



2024 PDA Medical Devices and Connected Health Conference

From Pilot to Population – A Roadmap for Successful Digital Health

04 – 05 June 2024

Antwerp, Belgium

Agenda

Tuesday, 04 June 2024

9:00	Welcome and Introduction from the Co-Chairs	Stephanie Göbel, <i>Genentech/Roche</i> & Paul Upham, <i>Genentech/Roche</i>
Opening Plenary: From Project to Product - Key Aspects for Your Roadmap		Moderator: Stephanie Göbel, <i>Genentech/Roche</i>
<p>The opening is going to stimulate your thinking about the entire healthcare ecosystem, from patients to healthcare providers, regulators, and insurance companies. We will cover challenges in regulatory pathways that need to be addressed to ensure the final commercial success of a product. These regulatory considerations are accompanied by two presentations that discuss the commercialization of digital solutions:</p> <p>In the keynote presentation use cases and reimbursement strategies in different markets will be discussed - sharing emerging best practices on how to address the needs of healthcare providers as well as of patients. Related to patients, learn about the interaction of patient behavior and environmental impact and how to address these aspects to result in a connected product solution that improves patient outcomes while reducing the environmental footprint and related healthcare costs.</p>		
09:15	Show Me the Money – Commercialization, Business Models and Case Studies	John Mulcahy, <i>S3 Connected Health</i>
09:40	Regulatory Pathways for Connected Combined Products	Christoph E. Joosten, <i>F. Hoffmann-La Roche</i>
10:05	Remote Patient Monitoring: A Win for Patients and the Environment?	Daniel Nickalls, <i>TTP</i> & Anna Wilson, <i>52North Health</i>
10:30	<p>Plenary Discussion</p> <p><u>Panelists:</u></p> <ul style="list-style-type: none"> • Christoph E. Joosten, <i>F. Hoffmann-La Roche</i> • John Mulcahy, <i>S3 Connected Health</i> • Daniel Nickalls, <i>TTP</i> • Anna Wilson, <i>52North Health</i> 	
11:15	Networking Coffee Break, Poster Session & Exhibition	



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Session 1: Data Management (Cybersecurity)		Moderator: Paul Upham, <i>Genentech/Roche</i>
Learn about how data are used in the different components of connected systems, how their use is viewed by health authorities, as well as the risks, mitigations, and regulations for ensuring that all of those data are secured and protected.		
11:45	New FDA Premarket Submission Requirements for Cybersecurity in Medical Devices	Paul Gardner, <i>Congenius AG/Ypsomed</i>
12:05	When Ransomware Halts Your Factory and Supply Chain	Kevin Fu, <i>Northeastern University</i> - Remote presentation -
12:25	Meeting the Evolving Requirements of SaMD and AI in Healthcare	Thomas Watts, <i>Team Consulting</i>
12:45	Q&A, Discussion	
13:15	Networking Lunch Break, Poster Session & Exhibition	
14:00	LIVE Guided Poster Walk Engage with our Poster Presenters in our Exhibition Hall	Moderator: Bernhard Gerl, <i>Körber</i>
Session 2: Patient Centricity		Moderator: Arnaud Guillet, <i>Biocorp</i>
Connectivity offers a technical solution to tackle the issue of non-adherence, but user acceptance is not a given. Any new solutions will inevitably create some minor disruptions for patients, which can be barriers to adoption. Therefore, health industrials must master all aspects of patient-centric design to come up with solutions that provide immediate benefits to patients, while minimizing impact to their current habits. This session will present concrete use cases of collaborations between pharma & MedTech/digital health players on how to effectively design and implement connected solutions. The first one will describe the deployment of a connected ecosystem in the GH space. Second will present insights from HIV patients engaged with a connected device and associated App, analyzing user opinions on features within a controlled testing setting. The last presentation will demonstrate how introducing behavioral diagnosis into a digital service allows more effective interventions in response to changing patterns of medication adherence.		
14:30	Interactive Questionnaire	Via Mentimeter



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14:40	Exploring Patient Perspectives on Self-Care and Self-Injection and the Implications for Digital Health Solutions	Philippe Müller, <i>Ypsomed</i>
15:00	Deploying Connected Drug Delivery Devices for Caregivers and Patients with Growth Hormone Deficiency	Liam McMorrow, <i>Novo Nordisk</i> & Fanny Sellier, <i>Biocorp</i>
15:20	The Role of Connected Health in Responding to Changing Patterns of Medication Adherence	Kevin Dolgin, <i>Observia Group</i> & Ashwani Kumar, <i>Phillips Medisize</i>
15:40	Q&A, Discussion	
16:10	Networking Coffee Break, Poster Session & Exhibition	
Session 3: Behavior Science – Designing for Engagement		Moderator: Geraint Davies, <i>F.Hoffmann-La Roche</i>
<p>Changing people’s behavior is hard. Changing people’s health behavior is REALLY hard! The health industry has always struggled with patient adoption and adherence to medications, monitoring, exercise, and a host of other lifestyle changes, despite their proven benefits. Digital Health is no different, and those in the industry for a while know that sustained engagement with a product is one of the biggest barriers to success.</p> <p>Behavior Design is the systematic application of the behavioral sciences to the development of products and services. It helps us understand the deeper reasons why people make the decisions they do and how to overcome subconscious and emotional barriers that prevent us from achieving the outcomes we desire.</p> <p>The talks in this session will not only introduce the core concepts of behavior design but also provide real-world examples to help the audience understand how to apply it and why this approach is fundamental to developing successful products.</p>		
16:40	Rethinking Patient Engagement: The Untapped Potential of Behavioral Design in Digital Health	Richard Mathera, <i>Irrational Labs</i>
17:00	How to Translate Behavioral Science to the Design of Tools that Benefit Patients Learning to Self-Inject	Ben Cox, <i>Team Consulting</i> &



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		Sabine Krawietz, <i>Novartis</i>
17:20	Building an Engagement Architecture in Medical Devices	Andrew Zimmermann, <i>Behavior Design Group</i>
17:40	Q&A, Discussion	
18:10	End of Conference Day 1 & Networking Event	
Wednesday, 05 June 2024		
9:00	Welcome Back by the Co-Chairs	
Session 4: Commercialization		Moderator: Andrei Yosef, <i>LTS Lohmann</i>
09:05	Strategies for Enhancing Adoption of Connected Combined Products in the Digital Health Landscape	Lina Abu-Qaoud & Jenny Estermann, <i>Kymanox</i>
09:25	Assessing the Impact of Connected Healthcare on the Adoption and Valuation of Drug Delivery Systems: A Detailed Perspective from Pharma and Biotech Stakeholders	Aaron Swick & Mehul Desai, <i>Enable Injections</i>
09:45	Breaking Barriers in Clinical Decision Support Systems: Navigating the Challenges of Regulation, Reimbursement, and Interoperability	Miriam Schulze, <i>BAYOOMED</i>
10:05	Q&A, Discussion	
10:35	Networking Coffee Break, Poster Session & Exhibition	
Session 5: Case Studies – Using the Data		Moderator: Iain Simpson, <i>Phillips Medisize</i>



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In this session, we will explore how the data collected from connected medical devices can be utilized to provide insights into device performance as well as medication use. The session starts with an overview of the importance of medication adherence and how connected devices can provide more accurate, real-time data to support this. Then subsequent talks will focus on 2 device-related case studies and consider how data transmitted from connected injection devices can provide important information on their performance as well as on medication use. It will be shown how these data can be used to improve device design and patient training as well as support adherence. The session will also explore some of the challenges and considerations in gathering and processing such data. The case studies will include both clinical and commercial examples of the use of connected devices.

11:05	Optimizing Medicines Through Connected Devices: Dosing History Data is Key!	Bernard Vrijens, <i>AARDEX Group</i>
11:25	Unveiling the Power of Injection Devices Transmitted Data: Use cases	Rodrigue Chatton, <i>Merck KgaA</i>
11:45	Unveiling Insights Through Wearable Drug Delivery Devices and Data Management	Tal Ohev Zion, <i>LTS Lohmann Therapie Systeme</i>
12:05	Q&A, Discussion	
12:35	Networking Lunch Break, Poster Session & Exhibition	
Closing Plenary: Navigating the Future: Sustainability, Handling Regulatory Compliance, and Reimbursement for Medical Devices and Connected Health		Moderator: Paul Upham, <i>Genentech/Roche</i>
In this dynamic plenary session, industry experts will delve into the critical aspects of sustainability, handling regulatory compliance, and reimbursement for medical devices and connected health solutions. This session will provide comprehensive insights into the evolving landscape of medical devices, offering practical guidance and innovative strategies to navigate these challenges effectively.		
13:35	Interactive Questionnaire	Via Mentimeter
13:45	Care Pathways: A Holistic Approach to Understanding the Sustainability Impacts and Benefits of Medical Devices and Encouraging Innovation	Simon Aumonier, <i>Consultant</i>



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14:10	Wondering How to Navigate the MDR GSPR's for Your PFS? Help Is Out There!	Bettine Boltres, <i>West</i>
14:30	Networking Coffee Break, Poster Session & Exhibition	
15:05	Passport Raffle	
15:10	Unlocking Reimbursement for Connected Medical Devices in Europe and the US: Key Success Factors	Alexandre Habib, <i>Simon Kucher</i>
15:35	<p>Plenary Discussion</p> <p><u>Panelists:</u></p> <ul style="list-style-type: none"> • Simon Aumonier, <i>Consultant</i> • Bettine Boltres, <i>West</i> • Alexandre Habib, <i>Simon Kucher</i> 	
16:15	Conference Summary from the Co-Chairs	
16:25	Closing Remarks & Farewell	Falk Klar, <i>PDA Europe</i>
16:30	End of Conference	

The agenda is subject to change without notice, Speakers are invited pending confirmation.