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April 15th-17th, 2019 | London, UK

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IMPACCT mHEALTH IN CLINICAL TRIALS

Driving Digital Innovation Towards Truly Patient-Centric Clinical Studies

20+ Expert Speakers Including:



Isabela Niculae
Global Associate
Director – Patient
Recruitment
& Retention
Strategist
Biogen



Sam Hariry
Head of Clinical
Strategy & Operations
**Novartis Institutes
for Biomedical
Research (NIBR)**



Bert Hartog
Senior Director,
Janssen Clinical
Innovation
**Janssen
Pharmaceuticals**



Lisa Shipley
VP, Digital
& Analytics
Technologies
Merck & Co.



Jyothis George
Global Head of
Diabetes Clinical
Development
**Boehringer
Ingelheim**

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Welcome to the 2nd annual IMPACCT: mHealth in Clinical Trials London 2019

Leveraging digital and mobile tools to enhance patient-centricity and outcomes in clinical trials

These are exciting times for everyone actively involved in the efforts to bring the use of digital health technologies in clinical research to the next level. We've been seeing exponential developments, more and more use-cases of actual implementation of these capabilities in clinical programs, and exciting initiatives taking place.

The 2nd annual **IMPACCT: mHealth in Clinical Trials London 2019** meeting will bring together the top leaders and innovators in the digital health and eclinical space for a comprehensive and open discussion on how to **support and drive the clinical innovation needed to make trials truly patient-centric with digital tools**.

Join your peers for a collaborative discussion platform that aims to **transform the way clinical trials are done, overcome key operational challenges and promote patient-centricity in clinical research** with mobile and digital-enabled clinical studies.

Hear what previous attendees have to say:

■■ A very useful meeting. Companies shared their experiences in implementing mHealth solutions in their drug development programs ■■

Novartis Institute for Biomedical Research

■■ This was a very well organized meeting with great, relevant content and engaging speakers ■■

Abbott



5 Highlights You Cannot Miss

1.

Novartis Institutes for Biomedical Research address what's next in patient-centric remote clinical trials



2.

Merck & Co. share their latest approaches to patient sampling in smart trials



3.

Janssen Pharmaceuticals and **Boehringer Ingelheim** delve into how to overcome key implementation and operationalisation challenges of digital innovation in clinical trials



4.

Humanity.co and **Janssen Pharmaceuticals** explore patient data access, return, and ownership



5.

Roche shares their latest case-studies on how digital technology, new digital endpoints and better clinically meaningful insights into disease are revolutionizing care from drug development to the clinic



YOUR EXPERT SPEAKERS



Alexander Klein
Global Medical Affairs &
Digital Health Lead
Roche



Anne-Marie Li-Kwai-Cheung
Project Team Lead for
the Multiple Sclerosis
(Neuroscience) PHC
Showcase
Roche



Bert Hartog
Senior Director,
Janssen Clinical
Innovation
**Janssen
Pharmaceuticals**



Bryan McDowell
Executive Director -
Global Program Lead
for Data & Digital
Novartis



Caroline Feys
Research &
Development
Operations Innovation
Leader
**Janssen
Pharmaceuticals**



Corey Fowler
Associate Director
- Global Clinical
Development
**Otsuka
Pharmaceutical
Co.**



David Goren
Independent
Consultant, (former-
VP of Digital
Health Innovation,
AstraZeneca)



Donna Finch
Associate Director,
Clinical Scientist,
Respiratory
MedImmune



Florent Schäfer
Clinical Affairs
& Human
Translational
Research
Danone Research



Isabela Nicolae
Global Associate
Director - Patient
Recruitment &
Retention Strategist
Biogen



Jeremy Wyatt
CTO & Senior
VP - Product
Development
ActiGraph



Jonas Dorn
Digital Solutions
Director
Novartis



Joss Langford
Chief Technology
Officer
Activinsights



Jyothis George
Global Head of
Diabetes Clinical
Development
Boehringer Ingelheim



Lisa Shipley
VP, Digital
& Analytics
Technologies
Merck & Co.



Manuela Schöner
Corporate Strategy &
Consulting
**Boehringer
Ingelheim**



Michaela Kazmaier
Senior Digital Strategist
Dimension Data



Michelle Longmire
CEO
Medable



Sam Hariry
Head of Clinical
Strategy & Operations
**Novartis Institutes
for Biomedical
Research (NIBR)**



Sheli Gupta
President, European
Operations
Hu-manity.co



Stuart Redding
COO
**Medical Research
Network (MRN)**



Theodoros Arvanitis
Professor of e-Health
Innovation & Head of
Research - Institute of
Digital Healthcare (IDH)
University of Warwick



Tom Denwood
Executive Director
of Data, Insights &
Statistics
NHS Digital



Zen Chu
Faculty Advisor for
MIT Healthcare
Ventures + Hacking
Medicine
MIT

PRE-CONFERENCE WORKSHOPS

MONDAY, APRIL 15TH, 2019

Workshop A

Advancing the Use of Blockchain Technology in Clinical Trials

9.00 - 12.00

The application of blockchain technology in clinical trials is sparking a lot of interest in the pharmaceutical industry. **Blockchain has the potential to be a game changer in the way clinical studies are conducted** – opportunities go from streamlining patient recruitment to ensuring patient data security and enhancing data transparency.

In this workshop, Manuela and Michaela transpose their expertise in emerging technologies being used in the pharmaceutical sector and **address the impact of blockchain in clinical trials, the opportunities and the challenges ahead.**

Join this brainstorming discussion to learn more about the potential of blockchain technology within the clinical trial setting.

Key areas to be discussed include:

- Systematic analysis of the current market and future trends
- Development of problem statement(s)
- Potential solutions
- Application of design-thinking methodologies

Workshop Leaders



Manuela Schöner
Corporate Strategy & Consulting
Boehringer Ingelheim



Michaela Kazmaier
Senior Digital Strategist
Dimension Data

Workshop B

Enhancing Patient Engagement & Succeeding Where Others Have Failed

13.00 - 16.00

Pharma is heavily dependent on finding the right patients for clinical trials to **accelerate recruiting and ensure that patients remain compliant** throughout the trial - to the end. In oncology this is especially critical to proving efficacy and ensuring that knowledge is maximized for current treatments and especially future ones. **The industry has seen trials delayed and even fail repeatedly due to identifying the wrong patients, as well as not maintaining their interest all the way to completion.** This costs pharma companies a lot of money.

This workshop aims to create a thought-provoking discussion led by David Goren, a pharma veteran and expert in the digital innovation space.

Join this interactive, comprehensive and collaborative session that will allow you to **employ innovative digital approaches in clinical programs to improve clinical and financial results.**

Key topics to be discussed include:

- Main hurdles faced in attracting the right patients and keeping them engaged in your clinical programs with digital tools and methodologies
 - Internal challenges – innovation as a driver for success
 - External challenges – the role and positioning of external stakeholders including patients, investigators and institutions
- Patient Engagement from start to finish
 - Start from patient needs
 - Follow the patients throughout the trial experience
 - What motivates the patient and what are the barriers?
 - What can be leveraged in the environment (e.g., caregivers)?

Workshop Leader



David Goren
Strategic Consultant
Epione Strategy, Ltd.

CONFERENCE DAY ONE

TUESDAY, 16TH APRIL, 2019

	8.45 Chair's Opening Remarks
Bert Hartog Janssen Pharmaceuticals Bryan McDowell Novartis Donna Finch MedImmune Jeremy Wyatt ActiGraph	9.00 'IMPACCT' Panel Discussion: Driving Digital Transformation & Clinical Innovation in Clinical Research – Bridging the Gap to True Patient-Centricity - Addressing the rapidly evolving mobile and digital health landscape and its potential to support, improve and drive clinical studies - Old vs. New – balancing optimisation of processes and approaches with digital tools vs. complete disruption of the clinical research paradigm (e.g. remote trials) - Ensuring the value and ROI of digital innovation in clinical trials – would we continue in our journey for patient-centricity, technology enabled trials without reductions in cost or time? - Advancing digital endpoint development – what are the current limitations? - Operationalising digital clinical innovation – recurrent pain points and moving forward, what's next? - Discussing long term extensions in clinical trials
Rethinking Clinical Research Methodologies	
Anne-Marie Li-Kwai-Cheung Project Team Lead for the Multiple Sclerosis (Neuroscience) PHC Showcase Roche	9.45 Digital technology: Revolutionizing Care from Drug Development to the Clinic - Understanding why neuroscience is one of the most difficult areas of drug research because diseases are poorly understood and disease processes are difficult to measure objectively - Using meaningful data at scale (MDAS), digital endpoints and outcomes to provide new, clinically meaningful insights into the disease, completely change our ability to measure disease processes, and reliably determine whether new therapies are impacting these processes - Changing how we manage disease by changing outcomes for patients, and in turn driving better research for the development of next generation therapies
	10.15 Speed Networking Session
	10.45 Morning Refreshments
Sam Hariry Head of Clinical Strategy & Operations Novartis Institutes for Biomedical Research (NIBR)	11.15 Patient-Centric Trials – What's next? - Discussing how remote trials are transforming clinical studies and supporting patient-centricity - Moving from purely home-based remote trials – how we incorporate the patients' own GP on these efforts?
Lisa Shipley VP, Digital & Analytics Technologies Merck & Co.	11.45 Sampling Approaches in Patient-Centric Trials - Discussing the need for patient-focused tools in clinical research - Exploring approaches for smart, home or outpatient sampling - Challenges and future directions
Michelle Longmire CEO Medable	12.15 The Data Revolution in Clinical Trials - Eliminating stagnation through real-time access - Optimizing performance with metaprise analytics - Drastically reducing barriers to new therapies - Medable E2E: first and only end-to-end cloud platform for clinical trials

	12.45 Lunch & Networking
 Corey Fowler Associate Director - Global Clinical Development Otsuka Pharmaceutical Co.	13.45 Building Patient Centricity into Clinical Trials with Digital Medicine & Digital Technologies - Utilising Digital Medicine as an objective measure of adherence in clinical studies and clinical practice - Exploring digital applications for conduct of virtual clinical trials in SMI patients - Applying technology to reduce placebo response while enrolling more diverse patient groups - Presenting the emerging challenges to measure traditional psychometric assessments in a remote environment, including technology and new innovations to combat these challenges
Digitisation in Clinical Studies – Behind the Spotlight	
 Bert Hartog Senior Director, Janssen Clinical Innovation Janssen Pharmaceuticals	14.15 Bridging the Gap Between Innovation & Implementation - Tackling the challenges to actual implementation of digital innovation tools in clinical research - Overcoming operationalisation barriers - case-studies on what needs to go on "behind the stage" - Driving innovation vs. legacy processes
 Jyothis George Global Head of Diabetes Clinical Development Boehringer Ingelheim	14.45 Streamlining Data Collection in Clinical Trials – Case-Studies - Analysing how the digitisation of clinical studies is transforming the collection and analysis of patient information - Challenges and opportunities in digitally-enabled data collection - Examples of recent digital innovations to streamline clinical trials
 Joss Langford Chief Technology Officer Activinsights	15.15 Exploring the Role of Behaviour and Lifestyle Insight in Clinical Trials - Identifying specific behaviours – data analytics - Exploring behaviour and lifestyle analytics - Data management (privacy, security & data management) - Enhancing data collection with wearables & mobile applications
	15.25 Afternoon Refreshments & Networking
 Theodoros Arvanitis Professor of e-Health Innovation & Head of Research - Institute of Digital Healthcare (IDH) University of Warwick	15.55 Accelerating Patient Recruitment & Managing Clinical Data with Digital Tools - Overviewing EU FP7 Project Transform – utilising digital tools for patient recruitment - Enhancing clinical data management – the C.U.R.e Framework - Presenting implementation case-studies
 Zen Chu Faculty Advisor for MIT Healthcare Ventures + Hacking Medicine MIT	16.25 MIT Hacking Medicine's Design Process to Maximize Clinical Impact Further details to be confirmed soon
 Tom Denwood Executive Director of Data, Insights & Statistics NHS Digital	16.55 Enabling World-Class Clinical Trials Using National NHS Data - Exploring how the NHS Digital is working with HDR UK's Oxford University site, and the National Institute for Health Research, to develop innovative clinical trial services - Using national NHS data, to support rapid, efficient trials that meet the needs of regulators (such as the MHRA and FDA) and NHS patients, while protecting individuals' data rights - Seeing the benefits from the pilots of these services, that specifically support clinical trial cohort feasibility, selection and identification, and how they can be utilised by life sciences industry, to deliver more efficient trials
	17.25 Chair's Closing Remarks

CONFERENCE DAY TWO

WEDNESDAY, APRIL 17, 2019

8.50 Chair's Opening Remarks

Driving Patient-Centricity with Digital-Enabled Approaches

Bryan McDowell
Executive Director -
Global Program Lead
for Data & Digital
Novartis

9.00 Patient-Focused Drug Development – Building Digital Innovation & Ecosystems in Clinical Research

- What does patient-focused drug development look like?
- Exploring digital and clinical innovation to change the paradigm of drug development and patient journey – what's next?
- Utilising information beyond clinical trials – complementing drug development & life cycles by redefining 'Health Records'

Caroline Feys
Janssen
Pharmaceuticals

Isabela Niculae
Biogen

Sheli Gupta
Hu-manity.co

9.30 'IMPACCT' Panel Discussion: The Patient – Driving Patient Centricity in Clinical Research

- Delving into patient-centric trials: transformation of trials is seen as key to patient-centric models, but are we focusing too much on other stakeholders (sponsor, site, CROs, etc.) and not enough on our primary 'stakeholders' – the patients?
- Analysing how digital health technology generates increased patient engagement, retention, and compliance
- Exploring the unique opportunity digital tools present for how clinical trials monitor, communicate and work alongside patients – the patient as a partner
- Patient data ownership – integrating the voice of the patient and enabling their active and central participation in clinical innovation and digital transformation of healthcare
- Giving patients control over their own data

10.15 Morning Refreshments & Networking

Caroline Feys
Research &
Development
Operations Innovation
Leader
Janssen
Pharmaceuticals

11.00 Engaging Patient by Providing Access to Patient Data Access In Clinical Trials: From Concept To Implementation

- Providing access to patient data while in a study – a case-study
- Overviewing the global implementation of data access through the Janssen Global Trial Community
- Exploring how a consortium creates new opportunities and greater value by increasing speed of innovation, adoption and responsiveness to customers

Sheli Gupta
President, European
Operations
Hu-manity.co

11.30 Your Data, Your Property – Delving into Patient Data Ownership

- Who owns patient data?
- Using Blockchain to enable patient data ownership
- Going further – compensation for ongoing use of patient data


12.00 Mastermind Session: Driving Digital Innovation Towards Truly Patient-Centric Clinical Studies

This session facilitates in-depth discussions among participants in an informal environment. After splitting into groups, participants will discuss key challenges and opportunities regarding the current landscape in mobile and digital-enable clinical research.

12.45 Lunch & Networking
Exploring the Scope of Mobile Health in Broader Healthcare Ecosystem Settings


Jonas Dorn
 Digital Solutions
 Director
Novartis

13.45 Digital Biomarkers in Clinical Trials – Learnings & Prospects

- Enabling the measurement of disease symptoms in home settings with digital devices
- Discussing whether clinical teams rightly worry whether patients would perform at-home assessments and perform them correctly
- Demonstrating that patients closely adhere to protocol and that at-home assessments relate to traditionally measured disease state, utilizing device data



Alexander Klein
 Global Medical Affairs
 & Digital Health Lead
Roche

14.15 Advancing Personalised Care & Access Models in Oncology Through Digital Health

- Addressing how digital health approaches can advance personalised care
- Highlighting findings from our digital Patient Monitoring project in cancer immunotherapy



Florent Schäfer
 Clinical Affairs &
 Human Translational
 Research
Danone Research

14.45 Advancing Nutrition Research Studies with Novel Technologies

- Overviewing the main operational challenges for the conduct of nutrition clinical trials
- Exploring opportunities for the use of digital markers in conventional nutrition clinical research
- Presenting perspectives for the use of innovative data sources and designs beyond RCT

15.15 Chair's Closing Remarks

■ ■ This conference did a great job of attracting the top minds, influencers and leaders in mobile health all in one place. These are the people that will change the face of research ■ ■

Medidata

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Expertise Partner

Medable was founded in 2014 to enable healthcare technology to be as seamless, integrated, and adaptive as the human body. Medable is transforming healthcare by enabling patient generated data on mobile to drive healthcare delivery, clinical research, and personalized and predictive medicine. Throughout this process, we have been mission driven to build the first Human Digitome, a comprehensive digital representation of human health and disease, that is created by aggregating the rich patient data generated by patients on the platform.

www.medable.com



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ActiGraph is the leading provider of medical-grade wearable physical activity and sleep

monitoring solutions for the global scientific community. Built on nearly two decades of real-world data capture and management expertise, ActiGraph's innovative ecosystem of hardware and software tools leverage cloud, mobile, and wireless technologies to deliver high quality patient insights, in real time.

www.actigraphcorp.com



Innovation Partner

Activinsights is a digital healthcare business. We provide clinical trial and data services to professionals about patient activity and lifestyle behaviours. The data is collected using wearables and other connected devices. Insights created from the data support the management of long-term conditions, enable independent living in aging populations and allow clinical interventions to be personalised. This lifestyle insight has never previously been available and is proving critical in the prevention and treatment of major modern disease killers.

www.activinsights.com



Innovation Partner

Medical Research Network (MRN) specializes in the conduct of clinical trial visits in

the patient's home and supporting clinical trial sites with nursing resources. At MRN we understand the complexities of today's clinical trial environment and the burden this places on both patients and sites. Our nursing services are designed to ease these burdens, therefore accelerating patient recruitment, enrollment and retention and maximizing the impact of the trial for the pharmaceutical sponsor.

www.themrn.co.uk

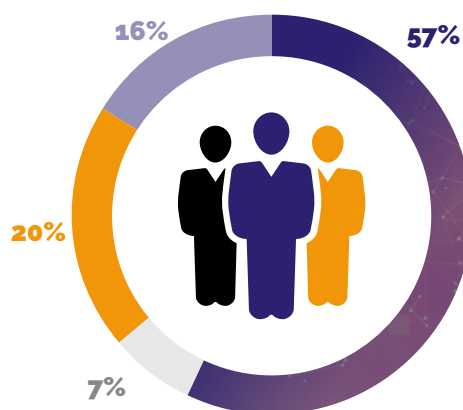


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Illingworth Research Group's is unique in that we provide two niche services as well as our tailored CRO services. These are on and off-site research nursing and medical photography. Research Nursing focuses on taking trials to the patient in their home, school or workplace. Providing a patient centric approach which can enhance both patient recruitment and retention. Our medical photography team offer an alternative approach by using imagery and video footage within the clinical trial.

www.illingworthresearch.com

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- ② Transform clinical research methodologies
- ③ Overcome key operational and regulatory challenges of running digitally-enabled studies

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