BIOTECH PHARMA SUMMIT

Companion Diagnostics & Biomarkers

26-27 October 2017 | Hotel HF Ipanema Park | Porto, Portugal

KEY PRACTICAL LEARNING POINTS OF THE SUMMIT

- Learn the recent advances and future perspectives in Companion Diagnostics & Biomarkers
- Understand the key aspects & challenges of Clinical Biomarker development & qualification
- Solutions for clinical development of precision therapies
- Regulatory considerations for Next Generation Sequencing (NGS)
- Main barriers to progression of precision medicine in drug development
- The Role of In Vitro Diagnostics in Successful Precision Medicine Market Access
- Options for biomarker based patient stratification in NON-ONCOLOGY clinical development
- Key trends in targeted and immuno-oncology companion diagnostics
- Overcoming challenges in the global commercialization of novel biomarkers Diagnostic
- Strategies for Cancer Immune Therapies
- Strategic Partnerships for CDx – Challenges and Opportunities

FEATURED SPEAKERS

Harry Glorikian, US
CEO, Sr. Executive, Board Director, Author, MoneyBall Medicine & Commercialization of Novel IVDs

evidation HEALTH

Eric Faulkner, US
MPH, Vice President, Precision and Transformative Technology Solutions at Evidera

Evidera
Evidence, Value & Access by PPD

Susanne Munksted, DK
Commercial Director, Companion Diagnostics at Agilent

Agilent Technologies

Paul Whittaker, UK
Vice President, Discovery Research at hVIVO

hVIVO
better treatments, faster

Jakob Gjørret, DK
Managing Director at Unilabs

Unilabs

Henrik Winther, SE
Senior Vice President, Precision Diagnostics at Immunovia AB

immunovia

PROGRAM CHAIR

Harry Glorikian, US
CEO, Sr. Executive, Board Director, Author, MoneyBall Medicine & Commercialization of Novel IVDs

Ali Ardakani, CA
Managing Director at Novateur Ventures Inc

SPEAKERS LIST

Dr. Nick Zhang, CN
Chairman and CEO at QIAGEN (Suzhou) Translational Medicine Co. Ltd.

Dr. Martina Kaufmann, DE
Managing Director at Martina Kaufmann Strategic Consulting

Prof. Robert Hawkins, UK
Cancer Research UK Professor at University of Manchester

Eric Faulkner, US
MPH, Vice President, Precision and Transformative Technology Solutions at Evidera

Dr. Stefan Müllner, DE
General Manager & Partner at Fundamenta Life Science

Rohit Nambisan, US
SVP Product Strategy & Partner Integration at Treato, Product Advisor at Neurolex Diagnostics

Dr. Paul Docherty, UK
Relationship and Alliance Management at Hologic

Henrik Winther, SE
Senior Vice President, Precision Diagnostics at Immunovia AB

SPEAKERS LIST

Dr. Alfred Hansel, DE
CEO
at oncgnostics GmbH

Jakob Gjørret, DK
Managing Director
at Unilabs

Dr. Birgitte Booij, NO
Vice President Product and
Business development
at SpinChip Diagnostics

Austin Speier, US
Vice President, Emerging Technologies
at Precision for Medicine

Christopher Ung, US
Chief Business Officer
at HistoGeneX

Paul Whittaker, UK
Vice President, Discovery
Research at hVIVO

Susanne Munksted, DK
Commercial Director,
Companion Diagnostics
at Agilent

Jürgen Doppke, DE
Director, Business Development
at Thermo Fisher Scientific

Dr. Morteza Minaee, US
VP, Regulatory Affairs
at Guardant Health

Gary Gustavsen, US
Partner, Personalized Medicine
at Health Advances

Jeffrey Jones, US
Executive Vice President,
Commercial Operations at SkylineDx

EXPERTS FROM AROUND THE WORLD IN ONE PLACE

The BioTech Pharma Summit is proud to present the Companion Diagnostics & Biomarkers edition. This innovative B2B event will enable the participants to learn about the latest trends, developments, business models and strategies in the companion diagnostics & Biomarkers.

Companion diagnostic co-development has the potential to significantly alter the drug development process and commercialization of drug candidates by yielding safer drugs with enhanced therapeutic efficacy in a faster, more cost-effective manner.

This year, for the second time, the BioTech Pharma Summit will meet to analyze and tackle the latest and greatest opportunities in the CDx. In this Summit you will learn more about doing partnership and commercialize CDx tests with pharmaceutical and biotech companies.

We will also provide solutions to assist in all stages of CDx development from the biomarker discovery process through CDx commercialization.

We sincerely hope you are able to join us for this year's meeting and be part of a new paradigm of precision medicine.

BENEFITS OF ATTENDANCE

The summit is an executive format where case study presentations and panel discussions enable an interactive exchange of ideas and experiences, you will be able to have many networking opportunities with senior peers and get post event follow up offering all documentation from the meeting and re-booking discounts.

WHO SHOULD ATTEND

The BioTech Pharma Summit 2017 is an exclusive event designed for senior level attendees from leading pharmaceutical, biopharmaceutical, biotechnology, diagnostics, CRO and solution provider companies, along with highly esteemed members of academic and government institutions.
Chief Executives, Executive Directors, Vice Presidents, Heads and Team Leaders and Managers including:

- Companion Diagnostics
- Molecular Diagnostics
- Personalized Healthcare
- Clinical Development
- Regulatory Affairs
- Molecular Diagnostics
- Biomarkers
- Medical Sciences
- Experimental Medicine
- Translational Medicine
- Immunology
- Genomics
- Insurers
- Patient Advocates
- Payers
- Market Access
- Commercialisation
- Oncology
- Non-oncology
- Rare Diseases
- Drug Development
- Research

ABOUT US

EPM Group is a unique company that promotes global summits, conferences, B2B (business-to-business) meetings, seminars, workshops and develops collaborations between all enterprises in order to promote business development in all areas.

New trends, Innovations, Modern technologies, New products, Emerging topics are generated for senior level executives to provide a cutting edge of business information and maximum return of investment for our clients from different areas, such as Pharmaceutical, Renewable Energy, Oil & Gas, Logistics and Supply Chain and Infrastructure.

Our goal is to become a top event company of designing, producing and delivering highly conceptual and fully integrated events.

DAY 1 - CONFERENCE

1

08:00 ▶ Registration and Welcome Coffee

08:50 ▶ Opening of the BioTech Pharma Summit: Companion Diagnostics & Biomarkers

CDx & Biomakers: Current, Future & Trends

09:00 ▶ **Case Study | Harry Glorikian, US** - CEO, Sr. Exec., Board Director, Author, MoneyBall Medicine & Commercialization of Novel IVDs
The changing face of healthcare: dawn of individualized medicine

- Shift to data driven and evidence based system to support value based health and healthcare decisions. Integration of multiplex diagnostics into development programs
- Efficient and effective use of genetic and molecular characterization to shape the way medicine is practiced and the way drugs are approved
- Greater integration of discovery, clinical trials, and ongoing clinical care to transform evidence generation for improved healthcare decisions

09:40 ▶ **Speed Networking |** Innovative approach to maximize networking capabilities through two minute periods, where delegates can meet their peers and exchange business cards before rotating to the next company representative

10:00 ▶ **Case Study | Dr. Martina Kaufmann, DE** - Managing Director at Martina Kaufmann Strategic Consulting
Companion diagnostics – recent advances and future perspectives

- How CDx did evolve
- The evolving regulatory landscape
- The emergence of new technologies, and the development of new concepts.

10:30 ▶ **Morning Coffee and Networking Break**

Progression & Challenges of Precision Medicine

11:00 ▶ **Case Study | Dr. Nick Zhang, CN -** Chairman and CEO at QIAGEN (Suzhou) Translational Medicine Co. Ltd.
Biomarker and CDx--- the first half of Precision Medicine

- Overview of biomarker and CDx
- Our CDx business model and case studies
- Biomarker and CDx development in China

11:40 ▶ **Case Study | Eric Faulkner, US** - Vice President, Precision and Transformative Technology Solutions at Evidera
How are Critical Success Factors for Precision Medicine Acceptance and Uptake Changing as we Move into the Next Generation of Personalized Patient Care?

- As precision medicine moves into a more mature technology phase with growing familiarity, acceptance and uptake challenges and opportunities continue to evolve. What is critical to commercial success in today's precision medicine environment? How will factors like the shift to next generation testing, advancement of machine learning, and changes in health system incentives alter the way that we develop and use precision medicines? Which commercial scenarios require more complex planning? What is commercially "got to have" versus "nice to have"? This session will consider how critical success factors for personalized medicine have shifted with a perspective on adapting value demonstration and commercial strategies to adjust for future considerations.

12:20 ▶ **Case Study | Prof. Robert Hawkins, UK** - Cancer Research UK Professor at University of Manchester
Adoptive cell therapy for cancer using both natural and engineered T-cells

13:00 ▶ **Business Lunch**

Development, Diagnostics & Testing in CDx & Biomarkers

14:00 ▶ **Case Study | Dr. Stefan Müllner, DE** - General Manager & Partner at fundamenta Life Science
Options for biomarker based patient stratification in NON-ONCOLOGY clinical development

- Current status of biomarkers used in clinical development of novel autoimmune drugs
- Market needs and customer demand
- Health economic aspects of more efficient biomarker based clinical development of new drugs in large indication areas, e.g. metabolism, cardiovascular, neurodegeneration

14:40 **Case Study | Dr. Paul Docherty, UK -** Relationship and Alliance Management at Hologic
The development of Biomarkers to Diagnostic products

- Few biomarkers ever make it into routine clinical use, using case studies this talk we present an overview of the process undertaken by a diagnostic company to develop and manufacture molecular biomarker based diagnostic products. Discussion will centre around the differences presented by Phase I to Phase III projects and how initial decisions and LDT/IVD development paths can be critical to success

15:20 **Coffee & Networking Break**

16:50 **Case Study | Rohit Nambisan, US -** SVP Product Strategy & Partner Integration at Treato, Product Advisor at Neurolex Diagnostics
Patient Perspectives on Diagnostics & Testing

- Assessing patient perspectives in Diagnostics development & commercialization programs
- Identifying Opportunities and Threats in early development through real world data & patient reported outcomes

17:30 **Case Study | Dr. Alfred Hansel** - CEO at Oncgnostics GmbH
Epigenetic markers in cancer diagnostics

- Basics on epigenetic markers
- Identification and diagnostic testing of markers
- The current use of epigenetic markers in diagnostics

18:00 **Panel discussion |** Moderated by the Chairman

Latest advances in overcoming tumor-induced immune suppression and immune escape
Standardization of existing assays and approaches
Clinical trials for cancer immunotherapy: specific features and the role of diagnostics

Panelists:

Dr. Paul Docherty, UK
Prof. Robert Hawkins, UK
Eric Faulkner, US
Dr. Nick Zhang, CN

18:30 **Chairman's Closing Remarks**

20:00 **Gala Dinner |** We have programmed a dinner in one of the finest restaurants of the city of Porto

DAY 2 - CONFERENCE

2

08:00 ▸ Registration and Welcome Coffee

08:25 ▸ Opening of the BioTech Pharma Summit: Companion Diagnostics & Biomarkers

Novel Technologies and approaches

08:30 ▸ **Case Study | Ali Ardakani, CA** - Managing Director at Novateur Ventures Inc.
Companion Diagnostics: a guide to cure?

Best practices of companion diagnostics for better drug development and successful reimbursement

- In this presentation will be looking at several best cases (and worst cases) of challenges of developing companion diagnostics and how the fait of both the drug and diagnostics changed based the clinical outcome

09:00 ▸ **Case Study | Dr. Birgitte Booij, NO** - Vice President Product and Business development at SpinChip Diagnostics
Moving Dx testing within precision medicine to the Point of Care

- Presentation of a new state of the art Point-of-Care testing platform
- The role of Point-of-Care testing in delivering personalized healthcare

09:30 ▸ **Coffee & Networking Break**

10:00 ▸ **Case Study | Austin Speier, US** - Vice President, Emerging Technologies at Precision for Medicine
Integrating Digital Medicine into a Biomarker Strategy

- Identifying opportunities to leverage digital medicine in targeted therapeutic strategies
- Understanding and de-risking "digital biomarkers" and other digital medicine development tools
- Practical approaches for integrating digital medicine into clinical studies for therapeutics

10:30 ▸ **Case Study | Christopher Ung, US** - Chief Business Officer at HistoGeneX
Digital Pathology in Immuno-Oncology - A Roadmap for Clinical Development

- Immuno-oncology has catalyzed histopathology applications, such as TIL location and spatial analyses, that benefit from digital pathology.
- Digital Pathology validation models are present for manufacturers and diagnostics but needed for clinical development.
- The rapid evolution of PD-L1 scoring algorithms create an acute need for pathologist training and proficiency. A well-designed training module addresses these needs

11:00 ▸ **Case Study | Paul Whittaker, UK** - Vice President, Discovery Research at hVIVO
Utilising human challenge studies to accelerate the development of new therapies for respiratory disease

- Human models of disease as a way to better understand human pathology
- Disease in motion - the power of clinical and molecular time course data sets and matched clinical samples
- Data mining to accelerate drug target and biomarker discovery

CDx & Biomakers: Strategies, Partnerships, Development and Commercialization

11:40 ▸ **Case Study | Henrik Winther, SE** - Senior Vice President, Precision Diagnostics at Immunovia ABt
Strategic Partnerships for CDx – Challenges and Opportunities

- What is required to become a successful CDx provider?
- What are the major challenges?
- How could these challenges potentially be solved?
- Trusted partnership is key within Rx-CDx development

12:20 ▸ **Case Study | Susanne Munksted, DK** - Commercial Director, Companion Diagnostics at Agilent
The PD-L1 CDx Commercialization Journey

- Experiences from the world's first PD-L1 CDx commercial launch
- Learnings from launching a complementary diagnostic, a new CDx category created by FDA
- Managing multiple PD-L1 assays and multiple partners in a competitive space
- PD-L1; a complex product lifecycle! Developing an assay in relation to global reach and new indications
- Demonstrating models and tools to sustain valuable partnerships and secure efficient CDx-Rx commercialization programs

13:00 ▸ **Business Lunch**

14:00 **Case Study | Jürgen Doppke, DE** - Director, Business Development at Thermo Fisher Scientific
Targeted Next Generation Sequencing Panels for the Rapid Development of CDx in Oncology

- A Universal Diagnostic for solid tumors
- NGS Panels for hematological Cancers
- NGS Panels for Immuno-Oncology Response
- Liquid Biopsy Panels

14:40 **Case Study | Dr. Morteza Minaee, US** - VP, Regulatory Affairs at Guardant Health
Regulatory considerations for Next Generation Sequencing (NGS)-based circulating tumor DNA (ctDNA) as biomarker candidates into companion diagnostics

- Evolving Regulatory environment for NGS and Cancer Comprehensive Genomic Profiling
- ctDNA assays- Challenges and opportunities
- ctDNA intended uses and indications- A changing model
- Analytical Performance Studies Consideration
- Clinical Validation Considerations
  - Three Alternative Pathways
    - _ Method Comparison Approach
    - _ Retrospective Clinical Bridging Approach
    - _ Prospective patient enrollment Approach

15:20 **Coffee & Networking Break**

15:50 **Case Study | Gary Gustavsen, US** - Partner, Personalized Medicine at Health Advances
Partnership Strategy Evolution over the CDx Lifecycle

- A strong CDx partnership strategy that spans the lifecycle of the associated therapeutic is critical for success. Partnership considerations evolve from clinical development to post-launch when creative engagements are necessary to ensure that the CDx is an advantage to the therapeutic rather than a barrier. This discussion will utilize case studies to highlight the evolution of these partnership considerations

16:30 **Case Study | Jeffrey Jones, US** - Executive Vice President, Commercial Operations at SkylineDx
Overcoming challenges in the global commercialization of novel biomarkers

- Building a comprehensive market access strategy – develop and validate your opportunity first.
- Generating powerful evidence – start your publication planning early.
- Communicating a compelling value proposition – leveraging an insight-driven commercialization strategy

17:10 **Case Study | Jakob Gjørret, DK** - Managing Director, Unilabs Denmark
Lab service component in development and commercialization of drug associated diagnostic services

- The role of a laboratory service partner in development
- Gaps and glitches in bringing drug associated diagnostic testing services into use – and ways to mend
- Examples from the field

18:00 **Panel discussion |** Moderated by the Chairman
Companion Diagnostics Development & Partnering Strategies

Panelists:

Jakob Gjørret, DK
Christopher Ung, US
Paul Whittaker, UK
Gary Gustavsen, US

18:30 **Chairman's Closing Remarks and End of Summit**

Speakers Biographies

Harry Glorikian, US

CEO, Sr. Executive, Board Director, Author, MoneyBall Medicine & Commercialization of Novel IVDs

evidation HEALTH

Harry Glorikian is an influential global business expert with more than three decades of experience building successful ventures in North America, Europe, Asia and the rest of the world. Harry is well known for achievements in life sciences, healthcare, healthcare IT and the convergence of these areas. He is a sought-after speaker, frequently quoted in the media, and regularly asked to assess, influence, and be part of innovative concepts and trends. He holds four US patents in telecommunications, and has others pending.

Dr. Nick Zhang, CN

Chairman and CEO at QIAGEN (Suzhou) Translational Medicine Co. Ltd.

QIAGEN

With over 25 years of drug R&D experience and years of experience in translational and diagnostics, Nick is now the board chairman and CEO for QIAGEN (Suzhou) Translational Medicine Co. Ltd. that provides an integrated technology platform for biomarker, companion diagnostics development and clinical testing for precision medicine.

Prof. Robert Hawkins, UK

Cancer Research UK Professor at University of Manchester

MANCHESTER 1824
The University of Manchester

Robert Hawkins is Cancer Research UK Professor at the University of Manchester and Christie Hospital. His research interests are in gene and immunotherapy of cancer. In addition to clinical training at the Royal Marsden Hospital and Addenbrookes Hospital in Cambridge he was an MRC Research Fellow with Dr Greg Winter and Dr Cesar Milstein at the MRC laboratory of Molecular Biology in Cambridge. His PhD was in antibody engineering and as a Cancer Research UK Senior Clinical Fellow he developed translational research interests in antibody based gene therapy.

Dr. Martina Kaufmann, DE

Managing Director at Martina Kaufmann Strategic Consulting

MARTINA KAUFMANN
STRATEGIC CONSULTING
Individual Solutions for Personalized Medicine

Dr. Martina Kaufmann, Managing Director at Martina Kaufmann Strategic Consulting (www.mk-stracon.com) has 15+ years industry experience in the field of personalized medicine - from biomarker validation, companion diagnostics development to implementation of such products in the market. She served in various roles of increasing responsibility in business and development functions in small biotech / diagnostic companies as well as in global pharmaceutical & diagnostics corporations (Hoffmann-La Roche AG, Novartis Pharma AG, Novartis Molecular Diagnostics), where she e.g. led the Herceptin® biomarker / companion diagnostics activities and did build up the oncology biomarker group in Basel, respectively.

Eric Faulkner, US

MPH, Vice President, Precision and Transformative Technology Solutions at Evidera

Evidera
Evidence, Value & Access by PPD

Eric Faulkner, MPH, Vice President, Precision and Transformative Technology Solutions at Evidera. Mr. Faulkner brings approximately 20 years of experience in the healthcare industry focusing on value demonstration, market access and commercialization of emerging health technologies. Mr. Faulkner is a recognized global thought leader in personalized medicine/diagnostic, regenerative medicine, biopharmaceutical, and medical technology market access, with extensive publication and over 80 global panel sessions on these topics.

Jakob Gjørret, DK

Managing Director at Unilabs

Unilabs

Jakob Gjørret is Managing Director, CEO for Unilabs Denmark in Copenhagen and is also leading Unilabs Group initiative for Serving Pharma, with efforts to combine and align capabilities for bioanalysis in drug development and commercializing drug associated diagnostic services. Before joining Unilabs in 2017 he was Director of Alliance Management within Agilent's Companion Diagnostics division.

Speakers Biographies
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Dr. Stefan Müllner, DE
General Manager & Partner
at Fundamenta Life Science

Stefan Müllner, a chemist by training, did his Ph.D. thesis in protein biochemistry and postdoc in molecular biology. During his long time as CEO of Protagen AG, he grew the company into the global technology leader in blood based patient stratification to enable novel autoimmune therapy. Before he co-founded Protagen, he worked as Head of Enzyme Technology at Henkel, as well as preclinical pharma research and corporate research at Hoechst, now Sanofi.

Henrik Winther, SE
Senior Vice President, Precision
Diagnostics at Immunovia AB

Henrik Winther has been at the forefront of companion diagnostics for over 10 years. He brings solid experiences within R&D, business development, regulatory, manufacturing and commercialization of IVD products. From 2006, Henrik was R&D Director at Dako A/S and spearheaded the design responsibility of their most successful product, the HercepTest CDx assay, and later was Head of Dako Business Development and involved in the acquisition of Dako by Agilent Technologies.

Dr. Paul Docherty, UK
Relationship and Alliance
Management at Hologic

Paul has worked for pharma/biotech and services companies since completing his post-doctoral studies in the late 1990s. For the last 5 years he has worked on Personalised Healthcare and CDx partnerships and projects which has led to an in depth understanding of the relationships between the contract provider and acceptor, enabling him to engage and empathise whether for transactional business or strategic partnerships. He has a strong belief that the relationship with the customer is key, communication is critical and he pushes all staff to take ownership of customer's projects.

Rohit Nambisan, US
SVP Product Strategy & Partner
Integration at Treato, Product
Advisor at Neurolex Diagnostics

As CEO of Cellanyx Diagnostics, Ashok is currently advancing a novel live cell biopsy-on-a-chip technology. As reported by Boston Business Journal, Urology Today and The Wall Street Journal's Venture Wire, Cellanyx provides a first-in-class live cell phenotypic cancer diagnostic platform to aid clinical decision making and reduce repeat biopsies. The Cellanyx live-cell biomarker platform has potential use in cancer diagnosis, risk stratification and prognostic applications in a wide range of human cancers and as a research tool for biomarker and drug development.

Dr. Alfred Hansel, DE
CEO
at oncgnostics GmbH

As CEO Dr. Hansel is responsible for business development at oncgnostics. He has long-lasting experience in project management obtained while working at several universities in Germany and abroad as well as operative experience in industrial product development, sales and marketing. The spin-off of oncgnostics is based on his research as well as works of a project group at the university hospital, which he has led.

Ali Ardakani, CA
Managing Director
at Novateur Ventures Inc

For the past 18 years, Ali Ardakani has been pivotal in start-up and development of several biotech companies, drugs and medical devices, for which he has raised over $100 M USD in private and grant financing. Most recently, he co-founded virtual biotech Niiki Pharma Inc in NYC, where he acquired two first-in-class oncology drugs from Europe and took them through US IND, UK CTA and Phase 1 and 2 clinical trials within 3 years.

Speakers Biographies

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Dr. Birgitte Booij, NO

Vice President Product and Business development at SpinChip Diagnostics

Birgitte Booij, Ph.D. is Vice President Product and Business development at SpinChip Diagnostics, a startup company developing a new state of the art platform for in vitro diagnostics aimed at the Point of Care market. Booij has 15 years' experience within commercial diagnostics development from both the Diagnostics' and Pharma industry. From 2010 to 2013 she led the biomarker and companion diagnostics development program for Clavis Pharmas' oncology drug candidate.

Christopher Ung, US

Chief Business Officer at HistoGeneX

Mr. Christopher Ung led the global development and commercialization efforts of HercepTest™ and pharmDx EGFR companion diagnostic assays. He continues to lead and implement global biomarker strategies for drug development and companion diagnostic projects. He has set up CAP, CLIA laboratories in the US, Scotland, China, and Singapore, all of which are connected via a digital pathology WSI scanning and analysis platform.

Jürgen Doppke, DE

Director, Business Development at Thermo Fisher Scientific

Dr. Juergen Doppke, received his PhD from the Ruhr University in Bochum in cooperation with Boehringer Ingelheim. Subsequently he gained 15 Years Experience in various Roles as Sales- and Product Specialist, Field Application Scientist and Product Line Leader for Lab Automation, Research Instrumentation and High Content Screening Products for Companies like Beckman Coulter, Molecular Devices and Perkin Elmer. He joined Thermo Fisher Scientific in 2014 as Director, Business Development Diagnostics Partnering for Central Europe. In his current role he is responsible for partnerships with European Pharma Partners to develop Customized Diagnostics and Companion Diagnostics; leveraging existing IVD platforms with focus on targeted Next Gen Sequencing Panels and Liquid Biopsy for Oncology as well as Immunodiagnostics.

Austin Speier, US

Vice President, Emerging Technologies at Precision for Medicine

Austin is Vice President, Emerging Technologies at Precision for Medicine, where he specializes in the design and execution of to-market clinical and regulatory strategies for innovative, first-in-class diagnostics, digital health and medical device technologies. He has over 10 years of experience supporting innovation in the life sciences and has worked on over 200 diagnostics, software apps, therapeutics and combination products across all clinical areas, with a focus on developing a strong evidence base, managing development risk, and securing product marketing approval.

Paul Whittaker, UK

Vice President, Discovery Research at hVIVO

Currently Vice President, Discovery Research at hVIVO (formerly RetroScreen Virology Ltd) with responsibility for strategic direction and leadership of scientific activities aimed at identifying and developing drug targets and biomarkers for respiratory disease. Previously Unit Head for pre-clinical biomarkers in the Respiratory Disease Area of the Novartis Institutes for Biomedical Research in the UK with experience in a range of activities from target identification and validation, through lead identification and optimisation to biomarker development for clinical trials. Prior to that 14 years as an academic researcher, including 7 years as a Research Lecturer at Southampton University Medical School.

Susanne Munksted, DK

Commercial Director, Companion Diagnostics at Agilent

Susanne Munksted holds a Master of Science in Pharmaceutical Sciences from The Royal Danish University of Pharmacy, followed by an Executive CBA (Certificate in Business Administration) and a number of Diplomas in People Management and Sales and Marketing. She worked +10 years in various International Commercial roles in the pharmaceutical industry before joining Dako (now Agilent) in 2009 and is now Global Commercial Director heading the Global Commercial Team for Companion Diagnostics.

Speakers Biographies

Dr. Morteza Minaee, US

VP, Regulatory Affairs
at Guardant Health

GUARDANT HEALTH

Dr. Morteza Minaee has more than 25 years of experience in the FDA-regulated medical devices and global diagnostic industry leading regulatory, quality-systems, and clinical -affairs organizations. He is currently Vice President of Regulatory Affairs at Guardant Health in Red Wood City California. Prior to Guardant Health he served as Senior Director, Regulatory Affairs at Roche leading many FDA clearances in digital pathology applications including breast cancer biomarkers.

Gary Gustavsen, US

Partner, Personalized Medicine
at Health Advances

HEALTH ADVANCES
Strategy Consultants for the Healthcare Industry

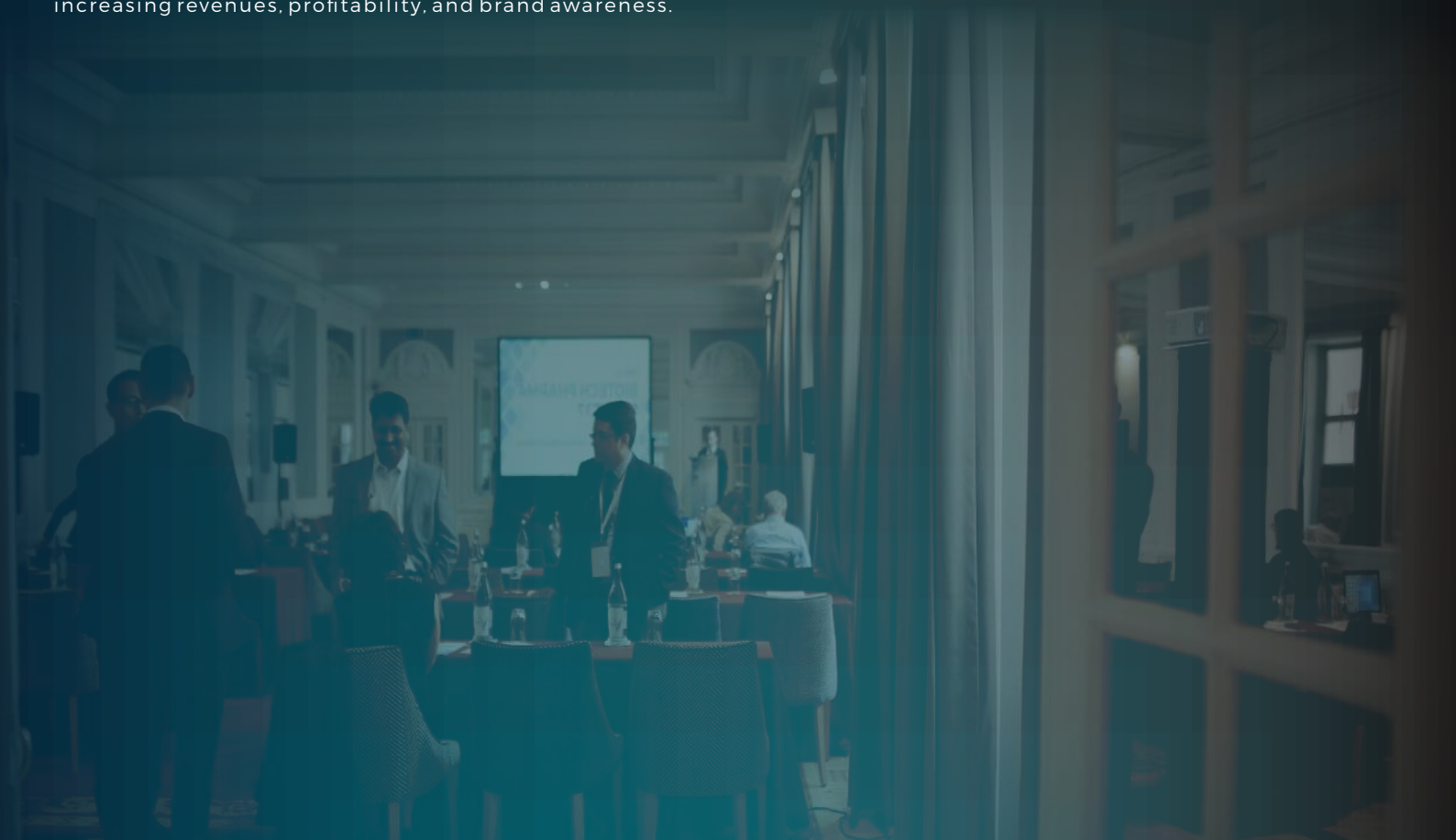
Gary Gustavsen joined Health Advances in 2005 and leads its PrecisionMedicine Practice. A noted writer and workshop leader in the field of companion diagnostics and personalized medicine, his work focuses on commercialization strategy, indication prioritization, pricing and reimbursement strategy, system economics, and business development opportunities for both diagnostic and therapeutic clients.

Jeffrey Jones, US

Executive Vice President,
Commercial Operations at SkylineDx

SkylineDx

Mr. Jones joined SkylineDx as the Executive Vice President, Commercial Operations in August 2015. He brings more than twenty-five years of experience to SkylineDx as a proven commercial leader in the global in-vitro diagnostics industry. With extensive experience in the oncology and laboratory services markets, Jeff has a demonstrated track record of bringing to the global market new and novel technologies, increasing revenues, profitability, and brand awareness.



PARTNERS

Pharma Technology Focus

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SWISS

HOTEL VENUE

The venue of the BioTech Pharma Summit 2017 will be at the Hotel Ipanema Park. The address is:

Hotel HF Ipanema Park
Rua de Serralves 124,
4150-125 Porto - Portugal