Digital Biomarkers in Clinical Trials Summit
How Digital Biomarkers and IoT Wearable Sensors will Create the Clinical Trials of the Future

JUNE 20TH, 2018
ROCHE BUILDING 1 - BASEL, SWITZERLAND

ORGANIZED BY: 
VENUE SPONSOR: Roche
CO-ORGANIZER: KARGER

A PRECOMPETITIVE CONSORTIA OF EXPERTS WORKING TO LEVERAGE DIGITAL BIOMARKERS AND ENDPOINTS TO DRIVE THE ACCELERATION OF DRUG DEVELOPMENT

CORE THEMES:

1. The State of Digital Biomarkers Today
2. Best Practices for Capturing Source Data for Digital Biomarkers
3. Moving Data from Capturing Source to Internal Data Analytics Systems via Pipelining
4. Best Practices on Analyzing Source Data for Digital Biomarkers
5. Current Landscape of Opportunities & Regulatory Hurdles for Digital Biomarkers to overcome

Wednesday, June 20th, 2018

08:00
Conference Registration Open in Roche Building 1 Lobby

08:45 – 09:05
Welcome / Opening Remarks from Roche

Chairpersons: Christian Gossens, Global Head, Digital Biomarkers, Roche
Bryn Roberts, Global Head of Operations & Basel Center Head, Roche Pharmaceutical Research and Early Development

09:05 – 09:10
Welcome Address Basel Area Swiss / Day One

Basel Region Industry/Science perspective of Digital Biomarkers

SESSION SPEAKERS:
Peter Groenen, Head of Translational Sciences, Idorsia
09:10 – 09:35  KEYNOTE PANEL DISCUSSION: The State of Digital Biomarkers

- Medical impact – what are the challenges that we want to address with those endpoints?
- Where can digital make the best impact?
- What data does to take to gain insight? Source data? Or derived data?
- How to begin the process of design thinking – what can we conclude from those measures?

SESSION SPEAKERS:
Shibeshih Belachew, MD PhD, Principal International Medical Director, Roche
Kirsten Taylor, Biomarker and Experimental Medicine Leader, Roche
Ieuan Clay, Group Lead, Digital Endpoints, Novartis
Emilio Merlo Pich, VP, Head of Digital Medicine, CNS, Takeda
Ashish Atreja, MD, MPH, Assistant Professor and Chief Innovation Officer, Medicine, Icahn School of Medicine at Mount Sinai, NY
Moderator: Bryn Roberts, Global Head of Operations & Basel Center Head, Roche Pharmaceutical Research and Early Development

09:35 – 10:00  CASE STUDY: Digital Biomarker Development – How Mobile Technology Can Innovate Clinical Endpoints

Christian Gossens, Global Head, Digital Biomarkers, Roche

10:05 – 10:30  CASE STUDY: Innovation Lab at Mount Sinai – Identification of Digital Biomarkers

Ashish Atreja, MD, MPH, Assistant Professor, Chief Innovation Officer, Medicine, Icahn School of Medicine at Mount Sinai, NY

10:30 – 10:50  NETWORKING COFFEE AND REFRESHMENT BREAK
Located in Pre-Conference Foyer and Exhibition Area – Sponsored by Medidata

10:50 – 11:15  PANEL DISCUSSION: BEST PRACTICES OF CAPTURING SOURCE DATA FOR DIGITAL BIOMARKERS

SESSION SPEAKERS:
Peter Groenen, Head of Translational Sciences, Idorsia
Jeff Arnett, CEO, ActiGraph
Paul Strijbos, Innovation Leader, Digital Health Platforms, Product Development PHC Center of Excellence, Roche
John Batchelor, Transcelerate Patient Technology Team, Sr. Outcomes Measurement Scientist, Roche
Paul Glimcher, PhD, CEO, DataCubed
Moderated by: Christian Gossens, Global Head, Digital Biomarkers, Roche
CASE STUDY: Floodlight: Towards the day when participants, physicians & scientists can monitor MS symptoms and health over time using a smartphone

Mike Baker, Group Leader, Digital Health, Global Medical Affairs, Roche

CASE STUDY CO-PRESENTATION: Using Wearables for Seizure Detection

Combining Byteflies’ versatile wearable health development platform with UCB’s world-leading expertise in the development of anti-epileptic drugs led to the creation of a user-friendly wearable device that accurately tracks epileptic seizures outside the hospital, in collaboration with the University Hospital of Leuven. This device, which continuously collects local EEG, heart rate and motion data, is used to generate objective seizure diaries to help refractory patients better manage their disease, triggers & treatment options, and will provide additional insights into the pathophysiology of SUDEP. Despite the wealth of biomarkers generated by the wearable, it’s still small enough to be worn comfortably behind the ear.

Gergely Vértes, Solution Accelerator Lead, Wearable for Epilepsy, UCB
Hans Danneels, CEO, ByteFlies

CASE STUDY: Walk This Way: Case study on Real-World Gait Behaviour

Due to advances in technology, our ability to capture data in clinical settings is better than ever. How we ensure that we are extracting the relevant information from that stream of data in a robust & sensitive way is the focus of our research. We will present examples and discuss how we are tackling these challenges in a case study focusing on assessing real-world walking behaviors using wearable inertial sensors, and look at how tailored analytic solutions are helping us gain insight in clinical settings.

Ieuan Clay, Group Lead, Digital Endpoints, Novartis

From Data Quality to Data Privacy: Overcoming Challenges to Adoption of Digital Biomarkers in Clinical Research

The collection of digital biomarker data is presenting new data management challenges for sponsors and technology providers alike. Traditional clinical data management may consist of thousands of discrete data endpoints per subject during the course of a clinical study. With the introduction of smart devices and sensors, there is an exponential jump in the volume of data that can be collected resulting in perhaps millions of data points for each subject. Developing methods for ensuring data quality is not an insignificant effort. Combined with evolving international regulations in the protections of patient rights, sponsors must work closely with technology partners to ensure that design of data management tools is sufficient to manage the collection, analysis, protection & rights governance models sufficient to meet tomorrows trials.

Michael Tucker, Senior mHealth Product Specialist, Medidata
12:35 – 13:15  EXECUTIVE NETWORKING LUNCHEON
Located in Foyer and Exhibition Area – Sponsors: Medable, Byteflies & UCB

13:15 – 13:40  PANEL DISCUSSION: BEST PRACTICES ON MOVING DATA FROM CAPTURING SOURCE TO SOURCE DATA ANALYTICS VIA PIPELINING

SESSION SPEAKERS:
Ieuan Clay, Group Lead, Digital Endpoints, Novartis
Philippe Marc, Global Head, Integrated Data Sciences, Novartis
Kees van Bochove, CEO, The Hyve
Bert Hartog, Innovation Leader, R&D Operations, Janssen
Moderator: Michelle Longmire, CEO, Medable

13:40 – 14:00  From Patient Engagement to Insight: Best Practices of Data Pipelining in Direct to Patient Trials

Medable is enabling a future where patient-centric data transforms clinical trials and drug discovery. Using the Medable cloud platform, sponsors can seamlessly configure and deploy clinical trials to patients’ mobile devices and sites. Data collected across studies, institutions, and companies, is de-identified and aggregated to create the first human digitome, a digital representation of health and disease that provides novel foundational data for digital biomarkers and digital endpoints. For health, for life – Medable.

Michelle Longmire, CEO, Medable

14:00 – 14:20  CASE STUDY: Data pipelining for Digital Biomarkers at Novartis

Working with datasets produced by sensors, wearables and IoT in Pharma research or clinical setting is still about refining ways to get things done. Data standards, data transfer and data processing are not yet well established. How to transfer, store, process raw/derived data while keeping data secured and compliant with regulations and internal processes? We will share our experience collecting digital biomarker raw data and integrating it with Clinical Trial data at Novartis Institute for Biomedical Research.

Philippe Marc, Global Head, Integrated Data Sciences, Novartis
CASE STUDY CO-PRESENTATION: Personalized Biosensor–enabled Safety Monitoring and Digital Biomarkers in Oncology Treatment

Today’s anti-cancer treatments offer tremendous potential to improve patient outcomes. However, these powerful agents can also present risks related to potentially-significant adverse events. PhysIQ (Chicago, IL) is working with HagaHospital (The Hague, Netherlands) to deploy its accelerateIQ™ continuous monitoring solution that captures multivariate data from a clinical-grade biosensors and applies FDA-cleared, Artificial Intelligence–based personalized physiology analytics to detect physiological anomalies during and after anti-cancer treatment. Funded by Janssen Pharmaceuticals, the study is evaluating how clinicians can leverage this technology to proactively identify and manage adverse events that may result from chemotherapy and immunotherapy, with potential to establish safety-related digital biomarkers.

Chris Economos, VP Business Development, PhysIQ
Bert Hartog, Innovation Leader, R&D Operations, Janssen

NETWORKING COFFEE AND REFRESHMENT BREAK

Located in Pre-Conference Foyer and Exhibition Area – Sponsored by Medidata

PANEL DISCUSSION: Best Practices on Analyzing Source Data for Digital Biomarkers

- Applications of AI and Machine Learning
- A discussion of analytic automation and visualization best practices
- Transforming clinically relevant symptoms into digitally measurable biomarkers

SESSION SPEAKERS:
Peter Groenen, Head of Translational Sciences, Idorsia
Jonas Dorn, Project Lead, Digital Health, Novartis
Emilio Merlo Pich, VP, Head of Digital Medicine, CNS, Takeda
Kees van Bochove, CEO, The Hyve
Florian Lipsmeier, pRED Informatics Data Science, Roche

Moderated by: Michael Tucker, Senior mHealth Product Specialist, Medidata
Exploring High Dimensional Clinical Data to Identify Subgroups of Patients

- Biomarkers are driving a better understanding of clinical outcomes in disease
- Contrasting biomarkers with claims, EMR, and other data allows for finding out what makes patients respond well to therapy
- Applying topological data analysis to identify subgroups in high dimensional data
- Preparing for new biomarkers that track high volume biometric data

Nikhil Gopinath, Sr. Product Manager, Saama

CASE STUDY: From Data to Insights: Measuring Morning Pain and Stiffness in Arthritis

Arthritis-related pain and stiffness are often most acute in the morning, yet by the time the patient makes it to the doctor’s office for assessment, the symptoms are much improved. We explored the utility of a wrist–worn actigraphy device for quantifying the effect of morning pain and stiffness on function. Patients were asked to perform a five times sit-to-stand test every other morning after waking, while wearing a three-axis accelerometer on their wrist. We present learnings from our actigraphy data analyses, demonstrating that the patients performed the unsupervised test correctly at home and that test duration was robustly related to the self-reported morning pain & stiffness.

Jonas Dorn, Digital Solutions Director, Novartis

CONCLUDING PANEL DISCUSSION: LOOKING AT CHALLENGES THAT INDUSTRY IS FACING ON DIGITAL BIOMARKERS

- A discussion by regulatory experts from pharma, their core concerns & objectives
- How can we take the learnings of the day to move forward in current regulatory environment
- What is the payer perspective?

SESSION SPEAKERS:
Austin Speier, VP of Emerging Technologies, Precision for Medicine
Emilio Merlo Pich, VP, Head of Digital Medicine, CNS, Takeda
Sarah Hemsley, Digital Project Leader, NIBR, Novartis
Lindsay Mark Ham, Global Franchise Head Neuroscience, Regulatory Affairs, Roche
Moderated by Christian Gossens, Global Head, Digital Biomarkers, Roche and Alain Bindels, Digital Innovation Lab Director, Roche

EVENING APERO & NETWORKING RECEPTION

Sponsored by: Medable & PhysIQ