VIRTUAL EVENT

DIA

Future of Evidence and Smart Health Conference

07-09 October 2020

PROGRAMME COMMITTEE

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International Regulatory Policy Lead, Topic Lead - RWD/RWE, F. Hoffmann-La Roche Ltd., Switzerland

Key Topics

- Global Impact of Digital Health
- Regulatory Landscape - Challenges and Opportunities
- Wearables and Collection Methods
- Innovative Design Using with RWE
- RWE Data Sources
- Data Sharing and impact of GDPR
- The Patient Perspective on Real-World Evidence
- RWE in Integrated Evidence Generation (including clinical trial and potentially qualitative data)
- RWE to Improve Efficiency in Healthcare Systems
- Digital Health - AI & ML
- Decentralized Clinical Trials
- Digital Therapeutics
- Cloud-based System
- Dynamic Dossier and Rapid Review

Overview

Following the success of last year's Future of Evidence and Digital Health Workshops, DIA is pleased to introduce a new two-track conference – the DIA Future of Evidence and Smart Health Conference.

In the Real World Evidence (RWE) track, we will continue discussing the quality of different types of RWE sources and how to best approach a unified framework for data collection. We will explore how RWE can help optimize clinical trial design, and support decision-making for Regulators and healthcare providers (physicians and others). There will also be a focus on understanding how various stakeholders are leveraging RWE to advance healthcare knowledge and decision-making processes at a time when they are being increasingly delegated to AI and related technologies.

The Digital Health track will be a deep dive into the fast-evolving Digital Healthcare ecosystem and review not just novel wearables and data collection methods, but also new formats of digital intervention in Health. We will be tackling topics and concepts such as the Dynamic Dossier in the Cloud, Rapid Reviews, and Digital Therapeutics which could potentially help fulfil unmet medical needs for patients facing roadblocks in traditional therapy and intervention.

This conference will bring together the two tracks to explore the data and digital ecosystem holistically and discuss the opportunities this provides to support optimisation of development and provision of healthcare.

Target Audience

Professionals involved in:

- Real World Evidence;
- Regulatory Innovation;
- Regulatory Science
- Digital Health and Solutions
- Patient Advocacy.
- Innovation
- Policy
- Epidemiology
- Data Science
- R&D big data
- Data and analytics
- Data Management, Privacy and Science
- Artificial Intelligence and Machine Learning
- Clinical operations and Clinical development
- Market Access & Reimbursement
- Bioethics

DAY ONE | WEDNESDAY, 7 OCTOBER 2020

13:00 LOG-IN

13:10 WELCOME AND ORIENTATION

Sara Torgal, Scientific Programmes Manager, DIA, Switzerland

13:30 SESSION 1

REGULATORY LANDSCAPE RWE AND DIGITAL HEALTH - CHALLENGES AND OPPORTUNITIES

Session Co-Chairs:
Virginia Acha, Executive Director, Global Regulatory Policy, MSD

Traditionally, the term "digital health" could be simply defined as using technology to help improve individuals' health and wellness. However, the area of digital (or smart) health has been rapidly evolving over the last decade and is now considered a diverse yet complicated space which could encompass everything from eHealth and mHealth (wearable tech and devices) to AI and Machine Learning (ML), from Digital endpoints and biomarkers to digital therapeutics, and from robotics to electronic health records (EHRs). Many of these have relevance and application within the regulatory setting in terms of evidence generation and use within regulatory decision making.

Real World Data (RWD) / Real World Evidence (RWE) is another emerging field of great interest for application in the regulatory space, yet is often viewed and treated as a separate, stand-alone topic from digital health. This could be due to the fact that RWD and its application in regulatory submissions and decision making is already more mature than some of the digital health applications, in addition to the fact there are numerous concept-specific considerations to the application of RWD/RWE not necessarily applicable to digital health. However despite this, the reality is that digital health and RWD are themes which are inherently linked, especially when we consider the fact that much of the data identified, collected and subsequently analysed through new digital technologies can in fact be considered as RWD to support decision making, and hence makes it challenging to discuss and debate one without the other.

The concept of this interplay and relationship between digital health and RWD/RWE underpins the unique narrative and flow for this two-day DIA workshop which will involve both joint sessions but also separate digital health and RWD/RWE track sessions.

This opening session will serve to introduce you to the evolving global regulatory landscape for digital health and RWD/RWE and through discussion with regulators and industry members from across the globe will debate what these topics mean in their respective areas and what are the emerging regulatory opportunities and challenges these novel digital fields are currently presenting us.

Panel discussion with Q&A

Ina Rondak, Biostatistician, Methodology, Data Analytics and Methods Task Force, EMA, EU
Nikolai Constantin Brun, Chair, HMA-EMA Joint Big Data Taskforce & Director of Division for Medical Evaluation and Biostatistics, Danish Medicines Agency (DKMA), Denmark
Emma du Four, Head of International Regulatory Policy, Abbvie, UK

15:00 BREAK

15:15 SESSION 2

DATA SOURCES

Session Chair:
Michael Lees, Head of Value, Evidence and Portfolio Strategy – EUCAN Takeda Pharmaceuticals International GmbH, Switzerland

As the importance of real world evidence to healthcare decision makers continues to grow, so do the questions addressed by real world evidence and the sources of such evidence. In addition to the various sources of claims data and data from health records in North America, EU and Asia, the number of registries developed to shed further light on disease management, outcomes and real world effectiveness continues to grow, while data captured from less traditional sources such as early access programs and social media is also increasingly used. This session aims to identify the emerging trends when making the choice about the most appropriate choices for the sources of real world evidence from the perspective of HTA bodies, real world evidence practitioners and pharmaceutical industry.

Panel discussion with Q&A

16:15 BREAK

16:30 SESSION 3

APPLICATION OF AI & ML IN DISCOVERING DRUG DEVELOPMENT

Session Chair:
Niels Leander, Consulting Director, NNIT, Denmark

Embracing Real World Evidence (RWE) & Robotic Process Automation to transform Regulatory Affairs Submission Process
Susant Mallick, Amazon Healthcare & Life Sciences Digital Evangelist, Amazon Web Services, the Netherlands

Panel discussion with Q&A

17:30 WRAP-UP

17:45 NETWORKING ACTIVITY

18:30 END OF DAY ONE

DAY TWO | THURSDAY, 8 OCTOBER 2020

13:00 LOG-IN

13:05 INTRODUCTION

Sara Torgal, Scientific Programmes Manager, DIA, Switzerland

13:20 SESSION 4

INNOVATIVE DESIGN USING RWE

Session Chair:
Adrian Cassidy, Global Head Real World Evidence, Novartis Oncology, Switzerland

Panel discussion with Q&A

14:20 BREAK

14:35 SESSION 5

NOVEL DIGITAL END POINTS

Session Chair:
Cécile Ollivier, Chief Operation Officer, Aparito, UK
Solène Thieffry, Global RWE policy lead, Real World Evidence Practice, UCB Biopharma, Belgium

Most endpoints used in clinical trials are not necessarily patients-preferred nor easy to collect in routine care on the long term. Enhancing endpoints measurement continuously from clinical practice to real-word would facilitate better healthcare decision making for individual patients and population-level health. The aim of the session is to provide regulatory requirements and current use cases to develop novel digital endpoints that would help to bridge the gap in endpoints measurement across drug life cycle.

Regulatory Perspective on Digital Endpoints
Lada Leyens, Regulatory Program Manager, F. Hoffmann-La Roche Ltd., Switzerland

SARAhome - a new Clinical Tool for assessing Ataxia at home
Marcus Grobe-Einsler, German Center for Neurodegenerative Diseases (DZNE), Bonn, Germany

Panel discussion with Q&A

15:45 BREAK

16:00 SESSION 6

BLOCK CHAIN

Session Chair:
Adama Ibrahim, Director, Digital Solutions, Global Drug Development, Novartis, Switzerland

To share the voice of core stakeholders and users of blockchain in drug development to discuss challenges, risks and benefits.

Regulator View

Patient Advocate View
Jeanne Barnett, Pathfinder for Patients and Caregivers, Teacher, CEO/Founder CysticFibrosis.com, USA

Vendor Representative
Heather Flannery, Health Circle Global Lead, ConsenSys Health, USA

PI Representative

Panel discussion with Q&A

17:00 WRAP-UP

17:15 NETWORKING ACTIVITY

18:00 END OF DAY TWO

Continuing Education

DIA meetings and training courses are approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and are honoured with credits for pharmaceutical medicine. All meeting and training course participants are eligible for applicable credits.

Disclosure Policy

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.

DAY THREE | FRIDAY, 9 OCTOBER 2020

13:00 LOG-IN

13:05 INTRODUCTION

Sara Torgal, Scientific Programmes Manager, DIA, Switzerland

13:20 SESSION 7

UNWRAPPING RCT DUPLICATE

Session Chair:
Claudia Cabrera, Senior Director Epidemiology & Evidence Excellence, Adj Researcher Karolinska Institute, Dept Epidemiology and Biostatistics, AstraZeneca, Sweden

The demand for data quality and quantity has expanded exponentially in the past decade. There has been a tremendous effort to investigate the potential of real world data (RWD) to provide real world evidence (RWE) based on real world science (RWS). Industry and governments are assessing the power of data to potentially drive health strategy, safety, clinical trial investigations, and more general public health decisions. This challenge was clearly elucidated through the passing of the 21st Century Cures Act in 2016, mandating legislation and guidance around the use and interpretation of RW data and evidence. It also highlighted that RWE will need to consider methodologies used to generate evidence and the reliability and relevance of the RWD. Currently available data sources often reflect local health policies and services, RW data may be generated from commercial sources, reflecting claims and billing activities. Other data source types include electronic health records (EHRs) from hospital and primary care facilities, an example being the UK CPRD; while national health registries are prominently available for research purposes in the Nordic countries for the monitoring and guidance of public health.
The RCT Duplicate Framework embraces this challenge. It is an FDA sponsored ~ 3-year series of studies conducted by Brigham Women's & Harvard University and AETION. It involves the replication of 30 published RCTs and contains additional FDA funding to predict the results of 7 ongoing Phase IV RCTs i.e. CAROLINA. Unwrapping RCT Duplicate will be a session where we describe an attempt to emulate their current efforts and invite others to discuss the topic, along with FDA representatives allowing for a more in-depth understanding of the work being conducted and the outcomes expected.

Capturing the precision of RCTs with RWD – can we do it?
Anja Schiel, Senior Adviser/Statistician, Unit for HTA and Reimbursement Norwegian Medicines Agency (NoMA), Chair EMA's Biostatistics Working Party, Chair EMA's Scientific Advice Working Party, Norway

The art of transparency, goodwill, and trust
Gregory Daniel, Head, US Healthcare Policy Edwards Lifesciences, USA

Panel discussion with Q&A

14:30 BREAK

14:45 SESSION 8

CLOUD BASED SYSTEMS FOR DATA STORAGE - DEMOCRATISING SCIENCE

Session Chair:
Alison Cave, ISCF Challenge Director, Innovate UK, UK Research and Innovation, UK

The healthcare sector is generating data at a faster rate than almost any sector and the availability of such data is already fundamentally changing the way we do scientific research and impacting on how we deliver clinical care. New digital tools and analytics offer the opportunity to better define and describe an individual over a lifetime and moreover how the interaction of biology, the environment and lifestyle underpins disease pathophysiology and the effectiveness of medicinal products and treatments. It is thus increasingly the vision that future scientific discoveries will be dependent on an ability to collate, share and interrogate the digital data related to our health status and generated through all walks of daily life.

Intrinsic to this vision is delivering infrastructures which can offer scalable and standardised tools for acquiring, organising, analysing and visualising this multi-dimensional data and allow opportunities offered by AI approaches to be realised. However, harnessing its value for economic and social benefit is difficult. Data is siloed by disease, institution, social care setting; data is of variable and often unknown quality and provenance; data is stored in different structures and terminologies and mechanisms of access are variable and geography dependent. Over and above this there are challenges around the culture of data sharing partly arising from ethical and legal considerations but also partly because of a belief that the data itself is a valuable commodity. Often however the intrinsic value does not lie in the data itself but in the processing, linkage and analysis of that data to enable differences in demographics, lifestyles and geographies to be captured.

Experts from regulatory, industry, technical and ethical fields will explore how data sharing platforms hosted on the cloud could be designed to remotely and securely store, manage and retrieve data globally, opening up opportunities for all to derive greater value from research, prevent duplication of effort and make evidence more generalisable.

DAY THREE | FRIDAY, 9 OCTOBER 2020

15:55	BREAK
16:10	SESSION 9

WHAT IS THE FUTURE OF EVIDENCE? DIGITAL STRATEGIES FROM X, Y, AND Z

Session Chair:
Thomas Brookland, International Regulatory Policy Lead, Topic Lead - RWD/RWE, F. Hoffmann-La Roche Ltd., Switzerland

Panel discussion with Q&A, with the participation of:
Alison Cave, ISCF Challenge Director, Innovate UK, UK Research and Innovation, UK

17:15	WRAP-UP
17:30	END OF THE CONFERENCE

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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. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.