September 11 - 12 | Main Conference
www.world-cdx.com

September 9 – 10 | CDx Engage Workshop Days

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WORLD CB & CDx

A Biomarker For Every Drug

10 YEARS ANNIVERSARY

Accelerate the Translation of Clinically Predictive Biomarkers & Enhance the Commercialization of Precision Medicines to Deliver on the Personalized Healthcare Reality

60+ Expert Speakers, Including:

Michele Cleary
CEO
The Mark Foundation for Cancer Research

Emmanuelle di Tomaso
Head, Biomarkers Oncology
Bayer

Shirin Khambata Ford
Head, Precision Medicine, Clinical Biomarkers & Companion Diagnostics
Daiichi Sankyo

Jaya Goyal
Vice President, Bioanalytical, Pharmacology & Biomarker Development
Wave Life Sciences

Kate Haviland
Chief Operating Officer
Blueprint Medicines

Lauren Leiman
Executive Director
BloodPAC

Kenna Mills Shaw
Executive Director, Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy
MD Anderson Cancer Center

Maria Orr
Franchise Leader, Oncology Companion Diagnostics, Precision Medicine & Genomics
AstraZeneca

Alice Walsh
Head Analytics Innovation, Oncology Translational Bioinformatics
Bristol-Myers Squibb

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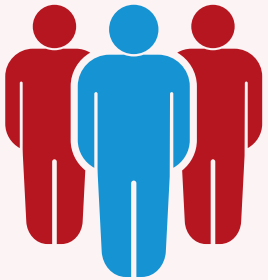
In Partnership with CXEngage

hansonwade

Focus for 2019

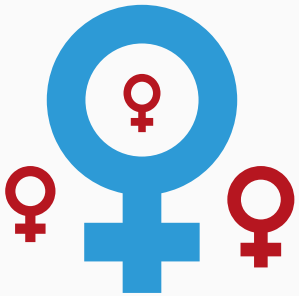


Developing Actionable Predictive Clinical Biomarkers

Prediction is the word. The translational and clinical streams are totally geared towards accelerating the journey from exploratory marker to the validation and implementation of novel signatures with truly predictive potential.

Commercializing Fit-For-Purpose Diagnostics

What works in a clinical trial may not be suitable for the real world. Commercial strategy needs to be implemented earlier to connect the innovation in R&D to what really matters – the ease of integration and access for patients.



Women in Precision Medicine

Science is a very inclusive discipline, however more needs to be done to address many challenges in gender disparity in the workplace - and the whole community need to play their part. In addition to the main content, the event will be advocating the role of female scientific and business leaders in precision medicine, with dedicated content sessions and better representation in the speaker faculty.

Fresh Content From Fresh Faces

Year on year we strive to bring a breadth, variety and freshness of insight and perspective. For 2019 we already have a whole host of new companies including **Inova Health System**, **Autolus**, **Cyteir Therapeutics**, **Wave Life Sciences**, **Olaris Therapeutics**, **The Mark Foundation for Cancer Research**, **Rain Therapeutics** and **CRAB**.

Dx Engage Workshop Days

Before the main conference, we're bringing you two days of exclusive, in-depth workshops. These sessions will explore some of the greatest challenges in biomarker and diagnostic precision medicine development and commercialization, providing you intimate access to a variety of stakeholders and thought leaders in a candid, closed door environment.

Welcome to Clinical Biomarkers & World CDx Boston 2019

Clinical Biomarkers Tracks

Built for **biomarker, translational** and **clinical** experts, these two streams will help you bring novel predictive biomarkers to fruition. Overcoming challenges in the heterogeneity of disease, exploratory biomarker endeavors, and validation of patient stratifying signatures, Clinical Biomarkers will help you accelerate the approval of next generation biomarker-driven precision medicines.

Discover data-driven clinical case studies across therapeutic areas and address paradigm shifts such as the utilization of multi-marker signatures. Ultimately, the Clinical Biomarker streams are here to ensure you, your team and your wider "precision medicine" function deliver valuable insight into patient selection and treatment decisions to prove the safety, efficacy and value of your targeted therapeutic candidates.

Key topics to be addressed:

- **Seattle Genetics** & **BeiGene** share insight on advancing clinical validation of predictive signatures, from protein to NGS markers
- **Olaris Therapeutics** & **Teva** showcase novel AI and *in silico* approaches to expedite the discovery of next generation predictive biomarkers
- **Sanofi** & **Bayer** highlight recent success in accelerating the translational from exploratory signature to clinical biomarker candidate for oncology therapeutics
- **MD Anderson** & **CRAB** guide you through executing biomarker-driven and diagnostic-enabled clinical trials
- **BloodPAC** & **Cyteir Therapeutics** present their project on improving the validation and standardization of biomarker assays

World CDx Track

Built for **diagnostic, precision medicine** and **commercial** leads, this stream will provide insight into the maturation of disruptive technology. Simultaneously, the World CDx track will tackle obstacles in reimbursement and commercialization to ensure the maximization of a diagnostic's global footprint and implementation in healthcare.

Be at the pinnacle of crucial and candid conversation to discover why, how and when to adopt a CDx strategy early in your drug development programs. Join CDx leaders to ensure you have the right collaboration to ultimately deliver a CDx strategy that brings true value to the market penetration and share of your drug.

Key topics to be addressed:

- **AstraZeneca** & **Autolus** show how they are thinking about commercializing diagnostics as fit-for-purpose in the real-world healthcare setting
- **GSK** discuss overcoming bottlenecks in reimbursement and access to streamline commercialization of diagnostic-enabled therapeutics
- **Inova** & **Clarity Foundation** advocate the role of clinician and patient perspectives in the advancement of precision medicine and diagnostic testing
- **Wave Life Sciences** & **TÜV SÜD** present case studies on accelerating the demonstration of clinical utility and regulatory success for drug-Dx products
- **Bristol-Myers Squibb** lead the debate on Rx-Dx business models and partnership alignment to further precision medicine collaboration

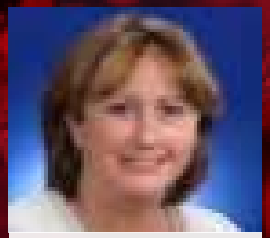
Your Expert Speakers: Drug Developers

Christina Bender
Exploratory Biomarker Lead, WW Oncology Commercialization
Bristol-Myers Squibb

Michael Burczynski
Senior Director & Head, Translational Medicine
Teva

Meggan Czapiga
Director, Companion Diagnostics
Autolus

Emmanuelle di Tomaso
Head, Biomarkers Oncology
Bayer



Julie Engel
Head, Molecular Diagnostics
Cyteir Therapeutics

Jaya Goyal
Vice President, Bioanalytical, Pharmacology & Biomarker Development
Wave Life Sciences

Shirin Khambata Ford
Head, Precision Medicine, Clinical Biomarkers & Companion Diagnostics
Daiichi Sankyo

Kate Haviland
Chief Operating Officer
Blueprint Medicines

Philina Lee
Vice President, Commercial Strategy & Operations
Blueprint Medicines

Elizabeth O'Day
Founder & CEO
Olaris Therapeutics

Matt Onsum
Head, Diagnostics, Bioanalytics & Biomarkers
Seattle Genetics

Maria Orr
Franchise Leader, Oncology Companion Diagnostics, Precision Medicine & Genomics
AstraZeneca

Terri Ozegovich
Commercial Head, Oncology Companion Diagnostics
AstraZeneca

Omar Perez
Head, Precision Medicine & Diagnostics
GSK

Julie Ramage
National Account Director Diagnostics
Pfizer

Gerard Sanderink
Global Head, Biomarkers & Clinical Bioanalyses
Sanofi

Mitch Raponi
Vice President, Biomarker Development & Translational Research
BeiGene

Vijaya Tirunagaru
Vice President & Head, Biology & Non-Clinical Development
Rain Therapeutics

Alice Walsh
Head Analytics Innovation, Oncology Translational Bioinformatics
Bristol-Myers Squibb

Describe your experience at CB & CDx Boston 2018 in 3 words:

"Collaborative, visionary, innovative"

Riadh Lobbardi, Blueprint Medicines

Associations, Academics & Advocates

Timothy Cannon
Medical Oncologist & Clinical Director, Inova Schar Cancer Institute Molecular Tumor Board
Inova Health System

Michele Cleary
CEO
The Mark Foundation for Cancer Research

Joseph Ferrara
President & CEO
Boston Healthcare

Antje Hoering
President & CEO
Cancer Research And Biostatistics

Ryan Keeling
Chief Innovation Officer
Diaceutics

Lauren Leiman
Executive Director
BloodPAC

Kenna Mills Shaw
Executive Director, Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy
MD Anderson Cancer Center

Andreas Stange
Vice President, Global IVD
TUV SUD

Deborah Zajchowski
Scientific Director
The Clearity Foundation

Describe your experience at CB & CDx Boston 2018 in 3 words:
"A great event" **Andreas Stange, TÜV SÜD Japan**

Diagnostic & Technology Developers

Bonnie Anderson
Chairman & CEO
Veracyte

Kathryn Becker
Global Marketing Director, Companion Diagnostics
Abbott Molecular

Sara Call
Business Development
Quansys Biosciences

Andrew Crenshaw
Global CDx Discipline Director
Q² Solutions

Corinne Danan
EVP, Partnerships BU
HalioDx

Jim Godsey
Vice President, R&D, Clinical Sequencing, Division
Thermo Fisher Scientific

Claire Huguet
Head, Biomarker Services
Randox

Stefan Jellbauer
Technical Liaison, Translational Applications
Mitra Biotech

Wendell Jones
Principal Bioinformaticist & Scientific Advisor
Q² Solutions

Diagnostic & Technology Developers

Bill Keating
Head of Pharma Business Development
Philips Digital and Computational Pathology

Mark Kiel
Co-Founder & Chief Scientific Officer
Genomenon

Gillian Livock
Vice President, Corporate Business Development
Definiens

Dawn McHugh
Vice President, Business Development, Personalized Diagnostics
Corgenix

David Messina
Chief Operating Officer,
Cofactor Genomics

Jeffrey Miller
CSO & CEO
Invivoscribe Technologies

Philippe Mourere
Senior Vice President, Commercial Operations
Ultivue

Courtney Nicholson
Director, Business Development
Abcam

Dan O'Shannessy
Chief Scientific Officer
ANGLE

Hans-Christian Pedersen
Director, Business Development
Unilabs Denmark

Gary Pestano
Chief Development Officer
Biodesix

Lidija Pestic-Dragovich
Senior Director, CDx Pharma Services & Pharma Alliance
Roche Tissue Diagnostics

Aditya Rajagopal
Chief Technical Officer
ChromaCode

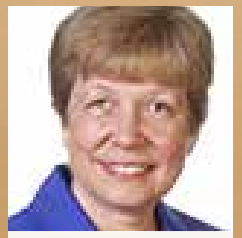
Jessica Riley
Senior Director, Companion Diagnostics, Business Development
Guardant Health

Mark Roberts
Senior Director, Diagnostics Development
Covance

Steven Rosen
Vice President, Business Development & Strategy
Elucida Oncology

Vishal Sikri
US General Manager
Biocartis

John Simmons
Vice President, Translation Medicine
PGDx



Cindy Spittle
Vice President, Development & Scientific Affairs
Molecular MD

Josh Stahl
Chief Scientific Officer
Archer Dx

Lawrence Weiss
Chief Scientific Officer
NeoGenomics Laboratories

Keith Wharton
Senior Medical Director
Leica Biosystems

Katarina Wikstrom
Head, US Operations
Almac Diagnostic Services

Jay Wohlgemuth
SVP R&D & CMO
Quest Diagnostics

Xiaolei Xu
Director
Global Regulatory Affairs, Companion Diagnostics
Agilent Technologies

Conference Day One | Wednesday September 11, 2019

8.20 Chair's Opening Remarks

Keynote Address: A Candid Look at Value, Adoption and Patient-Centricity in Precision Medicine

8.30 Keynote Address: Government, Policy & Socioeconomics – The Battle to Embed Precision Medicine at the Heart of Healthcare

Kate Haviland
Chief Operating Officer
Blueprint Medicines

- Is precision medicine currently delivering on its promise to patients?
- How do we better link the work we are doing in clinical development with the real world parameters for the best delivery of personalized healthcare?
- Weighing up the cost of biomarkers and diagnostics. With the expense of a biomarker/Dx route vs. traditional drug development route, are all stakeholders seeing value in this investment and is this ultimately leading to a better standard of care for patients?

Mark Roberts
Senior Director, Diagnostics Development
Covance

9.00 Achieving Global Commercialization of Companion Diagnostics to Enable Precision Therapeutics

- Discussing the continuum of biomarker development and how to align development with the preparation for achieving a global footprint
- What does global commercialization mean and how do we build a strategy for this in the context of companion diagnostics

Jessica Riley
Senior Director, Companion Diagnostics, Business Development
Guardant Health

9.30 Comprehensive Liquid Biopsy – Clinical and Commercial Use Cases

- Emerging data on ctDNA in clinical trials
- Using ctDNA for immunotherapy development
- Maximizing patient access commercially

10.00 Speed Networking

10.20 Morning Refreshments

Shirin Khambata Ford
Head, Precision Medicine, Clinical Biomarkers & Companion Diagnostics
Daiichi Sankyo

Kathryn Becker
Global Marketing Director, Companion Diagnostics
Abbott Molecular

10.50 Keynote Panel Discussion: Women In Precision Medicine

Coming soon. Uniting scientific and business leaders from all key stakeholders of the community, this keynote session will highlight and discuss the critical issues facing gender equality in the workplace and will provide actionable takeaways for increased advocacy in individual workplaces. Stay tuned!

Jay Wohlgemuth
SVP R&D & CMO
Quest Diagnostics

11.30 Closing Gaps in Care with Population Health Analytics and Community-Based Implementation Programs

- Analyzing the role of new technologies and advances in "big data" for generating insight for precision medicine
- How best to blend scientific data (i.e omic data) with data on social, environmental and behavioural influences
- Understanding how to utilize the wealth of data obtained from multiple stakeholders including pharma, labs, hospitals, community hospitals to accelerate utilization of precision medicine
- Integrating genomic and other patient data into clinical care to overcome barriers to access

Andrew Crenshaw
Global CDx Discipline Director
Q² Solutions

12.00 Adapting Clinical Trial Best Practices to a Complex Global CDx Landscape

- Evaluating the central laboratory as a key component for developing, validating and executing companion diagnostics globally
- Developing strong collaboration with pharmaceutical and IVD companies to streamline biomarker deployment in clinical trials and discussing the clinical validation of predictive biomarkers as CDx assays
- Describing the role of the central laboratory and some of the key attributes required when using traditional and more complex technologies across the globe

12.30 Networking Lunch

Biomarker Discovery & Translation

Discovering the Next Generation of Robustly Predictive Biomarkers

13.30 NMR-Metabolite-Resonance Signature Predicts HR+ Breast Cancer Patient Response to CDK4/6 Inhibitors

- Correlating metabolite expression profiles to clinical outcomes to identify a metabolic signature that could differentiate CDK4/6 responders and resistant patients with a predictive accuracy of > 90%
- Identifying independent signatures predictive of response for individual CDK4/6 inhibitors palbociclib and ribociclib
- Discussing a paradigm shift in the administration of CDK4/6 inhibitors wherein prior to treatment and during treatment patient plasma is screened to determine whether that individual patient is responsive or resistant to a CDK4/6 inhibitor

Elizabeth O'Day, Founder & CEO, **Olaris Therapeutics**

Clinical Biomarker Development

Advancing Clinical Validation of Predictive Biomarkers

13.30 Designing Biomarkers and Companion Diagnostics for Antibody-Drug Conjugates

- Discussing predictive biomarker development for ADC therapeutics
- How to best navigate the complex process of translating biological data into a predictive biomarker utilized in pivotal clinical trial
- Showcasing Seattle Genetics' current companion diagnostic projects

Matt Onsum, Head, Diagnostics, Bioanalytics & Biomarkers, **Seattle Genetics**

Drug-Dx Commercialization

Overcoming Bottlenecks in Commercialization: From Reimbursement to Market Access

Moderated by: Steven Rosen, Vice President, Business Development & Strategy, **Elucida Oncology**

13.30 Key Market Access Challenges For Drug-IVD Commercial Success

- Evaluating the pros and cons of commercial viability for established vs cutting edge technology: what are the key considerations for commercial success?
- Debating the current reimbursement paradigm for the spectrum of IVD tests to assess viability of commercial penetration

Omar Perez, Head, Precision Medicine & Diagnostics, **GSK**

14.00 The Increasing Adoption of RNA-Seq as a Biomarker Discovery Tool and How to Solve the Complex Data Challenge

- The opportunity of RNA-Seq as a biomarker discovery tool
- Challenges in analysing and interpreting large volumes of complex RNA-Seq data
- How Almac Diagnostic Services' claraT report solves this challenge, simplifying the process whilst saving time & resource
- Detailed overview of the claraT reporting solution, including cohort and sample report interpretation
- Case Study: In a real world RNA dataset utilising claraT

Katarina Wikstrom, Head, US Operations, **Almac Diagnostic Services**

14.00 High Definition Multiplexing for Biomarker Strategies & CDx Development

- Unravelling the complexity of biological samples
- Combining multiplexed detection with spatial resolution to analyse heterogeneous cell populations and colocalize multiple markers in scarce samples
- Discussing the impact of multiplexing on tissue integrity and throughput

Philippe Mourere, Senior Vice President, Commercial Operations, **Ultivue**

14.00 Democratization and Globalization of Next Generation Sequencing for Companion Diagnostics

- Outlining the democratization of NGS in routine clinical testing and as a commercially viable CDx for drug development
- Evaluating biomarker discovery and translational research efforts driving the need for new solutions with potential to become a predictive CDx in the future
- Showcasing a holistic approach to enable success through the whole spectrum, from discovery through development of companion diagnostics

Jim Godsey, Vice President, R&D, Clinical Sequencing, Division, **Thermo Fisher Scientific**

14.30 Utilizing In Silico Approaches to Design Translational Medicine Strategies

- Harnessing transcriptomic data sets for biomarker identification in Asthma
- Showcasing an approach for data analysis to understand and characterize subsets of Asthma
- Discussing the discovery of a biomarker of a subtype of Asthama with high unmet need

Michael Burczynski, Senior Director & Head, Translational Medicine, **Teva Pharmaceuticals**

14.30 PARPi Development in Prostate Cancer: Limitations and Opportunities for Companion Diagnostic Development

- PARP inhibitors have demonstrated clinical utility in treating metastatic prostate cancer due to enrichment of DNA repair deficiencies in a subset of these tumors
- NGS testing of tumor tissue to identify patients with BRCA defects or other homologous recombination repair deficiencies has limited utility due to limited amount of tumor isolated from bone biopsies
- Opportunities of developing liquid biopsy-based companion diagnostics for this disease will be discussed

Mitch Raponi, Vice President, Biomarker Development & Translational Research, **BeiGene**

14.30 Payer Perspective: Demonstrating Value of Next Generation Biomarkers & Diagnostics for Precision Medicine

- Evaluating the impact of the CMS guidance on NGS reimbursement: From IVD to LDT, is there now a path forward for the commercial viability of these tests?
- What is the weighting of clinical evidence vs RWE needed
- A guide to generating evidence either in conjunction with or post trial to maximize the case for diagnostic reimbursement

Payor presentation confirming

15.00 Advancing the Personalization of Cancer Treatment and Care

- Delivering powerful predictions for truly personalized cancer treatment selection and enhanced drug development
- Discussing the ex vivo modelling of the tumor microenvironment to advance IO precision medicine development

Stefan Jellbauer, Technical Liaison, Translational Applications, **Mitra Biotech**

15.00 Multiplex Immunohistochemistry for Precision Medicine

- Discussing mIHC for the development of robust biomarkers
- Evaluating the challenges with mIHC from an implementation and clinical approval standpoint
- Showcasing the benefits to the user community and what needs to be done to ensure market and regulatory approval of these platforms

Courtney Nicholson, Director, Business Development, **Abcam**

15.00 Driving CDx Uptake and Drug Prescription: Challenges, Strategies and Case Stories

- Identification of key challenges for CDx introduction and impact on drug prescription
- Evaluating the laboratory partnered approach (Lx)
- Discussing alignment of Dx, Rx and Lx commercialization plans
- Showcasing case studies on market access

Hans-Christian Pedersen, Director, Business Development, **Unilabs Denmark**

15.30 Afternoon Refreshments & Networking

Accelerating the Translational from Exploratory Signature to Clinical Biomarker Candidate

16.00 Improving the Validation and Utility of Multiplexed Assays

- Using predictive biomarkers to better understand disease
- Complex biomarker profiles providing insights into complex health states
- Development of a cardiac prognostic multiplex biomarker assay

Sara Call, Business Development, **Quansys Biosciences**

16.10 Strategizing Early Biomarker Decisions for Future Precision Medicine Success

- Utilizing response rate and predictive biomarkers in early strategy decision making
- From target engagement to surrogate endpoints
- Discussing Sanofi's current thinking on the strategies for biomarker-CDx co-development
- Less is more: How harnessing fewer, yet more informed samples and biomarkers in large population sizes can be more beneficial than using a multitude

Gerard Sanderink, Global Head, Biomarkers & Clinical Bioanalyses, **Sanofi**

16.40 Discussing the Immunogram for IO Precision Medcine

- Debating scoring systems and cut offs for immuno-oncology biomarkers
- Discussing the development of single and combined immunotherapies and the context dependency upon tumor immune microenvironment status

Corinne Danan, EVP, Partnerships BU, **HalioDx**

Executing Biomarker-Driven & Diagnostic-Enabled Clinical Trials

16.00 Biomarker Multiplexing for Early Detection of Bladder Cancer

- Discussing intended use for early detection of bladder cancer patients
- Evaluating the biomarker selection process
- Discussing the technical characteristics of the panel
- Showcasing pilot study data

Claire Huguet, Head, Biomarker Services, **Randox**

16.10 A Guide to Biomarker-Driven Precision Medicine Clinical Trials

- Discussing the landscape of biomarker use in clinical trials
- Showcasing recent data from MDACC and GENIE re: the percentage of patients with a potential biomarker or without and what the field is doing in terms of next steps for these patients
- Putting all of this into the context of precision oncology decision support

Kenna Mills Shaw, Executive Director, Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy, **MD Anderson Cancer Center**

16.40 Successes and Challenges in Pre-Market Registration and Approval of Companion Diagnostic in Global Markets

- Agilent experiences and alignment with co-development guidance in obtaining premarket approvals with original submissions as well as expansion of indications
- CDx Regulatory considerations in global markets
- Challenges in assay development and registration to meet pharma partners needs

Xiaolei Xu, Director, Global Regulatory Affairs, Companion Diagnostics, **Agilent Technologies**

Commercializing Diagnostics as Fit-For-Purpose in the Real-World Healthcare Setting

16.00 Companion Diagnostic Co-Development and the Value of Globally Distributed IVD Kits for Market Adoption

- Discussing the complexity of companion diagnostic development and how this process has changed with the advent of NGS
- Highlighting kitted IVD globally distribution models to drive future testing volume and patient identification. Where is the market today and what does the future hold?

Josh Stahl, Chief Scientific Officer, **Archer Dx**

16.10 From Turnaround Time to Distribution: Addressing the Greatest Bottlenecks in Diagnostic Testing in Healthcare

- Assessing the impact of platform cost and turn around time on the potential commercialization of a diagnostic-enabled therapeutic
- What impact does a centralized vs decentralized approach have on adoption and penetration?
- Evaluating strategies to prepare for day one launch, raise awareness, improve education and maximize commercial success of diagnostic-enabled precision medicines

Terri Ozegovich, Commercial Head, Oncology Companion Diagnostics, **AstraZeneca**

16.40 Multiplex IHC Development Updates and Impact on Commercialization

- Discussing next generation tissue assays and digital pathology for multi-marker approaches
- Highlighting multiplexing as a tool to innovate medicines in precision oncology

Lidija Pestic-Dragovich, Senior Director, CDx Pharma Services & Pharma Alliance, **Roche Tissue Diagnostics**

17.10 Developing Biomarkers for an NTRK Inhibitor in a Tissue Agnostic Indication

- From proof-of-concept to clinical: Showcasing the development of biomarkers for TRK inhibitors
- How to best design and execute an exploratory biomarker program to quickly inform a pivotal study
- Lessons learnt to develop rare biomarkers in tissue agnostic manner

Emmanuelle di Tomaso, Head, Biomarkers Oncology, **Bayer**

17.10 Integrating Predictive Biomarkers in Phase III Clinical Trial Designs

- Discussing the strengths and weaknesses of different confirmatory phase III trial designs in the era of precision medicine in oncology
- Presenting recommendations about when specific trial designs are most appropriate
- Evaluating umbrella and basket trials that test multiple therapies simultaneously and identify biomarker-matched subgroups of patients who are mostly likely to benefit from novel targeted treatments

Antje Hoering, President & CEO, **Cancer Research And Biostatistics**

17.10 Key Considerations for Accelerating the Integration of Diagnostic Testing

- Building commercial diagnostic considerations earlier into clinical development Discussing infrastructure and the operationalization of CDx testing internationally
- Delivering NGS diagnostics in oncology, the value of panel based diagnostic testing, regulatory considerations for NGS panel based test development and approval

Maria Orr, Franchise Leader, Oncology Companion Diagnostics, Precision Medicine & Genomics, **AstraZeneca**

17.40 Panel Discussion: Multidimensional Biomarkers and Machine Learning Based Approaches for Precision Medicine

- Discussing the utility of multidimensional biomarkers in the translational and clinical space
- Distilling down complex biological signals into actionable biomarkers utilizing machine learning
- Evaluating the enhanced role of multiplexing in early biomarker selection

Bonnie Anderson, Chairman & CEO, **Veracyte**
David Messina, Chief Operating Officer, **Cofactor Genomics**
Wendell Jones, Principal Bioinformaticist & Scientific Advisor, **Q² Solutions**

17.40 Panel Discussion: Executing Biomarker Driven & Diagnostic Enabled Clinical Trials

- Discussing the standard of care in precision immunotherapy – how are the use of biomarkers and diagnostics evolving to define response?
- How to best translate "continuum" biomarkers into robust patient selectors
- Analyzing timings for submitting PMAs and 510ks for companion diagnostics: When's best to streamline clinical studies?
- How will precision medicine trials evolve given the hyper-competition for patient populations and sample biopsies?
- Is there a better way to manage studies and patient recruitment, particularly where a biomarker/disease is being heavily investigated, to get the maximum impact from every new trial?
- What Dx strategy do we use to support clinical drug development in cases of accelerated approval?
- How do you best match the assay used in the clinical study with the assay used in clinical practice?

Christina Bender, Exploratory Biomarker Lead, WW Oncology Commercialization, **Bristol-Myers Squibb**
Shirin Khambata Ford, Head, Precision Medicine, Clinical Biomarkers & Companion Diagnostics, **Daiichi Sankyo**
Gillian Livock, Vice President, Corporate Business Development, **Definiens**
Alice Walsh, Head Analytics Innovation, Oncology Translational Bioinformatics, **Bristol-Myers Squibb**

17.40 Panel Discussion: Commercializing Diagnostics as Fit-For-Purpose in the Real-World Healthcare Setting

- Discussing International strategy for implementation of diagnostics in healthcare to create a global footprint
- Debating targeted vs broad panels and their comparisons for real-world application
- What are the respective roles and areas of improvement for CLIA and FDA regulation to drive advances in testing?
- How do you channel clinical and post market evidence generation to optimize access and uptake?
- Assessing the impact of platform cost pricing and TAT on the potential global commercialisation of a diagnostic-enabled therapeutic
- What impact does a centralized vs decentralized approach have on adoption and penetration?
- Discussing the role of the lab and their impact on precision medicine nearer patient care

Philina Lee, Vice President, Commercial Strategy & Operations, **Blueprint Medicines**
Meggan Czapiga, Director, Companion Diagnostics, **Autolus**
Speaker confirming, Agilent Technologies
Julie Ramage, National Account Director, Diagnostics, **Pfizer**

18.25 End of Day One

18.30 10th Anniversary Clinical Biomarkers & World CDx Evening Reception

Conference Day Two | Thursday September 12, 2019

7.50 Chair's Opening Remarks

Plenary Address: Showcasing Cutting Edge Innovation in Precision Medicine & the Impact on Patient Care

Michele Cleary
CEO
The Mark Foundation for Cancer Research

8.00 The Role of Philanthropy in Delivering Breakthroughs for Cancer Patients

- Discussing critical barriers for delivering treatments that are optimal for each individual cancer patient, namely gaps in the discovery and development of platforms for early detection and intervention, forecasting resistance to therapies, tracking patient trajectories, and diagnosing recurrence
- Highlighting obstacles in translating data and platforms to practical clinical applications as well as in increasing uptake among end-users
- Showcasing our collaboration with the cancer research community to identify critical unmet needs and mechanisms to support highly innovative solutions
- Rapidly establishing a robust portfolio of funded projects poised for near-term patient benefit and centered on novel technology-driven insights difficult to achieve with conventional strategies

Lawrence Weiss
Chief Scientific Officer
NeoGenomics Laboratories

8.30 Cradle to Grave – CDx Development Lifecycle Case Studies

- Evaluating the key considerations for being day one ready - a focus on PD-L1
- PIK3CA cast study – discussing the full spectrum of CDx development from bench to bedside
- Perspectives on lessons learned and future paradigms for diagnostic development

Cindy Spittle
Vice President, Development & Scientific Affairs
Molecular MD

9.00 Advancements in Immuno-Oncology Patient Selection Through the Use of Multi-Diagnostic Approaches Designed to Interrogate the Tumor Microenvironment

- Advances in clinical research underscore the importance of new markers to assess immune infiltration and abnormal activity in cellular pathways, including DNA damage repair and DNA replication
- Precise molecular tests which can pinpoint the right biomarkers to predict patient response are crucial to the clinical success of an immune-oncology candidate.
- Data presentation on the potential utility and performance of tumor mutation burden (TMB), microsatellite instability (MSI), and gene expression for tumor infiltration (TILs)

Ryan Keeling
Chief Innovation Officer
Diaceutics

9.30 How Can We Use Data More Intelligently to Improve Companion Diagnostic Commercialization?

- Discussing data requirements to commercialize CDx
- What gaps exist in the data?
- How can we fill in those gaps to ensure seamless test integration?
- Showcasing most effective uses for available testing data
- Leveraging data to drive ROI & improve patient care

Dan O'Shannessy
Chief Scientific Officer
ANGLE

10.00 Multiplexed Analysis for Complete Liquid Biopsy Solutions

- Discussing highly sensitive techniques for small samples and harvested rare cells
- Harnessing clinically useful CTC liquid biopsy tests for treatment and patient outcomes
- Future trends for CTC liquid biopsies as powerful precision medicine tool

10.30 Morning Refreshments & Networking

Biomarker Discovery & Translation

Improving the Validation & Standardization of Biomarker Assays to Advance Development & Adoption

11.00 Standardization and Validation: The Challenges Associated with Establishing Accuracy of Liquid Biopsy Assays

- Discussing BloodPAC's efforts to develop standards to improve the reliability and reproducibility of liquid biopsy testing
- Understanding how to best safeguard result reproducibility across geographies to avoid false readings
- Exploring the pre-competitive development of standard materials to create gold standards for certain biomarkers and indications

Lauren Leiman, Executive Director, **BloodPAC**

11.30 Development of a Blood-Based Clinical Dx for a ssPMA

- Evaluate key challenges with bringing a liquid biopsy from concept to commercialization
- Understand the developmental timelines and execution to achieve clinical readiness
- Discuss PMA/510k and distribution readiness for liquid biopsy assays

Gary Pestano, Chief Development Officer, **Biodesix**

Clinical Biomarker Development

Achieving Regulatory Success for Diagnostic-Enabled Precision Medicines

11.00 Translating New Technologies into Personalized Medicine and Diagnostic Sphere

- Introducing the promise of precision medicine in molecular target therapeutics against diseases such as Huntington's disease (HD)
- Evaluating allele-specific targeting of the mHTT transcript as a personalized approach to HD treatment
- Discussing bioanalytical and bioinformatic methods, approaches and strategies used for the development, validation and implementation of a long-range sequencing assay to prescreen subjects for enrollment into clinical studies

Jaya Goyal, Vice President, Bioanalytical, Pharmacology & Biomarker Development, **Wave Life Sciences**

11.30 Streamlined CDx™: A Pipeline that Accelerates Drug Approvals

- Reducing the complexity and risk of CDx development
- Invivoscribe's Streamlined CDx™ program has been shown to collapse the development timelines of biomarker assays, improve and accelerate selection of more consistent patient cohorts
- Establishing earlier international submissions and accelerated FDA, EMA and PMDA approvals of new targeted therapies

Jeffrey Miller, CSO & CEO, **Invivoscribe Technologies**

Drug-Dx Commercialization

Clinician & Patient Perspectives on the Advancement of Precision Medicine & Diagnostic Testing

11.00 Molecular Medicine in a Community Practice

- Molecular Tumor Boards are an effective means of allowing end users to more effectively incorporate molecular results into clinical decision making
- Clinical trials designs are now meeting community practices desire to match patients to treatments based on molecular subtype rather than tissue of origin
- While most patients are treated in community settings, molecular tests are often not built with community practices in mind as they typically originate from academic medical centers

Timothy Cannon, Medical Oncologist & Clinical Director, Inova Schar Cancer Institute Molecular Tumor Board, **Inova Health System**

11.30 Companion Diagnostics in Immuno-Oncology: Global Commercial and Partnership Considerations

- The testing paradigm in immuno-oncology is growing increasingly complex, moving beyond PD-L1, to include mismatch repair, microsatellite instability, tumor mutational burden, and others
- Key commercialization considerations for drug and test innovators, including balancing test access and quality, and embedding CDx global commercial considerations in pharma and diagnostic company partnerships will be highlighted

Joseph Ferrara, President & CEO, **Boston Healthcare**

12.00 From Big Pharma to Innovative Start-up – Challenges for Precision Medicine

- Resources – is there enough money and how long will it last?
- Personnel – how can we get the help we need?
- Outsourcing – who to trust; cost; so many contracts and capabilities presentations
- Partnering – identifying the right partners and forming strategic alliances
- The right balance between basic research and development activities
- Educating the organization
- And here come the Investors!

Julie Engel, Head, Molecular Diagnostics, **Cyteir Therapeutics**

12.30 Advancing RNA-ISH Detection in Companion Diagnostics

- Advantages and applications of in situ RNA detection
- Collaboration of key stakeholders for co-development of a drug and RNA-ISH diagnostic device
- Regulatory and commercial considerations for new innovative technologies

Keith Wharton, Senior Medical Director, **Leica Biosystems**

13.00 Impact of Digital and Computational Pathology on Precision Medicine

- Introducing digital pathology and its potential applications for precision medicine
- Barriers being to overcome to drive global adoption
- Efficiency implications for future clinical trials

Bill Keating, Head, Pharma Business Development, **Philips Digital and Computational Pathology**

13.10 Lunch & Networking

12.00 IVDR: Where Are We? The Notified Body Perspective

- Implementing the IVDR: The view from a notified body
- The role of notified bodies on approvals under new regulation
- Discussing the effect of a decrease in accredited notified bodies and how you can make preparatory steps now to avoid last minute bottlenecks
- Evaluating your regulatory options for Dx approval, from IVD to LDT

Andreas Stange, Vice President, Global IVD, **TÜV SÜD**

12.30 Democratizing Precision Medicine

- Targeted Companion Diagnostics today are too complicated, too slow and too expensive
- HDPCR translates sequencing discovery into low cost precision medicine diagnostics using highly multiplexed digital PCR
- HDPCR enables broad access to oncology and genetic screening

Aditya Rajagopal, Chief Technical Officer, **ChromaCode**

13.00 Immunoassays in Personalized Medicine –Is It Time for Circulating Proteins to Join the Party?

- Proteomics research has led to the discovery of new therapeutic targets and circulating protein biomarkers for disease detection, prognosis and therapy response
- Circulating protein biomarkers gives the immunoassay a new role in personalized medicine, and can provide clinicians with more diagnostic tools to detect, select for treatment, and monitor disease

Dawn McHugh, Vice President, Business Development, Personalized Diagnostics, **Corgenix**

13.30 Lunch & Networking

12.00 Informing Patient Treatment Decisions: The Clearity Foundation Experience

- Overview of ovarian cancer histotypes, genomics, targeted therapy, and CDx
- Clearity provides patients with individualized treatment information based on their clinical situation and tumor characteristics
- Phone consults and online tools help patients understand results from biomarker testing and identify standard of care and clinical trial options to discuss with their medical team
- Examples illustrate how patient education/ engagement can positively impact outcomes

Deborah Zajchowski, Scientific Director, **The Clearity Foundation**

12.30 Maximizing Patient Access to Unlock the Potential of Precision Medicine

- Discussing considerations and choice of CDx strategy for novel precision medicines
- Evaluating and deciding upon the variety of diagnostic technologies
- Deciding between solutions for centralized versus decentralized testing
- Discussing the development of a fully automated, highly accurate MDx platform
- Demonstrating the value of such a platform to the advancement of patient access to ensure the right treatment at the right time

Vishal Sikri, US General Manager, **Biocartis**

13.00 Characterizing Targeted Cancer Therapies via a Structural Alteration Database

- What is the best way to understand the pathophysiology of a pathway or disease?
- How do you identify gene fusion partners to facilitate the development of targeted drugs?
- Why is it important to understand the genomic landscape of a pathway or disease prior to selecting patient cohorts for clinical trials?

Mark Kiel, Co-Founder & Chief Scientific Officer, **Genomenon**

13.10 Lunch & Networking

Discovering & Developing Novel Biomarkers in New Areas of Precision Medicine

14.00 Standardization of NGS for Oncology Trials and Practice–The PGDx elio Model

- Discussing the role of NGS testing in informing clinical decisions and enrolling clinical trials, including biomarkers like MSI and Tumor Mutational Burden (TMB) for immune therapies
- Developing IVD NGS assays optimized for complex and comprehensive tumor profiling applications
- Evaluating ctDNA and tissue assays designed to empower local laboratories, bringing NGS technologies into standard of care for patients worldwide

John Simmons, Vice President, Translation Medicine, **PGDx**

14.10 Accurate Plasma Biomarker Detection for Clinical Trials & Clinical Practice: Why Sensitivity Matters

- Advantages of plasma mutation testing for patient stratification and response monitoring
- OncoBEAM and SafeSEQ technologies: Overcoming the technical challenges of low frequency mutation detection
- Advantages of focused biomarker detection

Speaker confirming, Sysmex Inostics

14.40 STEAP4 ISH Diagnostics for Tarloxotinib Activation in EGFR/HER2 Mutant Cancers

- Discussing best practice for optimizing and validating an ISH assay
- Correlating STEAP4 mRNA as a biomarker for Tarloxotinib patient stratification and clinical enrolment

Vijaya Tirunagaru, Vice President & Head, Biology & Non-Clinical Development, **Rain Therapeutics**

Analytical Advancements to Power Biomarker Development

14.00 Creating Predictive Diagnostics Measuring Tumor Infiltrating Immune Cells (TIICs)

- Discussing the presence of Tumor Infiltrating Immune Cells (TIICs) as predictive of a higher response rate for immuno-oncology therapies
- How to best overcome challenges in the inability to accurately and reproducibly measure TIICs in cancer biopsies in the clinical environment
- Introducing methods for quantification of TIICs in cancer biopsies which are suitable for the clinical environment and regulatory approval

Speaker confirming, Flagship Biosciences

14.10 Leveraging AI to Drive Advances in Precision Medicine, Diagnostic Development and Real-World Impact

- How can we harness advances in predictive analytics and algorithmic development to elucidate actionable biomarkers from complex biology
- How can real-world data be harnessed to create more clinically meaningful biomarkers?
- How are we creating new opportunities in the identification of new therapies using machine learning and other predictive tools?

Speaker confirming shortly

Addressing Rx-Dx Business Models & Partnership Alignment to Further Precision Medicine Collaboration

14.00 Roundtable Discussion:

- How will advancements in platform technology and cost impact the diagnostic business model?
- Stayin' Aligned: Developing deeper, non-transactional relationships between Rx and Dx to better align co-development
- Discussing innovation in revenue models, novel revenue streams and how deal structures will evolve over time. What does great look like?
- How do we "deal" with the issues of exclusivity? What should be the industry standard moving forward?
- Addressing the risk:value scale for precision medicine stakeholders
- Non-traditional partnerships - How do you partner outside of your formal CDx provider to gain access to testing?

Moderated By: Christina Bender, Exploratory Biomarker Lead, WW Oncology Commercialization, **Bristol-Myers Squibb**

15.10 End of Day Two & Close 10th Clinical Biomarkers & World CDx Boston 2019

PRE-CONFERENCE WORKSHOPS

IN PARTNERSHIP WITH

GXEngage

In addition to the two main conference days, the 10th Clinical Biomarkers & World CDx Boston summit will have two pre-conference workshop days.

Each day will have 4-hours of deep dive workshops. Workshops are free to attend and subject to the workshop organizers final approval. If you would like to be considered for these sessions please email **Fionnuala.Lane@hansonwade.com**

PRE-CONFERENCE AGENDA

	Monday September 9	Tuesday September 10
AM	COMING SOON	Diaceutics
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TOP 3 BENEFITS OF ATTENDING:

1. Advance the clinical validation of predictive biomarkers
2. Accelerate the development and approval of novel precision medicine candidates
3. Streamline commercialization and access for diagnostic enabled therapeutics

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Package Details	Register & Pay Before 06/28/19	Pre-Event Registration	On The Door
Drug Developer* (Conference Only)	$1,799.00 **(SAVE $700)**	$2,199.00	$2,499.00
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*Must have a drug candidate within a development pipeline or market approved compound

Describe your experience at CB & CDx Boston 2018 in 3 words:

"Best one yet."
Mike Gorman, Sysmex Inostics

"Useful partnership-oriented networking."
Sri Venkatram, AbbVie

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