

MarketsandMarkets Biomarker and Companion Diagnostics Virtual Conference



Leveraging next gen technologies beyond
conventional biomarker drug discovery

20 - 23 October 2020

EVENT OVERVIEW

The emergence of the need for safety and efficacy of a drug subjected to individual patients has made companion diagnostics one of the most sought after topics in the field of In-Vitro Diagnostics. The surge of investment in companion diagnostics has brought forward issues regarding regulations and their intricacies and boosted new trends in immuno-oncology, immuno-therapies, data interpretation and unconventional design of clinical trials.

The Biomarker and Companion Diagnostics Virtual Conference scheduled to be held on 20-23 October 2020 would address the gaps between early stage biomarker development and the commercialization stage of biomarkers.

This conference would also highlight case studies on leveraging emerging technologies in Digital Biomarkers, Precision Medicine and Big Data.

Regarding commercialization of biomarkers, leading industry and academic experts would share their case studies focusing on advancements in companion diagnostics area. The keynote presentations would also help the attendees understand the issues related to clinical translation of biomarkers.

KEY HIGHLIGHTS

- Biomarker Drug Discovery and Assay Development
- Proteomics and Genomics based Biomarkers
- Digital Biomarkers, Predictive Biomarkers, Precision Medicine and Big Data
- Clinical Applications of Biomarkers in Immuno-Oncology, Neurology and Inflammatory Diseases
- Commercialization of CDx
- Multiplex Companion Diagnostics and Regulatory Guidelines
- Design of clinical trials in CDx

WHO SHOULD ATTEND

Researchers, scientists, clinicians, academicians and professionals from

- Pharmaceutical companies
- Bio-pharma companies
- Universities and Research institutes

Working in:

- Biomarker discovery/development
- Translational research
- Clinical Biomarker
- Biomarkers in IO and Neurological disorders
- Imaging Biomarkers
- Pathology
- Companion Diagnostics
- Biomarker Imaging
- Proteomics Biomarkers
- Experimental Medicine
- Data Science
- Biomarkers in Clinical Discovery
- Immuno-oncology/Neuroscience Drug Discovery
- Diagnostic Biomarkers development
- Personalized Medicine
- Immunology Biomarkers

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SPEAKERS PANEL

- **Roy Baynes**, Senior Vice President, Global Clinical Development, Chief Medical Officer, **Merck Research Laboratories, USA**
- **John Rossi**, Senior Director, Head, Cell Therapy, **Kite Pharma, USA**
- **Mike Baratta**, Scientific Director, Chief of Staff, Clinical Biomarker Development and Innovation, **Takeda Pharmaceuticals, USA**
- **Pallavi Sachdev**, Senior Director, **Eisai, USA**
- **Shashi Ramaiah**, Head, Safety Biomarkers, Translational Sciences, **Pfizer, USA**
- **Nadia Hassounah**, Principal Scientist, **Novartis, USA**
- **Adil Daud**, Director, Melanoma Clinical Research, **UCSF, USA**
- **Ben Chih**, Translational Scientist, **Genentech, USA**
- **Saumya Pant**, Director, Clinical Genomics and Genetics, **Bristol-Myers Squibb, USA**
- **Xinyin Lai**, Senior Research Scientist, **Eli Lilly, USA**
- **Shamim Mollah**, Assistant Professor, Department of Genetics, **Washington University School of Medicine, USA**
- **Yuk Yee Leung**, Assistant Professor, Pathology and Laboratory Medicine, **University of Pennsylvania, USA**
- **Parag Mallick**, Associate Professor, Radiology, **Stanford University, USA**
- **Tanja Zabka**, Principal Scientist, Pathologist, **Genentech, USA**
- **Nancy Casanova**, Professor, **University of Arizona, USA**
- **Michelle Graham**, Principal Scientist, Translational Medicine and Biomarkers, **AbbVie, USA**
- **Kevin Wang**, Director, Program for Neurotrauma, Neuroproteomics and Biomarkers Research, **University of Florida, USA**
- **Paul Wood**, Director, Metabolomics Unit, Lincoln Memorial University, **USA**
- **Scott Reid**, Executive Director, Strategic Alliances and CDx, **Neogenomics, USA**
- **Tom Li**, Head of US Biopharma BD, **Burning Rock Dx, USA**
- **Bryan Downie**, Senior Scientist, **Gilead Sciences, USA**
- **Dhiman Ghosh**, Scientist, DMPK, **Takeda, USA**
- **Ian Pike**, Chief Executive Officer, **Proteome Sciences, UK**
- **Senior Representative**, **Larvol, USA**
- **George Pell**, Principal & Chief Strategy Officer, **Thirty-Six, USA**
- **Marc van der Schee**, Head, Clinical and Translational Science, **Owlstone Medical Ltd., UK**
- **Senior Representative**, **Qiagen, Germany**
- **Reinhard Ortmann**, Director Oncology & Precision Diagnostics, **Qiagen, Germany**
- **Michael Cardone**, CEO, **Eutropics, USA**
- **Senior Representative**, **Agilent, USA**

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Day 1, 20th October 2020

(PST TIME ZONE)

10:00 Online Registration

10:25 Welcome note from MarketsandMarkets

10:30 Opening Remarks from the Chairman

10:35 **Keynote Presentation: Vignettes of Innovative Safety Biomarker Applications to Drug Development**

- Attrition due to safety is a major issue in drug development
- Biomarker is an enabler to mitigate safety issues
- Case examples and biomarker qualification to implement biomarkers will be shared

Shashi Ramaiah, Head, Safety Biomarkers, Translational Sciences, **Pfizer, USA**

BIOMARKERS IN CLINICAL & TRANSLATIONAL DEVELOPMENT: DRUG DISCOVERY AND ASSAY DEVELOPMENT

11:00 **Enhanced Biomarker Discovery and Validation Using TMT® Proteomics**

- Applying advanced proteomic based Mass Spectrometry techniques in oncology based research through to clinical trials.
- Visualise >8,000 proteins from human serum/plasma and apply extensive bioinformatics to identify those proteins that predict disease, help stratify patients or monitor drug trials.
- Targeted Mass Spectrometry applications to solve protein quantification where ELISA fails or antibodies do not exist.
- Quantify 100's of site specific phospho protein epitopes in one multiplex experiment.
- New! Quantifying protein degradation (PROTAC) experiments, measuring class 1 and 2 MHC peptides and Tryptophan and its downstream metabolites.

Ian Pike, Chief Executive Officer, **Proteome Sciences, UK**

11:25 **Presentation by Qiagen, Germany**

11:50 **Predictive biomarkers of response to PD-L1 inhibition**

12:15 **Non-invasive Biomarker Discovery and Clinical Investigation Using Breath Biopsy®**

- Non-targeted and targeted workflows for the discovery and analysis of biomarkers in exhaled breath using the Breath Biopsy OMNI Assay
- Case studies in non-invasive early disease detection and phenotyping in oncology, liver and respiratory diseases
- Strategies for moving breath testing from decentralised analysis to point-of-care solutions

Marc van der Schee, Head, Clinical and Translational Science, **Owlstone Medical Ltd., UK**

12:40 *Solution Provider Presentation*

13:05 **Clinical biomarker development for an intratumoral TLR7 agonist**

- LHC165 is an intratumoral TLR7 agonist that is absorbed to aluminum hydroxide and is hypothesized to induce a type 1 interferon response driven by Th1 promoting chemokines/cytokines resulting in local and abscopal antitumor activity
- LHC165 single agent and in combination with PDR001 is currently underway in a Phase I/Ib FIH clinical trial in patients with advanced solid tumors
- Preclinical data and the anticipated mechanistic role of LHC165 in driving antitumor activity guided clinical biomarker assay development

Nadia Hassounah, Principal Scientist, **Novartis, USA**

13:30 **Panel Discussion: Use of biomarkers in clinics-success and challenges of getting a good biomarker**

- How do we identify patients for the biomarker combination trials?

13:55 **Closing Remarks from the Chairman**

14:00 **Networking and One-on-One Meetings**

End of Day 1

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Day 2, 21st October 2020

(PST TIME ZONE)

10:00 Online Registration

10:25 Welcome note from MarketsandMarkets

10:30 Opening Remarks from the Chairman

10:35 Keynote Presentation: Precision Medicine Tools and Immuno-Oncology

- Initial phase 2 screening was enabled by precision medicine
- Precision medicine tools enabled and accelerated monotherapy clinical development
- Precision medicine tools have led to histology agnostic approvals
- Precision medicine tools have provided insights to mechanisms of resistance and combination therapy selection

Roy Baynes, Senior Vice President, Global Clinical Development, Chief Medical Officer, **Merck Research Laboratories, USA**

INNOVATIONS IN BIOMARKER RESEARCH: DIGITAL BIOMARKERS, PRECISION MEDICINE AND BIG DATA

11:00 Applying Big-Data and Mathematical Modeling to Biomarker Discovery

- Low cost diagnostic strategies for cancer early detection and treatment strategy personalization are expected to radically improve patient outcomes and decrease healthcare costs
- We hypothesize that the tumor-blood relationship is driven by combinations of non-linear processes, which lead some proteins to not shed from the tumor into the blood or, once shed drive to not persist (possibly due to slow intratumoral diffusion kinetics or fast degradation kinetics)
- By integrating data from large-scale studies with a novel mathematical model, we have recently developed a new software tool that is able to prioritize markers based upon their likely circulating kinetics

Parag Mallick, Associate Professor, Radiology, **Stanford University, USA**

11:25 *Solution Provider Presentation*

11:50 Mechanism of Immune Checkpoint Therapy: new data

- How does Immunotherapy work?
- Converting cold to hot with immunotherapy
- Systemic response to cancer-exploiting it

Adil Daud, Director, Melanoma Clinical Research, **UCSF, USA**

12:15 Automated high-parameter FACS data analysis effectively and efficiently identifies impactful pharmacodynamic biomarkers

- Advances in flow and mass cytometry have enabled the biomarker community to generate an abundance of data, thus there is an unmet need to employ bioinformatic approaches for biomarker identification and discovery
- Implementing two validated algorithms (algorithm-assisted gating and algorithm-based clustering) to efficiently reduce dimensionality and to effectively identify pharmacodynamic biomarkers in the context of drug development
- Case studies of high-parameter preclinical studies recapitulates results found through manual gating analysis and identifies novel pharmacodynamic biomarkers.

Michelle Graham, Principal Scientist, Translational Medicine and Biomarkers, **AbbVie, USA**

12:40 Multi-purpose approach to biomarker development: Diagnostic, Prognostic, Safety and Response biomarkers

- Define types of biomarkers based on the FDA BEST document to establish common understanding
- Review approach and strategy to enable multiple uses for biomarkers as diagnostic, prognostic, safety and response biomarkers
- Provide case studies to exemplify considerations for using this approach that is being leveraged at Genentech as well as through Consortia Qualification work

Tanja Zabka, Principal Scientist, Pathologist, **Genentech, USA**

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Day 2, 21st October 2020

- 13:05 Next Generation Intelligence | precision and personalized medicine for the brain, mind, and nervous system**
- Psychiatric and Neurocognitive | tracing the molecular, cellular, and metabolic basis of every presentation, for every individual
 - Microbes and Pathogens | modeling individual host response to microbes, the products they make, and their true collective impact
 - Injury and Trauma | a more precise, meaningful, and actionable picture of the biological and neurophysiological cascades of neurotrauma
 - Autoimmunity and Neurodegeneration | mapping the details and dynamics of each individual's perfect storm, and how to unwind it
- George Pell, Principal & Chief Strategy Officer, Thirty-Six, USA**
- 13:30 Closing remarks from the Chairman**
- 13:35 Networking and One-on-One Meetings**
- End of Day 2**

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Day 3, 22nd October 2020

(PST TIME ZONE)

10:00 Online Registration

10:25 Welcome note from MarketsandMarkets

10:30 Opening Remarks from the Chairman

10:35 **Keynote Presentation: The common thread running through CNS biomarkers - implications on new drug development**

- Learn about the current state of CNS biomarkers
- Be informed on the use of CNS biomarkers in new drug development
- Learn the state-of-the-art biomarker detection technology

Kevin Wang, Director, Program for Neurotrauma, Neuroproteomics and Biomarkers Research, **University of Florida, USA**

EMERGING TRENDS IN CDX: IDENTIFICATION OF RIGHT BIOMARKERS & DESIGN OF CLINICAL TRIALS IN CDX

11:00 **Overcoming technical hurdles of sensitivity to perform copy no. variations and gene expression profiling in liquid biopsy**

11:25 *Solution Provider Presentation*

11:50 **Targeting chromatin remodeling for cancer therapy**

- Epigenetic modifications that control chromatin remodeling are flexible and dynamic, thereby making them promising therapeutic targets
- The regulation of chromatin remodeling is carried out by the precise coordination of covalent histone modifications and remodeler proteins through catalytic activities
- Integrative frameworks can reveal the mechanisms of action of specific drugs on chromatin remodeling machinery in cancer cells potentiate for improved development of chromatin-based cancer therapy

Shamim Mollah, Assistant Professor, Department of Genetics, **Washington University School of Medicine, USA**

12:15 **Unravel the molecular mechanisms of non-coding genetic variants in Alzheimer's Disease using a scalable high-throughput pipeline**

- Present a scalable platform for harmonizing functional genomics data
- Describe a robust and powerful pipeline for dissecting noncoding regulatory mechanisms for human diseases
- Summarize mechanistic findings from non-coding genetic variants from the world's largest Alzheimer's disease GWAS data

Yuk Yee Leung, Assistant Professor, Pathology and Laboratory Medicine, **University of Pennsylvania, USA**

12:40 *Solution Provider Presentation*

13:05 **Biomarker Identification, Selection, and Development**

- 8 ways to identify biomarker candidates
- 24 biomarker properties to enable biomarker selection
- 1 solution for biomarker development

Xinyin Lai, Senior Research Scientist, **Eli Lilly, USA**

13:30 **International harmonization of biomarkers used in CDx**

13:55 **Closing Remarks from the Chairman**

14:00 **Networking and One-on-One Meetings**

End of Day 3

MarketsandMarkets Biomarker and Companion Diagnostics Virtual Conference

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Day 4, 23rd October 2020

(PST TIME ZONE)

10:00 Online Registration

10:25 Welcome note from MarketsandMarkets

10:30 Opening Remarks from the Chairman

10:35 Keynote Presentation: Merging cross-functional groups to commercialize a successful CDx test

CDX COMMERCIALIZATION, REGULATORY UPDATES, STATISTICS & DATA IN CDX

11:00 Transition to commercially viable platforms to detect multiple targets for CDx

11:25 Launching a Companion Diagnostic (CDx): Research and Development Through Commercialization

- Case Studies (ssPMA, IVD PMA)
- Regulatory pathways & considerations
- Commercial Launch: Day-One Launch of a CDx (e.g. PIK3CA CDx)

Scott Reid, Executive Director, Strategic Alliances and CDx, Neogenomics, USA

11:50 1) Challenges of getting Trial/Study approval and NGS CDx commercial launch in China

- Changing trends of NMPA/HGR approval process.
- Biosample export restrictions and solutions.
- Opportunities for global trial utilizing IVD Kits.

2) Large cohort prospective study: ctDNA abundance and mutation load correlated with OS. ctDNA clearance predicts longer PFS and OS.

- Largest study of its kind in China.
- Evaluating utility of ctDNA as a predictive and prognostic marker in disease monitoring of advanced NSCLC patients.
- Further evidence supporting the use of liquid biopsy as a tool for MRD and monitoring treatment efficacy.

Tom Li, Head of US Biopharma BD, Burning Rock Dx, USA

12:15 Global companion diagnostic commercialization: Day-One matters

- Closing the time gap between new drug availability and patient access to testing
- Key learnings of the Day-One Lab Readiness Program roll-out
- Global expansion

Reinhard Ortmann, Director Oncology & Precision Diagnostics, Qiagen, Germany

12:40 Assessing lab developed tests to achieve standardization in CDx

13:05 *Solution Provider Presentation*

13:30 Closing remarks from the Chairman

13:35 Networking and One-on-One Meetings

End of Conference