WORKSHOP AGENDA

Day 1 **Monday, 18 May 2015** **Registration & Check-In at 0830, Workshop begins at 0900**	
TIME	**SESSION**
0900-1015	***An Overview of the Current Regulatory Landscape for Personalised Medicines and Companion Diagnostics*** Stuart Hogarth, PhD, Department of Social Science, Health and Medicine, King's College, United Kingdom
1015-1030	**BREAK**
1030-1130	***The EMA Experience: Biomarkers and –omics*** Falk Ehmann, MD, PhD, MSc, Science and Innovation - Clinical Pharmacology, European Medicines Agency, United Kingdom
1130-1215	***Personalised Medicines (Medicinal Products)*** Patrick Larcier, PharmD, MBA, Vice President, Drug Development & Vigilance Operations, Voisin Consulting, France Sylvie le Gledic, PhD, Director, Medical Devices & IVD, Voisin Consulting, France
1215-1315	**LUNCH**
1315-1415	***Drug & Device Co-Development*** Patrick Larcier, PharmD, MBA, Vice President, Drug Development & Vigilance Operations, Voisin Consulting, France Sylvie le Gledic, PhD, Director, Medical Devices & IVD, Voisin Consulting, France Falk Ehmann, MD, PhD, MSc, Science and Innovation - Clinical Pharmacology, European Medicines Agency, United Kingdom
1415-1430	**BREAK**
1430-1530	***The Real Value and Practical Implications of Big Data*** Nigel Hughes, Director Integrative Healthcare Informatics, Janssen R&D, Belgium
1530-1630	***Beyond Licensing: Hurdles for Implementation of Personalised Medicine in Clinical Practice*** Marjolein Weda, PhD, PharmD, Senior Scientific Officer, National Institute for Public Health and the Environment (RIVM), The Netherlands

WORKSHOP AGENDA

Day 2 **Tuesday, 19 May 2015** **Workshop begins at 0900**	
TIME	**SESSION**
0900-1015	***The New IVD Regulation: Implications for Genetic Testing*** David Barton, PhD, Chief Scientist, Molecular Genetics Laboratory, Our Lady's Children's Hospital, Ireland
1015-1030	**BREAK**
1030-1130	***Companion Diagnostics*** Michael Murphy, President, Conatus Consulting, United States
1130-1230	***Regulatory Framework and Strategy*** David Kern, Senior Director, Regulatory Affairs, Illumina, Inc., United States
1230-1330	**LUNCH**
1330-1445	***Market Access*** Leeza Osipenko, PhD, Associate Director, Center for Health Technology Evaluation, National Institute for Health and Care Excellence, United Kingdom
1445-1500	**BREAK**
1500-1600	***Considerations for Short- and Long-Term co-Diagnostic Strategy Development*** Geert Callaerts, Director of Regulatory Affairs, Janssen Diagnostics BVBA, Belgium
1600-1700	***Companion Diagnostics: Leveraging Submissions for Success in the U.S. and Beyond*** Pamela Swatkowski, Director of Global Regulatory Affairs, Abbott Molecular, United States