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Inaugural



mHealth

for Clinical Trials EU

Driving the Implementation & Adoption of mHealth

April 16-18, 2018, **London, UK**

Maximising Patient-Centricity, Decentralising
Clinical Studies & Operationalising mHealth

Hear from 18 Experts Including:



Tim Cave

VP – Head Strategic Planning & Digital
Practices, Global Medical Affairs

GlaxoSmithKline



Mikael Eliasson

Global Head, Strategic Innovation, Personalized
Health Care, Product Development

Roche



Bert Hartog

Senior Director, Janssen Clinical Innovation

Janssen Pharmaceuticals



Seleen Ong

Clinical Sciences Group Lead & Clinical
Program Lead for Clinical Trial Innovation

Pfizer

“This was a very well organized meeting with great, relevant content and engaging speakers.”

Abbott

Innovation Partners

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Welcome to mHealth for Clinical Trials Europe 2018

Join the Digital Transformation in Clinical Research

mHealth capabilities and use cases in pharma clinical development have been exploding with exciting advances. Innovating the way clinical trials are conducted by progressing the application of mobile tools is, more than ever, a key factor to **accelerating drug development**, and ensuring drugs are successfully brought to patients faster.

mHealth for Clinical Trials, coming for the first time to Europe, provides you with a focused platform for discussion with other leaders in this space at a time of fast-pacing transformation in the mHealth and healthcare ecosystem.

By sharing details of the latest success stories and **evaluating strategies to overcome existing operational and regulatory challenges**, this meeting aims to accelerate the efforts to **bring the implementation of mobile technologies in clinical trials to the next level**: from boosting patient-centricity, to wearables, regulation, decentralised studies and adoption.

Join your peers to discuss and explore the growing possibilities these technologies are offering to accelerate clinical research and advance the use of patient-facing data.

Top 5 Reasons to Attend

- 1** **Roche** and **GSK** detail their endeavours in **digital innovation** to accelerate clinical development.
- 2** **Pfizer** and the **NIHR Clinical Research Network** share insights on how to promote **patient-centricity** in clinical trials with **eRecruitment**, and enhanced **patient engagement and involvement** strategies.
- 3** **Janssen Pharmaceuticals** and **Novartis** explain how they are tackling the opportunity to change the face of clinical studies with **decentralised trial** methodologies.
- 4** **Actelion** and **Myokardia** delve into the development, implementation and **operationalisation** of new technologies to tap into new forms of **data collection** and **new digital endpoints**.
- 5** **Sanofi** and **Janssen Pharmaceuticals** discuss how to **tackle organisational barriers** to support and drive the adoption of mobile tools in clinical trials.

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 Institutes for Biomedical Research

“Great conference. One of the most targeted conferences I have been to with lots of knowledgeable senior people.”

Shimmer Research, Inc.

“The conference was great. I enjoyed all the speakers and really enjoyed that the conference is very focused with all the right people in the room.”

Abbott



Speakers



Alain Bindels
Innovation Task
Force & Vendor
Alliance Leader
Roche



Alistair Stuart
Director, Clinical
Projects &
Digital Platforms
GlaxoSmithKline



Anthea Mould
Head of AHP/
Pharmacy and
Continuous
Improvement
**NIHR Clinical
Research Network**



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



Bryan McDowell
Global Program Lead,
Digital Development
Novartis



Carsten Spannhuth
Director, Clinical
Project Physician
**Idorsia
Pharmaceuticals**



Charles Wolfus
Executive Director
- Digital Health,
Technology &
Business Operations
MyoKardia



Daragh Ryan
Clinical Trials
Technology Consultant
**Actelion
Pharmaceuticals**



David Goren
Strategic Consultant,
Epione Strategy, Ltd.



Derek Stewart
Associate Director
- Patient & Public
Involvement
**NIHR Clinical
Research Network**



Hilde Vanaken
Director, Janssen
Clinical Innovation
**Janssen
Pharmaceuticals**



Jess Radcliffe
Improvement and
Programme Manager
**NIHR Clinical
Research Network**



Kai Langel
Director, R&D
Operations Innovation
**Janssen
Pharmaceuticals**



Lucien Rapp
Senior Consultant
**Watson Farley
& Williams**



Michelle Longmire
CEO
Medable



Mikael Eliasson
Global Head, Strategic
Innovation, Personalized
Health Care, Product
Development
Roche



Myriam Cohen
Clinical Sciences
Operations - Alliance
& Partners Leader
Sanofi



Philipp Hesse
Managing Consultant
PA Consulting



Seleen Ong
Clinical Sciences
Group Lead & Clinical
Program Lead for
Clinical Trial Innovation
Pfizer








Shiyan Caan
Marketing & Business
Development
Coordinator
SQN Clinical






Tim Cave
VP - Head Strategic
Planning & Digital
Practices, Global
Medical Affairs
GlaxoSmithKline

Conference Day One | Tuesday, 17th April, 2018


 <p>Daragh Ryan, Actelion Pharmaceuticals</p>	<p>8.45 Chair's Opening Remarks</p>
 <p>Bryan McDowell, Novartis</p>  <p>Kai Langel, Janssen Pharmaceuticals</p>  <p>Mikael Eliasson, Roche</p>	<p>9.00 Opening Keynote Panel Discussion: From Start, to Finish – How to Innovate the Conduct of Clinical Studies & Accelerate the Delivery of New Therapies to Patients with Mobile-Enabled Clinical Trials</p> <ul style="list-style-type: none"> • Addressing the rapidly evolving mHealth landscape in pharma, the growing interest and the latest and exciting advances on the use of these technologies to support and drive clinical studies • Overcoming the operational and regulatory challenges of running mHealth supported clinical trials • Maximising patient centricity and innovation, improving trial efficiency and reducing costs – embracing the growing possibilities of mHealth-enabled clinical research to accelerate drug development • Discussing the role of big tech companies in the future of digital innovation in clinical trials • Outlining where we are and where we are going – important learnings to date and perspectives on future directions
 <p>Mikael Eliasson, Global Head, Strategic Innovation, Personalized Health Care, Product Development, Roche</p>	<p>9.45 Going Digital – Accelerating Clinical Development</p> <ul style="list-style-type: none"> • Detailing on Roche's experiences using digital tools in clinical trials • Overviewing the promise of meaningful data at scale • What will "digital 2.0" look like?
<p>10.15 Speed Networking Session</p>	
<p>11.15 Morning Refreshments</p>	

Patient Centricity – An Evolving Paradigm in Clinical Development

 <p>Seleem Ong, Clinical Sciences Group Lead & Clinical Program Lead for Clinical Trial Innovation, Pfizer</p>	<p>11.45 Right Patient, Right Trial – Leveraging Technology For Recruitment, Enrolment & Consent in Clinical Trials</p> <ul style="list-style-type: none"> • Enhancing awareness of trials available • Refining pre-screening algorithms • Improving the experience of informed consent for patients
 <p>Tim Cave, VP - Head Strategic Planning & Digital Practices, Global Medical Affairs, GlaxoSmithKline</p>	<p>12.15 Promoting the Patient as a Partner & Not a Subject of the Study</p> <ul style="list-style-type: none"> • Supporting patient engagement and involvement across all stages of the clinical trial • Maximising awareness and sharing of information – enabling easier communication with investigators and sponsors including communication of results
 <p>Shiyan Caan, Marketing & Business Development Coordinator, SQN Clinical</p>	<p>12.45 Elevating Patients to the Centre of Clinical Research – an Innovative Approach</p> <ul style="list-style-type: none"> • Collecting wellness data alongside protocol required data • Better understanding a patient and their response to a trial • Communication is key • Protocol compliance and clinical oversight

Conference Day One | Tuesday, 17th April, 2018

12.55 Lunch & Networking



Anthea Mould, Head of AHP/Pharmacy and Continuous Improvement, **NIHR Clinical Research Network**



Jess Radcliffe, Improvement and Programme Manager, **NIHR Clinical Research Network**

14.00 Accelerating Digital – Overviewing the NIHR Clinical Research Network’s Endeavours To Support the Operational Embedding & Adoption of Digital Across the Research Network, NHS & Industry Partners

- Promoting and developing a focused digital programme at the NIHR CRN
- Enabling and supporting the adoption of digital across commercial and non-commercial studies to maximise patient centricity and involvement in clinical research



14.30 Mastermind Session: Supporting the Successful & Efficient Adoption Of mHealth Solutions Within Clinical Trials

This session facilitates in-depth discussions between participants in an informal environment.

After splitting into small groups, participants will discuss key issues and challenges regarding the implementation of mobile technology in clinical trials.

15.30 Afternoon Refreshments & Networking



Derek Stewart, Associate Director – Patient & Public Involvement, **NIHR Clinical Research Network**

16.00 The Patient Perspective – What Do Patients Participating in Clinical Trials Expect from mHealth?

- Patient advocate view on the role of mHealth in patient-centric clinical research
- Discussing how mobile technology can promote and enhance patient involvement in and awareness of clinical studies



Carsten Spannhuth, **Idorsia Pharmaceuticals**



David Goren, **Epione Strategy, Ltd.**



Derek Stewart, **NIHR Clinical Research Network**



Seleen Ong, **Pfizer**

16.30 Panel Discussion: Transforming the Clinical Development Paradigm With Digital Health Innovation

- Embracing the patient as a crucial partner in study design and conduct
- Deploying mHealth technologies and tools to maximise patient centricity in clinical research – from data collection to patient adherence
- Leveraging mHealth approaches for improved trial recruitment and design – promises and challenges



Daragh Ryan, **Actelion Pharmaceuticals**

17.15 Chair’s Closing Remarks

Conference Day Two | Wednesday, 18th April, 2018



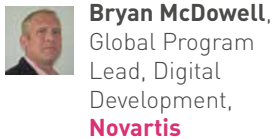
8.50 Chair's Opening Remarks
Key Takeaways & Lessons Learned from Day One

Thinking of Going Remote?



9.00 Discussing the Current State of Decentralised / Remote Clinical Trial Methods

- Where is the value today and what is still "science fiction"?
- Analysing why pharma needs decentralised trials
- Overviewing collaborative industry initiatives around decentralised trials
- Outlining Janssen's endeavours in remote clinical studies



9.30 Decentralised Clinical Trials – Providing an Opportunity to Enable Radical Transformation in Clinical Trial Methodology

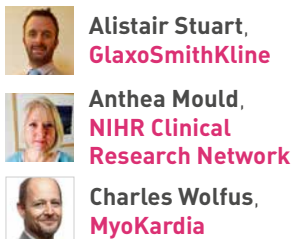
- Building trials around the patient – how decentralised clinical studies enhance patient centricity
- Overcoming specific challenges presented by a decentralised model - while advances in technology support decentralised models and patient centricity, targeted solutions are required
- Deep diving into the challenges and potential solutions

Moving Beyond the Hype – Operationalising mHealth in Clinical Trials



10.00 Patient Generated Data & the Human Digitome in Clinical Trials

- Leveraging ResearchKit and CareKit to create digital representations of clinical trial participants
- Applying AI to patient generated data for digital biomarkers
- Discussing the future of blockchain in mobile clinical trials



10.10 Panel Discussion: Establishing Solid Framework for mHealth Implementation – Overcoming Operational Barriers, Implications & Biases

- Disrupting the traditional processes and structure in clinical research – challenges to operationalising mHealth and improving trial efficiency and outcomes
- Tackling digital data – looking at privacy, security, volume, data management, integration and analytics
- Collaborating with vendors to develop innovative approaches to improve trial efficiency
- Integrating wearables and sensors – potential for supplementing or replacing standard measures in clinical trial reporting
- Feedbacking to the community – inspiring transparency and sharing of learning from trials running with support of mHealth tools to advance the field and accelerate drug development

10.55 Morning Refreshments & Networking

Conference Day Two | Wednesday, 18th April, 2018



Alistair Stuart,
Director, Clinical
Projects & Digital
Platforms,
GlaxoSmithKline

11.25 mHealth Clinical Trials: From Potential to Performance

- Understanding where the pharmaceutical sector sits in the digital evolution of industries
- Outlining some of the challenges in making clinical trials digital
- What do efforts in clinical research look like to date? – illustrative case-studies
- How do we as an industry take these outward to business as usual - who are our key partners?



Daragh Ryan,
Clinical Trials
Technology
Consultant, **Actelion
Pharmaceuticals**

11.55 Planning & Designing Tomorrow's Study with Today's Emerging Tool-set

- mHealth strategy to support clinical studies
- Implementing new technologies in a fast-changing landscape
- Integrating new technologies into routine Clinical Operations
- Handling the shift from site to patient

12.25 Lunch & Networking



Charles Wolfus,
Executive
Director - Digital
Health, Technology &
Business Operations,
MyoKardia

13.25 Presenting Digital Health Data from Substudy of PIONEER-HCM – a Case-study on Wearables & Machine Learning

- Developing a novel machine learning algorithm intended to identify patients with obstructive hypertrophic cardiomyopathy (oHCM)
- Designing an exploratory digital health substudy as part of the Phase 2 PIONEER-HCM trial to determine if an optical biosensor could identify patients with oHCM
- How a machine learning algorithm is able to identify digital signatures of oHCM



Hilde Vanaken,
Director, Janssen
Clinical Innovation,
**Janssen
Pharmaceuticas**

13.55 Value Creation Through Collaboration: Smart Technologies Implemented in a Phase II Clinical Trial

- Outlining the value of pre-engagement and direct involvement of patients, sites, health authorities and ethics committee during the development of smart technologies
- Discussing the power of cross-industry collaborations with technical, mobile and package vendors, and open communications
- Ensuring the right pill to the right patient at the right time – implementing smart technologies (e.g. smart packages, digital drug labels, tailored notifications, scanning devices) in a phase II clinical trial with Alzheimer patients



Alain Bindels,
Innovation Task
Force & Vendor
Alliance Leader,
Roche

14.25 How Can Design Thinking Transform the Pharma Industry?

- Exemplifying of how an agile approach is being used in pharma to transform the way we work to implement new technologies across different organisations
- Analysing this patient centric approach, which can have real impact on the way we address clinical research
- Presenting concrete examples on how we apply design thinking to mobile technology innovation in pharma
- Learning more about design thinking and how to set yourself up for innovation

14.55 Afternoon Refreshments & Networking

Conference Day Two | Wednesday, 18th April, 2018

Overcoming Organisational Barriers to mHealth Implementation



Myriam Cohen,
Sanofi



Bert Hartog,
Janssen
Pharmaceuticals

15.25 **Panel Discussion: Innovation, Adoption & Implementation – What is Needed to Deploy Digital Tools in Clinical Trials**

- mHealth technologies make everything more complex – but it does not need to be like that
- How to place digital innovation in the organisation?
- Overcoming ROI considerations and achieving leadership buy-in
- Disrupting preconception and making mobile tools from the exception to the norm in development programs – debugging reticent clinical teams with more knowledge and certainty around regulatory requirements for acceptance of the data



Daragh Ryan,
Actelion
Pharmaceuticals

16.10 **Chair's Closing Remarks**

“A great meeting. The networking opportunities were fantastic.”

Pfizer



4h+

networking opportunities

12+

real-world case-studies being presented



20+

leading industry experts speaking



4h+

interactive panel discussions and roundtables

Pre-Conference Workshop Day | Monday, 16th April, 2018

Workshop A

Time: 9.00 – 12.00

Disrupting the Status Quo in mHealth & Rethinking the Clinical R&D Model

Pharma is heavily investing in the implementation of innovative mobile and digital health approaches in their clinical studies. Over the years, **incremental improvements in patient centricity and in valuable insight being collected from these tools have been gradually changing the way we look and understand clinical trials – but is this enough?** Should we start completely afresh, and rethink the way clinical research is done – through true disruption and transformation?

In a thought-provoking discussion led by David Goren, a pharma veteran and expert in the digital innovation space, you will be sure to leave inspired by a collaborative open dialogue on **how to disrupt the model and truly put the patient at the center of clinical research.**

Join this interactive and comprehensive session that will allow you to better **streamline and boost innovative mHealth approaches in clinical programs** that match the potential of your drug candidates.

Key topics to be discussed include:

- Main hurdles faced in planning, setting up and conducting clinical trials that could be solved with digital tools and methodologies
- Internal challenges to changing the way we operate – innovation as a driver for success
 - External challenges – the role and positioning of external stakeholders including regulators
- Patient centricity from start to finish
 - How do we truly start from patient needs?
 - Is there a bridge from R&D to commercial through digital?
 - How could digital make a clinical trials also support the goal of RWE generation for payors without risking meeting targets and goals?



David Goren, Strategic Consultant, **Epione Strategy, Ltd.**
former VP, Digital Health Innovation, **AstraZeneca**

Workshop B

Time: 13.00 – 16.00

Navigating the Regulatory Frameworks for mHealth Applications in Clinical Research

More than ever, **Europe is now focusing on the rapidly evolving legal and regulatory aspects facing mHealth applications.** The biopharmaceutical sector, in particular, is striving to incorporate innovative mobile health initiatives and tools in their drug development process. Questions around how to make sure their endeavours are **compliant with current regulation and new guidelines around data collection and validity** are key focus points.

In this highly collaborative session, Lucien Rapp and Philipp Hesse share their thoughts and expertise, and open this topic up for collective discussion. With extensive focus in regulation and legal aspects of the mobile world, this workshop will allow you to fill **in the gaps and delve into the regulatory shift of mHealth applications in clinical research and clinical trials.**

Key topics to be discussed include:

- Analysing the regulatory perspectives on the evolving landscape in the mHealth space and the legal challenges of mHealth in Europe
- Regulators views on digital health in clinical research and trials – acceptance, openness and guidance
- Discussing the influence of the new GDPR EU regulation in the future of mHealth strategies in pharma
- Evaluating data privacy, sharing and ownership issues underlying the application of mobile tools in the clinical context

Join your peers for a **wide-ranging debate on the legal and regulatory limits to digital innovation in clinical trials**, and make sure your studies are prepared to face 2018.



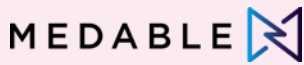
Lucien Rapp, Senior Consultant,
Watson Farley & Williams
Professor, **University of Toulouse1-Capitole**



Philipp Hesse,
Managing Consultant,
PA Consulting

Partnership Opportunities

Innovation 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.
www.medable.com

Innovation Partner



With over 21 years of experience across a breadth of therapeutic areas, SQN Clinical has been established as one of the largest specialist biometric CRO's in Europe. We are the preferred development partner for many pharmaceutical and biotechnology companies globally, supporting the diverse needs of large and small organisations alike.
www.synequanon.com

Why Partner

One of the greatest challenges biopharmaceutical companies face when looking to use mobile and wearable technologies in clinical trials is knowing who to partner with. Finding partners with solutions that are effective and that comply with regulations concerning data collection and management of clinical data is crucial to the successful support of clinical programs.

Do you have a product or solution in mHealth that could be applied in clinical trials to reduce costs, enhance data collection, or boost patient engagement?

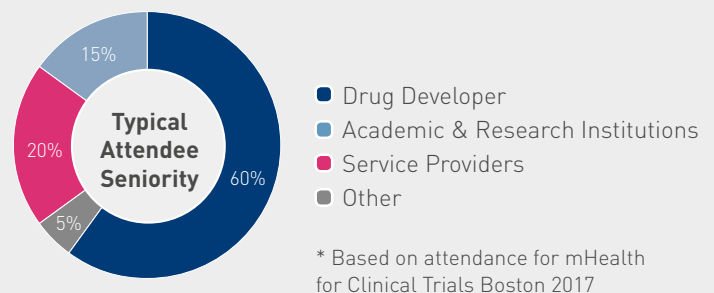
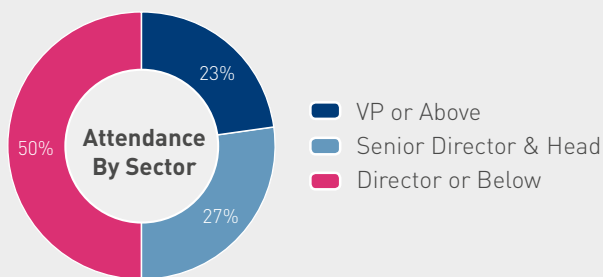
mHealth for Clinical Trials is the place to be if you want to engage with an audience of **leading pharma and biotech companies actively seeking partners** to develop a range of digital initiatives in clinical studies.

They are looking specifically for solutions in:

- App design and development
- Mobile devices, wearable sensors and smart sensors
- Electronic data capturing
- Clinical data management
- Patient recruitment
- Patient monitoring

Demonstrate your expertise and innovative capabilities, and promote your position as a trusted partner in this rapidly expanding market, by becoming one of our exclusive partners.

You'll Meet People From...



▀▀ 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 Solutions,
Partner of mHealth for Clinical Trials USA 2017

Become a Partner

Contact

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Partnerships Manager

Tel: +44 (0)20 3141 8700

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Pricing

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London, SW1W 0AU

Team Discounts*

- **10% discount** – 3 delegates
- **15% discount** – 4 delegates
- **20% discount** – 5+ delegates

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Top 3 Benefits of Attending

- 1** Harness the power of mHealth technologies in transforming clinical trial success
- 2** Overcome operational and regulatory challenges of running mobile and wearable-enabled clinical studies
- 3** Enable the patient as a partner in clinical research

	Register & Pay before 16th March*	Standard Prices
Conference + 2 workshops	£2,997 (Save £300)	£3,097 (Save £200)
Conference + 1 workshop	£2,498 (Save £200)	£2,598 (Save £100)
Conference Only	£1,999 (Save £100)	£2,099
Workshop Only	£599	

VAT at 20%

* Special 40% off for academics and non-profit available upon request

Venue

Hilton London Olympia

380 Kensington High Street
W14 8NL, London,
United Kingdom

www.hilton.com



“This is a great scientific meeting and networking opportunity. It intentionally brought together key players in the field to discuss important strategic issues of mutual interest. Very well done and energizing.”

GlaxoSmithKline

“Very informative meeting and I learned a lot in how this technology is transforming how Pharma engages with partners and subjects.”

Oracle

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

Changes to Conference & Agenda: Hanson Wade reserves the right to postpone or cancel an event, to change the location or alter the advertised speakers. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.

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