and Use of Facilitated Regulatory Pathways by ICH and Maturing Agencies
Lawrence Liberti, Director, Center for Innovation in Regulatory Science (CIRS), USA

Panel with Alastair Kent, Director, Genetic Alliance UK

Session 1007 | Friday 8 April, 14:00-15:30
INNOVATION IN THE DEVELOPMENT AND APPROVAL OF GENERIC MEDICINES
Session Chair:
Beata Stepniewska, Deputy Director, Head of Regulatory Affairs, European Generics Medicines Association (EGA), Belgium

As generic medicines companies are becoming more global and sophisticated in their R&D, they are seeking a more globally integrated approach to scientific and clinical data generation to avoid duplication. The objective of this session is to discuss the possibility of a single development programme to support the registration of a generic medicine in multiple world regions.

Does the Current Regulatory Framework Facilitate Global Access and International Regulatory Strategy for Generic Medicines?
Michael Banks, Senior Vice President, Regulatory Affairs, Research & Development, Teva Pharmaceuticals Europe, UK

International Generic Drug Regulators Programme (IGDRP): The Path towards Information and Work Sharing for Generic Medicines
Cordula Landgraf, Head of Networking, Swissmedic, Switzerland

Is the Single Development Programme for Generic Medicines a Dream or a Realistic Scenario?
Speaker invited
Paediatric medicinal product development has a number of challenges based on the specific, unchangeable aspect of the population. The focus of agencies and applicants should therefore be on the harmonisation of the requirements to achieve marketing authorisation in the respective regions and at the same time avoiding unnecessary trials across the regions and consequently reducing uncontrolled or off-label treatment of children.

**Vision 2020: Paediatric Development as Integral Part of New R&D Models**

**Angelika Joos**, Executive Director, Global Regulatory Policy, Merck Sharp & Dohme (Europe), Belgium

**PIP-Experienced CRO Perspective**

**Speaker invited**


**Marie Isabel Manley**, Partner, Head of the Regulatory Legal Group, Bristows LLP, UK

**Session 1102 | Thursday 7 April, 11:00-12:30**

**Symposium – Frailty as a Baseline Stratification Parameter and Potential Therapeutic Target**

**Session Chair:**

**Florian von Raison**, Senior Global Program Head, Novartis Pharma, Switzerland

Progress made in drug development for and with older People? This session will announce and discuss the brand new EMA geriatric working party frailty definition selected for study baseline characteristics for clinical studies and propose how this will change the research landscape in geriatric studies in Europe and beyond.

The EMA Geriatric Medicines Strategy, Good Pharmacovigilance Practice (GVP) and What Leads Us to Single out Frailty

**Susan Morgan**, Medical Assessor, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

**SPRINTT- IMI**

**Susanna Del Signore**, Director and Founder, Bluecompanion, UK

The Frailty Guideline under Consultation: What Does It Mean in Terms of CT Population and Registries?

**Antonio Cherubini**, Head of Geriatrics at IRCCS-INRCA, Ancona; Associate Professor of Gerontology and Geriatrics, University of Perugia, Italy

**Addressing Areas of Need / Insufficient Research**

**Cynthia Bens**, Vice President Public Policy, Alliance for Ageing Research, USA

Roundtable discussion with speakers and Francesca Cerreta, Senior Scientific Officer, European Medicines Agency (EMA), EU

**Session 1104 | Thursday 7 April, 16:00-17:30**

**Women’s Health and Drug Development**

**Session Chair:**

**Francesca Cerreta**, Senior Scientific Officer, European Medicines Agency (EMA), EU

Real-world population: Are women part of it? This session will explore what targeted efforts are needed to address improvement of data collection on women.

**FDA Snapshot Programme**

**Speaker invited**

Gender Initiative for EU Women’s Health

**Speaker invited**
Pregnancy – What Post-Approval Registry Can Do
Lode Dewulf, Vice President and Chief Patient Affairs Officer, UCB BioPharma, Belgium

Panel discussion with EMA representative

Session 1105 | Friday 8 April, 09:00-10:30
FORMULATIONS FOR BOTH ENDS OF LIFE
Session Chair:
Diana van Riet, Senior Assessor, Medicines Evaluation Board (MEB), Netherlands

The safe and effective use of medicines is based on the premise that the medicine is taken as intended. However, patients may have practical difficulties such as opening packaging or breaking tablets. As such problems are more likely in special patient populations, there is a need for guidance on the development of “senior-friendly” medicines.

Geriatric Formulations from a Patient Perspective
Mine Orlu Gul, Department of Pharmaceutics, UCL School of Pharmacy, UK

Formulations for Older People and Synergies with Paediatrics – Industry Perspective
Sven Stegemann, Director of Pharmaceutical Business Development, Capsugel, Professor for Patient-Centric Drug Development and Manufacturing, Graz University of Technology, Austria

New Regulatory Reflections on the Pharmaceutical Development of Medicines for Older People
Diana van Riet, Senior Assessor, Medicines Evaluation Board (MEB), Netherlands

Session 1106 | Friday 8 April, 11:00-12:30
EXTRAPOLATION
Session Chair:
Solange Rohou, Director, Global Regulatory Affairs, AstraZeneca R&D, France

Since 2012, when the EMA issued their concept paper on extrapolation of efficacy and safety in medicine development, the interest in the appropriate use of extrapolation in paediatrics has increased. Along with this shift, including the revision of the ICH E11 paediatric guideline, have emerged at the global level.

Prior knowledge and a systematic approach to extrapolation are key for any paediatric development strategy. How to conduct high quality and ethical research without subjecting children to unnecessary studies? How to appropriately develop a new medicine so that children in need can access it in a timely manner? Is it possible to successfully complete a global paediatric development plan? This session will address these questions through case examples

Session in development
Session 1201 | Thursday 7 April, 09:00-10:30  
NEW MEDICAL DEVICE REGULATIONS IN THE EU  
Session Chair: 
John Wilkinson, Director of Devices, Medicines & Healthcare Products Regulatory Agency (MHRA), UK  
This session will focus on the new EU Medical Device Regulation. Updates on legislative process, expectations and content and implementation of the upcoming changes will be extensively discussed. After this session, you will be up to date on the latest developments around this very important regulation and its implications across the medtech sector. The session will include an interactive panel, in which the panelist will share their insights on any questions you might have. 
Gert Bos, Executive Director and Partner, QServe, Netherlands  
Peter Schroer, Director QSRA, Johnson & Johnson, Germany  
Interactive panel discussion with all speakers and Reinhard Berger (AGES) chaired by Sabina Hoekstra-van den Bosch, Global Regulations and Standards, Philips Healthcare, Netherlands

Session 1202 | Thursday 7 April, 11:00-12:30  
PUBLIC EXPECTATION VS. REGULATORY COMPLEXITY: SCENARIOS FOR SAFE INNOVATION IN MEDICAL TECHNOLOGY  
Session Chair: 
Christopher Hodges, Professor, Head of the CMS Research Programme on Civil Justice Systems, Oxford University, UK  
Panellists: 
Gert Bos, Executive Director and Partner, QServe, Netherlands  
Robert Geertsma, Senior Scientist, National Institute for Public Health and the Environment (RIVM), Netherlands  
Erik Hansson, Deputy Head of Unit, Health Technology and Cosmetics, European Commission, EU

Session 1203 | Thursday 7 April, 14:00-15:30  
INNOVATIVE DEVELOPMENTS IN MEDICAL TECHNOLOGY  
Session Chair: 
Robert Geertsma, Senior Scientist, National Institute for Public Health and the Environment (RIVM), Netherlands  
This session is dedicated to new and emerging technologies in medical devices. Three of the most important innovative application fields will be examined for their specific features. You will learn about the application of nanotechnologies in medical devices, 3D printing techniques in healthcare and the booming field of M-health and medical apps.  
Nanotechnology  
Robert Geertsma, Senior Scientist, National Institute for Public Health and the Environment (RIVM), Netherlands  
3D Printing  
Roberto Liddi, Head of Corporate Quality and Regulatory, Healthcare Divisions, Renishaw Healthcare, UK  
M-Health Apps and Medical Apps  
Erik Vollebregt, Attorney, Axon Lawyers, Netherlands
**Session 1204 | Thursday 7 April, 16:00-17:30**

**COMBINATION PRODUCTS**

Session Chair:
Sabina Hoekstra-van den Bosch, Global Regulations and Standards, Philips Healthcare, Netherlands

Gert Bos, Head of Regulatory and Clinical Affairs, BSI, Netherlands

Session in development

**Session 0805/1205 | Friday 8 April, 09:00-10:30**

**POST-MARKETING SURVEILLANCE AND CE MARKETING**

Session Chair:
Reinhard Berger, Head of Department, Medical Device Market Surveillance, Agency for Health and Food Safety (AGES), Austria

This session will focus on vigilance and post-market surveillance in the medical device field. You will learn the principles and methods from various perspectives - manufacturer, user and authorities. Participants will also learn about the different new approach in the medical device arena compared to pharma.

**Post-Market Surveillance – A Legal Requirement for Patient Safety and Benefit**
Reinhard Berger, Head of Department, Medical Device Market Surveillance, Agency for Health and Food Safety (AGES), Austria

**Post Market Surveillance – Compliance, Burden and Benefit with the Legal Requirements from a Manufacturer’s Perspective**
Speaker invited

**Post Market Surveillance – Product Performance and Quality Aspects Including Reporting from a User’s Perspective**
Speaker invited

**Session 1206 | Friday 8 April, 11:00-12:30**

**SUBSTANCE-BASED MEDICAL DEVICES: SHIFT IN BORDERLINE BETWEEN DEVICES AND PHARMA?**

Session Chair:
Anja Wiersma, CEO and Senior Consultant, mi-CE Consultancy, Netherlands

Miranda Moussa, Manager Medical Devices, AESGP, Belgium

Judite Neves, Head of Health Products Directorate, Infarmed, Portugal

Vincent Bouwmeester, Senior Consultant Inspection Board for the Public Promotion of Medicines, Health Products and Medical Devices (KOAG/KAG), Netherlands

**Session 1207/1307 | Friday 8 April, 14:00-15:30**

**IVDS AND COMPANION DIAGNOSTICS**

Session Chair:
Chair invited

Session in development

**Session 1208 | Friday 8 April, 16:00-17:30**

**HTA FOR MEDICAL DEVICES**

Session Chair:
Petra Laestadius, Executive Vice President, Swedish Medtech, Sweden

This session will cover the special features of HTA for medical devices and what the pharmaceutical sector can learn from them. Issues like evidence hierarchies, possibilities to gather, assessing and appraising evidence as well as uncertainty will be discussed.

The focus will also be on how to make HTA-based decisions and recommendations for medical devices and how to draw a line between pharmaceuticals and medical devices in the future.

**The Swedish Joint Project on HTA for Medical Devices**
Malin Blixt, Head of Unit, Dental and Pharmaceutical Benefits Agency (TLV), Sweden

**The Industry Perspective on HTA for Medical Devices**
Speaker invited

**The Professional’s Perspective on Evidence and Uncertainty for Medical Devices versus Pharmaceuticals**
Speaker invited

**Answering a true need**

In 1964, a small group of visionary pharmaceutical research professionals founded the DIA as a neutral global membership association dedicated to increasing communication and collaboration in drug development. They recognized the need for the organization after multiple countries learned that a drug used to treat morning sickness, Thalidomide, caused birth defects, spawning sweeping federal regulations.

From these humble beginnings, DIA has grown into a global organization with members in more than 80 countries and regional offices covering the Americas, Europe, Asia, Middle East, and Africa. Our members represent every aspect of the discovery, development, regulation, and life cycle management of medical products.

**Take this journey with us**

Health care is evolving and transforming right before our eyes. There is no better time to join DIA—at the forefront of exciting breakthroughs in medicine and world health.

Join DIA by visiting DIAglobal.org/Membership
How Will Payers React to the Future of Drug Development?
Steffen Thirstrup, Medical Advisor, Regulatory Advisory Board, NDA Group, UK

How Can a Joint Regulatory-HTA Scientific Advice Process (Both Pre- and Post-Launch) Help Deliver the Right Evidence?
Speaker invited

Shall HTA Depend on Randomised Controlled Trials (RCT) or Real-World Data (RWD) or Both?
Session Chair:
Luca Pani, Director General, Italian Medicines Agency (AIFA), Italy

We see a world where more and more HTA and payer decisions depend on evidence generation. Can RWD be useful/acceptable to all? Can we find scientific ways to link evidence from RCT and RWD? Which are the main challenges to deliver the right evidence?

Understanding Methods and Timings for Developing a Robust, Comprehensive and Systematic Evidence Strategy Building on RCT and RWD that Can Meet the Needs of all Stakeholders in a Single Life Cycle Programme for a Medication
Chris Chinn, Head of Real World Investigations, Sanofi; GetReal, UK

Applying RCT Standards to RWD: Experiences with Post-Authorisation Efficacy Studies (PAES)
EMA representative invited

Conducting HTA Using RWD
François Meyer, Advisor to the President, HAS, France

Initiatives to Enhance the Development and Regulation of Medicines – Before and After Marketing Authorisation
Robert Hemmings, Statistics Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

How Can Real-World Data Support Decisions on Early Reimbursement of New Technologies?
Wim Goettsch, Project Leader EUnetHTA JA2 WP Rapid Assessments, Health Care Insurance Board (CVZ), Netherlands

The Age of Big Data and Better Analytics: How to Achieve Operational and Clinical Gains
Ricky Lakhani, Lead Product Manager, Medidata Solutions Worldwide, UK

The Needs of the Payers Shape the Evidence for Market Access
Session Chair:
Stanislav Primožič, Head, Sector for Pharmacoeconomics, Pharmacovigilance and HTA, Agency for Medicinal Products and Medical Devices, Republic of Slovenia

Edith Frénoy, Director Market Access/HTA, EFPIA, Belgium
Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits Agency (TLV), Sweden

Attendees will get an overview of the relevant topics at the crossroads of regulatory, traditional HTA and followed into the discussions with the payers; they will better understand why HTA is relevant across the life cycle of products, and why it should matter to regulatory experts within both authorities and companies. They will get an overview of the current policy discussions and will be able to contribute to future policy debates.
Session 1305 | Friday 8 April, 09:00-10:30

HOW CAN THREE PARTIES; PAYERS, INDUSTRY AND HTA, MAKE AGREEMENTS AND SHARE THE ECONOMIC RISK?

Session Chair:
Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits Agency (TLV), Sweden

This session will focus on how national integration between different parties can build a sustainable process to give true access to novel medicines based on the patients’ needs. In addition, the session will cover parts of the life cycle of a drug from registration, HTA, budgeting to implementation and actual access; it will also show what we can learn from some European examples like Sweden and the UK.

The Payer Perspective on Agreements, Shared Economic Risk, and Access
Magnus Thyberg, Head of Department, Stockholm County Council, Sweden

The Industry Perspective on Agreements, Shared Economic Risk and Access
Richard Torbett, Executive Director, Commercial, Association of the British Pharmaceutical Industry, UK

The HTA Perspective on Agreements, Shared Economic Risk and Access
Jo de Cock, RIZIV-INAMI (National Health Insurance Agency), Belgium

Session 1308 | Friday 8 April, 16:00-17:30

EUROPEAN RELATIVE EFFECTIVENESS ASSESSMENTS

Session Co-Chairs:
Wim Goettsch, Project Leader EUnetHTA JA2 WP Rapid Assessments, Health Care Insurance Board (CVZ), Netherlands
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden

How Can European Assessments Help National Evidence-Based Decision-Making Country with Established HTA Agency, Methods, Processes and Impact on Access
Anne D’Andon, HAS, France

Country with Developing HTA Methods
Tatyana Benicheva, Professor in Drug Regulatory Affairs, Bulgarian Association for Drug Information, Bulgaria

The Future of European Assessments
Speaker invited
CHALLENGES AND BEST PRACTICES FOR WRITING LAY SUMMARIES OF CLINICAL STUDY RESULTS

Session Chair: Thomas M. Schindler, Head Medical Writing Europe, Boehringer Ingelheim Pharma, Germany

The EU Regulation 536/2014 requires that sponsors provide summaries of study results that are understandable for lay people. While the regulation provides a framework in regard to the content, many questions remain. Which information is most important for lay readers? How much numerical information should be provided? This session will address the key challenges in the writing of lay summaries and will demonstrate potential solutions.

Returning Overall Trial Results in “Lay Language” – Successes and Challenges in Global Implementation
Zachary Hallinan, Director, Patient Communication and Engagement Programs, Center For Information and Study on Clinical Research Participation (CISCRP), USA

Feedback from Lay Summary Testing and General Principles in Writing Summaries for Lay Audiences
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

Lay Summaries of Trial Results – How to Provide Adequate Information
Gabriele Dreier, University Medical Center Freiburg, Germany

COMMUNICATING BENEFIT-RISK INFORMATION IN RISK MANAGEMENT PLANS TO MEDICAL PROFESSIONALS AND THE GENERAL PUBLIC

Session Chair: Tiziana von Bruchhausen, Senior Safety Writer, Boehringer Ingelheim, Germany

The new pharmacovigilance legislation has brought into focus benefit-risk management and communication in a medicine’s life cycle. The risk management plan (RMP) has become a complex living document that encompasses the pre- and post-authorisation phases and requires a multidisciplinary approach and alignment with other submission documents. In line with the new requirements on transparency, the RMP template mandates to provide a summary of safety and efficacy information for two antipodal audiences – medical professionals and the general public. This session will explore the challenges of communicating benefit-risk information and will discuss experiences of the industry and the EMA perspective.

Benefit-Risk Communication in the Life Cycle and How It Is Reflected in RMPs
Shelley Gandhi, Director Pharmacovigilance and Drug Safety, NDA Group, UK

The Role of a Medical Writer in Effective Benefit-Risk Communication
Budhesh Dhamija, Safety Medical Writer, Novo Nordisk, Denmark

Writing the Lay Summary (Section VI) of Risk Management Plans – Why and How?
Lisa Chamberlain, Senior Partner, Trilogy Writing & Consulting, UK

Thomas M. Schindler, Head Medical Writing Europe, Boehringer Ingelheim Pharma, Germany

These are exciting times in regulatory medical writing! The new requirements for transparency (EMA policies 43 and 70) and the new focus on lay audiences are reshaping and expanding the role of the profession. The new EMA policies mandate that all clinical documents contributing to a Marketing Authorisation Application need to be prepared for public sharing. This will involve redaction of information, that is, patient identifiers and commercially confidential details.

In the near future, all clinical study reports will have to be accompanied by summaries that can be understood by lay persons. As the guidance on the content of lay summaries is scant, many issues still need to be resolved. In regards to lay language summaries for risk management plans (EMA Section VI.2), medical writers are challenged with summarising safety information in a way that is useful both for medical professionals and for members of the public. As a separate aspect, one session will illustrate how new technologies can help streamline the creation of regulatory documents across a drug’s life cycle.
Session 1403 | Thursday 7 April, 14:00-15:30

PREPARING CLINICAL DOCUMENTS FOR PUBLIC RELEASE: THE ISSUES OF TRANSPARENCY AND REDACTION
Session Chair:
Kerstin Dahlström, Manager Publications and Clinical Trials Registry, H. Lundbeck, Denmark

EU Regulation No. 536/2014 (EMA policies 43+70) and EFPIA/PhRMA’s ‘Principles for Responsible Clinical Trial Data Sharing’ are both initiatives to increase transparency of information on medical products and data on which regulatory decisions are based. The overall ambition is to support patients and society. However, we also have to protect patients’ privacy and safeguard personal data before sharing any information. This session will elaborate on this challenge but also give guidance on potential solutions and future ways of working.

De-Identification of Patient Data in Rare Disease Clinical Studies – Special Considerations
Adel Salem, Senior Programmer, Novo Nordisk, Denmark

The Impact of Clinical Trial Data Disclosure on Trial-Related Documents: Redaction Requirements and Future Document Structure
Tracy Farrow, Senior Director Medical Writing, PPDI, UK

How We Deliver It All Together – Reflections on Medical Writers’ Collaboration with Other Skill Groups
Kerstin Dahlström, Manager Publications and Clinical Trials Registry, H. Lundbeck, Denmark

Session 1404 | Thursday 7 April, 16:00-17:30

USING COMPUTER-ASSISTED WRITING TO INCREASE THE EFFICIENCY OF CREATING REGULATORY DOCUMENTS
Session Chair:
Ambrish Mathur, Life Sciences Business Technology Consultant, USA

Authoring of reports for regulatory submission is an expensive resource-intensive activity. This session looks at tools and technologies that can bring efficiencies to this important medical writing function.

An Overview of a CRO’s Experience with Content Management Software
Kassel Fotinos Hoyer, Medical Writer II, PAREXEL Informatics, Germany

Algorithmic Narratives: The Role of Natural Language Generation in the Composition of Periodic Safety Update Reports
Ambrish Mathur, Life Sciences Business Technology Consultant, USA

The Making of Lay Texts: Computerised Analysis and Optimisation
Gunnar Box, Expert Readability-User-Testing, Communication Lab, Germany
HOT TOPIC/STAND ALONE SESSIONS

Session 1506 | Friday 8 April, 11:00-12:30
FROM TRADITION TO REGULATION – GLOBALISATION OF HERBAL MEDICINES
Session Chair:
Werner Knöss, Head of Division, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Interest in global usage of traditional medicines is continuously increasing. This session will explore the divergence of the existing regulatory framework for traditional medicines and options to strive for convergence of adequate requirements.

Herbal and Traditional Medicines in the World – Regulatory Diversity
Werner Knöss, Head of Division, Federal Institute for Drugs and Medical Devices (BfArM), Germany

The EU System for Traditional Herbal Medicines Meets Non-Western Medicine: A Live Experiment
Emiel van Galen, Head of Botanicals and Novel Foods, Medicines Evaluation Board (MEB), Netherlands

Globalisation of Herbal Medicines – Industry Experience
Bernd Roether, Head of Drug Regulatory Affairs, Bionorica, Germany

Session 1604 | Thursday 7 April, 16:00-17:30
IMPORT TESTING: CURRENT REQUIREMENTS AND OPPORTUNITIES TO SIMPLIFY ACCESS OF MEDICINES FOR PATIENTS
Session Chair:
Joerg Garbe, Global Quality Manager In-Country Testing, F. Hoffmann-La Roche, Switzerland

This session will demonstrate the legal requirements and clarify misconceptions on import testing. Product knowledge as well as good manufacturing and distribution practices provides assurance of safe and effective medicines delivered to patients. Delays and impact to supplies of medicines to patients due to duplicate/redundant testing will be highlighted.

Regulatory Framework on Import Testing
Speaker invited

Opportunities for Improved Access to Safe and Efficient Medicines
Stephan Rönninger, Director, External Affairs/International Quality, Amgen (Europe), Switzerland

Market Surveillance Testing of Medicinal Products by the European OMCL Network
Michael Wierer, Head of Division, Biological Standardisation, OMCL Network, Blood Transfusion and Transplantation, European Directorate of Quality of Medicines (EDQM), EU

Panel discussion

Session 1607 | Friday 08 April, 14:00-15:30
MAPPS: THE IMI ADAPT SMART PROJECT
Session Co-Chairs:
Luk Maes, Executive Director Scientific Policies Europe, BMS, Belgium
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA), EU

The opportunities, challenges and impact of MAPPs (Medicines Adaptive Pathways to Patients) are debated by multiple stakeholders in an IMI2 public-private consortium “ADAPT SMART”. This session will give an overview of the diversity of stakeholder positions.

Payer’s Perspective
Ad Schuurman, Head of Business Contact Center & International Affairs, National Health Care Institute, Netherlands

Consumer’s Perspective
Ilaria Passarani, Head of the Food and Health Department, BEUC - The European Consumer Organisation, Belgium

HTA Perspective
Sarah Garner, Associate Director - Research & Development, National Institute for Health and Care Excellence (NICE), UK

30-minute panel discussion with speakers and co-chairs
Improving health care through global collaboration, communication, and education

Health issues know no borders. Fortunately, neither do innovative ideas, novel treatments, and effective drug development designed to meet those issues head on.

DIA is the only organization that enables everyone in health product development and life cycle management to share information on a global scale. Our goal is simple: to improve health and wellbeing by transferring knowledge from those who have it to those who need it.
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.

“Welcome to Hamburg” Opening Reception  
Wednesday, 6 April 2016 | 18:00 – 20:00

Network with 2,500+ attendees and 160 + Exhibiting Companies at the “Welcome to Hamburg” Opening Reception taking place in Hall 3. Stay tuned for more information on this special evening.

Thursday Networking Reception in the Exhibit Hall  
Thursday, 7 April, 2016 | 17:30 – 18:30

Network with 2,500+ attendees at the Thursday Networking Reception held in the Exhibit Hall.

Refreshment and Lunch Breaks
Meet with your colleagues to plan your day, and discuss what you learned the day before, all while networking with other attendees and take advantage of extended breaks to visit more than 160 exhibiting companies. All refreshment breaks and lunches will be held in designated areas of the Exhibit Hall.

Lunch Breaks  
Wednesday, 6 April 2016 | 12:30 – 14:30  
Thursday, 7 April 2016 | 12:30 - 14:30  
Friday, 8 April 2016 | 12:30 - 14:30

Refreashment Breaks  
Wednesday, 6 April 2016 | 15:00 – 16:00  
Thursday, 7 April 2016 | 10:15 – 11:00 and 15:15 – 16:00  
Friday, 8 April 2016 | 10:15 – 11:00 and 15:15 – 16:00

We invite you to also take advantage of the additional features of the Exhibit Hall.

Other networking events such as student poster award ceremony, speed networking sessions, communities’ activities and much more are in preparation. Detailed information will be available soon, stay tuned.
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Designed just for you, this year’s all new programme showcases A-list marketing opportunities within the Exhibit Hall and beyond with in-house networking venues and a 21st-century mobile application.

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Surround yourself with a built-in network of the industry’s most successful leaders, allowing you to identify potential new customers to build long-lasting partnerships.

GROW YOUR NETWORK
Our integrated international platform invites you to meet new clients, reunite with existing customers and create multiple opportunities for meaningful face-to-face meetings.

SHOWCASE YOUR SERVICES
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Don’t miss the chance to exhibit at the 28th Annual EuroMeeting and apply now to secure your best space! Space is limited and will be sold on a first come, first served basis.

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Prepare to be overwhelmed and excited about the abundance of information available in the Exhibit Hall. This is an essential part of your conference experience.

Every aisle is filled with displays of the latest product innovations and tools to help make your job easier and more rewarding. The EuroMeeting is where talent and experience meet.

We urge you to schedule several visits to the Exhibit Hall at any time it is open to examine the wide variety of new materials available and to speak with representatives of the exhibiting companies.

Guests of conference attendees may purchase Exhibit Show passes at the Registration Desk.

**EXHIBITION HALLS OPENING HOURS**

- **Wednesday, 6 April 2016:** 12:00 - 18:00
- **Thursday, 7 April 2016:** 09:00 - 18:30
- **Friday, 8 April 2016:** 09:00 - 16:00

**BREAKS AND RECEPTION**

All refreshment and lunch breaks are taking place in the Exhibition Hall as well as the Thursday Networking Reception.

All offer an excellent opportunity to visit exhibitors in a casual, yet professional setting, and at your own pace. At the same time, you can network with friends and colleagues.
**EXHIBITING COMPANIES AS OF 8 FEBRUARY 2016**

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Contact details can be found on www.staralliance.com/conventionsplus/delegates/ under “Conventions Plus Booking Contacts”, please quote the event code LH06S16 for ticket reservation.

HOTEL INFORMATION

SPECIAL HOTEL RATES FOR
YOUR EUROMEETING 2016
ACCOMMODATION IN HAMBURG

DIA Europe, Middle East & Africa has negotiated special conference hotel rates with K.I.T. Group GmbH, for the EuroMeeting 2016.

Please be advised that DIA has only contracted K.I.T. Group GmbH as exclusive hotel agent for the EuroMeeting 2016.

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

To book your room, visit www.DIAglobal.org/EM2016, scroll the menu and click on Hotel/Travel Information.
### Wednesday, 6 April 2016

**09:00-12:30** Pre-conference Tutorials

**11:00-12:30** German Satellite Session | 13:30-15:00 Regulatory Town Hall Meeting | 15:00-16:00 Coffee Break | 16:00-17:45 Plenary Session

**18:00-20:00** EuroMeeting Welcome to Hamburg Opening Reception in Hall 3

<table>
<thead>
<tr>
<th>Theme 1</th>
<th>Theme 2</th>
<th>Theme 3</th>
<th>Theme 4</th>
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</thead>
<tbody>
<tr>
<td>Innovation</td>
<td>Clinical Research</td>
<td>Clinical Trials</td>
<td>Regulatory Science</td>
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</table>

### Thursday, 7 April 2016

<table>
<thead>
<tr>
<th>Session 1</th>
<th>Session 0101/0701/0901/1301 Benefit-Risk Management Planning through the Life Cycle of a Product</th>
<th>Session 0201 Translation of Cell and Gene Therapies</th>
<th>Session 0301 New European Clinical Trial Regulation</th>
<th>Session 0401 Regulatory Science Hand in Hand with Health Technology Assessment for Better Outcomes</th>
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<tbody>
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<td>09:00-10:30</td>
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**Coffee Break**

<table>
<thead>
<tr>
<th>Session 2</th>
<th>Session 0102 Gene Therapy – A New Treatment Modality</th>
<th>Session 0202 Real-World Evidence in Drug Development</th>
<th>Session 0302 ICH E6- GCP Addendum: Risk Proportionate Approaches to Trial Design and Conduct</th>
<th>Session 0402/0702 Fast Forward to the Future – How Big Data and Artificial Intelligence Will Change Our Regulatory Environment</th>
</tr>
</thead>
<tbody>
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<td>11:00-12:30</td>
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</table>

**Extended Lunch**

<table>
<thead>
<tr>
<th>Session 3</th>
<th>Session 0103 The Voice of the Patient – Innovative Ways of Patient Engagement in R&amp;D</th>
<th>Session 0303 Clinical Trial Disclosure</th>
<th>Session 0403 The Future of Regulatory Affairs is Digital</th>
<th>Session 0404 Adaptive Pathways and Conditional Approval- Panel Discussion</th>
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<tbody>
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<td>14:00-15:30</td>
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</table>

**Extended Coffee Break**

| Session 4 | Session 0104 Start-Ups Meet Regulatory and Industry | | | |
|-----------|-------------------------------------------------| | | |
| 16:00-17:30 | | | | |

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

### Friday, 8 April 2016

<table>
<thead>
<tr>
<th>Session 5</th>
<th>Session 0205 Improving Productivity in R&amp;D</th>
<th>Session 0305 Enhancing Clinical Trials Efficacy</th>
<th>Session 0405 Innovation of Mature Products – New Uses for Old Products</th>
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<tr>
<th>Session 6</th>
<th>Session 0106 Cutting Blockbuster Indications into Orphan-Sized Bites</th>
<th>Session 0206/0306 Oxford Debate: ‘This House Believes that Over-Engineered Clinical Development Has Inhibited Innovation’</th>
<th>Session 0206/0306 Oxford Debate: ‘This House Believes that Over-Engineered Clinical Development Has Inhibited Innovation’</th>
<th>Session 0406 Evolving Areas of Regulatory Science</th>
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**Extended Lunch**

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<tr>
<th>Session 7</th>
<th>Session 0107 Shaking the Toolbox: Evolutions in Approaches in Trial Design</th>
<th>Session 0207 Development of New Medicines: Engaging with Stakeholders</th>
<th>Session 0407 It’s Never Too Soon - Early Access and Early Dialogue in Drug Development</th>
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**Extended Coffee Break**

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<tr>
<th>Session 8</th>
<th>Session 0108 Bringing NGS into Drug Development: The Impact of Sequencing on the Future of Clinical Trials and Drug Registration</th>
<th>Session 0208 Challenges &amp; Opportunities in the Clinical Development of Biopharmaceuticals</th>
<th>Session 0308 Challenges for Academic Clinical Trials</th>
<th>Session 0408 Where is the Orphan Drug Journey Going?</th>
</tr>
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<tbody>
<tr>
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**End of Conference**
### Wednesday, 6 April 2016

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</table>

**Session Themes**

- **Theme 5**: Medical Affairs
- **Theme 7**: eHealth/Big Data
- **Theme 8**: Pharmacovigilance
- **Theme 9**: Life Cycle Benefit-Risk Management
- **Theme 10**: Globalisation

### Thursday, 7 April 2016

**Session Themes**

- **Session 0501**: Patient-Focused Medicine – To Understand Patients, You Must Engage Them
- **Session 0101/0701/0901/1301**: Benefit-Risk Management Planning through the Life Cycle of a Product
- **Session 0801**: Innovation for Patient Reporting
- **Session 0101/0701/0901/1301**: Benefit-Risk Management Planning through the Life Cycle of a Product
- **Session 1001**: What Happens in and Around Europe – Beyond the European Union?

**Coffee Break**

**Extended Lunch**

**Extended Coffee Break**

**Friday, 8 April 2016**

**Session Themes**

- **Theme 6**: Availability of Medicinal Products
- **Theme 7**: eHealth/Big Data
- **Theme 8**: Pharmacovigilance
- **Theme 9**: Life Cycle Benefit-Risk Management
- **Theme 10**: Globalisation

**Extended Coffee Break**

**Extended Lunch**

**Extended Coffee Break**

**End of Conference**
### Wednesday, 6 April 2016

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<td>16:00-17:45</td>
<td>Plenary Session</td>
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**Themes:**
- Theme 11: Special Populations
- Theme 12: Medical Devices
- Theme 13: HTA
- Theme 14: Medical Writing

### Thursday, 7 April 2016

<table>
<thead>
<tr>
<th>Session 1101</th>
<th>Conduct and Completion of Paediatric Development Plans, As Agreed in PIPs or PSPs</th>
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</thead>
<tbody>
<tr>
<td>Session 1201</td>
<td>New Medical Device Regulations in the EU</td>
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<tr>
<td>Session 0901/0901/1301</td>
<td>Benefit-Risk Management Planning through the Life Cycle of a Product</td>
</tr>
<tr>
<td>Session 1401</td>
<td>Challenges and Best Practices for Writing Lay Summaries of Clinical Study Results</td>
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**Themes:**
- Theme 11: Special Populations
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- Theme 14: Medical Writing

### Friday, 8 April 2016

<table>
<thead>
<tr>
<th>Session 1105</th>
<th>Formulations for Both Ends of Life</th>
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<tr>
<td>Session 1205</td>
<td>Post-Marketing Surveillance and CE Marketing</td>
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<tr>
<td>Session 1305</td>
<td>How Can Three Parties: Payers, Industry and HTA, Make Agreements and Share the Economic Risk?</td>
</tr>
<tr>
<td>Session 1506</td>
<td>From Tradition to Regulation-Globalisation of Herbal Medicines</td>
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**Themes:**
- Theme 11: Special Populations
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- Theme 13: HTA
- Theme 14: Medical Writing

### Events
- 18:00-20:00 EuroMeeting Welcome to Hamburg Opening Reception in Hall 3
- 17:30-18:30 Networking Reception in the Exhibition Hall
- 16:00-17:45 Plenary Session

**Extended Coffee Breaks:***
- Extended Lunch

**Extended Coffee Breaks:***
- Extended Coffee Break
Early-bird discount: Register by 24 February 2016 and Save!

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.

<table>
<thead>
<tr>
<th>CATEGORY (after 24 February 2016)</th>
<th>Member*</th>
<th>Non-Member*</th>
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<tr>
<td>Early-Bird Industry</td>
<td>€ 1'860.00</td>
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<tr>
<td>Industry</td>
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<tr>
<td>Government/Charitable/Non-profit/Academia (Full-Time)</td>
<td>€ 1'860.00</td>
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</tr>
<tr>
<td>Optional Pre-Conference Tutorials on Wednesday, 6 April</td>
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<tr>
<td>See page 8-12 for Tutorial description</td>
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<tr>
<td>Optional ICH Info Day on Wednesday, 6 April</td>
<td>€ 450.00</td>
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<td>See page 12 for description</td>
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</tbody>
</table>

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

- I do not want complimentary membership

TERMS AND CONDITIONS

Registration Fee

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to availability. Exhibition hall only passes available. Please contact DIA EMEA for more information. Registration fee includes: refreshments, lunches, receptions and meeting materials.

Cancellations

All cancellations must be in writing and received at the DIA EMEA office by 17:00 CET on 4 March 2016 and will be subject to an administrative fee (Member/Non-member):

- Full Meeting Cancellation: Industry = € 200.00
- Academic/Charitable/Government/Non-profit = € 100.00
- Tutorial cancellation: € 50.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

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

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

Email EMEA@DIAglobal.org

Tel. +41 61 225 51 51 | Fax +41 61 225 51 52 | Web www.DIAglobal.org

Mail DIA EMEA, Kuechengasse 16, 4051 Basel, Switzerland © DIA 2015

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- Please charge my
  - Card N° [ ]
  - VISA [ ]
  - MC [ ]
  - AMEX [ ]

- Exp. Date [ ]/ [ ]

- Cardholder’s Name

Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to “Account Holder: DIA.” Please include your name, company, Course ID#16101 as well as the invoice number to ensure correct allocation of your payment.

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

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

Date

Signature