25th Annual

EuroMeeting Amsterdam 2013

4-6 March 2013
RAI, Amsterdam, Netherlands

Final Programme

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Continuing Professional Development Credits

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

The 25th Annual EuroMeeting has been awarded 14 CPD credits from the Faculty of Pharmaceutical Medicine (FPM) of the Royal College of Physicians (RCP) of the UK. Medical practitioners who are eligible for credits can click on http://www.fpm.org.uk/cpd/registration for more information. If you are already a CPD member, please go directly to http://cpd.fpm.org.uk to claim your credits.

EuroMeeting Quick Facts

- Neutral, global forum featuring over 110 sessions attracting more than 3,000 professionals involved in the development of medicines from more than 50 countries
- Speakers from the European Medicines Agency, the European Commission, the FDA and other regulatory agencies from European countries and other regions of the world
- More than 200 exhibitors on one of the largest exhibition floors in Europe
- Unparalleled multi-disciplinary networking opportunities
- Student and professional poster sessions
- Active involvement of patient organisations
- Pre-conference tutorials led by expert faculty
- Hot topics

Disclosure Statement

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

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

Advisors

Angelika Joos, Director, Head Regulatory Policy, EU & Most of World, Merck Sharp & Dohme (Europe) Inc., Belgium
Aginus Kalis, Chair HMA, Executive Director, Medicines Evaluation Board, Netherlands
Catherine Levinson-Bates, Manager Patient Advocacy, Merck Serono, Switzerland
Beatriz Silva Lima, CHMP and SAWP Member, SWP Chair; Professor, Pharmacology, Faculty of Pharmacy, University of Lisbon, Portugal

Welcome from the EuroMeeting 2013 Co-Chairs

Dear Colleague,

We are delighted to welcome you to the 25th DIA Annual EuroMeeting! Amsterdam is the ultimate "small big city" and combines all the advantages of a cosmopolitan capital with a compact, easy-to-navigate size which translates in less time spent in commuting and more time enjoying what the city has to offer.

The city has a rich cultural heritage and 2013 is a year to celebrate important events there. Besides the 400-year anniversary of the Canal Ring, Amsterdam will be celebrating the re-opening of the fully renovated Rijksmuseum, the 125th anniversary of the Concertgebouw (concert hall) and the Royal Concertgebouw Orchestra, the 225th anniversary of Felix Meritis conference and event centre, and the 175th anniversary of Artis Royal Zoo.

With a focus on better public health protection, greater transparency of the processes and the rational use of medicinal products, the proposed areas for discussion for the EuroMeeting 2013 are classified into general disciplines including pharmacovigilance and regulatory affairs for medicinal products and medical devices, R&D and clinical trials. The scope of the presentations will cover the experience gathered after the implementation of the new Pharmacovigilance legislative framework, as well as from the patients' and Health Technology Assessment (HTA) perspective. Experts and authorities in the fields will be presenting their considerations for debate.

By 2013, the new Pharmacovigilance Directive will have been in place for almost a year; knowing what still needs to be done - or improved, and most importantly: are we getting what was initially expected? These are some of the key areas that the professionals attending the meeting will be able to learn about and debate. Other important topics to be covered include the Falsified Medicines Directive, the Information to Patients – what is the status? - the role played by scientific societies as experts, and considerations over an ageing population and the potential impact on hospitalisations.

With such an appealing outline of topics, we look forward to fruitful and engaging discussions that serve to improve further our healthcare systems and warmly welcome your participation.

Beatriz Vicén Banzo and Peter Bachman

Beatriz Vicén Banzo

Mrs. Vicén has been Head of Public Affairs and Technical Department in Bayer Spain since July 2011. She qualified as pharmacist with specialisation in Biochemistry in 1988. In addition she has a Master in Business Administration of the Pharmaceutical Industry from the University of Barcelona (1992), a Master in European Regulatory Procedures from the Autonomous University of Barcelona (1999), and a Master in Business Administration from the Business School ESADE (2005) Barcelona, Spain. Mrs. Vicén was Head of Regulatory Affairs in Novartis Pharma (Spain) until 2008, and Head of Regulatory Affairs and Quality Assurance in Bayer Spain until June 2010.

Peter Bachmann

Peter Bachmann is the recently appointed Chair of The Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh). Prior to that he was at the Department "European and International Affairs" at the Federal Institute for Drugs and Medical Devices (BfArM), Senior Expert 'European Drug Regulatory Affairs', German Member of the CMDh, German Member of the NtA and Member of different European and AdHoc Working Parties. Dr Bachmann was educated at the 'Bayerische Julius-Maximilians-Universität Würzburg', Germany, and obtained his PhD from the Institute for Pharmaceutical Biology of the University Würzburg, Germany.

Christer Backman
Member CMDh, EU Coordinator and Senior Expert, Medical Products Agency, Sweden

Gesine Bejeuhr
Regulatory Affairs/Quality, vfa Research-Based Pharm Companies, Germany

Richard Bergström
Director General, EFPIA, Belgium

Gonzalo Calvo Rojas
President of the European Association for Clinical Pharmacology and Therapeutics (EACPT), Spain

Judith Creba
Head EU Liaison & Policy, Novartis, Switzerland

Luca De Nigro
Coordinator, Drugs Monitoring Registers Unit, Italian Medicines Agency, Italy

Vicki Edwards
Senior Director, European Pharmacovigilance, Abbott, UK

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

Christine Gispen-De Wied
Clinical Coordinator; Member of SAWP, Medicines Evaluation Board (MEB), Netherlands

Susanne Keitel
Director European Directorate for the Quality of Medicines and Healthcare (EDQM), Council of Europe, EU

John Kerridge
Quality Leader, EU QA External Relations, Lilly, France

Andrei Kravchenko
Head of Office, Harrison Clinical Research, Ukraine

Jürgen Kübler
Global Head, Clinical Sciences, CSL Behring, Germany

Hubert Leufkens
Chairman, Medicines Evaluation Board (MEB), Netherlands

Hans Lindén
Leader European Projects, European Federation for Pharmaceutical Sciences (EUFEPS), Sweden

Marta Marcelino
Member CMDh, Medicines Evaluation Department, National Authority of Medicines and Health Products (INFARMED), Portugal

Rob Middel
Head of R&D Business Development, Pharmaceutical R&D Quality and Compliance Senior Director, Janssen Biologics, Netherlands

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Head of Regulatory Affairs & Quality Assurance, Boehringer Ingelheim, Turkey

Markus Pasterk
COO and VP of Science, International Prevention Research Institute, France

Jan Petracek
CEO, Director of Pharmacovigilance Services, Pharminvent, Czech Republic

Lidia Retkowska-Mika
Head Legal Unit, Office for Registration of Medicinal Products, Poland

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

Burkhard Sträter
Lawyer Kanzlei Sträter, Germany

Steven Teerenstra
Biostatistics Working Party (BSWP), Statistical Evaluator, Medicines Evaluation Board, Netherlands

Siniša Tomić
Counselor for European Affairs, Agency for Medicinal Products and Medical Devices, Croatia

Jan Willem Van der Laan
Senior Pharmacological Toxicological Assessor, Medicines Evaluation Board (MEB), Netherlands

Hans van Bruggen
Director, eCTDConsultancy, Netherlands

Nermeen Varawalla
Founder and CEO, ECCRO, UK

Maren von Fritschen
Managing Partner, Director Regulatory Affairs, PharmaLex, Germany

Ning Xu
Executive Director, Head of CDS, Covance Pharmaceutical R&D, China

SCHEDULE AT-A-GLANCE

SUNDAY, 3 MARCH 2013

Registration Hours:

10:00-18:00	Exhibitor Registration and Set-up
15:00-18:00	Attendee and Speaker Registration
	Avoid the rush on Monday by picking up your badge and conference material on Sunday afternoon
17:45-18:45	Students and Young Professionals Welcome Reception

MONDAY, 4 MARCH 2013

Registration Hours:

07:30-18:30	Attendee, Speaker and Exhibitor Registration
07:30-10:00	Exhibitor Set-up

Schedule:

09:00-12:30	Pre-Conference Tutorials
09:00-12:30	Student Sessions
11:00-12:30	Young Professional Session
12:30-14:00	Lunch in the Exhibition Hall
12:30-17:30	Conference and Exhibition Open
14:00-17:15	Opening Plenary Session
15:00-15:40	Coffee Break in the Exhibition Hall
17:30-19:00	EuroMeeting 25th Anniversary Reception in the Exhibition Hall

TUESDAY, 5 MARCH 2013

Registration Hours:

07:30-18:30	Attendee, Speaker and Exhibitor Registration

Schedule:

08:00-09:00	Welcome Coffee
10:00-18:30	Exhibition Open
09:00-10:30	Session 1 - Choose from Parallel Sessions
10:30-11:00	Coffee Break in the Exhibition Hall
11:00-12:30	Session 2 - Choose from Parallel Sessions
12:30-14:30	Lunch in the Exhibition Hall
12:30-13:15	DIA SIACs - Meet and Eat

TUESDAY, 5 MARCH 2013

13:30-14:00	Speed Networking Session
14:00-15:30	Session 3 - Choose from Parallel Sessions
15:30-16:00	Coffee Break in the Exhibition Hall
16:00-17:30	Session 4 - Choose from Parallel Sessions
17:30-18:30	The Tuesday Reception in the Exhibition Hall
17:45-18:15	Student Poster Award Ceremony at the DIA Booth

WEDNESDAY, 6 MARCH 2013

Registration Hours:

07:30-17:30	Attendee, Speaker and Exhibitor Registration

Schedule:

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

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A-Z of General Information

The 25th Annual EuroMeeting takes place at the:
Amsterdam RAI
Entrance C
Europaplein
NL 1078 GZ, Amsterdam, Netherlands

Attendee Lounge

The Attendee Lounge on the Exhibition Hall offers comfortable seating for conference participants to rest their feet, meet with colleagues or contacts, or catch up on emails. See Exhibition for opening hours.

Banking/ATM

There are two cash dispensers in entrance hall C.

Business Centre

Contact the Information Desk in the entrance hall C to get directions.

Monday	**09:00 - 17:00**
Tuesday	**09:00 - 17:00**
Wednesday	**09:00 - 17:00**

Café — Outside Exhibition Hall 11

The La Place Café is a pay-café selling drinks and snacks to keep you refreshed throughout the day located in front of Exhibition Hall 11.

Monday	**12:30 - 17:30**
Tuesday	**08:30 - 15:30**
Wednesday	**08:30 - 15:30**

Check-in for your Flight Online — Exhibition Hall 11

Save time by checking-in online and printing your boarding card at one of the Check-In Online terminals in the Exhibition Hall.

Certificate of Attendance — Entrance Hall

A Certificate of Attendance can be printed at the Scan-and-Go desks in the registration area on Wednesday.

Cloakroom/Baggage — Entrance Hall C

The cloakroom is in the Entrance Hall C.
There is a charge of € 2,- per coat and € 3.- per suitcase.

Monday	**08:00 - 19:30**
Tuesday	**08:00 - 19:00**
Wednesday	**08:00 - 18:15**

Conference Bags — Outside Exhibition Hall 11

All attendees with a full meeting registration can collect a conference bag from the Conference Bag Distribution Point in front the Exhibition Hall 11. Please bring the bag voucher you received when you collect your badge.

DIA Booth — Exhibition Hall 11

Find out more about all DIA can offer you. Stop by the DIA Booth on the Exhibition Floor. See Exhibition for opening hours

DIA Patient Fellowship Booth — Exhibit Hall (Booths 146/148)

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

Exhibition — Exhibit Hall 11

With many new companies exhibiting this year, the EuroMeeting exhibition offers more opportunities than ever to connect with attendees.

Monday	**12:30 - 19:00**
Tuesday	**10:00 - 18:30 Public Access 14:00 - 15:30**
Wednesday	**10:00 - 16:00**

Please see the exhibit floorplan on page 59.

Exhibitor Services — Exhibit Hall

The Exhibitor Services and Lead Retrieval Desks are located in Entrance Hall C. See Exhibition for opening hours.

First Aid — Exhibition Hall 11

A medical professional will be on duty during conference hours. Contact the Information Desk in the entrance hall C for assistance.

Get Involved in DIA — Exhibition Hall 11

Find out how you can propose an educational idea, volunteer to speak, join a DIA Community, submit an article for publication and lots more at the DIA booth.

Monday	**12:30 - 19:00**
Tuesday	**10:00 - 18:30**
Wednesday	**10:00 - 16:00**

Information Desks — Entrance Hall C

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

Monday	**08:00 - 19:00**
Tuesday	**08:00 - 18:00**
Wednesday	**08:00 - 16:00**

Internet Access — Exhibition Hall 11

Permanent workstations will be available in the Cyber Cafés in the Exhibition Hall. Wireless access is available in the Attendee Lounge.

Lost and Found — Entrance Hall C

All items will be stored at the DIA Query Desks in the entrance hall until the end of the conference.

Messaging Services — Entrance Hall C

Download the EuroMeeting conference mobile apps for iPhone and Android. A mobile web version is also available for BlackBerry. See the EuroMeeting Extra publication in your conference bag or ask for further information at a EuroMeeting Information Desk.

Search for "DIA Euro" in your iTunes or PlayStore

Posters — Exhibition Hall 11

Student, professional and patient representative posters will be displayed in the Exhibition Hall.

Come and talk to our student poster presenters during lunchtime on Tuesday between 13:00-14:00. A selected group of professional poster presenters will share their research results in various topics. Visit the Exhibition Hall to view the Posters.

Join us at the DIA booth on the Exhibition Floor for the Student Poster Award Ceremony on Tuesday at 17:45.

Press Office — Exhibition Hall 11

DIA welcomes qualified representatives of news organisations for the purpose of reporting and publishing/broadcasting articles/stories. All journalists must present a copy of their press credentials upon arrival at the press office in the main entrance hall where they can pick up their badges.

Monday	**12:30 - 19:00**
Tuesday	**10:00 - 18:00**
Wednesday	**10:00 - 16:00**

Refreshments — Exhibition Hall 11

Refreshments and Lunch will be served each day on the Exhibition Floor.

Monday

12:30-14:00	Lunch
15:00-15:40	Afternoon tea/coffee with snack

Tuesday

10:30-11:00	Morning tea/coffee with snack
12:30-14:30	Lunch (Extended lunch break)
15:30-16:00	Afternoon tea/coffee with snack

Wednesday

10:30-11:00	Morning tea/coffee with snack
12:30-14:30	Lunch (Extended lunch break)
15:30-16:00	Afternoon tea/coffee with snack

Complimentary tea/coffee served all day in the Attendee Lounge. Water dispensers are located around the Exhibition Hall.

Registration — Entrance Hall C

Registration is located in the main entrance hall.

Sunday	**15:00-18:00**
Monday	**07:30 - 18:30**
Tuesday	**07:30 - 18:30**
Wednesday	**07:30 - 17:30**

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 Amsterdam RAI.

Speaker Resource Centre — Holland Lounge

All speakers are required to visit the Speaker Resource Centre in the Amsterdam RAI and re-check their slides at least 2 hours before the start of their session(s).

Sunday	**15:00- 18:00**
Monday	**08:00- 18:00**
Tuesday	**08:00- 18:00**
Wednesday	**08:00- 16:00**

Tourism Information — Foyer Exhibition Hall/Holland Lounge

Iamsterdam (Amsterdam Tourism Office) in the foyer between the Exhibition Hall C and the Holland Lounge, on your way to session rooms. They will be happy to provide you with all the information you need to make the most of your stay in Amsterdam.

Monday	**12:30 - 17:30**
Tuesday	**09:00 - 18:30**
Wednesday	**09:00 - 16:00**

Alternatively, visit www.iamsterdam.nl

Transportation

Amsterdam RAI is easy to reach by both public transport or by car and has ample parking facilities on and outside its site. Amsterdam RAI is situated 8 minutes from Amsterdam's city centre and 15 minutes from Schiphol Airport.

By train

The RAI has its 'own' station, Amsterdam RAI which is located a stone's throw from the RAI complex and is easy to reach from anywhere in the Netherlands. When you leave the station follow the signs for Amsterdam RAI. For further information consult the NS [Dutch railways] travel planner by visiting: www.ns.nl.

By tram, metro or bus

Tram 4 runs between the RAI (Europaplein stop), Amsterdam's city centre and Amsterdam Central Station. You can reach the RAI from the Amstel railway station by taking Metro 51 and Bus 65. Metro 51 also runs to Amsterdam Central Station. Metro 50 runs regularly between the Amsterdam Sloterdijk and Gein stations and stops at the Amsterdam RAI station.

By car

The RAI is clearly signposted on roads signs on the ring road drivers end up on after approaching Amsterdam from the A1 motorway (Amersfoort/Amsterdam), the A2 (Utrecht/Amsterdam) or the A4 (Den Haag [The Hague]/Amsterdam). Amsterdam RAI is situated right next to the ring road (Exit 9). The RAI's car parks are signposted immediately after leaving the ring road.

Twitter

Tweet about the EuroMeeting using #EuroMeeting2013 and @DIA_Europe

AMSTERDAM 2013

OPENING PLENARY

MONDAY | 4 MARCH 2013 | 14:00-17:15

Opening Address
Aginus Kalis, Executive Director, Medicines Evaluations Board, Netherlands

Panel discussion

Public/Private Partnerships: Working together in the interest of patients

Public-private partnerships (PPP) are collaborative relationships which transcend national boundaries. Each partnership brings together at least a corporation or an industry association and intergovernmental organisations to achieve a shared health-creating goal on the basis of a mutually agreed division of tasks.

Considering the benefits that these initiatives can bring to the public health, the current goodwill and disposition of public and private sectors to move forward cannot be ignored. The positive aspects and concerns of these initiatives will be discussed.

Moderator
Steffen Thirstrup, Head of Division: Medicines Assessment and Clinical Trials, Danish Health and Medicines Authority, Denmark

Panel
Jan Geissler, Director, EUPATI, Belgium
Kemal Malik, Head of Global Development, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer, Bayer HealthCare Pharmaceuticals, Germany
Pat O'Mahony, Chief Executive, Irish Medicines Board, Ireland
Luca Pani, Director General, Italian Medicines Agency (AIFA), Italy
Andrzej Rys, Director of Health Systems and Products, European Commission, EU
Harpreet Singh, Managing/CSO, Immatics Biotechnologies, Germany

The DIA Award Ceremony will take place during the Opening Plenary

AMSTERDAM 2013

EUROMEETING 25TH ANNIVERSARY

Join us to celebrate the EuroMeeting 25th Anniversary!

EUROMEETING 2013 | 1988-2013
25 YEARS
DIA www.diahome.org

This year, our Monday Reception is a special one! Come and join us in the Exhibition Hall for a very special networking cocktail reception to celebrate the anniversary of the 25th EuroMeeting, as well as all past EuroMeetings, and many more to come.

Not only have we extended the reception by an extra half hour, but you can look forward to a few EuroMeeting Anniversary Surprises we have in store for you.

As usual, the Monday reception will provide an excellent networking opportunity for you to renew your existing contacts and to make new ones.

Monday, 4 March 2013 | Exhibition Hall 11 | 17:30 - 19:00

Regulatory Town Hall Meeting

Session 1207 | Wednesday, 6 March 2013 | 14:00-15:30
Session Co-Chairs:
Guido Rasi, Executive Director, European Medicines Agency, EU
Christa Wirthumer-Hoche, Member CMDh, Deputy Head, Austrian Medicines and Medical Devices Agency (AGES), Austria

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

- Latest views on legislative changes
- Implementation of the new pharmacovigilance legislation
- Transparency
- Drug shortages
- Decision making
- New approaches to licensing

Panelists:

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

Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, Medical Products Agency (MPA), Sweden

Aginus Kalis, Chair HMA, Medicines Evaluations Board, Netherlands

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

Satellite Session

Session 1904 | Tuesday 05 March 18:00-19:30
PHARMACEUTICAL LAW IN THE NETHERLANDS: BUILDING AN EU ASSOCIATION?
Session Chair:
John Lisman, Board Member of the VFenR, Lawyer, Lisman Legal Life Sciences, Netherlands

This special session will offer a showcase of the Dutch Pharmaceutical Law Association (VFenR) presenting Dutch case law with implications for other EU member states. Furthermore, the session aims at bringing together Europeans interested in pharmaceutical law to explore extension of the activities of the DIA Legal Affairs SIAC and the establishment of a European Pharmaceutical Law Association.

Dutch Case Law about Classification, Demarcation and Early Access to Medicinal Products
Koosje van Lessen Kloeke, Board Member of the VFenR, Pharma & Life Sciences Lawyer, Leijnse Artz, Netherlands

The Decentralised Procedure under National and EU Law: Examples
John Lisman, Board Member of the VFenR, Lawyer, Lisman Legal Life Sciences, Netherlands

The Dutch Pharmaceutical Law Association, Legal Affairs SIAC and a New European Association: A panel discussion
René van Ierschot, Partner, Barbers, Netherlands

Focus on the European Medicines Agency

Session 1805 | Wednesday, 6 March 2013 | 09:00-10:30
EMA ROUNDTABLE - SCIENTIFIC COMMITTEES UNITED IN DIVERSITY
Session Chair:
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU

This roundtable will discuss how the EU Scientific Committees come together and interact at the European Medicines Agency to foster scientific excellence in the evaluation and supervision of medicines for the benefit of public health, while at the same time being enriched by the EU's many different cultures and traditions.

Please see page 47 for more details

GCP Hot Topics

Session 1803/1804 | Tuesday, 5 March 2013 | 14:00-17:30
Session Co-Chairs:
Gabriele Schwarz, Head, GCP Inspection Services, German Federal Institute for Drugs and Medical Devices (BfArM), Germany
Beat Widler, Senior Partner, Widler & Schiemann, Switzerland

This session is now a "pièce de résistance" at the EuroMeeting. This year we will again review and discuss new trends in GCP, quality management in clinical trials and pharmacovigilance. As in previous years thought leaders from regulatory authorities, industry and academia will share new trends in an interactive session

Japanese Regulatory Session

Session 1806 | Wednesday, 6 March 2013 | 11:00-12:30
Session Chair:
Nobumasa Nakashima, Office Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The PMDA will explain the latest activities and Japanese regulation, and answer questions from the audience about PMDA's current situation, activities and future initiatives/challenges in reviewing and managing drugs through their life cycle.

Please see page 48 for more details

New Session

Session 1907 | Wednesday 65 March 14:00-15:30 | Room G109
PERSPECTIVES AND COLLABORATION BETWEEN PATIENTS AND STUDENTS

Facilitator:
Maria Mavris, Therapeutic Development Director, EURORDIS, France

Patient organisations are gaining increasing strength when voicing its members' concerns. Student organisations on the other hand have a long established and flexible perspective. This session will provide a brief overview of how these populations are organised and aim to pinpoint the aspects where collaboration will lead to synergy.

Student Representation
Milos Stojkovic, Vice President of Public Relations, European Pharmaceutical Students' Association (EPSA), Belgium, DIA Europe Intern, Switzerland

Patient Representation
Gerard Nguyen, President, Rett Syndrome Europe, Avicenne Hospital University Paris Nord, France

DIA Award Winners

The DIA Awards Ceremony at the 25th Annual EuroMeeting will take place during the plenary session on Monday, 4 March 2013 in the Auditorium. The plenary commences at 14:00. Please join us in recognising the contributions of our European award winners.

President's Award for Outstanding Achievement in World Health

Yann Le Cam
Chief Executive Officer, European Organisation for Rare Diseases, EURORDIS, France

Mr Le Cam has 25 years of professional experience, and personal commitment, in health and medical research non-governmental organisations in France, Europe and the United States in the fields of cancer, HIV/AIDS, genetic disorders and rare diseases.

EURORDIS is an International Non Governmental Organisation gathering over 500 member patient advocacy and support associations in 45 countries, therefore representing 30 million people living with rare diseases in Europe.
EURORDIS operates thanks to 25 staff persons, 60 volunteers and a budget of over 3 million euros.
EURORDIS is the largest European NGO in the health area of rare diseases in the European Union.
EURORDIS has forged the concept of rare diseases, promoted it as a public health priority and shaped the policy framework at EU and national level both on orphan drugs and rare diseases which translate now in seven different EU legislations and policies.
EURORDIS is active in the field of research, drug development, centres of care, information, social support, through capacity building of patients and patient representatives and advocacy.

Outstanding Service Award

Julianne Hull BSc MSc
CEO, WenStar Enterprises, UK

With over 20 years' experience in clinical development Julianne has successfully held global leadership roles in vendor management/outsourcing and clinical operations for several large pharmaceutical companies (Pfizer, Wyeth and Marion Merrell Dow). In these roles she has been an accomplished manager and motivator of staff based in China, India, Japan, Europe and US. Within Wyeth, Julianne developed, implemented and ran the key cross-functional governance body to drive successful delivery for inspection ready clinical trials.

Responsible for the strategic development and implementation of unique, quality and cost effective methods of outsourcing Clinical Data Management led to the establishment of the ground-breaking Wyeth Accenture strategic alliance in 2003. Julianne had business and operational oversight of the Wyeth/Accenture alliance through the acquisition of Wyeth by Pfizer in 2010.

Julianne has presented and chaired many sessions for DIA and is a recent alumnus of the Advisory Council for Europe. An active strategic driver for the DIA Clinical Forum, Julianne established the plenary debate a popular educational and entertaining tool to address challenging cross-functional questions.

Julianne is currently CEO of WenStar Enterprises a company she formed to provide consultancy to the pharmaceutical industry in the areas of clinical outsourcing and clinical operations.

Founders Service Award

Françoise Augier de Crémiers
FdC Consulting, France

Françoise Augier de Crémiers, Pharm D, BSc, ML, is currently CEO of FdC Consulting. Before she was Senior Vice President, Chief Scientific and Stakeholder Officer E/ME/A at Wyeth Pharmaceuticals.

She has more than 30 years of experience of global drug development and registration in Europe and in the US.

Currently she is advising small companies and start-ups on product development and registration strategies to be carried out in Europe and in the US.

Françoise has been actively involved in the DIA since 1989 as speaker, session chair, track chair and programme committee chair/ member. She chaired several DIA workshops (mostly on CTD, Clinical Study Report Guidance ICH E3 and Medical Writing).

Françoise was the programme chair of two DIA EuroMeetings (Paris 1995, Nice 2000). She was also the first European Programme chairperson of the US DIA Annual Meeting in Boston in 1998. Françoise was also track chair for Clinical Research and Development sessions in many DIA annual meetings such as the one at the DIA Annual Meeting in Philadelphia in 2006.

Françoise was the chair of the DIA Advisory Council of Europe (ACE), and a member of the DIA European Program Committee until 2009. She was also an active member of the DIA Board and is still actively joining DIA European meetings.

Outstanding Service Award

Angelika Joos
Executive Director Regulatory Policy EU & Most of World
Merck Sharp & Dohme (Europe) Inc., Belgium

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

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

She is a member of the DIA Advisory Council Europe since 2008 and has been involved in the organisation of several DIA Forums as well as two DIA EuroMeetings. She will co-chair the EuroMeeting in 2014.

Welcome to a new era for DIA Communities* (formerly SIACs)

Reaching around the world to create a global community!

**DIA Community is the new global name for DIA Special Interest Area Communities (SIACs). The new name will be adopted by June 2013.*

Meet colleagues who share your professional interests, share experience and knowledge

GET INVOLVED

DIA Booth 404 | Monday, 4 March 2013 12:30 – Wednesday, 6 March 16:00

Pick up your community ribbons, view a demonstration of the global community communications tool ConneX, and find out how to get more involved in DIA and what's in it for you:

- 33 communities exclusively for DIA members
- Network with specialists you wouldn't normally meet
- Keep your finger on the pulse of hot topics and shared learning
- Easier access to speaking opportunities

DIA COMMUNITIES MEET AND EAT

Onyx Lounge | Tuesday, 5 March 2013 | 12:30 – 14:30

New in 2013: Speakers Corner with Open Microphone

- Welcome from Community Leadership Council Chairs
- Talking point to share best practices and recent developments
- Launch of the Anti-Doping Community
- Selected Community Chairs available for discussion and present Community activities
- Your say!

SPEED NETWORKING

Topaz Lounge | Tuesday, 5 March 2013 | 13:30 – 14:00

- Get to know at least six new professionals in twenty minutes and have a laugh!
- Limited number of places, first-come, first-served

DIA COMMUNITIES:

- Anti-doping
- Biotechnology and Innovative Preclinical Sciences
- Chemistry, Manufacturing and Controls and Quality System
- Clinical Data Management
- Clinical Pharmacology
- Clinical Research
- Clinical Safety and Pharmacovigilance
- Clinical Trial Disclosure
- Devices and Diagnostics
- Document and Records Management
- eClinical
- Electronic Regulatory Submissions
- Emerging Professionals
- Evidence Based Medicine
- Global Sourcing
- Good Clinical Practices and Quality Assurance
- Information Technology
- Investigator and Investigative Sites
- Legal Affairs
- Marketing and Sales
- Medical Communications
- Medical Writing
- Medical Science Liaison
- Natural Health Products
- Paediatrics
- Professional Education, Training and Development
- Project Management
- Quality Risk Management
- Regulatory Affairs
- Statistics
- Study Endpoints
- Translational Medicine
- Validation

Professional Poster Authors

A selected group of professional poster presenters will share their research results in various topics.

Visit the Exhibition Hall to view the Professional Posters.

P1 **Swapu Banerjee, Deputy Managing Director, Pope Woodhead & Associates, UK**
Patient Reported Outcomes (PRO) in Safety Adverse Event Reporting – A New Framework

P2 **Henk Broekhuizen, University of Twente, Netherlands**
Integrating Elicited Patient Preferences and Clinical Trial Data in a Quantitative Model for Benefit-Risk Assessment

P3 **Paul Caldron, Arizona Arthritis and Rheumatology Associates, PC, US**
Why (not) go east?
Comparison of FDA Inspections from Central Eastern Europe (CEE) Western Europe (WE) and United States (US) Investigational Site Inspections

P4 **Fiori Giovanni, Scientific Director, EUCROF, Italy**
International Observational Studies: The Increased need for a Common European Regulation

P5 **Frank Holtkamp, Clinical Expert, Dutch Medicine Evaluation Board (MEB), Netherlands**
The role of the thorough QT study in Drug Development: A review of Centrally Approved Drugs in Europe (2009-2012)

P6 **Sherri Hubby, Director, US Quality Assurance, Premier Research, US**
Applying Quality by Design and Risk Management Strategies for selecting vendors to perform trials in emerging markets

P7 **Sherri Hubby, Director, US Quality Assurance, Premier Research, US**
Applying Risk Management Plan Strategies to Project Management /Monitoring in Electronic Data Capture (EDC) and Electronic Trial Master File (eTMF) Global Clinical Trials

P8 **Weng Lee, Medical Director, Quintiles, Ireland**
Determinants for Predicting Serious Adverse Event (SAE) Rates across Study Duration in selected Central Nervous System (CNS) indications.

P9 **Agata Lazowska, University of Bonn, Germany**
Comparative analysis of Spontaneous Adverse Drug Reaction reporting forms for Health Care Professionals in European Economic Area (EEA) Countries.

P11 **Laura Mulligan, Account Delivery Manager, Lifecycle Manager, Quintiles, Ireland**
A Review of Indexing used in MEDLINE and EMBASE as means of Facilitating the Identification of Adverse Drug Reactions.

P12 **Sinziana Oncioiu, Pharmacist, Terrapharm, Romania**
Evaluation of Medication errors in Paediatric Patients with Respiratory Diseases: a Community Pharmacy-Based Study

P13 **Kseniia Patushna, National University of Pharmacy, Ukraine**
Assessment of the Non-Therapeutic Factors Impact on the Accuracy of Clinical Parameters in Clinical Trials

P14 **Peter Schueler, Senior Vice President, Medical & Safety, ICON Clinical Research GmbH, Germany**
Do we measure Safety Case Reporting Compliance consistently across the EU?

P15 **Anika Staak, Senior Manager Drug Safety, ICON Clinical Research GmbH, Germany**
How Electronic is Electronic Reporting?

P16 **Egle Svitojute, Assistant of Pharmacology, Lithuanian University of Health Sciences, Lithuania**
Development of Experimental Nephrotoxicity Model in vivo and Assessment of its' Applicability for Stem Cell Research

P17 **Valdo Arnera, General Manager Europe, PHT Corporation, Switzerland**
Effective Use of Electronic Patient-Reported Outcomes (PROs) in Oncology

P18 **Bridget Walton, Director, Sunovion Pharmaceuticals Inc., US**
Comparison of Clinical Trial Application Approval Timelines of Global Studies for a Late Stage Investigational Compound

P19 **Charles Wilcox, Executive Director, Pharmacology Research Institute, US**
Research Fraud and Failed Clinical Trials via Fictitious Study Participants: is it an American or an International Problem?

P20 **Yang Yu, Dutch Medicine Evaluation Board (MEB), Netherlands**
The role of the thorough QT study in drug development: A review of centrally approved drugs in Europe (2009-2012)

Student Poster Authors

Poster Committee
Katrin Rupalla, Vice President, BMS, France
Peter Schiemann, Managing Partner, Widler & Schiemann, Switzerland
Aamir Shahzad, Director of Administration and Secretary General, International Society for Translational Medicine, Austria

Student abstracts selected by the student poster review committee, addressing similar topics to those in the programme, will be on display on the exhibition floor. Presenters will be able to discuss their work during the coffee and lunch breaks on Tuesday, 5 March. An awards ceremony will be held on Tuesday, 5 March at 17:45 at the DIA Booth in the exhibition hall to award the first, second and third-place student poster winners.

SP1 **Alan Abraham, University of Bristol, UK**
The Implementation of Global Access Licensing in Europe and North America and its role in improving Access to Biomedical Innovations

SP2 **Annaelle David and Hèlène Denis, Eudipharm, University Claude Bernard Lyon 1, France**
Tailored therapy based on Pharmacogenomic Parameters: an Update for Blood Pressure Lowering Drugs

SP3 **Myrthe Doeve, University of Utrecht, Netherlands**
Not all commercially available splitting devices are sufficiently accurate and precise to use in Clinical Practice

SP4 **Alice Fouretier, Claude Bernard Lyon 1, France**
Adverse Drug Reaction reporting by patients: a new European challenge?

SP5 **Yvonne Gautam, University of Copenhagen, Denmark**
Fixed dose/ fixed ratio Combinations: are current EU and US Regulatory Guidelines adequate?

SP6 **Jaroslaw Jarzebowski, Medical University in Wroclaw, Poland**
Socioeconomic costs of heroine dependence and evaluation of methadone maintenance therapy (MMT) from social perspective

SP7 **Raul Nicoara, University of Medicine and Pharmacy, Romania**
Enantiospecific interaction of propranolol stereoisomers with ß-cyclodextrin conjugated Ag nanoparticles probed by SERS

SP8 **Claudia Oliveira, Faculty of Pharmacy, University of Coimbra, Portugal**
DNA microencapsulation through external gelation

SP9 **Renaldas Pavydis, Lithuanian University of Health Sciences, Lithuania**
The assessment of hepatoprotective activity of wormwood (artemisia absinthium) medicinal plant in experimental study in vivo

SP10 **Natalija Peric, Faculty of Pharmacy, University of Belgrade, Serbia**
Synthesis, Chemical and Biological Characterization of 21-ester of fluocinolone acetonide with 2-isoxypropanoic acid

SP11 **Ana Preglav, Faculty of Pharmacy, University of Ljubljana, Slovenia**
Preparation and Evaluation of chitosan microspheres used for increasing permeability of urinary bladder wall

SP12 **Audrey Robin, Elodie Chaissac, Perrine Janiaud, Eudipharm, Claude Bernard, Lyon 1, France**
A checklist to assess the impact of the European Regulation n°1901/2006 on paediatric protocols quality

SP13 **Aditi Shah, Topiwala National Medical College, India**
Assessment of Disease Activity in Patients of Rheumatoid Arthritis on Disease Modifying Anti-Rheumatic Drugs (DMARDs)

SP14 **Migle Skadauskaite, Lithuanian University of Health Sciences, Lithuania**
Motherwort's extract effects on rat mesenteric arterioles

SP15 **Katja Srpan, University of Ljubljana, Slovenia**
Development of Specific Antibodies by the method of phage display for targeting the circulating tumor cells marker E-Cadherin

SP16 **Monika Turska, Medical University, Lublin, Poland**
Kynurenic Acid - A newly identified beneficial tea component

SP17 **Vladimir Vujovic, University of Belgrade, Serbia**
The influence of co medication and gender on lamotrigine pharmacokinetics in paediatric patients with epilepsy

SP18 **Karolina Zigaite, Lithuanian University of Health Sciences, Lithuania**
Role of Pharmacists in consulting patients for need of antibiotic treatment

Student Sessions

Session 1900a | Monday, 4 March 2013 | 09:00-10:30 | Room D201/D202

STUDENT SESSION 1

MAKING THE MOST OF THE DIA EUROMEETING IN ORDER TO ENTER THE INDUSTRY

Session Chair:
Manu Chhokra
Director of Operations and Business Development, CTC Clinical Trial Consulting, Switzerland

Introducing DIA EuroMeeting and Utilising its Oppurtunities
Milos Stojkovic, Vice President of Public Relations, European Pharmaceutical Students' Association (EPSA), Belgium, DIA Europe Intern, Switzerland

What you Need to Know about Regulatory Affairs and its Current Hot Topics
Marloes Van Bruggen, Regulatory Intelligence and Policies Manager, F.Hoffmann-La Roche, Switzerland

What is Behind Hiring Decisions?
Manu Chhokra, Director of Operations and Business Development, CTC Clinical Trial Consulting, Switzerland

Approach to Attracting, Hiring and Retaining Talent in the Pharmaceutical Industry
Kerry Bambrick-Satter, Global Staffing, Clinical Customer Delivery EMEA, Quintiles, UK

Session 1900b | Monday, 4 March 2013 | 11:00-12:30 | Room D201/D202

STUDENT SESSION 2

ENHANCING YOUR SOFT SKILLS BY IMPROVING YOUR EMOTIONAL INTELLIGENCE (EQ)

Session Chair:
Judy Churchill, Director, Language Consulting Services Ltd, United Kingdom/ France

Brief Overview/Introduction of Soft/EQ Skills Needed to Succeed in the Real World
Simona Lo Cascio Aganovic, Medical information Associate Specialist Pfizer, UK

Your IQ will have given you the qualifications that show you have the hard skills for the job but these are worth little today if you don't possess the right soft skills. Increasingly employers are paying as much, if not more attention to the level of Emotional Intelligence (EQ) a job applicant possesses as an indicator that they have the required soft skills for the job and can function as effective team members. This session will give you insights into the typical skills required and tips on how to improve your EQ.

DIA Young Professional Fellowship Programme

DIA welcomes the involvement of young professionals in the EuroMeeting. The following young professionals received a young professional fellowship for the EuroMeeting 2013:

- Sieta de Vries, University Medical Center Groningen, Netherlands
- Sebastian Eidam, WWU Munster, Germany
- Sara Green, Merrimack Pharmaceuticals, USA
- Gareth James, Phastar, UK
- Nikolina Kelava, Primapharme, Croatia
- Katrine Lind, Takeda Pharma A/S, Denmark
- Sinziana-Ioana Oncioiu, Terrapharm, Romania
- Léna Pédraut, Orphan Europe, France
- Niki Peiou, Pharmassist (CRO), Greece
- Andreea-Raluca, Ghinea, Novartis Consumer Health, Romania
- Kseniya Ratushnaya Clinical Diagnostic Center of National University of Pharmacy, Ukraine
- Egle Svitojute, Lithuanian University of Health Sciences, Lithuania
- Marko Veselinovic, Merck Sharp & Dohme, Serbia
- Yang Yu, Maastricht University, Dutch Medicine evaluation Board (CBG-MEB), Netherlands

DIA Patient Fellowship Programme

The Patient Fellowship, now in its eighth year, is a programme to promote the participation of representatives of patients' organisations in the EuroMeeting. Each year, DIA supports patients' representatives and speakers to attend the EuroMeeting by either offering full support or a registration fee waiver. The patients' representatives whom the DIA supported to attend the EuroMeeting in 2013 are:

- Nezabravka Asenova, Debra Bulgaria, Bulgaria
- Nicola Bedlington, European Patients' Forum, Belgium
- Vassiliki Biliou, Prader Willi Syndrome Hellas, Greece
- Jolanta Bilińska, Alliance of Patient Organisations (IAPO), Poland
- Manon Bosch, Dutch Adrenal Society, Netherlands
- Edward Callus, AICCA Italian GUCH Association, (Congenital Heart Disease), Italy
- Tove Cassoe, SLE-LED Lupus Network, Denmark
- Helene Cederroth, Wilhelm Foundation Ds, Sweden
- Mikk Cederroth, Wilhelm Foundation Ds, Sweden
- Gema Chicano, Association Ectodermal Dysplasia, Spain
- Philip Chircop, Malta Health Network, Malta
- Tatiana Dmitrieva, Federation of Patients with Rare Diseases from Central and Eastern Europe, Russia
- Mariette Driessens, Netherlands Haemophilia Society, Netherlands
- Efterpi Floka, Greek Alliance of Rare Diseases, Greece
- Breda Flood, European Federation of Allergy and Airways Diseases Patients Associations, Belgium
- Costin Radu Ganescu, Romania Thalassaemia Association, Romania
- Jan Geissler, EUPATI
- Sorin Gradinaru, Associatia Copilul Meu-Inima Mee (ACMIM), Romania
- Stanimir Hasardzhiev, European Liver Patients' Association, Belgium
- David Head, RP Fighting Blindness, UK
- Charo Hierro, Association of Affected by Ovarian Cancer (ASACO), Spain
- Sigurdur Johannesson, Alternating Hemiplegia of Childhood Association of Iceland (ACH)
- Julia Krapivkina, French Rett Syndrome, France
- Christine Lavery, Society for Mucopolysaccharide Diseases, UK
- Yann Le Cam, EURORDIS, France
- Eric Low, Myeloma UK
- Maria Mavris, EURORDIS, France
- Anna Meriluoto, Rare Disease of Finland, Fabry International Network, Finland
- Lise Murphy, Patients' and Consumers' Working Party (PCWP), EURORDIS, France
- Gerard Nguyen, Rett Syndrome Europe, Avicenne Hospital University Paris Nord, France
- Anders Olauson, European Patients' Forum, Sweden
- Kay Parkinson, Alstrom Syndrome, UK
- Chris Phillips, Behcets Syndrome Society, UK
- Andriy Shatillo, Foundation Children with Spinal Muscular Atrophy
- Jayne Spink, Tuberous Sclerosis Association, UK
- Danijela Szili, Hungarian Rett Syndrome Foundation, Hungary
- Christoph Thalheim, European Multiple Sclerosis Platform (EMSP), Belgium
- Oliver Timmis, Alkaptonuria Society (AKU), UK
- Masja van het Hoofd, Parkinson Vereniging (Dutch Parkinson's Disease Association), Netherlands
- Mary Lynne van Poelgeest-Pomfret, World Federation for Incontinent Patients (WFIP), Netherlands
- Ellen van Veldhuizen, Dutch Adrenal Society (Bijniervereniging NVACP), Netherlands
- Markus Wartenberg, Sarcoma Patients EuroNet e.V., Germany
- Joep Welling, NVLE Patient organisation for lupus, scleroderma and mixed connective tissue disease (MCTD), Netherlands
- Ariane Weinman, EURORDIS, France

Young Professional Session

Session 1900c | Monday, 4 March 2013 | 11:00-12:30 | Room D203/D204

YOUNG PROFESSIONALS IN THE PHARMACEUTICAL INDUSTRY

Session Chair:

Julianne Hull, Chief Executive Officer, WenStar Enterprises, UK

Allen Mayhew, Associate Director, Human Resources UK and Ireland, PPD, UK

Understanding clinical trials is a complex and constantly evolving process. We aim to provide an overview of the current and emerging roles that contribute to the delivery of clinical trials from pharma/biotech companies, from CROs and other service providers and how these roles interact with industry regulators.

This session will provide advice on how young professionals can maximise personal skills to enhance their career options. Some soft skills will be included e.g., aspects of global working, remote working, teleconferences and cultural understanding.

DIA Student Fellowship Programme

DIA Europe promotes the participation of students in the annual EuroMeeting by offering up to 15 complimentary registrations to full time undergraduate students and up to 5 complimentary registrations to graduate students.

- Baptiste Barbier, University of Burgundy, France
- Pedro Barroca, Faculty of Pharmacy University of Lisbon, Portugal
- Neli Boseva, Medical University, Sofia, Bulgaria
- Henk Broekhuizen, University of Twente, Netherlands
- Oner Deniz, KU Leuven, Belgium
- Guilherme Ferreira, Utrecht University, Netherlands
- Aleksandra Grković, Faculty of Pharmacy, University of Belgrade, Serbia
- Suzanne Jansen, University of Groningen, Netherlands
- Eliška Konigova, Charles University, Czech Republic
- Irem Konuk, Marmara University, Turkey
- Mara-Ioana Lefter, University of Medicine & Pharmacy Carol Davila, Bucharest
- Tiia Metiäinen, University of Helsinki, Finland
- Guilherme Monteiro Ferreira, Faculty of Pharmacy University of Lisbon, Portugal
- Tadeas Pesek, Charles University, Czech Republic
- Nikolaos Settas, School of Medicine, University of Athens, Greece
- Marija Todosijevic, Faculty of Pharmacy, University of Belgrade, Serbia
- Sander Van den Bogert, Utrecht University, Netherlands
- Diogo Viana, University of Lisbon, Portugal

Patient Networking Lunch

MONDAY, 4 MARCH 2013 12:45-13:45 | ONYX LOUNGE

Patients' Representatives Networking Lunch – Patient Representatives and Patient Speakers only

Facilitator:
Maria Mavris, Therapeutic Development Director, EURORDIS, France

An opportunity for Patient Representatives to meet and network with each other.

Award Ceremonies

Monday

DIA Volunteer Awards for Europe will be presented during the opening plenary session in the Auditorium. The plenary session starts at 14:00 on Monday. Please see page 8 for more details.

Tuesday

The Student Poster Award ceremony will take place at the DIA booth on the Exhibition Floor at 17:45.

Speed Networking

Tuesday, 5 March 2013 | 13:30-14:00 in the Topaz Lounge

EuroMeeting Speed Networking aims to facilitate conversations amongst participants. It will help you to make new contacts and intensify your networking experiences. The goal is to ensure that each participant will make at least six new professional contacts during the speed networking sessions.

DIA EUROPE 2013 TRAINING PROGRAMME

Safety and Pharmacovigilance

- **Benefit/Risk Management**

13-14 May 2013 | Zurich, Switzerland | ID 13523
26-27 September 2013 | Prague, Czech Republic | ID 13524

- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**

19-20 September 2013 | Paris, France | ID 13563

- **How to Prepare for Pharmacovigilance Audits and Inspections**

11-12 June 2013 | Nice, France | ID 13555
7–8 November 2013 | Paris, France | ID 13556

- **Pre-Marketing Clinical Safety**

18-19 April 2013 | Vienna, Austria | ID 13526

- **Signal Management in Pharmacovigilance**

10-11 June 2013 | Nice, France | ID 13557
6–7 November 2013 | Paris, France| ID 13558

European Medicines Agency Information Days and Courses

- **EudraVigilance Information Day**

17 May 2013 | London, United Kingdom | ID 13529
22 October 2013 | London, United Kingdom | ID 13530

- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**

18-22 November 2013 | London, United Kingdom | ID 13522

- **IDMP International Standards ICH M5/M2 and the Implementation of eSubmission of MPIs in the EU, Article 57(2) Information Day**

20 November 2013 | London, United Kingdom | ID 13531

- **EudraVigilance courses:**

EudraVigilance – Electronic reporting of ICSR
eXtended EudraVigilance Medicinal Product Dictionary
Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses.

For more information and a complete listing of all DIA conferences and training courses, please visit:

www.diahome.org > click on Meetings & Training

Call DIA Europe on +41 61 225 51 51 or email: diaeurope@diaeurope.org

PRE-CONFERENCE TUTORIALS
MONDAY, 4 MARCH 2013 | 09:00-12:30

Tutorial 1 — Room E104-105

HIGHLIGHTS OF THE IMPLEMENTATION OF THE NEW PHARMACOVIGILANCE LEGISLATION WITH REGARD TO ADVERSE REACTION REPORTING RULES, USE OF NEW INTERNATIONAL STANDARDS AND SIGNAL MANAGEMENT IN EUDRAVIGILANCE

Gro Laier, Deputy QPPV, Novo Nordisk A/S, Denmark
Sarah Vaughan, Pharmacovigilance Information Unit Manager Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Following publication of the new pharmacovigilance legislation in December 2010, the Commission's implementing measures for the performance of pharmacovigilance activities and the Good Pharmacovigilance Practices (GVP) replacing Volume 9A bring significant changes to the conduct of pharmacovigilance. Furthermore, the new ICH Individual Case Safety Report (ICSR) Implementation Guide will introduce substantial modifications to the format and content of electronic adverse reaction reporting. These changes have a big impact on the operational procedures and the day to day activities of stakeholders working in pharmacovigilance. This tutorial will focus on the impact of the changes in relation to the new reporting rules and requirements as set out in the Commission's Implementing Measures and the GVP Modules. It will also highlight the strengthening of the EudraVigilance System to improve transparency, data quality and to support signal detection and management activities in the EU. In addition, specific emphasis will be put on informing, explaining and helping stakeholders as how to apply the new rules taking into account the international standardisation and harmonisation activities and data privacy challenges.

Learning Objectives
At the conclusion of this tutorial, participants will be able to:
- Understand the adverse reaction reporting rules described in the new pharmacovilance legislation
- Describe the new international standards and terminologies for reporting to EudraVigilance
- Describe the obligations for marketing authorisation holders regarding signal detection and management

Target Audience
Qualified Persons Responsible for Pharmacovigilance Staff involved in:
- Pharmacovigilance in Companies and National Competent Authorities
- Clinical Data Management
- Regulatory Intelligence
- Information Management
- Safety Databases

Tutorial 2 — Room G104

ANALYSIS OF SAFETY DATA FROM CLINICAL TRIALS

Joachim Vollmar, International Clinical Development Consultants, LLC, USA
Andreas Brueckner, Quantitative Safety Scientist, Novartis Pharma AG, Switzerland

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 Contract Research Organisation (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:
- Understand relevant guidelines and regulatory requirements
- Contribute to safety analysis plans
- Assess statistical safety analyses
- Identify pitfalls in safety analyses

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

Tutorial 3 — Room G102

UPDATE ON PRACTICAL WORK WITH VARIATIONS UNDER THE REVISED REGULATION

Susanne Winterscheid, Head of Project Management of Licensing Division 3, BfArM, Germany
Maren von Fritschen, Managing Partner, Director Regulatory Affairs, PharmaLex, Germany

The aim of this tutorial is to focus on identified challenges and how they can be solved by common/pragmatic solutions and interpretations agreed by the different stakeholders. Furthermore, the tutorial will give an outlook to the situation when the Variation Regulation will also apply to purely nationally authorised licences and how the regulation and the corresponding guidelines have been changed in order to comply with the new pharmacovigilance legislation.

Learning Objectives
At the conclusion of this tutorial, participants will be able to:
- Operate variation applications adhering to all available guidance documents
- Identify and categorise variations correctly
- Recognise advantages and pitfalls of the Variation Regulation
- Elaborate strategies for grouping and work sharing
- Explain the impact of the implementation of the Variation Regulation for purely national licenses and apply changes related to the new pharmacovigilance legislation

Target Audience
Regulatory affairs professionals from industry involved in the strategic preparation, compilation, organisation and management of Variations in the EU for all procedures, Centralised Procedure (CP), Mutual Recognition Procedure (MRP), National Procedure (NP).

Tutorial 4 — Room G105

INTRODUCTION TO EU MEDICAL DEVICE REGULATION

Sabina Hoekstra-van den Bosch, Senior Manager, Standards & Regulations, Philips Healthcare - Global Quality & Regulatory, 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 behind it. It will explain the definition of a medical device and subsequently the delineation between medical devices and pharmaceuticals. Also the characteristics and the organisational structure of the medical device sector and the role of the various stakeholders in it will be highlighted. It will explain the concept of risk classification of medical devices and the relationship between risk classification and conformity assessment procedures. It will highlight the role of the notified bodies in the

system and the main provisions on clinical evaluation and clinical investigation. It will discuss the headlines of the EU regulation of In-Vitro Diagnostics, with a focus on the differences with the medical device regulation. The theoretical concepts will be illustrated with practical examples. Finally, an impression will be given of the impact of the main provisions in the future new Medical Device and IVD Regulations, which are currently being discussed in the legislative process in Brussels.

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

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

This tutorial provides a knowledge base for Theme 7, Devices & In-Vitro Diagnostics and Combination Products.

Tutorial 5 Room G103

RECENT AND CURRENT DEVELOPMENTS IN PHARMACEUTICAL LAW

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

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

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

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

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Discuss new and amended legislation in the EU
- Understand the implementation of this legislation and future developments

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

Tutorial 6

INCENTIVES FOR DRUG DEVELOPMENT: EXPAND YOUR REGULATORY INTUITION

Zaide Frias, Head of Regulatory Affairs, European Medicines Agency, EU

CANCELLED

This tutorial will present, in the light of an ever changing EU legislative environment, the recent incentives to drug development which are of scientific, financial and regulatory or procedural nature or a combination of those. The session will cover in detail the various data exclusivity provisions, the orphans, paediatrics and Advanced Therapy Medicinal Products (ATMPs) incentives as well as provide an insight into the experience with the operation of "early access tools" such as the accelerated review and the conditional and exceptional circumstances Marketing Authorisations (MAs) by the European Medicines Agency (EMA) and Committee for Medicinal Products (CHMP) so far.

Each aspect will be applied in practice through interactive case studies.

Learning Objectives
Having a detailed knowledge and early consideration of these incentives and tools should enable the participants in the session to expand their regulatory intuition; and as a result enable them to:
- Anticipate, plan and streamline the milestones for their drug development and registrations
- Develop a sound regulatory strategy optimising the use of the various incentives and tools
- Discuss advantages and disadvantages of different regulatory strategies for their business pipeline with concerned regulatory authorities

Target Audience
All persons involved in business intelligence, regulatory affairs, business pipeline and regulatory authorities.

Tutorial 7 Room G107

THE DIALOGUE AND NEGOTIATION PROCESS BETWEEN APPLYING COMPANY AND THE PAEDIATRIC COMMITTEE OF THE EUROPEAN MEDICINES AGENCY

Klaus Rose, Chief Executive Officer, KlausRose Consulting, Basel, Switzerland
Birka Lehmann, Director and Professor, Head of Executive. Department, P2 EU & International Affairs, BfArM, Germany

No new drug or biological can be submitted for marketing authorisation in the EU in adults, without an agreed Paediatric Investigation Plan (PIP) or a waiver from the European Medicines Agency (EMA). The development of a paediatric strategy can be divided into the three phases;

1. Strategic preparation and homework
2. The dialogue and negotiation procedure with the Paediatric Committee (PDCO) of the EMA
3. Follow-up activities including performing agreed studies & other measures, PIP modification(s), and finally the compliance check by EMA.

The EU paediatric legislation is exposing drug developers to new requirements. Applicant and EMA / PDCO may have different opinions about the necessary development steps. If the applicant cannot agree a PIP or a waiver with the PDCO, a negative opinion is possible, which will require submission of a new PIP/waiver application. It is EMA / PDCO'S responsibility to ensure access to safe and effective new medicines for children, while not delaying or preventing marketing authorisation of new drugs for adults.

This tutorial will focus on the dialogue and negotiation procedure during its different stages, from the submission of the initial letter of intent to the adoption of the final PDCO position and will present key learning's on frequently encountered difficulties/misunderstandings from EMA / PDCO and applying companies. The tutorial will be as interactive as possible and should help attendees reduce avoidable misunderstandings in the future.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
Recognise the key challenges in negotiating a paediatric investigation plan or a waiver; identify key misunderstandings in the PIP negotiation procedure; evaluate options in the PIP dialogue with both the EMA/PDCO.

Target Audience
Associates in regulatory affairs, medical affairs, clinical operations and project management who are involved with paediatric investigation plans (PIPs). Attendees interested in getting a hands-on feeling on how PIPs work.

Tutorial 8 Room E103

HEALTH TECHNOLOGY ASSESSMENT (HTA) OF DRUGS AND MEDICAL DEVICES

Katarzyna Kolasa, Head of Market Access Central Europe, Biogen Idec, Switzerland
Cynthia Iglesias Urrutia , Senior Research Fellow, University of York, UK

Health Technology Assessment processes have recently been introduced in a number of countries to facilitate health care decision making on reimbursement of both drugs and medical devices. This worldwide trend has highlighted a need to recognise the main characteristics of HTA and distinguish it from other evaluation processes. Similarly, the differences in product development and the regulatory framework for market access between medical devices and drugs have been perceived as an obstacle to conduct HTA in medical devices. In this tutorial we will describe both:
- Key components of a HTA process
- A framework to facilitate the implementation of HTA process of drugs and medical devices

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Recognise the distinction between key concepts in HTA (e.g. evidence-base and medicine, clinical effectiveness and Health Technology Assessment)
- Describe the necessary steps involved in an HTA process
- Understand the iterative nature of HTA processes
- Identify the way in which differences in product development and market access regulation impacts on HTA processes of drugs and pharmaceuticals

Target Audience
Individuals who in different capacities contribute to the preparation and submission of health technology dossiers to HTA regulatory agencies such as the National Institute for Health and Clinical Excellence, (NICE), UK

Tutorial 9 Room G109

THE EUROPEAN QUALIFIED PERSON (QP) FOR PHARMACOVIGILANCE; EVERYTHING YOU EVER WANTED TO KNOW BUT WERE AFRAID TO ASK

Brian Edwards, Principal Consultant, NDA Regulatory Science Ltd, UK
Vicki Edwards, QPPV/Senior Director, Affiliate Vigilance Excellence Global Pharmacovigilance, Abbott Laboratories, UK

EU legislation requires all marketing authorisation holders to have a Qualified Person for Pharmacovigilance (QPPV) with responsibility for establishing and maintaining all aspects of a marketing authorisation holder's (MAH's) pharmacovigilance system in the EU, as well as this system's interfaces with other regions of the world. The responsibilities of the QPPV apply wherever there is an active Marketing Authorisation (MA) for a product authorised in the EU/EEA. Thus the role in many companies has a global impact. During this tutorial we will discuss and advise on current practice to help address these and other issues.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Explain legal, regulatory and business implications of the QPPV function
- Describe the expectations of different stakeholders
- Understand the different approaches taken by various companies
- Gain better insight into the evolving requirements of regulators and inspectors

Target Audience
- Qualified person for pharmacovigilance
- Deputy qualified persons for pharmacovigilance
- Heads of pharmacovigilance or drug safety
- Pharmacovigilance auditors and inspectors
- Head of regulatory affairs

Tutorial 10 Room G110

NON-CLINICAL SAFETY ASSESSMENT IN GLOBAL PHARMACEUTICAL DEVELOPMENT

Klaus Olejniczak, Non-clinical Regulatory Consultant, Germany
Gerd Bode, Consultant, Germany

This tutorial has been prepared to provide attendees with an overview of the importance of non-clinical studies and where they fit in the pharmaceutical development.

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

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

Tutorial 11 Room G111

INTERACTIONS BETWEEN REGULATORY AND INTELLECTUAL PROPERTY, PRIVACY AND PRODUCT LIABILITY

Geneviève Michaux, Esq of Counsel, Covington and Burling LLP, Belgium
Jorg Hladjk, Senior Associate, Hunton & Williams LLP, Belgium

Interactions between, on the one hand, the regulatory regime and, on the other hand, intellectual property (paediatric regulation), privacy (clinical trials or pharmacovigilance), product liability (content of the SmPC) and competition (delay of generic entry), 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, privacy, product liability and competition 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, privacy, product liability and competition. This should allow the participants to have a broader perspective when approaching regulatory issues and to identify the possible ramifications of solutions. 45

minutes will be dedicated to each set of rules (intellectual property, privacy, product liability and competition), and the presentation of each set will emphasise the regulatory implications of the rules.

Learning Objectives

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

- Explain and discuss the basics of intellectual property, privacy, and product liability rules applicable to medicinal products
- Identify and better address the regulatory issues that present an intellectual property, privacy, or product liability aspect

Target Audience

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

Tutorial 12 Room E106

DEVELOPMENT SAFETY UPDATE REPORT (DSUR) KICK-OFF IN 2011; AND NOW IN PRACTICE

Margreet Ockhorst-Besijn, Senior Safety Executive, Vigilex B.V., Netherlands
David Lewis, Global Head of Pharmacovigilance, Novartis Pharma, Switzerland

The Development Safety Update Report (DSUR), introduced in 2011, is a much more comprehensive report with new sections, also requiring more input from various departments within a company. During the DSUR writing process, good oversight and project coordination is crucial. During the tutorial the various sections of the DSUR will be addressed. Examples of challenges faced will be presented and approaches towards handling of specific challenges as observed in various companies. The modular approach and the interface with the Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP) will be addressed. Managing a DSUR project will also be an important section of this tutorial.

Learning Objectives

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

- Manage a DSUR project effectively and efficiently
- Explain the general principles of DSUR preparation and submission
- Describe the relationship between the DSUR and the Periodic Safety Update Report (PSUR)
- Outline the content of DSUR sections as described in ICH E2F guideline
- Interpret the guidelines and translate into practice

Target Audience

- Pharmacovigilance (PV) staff and medical staff involved in medical writing of DSURs
- PV staff and medical staff involved in medical writing of other periodic reports (PSURs, RMPs)
- Clinical/regulatory and other staff involved in medical writing of DSURs
- Staff involved in the review of DSURs

Tutorial 13 Room G106

TECHNOLOGY TRANSFER FOR BIOPHARMACEUTICALS

Richard Dennett, Director, Voisin Consulting Life Sciences, France

Technology Transfer, such as change of manufacturing site or scale, is crucial during the product/process development lifecycle. Poor planning, management and execution of technology transfer can result in major project impact and cause several months delay at each occurrence, leading to a cumulative effect on cost and time, and delayed clinical material. In this tutorial we will provide an overview of some of the practices and principles of Technology Transfer including process and analytical methods transfer and acceptance criteria, process and product comparability, risk management, outsourcing, regulatory guidance, as well as including case studies. The tutorial will be highly interactive with team based practical exercises which will examine the basic concepts of technology transfer and progress this through to real life scenarios. The tutorial will provide you with the basic tools of technology transfer enabling you to plan effectively and limit the risk of technology transfer on the critical path.

Learning Objectives

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

- Recognise the fundamental concepts and different stages of Technology Transfer
- Translate the principles of technology transfer into working practice

Target Audience

Scientists and managers working in the areas of process and analytical development, current good manufacturing practices (Cgmp), strategic decision making

Tutorial 14 Room E107

PHARMACOVIGILANCE AUDITS AND INSPECTIONS

Leonardo Ebeling, Managing Director, Dr. Ebeling & Associates, Germany
Patricia Moore, Operations Manager GCP/PV, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Every Pharmacovigilance (PV) department undergoes pharmacovigilance inspections by regulatory or health authorities as well as internal audits and audits conducted by service providers or partners. It is important to know how to handle audits and inspections and how to respond to requests and findings. In order to support the implementation of and compliance with the new legislation for Marketing Authorisation Holder s (MAHs) we focus on the discussion of specific PV issues becoming more important in line with the new legislation and presenting the most challenging areas, such as;

- Quality Management and Quality Assurance within the PV System
- Continuous Benefit Risk Assessment including signal detection
- Risk Management Plan (RMP) and expedited Periodic Safety Update Report (PSUR)

To avoid deficiencies in inspections and to understand the expectations of authorities, it is important to know how to handle audits and inspections and how to respond to requests and findings. In this context, the MHRA will give an overview on the inspection process, actions required by MAHs and follow-up actions once the inspection has been completed as well as common issues that have been noted on inspection following implementation of the new legislation. During this tutorial, the challenge of combining different PV systems and the obligation to comply with national, as well as international legislation will be addressed. We will focus in particular on the interaction between the PV responsible person nominated at national level, EU-QPPV and the Global PV responsible person, their responsibilities and an adequate safety data exchange process for an overall functional PV System. This tutorial will provide participants with hands-on knowledge of their legal responsibilities in a global environment.

Learning Objectives

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

- Understand the challenges of national and international regulatory PV legislation in light of common issues seen on inspection
- Create audit plans which anticipate the activities of regulatory PV inspections
- Respond to PV audit/inspection questions and/or requests in a comprehensive and structured way

Target Audience

Professionals who work in:

- Pharmacovigilance / Drug Safety
- Regulatory Affairs
- Quality Management
- Compliance

Tutorial 15 Room G101

CODING WITH CONFIDENCE

Tomás Moraleda García, International Medical Officer, MSSO (Maintenance and Support Services Organisation), Spain
Hilary Vass, Global Clinical Dictionary Manager, AstraZeneca, UK

Coding conventions promote consistency in term selection and facilitate a common understanding of the MedDRA-coded data that is shared with regulatory authorities, within companies, and in collaborations with development and marketing partners. This tutorial will present an overview of the key principles described in the ICH-endorsed "MedDRA Term Selection", "Points to Consider" (MTS:PTC) document to provide a framework for the consistent and medically accurate coding of clinical data. Practical approaches will be demonstrated. The focus will be on common coding challenges (such as combination terms) and on the newer sections in the MTS:PTC such as medication errors, device-related terms, medication exposures, and product quality issues. Participants will have the opportunity to apply term selection principles by engaging in practical coding exercises with different types of clinical data. In an interactive group setting, participants will be encouraged to share best practices and discuss solutions to coding challenges that they have encountered in their daily work.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Describe how to code clinical safety data accurately and consistently with MedDRA
- Apply the principles described in the ICH-endorsed "MedDRA Term Selection: Points to Consider" document

Target Audience
This workshop is designed for coders who already have experience using MedDRA and who wish to become more confident in their ability to perform medically accurate and consistent term selection.

Tutorial 16 Room E108

UNDERSTANDING TRANSLATIONAL MEDICINE

Aamir Shahzad, Director of Administration and Secretary General, International Society for Translational Medicine (ISTM), Austria

The goal of Translational Medicine (TM) is to expedite the development of newly identified compounds to enhance the patient's quality of life. Translational Medicine is the synergy between epidemiology, basic research and clinical trials. In the recent past, TM has gained significant importance due to its promising role for accelerating Research and Development in academia and industry. Translational Medicine has great potential to enhance health-care starting from prevention, diagnosis, and drug/device developments for clinical disorders. However, there are few clinician/scientists critically trained in translational research and more programmes to foster their development are required. This tutorial will provide an overview of the Translational Medicine field including definitions and concepts, potential benefits as well as global initiatives and programs. This tutorial will help the professionals working at various positions in pharma, biotech, medical device industries and academia to better understand Translational Medicine.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Describe translational medicine definitions, concepts and potential benefits for industry and academia.
- Describe global translational medicine initiatives and programmes

Target Audience
- Pharmaceutical, Biotechnology and Medical Device fields, professionals seeking better knowledge and understanding of Translational Medicine.
- Head/VP/director/senior managers, pharmaceutical/ biotechnology/ healthcare
- Research and Development Personals
- Clinical Services / Clinical Trials Personals
- Medical affairs persons
- Medical directors
- Medical advisors
- Medical science liaison
- Clinical investigators
- Clinical research associates
- Clinical trial leaders and managers
- Clinician research physicians

Tutorial 17 Room G108

CREATING COMPLIANT CLINICAL STUDY REPORTS (CSRS) FOR THE EU AND US

Nancy Smerkanich, Vice President Regulatory Affairs Consulting, Octagon Research Solutions, USA
Teresa Eastwood, DRA Operations Group Leader, Actelion Pharmaceuticals, Switzerland

This tutorial will examine the myriad of issues around the authoring and publishing of clinical study reports and their related components for submission to the US and EU. This includes but is not limited to granularity, hyperlinking and bookmarking best practices, content of appendices and the relationship between tables, figures and listings. Not all CSRs are created equally and the US requirements for additional components such as case report forms and datasets will also be addressed. An industry perspective will focus on the change management required to move from legacy clinical study reports to a granular report and its utilisation across Europe will also be presented. Demonstrations of published clinical study reports will be used as teaching aid.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Evaluate legacy formats and the need to employ granularity in creating CSRs
- Understand and utilise granular CSRs for submissions in both the US and EU
- Be aware of unique requirements that support US submissions and are associated with clinical study reports (datasets and case report forms)
- Establish best practices for publishing standards for clinical reports utilising ICH E3

Target Audience
- Regulatory Operations
- Medical Writing
- Biometrics/Clinical Programming
- Clinical Operations

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Tutorial 18 - Roundtable Discussion Room E102

GCP INSPECTION AND AUDIT FINDINGS

Gabriele Schwarz, Head, GCP Inspection Services, German Federal Institute for Drugs and Medical Devices (BfArM), Germany
Beat Widler, Senior Partner, Widler & Schiemann, Switzerland

During the course of Good Clinical Practice (GCP) Inspections some important themes are identified by the inspectors as being common to multiple inspections. In a similar way GCP auditors working for industry identify key issues of concern. This roundtable provides an opportunity to identify and discuss some of these key findings with a panel of GCP inspection experts from regulatory authorities and GCP audit experts from industry/academia. The topics selected for discussion will be chosen, by the panel, from responses to a short questionnaire circulated to registered participants.

Discussion Objectives
The purpose of this roundtable is to provide an opportunity for open, timely discussion of key GCP issues arising from inspection and from audits:
- Establish a common understanding of inspection and audit findings and their basis in regulation, guidance and quality principles
- Build consensus on the priority issues for resolution
- Better evaluate audit and inspection findings and their impact on GCP compliance and the ethical and scientific validity of clinical trials
- Update on new issues/initiatives of regulators and of auditors
- Discuss how inspectors are implementing new legislation and guidelines such as risk-based approach to clinical trials

Target Audience
- GCP compliance auditors and management, and staff with GCP related QC responsibilities from both industry and academia
- Clinical research management and project leaders from both industry and academia
- GCP inspectors

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- **Global CTD Dossier – Regulatory aspects and focus on quality documentation including concepts of Quality by Design**
  1-3 December 2013 | Dubai, United Arab Emirates | ID 13562
- **Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators**
  11-13 September 2013 | Vienna, Austria | ID 13559

Clinical Research

- **Advanced GCP Study Monitoring**
  5-6 June 2013 | Basel, Switzerland | ID 13549
- **Clinical Aspects of Quality Risk Management and Quality by Design**
  19-20 September 2013 | Basel, Switzerland | ID 13560
- **Clinical Project Management – Part I**
  18-20 September 2013 | Basel, Switzerland
- **Clinical Project Management – Part II**
  Dates and location to be confirmed
- **Clinical Statistics for Non-Statisticians**
  24-25 October 2013 | London, United Kingdom | ID 13551
- **Essentials of Clinical Study Management**
  17-19 April 2013 | Vienna, Austria | ID 13527
  20-22 November 2013 | Paris, France | ID 13554
- **Practical GCP Compliance Auditing of Trials and Systems**
  23-25 October 2013 | London, United Kingdom | ID 13548

Non-Clinical Safety Sciences

- **Non-Clinical Safety Sciences and Their Regulatory Aspects**
  November 2013 | Lisbon, Portugal

Regulatory Affairs

- **Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe**
  18-20 September 2013 | Basel, Switzerland | ID 13546
- **European Regulatory Affairs: In-depth review of current registration procedures in the European Union**
  6-7 June 2013 | Basel, Switzerland | ID 13550
  21-22 November 2013 | Paris, France | ID 13553
- **Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices**
  10-12 June 2013 | Amsterdam, the Netherlands | ID 13547
- **Health Authority Interactions – Preparation, consultation and implementation**
  15-16 October 2013 | Location to be confirmed
- **Health Technology Assessment (HTA)**
  26-27 November 2013 | Zurich, Switzerland | ID 13561
- **Paediatric Investigation Plans (PIP)**
  15-16 April 2013 | Amsterdam, the Netherlands | ID 13503
- **The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)**
  2-4 October 2013 | Basel, Switzerland | ID 13532
- **US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US**
  6-8 November 2013 | Paris, France | ID 13552

Theme 1 | Health Technology Assessment (HTA)/ Sustainability of Health Systems in Europe

Luca De Nigro, Coordinator, Drugs Monitoring Registers Unit, Italian Medicines Agency, Italy
Lidia Retkowska-Mika, Director Legal Department, Offices of Medicinal Products, Medical Devices and Biocides, Poland

There is no doubt that the criteria for authorising the medicinal product to be placed on the market are distinctly different from those applied to Health Technology Assessment and the two procedures have different objectives. However, in recent years efforts have been undertaken to define a link between the two procedures, which may facilitate the product development and coherent data collection for both processes. Recent EU pharmacovigilance legislation has added new instruments which may be helpful to bring closer regulatory activities and HTA and this theme will be devoted to discussion on the new developments in this area.

Session 0102 | Tuesday, 5 March 2013 | 11:00-12:30 | Room G107

THE EUROPEAN LANDSCAPE ON HTA - THE EUnetHTA JOINT ACTION

Session Chair:
Finn Børlum Kristensen, Secretariat Director Chair, EUnetHTA Executive Committee, Denmark

The aim of this session is to introduce the current scenarios of HTA in the European context. In particular, three points of view are considered as significant in order to match the highest purposes of dissemination of HTA methods and finalities: the status of the European Network for Health Technology Assessment (EUnetHTA) joint action, one of the most collaborative experiences among stakeholders in Europe, the engagement of industry as key partner for institutions to have results in terms of improved medicines and sustainability for healthcare systems and the perspective of patients as the final target of a complex and challenging process.

The European landscape on HTA – Update on the EUnetHTA Joint Action
Finn Børlum Kristensen, Secretariat Director Chair, EUnetHTA Executive Committee, Denmark

Improving Collaboration between Industry and Regulatory world: HTA as a pivotal challenge to match wider needs
Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

The European Landscape on HTA - The EUnetHTA Joint Action
Eric Low, Chief Executive, Myeloma UK

Session 0103 | Tuesday, 5 March 2013 | 14:00-15:30 | Room G107

COMPARATIVE EFFECTIVENESS AS PART OF THE PUBLIC ASSESSMENT REPORT (PAR)

Session Chair:
Margaret Vernon, Research Scientist Centre for Health Outcomes Research, United Biosource, UK

Benefits of comparative effectiveness research in evaluating medicines, in terms both of health and costs, have been widely discussed during last several years. There is a general accordance that comparative data, above all coming from the real world of clinical practice, are a key factor to verify and describe the actual potential of new and old drugs. The session will be focused on fieldwork from industry, healthcare centres and institutions with the aim of suggesting guidelines and better-focused policy making decisions.

How Can Public Assessment Reports Contribute to Relative Effectiveness Assessments?
Speaker invited - see EuroMeeting Extra for details

Integrated Patients Care Pathways for Evaluating Real-World Outcomes
Marisa De Rosa, Head of Systems and Services for Health Department (SISS), CINECA Inter University Consortium, Italy

The Evolution of Public Assessment Reports for Increased Regulatory Transparency in Europe
César Hernández García, Head of Department, Department of Medicines for Human Use, Spanish Agency for Medicines and Medical Devices (AEMPS), Spain

Session 0104 | Tuesday, 5 March 2013 | 16:00-17:30 | Emerald Room

HTA AND PRICING POLICIES IN EU AFTER THE TRANSPARENCY DIRECTIVE

Session Chair:
Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

The EU Transparency Directive has been in force since more than 20 years. The European Commission has proposed to update the directive and to also subject HTA to the procedural rules, (including timelines) of the directive. The proposal is currently under discussion in Council and the European Parliament. Regardless of the outcome of these discussions, HTA is at the core of EU policy-making on pharmaceuticals. This session will explore the latest developments of the directive and discuss how the legal framework for HTA is evolving.

HTA in Europe: Within or outside the Directive - does it make a difference?
Andrea Rappagliosi, Vice-President Market Access, Sanofi Pasteur MSD, Co-chair of EFPIA's HTA Task Force, France

Session under development - see EuroMeeting Extra for details

Session 0105 | Wednesday, 6 March 2013 | 09:00-10:30 | Room G107

FOCUS ON MANAGED ENTRY AGREEMENTS (AND REAL WORLD DATA)

Session Chair:
Luca De Nigro, Coordinator, Drugs Monitoring Registers Unit, Italian Medicines Agency, Italy

Managed Entry Agreements (MEA) are arrangements between manufacturers and payers that enable access, or coverage, to medicines under predefined conditions. In recent past years, the growing use of MEAs in Europe has been one of the notable novelties in healthcare decision making - this methodology, in fact, allowed to address uncertainty about the performance of drugs or maximise their effective use in the real context of clinical practice, possibly limiting uncontrolled budget impacts.

New Therapeutic Paradigms, Real-life Data Development and Adaptive Health Technology Assessment
Paolo Morgese, Director of Research, Deerfield Institute for Healthcare Research, Switzerland

Early Benefit Assessment in Germany – Impact on pricing and licensing in the EU
Burkhard Sträter, Lawyer, Kanzlei Sträter, Germany

How to Manage Risks and Obtain Benefits with Wide Collaboration among Stakeholders - Examples on the field
Eric Low, Chief Executive, Myeloma UK, UK

Session 0106 | Wednesday, 6 March 2013 | 11:00-12:30 | Room G103

THE IMPACT OF THE NEW PHARMACOVIGILANCE LEGISLATION INSTRUMENTS ON HTAs

Session Chair:
Wolfram Hildebrandt, Head of Health Technology Assessment/ Head of Pharmacovigilance, PharmaLex, Germany

Ensuring patient safety is a fundamental aim in the context of the New European Pharmacovigilance Legislation; nevertheless, new pharmacovigilance instruments, as more patient-centred systems, have a potential deep impact on all aspects of drug development and assessment. The possible role of industry in interaction with patients and the way HTA bodies are committed to modify their way of thinking at risk management are underlying topics discussed in this session.

HTA and Pharmacovigilance Data in the Changing World of Regulations
Wolfram Hildebrandt, Head of Health Technology Assessment/ Head of Pharmacovigilance, PharmaLex, Germany

How Will Health Technology Assessment Interface with Pharmacovigilance in a Pharmaceutical Company and in a Regulatory Agency?
Thomas Lönngren, Strategic Advisor, NDA Group, UK

The Impact of the New Pharmacovigilance Practice on HTA
Adam Przybyłkowski, Member of PRAC, Associate Professor Department of Clinical and Experimental Pharmacology, Medical University of Warsaw, Poland

Session 0107 | Wednesday, 6 March 2013 | 14:00-15:30 | Room G103

THE PATIENT'S PERSPECTIVE ON HTA

Session Chair:
Anders Olauson, President, European Patients' Forum, Sweden

Patients are now at the very centre of many policy decisions in the context of drug development, assessment and administration. Nevertheless, while the direction of travel is well traced, many are the points still to study in depth in order to have an effective application on patient and healthcare systems. Engaging patients in clinical trials design, including patient representatives in HTA bodies, and improving transparency in decision making are only examples of good practices to encourage.

Health Technology Innovation in Hospitals and Patients' Perception
Marco Marchetti, Director Health Technology Assessment Unit, Policlinico Universitario "Agostino Gemelli", IT

Involving Patients in Research as a Key Factor for Better HTAs
Chris Kula-Przezwanski, Partnering Director, Digital Patient Unit, Quintiles, UK

The Patient's Perspective on HTA
Jolanta Bilińska, Secretary, International Alliance of Patient Organizations (IAPO), Poland

Session 0108 | Wednesday, 6 March 2013 16:00-17:30 | Emerald Room

HTA AND OFF-LABEL USE

Session Chair:
Lidia Retkowska-Mika, Director Legal Department, Offices of Medicinal Products, Medical Devices and Biocides, Poland

Off-label use of medicinal products entails issues related to its legal aspects, its impact on HTA and reimbursement, its influence on strategies of marketing authorisation holders and the shaping of expectations of patients from their healthcare systems. The session will be devoted to presentations of views on these issues from different angles, with the opportunity to discuss the extent to which the assessment of off-label use of medicinal products should become part of HTA .

Legal Constraints on Off Label Use and HTA and Reimbursement Decisions
Peter Bogaert, Partner, Covington & Burling LLP, Belgium

Off-Label Use of Medicinal Products - A solution for the healthcare system or escape from cost for Marketing Authorisation Holder?
Anna Cieślik, Director, Department of Documentation Assessment, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland

The "Incurable" Patients' Perspective
David Head, Chief Executive, RP Fighting Blindness, UK

Theme 2 | Development of Medicinal Products for Paediatric, Elderly and Other Special Populations

Gesine Bejeuhr, Regulatory Affairs/Quality, vfa Research-Based Pharm Companies, Germany
Markus Pasterk, COO and VP of Science, International Prevention Research Institute, France

Special populations such as children, the elderly or ethnic minorities require particular attention during drug development. As for the younger population, the Paediatric Regulation started slowly to deliver better and more data for medicines used in children. The European Commission's conclusions after five years of experience are eagerly awaited and should be discussed here. Practical solutions for questions during paediatric clinical trials will be presented.

The changing demography with a dramatic increase of the elderly causes reconsideration in other aspects. Multiple conditions and specific settings and other specific difficulties to perform clinical trials in the elderly and practical experience will be shared on design, modelling and recruitment. The European Commission launched the initiative "healthy ageing" and has funded several new research projects for which first results will be presented. These cohort studies and developments in the biobanking domain form innovative new tools for drug development and testing. These initiatives will be presented and analysed.

Session 0201 | Tuesday, 5 March 2013 09:00-10:30 | Emerald Room

MECHANISM OF ACTION – THE LEADING PARADIGM

Session Co-Chairs:
Henk van den Berg, Member Paediatric Committee, Medicines Evaluation Board, (MEB), Netherlands
Max Wegner, Head Global Regulatory Affairs, General Medicine, Bayer Healthcare Pharmaceuticals, Germany

PDCO's leading paradigm shifted more towards assessing the mechanisms of action during the assessment of Paediatric Investigation Plans (PIPs). How does this influence the development of medicinal products? This will be explored with practical examples in oncology.

Mechanism of Action - The leading line
Daniel Brasseur, PDCO Chairman, General Directorate Medicine, Federal Ministry of Public Health (AFMPS), Belgium

Model PIPs in Oncology - The way forward?
Henk van den Berg, Member Paediatric Committee, Medicines Evaluation Board, (MEB), Netherlands

Clinical Development in Oncology – How to draft the PIP?
Raphaël F. Rousseau, Associate Group Medical Director, Product Development Oncology Global Development Team Leader, Pediatrics, Genentech, USA

Session 0202 | Tuesday, 5 March 2013 | 11:00-12:30 | Emerald Room

COHORT STUDIES OF THE ELDERLY AS A TOOL FOR DRUG DEVELOPMENT AND TESTING

Session Chair:
Markus Pasterk, COO and VP of Science, International Prevention Research Institute, France

Large-scale longitudinal studies are ongoing in many countries, which include elderly populations. These studies typically comprise a good assessment of comorbidities and other risk factors, as well as prospective outcome assessment. They represent a potentially useful tool to develop ad hoc projects for drug development and testing. The overarching goal of the session will be to offer a discussion forum on the possible use of large-scale observational studies for drug development and testing studies. The session will comprise a presentation of a large consortium of prospective studies of elderly in Europe and North America (the CHANCES Consortium), a discussion of the advantages and limitations of observational studies for drug development, and a critical assessment of the important of pharmacologic interventions in healthy aging.

Opportunities in the CHANCES Consortium
Paolo Boffetta, Director Institute for Translational Epidemiology, Mount Sinai School of Medicine, USA

Drug Development in Dementia Disease - The interplay of observational studies and experimental interventions studies
Sture Eriksson, Community Medicine and Rehabilitation, Umeå University, Sweden

Biobanking as a Tool for Drug Development within Special Populations
Kurt Zatloukal, Professor of Pathology, Medical University Graz, Austria

Session 0203 | Tuesday, 5 March 2013 | 16:00-17:30 | Emerald Room

DEVELOPMENT OF INNOVATIVE INTERVENTIONS FOR HEALTHY AGEING: HOW FAR DID WE GET?

Session Chair:
Susanna Del Signore, Associate Vice President, Global Regulatory Affairs, Sanofi, France

One year after the call for European Innovation Partnership on Healthy and Active Ageing by the European Commission, one ongoing programme will be presented by its respective Partnership representative and subsequently discussed. The main objectives, intervention outlines and identified bottlenecks (e.g. methodology, business model, and regulatory aspects) will be opened to discussion. This will focus on actual expected benefits for older people and industrial sustainability of the innovative interventions.

CHMP-assessment templates – do they lead to new knowledge?
Catherine Deguines, National Agency of Medicine and Health Product Safety (ANSM), France

The Contribution of New Drugs to Healthy Ageing
Deborah Gustafson, Associate Professor, Neuropsychiatric Epidemiology, University of Gothenburg, Sweden

Session 0205 | Wednesday, 6 March 2013 | 09:00-10:30 | Emerald Room

HOW TO OPTIMISE CLINICAL DEVELOPMENT IN THE ELDERLY: SOME PRACTICAL EXAMPLES

Session Chair:
Solange Rohou, Director, European Regulatory Affairs, AstraZeneca, UK

Populations are ageing thereby increasing the need to provide the elderly with effective and safe medicines. Frailty may limit participation in clinical trials and other ways of gaining knowledge need to be explored despite obvious recruitment challenges. This session will focus on clinical development in the elderly and how it can be optimised. Through specific practical case examples this session will provide an insight on how to improve recruitment, how to innovate when collecting data or when designing studies by use of Modelling and Simulation.

How to Optimise Patient's Recruitment
Florian von Raison, Global Program Head, Novartis, Switzerland

How to Optimise Data Collection in the Elderly
Valdo Alnera, General Manager Europe, PHT Corporation, Switzerland

How Modelling and Simulation Can Optimise Drug Development
Eva Bredberg, Director of Global Clinical Pharmacology, AstraZeneca, Sweden

Session 0206 | Wednesday, 6 March 2013 | 11:00-12:30 | Emerald Room

PAEDIATRIC CLINICAL TRIALS – TRIAL DESIGN

Session Chair:
Martine Dehlinger Kremer, Chair of the Paediatric Working Group, EUCROF & Global Vice President, Regulatory Affairs, RPS Research, Germany

The session will provide a comprehensive overview, assessment and understanding of the development of medicinal products and clinical trials for paediatrics. A general learning along with more specific and relevant challenges that occur throughout the design and realisation of clinical trials in children will be given. Proactive resolutions of challenges and forward &andinnovative development in paediatric trials will provide a strong platform to focus and optimise paediatric research and show the necessary resources in comparison to adult trials.

Considerations for the Design of Clinical Trials in Children
Martine Dehlinger Kremer, Chair of the Paediatric Working Group, EUCROF & Global Vice President, Regulatory Affairs, RPS Research, Germany

Overcoming the Challenges of Recruiting Paediatric Patients
Sylvie Jouve, Senior Project Manager, Paediatric Clinical Research, Premier Research Group, France

eDiaries for Clinical Trials – An example of recruiting paediatric patients
Valdo Arnera, General Manager, Europe, PHT Corporation, Switzerland

Session 0208 | Wednesday, 6 March 2013 | 16:00-17:30 | Room E102

PAEDIATRIC REQUIREMENTS – DO THEY DELIVER AND AT WHAT COST?

Session Chair:
Gesine Bejeuhr, Regulatory Affairs/Quality, vfa Research-Based Pharm Companies, Germany

This session will illustrate the regulatory efforts to provide better age adapted medicines and better information on medicines for children. It will also address paediatric formulations, the important aspect of development of medicines for children. The new draft guideline should be discussed.

Paediatric Information in Medicines: Improving paediatric access to medicinal products
Dinah Duarte, Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

Paediatric Formulations - the EMA guideline
Diana Van Riet, Coordinator, Regulatory Affairs, National Institute for Public Health and the Environment (RIVM), Netherlands

How do Companies Manage These Challenges?
Bettina Doepner, Global Senior Regulatory Affairs Manager, Boehringer Ingelheim Pharma GmbH , Germany

Theme 3 | Legal/Transparency-Risk Assessment

Burkhard Sträter, Lawyer, Kanzlei Sträter, Germany

Approval procedures for pharmaceuticals, biosimilars and clinical trials as well as for paediatric investigation plans are based on European public administrative law. This sets the legal framework for scientific assessment and protection of intellectual property rights of innovators. The European Commission's sector investigation establishes a new cartel-law-based framework for generic applications and regulatory data protection.

The aim of Theme 3 is to provide scientists and regulators guidance in European approval procedures for clinical research and marketing authorisations.

Session 0301 | Tuesday, 5 March 2013 | 09:00-10:30 | Room D203-204

REGULATORY DATA PROTECTION

Session Chair:
Burkhard Sträter, Lawyer, Kanzlei Sträter, Germany

The intellectual property of pharmaceutical companies is protected by different types of rights, namely patent, supplementary protection certificate and market exclusivity for orphan drugs. Data protection exists for documents submitted with the marketing authorisation dossier. Authorities are forbidden from using the documents submitted in favour of generic applicants before the protection periods expires.

The session will show how rights of innovators are protected in the centralised and decentralised procedure. The presentation "Drug Rediscovery" will explain the options of regulatory data protection for new research with known substances.

Protection of Intellectual Property Rights in Centralised Procedures with the EMA
Speaker invited - see EuroMeeting Extra for details

Regulatory Data Protection in MRP and DCP
Angela Büttrich, Member, EMALCOLEX, BfArM, Germany

Drug Rediscovery – Incentives and protection mechanisms
John Lisman, Lawyer, Lisman Legal Life Sciences, Netherlands

Session 0302 | Tuesday, 5 March 2013 | 11:00-12:30 | Room E102

INCENTIVES FOR PAEDIATRIC CLINICAL RESEARCH

Session Chair:
Marie Manley, Partner, Head of Regulatory Practice, Bristows, UK

The session will analyse the interaction of the Paediatric Regulation with the SPC Regulation in the context of the rewards and incentives available for paediatric research, focusing particularly on the inherent uncertainties (for example, in the case of multiple orphan designations or where the marketing authorisation holder has one orphan indication and one non-orphan indication). Furthermore, the session will examine the impact of the decision in Nycomed Danmark ApS v EMA (Case T-52/09) regarding the scope of the Paediatric Committee's (PDCO's) competence in assessing whether a waiver is appropriate in a particular case, as well as the recent criticism of the European Medicines Agency (EMA) by the Ombudsman regarding transparency in decision making.

Setting the Scene on the Rewards Available and the Pitfalls
Marie Manley, Partner, Head of Regulatory Practice, Bristows, UK

Risk and Changes for Pharmaceutical Industry
Victoria Kitcatt, Assistant General Counsel, Pfizer, UK

Confirmation of PIP Compliance – Procedures and criteria
Sarah Branch, Special Populations Group Manager, VRMM Division, Group Manager, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Session 0303 | Tuesday, 5 March 2013 | 14:00-15:30 | Room E102

LEGAL COMPLIANCE FOR REGULATORY FUNCTIONS - LEARNINGS FROM RECENT ENFORCEMENT ACTIVITIES

Session Chair:
Samantha Regenthal, Attorney at Law, SFL Regulatory Affairs and Scientific Communication, Switzerland

The session aims to highlight the impact of recent enforcement activities on regulatory strategies and the roles of regulatory functions in the general corporate compliance setting. It provides examples on potential pitfalls in regulatory strategy and life cycle management, as well as the possible consequences of non-compliance.

The AstraZeneca Case and the Pharma Sector Investigation: Impact on Regulatory Strategies
Samantha Regenthal, Attorney at Law, SFL Regulatory Affairs and Scientific Communication, Switzerland

The GSK US Case: Relevance for European Regulatory Activities
Heidi Bürgi, Attorney at Law, F. Hoffmann-La Roche, Switzerland

Panel with speakers and Burkhard Sträter, Lawyer, Kanzlei Sträter, Germany

Session 0304 | Tuesday, 5 March 2013 | 16:00-17:30 | Room E102

BIOSIMILARS

Session Chair:
Christian Schneider, Chair Committee for Advanced Therapies (CAT), Senior Medical Officer, Danish National Board of Health, Denmark

Genetically engineered proteinaceous macromolecules are required to pass through the centralised marketing authorisation procedure according to the Annex to Regulation (EU) 726/2004. The first growth hormones, epoetines, interferons, insulins and monocular antibodies are no longer covered by patent. They were authorised over 10 years ago. Generic companies therefore wish to conquer this market and obtain the necessary marketing authorisations – called biosimilars, not biotech generics!

The session will explain the requirements for marketing authorisations and pharmacovigilance. An important subject is also the substitution of prescribed biosimilars by pharmacists. It is currently being discussed throughout Europe. The scientific experts will discuss this topic from a pharmacovigilance perspective.

Biologicals in Pharmacovigilance – Adverse Drug Reaction (ADR) reporting

and traceability
Thijs Giezen, Biosimilar Medicinal Products Working Party (BMWP) Medicines Evaluations Board, Netherlands

Biosimilars: Robust pharmacovigilance principles and patient safety
Peter de Veene, EU QPPV, Roche Products Ltd, UK

Biosimilar Industry's Point of View
Pascale Burtin, Head Global Clinical Develop. Biopharma, Sandoz International, Germany

Session 0305 | Wednesday, 6 March 2013 | 09:00-10:30 | Room G103

FROM VOLUNTARY HARMONISATION TO CLINICAL TRIAL REGULATION

Session Chair:
Hartmut Krafft, Chairman, Clinical Trials Facilitation Group (CTFG), Head, Clinical Trial Unit, Paul-Ehrlich-Institute, Germany

Experience in the implementation of the Clinical Trial Directive 2001/20/EC has varied. This was the reason for the European Commission to review and reorganise the monitoring system for clinical trials in the EU. After hearing stakeholders, a draft of an EU Regulation is now published. In particular "Pan European Studies" call for a consistent set of regulations. Otherwise, the studies run the risk of failing due to the different requirements in the individual Member States.

Introduction
Hartmut Krafft, Chairman, Clinical Trials Facilitation Group (CTFG), Head, Clinical Trial Unit, Paul-Ehrlich-Institute, Germany

The New Clinical Trial Regulation – policy development
Anna Hallersten, Public Affairs Director, SFL Regulatory Affairs & Scientific Communication, Switzerland

The New Clinical Regulation – views of an innovator company
Sabine Atzor, Head of EU Regulatory Intelligence and Policies, F. Hoffmann-La Roche, Switzerland

Session 0306/1206 | Wednesday, 6 March 2013 | 11:00-12:30 Auditorium Ground Floor

TRANSPARENCY ON DOSSIER AND DECISION MAKING – HAS PUBLIC TRUST INCREASED?

Session Chair:
Ragnar Löfstedt, Director, King's Centre for Risk Management, Department of Geography, King's College London, UK

Over the past ten years there have been a number of regulatory incidents affecting the pharmaceutical sector in both United States and Europe that have led to widespread public and stakeholder distrust of the sector as a whole. As a result, European regulatory agencies have become strong promoters of transparency. The aim of this session is to shed further light on the transparency agenda in Europe. Issues that will be addressed include: Where are we in terms of the EMA proposal of sharing raw data from clinical trials, how are the public, patient groups and general medical practitioners responding to these changes and new challenges?

To address these questions we have assembled a stellar panel composed of:

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

Andrew Jack, Pharmaceutical Correspondent, Financial Times, UK

Discussant:
Aginus Kalis, Chair HMA, Executive Director, Medicines Evaluation Board, Netherlands

Session 0307 | Wednesday, 6 March 2013 | 14:00-15:30 | Emerald Room

LEGAL AND PRACTICAL ASPECTS OF OFF-LABEL USE

Session Chair:
John Lisman, Lawyer, Lisman Legal Life Sciences, Netherlands

Off-Label use of medicinal products has positive and negative aspects. Both good and bad aspects will be discussed from the perspective of the regulator, the lawyer and the pharmaceutical industry.

Off-Label Use from the Regulatory Perspective: A necessary evil or a blessing in disguise?
Yechiel Hekster, Member, Medicines Evaluation Board (MEB), Netherlands

Off-Label Use from the Industry Perspective: Walking a tight rope?
Héctor Röthlisberger, Actelion, Switzerland

Legal and Practical Aspects of Off-Label Use
John Lisman, Lawyer, Lisman Legal Life Sciences, Netherlands

Theme 4 | Pharmacovigilance

Vicki Edwards, Senior Director, European Pharmacovigilance, Abbott, UK
Jan Petracek, CEO, Director of Pharmacovigilance Services, Pharminvent, Czech Republic

Some say that the new pharmacovigilance legislation represents the biggest change in pharmaceutical legislation since 1995 – some say even longer. The Pharmacovigilance Theme will look at the impact of these changes and explore how both regulators and the industry are rising to the challenges of implementation. The sessions will look at some of the more practical aspects of implementation such as the Pharmacovigilance System Master File (PSMF) but also explore the impact of some of the less tangible elements such as transparency and communication issues. Additionally, the theme will look at other advances in PV such as the IMI PROTECT initiative relating to benefit/risk methodology and the use of new technologies.

Session 0401 | Tuesday, 5 March 2013 | 09:00-10:30 | Elicium 2

IMPLEMENTATION OF THE NEW PHARMACOVIGILANCE LEGISLATION

Session Chair:
Vicki Edwards, Senior Director, European Pharmacovigilance, Abbott, UK

Since July 2012, the step-by-step implementation of the new EU legislation on pharmacovigilance has brought about the first operational experience in meeting the new requirements for both regulatory authorities and industry. Senior speakers representing the key players in the field will share their experience and discuss with attendees their points of view on burning questions the new reality brings.

A Regulator's View of the Early Implementation of the New PV Legislation
Mick Foy, Group Manager, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Update from the Innovative Pharma Industry
Laurent Auclert, EFPIA Observer, EU QPPV, Sanofi, France

Update from the Generic Pharma Industry
Maarten Van Baelen, Medical Affairs Manager, European Generic Medicines Association (EGA), Belgium

Session 0402 | Tuesday, 5 March 2013 | 11:00-12:30 | Elicium 2

BEST PRACTICES IN PHARMACOVIGILANCE GOVERNANCE

Session Chair:
Jan-Willem Van der Velden, CEO, Mesama Consulting, Switzerland

Ever-increasing workload and limited resources create an unprecedented pressure on effectiveness in performance of pharmacovigilance operations of all players regulated by EU pharmaceutical law. Best practices in governance are high on the agenda of all PV directors and leaders. Session speakers will share their approaches, and discuss with participants various options meeting some of the most resource intensive requirements.

The Growing Importance of Independent Adjudication for Post-Marketing Studies
Donna Davison, Director, Medical Operations, INC Research, USA

How Can We Build Reliability and Quality when Outsourcing Pharmacovigilance?
Brian Edwards, Principal Consultant Pharmacovigilance and Drug Safety, NDA Group, UK

The Pharmacovigilance System Master File
Maria Wishart, Deputy EU QPPV, GlaxoSmithKline R&D Ltd, UK

Session 0403 | Tuesday, 5 March 2013 | 14:00-15:30 | Elicium 2

BENEFIT/RISK MANAGEMENT IN PHARMACOVIGILANCE

Session Chair:
Saad Shakir, Director, Drug Safety Research Unit, UK

Management of risks has been well established in the EU, and further reinforced by the new EU legislation. In addition, new regulatory possibilities allowing for more effective management of benefit have been created by good pharmacovigilance guidelines. Session speakers will explore how they have used these new options in their practice as academia, industry, and regulatory authorities.

Risk Management PASS and PAES; the impact of the new legislation and the way forward
Saad Shakir, Director, Drug Safety Research Unit, UK

Failure Modes, Effects and Criticality Analysis Techniques (FMECA) to Optimise Benefit/Risk Management
Samuel Ramsden, Senior Safety Medical Writer, Novo Nordisk A/S, Denmark

Additional speaker invited - see EuroMeeting Extra for details

Session 0405 | Wednesday, 6 March 2013 | 09:00-10:30 | Elicium 2

NEW OPPORTUNITIES FOR INFORMATION TECHNOLOGY IN PHARMACOVIGILANCE

Session Chair:
Maria Wishart, Deputy EU QPPV, GlaxoSmithKline R&D Ltd, UK

Use of computerised systems is critical for effective performance of all pharmacovigilance operations. Quick development of new software, implementation of new standards, and increasing deployment of electronic exchange of information between the pharmacovigilance players create new challenges, efficiency gains, and opportunities for errors. Speakers will guide audience through some of the highlights in the latest development that may change the way we do pharmacovigilance in the near future.

Social Media and Pharmacovigilance: Socialvigilance
Maria Vazquez-Gragg, Global Head, Safety and Pharmacovigilance, RTI International - Health Solutions, USA

Adverse Drug Reaction (ADR) Reporting via Mobile Devices
Maiken Hedegaard, Life Science IT Consultant, NNIT A/S, Denmark

Online Patient Reporting of Adverse Events: A case study
Monica Plöen, Manager, Signal Detection and Analysis, Uppsala Monitoring Centre, Sweden

Session 0406 | Wednesday, 6 March 2013 | 11:00-12:30 | Elicium 2

RISK COMMUNICATION AND TRANSPARENCY

Session Chair:
Angelika Joos, Director, Head Regulatory Policy, EU & Most of World, Merck Sharp & Dohme (Europe) Inc., Belgium

Feedback to healthcare professionals and public about outcomes of pharmacovigilance processes and assessments used to be a weak point in Community Pharmacovigilance system. New EU legislation enables a significant increase in transparency of regulatory authorities, sharing the results of work done by industry. This includes safety web portals, central assessment of risk communication documents by the Pharmacovigilance Risk

Assessment Committee (PRAC), publishing summaries of risk management plans, agendas and minutes of pharmacovigilance meetings, access to data in EudraVigilance and meeting requirements of EU Good Pharmacovigilance Practice Module 15 on safety communication.

Role of PRAC in Transparency and Communication
Mick Foy, Group Manager, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Impact of Increased Transparency on the Industry
Angelika Joos, Director, Head Regulatory Policy, EU & Most of World, Merck Sharp & Dohme (Europe) Inc., Belgium

Determinants of Impact of Drug Safety Warnings - A retrospective analysis of direct healthcare professional communications
Peter Mol, Assistant Professor, University Medical Center Groningen, Netherlands

Session 0407 | Wednesday, 6 March 2013 | 14:00-15:30 | Elicium 2

IMPACT OF ICH E2C (R2) AND GVP MODULE VII

Session Chair:
Michael Richardson, International Head GPV&E and EU QPPV, Bristol-Myers Squibb, UK

Periodic Safety Update Reports (PSURs) represent a large proportion of pharmacovigilance work for both industry and regulatory authorities. The dramatic shift from the limited focus of PSURs on post-authorisation safety to the comprehensive and critical report on continuous update of benefit/risk balance created uncertainties about ownership of the document, its use, teams that need to be involved, data to process, and impact of the report conclusions. Speakers will share their first practical experience with implementation of the new standards in the EU and globally.

Implications of the PBRER for industry
Michael Richardson, International Head GPV&E and EU QPPV, Bristol-Myers Squibb, UK

Challenges in the Management of the PSURs world
Wendy Huisman, EU QPPV, Teva Pharmaceuticals Europe, Netherlands

Is the "Modular Principle" Working for New PSURs
Jan Petracek, CEO, Director of Pharmacovigilance Services, Pharminvent, Czech Republic

Session 0408 | Wednesday, 6 March 2013 | 16:00-17:30 | Elicium 2

DEVELOPMENT OF PHARMACOVIGILANCE METHODOLOGY

Session Chair:
Monika Pietrek, Managing Director, Pietrek and Associates, Germany

Computerised systems, databases in healthcare, and new scientific methodology enable innovative approaches to the search for answers we face in pharmacovigilance every day. Speakers will share their stories about implementation of these new approaches that attendees might find useful when selecting the best way to meet requirements for data, signal and risk management.

Benefit/Risk Assessment in a Post-Market Setting: A case study integrating real-life experience into benefit/risk methodology
Christine Hallgreen, Novo Nordisk A/S, Denmark

PROTECT the Patient – Novel tools for adverse drug reaction surveillance
Andreas Brückner, Quantitative Safety Scientist, Bayer Healthcare Pharmaceuticals, Germany

Behavioural Assessment of Risk Minimisation Tools
Swapu Banerjee, Board Member & Head of Risk Management, Drug Safety & Regulatory, Pope Woodhead & Associates, UK

Theme 5 | Clinical Research and Development

Nermeen Varawalla, Founder and CEO, ECCRO, UK
Andrei Kravchenko, Head of Office, Harrison Clinical Research, Ukraine

The potential to adopt game changing technologies and innovative methodologies, the demand for "real world" outcome data and the continued drive for efficiency make clinical research today more challenging and exciting than perhaps ever before. These drivers of change notwithstanding, the relevance of more traditional approaches to deliver data quality and operational effectiveness remains. The sessions in the Clinical Research Theme present latest thinking and best practices in the context of the current environment, addressing both newer trends and reviewing established approaches.

Session 0501 | Tuesday, 5 March 2013 | 09:00-10:30 | Elicium 1

NEW APPROACHES FOR MONITORING

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

Participants will learn about the essentials of risk-based monitoring, what needs to be considered when switching from traditional monitoring to a risk-based approach and what the challenges are that need to be overcome when establishing a risk-based monitoring approach.

Assessing Global CRA Workload and Utilisation
Kenneth Getz, Senior Research Fellow, Tufts CSDD, Chairman, CISCRP, Tufts University, USA

Sites Unseen: Game plan for sponsors moving to risk-based monitoring
Rick Morrison, CEO, Comprehend Clinical, USA

Risk-Based Monitoring: Principles and practical implementation
Francois Beckers, Head of Biostatistics and Data Management, GlaxoSmithKline Biologicals, Belgium

Session 0502 | Tuesday, 05 March 2013, 11:00-12:30 | Elicium 1

WHY TRIALS FAIL AND HOW TO PREVENT THIS

Session Chair:
Lollo Eriksson, VP - Clinical Research Services, PAREXEL International, USA

Benchmarking the Clinical Trial Site Initiation Process
Mary Jo Lamberti, Senior Project Manager, Tufts Center for the Study of Drug Development, Tufts University, USA

Pharmaceutical R&D Process - Why do clinical trials fail?
Erika Buonansegna, DTU Business, Technical University of Denmark, Denmark

Reasons for Project Discontinuation in the Pharmaceutical Industry
Jorge Mestre-Ferrandiz, Senior Economist, Office of Health Economics, UK

Session 0503 | Tuesday, 5 March 2013 | 14:00-15:30 | Elicium 1

ENHANCING CLINICAL RESEARCH EFFECTIVENESS

Session Chair:
Andrei Kravchenko, Head of Office, Harrison Clinical Research, Ukraine

Clinical research has become more complex than ever, thus requiring continual enhancement of its effectiveness. Numerous different scientific, operational and financial approaches have been proposed to do so. Of these, this session will examine streamlining protocol design, the set up of an alliance for clinical research in Europe and accelerating early phase drug development. Presenters will share new thinking, innovative processes and best practices.

Measuring the Magnitude and Cost of Collecting Extraneous Protocol Data
Kenneth Getz, Senior Research Fellow, Tufts CSDD, Chairman, CISCRP, Tufts University, USA

The Alliance for Clinical Research Excellence and Safety (ACRES): A mechanism for helping implement the new EU clinical trial regulations
Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Group, UK

Product Candidate to Proof of Concept – An integrated approach to accelerate programmes
John Shillingford, Consultant, Germany

Session 0504 | Tuesday, 5 March 2013 | 16:00-17:30 | Elicium 1

ADAPTIVE CLINICAL TRIAL DESIGNS

Session Chair:
Nermeen Varawalla, Founder and CEO, ECCRO, UK

Adaptive clinical trial designs promise the flexibility to redesign the trial at an interim stage with the benefits of time and resource savings. However, despite this promise, the implementation of such designs continues to be patchy. This session will explore the reasons for poor adoption and describe best practices for the conduct of adaptive clinical trials.

The Learning/Confirming Continuum and Adaptive Designs
Andrew Grieve, Senior Vice President Clinical Trial Methodology, Aptiv Solutions, Germany

Recent Advances in Adaptive Clinical Trial Designs
William Sietsema, Director, Global Regulatory Affairs, Amgen, USA

Multi-Centre Early Phase Cohort Studies: Lessons for conducting adaptive trials
Andreas Geissler, Director Client Services, RTSM Division, PAREXEL, Germany

Session 0506 | Wednesday, 6 March 2013 | 11:00-12:30 | Elicium 1

ADOPTION OF GAME CHANGING TECHNOLOGIES

Session Chair:
William Gluck, Vice President of Clinical and Consulting Services, DATATRAK International, USA

In this session we will explore how new technology presents opportunities to streamline and improve the clinical trial process in both traditional and virtual settings, as well as to understand some of the challenges involved in adopting and implementing new technology into our respective clinical workflows. By leveraging technology we also have the opportunity to implement standards such as the CDISC Protocol Representation and gain insights into better trial design and the impact a poorly designed trial will have on trial cost, study complexity, and cycle times.

The Real Potential of Using Routine Electronic Health Records for Clinical Trials: Putting them to the test
Tjeerd van Staa, Head of CPRD Research, Clinical Practice Research Datalink, UK

Raiders of the Lost Protocol: Better study design through protocol archaeology
Joshua Pines, Senior Product Marketing Manager, Medidata Solutions Worldwide, USA

Virtual Clinical Trial Conduct: Way forward
Miguel Orri, Senior Director, Clinical Sciences, Pfizer, UK

Session 0507 | Wednesday, 6 March 2013 | 14:00-15:30 | Elicium 1

PATIENT RECRUITMENT AND RETENTION

Session Chair:
Ingrid Klingmann, Managing Director, Pharmaplex, Belgium

Optimising Clinical Trial Feasibility by Consulting with Investigators, Patient Advocacy Groups and Electronic Health Records
Lisa Palladino Kim, MS Graduate Clinical Trial Sciences, University of Medicine and Dentistry, New Jersey (UMDNJ) USA

Improving Trial Success through Effective Protocol and Trial Feasibility Analysis
Srinivasan Anadakumar, Senior Manager, Projects, Cognizant Technology Solutions, USA

Site-Based Recruitment and Retention Initiatives
Nermeen Varawalla, Founder and CEO, ECCRO, UK

Session 0508 | Wednesday, 6 March 2013 | 16:00-17:30 | Elicium 1

COLLECTING RELEVANT HEALTH OUTCOME DATA

Session Chair:
Vikki Brown, Medical Director Post Approval and Strategic Services, INC Research, US

Real-World Clinical Studies - From the bench to the clinic to economic feasibility
Felix Frueh, President, Medco Research Institute, USA

Data at the Heart of Clinical Trials – The key to successful health outcomes Research
Laura Browne, Account Director, the Scott Partnership, UK

Best Use of Late-Phase Clinical Trials: How to meet healthcare research purposes and secure drug effectiveness claims?
Markus Hartmann, Principal Consultant, European Consulting and Contracting in Oncology, Germany

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Theme 6 | Quality (including Falsified Medicines)

Susanne Keitel, Director, European Directorate for the Quality of Medicines and Healthcare (EDQM), Council of Europe, EU
John Kerridge, Quality Leader, EU QA/External GMP Relations, Lilly, France

Supply chain security and medicine availability, vitally important areas, will be discussed in the context of the EU Falsified Medicines Directive (2011/62/EU) provisions which are due to be implemented in 2013. Active substance supply, the future of pack serialisation and the impact of the changes on the EU Qualified Person operating in the global environment will be considered. Additionally, anticipated guidance on the prevention and management of drug shortages will be explored.

The Quality Theme will also involve experts discussing key technical topics and examining the future of international harmonisation activities concerning pharmacopoeias and other standards.

Session 0601 | Tuesday, 5 March 2013 | 09:00-10:30 | Room G102

DRUG SHORTAGE MANAGEMENT - ENSURING MEDICINE SUPPLY

Session Chair:
Gerald Heddell, Director, Inspection Enforcement and Standards Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Maintaining medicine supply is of prime importance to patients and a key area of focus for regulators and pharmaceutical companies. The reality is that a number of factors including world events, unforeseen manufacturing problems and poor compliance can lead to shortages of medicines. How best to manage these situations and how to be proactive to minimise risks of shortages of vital medicines needs proper consideration. This is a complex area and this session will consider the issues from the perspectives of patients, industry and regulators, seeking to understand some of the challenges and how all stakeholders can better manage the risks.

Perspective from the European Medicines Agency
Noël Wathion, Head of Patient Health Protection, European Medicines Agency, EU

Patient Perspective
Christine Lavery, Chief Executive, Society for Mucopolysaccharide Diseases, UK

Industry Perspective
Raj Gokani, Country Manager, Hospira, UK

Session 0602 | Tuesday, 5 March 2013 | 11:00-12:30 | Room D203-204

THE EU QUALIFIED PERSON IN A GLOBAL ENVIRONMENT

Session Chair:
Jacques Morenas, Deputy Director of the Inspection Directorate, National Agency of Medicine and Health Product Safety (ANSM), France

The EU pharmaceutical legislation puts a lot of responsibilities on the QP's shoulders. The session will examine new challenges of the QP implied by the Falsified Medicines Directive and explain the role of the QP in daily practice, including the current revision of Annex 16 to the GMP Guide. In addition, it will summarise the QP's involvement in the oversight of supplier management.

The Impact of the Falsified Medicines Directive on the QP Role
Jacques Morenas, Deputy Director of the Inspection Directorate, National Agency of Medicine and Health Product Safety (ANSM), France

What does QP Oversight Really Mean
Lynne Byers, Vice President Quality, GlaxoSmithKline, UK

QP and Involvement in Oversight of Supplier Management
John O'Sullivan, Senior Director Quality Operations Ireland/Singapore/UK, Pfizer, Ireland

Session 0603 | Tuesday, 5 March 2013 | 14:00-15:30 | Room D203-204

FALSIFIED MEDICINES DIRECTIVE AND ACTIVE SUBSTANCES

Session Chair:
John Kerridge, Quality Leader, EU QA External Relations, Lilly, France

A vitally important topic, this session will discuss the current status of the implementation of the EU Falsified Medicines Directive as it relates to active drug substances including the provisions for importation. It is vital that all stakeholders work together to ensure a smooth implementation of the provisions to allow a continued supply of quality and safe medicines in the European Union. The active participation of third countries is a key element of making these provisions a success and the status of this and future plans will be discussed.

European Commission – Update on the FMD and implementation of provisions for active substances
Stefan Führing, Administrator Pharmaceuticals, DG Health and Consumers, European Commission, EU

Stakeholder Perspective on Active Substance Control
Isabelle Clamou, Director Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Regulator's Perspective on Active Substance Control
Gerald Heddell, Director, Inspection Enforcement and Standards Division, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Session 0604 | Tuesday, 5 March 2013 | 16:00-17:30 | Room D203-204

FALSIFIED MEDICINES DIRECTIVE AND SERIALISATION

Session Chair:
Domenico Di Giorgio, Director Counterfeit Protection Unit, Italian Medicines Agency (AIFA), Italy

The EU Directive 2011/62 will change the European pharmaceutical distribution framework by defining new obligations and procedures aimed at strengthening the barriers against falsified medicines. One of the key features of the Directive is the traceability scheme to be developed at the European level, based on the concept of serialisation of the packages of medicines. The session goal is the discussion between experts from private stakeholders and administration on the current situation and experiences in the field of traceability and serialisation, with an eye on future technical and regulatory development.

EU Directive 2011/62 - Features and points of view
Domenico Di Giorgio, Director Counterfeit Protection Unit, Italian Medicines Agency (AIFA), Italy

The Implementation of the FMD vs. The Improvement of Supply Chain Management
Maarten Van Baelen, Medical affairs Manager, European Generic Medicines Association (EGA), Belgium

eTACT- The EDQM Anti-Counterfeiting Traceability Service for Medicines
François-Xavier Lery, Head of Section for Pharmaceutical Care, Consumer Health Protection and Anti-Counterfeiting, European Directorate for the Quality of Medicines and Healthcare (EDQM), Council of Europe, EU

The European Stakeholder Model
John Chave, Secretary General, Pharmaceutical Group of the European Union (PGEU), Belgium

Session 0605 | Wednesday, 6 March 2013 | 09:00-10:30 | Room D203-204

QUALITY UPDATE - CURRENT DEVELOPMENTS

Session Chair:
Georges France, Head QA & Compliance, EU Region, Novartis Consumer Health Services, Switzerland

The purpose of this session is to consider the major trends and challenges driven by the new quality paradigm. The principles have been established by ICH Q8, Q9, Q10 and Q11. Some major regional training, Q&A and points to consider led to the clarification of how to implement this new concept, however in practical term, room for interpretation is still important creating a barrier to an easy implementation for regulatory submission. The next steps to consider will be to clarify some specific points such as:

- How to consider the process validation in the context of the new paradigm
- How to discuss and explain the critical aspect of the pharmaceutical development and where in the CTD document to provide the relevant information binding and no binding
- The changes lead by the continuous improvement and how to address the change Control
- The challenges and the opportunities offered by post-approval management

Based on practical example the session will illustrate challenges and possible proposal around these questions.

Introduction: Challenges and Opportunity from New Quality Paradigm
Georges France, Head QA & Compliance, EU Region, Novartis Consumer Health Services, Switzerland

CTD Document and New Quality Paradigm
Jean-Louis Robert, Head of Department, Drug Control Laboratory, National Health Laboratory, Luxembourg

Process Validation
Speaker invited - see EuroMeeting Extra for details

Post Approval Management and Change Control
Bernadette Doyle, Vice-President & GMS Technical Operations Head, GlaxoSmithKline, Ireland

Session 0607 | Wednesday, 6 March 2013 | 14:00-15:30 | Room D203-204

PHARMACOPOEIAL HARMONISATION - A NEVER ENDING STORY

Session Chair:
Susanne Keitel, Director, European Directorate for the Quality of Medicines and Healthcare (EDQM), Council of Europe, EU

The need to harmonise pharmacopoeial requirements in a globalised world has already been identified in the late 80s. However, the outcome of the Pharmacopoeial Discussion Group, an informal harmonisation initiative set up by three major pharmacopoeias, has yet to meet the pharmacopoeias' and stakeholders' expectation. This session will provide an update on industry needs, current harmonisation initiatives and the approaches taken, and will offer a platform for open discussion with the panel of speakers.

Pharmacopoeial Harmonisation – Stakeholder expectations
Neil Schwarzwalder, Quality Consultant Compendial Affairs, Eli Lilly, USA

Current Global Pharmacopoeia Activities
Sabine Kopp, Manager, Medicines Quality Assurance Programme, Quality Assurance & Safety: Medicines, Anti-Counterfeiting Programme, World Health Organization, Switzerland

Regional and PDG Activities
Susanne Keitel, Director, European Directorate for the Quality of Medicines and Healthcare (EDQM), Council of Europe, EU

Session 0608 | Wednesday, 6 March 2013 | 16:00-17:30 | Room D203-204

HARMONISATION – PITFALLS AND HOW CAN WE SPEED IT UP?

Session Chair:
Jean-Louis Robert, Head of Department, Drug Control Laboratory, National Health Laboratory, Luxembourg

In the world of globalisation, harmonisation of requirements in the pharmaceutical area has become a real challenge. This session will present a brief history of what has been achieved so far (successes and pitfalls) for instance within EU, ICH including Global Cooperation Group, PICs and the EU/US work sharing programme. Representatives from industry will present their experience and expectations for the future.

Regulatory Harmonisation Initiatives - Past present and future
Jean-Louis Robert, Head of Department, Drug Control Laboratory, National Health Laboratory, Luxembourg

Collaboration between Regulators and Work Sharing Experiences – A way forward or an additional burden for industry?
Graham Cooke, Senior Director, Global Quality Strategy, Pfizer, UK

Benefits and Impact of Harmonisation for Generic Manufacturers
Julie Maréchal, Senior Manager, Quality & Regulatory Affairs, European Generics medicines Association (EGA), Belgium

The Need for Harmonisation from the API Manufacturers' Point of View and How to Encourage Regions to Align Requirements
Matt Moran, Director, Pharmachemical Ireland, Ireland

Theme 7 | Devices, In Vitro Diagnostics and Drug/ Device Combination Products

Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs and Scientific Communication, Switzerland
Siniša Tomić, Counselor for European Affairs, Agency for Medicinal Products and Medical Devices, Croatia

In this theme there will be a special focus on the impact that the European Commission's proposals for the regulation of medical devices and IVDs on the drug/device combinations, borderline products and companion diagnostics.

The impact of the most significant proposed changes to the EU's medical device and IVD regulations will be assessed, including the potential impact of the new "scrutiny procedure" and the new requirements for combinations regulated as drugs. The meeting will consider the likely reactions of the European Parliament and Council. The meeting will also consider the latest work towards global convergence by the International Medical Device Regulators Forum.

Companies will learn how they should start to adapt their regulatory strategies to avoid any risk of regulatory bottlenecks. As well as providing the regulatory context, practical guidance on developing combination products will be given. In addition, the development and approval of e-Health/tele-health solutions designed to improve patient adherence to their medication will be addressed.

The future regulation of companion diagnostics, including the new role for notified bodies and the involvement of drug authorities in the premarket phase are on the agenda. Case studies will provide advice on how to develop companion diagnostics in compliance with the regulatory requirements in the EU and US.

Session 0701 | Tuesday, 5 March 2013 | 09:00-10:30 | Room E102

CURRENT STATUS OF REVISION OF EU MEDICAL DEVICE DIRECTIVES: THE KEY THEMES AND CONTROVERSIES

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

The EU's three main medical device directives are being revised into two regulations. The first will cover active implantable medical devices and medical devices in general in one text, the second will regulate IVDs. This first session will assess the main changes of the texts that were issued as draft revisions in September 2012, the reaction of stakeholders, including industry, and assess the debate ahead as the text is reviewed by the European Parliament and Council.

Overview of the Main Changes Being Introduced in the Revision of the Medical Device Directives
Speaker invited- see EuroMeeting Extra for details

How the Revision of the Medical Device Directives Will Impact the New Regulatory Oversight and Management Structure, and the Way Notified Bodies, Competent Authorities and Industry Relate to One Another and to the European Commission
Speaker invited- see EuroMeeting Extra for details

Most Contentious Issues for Industry Surrounding the Revisions: Predicted impact on innovation and likely battles ahead at the European Parliament and Council
Dario Pirovano, Consultant Regulatory Affairs, Eucomed, Belgium

Session 0702 | Tuesday, 5 March 2013 | 11:00-12:30 | Room G102

DEVELOPMENT AND REGULATORY FRAMEWORK FOR COMPANION DIAGNOSTICS

Session chair:
Thomas Metcalfe, Chief Operating Officer, Oncotest, Germany

The EU is regulating companion diagnostics for the first time. This session will provide an overview of the development of companion diagnostics explain the new framework for drug and IVD companies and how manufacturers of the drug and IVD elements of companion diagnostics are likely to be impacted by the evolving EU IVD Regulation. Is EU dialogue with US IVD experts and with the EU drug sector, shaping a new, and more co-operative way forward for companion diagnostics? And what impact is the IMDRF having?

Regulatory Oversight of Companion Diagnostics - Current and future plans
Shuna Mason, Head of Regulatory, CMS Cameron McKenna LLP, UK

Developing a Companion Diagnostic: How pharma and IVD companies need to co-operate, and liaise with authorities including case studies
Tim Kievits, Director of Healthcare Innovation VitrOmics, Netherlands

Personalised Medicine and Pharmacogenomic Tests: From label to clinical practice
Marjolein Weda, Scientific Officer, National Institute for Public Health and the Environment (RIVM), Netherlands

Session 0703 | Tuesday, 5 March 2013 | 14:00-15:30 | Room G103

CHANGES IN EU APPROVAL OF DRUG/DEVICE COMBINATIONS – THE NEW REGULATORY STRUCTURE AND HOW IT WILL IMPACT INNOVATION

Session chair:
Amanda Maxwell, Head of UK Office, SFL Regulatory Affairs Consulting, UK

How the forthcoming EU Regulation of medical devices will impact the regulatory approval of drug/device combination products and how the new rules will impact innovation in this area will be addressed. This session will report on high-level policy discussions, and highlight the need for better cooperation, between the drug and device regulatory regimes, including the EMA.

How the Revision of the Medical Device Directives Will Impact the Future EU Regulation of Drug/Device Combinations
Amanda Maxwell, Head of UK Office, SFL Regulatory Affairs Consulting, UK

Cooperation With and Between Drug and Device Regulators Under the Revised EU Regulations and How to Foster Innovation
Ann O'Connor, Director of Human Products Authorisation and Registration, Irish Medicines Board (IMB), Ireland

How Products on the Drug/Device Borderline Will be Impacted by the New EU Regulations; Future options for achieving consensus, including case studies
Geneviève Michaux, Covington and Burling, Belgium

Session 0704 | Tuesday, 5 March 2013 | 16:00-17:30 | Room G103

HOW TO ADDRESS DIFFERENT REQUIREMENTS DEVELOPING COMBINATION PRODUCTS: THE CHALLENGES OF MANAGING TWO SETS OF RULES

Session chair:
Josee Hansen, Chief Inspector, Healthcare Inspectorate, Netherlands

What challenges do companies face when it comes to complying with the different quality system rules that apply to drugs and devices or drugs and IVDs

for combination products? How do Good Manufacturing Practice requirements fit with EN ISO 13485, the medical device quality system standard? And what are the challenges for the notified bodies and regulators?

Medicinal Products and Medical Devices: The best of both worlds
Josee Hansen, Chief Inspector, Healthcare Inspectorate, Netherlands

Human Factors Studies – Impact and protocol design
Alan Touch, Principal Strategist, Medical Devices and In Vitro Diagnostics, INC Research, USA

The Subtle Differences between US Quality System Regulation Standards and ISO Rules and FDA's Expectation of Risk Assessment for Combination Products
Toni Jörgensen, Head of Corporate Regulatory Affairs, Institute Straumann, Switzerland

Session 0705 | Wednesday, 6 March 2013 | 09:00-10:30 | Room G106

LATEST US REGULATORY MOVES TOWARDS FOSTERING INNOVATION: UPDATE ON MAIN NEW AND REVISED REGULATIONS AND GUIDANCE

Session chair:
Jill Hartzler Warner, Acting Associate Commissioner for Special Medical Program, FDA, USA

The FDA has been working to enhance the transparency, consistency, and efficiency of procedures applicable to combination products. This session looks at how it is helping to ensure that regulatory needs are met while lessening the burden to industry. How will the changes affect incentives for companies to market in the US versus the EU, which is tightening its requirements?

Latest US Regulatory and Policy Developments for Combination Products
Jill Hartzler Warner, Acting Associate Commissioner for Special Medical Program, FDA, USA

Will the Regulatory Shifts in the US and the EU Make the US Market More Attractive to Innovators and the EU Less So? How Far Has the Balance Swung?
Rita Peeters, Executive Director, Regulatory Affairs EMEA MD&D, Johnson & Johnson, Belgium

US and Global Moves Towards the Regulation of Companion Diagnostics
Peter Martin, Senior Director Global Regulatory Affairs RPD, Roche Professional Diagnostics, Germany

Session 0706 | Wednesday, 6 March 2013 | 11:00-12:30 | Room G106

INTERNATIONAL HARMONISATION: GLOBAL REGULATORS' PROGRESS FROM GHTF TO IMDRF - ARE WE ANY NEARER TO REGULATORY CONVERGENCE?

Session chair:
Siniša Tomić, Counselor for European Affairs, Agency for Medicinal Products and Medical Devices, Croatia

The International Medical Device Regulators Forum (IMDRF) has now officially taken over from the Global Harmonisation Task Force (GHTF), the organisation whose guidelines have inspired so much of the EU's current regulatory approach and which ceased operations at the end of 2012. What progress has it made so far? What are the advantages of a regulators-only forum? And what has been lost by having regulators only involved? What items are calling out to be addressed at a global level? Additionally, regulation of medical device law in Croatia will be addressed.

Latest News from the International Medical Device Regulators Forum and Future Goals: IMDRF
Mike Ward, Manager, International Programs Division, Health Canada, Canada

How Industry Is Working to Make Its Voice and Priorities Heard at the Global Regulatory Level
Sabina L. Hoekstra-van den Bosch, Senior Manager Standards & Regulations, Philips Healthcare, Netherlands

Regulating Medical Devices in the Transition Period in Croatia
Siniša Tomić, Counselor for European Affairs, Agency for Medicinal Products and Medical Devices, Croatia

Session 0708 | Wednesday, 6 March 2013 | 16:00-17:30 | Room G106

WHICH EU REGULATORY RULES FOR TELEMEDICINE, eHEALTH AND mHEALTH? HOW CAN INNOVATION BE ENCOURAGED?

Session chair:
Erik Vollebregt, Attorney, Axon Lawyers, Netherlands

How are drug/device Combinations Intended for eHealth and mHealth currently regulated? Is the regulatory environment keeping up with rapid pace of development in this cross-sector area? How are regulations likely to change? What about software and IT regulation and bandwidth issues? What about personal data rules?

European Commission Overview of the Importance of and Investment in eHealth and mHealth for Future Healthcare Sustainability
Tapani Piha, Head of Unit SANCO D3 Risk Assessment, European Commission, EU

Action Underway to Address Regulatory Needs for mHealth and eHealth to Encourage Innovation, and the Impact on Combination Product Manufacturers
Marielle Fournier, Director, Combination and Borderline Products, Voisin Consulting, France

How to Manage IT, Telecommunications Personal Data Rules and Software Regulatory Requirements in the EU and Global Environment, Including Case Studies
Erik Vollebregt, Attorney, Axon Lawyers, Netherlands

Theme 8 | eTools and Data Management

Hans van Bruggen, Director, eCTDConsultancy, Netherlands
Rob Middel, Head of R&D Business Development, Pharmaceutical R&D Quality & Compliance, Senior Director Janssen Biologics, Netherlands

Data about products is exchanged between industry and agencies in the context of a dossier. Product data or study data is also captured in databases not necessarily in context of a specific dossier. Data is often copied, but it would be easier to reuse or refer to the authoritative data sources for various purposes.

The use of standards, standardised processes and tools improves consistency and reliability of information. This applies to data managed in conventional ways and also using methods such as social media. The challenge is improved transparency raises doubts about the security of confidential data.

Session 0801 | Tuesday, 5 March 2013 | 09:00-10:30 | Room G103

MIGRATION FROM PAPER TO ELECTRONIC

Session Chair:
Rob Middel, Head of R&D Business Development, Pharmaceutical R&D Quality and Compliance Senior Director, Janssen Biologics, Netherlands

Can We Destroy Paper? Framework for the destruction of paper
Gillian Gittens, Client Account Manager, Phlexglobal, USA

What Can Industry Learn? A comprehensive review and analysis of FDA warning letters on computer system compliance
James Huang, Associate Director, Forest Research Institute, USA

Introducing Clinic Automation in a Phase I Unit with End-to-End eSource Data Processing
Joris De Bondt, Head of EDC and Data Standards, SGS Life Science Services, Belgium

Session 0802 | Tuesday, 5 March 2013 | 11:00-12:30 | Room G103

CLINICAL STANDARDS AND METADATA

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

Interoperability across heterogeneous systems, end to end data quality from clinical study protocol to submission and secondary data use are objectives we need to achieve as an industry to lower development cost while keeping high quality. This session will shed more light on how these objectives can be met with effective meta-data management in clinical development.

Data and Metadata Validation Strategies from Source to Submission
Dimitri Kutsenko, Sales and Product Manager, Entimo, Germany

CDISC Standards and MDR Bring Measurable Data Quality
Hanming Tu, Director, Clinical information Technologies, Octagon Research Solutions, USA

Collecting Clinical Data in Submission-Ready Format: The need for meta-data management from protocol onwards
Isabelle de Zegher, Senior Director, Clinical Data Standards and Consulting, Perceptive Informatics, Belgium

Session 0803 | Tuesday, 5 March 2013 | 14:00-15:30 | Room G105

PHARMACOVIGILANCE AND MEDICINAL PRODUCT STANDARDS AND METADATA

Session Chair:
Andrew Marr, Managing Director, Marr Consultancy, UK

The initial requirement for submission of Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) data by July 2012 has passed and now product records need to be maintained. This session addresses the experiences, successes and challenges currently being encountered. Furthermore, as the interim XEVMPD standard move towards being replaced by the ISO IDMP standards in 2016 the issues associated with these changes are also addressed.

XEVMPD Experience to Date - The ongoing activities and the future towards IDMP
John Kiser, Senior Director, Regulatory Operations, Abbott Laboratories, USA

From XEVMPD to IDMP - Challenges, pain, joy?
Christian Kravogel, Product Manager, EXTEDO, Germany

Transitioning to IDMP – Challenges and opportunities
Andrew Marr, Managing Director, Marr Consultancy, UK

Session 0804 | Tuesday, 5 March 2013 | 16:00-17:30 | Elicium 2

MESSAGES FROM THE AGENCIES

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

Electronic submissions have almost become a commodity within Canada, the EU, and the US. Agencies of other countries have also implemented electronic systems to be able to manage dossiers electronically. Agency representatives of Serbia and Turkey will give an update on the progress concerning electronic submissions in the Balkan and Turkey, respectively. The current pharmacovigilance legislation to improve public health. Several initiatives have been implemented to improve signal detection. The latter is also supported by an electronic register of (clinical) studies called ENCePP. The impact and importance of this register will be explained by an EMA representative.

Electronic Submissions in Balkan Countries
Igor Vanevski, Associate, Information Technology Group, Centre for Support, Agency of Medicines and Medical Devices, Serbia

eCTD and e-Health Applications in Turkey
Eda Cindoğlu , Ministry of Health, Turkey

Electronic Register of Studies: European Network of Centres for Pharmacoepideiology and Pharmacovigilance (ENCePP)
Hubert Leufkens, Co-Opted member, CHMP, Chairman, Medicines Evaluation Board (MEB), Netherlands

Session 0805 | Wednesday, 6 March 2013 | 09:00-10:30 | Room G102

SOCIAL MEDIA/USE OF TABLETS AND SMARTPHONES

Session Chair:
Rob Middel, Head of R&D Business Development, Pharmaceutical R&D Quality and Compliance Senior Director, Janssen Biologics, Netherlands

Social Media - Why it matters
Murali Parthasarathy, Managing Director, Saaraa Medical Solutions, USA

Patient Perspective
Gerard Nguyen, President, Rett Syndrome Europe, Avicenne Hospital University Paris Nord, France

Empowering the Patient – How to capitalise on a nationwide eHealth platform by introducing mHealth solutions
Thomas Hornbaek Svendsen, Principal Consultant, NNIT Life Science Solutions, Denmark

Session 0806 | Wednesday, 6 March 2013 | 11:00-12:30 | Room G102

ATTRIBUTING SAFETY REPORTS TO MEDICINAL PRODUCTS

Session Chair:
Ola Strandberg, Chief Product Officer, Uppsala Monitoring Centre, Sweden

Recent years have seen significant progress towards international harmonisation in data transfer formats for safety information. The new ICSR message format E2B(R3) requires structured medicinal product information as described in the family of Identification of Medicinal Products (IDMP) standards, which will have a large impact on the industry. While the European Medicines Agency have taken concrete steps towards IDMP in the implementation of the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD), the future is sketchier for the remaining ICH regions, which will all have regional variations.

This session will cover what is included in IDMP and how it relates to XEVMPD, practical implications and roadmaps thereof. In addition, it will outline the challenges of operating in a global regulatory landscape that goes far beyond the ICH countries, with a case study of incorporating ICSRs from the Chinese National Center for ADR Monitoring into the VigiBase™ database.

ICSRs Monitoring in Global Pharmacovigilance, Communication in the Evolving Pharmacovigilance Community
Madeleine Krieg, Uppsala Monitoring Centre, Sweden

The Impacts and Challenges of XEVMPD and its Future in IDMP
Jo English, Director of Regulatory Implementation Consulting, Liquent, UK

EVMPD is Done, Long Live IDMP
Wim Cypers, Vice President, Regulatory Affairs, ArisGlobal, Belgium

Session 0807 | Wednesday, 6 March 2013 | 14:00-15:30 | Room G102

HOW SYNERGY BETWEEN DATA MANAGEMENT AND TECHNOLOGY WILL DRIVE CLINICAL DEVELOPMENT IN THE NEXT DECADE

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

Entering the eWorld led to a dramatic increase in available data not just CRF and other subject related data, but also data on these data. Data Management has access to that data pool. This session will explore from a company perspective how utilisation of that data can have a huge impact on speed, quality and efficiency of clinical development, as well as data management on the long road from data cleaner to information and knowledge broker.

Non-eCRF Data: How availability of data can increase the accuracy of data acquisition
Johann Pröve, Head Global Data Management, Bayer Healthcare Pharmaceuticals, Germany

Risk-Based Monitoring: What data can CDM provide to reduce risks?
Dirk Langeneckhardt, Director, Global Project Data Management, Merck KGaA, Germany

How Do We Deliver Data to Drive Decisions: What to share with whom and how?
Pieter Voermans, Clinical Data Management Therapeuric Area Head CNS and Metabolism, F. Hoffmann La Roche AG, Switzerland

Theme 9 | Involvement of Experts in the Drug Approval Process

Gonzalo Calvo Rojas, President of the European Association for Clinical Pharmacology and Therapeutics (EACPT), Spain
Judith Creba, Head EU Liaison & Policy, Novartis Pharma, Switzerland

There is an increasing perception that involvement of all stakeholders during the regulatory review process of drug marketing authorisation applications is a valuable tool to widen the perspective under which the assessment is conducted and hence increase the quality of the outcome. Experts and patients are in a privileged position to provide a reliable and practice-based view on how the demonstrated and expected benefits and risks of any new therapeutic options are perceived. As with any other contribution, transparency in the process of involvement of patients and experts, and in the management of potential conflict of interest, is paramount. The European Regulatory System has made significant steps forward in this respect during the last years.

Discussions will focus on what is the added value of patient and expert contributions and the daily problems that academic and patient bodies and regulators need to face to secure quality and transparency during the whole process.

Session 0901 | Tuesday, 5 March 2013, 09:00-10:30 | Room G105

LEARNED SOCIETIES AND DRUG REGULATION

Session Chair:
Gonzalo Calvo Rojas, President of the European Association for Clinical Pharmacology and Therapeutics (EACPT), Spain

Drug development and drug assessment must be closely linked to the understanding of what the needs of patients are. The importance of setting up fora for interactions between regulators, academic associations and industry, ensuring high scientific standards and transparency will be discussed.

Regulators and Healthcare Professional Associations
Arantxa Sancho-López, CHMP Member, Spanish Agency on Medicines and Medical Devices (AEMPS), Spain

Interactions Between Industry and Learned Societies
Susan Longman, US Head, Drug Regulatory Affairs, Novartis, USA

Cardiovascular Clinical Trialists (CVCT) Forum as an Example of Interaction - is it exportable to other scientific disciplines?
Faiez Zannad, CVCT Chair, Past Chairman of the European Society of Cardiology Working Group on Cardiovascular Pharmacology and Drug Therapy, Inserm, University of Lorraine and CHU, France

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Session 0902 | Tuesday, 5 March 2013 | 11:00-12:30 | Room G105

PATIENTS AS EXPERTS IN DRUG REGULATION

Session Chair:
Ian Hudson, Director, Licensing Division, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Regulatory View
Ian Hudson, Director, Licensing Division, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Patient View
Jayne Spink, Chief Executive, Tuberous Sclerosis Association, UK

Industry and Patient Associations
Keith Allan, Director of Global Advocacy, Novartis, Switzerland

Session 0904 | Tuesday, 5 March 2013 | 16:00-17:30 | Room G105

HANDLING CONFLICT OF INTEREST (COI)

Session Chair:
Noël Wathion, Head of Patient Health Protection, European Medicines Agency, EU

Patients and experts are increasingly involved in drug regulatory assessment. Transparency in the management of potential conflict of interest is of paramount importance. The session elaborates on finding the right balance between minimising conflicts of interests versus the availability of the best possible expertise.

EMA Handling of Conflicts of Interests: Current status and how to move forward
Noël Wathion, Head of Patient Health Protection, European Medicines Agency, EU

Searching for the Perfect Expert: Regulatory and academic experience
Gonzalo Calvo Rojas, President of the European Association for Clinical Pharmacology and Therapeutics (EACPT), Spain

Interaction between Industry and Academia: Impact of conflicts of interest
Ruth Diazaraque-Marin, Senior Medical Affair Director Southern Europe, Gilead Sciences, UK

Theme 10 | Known Active Substances

Maren von Fritschen, Managing Partner, Director Regulatory Affairs, PharmaLex, Germany
Marta Marcelino, Member CMDh, Medicines Evaluation Department, National Authority of Medicines and Health Products (INFARMED), Portugal

In overall regulatory affairs business most activities and the majority of resources are spent on or around known active substances.

Seven sessions shed light on the different aspects of known active substances covering regulatory product life-cycle and the rules for assessment as well as specific aspects for fixed combination medicinal products. Specifically, an approach on known active substances in the self-care sector is discussed, as well as a more thorough understanding of a known active substance in terms of biosimilars. Also, in pharmacovigilance legislation, known active substances play a key role and are among the base data elements for the new European database on authorised products (EVMPD). One session will focus on the efforts spent to build up this database.

The view of industry and authority will be presented for all aspects with respect to efficiently fulfilling agencies' and legal demands, safe resources, and keep products on the market.

Session 1001 | Tuesday, 5 March 2013 | 09:00-10:30 | Room D201-202

NEW RULES FOR ASSESSMENT OF KNOWN ACTIVE SUBSTANCES

Session Chair:
Christa Wirthumer-Hoche, Member CMDh, Deputy Head, Austrian Medicines and Medical Devices Agency (AGES), Austria

The same Active Substance Master File (ASMF) is often used in different dossiers for multiple procedures assessed by different assessors. Currently there is no common platform/repository for information on ASMFs in Europe, which may result in divergent assessments and a list of questions. Furthermore, ASMF and related Assessment Reports (ARs) are kept and managed by each NCA individually, possibly lacking awareness of the same ASMF having been assessed in another NCA which can result in duplication of work and inefficient use of assessor resources. A new EU ASMF numbering system will help to identify identical dossiers. Information will be given about the project, setting up an ASMF-AR repository and starting a work sharing procedure for ASMF assessment. At the EU level we also have the CEP-procedure. Closer cooperation and exchange of ARs is ongoing. Industry will also present its point of view concerning this harmonised assessment and the principle of work sharing.

ASMF-Work Sharing in the EU - Will it work?
Christa Wirthumer-Hoche, Member CMDh, Deputy Head, Austrian Medicines and Medical Devices Agency (AGES), Austria

Provision of CEP Assessment – Options for harmonised review
Susanne Keitel, Director, European Directorate for the Quality of Medicines and Healthcare (EDQM), Council of Europe, EU

Expectations of Industry in Respect to Harmonisation of ASMF Documentation
Marieke van Dalen, Associate Director Regulatory Affairs, Global CMC Regulatory Affairs, Merck Sharpe & Dohme, Netherlands

Session 1002 | Tuesday, 5 March 2013 | 11:00-12:30 | Room D201-202

HARMONISATION: CHALLENGES IN PRODUCT INFORMATION / LABELLING

Session Chair:
Dinah Duarte, Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

This year will be challenging in terms of drug product information. The implementation of the pharmaceutical package and the European Commission report on patient information will lead to improved product information in order to increase their value for the healthcare professionals and the general public. The key need for many patients is to have access to harmonised information of multi source products. This session therefore will explore amongst regulators and consumer organisations ways to improve patient information and their contribution to the rational use of medicines and patient safety.

Labelling Information to Patients/Consumers: Can we all speak the same language?
Christoph Thalheim, Deputy CEO & Director External Affairs, European Multiple Sclerosis Platform (EMSP), Belgium

The Changing Environment for Product Information Harmonisation – A regulator's perspective
Sandra Petraglia, Scientific Administrator, Italian Medicines Agency (AIFA), Italy

Bridging Labelling Expectations in the New Regulatory Framework - The industry's challenge
Barbara Lachmann, Senior Advisor, Center of Excellence Product Information, Merck KGaA, Germany

Session 1003 | Tuesday, 5 March 2013 | 14:00-15:30 | Room D201-202

MAINTENANCE OF MEDICINAL PRODUCTS WITH KNOWN ACTIVE SUBSTANCES – VARIATIONS

Session Chair:
Susanne Winterscheid, Member CMDh, Head of Project Management of Licensing Division 3, German Federal Institute for Drugs and Medical Devices (BfArM), Germany

Experiences with the maintenance of medicinal products by variation procedures are presented from different points of view: Authority representatives will present statistics on grouping and work sharing. Industry representatives will show examples on the efforts and necessary actions in keeping product licences up-to-date. Furthermore, the impact of the new pharmacovigilance legislation on the maintenance of medicinal products will be discussed.

Success of Grouping and Work Sharing
Susanne Winterscheid, Member CMDh, Head of Project Management of Licensing Division 3, German Federal Institute for Drugs and Medical Devices (BfArM), Germany

Case Study of a Centralised Product Highly Active in Product Maintenance Activities
Gerhard Schlüter, Vice President Specialty Medicine, Bayer Healthcare Pharmaceuticals, Germany

Impact of the Pharmacovigilance Legislation on Variations for Generic Products
Beata Stepniewska, Deputy Director General, European Generics Medicines Association (EGA), Belgium

Session 1004 | Tuesday, 5 March 2013 | 16:00-17:30 | Room D201-202

XEVMPD: LONG-TERM EXPECTATIONS AND BENEFITS

Session Chair:
Karl-Heinz Loebel, Director Regulatory Operations, PharmaLex

In the last two years major resources have been allocated to support the data collection and to feed EMA's Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) database with the requested information on authorised medicinal products. After a comparatively slow start, especially since October 2011, the pharmaceutical industry has had to make tremendous efforts to gather detailed knowledge of the requirements, develop or acquire software solutions and train staff to meet the legal deadline of 2 July 2012. On the other hand, EMA had to deal with administrative, organisational and technical challenges and with more than 250,000 medicinal product datasets submitted by more than 1300 pharmaceutical companies.

This session will analyse the experience gained so far and aim to project the future use of EMA's XEVMPD database from the Agency's and industry's perspective. It will focus on the resources spent on data collection, critically discuss benefits and risks for industries of different sizes and market orientation and give an outlook on the future development of the database, the transmission standards and their consequences for marketing authorisation holders.

Electronic Submission of Information on Medicines in the Context of the New Pharmacovigilance Legislation in the EU: Current status and next steps
Speaker invited - see EuroMeeting Extra for details

XEVMPD and IDMP: Current challenges and future chances, lessons learned from industry perspective, impact of XEVMPD and IDMP on RIMS: A holistic approach, IDMP standards as a chance for effective and efficient regulatory data management
Timm Pauli, Head of Darmstadt Global Regulatory Operations Manager, Merck KgaA, Germany

EVMPD/XEVPRM from SMEs' perspectives, EVWEB – challenges, limitations and opportunities, overall long-term effects and expectations
Karl-Heinz Loebel, Head of Regulatory Operations, PharmaLex

Session 1005 | Wednesday, 6 March 2013 | 09:00-10:30 | Room D201-202

KNOWN ACTIVE SUBSTANCES FOR THE SELF-CARE SECTOR

Session Chair:
Horst Kastrup, Senior Regulatory Advisor, Meda Pharma, Germany

Responsible self-care practices are an important contribution to public health, even more in view of limited resources in public health systems. Self care practice has long, but differing traditions in the European nations. These differences and a tendency to use standards for prescription drugs in regulations for self-care products have been limiting the potential of self-care medicine. The session will provide updates on the progress made to tackle these issues and to provide views for the future.

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Current Trends to Switch from Medicinal Products to Self-Care medical Devices, Cosmetics and Health Food Containing Known Active Substances.
Horst Kastrup, Senior Regulatory Advisor, Meda Pharma, Germany

Better Market Access for Non-Prescription Medicines in the MRP and DCP: The CMDh Best Practice Guide for authorisation of non-prescription medicines in the MRP and DCP – goals and achievements
Colette McCreedy, Specialist in Self- Medication Vigilance and Risk Management of Medicines (VRMM), Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Agenda for the Medical Self-Care Sector – Potential de-regulation for well known active substances: Best information access for the consumer to ensure maximum benefit and safe use of self-medication products
Sheila Kelly, Board Member, Association of the European Self-Medication Industry (AESGP); Executive Director, Proprietary Association of Great Britain (PAGB), UK

Panel discussion – What may be done over the next few years to strengthen the role of safe self medication in the markets?

Session 1006 | Wednesday, 6 March 2013, 11:00-12:30 | Room D201-202

BIOSIMILARS: DEVELOPING A MORE THOROUGH UNDERSTANDING OF A KNOWN ACTIVE SUBSTANCE

Session Chair:
Virginia Acha, Director, International Policy - Global Policy, Pfizer, UK

Just when you thought you knew all you needed to know about known actives, the rapidly developing field of biosimilars is presenting new challenges and opportunities. Taken from three perspectives, this session will address how establishing biosimilarity advances our understanding of known actives. Ironically, this is done whilst biosimilars themselves are not well understood by key stakeholders, such as physicians, patients and the wider public. Each of the presenters will discuss these points, reflecting on key developments and initiatives underway in both the regulatory and policy arenas in Europe.

Biosimilarity: A better definition of terms and concepts
Christian Schneider, Chair Committee for Advanced Therapies (CAT), Senior Medical Officer, Danish National Board of Health, Denmark

Biosimilars: Case studies on how to hit the target
Jörg Windisch, Chief Science Officer, Sandoz, Austria

Trust through Engagement: Explaining biosimilarity to a wider audience
Virginia Acha, Director, International Policy - Global Policy, Pfizer, UK

Session 1007 | Wednesday, 6 March 2013 | 14:00-15:30 | Room D201-202

COMBINATION MEDICINAL DRUG PRODUCTS OF KNOWN ACTIVE SUBSTANCES

Session Chair:
Christer Backman, Member CMDh, EU Coordinator and Senior Expert, Medical Products Agency, Sweden

Form the patient's perspective combination medicinal products bear potential benefits. For industry such products may be promising as they provide innovations with only incremental research efforts. National agencies' attitudes towards combination medicinal products, however, are still diverse and lack a harmonised approach.

Agency's View on Combination Medicinal Products – A disputed topic
Christer Backman, Member CMDh, EU Coordinator and Senior Expert, Medical Products Agency, Sweden

Known Active Substances in Fixed Dose Combination Products: An area of investigation for industry?
Alexander Natz, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Belgium

Expectations and Benefits of Combination Medicinal Products from the Patient's Perspective
Patient representative invited- see EuroMeeting Extra for details

Theme 11 | Effective Antibacterials: The present and the future

Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Multi-resistant bacteria are a threat not only due to the infections they cause, but to modern medicine. Transplantation, percutanepus choronaru interventions, elective surgery or saving preterm babies require effective antibiotics. There are very few antibiotics in development. The session will explore the scientific and regulatory challenges; the necessary market incentives; alternative approaches; and the need to preserve new antibiotics for future generations.

Session 1101 | Tuesday, 5 March 2013 |09:00-10:30 | Room G104

BOTTLENECKS IN RESEARCH: HOW DO WE REPLENISH THE PIPELINE?

Session Chair:
Chair invited - see EuroMeeting Extra for details

Setting the Scene: Superbugs - Have we already run out of options or is there hope? What are the needs?
Otto Cars, Uppsala University, Sweden

It Is Not That Easy - The scientific challenges
David Payne, Vice President Antibacterial DPU, GlaxoSmithKline, USA

ND4BD - New Drugs for Bad Bugs - A new project in IMI
Michel Goldman, Executive Director, Innovative Medicines Initiative (IMI), Belgium

Session 1102 | Tuesday, 5 March 2013 | 11:00-12:30 | Room G104

PRAGMATIC REGULATION - ROLE OF GUIDELINES IN STIMULATING DEVELOPMENT OF NEW ANTIBIOTICS

Session Chair:
Chair invited - see EuroMeeting Extra for details

In order to streamline antibacterials development, clear regulatory requirements are deemed essential in order to allow developers to proceed smoothly in the definition of their clinical development plans. Regulatory pathways, in accordance with current legislative tools that would allow rapid approval for new antibacterials targeting unmet medical needs, should be further considered.

EMA - Moving towards more pragmatic solutions
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, Medical Products Agency (MPA) Sweden

Industry Perspective: The need for predictable requirements
Laurenz Kellenberger, Chief Scientific Officer, Basilea Pharmaceutica, Switzerland

Case study: Getting over the regulatory hurdles with the new drug Ceftarolin
John Rex, VP and Head of Infection, Global Medicines Development, AstraZeneca

Session 1103 | Tuesday, 05 March 2013 | 14:00-15:30 | Room G104

PRESERVING WHAT WE HAVE - PRUDENT AND CONTROLLED USE

Session Chair:
Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

National Experience with Training and Education: How can we make prescribers aware?
Laura Piddock, President, British Society of Antimicrobial Chemotherapy, Division of Immunity and Infection, Antimicrobial Agents Research Group, University of Birmingham, UK

The Role of Resistance Monitoring in fostering rational use
Speaker invited

The Role of Industry: Time for a global compact?
Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Session 1104 | Tuesday, 5 March 2013 | 16:00-17:30 | Room G104

NEW APPROACHES TO COMBAT RESISTANCE

Session Chair:
Chair invited - see EuroMeeting Extra for details

Approaches other than antibacterials should also be considered as an alternative way to mitigate the impact of antimicrobial resistance on the current armamentarium. In this sense, development of vaccines for preventing infections caused by pathogens for which antimicrobial resistance is problematic, or innovative medicines that act differently traditional to antibiotics, should be fostered. Point-of-care diagnostics are eagerly awaited in order to allow more rational use of antibacterials and to support the development of new antibacterials targeting specific pathogens.

Vaccines: A forgotten tool. What is the pipeline for Pseudomonas Aeruginosa?
Gerd Döring, Professor Microbiology, Institute of Medical Microbiology and Hygiene University of Tübingen, Germany

Nanotechnology - A tiny but effective weapon
Speaker invited - see EuroMeeting Extra for details

The Role of Diagnostics
Herman Goossens, Professor of Microbiology, University of Antwerp, Belgium

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Theme 12 | Effectiveness and Efficiency of the EU Regulatory System - Does new legislation enable innovation and facilitate co-operation?

Isabelle Stöckert, Head Global Regulatory Affairs Europe/Canada, Bayer Healthcare Pharmaceuticals, Germany
Melek Bostanci Önol, Head of Regulatory Affairs & Quality Assurance, Boehringer Ingelheim, Turkey

This theme provides a high level discussion on the efficiency of the current legislation and various new legislative proposals in Europe. How will they shape the regulatory system? How can quality be built into a new legislation? Is it effectively implemented? Has it reached its primary objective? Does it improve public health? Does it increase efficiency and decrease bureaucracy? Does it increase competitiveness?

Session 1201 | Tuesday, 5 March 2013 | 09:00-10:30 Auditorium Ground Floor

THE EU DRUG DEVELOPMENT AND APPROVAL SYSTEM: ADAPTING THE FRAMEWORK OF DRUG DEVELOPMENT AND APPROVALS TO ENABLE R&D INNOVATION AND SUPPORT SOCIETAL NEEDS - AN OUTLOOK ON THE CHANGING ENVIRONMENT FOR 2020

Session Chair:
Susan Forda, Vice President, International Regulatory Affairs, Lilly, UK

There is a consensus among stakeholders that the current drug regulatory system must be changed to support innovation. Many initiatives and valuable ideas are being explored on how to foster the development and approval of new drugs and at the same time ensure robustness of decision-making: Progressive/adaptive licensing, targeted medicines, targeted patients, adaptive clinical trial design, global development, use of patients in the benefit risk assessment are some of the keywords. This session will debate possible new regulatory approaches from the European Medicines Agency, patient and industry perspective. What could be the next practical and actionable steps towards a more efficient drug regulatory system?

Patient Perspective
Yann Le Cam, CEO, EURORDIS, France

Industry Perspective
Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Panel with Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, Medical Products Agency (MPA) Sweden

Session 1203 | Tuesday, 5 March 2013 | 14:00-15:30 Auditorium Ground Floor

FIRST EXPERIENCE WITH THE PHARMACOVIGILANCE LEGISLATION

Session Co-Chairs:
Hubert Leufkens, Co-Opted member, CHMP, Chairman, Medicines Evaluation Board (MEB), Netherlands
Isabelle Stöckert, Head Global Regulatory Affairs Europe/Canada, Bayer Healthcare Pharmaceuticals, Germany

The new pharmacovigilance legislation is the biggest change to the regulation of human medicines in the European Union since 1995. This session will focus on how the different stakeholders in the European Regulatory Network interact. Does communication and co-operation work? What are the first experiences?

New Tasks for CMDh – How do the new pharmacovigilance processes work?
Peter Bachmann, Senior Expert, European Drug and Regulatory Affairs, German Federal Institute for Drugs and Medical Devices (BfArM), Germany

Sharing Perspectives in a Complex Environment – CHMP's first experiences with the new pharmacovigilance processes
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, Medical Products Agency (MPA) Sweden

First Experience with the New Pharmacovigilance Processes in Close Interaction with CHMP and CMDh – the PRAC perspective
George Aislaitner, Head of Pharmacovigilance Section, National Organisation for Medicines (EOF), Greece

Session 1204 | Tuesday, 5 March 2013 | 16:00-17:30 Auditorium Ground Floor

EARLY DIALOGUE IN DRUG DEVELOPMENT

Session Chair:
Christine Mayer-Nicolai, Global Regulatory Intelligence & European Regulatory Policy, Merck KgaA, Germany

How can we optimise and de-risk new product development by early stakeholder involvement (i.e. EMA Scientific Advice, portfolio meetings, qualification of novel methodologies, ITF briefing meetings and other options)? This session will provide an overview of options for drug developers to intensify early dialogue with regulators and other stakeholders. The diversity of possibilities for interaction has increased over the last years. It has thus become more and more important to be aware of the different processes (e.g. EMA or national advice, novel methodology qualification, ITF briefing meetings, parallel EMA and HTA advice) and their pros and cons in order to define the best strategy to optimise drug development based on early dialogue.

Overview of Available Options for Early Dialogue and Which Procedure to Use for What Kind of Topic
Jan Müller Berghaus, Member Scientific Advice Working Party (SAWP), Head of the Mono and Polyclonal Antibodies division, Immunology Section, Paul-Ehrlich-Institute, Germany

Qualification of Novel Methodologies for Drug Development: Experience to date and further options for use of the process
David Neil, Alternate, Scientific Advice Working Party (SAWP), Senior Medical Assessor, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Industry Experience and Needs
Max Wegner, Head Global Regulatory Affairs, General Medicine, Bayer Healthcare Pharmaceuticals, Germany

Session 1205 | Wednesday, 6 March 2013 | 09:00-10:30 Auditorium Ground Floor

INNOVATIVE APPROACHES TO PRODUCT INFORMATION FOR PHYSICIANS AND PATIENTS

Session Chair
Lisette Vromans, Associate Director, Regulatory Liaison, Merck Sharp & Dohme, Belgium

Are today's package leaflets a betrayal of European patients? This session will provide stakeholders views on how the SmPC and Package Leaflet can be made fit for the future and for purpose. Patient/physician needs will be at the centre of this session. Regulators will be invited to explain their ideas for future options to create better SmPCs and better Package leaflets and the steps needed to get there. And industry will show their concept on how to make product information useful communication tools to enable better outcomes and possibly contribute to improving health literacy by using innovative technologies (electronic leaflets, visualisations).

Patient Perspective on What is Needed to Make the Patient Leaflet a Communication Tool
Nicola Bedlington, Director, European Patients' Forum, Belgium

Improving Information for Patients and Healthcare Professionals: View of a regulator
Jan MacDonald, Head Patient Information Quality, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

The Way Forward: From package leaflets towards electronic product information tailored to the individual need of patients and healthcare professionals
Gesine Bejeuhr, Regulatory Affairs/Quality, vfa Research-Based Pharm Companies, Germany

Session 0306/1206 | Wednesday, 6 March 2013 | 11:00-12:30 Auditorium Ground Floor

TRANSPARENCY ON DOSSIER AND DECISION MAKING – HAS PUBLIC TRUST INCREASED?

Session Co-Chairs:
Ragnar Löfstedt, Director, King's Centre for Risk Management, Department of Geography, King's College London, UK

Over the past ten years there have been a number of regulatory incidents affecting the pharmaceutical sector in both the United States and Europe that have led to widespread public and stakeholder distrust of the sector as a whole. As a result, European regulatory agencies have become strong promoters of transparency. The aim of this session is to shed further light on the transparency agenda in Europe. Issues that will be addressed include: Where are we in terms of the EMA proposal of sharing raw data from clinical trials, how are the public, patient groups and general medical practitioners responding to these changes and new challenges?

To address these questions we have assembled a stellar panel composed of:

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

Andrew Jack, Pharmaceutical Correspondent, Financial Times, UK

Discussant:
Aginus Kalis, Chair HMA, Executive Director, Medicines Evaluation Board, Netherlands

Session 1207 | Wednesday, 6 March 2013 | 14:00-15:30 Auditorium Ground Floor

REGULATORY TOWN HALL MEETING

Session Co-Chairs:
Guido Rasi, Executive Director, European Medicines Agency, EU
Christa Wirthumer-Hoche, Member CMDh, Deputy Head, Austrian Medicines and Medical Devices Agency (AGES), Austria

At the Town Hall Meeting attendees can put their burning questions to expert regulators about these topics:
- Latest views on legislative changes
- Implementation of the new pharmacovigilance legislation
- Transparency
- Drug shortages
- Decision making
- New approaches to licensing

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

Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, Medical Products Agency (MPA) Sweden

Aginus Kalis, Chair HMA, Medicines Evaluations Board, Netherlands

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

Session 1208 | Wednesday, 6 March 2013 | 16:00-17:30 Auditorium Ground Floor

CLINICAL TRIALS IN EUROPE: WILL THE REVISED LEGISLATION MEET THE DEMANDS OF TOMORROW?

Session Chair:
Angelika Joos, Director, Head Regulatory Policy, EU & Most of World, Merck Sharp & Dohme (Europe) Inc., Belgium

The revision of the Clinical Trials Directive can play an important role for Europe's competitiveness to create a more favourable environment for R&D investment. This will be crucial, not only for clinical trial conduct, but as part of the bigger picture to facilitate ongoing work to make the drug development process more efficient.

This session will examine how the new proposal will overcome the current barriers and discuss specific procedural and regulatory aspects from various viewpoints (regulator, industry and EU commission). It will provide an update on the current state of the debate and make suggestions for moving forward to ensure that this revision is not only focused on codifying existing experience, but lives up to the fast-changing and ever-developing scientific state-of-the-art.

Commission Objectives and Observations in the Current Debate
Stefan Führing, Administrator Pharmaceuticals, DG Health and Consumers, European Commission, EU
Industry Perspective on the Proposal and the Practical Implications
Nick Sykes, Senior Director, EU Regulatory Policy, Pfizer UK

Regulator's View on the Legal Proposal and the Practical Implications
Greet Musch, Director-General DGPRE, Federal Agency for Medicines and Health Products (AFMPS), Belgium

Panel with Geneviève Michaux, Covington & Burling, Belgium

Theme 13 | Globalisation

Christer Backman, Member CMDh, EU Coordinator and Senior Expert, Medical Products Agency, Sweden
Ning Xu, Vice President, Head of Clinical Development Service, Covance, China

Globalisation is one of the drivers that can bring a new drug to the global market faster, especially the emerging and developing market. To further speed up the drug development, the industry, regulators, and academics are working together trying to harmonise regulations; to standardise quality; to overcome cultural differences; to better understand various markets; to drive cross-national communication and collaboration. There are still a lot of challenges in the process of globalisation but the good understanding and managing of those challenges will turn them into opportunities for more successful drug development to save the limited resources, promote common global harmonisation and enhance healthcare for the benefit of patients.

Session 1301 | Tuesday, 5 March 2013 | 09:00-10:30 | Forum

SAFE, EFFECTIVE AND AFFORDABLE MEDICINAL PRODUCTS FOR A GLOBAL POPULATION

Session Chair:
Marijke Pubben, Vice President EMEA Quality, Sharpe & Dohme, Netherlands

It is in the best global public interest to accelerate availability of affordable drug products to the world's patients, consumers and healthcare providers. To enable this, regulators and industry are looking for ways to collaborate, build trust, mutual confidence and common understanding within their own community and amongst each other.

This session will provide opportunities and challenges from industry and regulators to drive towards this promising future.

Building a Global Quality Culture
Marijke Pubben, Vice President EMEA Quality, Sharpe & Dohme, Netherlands

International Cooperation on GxP/GCP Inspections
Tor Gråberg, Head of Inspections Unit, Medical Products Agency (MPA), Sweden

Improving Site Selection and Regulatory Transparency through Global Infrastructure Mapping and Collaborative Analytics
Gustavo Kesselring, Executive Director, ViS Research Institute, Brazil

Session 1302 | Tuesday, 5 March 2013 | 11:00-12:30 | Forum

INTERNATIONAL COLLABORATION IN THE REVIEW OF GENERIC DRUGS

Session Chair:
Beata Stepniewska, Deputy Director General, European Generics Medicines Association (EGA), Belgium

With the globalisation trend, an increasing number of generic medicines manufacturers are keen to introduce their products on a global scale. For health authorities, a need for fast supply of medicinal products from other markets may occur in case of unexpected shortages in their region. A single development programme and more harmonised assessments of generic medicinal products between various markets in order to avoid unnecessary duplications of effort shall be discussed among the authorities and industry.

Single Development Programme and More Harmonised Assessments of Generic Medicinal Products - EGA proposal
Beata Stepniewska, Deputy Director General, European Generics Medicines Association (EGA), Belgium

Single Development Programme and More Harmonised Assessments of Generic Medicinal Products - View of the CMDh
Peter Bachmann, Senior Expert, European Drug and Regulatory Affairs, German Federal Institute for Drugs and Medical Devices (BfArM), Germany

Single Development Programme and More Harmonised Assessments of Generic Medicinal Products - FDA perspective
Speaker invited - see EuroMeeting Extra for details

Single Development Programme and More Harmonised Assessments of Generic Medicinal Products - Health Canada perspective
Mike Ward, Manager, International Programs Division, Health Canada , Canada

Session 1303 | Tuesday, 5 March 2013 | 14:00-15:30 | Forum

GMP IN CHINA

Session Chair:
Ning Xu, Vice President, Head of Clinical Development Service, Covance, China

Chen Huiping, Senior Engineer, Center for Drug Certification, State Food and Drug Administration (SFDA), China

Ye Jiahui, Section Chief, Drug Safety Inspection Department, State Food and Drug Administration (SFDA), China

Session 1304 | Tuesday, 5 March 2013 | 16:00-17:30 | Forum

INTERNATIONAL COOPERATION OF GLOBAL REGULATORS

Session Chair:
Marie Dray, President, International Regulatory Affairs Group LLC, USA

Heads of regulatory agencies have increased their cooperation and communication with each other over the past decade and have shared their experiences at DIA EuroMeetings and Annual Meetings for more than 8 years. An interested international following has gathered to hear each annual update.

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

Additional speakers invited - see EuroMeeting Extra for details

Session 1305 | Wednesday, 6 March 2013 | 09:00-10:30 | Room E102

EXPANSION IN EMERGING MARKETS: OPPORTUNITIES AND CHALLENGES

Session Chair:
Xiaoxiang Chen, Vice President Drug Development, Boehringer Ingelheim, China

Globalisation is one of the drivers that can bring the new drug to the global market faster, especially the emerging and developing market. To further speed up the drug development, the industry, regulators, and academia are working together trying to harmonise regulations, to standardise quality, to overcome cultural differences, to better understand various markets, and to drive cross-national communication and collaboration. There are still a lot of challenges in the process of globalisation but a good understanding and managing of those challenges will turn them into opportunities for more successful drug development to save the limited resources, promote common global harmonization, and enhance healthcare for the benefit of patients.

Resizing the Global Contract R&D Services Market
Stella Stergiopoulos, Project Manager, Tufts Center for the Study of Drug Development, USA

Clinical Trial Landscape in Asia: Focus and global connection
Yan Wu, General Manager, Division of Medical and Drug Development China, Daiichi-Sankyo, China

Speed Up Clinical Development Programmes in China through Robust Site Expansion and Development
QingAn Jiao, Head of Clinical Operations, Asia Pacific, Roche Product Development in Asia Pacific, China

Session 1306 | Wednesday, 6 March, 11:00-12:30 | Room E102

ENVIRONMENTAL CONSIDERATIONS IN PRODUCTION OF MEDICINAL PRODUCTS

Session Chair:
Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Anette Küster, Environmental Risk Assessor, Federal Environment Agency, Germany

Charlotte Unger, Scientific Director Environment, Medical Products Agency (MPA), Sweden

Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Session 1307 | Wednesday, 6 March 2013 | 14:00-15:30 | Room E102

ASIAN STRATEGY OF THE USA, EUROPE AND JAPAN

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

Asia is gaining in importance in drug development, production, and marketing. This session discusses the efforts by the regulatory authorities and industry from Japan, the US and the EU to promote drug development in Asia and global cooperation with the international community.

International Cooperation and Consideration on Multi-Regional Clinical Trial among Asia
Shinobu Uzu, Office Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Asia – the world's fastest growing market: Perspective from the pharmaceutical industry
Ira Wolf, Japan Representative, Pharmaceutical Research and Manufacturers of America, Japan

Challenges to Asian Companies to Comply with European Legislation on (Traditional) Herbal Medicinal Products
Werner Knöss, Chair Committee on Herbal Medicinal Products (HMPC), Head of Complementary and Alternative Medicines and Traditional Medicinal Products, BfArM, Germany

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Theme 14 | Regulatory Science

Christine Gispen-De Wied, Scientific Program Manager, Medicines Evaluation Board (MEB), Netherlands
Hubert Leufkens, Co-Opted member, CHMP, Chairman, Medicines Evaluation Board (MEB), Netherlands

Regulatory science contributes to the scientific basis of regulation and decision making. The urge of society for transparency and understanding has sped up FDA, EMA and its member states to put regulatory science high on their agenda. The spin-off of such interest is highlighted in Theme 14. The first session starts out with setting the scene: What can we learn from regulatory science? What is the scope? What can be gained? In the subsequent session, this is illustrated through regulatory procedures, modelling of the decision making process, and communication with consumers.

Session 1401 | Tuesday, 5 March 2013 | 09:00-10:30 | Room G106

SETTING THE SCENE: IMPORTANCE OF REGULATORY SCIENCE THROUGHOUT

Session Chair:
Hubert Leufkens, Co-Opted member, CHMP, Chairman, Medicines Evaluation Board (MEB), Netherlands

In this session, regulatory science as a relative new applied science discipline will be highlighted and its contribution to discussion and debate with regard to further improve and optimise drug development and innovation.

The European View
Speaker invited - see EuroMeeting Extra for details

FDA Perspective
Frank Weichold, Director, Science and Innovation, OCS, OC, FDA, USA

MEB Achievements
Christine Gispen-De Wied, Scientific Program Manager, Medicines Evaluation Board (MEB), Netherlands

Session 1402 | Tuesday, 5 March 2013 | 11:00-12:30 | Room G106

THE WAY FORWARD IN CNS: REGULATORY SCIENCE AT THE EDGE

Session Co-Chairs:
Barbara van Zwieten-Boot, Medicines Evaluation Board (MEB), Netherlands

In this session progress in the field of CNS (Central Nervous System) drug development is presented from a regulatory perspective, e.g. the usefulness of qualifying biomarkers for various purposes and the updating of regulatory guidelines.

Biomarker Qualification Procedure
Violet Stoyanova, Clinical Assessor and COMP member, Medicines Evaluation Board (MEB), Netherlands

Challenges in the Revised Guideline for Depression
Karl Broich, Vice President, German Federal Institute for Drugs and Medical Devices (BfArM), Germany

Changes in the Field of Multiple Sclerosis
André Elferink, Head CNS Assessor, Medicines Evaluation Board (MEB), Netherlands

Session 1403 | Tuesday, 5 March 2013 | 14:00-15:30 | Room G106

THE ESCHER PROJECT: REGULATORY SCIENCE IN PRACTICE

Session Chair:
Pieter de Graeff, Groningen University, Medicines Evaluation Board (MEB), Netherlands

In this session, the Escher project of Top Institute Pharma will be highlighted, a project that investigated regulatory practices and processes over the past 4 years: Risk/benefit modelling and the in-depth investigation of the approval process are among the cases that have been worked out.

Escher Deliveries and Future Perspective
Pieter Stolk, Faculty of Science, Division of Pharmacoepidemiology and Pharmacotherapy, Utrecht Institute for Pharmaceutical Sciences, Utrecht University, Netherlands

The ADDIS Model for Benefit/Risk Assessment
Hans Hillege, Clinical Assessor, Medicines Evaluation Board (MEB), University Medical Centre Gröningen, Netherlands

Success and Failure Factors for Positive MA
Michelle Putzeist, PhD Student, University of Utrecht, Netherlands

Session 1404 | Tuesday, 5 March 2013 | 16:00-17:30 | Room G106

PATIENT AND CONSUMER ROLES: THEIR INPUT IN REGULATORY SCIENCE

Session Chair:
Ragnar Lofstedt, Director, the King's Centre for Risk Management, the International Policy Institute, King's College London, UK

In this session the role of the patient and consumer as stakeholders in drug regulation will be put forward both from the perspective of their input to us as well as our input to them: Are we reaching the patient consumer, and can we improve?

Risk Communication and Perception
Peter Mol, Assistant Professor, University Medical Center Groningen, Netherlands

Patient View on Risk Communication
Lise Murphy, Co-Chair Patients' and Consumers' Working Party (PCWP), EURORDIS, France

Lessons to Be Learned
Alasdair Breckenridge, Emerging Science and Bioethics Advisory Committee (ESBAC), Chair, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Theme 15 | Growing Demand for Quantitative Approaches in Drug Development

Jürgen Kübler, Global Head, Clinical Sciences, CSL Behring, Germany
Steven Teerenstra, Biostatistics Working Party (BSWP), Statistical Evaluator, Medicines Evaluation Board, Netherlands

The last decade has witnessed a rapidly growing amount of data as well as the increasing accessibility of data. The expectation to optimally exploit this wealth of data has grown. The theme will touch on various areas where sound statistical approaches play an integral role to ensure informed decision making. This includes a thorough discussion of new approaches as well as a critical appraisal of current recommendations and guidelines. The theme aims to provide a forum for discussion between industry, academic and regulatory thought leaders. Relevant experience will be shared and discussed, reflecting on lessons learned. Recommendations for best practice will be developed.

Session 1505 | Wednesday, 6 March 2013 | 09:00-10:30 | Forum

A CASE STUDY USING THE FRAMEWORK SUPPORTED BY QUANTATATIVE METHODS FOR BENEFIT/RICK ASSESSMENT

Session Chair:
Deborah Ashby, Imperial College London, UK

We apply the BRAT framework to a case study assessing the Benefit/Risk of Tysabri for the treatment of Multiple Sclerosis. Two quantitative methods, the NNT and Multi-Criteria Decision Analysis are compared; followed by a regulatory perspective.

Christoph Dierig, Head Global Integrated Analysis, Bayer Pharma AG, Germany

Richard Nixon, Expert Modeler, Novartis Pharma, Switzerland

Andrew Thomson, Head of Epidemiology, MHRA, UK

Session 1506 | Wednesday, 6 March 2013 | 11:00-12:30 | Forum

EQUIVALENCE OF ORALLY INHALED PRODUCTS

Session Chair:
Steven Teerenstra, Biostatistics Working Party (BSWP), Statistical Evaluator, Medicines Evaluation Board, Netherlands

Drugs used for asthma or COPD are often orally inhaled products. In applications for generic drugs for orally inhaled products, typical design and analysis challenges that arise are to prove assay sensitivity in the presence of flat dose-response curves, and to deal with highly variable reference products. We will discuss these issues from a statistical, clinical and pharmacokinetic perspective.

Proof of Assay Sensitivity in Equivalence/Non-inferiority Studies
Dieter Hauschke, Professor in Biometrics, Institute for Medical Biometrics and Medical Informatics, University of Freiburg, Germany

Establishing PK Equivalence in Orally Inhaled Products with Highly Variable Reference Products
Alfredo Garcia-Arieta, Head of the Service of Generics and Pharmacokinetics, Division of Pharmacology and Clinical Evaluation, Human Use Medicines, Spanish Agency for Medicines and Health Care Products (AEMPS) Spain

Clinical Considerations on Design of Studies to Support Generics Applications for Orally Inhaled Products
Hanneke van der Woude, Clinical Assessor, Medicines Evaluation Board (MEB), Netherlands

Session 1507 | Wednesday, 6 March 2013 | 14:00-15:30 | Forum

SUBGROUP ANALYSES

Session Chair:
Joachim Vollmar, Executive Consultant, International Clinical Development Consultants, USA

Sub-group analyses are commonly conducted in completed confirmatory clinical trials with the objective of learning about differential treatment effect across sub-groups. This is important for a comprehensive assessment of trials in marketing authorisation applications, however, clinical trials are seldom properly planned for establishing an efficacy or safety claim for a subgroup in case the trial fails to establish the same claim for the total population. The CHMP is currently preparing a guideline on this topic. Presentations in this session will focus on methodological issues related to interpretation of subgroup findings from completed clinical trials and designing clinical trials with the objective of establishing efficacy/safety claims for the total population or a targeted subgroup.

Assessment of Sub-groups in Significant and Non-Significant Clinical Trials
Armin Koch, Professor, Head Institute of Biometry, University of Hannover, Germany

Confirmatory Sub-group Analyses: Case studies
Frank Bretz, Global Head of Statistical Methodology, Novartis Pharma, Switzerland

Sub-group Selection: Adaptive clinical trials
Vladimir Dragalin, Senior Vice President Innovation Center, Aptiv Solutions, USA

Session 1508 | Wednesday, 6 March 2013 | 16:00-17:30 | Forum

STATISTICAL HOT TOPICS IN SCIENTIFIC ADVICE

Session Chair:
Rob Hemmings, Chair Scientific Advice Working Party (SAWP), Medicines and Healthcare Products Regulatory Agency (MHRA), UK

This session is intended to focus on statistical subjects that have been recently of particular interest in the regulatory arena. The “hot topics” are presented as a case-study for recurrent event data in cardiovascular diseases, multiplicity issues in the context of a European regulatory guideline and clinical development considerations when different agencies require different primary endpoints.

Recurrent Event Data Approaches in Cardiovascular Outcome Trials
Mouna Akacha, Statistical Methodologist, Novartis Pharma, Switzerland

Feedback from the EMA 2012 Workshop on Multiplicity Issues in Clinical Trials
Norbert Benda, Head of Biostatistics and Special Pharmacokinetics, BfArM, Germany

Clinical Development Considerations when Different Agencies Require Different Primary Endpoints
David Wilson, Statistical Science Director, AstraZeneca, UK

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Theme 16 | Developments in Non-Clinical

Jan Willem Van der Laan, Senior Pharmacological Toxicological Assessor, Medicines Evaluation Board (MEB), Netherlands

New therapeutic areas as well as new technical methodologies are challenging the classical way of thinking in the non-clinical area. Furthermore, the public and political pressure to reduce the use of animals is a factor that cannot be ignored. These themes come together in new areas such as the in-vitro assessment of toxicology, but also in new products areas and even an old issue, such as carcinogenicity testing, can learn from this.

Session 1605 | Wednesday, 6 March 2013 | 09:00-10:30 | Room G105

NON-CLINICAL TESTING FOR ADVANCED THERAPY

Session Chair:
Carla Herberts, Assessor, Medicines Evaluation Board (MEB), Netherlands

Advanced Therapy Medicinal Products (ATMPs) are a group of medicinal products consisting of Gene Therapy Medicinal Products (GTMPs), Somatic Cell Therapy Medicinal Products (CTMPs) and tissue engineered products (TEPs). Non-clinical development of advanced therapy medicinal products are particularly challenging due to their complexity and innovative nature. Presentations in this session will consist of a general overview of possible approaches to tackle the challenges, of experiences gained with the currently only registered cell therapy product, and of a promising gene therapy product earlier in development.

Non-Clinical Issues Discussed in Scientific Advice of Advanced Therapy Medicinal Products
Carla Herberts, Assessor, Medicines Evaluation Board (MEB), Netherlands

The Experiences Gained with ChondroCelect
Gert De Beckker, Director Regulatory Affairs, Tigenix, Belgium

Stem Cell Gene Therapy for Pompe's Disease
Merel Stok, Scientist, Erasmus Medical Center, Netherlands

Session 1606 | Wednesday, 6 March 2013 | 11:00-12:30 | Room G105

NEW TRENDS IN IN-VITRO NON-CLINICAL TESTING

Session Chair:
Sonja Beken, Chair JEG 3Rs & SWP Member (EMA), Coordinator Non-Clinical Assessors, Federal Agency for Medicines and Health Products (AFMPS), Belgium

This session will provide an overview of the new and emerging trends in in vitro non-clinical testing. On one hand the recent advances in regulatory acceptance of in-vitro testing paradigms will be highlighted. On the other, industry experience will be given on the use of 3D cell cultures and of induced pluripotent stem cells in predictive toxicology and on the use of the MIMIC system for in vitro assessment of immunogenicity.

Update on Acceptance of in-vitro Testing Paradigms
Sonja Beken, Chair JEG 3Rs & SWP Member (EMA), Coordinator Non-Clinical Assessors, Federal Agency for Medicines and Health Products (AFMPS), Belgium

New Trends in in-vitro Test Systems for Predictive Toxicology
Laura Suter-Dick, University of Applied Sciences and Arts Northwestern Switzerland, School of Life Sciences, Switzerland

Biomimetic in-vitro Models: Getting human responses in a "test tube"
William Warren, Vice-President, Sanofi Pasteur, Vax Design, USA

Session 1607 | Wednesday, 6 March 2013 | 14:00-15:30 | Room G105

NEW ICH INITIATIVES IN SAFETY TESTING

Session Chair:
Beatriz Silva Lima, iMED.UL University of Lisbon, Non-Clinical Expert, NDA Regulatory Sciences, UK

This session will cover the non-clinical topics and new initiatives to trigger the improvement of the non-clinical testing paradigms.

Revisiting the Carcinogenicity Testing Strategy (S1)
Jan Willem Van der Laan, Senior Pharmacological Toxicological Assessor, Medicines Evaluation Board (MEB), Netherlands

Linking Innovation and Regulatory Toxicology – A proposed ICH approach
Steven Spanhaak, Scientific Director, Janssen Research & Development, Belgium

Session 1608 | Wednesday, 6 March 2013 |16:00-17:30 | Room G105

OVERVIEW OF CURRENT DISCUSSIONS IN ICH

Session Chair:
Klaus Olejniczak, Non-Clinical Regulatory Consultant, Germany

The major objectives of this session will be to enumerate acceptable levels and to describe potential approaches to the control of genotoxic and metal impurities in pharmaceuticals during development (clinical trials) and for marketing. The discussions will clarify when and how a genotoxic or a metal impurity should be identified and how it can be qualified and controlled.

Introduction to the ICH Topic M7 and Q3D
Klaus Olejniczak, Non-Clinical Regulatory Consultant, Germany

The ICH Guideline on Mutagenic Impurities in Drugs – Current status, options and issues for drug development
Lutz Müller, Lead, Late Stage Products, F. Hoffmann-La Roche, Switzerland

ICH S10 - Photosafety: Pre-clinical safety harmonisation topics currently at step 2
Ulla Wändel Liminga, Scientific Director Pharmacology / Toxicology, Medical Products Agency (MPA), Sweden

Theme 17 | IMI Public-Private Partnership in Medicines Research Education and Training – For Professionals and for Patients

Hans Lindén, Leader European Projects , European Federation for Pharmaceutical Sciences (EUFEPS), Sweden

IMI supports projects in these pre-competitive areas: Predicting safety, predicting efficacy, knowledge management, and education and training. There are five IMI Education and Training Projects. Three of them are developing, testing and establishing research master programmes on medicines safety (SafeSciMET), integrated medicines development (PharmaTrain), and on pharmacovigilance and pharmacoepidemiology in medicines usage (Eu2P). The fourth one (EMTRAIN) is on how to establish a European education and training network, including an extensive course catalogue and systems to serve up-to-date continuing professional development (CPD), meeting industrial, regulatory and academic needs. The fifth and newest one is the European Patients' Academy on Therapeutic Innovation (EUPATI), providing scientifically reliable, objective and comprehensive information to patients on medicines research and development, led by the European Patients' Forum (EPF).

Session 1705 | Wednesday, 6 March 2013 | 09:00-10:30 | Room G104

FOCUS ON MEDICINES EFFICACY, SAFETY AND USAGE IN EDUCATION AND TRAINING

Christian Freichel, Project Coordinator SafeSciMET

People need medicines and they want them to be safe. On medication, we call them patients. IMI was established to enable faster and more efficient development of safe and better medicines for patients. The research consortia include small- and medium-sized enterprises, universities and other research organisations, hospitals, patient organisations, public authorities and large pharmaceutical companies. Contracted deliverables, progress and plans will be presented.

Preparing a New Generation of Scientists to Foster Public-Private Partnerships
Michel Goldman, Executive Director, IMI

Safety Concerns Are All Over in Medicines Research and Development – Does the new education and training address real life situations in industry and elsewhere?
Dan Dietrich, Course Programme Leader SafeSciMET

Why Pharmacovigilance and Pharmacoepidemiology Education and Training in a Medicines Usage Perspective?
Ralph Schimmer, Project Co-coordinator Eu2P

Session 1706 | Wednesday, 6 March 2013 | 11:00-12:30 | Room G104

QUALITY CAREER DEVELOPMENT IN GLOBAL MEDICINES DEVELOPMENT

Session Chair:
Peter Stonier, Work Package Leader, PharmaTrain

Developing medicine from molecule to patient use is a process which was structured in post-graduate master programmes with detailed syllabus topics, translated into learning outcomes and competencies and bundled in 12 modules incl. two "elective" modules, offered on the PharmaTrain CPD Platform. Face-to-face learning is blended with (e)learning at master-level quality. There are additional training products e.g. Clinical Investigator Certification, CLIC, as well as a new Master programme for Regulatory Affairs, MRA. The partnership of 23 European universities, 15 private EFPIA partners and another 13 professional societies and regulatory agencies is growing to a global platform with another 10 extra-European universities from UCSF to Peking University. A new global quality training in medicines development.

Global Personalised Modular Training Platform for Medicines Development and Regulation
Fritz R. Bühler, Project Coordinator, PharmaTrain

The PharmaTrain Clinical Investigator Certification Initiative
Ingrid Klingmann, Deputy Coordinator, PharmaTrain

The PharmaTrain Virtual Learning Platform
Detlef Niese, Work Package Co-Leader, PharmaTrain

Session 1707 | Wednesday, 6 March 2013 | 14:00-15:30 | Room G104

EUPATI - THE EUROPEAN PATIENTS ACADEMY ON THERAPEUTIC INNOVATION – AN UNPRECEDENTED PUBLIC PRIVATE PARTNERSHIP TO EMPOWER PATIENTS TO ENGAGE AS REAL PARTNERS IN THE DRUG DEVELOPMENT PROCESS

Session Chair:
Jan Geissler, Project Director EUPATI

The aim of this session to share with the audience the rationale behind EUPATI, progress made since launch at the DIA EuroMeeting Copenhagen last March, next steps and opportunities for engagement, i.e. how others can play a constructive role, including on cross-learning and synergies.

A Snapshot of EUPATI – Who we are trying to reach and why this is so vital – case in point – the educated patient and clinical trials
Jan Geissler, Project Director, EUPATI

Understanding the Information Patients Need and the Best Ways This Can Be Achieved – The EUPATI needs and gap analysis
Bella Starling, Senior Researcher, University of Manchester, UK

Translating Patient Needs into Robust, Easily Accessible Quality Materials
Matthew May, Project Coordinator, EUPATI
Discussion: Q&A – What we need from you as key players in the drug information environment

Session 1708 | Wednesday, 6 March 2013, 16:00-17:30 | Room G104

TOWARDS A EUROPEAN FRAMEWORK FOR CONTINUING PROFESSIONAL DEVELOPMENT IN A LIFE-LONG LEARNING PERSPECTIVE

Session Chair:
Shirley Price, Co-chair, Cross Project Course Quality Task Force, IMI

All are, at many levels, talking about continuing professional development and life-long learning. In IMI a catalogue of existing optional and relevant courses and programmes has been built and will be presented, as will implementation of the IMI course quality standard arrived at, and outcomes of workshops and discussions with the stakeholders, including the professional and scientific community. How to create a solid European framework or platform to meet industrial and other education and training needs?

What Are Continuing Professional Development (CPD) and Life-Long Learning (LLL) – And why is this important for those in medicines research, development, processing and usage?
Mike Hardman, Leader, LifeTrain

Working towards a Shared Understanding of Quality Assurance
Cath Brooksbank, Leader Course Quality, EMTRAIN

www.on-course.eu: An education and training resource centre for post-graduate biomedical courses in Europe. What are the data and forums telling us, including on course quality, one year after launch?
Tony Payton, On-course Leader, EMTRAIN

STAND-ALONE SESSIONS

Session 1801 | Tuesday, 05 March, 09:00-10:30 | Room G107

PUBLIC PRIVATE PARTNERSHIP FOR BIOMEDICAL RESEARCH UNDER HORIZON 2020: PATIENTS' PERSPECTIVE ON SCIENTIFIC PRIORITIES

Session Chair:
Paul Peter Tak, Senior Vice President Immuno Inflammation, Therapy Area Unit Head, GlaxoSmithKline

The Innovative Medicines Initiative (IMI) set up under Framework Programme 7 has demonstrated its value in advancing biomedical research in a public private partnership set up. IMI sets a model for large scale open collaborations between industry and public partners (academia, SMEs, patient groups, authorities/regulators) and delivers results at a much better pace than any other existing research funding scheme. Building on the successes and achievements of the Innovative Medicines Initiative, EFPIA is envisaging renewing this public private partnership experience under Horizon 2020. Patient organisations will be invited to provide their views and in particular on the following questions:

- What are main treatment gaps/unmet medical needs (lack of treatment, poor response to existing treatment, side effects, dosage/form, etc.)?
- What are the barriers for delivery of adequate treatments (lack of screening or diagnostic, reimbursement, etc.)?
- What are other challenges not addressed in previous questions (patient care, adapted infrastructure, stigmatisation, information, etc.)?

Health Research Objectives in Horizon 2020
Ruxandra Draghia-Akli, Director Health Directorate, DG Research and Innovation, European Commission, EU

Key Objectives of the Future PPP – Combining research, health and regulatory agendas: Right prevention and treatment, for the right patient, at the right time
Paul Peter Tak, Senior Vice President Immuno Inflammation, Therapy Area Unit Head, GlaxoSmithKline

Discussion with all participants

GCP HOT TOPICS

The GCP Hot Topics Sessions that in recent editions of the EuroMeeting have been bringing together regulators, industry, CRO and academia professionals who want to get first hand information on newest trends, has by now become an EuroMeeting tradition.
In 2013 the impact of changes and evolution in technology on the conduct and quality management of clinical trials determine the programme of the GCP Hot Topic session. The focus will be on electronic health records (EHRs) when used as source documents or direct input source into clinical trial databases.

As a second topic the session will deal with the challenges presented to sponsors and CROs when clinical trial activities are outsourced. This topic is not new but becomes increasingly a root cause of major and critical inspection findings.

The programme will be completed by the presentation of the White Paper on protocol violations that has been authored by the GCP SIAC.

As in other years the roster of international speakers will involve senior representatives from health authorities, industry and CROs. The audience is invited to actively participate in the panel discussions by bringing examples or challenging statements. Delegates can anonymously submit topic-related questions or cases they would like to be discussed by the panel in advance to the session chairs via the DIA.

Session 1803 | Tuesday, 05 March 2013, 14:00-15:30 | Room G102

ELECTRONIC HEALTH RECORDS

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

Regulatory Requirements for Electronic Health Records Used in Clinical Trials - A European inspector's view
Christian Schörner, Inspector, RP (Regierungspräsidium) Darmstadt, Germany

The Industry View: Are EHRs playing a role in making clinical trials more efficient?
Miguel Orri, Senior Director, Clinical Sciences, Pfizer, UK

Compliance and Quality Requirements for EHRs in FDA-regulated Clinical Investigations
Sean Kassim, Acting Associate Director for Risk Science, Intelligence and Prioritisation, CDER, FDA, USA (remote participation)

Session 1804 | Tuesday, 05 March 2013, 16:00-17:30 | Room G102

THE CHALLENGES IN THE CRO-SPONSOR RELATIONSHIP

Session Chair
Beat Widler, Senior Partner, Widler & Schiemann, Switzerland

What Does a CRO Need to do To Effectively Plan Contracted Tasks, To Make A Reliable Offer and to Properly Implement the Contract? What are factors derailing a good CRO – sponsor relationship?
Dagmar Chase, Vice-President EUCROF, Managing Director, ClinRex, Germany

A Robust Relationship and Good Planning Are the Heart of a Successful Sponsor - CRO Relationship: What should sponsors consider from a quality and governance perspective?
Christian Kraus, VP, Head of Operational Oversight: Global Clinical Operations, Bayer HealthCare AG, Germany

What Do Regulators Observe When Inspecting Submissions Where Clinical Trial and Other Essential Activities Have Been Outsourced by the Sponsor?
Willem Verweij, Coordinating/Specialist Senior inspector, Health Care Inspectorate, Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport, Netherlands

Conclusion:
The DIA SIAC Whitepaper on Protocol Violations
Katharina Kurpanek, Independent Regulatory Compliance Consultant, Belgium

Session 1805 | Wednesday, 6 March 2013 | 09:00-10:30 | Elicium 1

EMA ROUNDTABLE - SCIENTIFIC COMMITTEES UNITED IN DIVERSITY

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

This roundtable will discuss how the EU Scientific Committees come together and interact at the European Medicines Agency to foster scientific excellence in the evaluation and supervision of medicines for the benefit of public health, while at the same time being enriched by the EU's many different cultures and traditions.

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

Bruno Sepodes, Chair Committee for Orphan Medicinal Products (COMP), Professor of Pharmacology, Immunopharmacology and Pharmacotherapy, University of Lisbon, Preclinical Expert for the Portuguese National Authority of Medicines and Health Products (INFARMED), Portugal

Werner Knöss, Chair Committee on Herbal Medicinal Products (HMPC), Head of Complementary and Alternative Medicines and Traditional Medicinal Products, BfArM, Germany

Daniel Brasseur, Chair Paediatric Committee (PDCO), General Directorate Medicine, Federal Ministry of Public Health (AFMPS), Belgium

Christian Schneider, Chair Committee for Advanced Therapies (CAT), Senior Medical Officer, Danish National Board of Health, Denmark

Rob Hemmings, Chair Scientific Advice Working Party (SAWP), Medicines and Healthcare Products Regulatory Agency (MHRA), UK

June Raine, Chair Pharmacovigilance Risk Assessment Committee (PRAC), Director of Vigilance and Risk Management of Medicines, Medicines and Healthcare Products Regulatory Agency (MHRA), UK – remote participation

Session 1806 | Wednesday, 6 March 2013 | 11:00-12:30 | Room D203-204

JAPANESE REGULATORY SESSION – PMDA UPDATE

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

The PMDA will explain the latest activities and Japanese regulation, and answer questions from the audience about PMDA's current situation, activities and future initiatives/challenges in reviewing and managing drugs through their life cycle.

PMDA Update: Its current situation and future direction
Tatsuya Kondo, Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PMDA's Efforts in Medical Innovation – Regulatory Science & Science Board
Hideo Utsumi, Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PMDA's Efforts in Safety Measures - Risk Management Plan(RMP) in Japan
Kazuhiko Mori, Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 1906 | Wednesday, 6 March | 11:00-12:30 | Room G109

QUALITY RISK MANAGEMENT WORKSHOP

Facilitator:
Fritz Erni, Consultant, Switzerland

This interactive workshop will give a brief overview of simple quality risk management (QRM) tools. In small groups, participants will work with common QRM tools such as Process Maps, Fishbone Diagrams and Failure Mode Effects Analysis (FMEA) to determine product critical quality attributes and critical process steps for a simple manufacturing process.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive early in order to ensure seating. Please note, as a workshop with interactivity, slides for this event will not be made available.*

Satellite Session

Tuesday 05 March 18:00-19:30 | Emerald Room

PHARMACEUTICAL LAW IN THE NETHERLANDS: BUILDING AN EU ASSOCIATION?

Session Chair:
John Lisman, Board Member of the VFenR, Lawyer, Lisman Legal Life Sciences, Netherlands

This special session will offer a showcase of the Dutch Pharmaceutical Law Association (VFenR) presenting Dutch case law with implications for other EU member states. Furthermore, the session aims at bringing together Europeans interested in pharmaceutical law to explore extension of the activities of the DIA Legal Affairs SIAC and the establishment of a European Pharmaceutical Law Association.

Dutch Case Law about Classification, Demarcation and Early Access to Medicinal Products
Koosje van Lessen Kloeke, Board Member of the VFenR, Pharma & Life Sciences Lawyer, Leijnse Artz, Netherlands

The Decentralised Procedure under National and EU Law: Examples
John Lisman, Board Member of the VFenR, Lawyer, Lisman Legal Life Sciences, Netherlands

The Dutch Pharmaceutical Law Association, Legal Affairs SIAC and a New European Association: A panel discussion
René van Ierschot, Partner, Barbers, Netherlands

New Session

Session 1907 | Wednesday 65 March 14:00-15:30 | Room G109

PERSPECTIVES AND COLLABORATION BETWEEN PATIENTS AND STUDENTS

Facilitator:
Maria Mavris, Therapeutic Development Director, EURORDIS, France

Patient organisations are gaining increasing strength when voicing its members' concerns. Student organisations on the other hand have a long established and flexible perspective. This session will provide a brief overview of how these populations are organised and aim to pinpoint the aspects where collaboration will lead to synergy.

Student Representation
Milos Stojkovic, Vice President of Public Relations, European Pharmaceutical Students' Association (EPSA), Belgium, DIA Europe Intern, Switzerland

Patient Representation
Gerard Nguyen, President, Rett Syndrome Europe, Avicenne Hospital University Paris Nord, France

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EUROMEETING 2013 GLOSSARY OF TERMS

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

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Be a speaker at the EuroMeeting 2014

Are you interested in speaking at the 25th Annual EuroMeeting in Vienna, 25-27 March 2014?

Please see the EuroMeeting 2014 Vienna Call for abstracts in your conference bag or ask for more information at the DIA Booth in the Exhibition Hall.

NETWORKING EVENTS

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

Student and Young Professionals Networking Reception

Sunday, 3 March 2013 | 17:45-18:45 | Onyx Lounge

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

EuroMeeting 25th Anniversary Reception

Monday, 4 March 2013 | 17:30-19:00 in the Exhibition Hall 11

This year, our Monday reception is a special one! The EuroMeeting is celebrating its 25th anniversary. Join us at a networking cocktail reception for an excellent opportunity to renew your existing contacts and to make new ones. It is exclusive to registered EuroMeeting attendees and will take place in the Exhibition Hall.

DIA Special Interest Area Communities (SIACs) – Meet and Eat

Tuesday, 5 March 2013 | 12:30-13:15 | Onyx Lounge

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

Speed Networking Session

Tuesday, 5 March 2013 | 13:30-14:00 | Topaz Lounge

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

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

Tuesday Reception

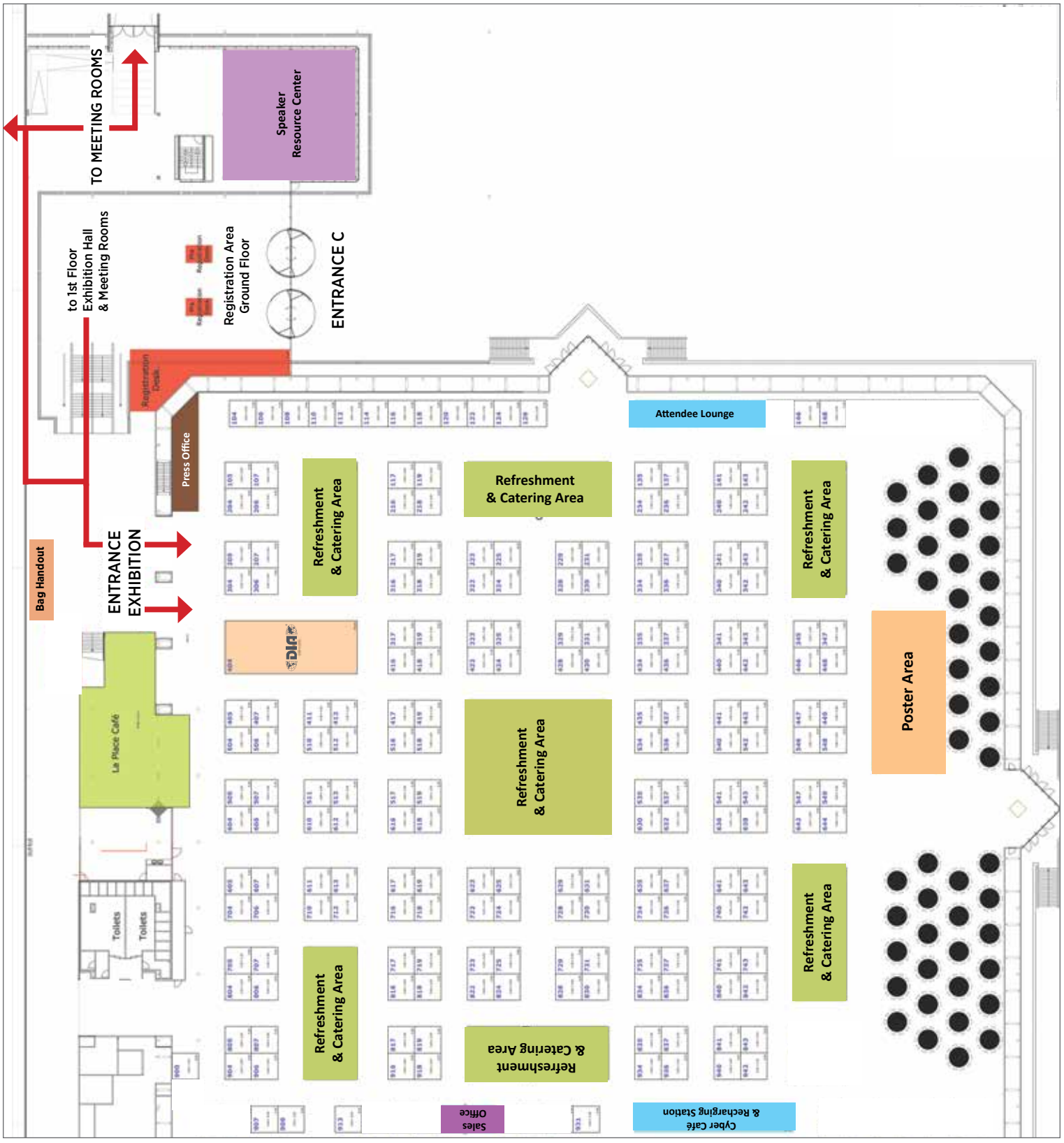
Tuesday, 5 March 2013 | 17:30-18:30 | Exhibition Hall 11

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

Network on the Exhibition Floor

All refreshments and lunches will be served in the Exhibition Hall 11, making it the ideal place to meet the people you want to meet. There will be an internet café and attendee lounge as well as a seating area.

EXHIBITION HALL FLOOR PLAN



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Acurian, Inc. — Booth 242
Contact: Kirk McPoyle
E-mail: info@acurian.com **Website: www.acurian.com**
Acurian is a full-service provider of clinical trial patient enrollment & retention solutions. Acurian increases enrollment performance of sites worldwide by identifying, contacting, prescreening & referring people who live locally, but are unknown to sites. As a result, sponsors complete enrollment without adding sites, time or CRO change orders.

Akos Ltd. — Booth 606
Contact: Amanda Cohen
E-mail: acohen@akosltd.com **Website: www.akosltd.com**
Since 1986, AKOS has been providing global, customized services in Pharmacovigilance, Medical, QPPV and Scientific Services to meet our client's specific clinical trial and post marketing obligations. Our model is to act as an extended arm to our clients by providing tailored service solutions. To learn more, go to www.akosltd.com.

ANALYTICA LA-SER — Booths 934, 835, 837
Contact: Patrizia Berto
E-mail: pberto@la-ser.com **Website: www.la-ser.com**
ANALYTICA LA-SER is an international leader in the field of population health intelligence, with a team of over 200 highly-trained scientists. Providing a wide range of evidence-based approaches, proprietary research services, HEOR consulting & highly sophisticated modelling capabilities, we support bringing safe and effective treatments to market.

Analytical Biochemical Laboratory ABL — Booth 446
Contact: Ep Oosting
E-mail: eoosting@abl.nl **Website: www.abl.nl**
Analytical Biochemical Laboratory (ABL) is a bioanalytical laboratory for the pharmaceutical industry (both innovative and generic), including veterinary and animal health companies. It is specialized in the analysis of endogenous (biomarkers) and exogenous (drugs) compounds in biological matrices derived from humans and animals.

Applied Clinical Trials — Booth 336
Contact: Anne Young
E-mail: ayoung@advanstar.com
Website: www.appliedclinicaltrialsonline.com
APPLIED CLINICAL TRIALS is a global peer reviewed journal that addresses the process of managing clinical trials at the intersection where pharmaceutical product developers meet the strictly regulated medical researchers who test their drugs. Applied Clinical Trials' audience is over 140,000 clinical trial professionals worldwide.

Aptiv Solutions — Booths 511, 513
Telephone: +1 703-483-6400 **Website: www.aptivsolutions.com**
Aptiv Solutions is a global biopharmaceutical and medical device services company focused on recognizing, understanding and enabling clients to capitalize on rapid and fundamental changes surrounding the development of pharmaceutical, biotech and medical device products. The company offers clients an extensive portfolio of innovative services supported by over 850 professionals in North America, Eastern & Western Europe, Israel and Japan.

ArisGlobal — Booths 405, 407
Contact: Kathy Capper
E-mail: kcapper@arisglobal.com **Website: www.arisglobal.com**
ArisGlobal (www.arisglobal.com) is a leading provider of software solutions for pharmacovigilance and safety, regulatory affairs, clinical research and medical information. Hundreds of life science companies rely on ArisGlobal's advanced solutions for maintaining regulatory compliance, workflow automation and improving operational efficiency.

Arkivum — Booth 741
Contact: Jim Cook
E-mail: info@arkivum.com **Website: www.arkivum.com**
Arkivum provides a '100% guaranteed' digital data archiving service which is specifically targeted at the healthcare and life sciences industries where organisations often have long term data requirements for a whole range of digital data types, including images, research data and records.

Arriello Group — Booth 436
Contact: Alan White
E-mail: info@arriello.com **Website: www.arriello.com**
We are Life Science industry service provider based in Ireland. We work with an experienced team of professionals with a project-oriented management focus from preparation to delivery, using a proactive approach to ensure that all your needs are fully covered (Regulatory, PV with an in house EU QP, Medical writing, Medical Devices, Translations).

AsahiKASEI Bioprocess Europe S.A./ N.V. — Booth 443
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ASPHALION — Booth 218
Contact: Lidia Cánovas
E-mail: info@asphalion.com **Website: www.asphalion.com**
ASPHALION is an International Drug Development and Regulatory Affairs Consultancy based in Barcelona.
Founded in 2000 and with over 35 professional consultants, ASPHALION has working groups for International Registration Procedures, Clinical and Medical Writing, Electronic Submission of Regulatory Data, CMC/Quality and Pharmacovigilance.

Astellas — Booth 931
Contact: Cherr van Dormolen / Tammera Canter Visscher
E-mail: cherr.vandormolen@astellas.com / tammera.cantervisscher@astellas.com
Website: www.astellas.eu
Astellas, an international pharmaceutical company with a focus on developing innovative and reliable products for patients worldwide. Over 16,000 people employed, combined global sales over 7 billion euro, strong R&D pipeline and key strenghts in the area of Urology, Dermatology, Transplantation, Anti-Infectives, Oncology and Pain Management.

AtoZ-CRO GmbH, Overath/Germany — Booth 909
Contact: Dr. Karl-Peter Klein
E-mail: kp.klein@atoz-cro.de **Website: www.atoz-cro.de**
AtoZ-CRO GmbH
- Full-service Clinical Research Organization
- Near Cologne/Germany since 1984
- Europe is a geographical focal area
- Clinical Studies with pharmaceuticals, medical devices, nutritionals all phases
- Many naïve patients available, esp. Eastern Europe
- Highly motivated investigators in Europe
- Very fast recruitment

August Research — Booth 231
Contact: Dana Leff Niedzielska
E-mail: info@augustresearch.com **Website: www.augustresearch.com**
August Research is an American-owned CRO working exclusively in Central and Eastern Europe. August Research has offices in Bulgaria, Croatia, Poland, Romania and Serbia as well as partners covering Czech, Hungary and Slovakia. With extensive experience across a wide variety of indications and our office-based staff, we support our clients with regulatory activities, monitoring and project management.

AXPHARMA SAS — Booth 707

Contact: contact@axpharma.com
E-mail: contact@axpharma.com **Website: www.axpharma.com**
Located in Paris - Brussels - Lausanne Axpharma was created in 2001
45 people are running 24/7 PV and Medical information services
PV post MA and CT run by 17 full time Physicians and Pharmacists
(4 are UEQPPV and 7 are QPPV and Eudravigilance certified)
Medical information run by Pharmacists using CRM and Call Center modern tools

Barrington James Ltd — Booth 641

Contact: Pippa Wilson/Karl Paddley
E-mail: pwilson@barringtonjames.com **Website: www.barringtonjames.com**
Barrington James are global specialists in the placement of permanent and contract staff across all areas of the Pharmaceutical and Medical Device Industry. Our consultants are experts in their niche functional areas delivering a thorough, professional and intelligent service and total recruitment solution.

BaseCon A/S — Booth 316

Contact: sales@basecon.com
E-mail: sales@basecon.com **Website: www.basecon.com**
Pharmacovigilance Solutions for the Modern Pharmaceutical Industry!
BaseCon provide a complete Pharmacovigilance Safety System hosted from our pre-validated GxP hosting center. SafetyBase Interchange is suitable for small to large scale drug safety departments
We provide apps for mobile devices in the pharmacovigilance and drug development fields

Bio-Optronics, Inc. — Booth 441

Contact: Leah Kuehn
E-mail: lkuehn@bio-optronics.com / cbliss@bio-optronics.com
Website: www.bio-optronics.com
Bio-Optronics, Inc. is a software and services provider specialized in solutions to help healthcare professionals manage and optimize workflow, thus enhancing quality, productivity and patient and staff satisfaction. Since 1985, Bio-Optronics has demonstrated leadership in innovation, expertise in workflow and integration and a focus on unparalleled customer service.

BioClinica — Booths 623, 625

Contact: Jim Dorsey
E-mail: sales@bioclinica.com **Website: www.bioclinica.com**
BioClinica a global provider of integrated, technology-enhanced clinical trial services. We supports pharmaceutical and medical device innovation with imaging core lab services, internet image transport, electronic data capture, interactive voice & web response, clinical trial management and clinical supply chain design and optimization solutions.

Brunel ICT — Booth 900

Description not available at time of printing

BSI Business Systems Integration AG — Booth 819

Contact: Jan Nielsen
E-mail: jan.nielsen@bsiag.com **Website: www.bsiag.com/ctms**
Are you looking to combine clinical trials with technological excellence? BSI CTMS is the next generation solution for clinical trial management for pharma, biotech and CROs.
The simplicitiy and user friendliness of BSI CTMS have convinced market leadets like Actelion, ALK Abelló and Allergopharma to use software from BSI.

C3i Inc — Booth 804

Contact: Marina Belenozova
E-mail: mbelenozova@c3i-inc.com **Website: www.c3i-inc.com**
C3i is the leading provider of technology services for sponsors and CROs running global clinical trials. C3i's portfolio of services for EDC, IVRS/IRT, CTMS, and ePRO applications includes: 24x7 multi-lingual service desk, technology training, hardware provisioning, and application hosting. C3i has global operations in NA, Europe, India, and China.

Cardio Analytics Ltd — Booth 422

Contact: Kerri Mellor
E-mail: Kerri.mellor@cardioanalytics.com **Website: www.cardioanalytics.com**
Cardio Analytics has been providing high quality Centralised Cardiology Services for clinical trials Phase I to III for over 19 years. Carrying out 12-Lead digital ECG (including TQT Studies), 12-Lead and 3-Lead Holter, Telemetry, Echo and ABP Measurement and Analysis.

Cardiocore — Booth 207

Cardiocore and its parent company, CardioNet, are world's largest cardiac analytics organization, offering centralized electrocardiography (ECG), Holter monitoring, cardiac event monitoring (CEM), mobile cardiac telemetry (MCOT), blood pressure monitoring (ABPM), echocardiography (ECHO), protocol development and statistical analysis for Phase I-IV clinical trials.

Catalent Pharma Solutions — Booth 135

Contact: Kerrie Levy
E-mail: Kerrie.levy@catalent.com **Website: www.catalent.com**
Catalent, the world's #1 Formulation and Development partner, leads the industry in lab and chamber capacity, operational excellence, on-time delivery, and effective regulatory assessment. Our integrated services provide unique partnering efficiencies to ensure advancement of your product through development and registration to commercialization.

CBG-MEB — Booth 417

Contact: T. Janse-de Hoog
E-mail: info@cbg-meb.nl **Website: www.cbg-meb.nl**
The MEB assesses and guards the efficacy, safety and quality of both human and veterinary products.
The MEB
- considers the protection of public health the main focus of its activities
- is the primary source of information on medicinal products
- aims to achieve a maximum transparency in its processes
- offers scientific advice

Central Laboratory INVITRO — Booth 817

Contact: Ann Chernuha
E-mail: achernuha@invitro.ru **Website: www.invitro.ru**
Central Laboratory INVITRO is the leading ISO certified Laboratory focused on providing high quality flexible solutions to the pharmaceutical and biotechnology industries. INVITRO offers full service central laboratory capabilities for the Clinical trials conducted in Russia and Ukraine.

Chiltern — Booths 216, 117

Contact: Natalie Chong
E-mail: natalie.chong@chiltern.com **Website: www.chiltern.com**
Established in 1982, Chiltern is a leading global clinical CRO with extensive experience in the management of Phase I-IV clinical trials across a broad range of therapeutic areas, functional service provision and contract staffing solutions. Chiltern has conducted trials in more than 40 countries and employs more than 1,500 people globally.

CK Clinical EU — Booth 942

Contact: Mylene Paumier

E-mail: mpaumier@ckclinical.co.uk **Website: www.ckclinical.co.uk**

CK Clinical is a leading clinical recruitment company working with prominent Pharmaceutical, Biotechnology and Clinical companies in Europe. As an ISO 9001 accredited company, we pride ourselves on our ethical and transparent service ensuring candidates and clients get the best possible experience. For more information visit www.ckclinical.co.

Clinical Contract Research Association — Booth 324

Contact: Ms Susan Dilks

E-mail: mail@ccra.org.uk **Website: www.ccra.org.uk**

If you are serious about the conduct of clinical trials to the highest standards and take any part in the industry (CRO or service provider in this sector) come and talk to us about membership! CCRA is the UK trade association which represents this sector and provides enhanced business opportunities, a badge of quality and a voice for the industry.

Clinical Professionals — Booth 229

Contact: Yvette Cleland

E-mail: apply@clinicalprofessionals.eu **Website: www.clinicalprofessionals.eu**

Clinical Professionals is one of Europe's leading pharmaceutical research and development staffing companies, and focuses on recruitment for roles in pharmacology, scientific and clinical development and post approval services.

Clinipace AG — Booth 635

Contact: bhennecke-janzer@clinipace.com

E-mail: contact-eu@clinipace.com **Website: www.clinipace.com**

As a global full-service digital contract research organization (dCRO), Clinipace has pioneered an innovative service model to serve the unique needs of venture-backed, mid-tier, and strategic pharmaceutical, biotechnology, and medical device firms.We maintain offices on four continents.

CluePoints — Booth 610

Contact: Marie-Laure Dyck

E-mail: marie-laure.dyck@cluepoints.com **Website: www.cluepoints.com**

CluePoints is a Central Statistical Monitoring solution that employs unique statistical algorithms to determine the quality, accuracy and integrity of clinical trial data.

Aligned with FDA and EMA guidances, CluePoints is deployed to support traditional on-site monitoring and implemented as the engine to drive a risk-based monitoring strategy.

Cmed Clinical Services — Booth 241

Contact: Ally Baker

E-mail: abaker@cmedresearch.com **Website: www.cmedresearch.com**

Cmed Clinical Services provides CRO services to significantly enhance the design and delivery of early phase clinical trials. This is accomplished through the coupling of deep regulatory capabilities, drug development consulting, with robust clinical operations, as well as the provision of our proprietary technology, Timaeus.

CMIC HOLDINGS Co., Ltd. — Booth 306

Contact: International Business Promotion Dept.

E-mail: aya-sasada@cmic.co.jp **Website: www.cmic-holdings.co.jp/e/**

CMIC is a leading one stop pharmaceutical service provider with rich experience of managing Global/Asian clinical trials. Our business scope encompasses not only CRO, but manufacturing, marketing and site management. Headquartered in Japan, such services are provided in East and Southeast Asia including China, Taiwan, Korea and Singapore.

Conversis Global — Booth 611

Contact: Briana McCrory

E-mail: enquiries@conversisglobal.com **Website: www.conversisglobal.com**

Conversis is a translation and localisation service provider specialising in the healthcare sector. We translate into more than 80 languages in more than 60 countries. We work closely with our clients ensuring that all of their needs are met. We are celebrating our 10 year anniversary this year so come visit our stand to join the celebrations!

Corporate Translations — Booth 105

Contact: Ted Gawlicki

E-mail: sales@corptransinc.com **Website: www.corptransinc.com**

Corporate Translations is an ISO9001:2008 and EN15038 certified and trusted provider of translation and linguistic validation solutions to the world's top life science companies. Our proven methodology and expertise in this highly regulated industry make us well qualified to translate and format documents throughout the entire lifecycle of a drug.

CRF Health — Booth 418

Contact: Heather Bilinski

E-mail: heather.bilinski@crfhealth.com **Website: www.crfhealth.com**

CRF Health delivers electronic Clinical Outcome Assessments (eCOA) solutions for global clinical trials. Since 2000, CRF Health has initiated more than 400 clinical trials in over 70 countries and more than 150 regional languages; all while delivering the industry's highest patient compliance, data accuracy and unmatched patient and site acceptance

CROMSOURCE srl — Booth 731

Contact: Margherita Mosconi

E-mail: Margherita.mosconi@cromsource.com **Website: www.cromsource.com**

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialized in clinical development and staffing solutions. CROMSOURCE is unique. We guarantee trials will be delivered on time and to the contract price (our End to End guarantee).

CTC Resourcing Solutions Ltd. — Booth 506

Contact: Mr. Manu Chhokra

E-mail: info@ctcon.ch **Website: www.ctcresourcing.co.uk**

Formed in 1997, CTC Resourcing Solutions is a pan-European provider of resourcing solutions to Pharma/Biotech, Med Devices and CRO. Our heritage is built on a strong track record of engaging and placing the very best talent in Clinical, Pre-Clinical, Regulatory, Medical Affairs and Biostatistics roles. Our offices are in Switzerland, UK and Germany

DATATRAK International — Booth 840

Contact: Jean-Pierre Deligny

E-mail: jean-pierre.deligny@datatrak.net **Website: www.datatrak.net**

DATATRAK is the leader of unified eClinical® technologies and related services for the clinical trials industry. Using the DATATRAK ONE™ multi-product, cloud-based clinical research platform, DATATRAK assists clients in conducting Phase I-IV drug and device studies in multiple languages throughout the world. For more information: www.datatrak.net

Dora Wirth (Languages) Limited — Booth 323

Contact: Samuel J. Wirth

E-mail: info@dwlanguages.com **Website: www.dwlanguages.com**

DWL Ltd. is a specialist translation service provider for the pharmaceutical industry with translation solutions in the fields of regulatory affairs and clinical & medical research. Celebrating its 50th year, DWL has grown through a dedication and commitment to quality and service. DWL focuses on the languages for traditional and emerging markets.

Dr. Ebeling & Assoc. GmbH — Booth 343

Contact: Dr. Leonardo Ebeling
E-mail: info@ebeling-assoc.com **Website: www.ebeling-assoc.com**

Headquartered in Hamburg, Germany, Dr. Ebeling & Assoc. GmbH is a global CSO with experience in regulatory and quality and compliance consulting as well as in project and data management, providing a wide range of services in the area of GCP and pharmacovigilance for the pharmaceutical, biotech, generic drug and medical device industry.

Drug Safety Research Unit — Booth 325

Contact: rachel.green@dsru.org
E-mail: rachel.green@dsru.org **Website: www.dsru.org**

The DSRU makes notable contributions to safety assessments of marketed medicines using a range of pharmacoepidemiological (PE) methods, e.g. Modified Prescription-Event Monitoring (M-PEM), Specialist Cohort Studies, Registries, Record-linkage and Drug Utilisation studies. We also offer expert advice on PE methods to support risk management plans.

DSG, Inc. — Booth 612

Contact: Al Campbell
E-mail: acampbell@dsg-us.com **Website: www.dsg-us.com**

DSG supports clinical trial data collection and management with innovative technology solutions including award winning EDC with specialized Data Management services, IWRS, CTMS, Safety and ePRO. DSG's fully integrated products allow user-friendly, accurate and efficient data capture at any investigator site regardless of technology platform.

e-novex — Booth 537

Contact: Aly Talen / Julie Bosiers
E-mail: aly.talen@e-novex.com **Website: www.e-novex.com**

e-novex provides innovative and web-based electronic data capture (EDC) solutions for the medical industries.
e-capture.net is the flagship EDC platform featuring compliance, safety, imaging, complex validation checks and data validation.
edc2go is a revolutionary and cost-effective new approach to post-marketing and data collection applications.

ECLINSO AG — Booth 710

Contact: Frank Pijpers
E-mail: frank.pijpers@eclinso.com **Website: www.eclinso.com**

ECLINSO's Trialforce platform is a comprehensive on-demand, Saas-based solution for conducting Clinical Trials. It offers software for Electronic Data Capture, Document Management and Regulatory Submissions for Sponsors and Clinical Research Organizations designed to accelerate clinical development

Ecron Acunova — Booth 730

Contact: Dr. Thomas Traxl
E-mail: bd@ecronacunova.com **Website: www.ecronacunova.com**

Ecron Acunova (EA) is a full-service expert CRO with 26 years of track record, offering phase I-IV clinical research to pharma, biotech, nutrition, device and diagnostic companies. EA covers 29 countries and operates each region as a priority market with Asian-Pacific HQ at Bangalore, European HQ at Frankfurt, and US HQ at Princeton.

emedcareers.com — Booth 116

Contact: Contact the sales team
E-mail: sales@emedcareers.com **Website: www.emedcareers.com**

emedcareers.com is the place to find the latest European jobs in the Pharmaceutical and Medical Device industries. Simply register for job alerts and we'll send you the latest matching jobs by email every day. Why not also upload your CV, make it searchable and let employers and recruitment agencies approach you with suitable jobs?

Entimo AG — Booth 512

Contact: Juergen Spieler
E-mail: js@entimo.com **Website: www.entimo.com**

Entimo provides IT products, custom solutions and services to shorten the drug development processes. entimICE® products facilitate data management and statistical analysis tasks controlled and traceable. entimICE® products cover data transformation to create SDTM domains, check their consistency and generate define.xml without any programming.

ERT — Booths 205, 304

Contact: Sheryl Walder
E-mail: eresearch@ert.com **Website: www.ert.com**

ERT is the leading provider of cardiac safety, respiratory & health outcome solutions to the global biopharm industry. ERT harnesses internet & telecom technology & services to streamline the clinical trials process by enabling its customers to automate the collection, analysis & distribution of data in all phases of clinical development.

EtQ, Inc. — Booths 637

Contact: Angela Lodico
E-mail: alodico@etq.com **Website: www.etq.com**

EtQ is the leading FDA Compliance, Quality, EHS, and Operational Risk Management software provider for identifying, mitigating and preventing high-risk events through integration, automation and collaboration. Founded in 1992, EtQ has always had a unique knowledge of FDA Compliance, Quality, EHS, and Operational Risk processes, and strives to make overall quality operations and management systems better for businesses. EtQ is headquartered in Farmingdale, NY, with main offices located in EMEA, the UK, and Arizona. EtQ has been providing software solutions to a variety of markets for more than 20 years.

EUDRAC Ltd — Booth 124

Contact: Carole Pugh
E-mail: carole.pugh@eudrac.com **Website: www.eudrac.com**

EUDRAC is a specialised regulatory affairs consultancy supporting pharmaceutical and medical device companies. Our services cover the development, registration and life cycle management phases (including publishing). We take pride in developing long-term relationships with our clients by producing high quality work according project timelines.

Eurotrials — Booth 335

E-mail: office@eurotrials.com

Eurotrials is a private independent company founded in 1995 in Lisbon, Portugal, providing CRO services in R&D and general consulting in the Health sector in Europe and Latin America. Eurotrials is in Brazil since 2001 and opened offices in Argentina and Chile in 2011. We are small enough to care and big enough to deliver!

EXTEDO GmbH — Booth 114

Contact: Thomas Kessler
E-mail: info@extedo.com **Website: www.extedo.com**

EXTEDO is the key solutions & services provider in the field of eRegulatory Affairs. The complete EXTEDOsuite covers: Product Registration Planning & Tracking, Submission Management, Pharmacovigilance Mgmt., Label Mgmt. and Document Mgmt.. Today EXTEDO serves more than 700 customers in 60 countries & more than 25 Regulatory Authorities incl. EMA.

Flex Databases — Booth 907

Contact: Olga Loginovskaya
E-mail: contactus@flexdatabases.com **Website: www.flexdatabases.com**

Flex Databases is a software company that offers web-based modular systems for automation of business processes in clinical trials: CTMS (Project Management, CRA Site visits, Invoicing, Subject Tracking, Investigators & Sites Management, Time Sheets) and Learning Management System (SOP Management, Classroom & Self-training, Knowledge Testing).

Foresight Group International AG — Booth 828
Contact: Joe Salamon
E-mail: jsalamon@foresightgroup.com **Website: www.foresightgroup.com**
Foresight Group focuses exclusively on clinical and post-marketing drug safety and surveillance. From simple software selection to business process redesign and hosting, all of our services and solutions are delivered with precise and timely execution, helping our clients achieve lower operational costs, minimized litigation costs and reduced risk.

GCP-Service International Ltd. & Co KG — Booth 328
Contact: Daniel Rojas
E-mail: drojas@gcp-service.com **Website: www.gcp-service.com**
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Contact: Angela Davie
E-mail: adavie@gf-associates.co.uk **Website: www.gf-associates.co.uk**
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Contact: Maxime Stevens
E-mail: maxime.stevens@harrison-cro.com **Website: www.harrisonclinical.com**
Founded in 1987 Harrison Clinical Research (HCR) is an international CRO (ISO 9001). From offices in Europe, Israel and the USA, HCR offers full service clinical Ph I (in our clinical unit) to Ph IV trials including development strategy, project management, monitoring, data management, biostatistics, medical writing, auditing, training, and FSP.

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Contact: Gerd Johnscher
E-mail: gjohnscher@imagine-sct.com **Website: www.imagine-SCT.com**

IMI Education and Training Programmes — Booth 918
Contact: Ulrike Mayerhofer-Sebera
E-mail: ulrike.mayerhofer-sebera@meduniwien.ac.at
Website: www.emtrain.eu
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Contact: Ian Waterman **Telephone: 01276481000**
E-mail: info@incresearch.com **Website: www.incresearch.com**
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Contact: Ingeborg Baars
E-mail: Ingeborg.baars@iperion.nl **Website: www.iperion.nl**
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E-mail: pharma@keypeople.co.uk **Website: www.keypeople.co.uk**
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Contact: Angela Potts
E-mail: angela.potts@kinapse.com **Website: www.kinapse.com**
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Contact: julie@konect.or.kr
E-mail: julie@konect.or.kr
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Contact: C M S Kenny
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E-mail: solveig.blomvik@lindeq.com **Website: www.lindeq.com**
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E-mail: Michelle.pappas@lionbridge.com **Website: www.lionbridge.com**
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E-mail: abhinay.yarlagadda@makrocare.com **Website: www.makrocare.com**
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MasterControl Global Ltd Booth 541
Contact: Caroline Baggs
E-mail: Cbaggs@mastercontrol.com **Website: www.mastercontrol.com**
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maxclinical GmbH — Booth 143

Contact: Dr. Max Horneck
E-mail: info@maxclinical.com **Website: www.maxclinical.com**

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Contact: Char Guy
E-mail: char.guy@ngc.com **Website: www/mssorequest@mssotools.com**

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Contact: Rachel Lowrey
E-mail: rlowrey@mdsol.com **Website: www.mdsol.com**

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Contact: Ms. Sherry Autwal
E-mail: sherry.autwal@monitorforhire.com **Website: monitorforhire.com**

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Contact: Libor Safar
E-mail: libors@moravia.com **Website: www.moravia.com**

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E-mail: info@ndareg.com **Website: www.ndareg.com**

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Contact: nginn@nextdocs.com
E-mail: mmottolo@nextdocs.com **Website: www.nextdocs.com**

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Contact: Anette Svane Vestergaard
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Contact: ARUN MATHEW
E-mail: arun.mathew@nova-transnet.com **Website: www.nova-transnet.com**

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Contact: Toby Leete
E-mail: tleete@nspirehealth.com **Website: www.nspirehealth.com**

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Contact: nicola.beall@accenture.com
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Contact: Claudia Horneck
E-mail: chorneck@omnicomm.com **Website: www.omnicomm.com**

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E-mail: Reed.mclaughlin@irmsonline.com **Website: www.irmsonline.com**
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Contact: Dr. Barbara Rodust and Paul-Peter Pokojski
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E-mail: jc@pec-services.com **Website: www.pec-services.com**
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Pharmaceuticals and Medical Devices Agency (PMDA) — Booth 605
Contact: Hiroshi Kato
E-mail: kato-hiroshi@pmda.go.jp **Website: www.pmda.go.jp**
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E-mail: michael.reynolds@pilgrimsoftware.com
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E-mail: d.smart@proclinical.co.uk
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E-mail: info@quartzbio.com **Website: www.quartzbio.com**
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E-mail: pcreed@realregulatory.com
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Contact: Sharon Schaffer
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Sharp Clinical Services (UK) Ltd — Booth 237
Contact: Ian Morgan
E-mail: ian.morgan@sharpclinical.com **Website: www.sharpclinical.com**
Sharp Clinical Services (UK) Ltd., a division of United Drug plc., has over 20 years expertise in the over-encapsulation, comparator sourcing, primary packaging and secondary assembly (including design, randomisation and label printing), global distribution, QP services, IxRS and retrieval and destruction of Investigational Medicinal Product (IMP).

Skills Alliance — Booth 716
Contact: Jemma McDonald
E-mail: london@skillsalliance.com **Website: www.skillsalliance.com**
Skills Alliance is a life science focused recruitment company with offices across Europe. We offer a full portfolio of bespoke solutions tailored to our client's requirements and includes executive search, contract solutions, benchmarking and RPO. Skills Alliance has placed across 20+ Countries ranging from pre-clinical through to post approval.

Sofus Stockholm Consulting AB — Booth 630

Contact: Linda Thunell
E-mail: Linda.thunell@sofus.se **Website: www.sofus.se**

We believe that a reliable regulatory affairs function is Determinant, Essential and Business critical. Since 2002, Sofus has specialized in regulatory affairs for pharmaceuticals. Throughout the product life-cycle; from the early development phase to the maintenance of the approved product, we supply comprehensive regulatory, quality and safety solutions to companies of all sizes – from multinational corporations to small businesses.

Springer — Booth 240

Contact: Carolin Rudnicki
E-mail: carolin.rudnicki@springer.com **Website: www.springer.com**

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SRG — Booth 141

Contact: Alan Brophy
E-mail: alan.brophy@srgclinical.com **Website: www.srg.co.uk**

SRG is an award-winning resourcing company dedicated to the science, clinical and engineering sectors. We provide our clients with expert recruitment solutions and through our niche CRO, Synergy, contract clinical research and scientific services. To industry professionals we offer access to some of the best career opportunities in Europe.

syneed medidata GmbH — Booth 712

Contact: Achim Zinggrebe, CEO
E-mail: info@medidata.de **Website: www.medidata.de**

syneed medidata GmbH is a CRO that provides complete solutions for European phase I to IV clinical trials, as well as for observational studies since 1985. Our experience includes

- full-service for clinical trials;
- Pharmacovigilance;
- Medical Imaging Core Lab;
- Proprietary EDC system, ready for tablet PCs;
- Medical device studies.

Synowledge Drug Safety Solutions — Booth 119

Contact: Sam Stein
E-mail: samuel.stein@synowledge.com **Website: www.synowledge.com**

Synowledge is a global provider of drug safety, regulatory affairs and related IT solutions to small, mid and large sized pharmaceutical, biotechnology and medical device companies. Our comprehensive outsourcing solutions combine the unique strengths of both onshore and offshore services to meet our clients' needs.

Synteract, Inc. — Booths 616, 517

Contact: Trisha Vonder Reith
E-mail: tvonderreith@synteract.com **Website: www.synteract.com**

Synteract is a global, full-service CRO offering Phase I-IV clinical development services to biopharma clients. We tailor services to meet the needs of each client while maintaining highest quality standards. We work cost-effectively across many therapeutic areas: oncology, CNS, infectious disease, endocrinology, cardiovascular & respiratory.

Tarius A/S — Booth 435

Contact: Nina Lindholst
E-mail: info@tarius.com **Website: www.tarius.com**

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TCTC Group (The Clinical Trial Company) — Booth 331

Contact: Suzanne Batchelor
E-mail: info@theclinicaltrialcompany.com **Website: www.TCTCGroup.com**

The CLINICAL TRIAL Company™ (TCTC) is a full-service clinical CRO and was formed in the UK in 2002. The founders saw an opportunity in the sector for a company which targeted medium-sized clinical trials and novel products which did not have a classical road map to market. TCTC is headquartered in the UK with offices in Berlin, Montreal and Sydney

the Uppsala Monitoring Centre — Booth 534

The Uppsala Monitoring Centre (UMC) offers tools & resources to enhance Clinical Trials & Drug Safety Operations.
UMC is the maintenance organization for the WHO Drug Dictionary Enhanced and WHO Herbal Dictionary, used globally for coding and analyses of concomitant medication data.

Theorem Clinical Research, Inc. — Booth 447

Contact: shawn.clary@theoremclinical.com
E-mail: information@theoremclinical.com
Website: www.TheoremClinical.com

Theorem Clinical Research Inc. is a leading midsized provider of comprehensive clinical research and development services with offices in more than 30 countries and a customer base comprised of some of the world's leading pharmaceutical, biotech and medical device companies.

Thomson Reuters — Booth 704

Contact: Steve Love
E-mail: stephen.love@thomsonreuters.com

IDRAC from Thomson Reuters is the leading source of information for RA professionals around the world. Search through Reference Documents and Regulatory Summaries, add input in your strategic initiatives using Regulatory Intelligence Reports, and quickly identify and compare common and divergent regulation requirements across multiple countries.

TOPRA — Booth 805

Contact: Erik Smit
E-mail: erik@topra.org **Website: www.topra.org**

TOPRA seeks to advance the status of the regulatory profession through networking, education and provision of information to its members. TOPRA supports professionals at all levels through our established conferences, continuing professional development courses, the popular MSc programmes, our monthly journal Regulatory Rapporteur and our website w

TransPerfect — Booths 411, 413

Contact: Ryan Simper
E-mail: info@transperfect.com **Website: www.transperfect.com**

TransPerfect is the leading provider of language services and technology solutions to organizations involved in drug development. Our services include translation, website localisation, and linguistic validation, as well as eTMF and other e-clinical technology solutions. TransPerfect has over 80 offices globally. lifesciences.transperfect.com

Trilogy Writing & Consulting GmbH — Booth 617

Contact: Sowmya Kalaivanan
E-mail: sowmya.kalaivanan@trilogywriting.com
Website: www.trilogywriting.com

Trilogy is a medical writing consultancy focused entirely on medical writing and medical writing training, offering the full range of regulatory clinical documentation across all therapeutic areas. Our clients include pharmaceutical companies and Clinical Research Organisations (CROs) of all sizes, worldwide.

United BioSource Corp. (UBC) — Booths 317, 319

Contact: Krista Huck
E-mail: kahuck@express-scripts.com **Website: www.ubc.com**

UBC unites unsurpassed experience in generating real-world evidence of product safety, value, and effectiveness, with the strength of its parent company, Express Scripts, the largest healthcare company in the US. UBC is uniquely positioned to seamlessly integrate best-in-class products, services and healthcare data to influence the lifecycle of a product.

Universal Medica Group — Booth 818

Contact: Rafi Mardachti
E-mail: rafi.mardachti@universalmedica.com
Website: www.universalmedica.com

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Veeva Systems — Booths 706, 607

Contact: Dan Goldsmith, General Manager
E-mail: eu_info@veevasystems.com **Website: www.veevasystems.com**

Veeva Systems is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence and customer success, Veeva has over 150 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Founded in 2007, Veeva is a privately held company headquartered in the San Francisco Bay Area, with offices in Philadelphia, Barcelona, Budapest, Paris, Beijing, Shanghai and Tokyo.
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Viedoc — Booth 535

Contact: urban.froderberg@pharmaconsultinggroup.com
E-mail: urban.froderberg@pharmaconsultinggroup.com
Website: www.viedoc.com

Viedoc™ is a 21CFR11 compliant web-based EDC software. It offers a faster, more efficient way to handle the data processing needed for your trial. Viedoc™ takes user-friendliness to a new level - experience of 260+ studies. Viedoc™ includes CTMS, coding of AE/ConMed, randomisation, external data uploads (eg lab) and helpdesk. Visit us for a demo!

Vitalograph — Booth 504

Contact: Jonathan Pritchard
E-mail: Jonathan.Pritchard@Vitalograph.co.uk
Website: www.Vitalograph.co.uk

Vitalograph has manufactured respiratory diagnostic equipment for the healthcare industry for 50 years. We provide a full range of services within Cardio-respiratory clinical trials and our equipment is able to capture a variety of spirometry data as well as FeNO, pulse oximetry, challenge testing, 12-lead ECG and 24 hour holter data.

vitaphone Telemedicines — Booth 705

Contact: vitaphone Netherlands
E-mail: rene.stenvert@vitaphone.nl **Website: www.vitaphone.nl**

Vitaphone is a full service provider for care management, telemonitoring, telemedical devices and patient coaching – everything from a single source.

WCI Consulting Limited — Booths 717, 816

Contact: Kate Derham
E-mail: kate.derham@wcigroup.com **Website: www.wcigroup.com**

Founded in 1986, WCI is the leading life science consulting practice focusing on Patient Safety, Risk Management, and Quality and Compliance. We have worked with over 50 pharmaceutical, biotechnology, consumer health, medical device, and dietary supplement organisations; helping to implement solutions which assure compliance and boost performance.

Wingspan Technology, Inc. — Booth 604

Contact: Meghan McKeown
E-mail: mmckeown@wingspan.com **Website: www.wingspan.com**

Wingspan Technology, Inc, the leading provider of Documentum to SharePoint integration software, is the maker of DocWay and Wingspan eTMF. Founded in 1996, Wingspan boasts a talented engineering team, which provides in-depth industry knowledge and experience to companies in the life sciences and pharmaceutical industries.

XClinical GmbH — Booth 505

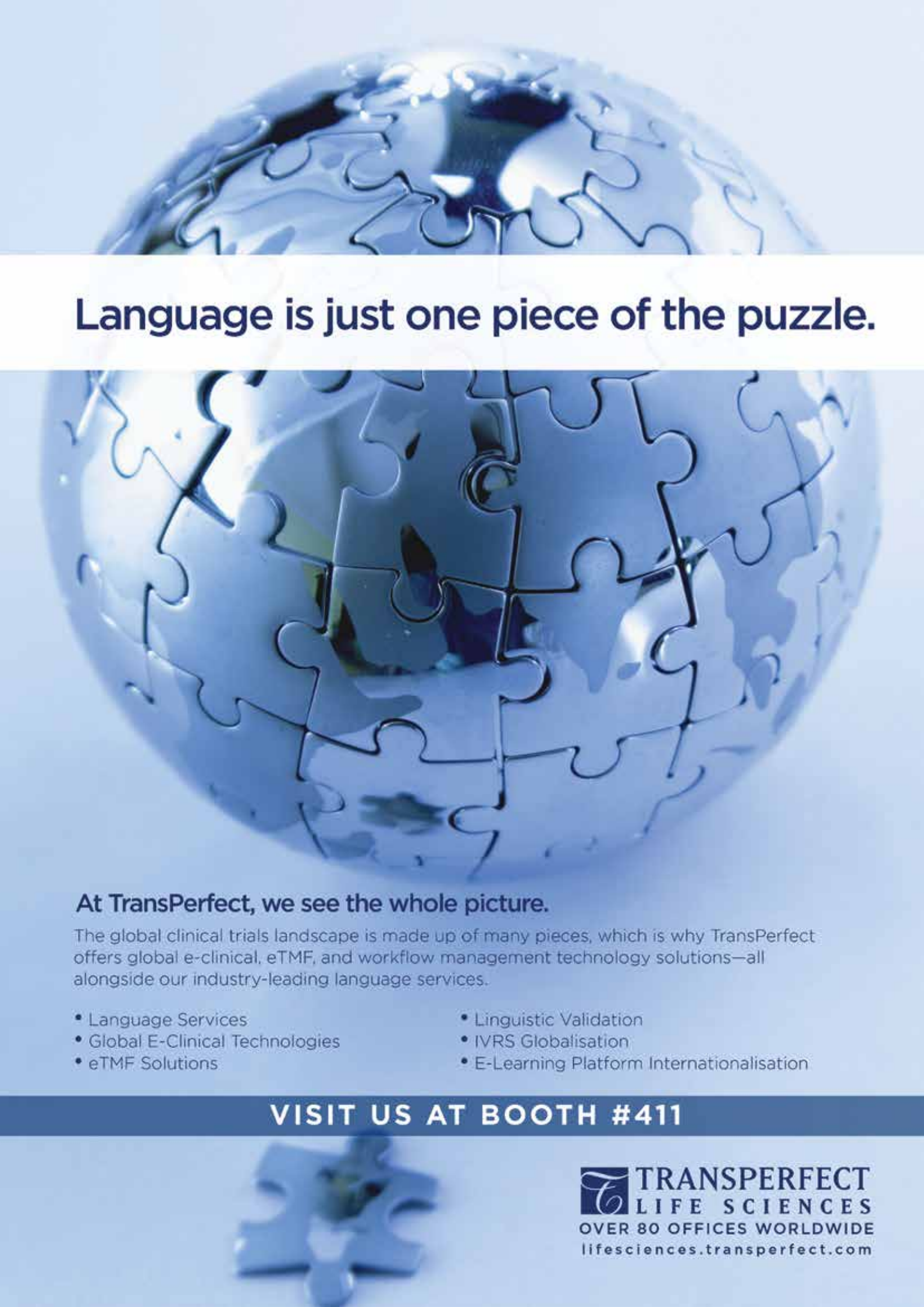
Contact: Dr. Philippe Verplancke
E-mail: info@xclinical.com **Website: www.xclinical.com**

XClinical provides solutions for the electronic conduct of all types of clinical trials, post-marketing studies and registries. XClinical develops and markets MARVIN, a CDISC ODM-certified online platform for EDC, CDM and CTM. STUDY COMPOSER provides an intuitive graphical user interface for study setup including CRF design and data validation plan

Xendo — Booth 737

Contact: Christine Degeling
E-mail: christine.degeling@xendo.com **Website: www.xendo.com**

Xendo is a consultancy for the pharmaceutical industry offering solutions for life sciences. Xendo's regulatory affairs team now presents a new service, called "Strategic Maintenance Partnership" bundling its 15 years of experience in regulatory life cycle consultancy into one single service package.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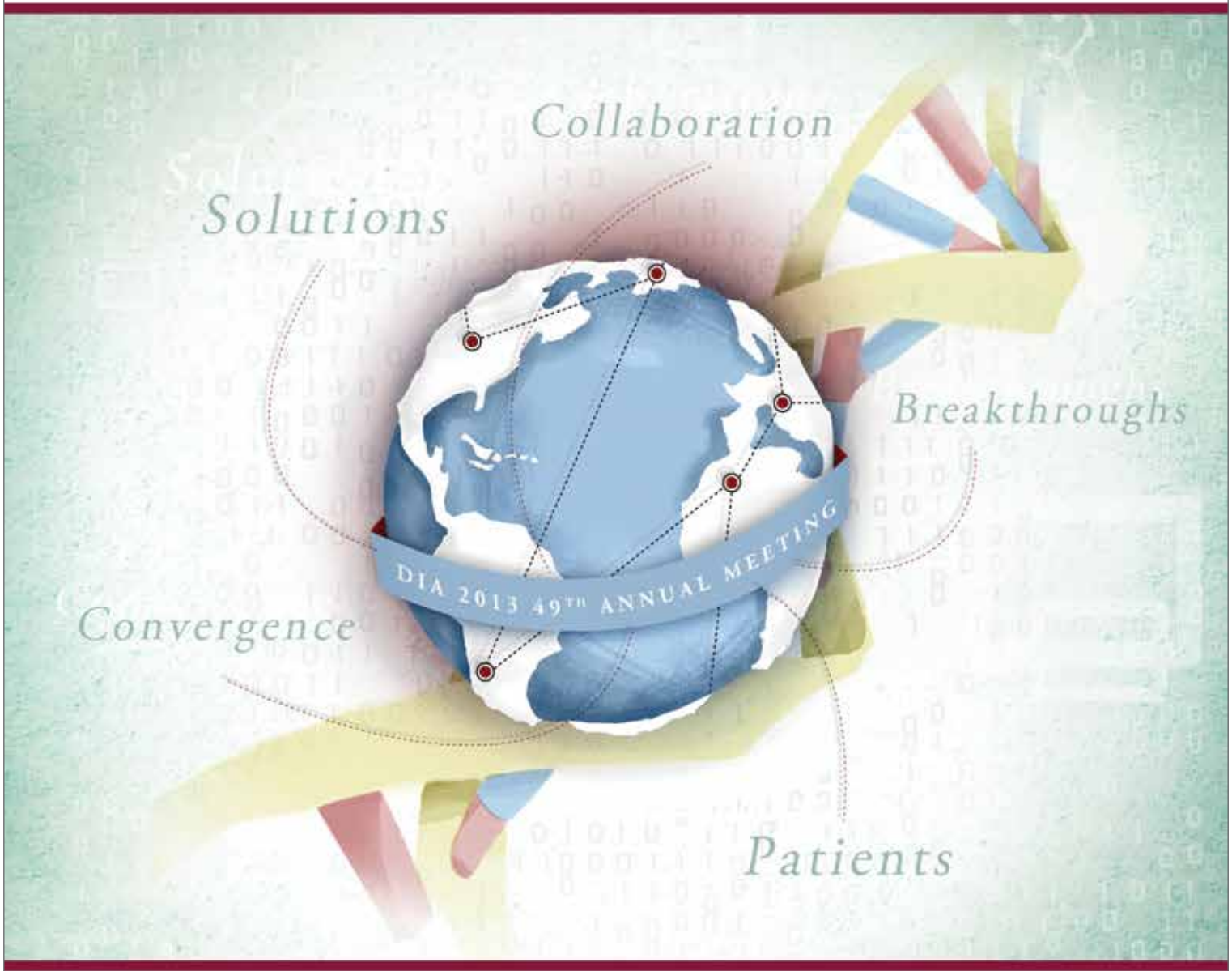

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Monday, 4 March 2013

09:00-12:30 Pre-conference Tutorials

14:00-17:15 Plenary

17:30-19:00 EuroMeeting 25th Anniversary Reception

	Theme 1	Theme 2	Theme 3	Theme 4
	Health Technology Assessment (HTA)/ Sustainability of Health Systems in Europe	Development of Medicinal Products for Paediatric, Elderly and other Special Populations	Legal/Transparency- Risk Assessment	Pharmacovigilance

Tuesday, 5 March 2013

Session 1 09:00-10:30		Session 0201 Mechanism of Action - the leading paradigm	Session 0301 Regulatory Data Protection	Session 0401 Implementation of the New Pharmacovigilance Legislation
		Emerald Room	Room D203-204	Elicium 2
Session 2 11:00-12:30	Session 0102 The European Landscape on HTA - the EUnetHTA Joint Action	Session 0202 Cohort Studies of Elderly as a Tool for Drug Development	Session 0302 Incentives for Paediatric Clinical Research	Session 0402 Best Practices in Pharmacovigilance Governance
	Room G107	Emerald Room	Room E102	Elicium 2
Session 3 14:00-15:30	Session 0103 Comparative Effectiveness as Part of the Public Assessment Report (PAR)	Session 0203 Development of Innovative Interventions for Healthy Ageing: How far did we get?	Session 0303 Legal Compliance for Regulatory Functions - Learnings from recent enforcement activities	Session 0403 Benefit/Risk Management in Pharmacovigilance
	Room G107	Emerald Room	Room E102	Elicium 2
Session 4 16:00-17:30	Session 0104 HTA and Pricing Policies in EU after the Transparency Directive	Session 0204 Special Populations- [illegible] age groups CANCELLED	Session 0304 Biosimilars	
	Emerald Room		Room E102	

18:00-19:30 Satellite Session -Pharmaceutical Law in the Netherlands: Building an EU association?

Wednesday, 6 March 2013

	Theme 1	Theme 2	Theme 3	Theme 4
	Health Technology Assessment (HTA)/ Sustainability of Health Systems in Europe	Development of Medicinal Products for Paediatric, Elderly and other Special Populations	Legal/Transparency- Risk Assessment	Pharmacovigilance

Session 5 09:00-10:30	Session 0105 Focus on Managed Entry Agreements (and Real World Data)	Session 0205 How to Optimise Clinical Development in the Elderly: Some Practical Examples	Session 0305 From Voluntary Harmonisation to Clinical Trial Regulation	Session 0405 New Opportunities for Information Technology in Pharmacovigilance
	Room G107	Emerald Room	Room G103	Elicium 2
Session 6 11:00-12:30	Session 0106 The Impact of the New Pharmacovigilance Directive Instruments on HTAs	Session 0206 Paediatric Clinical Trials- trial design	Session 0306/1206 Transparency on Dossier and Decision Making – has public trust increased?	Session 0406 Risk Communication and Transparency
	Room G103	Emerald Room	Auditorium Ground Floor	Elicium 2
Session 7 14:00-15:30	Session 0107 The Patients' Perspective on HTA		Session 0307 Legal and Practical Aspects of Off-Label Use	Session 0407 Impact of ICH E2C (R2) and GVP Module VII
	Room G103		Emerald Room	Elicium 2
Session 8 16:00-17:30	Session 0108 HTA and Off-Label Use	Session 0208 Paediatric Requirements- do they deliver and at what cost?		Session 0408 Development of Pharmacovigilance Methodology
	Emerald Room	Room E102		Elicium 2

Monday, 4 March 2013

09:00-12:30 Pre-conference Tutorials

14:00-17:15 Plenary

17:30-19:00 EuroMeeting 25th Anniversary Reception

Theme 5	Theme 6	Theme 7	Theme 8	Theme 9
Clinical Research and Development	Quality	Devices & In Vitro Diagnostics and Drug/Device Combination Products	eTools and Data Management	Involvement of Experts in the Drug Approval Process

Tuesday, 5 March 2013

Session 0501 New Approaches for Monitoring	Session 0601 Drug Shortage Management- ensuring medicine supply	Session 0701 Current Status of Revision of EU Medical Device Directives	Session 0801 Migration from Paper to Electronic	Session 0901 Learned Societies and Drug Regulation
Elicium 1	Room G102	Room E102	Room G103	Room G105
Session 0502 Why Trials Fail and How to Prevent This	Session 0602 The EU Qualified Person in a Global Environment	Session 0702 Development and Regulatory Framework for Companion Diagnostics	Session 0802 Clinical Standards and Metadata	Session 0902 Patients as Experts in Drug Regulation
Elicium 1	Room D203-204	Room G102	Room G103	Room G105
Session 0503 Enhancing Clinical Research Effectiveness	Session 0603 Falsified Medicines Directive and Active Substances	Session 0703 Changes in EU Approval of Drug/ Device Combinations	Session 0803 Pharmacovigilance and Medicinal Product Standards and Metadata	
Elicium 1	Room D203-204	Room G103	G105	
Session 0504 Adaptive Clinical Trial Designs	Session 0604 Falsified Medicines Directive and Serialisation	Session 0704 How to Address Different Requirements Developing Combination Products	Session 0804 Messages from the Agencies	Session 0904 Handling Conflict of Interest (CoI)
Elicium 1	Room D203-204	Room G103	Elicium 2	Room G105

Wednesday, 6 March 2013

Theme 5	Theme 6	Theme 7	Theme 8	Theme 15
Clinical Research and Development	Quality	Devices & In Vitro Diagnostics and Drug/Device Combination Products	eTools and Data Management	Growing Demand for Quantitative Approaches in Drug Development
	Session 0605 Quality Update - Current developments	Session 0705 Latest US Regulatory Moves Towards Fostering Innovation	Session 0805 Social Media/Use of Tablets and Smartphones	Session 1505 A Case Study Using the Framework Supported by Quantitative Methods for Benefit/Risk Assessment
	Room D203-204	Room G106	Room G102	Forum
Session 0506 Adoption of Game Changing Technologies	Session 1906 Quality Risk Management Workshop	Session 0706 International Harmonisation: Global Regulators' Progress from GHTF to IMDRF	Session 0806 Attributing Safety Reports to Medicinal Products	Session 1506 Equivalence of Orally Inhaled Products
Elicium 1	Room G109	Room G106	Room G102	Forum
Session 0507 Patient Recruitment and Retention	Session 0607 Pharmacopoeial Hamonisation- a never ending story		Session 0807 How Synergy between Data Management and Technology Drives Clinical Development in the Next Decade	Session 1507 Subgroup Analyses
Elicium 1	Room D203-204		Room G102	Forum
Session 0508 Collecting Relevant Health Outcome Data	Session 0608 Harmonisation – pitfalls and how can we speed it up?	Session 0708 Which EU Regulatory Rules for Telemedicine, eHealth and mHealth?		Session 1508 Statistical Hot Topics in Scientific Advice
Elicium 1	Room D203-204	Room G106		Forum

Monday, 4 March 2013

09:00-12:30 Pre-conference Tutorials

14:00-17:15 Plenary

17:30-19:00 EuroMeeting 25th Anniversary Reception

Theme 10	Theme 11	Theme 12	Theme 13	Theme 14	
Known Active Substances	Effective Antibacterials: The present and the future	Effectiveness and Efficiency of the EU Regulatory System	Globalisation	Regulatory Science	Stand-Alone Hot topics

Tuesday, 5 March 2013

Session 1001 New Rules for Assessment of Known Active Substances	Session 1101 Bottlenecks in Research: How do we replenish the pipeline?	Session 1201 The EU Drug Development and Approval System	Session 1301 Safe, Effective and Affordable Medicinal Products for a Global Population	Session 1401 Setting the Scene: Importance of Regulatory Science throughout	Session 1801 Public-Private Partnership for Biomedical Research under Horizon 2020
Room D201-202	Room G104	Auditorium Ground Floor	Forum	Room G106	Room G107
Session 1002 Harmonisation: Challenges in Product Information / Labelling	Session 1102 Pragmatic Regulation- role of guidelines in stimulating development of new antibiotics		Session 1302 International Collaboration in the Review of Generic Drugs	Session 1402 The Way Forward in CNS: Regulatory Science at the edge	
Room D201-202	Room G104		Forum	Room G106	
Session 1003 Maintenance of Medicinal Products with Known Active Substances – variations	Session 1103 Preserving What We Have-prudent and controlled us	Session 1203 First Experience with the Pharmacovigilance Legislation	Session 1303 SFDA Session: GMP in China	Session 1403 The Escher Project: Regulatory Science in Practice	Session 1803 GCP Hot Topic: Electronic Health Records
Room D201-202	Room G104	Auditorium Ground Foor	Forum	Room G106	Room G102
Session 1004 XEVMPD: Long-Term Expectations and Benefits	Session 1104 New Approaches to Combat Resistance	Session 1204 Early Dialogue in Drug Development	Session 1304 International Cooperation of Global Regulators	Session 1404 Patient and Consumer Roles: Their input in Regulatory Science	Session 1804 GCP Hot Topic: Challenges in the CRO-Sponsor relationship
Room D201-202	Room G104	Auditorium Ground Floor	Forum	Room G106	Room G102

18:00-19:30 Satellite Session -Pharmaceutical Law in the Netherlands: Building an EU association?

Wednesday, 6 March 2013

Theme 10	Theme 16	Theme 12	Theme 13	Theme 17	
Known Active Substances	Developments in Non-Clinical	Effectiveness and Efficiency of the EU Regulatory System	Globalisation	The IMI Public Private Partnership in Medicines Research Education and Training – for Professionals and for Patients	Stand-Alone Hot topics
Session 1005 Known Active Substances for the Self-Care Sector	Session 1605 Non-Clinical Testing for Advanced Therapy	Session 1205 Innovative Approaches to Product Information for Physicians and Patients	Session 1305 MNC's Expansion in Emerging Markets: Opportunities and Challenges	Session 1705 Focus on Medcines Efficacy, Safety, and Usage in Education and Training	Session 1805 EMA Roundtable - Scientific Committees United in Diversity
Room D201-202	Room G105	Auitorium Ground Floor	Room E102	Room G104	Elicium 1
Session 1006 Biosimilars: Developing a more thorough understanding of a Known Active Substance	Session 1606 New Trends in invitro Non-Clinical Testing	Session 0306/1206 Transparency on Dossier and Decision Making – has public trust increased?	Session 1306 Environmental Considerations in Production of Medicinal Products	Session 1706 Quality Career Development in Globl Medicines Development	Session 1806 Japanese Regulatory Session-PMDA update
Room D201-202	Room G105	Auditorium Ground Floor	Room E102	Room G104	D203-204
Session 1007 Combination Medicinal Drug Products of Known Active Substances	Session 1607 New Initiatives in ICH Testing	Session 1207 Regulatory Town Hall Meeting	Session 1307 Asian Strategy of the USA, Europe and Japan	Session 1707 EUPATI- An unprecedented public-private partnership to empower patients	Session 1907 Perspectives and Collaboration between Patients and Students
Room D201-202	Room G105	Auditorium Ground Floor	Room E102	Room G104	Room G107
	Session 1608 Overview of Current Discussions in ICH	Session 1208 Clinical Trials in Europe: Will the revised legislation meet the demands of tomorrow?		Session 1708 Towards a European Framework for Continuing Professional Development	
	Room G105	Auditorium Ground Floor		Room G104	

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