



2023 PDA Smart Devices and Digital Solutions Workshop

Novel Approaches in Behavior Change for Digital Combination Products

16 October 2023 | Gothenburg | Sweden

Agenda

Monday, 16 October 2023

09:30	Morning Coffee	
10:00	Welcome & Introductions	Iain Simpson, <i>Phillips Medisize</i>
Topic 1: The Patient		
10:15	The Behavioural Challenge of Medication Adherence <ul style="list-style-type: none">the nature and determinants of medication non-adherencewhy most apps fail to change adherenceusing behaviour change theory to design targeted adherence interventions	John Weinman, <i>Kings College London</i>
10:35	The Theory of Behavioural Change Interventions <i>Patient Support Programs in Practice</i> <i>Practical Aspects</i> <ul style="list-style-type: none">Implementing personalized solutions to change behaviourIntroduction to Patient Support Programmes (PSPs)PSPs and the integration of SMART devices	Niamh Ward, <i>Atlantis Health</i>
10:55	Workshop on the Case Study: About Patient Engagement <i>Following topics will be evaluated with inputs from the audience</i> <ul style="list-style-type: none">Use a behaviour framework to understand adherence challengesReview BCT opportunities for identified behaviour challengesConsider how to incorporate Behavior Change Technique into a digital PSP	Moderators : Iain Simpson, <i>Phillips Medisize</i> Geraint Davies, <i>Roche</i>
Topic 2: The Opportunity		
11:30	Value Creation with Smart Devices and Digital Solutions – <i>An example with connected injectors in the field of rare diseases</i>	Eric Dessertenne, <i>Biocorp & speaker to be announced</i>
11:50	Workshop on the Case Study: About the Opportunity <i>Following topics will be evaluated with inputs from the audience</i> <ul style="list-style-type: none">How to identify the stakeholders and relevant value drivers?	Moderators: Iain Simpson, <i>Phillips Medisize</i> Geraint Davies, <i>Roche</i>



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	<ul style="list-style-type: none">• How to link patient engagement and commercial success?• What are the expected impacts and return on investment?	
12:30	Lunch Break	
Topic 3: The Challenges		
13:30	<p>Regulatory challenges for Smart Drug-Delivery Devices under the MDR</p> <ol style="list-style-type: none">1. What are some of the unique regulatory challenges for smart drug-delivery devices?2. How has the change from MDD to MDR impacted smart drug-delivery devices?3. What are some practical recommendations for teams that are hoping to launch a smart solution?	Juan Carriquiry, Beyond Conception
13:50	<p>Workshop on the Case Study: Regulatory and Compliance Challenges</p> <p><i>Following topics will be evaluated with inputs from the audience</i></p> <ol style="list-style-type: none">1. What are some unique considerations for hardware and software systems under the MDR?2. How has the change from MDD to MDR impacted smart drug delivery device solutions?3. Which features and functionality of the system drive significant regulatory and compliance challenges?<ol style="list-style-type: none">a. Regulatory identity of the system components (hardware, apps, cloud analytics, portals)b. Data privacy and cybersecurity laws and regulationsc. Differences across countries and between the EU and the US?	<p>Moderators:</p> <p>Paul Upham, Roche/Genentech</p> <p>Arnaud Guillet, Biocorp</p>
14:30	Panel Discussion on Global Implementation Consideration	<p>Moderator: Iain Simpson, Phillips Medisize</p>
14:50	<p>Workshop on the Case Study: Global Implementation Consideration</p> <p><i>Following topics will be evaluated with inputs from the audience</i></p> <ol style="list-style-type: none">1. Mapping internal stakeholders – a participant activity<ol style="list-style-type: none">a. Create a list of stakeholders with key roles and what actions do you expect from them?b. Localization and Customizationc. Training and Customer supportd. Legal and Compliance Approvalse. Customer Engagement Strategy	<p>Moderators:</p> <p>Paul Upham, Roche/Genentech</p> <p>Arnaud Guillet, Biocorp</p>
15:30	Coffee Break	



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16:00	Key Take-Aways and Learnings from Discussions - Final Q&A and Audience Feedback	
17:00	Farewell & End of Workshop	Iain Simpson, <i>Phillips Medisize</i>

The program is subject to changes.