DIA 28th Annual EuroMeeting

INnovation • Do You Win by Being IN?

6-8 April 2016 | CCH | Hamburg, Germany

Final Programme

DIA DEVELOP INNOVATE ADVANCE

Message from DIA Global Chief Executive and EMEA Senior VP & Managing Director

Dear Colleagues,

It is our great pleasure to welcome you to the DIA 28th Annual EuroMeeting in Hamburg. Our theme this year, ***Do You Win By Being INnovative***?, will stimulate knowledge exchange and expansion of our thinking as we share the perspectives of thought leaders from our multistakeholder community. We hope your experience at the EuroMeeting is unforgettable!

We would like to thank our chairs, the programme committee, the theme leaders, our volunteers, members, and all staff, without whose incredible effort and dedication to DIA's mission, this meeting would not be possible.

We are confident that we are bringing an exciting programme to you that incorporates both the breadth and depth that you can expect from DIA. We encourage you to actively engage in the presentations and take advantage of the various opportunities to network, and also make new connections in order to exchange knowledge and to build ideas. Your voice and contributions are critical to the DIA mission to develop, innovate, and advance science in health care.

This year we are launching a novel exhibition experience to deliver on the overarching event theme of Innovation. We are pleased to offer you a diverse group of solution providers and see this as an optimal opportunity to tap into inspirational learnings and ways to bring enhancements back to your own organisation.

This 28th Annual DIA EuroMeeting is also an excellent opportunity for one of us (Holger Adelmann) to get fully on board with the DIA community. Holger started with DIA in February as the new Managing Director for Europe, Middle East, and Africa, and he looks forward to reconnecting with many of you who are known to him from his long-standing professional history in health care. We are, of course, also excited to make many new connections and learn more through stimulating conversations with you.

We both wish you a great meeting in Hamburg and hope you remember it as an event that made a difference to you!

All the best,

Barbara Lopez Kunz
DIA Global Chief Executive

Holger G Adelmann
DIA EMEA Senior VP & Managing Director

DIA 28th Annual **EuroMeeting**

INnovation • Do You Win by Being IN?

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.

Message from the Programme Co-Chairs

Dear Colleagues,

The DIA 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 honoured to serve as Program Co-Chairs of this important meeting.

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 28th Annual EuroMeeting will give us the chance to discuss many of the major trends occurring in health care.

This robust programme covering pharmaceuticals, biotechnology and medical products is an excellent 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.

Together with our DIA colleagues, we welcome you to Hamburg.

Karl Broich

President
BfArM, Germany

Kemal Malik

Member of the Board
of Management
Bayer, Germany

EuroMeeting 2016 Programme

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SCHEDULE AT-A-GLANCE

Tuesday, 5 April 2016

Registration Hours:

15:00-20:00	Exhibitor Registration and Set-up
15:00-18:00	Attendee and Speaker Registration*

* 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:

08:00-12:30	ICH Info Day*
09:00-12:30	Pre-Conference Tutorials*
10:30-11:00	Pre-Conference Tutorials & ICH Info Day Coffee Break
11:00-12:30	German Satellite Session
12:00-18:00	Conference and Exhibition Open
12:30-14:30	Lunch & Oral Poster Presentations in the Exhibition Hall
13:30-15:00	Regulatory Town Hall Meeting
15:00-16:00	Extended Refreshment Break & Oral Poster Presentations 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:

08:00-18:00	Attendee, Speaker and Exhibitor Registration

Schedule:

08:00-09:00	Welcome Coffee
09:00-18:30	Exhibition Hall Open
09:00-10:30	Parallel Scientific Sessions - Session 1 Choose from Parallel Sessions
10:15-11:00	Coffee Break & Innovation Theatre Presentation in the Exhibition Hall
11:00-12:30	Parallel Scientific Sessions - Session 2 Choose from Parallel Sessions
12:30-14:30	Lunch & Oral Poster Presentations in the Exhibition Hall
12:45-13:15	Speed Networking in the Attendee Oasis
13:00-14:00	DIA Communities - Meet and Eat in Foyer A-C, Level 1
14:00-15:30	Parallel Scientific Sessions - Session 3 Choose from Parallel Sessions
14:00-15:30	Exhibition Guest Passes
15:15-16:00	Coffee Break & Oral Poster Presentations in the Exhibition Hall
16:00-17:30	Parallel Scientific Sessions - Session 4 Choose from Parallel Sessions
17:30-18:30	"Oktoberfest" Reception in the Exhibition Hall
17:45-18:15	Student Poster Award Ceremony at the DIA Island

Friday, 8 April 2016

Registration Hours:

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

Schedule:

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

DIA DEVELOP INNOVATE ADVANCE

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 Hoekstra-van den Bosch
Global Regulations and Standards, Lead for European Regulation, Philips Healthcare, 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
Head Regulatory Affairs Europe Middle East Africa, 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, Merck Sharp & Dohme Ltd, 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**

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

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

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 Lönngren
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

Stay Connected

Navigate DIA Meetings from Your Smart Device with DIA's App

The DIA Global App is designed to enhance your meeting experience and provide valuable information in one place.

With the mobile app you have the conference at your fingertips:

- Create and manage your personal agenda
- Search for speakers, attendees and exhibitors to connect and network
- Interactive floor plans
- Share your EuroMeeting experiences through photos, posts, and more
- Activity stream provides real-time updates
- Interaction with your social media channels

To download, search for "DIA Global" in your app store

Access the EuroMeeting 2016:

- Sign in with the Email Address You Registered for the EuroMeeting 2016
- Password: ***global***
- Click on the Events Icon
- Select 28th Annual DIA EuroMeeting 2016
- Need assistance? See us at the DIA Island in the Exhibition Hall for support

Available on the App Store

ANDROID APP ON Google play

Get Social!

Stay connected with your colleagues around the world and all of the innovation happening in Hamburg by following #DIAeuro with social media.

- Upload pictures to Instagram
- Tweet updates
- Connect with colleagues on LinkedIn
- Share the excitement with colleagues on Facebook.

Search @**DrugInfoAssn** to follow DIA.

#DIAeuro

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GENERAL INFORMATION A-Z

App
The DIA Global App is designed to enhance participants' meeting experience and provide valuable information in one place. Create your session agenda, network with attendees and Exhibitionors, and connect to DIA resources, social media channels, member communities, and more.

Accessing the EuroMeeting 2016:

- Sign in with the email address used to register for the conference.
- Password: ***global***
- Click on the events icon
- Select 28th Annual EuroMeeting 2016

Only registered attendees have access to the mobile app. You can find assistance at the DIA Island in the Exhibition Hall.

ATM
There are several ATMs located in the Dammtor railway station next to the CCH.

Business Center
There is no business centre at the CCH. Participants needing to print something should use their hotel's business center.

Certificate of Attendance
This year, certificates of attendance will be emailed to participants who have picked up their badge after the conference. Certificates will not be printed onsite.

Cloakroom/Baggage
The cloakroom is located on Level 1 of the CCH. There is a charge of € 2 per coat/jacket or luggage item.

The cloakroom is open as follows:
Wednesday 08:00 – 20:30 | Thursday 08:00 - 19:00 | Friday 08:00 - 18:00

Conference Bags
All attendees with a full meeting registration can collect a conference bag from the Conference Bag Distribution Point in the entrance hall. Participants must bring their bag voucher received when collecting their badge (Booth personnel do not receive a bag).

Continuing Education Credits
DIA meetings are accredited by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine).

The 28th Annual EuroMeeting is expected to be awarded up to 14 CPD credits from the Faculty of Pharmaceutical Medicine (FPM) of the Royal College of Physicians (RCP) of the UK. Medical practitioners who are eligible for credits can click on http://www.fpm.org.uk/cpd/registration for more information. If you are already a CPD member, please go directly to http://cpd.fpm.org.uk to claim your credits.

DIA Island
Find out more about all DIA can offer you, how membership can advance your career, how to join a DIA Community, submit an article for publication and lots more. Stop by at the DIA Island in the Exhibition Hall. See "Exhibition" for opening hours.

DIA Patient Booth
DIA actively promotes the involvement of patient representatives in the EuroMeeting. Since 2006, more than 200 patient representatives have been involved as participants, speakers, session chairs, and also in the Programme Committee. The Patient Fellowship Booth D2 is located in the Exhibition Hall and acts as a focal point for patient fellows and other stakeholders to meet and network.

Exhibition
Visit the EuroMeeting Exhibition, with 140+ companies and service providers in a single venue. With many new companies exhibiting this year, the exhibition offers more opportunities than ever to connect with participants.

Wednesday	12:00 - 18:00
Thursday	09:00 - 18:30 | Exhibit Guest Passes 14:00 - 15:30
Friday	09:00 - 16:00

Please see the exhibition floor plan and list of exhibiting companies in the Exhibition Guide at the end of this programme, or use the interactive floor plan in the "DIA Global" mobile app.

Exhibitor Services
The Exhibitor Services Desks (stand building, onsite services and shipping) are located near the press room in the Exhibition Hall.

First Aid
A medical professional will be on duty during conference hours. Contact the DIA Onsite Registration Information Desk in the entrance hall for assistance. Alternatively, any staff member or DIA host/hostess will be more than happy to be of assistance.

Help Desk
If you have any questions about the EuroMeeting, from finding session rooms to networking activities, stop by the DIA Help Desk located at the entrance of the Exhibition Hall. Alternatively, any staff member or DIA host/hostess will be more than happy to be of assistance.

Wednesday	12:00 - 18:00
Thursday	09:00 - 18:30
Friday	09:00 - 16:00

Should you have general questions about the venue or Hamburg, the CCH general information desk located in the entrance hall will be open during conference times.

Hotel Accommodations Desk
KIT Group GmbH is the official hotel agent for the 28th Annual EuroMeeting in Hamburg. If you have any queries about hotel accommodation, please visit the Hotel Information counter at the DIA Registration Desk located in the entrance hall.

GENERAL INFORMATION A-Z

Internet Access / Wi-Fi
We provide free basic wireless internet access in all area spaces of the venue. To utilise this service, simply connect to complimentary WiFi.

Lost and Found
All items will be stored at the DIA Registration Desk in the entrance hall until the end of the conference.

Messaging Services
Download the "DIA Global" mobile app and use the messaging function to set appointments or send messages to other attendees.

Name Badge
Name badges must be worn at all times in the Conference Center. Participants will incur a € 25 fee for badge reprints. If you have misplaced your badge, you will be required to have a badge reprinted. Please visit Attendee Onsite Registration located in the Entrance Hall. Identification will be required.

Please note, allowing exhibitors to scan the barcode on the front of your badge will provide them with your contact information. No children under the age of 18 years will be allowed in the Exhibition Hall due to liability issues.

Posters
Student posters will be displayed in the Attendee Aosis on the ground level and professional posters will be displayed in the exhibition hall. Come and talk to our student poster presenters during breaks. A selected group of professional poster presenters will share their research results on various topics. Oral presentations where authors can provide a 5 minute overview of their work will be delivered in the Innovation Theatre located in the exhibition hall.

Join us at the DIA Island in the Exhibition Hall l 3 for the
Student Poster Award Ceremony on Thursday, 7 April 2016 at 17:45

Presentations
Presentations will be available to full conference attendees on the DIA web site from 4 April until 15 October 2016. Presentations are made available to full conference attendees only.
To access presentations, visit www.DIAglobal.org and log into your account, then and follow the links for the EuroMeeting presentations.

Press Room
The Press Room is located in in the Exhibition Hall and is open during Exhibition Hall hours.

DIA welcomes qualified representatives of news organisations for the purpose of reporting and publishing and broadcasting articles and stories. All media must present a copy of their press credentials upon arrival at the DIA Registration Desk.

Rechargin Station
A recharging station lounge is available in the Attendee Oasis outside the Exhibition Hall on the ground level.

Refreshments/Lunches
Refreshments and Lunches will be served each day in the Exhibition Hall. Enjoy extended refreshment and lunch hours to visit more than 140 exhibiting companies.

Wednesday

12:30 - 14:30	Lunch
15:00 - 16:00	Afternoon tea/coffee with snack

Thursday

10:15 - 11:00	Morning tea/coffee with snack
12:30 - 14:30	Lunch
15:15 - 16:00	Afternoon tea/coffee with snack

Friday

10:15 - 11:00	Morning tea/coffee with snack
12:30 - 14:00	Lunch
15:15 - 16:00	Afternoon tea/coffee with snack

Registration
The self scanning kiosks and registration desks are located in in the Entrance Hall of the CCH and will be open on the following days and times:

Tuesday	15:00 – 18:00
Wednesday	08:00 – 18:00
Thursday	08:00 – 18:30
Friday	08:00 – 16:00

Security
We take the safety of our participants very seriously. Please help us by cooperating fully with the security personnel on duty and wear your badge at all times. Only participants with a valid conference badge will be allowed into the conference center.

Services for the Disabled
All the rooms at the congress centre are fully accessible to participants with disabilities.

Speaker Resource Center
All speakers are required to visit the Speaker Resource Center located in the Foyer of Hall 4 on the Ground Level and re-check their slides at least 2 hours before the start of their session(s).

Tuesday	15:00 - 18:00
Wednesday	08:00 - 18:00
Thursday	08:00 - 18:00
Friday	08:00 - 16:00

Twitter
Tweet about the EuroMeeting using #Euro and @DIA_Europe

DIA Award Winners

Excellence in Service Award

Awarded to the "member of the year" who has consistently provided outstanding service as a DIA volunteer in the EMEA region, and who has contributed to the advancement of DIA's mission.

Margaret Walters

Deputy QPPV, Merck Sharp & Dohme Ltd., UK

Margaret Walters joined Merck Sharp & Dohme Ltd. in 1987 and is currently the Deputy EU Qualified Person for Pharmacovigilance (QPPV). Prior to this Margaret spent ten years in basic research with the Wellcome Foundation. A long-term member of the EFPIA PV EWG, Margaret has participated in the ICH process, co-chaired the EU PhRMA PV team, was part of the pre-ICH MedDRA team at the MHRA, co-chaired the EMA Joint Task Force on Electronic Submissions and now represents EFPIA to the EudraVigilance Steering Committee and Expert Working Group. Margaret has also authored papers on parasitology and drug safety and has acted a guest lecturer to two Postgraduate Pharmacovigilance programs in the UK.

Margaret has chaired four QPPV Forums (out of ten) successfully and been a key element in maintaining a good connection between the regulators and the industry. She is also regularly contributing to EMA Information Day programmes and is active within the other pharmacovigilance activities within DIA, such as the Pharmacovigilance Conference. As a part of her volunteer career, she has spoken in 29 DIA events and is a Theme Leader in the Euromeeting 2016.

Outstanding Contribution to Health Award

Awarded to an individual, group or organisation in the region who has made significant and innovative contributions to advancing global health

Tomas Salmonson

Senior Scientific Advisor, Medicines Product Agency, Sweden; Chair of Committee for Medicinal Products for Human Use at the European Medicines Agency

Tomas Salmonson, M.Sc., PhD, brings outstanding experience and expertise from a long career in the regulation of medicines both on a national and European level to his new role. A pharmacist by training, he is currently senior scientific advisor at the Swedish Medical Products Agency (MPA) in Uppsala, Sweden. He has been a member of the Committee for Medicinal Products for Human Use (CHMP) for more than 12 years. In 2012, Dr Salmonson was elected chair of the CHMP; he was Vice chair of the CHMP from 2007 till 2012.

Committee for Human Medicinal Products has a key role in medicines authorization in Europe. All medicines that apply for marketing authorization through the central route is examined carefully by the CHMP, followed by a Scientific Opinion whether to authorize the medicine or not. This work is of utmost importance in Europe in order to allow access to medicines and ensuring rigorous standards for authorization. The Chair leads the work of the Committee and has particular duties in ensuring the scientific grounds in the Committee's opinions. Additionally, CHMP has many other projects which the Chair oversees and participates in. For 2015, Tomas participated in projects, such as patient involvement in evaluation of medicines and documentation of the evaluation process, modeling and simulation, extrapolation, adaptive licensing initiative and EMA Working Party monitoring.

Tomas has been an EU representative in the International Council for Harmonisation (ICH) Steering Committee since 2007. ICH is a global initiative to harmonise standards across the globe and ensuring a strong representation from Europe is important, in which Tomas has made an excellent job. ICH has streamlined the standards for regulatory and quality requirements, which has accelerated the authorisation of products and thereby, access to medicines in ICH countries without compromising safety. This work has been recognized by all stakeholders. The Steering Committee has also established a Global Cooperation Group to ensure non-ICH countries are not left behind but that they can benefit of the work done by ICH as well.

Tomas obtained his PhD from Faculty of Medicine Uppsala University, Uppsala, Sweden in 1990 and an MSc (Pharm.), from Uppsala University, Sweden in 1986. Prior to that, he did research at UCSF, San Francisco, USA.

Tomas has been DIA Advisory Council of Europe Member during 1996-2002 and a speaker in over 20 DIA Events.

DIA Award Winners

Leader of Tomorrow Award

Awarded to a student or young professional who has made meaningful contributions to DIA and demonstrated outstanding local contributions to their student chapter and/or region.

João Duarte

Regulatory Intellingence Strategy Leader, H. Lundbeck A/S, France

João Duarte obtained his Pharmacy degree in 2011 from the University of Lisbon. During his studies, he carried out a research project that allowed him to present and win a student poster competition in DIA EuroMeeting back in 2010. Since then, he has been an active member of DIA, presenting several times at the EuroMeeting in sessions linked to young professionals' and students' paths to a career in drug development. He started his career in Medac GmbH, in Lisbon, as a Scientific Assistant.

Shortly after, he had the opportunity to join the European Medicines Agency as a trainee, in London, where he developed a passion for medicines' regulation and regulatory policy. He is currently Regulatory Intelligence Strategy Leader in H. Lundbeck A/S, based in Paris, where he supports a better understanding of the shifting regulatory environment and supports drug development within CNS disorders.

These professional experiences have been complemented by active roles in student and young professional NGOs such as the European Pharmaceutical Students' Association (EPSA), of which he has been recognised for as Honorary Life Member. He has also been active in other societies since the beginning of his career and has been an active promoter of the role of the regulatory affairs professional amongst students and young professionals in Europe. In parallel with his career, João is currently undertaking a Masters in Pharmaceutical Medicine at Trinity College Dublin and intends to keep developing competences that will contribute to a better drug development in the future. João has been very active within DIA establishing the Lisbon Student Chapter, presenting a student poster and participating Young Professional Fellowship Programme, speaking at various events and presented in DIA Communities monthly calls.

Marloes van Bruggen

Regional Regulatory Policy Lead, F. Hoffmann-La Roche Ltd, Switzerland

Marloes currently lives in Basel and is originally from the Netherlands. She has a MSc in Drug Innovation with focus on regulatory affairs. She started at Roche as an intern in 2010 and has since progressed to a Regulatory Intelligence Manager and currently works as Regional Regulatory Policy Lead. In her role, she focuses on acquiring and maintaining an overview of the global biotherapeutics environment (guidelines, policies and products) in order to develop and implement global regulatory strategies to support the Roche position of biologics and seek support and alignment with Innovator Pharma Associations.

Marloes' work contributes to ensuring robust global and local regulations and policies for biopharmaceuticals are in place to enforce safety and efficacy standards for patients and she focuses on the Eastern Europe, Middle East and Africa regions. She is a member of the EFPIA Middle East and Turkey Regulatory Network and was actively involved in the programme development of the DIA Biosimilars conference 2015. Marloes has participated DIA Young Professional Fellowship and been a speaker at Euromeeting student sessions.

EuroMeeting 2016

PROFESSIONAL POSTERS

A selected group of professional poster presenters will share their research results in various topics. The Professional Posters are located on the left and on the right of the Exhibition Hall.

New this year - Oral presentations where authors will provide a 5 minute overview of their work will be delivered. Presentations will be held in the Innovation Theatre located in the Exhibition Hall during break times on Wednesday and Friday.

P1 **Beate Wulff, Paediatric Haematologist / Oncologist, University Children´s Hospital Essen, Germany**
Supra Regional Study Centres (SRSC) Will Improve Patient Recruitment in Early Phase Trials in Paediatric Oncology
Oral Presentation scheduled Wednesday, 6 April at 12:40-12:45

P2 **Lena Gebert, Senior Consultant, NDA Regulatory Service GmbH, Germany**
Comparability Exercise - Case Studies for Submitted Data Packages and Agency´s Assessment for 24 Monoclonal Antibodies
Oral Presentation scheduled Wednesday, 6 April at 12:47-12:52

P3 **Florian Eichmann, Principal Scientific Affairs and Real World Evidence, Late Stage, Inventiv Health Clinical, Germany**
Community-Based (CB) and Cluster-Randomised (CR) Studies –'Pragmatic' Approaches for Life Cycle Evidence (LCE)
Oral Presentation scheduled Wednesday, 6 April at 12:54-12:59

P4 **Andreas Benesic, CEO / Partner, MetaHeps GmbH, Germany**
A Novel in Vitro Technology for Causality Assessment in Idiosyncratic Drug Induced Liver Injury (iDILI)
Oral Presentation scheduled Wednesday, 6 April at 13:01-13:06

P5 **Brian David Edwards, Vice President ACRES; Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK**
A Systems Based Model for Better Defining the Pharmaceutical System (STAMP)
Oral Presentation scheduled Wednesday, 6 April at 13:08-13:13

P6 **Simon Ingate, Principal Consultant, Pope Woodhead and Associates, UK**
Innovative Interactive Web Based Risk Minimisation Enables Rapid Effectiveness Evaluation and Tool Optimisation
Oral Presentation scheduled Wednesday, 6 April at 13:15-13:20

P7 **Maki Komamine, Pharmacoepidemiologist, Pharmaceuticals and Medical Devices Agency (PMDA), Japan**
Risk of Glucose Metabolism Disorder Associated with Thiazide Diuretic: A Nested Case Control Study

P8 **Maxim Kosov, Director of Medical Monitoring and Consulting, PSI CRO, USA**
Inter-Expert Agreement on Adverse Events' Evaluation
Oral Presentation scheduled Wednesday, 6 April at 13:22-13:27

P9 **Dominique Coleman, Associate Director, Pharmacovigilance, Quintiles Consulting, Inc., Ireland**
One Size Does Not Fit All Right Sized Signal Detection Systems that Meet Regulatory Expectations

P10 **Marijo Otero Lobato, Manager RMP Initiatives, Post Marketing, Janssen Biologics B.V, Netherlands**
Evaluation of Physician Awareness of Risks Described in the golimumab (GLM) EU RMP Educational Programme
Oral Presentation scheduled Wednesday, 6 April at 13:29-13:34

P11 **Lisa Bennett, Biomedical Informatics Scientist, AstraZeneca, UK**
Incorporating Patient Experience in a Clinical Trial Recruitment Strategy for a Resistant Rheumatoid Arthritis Population
Oral Presentation scheduled Wednesday, 6 April at 13:36-13:41

P12 **Tatsuya Ito, Senior Lecturer, Kyoto University Hospital, Japan**
Differences of Characteristics in Investigator Initiated Trials between Japan and Other Countries
Oral Presentation scheduled Wednesday, 6 April at 13:42-13:47

P13 **Andrew Melli, Senior Manager, SOUSEKAI Global Clinical Research Center, Japan**
Conducting PK Studies in Patients with Impaired Hepatic Function as a Phase 1 Clinical Research Site in Japan
Oral Presentation scheduled Wednesday, 6 April at 15:15-15:20

P14 **Eunhee Chung, Director, Scientific Affairs and Foreign Relations, SOUSEKAI Global Clinical Research Center, Japan**
Assessing Surveys of Volunteer Participation in Japanese Clinical Trials with Invasive Procedures
Oral Presentation scheduled Wednesday, 6 April at 15:22-15:27

P15 **Nozomu Miyawaki, SOUSEKAI Global Clinical Research Center, Japan**
The Characteristics of IRBs in Japan: Case Studies Based on Past Reviews
Oral Presentation scheduled Wednesday, 6 April at 15:29-15:34

PROFESSIONAL **POSTERS**

Professional Poster Session #1 | Wednesday, 6 April | 12:30 – 18:00
Professional Poster Session #2 | Thursday, 7 April | 09:00 – 18:30
Professional Poster Session #3 | Friday, 8 April | 09:00 – 16:00

P16 **Marlein Miranda Cona, German Cancer Research Center, Germany**
Synthesis of New Potential Theragnostic Agents Based on Duramicyn for Solid Cancers
Oral Presentation scheduled Wednesday, 6 April at 15:36-15:41

P17 **Paul O'Donohoe, Director Health Outcomes, CRF Health, UK**
An Electronic Solution for COPD Clinical Trial Challenges
Oral Presentation scheduled Wednesday, 6 April at 15:42-15:47

P18 **Jessica Thilaganath, CRF Health, UK**
Investigating Asthma Patient Preferences and Routines when Reporting Data in Clinical Trials

P19 **Karsten Roth, Director Clinical Operation / Clinical Development Lead, Cinfa Biotech GmbH, Germany**
Clinical Development Strategies for Biosimilars - A Mid Sized Pharma Perspective
Oral Presentation scheduled Thursday, 7 April at 12:40-12:45

P20 **Peter Schueler, Senior Vice President, Drug Development Services, ICON plc, Germany**
Cross Over A Neglected Study Design in CNS Research
Oral Presentation scheduled Thursday, 7 April at 12:47-12:52

P21 **Manfred Stapff, CMO, Trinetx, USA**
Use of Electronic Health Records for Development and Feasibility Testing of Clinical Trial Protocols
Oral Presentation scheduled Thursday, 7 April at 12:54-12:59

P22 **Marie Trad, Executive Medical Director, Quintiles, France**
Applying a Data driven Simulation Model to Accelerate Early Clinical Development in Rare Disease

P23 **C.A. (Sander) van den Bogert, PhD Candidate, University of Utrecht, Netherlands**
Taxonomy of Risk Indicators for Clinical Trials on Medicinal Products
Oral Presentation scheduled Thursday, 7 April at 13:01-13:06

P24 **Torsten Friedel, Managing Director, Intilaris Lifesciences, Switzerland**
A Real Life Implementation of the Protocol Representation Model
Oral Presentation scheduled Thursday, 7 April at 13:08-13:13

P25 **Hollie Farragher, Senior Regulatory Affairs Associate, Reckitt Benckiser Group, UK**
Factors that Influence Adults in Choosing Over the Counter Analgesics in a Large United Kingdom Sample Population

P26 **Katarina Ludajic, Senior Medical Writer, PAREXEL, Germany**
Establishing and Maintaining a Sponsor Vendor Relationship for the Writing of High Quality Document Templates

P27 **Yang Yu, Medicines Evaluation Board (MEB), Netherlands**
Intrasubject Variability in Drug Exposure: Are There Differences between Generic and Brand Name Formulations?
Oral Presentation scheduled Thursday, 7 April at 13:15-13:20

P28 **Arna Hrund Arnardottir, Senior Consultant, DADA Consultancy, Netherlands**
Understanding Drug Preferences - Different Perspectives
Oral Presentation scheduled Thursday, 7 April at 13:22-13:27

P29 **Simon Dalla Torre, Process Manager, Swissmedic, Switzerland**
Reasons for Rejecting Marketing Authorisation Applications - A Comparison between Swissmedic, EMA and FDA
Oral Presentation scheduled Thursday, 7 April at 13:29-13:34

P30 **Eve Roodhouse, Senior Regulatory Associate, Reckitt Benckiser Group, UK**
Impact of Digital on Healthcare

P31 **Mark Perrott, Head of Development, Pope Woodhead and Associates, UK**
Regulatory Challenges of Risk Management Material Evaluation
Oral Presentation scheduled Thursday, 7 April at 13:36-13:41

P32 **Katsura Tsukamoto, Professor, Global Regulator Science, Gifu Pharmaceutical University, Japan**
Influence of FDA Guidance on Antidiabetic Drugs Development in Japan
Oral Presentation scheduled Thursday, 7 April at 13:42-13:47

P33 **Natalia Vostokova, Chief Operating Officer, IPHARMA, Russia**
Adaptive Design in Dose Selection Studies of Next in Class Drugs
Oral Presentation scheduled Thursday, 7 April at 15:40-15:45

P34 **Thelvia Ramos Gómez, Professor and Investigator, Department of Life Sciences, University of the Armed Forces (ESPE), Ecuador**
Advances in Clinical Research in Ecuador

STUDENT POSTERS COMPETITION

Student abstracts selected by the review committee, addressing similar topics to those in the programme, will be on display in the Attendee Oasis located in the Foyer of the Exhibition Hall on the Ground Level.

Presenters will be able to discuss their work during the coffee and lunch breaks on Thursday, 7 April 2016. An awards ceremony will be held on Thursday, 7 April 2016 at 17:45 at the DIA Island in the exhibition hall to award the poster winners.

DIA STUDENT FELLOWSHIP

SP1 **Martin Tamtè, Integrative Neurophysiology, Lund University, France**
Electrophysiological brain signals as biomarkers for evaluating effects of centrally acting drugs

SP2 **Coline Piot, University Claude Bernard Lyon 1- Hospices Civils De Lyon, France**
Literature monitoring: description of the new European Medicines Agency service.

SP3 **Mylene Tisseyre, University Claude Bernard Lyon 1- Hospices Civils De Lyon, France**
Social Media and pharmacovigilance: what to expect?

SP4 **Silvia Caterina Burn, Karolinska Institute, Sweden**
Improving activities that reduce the safety risks of medicines by better evaluating their effectiveness

SP5 **Anaïs El Hachemi-Dumas, University Paris Descartes (Paris V) - Hospices Civils de Lyon, France**
Open access pharmacovigilance databases: Do they contain the same safety information?

SP6 **Mohammed Shoukri Alkhaldi Sr, University of Basel - Swiss Tropical and Public Health Institute, Switzerland**
Health research systems in four Middles East Countires: challenges and prospects

SP7 **Johannes Möller, Hamburg University of Technology, TUHH, Germany**
Co-author: Ralf Pörtner
Improving Quality by Design tools by model-based predictions applied for a CHO fed-batch cultivation

SP8 **Marko Brkić, IEDC Bled School of Management, Croatia**
Co-author: Damir Ivankovic
Supporting Interoperable EU Patient Registries: Survey of Registry Holders' Needs

SP9 **Espanet Sylvie Jr, Institut of Pharmaceutical Industry of Lyon, France**
Potentiel sex impact on anti glycoprotein IIb/IIIa therapy in acute coronary syndrome, a systematic review

SP10 **Arezou Ghorreshi, Université Claude Bernard Lyon 1, France**
Influence of Pharmaceutical Representatives towards Physicians' and Residents' Prescriptions

SPECIAL FELLOWSHIP PROGRAMME SUPPORTED BY BAYER

Science For A Better Life

SP11 **Chuan Shan, Technische Universtät München, Germany**
Snai1 accelerates pancreatic cancer progression by promoting cell proliferation and inflammation

SP12 **Pheena Abade, University of Nairobi, Kenya**
Assessment of Healthcare Associated Infection Prevention and Control

SP13 **Elfi De Weerdt, Ku Leeven, Belgium**
The Economic Impact of Drug Shortages on the Workload of Hospitals

SP14 **Jelena Mitrovic, University of Belgrade, Serbia**
Co-authors: Vladimir Stamenković and Ivan Milićević
Diazepam Nanoemulsions: Effect of Formulation and Preparation Variables on Physiochemical Characteristics and Stability

SP15 **Patricia Maric, Univeristy of Zagreb, Croatia**
Assessment of potentially innapropriate medications and clinical outcomes in hospitalised elderly patients

SP16 **Florian Hellen, Ludwig-Miximillians Universität Münche, Germany**
"Determinants of successful medical research: An empirical study of management practices in research laboratories"

SP17 **Arvind Ravichandran, University of Cologne, Germany**
Perpetually Motile Motor-Filament Systems in Confinement

STUDENTS

SP18 **Adriana Sofron, Institute of Pharmaceutical Sciences, Switzerland**
Variations in MHC class II presentation in health and disease

SP19 **Dan Daneasa, Vriej Universiteit Brussel, Belgium**
A Management View on Health Economics Case Study on Innovative Medicines

PATIENT ADVOCATE **FELLOWSHIP**

Meet the Patient Fellows
at Booth **#D2**
in the Exhibition Hall

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

Patient Involvement at the EuroMeeting

- Violeta Astratinei, Melanoma Patient Network Europe/Melanom Romania, Romania
- Dimitrios Athanasiou, Representative, Muscular Dystrophy Association Hellas, Greece
- Nicola Bedlington, Secretary General, European Patients Forum, Belgium
- Cynthia Bens, Vice President Public Policy, Alliance for Ageing Research, USA
- Tamas Bereczky, European AIDS Treatment Group, Hungary
- Giulio Maria Corbelli, European AIDS Treatment Group, Italy
- Sas Freeman, Stroke Survivor and Mentor, UK
- Jan Geissler, Director, EUPATI, Belgium
- Christina Grabowski, Morbus Osler Selbsthilfe e.V, Germany
- Rob Hagen, Parkinson Vereniging, Netherlands
- Virginie Hivert, Therapeutic Development Director, EURORDIS, France
- François Houÿez, Treatment Information and Access Director, Health Policy Advisor, EURORDIS, France
- Alastair Kent, Director, Genetic Alliance, UK
- Peter Lack, Childhood Cancer Switzerland, Switzerland
- Yann Le Cam, CEO, EURORDIS, France
- Birthe Lemley, KIU (Patient Organisation for Women with Gynaecological Cancers), Denmark
- Margaret Graham McDonald, Health&Social Care Alliance, Scotland
- Souzi Makri, AGORA, Cyprus
- Roberto Martin, ANHP (Asociacion Nacional Hipertension Pulmonar), Spain
- Bojana Mirosavljevic, LIFE association for fight against child rare diseases, Serbia
- Patricia Ryan, Irish Platform for Patient Organisations, Science and Industry, Ireland
- Bettina Ryll, Founder, Melanoma Patient Network, Sweden
- Isabel Sebastiao-Vieira, AMS-MSA Portugal (Atrofia Multi Sistemica/ Multiple System Atrophy Community) Portugal
- Richard Stephens, Patient Advocate, National Cancer Research Institute (NCRI), UK
- Willeke Van Eeckhoutte, MS Ireland, Ireland
- Diego Villalon, Más que Ideas Foundation, Spain

DIA Patient Booth
#PatientsInvolved

EUPATI
European Patients' Academy on Therapeutic Innovation

WEDNESDAY 6 APRIL 2016 | 09:00-12:30

OPTIONAL PRE-CONFERENCE TUTORIALS

Wednesday, 6 April 2016 | Room 8 Level 1

08:00-12:30 ICH INFO-DAY

This year's Information Day will focus on the recent reforms by ICH and what this means for global development of medicines. Participants will hear how ICH is moving towards being a truly global platform for regulators and industry to achieve the objective of 'Harmonisation for Better Health'.

Learn directly from the experts: Sessions include Q&A with Dawn Ronan, ICH, Switzerland, Tomas Salmonson EMA, EU and Richard Bergström, EFPIA, Belgium

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

Lenita Lindström Gommers, "ICH Assembly Chair" and Senior Expert, European Commission, EU

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

Tutorial 1 | Wednesday 6 April, 09:00-12:30 | Room 7 Level 1

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

Tutorial 2 | Wednesday 6 April, 09:00-12:30 | Room A-2.2 Level 1

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

WEDNESDAY 6 APRIL 2016 | 09:00-12:30

OPTIONAL PRE-CONFERENCE TUTORIALS

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 3 | Wednesday 6 April, 09:00-12:30 | Room B-2.1 Level 1

INTERACTIONS BETWEEN REGULATORY AND INTELLECTUAL PROPERTY, PRODUCT LIABILITY, AND DATA PRIVACY

Geneviève Michaux, Counsel, Hunton & Williams, Belgium
Christopher J. Foreman, Director, Legal Affairs, Nordic Sub-Region Merck Sharp & Dohme (Europe) Inc., Belgium

Interactions between the regulatory regime, and intellectual property regulatory issues (supplementary protection certificate, paediatric regulation, and regulatory exclusivities), privacy (clinical trials or pharmacovigilance), product liability (content of the SmPC) and competition (delay of generic entry) on the other, are increasing. As a result, those matters can no longer be approached in isolation, and a more comprehensive perspective is required when addressing regulatory issues.

The tutorial aims to explain the basic rules of intellectual property, product liability and privacy and to link them with regulatory aspects in order to highlight the interactions between the rules and therefore the impact that regulatory issues may have on intellectual property, product liability and privacy. This should allow the participants to have a broader perspective when approaching regulatory issues and to identify the possible ramifications of solutions. One hour will be dedicated to each set of rules (intellectual property, product liability and privacy), and the presentation of each set will emphasise the regulatory implications of the rules.

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

Target Audience
Members of regulatory affairs or product development teams and in-house lawyers who want to learn the basics of intellectual property, product liability, and privacy rules as applied to the pharmaceutical sector.

Tutorial 4 | Wednesday 6 April, 09:00-12:30 | Room B-2.2 Level 1

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

WEDNESDAY 6 APRIL 2016 | 09:00-12:30

OPTIONAL PRE-CONFERENCE TUTORIALS

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

Tutorial 5 | Wednesday 6 April, 09:00-12:30 | Room C-2.1 Level 1

EU RISK MANAGEMENT PLANS: USING (PRE) CLINICAL DATA TO WRITE THE MODULE SVII OF THE RMP PART II – SAFETY SPECIFICATIONS

Emil Andrei Cochino, Scientific Officer, European Medicines Agency, EU

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 6 April, 09:00-12:30 | Room C-2.2 Level 1

HOT TOPIC IN PHARMACOVIGILANCE AND ADVERSE REACTION REPORTING

Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd, 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 ISSO 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 ISCR 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

SPECIAL SESSIONS

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

WEDNESDAY 6 APRIL | 11:00-12:30 ROOM 6 GROUND LEVEL

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 ROOM 4 GROUND LEVEL

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

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

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) have adopted a common strategy to 2020 for the European medicines regulatory network, with joint key priorities and a high-level roadmap.

Join with selected heads of national agencies and EMA to hear how the strategy will make a difference to human health in the EU to 2020. The audience will be asked to give live feedback through interactive voting on the themes and priorities of the strategy.

Panellists:

Klaus Cichutek, President, Paul.Ehrlich-Institut (PEI), Germany

Emer Cooke, Head of International Affairs, European Medicines Agency (EMA), EU

Hugo Hurts, Executive Director, Medicines Evaluation Board (MEB), Netherlands

Lorraine Nolan, Chief Executive, Health Products Regulatory Authority (HPRA), Ireland

Bettina Ryll, Founder, Melanoma Patient Network, Sweden

WEDNESDAY 6 APRIL 2016

OPENING PLENARY SESSION
16:00- 17:45
ROOM 2 LEVEL 2

Challenge Your Mindset

How is our experience reflected in our perspectives on innovation? Join our six panelists as they debate the diverse roles of INnovation in drug development during the Opening Plenary of the 28th Annual EuroMeeting 2016.

"INnovation – Do you win by being IN?"

- Does innovation in Western world create innovation in the 3rd world?
- Which new questions and ethical dilemmas with intensive use of patient data?
- Who owns patient data?
- Where is the middle ground between having a profitable asset and saving lives?
- How to look at product innovation vs process innovation?

The Opening Plenary will present and discuss interesting and surprising views on pharmaceutical innovation with direct involvement of the audience.

Panellists

Nicola Bedlington
Secretary General, European Patients Forum, Belgium

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

Karl Broich
President, Federal Institute for Drugs and Medical Devices (BfArM), Germany

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

Sarah Garner
Associate Director – Science Policy and Research, National Institute for Health and Care Excellence (NICE), UK

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

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

NETWORKING EVENTS

Find it challenging to walk up to someone, introduce yourself and start a fresh conversation? How often can you make 6 new professional contacts in just minutes? The EuroMeeting focuses on ways to help you break the ice and make new connections to ultimately advance your development.

"Welcome to Hamburg" Opening Reception

Wednesday, 6 April 2016 | 18:00 – 20:00 | Hall 3, Ground Level

Through this key evening event you can challenge your new connections to a little friendly competition to break the ice through our gaming hall in a unique setting.

Thursday "Oktoberfest" Networking Reception in the Exhibition Hall

Thursday, 7 April, 2016 | 17:30 – 18:30

Network with 2,000+ attendees at the Thursday Networking Reception held in the Exhibit Hall.

THANK YOU to MAPI Group for their contribution and support to host the Oktoberfest Networking Reception. Visit them at Booth #05

Mapi™
Insight for solutions

Speed Networking

Thursday, 7 April 2016 12:45 - 13:15
Attendee Oasis, Ground Level

Speed Networking provides a framework where each participant will meet at least six new professionals during an informal and interactive 30 minute session.

Communities Meet & Eat

Thursday, 7 April 2016 | 13:00 - 14:00
Foyer A-C, Level 1

Join your Communities Live at the EuroMeeting!

We encourage all new and expert Communities members to join us at the Communities Meet & Eat.

This networking event is a great way to learn more about the opportunities within the Communities platform, as well as a chance to meet your colleagues directly.

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.

We invite you to also take advantage of the additional features of the Exhibit Hall during extended coffee breaks and lunch hours.

Wednesday	
12:30 - 14:30	Lunch
15:00 - 16:00	Afternoon tea/coffee with snack
Thursday	
10:15 - 11:00	Morning tea/coffee with snack
12:30 - 14:30	Lunch
15:15 - 16:00	Afternoon tea/coffee with snack
Friday	
10:15 - 11:00	Morning tea/coffee with snack
12:30 - 14:00	Lunch
15:15 - 16:00	Afternoon tea/coffee with snack

Innovation Theatre Presentation

Participating exhibiting company will showcase their expertise and solutions in this year's schedule.

APCER LIFE SCIENCES

Redefining PV: From Pharmacovigilance to Patient Voice and Product Value

Thursday, 7 April 2016 | 10:30-11:00
Innovation Theatre, Exhibition Hall

Suneet Walia, President and CEO, APCER Life Sciences
Mike Britt, Global Head of Quality and Compliance, APCER Life Sciences Europe
Carol Markwell, Director and Principal Consultant, Drug Safety Solutions Limited

Pharmacovigilance – PV – has evolved from adverse event cases and aggregate reports to signal detection and risk management. Yet to those outside of our niche, pharmacovigilance is still a long, strange word. For "PV" to have meaning to patients, providers, and payers, it must be re-defined in terms of Patient Voice and Product Value.

Learn why a tightly integrated global Safety and Medical Affairs function is necessary to capture the Patient Voice and maximize Product Value in the future. We'll discuss the practical steps that can be taken today to break down barriers, cross-train resources, and share knowledge.

DIA's Global Online Training Solutions

Learn at Your Own Pace, Virtually

Meet your organization's training needs with DIA's self-paced modules.

DIA's eLearning programs provide unique, realistic opportunities for professionals to learn best practices in their fields with Internet-based courseware that can be accessed 24 hours a day, 7 days a week.

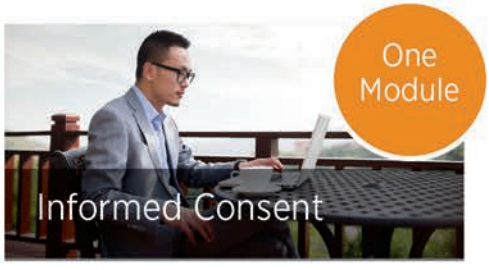
Coming Soon

The Clinical Trials eLearning Program is designed to provide practical content to help clinical research professionals learn about conducting clinical trials.

Group Discounts and Licensing Available

DIA offers licensing and discounted rates to organizations interested in purchasing modules for 10+ users.

Visit DIAglobal.org/elearning for more information.



Meet Julie Ho, Associate Director, Business and Market Development for an onsite demonstration at the DIA Island in the Exhibit Hall.

THEME 1

INNOVATION

Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA), EU
Monika Lessl, Head of Innovation Strategy, Bayer, Germany

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.

Session 0101/0701/0901/1301 | Thursday 7 April, 09:00-10:30 Room 4 Ground Level

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, CHMP, SAWP Chair, 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
Christopher Burke, Risk Based Monitoring Product Specialist, Medidata Solutions Worldwide, UK

Session 0102 | Thursday 7 April, 11:00-12:30 | Room B Level 1

GENE THERAPY – A NEW TREATMENT MODALITY: OPPORTUNITIES AND CHALLENGES FROM THE PATIENT'S, INDUSTRY, REGULATORY AND PAYER'S PERSPECTIVE

Session Chair:
Sam Wadsworth, Chief Scientific Officer, Dimension Therapeutics, USA

Modifying cellular gene expression to treat diseases has been a long-term goal which, due to novel technologies, now seems to be reachable. The panel will discuss emerging opportunities and hurdles that need to be overcome to make this dream a reality.

Regulatory Constraints
Marcel Hoefnagel, Medicines Evaluation Board (MEB), the Netherlands

Gene Therapy – The Patient's Perspective
Dimitrios Athanasiou, Representaive, Muscular Dystrophy Association Hellas, Greece

Challenges in Bringing New Treatment Modalities to Patients
Deya Corzo, Senior Vice President, Therapeutic Area Head, UniQure, USA

Adaptive Biomedical Innovation – A Supportive Framework for Accelerating the Development of Gene Therapy Products
Anne-Virginie Eggimann, Vice President, Regulatory Science, Bluebird Bio Inc., USA

Session 0103 | Thursday 7 April, 14:00-15:30 | Room C Level 1

THE VOICE OF THE PATIENT – INNOVATIVE WAYS OF PATIENT ENGAGEMENT IN R&D

Session Co-Chairs:
Jan Geissler, Director, EUPATI, Belgium
Matthias Gottwald, Head R&D Policy and Networking, Bayer Pharma, Germany

This session will look into novel approaches for patient engagement in R&D and discuss opportunities and challenges of this innovative partnership from different stakeholder perspectives.

The Patient's View
Alastair Kent, Director, Genetic Alliance UK, UK

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 | Room G2 Level 1

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.

Panellists:
Melanie Carr, Head of Corporate Stakeholders Department, European Medicines Agency (EMA), EU
Andreas Schmidt, CEO AYOXXA Biosystems, Germany
Sam Wadsworth, Chief Scientific Officer, Dimension Therapeutics, USA

New Treatment Paradigms – Regulatory challenges for SMEs
Ulrich Dauer, CEO, OMEICOS Therapeutics, 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

Session 0106 | Friday 8 April, 11:00-12:30 | Room B Level 1

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 | Room 6 Ground Level

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

Issues in Designing and Implementing a Clinical Trial in a Healthcare Database: Experiences from the Salford Lung Study
Lucy Frith, Director, Clinical Statistics, Respiratory, GSK, UK

Session 0108 | Friday 8 April, 16:00-17:30 | Room B Level 1

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
Benoit Destenaves, Director, Pharmacogenomics, AstraZeneca, UK

THEME 2

CLINICAL RESEARCH

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

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 0201 | Thursday 7 April, 09:00-10:30 | Room D Level 2

TRANSLATION OF CELL AND GENE THERAPIES

Session Chair:
Gopalan Narayanan, Biologics and Advanced Therapies Expert, NDA Group, UK

Challenges in Planning a First-in-Man Study with an Advanced Therapy Medicinal Product (ATMP)
Romaldas Maćiulaitis,Member CAT and CHMP, Clinical and Regulatory Expert, State Medicines Control Agency, Lithuania

Hematopoietic Stem Cell Gene Therapy for Inherited Disorders: Experience from an Academic Centre
Stefano Zancan, Tiget Clinical Trial Coordinator, Head of Clinical Development, Telethon, Italy

Gene Therapy for Leber Hereditary Optic Neuropathy: From Concept to Pivotal Trials
Jean-Philip Combal, Chief Operating Officer, Gensight, France

Session 0202 | Thursday 7 April, 11:00-12:30 | Room D Level 2

REAL-WORLD EVIDENCE (RWE) IN DRUG DEVELOPMENT – CREATING THE RIGHT ENVIRONMENT FOR ENHANCED PRE-LAUNCH EVIDENCE

Session Chair:
Pieter Stolk, Faculty of Science, Division of Pharmacoepidemiology and Pharmacotherapy, Julius Center for Health Sciences and Primary Care Utrecht Institute for Pharmaceutical Sciences, Netherlands

How Well Can Innovative Pre-Launch Study Designs Provide Information on the Relative Effectiveness of a New Medicine? And Under What Conditions Can Evidence Be Acceptable?
François Meyer, Advisor to the President, HAS, France

What Are the Operational/Feasibility Challenges in Conducting These Studies?
Iris Goetz, Medical Epidemiologist, Global Health Outcomes, Eli Lilly, UK

How Far Can a Pre-Launch Plan with RWE Lead to a More Predictable and More Efficient Post-Launch Programme?
Chris Chinn, Head of Real World Investigations, Sanofi, GetReal, UK

Session 0205 | Friday 8 April, 09:00-10:30 | Room 8 Level 1

IMPROVING PRODUCTIVITY IN R&D

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

This session will provide an overview of factors influencing R&D productivity, presented by leading speakers in the field.

An Analysis of Attrition Rates in Late-Stage Drug Development
Ke Zhang, Head of Segment, Pharma and Medical Devices, Thomson Reuters, UK

Improving R&D Productivity
Martin Møller, Partner, McKinsey & Company, Denmark

Does Partnering Have an Influence on Subsequent EMA Marketing Authorisations?
C.A. (Sander) van den Bogert, PhD Candidate, University of Utrecht, Netherlands

Session 0206/0306 | Friday 8 April, 11:00-12:30 | Room G2 Level 1

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.

Panellists:
Martin Landray, Professor of Medicine & Epidemiology, Nuffield Department of Population Health, University of Oxford, UK

Mike Ryan, Vice President Strategic Accounts, Medidata Solutions, Ireland

Bettina Ryll, Founder, Melanoma Patient Network, Sweden

Sam Wadsworth, Chief Scientific Officer, Dimension Therapeutics, USA

Session 0207 | Friday 8 April, 14:00-15:30 | Room 8 Level 1

DEVELOPMENT OF NEW MEDICINES – ENGAGING WITH STAKEHOLDERS

Session Chair:
Wim Leereveld, CEO, Access to Medicine Index, Netherlands

How Can Patients Be More Involved in the Development of New Medicines?
Tamás Bereczky, Communications Officer, European AIDS Treatment Group (EATG), 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 | Room C Level 1

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-Erhlich-Institute (PEI), Germany

THEME 3

CLINICAL TRIALS

Holger Maria Rohde, Director, Strategy Implementation Lead, Merck Serono, Germany
Fergus Sweeney, Head of Inspections & Human Medicines Pharmacovigilance Division, European Medicines Agency (EMA), EU

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 | Room G2 Level 1

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

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 | Room G2 Level 1

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

How Do Auditors Adapt to Risk-Based Monitoring?
Kristel Van De Voorde, Excecutive Director Global Quality and Regulatory Compliance clinical trials, BMS, Belgium

Session 0303 | Thursday 7 April, 14:00-15:30 | Room G2 Level 1

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".

Providing Access to Patient-Level Data – A Company's Experience and Perspective
Rebecca Sudlow, Global Lead Patient-Level Data Sharing, Roche Products, UK

Requesting and Using Shared Patient-Level Data – A Researcher's Experience and Perspective
Beverley Shields, Senior Lecturer in Medical Statistics, University of Exeter Medical School, 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 | Room G2 Level 1

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 | Room G2 Level 1

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.

Panellists:
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Mike Ryan, Vice President Strategic Accounts, Medidata Solutions, Ireland

Bettina Ryll, Founder, Melanoma Patient Network, Sweden

Sam Wadsworth, Chief Scientific Officer, Dimension Therapeutics, USA

Session 0308 | Friday 8 April, 16:00-17:30 | | Room G2 Level 1

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), Work Package Leader, Heinrich Heine University Düsseldorf, Germany

Global Initiatives to Facilitate International Cooperation in Clinical Trials
Jacques Demotes-Mainard, Director General, European Clinical Research Infrastructure Network (ECRIN), France

THEME 4

REGULATORY SCIENCE

Peter Bachmann, Chair CMDh, Senior Expert, European Drug and Regulatory and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Isabelle Stöckert, Head Regulatory Affairs Europe Middle East Africa, 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.

Session 0401 | Thursday 7 April, 09:00-10:30 | Room G1 Level 1

REGULATORY SCIENCE HAND IN HAND WITH HEALTH TECHNOLOGY ASSESSMENT FOR BETTER OUTCOMES

Session Chair:
Karin Van Baelen, Head Global Regulatory Affairs, Janssen, Belgium

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
Ioana-Raluca Siska, Policy Officer, Health Technology Assessment, DG Health & Food Safety (SANTE), European Commission, EU

Session 0402/0702 | Thursday 7 April, 11:00-12:30 Room 4 Ground Level

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 Room 4 Ground Level

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

The "EU Telematics Strategy" describes a set of initiatives and goals which influence the business processes and techniques in our business. Nearly all processes are concerned by the implementation. New opportunities appear and challenges have to be mastered on the way to the digital future. This session will present an overview how NCAs (national competent authorities) and industry prepare.

The Digital Landscape Grows Fast and Triggers Opportunities and Challenges at the NCA Level - What Does this Mean for Business Processes and How Do NCAs Prepare?
Georg Neuwirther, IT Director, Agency for Health and Food Safety (AGES), Austria

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

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 | Room 4 Ground Level

ADAPTIVE PATHWAYS AND CONDITIONAL APPROVAL – PANEL DISCUSSION

Session Chair:
Luca Pani, Director General, AIFA, Italy

This panel will outline the possible opportunities from increasing documentation of real life and post approval data and the support provided by regulators to develop innovative drugs.

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

Session 0405 | Friday 8 April, 09:00-10:30 | Room 4 Ground Level

IT´S NEVER TOO SOON – EARLY ACCESS AND EARLY DIALOGUE IN DRUG DEVELOPMENT

Session Chair:
Kate Beaujeux, Senior Director Regulatory Affairs, 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)
Zaide Frias, Head of Human Research & Development Support Division, European Medicines Agency (EMA), EU

Early Access/Compassionate Use in Europe
Kate Beaujeux, Senior Director Regulatory Affairs, AstraZeneca, UK

Session 0406 | Friday 8 April, 11:00-12:30 | Room 4 Ground Level

EVOLVING AREAS OF REGULATORY SCIENCE

Session Chair:
Beatriz Silva Lima, Professor, University of Lisbon, Portugal; Advisor NDA Advisory Board

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
Karl Broich, President, Federal Institute for Drugs and Medical Devices (BfArM), Germany

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 and Agnès Mathieu, Policy Officer, European Commission, EU

Session 0407 | Friday 8 April, 14:00-15:30 | Room 4 Ground Level

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
Joris Langedijk, University of Utrecht, Medicines Evaluation Board (MEB), Netherlands

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

Session 0408 | Friday 8 April, 16:00-17:30 | Room 4 Ground Level

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.

Optimisation of the Regulatory Framework for Orphan Medicines to Encourage Innovative Treatments for Patients
Agnès Mathieu, Policy Officer, European Commission, EU

Orphan Medicinal Products and the Major Contribution to Patient Care
Jordi Llinares, Head Of Department Of Product Development Scientific Support, European Medicines Agency (EMA), EU

The Patient's Perspectives on OMPs and Significant Benefit
Virginie Hivert, Therapeutic Development Director, EURORDIS, France

Evolution of the Significant Benefit Framework - An Industry Perspective
Mark Rutter, Director Policy and Intelligence, AbbVie, USA

THEME 5

MEDICAL AFFAIRS

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.

Session 0501 | Thursday 7 April, 09:00-10:30 | Room A Level 1

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 health care. 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.

PaCe'ing Medical Affairs
Guy Yeoman, Vice President Patient Centricity, AstraZeneca, UK

How the BMJ is Co-Creating Content with Patients
Tessa Richards, Assistant Editor, BMJ Publishing Group, UK

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

A Meaningful Future of the Patient Information Leaflet in Europe
Aimad Torqui, Merck Sharp & Dohme (Europe), Belgium

Session 0502 | Thursday 07 April, 11:00-12:30 | Room A Level 1

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.

Challenges in Education of Healthcare Professionals in Biopharmaceutical Industry
Gustavo Kesselring, President, IFAPP (International Federation of Association of Pharmaceutical Physicians and Pharmaceutical Medicine), Brazil

Otmar Kloiber, Secretary General, World Medical Association, France

Session 0503 | Thursday 7 April, 14:00-15:30 | Room A Level 1

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?

Patient Perspective
Sas Freeman, Stroke Survivor and Mentor, UK

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

Physician Perspective
Johannes Wimmer, 'Dr. Johannes', Physician, Germany

Session 0504 | Thursday 7 April, 16:00-17:30 | Room A Level 1

THE REALITY OF REAL-WORLD EVIDENCE – HOW VARIOUS STAKEHOLDERS ARE WORKING WITH RWE TO IMPROVE PATIENT OUTCOMES

Session Chair:
June Raine, Chair PRAC, Director Vigilance and Risk Management of Medicines Division, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

Real-world evidence (RWE) 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.

Big Data and Personalised Medicine for Better Care Outcomes
Matej Adam, Business Development Executive Healthcare IT, IBM Watson Health, Czech Republic

Using the OMOP/OHDSI System for RWE with a Focus on the 'E' for Commercial and Non-Commercial Stakeholders
Christian Reich, VP RWE Systems, IMS Health; OHDSI, USA

Towards a National Health System as a RWE Laboratory -The 100,000 Genome Project
Sir John Chisholm, Executive Chair, Genomics England, UK

THEME 6

AVAILABILITY OF MEDICINAL PRODUCTS

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 0605 | Friday 8 April, 09:00-10:30 | Room A Level 1

SETTING THE SCENE – IS THERE AN AVAILABILITY PROBLEM IN EUROPE?

Session Chair:
Luc Besançon, General Secretary and CEO, International Pharmaceutical Federation (FIP), Netherlands

This session will address availability of medicines – key bottlenecks and EU latest developments.

Early Access Programmes in Europe: Practical Strategies to Accelerate Time to Market
Natalie Thomas, jobtitle, Clinical Network Services, UK

Medicine Shortages: What is the Situation?
Luc Besançon, General Secretary and CEO, International Pharmaceutical Federation (FIP), Netherlands

Parallel Trade – Blessing or Curse of the Free Movement of Goods
Susanne Brendler-Schwaab, Head of Unit, Parallel Import, Parallel Distribution and Standard Marketing, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Session 0606 | Friday 8 April, 11:00-12:30 | Room A Level 1

MEDICINAL PRODUCTS IN NEED

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

The current translation from research to new health interventions offers a wide and growing range of opportunities, generating a rapidly growing number of product development, particularly in small targeted population and highly innovative products. But what triggers these developments? What are the drivers for companies' decision makers on their investment? Regulators, HTA and payers need to know what is coming up since new treatments bring with them series of new questions on the underlying science, on the delivery of treatment, on the impact on healthcare budget. Would horizon scanning be an appropriate answer and how could we envisage to perform it? Can we make better use of existing incentives and should we consider new incentives, if so which ones?

How to Improve Availability of Nonprescription Medicines?
Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, AESGP, Belgium

How to Stimulate Investment in Unmet Medical needs – Drivers and Incentives?
Alexander Natz, Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Belgium

Session 0607 | Friday 8 April, 14:00-15:30 | Room A Level 1

NO MARKETING OF AUTHORISED PRODUCTS

Session Chair:
Richard Bergström, Director General, EFPIA, Belgium

This session will explore the situation when a medicine is approved, but the company has chosen not to put the product on the market for commercial reasons. The panel will explore the practical consequences of international price referencing and (too?) effective off-patent policies, and discuss possible solutions.

What Are The Facts?
Frank Wartenberg, President Central Europe, IMS Health GmbH & Co. OHG, Germany

The Reality for Generic Companies
Maarten Van Baelen, Market Access Director, European Generic and Biosimilar Medicines Association (EGA), Belgium

The Reality for Originator Companies
Richard Bergström, Director General, EFPIA, Belgium

Reactions from a Healthcare System
Jo de Cock, RIZIV-INAMI (National Health Insurance Agency), Belgium

Session 0608 | Friday 8 April, 16:00-17:30 | Room A Level 1

SHORTAGES OF AUTHORISED PRODUCTS

Session Chair:
Brendan Cuddy, Head of Manufacturing and Quality Compliance, European Medicines Agency (EMA), EU

The shortages of medicines have been increasing in recent years. Do we have solutions for this global and multidimensional problem?

Medicinal Product Shortages
Brendan Cuddy, Head of Manufacturing and Quality Compliance, European Medicines Agency (EMA), EU

Supply Continuity – Regulatory Interventions
Gerald Heddell, Director, Inspection Enforcement & Standards Division, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Medicines Shortages – Towards an Integrated Approach to Tackling Medicines Shortages on the European Market
Koen Nauwelaerts, Manager Regulatory Affairs and Quality, European Generic and Biosimilar Medicines Association (EGA), Belgium

THEME 7

eHEALTH/ BIG DATA

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 0101/0701/0901/1301 | Thursday 7 April, 09:00-10:30 Room 4 Ground Level

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
Christopher Burke, Risk Based Monitoring Product Specialist, Medidata Solutions Worldwide, UK

Session 0402/0702 | Thursday 7 April, 11:00-12:30 Room 4 Ground Level

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 0703 | Thursday 7 April, 14:00-15:30 | Room D Level 2

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

Session 0704 | Thursday 7 April, 16:00-17:30 | Room B Level 1

VALUE PROPOSITION, CHALLENGES AND EXAMPLES FOR THE USE OF BIG DATA IN THE PHARMACEUTICAL INDUSTRY

Session Chair:
Duane Schulthess, Managing Director, Vital Transformation, Belgium

Whilst the term "Big Data" runs the risk of becoming a hackneyed cliché, the fact remains that harnessing multiple large data sets and tapping into real world evidence has the potential to provide one of the largest leaps forward in bringing new therapies to market since the development of the randomised clinical trial. However, simply saying the words "Big Data" loudly is not enough; what are actual examples of how to use these datasets to create new sources of evidence, improve targeting of patient segmentations, and create a better understanding of value for HTA? Further, what are the pitfalls of Big Data, and how do we avoid falling down a bottomless pit of rhetorical and analytical excess?

Challenges and Opportunities of Big Data for Observational Studies on Drug Safety and Effectiveness
Olaf Klungel, Professor of Pharmacoepidemiologic Methods, Utrecht Institute for Pharmaceutical Sciences & University Medical Center Utrecht, 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

Session 0705 | Friday 8 April, 09:00-10:30 | Room D Level 2

CHALLENGES AND OPPORTUNITIES RELATED TO THE INTEGRATION OF MULTIPLE DATA SOURCES

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

Big data warehouses collecting data from multiple sources represent a promising tool and a great opportunity for the future as we will be able to query on a very large scale and perform specific analysis. Data integration remains, though, an important challenge to face especially due to the increasing volume of data and to their different types, sometimes produced using standards which are not the same.

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

Challenges for Data and Privacy Protection in the Areas of eHealth and Big Data
Uwe Fiedler, Chief Privacy Officer & VP DP, PAREXEL International, Germany

Databases against Falsified Medicines
Domenico di Giorgio, Product Quality and Counterfeiting, Italian Medicines Agency (AIFA), Italy

Session 0707 | Friday 8 April, 14:00-15:30 | Room B Level 1

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 | Room D Level 2

EXAMPLES OF BIG DATA APPLICATIONS

Session Chair:
Andrew Lawton, Global Head of Clinical Data Management, Boehringer Ingelheim, UK

Big data is a term for data sets that are so large or complex that traditional data processing applications are inadequate. This creates multiple challenges including analysis, capture, search, sharing, storage, transfer, visualisation, etc. This session will examine multiple aspects of big data.

Risk Based Monitoring: All Aspects of "Big Data" in One Approach
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, Estonia

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

THEME 8

PHARMACOVIGILANCE

Maarten Lagendijk, Pharmacovigilance Coordinator, Medicines Evaluation Board (MEB), Netherlands
Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, Merck, Sharp & Dohme Ltd, 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 | Room 6 Ground Level

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.

Social Media and Mobile Technology; New Opportunities to Engage with Patients
Phil Tregunno, Signal Management & Quality Standards Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

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

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

Everything You Wanted to Know About Social Media and Pharmacovigilance, but Were Afraid to Ask...
Phil Tregunno, Signal Management & Quality Standards Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

Session 0802 | Thursday 7 April, 11:00-12:30 | Room G1 Level 1

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

This session will examine some real life examples of medication error and ask the question – 'could the industry have done anything to prevent this?' and will have informal and interactive elements.

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

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

Medication Errors – The Perspective of Patients and Healthcare Professionals Relating to Identification of Issues and Collection of Data
Kristina Strutt, SVP Global Pharmacovigilance and QPPV, Ipsen, UK

Session 0803 | Thursday 7 April, 14:00-15:30 | Room G1 Level 1

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 Room G1 Level 1

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
Wolfgang Lauer, Assistant to the Head of the Medical Devices Division, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Post-Market Surveillance – Compliance, Burden and Benefit with the Legal Requirements from a Manufacturer's Perspective
Philippe Soly, Director Regulatory Affairs, European Authorised Representative, Philips Healthcare, France

Post-Market Surveillance – Product Performance and Quality Aspects Including Reporting from a User's Perspective
Gerold Labek, President, European Arthroplasty Register Network (EAR-N), Switzerland

Session 0806 | Friday 8 April, 11:00-12:30 | Room G1 Level 1

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

Article 57, EudraVigilance Data Analysis and Signal Management: An Industry Perspective
Ulrich Vogel, Head Strategic Data Analysis, Global Pharmacovigilance, Boehringer Ingelheim, Germany

Use of EU PSMF Outside the EAA
Willemijn Van Der Spuij, Head International Operations, Global Pharmacovigilance & Epidemiology, Bristol-Myers Squibb, Switzerland

Session 0807 | Friday 8 April, 14:00-15:30 | Room G1 Level 1

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 | Room G1 Level 1

IMPACT OF REGULATORY MEASURES TO OPTIMISE BENEFIT-RISK DECISIONS

Session Chair:
June Raine, Chair PRAC, Director 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. It will also 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

THEME 9

LIFE CYCLE BENEFIT/ RISK MANAGEMENT

Peter Arlett, Head of Pharmacovigilance Department, European Medicines Agency (EMA), EU
Emma Du Four, Senior Director Regulatory Policy & Intelligence, Abbvie, UK

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 Room 4 Ground Level

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
Christopher Burke, Risk Based Monitoring Product Specialist, Medidata Solutions Worldwide, UK

Session 0903 | Thursday 7 April, 14:00-15:30 | Room 6 Ground Level

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

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
Marion Daverveldt, Medical Affairs Coordinator, 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 | Room G1 Level 1

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.

EMA Registries Pilot - Can a New Approach to Registries Better Support Real World Evidence Research
Peter Arlett, Head of Pharmacovigilance Department, European Medicines Agency (EMA), EU

Scientific Challenges for Post-Authorisation Safety and Efficacy Studies
Corinne De Vries, Head of Science and Innovation Support (ad interim), European Medicines Agency (EMA), EU

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

In the World of Expedited Pathways, will PAES and PASS Substantiate Benefit-Risk?
Ryan Kilpatrick, Senior Director and Head of Epidemiology, Baxalta, USA

Session 0905 | Friday 8 April, 09:00-10:30 | Room 6 Ground Level

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

Session Chair:
Corinne De Vries, Head of Science and Innovation Support (ad interim), European Medicines Agency (EMA), EU

This session will focus on the lessons learnt by regulators and industry from experience to date with post-authorisation safety and efficacy studies. Issues to be addressed include the opportunities and challenges of sharing and accessing data; how we can do joint studies involving multiple companies; when it is helpful for regulators to take the lead in evidence generation, and regulatory governance and the interface between observational and interventional studies.

Carrying Out Joint Studies between Multiple Companies: Lessons Learnt
Stephanie Tcherny-Lessenot, Head, Epidemiology Operations and Signal Detection, Sanofi, France

How Best to Develop Your Pharmacovigilance Plan - PRAC Experience with PASS Protocols
Valerie Strassmann, Head of Department 'Post-Authorisation Safety Studies, Pharmacovigilance Centres, Pharmacoepidemiology', Alternate PRAC Member, Federal Institute for Drugs and Medical Devices (BfArM) Germany

How Can We Facilitate the Conduct of Studies: A Regulator's Perspective
Peter Arlett, Head of Pharmacovigilance Department, European Medicines Agency (EMA), EU

Session 0906 | Friday 8 April, 11:00-12:30 | Room 6 Ground Level

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), Belgium

Panel discussion with June Raine, Chair PRAC, Director Vigilance and Risk Management of Medicines Division, Medicines & Healthcare Products Regulatory Agency (MHRA), UK and Peter Bachmann, Chair CMDh, Senior Expert, European Drug and Regulatory and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Session 0808/0908 | Friday 8 April, 16:00-17:30 | Room G1 Level 1

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. It will also 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 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 Devices (BfArM), Germany

THEME 10

GLOBALISATION

Petra Dörr, Head of Communication and Networking, Deputy Director, Swissmedic, Switzerland
Sabine Luik, Sr. Vice President, Medicine & Regulatory Affairs, Boehringer Ingelheim Pharmaceuticals, USA

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?

Session 1001 | Thursday 7 April, 09:00-10:30 | Room F Level 2

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

New Regulations on Medical Devices in Eurasian Economic Union
Vladimir Antonov, Deputy Head, Center for Monitoring and Clinical-Economic Expertise, Federal Service for Surveillance in Healthcare (Roszdravnadzor), Russia

Session 1002 | Thursday 7 April, 11:00-12:30 | Room F Level 2

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 fulfil 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

Session 1003 | Thursday 7 April, 14:00-15:30 | Room F Level 2

SECURING THE SUPPLY CHAIN: HOW TO TACKLE THE CHALLENGES

Session Chair:
Susanne Keitel, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), EU

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

Practical Implementation of the Falsified Medicines Directive: A Challenge for Industry?
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 | Room 6 Ground Level

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
Kazuhiro Shigeto, Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Science-Based Initiatives of PMDA
Takao Yamori, Director of Center for Product Evaluation, 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 | Room F Level 2

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.

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

Opportunities and Challenges for Industry to Help Regulators
Michel Stoffel, Vice-President, Head Early Portfolio & Europe Region, Global Regulatory Affairs, GSK Vaccines, Belgium

Session 1006 | Friday 8 April, 11:00-12:30 | Room F Level 2

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 | Room F Level 2

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

How can ICMRA Support a better Convergence in Regulatory Framework?
Birte van Elk, Medicines Evaluation Board (MEB), Netherlands

THEME 11

SPECIAL POPULATIONS

Francesca Cerreta, Senior Scientific Officer, European Medicines Agency (EMA), EU
Florian von Raison, Senior Global Program Head, Novartis Pharma, Switzerland

Do special populations still have a meaning in today's evolving pharmaceutical landscape?

Session 1101 | Thursday 7 April, 09:00-10:30 | Room C Level 1

WOMEN'S HEALTH AND DRUG DEVELOPMENT

Session Chair:
Corinne De Vries, Head of Science and Innovation Support (ad interim), 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
John Whyte, Director, Professional Affairs and Stakeholder Engagement, Food and Drug Administration (FDA), USA

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

Session 1102 | Thursday 7 April, 11:00-12:30 | Room C Level 1

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 | Room C Level 1

CONDUCT AND COMPLETION OF PAEDIATRIC DEVELOPMENT PLANS, AS AGREED IN PAEDIATRIC INVESTIGATIVE PLANS (PIPS) OR PAEDIATRIC STUDY PLANS (PSPS)

Session Chair:
Dirk Mentzer, Chair PDCO; Head of Pharmacovigilance Unit, Paul-Ehrlich-Institut (PEI), Germany

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
Dawn Gbekor, Regulatory Affairs Director, PPD, UK
Harris Darlymple, Senior Director Project Management, PPD, UK

Towards Better Medicines for Children – Exploring the Issues Relating to Off-Label Prescribing in the Paediatric Population
Marie Isabel Manley, Partner, Head of the Regulatory Legal Group, Bristows LLP, UK

Session 1105 | Friday 8 April, 09:00-10:30 | Room C Level 1

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 | Room C Level 1

USE OF EXTRAPOLATION IN PAEDIATRIC DRUG DEVELOPMENT: CAN WE ACHIEVE GLOBAL AGREEMENT THROUGH THE REVISION OF THE ICH E11 PAEDIATRIC GUIDELINE?

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, the revision of the ICH E11 paediatric guideline has started at the global level.

A systematic approach to extrapolation including use of prior knowledge is key for any paediatric development strategy when extrapolation is considered. 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 and at the light of the EMA draft extrapolation Reflection Paper which should be released soon.

Extrapolation in Paediatrics: The EMA Perspective and Global Compatibility?
Robert Hemmings, CHMP, SAWP Chair, Statistics Unit Manager, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

Extrapolation in Paediatrics: The FDA Perspective
Lynne Yao, Director, Division of Paediatric and Maternal Health (DPMH), CDER, Food and Drug Administration (FDA), USA

Extrapolation in Paediatrics: A Developer Perspective
Samuel D. Maldonado, VP, Head of CHILD – Child Health Innovation Leadership Department, Janssen, USA

Panel discussion with Cecile Olivier, Scientific Officer, European Medicines Agency (EMA), EU and Andrew Thomson, Statistician, European Medicines Agency (EMA), EU (both via remote participation)

THEME 12

MEDICAL DEVICES

Sabina Hoekstra-van den Bosch, , Global Regulations and Standards, Lead for European Regulation, Philips Healthcare, Netherlands
John Wilkinson, Director of Devices, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

The health care industry is increasingly embracing the opportunities offered by medical devices, in vitro diagnostics, companion diagnostics and combination products.

This theme examines the trends in this rapidly evolving field, e.g., nanotechnology, medical apps and 3D-printing.
It will also explore the requirements to a medical device regulatory system from societal perspective, and provide an update to the latest news on the new EU Medical Device Regulation and In Vitro Diagnostic Device Regulation, with special focus on combination products and medical devices consisting of substances.

Session 1201 | Thursday 7 April, 09:00-10:30 | Room B Level 1

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.

Perspective of a Member State
Matthias Neumann, Director, Medical Devices Unit, Federal Ministry of Health (BMG), Germany

Changing Role of Notified Bodies
Gert Bos, Executive Director and Partner, QServe, Netherlands

Impact on Industry
Peter Schroeer, 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, Lead for European Regulation, Philips Healthcare, Netherlands

Session 1202 | Thursday 7 April, 11:00-12:30 | Room 8 Level 1

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

In this session challenges and issues of the current European medical device regulatory system (such as inherent complexity, scarcity of available expertise and lack of public understanding) and lessons learnt from the pharmaceutical sector will be identified. The session will follow an interactive format, in which a panel of renowned experts together with the audience will formulate and discuss potential options and solutions.

Panellists:

Gert Bos, Executive Director and Partner, QServe, Netherlands
Robert Geertsma, Senior Scientist, National Institute for Public Health and the Environment (RIVM), Netherlands
Sabina Hoekstra-van den Bosch, Global Regulations and Standards, Lead for European Regulation, Philips Healthcare, Netherlands
Hugo Hurts, Executive Director, Medicines Evaluation Board, Netherlands
Eric Klasen, Vice President Regulatory Affairs & Quality, Medtronic, Switzerland
John Wilkinson, Director of Devices, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

Session 1203 | Thursday 7 April, 14:00-15:30 | Room 8 Level 1

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 | Room 8 Level 1

COMBINATION PRODUCTS

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

Combination in Evolution
Judite Neves, Head of Health Products Directorate, Infarmed, Portugal

Life Cycle Management of Combination Products
Mike Wallenstein, Director QA / Senior Compliance Professional, Novartis, Switzerland

Consultation in Evolution
Gert Bos, Head of Regulatory and Clinical Affairs, BSI, Netherlands

Session 0805/1205 | Friday 8 April, 09:00-10:30 | Room G1 Level 1

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
Wolfgang Lauer, Assistant to the Head of the Medical Devices Division, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Post-Market Surveillance – Compliance, Burden and Benefit with the Legal Requirements from a Manufacturer's Perspective
Philippe Soly, Director Regulatory Affairs, European Authorised Representative, Philips Healthcare, France

Post-Market Surveillance – Product Performance and Quality Aspects Including Reporting from a User's Perspective
Gerold Labek, President, European Arthroplasty Register Network (EAR-N), Switzerland

Session 1206 | Friday 8 April, 11:00-12:30 | Room 8 Level 1

SELF-CARE MEDICAL DEVICES: SHIFTING BORDERS BETWEEN DEVICES AND PHARMA?

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

In this session the impact for substance based medical devices of the upcoming new Medical Device Regulation (MDR), such as the new definition of pharmacological means and classification rule 21, will be discussed. Both regulators' and regulated industries' perspectives will be shared. As an example of best practice, the national regulatory controls on these products in the Netherlands will be highlighted.

The session will also include a panel discussion with ample opportunity for QA.

Substance-Based Medical Devices: Perspective from Regulated Industry
Miranda Moussa, Manager Medical Devices, AESGP, Belgium

Substance-Based Medical Devices: Perspective from a Regulator
Judite Neves, Head of Health Products Directorate, Infarmed, Portugal

National Regulatory Control on Substance-Based Medical Devices in the Netherlands
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 | Room G2 Level 1

HTA FOR MEDICAL DEVICES

Session Chair:
Petrus 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
Steffen Kruse, Manager Market Access, Global Government Affairs & Market Access, B. Braun Melsungen, Germany

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

Session 1208 | Friday 8 April, 16:00-17:30 | Room 8 Level 1

IVDS AND COMPANION DIAGNOSTICS

Session Chair:
Stephen Lee, Biosciences Team Manager (IVD, IVF + MD), Medicines & Healthcare products Regulatory Agency (MHRA), UK

The new conformity assessment route for companion diagnostics could see competent authorities taking more of a premarket role with Notified Bodies reviewing clinical evidence prior to CE marking. In this session you will learn about the roadmap for regulation of companion diagnostics.

Big Data and Precision Medicine
Austin Tanney, Head of Life Sciences, Analytics Engines, UK

Companion Diagnostics: Notified Body Perspective
Heike Möhlig-Zuttermeister, Technical Expert, Project Manager IVD/MDD, BSI Group, Germany

Companion Diagnostics: Competent Authority Perspective
Stephen Lee, Biosciences Team Manager (IVD, IVF + MD), Medicines & Healthcare Products Regulatory Agency (MHRA), UK

THEME 13

HEALTH TECHNOLOGY ASSESSMENT

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 0101/0701/0901/1301 | Thursday 7 April, 09:00-10:30 Room 4 Ground Level

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
Christopher Burke, Risk Based Monitoring Product Specialist, Medidata Solutions Worldwide, UK

Session 1302 | Thursday 7 April, 11:00-12:30 | Room 6 Ground Level

THE NEEDS OF THE PAYERS SHAPE THE EVIDENCE FOR MARKET ACCESS

Session Chair:
Stanislav Primožic, Head, Sector for Pharmacoeconomics, Pharmacovigilance and HTA, Agency for Medicinal Products and Medical Devices, Republic of Slovenia

How Companies Fit All Evidence Requirements into One Development Plan
Marlene Gyldmark, Head of Modelling, Outcomes Research, Statistics and Epidemiology, F. Hoffmann-La Roche, Switzerland

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?
Jane Moseley, Senior Scientific Officer, Scientific Advice, European Medicines Agency (EMA), EU

Session 1303 | Thursday 7 April, 14:00-15:30 | Room B Level 1

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)
Giovanni Tafuri, National Expert on Secondment, Scientific Advice, European Medicines Agency (EMA), EU

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

Session 1305 | Friday 8 April, 09:00-10:30 | Room B Level 1

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

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

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

Session 1207/1307 | Friday 8 April, 14:00-15:30 | Room G2 Level 1

HTA FOR MEDICAL DEVICES

Session Chair:
Petrus 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

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Steffen Kruse, Manager Market Access, Global Government Affairs & Market Access, B. Braun Melsungen, Germany

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

Session 1308 | Friday 8 April, 16:00-17:30 | Room 6 Ground Level

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

In the coming years (2016-2020) HTA collaboration in Europe will be intensified in the new EUnetHTA JA3. One of the goals of the EUnetHTA JA3 is facilitate joint assessments of relative effectiveness of pharmaceuticals and to support the use of these joint assessments in national practice. In this panel we will discuss the future of the joint relative effectiveness assessments, their possible use in different types of Member States and the possible alignment of these REAs with the benefit-risk assessments of pharmaceuticals for market authorisation by the EMA.

Experienced-Based Potentials and Hurdles of European Assessments of Medicines
Anne D'Andon, HAS, France

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

EU Cooperation on Health Technology Assessments
Ioana-Raluca Siska, Policy Officer, Health Technology Assessment, DG Health & Food Safety (SANTE), European Commission, EU

THEME 14

MEDICAL WRITING

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 1401 | Thursday 7 April, 09:00-10:30 | Room E Level 2

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
Behtash Bahador, Senior Project Manager, 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

The WHO Registry Perspective: 10 Years of Experience with Information on Clinical Trials in Lay Language
Gabriele Dreier, University Medical Center Freiburg, Germany

Session 1402 | Thursday 7 April, 11:00-12:30 | Room E Level 2

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.

The Role of Regulators in Providing Information on Medicines to Patients and Healthcare Professionals
Juan Garcia Burgos, Head of Medical and Health Information Service, European Medicines Agency (EMA), EU

Benefit-Risk Communication in the Life Cycle and How It Is Reflected in RMPs
Shelley Gandhi, Strategic Advisor, Pharmacovigilance & 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

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

Session 1403 | Thursday 7 April, 14:00-15:30 | Room E Level 2

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 | Room E Level 2

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 1601 | Thursday 07 April, 09:00-10:30 | Room 8 Level 1

PRIME INITIATIVE LAUNCH: FOSTERING TIMELY ACCESS FOR PATIENT-FOCUSED DRUG DEVELOPMENT

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

European Medicines Agency launched its new PRIME (PRIority MEdicines) scheme in March 2016 to strengthen support to medicines that address an unmet medical need. PRIME aims to bring promising innovative medicines to patients faster by optimising medicine development and facilitating accelerated assessment. The session will be the first opportunity for stakeholders to hear from and engage directly with EMA senior leadership and the CHMP chair, Tomas Salmonson, about PRIME. Participants will also get the opportunity to hear feedback from the patient perspective as EMA prepares to implement this critical initiative.

PRIME-ing the Development of Priority Medicines
Jordi Llinares, Head Of Department Of Product Development Scientific Support, European Medicines Agency (EMA), EU

EMA's Toolkit to Help Promote Innovation and Patient-Focused Development
Zaide Frias, Head of Human Research & Development Support Division, European Medicines Agency (EMA), EU

PRIME Impact on Patients and Public Health: The Bigger Picture
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA), EU

Session 1604 | Thursday 7 April, 16:00-17:30 | Room F Level 2

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 1605 | Friday, 08 April, 09:00-10:30 | Room E Level 2

CONTENT AND CONTEXT OF IDMP

Session Chair:
Hans van Bruggen, Senior Regulatory Affairs Consultant, eCTDconsultancy, Netherlands

IDMP - Friend or Foo? Targets were defined and deadlines have been differently explained, but what is clear is its relevance for individual products and relevance across products and countries. The current status of IDMP standards and implementation guides, status of industry and approaches to bridge the gaps will be explained.

Introduction on Standards, Implementation Guides and Timelines and High Level Impact
Hans van Bruggen, Senior Regulatory Affairs Consultant, eCTDconsultancy, Netherlands

IDMP Implementation – Current status and Issues Being Addressed
Andrew Marr, Managing Director, Marr Consultancy Ltd., UK

Deployment of the Data Model in Industry
David Wilson, Johnson & Johnson, USA

Session 1506 | Friday 8 April, 11:00-12:30 | Room D Level 2

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 1607 | Friday 08 April, 14:00-15:30 | Room E Level 2

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
Francesca Cattarin, Health Policy Officer, BEUC - The European Consumer Organisation, Belgium

HTA Perspective
Sarah Garner, Associate Director – Science Policy and Research, National Institute for Health and Care Excellence (NICE), UK

DIA 2016

JUNE 26–30 | PHILADELPHIA, PA

Join 7000+ of your life sciences colleagues from industry, academia, regulatory and government agencies, health, patient, and philanthropic organizations for DIA 2016, and foster innovation that leads to the development of safe and effective products and therapies for patients.

Keynote Speaker:

Larry Brilliant, MD, MPH

Monday, June 27 | 2:30–4:00PM

Larry Brilliant is the acting Chairman of the Board of the Skoll Global Threats Fund, whose mission is to confront global threats such as Pandemics, Climate Change, Water, Nuclear Proliferation, and the Middle East Conflict.

Featured Sessions:

- Advancing the Appropriate Use of Mobile Clinical Trials: The Clinical Trials Transformation Initiative
- Expanded Access: Ethical, Regulatory, and Policy Challenges and Considerations
- Envision the Future: How Big Data and Artificial Intelligence Change Our Regulatory Environment
- Strategies, Enablers, and Barriers to Medicine Development in the Emerging Markets: The 2025 Global Regulatory Landscape
- What's Your Preference? The Emerging Importance of Patient Preference Elicitation
- Design Thinking to Redesign the Clinical Trial Business Model and Improve Efficiency and Quality of Clinical Trials

Featured Tutorials:

- The Evolving Role of Payers in Drug Development: Pricing, Pharmacoeconomics, and Health Technology Assessment
- Stated Preference Methods and the Science of Patient Engagement
- Global Identification of Medicinal Products: Applied Principles for Practical Implementation to Support Regulatory Compliance
- Implementing a Risk-Based Monitoring Solution: Understanding the Basics of a Sustainable Model

Agenda Now Available

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A GATHERING OF GLOBAL PROPORTIONS

Visit **DIAglobal.org/DIA2016** for more information and to register.

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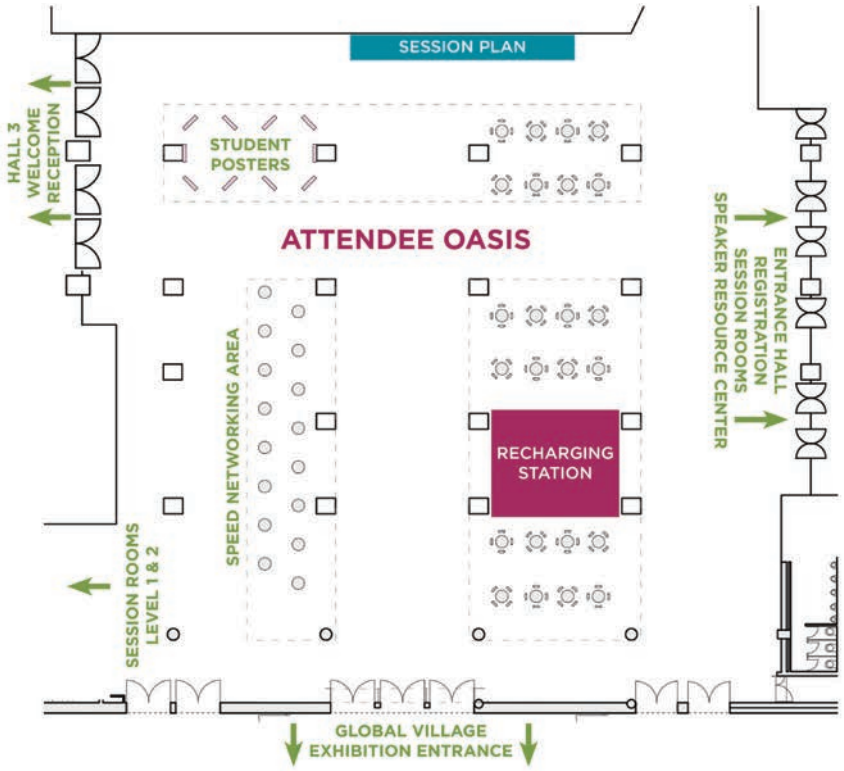

Attendee Oasis
Foyer Exhibition Hall

Ground Level

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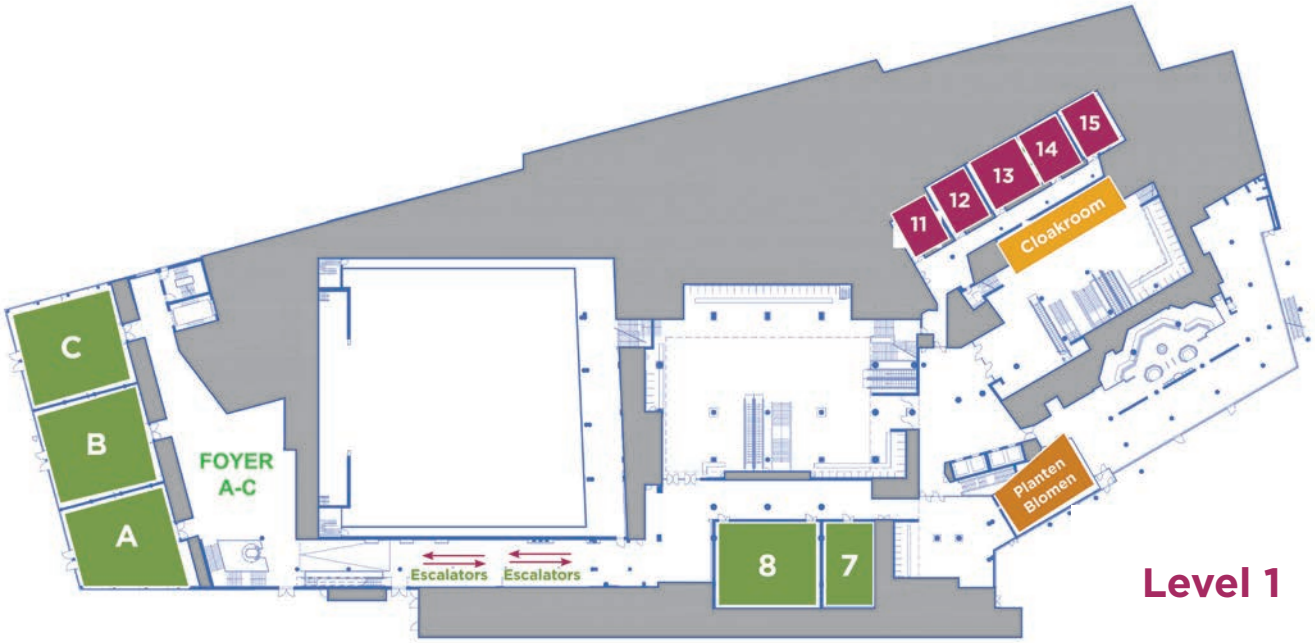
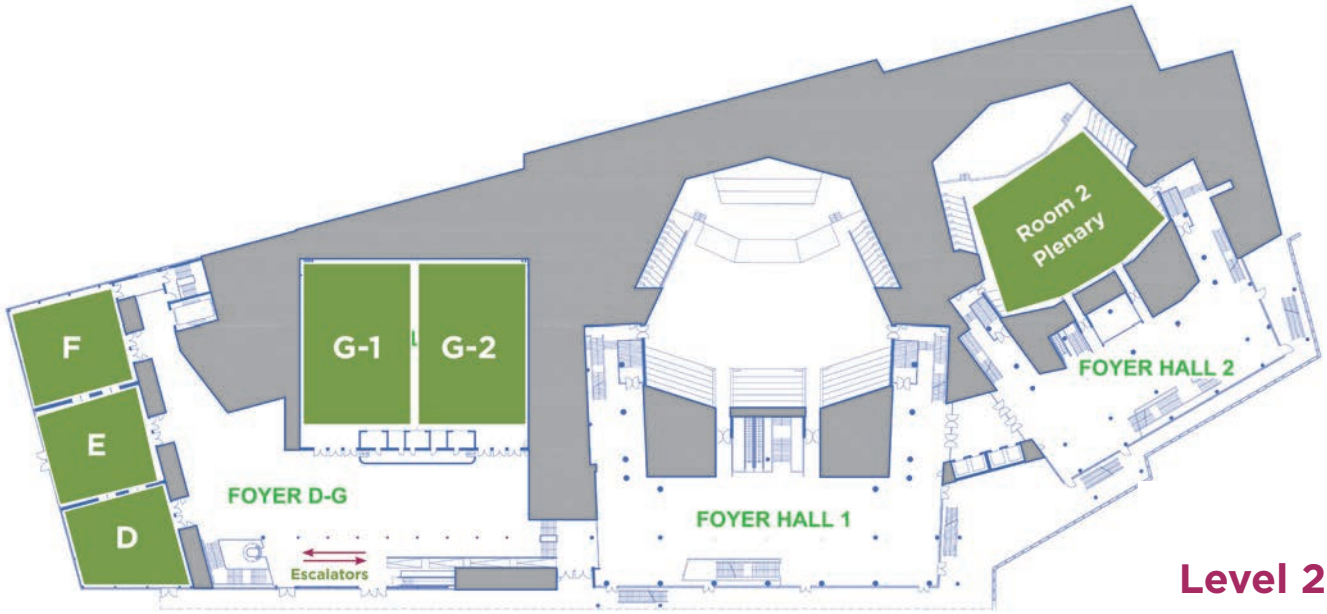
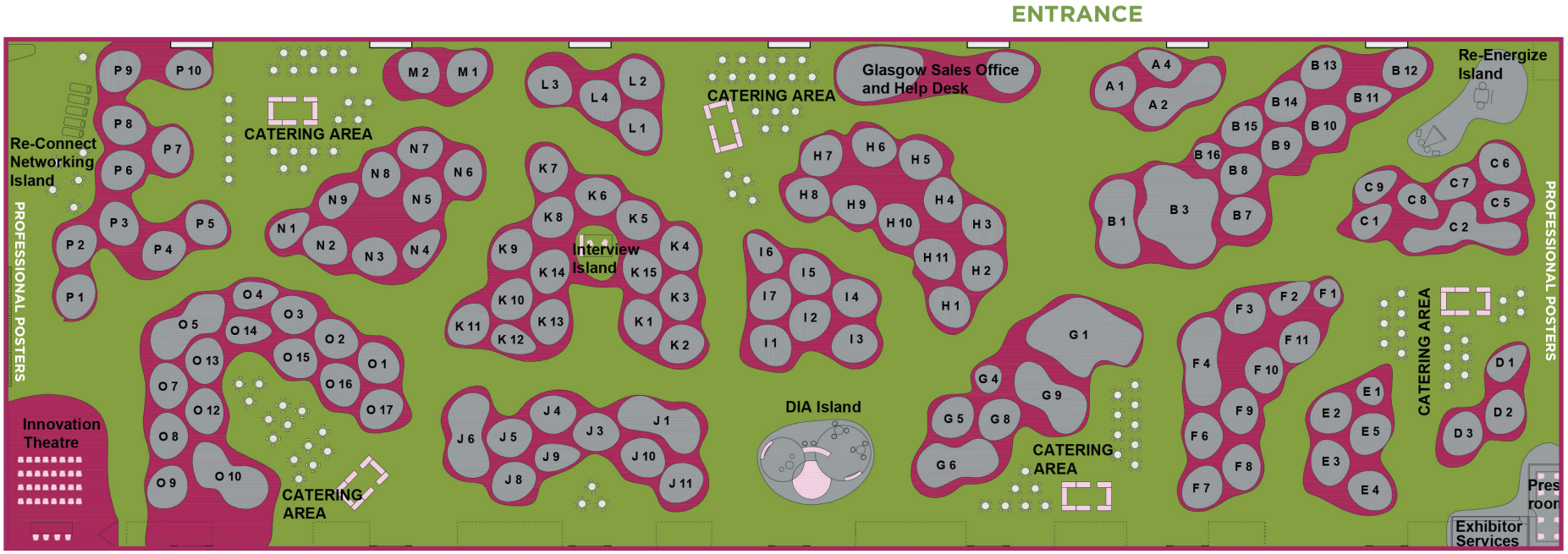


Level 1



Level 2

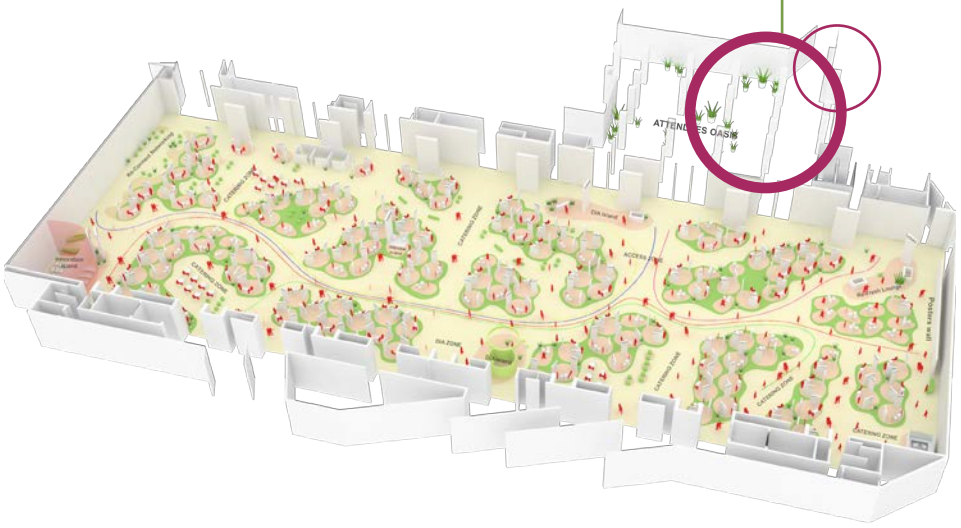
THE GLOBAL VILLAGE
EXHIBITION FLOOR PLAN



WELCOME TO
THE NEW GLOBAL VILLAGE

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.

CONNECT WITH HEALTHCARE COMPANIES AS THEY SHOWCASE THEIR NEWEST PRODUCTS

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 18 MARCH 2016

Company	Booth Number
4C Pharma Solutions, USA	J3
AB Cube, France	O13
Acadustri Ltd, UK	P3
ACCENTURE Accelarated R&D Services, UK	K5
Acurian, USA	P5
ADAMAS Consulting Group Ltd, UK	I6
Aerotek, UK	N7
AMPLEXOR, Slovenia	B8
Ancillare, USA	D1
APCER Life Sciences, UK	G1
Appian, Germany	N2
Applied Clinical Trials, USA	K7
ArisGlobal, UK	G6
arivis AG, Germany	O1
Arriello Group, Ireland	F2
ASPHALION, S.L., Spain	K11
AXPHARMA, France	H2
Barrington James, UK	C9
BaseCon, Denmark	H3
Biocair International Ltd, UK	J8
Bioclinica, USA	F8
bioskin GmbH, Germany	J5
Blue Reg Pharma Consulting, France	N6
BVMA e.V. – Bundesverband Medizinischer Auftragsinstitute e.V., Germany	J9
C3i Healthcare Connections, USA	K14
CAC Croit Corporation, Japan	I2
Chiltern, USA	E5
Clinical Professionals, UK	B10
CRF Health, USA	A4

Company	Booth Number
CSC, Germany	P6
Cunesoft GmbH, Germany	O14
DADA Consultancy, Netherlands	K1
Dassault Systèmes, Biovia, Ireland	K6
DDi, UK	B16
DIA Patient Booth, Switzerland	D2
DIA	DIA Island
DITA Exchange, USA	P7
Dora Wirth Languages, UK	K4
Drug Safety Research Unit, UK	H1
eClinicalHealth Ltd, UK	K3
ENNOV, France	G4
Entimo AG, Germany	F3
ERT, Inc., USA	J1
Eudrac Group, UK	G5
European Medicines Agency, European Union	H10
European Pharminvent Services, Czech Republic	B15
EXTEDO GmbH, Germany	K10
FLEX DATABASES, Switzerland	I7
fme AG, Germany	F10
Foresight Group International AG, USA	O12
GenPro International, USA	F1
Global Vision, Canada	H6
Hays Life Sciences, Germany	K8
Hobson Prior, UK	K12
HUREKA Resources, Sweden	C6
i4i, Canada	F11
INFERENTIAL, France	K9
Insight Medical Writing, UK	L1
Intergrated Clinical Systems, Inc., USA	P1

EXHIBITING COMPANIES AS OF 18 MARCH 2016

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IPHARMA LLC, Russia	N1
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LFK - Laboratorium für Klinische Forschung GmbH, Germany	B14
Life Science Academy, Italy	O16
LINICAL, Germany	K2
LORENZ Life Sciences Group, Germany	O17
Luto Research Ltd, UK	C5
MakroCare, UK	O4
MAPI, France	O5
MasterControl, UK	I4
Max Application Srl - Safety Drugs, Italy	L3
Mayo Validation Support Services, USA	P4
MedDRA MSSO, USA	H5
MEDICADEMY, Denmark	H4
Metronomia Clinical Research, Germany	B11
Moravia Life Sciences, Czech Republic	B7
mt-g medical translation GmbH & Co KG, Germany	J10
MyMeds&Me, UK	O15
NDA Group, UK	A2
NNIT, Denmark	B3
ORACLE Health Sciences, UK	O10
Paul-Ehrlich-Institute, Germany	C8
Pharma.Direct UK & Europe Ltd, UK	E2
Pharmaceuticals and Medical Devices Agency (PMDA), Japan	H7
PHARMATHEN, Greece	O2
PleaseTech Ltd, UK	E1
Pope Woodhead & Associates Ltd, UK	H8
PrimeVigilance Ltd, UK	J6
proDerm Institute, Germany	K15
ProductLife Group, France	G9

Company	Booth Number
Quadratek Data Solutions, Germany	N4
Quanticate, UK	N9
Real Life Sciences, UK	N3
Regulatory Pharma Net, Italy	I3
RWS Medical Translations, UK	C1
Sciformix, USA	N5
SDL plc, Germany	J4
SEC, UK	N8
SG Research International, USA	C7
SGS Life Science Services, Belgium	H11
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Sofus Regulatory Affairs, Sweden	D3
SOUSEIKAI Global Clinical Research Center, Japan	B9
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SYMOGEN, UK	B12
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TARIUS, Denmark	I1
THERAMetrics, Germany	C2
TRAC - The Regulatory Affairs Consultancy, UK	H9
TransPerfect, UK	B1
Trilogy Writing & Consulting GmbH, Germany	F4
UBC, USA	A1
Universal Medica, France	G8
UPPSALA MONITORING CENTRE, Sweden	L4
VCLS (Voisin Consulting Life Sciences), UK	O3
Veeva (Mederi) GmbH, Germany	M2
Woodley Equipment Company Limited, UK	M1
Worldwide Clinical Trials, USA	L2
XClinical GmbH, Germany	F7
Xendo, Netherlands	I5

EXHIBITOR DIRECTORY

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4C Pharma Solutions LLC ..... Booth J3

Contact : Dr. Yathendra Kumar Madineni
Email: yathendra.madineni@4cpharma.com
Website: www.4cpharma.com

4C is an Oracle partner with fully implemented Argus, and ISO 9001:2008 & 27001:2013 certified Service Provider excelling in Pharmacovigilance, Regulatory Affairs, Medical Writing, Healthcare Analytics and Clinical Staffing solutions. 4C provides comprehensive services including setting up processes, systems, certifications, trainings & operations.

AB Cube ..... Booth O13

Contact: Claudine Richon
Email: Claudine.richon@ab-cube.com
Website: www.ab-cube.com

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Acadustri Ltd ..... Booth P3

Contact: Dr Justina Orleans-Lindsay
Email: enquiries@acadustri.com
Website: www.acadustri.com

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Accenture Accelerated R& D Services ..... Booth K5

Contact : Nicola Beall
Email: nicola.beall@accenture.com
Website: www.accenture.com/lifesciences

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ADAMAS Consulting Group Ltd ..... Booth I6

Contact: Marianne Lambert
Email: marianne.lambert@adamasconsulting.com
Website: www.adamasconsulting.com

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Aerotek ..... Booth N7

Contact: Ray Brooks
Email: rbrooks@aerotek.co.uk
Website: www.aerotek.com

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AMPLEXOR ..... Booth B8

Contact: Maja Judez
Email: maja.judez@amplexor.com
Website: www.amplexor.com

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Ancillare ..... Booth D1

Contact: Michael Brown
Email: michael.brown@ancillare.com
Website: www.ancillare.com

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APCER Life Sciences ..... Booth G1

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Email: simon.johns@apcerls.com
Website: www.apcerls.com

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Contact: Jan Nadjsombati
Email: info.de@appian.com
Website: www.appian.com

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Applied Clinical Trials ..... Booth K7

Contact: Russell Pratt
Email: rpratt@advanstar.com
Website: www.appliedclinicaltrialsonline.com

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ArisGlobal ..... Booth G6

Contact: Dara O'Donnell
Email: dodonnell@arisglobal.com
Website: www.arisglobal.com

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Contact: Stephanie Horstmeier
Email: email@arivis.com
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Arriello Group ..... Booth F2

Contact: Alan White
Email: alan.white@arriello.com
Website: www.arriello.com

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ASPHALION ..... Booth K11

Contact: Cristina Ustrell
Email: custrell@asphalion.com
Website: www.asphalion.com

Asphalion is an International Scientific and Regulatory Affairs consultancy firm based in Barcelona and Munich. It has consistently grown and consists of over 60 professionals with backgrounds in Pharmacy, Chemistry, Biology, Biochemistry, Biotechnology and Medicine. Asphalion operates in a global environment offering comprehensive services for Drug Development and Regulatory Affairs to Pharma, Biotech and Medical Devices companies. Asphalion's expertise is based on a large number of submissions in Europe (CP, DCP, maintenance), USA (IND, NDA, ANDA, DMF, BLA) and RoW countries. Consultants of Asphalion are in direct contact with.

AXPHARMA SAS ..... Booth H2

Contact: Victor Benadava
Email: vbenadava@axpharma.com
Website: www.axpharma.com

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Barrington James ..... Booth C9

Contact: James Lewis
Email: ljackson@barringtonjames.com
Website: www.barringtonjames.com

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BaseCon ..... Booth H3

Contact: Morten Kjaer
Email: contact@basecon.com
Website: www.basecon.com

BaseCon offers a drug safety software which enables you to get everything you need done with minimum time and effort. SafetyBase Interchange handles your drug safety database in a pleasingly ingenious and simple way. It enables you to enter AE data quicker, while ensuring compliance to latest regulations.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 18 MARCH 2016

Biocair International Ltd ..... Booth J8

Contact: Natalie Gerrard
Email: natalie.gerrard@biocair.com
Website: www.biocair.com

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Bioclinica – Safety and Regulatory Services..... Booth F8

Contact: Dr. Ram Govindarajan
Email: Ramprasad.G@Synowledge.com
Website: www.bioclinica.com

Bioclinica creates clarity in the clinical trial process through eHealth, Medical Imaging & Biomarker, and Global Clinical Research business segments. Our eHealth expertise and multifaceted technologies include eClinical, financial lifecycle, and safety and regulatory solutions with end-to-end Pharmacovigilance and regulatory affairs services.

bioskin GmbH ..... Booth J5

Contact : Ilka Schmeichel
Email: DermTrials@bioskinCRO.com
Website: www.bioskinCRO.com

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Blue Reg Pharma Consulting ..... Booth N6

Contact: Corinne Schmitz
Email: contact@blue-reg.com
Website: www.blue-reg.com

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BVMA e.V. – Bundesverband Medizinischer Auftragsinstitute e.V. Booth J9

Contact: Dr. Dagmar Chase
Email: bvma@bvma.de
Website: www.bvma.de

The "Bundesverband Medizinischer Auftragsinstitute"(BVMA) was founded in July 1991 to represent CROs (Contract Research Organisations) that are based in Germany or German speaking countries. Its headquarters are located in Munich. At present, 40 companies operating in the field of clinical research at a national and international level, are members of the association.

C3i Healthcare Connections..... Booth K14

Contact: Sarah Skaggs
Email: sskaggs@c3i-inc.com
Website: www.c3ihc.com

C3i Healthcare Connections, a division of Telerx, is an industry-leading business process outsourcer specializing in the multi-channel engagement of patients, healthcare professionals and enterprise personnel via a network of global contact centers in North America, Europe, India and China. C3i is the leading provider of specialty support services for life sciences companies, health care providers and patients leveraging digital health technology. Services includes: 24x7 multi-lingual service desk, patient and site training technology, mobile devices provisioning, application hosting and kitting services. C3i supports 9 of the top 10 pharmaceutical companies.

CAC Croit Corporation ..... Booth I2

Contact: Kazutoshi Izawa
Email: izawak@cac.co.jp
Website: http://www.croit.com

CAC Croit, your ideal IT and business partner in the drug development process. We are a one-stop support services provider, from clinical studies through regulatory submission to post-marketing activities including pharmacovigilance by leveraging the power of IT and efficient collaborations with our worldwide group of companies and partners.

Clinical Professionals ..... Booth B10

Contact: Yvette Cleland
Email: info@clinicalprofessionals.co.uk
Website: www.clinicalprofessionals.co.uk

Clinical Professionals are Europe's leading Life Science staffing provider offering outsourced solutions via Functional Service Provision (FSP) and traditional, high quality staffing solutions. We recruit for a variety of roles including permanent, freelance, contract and interim vacancies and operate a Life Science Training Academy for the industry.

CRF Health ..... Booth A4

Contact: Dana Perotti
Email: Dana.perotti@crfhealth.com
Website: www.crfhealth.com

CRF Health is the leading provider of electronic Clinical Outcome Assessment (eCOA) solutions for global clinical trials. With experience in more than 650 trials, 100+ languages and across 74 countries, CRF Health's TrialMax eCOA solutions consistently demonstrate the industry's highest data accuracy, patient and site compliance, and retention.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 18 MARCH 2016

Cunesoft GmbH ..... Booth O14

Contact: Rainer Schwarz
Email: rainer.schwarz@cunesoft.com
Website: www.cunesoft.com

Cunesoft GmbH is a provider of regulatory master data mangement software solutions and services for all segments within the life sciences industry. Solutions include management of eCTD, xEVMPD, IDMP data and document management as well as regulatory information management (RIM). Software provisioning is provided as Software as a Service (SaaS).

DADA Consultancy ..... Booth K1

Contact: Arna Hrund Arnardottir
Email: office@dada.nl
Website: www.dada.nl

As one of the leading independent consulting agencies for regulatory affairs in Europe, DADA Consultancy offers a full range of high quality and tailored regulatory, clinical and pharmacovigilance services for human and veterinary products. Additionally, DADA has extensive experience in managing pharmaceutical development projects. DADA's experts are dedicated and highly trained chemical, pharmaceutical and biomedical professionals, supported by a wide network of external scientific experts. DADA has up-to-date knowledge of regulatory, clinical and pharmacovigilance affairs and maintains long-term partnerships with its clients. We have a passion for quality and detail and focus on the customer's needs. The problems we are asked to solve are often uncommon, as uncommon as the approaches with which we are able to solve them, thus helping to unlock your data's full potential. Challenge us to help solve any developmental, regulatory, clinical or pharmacovigilance issues: come find us at www.dada.nl.

Dassault Systèms, BIOVIA ..... Booth K6

Contact: Aisling Mulhall
Email: biovia.marketing@3ds.com
Website: https://www.3ds.com/products-services/biovia/

Dassault Systèmes BIOVIA focuses on scientific collaborative environments for advanced biological, chemical and materials experiences. The sophisticated enterprise system of modeling, simulation, laboratory and quality management enables innovation for science-based industries.

DDi ..... Booth B16

Contact : Mahesh Malneedi
Email: mahesh@ddismart.com
Website: www.ddismart.com

DDi provides smarter technology for Clinical Development, Regulatory and Enterprise domains by providing innovative technology products and solutions for the Life Science organizations of various sizes. DDi has built its solution competency with a unique blend of functional and domain expertise to serve the technology needs of global clients. DDi's cost-effective & robust IT are validated following 21 CFR Part 11 guidelines and support regulatory guidelines standards like ICH-GxP, CDISC, HIPAA, and HL7. DDi is a Makro Company.

DIA Patient Booth ..... Booth D2

DIA actively promotes the involvement of patient representatives and advocates in the EuroMeeting. The Patient Booth on the Exhibition Floor acts as a focal point for you to meet DIA Patient Fellows and Patient Speakers, network, and learn about how patient involvement can influence the way you work.

DITA Exchange ..... Booth P7

Contact: Christine Myers
Email: csm@ditaexchange.com
Website: www.ditaexchange.com

DitaExchange simplifies the way organizations create, manage, share and deliver important content though structured content management solutions built to run on the SharePoint platform. By helping companies produce and maintain important information quickly and by following compliance guidelines, employees spend less time keeping up with regulations and more time reaching company goals.

Dora Wirth (Languages) Ltd ..... Booth K4

Contact: Kim Shouler
Email: info@dwlanguages.com
Website: www.dwlang.com

DWL has over 50 years' experience in providing the life science industry with global translation solutions and language services in the following specialist areas: • Regulatory Affairs • Clinical Research • Medical Research • Medical Publishing • Manufacturing • Medical Devices

Drug Safety Research Unit ..... Booth H1

Contact: Dr Liz Lynn
Email: elizabeth.lynn@dsru.org
Website: www.dsru.org

The DSRU is an independent academic unit with respected pharmacovigilance and pharmacoepidemiology expertise which conducts studies to support risk management plans in primary and secondary care. Our methods include Specialist Cohort Event Monitoring (SCEM), Modified Prescription-Event Monitoring (M-PEM), registries and drug utilisation studies.

eClinicalHealth Ltd ..... Booth K3

Contact: Kai Langel
Email: klangel@eclinicalhealth.com
Website: www.clinpal.com

eClinicalHealth was founded by a core team of innovators and eClinical pioneers. The team set out with the ambitious plan of not creating 'yet another system', but to build something to truly transform clinical trials to be more modern, efficient and patient-centric. Thus, the Clinpal platform was born and has since been received with great enthusiasm in the industry. Today, the platform is already transforming clinical trials and in use in studies ranging from very small (50 patients) to very large (10,000+ patients). Clinpal has been adopted by several organizations, ranging from patient recruitment companies and research institutions to several top 10 pharmaceutical companies.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 18 MARCH 2016

ENNOV ..... Booth G4

Contact: Ferréol Perez Castillo
Email: contact@ennov.com
Website: www.ennov.com

With over 15 years' experience and 500 clients worldwide, Ennov makes the most integrated, cost-effective and user-friendly software for Life Sciences. Our 4 mobile solutions: Quality, Regulatory, Clinical and Pharmacovigilance integrate with your workflow to help you reach your compliance and productivity goals faster, with no IT skills required.

Entimo AG ..... Booth F3

Contact: Jörn Bilow
Email: bil@entimo.com
Website: www.entimo.com

Entimo provides superior quality IT products, custom solutions and reliable services streamlining the clinical development process. entimICE® Integrated Clinical Environment provides: -Data/Metadata repository -Standards management -Data transformation to SDTM, ADaM and other models -Statistical computing environment -Define.xml generation.

ERT ..... Booth J1

Contact: Sheryl Walder
Email: eresearch@ert.com
Website: www.ert.com

ERT is a leading provider of high-quality patient safety and efficacy endpoint data collection solutions for use in clinical drug development. ERT delivers a combination of technology, services, and consulting that increase the accuracy and reliability of patient data and improve the efficiency of the clinical development process throughout the product lifecycle.

EUDRAC Group ..... Booth G5

Contact: Carole Pugh
Email: carole.pugh@eudrac.com
Website: www.eudrac.com

EUDRAC is an EU regulatory affairs consultancy based in UK, Germany and France. Our services to pharmaceutical & medical device companies extend through the development, registration, market launch and life cycle management phases, including e-CTD publishing. Our clients value our high quality work performed according to project timelines.

European Medicines Agency ..... Booth H10

Contact: Beatrice Fayl von Hentaller
Email: beatrice.fayl@ema.europa.eu
Website: www.ema.europa.eu

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by member states for the evaluation, supervision, and pharmacovigilance of medicinal products.

European PharmInvent Services s.r.o. ..... Booth B15

Contact: Adam Scheuer
Email: scheuer@pharminvent.com
Website:www.pharminvent.com

Founded in 2010 PharmInvent is a known and established provider of pharmacovigilance and regulatory science consulting services. Our clients include Pharmaceutical, Biotech and Medical Device companies, as well as Health Authorities around the world. PharmInvent driven by an unwavering commitment to quality and to its clients.

EXTEDO GmbH ..... Booth K10

Contact: Thomas Kessler
Email: info@extedo.com
Website: www.extedo.com

EXTEDO is the key software and service solutions provider in the field of Regulatory Information Management (RIM). The EXTEDOsuite covers product registration planning & tracking (IDMP), submission publishing & lifecycle mgmt. and pharmacovigilance. Today, EXTEDO serves over 700 customers in 60 countries, including the EMA and more than 25 regulatory authorities worldwide.

Flex Databases ..... Booth I7

Contact: Pelageya Grosheva
Email: Pelageya.Grosheva@flexdatabases.com
Website: www.flexdatabases.com

Flex Databases is a software solutions company that provides instant access to PM & Budgeting, CTMS, EDC, TMF, IWRS, Learning Management System, etc. Unlike traditional E-Systems developer, Flex Databases provides a combination of extraordinary flexibility, fair prices, go-the-extra-mile service and support with a constant focus on quality.

fme AG ..... Booth F10

Contact: Carina Jansen
Email: marketing@fme.de
Website: www.fme.de

fme helps clients from the life sciences industry worldwide to structure and manage information more effectively and efficiently using Enterprise Content Management. migration-center moves and classifies large volumes of documents from various sources to the chosen ECM repository. It saves time & costs compared to individual scripts or frameworks.

Foresight Group International AG ..... Booth O12

Contact: Harumi Sato
Email: hsato@foresightgroup.com
Website: www.foresightgroup.com

Foresight Group International AG is a global professional services company focused exclusively on clinical and post-marketing product surveillance and risk management activities. From system implementation to business process redesign, our comprehensive PV and Risk management services and tools cost-effectively meet our clients' requirements.

EXHIBITOR DIRECTORY

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GenPro International ..... Booth F1

GenPro is a Boston-based contract research organization whose mission is to provide the highest quality services in the areas of biostatistics, statistical programming, medical writing, and regulatory submissions to our clients in the pharmaceutical, biotechnology, and medical device industries.

Global Vision ..... Booth H6

Contact: Christine Vannelli
Email: cvannelli@globalvisioninc.com
Website: www.globalvisioninc.com

Global Vision is the world leader in the design and delivery of Innovative Proofreading Technologies. Our solutions are widely interoperable and have been integrated into the packaging workflows of leading consumer packaged goods companies, printing firms and over 72% of the major pharmaceutical industry worldwide. Global Vision's complete suite of advanced solutions featuring text-based, pixel-based and Braille inspection technologies are designed to eliminate printed artwork and copy related errors, providing end-to-end security at every stage of the packaging workflow. All our proofreading solutions meet FDA 21 CFR Part 11 / EMA Annex 11 requirements.

Hays Life Sciences ..... Booth K8

Contact: Paul Strouts
Email: paul.strouts@hays.com
Website: www.hayssplc.com

Hays Life Sciences is a leading global pharmaceutical, biotech and medical technology staffing business, providing staff for both contract and permanent projects involved in drug discovery, medical device development, clinical development, post-approval services and commercial activities to many of the top life sciences organizations globally.

Hobson Prior ..... Booth K12

Contact: Peggy McGregor
Email: peggy.mcgregor@ukicks.com
Website: www.hobsonprior.com

Hobson Prior is a specialist recruitment company for the life sciences sector, finding and placing outstanding candidates across the UK, Europe and Asia Pacific. We provide exceptional interim and permanent staff within the clinical, quality, biostatistics, medical, production and regulatory functions. Visit hobsonprior.com for more information.

HUREKA Resources ..... Booth C6

Contact: Charlotta Babington Thorzelius
Email: charlotta.babingtonthorzelius@hurekaresources.com
Website: www.hurekaresources.com

We engage talent, through people centric Search Recruitment and HR solutions. Our approach to Executive Search and HR makes us unique in its field. Executive Search – We have helped senior people grow their careers and their businesses. HR Solutions - We are unique in offering HR services in combination with industry knowledge.

i4i ..... Booth F11

Contact: Ruth Wylie
Email: rwylie@i4i.com
Website: www.i4i.com

i4i is a world leader in the development of structured content applications. i4i has brought its innovative technology and regulatory expertise to the Life Sciences industry. Our solutions enhance compliance delivering intelligent content reuse and tracking of key Corporate, Clinical, CMC, Safety and Labelling documents.

INFERENTIAL ..... Booth K9

Contact: Anne Hummler
Email:ahummler@inferential.fr
Website: www.inferential.fr

Inferential provides Premium Biostatistical and Data Management Services to pharmaceutical and biotechnology companies as well as CROs. Located in Paris, our team is proud to serve over 35 clients located in 8 different countries across Europe, North-America and Asia. We deal with any kind of study including clinical, post-marketing, PROs, health-economics, real-life etc.

Insight Medical Writing ..... Booth L1

Contact: Tim Griffiths
Email: tim.griffiths@insightmw.com
Website: www.insightmw.com

Our professional documents ensure smooth progress through approval and beyond. If you are looking for clear, accurate and quality-led medical writing (clinical, regulatory & pharmacovigilance), you will find it at Insight. We are the reliable, flexible and highly qualified team who always deliver on time and on budget.

Integrated Clinical Systems, Inc. ..... Booth P1

Contact: Eric S. Herbel
Email: eherbel@i-review.com
Website: www.i-review.com

Integrated Clinical Systems - developers of Integrated Review™ and JReview® the fastest and easiest way to review, graph, visualize, report, analyze, do patient profiles and patient narratives and Risk Based Monitoring for your clinical data. Works with OC, Clintrial, SAS datasets, Oracle LSH, SAS DD, Medidata Rave, OmniComm TrialMaster, ClinicalInk TrueSource, EntimICE, etc. With special focus on Risk Based Monitoring support.

IPHARMA LLC ..... Booth N1

Contact: Anna Chernukha
Email: chea@ipharma.ru
Website: www.ipharma.ru

IPHARMA is a fast-growing innovative CRO in Russia and EAEU. Our pipeline consists of over 40 clinical trials in oncology, virology, endocrinology, pulmonology, neurology, transplantology, etc. We provide agile clinical services in both early-phase and registration trials,as well as medical,regulatory and PV expertise to ensure optimal timeline for your drug development.

EXHIBITOR DIRECTORY

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Kinetiq ..... Booth B13

Contact: Michael Quinn
Email: info@kinetiqideas.com
Website: www.kinetiqideas.com

Kinetiq is a consulting and technology company that delivers innovative solutions for human subject protection and compliance in clinical research. Kinetiq works with clinical researchers, research institutions, pharmaceutical, biotech and medical device companies to develop contemporary approaches to a changing landscape.

Life Science Academy ..... Booth O16

Contact: Enrico Pedroni
Email: enrico.pedroni@easy-b.it
Website: www.LSacademy.it

LS Academy is the EasyB's business unit, running technical and scientific training and conferences for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices and related medical products. Furthermore, scientific translations and market research services.

LINICAL ..... Booth K2

Contact: Michael Sommer
Email: michael.sommer@linical.com
Website: www.linical.com

Linical is a premier global CRO headquartered in Osaka, Japan, listed in the prime segment of the Tokyo Stock exchange, and dedicated to serve its client as a true partner in development. Our philosophy: "As professionals in all facets of the drug development field, we strive continuously to provide highest-quality services and add value to our stakeholders, who are the pharmaceutical companies, medical institutions, patients, shareholders, and our employees." With approximately 500 employees Linical has presence in a total of ca. 25 countries in Asia-Pacific including Japan, Europe and N. America via its own offices and entities. We offer full service capabilities during all Early and Late Stage phases of development and consulting services, including Project Management, Clinical Monitoring, Data Management, Biostatistics, Medical Writing, Medical Management and Pharmacovigilance services as well as Training and QA. We have more than 20 years experience and track record in the conduct of clinical studies with a focus on Oncology, Immunology and CNS.

LKF - Laboratorium für Klinische Forschung GmbH ..... Booth B14

Contact: Bärbel Wilke
Email: project@lkf-kiel.de
Website: www.lkf-kiel.de

LKF is an independent medical laboratory dedicated exclusively to supporting clinical trials of phases I – IV. LKF offers a broad spectrum of services including medical consulting, provision of study specific laboratory supplies, specimen management and logistics as well as safety and special laboratory analysis.

LORENZ Life Sciences Group ..... Booth O17

Website: www.lorenz.cc

LORENZ Life Sciences Group (www.lorenz.cc) has been developing and marketing software solutions for the Life Sciences market since 1989. LORENZ's solutions are geared specifically for submission assembly, review, publishing, validation and management. LORENZ docuBridge® is the most widely used eCTD submission management system for U.S., European and Japanese formats among many others, and is popular with regulatory agencies and industry alike. With over 500 installations in over 25 countries, LORENZ has a strong worldwide customer base.

Luto Research Limited ..... Booth C5

Email: solutions@luto.co.uk
Website: www.luto.co.uk

Luto creates and tests clear health information. We design Lay Summaries, Risk Communication Materials, Package Leaflets, IFUs, Clinical Trial Information and Educational Materials and other information. We have experience of working with international pharmaceutical and medical device companies. Our process is proven to enhance readability.

MakroCare ..... Booth O4

Contact: Mahesh Malneedi
Email: mahesh@makrocare.com
Website: www.makrocare.com

MakroCare is an international Drug/Device development and consulting services firm operating since 1996. MakroCare has successfully helped many Pharma, Biotech and Device companies right from designing their Regulatory Strategy to getting product approvals globally. Our functional services include Reg Intel, Affiliate support, RIM Operations, CMC Authoring, LCM, Labeling & Submission Management.

MAPI ..... Booth O5

Contact: Agnès Flori
Email: aflori@mapigroup.com
Website: http://www.mapigroup.com

Mapi is the leading Patient-Centered Research Company serving academia, life science researchers, and the pharmaceutical industry for over 40 years. Mapi's commitment to patient-focused research is demonstrated not only by our expertise and nearly four decades of service but also through our direct contribution back to the industry. Mapi is among only a handful of global organizations that is capable of engaging with a patients' complete ecosystem, their HCPs, Patient Communities, payers, and even regulators. And only Mapi has the unique history to make us the most experienced at interacting with all of them.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 18 MARCH 2016

MasterControl Inc. ..... Booth I4

Contact: Jill Bumgardner
Email: info@mastercontrol.com
Website: www.mastercontrol.com

MasterControl develops software solutions that enable pharmaceutical companies to deliver their products to market faster while reducing overall costs and increasing compliance. MasterControl solutions include quality management, document control, clinical and regulatory management, training management, supplier management, CAPA and much more.

Max Application s.r.l. / Safety Drugs..... Booth L3

Contact: Francesca Brigneti / Andrea Garlanda
Email: f.brigneti@maxapplication.it / a.garlanda@maxapplication.it Website: www.safetydrugs.it

Max Application is a development company of operating systems based on Oracle® database. It was founded on 2003 on the initiative of a group of associates who has been cooperating since 1998 and who combined their skills in information services for business management. On 2008 the department devoted to pharmaceutical companies, creates SafetyDrugs® Pharmacovigilance Software System, a product developed specifically for pharmacovigilance.

SafetyDrugs® is an adverse event reporting system that supports the capture, management, reporting and analysis of adverse events of all medical products: drugs, devices, biologics, vaccines and cosmetics. Our system is compliant with EMA and FDA rules and supports both MeDRA and WHO-Drug dictionaries.

Mayo Validation Support Services (MVSS).....Booth P4

Contact: Deke Haefner
Email: mvss@mayo.edu
Website: http://www.mayovalidation.com

Mayo Validation Support Services (MVSS) is a service line within Mayo Clinic's Department of Laboratory Medicine and Pathology. MVSS facilitates collaborations between Mayo Clinic scientists and industry or academic partners related to clinical validations, acquisition of biospecimens, laboratory testing to support clinical trials, or validation of new technologies. Mayo Clinic's integrated practice of medicine, large patient population, and associated medical data provides opportunities to access information on numerous disease states and conditions which can support research needs. MVSS coordinates these research interactions with clients.

MedDRA MSSO.....Booth H5

Contact: Scott Vitiello
Email: mssorequest@meddra.org
Website: www.meddra.org

MedDRA Maintenance and Support Services Organization (MSSO) maintains MedDRA - the Medical Dictionary for Regulatory Activities – which is a medical terminology used to classify adverse event information associated with the use of biopharmaceuticals and other medical products (e.g., medical devices and vaccines).

MEDICADEMY..... Booth H4

Contact: Tina Jensen
Email: tj@medicademy.net
Website: www.medicademy.net

Medicademy – Regulatory Affairs and Pharmacovigilance - Education, Seminars and Conferences! 23 modules offered in cooperation with the University of Copenhagen, University of Southern Denmark and The Danish Health and Medicines Authority, can lead to: • Master Degree at the University of Copenhagen, Denmark •Diploma • Individual Modules

Moravia Life Sciences .....Booth B7

Website: www.moravia.com

Moravia Life Sciences is a global translation services provider that helps you bring your products to international markets. Founded in 1990, we are triple-certified (ISO 9001, ISO 13485 and EN 15038) and rank among the top language services providers globally. We are life sciences translation experts offering translations in over 140 languages.

mt-g medical translation GmbH & Co KG .....Booth: J10

Contact : Szilvia Bíró
Email:info@mt-g.com
Website: www.mt-g.com

As a language service provider, we specialise exclusively in medical and pharmaceutical translations in the following areas: medical technology, global regulatory affairs, clinical studies, marketing and communications as well as dentistry and dental technology. The range of services we offer covers the entire translation workflow. The language portfolio currently comprises more than 60 languages with around 600 language pairs.

Metronomia Clinical Research GmbH ..... Booth B11

Contact: Rudolf Koehne-Volland
Email: rkvolland@metronomia.net
Website: www.metronomia.net

Metronomia is a Munich, Germany, based CRO dedicated to tailored premium services in statistical consulting and programming, clinical data management as well as partnered full-service. Our mission and key to our success is constant commitment to high quality, flexibility and sustainability. Metronomia has successfully been involved in more than 500 clinical projects for clients from all over the world.

MyMeds&Me Limited.....Booth O15

Contact: Andy Watson
Email: info@mymedsandme.com
Website:www.mymedsandme.com

MyMeds&Me is a leading SaaS provider of web-based adverse event and product quality capture solutions for life sciences. Client companies are already seeing efficiency and effectiveness benefits and more rapidly accessing their safety data for the earliest detection of safety or quality issues. Visit us at booth O15 to see the Reportum® solution.

EXHIBITOR DIRECTORY

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NDA Group ..... Booth A2

Contact: John Reynolds
Email: john.reynolds@ndareg.com
Website: www.ndareg.com

NDA is Europe's leading regulatory drug development, pharmacovigilance & HTA consultancy. Our goal is to streamline the global development and commercialization process in order to accelerate patient access to important medical therapies. We support clients with critical insights and strategic advice from early phases all through to maintaining the product in the market. Our experts are leaders in the fields of clinical and regulatory drug development and reimbursement strategy. NDA supported over 45% of the new medicinal products that were approved in the EU during the past three years. In order to achieve the same results in the US NDA is expanding rapidly to provide unmatched expertise in managing critical FDA interactions. Do you want your product to reach the world's two largest markets with minimum delay? Visit the stand A2 or contact us at info@ndareg.com

NNIT ..... Booth B3

Contact: Mads Torry Lindeneg
Email: mtld@nnit.com
Website: www.nnit.com

NNIT is an international consultancy in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry's strictest requirements for quality. We apply the latest advances in technology to make our clients' software, business processes and communication more effective.

Oracle Health Sciences..... Booth O10

Contact: Kate Andrews
Email: kate.andrews@oracle.com
Website: www.oracle.com/healthsciences

Oracle Health Sciences is a leading strategic software solutions provider to pharmaceutical, biotechnology, medical device and healthcare organizations. We are transforming clinical R&D from pipeline to patient; helping organizations improve patient outcomes by providing actionable insights from aggregated clinical and healthcare data while optimizing clinical trial efficiency and productivity.

Paul-Ehrlich-Institut ..... Booth C8

Contact: Bettina Ziegele
Email: Bettina.Ziegele@pei.de
Website: www.pei.de

The Paul-Ehrlich-Institut (PEI) is the senior federal authority for Vaccines and Biomedicines in Germany, located in Langen near Frankfurt/Main. The PEI is responsible for the authorization of clinical trials and national marketing authorizations of biomedicines for human use and immunological veterinary medicinal products, including pharmacovigilance, i.e. recording and evaluation of potential adverse effects, and research in the biomedical field. At the European level the PEI is involved in the assessment of centralized marketing authorization applications and is one of the leading institutes participating in working groups, committees and the development of guidelines at the European Medicines Agency, EMA. The scientific and regulatory competence of the PEI plays a key role in the development of biomedicines from drug discovery to first clinical use and subsequent licensing, establishing standards in quality, safety and efficacy of the biological medicinal products.

Pharma.Direct UK & Europe Ltd ..... Booth E2

Contact: Simon Thomas
Email: simon@pharmadirect.org.uk
Website: www.pharmadirect.org.uk

Pharma.Direct UK & Europe Ltd is a European recruitment company specialising in the recruitment of staff within the Pharmaceutical and Healthcare industries. As specialists in the European market, we provide support to our clients and candidates in the following areas; Clinical Development, Biometrics,QA and Regulatory Affairs and Medical Communications.

Pharmaceuticals and Medical Devices Agency (PMDA)..Booth H7

Contact: Tamami Fukushi
Email: fukushi-tamami@pmda.go.jp
Website: www.pmda.go.jp/english

Pharmaceuticals and Medical Devices Agency (PMDA) is the regulatory agency in Japan. Our major services are review and safety measures of drugs and medical devices for human use, and relief measures for health damage caused by adverse health effects of drugs. Our mission is protecting public health while play an active role in the global community.

PHARMATHEN ..... Booth O2

Contact: Eva Dova
Email: edova@pharmathen.com
Website: www.pharmathen.com

Pharmathen, located in Athens, Greece, was founded in 1969 as a private pharmaceutical company, and is focused on developing and marketing innovative health care products. Today, the in-house development products of Pharmathen are registered in all major EU markets and licensed out to the largest pharmaceutical companies in Europe, Canada, Australia, South Africa and the United States. Pharmathen provides a complete backwardly integrated service to its clients, from the synthesis of the API, clinical development, quality and production of the finished product, global registration and finally post approval marketing surveillance. Pharmacovigilance and Medical Operations department, represents Pharmathen's latest strategic investment, consisting of vastly experienced and skilled professionals. Its primary targets: maximization of innovation & research investment, increased revenue streams, and in parallel continuous assurance of patient safety and quality of life.

PleaseTech Ltd ..... Booth E1

Contact: Barry Lyne
Email: info@pleasetech.com
Website: www.pleasetech.com

PleaseTech specializes in document co-authoring and review. Our flagship product, PleaseReview, is a unique collaborative review and co-authoring solution for Microsoft Word and other document types. Used extensively by Life Sciences organizations, it facilitates controlled, simultaneous and secure collaboration for document review and editing.

EXHIBITOR DIRECTORY

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Pope Woodhead & Associates Ltd ..... Booth H8

Contact: Marianne Cassidy
Email: marianne.cassidy@popewoodhead.com
Website: www.popewoodhead.com

We are a leading consultancy providing innovative solutions and integrated thinking in benefit-risk (assessment, communication and evaluation), specializing in: • Risk management, drug safety and regulatory strategy •Outcomes studies/registry implementation •Value strategy and market access •Capability building

PrimeVigilance Ltd ..... Booth J6

Contact: Florence Denance Habek
Email: florence.denance.habek@primevigilance.com
Website: www.primevigilance.com

PrimeVigilance is a global service provider dedicated to deliver high quality, compliant and cost-effective Pharmacovigilance & Medical Information services. PrimeVigilance sits between the large clinical trials focused CROs and small service providers requiring the expertise or international presence needed for reliable scientific & safety services.

proDERM Institue ..... Booth K15

Contact: Sascha Faust
Email: sfaust@proderm.de
Website: www.proderm.de

proDERM is an international CRO with a strong focus on studies relating to skin, hair and mucous membranes. The institute today has over 100 permanent staff including over 30 scientists with a university education supported by GCP-experienced board-certified investigators in dermatology, ophthalmology, dentistry, pediatrics and gynecology.

ProductLife Group ..... Booth G9

Contact: Sebastien Schmitt
Email: sschmitt@productlife-group.com
Website: www.productlife-group.com

ProductLife Group is a trusted partner that helps clients stay ahead of the changing R&D landscape. We provide support across all stages of the product life cycle and have experience in working with companies in all segments of the life sciences industry.With an established presence in six European countries, extensive capabilities in key markets, and more than two decades of serving the industry, ProductLife Group has a solid platform from which to provide clients a range of services, consulting, and outsourcing solutions.

Quadratek Data Solutions ..... Booth N4

Contact: Dana Lee
Email: info@clincase.com
Website: www.clincase.com

Clincase, a product of Quadratek Data Solutions (QDS), is an end-to-end electronic data capture and clinical data management system providing a complete and integrated environment for the implementation, testing and conduct of clinical trials. A seamless, versatile and robust EDC software, Clincase keeps data managers, monitors and sponsors connected to study performance and progress while encouraging increased site and investigator participation.

Quanticate International Ltd ..... Booth N9

Contact: Thomas Underwood
Email: thomas.underwood@quanticate.com
Website: www.quanticate.com

Quanticate, headquartered in the UK and USA, is a leading global Clinical Research Organization (CRO) primarily focused on the management, analysis and reporting of data from clinical trials and post-marketing surveillance. Our team has a passion for excellence and provides high quality, efficient outsourcing solutions for companies who need additional capacity or who want to outsource certain activities in their entirety. Clinical and post-marketing services include scalable on-site and off-site clinical data management, biostatistics, clinical programming, PK/PD analysis, medical writing, pharmacovigilance and statistical consultancy. Quanticate was announced a five category winner in the annual CRO Leadership Awards for Quality, Reliability, Productivity, Regulatory and Innovation. Quanticate was the first CRO to introduce the Centralized Service Provision (CSP) approach to outsourcing supported by its data centralization and visualization tool for both single study and cross-study data analysis.

Real Life Sciences ..... Booth N3

Contact: Gemma Reyes
Email: g.reyes@realstaffing.com
Website: www.realstaffing.com

Real Life Sciences is a global leader in the provision of pharma, biotech and medical devices recruitment services. Working across Europe, the US and Asia Pac we are one of the world's most extensive pharma, biotech and medical devices recruiters and have one of the largest networks of specialist recruiters globally.

Regulatory Pharma Net ..... Booth I3

Contact: Dr Anita Falezza
Email: a.falezza@regulatorypharmanet.com
Website: www.regulatorypharmanet.com

Regulatory Pharma Net (RPN) offers full regulatory affairs assistance during the whole development process, registration and maintenance phase of a medicinal product. The highly qualified RPN team works with its clients, complementing their skill-sets and resources to help them overcome obstacles in the management of regulatory affairs activities.

RWS Medical Translations ..... Booth C1

Contact: Julia Bromhead
Email: medtrans@rws.com
Website: www.rws.com

RWS's Medical Translation Division is a one-stop solution for all your language needs. We provide a unique combination of translation, linguistic validation and interpreting services to assist life science companies and CROs – from research and clinical trials through to marketing authorization, pharmacovigilance and post-marketing surveillance.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 18 MARCH 2016

Sciformix Corporation ..... Booth N5

Contact: Susan Najjar
Email: Susan.najjar@sciformix.com
Website: www.sciformix.com

Sciformix is a leading global service provider that partners with life science companies to develop, launch and sustain medical products that aim to improve the quality of healthcare worldwide. We collaborate with our clients through the entire product lifecycle to provide a full range of Safety & Risk Management, Regulatory and Clinical support services.

SDL plc ..... Booth J4

Contact: Language Solutions
Email: kontakt@sdl.com
Website: www.sdl.com

SDL provides a range of Life Sciences solutions to 75% of the top pharmaceutical companies and 80% of top medical device companies, helping organizations to streamline their content processes and take clinical programs and products to global markets. SDL has over 1,500 enterprise customers and a global infrastructure of 70 offices in 38 countries.

SEC ..... Booth N8

Contact: Fiona Peter
Email: fiona.peter@secrecruitment.com
Website: www.secrecruitment.com

SEC has become an innovative and award-winning provider of recruitment and talent acquisition services, concentrating on specific, candidate scarce markets operating our services within the Pharmaceutical recruitment industry. We provide an unmatched level of satisfaction, driven by the core principles of: Trust, Honesty, Acting with Integrity & Commitment.

SG Research International ..... Booth C7

Contact: Stephen Gilbride
Email: sgilbride@sgrintl.com
Website: www.sgrintl.com

SG Research International (SGRI) with offices in Wyckoff, NJ and Beijing, China was founded in 2006 and is owned and managed by Stephen Gilbride, MS. He has more than twenty years of experience in the Pharmaceutical Industry and holds a Master's Degree in Drug Regulatory Affairs. SGRI has a talent network of seasoned and regionally-based GxP auditors with backgrounds in the Global Pharmaceutical and Biotech Industries as well as with Regulatory Authorities. They are positioned to leverage their broad range of experience to reduce risk in clinical trials. All SGRI Auditors are 100% independent. Our goal is your success. We are uniquely positioned to offer you customized solutions to your clinical research challenges. We offer professional services with competitive pricing. We are driven to deliver solutions to our clients with Quality and Efficiency. We can help protect as well as optimize your investment. We are committed to matching talented and experienced clinical research professionals with the needs of our clients.

SGS Life Science Services..... Booth H11

Contact: Laurence Frémond
Email: laurence.fremond@sgs.com
Website: www.sgs.com/cro

SGS Life Science Services is a leading contract service organization providing clinical research, analytical development, biologics characterization, biosafety, and quality control testing. Delivering solutions for bio-pharmaceutical companies, SGS provides clinical trial management (Phase I to IV) services encompassing clinical project management and monitoring, PK/PD Simulation & Modeling services, data management, biostatistics, and regulatory consultancy.

Sharp Clinical Services ..... Booth F6

Contact: Luke Beedle
Email: luke.beedle@sharpclinical.com
Website: www.sharpservices.com

Sharp Clinical Services is a leading provider of specialist clinical supply chain services, from drug product development and manufacturing services through to increasingly complex clinical supplies packaging, clinical labeling and clinical distribution services. We are big enough to deliver your global project while remaining small enough to care.

Sofus Regulatory Affairs AB ..... Booth D3

Contact: Linda Thunell
Email: linda.thunell@sofus.se
Website: www.sofus.se

Sofus has specialized in regulatory affairs in pharmaceuticals since 2002. We supply comprehensive regulatory, quality and safety solutions on a global or local level.No matter whether you are a multinational corporation or a small business – we can help you shorten the time and distance between your product and the patient.

SOUSEIKAI Global Clinical Research Center..... Booth B9

Contact: Nozomu Miyawaki
Email: nozomu-miyawaki@lta-med.com
Website: http://www.lta-med.com/SouseikaiGlobal/

Founded in 1986, SOUSEIKAI Global Clinical Research Center is one of the largest and oldest clinical research centers in Japan. With a track record of 1600+ studies, 4000+ protocols, and 47 NAI GCP inspections, we take pride in our art of pivotal Phase I-IV clinical trial support for world leading pharmaceutical companies and CROs.

SRG..... Booth J11

Contact: Ben Jaggers
Email: ben.jaggers@srgclinical.com
Website: www.srg.co.uk

SRG is an award-winning recruiter for the life sciences market place. Simply put, we place the best candidates with the best job opportunities.We are proud to work with many of the top pharmaceutical, biotech and clinical research organisations, supplying permanent and contract staff across the UK, US and Europe. Let SRG be your next success story...

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 18 MARCH 2016

SYMOGEN ..... Booth B12

Contact: Bobby Mahajan
Email: info@symogenlimited.com
Website: www.symogenlimited.com

Symogen is a niche service provider for all aspects of Pharmacovigilance, Pharmacoepidemiology, Medical Writing & Regulatory Services. Established in 2007, our clients are large and midsize pharmaceutical, biotech and medical device companies. Symogen Limited is 9001:2008 (Quality Management Systems) and ISO 22301:2012 (Business Continuity Strategy) certified. Our emphasis regarding the provision of PV, Regulatory or any other services focuses on both quality and compliance. Quality is fundamental to the successful operation of any outsourced services, particularly where customer satisfaction is concerned; Compliance in terms of PV, Regulatory services is paramount to adherence to applicable legislation and regulatory time-frames and SYMOGEN staff aim only for 100% in this regard.

Synchrogenix, A Certara Company ..... Booth K13

Contact: Lauren Sobocinski
Email: Kirra.sponenberg@synchrogenix.com
Website: www.synchrogenix.com

Synchrogenix is a global regulatory and medical writing consultancy providing strategic solutions to address the industry's greatest regulatory challenges. We offer cross-functional expertise; nonclinical, clinical, CMC, and drug safety; and the only Artificial Intelligence-enabled solutions to meet transparency and disclosure requirements.

Tarius A/S ..... Booth I1

Contact: Nina Lindholst
Email: info@tarius.com
Website:www.tarius.com

Tarius provides subscription-based Global Regulatory Intelligence for Drugs, Biologics, Devices, IVDs. Cross-country tables enable comparison of national requirements. Local experts' summaries explain key regulatory questions. More than 150.000 authentic documents from national authorities support compliance. Google-like-easy, updated continuously.

THERAMetrics ..... Booth C2

Contact: Birgit B. Koch
Email: b.koch@therametrics.com

A full-service TCRDO (Technology-driven Contract Research & Development Organization including cGMP IP Services) that provides technological services and solutions to innovative pharmaceutical, biotechnology and medical device Companies throughout the entire drug discovery & development cycle – from Preclinical to Market Access.

TRAC – The Regulatory Affairs Consultancy ..... Booth H9

Contact: Jonathan Trethowan
Email: jtrethowan@tracservices.co.uk
Website: www.tracservices.co.uk

TRAC is a regulatory affairs consultancy dedicated to serving the global pharmaceutical industry. Creating lasting partnerships is key to how we operate and our team of regulatory affairs professionals consistently deliver enterprising and highly individualised solutions. Talk to TRAC and find out how we can help you.

TransPerfect ..... Booth B1

Contact : Terra Scott
Email: tscott@transperfect.com
Website: www.transperfect.com

TransPerfect Life Sciences specialises in supporting global development and commercialisation of drugs, treatments and devices designed to improve and save lives. Our comprehensive solutions include eTMF and eClinical technologies, paper TMF migration, pharmacovigilance and safety solutions, translation and language services, and call centre support. With offices in over 90 cities worldwide, TransPerfect is the ideal partner to ensure that your global launch makes a global impact.

Trilogy Writing and Consutling GmbH ..... Booth F4

Contact: Evija Kuemmel
Email: writers@trilogywriting.com
Website: www.trilogywriting.com

Trilogy is a medical writing consultancy. We work as an outsourcing partner for our clients: proactively planning, coordinating and writing their clinical and medical communications documentation to meet aggressive timelines, with a readability that reduces the time for review and approval.

United BioSource Corporation (UBC)..... Booth A1

Contact: Krista Huck
Email: krista.huck@ubc.com
Website: ubc.com

UBC is a leading provider of pharmaceutical support services, partnering with life science companies to make medicine and medical products safer and more accessible. Our diverse suite of services helps bridge the gap between development and delivery and builds brand loyalty through patient access and adherence. UBC is well known for our ability to generate authoritative, real-world evidence of product effectiveness, safety, and value to assist healthcare decisions and enhance patient care.

Universal Medica Group ..... Booth G8

Contact : Aurélia Ringard
Email: aurelia.ringard@universalmedica.com
Website: www.universalmedica.com

Global Provider for Health Management Services. Launched in 2000, Universal Medica is a contracts & operationnal health management services organization which offer a full range of services including pharmacovigilance, medical information, crisis management, Medical Science Liaison, post-marketing studies and market access.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 18 MARCH 2016

Uppsala Monitoring Centre ..... Booth L4

Contact: Anna Mattsson
Email: info@who-umc.org
Website: www.who-umc.org

Uppsala Monitoring Centre (UMC) is an independent non-profit foundation and centre for international service and scientific research. Our vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Our mission is to support and promote patient safety through effective global pharmacovigilance practice.

VCLS (Voisin Consulting Life Sciences) ..... Booth O3

Contact: Jason Marks
Email: brown@voisinconsulting.com
Website: www.voisinconsulting.com

VCLS is a global product development consultancy supporting Biotech, Pharma and Medtech manufacturers throughout product life cycle in North American and European markets. With a team of 100+ life science professionals in the US, Europe and Asia, VCLS designs product development strategies, and engages in communication with regulators and payers.

Veeva Systems ..... Booth M2

Contact: Rachel Lowrey
Email: Rachel.lowrey@veeva.com
Website: www.veeva.com

Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 300 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. For more information, visit www.veeva.com/eu.

Woodley Equipment Company Limited ..... Booth M1

Contact: Vijay Manchha
Email: vijaym@woodleyequipment.com
Website: www.woodleyequipment .com

Woodley Equipment is a leading global provider of medical and laboratory equipment solutions to the Clinical Trials Industry. With rental and purchase options available, a unique range of tailored services, and the ability to source, supply and maintain equipment we deliver a value for money equipment solution, every time.

Worldwide Clinical Trials ..... Booth L2

Contact: Enrico de Leon, Jr.
Email: enrico.deleon@wwctrials.com
Website: www.worldwide.com

Worldwide Clinical Trials provides full-service drug development solutions to the biopharmaceutical industry from Early Phase and Bioanalytical Sciences through Phase II and III trials to Peri-Approval studies. worldwide.com

XClinical GmbH ..... Booth F7

Contact: Sabine Birkner
Email: Sabine.birkner@xclinical.com
Website: www.xclinical.com

XClinical offers a complete integrated eClinical Software, marvin. Built on the same platform it includes a CDISC-certified EDC system with numerous modules such as CDM, IWRS, WebPRO etc. An intuitive interface and easy-to-use tool without the need of programming knowledge. Clinical Trials can be conducted straightforward and very cost-effective.

Xendo ..... Booth I5

Contact: Nick Veringmeier
Email: Nick.veringmeier@xendo.com
Website: www.xendo.com

Xendo is a leading, independent consultancy and project management organization in the life sciences, pharmaceutical and healthcare fields. Our ambition is to enhance the quality and safety of medicine and help shorten the time to market for drugs and medical devices that improve the quality of life. For over 20 years we have supported hundreds of clients in more than 25 countries worldwide.

NEW EXHIBITING COMPANY AS OF 21 MARCH 2016

CSC ..... Booth P6

Contact: Katrin Braun
Email: kbraun3@csc.com
Website: www.csc.com/de

CSC leads clients on their digital transformation journey, providing innovative next-gen solutions and services that leverage deep industry expertise, global scale, technology independence and an extensive partner community. Our people help our clients by modernizing their business processes, applications and infrastructure with next-gen solutions.

Chiltern ..... Booth E5

Contact: Dee Fuehrer
Email: dee@scorrmarketing.com

THANK YOU to our Contributors

DIA would like to express its sincere thanks to the following exhibitors for their contributions and support of the 28th Annual EuroMeeting

Thursday "Oktoberfest" Networking Reception

Visit them at Booth #O5

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Insight for solutions

Welcome Coffee Thursday and Friday

Visit them at Booth #K8

HAYS Recruiting experts in Life Sciences

Vespresso Coffee Bar Thursday

Visit them at Booth #L2

WORLDWIDE CLINICAL TRIALS
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- Exclusive interviews with global thought leaders from research to regulation
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UPCOMING SPECIAL SECTIONS:

- Patient Engagement in Product Discovery, Development & Regulation (June 2016)
- Rare Diseases & Unmet Medical Needs (August 2016)
- Safety (October 2016)
- Market Access (December 2016)
- Legislation & Regulation (February 2017)

If you have an idea for a Special Section or topical report on another critical issue in the global health care product continuum, please contact us at Publications@DIAglobal.org.

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Wednesday, 6 April 2016

08:00 - 12:30 ICH Info Day and 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

	Theme 1	Theme 2	Theme 3	Theme 4
	Innovation	Clinical Research	Clinical Trials	Regulatory Science

Thursday, 7 April 2016

Session 1 09:00-10:30	Session 0101/0701/0901/1301 Benefit-Risk Management Planning through the Life Cycle of a Product	Session 0201 Translation of Cell and Gene Therapies	Session 0301 New European Clinical Trial Regulation	Session 0401 Regulatory Science Hand in Hand with Health Technology Assessment for Better Outcomes
	Room 4 Ground Level	Room D Level 2	Room G2 Level 1	Room G1 Level 1
Session 2 11:00-12:30	Session 0102 Gene Therapy – A New Treatment Modality	Session 0202 Real-World Evidence in Drug Development	Session 0302 ICH E6- GCP Addendum: Risk Proportionate Approaches to Trial Design and Conduct	Session 0402/0702 Fast Forward to the Future – How Big Data and Artificial Intelligence Will Change Our Regulatory Environment
	Room B Level 1	Room D Level 2	Room G2 Level 1	Room 4 Ground Level
Session 3 14:00-15:30	Session 0103 The Voice of the Patient – Innovative Ways of Patient Engagement in R&D		Session 0303 Clinical Trial Disclosure	Session 0403 The Future of Regulatory Affairs is Digital
	Room C Level 1		Room G2 Level 1	Room 4 Ground Level
Session 4 16:00-17:30	Session 0104 Start-Ups Meet Regulatory and Industry			Session 0404 Adaptive Pathways and Conditional Approval- Panel Discussion
	Room G2 Level 1			Room 4 Ground Level

Friday, 8 April 2016

	Theme 1	Theme 2	Theme 3	Theme 4
	Innovation	Clinical Research	Clinical Trials	Regulatory Science
Session 5 09:00-10:30		Session 0205 Improving Productivity in R&D	Session 0305 Enhancing Clinical Trials Efficacy	Session 0405 It´s Never Too Soon - Early Access and Early Dialogue in Drug Development
		Room 8 Level 1	Room G2 Level 1	Room 4 Ground Level
Session 6 11:00-12:30	Session 0106 Cutting Blockbuster Indications into Orphan-Sized Bites	Session 0206/0306 Oxford Debate: 'This House Believes that Over-Engineered Clinical Development Has Inhibited Innovation'	Session 0206/0306 Oxford Debate: 'This House Believes that Over-Engineered Clinical Development Has Inhibited Innovation'	Session 0406 Evolving Areas of Regulatory Science
	Room B Level 1	Room G2 Level 1	Room G2 Level 1	Room 4 Ground Level
Session 7 14:00-15:30	Session 0107 Shaking the Toolbox: Evolutions in Approaches in Trial Design	Session 0207 Development of New Medicines - Engaging with Stakeholders		Session 0407 Innovation of Mature Products – New Uses for Old Products
	Room 6 Ground Level	Room 8 Level 1		Room 4 Ground Level
Session 8 16:00-17:30	Session 0108 Bringing NGS into Drug Development: The Impact of Sequencing on the Future of Clinical Trials and Drug Registration	Session 0208 Challenges & Opportunities in the Clinical Development of Biopharmaceuticals	Session 0308 Challenges for Academic Clinical Trials	Session 0408 Where is the Orphan Drug Journey Going?
	Room B Level 1	Room C Level 1	Room G2 Level 1	Room 4 Ground Level

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

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

Thursday, 7 April 2016

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?
Room A Level 1	Room 4 Ground Level	Room 6 Ground Level	Room 4 Ground Level	Room F Level 2
Session 0502 Physician Engagement, Education & Communication in an Era of Transparency	Session 0402/0702 Fast Forward to the Future – How Big Data and Artificial Intelligence Will Change Our Regulatory Environment	Session 0802 Perspectives on Medication Errors		Session 1002 Strengthening of Regulatory Systems: How is it Achieved and When?
Room A Level 1	Room 4 Ground Level	Room G1 Level 1		Room F Level 2
Session 0503 Digital Health: How Digital Technology is Transforming Healthcare	Session 0703 Real-World Data Making Personalised Medicine a Reality	Session 0803 End-to- End PV Quality and Compliance	Session 0903 Assessing the Benefits and Risks as the Basis of Benefit-Risk Management	Session 1003 Securing the Supply Chain: How to Tackle the Challenges
Room A Level 1	Room D Level 2	Room G1 Level 1	Room 6 Ground Level	Room F Level 2
Session 0504 The Reality of Real-World Evidence	Session 0704 Value Proposition, Challenges and Examples for the Use of Big Data in the Pharmaceutical Industry		Session 0904 Post-Authorisation Safety and Efficacy Studies: Scientific Challenges and Factors for Success	Session 1004 Japanese Regulatory Session: PMDA Update
Room A Level 1	Room B Level 1		Room G1 Level 1	Room 6 Ground Level

Friday, 8 April 2016

Theme 6	Theme 7	Theme 8	Theme 9	Theme 10
Availability of Medicinal Products	eHealth/Big Data	Pharmacovigilance	Life Cycle Benefit-Risk Management	Globalisation
Session 0605 Setting the Scene – Is There an Availability Problem in Europe?	Session 0705 Challenges and Opportunities Related to the Integration of Multiple Data Sources	Session 0805/1205 Post-Marketing Surveillance and CE Marketing	Session 0905 Post-Authorisation Safety and Efficacy Studies: Operational Challenges and Factors for Success	Session 1005 Improving Global Health: How Can Regulators Help?
Room A Level 1	Room D Level 2	Room G1 Level 1	Room 6 Ground Level	Room F Level 2
Session 0606 Medicinal Products in Need		Session 0806 Planning and Oversight for Success	Session 0906 Understanding Important Risks and the Evolution to Benefit-Risk Management Planning	Session 1006 New Approaches to the Approval of Innovative Medicines: Do They Keep Their Promise?
Room A Level 1		Room G1 Level 1	Room 6 Ground Level	Room F Level 2
Session 0607 No Marketing of Authorised Products	Session 0707 The Growing Role and Importance of Interoperability and Standardisation	Session 0807 Effective and Balanced Risk Communication		Session 1007 Innovation in the Development and Approval of Generic Medicines
Room A Level 1	Room B Level 1	Room G1 Level 1		Room F Level 2
Session 0608 Shortages of Authorised Products	Session 0708 Examples of Big Data Applications	Session 0808/0908 Impact of Regulatory Measures to Optimise Benefit-Risk Decisions	Session 0808/0908 Impact of Regulatory Measures to Optimise Benefit-Risk Decisions	
Room A Level 1	Room D Level 2	Room G1 Level 1	Room G1 Level 1	

Wednesday, 6 April 2016

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

Theme 11	Theme 12	Theme 13	Theme 14	
Special Populations	Medical Devices	HTA	Medical Writing	Hot Topics/Stand Alone Sessions

Thursday, 7 April 2016

Session 1101 Women's Health and Drug Development	Session 1201 New Medical Device Regulations in the EU	Session 0101/0701/0901/1301 Benefit-Risk Management Planning through the Life Cycle of a Product	Session 1401 Challenges and Best Practices for Writing Lay Summaries of Clinical Study Results	Session 1601 PRIME Initiative Launch: Fostering Timely Access for Patient-Focused Drug Development
Room C Level 1	Room B Level 1	Room 4 Ground Level	Room E Level 2	Room 8 Level 1
Session 1102 Frailty as a Baseline Stratification Parameter and Potential Therapeutic Target	Session 1202 Public Expectation vs. Regulatory Complexity: Scenarios for Safe Innovation in Medical Technology	Session 1302 The Needs of the Payers Shape the Evidence for Market Access	Session 1402 Communicating Benefit-Risk Information in Risk Management Plans to Medical Professionals and the General Public	
Room C Level 1	Room 8 Level 1	Room 6 Ground Level	Room E Level 2	
	Session 1203 Innovative Developments in Medical Technology	Session 1303 Shall HTA Depend on Randomised Controlled Trials or Real-World Data or Both?	Session 1403 Preparing Clinical Documents for Public Release: The Issues of Transparency and Redaction	
	Room 8 Level 1	Room B Level 1	Room E Level 2	
Session 1104 Conduct and Completion of Paediatric Development Plans, As Agreed in PIPs or PSPs	Session 1204 Combination Products		Session 1404 Using Computer-Assisted Writing to Increase the Efficiency of Creating Regulatory Documents	Session 1604 Import Testing: Current Requirements and Opportunities to Simplify Access of Medicines for Patients
Room C Level 1	Room 8 Level 1		Room E Level 2	Room F Level 2

Friday, 8 April 2016

Theme 11	Theme 12	Theme 13		
Special Populations	Medical Devices	HTA	Hot Topics/Stand Alone Sessions	Hot Topics/Stand Alone Sessions
Session 1105 Formulations for Both Ends of Life	Session 0805/1205 Post-Marketing Surveillance and CE Marketing	Session 1305 How Can Three Parties; Payers, Industry and HTA, Make Agreements and Share the Economic Risk?		Session 1605 Content and Context of IDMP
Room C Level 1	Room G1 Level 1	Room B Level 1		Room E Level 2
Session 1106 Extrapolation	Session 1206 Self-Care Medical Devices: Shifting Borders between Devices and Pharma?		Session 1506 From Tradition to Regulation-Globalisation of Herbal Medicines	
Room C Level 1	Room 8 Level 1		Room D Level 2	
	Session 1207/1307 HTA for Medical Devices	Session 1207/1307 HTA for Medical Devices		Session 1607 MAPPs: The IMI ADAPT SMART Project
	Room G2 Level 1	Room G2 Level 1		Room E Level 2
	Session 1208 IVDs and Companion Diagnostics	Session 1308 European Relative Efficacy Assessments		
	Room 8 Level 1	Room 6 Ground Level		

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