Day 1
Wednesday October 19th, 2016

08.00 Registration & Breakfast

09.00 Chairman's Opening Remarks
Chris Anderson, Editor in Chief, ClinicalOMICs

Targeted Immunotherapies, Complementary & Companion Diagnostics

09.05 Predictive Biomarkers for Pembrolizumab
Eric Rubin, Vice President & Therapeutic Area Head, Oncology Early Development, Merck

09.30 Decentralized Multiplexed Companion Diagnostics on the NanoString nCounter Analysis System
Sean Ferree, Vice President, Diagnostic Development, NanoString Technologies

10.00 Diagnostics for Cancer Immunotherapies: Present and Future Outlook in Healthcare and Precision Medicine
Miro Venturi, Global Head, Diagnostics, Biomarkers, Roche

10.25 Immuno-Oncology Targeting Therapies: Developing Diagnostics to Meet Patient Needs
Steven Averbuch, Vice President, Development, Oncology & Pharmacodiagnostics, Bristol Myers Squibb

10.50 Speed Networking & Morning Refreshments

11.40 The Art of Oncology: How to Utilize Biomarker Tests for Immuno-Oncology Treatments in the Real-World
Zhen Su, Vice President & Head, Global Medical Affairs, Oncology, EMD Serono

12.05 Fast to Pivotal: An Approach to Cut-Off Determination to go Directly to Pivotal Trial
Jay Foust, VP, CDx Partnering, Roche Tissue Diagnostics (Ventana)

12.35 How to Maximise the Value of Biomarkers in Immuno-Oncology: A Role for Companion and Complementary Diagnostics
Steven Anderson, CSO, Covance

13.05 Networking Lunch

14.15 Panel Session hosted by Roche Diagnostics: What are the Evolving Roles of Complementary and Companion Diagnostics in Oncology and Beyond?
Moderator: Bruce Jordan, Vice President, International Business Leader, Companion Diagnostics, Roche Diagnostics
Miro Venturi, Global Head, Diagnostics, Biomarkers, Roche
Eric Rubin, Vice President & Therapeutic Area Head, Oncology Early Development, Merck
Steven Anderson, CSO, Covance
Zhen Su, Vice President & Head, Global Medical Affairs, Oncology, EMD Serono
Steven Averbuch, Vice President, Development, Oncology & Pharmacodiagnostics, Bristol Myers Squibb

Liquid Biopsies in Precision Medicine

15.00 Liquid Biopsies: Changing Treatment Paradigms for Patients
Stefan Scherer, Vice President, Global Head, Correlative Sciences, Novartis

15.30 Epitope-Independent Capture and Harvest of CTCs from Blood
Claudia Hille, PhD Student, University Medical Center Hamburg – Eppendorf (UKE), in partnership with ANGLE plc

16.00 Afternoon Refreshments

Precision Therapy, Diagnostic & Technology Regulation & Policy

17.00 The Regulatory & Policy Landscape of Precision Medicine's and Diagnostics: What have we Accomplished?
Girish Putcha, Director, Laboratory Science, Palmetto GBA

17.30 Panel Session: Achieving Drug, Diagnostic and Tech Regulatory Approval in the U.S. and Other Leading Geographies
Moderator: Chris Anderson, Editor in Chief, ClinicalOMICs
Jennifer Dickey, Senior Scientific Reviewer, CDRH, OIR, FDA
Jean-Claude Marshall, Director, Clinical Pharmacogenomics Lab, Pfizer
Girish Putcha, Director, Laboratory Science, Palmetto GBA

18.00 Chairman's Closing Remarks
Chris Anderson, Editor in Chief, ClinicalOMICs

18.10 Close of Day 1
Boston Tea Party Evening Reception, Hosted by Abbott Molecular

Day 2
Thursday October 20th, 2016

08.00 Breakfast & Networking

How Far Have We Actually Come with Precision Medicine & Companion Diagnostics?

09.00 Chairman's Opening Remarks
Hakan Sakul, Vice President & Head of Diagnostics, Pfizer

09.10 Changing the Paradigm for the Development of Multiple Biomarker Companion Diagnostic Tests
Brian Kelly, Director, Diagnostic Partnering, Thermo Fisher Scientific

09.40 State of Address: What has been our Journey along the Precision Medicine Timeline to this Point?
Carl Barrett, Vice President, Translational Science, AstraZeneca

10.10 Panel Session: What have we Achieved with Precision Medicine and Companion Diagnostics and Where Are We Going?
Moderator: Hakan Sakul, Vice President & Head of Diagnostics, Pfizer
Carl Barrett, Vice President, Translational Science, AstraZeneca
Mark Roberts, Director, Companion Diagnostics, Covance
Sean Ferree, Vice President, Diagnostic Development, NanoString Technologies

10.45 Morning Refreshments & Networking

STREAM A **Biomarker Discovery & Validation Stream** **Chair: Daniel O'Shannessy, Translational Diagnostics**	**STREAM B** **Clinical Co-Development Stream** **Chair:** Mark Oldroyd, Senior Director, Regional Payer Relations & Reimbursement, Foundation Medicine	**STREAM C** **Precision Medicine Commercialization Stream** **Chair:** Sangeetha Ramsagar, Director, Strategic Business Improvement, Johnson & Johnson
Liquid Biopsies	**Accessing Patients**	**ROI vs. Patient Population Size**
11.30 Circulating Tumor DNA: Applications and Challenges Theresa Zhang, Vice President, Research Services, Personal Genome Diagnostics	**11.30 Developing and Validating Patient Selection Assays** Steven Pirie-Shepherd, Director, Oncology Translational Research, Pfizer	**11.30 How can Companion Diagnostics Robustly Add Value to Targeted Drug Development?** Abdel Halim, Vice President, Translational Medicine, Biomarkers & Diagnostics, Celldex Therapeutics
12.00 Prognostic and Predictive Relevance of ctDNA and CTC's in Patients with Advanced Small Cell Lung Cancers Huifeng Niu, Director, Translational Medicine, Takeda	**12.00 Accelerating the Adoption of Companion Diagnostics and Therapeutic Uptake with Decentralized Testing Models** Kathryn Becker, Franchise Director Oncology & Companion Diagnostics, Abbott	**12.00 Start With the End in Mind – A Diagnostic Company's Perspective on Companion Diagnostic Development** Bob Holt, Companion Diagnostic Development Manager, Hologic

	Molecular	
12.30 Liquid Biopsy for Clinical Diagnostic Use: Development and Commercialization of the OncoBEAM Platform Vishal Sikri, Vice President, Commercial Operations, Sysmex Inostics	**12.30 Getting the Right Patient(s) the Right Drug(s) at the Right Time(s)** Kenna Mills Shaw, Executive Director, Institute for Personalized Cancer Therapy, MD Anderson Cancer Center	**12.30 Commercial Trade-Off vs. Helping Small Populations of Patients: What's the Right Thing to do?** Cecilia Schott, Head, Personalized Healthcare, Corporate Development & Ventures, AstraZeneca
13.00 Networking Lunch in Exhibition Room **13.00 Invited Workshop Lunch Hosted by Cancer Genetics Inc.** **Speaker: Daniel Duncan, Medical Director MD,Cancer Genetics, Inc.** • **Overcoming Challenges in Companion Diagnostic Development - CGI insights into Multiple Myeloma, Renal Cell Carcinoma, and Lymphoma** • **A series of case studies demonstrating capabilities in hematologic and solid tumor testing will be used to highlight the importance of well planned clinical studies**		
Emerging Assays & Tech	**Clinical Trial Design**	**Aligning Drug-CDx Co-Development**
14.15 Understanding Disease Heterogeneity Through Liquid Biopsies Michael Heller, Professor, University of California, San Diego	**14.15 Combining Molecular and Histological Techniques to Effectively Stratify Patients to Cancer Therapies** Darrell Borger, Director, Biomarker Laboratory, Massachusetts General Hospital	**14.15 Ultra-Sensitive Protein Multiplex Arrays – Going Where No One Has Gone Before** Andrew Nixon, Associate Professor of Medicine, Duke University
14.45 Prediction of Homologous Recombination Deficiency (HRD) Phenotype Utilizing a Liquid Biopsy for PARP Inhibitor Patient Selection and Monitoring Mark Landers, VP Translational Research, Epic Sciences	**14.45 Development and Commercialization of Companion Diagnostic Tests** Peter Kerr, Vice President, Companion Diagnostic Development, Almac	**14.45 Best Practice in Partnering With Your Laboratory for Successful Companion Diagnostic Development** Richard Heichemer, Senior Scientific Advisor, CDx, Q^2 Solutions
15.15 Pivotal Role of Tissue Samples in CDx Development Chris Womack, Senior Consulting Pathologist, TriStar Technology Group LLC **15.25 Expanding the CDx Strategy Options with RNAscope – A clinically-validated, Quantitative in situ RNA Biomarker Expression Platform**	**15.15 Immuno-Oncology Therapeutic and Companion Diagnostic Co-Development: A Match Made in Heaven?** Roy Baynes, SVP and Head, Global Clinical Development and Chief Medical Officer, Merck Research Laboratories	**15.15 How is Companion Diagnostics Adding Value Outside of Oncology?** George Bashirians, Director, Diagnostics Lead, Pfizer

Christopher Bunker, Vice President Business Development, Advanced Cell Diagnostics **15.35 Innovation Presentation** Olga Potapova, Managing Partner, President & CEO, Cureline		
15.45 Afternoon Refreshments		
Data, NGS & Multi-Omic Approaches	**Refining Clinical Drug-CDx Co-Development**	**The Fit of Precision Medicine in Pharma**
16.30 The VA Precision Oncology Program (POP) Louis Fiore, Executive Director, MAVERIC, US Department of Veterans Affairs	**16.30 A Biomarker-Driven Approach to Combating EGFR Inhibitor Resistance in Colorectal Cancer** Gavin MacBeath, Co-Founder & Senior Vice President, Merrimack Pharmaceuticals	**16.30 Overcoming the Challenges and Harnessing the Opportunities of Drug-Diagnostic Partnering** Andrew Beard, Head of Companion Diagnostics & Strategic Biomarker Group & Molecular Marketing, Siemens Healthcare Diagnostics
17.00 Companion Diagnostic Harmonization: Making a Difference for Patients Brian Burke, Business Development Director, Horizon	**17.00 Improving Patient Access to High Precision Diagnostics** Rudi Pauwels, Chief Executive Officer & Co-Founder, Biocartis	**17.00 Beyond Oncology: Implementing Precision Medicine and Companion Diagnostics Principles in Other Therapeutic Areas** Meggan Czapiga, Precision Medicine and Companion Diagnostics Leader, R&D ImmunoInflammation , GSK
17.30 Using Next Generation Sequencing to Direct Patients to the Right Study David Roth, Director, Penn Center for Precision Medicine, University of Pennsylvania	**17.30 Combination Trials for Cancer Immunotherapy Development** David Weaver, Vice President, Translational Research, Verastem	**17.30 Title TBC**

18.00 Close of Day Two

Day 3
Friday October 21st, 2016

08.00 Breakfast & Networking

Impact of Precision Medicine on the Healthcare System

09.00 Chairman's Opening Remarks
Sangeetha Ramsagar, Director, Strategic Business Improvement, Johnson & Johnson

09.15 How Can we Improve Patient Access to Testing for Earlier Diagnosis?
Jack Whelan, From Research Analyst to Research Advocate, Patient Advocate

09.35 Panel Session: How do We Improve the Integration of Precision Medicine & Multi-Biomarker Diagnostic Tests in Healthcare Systems?
Jack Whelan, From Research Analyst to Research Advocate, Patient Advocate
Edmund Pezalla, Vice President, National Medical Director, Pharma Policy & Strategy, Aetna
Kenna Mills Shaw, Executive Director, Institute for Personalized Cancer Therapy, MD Anderson Cancer Center
Louis Fiore, Executive Director, MAVERIC US Department of Veterans Affairs
Erik Faulkner, VP, Precision & Transformative Technology Solutions, Evidera

10.15 A Pragmatic Approach for the Successful Co-Development of Drugs and Diagnostics: Case Studies with Focus on Mitigating Risk in Oncology Drug Development
Dan Snyder, President & CEO, MolecularMD

10.45 Morning Refreshments & Networking

STREAM A **Biomarker Discovery & Validation Stream** **Chair: Daniel O'Shannessy, Translational Diagnostics**	**STREAM B** **Clinical Co-Development Stream** **Chair:** Mark Oldroyd, Senior Director, Regional Payer Relations & Reimbursement, Foundation Medicine	**STREAM C** **CDx Roundtables**
Emerging Biomarkers & Approaches	**Late Phase Clinical Case Studies**	**CDx & Precision Medicine Roundtables**
11.05 Automated, Sensitive Microfluidic Device for CTC Capturing and Characterization Kalyan Handique, President & Chief Executive Officer, Celsee Diagnostics	**11.05 Diagnostic Test to Support PML Risk Stratification in Multiple Sclerosis Patients** Meena Subramanyam, Vice President, Translational Sciences & Technology, Biogen Idec	**11.05 – 12.05** **Drive your own learning, crowd-source ideas and get inspired:** 1. Demonstrating Clinical Utility with Liquid Biopsies 2. Is NGS the Future of Precision Medicine? 3. How to evolve the pharma-diagnostic partnering paradigm to ensure continued CDx & precision medicine development?

11.35 Next-Generation Biomarkers for the Era of Combination Cancer Immunotherapy David Kaufman, Executive Director, Translational Immuno-Oncology Lead, Oncology Clinical Research, Merck	**11.35 Parameters and Models when Efficiently Managing CDx-Rx Programs to Sustain Successful Partnerships** Karina Kulangara, Scientific Manager, Companion Diagnostics, R&D, Agilent Technologies	

12.05 Networking Lunch

Securing Evidence-Based Drug, Diagnostics & Test Reimbursement in Precision Medicine

13.35 Deciphering Drug and Diagnostic Reimbursement: Who's Paying for What?
Edmund Pezalla, Vice President, National Medical Director, Pharma Policy & Strategy, Aetna

14.05 Evidence Street™: Where the Market Meets Evidence
Suzanne Belinson, Executive Director, Center for Clinical Effectiveness, BlueCross and BlueShield Association

14.35 Panel Session: Securing Evidence-Based Drug, Diagnostics & Tech Reimbursement in Precision Medicine
Moderator: Sangeetha Ramsagar, Director, Strategic Business Improvement, Johnson & Johnson
Girish Putcha, Director, Laboratory Science, Palmetto GBA
Edmund Pezalla, Vice President, National Medical Director, Pharma Policy & Strategy, Aetna
Suzanne Belinson, Executive Director, Center for Clinical Effectiveness, BlueCross and BlueShield Association

15.05 Chair's Closing Remarks
Sangeetha Ramsagar, Director, Strategic Business Improvement, Johnson & Johnson

15.10 Close of 7th World CDx Boston 2016, Afternoon Refreshments & Final Networking