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July 18 - 20 2017, **Washington, DC**

WORLD CDx Market Access for Precision Medicine

- **Regulatory Approval**
- **Reimbursement Coverage**
- **Commercial Success**

Attain Regulatory Approval, Reimbursement Coverage & Demonstrate the Value of Next Generation Precision Medicines

Expert Speakers Include:

Boxiong Tang
Senior Director, Global Health Economics & Outcomes Research (GHEOR)
Teva Pharmaceuticals

Franziska Moeckel
Assistant Vice President, Personalized Health
Inova Health System

Tehseen Salimi
Vice President & Head, Medical Affairs
Trevena

Omar Dabbous
Head, Quantitative Science Payer Evidence Group
GSK

Jonathan Pan
Vice Present, Head of Biomarker Strategy & Development
Aevi Genomic Medicine

Janaki Veeraraghavan
Senior Scientific Reviewer, Division of Molecular Genetics & Pathology, Center for Devices & Radiological Health
US Food & Drug Administration (FDA)

Program Partner: Diaceutics

cdx-marketaccess.com

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Welcome to MA4PM Summit 2017

Your roadmap for laying down and executing a robust market access strategy

Assembling pharma, biotech, diagnostic developers, regulators and payers, the Market Access for Precision Medicine Summit is set to provide much needed clarity on key regulatory, reimbursement and commercialization challenges facing precision medicines. **Attend this event to engage and sit alongside the pioneers who are driving forward effective access and pricing strategies.**

In the current climate, uncertainty surrounds healthcare policy, global regulatory guidelines change and disparities in the demonstration of value grow wider. More than ever, a conduit is needed to streamline the transition from clinical development to commercialization that delivers on the investment made in research and ultimately brings ground breaking medicines to patients in need.

MA4PM 2017 provides this conduit by defining the roadmap for laying down and executing a robust market access strategy to ensure the approval and commercial success of precision medicine drug and diagnostic products.

Curated for drug developers, MA4PM 2017 provides insight on harnessing the likes of health economics, IVDs, RWE and clinical labs to achieve your market access goals. **Register for MA4PM 2017 and join the discussion to ensure your drug and diagnostic assets reach the right patient, at the right time and at the right cost.**

Why Attend:

1. Engage with payers and regulators to get to the **crux of value demonstration** and ensure market access and drug pricing strategies align with reimbursement requirements
2. Develop a **robust RWE strategy** and learn how to integrate it into your wider commercial strategy to ensure valuable evidence is generated cost effectively
3. **Harness next generation IVDs** to get your drug approved, launched and adopted quicker for its intended patient population
4. Streamline internal collaboration of R&D, regulatory, market access and medical affairs functions to achieve **greater commercial alignment and safeguard success** early in development
5. Understand how to **build a network and implement a market access strategy** in developing and self-pay dominated countries

What Last Year's Attendees Had to Say

"I thought it was a great meeting that allowed for great interactions and the time and space to process the information. It is always great to have representatives of the FDA join the meeting. Their perspective is so important."

"A very informative meeting. As a regulator, it was very helpful to learn about the reimbursement challenges faced by industry."

"It was great that people with a broad range of expertise were present at the meeting to facilitate discussion from different perspectives. Great opportunities to network- great information!"

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Expert Speaker Faculty

Brian Abbott
Senior Principal Scientist, Regulatory Liaison
Merck & Co.

Rafael Alfonso
Lead Evidence Analytics & Innovation, Value Evidence Outcomes
GSK

Michael Benecky
Senior Director, Global Regulatory Affairs
GSK

Elise Berliner
Director, Technology Assessment Program
AHRQ

Jordan Clark
Managing Director
Labceutics Diaceutics Group

Vivian Coates
Vice President, Information Services & HTA
ECRI Institute

Omar Dabbous
Head, Quantitative Science Payer Evidence Group
GSK

Bill Goodson
Director, Market Access & Reimbursement Services
Eisai

Stefanie Knoll
Global Access Product Lead, Early Assets & CDx, Global Oncology Value & Access (GVA)
Novartis

Hisani Madison
Scientific Reviewer, Division of Molecular Genetics & Pathology, Center for Devices & Radiological Health
US Food & Drug Administration (FDA)

Franziska Moeckel
Assistant Vice President, Personalized Health
Inova Health System

Allison Mitchell
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Tehseen Salimi
Vice President & Head, Medical Affairs
Trevena

Boxiong Tang
Senior Director, Global Health Economics & Outcomes Research (GHEOR)
Teva Pharmaceuticals

Satish Valluri
Director, Global Market Access
Pfizer

Janaki Veeraraghavan
Senior Scientific Reviewer, Division of Molecular Genetics & Pathology, Center for Devices & Radiological Health
US Food & Drug Administration (FDA)

Clorinda Walley
Executive Director
Good Days

Conference Day One | Wednesday, July 19, 2017

8.00 **Registration and Breakfast**

8.50 **Chair's Opening Remarks**

Defining the Value of Precision Medicines in Healthcare

Tehseen Salimi, Vice President & Head, Medical Affairs, **Trevena**

9.00 **The Pharma Perspective on Delivering the Value of Precision Medicines to Patients**

- Holding value at the heart of R&D to ensure product development is aligned with demonstrating a closing of the value gap for all stakeholders
- How do we transform our commercial strategy based on a value construct to connect all functions and provide patient centric value to the development of precision medicines?
- Understanding how to generate dynamic evidence for value based reimbursement in a rigid R&D clinical program

Jordan Clark, Managing Director, **Labceutics, Diaceutics Group**

9.30 **The Real World Impact of a Challenging Market Access Environment for Diagnostic Testing**

- Understanding the common reimbursement challenges facing the diagnostic industry
- How can diagnostic reimbursement impact upon therapy prescribing?
- Considering the options available to laboratories when faced with reimbursement issues

Michael Benecky, Senior Director, Global Regulatory Affairs, **GSK**

Tehseen Salimi, Vice President & Head, Medical Affairs, **Trevena**

10.00 **Keynote Panel: How can We Evolving the Definition of Value for Targeted Therapeutics to be Relevant to Payers, Providers and Patients**

- Discussing the major funding schemes in major markets and key considerations for drug-biomarker reimbursement
- How significant does an outcome improvement need to be in order to get a drug reimbursement?
- Discussing the impact of wider geopolitical changes on the on the value proposition of precision medicines:
  - Second guessing Washington: Expected changes and the perceived ramification to healthcare and the impact on patients
  - Big picture thoughts on the impact of Brexit on European market access
  - Dissecting the impact of 21st Century Cures and the potential repealing of ACA

10.45 **Speed Networking & Morning Refreshments**

Navigating the Regulatory & Reimbursement Hurdles for Drug & Diagnostic Success

Michael Benecky, Senior Director, Global Regulatory Affairs, **GSK**

11.30 **A 2017 CDx US and EU Regulatory Update**

- Discussion of the EU up-regulation of CDx Tests, including new clinical evidence and notified body certification requirements and the challenge of the regulatory coordination between the therapeutic and companion diagnostic test
- An update on FDA organizational and staffing changes impacting personalized medicine
- LDT regulatory update
- Discussion of the FDA Drug/CDx Co-Development Guidance with focus on the Investigational Device Exemption (IDE) submission requirements for investigational companion diagnostic tests used in clinical trials

NOVARTIS

Stefanie Knoll, Global Access Product Lead, Early Assets & CDx, Global Oncology Value & Access (GVA), **Novartis**

12.00 **The Novartis Perspective on the Future of Precision Medicine**

- Understanding how to support the launch of NGS based diagnostics and key considerations for payer interactions
- Developing best practice in Rx-Dx collaboration to support the launch of drug-diagnostic products
- A current overview of expected launches, market access strategy and how to best connect with payers in the 2017 healthcare environment

12.30 **Lunch & Networking**

Hisani Madison, Scientific Reviewer, Division of Molecular Genetics & Pathology, Center for Devices & Radiological Health, **US Food & Drug Administration (FDA)**

13.30 **Drug and Diagnostic Co-Development: Developing Value as a "System of Care" Package to Improve the Approval Process**

- Understanding the regulatory perspective on drug-Dx co-development for approval
- How to best evaluate the drug and diagnostic test as a "system of care" in order to most show clinical outcome value
- Regulatory strategies for overcoming common challenges in co-development

Hisani Madison, Scientific Reviewer, Division of Molecular Genetics & Pathology, Center for Devices & Radiological Health, **US Food & Drug Administration (FDA)**

FDA

Janaki Veeraraghavan, Senior Scientific Reviewer, Division of Molecular Genetics & Pathology, Center for Devices & Radiological Health, **US Food & Drug Administration (FDA)**

Brian Abbott, Senior Principal Scientist, Regulatory Liaison, **Merck & Co.**

Franziska Moeckel, Assistant Vice President, Personalized Health, **Inova Health System**

14.00 **Panel Discussion: The Role of In Vitro Diagnostics in Successful Precision Medicine Market Access**

- Discussing the impact of regulatory delineation of complementary and companion diagnostics on commercialization strategy
- An evolving landscape: How do we pay and reimburse for complementary diagnostics?
- Understanding the regulatory perspective on drug and diagnostic co-development
- Building a more open and interactive dialogue between pharma, IVD developer, regulatory and payer
- What will it take to evolve the current "case by case" model of reimbursement into a more standardized model for drug-IVD combinations?
- Is CDx a help or hindrance? Examining the impact of Opdivo vs. Keytruda on embarking on a future CDx strategy for a targeted therapeutic
- Is CDx a pre-competitive market place? Do we need multiple tests for a specific biomarker? How do we develop a sustainable operating environment?
- Is the current reimbursement paradigm pushing drug developers to complementary over companion diagnostics?
- Aligning regulatory approval with reimbursement in the marketplace: Is there a mechanism in policy or regulation that can encourage better payment for approved precision medicine-diagnostic products?

14.45	**Afternoon Refreshments & Networking**

Breakout Roundtables on Market Access

15.15 Our MA4PM breakout roundtables will allow you to have more intimate discussions with market access and commercial 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 Sharing the value:
Debating how to progress the Rx & Dx partnership model to provide ROI for both parties and deliver commercial success of drug-IVD products

2 Discussing the intersection of clinical labs, LDTs and IVDs:
How can pharma better align with the clinical lab to improve market access?

3 Physician and patient education:
An evidence based approach to precision medicine access and adoption

Franziska Moeckel
Assistant Vice President, Personalized Health
Inova Health System

16.30	**Chair's Closing Remarks**
16.45	**End of Day One**

"Excellent meeting with great overview of current issues in co-development of CDx. I particularly liked the intimate setting and potential for networking."

Event Attendee, World CDx: Regulation & Reimbursement 2016

"A great balance between pharma, industry and academia. The event covered a broad range of technical, regulatory and business issues related to the advancement of personalized medicine. The meeting size is just right for networking and has a great mix in the variety of presentations."

Biomarkers & Diagnostics Event Series Attendee 2016

Conference Day Two | Thursday, July 20, 2017

8.00 **Breakfast and Networking**

8.50 **Chair's Opening Remarks**

Economics & Evidence: Key Ingredients for Precision Medicine Market Access

Omar Dabbous, Head, Quantitative Science Payer Evidence Group, **GSK**

9.00 **Integrating a RWE Plan into Precision Medicine Market Access Strategy**

- Understanding how to differentiate "got to have" vs "nice to know" RWE in a multiple stakeholder environment
- Discussing systematic processes for honing in on and prioritizing "data gaps" and the role for rethinking study design and market research
- Understanding best practice in constructing real world studies and the use of hybrid models to generate valuable and insightful data
- Utilizing real world data to help us better make decisions and articulate market access commercial strategies
- Developing a long-term evidence plan for the optimal execution of a RWE strategy: Who's paying, what evidence do we need, who is generating what and how does the strategy support brand positioning?

Boxiong Tang, Senior Director, GHEOR Oncology, **Teva Pharmaceuticals**

9.30 **The Impact of Economic Analysis (Modelling) on Precision Medicine Market Access**

- Understanding budget impact / cost effectiveness models and their importance to market access strategy
- Distilling the data: What information is necessary for a budget impact model?
- Evolving economic modelling to close the gap to support access and reimbursement between the R&D setting and the real world application of precision medicines and companion diagnostics

Rafael Alfonso, Director, Value Evidence Analytics, **GSK**

10.00 **How to Provide the *Right* Evidence for Decision Makers**

- Establishing a systematic approach for evidence generation and identifying subpopulations
- Discussing how to explore and visualize datasets effectively for comparative effectiveness research
- Setting up an early data strategy to safeguard value and access

10.30 **Morning Refreshments & Networking**

Elise Berliner, Director, Technology Assessment Program, **AHRQ**

11.00 **Bringing the R&D and Market Access Worlds Together: How to Align Orbits**

- Widening the scope of R&D focus beyond regulatory approval to streamline the transition from clinical program to commercial launch
- Keeping the target population at heart: Mapping market access pathways around the biomarker strategy planning ahead for evidence needs of payers, physicians, and patients.
- Integrating market access strategy pre phase II to strengthen the selection of clinical programs with a greater likelihood of commercial success
- Making the case that the product solves a real patient problem and improves patient outcomes

Vivian Coates, Vice President, Information Services & HTA, **ECRI Institute**

11.30 **Health Technology Assessment for Genetic Testing: Demonstrating Value to Multiple Stakeholders**

- The ins and outs of a HTA: Demonstrating the sensitivity, specificity and performance to give payers confidence that the drug results in improved patient outcomes
- What to bring to the table: How providing the right social, economic, organizational and ethical evidence can streamline the HTA process
- Integrating early advice from HTA bodies into clinical development and market access strategy to streamline product development and commercialization

12.00 **Panel Discussion: How can RWE and Health Data Add Value Across the Precision Medicine Market Access Strategy?**

Rafael Alfonso, Director, Value Evidence Analytics, **GSK**

Omar Dabbous, Head, Quantitative Science Payer Evidence Group, **GSK**

- What constitutes good real world data?
- Pre-market: Are there relevant, real world studies that we can harness to improve commercial product differentiation?
- Understanding the importance of real world evidence to the payer and how to develop a targeted and specific RWE study
- Harnessing digital channels to promote insightful data collection in clinical and real world data studies
- Beyond reimbursement: How do you maintain your differentiated position with RWE for precision medicine?
- Discussing what kind of insights we can generate from health data mining to advance the value proposition of biomarker, drug, diagnostic and whole drug-diagnostic product
- How to best connect and mine different data silos accurately and efficiently to generate value based insight?
- With all the uncertainty surrounding real world adoption pre-launch, how can pharma create dynamic data to demonstrate value?
- Harnessing RWE and data to generate robust scientific communication platforms to develop engaging product messaging
- How do we deal with the evolution of health data and the intersection with precision medicine for building and supporting commercialized precision medicine products?
- Future thinking: How can we harness machine learning to inform what trials to develop and what precision medicine products will be successful?

12.45 **Networking Lunch**

Advancing Patient Access in the Global Context

Allison Mitchell, Certified Genetic Counselor, Inova Translational Medicine Institute, **Inova Health System**

13.45 **MediMap™: Implementation of a Personalized Medicine PGx Testing Program**

- An overview of the implementation of the MediMap™ program within the Inova Helath System
- Integration of the PGx testing into the wider hospital EHR
- Debating participation, uptake and patient engagement

14.15 **Panel Discussion: How Do We Ensure Patients Worldwide Get Access to Future Precision Medicines?**

Clorinda Walley, Executive Director, **Good Days**

Bill Goodson, Director, Market Access & Reimbursement Services, **Eisai**

- Discussing compliance regulation: What can we as pharma do and not do with patients?
- How to best choose a patient support service that provides the right expertise and distribution model to get speciality medicines to patients in need at the right price
- Investigating the plethora of digital channels and technology that can be harnessed to bring patients closer to the medicines
- Discussing the cans and cannots of charitable contributions to 501(c)3 organizations to assist Medicare part B and part D patient access
- How do we develop a sophisticated lab set up in a developing country in order to allow access to precision speciality drugs and their diagnostics?
- What is the appropriate network needed in a given country to efficiently organise and implement optimal support and service for the target population? How does that network need to differ from South America to the Middle East to Asia?
- Discussing how to approach the self-pay systems of developing countries and the impact this has on market access strategy and drug pricing
- Embedding logistical requirements into commercial strategy to ensure the effective dissemination of both the drug and diagnostic test to developing countries
- Debating the nuts and bolts of partnering strategy in the EMEA, South America and Asian markets: Why do this, who to choose and in what situation?
- What are the key regulatory, pricing and commercial components that can be universally applied independent of geography?

15.00 **Chair's Closing Remarks**

15.15 **Close of 3rd Market Access for Precision Medicine Summit 2017**

Pre-Conference Workshop A

Precision Medicines: More Data, More Research & More Cost for Fewer Patients - What's in it for the Payer & Other Stakeholders?

Date: Tuesday, July 18, 2017 | Time: 9.00 - 12.00

As precision medicine continues to receive the attention and backing of healthcare policy makers worldwide, the commercial opportunity it presents for drug developers is under the microscope. Join this intimate, informal and interactive workshop to take a deeper dive into the following topics of discussion:

- Is precision medicine an intervention for the rich to live longer?
- Does precision medicine make treatment predictive and personalised and the doctor superfluous, thereby reducing overall healthcare costs?
- Should there be a charge for the diagnostic? For the drug? For the outcome? Where is the value for the pricing proposition?
- Can precision medicines avoid the unfair outcomes of price referencing that is rapidly expanding outside of Europe to become a significant contributor of delayed patient access?
- Developing a value proposition to convince payer and hospitals of the need to pay for the drug-diagnostic product
- Aligning strategy beyond regulatory approval to incorporate potential price point strategy
- Patient access programs: Discussing program structure, patient demographic eligibility and the impact on wider patient access to speciality drugs
- Discussing the nuts and bolts of HTAs and the final outcome on pricing strategy

Workshop leader

Anthony Nash, **Expert pharma advisor for market entry and patient access**

Anthony Nash is a passionate expert in Patient Access and Market Entry who deeply believes that those companies that will not merely survive but prosper in the 21st century pharma economy are those that are able to harmonise social responsibility with sound business acumen. He likes to negotiate pragmatic win-win solutions and build trust with all customers along the way.

To that end he brings a depth and breadth of thought leadership on strategy creation and tactical implementation drawing on experiences from leading quite different functions in multiple pharma companies across different cultures over six continents.

He started his career in academia before moving into retail pharmacy in Cape Town and then worked for the National Health Services (NHS) in London. He subsequently moved into R&D in the Pharma Industry and from there took on leading roles in Regulatory Affairs, Sales and Marketing, Government Affairs and Policy, Corporate Strategy and Social Responsibility and Market Access.

"This was an excellent experience. Plenty of information and networking opportunities"

Past Attendee, World CDx Regulation 2015

Pre-Conference Workshop B

Developing the Precision Medicine Commercial Opportunity Outside of Oncology

Date: Tuesday, July 18, 2017 | Time: 13.00 - 16.00

While oncology has been an area of focus, precision medicine principles and concepts are applicable in other diseases areas, such as CNS, Cardiovascular and rare diseases. As R&D pipelines begin to build in these therapeutic areas, the focus begins to shift from a limit of detection issue as is the case in Oncology to volume-base issues, from larger numbers of patients and larger germline variants that contribute to disease. This interactive workshop will drive in depth discussion on the following questions:

- What does the underlying science on germline mutations tell us?
- How does the volume of genes and patients change the business model, compared to the known Oncology model?
- How do these new precision medicines work for patients with lifelong chronic diseases, in the context of regulation, reimbursement and commercialization?
- What can we learn from NIPT as the basis for genetically-defined diseases?
- What are the opportunities and new barriers to entry of this new model?

Workshop leader

Jonathan Pan, Vice President, Head of Biomarker Strategy & Development, **Aevi Genomic Medicine**

Jonathan is currently VP, Head of Biomarker Strategy and Development at Aevi Genomic Medicine, a biotechnology firm focused in translating genetic discoveries into novel therapies to improve the lives of children and adults with pediatric onset life altering diseases. At Aevi, he is focused on bringing precision medicine and companion diagnostic testing to diseases outside of oncology, such as ADHD and IBD. Prior to Aevi, Jonathan led competitive strategy for the I-O franchise at BMS and was the Head of Oncology Companion Diagnostics and Disease Strategy at GSK, launching companion diagnostic testing globally. He was a former management consultant at Deloitte, IMS Consulting and Scientia Advisors. He has a PhD and MBA from the University of Michigan.

"Stimulating meeting with a broad attendance from multiple stakeholders. This facilitated open discussions with different viewpoints and was a great opportunity to learn everyone's challenges."

Past Attendee, World CDx: Regulation & Reimbursement 2016

"This was an excellent meeting. It was super interactive."

Past Attendee, World CDx Regulation 2015

Partners

Program Partner

Diaceutics

We leverage analytics, software, services and strategy to enable the effective integration of therapies and diagnostics into the treatment pathway. The Group's divisions, Labceutics, Diaceutics AIS, Iceutics and Bioceutics, together provide a comprehensive suite of services to ensure that testing enables therapy prescribing across all key markets.

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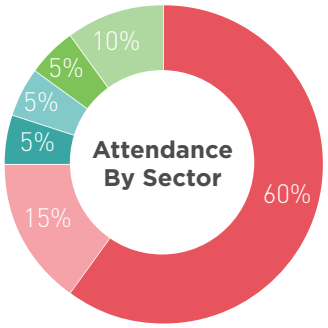
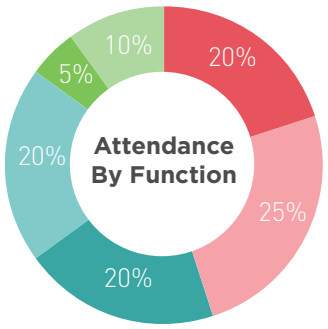
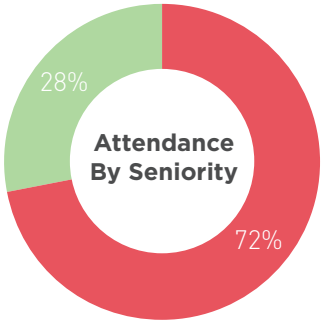
Partnership Opportunities

Meet People From...







Why Partner?

POSITION YOURSELF AS AN INDUSTRY THOUGHT LEADER
Demonstrate your expertise by moderating panel discussions and roundtables. Influence future best practice to launch precision medicines to patients in need globally.

BENEFIT FROM MARKET INTELLIGENCE
Discuss and network with the pioneers who are driving forward effective access and pricing strategies. Gain a unique opportunity to hear about the hot topics surrounding precision medicine and feed back into your business to create products and services that you know are going to be in line with what your clients are wanting now.

RAISE BRAND AWARNESS
Align your brand with the only precision medicine meeting set to tackle the full market access roadmap. Increase market share through unique branding formats allowing you to reach different audiences and make a lasting impression

GENERATE NEW BUSINESS LEADS
Get a unique opportunity to network with prospective clients in an informal setting during dedicated speed networking breaks, personal introductions and multiple industry wide touch points via our wider Biomarker and Diagnostic Event Series community. Have a wish-list of your choice contacted in advance of the conference, to help ensure that your hottest prospects are in the room.

Get In Touch

Sam Sarwar
Commercial Director –
Biomarkers & Diagnostics Event Series

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Pricing

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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.

Top 3 Benefits of Attending

1. Achieve Regulatory Approval
2. Tackle Value/Outcomes Based Reimbursement Coverage
3. Elevate Your Market Access Strategy

	Register & Pay before Friday April 14, 2017	Standard Prices
Conference + 2 Workshops	**SAVE $900** $2,997	**SAVE $200** $3,697
Conference + 1 Workshop	**SAVE $800** $2,498	**SAVE $100** $3,198
Conference Only	**SAVE $700** $ 1,999	$2,699
Workshop Only	$599	
2 Workshops	**SAVE $200** | $998	

"Focused speakers allowed for streamlined discussion and open conversation. I left the meeting aligned on the latest developments and carried away clear messages."

Biomarkers & Diagnostics Event Series Attendee 2016

Venue

Hilton Crystal City at Washington Reagan National Airport
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22202
USA

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