5th Annual

Clinical Forum

Basel 2011

Cross-Functional Working for Better Results

10-12 October 2011
Congress Center Basel | Basel, Switzerland

- CDM/eClinical
- Clinical Operations
- Clinical Research
- Drug Safety and Risk Management
- Peri- and Post-Approval Studies
- Validation
- Medical Writing
- Medical Information and Communications

Updated Advance Programme

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Continuing Education

DIA meetings and trainings are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available on request from the DIA registration desk.

PLAN YOUR CLINICAL FORUM EXPERIENCE

Monday, 10 October 2011

08:00-09:00	Registration and Welcome Coffee
09:00-12:30	Tutorial: CDISC STANDARDS: DETAILING THE DATA FLOW
09:00-12:30	Workshop I: THE FUTURE OF THE REGULATORY CLINICAL TRIALS ENVIRONMENT
09:00-12:30	Workshop II: MID-LIFE CAREER CHANGE – A CHALLENGE OR AN OPPORTUNITY
14:00-15:30	Workshop III: A CAREER IN THE PHARMA AND ASSOCIATED INDUSTRIES
09:00-12:30	Pre-Session 1+2: Medical Information and Communications
10:30-11:00	Coffee Break in the Exhibition Hall
12:30-14:00	Conference Registration – Lunch in the Exhibition Hall
14:00-15:30	Session 1 - Choose from five parallel sessions
15:30-16:00	Coffee Break in the Exhibition Hall
16:00-17:30	Session 2 - Choose from five parallel sessions
17:30-18:30	SIAC Networking Reception in the Exhibition Hall
19:00-22:00	Networking Dinner at the Restaurant Safran Zunft

Tuesday, 11 October 2011

08:00-09:00	Registration and Welcome Coffee
09:00-10:30	Session 3 - Choose from five parallel sessions
10:30-11:00	Coffee Break in the Exhibition Hall
11:00-12:30	Session 4 - Choose from five parallel sessions
12:30-14:00	Lunch in the Exhibition Hall
14:00-15:30	Session 5 - Plenary Debate
15:30-16:00	Coffee Break in the Exhibition Hall
16:00-17:30	Session 6 - Choose from five parallel sessions
17:30-18:30	Tuesday Drinks Reception in the Exhibition Hall

Wednesday, 12 October 2011

08:00-09:00	Registration and Welcome Coffee
09:00-10:30	Session 7 - Choose from five parallel sessions
10:30-11:00	Coffee Break in the Exhibition Hall
11:00-12:30	Session 8 – Closing Plenary
12:30	End of Conference

About DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal. The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications at a reasonable, competitive cost.

Headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and further regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China. For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

Welcome from the Clinical Forum 2011 Chair

Dear Friends and Colleagues,

I warmly invite you to participate in the 5th Annual DIA Clinical Forum to be held in Basel from the 10th – 12th October 2011. The DIA Clinical Forum is widely recognised as perhaps the only conference that brings together industry leading thinking and practices across the key disciplines of data management, clinical operations, drug safety and medical communication as they relate to the practical and operational aspects of drug development. My programme committee and I have crafted an exciting and stimulating programme that will have five concurrent tracks over two full days including cross-functional sessions with speakers from different disciplines addressing topics such as ePRO and paediatric clinical trials.

One of the hottest topics that the pharmaceutical and clinical research industry is facing is our loss of public confidence. We have been the subject of a number of high profile, albeit poorly researched, media articles alluding to how we, as an industry, have failed to deliver the promise of safe, cost effective and efficacious medicines. Given my expertise in clinical trial conduct in emerging countries, in particular in India, I am regularly quizzed at social occasions about the ethics of my business. Strangely it is rarely that I am complimented on the positive contributions that CROs make to healthcare delivery in India. This is a reflection of how our industry has failed to communicate what we do and that, in spite of all our efforts, the public does not trust us. In order to understand and address this growing public distrust and ignorance, the plenary session of the 5th Annual DIA Clinical Forum will be a debate on "This house believes that clinical research has lost customer confidence".

The final session of the conference will be a "mini-plenary" joint session on the "Impact of social media on the pharmaceutical sector". Social media has become an integral part of society and has diverse legal, regulatory and commercial implications on every aspect of the development and use of treatments. The views of patients both as consumers of medicines and as participants in clinical research are of increasing relevance for our sector. Recognising this, speakers from patient support groups feature on the programme, including in the debate and in the plenary session on social media.

Basel, home to the world's leading large pharmaceutical companies and Europe's innovative biotechnology companies, promises to be an ideal venue for the exchange of ideas amongst colleagues who strive to achieve similar objectives, albeit in different organisational settings.

See you in Basel!

Dr Nermeen Varawalla, MD, PhD, MBA
Programme Chair
Founder & CEO
ECCRO
UK

Included in the conference registration fee:

Workshops | Monday, 10 October 2011 | 09:00-12:30
SIAC Networking Reception | Monday, 10 October 2011 | 17:30-18:30
Plenary Debate | Tuesday, 11 October 2011 | 14:00-15:30
Tuesday Drinks Reception | Tuesday, 11 October 2011 | 17:30-18:30
Closing Plenary | Wednesday, 12 October 2011 | 11:00-12:30

Early-Bird rates are available for DIA members
Register by 29 August 2011 to save EUR 200.00

Additional events:

Half-day Tutorial EUR 250.00 plus VAT | Monday, 10 October 2011 | 09:00-12:30
To register please indicate on the registration form if you would like to attend the tutorial.

Networking Dinner EUR 75.00 per person including VAT | Monday, 10 October 2011 | 19:00-22:00
For further details please see page 23 of this Programme

CLINICAL FORUM

	Tutorial (See page 6)	Workshops (See page 6)		
Monday, 10 October 2011 (Morning)				
09:00-12:30	Tutorial CDISC STANDARDS: DETAILING THE DATA FLOW	Workshop I: THE FUTURE OF THE REGULATORY CLINICAL TRIALS ENVIRONMENT	Workshop II: MID-LIFE CAREER CHANGE – A CHALLENGE OR AN OPPORTUNITY	14:00-15:30 - Workshop III: A CAREER IN PHARMA AND ASSOCIATED INDUSTRIES
	Theme 1 CDM/eClinical (See pages 8-9)	Theme 2 Clinical Operations (See page 10)	Theme 3 Clincial Research (See pages 11-12)	Theme 4 Drug Safety and Risk Management (See pages 12-13)
Monday, 10 October 2011 (Afternoon)				
Session 1 14:00-15:30	THE REVOLVING WORLD OF eCLINICAL	*Choose from five parallel sessions*	APPROACHES TO CHALLENGING SETTINGS	*Explore another theme*
Session 2 16:00-17:30	*Cross-Functional Session* THE QUALITY ePRO STORY FROM VALIDATION TO INSPECTION		*Select a cross-functional session*	WHAT IS NEW IN CLINICAL SAFETY MONITORING AND REPORTING?
Tuesday, 11 October 2011				
09:00-10:30 Session 3	THE QUALITY STANDARD STORY	*Cross-Functional Session* THE CONDUCT OF A RELIABLE STUDY FEASIBILITY ASSESSMENT		*Five parallel sessions – make your choice*
11:00-12:30 Session 4	INBUILT AND MEASURABLE – DATA QUALITY IN THE eWORLD			*Explore other themes for sessions at this time*
14:00-15:30 Session 5	PLENARY DEBATE THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE			
16:00-17:30 Session 6	THE ARTISTIC PRACTICE AND EXACT SCIENCE OF DATA	OPERATIONAL REQUIREMENTS FOR ADAPTIVE CLINICAL TRIALS	*Choose from five parallel sessions*	HOW TO MANAGE RISKS IN CLINICAL TRIALS EFFECTIVELY?
Wednesday, 12 October 2011				
09:00-10:30 Session 7	*Choose from five parallel sessions*	*Explore other themes for sessions at this time*	PLANNING AND OPERATIONAL DEVELOPMENT IN PAEDIATRIC DEVELOPMENT	EXPECTATIONS AND EXPERIENCE IN COMMUNICATING RISKS DURING CLINICAL DEVELOPMENT
11:00-12:30 Session 8	CLOSING PLENARY IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR			

2011 AT A GLANCE

Theme 8: Medical Information and Communications (See pages 18-20)			
Pre-Session 1 09:00-10:30 IS GLOBALISATION OF MEDICAL INFORMATION REALLY POSSIBLE?		Pre-Session 2 11:00-12:30 SOCIAL MEDIA – ENSURING A PATIENT-FOCUSED, RESPONSIBLE APPROACH	
Theme 5 **Peri- and Post-Approval Studies** **(See pages 13-14)**	**Theme 6** **Validation** **(See pages 14-15)**	**Theme 7** **Medical Writing** **(See pages 16-17)**	**Theme 8** **Medical Information and Communications** **(See pages 18-20)**
Five parallel sessions – make your choice	THE RISK-BASED VALIDATION: KEYS TO SUCCESS	THE ICH E3 GUIDELINE – NAVIGATING WITHIN ITS FRAMEWORK	GLOBAL MEDICAL INFORMATION OUTSIDE EU AND USA – WHAT DOES THIS MEAN IN PRACTICE?
FIT FOR PURPOSE: WHICH APPROACH FOR WHICH QUESTION?	*Cross-Functional Session* THE QUALITY ePRO STORY FROM VALIDATION TO INSPECTION	CLINICAL TRIAL REGISTRIES AND RESULTS DATABASES	NEW MODELS FOR MEDICAL INFORMATION SERVICE DELIVERY
Select a cross-functional session	VALIDATION CASE STUDIES: APPROACHES, TECHNIQUES, CLOUDS...	GLOBAL WRITING TEAMS	PHARMACEUTICAL PARTNERSHIPS
OUTCOMES RESEARCH, CONCEPT, DESIGN AND MEASUREMENTS	*Choose from five parallel sessions*	EUROPEAN SPONSOR SUCCESS WITH FDA	COMPETENCIES, TRAINING AND QUALITY
PLENARY DEBATE THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE			
Explore other themes for sessions at this time	*Five parallel sessions – make your choice*	MANAGING DOCUMENT REVIEW	INTERNAL AUDITS – DRIVING QUALITY STANDARDS AND COMPLIANCE?
NIS IN EUROPE – PRACTICAL CHALLENGES	*Choose from five parallel sessions*	THE TIPPING POINT: A TRANSFORMATIVE SHIFT IN MEDICAL PUBLICATION	PUTTING THEORY INTO PRACTICE
CLOSING PLENARY IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR			

TUTORIAL | WORKSHOPS

MONDAY | 10 OCTOBER 2011 | 09:00-12:30

08:00 - 09:00	Registration and welcome coffee
10:30 - 11:00	Coffee break
12:30 - 14:00	Lunch

09:00-12:30 Tutorial

CDISC STANDARDS: DETAILING THE DATA FLOW

Co-Instructors:

Pierre-Yves Lastic, Senior Director, Data Privacy & Healthcare Interoperability Standards, Sanofi, France

Stephen E. Wilson, Director, Division of Biometrics III, CDER, FDA, USA

Overview

This tutorial will describe the CDISC standards (SDTM, ODM, ADaM, LAB, define XML and protocol), demonstrating how the models can be leveraged to achieve the true eClinical trial. The tutorial will detail, at a practical level, the flow of information using the standards from protocol setup through data capture, analysis and onwards to submission.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Discuss the basics of the SDTM, ODM, define .xml, LAB and ADaM standards
- Explain the CDISC standards and their value to eClinical trials
- Describe the data flow, using the CDISC standards, from clinician to submission
- Explain how to leverage the standards to improve regulatory compliance

Who Will Attend

All those who are involved in implementing new technologies and/or data standards to streamline clinical trials, especially project managers, CRAs, data managers and those managing or implementing trials across departments.

09.00-12:30 Workshop I

THE FUTURE OF THE REGULATORY CLINICAL TRIALS ENVIRONMENT

New clinical trial legislation is under preparation. There is broad consensus on the need for a change but the pros and cons of options provided in DG SANCO's concept paper for public consultation need thorough consideration and discussion by the future users of the new system. Fundamental changes to the regulatory approach will provide a chance to achieve a risk-adapted approach to approval and supervision of trials. However, what will be the implications for patient protection, quality of data, timelines and workload for all stakeholders?

This workshop will give an opportunity for updates on newest developments as well as consensus building on the desired way forward towards the future European clinical trial legislation.

Session 1: THE CLINICAL TRIAL APPROVAL PROCESS

Session Chair:

Monika Pietrek, Managing Director, Pietrek Associates GmbH, Germany

Update on the Development of new European Clinical Trial Legislation

Ingrid Klingmann, Managing Director, Pharmaplex bvba, Belgium

The German Experience – Approval of clinical trials

Thorsten Ruppert, Senior Manager Research/Development/Innovation, vfa - German Association of Research-Based Pharmaceutical Companies, Germany

Open Forum Discussion

Are voluntary harmonisation procedures or DG SANCO's CAP proposal better options for a European clinical trial authorisation procedure?

Session 2: THE RISK-BASED APPROACH

Session Chair:

Ingrid Klingmann, Managing Director, Pharmaplex bvba, Belgium

Risk-Based Approach to Clinical Trial Legislation – Improvement options in the current and new legislation

Beat Widler, Clinical Quality and Risk Management Expert, Switzerland

Existing Patterns for Risk-Based Drug Trial Authorisation Processes – Any lessons to learn from the medical devices sector?

Markus Hartmann, Senior Consultant, European Consulting & Contracting in Oncology, Germany

Panel and Open Forum Discussion: Impact of a risk-based approach on approval, supervision, patient protection, timelines and workload

Speakers and Marius Kränzlin, Vice-President Ethics Committee beider Basel (EKBB), Switzerland

09:00-12:30 Workshop II

MID-LIFE CAREER CHANGE – A CHALLENGE OR AN OPPORTUNITY

Workshop Co-Chairs:

Carl Metzdorff, Principal, ACES Health Care, Belgium

Grant R. Coren, Managing Director, Pharma-Search Limited, UK

Mid-life career change may be planned and voluntary or come as a complete surprise. This workshop is based on a series of presentations where speakers, who have made significant and successful career changes, will address the various transition phases: Before, during and after. They will share their personal experiences and discuss the concerns, issues and difficulties with which they dealt, together with the fruits that ultimately they harvested.

Delegates will have the opportunity to ask questions and to discuss their own specific career issues with the speakers and the workshop chairs.

The Move from Academia to the Pharmaceutical Industry

Dietrich Rothenbacher, Director, Institute of Epidemiology and Medical Biometry, University of Ulm, Germany

The Move from Big Pharma to Small Biotech

Seng Chin Mah, CEO Canyon Pharma, Switzerland

Part 1: The Move from a Large Pharmaceutical Company to a CRO

Alan Boyce, Managing Director, Donard Consulting, UK

Part 2: The Move from the Pharmaceutical Industry to the Consultancy World

Alan Boyce, Managing Director, Donard Consulting, UK

Going It Alone – Setting up your own business, and succeeding

Mary E. D'Arcy-Baguley, Director, CTC Clinical Trial Consulting AG, Switzerland

What can you do yourself to Remain Employable and Attractive to a Future Employer?

Panel Discussion

NOT YET REGISTERED FOR THE TUTORIAL?

Onsite registration possible on Monday from 08:00 to 09:00 at the Registration Desk (EUR 250 + 8% VAT)

WORKSHOP

14:00-15:30 Please note the new session time Workshop III

A CAREER IN PHARMA AND ASSOCIATED INDUSTRIES

Workshop Chair:

Annette Mollet, Head of Education & Training, ECPM Institute of Pharmaceutical Medicine, University of Basel, Switzerland

Reality meets expectations! This workshop will clarify and define expectations of students and explore the real life experience from young professionals from pharmaceutical industry (and young scientists?): What can you expect when stepping into professional life? What opportunities are there? How do you successfully apply? What are industry's expectations of young professionals? What is the experience of young professionals who have recently made the transition?

Speakers from the industry and HR professionals will provide their expectations and describe the views from biotech and pharma companies. We will hear several employees new to the industry tell of their recent experiences and give their tips and advice. Attendees will have the opportunity to ask questions and discuss their situation with speakers who are new to the industry.

The session aims to stimulate mutual understanding and co-operation and to allow knowledge acquisition for students to prepare for next steps ahead. This session also provides an insight to DIA as a platform to facilitate successful transition.

Who Will Attend: Students, graduates and post graduates from academic institutions in life sciences.

Starting a Career in Regulatory Affairs: A Romanian pharmacist's perspective
Dan Daneasa, Regulatory Affairs Coordinator, Merck Sharp and Dohme (Europe) Inc., Belgium

A Biologist Beyond the Lab – An alternative life for scientists
Lisa Weiss, Programme Manager, EUCRAF, Germany

Pharmacovigilance as a Career Option – A molecular biologist's perspective
Lena Brüstle, Scientist, Pietrek Associates GmbH, Germany

Careers in Pharma and Beyond
Michael Wagener, Specialist for General Internal Medicine and Pharmaceutical Medicine Medical Director ProSentioTM and SWISS GERMAN Center for Fibromyalgia, Switzerland

PLENARY SESSIONS

TUESDAY | 11 OCTOBER 2011 | 14:00-15:30

Welcome Address

Brigitte Franke-Bray, Director, DIA Europe, Switzerland
Paul Pomerantz, Worldwide Executive Director, DIA, USA
Nermeen Varawalla, Programme Chair, Founder and CEO, ECCRO, UK

Plenary Debate

THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE

Session Chair:
Julianne Hull, Independent, UK

One of the hottest topics facing the pharmaceutical and clinical research industry is our loss of public confidence. We have been the subject of a number of high profile, albeit poorly researched, media articles alluding to how we as an industry have failed to deliver the promise of safe, cost effective and efficacious medicines.

In order to understand and address this growing public distrust and ignorance, the plenary session of the 5th Annual DIA Clinical Forum will be a debate on "This house believes that clinical research has lost customer confidence". The debate will follow Oxford Union debating rules with speakers representing the pharmaceutical industry, regulatory agencies and patient support groups. As always, audience participation will be encouraged.

Debaters
For the motion:
Mary Baker, President of the European Brain Council, President of the European Federation of Neurological Associations, UK
Kenneth A. Getz, Senior Research Fellow, Tufts CSDD; Chairman, CISCRP, Tufts University, USA

Against the motion:
Mike Hardman, VP R&D Science Policy (UK), AstraZeneca Science Policy and Relations, UK
Peter Stonier, Medical Director, Amdipharm Plc., UK

WEDNESDAY | 12 OCTOBER 2011 | 11:00-12:30

Closing Plenary

IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR

Session Co-Chairs:
Janet Davies, Director, International Medical Information and Medical Affairs Project Management, Gilead Sciences, UK
Pierre-Yves Lastic, Senior Director, Data Privacy & Healthcare Interoperability Standards, Sanofi, France

The increasing and widespread adoption of social media, in its numerous formats, is revolutionising the way we communicate and share information. The changes are primarily related to speed, wide access and minimal peer review. The implications of this, for both the provision and development of medicines, are profound. To share latest thinking and recent experience on this subject we have presentations from the pharmaceutical industry and patient organisations. This will set the stage for a thought-provoking discussion.

Speakers
Myriam Menter, President ADHD Europe aisbl, Belgium

Alex Butler, EMEA Marketing Communications Manager, EMEA Strategic Marketing, Janssen, UK

Paul Grant, Head of Strategy Implementation, Creation Healthcare, UK

Panel discussion and open forum

Theme 1 | Clinical Data Management/eClinical

Theme Leaders
Julianne Hull, Independent, UK
Pierre-Yves Lastic, Senior Director, Data Privacy & Healthcare Interoperability Standards, Sanofi, France
Detlef Nehrdich, Director Global EDC Operations, Site Head Biostatistics & Data Management Ludwigshafen, Abbott GmbH & Co. KG, Germany

Programme Sub-Committee
Nick Lucas, Senior VP Clinical Development, INC Research, UK
Peter Stokman, Head Global Data Management & Standards Oss, , Merck Sharp and Dohme, The Netherlands
Wolfgang Summa, Vice President Operations, invivodata inc., USA

This theme incorporates the 21st Annual DIA European CDM and 7th Annual DIA European eClinical Conferences.

eClinical, Clinical Data Management: How do we use the many tools available to ensure that data is central to every process and technology consideration? In a revolving world it often feels we take one step forward and two steps back – how do we keep up with the ever changing environment?

This theme will explore the revolving world of eClinical and CDM to include key insights from the global INCDMA community. Jointly with our validation, clinical and clinical operations colleagues, we will explore getting ePRO right from validation through to inspection. How are companies implementing standards and how are they understood and used to best advantage cross-functionally? We will explore the tools and processes to ensure data quality is both inbuilt and measurable in the eWorld. Finally we will study how, with maximum efficiency with data and timely data reporting implicit, we drive the artistic practice and the exact science of data.

MONDAY | 10 OCTOBER 2011

14:00-15:30 **Session 1**

THE REVOLVING WORLD OF eCLINICAL

Session Chair:
Wolfgang Summa, Vice President Operations, invivodata inc., USA

eClinical systems have been used for more than two decades now and some corporations have even completely abandoned the traditional paper system for collecting data. This session will show the influence of this paradigm shift on roles and processes in clinical and data management, and will also point out some areas where we still struggle with amazingly persistent relics of the paper past.

Data Management State of the Union: Review of past and present to redefine the future
Nick Lucas, Senior VP Clinical Development, INC Research, UK

Lessons Learned: The changing role of clinical data management and the associated processes when collecting data via eSource
Bill Gluck, Vice President Clinical and Consulting Services, DATATRAK International, USA

Panel Session: International Network of Clinical Data Management Associations (INCDMA)
- Jonathan R. Andrus, Vice President, Data and Study Operations, BioClinica, Inc., USA
- Julianne Hull, Independent, UK
- Nick Lucas, Senior VP Clinical Development, INC Research, UK
- Detlef Nehrdich, Director Global EDC Operations, Site Head Biostatistics & Data Management Ludwigshafen, Abbott GmbH & Co. KG, Germany

16:00-17:30 **Session 2 (Joint Session with Themes 2 and 6)**

THE QUALITY ePRO STORY FROM VALIDATION TO INSPECTION

Session Chair:
Julianne Hull, Independent, UK

Many clinical trials now use ePRO as an important collection instrument. Multiple functions from sites, site management, clinical operations, CDM and validation can be involved to ensure a quality end story. This cross-functional session will cover the best practices from ePRO inception, implementation and validation as well as the key points that are critical to ensure data integrity throughout. The goal: To implement ePRO so that a successful inspection is the only possible outcome.

An Adequate UAT Is Key for Smooth Conduct of a Trial and Helps Mitigate Quality Risks to Data
Hans Poland, CEO, Dr. Hans Poland Consulting GmbH, Germany

Use and Evaluation of ePRO System as Part of a Regulatory Inspection
Jan Breemans, eClinical Manager, Grünenthal, Germany

ePRO Regulatory Inspections – Best practices for smooth and successful outcomes
Gretchen Craig, Director of Quality, invivodata inc., USA

TUESDAY | 11 OCTOBER 2011

09:00-10:30 **Session 3**

THE QUALITY STANDARD STORY

Session Chair:
Pierre-Yves Lastic, Senior Director, Data Privacy & Healthcare Interoperability Standards, Sanofi, France

Clinical data standards have become a key enabler for eClinical trials as well as for novel areas of drug development such as translational and personalised medicine. This session will offer practical advice on the implementation and use of these standards in the daily work of clinical research professionals.

Different Departments, Different Needs – Is there really ONE standard management possible?
Claus Lindenau, Managing Director, ClinFusion, Germany

Standards Shock Therapy: Monitoring the state of CDISC and HL7 standards for clinical research and regulatory submissions
Wayne R. Kubick, Senior Director Product Safety, Oracle Health Sciences, USA

"Enter Once, Used Everywhere" eClinical Solution: The challenge of integrating different, changing technologies for each trial
Isabelle M. de Zegher, WW Senior Director Technology Integration & Data Standards PAREXEL, Belgium

11:00-12:30 **Session 4**

INBUILT AND MEASURABLE – DATA QUALITY IN THE eWORLD

Session Chair:
Detlef Nehrdich, Director Global EDC Operations, Site Head Biostatistics & Data Management Ludwigshafen, Abbott GmbH & Co. KG, Germany

The tools and processes used to achieve appropriate data quality are enduring topics for everyone involved in the collection, processing and analysis of data from clinical trials. This session includes a presentation on the impact and importance of medical review in the eWorld and how it differs (if at all) from the paper world. An interesting big pharma approach for an efficient data cleaning strategy, enabled by eTechnology, will be presented and discussed. Finally, potential methods of ensuring data quality by design in EDC studies, as well as measuring it, will be shown from a CRO perspective.

How Clean Are 'Clean Data' before Medical Review?
Petra Weissenberger, MD, Senior Medical Advisor, PharmaProjekthaus GmbH & Co. KG, Germany

Transparent and Clean – Windows and data in an EDC system
Franziska Werner, EDC Coordinator Europe, Abbott GmbH & Co. KG, Germany

Ensuring Data Quality in an EDC Study: When traditional QC no longer applies
Ellen Morrow, Senior Director, Global Data Standards and Solutions, Quintiles, Inc., USA

14:00-15:30 **Session 5**

Plenary Debate: THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE

See page 7 for details

16:00-17:30 **Session 6**

THE ARTISTIC PRACTICE AND EXACT SCIENCE OF DATA

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

Clinical Data Management is based on the interplay between processes, technologies and people. Perfect processes, perfect technologies and perfect people will not necessarily lead to perfect data management if the interfaces are not optimal. This session is about interfaces: How to optimise the relationship between man and technology, between technology and process, and between process and man. And at some interfaces, art may be the result...

The Art and Science of Data
Nikki Dowlman, Product Director, Perceptive Informatics, UK

eClinical – Using a pharma architecture to optimise R&D
John Aggerholm, Project Director, HERAX, Denmark

Accuracy and Medical Relevance of Clinical Data
Valérie Pellan, Team Leader Oncology, Clinical Sciences & Operations, Sanofi, France

WEDNESDAY, 12 OCTOBER 2011

11:00-12:30 **Session 8**

Closing Plenary: IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR

See page 7 for details

Presentations will be available online

Registered participants will be able to download presentations from 30 September 2011.

DIA will send you an email with instructions on how to access them.

INCDMA - International Network of Clinical Data Management Associations

Aiming to further the globalisation of Clinical Data Management (CDM), promoting collaboration among CDM groups around the world and providing an international forum for discussion of and feedback on current topics of relevance to the discipline of CDM.

Countries represented within the INCDMA include:

- Australia, AHR-DMA - Australasian Health and Research Data Managers Association and ARCS - Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical Industry Ltd
- Denmark, DADM - Danish Association of Data Managers
- Finland, FIADM - Finnish Data Management Association
- France, DMB - Data Management Biomedical
- Germany, DVMD - German Association for Medical Documentalists
- North America, SCDM - Society for Clinical Data Management
- The Netherlands, PSDM - Pharmaceutische Statistiek en Data Management
- United Kingdom, ACDM - Association for Clinical Data Management
- Israel, Italy, Japan, Spain, Sweden, Switzerland

Please note INCDMA will be present in the Exhibition Hall.

Theme 2 | Clinical Operations

Theme Leader
Nermeen Varawalla, Founder and CEO, ECCRO, UK

Programme Sub-Committee
Johanna Schenk, Senior Partner and Managing Director, PharmaProjekthaus GmbH & Co. KG, Germany

The conduct of a reliable feasibility assessment continues to be one of the most challenging and critical issues in clinical operations. This will be addressed in a workshop style double session. The other highlight will be a session on the operational aspects of adaptive clinical trial conduct. There has been a lot of discussion about study design and statistical analysis but relatively little guidance on the practical aspects of conducting these trials. Such aspects include the management of clinical trial supplies, study start up in different countries and conduct of early phase trials, which will be addressed in this session.

MONDAY | 10 OCTOBER 2011

16:00-17:30 **Session 2 (Joint Session with Themes 1 and 6)**

THE QUALITY ePRO STORY FROM VALIDATION TO INSPECTION

Session Chair:
Julianne Hull, Independent, UK

Many clinical trials now use ePRO as an important collection instrument. Multiple functions from sites, site management, clinical operations, CDM and validation can be involved to ensure a quality end story. This cross-functional session will cover the best practices from ePRO inception, implementation and validation as well as the key points that are critical to ensure data integrity throughout. The goal: To implement ePRO so that a successful inspection is the only possible outcome.

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Hans Poland, CEO, Dr. Hans Poland Consulting GmbH, Germany

Use and Evaluation of ePRO System as Part of a Regulatory Inspection
Jan Breemans, eClinical Manager, Grunenthal, Germany

ePRO Regulatory Inspections – Best practices for smooth and successful outcomes
Gretchen Craig, Director of Quality, invivodata inc., USA

TUESDAY | 11 OCTOBER 2011

09:00-12:30 **Session 3-4 (Joint Double Session with Theme 3)**

THE CONDUCT OF A RELIABLE STUDY FEASIBILITY ASSESSMENT

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

This double session will address one of the most challenging and critical issues in clinical operations: The conduct of a reliable feasibility assessment. There will be presentations on the use of data mining tools, extrapolation of data across different ethnic populations, predicting site performance and streamlined operating practices. These presentations will set the stage for the practical part of the session where attendees will be invited to form breakout groups and develop a feasibility plan. Finally these plans will be presented and critiqued by the rest of the audience. The session will result in a productive discussion with the sharing of best practices so that attendees leave with practical tools and insights into how better to conduct feasibility assessments of their clinical studies.

Data Mining to Make Global Feasibility Assessment More Reliable
David J. Cocker, Senior Partner and Lead Consultant Business Intelligence Systems, MDC Partners, Belgium

Regional Differences in Patient Populations: Impact on feasibility assessment
John Shillingford, VP BD Early Phase Services, Aptiv Solutions, Germany

Making the Feasibility Assessment Process More Reliable
Andrei Kravchenko, Head of office in Ukraine, Harrison Clinical Research Deutschland GmbH, Ukraine

Predicting Site Performance: A critical component of feasibility assessment
Kenneth A. Getz, Chairman, CISCRP & Senior Research Fellow, Tufts CSDD, USA

Breakout sessions: Development of feasibility plans

Re-group: Presentation of plans, critique, sharing of best practices and discussion

14:00-15:30 **Session 5**

Plenary Debate: THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE

See page 7 for details

16:00-17:30 **Session 6**

OPERATIONAL REQUIREMENTS FOR ADAPTIVE CLINICAL TRIALS

Session Chair:
Johanna Schenk, Senior Partner and Managing Director, PharmaProjekthaus GmbH & Co. KG, Germany

Operational aspects of conducting adaptive clinical trials remain complex and deserve greatest attention in order to yield the intended benefit deriving from statistical design. After elucidating the principles of adaptive statistical methodologies and the regulators' position, this session will identify clinical trial research situations for which adaptive design methodologies would be justified or appropriate, explore issues such as country selection, navigating multi-country study start-up, management of clinical trial supplies and flexible resourcing, and describe prerequisites and ultimately solutions for the effective conduct of adaptive clinical trials.

The session concludes by providing evidence that the use of adaptive study designs provides tangible time savings in early phase research programs and how a focus on stopping criteria during the clinical conduct can enhance the safety of early phase studies, whilst maximising data yield.

Best Practices with Adaptive Trial Designs – How successful are they?
Eva R. Miller, Director, Biostatistics, ICON Clinical Research, USA

Clinical Trial Conduct: Lessons from adaptive trials
Judith Quinlan, Senior Vice President Innovation Center, AptivSolutions, USA

The Practical Application of Adaptive Study Designs in Early Phase Clinical Research
Ulrike Lorch, Medical Director, Richmond Pharmacology Ltd, UK

WEDNESDAY | 12 OCTOBER 2011

11:00-12:30 **Session 8**

Closing Plenary: IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR
See page 7 for details

Theme 3 | Clinical Research

Theme Leader
Ingrid Klingmann, Managing Director, Pharmaplex bvba, Belgium

Programme Sub-Committee
Wolfgang Eglmeier, Clinical Development Expert, Germany

Clinical research methodology has developed very successfully in the course of the last thirty years. In designing clinical trials reliably to prove efficacy, efficient clinical development planning and execution has helped to mitigate the risk of clinical development of very different types of drugs. However, new requirements like the obligatory development of drugs in children and increasingly in elderly patients or in so far neglected areas, like clinical trials in emergency situations, demand constant further learning and exchange of experience. The Clinical Research Theme of the Clinical Forum 2011 will focus on the still challenging areas in clinical research.

MONDAY | 10 OCTOBER 2011

14:00-15:30 **Session 1**

APPROACHES TO CHALLENGING SETTINGS
Session Chair:
Christoph Gleiter, Managing Director, CenTrial GmbH, Coordination Centre for Clinical Trials at University Hospitals Tübingen and Ulm, Germany

Despite the use of many new technologies, trial lengths still increase. Trials become more and more complex and new regulatory demands create additional burden. On the other hand development budgets get tighter. Most of the delays in drug development are caused by problems in recruiting patients and retaining them in the trials. Solutions to overcome some problems are presented: Regarding trials performed in difficult settings (ICU), improved training by a better understanding of the learning theory or a better focus on patients.

Hints and Tips on Conducting and Executing Successful Clinical Trials in the ICU
Angela Ruck, Senior Clinical Study Manager, Orion Pharma, UK, Ltd, UK

Dynamic and Productive Investigator Meetings
Alison Messom, Senior Director CRA Management, ICON Clinical Research GmbH, Germany

Dealing with Challenging Patient Populations – Better focus on patients to improve their recruitment and retention in geriatric settings
Wolfgang Eglmeier, Clinical Development Expert, Germany

TUESDAY | 11 OCTOBER 2011

09:00-12:30 **Session 3-4 (Joint Double Session with Theme 2)**

THE CONDUCT OF A RELIABLE STUDY FEASIBILITY ASSESSMENT
Session Chair:
Nermeen Varawalla, Founder and CEO, ECCRO, UK

This double session will address one of the most challenging and critical issues in clinical operations: The conduct of a reliable feasibility assessment. There will be presentations on the use of data mining tools, extrapolation of data across different ethnic populations, predicting site performance and streamlined operating practices. These presentations will set the stage for the practical part of the session where attendees will be invited to form breakout groups and develop a feasibility plan. Finally these plans will be presented and critiqued by the rest of the audience. The session will result in a productive discussion with the sharing of best practices so that attendees leave with practical tools and insights into how better to conduct feasibility assessments of their clinical studies.

Data Mining to Make Global Feasibility Assessment More Reliable
David J. Cocker, Senior Partner and Lead Consultant Business Intelligence Systems, MDC Partners, Belgium

Regional Differences in Patient Populations: Impact on feasibility assessment
John Shillingford, VP BD Early Phase Services, Aptiv Solutions, Germany

Making the Feasibility Assessment Process More Reliable
Andrei Kravchenko, Head of office in Ukraine, Harrison Clinical Research Deutschland GmbH, Ukraine

Predicting Site Performance: A critical component of feasibility assessment
Kenneth A. Getz, Chairman, CISCRP & Senior Research Fellow, Tufts CSDD, USA

Breakout sessions: Development of feasibility plans

Re-group: Presentation of plans, critique, sharing of best practices and discussion

14:00-15:30 **Session 5**

Plenary Debate: THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE
See page 7 for details

WEDNESDAY | 12 OCTOBER 2011

09:00-10:30 **Session 7**

PLANNING AND OPERATIONAL DEVELOPMENT IN PAEDIATRIC DEVELOPMENT

Session Chair:
Holger Maria Rohde, Head of Preclinical & Medical Affairs, PharmaLex GmbH, Germany

In the 5th year after introduction of the paediatric regulation, considering the development of a drug in children is part of the usual developmental programme of any investigational medicinal product. The EMA states that first implementation issues have been overcome and a steady PIP procedure has been established by both industry applicants and the EMA/Paediatric Committee. Overall, these interactions occur on a high scientific level and require profound knowledge in current best paediatric practices. Often creativity and intelligent strategies are required when addressing certain non-standardised PIP situations that do not directly fall within the scope of the paediatric regulation but nevertheless require the preparation of a PIP document.

This session presents lessons learnt and practical experiences of how to implement a paediatric development strategy. It provides case studies of non-standardised PIP-preparations and practical implications of paediatric trials from a laboratory perspective.

Operational and Medical Challenges with EU PIPs
Klaus Rose, Managing Director, klausrose Consulting, Pediatric Drug Development & More, Switzerland

Paediatric Investigational Plan: How to write a PIP without a medicinal product
Holger Maria Rohde, Head of Preclinical & Medical Affairs, PharmaLex GmbH, Germany

Paediatric Studies: Specific requirements for sample collection in children; checklists for study directors, investigators and CRAs/ monitors
Hermann Schulz, CEO, INTERLAB Central Lab Services - Worldwide Gmbh, Germany

11:00-12:30 **Session 8**

Closing Plenary: IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR

See page 7 for details

Presentations will be available online

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DIA will send you an email with instructions on how to access them.

Theme 4 | Drug Safety and Risk Management

Theme Leader
Monika Pietrek, Managing Director, Pietrek Associates GmbH, Germany

Programme Sub-Committee
Liliana Hansen, Director, Safety Surveillance Diabetes- Insulin & Devices, Global Safety, Novo Nordisk A/S, Denmark

This theme will deal with the new rules for safety reporting in clinical trials and also share practical experience in risk minimisation and communication during clinical development. The audience will learn about the operational implications and challenges the industry is facing during the adjustment of working practices. For example, given that the DSUR is coming into effect this year, the regulators of the ICH region have agreed to harmonise safety reporting at the aggregated level. However, at the same time, requirements for the individual SUSAR reporting in Europe and IND safety reporting in the USA are shifting apart.

MONDAY | 10 OCTOBER 2011

16:00-17:30 **Session 2**

WHAT IS NEW IN CLINICAL SAFETY MONITORING AND REPORTING?

Session Chair:
Liliana Hansen, Director, Safety Surveillance Diabetes- Insulin & Devices, Global Safety, Novo Nordisk A/S, Denmark

The new European legislation on pharmacovigilance and the new IND Safety Reporting Rule guidance from FDA, issued over the past months, aim at faster and more precise identification and evaluation of the true adverse reactions with medicines and biologics, with the ultimate goal of ensuring the patients' safety in the context of a positive benefit/risk assessment.

This session will present the new rules in the EU and the USA and will discuss the practical implications and challenges for the industry both at individual case report level and at aggregated level, as dictated by the DSUR report.

What do we Report from Clinical Trials? A briefing on the new safety reporting rules in the EU and the USA
Liliana Hansen, Director, Safety Surveillance Diabetes- Insulin & Devices, Global Safety, Novo Nordisk A/S, Denmark

Implications of the New Safety Reporting Rules on Global Working Practices – A view from industry
Peter de Veene, EU QPPV, F. Hoffmann-La Roche Ltd, UK

Implementing the DSUR – Practical considerations and challenges
Barbara De Bernardi, Deputy EU QPPV, Pfizer Inc., Italy

TUESDAY | 11 OCTOBER 2011

14:00-15:30 **Session 5**

Plenary Debate: THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE

See page 7 for details

16:00-17:30 **Session 6**

HOW TO MANAGE RISKS IN CLINICAL TRIALS EFFECTIVELY?

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

The protection of clinical trial subjects is of utmost importance to all stakeholders in clinical development. There is an inherent trade-off between innovation and risk management, however, several principles and tools have proven to contribute to increased benefits and risk mitigation.

Risk Management in Clinical Trials – Approach and implication
Monika Pietrek, Managing Director, Pietrek Associates GmbH, Germany

Reducing Variability to Improve Safety in Clinical Trial
Drew Kilpatrick, Vice President, Safety and Pharmacovigilance INC Research, UK

What to Consider When Planning Event Adjudication in Clinical Trials
Jonas Petersson, Event Adjudication Coordinator, Novo Nordisk A/S, Denmark

WEDNESDAY | 12 OCTOBER 2011

09:00-10:30 **Session 7**

EXPECTATIONS AND EXPERIENCE IN COMMUNICATING RISKS DURING CLINICAL DEVELOPMENT

Session Chair:
Christine Bendall, Consultant, Arnold & Porter (UK) LLP Solicitors, UK

The patient's willingness to participate or continue in a clinical trial relies on both the information provided by the study sponsor and the mode of delivery by the investigator. The volume of the written information about the study, the investigational medicinal product and its potential risks has increased; however, it may often not effectively support the patient's decision for or against clinical trial participation. The appropriate communication of potential drug related risks remains an unresolved challenge, even more when new, important risks have emerged either during the study conduct or upon its completion.
In this session various stakeholders will share their experience and ideas. Are there any lessons learnt from previous experience? What are the patients and investigator's needs and expectations?

What are the Expectations of Regulatory Authorities? Relevant legal aspects
Christine Bendall, Consultant, Arnold & Porter (UK) LLP Solicitors, UK

How do we Communicate Risks to Clinical Trial Subjects and Investigators – A case study
Koenraad Blot, Managing Director, Xintera Consulting bvba, Belgium

What do Patients Need? Ethics committee perspective
Marius Kränzlin, Vice-President Ethics Committee beider Basel (EKBB), Switzerland

11:00-12:30 **Session 8**

Closing Plenary: IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR

See page 7 for details

Theme 5 | Peri- and Post-Approval Studies

Theme Leader
Jens Reinhold, Head Global NIS, Bayer HealthCare Pharmaceuticals, Germany

Programme Sub-Committee
Heike Schön, Managing Director, CSG Clinische Studien GmbH, Germany

Due to evolving developments in the post-authorisation study field (e.g. new pharmacovigilance legislation and FDA post-marketing guidance) and new initiatives for active safety surveillance of products on the market looking at the risks and benefits on a continuous basis (Sentinel, OMOP), pharmaceutical companies need to find ways to manage these developments on an organisational, medical and methodological level. The variety of methods is large. The key is to find the appropriate path from the scientific question to the final answer; selecting the right design and implementing it correctly. This theme provides answers to important questions in this environment as well as a discussion forum for experts and interested colleagues.

MONDAY | 10 OCTOBER 2011

16:00-17:30 **Session 2**

FIT FOR PURPOSE: WHICH APPROACH FOR WHICH QUESTION?

Session Chair:
Jens Reinhold, Head Global NIS, Bayer HealthCare Pharmaceuticals, Germany

The range of methodology in observational research is wide and one of the most critical issues is to select the right design and operational implementation method based on the objectives of the study. In this session, both design and implementation methodologies will be evaluated.

Population Based Registers as a Source for Post-Approval Drug Research: A case study on anti-psychotics use in Finland
Pasi Korhonen, CEO, EPID Research Oy, Finland

The Use of Large Simple Trials to Answer Comparative Effectiveness Research and Safety Questions
Louise Helen Parmenter, Senior Director, Late Phase, Quintiles Ltd, UK

Case Study: Comparison of quality results using hybrid data collection (EDC and paper) in two large prospective observational cohort studies in different therapeutic areas
Jens Reinhold, Head Global NIS, Bayer HealthCare Pharmaceuticals, Germany

TUESDAY | 11 OCTOBER 2011

11:00-12:30 **Session 4**

OUTCOMES RESEARCH, CONCEPT, DESIGN & MEASUREMENTS

Session Chair:
Jens Reinhold, Head Global NIS, Bayer HealthCare Pharmaceuticals, Germany

PROs become increasingly important for post-authorisation studies looking at questions in comparative effectiveness, providing data for value dossiers and collecting safety data. However, there are aspects to be looked at for post-authorisation studies compared to PROs in clinical trials. This begins with the methods used to contact patients and does not end with cost considerations. This session will discuss strategies covering those specific requirements.

The Role of Patient Reported Outcomes in Observational Research
Deborah Lubeck, Vice President, Health Economics and Outcomes Research, PAREXEL International, USA

Importance of Quality of Life Data for Benefit Assessment
Stefan Lange, Institute for Quality and Efficiency in Health Care (IQWIG), Germany

Additional industry speaker invited

14:00-15:30 **Session 5**

Plenary Debate: THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE

See page 7 for details

WEDNESDAY | 12 OCTOBER 2011

09:00-10:30 **Session 7**

NIS IN EUROPE - PRACTICAL CHALLENGES

Session Chair:
Heike Schön, Managing Director, CSG Clinische Studien GmbH, Germany

The situation of observational studies in European countries is still scattered from a regulatory and health authority perspective. Sometimes definitions are understood in different ways, local requirements differ significantly. This session will discuss the current situation in various countries and provide a forum to discuss how to overcome the mismatches.

Rules, Regulations and Guidelines for NIS in Europe: Practice meets theory
Jean-Louis Merot, Senior Project Management Director, Quintiles Transnational, France

NIS in Ukraine: How to benefit?
Andrei Kravchenko, Head of office in Ukraine, Harrison Clinical Research Deutschland GmbH, Ukraine

Potentials and Pitfalls in Registry Implementation in Switzerland
Christoph Röder, Director, MEM Research Center, Institute for Evaluative Research in Medicine, University of Bern, Switzerland

11:00-12:30 **Session 8**

Closing Plenary: IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR

See page 7 for details

Theme 6 | Validation

Theme Leader
Rolf Banholzer, Global Head CQA Computerized System Services, Novartis Pharma AG, Switzerland

Programme Sub-Committee
Breffni Martin, Director, OptumInsight Strategic Regulatory Services, Ireland

Electronic Clinical Data Management was just the beginning of a journey towards a computer system-supported and technology-driven clinical development environment. Clinical study design necessitates an ever increasing technical expertise which is typically not well established in current pharma organisations.

Ensuring data integrity requires a comprehensive, risk-based approach to the validation of a network of computerised systems. Concrete case studies of risk-based validation approaches of newest e-technology, as well as health authority inspection experiences from a sponsor's perspective, will be discussed.

MONDAY | 10 OCTOBER 2011

14:00-15:30 **Session 1**

THE RISK-BASED VALIDATION: KEYS TO SUCCESS

Session Chair:
Breffni Martin, Director, OptumInsight Strategic Regulatory Services, Ireland

Validation is increasingly taken up with risk assessment. While this has produced gains in terms of efficiency, costs and quality, it is dependent on the correct implementation of the methodology. This session will review risk-based approaches in terms of identification, evaluation, resolution, and mitigation of risk, giving real life examples of correctly implementing risk-based approaches in an eClinical context.

IT Systems Validation – Where to find risks
William Kane, Director, Almac Clinical Technologies, Quality Assurance and Regulatory Compliance, USA

The Risk Factor: Does your validation approach properly evaluate risk?
Philip J. Kelly, Head of Software Development, Datatrial Ltd, UK

New Paradigm to Define Risks in Computerised System Validation
Volker Erat, Global Head DI/QM & P Quality Mgt, Project Quality Management, Novartis Pharma AG, Switzerland

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16:00-17:30 **Session 2 (Joint Session with Themes 1 and 2)**

THE QUALITY ePRO STORY FROM VALIDATION TO INSPECTION

Session Chair:
Julianne Hull, Independent, UK

Many clinical trials now use ePRO as an important collection instrument. Multiple functions from sites, site management, clinical operations, clinical CDM and validation can be involved to ensure a quality end story. This cross-functional session will cover the best practices from ePRO inception, implementation and validation as well as the key points that are critical to ensure data integrity throughout. The goal: To implement ePRO so that a successful inspection is the only possible outcome.

An Adequate UAT Is Key for Smooth Conduct of a Trial and Helps Mitigate Quality Risks to Data
Hans Poland, CEO, Dr. Hans Poland Consulting GmbH, Germany

Use and Evaluation of ePRO System as Part of a Regulatory Inspection
Jan Breemans, eClinical Manager, Grunenthal, Germany

ePRO Regulatory Inspections – Best practices for smooth and successful outcomes
Gretchen Craig, Director of Quality, invivodata inc., USA

TUESDAY | 11 OCTOBER 2011

09:00-10:30 **Session 3**

VALIDATION CASE STUDIES: APPROACHES, TECHNIQUES, CLOUDS...

Session Chair:
Rolf Banholzer, Global Head CQA Computerized System Services, Novartis Pharma AG, Switzerland

Techniques, such as automated testing, provide new opportunities to improve validation quality and efficiency needed to cope with the ever increasing complexity of computerised systems in clinical development. New IT technologies such as cloud computing will be discussed in the context of global requirements as to information security and data privacy.

Automated Testing of IVR/IWR Systems
Speaker invited

Web-Based ePRO: Validation, equivalence, and data quality
Brian Tiplady, Senior Scientist, PRO Consulting, a division of invivodata inc., UK

Security, Privacy and Validation for eClinical in the Age of Cloud Computing
Michael Owings, Senior Director, Audit and Compliance, Oracle Health Sciences, USA

14:00-15:30 **Session 5**

Plenary Debate: THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE

See page 7 for details

WEDNESDAY, 12 OCTOBER 2011

11:00-12:30 **Session 8**

Closing Plenary: IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR

See page 7 for details

Theme 7 | Medical Writing

Theme Leaders
Mary Gardner Stewart, Divisional Director, Medical Documentation, H. Lundbeck A/S, Denmark
Janet Stoltenborg, Director, Medical Communications, AstraZeneca Pharmaceuticals LP, USA

Programme Sub-Committee
Amanda Bennett, Medical Writing Director, Shire Plc., UK

Medical Writers are continuously faced with new challenges in their daily work:
- How to fit new clinical development concepts into old frameworks
- How to ensure that we are aligned in the face of ever changing guidelines and prepared to address their implications
- How to align work processes in global organisations
- How to meet the expectations of multiple, global regulatory authorities and other customers

The Medical Writing theme will shed some light on these challenges with sessions from those who have been there and are willing to share their experiences.

MONDAY | 10 OCTOBER 2011

14:00-15:30 **Session 1**

THE ICH E3 GUIDELINE – NAVIGATING WITHIN ITS FRAMEWORK

Session Chair:
Mary Gardner Stewart, Divisional Director, Medical Documentation, H. Lundbeck A/S, Denmark

More than 15 years ago, the ICH E3 guideline on the structure and content of CSRs came into effect. Even at that time, many of us came up with our own interpretation of what the guideline authors actually intended for us to include in our CSRs. Since then, clinical development has undergone substantial changes with the advent of new molecular entities as well as new classes of efficacy and safety endpoints. While there is broad agreement that the key concepts of ICH E3 still hold true, the challenge is how to handle special study design and outcome issues within the ICH E3 framework.

This session will provide examples of how different companies interpret the ICH E3 guideline and open a panel discussion with the audience.

Speakers:
Sybille Eibert, Senior Medical Writer / Team Leader, Medical Writing Europe, Boehringer Ingelheim Pharma GmbH & Co KG, Germany

Christopher J. Preston, International Documentation Manager, F. Hoffmann-La Roche Ltd, Switzerland

Mary Gardner Stewart, Divisional Director, Medical Documentation, H. Lundbeck A/S, Denmark

16:00-17:30 **Session 2**

CLINICAL TRIAL REGISTRIES AND RESULTS DATABASES

Session Chair:
Gerard Lynch, Global Lead, Clinical Trial Disclosure, AstraZeneca, UK

The requirements for Clinical Trial Registries and Results Databases continue to evolve and grow. This session will examine the current and future requirements for disclosing results – from regulators and journal editors – and how clinical scientists can cope in this shifting landscape.

Clinical Trial Registries and Results Databases – How to cope with heterogeneous requirements?
Hanna Hasselblatt, University Medical Center Freiburg, Germany

Posting and Publishing of Trial Results – What will satisfy transparency demands?
Gerard Lynch, Global Lead, Clinical Trial Disclosure, AstraZeneca, UK

Preparing for Clinical Trial Disclosure Audits
Barbara Godlew, Director, Huron Consulting Group, USA

TUESDAY | 11 OCTOBER 2011

09:00-10:30 **Session 3**

GLOBAL WRITING TEAMS

Session Chair:
James Wolfe, Associate Director, Medical Writing Services, Europe, PAREXEL International, France

Establishing and maintaining medical writing teams in different market regions will be discussed in three topics: Similarities and differences of documents across markets; practical examples in recruiting, training and retaining in emerging markets; cultural differences and overall team performance.

Regional and Global Considerations for Preparing Clinical Documents Included in International Dossiers
Inger Magnusson, Group Director, Global Regulatory Documentation, Bristol-Myers Squibb, USA

Medical Writer Recruitment, Retention and Training in Emerging Regions
Ashwini Kumar Mathur, Head, Clinical Information Sciences – India, Novartis Healthcare Pvt Ltd, India

The Cross-Cultural Medical Writing Team
James Wolfe, Associate Director, Medical Writing Services, Europe, PAREXEL International, France

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11:00-12:30 **Session 4**

EUROPEAN SPONSOR SUCCESS WITH FDA

Session Chair:

Stephen E. Wilson, Director, Division of Biometrics III, CDER, FDA, USA

Session goals:

- Help Europeans both identify and meet FDA data and content writing requirements
- Prevent European project delays and unnecessary expense in the US caused by filing documents/data inappropriate for the FDA

European sponsors without US offices/staff must work through a US agent, as per FDA regulations. Yet, often inappropriately written documents are filed with the FDA because the US agent is not aware of US requirements and/or FDA expectations for CTA documents. This results in project delays that can worsen into a bad relationship with FDA, despite the sponsor's great success in other parts of the world.

This session will examine the statistical, medical writing and regulatory requirements and FDA expectations that European sponsors need to meet when filing INDs and CTDs in the US. Topics will include FDA expectations concerning data and statistical analyses, how to choose expert US agents so that sponsor clinical trial and marketing application documents meet FDA standards and how large multi-national sponsors effectively manage global projects filed with the FDA and many other agencies.

Submission goals include ensuring that FDA and sponsor time is not wasted and that a good working relationship is fostered between the European sponsor and the FDA, resulting in much greater and more frequent project success in the US. We will present case studies highlighting projects that were very successful in other parts of the world – including Europe – indicating they were good products that met medical needs, but because of inappropriate or faulty submissions to the FDA floundered in the US, leading to years of project delay and significant additional costs.

US Agent Appropriate Writing
Sandra J. Hecker, US Agent, Regulatory Consultant, Hecker & Associates, LLC, USA

Getting It Right: Successful communication with FDA statisticians
Stephen E. Wilson, Director, Division of Biometrics III, CDER, FDA, USA

Meeting FDA Regulatory Requirements; A Global Pharma Company`s Perspective
Leyna Mulholland, Director, Global Regulatory Affairs, Hoffmann-La Roche Inc., Japan

14:00-15:30 **Session 5**

Plenary Debate: THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE

See page 7 for details

16:00-17:30 **Session 6**

MANAGING DOCUMENT REVIEW

Session Chair:

Amanda Bennett, Medical Writing Director, Shire Plc., UK

Document review practices in many pharmaceutical companies are often frustrating, inefficient and poorly managed. The weaknesses of typical review processes and applications are evident from the extra resources and time that companies are putting into submission review cycles. However, document development can be managed, reviewers can be trained, reviews can be made more systematic, and tools can be implemented to support best practice. In this session, some of the major challenges encountered with document review processes and applications are discussed along with proposals for improving quality, reducing noncompliance, and minimising the risk of rejection by regulatory authorities.

Why Most Document Reviews Are Not Really Reviews: The good, the bad and the ugly of review practices in the clinical sciences
Gregory P. Cuppan, Managing Principal, McCulley/Cuppan, USA

Optimising the Document Review Process
Barry Drees, Trilogy Writing & Consulting Gmbh, Germany

Implementing Strategic Authoring and Review Principles
Rhys G. Stoneman, Medical Writing Manager, Clinical Development, Oncology R&D, GlaxoSmithKline, UK

WEDNESDAY | 12 OCTOBER 2011

09:00-10:30 **Session 7**

THE TIPPING POINT: A TRANSFORMATIVE SHIFT IN MEDICAL PUBLICATION

Session Chair:

Altha Edgren, Senior Manager, Medical Writing, Millennium: The Takeda Oncology Company, USA

The integration of medical writers, editors, publishers, and publication planners into a global community requires education and discussion around topics like interpreting ethical publishing guidelines, learning the "how tos" of writing and editing, and exploring that balance between in-house versus agency writing and publication planning. Exploration of these issues is important to get us 'all on the same page' ...so to speak.

Yet, in this age of instant messaging, twittering, blogging, and the immediate delivery of information around the world, it still takes over a year (in many instances) to publish in a medical journal. A transformative shift that moves us beyond discussions around ghost-writing, impact values, and author guidelines may be required.

Publication Policy Development and Next Steps
Susan C. Glasser, Senior Director Scientific and Medical Publications, Johnson & Johnson, Pharmaceutical Research & Development, LLC, USA

Publication Planning and Gap Identification: Clinic-to-journal roadmap
Jelena Veljkovic, Senior Manager, Publications & Analytics, Millennium: The Takeda Oncology Company, USA

Rapid Publication Journals
Philip Walson, Visiting Professor, Dept. Clinical Chemistry, University Medical Center Göttingen, Germany

11:00-12:30 **Session 8**

Closing Plenary: IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR

See page 7 for details

Theme 8 | Medical Information and Communications

Theme Leader

Janet Davies, Director, International Medical Information and Medical Affairs Project Management, Gilead Sciences, UK

Programme Advisors

Lillian Auberson, Senior Director, Global Medical Information, Actelion Pharmaceuticals Ltd, Switzerland
Nathalie Barrillon, Medical Information and Documentation Manager, , Laboratoires Merck Sharp & Dohme – Chibret, France
Aaron Cockell, Head of Medical Operations and Information, Pfizer Ltd, UK
Victoria Dalensi, Associate Director, International Medical Communications, Shire AG, Switzerland
Ainhoa Del Romero, Director International Medical Information, International Scientific Affairs, Amgen (Europe) GmbH, Switzerland
Sarah Dunnett, Senior Medical Affairs Manager, Baxter Healthcare Ltd, UK
Stephane Gamboni, Associate Director, Medical Communication and Information, MerckSerono International SA, Switzerland
Katie Gibson, Scientific Communications Director, Europe Middle East and Africa, Janssen-Cilag AB, Sweden
Françoise Hanotte, Associate Director, Medical Information, Global Medical Affairs, UCB Pharma SA, Belgium
Sharon Leighton, Owner, Sharon Leighton Consultancy, UK
Ozgur Yuksel, Medical Director, NSO, AMAC Region, Novartis Pharma AG, Switzerland

This theme is the 5th European Medical Information and Communications conference to be included in the DIA Clinical Forum and is organised by the DIA Medical Communications SIAC. The sessions will cover key issues relevant to professionals working in medical information, medical communications and medical affairs roles.

The content will be of particular interest to managers and leaders of Medical Information services. The sessions will include practical case studies and real-life examples of innovation in Medical Information services. There will be opportunity for interactive discussion and networking with other professionals working in medical information, medical communications and medical affairs roles.

MONDAY | 10 OCTOBER 2011

09:00-10:30 **Pre-Session 1**

IS GLOBALISATION OF MEDICAL INFORMATION REALLY POSSIBLE?

Session Chair:
Janet Davies, Director, International Medical Information and Medical Affairs Project Management, Gilead Sciences, UK

Globalisation of medical information has been an increasing trend across the pharmaceutical industry. This is driven by a desire for consistency, quality and risk minimisation. This will be an interactive session exploring the globalisation of medical information activities. Two presentations will provide global and local perspectives on the growing trend for globalisation. Attendees will take part in group discussion on issues that can be encountered when taking a global approach to medical information services, and identification of possible solutions.

Is Globalisation of Medical Information Really Possible?
Siân Slade, Group Director, Global Core Content & Knowledge Management, Bristol-Myers Squibb, Global Medical Information, USA

Is Globalisation of Medical Information Really Possible? - A European perspective
Andrew Williams, Head European Medical Operations, GlaxoSmithKline, UK

Britta Bohm, Director European Medical Information and Operations, GlaxoSmithKline, UK

Is it Possible to Have Global Responses from a Local Country Perspective?
Sophia Andeh, Medical Information Manager, Genzyme Therapeutics, UK

11:00-12:30 **Pre-Session 2**

SOCIAL MEDIA – ENSURING A PATIENT-FOCUSED, RESPONSIBLE APPROACH

Session Chair:
Sarah Dunnett, Senior Medical Affairs Manager, Baxter Healthcare Ltd, UK

With the escalation of web-based communication and networking, we recognise that patients are thirsty for quality information and discussions regarding their health and treatment options. To help us engage appropriately with patients in this way, this session will highlight the expectations, experiences and impact of the digitally-connected 'ePatient' while exploring the various US and European regulations and legal principles we need to consider within the EU.

The ePatient – Empowered, enabled and electronic
Paul Grant, Head of Strategy Implementation, Creation Healthcare, UK

Legal Considerations Relating to Social Media – An EU perspective
Héctor Röthlisberger, Legal Counsel, Actelion Pharmaceuticals Ltd, Switzerland

14:00-15:30 **Session 1**

GLOBAL MEDICAL INFORMATION OUTSIDE EU AND US – WHAT DOES THIS MEAN IN PRACTICE?

Session Chair:
Ainhoa Del Romero, Director International Medical Information, International Scientific Affairs, Amgen (Europe) GmbH, Switzerland

External and internal factors are pushing for a transformation in the practice of medical information. With the evolving pharmaceutical environment in emerging and established markets outside EU and US and increasing customer demands, medical information must be optimised to ensure a customer centric approach and take into consideration the reality of limited resources. This session will focus on how to critically evaluate needs in those markets and to leverage global resources for streamlining processes, reducing duplication of effort, and creating a best in class framework for medical information.

Globalisation in Asia: Opportunities and challenges
Siân Slade, Group Director, Global Core Content & Knowledge Management, Bristol-Myers Squibb, Global Medical Information, USA
Globalisation in Emerging Markets

Peter Geiser, Medical Information Program Leader, Novartis Pharma, Switzerland

Pauline Frank, Region AMAC Medical Communications Director, Novartis Pharma, Switzerland

16:00-17:30 **Session 2**

NEW MODELS FOR MEDICAL INFORMATION SERVICE DELIVERY

Session Chair:
Katie Gibson, Scientific Communications Director, Europe Middle East and Africa, Janssen-Cilag Ltd, UK

Regional and global models for medical information services have been implemented across the industry in recent years. This session will provide insights into how two different organisations are optimising these models to meet evolving customer and business needs. Local, regional and global perspectives will be shared.

Transforming Medical Information at Roche – Local vs. regional vs. global
Samantha Knott, Head of Medical Information, Roche Products Ltd, UK

Julie Moody, Medical Information Manager, Roche Products Ltd, UK

Global Medical Information Centres of Excellence and Regional Implementation
Michael Burman, Director Global Medical Contact Center, Bristol-Myers Squibb, USA
Ros O'Callaghan, Director Medical Information Director, Europe, Bristol-Myers Squibb, UK

TUESDAY | 11 OCTOBER 2011

09:00-10:30 **Session 3**

PHARMACEUTICAL PARTNERSHIPS

Session Chair:
Stephane Gamboni, Associate Director, Medical Communication and Information, Merck Serono International SA, Switzerland

The medical information function should not be seen in isolation, but in the context of interplay between various departments or stakeholders in a company. In this respect, working in partnership with internal colleagues is an important skill for medical information professionals, with a view to achieving common goals better. Our speakers will deliver presentations that illustrate successful cross-functional working that involves medical information as a key partner.

How Can Medical Information Support Other Internal Departments?
Dung Vu, Associate Director, Medical Communication and Information, Merck Serono SA, Switzerland

Global Product Safety Surveillance: A global cross-functional programme for medical information enquiries, adverse events and product complaints
Ainhoa del Romero, Director International Medical Information, International Scientific Affairs, Amgen (Europe) GmbH, Switzerland

Lynne Love, Senior Manager, International Medical Information, International Scientific Affairs, Amgen Ltd, UK

11:00-12:30 **Session 4**

COMPETENCIES, TRAINING AND QUALITY

Session Chair:
Victoria Dalensi, Associate Director, International Medical Communications, Shire AG, Switzerland

As we start to globalise and regionalise our functions and regulations tighten, there becomes an increasing pressure to monitor and maintain high quality services provided across the globe. However, with such local variations from one-man bands in one country to a dedicated call centre and second line support in another, it becomes a challenge. We look at what solutions some organisations have put in place in order to ensure continuous high standards of quality. Solutions range from call centre quality monitoring to surveys and assessing individual needs for personalised training and coaching in a multilingual environment.

QA Programme for Medical Information
Stacey Fung, Senior Manager, Medical Communications, BioOncology, Genentech, Inc., USA

Quality Monitoring Strategies: Perspectives from a multilingual medical information contact centre
Michele Simon, Associate Director of Operations, PPD Medical Communications Europe, UK

Assessing Training Needs of Affiliates
Isabelle Widmer, Global Medical Information Manager, F. Hoffmann-La Roche Ltd, Switzerland

14:00-15:30 **Session 5**

Plenary Debate: THIS HOUSE BELIEVES THAT CLINICAL RESEARCH HAS LOST CUSTOMER CONFIDENCE

See page 7 for details

16:00-17:30 **Session 6**

INTERNAL AUDITS – DRIVING QUALITY STANDARDS AND COMPLIANCE?

Session Chair:
Sharon Leighton, Consultant, Sharon Leighton Consultancy, UK

As regulations and legislation hold a tighter grip on medical information activities, devising and implementing a quality assurance programme becomes an essential management responsibility, not just an add-on. Internal audits can reveal gaps, inconsistencies and potential compliance failures. This facilitated workshop will draw out the main considerations when faced with an internal audit.

Internal Audits: Just a pain or a useful gap analysis?
Peter Nacke, Global Medical Information Senior Manager, Vifor Pharma, Switzerland

Internal Audit: The auditor's perspective
Sharon Leighton, Consultant, Sharon Leighton Consultancy Ltd, UK

Presentations will be available online

Registered participants will be able to download presentations from 30 September 2011.

DIA will send you an email with instructions on how to access them.

WEDNESDAY | 12 OCTOBER 2011

09:00-10:30 **Session 7**

PUTTING THEORY INTO PRACTICE

Session Chair:
Lillian Auberson, Senior Director, Global Medical Information, Actelion Pharmaceuticals Ltd, Switzerland

This session will include brief presentations on best practices and shared lessons in medical information and communications. It is back by popular demand after it was tried for the first time at the 2010 conference. The format creates a high energy session where speakers will take a very hands-on approach to share their practical experiences. It is the personal experience gained that counts, regardless of project size or duration.

Dear Medical Information: Do I risk an allergic reaction if I take your drug?
Michael Stouffs, Senior Specialist, Medical Communication and Information, Fertility and Rheumatology, Merck Serono International SA, Switzerland

International Rollout of a Global Medical Information System
Jérôme Mandin, Associate Director Global IT Medical Information, UCB Pharma SA, Belgium

It's Not Just (for) Squares – Use of QR codes in medical communications
Jürgen Wiehn, Director, Global Publications, Clinical Development - Medical Affairs, Shire AG, Switzerland

Supporting Social Media Applications for Psoriasis Patients – The impact on medical information
Vivien Ball, Head of Scientific Knowledge Management, Medical Department, Janssen-Cilag Ltd, UK

Fine-Tuning Inquiry Handling
Lillian Auberson, Senior Director, Global Medical Information, Actelion Pharmaceuticals Ltd, Switzerland

11:00-12:30 **Session 8**

Closing Plenary: IMPACT OF SOCIAL MEDIA ON THE PHARMACEUTICAL SECTOR

See page 7 for details

Share Best Practices

Network with Professional Colleagues

Exchange Knowledge

Join a SIAC!

DIA®
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What Are SIACs?

Special Interest Area Communities (SIACs) are discipline-specific global communities of industry, academic, and regulatory professionals who share best practices.

A Home for Every Professional

Looking for new ideas in your area of expertise?
Interested in learning about best practices to help you do your job better?
Want to build a global network of like-minded professionals who face the same daily challenges and opportunities as you?

Then it is time to maximise your DIA membership by joining one or more of DIA's SIACs.

Benefits

- Join a global community where members can share common experiences and knowledge and connect with others in their particular field
- Gain exclusive access to DIA ConneX, the new interactive, global, professional networking tool. Every SIAC has its own community home page through which members can:
  - Share breaking news with community members
  - Store, organise and manage community information and documents
  - Participate in online discussions grouped by issues and topics, ask and answer questions, and share expertise to develop best practices
  - Manage their own community experience based on their professional profiles
  - And more

DIA CONNEX professional networking

SIACs

- Clinical Data Management
- Clinical Pharmacology
- Clinical Research
- Clinical Safety and Pharmacovigilance
- Clinical Trial Disclosure
- Document and Records Management
- eClinical
- EDM Reference Model
- Evidence-Based Medicine
- Good Clinical Practice and Quality Assurance
- Investigators and Investigative Sites
- Medical Communications
- Medical Writing
- Paediatrics
- Professional Education, Training and Development
- Project Management
- Quality Risk Management
- Regulatory Affairs
- Statistics
- Study Endpoints
- Validation

How Do I Join?

Joining a SIAC is easy, convenient and free as part of your DIA membership.

Go to **www.diahome.org/SIACs** to join the SIACs of your choice.

To become a DIA member, go to www.diahome.org/membership

w w w . d i a h o m e . o r g / S I A C s

EXHIBITION
BASEL 2011

CLINICAL FORUM 2011 EXHIBITION

Join over 30 exhibitors in Basel to showcase your products and services to more than 400 key decision makers!

The DIA provides you with the opportunity to interact with a truly global audience of qualified professionals in the biopharmaceutical industry, contract service organisations, regulatory agencies, health ministries, from patient organisations, universities and student associations throughout Europe and worldwide.

The Clinical Forum exhibit hall reaches full capacity early. Booth space is sold on a first-come, first-served basis.

The fee is EUR 3,500 plus 8% Swiss VAT for a 3x3m space, standard electrical supply, carpet, one table, two chairs, coffee breaks, lunch and receptions, one full meeting registration (which allows access to all scientific sessions) and up to two exhibit booth personnel registrations.

Sign up now to ensure the space of your choice. Download the application form today at www.diahome.org > Click on the Clinical Forum icon > Exhibition

For more information on exhibition space and facilities or hosting opportunities, please contact Natacha Scholl at DIA Europe on +41 61 225 51 59 or email: natacha.scholl@diaeurope.org

EXHIBITION OPENING HOURS

Monday, 10 October 2011
From 08:00–18:30
SIAC Networking Reception:
from 17:30-18:30 in the exhibition hall
followed by an optional
networking dinner at restaurant
Safran Zunft from 19:00-22:00

Tuesday, 11 October 2011
From 08:00–18:30
Tuesday Drinks Reception:
from 17:30-18:30 in the exhibition hall

Wednesday, 12 October 2011
From 08:30–12:30

Reach your ideal target audience in Basel!

The Clinical Forum 2011 Exhibition will feature the innovations below, to ensure an optimal networking environment for exhibitors and delegates:

- Delegate refreshments will be served inside the exhibition hall during all breaks and before sessions
- Catering, coffee stations and tables will be situated around the exhibition hall to encourage the flow of delegate traffic
- Relaxation areas will be situated around the exhibition hall
- The direct proximity of the session rooms to the exhibition area will allow delegates sufficient break time to explore the exhibition floor
- Networking events will be held in the exhibition hall on both Monday and Tuesday evenings
- ***NEW THIS YEAR!*** Hosting opportunities available. Maximise your exhibiting experience and increase your company's exposure

Exhibiting Companies as of 8 September 2011

Company	Country	Company	Country
Amedon GmbH	Germany	Key People Ltd.	UK
Aptiv Solutions	USA	MakroCare	India
Aris Global	Germany	Medidata Solutions Worldwide	UK
Bioclinica	Germany	MZD - The Staffing Company	Germany
Biotrial	UK	NextDocs	USA
BSI Business Systems Integration AG	Switzerland	NNIT	Denmark
CRF Health	USA	Omnicomm	UK
CROS NT	Italy	Online Business Applications	USA
CTC Clinical Trial Consulting	Switzerland	Perceptive Informatics	USA
Datatrak International	USA	PFC Pharma Focus	Switzerland
Datatrial Ltd.	UK	PHT Corporation	USA
DIA	Switzerland	SIRO Clinpharm Germany GmbH	Germany
Dianthus Medical	UK	TAKE Solutions	UK
EPID Research	Finland	the Uppsala Monitoring Centre	Sweden
ERT	USA	TransPerfect	USA
Guy's and St Thomas' NHS Foundation Trust	UK	Venn Life Sciences	Switzerland
Hays (Schweiz) AG	Switzerland	Viedoc	Sweden
invivodata, inc.	USA		

NETWORKING
BASEL 2011

NETWORKING OPPORTUNITIES

The Clinical Forum offers delegates the opportunity to build business relationships and expand their professional contacts at social and networking events while enjoying excellent local food and wine.

Gain new perspectives, exchange ideas and generate new clients from one-on-one discussions with speakers, exhibitors and fellow delegates from various industry sectors and over 20 countries. Explore the latest technologies on the exhibit floor and connect with colleagues from the industry, government and academia.

From refreshment and coffee breaks to interactive working lunches, evening receptions and an optional networking dinner at a unique venue, the Clinical Forum's planned schedule of social and networking events offers something for everyone.

WHO YOU WILL MEET

Pharmaceutical and biotech industry professionals, professionals from academia, CROs, clinical trial sites, health regulatory agencies and delegates from patient organisations.

Areas of interest include:
- Clinical Data Management/eClinical
- Clinical Operations, Clinical Research, Clinical Safety and Pharmacovigilance
- Quality Assurance
- Clinical Study Endpoints
- Project Management, Medical Affairs
- Non-Interventional Studies
- Business and IT, Computer System Validation
- Medical Information, Medical Communications
- Medical Writing

Your registration includes two fabulous networking events

SIAC Networking Reception
Exhibition Hall
Monday, 10 October 2011 | 17:30-18:30

Join fellow delegates at the SIAC (Special Interest Area Community) Networking Reception which offers existing SIAC members and those who would like to learn more about SIACs, the opportunity to network and to identify people onsite who share the same interests or job responsibilities while enjoying excellent wine and nibbles.

For more information on SIACs please visit our website:
http://www.diahome.org/DIAHome/Membership/SIAC.aspx

Tuesday Drinks Reception
Exhibition Hall
Tuesday, 11 October 2011 | 17:30-18:30

The Tuesday Drinks Reception is open to all delegates and will take place in the Congress Center Basel.

Optional Event | Networking Dinner
Restaurant Safran Zunft
Monday, 10 October 2011 | 19:00-22:00

The Networking Dinner will take place in the ballroom of a historical guild house, the Safran Zunft. The Safran Zunft is located right next to the Marktplatz, which is dominated by the magnificent City Hall, the seat of Basel's government.

This is an optional event and not included in the registration fee. Tickets are available for EUR 75.00 including VAT.

Typically more than 90% of conference participants attend the Networking Dinner. Places are limited and on a first-come, first-served basis, so please secure your place early.

To obtain tickets please contact our Customer Services team on: + 41 61 225 51 51 or email diaeurope@diaeurope.org

About Basel

In the Basel region you will find a unique concentration of innovative pharmaceutical companies, research institutes and universities, a cosmopolitan culture and an international atmosphere.

The city on the Rhine is regarded as the centre of Swiss life sciences and the chemical-pharmaceutical industry and holds important companies in the logistics, transport and financial industry. In addition, Basel is considered Switzerland's most important trade fair and congress location and the Basel region also profiles itself as part of the "BioValley."

The Switzerland-Germany-France border triangle offers multi-faceted cultural performances and activities: Almost 40 museums, some of world renown such as the 'Fondation Beyeler' and the 'Kunstmuseum', the Basel Theatre staging plays, operas and ballet, countless galleries, music stages of all sizes and over 40 cinema screens all contribute to a rich cultural life. The city ranks with the European élite in the fine arts, as is demonstrated by its hosting 'Art Basel', the world's leading contemporary art fair.

The Old Town of Basel is one of the best-preserved and most beautiful old towns in Europe and the people in Basel know how to enjoy life. If you long for a more quiet spot, jump on a ferry, a river boat or a tram that will take you out to nature in no time at all.

Congress Center Basel

MCH Swiss Exhibition (Basel) Ltd
Messeplatz 21
CH-4058 Basel
www.congress.ch

Certificate of Attendance

Pick up your Certificate of Attendance!

The DIA Customer Services Team will have your Certificate of Attendance available onsite at the registration desk on Wednesday, 12 October 2011. If you prefer to receive your certificate after the conference, please call us on +41 61 225 51 51.

Onsite Registration Desk

The DIA Customer Services team will be pleased to assist you with your tutorial and conference registration, registration changes, registration for the networking dinner, group and one-day tickets. Attendee, Speaker and Exhibitor Registration are all located at the Main Entrance to the Congress and Exhibition area, second floor.

Opening hours:

Monday, 10 October 2011	08:00 - 18:30
Tuesday, 11 October 2011	08:00 - 18:30
Wednesday, 12 October 2011	08:00 - 12:30

Presentations

Presentations will be available online

Registered participants will be able to download presentations from 30 September 2011.

DIA will send you an email with instructions on how to access them.

Hotel Information

DIA has blocked a number of rooms at special rates and conditions in the hotels mentioned below.

Demand for hotel accommodation in Basel during the conference dates is high. As such we encourage delegates to book their hotel room as soon as possible.

Dorint an der Messe Basel***
Superior single room CHF 241.00
Superior double room CHF 267.00

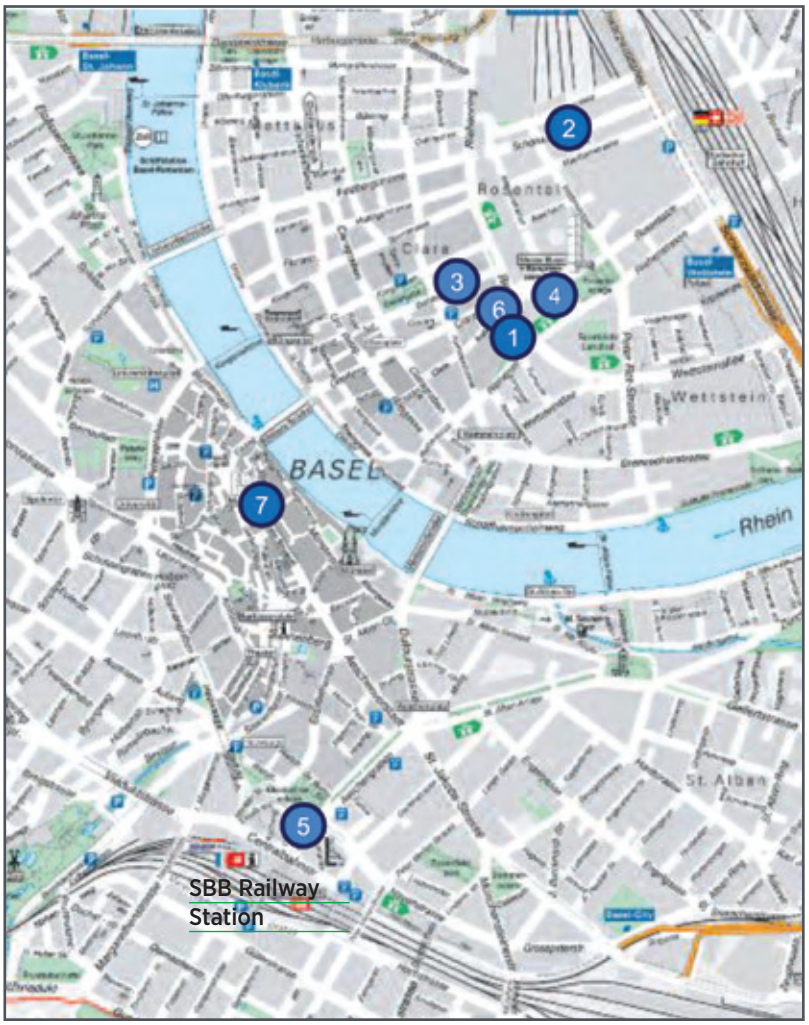
Mercure Hotel Europe Basel****
Standard single room CHF 235.00

Ramada Plaza Basel Hotel & Conference Center ******Superior
Single comfort room CHF 259.00

Hotel Schweizerhof***
Single standard room CHF 195.00

Swissôtel Le Plaza Basel****
Single room CHF 265.00

Attendees must make their own hotel reservations. For detailed information including booking deadlines please visit our website www.diahome.org > click on the Clinical Forum icon > Hotel/Travel Information > Hotel Information.



1 = Basel Congress Center
2 = Dorint an der Messe Basel
3 = Mercure Hotel Europe Basel
4 = Ramada Plaza Basel Hotel & Conference Center
5 = Hotel Schweizerhof
6 = Swissôtel Le Plaza Basel
7 = Restaurant Safran Zunft, Networking Dinner, Monday 10 October 2011

Travel Information

Receive up to 20% off airfares in the Star Alliance Network
The Star Alliance™ member airlines are pleased to be appointed as the Official Airline Network for the 5th Annual Clinical Forum. For more information, please visit our website www.diahome.org > click on the Clinical Forum icon > Hotel/Travel Information > Transportation.

Basel's EuroAirport (BSL) is located 8 kilometres north of the city centre. Public transport and taxis are available outside the airport.

Public Transport
There is an easy connection from the EuroAirport to the Congress Center Basel via the central railway station (Bahnhof SBB). The bus service No. 50 runs every 7-10 minutes between the airport and the central Swiss railway station. From there you can change to a tram line No. 2, which takes you directly to the Congress Center Basel.
Note: If you have booked a hotel in Basel, please note that your mobility ticket (free public transport for Basel) is included for the duration of your stay. Please carry your hotel confirmation with you when travelling on public transport.

Taxis
Taxis are available outside the airport terminal. A regular taxi ride to the congress center will take 15-20 minutes.

Alternatively you can travel to Zurich International Airport (ZRH). The train from Zurich Airport to Basel main station (Bahnhof SBB) will take approximately 1 hour 15 minutes.

Passport and Visa Requirements
Delegates from countries within the European Union need a valid passport or ID to travel to Switzerland. All other delegates should contact the nearest Swiss Embassy or Consulate for visa requirements. For more information, please visit www.bfm.admin.ch

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DIA's new members-only social networking-style website is a vital resource for professionals like you looking to connect with others in your field and improve your job performance.

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- Access shared resources such as white papers and articles
- Network with thousands of your colleagues worldwide

Get connected at www.diahome.org/DIAconnex.

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Glossary

ACDM	Association for Clinical Data Management
AHR-DMA	Australasian Health and Research Data Managers Association
ARCS	Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical Industry Ltd
CAP	Coordinated Assessment Procedure
CCDM	Certified Clinical Data Manager
CDM	Clinical Data Management
CDISC	Clinical Data Interchange Standards Consortium
CRA	Clinical Research Associate
CRO	Contract Research Organisation
CSR	Clinical Study Report
DADM	Danish Association of Data Managers
DG SANCO	Directorate General for Health and Consumers of the European Commission
DMB	Data Management Biomedical
DVMD	German Association for Medical Documentalists
DSUR	Development Safety Update Report
EDC	Electronic Data Capture
EMA	European Medicines Agency
ePRO	Electronic Patient-Reported Outcomes
FDA	Food and Drug Administration
FIADM	Finnish Data Management Association
HL7	Health Level Seven
ICH	International Conference of Harmonisation
ICU	Intensive Care Unit
INCDMA	International Network of Clinical Data Management Associations
IND	Investigational New Drug (IND) Application
IT	Information Technology
IVR	Interactive Voice Response
IWR	Intelligent Word Recognition
NIS	Non-Interventional Studies
OMOP	Observational Medical Outcomes Partnership
PIP	Paediatric Investigational Plan
PRO	Patient-Reported Outcomes
PSDM	Pharmaceutische Statistiek en Data Management
QA	Quality Assurance
QC	Quality Control
QR	Quick Response (QR) Code
R&D	Research and Development
SCDM	Society for Clinical Data Management
SIAC	Special Interest Area Community (DIA)
SMO	Site Management Organisation
SUSAR	Suspected Unexpected Serious Adverse Reaction
UAT	User Acceptance Test

REGISTRATION FORM

5th Annual Clinical Forum
10-12 October 2011 | Congress Center Basel, Basel, Switzerland

ID # 11103

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.
The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

Early-bird rates available for members: Register by 29 August 2011

Join DIA now to qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. **Does not apply to government/academia/non-profit members**

Early-bird industry fee for members (by 29 August 2011)*	€ 1'165.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑

CATEGORY	Member (after 29 August 2011) Fee*	Non-Member Fee*
Industry	€ 1'365.00 ❑	€ 1'480.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 683.00 ❑	€ 798.00 ❑

* All fees will be subject to the local Swiss VAT at 8%

Tutorial | Monday, 10 October 2011	Fee*	Networking Dinner | Monday, 10 October 2011	Fee*
Tutorial Fee	€ 250.00 ❑	Networking Dinner Fee	€ 69.45 ❑

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

SMEs, STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT THE DIA FOR MORE INFORMATION. 11103DIAWEB

REGISTRANT

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

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First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

Please indicate which sector you represent:

❑ Big Pharma ❑ BioTech ❑ CRO ❑ Specialist CRO ❑ Consultant ❑ Other

For company billing, please add your company's VAT number: _____

If you wish to be billed privately, please contact our Customer Services Team, as below

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ Please charge my credit card - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

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❑ Cheques should be made payable to: DIA and mailed together with a copy of the registration form to facilitate identification to: DIA, Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 11103 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer.

CANCELLATION POLICY

All cancellations must be in writing and received with DIA Europe by 17:00 CET on 30 September 2011

Cancellations received by the date above are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/non-member) = € 200.00. Government/Academia/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. Registered attendees who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registered attendees are responsible for cancelling their own hotel reservations. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees.

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

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.**

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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

All registrations received at the DIA Europe office by 18:00 CET on 3 October 2011 will be included in the attendee list