PRECISION MEDICINE & BIOMARKERS LEADERS SUMMIT: USA

BOSTON, USA
May 7-8 2018

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#PrecisionBiomarkersSummit

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Examining groundbreaking biomarker, companion diagnostic, immuno-oncology, genomic, big data and AI research to facilitate the development of impactful personalized treatments for patients. Global Engage is proud to host the Precision Medicine & Biomarkers Leaders Summit USA taking place on May 7-8, 2018 at the Boston Park Plaza Hotel in Boston, MA, USA. The meeting is the sister event to the European Summit now in its fifth year.

The Summit will provide a forum to network, learn and engage with senior representatives of leading pharmaceutical and biotech companies worldwide who are there to further their research in Personalized medicine and enable impactful treatments for patients.

Tracks focus on R&D strategies, Biomarker development, Immuno-oncology, CDx development, AI and Big data analysis and approaches – Attending this Summit will provide you with the opportunity to mix and interact with experts working in all facets of Precision Medicine through the individual, panel and roundtable discussions on offer.

EXPERT SPEAKERS Include:

JAN LUNDBERG  
President Lilly Research Labs (Head of R&D), Eli Lilly

PAMELA CARROLL  
Senior Vice President, Immuno-oncology, Genocea Biosciences

ERIC PERAKSLIS  
Chief Scientific Officer, Datavant

CARL BARRETT  
Vice President, Translational Science, Oncology, AstraZeneca
DAY 1 – TRACK 1

Strategies and Technologies to Deliver Precision Medicine
- Current & future perspectives - Innovative initiatives, strategies and approaches
- Delivering superior outcomes for patients through personalized healthcare
- Technologies to enable Precision Medicine
  - AI for Precision medicine
  - Gene editing to deliver Precision Medicine
- Innovative clinical trial design
- Understanding physician, payer and patient perspectives
- Economics for precision medicine - Adding value
  - Incentivising pricing & reimbursement strategies
  - Market access considerations
- Ethical, regulatory & IP implications of individualizing medicine

DAY 1 – TRACK 2

Biomarkers in Clinical and Translational Development
- Patient selection strategies
  - Biomarkers for patient selection
- Clinical and translational biomarkers
  - Clinical biomarker discovery
  - Biomarker validation & qualification
  - Digital biomarkers

DAY 2 – TRACK 1

Companion Diagnostic Partnerships & Development
- CDx strategies and accelerating development
  - Evolution of companion diagnostics
  - Delivering a successful biomarker strategy alongside a companion diagnostic
- Lessons learnt and case studies from successful CDx collaborations & approvals
  - CDx development in Immuno-oncology
  - PDL1 Assays
- Rx-Dx partnerships, integration and co-development
- Overcoming regulatory issues; updates and future developments
- Reimbursement, market access & commercialization
- Complementary diagnostics

DAY 2 – TRACK 2

Immuno-Oncology
- Strategies
- Predictive biomarkers
- Immune checkpoint inhibitors
- Immune response monitoring
- Circulating Tumour DNA (ctDNA) - detection & monitoring - unlocking realtime information
  - Liquid biopsies - clinical utility

CONFERENCE SYNOPSIS

Panel 1: Identifying the most promising directions for Precision research
Panel 2: Biomarker Patient Selection Strategies
Panel 3: Artificial Intelligence and machine learning – A paradigm shift in Pharma R&D
Panel 4: Companion Diagnostic regulation and reimbursement challenges - Accelerating development
Panel 5: Precision Immuno-oncology where are we heading?
Panel 6: Developing successful Rx-Dx partnerships, integration and co-development

ROUNDTABLES

Roundtable 1: Harnessing AI to drive precision medicine
Roundtable 2: Conducting Precision medicine clinical trials
Roundtable 3: Advancing Liquid biopsy to the clinic
Roundtable 4: Developing “lean start up” commercialization strategies across clinical trials, strategic partners, and biomarker development
Roundtable 5: How to Shift Precision Medicine from Treating Cancer to its Prevention: Developing Preventive Therapies for Cancer
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<th>Name</th>
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<td>ERIC PERAKSLIS</td>
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<td>Jackson Laboratory for Genomic Medicine</td>
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<td>JAN LUNDBERG</td>
<td>President Lilly Research Labs (Head of R&amp;D)</td>
<td>Eli Lilly</td>
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<td>Director, Global Regulatory Strategy - Oncology</td>
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<td>Incyte Corporation</td>
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<td>Co-Founder &amp; Chief Scientific Officer</td>
<td>Rafael Pharma</td>
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<td>Global Product General Manager</td>
<td>Amgen, Inc.</td>
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<td>US Oncology, Novartis</td>
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<td>Senior advisor to various companies in the Artificial Intelligence and Biotechnology sectors</td>
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<td>Global VP of Biomarker Development &amp; Medical Director</td>
<td>Arcadia Medical Diagnostics</td>
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CONFIRMED SPEAKERS

ARIS BARAS
Vice President, Head, Regeneron Genetics Center - Regeneron Pharmaceuticals, Inc.

SHARON BENZENO
Senior Vice President, Business and Corporate Development, Adaptive Biotechnologies Corp

MICHAEL HERMAN
Head of Business Development BioPharma, OncoDNA, Belgium

MARTIN TOLAR
Founder, President & CEO, Alzheon

ALINA KHROMYKH
Precision Medicine Integration Manager, Personalized Health, Inova Center for Personalized Health

FAINA SHTERN
President & CEO, AdMeTech Foundation

THOMAS BOCK
CEO, HeritX

ZHEN SU
Senior Vice President & Chief Medical Officer, EMD Serono

STEVE GARDNER
CEO RowAnalytics/precisionlife

SHARON BENZENO
Senior Vice President, Business and Corporate Development, Adaptive Biotechnologies Corp

DAVID K. THOMAS
Director, Cachexia Discovery & Therapeutic Development, Broad Institute of MIT & Harvard

SOMA RAY
Senior Director, Head of Clinical Biomarkers, Vertex

JENNIFER DACPANO-KOMANSKY
Associate Director, Global Regulatory Affairs - Oncology Precision Medicine, Novartis

PETER BLUME-JENSEN
(Chair)
President and Founder, Acrivon Therapeutics

CHRISTOPHER IANELLI
CEO, iSpecimen

ANA M GONZALEZ
Associate Director of Translational Medicine, Agenus

LAKSHMAN RAMAMURTHY
Global Regulatory Lead, Foundation Medicine

JILL STEFANELLI
Senior Director of Diagnostic Development, ArcherDX, INC

RICHARD BARKER
Founding Director, New Medicines Partners
SUMMIT SCHEDULE

DAY 1 MONDAY 7TH MAY 2018

8:00-8:50 Registration & Refreshments

8:50-8:55 Global Engage Welcome Address and Morning Chair’s Opening Remarks: Richard Barker Founding Director, New Medicines Partners

KEYNOTE ADDRESS:
ERIC PERAKSLIS
Chief Scientific Officer, Datavant
Bringing it All Together, the Takeda Data Science Institute
• Data must flow smoothly throughout the entire biopharmaceutical product lifecycle
• Takeda has built a multi-disciplinary Data Institute that houses more than 165 data scientists from all disciplines

KEYNOTE ADDRESS:
ZHEN SU
Senior Vice President & Chief Medical Officer, EMD Serono
Evolution of the IO landscape: understanding resistance mechanisms in IO-refractory patients
With the advent of IO therapy in oncology, we have seen significant improvements in the response rates and overall survival of cancer patients. However, the challenges to identify responsive patient populations, as well as understand mechanisms of resistance continue to dampen our progress. Recent advances in biomarkers and preliminary combination regimens present a promising path forward, however will this be enough to ensure durable responses in patients, especially in real-world settings?

SPONSORED PRESENTATION:
ESKE RYGAARD-HJALSTED
VP Sales, Marketing and BD, Intomics
Precision Medicine in a Data-rich Era – Challenges and Successful Bioinformatics Approaches
Biomedical data is generated in almost every stage of drug discovery and development and holds great promise as a powerful tool for enabling precision medicine.
• There are, however, a number of challenges that need to be overcome to make effective use of big data in R&D processes. One area of focus is establishing reliable hypotheses that can be tested with relatively small patient numbers in clinical trials given an incomplete biological understanding of the underlying disease.
• Using real world biomarker cases from non-oncology projects as a basis, the talk will present typical challenges and successful multi-omics approaches for identifying response biomarkers that correctly identify 85-95 % of the responding patients.

10:35-11:45 Morning Refreshments / One-to-One Meetings

STRATEGIES & TECHNOLOGIES TO DELIVER PRECISION MEDICINE

Track Chair: Richard Barker Founding Director, New Medicines Partners

CARL BARRETT
Vice President, Translational Science, Oncology, AstraZeneca
Utility and challenges of ctDNA
• Plasma based assay using ctDNA can be used for patient selection, monitoring clinical responses and discovering mechanism of resistance to targeted therapies
• The development of an FDA approved EGFR ctDNA will be discussed
• Not all ctDNA assay provide the same results and the basis for this discordance will be provided

BIOMARKERS IN CLINICAL AND TRANSLATIONAL DEVELOPMENT

Track Chair: Peter Blume-Jensen, President and Founder, Acrivon Therapeutics

JEFFREY EVELHOCH
Vice President, Head of Translational Biomarkers, Merck Research Laboratories
Biomarkers in Immuno-Oncology and Alzheimer’s Disease
In the development of novel therapeutics, biomarkers can provide information critical to internal decision-making, identifying patients most likely to benefit from a specific treatment, establishing efficacy and/or safety for regulatory approval and generating new hypotheses for testing in additional preclinical or clinical studies. This talk will give several examples of how biomarkers are impacting clinical and translational development in immuno-oncology and Alzheimer’s disease.
Lunch / One-to-One Meetings
1:35-2:35

MICHAEL SIERRA
Vice President, LEO Science & Tech Hub
Making Precision Medicine in Dermatology
• Defining precision medicine in dermatology
• Developing new technologies for data acquisition
• Building a platform that goes across indications
• Addressing the challenges of going from data to better patient care

SUMMIT SCHEDULE
DAY 1 MONDAY 7TH MAY 2018

50 MINUTE EXECUTIVE PANEL DISCUSSIONS: Identifying the most promising directions and preparing for the future of Precision medicine research

FAINA SHTERN (Chair)
President & CEO, AdMeTech Foundation

MICHAEL SIERRA
Vice President, LEO Science & Tech Hub

MARTIN TOLAR
Founder, President & CEO, Alzheon

STEFAN SCHERER
VP & Head Early Development, Strategy and Innovation, US Oncology, Novartis

SOMA RAY
Senior Director, Head of Clinical Biomarkers, Vertex

RICHARD BARKER
Founding Director, New Medicines Partners

50 MINUTE EXECUTIVE PANEL DISCUSSIONS: Biomarker Patient Selection Strategies

SCOTT D. PATTERSON (Chair)
Vice President, Biomarker Sciences, Gilead Sciences, Inc

PALLAVI SACHDEV
Director, Oncology Biomarker Research, Clinical Research Oncology Business Group, Eisai

JONATHAN PAN
Vice President, Head of Translational Medicine and Biomarker Strategy, Aevi Genomic Medicine, Inc

AMIR HANDZEL
Co-founder and CEO, Pangea Diagnostics

LISA ELI
Director, Translational Medicine and Diagnostics, Puma Biotechnology, Inc.

RICHARD KENNEDY
Global VP of Biomarker Development & Medical Director, Almac Diagnostics

ALINA KHROMYKH
Assistant Vice President, Personalized Health, Inova Center for Personalized Health
Precision Medicine in Practice: Overcoming adoption obstacles
• Providing a perspective on how innovative precision medicine initiatives can be successfully implemented in a health system.
• Using pharmacogenomics (PGx) as a use case to illustrate

MICHAIL SIERRA
Vice President, LEO Science & Tech Hub
Making Precision Medicine in Dermatology a Reality
• Defining precision medicine in dermatology
• Developing new technologies for data acquisition
• Building a platform that goes across indications
• Addressing the challenges of going from data to better patient care
SUMMIT SCHEDULE

DAY 1 MONDAY 7TH MAY 2018

3:05-3:35

15 MINUTE SOLUTION PROVIDER PRESENTATION:
JANUSZ DUTKOWSKI
Co-founder and CEO, Data4Cure
The Biomedical Intelligence Cloud: Integrating Systems Biology and AI to continuously grow biomedical knowledge
- The CURIE Knowledge Graph as a dynamic knowledge base integrating information across millions of computational analysis on public and proprietary data
- Building data-driven maps of disease
- Deep molecular and immune-infiltrate disease characterization and subtyping
- Predicting and understanding pathways leading to response and resistance to single-agent therapies and drug combinations

3:05-3:35

15 MINUTE SOLUTION PROVIDER PRESENTATION:
JILL STEFANELLI
Senior Director of Diagnostic Development, ArcherDX, INC
Universal NGS-based CDx assays for solid tumor patient stratification and monitoring
Diverse genetic mutations involving numerous tyrosine kinases including EGFR, ALK, ROS1, MET and NTRK have the potential to be oncogenic drivers. Clinical utility has been demonstrated for select EGFR and BRAF mutations as well as gene fusions with ALK or ROS1 in lung cancer. Additional genes are currently targeted in various phases of clinical development and are often present in small proportions of a variety of tumor types, including lung, colorectal, breast, melanoma and prostate cancers making them challenging to detect for potential patient enrollment. We are developing a universal CDx assay based on ArcherDX AMP technology to be used as a “one test, multiple drug” approach to solve some of the current challenges including sufficient sample material, development and regulatory costs.

3:35-4:25

50 MINUTE EXECUTIVE PANEL DISCUSSIONS:
Artificial Intelligence and machine learning – A paradigm shift in Pharma R&D
LEO RODRIGUES (Chair)
Senior Director, AI & Machine Learning, Berg
ASIM SIDDIQUI
Chief Technology Officer, NuMedii, Inc.
DAVID SAHNER
Senior advisor to various companies in the Artificial Intelligence and Biotechnology sectors

3:35-4:25

SPONSORED PRESENTATION:
SHARON BENZENO
Senior Vice President, Business and Corporate Development, Adaptive Biotechnologies Corp
Next-Gen Sequencing for Next-Gen Drugs — T Cell Receptor Sequencing in Immuno-Oncology
- The Adaptive Biotechnologies immunosequencing technology platform combines bias-controlled multiplex PCR amplification with high-throughput sequencing and sophisticated bioinformatics.
- Adaptive's immunoSEQ TCRB Assay is being incorporated as a novel immune molecular biomarker with potential predictive value in response to diverse immunomodulatory agents in different tumor types.
- This presentation will demonstrate use of the TCRB Assay to profile, track and monitor T cell receptor (TCR) repertoire changes in patients with solid tumors. The accurate quantitation of TCR density and clonality from either tumor tissue or blood samples informs immune repertoire dynamics with meaningful clinical implications.
- In addition, Adaptive applies its innovative multiplex approach to map TCR clonotypes to antigens to address TCR antigen specificity and functionality with applications in vaccine development plus TCR discovery and development of TCR-based cellular therapeutics.

3:35-4:25

MICHAEL HOWELL
Senior Director of Translational Research, Incyte Corporation
Precision Medicine Approaches in Inflammatory Skin Diseases
- Use of Omics approaches to understand disease heterogeneity and pathogenesis
- Integration of precision medicine approaches in clinical trials
- Define innovative approaches to predictive medicine

3:35-4:25

LISA ELI
Director, Translational Medicine and Diagnostics, Puma Biotechnology, Inc.
Neratinib for treatment of HER2-mutant breast cancer
- Somatic mutations in the ERBB2 (HER2) gene are a new class of oncogenic driver mutations detected in approximately 2% of breast cancer.
- ERBB2 mutations have been demonstrated to result in constitutive kinase signaling and increased tumor cell proliferation and growth in preclinical models.
SHENG FENG  
Senior Principal Research Statistician, Abbvie

STEFAN SCHERER  
VP & Head Early Development, Strategy and Innovation, US Oncology, Novartis

DAVID K. THOMAS  
Director, Cachexia Discovery & Therapeutic Development, Broad Institute of MIT & Harvard

**ONE HOUR ROUNDTABLE DISCUSSIONS:**

**Table 1: Harnessing AI to drive precision medicine**  
MICHAEL A. KIEBISH  
Chief Precision Medicine Officer, Berg

**Table 2: Conducting Precision medicine clinical trials**  
PALLAVI SACHDEV  
Director, Oncology Biomarker Research, Clinical Research, Oncology Business Group, Eisai

**Table 3: Advancing Liquid biopsy to the clinic**  
STEFAN SCHERER  
VP & Head Early Development, Strategy and Innovation, US Oncology, Novartis

**Table 4: Developing “lean start up” commercialization strategies across clinical trials, strategic partners, and biomarker development**  
JEFF JUNE  
CEO, Ischemia Care

**Table 5: How to Shift Precision Medicine from Treating Cancer to its Prevention: Developing Preventive Therapies for Cancer**  
THOMAS BOCK  
CEO, HeritX

- Neratinib, an irreversible pan-HER inhibitor, has been shown to have potent anti-tumor activity in HER2-amplified or ERBB2-mutated breast tumor cell lines and xenografts.
- Encouraging clinical activity of neratinib has been observed in patients with HER2-negative, ERBB2-mutation-positive metastatic breast cancers.
- The association of specific mutation patterns and response to neratinib is under analysis.

CAROLYN CUFF  
Associate Director, Translational Immunology, Immunology Discovery, Abbvie

**Frontiers in Immunology: Targeting therapies to the right patients**
- Autoimmune diseases are recognized as having significant heterogeneity that complicates the development of novel therapies as well as the ability to target approved therapies to the right patients.
- Pathway biomarkers can play a vital role in dose setting in clinical trials as well as identifying patients who are most likely to respond to specific treatments.
- A case study on the CD40 pathway in both pre-clinical and patient tissue will be presented to highlight the strategies that can be used to identify patients who might benefit from blockade of this pathway.

SHENG FENG  
Senior Principal Research Statistician, Abbvie

STEFAN SCHERER  
VP & Head Early Development, Strategy and Innovation, US Oncology, Novartis

DAVID K. THOMAS  
Director, Cachexia Discovery & Therapeutic Development, Broad Institute of MIT & Harvard

**Chair’s Closing Remarks / End of Day 1**  

**Drinks Reception**
Artificial Intelligence (AI) is poised to transform the entire pharmaceutical development lifecycle accelerating clinical development paradigm. Employing AI for target selection, drug design, integrating molecular/clinical data to define the intended population to treat, as well as the healthcare economic model can radically expedite progress in precision medicine. However, not all AI is created equal. Whether machine learning, neural networks, or Bayesian approaches, each have evolved independently within the drug development space. As technologies and analytics evolve, the harmonization of these approaches will make transformative progress toward using AI to align the right drug to the right patient at the right time. In this round table, we will discuss the challenges, successes, and strategies moving forward towards integrating AI for precision medicine impacting drug development and patient stratification.

Conducting Precision medicine clinical trials

- Innovative Clinical Trial Design
  - Basket Trials, Adaptive design
- Enabling Patient selection strategies
  - Biomarkers for patient selection
- Use of liquid biopsies for patient selection and response monitoring
- Overcoming CDx regulatory issues

Cancer is a heterogeneous disease and personalized therapy relies on the ability to characterize the tumor every time new treatment is needed. Potential detection of circulating tumor cells (CTCs) or circulating free tumor DNA (ctDNA) to provide molecular characterization and guide patient treatment offers a potential path forward to address this challenge. Despite this significant advance in technology many questions remain to be answered on the clinical utility of ctDNA. Three major areas should be investigated in depth as they would provide a true step forward for personalized medicine. First, the validation of the potential as a diagnostic tool (prognostic and or predictive) in patients where tissue is no longer available; Second the validation of ctDNA as an appropriate platform to follow response and/or progression to treatment; finally validation of ctDNA to detect resistance mechanism and provide information on the next most appropriate treatment for the patient. Although tumor tissue is the gold standard for clinical and investigational sequencing, major barriers exist in terms of acquisition and utilization. Hence, appropriate analytical and clinical validation of ctDNA as a surrogate endpoint should be a priority in the field of oncology.

This discussion will be based upon the popular book, The Lean Start Up, by Eric Ries, and will explore how companies, from start up to multi billion dollar companies can foster a more capital efficient innovative approach in precision medicine across disease states that leverages resources more effectively to shorten development cycles, recruit strategic partners, build effective teams to achieve measurable meaningful metrics. This panel will provide a scientific approach to creating and managing successful innovation in an age when companies need to innovate more than ever. Participants will engage in a dialogue spanning the care continuum to understand how to advance from scientific discovery to patient care, while integrating core concepts in precision medicine, biomarker development, and beyond.

How to Shift Precision Medicine from Treating Cancer to its Prevention: Developing Preventive Therapies for Cancer
KEYNOTE ADDRESS: JAN LUNDBERG
President, Lilly Research Labs (Head of R&D), Eli Lilly

Precision Medicine and Biomarkers Technologies: Directions Across Different Therapeutic Areas
The talk will cover the following aspects, including lessons learned with examples from the Eli Lilly perspective:
• Biomarker technologies for patient selection with emphasis on oncology and Alzheimer’s disease
• Evolution of companion diagnostics internally and through external collaborations
• Overcoming regulatory issues and market access

KEYNOTE ADDRESS: ARIS BARAS
Vice President, Head, Regeneron Genetics Center - Regeneron Pharmaceuticals, Inc.

Genetics to Therapeutics: Large Scale Human Genetics at Regeneron
The Regeneron Genetics Center (RGC) leverages large scale human genetics to identify new drug targets and to guide the development of therapeutics programs and precision medicine strategies. Building upon Regeneron's strengths in mouse genetics and genetics-driven drug development (Arcalyst® in Cryopyrin-Associated Periodic Syndromes, Praluent® for Hypercholesterolemia and atherosclerotic cardiovascular disease, fasinumab for pain conditions, and more), the RGC has developed large scale sequencing and human genetics capabilities and has delivered numerous novel gene discoveries of large effect on disease traits, translating these discoveries into new biology and drug discovery programs. The RGC has built one of the largest human genetics databases, including some of the largest sequencing studies in the world, such as the DiscovEHR study in collaboration with Geisinger Health System and an initiative to sequence 500,000 participants with the UK Biobank. Select examples will be highlighted where these initiatives have enabled novel discoveries that have fueled drug development efforts.

SPONSORED PRESENTATION: MICHAEL HERMAN
Head of Business Development BioPharma, OncoDNA, Belgium

NGS & IHC Based Patient Enrollment and Sourcing using Solid and Liquid Biopsies Profiling Combined with Precision Medicine Knowledge Database
Daily, OncoDNA draws the complete molecular profile of cancer patients, combining DNA and molecular pathology in the analysis of a solid and of a liquid biopsy. Most of the treatment options are FDA or EMA approved drugs, but often, the best or the only option for those patients are compounds which are still under clinical investigation. Biopharma sponsors are more and more facing the challenge of finding patients who may be eligible for open trials. As the European cancer precision medicine leader, and beside helping patients and oncologists, OncoDNA is also helping biopharma companies through their drug development process. We serve as a central lab for molecular characterization or we do improve compound theranostic knowledge through our cancer precision medicine expertise, but we also have initiated this unique and innovative approach to improve patient recruitment. This presentation will be an illustration of how OncoDNA is putting together its cancer precision medicine expertise, the oncologist and the biopharma to give patients access to the best cancer care.
SPONSORED PRESENTATION: COURTNEY NICHOLSON
Director of Business Development, Abcam Plc
Targeted analytics and High-Performance Antibody solutions to transform biomarker discovery for diagnostic and therapeutic applications for use in clinical applications
- The use of targeted analytics to improve selection targets for development in diagnostics and therapeutic programmes.
- Application of Next-Generation Sequencing for antibody development to increase the functionally relevant candidate pool for recombinant antibodies to be used in diagnostic and therapeutic applications.
- True end-to-end custom solutions: from antibody discovery to assay development and commercialisation. Abcam works with diagnostic and therapeutic partners, delivering best-in-class antibodies against key and challenging targets in areas including immune-oncology, neuroscience, cancer, immunology and epigenetics.

11:40-12:10
LAURA KOONTZ
Personalized Medicine Staff, Office of In Vitro Diagnostics and Radiological Health, FDA
Recent Initiatives in Precision Medicine
- Discuss FDA’s recent authorization of several companion diagnostics in oncology, including the Agency’s approach to analytical and clinical validation of oncopanels
- Discuss our regulatory approach for NGS-based tests
- Discuss other CDRH priorities in precision medicine for 2018

STEFAN SCHERER
VP & Head Early Development, Strategy and Innovation, US Oncology, Novartis
Integrated Precision Cancer Care – A New Paradigm
Cancer is a heterogeneous disease and personalized therapy relies on the ability to characterize the tumor every time new treatment is needed. Potential detection of circulating tumor cells (CTCs) or circulating free tumor DNA (ctDNA) to provide molecular characterization and guide patient treatment offers a potential path forward to address this challenge. Despite this significant advance in technology many questions remain to be answered on the clinical utility of ctDNA. Three major areas should be investigated in depth as they would provide a true step forward for personalized medicine. First, the validation of the potential as a diagnostic tool (prognostic and or predictive) in patients where tissue is no longer available; Second the validation of ctDNA as an appropriate platform to follow response and/or progression to treatment; finally validation of ctDNA to detect resistance mechanism and provide information on the next most appropriate treatment for the patient. Although tumor tissue is the gold standard for clinical and investigational sequencing, major barriers exist in terms of acquisition and utilization. Hence, appropriate analytical and clinical validation of ctDNA as a surrogate endpoint should be a priority in the field of oncology.

12:10-12:40
SPONSORED PRESENTATION:
COURTNEY NICHOLSON
Director of Business Development, Abcam Plc
Targeted analytics and High-Performance Antibody solutions to transform biomarker discovery for diagnostic and therapeutic applications for use in clinical applications
- The use of targeted analytics to improve selection targets for development in diagnostics and therapeutic programmes.
- Application of Next-Generation Sequencing for antibody development to increase the functionally relevant candidate pool for recombinant antibodies to be used in diagnostic and therapeutic applications.
- True end-to-end custom solutions: from antibody discovery to assay development and commercialisation. Abcam works with diagnostic and therapeutic partners, delivering best-in-class antibodies against key and challenging targets in areas including immune-oncology, neuroscience, cancer, immunology and epigenetics.

11:40-12:10
LAURA KOONTZ
Personalized Medicine Staff, Office of In Vitro Diagnostics and Radiological Health, FDA
Recent Initiatives in Precision Medicine
- Discuss FDA’s recent authorization of several companion diagnostics in oncology, including the Agency’s approach to analytical and clinical validation of oncopanels
- Discuss our regulatory approach for NGS-based tests
- Discuss other CDRH priorities in precision medicine for 2018

STEFAN SCHERER
VP & Head Early Development, Strategy and Innovation, US Oncology, Novartis
Integrated Precision Cancer Care – A New Paradigm
Cancer is a heterogeneous disease and personalized therapy relies on the ability to characterize the tumor every time new treatment is needed. Potential detection of circulating tumor cells (CTCs) or circulating free tumor DNA (ctDNA) to provide molecular characterization and guide patient treatment offers a potential path forward to address this challenge. Despite this significant advance in technology many questions remain to be answered on the clinical utility of ctDNA. Three major areas should be investigated in depth as they would provide a true step forward for personalized medicine. First, the validation of the potential as a diagnostic tool (prognostic and or predictive) in patients where tissue is no longer available; Second the validation of ctDNA as an appropriate platform to follow response and/or progression to treatment; finally validation of ctDNA to detect resistance mechanism and provide information on the next most appropriate treatment for the patient. Although tumor tissue is the gold standard for clinical and investigational sequencing, major barriers exist in terms of acquisition and utilization. Hence, appropriate analytical and clinical validation of ctDNA as a surrogate endpoint should be a priority in the field of oncology.

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GEOFFREY KUESTERS
Head of Companion Diagnostics and Biomarkers, Merrimack Pharmaceuticals

Translating preclinical mechanistic data to enable patient selection: Case studies for a Her-3-targeted monoclonal antibody and an EphA2-targeted antibody-directed nanotherapeutic

- Mechanism of action of MM-310, an EphA2-targeted antibody-directed nanotherapeutic, and biomarker translation approach
- Development of a first in class Her-3-targeted monoclonal antibody and biomarker hypothesis testing in the clinic

1 HOUR PRESENTATION:
DAVID SAHNER
Senior advisor to various companies in the Artificial Intelligence and Biotechnology sectors

Predictive Analytics in a Health Care: General Overview and a Potential Role for Quantum Annealing in the Enhancement of Patient Outcomes?

Machine learning in medicine has become a marquis phrase. We will review some of the methods and efforts in the field, which generally offer the hope of enhancing the accuracy and timeliness of specific clinical predictions. A novel quantum annealing-based approach, which may furnish the possibility of granting wide-ranging insights into a panoply of risks and possible outcomes for an individual patient, will be discussed. This experimental method entails the solving of inference problems, grounded in large, complex, population-based graphical models, which may be refractory to classical solvers.

FRANCESCO GALIMI
Global Product General Manager, Early Development, Amgen, Inc.

Bi-specific T-cell Engagers (BiTE®) in Hematological Malignancies

The bispecific T-cell engager (BiTE®) blinatumomab (Blincyto®) has recently been approved for Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia. It consists of two single chain variable fragments (scFvs) specific for CD19 present on the B-cell lineage, and CD3 expressed on almost all T cells. Based on the potent anti-tumor activity of Blincyto® in B-cell malignancies, BiTE® antibody constructs directed against other target antigens are being tested in a number of malignancies, in particular acute myeloid leukemia and multiple myeloma. We will review the ongoing activities in this field.

PAMELA CARROLL
Senior Vice President, Immuno-oncology, Genocea Biosciences

Comprehensive discovery of tumor antigens for better personalized vaccines

- Personalized cancer vaccines are designed to activate tumor-specific neoantigen-activating T cells.
- The looming problem in the field are good technologies that can identify potent neoantigens from a patient’s mutanome.
- The ATLAS technology detects bona fide antigens, without predictions, by rapidly screening a patient's peripheral blood T cells with their tumor-specific mutations presented by autologous dendritic cells.
- ATLAS-identified antigens have limited overlap with those identified by in silico methods.
- Neoantigens that induce either CD4+ or CD8+ T cell responses (or both) are identified.

KEVIN KELLY
Supervisor, Clinical Genomic Testing, Jackson Laboratory for Genomic Medicine

ANDREW HESSE
Manager, Clinical Data Analytics & Reporting, Jackson Laboratory for Genomic Medicine

Liquid biopsies are currently being used by oncologists to monitor the effectiveness of treatment, in terms of resistance to therapies, to monitor disease recurrence, detect metastasis, and measure minimal residual disease. The JAX Liquid Biopsy test is a plasma based test evaluating 14 genes across 84 hotspots. The development and validation of this panel will be discussed.
MAKING A POSTER PRESENTATION

Poster presentation sessions will take place in breaks and alongside the other breakout sessions of the conference. Your presentation will be displayed in a dedicated area, with the other accepted posters from industry and academic presenters. We also issue a poster eBook to all attendees with your full abstract in and can share your poster as a PDF after the meeting if you desire (optional). Whether looking for funding, employment opportunities or simply wanting to share your work with a like-minded and focused group, these are an excellent way to join the heart of this congress.

In order to present a poster at the congress you need to be registered as a delegate. Please note that there is limited space available and poster space is assigned on a first come first served basis (subject to checks and successful registration). We charge an admin fee of €100 to industry delegates to present, that goes towards the shared cost of providing the poster presentation area and display boards, guides etc. This fee is waived for those representing academic institutions and not for profit organisations.
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