Clinical Trial Registries Conference

Event #12108
15-16 November 2012
Hilton London Docklands Riverside Hotel, London, UK

Programme Chairs

Barbara Godlew
President, The FAIRE Company, LLC, USA

Detlef Niese
Head, Global Development External Affairs, Novartis Pharma AG, Switzerland

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

Programme Committee

Gabriele Dreier
University Medical Center Freiburg, Clinical Trials Unit, WHO Primary Registry DRKS, Germany

Sarah D. Larson
Associate Director, Clinical Operations, Biogen Idec, USA

Carlo Tomino
Head of Research and Clinical Trials, Italian Medicines Agency (AIFA), Italy

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

Programme Advisor

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

Learning Objectives

At the end of this conference, you will:

- Understand the trial disclosure requirements for the EU, USA, Germany, Italy, and other countries and identify the similarities and differences
- Recognise how companies and research institutions fine-tune and optimise processes surrounding disclosure activities
- Understand the interrelationship between clinical trials, medical writing, regulatory affairs and disclosure teams to maintain consistency for protocol registration and results reporting
- Be able to describe the impact and applicability of technology, HL7, and CDISC to the overall disclosure process
- Have the tools necessary to discuss the influence of changing clinical trial disclosure requirements on peer-reviewed publications
- Understand what drives compliance with registry standards and how non-compliance can be averted
- Recognise the patient's point of view and expectations of clinical trial disclosure

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.

Overview

Transparency of information in ongoing and completed clinical trials is an established expectation of society reinforced by regulation and by codes of practice in many parts of the world. It is a necessary pillar to ensure public trust in the clinical trial process and the evaluation of clinical trial outcomes. Discussion is now focused on the different mechanisms for transparency, their scope, objectives and audience. This increased transparency changes the landscape of availability and use of information from clinical trials, and brings with it new opportunities and challenges.

The EU Clinical Trials Register (EU CTR) was launched in March 2011 and as of March 2012 provides information on more than 16,500 clinical trials. During 2012 and 2013, EudraCT and EU CTR will be extended to include summaries of clinical trial results.

EU CTR joins ClinicalTrials.gov and an increasing number of clinical trials registries from different countries and regions covering varying types of trials, which ushers in new challenges and complexities for clinical trial sponsors. Among these challenges is the need for standardisation of the core clinical trial data so that the same trial is correctly represented in the same way in different registries.

Increased numbers of national and industry sponsored registries leave many sponsors pondering strategy, developing operational measures, and looking for efficient ways to manage dissemination of clinical trial protocol information and results data. In spite of considerable sponsor effort and investment, dissatisfaction with the degree of transparency and compliance with existing rules with media, politicians and other stakeholders is still high. Although the original purpose of facilitating the patients' access to clinical trials has had limited success, other stakeholders including patients find the registries and results databases useful and necessary. Publicly available results databases ensure non-selective data sharing and may reduce the risk that important trial results go undisclosed.

Conference Highlights

- To provide perspective on the clinical trial disclosure challenges faced by industry, academia, regulators, journal editors, software developers, and others, we are proud to present a distinguished panel of international speakers who will delve into the details of clinical trial disclosure regulations, operations, publications, and other issues relevant to the topic.
- Find out how sponsors ensure the consistency and traceability of all the information submitted to these various repositories and how they organise their processes to deliver the required information in time with limited resources.
- Join us to discuss the status of clinical trial registries worldwide and to hear from the authorities that operate them. Listen to real-life implementations in industry and academic institutions and to the voice of the regulators and journal editors and learn about their expectations. Get insights into the development of worldwide information management for registries and discuss with us how worldwide registries can be harmonised and improved.

Who Will Attend

Professionals working in:

- Clinical operations
- Clinical research
- Clinical trial IT support
- Ethics
- Government agencies
- Journals
- Medical research
- Patient advocacy
- Registry management
- Regulatory affairs
- Research and development
- Lawyers

Key Topics

- Clinical trial registries - Overview of current worldwide situation: EU, USA, Germany, Italy, and other countries
- Impact of changing international legislation on journal editors and publication issues
- Initiatives to standardise data requirements of clinical trial registries and results databases to facilitate reproducibility and data querying
- Challenges faced by academia with moving regulatory targets and emergence of new registries/results databases
- Operational and technical implementation of automating processes and streamlining data transfer for clinical trial disclosure
- Access and data use of clinical trial protocol/results information by patients, informatics organisations, third-party payers, and others
- "State of the nation" of ClinicalTrials.gov and EU CTR

DIA®
www.diahome.org

THURSDAY | 15 NOVEMBER 2012

08:00 REGISTRATION

09:00 Session 1

CLINICAL TRIAL REGISTRIES - OVERVIEW OF CURRENT WORLDWIDE SITUATION

Session Chair: **Fergus Sweeney**, Head, Compliance and Inspection, European Medicines Agency, European Union

Speakers will provide an overview of major developments in clinical trial registries at global level. Initiatives to promote cooperation and harmonisation of data requirements between registries will be described.

Registration of Clinical Trials: A key element to strengthen the ethical oversight of clinical trials
Marie-Charlotte Bouësseau, Ethics and Health Team Leader, World Health Organization (WHO), Switzerland

The European Clinical Trial Register (EU CTR) and Result Related Data
Noémi Manent, Scientific Administrator, Compliance and Inspection, European Medicines Agency, European Union

What Have We Learned from the ClinicalTrials.gov Registry and Results Database?
Deborah Zarin, Director, ClinicalTrials.gov, National Library of Medicine, National Institutes of Health (NIH), USA

10:30 COFFEE BREAK

11:00 Session 2

IMPACT OF CHANGING INTERNATIONAL LEGISLATION ON JOURNAL EDITORS AND PUBLICATION ISSUES

Session Chair: **Barbara Godlew**, President, The FAIRE Company, LLC, USA

This session will consist of a panel of editors from top-tier medical journals, publication professionals, industry disclosure professionals, and academic clinical researchers addressing topics such as:

- Legislative and ICMJE requirements and the impact on publishing clinical trial results
- Public access to clinical trial protocols
- Academia's response to clinical trial disclosure requirements and publishing trial results

Maureen Garrity, Director Publications, Astellas Pharma, Inc., USA

Trish Groves, Deputy Editor, British Medical Journal (BMJ), Editor-in-chief, BMJ Open, UK

Tesheia Johnson, Chief Operating Officer, Yale Centre for Clinical Investigation, Yale University, USA

Lucas Rems, Head of Neurology, Psychiatry Unit, BfArM, Germany

12:30 LUNCH

14:00 Session 3

INITIATIVES TO STANDARDISE DATA REQUIREMENTS OF CLINICAL TRIAL REGISTRIES AND RESULTS DATABASES TO FACILITATE REPRODUCIBILITY AND DATA QUERYING

Session Chair: **Sarah D. Larson,** Associate Director, Clinical Operations, Biogen Idec, USA

During this session the speakers will first provide an overview of HL7 CTR&R Standards and then present on what is driving the desire for standards, what is addressed by various types of standards and the various outcome measures. The concluding part of the session will focus on the authoritative data sources typically used in the registration and results disclosure process.

Overview of HL7 CTR&R Standards
Sarah D. Larson, Associate Director, Clinical Operations, Biogen Idec, USA

Data Standards - Promise and pain
Nick Ide, Chief Architect, ClinicalTrials.gov, National Library of Medicine, National Institutes of Health (NIH), USA
Rebecca J. Williams, Assistant Director, ClinicalTrials.gov, National Library of Medicine, National Institutes of Health (NIH), USA

Using Internal Standards to Facilitate Downstream Content Re-Use

15:30 COFFEE BREAK

16:00 Session 4

CHANCES AND CHALLENGES INDUCED BY MOVING REGULATORY TARGETS FOR INDUSTRY AND ACADEMIA

Session Chair: **Gabriele Dreier**, University Medical Center Freiburg, Clinical Trials Unit, WHO Primary Registry DRKS, Germany

Challenges for a Company to Cope with the Growing Number of Registries and Regulations
Claus Goebel, Head, Global Clinical Development Operations, Merz Pharmaceuticals GmbH, Germany

The Act on the Reform of the Market for Medicinal Products – Benefit assessment and the new role for clinical trial registries
Susanne Jena, Project Manager, Institute of Medical Biometry and Medical Informatics, University of Freiburg, Germany

Advantages for a Medical Society of Working with a WHO Clinical Trial Registry
Bernd Wullich, Director, Department of Urology, University Hospital, Germany

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

FRIDAY | 16 NOVEMBER 2012

09:00 Session 5

OPERATIONAL AND TECHNICAL IMPLEMENTATION OF AUTOMATING PROCESSES AND STREAMLINING DATA TRANSFER FOR CLINICAL TRIAL DISCLOSURE

Session Chair: **Beat Widler**, Managing Partner, Widler & Schiemann Ltd., Switzerland

The speakers will review and discuss what the technical and logistics prerequisites to implement an automated process for the updating of Clinical Trial Disclosure systems such as www.clinicaltrials.gov or EUDRACT are. Two of the speakers will address the issue from the perspective of a vendor of disclosure software and share their experience of opportunities, challenges or even source of failure with the audience. A third speaker will discuss points to consider when implementing a streamlined approach to disclosure in sponsor companies, how process continuity can be ensured or is jeopardised in a world of continuous operational change.

Optimising Basic Results Data Entry: Challenges, lessons, and next steps
Christopher Dedels, Global Product Manager - Clinical Trial Disclosure Solutions, Virtify, Inc., USA

Aligning the Clinical Trial Registration Process with Quality Risk Management (QRM)
Lars Schmiedeberg, Risk Management Consultant, ii4sm, Switzerland

Coordinating the Processes and Data Required for Clinical Trial Applications, Global Trial Disclosure, and Publication
Thomas Wicks, PharmaCM Lead, Deloitte Analytics LLC, USA

10:30 COFFEE BREAK

11:00 Session 6

REQUIREMENTS BY PATIENTS, RESEARCHERS, AND PUBLIC HEALTH REGARDING ACCESS TO AND USE OF PROTOCOL/RESULT INFORMATION OF CLINICAL TRIALS FROM PUBLICLY ACCESSIBLE REGISTERS

Session Chair: **Detlef Niese**, Head, Global Development External Affairs, Novartis Pharma AG, Switzerland

In this session a patient representative, a member of a multi stakeholder organisation with an interest in clinical trials, and a representative of a governmental body will discuss what they expect from trial and result registries regarding access to and use of trial related information. We will also hear about the considerations of a governmental body when deciding on implementation of a national registry.

Specific aspects to be discussed include
- Type of information to be provided
- Ease of access for a non-expert audience
- Use in a multi-language environment
- Relevance of the information provided for experts and lay audiences
- Pro's and con's of implementing a national registry compared to use of existing registries

The Swiss Way to Clinical Trials Registration - Transparency, but for whom?
Andri Christen, Swiss Federal Office of Public Health (BAG), Section of Human Research and Ethics, Switzerland

Patients' Expectations on Public Information about Trials, Trial Results and Trial Registers
Francois Houyez, Health Policy Officer, Eurordis, France

Ethical Issues of Publicly Accessible Clinical Trial Registries
Ingrid Klingmann, Chair, The European Forum for Good Clinical Practice (EFGCP), Belgium

12:30 LUNCH

14:00 Session 7

ROUND TABLE DISCUSSION: HOW WILL INCREASED AVAILABILITY OF INFORMATION AFFECT RESEARCH AND DATA USE?

Session Chairs: **Fergus Sweeney**, Head, Compliance and Inspection, European Medicines Agency, European Union and **Deborah Zarin**, Director, ClinicalTrials.gov, National Library of Medicine, National Institutes of Health (NIH), USA

Marie-Charlotte Bouësseau, Ethics and Health Team Leader, World Health Organization (WHO), Switzerland

Richard Horton, Editor, The Lancet, UK

Francois Houyez, Health Policy Officer, Eurordis, France

Tesheia Johnson, Chief Operating Officer, Yale Centre for Clinical Investigation, Yale University, USA

Ingrid Klingmann, Chair, The European Forum for Good Clinical Practice (EFGCP), Belgium

Detlef Niese, Head, Global Development External Affairs, Novartis Pharma AG, Switzerland

Carlo Tomino, Head of Research and Clinical Trials, Italian Medicines Agency (AIFA), Italy

15:30 END OF CONFERENCE

HOTEL INFORMATION

The DIA has blocked a number of rooms at the:

Hilton London Docklands Riverside
265 Rotherhithe Street
SE16 5HW London
United Kingdom

Tel.: +44 (0)20 7231 1001
Fax: +44 (0)20 7231 0599
Email: reservations.docklands@hilton.com
Website: http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-hotel/index.do

At the special rate of GBP 169.00 per room inclusive of breakfast, exclusive of VAT.
The special room rate will be available until 30 September 2012 or until the group block is sold-out, whichever comes first.

If cancellation occurs within 7 days of arrival, a 100% cancellation charge will apply.

REGISTRATION FORM

Clinical Trial Registries Conference | 15-16 November 2012
Hilton London Docklands Riverside Hotel, London, UK

ID #12108

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

Early-bird rates available for members: Register by 4 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/charitable/non-profit/academia members.**

Early-bird industry fee for members (valid until 4 October 2012)	€ 950.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑

STANDARD FEES	Member (after 4 October 2012) Fee	Non-Member Fee
❑ I wish to register for the Clinical Trial Registries Conference (15–16 November 2012)		
Industry	€ 1'100.00 ❑	€ 1'215.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 550.00 ❑	€ 665.00 ❑

SPECIAL FEES

Benefit from a reduced rate to attend both conferences in London – GCP Forum on 14 November 2012 followed by the Clinical Trial Registries Conference on 15-16 November 2012.

❑ I wish to register for the GCP Forum (14 November 2012) and the Clinical Trial Registries Conference (15–16 November 2012)	Member Fee	Non-Member Fee
Industry	€ 1'500.00 ❑	€ 1'615.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 750.00 ❑	€ 865.00 ❑

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

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

REGISTRANT

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

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

Exp. 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, Küchengasse 16, Postfach, 4002 Basel, Switzerland

❑ Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID #12108 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

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date

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

Transfer Policy

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

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

HOW TO REGISTER

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

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