

## Cardiovascular Round Table Plenary Meeting

**“The Digital Health Transformation: Implications on Research and Development, Patient Management and the Regulatory Framework”**

**4 October 2019 - 08:45 - 17:45 - Swissotel - Tallinn, Estonia**

### Chairs

**Prof. S. Achenbach (ESC), Prof. M. R. Cowie (ESC), Prof. M. Viigimaa (ESC)  
Dr I. Lordereau-Richard (Amgen), Dr F. Fuchs (Siemens)**

<b>8:45 - 9:00</b>	<b>Welcome – Introduction</b>	<i>Prof. Stephan Achenbach – Dr Isabelle Lordereau-Richard</i>
<b>9:00 -10:45 - SESSION 1 - DIGITAL HEALTH – NEW OPTIONS FOR DRUG AND DEVICE DEVELOPMENT</b>		
<b>MODERATED BY PROF. C. GALE AND PROF. A. HIMMELMANN</b>		
<b>9:00 - 9:20</b>	<b>Extracting Relevant Endpoints from Routine Clinical Data</b>	<i>Dr Dipak Kotecha University of Birmingham</i>
<b>9:25 - 9:45</b>	<b>Wearables and Patient Reported Outcomes in Research and Post-Market Surveillance</b>	<i>Dr Christian Müller (Bayer) Team Leader Data Generation</i>
<b>9:50 - 10:10</b>	<b>Within-registry trials: do they work?</b>	<i>Prof. Chris Gale - University of Leeds</i>
<b>10:15 - 10:45</b>	<b>Discussion</b>	
<b>10:45 – 11:15</b>	<i>Coffee break</i>	

<b>11:15 - 13:00 - SESSION 2 - ASSESSING DIGITAL TECHNOLOGIES - WHAT IS PROPORTIONATE?</b>		
<b>MODERATED BY PROF. M. VIIGIMAA AND DR F. FUCHS</b>		
<b>11:15 - 11:35</b>	<b>An Update on EU Device Regulation</b>	<i>Prof. Alan Fraser- Wales Heart Research Institute</i>
<b>11:40 - 12:00</b>	<b>Digital Health and Artificial Intelligence in the European Market</b>	<i>Dr Ceri Thompson EU Commission - Head of Unit, responsible for eHealth, Well-Being and Ageing</i>
<b>12:05 - 12:25</b>	<b>Regulatory Aspects of m-Health</b>	<i>Prof. Enrico G Caiani - Politecnico Di Milano</i>
<b>12:30 - 13:00</b>	<b>Discussion</b>	
<b>13:00 – 13:45</b>	<i>Lunch</i>	



<b>13:45 - 15:30 - SESSION 3 - DIGITAL TECHNOLOGY: OPTIONS FOR POST-MARKET SURVEILLANCE</b>	
<b>MODERATED BY PROF. M. COWIE AND PROF. A. GONCALVES</b>	
<b>13:45 - 14:05</b>	<b>The concept of Real-World Data for Regulators and Reimbursement</b> <i>Dr Gillian Leng Deputy CEO of NICE</i>
<b>14:10 - 14:30</b>	<b>Digital Health Options for Post-Market Surveillance: Pharma perspective</b> <i>Prof. Magnus Nord (AstraZeneca) Vice President - Global Patient Safety CVRM</i>
<b>14:35 - 14:55</b>	<b>Digital Health Options for Post-Market Surveillance: Device perspective</b> <i>Dr Alan Cheng (Medtronic) Vice President - Cardiac Rhythm Management Clinical Research and Therapy Development</i>
<b>15:00 - 15:30</b>	<b>Discussion</b>
<b>15:30 - 16:00</b>	<i>Coffee break</i>

<b>16:00 - 17:45 - SESSION 4 - DATA-DRIVEN PERSONALIZED MEDICINE</b>	
<b>MODERATED BY PROF U. LANDMESSER AND DR I. LORDEREAU-RICHARD</b>	
<b>16:00 - 16:15</b>	<b>Applications of More Personalized Medicine in 2019</b> <i>Prof. Folkert Asselbergs - UMC Utrecht</i>
<b>16:20 - 16:35</b>	<b>Access to Hospital Data and their Use to Train and Validate Models</b> <i>Prof. Mikhail Zaslavskiy OWKIN- Chief Research Officer</i>
<b>16:40 - 16:55</b>	<b>How Data Sciences Transform Patient Management: Best Practice Sharing</b> <i>Assistant Prof. Pedro F. Monteiro University Hospitals of Coimbra</i>
<b>17:00 - 17:15</b>	<b>Digital Health and Clinical Practice Guidelines</b> <i>Prof. Ulf Landmesser Charite Universitaetsmedizin - Berlin</i>
<b>17:15 - 17:45</b>	<b>Discussion &amp; Wrap-up</b>
<b>17:45</b>	<i>End of Plenary Meeting</i>