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SMi Group Proudly Present the 2nd Annual Conference...

Wearable Injectors and Connected Devices Conference

Copthorne Tara Hotel, Kensington, London, UK

CONFERENCE:
18TH - 19TH
WORKSHOPS: 20TH

OCT
2021

The latest innovations in digital health and
on-body drug delivery for the pharmaceutical
industry



HIGHLIGHTS FOR 2021:

- **Gain** insight into developments in wearable devices in clinical trials and adapting to decentralised trials during the pandemic
- **Explore** design strategies for connectivity and digital health with sessions from Novartis and Bayer
- **Hear** key regulatory updates from regulatory and notified bodies including TÜV SÜD
- **Discover** advances in device design for large volume delivery via on-body injectors
- **Explore** and benchmark against industry developments through case studies and real world examples in device development for on-body injectors

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Medical



CHAIR FOR 2021:



Tiffany McIntire,
Senior Human Factors Engineer,
Roche



Oliver Gazeley,
Senior Device Engineer,
Roche

FEATURED 2021 SPEAKERS INCLUDE:

- **Julia Frese**, Director, Medical & Health Services, **TÜV SÜD**
- **Daniel Latham**, Head of Connected Health Product Development, **Novartis**
- **Solange Corriel-Rohou**, Senior Director Regulatory Affairs and Policy, Europe, **AstraZeneca**
- **Mark Milton-Edwards**, Head of Health Solutions, **Teva Pharmaceuticals**
- **Ning Yu**, Director, Head of Device Design and Process Development, **Biogen**
- **Barbara Stollfuss**, Team Lead Medical Affairs, Digital Strategy & Transformation, **Bayer**
- **James Birchall**, Professor of Pharmaceutical Sciences and Deputy Head of School, **Cardiff University**
- **Olaf Lebau**, Professional Design Engineer, **Boehringer Ingelheim**
- **Emmanuel Monnin**, Device Development Lead, **Merck KGaA**
- ...And Many More!

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
WEDNESDAY 20TH OCTOBER 2021, COPTHORNE TARA HOTEL, KENSINGTON, LONDON UK

**A: Cross company collaboration to develop
digital therapeutic solutions using connected devices**

Workshop Leader:

Digby Harris, Global Procurement Lead – Digital Therapeutics, **AstraZeneca**

8.30 - 12.00

**B: Optimising Patient Engagement and Creating
Novel Company Value through Digital Technologies**

Workshop Leaders:

Alex Gilbert, Digital Medicine, **Huma**

13.00 - 17.00

www.wearable-injectors.co.uk

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Wearable Injectors and Connected Devices Conference

Day One | Monday 18th October 2021

www.wearable-injectors.co.uk

LETTER FROM THE CHAIRS:

Dear Colleague,

As co-chairs of SMI's Wearable Injectors and Connected Devices conference, we cordially invite you to attend this highly anticipated event taking place on the 18th-19th of October 2021 in London. The 2nd annual Wearable Injectors and Connected Devices conference will bring together expertise from individuals in multiple disciplines in the field addressing key drivers of the market including large volume delivery, user-centric self-administration and digital applications for an enhanced user interface.

Delegates stand to gain many valuable insights from this event such as:

- Regulatory outlooks on on-body injectors, medical apps and connected devices
- Case studies and industry insights into patch pump pipeline planning, early technology evaluations and selection for large volume delivery
- Design strategies for connected solutions and digital product development real-world examples
- Enhancing the patient administration experience for large volume delivery

Following to the main event, two post-conference workshops will be held on Wednesday 20th October. There will be the opportunity to discuss 'Cross Company Collaboration to Develop Digital Therapeutic Solutions Using Connected Devices' and engage in 'Optimising Patient Engagement & Creating Novel Company Value through Digital Technologies'.

As co-chairs of this event, we look forward to welcoming you to this must-attend conference in London this October.

Yours Sincerely,



Tiffany McIntire,
Senior Human Factors Engineer,
Roche



Oliver Gazeley,
Senior Device Engineer,
Roche

08.00 Registration & Coffee

09.00 Chairs' Opening Remarks

Tiffany McIntire, Senior Human Factors Engineer, **Roche**
Oliver Gazeley, Senior Device Engineer, **Roche**

A REGULATORY OUTLOOK

09.10 OPENING ADDRESS

Impact of Medical Device Regulation on Drug Device Combination Products

- Introduction of MDR requirements
- Impact of MDR requirements on Drug Device Combinations
- Complexity in regulating connected devices

Julia Frese, Director, Medical & Health Services, **TÜV SÜD**



09.40 A regulatory outlook for wearable connected devices

- The use of digital technologies – how are they used in industry and in decision-making
 - An overview of the current regulatory framework
 - Currently existing recommendations
 - Data generation and future considerations
- Solange Coriol-Rohou**, Senior Director Regulatory Affairs and Policy, Europe, **AstraZeneca**

10.10 MDR Implementation for On-Body Injectors

- Integral drug/device combination products and Article 117
- Non-integral drug/device combination products and aspects to be considered for import, distribution, authorised representative, re-packaging & re-labelling
- Considerations for pharma industry when implementing relevant MDR requirements
- How will the MDR impact the future of the drug/device combination products industry

Andreas Brand, Managing Director, **Pro3 Management** partnering with **Congenius**

10.40 Morning Coffee

11.10 Regulatory Considerations for On-Body Delivery Systems

- Regulatory analysis of on-body delivery systems as complex delivery devices
- FDA expectations for on-body delivery systems
- Regulatory considerations for on-body delivery systems as a combination product

Priti Baker, Manager Regulatory Affairs Combination Products and Devices, **Biogen**

DEVICE DESIGN, DEVELOPMENT AND A PATIENT CENTRIC APPROACH PART I

11.40 Considerations for product development in Connected Health

- **Future trends in connected health**
 - Outlook for connected devices
 - Exploring the ecosystem in healthcare
- **User Experience**
 - Improving the entire patient journey using digital technology
- **Setting up a connected eco-system**
 - Practical considerations for implementation
 - Exploring technical and regulatory aspects needed for success

Daniel Latham, Head of Connected Health Product Development, **Novartis**

12.10 Human Factors Patch Pump Pipeline Planning

- Forming a platform HF strategy
- Gather inputs: Device competitive intelligence and analysis of known use problems
- Assessing the potential users in your pipeline
- Leveraging existing development activities to gain additional insights

Tiffany McIntire, Senior Human Factors Engineer, **Roche**
Flavia Pircher, Human Factors Engineer, **Roche**

12.40 Networking Lunch

13.40 Quantex Single-Use Micro-Pumps – Cutting Edge Tech Behind Drug Delivery IoT Devices of the Future

- Compact, low cost, disposable, accurate dosing without software calibration; can pump viscous fluids against high back pressures with flowrates from 1ul up to 2.4L/hr
- Pump forms part of the disposable pack and is primary container agnostic
- Pump driver platform programmable by doctors, smartphone controlled and connected to the cloud for monitoring and analysis
- Low power consumption and ability to communicate with sensors for closed feedback loop



Rachel An, Medical Device Manager, **Quantex Arc Ltd**

14.20 Considerations for early technology evaluation and selection of large-volume, on-body injectors

- Patient-centric evaluation: incorporating early human factors evaluations to inform use case boundaries
- Technical approaches to maximize characterization when drug product is scarce or unknown
- Balancing use, technical, and manufacturing tradeoffs in technology selection

Megan Heft, Engineering Manager, Device Development, **AstraZeneca**

14.50 The power of collaboration to deliver sustainable healthcare

- The presentation will outline how the Sustainable Healthcare Coalition, a partnership of leading companies and public sector agencies, addresses some of the most pressing sustainability issues in global healthcare
- Case studies of digital approaches and connected devices will demonstrate how healthcare sector industry partners can help the NHS achieve NetZero and bring together clinicians and industry to meet the challenges of improving sustainability through innovation

Fiona Adshead, Chair, **Sustainable Healthcare Coalition**

DIGITAL APPLICATIONS FOR ON-BODY DEVICES

15.20 Afternoon Tea

15.50 Overcoming the Divide Between Telemedicine and Clinic with High-fidelity Data and Low Impact Devices

- Contemporary medicine has become increasingly reliant on cutting edge tools and treatments which are built out within large medical centers - requiring patients to come to the care they need
- This care model is not adequate for those whom are disadvantaged by traditional health disparities, those whom are aging in place and, evidenced by the global pandemic, those whom we need to reduce the probability of acquiring a communicable disease
- The National Cancer Institute and, more broadly, the U.S. National Institutes of Health have been developing and funding initiatives aimed at moving the needle towards bringing care-to-patient
- This session will focus on these efforts and the strategy behind them for the future of remote patient monitoring

Christopher Hartshorn, Program Director, Division of Cancer Treatment and Diagnosis, **National Cancer Institute of the U.S. National Institutes of Health**

16.20 Digital Product Development - Connecting the team as well as the device

- Case Study: Illustrating how the development process for digital medical devices requires effective collaboration across a wide range of technical disciplines
- The challenges that this can present
- Strategies to address these challenges

Chris Hurlstone, Director of Engineering, **Team Consulting**

16.50 Wearable injectors and digital applications

- How to reconcile the areas drug development, medical device and advanced digital applications
- Development, LCM and regulatory strategy, from data collection to medical devices

Norbert Lauber, Head Autoinjector & Large Volume Delivery Systems, **Novartis**

17.20 Chair's Closing Remarks and Close of Day One

Tiffany McIntire, Senior Human Factors Engineer, **Roche**
Oliver Gazeley, Senior Device Engineer, **Roche**

Register online at www.wearable-injectors.co.uk

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Quantex is the global leader in single-use pump technology enabling big-impact, game-changing fluid delivery solutions across sectors. Privately owned, Quantex holds 74 global patents commercially deployed for customised-catalogue pumps, bespoke-designed pumps and entire system designs. The pumps provide precision dosing with low power consumption enabling equipment to be more compact, less expensive and requiring zero cleaning/calibration. www.quantex-arc.com

Wearable Injectors and Connected Devices Conference

Day Two | Tuesday 19th October 2021

www.wearable-injectors.co.uk

08.30 Registration & Coffee

09.00 Chair's Opening Remarks

Tiffany McIntire, Senior Human Factors Engineer, Roche
Oliver Gazeley, Senior Device Engineer, Roche

WEARABLE DEVICES IN CLINICAL TRIALS

OPENING ADDRESS

09.10 Digital data collection within observational studies

- Challenges in digital data collection within observational studies
- The VENTASTEP Study (Clinical Outcomes and Simultaneous Digital Tracking of Daily Physical Activity, Heart Rate, and Inhalation Behavior in Patients With Pulmonary Arterial Hypertension)
- An overview of further digital case studies

Barbara Stollfuss, Team Lead Medical Affairs, Digital Strategy & Transformation, Bayer



09.40 Remote patient monitoring - what have the last 18 months taught us?

- I will discuss how decentralised trials can help overcome another pandemic like COVID-19 in relation to ongoing clinical trials
- How empowering the patient and/or carer to get them recording their own health data can at least ensure that some results can come from a trial impacted by a pandemic
- Future trials must have a contingency plan in place if trial sites are in lockdown
- How regulators need to be willing to discuss changes to trials and protocols during a time of crisis so that a trial can continue

Daniel Lewi, Head of Business Development, Aparito

PANEL DISCUSSION

10.10 Wearable Injectors and Connected Devices: Challenges from Design to Market

- Considering feedback from clinical trials to incorporate human factors and usability in device design
- Usability testing for effective/clear instructions for use (IFU)
- Clinical trials for digital therapeutics: key considerations for regulatory approval
- Post-market surveillance studies and considering the evolving regulatory landscape

Moderators:

Tiffany McIntire, Senior Human Factors Engineer, Roche
Oliver Gazeley, Senior Device Engineer, Roche

Panellists:

Mark Milton-Edwards, Head of Health Solutions, Teva Pharmaceuticals
Norbert Lauber, Team Head Packaging & Device Development, Novartis
Blaine Martin, Director, Medical Device Customer Success & Training, Merck KGaA



10.50 Morning Coffee

DEVICE DESIGN, DEVELOPMENT AND A PATIENT CENTRIC APPROACH PART II

11.20 Pharmaceutical company challenges with large volume wearable injectors

- Wearable injector market overview
- Existing technologies
- Therapy perspectives
- User perspectives

Emmanuel Monnin, Device Development Lead, Merck KGaA

11.50 What does it take to design a good digital experience in healthcare products?

- How to design a digital product while understanding behaviours
- How important user-centric design is for digital solutions
- Latest design tools and techniques used to develop digital products exploring best practice in screen layouts; prompts; language and more
- Approaches to prototyping and user testing

Paul Greenhalgh, Director of Design, Team Consulting
Ben Cox, Head of Digital Design, Team Consulting

12.20 Patient centric design paradigms for wearable injectors and connected devices

- Why different PrimPacks and fill volumes are needed for different therapeutic areas
- How to utilize the various wearable injector variants currently under development
- What connectivity provides for user guidance and patient adherence

Olaf Lebau, Professional Design Engineer, Boehringer Ingelheim

12.50 Networking Lunch

CASE STUDIES IN WEARABLE DEVICES AND CONNECTED PLATFORMS

13.50 Digital Inhaler Case Study: New Variables and New Analyses

- Framing the question (objective) is key
- Design thinking is not about human error, it is a simply a tough design challenge
- It is not always possible to work a priori

Mark Milton-Edwards, Head of Health Solutions, Teva Pharmaceuticals

SPOTLIGHT SESSIONS

14.20 Introduction to microneedle technology

- Healthcare applications for microneedles
- Microneedle design and state of the art
- Human centred design of microneedle products
- Considerations for regulatory and clinical adoption

James Birchall, Professor of Pharmaceutical Sciences and Deputy Head of School, Cardiff University



14.40 Emerging Technologies for Intelligent Delivery and Diagnostics

- Microneedle technologies for minimally invasive skin interface
- Programmable micropumps and actuators for precise drug delivery on demand
- Embedded sensors and communications will enable closed-loop diagnostics and increased patient adherence
- Circular economy principles will play a key role in the design of next generation injector devices

Conor O'Mahony, Principal Scientist, Tyndall National Institute

15.00 Afternoon Tea

15.30 Smart Packaging to Improve Patient Adherence

- Adherence is Key to Therapeutic Success
- Smart Packaging Landscaping
- Opportunities in Clinical Trial
- Bringing Smart Packaging to Commercial Markets

Ning Yu, Director, Head of Device Design and Process Development, Biogen

16.00 Innovations in Patient Medical Device Training

- Today, more than ever, it is possible to reinforce key device training messages found in the IFU by using engaging, interactive technologies that can be easily accessed on a patients' smartphone or tablet
- The Merck Connected Health & Devices training team have had success exploring the potential for emerging technologies that will soon become commonly available, to enhance the overall patient experience at the start of their treatment
- Providing digital tools to support patients as they use their device at home may also help mitigate common device complaints

Blaine Martin, Director, Medical Device Customer Success & Training, Merck KGaA

16.30 Chair's Closing Remarks and Close of Day Two

Tiffany McIntire, Senior Human Factors Engineer, Roche
Oliver Gazeley, Senior Device Engineer, Roche

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Half-Day Post-Conference Workshops

Wednesday 20th October 2021

PRE-CONFERENCE WORKSHOP A 08.30 - 12.00

Workshop Leader:
Digby Harris, Global Procurement Lead – Digital Therapeutics,
AstraZeneca

Cross company collaboration to develop digital therapeutic solutions using connected devices

Overview of the workshop:

Digital therapeutics using connected devices are often developed in collaboration between pharma, device and software developers, data platform owners, data providers, wearables and sensor providers and others.

This workshop will focus on:

- Reviewing the typical scope and component elements of a digital therapeutic
- Key considerations for a successful multi-party collaboration
- Development of the collaborations of the future

About the workshop leader:



Digby Harris is AstraZeneca's Global Procurement lead for Digital Therapeutics and has been involved in developing Digital Therapeutics alliances for over 6 years (including connected device development). During that time Digby has also been AstraZeneca's Global Procurement lead for drug delivery device development. Previously Digby has worked in technology licensing and research collaborations in the Oncology and Respiratory areas.

About the Organisation:

AstraZeneca is a global, science-led biopharmaceutical business and our innovative medicines are used by millions of patients worldwide.

Programme

- 08.30 Registration and Coffee**
- 09.00 Opening Remarks and Introductions**
- 09.10 Session 1: Scope and Components of a Digital Therapeutic**
 - Hardware
 - Software
 - What else?
 - Case Studies
- 09.50 Session 2: What makes a successful multi-partner, digital therapeutic collaboration?**
 - What are the key attributes of a digital therapeutic collaboration that distinguish them from other, more traditional types of collaboration?
 - What attributes does a digital therapeutic client (e.g. a pharma) seek in its technology provider partners?
 - What attributes does a digital therapeutic technology provider (e.g. a connected device supplier) seek from its clients?
 - What other factors make a successful digital therapeutics collaboration?
- 10.30 Morning Coffee**
- 11.00 Session 3: What is the Digital Therapeutic landscape today and how is it evolving?**
 - Who are the key players currently?
 - Who is emerging on the scene?
 - How is the technology landscape evolving?
 - What alliances are developing?
 - What factors are shaping the alliances of the future?
 - What will the landscape look like in 5 to 10 years time?
- 11.50 Closing Remarks**
- 12.00 End of Workshop**

PRE-CONFERENCE WORKSHOP B 13.00 - 17.00

Workshop Leader:
Alex Gilbert, Digital Medicine,
Huma

Optimising Patient Engagement and Creating Novel Company Value through Digital Technologies

Workshop Overview:

During this workshop, Huma (a global leader in the field of Digital Health) will share their experience and learnings on creating engaging Patient Support Programs to support the Life Sciences and Medical device industries.

Huma will also explore the opportunities that arise from digitized patient support, such as the collection of real-world-evidence (RWE) for value dossiers, and the creation of novel digital biomarkers for quantifying illness.

Why you should attend this workshop:

- Insights on digital engagement from a market authority
- Step-by-step guides to creating successful digital programs
- Improved understanding of value-adds such as RWE
- Introductory guide to digital biomarkers
- In-market case studies on all of the above

About the workshop leader:



Alex has worked within the Digital Health industry for a number of years alongside healthcare, pharmaceutical and tech organisations. He joined Huma as one of their first employees and currently manages some of their global Life Sciences Partnerships and Digital Medicine development. His passion is the use of technology to empower and engage the patient to take control of their care.

About the Organisation:

Huma is one of the UK's highest-growth digital health companies, having raised over 50 Million in funding, whilst partnering with Apple and Tencent. They work with the leading brands within the Life Sciences and Medical Device sector to deliver engaging patient support, collect market data, enable improved clinical trials and create digital medicines.

Programme

- 13.00 Registration and Coffee**
- 13.30 Opening Remarks and Introductions**
- 13.40 Session 1: Creating Successful Digital Support Programs**
 - Overview of the Huma process to creating digital tools
 - Huma's levers of success to engage patients
 - A guide to implementation and scaling
 - Key considerations
- 14.20 Session 2: Maximising Value through RWE**
 - An introductory guide to RWE
 - The benefits of collecting RWE
 - Key Considerations
 - Group exercise
- 15.00 Afternoon Tea**
- 15.30 Session 3: How (and Why) to Create Digital Biomarkers**
 - An introductory guide to Digital Biomarkers
 - The Long-term value and benefits of creating Digital Biomarkers
 - Key Considerations
 - Group exercise
- 16.10 Session 4: Case Studies**
 - Case Study 1 – Patient Support Program for drug delivery device
 - Case Study 2 – RWE Collection for a medical device player
 - Case Study 3 – Digital Biomarker to track Neurological symptoms
 - Group Exercise
- 16.50 Closing Remarks**
- 17.00 End of Workshop**

WEARABLE INJECTORS AND CONNECTED DEVICES CONFERENCE 2021

Conference: Monday 18th & Tuesday 19th October 2021, Copthorne Tara Hotel, Kensington, London, UK

Workshops: Wednesday 20th October 2021, Copthorne Tara Hotel, Kensington, London UK

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