DIA

Future of Evidence Workshop

RWE & RCT as building blocks for
transformative evidence generation

24-25 October 2019 | Swissotel, Basel, Switzerland

PROGRAMME COMMITTEE

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Venue

Swissotel Le Plaza Basel
Messeplatz 25
4005 Basel

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Overview

This conference will explore the macro trends affecting RWE across the lifecycle of medicines from development to post approval market use. Advanced analytics and integrated solutions are taking RWE use to the next level, inviting conversations about the quality of different types of RWE sources and how to best approach a unified framework for clinical data collection. We will discuss how RWE can support regulatory, physician and health care provider decision-making as well as optimization of clinical trial design. Join the discussions about patient involvement in RWE design and discover how various stakeholders are leveraging RWE to advance healthcare knowledge and decision-making processes as they are increasingly delegated to AI and related technologies.

Objectives

- Explain and demonstrate different uses of RWE in the design of Clinical Trials
- Clarify the usage of analytics in supporting Clinical Trials Outcomes and RWE
- Discuss patient involvement in RWE design
- Showcase a patient-focused, clinical outcome assessment (COA)

Key Topics

- Using RWE to support regulatory decision making
  - What do Regulators say? – Challenges / Cases Studies of RWE for Regulatory Purposes
- Safety vs. Efficacy
  - Industry insights – Cases Studies
- Understanding the compliance gap – validating patient centric endpoints and outcomes with RWE
- Enhancing Patient involvement in RWE design
- Adopting RWE to fine-tune the design and efficiency of randomized clinical trials
- Using analytics to support Clinical Trials Outcomes and RWE- Case Study
- Leveraging analytics: next-generation clinical decision-making systems
- Informing product and therapy - What Are the Data Sources of the Future?
  - Including overview: which RWD data sources support which purposes (covering quality requirements, applicable standards etc.)?
- Using RWE to enhance the design and efficiency of randomized clinical trials

Who Should Attend

- Real World Evidence
- Epidemiology
- Policy
- Regulatory Science
- Data Science
- Personalized healthcare
- Data and analytics
- R&D big data

DAY ONE | THURSDAY, 24 OCTOBER 2019

08:00 REGISTRATION

08:30 KEYNOTE

THE IMPACT OF DIGITAL TECHNOLOGIES IN HEALTH

Speaker: Stephen Moran, Global Head of Strategy, Novartis, Switzerland

09:15 SESSION 1

SETTING THE STAGE, GLOBAL REGULATORY EXPERIENCE (AND DATA QUALITY STANDARDS)

Session Chair:
Inger Mollerup, External Regulatory Consultant, Denmark

Sources for Real World Data supporting RWE are multiple and include electronic medical records, medical charts, claims data, product and disease registries, and patient generated data/patient reported outcomes. In the regulatory environment, safety databases (e.g. FDA's Sentinel System and PMDA's MID-NET) are used to follow drug safety in the postmarketing space, and examples of other regulatory use of RWD such as the supportive RWE to provide data on historical response rates drawn from chart are appearing. In this session we will hear about the approach for utilising RWE for regulatory purposes from the 3 major regions, EU, US and Japan, what requirements they have to ensure that the quality of the data can support regulatory decisions, and what their expectations are for future use of RWE.

Utilising Real World Data: PMDA's Perspective and Experience Based on Japanese Databases (Remote Presentation)
Yoshiaki Uyama, Director, Office of Medical Informatics and Epidemiology Director, PMDA, Japan

Incorporating Real World Evidence into Regulatory Decision Making: FDA Perspective, Guidance and Experience
Khair ElZarrad, Deputy Director, Office of Medical Policy, CDER FDA, USA

Panel discussion with Q&A, Addressing the Regulatory Landsacape Evolution on RWE

10:30 COFFEE BREAK

11:00 SESSION 2

AI & ADVANCED ANALYTICS ENABLING NEXT-GENERATION CLINICAL DECISION SUPPORT SYSTEMS

Session Co-Chairs:
Frederik Flöther, IBM Q Industry Consultant - Life Sciences & Healthcare, Quantum Computing & AI, Switzerland
André Rausch, Strategic Account Executive Nordics, IBM Watson Health, Germany

The decisions that need to be made by providers and health plans are becoming increasingly complex despite, or perhaps due to, the fact that more and more relevant data (e.g. from electronic medical records, genomic databases, and wearable devices) is becoming available. This has stimulated interested in artificial intelligence and advanced analytics, which are now increasingly being used to support next-generation clinical decision-making.

Advanced Analytics on RWE: Electronic Medical Records & Wearables Data
Frederik Flöther, IBM Q Industry Consultant - Life Sciences & Healthcare, Quantum Computing & AI, Switzerland

Prediction of Prodromal Schizophrenia Based on EHR Data
Christian Brasen, Project Manager, Biometrics, H. Lundbeck A/S, Denmark

The Wisdom of the Crowd - Leveraging Advanced Analytics at Scale
James Black, Associate Group Director, Epidemiologist, Personalised Healthcare Data Science, Roche/Genentech, Switzerland

Leveraging Precision Medicine to Enable Value-Based Care
Jan Kimpen, Chief Medical Officer, Philips, The Netherlands

Panel discussion with Q&A

12:30 LUNCH

14:00 SESSION 3

DATA SOURCES OF THE FUTURE

Session Chair:
Michael Seewald, Worldwide Head Real World Evidence and Digital, Novartis, Switzerland

Real-world data can support to develop, evaluate, and monitor the safety and effectiveness of medicines and medical devices, especially once inherent limitations such as biases, gaps in coverage, outcomes are addressed with appropriate methodology. However, many hurdles have to be overcome in areas like data access, transfer, interoperability and quality before real-world data sources can be considered adequate for a given evidence generation purpose. This session will explore the long-term creation of data assets in the real-world, including the role of trusted, multi-stakeholder collaborations, the need to agree on data formats and standards, promoting the wider use of data to continuously enhance the data asset in a long-term, sustainable fashion. A panel discussion in conclusion shall help to raise a call to action in support of broader collaboration and focusing on approaching data as a strategic asset.

The Value of Trusted Partnerships between Pharma and Healthcare facilitated by Real-world data
Michael Seewald, Global Head Real World Evidence & Digital, Novartis Pharmaceuticals AG, Switzerland

Disclosure Policy

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DAY ONE | THURSDAY, 24 OCTOBER 2019

EU-Funded Initiatives for Real-World Evidence: Relevance for Regulatory Decision-Making and Proposal for the Future
Nikolai Constantin Brun, Chair, HMA-EMA Joint Big Data Taskforce & Director of Division for Medical Evaluation and Biostatistics, Danish Medicines Agency (DKMA), Denmark

IMI EHDEN: Building a Trusted Observational Research Ecosystem to Enable Better Health Decisions, Outcomes and Care
Nigel Hughes, Scientific Director, Janssen Clinical Innovation, Belgium

E-Health in Estonia: Digital Healthcare Will Revolutionise Industry – if we let it
Madis Tiik, Senior Lecturer, Tallinn University of Technology (Taltech), Estonia

Panel discussion with Q&A

15:30 COFFEE BREAK

16:00 SESSION 4

PATIENT INVOLVEMENT IN RWE: DEVELOPMENT AND INTEGRATED EVIDENCE GENERATION

Session Chair:
Michael Lees, Head Value, Evidence and Portfolio Strategy, Takeda, Switzerland

The involvement of patients in the design, analysis and interpretation of clinical research is increasing, leading to improvements in the design and execution of research as well as the use of the resulting data. While much of the focus is on patient involvement in clinical trials, the design, execution and interpretation of real world research is also improved by the active involvement of patients, as is the potential to integrate clinical and real world research. This session will explore optimal patient involvement in real world research while addressing issues such as the end uses of data and issues of data ownership from the perspective of leading patient advocates, the pharmaceutical industry and from HTA decision makers. A panel discussion in conclusion will give a chance for the development of a call to action to further improve the role of patients in real world research in future.

Patient Involvement in Integrated Evidence Generation: What, When, How?
Bettina Ryll, Melanoma Patient Network Europe, Sweden

How patient Involvement Improves Evidence Quality: A Pharmaceutical Industry Perspective
Jessica Scott, Head Global Patient Engagement, Takeda, USA

HTA Decisions and Patient Driven Evidence
Anja Schiel, Chair, EMA Biostatistics Working Party & Senior Adviser and Statistician, Unit for HTA and Reimbursement, Norwegian Medicines Agency (NoMA), Norway

Panel discussion with Q&A

17:30 RWE NETWORKING RECEPTION – SPONSORED BY OUR PARTNER CLINERION LTD

SHORT TALK: GATHERING OF REAL WORLD EVIDENCE IN EUROPE USING MULTIPLE DATA SOURCES IN A CHALLENGING ENVIRONMENT

Lenka Kellermann, Managing Director, OncologyInformationService, Germany
Ian Rentsch, Chief Executive Officer, Clinerion Ltd, Switzerland

DAY TWO | FRIDAY, 25 OCTOBER 20

08:30 REGISTRATION

09:00 SESSION 5

LEVERAGING RWD TO FINE-TUNE THE DESIGN AND EFFICIENCY OF RANDOMISED CLINICAL TRIALS

Session Co-Chairs:
Michael Seewald, Worldwide Head Real World Evidence and Digital, Switzerland
Solène Thieffry, Global RWE policy lead, Real World Evidence Practice, UCB Biopharma, Brussels

Real-world data has the potential to play a major role in RCT design to inform decisions on key protocol components such as inclusion criteria, comparators and endpoints. This session will provide with use cases on RCTs enhancement and discuss on acceptability from different stakeholders in these new approaches. In addition, the rise of RWD allows to advance efficiency of RCT such as site selection and patient recruitment. Different examples will be discussed on how RWE can improve RCTs execution.

RWD Informs the Choice of Endpoints & how such Endpoints Become Part of a Clinical Development Plan
Somnath Sarkar, PhD, VP, Head of Quantitative Sciences, Flatiron Health, USA

Accelerating Clinical Research by Unleashing the Power of Real-World Data at Scale
Rachel Higgins, Vice President Account Management, TriNetX, USA

Observational Study to Strengthen the Evidence Collected in a Phase III Program
Elina Asikanius, Statistician, F. Hoffmann-La Roche Ltd., Switzerland

Panel discussion with Q&A

10:30 COFFEE BREAK

DAY TWO | FRIDAY, 25 OCTOBER 2019

11:00 SESSION 6

USING DATA FROM CLINICAL CARE FOR EVIDENCE GENERATION

Session Chair:
Rob Hemmings, Partner, Consilium Salmonson and Hemmings

Towards More RW Trials - Pragmatic Trials Using Data from Clinical Care for Evidence Generation
Christian Stock, Principal Statistician, Boehringer Ingelheim Pharma GmbH, Germany

Learning from Regulatory Submission of a Pragmatic Clinical Trial Using Real World Data for an Indication Seeking Study
Claudia Cabrera, Senior Director Epidemiology & Evidence Excellence, AstraZeneca, Sweden

Evidence Generation Through Network Meta-Analysis: Is it a RCTs-only exercise?
Andreas Karabis, Senior Principal RWAS, IQVIA, The Netherlands

Panel discussion with Q&A

12:30 LUNCH

13:30 SESSION 7

RWE, DATA SHARING AND DATA TRANSPARENCY (DATA STEWARDSHIP)

Session Chair:
René Allard, External Consultant, Germany

The future of clinical evidence will be determined by the willingness to share data. There are numerous important components in striving for the maximum clinical utility that was identified by the Institute of Medicine in 2015. A culture of sharing with effective incentives is essential, including that stakeholders can identify the platform that is most appropriate for their needs. The panellists will share insights into different initiatives for data sharing and give insights on evolving voluntary data sharing models. Presentation and Q&A session.

Insights on How to Prepare and Plan Data Collection
Nikolai Constantin Brun, Chair, HMA-EMA Joint Big Data Taskforce & Director of Division for Medical Evaluation and Biostatistics, Danish Medicines Agency (DKMA), Denmark

Federated Networks to Improve Trust
Nigel Hughes, Scientific Director, Janssen Clinical Innovation, Belgium

Finding New Solutions to Problems and Concerns in Clinical Data Sharing – Outcomes from Datathon (Remote Presentation)
Rebecca Li, Executive Director, Vivli Center for Global Clinical Research Data, USA

15:00 COFFEE BREAK

15:30 SESSION 8

RWE - CLOSING THE EFFICACY EFFECTIVENESS GAP, OR JUST A BUNCH OF MARKETING HYPE?

Session Chair:
Duane Schulthess, Managing Director, VitalTransformation, Belgium

There are many challenges in determining the long-term relative effectiveness of treatments, despite regulatory approval and robust clinical efficacy. The dilemma for payers is making an accurate assessment when evidence is derived from clinical studies that are extrapolated from outcomes of less than two years. This presentation will give several examples of the work that Vital Transformation has done for several clients harnessing Real-World Data. The most recent example includes evidence extracted from an academic medical center EHR dataset to measure the relapse-free survival (RFS) and cost of treating acute lymphocytic leukemia (ALL) with CAR-T compared to allogeneic hematopoietic cell transplant (HCT). It assesses the clinical effectiveness of CAR-T compared to the current standard of care.

16:30 WRAP-UP SESSION

LOOKING FORWARD: SYNTHESIS OF WORKSHOP DISCUSSIONS AND CALL TO ACTION

17:00 END OF WORKSHOP

EVALUATION

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A Certificate of Attendance will be sent to all attendees electronically after the conference. Please note certification requires full attendance. For more information please liaise with our DIA Contact Centre on Basel@DIAglobal.org or call +41 61 225 51 51.