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Sixth Annual

Next Generation Dx Summit

Moving Assays to the Clinic

August 19-21, 2014
Capital Hilton, Washington, DC

The Next Generation Dx Summit brings together all of the major players in the evolving areas of diagnostics

CONFERENCE PROGRAMS

August 19 - 20

- Enabling Point-of-Care Diagnostics
- Predictive Cancer Biomarkers
- Companion Diagnostics: Strategy & Partnerships
- Inherited Disease Diagnostics – *NEW!*
- NGS-Based Assays in the Clinical Setting – *NEW!*

August 20 - 21

- Molecular Diagnostics for Infectious Disease
- Companion Diagnostics: Technology & Reimbursement
- Commercialization of Molecular Diagnostics
- Clinical Application of Cell-Free DNA – *NEW!*
- Single-Cell Sequencing – *NEW!*

PLENARY SESSION: Think Tank on Next-Generation Sequencing Diagnostics

Discussion: Regulatory Review of Clinical Sequencing Assays

Moderator: *Harry Glorikian, Healthcare Consultant*

Guest Speaker: *Jennifer Dickey, RAC, Ph.D., Office of In Vitro Diagnostics, DIHD, US Food and Drug Administration*

Co-Organized with AMP Association for Molecular Pathology

Next-Generation Sequencing in Clinical Practice: Case Reports of Clinical Utility and Reimbursement

Moderator: *Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP*

Case Presenters:

Andrea Ferreira-Gonzalez, Ph.D., Professor, Pathology; Director, Molecular Diagnostics Lab, Virginia Commonwealth University

Madhuri Hegde, Ph.D., FACMG, Professor, Human Genetics; Executive Director, Emory Genetics Laboratory, Emory University School of Medicine

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Event-at-a-Glance

	DETECTION	BIOMARKERS	BUSINESS & STRATEGY	GENOMIC ANALYSIS	SEQUENCING
Monday	Pre-Conference Short Courses*				
Tuesday AM	Enabling Point-of-Care Diagnostics	Predictive Cancer Biomarkers	Companion Diagnostics: Strategy and Partnerships	Inherited Disease Diagnostics	NGS-Based Assays in the Clinical Setting
Tuesday PM	Enabling Point-of-Care Diagnostics	Predictive Cancer Biomarkers	Companion Diagnostics: Strategy and Partnerships	Inherited Disease Diagnostics	NGS-Based Assays in the Clinical Setting
Wednesday AM	Enabling Point-of-Care Diagnostics	Predictive Cancer Biomarkers	Companion Diagnostics: Strategy and Partnerships	Inherited Disease Diagnostics	NGS-Based Assays in the Clinical Setting
	Plenary Keynote Session				
Wednesday PM	Molecular Diagnostics for Infectious Disease	Companion Diagnostics: Technology and Reimbursement	Commercialization of Molecular Diagnostics	Clinical Application of Cell-Free DNA	Single-Cell Sequencing
	Dinner Short Courses*				
Thursday AM	Molecular Diagnostics for Infectious Disease	Companion Diagnostics: Technology and Reimbursement	Commercialization of Molecular Diagnostics	Clinical Application of Cell-Free DNA	Single-Cell Sequencing
Thursday PM	Molecular Diagnostics for Infectious Disease	Companion Diagnostics: Technology and Reimbursement	Commercialization of Molecular Diagnostics	Clinical Application of Cell-Free DNA	Single-Cell Sequencing

Separate Registration Required

About the Summit

Access to next generation diagnostics will only be gained through careful creation and management of partnerships in the community around development, commercialization, reimbursement and regulation. This year's **Next Generation Dx Summit** will showcase advances in personalized medicine through a comprehensive program encompassing companion diagnostics, infectious disease, cancer molecular markers, point-of-care, inherited disorders, cell-free DNA and single-cell sequencing.

This event has become the meeting place for major players in the expanding arena of diagnostics. It will showcase key components of their successful adoption in the clinic and advancement to the market. Please join the leaders in the community for another exceptional year.

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Short Courses*

MONDAY, AUGUST 18 (9:00AM-12:00PM)

SC1: Overcoming Challenges of Working with FFPE Samples

W. Fraser Symmans, M.D., Professor & Director, Research Operations, Pathology, UT MD Anderson Cancer Center

Sidney W. Fu, M.D., Ph.D., Professor & Associate Director, Genomic Medicine and of Medicine, Microbiology, Immunology and Tropical Medicine, George Washington University School of Medicine and Health Sciences

Professor Beatrice S. Knudsen, M.D., Ph.D., Director, Translational Pathology, Cedars Sinai Medical Center

- Assay development and understanding pre-analytic effects on RNA gene expression
- Profiling microRNA expression
- FFPE DNA quality control and its correlation with NGS data

SC2: Leading Product Innovation

John C. Carrano, Ph.D., President and Founder, Paratus Diagnostics, LLC

- Raising capital for your company or your project; pitching new ideas and writing a winning proposal, product development processes for FDA QSR
- Mathematics of cost-benefit analysis to establish a value proposition
- ISO 13485 and leadership and management techniques

SC3: NGS Data Analysis – Determining Clinical Utility of Genome Variants

Heather McLaughlin, Ph.D., MB(ASCP)^{CM}, Instructor of Pathology, Massachusetts General Hospital and Harvard Medical School and Assistant Laboratory Director, Laboratory for Molecular Medicine, Partners HealthCare Personalized Medicine

Erica Ramos, MS, CGC, Clinical Genomics Specialist, Certified Genetic Counselor, New and Emerging Opportunities, Illumina, Inc.

Gabe Rudy, Vice President, Product Development, Golden Helix

- Review advances in NGS, identify genetic variants to link sequence data with disease and explore genetic data science
- Learn how to determine informed healthcare decisions

MONDAY, AUGUST 18 (2:00-5:00PM)

SC4: Microfluidics for POC: Technologies, Applications and Products

Holger Becker, Ph.D., Founder & CSO, microfluidic ChipShop GmbH

- Understand the role of microfluidics technology in the development of new products and the current state of the markets and obstacles in the commercialization process; and the different microfabrication methods for low and high volume production
- Learn about development strategies in product development and about examples of successful and unsuccessful microfluidic product introductions
- Get an overview on existing microfluidics-enabled products in the POC market

SC5: NGS as a Diagnostics Platform

Madhuri Hegde, Ph.D., FACMG, Associate Professor, Human Genetics; Executive Director, Emory Genetics Lab, Emory University School of Medicine

Jennifer Morrissette, Ph.D., Scientific Director, Clinical Cytogenetics Laboratory; Clinical Director, Center for Personalized Diagnostics (CPD), University of Pennsylvania School of Medicine

Justin Zook, Ph.D., Biomedical Engineer, NIST

- Technical aspects, tremendous power and pitfalls of NGS
- NGS for cancer genomic analysis and companion diagnostics
- Risks of genetic discrimination and impacts of gene patents, government regulation, and direct-to-consumer marketing
- Standardization of NGS assay development

**Please visit the event website for more details. Separate registration is required.*

Short Courses*

SC6: Clinical Trials to Establish the Value of Diagnostic Tests: Design and Management

Adrienne Bambach, Ph.D. Manager, Scientific Affairs; Acting Director, Clinical Affairs NanoSphere, Inc.

Anita Borek, Senior Manager, Clinical Affairs & Specimen Mgmt., Nanosphere, Inc.

Scott Powell, Clinical Marketing Manager, Nanosphere, Inc.

- Sponsored/Investigator-Initiated-Study clinical diagnostics processes
- Specimen Acquisition and Management—who from, how to acquire, when to acquire, what to acquire and management best practices
- Clinical study publication planning and execution—microbiology molecular diagnostic test case presented from market development studies through clinical outcomes/cost-effectiveness studies

SC7: Sample Prep Methods for Liquid Biopsy and POC Molecular Diagnostics

Michael J. Heller, Ph.D., Professor, Bioengineering and Nanoengineering, UCSD

- Isolation of circulating cell-free DNA, ccf-RNA and exosomes from blood, plasma, serum and other clinical samples
- Isolation of circulating tumor cells from blood and of bacteria and virus from blood and other clinical samples
- New seamless sample to answer devices and finding needles in a haystack

MONDAY, AUGUST 18 (DINNER 5:30-8:30PM)

SC8: Use of CLIA-Waived POC and Rapid Diagnostic Tests in Community Pharmacies

Michael E. Klepser, Pharm.D., FCCP, Professor, Pharmacy Practice, Ferris State University College of Pharmacy

Donald G. Klepser, Ph.D., MBA, Assistant Professor, Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy

Allison Dering-Anderson, Pharm.D., RP, Clinical Assistant Professor, Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy

- Community pharmacies and how it is a growth market for diagnostics
- Legislation and state practice acts regarding the use of CLIA-waived POC and RDTs in community pharmacies
- Developing a sustainable business using POC and RDTs in community pharmacies

SC9: Regulatory Compliance in Drug Diagnostics Co-Development

Tracy Bush, Ph.D., Director & Global Coordinator, Companion Diagnostics, Regulatory Affairs, Roche Diagnostics

Pamela L. Swatkowski, Director, Regulatory Affairs, Abbott Molecular, Inc.

Sabah Malek, Associate Director, Global Regulatory Affairs, Eisai, Inc.

- U.S. requirements and processes; U.S. government oversight of diagnostics, diagnostic clearance and approval pathways
- Co-development process & timelines and integration of Rx and Dx development plansl navigating the development process and co-development examples and lessons learned
- Diagnostics regulation in the EU, Japan, China and other complex emerging markets; developing a successful CDx global regulatory strategy

WEDNESDAY, AUGUST 20 (DINNER 6:30-8:30PM)

SC10: Regulatory & Reimbursement Issues with NGS and Multiplex Assays

Melina Cimler, Ph.D., Vice President, Head, Global Quality Illumina, Inc.

Danielle Scelfo, Director, Government Affairs, Genomic Health

- Part 1: NGS applications and implications; Current regulatory pathways; Things to consider in developing NGS applications for clinical use; NGS in companion diagnostics – roles of pharma and diagnostic partners
- Part 2: Coding, coverage, policies and payment fees for NGS assays; Medicare /CMS view; How to generate cost effectiveness data; Clinical utility data

SC11: NGS for Infectious Disease Diagnostics

Samia Naccache, Ph.D., Associate Specialist, Laboratory Medicine, UCSF

Erik Samayoa, Clinical Lab Scientist, UCSF Viral Diagnostics and Discovery Center

- Clinical laboratory implementation of an unbiased NGS assay for pathogen detection
- From sequence-to-answer: bioinformatics analysis of NGS data in infectious diseases
- Other applications of NGS in infectious diseases – 16S/18S amplicon sequencing, whole-genome sequencing of bacteria and viruses, microbiome analysis, pathogen enrichment panels, host transcriptome sequencing

**Please visit the event website for more details. Separate registration is required.*

Recommended Pre-Conference Short Courses*

Microfluidics for Point-of-Care: Technologies, Applications and Products

Use of CLIA-Waived Point-of-Care and Rapid Diagnostic Tests in Community Pharmacies

**Separate registration required, please see page 3-4 for details*

TUESDAY, AUGUST 19

7:30 am Main Conference Registration & Morning Coffee

OPENING SESSION

8:30 Chairperson's Opening Remarks

Matthew Lorence, Ph.D., MBA, Executive Vice President, Marketing and Sales, Edge Biosystems, Inc.

8:40 Point-of-Care Diagnostics: Regulatory Perspective

Pawan K. Jain, M.D., Ph.D., Senior Regulatory Scientist, Division of Emerging and Transfusion Transmitted Disease, Office of Blood Research and Review, Center for Biologics Evaluation Research, FDA

CBER at FDA reviews the HIV diagnostic devices. The approved point-of-care devices for aid in diagnosis of HIV are being presented from the perspective of regulations and performance characteristics.

EXPERT PANEL DISCUSSION: POINT-OF-CARE FOR GLOBAL HEALTH

9:00 *Moderator: Matthew Lorence, Ph.D., MBA, Executive Vice President, Marketing and Sales, Edge Biosystems, Inc.*

Advancements in diagnostics technologies and communications are driving increased interest in delivering diagnostic solutions for resource limited settings (RLS). Diagnostics for RLS can be developed more effectively through the establishment of product, regulatory and business standards. This panel will discuss the opportunities for cost-effective POC diagnostics in RLS and current efforts to establish standards to develop POC diagnostics for the global health market.

Panelists:

George M. Whitesides, Ph.D., Woodford L. & Ann A. Flowers Professor, Chemistry & Chemical Biology, Harvard University

Pawan K. Jain, M.D., Ph.D., Senior Regulatory Scientist, CBER/OBRR/DETTD/PRB/FDA

Eric van Gieson, Ph.D., R&D Director, Diagnostics and Biosurveillance, MRIGlobal

John C. Carrano, Ph.D., President and Founder, Paratus Diagnostics, LLC

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

WHAT TECHNOLOGY MIGHT OFFER TO HELP QUALITY AND OUTCOMES

10:55 Chairperson's Remarks

Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center

11:00 A Handheld Point-of-Care Medical Tricorder and Wearable Lab-on-a-Chip System Based on Novel Microfluidics

Zhenyu Li, Ph.D., Assistant Professor, School of Engineering and Applied Science, George Washington University

Co-Presenter: Baabi Das, MBA, President and Founder, Zansors

Recent microfluidic technology developments in the laboratories of George Washington University and commercialized by Zansors offer next-generation tools for realizing both medical tricorder-like handheld *in vitro* diagnostic (IVD) systems and wearable lab-on-a-chip systems. A fully automated handheld immunoassay system will be discussed as well as a bendable, stretchable microfluidic system based on oxidative stress and other biomarkers.

11:30 Technological Advances in Point-of-Care Diabetes Diagnosis and Management

Asad R. Zaidi, President & CEO, Epinex Diagnostics, Inc.

Analysis of the current status and potential impact of POCT on the diabetic and prediabetic population, changing healthcare guidelines, and patient outcomes. Includes a discussion on the latest, up and coming technologies, test markers, and testing systems and how these can change healthcare delivery and outcomes for millions of diabetics worldwide.

12:00 pm Utilizing High Sensitive Troponin I Assay in the Emergency Department

Shahriar Dadkhah, M.D., MBA, FACC, FSCAI, Associate Professor, Medicine, University of Illinois; Director, Cardiology Research, Saint Francis Hospital

12:30 Genedrive®: A Major Advance in Molecular Diagnostic Testing of Infectious Disease in POC Settings *Sponsored by* epistem

Matthew Walls, CEO, Epistem Plc

Genedrive® is targeting a major advance in molecular diagnostic testing by providing a rapid, low cost, simple to use 'Point of Care' device with high sensitivity and specificity for use in diagnosis of infectious diseases and companion diagnostics. The first infectious disease assay for launch on Genedrive® is in Tuberculosis (TB) and aims to set a 'new standard' for the testing of TB & antibiotic resistance in low resource settings.

Achieving Laboratory Quality

1:00 Luncheon Presentation I: What Point-of-Care Product Developers Need to Know—Advice from the Field

Sponsored by Invetech

Judy Macemon, Director, Marketing, Invetech Diagnostics

Marjorie Toth, Project Manager, Invetech Diagnostics

Development of point-of-care (POC) products presents a range of challenges at every stage from initial concept and design through to launch. This session will provide field-proven strategies to address the risks and roadblock in the product development process in order to improve the chances of commercial success. Through working on more than 30 different POC projects, real-world insights will be provided on how to balance market needs with quality, performance and costs factors.

1:30 Luncheon Presentation II: *(Sponsorship Opportunity Available)*

2:00 Session Break

NOVEL TOOLS FOR POINT-OF-CARE

2:15 Chairperson's Remarks

Holger Becker, Ph.D., Founder & CSO, microfluidic ChipShop GmbH

2:20 Next-Generation Imaging and Diagnostics through Mobile Phones

Aydogan Ozcan, Ph.D., Chancellor's Professor, Electrical Engineering and Bioengineering, University of California Los Angeles; Associate Director, California NanoSystems Institute (CNSI)

As computational resources are becoming more powerful, while getting cheaper and more widely available, traditional imaging, sensing and diagnostic tools will continue to experience a revolution. We will summarize our recent work on emerging computational imaging, sensing and diagnostics techniques that utilize mobile phones to potentially transform the delivery of health care globally.

2:50 Smartphone-Based Lab-on-a-Chip Diagnostics

David Erickson, Ph.D., Associate Professor, Sibley School of Mechanical & Aerospace Engineering, Cornell University

In this talk I will discuss the transformative opportunity for the use of smartphone based technology in lab-on-a-chip diagnostics. Applications will focus on nutrition monitoring and cancer diagnostics in limited resource settings.

3:20 Moving Molecular Diagnostics for Infectious Diseases to Point-of-Care

Sponsored by Lucigen Dx Simplifying Diagnostics

Hemanth Shenoi, Ph.D., Director, Business Development, Lucigen Corporation

Point-of-care testing can lower cost and improve healthcare outcomes; however molecular diagnostic tests are currently not available at POC. Through a case study example, attendees will gain an understanding of the product development and regulatory approval path for a CLIA-waivable molecular diagnostic point of care test platform.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

4:30 Sample Preparation for Point-of-Care Multiplexed Bloodstream Infection Diagnostics

Ian White, Ph.D., Assistant Professor, Fischell Department of Bioengineering, University of Maryland

In this presentation we will review the challenges of a sample-to-answer PCR-based microfluidic bloodstream infection diagnostics system. We will then present novel approaches to enable automated sample preparation in a pragmatic integrated microsystem.

5:00 Digital Microfluidics for Clinical Applications

Aaron Wheeler, Ph.D., Director, Wheeler Microfluidics Lab, University of Toronto

Digital microfluidics (DMF) is an emerging alternative to traditional channel-based microfluidics. In DMF, discrete droplets of samples and reagents are controlled electrodynamically on the surface of an array of electrodes. In this talk, I will review several clinical applications that my lab has implemented that take advantage of the unique properties of DMF.

5:30 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by SLONEPARTNERS

6:30 Close of Day

WEDNESDAY, AUGUST 20

7:15 am Registration

7:30 – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast

POINT-OF-CARE DIAGNOSTICS WITH LABORATORY QUALITY

8:20 Chairperson's Opening Remarks

Chong H. Ahn, Ph.D., Mitchell P. Kartalia Chair and Professor, Microsystems and BioMEMS Laboratory, School of Electronics and Computing Systems, University of Cincinnati

8:30 Challenges of Point-of-Care Testing to Measure Troponins

Vincent Ricchiuti, Ph.D., Associate Professor, Director, Clinical Chemistry and Toxicology, Department of Pathology and Laboratory Medicine, UC Health University Hospital

This talk will explore different cardiac troponin assays available to the clinical laboratories and as point-of-care testing and review the definition of high sensitive cardiac troponin (hs-cTn) assays versus sensitive assays and how the hs-cTn assay is taking laboratory diagnosis of AMI to the future.

Achieving Laboratory Quality

9:00 A Universal, Open POCT System for High-Performance Tests

Chong H. Ahn, Ph.D., Mitchell P. Kartalia Chair and Professor, Microsystems and BioMEMS Laboratory, School of Electronics and Computing Systems, University of Cincinnati and Chairman, Siloam Biosciences, Inc.

This talk will focus on the Siloam's TROVA™ POCT platform – developed as a high-performance point-of-care-test platform. We will review how TROVA™ POCT system uses the same microfluidic reaction cells as the lab-based Optimiser™ platform allowing for (a) seamless migration of assays developed for lab environment to POCT applications and (b) true comparison of results in lab and POC test settings.

9:30 Future of HCV in The U.S. after Implementing Point-of-Care Rapid Assays

Ahmed Saleh, Ph.D., Director, Clinical Trials, Laboratory of Viral Diagnostics, University of Maryland

Lessons learned from HIV diagnostics should guide our decisions in the fight against HCV. The current model of linkage to care used in most successful HIV clinics, can add the HCV to the matrix. In the intravenous drug addiction users (IVDA), which is the most common risk factor for HCV, 64% are chronically infected with HCV. Our observation (Constantine and Saleh, 2011, unpublished) in 2 methadone maintenance programs in Baltimore, showed that more than half were unaware of their HCV status. Based on a new proposal submitted to the PCORI (Patient Centered Outcome Research Institute) our group in the University of Maryland, led by Dr. Niel Constantine, is proposing this new model that will shift our plans towards HCV screening. With the new treatments for HCV with near 100% effectiveness, it is critical to identify the infection and start the treatment earlier.

10:00 Rapid, Enzyme-Free Molecular Detection for Fully Automated, On-Demand Infectious Disease Diagnosis

Sponsored by Xagenic

Shana Kelley, Ph.D., CTO, Xagenic Inc.

The easy-to-use Xagenic X1™ System delivers a molecular diagnostic result in 20 minutes, enabling definitive patient treatment at the point of care. Xagenic's molecular technology permits rapid electrochemical detection of infectious pathogens at clinically-relevant levels without reliance on PCR or other enzymatic amplification methods. This novel multiplexed platform, which has the advantage of low cost instrumentation and consumables, is being commercialized with a menu of infectious disease tests.

10:15 Point-of-Care Diagnostics

Sponsored by atlas

John Clarkson, CEO, Atlas Genetics Ltd.

Atlas has developed the IO™ system for ultra-rapid near-patient molecular tests for infectious diseases. Based on novel sensor and fluidics technology, this low cost system will change the way that patients are treated. Key benefits include high multiplex, low complexity and expanding menu for sexually transmitted and hospital acquired infections.

10:30 Coffee Break in Exhibit Hall with Poster Viewing

PLENARY SESSION: Think Tank on Next-Generation Sequencing Diagnostics

11:00 Chairperson's Opening Remarks

11:10 Discussion: Regulatory Review of Clinical Sequencing Assays

Moderator: Harry Glorikian, Healthcare Consultant

Guest Speaker: Jennifer Dickey, RAC, Ph.D., Office of In Vitro Diagnostics, DIHD, US Food and Drug Administration

In November of 2013, the FDA issued the first clearances of Next Gen Sequencing- (NGS) based assays. There have additionally been a number of clinical trials approved recently that utilize NGS-based assays for patient enrollment or stratification. In light of the expanding roles that new sequencing technologies are playing in clinical decision making, this talk will focus on critical elements that FDA considers when evaluating NGS validation using the recent clearances/approvals as examples. There will also be a discussion of any new communications that FDA has issued in regard to the regulatory review of NGS- based assays. Following the discussion there will be a Q&A with the audience.

11:55 Next-Generation Sequencing in Clinical Practice: Case Reports of Clinical Utility and Reimbursement

Co-Organized with AMP Association for Molecular Pathology

Moderator: Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP

Case Presenters:

Andrea Ferreira-Gonzalez, Ph.D., Professor, Pathology; Director, Molecular Diagnostics Lab, Virginia Commonwealth University

Madhuri Hegde, Ph.D., FACMG, Professor, Human Genetics; Executive Director, Emory Genetics Laboratory, Emory University School of Medicine

The landscape of next-generation sequencing diagnostics is changing rapidly. Clinical laboratories are offering highly complex tests using new technologies, but face challenges in reimbursement. To be reimbursed for these tests, laboratories will need to address clinical utility as well as clinical validity. Clinical cases that demonstrate the utility of genomic oncological and inherited disease testing will be presented. Experiences with reimbursement of these tests will be discussed.

12:40 pm Close of Conference

Recommended Pre-Conference Short Courses*

Overcoming Challenges of Working with FFPE Samples

NGS as a Diagnostics Platform

**Separate registration required, please see page 3 for details*

TUESDAY, AUGUST 19

7:30 am Main Conference Registration & Morning Coffee

FUNCTIONALIZING CANCER GENOMICS: IDENTIFYING AND PRIORITIZING MARKERS

8:30 Chairperson's Opening Remarks

Robert D. Daber, Ph.D., Bio-Reference Laboratories

» 8:40 KEYNOTE PRESENTATION: THE VISION AND THE REALITY: ONE CANCER CENTER'S JOURNEY TOWARD GENOMIC MEDICINE

Jeff Boyd, Ph.D., Senior Vice President, Molecular Medicine; The Robert C. Young, M.D., Chair in Cancer Research; Executive Director, Cancer Genome Institute; Chief, Division of Molecular Pathology; Professor, Cancer Biology Program, Fox Chase Cancer Center

9:10 Clinical Validation Studies of Chemopredictive Gene Expression Profiles in Breast Cancer

W. Fraser Symmans, M.D., Professor & Director, Research Operations, Department of Pathology, UT MD Anderson Cancer Center

This presentation will discuss a method to quantify intratumor heterogeneity of cancers using gene expression data. We compared gene expression heterogeneity between different molecular subtypes of breast cancer and between basal like cancers with or without pathologic complete response (pCR) to neoadjuvant chemotherapy. We concluded that breast cancer subtypes differ in intratumor gene expression heterogeneity. Greater degree of heterogeneity correlate with greater chemotherapy sensitivity.

9:40 Clinical NGS in Oncology: MD Anderson Experience

Rajyalakshmi Luthra, Ph.D., Director, Molecular Diagnostic Laboratory (MDL) and Molecular Genetic Pathology Fellowship Program; Medical Advisor, Molecular Genetic Technology Program, School of Health Professions; Professor, Hematopathology, The University of Texas MD Anderson Cancer Center

Rapid advancements in next-generation sequencing technologies are enabling transition of high-throughput genotyping of cancer genomes from research in to clinical arena. This presentation will discuss the extensive experience gained in clinical NGS-based targeted sequencing of cancer specimens using Ion Torrent PGM (Life Technologies) and MiSeq (Illumina) and challenges associated with data processing, interpretation and reporting.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

INTERROGATING CANCER GENES WITH NGS AND MICROARRAY

10:55 Chairperson's Remarks

Rajyalakshmi Luthra, Ph.D., University of Texas MD Anderson Cancer Center

11:00 "Personalized" Breast Cancer Treatment

Peter J. Tonellato, Ph.D., Director, Laboratory for Personalized Medicine, Center for Biomedical Informatics, Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

Essential to a future of preventive and predictive medicine is the integration of whole genome technologies into clinical and health practice. We pursue the use of WGS in breast cancer care to create a post-genome paradigm shift in health, disease prevention, and personalized medicine. These and parallel efforts, though difficult, will catalyze the adoption and widespread implementation of the post-genome competency and thereby promote the era of personalized medicine.

11:30 Development and Implementation of Clinical NGS Testing: Assay Development and Informatic Challenges

Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories

Currently, the major bottleneck to unlocking the full potential of this technology remains creating bio-informatic workflows that accurately identify variants within the data. During development and clinical validation of two oncology sequencing panels we were confronted with the lack of a clinical grade solution for data analysis that was adequately tested to identify hard limits of detection.

12:00 pm Incorporating NGS Assays in a Routine Molecular Oncology Laboratory

Helen Fernandes, Ph.D., Pathology & Laboratory Medicine, Weill Cornell Medical College

As genomic technologies continue to advance and new bio-markers emerge, rapid NGS assay development becomes critical in the age of Precision Diagnostics. Here we will discuss emerging methods to capture important biological markers and their associated informatic challenges during both the development and implementation phases.

12:30 Biomarker Discovery Through Pathway Analysis- Bringing Together Multiple Data Types for a Better Picture

Sponsored by THOMSON REUTERS

Melinda Baker, Ph.D., Solution Scientist, IP & Science, Life Science, Thomson Reuters

'Next Gen Sequencing' (NGS) technologies produce massive amounts of data which can contain valuable information, connecting genetic variation with clinical phenotypes, and yet represent just one possible layer of biological perturbations. Here we will discuss newly released genomic analysis tools available within MetaCore™ that facilitate functional annotation of human variants and leverage pathway analysis to integrate NGS data with multiple other OMICs data types for biomarker discovery and validation.

1:00 Luncheon Presentation: Introduction to the Response Genetics Tissue of Origin Test

Sponsored by affymetrix

Debbie Corazzelli, Director, Product Marketing, Response Genetics

Response Genetics, a company focused on molecular diagnostic tests that help determine a patient's response to cancer therapy, recently introduced the FDA-cleared Response DX: Tissue of Origin Test. Looking at 2000 genes, it compares the tumor's gene expression patterns to those of 15 known tissues, with 89% sensitivity. It is the most accurate, most published, and best validated test of its kind. The objective test results can help guide physicians in managing cancer patients.

2:00 Session Break

NGS-BASED APPROACHES TO GUIDE TREATMENT

2:15 Chairperson's Remarks

Seth D. Crosby, M.D., Washington University School of Medicine

2:20 Clinical NGS of Hematological Malignancies

Jennifer Morrissette, Ph.D., Scientific Director, Clinical Cytogenetics Laboratory; Clinical Director, Center for Personalized Diagnostics (CPD), University of Pennsylvania Perelman School of Medicine

The use of multi-gene testing in hematologic malignancies using NGS reliably detects somatic mutations and provides insights into prognosis and therapeutic choice. We will describe our approach to AML mutation detection, including capture of difficult to sequence regions (e.g. CEBPA and large FLT3-ITDs), and mutation profiles with respect to conventional cytogenetic findings. Finally, the utility of in clinical prognostication and treatment decisions will be discussed.

2:50 Clinical Sequencing in the Pediatric Oncology Clinic: Challenges and Opportunities

Donald "Will" Parsons, M.D., Ph.D., Assistant Professor, Pediatrics, Molecular & Human Genetics, Baylor College of Medicine, Texas Children's Cancer Center

This talk will report results of the ongoing BASIC3 study, which aims to determine the clinical impact of incorporating tumor and constitutional whole exome sequencing into the care of children with newly diagnosed solid tumors at Texas Children's Cancer Center, with a particular focus on the diagnostic yield and limitations of WES in this setting.

3:20 Sponsored Presentation *(Opportunity Available)*

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

CIRCULATING BIOMARKERS

4:30 cfDNA Rare Alleles – How Low Can We Go?

Seth D. Crosby, M.D., Director, Alliances and Partnerships, Genetics, Washington University School of Medicine

This talk will review successful efforts at Washington University to employ novel reagents and informatics to the problem of rare allele detection.

5:00 Circulating microRNAs as Liquid Biopsies in Diagnostics and Therapy

Anton Wellstein, M.D., Ph.D., Professor, Oncology, Pharmacology and Medicine, Georgetown University Medical School; Associate Director, Basic Science, Lombardi Comprehensive Cancer Center

Altered patterns of microRNAs detected in the circulation may indicate the presence of cancer as well as the impact of treatment. It is conceivable that distinct changes of circulating microRNA patterns will indicate different therapeutic interventions that impact different pathways.

5:30 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by SLONEPARTNERS

6:30 Close of Day

WEDNESDAY, AUGUST 20

7:15 am Registration

7:30 – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast

MAKING DATA ACTIONABLE

8:25 Chairperson's Opening Remarks

Jennifer Morrissette, Ph.D., University of Pennsylvania Perelman School of Medicine

8:30 My Cancer Genome - Cancer Genomics Knowledge Resource

Christine M. Lovly, M.D., Ph.D., Assistant Professor, Medicine and Cancer Biology, Department of Medicine/Division of Hematology-Oncology, Vanderbilt University School of Medicine, Vanderbilt Ingram Cancer Center

Evidence regarding the clinical significance of tumor gene mutations for predicting response to cancer treatments is evolving at a rate that outpaces traditional approaches to knowledge dissemination. My Cancer Genome addresses this challenge by providing up-to-date information on mutation-specific treatments and clinical trials. Current content covers 293 mutations across 18 cancer types.

9:00 Driving Personalized Medicine and Clinical Diagnostics Using Genome Sequencing, Exome Sequencing, and Integrative Genomics

Rong Chen, Ph.D., Assistant Professor, Genetics and Genomic Sciences; Director, Clinical Genome Informatics, Icahn Institute for Genomics and Multiscale Biology, Icahn School of Medicine at Mount Sinai

This presentation will discuss applying data from WES and WGS for diagnosis and decision making in the clinical lab. Integrating and targeting various molecular mesurements into biomarkers doe disease diagnostics will also be discussed. Finally, discovery of casual variants, pathway, and mechanisms to illlustrate human cancers will be explored.

Organized by
Cambridge Healthtech Institute

9:30 Creating and Using Tumor Genome Profiles with Galaxy

Jeremy Goecks, Ph.D., Assistant Professor, Computational Biology, Integrative Systems Biology and The Computational Biology Institute, George Washington University

We describe open, reproducible pipelines that create a genomic profile of a tumor and use the profile to identify mutations associated with disease and pertinent drugs. These pipelines analyze tumor exome and transcriptome sequence data together with public databases to find mutations and drugs and they are integrated into the Galaxy platform to make them accessible and reproducible, thereby providing an approach for doing standardized, distributed analyses in clinical studies.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in Exhibit Hall with Poster Viewing

PLENARY SESSION: Think Tank on Next-Generation Sequencing Diagnostics

11:00 Chairperson's Opening Remarks

11:10 Discussion: Regulatory Review of Clinical Sequencing Assays

Moderator: Harry Glorikian, Healthcare Consultant

Guest Speaker: Jennifer Dickey, RAC, Ph.D., Office of In Vitro Diagnostics, DIHD, US Food and Drug Administration

In November of 2013, the FDA issued the first clearances of Next Gen Sequencing-(NGS) based assays. There have additionally been a number of clinical trials approved recently that utilize NGS-based assays for patient enrollment or stratification. In light of the expanding roles that new sequencing technologies are playing in clinical decision making, this talk will focus on critical elements that FDA considers when evaluating NGS validation using the recent clearances/approvals as examples. There will also be a discussion of any new communications that FDA has issued in regard to the regulatory review of NGS- based assays. Following the discussion there will be a Q&A with the audience.

Co-Organized with AMP Association for Molecular Pathology

11:55 Next-Generation Sequencing in Clinical Practice: Case Reports of Clinical Utility and Reimbursement

Moderator: Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP

Case Presenters: *Andrea Ferreira-Gonzalez, Ph.D., Professor, Pathology; Director, Molecular Diagnostics Lab, Virginia Commonwealth University*

Madhuri Hegde, Ph.D., FACMG, Professor, Human Genetics; Executive Director, Emory Genetics Laboratory, Emory University School of Medicine

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12:40 pm Close of Conference

Sponsoring Organizations

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AMP Association for Molecular Pathology

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Organized by
Cambridge Healthtech Institute

Recommended Pre-Conference Short Courses*

Regulatory Compliance in Drug Diagnostics Co-Development

Regulatory and Reimbursement Issues with NGS and Multiplex Assays

**Separate registration required, please see page 4 for details*

TUESDAY, AUGUST 19

7:30 am Main Conference Registration & Morning Coffee

KEYNOTE SESSION: CONVENING MAJOR STAKEHOLDERS

8:30 Chairperson's Opening Remarks

Mitch Raponi, Clovis Oncology

8:40 15 Years of Personalized Medicine in Patient Care: Past, Present and Future

Eric Lai, Ph.D., Senior Vice President & Head, Pharmacogenomics, Takeda Pharmaceuticals

Despite the complete sequencing of the Human Genome and the development of new molecular technologies, especially high-throughput DNA sequencing, the clinical application of personalized medicine is still limited. This presentation will discuss other potential ways of applying pharmacogenomics to drug development and the use of big research datasets to address unmet medical needs and patient stratification strategies for personalized medicine.

9:10 Challenges in Developing Companion Diagnostics with the Complexity of Cancer: Is NGS Assay a Solution?

J. Carl Barrett, Ph.D., Vice President, Translational Sciences, Onc iMed, AstraZeneca

Limitations of tissue and heterogeneity of cancers are both addressed by using NGS to interrogate cancers and select appropriate targeted therapies. Using NGS as a diagnostic however requires a better understanding of the challenges of NGS including target capture, sequencing platforms, variant calling and variant classification. The potential and pitfalls of NGS in clinical trials and diagnostic development will be discussed and illustrated.

9:40 Enabling Precision Medicine in the Age of Big Data

John Quackenbush, Ph.D., Co-Founder and CEO, GenoSpace; Professor, Dana-Farber Cancer Institute and Harvard School of Public Health, Biostatistics and Computational Biology

Built on a secure, cloud-based infrastructure and using advanced analytical tools, GenoSpace has created a system enabling precision medicine application in research, in the practice of clinical medicine, and in support of patients and patient communities.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

10:55 Chairperson's Remarks

11:00 International Case Study: Brazilian Strategy to Improve Access to Molecular Testing in Oncology - Building a Local Companion Diagnostics Platform

Carlos Gil Ferreira, M.D., Executive Director, INOVA-CANCER; Director, Clinical Research, Brazilian National Cancer Institute

In order to increase the access to high quality molecular testing in oncology, the Ministry of Health has launched a program that aims to develop the industry of companion diagnostics in the country. To that end partnerships between academia, pharma and diagnostic companies, regulatory agencies and government are being built.

11:30 HECON of Personalized Medicine

Nick Poulios, Ph.D., Head, MORE, Medical Outcomes: Reimbursement & Economics, Roche Molecular Systems, Inc.

This presentation will discuss health economics of personalized medicine in general and market access and reimbursement of companion diagnostics in particular.

12:00 pm Cancer Diagnostics in the Genomic Era

Sponsored by illumina

Daniel S. Grosu, M.D., MBA, Vice President, Clinical Development & Medical Affairs, Illumina, Inc.

The rapid evolution of high-accuracy and high-throughput genomic technologies has created unprecedented opportunities for translational and clinical applications in cancer. Next generation sequencing approaches now allow the interrogation of germline and somatic variation associated with malignancy across DNA and RNA sequence, structural variation, and epigenetic changes in many tissue types including blood. Potential applications span the continuum of cancer care, from inherited risk assessment and early detection to prediction of treatment response and recurrence monitoring.

12:30 BioMarker Development from Discovery to the Clinic

Sponsored by Luminex

Hongwei Zhang, Ph.D., Director, R&D and Process Engineering, Luminex Corporation

The development of biomarkers from discovery to clinical implementation as a CDx is a process which is inherently unpredictable; no two development pathways are alike. Given this unpredictability, it is desirable to develop biomarkers using a platform which provides flexibility, but which also reduces complexity as much as possible. The xMAP platform has been used extensively at all stages of biomarker development. The speaker will highlight some examples of discovery, validation and clinical implementation of biomarkers on xMAP.

Organized by
Cambridge Healthtech Institute

1:00 Luncheon Presentation: Development and Commercial Impact of FDA and Payer Evidence Needs for IVDs

Sponsored by Precision for Medicine

David Parker, Ph.D., Vice President, Market Access Strategy, Precision for Medicine

Judi Smith, Vice President, In Vitro Diagnostics and Quality, Precision for Medicine

Choices made during IVD conceptualization and early development can have a large impact on eventual clinical evidence needs for both FDA and payers. Precision will examine the IVD development process to illustrate how and when choices about diagnostic test type, regulatory pathway, and use in guiding clinical decision-making affect FDA's and payers' evidence needs. We will explore implications for the ROI on test development of considering these needs early in the process.

1:30 Luncheon Presentation II: *(Sponsorship Opportunity Available)*

2:00 Session Break

NEW PARTNERSHIP PARADIGM

2:15 Chairperson's Remarks

Kevin M. Harter, Saladax Biomedical

2:20 Joint Presentation: Development of an NGS-Based Companion Diagnostic for the PARP Inhibitor Rucaparib

Mitch Raponi, Senior Director, Molecular Diagnostics & Translational Medicine, Clovis Oncology

Matthew J. Hawryluk, Ph.D., Senior Director, Corporate & Business Development, Foundation Medicine, Inc.

PARP inhibitors (PARPi) are active in patients (pts) with mutations in BRCA1/2, a critical component of homologous recombination repair (HRR). However, PARPi activity extends beyond BRCA, most likely in pts with tumors with other alterations leading to homologous recombination deficiency (HRD). Rucaparib, an oral PARPi, is being developed for treatment of relapsed, platinum-sensitive high grade serous ovarian cancer (HGSOC). A unique, integrated, translational-clinical program (Assessment of Rucaparib In ovarian cancEr triaLs (ARIEL)) is ongoing to identify HGSOC pts who may benefit from rucaparib treatment. In collaboration with Foundation Medicine, NGS of tumor tissue is being performed to identify somatic BRCA1/2 mutations as well as genomic defects caused by HRD that may be predictive of rucaparib response. The ARIEL trials are strategically aligned to allow for prospective clinical validation of a novel NGS-based companion diagnostic for rucaparib.

3:20 Advances in Genomic Characterization of FFPE Cancer Samples

Sponsored by affymetrix

Eric T Fung, M.D., Ph.D., Vice President, Research and Development Clinical Applications, Affymetrix

FFPE samples are valuable resources for cancer research and for clinical diagnosis. However, FFPE preservation was developed to preserve morphology with no consideration for the preservation of RNA and DNA. Here we will discuss two approaches for the analysis of degraded, low quality FFPE samples: an assay that provides whole genome copy number with enriched resolution in cancer genes and a fully automated RNA in situ assay for sensitive and specific detection of any RNA transcript.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

4:30 Matching the Evolution of Diagnostic and Therapeutic Development: How Early is Early Enough?

Kevin M. Harter, President and CEO, Saladax Biomedical

The convergence of diagnostic and therapeutic development continues. Companion diagnostic development requires proper timing to avoid development and regulatory delays while also avoiding unnecessary costs during the process. This session will explore some critical time parameters in the co-development cycle and provide a framework for decision-making.

5:00 The Art of the Partnership - Claritas Genomics and Boston Children's Hospital

Catherine Brownstein, M.D., Instructor, Pediatrics, Harvard Medical School and Boston Children's Hospital

Offering clinical pharmacogenomics programs using state-of-the-art drug/gene knowledge is paramount to offering world-class patient care. In order to attain this goal, Boston Children's has partnered with Life Technologies to create Claritas Genomics. BCH and Claritas are devoted advancing clinical pharmacogenomics to improve medication safety through precision medicine. There has been an explosion of interest in identifying and classifying genes with pharmacogenomic impact, and institutions, including at BCH, and our clinicians and researchers have been working towards incorporating this information into the medical record and clinical practice.

5:30 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by SLONEPARTNERS

6:30 Close of Day

WEDNESDAY, AUGUST 20

7:15 am Registration

7:30 – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast

GOING GLOBAL AND GOING NGS: REGULATORY PERSPECTIVE

8:25 Chairperson's Opening Remarks

Catherine Brownstein, M.D., Harvard Medical School and Boston Children's Hospital

8:30 Regulatory Challenges in Co-Development of CDX and Drugs: A Diagnostics Perspective

Tracy Bush, Ph.D., Director and Global Coordinator, Companion Diagnostics, Regulatory Affairs, Roche Diagnostics

Globally, Pharma and Diagnostics operate under different regulations, with different statutory requirements and timelines. Drug and diagnostic codevelopment timelines are not always optimally aligned to meet the needs of the various regulatory processes. This presentation will explore various regulatory

challenges that ensue when the standard diagnostics development pathway is asked to flex to meet the needs of a drug clinical program; and offer possible pathways for their resolution.

9:00 Global Clinical Trial Design Considerations When Incorporating a Companion Diagnostic

Sabah Malek, Associate Director, Global Regulatory Affairs, Eisai, Inc.

A well thought-out clinical trial, especially one that will be the basis for the approval of two products from different divisions within FDA not to mention different governing bodies in the EU, is imperative for a successful launch. Since the recognition of personalized medicine, FDA and other health authorities have been resolute regarding the ideal co-development plan for targeted therapeutics and companion diagnostics. However in practice, this proves to be difficult for numerous reasons. One example of this is the identification of the need for a companion diagnostic in a mature program.

9:30 NGS-Based Companion Diagnostics: Points to Consider

Jennifer Dickey, RAC, Ph.D., Office of In Vitro Diagnostics, DIHD, US Food and Drug Administration

While there has not yet been a companion diagnostic approval of a Next Gen Sequencing-based assay, there has been considerable interest in using gene panels or single gene sequencing to select the patient population that will benefit from targeted therapy. This talk will highlight points to consider in developing a NGS-based companion diagnostic.

10:00 Cellular Multiplex™, a Pathway Approach to Companion Diagnostics

Sponsored by

Bruce K. Patterson, M. D., CEO, Incell Dx, Inc

Cellular Multiplex™, a diagnostic approach that allows multiplexing of proteins using antibodies, mRNA using in situ hybridization, and DNA cell cycle using dyes. Morphologic measurements such as mean corpuscular volume, nuclear area, and nuclear-to-cytoplasmic ratio can be determined. It provides prognostic information, companion diagnostic functions when deployed in our novel bioinformatics algorithms.

10:30 Coffee Break in Exhibit Hall with Poster Viewing

PLENARY SESSION: Think Tank on Next-Generation Sequencing Diagnostics

11:00 Chairperson's Opening Remarks

11:10 Discussion: Regulatory Review of Clinical Sequencing Assays

Moderator: Harry Glorikian, Healthcare Consultant

Guest Speaker: Jennifer Dickey, RAC, Ph.D., Office of In Vitro Diagnostics, DIHD, US Food and Drug Administration

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11:55 Next-Generation Sequencing in Clinical Practice: Case Reports of Clinical Utility and Reimbursement

Co-Organized with

Moderator: Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP

Case Presenters:

Andrea Ferreira-Gonzalez, Ph.D., Professor, Pathology; Director, Molecular Diagnostics Lab, Virginia Commonwealth University

Madhuri Hegde, Ph.D., FACMG, Professor, Human Genetics; Executive Director, Emory Genetics Laboratory, Emory University School of Medicine

The landscape of next-generation sequencing diagnostics is changing rapidly. Clinical laboratories are offering highly complex tests using new technologies, but face challenges in reimbursement. To be reimbursed for these tests, laboratories will need to address clinical utility as well as clinical validity. Clinical cases that demonstrate the utility of genomic oncological and inherited disease testing will be presented. Experiences with reimbursement of these tests will be discussed.

12:40 pm Close of Conference

Recommended Pre-Conference Short Courses*

NGS Data Analysis – Determining Clinical Utility of Genome Variants

NGS as a Diagnostics Platform

**Separate registration required, please see page 3 for details*

TUESDAY, AUGUST 19

7:30 am Main Conference Registration & Morning Coffee

8:30 Chairperson's Opening Remarks

» 8:40 KEYNOTE PRESENTATION: WE HAVE THE TECHNOLOGY, NOW WHAT HAPPENS? POLICY, ETHICS, AND LAW MEET CLINICAL SEQUENCING

Robert Cook-Deegan, M.D., Research Professor, Institute for Genome Sciences & Policy, Sanford School of Public Policy, Duke University

Controversies have flared up through patent litigation; problems in constructing pipelines for interpreting the clinical significance of sequence variants; complications in developing databases constructed for clinical rather than scientific use; privacy, confidentiality, and informed consent; inconsistent policies about who controls and has access to raw data; weak norms over data access and research transparency; and strong disagreement over what and when to convey clinical interpretations of the data to patients and families. Policy needs to catch up. Can we glimpse the road ahead through the fog?

DIAGNOSING GENETIC DISORDERS WITH NGS

9:10 Use of Exome Sequencing for Genetic Diagnosis: Clinical Experience and Case Examples

Wayne W. Grody, M.D., Ph.D., Professor, Medical Genetics and Molecular Pathology, Pathology & Lab Medicine, Pediatrics, and Human Genetics; Director, Molecular Diagnostic Laboratories and Clinical Genomics Center, UCLA School of Medicine

The advent of massively parallel or next-generation DNA sequencing has finally brought into reach the long-anticipated "Thousand Dollar Genome", or the ability to sequence an individual's entire genome at reasonable cost. This presentation will review such aspects as clinical utility, challenges in test interpretation and genetic counseling, return of incidental findings and reimbursement, all within the context of our own experience performing clinical whole-exome sequencing at an academic medical center.

9:40 Disease Causing Potential of Variants in Untranslated Regions

Peter Nagy, Ph.D., Director, Clinical Next-Generation Sequencing Lab; Assistant Professor, Pathology and Cell Biology, Columbia University

Our laboratory offers whole-exome sequencing for clinical diagnosis of inherited disorders since the beginning of 2013. Using the Agilent SureSelect v.5 +UTRs kit allows us to capture the UTRs in addition to the coding regions. We currently do not report variants of unknown significance in the UTRs, but we are developing tools to predict the structural and functional consequences of the variants to assess their pathogenic role.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

ANNOTATION OF VARIANTS

10:55 Chairperson's Remarks

Peter Nagy, Ph.D., Columbia University

11:00 An Integrated Approach to Genome-Wide Variant Analysis in the Pediatric Population

Laura Conlin, Ph.D., FACMG, Scientific Director, Division of Genomic Diagnostics, Children's Hospital of Philadelphia; Assistant Professor, Pathology and Laboratory Medicine, Perelman School of Medicine at the University of Pennsylvania

With advances in technology, both copy number and point mutations can be detected from genome-wide testing. Taken together, a more comprehensive genetic diagnosis is provided for the patient. This talk will focus on the benefits and challenges related to integrative variant interpretation in the pediatric population.

11:30 Beyond Sanger Confirmation of Genomic Results: The Role of Expert Interpretation, Clinical Correlation, and Collaboration

Carol Saunders, Ph.D., FACMG, Director, Molecular Genetics Laboratory, Department of Pathology & Laboratory Medicine; Associate Professor, Department of Pathology, UMKC School of Medicine, Children's Mercy Hospital

I will discuss the strategies and assumptions used for interpreting genomic variants in pediatric patients, and how to determine what is diagnostic. Illustrative cases will be presented, including those where such assumptions would backfire.

12:00 pm ClinVar: An Archive of Clinically Relevant Variant-Phenotype Relationships

Melissa J. Landrum, Ph.D., Staff Scientist, NIH/NLM/NCBI

ClinVar is a freely available archive of reports of the relationship between clinically relevant variants and phenotypes, along with supporting evidence. ClinVar aggregates submissions genetic testing labs, research labs, LSDBs, and expert curation groups such that agreement or disagreement in clinical assertions is evident. The data is available on the web for interactive users and as downloadable files that can be incorporated into users' daily workflows.

1:00 Luncheon Presentations I *(Sponsorship Opportunity Available)*

1:30 Luncheon Presentation II *(Sponsorship Opportunity Available)*

2:00 Session Break

Organized by
Cambridge Healthtech Institute

INCIDENTAL FINDINGS AND PRE- AND POST-TEST COUNSELING

2:15 Chairperson's Remarks
Wayne W. Grody, M.D., Ph.D., UCLA School of Medicine

2:20 Incidental Findings in Genomic Testing
Lora J.H. Bean, Ph.D., F.A.C.M.G., Assistant Professor, Senior Director, Molecular Diagnostic Laboratory, Emory Genetics Laboratory, Human Genetics, Emory University
Clinical sequencing of single genes, gene panels, whole exomes or genomes, and gene-targeted and whole genome array CGH have become important tools in diagnosing genetic conditions in children. The huge amount of data generated by these tests may include unexpected or unwanted clinically relevant findings such as carrier status or diagnostic findings unrelated to the current clinical presentation. Incidental findings from testing performed at Emory Genetics Laboratory will be discussed.

2:50 Incidental Findings, Unwanted Information, and the "Safety" of Genomic Testing
Kimberly Strong, Ph.D., Assistant Professor and Primary Faculty, Program in Genomics and Ethics, Institute for Health and Society - Center for Bioethics and Medical Humanities & Human and Molecular Genetics Center, Medical College of Wisconsin
This presentation will examine the different frameworks potentially relevant to assessing the desirability of genomic information; that is, the ways in which different perspectives are likely to drive perceptions of risk and benefit. Based on several empirical studies, special attention will be devoted to how expressed attitudes appear to be influenced by health contexts, professional roles and person experience, as well as common themes less effected by contextual frameworks.

3:20 Sponsored Presentation *(Opportunity Available)*

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

INTERPRETATION OF RESULTS

4:30 Generating a Comprehensive Genomic Profile Using the High-Performance Integrated Virtual Environment (HIVE)
Raja Mazumder, Ph.D., Associate Professor, Biochemistry and Molecular Biology, George Washington University
The High-performance Integrated Virtual Environment (HIVE) platform provides a means to store, analyze, and compute extra-large NGS data. HIVE contains computational tools allowing for this type of variation analysis and therefore serves as a vital tool in attempts to bridge whole genome analysis to disease diagnostics. Comparative analysis of mutation profiles allows better classification, and further comparison across different groups and strata can be used to create phylogenetic trees of the data set samples.

5:00 Interpretation of Clinical Genetic Data in the NGS Era
Sami S. Amr, Ph.D., Instructor, Pathology, Harvard Medical School; Director, PCPGM Research Core; Assistant Director, Lab for Molecular Medicine, Partners Center for Personalized Genetic Medicine
The rapid transition of genetic testing from Sanger sequencing to NGS technologies has paved the way for expanded gene panels as well as exome/genome sequencing. While the influx of genetic data led to increased detection rates for inherited diseases, it has also become a double-edged sword due to interpretative challenges. Standardized variant and gene assessment approaches, coupled with data sharing across diagnostic laboratories, will alleviate the interpretation bottleneck and provide more meaningful genetic results to patients.

5:30 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by
SLONE PARTNERS

6:30 Close of Day

WEDNESDAY, AUGUST 20

7:15 am Registration

7:30 – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast

INTEGRATION CHALLENGES AND SOLUTIONS

8:25 Chairperson's Opening Remarks
Sami S. Amr, Ph.D., Harvard Medical School; Partners Center for Personalized Genetic Medicine

8:30 Integration of Genomics into Medical Practice: Educational Challenges
Bruce Korf, M.D., Ph.D., Wayne H. and Sara Crews Finley Chair, Medical Genetics; Professor and Chair, Genetics; Director, Heflin Center for Genomic Sciences, University of Alabama at Birmingham
Genomic approaches offer new possibilities to improve the approach to maintaining health as well as diagnosing and treating disease. Most practicing health providers were educated prior to the genomics era, however, and the pace of progress in genomics is very rapid. New paradigms are therefore needed to help providers gain competency in the use of genomics in their practice. This talk will discuss some of the educational challenges and possible approaches to improve health professional education in genomics.

9:00 The Implementation of Clinical Genome-Wide Sequencing into Practice: Where We Are Coming From and Where We Are Going
David P. Dimmock, M.D., Associate Professor, Pediatrics, Medical College of Wisconsin

9:30 CLOSING PANEL: Examining the Future of Genomic Medicine

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in Exhibit Hall with Poster Viewing

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10:10 Coffee Break in the Exhibit Hall with Poster Viewing

INTERROGATING CANCER GENES WITH NGS AND MICROARRAY

10:55 Chairperson's Remarks

Rajyalakshmi Luthra, Ph.D., The University of Texas MD Anderson Cancer Center

11:00 "Personalized" Breast Cancer Treatment

Peter J. Tonellato, Ph.D., Director, Laboratory for Personalized Medicine, Center for Biomedical Informatics, Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

Essential to a future of preventive and predictive medicine is the integration of whole genome technologies into clinical and health practice. We pursue the use of WGS in breast cancer care to create a post-genome paradigm shift in health, disease prevention, and personalized medicine. These and parallel efforts, though difficult, will catalyze the adoption and widespread implementation of the post-genome competency and thereby promote the era of personalized medicine.

11:30 Development and Implementation of Clinical NGS Testing: Assay Development and Informatic Challenges

Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories

Currently, the major bottleneck to unlocking the full potential of this technology remains creating bio-informatic workflows that accurately identify variants within the data. During development and clinical validation of two oncology sequencing panels we were confronted with the lack of a clinical grade solution for data analysis that was adequately tested to identify hard limits of detection.

12:00 pm Incorporating NGS Assays in a Routine Molecular Oncology Laboratory

Helen Fernandes, Ph.D., Pathology & Laboratory Medicine, Weill Cornell Medical College

The presentation will address the practical processes that need to be adopted for a NGS based assay to be run in a routine clinical laboratory. Validation and implementation of NGS assays for analysis of cancer-related variants will be discussed. The presentation will focus on the pros and cons of incorporating NGS assays in molecular diagnostics laboratories.

12:30 Biomarker Discovery Through Pathway Analysis- Bringing Together Multiple Data Types for a Better Picture

Sponsored by THOMSON REUTERS

Melinda Baker, Ph.D., Solution Scientist, IP & Science, Life Science, Thomson Reuters

'Next Gen Sequencing' (NGS) technologies produce massive amounts of data which can contain valuable information, connecting genetic variation with clinical phenotypes, and yet represent just one possible layer of biological perturbations. Here we will discuss newly released genomic analysis tools available within MetaCore™ that facilitate functional annotation of human variants and leverage pathway analysis to integrate NGS data with multiple other OMICs data types for biomarker discovery and validation.

1:00 Luncheon Presentation: Introduction to the Response Genetics Tissue of Origin Test

Sponsored by affymetrix

Debbie Corazzelli, Director, Product Marketing, Response Genetics

Response Genetics, a company focused on molecular diagnostic tests that help determine a patient's response to cancer therapy, recently introduced the FDA-cleared Response DX: Tissue of Origin Test. Looking at 2000 genes, it compares the tumor's gene expression patterns to those of 15 known tissues, with 89% sensitivity. It is the most accurate, most published, and best validated test of its kind. The objective test results can help guide physicians in managing cancer patients.

2:00 Session Break

NGS-BASED APPROACHES TO GUIDE TREATMENT

2:15 Chairperson's Remarks

Seth D. Crosby, M.D., Washington University School of Medicine

2:20 Clinical Next-Generation Sequencing of Hematological Malignancies

Jennifer Morrissette, Ph.D., Scientific Director, Clinical Cytogenetics Laboratory; Clinical Director, Center for Personalized Diagnostics (CPD), University of Pennsylvania Perelman School of Medicine

The use of multi-gene testing in hematologic malignancies using NGS reliably detects somatic mutations and provides insights into prognosis and therapeutic choice. We will describe our approach to AML mutation detection, including capture of difficult to sequence regions (e.g. CEBPA and large FLT3-ITDs), and mutation profiles with respect to conventional cytogenetic findings. Finally, the utility of in clinical prognostication and treatment decisions will be discussed.

2:50 Clinical Sequencing in the Pediatric Oncology Clinic: Challenges and Opportunities

Donald "Will" Parsons, M.D., Ph.D., Assistant Professor, Pediatrics, Molecular & Human Genetics, Baylor College of Medicine, Texas Children's Cancer Center

Current experience with the clinical application of genomic sequencing for childhood cancer patients is limited. This talk will report results of the ongoing BASIC3 study, which aims to determine the clinical impact of incorporating tumor and constitutional whole exome sequencing into the care of children with newly diagnosed solid tumors at Texas Children's Cancer Center, with a particular focus on the diagnostic yield and limitations of WES in this setting.

3:20 Sponsored Presentation *(Opportunity Available)*

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

INTERPRETATION OF RESULTS

4:25 Chairperson's Remarks

Wayne W. Grody, M.D., Ph.D., UCLA School of Medicine

4:30 Generating a Comprehensive Genomic Profile Using the High-Performance Integrated Virtual Environment (HIVE)

Raja Mazumder, Ph.D., Associate Professor, Biochemistry and Molecular Biology, The George Washington University

The High-performance Integrated Virtual Environment (HIVE) platform provides a means to store, analyze, and compute extra-large NGS data. HIVE contains computational tools allowing for this type of variation analysis and therefore serves as a vital tool in attempts to bridge whole genome analysis to disease diagnostics. Comparative analysis of mutation profiles allows better classification, and further comparison across different groups and strata can be used to create phylogenetic trees of the data set samples.

5:00 Interpretation of Clinical Genetic Data in the NGS Era

Sami S. Amr, Ph.D., Instructor, Pathology, Harvard Medical School; Director, PCPGM Research Core; Assistant Director, Lab for Molecular Medicine, Partners Center for Personalized Genetic Medicine

The rapid transition of genetic testing from Sanger sequencing to NGS technologies has paved the way for expanded gene panels as well as exome/genome sequencing. While the influx of genetic data led to increased detection rates for inherited diseases, it has also become a double-edged sword due to interpretative challenges. Standardized variant and gene assessment approaches, coupled with data sharing across diagnostic laboratories, will alleviate the interpretation bottleneck and provide more meaningful genetic results to patients.

5:30 Wine and Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by SLONEPARTNERS

6:30 Close of Day

WEDNESDAY, AUGUST 20

7:15 am Registration

7:30 – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast

MAKING DATA ACTIONABLE

8:25 Chairperson's Opening Remarks

Jennifer Morrissette, Ph.D., University of Pennsylvania Perelman School of Medicine

8:30 My Cancer Genome - Cancer Genomics Knowledge Resource

Christine Micheel, Ph.D., Research Assistant Professor, Medicine, Vanderbilt-Ingram Cancer Center; Managing Editor, MyCancerGenome.org

Evidence regarding the clinical significance of tumor gene mutations for predicting response to cancer treatments is evolving at a rate that outpaces traditional approaches to knowledge dissemination. My Cancer Genome addresses this challenge by providing up-to-date information on mutation-specific treatments and clinical trials. Current content covers 293 mutations across 18 cancer types.

Managing the New Treatment Paradigm from Phenotype to Genotype

9:00 Driving Personalized Medicine and Clinical Diagnostics Using Genome Sequencing, Exome Sequencing, and Integrative Genomics

Rong Chen, Ph.D., Assistant Professor, Genetics and Genomic Sciences; Director, Clinical Genome Informatics, Icahn Institute for Genomics and Multiscale Biology, Icahn School of Medicine at Mount Sinai

This presentation will discuss applying data from WES and WGS for diagnosis and decision making in the clinical lab. Integrating and targeting various molecular mesurements into biomarkers doe disease diagnostics will also be discussed. Finally, discovery of casual variants, pathway, and mechanisms to illlustrate human cancers will be explored.

9:30 Creating and Using Tumor Genome Profiles with Galaxy

Jeremy Goecks, Ph.D., Assistant Professor, Computational Biology, Department of Integrative Systems Biology and The Computational Biology Institute, George Washington University

We describe open, reproducible pipelines that create a genomic profile of a tumor and use the profile to identify mutations associated with disease and pertinent drugs. These pipelines analyze tumor exome and transcriptome sequence data together with public databases to find mutations and drugs. These pipelines are integrated into the Galaxy platform to make them accessible and reproducible, thereby providing an approach for doing standardized, distributed analyses in clinical studies.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in Exhibit Hall with Poster Viewing

PLENARY SESSION: Think Tank on Next-Generation Sequencing Diagnostics

11:00 Chairperson's Opening Remarks

11:10 Discussion: Regulatory Review of Clinical Sequencing Assays

Moderator: Harry Glorikian, Healthcare Consultant

Guest Speaker: Jennifer Dickey, RAC, Ph.D., Office of In Vitro Diagnostics, DIHD, US Food and Drug Administration

In November of 2013, the FDA issued the first clearances of Next Gen Sequencing-(NGS) based assays. There have additionally been a number of clinical trials approved recently that utilize NGS-based assays for patient enrollment or stratification. In light of the expanding roles that new sequencing technologies are playing in clinical decision making, this talk will focus on critical elements that FDA considers when evaluating NGS validation using the recent clearances/approvals as examples. There will also be a discussion of any new communications that FDA has issued in regard to the regulatory review of NGS- based assays. Following the discussion there will be a Q&A with the audience.

Co-Organized with AMP Association for Molecular Pathology

11:55 Next-Generation Sequencing in Clinical Practice: Case Reports of Clinical Utility and Reimbursement

Moderator: Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP

Case Presenters:

Andrea Ferreira-Gonzalez, Ph.D., Professor, Pathology; Director, Molecular Diagnostics Lab, Virginia Commonwealth University

Madhuri Hegde, Ph.D., FACMG, Professor, Human Genetics; Executive Director, Emory Genetics Laboratory, Emory University School of Medicine

The landscape of next-generation sequencing diagnostics is changing rapidly. Clinical laboratories are offering highly complex tests using new technologies, but face challenges in reimbursement. To be reimbursed for these tests, laboratories will need to address clinical utility as well as clinical validity. Clinical cases that demonstrate the utility of genomic oncological and inherited disease testing will be presented. Experiences with reimbursement of these tests will be discussed.

12:40 pm Close of Conference

WEDNESDAY, AUGUST 20

10:30 am Registration

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12:40 pm Enjoy Lunch on Your Own

OUTCOME STUDIES & CLINICALLY ACTIONABLE DIAGNOSTIC ASSAYS FOR PATHOGENS PART I

1:50 Chairperson's Opening Remarks

Nathan A. Ledeboer, Medical College of Wisconsin

2:00 Impact of Molecular Diagnostics on Infection-Related Patient Outcomes

Jerod Nagel, Pharm.D., BCPS (AQID), Clinical Specialist, Infectious Diseases, Clinical Assistant Instructor, Director Infectious Diseases Residency, University of Michigan Hospital and Health Systems, University of Michigan, College of Pharmacy

Demonstrating the impact on patient outcomes and overall hospital expenditure should be an important component in deciding the role of molecular diagnostics in clinical laboratories. This presentation aims to review the outcomes associated with new diagnostics and discuss strategies to optimize patient outcomes.

2:30 Unbiased Next-Generation Sequencing — Moving Towards Clinically Actionable Diagnostic Assays for Pathogens

Charles Chiu, M.D., Ph.D., Assistant Professor, Lab Medicine and Medicine, Infectious Diseases, University of California San Francisco

Unbiased next-generation sequencing technology enables the detection of novel or uncommon pathogens directly from clinical samples. Here we describe the use of the technology in the clinical laboratory to validate novel, ultra-sensitive assays that have the potential to transform infectious diseases diagnosis, including a case where NGS rapidly identified a rare pathogen.

GI PANELS: EMERGING TECHNOLOGIES AND EFFECTIVENESS IN PATIENT CARE AND OUTCOME

2:50 From Culture to the Future: Molecular Detection of Enteric Pathogens

Nathan A. Ledeboer, Ph.D., D(ABMM), Assistant Professor & Medical Director, Clinical Microbiology, Medical College of Wisconsin

The diagnosis of enteric pathogens is challenging given the large amount of vastly diverse indigenous gastrointestinal flora present in stool. Molecular methods, including real-time PCR, microarray, and liquid array assays, boast increased sensitivity and specificity when compared to stool culture.

3:10 The Use of Molecular Stool Panels in the Diagnosis of Infectious Gastroenteritis

Susan M. Novak-Weekley, Ph.D., D(ABMM), Director, Microbiology, Kaiser Permanente, SCPMG Regional Reference Laboratories

The landscape is changing in regards to bacterial, viral and parasitic stool pathogen diagnosis. This session discusses multiplex molecular panels coming out on the market and performance data related to those assays.

3:30 Dual Site Clinical Evaluation of the xTAG Gastrointestinal Pathogen Panel for Detection of Infectious Gastroenteritis

Sponsored by Luminex

Anami Patel, Ph.D, MB (ASCP) DLM, Technical Director, Molecular Diagnostics Laboratory, Le Bonheur Children's Hospital

We evaluated the clinical performance and laboratory cost and time efficiencies gained through use of the xTAG gastrointestinal pathogen *in vitro* diagnostic (IVD) assay in a comparison between clinical and public health laboratories. The site reproducibility study showed 98.7% agreement with high positive and negative agreement values (96.2% and 99.8%, respectively). High throughput detection of multiple GI pathogens improved turnaround time, consolidated laboratory workflow, and simplified stool culture practices, thus reducing the overall cost and number of specimens processed.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

USE OF NEXT-GEN SEQUENCING TECHNOLOGIES IN PATIENT CARE & OUTCOME WITH ID

4:45 From Genome to Biomarker: The Path Forward

David A. Rasko, Ph.D., Associate Professor, Microbiology & Immunology, University of Maryland School of Medicine Institute for Genome Sciences

Identification of stable genomically derived biomarkers will allow more robust identification of bacterial pathogens. Genomic sequencing is opening this avenue of biomarker development.

5:15 Next-Generation Sequencing for Pathogen Detection - HIVE Platform Solutions and Applications to Viral Detection and Other Bioinformatics Pipelines

Vahan Simonyan, Ph.D., HIVE Project Lead, CBER, FDA

HIVE, the High-performance Integrated Virtual Environment, is a cloud-based environment used for pathogen detection via: big data management; alignment of unknown or mixed samples to reference viral genome sets; computation and comparison of SNP profiles; discovery of recombination events implicated in virulence recovery and pathogenicity; facilitation of collaborative discovery.

5:45 Novel Methods for Sample Preparation & Target Enrichment in Molecular and Protein Diagnostics for Infectious Disease and Beyond - Lessons from Mass Spec and NGS

Michael Super, Ph.D., Senior Staff Scientist, Advanced Technology Team, Wyss Institute at Harvard

We have developed methods for sample extraction from complex biological environments using broad-spectrum pathogen binding proteins attached to nanomagnetic particles. These have been used to enrich samples for molecular and protein analysis without the need for culturing, thereby saving significant time and providing same-day pathogen identification. An overview of the challenges of sample prep in the current environment of NGS and genomic testing will also be discussed.

6:15 Close of Day

6:00 Dinner Short Course Registration

Recommended Dinner Short Course*

6:30-8:30 pm NGS for Infectious Disease Diagnostics

**Separate registration required, please see page 4 for details*

THURSDAY, AUGUST 21

7:30 – 8:25 am Problem-Solving Breakout Discussions with Continental Breakfast

SEPSIS AND BLOODBORNE INFECTIONS

8:25 Chairperson's Opening Remarks

Gregory Storch, M.D., Ruth L. Siteman Professor of Pediatrics, Director, Divisions of Pediatric Infectious Diseases and Pediatric Laboratory Medicine, Washington University School of Medicine; Medical Director of Clinical Laboratories, St. Louis Children's Hospital

8:30 Impact of Rapid Diagnostics on Management of Pneumonia and Sepsis

Thomas M. File, Jr. M.D., MSc, MACP, FIDSA, FCCP, Chair, Infectious Disease Division, Summa Health System; Professor, Internal Medicine; Master Teacher; Chair, Infectious Disease Section, Northeast Ohio Medical University (NEOMED)

Sepsis syndromes, including serious pneumonia, are associated with significant morbidity and mortality. Prompt and accurate detection and identification of causative pathogens are critical to providing early effective therapy. Rapid diagnostic tests, including molecular techniques, are changing microbiological diagnosis rapidly and will provide far more specific information more quickly which is vital to optimal clinical outcomes.

9:00 PANEL DISCUSSION: Sepsis and Bloodborne Infections

Moderator: Nathan A. Ledeboer, Ph.D., D(ABMM), Medical College of Wisconsin

Gregory Storch, M.D., Washington University School of Medicine & St. Louis Children's Hospital

Ephraim L. Tsalik, M.D., MHS, Ph.D., Duke University Medical Center

Antony Rapisarda, Director, Clinical Trials, Immunexpress Grp

9:30 A Novel Randomly Accessible 20-Minute Real-Time PCR Thermal Cycler Platform

Sponsored by Elbit Systems of America Medical - KMC Systems

Matthew Kreifels, Manager, Research and Development, Molecular Technology, Streck

True 20-minute, random accessible, 6-color multiplex qPCR with the Philisa instrument, developed in conjunction with KMC Systems, is accelerating workflow for molecular diagnostic analysis. Critical assays for infectious disease, HLA genotyping, antibiotic resistance detection, and forensics are benefiting from the design of the Philisa qPCR instrument.

9:45 HyBeacons – A Novel Approach for Real Time PCR Using Melt Curve Differentiation

Sponsored by evogen

Richard St.Clair, Vice President, Commercialization, Evogen Inc.

HyBeacons probes have been developed as a novel tool for rapid sequence detection and discrimination. They are ideally suited for a variety of real-time PCR applications because of the inherent sensitivity and specificity - inclusive of melt curve identification. Multiplex and SNP assays can be designed for identification of multiple targets for DNA and RNA targets.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

VIRAL INFECTIONS

10:45 Clinically Relevant Viral Diagnosis

Gregory Storch, M.D., Ruth L. Siteman Professor, Pediatrics, Director, Divisions of Pediatric Infectious Diseases and Lab Medicine, Washington University School of Medicine; Medical Director, Clinical Labs, St. Louis Children's Hospital

This talk includes discussion on respiratory and gastrointestinal multiplex PCR panels, potential applications of next-generation sequencing, and the possibility of including assessment of host response as an adjunct to pathogen-based diagnosis.

11:15 Host-Based Diagnostics for Detection and Diagnosis of Infectious Disease

Ephraim L. Tsalik, M.D., MHS, Ph.D., Assistant Professor, Medicine, Division of Infectious Diseases, Institute for Genome Sciences & Policy, Duke University Medical Center

We used the host-response to develop highly accurate assays for pathogen class detection, including gene-expression, proteomic, and metabolomic data derived from both challenge experiments and community-acquired disease.

Organized by
Cambridge Healthtech Institute

11:45 Determination of Viral Load: Higher Accuracy by Digital PCR?

Heinz Schimmel, Ph.D., Scientific Officer, Standards for Innovation and Sustainable Development (SID), European Commission - Joint Research Centre (JRC)

Molecular methods are being developed to determine the viral or bacterial load of human pathogens in clinically relevant samples. For RNA viruses, influenza has been chosen as a model for demonstration of innovative concepts in clinical routine and predominantly in quality control of *in vitro* diagnostic assays.

12:15 A Four-Gene Host Response Assay Discriminates Sepsis from Infection-Negative Systemic Inflammation

Sponsored by Immunexpress

Roslyn Brandon, Ph.D., CEO and Co-Founder, Immunexpress

The SeptiCyte® Lab test is a ~3 hour RT-qPCR assay in commercial development to aid diagnosis of infection in critical-care patients with systemic inflammation. In a prospective, multi-center study, the assay showed improved area under curve relative to Procalcitonin, was 95% sensitive for all sepsis patients, and 100% sensitive for blood culture-positive patients.

12:45 Luncheon Presentation I: Simoa HD-1: A Fully Automated, Multiplexed Immunoanalyzer with Single Molecule Sensitivity

Sponsored by Quanterix

Andreas Jeromin, Scientific and Medical Advisor, Quanterix Corporation

We will describe the Single Molecule Array (Simoa) technology and how it compares with current technologies. We will illustrate the power of this analytical sensitivity in diagnosing cancer, neurological diseases, and infectious diseases. We will describe a fully automated instrument for performing Simoa—the Simoa HD-1 Analyzer—that has been designed for use in clinical research and diagnosis.

1:15 Luncheon Presentation II: *(Sponsorship Opportunity Available)*

1:45 Session Break

OUTCOME STUDIES & CLINICALLY ACTIONABLE DIAGNOSTIC ASSAYS FOR PATHOGENS PART II

2:00 Chairperson's Remarks

Robin Patel, M.D.(CM), FRCP(C), D(ABMM), FIDSA, FACP, F(AAM), Mayo Clinic

2:05 Matrix-Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry in Patient Care

Robin Patel, M.D.(CM), FRCP(C), D(ABMM), FIDSA, FACP, F(AAM), Chair, Clinical Microbiology; Consultant, Clinical Microbiology and Infectious Diseases; Professor, Microbiology and Medicine, College of Medicine, Mayo Clinic

With the advent of MALDI-TOF-MS, rapid and accurate species-level identification is possible. This information can be used to inform patient management, differentiate pathogens from contaminants and inform selection of appropriate therapy.

2:30 "Salvage Microbiology"—Identifying Pathogens in Culture Negative Infections

Federico Perez, M.D., Assistant Professor, Medicine, Case Western Reserve University, Division of Infectious Diseases & HIV Medicine, Infectious Diseases, Louis Stokes Cleveland VA Medical Center

In many cases, bacterial cultures are unrevealing due to improper handling of samples, previous use of antibiotics, or low colony counts. We present a case series describing how PCR coupled with electrospray ionization mass spectrometry (PCR/ESI-MS) can be used to guide choices for therapy.

DEVELOPING NEW COMPANION TESTS TO RAPIDLY DIAGNOSE AND MANAGE PATIENTS

2:55 The Use of Molecular Diagnostics to Develop Novel Vaccines and Monoclonal Antibodies Against Respiratory Syncytial Virus (RSV), *Staphylococcus aureus* and *Pseudomonas aeruginosa*

Mark T. Esser, Ph.D., Director, Translational Medicine, Infectious Diseases and Vaccines, MedImmune

This presentation will discuss how MedImmune is using diagnostics and biomarkers in clinical trials to develop novel vaccines and monoclonal antibodies for the prevention or treatment of influenza, respiratory syncytial virus, *Pseudomonas aeruginosa* or *Staphylococcus aureus* infections.

3:25 Next Generation Non-Invasive Molecular Diagnostics for Emerging and Re-Emerging Human Viral Diseases: An Interdisciplinary Approach at the Interface of Molecular Virology and Clinical Proteomics

François Jean, Ph.D., Scientific Director, UBC Facility for Infectious Disease and Epidemic, Research (FINDER); Associate Professor, Microbiology and Immunology, Laboratory for Antimicrobial Therapy, University of British Columbia

Dr. Jean's presentation focuses on the immense potential of multiple reaction monitoring mass spectrometry (MRM-MS) in clinical proteomics. Dr. Jean will discuss the development and potential downstream applications of his novel MRM-MS assays for early diagnosis of viral infectious diseases of great concern around the world. The novel multiplex technology is based on a breakthrough discovery by Dr. Jean submitted to UBC's University-Industry Liaison Office.

3:45 Enabling Point of Care Test Development for the STD Market

Joany Jackman, PhD, Investigator, Center for Point of Care Tests for STD, Johns Hopkins University School of Medicine

The mission of the Johns Hopkins University Center for Point of Care Tests for Sexually Transmitted Diseases (JHUC) is to provide expertise, guidance and samples to enable the development of the best available test platforms for diagnosis of sexually transmitted infections (STIs). To that end JHUC has conducted focus groups, facilitated meetings and other studies to determine the most important attributes of a successful test for STIs in a variety of point of care settings. These data and their relevance to the global market for POCT for STIs will be presented.

4:15 Close of Conference

Recommended Pre-Conference Short Courses*

Next-Generation Sequencing as a Diagnostics Platform

Clinical Trials to Establish Value of Diagnostic Tests: Design and Management

**Separate registration required, please see page 3 for details*

WEDNESDAY, AUGUST 20

10:30 am Registration

PLENARY SESSION: Think Tank on Next-Generation Sequencing Diagnostics

11:00 Chairperson's Opening Remarks

11:10 Discussion: Regulatory Review of Clinical Sequencing Assays

Moderator: Harry Glorikian, Healthcare Consultant

Guest Speaker: Jennifer Dickey, RAC, Ph.D., Office of In Vitro Diagnostics, DIHD, US Food and Drug Administration

In November of 2013, the FDA issued the first clearances of Next Gen Sequencing-(NGS) based assays. There have additionally been a number of clinical trials approved recently that utilize NGS-based assays for patient enrollment or stratification. In light of the expanding roles that new sequencing technologies are playing in clinical decision making, this talk will focus on critical elements that FDA considers when evaluating NGS validation using the recent clearances/approvals as examples. There will also be a discussion of any new communications that FDA has issued in regard to the regulatory review of NGS- based assays. Following the discussion there will be a Q&A with the audience.

Co-Organized with AMP Association for Molecular Pathology

11:55 Next-Generation Sequencing in Clinical Practice: Case Reports of Clinical Utility and Reimbursement

Moderator: Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP

Case Presenters:

Andrea Ferreira-Gonzalez, Ph.D., Professor, Pathology; Director, Molecular Diagnostics Lab, Virginia Commonwealth University

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12:40 pm Enjoy Lunch on Your Own

NGS-BASED COMPANION TESTS: THE FUTURE IS NOW

1:50 Chairperson's Opening Remarks

Kenneth Emancipator, M.D., Merck Research Laboratories

2:00 Development and Clinical Impact of a Comprehensive NGS-Based Cancer Genomic Profiling Test

Roman Yelensky, Ph.D., Senior Director, Biomarker and Companion Diagnostic Development, Foundation Medicine, Inc.

In recent years the field of oncology has experienced a paradigm shift toward thinking about cancer as a disease of the genome. Our understanding of cancer biology has been furthered through the use of next-generation sequencing (NGS) to more comprehensively characterize the genomic alterations in an individual patient's cancer. Foundation Medicine has overcome key scientific and clinical challenges to develop a comprehensive profiling approach that, when used in a clinical trial setting, can help to decrease costs and overall time to market for targeted therapies, and when used in the clinic, can help to more appropriately identify candidates for therapy. Utilizing this approach enables more rapid trial accrual to ongoing and planned trials of agents targeting pathways under study and help us to better understand the characteristics of responders and non-responders to therapy, accelerating the field toward precision medicine.

2:30 Personalized Genomic Analyses of Human Cancer

Victor E. Velculescu, M.D., Ph.D., Professor, Oncology; Co-Director, Cancer Biology, Johns Hopkins Kimmel Cancer Center

Analyses of cancer genomes have revealed mechanisms underlying tumorigenesis and new avenues for therapeutic intervention. We now face challenges in translating these analyses to the clinic as well as opportunities with development of new technologies to analyze molecular alterations in the circulation of cancer patients as cell-free tumor DNA. These approaches have important implications for therapeutic stratification, identification of mechanisms of resistance to targeted therapies, and non-invasive detection and monitoring of human cancer.

3:00 What Does the History of *in vitro* Diagnostics Tell Us About the Future of Personalized Medicine?

Kenneth Emancipator, M.D., Director, Companion Diagnostics, Merck Research Laboratories

The promise of personalized medicine is finally becoming a reality, as more drugs are regularly approved with companion diagnostics. However, as personalized medicine continues to progress, the current one-drug, one-test paradigm will become increasingly impractical. While next-generation sequencing (NGS) is certainly part of the solution, it is not a panacea. A look at how generally diagnostic testing evolved provides clues to the future of companion diagnostics and personalized medicine.

Organized by
Cambridge Healthtech Institute

3:30 From Anatomical to Molecular: Technological Approaches for CDx Research and Development

Sponsored by Dako, An Agilent Technologies Comp

Sheila Purim, Ph.D., Director, Strategic Marketing, Diagnostics and Genome, Agilent Technologies

During this talk we will cover some past, current and emerging technologies being explored for research and development of Companion Diagnostic tools. We will highlight the advantages and pitfalls of such technologies and discuss the advantages of combining anatomical and molecular profiles for the analysis of tumor samples. Some research technologies that will be covered include: IHC, Next Generation Sequencing, Microarrays and FISH.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Use of POC in Oncology Outpatient Practices

Richard A. White, Ph.D., Director, Global Strategy, Breast and Colon Products, Genomic Health, Inc.

With the increased cost of treatment of patients in inpatient settings, economic pressure mounts to reduce overall cost of hospitalization for both acute and chronic treatment. Advances in treatment and diagnostic options have uncovered an opportunity for near-patient testing platforms to serve diagnostic and monitoring purposes.

5:15 NGS: The Case for Quality

Melina Cimler, Ph.D., Vice President, Head, Global Quality, Illumina, Inc.

Through the Case for Quality, the FDA is working with stakeholders to foster medical device quality. Focus is shifting to critical-to-quality (CTQ) practices that, when present in day-to-day device design and production, correlate to higher-quality outcomes. With the rapid evolution of NGS technologies, the implementation of CTQ's is challenging. What are the elements to successful quality practices.

5:45 Genome in a Bottle: A Benchmark to Understand Genome Sequencing Accuracy for Companion Diagnostics

Justin Zook, Ph.D., Biomedical Engineer, National Institute of Standards and Technology

Marc Salit, Ph.D., Genome-Scale Measurements Group Leader, National Institute of Standards and Technology

To help clinical and research labs understand the trustworthiness of variant calls from Next-Generation Sequencing, the Genome in a Bottle Consortium (www.genomeinabottle.org) is developing well-characterized whole human genomes. We will describe how labs are using our high-confidence SNP, indel, and homozygous reference genotypes for our pilot NIST human genome Reference Material, and our plans for future Reference Materials.

6:15 Close of Day

6:00 Dinner Short Course Registration

Recommended Dinner Short Course*

6:30-8:30 pm Regulatory and Reimbursement Issues with NGS and Multiplex Assays

**Separate registration required, please see page 4 for details*

THURSDAY, AUGUST 21

7:30 am – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast

SEQUENCING-DRIVEN CLINICAL DEVELOPMENT

8:25 Chairperson's Opening Remarks

Michael T. Barrett, Ph.D., Associate Professor, TGen

8:30 Preparing a Multi-Analyte NGS Assay for Use in Clinical Studies for Cancer

P Mickey Williams, Ph.D., Director, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Fredrick National Laboratory for Cancer Research

NGS offers a powerful tool for assessment of molecular defects found in cancer. The utilization of NGS is becoming common practice in clinical laboratories. This complex technology requires a new level of analytical performance testing and validation. This discussion will focus on approaches used for analytical validation of the NGS clinical assay used for treatment selection in the NCI-MPACT Study.

9:00 Considerations in the Implementation of Clinical Trials with an Integral Next-Generation Sequencing Assay

Barbara Conley, M.D., Associate Director, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute

Improved technological feasibility, the availability of targeted pharmaceutical agents and the need for new therapies spur interest in NGS to identify patients that can benefit from particular treatments. Clinical trials attempt to gain such evidence, using one or any of these assays. Considerations for different types of trials, and current and planned NCI Clinical Trials using NGS will be presented.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Clonal Analyses and Clinical Phenotypes

Michael T. Barrett, Ph.D., Associate Professor, TGen

Next-generation sequencing has broadly surveyed the genomes of many tumor types. However, heterogeneous genomic landscapes make it difficult to identify clinical drivers of disease. Furthermore analyses of serially sampled tumors have identified lineages with different mutation patterns arising throughout different stages of disease. This presentation will describe methods to address this complexity of clinical samples and to interrogate the genomes of clonal populations arising in solid tumors.

From Technology to Implementation

11:15 Case Studies in Cancer Genomics: Big Data + Analytics = Better Outcomes

Mr. Richard Kellner, CEO, Genome Health Solutions Inc

Advanced methods of genome analysis for precision diagnostics hold great promise for improving the outcomes of patients with cancer and other diseases. However there is a huge education gap among healthcare professionals in regional and community settings where 80% of cancer care is delivered. Traditional routes for the diffusion of knowledge and innovation are proving to be inadequate to meet these needs. Furthermore the value propositions supporting the adoption of these technologies are very unclear among healthcare executives and payers. Biomedical information solutions can go a long way toward meeting these challenges but only if properly design and deployed for the audiences that most need them.

11:45 Data Integration for Biomarker Driven Clinical Trials and Personalized Medicine

Jomol Mathew, Ph.D., Director, Clinical and Translational Informatics, IS, Dana-Farber Cancer Institute

Patient's genetic/genomic profile is becoming increasingly important for disease diagnosis and subtyping, identifying drug targets, drug therapy, dose selection, and risk assessment for adverse drug reaction. Integrating genotypic and phenotypic information and presenting results to providers in an easily interpretable ways is critical for identification of potential candidate patients for clinical trials. We present a strategy, process, systems and tools that we have developed at Dana-Farber Cancer Institute in integrating genome-phenome information for developing clinical trials and personalized medicine.

12:15 pm Redefining Reference Standards for Next Generation Sequencing

Sponsored by horizon diagnostics

Jonathan Frampton, Ph.D., Global Product Manager, Horizon Diagnostics

In response to the growing number of scientists using NGS instruments to study tumor genetics, Horizon Diagnostics has developed a range of oncology specific Quantitative Multiplex Reference Standards. These reference standards have been used to analyze the specificity and sensitivity of the pre-defined cancer panels Ampliseq™ andTruseq™ using the MiSeq™ and Ion Torrent™ platforms respectively.

12:30 Sponosred Presentation *(Opportunity Available)*

12:45 Luncheon Presentations
(Sponsorship Opportunities Available) **or Enjoy Lunch on Your Own**

1:45 Session Break

FORUM TO FORMULATE PROPOSALS AND SOLUTIONS TO THE CURRENT REIMBURSEMENT CRISIS

(Shared session with Commercialization of Molecular Diagnostics)

2:00 Chairperson's Remarks

Jorge A. Leon, Ph.D., Leomics Associates, Inc.

2:05 Approaches to Partnerships between Payers and Molecular Diagnostic Companies

Robert M. Honigberg, M.D., Senior Director, Medical Affairs, CardioDx, Inc.

Creating real-world evidence to support coverage of your test by payers can be a challenging process. While few provide a blueprint for success, some payers are open to collaborations designed to demonstrate the value of the test. This session will provide a step-by-step guide on how to design, pitch and execute the types of studies payers want to see when establishing coverage policies.

2:35 Real Cases and Solutions for the Reimbursement Crisis

Jorge A. Leon, Ph.D., President & CEO, Leomics Associates, Inc.

3:05 PANEL DISCUSSION

Panelists:

Sean R. Tunis, M.D., MSc, President & CEO, Center for Medical Technology Policy
Mike Barlow, Vice President, Palmetto GBA
Robert M. Honigberg, M.D., Senior Director, Medical Affairs, CardioDx, Inc.

4:05 Close of Conference

Ensuring Success of Innovative Tests

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Cambridge Healthtech Institute

Recommended Pre-Conference Short Courses*

Regulatory Compliance in Drug Diagnostics Co-Development

Clinical Trials to Establish Value of Diagnostic Tests: Design and Management

**Separate registration required, please see page 3 for details*

WEDNESDAY, AUGUST 20

10:30 am Registration

PLENARY SESSION: Think Tank on Next-Generation Sequencing Diagnostics

11:00 Chairperson's Opening Remarks

11:10 Discussion: Regulatory Review of Clinical Sequencing Assays

Moderator: Harry Glorikian, Healthcare Consultant

Guest Speaker: Jennifer Dickey, RAC, Ph.D., Office of In Vitro Diagnostics, DIHD, US Food and Drug Administration

In November of 2013, the FDA issued the first clearances of Next Gen Sequencing-(NGS) based assays. There have additionally been a number of clinical trials approved recently that utilize NGS-based assays for patient enrollment or stratification. In light of the expanding roles that new sequencing technologies are playing in clinical decision making, this talk will focus on critical elements that FDA considers when evaluating NGS validation using the recent clearances/approvals as examples. There will also be a discussion of any new communications that FDA has issued in regard to the regulatory review of NGS- based assays. Following the discussion there will be a Q&A with the audience.

Co-Organized with AMP Association for Molecular Pathology

11:55 Next-Generation Sequencing in Clinical Practice: Case Reports of Clinical Utility and Reimbursement

Moderator: Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP

Case Presenters:

Andrea Ferreira-Gonzalez, Ph.D., Professor, Pathology; Director, Molecular Diagnostics Lab, Virginia Commonwealth University

Madhuri Hegde, Ph.D., FACMG, Professor, Human Genetics; Executive Director, Emory Genetics Laboratory, Emory University School of Medicine

The landscape of next-generation sequencing diagnostics is changing rapidly. Clinical laboratories are offering highly complex tests using new technologies, but face challenges in reimbursement. To be reimbursed for these tests, laboratories will need to address clinical utility as well as clinical validity. Clinical cases that demonstrate the utility of genomic oncological and inherited disease testing will be presented. Experiences with reimbursement of these tests will be discussed.

12:40 pm Enjoy Lunch on Your Own

EXPERT PANEL: GLOBAL ACCESS TO PRECISION MEDICINE

1:50 *Moderator: Kristin Ciriello Pothier, Partner/Principal, Ernst and Young*

This panel will discuss the challenges of reactive partnering in precision medicine and discuss, with industry leaders who have been both proactive and reactive in this industry, how stakeholders can access the help they need to develop precision medicine programs with the right partners in the right locations at the right time.

Panelists:

Eric Lai, Ph.D., Senior Vice President & Head, Pharmacogenomics, Takeda Pharmaceuticals

Glenn A. Miller, Ph.D., CTO & Executive Vice President, Molecular MD

BEST PRACTICES IN COMMERCIALIZATION

3:20 Chairperson's Opening Remarks

Ali Tinazli, Vice President & Head, Business Development & Sales, Sony DADC BioSciences, Sony DADC

Sponsored by XIFIN

3:30 Understanding the Current Reimbursement Environment and the Impact to Your Bottom Line

Rina Wolf, Vice President, Commercialization Strategies, Consulting and Industry Affairs, XIFIN, Inc.

The reimbursement environment is continually changing, often presenting new challenges and hurdles on a frequent basis. This presentation will review the most recent changes from both CMS and the commercial payor perspective. Labs must maintain their awareness of these changes and updates in order to best manage their current reimbursement practices and plan for success in the future.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 PANEL DISCUSSION: What's Ahead? How to Protect Yourself from Commercialization Practices that Put You in Jeopardy of an Audit

Moderator: Rina Wolf, XIFIN, Inc.

With new codes and reimbursement rates in effect, molecular labs are facing an unprecedented convergence of disruptive and potentially game-changing factors. In the current audit heavy environment, laboratories must be certain that their business practices align with relevant laws and guidelines. With these changes, you need to ensure you minimize the risk of having your company audited for non-compliance.

Panelists:

David W. Gee, Partner, Davis Wright Tremaine LLP

Patric Hooper, Founding Partner, Hooper, Lundy & Bookman, PC

6:15 Close of Day

6:00 Dinner Short Course Registration

Recommended Dinner Short Course*

6:30-8:30 pm Regulatory and Reimbursement Issues with Next-Generation Sequencing and Multiplex Assays

**Separate registration required, please see page 3-4 for details*

Organized by
Cambridge Healthtech Institute

THURSDAY, AUGUST 21

7:30 am – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast

REGULATION OF LDTs

8:25 Chairperson's Opening Remarks
Andrew C. Fish, Executive Director, AdvaMedDx

8:30 Validation and Regulation of Laboratory-Developed Procedures (LDP) in the Current Environment
Andrea Ferreira-Gonzalez, Ph.D., Professor, Pathology; Director, Molecular Diagnostics Lab, Virginia Commonwealth University
Development and implementation of LDPs in the clinical laboratory setting requires the adoption of many processes and procedures, such as analytic and clinical validation of the test, standards for reference materials, proficiency testing, reimbursement and informed consent. The success of implementation of LDPs as a viable diagnostic modality depends on many branches of the health care community working together. This session will be informative for laboratorians who are considering launching LDPs as clinical tests.

9:00 The IVD Industry, FDA, and Clinical Labs – the LDT Battle Rages On
Mark Del Vecchio, Senior Director, Regulatory Affairs, Molecular Diagnostics, Women's Health and Cancer Corporate, BD Diagnostics
Regulatory discussions and actions involving Laboratory Developed Tests (LDTs) have had a complicated and passionate history over the last two decades. This presentation will explore several aspects of this on-going interaction between the IVD Industry, FDA, and clinical laboratories, including their past and current positions, the actions each have taken while attempting to reach common solutions, the key role parity plays in the debate, the many challenges faced, and the impact to both the players and patients.

9:30 Cross-Industry Partnerships to Foster Innovation and Decrease Manufacturing Time to Market in the Biomedical Continuum *Sponsored by* Sony DADC
Ali Tinazli, Vice President & Head, Business Development & Sales, Sony DADC BioSciences, Sony DADC
Smart Consumables based on polymer materials with microscale or supreme optical features are prerequisites for emerging applications in the biomedical markets as in in-vitro diagnostics. The increasing complexity of such new products requires new manufacturing technologies. Sony DADC BioSciences offers development, manufacture and supply of polymer-based smart consumables to OEM partners. Specializing in customized mass manufacturing of highly sophisticated consumables, Sony DADC actively applies expertise in innovation to offer state-of-the-art solutions to the biomedical industry.

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

PANEL DISCUSSION: IMPLEMENTATION OF MOLECULAR TESTING: Demonstrating Clinical Utility and Measuring Health Outcomes

10:45 *Moderator: Julie Lynch, Ph.D., MBA, RN, Veterans Health Administration*
This panel will address the questions of third party payers and their requirements for clinical utility as well as review the source of the funding. From there, the discussion will cover how the higher level of evidence will impact the implementation, equity and access.
Donna Polizio, Associate Director, Government Accounts, Genomic Health
Vickie L. Venne, MS, LGC, Senior Genetic Counselor, Genomic Medicine Service, Department of Veterans Affairs, VA Salt Lake City Health Care System
John W. Hanna, Senior Director, Policy & Reimbursement, Veracyte
Michael J. Kelley, M.D., Professor, Medicine, Duke Medical Oncology, Duke University

12:15 pm Breaking the fg/ml Barrier with Ultrasensitive Immunoassays *Sponsored by* MSD
Pankaj Oberoi, Ph.D., Vice President, Commercial Assay, Meso Scale Discovery
MSD's MULTI-ARRAY® electrochemiluminescence technology is used extensively to measure low levels of proteins in biological and clinical samples. We developed a next-generation assay format that is 100 to 1000 times more sensitive than the current limits of ELISA technology. We will present the ability to measure sub-fg/ml levels of cytokines and other biomarkers on established MSD® instrumentation. These new assays allow quantitation of previously unmeasurable baseline samples and have the capability of being multiplexed, allowing for the preservation of precious samples. These assays allow for the measurement of previously undetected biomarkers and could lead to the development of the next set of high sensitivity companion diagnostics and clinical assays.

12:45 Luncheon Presentation: A Novel Approach to Commercializing MDX Tests: Partnering With an Expert in Product Commercialization *Sponsored by* INTERPACE DIAGNOSTICS
Greg Richard, Senior Vice President & General Manager, Interpace Diagnostics, PDI, Inc.
For many years, pharmaceutical companies have engaged outsourced product commercialization teams to assist them in supporting and launching their products. One of the leaders in this industry, PDI, Inc., has formed a subsidiary, Interpace Diagnostics, to focus specifically on assisting molecular diagnostics companies commercialize their products as well. Interpace's services include field sales management, reimbursement support, marketing, and comprehensive financial partnerships. Find out how this new approach to commercializing molecular diagnostics could possibly help you.

1:15 Session Break

Ensuring Success of Innovative Tests

FORUM TO FORMULATE PROPOSALS AND SOLUTIONS TO THE CURRENT REIMBURSEMENT CRISIS

(Shared session with Companion Diagnostics: Technology & Reimbursement)

2:00 Chairperson's Remarks

Jorge A. Leon, Ph.D., Leomics Associates, Inc.

2:05 A Do-It-Yourself Guide to Partnerships between Payers and Molecular Diagnostic Companies

Lon Castle, M.D., Medical Science Liaison, Medical Affairs, CardioDx

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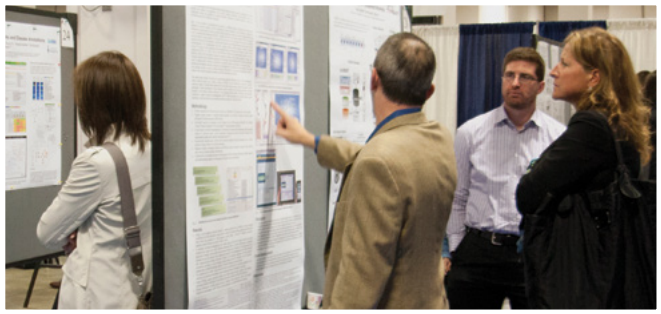

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- Your research will be seen by leaders from top diagnostic technology developers and academic and government institutes
- Your poster abstract will be published in the conference materials
- Receive $50 off your registration fee

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Cambridge Healthtech Institute

Recommended Pre-Conference Short Courses*

Overcoming Challenges of Working with FFPE Samples

Sample Prep Methods for Liquid Biopsy

**Separate registration required, please see page 3-4 for details*

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KEYNOTE SESSION: SEQUENCING AT THE LIMITS OF DETECTION

1:50 Chairperson's Opening Remarks

James Hicks, Ph.D., Cold Spring Harbor Laboratory

» 2:00 LIFE AT THE SINGLE-MOLECULE LEVEL: SINGLE-CELL GENOMICS

Sunney Xie, Ph.D., Mallinckrodt Professor, Chemistry and Chemical Biology, Harvard University

Point mutation and copy number variation in DNA can now be studied at the single-cell level by whole-genome amplification and sequencing. We will describe experiments probing the biology of meiosis and cancer, demonstrate proof of principle of selecting oocytes in *in vitro* fertilization to avoid miscarriage and genetic diseases and show individual CTCs can be sequenced, providing tumor genetic signatures for personalized therapy.

» 2:45 ULTRASENSITIVE DETECTION OF CIRCULATING TUMOR DNA BY DEEP SEQUENCING

Maximilian Diehn, M.D., Ph.D., Assistant Professor, Radiation Oncology, Stanford Cancer Institute, Institute for Stem Cell Biology & Regenerative Medicine, Stanford University

Circulating tumor DNA (ctDNA) represents a promising biomarker for sensitive, specific, and dynamic detection of disease burden in cancer patients. Additionally, ctDNA analysis allows non-invasive access to cancer genomes and therefore can be used for non-invasive tumor genotyping and monitoring of resistance mutations. This presentation will describe the development of a novel next-generation sequencing-based approach for detection of ctDNA and its potential clinical applications.

INTRODUCTION TO CFDNA AND BIOLOGY

3:30 Chairperson's Remarks: Introduction and Overview

Luis A. Diaz, M.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Detection of Circulating Tumor DNA in Early and Late-Stage Human Malignancies

Chetan Bettegowda, M.D., Ph.D., Assistant Professor, Neurological Surgery, Johns Hopkins University School of Medicine

The development of non-invasive methods to detect and monitor tumors continues to be a major challenge in oncology. We used digital PCR-based technologies to evaluate the ability of circulating tumor DNA (ctDNA) to detect tumors in 640 patients with various cancer types. This presentation will review the results of the study.

5:15 Circulating Tumor DNA Use for Noninvasive Analysis Of Cancer Drug Resistance Mechanisms

Muhammed Murtaza, MBBS, Research Assistant Professor and Co-Leader, Program in Circulating Nucleic Acids, TGen, Translational Genomics Research Institute

Cancers acquire resistance to systemic treatments through molecular evolution. This necessitates analysis of relapsed tumors to understand mechanisms of acquired resistance and to choose subsequent treatments. However, repeated biopsies are costly, invasive and confounded by spatial heterogeneity. Circulating tumor-specific DNA allows analysis of the cancer genome non-invasively. I will share proof-of-principle examples where analysis of serial plasma samples was used to assess mechanisms of drug resistance advanced solid cancer patients.

5:45 Rapid Isolation and Detection of Cancer Related Circulating Cell-Free DNA and RNA from Patient Blood and Plasma Samples

Michael J. Heller, Ph.D., Professor, Nanoengineering & Bioengineering, University of California San Diego

Circulating cell-free (ccf) DNA and ccf-RNA continue to become more widely used for cancer detection, and may ultimately allow "liquid biopsy" based diagnostics. This talk will review how we demonstrated a dielectrophoretic- (DEP) based approach that allows ccf-DNA/RNA to be isolated in 10-15 minutes directly from a small volume (25ul-50ul) of blood or plasma.

6:15 Close of Day

THURSDAY, AUGUST 21

7:30 am – 8:25 Problem-Solving Breakout Discussions with Continental Breakfast

EMERGING TECHNOLOGIES TO ADVANCE THE FIELD

8:25 Chairperson's Opening Remarks

Dave S. B. Hoon, MSc, Ph.D., John Wayne Cancer Institute

8:30 Prognostic Clinical Utility of Methylated CFDNA of Coding and Non-Genomic Sequences in Solid Tumor Patients

Dave S. B. Hoon, MSc, Ph.D., CSI & Director, Molecular Oncology; Director, JWCI Sequencing Center, John Wayne Cancer Institute

The majority of the clinical translational studies on CFDNA have been focused on genomic aberration detected in cancer patients. Assessment of methylated CFDNA also can be detected in plasma/serum and used to monitor cancer patients. Assessment of both non-coding and coding genomic sequences CFDNA offers new informative approaches in monitoring a patient's tumor progression and responses to treatment.

9:00 Detection and Genotyping of Structural Alterations in the Circulation of Cancer Patients

Mark Sausen, Ph.D., Director, R&D, Personal Genome Diagnostics

To identify incipient, residual, and recurrent tumors, we developed a non-invasive approach for the identification of structural alterations in cancer patients. Subsets of these rearrangements were associated with amplification of MET, ERBB2, and CDK6. Given that chromosomal abnormalities are present in nearly all tumors, this approach represents a method for the non-invasive detection and genotyping of cancer where tissue biopsies are unavailable.

Sponsored by TROVAGENE

9:30 Targeted Detection and Monitoring of Cell-Free Tumor DNA in Urine

Jason C Poole, Ph.D., Director, R&D, Trovagene, Inc.

An optimized isolation technique for cell-free DNA makes it possible to detect systemically derived cfDNA in urine. Using a small footprint capture and enrichment technique, we demonstrate the analytical detection and quantification of these tumor fragments down to a sensitivity of less than 0.01%, creating a truly non-invasive cancer mutation detection platform.

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

APPLICATIONS IN FETAL MATERNAL MEDICINE

10:40 Chairperson's Remarks

10:45 Noninvasive Prenatal Testing for Fetal Aneuploidies Using ccffDNA in Maternal Plasma: An Overview

Brigitte Faas, Ph.D., Clinical Laboratory Geneticist, Human Genetics, Radboud University Nijmegen Medical Center

Offering NIPT to pregnant women with an increased risk for fetal aneuploidies is supported by statements of different societies and NIPT is offered almost worldwide now and its accuracy has been reported in many publications. In this presentation, an overview of the currently offered tests and the pitfalls of NIPT will be given.

11:15 Non-Invasive Prenatal Diagnosis for Single Gene Disorders – Experience of Running a Clinical Diagnostic Service

Nicholas J. Lench, Ph.D., FRCPath, Director, NE Thames Regional Genetics Service, Great Ormond Street Hospital for Children NHS Foundation Trust

11:45 Targeted Sequencing Approaches for Cell-Free DNA

Matthew Snyder, Graduate Student, Genomic Sciences, University of Washington

Methods for target enrichment in cell-free DNA are challenged by low sample yields and short fragment length. We discuss approaches for sequencing-based target enrichment with applications to prenatal samples.

Enabling Non-Invasive Diagnostics

12:15 A Novel Approach for Multiplex Ultrasensitive Detection of Somatic Mutations in Circulating Cell-Free Tumor DNA

Sponsored by Agena Bioscience

Anders Nygren, Ph.D., Director, Research & Development, Agena Bioscience, Inc.

Driver mutations and therapeutic escape variants could provide invaluable treatment optionsif they could be detected early in circulating cell-free DNA. A multimarker detection method capable of detecting these rare variants enables identification for initiation and proliferation in primary tumorsand as a noninvasive method for early detection of metastasis. This seminar will detail MALDI-TOF mass spectrometry using an UltraSEEK™Oncogene Panel and its ability to detect low level mutations in clinical specimens.

12:45 Luncheon Presentation I: 'Perfect Pairing': ICE COLD-PCR with cfDNA for Highly Sensitive Mutation Detection

Sponsored by Transgenomic® Advancing Personalized Medicine

Katherine Richardson, Vice President, R&D, Transgenomic

ICE COLD-PCR with Sanger sequencing is a cost-effective assay showing greater than 400-fold enrichment for mutation detection interrogating cfDNA for small numbers of mutations. For analysis of larger numbers of mutations, ICE COLD-PCR can be multiplexed prior to mutation characterization on next-generation platforms. With the potential to monitor greater than 600 mutations from the same sample of cfDNA, this provides greater sensitivity making "liquid biopsy" the methodology for cancer patient care decisions, monitoring and surveillance.

1:15 Luncheon Presentation II: *(Sponsorship Opportunity Available)*

1:45 Session Break

ONCOLOGY APPLICATIONS

2:00 Chairperson's Remarks

Alain R. Thierry, Ph.D., INSERM

2:05 Multi-Marker Analysis of Circulating Cell-Free DNA toward Personalized Medicine for Colorectal Cancer

Alain R. Thierry, Ph.D., Senior Investigator, Research Institute in Oncology of Montpellier, INSERM

A.R. Thierry's team demonstrated the crucial importance of detecting short cfDNA fragments to improve the specificity and sensitivity of cfDNA analysis. Those observations enabled to develop methods without having to require expensive sophisticated material. In addition to mutation detection, cfDNA appears as a powerful tool for personalized medicine and follow-up. Dr. Thierry will present a multi-marker approach providing innovative basics for diagnosis and prognosis in respect to cancer management care.

2:35 Improving Patient Care Through Tailored Non-Invasive Testing

Sponsored by sysmex

Frank Holtrup, Ph.D.,Head, R&D Lab Services, Sysmex Inostics GmbH

There is a rising interest in the clinical utility of cell-free tumor DNA for directing targeted therapies and monitoring. Mature technologies, such as BEAMing, are taking the next step and becoming incorporated into companion diagnostic products. This presentation will highlight the technological background as well as provide updates on the implementation of non-invasive, blood-based cell-free DNA testing in clinical environments.

3:05 Use of cfDNA for Interrogating Cancer Genomics and Treatment-Induced Dynamics

Scott Kopetz, M.D., Ph.D., Associate Professor, Gastrointestinal Medical Oncology, Division of Cancer Medicine, MD Anderson Cancer Center

cfDNA has the potential to be a clinically useful diagnostic for advanced cancers. The utilization of these tests can also provide insights into treatment related changes in various clones in the tumors, allowing insights into the "ecology" of cancer.

3:35 Use of Non-Invasive Tumor Sequencing Assay on Patients with Advanced Cancers and its Clinical Utility

AmirAli Talasaz, Ph.D., President & CTO, Guardant Health, Inc.

Analysis of genomic alterations in advanced malignant disease is quickly becoming the standard of care in oncology. GUARDANT360, a blood-based liquid biopsy approach that analyzes circulating tumor DNA (ctDNA), offers a simple and comprehensive tool for real-time tumor genetic profiling in advanced refractory cancer patients.

4:05 Close of Conference

Organized by
Cambridge Healthtech Institute

Recommended Pre-Conference Short Courses*

NGS Data Analysis – Determining Clinical Utility of Genome Variants

NGS as a Diagnostics Platform

**Separate registration required, please see page 3 for details*

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Sponsored by
janssen

3:30 Molecular Characterization of Circulating Tumor Cells: Opportunities and Challenges

Denis Smirnov, Associate Scientific Director, US Biomarker Oncology, Janssen R&D US

Molecular characterization of circulating tumor cells (CTCs) offers a unique opportunity to dynamically monitor metastatic process so optimal therapy regimens can be developed and applied in clinic. Potential and challenges of molecular characterization of CTCs will be discussed.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Organized by
Cambridge Healthtech Institute

SINGLE-CELL ANALYSIS: FROM DIAGNOSIS TO THERAPY

4:40 Chairperson's Remarks
James Hicks, Ph.D., Cold Spring Harbor Laboratory

4:45 Quantitative Single-Cell Analysis of Patient-Derived Cancer Stem Cells Identifies Unique Chemotherapy Response Signatures
Michael Masterman-Smith, Ph.D., Entrepreneurial Scientist, UCLA California NanoSystems Institute
Microfluidic chip-based assay technologies permitting molecular characterization of microscopic patient samples may transform cancer diagnosis and treatment. A quantitative immunocytometry approach was used to profile EGFR-PTEN-Akt-mTOR signaling in single cells of human cancer stem cell (CSC) lines in ~1000 cells/sample. Bioinformatic analysis revealed drug response and resistance signatures and showcased the clinical utility of microfluidics platforms and personalized CSC models.

5:15 Diagnosing Intratumor Heterogeneity in Breast Cancer with Single-Cell Genome Sequencing
Yong Wang, Ph.D., Research Scientist, Nicholas E. Navin Laboratory, Genetics, Bioinformatics, MD Anderson Cancer Center
We developed a whole-genome and exome single-cell sequencing approach to study clonal diversity and mutational evolution in breast cancer. Our data shows that copy number profiles are highly stable in the tumor mass, while point mutations evolve gradually, generating extensive clonal diversity. We apply these tools to diagnose genetic heterogeneity in breast tumors and develop new therapeutic targeting strategies.

5:45 Single-Cell Metabolomics and Proteomics: Toward Complementing Single-Cell Genomics for Cancer Research
Peter Nemes, Ph.D., Assistant Professor, Chemistry, George Washington University
Single-cell mass spectrometry is a recent technological development. Here we demonstrate that it can detect, identify and profile hundreds of metabolites and peptides in single isolated cells without *a priori* knowledge of specimen composition or chemical labels. The combination of single-cell genomics and single-cell mass spectrometry would extend bioanalysis to the level of systems biology, potentially aiding cancer research.

6:15 Close of Day

6:00 Dinner Short Course Registration

Recommended Dinner Short Course*

6:30-8:30 pm Regulatory and Reimbursement Issues with NGS and Multiplex Assays
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THURSDAY, AUGUST 21

7:30 – 8:25 am Problem-Solving Breakout Discussions with Continental Breakfast

TIPS 'N TRICKS FOR A NEW SEQUENCING FRONTIER

8:25 Chairperson's Opening Remarks
Jan Vijg, Ph.D., Albert Einstein College of Medicine

8:30 1000 Genomes: Methods for CTC Analysis
James Hicks, Ph.D., Research Professor, Cancer Genomics, Cold Spring Harbor Laboratory
We will discuss methods for cell capture, amplification and informatics for CNV profiling and the focused resequencing of rare circulating cells from various forms of metastatic cancer.

9:00 Single-Cell Molecular Profiling of a Brain Tumor
John F. Zhong, Ph.D., Associate Professor, Pathology, University of Southern California School of Medicine
With microfluidic technology, we are able to obtain transcriptomes of single tumor cells from a brain tumor. Comparing mutations detected by next-generation sequencing in a primary tumor and cell lines derived from a primary tumor, we identified genes that play a role in treatment-resistant clones.

9:30 Flow Cytometric Sorting of Dissociated Cells from PDX Model Derived Human Solid Tumors Enables Targeted Downstream Analysis
Sponsored by BD
Rainer Blaesius, Technology Manager, Genomic Sciences Group, BD Technologies
Current molecular analysis methods for solid tumor biopsies generally use bulk material and ignore intratumor heterogeneity. We have developed methods to dissociate tissue samples and select subpopulations based on FACS® sorting. Our methods have been used for species specific sequencing as well as single cell index sorting to enable a variety of downstream analysis modalities.

9:45 Streamlining Single-Cell RNA Sequencing Analysis for Biologists with the Maverix Analytic Platform
Sponsored by Maverix Biomics
Patricia Chan, CTO, Maverix Biomics, Inc.
With the advancement of single-cell sequencing methodologies, the demand for analytic tools to handle complex data has grown rapidly. We will present the Maverix Analytic Platform, a cloud-based environment built for biologists that leverages best-in-class tools and provides an integrated UCSC-genome browser to enable visualization of results in broad context.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

Diagnosing and Dissecting Cancer as a Disease of the Genome

10:45 Genome-Wide Mapping of DNA Rearrangements in Single Cells Using DNA Template Strand Sequencing

Mark Hills, Ph.D., Research Scientist, Peter M. Lansdorp Laboratory, BC Cancer Research Centre

While genomic sequencing from single cells push the boundaries of current technologies, an unprecedented amount of new information can be gained from these types of analyses. Using Strand-seq, we have generated quantitative data across all chromosomes within a single cell that presents us with a novel means to characterize genomes. This characterization includes identifying structural variation within the human population, together with the fine-mapping of diverse "cancer genomes", whereby in a single cancer we are able to localize common structural changes as well as rare variants present in a small subset of cells. In addition, the power of Strand-seq to assemble and fine-tune reference genomes will be illustrated.

11:15 Genome-Wide Analysis of Copy Number Variations and Mutation Profiles of Single Tumor Cells Using Massively Parallel Paired-End Sequencing

Parveen Kumar, Research Scientist, Thierry Voet Laboratory, Human Genetics, University of Leuven

We will compare different whole-genome amplification methods to analyze single cells for CNVs. We will also discuss the study of intra-tumor genetic heterogeneity in breast cancer to single-cell resolution, as well as the study of CTCs at single-cell level using low-coverage paired-end sequencing for copy number variation (CNV) analysis and targeted re-sequencing of 453 cancer-related genes for somatic mutation analysis.

FEATURED PRESENTATION

11:45 Single-Cell Genomics in Aging and Cancer

Jan Vijg, Ph.D., Professor and Chairman, Genetics, Albert Einstein College of Medicine

Massively parallel sequencing has enabled the quantification and characterization of high-abundant DNA mutations in the tumor genome. However, low-abundant mutations in the normal and tumor genome thus far remain out of reach. We are using single-cell genomics assays to study the landscape of low-abundant somatic DNA mutations in the genome of normal animal and human tissues from which tumors arise.

12:15 pm Sponsored Presentation *(Opportunity Available)*

12:45 Luncheon Presentations: *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:45 Session Break

TRANSLATING INTO THE CLINIC

2:00 Chairperson's Remarks

Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

2:05 First FDA Clearances of Next-Generation Sequencing Technology and Tests

Živana Težak, Ph.D., Associate Director, Science and Technology, Personalized Medicine, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH), FDA

With the rapid emergence of novel, ultrahigh-throughput technologies, the FDA has met new regulatory challenges while still applying scientific evidence-based oversight of diagnostics. Recently, the FDA authorized for marketing four high-throughput gene sequencing diagnostic devices, marking the first time a next-generation sequencing system has received FDA premarket clearance. The regulatory pathway and performance evaluation for these devices will be discussed.

2:35 Magnetic Microchip Technology for Large-Scale Single-Cell Analysis

Benjamin Yellen, Ph.D., Associate Professor, Mechanical Engineering and Materials Science, Duke University

Here we describe a microchip technology that can organize single cells and cell pairs into large arrays, continuously evaluate the single cell and cell pair behavior for long durations when exposed to different ambient conditions and/or pharmaceutical compounds and retrieve specific cells for downstream gene expression analysis and/or clonal expansion. The comprehensive characterization of individual cell-cell interactions from the live state to the cell lysis is paramount to furthering our understanding of immunology, cancer and neuronal networks, and will lead to the development of new therapies for human disease.

3:05 Cross-Cancer Analysis

Theresa Zhang, Ph.D., Vice President, Research Services, Personal Genome Diagnostics

3:35 PANEL DISCUSSION: From Discovery to Diagnostic

Personalized medicine principles now influence business plans across pharma. However, the business model underpinning individualization, which requires integrating drugs and diagnostics, is unclear. Implementing discovery and development programs that capitalize on this integration has been challenging, but not impossible. This panel will explore the path from scientific discovery to the clinic, looking at the key drivers of commercial success.

Moderator: Edward Abrahams, Ph.D., Personalized Medicine Coalition

Panelists:

Elaine Lyon, Ph.D., ARUP

Michael Masterman-Smith, Ph.D., UCLA California NanoSystems Institute

Živana Težak, Ph.D., FDA

Benjamin Yellen, Ph.D., Duke University

Theresa Zhang, Ph.D., Personal Genome Diagnostics

4:05 Close of Conference

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Select specific delegates from the pre-registration list to attend a private function at an upscale restaurant or a reception at the hotel. From extending the invitations, to venue suggestions, CHI will deliver your prospects and help you make the most of this invaluable opportunity.

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Joseph Vacca
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781-972-5431
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HOTEL & TRAVEL INFORMATION

CONFERENCE HOTEL:

Capital Hilton Hotel
1001 16th Street NW
Washington, DC 20036
Phone: 202-393-1000

Discounted Room Rate: $199 s/d
Discounted Reservation Cutoff Date: July 21, 2014

Please visit our conference website (NextGenerationDX.com) to make your reservations on-line or call the Hotel directly. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate-availability basis. Rooms are limited, so please book early.

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We understand that you have many choices when making your travel arrangements. Please understand that reserving your room in the CHI room block at the conference hotel allows you to take full advantage of the conference sessions, events and networking opportunities, and ensures that our staff will be available to help should you have any issues with your accommodations.

FLIGHT DISCOUNTS:

Special discounts have been established with American Airlines for this conference:

- Call American Airlines Directly at 1-800-433-1790 and use Conference Code 2984AA
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Pricing and Registration Information

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Summit Pricing BEST VALUE! (Includes access to 2 conferences, excludes short courses)	**Commercial**	**Academic, Government, Hospital-affiliated**
Registrations after July 18, 2014, and on-site	$2545	$1170
Single Conference Pricing (Includes access to 1 conference, excludes short courses)		
Registrations after July 18, 2014, and on-site	$1925	$825

August 19 - 20	August 20 - 21
C1: Enabling Point-of-Care Diagnostics	C6: Molecular Diagnostics for Infectious Disease
C2: Predictive Cancer Biomarkers	C7: Companion Diagnostics: Technology & Reimbursement
C3: Companion Diagnostics: Strategy & Partnerships	C8: Commercialization of Molecular Diagnostics
C4: Inherited Disease Diagnostics	C9: Clinical Application of Cell-Free DNA
C5: NGS-Based Assays in the Clinical Setting	C10: Single-Cell Sequencing

SHORT COURSES

(Includes access to short courses only)

Single short course	$695	$395
Two short courses	$995	$695
Three short courses	$1195	$795
Four short courses	$1295	$845

Monday, August 18		
9:00 am - 12:00 pm	2:00 - 5:00 pm	5:30 - 8:30 pm (Dinner Short Course)
SC1: Overcoming Challenges of Working with FFPE Samples	SC4: Microfluidics for Point-of-Care: Technologies, Applications and Products	SC8: Use of CLIA-Waived Point-of-Care and Rapid Diagnostic Tests in Community Pharmacies
SC2: Leading Product Innovation	SC5: NGS as a Diagnostic Platform	SC9: Regulatory Compliance in Drug-Diagnostics Co-Development
SC3: NGS Data Analysis – Determining Clinical Utility of Genome Variants	SC6: Clinical Trials to Establish Value of Diagnostic Tests: Design and Management	
	SC7: Sample Prep Methods for Liquid Biopsy	
Wednesday, August 20 6:30 - 8:30 pm (Dinner Short Course)		
SC10: Regulatory and Reimbursement Issues with Next-Generation Sequencing and Multiplex Assays		
SC11: NGS for Infectious Disease Diagnostics		

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Poster Submission - Discount ($50 Off): Poster abstracts are due by July 18, 2014. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. *CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

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Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

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