Quality Risk Management in Clinical Drug Development Conference 2012

Event #12115
26-27 November 2012
NH Harrington Hall, London, UK

Programme Chairs

Barbara Leishman
Head, Quality Risk Management-Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

Peter Schiemann
Managing Partner, Widler & Schiemann Ltd., Switzerland

Programme Committee

Pierre-Henri Bertoye
Deputy Director in charge of National and International Medical Affairs, ANSM, France

Xavier Dubarle
Global Quality Risk Management Expert, sanofi-aventis, France

Oliver Fink
Global Project Compliance Manager, Boehringer Ingelheim RCV Gmbh & Co KG, Austria

Regina Freunscht
Director Marketing and Communication, Accovion, Germany

Ann Meeker-O'Connell
Acting Associate Director, Risk Science, Intelligence, and Prioritization, Office of Scientific Investigations, Office of Compliance, CDER, FDA, USA

Roland Rich
Operational Expert, Clinical Quality Assurance, Novartis Pharma AG, Switzerland

Kenneth J. Sprenger
Executive Director, Medicine Team Leader Pfizer Inc

Who Will Attend

This conference is of interest to those who are applying Quality Risk Management principles in the following areas:

- Clinical/medical science
- Clinical trial management/clinical operations
- Data management
- Drug safety
- Transitional medicine
- Process development
- Project management/functional excellence
- Quality risk management/quality assurance
- Regulatory affairs
- Statistics
- Systems development

Following the success of our previous conference on this topic in 2011, we are pleased to announce the 2nd conference on 'Quality Risk Management in Clinical Drug Development' on 26-27 November 2012.

Managing risks to quality throughout the development lifecycle

Overview

Quality Risk Management is a process for identifying quality-related hazards associated with a product, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the control. Effective quality risk management ensures the high quality of a drug product for the patient. The FDA has been particularly active in fostering this concept - FDA's Quality by Design (QbD) initiative emphasises building quality into a product during development rather than attempting to "test" in quality retrospectively

Evolving beyond their origin in manufacturing, risk-based approaches are expanding rapidly, as is reflected by the large number of regulatory initiatives such as the FDA's "Pharmaceutical Quality for the 21st Century" and EMA papers on risk-based quality management of clinical trials, as well as the quality requirements of the new EU pharmacovigilance legislation. Important drivers of this evolution include the constant increase in complexity, size, diversity and geographical distribution of clinical trials and the challenges of managing "fit for purpose" global pharmacovigilance systems. This is matched by a parallel development within the research-based pharmaceutical industry, service organisations and academia.

In the absence of a single, practice-oriented guidance on how to implement these approaches in the clinical development setting, different approaches and techniques are being developed, with different scope and targets. The purpose of this conference is to pull together a broad range of experience in the application of risk-based approaches to the entire spectrum of clinical drug development, with a view to increasing the accessibility of such experience and stimulating its wider use.

The conference takes a practice-based approach to QbD/QRM, mapped across the clinical development lifecycle, and provides tried and tested "how-to" guidance from European and US experts with real-life experience.

Key Topics

Presentations on potential use and actual experience in applying risk-based approaches to a range of activities, including:

- Patient protection, including safety risk signal detection, safety risk management, pharmacovigilance and benefit-risk assessment
- Clinical trial design and conduct
- GCP compliance
- Ensuring high-quality data/data integrity
- Process development and application

The programme will include:

- Overview of regulatory initiatives
- A holistic view of QbD/QRM in the development lifecycle: What fits where?
- Working with regulators: Their expectations and how to address them
- Focus on drug safety/pharmacovigilance (new EU pharmacovigilance legislation, US REMS)
- Clinical trials: Application of risk-based approaches
- Application of QRM concept to devices development
- The business case for QbD/QRM: Is it worth it?
- Regulators' panel on future development and expectations in implementing risk-based approaches: From concept to reality!

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 and certificates are available.

DIA®
www.diahome.org

MONDAY | 26 NOVEMBER 2012

08:00 **REGISTRATION**

09:00 **INTRODUCTION AND WELCOME**

09:10 **Session 1**

SETTING THE SCENE
Session Chair:
Peter Schiemann, Managing Partner, Widler & Schiemann Ltd., Switzerland

Current Regulatory Landscape and Future Perspectives
Fergus Sweeney, Head, Compliance and Inspection, European Medicines Agency, European Union

Integrating QbD into the Development Lifecycle: Adding Value Where it Counts Most
Barbara Leishman, Head, Quality Risk Management-Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

Regulatory Risk Management Plan
Katrin Rupalla, VP EU Regulatory Sciences, Bristol-Myers Squibb, France

10:40 **COFFEE BREAK**

11.10 **Session 1 (continued)**

Regulators' Expectations of Risk-Based Development of Drugs

FDA perspective
Ann Meeker-O'Connell, Acting Associate Director, Risk Science, Intelligence, and Prioritization, Office of Scientific Investigations, Office of Compliance, CDER, FDA, USA

MHRA perspective
Rebecca Stanbrook, Group Manager Inspections, MHRA, UK

12:10 **LUNCH**

13:10 **Session 1 (continued)**

Implementing regulatory recommendations for QRM, and experience with sharing these plans with the FDA
Kenneth J. Sprenger, Executive Director and Medicine Team Leader, Pfizer, USA

13:40 **Session 2**

PRACTICAL IMPLEMENTATION OF QRM IN DESIGNING, CONDUCTING AND REPORTING CLINICAL TRIALS

Session Chair:
Kenneth J. Sprenger, Executive Director and Medicine Team Leader, Pfizer, USA

Protocol Design – Optimising quality

- **Medical and scientific perspective**
  Jocelyne Flamant, Senior Director Clinical R&D Celgene, Switzerland
- **Statistics perspective**
  Speaker invited

Feasibility and practical management considerations
Oliver Fink, Global Project Compliance Manager, Boehringer Ingelheim RCV Gmbh & Co KG, Austria

15:10 **COFFEE BREAK**

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe.

Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

15:40 **Session 2 (continued)**

Study Conduct and Management

- **Experience with the Development of a Quality Management Plan**
  Kenneth J. Sprenger, Executive Director and Medicine Team Leader, Pfizer, USA
- **Risk-based monitoring**
  Chafik Azizi, Group Leader - Clinical & Scientific Operations, Sanofi, France

Data Analysis and Reporting

- **QbD in Data Management**
  Rachel Edwards, Director & Regional Head, Clinical Site Management, Amgen, UK
- **Building Quality into Data Analysis**
  Speaker invited

17:30 **DRINKS RECEPTION**

18:30 **END OF DAY ONE**

TUESDAY | 27 NOVEMBER 2012

09:00 **Session 3**

HOW DOES QBD ADD VALUE TO DEVELOPMENT OF MEDICINES AND DEVICES?
Session Chair:
Regina Freunscht, Director Marketing and Communication, Accovion, Germany

The Business Case for QbD in Medicines Development
Peter Schiemann, Managing Partner, Widler & Schiemann Ltd., Switzerland

The Value of QRM in the Devices Industry
Paul Sim, Regulatory Affairs Manager, BSI Group, UK

10:00 **COFFEE BREAK**

10:30 **Session 4**

QRM IN SAFETY RISK MANAGEMENT AND PHARMACOVIGILANCE
Session Chair:
Barbara Leishman, Head, Quality Risk Management-Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

Safety Risk Management During the Development Lifecycle – A risk-based approach
Michael Forstner, Integrated Safety Risk Manager, F. Hoffmann–La Roche Ltd., Switzerland

EU Pharmacovigilance Legislation and its Impact: Implications for QRM approaches
Anne-Marie De Ferran, Head of Quality, Training and Compliance for Global PV and Epidemiology, Sanofi, France

12:00 **LUNCH**

13:00 **Session 5**

WHAT'S NEXT? FUTURE TRENDS FROM THE REGULATORS' PERSPECTIVE
Session Chair:
Barbara Leishman, Head, Quality Risk Management-Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

Pierre-Henri Bertoye, Deputy Director in charge of National and International Medical Affairs, ANSM, France

Ann Meeker-O'Connell, Acting Associate Director, Risk Science, Intelligence, and Prioritization, Office of Scientific Investigations, Office of Compliance, CDER, FDA, USA

Rebecca Stanbrook, Group Manager Inspections, MHRA, UK

Fergus Sweeney, Head, Compliance and Inspection, European Medicines Agency, European Union

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:

NH Harrington Hall
5-25 Harrington Gardens
South Kensington
London SW7 4JW
United Kingdom

Tel.: +44 (0) 207 396 9696
Fax: +44 (0) 207 396 9090
Email: nhharringtonhall@nh-hotels.com

at the special rate of
162.00 GBP per room inclusive of breakfast and VAT.

To make your reservation please:
Email: bookings@nh-hotels.com
Tel.: 0870 735 0358

Please quote the booking reference: 185435732

Important: Please complete your reservation by 28 October 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

DIA 2012-2013 Training Courses in Safety and Pharmacovigilance

■ **Benefit/Risk Management**
15–16 October 2012 | Paris, France | ID 12594
13-14 May 2013 | Nice, France
26-27 September 2013 | Prague, Czech Republic

■ **EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing**
18-22 February 2013 | London, United Kingdom | ID 13502

■ **EudraVigilance Information Day at the European Medicines Agency**
5 October 2012 | London, United Kingdom | ID 12534

■ **How to Prepare for Pharmacovigilance Audits and Inspections**
15-16 November 2012 | Prague, Czech Republic | ID 12575

■ **IDMP Information Day at the European Medicines Agency**
4 December 2012 | London, United Kingdom | ID 12536

■ **Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency**
16 October 2012 | London, United Kingdom | ID 12539
13 November 2012 | London, United Kingdom | ID 12540

■ **Introduction to Signal Detection and Data Mining in Pharmacovigilance**
14-15 November 2012 | Prague, Czech Republic | ID 12574
10-12 June 2013 | Amsterdam, The Netherlands

■ **Medical Approach in Diagnosis and Management of ADRs**
15–16 October 2012 | Paris, France | ID 12565

■ **EudraVigilance (EV) - Electronic reporting of ICSR**
eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For course details on EV, please visit www.diahome.org > Meetings & Training > Find Meetings & Training > Click on EudraVigilance > Search

ABOUT DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

REGISTRATION FORM

Quality Risk Management in Clinical Drug Development Conference 2012
26-27 November 2012 | NH Harrington Hall, London, UK

ID # 12115

DIA

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes lunch and coffee breaks.

Early-Bird rates available for Members:

Deadline on or before 15 October 2012

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 15 October 2012)	FEE
Join DIA now to qualify for the Early-Bird Rate	€ 115.00 ❑

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

Join DIA now to qualify for the member rate — Fee € 115.00 ❑

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

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

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'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 - Credit cards are the preferred payment method.

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

❑ VISA ❑ MC ❑ AMEX

Card Number

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ Cheques should be made payable to: DIA and mailed together with a copy of the registration form to facilitate identification to:
DIA Europe, Kuechengasse 16, Postfach, 4002 Basel, Switzerland

❑ Bank transfers: When DIA Europe 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#12115 as well as the invoice number to ensure correct allocation of your payment.
Payments must be net of all charges and bank charges must be borne by the payer.

CANCELLATION POLICY: All cancellations must be in writing and received with DIA Europe by 17:00 CET on 20 November 2012

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

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

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

HOW TO REGISTER

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

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

© DIA 2012