OXFORD GLOBAL

Biomarkers & Precision Medicine USA Congress

3-4 October 2016, San Diego, USA

Day 1 Stream 1
The Role Biomarkers in Translational Science and Precision Medicine
Improving Cancer Patient Care Through Translational Science
Safety, efficacy and PK/PD biomarkers in drug development
Predictive biomarkers for drug development
Translating biomarkers from discovery stages through to exploratory clinical testing
Advancing Clinical Data and Precision Medicine
Big Data challenges in biomarker research

Day 1 Stream 2
Personalised Medicine, Companion Diagnostics & Patient Testing
Personalised healthcare: translating scientific innovation into patient benefit
The future of targeted therapy and precision medicine
Updates on companion diagnostics development
The impact of patient self-monitoring in healthcare
Challenges of drug & diagnostics co-development

Day 1 Stream 3
Biomarker: Clinical Development & Clinical Trials
Overcoming challenges of clinical validation & translation
Surrogate endpoints: utilising biomarkers in clinical trials
Implementing clinical biomarker in Auto-Immune Diseases
Transforming clinical development through biomarker driven clinical trials design
Predictive biomarker discovery in proof – of concept clinical

Day 2 Stream 1
Biomarker Discovery and Development
Biomarker assay development and validation
Novel biomarker discovery & identification
Discovery and Development of neurological and immune-oncology disease markers, Rare Diseases, Organ and Cardiovascular diseases
Predictive cancer biomarkers for targeting therapy
New advances in biomarker technologies and platform
Imaging and Cytometry Technologies

Day 2 Stream 2
Clinical Diagnostics, NGS & Genomic Marker Development
NGS for clinical testing & diagnostics
Case Studies: mircoRNA's, CTCs, circulating free DNA & exosomes
Biomarkers for non-invasive diagnosis
The importance of liquid biopsies
Clinical effectiveness of diagnostic markers & screening of new markers

Speakers for 2016

Anka G. Ehrhardt
Bristol-Myers Squibb Co

Johan Luthman
Eisai

Arijit Chakravarty
Takeda Pharmaceuticals

Benefits to Attending

- ✓ **Hear from and meet with the key innovators in** biomarker research from **Merck, AstraZeneca, Genentech, Pfizer, Bristol Myers Squibb, Takeda, Bayer and c-Path, NIH, Translational Genomics Institute**
- ✓ **Discover novel pre-clinical and clinical biomarker research strategies in therapeutic areas** including: Oncology, COPD, Immune-oncology, Autoimmune Diseases, Cardiovascular, Fibrotic Disorders
- ✓ **Discover** successful case studies on the application of Biomarker research in Clinical Development & Clinical Trials Design and Management
- ✓ **Learn about** approaches of Biomarkers research in Precision Medicine, Personalised Healthcare & Companion Diagnostics Development
- ✓ **Advance your understanding** in the recent developments in Integrative Biology, Clinical Diagnostics and NGS & Genomic Markers, and deployment in the clinic.
- ✓ **Advancing Precision Medicine in** managing clinical data and managing biomarker data
- ✓ **A high quality programme devised with the help of our esteemed advisory board.** Presentations will cover areas including drug design, discovery informatics and discovery data, computational chemistry, open innovation and external research strategies
- ✓ **Co-located with our Drug Discovery USA Congress**

Do not miss out on our 2 complimentary webinars. Register now by visiting http://www.biomarkersusa-congress.com

- ✓ **Immuno-Oncology – Translation in the Clinic– 16th July**
- ✓ **Driving Precision Medicine and Advancing Clinical Data– 30th August**

Meet Senior Decision Makers
Over 180 VPs, Directors & Senior Managers from leading pharmaceutical organisations, biotech companies and academic institutions will attend the event. Delegate job titles include:

Biomarker Discovery	Imaging Technologies
Biomarker Validation	Personalised Medicine
Companion Diagnostics	Preclinical Safety
Clinical & Genomic Biomarkers	Translational Medicine

Discover New Solutions
Formal and informal meeting opportunities offer delegates the chance to discuss key solutions with leading service providers. Services to be discussed include:

Assay Validation	Patient Selection Markers
Biomarker Verification	Regulatory Services
Biomarker Data Management	Genomic Biomarkers
Diagnostic Development	Clinical Validation

For booking details & registration fees please refer to the last page or visit: http://www.biomarkersusa-congress.com/marketing

2016 Confirmed and Reserved Biomarkers USA Congress Speakers include:

- Jianda Yuan, Director, Translational Immuno-Oncology Research, Merck Research Laboratories
- Jean-François Martini, Senior Director, Immuno-oncology, Early Development & Translational Oncology, Global Product Development, Pfizer
- John-Michael Sauer, Executive Director, Predictive Safety Testing Consortium, Critical Path Institute
- Mark Curran, Vice President Immunology, Janssen Research & Development, LLC
- Ann Kapoun, Vice President, Translational Medicine, OncoMed Pharmaceuticals
- J. Carl Barrett, Vice President, Translational Science, Oncology Innovative Medicines Division, AstraZeneca Pharmaceuticals
- Philip M. Arlen, President & Chief Executive Officer, Precision Biologics
- Johan Luthman, Vice President Neuroscience R&D, Franchise Integrator, Eisai
- Mark Day, Executive Director and Head of External Research and Scouting, Alexion Pharmaceuticals
- Zhenhao Qi, Associate Director, Clinical Genetics and Genomics, Bristol Myers Squibb
- Arijit Chakravarty, Director, Modeling & Simulation (DMPK), Takeda Pharmaceuticals
- Frank Kramer, Director Biomarker Expert Cardiovascular, Bayer Pharma AG / Experimental Medicine Cardiology & Hematology
- Chan Whiting, Director, Aduro Biotech
- Michael A. Kiebish, Chief Precision Medicine Officer, BERG Health
- David L. Boyle, Professor of Medicine, Director, Biomarker Laboratory, Director, Translational Technology Division, ACTRI
- Geoffrey Kuesters, Senior Scientist, Companion Diagnostic & Clinical Assays, Merrimack Pharmaceuticals
- Jean-Marie Bruey, Oncology Biomarker Development, Diagnostics, Genentech
- Robert Pierce, Chief Scientific Strategist, OncoSec Medical, Inc.
- Richard Baumgartner, Senior Principal Scientist, Merck & Co.
- Anka G. Ehrhardt, Director Clinical Cytometry, Bristol-Myers Squibb
- Nikolai Ivanov, Manager, Research Technologies, Philip Morris International R&D
- Zoë Johnson, Head of Bioanalytical Sciences, Novimmune SA
- Luc Van Rompaey, Vice President Translational Medicine, Argenx BVBA
- Eric Kowack, Vice President, Program Team Leader, Ignyta Inc
- Anand Giddabasappa, Principal Scientist, Global Science and Technology, Pfizer
- Nathan Hedrick, Principle Scientist Clinical Cytometry, CTTO, ECTR, Bristol-Myers Squibb
- David Jackson, Vice President - Diagnostic / Companion Diagnostics, Arno Therapeutics, Inc
- Oliver Poetz, Head of Protein Analytics, NMI Natural & Medical Sciences Institute, University of Tuebingen
- Stephen Pennington, Professor of Proteomics, University College Dublin & Atturos
- Murtaza Mehdi, Director, Corporate & Business Development, Foundation Medicine
- John Beeler, Vice President, Business Development, Inivata
- Subrata Sen, Professor & Deputy Chair, Department of Translational Moelcular Pathology, University of Texas MD Anderson Cancer Center
- Adil Daud, Director, Melanoma Program, Clinical Professor of Medicine Division of Hematology/Oncology, University of California, San Francisco
- Bodour Salhia, Assistant Professor, Integrated Cancer Genomics, University of Southern California
- Marina Sirota, Assistant Professor, University of California, San Francisco
- Kevin Knopf, Medical Director, Cancer Commons
- Sami Mahur, Scientist, Genentech

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Biomarkers and Precision Medicine USA Congress
Day 1 – 3rd October 2016

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<tr><td>08.20 – 08.25</td><td colspan="2">Oxford Global's Welcome Address</td></tr>
<tr><td>08.25 – 08.30</td><td colspan="2">Chairperson's Opening Address: Daniel Chelsky, Chief Scientific Officer, Caprion</td></tr>
<tr><td>08.30 – 09.00</td><td colspan="2">Keynote Address
Next Generation Biomarkers For The Era Of Combination Cancer Immunotherapy
• First- and second-generation biomarkers that predict response to PD-1-directed monotherapy
• Biomarker challenges in an era with an enhanced cancer immunotherapy armamentarium
• Precision medicine in cancer immunotherapy

Jianda Yuan, Director, Translational Immuno-Oncology Research, Merck Research Laboratories</td></tr>
<tr><td>09.00 – 09.30</td><td colspan="2">Improving Patient Care Through Translational Science
• Biomarkers- improving the probability of success
• The utility of Biomarkers for rare diseases
• FDA updates on Orphan and rare diseases
Mark Day, Executive Director & Head of External Research & Scouting, Alexion Pharmaceuticals</td></tr>
<tr><td></td><td>Conference Room: Cortez 3</td><td>Conference Room: Hillcrest 2</td></tr>
<tr><td></td><td>The Role Biomarkers in Translational Science and Precision Medicine</td><td>Biomarker: Clinical Development & Clinical Trials</td></tr>
<tr><td></td><td>Stream Chair: Daniel Chelsky, Chief Scientific Officer, Caprion</td><td>Stream Chair: Paul Ko Ferrigno, Director, External Collaborations, Avacta</td></tr>
<tr><td>09.30 – 10.00</td><td colspan="2">Solution Provider Presentation

Daniel Chelsky, Chief Scientific Officer, Caprion

CAPRION</td></tr>
<tr><td>10.00 – 11.20</td><td colspan="2">Exhibition Room: Cortez Ballroom
Coffee & Refreshments, One to One Meetings x4, Poster Presentation Sessions</td></tr>
<tr><td>11.20 – 11.50</td><td>Development of Preclinical Models and Translation in the Clinic
• Strategies in diagnostics development
• Presenting early clinical data

Ann Kapoun, Vice President, Translational Medicine, OncoMed Pharmaceuticals</td><td>Challenges of Drug and Diagnostic Co-Development: Examples in Auto-Immune Disorders
• Precision Medicine remains a critical unmet need in auto-immune disorders
• Progress toward prognosis and prediction in RA and IBD
• Importance of genetic factors in drug response – learnings from genome sequencing in RA
• Role of disease phenotypes in companion diagnostic development

Mark Curran, Vice President Immunology, Janssen Research & Development, LLC</td></tr>
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Biomarkers and Precision Medicine USA Congress
Day 1 – 3rd October 2016

	Conference Room: Cortez 3	Conference Room: Hillcrest 2
11.50 – 12.20	**Translational Sciences In Oncology: From The Bench To The Clinic And Back Again** • Precision Medicine and Companion Diagnostics • Development of PARP and EGFR inhibitors • NGS and ctDNA **J. Carl Barrett, Vice President of Translational Science, Oncology Innovative Medicines Division, AstraZeneca Pharmaceuticals**	**Paving the Roads For Discoveries: Clinical Biomarkers At The Intersection Between Science and Logistics** • The importance of top quality in balance with the need for speed in clinical studies • The impact of logistics on science and innovation in clinical studies, and ways to use collaboration to overcome these challenges and deliver valuable biomarker data **Anka G. Ehrhardt, Director Clinical Cytometry, Bristol-Myers Squibb**
12.20 – 12.50	**A Novel Strategic Approach to Conducting Dx-Driven Oncology Trials Drives Enrollment in Rare Patient Populations** **Eric Kowack, Vice President, Program Team Leader, Ignyta Inc**	**How Medical Device-Derived Biomarkers Can Support Patient Selection And Monitoring In Clinical Studies In Cardiovascular Indications** • Biomarkers play a different role in cardiovascular indications compared to oncology • The complexity of cardiovascular diseases require a thorough characterization of patients at entry and during clinical studies, which can be achieved using blood biomarkers and functional measurements • Implantable and wearable medical device represent a rich source of functional biomarkers **Frank Kramer, Director Biomarker Expert Cardiovascular, Bayer Pharma AG / Experimental Medicine Cardiology & Hematology**
12.50 – 13.50	**Exhibition Room: Cortez Ballroom** **Lunch and One to One Meetings x2**	
	Stream Chair: Daniel Chelsky, Chief Scientific Officer, Caprion	**Stream Chair: Tanja Schubert, General Manager, Biochemical Marker Laboratory, Bioclinica**
13.50 – 14.20	**Innovative Use of PK/PD In The Development Of A Biologic Drug For A Rare Pediatric Disease** • Based on the growing evidence that IFNɣ plays a pivotal role in HLH, NI-0501, an anti-IFNɣ monoclonal antibody, is being developed as the first targeted treatment of HLH. • On the basis of calculated neutralizing NI-0501 concentrations, NI-0501 PK parameters in healthy volunteers and PK information from use of recombinant IFNɣ in humans, we predicted, by means of PK modelling and simulation, the dose needed to neutralize existing and *de novo* IFNɣ production. • IFNɣ neutralization in serum following NI-0501 infusion was confirmed through down-modulation of IFNɣ-inducible proteins, such as CXCL9 and CXCL10. **Zoë Johnson, Head of Bioanalytical Sciences, Novimmune SA**	**The Case Study – Clinical Studies in COPD and Cardiovascular therapeutic areas and the Role of Biomarkers** • Biomarkers of exposure measured in pre-clinical and clinical studies • Biomarkers of disease risk, COPD and CVD end points **Nikolai Ivanov, Manager, Research Technologies, Philip Morris International R&D**

	Conference Room: Cortez 3	Conference Room: Hillcrest 2
14.20 – 14.50	**Population Medicine: Selection of Phase II Indications Based on Patient Biology** • Prior to initiating Phase II trials, performing comprehensive assessment of molecular presentation of patient populations responding/not responding to 1st or 2nd line therapy. • Defining populations for rapid progression/metastasis as well as long term survival • An example will be given for BERG's BPM 31510 clinical trial development as well as selection of indications based on OMICs signatures **Michael A. Kiebish, Chief Precision Medicine Officer, BERG Health**	**Functional Magnetic Resonance (fMRI) in Early Drug Development, Integration and Considerations For Test-Retest In Clinical Studies** • We will review current status of the implementation of the functional MRI (fMRI) in clinical studies. In particular we will discuss desiderata on design and planning of clinical studies with fMRI. • We will discuss the merits of the assessment of test-retest repeatability in fMRI and pharmaco-MRI studies as an integral part of fMRI/phMRI biomarker validation for early drug development. We will also discuss the relationship of test-retest evaluation to the elucidation of sensitivity of fMRI endpoints to treatment effect. **Richard Baumgartner, Senior Principal Scientist, Merck & Co**
	Conference Room: Cortez 3	
14.50 – 15.20	**Affimer® Binders As Alternatives To Antibodies For Biomarker Detection** • Biomarker assays frequently rely on antibodies • The availability of antibodies with requisite specificity and affinity can be rate-limiting • Affimer® technology offers an alternative, more rapid route to the production of specific, high affinity binders • This presentation will focus on internal projects where high quality Affimer® binders have been developed and applied in assay development **Paul Ko Ferrigno, Director, External Collaborations, Avacta** Avacta® LIFE SCIENCES	**Solution Provider Presentation** • AFFINImeter: filling the gaps existing in other existing software packages • Exploiting the full potential of Isothermal Titration Calorimetry with AFFINImeter: presenting the tools KinTC, for the kinetic characterization of interactions, and the model builder, for the thermodynamic analysis of complex binding • AFFINImeter in Drug discovery & Development **Eva Muñoz, Senior Scientist, AFFINImeter** AFFINIMETER
	Conference Room: Cortez 3	**Conference Room: Hillcrest 2**
15.20 – 15.50	**Precision Medicine in the Community Oncology Clinic** • Real time application of precision medicine in actively treated cancer patients • Challenges in dissemination of genomic knowledge and next generation sequencing in real time • Economic challenges and opportunity in precision oncology **Kevin Knopf, Medical Director, Cancer Commons**	**Discovery of Novel Biomarkers in Solid Tumors and Their Application for both therapeutic and companion diagnostics in Clinical Trials** • Utilization of an allogeneic cancer vaccine platform previously tested in patients • Screening for functional antibodies demonstrating both sensitivity and specificity to tumor, as well as antitumor immune function • Identifying novel epitopes and developing these antibodies as potential therapeutic compounds and companion diagnostics **Philip M. Arlen, President & Chief Executive Officer, Precision Biologics**
15.50 – 16.30	**Exhibition Room: Cortez Ballroom** **Afternoon Refreshments, One to One Meetings x2, Poster Presentation Sessions**	
16.30 – 17.00	**Integrating Clinical and Omic Data To Advance Precision Medicine** • How to leverage publicly available data for research • Biomarker and therapeutic discovery integrating clinical and omic data • Drug discovery in the era of precision medicine **Marina Sirota, Assistant Professor, University of California, San Francisco**	**Leveraging Personalized Medicine to Optimize Therapeutic Approaches in Cancer Immunotherapy** • Personalised Medicine, Companion/Complementary Diagnostics • Cancer Immunotherapy at Genentech • Next Generation Companion Dx in clinical development **Jean-Marie Bruey, Companion Diagnostics Group Leader/ Sr Scientist, Oncology Biomarker Development & Diagnostics, Genentech**

17.00 – 17.30	**Turning Data Into Information Into Knowledge – Current Challenges With Biomarker Data** • Utilization of Genomic data for clinical trial design • Utilization of a broad NGS platform for enrollment acceleration of targeted clinical trials • Associated Time and Cost savings to the therapeutic program **Murtaza Mehdi, Director, Corporate & Business Development, Foundation Medicine**	**Companion Diagnostic and Clinical Assay Development and Implementation** **Geoffrey Kuesters, Senior Scientist, Companion Diagnostic & Clinical Assays, Merrimack Pharmaceuticals**
17.30- 18.00	**Healthy Donor Studies And The Importance Of A Reference Cohort For Establishing Personalized Biomarker Strategies** **Sami Mahur, Scientist, Cancer Immunology, Genentech**	**Case Study: Development And IDE Approval Of A Companion Diagnostic** • Strategic planning • Partnering • Co-development program • Regulatory interactions **David Jackson, Vice President - Diagnostic / Companion Diagnostics, Arno Therapeutics, Inc**
18.00	**Exhibition Room: Cortez Ballroom** **Networking Drinks** **End of Day One**	

Biomarkers and Precision Medicine USA Congress
Day 2 – 4th October 2016

7.50 – 8.00	**Conference Room: Cortez 3**
	Stream Chair: Senior Representative, Axio
08.00 – 08.30	**Stream Keynote Address:** **Developments in Neuroscience and Translational Medicine** **Johan Luthman, Vice President Neuroscience R&D, Franchise Integrator, Eisai**
08.30 – 9.00	**Critical Path Institute's Predictive Safety Testing Consortium – The Road to Translational Safety Biomarker** • This presentation will describe in detail the current approach accepted by the FDA, EMA, and PMDA for the qualification of translational safety biomarkers for use in nonclinical species and humans. • Several illustrative examples will also be discussed from both their biological and regulatory science prospective. • The objective of the presentation will be to highlight the importance of safety biomarkers in drug development and the value of biomarker qualification **John-Michael Sauer, Executive Director, Predictive Safety Testing Consortium, Critical Path Institute**

Biomarkers and Precision Medicine USA Congress
Day 2 – 4th October 2016

	Conference Room: Cortez 3	Conference Room: Hillcrest 2
	Biomarker Discovery and Development – Qualification, Validation, Assay Development, Imaging in Different Therapeutic Approaches	**Innovative Biology - Clinical Diagnostics, NGS & Genomic Marker Development**
	Stream Chair: Senior Representative, Axio	**Stream Chair: Senior Representative, Fios Genomics**
09.00 – 09.30	**The SAFE-T Consortium - Drug Induced Organ Injury Biomarker Across the Species Barrier** • Mass spectrometry-based immunoassays for animal models • Drug-induced kidney injury marker in monkey, dog and men • Drug-induced liver injury marker in monkey, dog and men **Oliver Poetz, Head of Protein Analytics, NMI Natural & Medical Sciences Institute, University of Tuebingen**	**Managing the Cancer Genome Atlas and Implications on Biomarker Discovery and Development** **RESERVED: Jean C. ZenKlusen, Director, The Cancer Genome Atlas, National Cancer Institute**
09.30 – 10.00	**Biomarker Strategy Supporting The Development of ARGX-110** • CD70 is an attractive target for the treatment of oncology and autoimmune diseases • ARGX-110 is an engineered, differentiated antibody targeting CD70, currently in Phase I/II clinical trials **Luc Van Rompaey, Vice President Translational Medicine, Argenx BVBA**	**The Use of cfDNA ("Liquid Biopsy") In Clinical Trials for Novel Agents** • Collection of tumor tissue biopsy in the recurrent/metastatic setting can be challenging due to accessibility of biopsiable site, potential risk for patient's safety and also cost. • Circulating free (tumor) DNA (cfDNA) is blood based biospecimen that is a reliable yet less invasive source of tumor DNA (and/or RNA). • We will review 2 examples of mutation detection in plasma in Breast Cancer (ESR1 mutations) and Lung Cancer (ALK/ROS1 mutations), and discuss advantages and pitfalls of currently available platforms. **Jean-François Martini, Senior Director, Immuno-oncology, Early Development & Translational Oncology, Global Product Development, Pfizer**
10.00 – 11.00	**Exhibition Room: Cortez Ballroom** **Morning Coffee, One to One Meetings x3, Poster Presentation Sessions**	
	Conference Room: Cortez 3	
11.00 – 11.30	**The Use Of Targeted Metabolomics To Develop Metabolic Biomarker Signatures For Diagnosis, Differential Diagnosis And Treatment Stratification** • Clinicians already use metabolic markers in their routine, but so far only use a fraction of metabolic information available • Metabolomics, in that sense, builds upon clinical routine and extends the information that can be obtained about the metabolic (=physiological) state of a patient • This talk will be discussing how targeted metabolomics has provided relevant biomarkers for diagnosis, differential diagnosis and treatment stratification, with a focus on applications in cancer pharmacology • Biocrates' technology is designed to facilitate transfer to routine clinical use by providing quantification, reproducibiltiy, and high thoughput. It is based upon an analytical platform that is well established in clinical use, e.g. for newborn screening, pharmacology and toxicology. An Example of the use of targeted metabolomics will be given to identify Plasma Metabolomic Changes following PI3K Inhibition as Pharmacodynamic Biomarkers for Preclinical Discovery to Phase I Trial Evaluation **Matthias Scheffler, Chief Business Officer, Biocrates** BIOCRATES LIFE SCIENCES The Deep Phenotyping Company	

	Conference Room: Cortez 3	Conference Room: Hillcrest 2
11.30 – 12.00	**Imaging (In vivo) in Pre-clinical Discovery and Development** Molecular Imaging has been a great tool in clinical oncology and oncology drug discovery/development. Imaging has been a good tool in diagnosis, evaluation of predictive and prognostic biomarkers and determining of therapeutic benefit of a drug. In this presentation we will discuss various imaging modalities with examples from pre-clinical oncology drug discovery. **Anand Giddabasappa, Principal Scientist, Global Science & Technology, Pfizer**	**Precision of Circulating Tumor DNA (ctDNA) Analysis in Oncology** • In the absence of an invasive tissue biopsy, *ct*DNA can be used as a 'liquid biopsy' for molecular profiling of actionable genetic alterations in cancer patients. • Many of the mutations present in ctDNA exist at low allele fractions that would be routinely missed using less sensitive assays thus reinforcing the importance of using a high sensitivity assay for ctDNA analysis. • This presentation will focus on the clinical application of InVision™, a robust and reproducible platform exhibiting high sensitivity and specificity for the detection of genomic alterations in ctDNA. **John Beeler, Vice President, Business Development, Inivata, Ltd**
12.00 – 12.30	**Biomarkers In Proof of Concept Trials In Rheumatoid Arthritis** • Presentation of data from numerous studies, methods, results, clinical and translational challenges **David L. Boyle, Professor of Medicine, Director, Biomarker Laboratory. Director, Translational Technology Division, ACTRI**	**From Innovation Pilot to Clinical Trials: Which Technologies Deliver Reliable Gene Expression in Clinical FFPE samples?** • Highly fragmented RNA in FFPE presents a significant challenge for reliably detecting gene expression using traditional TaqMan qPCR • We tested four new technologies to determine which platform will improve gene expression in CRC archival FFPE, thus enable accurate gene expression analysis of FFPE samples in clinical programs and alignment of best method to future diagnostic development **Zhenhao Qi, Associate Director, Clinical Genetics and Genomics, Bristol Myers Squibb**
12.30 – 13.30	**Exhibition Room: Cortez Ballroom** **Lunch & One to One Meetings x3**	
13.30 – 14.00	**Biomarker Development for Intratumoral Gene Therapy with DNA-encoded IL-12** • Patient selection biomarkers for low TIL/low anti-PD1 responder population • Pharmacodynamic (PD) biomarkers of effective in-situ vaccination **Robert Pierce, Chief Scientific Strategist, OncoSec Medical, Inc.**	**Deregulated MicroRNAs as Cancer Biomarkers** **Subrata Sen, Professor & Deputy Chair, Department of Translational Moelcular Pathology, University of Texas MD Anderson Cancer Center**
14.00 – 14.30	**Biomarker Assay Development in Immunology** **Nathan Hedrick, Principal Scientist, Clinical Cytometry, CTTO, ECTR, Bristol-Myers Squibb**	**Role of Biomarker in Genomic Medicine - Identification of Predictive DNA Methylation Biomarkers** • feasibility of DNA methylation liquid biomarkers • the need for biomarkers to prognosticate/predict breast cancer recurrence **Bodour Salhia, Assistant Professor, Integrated Cancer Genomics, University of Southern California**

Biomarkers and Precision Medicine USA Congress
Day 2 – 4th October 2016

	Conference Room: Cortez 3
14.30– 15.00	**Panel Discussion- Immuno-oncology Biomarker Development** • Challenges in Precision medicine • Status of PDL1 assay and biomarker development and other pathways • Non Respondence of PDL1 • Lessons learnt **Chair: Adil Daud, Director, Melanoma Program, Clinical Professor of Medicine Division of Hematology/Oncology, University of California, San Francisco** **Panellists:** **Robert Pierce, Chief Scientific Strategist, OncoSec Medical, Inc.** **Chan Whiting, Director, Aduro Biotech** **Nathan Hedrick, Principle Scientist Clinical Cytometry, CTTO, ECTR, Bristol-Myers Squibb**
15.00 – 15.30	**Exhibition Room: Cortez Ballroom** **Afternoon Refreshments & One to One Meetings x2**
15.30 – 16.00	**Biomarker Strategy To Guide Clinical Development Of Cancer Immunotherapy** • Review novel Biomarkers • Discuss clinical and Biomarkers correlations • Mutation burden and response **Adil Daud, Director, Melanoma Program, Clinical Professor of Medicine Division of Hematology/Oncology, University of California, San Francisco**
16.00 – 16.30	**Cancer Immunotherapy Using Live-Attenuated *Listeria monocytogenes*: Biomarker Perspective** • Overview of Aduro's core LADD platform (Live, Attenuated, Double-Deleted *Listeria mononcytogenes*) • Clinical trial updates in pancreatic cancer and mesothelioma • Ongoing analyses in tumor infiltrating immune cells, circulating cellular, tumor/protein biomarkers that may account for differential patient responses **Chan Whiting, Director, Aduro Biotech**
16.30 – 17.00	**The Signal Is The Noise: Heterogeneity As A Biomarker of Treatment Response** ▪ The evolutionary view of cancer and why it changes things ▪ Heterogeneity as the raw material of evolution ▪ Applying evolutionary theory in a practical drug development setting **Arijit Chakravarty, Director, Modeling & Simulation (DMPK), Takeda Pharmaceuticals**
17.00	**End of Conference**