Digital Health Workshop

24-25 October 2019 | Swissotel, Basel, Switzerland

Programme Committee

Katarzyna Kolasa
Professor of Health Economics, Head of Dept. of Health Economics and Health Mgmt, Kozminski University, Poland

Maria Raad
Vice President, Customer and Digital Strategy, Janssen EMEA Commercial, Switzerland

Michael Forstner
Senior Vice President, Head of Risk Management and Pharmacoepidemiology, PrimeVigilance, Switzerland

Scott Askin
Global Program Regulatory Director, Regulatory Affairs Innovation, Novartis, Switzerland

Who Should Attend

Professionals involved in:

- Digital health
- Digital solutions
- Data Management, Privacy and Science
- R&D
- Innovation
- Artificial Intelligence and Machine Learning
- Clinical operations and Clinical development
- Market Access & Reimbursement
- Bioethics
- Real World Evidence
- Regulatory Innovation
- Patient Advocacy

Overview

Digital Health can be described as the convergence between digital technologies and healthcare solutions. However, multiple questions concerning both the usage and sharing of data and the pricing and reimbursement of digital health solutions remain unanswered.

By putting in the same table Industry representatives, involved in the multiple Digital Health related disciplines, together with Regulatory Agencies and other relevant stakeholders, this Workshop aims to be a discussion platform for the currently most relevant Digital Health topics, such as the qualification procedures across the globe, Real World insight generation, Data ethics, pricing and reimbursement of Digital Health solutions, virtual and remote trials, among many others. Join us to learn more on the fast evolving Digital Healthcare ecosystem and to listen to the aspiration from various stakeholders on the future of Digital health and the value to patients, HCP, Payers and many other players in healthcare

Objectives

By the end of this Workshop, participants will:

- Recognise which are the current challenges and opportunities in Digital Health, both scientifically, in terms of value proposition and credibility of Data;
- Discuss what is Digital Ethics and how to use it;
- Understand the current regulatory thinking regarding new technologies.

Key Topics

- Early dialogue with regulators and qualification procedure across the globe
- Patient centricity as the key – the link between the biology of the disease and Digital Health solutions
- Real World insight generation
- Technology:
  - Mobile health
  - Sensors and endpoints
  - Artificial Intelligence and Machine learning
- Aspirations towards the future of Digital Health
- Data ethics: access, usage, and sharing of data
- Pricing and reimbursement of Digital Health solutions
- Decentralised, virtual and remote trials

Venue

Swissotel Le Plaza Basel
Messeplatz 25
4005 Basel

WIFI Access

Username: **Swissotel**

Password: **DIA**

DAY ONE | THURSDAY, 24 OCTOBER 2019

07:45 REGISTRATION

08:30 KEYNOTE 1

THE IMPACT OF DIGITAL TECHNOLOGIES IN HEALTH

Stephen Moran, Global Head of Strategy, Novartis, Switzerland

What are the great trends shaping the pharmaceutical industry and what are the implications for the future business model? In addition to the latest perspectives on Biomedical Innovation, Stephen will focus on the future role of technology in shaping health systems and the innovative biopharma companies that serve them. He will illustrate these technology trends with some practical examples and the priorities for the future.

09:15 SESSION 1 - FREE SESSION

SESSION 1 - FUTURE OF EVIDENCE WORKSHOP

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

Session Chair:
Inger Mollerup, External Regulatory Consultant, Denmark

Use of Real World Data for Regulatory Purposes Pre-and Post-Approval, European Perspective and Experience
Peter Mol, Principal Assessor & SAWP Vice-Chair, MEB, The Netherlands

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

SESSION 1 - VALUE, ACCESS & REGULATORY EVIDENCE

OVERVIEW OF EXISTING EVIDENCE GAPS AND MISALIGNMENTS ACROSS REGULATORY AND REIMBURSEMENT ECOSYSTEM – IMPLICATIONS FOR THE PATIENT ACCESS

Session Chair:
Mira Pavlovic, Associate Professor for Regulatory and HTA Science, Portugal & Medicines Development and Training Services, France

Evolution of Policies and Standards for Handling the Evidence for Decision Making – Selected "Hot Topics" to Set the Scene
Michael Berntgen, Head of Product Development, Scientific Support Department, European Medicines Agency, EU

Existing Gaps in the Use of Evidence across Regulatory and Reimbursement Agencies, Misalignment of Standards and Practices and their Implications for Patient Access
Niklas Hedberg, Chair EUnetHTA Executive Board & Chief Pharmacist Dental and Pharmaceutical Benefits Agency, TLV, Sweden

Reimagining the Use of Evidence across Regulatory and Reimbursement Continuum – What are the Promising Ways Forward?
Edith Frenoy, Director Market Access, EFPIA, Belgium

Panel Discussion with Q&A

10:45 COFFEE BREAK

11:00 SESSION 2

DATA ETHICS & GOVERNANCE

Session Chair:
Katarzyna Kolasa, Professor of Health Economics, Head of Dept. of Health Economics and Health Mgmt, Kozminski University, Poland

AI in Healthcare: the Value of Data and the GDPR Challenge
Francesca Mazzi, Marie Curie Early Stage Researcher, Queen Mary University of London - Maastricht University, UK

GDPR and CTR interplay
Sigrid Achenbach, Senior Legal Counsel, Bayer, Germany

The Patients' Perspective
Kostas Aligiannis, Digital Health Lead, EPF, Belgium

Q&A and Panel Discussion

12:30 LUNCH

DAY ONE | THURSDAY, 24 OCTOBER 2019

14:00 SESSION 3

IN THE SEARCH FOR THE BEST VALUE FRAMEWORK OF DIGITAL HEALTH INTERVENTIONS: OPPORTUNITIES AND CHALLENGES ON THE WAY TO PRICING AND REIMBURSEMENT (P&R) OF DIGITAL HEALTH INTERVENTIONS

Session Chairs:
Katarzyna Kolasa, Professor of Health Economics, Head of Dept. of Health Economics and Health Mgmt, Kozminski University, Poland
Michael Forstner, Senior Vice President, Head of Risk Management and Pharmacoepidemiology, PrimeVigilance, Switzerland

This session will address how the increasing use of digital health interventions (DHI) can improve patients' health and lead to a more efficient allocation of limited healthcare resources. As so, we will discuss the pricing & reimbursement challenges for DHIs, the role of clinical and economic data in the value assessment of DHIs and real life examples of successful introduction of DHIs into the public and healthcare systems.

Evidence Standards Framework for Digital Health Technologies
Joanne Holden, Associate Director for the Medical Technologies Evaluation Programme & Interventional Procedures Programme, NICE, UK

The Challenges with the Digital Transformation of Healthcare
Linus Jönsson, Vice President of Medical Outcomes Research, H. Lundbeck A/S, Denmark

Digital Transformation of Healthcare: the Search for the Best Value Framework
Speaker invited

Q&A and Panel Discussion

15:30 COFFEE BREAK

16:00 SESSION 4

REGULATORS' VIEW ON DIGITAL HEALTH

Session Chair:
Rebecca Stanbrook, Global Head, Compliance and Regulatory Affairs Quality, Novartis, Switzerland

In this ever-increasing age of digitalisation, digital health finds itself at the heart of the patient experience. From recruitment to notifications to take medicine, digital Apps and devices are being found increasingly in the industry. Hear from Regulators how they will respond to this challenge. Listen to industry colleagues on innovation and what guidance is needed.

Qualification Advice Procedure: a framework for success
Francesca Cerreta, Principal Scientific Officer, EMA, EU

National Experiences with Digital Health: What can we learn from our successes and mistakes?
Nikolai Brun, Director of Division for Medical Evaluation and Biostatistics, Danish Medicines Agency & Chair, HMA-EMA Joint Big Data Taskforce, Denmark

What is Industry expecting from Regulators in Digital Health?
Kathleen Meely, Director, Programme Lead GCP, R&D QA, AstraZeneca, UK

Q&A and Panel Discussion

17:30 NETWORKING RECEPTION - SPONSORED BY 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

18:30 END OF DAY ONE

DAY TWO | FRIDAY, 25 OCTOBER 2019

08:30 WELCOME

09:00 SESSION 5, PART I

TECH INNOVATION FOR LIFE SCIENCES: SPOTLIGHT ON EMERGING PARTNERSHIPS

Session Chair:
Michael Forstner, Senior Vice President, Head of Risk Management and Pharmacoepidemiology, PrimeVigilance, Switzerland
Scott Askin, Global Program Regulatory Director, Regulatory Affairs Innovation, Novartis, Switzerland

AI Application for Early Diagnosis in Rare Disease
Greg Davis, COO, Analytics4Life (A4L), USA

(Workshop with Q&A)

09:45 SESSION 5, PART II

THE PARADIGM SHIFT: FROM TREATMENT TO PREVENTION

Session Chair:
Maria Raad, Vice President, Customer and Digital Strategy, Janssen EMEA Commercial, Switzerland
Scott Askin, Global Program Regulatory Director, Regulatory Affairs Innovation, Novartis, Switzerland

Setting the Scene: Digital Biomarkers in Clinical Research from a Pharma Industry Perspective
Christian Gossens, Digital Biomarker Informatics & Global Area Head, pRED Informatics, F. Hoffmann-La Roche Ltd., Switzerland

Panel Discussion: **Where are we with Digital Biomarkers for Disease Monitoring?**
Christian Gossens, Digital Biomarker Informatics & Global Area Head, pRED Informatics, F. Hoffmann-La Roche Ltd., Switzerland
Foteini Orfaniotou, Group Digital Health Leader, F. Hoffmann-La Roche Ltd., Switzerland
Trishna Bharadia, Health Advocate, Patient Engagement Consultant and Expert Patient in MS, Chronic Illness & Diversity issues, UK
Marcus D'Souza, Head Neurostatus-UHB, University Hospital Basel, Switzerland

10:30 COFFEE BREAK

11:00 SESSION 6 - FREE SESSION

SESSION 6 - FUTURE OF EVIDENCE WORKSHOP

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

SESSION 6 - VALUE, ACCESS & REGULATORY EVIDENCE

PARALLEL SCIENTIFIC ADVICE

Session Chair:
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

Regulatory Perspective
Michael Berntgen, Head of Product Development, Scientific Support Department, European Medicines Agency, EU

HTA Body Perspective
Pilar Martin, Norwegian Medicines Agency (NoMA), Norway

Industry Perspective
Judith Creba, Executive Director, EU Regulatory Strategy Novartis, Switzerland

Panel Discussion with Q&A

12:30 LUNCH

13:30 SESSION 7

DECENTRALIZED, VIRTUAL AND REMOTE TRIALS

Session Chairs:
Scott Askin, Global Program Regulatory Director, Regulatory Affairs Innovation, Novartis, Switzerland
Francesca Cerreta, Principal Scientific Officer, EMA, EU

In this session, we will review the current Decentralized Trials landscape, highlighting ongoing Industry initiatives which are helping to advance Telehealth adoption. We will hear from the Healthcare Industry and discuss how they have overcome challenges in delivering Telemedicine to patients. Additionally, we will hear from the EMA on how EU regulations could be shaped to enable Decentralized Trials, while FDA will explore Innovative Clinical Trial Designs using Digital Tools. To conclude, we will round off with an opportunity for the audience to ask questions to our leading experts on a topic that is set to become one of the biggest disrupters in Clinical Research.

Introduction: Current Regulation and Guidance
Scott Askin, Global Program Regulatory Director, Regulatory Affairs Innovation, Novartis, Switzerland

TeleMedicine: Setting the Standards in Remote Trials
Andy Fischer, President, ISfTeH & CEO, Medgate, Switzerland

Decentralized, Virtual and Remote Trials – How is the EU Enabling Success?
Francesca Cerreta, Principal Scientific Officer, EMA, EU

Innovative Clinical Trial Designs using Digital Tools
Khair ElZarrad, Deputy Director, Office of Medical Policy, CDER FDA, USA

Q&A and Panel Discussion

15:00 COFFEE BREAK

15:30 SESSION 8

ASPIRATIONS TOWARDS THE FUTURE OF DIGITAL HEALTH

Session Chairs:
Maria Raad, Vice President, Customer and Digital Strategy, Janssen EMEA Commercial, Switzerland
Scott Askin, Global Program Regulatory Director, Regulatory Affairs Innovation, Novartis, Switzerland

The Future of Digital Technologies in Healthcare: Clinical Research
Bryan McDowell, Chief Executive Officer, DataFusion GmbH, Switzerland

The Future of Digital Technologies in Healthcare: The Healthcare Professionals' Perspective
Sofia Couto da Rocha, Unit Manager, Lusiadas Clinics Lisboa; Founder, SKIN SOUL & President, IT Commission, Health Parliament, Portugal

Patients' Future Needs and Expectations on Digital Health
Kostas Aligiannis, Digital Health Lead, EPF, Belgium

Q&A and Panel Discussion, with the additional participation of the Speakers from the previous sessions

17:00 CLOSING REMARKS

17:15 END OF THE WORKSHOP

| Venue

Swissôtel Le Plaza Basel
MessePlatz 25
4005 Basel, CH
Tel: +41 61 555 3333
Email: basel@swissotel.com

HOW TO GET THERE From Basel EuroAirport: a direct bus (Line Nr. 50) runs every 20 min. taking you to the Basel SBB train Station. The main train station 'SBB Basel' is approximately 2km away - take the tram Nr. 1 or Nr. 2 to Messeplatz Basel | the train station 'Basel Badischer Bahnhof' is approximately 1km away - take the tram Nr. 6 to Messeplatz Basel.

ACCOMMODATION

DIA has blocked a limited number of rooms for the participants at the Hyperion Hotel, next to the event venue. This special room rate will be available until 10 September 2019 or until the group block is sold-out, whichever comes first. Please contact Hyperion hotel and mention DIA group to book:

HYPERION Hotel Basel
Messeplatz 12. CH-4058 Basel
Tel: +41 (0)61 560 40 00
E-mail: hyperion.basel@h-hotels.com
Standard Double room rate: CHF 279, including Breakfast & VAT, city tax and BaselCard for public transport. What to see in Basel?