



The Second Annual

LIQUID BIOPSY SUMMIT

JUNE 21 - 23, 2017
SAN FRANCISCO, CA

HOTEL KABUKI

Refining Circulating Biomarkers and
Technologies for Translational Research

THIS IS AN UNPRECEDENTED TIME IN BIOMOLECULAR MEDICINE.

Rapid development of highly sensitive and accurate detection technologies has empowered researchers to analyze and determine the role of circulating biomarkers in health, disease and treatment response, leading to targeted therapies. However, uncertainties with biofluid-based DNA/RNA analytical methods must be solved before liquid biopsies can be implemented for broader routine applications. At **The Liquid Biopsy Summit**, experts navigate process and technology refinements that can pave a smoother road toward precision medicine.

KEYNOTE AND FEATURED PRESENTATIONS



Pre-Analytical Variables in Blood Collection Impact on Precision Medicine

Carolyn Compton, M.D., Ph.D.,
Arizona State University & Mayo Clinic School of Medicine



Epigenetic and Genetic Analysis of Circulating Biomarkers for Prostate Cancer Prognosis

Tim H-M Huang, Ph.D.,
University of Texas Health Science Center at San Antonio



New Tools for Liquid Biopsies: Microfluidic Platforms for the Isolation of CTCs, cfDNA and Exosomes

Steven A. Soper, Ph.D.,
Center of BioModular Multi-Scale Systems for Precision Medicine, The University of Kansas

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WEDNESDAY, JUNE 21

11:00 am Short Course Registration

11:30 am - 2:30 pm Pre-Conference Lunch Short Course*

SC1: Blood from Patient ► Needle ► Freezer ► Analysis ► Diagnosis

* Separate registration required. See page 4 for details.

2:00 Main Conference Registration

Precision Medicine: Sample & Standards

3:00 Organizer's Opening Remarks

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

3:05 Chairperson's Opening Remarks

Theral Timpson, Host and Producer, MendelSpod

3:15 FEATURED PRESENTATION: Pre-Analytical Variables in Blood Collection Impact on Precision Medicine

Carolyn Compton, M.D., Ph.D., Professor of Life Sciences, School of Life Sciences, Arizona State University; Professor of Laboratory Medicine and Pathology, Department of Pathology, Mayo Clinic School of Medicine

This presentation focuses on the importance of evidence-based standardization of the pre-analytical steps in biospecimen acquisition and handling for liquid biopsies in order to assure reproducible, clinically meaningful analysis results. The work of the Pre-analytics for Precision Medicine Project Team of the College of American Pathologists (CAP), the American Society of Clinical Oncology (ASCO)-CAP Liquid Biopsies Working Group and the Beau Biden Cancer Moonshot Blood Profiling Atlas in Cancer (Blood PAC) will be highlighted.

3:45 CO-PRESENTATION: Improving the Quality of Circulating Tumor DNA Measurements by a Multi-Laboratory Assessment of Expert-Designed Reference Materials

Kenneth D. Cole, Ph.D., Group Leader, Bioassay Methods, National Institute of Standards and Technology (NIST)

Russell K. Garlick, Ph.D., CSO, SeraCare Life Sciences, Inc.

Analytical validation of ctDNA assays must be accomplished before clinical validation. ctDNA assays present unique sensitivity and specificity challenges due to the biochemical nature of circulating cell-free DNA and multiple analytical measurement techniques. This presentation discusses the design, development and characterization of expert-designed reference materials for use in a multi-lab assessment of ctDNA measurements. Commutability to patient samples and concordance between analytical methods will be discussed.

4:30 Deep Sequencing QC: A Component Study of the FDA-Led Sequencing Quality Control Project Phase 2 (SEQC2)

Joshua Xu, Ph.D., Senior Computer Scientist, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, Food and Drug Administration (FDA)

Deep sequencing focuses its sequencing reads on few small regions of the genome and thus achieves very sensitive detection of sub-clonal mutations. Liquid biopsy, an application of deep sequencing, has gained tremendous interest in the oncology research community. Before deep sequencing is ready for use in clinical and regulatory settings, some major uncertainties need to be addressed. The FDA-led MicroArray Quality Control (MAQC) consortium seeks to assess validity and reliability, as well as recommend sound analysis methods for deep sequencing and whole-genome sequencing in its fourth project that is also named Sequencing Quality Control Phase 2 (SEQC2).

5:00 PANEL DISCUSSION: Enhancing the Science and Clinical Utility of Liquid Biopsies

All agree that the potential of liquid biopsies will allow for detection of disease faster, diagnosis of disease earlier, and tracking of disease progression and treatment response more efficiently.

This panel discusses progress in:

- collection, preservation, and storage of biosamples
- advances in detection technologies
- determining reference materials and standards
- developing safe and effective blood profiling diagnostics
- creating an open database of liquid biopsy results

Moderator:

Theral Timpson, Host and Producer, MendelSpod

Panelists:

Kenneth D. Cole, Ph.D., NIST

Carolyn Compton, M.D., Ph.D., Arizona State University & Mayo Clinic School of Medicine

Russell K. Garlick, Ph.D., SeraCare Life Sciences, Inc.

Joshua Xu, Ph.D., FDA

Additional Panelists to be Announced

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

THURSDAY, JUNE 22

8:00 am Morning Coffee

Precision Oncology: Cells & Cell Targets

8:45 Chairperson's Remarks

Rebecca (Becky) Suttman, MS, Senior Scientific Researcher, Oncology Biomarker Development, Genentech, Inc.

8:50 High-Content Analysis of Prostate Cancer Cells in Bone Marrow and Blood

James Hicks, Ph.D., Professor, Department of Biological Sciences, University of Southern California

An array of blood-based assays is being developed that can provide a real-time window into the course of cancer and its response to treatment. HD-SCA is an integrated proteogenomic liquid biopsy platform for assessing cancer heterogeneity at both the cellular and molecular levels. We will describe its integration into the Blood Profiling Atlas of Cancer (BloodPAC), a joint industry and academic effort spawned from the Biden Cancer Moonshot initiative of 2016.

9:20 Retrospective Analysis of CellSearch CTC Enumeration Data across Clinical Trials

Rebecca (Becky) Suttman, MS, Senior Scientific Researcher, Oncology Biomarker Development, Genentech, Inc.

9:50 Multi-Component Liquid Biopsy Enabled by High-Throughput Optical Scanning Technologies

Zheng Ao, Ph.D., Postdoctoral Fellow, Biosciences Division, SRI International

Liquid biopsies provide a non-invasive means to access molecular and genetic information of the tumor. Using the high-throughput optical scanning technology here at SRI, we aim to interrogate not only the tumor cells in circulation (CTCs) but also components of the tumor microenvironment such as cancer-associated fibroblasts (CAF), tumor-associated lymphocytes (TAL) and extracellular vesicles (EVs). This multi-component analysis is more representative of the whole tumor than CTCs alone and will better enable us to put the puzzle together to understand the tumor through a tube of blood.

10:20 Coffee Break in the Exhibit Hall with Poster Viewing

Diagnosing & Tackling Other Circulating Targets

11:00 Liquid Biopsy in Neurovascular Inflammation

J. Winny Yun, Graduate Assistant, JS Alexander Lab, Department of Molecular and Cellular Physiology, Louisiana State University Health Sciences Center

Inflammatory cytokines promote cerebrovascular stress in several neurodegenerative diseases, including multiple sclerosis (MS), and may provoke endothelial disturbances, contributing to blood-brain barrier breakdown and exacerbation of disease. We recently identified lymphatic endothelial-specific proteins in human brain tissue and in the serum, with altered expression in MS patient samples. This indicated the possibility that circulating lymphatic biomarkers may be derived from brain endothelial cells in the form of circulating microparticles.

11:30 Detection of Human Cardiomyocyte Death Using Cell-Free DNA

Hai Zemmour, Research Scientist, Department of Developmental Biology and Cancer Research, The Institute for Medical Research Israel-Canada, The Hebrew University-Hadassah Medical School

I present a totally new approach for studying onset cell type-specific death, especially cardiomyocyte degeneration in various pathological contexts, and envision a new type of blood test that aimed sensitive detection of tissue damage without *a priori* suspicion of disease. I believe that such a tool will have broad utility in diagnostic medicine and in the study of human biology.

12:00 pm Circulating RNA in the Blood of Cancer Patients: Isolation and Analysis to Determine Tumor Gene Expressions

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Kathleen Danenberg, CEO, Liquid Genomics, Inc

Circulating tumor (ct) RNA contains the same mutational information as ctDNA but only for expressed genes and also allows quantitative determination of gene expression levels. CtRNA was successfully isolated from blood using Streck's Cell-Free RNA blood collection tube. Healthy individuals had uniformly low blood levels of ctRNA compared to cancer patients. Analysis of ctRNA in 329 NSCLC patients showed similar frequency of PD-L1 gene positivity (64%) as found by IHC of solid tissue biopsies (66%).

12:30 Session Break

12:45 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

Precision Oncology: Monitoring Therapy Response

2:00 Chairperson's Remarks

2:05 Liquid Biopsies in Cancer Immunotherapy Clinical Drug Development

Shidong Jia, M.D., Ph.D., Founder & CEO, Predicine, Inc.

Cancer immunotherapy offers great promise where biomarkers have been shown to predict therapy outcome in various types of cancer patients. The talk describes the development and clinical application of a next-generation sequencing-based liquid biopsy test to support cancer immunotherapy clinical trials.

2:35 Microfluidic Cell Tethering to Rapidly Measure Drug Responses in Patient Tumor Cells

Stuart S. Martin, Ph.D., Professor of Physiology, Greenebaum NCI Comprehensive Cancer Center, University of Maryland School of Medicine

Non-adherent tumor cells display four phenotypes that are indicative of metastatic potential (microtentacles, clustering, deformability, stem cell sphere formation). However, technical challenges prevent high-resolution imaging of non-adherent tumor cells. Integrating hydrophobic lipids into an engineered microfluidic surface tethers tumor cells while preserving the dynamic behaviors of non-adherent tumor cells. This technology enables rapid testing of patient cells for responses to drug treatments that could influence CTC reattachment during metastasis.

3:05 Sponsored Presentation (Opportunity Available)

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

Precision Oncology: Diagnosis & Prognosis

4:00 FEATURED PRESENTATION: Epigenetic and Genetic Analysis of Circulating Biomarkers for Prostate Cancer Prognosis

Tim H-M Huang, Ph.D., Professor & Chair, Department of Molecular Medicine, University of Texas Health Science Center at San Antonio

Increased cell-free DNA methylation of androgen-biosynthesis loci is frequently associated with rising PSA in patients with recurrent prostate cancer. In separate studies, we observed that increased adhesiveness and deformability of circulating tumors cells are often accompanied with the acquisition of epithelial-mesenchymal transition in these patients. Together, this integrative assay of exfoliated cell sources can improve early detection of recurrent cancer and is useful to monitor disease progression.

4:30 Proteomic Alterations of Tumor Cell Adhesion Are Detectable in Patient Biofluids and Report on Their Outcome

Andries Zijlstra, Ph.D., Associate Professor, Department of Pathology,

Microbiology and Immunology, Vanderbilt University Medical Center

Proteins mechanistically involved in tumor cell migration and metastatic dissemination have the potential to serve as markers of invasive disease and predict patient outcome. The activity of the cell adhesion molecule ALCAM (Activated Leukocyte Cell Adhesion Molecule) is regulated dynamically through proteolytic release of its extracellular domain. As such, the detection of shed ALCAM acts as a prognostic biomarker for solid tumors.

5:00 Heterogeneity of Cancer-Derived Extracellular Vesicles: The Emerging Role of Large Oncosomes

Dolores Di Vizio, M.D., Ph.D., Associate Professor, Pathology & Laboratory Medicine, Biomedical Sciences, Cancer Biology Program, Cedars-Sinai Medical Center; Associate Professor, Medicine, University California, Los Angeles; Assistant Professor, Boston Children's Hospital, Harvard Medical School

Extracellular vesicles (EVs) are important mediators of intercellular mechanisms as they can shuttle from one cell to another a reservoir of functional molecules. EVs are being recognized as appealing biomarkers of diagnosis and prognosis. We have demonstrated that the abundance of large oncosomes in the circulation and in tissues correlates with advanced disease in mouse models and human subjects, and that these vesicles are promising candidates for liquid biopsy approaches through large-scale profiling of protein, DNA and mRNA.

5:30 Short Course Registration

5:45 - 8:45 Dinner Short Course*

SC2: Innovative Imaging Technologies for Patient CTCs

* Separate registration required. See page 4 for details.

FRIDAY, JUNE 23

7:30 am Breakfast Breakout Discussion Groups

Chew over breakfast and provocative discussion topics with your peers. These are moderated discussions with brainstorming and interactive problem-solving, allowing conference participants from diverse backgrounds to exchange ideas and experiences and develop future collaborations around a focused topic.

Translation into the Clinic

9:00 Chairperson's Remarks

Gary Spitzer, M.D., Director, Clinical Validity and Clinical Utility Evaluation, MolDX, Palmetto GBA

9:05 Clinical Utility Needs of ctDNA Assays versus Research Utility

Gary Spitzer, M.D., Director, Clinical Validity and Clinical Utility Evaluation, MolDX, Palmetto GBA

I present design of prospective transparent registries to validate the clinical utility of a test in a clear intent to study patient population. I also discuss obstacles of existing registry and trial design and present ideas on how costs can be diminished through non-traditional data extraction techniques, but with emphasis on transparency, scientific independence and open data collection.

9:35 Liquid Biopsies in Oncology and the Current Regulatory Landscape

Mark W. Linder, Ph.D., DABCC, Professor, Department of Pathology and Laboratory Medicine, University of Louisville School of Medicine

There is a need to detect cancer earlier, guide therapies and monitor progress during treatment. However, solid tissue biopsy is at times limited by the invasiveness and tumor size. A liquid biopsy can overcome these barriers and allow samples to be collected over time. Liquid biopsies include the analysis of circulating tumor cells (CTCs) and/or cell-free nucleic acids obtained from a variety of biofluids.

10:05 Validating Liquid Biopsies in Cancer: How Sensitive Is Clinically Meaningful?

John Beeler, Ph.D., Vice President, Corporate and Business Development, Invata, Inc.

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10:20 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Colvera™: A ctDNA Liquid Biopsy Assay for Colorectal Cancer - Our Journey from Discovery to the Clinic

Jason Ross, Ph.D., Senior Research Scientist, Health and Biosecurity, CSIRO

We have developed Colvera™, a ctDNA liquid biopsy assay to diagnose and monitor colorectal cancer. The assay is based upon detecting circulating

tumor DNA from two genes methylated in colorectal cancer, but unmethylated in non-neoplastic tissue or blood. I discuss the journey we and our collaborators undertook: from biomarker discovery and validation, to assay design and then to clinical trials and the launch of a commercial lab test.

11:15 Development and Validation of a Pan-Cancer Liquid Biopsy Test: Criteria and Considerations

Honey V. Reddi, Ph.D., FACMG, Clinical Laboratory Director, The Jackson Laboratory for Genomic Medicine

The presentation delineates the criteria that went in content evaluation, steps involved in validation including sample extraction methods, and also covers the limitations and challenges involved in the process.

11:45 Sponsored Presentation (Opportunity Available)

12:15 pm Session Break

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

New Tools: Advancing Detection for Liquid Biopsies

1:30 Chairperson's Remarks

Lynne Bemis, Ph.D., Chair, Biomedical Sciences, University of Minnesota

1:35 KEYNOTE PRESENTATION: New Tools for Liquid Biopsies: Microfluidic Platforms for the Isolation of CTCs, cfDNA and Exosomes

Steven A. Soper, Ph.D., Foundation Distinguished Professor, Department of Chemistry, Department of Mechanical Engineering and Bioengineering; Director, Center of BioModular Multi-Scale Systems for Precision Medicine, The University of Kansas

Liquid biopsies are generating great interest within the medical community due to the simplicity for securing important biomarkers to manage complex diseases, such as cancer-related diseases. These circulating markers consist of CTCs, cfDNA and exosomes. We are developing a suite of microfluidic devices that can process whole blood directly and are engineered to efficiently search for a variety of disease-associated liquid biopsy markers from divergent subpopulations comprising the tumor microenvironment.

2:20 Optofluidic Systems for On-Chip Detection of Cancer and Infectious Disease Biomarkers

Holger Schmidt, Ph.D., Professor, Electrical Engineering; Narinder Kapany Chair of Optoelectronics; Director, W.M. Keck Center for Nanoscale Optofluidics, University of California, Santa Cruz

Optofluidic devices combine microfluidics with integrated optics, creating a single chip-based system for both preparation and analysis of biological samples such as liquid biopsies. I describe a versatile, optofluidic platform using liquid-core optical waveguides for optical analysis of single biomolecules. Examples for its capabilities include amplification-free

detection of Ebola RNA, multiplex detection of single influenza viruses and cancer DNA biomarkers starting with a whole blood sample.

2:50 Multitarget Serum MicroRNA Assays for Early Detection of Lung and Gastric Cancers

Lihan Zhou, Ph.D., CTO & Founder, MiRXES Pte Ltd.

Lung and gastric cancers rank 1st and 3rd in mortality globally. Current screening methods of LDCT and gastroscopy are limited by specificity, invasiveness and cost. Using a proprietary ultra-sensitive qPCR technology, we have developed serum miRNA assays to serve as an alternative for blood-based lung and gastric cancer screening. These assays have been validated in multi-center studies with encouraging accuracy in detecting Stage I and II cancers (AUC>0.9).

3:20 Networking Refreshment Break

3:30 Sizing Up Cancer in Cell-Free DNA

Hunter R. Underhill, M.D., Ph.D., Assistant Professor, Pediatrics, Division of Medical Genetics, University of Utah

Detection of cell-free DNA derived from non-metastatic solid tumors remains challenging. Identification of tumor-associated variants in cell-free DNA that occur at very low frequency (<1%) requires methods with ultra-high sensitivity. Here, the role of size selecting for specific cell-free DNA fragment lengths to improve detection of solid tumors will be discussed. Size selection will be considered within the context of mutant allele enrichment and potential effects on next-generation sequencing.

4:00 Making and Using RNA Standards: Can You Trust Your Genome-Scale Measurements?

Sarah A. Munro, Ph.D., Team Leader, Genome-Scale Measurements Group, Joint Initiative for Metrology in Biology, National Institute of Standards and Technology (NIST)

When you're assaying thousands of molecules at the same time, how do you know that you have the right answers? To make the 21st century of biology a reality, we need genome-scale measurement results we can trust. In our Joint Initiative for Metrology in Biology (JIMB), we are working to systematically address these needs with RNA spike-in controls, mixture samples, and turn-key analysis tools.

4:30 tRNA Fragments in Accessible Samples: Expression, Biogenesis and Function

Lynne Bemis, Ph.D., Chair, Biomedical Sciences, University of Minnesota

tRNA fragments are common in RNA-seq libraries and were originally thought to be breakdown products. We identified a tRNA fragment that is present at high levels in the urine of patients with ovarian cancer and we have now shown that its cleavage is regulated by the RNase, angiogenin. The function of this and other tRNA fragments in cancer cell lines will be described.

5:00 Close of Conference

SHORT COURSES*

PRE-CONFERENCE LUNCH SHORT COURSE

WEDNESDAY, JUNE 21 | 11:30 AM - 2:30 PM

SC1: Blood from Patient ► Needle ► Freezer ► Analysis ► Diagnosis: Biobanks and Their Critical Role in Moving Precision Medicine Forward

With advancement in next-generation sequencing technologies where cell-free DNA and RNA are being used for cancer genomics and non-invasive prenatal screening assays, blood, as a biospecimen source, has proven to be all the more important to collect for research. Thus, for liquid biopsies, optimal conditions for blood collection, transport, and storage are still under development. To help advance these efforts, many healthcare organizations are developing large biorepositories to collect biospecimens from patients and healthy individuals who are consenting to participate in medical research to advance technologies and knowledge for improvement of human health. This short course discusses what factors are important to consider in the blood collection and handling process for downstream analysis for genomics and proteomics assays.

Instructors:

*Nazneen Aziz, Ph.D., Executive Director, Kaiser Permanente Research Bank
Stacey A.A. Honda, M.D., Ph.D., Associate Medical Director, Diagnostic Specialties and Research; Chief, Pathology and Medical Director, Center for*

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

Health Research, Hawaii, Hawaii Permanente Medical Group; Medical Director, Laboratories, Kaiser Hawaii Health Plan and Hospital

Additional Instructors to be Announced

DINNER SHORT COURSE

THURSDAY, JUNE 22 | 5:45 - 8:45 PM

SC2: Innovative Imaging Technologies for Patient CTCs

This course covers viable CTC capture technologies and propagation strategies, as well as existing microscopy and flow-based imaging technologies. Participants also learn about emerging confocal, light sheet and super-resolution techniques, plus connecting CTC characteristics with patient outcome and drug response.

Who should attend: Researchers from biopharma, research laboratories, and diagnostic organizations who are developing liquid biopsy assays/kits and relevant technologies, and who desire to understand and improve clinical utility at the starting point of blood collection.

Instructors:

*Stuart S. Martin, Ph.D., Professor of Physiology, Greenebaum NCI Comprehensive Cancer Center, University of Maryland School of Medicine
Additional Instructors to be Announced*

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For more information, contact:

Uma Patel, Business Development Manager
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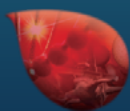
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The Second Annual

LIQUID BIOPSY SUMMIT

June 21 - 23, 2017 | Hotel Kabuki | San Francisco, CA

Pricing and Registration Information

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	Commercial	Academic, Government, Hospital-affiliated
1 Short Course	\$699	\$359
2 Short Courses	\$999	\$599

WEDNESDAY, JUNE 21 11:30 AM - 2:30 PM	THURSDAY, JUNE 22 5:45 - 8:45 PM
SC1: Blood from Patient ▶ Needle ▶ Freezer ▶ Analysis ▶ Diagnosis: Biobanks and Their Critical Role in Moving Precision Medicine Forward	SC2: Innovative Imaging Technologies for Patient CTCs

CONFERENCE PRICING

Standard Package (Includes Conference Program and 2 Short Courses)

Advance Registration Discount until May 12	\$2349	\$1179
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Alumni Discount: Cambridge Healthtech Institute (CHI) appreciates your past participation at The Liquid Biopsy Summit. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an

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additional 20% off the registration rate.

Group Discounts: Discounts are available for multiple attendees from the same organization. For more information on group rates contact Jeff Knight, 781-247-6264, jknight@healthtech.com.

Additional registration details: Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link. 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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