4th Annual

BOOK EARLY AND SAVE UP TO $700

WORLD CDx

Boston 2013

November 12-15 2013

Accelerate Speed to Market

TRACK 1:
CLINICAL BIOMARKERS

TRACK 2:
TECHNOLOGY APPLICATIONS

TRACK 3:
CDx COMMERCIALIZATION

> "Expertise from thought leaders is rarely so freely given, or as earnestly debated"
>
> CHI Center for Translational Research

52 Industry Experts:

Lawrence Lesko
Clinical Professor, Director, Center for Pharmacometrics & Systems Pharmacology
University of Florida

Scott Rairigh
Global Marketing Leader, Companion Diagnostics
Janssen

Devon Campbell
Director, Head of Engineering & Systems
Novartis Molecular Diagnostics

George Bashirians
Director, Diagnostics Lead, Clinical Research & Precision Medicine
Pfizer

Sponsors:

PrimeraDx The Multiplex PCR Company
ALMAC
VENTANA a member of the Roche Group
PangaeaBiotech S.L.
Dako
Abbott Molecular
AFFYMETRIX
QIAGEN
BOSTON HEALTHCARE
AsuraGen

Tel: +1 212 537 5898 | **Email:** info@hansonwade.com | **www.world-cdx.com**

hansonwade

WELCOME TO WORLD CDx:

A Note from the Chairman

Dear Friends and Colleagues,

As scientists working in the exciting field of companion diagnostics, we each have the opportunity to realize personalized medicine for patients. As passionate researchers we strive each and every day to make the discoveries that are critical for evolving Precision Medicine from objective to reality. To achieve this goal, we must come together as a community and share what has worked well and what has not, such that we can move forwards as an industry.

To realize the vision of Precision Medicine and to perform the difficult experiments required to develop and commercialize new diagnostics, close partnership across key functions in the healthcare continuum is required. **World CDx** is *the* meeting which facilitates these connections by bringing together large and small enterprises with representatives from the clinical, scientific, commercial and diagnostic communities. With such a diverse attendee group and with numerous opportunities to network, I find the opportunity to meet with current and future colleagues to be as valuable as the presentations.

I hope you are able to join us for this exciting discussion and look forward to meeting, and welcoming you to Boston.

Mark Curran
Janssen
Chairman of World CDx

Attending companies for 2013 include:

Abbott Molecular, MERCK, biogen idec, janssen, MERRIMACK PHARMACEUTICALS, AstraZeneca, CLOVIS ONCOLOGY, Eisai, ALMAC, BAYER, Asuragen, AFFYMETRIX, NOVARTIS, gsk GlaxoSmithKline, Bristol-Myers Squibb, astellas Leading Light for Life, PangaeaBiotech s.l., PrimeraDx The Multiplex PCR Company, QIAGEN, Roche

> **"Successful in bringing together pharma and diagnostics for information sharing, discussion and networking. Very informative, good representation, great networking."**
>
> Abbott Molecular

> **"Excellent cross section of core science, regulatory, commercialization and project management from both pharma and diagnostic companies. Very educational."**
>
> Eli Lilly

> **"One of the best meetings I've attended. Outstanding!"**
>
> Merck

> **"An eye-opening and extremely valuable experience, especially for those new to the field."**
>
> Novartis Molecular Diagnostics

> **"Crash course introduction led by top thought experts in the field with excellent networking opportunities."**
>
> Biogen Idec

WORLD CDx Boston 2013 November 12-15 2013 | **Boston MA**

BENEFITS OF ATTENDING:

The Definitive Meeting for Fuelling Rx/Dx Collaborations

World CDx is bursting with drug and diagnostic developers who share your passion for realizing personalized medicine through companion diagnostics.

World CDx recognizes the immense value of face-to-face time with your peers. That's why the agenda is overflowing with networking opportunities, to ensure you have the conversations you need to **secure productive and long lasting partnerships.**

Whether you are part of an internal diagnostic power-house or seeking established partners to join forces with, you can be sure that **this is where the action happens**.

Over 100 industry participants will be coming together to meet and learn from each other. Your two days at **World CDx** will be packed full of opportunities to **share and reflect on the field's experiences in order to advance your own research**.

Benefit from the **dynamic Rx/Dx balance in attendance** to ensure the most productive partnership discussions can begin.

Top 10 reasons to attend **World CDx Boston** 2013:

1. Meet and network with the **world's leading drug and diagnostic developers**, as they come together to actively expand cross-industry collaborations
2. **Improve the integration of your biomarker strategies** into early drug discovery to progress your companion diagnostic programmes
3. Be part of a dynamic community. Make long-lasting contacts which will lead to **new opportunities and potential business partnerships**
4. Interact with scientists with exactly the same job as you to **be confident your contribution to CDx development is going to deliver success**
5. Learn how others are co-ordinating communications and pre-submissions with the FDA to put yourself in the best position to **achieve regulatory approval in the US**
6. Understand how you can **maximize ROI from next-generation sequencing technologies** by using them at the right time in development and achieving the best results in patient selection
7. Strengthen your biomarker hypotheses to **optimize your patient selection strategies** and reach out to patients you can be sure will respond
8. Explore the latest advances in sophisticated assay development to **secure more robust and controlled assays** for your diagnostics
9. Revisit your clinical trial designs to ensure they are **optimized for biomarker validation as well as supporting regulatory approval** for both Rx and Dx
10. Explore how a systems approach for your company could speed up your overall development and **reduce outsourcing costs**

> **"Outstanding meeting with first class speakers. I learned a lot and I will certainly recommend the meeting to my colleagues..."**
>
> Sanofi

SELECT YOUR TRACK:

World CDx is designed to **strengthen each link in your CDx development**. Supporting your programmes from biomarker discovery to CDx commercialization, the meeting will ensure every step in your development is as smooth as the next. To ensure you can access the practical advice and guidance you need to **maximize your contribution in your role**, this year **World CDx** has expanded to give you three tracks to choose from.

So select your track and **let your World CDx experience begin...**

TRACK 1: CLINICAL BIOMARKERS

Clinical Biomarkers will help you to **improve the integration of biomarker strategies** into early drug discovery to support your companion diagnostic programmes down the line.

Strengthen your biomarker hypotheses to understand which patients will respond and **optimize the performance of your predictive biomarkers in the clinic.**

Evaluate and validate predictive biomarkers with the potential for further CDx development to **ensure each clinical candidate has a complimentary biomarker.**

Featured Speakers:

Yoshiya Oda
President, Biomarkers & Personalized Medicine Core Function Unit
Eisai

Suso Platero
Director, Oncology Biomarkers
Janssen

Claudio Carini
Global Clinical Immunology/ Biomarkers Lead
Pfizer

TRACK 2: TECHNOLOGY APPLICATIONS

Technology Applications will explore the latest in sophisticated assay development to **achieve more robust and controlled assays for CDx development.**

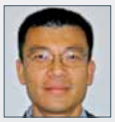
Overcome your development issues associated with validating multiplex assays and **advance your assay specificity, sensitivity, post-collection sample stability and instrument standardization.**

Ensure your data is the highest quality and learn how to implement biomedical informatics to **improve patient stratification, predictive modelling and biomarker qualification.**

Featured Speakers:

Robert Dunstan
Distinguished Investigator, Head, Translational Pathology Laboratory
Biogen Idec

Dianna Wu
Director & Head of Molecular Pathology & Flow Cytometry
Merck



Zhaohui Cai
Biomedical Informatics Director
AstraZeneca

TRACK 3: CDx COMMERCIALIZATION

CDx Commercialization will tackle every hurdle you face in getting your companion diagnostic from development onto the market.

Understand how you can **support the regulatory approval for your CDx programs** by learning how others are successfully designing clinical trials and co-ordinating pre-submissions with the FDA.

Successfully implement CDx strategies with early establishment of key collaborations. Optimize relationships with partners and evaluate the latest successes in risk-sharing strategies to **deliver on essential timelines.**

Featured Speakers:

Peggy Carter
Director Regulatory Affairs
Novartis

Kenneth Emancipator
Director, Companion Diagnostics
Merck

Gianrico Farrugia
Director, Center for Individualized Medicine
Mayo Medical School

EXPERT SPEAKERS:

PLENARY SPEAKERS:

Salvatore DeSena
Director, Diagnostic Imaging
Bayer

Gianfranco de Feo
Senior Director, North American Regional Marketing
Affymetrix

Lawrence Lesko
Director, Center for Pharmacometrics & Systems Pharmacology
UCF College of Medicine

Jean-Claude Marshall
Laboratory Manager, Center for Translational Research

Jonathan Pan
Director, Oncology Companion Diagnostic & Disease Strategy
GSK GlaxoSmithKline

Doug Ward
Vice President & Lifecycle Leader, Companion Diagnostics
Ventana

Shane Weber
Director Diagnostics, Clinical Research & Precision Medicine
Pfizer

John Quackenbush
Professor, Bioinformatics
Dana-Farber Cancer Institute

Joe Walker
Senior Director, Companion Diagnostics & Pharmacogenomics
Daiichi-Sankyo

Rafael Rosell
Co-Founder, Chairman & Chief Scientific Officer
PangaeaBiotech

Lilly Kong
Chief Scientific Officer
PrimeraDx

Richard Watts
Vice President, Companion Diagnostic Partnerships
QIAGEN

Mark Curran
Vice President, Immunology Biomarkers
Janssen

Larry Brooks
Director, Business Model & Healthcare Innovation
Boehringer Ingelheim

Paul Ravetto
Director of Programme Management & Personalized Healthcare
QIAGEN

Jack Whelan
From Research Analyst to Research Advocate

TBC
Dako

> "Very good mix of speakers from various origins. Very valuable."
> UCB Pharma

TRACK 1 CLINICAL BIOMARKERS SPEAKERS:

Claudio Carini
Global Clinical Immunology/ Biomarkers Lead
Pfizer

Ann Kapoun
Vice President, Translational Medicine
OncoMed

Sharon Moulis
Principal Business Scientist
Merrimack

Yoshiya Oda
President, Biomarkers & Personalized Medicine Core Function Unit
Eisai

Suso Platero
Director, Oncology Biomarkers
Janssen

Oscar Puig
Biomarker & Experimental Medicine Leader, Translational Clinical Research Center
Roche

Mitch Raponi
Senior Director
Clovis Oncology

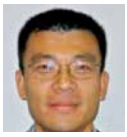
Austin Tanney
Scientific Liaison Manager
ALMAC

> "Great speakers, great networking and stimulating discussions."
> Sanofi

EXPERT SPEAKERS CONTINUED...

TRACK 2 TECHNOLOGY APPLICATIONS SPEAKERS:

Jonathan Beer
Manager, Systems Integration
NOVARTIS



Zhaohui Cai
Biomedical Informatics Director
AstraZeneca

Devon Campbell
Director, Systems & Engineering
NOVARTIS

Robert Dunstan
Distinguished Investigator, Head, Translational Pathology Laboratory
biogen idec

Amir Handzel
Associate Director Bioinformatics
astellas

Xiaolan Hu
Associate Director
Bristol-Myers Squibb

Pavan Kumar
Senior. Scientist, Biomarkers & Personalized Medicine
Eisai

Janet Waldron
Program Leader, Companion Diagnostics
NOVARTIS

Dianna Wu
Director & Head of Molecular Pathology & Flow Cytometry
MERCK

TRACK 3 CDX COMMERCIALIZATION SPEAKERS:

George Bashirians
Director, Diagnostics Lead, Clinical Research & Precision Medicine
Pfizer

Peggy Carter
Director Regulatory Affairs
NOVARTIS

Kenneth Emancipator
Director, Companion Diagnostics
MERCK

Gianrico Farrugia
Director, Center for Individualized Medicine
MAYO CLINIC

Charles Mathews
Vice President
BOSTON HEALTHCARE

Scott Rairigh
Global Marketing Leader
janssen

Carol Berry
Senior Vice President, Pharmacogenomics Services Division
Asuragen

Christine Vitkauskas
Director, Companion Diagnostics
MERCK

TBC
BAYER

> **"Outstanding... Excellent presentations, variety, very good organization, great networking sessions. Thanks for preparing and please repeat next year!"**
>
> GSK

LinkedIn

Start discussions with **World CDx** speakers and attendees months before the meeting! Just search Linkedin groups for **Companion Diagnostics** to join our growing online community. Be part of the group with over 1300 members from industry worldwide, to make connections and discuss some of the most exciting new developments in the field.

Follow us on twitter at **@worldcdx**

PRE CONFERENCE WORKSHOPS

WORKSHOP A: Development and Application of Biomarkers in Early Phase Clinical Trials

Date: **TUESDAY 12TH NOVEMBER**
Time: **9.00am - 12.00pm**

The workshop will present the detail of taking a biomarker from discovery in a pre-clinical setting to the use of a clinical test based on this biomarker for enrichment of a Phase I / Phase II clinical trial.

The workshop will present the process from the point of view of the three key players:

- Pharma company
- Diagnostics company
- Clinician

You will leave this workshop with the tools to accurately identify powerful and relevant biomarkers in the clinic, translate effectively into a clinical test, and understand fully the role of each stakeholder in early phase clinical trials for CDx development.

WORKSHOP LEADERS:

Richard Kennedy
Vice President, Experimental Medicine
Almac

Matt Marton
Director, Genomics, Clinical Biomarker Development
Merck & Co

Ann Kapoun, Ph.D
Vice President, Translational Medicine
OncoMed

Michael Sloan
Vice President, Business Development
Almac

WORKSHOP B: Incorporating NGS into Companion Diagnostics

Date: **TUESDAY 12TH NOVEMBER**
Time: **1.00pm - 4.00pm**

As the costs of NGS decreases, the opportunity to use personalized genomics in clinical studies has become more accessible than ever. And the development of genomic sequencing methods could help to rapidly identify genetic alterations which may serve as targets for new diagnostic tests.

But how can we ensure we are maximizing the returns on investment for these technologies and achieving the best results we can for patient selection?

This session will explore how you can realistically make NGS an integral part of your personalized medicine strategies:

- Find out how to identify and evaluate cancer-causing mutations using sophisticated sequencing technologies
- Explore the possibilities of NGS to identify new targets for clinically relevant companion diagnostic tests
- Evaluate what NGS technologies and services are available to you to successfully to optimize your patient population approaches

WORKSHOP LEADERS:

Obi Griffith
Research Assistant Professor, The Genome Institute
Washington University

Sami Samir Amr
Assistant Laboratory Director, Sequencing Core Laboratory Director
Partners Healthcare Center for Personalized Genetic Medicine

Matthew Lebo
Assistant Laboratory Director, Whole Genome Sequencing
Partners Healthcare Center for Personalized Genetic Medicine

TRACK 1: CLINICAL BIOMARKERS

DAY ONE 13TH NOVEMBER 2013

7.00 REGISTRATION & COFFEE

8.00 Chairman's Opening Remarks

Mark Curran
Vice President, Immunology Biomarkers, **Janssen**

PLENARY SESSIONS: **Realizing Personalized Medicine with Companion Diagnostics**

8.15 Personalized Healthcare: Dependent on the Pharma / Diagnostic Relationship
- Implementing strong translational strategies
- Creating partnerships to speed the 'lab to market' evolution
- Utilizing clinical biomarker data to create better diagnostic tools

Doug Ward
Vice President & Lifecycle Leader, Companion Diagnostics
Ventana

8.45 Keynote: What are the Main Obstacles to Overcome to Deliver Personalized Medicine?
- What can we, as an industry, do to make co-development strategies more efficient and cost-effective?
- Understanding the FDA's current role in developing & delivering personalized medicine to patients
- Managing communications between CDER and CDRH during the co-development of CDx

Lawrence Lesko
Director, Center for Pharmacometrics & Systems Pharmacology
University of Florida

9.15 Real-Life Challenges in the Co-Development of Drugs & Diagnostics

This powerful, interactive workshop will provide thought provoking insights from both QIAGEN's past experiences and audience participation to fuel discussions over the two days. The format will be interactive, with in-depth discussion and an audience survey. Attendees will leave with a greater appreciation of the critical decisions to be made within the context of Rx/Dx co-development.

Richard Watts, Vice President, Companion Diagnostic Partnerships
QIAGEN

Paul Ravetto, Director of Programme Management & Personalized Healthcare, **QIAGEN**

10.15 SPEED NETWORKING & MORNING REFRESHMENTS

INTEGRATING BIOMARKER STRATEGIES

11.30 From Discovery to the Clinic: Using Biomarkers to Speed Up Drug Development
- Demonstrating various methods to discover biomarkers from *in vitro* systems
- Evaluating and rigorously validating pharmacodynamic and predictive biomarker properties for several case study compounds
- Exploring the use of biomarkers for decision making in drug development programs

Suso Platero
Director, Oncology Biomarkers
Janssen

12.00 Discovery, Development and Delivery of Clinically Relevant Biomarkers
- Almac will present a model for the discovery of biomarkers of clinical relevance and how to translate them into the clinic

Austin Tanney
Scientific Liaison Manager
Almac

12.30 Building and Implementing Strong Predictive Biomarker Strategies for Early Phase Trials
- Incorporating predictive biomarkers into early stage R&D to ensure each clinical candidate has a complimentary biomarker when it reaches the clinic
- Improving clinical execution and implementation of predictive biomarkers in patient stratification
- Embedding personalized medicine strategies into drug discovery to fast-track CDx programs

Ann Kapoun
Vice President, Translational Medicine
OncoMed

1.00 LUNCH & NETWORKING

TRACK 1: CLINICAL BIOMARKERS CONTINUED...

DAY ONE 13TH NOVEMBER 2013

IMPROVING BIOMARKER VALIDATION

2.00 Validating Biomarkers Early in Discovery to Improve Translation into the Clinic

- Evaluating successful case studies of PD biomarkers during phase 1: What did we do right?
- Exploring proof-of-mechanism for predictive biomarkers in both pre-clinical and clinical studies
- Selecting patient stratification biomarkers from phase 2 results and using reverse translational research to elucidate additional mechanisms

Yoshiya Oda
President, Biomarkers & Personalized Medicine Core Function Unit, **Eisai**

2.30 Identification and Validation of Predictive Biomarkers in Oncology: An Example in Hepatocellular Carcinoma

- Integrating data from multiple sources (imaging, gene expression, protein metabolites, etc) into a single mode of action for the identification and validation of robust predictive biomarkers
- Solving common hurdles such as multiplicity issues, assay performance, biological proof of concept and feasibility of diagnostic test development

Oscar Puig
Biomarker & Experimental Medicine Leader, Translational Clinical Research Center
Roche

3.00 AFTERNOON REFRESHMENTS & NETWORKING

PLENARY SESSIONS: **The Challenges of Managing Co-Development from Rx & Dx Perspectives**

3.30 Leading the Way in Cancer Diagnostics

- Delivering the highest standards and accuracy in cancer diagnostics
- Making companion diagnostics available to all types of pathology laboratories

Dako

4.00 Maximizing Efficiency in Partnerships: A Dx Perspective

- Taming complex CDx biomarker signatures with a novel multiplex, multimodal platform
- Assess previously complex multimodal assays for disparate target types all in one well
- Building a culture of strong communication and risk sharing between partners

Lilly Kong
Chief Scientific Officer
PrimeraDx

4.30 Co-Development Question Time:

This interactive session will pull questions from the audience and direct them to the panel to discuss how we can improve collaboration efforts between Dx and Rx partnerships. With viewpoints from both drug and diagnostic developers, the audience is encouraged to submit their questions before the panel so that the moderator may give each panellist an opportunity to answer.

Panelists:

Doug Ward, Vice President & Lifecycle Leader, Companion Diagnostics, **Ventana**; **Shane Weber,** Director Diagnostics, Clinical Research & Precision Medicine, **Pfizer**; **Joe Walker,** Senior Director, Companion Diagnostics & Pharmacogenomics, **Daiichi Sankyo**; **Salvatore DeSena,** Director, Diagnostic Imaging, **Bayer**; **Richard Watts,** Vice President, Companion Diagnostic Partnerships, **QIAGEN**

5.15 Chairman's Closing Remarks

5.30 DRINKS RECEPTION & NETWORKING

> "Strong program, great speakers and a genuine focus on identifying solutions."
>
> Novartis

TRACK 1: CLINICAL BIOMARKERS

DAY TWO 14TH NOVEMBER 2013

7.30 **Breakfast Lecture: A Unique Patient Perspective of Personalized Medicine in Practice**

Patient perspective is critical to understanding how to develop therapeutics and conduct clinical trials. Jack Whelan will be presenting his experiences of participating in five different clinical trials. Explore his story and be part of his journey as he takes you through his involvement in the development of personalized medicine.

Jack Whelan
From Research Analyst to **Research Advocate**

8.00 REGISTRATION & COFFEE

8.15 **Chairman's Opening Remarks**

Lawrence Lesko, Director, Center for Pharmacometrics & Systems Pharmacology, **University of Florida**

PLENARY SESSIONS: **Exploring Novel Technologies for Personalized Therapies**

8.30 **Preemptive Biomarkers for Precision Medicine in Lung Cancer**

- EGFR mutations and EML4-ALK fusion genes/translocations
- Discovering preemptive markers
- Synthetic lethal therapeutic combinations

Rafael Rosell
Co-Founder, Chairman & Chief Scientific Officer
Pangaea Biotech

9.00 **Creating a Long-Range Roadmap for CDx Commercialization**

- Addressing the challenges of a confused market place: The technology conundrum
- Evaluating different models for CDx commercialization based on diagnostic market requirements
- Optimizing lifecycle management of primary CDx with new technologies and workflows: How to complement the lifecycle of the medicine

Jonathan Pan, Director, Oncology Companion Diagnostic & Disease Strategy
GSK

9.30 **Translating Genomic Discoveries to the Clinic: The Right Tools for the Job**

- Understanding the most current challenges and successes in PGx development
- How to speed-up discovery, validation and clinical deployment of biomarker signatures
- Choosing the right scientific tools for translation into the clinic

Gianfranco de Feo, Senior Director, North American Regional Marketing
Affymetrix

10.00 MORNING REFRESHMENTS

SIMPLIFYING PATIENT STRATIFICATION & SAMPLE COLLECTION

11.00 **Driving Stratified Medicine in the Autoimmune Disease Area**

- When will individualized medicine start to make a real impact the field of autoimmune diseases?
- Addressing the need for a better understanding of the genotype and phenotype relationship as well as epigenetic factors in the pathogenesis of autoimmune diseases
- Integrating data-intensive biology with medicine in order to accomplish personalized medicine

Claudio Carini
Global Clinical Immunology/ Biomarkers Lead
Pfizer

11.30 **Genomic Profiling Strategies for Selecting Patients who May Benefit from PARP Inhibitor Therapy**

- What biomarkers should we be focusing on to identify appropriate patients who will likely benefit from PARP inhibitors?
- Understanding how can we validate companion diagnostics that are based on tumor suppressor genes
- Applying next generation sequencing technologies to identify all patients who will respond to the PARP inhibitor rucaparib

Mitch Raponi,
Senior Director
Clovis Oncology

"Perfect organization. Program well planned with sufficient time for networking."

Bristol Myers-Squibb

TRACK 1: CLINICAL BIOMARKERS CONTINUED...

DAY TWO 14TH NOVEMBER 2013

12.00 Managing the Challenges of Human Tissue Collection from the Hospital Bed to the Lab

- Understanding critical considerations in tissue collection from patient and industry perspectives
- Overcoming the many challenges associated with managing collection of patient samples at multiple clinical sites
- What can you do to get reference labs invested in your project?

Sharon Moulis
Principal Business Scientist
Merrimack Pharmaceuticals

12.30 LUNCH & NETWORKING

PLENARY SESSION: **Navigating the Regulatory Landscape for Companion Diagnostics**

1.30 Companion Diagnostics & FDA Pre-Submission; Maximizing the Results of Your Interactions to Gain a Clear Path to US Regulatory Approval

- Timing and coordination of pre-submission meetings to ensure that you are getting the most out of the interactions
- Understanding clinical considerations that can facilitate the development of the companion diagnostic and support the premarket approval
- Reviewing present case studies (in progress) of ongoing programs and how the different scenarios are playing out so far

Peggy Carter
Director Regulatory Affairs,
Novartis

2.00 Panel Discussion: Achieving Regulatory Approval for Companion Diagnostics

This concluding regulatory session will pull from all the speaker's expertise to answer the questions from the audience. Explore how these companies have been moving forwards in their discussions with regulatory bodies as well as the issues others are currently facing. Various stages of the regulatory process will be discussed and all questions are welcome.

Panelists:

Salvatore DeSena, Director, Diagnostic Imaging, **Bayer Healthcare**; **Peggy Carter,** Director, Regulatory Affairs, **Novartis**; **Kenneth Emancipator,** Director, Companion Diagnostics, **Merck**

2.45 AFTERNOON REFRESHMENTS

PLENARY SESSIONS: **Implementing Personalized Medicine in Practice**

3.15 Solving the Personalized Medicine Puzzle: Novel Computational Techniques for Implementing Personalized Medicine Strategies

- Personalized Medicine requires integration of clinical and genomic data and applications must be understood in the context of both research and the practice of medicine
- Understanding the distinct requirements and endpoints for research and medicine
- Research can accommodate more complex, long-term analyses

John Quackenbush
Professor, Bioinformatics
Dana Farber

3.45 Challenges for the Integration of Personalized Medicine in Community Hospitals

- Look at the effect of personalized medicine on community based cancer centers
- The integration of approved companion diagnostics in community based cancer centers and challenges for its uptake compared to LDT's
- The need for continued engagement and education of physicians in the area of genomics
- Experience of the CTR laboratory in bringing personalized medicine diagnostics into the CHI system

Jean-Claude Marshall
Laboratory Manager, Center for Translational Research
Catholic Health Initiatives

4.15 Optimizing Consumer Engagement Through Innovative Technologies

- A commercial perspective on patient focused, novel technologies
- Examples of what has worked and what hasn't worked to engage patients

Larry Brooks, Director, Business Model & Healthcare Innovation
Boehringer Ingelheim

4.45 End of Conference: Chairman's Closing Remarks

TRACK 2: TECHNOLOGY APPLICATIONS

DAY ONE 13TH NOVEMBER 2013

7.00 REGISTRATION & COFFEE

8.00 **Chairman's Opening Remarks**

Mark Curran
Professor of Clinical Genetics
Janssen

PLENARY SESSIONS: **Realizing Personalized Medicine with Companion Diagnostics**

8.15 **Personalized Healthcare: Dependent on the Pharma / Diagnostic Relationship**

- Implementing strong translational strategies
- Creating partnerships to speed the 'lab to market' evolution
- Utilizing clinical biomarker data to create better diagnostic tools

Doug Ward
Vice President & Lifecycle Leader, Companion Diagnostics
Ventana

8.45 **Keynote: What are the Main Obstacles to Overcome to Deliver Personalized Medicine?**

- What can we, as an industry, do to make co-development strategies more efficient and cost-effective?
- Understanding the FDA's current role in developing & delivering personalized medicine to patients
- Managing communications between CDER and CDRH during the co-development of CDx

Lawrence Lesko
Director, Center for Pharmacometrics & Systems Pharmacology
University of Florida

9.15 **Real-Life Challenges in the Co-Development of Drugs & Diagnostics**

This powerful, interactive workshop will provide thought provoking insights from both QIAGEN's past experiences and audience participation to fuel discussions over the two days. The format will be interactive, with in-depth discussion and an audience survey. Attendees will leave with a greater appreciation of the critical decisions to be made within the context of Rx/Dx co-development.

Richard Watts
Vice President, Companion Diagnostic Partnerships
QIAGEN;

Paul Ravetto
Director of Programme Management & Personalized Healthcare, **QIAGEN;**

10.15 SPEED NETWORKING & MORNING REFRESHMENTS

IMPROVED ASSAY DEVELOPMENT

11.30 **Striving for Robust Flow Cytometry Assays to Improve Quality of Clinical Biomarker Data**

- Flow cytometry as a powerful technology to assess cell-based biomarkers for clinical decision making
- Improving assay robustness, including specificity, sensitivity, post-collection sample stability, assay and instrument standardization and proper QC to secure high quality data
- Ensuring sample collection and handling is completed correctly to guarantee high quality of clinical specimens received at analytical labs

Dianna Wu
Director & Head of Molecular Pathology & Flow Cytometry
Merck

12.00 **Systems Tools to Accelerate Companion Diagnostics Development**

- Discussing the use of systems engineering based methodologies such as rigorous requirements management, systems thinking, DOE, FMEA, and other design for Six Sigma (DFSS) tools to reduce the time for CDx development, increase agility, and ultimately result in a more robust CDx assay
- Learn about the value systems engineering can bring to developing robust assay systems, what pitfalls can slow CDx assay development, and how implementing a systems perspective can keep a complicated Rx/CDx co-development project on-track

Devon Campbell
Director of Systems & Engineering
Novartis Companion Diagnostics;

Jonathan Beer
Manager, Systems Integration
Novartis Companion Diagnostics

1.00 LUNCH & NETWORKING

TRACK 2: TECHNOLOGY APPLICATIONS CONTINUED...

DAY ONE 13TH NOVEMBER 2013

APPLYING NEXT-GENERATION SEQUENCING

2.00 Clinical Genetics in the Age of Next Generation Sequencing

- Exploring the current potential of next generation sequencing in the development of companion diagnostics and the real challenges still left to overcome
- Using genome-wide association studies to identify genomic markers for disease progression
- Creating next generation sequencing strategies for various disease areas, to improve patient selection across drug development

Xiaolan Hu
Associate Director
Bristol Myers-Squibb

2.30 Next-Generation Sequencing Panel Discussion

- Successfully applying NGS to optimize your patient population approaches
- Incorporating personalized genomics into routine clinical applications for effective patient stratification
- Validating genomic biomarkers for personalized medicine and exploring the possibilities of NGS to identify new targets for clinically relevant companion diagnostic tests

Panelists:

Pavan Kumar, Senior Scientist, Biomarkers & Personalized Medicine, **Eisai; Janet Waldron,** Program Leader, Companion Diagnostics, **Novartis; Jonathan Pan,** Director, Oncology Companion Diagnostic & Disease Strategy, **GSK;**

3.15 AFTERNOON REFRESHMENTS & NETWORKING

PLENARY SESSION: **The Challenges of Managing Co-Development from Rx & Dx Perspectives**

3.30 Leading the Way in Cancer Diagnostics

- Delivering the highest standards and accuracy in cancer diagnostics
- Making companion diagnostics available to all types of pathology laboratories

Dako

4.00 Maximizing Efficiency in Partnerships: A Dx Perspective

- Taming complex CDx biomarker signatures with a novel multiplex, multimodal platform
- Assess previously complex multimodal assays for disparate target types all in one well
- Building a culture of strong communication and risk sharing between partners

Lilly Kong
Chief Scientific Officer
PrimeraDx

4.30 Co-Development Question Time:

This interactive session will pull questions from the audience and direct them to the panel to discuss how we can improve collaboration efforts between Dx and Rx partnerships. With viewpoints from both drug and diagnostic developers, the audience is encouraged to submit their questions before the panel so that the moderator may give each panellist an opportunity to answer.

Panelists:

Doug Ward, Vice President & Lifecycle Leader, Companion Diagnostics, **Ventana; Shane Weber,** Director Diagnostics, Clinical Research & Precision Medicine, **Pfizer; Joe Walker**, Senior Director, Companion Diagnostics & Pharmacogenomics, **Daiichi Sankyo; Salvatore DeSena,** Director, Diagnostic Imaging, **Bayer; Richard Watts**, Vice President, Companion Diagnostic Partnerships, **QIAGEN**

5.00 Chairman's Closing Remarks

5.30 DRINKS RECEPTION & NETWORKING

"Very good mix of speakers from various origins. Very valuable."

UCB Pharma

TRACK 2: TECHNOLOGY APPLICATIONS

DAY TWO 14TH NOVEMBER 2013

7.30 **Breakfast Lecture: A Unique Patient Perspective of Personalized Medicine in Practice**

Patient perspective is critical to understanding how to develop therapeutics and conduct clinical trials. Jack Whelan will be presenting his experiences of participating in five different clinical trials. Explore his story and be part of his journey as he takes you through his involvement in the development of personalized medicine.

Jack Whelan
From Research Analyst to **Research Advocate**

8.00 REGISTRATION & COFFEE

8.15 **Chairman's opening remarks**

Lawrence Lesko, Clinical Professor, Director, Center for Pharmacometrics & Systems Pharmacology,
University of Florida

PLENARY SESSIONS: **Exploring Novel Technologies for Personalized Therapies**

8.30 **Preemptive Biomarkers for Precision Medicine in Lung Cancer**

- EGFR mutations and EML4-ALK fusion genes/translocations
- Discovering preemptive markers
- Synthetic lethal therapeutic combinations

Rafael Rosell
Co-Founder, Chairman & Chief Scientific Officer
Pangaea Biotech

9.00 **Creating a Long-Range Roadmap for CDx Commercialization**

- Addressing the challenges of a confused market place: The technology conundrum
- Evaluating different models for CDx commercialization based on diagnostic market requirements
- Optimizing lifecycle management of primary CDx with new technologies and workflows: How to complement the lifecycle of the medicine

Jonathan Pan
Director, Oncology Companion Diagnostic & Disease Strategy
GSK

9.30 **Translating Genomic Discoveries to the Clinic: The Right Tools for the Job**

- Understanding the most current challenges and successes in PGx development
- How to speed-up discovery, validation and clinical deployment of biomarker signatures
- Choosing the right scientific tools for translation into the clinic

Gianfranco de Feo
Senior Director, North American Regional Marketing
Affymetrix

10.00 MORNING REFRESHMENTS

INCORPORATING BIOINFORMATICS & COMPUTATIONAL STRATEGIES

11.00 **Quantitative Morphology: Bringing Structural Analysis into Bioinformatics**

- Making morphology reproducible by digitization, quantitation and standardization
- Progressing the transition of anatomic pathology from a descriptive to a quantitative discipline
- Optimizing whole slide imaging: an essential but over-regulated and under-standardized technology

Robert Dunstan
Distinguished Investigator, Head, Translational Pathology Laboratory
Biogen Idec

11.30 **Computational Strategies for Biomarker Discovery & CDx Development**

- Addressing strategic and computational considerations in the development of multiplexed CDx
- Selecting and validating biomarkers from the large universe of molecular entities in a statistically robust way
- Using an array of technical, operational and organizational approaches available to improve validation and avoid common pitfalls

Amir Handzel
Associate Director Bioinformatics
Astellas Pharma

"Both the speed networking session and the organized drinks provided a great environment to connect with other conference attendees."

Janssen

TRACK 2: TECHNOLOGY APPLICATIONS CONTINUED...

DAY TWO 14TH NOVEMBER 2013

12.00 Predictive Analytics to Achieve Personalized Healthcare

- Understanding the restrictions behind applications of new technologies such as complexity in trial designs, cost, time, and uncertainty in regulatory and commercial consequences
- Exploring predictive analytics approaches without applying new technologies, but utilizing available clinical data to enable patient stratification in late phase drug development and personalized healthcare in clinical practice

Zhaohui Cai
Biomedical Informatics Director
AstraZeneca

12.30 LUNCH & NETWORKING

PLENARY SESSION: **Navigating the Regulatory Landscape for Companion Diagnostics**

1.30 Companion Diagnostics & FDA Pre-Submission; Maximizing the Results of Your Interactions to Gain a Clear Path to US Regulatory Approval

- Timing and coordination of pre-submission meetings to ensure that you are getting the most out of the interactions
- Understanding clinical considerations that can facilitate the development of the companion diagnostic and support the premarket approval
- Reviewing present case studies (in progress) of ongoing programs and how the different scenarios are playing out so far

Peggy Carter
Director Regulatory Affairs
Novartis

2.00 Panel Discussion: Achieving Regulatory Approval for Companion Diagnostics

This concluding regulatory session will pull from all the speaker's expertise to answer the questions from the audience. Explore how these companies have been moving forwards in their discussions with regulatory bodies as well as the issues others are currently facing. Various stages of the regulatory process will be discussed and all questions are welcome.

Panelists:

Salvatore DeSena, Director, Diagnostic Imaging, **Bayer Healthcare; Peggy Carter** Director, Regulatory Affairs, **Novartis; Kenneth Emancipator** Director, Companion Diagnostics **Merck;**

2.45 AFTERNOON REFRESHMENTS

PLENARY SESSION: **Implementing Personalized Medicine in Practice**

3.15 Solving the Personalized Medicine Puzzle: Novel Computational Techniques for Implementing Personalized Medicine Strategies

- Personalized Medicine requires integration of clinical and genomic data and applications must be understood in the context of both research and the practice of medicine
- Understanding the distinct requirements and endpoints for research and medicine
- Research can accommodate more complex, long-term analyses

John Quackenbush
Professor, Bioinformatics
Dana Farber

3.45 Challenges for the Integration of Personalized Medicine in Community Hospitals

- Look at the effect of personalized medicine on community based cancer centers
- The integration of approved companion diagnostics in community based cancer centers and challenges for its uptake compared to LDT's
- The need for continued engagement and education of physicians in the area of genomics
- Experience of the CTR laboratory in bringing personalized medicine diagnostics into the CHI system

Jean-Claude Marshall, Laboratory Manager, Center for Translational Research,
Catholic Health Initiatives

4.15 Optimizing Consumer Engagement Through Innovative Technologies

- A commercial perspective on patient focused, novel technologies
- Examples of what has worked and what hasn't worked to engage patients

Larry Brooks, Director, Business Model & Healthcare Innovation
Boehringer Ingelheim

4.45 End of Conference: Chairman's Closing Remarks

TRACK 3: CDx COMMERCIALIZATION

DAY ONE 13TH NOVEMBER 2013

7.00 REGISTRATION & COFFEE

8.00 Chairman's Opening Remarks

Mark Curran, Vice President, Immunology Biomarkers, **Janssen**

PLENARY SESSIONS: **Realizing Personalized Medicine with Companion Diagnostics**

8.15 Personalized Healthcare: Dependent on the Pharma / Diagnostic Relationship

- Implementing strong translational strategies
- Creating partnerships to speed the 'lab to market' evolution
- Utilizing clinical biomarker data to create better diagnostic tools

Doug Ward
Vice President & Lifecycle Leader, Companion Diagnostics
Ventana

8.45 Keynote: What are the Main Obstacles to Overcome to Deliver Personalized Medicine?

- What can we, as an industry, do to make co-development strategies more efficient and cost-effective?
- Understanding the FDA's current role in developing & delivering personalized medicine to patients
- Managing communications between CDER and CDRH during the co-development of CDx

Lawrence Lesko
Director, Center for Pharmacometrics & Systems Pharmacology
University of Florida

9.15 Real-Life Challenges in the Co-Development of Drugs & Diagnostics

This powerful, interactive workshop will provide thought provoking insights from both QIAGEN's past experiences and audience participation to fuel discussions over the two days. The format will be interactive, with in-depth discussion and an audience survey. Attendees will leave with a greater appreciation of the critical decisions to be made within the context of Rx/Dx co-development.

Richard Watts, Vice President, Companion Diagnostic Partnerships, **QIAGEN;**
Paul Ravetto, Director of Programme Management & Personalized Healthcare
QIAGEN;

10.15 SPEED NETWORKING & MORNING REFRESHMENTS

CDx DEVELOPMENT IN PRACTICE

11.30 Integrating the Latest in Genomic Science into Modern Medical Practice

- Creating new infrastructure to deliver individualized genomic medicine
- Improving partnerships between physicians and scientists to make new discoveries in genomic and clinical science
- Translating genomic breakthroughs into new ways to predict, diagnose and treat disease

Gianrico Farrugia
Director, Center for Individualized Medicine
Mayo Medical School

12.00 Featured Spot Light Presentation

Carol Berry
Senior Vice President, Pharmacogenomics Services Division, **Asuragen**

12.15 Companion Diagnostics Development – The Need for Establishing Early Partnerships

- Successful implementation of a CDx strategy depends on early recognition of the opportunity and early establishment of key collaborations
- Working with internal and external partners to deliver the right product on essential timelines
- Outlining the key partnerships and offer perspectives based on the Xalkori Rx/Dx program

George Bashirians
Director, Diagnostics Lead, Clinical Research & Precision Medicine
Pfizer

12.45 LUNCH & NETWORKING

"High quality speakers, high content presentations and lots of opportunities for networking."

Pfizer

TRACK 3: CDx COMMERCIALIZATION CONTINUED...

DAY ONE 13TH NOVEMBER 2013

OPTIMIZING CDx COLLABORATIONS

2.00 Achieving Global Commercialization for Your Companion Diagnostics

- Understanding the differences between global market access pathways for diagnostics vs. drugs
- Reviewing the current laboratory testing and market access landscape in several key markets
- Learn how to align timing and manage support activity associated with CDx
- Explore possible opportunities and hurdles associated with collaborations between clinical development and commercialization strategy teams

Charles Mathews
Vice President
Boston Healthcare

2.30 Leveraging Diagnostics Development Expertise within Merck to Develop a Companion Diagnostic

- Understanding the benefits of how current companion diagnostics development works within Merck
- Balancing out the pros & cons of outsourcing various parts of the process in order to maximize return on investments
- Securing regulatory approval to start clinical trials using clinical trials assays on the path to regulated companion diagnostics

Christine Vitkauskas
Director, Companion Diagnostics
Merck

3.00 AFTERNOON REFRESHMENTS & NETWORKING

PLENARY SESSIONS: **The Challenges of Managing Co-Development from Rx & Dx Perspectives**

3.30 Leading the Way in Cancer Diagnostics

- Delivering the highest standards and accuracy in cancer diagnostics
- Making companion diagnostics available to all types of pathology laboratories

Dako

4.00 Maximizing Efficiency in Partnerships: A Dx Perspective

- Taming complex CDx biomarker signatures with a novel multiplex, multimodal platform
- Assess previously complex multimodal assays for disparate target types all in one well
- Building a culture of strong communication and risk sharing between partners

Lilly Kong
Chief Scientific Officer
PrimeraDx

4.30 Co-Development Question Time:

This interactive session will pull questions from the audience and direct them to the panel to discuss how we can improve collaboration efforts between Dx and Rx partnerships. With viewpoints from both drug and diagnostic developers, the audience is encouraged to submit their questions before the panel so that the moderator may give each panellist an opportunity to answer.

Panellists:

Doug Ward, Vice President & Lifecycle Leader, Companion Diagnostics, **Ventana; Shane Weber,** Director Diagnostics, Clinical Research & Precision Medicine **Pfizer; Joe Walker,** Senior Director, Companion Diagnostics & Pharmacogenomics **Daiichi Sankyo; Salvatore DeSena,** Director, Diagnostic Imaging **Bayer; Richard Watts,** Vice President, Companion Diagnostic Partnerships, **QIAGEN**

5.00 Chairman's Closing Remarks

5.30 DRINKS RECEPTION & NETWORKING

> "Outstanding... Excellent presentations, variety, very good organization, great networking sessions. Thanks for preparing and please repeat next year!"
>
> GSK

TRACK 3: CDx COMMERCIALIZATION

DAY TWO 14TH NOVEMBER 2013

7.30 **Breakfast Lecture: A unique patient perspective of personalized medicine in practice**

Patient perspective is critical to understanding how to develop therapeutics and conduct clinical trials. Jack Whelan will be presenting his experiences of participating in five different clinical trials. Explore his story and be part of his journey as he takes you through his involvement in the development of personalized medicine.

Jack Whelan
From Research Analyst to
Research Advocate

8.00 REGISTRATION & COFFEE

8.15 **Chairman's Opening Remarks**

Lawrence Lesko
Clinical Professor, Director,
Center for Pharmacometrics
& Systems Pharmacology
University of Florida

PLENARY SESSIONS: **Exploring Novel Technologies for Personalized Therapies**

8.30 **Preemptive Biomarkers for Precision Medicine in Lung Cancer**

- EGFR mutations and EML4-ALK fusion genes/translocations
- Discovering preemptive markers
- Synthetic lethal therapeutic combinations

Rafael Rosell
Co-Founder, Chairman &
Chief Scientific Officer
Pangae Biotech

9.00 **Creating a Long-Range Roadmap for CDx Commercialization**

- Addressing the challenges of a confused market place: The technology conundrum
- Evaluating different models for CDx commercialization based on diagnostic market requirements
- Optimizing lifecycle management of primary CDx with new technologies and workflows: How to complement the lifecycle of the medicine

Jonathan Pan
Director, Oncology Companion
Diagnostic & Disease Strategy
GSK

9.30 **Translating Genomic Discoveries to the Clinic: The Right Tools for the Job**

- Understanding the most current challenges and successes in PGx development
- How to speed-up discovery, validation and clinical deployment of biomarker signatures
- Choosing the right scientific tools for translation into the clinic

Gianfranco de Feo
Senior Director, North
American Regional Marketing
Affymetrix

10.00 MORNING REFRESHMENTS

PREPARING FOR CDX COMMERCIALIZATION

11.00 **Complimentary and Companion Diagnostics: Asking the Right Questions at the Right Time**

- Incorporating the complimentary or companion diagnostics information into the therapeutic target product profile
- Understanding what are the appropriate key business questions to ask at each phase of pharmaceutical development
- What are the critical planning elements that are necessary to ensure success?

Scott Rairigh
Global Marketing Leader
Janssen Diagnostics

11.30 **Title TBC**

Bayer, Sponsored by **Ventana**

TRACK 3:
CDx COMMERCIALIZATION CONTINUED...

DAY TWO 14TH NOVEMBER 2013

12.00 Clinical Trial Designs to Support Approval Of Companion Diagnostics: It's Not All About The Drug!

- Understanding the regulatory concepts governing companion diagnostic development
- Exploring the options for clinical trial design and the key elements of successful clinical co-development programs
- Avoiding the common pitfalls encountered in co-development programs

Kenneth Emancipator
Director, Companion Diagnostics
Merck

12.30 LUNCH & NETWORKING

PLENARY SESSIONS: **Navigating the Regulatory Landscape for Companion Diagnostics**

1.30 Companion Diagnostics & FDA Pre-Submission; Maximizing the Results of Your Interactions to Gain a Clear Path to US Regulatory Approval

- Timing and coordination of pre-submission meetings to ensure that you are getting the most out of the interactions
- Understanding clinical considerations that can facilitate the development of the companion diagnostic and support the premarket approval
- Reviewing present case studies (in progress) of ongoing programs and how the different scenarios are playing out so far

Peggy Carter
Director Regulatory Affairs
Novartis

2.00 Panel Discussion: Achieving Regulatory Approval for Companion Diagnostics

This concluding regulatory session will pull from all the speaker's expertise to answer the questions from the audience. Explore how these companies have been moving forwards in their discussions with regulatory bodies as well as the issues others are currently facing. Various stages of the regulatory process will be discussed and all questions are welcome.

Panellists:

Salvatore DeSena, Director, Diagnostic Imaging **Bayer Healthcare; Peggy Carter,** Director, Regulatory Affairs **Novartis; Kenneth Emancipator,** Director, Companion Diagnostics, **Merck**

2.45 AFTERNOON REFRESHMENTS

PLENARY SESSION: **Implementing Personalized Medicine in Practice**

3.15 Solving the Personalized Medicine Puzzle: Novel Computational Techniques for Implementing Personalized Medicine Strategies

- Personalized Medicine requires integration of clinical and genomic data and applications must be understood in the context of both research and the practice of medicine
- Understanding the distinct requirements and endpoints for research and medicine
- Research can accommodate more complex, long-term analyses

John Quackenbush
Professor, Bioinformatics
Dana Farber

3.45 Challenges for the Integration of Personalized Medicine in Community Hospitals

- Look at the effect of personalized medicine on community based cancer centers
- The integration of approved companion diagnostics in community based cancer centers
- The need for continued engagement and education of physicians in the area of genomics

Jean-Claude Marshall
Laboratory Manager, Center for Translational Research
Catholic Health Initiatives

4.15 Optimizing Consumer Engagement Through Innovative Technologies

- A commercial perspective on patient focused, novel technologies
- Examples of what has worked and what hasn't worked to engage patients

Larry Brooks, Director, Business Model & Healthcare Innovation
Boehringer Ingelheim

4.45 End of Conference: Chairman's Closing Remarks

POST CONFERENCE WORKSHOPS

WORKSHOP C: Transforming Your Product and Company with Companion Diagnostics

Date: **FRIDAY 15TH NOVEMBER**
Time: **9.00am - 12.00pm**

The field is maturing, discovering creative new uses for CDx and carving new paths through the changing, treacherous landscape of court rulings, regulatory standards, technology advances and business models.

The implications now reach beyond clinical trial design and reimbursement strategies to preclinical science, company portfolio and partnering strategies, governance structures and even the rise of data scientists.

Attend this workshop to understand how to align opportunities, science and business in a changing world.

- Scientists: Understand how to gain the support of commercial and senior management for your program
- Commercial: See how marketing with companion diagnostics differentiates products and increases success
- Investors & Senior Managers: Identify what it takes to seize the CDx opportunities and avoid the pitfalls

Propel the success of your specific projects and catalyze the transformation of your organization to succeed in a world dominated by companion diagnostics.

WORKSHOP LEADER:

Mark Trusheim
Executive in Residence & Visiting Scientist
MIT

Mark is executive in residence and visiting scientist at the MIT sloan school of management and a special government employee for the FDA's office of the commissioner. He is the former member of the Massachusetts Biotechnology Council's Board of Directors and in 2004 he further served as the Interim President of the MBC, leading its successful legislative agenda, its expansion of MassBioEd education programs and its continued membership growth.

WORKSHOP D: Maximizing Return on Investment in Collaborative Agreements

Date: **FRIDAY 15TH NOVEMBER**
Time: **1.00pm - 4.00pm**

Are diagnostic collaborations true partnerships or fee-for-service based contracts? It is a matter of negotiation.

It's important that you understand the economics and risk allocations behind various models available for your collaborations. Creating an agreement which is mutually beneficial for both parties can be challenging and avoiding disputes along the way is key for success.

This workshop will outline how both partners within Rx/Dx agreements can maximize their returns and manage risk sharing to deliver results.

Attend this session to:

- Identify the common themes across collaborative agreements with the industry
- Discuss alternative approaches for your partnerships
- Gain practical advice on negotiating to improve your collaborations

WORKSHOP LEADERS:

Mark Kass
Partner
Nixon Peabody

Mark Kass focuses his practice on corporate finance, mergers and acquisitions and commercial transactions. His industry experience encompasses information technology, new media, telecommunications and life sciences. He has extensive experience in international transactions including Europe, Israel and the Far East. A significant portion of his practice involves representation of leading Israeli and Israeli-related hi-tech and life science companies doing business in the United States.

NETWORKING OPPORTUNITIES

SPEED NETWORKING

The Speed Networking session is the most valuable hour you will spend at the conference. Here you will have an unrivalled opportunity to make connections with leading drug and diagnostic develops and introduce yourself to the attendees that you would like to have more in-depth conversations with later in the week.

Make sure you bring plenty of business cards!

NETWORKING DRINKS RECEPTION

After the formal presentations have finished, the networking carries on. The networking drinks reception is a highlight at **World CDx** and allows you to connect with industry leaders and senior level decision makers to build rapport and lasting business relationships in an informal setting.

INTERACTIVE WORKSHOPS

Have your specific challenges tackled by an industry expert. Workshops are 3 hour interactive, intimate sessions run with 1-2 leaders and consisting of 2-4 short presentations. This allows for in-depth discussion between talks and Q&A. The main aim is to encourage participation from the audience members and allow you to have your specific issues addressed.

PANEL DISCUSSIONS AND QUESTION TIME

With so much at stake when it comes to getting your CDx partnerships right you need to stay up-to-date with the latest innovative strategies and approaches taken by the industry.

The panel discussions and question time sessions, lead by industry leaders, are highly interactive to ensure you leave the meeting will all your CDx questions answered.

VENUE

Venue:
The Colonnade Hotel
120 Huntington Avenue,
Boston, MA 02116,
United States

www.colonnadehotel.com

THE Colonnade HOTEL

MEDIA PARTNERS

BioPortfolio
BioMed Central The Open Access Publisher
ecancer
genomeweb
JCDR Journal of Clinical and Diagnostic Research
nature
BENTHAM SCIENCE
ColoradoBioScience ASSOCIATION
espicom BUSINESS INTELLIGENCE
IOS Press
infinata
the Journal of Molecular Diagnostics
PharmaVOICE
drug discovery world DDW Turning science into business
GEN Genetic Engineering & Biotechnology News
INDERSCIENCE PUBLISHERS
Lifescience Global
Technology Networks.com Scientific Communities
Medical News TODAY
SelectScience The Fastest Way to Expert Opinion

INTRODUCING OUR SPONSORS

World CDx would like to welcome on board the following sponsors...

LEAD SPONSOR

VENTANA
a member of the Roche Group

Through innovative solutions, **Ventana** empowers anatomic pathologists and laboratory professionals to increase testing efficiency. Our intuitive, integrated slide staining and workflow management platforms optimize laboratory operations to minimize errors, support diagnosis, and inform treatment decisions for anatomic pathology professionals.

EXPERTISE PARTNER

BOSTON HEALTHCARE

Boston Healthcare's unique approach, combining strategic consulting with a deep understanding of the patient and provider access, reimbursement, and health economic environment gives drug, device, diagnostics companies a real-world edge in assessing and capturing global market and business development opportunities.

EXPERTISE PARTNER

QIAGEN

QIAGEN work with pharmaceutical partners to support development of targeted cancer therapies by providing molecular companion diagnostic assays for mutational profiling, gene signature and methylation analysis. QIAGEN have also developed novel diagnostics for monitoring immunomodulators.

PROGRAMME PARTNER

PangaeaBiotech s.l.

Based in Barcelona, **Pangaea Biotech**'s mission is to implement a global R&D strategy that results in the personalized treatment of cancer patients. PB's team is led by Chairman Rafael Rosell, MD PhD (President of the Spanish Lung Cancer Group) and Chief Executive Officer, Jose Jimeno, MD PhD (former EVP of Scientific Development at Pharmamar).

EXPERTISE PARTNER

PrimeraDx
The Multiplex PCR Company

PrimeraDx is a molecular diagnostic company that has developed a game-changing clinical platform which combines PCR with capillary electrophoresis. The result of combining these two technologies into a bench-top instrument is the ability to deliver highly multiplexed and quantitative, answers to the clinic.

SPOTLIGHT PARTNER

Asuragen

Asuragen is a molecular diagnostic company focused on personalizing oncology treatment through the development of clinically useful diagnostics for both pathological diagnosis and as companions to therapy. Asuragen's diagnostic development leverages a number of genomic research technologies, including next generation sequencing, microarrays, qPCR, Luminex, and more.

INTRODUCING OUR SPONSORS: CONTINUED...

CONFERENCE PARTNER

Abbott Molecular

Abbott Molecular is an experienced global health care partner and a proven leader in successful companion diagnostic development.

Abbott Molecular provides physicians with critical information, allowing for earlier diagnosis, selection of appropriate therapies and monitoring of disease progression.

EXPERTISE PARTNER

ALMAC

Almac partners with the biopharmaceutical industry to provide biomarker discovery and development solutions ranging from pre-clinical biomarker discovery, through to full companion diagnostic development, biomarker clinical trial management and clinical test delivery from our CLIA lab.

EXPERTISE PARTNER

Dako

Dako is a global diagnostic company with more than 45 years of experience in pathology. Dakos mission is to connect with oncologists, pathologists, lab technicians and pharmaceutical companies in the fight against cancer. We want to be the first choice for staining in pathology laboratories and deliver the highest standards and accuracy in cancer diagnostics.

EXPERTISE PARTNER

AFFYMETRIX®

Affymetrix's extensive portfolio of transitional and clinical solutions enables scientists and clinicians to rapidly translate their research into understanding underlying disease mechanisms, identifying biomarkers for personalized medicine, creating novel molecular diagnostic tests, and improving genetic marker-assisted breeding programs in agriculture for human health and wellness.

SPONSOR OPPORTUNITIES

Pharma are doing everything they can to secure success for their companion diagnostics. And choosing the right partner to work with is the most critical decision they face. Sponsoring or exhibiting at **World CDx** represents the best platform for you to position your capabilities and expertise to an audience of decision makers from the CDx community.

Be seen as a credible and valuable partner to work with to make sure you are front of mind for pharma as they evaluate the best partners for their programmes. Use **World CDx** to put yourself in the best position to win new business this year and build valuable partnerships to deliver the promise of personalized medicine to patients.

GET IN TOUCH

If your organization needs to raise profile, promote products and services or develop new partnership opportunities in the CDx sector then contact us now to find out more.

Nick Alderslade is Hanson Wade's commercial director who can help you to design the perfect sponsorship package to meet your business needs.

Nick Alderslade, Commercial Director

Tel: +44 20 3141 8709

Email: nick.alderslade@hansonwade.com

PRICES AND DISCOUNTS:

PACKAGE PRICES	Register & Pay before 5th July	Register & Pay before 16th August	Register & Pay before 27th September	Standard Price
2 day conference + 4 workshops	$4095 **(save $700)**	$4195 **(save $600)**	$4295 **(save $500)**	$4495 **(save $300)**
2 day conference + 3 workshops	$3596 **(save $600)**	$3696 **(save $500)**	$3796 **(save $400)**	$3996 **(save $200)**
2 day conference + 2 workshops	$3097 **(save $500)**	$3197 **(save $400)**	$3297 **(save $300)**	$3497 **(save $100)**
2 day conference + 1 workshop	$2598 **(save $400)**	$2698 **(save $300)**	$2798 **(save $200)**	$2998
2 day conference only	$2099 **(save $300)**	$2199 **(save $200)**	$2299 **(save $100)**	$2399
Workshop only	$599			

REGISTRATION INCLUDES FULL ACCESS TO 2 FULL CONFERENCE DAYS AND...

- Access to exhibition area
- Networking drinks reception
- Event Guide
- Speed Networking session
- Participation in interactive polling session
- Discounted rates on accommodation
- 2x Networking lunches
- Discounted interactive workshop places
- Access to presentation slides

BOOK YOUR PLACE TODAY*

PRIORITY CODE: **MKT**

register@hansonwade.com
www.world-cdx.com/register

*For full T&C's visit the website

BOOK IN A GROUP

Many delegates attend World CDx meetings in groups. This year, with 3 content streams covering all aspects of CDx discovery, development and commercialization, there is value for your biomarker scientists and commercial directors to attend as a group.

Over 4 days, your group will benefit from multi disciplinary roundtables, content sharing and networking. Ensure that information sharing between departments begins onsite.

TEAM DISCOUNTS

3 delegates: 10% Discount
4 delegates: 15% Discount
5 delegates: 20% Discount

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

TERMS & CONDITIONS

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

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

Data Protection: The personal information shown and/or provided by you will be held in a database. It may be used to keep you up to date with developments in your industry. Sometimes your details may be obtained or made available to third parties for marketing purposes. If you do not wish your details to be used for this purpose, please write to: Database Manager, Hanson Wade, Charter House, 13-15 Carteret Street, London SW1H 9DJ

Event code: 2888