Clinical Forum for Operational Excellence

27-28 October 2016

Hilton Düsseldorf Hotel

Düsseldorf, Germany

DIA

Clinical Forum for Operational Excellence

Hello from DIA's Senior Vice President and Managing Director, Europe, Middle East and Africa

In listening to our audiences we have identified a need to provide practical experiences to drive operational excellence while implementing all aspects of Clinical Development.

That is why we are re-formatting our Clinical Forum Conference to a platform where you will hear more about best practice from experienced instructors and your peers!

Starting this year you have the opportunity to bring your own operationally challenging case study and seek advice from the broad group of operational excellence experts attending the conference. This event will be unique in its highly interactive format.

In order to support professionals in the Clinical Development arena in their day to day challenges, the Clinical Forum has evolved into a problem-solving meeting for Clinical Operations, R&D and Data Management professionals. The focus is on real-life solutions to real-life scenarios provided by speakers, attendees, and selected solution providers that all are committed to engage in active exchange in the pursuit of best practices.

I am looking forward to welcoming you to Düsseldorf in October!

Holger Adelmann, MD, PhD
Senior VP and Managing Director
DIA Europe, Middle East & Africa

Programme Committee

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

Hans-Ulrich Burger
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Head of Clinical Development Operations, Almirall, Spain

Julianne Hull
CEO, WenStar Enterprises, UK

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Team Leader, Novo Nordisk A/S, Denmark

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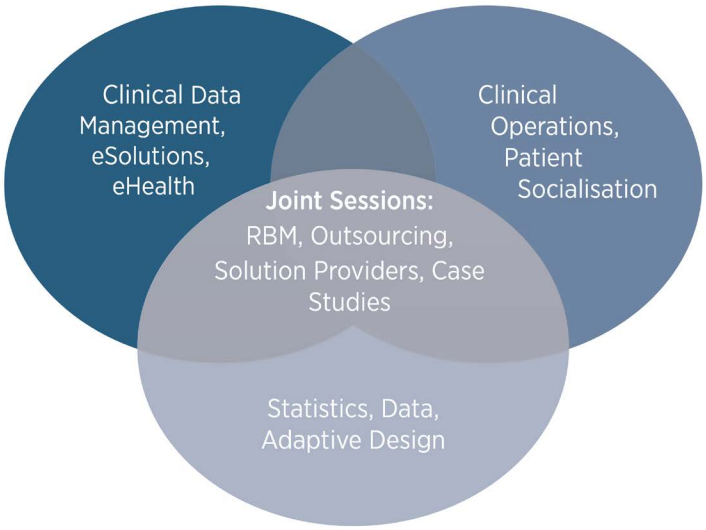
Managing Director,
LUMIS International GmbH, Germany

Peter Stokman
StokmanPharmaConsulting,
the Netherlands



The **Clinical Forum for Operational Excellence** is organised in three tracks with multiple joint sessions to break up operational silos

Clinical Forum for Operational Excellence

Conference 27-28 October 2016		Training Cource 27 October 2016
Clinical Forum for Operational Excellence		Real World Data
DAY ONE | 27 OCTOBER 2016		
09:00 - 10:30	Risk-Based Quality Management in Your Organization	The Importance of Real-World Evidence to the Healthcare Sector: General Introduction
Coffee break		
11:00 - 13:00	How RBM Binds all Stakeholders - Data Managers, Statisticians, Monitors	How to Design and Conduct Observational Studies and the Regulatory Framework
Lunch		
14:00 - 15:30	Cultural Diversity in Global Clinical Trials	How to Analyse and Use Real World Data: Challenges, Solutions and Outlook
Coffee Break		
16:00 - 17:30	How the Patient Socialisation Affect Clinical Trials	Case Studies
17:30 - 18:30 Networking		

DAY TWO | 28 OCTOBER 2016		
09:00 - 10:30	Outsourcing	
Coffee Break		
11:00 - 12:00	Outsourcing – Case Studies	
Lunch		
	TRACK A	TRACK B
13:00 - 14:30	E-solutions: eSource, e-Trial Master File, Cloud Solutions, e-Health	Data Sharing and Anonymisation
Coffee break		
14:45- 16:00	Inspections and E-Solutions: Case Studies on Regional Differences	Adaptive Design – Operational Aspect
16:00 End of Conference		

Clinical Forum for Operational Excellence

DAY ONE | 27 OCTOBER 2016

08:00 REGISTRATION AND WELCOME COFFEE

09:00 SESSION 1

RISK-BASED QUALITY MANAGEMENT IN YOUR ORGANISATION

Session Chair:
Peter Stokman, Managing Director, StokmanPharmaConsulting, Netherlands

Ten years ago ICH suggested Risk Based Quality Management as a tool in Clinical Development. This suggestion was picked up by the Transcelerate initiative to improve the quality of site monitoring by leveraging the trove of data that became available in the wake of electronic data capture. Now: what is the role of RBQM in the other areas of clinical development? Can we wait for a technical solution? Why is it needed in the first place? With the adoption of ICH E6 (R2) - the Addendum to CGP - RBQM in Clinical Development is no longer optional; it has to become an integral part of your clinical quality management system. This presentation will zoom in on background and need for RBQM in Clinical Development, and it will give practical suggestions on how to implement RBQM in your processes.

Presentations

Gunnar Danielsson, Senior Regulatory Advisor, Pharma Consulting Group, Sweden — **RBQM – Philosophy versus Reality**

Fergus Sweeney, Head of Inspections and Human Medicines Pharmacovigilance (Division) European Medicines Agency, European Union — **Regulatory Background and Impetus for Design Driven, Risk Proportionate, Processes in Clinical Trials**

Kerstin Koenig, Head Global Research & Development Quality, Merck KGaA — **RBQM: TransCelerate's Support to turn Principles into Practice**

10:30 COFFEE BREAK

11:00 SESSION 2

HOW RBM BINDS ALL STAKEHOLDERS - DATA MANAGERS, STATISTICIANS, MONITORS, INVESTIGATORS AND INSPECTORS

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

Presentations

Johann Proeve, Consultant, Clinical Data Management Consulting, Germany — **The Evolving Role of the Clinical Data Manager in the Times of Risk based Monitoring**

Nicola Schmitt, Global Product Statistician, AstraZeneca, UK — **View from the Statistician**

Jon Roth, VP Data Sciences, Biorasi LLC, USA — **Big Data' Analytic Methods to Simplify Risk-Based-Monitoring and Fraud Detection in Clinical Trials**

Erik Doffagne, Product Manager, CluePoints, Belgium — **Using Powerful and Pragmatic Central Statistical Analytics to Drive Quality into Clinical Trials**

13:00 LUNCH

14:00 SESSION 3

MANAGING CULTURAL DIVERSITY IN GLOBAL CLINICAL TRIALS

Session Chair
Heike Schoen, Managing Director, LUMIS International GmbH, Germany

Fernando Martinez, Executive Director Operations, Covance

Estrella Garcia, Head of Clinical Development Operations, Almirall, Spain

Miguel Nilsson, Executive Director, Project Management, TFS, Sweden

The ever increasing geographical complexity of clinical trials still underestimates the importance to deal with diversity of global/ international teams. Diversity offers a rich resource for innovative solutions, but how to make best use of diversity in managing global teams? It requires a cultural intelligent strategy for effectively using a team`s diversity. Global/International Clinical trial management is a great example how diversity can lead to innovative solution when properly managed. The session will discuss approaches towards managing diversity and present case studies.

15:30 COFFEE BREAK

16:00 SESSION 4

HOW PATIENT SOCIALISATION AFFECT CLINICAL TRIALS

Session Chair:
Estrella Garcia, Head of Clinical Development Operations, Almirall, Spain

The eAge is affecting our daily lives, jobs and socialization. Indeed is also affecting how patients are being involved in Clinical Trials. Patient are indeed fully connected to internet. Before visiting they doctor, they normally search bout the illness and the treatment they may receive. In addition the transparency on clinical trials is giving them the possibility to find out about new treatments, event site location where the studies are being conducted. They even public some facts in the social media networking that for sure, come positive and negative feelings, that could affect clinical trial participation in either positive or negative way, or even altering study results in a blinded manner.

How is the Pharma Industry, and the Medical Community preparing the Digitalization of patients participating in clinical trials? The new place in the Clinical Trial arena of the Community Manager in Clinical Trials.

Christine Phillips, Director, INC Research, United Kingdom — **Patient Engagement: Collaboration, Innovation and new ways to Achieve Success**

Doris Schmitt, Board member, Foundation PATH; Executive Team, EUPATI Germany — **Patient Experts supporting Treatment Protocols and Informed Consent – YES, WE CAN!**

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

DAY TWO | 28 NOVEMBER 2016

09:00 SESSION 5

OUTSOURCING: OVERSIGHT IN A FRAGMENTED WORLD

Session Chair
Julianne Hull, CEO, WenStar Enterprises, United Kingdom

Outsourcing is a fact in clinical development. There are now more employees in Clinical Research Organizations (CROs) than in pharmaceutical or Biotech companies. The shift from 'doing' to 'outsourcing, managing and overseeing' falls to the pharma and biotech companies. The CROs are responsible for the majority of the operational delivery. On top of this we see an increase in the complexity of technology and services available to deliver clinical trials from more conventional EDC, CTMS, IXRS through eCOA, risk based monitoring, Study start up specialists, spirometry, ECGs, and functional outsourcing e.g. Pharmacovigilance or Clinical Data Management. More Pharma or Biotech companies are having full service CROs subcontract on their behalf to the ancillary vendors. What does this third party outsourcing mean for CROS and for oversight by pharma/Biotech's? How do we provide evidence of appropriate oversight of our service providers? How do we reduce complexity in clinical trials?

Speakers	Presentations
Detlef Nehrdich, Senior Associate, Waife & Associates, Inc., Germany	**Outsourcing Complexity Managing the Impossible**
Bert van Leeuwen, Deputy Qualified Person for Pharmacovigilance, Astellas Pharma Europe B.V, the Netherlands	**Pharmacovigilance Outsourcing Standards**

10:30 COFFEE BREAK

11:00 SESSION 5 - CONTINUED
CASE STUDIES

Session Chair
Julianne Hull, CEO, WenStar Enterprises, United Kingdom

The participants are invited to submit case studies to be discussed on the session. The case studies are presented and discussed with the audience giving participants the opportunity for achieving operational excellence through sharing best practices and finding solutions for day-to-day business.

Speaker
Michael Walega, Executive Director, Monitoring and Data Flow Optimization, Clinical Development Services, Covance, Inc, US & **Jacqueline Gough**, Advisor, Clinical Risk Management, Eli Lilly and Company, US

Presentation
Challenging Aspect of RBM Implementation – Stakeholder and Change Management

12:00 LUNCH

13:00 SESSION 6

PARALLEL SESSION

TRACK A: E-SOLUTIONS: ESOURCE, E-TRIAL MASTER FILE, CLOUD SOLUTIONS, E-HEALTH

Session Chairs:
Valdo Arnera, General Manager, ERT, Switzerland

Multiple new 'e' technology tools and IT systems are available to enable the collection of higher volume and higher quality of data, available for data quality trending analysis at the time of data collection. The use of electronic tools and systems should allow us to improve patient safety and to collect more relevant and accurate clinical data. As a consequence, new strategies to risk based approaches to computerized system validation could be implemented, based on the facts that technology should be understood as the risk mitigator rather than as a risk for clinical data quality and integrity.

Speaker	Presentation
Valdo Arnera, General Manager, ERT, Switzerland **Tony Hewer**, Senior Director, Quality & Regulatory Affairs, Medidata Solutions Inc, United Kingdom	**Setting the Scene** **The PhUSE Framework for Cloud Adoption in the Regulated Life Sciences Industry**
Bryan McDowell, Head of Operations, Digital Development, Novartis, Switzerland	**Deconstructing the Clinical Trial Process End-to-End and Developing Disruptive Solutions that Leverage Leading-Edge Technologies, Digital Health (Mobile Health, Wearable Devices & Sensors) and Novel Settings**
Isabelle De Zegher, Vice President, PAREXEL Informatics, Belgium	**eSolutions and the Need for Convergence to Support Clinical Operations**

TRACK B: DATA SHARING AND ANONYMISATION

Session Chair
Hans-Ulrich Burger, Senior Director of Biostatistics, F. Hoffmann-La Roche Ltd., Switzerland

Data sharing is a topic which was originally kicked off by the EMA announcement that in future clinical study reports and individual patient data would be released to the public for every submission to ensure full transparency. This initiative triggered an intensive discussion globally. Pharmaceutical companies agreed to provide individual patient level data by themselves to independent researchers. There are significant consequences for the pharmaceutical industry. This concerns their dialogue with physicians, the way clinical study reports will be written, clinical studies designed, what kind of data to be sampled within a trial and last but not least also how patient confidentiality could be protected. It is important to have an overview on all these aspects when conducting studies in the future. This session should provide an overview where we are today as well as on potential consequences.

Speakers	Presentation
Sally Hollis, Head of Statistical Consulting, Phastar, United Kingdom	**Where we are with Data Sharing and Patient Level Data Sharing in the EU and Industry**
Franz Koenig, Medical University of Vienna, Austria	**Academic and Regulatory Aspects of Data Sharing**
Rebecca Sudlow, Global Lead Patient Level Data Sharing, Roche, United Kingdom	**Practical Aspects of Data Sharing: What Does this Mean for Running Trials**

14:30 COFFEE BREAK

14:45 SESSION 6 CONTINUED

PARALLEL SESSION

TRACK A: INSPECTIONS AND E-SOLUTIONS: CASE STUDIES ON REGIONAL DIFFERENCES

Session Chair:
Bryan McDowell, Head of Operations, Digital Development, Novartis, Switzerland

Today, we need to understand IT systems and e-technology as clinical development process enablers. Relative to the legacy paper processes, technology reduces and mitigates risks, provided we understand how we setup and properly validate an e-technology-enabled clinical trial.

In order to use the full potential of the currently available technology, the pharmaceutical industry, the regulatory authorities and the service providers need align to continuously improve the compliance and quality standards. The paper process as a quality reference appears to become an outdated quality concept, but major regulatory authorities nevertheless have a different understanding on how data quality and data integrity should be achieved in today's clinical trial environment.

Speaker	Presentation
Beat Widler, Co Founder and Vice President, ACRES; Managing Director, Widler & Schiemann AG, Switzerland	**Regional Differences Between Europe and USA**

TRACK B: ADAPTIVE DESIGN – OPERATIONAL ASPECTS

Session Chair:
Hans-Ulrich Burger, Senior Director of Biostatistics, F. Hoffmann-La Roche Ltd., Switzerland

The development of adaptive designs started more than 20 years ago and since then not only the number of potential designs went up but also their acceptability within companies and by regulators. In essence, adaptive designs are already today frequently part of standard design options for clinical studies, in early as well as in late development. Adaptive designs have the potential to speed up development or save cost or increase probability of success depending on the context. The discussion on adaptive designs concentrated a lot on theoretical parts, on how to maintain type 1 error or how to ensure integrity of the trial, less on the operational consequences in their implementation. This session will provide an overview on adaptive designs in the first part, but then concentrate on operational aspects. Especially, when using adaptive designs to control cost, operational aspects are critical and more information and experience will be shared on these aspects in this session.

Speaker	Presentation
Franz Koenig, Medical University of Vienna, Austria	**Adaptive Designs Today, Key Principles and Outlook**
Andrew Grieve, Senior Vice President Clinical Trial Methodology, Aptiv Solutions, Germany	**Practical Aspects of Adaptive Designs During Implementation**
All speakers	**Panel Discussion on Data Sharing and Adaptive Designs**

16:00 END OF THE CONFERENCE

Clinical Forum for Operational Excellence

27th October 2016

DIA Training Course on

The Use of Real World Data in Healthcare

Real world data is an area applicable to a variety of fields from pharmacovigilance to health technology assessment and reimbursement. It is gaining more and more importance in areas such as accelerated approval of new medicines and risk management plans.

This one-day workshop will teach you the basic concepts of using real world data. You will learn about the setup and regulatory framework of observational studies and discuss hot topics, such as use of real world data versus randomised clinical trials. Examples from day-to-day work will be explored to ensure that you are able to apply the learnings later on.

Learning Objectives

- Ability to choose the right data source for each research question
- Understand how RWD (Real World Data) can resolve business pains
- Using different sources of data and identifying the sources of bias
- How to avoid common RWD pitfalls when planning and conducting a study
- Interpret the results and increase their robustness when planning a study

Find out more at www.DIAglobal.org

Venue

Hilton Dusseldorf Hotel
Georg-Glock-Strasse 20
40474 Dusseldorf
Germany

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Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

SwAPP Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organiation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

REGISTRATION FORM

Clinical Forum for Operational Excellence | ID#16103
27-28 October 2016 | Hilton Düsseldorf Hotel, Düsseldorf, Germany

Early-bird discount: Register by 30 September 2016 and save!

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.

Early-bird fee applies to industry members only. **€ 1'030.00** ❑

CATEGORY (AFTER 30 SEPTEMBER 2016)	Member*	Non-Member*
Industry until 17 October 2016	€ 1'230.00 ❑	€ 1'585.00 ❑
Industry after 18 October 2016	€ 1'430.00 ❑	€ 1'585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 715.00 ❑	€ 870.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Exhibition hall only passes available. Please contact DIA EMEA for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

*All fees are subject to the applicable VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

ATTENDEE DETAILS

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

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Please provide your European VAT number

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

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❑ **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." Please include your name, company, Course ID#16103 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. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here**.

Date	Signature

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DIA offers one year complimentary membership against event registration at non-member rate

❑ **I do not want complimentary membership**

TERMS AND CONDITIONS

Cancellations

All cancellations must be in writing and received at the DIA EMEA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00
Academia/Charitable/Government /Non-profit (Member/Non-member) = € 100.00
Tutorial cancellation: € 50.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

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

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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