DIA

Registry Workshop - Preparing for Future Requirements

19-20 September 2017
Chelsea Harbour Hotel, London, UK

PROGRAMME COMMITTEE

Michael Busch-Sørensen
Board Member, Danish Society for Pharmacoepidemiology, Denmark

David Hans-U. Haerry
Member of Board of Directors, European AIDS Treatment Group, Belgium

Maren v. Fritschen
Managing Director
AddOn Pharma GmbH, Germany

OVERVIEW

This workshop is very timely because of the latest regulations changes and it will assemble multiple stakeholders including: regulators, industry and academia representatives who will assess the challenges and technical issues of the registries and discuss possible solutions. The sessions will help you have a better understating on the registries used in post and pre authorisation, but it will also focus on understanding the existing registries and the differences between them. Also, it will facilitate your comprehension on how to use the data from registries and the protocols you need to follow when doing so.

OBJECTIVES

- Understanding the value of registries
- Patient, disease and product registries – an optimal solution?
- Identify the differences between US and EU registries
- Understand how to use data from registries
- Assess the challenges and find possible solutions

KEY TOPICS

- Types of registries & terminology
- Case studies: patient and disease registries
- Use of data from registries for pre and post-authorization
- The coding system
- Data privacy & data protection provisions

WHO WILL ATTEND

- Associate Director Pharmacovigilance and Risk Management
- QPPV and Deputy
- Risk Management & Business Process Management Practice
- Medical Safety Officer
- Pharmacovigilance Assessor
- Pharmacovigilance Officer
- Pharmacovigilance Technician
- Research and Development (R&D)
- Medical Affairs Director / Manager
- Regulatory Affairs Director / Manager
- Global Regulatory Strategist
- Senior Clinical Safety Manager
- Senior Global Medical Science Lead
- Compliance Specialist
- Epidemiologists

LEARN MORE

Visit **www.DIAglobal.org/Registry** for programme updates or contact **EMEA@DIAglobal.org** with questions.

Registry Workshop

DAY ONE | TUESDAY, 19 SEPTEMBER

08:15 REGISTRATION

09:00 SESSION 1

SETTING THE SCENE – GLOBAL BASIS

Session Chair:
Michael Busch-Sørensen, Board Member, Danish Society for Pharmacoepidemiology, Denmark

With the implementation of Benefit/risk assessment of medicine post approval, data from usual practice has become even more important. Even though registries/database have been used for decades, the terminology, coding systems, design, regulations, funding, analysis, reporting etc. is inconsistent. Even the basic terms as registry and database are used with opposite meanings. Current activities focus on the basic registries: product and disease registries. These registries are typically short lived due to funding, and clearly inferior to patient and other global registries with unique person identifiers. This session sets the scene from a EU/USA perspective.

Introduction in the Registries
Michael Busch-Sørensen, Board Member, Danish Society for Pharmacoepidemiology, Denmark

Sandra L. Kweder, Deputy Director Europe Office Liaison to the EMA, Food and Drug administration, United States of America

Dr. Xavier Kurz, Head of Surveillance and Epidemiology Service European Medicines Agency

Panel discussion with Q&A

10:30 COFFEE BREAK

11:00 SESSION 2

STATUS IN THE EU AND USE CASES

Session Chair:
Maren v. Fritschen, Managing Director, AddOn Pharma GmbH, Germany

The benefits of patients' registries and disease registries are increasingly recognized and various initiatives for data gathering are established by multiple stakeholders. The European Union plays a key role in facilitating the development of registries across borders within Europe by the PARENT JA and the European Medicines Agency Registry initiative whereas a variety of national registries are established and maintained. What is the current status in the EU and what can we learn from use cases?

Expectations and achievements of Registries from industry perspective
Chris Chinn, Head of Real World Data Strategy and Partnerships, Sanofi, United Kingdom

A Registry supporting continuous improve of treatment: case study of a breast cancer registry
Bent Ejlertsen, Medical Director, Danish Breast Cancer Cooperative Group Statistical Center, Denmark

Multi stakeholder collaboration on a prospectively used Registry: case study of a HPV vaccine
Bo Terning Hansen, Researcher, Cancer Registry of Norway, Norway

Panel discussion with Q&A

12:30 LUNCH

13:30 SESSION 3

WHERE TO HEAD IN THE EU? WHAT ARE THE CHALLENGES FOR COLLECTING AND ANALYSING HIGH QUALITY DATA IN ORDER TO BE USEFUL FOR REGULATORY DECISIONS

Session Chair:
Maren v. Fritschen, Managing Director, AddOn Pharma GmbH, Germany

Registries can play an important role not only in monitoring the safety of medicines but also in providing adequate source for regulatory decision making. High quality patient registries can make valuable contributions to the evaluation and monitoring of medicines for public health benefit. The objective of the European Medicines Agency Patient Registry initiative is to facilitate discussions at an early stage in the authorisation procedure to increase use of existing patient registries and to support the creation of a new registry based on standard methodological approaches. This session will provide insides in challenges and opportunities for the use of registries in decision making processes based on case studies and the regulator's expectations.

What are the expectations from the regulators?
Jane Moseley, Senior Scientific Administrator, European Medicines Agency, European Union

Case study on a global registry of Soliris (eculizumab) for an additional indication
Martine Zimmermann, Global Head of Regulatory Affairs, Alexion Pharma GmbH, CH

Case study on a recent CHMP approval for an OMP on accelerated assessment based on registry data
Chay Morgan, Head EU, Biomarin Pharmaceutical Inc.

Panel discussion with Q&A
European Medicines Agency Representative Invited, European Union

15:00 COFFEE BREAK

15:30 SESSION 4

STATUS IN THE US

Session Chair:
Michael Busch-Sørensen, Board Member, Danish Society for Pharmacoepidemiology, Denmark

The large claims databases in US are extensively being used, not least due to the large amount of data. Extraction of data directly from patient records is under development. In addition to medicine post approval studies, US is now implementing "device post approval studies". Prospective data collection in "pregnancy registries" is currently ongoing in 50 product specific registries. FDA are now placing "pregnancy registries" in the Nordic countries with a population of almost 30 mill. People. Why go to a region with 10 times less people than in USA? This session will share the position of FDA, and give an insight in the benefit/challenges using data in US versus Nordic Countries, which in many ways exemplifies the current status for Registries/Databases.

Patient pregnancy registries from academia perspective
Jon Thor Traerup Andersen, Medical Director, Copenhagen University Hospital Bispebjerg, Denmark

Experiences from industry
Hu Li, Principle Research Scientist, Eli Lilly and Company, United States of America

Expectations from the FDA
- Why is the FDA requesting studies from the Nordic Countries?
- Claims databases, sentinel databases, CER
- Learnings and challenges
- FDA guideline on medical devices – impact on pharmaceutical

Sandra L. Kweder, Deputy Director Europe Office Liaison to the EMA, Food and Drug administration, United States of America

Panel discussion with Q&A

17:30 NETWORKING RECEPTION

17:00 END OF THE DAY 1

Registry Workshop

DAY TWO | WEDNESDAY, 20 SEPTEMBER

09:00 SESSION 5

BIOBANKING AND GENOME DATA – RISKS AND OPPORTUNITIES

Session Chair:
Michael Busch-Sørensen, Board Member, Danish Society for Pharmacoepidemiology, Denmark
David Hans-U. Haerry, European AIDS Treatment Group, Belgium

Tissue and DNA are special types of "data" which carries high amount of data and with that a lot of potential benefit for the patients, while at the same time the same data contains major risk for the same patients from a data privacy point of view. This session will give an insight in the structure and function of a country wide biobank covering a whole population, integrated with the healthcare system and linked to all kinds of registries. The benefit and risks with tissue and DNA is then addressed from industry and ethical committee point of view.

Speakers:

National Biobanking - Biobank governance models
Estrid Høgdall, Clinical Senior Investigator, Head of Danish Biobank, Herlev Hospital, Denmark

Benefit and Challenges from industry perspective
- **Personalised medicine – immune-oncology examples**

Ethical challenges – from data to DNA

Panel discussion with Q&A

10:30 COFFEE BREAK

11:00 SESSION 6

HOW TO USE DATA WITHIN AND ACROSS THE COUNTRIES – ROUNDTABLE?

Session Chair:
David Hans-U. Haerry, European AIDS Treatment Group, Belgium

- Anonymization – deletion
- Re-use of data
- Ethics committees
- Public vs. Patient interests – Under the new regulation
  - PV
  - B/R studies
  - Access to patient data
    - Sentinel data – US started – EU is following
  - Data – tissue – DNA
- Respect for privacy - Data privacy

Speakers:

Heide A. Stirnadel, Director Epidemiology, GlaxoSmithKline, United Kingdom

Estrid Høgdall, Clinical Senior Investigator, Head of Danish Biobank, Herlev Hospital, Denmark

Xavier Kurz, Head of Surveillance and Epidemiology Service, European Medicines Agency, European Union

Panel discussion with Q&A

12:30 LUNCH

Conference Venue

Chelsea Harbour Hotel
Chelsea Harbour
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E: events.chelseaharbour@millenniumhotels.co.uk

13:30 SESSION 7

SUSTAINABILITY AND PUBLIC FUNDING

Maren v. Fritschen, Managing Director, AddOn Pharma GmbH, Germany

Sustainability of a registry is an issue faced by most registries following the initial phase of funding for their creation. Different sources of funding, sometimes temporary or transitional, often co-exist. Sustainability should generally be based on a development strategy, a professional management structure and the development of clear partnership with stakeholders to safeguard independence. Experiences and challenges from successful registries in ensuring sustainability will be presented for discussion.

Speakers:

Public funding of national registries – achievements and limitations
- **Health care registries in Denmark/Nordic countries**

Jon Thor Traerup Andersen, Medical Director, Copenhagen University Hospital Bispebjerg, Denmark

How can we sustain public registries in the future?
- **Common standards and cross European collaboration**
- **Coding/schema**

Bent Ejlertsen, Medical Director, Danish Breast Cancer Cooperative Group (DBCG), Denmark

How can we sustain public registries in the future?
- **Open source benefit/risk**
- **Cost benefit supporting registries**

Panel discussion with Q&A

15:00 COFFEE BREAK

15:30 SESSION 8

FAST FORWARD 10 YEARS – WHAT DO WE NEED TO BUILD NOW? HOW TO ENVISION THE FUTURE?

- Regulator's Perspective EU and US
- Academia perspective
- Patient's perspective
- Industry perspective

17:00 END OF WORKSHOP

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact Zsofia.Molnar@DIAglobal.org for a custom group rate.

REGISTRATION FORM | ID# 17115

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Early-bird discount and Advance rate

To qualify for the discount, registration form and accompanying payment must be received by the dates below. Early-bird/Advance rate applies to industry members only.

Early bird discount: register by 27 June 2017 **€ 1'230.00** ❑

Advance rate: register by 8 August 2017 **€ 1'330.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 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. 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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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.

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Exp. Date /

Cardholder's Name

❑ **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, Event ID#17115 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 made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

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 and Video 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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