Register TODAY!

5th International

Leaders in Biobanking CONGRESS 2013

NOVEMBER 4-5, 2013

Sheraton Indianapolis City Centre
Indianapolis, IN

Maximizing Your Investment in Biospecimens

Don't Miss:

- **KEYNOTE PRESENTATIONS:**

  Andrew M. Dahlem, Ph.D., Eli Lilly and Company

  Norma J. Nowak, Ph.D., Empire Genomics LLC

  Anantha Shekhar, M.D., Ph.D., Indiana University School of Medicine

  Traci Runge, Breast Cancer Survivor and Stem Cell Therapy Recipient

- **Pre-Conference Events:**

  Short Course: Translational Medicine Collaborations

  Complimentary Onsite Tour of BioStorage Technologies & Reception

- **Post-Conference Event:**

  Informed Consent Content & Process Requirements for Biobanking Studies

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Organized by Cambridge Healthtech Institute

healthtech.com/biobanking

Today, biospecimen collections are used by multiple research groups for varying research aims, from basic research through clinicaltrials. A well-managed biobank is a critical prerequisite for high-quality biological research. The proper collection, processing, storage and tracking of biospecimens are critical components allowing researchers to better link molecular and clinical information. Thus,by necessity, biobanking is both a science and a business. Cambridge Healthtech Institute's Fifth Annual *Leaders in Biobanking: Maximizing Your Investment in Biospecimens* addresses both the **business** and **science** of biobanking, bringing together biomedical and biopharmaceutical researchers, regulators, biorepository managers and practitioners to investigate the best strategies for effective use of biospecimens within today's cutting-edge research.

Pre-Conference Events

Sunday, November 3

Short Course: Translational Medicine Collaborations* 1:30-4:30 pm

Because biospecimen collections exist to enhance many areas of biologicalscience, it is critical to establish processes that bridge the practical, daily operations of running biobanks and the needs of groups that access them. This short course presents academic, industry and diagnostics/non-profit perspectives on biorepository management approaches to ensure the research utility of samples are fit-for-purpose.

Instructors:

Partnerships in Biobanking: Biobanking Opportunities for Patients in the Community Hospital Setting

M. Sharon Stack, Ph.D., Professor, Chemistry and Biochemistry, Ann F. Dunne and Elizabeth Riley Director, Harper Cancer Research Institute, University of Notre Dame

The Harper Cancer Research Institute (HCRI) Tissue Biorepository procures and stores tissues donated by patients undergoing surgery in several community hospitals. As the Institute and hospitals do not represent a single entity, unique logistical challenges are presented.

Biobanking with Diagnostic Samples

Colleen M. Mitchell, Joint Biorepository Operations Manager, IU Simon Cancer Center Tissue Bank and National Cell Repository for Alzheimer's Disease, Indiana University School of Medicine

Technology has advanced and patient samples are not consumed in their entirety for diagnostic purposes. What happens to the leftover samples? Discard them or create a biobank. This presentation will show how you can build a biobank from them.

Developing a Biobanking Standard Terminology for Use in a Centrally Supported Enterprise-Wide Biobanking Software Platform

Helena J. Ellis, Director, Duke BioBank, Duke Translational Medicine Institute, Duke University

Duke is engaged in the implementation of an Enterprise-Wide Biobanking Information System (LabVantage). The system will be centrally supported by dedicated staff and provide an inventory management system for diverse biobanking groups at Duke. These diverse groups, and other subject matter experts, have developed a standard biobanking terminology that will be required for use of the LabVantage system. Five Working Groups met regularly for several months and defined biobanking data elements, terminology and permissible values.

**Separate registration required*

Onsite Tour of BioStorage Technologies & Reception

(Open to All)

5:30-8:30 pm

5:15 Shuttle Service to BioStorage Technologies

Complimentary roundtrip shuttle service to and from the Sheraton Indianapolis

City Centre Hotel will be provided for all conference attendees.

5:30-7:15 BioStorage Tour

Join your colleagues for a comprehensive tour of the BioStorage Technologies biorepository and sample management facility. The tour will highlight our:

- State-of-the-art global biorepository and sample registration center
- Innovative sample preparation center
- ISISS, virtual sample management technology system
- Consistent temperature control and monitoring system
- Relofleet, the revolutionary mobile biorepository

7:15 Board Shuttle and Depart for Hotel

7:30 Sky View Dinner Reception in the Panorama

Ballroom Hosted by BioStorage

8:30 Close of Day

For updates, please visit www.healthtech.com/biobanking

Monday, November 4

»7:30» AM MAIN CONFERENCE REGISTRATION PLENARY KEYNOTE SESSION: IT TAKES A VILLAGE

8:30 Welcome and Chairperson's Opening Remarks

Brian Stemme, Project Director, BioCrossroads

8:45 The Strategic Importance of Biobanking to the Discovery and Development of New Medicines

Andrew M. Dahlem, Ph.D., Vice President, LRL Operations-LRL Europe, Eli Lilly and Company

This presentation will focus on the strategic necessity of collection and storage of biospecimens for the identification of new pharmaceutical targets and the delivery of the potential for tailored medicines to patients. Safe and reliable storage, dependable and reliable service providers and the factors that go into the decision to store samples in-house or through third parties will be evaluated. We will highlight how effective use and storage of biospecimens are critical for discovering and developing new medicines and for ensuring the right doses are given to the right patients to treat their unique needs.

9:25 Key Assets in the Development of Companion Diagnostics towards Personalized Medicine

Norma J. Nowak, Ph.D., CSO and Founder, Empire Genomics LLC

As medicine is transformed from reactionary treatment to a health management approach, development of companion diagnostics is critical to achieving the goal of personalized medicine. Access to patient specimens is paramount, as is the data surrounding patient history and response to drug therapy. The timeframe for development of these pivotal assays is directly related to the availability of patient samples for testing, thus emphasizing the direct need for access to biobanks with appropriately stored and annotated clinical specimens. We will discuss our proprietary assays and the role biospecimens play in their development.

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

10:45 Academia and Pharma: New Approaches for Bi-Directional Collaborations

Anantha Shekhar, M.D., Ph.D., Director, Indiana Clinical and Translational Sciences Institute, Indiana University School of Medicine

There is great need to translate the explosion in our fundamental understanding of biology into better therapeutics. Pharma Industry faces several challenges such as increasing cost of drug development and declining R&D productivity. Academia is challenged with declining public funding for research and lack of investor base for early stage development of therapeutics. Academic scientists are a critical source for new discovery and Pharma has deep experience in successful drug development, making it imperative that we create better models for collaborative drug discovery and development between these two worlds. This talk will discuss the current state, challenges and some solutions being tried in this area.

11:20 A Personal Story: Inner Strength

Traci Runge, Breast Cancer Survivor and Stem Cell Therapy Recipient

You never know who holds a key to offering something bigger in the biocommunity ormedical world — a group that is ever growing, learning and discovering. I wish to sharemy experiences that they may show support and encouragement in some way so thatI too can be a "Part of this Village." I found an inner strength that I didn't know existed; when I was first diagnosed with breast cancer, I knew immediately I wanted my personal journey in some way to have an impact on others in the future. One simple phone call offering my cancerous tissue has been the catalyst for hopefully making that impact.

11:55 Close of Session

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* or Lunch on Your Own

Concurrent Tracks

Business of Running a Biobank

1:30 Chairperson's Opening Remarks

Beatrice Knudsen, M.D., Ph.D., Medical Director, Pathology and Laboratory Medicine, Cedars-Sinai Medical Center

1:35 Sample Acquisition and Sample Management: Still an Emerging Market

Brian Chadwick, Managing Member and Consultant, LookLeft Group LLC

Demand exceeds supply of usable biospecimens to meet research objectives. While the literature suggests there may be a billion biospecimens stored globally, numerous sample collection efforts require prospective clinical trials because commercial sale of samples is a disparate and regulatory-challenged marketplace. Commercial biobanking facilities often have too few acceptable samples "on the shelf," and protocols often require specifically targeted biospecimens, which are less available through commercial channels.

2:05 The Impact of Differing National Regulations and Policies on Multinational Trials Involving Specimen Collection

Amelia Warner, Pharm.D., President, Gentris Corporation; Founder and CEO, Global Specimen Solutions, Inc.

Complex global regulation and law for human specimen research continue to evolve as policymakers assess what tenets of ethical specimen procedures should be required for future biomedical research. This greatly impacts researchers' ability to collect and study representative specimen sets from global clinical trials. We will address current ongoing issues and discuss potential strategies to address successful global specimen collection.

2:35 Liver Disease Biobank: A Moving Target for Research and Clinical Study Integration

Anthoula Lazaris, Associate Director, HPB Transplant and Research Unit, Surgery, McGill University Health Centre Research Institute

We are involved in a large-scale FRSQ project to study the cell biology of NAFLD and NASH at the mechanistic level using an innovative Systems Medicine approach that combines quantitative modeling and wet-lab research. We are performing (i) enhanced phenotyping of clinical samples through transcriptomics, proteomics and lipidomics, followed by (ii) high-end bioinformatics and systems analysis to identify disease biomarkers and (iii) biomarker validation through clinical cohorts. This presentation will describe our experiences in the creation of the MUHC-RI Liver Disease Biobank, where high-quality liver specimens are collected.

Science of Supplying High-Quality Specimens

1:30 pm Chairperson's Opening Remarks

Jay A. Tischfield, Ph.D., CEO, RUCDR Infinite Biologics, Distinguished Professor, Genetics, Rutgers University

1:35 Preventing "Identity Theft" at a Biobank via Analytical and Functional Quality Control

Jay A. Tischfield, Ph.D., CEO, RUCDR Infinite Biologics, Distinguished Professor, Genetics, Rutgers University

Nucleic acid quality control is essential for accurate and reproducible genomic analysis in both research and clinical settings. However, most sample processing is decentralized, leading to differential results between laboratories. To this end, standardized functional quality control methods have been developed to qualify nucleic acid quality and, most importantly, provide a metric for comparing samples extracted at different sites. The critical need to develop a quality gold standard for nucleic acid and implement best practices in sample management focusing on integrity, quality and control will be discussed.

2:05 Development of a High-Throughput RNA Extraction and Quality Control Process

Victoria Kelly, Ph.D., Molecular Biology Group Leader, Molecular Biology, Coriell Institute for Medical Research

RNA from whole blood is a common sample type collected in longitudinal clinical research studies, with many of these studies aiming to discover miRNA biomarkers. Developing high-throughput methods by which to extract whole RNA including miRNA and analyze quality while maintaining integrity from sample accession to distribution is critical for the value of these collections. We will present our process including data collected to optimize and validate methods of extraction and quality control testing.

2:35 The SPIN and SMART Metrics: The New Generation of Biorepository Sample Quality Assessment for Downstream Analysis

Timothy J. Geddes, Manager, Erb Family Core Molecular Laboratory, Beaumont

BioBank, William Beaumont Hospital We describe the development of two metrics designed to keep up with emerging proteomic and genomic analysis technologies. The first of these is known as SPIN (Sample-specific Protein Integrity Number) and is designed to discover proteins in individual sample types with the goal of establishing an index to assess the integrity of stored specimens for protein-based biomarker studies. The second metric is referred to as SMART (Size Metric Analysis RNA Threshold), which is formulated to determine the usability of highly degraded RNA isolated from archived FFPE blocks.

3:05 Selected Oral Poster Presentation: Cincinnati Children's Heart Institute BioRepository (HIBR) for Pediatric Heart Disease

Robert B. Hinton, M.D., Associate Professor, Pediatrics; Director, Cardiovascular Genetics; Director, Heart Institute BioRepository, The Heart Institute, Division of Cardiology, Cincinnati Children's Hospital Medical Center

The objective of the Heart Institute BioRepository (HIBR) is to facilitate a broad spectrum of current and future research by combining tissue specimens with deep phenotype information on patients with pediatric heart disease. The HIBR is an ongoing repository using a Human Subjects Research approach. The basic goals of the HIBR are to collect, maintain and govern whole blood, heart tissue and urine, and combine these specimens with a comprehensive phenotype Registry using an Honest Broker system.

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

4:00 Customized Biobanking in the Era of Precision Medicine – Strategies and Opportunities

Beatrice Knudsen, M.D., Ph.D., Medical Director, Pathology and Laboratory Medicine, Cedars-Sinai Medical Center

We have established an innovative and centralized biobank at Cedars-Sinai Hospital, a 1000-bed tertiary care medical center in Los Angeles. This infrastructure includes a novel approach to consenting patients and a pipeline from tissues to data in a biobankassociated translational research core. The presentation will highlight our strategies, accomplishments and analytical methods development in the endeavor.

4:30 From Many to One: An Initiative to Develop an Institution-Wide Human Specimen Resource at an Academic Medical Center

Devon D. Kelly, Director, OHSU Knight BioLibrary, Oregon Health & Science University, Knight Cancer Institute

OHSU has been collecting and storing specimens for decades. Implementation of a standardized model is necessary to best organize and utilize individually maintained repositories. We will describe our efforts to aggregate multiple repositories under a single umbrella, in areas like governance, community engagement, business modeling, process improvements and informatics platforms, plus change process management strategies, current examples of collaborative relationships and uses of the specimens.

5:00 Governance Model for a Pathology-Based Tissue Procurement Core at the Duke Cancer Institute

Shannon McCall, M.D., Director, Duke Biospecimen Repository and Processing Core, Pathology, Duke University School of Medicine

Duke's Department of Pathology has established a shared resource for tissue procurement: the Biospecimen Repository and Processing Core (BRPC). It operates under one IRB protocol and its "customers" are the DCI's 10 Disease-Specific Working Groups, which each determine priorities for specimen collection and utilization. This governance model reduces not only competition between investigators to enroll patients and collect specimens but also the risk to patients. It supports efficiencies in research expenditures by fostering collaboration, increasing cohort sizes and utilizing biospecimens for multiple ownstream analyses.

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

6:30 Close of Session

3:05 Selected Oral Poster Presentation: Long-Term Storage of Dry RNA in a Skin Cancer Biorepository for Next-Generation Molecular Studies

Steven Robinson, Ph.D., Research Manager, Skin Cancer Biorepository, Division of Medical Oncology, University of Colorado

High-quality RNA is required for molecular biology experiments. Novel techniques for desiccating and storing RNA at room temperature have recently been developed. In this presentation, we will look at the comparative quality of desiccated versus frozen RNA stored over long periods for use in next-generation molecular studies, including gene expression assays and whole-transcriptome sequencing.

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

4:00 What We Know about the Influence of Storage Temperature on Biospecimen Quality

Allison Hubel, Ph.D., Professor, Mechanical Engineering and Director, Biopreservation

Core Resource, University of Minnesota Selection of a temperature at which to store your biospecimens can be a daunting task. There are scientific principles for the selection of a storage temperature that can help guide selection. A summary of studies on storage temperature will also be described.

4:30 Appropriate Freezing Processes and Optimal Storage Containers for Biological Specimens

Alexandra Lerch-Gaggl, Ph.D., Scientific Director, Pediatric BioBank & Analytical Tissue Core, Children's Research Institute and Medical College of Wisconsin Best sample quality even after long-term storage should be a priority of sample banking. This presentation will discuss advantages and differences between various freezing techniques, introduce the purpose of using cryoprotective agents, demonstrate differences in storage containers and raise the awareness for factors influencing samples integrity related to freezing and thawing after long-term storage.

5:00 CAP Accreditation for Biorepositories: A New Approach to Biospecimen Quality

Philip Branton, M.D., Consulting Pathologist, Biorepositories and Biospecimens

Research Branch, National Cancer Institute, National Institutes of Health CAP Accreditation offers an opportunity for standardization of practice. Today, there are few resources for biobanks that seek external verification/quality assurance of how they are performing and how they are conforming to benchmark standards of quality. The CAP Biorepository Accreditation Program features a unique peerbased inspector model that integrates education and a sharing of best practices to advance quality.

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

6:30 Close of Session

Tuesday, November 5

7:30 am Breakfast Presentation *(Sponsorship Opportunity Available)*

8:15 Biobanking 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: International Harmony

Pedro Rondot Radío, M.D., Executive Director, Public Oncologic Serum Biobank, Institute of Oncology "Angel H. Roffo," Research Área, University of Buenos Aires

- Why and how do we need to harmonize in biobanking?
- Which are the most debated and recognized ELSI challenges related to this issue?
- Do we need to use the same e-infrastructure (ontology resource) for a proper and secure interchange of personal and biological information in "International Harmonization"?
- e-BRAIN (Biobanking Resources American Infrastructures Network): Exploring the potential for a harmonized North and South American approach to the networking of human biobanks. Is it possible to think about this, as the EU did?

Table 2: Using Business Strategy to Maintain and Build Biospecimen Collections

Dawn E. Bowles, Ph.D., Assistant Professor, Department of Surgery, Division of Surgical Sciences and Co-Director, Duke Human Heart Repository

- How can we garner institutional support for our biospecimen collections?
- How do we develop a cost model to monetize biospecimens?
- How do we create a market-driven biobanking enterprise to drive science?

Table 3: Development of Patient-Derived Xenograft (PDX) Tumor Models for Clinical Translational Studies: A Live Biobanking Approach

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 biobanking approach and its novel features, such as recreating parent-like tumor heterogeneity and forming a renewable tumor tissue resource?
- How is live biobanking advantageous over conventional biobanking in the discovery of clinically relevant biomarkers and in developing patient-specific therapeutics?

Table 4: Innovations in Biospecimen Acquisition

Brian Chadwick, Managing Member and Consultant, LookLeft Group LLC

- Prospective targeted sample collection clinical trials
- Commercial acquisition of biospecimens
- Sample pricing/sample costs
- Relationships between biopharmaceutical and diagnostic companies with academic medical centers for ongoing biospecimen collection
- Online biospecimen buy/sell/exchange systems
- Regulatory/IRB issues

Table 5: Logistics and Utility of Induced Pluripotent Stem Cell Banks

Jay A. Tischfield, Ph.D., CEO, RUCDR Infinite Biologics, Distinguished Professor, Genetics, Rutgers University

- Is there a "best" source cell type for iPSCs?
- What are the early candidate diseases for drug screening with iPSCs?
- How many iPSC lines need to be banked?
- What characterization of banked iPSCs is required?
- What are the prospects for using iPSCs for autologous cell therapy?

Table 6: Cryopreservation of Biospecimens: Myths and Realities

Allison Hubel, Ph.D., Professor, Mechanical Engineering and Director, Biopreservation Core Resource, University of Minnesota

- What do we know about the cryopreservation process and the effect that it has on biospecimen quality, and what do we need to investigate?
- What resources are available to improve my preservation when my organization or I have problems with our biospecimen quality?
- Cost and workflow issues are important in biobanking. What needs to exist to reduce cost of preserving and improve biospecimen quality?

Biospecimens and Translational Science

9:00 Chairperson's Opening Remarks

Sherilyn Sawyer, Ph.D., Scientific Director, BWH/Harvard Cohorts Biorepository, Channing Division of Network Medicine, Brigham and Women's Hospital

9:05 Developing and Using the Duke Human Heart Repository (DHHR) for Basic and Translational Research

Dawn E. Bowles, Ph.D., Assistant Professor, Department of Surgery, Division of Surgical Sciences and Co-Director, Duke Human Heart Repository

Few human heart tissue repositories exist in the United States. At Duke, we have created a readily accessible, well-curated, clinically relevant human heart tissue repository. From our well-established collaborations with Duke Surgery and local organ procurement organizations, we have acquired and banked 36,000 specimens from 374 diseased as well as non-failing human hearts over the last four years. In addition to banking tissues, the DHHR provides derivatives such as primary human cardiomyocytes, cardiac fibroblasts and cardiac progenitor cells as well as expertise in assessment of cardiac function and physiology at the cellular, tissue and whole-organ level.

9:35 Employing Quantitative PK/PD Approaches for Bench-to-Bedside Translation of Antibody Drug Conjugates

Dhaval K. Shah, Ph.D., Assistant Professor, Pharmaceutical Sciences, The State University of New York, University at Buffalo

The presentation will highlight how to integrate data from tumor biomeasure studies, in vitro and in vivo ADC ADME studies and biodistribution studies, using quantitative PK/PD approaches. Tumor biomeasures were obtained from cancer cell lines and PDX xenograft models for preclinical work, and from patient samples for the clinical translation. Use of an integrated PK/PD model to guide the discovery of ADC and precision medicine efforts will be discussed.

10:05 Selected Oral Poster Presentation: Partners in Progress: Changing Clinical Practice through Biomarker Research

Diane Uzarski, MPH, RN, Associate Director, Biobanking, Duke Translational Research Institute, Duke University

Duke has developed an innovative systems approach to translational biomarker research, covering all aspects of drug and diagnostic development, and integrating experience and expertise of an array of internal and external organizations and industry partners. Duke continues to develop and refine this system and has fostered translational breakthroughs by bridging basic and clinical researchers with these research partners. An overview of Duke's systems approach to the integration of clinical and translational research will be presented, highlighting real-world applications including Duke's premier biospecimen repositories and recent biospecimen informatics advances.

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

11:00 Bioinformatics Support for Clinical Genomic Testing: A Tale of One City

Gail H. Vance, M.D., Professor, Medical & Molecular Genetics; Professor, Pathology & Lab Medicine; Director, Division Diagnostic Genomics; Director, Indiana Familial Cancer Program, Indiana University School of Medicine

Biorepository specimens are a rich resource of genomic information for clinical and research investigation. This presentation will highlight the journey of one clinical molecular laboratory's efforts to establish next-generation sequencing as a clinical service and the hurdles encountered to acquire clinical bioinformatic support.

11:30 Fit-for-Purpose Biospecimens: Ensuring Effective Use of Legacy Collections

Sherilyn Sawyer, Ph.D., Scientific Director, BWH/Harvard Cohorts Biorepository, Channing Division of Network Medicine, Brigham and Women's Hospital

One of the greatest challenges faced by legacy biobanks is the age and rarity of their biospecimens. The decision to commit rare specimens to research studies without insight into how specimens will perform with different analytic platforms, or with biomarkers of interest, can result in a waste of resources. With biospecimens in continuous use for the last 40 years, the BWH/Harvard Cohorts Biorepository uses a rigorous profile of pilot experiments and assay quality controls (QCs) that are traceable over time to assure fit-for-purpose use of specimens. The Cohorts Biorepository monitors biospecimen performance over time, assesses the impact of specimen age and processing/collection method on analytic outcomes and measures the stability of biomarkers over time within cohort participants.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

Case Studies: Biobanker/Biouser Partnerships
(Sponsorship Opportunities Available)

1:30 Chairperson's Opening Remarks

Sponsored by BioStorage Technologies

Lori Ball, COO, BioStorage Technologies, Inc.

1:35 Case Study #1: Future Use of Clinical Specimens: Ensuring Adherence to the Informed Consent

Lynn Wetherwax, Senior Manager, Research Operations Clinical Immunology & BSM, Amgen

Catherine Weaver, Global Head of Solution Design, BioStorage Technologies, Inc.

As custodians for patient specimens, we must ensure sample management practices demonstrate compliance to the informed consent and protection of patient privacy on behalf of the investigator. This presentation will focus on planning for ethical and compliant use of human specimens for future research, optimizing specimen collection and monitoring strategies, and managing for compliant and efficient use and destruction of human specimens.

2:20 Case Study #2: Building a Quality Biological Collection – The Practical Application of Best Practices

Sponsored by Precision BioServices

Katheryn Shea, Vice President, Precision Bioservices and Past President, ISBER

Eric M. Eastman, Ph.D., CSO, DioGenix, Inc.

Building quality biological collections begins with the incorporation of best practices into each aspect of the collection. Multiple best practice guidelines are available, such as the third edition of ISBER's "Best Practices for Repositories," which was published in 2012. The practical application of these best practices depends on the intended use of the specimens, as the goal is to ensure the preserved specimen is fit for the purpose intended. This case study will show how these best practices were implemented for a study being conducted by DioGenix for the development of a unique test for the early diagnosis of multiple sclerosis (MS). This assay, MSPrecise™, measures codon replacement frequencies in the variable region of immunoglobulin (Ig) heavy chain (IGHV) genes in B cells isolated from cerebrospinal fluid (CSF) and peripheral blood B cells. Standardized processing and QC have been a critical component in the execution of this study.

3:05 Refreshment Break in the Exhibit Hall with Poster Viewing

3:30 Case Study #3 Accurate, Rapid, High-Throughput DNA Sample Identification and Quality Control for BioBanking

Sponsored by sequenom Bioscience

Divya Neelam, Senior Scientist, Applications & Technology, Field Sales, Sequenom®, Inc

Bryan Thibodeau, Ph.D., Research Associate, Beaumont BioBank, Beaumont Health System

World-wide biobanking is on the rise with ongoing efforts at these biorepositories to standardize sample collection, quality and sharing practices in order to provide broader access to samples. The Beaumont BioBank is a comprehensive biorepository and core molecular facility that has selected Sequenom's iPLEX® Pro Sample ID Panel to relate multiple sample types from each donor, generate a DNA fingerprint and assess the quality of samples prior to downstream analysis due to its high discriminatory power.

4:15 Case Study #4: Biobanking Across the Portfolio: A Pharma Approach and Case Study to Enable Decision-Making

Donna Farley, Associate Consultant, Eli Lilly and Company

Dennis A. Laska, Consultant Biologist, Tailored Therapeutics, Eli Lilly and Company

Mary Zuniga, Clinical Diagnostic Services Consultant and Clinical Trial Sample Coordinator, Eli Lilly and Company

High-quality biospecimens are necessary to meet the research needs of scientists and enable decision-making. Discovery and Clinical Operational groups at Lilly are working collaboratively to help scientists meet those needs. Biobanking perspectives from sample management experts working in Discovery and Clinical Operations will be shared. The case study entitled, "Discovery and Tailoring Therapeutics through Human Biobank-Facilitated Biomarker Development" will be presented by a Lilly scientist in the Tailored Therapeutics group.

5:00 Closing Panel Discussion

5:30 Close of Conference

Post-Conference Event

BARNETT Educational Services

Wednesday, November 6

Informed Consent Content & Process Requirements forBiobanking 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*

Sponsorship and Exhibit Opportunities

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space and branding, as well as the use of the pre and post-show delegate lists. Customizable sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on earlier will allow you to maximize exposure to qualified decision-makers!

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- If choosing a whitepaper program, we can offer editorial experience and provide an industry recognized author to write your whitepaper. We can also host and promote an existing paper.

Hotel & Travel Information

Conference Hotel:

Sheraton Indianapolis City Centre
31 West Ohio Street
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P: 317-635-2000

Discounted Room Rate $135 s/d
Discounted Cut-off Date October 8, 2013

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

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Special discounts have been established withAmerican Airlines for this conference. Please use one of the following methods:

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Maximizing Your Investment in Biospecimens

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SHORT COURSE (November 3)		
Translational Medicine Collaborations	$699	$399
CONFERENCE PRICING (November 4-5)		
(Includes access to Leaders in Biobanking Congress PLUS the onsite tour of BioStorage Technologies, excludes short course)		
Advance Registration Discount until September 27, 2013	$1799	$899
Registrations after September 27, 2013, and on-site	$1999	$999
☐ Yes, I will attend the Onsite Tour. *(Included in Registration)*		
POST-CONFERENCE EVENT (November 6)		
(Includes access to Informed Consent Content & Process Requirements for Biobanking Studies ONLY)		
Registration Discount until October 11, 2013	$800	$700
Registrations after October 11, 2013, and on-site	$1000	$800

Poster Submission - Discount ($50 Off): Poster abstracts are due by October 10, 2013. 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**.

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: Alumni Discount SAVE 20%: Cambridge Healthtech Institute (CHI) appreciates your past participation at BioBanking Congress. 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. Please note: Our records must indicate you were an attendee of BioBanking Congress in the past in order to qualify.

Alumni Discount and Register 3 - 4th IS FREE discounts cannot be combined.

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

If you are unable to attend but would like to purchase the **Leaders in BioBanking Congress CD** for $350 (plus shipping), please visit www.healthtech.com/biobanking. Massachusetts delivery will include sales tax.

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.

To view our Substitutions/ Cancellations Policy, go to http://www.healthtech.com/regdetails

Video and or audio recording of any kind is prohibited onsite at all CHI events.

How to Register: healthtech.com/biobanking

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **BNK RX3** when registering!

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