January 30-31, 2018 | San Diego, CA

www.lbx-summit.com

PRECISION LBx
Translating Next Generation Liquid Biopsies into Clinical Reality

Improving the Standardization, Clinical Validation & Commercialization of Liquid Biopsies to Enhance Patient Stratification, Diagnosis and Monitoring with Circulating Biomarkers

Expert speakers include:

Jean-Francois Martini
Senior Director, Translational Oncology Lead
Pfizer

Stefan Scherer
Vice President, Head Early Development, Strategy & Innovation
Novartis

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

Partners

Tel: +1 212 537 5898 Email: info@hansonwade.com
www.lbx-summit.com Precision LBx – Liquid Biopsy Diagnostics
Precision LBx Summit 2018

Proving the Clinical Utility of Liquid Biopsies to Advance Molecular Pathology and the Impact 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 and molecular pathology communities on a journey to develop and stratify patient responders with circulating biomarkers, standardize tests to be more specific, sensitive and reproducible and prove the clinical utility of liquid biopsy testing.

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 of assay platforms and pre-analytical processes to improve the sensitivity, specificity 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

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Position/Role</th>
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<tbody>
<tr>
<td>Agnes Ang</td>
<td>Principal Scientist, Amgen</td>
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<tr>
<td>Dave Hoon</td>
<td>Director, Department of Molecular Oncology, John Wayne Cancer Institute</td>
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<tr>
<td>Hatim Husain</td>
<td>Assistant Professor of Medicine, UCSD Moores Cancer Center</td>
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<tr>
<td>Gary Kellogff</td>
<td>Special Advisor, NIH</td>
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<tr>
<td>Fred Kramer</td>
<td>Professor of Microbiology, Biochemistry &amp; Molecular Genetics, Rutgers University</td>
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<tr>
<td>Razelle Kurzrock</td>
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<tr>
<td>Kim Langone</td>
<td>Senior Director, Product Science, Genomic Health</td>
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<tr>
<td>Louis Mack</td>
<td>Director of Molecular Pharmacology, UC Davis</td>
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<tr>
<td>G. Mike Makrigiorgos</td>
<td>Professor &amp; Director, Medical Physics &amp; Biophysics Division, Radiation Oncology, Dana Farber Cancer Institute &amp; Harvard Medical School</td>
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<td>Jean-Francois Martini</td>
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<td>Morteza Minaae</td>
<td>Vice President, Regulatory Affairs, Guardant Health</td>
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<td>Sandip Patel</td>
<td>Medical Oncologist, Assistant Professor of Medicine, UCSD</td>
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<td>Vicki Plaks</td>
<td>Scientist, Cancer Immunotherapy Drug Development, Genentech</td>
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<tr>
<td>Howard Scher</td>
<td>Co-Chair, Center for Mechanism Based Therapy &amp; Head of the Biomarker Development Initiative, Memorial Sloan Kettering</td>
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<td>Stefan Scherer</td>
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<td>Elad Kfir</td>
<td>BioView</td>
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Intriguing discussions among leading pharmaceutical and academic experts on the future roll of liquid biopsy in cancer detection and treatment.

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Tel: +1 212 537 5898  Email: info@hansonwade.com  www.lbx-summit.com  Precision LBx – Liquid Biopsy Diagnostics
### Conference Day One | Tuesday, January 30, 2018

#### 8.50 Chair’s Opening Remarks

**Applying Liquid Biopsy for the Advancement of Precision Medicine**

<table>
<thead>
<tr>
<th>Time</th>
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<th>Title</th>
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| 9.00  | The Liquid Biopsy State of Play: From Prognostic to Predictive | Gary Kelloff | 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? |
| 9.25  | Harnessing Liquid Biopsy Testing for Precision Medicine Patient Selection | Stefan Scherer | 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 | - 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 |
| 9.50  | Session Q&A | Gary Kelloff, Stefan Scherer | 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? | - 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? |

#### 10.35 Speed Networking & Morning Refreshments

**Evaluating the Scope of Clinical Utility for Circulating Biomarkers**

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| 11.20 | Analyzing the Clinical Impact of ctDNA Based Testing | Philip Mack | Dissecting clinical utility: Is there a limit on how impactful a clinical decision can be made from 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? |
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<th>Presenter/Institution</th>
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<tbody>
<tr>
<td>11.45</td>
<td>Evaluating the Evolving Use of Circulating Tumor Cells for Liquid Biopsy</td>
<td>Dave Hoon, Director, Department of Molecular Oncology, John Wayne Cancer Institute</td>
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<td></td>
<td>• Addressing phenotypic heterogeneity of CTCs and their effectiveness for prognostic clinical monitoring</td>
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<td>• Evolving sampling detection of circulating tumor cells to improve sensitivity of testing</td>
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<td>12.10</td>
<td>Lunch &amp; Networking</td>
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<td>13.10</td>
<td>The Clinical Application of CXCR4 Expression on Tumor and Circulating Tumor Cells as a Predictive Response Marker in Extensive-Disease Small Cell Lung Cancer</td>
<td>John Stille, Senior Clinical Research Advisor, Eli Lilly</td>
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<tr>
<td></td>
<td>• Exploratory analyses evaluated CXCR4 expression on available baseline tumor tissue and on circulating tumor cells (CTCs) collected at baseline in patients with extensive disease small cell lung cancer (ED-SCLC).</td>
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<td>• Patients with ED-SCLC were treated with either standard of care etoposide/carboplatin (CE) or CE+LY2510924.</td>
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<td>• Baseline CXCR4 expression in tumor tissue and on CTCs was explored for the potential to be prognostic of survival or predictive of LY2510924 treatment response.</td>
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<td>• Evaluating the scope for the clinical applicability of extracellular vesicles as circulating biomarkers</td>
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<td>• Building the methodology and technical expertise for fluid based extracellular vesicle testing</td>
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<td>14.00</td>
<td>Exploiting Extracellular Body Fluid RNA for Precision Medicine Purposes</td>
<td>Jo Vandesompele, CSO, Biogazelle</td>
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<td>• Discussing various workflows for RNA sequencing of body fluid derived RNA, including probe based target capture as a sensitive RNA sequencing workflow to study thousands of mRNA and IncRNA genes in cell-free RNA from cancer patients’ plasma and urine</td>
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<td>• Debating the pre-analytical jungle of RNA targeted liquid biopsies and need for standardization, as part of the ongoing exRNAQC study</td>
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<td>14.25</td>
<td>Session Q&amp;A</td>
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<td></td>
<td>• Q&amp;A with the sessions speakers</td>
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<td>• Where does the most clinical value lie for liquid biopsies?</td>
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<td>• Evaluating the pros and cons of circulating biomarkers and their attribution across disease indications</td>
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<tr>
<td>15.10</td>
<td>Precision LBx Summit Poster Session &amp; Afternoon Refreshments</td>
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Standardization and Validation: The Challenges Associated with Establishing Accuracy of Liquid Biopsy Assays

15.40 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 resequencing.
- Discussing implementation of mutation enrichment via COLD-PCR or NaME-PrO together with high resolution melting.
- Highly sensitive detection of micro-satellite instability in plasma as a unique application
- Application in circulating DNA from clinical cancer samples will be presented

16.05 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

16.30 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
- Discussing the challenges of validation, the best materials and controls to use and best approaches for robust validation
- Developing standards for downstream bioinformatics: How do we or can we unify research, academic and commercial lab processes?
- Discussing the lack of adequate reference materials (both positive and negative), what does one use as a “gold standard” reference method to compare against?
- Standardizing terms: Aligning metrics and endpoints for analytical performance to truly assess assay capabilities
- Debating trade-offs between assay technology and ultimately from a physician’s perspective, what is most important?
**Conference Day Two | Wednesday, January 31, 2018**

### The Evolving Role of Liquid Biopsy in Cancer: IO & Oncology Case Studies

**8.50 Chair’s Opening Remarks**

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

#### Daniel Simon
Vice President, BioPharma Business Development
Guardant Health

**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

**9.25 Circulating Tumor DNA and Oncology Immunotherapy – The Next Frontier**
- Adopting ctDNA to support development of oncology immunotherapies
- Discussing ctDNA applications, including positive and negative selection of patients, monitoring for rapid insights into patient response
- Developing new, larger, panels to support evaluation of a broader set of genes and tumor mutational burden

**9.55 Morning Refreshments**

#### Sandip Patel
Medical Oncologist & Assistant Professor of Medicine
UCSD

#### Hatim Husain
Assistant Professor of Medicine
UCSD Moores Cancer Center

**10.25 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

**10.50 Why Molecular Diagnostic Testing is Important in Lung Cancer**
- Exploring the early detection and analysis of lung cancer patients harnessing liquid biopsy testing
- Discussing the initial genotyping and characterisation of tumours and implications for treatment
- Understanding how we can develop algorithms and metrics to measure tumour response and evaluating the dynamics in how genotyping changing over time

**11.15 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

**12.00 Networking Lunch**

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**AMGEN**

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**Precision LBx – Liquid Biopsy Diagnostics**
Regulation, Reimbursement & the End Result for Patient Welfare

13.00  Regulatory Considerations for ctDNA as Biomarker Candidates Into Companion Diagnostics

- Evaluating the promise of ctDNA for improving cancer diagnosis and monitoring as well as drug development and utility as companion diagnostics
- Discussing the unique set of regulatory concerns with this technology, particularly in establishing analytical and clinical validity
- Considering challenges and opportunities in analytical and clinical study design

Morteza Minaee
Vice President, Regulatory Affairs
Guardant Health

13.20  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

Lou Riceberg
Owner
BioBridge Strategies

13.45  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

Morteza Minaee
Vice President, Regulatory Affairs
Guardant Health

14.30  Chairs’ Closing Remarks

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

“This was one of the best symposiums I’ve attended in the past 2 years. Congratulations to the organizers for getting such engaging presenters”

Jean-Francois Martini, Pfizer
**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

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**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.

www.horizondiscovery.com

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**Exhibition Partner**

Cureline, Inc., is a global commercial biobank and human biospecimen CRO providing for 12 years effective solutions to biopharmaceutical and academic researchers. We maintain an extensive biorepository of human biospecimens in San Francisco Bay area (CA, USA) and specialize in contract services for human sample validation studies.

www.cureline.com

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**Panel Partner**

Genomic Health, Inc. is the world’s leading provider of genomic-based diagnostic tests that help optimize cancer care, including addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IQ® Genomic Intelligence Platform, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, from diagnosis to treatment selection and monitoring.

www.GenomicHealth.com

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**Program Partner**

Guardant Health is a pioneer in non-invasive cancer diagnostics, addressing challenges across the cancer care continuum. The company has raised more than $200 million from leading venture capital firms and in 2014 launched Guardant360, the first comprehensive liquid biopsy for clinical use. Guardant Health is improving therapy selection for advanced cancer patients across the globe using its proprietary cell-free circulating tumor DNA NGS platform. Guardant Health is partnered with biopharmaceutical companies to prospectively screen patients for trial enrollment, develop companion diagnostics to support clinical adoption, and use retrospective analysis for early insights into patient response and tumor evolution, as well as accelerate the development of new therapies.

www.guardanthealth.com

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**Program Partner**

Personal Genome Diagnostics (PGDx) advances the frontiers of cancer medicine through innovative genomic technologies for oncology researchers, drug developers, clinicians and patients. The expert team at PGDx draws on a deep understanding of cancer biology, extensive experience in cancer genomics and clinical oncology, and the company’s distinctive technologies. These novel technologies precisely identify and characterize unique genomic alterations in tumors. PGDx is working toward broad patient access to its genomic approaches, through a CLIA-certified facility providing comprehensive genomic services, PROGENEUS™ technology transfer solutions and in-vitro diagnostic products enabling other molecular laboratories to easily internalize testing.

www.personalgenome.com

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Sam Sarwar
Commercial Director – Biomarkers & Diagnostics Event Series
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GET INVOLVED

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<table>
<thead>
<tr>
<th><strong>Solution &amp; Technology Providers</strong></th>
<th><strong>Register before December 15</strong></th>
<th><strong>Save Up To $400</strong></th>
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<th><strong>Academics &amp; Clinicians</strong></th>
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* **Team Discounts***
  - 10% discount – 3 delegates
  - 15% discount – 4 delegates
  - 20% discount – 5 or more delegates

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

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Full payment is due on registration. Cancellation and Substitution Policy:

Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

Changes to Conference & Agenda: Hanson Wade reserves the right to postpone or cancel an event, to change the location or alter the advertised speakers. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including, without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.

### VENUE

**DoubleTree by Hilton San Diego – Mission Valley**

7450 Hazard Center Drive, San Diego California, 92108, USA

For further information or assistance, please visit [www.doubletree3.hilton.com](http://www.doubletree3.hilton.com)

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