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January 30-31, 2018 | San Diego, CA

www.lbx-summit.com



PRECISION **LBx**

Translating Next Generation Liquid Biopsies into Clinical Reality

Advancing the Impact, Clinical Validation & Commercialization of Liquid Biopsies within Personalized Healthcare

Expert speakers include:



**Jean-Francois
Martini**
Senior Director,
Translational
Oncology Lead
Pfizer



Carl Barrett
Vice President,
Translational
Sciences, Oncology
AstraZeneca



John Stille
Senior Clinical
Research Advisor
Eli Lilly



Razelle Kurzrock
Chief, Division of
Hematology & Oncology,
Director, Center for
Personalized Cancer
Therapy & Clinical Trials
Office
UCSD

Lead Partner



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www.lbx-summit.com  Precision LBx – Liquid Biopsy Diagnostics



Precision LBx Summit 2018

Advancing the Impact of Liquid Biopsies on Personalized Healthcare

The 2nd annual Precision LBx Summit will unite the biopharma, clinical and diagnostic worlds to champion the application of liquid biopsy testing, across biofluids, biomarkers and disease indications, as the needle shifts on the gold standard of personalized healthcare testing.

Join leaders in the liquid biopsy community on a journey to develop and stratify patient responders with biofluid-based biomarkers, prove the clinical utility of liquid biopsy testing and advance the validation of tests to be more accurate, sensitive and reproducible to make meaningful impacts on patient treatment and healthcare outcomes.

Very informative talks with excellent networking opportunities. **Jad Walters, Almac Diagnostics**

It was such a great conference, very informative for practical settings in this field. **Muhit Rana, University at Albany**

It is a great opportunity to learn the most recent advancement of liquid biopsy and to talk with the field experts on detailed information and set up useful connections. **John Huang, TP Therapeutics**

Why Attend Precision LBx in 2018?

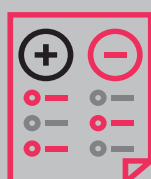
1.

Understand how to apply liquid biopsies for the advancement of precision medicine, from patient selection to predictive screening



2.

Evaluate the scope of clinical utility for circulating biomarkers, delving into the benefits and limitations of ctDNA, CTCs, exosomes and extracellular RNA



3.

Challenge the standardization and validation of assays to improve the sensitivity, accuracy and reproducibility of liquid biopsy testing



4.

Address the regulation, value demonstration and reimbursement of liquid biopsy diagnostics to advance the adoption and integration of these assays in healthcare



5.

Debate the IVD and LDT landscape and market dynamics and identify preferred strategies for maximizing the impact of liquid biopsy applications on patient welfare



Your Precision LBx Expert Speakers



Agnes Ang
Principal Scientist
Amgen



Carl Barrett
Vice President,
Translational
Sciences, Oncology
AstraZeneca



Brian Dougherty
Director, Translational
Genomics Oncology
AstraZeneca



Dave Hoon
Director,
Department of
Molecular Oncology
**John Wayne Cancer
Institute**



Gary Kelloff
Special Advisor
NIH



Fred Kramer
Professor of
Microbiology,
Biochemistry and
Molecular Genetics
Rutgers University



Razelle Kurzrock
Chief, Division
of Hematology
& Oncology,
Director, Center for
Personalized Cancer
Therapy & Clinical
Trials Office
UCSD



Mike Makrigiorgos
Director of Medical
Physics & Biophysics
Division
**Dana-Farber
Cancer Institute**



**Jean-Francois
Martini**
Senior Director,
Translational
Oncology Lead
Pfizer



Sandip Patel
Medical Oncologist
& Assistant Professor
of Medicine
UCSD



Vicki Plaks
Scientist, Cancer
Immunotherapy
Drug Development
Genentech



Lou Riceberg
Owner
**BioBridge
Strategies**



Howard Scher
Co-Chair, Center for
Mechanism Based
Therapy & Head
of the Biomarker
Development
Initiative
**Memorial Sloan
Kettering**



John Stille
Senior Clinical
Research Advisor
Eli Lilly



Speaker Confirming
ANGLE plc



Speaker Confirming
Horizon Discovery

◀ Intriguing discussions among leading pharmaceutical and academic experts on the future roll of liquid biopsy in cancer detection and treatment ▶

Elad Kfir, BioView

Conference Day One | Tuesday, January 30, 2018

8.50 Chair's Opening Remarks

Applying Liquid Biopsy for the Advancement of Precision Medicine

Gary Kelloff
Special Advisor
NIH

9.00 The Liquid Biopsy State of Play: From Prognostic to Predictive

- Where do we currently stand with the clinical impact of liquid biopsy on the delivery of personalized care?
- Analyzing the application of liquid biopsy for longitudinal disease monitoring to inform resistance, treatment selection and disease recurrence
- Discussing the evolution of liquid biopsy testing towards a future of early detection and screening of prodromal populations
- How far have we come, and what do we need to do, in order to continue the integration of liquid biopsies into the precision medicine paradigm?

Carl Barrett
Vice President,
Translational
Sciences, Oncology
AstraZeneca

9.30 Harnessing Liquid Biopsy Testing for Precision Medicine Patient Selection

- Utilizing circulating biomarkers as clinical research tools to produce novel predictive biomarker signatures
- Understanding how liquid biopsies can add another dimension to the robust selection of patient responders for targeted therapeutics
- Discussing the route for bridging liquid biopsy patient selection assays to IDEs for pivotal clinical studies

10.00 Session Q&A

- Q&A with the sessions speakers
- Beyond NSCLC, where are we seeing benefit from the use of liquid biopsy and how do we advance the clinical utility of testing in such indications?
- Despite all the investment and innovation in precision medicine we are still prognostic in our use, how do we get to a place where we are getting predictive utility?
- What will the precision medicine field look like over the next 5-10 years with the fast developing applications of liquid biopsies?



Gary Kelloff
Special Advisor
NIH



Carl Barrett
Vice President,
Translational Sciences,
Oncology
AstraZeneca

10.45 Speed Networking & Morning Refreshments

Evaluating the Scope of Clinical Utility for Circulating Biomarkers

Brian Dougherty
Director, Translational
Genomics Oncology
AstraZeneca

11.30 Analyzing the Clinical Impact of ctDNA Based Testing

- Dissecting clinical utility: Is there a limit on how impactful a clinical decision can be made from ctDNA based testing?
- Validating the impact of ctDNA testing on the accuracy of clinical decision: What's real, what's technical, what's just tumor heterogeneity?



Dave Hoon
Director, Department
of Molecular
Oncology
**John Wayne Cancer
Institute**

12.00 Evaluating the Evolving Use of Circulating Tumor Cells for Liquid Biopsy

- Addressing phenotypic heterogeneity of CTCs and their effectiveness for prognostic clinical monitoring
- Evolving sampling detection of circulating tumor cells to improve sensitivity of testing

12.30 Lunch & Networking



John Stille
Senior Clinical
Research Advisor
Eli Lilly

13.30 Defining a Clinical Role for Exosome Liquid Biopsies

- Harnessing exosomes to monitor preserved RNA and gene expression profiles
- Understanding how to best delineate tumour specific exosomal RNA
- Discussing the optimal methods for detecting and measuring exosomes and strategies for deriving value and thresholds for clinical decision making



Vicki Plaks
Scientist, Cancer
Immunotherapy Drug
Development
Genentech

14.00 Addressing the Potential of Extracellular Vesicles to Inform Clinical Decision Making

- Evaluating the scope for the clinical applicability of extracellular vesicles as circulating biomarkers
- Building the methodology and technical expertise for fluid based extracellular vesicle testing

14.30 Session Q&A

- Q&A with the sessions speakers
- Where does the most clinical value lie for liquid biopsies?
- Evaluating the pros and cons of circulating biomarkers and their attribution across disease indications



Vicki Plaks
Scientist, Cancer
Immunotherapy Drug
Development
Genentech



Dave Hoon
Director, Department
of Molecular Oncology
**John Wayne Cancer
Institute**



Brian Dougherty
Director,
Translational
Genomics Oncology
AstraZeneca



John Stille
Senior Clinical
Research Advisor
Eli Lilly



Howard Scher
Co-Chair, Center for
Mechanism Based Therapy
& Head of the Biomarker
Development Initiative
Memorial Sloan Kettering

15.15 Afternoon Refreshments & Networking

Standardization & Validation: Improving the Sensitivity & Accuracy of Liquid Biopsy Testing



Mike Makrigiorgos
Director of Medical
Physics & Biophysics
Division
**Dana-Farber Cancer
Institute**

15.45 Improving Sensitivity and Accuracy While Reducing Cost: HRM Enables Rapid Mutation Assessment Prior to Targeted Re-Sequencing

- Discussing novel forms of real time PCR that reduce the effort for sample preparation while also providing rapid assessment of mutation status prior to targeted re-sequencing.
- Discussing how the new method incorporates implementation of mutation enrichment via COLD-PCR or NaME-PrO together with high resolution melting
- Application in circulating DNA from clinical cancer samples will be presented.



Fred Kramer
Professor of
Microbiology,
Biochemistry and
Molecular Genetics
Rutgers University

16.15 Super Selective Primers for Multiplex Real-time PCR Assays that Assess the Abundance of Rare Mutations Associated with Cancer

- “SuperSelective” PCR primers, due to their unique design, are extraordinarily specific, able to selectively initiate the synthesis of amplicons on ten mutant DNA fragments in the presence of 1,000,000 wild-type DNA fragments
- Sets of SuperSelective primers, each possessing unique 5'-tag sequences, enable the amplicons generated from each mutant to be distinguished by differently colored molecular beacon probes
- Inclusion of primers for a wild-type reference gene enables the abundance of each type of mutant DNA fragment to be assessed by determining the difference between its threshold value and the threshold value of the reference gene

16.45 Session Q&A

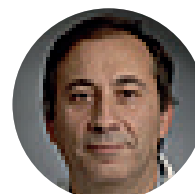
- Q&A with the sessions speakers
- In such a dynamic, multi-stakeholder industry, how can we work together to derive a level of standardization and validation across the field?
- Debating the improvement in the sharing of data, particularly for LDTs, for test validation and standard comparison
- Developing standards for downstream bioinformatics: How do we or can we unify research, academic and commercial lab processes?
- Discussing the challenges of validation, the best materials and controls to use the and best approaches for robust validation



Jean-Francois Martini
Senior Director,
Translational Oncology
Lead
Pfizer



Fred Kramer
Professor of Microbiology,
Biochemistry and
Molecular Genetics
Rutgers University



Mike Makrigrigors
Director of Medical
Physics & Biophysics
Division
**Dana-Farber
Cancer Institute**

17.30 Chairs' Closing Remarks

17.40 End of Day One

▀▀ The LBx meeting was an intimate meeting that was informative and had opportunity for interaction within the community ▀▀

Rob Bennet, Thermo Fisher



Conference Day Two | Wednesday, January 31, 2018

8.50 Chair's Opening Remarks

The Evolving Role of Liquid Biopsy in Immuno-Oncology



Razelle Kurzrock
Chief, Division
of Hematology
& Oncology &
Director, Center for
Personalized Cancer
Therapy
UCSD

9.00 Utilizing ctDNA to Predict and Inform Response to Immune Targeted Therapeutics

- Examining the mutational and antigenic load to advise immuno-oncology treatment
- Utilizing liquid biopsies to study host immune responses, T-cell repertoires and antigen profiles
- Understanding and monitoring the inflammatory response to immunotherapy treatment



Sandip Patel
Medical Oncologist &
Assistant Professor of
Medicine
UCSD

9.30 Predictive Biomarkers for Immunotherapeutic Response in Cancer

- Discussing the nuances in the development of PD-L1 assays
- Evaluating the development of alternative predictive biomarkers to better determine patient response to immune checkpoint modulation
- Analyzing the next generation of cancer immunotherapeutic currently under development, including cell-based approaches

10.00 Session Q&A

- Q&A with the sessions speakers
- How can liquid biopsy improve the testing of complex combination treatments in immuno-oncology
- Discussing future developments in the IO space and the role circulating biomarkers will have in the selection of potential responsive cohorts



Razelle Kurzrock
Chief, Division of Hematology &
Oncology & Director, Center for
Personalized Cancer Therapy
UCSD



Sandip Patel
Medical Oncologist &
Assistant Professor of
Medicine
UCSD



Agnes Ang
Principal Scientist
Amgen

10.45 Morning Refreshments

Debating IVDs, LDTs & the End Result for Patient Welfare



Lou Riceberg
Owner
**BioBridge
Strategies**

11.15 Proving Value for Reimbursement: The Bottleneck to the Impact of Liquid Biopsies on Personalized Healthcare?

- What data do we need to prove the clinical utility of liquid biopsy tests? How does this differ from LDT to IVD?
- Strategies for improving the quality and "completeness" of data to more persuasively prove the case for impact on clinical outcomes
- Building a level of standardization across insurers to benchmark the evidence needed for sufficient value demonstration

Speaker confirming

11.45 Overcoming Challenges in the Development of a Liquid Biopsy Based IVD

- Discussing sensitivities, effectiveness and the future of liquid biopsy IVDs
- Analyzing what the CellSearch and Cobas systems can tell us about the commercial viability of liquid biopsy IVDs
- Debating how to protect the backend development of an IVD to prevent “me-too” tests and maintain market share
- Streamlining the accelerated transition from LDT to IUO and fully fledged IVD: What to do when to ensure success

12.15 Session Q&A

- Q&A with the sessions speakers
- IVD or LDT: What is the best path for commercial success, and more importantly, for maximizing patient benefit?
- The black box of concordance: How do we approach a difference in readout between tissue and liquid samples and what do we need to do to validate such a scenario?
- How do we engage payers with the clinical utility we are currently demonstrating to improve the income stream needed to support future R&D and commercialization of liquid biopsy tests?



Lou Riceberg
Owner
BioBridge Strategies

Additional panelists confirming

13.00 Lunch & Networking

Precision LBx Breakout Roundtables

14.00 Our breakout roundtables will allow you to have more intimate discussions with biomarker and diagnostic leaders around some of the hottest topics in the field. Discover multiple perspectives on these key issues, so that you can learn from your fellow experts in the audience. Drive your own learning, crowd-source ideas and get inspired. Immerse yourself in the following discussions:

1.

Opening the gateway to more liquid biopsy IVDs: What should the roadmap for liquid biopsy regulatory approval look like?

2.

How do we educate and challenge pathologists and clinicians to increase the adoption of liquid biopsy testing?

3.

For a model of longitudinal monitoring, how do we price liquid biopsy tests? How do we change the paradigm to include payment for monitoring assays?

15.00 Chairs' Closing Remarks

15.10 End of Day Two & Close of 2nd Precision LBx Summit



Lead Partner

ANGLE's Parsortix technology enables the capture and harvest of circulating tumor cells from patient blood. The resulting liquid biopsy (simple blood test) provides a powerful tool to deliver personalized cancer care. ANGLE is currently developing its first diagnostic product in the area of ovarian cancer. The Parsortix system has CE Mark regulatory approval in Europe and an FDA approval process is underway in the US.

www.angleplc.com

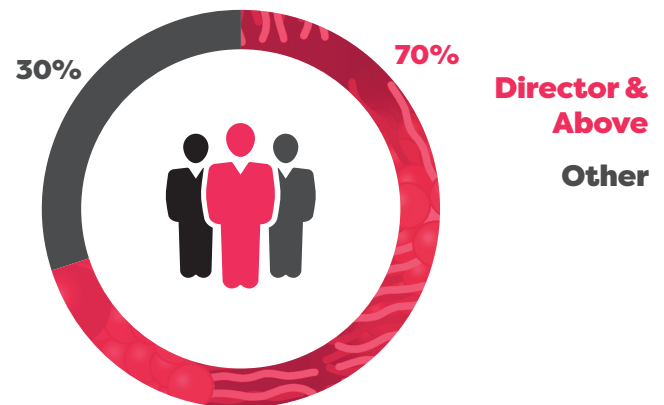


Spotlight Partner

Horizon Diagnostics, a business unit of Horizon Discovery Group plc, is a leading provider of genetically defined, human genomic reference standards, including FFPE cell line sections and purified genomic DNA. HDx™ Reference Standards offer a sustainable source of reference material to laboratories, proficiency schemes and manufacturers, providing an unprecedented level of control.

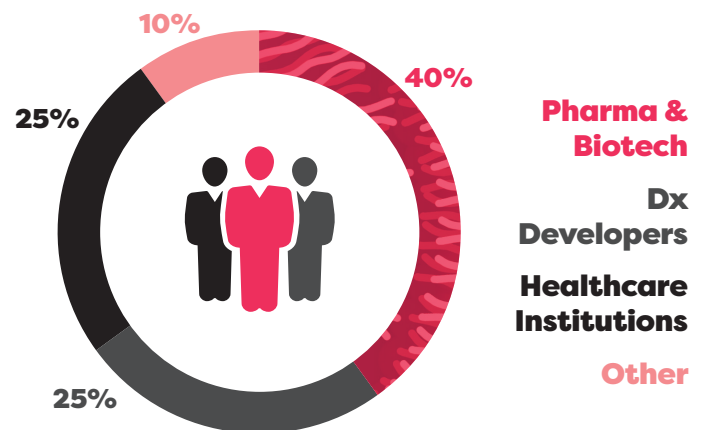
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*Based on market research and previous events' statistics



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Sam Sarwar

Commercial Director – Biomarkers & Diagnostics Event Series

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- 1 Understand how to apply liquid biopsies for the advancement of precision medicine
- 2 Evaluate the scope of clinical utility for circulating biomarkers
- 3 Challenge the standardization and validation of liquid biopsy testing

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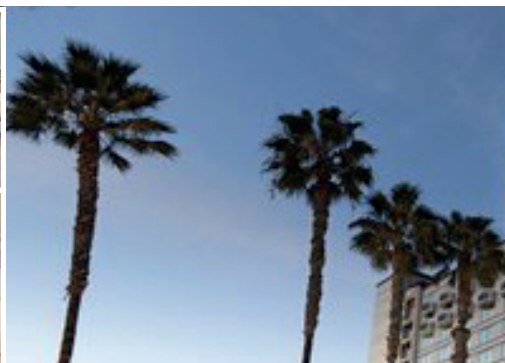
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