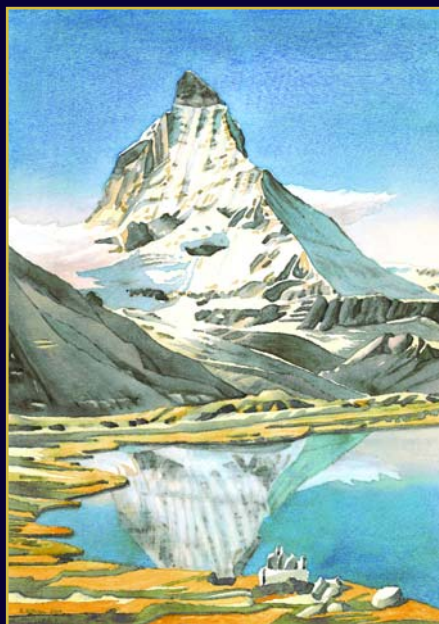




23RD ANNUAL
EUROMEETING
GENEVA 2011

CALL FOR ABSTRACTS



28-30 MARCH 2011
PALEXPO
GENEVA, SWITZERLAND

Welcome from the EuroMeeting 2011 Co-Chairs

Dear Colleague,

The landscape of drug development is changing. At DIA's 23rd Annual EuroMeeting in Geneva, taking place from 28-30 March 2011, we are introducing important new themes such as Global Drug Development in the Real World. These will highlight new perspectives on current systems and stimulate discussion on new ways of working and opportunities for new partnerships. Discovering new synergies will be an important focus and will be particularly appropriate in the truly international setting of Geneva.

Innovation is always centre stage at the DIA - this EuroMeeting will ask whether we are really delivering the benefits of new science and technology. Are the products of pharmacogenomics coming on stream? Is patient safety improving as a result of pharmacogenetic knowledge and will the drug-device boundary disappear? Hand-in-hand with this debate will be a discussion on better and early access to innovative treatments.

Risk management throughout the product lifecycle is now embedded in practice both in industry and the regulatory world. It is time to move on to benefit/risk management in practice and to align regulatory process and health technology assessment.

By 2011, regulation will have reached another significant milestone with the package of measures on pharmacovigilance and counterfeit medicines. The challenges will be in implementing these new measures to achieve the aimed-for benefits in public health protection without compromising the better regulation principles of proportionality and targeting.

Better risk communication remains perhaps the biggest challenge of all. No medicine or healthcare product is completely risk-free. Tools and methodologies for detecting and managing risk have advanced significantly but arguably industry and regulators have yet to benefit from the science of risk communication. Can we embrace the best practices from other fields and disciplines?

With so many new topics to debate, you may ask what will you not see on the Geneva EuroMeeting 2011 scientific programme! At this meeting the patient perspective will no longer be addressed in a separate theme. This does not mean that the patient perspective is being ignored. On the contrary, it will be evident in every theme and throughout the whole meeting. We feel strongly that no longer should patients' contributions be an add-on or an after-thought but integrated in every aspect.

We wish to ensure that DIA's 23rd Annual EuroMeeting in Geneva will be a milestone in drug development science, regulatory evolution, stakeholder involvement and partnership working. Join us there, contribute your views and participate in debate - we will all benefit.

Valdo Arnera and June Raine



Valdo Arnera

General Manager, PHT Corporation, Geneva, Switzerland



A medical doctor by training, Dr. Valdo Arnera has over 25 years of experience in the pharmaceutical industry. After having practiced medicine in various positions, he started his career in the industry as a clinical pharmacologist in a Ciba-Geigy subsidiary. In 1992, he founded the first European Central Clinical Laboratory dedicated to clinical trials, SciCor (now Covance Central Laboratory). He joined PHT in 2000, an electronic diary technology provider, and founded its European affiliate in Geneva in January 2001. Skilled in both science and management, Dr. Arnera currently serves as the General Manager of PHT's European operations. He has also been an active Co-chair of the DIA's Special Interest Area Communities (SIAC) eClinical and Standards.

June Raine

Director, Division of Vigilance Risk Management of Medicines, MHRA, UK



Dr June Raine trained in general medicine in Oxford after completing a Masters degree by research in Pharmacology. Her interest in drug safety led to a career in medicines regulation which has spanned a number of roles in assessment, management and strategic development within the UK national authority. Appointed in 1999 to head Pharmacovigilance in the Medicines Control Agency (now Medicines and Healthcare products Regulatory Agency), she was elected in 2005 to chair the CHMP's Pharmacovigilance Working Party. She is also a member of the WHO Advisory Committee on Safety of Medicinal Products. Her special interests are in monitoring the outcomes of regulatory action, risk communication and patient involvement in the regulatory process.

About the EuroMeeting and the DIA

The Drug Information Association's Annual EuroMeeting is global in scope, attracting more than 3,000 professionals from over 50 countries. It brings together professionals from the biopharmaceutical industry, contract service organisations, clinical research, regulatory agencies, health ministries, patients organisations and universities. This convergence affords attendees the opportunity to network with professional colleagues from around the world.

The DIA is a global forum for knowledge exchange that fosters the innovation of products, technologies, and services to improve health and well-being worldwide. It organises international meetings, training courses, online learning and myriad networking opportunities. The neutral, global, professional, member-driven association comprises nearly 18,000 biotechnology, pharmaceutical, clinical research, academic and regulatory professionals and patient representatives.



Submit an Abstract – Deadline Friday, 23 April 2010

The DIA invites you to submit presentation and/or session and/or tutorial abstracts for the 23rd Annual EuroMeeting in Geneva, 28-30 March 2011. You may submit more than one abstract.

Presentation Abstracts

You are invited to submit abstracts for presentations that fall under one of the themes detailed on the following pages. If selected, your presentation will be a single presentation which will fit within a session.

Please note:

- Only one presenter per presentation will be allowed.
- A presentation abstract should be for a 20-minute non-commercial presentation.

Session Abstracts

You are invited to submit abstracts for a complete session that falls under one of the theme detailed on the following pages. If selected, your presentation will be a complete session.

Please note:

- Session abstracts must be for a complete 90-minute session.
- As the session chair, you will be responsible for recruiting at least two additional speakers representing other companies/organisations. Each session will have a maximum of three speakers.
- Co-chairs are not permitted.

Tutorial Abstracts

Pre-conference tutorials will take place before the EuroMeeting on the morning of Monday, 28 March 2010. A tutorial is a 'hands-on', interactive learning experience which takes a different format than a session. Tutorials are attended by a smaller number of participants and are more interactive.

Please note:

- Tutorials consist of three hours of instruction with a 30-minute break in the middle.
- You will serve as the lead instructor. You may recruit a maximum of one other co-instructor from another company/organisation.

How to maximise the possibility of your abstract being accepted

- Abstracts will be selected by the EuroMeeting Programme Committee. The theme leaders have indicated the strategic topics they would like to address. Focus your abstracts on these topics. If your abstract clearly does not fit, submit it as a hot topic/stand-alone presentation/session (see page 11).
- Your abstract should be as clear and detailed as possible to enable the theme leaders to make a judgement on its fit in the programme.

If you have any questions about abstract submission please email the EuroMeeting team:
euromeetingspeakers@diaeurope.org



Submit an Abstract – Deadline Friday, 23 April 2010

How to Submit an Abstract

The deadline for submitting abstracts is Friday, 23 April 2010.

All abstracts have to be submitted online at www.diahome.org

Go to the menu at the left-hand side and click “Get Involved”, then click on “Opportunities to Get Involved” and then “Submit an Abstract”

The screenshot shows the DIA website interface. At the top left is the DIA logo. The top right navigation bar includes links for 'About Drug Information Association', 'Sign In', 'My DIA', 'Cart[0]', and 'Contact Us'. Below this is a search bar with a 'Region:' dropdown menu set to 'Global', a 'Search' button, and a 'Search entire site' input field. On the left is a vertical navigation menu with categories like Home, About DIA, Conferences / Meetings, Exhibits, Training, Online Learning, Continuing Education, Publications, Membership, Get Involved (expanded to show Opportunities to Get Involved, Volunteer Roles, and Volunteer Program), Career Center, DIA ConneX / Communities, and Help / FAQs. The main content area is titled 'Opportunities to Get Involved' and features a banner with the text 'Your Future Starts Today – Get Involved with DIA' and a photo of a man in a suit. Below the banner, a paragraph states: 'DIA offers many opportunities for members to initially get involved in support of DIA’s Mission and their professional colleagues worldwide. To get started, members can:'. This is followed by a bulleted list of opportunities:

- Join a discipline-specific **Special Interest Area Community (SIAC)** (Members Only)
 - Enjoy global and regional networking;
 - Exchange information;
 - Discuss ideas and debate new initiatives; or
 - Work with your SIAC leadership to develop ideas and content for programs and publications to serve your fellow professionals.
- **Submit** ideas or abstracts for DIA meeting sessions
- **Write** articles for the DIA Global Forum magazine
- **Submit** scientific articles for the scholarly, peer-reviewed DIA Journal
- **Nominate** a colleague for the DIA Board of Directors (Members Only)
- **Nominate** a colleague for an Award (Members Only)
- **Apply** for a grant.

 Below this list is a 'Learn more...' section with links for 'Volunteers Roles' and 'Volunteer Program'. At the bottom of the page are three promotional banners: 'Discover Membership JOIN TODAY', 'Career Center', and 'MY DIA CONNEX social networking'.



THEME 1 | INNOVATION AND THE FUTURE OF TREATMENT; PERSONALISED MEDICINE

Theme Leader: **Duncan McHale**, Vice President, Translational Sciences, AstraZeneca Pharmaceuticals LP, UK

Suggested topics:

- Drug diagnostic co-development
- Identifying patient selection biomarkers
- Study designs to identify responder patient populations
- Statistical approaches to identifying patient selection biomarkers
- Developing novel drug combinations
- Innovative trial designs
- Current regulatory framework - supportive of impediment to innovative drug development?
- New therapeutic approaches - stem cells, micro RNA, gene therapy
- Creating a culture of innovation
- Biomarker qualification
- Innovation through consortia - IMI, PSTC, SAEC. What is pre-competitive?
- Open innovation techniques (e.g. social networking sites) and drug discovery and development.

THEME 2 | REGULATORY AFFAIRS

Theme Leader: **Henrik Kim Nielsen**, Corporate Vice President, Novo Nordisk A/S, Denmark

Suggested topics:

- European Medicines Agency Roadmap 2015
- Proportionate regulation - when is regulation needed?
- Good guideline practice - when is regulation needed? How should it be created?
- Meeting the needs of the patient - labelling
- Advanced therapies - status of the regulation
- Quality by Design - is the regulation appropriate and is it being used?
- Variations regulation 2009 - was the simplification achieved; what are the future trends?
- Harmonisation of regulations - ICH/GCG implementation and interpretation
- Clinical trial applications - experience with EU worksharing; review of the directive
- The regulatory decision: Benefit/risk. Systematic approaches?

THEME 3 | RISK MANAGEMENT/PATIENT SAFETY

Theme Leader: **Sabine Straus**, Head of Pharmacovigilance, Medicines Evaluation Board (MEB), The Netherlands

Suggested topics:

- Update on guidelines on risk management plans
- Feedback from experiences with risk management plans from the pharmaceutical industry as well as from European Medicines Agency and from national agencies
- How should risk management obligations that have been agreed/implemented for the innovator product be handled for generics? Is there a possibility to work together? What about registers?
- Additional risk minimisation measures: pregnancy prevention programmes
- The thin line between educational material and promotional material



- If the risk management plan educational program is agreed, how can patients be involved?
- Risk minimisation and its implementation
- Risk communication

THEME 4 | HTA/COST EFFECTIVENESS

Theme Leader: **Olivier Chassany**, Medical Head, Clinical Research & Development Department, Assistance Publique - Hôpitaux de Paris, France

Suggested topics:

- Can we trust in cost-effectiveness studies and models? Should cost-effectiveness studies be sponsored by industry?
- Update on how agencies assess the therapeutic value and the therapeutic added value?
- Can we reach some harmonisation among Europe on HTA review? Assessment of value product, added value product and reimbursement decision process?
- Can we merge two different worlds: regulatory approval (for market authorisation) and HTA assessment (for reimbursement decision)?
- Real-life post-reimbursement trials
- Facilitating access to market for drugs in countries not being used to HTA review
- The light of final FDA guidance on PRO, the European Medicines Agency Paper on health-related quality of life and the interaction between the FDA and the European Medicines Agency
- Multinational clinical trials – issues and best practice for measuring clinical endpoints (i.e. PROs)
- Public-private partnership initiatives to reach a consensus on measures
- Comparative effectiveness trials

THEME 5 | WIDER ACCESS (SWITCHING/GENERICS)

Theme Leader: **Christa Wirthumer-Hoche**, Deputy Head, Ages PharmMed, Austria

Suggested topics:

- Switching: Is there an ideal route?
- Switching: Are the expectations met?
- New regulatory environment: Impact on non-prescription medicines and switches
- Switching: Is the empowered patient adequately informed?
- Is there a need to enhance information on generics and OTC?
- Pros and cons of the current DCP for generics and OTC
- Improvement of the regulatory environment for generic and biosimilar medicines in the view of future revision of the pharmaceutical legislation
- What is the benefit for abridged WHO qualification procedure for generic products?



THEME 6 | ENGAGING THE RESEARCH WORLD: PRE-CLINICAL RESEARCH AND DEVELOPMENT

Theme Leader: **Per Spindler**, Director, BioLogue, University of Copenhagen, Denmark

Suggested topics:

- Safety guidelines: ICH and CHMP priorities and updates (S6, S9, M3)
- Liver toxicity and medicines to children: Pre-clinical revisited
- Pre-clinical development of medical devices
- Public-private partnerships: IMI and top institute models
- Bridging disciplines and translational biosciences
- Biotech products and vaccines
- Better financing innovation: Valley of death and the challenge of attrition
- Imaging technologies – bridging the gaps
- Managing seamless product discovery and development
- High value research tools: biobanks

THEME 7 | STATISTICS

Theme Leader: **Jürgen Kübler**, Global Head, Statistical Safety Sciences, Novartis Pharma AG, Switzerland

Suggested topics:

- Adaptive Design
- Dose-finding
- Signal Detection from clinical trials
- Systematic approaches to pre-marketing risk assessment
- Quantitative benefit/risk evaluations
- Non-inferiority
- Meta-analyses
- Quantitative, data-driven decision making

THEME 8 | SPECIAL POPULATIONS

Theme Leader: **Angelika Joos**, Director, Regulatory Policy, Europe, Merck Sharp & Dohme (Europe) Inc., Belgium

Suggested topics:

- Globalisation of paediatric development
- Paediatric development: Methodological aspects and standards
- Modelling and extrapolation of data to other populations
- Establishing paediatric medical needs in selected therapeutic areas
- Paediatric pharmaco-epidemiology
- Pharmaceutical formulation development
- Development of geriatric medicines
- Medicines for pregnant and lactating women
- Biomarker development for special populations



THEME 9 | PHARMA E-WORLD

Theme Leader: **Pierre-Yves Lastic**, Senior Director, Data Privacy & Healthcare Interoperability Standards, sanofi-aventis, France

Suggested topics:

- IMI knowledge management
- New approaches to pharmacovigilance-based use of Electronic Health Records (EHRs)
- Technologies enabling the use of bio-banking, imaging and more generally biomarkers in clinical trials
- Ethical and data privacy aspects around bio-banking, personalised medicine and use of EHRs
- New ISO, HL7 and CDISC standards development and their implementation
- Computational Sciences: New FDA buzzword?
- What's new in clinical development technology?
- Updates on technologies in clinical trials

THEME 10 | INSPECTORS, CMC AND COUNTERFEITS

Theme Leader: **Georges France**, VP Quality Strategy, Global Quality Operation, Pfizer, UK

Suggested topics:

- Counterfeited and falsified medicine
- Post-approval change management protocol
- New paradigm in pharmaceutical quality: latest development
- Analytical methods: new approaches in development and validation
- New approaches in process validation
- Globalisation of manufacturing for drugs and API: Maintaining quality of the supply chain
- API, Excipients subcontractor, broker: impact on inspection and audit
- Development of paediatric formulation
- European pharmacopoeia

THEME 11 | THE DISAPPEARING DRUG/DEVICE BOUNDARY

Theme Leader: **Michael Hotze**, Director, Head of Clinical Research, Institut Straumann AG, Switzerland

Suggested topics:

- Introduction to medical devices
- Clinical studies with medical devices
- Clinical evaluation
- GHTF Process
- Development process of medical devices
- Regulatory process in medical device industry
- Device combination products



THEME 12 | GLOBAL DRUG DEVELOPMENT IN THE REAL WORLD

Theme Leader: **Philippa Smit-Marshall**, Vice President Medical and Scientific Affairs, PharmaNet B.V., The Netherlands

Suggested topics:

- Changes in the medicines industry
- Global healthcare issues
- Impact of recent and anticipated regulations on the industry infrastructure
- Priorities of non-governmental organisations and their influence of drug development and access to medicines
- Global march of clinical research
- Emergence of generics and biosimilars
- ICH renewal process and its impact on R&D processes
- Acceptance of ethnic data: race-based modelling and genetics
- Cost management and efficiencies in research and development
- Marketing approaches
- Impact of the US health reforms

THEME 13 | BIOLOGICALS AND VACCINES

Theme Leader: **Thomas Verstraeten**, Head Biologicals Clinical Safety & Pharmacovigilance, GlaxoSmithKline Biologicals, Belgium

Suggested topics:

- Pharmacovigilance
- Paediatric requirements
- New technologies
- Generic components of biologicals
- The developing world and Europe's role
- Recent developments in specific regulations for biologicals
- Clinical trials

THEME 14 | KNOWLEDGE MANAGEMENT/TELEMATICS

Theme Leader: **Andrew P. Marr**, Director, Global eRegulatory Development, Global Regulatory Operations, GlaxoSmithKline, UK

Suggested topics:

- Use of e-submissions in support of new variations regulations
- National implementation of e-submissions programmes, e-submission management in MRP/DCP
- e-submission in support of Active Substance Master Files, Certificates of Suitability, Plasma Master Files
- PIM implementation
- HL7 and ISO standards for regulatory information exchange (RPS, ICSR, IDMP)
- Knowledge management and innovation



- Predictive analytics in drug safety signal detection
- Optimising clinical trials using modelling and simulation
- The potential of text mining and analytics for pharma
- Aggregating disparate data types using semantic technologies

HOT-TOPIC/STAND-ALONE SESSIONS

Each year, there are a number of sessions which do not fit directly under the programme themes. If your abstract clearly does not fit with any of the themes/topics outlined, you may submit it for consideration as a hot-topic/stand-alone presentation/session.

TUTORIALS

A tutorial is a 'hands-on', interactive learning experience which takes a different format from a session (there are not speakers but instructors). Tutorials are attended by a smaller number of participants, are more interactive and can reflect the multi-disciplinary nature of the EuroMeeting.

EUROMEETING 2011 EXHIBITION

Exhibit at the EuroMeeting 2011



Showcase your company's product or service to over 3,000 drug development professionals at the EuroMeeting 2011 in Geneva.

Join over 200 exhibitors to interact with professionals from over 50 countries in the pharmaceutical, devices, government, academia, healthcare delivery and related industries and with representatives from patients organisations.

For further information, please contact Natacha Scholl at the DIA in Europe: natacha.scholl@diaeurope.org or call +41 61 225 51 59



Join us in Geneva... Rejoignez-nous à Genève...

About Geneva



Geneva has the perfect location – on the banks of Lake Geneva and at the foot of the Alps. Its cosmopolitan flair perfectly reflects the international attendance of the EuroMeeting which attracts attendees from over 50 countries. Geneva hosts the European headquarters of the United Nations, the headquarters of the International Red Cross as well as around 20 more major international organisations, 170 NGOs and 200 diplomatic missions. The Jet d'Eau on the lake, one of the world's tallest water fountains shooting water 140 metres in the air, provides an excellent point of reference. In your free time, explore Geneva's past in the old town or visit one of the more than 40 museums in the city.

Geneva is very much a city of culture. Take a cruise on the lake or stroll through one of the waterfront parks. There is something for everyone. If you are thinking of extending your visit, head for the mountains. In an hour you can be on top of the world – whether to ski or just to enjoy the view and the fresh air.

Geneva has sometimes been described as one of Europe most unavoidable cities – everybody passes through here at one point thanks to Geneva's excellent transportation connections. Geneva International Airport links the city with the world, complemented by the excellent high speed train services to Paris, London and Milan as well as its location at the junction of the northern and southern motorway systems.

Quick Facts

- Location:** Geneva is located in the south-western corner of Switzerland, on the banks of Lake Geneva
- Population:** The second largest city in Switzerland with a population of 185,000 – over one third are foreign
When dual-citizenship is taken into account, over half of its citizens hold a foreign passport
- Climate:** Pleasant all year round due to the tempering effects of the lake and surrounding mountains
- Currency:** Swiss Franc
- Language:** French, but English is widely spoken
- Hotels:** Over 125 quality hotels

The Convention Centre



Geneva Palexpo is ideally located right next to the international airport with its own underground railway station about 300m (328 yards) away from the arrival and departure levels. Simply leave the Palexpo Convention Centre and check in for your flight. Downtown is only 6 minutes away by train. In a city with a long tradition of high-level meetings, Geneva Palexpo has proved itself to be one of Europe's most versatile convention centres.

