8th Annual Clinical Forum

Clinical Development Riding the iWave

14-15 April 2015 | Palais des Congrès | Paris

Clinical Operations
Technical Operations
Peri-Approval Research
Medical Writing

DIA DEVELOP INNOVATE ADVANCE

Final Programme

CLINICAL FORUM 2015 **PROGRAMME CHAIR**

Julianne Hull
CEO, WenStar Enterprises, UK

WELCOME FROM **THE CLINICAL FORUM 2015 CHAIR**

Dear Friends and Colleagues,

It is my great pleasure to invite you to attend the 8th Annual DIA Clinical Forum, Paris from 14–15 April 2015.

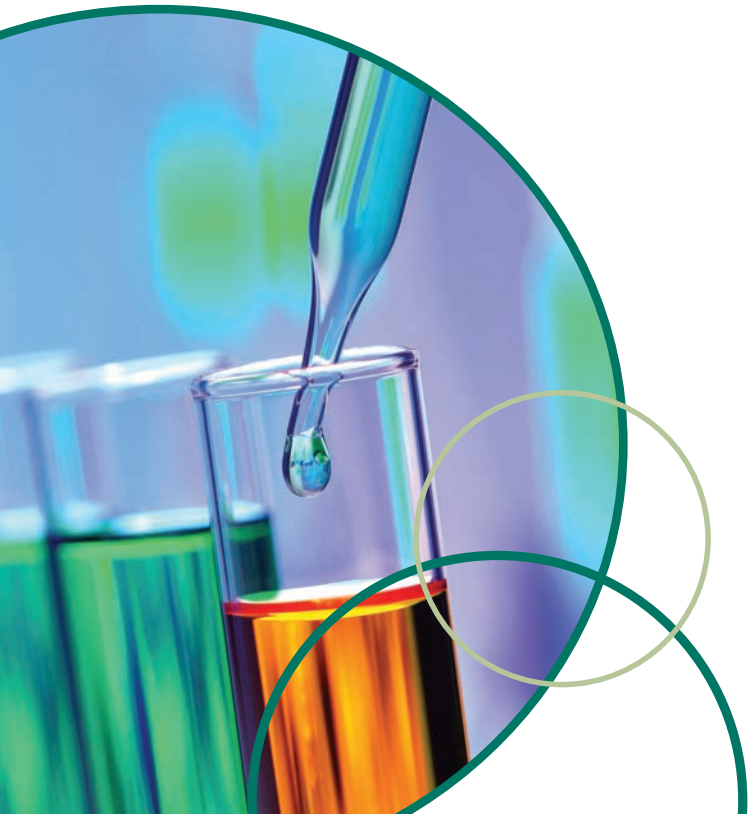
The Clinical Forum is acknowledged as the European conference for Clinical Development. This Clinical Forum will be particularly exciting as it benefits from being run in parallel with the DIA EuroMeeting. This will offer great opportunities for networking with academic and industry leaders as well as regulators across clinical development and beyond.

For 2015, although the core principles of GCP, patient safety and data integrity have not changed, how we get there is evolving at high speed. EDC is commonplace though getting to fully integrated technologies is still being surmounted. Risk Based Monitoring is an accepted expectation and real life experience should be a reality come 2015. Clinical transparency and disclosure are recognised as essential, but efficiently ensuring either is not always logistically straightforward. Technology is crucial to support and alleviate all of these challenges, however it is expensive as it is constantly changing and not always easy to integrate cross functionally.

Paris has a noble and long history in supporting science and innovation from Abelard and Heloise through Rene Descartes, Louis Pasteur, Marie Curie and more recently Jules Hoffmann. Paris in spring 2015 will help us come to grips with clinical development in the maddeningly evolving iWorld.

I look forward to welcoming you to Paris in April 2015.

Julianne Hull



About the Clinical Forum

The DIA Clinical Forum is unique amongst European conferences, bringing together thought leaders from industry in all the core disciplines; data management, clinical operations, drug safety and medical writing.

The conference provides the opportunity to share experience with peers, examine case studies, review lessons learned and discover best practice with professional colleagues from all disciplines. The increasing success of the cross-functional sessions has secured their place in the programme.

You will meet professionals from the pharmaceutical and biotech industries, CROs, clinical trial sites, health regulatory agencies and delegates from academia and patient organisations, and many more.

Make sure you don't miss out. Join us for what will be a memorable April in Paris.

CLINICAL FORUM 2015 **PROGRAMME COMMITTEE**

Mette Mackeprang Bruhn
Team Leader
Novo Nordisk A/S, Denmark

Estrella Garcia
Head of Global Clinical Operations
Almirall S.A., Spain

Detlef Nehrdich
Senior Associate
Waife & Associates, Inc., Germany

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Director, Strategy
Implementation Lead
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Thomas Martin Schindler
Head Medical Writing Europe
Boehringer Ingelheim Pharma
GmbH & Co.KG, Germany

Heike Schön
Managing Director
LUMIS International GmbH,
Germany

Mary Stewart
Vice President,
Medical Documentation
H. Lundbeck A/S, Denmark

PLENARY SESSION | TUESDAY, 14 APRIL | 16:00-17:30 | ROOM 351 LEVEL 3

Oxford Debate

Moderator:
Julianne Hull, CEO, WenStar Enterprises, UK

This house believes that people are unwilling to make their data available anonymously to aid the battle against serious diseases while carelessly sharing personal data through social media.

Panellists:
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU
Jan Geissler, Director, EUPATI, EU
Alastair Kent, Director, Genetic Alliance, UK
Pierre-Yves Lastic, Associate Vice-President, Chief Privacy Officer, Sanofi, France

PROGRAMME ADVISOR ON **VALIDATION**

Rolf Peter Banholzer
Global Head GxP IT Systems & Processes
Novartis Pharma AG, Switzerland

PROGRAMME ADVISOR ON **DATA PRIVACY AND ETHICAL ISSUES**

Pierre-Yves Lastic
Associate Vice-President, Chief Privacy Officer
Sanofi, France

SCHEDULE AT-A-GLANCE

Sunday, 12 April 2015

Registration Hours:

14:00-19:30	Exhibitor Registration and Set-up
14:00-18:00	Attendee and Speaker Registration*
17:30-18:30	Students and Young Professionals Welcome Reception

** Avoid the rush on Monday/Tuesday by picking up your badge and conference material on Sunday afternoon*

Monday, 13 April 2015

Registration Hours:

07:30-11:00	Exhibitor Registration and Set-up
07:30-18:00	Attendee, Speaker and Exhibitor Registration

Schedule:

09:00-12:30	Optional EuroMeeting Pre-Conference Tutorials*
10:30-11:00	Coffee Break
11:00-12:30	Optional EuroMeeting HAS Satellite Session
12:00-18:00	EuroMeeting Conference and Joint Exhibition Open
12:00-14:00	Lunch & Innovation Theatre Presentation in the Exhibition Hall
13:30-15:00	Optional EuroMeeting Regulatory Town Hall Meeting
14:00-17:30	Clinical Forum Pre-Conference Tutorials*
15:00-16:00	Extended Refreshment Break in the Exhibition Hall
16:00-17:45	Optional EuroMeeting Opening Plenary Session
18:00-20:30	Optional "Bienvenue à Paris" Reception

**Space is limited for Pre-Conference Tutorials, therefore pre-registration is strongly recommended. Availability for onsite registration is not guaranteed*

Tuesday, 14 April 2015

Registration Hours:

08:00-18:30	Attendee, Speaker and Exhibitor Registration

Schedule:

08:00-09:00	Welcome Coffee in the Exhibition Hall
08:00-18:30	Exhibition Hall Open
09:00-10:30	Parallel Scientific Sessions Choose from Parallel Sessions
10:15-11:00	Coffee Break in the Exhibition Hall
11:00-12:30	Parallel Scientific Sessions Choose from Parallel Sessions
12:00-14:00	Lunch & Innovation Theatre Presentation in the Exhibition Hall
12:30-13:00	Speed Networking
13:00-14:00	DIA Communities - Meet and Eat
14:00-15:30	Parallel Scientific Sessions Choose from Parallel Sessions
14:00-15:30	Exhibition Guest Passes
15:15-16:00	Coffee Break in the Exhibition Hall
16:00-17:30	Clinical Forum Plenary Session Choose from Parallel Sessions
17:30-18:30	Wine & Cheese Networking Reception in the Exhibition Hall
17:45-18:15	Student Poster Award Ceremony at the DIA Booth

Wednesday, 15 April 2015

Registration Hours:

08:00-17:30	Attendee, Speaker and Exhibitor Registration

Schedule:

08:00-09:00	Welcome Coffee
08:00-16:00	Exhibition Hall Open
09:00-10:30	Parallel Scientific Sessions Choose from Parallel Sessions
10:15-11:00	Coffee Break in the Exhibition Hall
11:00-12:30	Parallel Scientific Sessions Choose from Parallel Sessions
12:00-14:00	Lunch & Innovation Theatre Presentation in the Exhibition Hall
14:00-15:30	Parallel Scientific Sessions Choose from Parallel Sessions
15:15-16:00	Coffee Break in the Exhibition Hall
16:00-17:30	Parallel Scientific Sessions Choose from Parallel Sessions
17:30	End of Conference

DIA 8th Annual Clinical Forum 2015
Clinical Development Riding the iWave
14-15 April, Palais des Congrès, Paris

SESSION OVERVIEW

Monday, 13 April 2015				
09:00-12:30	Optional EuroMeeting Pre-Conference Tutorials			
11:00-12:30	Optional EuroMeeting HAS Satellite Session			
13:30-15:00	Optional EuroMeeting Town Hall Meeting			
14:00-17:30	Optional Clinical Forum Pre-Conference Tutorials			
16:00-17:45	Optional EuroMeeting Opening Plenary			
18:00-20:30	Optional Welcome to Paris Reception			
	Theme 1 Clinical Operations	Theme 2 Technical Operations	Theme 3 Peri-Approval Research	Theme 4 Medical Writing
Tuesday, 14 April 2015				
Session 1 09:00-10:30	CF0101 New EU-Clinical Trial Regulation	Session CF0201 Bring your own Device – Approaches to the collection of Electronic Patient – Reported Outcome Data		Session CF0401 Sponsor-Vendor Relationship
	Room 351 Level 3	Room 352B Level 3		Room 352A Level 3
10:30-11:00	Coffee Break in the Exhibition Halls			
Session 2 11:00-12:30		Session CF0202 Mobile EDC Technology	Session CF0302 All you need for Patient-Centered Studies	Session CF0402 Information Re-use and Artificial Intelligence in Reporting
		Room 352B Level 3	Room 351 Level 3	Room 352A Level 3
12:30-14:00	Lunch in the Exhibition Halls			
Session 3 14:00-15:30	Session CF0103 Pre-competitive Collaboration		Session CF0303 Big Data in the Late Phase – As clear as big?	Session CF0403 Metrics in Medial Writing
	Room 351 Level 3		Room 352B Level 3	Room 352A Level 3
15:30-16:00	Coffee Break in the Exhibition Halls			
Session 4 16:00-17:30	Plenary Session - Oxford Debate "This house believes we carelessly share personal data through social media yet are unwilling to allow our anonymised data support the battle against serious disease"			
	Room 351 Level 3			
17:30-18:30	Networking Reception in the Exhibition Halls			
Wednesday, 15 April 2015				
Session 5 09:00-10:30	Session CF0105/0405 Disclosure and Transparency		Session CF0305 Pharmacovigilance in the New Era	Session CF0105/0405 Disclosure and Transparency
	Room 352A Level 3		Room 351 Level 3	Room 352A Level 3
10:30-11:00	Coffee Break in the Exhibition Halls			
Session 6 11:00-12:30	Session CF0106/0206/0306 Risked Based Monitoring - Experiences and Challenges			Session CF0406 Lay Summaries
	Room 351 Level 3			Room 352A Level 3
12:30-14:00	Lunch in the Exhibition Halls			
Session 7 14:00-15:30	Session CF0107/0307 New Technologies to Facilitate Study Participation	Session CF0207 Using Technology - The art to know-how	Session CF0107/0307 New Technologies to Facilitate Study Participation	Session CF0407 Competencies
	Room 352B Level 3	Room 351 Level 3	Room 352B Level 3	Room 352A Level 3
15:30-16:00	Coffee Break in the Exhibition Halls			
Session 8 16:00-17:30	Session CF0108 Operational Excellence Endeavors in Clinical Research	Session CF0208 Operational Challenges in Data Management		
	Room 352B Level 3	Room 351 Level 3		

GENERAL INFORMATION A - Z

The 8th Annual Clinical Forum takes place at:
Le Palais des Congrès de Paris
2, Place de la Porte Maillot
75017 Paris – France

Registration will be located on Level 3. The conference and exhibition will take place on levels 2 and 3.

For the first time ever, the Clinical Forum is organised in parallel to another DIA flagship meeting in Europe, the 27th Annual EuroMeeting. This will afford delegates unparalleled opportunities to interact and network with qualified professionals from throughout Europe and the world, and to meet a wealth of exhibiting companies, all under one roof.

App

Download the Free DIA Global App Today.

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

To download, search for "DIA Global" in your App store.
Access the EuroMeeting 2015 App:
- Sign in with the email address you registered for the EuroMeeting 2015
- Click on the Events Icon
- Select 27th Annual DIA EuroMeeting 2015

You can find assistance at the DIA Booth #3.D17 on Level 3

Banking/ATM

Cash dispensers are available on levels -1 and 0.

Business Centre

Please note that there is no business centre at the Palais des Congrès de Paris. There is a copy/printing shop within 5 minutes walking distance from the Palais des Congrès, located at 62, Avenue de la grande Armée.
www.copytop.com/agence-grande-armee-maillot

Certificate of Attendance

A Certificate of Attendance can be printed at the Scan-and-Go desks in Hall Bordeaux on Level 3 on Wednesday, 15 April 2015 from 10:30.

Cloakroom/Baggage

The cloakroom is in the Entrance Hall in Hall Bordeaux on Level 3. There is a charge of € 2 per coat/jacket and € 3 per piece of luggage.

Monday	08:00 - 21:00
Tuesday	08:00 - 19:00
Wednesday	08:00 - 18:00

Conference Bags

All attendees with a full meeting registration can collect a conference bag from the Conference Bag Distribution Point in Hall Bordeaux on Level 3. Please bring the bag voucher you received when collecting your badge.

Credits

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

The 8th Annual Clinical Forum has been awarded 12 CPD credits from the Faculty of Pharmaceutical Medicine (FPM) of the Royal College of Physicians (RCP) of the UK. Medical practitioners who are eligible for credits can click on http://www.fpm.org.uk/cpd/registration for more information. If you are already a CPD member, please go directly to http://cpd.fpm.org.uk to claim your credits.

DIA Booth

Find out more about all DIA can offer you, how membership can advance your career, how to join a DIA Community, submit an article for publication and lots more, at the DIA Booth # 3.D17. Stop by at the DIA Booth in the Havane Exhibition Hall on Level 3. See "Exhibition" for opening hours.

DIA Patient Booth

DIA actively promotes the involvement of patient representatives in the EuroMeeting. Since 2006, more than 200 patient representatives have been involved as participants, speakers, session chairs, and also in the Programme Committee. The Patient Fellowship Booth #3.D06 is located on Level 3 and acts as a focal point for patient fellows and other stakeholders to meet and network.

Exhibition

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

Monday	12:00 - 18:00
Tuesday	08:00 - 18:30 | Public Access 14:00 - 15:30
Wednesday	08:00 - 16:00

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

Exhibitor Services

The Exhibitor Services Desks are located in Hall Maillot on Level 2. See Exhibition for opening hours.

First Aid

A pharmacy located in the shopping center on Level 0 is open daily from 09:00 to 20:00. For medical assistance during the conference hours, please visit the DIA Onsite Registration Desk. Alternatively, any DIA host/hostess will be more than happy to be of assistance.

Hotel Accommodation Information

If you have any queries about hotel accommodation, please visit the Hotel Information counter at the DIA Registration Desk located in Hall Bordeaux on Level 3.

Information Desks

If you have any questions about the Clinical Forum or the EuroMeeting, from finding session rooms to networking activities, stop by the DIA Information Desks located on Level 2 and Level 3. Alternatively, any staff member or DIA host/hostess will be more than happy to be of assistance.

Monday	08:00 - 18:00
Tuesday	08:00 - 18:30
Wednesday	08:00 - 16:00

GENERAL INFORMATION A - Z

Lost and Found
All items will be stored at the DIA Registration Desk in Hall Bordeaux on Level 3 until the end of the conference.

Members Lounge
V.I.P. Feeling for DIA Members
DIA Members can relax in the Members-only Lounge in the Exhibition Hall on level 3 during breaks, or whenever a few minutes in a quiet setting is needed. Coffee and drinks are served throughout exhibition opening hours and charging stations for your electronic devices are available. Make sure you bring your membership card to identify yourself as a DIA Member at the desk. Access exclusively for DIA Members.

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

Posters
Student, professional and patient representative posters will be displayed in the Bordeaux/Havane Hallway on Level 3. Come and talk to our student poster presenters during lunchtime on Tuesday between 13:00 and 14:00. A selected group of professional poster presenters will share their research results on various topics.

Join us at the DIA Booth #3.D17 on Level 3 on the Exhibition Floor for the Student Poster Award Ceremony on Tuesday, 14 April 2015 at 17:45.

Name Badge
Name badges must be worn at all times in the Conference Center. Participants will incur a € 25 fee for badge reprints. If you have misplaced your badge, you will be required to have a badge reprinted. Please visit Attendee Onsite Registration located in Hall Bordeaux on Level 3. Identification will be required. Please note, allowing exhibitors to scan the barcode on the front of your badge will provide them with your contact information. No children under the age of 18 years will be allowed in the Exhibition Halls due to liability issues.

Presentations
Presentations will be available to full conference attendees on the DIA web site from 9 April until 15 October 2015. Presentations are made available to full conference attendees only.
To access presentations, visit diahome.org/EM2015 and follow the links for the EuroMeeting presentations.

Press Lounge
The Press Lounge is located in Room 204 on Level 3.
DIA welcomes qualified representatives of news organisations for the purpose of reporting and publishing and broadcasting articles and stories. All media must present a copy of their press credentials upon arrival at the DIA Registration Desk. For more information, please contact Jacqueline Bowman on EUPress@diaeurope.org

Monday	12:00 - 17:45
Tuesday	08:00 - 18:30
Wednesday	08:00 - 16:00

Refreshments/Lunches
Refreshments and Lunches will be served each day on the Exhibition Floors on Levels 2 and 3. Enjoy extended refreshment and lunch hours to visit more than 140 exhibiting companies.

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

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

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

Water dispensers are located around the Exhibition Hall and session room hallways.

Registration
Registration is located in Hall Bordeaux on Level 3 and will be open as follows:

Sunday	14:00 - 18:00
Monday	08:00 - 18:00
Tuesday	08:00 - 18:00
Wednesday	08:00 - 17:30

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

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

Shopping centre
The Palais des Congrès de Paris has a shopping center with 70 shops: Palais Boutiques (www.lesboutiquesdupalais.com).

Speaker Resource Center
All speakers are required to visit the Speaker Resource Center located in room 341 on Level 3 and re-check their slides at least 2 hours before the start of their session(s).

Sunday	14:00 - 18:00
Monday	08:00 - 18:00
Tuesday	08:00 - 18:00
Wednesday	08:00 - 16:00

Student Corner
A dedicated area is located in Booth #3.A07 in the Exhibition Hall on Level 3 for students to network, plan their day, and meet for lunch.

Twitter
Tweet about the EuroMeeting using #Euro and @DIA_Europe

WiFi
Wireless internet access is available throughout the conference center and is powered by Oracle Health Sciences.

Network: DIA 2015 Password: PARIS2015

The 8th Annual Clinical Forum will take place in parallel of the 27th Annual EuroMeeting. Participants have the opportunity to register for optional tutorials for both conferences.

OPTIONAL CLINICAL FORUM PRE-CONFERENCE TUTORIALS MONDAY, 13 APRIL 2015 | 14:00-17:30

CF Tutorial 1 | Monday 13 April 2015, 14:00-17:30 | Room 242A Level 2

A LEGAL UPDATE: RECENT AND CURRENT DEVELOPMENTS IN EUROPEAN PHARMACEUTICAL LAW

John Lisman, Lawyer, Lisman Legal Life Sciences, Netherlands
Koosje van Lessen Kloeke, Life Sciences Lawyer – Partner, Leijnse Artz advocaten, Netherlands

Pharmaceutical law is at the basis of daily business in the pharmaceutical and biotech industry. In the last few years many developments have occurred in the field of pharmaceutical law, as well as in the marketing authorisation practice.

This tutorial brings you up to date with respect to the Marketing Authorisation (MA) for Biosimilars - Paediatric Regulation - Advanced Therapy Medicinal Products Regulation - Clinical Trials Regulation - Early Access to promising new medicines - Adaptive licensing - Transparency. For each of these topics the most relevant highlights will be presented in an interactive manner. Furthermore, recent European Court of Justice (ECJ) case law relevant for the audience will be discussed.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Apply pharmaceutical legislation in their daily practice.
- Explain the changes in pharmaceutical legislation in their companies.
- Participate actively in the Clinical Forum sessions dealing with new legislation, e.g. Clinical Trial Regulation.
- Recognise recent case law of the Court of Justice and the General Court.

Target Audience
Non-lawyers who work in a regulated (clinical or medical) environment from industry, government agencies and competent authorities. Lawyers from industry, government agencies and competent authorities who have recently started in their position.

CF Tutorial 2 | Monday 13 April 2015, 14:00-17:30 | Room 242B Level 2

ENSURING DATA QUALITY AND DETECTING POTENTIAL FRAUD/GCP MISCONDUCT

Marc Buyse, Chairman, IDDI (International Drug Development Institute) Inc., USA
Stephen George, Department of Biostatistics and Bioinformatics, Duke University School of Medicine, USA

A large number of options are available to operationalise the recommendations outlined in the FDA Guidance on Risk-Based Monitoring (RBM) and the EMA Reflection Paper on Quality by Design. TransCelerate's position paper provides a detailed view of some of the tools and processes that can be used for a successful implementation of RBM. This tutorial session will review the landscape of current practices with a focus on data quality and integrity. The session will demonstrate how analytical tools can support an RBM strategy by analysing clinical data to identify risks in some sites arising from lack of training, misunderstanding, carelessness, negligence or even fraud.

The session will cover the tenets of CSM (Central Statistical Monitoring) and KRI (Key Risk Indicators). The types of findings that can be detected by these two approaches will be discussed and illustrated with concrete examples. Importance will be given on how the cause of the findings can be identified and classified by seriousness, from poor protocol understanding to intent to cheat. The operational implications of the findings in terms of corrective actions to take will also be discussed.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Implement the recommendations outlined in the FDA Guidance on Risk-Based Monitoring
- Demonstrate how the use of objective, analytical tools can be used to identify sites at risk and detect potential fraud
- Interpret findings from KRIs and CSM to drive operational corrective actions

Target Audience
Professionals involved in the management of clinical trials: Data Managers, statisticians, medical reviewers, study physicians, project managers, study coordinators, quality anagers and senior management.

OPTIONAL EUROMEETING PRE-CONFERENCE TUTORIALS MONDAY, 13 APRIL 2015 | 09:00-12:30

EM Tutorial 1 | Monday 13 April 2015, 09:00-12:30 | Room 252B Level 2

HOT TOPICS IN PHARMACOVIGILANCE AND ADVERSE REACTION REPORTING

Sabine Brosch, Principle Scientific Administrator, European Medicines Agency, EU
Gaby Danan, Pharmacovigilance Expert, France

Taking into account the implementation experience with GVP module VI, which came into force on 2 July 2012, this tutorial will focus on frequently asked questions from stakeholders with regards to the day-to-day operational aspects.

In addition, practical considerations on the update of GVP module VI focusing on a simplification of the reporting of suspected adverse reactions from non-interventional post-authorisation studies, compassionate use and patient support programmes will be addressed.

At the start of 2015, the European Medicines Agency will launch a new process of monitoring medical literature for selected substances and selected medical literature in line with the provisions set out in Article 27 of Regulation 726/2004. The tutorial will provide the opportunity to discuss first experiences of marketing authorisation holders (MAHs) and to address specific implementation questions.

Article 24 of Regulation 726/2004 also outlines a new approach for marketing authorisation holders to access EU adverse reaction reports directly in EudraVigilance, following the successful outcome of an audit of the European pharmacovigilance database. In preparation of these changes, the EudraVigilance Access Policy will be updated to define the data elements of Individual Case Safety Reports (ICSR) for which access can be provided in compliance with EU personal data protection legislation. The tutorial will provide an opportunity to discuss those data elements in support of the marketing authorisation holders' pharmacovigilance obligations.

The tutorial will conclude with a detailed discussion of the reporting principles in line with the new ICH Individual Case Safety Report E2B (3) guideline thereby highlighting new concepts such as causality assessment at event level, drug reaction relatedness, amendment reports and reporting of special situations (e.g. counterfeit medicines, product defects, medication errors).

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Address FAQs on GVP Module VI "Management and reporting of adverse reactions to medicinal products" and recent updates
- Discuss the new process for monitoring of medical literature by the EMA and the potential impact on MAHs
- Describe the principles of access to EudraVigilance based on revised policy
- Discuss reporting principles based on the new ICH ICSR E2B(R3) guideline

Target Audience
This tutorial is designed for Qualified Persons Responsible for Pharmacovigilance (QPPVs) and individuals involved in Pharmacovigilance, clinical development, information management, and safety databases.

EM Tutorial 2 | Monday 13 April 2015, 09:00-12:30 | Room 253 Level 2

INTERACTIONS BETWEEN REGULATORY AND LEGAL IN INTELLECTUAL PROPERTY, PRODUCT LIABILITY AND COMPETITION

Geneviève Michaux, Counsel, Hunton & Williams, Belgium

Interactions between the regulatory regime and intellectual property (for example, SPC, data exclusivity), product liability (e.g., off label information in summary of product characteristics (SmPC), competition (for example, public procurement) and privacy (e.g., clinical trials) rules are increasing. As a result, those matters can no longer be approached in isolation, and a more comprehensive perspective is required when addressing regulatory issues.

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

Target Audience
The tutorial is designed for non lawyers with good regulatory experience and for regulatory lawyers who want to learn the basics of intellectual property, competition, and product liability rules as they apply to the pharmaceutical sector.

EM Tutorial 3 | Monday 13 April 2015, 09:00-12:30 | Room 251 Level 2

ANALYSIS OF SAFETY DATA FROM CLINICAL TRIALS

Joachim Vollmar, International Clinical Development Consultants, LLC, USA
Jürgen Kübler, Global Head, Clinical Design, Analysis and Reporting, CSL Behring AG, Germany

This tutorial is a combination of theory, guidelines, practical considerations, and real-life solutions for those working in the clinical development environment (pharmaceutical, biotech industry, or CRO). The aim of this tutorial is to provide a basic understanding of the underlying methodology and the current guidelines on safety data. Aspects of the planning of clinical trials as well as the problems and pitfalls during the analysis of safety data will be presented. Opportunities for prospective planning of safety analysis at the project level will be discussed. The presentations will also include case studies.

OPTIONAL EUROMEETING PRE-CONFERENCE TUTORIALS MONDAY, 13 APRIL 2015 | 09:00-12:30

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Examine relevant guidelines and regulatory requirements for clinical trials
- Recognise how to contribute to safety analysis plans
- Assess statistical safety analysis and identify pitfalls in safety analysis
- Recognise the impact of benefit/risk assessment in safety data

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

EM Tutorial 4 | Monday 13 April 2015, 09:00-12:30 | Room 252A Level 2

PRIVACY AND PERSONAL DATA PROTECTION IN DRUG DEVELOPMENT

Pierre-Yves Lastic, Associate Vice President, Chief Privacy Officer, Sanofi, France

This tutorial addresses issues in data privacy today:
- 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 impacting drug development
- How to comply?
- Information & consent
- Communication & training
- IT security & validation
- Legal instruments (contracts, Safe Harbor, BCRs)
- Data Privacy organisation

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Understand the principles of personal data protection in the European Union
- Understand the differences between European, US and Asian data privacy regulations
- Have a basic knowledge on how to comply with regulations in the specific field of drug development

Target Audience
This tutorial is designed for:
- All individuals involved in the organisation and management of clinical trials and pharmacovigilance, or handling data collected to perform these activities
- Professionals working with health data, clinical data, genetic data, tissue samples, medical imaging, mobile health apps, and any kind of personal data in the field of drug development

EM Tutorial 5 | Monday 13 April 2015, 09:00-12:30 | Room 241 Level 2

MOVING FROM RISK MANAGEMENT TO BENEFIT/RISK MANAGEMENT EMBEDDING PHARMACOVIGILANCE PRINCIPLES INTO THE PRODUCT LIFE CYCLE

Shelley Gandhi, Director Pharmacovigilance and Drug Safety, NDA Group, UK

Pharmacovigilance, or the activity of monitoring the safety of medicines in clinical use and taking appropriate action to minimise risk, is governed by a range of new EU legislation, a new Pharmacovigilance Risk Assessment Committee and guidance. The value that can be gained from adopting a benefit/risk management system not only addresses known and potential risks to support the current regulatory status of product but also will feed into the further development of a product as regard new indications and potentially moving from prescription only to over the counter.

This tutorial will discuss how access to robust evidence on emerging risk in post-authorisation phase, good data on how a medicine is used in clinical practice and data on background rates in the exposed population – gathering evidence throughout the product lifecycle will help move companies to a benefit/risk system. The ultimate challenge – is working towards an integrated regulatory system so you can query across all information within a company, designing safety studies, monitoring the effectiveness of the risk management systems and gather robust evidence from clinical practice.

The lessons learned and our experiences so far with post-authorisation commitments (e.g. BRMPs, PASS, PSURs) will be reviewed as will whether these commitments really do support an acceptable benefit/risk profile. This will include the novel approaches to managing benefit/risk to meet the needs of licensing medicines in biotechnology such as advanced therapies. Communicating benefit/risk will also be discussed as the new legislation will push for greater patient involvement within a benefit/risk system. Better methodologies and tools are required to support this integrated approach and adoption of a quality management system across global enterprise could achieve this.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:
- Learn about what are effective strategies and the current thinking on risk mitigation in the context of benefit throughout the product lifecycle. Access to robust evidence on emerging risk is critical
- Discover what the principles are for proportionate risk based assessment
- Find out about hurdles which get in the way to a systematic approach and how these might be tackled

DIA 8th Annual Clinical Forum 2015
Clinical Development Riding the iWave
14-15 April, Palais des Congrès, Paris

OPTIONAL EUROMEETING PRE-CONFERENCE TUTORIALS MONDAY, 13 APRIL 2015 | 09:00-12:30

Target Audience
Professionals in companies or regulatory authorities who are involved in pharmacovigilance operations and with responsibilities for post marketing clinical safety including those who are involved in:

- Pharmacovigilance
- Regulatory
- Clinical research
- Risk management
- Medical product safety assessment
- Data analysis
- Epidemiology
- Labelling
- Quality assurance and compliance

EM Tutorial 6 | Monday 13 April 2015, 09:00-12:30 | Room 242A Level 2

MODELLING AND SIMULATION

Instructor Invited

The tutorial will be an opportunity to understand better the value of Modelling and Simulation/Model Informed Drug Discovery and Development (MID3) in the development of new medicinal products, and the impact of MID3 on regulatory decision making and product labelling.

Identifying the challenges and the need for an interactive discussion between all functions involved in development, including the regulators, will be addressed.

The opportunity to hear about the expectations from regulators when M&S/MID3 approaches are used in a dossier will presented along with examples.

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To help you gain the knowledge you need to improve health and wellbeing worldwide.

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DIA Members Lounge

Hall Bordeaux Level 3

Are you looking for a space to relax or connect with other DIA members? Stop by the Members Lounge located in the Hall Bordeaux on Level 3.

This exclusive lounge offers members a place to take an important call, get online, charge devices or just relax.

Coffee and drinks are served throughout exhibition opening hours and charging stations for your electronic devices are available. Make sure you bring your membership card to identify yourself as a DIA Member at the desk. A**ccess exclusively for DIA Members.**

Note: if you have not yet received your new membership card, have it printed onsite in the Members Lounge.

Scan this QR code to learn more about DIA Membership

Theme 1
Clinical Operations

Estrella Garcia, Head of Global Clinical Operations, Almirall S.A., Spain
Holger Maria Rohde, Director, Strategy Implementation Lead, Merck Serono, Germany

Health authorities, industry and professionals of clinical operations are in continuous changes: The new EU Clinical Trial Legislation is appearing on the operational horizon, risk-based monitoring activities will deploy first results, pre-competitive industrial associations such as Transcelerate are gearing up, etc.

It's time for these professionals to come together in Paris in 2015 to discuss the operational exploitation of these new concepts. The integration of these challenges into the existing clinical operations landscape is key to success, especially to deliver in times of demanding cost constraints. New management principles such as LEAN and Six Sigma have been adapted for the R&D environment and are going to affect the way we work, trying to be more focused on patients and delivery even better quality in clinical research in record timelines.

Session CF0101 | Tuesday, 14 April, 09:00-10:30
Room 351 Level 3

NEW EU CLINICAL TRIAL REGULATION

Session Chair:
Norbert Clemens, Managing Director, Head of Clinical Development, CRS Clinical Research Services Mannheim, Germany

EU Regulation 536/2014 has been adopted by the EU Parliament and Council and is scheduled to coming fully into effect in 2016. This session aims to highlight from different ankles the most prominent administrative and operational changes stemming from the Regulation.

The Alliance for Clinical Research Excellence and Safety (ACRES): A mechanism for helping implement the new EU Clinical Trials Regulation
Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

Voluntary Harmonisation Procedure (VHP): A blueprint for the EU Clinical Trials Regulation?
Catherine Akers, Senior Manager - Regulatory Policy, Amgen Ltd, UK

Investigator Training for Clinical Trials – Opportunities in the framework of the new EU Clinical Trial Legislation
Esther Daemen, Director of Professional Development, Association of Clinical Research Professionals (ACRP), USA

Session CF0103 | Tuesday, 14 April, 14:00-15:30
Room 351 Level 3

PRE-COMPETITIVE COLLABORATIONS

Session Chair:
Christine Mayer-Nicolai, Senior Director, Head Europe Global Regulatory & Scientific Policy (GRASP), Merck Serono, Germany

Pharmaceutical industry and other sponsor groups have identified collaboration in the field of clinical trials as a key opportunity for generating efficiencies. This session is discussing several different pre-competitive models aiming to leverage these efficiencies for the benefit of the patients and faster advancement of clinical science.

The ACRES Audit Sharing Project
Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

Increasing Competitiveness of the Nordic Countries in Clinical Research through Collaboration
Mia Bengtström, Senior Advisor, Pharma Industry Finland, Finland

Solving common R&D challenges through Collaboration in R&D: TransCelerate BioPharma's Accomplishments
Peter Milligan, Vice President, Clinical Platforms Transformation, GlaxoSmithKline, UK

CF Plenary | Tuesday, 14 April, 16:00-17:30
Room 351 Level 3

PLENARY: OXFORD DEBATE

Moderator:
Julianne Hull, CEO, WenStar Enterprises, UK

This house believes that people are unwilling to make their data available anonymously to aid the battle against serious diseases while carelessly sharing personal data through social media.

Panellists:
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU
Jan Geissler, Director, EUPATI, EU
Alastair Kent, Director, Genetic Alliance, UK
Pierre-Yves Lastic, Associate Vice-President, Chief Privacy Officer, Sanofi, France

Session CF 0105/0405 | Wednesday, 15 April, 09:00-10:30
Room 352A Level 3

DISCLOSURE & TRANSPARENCY

Session Chair:
Cornelia Weiss-Haljiti, Medical Writer, Boehringer Ingelheim Pharma, Germany

Disclosure of clinical trials and transparency of clinical data are topics that have gained momentum over the past few years. Regulatory guidances and legal frameworks have been implemented in various regions. These developments affect medical writers not only as authors of regulatory documents but also as facilitators of those processes related to disclosure of study results and transparency of clinical documents. This session will focus on the various aspects of the involvement and contributions of medical writers to these processes.

Considerations on How to Audit/Assess Compliance for Publications and Clinical Trial Disclosure
Helen Powell, Principal Consultant Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

Synopsis of Clinical Study Report: A key document for disclosure
Cornelia Weiss-Haljiti, Medical Writer, Boehringer Ingelheim Pharma, Germany

The Growing Role of Medical Writers in the Era of Disclosure & Transparency
Uma Swaminathan, Director Head Clinical Process Excellence, GlaxoSmithKline, Belgium

Session CF0106/0206/0306 | Wednesday, 15 April, 11:00-12:30
Room 351 Level 3

RISKED-BASED MONITORING (RBM) - EXPERIENCES AND CHALLENGES

Session Co-Chairs:
Estrella Garcia, Head of Global Clinical Operations, Almirall S.A., Spain
Detlef Nehrdich, Senior Associate, Waife & Associates, Inc., Germany

After several years of talking about RBM guidelines and how to implement them, we believe it is time to have a look at the most recent case studies from different perspectives and to learn from real hands on experiences. Big Pharma case studies will be presented and analysed, but also the Investigator's point of view and how the new approach in monitoring is affecting the responsibilities of any involved stakeholders. Continuous improvement thinking needs to be applied in order to homogenise the way RBM is being implemented across pharma industry and is accepted by the regulators.

7 Most Essential RbM Pitfalls and Quick Way to Fix Them
Artem Andrianov, CEO, Cyntegrity Germany GmbH, Germany

RBM from the Investigator's/Site Point of View
Jutta Beier, Managing Director, insaf Respiratory Research, Germany

Risk-Based Study Management Challenges and Best Practices - case study
Robert Janiak, Director, Strategic Partnership Delivery& Continuous Improvement, Merck KGaA, Germany

Session CF0107/0307 | Wednesday, 15 April, 14:00-15:30
Room 352B Level 3

NEW TECHNOLOGIES TO FACILITATE STUDY PARTICIPATION

Session Chair:
Graham Bunn, Vice President, Perceptive Partner Program, UK

Initially new technologies focused on making studies easier for the Sponsor and CRO staff. New technology then focused on ease of access to integrated information and analytics including Sponsors, CROs and Clinical Sites. Now new technology has moved on to the Patient and this session focuses on the latest ways to improve recruitment, gather information and maintain engagement with the patient.

Designing mHealth Prototypes to Transform our Ecosystem
Alain D.G. Bindels, Global CSR Narrative Leader, F. Hoffmann-La Roche AG, Switzerland

Transforming Clinical Trials through Patient-Centric Approach and Home Monitoring Technologies
Scott Dixon, Vice President, Marketing, ERT, USA

Designing Observational Trials on Lifestyle Interventions Using Patient Reported Outcomes
Jim Roldan, CEO, Linkcare Health Services, Spain

Session CF0108 | Wednesday, 15 April, 16:00-17:30
Room 352B Level 3

OPERATIONAL EXCELLENCE ENDEAVORS IN CLINICAL RESEARCH

Session Chair:
Holger Maria Rohde, Director, Strategy Implementation Lead, Merck Serono, Germany

In clinical research, operational excellence methods such as LEAN management and Six Sigma are increasingly employed for analysing and improving clinical research. Due to the amount of stakeholders and responsibilities involved, unnecessary work has been piled up within the underlying operational processes. This "waste" can be cut back by fostering activities that create value and accelerate the flow of underlying work processes. These value improvement objectives are built around the necessity and benefits of working cooperatively across functional barriers and basic to this is a shared end-to-end process thinking mindset that often requires extensive organisational development. In this session, you will hear how operational excellence programs have been implemented in R&D and demonstrated benefits in clinical research.

Holger Maria Rohde, Director, Strategy Implementation Lead, Merck Serono, Germany

Nancy Meyerson-Hess, Global Late Clinical Development Head Quality Management GI-LCD-QM
Grünenthal, Germany

Automated Workflows as a Continuous Improvement Tool – Enhancing clinical operations efficacy
Mikhail Samsonov, Chief Medical Officer, R-Pharm, Russian Federation

Theme 2
Technical Operations

Detlef Nehrdich, Senior Associate, Waife & Associates, Inc., Germany
Mette Mackeprang Bruhn, Team Leader, Novo Nordisk A/S, Denmark

A focus of this theme will be the use of mobile, wearable technology, including patient owned devices (BYOD) and its use in clinical trials. Operational challenges in Data Management caused by an increasing trend towards outsourcing and ever-changing technologies require appropriate strategies. Corresponding examples and ideas will be shared. Finally, in a cross-functional session together with the Clinical Operations Theme on Risk- Based Monitoring, case studies and the site perspective will be presented.

Session CF0201 | Tuesday, 14 April, 09:00-10:30

Room 352B Level 3

BRING YOUR OWN DEVICE (BYOD) – APPROACHES TO THE COLLECTION OF ELECTRONIC PATIENT – REPORTED OUTCOME DATA

Session Chair:
Chad Gwaltney, Senior Director, Consulting Services ERT, UK

Bring Your Own Device (BYOD) approaches allow study subjects to use their personal telecommunication devices to complete remote (i.e., off-site) patient-reported outcome measures. This session will describe key scientific, regulatory, and operational issues when using BYOD.

Introduction to Bring Your Own Device (BYOD) Approaches
Chad Gwaltney, Senior Director, Consulting Services ERT, UK

Strengths of BYOD Approaches
Chris Watson, Product Manager, Exco InTouch, UK

Challenges Associated with BYOD Approaches
Karl McEvoy, Manager, Health Outcomes, CRF Health, UK
Open Scientific, Regulatory, and Operational Questions Regarding BYOD
Stephen Joel Coons, Executive Director, PRO Consortium, Critical Path Institute, USA

Session CF0202 | Tuesday, 14 April, 11:00-12:30

Room 352B Level 3

MOBILE ELECTRONIC DATA CAPTURE (EDC) TECHNOLOGY

Session Chair:
Mette Mackeprang Bruhn, Team Leader, Novo Nordisk, Denmark

This session will explore the potential and consequences of mobile technology used in clinical trials: from the data quality aspects of sophisticated real-time validation offered by the tablet to the unlimited data volumes that can be collected 24-7 via wearables. A new item has presented itself on the eClinical agenda: how do we scope the unlimited, and what are the regulatory and practical implications?

Improved Data Quality by Using Mobile EDC Technology with Implemented Feedback and Data Clarification Functionality
Roland John, COO, Neurostatus Systems GmbH, Switzerland

Extending from Personal Wellness – Considerations for using wearables in clinical trials
Marie McCarthy, Director of Product Innovation, ICON plc, Ireland

Not Just Clinical: The impact of wearables on your organisation
Mike Bartlett, Technical Architect, Drug Development, H. Lundbeck A/S, Denmark

CF Plenary | Tuesday, 14 April, 16:00-17:30

Room 351 Level 3

PLENARY: OXFORD DEBATE

Moderator:
Julianne Hull, CEO, WenStar Enterprises, UK

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Session CF0106/0206/0306 | Wednesday, 15 April, 11:00-12:30

Room 351 Level 3

RISKED-BASED MONITORING (RBM) - EXPERIENCES AND CHALLENGES

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Jutta Beier, Managing Director, insaf Respiratory Research, Germany

Risk-Based Study Management Challenges and Best Practices - case study
Robert Janiak, Director, Strategic Partnership Delivery& Continuous Improvement, Merck KGaA, Germany

Session CF0207 | Wednesday, 15 April, 14:00-15:30

Room 351 Level 3

USING TECHNOLOGY: THE ART OF KNOW-HOW

Session Chair:
Mike Bartlett, Senior Enterprise Architect, Drug Development, H. Lundbeck A/S, Denmark

Constant innovation in Information Technology give us unprecedented opportunities to find new and more efficient ways to run our clinical trials, however this innovation must be tempered by the regulated nature of our industry. This session looks at some of the challenges facing all of us as we move deeper into the information age.

Clinical Research in the Cloud
Nikki Dowlman, Product Director, Perceptive Informatics, UK

EDC vs. CDR – Can your Solution go 12 Rounds?
John Cline, Vice President, Client Solutions, DATATRAK, USA

Feeding the Data-Hungry (CTMS) Beast
David Stein, Independent Consultant, USA

Session CF0208 | Wednesday, 15 April, 16:00-17:30

Room 351 Level 3

OPERATIONAL CHALLENGES IN DATA MANAGEMENT

Session Chair:
Detlef Nehrdich, Senior Associate, Waife & Associates, Inc., Germany

This session will cover recent challenges in Data Management. A case study will be presented describing the migration from an insourced to a fully outsourced operational model. The challenges of managing vendors will be tackled from two sides. While one approach focuses on the potential value which successful vendor management can add to data management, another concept will be presented in which even the management of eClinical vendors has been outsourced.

A Transformation Journey for a New Data Management
Diego Herrera, Head Global Data Management & Project Information, Almirall SA, Spain

Vendor Value Data Management
Pieter Voermans, Therapeutic Area Head CNS & Metabolism, F. Hoffmann-La Roche Ltd, Switzerland

eClinical Vendor Management through CROs – a growing trend?
Graham Bunn, Vice President, Perceptive Partner Program, Perceptive, UK

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Theme 3
Peri-Approval Research

Heike Schön, Managing Director, LUMIS International GmbH, Germany
Jens Reinhold, Head Scientific Initiatives Xarelto, Bayer Pharma AG, Germany

Peri-approval research as the science to combine results and conclusions from clinical research activities with real-life experience, focuses this year on the transition from clinical development to medical affairs and related integrated topics. These range from patient-centred studies, data privacy and ethical challenges to early-stage planning of real-life evidence strategies. With the public data accessibility and data sharing for observational studies we also need a discussion around the type of governance which is needed for the industry, agencies and the public. The topics for the theme will provide the audience and the presenters an opportunity to discuss new challenges in peri-approval research as well as sharing recent experiences related to the regulatory guidances and recommendations.

Session CF0302 | Tuesday, 14 April, 11:00-12:30

Room 351 Level 3

ALL YOU NEED FOR PATIENT-CENTRED STUDIES

Session Chair:
Klaas Heinemann, Managing Director, ZEG Berlin, Germany

The term "patient-centered studies" has gained popularity only very recently. Whilst patients clearly have been in the focus of medical research all the time, information about patients was very often almost exclusively channelled through the filter of healthcare providers. Direct information from patients adds significant value to studies; this session addresses the status of the methodology.

Learnings from a Remote, Online Glucose Profiling Trial
Kai Langel, Director of Patient Solutions, eClinicalHealth Ltd., UK

Complex Study Design in Phase I Research
Ulrike Lorch, Medical Director, Richmond Pharmacology Ltd., UK

What Will Patients Tell, What Will They Distort, What Needs Clarification by Healthcare Providers?
Alfred Pauls, Board Member Research, Wilhelm-von-Humboldt Foundation, Charité University Medicine Berlin, Germany

Session CF0303 | Tuesday, 14 April, 14:00-15:30

Room 352B Level 3

BIG DATA IN THE LATE PHASE – AS CLEAR AS BIG?

Session Chair:
Heike Schön, Managing Director, LUMIS International GmbH, Germany

This session will be highly interesting for all professionals who are involved in the handling and the evaluation of real life data from multiple sources in big heterogeneous datasets. Those include, but are not limited to data obtained from social media and patients themselves, also using newly developed devices that are supposed to improve patients quality of life. When it comes to regulatory needs and reimbursement decisions, it's still an unclear and partially defined environment and aspects of needed consolidation and improvement in this area will be elaborated. Topics like probabilistic analysis, semantic analysis, cloud-based data management will be covered amongst others.

New Horizons: Do we need to validate 'big data' and social media to gain insights?
Jack Bowman, CEO & Founder, Handle My Health, UK

Exploring the Regulatory and Market Access Landscape for eHealth/ mHealth in the EU
Christophe Amiel, Senior Director, Voisin Consulting Life Sciences, France
Marcus Deans, Vice President, Global Market Access, Voisin Consulting Life Sciences, France

Implementation of Cloud Based-Data Management Solutions for Managing Complex Biologics: Challenges, risks, and best practices
Dinesh Singh, Senior Manager – Business Consulting, Cognizant Technology Solutions Corporation, UK

CF Plenary | Tuesday, 14 April, 16:00-17:30

Room 351 Level 3

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Session CF0305 | Wednesday, 15 April 09:00-10:30

Room Room 351 Level 3

PHARMACOVIGILANCE IN THE NEW ERA

Session Chair:
Jim Slattery, Statistician, European Medicines Agency, EU

Pharmacovigilance generates vast quantities of data ill and analysis processes often struggle to keep up with this process. This session examines how we deal with the data we have, how we will deal with the still larger datasets that are already planned and how we can predict and influence the future in a rational fashion.

Comparison of Statistical Signal Detection Methods
Jim Slattery, Statistician, European Medicines Agency, EU

Patient Reporting of Events: How do we cope with a pharmacovigilance tsunami?
Jack Bowman, CEO & Founder, Handle My Health, UK

Using Virtual Patient Simulation to Generate Insights on Drug Performance in Special Populations
Badri Rengarajan, Board of Directors, International Pemphigus and Pemphigoid Foundation, USA

Session CF0106/0206/0306 | Wednesday, 15 April, 11:00-12:30

Room 351 Level 3

RISKED-BASED MONITORING - EXPERIENCES AND CHALLENGES

Session Co-Chairs:
Estrella Garcia, Head of Global Clinical Operations, Almirall S.A., Spain
Detlef Nehrdich, Senior Associate, Waife & Associates, Inc., Germany

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Session CF0107/0307 | Wednesday, 15 April, 14:00-15:30

Room 352B Level 3

NEW TECHNOLOGIES TO FACILIATATE STUDY PARTICIPATION

Session Chair:
Graham Bunn, Vice President, Perceptive Partner Program, UK

Initially new technologies focused on making studies easier for the Sponsor and CRO staff. New technology then focused on ease of access to integrated information and analytics including Sponsors, CROs and Clinical Sites. Now new technology has moved on to the Patient and this session focuses on the latest ways to improve recruitment, gather information and maintain engagement with the patient.

Designing mHealth prototypes to transform our Ecosystem
Alain D.G. Bindels, Global CSR Narrative Leader, F. Hoffmann-La Roche, Switzerland

Transforming Clinical Trials through Patient-Centric Approach and Home Monitoring Technologies
Scott Dixon, Vice President, Marketing, ERT, USA

Designing observational trials on lifestyle interventions using patient reported outcomes
Jim Roldan, CEO, Linkcare Health Services, Spain

Theme 4
Medical Writing

Mary Stewart, Vice President, Medical Documentation, H. Lundbeck A/S, Denmark
Thomas Martin Schindler, Head Medical Writing Europe, Boehringer Ingelheim Pharma GmbH & Co.KG, Germany

With the new requirements for transparency and data disclosure, medical writing has entered a new era. The EMA Transparency Policy and the new EU trials regulation provide both challenges and opportunities for medical writers. Therefore, the sessions in the medical writing theme will focus on the current hot topics in the field: managing transparency of clinical trial documents, creating layperson summaries, writing PBRERs and other pharmacovigilance documents, further developing the medical writers' competencies, and designing metrics for medical writing projects. Since many of these new tasks will be addressed using external providers, the sponsor-vendor relationship in medical writing projects is of great importance.

Session CF0401 | Tuesday, 14 April, 09:00-10:30

Room 352A Level 3

SPONSOR-VENDOR RELATIONSHIP

Session Chair:
Julie De Wever, Medical and Scientific Communication Manager, Keyrus Biopharma, Belgium

This session examines the intricacies of the relationship between a sponsor and a contract research organisation (vendor) for medical writing projects. Determinants of success or failure of this relationship, practical experiences and lessons learnt will be shared with the audience through examples of different types of relationships with different sponsors.

Clinical Outsourcing Partnership between Contract Research Organisation and Sponsor for Medical Writing Services
Julie De Wever, Medical and Scientific Communication Manager, Keyrus Biopharma, Belgium

Six Key Factors for Effective Document Review: The CRO perspective
Douglas Fiebig, Senior Partner, Trilogy Writing & Consulting GmbH, Germany

Considerations for Entering a Successful Sponsor-CRO Collaboration in Scientific/Medical Writing
Anthony Durbin, Senior Manager, GSK Bio Wavre Nord, Belgium

Session CF0402 | Tuesday, 14 April, 11:00-12:30

Room 352A Level 3

INFORMATION RE-USE AND ARTIFICIAL INTELLIGENCE IN REPORTING

Session Chair:
Ross Baird, Specialist in Processes and Systems, H. Lundbeck A/S, Denmark

Employing information re-use and artificial intelligence to produce study protocols and clinical study reports might sound like science fiction, but for some medical writers it is science fact. This session will show how information re-use and artificial intelligence is being used to improve the key performance indicators for those submission documents.

Information Reuse Potential with Protocols
Mitzi Allred, Clinical Domain Program Leader, Sanofi-Aventis, USA

How Automation and Technological Advances Reduce Time and Increase Accuracy for Study Reporting
Keith Kleeman, Chief Executive Officer, ClinGenuity, USA

Session CF0403 | Tuesday, 14 April, 14:00-15:30

Room 352A Level 3

METRICS IN MEDICAL WRITING

Session Chair:
Nancy Katz, President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc., USA

"What's measured gets better." The more we understand the realities and roadblocks involved in writing clinical regulatory documents included in a drug application in electronic Common Technical Document (eCTD) format, the better we can establish meaningful metrics that ensure their accurate and timely completion. This session will describe how to define realistic metrics for writing clinical study reports (CSRs), Summary of Clinical Efficacy (Section 2.7.3 of the CTD), Summary of Clinical Safety (Section 2.7.4 of the CTD), Integrated Summary of Effectiveness (ISE), and Integrated Summary of Safety (ISS). CSRs and Sections 2.7.3 and 2.7.4 are required parts of any eCTD-based drug application, regardless of the world region in which the application is submitted. The ISE and the ISS are required parts of an application to the United States (US) Food and Drug Administration (FDA).

The Scope of Summary Documents: Results of a Questionnaire Regarding Tasks Involved in Writing 4 Clinical Documents Included in an eCTD-based Drug Application
Nancy Katz, President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc., USA

Metrics to Optimise CSR Quality and Make Effective Management Decisions
Cathy Jane Tyrrell, Senior Manager, Medical Writing and Medical Information, Kinapse, UK

Metrics – A tool to ensure quality and submission readiness of regulatory documents
Gaitry Iyer, Senior Director, Global Head of Scientific Writing Services, LS BPS, Cognizant Technology, India

CF Plenary | Tuesday, 14 April, 16:00-17:30

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Session CF0105/0405 | Wednesday, 15 April, 09:00-10:30

Room 352A Level 3

DISCLOSURE & TRANSPARENCY

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Cornelia Weiss-Haljiti, Medical Writer, Boehringer Ingelheim Pharma, Germany

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Considerations on How to Audit/Assess Compliance for Publications and Clinical Trial Disclosure
Helen Powell, Principal Consultant Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

Synopsis of Clinical Study Report: A key document for disclosure
Cornelia Weiss-Haljiti, Medical Writer, Boehringer Ingelheim Pharma, Germany

The Growing Role of Medical Writers in the Era of Disclosure & Transparency
Uma Swaminathan, Director Head Clinical Process Excellence, GlaxoSmithKline, Belgium

Session CF0406 | Wednesday, 15 April, 11:00-12:30

Room 352A Level 3

LAY SUMMARIES

Session Chair:
Thomas Schindler, Head Medical Writing Europe, Boehringer Ingelheim Pharma GmbH & Co.KG, Germany

The new EU Regulation (536/2014) introduced the requirement for a summary of study results understandable for laypersons. The guidance provided is scant and therefore sponsors need to define their processes to comply with the regulation. This session will identify potential issues and present strategies to fulfil the new requirements.

Strategies and Best Practices for the Writing and Provision of Layperson Summaries of Clinical Study Results
Thomas Schindler, Head Medical Writing Europe, Boehringer Ingelheim Pharma GmbH & Co.KG, Germany

Writing the Lay Summary (Section VI) of Risk Management Plans – Why and how?
Lisa Chamberlain James, Senior Partner, Trilogy Writing & Consulting Ltd, Germany

Information on benefit-risk of medicines to lay audiences: the EMA approach
Juan García-Burgos, Head of Medical and Health Information Service, Communication Department, European Medicines Agency, EU

Session CF0407 | Wednesday, 15 April, 14:00-15:30

Room 352A Level 3

COMPETENCIES

Session Chair:
Julia Forjanic Klapproth, Senior Partner, Trilogy Writing & Consulting GmbH, Germany

What skills and abilities are required for a medical writer to really do their job well? This session will use different document types and settings to highlight what it takes for a medical writer to not only write well but to effectively manage the whole process of interacting with multifunctional, multicultural, overworked teams.

Battling with Clinical Submissions: War rooms and other tricks of the trade
Julia Forjanic Klapproth, Senior Partner, Trilogy Writing & Consulting GmbH, Germany

Risk Management Plans (RMPs) – Hurdles and opportunities?
Bridget King, Principal Consultant Pharmacovigilance and Drug Safety, NDA Group, UK

The Essential Role for Medical Writing in IMPD/IND Submissions: Perspectives from a global pharmaceutical company
Michael John Mihm, Associate Director, Medical Writing, Astellas Pharma, Inc., USA

NETWORKING OPPORTUNITIES

Optional "Welcome to Paris" Reception

Take the exceptional opportunity to join colleagues from the EuroMeeting for an inspirational evening of networking

Monday, 13 April 2015 | 18:00-20:30 on level one of the Palais des Congrès

Join us at the the best-attended networking event of the EuroMeeting for an excellent opportunity to renew your existing contacts and to make new ones. The "Welcome to Paris" Reception will take place in a unique setting in Hall Passy on level one of the conference center. This reception is optional and not included in the registration fee. Tickets are available at the price of 60 EUR. Please visit the DIA onsite registration desk in Hall Bordeaux on level 3 to buy your tickets.

Patient Welcome Lunch

Monday, 13 april 2015 | 12:30-14:00 | Room Arlequin Level 3

Reserved for patient representatives and patient speakers only. Overview of the EuroMeeting scientific programme and an opportunity for patient representatives to meet and network with each other prior to the conference.

Speed Networking Sessions

Monday, 13 April 2015 13:00 – 13:00-13:30 in Room Arlequin Level 3 | Tuesday, 26 March 12:30-13:00 in the Exhibition Area 3B on Level 3

The EuroMeeting is used as a networking opportunity by all participants. However, it is not easy to walk right up to someone, introduce yourself and have a conversation. The EuroMeeting Speed Networking session aims to make this process a lot easier.

DIA Communities – Meet and Eat

Tuesday, 14 April 2015 | 13:00-14:00 Room Arlequin Level 3

An opportunity for all Community members – and those interested in joining one – to get together for networking at lunchtime.

Tuesday Networking Cheese & Wine Reception

Tuesday, 14 April 2015| 17:30-18:30 | Exhibition Halls Level 2 and 3

Tuesday's networking reception takes place in the Exhibition Halls on both floors. Drinks and snacks are included. It is open to all registered attendees.

Student Poster Award Ceremony

Tuesday, 14 April 2015 | 17:45-18:15

Students from around Europe will be showcasing their research in this year's Student Poster Session. Posters will be located in the Bordeaux Hallway on Level 3. In addition, join us at 17:45 in the DIA Booth 3.D17 as we present the awards for the first and second place student poster winners.

Patient Feedback Lunch

Wednesday, 15 April 2015 | 12:45-13:45 | Room Arlequin Level 3

Reserved for patient representatives and patient speakers only.

Young Professional Mentoring Lunch

Wednesday, 15 April 2015 | 12:45-13:45 | Exhibition Area 3B on Level 3

Network on the Exhibition Floors

All refreshments and lunches will be served in the Exhibition Halls, making it the ideal place to meet the people you want to meet.

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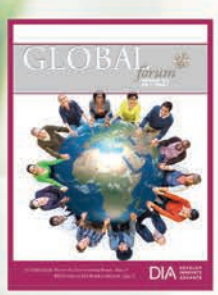

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Our bi-monthly magazine delivers thoughtful insights and analysis on health care product development, regulation, and market access. Check out the improved *Global Forum* by viewing the April issue at **GlobalForum-online.com**

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DIA Communities:
Get Engaged.
Develop Your Horizons.

Together We Can Do So Much

DIA's Communities provide our members with an opportunity to build relationships across disciplines and around the world... and at the same time contribute to improving the process of health care product development.

DIA Communities

provide a way for members across the globe to interact with their peers and to form cross-disciplinary teams. It is here that members share information, raise concerns, mentor one another, and find answers together—accomplishing more as a group than any one person could accomplish alone. DIA members are encouraged to join those Communities that match their interest areas.

To learn more about DIA Communities visit the DIA Booth #3.D17 or stop by the Membership Lounge located on Level 3 or scan the QR code below.

DIA Communities Meet & Eat

Tuesday, 14 April 2015 | 13:00-14:00
Room Arlequin, Level 3

Are you active in a Community? Come attend a relaxed, informal and rare opportunity to meet your fellow Community members face-to-face. Enjoy your lunch and share your experiences with those who are curious about DIA Communities.

New to DIA? Not part of a Community? You're invited too! This is an opportunity to ask questions and learn more about this member benefit. Look for DIA Community members who will be wearing a special button.

Scan this QR code to learn more about DIA Communities

6-8
April 2016

28th Annual **EuroMeeting**

CCH Congress Center Hamburg

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