CANCER DIAGNOSIS AT THE CROSSROADS

PRECISION MEDICINE DRIVING CHANGE

SEPTEMBER 15-17, 2014 | SHERATON SEATTLE HOTEL | SEATTLE, WA

KEYNOTE SPEAKERS:

Carolyn Compton, M.D., Ph.D.
National Biomarkers Development Alliance, Complex Adaptive Systems Institute, Mayo Medical School and Arizona State University

James M. Olson, M.D., Ph.D.
Fred Hutchinson Cancer Research Center, University of Washington, Seattle Children’s Hospital, Presage Biosciences and Blaze Bioscience

Nathan D. Price, Ph.D.
Institute for Systems Biology

John T. Slattery, Ph.D.
University of Washington School of Medicine

SUNDAY, SEPTEMBER 14
• Complimentary Onsite Laboratory Tour and Reception: University of Washington’s Center for Cancer Innovation

TUESDAY, SEPTEMBER 16
• Short Course: Biobanking Operations Management

THURSDAY, SEPTEMBER 18
• Seminar: Informed Consent Content & Process Requirements for Biobanking Studies

REGISTER BY AUGUST 15TH & SAVE UP TO $150!
Tumor collections provide insight into the great variability of cancer, its progression and its response to treatment. Patient xenografts (PDX) and cell models allow researchers to link and integrate information and determine personal variations in cancer molecular profiles. The recent advancements in high-throughput genomics, proteomics and other -omics platforms allow profiling of large numbers of cancer analytes in a single assay. Thus, knowledge of these altered molecular landscapes offers great promise for developing molecular tests to improve cancer diagnosis and optimize treatment. Cambridge Healthtech Institute’s Inaugural Cancer Diagnosis at the Crossroads: Precision Medicine Driving Change convenes international oncology experts in the fields of tumor biospecimen research, PDX models, molecular diagnostics/prognostics and pharmacogenomics.

SUNDAY, SEPTEMBER 14

ONSITE LABORATORY TOUR AND RECEPTION:
UNIVERSITY OF WASHINGTON’S CENTER FOR CANCER INNOVATION
(Limited to 50 participants)
6:00-8:00 pm

Join your colleagues for an evening of networking at the University of Washington’s Center for Cancer Innovation (CCI) at UW Medicine’s South Lake Union Research Campus.

- Hear about a novel approach to advancing clinical cancer research and personalized medicine
- Visit the Quellos High Throughput Screening Core facility

A networking reception precedes and follows the tour.

The tour and reception are hosted by NWBioTrust (NWBT), a collaborative project between Fred Hutchinson Cancer Research Center, Institute of Translational Health Sciences, Seattle Cancer Care Alliance, Seattle Children’s Hospital and University of Washington Medicine. This innovative hub-and-spokes resource system connects donated biospecimens from consenting individuals with innovative research projects aimed at advancing biomarker discovery and improving prevention, diagnosis and treatment of human disease.

5:30 pm Check-in for Laboratory Tour
5:45 Shuttle Service to Laboratory Tour
*Complimentary roundtrip shuttle service to and from the Sheraton Seattle Hotel

6:00 Reception Begins and Continues until 8:00
*Includes light food and beverage

6:05 Welcome from NWBioTrust Director, Stephen Schmechel, M.D., Ph.D.
6:10 University of Washington’s Center for Cancer Innovation
6:30 Tours of Quellos HTS Core Begin
*Anticipate 3 Groups Starting at 6:30, 6:50 and 7:10
7:30 Tours of Quellos HTS Core Conclude
8:00 Reception Concludes; Board Shuttle and Return to Hotel
8:15 Close of Day
For updates, please visit healthtech.com/Precision-Medicine-Cancer
**Plenary Keynote Session: Defining Precision Medicine - It Takes a Village**

**8:30 Welcome and Chairperson’s Opening Remarks**
Michael Dorschner, Ph.D., Research Assistant Professor, Psychiatry & Behavioral Sciences and Pathology and Adjunct Professor, Genome Sciences and Laboratory Medicine, University of Washington; Director, Northwest Genetic Genomics Laboratory, Center for Precision Diagnostics

**8:40 Northwest BioTrust: Consented Specimens, Medical Data and Patient Registry**
John T. Slattery, Ph.D., Vice Dean, Research and Graduate Education, School of Medicine and Professor, Pharmacology and Medicine, University of Washington School of Medicine

The guiding principles and formation of Northwest BioTrust, a system that collects and distributes consented medical data and specimens, and identifies patients interested in participating in clinical research from patients encountering the UW Medicine and Seattle Cancer Care Alliance, will be discussed.

**9:25 The National Biomarkers Development Alliance (NBDA): Advancing Biomarkers Development for Precision Medicine Beginning with Biospecimens**
Carolyn Compton, M.D., Ph.D., CMO, National Biomarkers Development Alliance; CMO, Complex Adaptive Systems Institute; Adjunct Professor, Pathology, Mayo Medical School; Professor, School of Life Sciences, Arizona State University

The development of new robust biomarkers is essential to the realization of the vision of precision medicine. At present, the high costs and failure rates in biomarker development represent a significant roadblock to medical progress. The biomarker development process itself requires re-engineering, beginning with standards for biospecimens, to reduce the massive inefficiencies, fragmentation and failure rates that now characterize the system. This can only be accomplished through broad coordination of effort and consensus, which is the goal of the NBDA.

**10:10 Coffee Break**

**10:30 Integrating the Principles of Preventative and Personalized Medicine to Advance Wellness**
Nathan D. Price, Ph.D., Associate Director, Institute for Systems Biology

Radical, exponentially accelerating technological advancements are enabling individuals to gain greater control over their health than ever before. These endeavors focus on unlocking the power of an expanding array of scientific discoveries and deliver simple, actionable information to each individual to maximize health and minimize disease – even eliminating it at its earliest stages. I will discuss the beginnings of our ISB 10K wellness project aimed at providing a proof-of-concept study for these new approaches to optimizing wellness and minimizing disease.

**11:15 Avatar Models of Rare Pediatric Cancer: An International Resource**
James M. Olson, M.D., Ph.D., Member, Clinical Research Division, Fred Hutchinson Cancer Research Center; Professor, Pediatric Hematology and Oncology, University of Washington; Attending Physician, Seattle Children’s Hospital; Founder, Presage Biosciences and Blaze Bioscience

To enable drug discovery and development tailored to pediatric brain tumors, we created > 30 PDX models (avatars) of pediatric brain cancer. Fred Hutchinson Center’s lab team implanted surgically resected patient cells into mouse brains typically within hours of surgery. The tumors in mice were propagated through multiple passages and extensive genomic profiling was conducted to relate the avatars to the original patient sample. With philanthropic support, these models are available to investigators globally to enable discovery and translational science.

**12:00 pm Close of Session**

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

**Multiple Paths Lead to Precise Cancer Medicine**

**2:00 Chairperson’s Remarks**
Walter C. Darbonne, Group Leader, Clinical Assays and Technologies Group, Oncology Biomarker Development, Genentech, Inc.

**2:05 Developing an Institutional Cancer Biorepository for Personalized Medicine**
Angen Liu, M.D., Ph.D., Director, Specimen Accessioning Core, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University

High-quality human biospecimens and associated patient clinical information are key elements of a scientific infrastructure that supports discovery and identification of molecular biomarkers and diagnostic agents. The availability of low-cost whole-genome profiles of individual tumors has opened up new possibilities for personalized medicine to deliver appropriate treatments to individual patients with minimal toxicity. Reliable access to high-quality biospecimens with patient clinical information is crucial. With new genetic and proteomic techniques being developed continuously, the biorepository will greatly advance personalized medicine.

**FEATURED PRESENTATION**

**2:35 A Patient-Scientist Partnership to Characterize and Defeat a Rare Pediatric Cancer: Fibrolamellar Hepatocellular Carcinoma**
Sanford M. Simon, Ph.D., Professor, Laboratory of Cellular Biophysics, The Rockefeller University

The ability to study rare cancers is limited by the number of patients that are seen in any one institution. This limitation was overcome by the formation of a patient-driven partnership. Patients used social media (Facebook and YouTube) to reach other patients to form a tissue repository, a patient medical registry, and to raise funds. Patients also worked in the lab on the analysis of genomic and cellular data which led to a publication in Science with two of the patients as authors. The results are forming the basis of two clinical trials.

**3:05 Are You Prepared for the Next Research Question? Optimising the Value of Your Biospecimens Collections**
Katheryn Shea, Vice President, Bioservices, Precision for Medicine

The clinical trials you’re running today can be the key to the next discovery. This talk will cover the essentials required to consent, collect and characterize your biospecimens for future use scenarios to streamline your biomarker research, reduce costs and optimize quality results and data.

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

**4:15 Patient-Derived Xenograft (PDX) Models of Human Cancers towards Identifying Tumor-Initiating Cells and Discovery of Patient-Specific Therapeutics**
Vinagolu K. Rajasekhar, MSc, MPhil, Ph.D., Senior Research Scientist, Memorial Sloan-Kettering Cancer Center

Why, to date, have none of the conventional biobanks for patient tumor specimens delivered on our goals for a cancer cure? What is the live tumor tissue banking approach and how it can help recreate the original parent tumor heterogeneity and also form a renewable tumor tissue resource? How does live biobanking facilitate identification of cancer stem cells and discovery of patient-specific therapeutics? We discuss the importance of warm autopsies, live tissue bankonomics and sustainability of viable tumor banks.

**4:45 Fluorescently Labeled Chimeric Anti-CEA Antibody Improves Detection and Resection of Gastrointestinal Cancers in Patient-Derived Orthotopic Xenograft (PDX) Nude Mouse Models**
Michael Bouvet, M.D., Professor, Surgery; Director, Endocrine Surgery; Co-Director, GI Cancer Unit, Moores Cancer Center, University of California San Diego

Surgeons face many challenges when attempting curative resection for gastrointestinal cancers. The ability to properly delineate tumor margins for complete resection is of utmost importance in achieving cure and giving the patient the best chance of prolonged survival. Using unique characteristics of the tumor to fluoroscence label.
CURRENT AGENDA

the tissue can delineate tumor margins from normal surrounding tissue, allowing improved precision of surgical resection. We discuss different methods of fluorescently labeling native tumor as well as the development of fluorescence laparoscopy and potential role for fluorescence-guided surgery in the treatment of gastrointestinal cancers.

5:15 Novel Technologies Enabling Exploratory Biomarker Analysis in the Clinic
Walter C. Darbonne, Group Leader, Clinical Assays and Technologies Group, Oncology Biomarker Development, Genentech, Inc
Biomarker analysis of tumor biopsies is essential for prognostic and predictive purposes, to identify new drug targets and to understand drug resistance mechanisms. Since the availability of archival patient samples are often extremely limited, we have focused our efforts to develop technologies that increase the sensitivity of molecular analysis of FFPE tissues, allow high degree of multiplexing and minimize the RNA/DNA input requirements for assays, while ensuring robust and high-quality data. Several such approaches will be discussed.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing
Sponsored by illumina

6:30 Close of Day

TUESDAY, SEPTEMBER 16

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

8:00 Brainstorming Breakfast Discussion Groups
Grab a cup of coffee and join a discussion group. 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.

Table 1: Key Hurdles in Biomarker Development
Chad R. Borges, Ph.D., Assistant Professor, Chemistry and Biochemistry, The Biodisgn Institute – Center for Personalized Diagnostics, Arizona State University
How do we improve our approaches to matching clinical needs for cancer markers with analytical scientists and their platforms?
• The biospecimen procurement process: dos and don’ts
• What constitutes acceptable marker validation?
• How do we efficiently transition from discovery platforms to viable clinical platforms? When might transition not be necessary?

Table 2: Historical Samples for Biobanking
Allison Hubel, Ph.D., Professor, Mechanical Engineering and Director, Biopreservation Core Resource, University of Minnesota
• How do we define what a “historical sample” is?

Table 3: Sample Annotation: Investing in the Future and the Value
Michael Liebman, Ph.D., Managing Director, IPO Analytics, LLC
• What is the live tumor tissue banking approach and how it can help recreate the original parent tumor heterogeneity and also form a renewable tumor tissue resource?
• How do we garner public support for pediatric biobanks?
• What constitutes acceptable marker validation?
• What level of patient/sample annotation is critical?
• Can this exist in a linkable database or does it have to be embedded with the sample?
• Anonymization vs. de-identification: Creating value in the biobank and its use

Table 4: Biospecimens and Whole-Genome Sequencing: Are There New Considerations for Privacy and Data Sharing?
Geoffrey P Lomax, Ph.D., Senior Officer, Standards Working Group, California Institute for Regenerative Medicine
Is whole genome sequencing appropriate for “historical” samples?
• What access controls, if any (e.g., open access vs. controlled access) should be imposed on “raw” sequencing data to protect donors’ privacy interest?
• Does genomic characterization create substantial new risks to donors, families or groups? Can potential risks be effectively mitigated?

Table 5: Population-Based and Disease-Oriented Biobanking for the Biopreservation of Liquid-Based Gynecological Cell Samples
Nasrin Persikivist, Ph.D., Director and National Coordinator, Cervical Cytopology Biobank, Pathology and Cytology, Karolinska Institute and BBMRI.se
Legal and ethical aspects of a population-based and hospital-integrated biobank: How far are we willing to go?
• The process of moving from a regionally based Cervical Cytopology Biobank to a national infrastructure: Is it applicable to the full scope of the population?
• Providing samples to researchers without any risk of leaving insufficient sample volumes for the care of the woman herself: Quality vs. Quantity

Table 6: Patient-Derived Xenograft (PDX) Models of Human Cancers towards Identifying Tumor-Initiating Cells and Discovery of Patient-Specific Therapeutics
Vinagolu K. Rajasekhar, MSc, MPhil, Ph.D., Senior Research Scientist, Memorial Sloan-Kettering Cancer Center
Why, to date, have none of the conventional biobanks for patient tumor specimens delivered on our goals for a cancer cure?
• What is the live tumor tissue banking approach and how it can help recreate the original parent tumor heterogeneity and also form a renewable tumor tissue resource?
• How do we garner public support for pediatric biobanks?

Table 7: Ethical Considerations in Building Future Use Collections
Katheryn Shea, Vice President, Bioservices, Precision for Medicine
• Key considerations in creating informed consent language
• Global challenges and regulatory differences that affect designing your future use collection

Table 8: Pediatric Participants in Biobanks
Suzanne Vercauteren, M.D., Ph.D., FRCP, Head, Division of Hematopathology, BC Children's Hospital and Clinical Assistant Professor, Pathology and Laboratory Medicine, University of British Columbia
• Does the opinion of children of non-consenting age matter? At what age?
• Do we need to reconsent at age of majority?
• How do we garner public support for pediatric biobanks?
• How can we improve the quantity and quality of pediatric specimens?

Table 9: Biobanking: How Can Collections Be Maximized without Dedicated Funding?
Wendell G. Yarbrough, M.D., MMHC, FACS, Professor of Surgery, Otolaryngology and Pathology; Section Chief, Otolaryngology; Co-Director, Molecular Virology Research Program; Director, Head and Neck Cancer Program, Smilow Cancer Hospital, Yale University
• Collaborations with researchers who have LN and -80oC storage
• Engagement of clinicians interested in the disease
• Engagement of pathologists

Genomics’ Role in Individualized Cancer Therapy from Assay Development to Clinical Implementation

9:00 Chairperson's Remarks
Colin C. Pritchard, M.D., Ph.D., Assistant Professor and Associate Director, Genetics and Solid Tumors Laboratories, Laboratory Medicine, University of Washington

9:05 Bringing Comprehensive Molecular Information into Routine Clinical Care
Josephine N. Harada, Ph.D., MBA, Director, Strategic Alliances, Foundation Medicine, Inc.
Oncology has experienced a recent paradigm shift toward thinking about cancer as a disease of the genome. Next-generation sequencing has furthered our understanding of cancer biology and let us more comprehensively characterize the genomic alterations in an individual patient’s cancer. This profiling approach enables precision medicine in clinical cancer care. Its widespread use could provide more treatment options and enable more rapid accrual to ongoing and planned trials of agents targeting pathways under study, thereby continuing to advance precision medicine.

9:35 Successful Implementation of Precision Medicine in Clinical Cancer Care: The UW Experience
Colin C. Pritchard, M.D., Ph.D., Assistant Professor and Associate Director, Genetics and Solid Tumors Laboratory, Laboratory Medicine, University of Washington

Genomic sequencing technology for diagnostic testing is especially promising for cancer patients, both for hereditary cancer risk assessment and for tumor-based sequencing for precision cancer therapy. Since 2011, the UWMC genetics lab has offered clinical assays for precision medicine in clinical cancer care that harness genomic next-generation sequencing. We will review considerations related to clinical implementation of this technology and cover gene panels currently in clinical use for cancer patients and their families at UW and SCCA.

10:05 Next-Generation Applications for Personalised Genomics: from CARTaGENE to the Clinic
Philip Awadalla, Ph.D., Professor, Faculty of Medicine, University of Montreal; Director, CARTaGENE

CARTaGENE was developed to produce an internationally competitive, cohort-based biobank facilitating the emergence of new and novel research projects. As a result, these investigations will generate new healthcare knowledge for and about Quebec, Canada and the international community. By acting as a springboard, scientists can expand their research questions by investigating the genomic, metabolomic, epigenomic and environmental control points of complex chronic disorders and related quantitative traits. My own research program has exploited the deep clinical and phenotypic data collected from over 40,000 participants to discover novel genomic factors associated with disease and quantitative traits.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Development and Validation of a Clinical Trial Patient Stratification Assay that Interrogates 27 Mutation Sites in MAPK Pathway Genes
Ken C. N. Chang, Ph.D., Clinical Assay Development and Outsourcing Lead, Clinical Biomarkers and Diagnostics, Merck & Co., Inc.

A custom-designed Single Nucleotide Primer Extension (SNPE) multiplexing mutation assay was developed and analytically validated as a clinical trial assay for more than 30 specific mutations among three targeted RAS/RAF oncogenes. We used next-generation sequencing to resolve discordant calls between the SNPE mutation assay and Sanger sequencing. We also applied a triplicate rule to reduce potential false positives and false negatives, and proposed special considerations for clinically significant level of mutations including pre-defining a cut-off percentage for each mutant and wild-type.

11:45 Integrating Laboratory and Clinical Informatics for Next-Generation Sequencing Assays
Noah Hoffman, M.D., Ph.D., Assistant Professor, Laboratory Medicine, University of Washington

Next-generation sequencing assays, like human germline and somatic mutations surveys and deep sequencing of mixed bacterial populations, introduce significant complexity to the laboratory and healthcare system. To manage this complexity, our laboratory has invested heavily in staff and infrastructure to support data analysis, interpretation and clinical reporting. We will discuss challenges encountered related to quality control, data management, case signout and reporting into electronic medical records, and describe approaches for addressing these challenges within the UW Medicine healthcare system.

12:15 pm Close of Session

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

Deciphering Cancer’s Complexity Takes Multidisciplinary Integration

2:00 Chairperson’s Remarks
Sui Huang, M.D., Ph.D., Professor, Institute for Systems Biology

2:05 Glycan “Node” Analysis for Detecting and Monitoring Cancer
Chad R. Borges, Ph.D., Assistant Professor, Chemistry and Biochemistry, The Biodesign Institute – Center for Personalized Diagnostics, Arizona State University

Cancer biologists have known for many years that tumor cells display abnormal glycan structures. Dr. Borges has developed a technique to quantify glycan structural characteristics in blood serum that provides a completely new angle by which to leverage glycans as markers to identify and classify cancer. Results from studies of lung cancer and several other different types of cancer will be presented.

2:35 Integrative Genomic Analysis of Gastric Cancer
Kai Wang, Ph.D., Principal Scientist, Computational Biology and Precision Medicine, Pfizer Oncology

Gastric cancer is a heterogeneous disease with diverse molecular and histological subtypes. We performed comprehensive genomic profiling in a large cohort of gastric cancers for integrative genomic analysis. Our data revealed subtype-specific genetic, epigenetic perturbations and unique mutational signatures. We identified previously known (TP53, ARID1A and CDH1) and new significantly mutated driver genes. These findings illustrate a multidimensional and comprehensive genomic landscape that highlights the molecular complexity of gastric cancer and provides a roadmap to facilitate genome-guided personalized therapy.

3:05 Selected Oral Poster Presentation: Development of Statistical Process Control Parameters for Tissue Quality in a Pregnancy-Related Biorepository
Donald O. Chaffin, Laboratory Manager, Global Alliance to Prevent Prematurity and Stillbirth (GAPPS), Seattle Children’s Hospital

It is vital that specimens obtained though biobanks preserve a level of quality consistent with research needs. Several factors can impede this goal: the heterogeneous nature of starting materials, artifacts introduced by collection, processing and storage and the often destructive nature of test regimes. It is a requisite that specimens are robustly characterized against a set of normative values which can determine suitability for use and that the effects of post-collection events are known and remain “in control” with respect to these values. We present the quality control regime for placental tissue collected by the GAPPS repository, a pregnancy-related biobank, with a cohort of over 1540 women. This regimen sets the expectation for achievable quality levels with the current protocols and allows evaluation of collection design changes to increase quality and lower variance. The use of statistical process control methods described here assure consistent specimen quality and can drive future improvement in methods of collection.

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

4:00 Complex Cell Response to Therapy as Basis for Therapy Resistance in Cancer Cells: “What Does Not Kill Me Makes Me Stronger”
Sui Huang, M.D., Ph.D., Professor, Institute for Systems Biology

Current cancer research operates with the tacit assumption that our understanding of cancer cell behavior is established, and all that is needed is to identify new molecular targets and target them. But as single-cell analysis and new theories reveal, beyond this paradigm exists the realm of complex adaptive systems dynamics, endowing cancer cells with the unfathomable ability to act collectively as a population to mount an evasive response to treatment, allowing non-killed cells to become even more malignant.
CURRENT AGENDA

4:30 Molecular Alterations and Biomarkers in Colorectal Cancer
William M. Grady, M.D., Director, Translational Research and Rodger C. Haggitt Professor, Gastroenterology; School of Medicine, University of Washington Medical Center; Medical Director, GI Cancer Prevention Program, Seattle Cancer Care Alliance; Member, Clinical Research Division, Fred Hutchinson Cancer Research Center

The promise of precision medicine is a clinical reality. Our advanced understanding of the molecular genetics of colorectal cancer is helping us develop biomarkers that are being used as early detection markers, prognostic markers and markers for predicting treatment responses. We will discuss our current understanding of the molecular pathogenesis of colorectal cancer and how these alterations relate to emerging biomarkers for early detection and risk stratification (diagnostic markers), prognosis (prognostic markers) and the prediction of treatment responses (predictive markers).

5:45-9:00 DINNER SHORT COURSE: WHAT IT TAKES TO BE A BIOBANKING OPERATIONS MANAGER: FROM PATIENT INTERACTION TO FREEZER INSPECTION*

Learning Objectives
- Share effective program and project launches
- Describe program governance
- Explain the establishment of a strong communication plan
- Discuss quality assurance and control
- Describe the process of controlling and mitigating risk
- Provide tips for managing stakeholder expectations
- Explain the importance of properly closing a project
- Provide guidelines for formatting and streamlining an SOP
- Discuss the contents to include in different SOP sections
- Describe training records and how to best maintain them
- Share the factors and circumstances a site auditor will want to see
- Describe the process of version controlling both training records and SOPs
- Explain disaster management and the need for backup SOPs

Who Should Attend
- Biobank and Biorepository Operations Managers
- Sample Collection and Storage Administrators
- Nurses
- Research Scientists

Instructors
Stephanie Frahm, Senior Project Manager and Technology Developer, RUCDR Infinite Biologics, Rutgers University
Coleen M. Mitchell, Joint Biorepository Operations Manager, Indiana University Genetics Biobank and Indiana Biobank

Course Length and Time
3.25 hours 5:45 – 9:00 p.m.

Course Date
September 16, 2014

FEE: $699 Commercial/ $399 Academic, Government, Hospital-Affiliated

ACCREDITATION
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 3.25 hours (0.325 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion.

ACPE#: 0778-0003-14-091-L01-P
Released: 9/14.

*Separate registration required

WEDNESDAY, SEPTEMBER 17

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

Patient-Derived Xenograft (PDX) Tumor Models: Bridging Bench to Bedside

8:15 Chairperson’s Remarks
James M. Olson, M.D., Ph.D., Member, Clinical Research Division, Fred Hutchinson Cancer Research Center; Professor, Pediatric Hematology and Oncology, University of Washington; Attending Physician, Seattle Children’s Hospital; Founder, Presage Biosciences and Blaze Bioscience

8:20 Next-Generation Patient-Derived Prostate Cancer Xenograft Models
Yuzhuo Wang, Ph.D., Senior Scientist, BC Cancer Agency and Vancouver Prostate Centre; Associate Professor, Urologic Sciences, University of British Columbia; Leader, Living Tumor Laboratory At the Living Tumor Laboratory, we have developed > 200 transplantable patient-derived “high fidelity” xenograft models (>30 prostate cancer models). These xenografts retain all the salient features of the donor tumor, including pathology, growth dynamics, global gene expression, genome structure and response to therapy including resistance development. The xenografts are powerful systems for development of novel therapeutics, cancer discovery and translational oncology. This presentation will focus on properties of such next-generation models and examples of their applications.

8:50 Understanding Cancer Stem Cells in Human Melanoma Using a Patient-Derived Tumor Xenograft Model
Mayumi Fujita, M.D., Ph.D., Associate Professor, University of Colorado Denver School of Medicine
To understand the complex biology of cancer stem cells in human melanoma, we established a patient-derived tumor xenograft (PDTX) model of human melanoma and used functional properties (side population and aldehyde dehydrogenase activity) to enrich cancer stem cells. We will explain how to isolate and analyze their properties using this model, show effects of tumor isolation methods on melanoma, we established a patient-derived tumor xenograft (PDTX) model of human melanoma and used functional properties (side population and aldehyde dehydrogenase activity) to enrich cancer stem cells. We will explain how to isolate and analyze their properties using this model, show effects of tumor isolation methods on
9:20 Patient-Derived Pancreatic Tumor Xenograft Models Bridging Preclinical Drug Discovery and Translational Clinical Development
Pia M. Challita-Eid, Ph.D., Director, Applied Molecular Biology, Agensys, Inc.

The advantage of PDX models over cell line xenograft models in predicting clinical efficacy of novel therapies has been largely realized in drug development. But are tumor characteristics stable and maintained during extensive passaging for drug screening? Whole-genome molecular characterization to compare genomic profiles of xenograft models to corresponding original patient tumors, and examination of models’ genomic stability after extensive passaging, validates the model and leads to important preclinical translational information guiding clinical trial designs using a precision medicine approach.

9:50 Advances in Patient-Derived Xenograft Models
Walter Ausserer, Ph.D., Senior Business Unit Manager, In Vivo Pharmacology Services

The Jackson Laboratory is investigating novel strategies for facilitating and accelerating PDX-based research. We have established an open resource of more than 300 early-passage tumors with detailed characterization data that can be queried by tumor site, gene variant and expression level. Many of these tumors are available off-the-shelf in engrafted mouse cohorts for rapid study enrollment.

11:00 Development of New Therapeutic Agents Targeting Key Cancer Stem Cell Pathways
Timothy Hoey, Ph.D., Senior Vice President, Cancer Biology, OncoMed Pharmaceuticals, Inc.

Cancer stem cells (or tumor-initiating cells) mediate tumor progression, metastasis and recurrence after therapy. Using our platform of patient-derived xenografts, we have developed first-in-class biologic agents that block key CSC pathways, including Notch, Wnt and RSPo-LGR. We have developed five therapeutics currently in clinical testing: anti-DLL4 (demcizumab), anti-Notch2/3, anti-Notch1, anti-FZD (vantictumab), and Fzd8-Fc. In addition, we have developed two new clinical candidates: anti-DLL4/VEGF and anti-Rspo3. These agents inhibit tumor growth through multiple mechanisms including a reduction of CSC frequency.

11:30 PANEL DISCUSSION: The Promise of Tumor Tissue and Cell Models for Personalized Medicine
Patient-derived xenograft and cell models help researchers reveal genomic variants in cancer patients that could lead to better tailored and more actionable clinical care. This panel brings together experts from academia and industry to discuss models and strategies for optimizing tumor collections via such models to improve cancer therapies.

12:00 pm Close of Session

Case Studies: Biobanker/Biouser Partnerships

Biomedical researchers and drug developers require accessible, high-quality biospecimens that allow them to extract reliable and useful data. Oncology experts, for instance, use patient-derived tumor collections to connect datasets, pinpoint and assess variants within cancer patients post-diagnosis and zero in on the data that matter when tailoring therapies. Early, strategic collaborations with the biobanks that house specimens can be mutually beneficial, maximizing the financial and technological investments of the operation managers who collect, store, annotate and distribute the biological samples (“biobankers”) and supporting the research goals of the scientists who need those samples (“biousers”) – all to fulfill the promise of personalized medicine.

This session brings together both partners in a co-presentation to illustrate their collaboration and elaborate on the following issues:

- How does the partnership work?
- What are the bottlenecks?
- What does each bring to the table?
- What are the needs?
- Ultimately, what are the scientific results?

1:30 Chairperson’s Remarks

1:35 Case Study #1: A Clinical Trial of Cellular Adoptive Immunotherapy in Patients with Melanoma: Integrating Biospecimen Procurement and Therapeutics
Sylvia M. Lee, M.D., Research Associate, Immunology Program, Clinical Research Division, Fred Hutchinson Cancer Research Center and Medical Oncologist, Seattle Cancer Care Alliance
Stephen Schmechel, M.D., Ph.D., Associate Professor, UW Medicine Pathology and Director, NWBioTrust, University of Washington

Infusion of tumor-infiltrating lymphocytes after combination chemotherapy may provide benefit in patients afflicted with melanoma. This presentation will highlight successful operationalization of a cellular adoptive immunotherapy clinical trial integrating biospecimen procurement and laboratory science.
2:20 Case Study #2: Implementation of a Centralized Biorepository at a Large Academic Medical Center

Victoria M. Blanc, Ph.D., Director, University of Michigan Health System Central Biorepository
W. Troy Shelton, M.S., P.M.P., Vice President, Operations, International Genomics Consortium

The University of Michigan Health System (UMHS) identified the need for a centralized biorepository due to the existing structure being fragmented, non-standardized and costly. A phased development of an individual investigator-driven UMHS Central Biorepository began from the ground up in early 2013. This case study describes lessons learned to date by the UMHS and The International Genomics Consortium (IGC), its partnering consultants.

3:05 Case Study #3: Talk Title to be Announced

Colin Collins, Ph.D., Professor, Urologic Sciences, University of British Columbia and Senior Research Scientist and Director, Laboratory for Advanced Genome Analysis, Vancouver Prostate Centre
Yuzhuo Wang, Ph.D., Senior Scientist, BC Cancer Agency and Vancouver Prostate Centre; Associate Professor, Urologic Sciences, University of British Columbia; Leader, Living Tumor Laboratory

3:50 Closing Remarks

4:00 Close of Conference

Post-Conference Event

THURSDAY, SEPTEMBER 18

Informed Consent Content and Process Requirements in Biobanking Studies*

8:30 am-5:00 pm

This course presents the elements of the informed consent document and the components of the process, specifically as they relate to biobanking studies.

Instructor: Elizabeth Ronk Nelson, MPH, Barnett International

Participants will receive 7 hours (0.7 CEUs) from Accreditation Council for Pharmacy Education for full participation.

For further information please visit barnettinternational.com

*Separate registration required
HOTEL & TRAVEL INFORMATION

Conference Hotel: Sheraton Seattle Hotel
1400 5th Avenue
Seattle, WA 98101
Telephone: 206-621-9000

Discounted Room Rate: $185 s/d
Discounted Cut-off Date: August 18, 2014

Why Stay at the Sheraton Seattle?
The Sheraton Seattle is a vibrant, modern slice of Seattle. Located in the heart of downtown, the Sheraton Seattle is just steps away from dining, shopping, sites and all the best Seattle has to offer. Meeting attendees receive complimentary wireless internet in their guest room, and access to the hotel’s state-of-the-art fitness center. Combine these with a modern business center and several restaurants on premises, and the Sheraton Seattle becomes the clear and easy choice for the conference attendee.

We understand that you have many choices when making your travel arrangements. Please understand that reserving your room in the CHI room block 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. Please use one of the following methods:
Call 1-800-433-1790 and use Conference code 8594BS
Go to www.aa.com/group and enter Conference code 8594BS in promotion discount box
Contact our designated travel agent, Rona Meizler at 617-559-3735 or Rona.Meizler@protravelinc.com

Car Rental Discounts:
Special discount rentals have been established with Hertz for this conference. Call Hertz directly at 800-654-3131 and reference our Hertz Convention Number (CV) 04KL0005
CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding and networking with specific prospects. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company’s needs and budget. Signing on early will allow you to maximize exposure to qualified decision makers.

Podium Presentations – Within Main Agenda!
Showcase your products/solutions to a guaranteed, targeted audience. Package includes a 15 or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding, access to cooperative marketing efforts by CHI, and more.

Breakfast & Luncheon Podium Presentations
Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner/Hospitality Suite
Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor’s objectives (i.e. purely social, focus group, reception style, plated dinner with specific conversation focus).

Exhibit
Exhibitors will enjoy facilitated networking opportunities with qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

*Additional branding & promotional opportunities are available!

For sponsorship and exhibit information, please contact:
Carolyn Benton
Business Development Manager
cbenton@healthtech.com
781-972-5412

Official Media Partner

Bio-IT World

Lead Sponsoring Publications

Genetic Engineering & Biotechnology News
nature
TheScientist
Science AAAS

Sponsoring Publications

Biopreservation and Biobanking
DDNEWS
INSIGHT
CLINICAL INFORMATICS NEWS

Web Partners

labroots
EIN NEWS
Pricing and Registration Information

**SHORT COURSES**

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
<th>Academic, Government, Hospital-affiliated</th>
</tr>
</thead>
<tbody>
<tr>
<td>One short course</td>
<td>$699</td>
<td>$399</td>
</tr>
<tr>
<td>Two short courses</td>
<td>$999</td>
<td>$699</td>
</tr>
</tbody>
</table>

**CONFERENCE PRICING**

STANDARD PACKAGE (Includes access to Cancer Diagnosis at the Crossroads: Precision Medicine Driving Change PLUS onsite tour of NWBiOTrusT, excludes short courses)

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
<th>Academic, Government, Hospital-affiliated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special Early Discount until May 30, 2014</td>
<td>$1899</td>
<td>$899</td>
</tr>
<tr>
<td>Early Discount until June 27, 2014</td>
<td>$1999</td>
<td>$999</td>
</tr>
<tr>
<td>Advanced Discount until August 15, 2014</td>
<td>$2099</td>
<td>$1069</td>
</tr>
<tr>
<td>Registrations after August 15 and on-site</td>
<td>$2249</td>
<td>$1129</td>
</tr>
</tbody>
</table>

- Yes, I will attend the Onsite Tour. (Included in Registration. Tour limited to first 50 participants.)

**CONFERENCE DISCOUNTS**

Poster Submission - Discount ($50 Off): Poster abstracts are due by August 15, 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.

**REGISTER 3 - 4th IS FREE:** Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

**Alumni Discount:** Cambridge Healthtech Institute (CHI) appreciates your past participation at any CHI conference. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an 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 David Cunningham at +1-781-972-5472

**POST-CONFERENCE EVENT**

(Requires access to Informed Consent Content & Process Requirements for Biobanking Studies ONLY)

| Registration Discount until August 15, 2014 | $800       | $700                                    |
| Registrations after August 15, 2014, and on-site | $1000       | $800                                    |

If you are unable to attend but would like to purchase the Cancer Diagnosis at the Crossroads: Precision Medicine Driving Change CD for $350 (plus shipping), please visit healthtech.com/biobanking. Massachusetts delivery will include sales tax.

---

How to Register: healthtech.com/precision-medicine-cancer

reg@healthtech.com
P: 781.972.5400 or Toll-free in the U.S. 888.999.6288
Please use keycode CGN F when registering