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June 19 - 20, 2019 | Boston, MA

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BM&Dx

For Complex & Rare Diseases

Precision medicine advances outside of oncology

Advancing the Application of Biomarkers & Diagnostics to Enhance the Discovery & Development of Precision Medicines & the Management & Treatment of Complex & Rare Diseases

Expert speaker faculty includes:

Franziska Moeckel
Assistant Vice President, Personalized Health
Inova Health System

George Bashirians
Senior Director & Diagnostics Lead
Pfizer

Kenneth Rhodes
Chief Scientific Officer
Yumanity Therapeutics

Naomi Aronson
Executive Director, Clinical Evaluation, Innovation & Policy, Office of Clinical Affairs
Blue Cross Blue Shield Association

Gabriel Cohn
Vice President & Clinical Development Lead
AvroBio

Michael Hutton
Chief Scientific Officer & Vice President, Neurodegeneration Research
Eli Lilly & Co.

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WELCOME TO THE BM&Dx SUMMIT 2019!

The precision medicine industry is bigger than oncology. As diseases such as CVD and Alzheimer's become the biggest healthcare burdens, the application of the precision medicine paradigm is now being heralded as the ticket to improving therapeutic landscapes outside of oncology. The inaugural Biomarkers & Diagnostics for Complex & Rare Diseases Summit will focus on **discovery, translational, clinical** and **commercial barriers** to advancing the **application of biomarker-driven** and **Dx-enabled therapeutics** in a range of complex and rare diseases.

Showcasing innovations in technologies for **discovering** and **translating novel predictive biomarkers** and the **utilization of diagnostics as management tools for patient care**, the meeting will draw on learned experience for advancing the application of precision medicine to improve patient outcomes.

Built for **biomarker, translational, clinical** and **diagnostic leaders** throughout the industry, the meeting will tackle the gap in biomarker development and translational approaches and pave the path for the successful development of Dx-enabled precision medicines in complex and rare disease areas.

Different Disease Areas the Meeting Covers

- ✓ **Neurology**
- ✓ **Cardiovascular**
- ✓ **Renal**
- ✓ **Rare Disease**
- ✓ **Metabolic**
- ✓ **Dermatology**
- ✓ **NASH**

Key Topics for 2019:

Exploring methods for uncovering **disease pathophysiology** to drive **biomarker identification, patient selection** and stratification, with insight from **Yumanity Therapeutics** and **George M. O'Brien Kidney Translational Core Center**

Understanding the unmet clinical need in complex and rare diseases to **improve patient advocacy and engagement** with precision medicine programs, led by the **Global Alzheimer's Platform Foundation and Mayo Clinic**

Navigating the reimbursement and regulatory systems to build **effective market access and clinical development** strategies, with help from **Blue Cross Blue Shield Association**

Applying innovative **diagnostic technologies** to expedite drug development and patient care management, championed by **Inova Health System** and **Pfizer**

Building biomarker powered clinical trials to accelerate the **commercial-stage demonstration** of therapeutic efficacy, with lessons from **Eli Lilly, AvroBio** and **Cavion**

EXPERT SPEAKERS

Naomi Aronson
Executive Director, Clinical Evaluation, Innovation & Policy, Officer of Clinical Affairs
Blue Cross Blue Shield Association

Heather Ascani
Director, Business Operations, Applied Systems Biology Core
University of Michigan

George Bashirians
Senior Director & Diagnostics Lead
Pfizer

Gabriel Cohn
Vice President & Clinical Development Lead
AvroBio

John Dwyer
President
Global Alzheimer's Platform Foundation

Mike Hutton
Chief Scientific Officer & Vice President, Neurodegeneration Research
Eli Lilly & Co.

Wenjun Ju
Deputy Director, George M. O'Brien Kidney Translational Core Center & Co-Director, UMHS-PUHSC Joint Institute for Translational & Clinical Research Renal Core
University of Michigan

Michael Kiebish
Chief Precision Medicine Officer & Vice President, Systems Medicine
Berg Health

Zhen Mahoney
Head, Business Development
Asuragen

Michelle Mielke
Professor, Epidemiology & Neurology
Mayo Clinic

Vijay Modur
Global Project Head, Rare Disease Clinical Development
Sanofi Genzyme

Franziska Moeckel
Assistant Vice President, Personalized Health
Inova Health System

Spyros Papapetropoulos
Chief Medical Officer & Executive Vice President & Head, Research & Development
Cavion

Kenneth Rhodes
Chief Scientific Officer
Yumanity Therapeutics

Gordon Vanscoy
Chairman & CEO
PANTHERx Specialty Pharmacy

Szilard Voros
Founder & Chief Executive Officer
Global Genomics Group

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Speaker confirming
Covance

John Reilly
Vice President, Biology
Goldfinch Bio

Charles Mathews
Principal
ClearView Healthcare Partners

CONFERENCE DAY ONE
WEDNESDAY, JUNE 19, 2019

Szilard Voros
Founder & Chief Executive Officer
Global Genomics Group

8.50 **Chair's Opening Remarks**

Putting Pathophysiology First: Accurate Biomarker Identification for Patient Selection & Stratification

Kenneth Rhodes
Chief Scientific Officer
Yumanity Therapeutics

9.00 **Patient Stratification in Parkinson's Disease**

- Challenges in biomarker identification and patient stratification in neurodegenerative disease
- Opportunities presented by recent advances in disease genetics, imaging and biomarker identification
- Use of pharmacodynamics markers to improve dose selection

Wenjun Ju
Deputy Director, George M. O'Brien Kidney Translational Core Center & Co-Director, UMHS-PUHSC Joint Institute for Translational & Clinical Research Renal Core
University of Michigan

9.30 **Toward Precision Medicine in Chronic Kidney Disease: Tissue-Driven Non-Invasive Mechanistic Biomarker Identification for Patient Stratification**

- Challenges to practice precision medicine in complex & multifactorial diseases: the need for early risk stratification versus the one size fit all treatment approached used to date
- Addressing the challenges: Tissue-driven integrative approach to identify biomarkers for risk stratification, molecular subgrouping, and targeted therapy
- Identification of non-invasive surrogates and final validation in the global research network

Speaker confirming
Covance

10.00 **Evolving CDx Landscape: Models, Applications & Therapeutic Areas**

- Role of biomarkers and CDx in cell and gene therapy, and implications within precision medicine
- Spotlight on cardiovascular, metabolic and NASH biomarkers
- Evolving applications of multianalyte biomarker analysis

10.30 **Speed Networking & Morning Refreshments**

Mike Hutton
Chief Scientific Officer & Vice President, Neurodegeneration Research
Eli Lilly & Co.

11.15 **How Unsuccessful Trials Move Precision Medicine Ahead: Learnings from Previous Fall Backs**

- How have trials been unsuccessful in the past and how can we learn from their mistakes?
- Evaluating the key points setting trials behind in non-oncology precision medicine development and establishing how these are informing practise now
- Discussing the effects of poor stratification and patient selection on clinical trials from economic and time standpoints
- Establishing improved internal strategies for biomarker validation to ensure pipeline success

Michelle Mielke
Professor, Epidemiology & Neurology
Mayo Clinic

11.45 Investigating Fluid-Based Biomarkers for Improved Clinical Decision Making

- Evaluating and comparing fluid-based biomarkers for identifying patient populations
- Exploring key factors affecting these markers in an effort to understand their role and interpretation for clinical decision making
- Approaching assay development to reflect and relate to real-life populations and exploring methods of accurate interpretation

12.15 Networking Lunch

Harnessing Precision Medicine to Address Unmet Clinical Need in Complex & Rare Diseases

John Dwyer
President
Global Alzheimer's Platform Foundation

13.15 The Patient Perspective: How Patient Advocacy Organisations Help Enhance Pipelines Through Clinical Trial Awareness

- Discussing the importance of patient advocacy to the non-oncologic space for trials within small and complex patient populations to enhance patient recruitment and increase sample availability for reliable and robust clinical trials
- How to best establish a patient advocacy partnership to obtain valuable research funds for disease-specific trials to overcome the restrictions of significantly smaller budgets
- Harnessing patient advocacy partnerships to enhance the public awareness of disease for funding and maximal patient reach

Gordon Vanscoy
Chairman & CEO
PANTHERx Specialty Pharmacy

13.45 Precision Medicine Channel Strategies: What is the Role of Specialty Pharmacy?

- Precision medicines offer the potential of unprecedented breakthroughs for some of the 7,000 rare diseases which have no known treatments. However, medical advancements must be managed appropriately due to significant financial cost to society, the payer, the employer, and patient
- Specialty pharmacy is poised to be a key to transform and maximize patient outcomes in an efficient/data driven manner
- Approaches to specialty pharmacy channel strategy management will be discussed

14.15 Afternoon Refreshments

Effective Reimbursement & Market Access Strategies for the Advancement of Precision Medicine Beyond Oncology

Naomi Aronson
Executive Director, Clinical Evaluation, Innovation & Policy, Officer of Clinical Affairs
Blue Cross Blue Shield Association

15.00 The Payer Perspective on Novel Targeted Therapeutics

- Evaluating the key evidence requirements of payers for approval for a streamlined drug market access strategy
- How to demonstrate the clinical applicability of novel therapies for real world use and avoid late-stage rejections

John Reilly
Vice President, Biology
Goldfinch Bio

15.30 Leveraging Precision Medicine Approaches to Accelerate Clinical Trials in Kidney Disease

- Applications of targeted and unbiased biomarker discovery from accessible samples in chronic kidney disease
- Importance of sample collection methods and controlling preanalytical factors
- Innovative trial designs to incorporate, leverage and learn from biomarkers

16.00 Panel Discussion: Evaluating Key Considerations Throughout Drug Development to Ensure Late-Stage Approval

- What is the impact of pricing strategy on healthcare utilization?
- How can biomarker/Dx strategy affect market access and value demonstration?
- Evaluating the effect of diagnostic use on market positioning, differentiation and overall drug sales
- With the majority of rare disease patients inevitably ineligible for drug use, how will the high-volume screening affect payer approval?
- How does trial design impact the later success of regulatory applications, and how can this be improved?
- What are the key considerations in biomarker strategy to set drug development up for success from the get-go?
- How can key learnings from this session be applied in a real world setting across disease types?

Kenneth Rhodes
Chief Scientific Officer
Yumanity Therapeutics

Gabriel Cohn
Vice President & Clinical Development Lead
AvroBio

Vijay Modur
Global Project Head, Rare Disease Clinical Development
Sanofi Genzyme

Szilard Voros
Founder & Chief Executive Officer
Global Genomics Group

17.00 Chair's Closing Remarks

17.05 End of Day One

"Great networking opportunity"
Marketing Director CDx, AbbVie, 2018 attendee

"Organized, diverse, informative"
Senior Biomarker & Diagnostic Operations Lead, Regeneron, 2018 attendee

"Educational, friendly, worthwhile"
Translational Sciences Team Leader, GSK, 2018 attendee

CONFERENCE DAY TWO
THURSDAY, JUNE 20, 2019

Szilard Voros
Founder & Chief Executive Officer
Global Genomics Group

8.50 **Chair's Opening Remarks**

Diagnostics, Technologies & Trial Design for Smaller, Focused Markets

Michael Kiebish
Chief Precision Medicine Officer & Vice President, Systems Medicine
Berg Health

9.00 **Harnessing Patient Biology & Artificial Intelligence for Population Health & Drug Discovery**

- Use of Bayesian artificial intelligence for biomarker and drug discovery
- Engaging artificial intelligence for digital health
- Emerging OMIC technologies for population health as well as metabolic/ neurologic diseases

Franziska Moeckel
Assistant Vice President, Personalized Health
Inova Health System

9.30 **A Case Study: Pre-Emptive Pharmacogenomic Testing for Behavioral Health Patients**

- Overview of pharmacogenomic (PGx) testing at Inova, including aspects of clinical clinical process integrations
- Case study of PGx pilot in a behavioral health outpatient clinic
- Summary of clinical outcomes and findings

10.00 **Panel Discussion: A Conversation on the Development of the Neurological CDx Market**

Neurogenerative disorders exact a high burden on affected individuals, their families, and the healthcare system. The frequently devastating human toll and high economic costs contribute to the urgency for developing new therapies and are driving interest in personalized approaches to diagnosis and treatment. This panel invites various stakeholders to discuss how to overcome some of the challenges to advancing neurological CDx strategies, in order to integrate precision medicine into a patient's journey.

Zhen Mahoney
Head, Business Development
Asuragen

George Bashirians
Senior Director & Diagnostics Lead
Pfizer

11.00 **Morning Refreshments**

Gabriel Cohn
Vice President & Clinical Development Lead
AvroBio

11.30 **Maximising Reliability of Clinical Trials in Rare Diseases to Ensure Late-Stage Success Through Trial Design, Patient Recruitment & Sample Management**

- Starting with the end in mind: Unmet needs, market analysis, and target product profiles
- Charting the course: Surveying the regulatory landscape, navigating hurdles and leveraging pathways
- Pushing the boundaries early for late-stage success: The critical role of early stage trial design
- Critical success factor - it takes a village: PIs, clinical trial sites, laboratories, data & sample management

Heather Ascani
Director, Business Operations, Applied Systems Biology Core
University of Michigan

12.00 Advancing Biomarker Research for Precision Medicine in Kidney Disease: Benefits of Public-Private Partnership

- The march toward Precision Medicine through large-scale data set analysis as a driver of science necessitates a collaborative research approach between all sectors
- A flexible approach to the development of diverse public-private partnership business models for biomarker research
- How to successfully share responsibility in the drug development process through public-private partnership during all phases of the translational research process and significantly accelerate the drug development pipeline

12.30 Networking Lunch

Getting Across the Finish Line: Regulatory Pathways & Requirements for Treatments & Tests

Speaker Confirming Shortly

13.30 Key Regulatory Considerations & Requirements for Drug Approval

- Understanding the different regulatory and validity pathways for diagnostics and the impact for biomarker development and drug approval: IVD, LDT, direct-to-consumer, POC
- Evaluating the latest updates in Orphan Drug Act and how this could impact the approval of your therapy
- Ensuring all evidence requirements and standards throughout trials are met to avoid last minute setbacks and costly errors

14.00 Panel Discussion: Forward-Thinking Approaches for Successful Trial Design to Ensure Regulatory Approval in a Time-Efficient & Cost-Effective Manner

- How have trials been unsuccessful in the past and how can we learn from their mistakes to avoid the typical late-stage setbacks?
- Establishing common best practise for drug development in this highly varied and developing space
- How can AI and machine learning be integrated to precision medicine for the improvement of patient stratification and therapeutic decisions?

Spyros Papapetropoulos
Chief Medical Officer & Executive Vice President & Head, Research & Development
Cavion

Additional panellists confirming

Szilard Voros
Founder & Chief Executive Officer
Global Genomics Group

15.00 Chair's Closing Remarks

15.15 End of Day Two & Close of Biomarkers & Diagnostics for Complex & Rare Diseases 2019

"Great discussion engagement"
Senior Manager, Regulatory Affairs, Agios, 2018 attendee

"Good program, interested speakers, valuable discussion"
Associate Regulatory Affairs Director, Astellas, 2018 attendee

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Founded in 2007, ClearView Healthcare Partners is a global strategy consulting firm serving the life science sector. The firm combines global industry knowledge and deep scientific expertise across a range of therapeutic areas with an extensive network of external stakeholders to deliver practical and actionable recommendations to our clients' most complex challenges. The firm's projects include cross-functional support at the corporate, franchise, and product levels for pharmaceutical, biotech, medical device, and diagnostics companies worldwide.

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Almac Diagnostics is a stratified medicine company specialising in biomarker driven clinical trials. Our diagnostic experience spans oncology, immunology, CNS and infective diseases. Our global laboratories, based in the UK and US offer tailored solutions from discovery to commercialisation: Biomarker discovery. Custom assay development & validation. DNA and RNA panel solutions. Flexible CDx development & commercialisation. Expert regulatory support. Bioinformatics & software development. Your Clinical Trial Diagnostic Partner.

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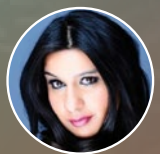

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Email: register@hansonwade.com

1. Understand key methods for reliable biomarker identification and patient stratification
2. Address market access, reimbursement and regulatory hurdles to optimize commercial success of drug-Dx products
3. Discover innovative technologies to advance pipelines in smaller, targeted markets

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.
Contact: register@hansonwade.com

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Package Details	Register & Pay Before 04/12/19	Pre-Event Registration	On The Door
Drug Developer* (Conference Only)	$1,799 **(SAVE $700)**	$2,199	$2,499
Service Provider (Conference Only)	$2,499 **(SAVE $700)**	$2,899	$3,199

*must have a drug candidate within a development pipeline or market approved compound
**academics eligible for 30% discount on drug developer pricing upon request

VENUE

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