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
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 pre- and post-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 the 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

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, European Union

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

When generating real world evidence on the impact of a disease or treatments for that disease, the utilisation of registries can be an efficient mechanism. As such, research based life science companies support the ongoing initiatives to enhance the utility of registries, such as the EMA workshops. However, the value of registries to life science industry goes beyond regulatory commitments, and covers the whole life cycle from enhanced R&D & efficient trial delivery, to market access and outcomes based contracts. Additionally, many of the challenges in creating and using registry data are common to other forms of real world evidence generation, and must be tackled with the bigger picture in mind.

Ideally, patient registries (health service or disease based) should be maintained as a core part of the health information infrastructure, supporting healthcare systems to deliver quality care to patients and providing a high quality research platform for the life science sector to utilise in the discovery and development of new treatments and the optimisation of existing treatments.

National level patient registries should, therefore, be funded by healthcare systems as an important part of the Health Information Technology infrastructure to improve delivery of healthcare and patient outcomes.

Industry contributions (made via Public Private Partnerships wherever possible) can then be targeted to improve the utility of registries in addressing broader stakeholder questions and establishing international research infrastructures.
Distributed health data networks could be used to connect individual registries; individual registries should be incentivised to join such networks and should apply common standards and definitions for disease outcome data. The ongoing IMI programmes are good examples of such partnerships.

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

Human papillomavirus (HPV) infection may cause cervical cancer through a progression of intermediate stages that occur over a period of several years. An extensive period of follow-up is thus needed to assess the impact of the recently developed prophylactic vaccines against HPV. Following the completion of phase III clinical trials and regulatory approval, the effect and safety of the HPV vaccine Gardasil are monitored by passive follow-up of clinical trial participants through health registries in Denmark, Iceland, Norway and Sweden. In another study, we use registry data to make population-based assessments of HPV vaccination at the national level. The studies are a joint effort by the vaccine manufacturer and research teams in each country, and depend on the Unique Personal Identifier (PIN) that is universally used in nationwide health and administrative registries in the Nordic countries. In the present talk, I will present the rationale, design and experiences from registry-based HPV vaccine studies in the Nordic countries.

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, Switzerland

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

Panel discussion with speakers

15:00 COFFEE BREAK

Registry Workshop

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

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

17:00 NETWORKING RECEPTION

18:00 END OF THE DAY 1

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

ACCESS PRESENTATIONS

As a benefit of your registration, presentations are made available on the DIA website.

- Presentations are made available to full conference attendees
- To access presentations, go to www.diaglobal.org and click on "Sign in" at the very top. Once you have successfully logged in, go to My Presentations
- No paper copies of the presentations will be provided

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with their presentation. Updated versions of the slides will be made available shortly after the conference.

EVALUATION

Your comments and views on the content and organisation of the event are highly valued. The evaluation form will be available online:

http://bit.ly/2eAXQon

To get a **free USB stick** at the end of the meeting, simply come to see a DIA staff member. We will give this USB **to all attendees who have completed the evaluation**!

CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be sent to all attendees electronically after the conference. Please note certification requires full attendance to the conference.

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 13.5 credits.

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- Sign in with the Email Address You Used to Register for the Registry Workshop

- If needed, use the *Reset Password* link to set your password
- Need assistance? Please feel free to ask one of our staff.

Registry Workshop

DAY TWO | WEDNESDAY, 20 SEPTEMBER

09:00 SESSION 5

BIOBANKING AND GENOME DATA – RISKS AND OPPORTUNITIES

Session Chairs:

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 - academia collaboration

- **Personalised medicine – immune-oncology examples**

Torben Steiniche, Head of Department and Professor - Department of Histopathology, Aarhus University Hospital, Denmark

Ethical challenges – from data to DNA
David Hans-U. Haerry**,** European AIDS Treatment Group, Belgium

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

David Hans-U. Haerry**,** European AIDS Treatment Group, Belgium

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

Nick Meade, Director of Policy, Genetic Alliance, United Kingdom

Panel discussion with Q&A

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12:30 LUNCH

13:30 SESSION 7

SUSTAINABILITY AND PUBLIC FUNDING

Session Chair:

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**

Torben Steiniche, Head of Department and Professor - Department of Histopathology, Aarhus University Hospital, Denmark

Registries & Repositories – Perspectives of a Research Funder
Ayşim Yılmaz, Head, Division Biology & Medicine, Swiss National Science Foundation, Switzerland

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?

Panel discussion with the Programme Committee and Speakers

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

Industry perspective

The Registry of the future could be very different from today: the complete electronic health record data of each patient would be automatically imported, and include codified, researchable information from images, labs and genetics. The use of the registry for life science research, by providers, academics, and industry would be facilitated by clear, practical processes to protect patients' rights. With patients holding greater power over their own data, a healthy dialogue between industry and the public must emerge to build trust and raise engagement in the research process.
Over the next ten years, the technical challenges of bringing quality data together into an efficient registry are matched by the challenges in gaining trust of governments and the public.

17:00 END OF WORKSHOP

Conference Venue

Chelsea Harbour Hotel
London, SW10 0XG
United Kingdom
T: +44 (0)20 7300 8477
E: events.chelseaharbour@millenniumhotels.co.uk

REGISTRATION FORM | ID# 17115

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DIA

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: € _____

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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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- 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.

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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.

Email emea@DIAglobal.org
Tel. +41 61 225 51 51
Fax +41 61 225 51 52
Web www.DIAglobal.org
Mail DIA EMEA, Kuechengasse 16, 4051 Basel, Switzerland