OVERVIEW

Registries are constantly a topic of discussion throughout drug and device development. Challenges exist in terms of ambiguity with structured data collection from existing sources, quality discrepancies, data privacy and data ownership, defining the future of observational data. You know all of this.

How will attending this Registry Meeting make an impact and help YOU overcome these challenges?

This is the only opportunity, to not just listen, but to bring your own views and exchange knowledge, beyond what you can simply read online.

The EMA hosted the Patient Registries Workshop in 2017 to encourage increased stakeholder collaboration. The DIA Registry Meeting 2017 will build upon on this workshop by providing you with a forum to put collaboration into practice.

KEY TOPICS

• Discuss best practices with key opinion leaders
• Equip yourself and your teams with the right knowledge and the right tools
• Fine-tune an optimal solution for patient & disease registries
• Define a clear plan for data collection prior to marketing approval
• Prime your organisation for future increases in observational data
• Enhance the functionality and usefulness of data from registries

WHO WILL ATTEND

• Associate Directors of Pharmacovigilance and Risk Management
• QPPVs / Deputy QPPVs
• Pharmacovigilance Assessors
• Pharmacovigilance Officers
• Pharmacovigilance Technicians
• Medical Safety Officers
• Senior / Clinical Safety Managers
• Senior / Global / Medical Science Leads
• Compliance Specialists
• Epidemiologists
• Medical Affair Experts
• Risk Management & Business Process Management Professionals

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

- Registries in the EU vs US
- Activities going on in disease and patient registries
- EMA activities
- Common big databases or can we learn from existing registries
- Bringing all countries to speed

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

10:30 COFFEE BREAK

11:00 SESSION 2

### STATUS IN THE EU

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

- Introduction: Overview of initiatives in the EU and how can data generated from Registries be useful?
- Challenge of fragmented landscape
- Experience and challenges with Registries and cohorts: Intro to sustainability, data quality, methodology, consistency
  - Case study: Breast cancer registry
  - Case study: HIV registry

12:30 LUNCH

13:30 SESSION 3

### WHERE TO HEAD IN THE EU?

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

- EMA and NCA experiences and requirements: What are the expectations from the regulators?
- Updates from the EMA initiative
- Industry perspective: HPV vaccine studies

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

15:00 COFFEE BREAK

15:30 SESSION 4

### STATUS IN THE US

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

- Overview of Registries in US
- Pregnancy registries – what can we learn?
  - A systematic review of pregnancy exposure registries: examination of protocol-specified pregnancy outcomes, target sample size, and comparator selection;
  - Advantages and problems with pregnancy registries: observations and surprises throughout the life of the International Lamotrigine Pregnancy Registry
  - Case study: EUROCAT
- FDA guideline on medical devices – impact on pharmaceuticals
- Claims databases, sentinel databases, CER
  - Learning from Big Health Care Data
  - Learnings and challenges
  - Evaluation of pregnancy outcomes from the Tysabri® (natalizumab) pregnancy exposure registry: a global, observational, follow-up study

17:00 END OF THE DAY 1

09:00 SESSION 5

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Unless otherwise disclosed, DIA 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. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.
BIOLABNEK AND GENOME DATA – RISKS AND OPPORTUNITIES
Session Chair:
Michael Busch-Sørensen, Board Member, Danish Society for Pharmacoeconomics, Denmark
David Hans-U. Haerry, European AIDS Treatment Group, Belgium
- National biobanking
- Biobank governance models
- Patient organisations
  - Benefit/Risk for the patient
  - Sharing your genome with private insurance companies
- EMR data
- Personalised medicine – immune-oncology examples

10:30 COFFEE BREAK

11:00 SESSION 6
HOW TO WE USE DATA WITHIN AND ACROSS THE COUNTRIES – ROUNDTABLE?
Session Chair:
David Hans-U. Haerry, European AIDS Treatment Group, Belgium
- Sentinel data – US started – EU is following
- Data privacy
- Anonymisation
  - GVP recommendation identification or better deletion.
  - CAVE reuse of data
- Consent from everybody – result should be shared with “participants”
- Consent guides how to inform the patients
- Direct information to individuals
- Goes through competent authorities who issue guidance, and patient decide on getting risk advise or not
- Re-use of data
- Ethics committees
- Patient expectations and concerns

12:30 LUNCH

13:30 SESSION 7
SUSTAINABILITY AND PUBLIC FUNDING
Maren v. Fritschen, Managing Director, AddOn Pharma GmbH, Germany
- Public health care registries: Nordic
  - Why is the public paying
  - A designed ideal situation
  - Twinning between countries
- How can we sustain public registries in the future? Who benefit most going forward
- Open source: benefit/risk management
- Coding/schema
- Common standards – have a working group? EORTC, BIG etc

15:00 COFFEE BREAK

15:30 SESSION 8
FAST FORWARD 10 YEARS – WHAT DO WE NEED TO BUILD NOW?
- Structure around data / methodology
- System improvements
  - Oracle Health Sciences
- Guidance from regulators
- ICH-GCP developments on observational data
- Hybrids – do we need to consider those for Europe?
- Convergence of standards of different regions
- HTA, personalised medicine, payers’ perspectives

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

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 Vishal.Bharadwaj@DIAglobal.org for a custom group rate.
REGISTRATION FORM | ID# 17115
Registry Workshop | 19-20 September 2017 | London, UK

Early-bird discount available for members: Register by 7 August 2017
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.

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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 availability. Please contact DIA EMEA for more information.

Registration fee includes: refreshments, lunches, reception and meeting materials.

TOTAL AMOUNT DUE: €_____________________

*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.

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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.

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, 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 __________________

DIA EMEA, Kuechengasse 16, 4051 Basel, Switzerland

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