The Fourth Annual

LIQUID BIOPSY SUMMIT

Defining Circulating Biomarkers and Technologies for Translational Research

Final Days to Register

RESERVE YOUR SPOT TODAY!

JUNE 17-19, 2019 | SAN FRANCISCO, CA | HOLIDAY INN GOLDEN GATEWAY

Join world-renowned leaders at **The Liquid Biopsy Summit** to share case studies, breakthroughs, and solutions that support and enhance research, and discuss process and technology refinements that will impact the future of precision medicine.

KEYNOTE SPEAKER

WALTER KOCH, PHD, Vice President, Head, Global Research, Roche Molecular Systems, Inc.

FEATURED SPEAKERS

MUNEESH TEWARI, MD, PHD, Professor, Internal Medicine & Biomedical Engineering, University of Michigan Medical School

CHRIS KARLOVICH, PHD, Associate Director, Molecular Characterization & Clinical Assay Development Laboratory, Leidos BioMedical Research, Inc., Frederick National Laboratory for Cancer Research

EVENT FEATURES

- 1-on-1 Networking with More Than 150 Global Participants
- Collegial Atmosphere
- Two In-depth Short Courses
- Interactive Fireside Chat
- Start-up Innovation Spotlights
- Thought-provoking Breakout Groups

SESSION TOPICS

- Samples & Standards
- Isolating & Analyzing CTCs & ctDNA
- Exploring Extracellular Vesicles
- Evaluating Epigenetic Markers
- Monitoring Patients' Analytes for Treatment Response

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PRE-CONFERENCE

Short Courses

MONDAY, JUNE 17 | 10:00 AM - 1:00 PM

SC1: Preanalytical Variables: Effects of Blood Collection and Processing Procedures for Liquid Biopsies

Preanalytical variables are essential to consider when using liquid biopsies, as factors such as collection tubes, processing procedures, and extraction methods can affect yields and detection of low frequency variants. This is especially important in cancer studies as detection of variants can have important clinical implications for patients. This course will cover the optimization and best practices of Liquid Biopsy.

Topics to be covered:

- The importance of considering preanalytical variables
- How to deploy controls and error correction to minimize physical and *in silico* inaccuracies
- Clinical and laboratory SOPs & workflows for specimen acquisition and processing
- Considerations when choosing between options

Instructors:
Caitlin Stewart, PhD, Postdoctoral Research Fellow, Genomics, Memorial Sloan Kettering Cancer Center
Chih Long Liu, PhD, Research Scientist, Department of Medicine/Oncology, Stanford University School of Medicine
Additional Instructors to be Announced

1:00 - 1:30 pm Lunch Provided for Short Course Participants

MONDAY, JUNE 17 | 1:30 - 4:30 PM

SC2: Advancing Liquid Biopsy Technologies from the Bench to the Clinic

This short course will provide a thorough grounding in the clinical application of the "liquid biopsy," focusing in particular on the utility of circulating tumor DNA (ctDNA). An initial session will address the basic work in recognizing the existence of cell free and circulating tumor nucleic acids, their significance in cancer patient care, and the recent adoption by clinical laboratories of novel ctDNA tests. This will be followed by a review from a clinical laboratory perspective of the expectations for a robust clinical lab assay. And finally, an "in the trenches" look at adoption of patient testing in a major cancer center.

Topics to be covered:

- History of the ctDNA field
- Identify regulatory hurdles to adoption of ctDNA testing
- The pre-analytic and analytic variables important in clinical lab testing
- Understanding practical issues a lab director might face when introducing ctDNA assays

Instructors:
Christopher D. Gocke, MD, Associate Professor, Pathology and Oncology; Director, Division of Molecular Pathology, Johns Hopkins University School of Medicine
Christina Lockwood, PhD, Associate Professor, Director of Genetics and Solid Tumors Lab, Laboratory Medicine, University of Washington
Mark Routbort, MD, PhD, Professor, Department of Hematopathology, Division of Pathology/Lab Medicine, UT MD Anderson Cancer Center

PRESENT A POSTER AND SAVE $50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions.

To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by **May 10, 2019. Visit LiquidBiopsySummit.com/Posters for details.**

THE LIQUID BIOPSY SUMMIT
Program Agenda

MONDAY, JUNE 17

9:30 am Morning Coffee and Short Course Registration

10:00 am - 1:00 pm Pre-Conference Lunch Short Course

SC1: Preanalytical Variables: Effects of Blood Collection and Processing Procedures for Liquid Biopsies
Instructors: Caitlin Stewart, PhD, Postdoctoral Research Fellow, Genomics, Memorial Sloan Kettering Cancer Center
Chih Long Liu, PhD, Research Scientist, Department of Medicine/Oncology, Stanford University School of Medicine

1:00 - 1:30 Lunch for Short Course Participants

1:30 - 4:30 Pre-Conference Lunch Short Course

SC2: Advancing Liquid Biopsy Technologies from the Bench to the Clinic
Instructors: Christopher D. Gocke, MD, Associate Professor, Pathology and Oncology; Director, Division of Molecular Pathology, Johns Hopkins University School of Medicine
Christina Lockwood, PhD, Associate Professor, Director of Genetics and Solid Tumors Lab, Laboratory Medicine, University of Washington
Mark Routbort, MD, PhD, Professor, Department of Hematopathology, Division of Pathology/Lab Medicine, UT MD Anderson Cancer Center

4:00 Main Conference Registration

4:45 Organizer's Welcome
Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

4:50 Chairperson's Opening Remarks
Theral Timpson, Host & Producer, Mendelspod.com

5:00 KEYNOTE PRESENTATION: Taking Liquid Biopsy Tests to the Next Level in Routine Clinical Oncology Patient Care

Walter Koch, PhD, Vice President, Head, Global Research, Roche Molecular Systems, Inc.

The FDA approved the first "liquid biopsy" assay for EGFR mutation status in NSCLC in 2016. ctDNA mutation analyses have established proof of concept for early detection of cancers by detecting minimal residual disease after curative treatment of early stage disease, selecting targeted therapies, determining treatment efficacy and the presence of resistance mutations, disease progression or recurrence, and assessing tumor heterogeneity. Much like drug development trials, each of these clinical indications will require prospective trials to establish clinical utility.

5:45 FIRESIDE CHAT: 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:

- State of the technology
- Impacts on immunotherapy
- Alternative sampling and processing methods
- Overcoming barriers to routine testing
- Applications on the cusp of gaining regulatory approval and clinical acceptance

Host:
Theral Timpson, Host & Producer, Mendelspod.com
Participants: Walter Koch, PhD, Vice President, Head, Global Research, Roche Molecular Systems, Inc.
Additional participants to be announced

6:30 Welcome Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, JUNE 18

7:45 am Morning Coffee

SAMPLES & STANDARDS

8:15 Chairperson's Remarks
Muneesh Tewari, MD, PhD, Professor, Internal Medicine & Biomedical Engineering, University of Michigan Medical School

8:20 FEATURED PRESENTATION: A Public-Private Consortium to Develop Quality Control Materials for Circulating Tumor DNA

Chris Karlovich, PhD, Associate Director, Molecular Characterization & Clinical Assay Development Laboratory, Leidos BioMedical Research, Inc., Frederick National Laboratory for Cancer Research

We are developing quality control materials for the cell-free DNA (cfDNA) testing community. The materials are intended to aid in the establishment of the performance characteristics of ctDNA assays, monitor test performance over time, or to function as test material for proficiency testing. The project is being conducted in two phases: an analytical phase to establish performance and a clinical phase where the materials will be tested by approximately 10 labs in a real-world setting.

9:05 Harmonization of Novel Biomarkers: Tumor Mutational Burden
Mark Stewart, PhD, Vice President, Science Policy, Friends of Cancer Research

Tumor mutational burden (TMB) measures the quantity of mutations found in a tumor and is currently being used in clinical trials to identify patients likely to benefit from an immunotherapy agent. Currently, there is a lack of standardization for calculating and reporting TMB. Friends of Cancer Research has convened a multi-stakeholder consortium to analyze the current variability among TMB assays and propose methods for alignment.

9:35 Versatile Exclusion-Based Sample Preparation Platform for Integrated Rare Cell Isolation and Analyte Extraction
Scott Berry, PhD, Associate Scientist, University of Wisconsin-Madison; CSO, Salus Discovery, LLC

Exclusion-based sample preparation (ESP) enables highly efficient cell selection and molecular biomarker extraction. ESP has been used to isolate a variety of rare cells, including tumor cells from liquid biopsy samples. Our integrated platform also facilitates quantification of mRNA, DNA, and/or protein, enabling a broad range of endpoints. In this presentation, I will share recent results regarding ESP-based analysis and discuss ongoing efforts to translate ESP into clinical labs.

9:55 Talk Title to be Announced *Sponsored by*
Ricky Chiu, PhD, Chairman & CEO, Phase Scientific International Limited PHASE SCIENTIFIC

10:25 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 A New Highly Efficient, Sensitive and Specific NGS Library Preparation Technology Allows for Error Correct Detection of Ultra-Low Frequency Mutations in Liquid Biopsies
Guoliang Fu, PhD, Chief Scientist, R&D, GeneFirst

A technology for preparing targeted NGS libraries, which is highly resilient to inefficiencies associated with low integrity DNA, has been developed. The technology, Adaptor Template Oligo Mediated Sequencing (ATOM-seq), is based on a novel method for generating unique molecular identifiers (UMIs) directly to the 3' end of starting single stranded DNA/RNA with very high efficiency which allows mutations to be interrogated with ultra-high sensitivity.

11:20 FEATURED PRESENTATION: Comprehensive Multi-Center Assessment of Small RNA-Seq Methods for Quantitative miRNA Profiling

Muneesh Tewari, MD, PhD, Professor, Internal Medicine & Biomedical Engineering, University of Michigan Medical School

Small RNA sequencing is a commonly used technology for profiling microRNAs for which diverse library preparation approaches exist and are known to have biases. I will describe results from a multi-center study involving nine laboratories in which we assessed the bias, accuracy and reproducibility of multiple protocols with respect to quantitative microRNA profiling using standardized reference samples.

12:05 pm Session Break

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:45 Session Break

ISOLATING & ANALYZING CTCs & ctDNA

2:00 Chairperson's Remarks
Janusz Rak, MD, PhD, Professor of Pediatrics, Experimental Medicine and Biochemistry, McGill University

2:05 Illuminating Asian Cancers: Detecting Cancer-Associated Genomic Alterations and Viral DNA Using Liquid Biopsy
Jack Challis, PhD, Director, Healthcare Analytics, Lucence Diagnostics

Liquid biopsy provides non-invasive targeted detection of somatic cancer-associated variants in blood, including: tumor-derived mutations, structural rearrangement, microsatellite instability (MSI), and cancer-derived viral DNA. This disruptive technology bears particular promise for Asian patients in improving cancer screening, management, and recurrence monitoring across the region. Lucence Diagnostics has developed an enhanced error-correction sequencing platform (AmpliMARK™) to detect somatic-associated cancer variants commonly found in high-prevalence Asian cancers.

2:35 Leukocytes as a Reservoir of Oncogenic DNA in Blood
Janusz Rak, MD, PhD, Professor of Pediatrics, Experimental Medicine and Biochemistry, McGill University

We investigated the distribution of extracellular oncogenic gDNA sequences (HRAS and HER2) in the circulation of tumor-bearing mice. Surprisingly, circulating leukocytes, especially neutrophils, contained the highest levels of mutant gDNA, which exceeded the amounts recovered from soluble fractions of plasma, extracellular vesicles, platelets, erythrocytes and peripheral organs, as quantified by digital droplet PCR. Tumor excision resulted in disappearance of the leukocyte-associated gDNA signal according to the half-life of these cells.

3:05 Profiling cfDNA using Targeted and Unbiased Genomic Methods for Biomarker Discovery and Residual Disease Detection *Sponsored by* DISCOVERY LIFE SCIENCES
Shawn Levy, PhD, CSO, Genomics, Discovery Life Sciences

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 Diagnosis of Low Burden Tumors Using Circulating Cell-Free DNA
Milana Frenkel-Morgenstern, PhD, Head, Cancer Genomics and BioComputing of Complex Diseases Lab, The Azrieli Faculty of Medicine, Bar-Ilan University

Gliomas are the most malignant brain tumors worldwide. Diagnosis of the glioma tumor type and its grade is a most essential step to suggest a personalized treatment for the patients. We present a comprehensive study of the brain tumors with a low burden in plasma, matched with the cfDNA extracted from a clinical cohort of patients' plasma, to find unique tumor fusion genes as biomarkers.

4:45 Analyzing Circulating Tumor Cells for Molecular Mechanisms of Metastasis
Min Yu, MD, PhD, Assistant Professor, Department of Stem Cell Biology and Regenerative Medicine, Norris Comprehensive Cancer Center, Keck School of Medicine, University of Southern California

Circulating tumor cells (CTCs) are expected to contain metastasis-initiating cells that can shed light on the mechanisms of cancer metastasis. However, due to limited patient-derived material, the metastatic capability of CTCs has yet to be proved. Using our recently established patient-derived CTC lines, we found that different patient CTC lines demonstrated distinct metastatic tissue tropisms in immunodeficient mice and identified associated pathways to specific organs via RNA-seq and ATAC-seq analysis.

5:15 Capiocyte: A Highly Sensitive Circulating Tumor Cell Capture Assay for Improving Cancer Management
Andrew Z. Wang, MD, CEO, Capio Biosciences

This presentation will discuss the development of CapioCyte CTC technology. We will examine the innovations in CapioCyte that improves the sensitivity and specificity of CTC capture. We will then share our clinical findings using CapioCyte.

5:35 Close of Day

WEDNESDAY, JUNE 19

8:00 am Breakfast Breakout Discussion Groups

Chew over continental breakfast and thought-provoking 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.

EXPLORING EXTRACELLULAR VESICLES

9:15 Chairperson's Remarks
Xianghong Jasmine Zhou, PhD, Professor, Pathology and Laboratory Medicine, University of California, Los Angeles

9:20 Post-Translationally Modified Proteins in Extracellular Vesicles as Disease Biomarkers: Promise and Challenges
W. Andy Tao, PhD, Professor, Departments of Chemistry and Biochemistry, Purdue University

The state of protein modification can be a key determinant of cellular physiology such as early stage cancer. Here we demonstrate, for the first time, a strategy to isolate and identify glyco- and phospho-proteins in extracellular vesicles (EVs) from human plasma as potential markers to differentiate disease from healthy states. Using label-free quantitative proteomics, we identified proteins with PTMs in plasma EVs that are significantly higher in patients diagnosed with breast cancer as compared to healthy controls.

9:50 Exomeres: A Novel Population of Extracellular Nanoparticles Identified as Potential Biomarkers
Haiying Zhang, PhD, Assistant Professor, Department of Cell and Developmental Biology in Pediatrics, Weill Cornell Medicine

Tumor cells secrete a variety of soluble factors and extracellular particles/vesicles to mediate intercellular communication. We recently identified exomeres as a novel population of nanoparticles secreted by tumor cells. These nanoparticles are smaller than 50nm, lack external membranous structure, and have unique protein, lipid, DNA and RNA profiles and biophysical properties. Exomeres are released into various types of body fluids, therefore representing a novel potential biomarker for lipid biopsy.

10:05 Sponsored Presentation *(Opportunity Available)*

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

EVALUATING EPIGENETIC MARKERS

11:00 Ultrasensitive Detection of Cancer Using cfDNA Methylation Sequencing
Xianghong Jasmine Zhou, PhD, Professor, Pathology and Laboratory Medicine, University of California, Los Angeles

The detection of tumor-derived cell-free DNA in plasma is one of the most promising directions in cancer diagnosis. The major challenge in such an approach is how to identify the tiny amount of tumor DNAs out of total cell-free DNAs in blood. Here we propose an ultrasensitive cancer detection method, termed 'CancerDetector', using the DNA methylation profiles of cell-free DNAs.

11:30 Reimagining Liquid Biopsy Applications with Epigenomics
Samuel Levy, PhD, CSO, Bluestar Genomics

Epigenomic events like DNA methylation and hydroxylation appear to underpin gene suppression and the process of gene activation respectively. The ability to detect hydroxymethyl cytosine (5hmC) through precise labelling methodologies enables their application to cell free DNA (cfDNA). 5hmC labelling, NGS sampling and machine learning algorithms can detect cancer patients with high sensitivity and specificity. We will describe the application of this methodology to detect the presence of cancer and the nature of the underlying disease.

11:50 Applying New cfDNA Lab and Computational Methods to Analysis of Liquid Biopsies from Breast Cancer Patients
Jadwiga Bienkowska, PhD, Senior Director, Computational Biology, Oncology Research and Development, Pfizer

We have developed a custom 87-gene NGS assay to identify single nucleotide variants and copy number amplification (CNA) in liquid biopsies. The assay utilizes molecular barcoding, high NGS coverage (10,000-20,000 reads per nucleotide position), and background error correction algorithms to achieve high sensitivity. We have applied this assay to profile pre and post-treatment liquid biopsies from metastatic BrCa patients.

12:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:50 Session Break

MONITORING PATIENTS' ANALYTES FOR TREATMENT RESPONSE

1:30 Chairperson's Remarks
Manish Kohli, MD, Vice Chair, Department of Genitourinary Oncology, Director, DeBartolo Family Personalized Medicine Institute, H. Lee Moffitt Cancer Center

1:35 Analysis of Circulating Tumor Cell and the Epithelial Mesenchymal Transition (EMT) Status during Eribulin-Based Treatment in Patients with Metastatic Breast Cancer
Yoshiya Horimoto, MD, PhD, Lecturer, Department of Breast Oncology, Juntendo University School of Medicine

Using a Microfluidic Chip device, we investigated CTCs from 22 patients with metastatic breast cancer who had received eribulin-based treatment. Numbers of total (mesenchymal and epithelial) CTCs were significantly increased in patients with progressive disease during treatment. A small number of total baseline CTCs were related to long progression-free survival. Determining both mesenchymal and epithelial CTCs at baseline might be a good tool for predicting eribulin responsiveness.

2:05 Tracking MSI Status in Liquid Biopsies from MSI-H Colorectal Cancer Subjects on Immunotherapy
Pamela Ward, PhD, Associate Professor, Pathology, University of Southern California

The success of checkpoint inhibitors in the treatment of patients with colorectal cancers displaying microsatellite instability underscores the need for novel technologies to evaluate the progression of such instability to enable monitoring of therapeutic response. We have conducted research in monitoring the MSI status of liquid biopsies from MSI-H colorectal cancer patients to determine if MSI has the potential to be used as a biomarker for immunotherapy response.

2:35 Real-Time Application of ctDNA Testing for Patients with Gastrointestinal Malignancies
Pashtoon Murtaza Kasi, MD, MS, Assistant Professor, College of Medicine and Oncology, University of Iowa

This talk will illustrate the feasibility and value of real-time application of ctDNA testing in patients with GI malignancies. We have been able to integrate the use of 'liquid biopsies' into standard of care for our metastatic cancer patients. Its use has been complementary to comprehensive, tissue-based genetic testing. Clinical trials incorporating some of the commercially available platforms that are open or in development will also be discussed.

3:05 Atlas of Plasma Cell Free DNA (cfDNA) Based Somatic Aberrations in Metastatic Hormone Sensitive Prostate Cancer (mHSPC) and Metastatic Castration Resistant Prostate Cancer (mCRPC) States and the Impact on Survival
Manish Kohli, MD, Vice Chair, Department of Genitourinary Oncology, Director, DeBartolo Family Personalized Medicine Institute, H. Lee Moffitt Cancer Center

We identified plasma cell free DNA (cfDNA) based copy number variations (CNV); single nucleotide variants (SNVs) & TMPRSS-ERG fusion in four sub states of metastatic prostate cancer (mPCa) and determined the impact on survival. Plasma cfDNA based somatic aberrations were detected in metastatic hormone sensitive PCa (mHSPC) and with greater prevalence in the more advanced metastatic castration resistant PCa (mCRPC) state. AR amplification was prognostic in mCRPC state and SNVs in ATM/CHEK2 were predictive for shorter response to androgen deprivation efficacy in mHSPC.

3:35 Treatment Monitoring and Residual Disease Detection Using Personalized Circulating Tumor DNA Analysis
Bradon R. McDonald, PhD, Computational Scientist, Center for Non-invasive Diagnostics, Translational Genomics Research Institute (TGen)

Accurate treatment monitoring can guide individualized management of cancer patients, but current diagnostic approaches lack adequate sensitivity. We have developed TARDIS to simultaneously analyze multiple patient-specific cancer mutations from plasma DNA. We observed 93.5% sensitivity in control samples (mutation fraction: 1%-0.03%) from only 5-8ng of DNA, and find a strong association between ctDNA detection and disease presence in clinical samples from early stage patients. TARDIS shows promise as a useful tool for enabling non-invasive monitoring of tumor dynamics.

4:05 Conference Wrap-up
Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

4:15 Close of Conference

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For sponsorship and exhibit information, please contact:

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HOTEL & TRAVEL INFORMATION

CONFERENCE VENUE & HOTEL:

Holiday Inn San Francisco - Golden Gateway

1500 Van Ness Avenue
San Francisco, CA 94109
Phone: 415-441-4000

Reservations:
Go to the travel page of LiquidBiopsySummit.com

Discounted Room Rate: $249 s/d

Discounted Room Rate Cut-off Date: May 20, 2019

Go to the travel page of LiquidBiopsySummit.com for additional information.