5TH PRECISION MEDICINE & BIOMARKERS LEADERS SUMMIT: EUROPE

Examining groundbreaking biomarker, companion diagnostic, immuno-oncology, genomic, big data and AI research to facilitate the development of impactful personalized treatments for patients.

MUNICH, GERMANY
13-14 September 2018

Platinum Sponsor

Gold Sponsors

#PrecisionBiomarkersSummit

www.global-engage.com
Global Engage is proud to host the 5th Precision Medicine & Biomarkers Leaders Summit: Europe, taking place on September 13-14 at the Holiday Inn Munich City Centre, Germany.

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:**

- **RICHARD BARKER**
  Founding Director, New Medicines Partners

- **YIU-LIANG FONG**
  Global Head Diagnostic Innovation, Research and Early Development, and Lab Operation, Johnson & Johnson

- **KATHERINE CALL**
  Senior Director & Head, Proteogenomics, Translational Sciences, Sanofi

- **THORSTEN GUTJAHR**
  VP, Global Head of Companion Diagnostics, AstraZeneca
DAY 1 TRACK 1 - STRATEGIES AND TECHNOLOGIES TO DELIVER PRECISION MEDICINE

- Themes: Current & future perspectives - Innovative initiatives, strategies and approaches
- Themes: Delivering superior outcomes for patients through personalized healthcare
- Case Study Topic: AI & machine learning for Precision Medicine
- Case Study Topic: Microbiome research for Precision Medicine
- Case Study Topic: Real world evidence approaches
- Case Study Topic: Assessing and evaluating analytical validity, clinical validity & clinical utility
- Case Study Topic: Innovative clinical trial design
  - Digital tools in clinical trials
- Case Study Topic: Understanding physician, payer and patient perspectives
- Case Study Topic: Precision Medicine in practice: Overcoming adoption obstacles

DAY 1 TRACK 2 / DAY 2 TRACK 1 - BIOMARKER IN DISCOVERY, TRANSLATIONAL & CLINICAL DEVELOPMENT

- Themes: Biomarker strategy and approaches in oncology & non-oncology
- Themes: Biomarker impact on clinical & translational development
- Case Study Topic: Biomarker discovery
  - Biomarker data analysis
- Case Study Topic: Biomarker validation and qualification
- Case Study Topic: Patient selection strategies & Biomarkers for patient selection
- Case Study Topic: Biomarker impact on clinical & translational development
  - Clinical biomarker discovery
  - Multi-omic approaches
  - Digital biomarkers
- Case Study Topic: Biomarker LDTs v FDA-approved test analysis
- Case Study Topic: Statistical studies for clinical significance and reimbursement
- Case Study Topic: Non-Oncology case studies
- Case Study Topic: Regulatory perspective
- Case Study Topic: CDx strategies and accelerating development

DAY 2 TRACK 2 - ADVANCING IMMUNO-ONCOLOGY AND CDX

- Themes: Advancing I-O drug development
- Case Study Topic: Utilizing biomarkers as predictors of response
  - Tumor Mutation Burden analysis
- Case Study Topic: Precision pathology & Image analysis for I-O biomarkers
- Case Study Topic: Combining immunotherapy & targeted therapy
- Case Study Topic: Lessons learnt from successful CDx collaborations & approvals
- Case Study Topic: Circulating Tumour DNA (ctDNA) - detection & monitoring - unlocking realtime information
- Case Study Topic: Liquid biopsies – clinical utility
  - Immune checkpoint inhibitors / Immune response monitoring

ONE HOUR ROUNDTABLES – SESSION ONE & TWO

- Table 1 - Conducting Digital Clinical Trials: Precision Recruitment, Precision Enrollment and Precision Engagement
- Table 2 - Personalised Medicine and Adverse Events
- Table 3 - Microbiome research for Precision Medicine
- Table 4 - Conducting Precision medicine clinical trials
- Table 5 - Utilizing AI for Precision Medicine
- Table 6 - Tumor Mutation Burden
- Table 7 - Rare Diseases Precision Medicine
- Table 8 - Patient selection biomarkers
- Table 9 - Immuno-oncology Precision Medicine
- Table 10 - Advancing Liquid biopsy to the clinic
- Table 11 - Successful Companion Diagnostic partnership and co-development
- Table 12 - Big Data Approaches
- Table 13 - CNS Precision Medicine
- Table 14 - Cardio-Metabolic Precision Medicine
- Table 15 - Immunology and Respiratory Precision Medicine
- Table 16 - Infectious Disease Precision Medicine
Platinum Sponsor

intomics®

Gold Sponsors

FLUIDIGM®  OncoDNA  Leica BIOSYSTEMS

BGI GLOBAL GENOMIC SERVICES  METABOLON®  abcam

Silver Sponsor

ULTIVUE

Other Exhibitors & Sponsors

ALMAC  Data4Cure  Cureline

TRANS-HIT BIO  PRECISION® for MEDICINE  biotechne

Supporters

Genedata  biogazelle  MYRIAD®RB M  protagen DIAGNOSTICS
CONFIRMED SPEAKERS

RICHARD BARKER
Founding Director, New Medicines Partners

THOMAS S. JENSEN
CEO, Intomics A/S

RUTH KRESTIN
Director, Precision Medicine Policy and Business Insights, AstraZeneca

KATHERINE CALL
Senior Director & Head, Proteogenomics, Translational Sciences, Sanofi

THOMAS WILCKENS
CEO, InnVentis

WILL SPOONER
Commercial Programme Delivery Lead, Genomics England

JAREMA KOCHAN
Director Clinical Biomarkers, Quantitative Clinical Pharmacology & Translational Sciences, Daiichi Sankyo Inc

JANUSZ DUTKOWSKI
Co-founder and CEO, Data4Cure

AMY HAMILTON
Sr. Marketing Manager, EMEA, Fluidigm Corporation

THORSTEN GUTJAHR
VP, Global Head of Companion Diagnostics, AstraZeneca

SENIOR REPRESENTATIVE
Almac

TRACI DEGEER
Global Product and Innovation Manager – BOND RX, Leica Biosystems

PRADUMAN JAIN
Founder and CEO, Vibrent Health Inc. Principal Investigator (PI), Participant Technology Systems Center (PTSC), Co-Chair, Data Privacy and Security Work Group, Precision Medicine Initiative, National Institutes of Health (NIH)

FERGA GLEESON
Professor of Medicine, Mayo Clinic

BENJAMIN DIZIER
Director, Immunology Translational Medicine, UCB

CORINNA BARZ
Head Translational and Clinical Projects, Helmholtz Zentrum München

PIROUZ DAFTARIAN
Senior Manager, Applications for Immuno-oncology and Vaccines, JSR Micro, Life Sciences and MBLI

DOLORES CAHILL
Professor of Translational Science, University College Dublin

CORINNA WOLF
Senior Scientist Clinical Biomarker Biobanking, Clinical Biomarkers & Companion Diagnostics, Merck KGaA

CLAUDIA DOLLINS
Head, Global Regulatory Affairs, Biomarkers & Diagnostics, Merck KGaA

YIU-LIAN FONG
Global Head Diagnostic Innovation, Research and Early Development, and Lab Operation, Johnson & Johnson

CIARAN FULTON
Head of Diagnostics, LifeArc

STEPHAN JÄEGER
PHC Partnering Director, Roche Diagnostics GmbH

ALEXANDER BASTIAN
Head, Global Value, Access, & Pricing, Incyte

SHAHRAM KORDASTI
Senior Lecturer (Associate Professor) and Group Leader in Applied Cancer Immunopathology, Systems Cancer Immunology Lab, Guy’s Hospital

JEAN-MARIE BRUEY
Head of Oncology Biomarkers, Bristol-Myers Squibb

ANDRES HURTADO-LORENZO
Senior Director - Translational Research, Crohn’s & Colitis Foundation

AMIR HANDZEL
Co-founder and CEO, Pangea Diagnostics

SALLY LUKE
Associate Principal Scientist, Science and Enabling Units IT, AstraZeneca

SVETLANA MUKHINA
Manager Global Regulatory Affairs, Biomarkers and Diagnostics, Merck KGaA

MICHAEL HERMAN
Head Business Development Biopharma, OncoDNA

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

5TH PRECISION MEDICINE & BIOMARKERS LEADERS SUMMIT: EUROPE 2018
KEYNOTE ADDRESS: RICHARD BARKER
Founding Director, New Medicines Partners
Topic: An enabling platform to close the widening gap between PM knowledge and clinical practice

KEYNOTE ADDRESS: PRADEMAN JAIN
Founder and CEO, Vibrant Health Inc. Principal Investigator (PI), Participant Technology Systems Center (PTSC), Co-Chair, Data Privacy and Security Work Group, Precision Medicine Initiative, National Institutes of Health (NIH)
Large, Distributed Digital Recruitment Approach for Precision Medicine Research
Digital technologies offer potential to recruit distributed and large direct volunteers (DVs), for biomedical research and clinical trials, at a significantly lower cost compared to traditional methods. President Obama announced launch of the Precision Medicine Initiative® (PMI) “to bring us closer to curing diseases like cancer and diabetes, and to give all of us access to the personalized information we need to keep ourselves and our families healthier”. In order to achieve this plan, the PMI Cohort Program is building a national research cohort of 1+ million volunteers that will provide the platform for expanding knowledge of precision medicine approaches. The purpose is to Recruit, Enroll, Engage, Motivate and Sustain a Cohort that is nationally representative of inclusion, diversity and richness. Rapid advances in medical science, discovery of new diagnostic biomarkers and consumer adoption of latest Mobile and Cloud technologies is enabling new sources of data and insights. We will focus on principles of usability, trust, value and service to increase engagement, retention and achieve outcomes. This talk will discuss large initiatives such as NIH PMI (AllofUs Research program) that are emerging to harness convergence of multiple sources of data to gain insights into prevalence and progression of health and diseases. We will also discuss outcomes that are being achieved and a roadmap for research in consumer health using digital approaches.

SOLUTION PROVIDER PRESENTATION: THOMAS S. JENSEN
CEO, Intomics A/S
Title TBC

SOLUTION PROVIDER PRESENTATION: SENIOR REPRESENTATIVE
Novogene
Title TBC

SOLUTION PROVIDER PRESENTATION: SENIOR REPRESENTATIVE
Metabolon
Title TBC

50 MINUTE EXECUTIVE PANEL DISCUSSION:
Artificial Intelligence and machine learning – A paradigm shift in Pharma R&D
THOMAS WILCKENS (Chair)
CEO, InnVentis

50 MINUTE EXECUTIVE PANEL DISCUSSION:
Topic: Biomarker Patient Selection Strategies
AMIR HANDZEL
Co-founder and CEO, Pangea Diagnostics
PIROUZ DAFTARIAN
PhD, Senior Manager, Applications for Immuno-oncology and Vaccines, JSR Micro, Life Sciences and MBLI

Biomarkers
KATHERINE CALL
Senior Director & Head, Proteogenomics, Translational Sciences, Sanofi
Translational biomarker and patient stratification approaches and therapeutic applications
• Translational biomarker and patient stratification approaches
• Protein profiling – improved sensitivity and single cell analysis to advance projects
• Therapeutic project examples
Genomics England has, over the past 4 years, successfully demonstrated the clinical utility of whole genome sequencing (WGS) in the diagnosis of rare disease. From October 2018 the NHS is commissioning WGS in clinical practice. This means that the collection of whole genomes that Genomics England holds, which is already world’s largest, is set to increase dramatically over the coming years. This talk considers how academia and industry has started to use the Genomics England dataset of linked genotypic-clinical data, the byproduct of genomic medicine, to address critical research questions, and how new insight can be translated into improved diagnostics and therapeutics.

**JAREMA KOCHAN**
Director Clinical Biomarkers, Quantitative Clinical Pharmacology & Translational Sciences, Daiichi Sankyo Inc

**Understanding the Biological Complexities of Disease and Therapeutics with Biomarkers**
- Utilizing biomarkers to better understand biological processes and drug activity
- Potential problems & pitfalls of antibodies used in subject selection
- Next generation sequencing to understand disease, PD responses, and responders

**FERGA GLEESON**
Professor of Medicine, Mayo Clinic

**The Evolving Clinical Interface between Gastrointestinal Endoscopy and Precision Oncology**
Clinical role and utility of endoscopic ultrasound in precision oncology with respect to:
- Tumor genotyping
- Determining tumor suitability for targeted therapy
- Determining tumor suitability targeted immunotherapy
- Assess eligibility for clinical trials
select optimal treatment strategies for patients. This talk will present UCB biomarker strategy in IMID Translational Medicine approach with examples from our portfolio.

ONE HOUR ROUNDTABLES – SESSION 1:

Table 1: Conducting Digital Clinical Trials: Precision Recruitment, Precision Engagement
PRADUMAN JAIN
Founder and CEO, Vibrent Health Inc. Principal Investigator (PI), Participant Technology Systems Center (PTSC), Co-Chair, Data Privacy and Security Work Group, Precision Medicine Initiative, National Institutes of Health (NIH)

Table 2: Personalised Medicine and Adverse Events
DOLORES CAHILL
Professor of Translational Science, University College Dublin

- Can lessons learned from cancer immunotherapy and immune related Adverse Events provide lessons for personalised medicine in other disease, including a greater understanding of Adverse Events and finding AE predictive biomarkers.

Table 3: Microbiome research for Precision Medicine
Table 4: Conducting Precision medicine clinical trials
Table 5: Utilizing AI for Precision Medicine
Table 6: Tumor Mutation Burden
Table 7: Rare Diseases Precision Medicine
Table 8: Patient selection biomarkers

We will discuss the impact of annotated, high quality samples on companion diagnostics development. This includes:
- Standardized collection of samples in large, multi-centric clinical trials and targeted sample preparation timely after collection to meet the needs for specific biomarker analyses
- Collection of comprehensive sample annotation information and quality attributes which are required for analyses and which might be requested by Regulatory Agencies
- Active informed consent management to ensure samples can be used for companion diagnostics development (e.g. assay validation, bridging study)

AMIR HANDZEL
Co-founder and CEO, Pangea Diagnostics
Biomarker-driven clinical trials: Innovative designs for Precision
A decade ago the iSPY and BATTLE trials ushered in a new type of clinical trials specifically tailored for Precision Medicine. These novel designs have addressed difficulties in using standard randomized trials for testing increasingly complex scientific hypotheses leveraging biomarker information for patient stratification and selection. They allow us to develop drugs for patient segments that otherwise would not be operationally feasible, clinically meaningful or financially viable. These significant advantages are extending beyond Oncology to other therapeutic areas which can benefit from biomarker-driven patient selection within broadly defined diseases.

CORINNA BARZ
Head Translational and Clinical Projects, Helmholtz Zentrum München
Helmholtz Zentrum München - From Idea to Proof of Concept

Helmholtz Zentrum München aims at developing personalized medical approaches for the prevention and therapy of major common diseases such as diabetes mellitus, allergies and lung diseases. To achieve this, the center investigates the interaction of genetics, environmental factors and lifestyle. The research approach relies on excellent basic research, cutting-edge experimental platforms, and centers for translational medicine in cooperation with Munich’s universities and other leading national and international institutes. Drug discovery activities focus on clinically relevant targets. The center encourages value creation and promotes the commercial use of new technologies and application of results. Innovative knowhow produced at the center is systematically protected by patents for successive licenses and spinoffs in order to deliver concrete benefits to society. This approach will be illustrated by selected examples.

ANDELS HURTADO-LORENZO
Senior Director - Translational Research, Crohn’s & Colitis Foundation
Towards Precision Medicine in Inflammatory Bowel Disease

Inflammatory bowel diseases or IBD, are characterized by chronic inflammation of the gastrointestinal tract. The course of the disease is variable, with some patients having much more aggressive disease than others and half of the patients developing severe complications. The main challenge in IBD is the early detection of patients with potentially severe disease course and variability in treatment outcomes. In this presentation I will highlight current advances towards the integration of clinical and molecular phenotyping for early prediction of complicated disease course at diagnosis and response to biological therapy. I will also highlight the efforts of the Crohn’s and Colitis Foundation to build the largest biorepository and research exchange platform called IBD Plexus, which aims to accelerate the path towards precision medicine in IBD.

CORINNA WOLF
Senior Scientist Clinical Biomarker Biobanking, Clinical Biomarkers & Companion Diagnostics, Merck KGaA
Enabling companion diagnostics development by tailored sample management

We will discuss the impact of annotated, high quality samples on companion diagnostics development. This includes:
- Standardized collection of samples in large, multi-centric clinical trials and targeted sample preparation timely after collection to meet the needs for specific biomarker analyses
- Collection of comprehensive sample annotation information and quality attributes which are required for analyses and which might be requested by Regulatory Agencies
- Active informed consent management to ensure samples can be used for companion diagnostics development (e.g. assay validation, bridging study)
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00-08:40</td>
<td>Refreshments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>08:40-09:20</td>
<td>Keynote Address:</td>
<td>THORSTEN GUTJAHR</td>
<td>Precision Medicine at AstraZeneca: a patient-centric approach</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VP, Global Head of Companion Diagnostics, AstraZeneca</td>
<td>- Describe AstraZeneca's approach in Precision Medicine with the focus on ‘the right patient’</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Explain actual diagnostic development examples including case studies for Osimertinib and Olaparib</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Outline the changing landscape in Precision Medicine and what it takes for future success</td>
</tr>
<tr>
<td>08:40-09:20</td>
<td>Keynote Address:</td>
<td>JEAN-MARIE BRUEY</td>
<td>Utilizing biomarkers as predictors of response</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Head of Oncology Biomarkers, Bristol-Myers Squibb</td>
<td></td>
</tr>
<tr>
<td>09:50-10:20</td>
<td>Solution Provider:</td>
<td>AMY HAMILTON</td>
<td>Visualize a New Path Forward: Mass Cytometry and Imaging Mass Cytometry for Translational Immune System Research</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sr. Marketing Manager, EMEA, Fluidigm Corporation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fluidigm is committed to empowering the cancer immunotherapy community with research tools to interrogate immune cell function and the tumor microenvironment with unprecedented resolution. Using proven mass cytometry and microfluidic technologies, we provide workflows to identify and characterize changes in cellular phenotypes at single-cell resolution. Whether you seek to target new biomarkers and pathways or to optimize the effectiveness of checkpoint inhibitors, CAR T cells or cancer vaccines, Fluidigm can help you identify new insights to reach your next research breakthrough. Together we will transform the future of cancer care.</td>
</tr>
<tr>
<td>09:50-10:20</td>
<td>Solution Provider:</td>
<td>SHAHRAM KORDASTI</td>
<td>Bench to Bytes: translating &quot;Big Data&quot; to the clinic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Senior Lecturer (Associate Professor) and Group Leader in Applied Cancer Immunopathology, Systems Cancer Immunology Lab, Guy's Hospital, London, UK</td>
<td>Mass cytometry yields new insights into systems biology by dramatically increasing the amount of information obtained from each cell. The Helios™ system provides a robust way to measure over 40 protein parameters per single cell using proven CyTOF® technology. King’s Health Partners-Cancer Research UK Cancer Centre has used mass cytometry and multidimensional data analysis to identify two distinct subpopulations of regulatory T cells (Treg A and Treg B) with distinct phenotypes, gene expression, expandability and function in patients with aplastic anemia (AA) and myelodysplastic syndrome (MDS). This approach also identifies an immune signature that is predictive of response to immunotherapy at the time of diagnosis of AA or MDS, which may allow a more patient-specific approach to future treatment decisions.</td>
</tr>
<tr>
<td>10:20-11:30</td>
<td>Morning Refreshments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:20-11:30</td>
<td>One-to-One Meetings</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**SOLUTION PROVIDER PRESENTATION**

**MICHAEL HERMAN**
Head Business Development Biopharma, OncoDNA

**Precision Oncology services or how daily testing cancer patients can help patient characterization for biopharma partners and clinical trial enrollment**

- OncoDNA is daily testing patients for characterizing their tumor and providing oncologists with the most suited treatment options.
- The tools developed by OncoDNA to predict the potential benefit of these treatments can serve biopharma drug developments by finding, testing and/or monitoring biomarkers in clinical trials.
- Characterization of patients in OncoDNA’s routine testing can improve and speed-up clinical trial recruitment.
- Specific strategies can be put in place to enlarge the basis of patients tested prior their enrollment in clinical trials.
- Identification of patients eligible for the treatment during the commercial life cycle on the market – Companion diagnostic considerations.

---

**PIROUZ DAFTARIAN**
Senior Manager, Applications for Immuno-oncology and Vaccines, JSR Micro, Life Sciences and MBLI

**A recall antigen-based potency assay for immunomodulatory biologics discriminates hosts to responders and non-responders. Can it be used to predict responders?**

- Will present an MHC tetramer guided recall antigen potency assay for functional screening of immune checkpoint blockades and agonist of co-stimulatory agents.
- Will present how the assay divides hosts’ PBMC in non-responders and responders.
- Will present data on how ex expression of immune checkpoint molecules may contribute in unresponsiveness to ICI.

---

**SALLY LUKE**
Associate Principal Scientist, Science and Enabling Units IT, AstraZeneca

**samurAI - a machine learning tool to predict high confidence variants in ctDNA**

- The calling of variants in sequencing data from circulating tumour DNA is challenging, because of the high level of artefacts, particularly at low allele frequency.
- We developed a machine learning algorithm to classify variant images from a genome browser as ‘clean,’ ‘noisy’ or ‘check,’ meaning further investigation needed. We also developed a web bot to capture the images automatically and then tested the tool with sequenced patient data against manually curated variants.
- The algorithm was 100% predictive for deciding on noisy versus clean images from a set of images that had been manually classified using data from NGS panel sequencing data with 613 genes.

---

**SUMMIT SCHEDULE**

**DAY 2 FRIDAY 14TH SEPTEMBER 2018**

**ONE HOUR ROUNDTABLES – SESSION 2:**

- **Table 9:** Immuno-oncology Precision Medicine
- **Table 10:** Advancing Liquid biopsy to the clinic
- **Table 11:** Successful Companion Diagnostic partnership and co-development
- **Table 12:** Big Data Approaches
- **Table 13:** CNS Precision Medicine
- **Table 14:** Cardio-Metabolic Precision Medicine
- **Table 15:** Immunology and Respiratory Precision Medicine
- **Table 16:** Infectious Disease Precision Medicine

---

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

**Topic: 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.

---

**CLAUDIA DOLLINS**
Head, Global Regulatory Affairs, Biomarkers & Diagnostics, Merck KGaA

**Changing EU IVDR Landscape: Focus on Companion Diagnostics**

- EU IVDR is introducing a number of changes to the regulation of IVDs and specifically companion diagnostics
- The changes and impact will be discussed

---

For sponsorship opportunities please contact Tony Couch at: tony@globalengage.co.uk

---

**5TH PRECISION MEDICINE & BIOMARKERS LEADERS SUMMIT: EUROPE 2018**
YIU-LIAN FONG  
Global Head Diagnostic Innovation, Research and Early Development, and Lab Operation, Johnson & Johnson  
*Topic: Diagnostic Innovation*

CIARAN FULTON  
Head of Diagnostics, LifeArc  
*A partnered development of a circulating tumour ESR1 Mutation Test for the detection of metastatic breast cancer mutations indicative of resistance to endocrine hormone therapy*

- ESR1 mutations have been identified as a mechanism for endocrine resistance in 30-50% of ER+ metastatic breast cancers previously treated with endocrine hormone therapy. Early detection of these ctESR1 mutations in circulating plasma could have a significant impact on the clinical management of patients with breast cancer and help guide treatment decision-making.
- The Biocartis Idylla ctESR1 Mutation Test, performed on the Biocartis Idylla System, is an in vitro diagnostic test intended for the detection of ten point mutations within the ESR1 (Estrogen Receptor 1) gene. Utilising plasma, the ctESR1 Test covers the isolation of circulating tumour DNA, the real-time PCR amplification, detection, analysis and interpretation.
- This presentation highlights the unique partnership between a charity, LifeArc and a diagnostic company, Biocartis as a model for collaborative developments between industry academia.

SVETLANA MUKHINA  
Manager Global Regulatory Affairs, Biomarkers and Diagnostics, Merck KGaA  
*CDx regulatory considerations for novel technologies*

- Overview of current CDx regulatory requirements
- Emerging regulatory approaches for novel diagnostic

STEPHAN JÄEGER  
PHC Partnering Director, Roche Diagnostics GmbH  
*Diagnostic opportunities in Rare Diseases*

To get the right diagnosis means still an odyssey for patients with a rare disease. On the other hand, Pharma companies increasingly invest in the development of efficacious drugs. But successful treatment requires early diagnosis in many cases even pre-symptomatic. This can be addressed using new technologies and data tools.
Holiday Inn, Munich City Centre
Hochstrasse 3,
Munich, 81669, Germany

A centrally located Munich hotel with free Wi-Fi, extensive meeting facilities and direct access to public transport.

Holiday Inn® Munich - City Centre hotel offers four-star facilities in the heart of Munich. From the Rosenheimer Platz S-Bahn station, in the same building complex, you can reach Munich Airport in 45 minutes. There is public underground parking and the city centre is a short walk away.

The Gasteig cultural centre, known for the Munich Philharmonic, is opposite the hotel, while the vast German Museum is only a five-minute walk away. Stroll to Marienplatz, the historic heart of Munich, in just 15 minutes. Visit the English Garden, two kilometres from the hotel, and Munich Residenz, a nearby Bavarian palace. In the evening try the beer gardens of Au-Haidhausen district, just seven minutes’ walk away, or ask the staff about nearby restaurants.

The hotel has one of the largest meeting centres in southern Germany. Book a function in one of 20 meeting spaces for up to 600 guests, and our friendly staff will help organise everything. There is free Wi-Fi throughout the hotel.

Enjoy a Starbucks coffee or meet colleagues for a Bavarian meal in the Open Lobby. Guests enjoy a buffet breakfast in the Grat3 restaurant with natural daylight. Executive rooms offer 180-degree city views, and kids eat and stay free.

There is a guaranteed rate at the venue available through Global Engage. For more information, please contact Haley Lim at haley@global-engage.com