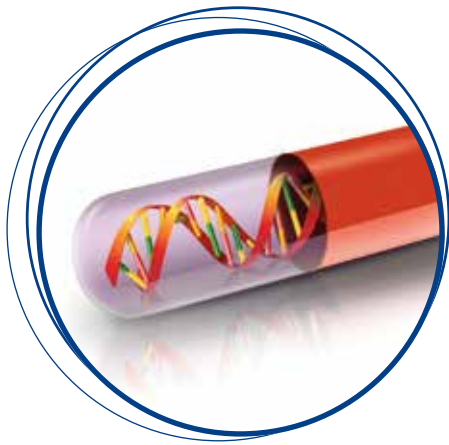


4TH GLOBAL PRECISION **MEDICINE** & **BIOMARKERS** LEADERS SUMMIT: EUROPE

MUNICH, GERMANY

21-22 September 2017



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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 **4th Global Precision Medicine & Biomarkers Leaders Summit** taking place on September 21-22, 2017 in Munich, Germany. The Summit will provide a forum to network, learn and engage with senior representatives of leading pharmaceutical and biotech companies worldwide. More than 200 industry representatives attended this well received event in 2016 and we expect it to grow once again with senior figures wishing to take home cutting edge strategies, analysis and solutions to further their research in Personalized medicine and enable impactful treatments for patients.

Tracks focus on Innovative strategies, Biomarker development, Immuno-oncology, CDx development 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. It is a Summit not to be missed!

EXPERT SPEAKERS Include:



MIRO VENTURI

Global Head Diagnostics Biomarkers
& Personalized Healthcare, Roche
Diagnostics Division



PALLAVI SACHDEV

Director, Oncology Biomarker
Research, Clinical Research, Eisai



STEFAN SCHERER

Vice President, Global Head
Correlative Science, Novartis



NING GO

Principal Scientist, Companion
Diagnostics, Amgen

DAY 1 - TRACK 1

Strategies and Technologies to Deliver Precision Medicine

- Keynote Presentations Future perspectives - Innovative initiatives, strategies and approaches
- Panel Discussion 1 Identifying the most promising directions & preparing for the future of precision research
- Panel Discussion 2 Next generation clinical trials for Precision Medicine
- Case studies Precision Medicine case studies
- Case studies Precision Medicine beyond oncology

DAY 1 - TRACK 2

Biomarkers in Clinical and Translational Development

- Panel Discussion 1 Biomarker Patient selection strategies
- Case studies Clinical and translational biomarkers
- Case studies Biomarker validation & qualification
- Case studies Digital biomarkers
- Case studies Clinical biomarker discovery

DAY 1 - TRACK 3

Immuno-Oncology

- Panel Discussion 1 Precision Immuno-oncology where are we heading?
- Case Studies Circulating Tumour DNA (ctDNA) - detection & monitoring - unlocking realtime information
- Case Studies Predictive biomarkers
- Case Studies Immune checkpoint inhibitors / Immune response monitoring
- Case Studies Liquid biopsies – clinical utility

DAY 2 - TRACK 1

Companion Diagnostic Partnerships & Development

- Panel Discussion 1 Overcoming CDx regulatory issues; updates/future developments & accelerating development
- Panel Discussion 2 Developing successful Rx-Dx partnerships, integration and co-development
- Case studies Successful CDx collaborations & approvals
- Case studies Overcoming regulatory issues; updates and future developments
- Case studies Reimbursement, market access & commercialization

DAY 2 - TRACK 2

From Big Data to Smart Data

- Panel Discussion 1 Artificial Intelligence and machine learning – A paradigm shift in Pharma R&D
- Case studies Data driven precision medicine – Improving the source & quality of data
- Case studies Integrating (multi-source) data into effective interpretation and the decision making process
- Case studies Overcoming challenges in data sharing and analysis

ROUNDTABLE DISCUSSIONS

1. Future of Precision medicine
2. Advancing Liquid biopsies to the clinic
3. Immuno-Oncology – Future developments
4. T-Cells
5. Successful Companion Diagnostic partnership and co-development
6. Fulfilling the potential of Big Data

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MIRO VENTURI

Global Head Diagnostics
Biomarkers & Personalized
Healthcare, Roche Diagnostics
Division


THOMAS WILCKENS

CEO, InnVentis


ARMIN FURTWÄNGLER

Global Senior Medical Director
- Health Care Innovation,
Boehringer Ingelheim Pharma


JOHN FERGUSON

SVP, Distinguished Fellow, Shire


DOUGLAS SANDERS

Principal Scientist - Clinical
Biomarker and Companion
Diagnostic Development, EMD
Sero


NING GO

Principal Scientist, Companion
Diagnostics, Amgen


JIANGWEN MAJETI

Biomarker and CDx Global
Category Manager, Roche


SVETLANA MUKHINA

Manager Global Regulatory
Affairs, Biomarkers and
Diagnostics, Merck KGaA


PIERS MAHON

Director Global Alliances,
Cancer Commons


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Senior Partner & Director,
Healthcare Business Unit, Frost
& Sullivan


MARK STEARMAN

International Product Manager,
Personalised Healthcare
Solutions, Roche Diagnostics
International Ltd.


THOMAS S. JENSEN

CEO, Intomics A/S


MIKE REA

CEO, Idea Pharma


FRANK SONG

Senior Director, Healthcare
Informatics, Human Longevity


STEFAN SCHERER

Vice President, Global Head
Correlative Science, Novartis


HONEY REDDI

Clinical Laboratory Director,
The Jackson Laboratory


NICOLE ST JEAN

Precision Medicine Director,
Global Product & Portfolio
Strategy (GPPS), AstraZeneca


NING GO

Principal Scientist, Companion
Diagnostics, Amgen


NIVEN NARAIN

Co-Founder, President & CEO,
Berg


**PREVEEN
RAMAMOORTHY**

Vice President, Global Scientific
& Clinical Affairs, Terumo BCT


MARTINA KAUFMANN

Managing Director, Martina
Kauffman Strategic Consulting


HENRY HESS

Director, Corporate Innovation
Strategy at Merck KGaA,
Darmstadt, Germany


PALLAVI SACHDEV

Director, Oncology Biomarker
Research, Clinical Research,
Eisai


JANUSZ DUTKOWSKI

Co-founder and CEO,
Data4Cure





THIBAUT HELLEPUTTE
CEO, DNAnalytics



PAUL STRIJBOS
Global Head Rare Disease
Clinical Development, Roche



JEFF WARING
Director, Pharmacogenomics
and Human Genetics, Abbvie



CHRISTIANE UNGER
Business Partner, Clinical
Sciences, Bayer Business
Services GmbH



KRISTÓF SZALAY
CTO, Turbine



DOUGLAS ROBINSON
Executive Director, Group
Head Biomarkers and
Diagnostics Biometrics, Novartis
Pharmaceuticals



CELINE PALLAUD
Executive Director, Oncology
Precision Medicine Hematology
DA Lead- Oncology BU, Novartis



PETER MOURITZEN
Vice President for Research and
Development, Exiqon



PETER BLUME-JENSEN
(Track Chair)
Chief Scientific Officer, XTuit
Pharmaceuticals, Inc.



LOUISE LEONG
(Track Chair)
Director Science Relations,
AstraZeneca



SALLY DAUB
CEO, Enlitic



LOUIS LEVY
Director, Corporate and
Business Development, Ultivue



KAI WILKENS
Senior Director Sales &
Marketing, Europe, Advanced
Cell Diagnostics, Inc



JOHN BEAVER
VP, Head of Global Biomarker
Discovery & Development,
Biogen



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



JOHN A. MARTIGNETTI
Associate Professor,
Departments of Genetics and
Genomic Sciences, Pediatrics,
Obstetrics/Gynecology &
Reproductive Sciences and Oncological Sciences,
Icahn School of Medicine at Mount Sinai



ROBERT BEZAR
Director Medical, SMA Lead
Europe and Canada, Biogen



GRAHAM POCKLEY
Director of the John van Geest
Cancer Research Centre
(JvGCRC) and Professor of
Immunobiology, Nottingham
Trent University; CEO,
multimmune GmbH



**SIDATH
KATUGAMPOLA**
Biomarker Development
Specialist, Cancer Research UK



THOMAS MROWIEC
Subject Matter Expert, Clinical
Biomarker & Companion
Diagnostics, Merck KGaA



CHRISTIAN RUIZ
Head Research Unit, Head
Laboratory Department,
Medical Genetics & Pathology,
University Hospital Basel



JÉRÔME WOJCIK
CEO, Quartz Bio



SOLANGE ROMAGNOLI
Senior Director Biomarker
Programs, Business
Development Diagnostics, Roche



AMIT M. DESHPANDE
Associate Director, Biomarkers,
ImmunoOncology Translational
Innovation Platform (TIP), EMD
Serono



BRUNO GOMES
(Track Chair)
Director of Tumor Immunology,
iTeos Therapeutics SA



THIERRY WURCH
Director, External Research &
Innovation Immuno-oncology,
Therapeutic Innovation
Pole in Oncology, Institut de
Recherches Servier



MICHAËL HERMAN
Head Business Development
Biopharma. OncoDNA



MARIE CUMBERBATCH
Consultant to Histologix, Director
of Immune Insight Limited



HONEY REDDI
Clinical Laboratory Director, The
Jackson Laboratory



IAIN MILLER
EPEMED Board Member; NICE,
Member Technology Appraisal
Committee C; Founder,
Healthcare Strategies Group

08:00-08:50

Forum 2 / Forum 3 / Foyer Grosser Saal

Registration & Refreshments

08:50-08:55

Room 1: Forum 1

Global Engage Welcome Address and Morning Chair's Opening Remarks

**TRACK CHAIR:
THOMAS WILCKENS**

CEO, InnVentis

09:00-09:35

**STEFAN SCHERER**

Vice President, Global Head Correlative Science, Novartis

Yin and Yang of Liquid Biopsies

09:35-10:05

**KEYNOTE ADDRESS:
THOMAS WILCKENS**

CEO, InnVentis

Precision Medicine beyond Cancer: Challenges & Opportunities

While stratifying patients into subgroups by the genomic profile of a given cancer has found entrance in clinical trial design as well as treatment strategies in cancer, there is still uncertainty how next generation clinical trials and diagnostics ecosystems should look for chronic debilitating non-communicable diseases, where chronic inflammatory conditions are the number one driver of the exploding financial burden of disease; i.e. individual molecular phenotypes of disease may vary greatly despite similar symptoms of a given disease reflecting a collection of "look-alike-syndromes" rather than a uniform pathology. I.e. most drugs work in limited subgroups which is indicative of differing molecular pathologies driving disease. For example, Humira, Ebrel and Remicade which are commercially most successful and also most expensive treatment option for conditions we currently call "rheumatoid arthritis" "inflammatory bowel disease" or "psoriasis" show efficacy in only 1 out of 4/5 patients. More generally we are lacking a molecular definition of the underlying pathologies. In order to achieve "google maps" of disease, we propose a new longitudinal, multi-omics and real-world data based approach combined with artificial intelligence to assign the right patient to the right drug first time at the right dose, as this is the ultimate goal of Precision Medicine. In order to enable this vision we propose vertically integrated flagships projects that will establish standards, best practices, concise business cases and foremost new AI/ ICT/IoT and multi-omics infrastructures that are exponentially scalable to enable large scale clinical trials and eventually to the clinic to serve the general population.

10:05-10:35

**SOLUTION PROVIDER PRESENTATION:
THOMAS S. JENSEN**

CEO, Intomics A/S

Precision Medicine in the Big Data Era - Challenges and Successful Bioinformatics Approaches

- Biomedical Big 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.
- Using real world biomarker cases from oncology and non-oncology projects as a basis, the talk will present typical big data challenges and successful multi-omics approaches for identifying response biomarkers that correctly identify 85-95 % of the responding patients.



10:35-11:45

Forum 2 / Forum 3 / Foyer Grosser Saal

Morning Refreshments / Poster Presentations / Scheduled One-to-One Meetings

Room: Forum 1

STRATEGIES AND TECHNOLOGIES TO DELIVER PRECISION MEDICINE

TRACK CHAIR: **THOMAS WILCKENS**

CEO, InnVentis

**ARMIN FURTWÄNGLER**

Global Senior Medical Director - Health Care Innovation, Boehringer Ingelheim Pharma

11:45-12:15

Room: Forum 4 + Forum 5

BIOMARKERS IN CLINICAL AND TRANSLATIONAL DEVELOPMENT

TRACK CHAIR: **PETER BLUME-JENSEN**

Chief Scientific Officer, XTuit Pharmaceuticals, Inc.

**JEFF WARING**

Director, Pharmacogenomics and Human Genetics, Abbvie

The use of epigenetic biomarkers for use in clinical trials – applications beyond oncology

- There has been much attention paid to the field of epigenetics in recent years, both for identifying new drug targets and for identifying mechanisms of disease etiology or response to therapy.
- In the past, this has been largely defined to the field of Oncology, but in recent years, the role of the epigenome and disease has been explored in areas such as immunological disorders, CNS disorders and infectious disease areas.
- Examples are shown demonstrating that epigenetic modifications can serve as valuable measurements in clinical trials for several therapeutic areas.

11:45-12:15

Room: Forum 7 + Forum 8

IMMUNO-ONCOLOGY

TRACK CHAIR: **BRUNO GOMES**

Director of Tumor Immunology, iTeos Therapeutics SA

**HONEY REDDI**

Clinical Laboratory Director, The Jackson Laboratory

Liquid Biopsies in the clinic: Development and validation of a Pan Cancer panel

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.

11:45-12:15

**SOLUTION PROVIDER PRESENTATION: MARK STEARMAN**

International Product Manager, Personalised Healthcare Solutions, Roche Diagnostics International Ltd.

Personalised Healthcare meets ART; Companion Diagnostics in infertility

- To date – personalised healthcare has focused on oncology with binary biomarker results
- Continuous biomarkers allow more elaborate 'personalisation' – such as individualised dosing
- The first companion diagnostic in fertility is presented, including a unique dosing algorithm

12:15-12:45

**SOLUTION PROVIDER PRESENTATION: PETER MOURITZEN**

Vice President for Research and Development, Exiqon

RNA biomarker discovery in exosomes**from liquid biopsies through sequencing and qPCR**

To identify new biomarkers and develop minimal invasive tests, we have developed robust methods for next generation sequencing of smallRNA in biofluids. For high-throughput profiling microRNA in biofluids, highly sensitive LNA™-based qPCR is applied. Recent results will be discussed from the prostate cancer program.

12:15-12:45

**SOLUTION PROVIDER PRESENTATION: MICHAËL HERMAN**

Head Business Development Biopharma, OncoDNA

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 the access to the best cancer care.

12:15-12:45



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

Confirmed:



DORMAN FOLLOWILL

Senior Partner & Director, Healthcare Business Unit, Frost & Sullivan



JOHN FERGUSON

SVP, Distinguished Fellow, Shire



MIKE REA

CEO, Idea Pharma



FRANK SONG

Senior Director, Healthcare Informatics, Human Longevity

12:45-13:35

50 MINUTE EXECUTIVE PANEL DISCUSSION: Biomarker Patient Selection Strategies

Confirmed:



JOHN BEAVER

VP, Head of Global Biomarker Discovery & Development, Biogen



JÉRÔME WOJCIK

CEO, Quartz Bio

Reserved:

- **Ivan Diaz-Padilla**, Medical Director, Global Drug Development (Oncology), Novartis Pharma AG
- **Marti Jett**, Chief Scientist, Systems Biology Enterprise US Army Medical Command (MEDCOM), US Army Center for Environmental Health Research

Invitation to Senior Representatives x1

12:45-13:35

50 MINUTE EXECUTIVE PANEL DISCUSSION: Precision Immuno-oncology where are we heading?

Confirmed:



SOLANGE ROMAGNOLI

Senior Director Biomarker Programs, Business Development Diagnostics, Roche



AMIT M. DESHPANDE

Associate Director, Biomarkers, ImmunoOncology Translational Innovation Platform (TIP), EMD Serono



PALLAVI SACHDEV

Director, Oncology Biomarker Research, Clinical Research, Eisai



PREVEEN RAMAMOORTHY

Vice President, Global Scientific & Clinical Affairs, Terumo BCT



MARTINA KAUFMANN

Managing Director, Martina Kauffman Strategic Consulting

12:45-13:35

13:35-14:35

Forum 2 / Forum 3 / Foyer Grosser Saal

Lunch / Scheduled One-to-One Meetings

14:35-15:05



JOHN FERGUSON

SVP, Distinguished Fellow, Shire

The Future of Patient Centered Product Development

- Patient-centered product development seeks to drive more value to patients faster, in ways that work for all stakeholders
- The role of patient-centeredness will vary by indication
- Precision medicine can inform patient-centered development in general but will be required for optimized product-delivery in some cases
- This session describes a view of adaptive, patient-centered, precision-medicine-enabled product development that optimizes stakeholder-value delivery

14:35-15:05



CELINE PALLAUD

Executive Director, Oncology Precision Medicine Hematology DA Lead- Oncology BU

Precision medicine in hematology: hope, hype or both?

The precision medicine paradigm applies to the care of AML patients by focusing on the potential roles of targeting therapy by patient-specific somatic mutations and aberrant pathways, ex-vivo drug sensitivity and resistance testing, high sensitivity measurements of residual disease burden

14:35-15:05



PALLAVI SACHDEV

Director, Oncology Biomarker Research, Clinical Research, Eisai

Optimizing immunotherapy combinations using data-driven molecular sub-typing and immune-infiltrate characterization

- Deep molecular and immune-infiltrate characterization and subtyping of tumor
- Identification of molecular subsets that will benefit from targeted agents and immunotherapy
- Predict combination therapy to combat single-agent resistance

15:05-15:35


**SOLUTION PROVIDER
PRESENTATION:
DORMAN FOLLOWILL**

Senior Partner & Director, Healthcare
Business Unit, Frost & Sullivan
Global Precision Medicine for Cancer



15:05-15:35


**SOLUTION PROVIDER
PRESENTATION:
KAI WILKENS**

Senior Director Sales & Marketing, Europe,
Advanced Cell Diagnostics, Inc
**Visualize any biomarker within the tissue
context**



Detection of biomarkers within the morphological context of tissue samples allows to assess interactions between cell type as well as heterogeneity. ACD has developed a novel RNA ISH technology called RNAscope® to detect any RNA species in FFPE and fresh or fixed frozen tissue or cell samples. It can be multiplexed, performed manually or by automation, and in many cases combined with IHC. The unique probe design and signal amplification system allows the visualization of each individual target RNA molecules as a single dot. The RNAscope assay has been applied in a broad range of research areas, including immuno-oncology, neuroscience, stem cells, inflammation and infectious disease and has been widely adopted in biotech and pharmaceutical R&D in various fields like drug safety, target and biomarker validation, the latter already in the process of the development of companion diagnostics.

15:05-15:35


**SOLUTION PROVIDER
PRESENTATION:
MARIE CUMBERBATCH**

Consultant to Histologix, Director of Immune
Insight Limited
**Interpreting Tissue-Based Immuno-
Oncology Biomarkers using Robust Image
Analysis Solutions**

- Understanding the tumour immune microenvironment in tissues from preclinical/clinical studies provides critical information for the drug discovery process on mode of action, efficacy and patient selection.
- Validation of immunohistochemistry immuno-oncology biomarker assays and application of next generation image analysis tools delivers valuable immunological insight into tumour immune processes.
- Robust approaches to the quantification, localisation and spatial relationships of immuno-oncology biomarkers in tumour tissues will be discussed.



15:35-16:25

**50 MINUTE EXECUTIVE PANEL DISCUSSION:
Next generation clinical trials for Precision Medicine**

Confirmed:


THOMAS WILCKENS

CEO, InnVentis


PIERS MAHON

Director Global Alliances, Cancer Commons


IVAN DIAZ-PADILLA (Reserved)

Medical Director, Global Drug Development
(Oncology), Novartis Pharma AG

Invitation to Senior Representatives x1

15:35-16:00


PAUL STRIJBOS

Global Head Rare Disease Clinical
Development, Roche

**Precision medicine in non-oncology rare
diseases: unique opportunities to develop
transformative treatments**

- Precision Medicine: a it-for-purpose approach for rare diseases
- Moving from the "average" patient to the individual
- Using the Precision Medicine toolbox to develop transformative medicines for rare diseases patients

16:00-16:25


ROBERT BEZAR

Director Medical, SMA Lead Europe and
Canada, Biogen

**Relevance of SPINRAZA to the concept of
precision medicine in rare disease - TBC**

15:35-16:00


THIERRY WURCH

Director, External Research & Innovation
Immuno-oncology, Therapeutic Innovation Pole
in Oncology, Institut de Recherches Servier
**Novel Strategies for Active Immunotherapy
based on T cell redirection**

- During the last decade, breakthrough therapies in Oncology emerged such as bi-specific antibody-like molecules engaging T cells and patients-derived T cells, engineered to express a chimeric antigen receptor (CAR) to trigger T cell activation upon binding to a tumor antigen.
- These two therapeutic approaches engaging effector T lymphocytes will be discussed through case studies of molecules from our immunotherapy pipeline in partnership with US and European Biotech.

16:00-16:25


AMIT M. DESHPANDE

Associate Director, Biomarkers, ImmunoOncology
Translational Innovation Platform (TIP), EMD Serono
Title - TBC

16:25-17:15

Forum 2 / Forum 3 / Foyer Grosser Saal

Afternoon Refreshments / Poster Presentations / Scheduled One-to-One Meetings

17:15-17:45

**FRANK SONG**

Senior Director, Healthcare Informatics,
Human Longevity

How individualized precision medicine can help improve outcome, reduce cost, transform care management significantly

- Current HC delivery has been symptom-based sick care, and it failed to improve outcome at population level, and the cost trend is unsustainable
- Individualized precision medicine that based on genomic and metabolic discoveries provides us the new tools to predict and stratify people's disease development risk far before its onset so that meaningful and effective prevention or lifestyle change can be implemented to reduce the chance of or delay its onset of the costly disease significantly
- Genomic risk integrated clinical risk screening application will transform HC delivery, the use and impact in care and disease management programs and the potential ROI will be demonstrated

17:15-17:45

**SIDATH KATUGAMPOLA**

Biomarker Development Specialist, Cancer
Research UK

Translational biomarkers in early phase oncology trials

- Why do we need biomarkers in early phase trials in oncology? How is it done? What are some of the current challenges and how do you overcome these?
- Case studies, including for first in class agents and cancer immunotherapies
- The importance and challenges that are faced in predictive biomarkers in early phase trials

17:15-17:45

**IAIN MILLER**

Founder & CEO, Healthcare Strategies Group;
Member (until August 2017) NICE Technology
Appraisal Committee C; Board Member, EPEMED

Emergence of high complexity testing in targeted and immuno-oncology: Strategic considerations and market access.

- Evolution of high complexity companion / complementary and baseline testing in targeted and immuno-oncology
- Market access for companion diagnostics – emerging global best practices in UK, broader EU and US
- Emerging business models and key regulatory developments

17:45-18:15

**GRAHAM POCKLEY**

Director of the John van Geest Cancer
Research Centre (JvGCRC) and Professor of
Immunobiology, Nottingham Trent University;
CEO, multimmune GmbH

The Theranostic Potential Of Membrane Hsp70 In Oncology

multimmune GmbH's unique and proprietary technology platform is based on the discovery that an unusual cell membrane surface localization of Hsp70 is selectively expressed on many tumour types by Gabriele Multhoff and Claus Botzler. multimmune is focused on the development of innovative therapeutic approaches for treating the large proportion of cancers that express this cell surface-expressed form of Hsp70. multimmune's strategy is to build a well-staged pipeline of differentiated products for the targeted therapy (tx) of cancer, specifically the use of autologous natural killer (NK) cells that have been activated using a synthetic Hsp70-derived peptide in combination with low-dose cytokine (ENKASTIM-ev, End-Phase I and ongoing Phase II product) and the induction of apoptosis of cancer cells / tumours expressing the membrane form of Hsp70 using granzyme B (mi-APO, Discovery and Pre-clinical product).

17:15-18:45

ONE HOUR ROUNDTABLE DISCUSSIONS:

Final tables to be decided.

Confirmed Speakers:

**1. Fulfilling the potential of Big data
NIVEN NARAIN**

Co-Founder, President & CEO, Berg



**2. Advancing Liquid biopsies to the clinic
STEFAN SCHERER**

Vice President, Global Head Correlative Science, Novartis



**3. T-Cells
PREVEEN RAMAMOORTHY**

Vice President, Global Scientific & Clinical Affairs,
Terumo BCT



**4. Successful Companion Diagnostic partnership and co-development
MARTINA KAUFMANN**

Managing Director, Martina Kauffman Strategic Consulting

Continued on to next page...

17:45-18:15

**THOMAS MROWIEC**

Subject Matter Expert, Clinical Biomarker &
Companion Diagnostics, Merck KGaA

Pathology meets Digital - Digital Pathology Strategies and Technologies in the context of Biomarker Development, CDx and Precision Medicine

Digital Pathology is an image-based information environment enabled by the combination of advanced image acquisition and computational technologies with powerful software algorithms. It allows for maximizing the extraction of information and management of big data generated from digital scans of tissue stains on conventional glass slides. In Precision Medicine at Merck KGaA in Darmstadt (Germany), it is being developed to help drive drug development by analyzing mode of action and predictive and prognostic tissue biomarkers in cancer from immunohistochemistry and multimarker immunofluorescence, or going forward in situ hybridization and imaging mass cytometry. Digital Pathology provides in depth biomarker results with greater accuracy and reproducibility to augment, and in some instances potentially replace, conventional pathologist visual interpretations.

Continued from previous page...

17:15-18:45

**5. Future of Precision medicine**
HENRY HESS

Director, Corporate Innovation Strategy at Merck KGaA, Darmstadt, Germany

**6. Immuno-oncology – Future Developments**
PALLAVI SACHDEV

Director, Oncology Biomarker Research, Clinical Research, Eisai

**JANUSZ DUTKOWSKI**

Co-founder and CEO, Data4Cure

18:15-18:45

**CHRISTIAN RUIZ**

Head Research Unit, Head Laboratory Department, Medical Genetics & Pathology, University Hospital Basel

Diagnostics for enabling precision medicine: opportunities and challenges

The success of precision medicine depends to a large extent on the appropriate application and examination of diagnostic assays by pathologists and medical geneticists. However, patients, medical doctors, pharmaceutical companies, diagnostic assay providers and health insurances have different needs and often, balancing acts are required in order to supply those. Further, due to different customer needs and despite the large number of available diagnostic solutions on the market, own research and development, as well as strategic alliances, are necessary to succeed in this fast-paced industry and to provide optimal diagnostic benefit to the patient.

18:45-19:45

Room: Forum 1

Chair's Closing Remarks / End of Day 1 / Networking Drinks Reception

08:00-08:40

Forum 2 / Forum 3 / Foyer Grosser Saal

Refreshments / One-to-One Meetings

08:40-09:15


**KEYNOTE ADDRESS:
MIRO VENTURI**

Global Head Diagnostics Biomarkers & Personalized Healthcare, Roche Diagnostics Division

The Future of Personalised Healthcare: The Interplay of Diseases, Information and Technologies

09:15-09:45

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities please contact
Ashley Sofiyani at ashleys@globalengage.co.uk

Room: Forum 1

COMPANION DIAGNOSTIC PARTNERSHIPS & DEVELOPMENT**TRACK CHAIR:**

09:50-10:20

**DOUGLAS SANDERS**

Principal Scientist - Clinical Biomarker and Companion Diagnostic Development, EMD Serono

The role of CDx Lead: Coordinating regulatory, technology and operational concerns in CDx development

- The challenges of demonstrating clinical utility for NGS cancer panels
- Operational challenges of converting existing biomarker assays to selection assays in existing trial structures
- Dealing with evolving requirements through the lifecycle of biomarker/CDx development

Room: Forum 4 + Forum 5

FROM BIG DATA TO SMART DATA**TRACK CHAIR: LOUISE LEONG**

Director Science Relations, AstraZeneca

09:50-10:20

**PRADUMAN JAIN**

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

Consumer-Directed Precision Health - Convergence of Multi-omics, Environment, Lifestyle, and Behaviors

Incredible and rapid advances in medical science, discovery of new diagnostic biomarkers, and consumer adoption of latest mobile and cloud technologies are enabling new sources of data. Convergence of longitudinal data from multiple sources such as multi-omics, environment, lifestyle and behaviors, electronic health records, and pharmacy provide opportunities to generate new predictive insights. Including consumers/patients/participants as Partners during medical research and the creation of new therapies would enable Precision Medicine that is personalized and contextual. This talk will discuss large initiatives that are emerging to harness the 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 industry research in consumer health.

10:20-11:30

Forum 2 / Forum 3 / Foyer Grosser Saal

Morning Refreshments / Poster Presentations / Scheduled One-to-One Meetings

11:30-12:00

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities please contact
Ashley Sofiyani at ashleys@globalengage.co.uk

11:30-12:00

**SOLUTION PROVIDER PRESENTATION:****THIBAUT HELLEPUTTE**

CEO, DNAlytics

Data-driven anti-rheumatic drugs prescription

Rheumatologists have no tool to objectively choose among available biologicals for rheumatoid arthritis patients, although these drugs represent the largest expense of most health care systems. Transcriptomic analysis of the joint tissue have recently led to precision medicine approaches, namely for differential diagnosis of arthritis. These data-driven IVD tests are progressively providing treatment guidance support as well.



45 MINUTE EXECUTIVE PANEL DISCUSSION:**Overcoming CDx regulatory issues; updates / future developments and accelerating development****Confirmed:****CHAIR: MARTINA KAUFMANN**

Managing Director, Martina Kauffman Strategic Consulting

**NING GO**

Principal Scientist, Companion Diagnostics, Amgen

**IAIN MILLER**

Founder & CEO, Healthcare Strategies Group; Member (until August 2017) NICE Technology Appraisal Committee C; Board Member, EPEMED

Invitation to Senior Representatives x1**45 MINUTE EXECUTIVE PANEL DISCUSSION:****Artificial Intelligence and machine learning – A paradigm shift in Pharma R&D****Confirmed:****CHAIR: NIVEN NARAIN**

Co-Founder, President & CEO, Berg

**KRISTÓF SZALAY**

CTO, Turbine

**SALLY DAUB**

CEO, Enlitic

**JANUSZ DUTKOWSKI**

Co-founder and CEO, Data4Cure

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities please contact
Ashley Sofiyani at ashleys@globalengage.co.uk

15 MINUTE SOLUTION PROVIDER PRESENTATION:**JANUSZ DUTKOWSKI**

Co-founder and CEO, Data4Cure

Using AI, systems biology and a lot of data to continuously grow biomedical knowledge

- 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

**15 MINUTE SOLUTION PROVIDER PRESENTATION:****LOUIS LEVY**

Director, Corporate and Business Development, Ultivue

High Definition Multiplexing for Biomarker Discovery

- Biomarker discovery in immuno-oncology requires the analysis of multiple protein markers (n>4) with their spatial relationships at an amenable throughput
- The scrutiny of the tumor micro-environment demands whole-slide multiplexed images featuring immune and tumor cells
- Ultivue's InSituPlex platform fulfills this need with the data reproducibility relevant to CDx



12:00-12:45

12:00-12:45

12:45-13:00

12:45-13:00

13:00-13:15

13:15-14:15

Forum 2 / Forum 3 / Foyer Grosser Saal

Lunch / One-to-One Meetings

14:15-14:45

**NING GO**

Principal Scientist, Companion Diagnostics, Amgen

Co-development and clinical validation of an in vitro diagnostic in support of a cardiovascular therapeutic product

The presenter will discuss the processes of co-developing an in vitro diagnostic and a cardiovascular therapeutic product, including the experience gained in analytical validation, clinical validation and implementation of central laboratory testing in a large global trial.

14:15-14:45

**CHRISTINE UNGER**

Business Partner, Clinical Sciences, Bayer Business Services GmbH

PORTIN – a game changer towards translational research

PORTIN is a platform in which biomarker/genomic, biosample and clinical/phenotype information is integrated to make better and more efficient use of the available data. For a successful implementation, besides technology and data, cultural and organizational aspects are just as important to consider.

Shift in Mindset:

Data often become "my" data. To motivate people changing behavior it's also important to have answers to the question: "what's in for me".

Collaboration:

Cross-functional teams with experts from biomarker, clinical and mathematical functions lay the foundation for a joint data approach and guidelines on data integration.

Governance:

In order to establish a sustainable organization for translational research, adequate processes need to be set up or adjusted internally and externally.

14:45-15:30

**DOUGLAS ROBINSON**

Executive Director, Group Head Biomarkers and Diagnostics Biometrics, Novartis Pharmaceuticals

Successful Implementation of Companion Diagnostics to Improve Precision Medicine

- The complexities of using bridging studies when your companion diagnostic is not available for patient selection at trial start
- How Novartis used new technologies like Next Generation Sequencing to select patients for treatment therapies in lung cancer
- The importance and challenges of the PMA submission and Health Authority interactions

15:30-16:00

**JOHN A. MARTIGNETTI**

Associate Professor, Departments of Genetics and Genomic Sciences, Pediatrics, Obstetrics/Gynecology & Reproductive Sciences and Oncological Sciences, Icahn School of Medicine at Mount Sinai

Opening Pandora's box of molecular diagnostics: NGS-based sequencing reveals both early stage endometrial cancers and previously unknown clones of indeterminate tumorigenic potential

- We describe an NGS-based test of uterine lavage fluid to prospectively detect early-stage, microscopic endometrial cancer.
- Identification of a previously unknown but highly prevalent landscape of cancer driver mutations in women without histopathologic evidence of endometrial cancer.
- Our findings, based on ultra-deep sequencing, may have implications for understanding the development and/or inhibition of clonal expansion of cancer driver mutations in early cancer and thus have broad implications for cancer diagnostics.

14:45-15:30

45 MINUTE EXECUTIVE PANEL DISCUSSION:**Developing successful Rx-Dx partnerships, integration and co-development****Confirmed:****CHAIR: NICOLE ST JEAN**

Precision Medicine Director, Global Product & Portfolio Strategy (GPPS), AstraZeneca

**JIANGWEN MAJETI**

Biomarker and CDx Global Category Manager, Roche

**IAIN MILLER**

Founder & CEO, Healthcare Strategies Group; Member (until August 2017) NICE Technology Appraisal Committee C; Board Member, EPEMED

Invitation to Senior Representatives x1

15:30-16:00

**SVETLANA MUKHINA**

Manager Global Regulatory Affairs, Biomarkers and Diagnostics, Merck KGaA

Regulatory aspects of CDx development

- Regulatory steps in CDx development
- Interaction with regulatory agencies
- Accelerated drug approval: implications for CDx development

16:00

End of Conference



**Holiday Inn,
Munich City Centre**
Hochstrasse 3,
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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



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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.

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