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27th International

Molecular Med TRI-CON

March 1-4, 2020 • San Francisco, CA
MOSCON SOUTH CONVENTION CENTER

Advancing Precision Medicine

3,100 Attendees
400+ Speakers
180 Exhibitors
150 Scientific Posters

Organized by Cambridge Healthtech Institute

#TRICON TriConference.com

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- C5: Companion Diagnostics and Clinical Biomarkers
- C6: Immuno-Oncology Biomarkers and Companion Dx
- C7: Point-of-Care Diagnostics Strategy and Implementation
- C8: Enabling Point-of-Care Technologies **NEW**
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- C10: Renaissance of Gene Therapy and Genome Editing **NEW**
  - (March 2-3)
- C11: Adoptive Cell Therapy **NEW**
  - (March 3-4)

#### Digital Health
- C12: Digital Health Tech
- C13: Digital Medicine **NEW**

### Bio-IT World Conference & Expo WEST
- C14: Digitization of Pharma R&D
- C15: AI-Enabled Drug Discovery and Development
- C16: Emerging Technologies for Life Sciences **NEW**
- C17: Software Tools, Services, and Applications **NEW**

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"The Tri-Conference is a worthwhile event because it gave me a nice cross-section view of the field of cloud and biomedicine in academic and commercial spaces."

Associate Research Scientist, Taylor Laboratory, Computational Biology and Genomics, Johns Hopkins University

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Sponsorship, Exhibit & Lead Gen Information

Comprehensive 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 hard-to-reach decision-makers.

Podium Presentations - Available within Main Agenda!
Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, or lunch. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees already seated in the main session room. Presentations do sell out early.

PLENARY KEYNOTE SPONSORSHIP
There are two types of plenary sessions: 1) One brings together all attendees across all conferences/tracks; 2) the other brings together all attendees within one of the three specific conferences (e.g. Bio-IT WEST or Digital Health or Precision Health). Plenary sessions have excellent attendance and provide your company the opportunity to reach hundreds of decision makers. Keynote is widely publicized on website, brochures and program guide. Sponsor will work with the conference director to identify the most relevant plenary session.

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Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or 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).

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- Keynote Chair Drop
- Staircase Wrap
- Tote Bag Exclusive Sponsorship
- Tote Bag Insert
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COMPANY TYPE
- Biotech & Pharma: 62%
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View Exhibit Schedule
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To learn more about sponsorship and exhibit opportunities, please contact:

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781-972-5483
jstroup@healthtech.com

Companies L-Z
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Director, Business Development
781-972-5431
jvacca@healthtech.com
About the Tri-Conference

The event and conference team at Cambridge Healthtech Institute (CHI) proudly presents the 27th International Molecular Medicine Tri-Conference at the beautifully remodeled Moscone Convention Center in San Francisco’s downtown district. This dedicated team, with a long tenure, continues to host one of the most comprehensive and leading industry events made available in the personalized medicine space today. The 2020 event will focus on emerging therapeutic, diagnostic, and technology approaches to advance precision medicine. We create a community to learn and make connections that are unique, impactful, and have lasting returns.

The Tri-Conference unites an ecosystem of over 3,100 innovative thinkers and thought leaders in the field of drug discovery, development and diagnostics, informatics, and digital health throughout pharma, biotech, and academia from around the world. The Tri-Conference remains one of the key industry meetings covering the latest trends, technologies, research breakthroughs, regulatory issues, and best practice examples of molecular and translational medicine advances, digital health, and bio-IT.

26 years ago, the Tri-Conference launched, during the Human Genome Project, as three back-to-back conferences. Spanning 7 days, the TRI-CON’s programs included:

- Conference 1: The Human Genome Project: Commercial Implications
- Conference 2: The Genetic Screening and Diagnosis of Human Diseases
- Conference 3: The Genomic Partnering Forum

Now in 2020, for our 27th year, the Tri-Conference is unveiling a new look and feel! We know that being out of the office is a luxury that many may not be able to manage every year, so the Tri-Conference is streamlining our 5-day event into a 4-day event. The Tri-Conference will revert to our roots with three core conference focuses:

- Conference 1: Precision Health
- Conference 2: Digital Health
- Conference 3: Bio-IT World Conference & Expo WEST
Plenary Keynote Session

MONDAY, MARCH 2 | 4:35 - 6:00 PM

4:35 Welcome Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

4:45 PLENARY KEYNOTE INTRODUCTION
Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia

5:00 PLENARY KEYNOTE PRESENTATION: High-Performance Medicine
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute (SRTI); Author, Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again

The use of artificial intelligence, and the deep-learning subtype in particular, has been enabled by the use of labeled big data, along with markedly enhanced computing power and cloud storage, across all sectors. In medicine, this is beginning to have an impact at three levels: for clinicians, predominantly via rapid, accurate image interpretation; for health systems, by improving workflow and the potential for reducing medical errors; and for patients, by enabling them to process their own data to promote health. The current limitations, including bias, privacy and security, and lack of transparency, along with the future directions of these applications will be discussed in this presentation. Over time, marked improvements in accuracy, productivity, and workflow will likely be actualized, but whether that will be used to improve the patient-doctor relationship or facilitate its erosion remains to be seen.

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing*, and Meetup Group

### Keynote Session for Precision Health

**TUESDAY, MARCH 3 | 3:15 - 4:50 PM**

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<td>3:15</td>
<td>Organizer’s Remarks</td>
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<td>Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute</td>
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<td>3:20</td>
<td>Keynote Introduction</td>
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<td>Allison Mallory, PhD, Director, R&amp;D Molecular Biology, Stilla Technologies</td>
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#### 3:35 KEYNOTE PANEL SESSION: What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics

20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

**Moderator:**

Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.

**Panelists:**

Stephen Kingsmore, MD, DSc, President/CEO, Rady Children’s Institute for Genomic Medicine
David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomolecular Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

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### Keynote Sessions for Digital Health

**MONDAY, MARCH 2 | 11:45 AM - 2:05 PM**

**DIGITAL HEALTH AT “BIG TECH”**

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<td>Julia Boguslavsky, Executive Director, Conferences, Cambridge Healthtech Institute</td>
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<td>11:50</td>
<td>Chairperson’s Remarks</td>
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<td></td>
<td>Thomas Kluz, MS, General Partner, dRx Capital; Head, Healthcare Investing, Qualcomm Ventures</td>
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#### 11:55 KEYNOTE PRESENTATION: How Is Wearable-Driven Digital Health Shaping Non-Critical Care?

Ravi Kuppuraj, PhD, CEO, Digital Innovator, Connected Sensing, Philips

Consumer wearable devices have already begun to reshape our general experience by putting people in the driver seat and back in charge of their healthcare – and now the healthcare industry has not only begun to see the same potential with clinical wearables, but they are becoming more widely adopted and sought after to address real concerns, like providing increased mobility for patients and decreasing costs for healthcare systems in non-critical care settings.

12:15 KEYNOTE PRESENTATION: AI and Its Disruptive Implications for Healthcare

Chris Gough, General Manager, Health & Life Sciences, Intel Corporation

In this talk, we will explore the disruptive potential of AI for the healthcare industry. This will include market insights, real-world examples of deployments and use cases in healthcare from around the world, and practical guidance for how to prepare your organization to take advantage of these capabilities.

12:35 Sponsored Presentation (Opportunity Available)

#### 12:55 KEYNOTE PANEL DISCUSSION: How Is “Big Tech” Implementing Digital Health?

**Moderator:**

Thomas Kluz, MS, General Partner, dRx Capital; Head, Healthcare Investing, Qualcomm Ventures

**Panelists:**

Chris Gough, General Manager, Health & Life Sciences, Intel Corporation
Ravi Kuppuraj, PhD, CEO, Digital Innovator, Connected Sensing, Philips
Thyge Sullivan Knuhtsen, Director, Healthcare Industry Solutions, AT&T Business

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It is a long journey from Munich to San Francisco but TRICON was worth every single hour and mile of it.

Manager, BioM Biotech Cluster Development GmbH
Keynote Sessions for Digital Health (cont.)

**TUESDAY, MARCH 3 | 8:00 - 9:40 AM**

**DIGITAL HEALTH AT BIG PHARMA**

8:00 Organizer's Remarks
Julia Boguslavsky, Executive Director, Conferences, Cambridge Healthtech Institute

8:05 Chairperson's Remarks
Geoff McCleary, Director, Digital Health & Therapeutics, PricewaterhouseCoopers

8:10 **KEYNOTE PRESENTATION:** Digital Transformation of the Pharmaceutical Industry
Dirk Schapeler, Vice President, Digital, Bayer LLC

Bayer made digital transformation a top priority a few years ago and thus can look back on a number of successes such as being one of the first companies to launch a cloud-connected drug delivery device, doing the first remote patient monitoring trial and engaging with digital therapeutics. At the same time there were also many lessons learned along the way. Dirk, as one of the drivers of innovation in the digital space at Bayer, will share insights into the digital transformation.

8:30 **KEYNOTE PRESENTATION:** The Experimental Science behind Empowering Teams
Matt Lasmanis, Vice President, Technology, GlaxoSmithKline

How do you make large organizations more agile, customer-centric and flexible? There are myriad answers, and GSK is using their science focused approach to guide the way. Matt Lasmanis, Vice President of Pharma US Tech, is leading the transformation of the GSK tech culture, empowering his teams to achieve outcomes with clarity over certainty. In the presentation, Matt will discuss: 1) leading experiment-driven data and product-oriented teams and avoiding non-failure driven culture; 2) empowering teams to make decisions closer to the ground; and 3) shifting mindset of teams to be more agile and business-minded.

8:50 Presentation to be Announced
Mila Malhotra, Digital Health Leader, Ophthalmology, Product Development Medical Affairs Personalized Healthcare and Patient Access, Roche

**WEDNESDAY, MARCH 4 | 10:40 AM - 1:20 PM**

**BUILDING DIGITAL HEALTHCARE**

10:40 Chairperson's Remarks
Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP

10:45 **KEYNOTE PRESENTATION:** Harmonizing Healthcare Innovation for Better, Faster Transformation
Leigh Anderson, President of Performance Services, Premier, Inc.

Leigh Anderson, Premier’s President of Performance Services, will address the evolving healthcare ecosystem and how technological innovation including the application of artificial intelligence and machine learning must occur using a collaborative framework in order to quickly meet our goals of providing more coordinated, patient-centric and high-quality care.

11:05 **KEYNOTE PRESENTATION:** Smart Health Communities
Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP

This presentation will cover how digital disruptions are going to completely change the way we live and empower communities to battle disease and create abundant wellness.

11:25 Sponsored Presentation (Opportunity Available)

11:45 **KEYNOTE PANEL DISCUSSION:** Building Digital Healthcare
Moderator:
Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP

Panelists:
Leigh Anderson, President of Performance Services, Premier, Inc.
John Mattison, MD, Chief Medical Information Officer, Emeritus, Kaiser Permanente
Claus Jensen, PhD, Chief Digital Officer and Head of Technology, Memorial Sloan Kettering Cancer Center
Mariya Filipova, Vice President, Innovation, Anthem, Inc.
Shrawan Patel, Vice President & Head, Clinical Transformation, Rx.Health

12:40 Session Break

12:50 **Digital Health Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own**
Keynote Sessions for Bio-IT World Conference & Expo WEST

**MONDAY, MARCH 2 | 11:45 AM - 2:05 PM**

11:45 Organizer's Opening Remarks  
*Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute*

11:50 Chairperson's Remarks  
*Allison Proffitt, Editorial Director, Bio-IT World*

11:55 Keynote Introduction, Benchling  
*Ashoka Rajendra, Head, Product, Registry, Inventory, Benchling*

**12:10 KEYNOTE PRESENTATION: The AI Bubble and the Emerging Thinking Economy**  
*Pietro Michelucci, PhD, Director, Human Computation Institute*

This presentation presents a realistic assessment of the “AI bubble” – where there is value, where there is hype, and how human-in-the-loop computing gives us futuristic AI capabilities today that co-evolve with AI technology and even help improve AI.

**12:40 KEYNOTE PANEL DISCUSSION: Data Quality in Human Computation Systems**

Is today’s artificial intelligence fervor based on hype or is it happening? We’ve seen some amazing results from AI-based systems, fueled by increases in processing speed that render traditional applications finally practicable. At the same time, powerful new techniques are emerging including fruitful human/AI partnerships and recent successes based on combining crowdsourcing with machine learning. These new methods dovetail nicely with special challenges posed by precision medicine, often entailing complex interdependencies among data acquisition, analysis, privacy, and ethics. That said, they also introduce a new set of challenges as we navigate issues of transparency, trust, and reliability where automated systems are involved. This panel will discuss recent work in online collective systems that combine human and machine-based information processing in the biomedical space, how these systems could be applied to precision medicine, and how to avoid some of the potential pitfalls associated with these approaches. We also discuss an information processing ecosystem designed to accelerate precision medicine research while mitigating associated complexity and resource needs.

*Moderator: Allison Proffitt, Editorial Director, Bio-IT World*

*Panelists:*

- Jennifer Couch, PhD, Chief, Structural Biology and Molecular Applications Branch, Division of Cancer Biology and Citizen Science Coordinator, National Cancer Institute
- Devin Krotman, Director, Global Learning XPRIZE and IBM Watson AI XPRIZE
- Van Mandava, Director, Data Science Outreach, Microsoft Research
- Pietro Michelucci, PhD, Director, Human Computation Institute
- Ginger Tsueng, PhD, Scientific Outreach Project Manager, Department of Integrative, Structural and Computational Biology, The Scripps Research Institute

**1:30 Bio-IT World WEST Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own**

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**TUESDAY, MARCH 3 | 8:00 - 9:40 AM**

8:00 Organizer’s Remarks  
*Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute*

8:05 Chairperson’s Remarks  
*Sudeep Basu, PhD, Practice Leader, TechVision-Innovation Services, Frost & Sullivan*

8:10 Keynote Introduction  
*Vasu Rangadass, President, CEO, L7 Informatics*

**8:25 KEYNOTE PRESENTATION: AI and Big Data Strategies in Accelerating Clinical Research for Faster Rare Disease Cures**  
*Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University*

After losing a child to a rare congenital disease, Dr. Rajasimha became determined to apply his clinical genomics data research experience to develop solutions to help accelerate clinical research leading to faster cures for rare disease. Dr. Rajasimha will discuss his efforts in fostering collaborative bridges between patient advocacy groups and researchers in the USA and their counterparts in India to help accelerate clinical research, trials, and therapy access across borders. The talk will include recent global initiatives to accelerate screening, diagnosis, and treatments of rare and undiagnosed diseases. He will also share work on the development of an AI-driven digital health platform to improve clinical trial operational efficiencies while significantly reducing costs and travel burden on patients.

**8:55 KEYNOTE PANEL DISCUSSION: Applications of AI Technologies in Pharmaceuticals: Facilitating Development of Therapeutics in Treating Rare Diseases**

The complex research framework involving industry, academia, and government to discover and develop new therapeutic products makes drug discovery a laborious process. With rapid strides that life sciences companies are making in the fields of gene and cell therapies, -omics technologies, and smart molecule approaches, an urgent need exists for cost-effective, time-effective, and advanced technologies to analyze large databases of information to help develop novel therapies. Organizations are recognizing the value of AI-based platforms and tools to leverage data to find hidden drug-disease correlations. Also, structured and unstructured data can be derived from multiple sources as never before. This panel brings senior level experts in pharma, AI-based technology, and government to discuss the role of AI platforms and tools to establish a robust pipeline as part of drug discovery portfolio and address new therapeutic areas, including rare diseases.

*Moderator: Sudeep Basu, PhD, Practice Leader, TechVision-Innovation Services, Frost & Sullivan*

*Panelists:*

- Tom Defay, Senior Director, R&D Strategy and Alliances, SPMD, Strategy, Program Management and Data Sciences, Alexion
- Annastasia Mhaka, PhD, President, The Alliance for Artificial Intelligence in Healthcare (AAIH)
Keynote Sessions for Bio-IT World Conference & Expo WEST (cont.)

**Keynote Sessions**

Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University
Vasu Rangadass, President, CEO, L7 Informatics, Inc.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

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**WEDNESDAY, MARCH 4 | 8:00 - 9:40 AM**

8:00 **Organizer’s Remarks**
Edel O’Regan, PhD, Vice President, Production, Cambridge Healthtech Institute

8:05 **Chairperson’s Remarks**
Joseph Ferrara, CEO, Boston Healthcare

8:10 **Keynote Sponsor Introduction** *(Sponsorship Opportunity Available)*

8:25 **KEYNOTE PRESENTATION:** The Value and Application of Informatics in Cancer Care Delivery

**Debra A. Patt, MD, Vice President, Public Policy & Academic Affairs, Medical Oncologist, Texas Oncology Cancer Center & Editor in Chief, Journal of Clinical Oncology-Clinical Cancer Informatics**

Dr. Patt will discuss how Clinical Informatics can be used in practice to improve the quality of cancer care. Specifically, how clinical decision support systems embedded in health records can facilitate concordance with evidence-based treatment. She will discuss how predictive analytics can be used in a practice to understand patient risk. She will discuss how the growth of mHealth applications can bridge the gap between patients and providers.

8:55 **KEYNOTE PANEL DISCUSSION:** Pragmatic Use of Informatics in Cancer Care Delivery and Cancer Research: Big Data and AI Take on Cancer

In oncology today, increasingly large amounts of heterogeneous data, created by multiple medical disciplines, is being collected and aggregated and technologies such as machine learning and deep learning are being tested to create knowledge and insight to improve cancer care and inform oncology research and drug discovery. This panel will bring together many of the stakeholders to discuss the challenges and opportunities in using big data and informatics tools to improve cancer care delivery and cancer research. This panel will include practicing oncologists, oncology researchers, machine learning experts, pharmaceutical and translational researchers, and technology solution providers.

Topics to include:
- The value and application of informatics in research and in practical cancer care delivery
- Predictive analytics to improve risk stratification in oncology
- State of comprehensive genomic profiling in oncology
- Aggregation and analysis of genomic and patient reported outcome data
- Aggregation and analysis of patient records, population level analysis and building cohorts of patients
- Translational research and informatics tools in support of clinical trials
- Big data from recurrence and resistance, informing identification of new targets and driving new drug discovery campaigns
- Transforming cancer, diagnosis, drug discovery and patient care with big data and AI
- Reproducible research, data conformance and semantic modeling

**Moderator:**
Joseph Ferrara, CEO, Boston Healthcare

**Panelists:**
- Mark Hulse, Chief Digital Officer, City of Hope
- Debra A. Patt, MD, Vice President, Public Policy & Academic Affairs, Medical Oncologist, Texas Oncology Cancer Center & Editor in Chief, Journal of Clinical Oncology-Clinical Cancer Informatics
- Nicholas Schork, PhD, Deputy Director of Quantitative Sciences, Distinguished Professor of Quantitative Medicine, The Translational Genomics Research Institute (TGen)
- Kristin Beaumont, PhD, Assistant Professor, Assistant Director of Single Cell Genomics Technology Development Icahn Institute, Dept. of Genetics & Genomic Sciences, Icahn School
- Ajay Shah, PhD, Executive Director & Head of IT for Translational Medicine, Bristol-Myers Squibb
- Paul A. Rejto, PhD, Vice President, Head of Translational Research, Pfizer Oncology R&D

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group
Cambridge Healthtech Institute is pleased to offer short courses taking place on Sunday-Tuesday at the Moscone South Convention Center. The short courses are designed to be instructional, interactive, and provide in-depth information on a specific topic. They allow for one-on-one interaction and provide a great way to explain more technical aspects that would otherwise not be covered during the main conference programs that take place Monday-Wednesday.

SUNDAY, MARCH 1 | 2:00 - 5:00 PM (AFTERNOON SHORT COURSES)

SC2: Development and Implementation of NGS Diagnostics for Precision Medicine
Karl V. Voelkerding, MD, Professor, Pathology, University of Utah; Medical Director for Genomics and Bioinformatics, ARUP Laboratories
Joshua Coleman, MD, Assistant Professor, Pathology, University of Utah, Medical Director for Molecular Oncology, ARUP Laboratories
Jillian Buchan, PhD, Clinical Assistant Professor, Pathology, Stanford University

SC4: Introduction to Data Visualization for Biomedical Applications
Nils Gehlenborg, PhD, Assistant Professor, Department of Biomedical Informatics, Harvard Medical School
Alexander Lex, PhD, Assistant Professor, SCI Institute, School of Computing, University of Utah

SC5: Artificial Intelligence and Machine Learning in Drug Discovery and Development – Part 1
Michael Liebman, PhD, Managing Director, IPQ Analytics, LLC
Pankaj Agarwal, PhD, Chief Computational Biologist, BioInf
Deepak Kumar Rajpal, PhD, Head, Bioinformatics, Translational Sciences, Sanofi
Arvind Rao, PhD, Associate Professor, Department of Computational Medicine and Bioinformatics, University of Michigan
Shruthi Bharadwaj, PhD, Senior Scientist, Novartis Oncology Precision Medicine

SC6: Translating CTCs and ctDNA for Clinical Use
Sonya Parpart-Li, PhD, RAC, Associate Director, Product Management, GRAIL, Inc.
Gozde Durmus, PhD, Assistant Professor, Department of Radiology, Molecular Imaging Program at Stanford (MIPS), Stanford University School of Medicine
Prachi Kothari, DO, Assistant Attending, Department of Pediatrics, Memorial Sloan Kettering Cancer Center

SUNDAY, MARCH 1 | 5:30 - 8:30 PM (DINNER SHORT COURSES)

SC9: Companion Diagnostics for Immuno-Oncology
Kenneth Emancipator, MD, Executive Medical Director and Head of Companion Diagnostics, Merck & Co., Inc.
Lakshman Ramamurthy, PhD, Head, CDx Global Regulatory, GlaxoSmithKline
Mary J. Savage, PhD, Senior Director, Companion Diagnostics, GlaxoSmithKline

SC10: Microfluidics and Other Devices for POCT
Chris Myatt, Founder & CEO, MBio Diagnostics, Inc.
Kris Buchanan, CEO, Phase Three Product Development
Evan F. Cromwell, President & CEO, Protein Fluidics
Richard Spero, PhD, Co-Founder, CEO, Redbud Labs

SC12: Liquid Biopsy Technologies and Applications
John Simmons, PhD, Vice President, Translational Medicine, Personal Genome Diagnostics

SC13: Artificial Intelligence and Machine Learning in Drug Discovery and Development – Part 2
Michael Liebman, PhD, Managing Director, IPQ Analytics, LLC
Stefan Harrer, PhD, Manager and Research Staff Member, Brain-Inspired Computing, IBM Research; Adjunct Professor, School of Engineering and Information Science, University of Technology Sydney
Shruthi Bharadwaj, PhD, Senior Scientist, Novartis Oncology Precision Medicine
Kuan-Fu Ding, MSc, PhD, Chief Science Officer, Catalytic Data Science

View More Short Courses (March 2-3) ▼

Attention Pharma!

25 for 25

If you are an employee of the following TOP 25 Pharmaceutical Companies as cited by Pharmaceutical Executive* you may attend this meeting at a 25% discount off the current rate. Enter Keycode PH25 upon checkout when registering for the Tri-Conference on-line.

Save 25% off the current rate!

Group registrations are encouraged and we suggest calling:

David Cunningham
Sales Director, Cambridge Healthtech Institute
T: 781-972-5472 | E: cunningham@healthtech.com
Short Course Manual for the Commercialization Boot Camp for Diagnostics**

The Commercialization Boot Camp Short Course provides an overview of the commercialization process, shares real-world case examples, and details some of the necessary requirements for bringing an IVD from product conception through market launch. Two IVD Guides, published by Insight Pharma Reports, are strongly recommended to attendees, authored by Harry Glorikian (the course instructor) himself:

- Commercializing Novel IVDs: A Comprehensive Manual for Success

For more info and to order, visit: TriConference.com/Bootcamp
Molecular diagnostics and devices along with point-of-care tools, AI, and companion diagnostics are enabling prediction, prevention, and precise treatment of cancer, infectious disease and will expand to include many other disease areas. The Molecular Medicine Tri-Conference is one of the industry’s leading events and will showcase new technologies along with emerging therapeutics across a spectrum of applications. This year, key opinion leaders in immunotherapy, liquid biopsy, and cell and gene therapy will discuss the latest tools, clinical advances, and commercial applications of a broad range of new and diverse products for vast improvements in medicine and healthcare.
## COMPANION DIAGNOSTICS WITH LIQUID BIOPSY

### MONDAY, MARCH 2

**10:30** Conference Program Registration Open

**11:45** Organizer’s Opening Remarks  
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

**11:50** Chairperson’s Remarks  
Klaus Pantel, MD, Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf

**11:55** Implementation of Liquid Biopsies in Clinical Trials – Promise, Progress, and Pitfalls  
Ralph Graeser, PhD, Senior Translational Medicine Expert, Boehringer Ingelheim Pharma GmbH

This talk will discuss the use of liquid biopsies in the clinic, and whether it is diagnostic, prognostic, or predictive, as well as CTCs vs. ctDNA: one or the other – or both? We will explore CANCER-id – a public-private partnership with the goal to clinically validate liquid biopsies, and BI in CANCER-ID: CTCs in NSCLC, and why there are so few.

**12:25 pm** CTCs and Their Value in a Multimodality Liquid Biopsy Analysis  
Markus Sprenger-Haussels, PhD, Senior Director, Head of Sample Technologies, Product Development Life Sciences, QIAGEN GmbH

Initial liquid biopsy research studies focused on correlation of single analytes, such as CTC epitopes, ctDNA mutations or exosomal RNA expression with clinical prognosis, therapy stratification, or disease monitoring. The field of liquid biopsy is developing toward a multi-analyte approach that better reflects clinical prognosis, therapy stratification, or disease monitoring. The field of such as CTC epitopes, ctDNA mutations or exosomal RNA expression with clinical prognosis, therapy stratification, or disease monitoring.

**12:55** Session Break

**1:05** LUNCHEON PRESENTATION: Advancing Liquid Biopsy  
Mark Connelly, Chief Industrial Operations and R&D Officer, Menarini Silicon Biosystems

**1:35** Session Break

### Tuesday, March 3

**2:20** Chairperson’s Remarks

**2:25** Molecular Signatures of Circulating Melanoma Cells for Monitoring Early Response to Immune Checkpoint Therapy  
Ryan J. Sullivan, MD, Associate Director, Melanoma Program, MGH Cancer Center

To optimize immunotherapy treatment selection for patients with metastatic melanoma, predictive biomarkers are needed. We aimed to develop an assay that could detect and monitor circulating tumor cells in patients with melanoma. To determine the clinical utility of this assay, we serially assayed patients treated with immune checkpoint inhibitor therapy, generated a "CTC-score" for each time-point, and correlated changes in the assay over time with efficacy.

**2:55** APOBEC Mutagenesis: A Tactic and a Vulnerability of Cancer  
Michael S. Lawrence, PhD, Assistant Professor of Pathology, Harvard Medical School; Assistant Geneticist, Massachusetts General Hospital Cancer Center

APOBECS enzymes mutate the DNA of cancer cells, especially in the context of targeted therapy, where they help speed the search of sequence space for resistance mutations. However, APOBEC overactivity also causes replication stress and renders cancer cells vulnerable to synthetic lethality with inhibitors of DNA damage sensing. Moreover, accumulation of APOBEC-derived neoantigens may predict increased response to immunotherapy.

New understanding of APOBEC’s favored genomic targets enables sensitive detection of APOBEC activity in tumors and CTCs.

**3:25** SBS-CTC Platform for Early Breast Cancer Diagnosis  
Roberta Carbone, PhD, Bio-Lab, Tethis S.p.A

CTC based diagnostic for cancer suffers from standardization, sensitivity and specificity, mainly in early cancer settings. SBS-CTC platform, from blood sample to single cells, provides a solution for liquid biopsy prepared at point of blood collection to preserve clinical sample integrity. Pilot study in a cohort of 60 pT1-T2 blinded early breast cancer patients will be presented to provide unprecedented evidences of the high sensitivity and versatility of SBS-CTC platform in early cancer diagnostics.

**3:55** Presentation to be Announced

**4:10** A Clinically Actionable Liquid Biopsy End-to-End Platform for Metastatic Solid Tumors  
Melissa McConhey, PhD, Senior Manager, Assay Development, Research and Development, Contextual Genomics

Use of liquid biopsy is quickly becoming part of personalized medicine approaches. In this talk, we will present a new end-to-end liquid biopsy platform, FOLLOW IT, that empowers clinical laboratories with the tools to perform in-house testing. Current studies for targeted treatment selection and disease monitoring will be discussed.

**4:25** Refreshment Break and Transition to Plenary Keynote

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**REGISTER EARLY & SAVE!**

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**PREDICTING IMMUNOTHERAPY RESPONSE THROUGH CIRCULATING CELLS: CIRCULATING VESICLES,**

**PLENARY KEYNOTE SESSION**  
(please see Keynotes pages for details)
enumeration, fixation severely degrades RNA and prohibits detailed molecular circulating tumor cell (CTC) isolation. While this method enables CTC chemical fixation remains the only FDA-cleared stabilization method for on the stability and hence repeatability of the blood specimens. Currently, Clinical translation of various liquid biopsy assays is critically dependent Center, The MGH Cancer Center Massachusetts General Hospital, Harvard Medical School; BioMEMS Resource Shannon L. Stott, PhD, Assistant Professor, Department of Medicine, 8:40 Whole Blood Stabilization for Liquid Biopsy DNA will also be discussed.

The landscape of epigenetic-based ctDNA assays and their potential impact on amenable to use as liquid biopsies. This presentation will review the current existing techniques. Alternative approaches include the detection of various epigenetic alterations within cell-free DNA. For instance, DNA methylation and hydroxymethylation are emerging as measurable features that are also amenable to use as liquid biopsies. This presentation will review the current landscape of epigenetic-based ctDNA assays and their potential impact on oncology. Technical challenges to measuring epigenetic alterations in cell-free DNA will also be discussed.

4:35 Welcome Remarks Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

4:45 PLENARY KEYNOTE INTRODUCTION Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia

5:00 PLENARY KEYNOTE PRESENTATION: High-Performance Medicine Eric Topol, MD, Founder and Director, Scripps Research Translational Institute (SRTI); Author, Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

7:30 End of Day

TUESDAY, MARCH 3

7:30 am Registration Open and Morning Coffee

TECHNICAL CHALLENGES ACROSS LIQUID BIOPSY PLATFORMS

8:00 Organizer’s Remarks Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

8:05 Chairpersons’ Remarks Stefanie Jeffrey, MD, John and Marva Warnock Professor, Surgery; Chief, Surgical Oncology Research, Stanford University School of Medicine
Ash Alizadeh, PhD, Associate Professor of Medicine, Divisions of Oncology & Hematology, Stanford University School of Medicine

8:10 The Use of Epigenetic Alterations for Measuring ctDNA Scott V. Bratman, MD, PhD, Radiation Oncologist, Radiation Medicine Program; Scientist, Princess Margaret Cancer Centre, University Health Network; Assistant Professor, Departments of Radiation Oncology and Medical Biophysics, University of Toronto

Mutation-based ctDNA assays are increasingly utilized in the clinic as liquid biopsies. For certain oncology applications, however, mutation-based liquid biopsy approaches have inherent limitations that are difficult to overcome with existing techniques. Alternative approaches include the detection of various epigenetic alterations within cell-free DNA. For instance, DNA methylation and hydroxymethylation are emerging as measurable features that are also amenable to use as liquid biopsies. This presentation will review the current landscape of epigenetic-based ctDNA assays and their potential impact on oncology. Technical challenges to measuring epigenetic alterations in cell-free DNA will also be discussed.

8:40 Whole Blood Stabilization for Liquid Biopsy Shannon L. Stott, PhD, Assistant Professor, Department of Medicine, Massachusetts General Hospital, Harvard Medical School; BioMEMS Resource Center, The MGH Cancer Center

Clinical translation of various liquid biopsy assays is critically dependent on the stability and hence repeatability of the blood specimens. Currently, chemical fixation remains the only FDA-cleared stabilization method for circulating tumor cell (CTC) isolation. While this method enables CTC enumeration, fixation severely degrades RNA and prohibits detailed molecular analysis which is invaluable in understanding disease progression and drug resistance mechanisms. The need to preserve blood in its viable state is exemplified by the very fact that rare-cell technologies require precisely engineered devices which are highly sensitive to minor degradations in blood cell quality. Our group challenges the current dogma that whole blood can only be held at room temperature for up to several hours prior to processing. In this talk, I will share our data that utilizes hypothermic preservation to extend the viability of whole blood cells. I will highlight the non-fixative nature of our approach and demonstrate its critical advantage in preserving RNA integrity for up to 72 hours.

9:10 Liquid Biopsy-Based Biomarkers for Cancer Immunotherapy: Opportunities and Challenges Sam Hanash, MD, PhD, Director, McCombs Institute for Cancer Detection and Treatment, University of Texas MD Anderson Cancer Center

Multiple circulating biomarkers that have the potential to serve as predictive prognostic biomarkers to guide cancer immunotherapy are currently being pursued. These include tumor-derived microvesicles, soluble immune proteins, and metabolites. The current opportunities and challenges will be presented.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

10:40 Saliva Liquid Biopsy (SLB) David T.W. Wong, DMD, DMSc, Associate Dean of Research and Felix & Mildred Yip Endowed Distinguished Professor, UCLA School of Dentistry

Saliva harbors multiple -omics constituents that can be harnessed non-invasively for liquid biopsy applications. PCR-based technologies cannot detect ctDNA in saliva samples, whereas an emerging liquid biopsy platform, EFIRM, can consistently detect ctDNA from NSCLC patients, plasma, and saliva, with concordance of 95%+ with biopsy-based genotyping. EFIRM detects ctDNA with a minimal footprint of 30bp, LOD of single-digit copy number, and conductance sensitivity inversely proportional to ctDNA fragment size.

11:00 Panel Discussion with Session Speakers

11:40 Introducing RNA Complete BCT (RUO), a Novel Blood Collection Tube Targeting Circulating RNA and Extracellular Vesicles Nicholas George, PhD, Research & Development, Scientific Manager, Research and Development, Streck

Liquid Biopsy assays exploiting EVs and cfRNA provide a comprehensive and dynamic view of the disease state. Here we describe the Streck RNA Complete BCT and its incorporation into the Liquid Biopsy workflow allowing for delayed sample processing without effect on sample integrity or downstream analyte analysis in research applications.

11:55 Limitations and New Methods in the Characterization of Microfluidic Devices for Manufacturing QC

Georg Bauer, Business Manager, STRATEC Consumables GmbH

As the momentum for microfluidic devices in Liquid Biopsy continues to grow, the implementation of effective QC for manufacturing processes is gaining importance. A number of startup companies as well as major diagnostic and biopharma companies are developing microfluidic devices for the sample prep.

12:10 pm Session Break

12:20 Luncheon Presentation I to be Announced

12:50 Luncheon Presentation II (Sponsorship Opportunity Available)
3:15 Organizer’s Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, Ph.D, Director, R&D Molecular Biology, Stilla Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.
Moderator: Kevin Davies, Ph.D, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.
Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children’s Institute for Genomic Medicine
David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomedical Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

8:00 Organizer’s Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks
Stuart S. Martin, PhD, Professor, Physiology, Marlene and Stewart Greenbaum NCI Comprehensive Cancer Center, University of Maryland School of Medicine

8:10 FEATURED PRESENTATION: Cytophone Platform for in vivo Noninvasive Liquid Biopsy
Vladimir Zharov, PhD, DSc, Professor, Josephine T. McGill Chair in Cancer Research; Director, Arkansas Nanomedicine Center, Winthrop P Rockefeller Cancer Institute, University of Arkansas for Medical Sciences; CSO, Cytoasta LLC
We developed the versatile Cytophone platform for real-time diagnosis and therapy (theranostics) of rare circulating disease markers in the whole blood pool (up to 5-liter) through intact skin. Based on the principle of photoacoustics, this platform with portable and wearable sensors provides noninvasive (no blood draw, no needle), label-free (no label injection) and safe identification of a single marker of interest in relatively deep vessels in minutes. The broad spectrum of the Cytophone application includes stroke prevention through circulating clot detection, diagnosis of infections (e.g., malaria), sickle anemia, and real-time drug efficiency monitoring, as well as diagnosis of other diseases by molecular targeting of CTCs and other circulating markers with conjugated nanoparticles having high photoacoustic contrast.

8:40 Profiling Protein Expression for Individual CTCs
Shana O. Kelley, PhD, Professor, Department of Biochemistry, Leslie Dan Faculty of Pharmacy, University of Toronto
The analysis of heterogeneous ensembles of rare, circulating tumor cells (CTCs) requires single-cell resolution to allow phenotypic and genotypic information to be collected accurately. We developed a new approach – magnetic ranking cytometry – that uses the magnetic loading of individual cells to be monitored as a means to report on biomarker expression at the single cell level. This approach can be used to profile circulating tumor cells in blood and provides a high-information content liquid biopsy in a single measurement. It profiles both protein (Nature Nanotechnology, 2017) and nucleic acid (Nature Chemistry, 2018) analytes at the single-cell level. We have used this approach to monitor markers of the epithelial-to-mesenchymal transition and predictors of response to therapy for lung and prostate cancer patient samples.

9:05 Chairperson’s Remarks
Paul Hastings, President and CEO, Nkarta Therapeutics, Inc

9:10 Tumor Antigen-Independent and Cell Size Variation-Inclusive Enrichment of Viable Circulating Tumor Cells via Integrated Ferrohydrodynamic Cell Separation (iFCS)
Leidong Mao, PhD, Professor, School of Electrical and Computer Engineering, University of Georgia
We developed a novel method based on contrast of cell magnetization in biocompatible ferrofluids, termed as integrated ferrohydrodynamic cell separation (iFCS), that enriches CTCs in a tumor antigen-independent and cell size variation-inclusive manner, with a high-throughput, high recovery rate and low WBC contamination, and is also biocompatible.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

ASSESSING FUNCTIONALITY OF CTCs AND
DETECTING METASTATIC CASCADE

Chairperson’s Remarks
Catherine Alix-Panabières, PhD, Director, Laboratory of Rare Human Circulating Cells (LCCRH), Pathology and Onco-Biology Department, University Medical Center of Montpellier

10:40 Novel Approaches to Large-Scale Collection and Downstream Analysis of Circulating Tumor Cells
Andrew Rhim, PhD, Associate Director for Translational Research, Ahmed Center for Pancreatic Cancer Research; Assistant Professor of Internal Medicine, UT MD Anderson Cancer Center

While current approaches to circulating tumor cells have focused on obtaining a relatively purified CTC population, such approaches hinder the study of larger numbers of cells and ex vivo expansion and characterization. Here, we will discuss our strategies to enhance large-scale CTC collections, analysis of large numbers of CTCs, and in vitro expansion of CTCs.

11:10 Liquid Biopsy in Cancer Patients: A Focus on Metastasis-Initiator Circulating Tumor Cells
Catherine Alix-Panabières, PhD, Director, Laboratory of Rare Human Circulating Cells (LCCRH), Pathology and Onco-Biology Department, University Medical Center of Montpellier

Circulating tumor cells (CTCs) in blood are promising new biomarkers potentially useful for prognostic prediction and monitoring of therapies in patients with solid tumors, including colon cancer. Moreover, CTC research opens a new avenue for understanding the biology of metastasis in cancer patients. However, an in-depth investigation of CTCs is hampered by the very low number of these cells, especially in the blood of colorectal cancer patients. Thus, the establishment of cell cultures and permanent cell lines from CTCs has become the most challenging task over the past year. In this talk, we will discuss data that may supply insights for the discovery of new biomarkers to identify the most aggressive CTC sub-populations and for the development of new drugs to inhibit metastasis-initiator CTCs in colon cancer.

11:40 Biology and Vulnerabilities of Circulating Tumor Cells (CTCs) and Multicellular CTC Clusters
Massimo Saini, PhD, Postdoctoral Researcher, Department of Biomedicine, University of Basel, Switzerland

Circulating tumor cells (CTCs) are itinerant cancer cells that transit through the bloodstream, where they mediate the hematogenous spread of cancer to distant organs. CTCs can travel as single, suspended cells or as multicellular CTC clusters. Our lab has assessed the molecular phenotype and the metastatic potential of individual CTCs versus CTC clusters matched within individual blood samples, in breast cancer patients and in mouse models of CTC-mediated metastasis.

12:10 pm Analytical Validation of the RareCyte Platform for Circulating Tumor Cell Analysis in Global Clinical Trials
Jeff Fill, Senior Director, Diagnostic and Experimental Pathology, Lilly Research Laboratories, Eli Lilly and Company

12:40 Session Break

12:50 PRECISION HEALTH LUNCHEON PRESENTATION: Validation of A Next Generation Sequencing Gene Panel for Detection of Variants in Plasma Total Nucleic Acid
Xin-Xing Tan, PhD, Principal Scientist, Molecular, NeoGenomics Laboratories, Inc.

Liquid biopsy next generation sequencing (NGS) gene panel assays provide a powerful non-invasive tool to detect tumor-derived variants for clinic diagnostics in a massively parallel manner. We present here an NGS assay designed specifically for liquid biopsy clinical applications, and its analytical and clinical validation to assess accuracy, specificity, sensitivity, repeatability, and reproducibility, etc.

1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

NON-BLOOD-BASED LIQUID BIOPSY DIAGNOSTICS: INVESTIGATING ALTERNATE INPUT MATERIALS

2:00 Chairperson’s Remarks
Steven A. Soper, PhD, Professor, Micro and Nanofabricated Tools for Biological Discovery and Medical Diagnostics, University of Kansas

2:05 A Non-Invasive Liquid Biopsy Approach Using Urine-Derived Exosomes as a Biomarker Source for Predicting Treatment Outcomes in Cancer
Rajagopal Ramesh, PhD, Professor, Jim and Christy Everest Endowed Chair in Cancer Developmental Therapeutics, Oklahoma TSET Cancer Research Scholar, Department of Pathology; Director, Experimental Therapeutics and Translational Cancer Medicine; Chair, Fellowship Training and Mentoring Program; Member, Stephenson Cancer Center, Stanton L. Young Biomedical Research Center

Exosomes are 30 - 120 nm cellular entities secreted from a variety of cell types and detectable in bodily fluids including urine. Studies demonstrate exosomes carry nucleic acids, proteins, lipids, etc., and can be used as source of biomarker. In cancer, tumor-derived exosomes contribute to tumorigenesis, metastasis, and resistance to therapy. Based on these reports we undertook a non-invasive approach of isolating exosomes from urine samples collected from patients diagnosed with non-small cell lung cancer (NSCLC) and receiving chemotherapy or chemotherapy plus anti-PD1 immunotherapy. We hypothesized that analysis of exosomal micro (m) RNA and immune checkpoint proteins (ICP) will aid in predicting treatment outcomes. To test our hypothesis urine samples were collected longitudinally before and after treatments from advanced NSCLC patients receiving chemotherapy or chemotheraphy plus anti-PD1 immunotherapy. Exosomes were isolated by differential ultracentrifugation method and analyzed for micro (m) RNAs using the Illumina MiSeq platform and for immune checkpoint proteins (ICP) by ICP array. The results of the ongoing study will be discussed to demonstrate the feasibility of utilizing urine-derived exosomes isolated from NSCLC patients as potential biomarker source for determining treatment outcomes.

2:35 Liquid Biopsies in Non-Oncological Diseases: Circulating Cells and Extracellular Vesicles as a Source of mRNA for the in vitro Diagnostics of Stroke
Steven A. Soper, PhD, Professor, Micro and Nanofabricated Tools for Biological Discovery and Medical Diagnostics, University of Kansas

Stroke is the third leading killer in the US and the main cause of over 795,000 cases of adult disability each year. The two major types of stroke, ischemic and hemorrhagic, cannot be clinically differentiated; 30% of patients presenting stroke-like symptoms do not have stroke and <5% of stroke patients are treated with available therapeutics (recombinant tissue plasminogen activator for acute ischemic stroke). Computed tomography is commonly used for diagnosis, which provides a clinical sensitivity of only 25%, and in most cases, does not provide clinical information to meet the necessary time requirements for proper therapeutic administration (<4.5 h). Unfortunately, there are no FDA-approved in vitro diagnostic tests for stroke that could address the aforementioned issues. In this presentation, we will provide data on the use of liquid biopsy markers, as well as isolation technologies and appropriate mRNA gene panels.

3:05 Close of Conference
March 2-4, 2020

10:30 Conference Program Registration Open

CURRENT STATUS OF PRECISION HEALTH

11:45 Organizer’s Opening Remarks
Ngoc ‘Emily’ Le, PhD, Conference Producer, Cambridge Healthtech Institute

11:50 Chairperson’s Remarks
Ralph Snyderman, MD, Chancellor Emeritus, Duke University; Director, Duke Center for Personalized Health Care

11:55 FEATURED PRESENTATION: The Precision Health Care Revolution – From Now into the Future
Ralph Snyderman, MD, Chancellor Emeritus, Duke University; Director, Duke Center for Personalized Health Care

Personalized, precision health is forging a transformation in care from its current focus on one-size-fits-all treatment for established diseases to a personalized, predictive approach that improves health, prevents disease, and treats it precisely when it occurs. This allows personalized care for each individual's specific needs. This field is driven by the explosive development of capabilities stemming from genomic technologies, targeted therapies, digital and mobile health technologies, big data collection, artificial intelligence, and clinical awareness of personalized, proactive, patient-driven approaches to care. The harmonization of the new technologies with effective clinical application is a great challenge, but an even greater opportunity.

12:25 pm AI-Enabled Precision Medicine in Clinical Decision Support and Point-of-Care Diagnosis
Matthew Lungren, MD, MPH, Associate Director, Stanford Center for Artificial Intelligence in Medicine and Imaging, Stanford Child Health Research Institute; Faculty Scholar; Assistant Professor of Radiology, Radiology, Stanford University School of Medicine, Lucile Packard Children’s Hospital

Can machine learning help all clinicians achieve expert-level diagnosis and patient-specific risk predictions at the point of care? We will explore framing research that opens new approaches to care delivery in a precision medicine paradigm while also discussing some of the pitfalls and lessons-learned from our field-leading medical AI work at Stanford with partner institutions all over the world.

12:55 Session Break

1:05 LUNCHEON PRESENTATION: Accelerate Assay Adoption by Partnering with a Proven Leader in Instrumentation
Sponsored by Thermo Fisher Scientific

Searching for a platform partner to meet your assay commercialization needs? Come learn about how working with Thermo Fisher Scientific, a proven leader in instrumentation, can accelerate test adoption in your target markets. Leverage the strength of Thermo Fisher’s nucleic acid extraction, PCR, qPCR, Capillary Electrophoresis, microarray and Next Generation Sequencing platforms. Partnership models include reagent rental agreements and private label options.

1:35 Luncheon Presentation II (Sponsorship Opportunity Available)

PHENOTYPING PATIENTS USING ELECTRONIC HEALTH RECORDS AND GENOMIC DATA

2:20 Chairperson’s Remarks
Kenna R. Mills-Shaw, PhD, Executive Director, Khalifa Institute for Personalized Cancer Therapy, MD Anderson Cancer Center

2:25 Machine Learning for Identifying Phenotypes in Electronic Health Records
Marylyn D. Ritchie, PhD, Professor, Genetics; Director, Center for Translational Bioinformatics, Institute for Biomedical Informatics (IBI); Associate Director for Bioinformatics, Institute for Biomedical Informatics (IBI); Associate Director, Penn Center for Precision Medicine, University of Pennsylvania, Perelman School of Medicine

Comprehensive collections of phenotypic data can be used in more integrated ways to better subset or stratify patients based on the totality of his or her health information. Through applying machine learning to the rich phenotypic data of the EHR, these data can be mined to identify new and interesting patterns of disease expression and relationships. We have been exploring machine learning technologies for evaluating the phenomic landscape to improve our understanding of complex traits. These techniques show great promise for the future of precision medicine.

2:55 Electronic Health Records and Computable Phenotyping
Dana C. Crawford, PhD, Associate Professor, Department of Population and Quantitative Health Sciences, Case Western Reserve University

Electronic health records capture individual-level data related to clinical care including medical history, diagnoses, medications, laboratory measures, and social history. While the recording of these data is intended for clinical care and billing, they can be repurposed for precision medicine research albeit with some limitations. In this session, strategies to access these data to extract research-grade variables will be discussed, including common rules-based approaches and more recent computable phenotyping approaches that leverage known genetic relationships to human diseases and traits.

3:20 Chairperson’s Remarks

3:25 Precision Cancer Medicine: Neither Silver Bullet nor an Illusion
Kenna R. Mills-Shaw, PhD, Executive Director, Khalifa Institute for Personalized Cancer Therapy, MD Anderson Cancer Center

Precision oncology is neither an illusion nor is it a panacea. Precision oncology has routinely been utilized in subsets of specific molecularly defined tumors to elicit dramatic and sometimes durable responses. As novel drugs enter clinical trials based on emerging biological discoveries, implementation of precision oncology grows into an unmanageable feat without a highly integrated decision support platform that is both proactive, providing timely updates, as well as responsive to the changing clinical landscape. This talk will discuss how decision support can be a necessary transformative force for precision oncology, ultimately resulting in systematic improvements in clinical care and improvements in patient outcome.

3:55 Presentation to be Announced
**NIH's All of Us Research Program, launched nationally in May 2018, is working to build the largest, most diverse research resource of its kind to accelerate biomedical discoveries and advance precision medicine. The program aims to enroll one million or more participants across the country, with a special focus on engaging populations that are historically underrepresented in research. This presentation will provide an overview of the program, an update on its progress to date, and information about the data and tools that will be broadly accessible to researchers for a wide range of studies.**

**9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group**

**DECODING DISEASES IN THE ERA OF PRECISION HEALTH USING AI AND MACHINE LEARNING**

**10:40 Chairperson's Remarks**

Keith L. Ligon, MD, PhD, Associate Professor, Pathology, Harvard Medical School; Associate Pathologist and Neuropathologist, Pathology, Director, DFCI Center for Patient Derived Models, Brigham and Women's Hospital

**10:45 Translating Ten Trillion Points of Data into Diagnostics, Therapies and New Insights in Health and Disease**

Atul Butte, MD, PhD, Priscilla Chan and Mark Zuckerberg Distinguished Professor; Director, Bakar Computational Health Sciences Institute, University of California, San Francisco; Chief Data Scientist, University of California Health (UC Health)

We build and apply tools that convert trillions of points of molecular, clinical, and epidemiological data – measured by researchers and clinicians over the past decade and now commonly termed “big data” – into diagnostics, therapeutics, and new insights into disease. Dr. Butte, a computer scientist and pediatrician, will highlight his center’s recent work on integrating electronic health records data across the entire University of California, and how analytics on this “real world data” can lead to new evidence for drug efficacy, new savings from better medication choices, and new methods to teach intelligence — real and artificial — to more precisely practice medicine.

**11:15 Using Networks to Decode Cancer Risk**

John Quackenbush, PhD, Professor and Chair, Biostatistics, Harvard TH Chan School of Public Health

Precision medicine is based on the idea that single mutations can inform our understanding of disease and response to therapy. But we know that cancer is multifactorial, with many genetic variants moderating disease and disease risk. By using network methods, we can better understand how and why cancer develops and assess disease risk.

**11:45 Machine Learning-Based Patient Subgroup Identification for Precision Medicine**

Jie Cheng, PhD, Director, Exploratory Statistics, Abbvie

Central to precision medicine is the ability to detect patient subgroups with differential treatment effects in clinical trial datasets. These patient subgroups are defined by clinical variables and biomarkers. We will provide a brief overview of existing methods for patient subgroup identification and then present our novel approach. The performance of our method is evaluated against other state-of-the-art methods using both simulation and real-world clinical trial dataset.

**12:15 pm Session Break**

**12:20 LUNCHENON PRESENTATION I: A Modern Molecular LIMS Built for Precision Medicine**

Nabil Hafez, MS, Senior Director, Product Management, Precision Medicine, Sunquest Information Systems

With the advent of precision medicine, molecular labs are facing greater testing demand than ever before. Molecular diagnostics are complicated,
rapidly changing, and subject to detailed regulatory auditing. Learn how modern labs are streamlining molecular testing, for volume and growth, and mastering compliance with purpose-built LIMS technology.

12:50 Luncheon Presentation II (Sponsorship Opportunity Available)

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Keynote Session

KEYNOTE SESSION

(please see Keynotes pages for details)

3:15 Organizer's Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three Established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.
Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children's Institute for Genomic Medicine; Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

6:00 End of Day

6:30 - 9:30 Dinner Short Courses* (please see Short Courses pages for details)
*Separate registration required

WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available)

8:00 Organizer's Remarks
Ngoc 'Emily' Le, PhD, Conference Producer, Cambridge Healthtech Institute

8:05 Chairperson's Remarks
Albine Martin, PhD, Executive in Residence, Johns Hopkins University

8:10 PANEL DISCUSSION: Drivers and Barriers of Advancing Innovation to Patients
Moderator: Albine Martin, PhD, Executive in Residence, Johns Hopkins University
Panelists: Elizabeth Sheppard, MBA, Senior Director, Global Market Access, Roche Tissue Diagnostics, United States; Hilja Ibert, PhD, CEO, Gentian Additional Panelists to be Announced

8:55 PANEL DISCUSSION: Coverage and Reimbursement of Advanced Diagnostics
As healthcare is transitioning from "sick" care to "well" care and shifting from fee-for-service to value-based models, it's essential that we develop evidence to demonstrate the new value of the laboratory for optimized reimbursement. Topics to be discussed:
- Understand how to define and measure value using appropriate KPIs to help influence reimbursement policy.
- Learn ways to survive financially as payment models shift and reimbursement is driven by outcomes and risk with potential upside depending upon the reimbursement model.
- Explore key partnership opportunities that are aligned with the changes in healthcare to help shape value.

Moderator: Khosrow R. Shotorbani, President, Executive Director, Project Santa Fe Foundation
Panelists: Gabriel Bien-Wilner, MD, PhD, Medical Director, Moldx, Palmetto GBA; Kristine Bordenave, MD, FACP, Former Corporate Medical Director, Humana; Lon Castle, CMO, Molecular Genetics and Personalized Medicine, eviCore Healthcare; Shivang Doshi, Director, Boston Healthcare Associates, Inc.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

FUNCTIONAL GENOMICS FOR PRECISION MEDICINE

10:40 Functional Precision Medicine in Brain Tumors and Other Cancers
Keith L. Ligon, MD, PhD, Associate Professor, Pathology, Harvard Medical
School; Associate Pathologist and Neuropathologist, Pathology; Director, DFCI Center for Patient Derived Models, Brigham and Women’s Hospital
We have developed large-scale cohorts of novel patient-derived cell lines (3D) and xenografts which represent the wide spectrum of phenotypes and genotypes seen in the diseases. We also developed large-scale pharmacogenomic screening approaches to prioritize the genotypes most responsive to such therapies and developed acute sensitivity assays based on novel biomarkers of mass and imaging to assess individual patient samples freshly derived from patients enrolling in clinical trials and standard of care therapy. Such acute sensitivity assays show reliable results for individual patients for both diagnosis and also represent novel approaches to generation of early-phase human evaluation of novel drugs in clinical trials and can shorten the time frame of data generation and lower costs for clinical trials in these diseases.

11:10 Leveraging Tumor Organoids for Functional Precision Medicine Applications
Alice Soragni, PhD, Principal Investigator, Orthopaedic Surgery, University of California Los Angeles
We have established a pipeline to process clinical samples obtained from tumor resection surgeries, develop tumor organoid models with success rates above 90% and perform high-throughput drug screenings. We take advantage of our ring approach that uses a modified ge-ometry to facilitate and automate changing media, adding drugs and performing assays (Phan et al, 2019). Our methodology allows us to successfully obtain and perform large drug screenings for various tumors, including low-grade tumors or heavily pre-treated tumors, which are typically refractory to grow in immunocompromised mice as patient-derived xenografts.

11:40 A Hybrid Genomic/Phenomic Approach to Personalizing Cancer Therapies
Clifford Reid, PhD, Founder and CEO, Trava
To make the wealth of genomic information broadly useful for patient care, we propose a new approach to identifying effective therapies for patients who have driver mutations in cancer genes but no FDA-approved matching therapies. First, we use genomics to identify a set of candidate drugs though cancer pathway analysis: we identify which pathways the patient’s mutations affect, and then identify the existing FDA-approved drugs that work on those pathways. Second, we use phenotypic testing to identify the subset of the candidate drugs that are most likely to be effective in the patient: we test each candidate drug ex vivo against the patient’s live cancer cells and identify the high-response drugs.

12:10 pm Sponsored Presentation (Opportunity Available)

12:40 Session Break

12:50 PRECISION HEALTH LUNCHEON PRESENTATION:
Validation of A Next Generation Sequencing Gene Panel for Detection of Variants in Plasma Total Nucleic Acid
Xin-Xing Tan, PhD, Principal Scientist, Molecular, NeoGenomics Laboratories, Inc.
Liquid biopsy next generation sequencing (NGS) gene panel assays provide a powerful non-invasive tool to detect tumor-derived variants for clinical diagnostics in a massively parallel manner. We present here a NGS assay designed specifically for liquid biopsy clinical applications, and its analytical and clinical validation to assess accuracy, specificity, sensitivity, repeatability, and reproducibility, etc.

1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Chairperson’s Remarks
Hsueh-Chia Chang, PhD, Bayer Corporation Professor of Chemical Engineering, Chemical and Biomolecular Engineering, University of Notre Dame

2:05 Diagnosing Disease with Rare Circulating EVs: Finding Heterogeneous, Nanoscale Needles in a Nanoscale Haystack
David A. Issadore, PhD, Assistant Professor, Bioengineering & Electrical & Systems Engineering, University of Pennsylvania
We developed a multichannel nanofluidic system to analyze crude clinical samples. Using this platform, we isolated EVs, profile the RNA cargo inside of these EVs, and apply a machine learning algorithm to generate predictive panels that could provide useful diagnostics for applications in traumatic brain injury and pancreatic cancer using both murine models and clinical samples.

2:35 Isolation/Fractionation of Blood Exosomes and Profiling of Exosomal miRNA for Precision Medicine Application
Hsueh-Chia Chang, PhD, Bayer Corporation Professor of Chemical Engineering, Chemical and Biomolecular Engineering, University of Notre Dame
We present two nano-fluidic technologies for high-yield and high-throughput fractionation of nanoparticles carriers in blood, like exosomes, lipoproteins and ribonucleoproteins, which carry most of the extracellular RNAs. Both use asymmetric nanopore membranes (ANM) that are asymmetrically etched from ion-track membranes. ANM allows high throughput (>5 ml/hour) isolation of nanoparticles of specific size range by nanofiltration, without lysing or coalescence and with high purity (low protein content). It also allows high-yield nano-magnetic bead capture of particles with specific surface antigens.

3:00 Precision Microfluidic Medicine: From Single-Cell Analysis to Single-Cell Engineering for Cell-Based Theranostics
Abraham “Abe” P Lee, Professor, Biomedical Engineering; Professor, Mechanical & Aerospace Engineering; Director, NSF I/UCRC, University of California at Irvine
We present a microfluidic trapping array which is able to rapidly and deterministically trap single cells in highly-packed microcavities. As the single-cell trapping efficiency is determined by the channel design instead of the flow rate, this trapping array can be coupled with different microfluidic sample processing units with different flow rates for various single-cell analyses.

3:35 Close of Conference
Cell-free DNA for Non-invasive Identification & Applications in Predicting Infections in High-Risk Immunocompromised Patients.

The Karius Test uses next-generation sequencing of microbial cell-free DNA in blood to help diagnose infections throughout the body, offering a non-invasive alternative with higher diagnostic yield than conventional methods. We present current applications in clinical practice and describe potential future regulatory and reimbursement hurdles.

Disruption of the larger MDx market will require POC Dx companies for each company to carve out differentiated market opportunities and become increasingly crowded, with hundreds of players narrowing the runway. Technologies have fallen short of their hype and promise. The field has clinical adoption and real-world use of point-of-care diagnostic (POC Dx) strategies. Disruption of the larger MDx market will require POC Dx companies to create “winning strategies” by establishing competitive differentiation from one another, driving successful adoption and implementation, and navigating regulatory and reimbursement hurdles.

Moderator: David Cavanaugh, Partner, DeciBio
Panelists: Ester Stein, Director, Corporate Reimbursement, Government Affairs, Abbott Laboratories
Gyorgy Abel, MD, PhD, Medical Director, Molecular Diagnostics, Pathology and Laboratory Medicine, Lahey Hospital & Medical Center, Beth Israel Lahey Health
Trevor Martin, PhD, Co-Founder and CEO, Mammoth Biosciences
Jenny Rooke, PhD, Managing Director, Genoa Ventures
Bryan Bothwell, Director, Strategy and Business Development, Qorvo Biotechnologies
Joseph San Filippo, PhD, Director, Business Development, Roche Molecular Solutions

3:55 Optimization of Biospecimen Selection and Processing for Successful NGS Outcomes
Cathie G. Miller, PhD, Director, Drug-Diagnostics Co-Development

Patrik Vitazka, PhD, Senior Director, Companion Diagnostics, Daiichi Sankyo Inc., USA

AstraZeneca, United Kingdom

Pharma companies continue to build and invest in targeted therapy pipeline. New diagnostic platforms are being developed to identify the patient most likely to respond to a given treatment. There is an ever-growing need to understand the precision medicine landscape through the eyes of the practicing clinician. Geographical differences in the access to various testing modalities and reimbursement must be accounted for in clinical development programs and go-to-market strategies. This presentation will provide an overview of the considerations for the global development and lifecycle management of patient diagnostic and monitoring tools.

How Clinical Practice Is Shaping the Precision Medicine Ecosystem
Cecilia Schott, PharmD, MBA, Head, Precision Medicine Strategy, Oncology Business Unit, Novartis
FFPE tissues, drug discovery workhorses, have obstacles when used in downstream applications. For 10 years, we have selected and processed specimens from BioIVT’s ASTERAND® Repository. We present case studies representing use-case scenarios: 1) Maximizing specific annotated specimens; 2) Maximizing annotated specimens across a cohort and 3) Replicating clinical validation cohort.

4:10 Using Prototype Comp Dx IHC Assays to Guide Clinical and Business Decisions
Frank Lynch, PhD, Executive Vice President, IHC Services, Discovery Life Sciences (legacy QualTek Molecular Laboratories)
Pursuing a Drug-Diagnostics co-development approach is a monumental decision for biopharmaceutical companies. This presentation will look at considerations to strategically leverage Prototype Companion Dx IHC assays to assist in making the decision and investment to pursue a Companion Dx or not.

4:25 Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION
(please see Keynotes pages for details)

4:35 Welcome Remarks
Cindy Crowningshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

4:45 PLENARY KEYNOTE INTRODUCTION
Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia

5:00 PLENARY KEYNOTE PRESENTATION: High-Performance Medicine
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute (SRTI); Author, Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

7:30 End of Day

TUESDAY, MARCH 3

7:30 am Registration Open and Morning Coffee

GLOBAL STRATEGIES FOR COMPANION DIAGNOSTICS

8:00 Organizer’s Remarks
Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks
Marielena Mata, PhD, Director and Diagnostic Lead, Companion Diagnostics, Pfizer

8:10 Companion Diagnostics in the Era of Consolidation and Globalization: Multiplexed Biomarkers across Therapeutic Areas and around the Globe
Omar Perez, PhD, Head, Precision Medicine and Diagnostics, GSK
This presentation will discuss the need of multiple CDx strategies based on local needs and local capabilities. Examples from Europe and Asia will be discussed.

8:25 Considerations on Discovery of Biomarkers at Global Level
Kate Sasser, PhD, Corporate Vice President, Head, Translational Research, Genmab
Developing a companion diagnostic that can be co-approved and co-launched with the appropriate drug product starts with a biomarker strategy that is fully integrated from the earliest stages of development. Diagnostic decision making should be automatically incorporated into the biomarker program, and should take into account global complexities. This presentation will provide a high level overview of incorporating diagnostics into early stage biomarker plans for clinical development in order to ensure late stage and launch success.

8:40 Integrating China in Global Clinical Trials with a Companion Diagnostic: Challenges and Opportunities
Marielena Mata, PhD, Director and Diagnostic Lead, Companion Diagnostics, Pfizer
Health challenges in China offer big opportunities for pharma. While the unmet need for oncology drugs in the China market represents a large opportunity, conducting the clinical trials needed for registration present a number of challenges, including changing regulations, restrictions for the exportation of samples, IP requirements, and availability of CROs. We will discuss these challenges and potential solutions.

8:55 Meaningful Use of Biomarker Data in the Era of GDPR
Hisham Hamadeh, PhD, MBA, Vice President, Global Head, Data Science, GenMab
Biomarker data, especially next generation sequencing data, is increasingly useful in clinical trials. However, the interpretation of GDPR has the potential to challenge the way such data is analyzed, shared and placed in the context of much larger datasets. We will discuss the intersection of the regulation, technology, and practical needs of researchers and offer recommendations to enable meaningful use of clinical biomarker data which adhere to patient protection regulation, especially in Europe.

9:10 The Future of Genomic Studies Must Be Globally Representative
Kari North, PhD, Professor, Department of Epidemiology, University of North Carolina at Chapel Hill
The past decade has seen a revolution in human genetics that has empowered population-level investigations into the biology of complex traits. Here I demonstrate the value of diverse, multi-ethnic participants in large-scale genomic studies by providing an overview of strategies to improve global representation in genomics research and highlighting the successes of studies and consortia that have provided unique knowledge.

9:25 Market Access Strategies for Companion Diagnostics Outside the US
Arushi Agarwal, Director, Personalized Medicine, Health Advances LLC

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

REGULATION AND PERSONALIZED ADOPTIVE CELL THERAPY

Chairperson’s Remarks
Ross Wilson, PhD, Project Scientist and Principal Investigator, UC Berkeley & the innovative Genomics Institute

10:40 Regulatory Approaches for Development of CAR T Therapies
Elena Spanjaard, PhD, Global Head of Regulatory Affairs, Regulatory Affairs, Celyad
I will define IND requirements for genetically-modified CAR T therapies and discuss the tailored regulatory strategies to address unique program features.
**KEYNOTE SESSION**

(please see Keynotes pages for details)

3:15 Organizer's Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics

20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.
Panelists: Gabriel Bien-Willner, MD, PhD, Medical Director, Moldx, Palmetto GBA
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

6:00 End of Day

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**DELIVERING PRECISION MEDICINE**

8:00 Organizer's Remarks
Ngoc ‘Emily’ Le, PhD, Conference Producer, Cambridge Healthtech Institute

8:05 Chairperson's Remarks
Albine Martin, PhD, Executive in Residence, Johns Hopkins University

8:10 PANEL DISCUSSION: Drivers and Barriers of Advancing Innovation to Patients
Moderator: Albine Martin, PhD, Executive in Residence, Johns Hopkins University
Panelists: Elizabeth Sheppard, MBA, Senior Director, Global Market Access, Roche Tissue Diagnostics, United States
Hilja Ibert, PhD, CEO, Gentian
Additional Panelists to be Announced

8:55 PANEL DISCUSSION: Coverage and Reimbursement of Advanced Diagnostics
As healthcare is transitioning from “sick” care to “well” care and shifting from fee-for-service to value-based models, it’s essential that we develop evidence to demonstrate the new value of the laboratory for optimized reimbursement. Topics to be discussed:

- Understand how to define and measure value using appropriate KPIs to help influence reimbursement policy.
- Learn ways to survive financially as payment models shift and reimbursement is driven by outcomes and risk with potential upside depending upon the reimbursement model.
- Explore key partnership opportunities that are aligned with changes in healthcare to help shape value.

Moderator: Khosrow R. Shotorbani, President, Executive Director, Project Santa Fe Foundation
Panelists: Gabriel Bien-Willner, MD, PhD, Medical Director, Moldx, Palmetto GBA
Kristine Bordenave, MD, FACP , Former Corporate Medical Director, Humana
Lon Castle, CMO, Molecular Genetics and Personalized Medicine, eviCore Healthcare
Shivang Doshi, Director, Boston Healthcare Associates, Inc.
REGISTER EARLY & SAVE!
SUNDAY, MARCH 1

2:00 - 5:00 pm Afternoon Short Courses* (please see Short Courses pages for details)
*Separate registration required

5:30 - 8:30 Dinner Short Courses* (please see Short Courses pages for details)
*Separate registration required

MONDAY, MARCH 2

8:00 - 11:00 am Morning Short Courses* (please see Short Courses pages for details)
*Separate registration required

10:30 Conference Program Registration Open

HARMONIZING NEW TECH WITH CLINICAL CARE

11:45 Organizer’s Opening Remarks
Ngoc ‘Emily’ Le, PhD, Conference Producer, Cambridge Healthtech Institute

11:50 Chairperson’s Remarks
Ralph Snyderman, MD, Chancellor Emeritus, Duke University; Director, Duke Center for Personalized Health Care

11:55 FEATURED PRESENTATION: The Precision Health Care Resolution – From Now into the Future
Ralph Snyderman, MD, Chancellor Emeritus, Duke University; Director, Duke Center for Personalized Health Care

Personalized, precision health is forging a transformation in care from its current focus on one-size-fits-all treatment for established diseases to a personalized, predictive approach that improves health, prevents disease, and treats it precisely when it occurs. This allows personalized care for each individual’s specific needs. This field is driven by the explosive development of capabilities stemming from genomic technologies, targeted therapies, digital and mobile health technologies, big data collection, artificial intelligence, and clinical awareness of personalized, proactive, patient-driven approaches to care. The harmonization of the new technologies with effective clinical application is a great challenge, but an even greater opportunity.

12:25 pm AI-Enabled Precision Medicine in Clinical Decision Support and Point-of-Care Diagnosis
Matthew Lungen, MD, MPH, Associate Director, Stanford Center for Artificial Intelligence in Medicine and Imaging, Stanford Child Health Research Institute; Faculty Scholar; Assistant Professor of Radiology, Radiology, Stanford University School of Medicine, Lucile Packard Children’s Hospital
Can machine learning help all clinicians achieve expert-level diagnosis and patient-specific risk predictions at the point of care? We will explore frame-shifting research that opens new approaches to care delivery in a precision medicine paradigm while also discussing some of the pitfalls and lessons-learned from our field-leading medical AI work at Stanford with partner institutions all over the world.

12:55 Session Break

1:05 LUNCHEON PRESENTATION: Accelerate Assay Adoption by Partnering with a Proven Leader in Instrumentation

Sponsored by Thermo Fisher Scientific

2:05 Session Break

BIOSENSORS FOR POINT-OF-CARE

2:20 Chairperson’s Remarks
Kiana Aran, PhD, Assistant Professor, Medical Diagnostics and Therapeutics, Henry. E. Riggs School of Applied Life Sciences, Keck Graduate Institute

2:25 Noninvasive Magneto-Nanosensors for Point-of-Care Gene Expression Analysis
Shan X. Wang, PhD, Professor, Materials Science and Engineering, and Electrical Engineering, Stanford University
Gene expression analysis at the POC is important for rapid disease diagnosis, but traditional techniques are limited by multiplexing capabilities, bulky equipment and cost. We present a giant magnetoresistive (GMR) biosensor platform well suited for multiplexed transcript detection and quantification. The technology has shown great promise in detecting influenza detection and vaccination response based on Influenza Meta Signature (IMS) resulting from host immune responses to viral infections.

2:55 CRISPR-Chip: CRISPR-Powered Transistors for DNA Biosensing
Kiana Aran, PhD, Assistant Professor, Medical Diagnostics and Therapeutics, Henry. E. Riggs School of Applied Life Sciences, Keck Graduate Institute
CRISPR-chip is a graphene field effect transistor (gFET) electronic biosensor that utilizes the sequence-specific targeting capabilities of CRISPR to detect target DNA sequences. The graphene surface of the CRISPR-Chip is functionalized with nuclease-deactivated CRISPR RNA-guided ribonucleoproteins (dRNPs) which scan the genomic sample, bind to their target sequence, and produce a detectable change in the gFET signal output. CRISPR-Chip harnesses the search function of CRISPR/Cas9 and the ultra-sensitivity of graphene-based nanoelectronics to detect two distinct mutations in patients with confirmed muscular dystrophy disorder without the need for gene amplifications.

ARTIFICIAL INTELLIGENCE IN POINT-OF-CARE TECHNOLOGIES

3:25 Artificial Intelligence-Enhanced Ecosystem of Point-of-Care Technologies for Antimicrobial Resistance Detection
Nam K. Tran, PhD, HCLD (ABB), FACC, Associate Professor and Director of Clinical Chemistry, Special Chemistry/Toxicology, and Point-of-Care Testing, Pathology and Laboratory Medicine, University of California, Davis
Artificial intelligence (AI) may provide new opportunities for predicting and perhaps preventing antimicrobial resistance in the community. The application of AI at the point of care (POC) could help identify infectious disease trends within patients and/or whole populations to optimize antimicrobial prescribing practices and combat the emergence of resistant pathogens. Lastly, the integration of POC testing with other laboratory methods under a diagnostic “ecosystem” is instrumental prior to leveraging AI analytics.

3:55 Point-of-Care, Quantitative Procalcitonin Test Using Electrochemistry Sensors
Ming Tan, PhD, CEO, Wainamics
Point-of-care (POC) testing of procalcitonin allows rapid confirmation of blood stream bacterial infection and assessment antibiotics treatment. Wainamics
presents here a low cost, disposable microfluidic cartridge for high-sensitivity, quantitative measurement of procalcitonin. Together with a compact instrument, such system provides a platform for high precision POC testing.

4:10 Drivers for Utilizing Cloud Solutions in POC Device Development

Christian Valcke, Global Director Software Engineering, Software Engineering, Invetech

The rise of connected devices, centralized data storage, and machine learning are changing the way POC diagnostics deliver value. We consider the critical success factors of POC device development (timeline, cost, differentiation) and how the adoption of cloud solutions can impact those factors as products are defined, developed and deployed.

4:25 Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION

(please see Keynotes pages for details)

4:35 Welcome Remarks

Cindy Crownesshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

4:45 PLENARY KEYNOTE INTRODUCTION

Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia

5:00 PLENARY KEYNOTE PRESENTATION: High-Performance Medicine

Eric Topol, MD, Founder and Director, Scripps Research Translational Institute (SRTI); Author, Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

7:30 End of Day

TUESDAY, MARCH 3

7:30 am Registration Open and Morning Coffee

BIOMARKER TECHNOLOGY

8:00 Organizer's Remarks

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

8:05 Chairperson's Remarks

Vipul Baxi, Principal Scientist, Digital Pathology Lead, Translational Bioinformatics, Bristol-Myers Squibb

8:10 Digital Pathology in Precision Oncology

Vipul Baxi, Principal Scientist, Digital Pathology Lead, Translational Bioinformatics, Bristol-Myers Squibb

Digital pathology – particularly with the combination of whole slide imaging, advanced staining methods, and artificial intelligence – has the potential to transform our understanding of the pathophysiology of disease, which in turn, may help to advance precision medicine. This talk will explore the role of digital pathology in translational research in immuno-oncology and other disease areas, as well as its potential as a platform for companion diagnostics.

8:40 Biomarkers in the Era of Immuno-Oncology: Update on Keytruda and Combinations

Andrea Webber, PhD, Assistant Head, Clinical Biomarkers in Translational Oncology, Merck Research Labs

This talk will discuss the evolving landscape of biomarkers in the field of immuno-oncology, on immunohistochemistry and genomic approaches, for both immune-checkpoint single-agent treatments and combination therapies.

9:10 An Introduction to Chip Cytometry: Bridging the Gap Between Pathology and Flow Cytometry

Spencer Schwarz, Field Application Specialist, Canopy Biosciences

Chip cytometry is a mature and flexible methodology combining the multi-dimensionality and single-cell discrimination of flow cytometry with the spatial and morphology information of pathology. Flow cytometry provides high-dimensional biomarker information resolved at the single-cell level. Yet flow's destructive sampling omits morphological and spatial relationship information. Conversely, pathology provides spatial and cell morphology information, but prohibits high-dimensionality biomarker interrogation. Chip cytometry intersects these methods, providing a complete and precise picture of proteomic expression.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

DECODING DISEASES IN THE ERA OF PRECISION HEALTH USING AI AND MACHINE LEARNING

10:40 Chairperson’s Remarks

Keith L. Ligon, MD, PhD, Associate Professor, Pathology, Harvard Medical School; Associate Pathologist and Neuropathologist, Pathology; Director, DFCI Center for Patient Derived Models, Brigham and Women’s Hospital

10:45 Translating Ten Trillion Points of Data into Diagnostics, Therapies and New Insights in Health and Disease

Atul Butte, MD, PhD, Priscilla Chan and Mark Zuckerberg Distinguished Professor; Director, Bakar Computational Health Sciences Institute, University of California, San Francisco; Chief Data Scientist, University of California Health (UC Health)

We build and apply tools that convert trillions of points of molecular, clinical, and epidemiological data – measured by researchers and clinicians over the past decade and now commonly termed “big data” – into diagnostics, therapeutics, and new insights into disease. Dr. Butte, a computer scientist and pediatrician, will highlight his center’s recent work on integrating electronic health records data across the entire University of California, and how analytics on this “real world data” can lead to new evidence for drug efficacy, new savings from better medication choices, and new methods to teach intelligence – real and artificial – to more precisely practice medicine.

11:15 Using Networks to Decode Cancer Risk

John Quackenbush, PhD, Professor and Chair, Biostatistics, Harvard TH Chan School of Public Health

Precision medicine is based on the idea that single mutations can inform our understanding of disease and response to therapy. But we know that cancer is multifactorial, with many genetic variants moderating disease and disease risk. By using network methods, we can better understand how and why cancer develops and assess disease risk.

11:45 Machine Learning-Based Patient Subgroup Identification for Precision Medicine

Jie Cheng, PhD, Director, Exploratory Statistics, Abbvie

Central to precision medicine is the ability to detect patient subgroups
with differential treatment effects in clinical trial datasets. These patient subgroups are defined by clinical variables and biomarkers. We will provide a brief overview of existing methods for patient subgroup identification and then present our novel approach. The performance of our method is evaluated against other state-of-the-art methods using both simulation and real-world clinical trial dataset.

12:15 pm Session Break

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Keynote Session

KEYNOTE SESSION
(please see Keynotes pages for details)

3:15 Organizer’s Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Still Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. These advances in throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.

Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children’s Institute for Genomic Medicine
David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomolecular Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

3:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

6:00 End of Day

6:30 - 9:30 Dinner Short Courses* (please see Short Courses pages for details) *Separate registration required

WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)
Moderator: Robin Toft, Author of WE CAN, The Executive Women’s Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search
Panelists: Camille Samuels, MBA, Partner, Venrock
Paul Hastings, President and CEO, Nkarta Therapeutics, Inc
Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration
Alice Zheng, MD, MPH, MBA, Engagement Manager and Women’s Health Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

LIVE CTC ASSESSMENT AND CAPTURE

8:00 Organizer’s Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks
Stuart S. Martin, PhD, Professor, Physiology, Marlene and Stewart Greenebaum NCI Comprehensive Cancer Center, University of Maryland School of Medicine

8:10 FEATURED PRESENTATION: Cytophone Platform for in vivo Noninvasive Liquid Biopsy
Vladimir Zharov, PhD, DSc, Professor, Josephine T. McGill Chair in Cancer Research; Director, Arkansas Nanomedicine Center, Winthrop P. Rockefeller Cancer Institute, University of Arkansas for Medical Sciences; CSO, Cytoastra LLC
We developed the versatile Cytophone platform for real-time diagnosis and therapy (theranostics) of rare circulating disease markers in the whole blood pool (up to 5-liter) through intact skin. Based on the principle of photoacoustics, this platform with portable and wearable sensors provides noninvasive (no blood draw, no needle), label-free (no label injection) and safe identification of a single marker of interest in relatively deep vessels in minutes. The broad spectrum of the Cytophone application includes stroke prevention through circulating clot detection, diagnosis of infections (e.g., malaria), sickle anemia, and real-time drug efficiency monitoring, as well as diagnosis of other diseases by molecular targeting of CTCs and other circulating markers with conjugated nanoparticles having high photoacoustic contrast.

8:40 Profiling Protein Expression for Individual CTCs
Shana O. Kelley, PhD, Professor, Department of Biochemistry, Leslie Dan Faculty of Pharmacy, University of Toronto
The analysis of heterogeneous ensembles of rare, circulating tumor cells (CTCs) requires single-cell resolution to allow phenotypic and genotypic information to be collected accurately. We developed a new approach – magnetic ranking cytometry – that uses the magnetic loading of individual cells to be monitored.
as a means to report on biomarker expression at the single cell level. This approach can be used to profile circulating tumor cells in blood and provides a high-information content liquid biopsy in a single measurement. It profiles both protein (Nature Nanotechnology, 2017) and nucleic acid (Nature Chemistry, 2018) analytes at the single-cell level. We have used this approach to monitor markers of the epithelial-to-mesenchymal transition and predictors of response to therapy for lung and prostate cancer patient samples.

9:10 Tumor Antigen-Independent and Cell Size Variation-Inclusive Enrichment of Viable Circulating Tumor Cells via Integrated Ferrohydrodynamic Cell Separation (iFCS)
Leidong Mao, PhD, Professor, School of Electrical and Computer Engineering, University of Georgia
We developed a novel method based on contrast of cell magnetization in biocompatible ferrofluids, termed as integrated ferrohydrodynamic cell separation (iFCS), that enriches CTCs in a tumor antigen-independent and cell size variation-inclusive manner, with a high-throughput, high recovery rate and low WBC contamination, and is also biocompatible.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

INTEGRATING MICROFLUIDICS, NANOSERNSORS, AND MINIATURIZED DEVICES

10:40 Miniaturized Electrofluidic Technologies for Health and Environmental Monitoring
Mehdi Javanmard, PhD, Associate Professor, Electrical and Computer Engineering, Rutgers University New Brunswick
In this talk, I will discuss my group’s work on fabricating micro- and nanosensing platforms for biomolecular and biochemical detection. In the first part of my talk, I will discuss a digital microfluidic platform for detection of inflammatory proteins in blood and saliva. I will then discuss a novel scheme for barcoding microparticles nanoelectronically, for multiplexed detection of analytes. We have also developed a novel electrochemical sensor using reduced graphene oxide for detection of inflammatory markers in exhaled breath condensate for management of chronic respiratory diseases. Finally, I will talk about my group’s efforts in developing novel probes for characterization of biological organisms on-the-field in environmental samples, along with sensors for detection of toxic compounds in our regional water sources.

MODERNIZING PAPER-BASED LATERAL FLOW ASSAYS

11:10 Recent Progress with Rapid Single-Use NAAT-Based Pathogen Detection Devices
Paul Yager, PhD, Professor, Department of Bioengineering, University of Washington
Detection of pathogens by untrained users in low resource environments is challenging. Our current approach is to use isothermal nucleic acid amplification. As opposed to the prevalent instrument/disposable paradigm, we have been emulating the simplicity of the user interface of the modern home pregnancy test. Ongoing projects include detection of tuberculosis using oral swabs, detection of chlamydia using urine, and detection of HIV from finger-stick blood samples.

11:40 Catalytic Enhancement of Lateral Flow Immunoassays: More Signal Amplifies Our Opportunity
Shawn P. Mulvaney, Section Head, Surface Nanoscience and Sensor Technology, Chemistry Division, U.S. Naval Research Laboratory
In field forward and remote settings, lateral flow immunoassays are one of the most important diagnostic technologies. However, they are limited by their sensitivity. We have developed a catalytic enhancement scheme where Pd replaces the traditional Au labels and we are realizing orders of magnitude more sensitivity. Our approach promises to reinvigorate a classic technology resulting in far more capable diagnostic that is perfectly suited for the most remote of locations, yet applicable to many more.

12:10 pm Reducing Manufacture Costs of Autologous Cellular Immunotherapy via a Benchtop System for QA/ QC Automation
Xinyi Zhou, PhD, Senior Engineer, Triple Ring Technologies
Autologous cell therapies have shown unprecedented promise for patients with previously incurable disease. However, skyrocketing costs limit patient access to these life-saving therapies. QA/QC of autologous cell therapies accounts for up to 50% of manufacture cost due to the need for QA/QC of a small (single-patient) batch. We present a prototype for benchtop automation of common sterility and purity assays. A compact QC/QA instrument paired with disposable cartridges can reduce labor costs in cell therapy manufacture and increase patient access to care.

12:25 Sponsored Presentation (Opportunity Available)

12:40 Session Break

12:50 PRECISION HEALTH LUNCHEON PRESENTATION: Validation of A Next Generation Sequencing Gene Panel for Detection of Variants in Plasma Total Nucleic Acid
Xin-Xing Tan, PhD, Principal Scientist, Molecular, NeoGenomics Laboratories, Inc.
Liquid biopsy next generation sequencing (NGS) gene panel assays provide a powerful non-invasive tool to detect tumor-derived variants for clinic diagnostics in a massively parallel manner. We present here a NGS assay designed specifically for liquid biopsy clinical applications, and its analytical and clinical validation to assess accuracy, specificity, sensitivity, repeatability, and reproducibility, etc.

1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

FUTURE FORWARD: DIGITAL HEALTH

2:00 Chairperson’s Remarks
Adrian Chernoff, Former Worldwide Vice President, Global Head of Research and Development, Johnson and Johnson

2:05 Wearables and Health
Michael Snyder, PhD, Stanford W. Ascherman Professor & Chair, Department of Genetics; Director, Center for Genomics & Personalized Medicine, Stanford University
We have been using smart watches and continuous glucose monitoring to track people’s health and find early signs of disease.

2:25 Patient-Centricity, the Future to Enabling Digital Health
Adrian Chernoff, Former Worldwide Vice President, Global Head of Research and Development, Johnson and Johnson

Payers, providers and patients are beginning to encounter changes to the healthcare landscape with the introduction of new digital tools. As we shift into this new reality a key component will be to put the patient at the center shifting the relationship dynamics in how we deliver digital applications and build digital ecosystems to meet the growing needs of patients at any stage of care from health-care, home-care or self-care.

2:45 Digital Health in Diabetes – It Is Not about the App
Søren Smed Østergaard, Vice President, Digital Health, Novo Nordisk
The recent emergence of reliable data streams on medication via smart insulin pens and the correlation of that data with other relevant data sources will transform diabetes care outcomes in the decade to come.

3:05 Close of Conference
1:35 LUNCHEON PRESENTATION II: Trends in Biomarker Performance and Selection in Immunotherapy

John Roberts, President, Interpace Pharma Solutions

With the approvals of the immune checkpoint inhibitors, there has been an explosion in the use of PD1/PD-L1 assays as a predictive biomarker for drug response. However, real-world evidence shows that this biomarker’s ability to predict response can be limited. We will review some of the published data on the clinical performance of this and other immunotherapy biomarkers (tumor mutation burden, gene expression profiling, etc.) and what future trends are unfolding in this space.

2:05 Session Break

BUSINESS AND PARTNERSHIPS

2:20 Chairperson’s Remarks

Scott Patterson, PhD, Vice President, Biomarker Sciences, Gilead Sciences

2:25 How Clinical Practice Is Shaping the Precision Medicine Ecosystem

Cecilia Schott, PharmD, MBA, Head, Precision Medicine Strategy, Oncology Business Unit, Novartis

Pharma companies continue to build and invest in targeted therapy pipeline. New diagnostic platforms are being developed to identify the patient most likely to respond to a given treatment. There is an ever-growing need to understand the precision medicine landscape through the eyes of the practicing clinician. Geographical differences in the access to various testing modalities and reimbursement must be accounted for in clinical development programs and go-to-market strategies. This presentation will provide an overview of the considerations for the global development and lifecycle management of patient diagnostic and monitoring tools.

2:55 CO-PRESENTATION: Leveraging the Benefits of a Strategic Collaboration: CDx Development for Trastuzumab Deruxtecan (DS-8201)

Anne-Marie Boothman, PhD, Diagnostics Director, Precision Medicine Unit, AstraZeneca, United Kingdom

Patrik Vitazka, PhD, Senior Director, Companion Diagnostics, Daiichi Sankyo Inc., USA

Companion diagnostics (CDx) have emerged as a distinct group of IVDs shaping the personalized health care spectrum. Global markets, each with distinct market access processes, evidence requirements, and evaluation measures create challenges to market access, and are a key barrier to identifying patients, and subsequently accessing precision medicines for those who may benefit.

3:25 PANEL DISCUSSION: Novel Collaborative Business Models in Drug-Diagnostics Co-Development

Moderator: Scott Patterson, PhD, Vice President, Biomarker Sciences, Gilead Sciences

Panelists: Shirin Khambata Ford, PhD, Head, Clinical Biomarkers & Companion Diagnostics, Global Oncology R&D, Daiichi Sankyo Inc.; Hakan Sakul, PhD, Vice President and Head, Diagnostics, Pfizer

Companion diagnostics (CDx) have emerged as a distinct group of IVDs shaping the personalized health care spectrum. Global markets, each with distinct market access processes, evidence requirements, and evaluation measures create challenges to market access, and are a key barrier to identifying patients, and subsequently accessing precision medicines for those who may benefit.

3:55 Optimization of Biospecimen Selection and Processing for Successful NGS Outcomes

Cathie G. Miller, PhD, Director, Product Marketing, Marketing, BioIVT
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Companion Diagnostics and Clinical Biomarkers

Science and Business of Drug-Diagnostics Co-Development

March 2-4, 2020

TUESDAY, MARCH 3

7:30 am Registration Open and Morning Coffee

TAKING THE SHOW AROUND THE GLOBE: BIOMARKERS TECHNOLOGY AND STRATEGY IMPLEMENTATION IN GLOBAL STUDIES

8:00 Organizer's Remarks
Marina Filipstinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

8:05 Chairperson's Remarks
Marielena Mata, PhD, Director and Diagnostic Lead, Companion Diagnostics, Pfizer

8:10 Companion Diagnostics in the Era of Consolidation and Globalization: Multiplexed Biomarkers across Therapeutic Areas and around the Globe
Omar Perez, PhD, Head, Precision Medicine and Diagnostics, GSK
This presentation will discuss the need of multiple CDx strategies based on local needs and local capabilities. Examples from Europe and Asia will be discussed.

8:25 Considerations on Discovery of Biomarkers at Global Level
Kate Sasser, PhD, Corporate Vice President, Head, Translational Research, GenMab
Developing a companion diagnostic that can be co-approved and co-launched with the appropriate drug product starts with a biomarker strategy that is fully integrated from the earliest stages of development. Diagnostic decision making should be automatically incorporated into the biomarker program, and should take into account global complexities. This presentation will provide a high level overview of incorporating diagnostics into early stage biomarker plans for clinical development in order to ensure late stage and launch success.

8:40 Integrating China in Global Clinical Trials with a Companion Diagnostic: Challenges and Opportunities
Marielena Mata, PhD, Director and Diagnostic Lead, Companion Diagnostics, Pfizer
Health challenges in China offer big opportunities for pharma. While the unmet need for oncology drugs in the China market represents a large opportunity, conducting the clinical trials needed for registration presents a number of challenges, including changing regulations, restrictions for the exportation of samples, IP requirements, and availability of CROs. We will discuss these challenges and potential solutions.

8:55 Meaningful Use of Biomarker Data in the Era of GDPR
Hisham Hamadeh, PhD, MBA, Vice President, Global Head, Data Science, GenMab
Biomarker data, especially next generation sequencing data, is increasingly useful in clinical trials. However, the interpretation of GDPR has the potential to challenge the way such data is analyzed, shared and placed in the context of much larger datasets. We will discuss the intersection of the regulation, technology, and practical needs of researchers and offer recommendations to enable meaningful use of clinical biomarker data which adhere to patient protection regulation, especially in Europe.

9:10 The Future of Genomic Studies Must Be Globally Representative
Kari North, PhD, Professor, Department of Epidemiology, University of North Carolina at Chapel Hill
The past decade has seen a revolution in human genetics that has empowered population-level investigations into the biology of complex traits. Here I demonstrate the value of diverse, multi-ethnic participants in large-scale genomic studies by providing an overview of strategies to improve global representation in genomics research and highlighting the successes of studies and consortia that have provided unique knowledge.

9:25 Market Access Strategies for Companion Diagnostics Outside the US
Arushi Agarwal, Director, Personalized Medicine, Health Advances LLC

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

TAKING THE SHOW AROUND THE GLOBE (CONT.)

10:40 Emerging Companion Diagnostic (CDx) Regulations and Global Differences Influence Regulatory Approval Timelines
Debra Rasmussen, Senior Director, Global Regulatory Affairs, Janssen Diagnostics LLC
Precision medicine uses approved CDx tests to select patients to receive the right drug, at the right dose, at the right time. Addressing regulations for drug and companion diagnostics has challenges running the gamut from global clinical trial enrollment, to co-approval, to post-market commitments. This presentation focuses on differences between countries and emerging CDx regulations, especially EU IVDR, AP region, and Australia.

Lakshman Ramamurthy, PhD, Senior Director, Global Regulatory Affairs,
March 2-4, 2020

**Companion Diagnostics and Clinical Biomarkers**

Science and Business of Drug-Diagnostics Co-Development

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**Oncology, GSK**

The advent of next-generation sequencing has been revolutionary, both for characterizing the genomic nature of cancer, and the rapid accessing of accurate patient tumor genomic information for targeted intervention. As NGS technologies gain acceptance, it has produced the need for consistency, regulatory oversight, and consideration for information privacy. The US and global markets have the challenge of evolving to seize oversight systems, while being careful to not stifle innovation. This presentation will compare the US with global markets, including Japan, China, Taiwan, and Brazil.

**11:10 Challenges of Clinical Specimen Management in the Era of Precision Medicine**

*Brenda Yanak, Principal, Clinical Transformation Partners*

In the era of precision medicine in the pharma industry, historical paradigms for clinical operations are giving way to new structures designed for maximum flexibility and speed. Biospecimen management is fundamental to the biomarker research informing our translational strategy. Traditional operations are no longer sufficient to respond to this need for speed and agility to pivot as scientific insights are revealed.

**11:25 Global Commercial and Partnership Considerations for Companion Diagnostics**

*Joseph Ferrara, President & CEO, Boston Healthcare*

Key commercialization considerations for drug and test innovators, including balancing test access and quality, and activating connections between oncologists, pathologists, payers, and industry stakeholders will be highlighted.

**11:40 PANEL DISCUSSION: Harmonizing Technology and Strategies Implementation around the Globe: Opportunities and Challenges from Early Development to Commercialization**

Topics to be Discussed:

- Tips for working across different cultures to implement successful biomarker strategies
- Best practices for global CDx strategies that take regional needs into consideration
- What the future looks like for the harmonization of regulatory requirements

*Moderator: Marielen Mata, PhD, Director and Diagnostic Lead, Companion Diagnostics, Pfizer*

*Panelists: Hisham Hamadeh, PhD, MBA, Vice President, Global Head, Data Science, GenMab*

*Omar Perez, PhD, Head, Precision Medicine and Diagnostics, GSK*

*Lakshman Ramamurthy, PhD, Senior Director, Global Regulatory Affairs, Oncology, GSK*

*Debra Rasmussen, Senior Director, Global Regulatory Affairs, Janssen Diagnostics LLC*

*Kate Sasser, PhD, Corporate Vice President, Head, Translational Research, GenMab*

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**1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group**

**2:00 Breakout Discussions in the Exhibit Hall (please see website for details)**

**3:00 Transition to Keynote Session**

**KEYNOTE SESSION**

*(please see Keynotes pages for details)*

**3:15 Organizer's Remarks**

*Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute*

**3:20 Keynote Introduction**

*Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies*

**3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics**

20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

*Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.*

*Panelists: Stephen Kingsmore, MD, Dsc, President/CEO, Rady Children's Institute for Genomic Medicine*

*David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomolecular Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)*

*Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine*

**4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group**

**6:00 End of Day**

**6:30 - 9:30 Dinner Short Courses* (please see Short Courses pages for details)**

*Separate registration required*

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**WEDNESDAY, MARCH 4**

**6:45 am Registration Open**

**7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)**

*Moderator: Robin Toft, Author of WE CAN, The Executive Woman's Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search*

*Panelists: Camille Samuels, MBA, Partner, Venrock*

*Paul Hastings, President and CEO, Nkarta Therapeutics, Inc*

*Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration*

*Alice Zheng, MD, MPH, MBA, Engagement Manager and Women's Health

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**12:20 pm LUNCHEON PRESENTATION I: Companion Diagnostics: Beyond Oncology to Rare and Complex Genetics Diseases**

*Bernard Andrus, PhD, SVP, Operations and Regulatory Affairs Asuragen, Inc.*

Recent advances offer new hope for rare and complex genetic disease treatment. Accurately diagnosing, selecting and predicting response in patients require novel technologies and information-rich diagnostic testing strategies. This talk will discuss how a biomarker-driven, diagnostics-enabled approach can facilitate the clinical, regulatory, and commercial success of drugs developed in these disease areas.

**12:50 Luncheon Presentation II (Sponsorship Opportunity Available)**
CIRCULATING BIOMARKERS IN IMMUNO-ONCOLOGY

10:40 The Wide World of Liquid Biopsy-Based Biomarker for Cancer Immunotherapy
Sam Hanash, MD, PhD, Director, McCombs Institute for Cancer Detection and Treatment, University of Texas MD Anderson Cancer Center

Multiple circulating biomarkers that have the potential to serve as predictive prognostic biomarkers to guide cancer immunotherapy are currently being pursued. These include tumor-derived microvesicles, soluble immune proteins, and metabolites. The current opportunities and challenges will be presented.

11:10 Blood-Based Biomarkers in Immuno-Oncology
Jonathan Baden, MS, Director, Pharmacodiagnostics, Bristol-Myers Squibb

Blood is accessible with minimally invasive and cost-effective methods, so it has always been considered an attractive source of biomarkers. With rapid technological advancements circulating tumor DNA (ctDNA), in particular, has become an invaluable diagnostic material with multiple potential applications across the disease continuum. Here, we review the recent findings on ctDNA to aid in patient selection and disease monitoring from an immuno-oncology perspective, and we discuss potential future directions.

8:05 Chairperson’s Remarks
Khosrow R. Shotorbani, President, Executive Director, Project Santa Fe Foundation

The increasing complexity of cancer care and accelerated approvals of targeted and immuno-oncology therapies has shifted CDx testing from a one test-one drug approach to a next-generation sequencing (NGS)-based multi-gene approach. Despite recent improvements, coverage and reimbursement remains fragmented and challenging for NGS testing.

8:40 Navigating the Reimbursement Landscape in the Era of Precision
Shivang Doshi, Director, Boston Healthcare Associates, Inc.

This talk will address the LCD process and how this relates to a new LCD request or to coverage under an existing LCD. We will review MolDX’s approach to evidence evaluation, including the ACCE model process and chains of evidence.

8:25 Humana’s Perspective on Personalized Medicine
Kristine Bordenave, MD, FACP, Former Corporate Medical Director, Humana

This presentation will explore the impact of coverage of genetic testing on precision medicine, and payment considerations based on these relationships.

8:10 Paradigms for MolDX Coverage
Gabriel Bien-Willner, MD, PhD, Medical Director, Moldx, Palmetto GBA

This talk will address the LCD process and how this process is implemented for molecular diagnostic testing by MolDX and its partner MACs. This presentation will review the information that is required for technical assessment and how this relates to a new LCD request or to coverage under an existing LCD. We will review MolDX’s approach to evidence evaluation, including the ACCE model process and chains of evidence.

8:00 Organizer’s Remarks
Marina Filitskiny, MD, Executive Director, Conferences, Cambridge Healthtech Institute

Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

REIMBURSEMENT OF COMPANION DIAGNOSTICS: A FIRST-HAND PERSPECTIVE

8:55 PANEL DISCUSSION: Coverage and Reimbursement of Advanced Diagnostics

As healthcare is transitioning from “sick” care to “well” care and shifting from fee-for-service to value-based models, it’s essential that we develop evidence to demonstrate the new value of the laboratory for optimized reimbursement. Topics to be discussed:

- Understand how to define and measure value using appropriate KPIs to help influence reimbursement policy.
- Learn ways to survive financially as payment models shift and reimbursement is driven by outcomes and risk with potential upside depending upon the reimbursement model.
- Explore key partnership opportunities that are aligned with the changes in healthcare to help shape value.

Moderator: Khosrow R. Shotorbani, President, Executive Director, Project Santa Fe Foundation

Panelists: Gabriel Bien-Willner, MD, PhD, Medical Director, Moldx, Palmetto GBA
Kristine Bordenave, MD, FACP, Former Corporate Medical Director, Humana
Lon Castle, CMO, Molecular Genetics and Personalized Medicine, eviCore Healthcare
Shivang Doshi, Director, Boston Healthcare Associates, Inc.
and clinical validation to assess accuracy, specificity, sensitivity, repeatability, and reproducibility, etc.

1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

LIQUID BIOPSY AND IO: A POWERFUL COMBINATION

2:00 Chairperson’s Remarks
Carol Pena, PhD, Executive Director and Distinguished Scientist, Translational Molecular Biomarkers & Companion Diagnostics, Merck & Co., Inc.

2:05 Liquid Biopsy in Clinical Oncology Diagnostics: Tissue is No Longer the Issue
Carol Pena, PhD, Executive Director and Distinguished Scientist, Translational Molecular Biomarkers & Companion Diagnostics, Merck & Co., Inc.

“Tissue is the issue” has long been the lament of the pathologist. The management of scarce tissue is made a major challenge by the growing list of biomarkers (predictive and otherwise) becoming part of the routine workup of solid tumors, coupled with the trend toward less invasive procedures. “Liquid biopsy” technologies, tests performed on circulating cell-free DNA, circulating tumor cells, or exosomes offer a solution to this challenge.

2:35 Noninvasive Detection of Minimal Residual Disease (MRD) in Solid Tumors
Mark Sausen, PhD, Associate Director, Clinical Genetics and Genomics, Bristol-Myers Squibb

Although surgery is curative for many patients with early-stage solid tumors, some are at a high risk for recurrence and progression. Recent technologies have permitted the analysis of circulating tumor DNA (ctDNA) to detect post-surgical MRD. MRD detection could help to identify patients who may benefit from adjuvant therapeutic intervention, and disease monitoring may allow for earlier prediction of recurrence and progression.

3:05 PANEL DISCUSSION: Liquid Biopsy and IO: A Powerful Combination

The emergence of immunotherapy in oncology requires the discovery, validation, and subsequent adoption of robust, sensitive, and specific predictive and prognostic biomarkers for daily practice. Liquid biopsy technologies offer radical solutions in achieving these goals.

Moderator: Carol Pena, PhD, Executive Director and Distinguished Scientist, Translational Molecular Biomarkers & Companion Diagnostics, Merck & Co., Inc.
Panelists: Walter Koch, PhD, Vice President, Head, Global Research, Roche Molecular System, Inc.
Mark Sausen, PhD, Associate Director, Clinical Genetics and Genomics, Bristol-Myers Squibb

3:35 Close of Conference

Molecular Medicine Tri-Conference’s inaugural Bioinformatics Pipelines for Preclinical Drug Discovery Hackathon will bring together stakeholders from across pharma R&D to tackle datasets and projects with maximum impact potential. Facilitated by leaders from the National Center for Biotechnology Information (NCBI), the Tri-Conference is proud to bring together innovative data scientists and developers from across the industry to solve real-world data challenges.

More info, visit: TriConference.com/hackathon
Immuno-Oncology Biomarkers and Companion Dx
Predicting Response and Guiding IO Trials and Patient Care

March 2-4, 2020

SUNDAY, MARCH 1

10:30 Conference Program Registration Open

11:45 Organizer’s Opening Remarks
Marina Filshitsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

11:50 Chairperson’s Remarks
Cecilia Schott, PharmD, MBA, Head, Precision Medicine Strategy, Oncology Business Unit, Novartis

11:55 Challenges and Opportunities for Biomarkers in Early Clinical Development
Luciana Molinero, PhD, Senior Scientist, Oncology Biomarker Development, Genentech

The presentation will present the opportunities and challenges in developing impactful biomarker strategies for early clinical development of new immuno-oncology drugs. We will focus on the design of fit-for-purpose entry into human clinical trials, proof or dis-proof of mechanism of action, and optimal biological dose finding.

12:25 pm Emerging Trends and Technologies in Companion Diagnostics
George Green, PhD, Executive Director, Head, Pharmacodiagnostics, Bristol-Myers Squibb

Patient selection strategies, technology, and understanding of disease are evolving. For example, tumor mutational burden and gene expression profiling have not yet met early expectations, and combination strategies and monitoring in earlier indications appear promising. Sequencing is becoming standard, and use of plasma may improve its utility. Additionally, technological advancements such as digital imaging, artificial intelligence, and single cell sequencing are approaching practical use. Here, we survey these emerging trends and perspectives in companion diagnostics.

12:55 Session Break

1:05 LUNCHEON PRESENTATION I: Circulating Stromal Cells Predict Clinical Response in the Immunotherapy Setting
Daniel L. Adams, Director, Clinical R&D, Creatv MicroTech Inc

Circulating stromal cells (CStC) act as a novel blood-based biomarker for immuno-oncology therapeutics. We will present the findings from a variety of IO clinical trials showing CStC’s ability to provide companion diagnostics and predict treatment response.

1:35 LUNCHEON PRESENTATION II: IVD Regulatory Landscape: What Challenges to Prepare for Before 2022
Ashleigh Dawley, RAC, Manager, Regulatory Affairs, Medical Device and Diagnostic Research, ICON plc

In vitro diagnostic (IVD) manufacturers are struggling to meet transition deadlines for the new European Union In Vitro Diagnostics Regulation. This regulation aims to ensure the safety and performance of devices. Yet, the increased responsibility on manufacturers to show that products meet the requirements has created challenges across the IVD lifecycle. The industry’s slow progress to meet the May 2022 deadlines will impact market access. Manufacturers will need a strategy to avoid product availability problems.

2:05 Session Break

MONDAY, MARCH 2

8:00 - 11:00 am Morning Short Courses* (please see Short Courses pages for details)
*Separate registration required

10:30 Conference Program Registration Open

ADVANCING PRECISION IMMUNO-ONCOLOGY

2:20 Chairperson’s Remarks
Ron Mazumder, PhD, MBA, Vice President, Oncology Biomarker Development & Companion Diagnostics, Genentech

2:25 Principals of Cell-Based Cancer Immunotherapy
Nicholas Restifo, MD,Executive Vice President for Research, Lyell Immunopharma, Inc.

Adoptive cell therapy (ACT) is a highly personalized cancer therapy that involves administration to the cancer-bearing host of immune cells with direct antitumor activity. ACT using naturally occurring or genetically engineered tumor-reactive lymphocytes has mediated durable, complete regressions in patients with melanoma and varieties of leukemias and lymphomas, as well as anecdotal but profound responses in patients with common epithelial cancers. The principals of cell-based therapies will be discussed.

2:55 PANEL DISCUSSION: New Frontiers in Companion Diagnostics in Oncology and IO

Panelists: George Green, PhD, Executive Director, Head, Pharmacodiagnostics, Bristol-Myers Squibb
Nicholas Restifo, MD, Executive Vice President for Research, Lyell Immunopharma, Inc.
Richard Bourgon, PhD, Director, Senior Scientist, Oncology Bioinformatics, Genentech
Mahesh Yadav, PhD, Scientist, Oncology Biomarker Development, Genentech

Topics to be Discussed:
- New Biomarkers and Technologies
- T-Cell Receptor Sequencing
- Neoantigen Approaches
- Biomarkers for T Cell Therapy

2:55 NEW FRONTIERS IN COMPANION DIAGNOSTICS IN ONCOLOGY AND IO

2:55 Session Break

3:55 How Biospecimen Sourcing Can Impact Your R&D
Vanessa Tumilasci, PhD, Commercial Director, Trans-Hit Bio

Biospecimen sourcing is becoming a challenge for many scientists who need to respect timelines for R&D plans as well as regulatory and ethical constraints. Are the scientists working with the samples aware of all the imperatives to obtain them; quality, respect of laws, ethics and regulations?
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**BIOMARKER-DRIVEN CLINICAL STUDIES IN ONCOLOGY AND IO**

8:00 Organizer’s Remarks  
Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks  
Thomas O’Brien, PhD, Director, Translational Oncology, Global Product Department, Pfizer Oncology

8:10 TMB as a Clinical Biomarker in Combination Trials  
Thomas O’Brien, PhD, Director, Translational Oncology, Global Product Department, Pfizer Oncology

Next-Generation Sequencing and Liquid Biopsies offer exciting novel opportunities to bring innovative drugs to patients. But these opportunities do not come without challenges and will need to be resolved, particularly when looking at genomic signatures, such as Tumor Mutational Burden.

8:40 Biomarker-Assisted Targeted Therapy – RET and BTK Inhibitors in Personalized Medicine  
Narasimha Marella, PhD, Director, Biomarker Operations, Loxo Oncology, Inc.

Genomic alterations in the RET kinase lead to overactive RET signaling and uncontrolled cell growth. LOXO-292 is an oral and selective investigational drug in clinical development for the treatment of patients with cancers that harbor abnormalities in the rearranged during transfection (RET) kinase. BTK is a validated molecular target found across numerous B-cell leukaemias and lymphomas. The long-term efficacy has been limited by acquired resistance and intolerance. LOXO-305 was designed to reversibly bind BTK and preserve activity in the presence of C481 acquired resistance mutations. Both therapies are currently being studied in global Phase I/II clinical trials.

9:10 Biomarkers Predicting Response to Neoadjuvant Immunotherapy in the Early-Stage Breast Cancer Setting: Lessons from the I-SPY 2 TRIAL  
Denise Wolf, PhD, Senior Bioinformatics Scientist, Department of Laboratory Medicine, University of California, San Francisco

I-SPY 2, a phase 2 adaptive neoadjuvant trial in high-risk breast cancer, evaluates novel agents added to standard chemotherapy. In addition to efficiently evaluating agent/subtype pairs, I-SPY 2 is biomarker-rich: samples are profiled for mRNA; protein; mutations; and immune cell subpopulations using multiplex immunofluorescence (miF). Here we present immune-related expression signatures, proteins, and miF as predictors of response to pembrolizumab, which graduated for efficacy in TN and HR+HER2- patients.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

**CIRCULATING BIOMARKERS IN IMMUNO-Oncology**

10:40 The Wide World of Liquid Biopsy-Based Biomarker for Cancer Immunotherapy  
Sam Hanash, MD, PhD, Director, McCombs Institute for Cancer Detection and Treatment, University of Texas MD Anderson Cancer Center

Multiple circulating biomarkers that have the potential to serve as predictive prognostic biomarkers to guide cancer immunotherapy are currently being pursued. These include tumor-derived microvesicles, soluble immune proteins, and metabolites. The current opportunities and challenges will be presented.

11:10 Blood-Based Biomarkers in Immuno-Oncology  
Jonathan Baden, MS, Director, Pharmacodiagnostics, Bristol-Myers Squibb

Blood is accessible with minimally invasive and cost-effective methods, so it has always been considered an attractive source of biomarkers. With rapid
technological advancements circulating tumor DNA (ctDNA), in particular, has become an invaluable diagnostic material with multiple potential applications across the disease continuum. Here, we review the recent findings on ctDNA to aid in patient selection and disease monitoring from an immuno-oncology perspective, and we discuss potential future directions.

11:40 **Using ctDNA to Monitor Disease Progression and Treatment Response in Advanced-Stage Lung Cancer**

_Jin Jen, MD, PhD, Professor, Laboratory Medicine and Pathology, Mayo Clinic_

Circulating tumor DNA (ctDNA) is a potentially powerful biomarker to monitor anticancer treatment response and disease progression in real time. We used Next Generation Sequencing (NGS) to track tumor-related mutations and mutational load in cell-free circulating DNA. The result of the ctDNA detection in plasma paralleled clinical observations by RECIST in patients with advanced stage NSCLC.

12:10 pm **Characterizing the Bone Marrow Immune Contexture of Acute Myeloid Leukemia Using MultiOmyx™**

_Qingyan (Sandy) Au, PhD, Principal Scientist, Pharma Services, NeoGenomics Laboratories, Inc._

Bone marrow (BM) constitutes the home niche for leukemia cells in AML. Emerging data indicates BM’s crucial role in cancer development.

MultiOmyx IF assay was used to characterize the BM immune contexture of AML. Direct assessment of immune phenotypes by MultiOmyx enables understanding of the immune landscape in AML.

12:25 **Combining Cell Harvesting and Imaging Technologies for CTC Liquid Biopsy Sample-to-answer**

_Anne-Sophie Pailhes-Jimenez, R&D Group Leader, Cell Biology, Imaging, ANGLE Ltd_

Alan Schwebel, President, CEO, BioView Ltd

Circulating Tumor Cells provide access to protein and genetic information on patient cancer through a simple blood draw. Here we share the combination of ANGLE’s Parsortix® system for CTC harvesting with BioView’s automated CTC cell imaging and analysis scanner to deliver robust workflow to support the drive towards precision medicine.

12:40 Session Break

12:50 **PRECISION HEALTH LUNCHEON PRESENTATION:**

_Version of A Next Generation Sequencing Gene Panel for Detection of Variants in Plasma Total Nucleic Acid_

_Xin-Xing Tan, PhD, Principal Scientist, Molecular, NeoGenomics Laboratories, Inc._

Liquid biopsy next generation sequencing (NGS) gene panel assays provide a powerful non-invasive tool to detect tumor-derived variants for clinic diagnostics in a massively parallel manner. We present here a NGS assay designed specifically for liquid biopsy clinical applications, and its analytical and clinical validation to assess accuracy, specificity, sensitivity, repeatability, and reproducibility, etc.

1:20 **Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group**

**LIQUID BIOPIXY AND IO: A POWERFUL COMBINATION**

2:00 **Chairperson’s Remarks**

_Carol Pena, PhD, Executive Director and Distinguished Scientist, Translational Molecular Biomarkers & Companion Diagnostics, Merck & Co., Inc._

2:05 **Liquid Biopsy in Clinical Oncology Diagnostics: Tissue is No Longer the Issue**

_Carol Pena, PhD, Executive Director and Distinguished Scientist, Translational Molecular Biomarkers & Companion Diagnostics, Merck & Co., Inc._

“Tissue is the issue” has long been the lament of the pathologist. The management of scarce tissue is made a major challenge by the growing list of biomarkers (predictive and otherwise) becoming part of the routine workup of solid tumors, coupled with the trend toward less invasive procedures. “Liquid biopsy” technologies, tests performed on circulating cell-free DNA, circulating tumor cells, or exosomes offer a solution to this challenge.

2:35 **Noninvasive Detection of Minimal Residual Disease (MRD) in Solid Tumors**

_Mark Sausen, PhD, Associate Director, Clinical Genetics and Genomics, Bristol-Myers Squibb_

Although surgery is curative for many patients with early-stage solid tumors, some are at a high risk for recurrence and progression. Recent technologies have permitted the analysis of circulating tumor DNA (ctDNA) to detect post-surgical MRD. MRD detection could help to identify patients who may benefit from adjuvant therapeutic intervention, and disease monitoring may allow for earlier prediction of recurrence and progression.

3:05 **PANEL DISCUSSION: Liquid Biopsy and IO: A Powerful Combination**

The emergence of immunotherapy in oncology requires the discovery, validation, and subsequent adoption of robust, sensitive, and specific predictive and prognostic biomarkers for daily practice. Liquid biopsy technologies offer radical solutions in achieving these goals.

_Moderator: Carol Pena, PhD, Executive Director and Distinguished Scientist, Translational Molecular Biomarkers & Companion Diagnostics, Merck & Co., Inc._

_Panelists: Speakers of the Session_

_Walter Koch, PhD, Vice President, Head, Global Research, Roche Molecular System, Inc._

3:35 **Close of Conference**
Prediction of Infections in Immunocompromised Patients

Cell-free DNA for Non-invasive Identification & invasive alternative with higher diagnostic yield than conventional methods. We in blood to help diagnose infections throughout the body, offering a non-

The Karius Test uses next-generation sequencing of microbial cell-free DNA

Tim Blauwkamp, PhD, CSO, Karius

12:55 pm Session Break

Joseph San Filippo, PhD, Director, Business Development, Roche Molecular Solutions Biotechnologies

Trevor Martin, PhD, Co-Founder and CEO, Mammoth Biosciences

Laboratory Medicine, Lahey Hospital & Medical Center, Beth Israel Lahey Health

Gyorgy Abel, MD, PhD, Medical Director, Molecular Diagnostics, Pathology and Laboratory Medicine, Lahey Hospital & Medical Center, Beth Israel Lahey Health

Trevor Martin, PhD, Co-Founder and CEO, Mammoth Biosciences

Juliette Zill, PhD, Chief Scientific Officer, Mammoth Biosciences

Panelists: Ester Stein, Director, Corporate Reimbursement, Government Affairs, Abbott Laboratories

Jenny Rook, PhD, Managing Director, Genoa Ventures

Bryan Bothwell, Director, Strategy and Business Development, Qorvo Biotechnologies

Joseph San Filippo, PhD, Director, Business Development, Roche Molecular Solutions

Moderator: David Cavanaugh, Partner, DeciBio

11:45 Organizer’s Opening Remarks
Kaitlin Searfoss Kelleher, Conference Producer, Cambridge Healthtech Institute

11:50 Chairperson’s Remarks
David Cavanaugh, Partner, DeciBio

11:55 Leading the Pack: The Strategic Revamp POC Dx Needs before Disrupting MDx
Clinical adoption and real-world use of point-of-care diagnostic (POC Dx) technologies have fallen short of their hype and promise. The field has become increasingly crowded, with hundreds of players narrowing the runway for each company to carve out differentiated market opportunities and strategies. Disruption of the larger MDx market will require POC Dx companies to create “winning strategies” by establishing competitive differentiation from one another, driving successful adoption and implementation, and navigating regulatory and reimbursement hurdles.

Moderator: David Cavanaugh, Partner, DeciBio

Panelists: Ester Stein, Director, Corporate Reimbursement, Government Affairs, Abbott Laboratories

Gyorgy Abel, MD, PhD, Medical Director, Molecular Diagnostics, Pathology and Laboratory Medicine, Lahey Hospital & Medical Center, Beth Israel Lahey Health

Trevor Martin, PhD, Co-Founder and CEO, Mammoth Biosciences

Jenny Rook, PhD, Managing Director, Genoa Ventures

Bryan Bothwell, Director, Strategy and Business Development, Qorvo Biotechnologies

Joseph San Filippo, PhD, Director, Business Development, Roche Molecular Solutions

12:55 pm Session Break

1:05 LUNCHEON PRESENTATION I: Karius Microbial
Cell-free DNA for Non-invasive Identification & Prediction of Infections in Immunocompromised Patients
Tim Blauwkamp, PhD, CSO, Karius

Immunocompromised patients are vulnerable to a wide variety of infections. The Karius Test uses next-generation sequencing of microbial cell-free DNA in blood to help diagnose infections throughout the body, offering a non-invasive alternative with higher diagnostic yield than conventional methods. We present current applications in clinical practice and describe potential future applications in predicting infections in high-risk immunocompromised patients.

1:35 LUNCHEON PRESENTATION II: Commercialization of an IVD in a Changing Global Environment
Lynn Stephenson, PhD, Marketing Manager, Dx Manufacturing & OEM, MilliporeSigma

Changes in international standards and regulations have created challenges and roadblocks to the commercialization of diagnostic devices. The choice of a contract manufacturing (CM) partner with the expertise to provide guidance and manufacturing capabilities is one strategy diagnostics companies can use to mitigate risk. A well-chosen CM partner can accelerate the commercialization process by anticipating potential roadblocks. In this session, we will discuss best practices and key considerations for vetting contract manufacturing partners.

2:05 Session Break

POCT IN THE HOSPITAL: ENSURING BETTER CARE

2:20 Chairperson’s Remarks
Elsie Yu, PhD, DABCC, FAACC, System Director, Chemistry, Toxicology and Point-of-Care Testing, Geisinger Medical Laboratories; Clinical Associate Professor, Geisinger Commonwealth School of Medicine

2:25 Is Faster Always Better? Identifying Care Opportunity and Ensuring Proper Clinical Utilization of Point-of-Care Testing
Elsie Yu, PhD, DABCC, FAACC, System Director, Chemistry, Toxicology and Point-of-Care Testing, Geisinger Medical Laboratories; Clinical Associate Professor, Geisinger Commonwealth School of Medicine

The ability to have test results immediately makes POCT an attractive option at a wide variety of settings. At this presentation, we will provide concrete examples of how POCT aids patient management. We will also review cases where POCT is not suitable and could potentially be harmful. Finally, we will explore some unfilled care opportunities where transitioning to POCT can provide significant improvement and cost saving.

Julie Shaw, Head, Division of Biochemistry and Director of Point-of-Care Testing, Pathology and Laboratory Medicine, The Ottawa Hospital and Eastern Ontario Regional Laboratories Association

Operator non-compliance with POCT policies and procedures is a significant risk. Repeat testing of critical POCT glucose results prevents potentially dangerous treatment in the case of an erroneous result. Our data demonstrate consistent operator non-compliance with critical glucose repeat policies. Analysis of POCT glucose results revealed significant differences with up to 30% of repeat results, highlighting the risk to patient safety when POCT policies and procedures are not adhered to.

3:25 Opportunities for Point-of-Care Testing in Modern Healthcare
James H. Nichols, Ph.D, DABCC, FAACC, Medical Director, Clinical Chemistry and Point-of-Care Testing, Professor of Pathology, Microbiology and Immunology, Vanderbilt University School of Medicine

Point of care testing (POCT) is laboratory testing performed close to the site of patient care. With the advantage of rapid turnaround time and device portability, POCT is finding new applications as healthcare expands into the community. This presentation will explore the variety of ways that POCT is being deployed and finding new avenues for delivering faster testing for improved patient management. The future of new POCT technologies will be explored with opportunities for personalized medicine through POCT mobile health and social media.

3:55 A Multiplexed Platform for Point-of-Care Precision Medicine and Clinical Trial Enrichment
Christopher Myatt, CEO, MBio Diagnostics, Inc.
Heterogeneity of septic shock is a major challenge. For clinical trials, it is unclear which patients will benefit from new treatment approaches. A robust risk stratification tool has been developed to aid decision-making in the context of pediatric sepsis. A 5-protein biomarker adaptation of the PERSEVERE risk stratification panel has been developed on the MBio point-of-care platform. The panel has been run on banked clinical samples, and comparisons with the original Luminex-based assay are underway.

9:00 PANEL DISCUSSION: Addressing Antimicrobial Resistance Through Public-Private Partnerships and the NIH-BARDA Grand Challenge

Antimicrobial resistance represents a growing public health concern, leading to BARDA and the NIH working with private companies to develop novel diagnostics. The NIH-BARDA Grand Challenge has charged participants with developing innovative and novel rapid diagnostic tests to identify resistant bacteria or to distinguish between viral and bacterial infections to reduce over-prescription of antibiotics. Two of the five finalists will present their work and the challenges their technologies address. We will also hear from a company collaborating directly with BARDA to advance and commercialize their assay.

Moderator: Gerald J. Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT-CTR), Emeritus Professor, School of Medicine, University of California, Davis

Panelists: Ephraim L. Tsai, MD, MHS, PhD, Founder, Predigen, Inc.
Gary Schoolnik, Director, Medical Affairs, Click Diagnostics
Timothy Sweeney, MD, PhD, CEO, Inflammatix

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

THE ROLE OF MOBILE HEALTH AND TELEMEDICINE IN POINT-OF-CARE

10:40 Point-of-Care Technologies (POCT) for Mobile Diagnostics and Connected Health

Ping Wang, PhD, DABCC, FAACC, Chief of Clinical Chemistry and Core Laboratory, Pathology and Lab Medicine, University of Pennsylvania

I will talk about the value proposition of POCT in mobile diagnostics and connected health, go over some examples of current applications of POCT in this field, and also review emerging POCT that are likely to have an impact on care delivery in the near future.

11:10 Errors, Risk Mitigation Strategies, and Quality Metrics in Point-of-Care Testing in Mobile Health and Other Settings

Anna K. Füzéry, North Sector POCT Medical Lead, Alberta Public Laboratories

This presentation focuses on errors in point of care testing (POCT). The presentation will first review error classification in POCT, followed by examples of errors in mobile health settings. The presentation will then discuss risk mitigation strategies and how to monitor their success through quality metrics. The presentation will conclude with an overview of some of the work that is happening in Alberta, Canada to develop quality metrics for POCT.

11:40 Optimized Lyophilization: Providing Options for You, Your Products, and Your IVD and RUO Customers

Meredith Pearson, Application Consultant, BIOLYPH

BIOLYPH provides lyophilization services for molecular diagnostics, IVD and RUO reagents. A single Master Mix LyoSphere™ can contain Enzymes, Oligonucleotides, Dyes, RNAses Inhibitors, Cations, dNTPs, Buffers and Exciptents in a stable, consistent form, which rehydrates instantly and can be packaged into any device, all stored at Room Temperature.
Gianpiero C. Spadola, Manager, Research and Development, Meridian Life Science

Ambient temperature stabilisation of molecular diagnostics assays is attractive for users and developers and is currently achieved through Lyophilisation or Air-drying technologies. Although, establishing designs compatible with these technologies is a time consuming and challenging activity, it can be facilitated by the newly developed MLS PCR formulations.

12:10 pm Session Break

12:20 LUNCHEON PRESENTATION I: Navigating Novel Product Development – Considerations for High-Value Commercialization

Rene Robert, Director, Engineering, Xmedica

As our industry’s attention turns to point-of-care platforms, life science companies struggle to deploy the power of their benchtop tools, like beads, buffers and centrifuges, in a microfluidic context. Fundamental microfluidics limitations cause protocols for lysis, purification, and amplification to underperform on-cartridge. Using cartridge-ready” components and Redbud Post technology, we have developed a method to achieve bead-based assays on cartridge with performance equal to or better than the laboratory equivalent.

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Keynote Session

KEYNOTE SESSION

(please see Keynotes pages for details)

3:15 Organizer’s Remarks

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction

Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics

20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.

Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children’s Institute for Genomic Medicine

David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomedical Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)

Elizabeth Worthy, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

6:00 End of Day

6:30 - 9:30 Dinner Short Courses* (please see Short Courses pages for details)

*Sponsorship opportunity available

WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)

Moderator: Robin Toft, Author of WE CAN, The Executive Woman’s Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search Panelists: Camille Samuels, MBA, Partner, Venrock

Paul Hastings, President and CEO, Nkarta Therapeutics, Inc

Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration

Alice Zheng, MD, MPH, MBA, Engagement Manager and Women’s Health Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

Saturday, March 7, 2020
It takes on average 17 years for a new healthcare innovation to scale – do you have time to wait for market penetration? Learn how to develop an “Implementation Strategy” specifically targeted for the community pharmacy using the most recent advances in our understanding of Implementation Science and tailored around the unique challenges of FDA, other regulatory bodies, and the POC industry.

**REGISTER EARLY & SAVE!**

Cambridge Healthtech Institute’s 9th Annual Point-of-Care Diagnostics Strategy and Implementation

Addressing Implementation and Clinical Use for Rapid Diagnostics and Improved Outcomes

**March 2-4, 2020**

Moscone South Convention Center

It takes on average 17 years for a new healthcare innovation to scale – do you have time to wait for market penetration? Learn how to develop an “Implementation Strategy” specifically targeted for the community pharmacy using the most recent advances in our understanding of Implementation Science and tailored around the unique challenges of FDA, other regulatory bodies, and the POC industry.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

**POINT-OF-CARE OUTSIDE THE HOSPITAL: PHARMACY AND SELF-TESTING (CONT.)**

10:40 Advanced Pharmacy Technician Roles: Ready for Point-of-Care Testing?

Hunter Hill, PharmD, Pharmacy Manager, Delta Division, Kroger Health

Point-of-care testing (POCT) is an increasingly popular service offered by community pharmacies, but it is often met with multiple barriers. As technicians’ roles continue to advance there is an opportunity to utilize them as pharmacy extenders and lead POCT services. Learn how pharmacy technician-supported POCT, including sample collection, can minimize these barriers.

11:10 PANEL DISCUSSION: The Future of Point-of-Care Testing in the Pharmacy

What’s next in POCT in the pharmacy? What implementation, technology, and business needs must be addressed to bring pharmacy-based POCT to the mainstream? How does self-testing come into the picture? This panel discussion will address these questions and more as it relates to the advancement of simple point-of-care tests in the pharmacy and beyond.

*Moderator: Donald Klepser, PhD, MBA, Associate Professor and Vice Chair, Pharmacy Practice, University of Nebraska Medical Center*

*Panelists: Michael Klepser, PharmD, FCCP, FIDP, Professor, College of Pharmacy, Ferris State University*

Kenneth C. Hohmeier, PharmD, Associate Professor, Director of Community Affairs, Clinical Pharmacy & Translational Science, University of Tennessee Health Science Center

12:10 pm Mobilising Diagnostics - Overcoming the Challenges in Testing Outside the Laboratory

Neil Polwart, PhD, Head, Mobile, BBI Solutions

Combining the ease of use of smartphones with low-cost POCT, we have revolutionized the application of diagnostic tests for some of the most challenging non-clinical settings, such as field applications in low-income countries or at home monitoring, using our Novarum™ technology. We will demonstrate the use of a smartphone to guide users through a POCT workflow, including critical test timings, visual cues and our patented image capture software to record and analyze the test outcome.

12:40 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

**FEATURED SESSION: IMPLEMENTING POINT-OF-CARE DIAGNOSTICS IN RESOURCE-LIMITED SETTINGS**

2:00 Chairperson’s Remarks

Michael Loeffelholz, Senior Director, Medical Affairs, Cepheid

2:05 Challenges and Opportunities in Resource-Limited Settings for POCT Manufacturers

Michael Loeffelholz, Senior Director, Medical Affairs, Cepheid

The impact of point-of-care technologies in resource-limited settings is profound, but the development, funding, and implementation of these technologies is not always easy. There are several challenges and opportunities for POC manufacturers in resource-poor settings: technology, development, regulatory, cost considerations, to name a few. We’ll examine the industry and business perspective, as well as the clinical implementation and, most importantly, the impact these point-of-care technologies have on patient care.

2:35 Options for Molecular Point of Care Testing - Challenges and Solutions

Gregory J. Berry, PhD, D(ABMM), Director, Molecular Diagnostics, Assistant Director, Infectious Disease Diagnostics, Northwell Health Laboratories; Director, Microbiology, Long Island Jewish Medical Center; Assistant Professor, Pathology and Laboratory Medicine, Donald and Barbara Zucker School of Medicine at Hofstra

There are numerous challenges associated with the implementation of point-of-care testing. We will touch on several of these challenges and also discuss strategies to handle them. We will also discuss how these challenges may differ in a resource-rich vs. a resource-limited setting.

3:05 Point-of-Care Testing: Bringing the Laboratory to the Patient in Low- and Middle-Income Country Settings

Jeffrey D. Klausner, MD, MPH, Professor of Medicine and Public Health, David Geffen School of Medicine, University of California, Los Angeles

I will review studies across three continents demonstrating the acceptability, feasibility, and value of point-of-care diagnostic testing for sexually transmitted infections in pregnant women.

3:35 Close of Conference

12:10 Lunchen Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

**Sponsored by**

BBI Solutions
March 2-4, 2020

**Prediction of Infections in Immunocompromised Patients**

Cell-free DNA for Non-invasive Identification & applications in predicting infections in high-risk immunocompromised patients.

The Karius Test uses next-generation sequencing of microbial cell-free DNA to detect two distinct mutations in patients with confirmed muscular dystrophy. It utilizes the sequence-specific targeting capabilities of CRISPR to detect target sequences. CRISPR-Chip is a graphene field effect transistor (gFET) electronic biosensor that harnesses the search function of CRISPR/Cas9 and the ultra-sensitivity of graphene-based nanoelectronics to scan the genomic sample, bind to their target sequence, and produce a detectable change in the gFET signal output. CRISPR-Chip is functionalized with nuclease-deactivated CRISPR RNA-guided ribonucleoproteins (dRNPs) which produce a detectable change in the gFET signal output. CRISPR-Chip harnesses the search function of CRISPR/Cas9 and the ultra-sensitivity of graphene-based nanoelectronics to detect two distinct mutations in patients with confirmed muscular dystrophy disorder without the need for gene amplifications.

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**DNA- AND RNA-BASED BIOSENSORS**

Gene expression analysis at the point of care is important for rapid disease diagnosis, but traditional techniques are limited by multiplexing capabilities, bulky equipment and cost. We present a giant magnetoresistive (GMR) biosensor platform well suited for multiplexed transcript detection and quantification. The technology has shown great promise in detecting influenza detection and vaccination response based on influenza meta signature (IMS) resulting from host immune responses to viral infections.

**ARTIFICIAL INTELLIGENCE IN POINT-OF-CARE TECHNOLOGIES**

Artificial intelligence (AI) may provide new opportunities for predicting and combat the emergence of resistant pathogens. Lastly, the integration of POC testing with other laboratory methods under a diagnostic “ecosystem” is instrumental prior to leveraging AI analytics.

**REGISTER EARLY & SAVE!**
Using Electrochemistry Sensors
Ming Tan, PhD, CEO, Wainamics
Point-of-care (POC) testing of procalcitonin allows rapid confirmation of blood stream bacterial infection and assessment antibiotics treatment. Wainamics presents here a low cost, disposable microfluidic cartridge for high-sensitivity, quantitative measurement of procalcitonin. Together with a compact instrument, such system provides a platform for high precision POC testing.

Drivers for Utilizing Cloud Solutions in POC Device Development
Christian Valcke, Global Director Software Engineering, Software Engineering, Invetech
The rise of connected devices, centralized data storage, and machine learning are changing the way POC diagnostics deliver value. We consider the critical success factors of POC device development (timeline, cost, differentiation) and how the adoption of cloud solutions can impact those factors as products are defined, developed and deployed.

PLENARY KEYNOTE SESSION
(please see Keynotes pages for details)

4:35 Welcome Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

4:45 PLENARY KEYNOTE INTRODUCTION
Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Alforia

5:00 PLENARY KEYNOTE PRESENTATION: High-Performance Medicine
Eric Topol, MD, Founder and Director, Scrips Research Translational Institute (SRTI); Author, Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again

PLENARY KEYNOTE SESSION
(please see Keynotes pages for details)

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6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

7:30 End of Day

TUESDAY, MARCH 3

7:30 am Registration Open and Morning Coffee

FEATURED SESSION: ADDRESSING ANTIMICROBIAL RESISTANCE THROUGH THE NIH-BARDA GRAND CHALLENGE

8:00 Organizer’s Remarks
Kaitlin Searfoss Kelleher, Conference Producer, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks
Tanya Gottlieb, PhD, Vice President, Scientific Affairs, MeMed

8:10 Point-of-Care Diagnostics for Antibiotic Stewardship in the Hospital and Beyond
Larissa May, MD, MSPH, MSHS, Professor and Director of ED and Outpatient Antibiotic Stewardship, Emergency Medicine, UC Davis Health
This presentation will focus on opportunities for expanding POC diagnostics for management of infectious diseases in the ED and other areas in the health system. We will demonstrate successful implementation, lessons learned, and regulatory and practical considerations.

8:35 Geospatial “Hot Spots” in Need of Rapid Point-of-care Diagnostics for Highly Infectious Threats and Antimicrobial Resistance
Gerald J. Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT-CTR), Emeritus Professor, School of Medicine, University of California, Davis
We will develop a framework for deploying novel point-of-care technologies that detect antimicrobial resistance. Hot spots occur across world locations no longer limited geospatially. We can integrate geoscience tools and point-of-care testing to quickly, directly, and efficiently detect microbial and viral threats. Spatial patterns of resistance will allow us to target therapy cost-effectively.

9:00 PANEL DISCUSSION: Addressing Antimicrobial Resistance Through Public-Private Partnerships and the NIH-BARDA Grand Challenge
Antimicrobial resistance represents a growing public health concern, leading to BARDA and the NIH working with private companies to develop novel diagnostics. The NIH-BARDA Grand Challenge has charged participants with developing innovative and novel rapid diagnostic tests to identify resistant bacteria or to distinguish between viral and bacterial infections to reduce over-prescription of antibiotics. Two of the five finalists will present their work and the challenges their technologies address. We will also hear from a company collaborating directly with BARDA to advance and commercialize their assay.
Moderator: Gerald J. Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT-CTR), Emeritus Professor, School of Medicine, University of California, Davis
Panelists: Ephraim L. Tsalik, MD, MHS, PhD, Founder, Predigen, Inc.
Gary Schoolnik, Director, Medical Affairs, Click Diagnostics
Timothy Sweeney, MD, PhD, CEO, Inflammatix

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

THE UPHEAVAL OF POC AND BLOOD-BASED DIAGNOSTICS DEVELOPMENT

10:40 PANEL DISCUSSION: The Altering Landscape of Diagnostics Development in the Age of Machine Learning and Advanced Data Analytics
Advanced data analytics and machine learning are driving the diagnostics business to points it’s never before been. This panel of experts will discuss how data technologies are altering the landscape of not only lab-based blood tests, but ultimately the point-of-care diagnostics industry.
Moderator: David Deetz, Co-Founder, CEO, Ativa Medical
Panelists: Richard Spero, Co-Founder and CEO, Redbud Labs
Marko Notar, PhD, CEO, Smart Blood Analytics Swiss SA
James Fackler, MD, Director, Pediatric Critical Care Medicine, Associate Professor of Anesthesiology and Critical Medicine, Johns Hopkins Medicine

11:25 Translating Benchtop Assays for Microfluidic POC Devices – The Secrets to Success
Brioni Cristiano, PhD, Head, Bioscience, Minifab
Creating a successful POC diagnostic product requires overcoming unique challenges associated with translating
3:00 Transition to Keynote Session

3:15 Organizer's Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

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Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children's Institute for Genomic Medicine
David Haussler, PhD, Investigator, Howard Hughes Medical Institute;
Distinguished Professor, Biomolecular Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group
Lisa Diamond, CEO, Pinpoint Science, Inc.

Pinpoint's novel nanosensor technology enables accurate, low-cost handheld detection and quantification of viral, bacterial and fungal pathogens in 30 seconds. Direct, label-free detection in biofluids (blood, saliva, milk, urine) with no laboratory, no technicians, no sample preparation, allows affordable real-time screening and surveillance of global health threats such as influenza, malaria, Ebola, and Zika. This presentation will describe the underlying science, validation results, market opportunities, and commercialization strategy for Pinpoint's revolutionary new nanosensor technology.

9:10 Miniaturized Devices for Point-of-Care Molecular Diagnostics in Resource-Limited Settings
Season Wong, President and Co-Founder, AI Biosciences, Inc.

Our company has been developing technologies that will enable low-cost and rapid molecular diagnostics in resource-limited settings. These enabling technologies are low-cost, portable, and easy to use. In this presentation, we will describe our recent efforts in optimizing technologies that isolate, amplify, and detect target nucleic acids from biospecimens. Examples of POC pathogen detection will be given.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

INTEGRATING MICROFLUIDICS, NANOSENSORS, AND MINIATURIZED DEVICES (CONT.)

10:35 Chairperson's Remarks
Shawn P. Mulvaney, Section Head, Surface Nanoscience and Sensor Technology, Chemistry Division, U.S. Naval Research Laboratory

10:40 Miniaturized Electro-fluidic Technologies for Health and Environmental Monitoring
Mehdi Javanmard, PhD, Associate Professor, Electrical and Computer Engineering, Rutgers University New Brunswick

In this talk, I will discuss my group's work on fabricating micro- and nanosensing platforms for biomolecular and biochemical detection. In the first part of my talk, I will discuss a digital microfluidic platform for detection of inflammatory proteins in blood and saliva. I will then discuss a novel scheme for barcoding microparticles nanoelectronically, for multiplexed detection of analytes. We have also developed a novel electrochemical sensor using reduced graphene oxide for detection of inflammatory markers in exhaled breath condensate for management of chronic respiratory diseases. Finally, I will talk about my group's efforts in developing novel probes for characterization of biological organisms on-the-field in environmental samples, along with sensors for detection of toxic compounds in our regional water sources.

MODERNIZING PAPER-BASED LATERAL FLOW ASSAYS

11:10 Recent Progress with Rapid Single-Use NAAT-Based Pathogen Detection Devices
Paul Yager, PhD, Professor, Department of Bioengineering, University of Washington

Detection of pathogens by untrained users in low resource environments is challenging. Our current approach is to use isothermal nucleic acid amplification. As opposed to the prevalent instrument/disposable paradigm, we have been emulating the simplicity of the user interface of the modern home pregnancy test. Ongoing projects include detection of tuberculosis using oral swabs, detection of chlamydia using urine, and detection of HIV from finger-stick blood samples.

11:40 Catalytic Enhancement of Lateral Flow Immunoassays: More Signal Amplifies Our Opportunity
Shawn P. Mulvaney, Section Head, Surface Nanoscience and Sensor Technology, Chemistry Division, U.S. Naval Research Laboratory

In field forward and remote settings, lateral flow immunoassays are one of the most important diagnostic technologies. However, they are limited by their sensitivity. We have developed a catalytic enhancement scheme where Pd replaces the traditional Au labels and we are realizing orders of magnitude more sensitivity. Our approach promises to reinvigorate a classic technology resulting in far more capable diagnostic that is perfectly suited for the most remote of locations, yet applicable to many more.

12:05 Challenges and Opportunities in Resource-Limited Settings for POC IVD Manufacturers
Michael Loeffelholz, Senior Director, Medical Affairs, Cepheid

The impact of point-of-care technologies in resource-limited settings is profound, but the development, funding, and implementation of these technologies is not always easy. There are several challenges and opportunities for POC IVD manufacturers in resource-poor settings: technology, development, regulatory, cost considerations, to name a few. We’ll examine the industry and business perspective, as well as the clinical implementation and, most importantly, the impact these point-of-care technologies have on patient care.

2:00 Chairperson's Remarks
Michael Loeffelholz, Senior Director, Medical Affairs, Cepheid

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2:35 Options for Molecular Point of Care Testing- Challenges and Solutions
Gregory J. Berry, PhD, D(ABMM), Director, Molecular Diagnostics, Assistant Director, Infectious Disease Diagnostics, Northwell Health Laboratories; Director, Microbiology, Long Island Jewish Medical Center; Assistant Professor, Pathology and Laboratory Medicine, Donald and Barbara Zucker School of Medicine at Hofstra
There are numerous challenges associated with the implementation of point-of-care testing. We will touch on several of these challenges and also discuss strategies to handle them. We will also discuss how these challenges may differ in a resource-rich vs. a resource-limited setting.

3:05 **Point-of-Care Testing: Bringing the Laboratory to the Patient in Low- and Middle-Income Country Settings**  
Jeffrey D. Klausner, MD, MPH, Professor of Medicine and Public Health, David Geffen School of Medicine, University of California, Los Angeles  
I will review studies across three continents demonstrating the acceptability, feasibility, and value of point-of-care diagnostic testing for sexually transmitted infections in pregnant women.

3:35 **Close of Conference**
Immunocompromised patients are vulnerable to a wide variety of infections. Hence, antibiotic prescriptions are rarely based on a definitive diagnosis and patients often receive inappropriate treatment. Rapid diagnostic tools have fallen short of their hype and promise. The field has experienced significant challenges. Disruption of the larger MDx market will require POC Dx companies to create “winning strategies” by establishing competitive differentiation from one another, driving successful adoption and implementation, and navigating regulatory and reimbursement hurdles. Disruption of the larger MDx market will require POC Dx companies to create “winning strategies” by establishing competitive differentiation from one another, driving successful adoption and implementation, and navigating regulatory and reimbursement hurdles. One strategy diagnostics companies can use to mitigate risk. A well-chosen CM partner can accelerate the commercialization process by anticipating potential roadblocks. In this session, we will discuss best practices and key considerations for vetting contract manufacturing partners.
Patrick Daugherty, PhD, CSO and Founder, Serimmune, Inc.
While clinical use of antibody serology for infectious disease generally has been limited to targeted assays for just a few organisms, numerous clinical scenarios could benefit from a broad view of serological immunity. Combining high diversity peptide display libraries, next-generation sequencing, and custom bioinformatics, we developed serum epitope repertoire analysis (SERA) to map circulating antibody specificities to their antigens and reveal one's immune history. Bioinformatic analysis of the resulting digital immune record enables effectively unlimited multiplexing of epitope-specific antibody assays. We analyzed the serological antibody repertoires from more than 10,000 individuals reflecting diverse disease states including viral, bacterial, parasitic and fungal infections, autoimmunity, and cancer to build a Human Immunity Map (HIMap). We demonstrate the utility of SERA coupled with HIMap to measure IgG and IgM serostatus for Lyme along with 50 other infectious and autoimmune markers in 1500 individuals referred for Lyme disease testing. Our results suggest that SERA has the potential to substantially increase diagnostic yields, thereby circumventing costly and burdensome diagnostic odysseys.

4:10 COVID-19 Could Be Identified in Minutes via Mobile Technology
Paul Pickering, PhD, Chairman & CEO, Ubiquitome Limited
Fast testing during viral outbreaks, such as the coronavirus COVID-19, could assist preventing its spread. Ubiquitome will present RT-PCR data, from its proprietary Liberty16 mobile molecular detection system, covering both animal and human health. Results are reported in real time via Ubiquitome's iPhone app interface for dynamic outbreak response.

4:25 Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION
(please see Keynotes pages for details)

4:35 Welcome Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute
4:45 PLENARY KEYNOTE INTRODUCTION
Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia

5:00 PLENARY KEYNOTE PRESENTATION: High-Performance Medicine
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute (SRTI); Author, Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again

9:00 PANEL DISCUSSION: Addressing Antimicrobial Resistance Through Public-Private Partnerships and the NIH-BARDA Grand Challenge
Antimicrobial resistance represents a growing public health concern, leading to BARDA and the NIH working with private companies to develop novel diagnostics. The NIH-BARDA Grand Challenge has charged participants with developing innovative and novel rapid diagnostic tests to identify resistant bacteria or to distinguish between viral and bacterial infections to reduce over-prescription of antibiotics. Two of the five finalists will present their work and the challenges their technologies address. We will also hear from a company collaborating directly with BARDA to advance and commercialize their assay.

Moderator: Gerald J. Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT-CTR), Emeritus Professor, School of Medicine, University of California, Davis
Panelists: Ephraim L. Tsaiik, MD, MHS, PhD, Founder, Predigen, Inc.
Gary Scolnik, Director, Medical Affairs, Click Diagnostics
Timothy Sweeney, MD, PhD, CEO, Inflammatix

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

ADVANCES IN SEQUENCING TECHNOLOGY AND ITS ROLE IN MODERN INFECTIOUS DISEASE DIAGNOSIS
10:40 Improving Openness, Reproducibility and Scalability in Microbial Genomics and Bioinformatics for Public Health
Duncan MacCannell, PhD, CSO, Office of Advanced Molecular Detection, Centers for Disease Control and Prevention
Advances in sequencing technology have fundamentally changed laboratory approaches to infectious disease diagnostics, pathogen characterization, molecular epidemiology and surveillance. Operationalizing these technologies requires significant investments in bioinformatics infrastructure and workforce. This presentation will discuss efforts to improve the openness, reproducibility and scalability of microbial genomics applications across a range of public health laboratory settings.
March 2-4, 2020

11:10 Role of NGS-Based Microbiome Studies in Pediatric Infectious Diseases
Prithvi Raj, PhD, Assistant Professor, Immunology, UT Southwestern Medical Center
Host microbiota impact virulence, infection load, and drug resistance of infectious agents in pediatric population is largely unknown. This talk will address how microbiota can impact the susceptibility to infectious diseases in pediatric population and how NGS-based microbiome studies can be new methods in infectious diseases diagnosis and treatment. Our longitudinal study investigates this question by profiling immune repertoire, microbiome, and clinical disease in a cohort of young children.

11:40 Semiconductor Biochip System for Rapid and High-multiplex Identification, Quantification, and Genotyping of Pathogens
Kirsten Johnson, PhD, Research and Development Senior Manager, InSilixa, Inc.
The emergence of pathogens resistant to antimicrobials is a growing worldwide health crisis. To curtail antimicrobial misuse, InSilixa has developed a fully integrated, miniaturized semiconductor biochip system that can rapidly identify pathogens, quantify microbial load and determine the drug resistance profile of up to 250 sequences simultaneously. Applications developed on this platform include an upper respiratory pathogen panel, antimicrobial resistance genotyping of M. tuberculosis, and viral load quantification and genotyping of HIV-1.

12:10 pm Session Break

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

12:50 LUNCHEON PRESENTATION II: Old Beads, New Tricks: Porting Legacy Assays to Point-of-Care
Richard Chasen Spero, PhD, CEO, Redbud Labs, Inc.
As our industry’s attention turns to point-of-care platforms, life science companies struggle to deploy the power of their benchtop tools, like beads, buffers and centrifuges, in a microfluidic context. Fundamental microfluidics limitations cause protocols for lysis, purification, and amplification to undergo fundamental changes. By utilizing Redbud Post technology, we have developed a method to achieve bead-based assays on cartridge with performance equal to or better than the laboratory equivalent.

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Keynote Session

3:10 KEYNOTE SESSION
(please see Keynotes pages for details)

3:15 Organizer’s Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine — David Haussler, Stephen Kingsmore, and Liz Worthey — offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.
Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children's Institute for Genomic Medicine
David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomolecular Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

6:00 End of Day

6:30 - 9:30 Dinner Short Courses* (please see Short Courses pages for details)
*Sponsorship Opportunity Required

WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)
Moderator: Robin Toft, Author of WE CAN, The Executive Woman’s Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search
Panelists: Camille Samuels, MBA, Partner, Venrock
Paul Hastings, President and CEO, Nkarta Therapeutics, Inc
Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration
Alice Zheng, MD, MPH, MBA, Engagement Manager and Women’s Health Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

UTILIZING ADVANCED ANALYTICS, ALGORITHMS, AND MACHINE LEARNING IN DIAGNOSIS

8:00 Organizer’s Remarks
Kaitlin Searfoss Kelleher, Conference Producer, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks
Jennifer Dien Bard, PhD, D(ABMM), Director, Microbiology and Virology, Pathology and Laboratory Medicine, Children's Hospital Los Angeles; University of Southern California

8:10 Machine Learning to Detect Antibiotic Resistance: Progress and Challenges
David Greenberg, MD, Associate Professor, Microbiology and Internal Medicine, University of Texas Southwestern
This talk will discuss the use of next generation sequencing approaches
for predicting antibiotic resistance. It will focus on the application and development of bioinformatic pipelines to help predict resistance accurately without the need for phenotypic testing. Examples of success as well as challenges in the field will be explored.

8:40 The Power of Bioconvergence: MeMed BV™, Using the Host Response to Distinguish between Bacterial and Viral Infections
Frederick Sweeney, PhD, Chief Business Development Officer, MeMed Diagnostics Ltd.
At the crossroad between medical evidence, biochemistry, engineering and machine learning, the MeMed team has developed a powerful platform to discover, develop, validate and commercialize new diagnostics tools. MeMed’s first test (MeMedBV™) relied on a machine learning approach of discovery and validation of over 100,000 biomarker combinations where the best performing combination computationally integrates three circulating host protein scores into a score with >90% accuracy which has been validated in multiple double-blind international studies.

9:10 Developing an mRNA-Based Panel for Pre-Symptomatic Detection of Sepsis
Kai Wang, PhD, Principal Scientist, Institute for Systems Biology
Using longitudinal samples from patients undergoing elective surgery, we identified a blood mRNA-based panel that could diagnose sepsis 2 to 3 days prior to the onset of clinical symptoms, allowing for much earlier therapeutic intervention. The panel was optimized using a biological function-based algorithm to reduce the number of features in the assay without affecting the performance. The diagnostic performance of the panel was validated with validation cohort.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

CASES IN MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE

10:40 CO-PRESENTATION: From Bench to Bedside: Real-World Cases in Molecular Diagnostics for Infectious Diseases
Jennifer Dien Bard, PhD, D(ABMM), Director, Microbiology and Virology, Pathology and Laboratory Medicine, Children’s Hospital Los Angeles; University of Southern California
Susan Butler-Wu, PhD, D(ABMM), Associate Professor of Clinical Pathology, Keck School of Medicine, University of Southern California, Director of Clinical Microbiology, LAC+USC Medical Center
Development of molecular assays has increased exponentially in the past decade and have revolutionized testing in the clinical laboratories. But how are tests being offered and reported in the laboratory? Further, how are results being interpreted by providers? This session will provide adult and pediatric case examples of the pros and cons of molecular diagnostics for infectious diseases. An interactive discussion on current and future directions of diagnostic assays will follow.

12:10 pm Improving Influenza Outcomes Through OTC Molecular Diagnostics
Frank Myers, PhD, Director of Engineering, Lucira Health
Nearly 90% of patients with influenza do not seek medical treatment within the 48 hour window necessary for antiviral treatment. Lucira Health is developing an over-the-counter influenza diagnostic which better fits patient relief-seeking habits at symptom onset, enabling more timely and effective access to antiviral treatment and improved flu outcomes.

12:25 Sponsored Presentation (Opportunity Available)
are deletions that prematurely terminate the dystrophin protein. The major genetic disorder diagnosed in childhood. The majority of DMD mutations gene cause Duchenne muscular dystrophy (DMD), the most common fatal matrix to maintain muscle integrity and function. Mutations in the dystrophin The Dystrophin protein connects the muscle cytoskeleton and extracellular

Therapies

Leonela Amoasii, PhD, Director, Gene Editing Research, Vertex Genetic

2:25 Correction of Duchenne Muscular Dystrophy by Genome Editing

Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.

2:20 Chairperson's Remarks

Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.

1:05 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

2:05 Session Break

OPENING FEATURED SESSION

11:45 Organizer's Opening Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

11:50 Chairperson's Remarks
Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.

11:55 Climbing Mt. OMIM: Genome Editing and “Rare” Disease
Fyodor Urnov, PhD, Professor, Department of Molecular and Cell Biology, University of California, Berkeley; Director, Innovative Genomics Institute

12:25 pm Genome Editing of Stem Cells to Create Human Medicines
Matthew Porteus, MD, Professor, Pediatrics, Stanford School of Medicine

Genome editing provides a method to precisely change the DNA sequence of a cell. It can be used to make single nucleotide changes or to precisely insert new genes into cells. We have developed a system combining the use of Cas9, synthetic guide RNAs, and AAV6 that is highly efficient in homologous recombination-based genome editing in a wide variety of primary human cells. I will discuss the development of this system and our use of this system to develop genetically engineered, cell-based drugs for a variety of diseases.

12:55 Session Break

3:25 Directed Evolution of New AAV Vectors for Gene Therapy and Genome Editing

Matthew Porteus, MD, Professor, Pediatrics, Stanford School of Medicine

3:55 FEATURED PRESENTATION: Facilitating the Use of Gene Therapy for Rare Disorders

Patrick W. Tansey, MD, Professor of Pediatrics, University of California, San Francisco

Gene therapy has succeeded in increasing numbers of human trials and approved products, establishing the strong therapeutic promise of viral vectors. However, highly efficient and targeted delivery remains a broad challenge. We developed and implemented directed evolution, a process that emulates natural evolution by generating large libraries of biomolecules and selecting for enhanced function, to greatly enhance the properties of numerous viral vectors. We have found T regulatory cells against AAV capsid that sustain long-term expression of transgene in the absence of immune suppression.

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4:25 Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION

(please see Keynotes pages for details)

4:35 Welcome Remarks
Cindy Crowninshield, RDN, LDN, HH, Executive Event Director, Cambridge Healthtech Institute

4:45 PLENARY KEYNOTE INTRODUCTION

Sponsored by

aiforia

Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia

5:00 PLENARY KEYNOTE PRESENTATION: High-Performance Medicine
Synthetic Zinc Finger Proteins (ZFPs) comprise a versatile platform for editing and regulating genes of therapeutic relevance and can target virtually any position within the human genome. Clinical-grade ZFPs can be rapidly developed and optimized using mix-and-match assembly of pre-defined components, including finger modules and base-skipping linkers, and tuned to provide high specificity. This presentation will detail the optionality and exquisite electrivity of the platform across several disease indications.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

REGULATION AND PERSONALIZED ADOPTIVE CELL THERAPY

Chairperson's Remarks
Ross Wilson, PhD, Project Scientist and Principal Investigator, UC Berkeley & the Innovative Genomics Institute

10:40 Regulatory Approaches for Development of CAR T Therapies
Elena Spanjaard, PhD, Global Head of Regulatory Affairs, Regulatory Affairs, Celyad

I will define IND requirements for genetically-modified CAR T therapies and discuss the tailored regulatory strategies to address unique program features.

11:10 Personalized Multi-Targeted Adoptive Cell Therapy
Steffen Walter, PhD, CSO, Immatics US

Despite its great potential, adoptive cellular therapy (ACT) has shown limited clinical success in solid tumors. Major challenges of ACT in solid tumors include heterogeneity of tumor antigen expression, tumor escape (e.g. after addressing only one target) and toxicities (e.g. due to expression of targets on healthy tissue). In this presentation, we will show recent data from several complementary clinical-stage approaches to treat solid tumors using personalized combinations of multiple novel targets.

11:40 Accelerating Biology in True Resolution – Single-Cell Genomics for Gene Editing and Cellular Therapies
Brian R. Fritz, PhD, Associate Director, AMR Regional Marketing, 10 X Genomics

12:10 pm Session Break

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

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Keynote Session

KEYNOTE SESSION

(please see Keynotes pages for details)

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20 years after the completion of the first draft of the Human Genome Project,
there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

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Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group
6:00 Close of Conference

6:30 - 9:30 Dinner Short Courses* (please see Short Courses pages for details)
*Separate registration required

Join your fellow Tri-Conference attendees during Speed Networking in the Exhibit Hall

Accelerate your business contacts through a dedicated time of facilitated networking with other delegates at the Molecular Medicine Tri-Conference. Participants will be paired up for a quick burst of conversation and business card exchange. When time is up, delegates will move down the line to their next connection. Pre-registration is not required for speed networking.

March 3: 10:00 – 10:20 am & 5:45 – 6:00 pm
March 4: 10:00 – 10:20 am & 1:25 – 1:40 pm

For more info, visit: TriConference.com/networking
March 3-4, 2020

**TUESDAY, MARCH 3**

7:30 am Registration Open

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

**REGULATION AND PERSONALIZED ADOPTIVE CELL THERAPY**

Chairperson's Remarks
Ross Wilson, PhD, Project Scientist and Principal Investigator, UC Berkeley & the Innovative Genomics Institute

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Elena Spanjaard, PhD, Global Head of Regulatory Affairs, Regulatory Affairs, Celyad

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Brian R. Fritz, PhD, Associate Director, AMR Regional Marketing, 10X Genomics

12:10 pm Session Break

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

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Keynote Session

**KEYNOTE SESSION**

(please see Keynotes pages for details)

3:15 Organizer's Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
Maria Fardis, PhD, MBA, President & CEO, Iovance Biotherapeutics

Despite the great potential of personalized medicine, there are major challenges in addressing small targets and toxicities. I will define IND requirements for genetically-modified CAR T therapies and discuss the tailored regulatory strategies to address unique program features.

**WEDNESDAY, MARCH 4**

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)
Moderator: Robin Toft, Author of WE CAN, The Executive Woman's Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search
Panelists: Camille Samuels, MBA, Partner, Venrock
Alice Zheng, MD, MPH, MBA, Engagement Manager and Women's Health Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

**THE PURSUIT OF TUMOR-INFLTRATING LYMPHOCYTE (TILs) FOR SOLID TUMOR**

8:00 Organizer's Remarks
Ngoc 'Emily' Le, PhD, Conference Producer, Cambridge Healthtech Institute

8:05 Chairperson's Remarks
Chantale Bernatchez, PhD, Assistant Professor, Melanoma Medical Oncology - Research, Cancer Medicine, The University of Texas MD Anderson Cancer Center

8:10 Investigating the Power of Tumor Infiltrating Lymphocytes for Treatment of Cancer
Maria Fardis, PhD, MBA, President & CEO, Iovance Biotherapeutics

Iovance is focused on the commercialization of autologous tumor infiltrating lymphocyte (TIL) therapies that enhance the body's own immune response to eradicate solid tumors. Iovance has reported clinically meaningful responses in disease areas or populations with unmet medical need. Iovance is conducting Phase II clinical trials to assess the efficacy and safety of

8:40 **Tumor-Infiltrating Lymphocyte (TIL) Therapy for Solid Tumors**
Chantale Bernatchez, PhD, Assistant Professor, Melanoma Medical Oncology, Research, Cancer Medicine, The University of Texas MD Anderson Cancer Center

Adaptive transfer of tumor-infiltrating lymphocytes (TIL ACT) is one of the first living immunotherapies to be tested in multiple clinical trials in metastatic melanoma and results consistently in a 40 to 50% overall response rate. In our recent publication, we evaluated the impact of pretreatment with anti-CTLA4 in TIL ACT-treated patients. New data and future outlook for TIL therapy for the treatment of checkpoint refractory metastatic melanoma patients will be discussed.

9:10 **Lymphodepletion-Generated Myeloid Derived Suppressor Cells (MDSC) Decrease the Efficacy of Adoptive T Cell Therapy**
Shari Pilon-Thomas, PhD, Associate Member, Immunology; Co-Director, Center for Immunization and Infection Research in Cancer (CIIRC), Moffitt Cancer Center

In melanoma and lung cancer patients, MDSCs rapidly expanded within one week after completion of a lymphodepleting regimen and infusion of autologous tumor infiltrating lymphocytes (TIL). Increased MDSC frequency was associated with disease progression, poor survival, and reduced TIL persistence in vivo.

9:40 **Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group**

**ADVANCES IN CLINICAL TRIALS**

10:40 **Clinical Evaluation of CD5 CAR T Cells for T Cell Malignancies**
Maksim Mamonkin, PhD, Assistant Professor, Pathology & Immunology, Center for Cell and Gene Therapy, Baylor College of Medicine

Development of effective CAR T cell therapies for T cell leukemia/lymphoma requires minimizing CAR-driven fratricide of normal T cells. We have developed a CD5-specific CAR that enables T cells to resist fratricide and retain high cytotoxicity against a broad range of T cell malignancies. In the clinic, CD5 CAR T cells produce high anti-tumor activity without eliminating the endogenous T cell compartment.

11:10 **Mechanisms of Resistance to Anti-CD19 CAR T Therapy**
John Rossi, Director, Translational Medicine, Kite a Gilead Co.

Limited data has been published describing mechanisms of resistance to CAR T cell therapy. The well-annotated ZUMA-1 clinical trial serves as a benchmark to address outstanding questions. Translational research focusing on the association between CAR T cell product attributes, tumor immune microenvironment and resistance will be presented.

11:40 **Advancing CAR T Cell Therapy for Solid Tumors**
Saul Priceman, PhD, Assistant Professor, Hematology & Hematopoietic Cell Transplantation, City of Hope Beckman Research Institute

While impressive clinical responses have been observed with CAR T cell therapy in B cell malignancies, the responses in solid tumors have to date been underwhelming. Building on our experience at City of Hope with CAR T cell therapy, and encouraging results in hematological malignancies and recurrent glioblastoma, we are expanding our translational research program to treat patients with other solid tumors, including prostate, breast, and ovarian cancer. Additionally, we are building more clinically relevant mouse models to address the major challenges in developing safe and effective CAR T cell therapies for solid tumors, including target selectivity, tumor antigen heterogeneity, and the immunosuppressive tumor microenvironment.

12:10 pm **Multifunctional Microfluidic Allows a New Level of Personalized Medicine**
Magdalena Schimke, Sales Specialist, Stratec Consumables GmbH

Single cell sorting, imaging and analytics become more and more important in the field of basic and applied sciences as well the drug discovery industries to serve clinical trials.

12:25 **Sponsored Presentation (Opportunity Available)**

12:40 **Session Break**

12:50 **Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own**

1:20 **Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group**

**THE FUTURE OF ALLOGENEIC CELL THERAPY**

2:00 **Chairperson’s Remarks**
Peggy Sotiropoulou, PhD, Director, R&D, Celyad

2:05 **Expansion and Engineering of Allogeneic Natural Killer Cells for Enhanced Anti-Tumor Activity**
James Trager, PhD, CSO, Nkarta

Natural Killer (NK) cells play an important role in tumor control; their lack of HLA restriction provides an opportunity for development of effective off-the-shelf NK cell products. Increasing understanding of the mechanisms by which NK cells are activated and inhibited in the tumor microenvironment has allowed targeted engineering to enhance their anti-tumor activity.

2:35 **Exploiting Natural Killer Cell Receptors for Autologous and Allogeneic CAR T Cell Therapy of Cancer**
Peggy Sotiropoulou, PhD, Director, R&D, Celyad

The NK cell activating receptor NKGD2 binds to eight different ligands commonly over-expressed in cancer, while being generally absent from healthy tissues. Preliminary data from clinical trials assessing NKGD2-based CAR T cells have shown promising clinical activity in both hematological and solid tumors. Our results in using autologous and allogeneic NKGD2-based CAR T cells will be discussed.

3:05 **Enhancing CAR T Cell Therapies with Precision Genome Engineering**
Alexandre Juilleralat, PhD, US Laboratory Head and Team Leader, Cellectis

We have successfully developed GMP-compliant manufacturing of TALENS®-based edited CAR T cells for clinical use, which has led to two allogeneic CAR T cell product candidates in the clinic. Using our proprietary nuclease-based gene editing technologies, we showed our ca-pability to efficiently edit any gene in primary T cells with very high precision. Here, we de-scribe how TALENS® gene-editing technology allows us to create CAR T cells that can be used in allogeneic setting and, additionally, empowers them with improved safety and efficacy at-tributes. Among others, new features include expression control properties, resistance to stand-ard oncology treatments, prevention of engineered CAR T cells fratricide and controlled release of key effector molecules.

3:35 **Close of Conference**
Digital Health promises to transform the practice of medicine by allowing continuous real-time patient monitoring, offering innovative digital therapeutics and combination products, and enabling patient-centric clinical research and healthcare. The Digital Health conference brings together the key thought leaders in enabling technologies, pharma, healthcare, investors, and entrepreneurs to foster collaboration and innovation in digitalization of medicine. The three keynote sessions convene industry leaders to discuss how “big tech,” “big pharma,” and “big insurers” are implementing digital health. The Digital Health Tech program will focus on the advances in enabling technologies, including sensors and wearables, artificial intelligence and machine learning, Internet of Medical Things, devices and apps for improving Rx adherence and safety monitoring. The parallel Digital Medicine program will highlight the latest innovations in digital therapeutics and digital companions, digital biomarkers and endpoints, Real-World Evidence, clinical trials and clinical research, patient centricity and integrating patient data, as well as the impact on big pharma and drug development. The meeting will also address the business strategies and value generation, commercialization and market access, and regulatory and reimbursement strategies; as well as offer introductory courses on digital medicine and digital therapeutics.

Learn More at: TriConference.com/Digital-Health

#TRICON
Ravi Kuppuraj, PhD, CEO, Digital Innovator, Connected Sensing, Philips

Panelists: Chris Gough, General Manager, Health & Life Sciences, Intel
Investing, Qualcomm Ventures

Moderator: Thomas Kluz, MS, General Partner, dRx Capital; Head, Healthcare
Implementing Digital Health?

12:55 KEYNOTE PANEL DISCUSSION: How Is “Big Tech”
Implementing Digital Health?
Moderator: Thomas Kluz, MS, General Partner, dRx Capital; Head, Healthcare
Implementing, Qualcomm Ventures
Panelists: Chris Gough, General Manager, Health & Life Sciences, Intel
Corporation
Ravi Kuppuraj, PhD, CEO, Digital Innovator, Connected Sensing, Philips

13:00 Q&A with the Speakers

13:30 Adjourn
9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

SENSORS, DEVICES AND APPS TO IMPROVE Rx ADHERENCE AND PATIENT MONITORING

10:40 Chairperson's Remarks
Christopher M. Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

10:45 Reading between the Lines to Reduce the ‘Last Mile’ Problem in Cancer Patient Care
Christopher M. Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health
Cancer patients disconnected from resource intensive cancer centers face challenges beyond simply the disease they are dealing with. These patient populations include rural communities as well as populations who have access hindered via disability, transportation or time. This ‘last mile’ problem of healthcare delivery is becoming more tractable than before with modern broadband connectivity and sensors. This talk will discuss efforts across NCI and NIH to help mitigate.

11:05 Use of an Implantable Sensor to Monitor Heart Failure
Nirav Dalal, Senior Director, Data Science & Analytics, Abbott
The CardioMEMS™ HF System is the first and only FDA-approved wireless heart failure (HF) monitor that has been proven to significantly reduce heart failure hospitalizations and improve quality of life in New York Heart Association (NYHA) Class III patients who have been hospitalized for heart failure in the previous year. The CardioMEMS HF System is a safe, reliable way to help patients manage their heart failure. This talk will discuss technology, workflow, and clinical impact.

11:25 Ingestible Sensors: A New Approach to Look at Digestive Disorders and Nutritional Balance
Chris van Hoof, PhD, Vice President, Connected Health Solutions, imec; Managing Director, OnePlanet Research Center
Digestive processes are hard to examine yet they determine our health and well-being on a daily basis. Ingestible sensors can make a huge difference by providing a more comprehensive and longitudinal measurement of key parameters. imec is using its advanced chip technologies for developing ingestible sensors with the aim to measure the mechanical, chemical and electrical processes in the gut. This requires innovations in many areas: sensing, (remote) powering, and wireless communications.

11:45 Digital Therapeutics Deliver Evidence of Results: The Example of DarioHealth
Olivier Jarry, Chief Commercial Officer & President, DarioHealth
Digital therapeutics is still a radically new approach in a traditionally conservative healthcare system. Holding DTX up to the same standards of clinically proven evidence as drugs and medical devices is indispensable to generate credibility and trust. DarioHealth accumulates individual medical and lifestyle data every day from which it generates analyses for the user to take action and for their healthcare practitioners, as well as to inform the healthcare community.

12:05 pm Talk Title to be Announced
Andrea Coravos, CEO & Co-Founder, Elektra Labs

12:35 Session Break

12:40 Digital Health Luncheon Presentation (Sponsorship

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10:30 Presentation to be Announced
Mila Malhotra, Digital Health Leader, Ophthalmology, Product Development Medical Affairs Personalized Healthcare and Patient Access, Roche

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9:10 KEYNOTE PANEL DISCUSSION: How Is “Big Pharma” Implementing Digital Health?
Moderator: Tim Pantello, Managing Director, PricewaterhouseCoopers

Panelists:
Matt Lasmanis, Vice President, Technology, GlaxoSmithKline
Joris van Dam, PhD, Head, Digital Therapeutics, Novartis Institutes for BioMedical Research
Michael Senical, Director, Strategy and Innovation, Astellas
Mila Malhotra, Digital Health Leader, Ophthalmology, Product Development Medical Affairs Personalized Healthcare and Patient Access, Roche
WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)

10:40 Chairperson’s Remarks
Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP

10:45 KEYNOTE PRESENTATION: Harmonizing Healthcare Innovation for Better, Faster Transformation
Leigh Anderson, President of Performance Services, Premier, Inc.
11:10 KEYNOTE PRESENTATION: Smart Health Communities
Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP

11:35 KEYNOTE PANEL DISCUSSION: Building Digital Healthcare
Moderator: Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP
Panelists: Leigh Anderson, President of Performance Services, Premier, Inc. John Mattison, MD, Chief Medical Information Officer, emeritus, Kaiser Permanente Claus Jensen, PhD, Chief Digital Officer and Head of Technology, Memorial Sloan Kettering Cancer Center

12:40 pm Session Break

12:50 Digital Health Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

PATIENT CENTRICITY: DIGITAL MEDICINE = PERSONALIZED MEDICINE

2:00 Chairperson’s Remarks
Adrian Chernoff, Former Worldwide Vice President, Global Head of Research and Development, Johnson and Johnson

2:05 Wearables and Health
Michael Snyder, PhD, Stanford W. Ascherman Professor & Chair, Department of Genetics; Director, Center for Genomics & Personalized Medicine, Stanford University
We have been using smart watches and continuous glucose monitoring to track people’s health and find early signs of disease.

2:25 Patient-Centricity, the Future to Enabling Digital Health
Adrian Chernoff, Former Worldwide Vice President, Global Head of Research and Development, Johnson and Johnson
Payers, providers and patients are beginning to encounter changes to the healthcare landscape with the introduction of new digital tools. As we shift into this new reality a key component will be to put the patient at the center shifting the relationship dynamics in how we deliver digital applications and build digital ecosystems to meet the growing needs of patients at any stage of care from healthcare, home care or self-care.

VIRTUAL REALITY IN MEDICINE

2:45 The Power and Potential of VR Medicine
Ramsay Brown, Director, Product Science, AppliedVR
With over 30 years of clinical research, the healthcare industry has embraced virtual reality (VR). Today, rapidly advancing mobile technology yielding ever more immersive experiences at a lower cost, is driving the use of VR beyond research environments into the clinical trenches and patient homes. Therapeutic VR is a promising new modality with the potential to treat serious and debilitating medical conditions, including pain – one of the most widely studied of all disease areas to date – by delivering a low-risk, non-pharmacological intervention.

3:05 Virtual Worlds, Real Results: How VR Is Transforming Healthcare
Howard Rose, MEd, CEO & Co-Founder, Firsthand Technology
Howard will share the compelling evidence from clinical applications of VR therapy. VR’s potential to induce deep changes in the brain unlocks new therapies for challenging conditions and populations. Propelled by the tsunami of consumer technologies, VR is poised to be the engine for personalized medicine that will fundamentally transform our health and the healthcare industry.

3:25 Close of Conference

TRICON Takes San Francisco Contest!
(#TRICONTakesSF)
Enter to win a $100 Amazon Gift Card!
1:30 Digital Health Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

2:05 Session Break

DIGITAL THERAPEUTICS

2:30 Chairperson’s Remarks
Joris van Dam, PhD, Head, Digital Therapeutics, Novartis Institutes for BioMedical Research

2:35 Digital Therapeutics in Pharma
Joris van Dam, PhD, Head, Digital Therapeutics, Novartis Institutes for BioMedical Research

The Digital Therapeutics Alliance often refers to digital therapeutics as “a new class of medicine.” In this talk, we will explore the opportunities and challenges of integrating digital therapeutics as a new therapeutic class within a more traditional medicines portfolio based on our experience at Novartis and based on our successes and challenges in our partnership with Pear Therapeutics.

3:00 Prescription Software as Treatments for Disease
Joel Sangerman, Chief Commercial Officer, Click Therapeutics, Inc.

Major deals, investments, and partnerships between pharmaceutical companies and burgeoning digital therapeutic companies have become regular headline news. As physicians, patients, and payers embrace technology to drive better treatment outcomes at lower costs, prescription digital therapeutics (PDTs) will play a prominent role in the healthcare ecosystem. This session will highlight the key aspects of this transformation in care.

3:25 Prescription Digital Therapeutics: Establishing a New Therapeutic Class
Alex Waldron, Chief Strategy Officer, Pear Therapeutics

Prescription digital therapeutics (PDTs) are a new modality of therapeutic providing efficacy in many disease areas previously untreated, or only partially treated.

3:50 Digital Medicine Extends to Peer Support
Adam Kaufman, PhD, President & CEO, Canary Health

So many of the outcomes we care about to improve health and impact costs are driven by individuals’ behaviors, emotions, relationships, lifestyle and system navigation. This talk will highlight how evidence-based, digital, peer-to-peer support groups are extending care models to engage individuals with chronic conditions and cost-effectively enable peers to support each other, often in ways that complement traditional provider-driven care.

4:15 Q&A with the Speakers

4:25 Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION

4:35 Welcome Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

4:45 PLENARY KEYNOTE INTRODUCTION
Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia
March 2-4, 2020

Implementing Digital Health?

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

7:30 End of Day

TUESDAY, MARCH 3

7:30 am Registration Open and Morning Coffee

DIGITAL HEALTH AT BIG PHARMA

(please see Keynotes pages for details)

8:00 Organizer’s Remarks
Julia Boguslavsky, Executive Director, Conferences, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks
Tim Pantello, Managing Director, PricewaterhouseCoopers

8:10 KEYNOTE PRESENTATION: Digital Transformation of the Pharmaceutical Industry
Dirk Schapeler, Vice President, Digital, Bayer LLC

8:30 KEYNOTE PRESENTATION: The Experimental Science behind Empowering Teams
Matt Lasmanis, Vice President, Technology, GlaxoSmithKline

8:50 Presentation to be Announced
Mila Malhotra, Digital Health Leader, Ophthalmology, Product Development Medical Affairs Personalized Healthcare and Patient Access, Roche

9:10 KEYNOTE PANEL DISCUSSION: How Is “Big Pharma” Implementing Digital Health?
Moderator: Tim Pantello, Managing Director, PricewaterhouseCoopers

Panelsists:
Matt Lasmanis, Vice President, Technology, GlaxoSmithKline
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Michael Senical, Director, Strategy and Innovation, Astellas
Mila Malhotra, Digital Health Leader, Ophthalmology, Product Development Medical Affairs Personalized Healthcare and Patient Access, Roche

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

DIGITAL BIOMARKERS AND ENDPOINTS

10:40 Chairperson’s Remarks
Dan Karlin, MD, CEO, HealthMode

10:45 Digital Measurement in Clinical Trials: Fitting the Tool to the Question
Dan Karlin, MD, CEO, HealthMode

Measurement in clinical trials is progressing from intermittent and imprecise, to highly granular and continuous. Making sense of this progression requires understanding the past/current means of measurement, the process for moving toward better measures, and having a vision for what the future might hold. Using four examples from our work, Dr. Karlin will address past, present, and potential future states in cough, bowel habits, agitation, pain, and performance status in oncology.

11:05 Digital Measures for Neurological Disorders
Ray Dorsey, MD, David M. Levy Professor, Neurology; Director, CHeT, University of Rochester

Current measures for neurological disorders are subjective, episodic, and insensitive. Consequently, we have no highly effective therapies for Alzheimer’s disease, the most effective therapy for Parkinson’s is more than 50 years old, and many rare neurological disorders have no treatments at all. Smartphones, wearable sensors, and newer technologies can provide objective, frequent, sensitive assessments in real-world settings. The result could accelerate development of new drugs for the world’s leading source of disability and improved care for millions.

11:25 Uncovering the Potential of Wearable Devices for Identifying and Monitoring neurological Events and Disease Progression
Jian Yang, MD, Senior Director, Digital Health, Eli Lilly

This presentation will dive into findings from research on recent digital neurology research conducted with consumer devices and sensors. It will share how these devices could eventually equip consumers with tools to support early disease detection and progression and share key insights on how these may apply to other chronic conditions.

Michelle Crouthamel, PhD, MSc, DBA, Director, Digital Health & Innovation, AbbVie

12:05 pm Delivering a Digital Biomarker for a Regulated Trial in Rare Disease
Dudley Tabakin, CEO, VivoSense

VivoSense is the first analytics company to develop novel digital biomarkers from wearable sensor data which constitute primary and secondary clinical endpoints in regulated international pharmaceutical trials. Several of these studies are in rare disease indications, and have reached the open-label phase. It will show how these devices could eventually equip consumers with tools to support early disease detection and progression and share key insights on how these may apply to other chronic conditions.

12:20 Sponsored Presentation (Opportunity Available)

12:35 Session Break

12:40 Digital Health Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Conference Programs

REGULATORY STRATEGIES FOR DIGITAL MEDICINE

3:15 Chairperson’s Remarks
Michael Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision & Digital Medicine, GlaxoSmithKline
3:20 Regulatory Considerations during Mobile Medical App Development for Commercial and Clinical Trial Use
Michael Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision & Digital Medicine, GlaxoSmithKline

Mobile medical apps are defined as medical devices from their intended use. Mobile medical app regulation is health risk-based to balance patient safety and barriers to technological innovation. Medical device patient risk analysis is a critical prerequisite prior to sensor/app inclusion within a clinical trial. Key components of quality management systems for mobile medical apps include: software requirements/specifications, user acceptance testing, software postmarket surveillance, software version control and medical device adverse event reporting.

3:50 Opportunities and Challenges in the Digital Landscape of Regulated and Non-Regulated Products
Darin Oppenheimer, Executive Director, Regulatory Affairs & Digital Health Solutions, Merck

Digital Health continues to make inroads in various applications within the pharmaceutical industry. From standalone mobile apps, connected products, as well as applications in clinical trials, the opportunities are evolving as we speak. The regulatory landscape for digital solutions also continues to evolve, as MoHs such as FDA and EMA continue to put out guidance and recommendations on how best to manage this rapidly changing area, taking risk into account. In this talk, we will lay the foundation from regulatory perspective on the past, present, and future of digital health solutions.

4:20 Talk Title to be Announced
Andrew C. Fish, PhD, Chief Strategy Officer, AdvaMed Center for Digital Health

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

6:00 End of Day

6:30 - 9:30 Dinner Short Courses* (please see Short Courses pages for details)
*Separate registration required

WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)
Moderator: Robin Toft, Author of WE CAN, The Executive Woman's Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search
Panelists: Camille Samuels, MBA, Partner, Venrock
Paul Hastings, President and CEO, Nkarta Therapeutics, Inc
Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration
Alice Zheng, MD, MPH, MBA, Engagement Manager and Women's Health Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

DIGITAL TOOLS ENABLING CLINICAL TRIALS, RESEARCH, AND REAL-WORLD EVIDENCE

8:00 Chairperson's Remarks
Ashish Atreja, MD, MPH, Assistant Professor, Chief Innovation Officer, Medicine, Icahn School of Medicine at Mount Sinai

8:05 A Platform Approach to Digital Transformation and Real-World Evidence
Ashish Atreja, MD, MPH, Assistant Professor, Chief Innovation Officer, Medicine, Icahn School of Medicine at Mount Sinai

The practice of medicine is exponentially evolving. This evolution is fueled by value-based transformation and incentives that are aligning for continuous, proactive care, within and outside the four walls of the hospitals. To address this need, the new generation of startups is leveraging disciplines like data science, informatics, digital medicine, genomics, and AI; but this is creating a problem of plenty. In spite of more than 350,000 mobile apps for healthcare, less than 4% of patients are recommended apps by providers today.

8:25 Digital Medicine Research: Harnessing Technology to Transform Clinical Trials and Clinical Care
Yu-Feng (Yvonne) Chan, MD, PhD, Senior Director, Medical Affairs for Digital Medicine, Otsuka

The Mount Sinai Asthma Mobile Health Study powered by Apple’s ResearchKit framework is a remote observation study that enrolled 10,000 participants from 3 countries. Yvonne Chan, MD, PhD, principal investigator of the study, will share the latest lessons learned from this pioneering mobile health research study and other ongoing efforts in digital medicine and real-world evidence.

8:45 Unleashing the Potential of ML in Clinical Development
Kyle Holen, MD, Head, Development Design Center, AbbVie

Kyle will discuss the latest techniques his team has been using in attempts to solve some of the biggest challenges in drug development today, including site selection challenges, patient dropouts, and placebo enrollment. He will share some of the successes and failures along their journey as well as a future look at new areas where machine learning can help us design and execute on more efficient and rapid clinical trials.

9:05 Importance of Reorientation of Digital Medicine Product and Service Designs to Focus on the Patient as an Individual Consumer – Consumer-Oriented Patient Engagement Strategies
Raj Pallapothu, mHealth Global Lead, Bayer

This presentation will cover: 1) new-generation digital biomarkers; 2) wearables in clinical trials; 3) evolving connected platforms and services (patient as consumer); 4) emerging digital study design and underlying protocol changes; and 5) growing need for adaptive clinical trials and underlying importance aligned with consumerization.

9:25 Q&A with the Speakers

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

BUILDING DIGITAL HEALTHCARE
(please see Keynotes pages for details)

10:40 Chairperson’s Remarks
Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP

10:45 KEYNOTE PRESENTATION: Harmonizing Healthcare Innovation for Better, Faster Transformation
Leigh Anderson, President of Performance Services, Premier, Inc.

11:00 KEYNOTE PRESENTATION: Smart Health Communities
Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP

11:10 KEYNOTE PRESENTATION: Smart Health Communities
Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP

11:35 KEYNOTE PANEL DISCUSSION: Building Digital Healthcare
Cambridge Healthtech Institute’s Inaugural
Digital Medicine NEW
Digital Therapeutics, Digital Biomarkers, and Real-World Evidence Enable Patient-Centric Precision Medicine

March 2-4, 2020

Moderator: Asif Dhar, Chief Health Informatics Officer, Principal, Deloitte Consulting LLP
Panelists: Leigh Anderson, President of Performance Services, Premier, Inc.
John Mattison, MD, Chief Medical Information Officer, emeritus, Kaiser Permanente
Claus Jensen, PhD, Chief Digital Officer and Head of Technology, Memorial Sloan Kettering Cancer Center

12:15 pm Session Break
12:50 Digital Health Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own
1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

PATIENT CENTRICITY: DIGITAL MEDICINE = PERSONALIZED MEDICINE

2:00 Chairperson’s Remarks
Adrian Chernoff, Former Worldwide Vice President, Global Head of Research and Development, Johnson and Johnson

2:05 Wearables and Health
Michael Snyder, PhD, Stanford W. Ascherman Professor & Chair, Department of Genetics; Director, Center for Genomics & Personalized Medicine, Stanford University
We have been using smart watches and continuous glucose monitoring to track people’s health and find early signs of disease.

2:25 Patient-Centricity, the Future to Enabling Digital Health
Adrian Chernoff, Former Worldwide Vice President, Global Head of Research and Development, Johnson and Johnson
Payers, providers and patients are beginning to encounter changes to the healthcare landscape with the introduction of new digital tools. As we shift into this new reality a key component will be to put the patient at the center shifting the relationship dynamics in how we deliver digital applications and build digital ecosystems to meet the growing needs of patients at any stage of care from healthcare, home care or self-care.

2:45 The Power and Potential of VR Medicine
Matthew Stoudt, CEO, AppliedVR
With over 30 years of clinical research, the healthcare industry has embraced virtual reality (VR). Today, rapidly advancing mobile technology yielding ever more immersive experiences at a lower cost, is driving the use of VR beyond research environments into the clinical trenches and patient homes. Therapeutic VR is a promising new modality with the potential to treat serious and debilitating medical conditions, including pain – one of the most widely studied of all disease areas to date – by delivering a low-risk, non-pharmacological intervention.

3:05 Virtual Worlds, Real Results: How VR Is Transforming Healthcare
Howard Rose, MEd, CEO & Co-Founder, Firsthand Technology
Howard will share the compelling evidence from clinical applications of VR therapy. VR’s potential to induce deep changes in the brain unlocks new therapies for challenging conditions and populations. Propelled by the tsunami of consumer technologies, VR is poised to be the engine for personalized medicine that will fundamentally transform our health and the healthcare industry.

3:25 Close of Conference
Pharmaceutical companies are undergoing a digital transformation. By experimenting with new initiatives, they are positioned to play a role in the revolution of healthcare. This transformation is driven by data from internal and external sources, including both -omic data and that from digital devices. Bio-IT World WEST, part of Molecular Medicine Tri-Conference, brings together all the stakeholders involved in this transformation.
It is hoped that combining real-world data with sophisticated statistical and machine learning algorithms could lead to realizing the dream of personalized healthcare. In order to make this dream a reality, data scientists need to embrace organizational data and methodological complexities not commonly encountered elsewhere. In this talk, the speaker would share his experiences in building data science teams ready to tackle the challenge of delivering personalized healthcare for everyone.

FEATURED SESSION: BUILDING A STRONG DATA FOUNDATION

2:20 Chairperson's Remarks
Alan S. Louie, PhD, Research Director, Life Sciences, IDC Health Insights

2:25 Running Too Fast with AI, Pitfalls of Bad Data
Faisal Khan, PhD, Executive Director, Advanced Analytics and AI, AstraZeneca

The use of artificial intelligence and data science approaches and technologies is experiencing explosive growth in the pharmaceutical industry. The plethora of opportunities provide an exciting range of applications to explore. However, as the field has grown, many folks are employing and leveraging AI without keeping in mind the rigors required for good science, including preparing the data and how it's analyzed. At the end of the data, it's still garbage in/garbage out.

2:55 Building Data Science Teams for Pharma – Myths and Realities
Mustaqhusain Kazi, Head of Personalized Healthcare, Pharma Informatics, Genentech

It is hoped that combining real-world data with sophisticated statistical and machine learning algorithms could lead to realizing the dream of personalized healthcare. In order to make this dream a reality, data scientists need to embrace organizational data and methodological complexities not commonly encountered elsewhere. In this talk, the speaker would share his experiences in building data science teams ready to tackle the challenge of delivering personalized healthcare for everyone.

3:25 Leveraging Omics for Discovery and Development of New Drugs
Howard J. Jacob, PhD, Vice President and Head, Genomic Research, Drug Discovery Science & Technology, Distinguished Research Fellow, Abbvie

3:55 Lightweight, Practical Cross-Domain Metadata
Chris Dwan, Senior Technologist and Independent Life Sciences Consultant

It is increasingly clear that robust metadata management is one of the keys to unlocking the potential of biomedical data. Creating and enforcing usable standards for this metadata without stifling innovation and productivity or violating compliance requirements is a crucial balancing act with both technical and non-technical components. This talk will discuss real-world examples of metadata systems in use for sequencing, sample management, technical and non-technical components. This talk will discuss real-world examples of metadata systems in use for sequencing, sample management, technical and non-technical components.

4:25 Refreshment Break and Transition to Plenary Keynote
5:00 PLENARY KEYNOTE PRESENTATION: High-Performance Medicine
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute (SRTI); Author, Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

7:30 End of Day

TUESDAY, MARCH 3

7:30 am Registration Open and Morning Coffee

KEYNOTE SESSION
(please see Keynotes pages for details)

8:00 Organizer's Remarks
Cindy Crowinshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

8:05 Chairperson's Remarks
Sudeep Basu, PhD, Practice Leader, TechVision-Innovation Services, Frost & Sullivan

8:10 Keynote Introduction
Vasu Rangadass, President, CEO, L7 Informatics

8:25 KEYNOTE PRESENTATION: AI and Big Data Strategies in Accelerating Clinical Research for Faster Rare Disease Cures
Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University

8:55 KEYNOTE PANEL DISCUSSION: Applications of AI Technologies in Pharmaceuticals: Facilitating Development of Therapeutics in Treating Rare Diseases
Moderator: Sudeep Basu, PhD, Practice Leader, TechVision-Innovation Services, Frost & Sullivan
Panelists: Tom Defay, Senior Director, R&D Strategy and Alliances, SPMD, Strategy, Program Management and Data Sciences, Alexion
Annastasiah Mhaka, PhD, President, The Alliance for Artificial Intelligence in Healthcare (AAIH)
Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University
Christina Waters, PhD, President, CEO and Founder, RARE Science, Inc.
Vasu Rangadass, President, CEO, L7 Informatics, Inc.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

WORK SMARTER (NOT HARDER) WITH YOUR DATA

10:40 Chairperson's Remarks
Pankaj Agarwal, Chief Computational Biologist, BioInfi

10:45 Advancing the Use of Real World Data to Support R&D and Personalized Healthcare

Ryan Copping, PhD, Global Head of Analytics, PHC Data Science, Personalized Healthcare (PHC), Product Development, Roche & Genentech
Generating insights from Real World Data (RWD) is a critical success factor for personalized healthcare. This presentation will look at some of the advancements being made in terms of data (access/growth/quality/linkages, etc.), analytics and technology and will share some specific examples from Roche/Genentech's R&D efforts as well as some of the challenges and opportunities for the future.

11:15 CO-PRESENTATION: Target Identification and Drug Repurposing: From Machine Learning Theory to Practical Experience
Pankaj Agarwal, Chief Computational Biologist, BioInfi
Deepak Kumar Rajpal, PhD, Head, Bioinformatics, Translational Sciences, Sanofi
AI and Machine Learning are being widely used in drug discovery, yet there are significant challenges because of the lack of training examples in the biological data space. We will show three case studies examining the same problem from different angles and using different methods. You will see the limitations of each approach and how different validation schemes impact results.

11:45 Massively Multitask Profile-QSAR: Applications of Experiment-Quality Models for >8500 Novartis Biochemical And Cellular Assays
Eric Martin, PhD, Director, Computer Aided Drug Design, Novartis Institutes for BioMedical Research, Inc.
Profile-QSAR predicts biological activity with unprecedented accuracy and applicability domain by combining 20 million IC50 measurements from 2 million compounds covering 12,000 assays. The 8600 “successful” models have average accuracy comparable to 4-concentration IC50 experiments. Models are updated monthly, storing 60 billion predictions for 5.5 million compounds in a databricks database. It has been applied to 150 projects for virtual screening, selectivity design, tox and MoA prediction, and more.

12:15 pm Session Break

12:20 BIO-IT WORLD WEST CO-LUNCHEON PRESENTATION I: Describing Chemistry to Algorithms: Why Scientific Expertise Improves Accuracy
Alpha Lee, PhD, Doctor, Physics, University of Cambridge
Matt BcBride, MS, Director, Science IP, CAS
If a picture is worth a thousand words, then a chemical structure is worth thousands of features. Join Dr. Alpha Lee from the University of Cambridge to see how impactful descriptors are on predictions. If your AI initiatives aren’t meeting expectations, see how better representations of chemistry structures improve algorithm performance. CAS descriptors are derived from centuries of scientific knowledge and are proven to improve AI accuracy.

12:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Keynote Session

KEYNOTE SESSION
(please see Keynotes pages for details)

3:15 Organizer's Remarks
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies
3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.
Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children’s Institute for Genomic Medicine
David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomolecular Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

6:00 End of Day

6:30 - 9:30 Dinner Short Courses* (please see Short Courses pages for details)
*Separate registration required

WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)
Moderator: Robin Toft, Author of WE CAN, The Executive Woman's Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search
Panelists: Camille Samuels, MBA, Partner, Venrock
Paul Hastings, President and CEO, Nkarta Therapeutics, Inc
Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration
Alice Zheng, MD, MPH, MBA, Engagement Manager and Women’s Health Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

KEYNOTE SESSION
(please see Keynotes pages for details)

8:00 Organizer's Remarks
Edel O'Regan, PhD, Vice President, Production, Cambridge Healthtech Institute

8:05 Chairperson's Remarks
Joseph Ferrara, CEO, Boston Healthcare

8:10 Keynote Sponsor, Amazon Web Services
Speaker to be Announced

8:25 KEYNOTE PRESENTATION: The Value and Application of Informatics in Cancer Care Delivery
Debra A. Patt, MD, Vice President, Public Policy & Academic Affairs, Medical Oncologist, Texas Oncology Cancer Center & Editor in Chief, Journal of Clinical Oncology-Clinical Cancer Informatics

8:55 KEYNOTE PANEL DISCUSSION: Pragmatic Use of Informatics in Cancer Care Delivery and Cancer Research: Big Data and AI Take on Cancer
Moderator: Joseph Ferrara, CEO, Boston Healthcare
Panelists: Mark Hulse, Chief Digital Officer, City of Hope
Debra A. Patt, MD, Vice President, Public Policy & Academic Affairs, Medical Oncologist, Texas Oncology Cancer Center & Editor in Chief, Journal of Clinical Oncology-Clinical Cancer Informatics
Nicholas Schork, PhD, Deputy Director of Quantitative Sciences, Distinguished Professor of Quantitative Medicine, The Translational Genomics Research Institute (TGen)
Kristin Beaumont, PhD, Assistant Professor, Assistant Director of Single Cell Genomics Technology Development Icahn Institute, Dept. of Genetics & Genomic Sciences, Icahn School
Ajay Shah, PhD, Executive Director & Head of IT for Translational Medicine, Bristol-Myers Squibb
Paul A. Rejto, PhD, Vice President, Head of Translational Research, Pfizer Oncology R&D

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

BUSINESS STRATEGY FOR PHARMA PIPELINES

10:40 Chairperson's Remarks
Faisal Khan, PhD, Executive Director, Advanced Analytics and AI, AstraZeneca

10:45 CASE STUDY: Shaping Your Business Strategy with Advanced Analytics
Nuray Yurt, Executive Director, Enterprise Analytics & Data Science, Novartis
In this presentation you will: 1) learn of the roles that big data and advanced analytics can play in forecasting demand to refocus your product pipeline; 2) deliver results via management of your pipeline along with the risk factors associated with using AI & ML; and 3) understand the importance of end-to-end visibility and see how this can drive efficiency and operational excellence.

11:15 PANEL DISCUSSION: Partnering for AI Startups and Pharma
Topics to be Discussed:
• Meeting expectations, what is good for both sides
• How we can facilitate the transformation of pharma R&D
• Best practices
Moderator: Annastasiah Mhaka, PhD, Co-founder, Convenor, President, The Alliance for Artificial Intelligence in Healthcare (AAIH)
Panelists: Joseph Szustakowski, PhD, Co-founder, Convenor, President, The Alliance for Artificial Intelligence in Healthcare (AAIH)
Jonathan Allen, PhD, Computational Scientist, ATOM Consortium
Christopher Willis, PhD, Lead IT Business Partner, Precision Medicine, BMS
Gini Deshpande, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

12:00 pm PANEL DISCUSSION: Recruiting Data Scientists
Given the massive expansion of Data Science and the consequent need for experts in this area across all industries, there is a massive competition to find...
and source the talent required. How can we identify, recruit and retain the best
data scientists? What are the pitfalls and challenges to avoid and success
stories we can learn from?

Moderator: Faisal Khan, PhD, Executive Director, Advanced Analytics and AI,
AstraZeneca
Panelists: Mustaqhusain Kazi, Head of Personalized Healthcare, Pharma
Informatics, Genetech
Zahra ‘Nasim’ Eftekari, Senior Manager, Head of Applied AI and Data Science,
City of Hope
José Duca, PhD, Global Head, Computer-Aided Drug Discovery, Novartis
Yuval Itan, PhD, Assistant Professor, Department of Genetics and Genomic
Sciences; Member, Charles Bronfman Institute for Personalized Medicine,
Icahn School of Medicine at Mount Sinai

FEATURED SESSION: DATA STRATEGIES FOR
GENOMICS

2:00 Chairperson’s Remarks
Zhao Shi Jiang, PhD, Executive Director of Bioinformatics & Clinical Data
Sciences, Gilead Sciences

2:05 Fake It ‘til You Make It (Reproducible): Synthetic Data
Resources for Genomics
Geraldine A. Van der Auwera, PhD, Director of Outreach and Communications,
Data Sciences Platform, Broad Institute
The computational reproducibility of published biomedical research is limited
by data access restrictions, affecting not just researchers who wish to reuse
published analysis code, but also tool developers and educators who lack
suitable example data for testing and training. We present: 1) a prototype
pipeline that wraps established open-source data simulation tools to generate
publicly shareable synthetic sequence data at any scale; and 2) a plan to
develop community resources.

2:35 Progress in Diagnosing Rare Disease Patients Leveraging NLP
and Genomic Sequencing
Tom Defay, Senior Director, R&D Strategy and Alliances, SPMD, Strategy,
Program Management and Data Sciences, Alexion
Diagnosing patients with rare disease is challenging. Whole exome and whole
genome sequencing have improved our diagnostic abilities but can still fall short
due to our lack of understanding of which mutations are most likely to be the
cause of disease. By combining phenotypic information automatically extracted
from the patient’s EMR with a patient’s genome sequence, we have developed a
system for prioritizing which mutations may be most significant and proposing
possible diagnoses. Advances on this approach will be discussed.

3:05 Drug Targets with Genomic Support
J. Wade Davis, PhD, ACOS Research Fellow, Director, Computational Genomics,
Genomics Research Center (GRC), AbbVie

3:35 Close of Conference

12:45 Session Break

12:50 Bio-IT World WEST Luncheon Presentation (Sponsorship
Opportunity Available) or Enjoy Lunch on Your Own

1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster
Viewing, Speed Networking, Book Signing, and Meetup Group

Molecular Medicine Tri-Conference’s inaugural Bioinformatics Pipelines for
Preclinical Drug Discovery Hackathon will bring together stakeholders from across
pharma R&D to tackle datasets and projects with maximum impact potential.
Facilitated by leaders from the National Center for Biotechnology Information
(NCBI), the Tri-Conference is proud to bring together innovative data scientists and
developers from across the industry to solve real-world data challenges.

More info, visit: TriConference.com/hackathon
AI-Enabled Drug Discovery and Development
Applying AI and Machine Learning Techniques to Solve Drug Discovery and Development Challenges

SUNDAY, MARCH 1

2:00 - 5:00 pm Afternoon Short Courses* (please see Short Courses pages for details)
*Separate registration required

5:30 - 8:30 Dinner Short Courses* (please see Short Courses pages for details)
*Separate registration required

MONDAY, MARCH 2

8:00 - 11:00 am Morning Short Courses* (please see Short Courses pages for details)
*Separate registration required

10:30 Conference Program Registration Open

11:45 Organizer's Opening Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

11:50 Chairperson’s Remarks
Allison Proffitt, Editorial Director, Bio-IT World

11:55 Keynote Introduction, Benchling
Ashoka Rajendra, Head, Product, Registry, Inventory, Benchling

12:10 pm KEYNOTE PRESENTATION: The AI Bubble and the Emerging Thinking Economy
Pietro Michelucci, PhD, Director, Human Computation Institute

12:40 KEYNOTE PANEL DISCUSSION: Data Quality in Human Computation Systems
Moderator: Allison Proffitt, Editorial Director, Bio-IT World
Panelists: Jennifer Couch, PhD, Chief, Structural Biology and Molecular Applications Branch, Division of Cancer Biology and Citizen Science Coordinator, National Cancer Institute
Devin Krotman, Director, Global Learning XPRIZE and IBM Watson AI XPRIZE
Vani Mandava, Director, Data Science Outreach, Microsoft Research
Pietro Michelucci, PhD, Director, Human Computation Institute
Ginger Tsueng, PhD, Scientific Outreach Project Manager, Director of Integrative, Structural and Computational Biology, The Scripps Research Institute

1:30 Bio-IT World WEST Luncheon Presentation: Accelerating the Exchange of Data in Healthcare and Life Sciences
Fred Lee, MD, MPH, Head of Health Care, Life Sciences Business Development, AWS Data Exchange, AWS

APPLYING AI TO PRECISION MEDICINE

2:20 Chairperson’s Remarks
Michael D. Miller, Head of Science Infrastructure, Roche

2:25 AI and Computer-Aided Drug Discovery: the Hype, the Myth, the Legend
José Duca, PhD, Global Head, Computer-Aided Drug Discovery, Novartis

2:55 Data-Driven Approaches for Improving Clinical Trial Lifecycle
Shameer Khader, PhD, Senior Director, Advanced Analytics, Data Science and Bioinformatics, AstraZeneca
A successful drug discovery project is under development for 10 years and costs around USD $2.6B. On a temporal scale, the clinical trial phase of the process lasts about 4-6 years. In this talk, I will discuss about big-data-driven, machine intelligence approach we are leveraging to identify factors driving enrollment and dropout in respiratory clinical trials. Further, I will also discuss about developing predictive models to improve the throughput of the clinical trial enrollment lifecycle.

3:25 PANEL DISCUSSION: AI in Genomics and Precision Medicine
The AI-Enabled Drug Discovery and Development conference assembles thought leaders who will discuss Genomics and Precision Medicine, taking data from multiple -omics sources, imaging, and lifestyle data and aligning it with clinical action. These can then be turned into clinical recommendations for disease prevention, prognosis, diagnostics, and therapeutics. Machine learning gives us the power to extract elusive indicators from the ever-increasing volume of heath information. This information also gives us the power to make patient clusters, well beyond single etiology or prognostic indicators, and the panelists will present the promise and application of these multifactorial approaches toward curing or treating diseases and cancers.
Moderator: Ben Busby, PhD, Principal Scientist, DNANexus, Mountain Genomics, consultant to Johns Hopkins University (opencravat project)
Panelists: Jenny Smith, MSc, MEd, Research Bioinformatician, Clinical Research Division, Fred Hutchinson Cancer Research Center
Lukasz Kidzinski, PhD, CTO, Saliency.ai, Researcher, Stanford University
Celeste Shelton, PhD, CGC, Clinical Variant Scientist & Genetic Counselor, Ariel Precision Medicine

4:25 Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION
(please see Keynotes pages for details)

4:35 Welcome Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

4:45 PLENARY KEYNOTE INTRODUCTION
Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia

5:00 PLENARY KEYNOTE PRESENTATION: High-Performance
March 2-4, 2020

**AI-Enabled Drug Discovery and Development**

Applying AI and Machine Learning Techniques to Solve Drug Discovery and Development Challenges

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

7:30 End of Day

**TUESDAY, MARCH 3**

7:30 am Registration Open and Morning Coffee

**KEYNOTE SESSION**

(please see Keynotes pages for details)

8:00 Organizer’s Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks
Sudeep Basu, PhD, Practice Leader, TechVision-Innovation Services, Frost & Sullivan

8:10 Keynote Introduction
Vasu Rangadass, President, CEO, L7 Informatics

8:25 KEYNOTE PRESENTATION: AI and Big Data Strategies in Accelerating Clinical Research for Faster Rare Disease Cures
Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc.; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University

8:55 KEYNOTE PANEL DISCUSSION: Applications of AI Technologies in Pharmaceuticals: Facilitating Development of Therapeutics in Treating Rare Diseases
Moderator: Sudeep Basu, PhD, Practice Leader, TechVision-Innovation Services, Frost & Sullivan
Panelists: Tom Defay, Senior Director, R&D Strategy and Alliances, SPM, Strategy, Program Management and Data Sciences, Alexion
Annastassiah Mhaka, PhD, President, The Alliance for Artificial Intelligence in Healthcare (AAI)
Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc.; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University
Christina Waters, PhD, President, CEO and Founder, RARE Science, Inc.
Vasu Rangadass, President, CEO, L7 Informatics, Inc.

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

**FEATURED SESSION: DATA-DRIVEN PRECISION MEDICINE**

10:45 Translating Ten Trillion Points of Data into Diagnostics, Therapies and New Insights in Health and Disease
Atul Butte, MD, PhD, Priscilla Chan and Mark Zuckerberg Distinguished Professor; Director, Bakar Computational Health Sciences Institute, University of California, San Francisco; Chief Data Scientist, University of California Health (UC Health)

We build and apply tools that convert trillions of points of molecular, clinical, and epidemiological data – measured by researchers and clinicians over the past decade and now commonly termed “big data” – into diagnostics, therapeutics, and new insights into disease. Dr. Butte, a computer scientist and pediatrician, will highlight his center’s recent work on integrating electronic health records data across the entire University of California, and how analytics on this “real world data” can lead to new evidence for drug efficacy, new savings from better medication choices, and new methods to teach intelligence – real and artificial – to more precisely practice medicine.

11:15 Using Networks to Decode Cancer Risk
John Quackenbush, PhD, Professor and Chair, Biostatistics, Harvard TH Chan School of Public Health

Precision medicine is based on the idea that single mutations can inform our understanding of disease and response to therapy. But we know that cancer is multifactorial, with many genetic variants moderating disease and disease risk. By using network methods, we can better understand how and why cancer develops and assess disease risk.

11:45 Machine Learning-Based Patient Subgroup Identification for Precision Medicine
Jie Cheng, PhD, Director, Exploratory Statistics, Abbvie

Central to precision medicine is the ability to detect patient subgroups with differential treatment effects in clinical trial datasets. These patient subgroups are defined by clinical variables and biomarkers. We will provide a brief overview of existing methods for patient subgroup identification and then present our novel approach. The performance of our method is evaluated against other state-of-the-art methods using both simulation and real-world clinical trial dataset.

12:15 pm Session Break

12:20 LUNCHEON PRESENTATION I: A Modern Molecular LIMS Built for Precision Medicine
Nabil Hafez, MS, Senior Director, Product Management, Precision Medicine, Sunquest Information Systems

With the advent of precision medicine, molecular labs are facing greater testing demand than ever before. Molecular diagnostics are complicated, rapidly changing, and subject to detailed regulatory auditing. Learn how modern labs are streamlining molecular testing, scaling for volume and growth, and mastering compliance with purpose-built LIMS technology.

12:50 Luncheon Presentation II (Sponsorship Opportunity Available)

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)

3:00 Transition to Keynote Session

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(please see Keynotes pages for details)

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Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute
March 2-4, 2020

8:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies

8:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.
Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal, Mary Ann Liebert, Inc.
Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children's Institute for Genomic Medicine
David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomolecular Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)
Moderator: Robin Toft, Author of WE CAN, The Executive Woman's Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search
Panelists: Camille Samuels, MBA, Partner, Venrock
Paul Hastings, President and CEO, Nkarta Therapeutics, Inc
Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration

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Debra A. Patt, MD, Vice President, Public Policy & Academic Affairs, Medical Oncologist, Texas Oncology Cancer Center & Editor in Chief, Journal of Clinical Oncology-Clinical Cancer Informatics

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Moderator: Joseph Ferrara, CEO, Boston Healthcare
Panelists: Mark Hulse, Chief Digital Officer, City of Hope
Debra A. Patt, MD, Vice President, Public Policy & Academic Affairs, Medical Oncologist, Texas Oncology Cancer Center & Editor in Chief, Journal of Clinical Oncology-Clinical Cancer Informatics
Nicholas Schork, PhD, Deputy Director of Quantitative Sciences, Distinguished Professor of Quantitative Medicine, The Translational Genomics Research Institute (TGen)
Kristin Beaumont, PhD, Assistant Professor, Assistant Director of Single Cell Genomics Technology Development Icahn Institute, Dept. of Genetics & Genomic Sciences, Icahn School
Ajay Shah, PhD, Executive Director & Head of IT for Translational Medicine, Bristol-Myers Squibb
Paul A. Rejto, PhD, Vice President, Head of Translational Research, Pfizer Oncology R&D

9:00 PUTTING THE -OMICS IN GENOMICS

10:40 Chairperson's Remarks
Kristen Fortney, PhD, CEO, BIOAGE

10:45 Data Science for Translational Research in Pharmaceutical Industry
Zhaoshi Jiang, PhD, Executive Director of Bioinformatics & Clinical Data Sciences, Gilead Sciences
The pharmaceutical industry is facing unprecedented challenges with its current R&D models. The key issue of the industry is the low successful rate of translational research. We would like to share our experience on leverage "omics data" to better support the translational research at Gilead.

11:15 Leveraging AI, ‘-Oomics,’ and Biobanks to Extend Human Lifespan and Healthspan
Kristen Fortney, PhD, CEO, BIOAGE
‘-Oomics’ data enables us to study aging directly in humans, rather than less translationally relevant model systems. At BIOAGE we focus on ‘-omic’ phenotyping of human aging cohorts that have healthy blood samples tied to decades of follow-up EHRs that include rich healthspan and mortality outcomes. We integrate multiple data modalities for data-driven discovery of key aging targets.

11:45 On the Road to Genetically Validated Targets in Kidney Diseases: Computational Challenges
Thomas Tibbitts, PhD, Senior Vice President, Computational Discovery, Goldfinch Bio
Focal segmental glomerulosclerosis (FSGS) is scarring of the kidney that can
lead to kidney failure. To discover genetic variants associated with FSGS, we built the Kidney Genome Atlas (KGA 1.0), which contains whole genomes (>30X) on 23000 individuals, including 2000 cases of FSGS and other proteinuric disorders. To efficiently process and analyze this large amount of genomic data we have implemented infrastructure and pipelines on AWS and launched a web portal to facilitate target discovery.

12:15 pm Session Break

12:50 Bio-IT World WEST Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

FEATURED SESSION: DATA STRATEGIES FOR GENOMICS

2:00 Chairperson’s Remarks
Zhaoshi Jiang, PhD, Executive Director of Bioinformatics & Clinical Data Sciences, Gilead Sciences

2:05 Fake It ‘til You Make It (Reproducible): Synthetic Data Resources for Genomics
Geraldine A. Van der Auwera, PhD, Director of Outreach and Communications, Data Sciences Platform, Broad Institute
The computational reproducibility of published biomedical research is limited by data access restrictions, affecting not just researchers who wish to reuse published analysis code, but also tool developers and educators who lack suitable example data for testing and training. We present: 1) a prototype pipeline that wraps established open-source data simulation tools to generate publicly shareable synthetic sequence data at any scale; and 2) a plan to develop community resources.

2:35 Progress in Diagnosing Rare Disease Patients Leveraging NLP and Genomic Sequencing
Tom Defay, Senior Director, R&D Strategy and Alliances, SPMD, Strategy, Program Management and Data Sciences, Alexion
Diagnosing patients with rare disease is challenging. Whole exome and whole genome sequencing have improved our diagnostic abilities but can still fall short due to our lack of understanding of which mutations are most likely to be the cause of disease. By combining phenotypic information automatically extracted from the patient’s EMR with a patient’s genome sequence, we have developed a system for prioritizing which mutations may be most significant and proposing possible diagnoses. Advances on this approach will be discussed.

3:05 Drug Targets with Genomic Support
J. Wade Davis, PhD, ACOS Research Fellow, Director, Computational Genomics, Genomics Research Center (GRC), AbbVie

3:35 Close of Conference
## Emerging Technologies for Life Sciences

**Utilizing New Technologies to Transform Outcomes**

**March 2-4, 2020**

**Moscone South Convention Center**

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**REGISTER EARLY & SAVE!**

**Cambridge Healthtech Institute's Inaugural**

**Emerging Technologies for Life Sciences**

**NEW**

**Utilizing New Technologies to Transform Outcomes**

**March 2-4, 2020**

**Moscone South Convention Center**

### SUNDAY, MARCH 1

**2:00 - 5:00 pm** Afternoon Short Courses* (please see Short Courses pages for details)
*Separate registration required

**5:30 - 8:30 Dinner Short Courses* (please see Short Courses pages for details)
*Separate registration required

### MONDAY, MARCH 2

**8:00 - 11:00 am** Morning Short Courses* (please see Short Courses pages for details)
*Separate registration required

**10:30 Conference Program Registration Open**

**KEYNOTE SESSION**

(please see Keynotes pages for details)

**11:45 Organizer’s Opening Remarks**

Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

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Allison Proffitt, Editorial Director, Bio-IT World

**11:55 Keynote Introduction, Benchling**

Ashoka Rajendra, Head, Product, Registry, Inventory, Benchling

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Pietro Michelucci, PhD, Director, Human Computation Institute

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**Moderator:** Allison Proffitt, Editorial Director, Bio-IT World
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Vani Mandava, Director, Data Science Outreach, Microsoft Research
Pietro Michelucci, PhD, Director, Human Computation Institute
Ginger Tsueng, PhD, Scientific Outreach Project Manager, Department of Integrative, Structural and Computational Biology, The Scripps Research Institute

**1:30 Bio-IT World WEST Luncheon Presentation:**

**Accelerating the Exchange of Data in Healthcare and Life Sciences**

Fred Lee, MD, MPH, Head of Health Care, Life Sciences Business Development, AWS Data Exchange, AWS

Predictive models and algorithms in healthcare and life sciences (HCLS) have emerged from the combination of patient data and advanced analytics. With machine learning and AI technologies becoming commoditized, scalable access to patient data now throttles the build of such predictive analytics. We will discuss how the AWS Data Exchange, as a digital marketplace for data, addresses this ‘data bottleneck’ by accelerating data exchange in a regulatory compliant, economically sustainable, and cloud-native manner.

**2:05 Session Break**

**INTERPRETABLE MACHINE LEARNING TECHNIQUES**

**2:20 Chairperson’s Remarks**

Zaha ‘Nasim’ Effekhari, Senior Manager, Head of Applied AI and Data Science, City of Hope

**2:25 Explainable Artificial Intelligence in Precision Medicine**

Su-In Lee, Associate Professor, Paul G. Allen School of Computer Science & Engineering, University of Washington

I will briefly describe my group’s efforts to develop interpretable ML techniques for varied biological and medical applications, including treating cancer based on a patient’s own molecular profile, identifying therapeutic targets for Alzheimer’s, predicting kidney diseases, preventing complications during surgery, enabling pre-hospital diagnoses for trauma patients, and improving our understanding of pan-cancer biology and genome biology. My talk will focus in greater detail on: MERGE, which uses ML to identify molecular markers for chemotherapy drugs for acute myeloid leukemia in collaboration with UW medicine.

**COMPUTER VISION APPLICATIONS FOR LIFE SCIENCE**

**2:55 The InnerEye Project: Medical Imaging AI to Empower Clinicians**

Aditya Nori, PhD, Healthcare Intelligence Lead, Senior Principal Researcher, Microsoft Research

Project InnerEye develops machine learning techniques for the automatic delineation of tumors as well as healthy anatomy in 3D radiological images. The InnerEye technology may enable: 1) extraction of targeted radiomics measurements for quantitative radiology; 2) efficient contouring for radiotherapy planning; and 3) precise surgery planning and navigation. In practice, Project InnerEye turns multi-dimensional radiological images into measuring devices.

**3:25 Computer Vision for AI Augmented Medicine**

Eric Oermann, MD, Instructor of Neurological Surgery, Mount Sinai Health System; Director, AISINAI

There are numerous applications of computer vision to augmenting medical care. We will discuss the latest advances in computer vision, and how they can be applied to making medical care faster, safer, and smarter.

**3:55 Talk Title to be Announced**

Thomas Bengtsson, Genentech

**4:25 Refreshment Break and Transition to Plenary Keynote**

**PLENARY KEYNOTE SESSION**

(please see Keynotes pages for details)

**4:35 Welcome Remarks**

Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

**4:45 PLENARY KEYNOTE INTRODUCTION**

Thomas Westerling-Bui, PhD, Senior Scientist, Regional Business Development, Aiforia

**Sponsored by Roche**

**Sponsored by Aiforia**
March 2-4, 2020

Cambridge Healthtech Institute’s Inaugural
Emerging Technologies for Life Sciences
Utilizing New Technologies to Transform Outcomes

TUESDAY, MARCH 3

7:30 am Registration Open and Morning Coffee

8:00 Organizer’s Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

8:05 Chairperson’s Remarks
Sudeep Basu, PhD, Practice Leader, TechVision-Innovation Services, Frost & Sullivan

8:10 Keynote Introduction
Vasu Rangadass, President, CEO, L7 Informatics

8:25 KEYNOTE PRESENTATION: AI and Big Data Strategies in Accelerating Clinical Research for Faster Rare Disease Cures
Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc.; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University

8:55 KEYNOTE PANEL DISCUSSION: Applications of AI Technologies in Pharmaceuticals: Facilitating Development of Therapeutics in Treating Rare Diseases
Moderator: Sudeep Basu, PhD, Practice Leader, TechVision-Innovation Services, Frost & Sullivan
Panelists: Tom Defay, Senior Director, R&D Strategy and Alliances, SPMD, Strategy, Program Management, and Data Sciences, Alexion; Annastasiah Mhaka, PhD, President, The Alliance for Artificial Intelligence in Healthcare (AAIH); Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc.; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University; Casey Greene, PhD, Associate Professor, Department of Systems Pharmacology and Translational Therapeutics, Perelman School of Medicine, University of Pennsylvania; Matt BcBride, MS, Director, Science IP, CAS; Alpha Lee, PhD, Director, Physics, University of Cambridge; Corrado Priami, PhD, Founder and CSO, COSBI

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

10:40 Chairperson’s Remarks

10:45 A Patient-Centered Analytic Learning Machine (PALM) for Learning Healthcare Systems
Parsa Mirhaji, MD, PhD, Associate Professor, Systems and Computational Biology, Chief Technology Officer, NY City Data Research Network, Director, Center for Health Data Innovations, Founder, Cognome, Inc.
PALM is a real-time system designed to scale advanced analytics and promote digital transformation of healthcare through analytically driven clinical decision support, patient experience, automation of operational processes and administrative support systems. PALM scales knowledge graphs to assimilate data from virtually any source and modality, and applies an ensemble of AI/ML/DL algorithms to generate predictive and prescriptive models to ultimately automate and drive patient care in complex healthcare systems environments.

11:15 Search Over Knowledge Graphs Predicts Cellular Mechanisms Underlying Statistical Associations
Casey Greene, PhD, Associate Professor, Department of Systems Pharmacology and Translational Therapeutics, Perelman School of Medicine, University of Pennsylvania
Knowledge graphs capture relationships between biomedical entities that can support drug repurposing, gene-disease association discovery, and other use cases. However, unsupervised analysis of paths across multiple node and edge types has been challenging because interpreting multi-edge scores depends significantly on node degrees. We developed an approach that provides well-calibrated estimates of the unexpectedness of a set of edges between a pair of entities given their node types and degrees. This can lay the groundwork for considering drug efficacy in the context of polypharmacology, identifying combinations of therapies that traverse different edges, predicting whether side effects arise from on-target or off-target binding events, and other efforts. Our proof-of-concept server implementing this methodology is available at https://het.io/search/

11:45 Data-Driven Modeling Platform
Corrado Priami, PhD, Founder and CSO, COSBI
A user-friendly graphical platform is presented to integrate different data types in a single framework and to abstract them into actionable models. The platform speeds up research and development process and promotes data sharing.

12:15 pm Session Break

12:20 BIO-IT WORLD WEST CO-LUNCHEON PRESENTATION: Describing Chemistry to Algorithms: Why Scientific Expertise Improves Accuracy
Matt BcBride, MS, Director, Science IP, CAS
If a picture is worth a thousand words, then a chemical structure is worth thousands of features. Join Dr. Alpha Lee from the University of Cambridge to see how impactful descriptors are on predictions. If your AI initiatives aren’t meeting expectations, see how better representations of chemistry structures improve algorithm performance. CAS descriptors are derived from centuries of scientific knowledge and are proven to improve AI accuracy.

1:20 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

2:00 Breakout Discussions in the Exhibit Hall (please see website for details)
KEYNOTE SESSION
(please see Keynotes pages for details)

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Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

3:20 Keynote Introduction
Allison Mallory, PhD, Director, R&D Molecular Biology, Stilla Technologies

3:35 What Does the New Era of Genomic Medicine Look Like? Effects on Patient Care, Therapeutics, and Diagnostics
20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.
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Panelists: Stephen Kingsmore, MD, DSc, President/CEO, Rady Children's Institute for Genomic Medicine
David Haussler, PhD, Investigator, Howard Hughes Medical Institute; Distinguished Professor, Biomolecular Engineering, University of California, Santa Cruz; Scientific Director, UC Santa Cruz Genomics Institute; Scientific Co-Director, California Institute for Quantitative Biosciences (QB3)
Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

6:00 End of Day

WEDNESDAY, MARCH 4

6:45 am Registration Open

7:00 BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available) (please see Special Events page for details)
Moderator: Robin Toft, Author of WE CAN, The Executive Woman's Guide to Career Advancement; Founder and Chairman, Toft Group Executive Search
Panelists: Camille Samuels, MBA, Partner, Venrock
Paul Hastings, President and CEO, Nkarta Therapeutics, Inc
Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration
Alice Zheng, MD, MPH, MBA, Engagement Manager and Women's Health Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

KEYNOTE SESSION
(please see Keynotes pages for details)

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Edel O'Regan, PhD, Vice President, Production, Cambridge Healthtech Institute

8:05 Chairperson's Remarks
Joseph Ferrara, CEO, Boston Healthcare

8:10 Keynote Sponsor, Amazon Web Services
Speaker to be Announced

8:25 KEYNOTE PRESENTATION: The Value and Application of Informatics in Cancer Care Delivery
Debra A. Patt, MD, Vice President, Public Policy & Academic Affairs, Medical Oncologist, Texas Oncology Cancer Center & Editor in Chief, Journal of Clinical Oncology-Clinical Cancer Informatics

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Panelists: Mark Hulse, Chief Digital Officer, City of Hope
Debra A. Patt, MD, Vice President, Public Policy & Academic Affairs, Medical Oncologist, Texas Oncology Cancer Center & Editor in Chief, Journal of Clinical Oncology-Clinical Cancer Informatics
Nicholas Schork, PhD, Deputy Director of Quantitative Sciences, Distinguished Professor of Quantitative Medicine, The Translational Genomics Research Institute (TGen)
Kristin Beaumont, PhD, Assistant Professor, Assistant Director of Single Cell Genomics Technology Development Icahn Institute, Dept. of Genetics & Genomic Sciences, Icahn School
Ajay Shah, PhD, Executive Director & Head of IT for Translational Medicine, Bristol-Myers Squibb
Paul A. Rejto, PhD, Vice President, Head of Translational Research, Pfizer Oncology R&D

9:40 Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group

IMAGING AND QUANTUM COMPUTING

10:40 Chairperson's Remarks
Carl Dukatz, Digital Tech Arch Principal Director, Accenture

10:45 Image-Based Profiling for Phenotyping Variants of Unknown Significance
Juan C. Caicedo, PhD, Schmidt Fellow, Principal Investigator, Broad Institute of MIT and Harvard
We use Cell Painting for image-based profiling as a rapid and inexpensive method to systematically map chemical and genetic perturbations. Image-based profiling extracts single-cell measurements from microscopy images to compute signatures of treatments at high-throughput, which encode variations in cell state that are analyzed to identify correlations between treatments. We developed computational tools, including deep learning-based methods, to discern the functional impact of variants of unknown significance in lung cancer.

11:15 Presentation to be Announced
11:45 PANEL DISCUSSION: Quantum Computing in Life Sciences - Research and Applications
The tiny particles that make up our universe behave very differently at the subatomic scale. Actually, they behave in awesome ways. Companies are building computers that take advantage of these behaviors. This is called quantum computing and a sufficiently powerful quantum computer could change everything. Come learn from a distinguished panel of quantum software and hardware manufacturers about how this technology is changing the bioinformatics space.

Moderator: Carl Dukatz, Digital Tech Arch Principal Director, Accenture
Panelist: Brian Martin, Head of AI in R&D Information Research, Senior Principal Data Scientist, AbbVie, Kam Chana, PhD, Director, Computational Platforms, Merck

12:45 pm Session Break
12:50 Bio-IT World WEST Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own
1:20 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing, Speed Networking, Book Signing, and Meetup Group

FEATURED SESSION: DATA STRATEGIES FOR GENOMICS

2:00 Chairperson's Remarks
Zhaoshi Jiang, PhD, Executive Director of Bioinformatics & Clinical Data Sciences, Gilead Sciences

2:05 Fake It 'til You Make It (Reproducible): Synthetic Data Resources for Genomics
Geraldine A. Van der Auwera, PhD, Director of Outreach and Communications, Data Sciences Platform, Broad Institute
The computational reproducibility of published biomedical research is limited by data access restrictions, affecting not just researchers who wish to reuse published analysis code, but also tool developers and educators who lack suitable example data for testing and training. We present: 1) a prototype pipeline that wraps established open-source data simulation tools to generate publicly shareable synthetic sequence data at any scale; and 2) a plan to develop community resources.

2:35 Progress in Diagnosing Rare Disease Patients Leveraging NLP and Genomic Sequencing
Tom Defay, Senior Director, R&D Strategy and Alliances, SPMD, Strategy, Program Management and Data Sciences, Alexion
Diagnosing patients with rare disease is challenging. Whole exome and whole genome sequencing have improved our diagnostic abilities but can still fall short due to our lack of understanding of which mutations are most likely to be the cause of disease. By combining phenotypic information automatically extracted from the patient's EMR with a patient's genome sequence, we have developed a system for prioritizing which mutations may be most significant and proposing possible diagnoses. Advances on this approach will be discussed.

3:05 Drug Targets with Genomic Support
J. Wade Davis, PhD, ACOS Research Fellow, Director, Computational Genomics, Genomics Research Center (GRC), AbbVie

3:35 Close of Conference

Student Access
Cambridge Healthtech Institute is proud to support and recognize the scientists of tomorrow!
Discounted pricing is available to full-time graduate students and PhD candidates qualify for the student rate. We also encourage students to present a research poster and they will receive an additional discount off their registration fee – plus they will also be recognized as a Student Fellow of the event.

For more info, visit: TriConference.com/posters-info
March 2-4, 2020

SUNDAY, MARCH 1

2:00 - 5:00 pm Afternoon Short Courses* (please see Short Courses pages for details)
*Separate registration required

5:30 - 8:30 Dinner Short Courses* (please see Short Courses pages for details)
*Separate registration required

MONDAY, MARCH 2

8:00 - 11:00 am Morning Short Courses* (please see Short Courses pages for details)
*Separate registration required

10:30 Conference Program Registration Open

KEYNOTE SESSION
(please see Keynotes pages for details)

11:45 Organizer's Opening Remarks
Cindy Crowninshield, RDN, LDN, HHC, Executive Event Director, Cambridge Healthtech Institute

11:50 Chairperson's Remarks
Allison Proffitt, Editorial Director, Bio-IT World

11:55 Keynote Introduction, Benchling
Ashoka Rajendra, Head, Product, Registry, Inventory, Benchling

12:10 pm KEYNOTE PRESENTATION: The AI Bubble and the Emerging Thinking Economy
Pietro Michelucci, PhD, Director, Human Computation Institute

12:40 KEYNOTE PANEL DISCUSSION: Data Quality in Human Computation Systems
Moderator: Allison Proffitt, Editorial Director, Bio-IT World
Panelists: Jennifer Couch, PhD, Chief, Structural Biology and Molecular Applications Branch, Division of Cancer Biology and Citizen Science Coordinator, National Cancer Institute
Devin Krotman, Director, Global Learning XPRIZE and IBM Watson AI XPRIZE
Vani Mandava, Director, Data Science Outreach, Microsoft Research
Pietro Michelucci, PhD, Director, Human Computation Institute
Ginger Tsueng, PhD, Scientific Outreach Project Manager, Department of Integrative, Structural and Computational Biology, The Scripps Research Institute

1:30 Bio-IT World WEST Luncheon Presentation: Accelerating the Exchange of Data in Healthcare and Life Sciences
Fred Lee, MD, MPH, Head of Health Care, Life Sciences Business Development, AWS Data Exchange, AWS

Predictive models and algorithms in healthcare and life sciences (HCLS) have emerged from the combination of patient data and advanced analytics. With machine learning and AI technologies becoming commoditized, scalable access to patient data now throttles the build of such predictive analytics. We will discuss how the AWS Data Exchange, as a digital marketplace for data, addresses this ‘data bottleneck’ by accelerating data exchange in a regulatory compliant, economically sustainable, and cloud-native manner.

2:05 Session Break

PLATFORMS TO FACILITATE DISCUSSION

2:20 Chairperson's Remarks
Matthew Trunnell, Vice President and Chief Data Officer Director, Hutch Data Commonwealth

2:25 Establishing a Regional Data Commons
Matthew Trunnell, Vice President and Chief Data Officer Director, Hutch Data Commonwealth

The focus of the commons will be enabling discovery of and access to life sciences research data and healthcare data to advance research and innovation. That is, the principal initial stakeholders are life & health sciences researchers and technology organizations looking to innovate in this space. We currently have three workstreams: one around data discovery, one around privacy-preserving technologies (differential privacy, synthetic data, etc.) to facilitate access to clinical data; and a third around governance focused on streamlining the process of establishing data use agreements.

2:55 Turning WGS Genetic Testing into a Dialogue between Physicians and Labs with GenomeDiver
Christian Stolte, Data Visualization Designer, Informatics Research Innovation, New York Genome Center

Developed as part of the NYCKidSeq project, GenomeDiver fosters a dialogue between the clinician and genetic testing lab. The software leverages the physician's knowledge of their patient by asking them to provide additional information to the lab, which then forms the basis for reanalysis. It delivers understandable information about mutations in the entire genome, using knowledge about functional variants coming from an increasing number of public sources, in particular the GTEx project.

3:25 Using Modern Frameworks to Process Genomic Data at Scale
Rajesh Mikkilineni, Lead Data Engineer, Data Engineering & Artificial Intelligence, Takeda

Using a generic framework like Hail and a scalable data process framework like Apache Spark to processing big genetic data set to power scientific analysis. These frameworks enable us to perform quality control and reanalysis. It delivers understandable information about mutations in the entire genome, using knowledge about functional variants coming from an increasing number of public sources, in particular the GTEx project.

3:55 Building a Knowledge Factory to Retain and Reuse Tacit Knowledge
Alan Pruitt, Principal Project Manager, Knowledge Management, Pharma Technical Development, Genentech, Inc.

Every pharma company struggles with capturing knowledge trapped in the minds of its most talented employees. Multiple reorganizations, turnover, and retirements all contribute to the loss of tacit knowledge that the business needs to thrive. One way to combat this is to establish strong user communities centered on the critical technologies and processes. Doing this at scale for dozens or even hundreds of communities requires standard processes and robust IT tools to deliver value efficiently and reliably.

4:25 Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION
(please see Keynotes pages for details)

4:35 Welcome Remarks
Cambridge Healthtech Institute's Inaugural
Software Tools, Services, and Applications
Tools and Best Practices for Pharma, Biotech, and Medical Centers

March 2-4, 2020

TABLE OF CONTENTS

8:25 KEYNOTE PRESENTATION: AI and Big Data Strategies in Accelerating Clinical Research for Faster Rare Disease Cures
Harsha K. Rajasimha, MS, PhD, Founder, Jeeva Informatics Solutions, Inc.; Founder and Chairman, IndoUSrare; Co-Director, Rare Diseases Systems Biology Initiative, George Mason University

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Christina Waters, PhD, President, CEO and Founder, RARE Science, Inc.
Vasu Rangadass, President, CEO, L7 Informatics, Inc.

10:45 Rare Diseases: Starting at the Beginning
Michael Liebman, PhD, Managing Director, IPQ Analytics, LLC
Rare diseases, typically pediatric, are notoriously heterogeneous; they are difficult to diagnose and manage except in limited cases. We are establishing a “knowledge network” involving clinicians and researchers, patients and families, and implementing it within a platform that looks at the fetus and the effects of maternal lifestyle, environment and clinical history on the evolving stages of organ system development to evaluate where and how risk may develop for (rare) diseases. This involves an international collaboration and is targeting the identification of biomarkers and behaviors that indicate risk and may enable early detection and even prevention/mitigation. The platform initially examines lung development and disease risk, e.g., ARD and BPD, and will enable integration of existing studies and extension to other organ systems.

11:15 Accelerating Research in Rare Disease through Patient-Partnered Collaborations
Ryan Leung, Vice President, Strategy & Corporate Development, Research to the People
Patient-centricity is becoming increasingly important in all areas of healthcare, but this is particularly the case for rare diseases. With so few patients, it is critical that we make the most out of every patients’ story and experience, engaging them at every point of research, development, care, and treatment. At Research to the People, we partner with patients directly to help them access and understand their health data. Leveraging advances in -omics, bioinformatics, deep learning and cloud computing, alongside a powerfully diverse community of physicians, scientists and patient advocates, we’ve created a uniquely collaborative platform for open-source rare disease research. With 5 successful collaborations to date, we’re incredibly excited by the future of patient-partnered healthcare.

11:45 Strategies to Study Rare Diseases with “Big Data”
Jaclyn N. Taroni, PhD, Principal Data Scientist, Childhood Cancer Data Lab, Alex's Lemonade Stand Foundation
We sometimes speak of “big data” in biology. In most cases, these data are wide, and have many more features than examples. This is particularly pronounced in the case of rare diseases, where we may have tens of samples but tens of thousands of measurements. I’ll discuss how we can use compendia of data with many training examples as a training dataset and then transfer the results of those analyses to rare disease datasets where the number of samples is particularly limited. I’ll also discuss how this feature of data, even outside of rare diseases, affects deep learning methods in this domain.

12:15 pm Session Break

12:20 BIO-IT WORLD WEST CO-LUNCHEON PRESENTATION I: Describing Chemistry to Algorithms: Why Scientific Expertise Improves Accuracy
Alpha Lee, PhD, Doctor, Physics, University of Cambridge
Matt BcBride, MS, Director, Science IP, CAS
If a picture is worth a thousand words, then a chemical structure is worth thousands of features. Join Dr. Alpha Lee from the University of Cambridge to see how impactful descriptors are on predictions. If your AI initiatives aren’t...
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1:20 **Refreshment Break in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group**

2:00 **Breakout Discussions in the Exhibit Hall (please see website for details)**

3:00 **Transition to Keynote Session**

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Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

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20 years after the completion of the first draft of the Human Genome Project, there is compelling evidence of genomics delivering the rich promise of precision medicine. There have been major advances in the throughput and affordability of genome sequencing, enhanced tools for genome analysis and interpretation, new paradigms for therapeutics and strong signs of clinical benefit using genome editing. But major challenges remain. In this special plenary roundtable, three established pioneers of genomic medicine – David Haussler, Stephen Kingsmore, and Liz Worthey – offer their insights on the extraordinary advances in genomic medicine over the past 1-2 decades and share their hopes and concerns for the future of our field.

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Elizabeth Worthey, PhD, Director, Genomic Medicine, University of Alabama, Birmingham School of Medicine

4:50 **Spring Fling Celebration in the Exhibit Hall with Poster Viewing, Speed Networking, Book Signing, and Meetup Group**

6:00 **End of Day**

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**WEDNESDAY, MARCH 4**

6:45 am **Registration Open**

7:00 **BREAKFAST PANEL DISCUSSION: The Time is NOW: Creating Meaningful Change for Women in the Workplace** (Sponsorship Opportunity Available) (please see Special Events page for details)
Moderator: Robin Toft, Author of WE CAN, The Executive Woman’s Guide to

Career Advancement; Founder and Chairman, Toft Group Executive Search
Panelists: Camille Samuels, MBA, Partner, Venrock
Paul Hastings, President and CEO, Nkarta Therapeutics, Inc
Teresa L. Wright, MD, Staff Physician, Medicine, San Francisco Veterans Administration
Alice Zheng, MD, MPH, MBA, Engagement Manager and Women’s Health Practice Leader, Pharmaceuticals and Medical Device and Global Public Health Practices, McKinsey & Company

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8:05 **Chairperson’s Remarks**
Joseph Ferrara, CEO, Boston Healthcare

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Speaker to be Announced

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10:40 **Chairperson’s Remarks**

Zahra ‘Nasim’ Eftekhari, Senior Manager, Head of Applied AI and Data Science, City of Hope

**CLINICAL CARE DECISION SUPPORT**

10:45 From Development to Deployment: Lessons Learned from Application of Machine Learning in Oncology Decision Support
11:15 Leverage Sage Data Lake for Translational Medicine Biomarker Analytics
Ying (Sherry) Li, PhD, Lead IT Business Partner – Precision Medicine, Translational Medicine IT, Bristol-Myers Squibb

Clinical biomarkers have shown great promise to improve drug development efficiency and to understand target engagement, drug efficacy, as well as clinical endpoint prediction. At Bristol-Myers Squibb (BMS), biomarker research is a routine practice for our ongoing clinical trials. To make data findable, accessible, interpretable and reusable (FAIR), we process and manage hundreds of BMS clinical trials’ biomarker data into our Sage Data Lake and integrate that with clinical information from Oracle Clinical and Rave databases. This information is fed into the Signals Translational (Signals) application (co-developed by BMS and Perkin Elmer) as well as Sage Clinical database. Using Sage Signals, our scientists can track biomarker assays, analyze biomarker data cross studies/diseases, drill into platform specific concerns, which help clinical programs to make informed decisions. We will share some use cases in our presentation and discuss how Sage Data Lake helps our biomarker research.

CUTTING-EDGE ALGORITHMS FOR SEQUENCING

11:45 Degradation Normalization Improves Accuracy in RNA-Seq Analysis
Ji-Ping Wang, PhD, Professor of Statistics, Adjunct Professor of Molecular BioSciences, Faculty Member, NSF-Simons Center for Quantitative Biology, Northwestern University

RNA degradation affects RNA-seq quality when profiling transcriptional activities in cells. Transcript degradation is both gene- and sample-specific and is a common and significant factor that may bias the results in RNA-seq analysis. Most existing global normalization approaches are ineffective to correct for degradation bias. We propose a novel pipeline named DegNorm to adjust read counts for transcript degradation heterogeneity on a gene-by-gene basis while simultaneously controlling for the sequencing depth.

12:00 QuickIsoSeq: A Unified and Flexible Workflow on Isoform Quantification in Clinical RNA Sequencing
Shanrong Zhao, PhD, Director, Computational Biology, Pfizer

What’s wrong with featureCounts, a gene level counting tool? Why do we need isoform level quantification? QuickIsoSeq: implementation, functionalities and features.

12:15 pm PANEL DISCUSSION: Cutting-Edge Algorithms for scRNAseq
Moderator: Shanrong Zhao, PhD, Director, Computational Biology, Pfizer
Panelists: Rob Patro, PhD, Assistant Professor, Department of Computer Science, Center for Bioinformatics and Computational Biology, University of Maryland
Ji-Ping Wang, PhD, Professor of Statistics, Adjunct Professor of Molecular BioSciences, Faculty Member, NSF-Simons Center for Quantitative Biology, Northwestern University
Jeffrey Rosenfeld, PhD, Manager, Biomedical Informatics Shared Resource, Assistant Professor of Pathology and Laboratory Medicine, Rutgers Cancer Institute of New Jersey

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FEATURED SESSION: DATA STRATEGIES FOR GENOMICS

2:00 Chairperson's Remarks
Zhaoshi Jiang, PhD, Executive Director of Bioinformatics & Clinical Data Sciences, Gilead Sciences

2:05 Fake It ‘til You Make It (Reproducible): Synthetic Data Resources for Genomics
Geraldine A. Van der Auwera, PhD, Director of Outreach and Communications, Data Sciences Platform, Broad Institute

The computational reproducibility of published biomedical research is limited by data access restrictions, affecting not just researchers who wish to reuse published analysis code, but also tool developers and educators who lack suitable example data for testing and training. We present: 1) a prototype pipeline that wraps established open-source data simulation tools to generate publicly shareable synthetic sequence data at any scale; and 2) a plan to develop community resources.

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Tom Defay, Senior Director, R&D Strategy and Alliances, SPMD, Strategy, Program Management and Data Sciences, Alexion

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3:05 Drug Targets with Genomic Support
J. Wade Davis, PhD, ACOS Research Fellow, Director, Computational Genomics, Genomics Research Center (GRC), AbbVie

3:35 Close of Conference
Present a Poster & SAVE $100

We encourage attendees to gain further exposure by presenting their work in the 2020 Poster Sessions:

**TRICON & Bio-IT World WEST Poster Sessions**  
Moscone South Convention Center  
March 2-4, 2020

**Reasons to present your research poster:**
- Your poster will be available to 3,100+ delegates
- You’ll automatically be entered into our poster competition where two winners each will receive an American Express Gift Certificate  
- $100 off your registration fee  
- Your research will be seen by leaders from pharmaceutical, biotech, academic and government institutes

**People’s Choice Poster Award Competition Criteria**
- Poster data should be well presented and visually easy to understand  
- Poster should be scientifically advanced and novel  
- Poster presenter should be present and engaging

Register and submit a poster abstract by January 17, 2020
Special Events

Special events at TRICON 2020 include:

Exhibit Hall Pass:
Interested in just an Exhibit Hall Pass? This year, we are offering our basic Exhibit Hall Pass. For more info, visit: TriConference.com/hallpass

Speed Networking:
Accelerate your business contacts through a dedicated time of facilitated networking with other delegates at the Molecular Medicine Tri-Conference. Participants will be paired up for a quick burst of conversation and business card exchange. When time is up, delegates will move down the line to their next connection. Pre-registration is not required for speed networking. For more info, visit: TriConference.com/networking

When:
March 3: 10:00 – 10:20 am & 5:45 – 6:00 pm
March 4: 10:00 – 10:20 am & 1:25 – 1:40 pm

Roundtable Breakout Discussions:
These interactive discussion groups are open to all attendees, speakers, sponsors, and exhibitors. Participants choose a specific breakout discussion group to join. Each group has a moderator to ensure focused discussions around key issues within the topic. This format allows participants to meet potential collaborators, share examples from their work, vet ideas with peers, and be part of a group problem-solving endeavor. The discussions provide an informal exchange of ideas and are not meant to be corporate or specific product discussions.

For more info, visit: TriConference.com/breakout_discussions

1-on-1 Networking:
The Tri-Conference provides attendees with 1-on-1 access to many of the brightest minds in our industry through our easy-to-use networking technology. The platform recommends connections based on areas of expertise and interests, so you can quickly connect, share knowledge, and build long-lasting partnerships – all on your own personalized schedule.

For more info, visit: TriConference.com/networking

Book Signings:
Meet with our speakers that have written books during our dedicated book signings. For a list of authors, times and location, visit: TriConference.com/book-signings

Hackathon:
Be part of the Bioinformatics Pipelines for Preclinical Drug Discovery Hackathon which is taking place March 2-4. Bring your projects to the Bioinformatics Pipelines for Preclinical Drug Discovery Hackathon!

For more info, visit: TriConference.com/hackathon

BREAKFAST PANEL DISCUSSION:
The Time is NOW: Creating Meaningful Change for Women in the Workplace (Sponsorship Opportunity Available)
This session will feature life science senior leaders who have the influence to adopt change in their respective companies. Throughout the event, we will foster collaboration, encourage deeper discussions, and provide meaningful solutions for companies seeking to remain competitive. Robin Toft’s session is designed to engage, inform, and connect participants on how together WE CAN advance female career progression and create inclusive working environments which recognize and champion the achievements of all leaders.

When:
March 4: 7:00 am

"The TRICON is the most comprehensive conference in the field."

Professor, Public Health Research Institute

Hotel & Travel Information

Main Conference Venue:
The Moscone South Convention Center
747 Howard Street
San Francisco, CA 94103
www.moscone.com

Host Hotel:
Hilton San Francisco Union Square
333 O’Farrell Street
San Francisco, CA 94102
Phone: 415-771-1400

Discounted Room Rate: $304 s/d
Discounted Room Rate Cut-off Date: February 3, 2020

Reservations:
Visit TriConference.com/Hotel-and-Travel

Reserve Your Hotel Room at the Hilton San Francisco Union Square and Save $100 off your Conference Registration! See our event website for details.
TRICON Takes San Francisco Contest! (#TRICONTakesSF)

With over 3,000 attendees converging in San Francisco for the Tri-Conference, we want to hear from our attendees on Twitter.

Before the Event
Share your excitement about the Tri-Conference leading up to the start of the event:
• Share the news with us when you register.
• We want to know what presentation you are most excited about.
• Which exhibitor you look forward to visiting with.
• Your poster details, if you are a poster presenter.
• En route to the Tri-Conference? Share news about your journey to get to San Francisco!

PLUS!! During the next few months, we will be choosing attendees to surprise with TRICON Swag. If you receive TRICON Swag, share photos with us by tweeting them and using the #TRICON and #TRICONTakesSF hashtags.

Onsite at the Event
When you arrive at the Tri-Conference, we still want to hear about your excitement about the event! Share photos of you onsite at the conference and your time in San Francisco.

We want to see:
• Your session photos
• Hear about the people you meet
• All the great products and services you learned about in the Exhibit Hall
• ... and anything else you want to share!

Contest Info:
On March 13th, we will announce two winners from our #TRICONTakesSF Contest. We will pick someone who tweeted before the event and someone who tweeted onsite during the event. Most creative tweeters will win; each winner will receive a $100 Amazon Gift Card.

Make sure to include #TRICON and #TRICONTakesSF in all your tweets.