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3rd Annual Clinical Forum Nice 2009

IMPROVING CLINICAL DEVELOPMENT TOGETHER

CDM, eCLINICAL
CLINICAL OPERATIONS
CLINICAL RESEARCH
POST-MARKETING DEVELOPMENT
DRUG SAFETY
QUALITY ASSURANCE

VALIDATION

MEDICAL INFORMATION & COMMUNICATIONS

STATISTICS

MEDICAL WRITING

October 19-21, 2009
Nice Acropolis, Nice, France

ACCESS TO 7 MULTIDISCIPLINARY TRACKS AND WORKSHOPS FOR 1 INCLUSIVE FEE

Dear Colleagues,

The first announcement for DIA's 3rd Annual Clinical Forum in Nice has raised a lot of interest. The conference title **"Improving Clinical Development Together"** obviously responds to the current need for bundling forces, sharing knowledge and experience and creating practical ideas together in these challenging times for drug development. In response to our Call for Abstracts we received over 100 very interesting abstracts. Thank you very much to those who submitted! This enthusiastic response enabled our Programme Committee to select the most currently relevant topics and to create a programme from "practitioners" for "practitioners". More than half of the submitted abstracts were accepted either as presentations or as topics for sessions, workshops or tutorials. **This programme is YOUR programme!**

A very important role in the programme preparation was played by several DIA Special Interest Area Communities (SIACs). As the CDM, IT/Validation, Medical Information & Communication, Statistics and Medical Writing SIACs will have their Annual Meeting within the Clinical Forum in Nice, these SIACs have spent a lot of time selecting "hot topics" and challenging speakers for the programme. (More information on SIACs is available at www.diahome.org > Membership + Communities > Communities > SIACs).

The Programme Committee has decided to establish a very successful event in the last two years as a tradition in the DIA Clinical Forum: **The Debate**. This year's provocative topic will be of great interest to our audience: **This House Believes that CRO Delivery is a Myth**. Eloquent presenters will defend and oppose this claim hoping that the audience will actively participate in this debate.

Please take the time to read this programme. You will find topics of great interest and relevance to you within your own professional area and in related areas, giving you an opportunity to better understand your colleagues' needs and common interests.

Looking forward to welcoming you - as presenter, participant or exhibitor - in Nice, October 19-21, 2009.

Ingrid Klingmann
Programme Chairperson
President, Pharmaplex bvba, Belgium

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HOW TO READ THIS PROGRAMME

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4. ***Explore your relevant track and plan your conference!***

The Drug Information Association (DIA) has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102.

DIA is authorised by IACET to offer 1.1 CEUs for this programme.

If you would like to receive a statement of credit, you must attend the programme, return your evaluation form and complete the online credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request.

Disclosure Policy

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the programme audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

THIS HOUSE BELIEVES THAT CRO DELIVERY IS A MYTH

Welcome Address
Ingrid Klingmann, Programme Chairperson, President, Pharmaplex bvba, Belgium
Brigitte Franke-Bray, Director DIA Europe, Switzerland

Session Chairperson
Julianne Hull, Senior Director, Global Development Data Operations, Wyeth Research, UK

"Improving Clinical Development Together" is the mantra for this forum. Our four debaters will explore the pros and cons of vendor delivery. Is vendor delivery just a story spread by business development, or do service and clinical development professionals work together for efficient clinical trial delivery?

The audience will have the opportunity to vote at the beginning and at the end of the debate, listen to seasoned professionals provide arguments for both sides and to ask questions of the debaters. These debates are designed to be entertaining and result in interesting and controversial topics being discussed non-confrontationally.

Debaters
For the motion
- **Andy Parrett,** Chairman of the Pharmaceutical Contract Management Group (PCMG), UK
- **Jens Reinhold,** Head of Non-Interventional Studies, Bayer Schering Pharma AG, Germany

Against the motion
- **Jorgen Seldrup**, Senior Director, Centre for Statistics in Drug Development, Quintiles, France
- **Nermeen Y. Varawalla**, President & CEO, ECCRO, UK

CLINICAL FORUM 2009

	Monday, October 19, 2009				
Session	Half-day Tutorials/ Workshops	Session 1	Session 2	Session 3	Sessi
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Track 3	Workshop 2 PUTTING MEDICAL INFORMATION ON THE CRITICAL PATH RISSO 6	MEDICAL INFORMATION COLLABORATION IN EUROPE RISSO 6	DRIVING CHANGE AND BREAKING THE MOULD RISSO 6	MANAGING THE MEDICAL INFORMATION SERVICE RISSO 6	RAISING THE MEDICAL IN RISS
Track 4	Workshop 3 INTRODUCTION TO PRACTICAL APPLICATION OF ADAPTIVE DESIGNS RISSO 8	HOW TO OPTIMISE THE USE OF PRE-CLINICAL INFORMATION IN THE DRUG DEVELOPMENT PROCESS? RISSO 8	INNOVATIONS IN MODELLING AND SIMULATIONS RISSO 8	BIOEQUIVALENCE RISSO 8	MISSIN RISS
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TRACK 1
CDM, eCLINICAL, CLINICAL OPERATIONS, CLINICAL RESEARCH, POST-MARKETING DEVELOPMENT, DRUG SAFETY, QUALITY ASSURANCE

TRACK 2
VALIDATION

TRACK 3
MEDICAL INFORMATION &COMMUNICATIONS

TRACK 4
STATISTICS

TRACK 5
MEDICAL WRITING

TUTORIALS

WORKSHOPS

PLENARY

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E PROFILE OF FORMATION SO 6		Track 3	CUSTOMER INTERACTIONS RISSO 6	ACHIEVING QUALITY RISSO 6	USING TECHNOLOGY FOR KNOWLEDGE MANAGEMENT Joint interest for Track 3 & 5 RISSO 6
G DATA SO 8		Track 4	QUESTION AND ANSWER SESSION RISSO 8	CLINICAL TRIAL DISCLOSURE Joint interest for Track 4 & 5 RISSO 8	STATISTICAL ISSUES WITH SAFETY DATA RISSO 8
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Session dates and timings may change.
For programme updates, please visit www.diahome.org >
click on the Clinical Forum icon > View PDF

CLINICAL FORUM 2009 EXHIBITION

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

DIA provides you with the opportunity to interact with a truly global audience of qualified professionals, from entry level to expert, in the pharmaceutical, biotechnology and related industries, government, academia and healthcare delivery.

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

The fee is EUR 4'186.00 including 19.6% French VAT for a 3x3m space, standard electrical supply, carpet, one table, two chairs, coffee breaks, lunches and receptions, one full meeting registration (which allows access to all scientific sessions) and up to two exhibit booth personnel registrations. Any other personnel will be required to pay the full meeting registration fee.

REACH YOUR IDEAL TARGET AUDIENCE

The Clinical Forum 2009 Exhibition will feature the innovations below, to ensure an optimal networking environment for exhibitors and delegates:

- All delegates must enter and exit via the exhibition area to reach all facilities and sessions
- Delegate refreshments will be served inside the exhibition hall during all breaks and before sessions. Exhibition hours will reflect this
- Catering, coffee stations and tables will be situated around the exhibition hall to further encourage the flow of delegate traffic
- The Meeting Point will be located in the exhibition hall
- Relaxation areas will be situated around the exhibition hall
- The direct proximity between the session rooms and 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

RESERVE YOUR BOOTH NOW!

Sign up now to reserve the space of your choice. Download an application form today at www.diahome.org > click on the Clinical Forum 2009 icon > Exhibits

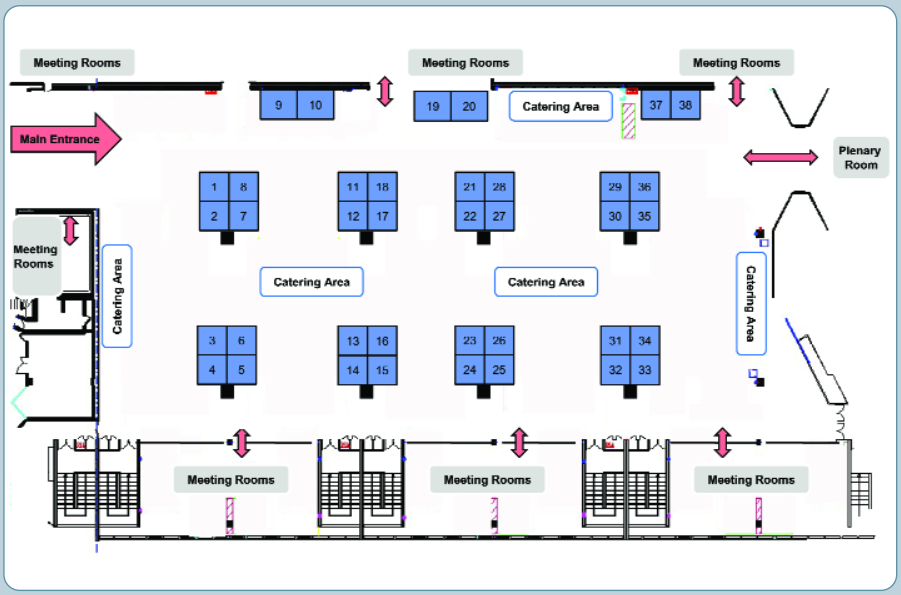
For more information on exhibition space and facilities, or for demographic information, please contact: Phyllis Suter, DIA Exhibits Manager, on +41 61 225 51 54 or email: phyllis.suter@diaeurope.org

THE CLINICAL FORUM 2009 EXHIBITION OPENING HOURS

Monday, October 19, 2009
- From 10:30 – 18:30
- SIAC Networking reception from 17:30-18:30 in the exhibition hall

Tuesday, October 20, 2009
- From 08:00 – 18:30
- Networking reception from 17:30-18:30 in the exhibition hall and followed by an optional networking dinner at the Grand Hotel Aston

Wednesday, October 21, 2009
- From 08:30 – 14:00
- Light lunch from 12:30 – 14:00 in the exhibition hall



EXHIBITING COMPANIES AS OF AUGUST 4, 2009

Company	Country	Booth Nr.	Company	Country	Booth Nr.
Ariana Pharmaceuticals SA	France	30	Makrocare	India	1
Aris Global	United Kingdom	11	Medidata Solutions Worldwide	United States	3
BSI AG	Switzerland	6	NNIT	Denmark	27
C3i Inc.	Bulgaria	17	OmniComm Europe GmbH	Germany	12
clinIT AG	Germany	7	Online Business Applications	United States	10
CRF Health	United States		PAREXEL International	United States	16
DATATRAK International	Germany	19	Perceptive Informatics	United Kingdom	13
Dianthus Medical Limited	United Kingdom	34	PharmaForms	Germany	26
ENNOV-CLINSIGHT	France	9	Pharmaprojekthaus GmbH & Co. KG	Germany	18
entimo AG	Germany	22	Richmond Pharmacology Ltd.	United Kingdom	20
ERT	United States	28	SciNopsis Scientific Writing Services	France	29
Kendle	United Kingdom	31	SGS Life Science Services	France	2
Kika Clinical Solutions	France	35	the Uppsala monitoring Centre	Sweden	21
Lambda-Plus	Belgium	8	XClinical	Germany	23

NETWORKING OPPORTUNITIES

The Clinical Forum will offer 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

Professionals at all levels in the following disciplines:

- Clinical Data Management
- Statistics
- eClinical
- IT
- Clinical Research
- Medical Information & Communications
- Clinical Safety & Pharmacovigilance
- Validation
- Clinical Operations
- Medical Writing

SPECIAL INTEREST AREA COMMUNITIES RECEPTION

Special Interest Area Communities – Provides a forum for members to exchange information, learn more about their field, explore industry hot topics and build a professional network.

JOIN FELLOW DELEGATES AT THE SIAC RECEPTION IN THE EXHIBITION HALL ON MONDAY, OCTOBER 19, 2009, 17:30 - 18:30

The SIAC reception during the 3rd Annual Clinical Forum Meeting 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 responsibility while enjoying excellent wine.

For more information on the reception, please visit the DIA registration desk, located in the Main Entrance Hall, Level 1. More information on SIACs is available at at www.diahome.org > Membership + Communities > Communities > SIACs.

NETWORKING DINNER

JOIN US FOR A SEATED NETWORKING DINNER AT THE GRAND HOTEL ASTON, LIVINGSTONE ROOM ON TUESDAY, OCTOBER 20, 2009, 19:00 - 21:00

The Grand Hotel Aston, an impressive 1928 building located on the Massena Square, is only ten minutes walking distance from the Acropolis Congress Centre.

The dinner will be held in the Livingstone Room, on the 7th floor with an exceptional panoramic view. This is an optional event and is not included in the registration fee. Tickets are available for € 58.00 including a welcome drink, a four-course meal, wine, water, coffee and VAT.

Typically over 90% of Conference Participants attend the Networking Dinner. Places are limited and on a first come first served basis, please secure your seat as early as possible. For more information visit www.diahome.org and click on the Clinical Forum icon.

Monday, October 19, 2009

SCHEDULE AT A GLANCE

Monday, October 19, 2009

08:00 - 09:00	Registration and Welcome Coffee	
09:00 - 12:30	Tutorial 1: **CDISC / CDASH STANDARDS: DETAILING THE DATA FLOW**	GALLIENI 5
09:00 - 12:30	Tutorial 2: **DATA PRIVACY IN CLINICAL TRIALS AND PHARMACOVIGILANCE**	GALLIENI AB
09:00 - 12:30	Tutorial 3: **EDC and ePRO BEST PRACTICES**	RISSO 7
09:00 - 12:30	Workshop 1: **PERSONAL CAREER DEVELOPMENT – NEW TO THE JOB OR READY FOR A CHANGE?**	HERMES
09:00 - 12:30	Workshop 2: **PUTTING MEDICAL INFORMATION ON THE CRITICAL PATH**	RISSO 6
09:00 - 12:30	Workshop 3: **INTRODUCTION TO PRACTICAL APPLICATION OF ADAPTIVE DESIGNS**	RISSO 8
09:00 - 12:30	Workshop 4: **WRITING THE PATIENT INFORMATION SHEET**	GALLIENI 3
10:30 - 11:00	Coffee Break in the Exhibition Hall	
12:30 - 14:00	Registration - Lunch in the Exhibition Hall	
14:00 - 15:30	Session 1	
15:30 - 16:00	Coffee Break in the Exhibition Hall	
16:00 - 17:30	Session 2	
17:30 - 18:30	SIAC Reception in the Exhibition Hall	

Tuesday, October 20, 2009

07:30 - 09:00	Registration and Welcome Coffee
09:00 - 10:30	Session 3
10:30 - 11:00	Coffee Break in the Exhibition Hall
11:00 - 12:30	Session 4
12:30 - 14:00	Lunch in the Exhibition Hall
14:00 - 15:30	Plenary Session
15:30 - 16:00	Coffee Break in the Exhibition Hall
16:00 - 17:30	Session 6
17:30 - 18:30	Networking Reception in the Exhibition Hall
19:00 - 21:00	Networking Dinner at the Grand Hotel Aston

Wednesday, October 21, 2009

08:00 - 09:00	Registration and Welcome Coffee
09:00 - 10:30	Session 7
10:30 - 11:00	Coffee Break in the Exhibition Hall
11:00 - 12:30	Session 8
12:30 - 14:00	Light Lunch in the Exhibition Hall
14:00	End of Conference

TUTORIAL 1 09:00-12:30

CDISC / CDASH STANDARDS: DETAILING THE DATA FLOW

Co-Instructors

Pierre-Yves Lastic, Senior Director, Data Privacy & Healthcare Interoperability Standards, sanofi-aventis, France
FDA representative invited

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. AL 1 09

GALLIENI 5

Monday, October 19, 2009

TUTORIAL 2 09:00-12:30

DATA PRIVACY IN CLINICAL TRIALS AND PHARMACOVIGILANCE

Instructor

Anne Bahr, R&D France Data Privacy Officer, sanofi-aventis, France

Overview

The exponential growth of information technology in the health sector as well as the globalisation of work and data flows is raising concerns that the privacy of individuals involved in clinical trials and pharmacovigilance activities may be breached, with negative impacts on the life of these individuals. In order to face this challenge, Data Protection Authorities around the world are raising the privacy bar through new regulations or a stricter interpretation of existing ones. Additionally, other stakeholders like Ethics Committees or Institutional Review Boards are requesting ever more safeguards to protect the privacy of study patients. Finally, different interpretations of the same rules in different countries make the life of clinical trial and data managers ever more difficult. This tutorial is aimed at improving the understanding of worldwide data privacy principles and regulations, as well as how to comply with them.

Learning Objectives

At the end of this tutorial participants should be able to:

- Understand the principles of Personal Data Protection in the European Union
- Have a basic knowledge on how to comply with European and other worldwide regulations
- Understand the differences between European, US and Asian Data Privacy regulations

Key Topics

- Why is Personal Data Protection important?
- Principles of Personal Data Protection, based on the European Regulations
- Overview of worldwide regulations and the differences between them
- Specific regulations for biomedical research and pharmacovigilance and their consequences
- How to comply?
- Information & consent
- Communication & training
- IT security & validation
- Legal instruments (contracts, Safe Harbour, BCRs)
- Data Privacy organisation

Who Will Attend

All individuals involved in the organisation and management of clinical trials and pharmacovigilance, or handling with data collected to perform these activities.

GALLIENI AB

TUTORIAL 3 09:00-12:30

EDC AND ePRO BEST PRACTICES

Co-Instructors

Bryan McDowell, Clinical Trial Head, Speciality and Mature Products, Novartis Pharma AG, Switzerland

Jonathan Andrus, Vice President – Data & Study Operations, Bioclinica, USA

Overview

Electronic Data Capture (EDC) and Electronic Patient Reported Outcomes (ePRO) tools are routinely used in hundreds of clinical trials each day. More sponsors are choosing EDC and ePRO as either an alternative, or a complement, to paper-based clinical trials.

This will be an interactive tutorial that will look at the many aspects of EDC and ePRO that are particularly important from a data management viewpoint. From an interactive standpoint, tutorial participants will be provided with case studies that they will be asked to explore together in groups. The intention of these case studies is to help the participant better understand the subject and apply best practice techniques using a real world case study.

EDC and ePRO will be explored in terms of data management activities pertinent during the Study Start, Conduct, and Study Closeout phases of a clinical trial. In particular:

- Deployment considerations
- Data integration of EDC and non-EDC sources
- SOP considerations
- Planning for the unplanned
- How to prepare your organisation to execute a trial in EDC and ePRO
- Training considerations
- Managing change in EDC and ePRO studies
- Partnering with clinical research to get the most efficiency during data clean-up and lock from using EDC and ePRO
- Data archival considerations

Learning Objectives

At the end of this tutorial participants should be able to:

- Understand best practices related to the implementation, management and close out of EDC and ePRO studies
- Understand how to apply some of these best practices through interactive group exercises
- Be better prepared to effectively manage technology-based clinical trials

Who Will Attend

All individuals involved in the organisation and management of clinical trials.

This includes:

- Clinical project managers
- Clinical data managers
- Clinical quality assurance professionals

RISSO 7

Monday, October 19, 2009

WORKSHOP 1 09:00-12:30

PERSONAL CAREER DEVELOPMENT – NEW TO THE JOB OR READY FOR A CHANGE?

In partnership with the European Pharmaceutical Student Association (EPSA)

Session Chairperson

Carl Metzdorff, Principal, Aces Health Care, Belgium

Introduction and Workshop Objective
Carl Metzdorff, Principal, Aces Health Care, Belgium

After Graduation: Opportunities and challenges
Nicolaos D. Gentis, PhD student, Industrial Pharmacy Lab, Basel, EPSA Parliamentarian 2009 / 2010, Switzerland

The First 100 Days as a New Manager
Carl Metzdorff, Principal, Aces Health Care, Belgium

Panel Discussion

Career Move Upwards within the Industry
Presenter invited

Ready for a Change: A new direction within the industry
Wim Souverijns, Director Marketing Operations, Celgene International, Switzerland

Complete Career Change
Max Beckmann, Founder and Principal, Beckmann Bio, Belgium

Panel Discussion

Overview
The Workshop is designed as an odyssey through a hypothetical pharmaceutical industry career, a kind of professional career life cycle, from entry to self-fulfilment.

Six speakers will address six different stages in this hypothetical industry career. The speakers will talk about the following career phases:

- How to get a job in the first place
- The Transition from Academia to Industry
- The first 100 day as a new manager
- The Upward career move within the Industry
- A New Direction within the industry
- The Complete career change, going independent, and share with the audience, their own personal experience after having done exactly that.

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

Learning Objectives
Through an interactive process, six presenters will share their personal experience and provide the audience with a series of ideas and tools in order to be better prepared

- in the search for a new job,
- in case of a new job start, or
- in the process of a job change.

Who Will Attend:
Students, Graduates, Post-Docs and Academics, who might consider a professional pharmaceutical industry career; Pharmaceutical industry professionals, looking for a career change.

The EPSA represents over 120,000 pharmacy students in 32 European countries. The objective of EPSA is to develop the interests and opinions of European pharmacy students and to encourage contact and co-operation between them.

HERMES

WORKSHOP 2 09:00-12:30

PUTTING MEDICAL INFORMATION ON THE CRITICAL PATH

Session Co-Chairpersons

Jayne Packham, Jayne Packham Consultancy Ltd., UK
Aaron Cockell, European Director Medical Information, Pfizer Inc., UK

Overview
How can you help your stakeholders really understand the value that Medical Information can bring to the business? By writing a compelling value proposition and then proposing your suggestion in a business plan.

This practical and interactive workshop will help you understand who the real stakeholders in your business are, to step into their shoes and to see what they want to achieve. We will analyse what you are currently doing to help them achieve their goals and what you may need to start doing. Finally, we will develop a business plan to ensure your proposals are fully thought out and are presented with the best chance of success.

By the end of the workshop, delegates will have developed a compelling value proposition for their own department and will have started to develop this into a business plan. Delegates will take away a business plan template, process flows for developing value propositions and new ideas from colleagues.

Learning Objectives
At the conclusion of this workshop, participants should be able to:

- Identify key stakeholders and understand their goals
- Analyse how to help stakeholders achieve their goals
- Develop a business plan
- Develop a value proposition

Who Will Attend
Professionals working in Medical Information, Medical Communications and Medical Affairs roles. Managers and leaders of Medical Information services.

RISSO 6

Monday, October 19, 2009

WORKSHOP 3 09:00-12:30

INTRODUCTION TO PRACTICAL APPLICATION OF ADAPTIVE DESIGNS

Session Co-Chairpersons

Eva R Miller, Director, Biostatistics, ICON Clinical Research, USA

Andrew Grieve, Professor, Division of Health & Social Care Research, Department of Public Health Sciences, School of Medicine, King's College, UK

Discussant:

David Wright, Senior Statistical Assessor, MHRA, UK

Overview

Logistical and operational considerations in designing and implementing adaptive designs have recently drawn greater attention because the infrastructure for managing traditional double-blind, randomized, parallel group clinical trial does not lend itself to the challenges presented in implementation of flexible designs. The CHMP defined a trial as "adaptive" if statistical methodology allows the modification of a design element (e.g. sample-size, randomization ratio, number of treatment arms) at an interim analysis with full control of type I error. The benefits of employing adaptive designs include acceleration of the clinical trial process, enhancement of trial efficiency, and improvements in patient safety. To achieve these benefits clinical teams must adhere to the scientific method by incorporating plans for change in the study protocol and they must implement those planned changes efficiently and effectively. Adaptive designs may have one or more of the following rules applied to the interim look at data: (1) allocation rule, (2) sampling rule, (3) stopping rule, and/or (4) decision rule. Adaptive trial designs require more teamwork and planning before the study starts and different business models for implementation and managing the logistics of the trial than traditional designs. Some of the challenges which need to be dealt with relate to: (1) Planning interim efficacy evaluations with potential early stopping decision or trial extension based on established benefits and managing the actions required after interpretation of results; (2) The possibility of adding or shutting down treatment arms while the study is in progress based upon predetermined rules and how that will impact drug supply management and be handled without compromising study integrity; (3) Changing the ratio of subjects to treatment group or changing drug cohorts, again greatly impacting drug supply management; and (4) Adaptive randomization algorithms for maximizing balance of subject allocation requiring clear delineation of the algorithm and an IVR System custom built and validated for the specific randomization algorithm. Particular statistical challenges are encountered with each type of adaptive design and designs combining several forms. For example, dose escalation studies may have a variety of experimental designs to best suit particular therapeutic areas and experimental problems.

Study design and practical implications of several case studies will be described in detail. One of these case studies will be for a dose-ranging trial. Another will be a two-stage seamless adaptive trial design. Often in two-stage seamless trials study endpoints are similar but different within each stage necessitating careful consideration of whether data can be combined from both stages in the final analysis.

Learning Objectives

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

- Identify potential studies within their portfolios which could benefit from the various types of adaptive trial designs and assess whether the teams could become sufficiently well prepared to execute the trials effectively.
- Discuss methods to avoid bias and maintain the interpretability of trial results in confirmatory studies with adaptive designs.
- Outline a strategy for implementation of an adaptive trial design from articulation within a protocol, increased planning for team communication and flow of confidential information, flexible drug supply management and availability of accurate and timely data for interim decision-making.

Who Will Attend

Clinicians, statisticians, those managing or implementing trials across departments, and medical supplies managers, interested in understanding more about Adaptive Trial Designs: purpose, theoretical statistical frameworks, practical implications, logistics, team communications, reporting requirements, flexible drug supplies management, and regulatory implications.

RISSO 8

Monday, October 19, 2009

WORKSHOP 4 09:00-12:30

WRITING THE PATIENT INFORMATION SHEET

Session Chairperson
Nadina C. Jose, Clinical Advisor, CRF Health; Associate Dean, School for Clinical Research, American University of Health Sciences

The Legal Basis for Patient Information Forms/Informed Consent
Wolfgang R. Eglmeier, Head Clinical Operations, Grunenthal GmbH, Germany

Patient Information Sheet/Informed Consent Issues from an Investigator's Perspective
Nadina C. Jose, Clinical Advisor, CRF Health; Associate Dean, School for Clinical Research, American University of Health Sciences

Written Patient Information in Clinical Trials – Maximising Readability through User Testing
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, School of Healthcare, UK

Patient information in Clinical Trials: Special Considerations for Parents, Teenagers and Children
Jane Lamprill, Paediatric Research Consultant/Specialist Paediatric Medical Writer, Paediatric Research Consultancy, UK

Overview
With increasing focus on conducting ethical, evidence based and economical research, high quality patient information sheets are essential for successful trial outcomes. Time and money are wasted when information cannot be easily read or understood by patients. This leads to, ethics/IRB review delays, uninformed patients, poor recruitment and low compliance.

This stimulating and interactive workshop will focus on key aspects of writing quality informed consent/assent material. Usability and best practice perspectives will be presented by a team of investigator, sponsor and writing expertise. Group exercises will mainly highlight issues surrounding information provision and user testing for adult studies. Consideration will also be given to the ethical and information needs of parents, teenage and child research participants

Learning Objectives
- Understand different viewpoints of the consent/assent process from the sponsor and investigator
- Write information sheets that are easily read and understood by patients
- Increase ability to write clearly and concisely for adults
- Gain knowledge of user testing methodology to ensure reader comprehension
- Learn about practical and ethical requirements for writing parent and child information sheets

Who Will Attend
- Project Managers
- Clinical Research Associates
- Quality Assurance
- Regulatory Affairs
- Investigators

GALLIENI 3

DIA Upcoming Training Courses in Regulatory Affairs

European Regulatory Affairs
November 19-20, 2009 / Paris, France

Comprehensive Training on European Regulatory Affairs: Expert Overview
January 24-26, 2010 / Dubai, United Arab Emirates

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
April 26-28, 2010 / Vienna, Austria
December 5-7, 2010 / Dubai, United Arab Emirates

European Regulatory Affairs: Review of Current Registration Procedures
February 11-12, 2010 / Lisbon, Portugal
June 3-4, 2010 / Prague, Czech Republic
November 18-19, 2010 / Paris, France

US Regulatory Affairs
November 9-12, 2010 / Lisbon, Portugal

Good Management of Medical Devices
April 26-28, 2010 / Paris, France

Building the eCTD
February 11-12, 2010 / Paris, France

An Introduction to Product Information Management (PIM)
April 26-27, 2010 / Vienna, Austria
October 28-29, 2010 / Geneva, Switzerland

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TRACK 1
CDM - eCLINICAL - CLINICAL OPERATIONS - CLINICAL RESEARCH
POST-MARKETING DEVELOPMENT - DRUG SAFETY - QUALITY ASSURANCE

Track Co-Chairs

Valdo Arnera
General Manager Europe, PHT Corporation, Switzerland

Julianne Hull
Senior Director, Global Development Data Operations, Wyeth Research, UK

Ingrid Klingmann
President, Pharmaplex bvba, Belgium

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

Monika Pietrek
Managing Director, Pietrek Associates GmbH, Germany

Jens Reinhold
Head of Non-Interventional Studies, Bayer Schering Pharma AG, Germany

Susan Trainor
CEO, Trainor & Partners International, Belgium

Nermeen Y. Varawalla
President & CEO, ECCRO, UK

Programme Sub-Committee

Jean-Michel Auger
Consultant in Clinical Quality Management, Strategic Services, France

Joris Cauquil
Consultant, Head of Training, Head of Quality Assurance, AMITIS/Effi-Stat, Chair DMB, France

Françoise de Crémiers
FdC Consulting, France

Brian Edwards
Director, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK

Christoph Gleiter
Managing Director, CenTrial GmbH, Coordination Centre for Clinical Trials at University Hospital Tübingen and Ulm, CenTrial GmbH, Germany

Nick Lucas
Vice President Global Data Management, INC Research, UK

Mette Mackeprang Bruhn
EDC Team Leader, H. Lundbeck A/S, Denmark

Detlef Nehrdich
Director Statistics, Data Management & EDC Project Office Europe, Abbott GmbH & Co KG, Germany

Heike Schoen
Managing Director, CSG Clinische Studien GmbH, Germany

Michael Wagener
Chief Medical Director, AC Immune SA, Switzerland

This conference is incorporating the 19th Annual DIA European CDM and 5th Annual DIA European eClinical Conferences

Clinical Data Management SIAC

The mission of the CDM SIAC is to:

- Establish a global forum to share, evaluate and disseminate information on processes, standards and technologies for the management of clinical data.
- Encourage participation of professionals in the biopharmaceutical and healthcare industries.
- Promote education, training and career development of clinical data management professionals.
- Promote multidisciplinary collaboration and understanding.
- Increase the visibility and recognition of clinical data management as a professional discipline.

If you are interested in joining this SIAC, please come and see us at the DIA booth

eClinical SIAC

The mission of the eClinical SIAC is to:

- Establish an international forum to share, evaluate and disseminate information on the application of electronic and other new information technologies, processes and standards in the conduct of clinical trials in the biopharmaceutical industry.
- Encourage participation and promote education, training and development of professionals in the biopharmaceutical and healthcare industries, including staff of sponsors, vendor organisations, contract research organisations and sites that implement, apply and maintain electronic and other new information technologies, processes and standards in the conduct of clinical trials.
- Promote open discussion and communication of regulatory issues, practices and metrics in the implementation, application and maintenance of electronic and other new information technologies, processes and standards in the conduct of clinical trials in the biopharmaceutical industry.

If you are interested in joining this SIAC, please come and see us at the DIA booth

Clinical Research SIAC

The mission of the Clinical Research SIAC is to identify and address the professional needs of worldwide DIA members whose primary interest is clinical research, by:

- Supporting education and training to ensure successful professional growth and development.
- Promoting best practices and education through international tutorials and workshops under DIA auspices at the DIA Annual Meeting, the DIA EuroMeeting and other satellite symposia worldwide.
- Maintaining an up-to-date website that provides an international forum for the exchange of information about best practices, current clinical trials, educational opportunities and other topics of interest to members.
- Fostering communication among industry, governmental agencies, healthcare delivery systems and academia on a global basis.

If you are interested in joining this SIAC, please come and see us at the DIA booth

TRACK 1.1
CDM - eCLINICAL - CLINICAL OPERATIONS - CLINICAL RESEARCH
POST-MARKETING DEVELOPMENT - DRUG SAFETY - QUALITY ASSURANCE

Monday, October 19, 2009

12:30 **Registration - Lunch in the Exhibition Hall**

14:00 **Session 1**

HOW TO MANAGE RECRUITMENT IN DIFFICULT SETTINGS AND INDICATIONS

Session Chairperson:
Philippa Smit-Marshall, Vice President Medical and Scientific Affairs, PharmaNet B.V., The Netherlands

The assessment of the risk for recruitment issues in clinical studies is critical to the timely execution of clinical development and in some situations recruitment presents a particularly difficult challenge. This session will focus on the practical aspects of subject recruitment in difficult settings, including paediatric research on rare diseases and competitive indications. The speakers will share firsthand experience of recruitment issues in clinical studies and will offer practical solutions to address them.

The Globalisation of Paediatric Research: Recruitment and retention issues and strategies to overcome them
Philippa Smit-Marshall, Vice President Medical and Scientific Affairs, PharmaNet B.V., The Netherlands

Recruitment in Clinical Trials for Rare Diseases
Khazal Paradis, Senior Vice President, Clinical Research Europe, Genzyme Europe B.V., The Netherlands

Recruiting Prevalent Conditions - Evolving global approaches
Linda Capsey, Client Services Director, Fast4wD Ogilvy, UK

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 2**

HOW PATIENTS CAN CONTRIBUTE TO EFFICIENT CLINICAL DEVELOPMENT

Session Chairperson:
Ingrid Klingmann, President, Pharmaplex bvba, Belgium

Traditionally, patients participate in clinical trials as test subjects. In recent years, however, patients and their self-help organisations have started to develop into a partnership role. With their unique knowledge about the practicalities of their diseases, they can provide valuable input into the design of protocols and patient information. They become members of ethics committees and advisory councils and even help with selection of indications and the development planning for new drugs. This session will provide a comprehensive understanding of how pharmaceutical companies can increase efficiency in their clinical trials by including patients as partners in the process.

Experience of Patients as Partners in Clinical Development - The PatientPartner Project
Kim Wevers, Project Officer PatientPartner, Dutch Genetic Alliance, The Netherlands

Patients as Partners in the Drug Development Planning Process - The EATG experience
David Haerry, EATG Representative, European AIDS Treatment Group, Belgium

A Patient's Experience as a Member of an Ethics Committee
Presenter invited

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

Tuesday, October 20, 2009

07:30 **Welcome Coffee and Registration**

09:00 **Session 3**

INTELLIGENT INTERACTION WITH INVESTIGATIVE SITES

Session Co-Chairpersons:
Christoph Gleiter, Managing Director, CenTrial GmbH, Coordination Centre for Clinical Trials at University Hospital Tuebingen and Ulm, CenTrial GmbH, Germany
Nermeen Y. Varawalla, President & CEO, ECCRO, UK

Investigative sites play a critical role in the effective conduct of clinical research, hence sponsors and CROs must adapt their practices so as to support and improve site interaction. Globalisation of clinical trials has created diverse site environments with a range of issues and challenges. However the fundamentals of contracting, study initiation and communication remain unchanged. In this session the view of investigative sites will be presented and approaches to improved site interaction discussed.

Intelligent Site Sponsoring / CRO Interactions
Michael Meisner, Director Clinical Operations, CTI Clinical Trial and Consulting Services, Germany

Role of the NHS in Hosting Academic Clinical Trials
Shona McDermott, Education & Training Officer, NHS Greater Glasgow & Clyde, Glasgow Clinical Research Facility, UK

What Do Investigators Expect from Sponsors?
Christoph Gleiter, Managing Director, CenTrial GmbH, Coordination Centre for Clinical Trials at University Hospital Tuebingen and Ulm, CenTrial GmbH, Germany

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 4**

DELIVERING THE EXPECTED VALUE FROM GLOBAL CLINICAL TRIALS

Session Chairperson:
Nermeen Y. Varawalla, President & CEO, ECCRO, UK

Global clinical trials remain a highly resource intensive and complex exercise. Hence it is disappointing that they often fail to fully match the expectations of regulators, sponsors and CROs. Given that globalisation of clinical research is set to increase, it is imperative that all stakeholders understand its challenges and continuously craft initiatives to improve the process and outcome. Speakers from a large pharmaceutical sponsor, academia and a global CRO will share experiences with such initiatives and discuss best practices.

Transformation of the Global Clinical Trials Footprint in a Big Pharma Company
Dennis N. Joseph, Area Head Clinical Operations, Pfizer, UK

TRACK 1.1
CDM - eCLINICAL - CLINICAL OPERATIONS - CLINICAL RESEARCH
POST-MARKETING DEVELOPMENT - DRUG SAFETY - QUALITY ASSURANCE

The Importance of Training in Trial Management with Emphasis on Randomised Controlled Trials in Developing Countries
John David Norrie, Professor of Biostatistics, Robertson Centre for Biostatistics, Glasgow University, UK

Managing 24-hour Medical Requests in Global Trials
Olga Nedok-Bigelow, Senior Medical Director, ICON Clinical Research GmbH, Germany

12:30 **Lunch in the Exhibition Hall**

14:00 **Session 5**

PLENARY SESSION

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 6**

OUTSOURCING
Session Chairperson:
Michael Wagener, Chief Medical Director, AC Immune SA, Switzerland

Creating Sustainable Outsourcing Partnerships
Nicki Haggan, Senior Project Manager, CSS Informatics EMEA, UK

Managing your Clinical Study Remotely: How remote can you afford to be?
Jamila Joseph, General Manager, Reliance Clinical Research Services, India

Do Niche CROs have a Role in Drug Development?
Nermeen Y. Varawalla, President & CEO, ECCRO, UK

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

18:30 - 21:00 **Networking Dinner at the Grand Hotel Aston**

Wednesday, October 21, 2009

08:00 **Welcome Coffee and Registration**

09:00 **Session 7**

LARGE POST AUTHORISATION STUDIES
Session Chairperson:
Heike Schoen, Managing Director, CSG Clinische Studien GmbH, Germany

The increasing complexity of large Late Stage and Post-Marketing studies are facing new regulatory and operational challenges. Whereas the regulatory challenges are to cope with international requirements to obtain ethical approval for Post-Marketing studies, the operational quality management is facing new procedures especially in the area of effective study monitoring. This session will provide an overview of how these important topics can be sufficiently managed. Practical examples will be given throughout the presentations.

International Post-Marketing Studies - A regulatory challenge
Olivier Chassany, Medical Head, Clinical Research & Development Department, Assistance Publique - Hopitaux de Paris, France

Centralised Monitoring in Late Phase Studies: Shifting the paradigm
Ramita Tandon, Senior Director, Global Portfolio Management, Peri-approval Services (PACE), PAREXEL International, USA

Monitoring in Non-Interventional Studies - Fit for purpose
Karin Achilles, Global Project Manager NIS, Bayer Schering Pharma AG, Germany

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 8**

NON-INTERVENTIONAL STUDIES
Session Chairperson:
Jens Reinhold, Head of Non-Interventional Studies, Bayer Schering Pharma AG, Germany

As post authorisation studies become more and more important in the product lifecycle today, they present unique challenges to the study teams compared to clinical trials. Therefore it is necessary to get alignment in the organisations regarding strategy, processes, tools, governance, regulatory requirements and implementation rules. In this session an overview will be given regarding those important aspects. This will be accompanied by practical case studies referring to which and how technology supports post approval trial and data management.

Organisational, Process and Technology Challenges in Late Phase Research
Ronald S. Waife, President, Waife & Associates Inc., USA

Integration of Technology in Post-Marketing Studies
Kate Trainor, Vice President, Operations, PAREXEL International, USA

Planning for Success in Post-Marketing Studies: Best practices for improving site retention and overall study results using electronic data capture systems
Patrick Chassaigne, Director, Late Phase Solutions, Medidata Solutions, USA

12:30 **Light Lunch in the Exhibition Hall**

14:00 **End of Conference**

Clinical Safety & Pharmacovigilance SIAC

The mission of the Clinical Safety & Pharmacovigilance SIAC is to support the professional needs of its members through high-quality training, peer interaction, and opportunities for personal growth. It also provides a collaborative forum to foster best practices and new ideas for enhancing the safety of medical products in the interest of public health.

If you are interested in joining this SIAC, please come and see us at the DIA booth



TRACK 1.2
CDM - eCLINICAL - CLINICAL OPERATIONS - CLINICAL RESEARCH
POST-MARKETING DEVELOPMENT - DRUG SAFETY - QUALITY ASSURANCE

Monday, October 19, 2009

12:30 **Registration - Lunch in the Exhibition Hall**

14:00 **Session 1**

HOW TO DEAL APPROPRIATELY WITH MISCONDUCT AND FRAUD

Session Chairperson:
Frank Wells, Vice-Chairman, Cambridgeshire 4 Research Ethics Committee, UK

Fraud is an emotive word, especially when applied to clinical research. Misconduct sounds less wicked but it can be devastating to a research project and difficult to detect. How to deal with it once it is detected remains poorly understood. This session will therefore deal with the importance of prevention of misconduct and then discuss practical details on how to detect and investigate it. Fraud is the intentional creation of false data and demands appropriate action: this will also be addressed.

Historical Reflections on the Prosecution of Research Fraud
Frank Wells, Vice-Chairman, Cambridgeshire 4 Research Ethics Committee, UK

The Whistleblower's Role, Relevance and Need for Protection
Jane Barrett, The Barrett Consultancy, UK

The Role of Information Technology in Maintaining Research Integrity
Jean-Marc Husson, Co -Director, European Diploma in Pharmaceutical Medicine, Eudipharm, France

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 2**

QUALITY ASSURANCE

Session Co-Chairpersons:
Jean-Michel Auger, Consultant in Clinical Quality Management, Strategic Services, France
Susan Trainor, CEO, Trainor & Partners International, Belgium

eTools have revolutionised and made more sophisticated the way we conduct clinical research. The success of eTools in clinical trials depends on the users' ability to implement, manage and control the technology with reliable quality to ensure efficient trial performance, quality of data and patient protection.

This session will cover the topics of eTools in-process quality control, illustrated with a practical example in ePRO, and the required qualification of auditors investigating the performance of these trials.

How to Manage In-Process Quality Control in eTools: How e-tools can help make your life easier in QC in clinical trials
Peter Schiemann, Global Head Quality Risk Management, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Simple Data Checks to Check for Fraud Data – A case study on the process of fraud detection in ePRO studies
Hannah Jane O'Gorman, Associate Director, ePRO Operations, Perceptive Informatics, UK

Conduct of Audits in Clinical Trials with eTools – Need for the development of "specialised" auditors?
Sylvie Simon, Senior Regulatory Compliance Auditor, Bristol-Myers Squibb, Belgium

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

Tuesday, October 20, 2009

07:30 **Welcome Coffee and Registration**

09:00 **Session 3**

PERSONAL MEDICINE - PRACTICAL CONSIDERATIONS ON BIOMARKERS

Session Chairperson:
Ronald S. Waife, President, Waife & Associates Inc., USA

As the pursuit of "personalised medicine" grows rapidly, new challenges will move from the laboratory to the discipline of clinical development. All aspects of clinical research will be affected, from study design to clinical trial conduct, from trial logistics to the analysis and reporting of results. These challenges are already surfacing when "only" adding biomarkers as a datapoint in traditional study design. This session will cover the range of challenges described

Challenges in Operationalising Clinical Trials for Personalised Drug Candidates
Ronald S. Waife, President, Waife & Associates Inc., USA

Design and Analysis of Clinical Studies Including a Biomarker Programme
Jean-Marc Limacher, Chief Medical Officer, Transgene, France

Laboratory Endpoints in Personalised Medicine: How to successfully handle logistics to achieve reliable lab results
Hermann Schulz, CEO, INTERLAB central lab services - worldwide GmbH, Germany

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 4**

GENE-BASED THERAPY - SHARING EXPERIENCE AND PRACTICAL ADVICE

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

Clinical trials with gene therapy require additional documentation and activities before, during and after the study conduct. For the CTA the sponsor additionally has to ask the biosafety committees of the individual Member States for authorisation. Experience has shown that approval times may considerably vary and delay the study start. Once the regulatory hurdles have been taken, the study practicalities such as IMP transport, storage, preparation and administration may offer its own challenges. Therefore, the planning of the clinical trial has to include appropriate resourcing in terms of expertise, funding and operational support as well as allow for realistic timelines.
Due to the heightened safety awareness of gene therapy, the safety planning of a clinical trial also requires the integration of long-term follow-up. The session will use case studies to illustrate the challenges and provide useful advice.



TRACK 1.2
CDM - eCLINICAL - CLINICAL OPERATIONS - CLINICAL RESEARCH
POST-MARKETING DEVELOPMENT - DRUG SAFETY - QUALITY ASSURANCE

Regulatory Experience for a Gene Therapy Product in a Large Phase II European Study
Catherine Mathis, Director of Regulatory Affairs, Transgene, France

Practical Aspects of the Clinical Trial Conduct
David Eckland, Director of Research and Development, Ark Therapeutics Ltd., UK

Safety Planning for Individual Studies and Long-Term Follow Up
Monika Pietrek, Managing Director, Pietrek Associates GmbH, Germany

12:30 **Lunch in the Exhibition Hall**

14:00 **Session 5**

PLENARY SESSION

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 6**

CLINICAL PROJECT MANAGEMENT – AN EFFICIENT APPROACH FOR COMPLEX CLINICAL TRIALS
Session Chairperson:
Alexander Gissler, Project Management Consulting and Training, Germany

During the last two decades, clinical trials, especially multi-centre and multi-national trials, have become highly complex projects with a large degree of unpredictability. Professional project management techniques, adjusted to the particular needs of clinical trials, can help to better predict the risks, identify the hurdles and plan for contingencies, in order to better manage the project's scope, timelines and budget. This session will give ideas on how to apply project management tools to clinical trials and provide project management experience in two particularly crucial areas.

Project Management Standards Applied to Clinical Trials
Alexander Gissler, Project Management Consulting and Training, Germany

Stakeholder Management in Complex Clinical Trials
Jennifer A. Kealy, Managing Director, Cascade Clinical Consulting LLC, France

Presentation title to be confirmed
Markus Lang, Clinical Operations, Section Head Clinical Study Manager II, Merz Pharmaceuticals GmbH, Germany

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

18:30 - 21:00 **Networking Dinner at the Grand Hotel Aston**

Presentations will be available online

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Wednesday, October 21, 2009

08:00 **Welcome Coffee and Registration**

09:00 **Session 7**

PRACTICAL ASPECTS OF ADAPTIVE DESIGNS
Session Chairperson:
David Wright, Senior Statistical Assessor, MHRA, UK

Many talks on adaptive designs focus on who much time can be saved and the efficiency gains that can be made over traditional designs. This is very interesting in theory but if in practice the proposed design is not feasible it may not be possible to realise these efficiency gains. This session focuses on some of the logistical challenges that using adaptive designs create. The speakers will give examples of how these challenges have been overcome and provide an insight into areas that future development programmes should focus on to ensure adaptive designs can be successfully implemented.

Practical Considerations in the Implementation and Logistics of Adaptive Trial Designs
Eva R Miller, Director, Biostatistics, ICON Clinical Research, USA

Putting Adaptive Design Into Practice
Fiona Guillard, Biostatistics Development Partners, Drug Development Sciences, GlaxoSmithKline, UK

An Example of how to Facilitate Simulations, Design, and Protocol Writing for a Combined Phase IIb/III Trial
Reinhard Eisebitt , Managing Director, ClinResearch GmbH, Germany

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 8**

CLINICAL DATA MANAGEMENT TRAINING
Session Co-Chairpersons:
Jean-Michel Auger, Consultant in Clinical Quality Management, Strategic Services, France
Joris Cauquil, Consultant, Head of Training, Head of Quality Assurance, AMITIS/Effi-Stat, Chair DMB, France

In ICH texts there is a requirement for "Qualified Data Managers". The Society for Clinical Data Management (SCDM), with the help of the International Network of Clinical Data Management Association (INCDMA) is writing the Good Clinical Data Management Practices (GCDMP), which could even possibly be a future ICH text. What are the training opportunities for current and future data managers (university, associations training groups, e-learning ...)? What about data managers' certification? What impact on training of the evolving role of data managers?

CDM training in Montpellier and Poitiers Universities
Gerard Hulbron, Teacher at Poitiers University, Pôle de Formation Biologie-Santé Licences professionnelles, DMB Board Member and DMB team leader (education group), France

Certification for Data Managers – How high is the bar?
Linda Talley, Chair SCDM, Global Manager-Biopharmaceutics, Eli Lilly and Company, USA

To Train or Not To Train? Managing Training in an Ever Changing Environment
Gail Kniveton, Director (Global), Data Services, i3, ACDM Training Committee, UK

12:30 **Light Lunch in the Exhibition Hall**

14:00 **End of Conference**

TRACK 1.3
CDM - eCLINICAL - CLINICAL OPERATIONS - CLINICAL RESEARCH
POST-MARKETING DEVELOPMENT - DRUG SAFETY - QUALITY ASSURANCE

Monday, October 19, 2009

12:30 **Registration - Lunch in the Exhibition Hall**

14:00 **Session 1**

LEADING TECHNOLOGIES – PART 1

Session Chairperson:
Mette Mackeprang Bruhn, EDC Team Leader, H. Lundbeck A/S, Denmark

In 2000 there was much discussion about Electronic Data Capture however clinical trials were still mainly paper based. As we look to 2010 the world is a very different place. Paper is history while new technologies are being developed and introduced monthly. The trick, to manage the technology while streamlining the whole clinical trial process without having technology as the raison d'etre! These technology sessions will cover practical technology today including EDC, SMS, Digital Pen, personal PDAs. There will also be discussions on the integration of multiple technologies while maintaining flexibility and the impact of technology on investigational sites

A Comparison of Data Capture Methods: Tablet PC, Personal Digital Assistant (PDA), Keyboard, and Digital Pen
Ronald Boldt, Managing Director, Allpen GmbH, Lecturer for Basics of Information Engineering, University of Applied Sciences, Berlin, Germany

Pros and Cons of Digital Pen and Paper in Clinical Trial Data Capture – Advantages and shortcomings in practical use
Petter Ericsson, Chief Science Officer, Anoto AB, Sweden

Structured Protocol Design and the Future of eClinical
Glen de Vries, President, Medidata Solutions Worldwide, USA

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 2**

LEADING TECHNOLOGIES – PART 2

Session Chairperson:
Julianne Hull, Senior Director, Global Development Data Operations, Wyeth Research, UK

2009 EDC Site Survey
Mette Mackeprang Bruhn, EDC Team Leader, H. Lundbeck A/S, Denmark

EDC Technology as a Catalyst for the Renewal of Data Management in Exploratory Drug Development
Stephan Laage-Witt, Global Head of Data & Process Management, F. Hoffmann-La Roche Ltd., Switzerland

Role of SMS Applications in Clinical Research
Sheila C Rocchio, Vice President, Marketing, Product Management, PHT Corporation, USA

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

Tuesday, October 20, 2009

07:30 **Welcome Coffee and Registration**

09:00 **Session 3**

DATA QUALITY

Session Chairperson:
Detlef Nehrdich, Director Statistics, Data Management & EDC Project Office Europe, Abbott GmbH & Co KG, Germany

Data quality has been an agenda item for many organisations in the pharmaceutical sector ever since it began. Which statistical and procedural measures are available to determine and to generate data quality? How can data quality be defined? What are the goals which can be achieved and how does this correspond to the efforts needed? This session will present the current perspectives of three individuals from industry and academia on this ever relevant topic.

The Role of Centralised Monitoring in Maximising Data Quality for Minimum Cost in Multicentre Randomised Controlled Trials
John David Norrie, Professor of Biostatistics, Robertson Centre for Biostatistics, Glasgow University, UK

Database Quality in Pharmacoepidemiology
David Pau, Senior Clinical Data Manager, Roche, France

Data Quality - How much is enough?
Detlef Nehrdich, Director Statistics, Data Management & EDC Project Office Europe, Abbott GmbH & Co KG, Germany

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 4**

CDM FOCUS ON THE FUTURE

Session Chairperson:
Nick Lucas, Vice President Global Data Management, INC Research, UK

Where is our most important focus now and in the future? In a technology-driven changing world, a profession very linked with new technologies is always looking to preparing for the future. After a presentation highlighting the current key items of focus there will be a panel session comprising representatives of major data management associations of the International Network of Clinical Data Management Associations (INCDMA).

Data Management: Where is our most important focus?
Daniela Harder, Team Leader Clinical Data Management, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Panel Discussion
- **Joris Cauquil**, Chair DMB, Consultant, Head of Training, Head of Quality Assurance, AMITIS/Effi-Stat, France
- **Fred Daniels**, Co-Chair ACDM /Premier Research Group Ltd., UK
- **Margarete Rudloff**, DVMD Representative, Director Clinical Data Management Europe / Asia Pacific, Kendle, Germany
- **Linda Talley,** Chair SCDM, Global Manager-Biopharmaceutics, Eli Lilly and Company, USA

12:30 **Lunch in the Exhibition Hall**

14:00 **Session 5**

PLENARY SESSION

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 6**

PROTOCOL DEVIATIONS

Session Chairperson:
Joris Cauquil, Consultant, Head of Training, Head of Quality Assurance, AMITIS/Effi-Stat, Chair DMB, France

During the "blind review" process we have to define precisely the populations to be analysed (ITT, PP, etc.) and to classify protocol deviations as minor or major ones. It is difficult to classify after the deviation occurs and often health authorities criticise the assigned classifications. This session is designed to share agency, industry and CRO viewpoints (including the use of "new" technologies), on how to classify and how to limit protocol deviations.

Management of Deviations from onsite Monitoring to Clinical Study Report: Proposal for an integrated process
Veronique Gelebart, R&D Clinical Data Management, sanofi-aventis, France
Dominique Fournie-loret, R&D Clinical Documentation, sanofi-aventis, France

FDA Point of View on Protocol Deviations
Sue-Jane Wang, Associate Director, Adaptive Design and Pharmacogenomics, OB/OTS/CDER, FDA, USA

Capturing Protocol Deviations in the eCRF Revolution: Is electronic always better?
David M. Girdwood, Global Data Management, Quintiles, UK

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

18:30 - 21:00 **Networking Dinner at the Grand Hotel Aston**

Wednesday, October 21, 2009

08:00 **Welcome Coffee and Registration**

09:00 **Session 7**

CLINICAL ENDPOINT ASSESSMENT

Session Chairperson:
Massimo Raineri, Head of System Development – Biometry, Actelion, Italy

Entities external to the sponsor, like Clinical Events Committees (CEC) or Independent Data Monitoring Committees (IDMC), play a fundamental role in an increasing number of clinical trials.

The review and assessment of clinical endpoints subject to interpretation is performed by CECs in order to achieve unbiased and centralised adjudication, with a homogeneous and high level of expertise which may not be available at local site.

Computerised systems can play a fundamental role in helping the sponsor to manage the full process and in providing the CEC members with best available data and integrating different data sources (CRF or e-CRF, site documents, images, eExternal providers) into a single interface. When data are dynamically updated, special attention must be given to handling and tracking the changes, enabling users to easily view and understand the impact of any update.

Similar tools can be used, in a different context, when providing data to IDMC in order to monitor patient safety and evidence of futility or evidence of benefit while the study is running.

This session will show how specifically designed online systems are used to optimise and streamline the information flow between sponsors and external committees.

Strategies and Systems Supporting the Adjudication Process in Clinical Events Committees
Massimo Raineri, Head of System Development – Biometry, Actelion, Italy

Reducing the Cost and Time of Endpoint Adjudication: A worthwhile goal?
Drew Kilpatrick, Director, Pharmacovigilance and Medical Affairs, Kendle, UK

Electronic Approaches for the Delivery of IDMC Reports
Ian Ford, Director, Robertson Centre for Biostatistics, Glasgow Clinical Trials, University of Glasgow, UK

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 8**

TECHNIQUES FOR CLINICAL ASSESSMENTS IN SPECIAL INDICATIONS

Session Chairperson:
John H. Greist, Director, Healthcare Technology Systems Inc., USA

This session will illustrate the broad range and growing use of computer applications in clinical studies through three presentations: ambulatory cognitive assessment in an everyday life setting; QT/QTc studies - ECG Data Management; and suicidality assessed directly by computer interview.

The first and third presentations will demonstrate the utility of computers in collection of data directly from subjects by computer interviews, real-time branching of an ideal human interviewer coupled with high procedural standardization, processing and reporting of collected data. The second presentation describes several roles for computer applications in management of ECG assessments.

Validation and integration of computer applications into clinical trials will also be addressed.

Ambulatory Cognitive Assessment: Measurement of Attention, Psychomotor Performance and Memory in an Everyday Life Setting
Brian Tiplady, Honorary Research Fellow, Department of Anaesthesia, Critical Care and Pain Medicine, University of Edinburgh, UK

Suicidality: Clinician and computer assessment
John H. Greist, Director, Healthcare Technology Systems Inc., USA

A Thorough Approach to QT/QTc Studies - ECG Data Management
Kjell Pennert, Richmond Pharmacology Ltd., UK

12:30 **Light Lunch in the Exhibition Hall**

14:00 **End of Conference**

TRACK 1.4
CDM - eCLINICAL - CLINICAL OPERATIONS - CLINICAL RESEARCH
POST-MARKETING DEVELOPMENT - DRUG SAFETY - QUALITY ASSURANCE

Tuesday, October 20, 2009

12:30 **Registration - Lunch in the Exhibition Hall**

14:00 **Session 5**

PLENARY SESSION

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 6**

STANDARDS – PART 1
Session Chairperson:
Pierre-Yves Lastic, Senior Director, Data Privacy & Healthcare Interoperability Standards, sanofi-aventis, France

In an increasingly complex healthcare information landscape, interoperability standards are one of the key areas to ensure a smooth flow of information between care givers, clinical trial sponsors, CROs, safety experts and regulatory agencies. Organisations like CDISC, HL7, IHE, SAFE and many others have become the main enablers healthcare information integration. These two sessions will give you an update of the latest developments in this area as well as help you better understand how things work and how they are evolving.

HL7 RIM – An introduction for non-technical professionals
Joerg Dillert, Principal Consultant, Phase Forward, Germany

The Future of Clinical Data: The evolving impact of CDISC and HL7 on data management, submission, and pharmacovigilance
Wayne Kubick, Senior Vice President, Chief Quality Officer, Lincoln Safety Group - Phase Forward, USA

Evolution of Data Standards for FDA Regulatory Submissions
FDA Representative invited

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

18:30 - 21:00 **Networking Dinner at the Grand Hotel Aston**

Wednesday, October 21, 2009

08:00 **Welcome Coffee and Registration**

09:00 **Session 7**

STANDARDS – PART 2
Session Chairperson:
Valdo Arnera, General Manager Europe, PHT Corporation, Switzerland

Standards in Your Future: How SAFE-BioPharma, IHE and CDISC are collaborating to improve safety reporting
Rich Furr, Head Global Regulatory Affairs and Chief Compliance Officer, SAFE-BioPharma Association, USA

Leveraging the use of Meta Data in Optimising Data Process Flows
Mike Bartlett, eClinical Technical Architect, H. Lundbeck A/S, Denmark

International Harmonisation of Standards in the Healthcare Area
Pierre-Yves Lastic, Senior Director, Standards Management & Data Privacy, sanofi-aventis, France

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 8**

ELECTRONIC HEALTH RECORDS
Session Chairperson:
Detlef Nehrdich, Director Statistics, Data Management & EDC Project Office Europe, Abbott GmbH & Co KG, Germany

The Electronic Health Record (EHR) is nowadays largely seen as the future vision of how to collect clinical trial data. Although many legal, technical and ethical barriers need to be overcome, this session presents two case studies which show successful integrations of EHRs into clinical research environment. In addition, the so far mainly ignored operational side of using eSource in clinical trials will be covered. What would such a trial using EHR need to look like? Who would do it? How? Would it work? More importantly, will it scale?

Connecting Healthcare and Clinical Research
Mathias Poensgen, Marketing Manager Clinical, Aris Global LLC, Germany

Electronically Enhanced Clinical Trials in Phase IV, Delivered Within the Setting of a Healthcare System
Sharon Kean, Director, Information Systems, Robertson Centre for Biostatistics, Glasgow Clinical Trials, UK

eSource and EMR: The view from the operational side
Joseph S. Anderson, Principal Associate, Waife & Associates Inc., USA

12:30 **Light Lunch in the Exhibition Hall**

14:00 **End of Conference**

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.



TRACK 2
VALIDATION

Track Chair

Breffni Martin
Director, CanReg Ltd., Ireland

Programme Sub-Committee

Andy G. Cochrane
Senior Project Analyst, MHRA, UK

This is the 9th Annual DIA European Validation Conference

The ever increasing use of computers and electronic processes for the capture, transfer, analysis and storage of clinical data means that the necessity to ensure that systems and processes are validated is all the more important. The validation track is about providing attendees with the tools, methodology and information necessary to validate those systems and keep them validated, in particular by way of case studies involving data quality and integrity. The track will also cover recent inspectional findings from the regulatory agencies.

Validation SIAC

The mission of the Validation SIAC is to:

- Be a unified voice that defines "best practices" for system validation and validation within the pharmaceutical, device and manufacturing industry, influencing vendors and communicating with regulatory agencies, globally in regard to validation standards and technologies.
- Interpret current and developing health authority guidances and regulations and their impact on business practices and to provide a common language from which to present ideas.
- Establish effective communication channels to agencies and vendors.

If you are interested in joining this SIAC, please come and see us at the DIA booth

Presentations will be available online

Registered participants will be able to download presentations after the Clinical Forum from October 30, 2009.

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

Monday, October 19, 2009

12:30 **Registration - Lunch in the Exhibition Hall**

14:00 **Session 1**

RISK VALIDATION AND eCLINICAL

Session Chairperson:
Breffni Martin, Director, CanReg Ltd., Ireland

This session will cover risk-based approaches to validation in an eClinical context covering data capture, storage and analysis.

Strengthening Relationships: How the new safety risk management requirements bring clinical and pharmacovigilance together
Mark Perrott, Managing Consultant, WCI Consulting Ltd., UK

QA Perspective on XP in a Regulated Industry
Andrea Bradbury, Vice President, Compliance and Quality, Clarix Products Group, Phase Forward, USA

Presentation title to be confirmed
Earl W. Hulihan, Senior Vice President, Regulatory Compliance, Medidata Solutions Worldwide, USA

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 2**

VALIDATION METHODOLOGY CASE STUDIES - CHALLENGES, FAILURES, AND SUCCESSES

Session Chairperson:
Teri E. Stokes, Director, GXP International, USA

What happens when validation work done in good faith is not good enough? Do validated systems guarantee valid data? How does change impact the validation of validated systems? Can validated systems be used to create fraud in clinical studies? How do you validate "bleeding edge" software applications for clinical research? This session addresses the practical outcomes of validation work in GCP environments with speakers who have experience to share. Time will also be provided for audience discussion of their experiences.

Do Validated Systems Assure Data Quality?
James Stafford, Principal Consultant, Business & Decision, UK

A CRO's Dilemma - The CDMS validation package that couldn't pass client audits
Teri E. Stokes, Director, GXP International, USA

A CRO's Challenge - Validating leading edge software for imaging clinical studies
Brenda Young, Senior Director, Clinical Operations / Clinical Trials Informatics, ACR Image Metrix, USA

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

TRACK 2
VALIDATION

Tuesday, October 20, 2009

07:30 **Welcome Coffee and Registration**

09:00 **Session 3**

COMPUTERISED SYSTEMS USED IN CLINICAL RESEARCH: BEST PRACTICES
Session Chairperson:
Earl W. Hulihan, Senior Vice President, Regulatory Compliance, Medidata Solutions Worldwide, USA

This session will present an update to industry on the "Computerised Systems in Clinical Research: Current Quality and Data Integrity Concepts," an event hosted by DIA with participants from around the world. Computerised systems and electronic data management have been embedded into clinical research at a rapid pace, in all kinds of applications. Sometimes this progress seems hardly noticed. Many of the users of these computerised systems in clinical research environments are aware of the importance for data quality and data integrity for their subjects. However, they often underestimate the impact that the use of electronic applications, use of computerised systems and transmission of patient data to remote sites may bring to the quality and integrity of data on subject safety. This initiative is intended to set a benchmark regarding requirements for computerised systems used in clinical research, at the time that awareness for this need is gradually increasing. It is simultaneously intended to support the many users struggling to implement validation processes into clinical research, stimulating innovation in the clinical research environment and promoting drug development. Proper validation and use of computerised systems will help ensure the safety of subjects, patients and the credibility of the clinical research data. After an introductory overview of the anticipated DIA publication - a result of over 100 industry professionals and regulators from around the world - presentations will be made from selected chapters.

An Overview of the Computerised Systems in Clinical Research: Current quality and data integrity concepts manual
Earl W. Hulihan, Senior Vice President, Regulatory Compliance, Medidata Solutions Worldwide, USA

Highlights from the Chapter on Data Integrity
Rolf Peter Banholzer, Global Head CQA Computerized System Services, Novartis Pharma AG, Switzerland

Stop the Madness
Ron Fitzmartin, Vice President Informatics and Knowledge Management, Daiichi Sankyo Inc., USA

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 4**

AUDITS AND INSPECTIONS
Session Chairperson:
Andy G. Cochrane, Senior Project Analyst, MHRA, UK

Has the change from paper to electronic methodology been seamless from a QA perspective? This session provides three perspectives of the impact of the change on quality assurance audits and regulatory inspection outcome: the regulator, the regulated and a e-CRF software vendor.

Inspection of an e-CRF Provider - A survivor's story
Earl W. Hulihan, Senior Vice President, Regulatory Compliance, Medidata Solutions Worldwide, USA

Presentation title to be confirmed
Innis Viviers, Senior Associate, Global Systems Quality Assurance, Johnson & Johnson Pharmaceutical R&D, UK

Additional presenter is invited

12:30 **Lunch in the Exhibition Hall**

14:00 **Session 5**

PLENARY SESSION

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 6**

CLOUD COMPUTING: AND INTERACTIVE SESSION

Moderators:
Andy G. Cochrane, Senior Project Analyst, MHRA, UK
Earl W. Hulihan, Senior Vice President, Regulatory Compliance, Medidata Solutions Worldwide, USA

Additional presenter is invited

IMPORTANT: THIS SESSION IS TAKING PLACE IN GALLIENI 4

TRACK 3
MEDICAL INFORMATION & COMMUNICATIONS

Track Chair

Janet Davies
Director, International Medical Information, Gilead Sciences, UK

This is the 3rd Annual DIA European Medical Information and Communications conference

It 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 to continue to develop a Medical Information and Communications community in Europe.

Monday, October 19, 2009

12:30 **Registration - Lunch in the Exhibition Hall**

14:00 **Session 1**

MEDICAL INFORMATION COLLABORATION IN EUROPE
Session Chairperson:
Janet Davies, Director, International Medical Information, Gilead Sciences, UK

The Medical Information and Communications track aims to build a European community of professionals working in these fields. The current status of this community, including feedback from a 2008 survey of Medical Information in Europe, will be provided. A perspective on Medical Information collaboration in the UK will be given by the Pharmaceutical Information and Pharmacovigilance Association (PIPA). In the US, the Medical Communications SIAC has been holding an annual workshop for 20 years. Relevant content and feedback from the 2009 US Medical Communications workshop will be shared. This will be followed by an interactive discussion on how to develop the Medical Information and Communications community within Europe.

Medical Information and the DIA in Europe
Janet Davies, Director, International Medical Information, Gilead Sciences, UK

Medical Information in the UK
Sarah Dunnett, PIPA President & Medical Affairs Manager, Baxter Healthcare Ltd., UK

Medical Information in the US - Feedback from the DIA Medical Communications workshop
Sharon Leighton, Consultant, Sharon Leighton Consultancy, UK
Lillian Auberson, Director Global Medical Information, Actelion Pharmaceuticals Ltd., Switzerland

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 2**

DRIVING CHANGE AND BREAKING THE MOULD
Session Chairperson:
Sharon Leighton, Consultant, Sharon Leighton Consultancy, UK

The pharmaceutical industry continues to face economic, regulatory and product portfolio pressures. Companies have responded to similar challenges in different ways. This session will look at different solutions being implemented by medical information departments across Europe. Using three case studies, delegates will learn about:
1. Different approaches adopted by companies
2. Overcoming the challenges of organisational change
3. How managers ensured that the changes delivered value to their customers, partners and organisation
4. Successfully outsourcing part of the medical information service

New European Model for Medical Information
Aaron Cockell, European Director Medical Information, Pfizer Inc., UK

Reshaping Medical Information in AstraZeneca to Maximise Business Impact
Richard Jones, Medical Information Manager, AstraZeneca, UK

Fit for the Future - A new strategic approach to Medical Information management within GSK
Andrew Williams, Director European Medical Operations, Pharma Europe, GlaxoSmithKline, UK

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

Medical Communications SIAC

Mission of the Medical Communications SIAC:
To provide a professional, neutral forum for discussion of issues and best practices related to medical communications components within the pharmaceutical and biotech industries, with an emphasis on the creation and provision of high-quality medical information to address the inquiries of healthcare professionals.

To both determine and address the educational needs of DIA members whose interest area is medical communications through such activities as:
- Designing and conducting introductory-, intermediate-, and advanced-level courses and workshops under DIA auspices.
- Contributing to DIA's Annual Meeting and EuroMeeting.

To raise awareness of medical communications and to encourage dialogue among regulators, academic institutions and other industry personnel.

If you are interested in joining this SIAC, please come and see us at the DIA booth

TRACK 3
MEDICAL INFORMATION & COMMUNICATIONS

Tuesday, October 20, 2009

07:30 **Welcome Coffee and Registration**

09:00 **Session 3**

MANAGING THE MEDICAL INFORMATION SERVICE

Session Chairperson:
Aaron Cockell, Head of Medical Operations and Information, Pfizer Ltd., UK

As managers and leaders of Medical Information functions, as well as looking at the future and seeing what that holds for us, it is vital that we deliver efficient and effective day-to-day Medical Information services to our clients, whether these are healthcare professionals or users of our products. This session will use case studies to look at two key areas of Medical Information Management:
1. Handling medical information requests
2. The recruitment of staff with the right skills

From these case studies and some lively debate you will gain a greater understanding of how other companies manage requests and the qualities they look for when recruiting staff.

24/24 – 7/7 Medical Request Handling Worldwide
Claire Laville de Lacombe, Medical Knowledge Manager, sanofi-aventis, France

Managing the Medical Information Service: Outsource and succeed
Bob Winslow, Global Director of Medical Informaiton, Quintiles, USA

How to Find People with the Right Skills
Jin Tompot-Vermaat, Medical Affairs Europe, Centocor BV, The Netherlands

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 4**

RAISING THE PROFILE OF MEDICAL INFORMATION

Session Chairperson:
Lillian Auberson, Director Global Medical Information, Actelion Pharmaceuticals Ltd., Switzerland

The quality of information is a commodity that is hard to quantify and one reason that surveys are useful for conveying the importance of a medical information service. Using surveys can help to capture the multitude of ways in which high quality product information delivered in a timely fashion can make a significant impact on other internal projects or processes. Demonstrating the value of a medical information service is good for consolidating the team and also helps to raise its profile within a company.

Using Surveys to Understand what our Internal Customers Value
Elisabeth C. Goodman, Business Operations Consultant, Enhancing Team Effectiveness, UK

Global Survey of Internal Customers
Marco Migliaccio, Global Medical Communication & Information, Head of Neurodegenerative diseases, Merck Serono SA, Switzerland

Using Surveys to Measure the Value of a Medical Information Service
Nancy Hijmans, System Support Specialist & Manager a.i., Medical Information & Operations, Medical Affairs, Centocor BV, The Netherlands

12:30 **Lunch in the Exhibition Hall**

14:00 **Session 5**

PLENARY SESSION

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 6**

CUSTOMER INTERACTIONS

Session Chairperson:
Ozgur Yuksel, Regional TA Head, CVM AMAC, Novartis Pharma AG, Switzerland

The balance between the benefits and risks of providing medical information to patients has always been a point of discussion. This session will not only provide an update on the current European regulations relating to pharmaceutical packages but will also cover challenges of communicating with patients. Interactions with healthcare professionals will also be reviewed in the session through a presentation on the issue of follow-up letters for reported adverse events.

EU Pharmaceutical Package and Impact on Communicating Medical Information to Patients
Paul Woods, Global Compliance Policy Director, AstraZeneca, UK and Co-Chair EFPIA Information to Patients Task Force

Information for Patients
Jayne Packham, Jayne Packham Consultancy, UK

Drug Safety Reporting and Powers of Persuasion
Rayna Malde, Knowledge Advisor, AstraZeneca, UK

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

18:30 - 21:00 **Networking Dinner at the Grand Hotel Aston**

Presentations will be available online

Registered participants will be able to download presentations after the Clinical Forum from October 30, 2009.

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



TRACK 3
MEDICAL INFORMATION & COMMUNICATIONS

Wednesday, October 21, 2009

08:00 **Welcome Coffee and Registration**

09:00 **Session 7**

ACHIEVING QUALITY
Session Chairperson:
Sabine Lischka-Wittman, Senior Manager Medical Information, Lilly Deutschland GmbH, Germany

Ensuring consistency and quality in Medical Information activities is increasingly important to ensure compliance with regulations and internal processes. However, the measurement of quality is not easy to achieve in practice. Three case studies will demonstrate the achievement and measurement of quality in different aspects of Medical Information activities. These case studies will illustrate quality issues for a global database, how to evaluate suppliers and using auditing to evaluate services across Europe.

A European Medical Information Audit: Achieving quality and compliance across different organisational models
Charlotte Wormleighton, European Medical Information Director, AstraZeneca, UK
Sharon Leighton, Consultant, Sharon Leighton Consultancy, UK

Producing a Balanced Quality Scorecard for Outsourcing
Sabine Lischka-Wittman, Senior Manager Medical Information, Lilly Deutschland GmbH, Germany

Validation of a Globalised Medical Information System
Serkan Oray, Head of COE Medical Systems, UCB Pharma SA, Belgium

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 8**

USING TECHNOLOGY FOR KNOWLEDGE MANAGEMENT
Joint Interest for Medical Information & Communications (Track 3) & Medical Writing (Track 5)
Session Chairperson:
Françoise Hanotte, Medical Information Coordinator, Global Medical Affairs, UCB Pharma SA, Belgium

The need for powerful knowledge management tools in pharmaceutical companies is acute and requires continuous adaptation to the "customer". These tools also require co-operation among multiple individuals and departments as well as the external scientific community. This session will share experiences in developing and implementing such tools.

Developing a Document Search and Request Web Application
Victoria Vowles, Medical Information Manager, Merck Serono S.A., Switzerland

Design and Implementation of a Global Medical and Scientific Knowledge Repository
Giovanni Angeli, Head of Global IT Medical Information, UCB, Belgium

Social Media, Online Physicians Networks and Medical Information
Daniel Palestrant, CEO and Founder, Sermo, Inc., USA

12:30 **Light Lunch in the Exhibition Hall**

14:00 **End of Conference**

Track Co-Chairs

François Aubin
Medical & Methodology Director, Cardinal Systems, France

David Wright
Senior Statistical Assessor, MHRA, UK

This is the 20th Annual DIA European Statistics Conference

The Statistics track provides seven sessions dedicated to practical examples of the latest developments in pharmaceutical statistics. Areas covered include the latest developments in two regulatory guidelines; bioequivalence and missing data. There are also sessions on the methodological challenges with using pre-clinical information in the drug development process and statistical Issues with safety data. The latest developments in modelling and simulation will also be showcased and the statistical issues with recent changes in requirements for clinical trial disclosure will also be discussed. There will also be a Q&A session to enable the audience to ask leaders in the field questions on the latest developments in methodology and their use in drug development.

Monday, October 19, 2009

12:30 **Registration - Lunch in the Exhibition Hall**

14:00 **Session 1**

HOW TO OPTIMISE THE USE OF PRE-CLINICAL INFORMATION IN THE DRUG DEVELOPMENT PROCESS?
Session Chairperson:
Emmanuel Pham, Manager for North Europe, Preclinical Biostatistics, sanofi-aventis, France

Currently, pre-clinical data are mostly used as a requirement for clinical trials and the dossier. They are included in the dossiers at different stages. However, they are not very often used as data, included in a warehouse and analysed more globally in an integrated manner. This session will provide examples of applicable integrated use of pre-clinical data with appropriate methods (for instance meta-analyses). Examples of context of interest might be safety assessment or the personalised medicine.

An Example of How Appropriate Statistical Methodology Allows Decision Making Based on Longitudinally Gathered High-dimensional Data
Geert NM Verbeke, Biostatistical Centre for Clinical Trials, Catholic University of Leuven, Belgium

Beyond the Pre-clinical Data: Crystal ball or traffic lights?
Emmanuel Pham, Manager for North Europe, Preclinical Biostatistics, sanofi-aventis, France

Improving Design of Clinical Trials Incorporating Clinical and Pre-clinical Data: Use of novel multidimensional data mining technology (KEM)
Mohammad M Afshar, CEO, Ariana Pharma, France

15:30 **Coffee Break in the Exhibition Hall**

Presentations will be available online
For more information, please go to page 28

16:00 **Session 2**

INNOVATIONS IN MODELLING AND SIMULATIONS
Session Chairperson:
Simon Day, Statistical Expert, Roche Products Ltd., UK

Simulation and modelling have been used for many years in statistical and other applied work but still their use in drug development is considered innovative and not main-stream. Do these tools increase speed but at the price of increased uncertainty or can they help us develop medicines more efficiently and without losing confidence in our decisions? Three speakers will present case studies of how modelling and simulation have been used to good effect in early and late-stage studies.

Informed Decision Making Using M&S: Case study of a selective PDE5 inhibitor for the treatment of BPH
Patrick J. Johnson, Statistician, Vifor Pharma Ltd., Switzerland

Mechanistically-Based Modelling in Clinical Drug Development: A case study with the use of a Target Mediated Drug Disposition (TMDD) model
Nicolas Frey, Global Head of Modelling and Simulation, F. Hoffmann-La-Roche AG, Switzerland

The Role of Modelling and Simulation in the Design of Adaptive Seamless Designs: A case study in secondary progressive multiple sclerosis
Tim Friede, Health Sciences Research Institute, Warwick Medical School, University of Warwick, UK

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

Tuesday, October 20, 2009

07:30 **Welcome Coffee and Registration**

09:00 **Session 3**

BIOEQUIVALENCE
Session Chairperson:
David Brown, Statistical Assessor, MHRA, UK

The CHMP bioequivalence guideline is currently being updated, detailing how bioequivalence studies should be performed to get generic products onto the market. Some of the revisions are to statistical aspects and this session outlines the changes and new ideas that are being introduced. One of the most contentious aspects has been the handling of highly variable drugs. Speakers will discuss the pros and cons of the use of scaled average bioequivalence to handle such products.

Statistical Aspects of Revision of CHMP Bioequivalence Guidelines
David Brown, Statistical Assessor, MHRA, UK

Additional presenters are invited

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 4**

MISSING DATA
Session Chairperson:
David Wright, Senior Statistical Assessor, MHRA, UK

The CHMP Missing Data guideline has been revised and has been released for public consultation. This session will explain the proposed changes made to the guideline and give an industry and

regulatory view on the changes. The 3rd speaker in this session will give a practical example of how to use different approaches in handling missing data in a dose finding adaptive trial.

Missing Data Mechanisms in a Dose Finding Adaptive Trial
Kenneth Liu, Associate Director, Merck & Co. Inc., USA

Revision of CHMP Missing Data Guideline
David Wright, Senior Statistical Assessor, MHRA, UK

Missing Data: Discussion points from the PSI Missing Data Expert Group
Alan Phillips, Vice President Biostatistics and Programming, Europe and Row, ICON Clinical Research, UK

12:30 Lunch in the Exhibition Hall

14:00 Session 5

PLENARY SESSION

15:30 Coffee Break in the Exhibition Hall

16:00 Session 6

QUESTION AND ANSWER SESSION
Session Co-Chairpersons:
François Aubin, Medical & Methodology Director, Cardinal Systems, France
David Wright, Senior Statistical Assessor, MHRA, UK

This session gives attendees the opportunity to ask the chairs of the sessions any questions they have on the latest statistical issues in drug development. Attendees will be invited to submit their questions before the session and the aim will be to cover a broad range of topics. This session will give the audience the opportunity to update their statistical knowledge base and find out in which areas the latest developments are being made in pharmaceutical statistics.

Panel Discussion
- **David Brown**, Statistical Assessor, MHRA, UK
- **Simon Day**, Statistical Expert, Roche Products Ltd., UK
- **Merete Joergensen**, Director, Global Clinical Registry, Novo Nordisk A/S, Denmark
- **Emmanuel Pham**, Manager for North Europe, Preclinical Biostatistics, sanofi-aventis, France
- **Emmanuel Pham**, sanofi-aventis, France
- **Michael Kevin Williams**, Safety Data Expert, GlaxoSmithKline, UK

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

18:30 - 21:00 Networking Dinner at the Grand Hotel Aston

Wednesday, October 21, 2009

08:00 Welcome Coffee and Registration

09:00 Session 7

CLINICAL TRIAL DISCLOSURE
Joint Interest for Statistics (Track 4) & Medical Writing (Track 5)
Session Chairperson:
Merete Joergensen, Director, Global Clinical Registry, Novo Nordisk A/S, Denmark

This is a joint session together with the Clinical Trial Registry session under the Medical Writing track.
The requirements for communicating information on clinical trials on publicly accessible websites are growing. The demands are for understandable information on design features and trial results. Statisticians and Medical Writers must take an active role. The information provided must be correct and consistent with scientific publications and reports for regulatory authorities. Also the information must be presented in a way to minimise the risk of being misleading. The session will give an overview of the present and upcoming requirements as well as sharing practical experience and challenges.

Disclosure of Information from EudraCT
Fergus Sweeney, Head of Inspections Sector, EMEA, EU

Ready, Fire, Aim - The challenge of the ever changing targets of clinical trial results posting
Jacqueline Sayers, Quality Projects Manager, PDQ, Roche Products Ltd., UK

Transparency of Clinical Trials Information, Challenges from an Operational Perspective Involving Trial Management, Statistics, Medical Writing, Publication Team and Others
Merete Joergensen, Director, Global Clinical Registry, Novo Nordisk A/S, Denmark

10:30 Coffee Break in the Exhibition Hall

11:00 Session 8

STATISTICAL ISSUES WITH SAFETY DATA
Session Chairperson:
Michael Kevin Williams, Safety Data Expert, GlaxoSmithKline, UK

The continued focus by the regulatory authorities, as well as the general public, on the way we present safety data has led to more statistically robust methodologies being applied to more fully characterise the nature and level of risk associated with drugs. By analysing data in an exploratory manner, opportunities also arise to account for other factors in a more efficient manner. In this session we will look at how application of analysis techniques can lead to a greater understanding of the safety of drugs, and how we can more effectively communicate the risks that could occur.

Quantitative Evaluation of Safety of Statins
Chitra Lele, Executive Vice President, Sciformix Corporation, India

Safety Signal Detection in Longitudinal Observational Data
William DuMouchel, Chief Statistical Scientist, Lincoln Safety Group - Phase Forward, USA

Adverse Event Data Mining
Harry Southworth, Statistical Scientist, AstraZeneca, UK

12:30 Light Lunch in the Exhibition Hall

14:00 End of Conference

Statistics SIAC

For more information on the mission of the Statistics SIAC or if you are interested in joining, please come and see us at the DIA booth






TRACK 5
MEDICAL WRITING

Track Co-Chairs

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

Janet Stoltenborg
Senior Director, Scientific Communications, AstraZeneca Pharmaceuticals LP, USA

Programme Sub-Committee

Barbara R. Kamm
Senior Manager II, Medical Writing Projects, Allergan Inc., USA

Jean H. Soul-Lawton
Global Medical Writing Director, Respiratory MDC, GlaxoSmithKline R&D, UK

This is the 7th Annual DIA European Medical Writing Conference

Monday, October 19, 2009

12:30 **Registration - Lunch in the Exhibition Hall**

14:00 **Session 1**

CLINICAL STUDY REPORT

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

This session will address some of the issues currently facing medical writers when preparing ICH E3 compliant clinical study reports. The content and placement of the various sections and appendices will be discussed, and some insights into producing reports that meet challenging timelines while maintaining quality will be presented.

Unravelling the ICH E3 Guideline - Tips for writing better clinical study reports.
Christopher J. Preston, International Documentation Manager, F. Hoffmann-La Roche Ltd., Switzerland

How to Shorten Clinical Study Report Preparation Time
Charlene Tucker, Senior Director & Group Leader, Regulatory Medical Writing, Cephalon, Inc., USA

CSR Metrics and Continuous Improvement
Henriett Totka-Rockwell, Astara Zeneca R&D, Sweden

15:30 **Coffee Break in the Exhibition Hall**

Presentations will be available online

Registered participants will be able to download presentations after the Clinical Forum from October 30, 2009.

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

16:00 **Session 2**

BEST MEDICAL WRITING PRACTICES IN THE OUTSOURCING OF AGGREGATE SAFETY REPORTS

Session Chairperson:
Brian Edwards, Director, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK

There are no current agreed standards about what constitutes safe outsourcing. Not only are there no agreed standards by means of which a sponsor assures value for money but, more importantly, there are no agreed standards to allow a sponsor or marketing authorisation holder to judge whether a contractor can be acceptably compliant and safe. This session will tackle this topic by assessing what Best Practice actually means for the writing of an aggregate safety report from the point of view of a freelance consultant and a global CRO. In addition, the argument will be presented that industry should develop the Safety Case as a way of better comparing contractors so that the most appropriate choice can be made for safely performing an allotted medical writing project.

The Safety Case as a Basis for More Effective Outsourcing of Writing of Aggregate Safety Reports
Brian Edwards, Director, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK

Writing the Development Safety Update Report (E2F): What you need to know
Sandra J. Hecker, RAC, Hecker & Associates LLC, USA

The European Annual Safety Report: A case study in best practice for outsourcing pharmacovigilance writing to a global CRO
Julia Cooper, Senior Director, Worldwide Head of Medical Writing Services, PAREXEL International Ltd., UK

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

Tuesday, October 20, 2009

07:30 **Welcome Coffee and Registration**

09:00 **Session 3**

PAEDIATRIC INVESTIGATIONAL PLANS (PIPs)

Session Chairperson:
Douglas Fiebig, Managing Director, Trilogy Writing & Consulting GmbH, Germany

The Paediatric Investigation Plan (PIP) is a new type of document required in the context of submitting a Marketing Authorisation Application in Europe. As such, project teams often have little or no previous experience to draw upon and the preparation of a PIP presents the medical writer with several challenges. Based on first-hand experience, the presentations in this session will show how the medical writer can proactively guide the project team through the process of preparing a PIP according to the EMEA guidance, thereby maximizing the chances for acceptance by the Paediatric Committee.

Better Medicines for Children: Compilation of PIPs
Holger Maria Rohde, Head of Preclinical & Medical Affairs, Pharmalex GmbH, Germany



Preparing Paediatric Investigation Plans
Douglas Fiebig, Managing Director, Trilogy Writing & Consulting GmbH, Germany

PIP Submissions and PDCO: Perspectives from industry
Presenter invited

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 4**

GLOBAL STRATEGIES IN MEDICAL WRITING

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

A successful global drug development programme is not just a matter of conducting studies in a few countries and then preparing a Marketing Authorisation Application (MAA) based on the data collected. Many regions, including the three ICH regions, have different requirements for their MAAs that go all the way back to what data were collected and where, despite the concept of the Common Technical Document (CTD). This session explores some of the differences between the EU, Japan and the US with respect to planning the development programme, including the incorporation of bridging strategies and the content of MAAs through the use of case studies.

Conducting Efficient Multi-Country Clinical Studies: Global protocols for streamlining drug development for international release
Leyna Mulholland, Director, Regulatory Affairs, Hoffmann-La Roche Inc., Japan

CTD - Does one size fit all?
Jo Vibe Tolshave, Medical Writer, Specialist, H. Lundbeck A/S, Denmark

How Common is the Common Technical Document - EU versus USA
Barry Drees, Senior Partner, Trilogy Writing & Consulting GmbH, Germany

12:30 **Lunch in the Exhibition Hall**

14:00 **Session 5**

PLENARY SESSION

15:30 **Coffee Break in the Exhibition Hall**

16:00 **Session 6**

PUBLICATIONS

Session Chairperson:
Helen Baldwin, Director, SciNopsis Scientific Writing Services, President of the European Medical Writers Association (EMWA), France

Publications are one of the vehicles the pharmaceutical industry uses to communicate the results of clinical research to the scientific community. Publications allow us to meet our ethical obligations while providing the transparency that is necessary in our profession. This session will, among other things, explore the guidelines relevant to publishing clinical data and provide suggestions for best practice.

Guidelines, Guidelines Everywhere: Which guidelines do medical writers need to know when working with publications
Noelle Holten Pind, Clinical Reporting, Global Development, Novo Nordisk A/S, Denmark

Medical Writers Role in Publications
Helen Baldwin, Director, SciNopsis Scientific Writing Services, President of the European Medical Writers Association (EMWA), France

Ethical Publications: A pharmaceutical company's experience
Laurence Rouxhet, Manager, Publications Management, GCRD, Scientific and Public Disclosure, GlaxoSmithkline Biologicals, Belgium

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

18:30 - 21:00 **Networking Dinner at the Grand Hotel Aston**

Wednesday, October 21, 2009

08:00 **Welcome Coffee and Registration**

09:00 **Session 7**

WRITING FOR PATIENTS
Joint Interest for Medical Information & Communications (Track 3) & Medical Writing (Track 5)

Session Chairperson:
Jean H. Soul-Lawton, Global Medical Writing Director, Respiratory MDC, GlaxoSmithKline R&D, UK

There are many pieces of information relating to clinical studies that are of relevance and interest to patients. These are routinely provided in documents that are created primarily for a regulatory audience and not necessarily written with the patient in mind. Achieving the latter is an ongoing challenge and this session will explore the advances made and challenges that remain in writing for patients. We will specifically look at patient information leaflets, the informed consent form and reporting of clinical study results.

The ICF - A balancing act
James Wolfe, Associate Director, Medical Writing Services Europe, Parexel International, France

The Complexities of Communicating Results to Study Participants
Jean H. Soul-Lawton, Global Medical Writing Director, Respiratory MDC, GlaxoSmithKline R&D, UK

Improving Written Health Information Materials
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, School of Healthcare, UK

10:30 **Coffee Break in the Exhibition Hall**

11:00 **Session 8**

CLINICAL TRIAL REGISTRY
Joint Interest for Statistics (Track 4) & Medical Writing (Track 5)
Session Chairperson:
Françoise de Crémiers, FdC Consulting, France

This is a joint session with the Clinical Trial Disclosure session under the Statistics track.

This session will focus on clinicaltrial.gov and the Implementation of the US Act, known as the FDAAA, the latest developments related to the Adverse Events Section as well as the International Dimension. The practical aspects, experiences and needs of Medical Writers' will also be discussed.

The panel discussion with presenters from both joint sessions will share the experiences and challenges of US and EU representatives covering clinicalTrials.gov and EudraCT.

Implementation of the FDAAA Requirements
Aaron B. Bernstein, Director, Global Head of Regulatory Planning, Hoffmann-La Roche Inc.,USA

The International Dimension of Registries and Databases
Fergus Sweeney, Head of Inspections Sector, EMEA, EU

Transparency in Clinical Trial Results: What the medical writer needs to know
Aaron B. Bernstein, Director, Global Head of Regulatory Planning, Hoffmann-La Roche Inc., USA

Panel Discussion on Registries and Result databases: International challenges and shared experiences
- **Aaron B. Bernstein**, Director, Global Head of Regulatory Planning, Hoffmann-La Roche Inc., USA
- **Merete Joergensen**, Director, Global Clinical Registry, Novo Nordisk A/S, Denmark
- **Jacqueline Sayers**, Quality Projects Manager, PDQ, Roche Products Ltd., UK
- **Fergus Sweeney**, Head of Inspections Sector, EMEA, EU

12:30 **Light Lunch in the Exhibition Hall**

14:00 **End of Conference**

Medical Writing SIAC

The Medical Writing SIAC just one of many member benefits that DIA offers. The SIAC provides a discipline-specific, global community where members can share common experiences and knowledge and connect with others in their particular field. Members will also find opportunities for leadership and networking within each SIAC.

The mission of the Medical Writing SIAC is to provide a professional, neutral forum for discussion of issues related to the definition and development of medical writing for the pharmaceutical and biotechnology industries, both regulated and non-regulated documents.
To both determine and address the educational needs of DIA members whose interest area is medical writing through such activities as:
- Designing and conducting introductory, intermediate and advanced level courses and workshops under DIA auspices
- Contributing to the Annual Meeting and EuroMeeting

To publicise the field, to stimulate members to engage in the evaluation of writing issues and to encourage dialogue between regulators, academic institutions and industry.

If you are interested in joining this SIAC, please come and see us at the DIA booth

DIA Upcoming Training Courses in Safety and Pharmacovigilance

EudraVigilance Information Day
November 4, 2009 / EMEA, London, UK

Practical Guide for Pharmacovigilance:
Clinical Trials and Post Marketing
November 18-20, 2009 / Paris, France

EudraVigilance (EV) and
EudraVigilance Medicinal Product Dictionary (EVMPD)
Courses throughout the year / EMEA, London, UK
For course details on EV, please visit www.diahome.org > Educational Offerings > EudraVigilance > Click on Related Courses

Excellence in Pharmacovigilance:
Clinical Trials and Post Marketing
February 8-12, 2010 / Paris, France
October 25-29, 2010 / Vienna, Austria

Practical Guide for Pharmacovigilance:
Clinical Trials and Post Marketing
June 2-4, 2010 / Prague, Czech Republic
December 1-3, 2010 / Paris, France

Medical Approach in Diagnosis and Management of ADRs
September 13-14, 2010 / Paris, France

EudraVigilance Information Day
June 22, 2010 / London, United Kingdom
October 19, 2010 / London , United Kingdom

DIA Upcoming Training Course in Non-Clinical Sciences

Non-Clinical Safety Sciences and their Regulatory Aspects
November 23-27, 2009 / Lisbon, Portugal

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www.diahome.org



Upcoming DIA Conferences

Pharmaceutical Quality Forum & Exhibition

November 9-10, 2009 | Prague, CZECH REPUBLIC ID#09106

Expert speakers from the EMEA, AGES Pharmed Austria, Laboratoire National de la Santé, Luxembourg, State Institute for Drug Control, Czech Republic and Swissmedic discuss hot topics in Pharmaceutical Quality.

This programme focuses on the assurance of quality throughout the drug lifecycle from the perspective of both, the regulatory authorities and the suppliers / manufacturers. Supply chain challenges and the paradigm change introduced by the ICH guidance on quality risk management are current hot topics. With the added complication of the economy being in turmoil, having robust processes and controls in place is a necessity.

Health Technology Assessment (HTA) Forum & Exhibition

November 25-26 | Paris, FRANCE ID#09105

- Understand the requirements of Health Technology Assessment (HTA)
- Added value and scientific methods for HTA, risk / benefit evaluations from regulatory assessment
- The drug development process and system of innovation
- The evolution process of the EU regulatory framework
- Build strategies for portfolio management, development, filing and market access.

10th Conference on European Electronic Document Management & sold out Exhibition

Before you ask "What can EDM do for me?" ask "What have I done for EDM?"

December 3-4 | Vienna, AUSTRIA ID#09111

- Operating and implementing EDMS Technologies
- Leveraging technologies for quality and efficiency
- Best practices in managing the document lifecycle
- Using metadata standards in the use and re-use of regulatory information
- XML developments and XML implementation
- Preparing eCTD filings for different European procedures
- 2009 into 2010 - Current agency experience and requirements
- Current and future submission formats

DIA/IFAPP Pharmaceutical Policy Forum 2010

February 4-5, 2010 | Hotel Hilton London Canary Wharf, London, UK ID#10102

- Transparency - EMEA Transparency Policy
- Future of Clinical Trial Legislation
- Intersection between Pharmaceutical/Device Industry and Healthcare
- Fraud and Misconduct
- Globalisation – Co-operation of EMEA and FDA
- Standardisation of Investigational Site Qualification

22nd Annual EuroMeeting & Exhibition

March 8-10, 2010 | MONACO ID#10101

- More than 3,000 professionals from over 50 countries
- Professionals from the biopharmaceutical industry, contract service organisations, academic research centres, regulatory agencies, health ministries, patient organisations and trade associations.
- Hear representatives from the EMEA, FDA and National Competent Authorities throughout Europe
- Attend presentations by more than 350 speakers
- Attend pre-conference tutorials
- Network with professional colleagues from around the world
- Visit more than 240 exhibitors in Europe's largest interactive exhibit hall
- Choose from over 125 sessions in 12 themes

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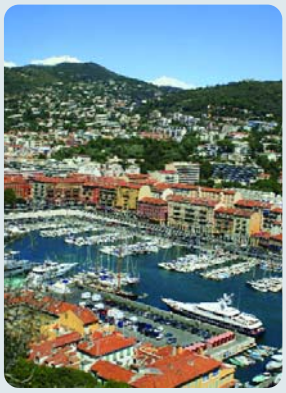
ABOUT NICE



DIA looks forward to welcoming you and your colleagues to Nice, France for the 3rd Annual Clinical Forum! Nice is the capital of the Alpes Maritimes. Located at the south eastern extremity of France, Nice is a privileged crossroad between the Alps, Provence and Corsica. The city occupies an exceptional natural site in the heart of the French Riviera. It stretches over a coastal plain open southward into the Mediterranean and bounded from East to West by a succession of wooded hills. Nice covers a surface area of 72 km^2 and has a population of 346,000. The region's climate is continental, with a pleasant average temperature of 18°C during October.

The city's seaside location and exceptional sunshine (yearly average 300 days) makes Nice a destination of choice. The Nice Acropolis Congress Centre is nestled in the heart of Nice, just 15 minutes from the airport and close to excellent hotels, restaurants and attractions.

For more information about the Clinical Forum 2009, please contact the DIA European Customer Services Team on +41 61 225 51 51; email: diaeurope@diaeurope.org, or visit www.diahome.org > Educational Offerings > click on the Clinical Forum icon.

CONGRESS CENTRE
Nice Acropolis
1, Esplanade Kennedy 63202 Nice, France
Tel: +33 4 93 92 83 00 Fax: + 33 4 93 92 82 55
www.nice-acropolis.com

PASSPORT & VISA REQUIREMENTS
Delegates from countries within the European Union need a valid passport or ID to travel to France. All other delegates should contact the nearest French Embassy or Consulate for visa requirements.

For further queries visit: http://www.diplomatie.gouv.fr > click on Going to France

PUBLIC TRANSPORTATION & TAXIS
Nice is a small town and you can manage easily on foot making the most of the opportunity to see Nice's beautiful architecture. Should you wish to use the extensive bus and tramway system in the city, you will find a bus and tram station outside the Acropolis Congress Centre.

Taxis are reasonably priced and there are taxi stands in front of the Acropolis Congress Centre and the Central Railway Station as well as on the Promenade des Anglais.

TRAVEL
The Nice-Côte d'Azur Airport is France's busiest international airport after Paris and represents an ideal gateway to the South of Europe. The airport is only 7 kilometres away from the city. A bus service runs every 20 minutes between the airport and the bus station which is located close to the Acropolis Congress Centre and the old town. Taxis are also available outside the airport.

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 in the Main Entrance Hall, Level 1

Opening hours:

Monday	**08:00 - 18:30**
Tuesday	**07:30 - 18:30**
Wednesday	**08:00 - 12:30**

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 from Wednesday, October 21, 2009.

If you would like to receive your certificate after the conference please call us on +41 61 225 51 51.

HOTEL INFORMATION

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

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

Hotel	Single Occupancy	Double Occupancy
2 Le Meridien Hotel ****		
Classic Rooms	€ 175.00	€ 190.00
Superior Rooms	€ 220.00	€ 235.00
15-20 min. walking distance to Acropolis Congress Centre		
3 NH Hotel Nice ****		
Standard Rooms	€ 175.00	€ 195.00
2 min. walking distance to Acropolis Congress Centre		
4 Grand Hotel Aston ****		
Superior Rooms	€ 182.00	€ 224.00
10 min. walking distance to Acropolis Congress Centre		
5 Novotel Nice ***		
Standard Rooms	€ 154.00	€ 179.00
2 min. walking distance to Acropolis Congress Centre		
6 Massena Hotel ***		
Privilège Rooms	€ 129.00	€ 139.00
10 min. walking distance to Acropolis Congress Centre		

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

REGISTRATION FORM

3rd Annual Clinical Forum Nice 2009
Nice Acropolis, Nice, France - October 19-21, 2009

ID# 09103

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Early-Bird rates available for Members: Deadline on or before September 4, 2009

Join DIA now to qualify for the early-bird member fee! 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 Fee (on or before September 4, 2009)	FEE	VAT 19.6%	TOTAL
Join DIA now to qualify for the Early-Bird Rate	€ 115.00	n/a	€ **115.00** ❑
Early-Bird Industry	€ 1'060.00	€ 207.76	€ **1'267.76** ❑

CATEGORY	MEMBER (after September 4, 2009) FEE	VAT 19.6%	TOTAL	NON-MEMBER (with optional membership) FEE	VAT 19.6%	Membership	TOTAL	NON-MEMBER (without optional membership) FEE	VAT 19.6%	TOTAL
Industry	€ 1'260.00	€ 246.96	€ **1'506.96** ❑	€ 1'260.00	€ 246.96	€ 115.00	€ **1'621.96** ❑	€ 1'375.00	€ 269.50	€ **1'644.50** ❑
Charitable/Non-profit/Academia (Full-Time)	€ 945.00	€ 185.22	€ **1'130.22** ❑	€ 945.00	€ 185.22	€ 115.00	€ **1'245.22** ❑	€ 1'060.00	€ 207.76	€ **1'267.76** ❑
Government (Full-Time)	€ 630.00	€ 123.48	€ **753.48** ❑	€ 630.00	€ 123.48	€ 115.00	€ **868.48** ❑	€ 745.00	€ 146.02	€ **891.02** ❑

Monday, October 19, 2009
Tutorial Fee € 350.00 € 68.60 € **418.60** ❑ Please indicate the tutorial number you wish to attend: _____

Tuesday, October 20, 2009
Networking Dinner € 48.50 € 9.50 € **58.00** ❑

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the event

PLEASE INDICATE WHICH TRACK YOU ARE INTENDING TO FOLLOW:

- ❑ **Track 1:** CDM, eClinical, Clinical Operations, Clinical Research, Post-Marketing Development, Drug Safety, Quality Assurance
- ❑ **Track 2:** Validation
- ❑ **Track 3:** Medical Information & Communications
- ❑ **Track 4:** Statistics
- ❑ **Track 5:** Medical Writing

STUDENT AND GROUP DISCOUNTS RATES ARE AVAILABLE! PLEASE CONTACT DIA FOR MORE INFORMATION. 09103DIAWEB

REGISTRANT

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

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name

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 your professional category: ❑ **Academia** ❑ **Government** ❑ **Industry** ❑ **Contract Service Organisation**

PAYMENT METHODS

❑ **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.

❑ **VISA** ❑ **MC** ❑ **AMEX**

Card Number

Exp. Date

Cardholder's Name

Date Cardholder's Signature

❑ **Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
D.I.A., 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# 09103 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.**

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

All cancellations must be in writing and received at the DIA office by 17:00 CET on October 12, 2009

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. Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify the DIA 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. If you have not received your confirmation within five working days, please contact the DIA in Europe.

HOW TO REGISTER

The DIA 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 European Office, Postfach, 4002 Basel, Switzerland

All registrations received at the DIA European Office by 18:00 CET on October 5, 2009, will be included in the Attendee List.