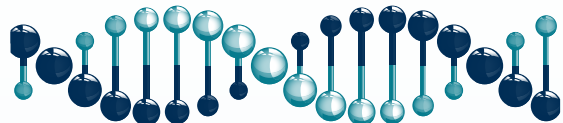


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Final Agenda

Cambridge Healthtech Institute's Second Annual

# MOLECULAR DIAGNOSTICS SUMMIT EUROPE



11 - 13 October 2011 • Exhibition Grounds • Hannover, Germany

11-12 October



Molecular Diagnostics for Cancer



Convergence of Technologies for Point-of-Care Diagnostics

12-13 October



Molecular Diagnostics for Infectious Disease



NGS: Molecular Diagnostics Magnified

## Keynote Speakers:



*J.W. (Hans) Hofstraat, Ph.D., Vice President Philips Research, Healthcare Strategic Partnerships, Philips Research Laboratories*



*Hans Lehrach, Ph.D., Director & Head, Vertebrate Genomics, Max Planck Institute for Molecular Genetics*



*Christopher R. Lowe, OBE, FREng, FInstP, FRSC, Director and Professor, Institute of Biotechnology, University of Cambridge*



*Andreas Plueckthun, Ph.D., Professor, Biochemical Institute, University of Zurich*



*Charles Swanton, Ph.D., Researcher, Translational Cancer Therapeutics Laboratory, Cancer Research UK London Research Institute*

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## Pre-Conference Short Course\*

**10:00-13:00 (SC5) MICRO- AND NANOFIUIDICS IN DIAGNOSTICS AND LIFE SCIENCES: TECHNOLOGIES, APPLICATIONS AND MARKETS**

This course is designed for scientists, managers, technicians and engineers who would like to acquire a comprehensive overview of the field of microfluidics. Starting with the underlying physical principles of miniaturization, the course includes an introduction into microfabrication technologies for microfluidic devices covering a wide range of existing materials (glass, silicon, polymers) and manufacturing technologies and describes the complete development cycle of a microfluidic device from the design to the ready-to-use device. Applications of microfluidics in point-of-care and clinical diagnostics, analytical and synthetic chemistry, biotechnology and cell biology will be presented. The course will also provide an insight into the business and commercialization aspects of the field and the uptake of microfluidic technology in various markets.

- Understand the basic physical principles and scaling laws governing miniaturization
- Identify the suitable material for a given microfluidic application
- Understand the basic technologies available for the microfabrication of glass, silicon and polymer materials and follow the device manufacturing process from design to the finished microfluidic device
- Learn application examples of microfluidic devices in a wide range of disciplines
- Understand the current state of the market and obstacles in the commercialization process

Instructor:

Holger Becker, Ph.D., CSO, microfluidic ChipShop

**14:00-17:00 (SC12) NOVEL DEVELOPMENTS IN IMMUNOASSAYS FOR DIAGNOSTICS**

High specificity of the formation of antibody-antigen complexes and advances in the sensitivity of labels make the use of immunoassays the method of choice for infectious disease diagnostics. In addition, immunoassays detect analytes at very low concentrations which measure drug and protein markers such as cancer and cardiac injury. The qualitative and quantitative results, ease, speed, and cost saving all combine to make immunoassays the method of choice for advancing diagnostics. This course is designed for bioengineers developing diagnostic assays and physicians, technicians, biotherapeutic researchers who wish to become informed about advances in the diagnostic pipeline.

Toon H. Evers, Ph.D., Senior Scientist, Molecular Diagnostics, Philips Corporate Technologies

\*Separate Registration Required

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MAGAZINE OF THE LIFE SCIENCES

# Molecular Diagnostics for Cancer

Improving Patient Outcomes



## TUESDAY, 11 OCTOBER

### 9:00 Conference Registration and Morning Coffee

## ASSURING TISSUE QUALITY FOR PATIENT STRATIFICATION AND DIAGNOSIS

### 9:30 Chairperson's Opening Remarks

*Dalia Cohen, Ph.D., CSO, Asterand*

### 9:35 Hard Measures of Tissue Quality and Data

*Beatrice Knudsen, M.D., Ph.D., Medical Director, Biorepository and Translational Pathology, Cedars-Sinai Medical Center*

I will discuss the challenges of designing Q/C measures for specimens in a biorepository that are used to develop predictive biomarkers for targeted therapies. I will also present real life examples of the importance of Q/C for tissue in the realm of personalized medicine.

### 10:05 Presentation to be Announced

### 10:35 Coffee Break - Networking with Sponsors

### 11:15 Ultra-Rapid BioBanking - Paving the Way for Next-Gen Personalized Health Care

*Michael H. A. Roehrl, M.D., Ph.D., Assistant Professor, Pathology and Laboratory Medicine, Boston Medical Center*

Highest-quality BioBanking of human specimens is of utmost importance for life science research and the future of personalized health care. We will use several of our ongoing tissue-based proteomic cancer biomarker research projects on human colorectal and lung adenocarcinomas to illustrate the critical steps necessary to make BioBanking a success. We will also present very recent work on colon cancer metabolomics using ultra-fresh tissue procurement and high-field 1H NMR spectroscopy.

### 11:45 Biobanking Tissue Samples for Medical Research, Possibilities and Impossibilities

*Peter Riegman, Ph.D., Head, Erasmus MC Tissue Research Support Unit, Department of Pathology, Josephine Nefkens Institute, Erasmus MC Rotterdam, The Netherlands; Chair, OEI WG European Biobanking; Vice President, ESBB*

Innovation of medical care is highly depended on progress in personalized medicine and identification of drug targets and biomarkers. Such studies need access to large numbers of well documented and exchangeable tissue samples of comparable quality. Individual institutes are no longer able to generate the large numbers in time and therefore need to join in multi-center research projects. As a consequence access rules, network infrastructures and quality issues are addressed in the EurocanPlatform and SPIDIA projects, respectively.

### 12:15 Translating Pre-Clinical Biomarkers and their Application in Clinical Trials

*Austin Tanney, Ph.D., Scientific Liaison Manager, Almac*

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ALMAC

### 12:30 Sponsored Presentations (Opportunities Available)

### 12:45 Lunch for Purchase in Exhibit Hall 9

### 13:45 Dedicated Poster Viewing in Exhibit Hall 9

## NOVEL MOLECULAR MARKERS FOR CANCER

### 14:30 Chairperson's Remarks

*Michael Berndt, Ph.D., Professor, Director, Biomedical Diagnostics Institute*

### 14:35 Companion Diagnostics: Addressing the Challenges to the Pharma Business Model

*Ruediger Weseloh, Ph.D., Senior Director, Head Strategic Transactions, Early-Stage Licensing, Merck KGaA*

The importance of biomarkers for patient stratification is rapidly increasing. This has implications for the future of the pharma business. For instance, patient stratification requires structured decisions for the alignment of Rx/Dx co-development. In addition, the need for pharma to partner with diagnostics companies is created. This requires pharma to define criteria for the selection of a diagnostics partner.

### 15:05 Circulating Specific microRNAs Associated with Breast Cancer

*Michael Berndt, Ph.D., Professor, Director, Biomedical Diagnostics Institute*

The Biomedical Diagnostics Institute is a Science Foundation Ireland funded academic-business-clinical consortia developing integrated point-of-care diagnostic devices for a variety of clinical diseases including cancer. We have defined a whole blood microRNA biosignature in breast cancer with potential as an adjunct in screening and in assessing response to therapy and disease recurrence.

### 15:35 Refreshment Break - Networking with Sponsors

### 16:15 Sponsored Presentation (Opportunity Available)

### 16:45 SOMAmers (Slow Off Rate Modified Aptamers) as Tools to Discover Cancer Biomarkers and Translate them to Diagnostic Products

*Stephen A. Williams, M.D., Ph.D., CMO, SomaLogic Inc.*

A high-throughput clinical assay will be described that uses a mixture over 1000 SOMAmers as affinity reagents to measure 1034 proteins with CVs of <5%, lower limits of quantitation of ~0.3pM, a dynamic range of 7 logs and a sample volume of <10 microliters. This assay has been used in a series of substantive case-control studies in different cancers (lung, ovarian, pancreas, mesothelioma, melanoma, renal cell) in plasma/serum samples from several thousand subjects. These have revealed individual signatures of cancer as well as proteins common to several cancers which are being translated into diagnostic products.

### 17:15 Non-Coding RNA - A Whole New World of Potential Diagnostic and Prognostic Biomarkers

*Sven Diederichs, Ph.D., Principal Investigator, Molecular RNA Biology & Cancer, German Cancer Research Center*

It is now evident that the human genome contains many more functionally important and clinically informative entities: the non-coding RNAs (ncRNA). To assess the expression landscape of these new class of molecules, we have profiled the expression of 17000 non-coding RNAs in three major tumor entities: breast, lung and liver cancer. These studies revealed molecular signatures associated with tumorigenesis (diagnostic), with histological subtypes as well as with the outcome or metastasis development (prognostic). Our research uncovers the functions at the cellular and molecular level of the differentially regulated ncRNAs as well as their clinical importance as diagnostic and prognostic markers.

### 17:45 The Detection of Cancer Biomarkers on Biosensor

## Surfaces

*Ajit Sadana, Ph.D., Professor, Chemical Engineering, University of Mississippi*

This presentation will model the binding and the dissociation of biomarker kinetics using fractals. The fractal dimension provides one with a quantitative measure of the degree of heterogeneity present on the biosensor surface. The predictive equations developed help to manipulate the biosensor performance parameters (such as the binding rate coefficient) in desired directions.

### 18:15 Interactive Breakout Discussion Groups

#### TOPIC: Circulating Tumor Cells: Uses, Pitfalls and Challenges

*Moderator: Wolfgang Janni, M.D., Ph.D., Professor, Gynecological Clinic, Heinrich-Heine University Hospital Düsseldorf*

- Solid evidence: CTC in metastatic breast cancer
- Early evidence: CTC in primary breast cancer
- Urgent Challenge: Phenotyping CTCs
- CTC and stem cells: what is the difference?
- CTC: which detection method is the best one?

#### TOPIC: Contamination and Quality Control in Biorepositories

*Moderators: Beatrice Knudsen, M.D., Ph.D., Medical Director, Biorepository and Translational Pathology, Cedars-Sinai Medical Center*

*Carolyn C. Compton, M.D., Ph.D., Director, Biorepositories and Biospecimen Research, National Cancer Institute*

- Optimizing prospective tissue collections: How can we reduce the pre-analytical variability?
- How to assess the quality of an existing biorepository: How and when should be assess quality?
- Biobanking and advanced technologies: Are existing biobanks adequate?
- Biobanking in difficult financial times: How can we prioritize the resources?
- Can technology development for biobanking overcome present challenges and limitations?
- Are we at the point of globaliation of reserach and product development that international standardization should be incentivized/mandated?

#### TOPIC: Identification and Utilization of Molecular Markers for the Clinic

*Moderator: Michael Berndt, Ph.D., Professor, Director, Biomedical Diagnostics Institute*

- Companion diagnostics and cancer drug development
- Importance of novel cancer biomarkers: early detection versus response to therapy
- Cancer biomarkers and patient stratification
- The role of CTCs in cancer diagnostics

**19:15 BIOTECHNICA EVENT NIGHT – Keynote Presentation followed by Networking Reception. Live music and dancing.**

## WEDNESDAY, 12 OCTOBER

### CLINICAL ASPECTS OF CTC ANALYSES

#### 9:30 Chairperson's Opening Remarks

*Wolfgang Janni, M.D., Ph.D., Professor, Gynecological Clinic, Heinrich-Heine University Hospital Düsseldorf*

#### 9:35 The Clinical Role of CTCs in Primary and Metastatic Breast Cancer

*Tanja Fehm, M.D., Ph.D., University of Tübingen*

In the past years the clinical role of CTCs has been widely investigated. This talk gives a summary about the important studies in this field.

#### 10:05 The Role of CTCs in the Adjuvant Treatment of Breast Cancer

*Wolfgang Janni, M.D., Ph.D., Professor, Gynecological Clinic, Heinrich-Heine University Hospital Düsseldorf*

Minimal residual disease (MRD), i.e. isolated tumor cells (ITC) in bone marrow, may be the source of potentially fatal overt distant metastases in solid tumors even years after primary treatment. Several trials currently analyze the prognostic relevance of circulating tumor cells (CTC) in peripheral blood in the adjuvant setting. In Germany, e.g., CTCs in peripheral blood of breast cancer patients at primary diagnosis and during adjuvant chemotherapy as well as endocrine and bisphosphonate treatment within the SUCCESS-Trial (n=3658 pts) are currently analyzed.

#### 10:35 Coffee Break - Networking with Sponsors

#### 11:00 Sponsored Presentation (Opportunity Available)

#### 11:30 Challenges in Clinical Trials on CTCs in Breast Cancer

*Jean-Yves Pierga, M.D., Ph.D., Medical Oncology, Institute Curie, Paris*

CTC detection and level changes during treatment have been shown to be strong prognostic and predictive markers in metastatic breast cancer. However, clinical benefit to use this biological test for patients' management in daily practice remains controversial. Level of evidence, pooled analysis and clinical trials using CTC monitoring to adapt treatment strategies in breast cancer will be discussed.

#### 12:00 CTC in the Neoadjuvant Setting: Why Do We Need More Information than Tumor PCR?

*Volkmar Müller, M.D., Ph.D., Department of Gynecology, University Medical Center Hamburg-Eppendorf*

Neoadjuvant treatment strategies allow the assessment of therapeutic efficacy in breast cancer patients since the therapy response is a surrogate parameter for long term outcome. Nevertheless, even a part of patients with a complete tumor remission will relapse. This highlights the need for approaches allowing the identification of therapeutic strategies to overcome resistance. In this context, the detection of circulating tumor cells will be a valuable tool.

#### 12:30 Lunch for Purchase in Exhibit Hall 9

#### 13:00 Dedicated Poster Viewing in Exhibit Hall 9

#### 13:30 Close of Conference

# Molecular Diagnostics for Infectious Disease

*Adapting Tools for Clinical Use*



## WEDNESDAY, 12 OCTOBER

**13:00 Conference Registration**

### MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE

**14:00 Chairperson's Remarks**

**14:05 Next-Generation Sequencing for Infectious Disease Surveillance - from "Base Pair to Bedside"**

*Dag Harmsen, M.D., Head of Research, Periodontology Department, University Hospital Münster*

Next-generation sequencing (NGS) has fundamentally altered genomic research. New developments will bring NGS costs and performance down to an everybody's technology with extreme potential for ultra fast and accurate molecular bacterial typing as it provides the ultimate whole genome information. However, the current bottleneck in analysis, i.e. bioinformatics, needs to be overcome to make successfully the transition from data to knowledge in routine infectious disease surveillance.

**14:35 Adaptation of Next-Generation Sequencing for Exploration of the Malaria Epigenome**

*Richard Bartfai, Ph.D., Postdoctoral Fellow, Molecular Biology, Nijmegen Center for Molecular Life Sciences, Radboud University Nijmegen*

Exploration of epigenetic regulatory mechanism unique to *Plasmodium falciparum*, the causative agent of malaria, could provide novel targets for drug development. We have developed the Linear Amplification for Deep Sequencing (LADS) method that enables preparation of highly representative sequencing libraries from the extremely AT-rich *P. falciparum* genome. Using this novel method we analyzed the epigenome (ChIP-seq) and transcriptome (RNA-seq) of the parasite at unprecedented depth, during multiple stages of development.

**15:05 The Transcriptional Landscapes of Human Pathogenic Fungi Revealed by Next-Generation Sequencing**

*Kai Sohn, Ph.D., Molecular Biotechnology, Fraunhofer Institute for Interfacial Engineering and Biotechnology*

Human pathogenic fungi are causing superficial infections of the skin but also life-threatening systemic diseases. To define the pathogenicity at the molecular level, information about the genomes and the corresponding transcriptomes is crucial. We applied next-generation sequencing for the qualitative annotation as well as for the quantitative analysis of the transcriptional landscapes in different *Candida* species that represent the most important fungal pathogens.

**15:35 Refreshment Break - Networking with Sponsors**

**16:15 Sponsored Presentations (Opportunities Available)**

**16:45 An iPod Touch-Based Hand-Held Gene Analyzer for Pathogen Screening in Limited Resource Settings**

*Syed Hashsham, Ph.D., Professor, Civil and Environmental Engineering, Michigan State University*

Currently available genetic analysis platforms are powerful but they are expensive and too complicated for use by non-experts. We have developed a small and low cost device, called the GeneZ(TM) analyzer, which is a small smart phone-driven (both Apple's iPod Touch and Google's Android based phones) genetic analysis platform capable of analyzing 64 assays using an LED-photodiode system. The functionality and versatility of the platform will be discussed.

**17:15 Application of Intact Cell MALDI-TOF MS to the Identification of Bacteria: From Colonies to Clinical Samples**

*Bernard LaScola, M.D., Ph.D., Faculty of Medicine, University of the Mediterranean, Marseille*

Matrix-assisted laser desorption ionization time-of-flight (MALDI-TOF) mass spectrometry (MS) on intact cells is on the front end of a new revolution in the routine identification of microorganisms in clinical microbiology laboratories. It provides results in a few minutes and by its accuracy has the potential to replace or at least complement all other methods for microorganism identification.

## » PLENARY KEYNOTE SESSION

**18:00 Keynote Introduction**



**18:05 Protein Engineering: Benefitting Therapeutic Proteins and Small Molecule Drugs Alike**

*Andreas Plueckthun, Ph.D., Professor, Biochemical Institute, University of Zurich*

**18:40 'Systems Patientomics': The Future of Medicine**

*Hans Lehrach, Ph.D., Director & Head, Vertebrate Genomics, Max Planck Institute for Molecular Genetics*

Ten years after the completion of the human genome in a ten year international collaboration at a cost of between 1 and 3 billion Dollar, we are now getting ready to be able to sequence genomes/ transcriptomes as part of routine medical practice in oncology. The flagship project IT Future of Medicine would extend this approach to generate integrated anatomical/molecular models of every patient in the healthcare system, as the basis for a data rich, computation intensive, individualized medicine of the future.

**19:15 – 21:00 CHI Networking Dinner Reception**

## THURSDAY, 13 OCTOBER

### MOLECULAR DIAGNOSTICS FOR PERSONALIZED MEDICINE

**9:30 Chairperson's Opening Remarks**

*Alain Huriez, M.D., Founder and Chairman, EPEMED*

**9:35 Market Access Challenges in Europe**

*Alain Huriez, M.D., Founder and Chairman, European Personalized Medicine Association (EPEMED); CEO, TcLand Expression*

This presentation will cover the development and use of companion diagnostics and the impact on the business model of the pharmaceutical, diagnostic and biotechnology industry. The needs of guidelines and "Market Access Issues: The European Case" will be discussed.

## 10:05 Overview of IVD/MDx and Europe

*Harry Glorikian, Managing Partner, Scientia Advisors*

This presentation will provide an overview of the Molecular Diagnostics market in Europe, including the Regulatory & Reimbursement Infrastructure in the Top 7 EU countries. The question of “What does it take to launch high value diagnostics in top 7 EU countries” will also be addressed.

## 10:35 Coffee Break - Networking with Sponsors

## 11:00 Sponsored Presentations (Opportunities Available)

### 11:30 Value-Based Payment for Personalized Medicine Diagnostics

*Joseph V. Ferrara, President, Boston Healthcare*

While personalized medicine offers the potential to change well-established practices for physicians and patients, the concept presents a direct challenge to two other health care stakeholders essential to the realization of personalized medicine— pharmaceutical and diagnostics companies. At the core of the challenge is the question— how will a personalized medicine paradigm change these companies’ innovation and commercialization approaches? This presentation will focus on the key commercial factors that shape the personalized medicine opportunity for companion diagnostics and strategic considerations for pharma and diagnostics innovators.

### 12:00 Making Personalized Medicine a Reality for Patients

*Jens Dhein, Ph.D., Scientific Director, Abbott Molecular*

As a leader in the field of molecular diagnostics, Abbott Molecular has been developing and commercializing successful products for more than 25 years. In 2001, Abbott Molecular’s PathVysion was the first gene-based test (HER2 amplification) linked to a therapeutic Herceptin® (trastuzumab). Today, Abbott Molecular develops tests in collaboration with drug companies to help physicians select appropriate patients for targeted drug therapy, making the promise of personalized medicine a reality.

## 12:30 Lunch for Purchase in Exhibit Hall 9

## 13:45 Dedicated Poster Viewing in Exhibit Hall 9

## REIMBURSEMENT POLICIES AND THE FUTURE OF PERSONALIZED MEDICINE IN EUROPE

### 14:30 Sponsored Presentation (Opportunity Available)

#### 15:00 Overview of EU Reimbursement Policies

*Moderator: Edward Abrahams, Ph.D., President, Personalized Medicine Coalition*

#### 15:10 Personalized Medicine Coalition Report on EU Reimbursement Policies and Future Trends

*Susan Garfield, Dr.P.H., Vice President, Bridgehead International*

The Personalized Medicine Coalition has recently released a comprehensive review of the European reimbursement systems and how each impacts the availability of personalized medicine diagnostics. Details from this report will be presented, including considerations for how each country’s system will evolve from both an HTA, evaluation and pricing perspective. The presentation will include case studies to provide real world examples of key issues discussed.

### 15:30 Stakeholder Panel: Pharma and Diagnostic Stakeholders Discuss How Reimbursement Impacts Commercialization of New Targeted Therapies

Representatives from pharma and diagnostics companies will explain their company’s approach to developing targeted therapies in Europe and how to balance the requirements, goals and development timeline of the therapeutic and diagnostic. The discussion will include a review of evidence development planning, internal team alignment, and interaction with payer/HTA stakeholders.

#### *Panelists:*

*Allen Crook, Vice President, Pfizer*

*Juliette Plun-Favreau, Director, Reimbursement & Market, Genomic Health*

## 16:10 Refreshment Break - Networking with Sponsors

**16:30 Payer Panel:** Market Access Decision-Makers From Key European Countries Will Explain Their Role in Evaluating Novel Personalized Medicine Diagnostics, Evolving Systems for HTA and Coverage, and the Opportunities for Value Based Pricing  
Panelists will cover key developments in HTA from IQWiG and NICE’s Diagnostic Assessment Committee, payer attitudes towards personalized medicine and the role of diagnostics, and changing paradigms for coverage and payment.

#### *Panelist:*

*Stefan Sauerland, M.D., M.P.H., Head, Department of Non-Drug Interventions, Institute for Quality and Efficiency in Healthcare (IQWiG)*

*Ansgar Hebborn, Ph.D., Head, Global Payer & HTA Program Policy, Global Health Economics & Pricing (GHEP), F. Hoffmann-La Roche AG*

### 17:00 Response from EU to Country and Country Initiatives to Further the Adoption of Personalized Medicine Technologies

While coverage and reimbursement decisions occur at the country level in Europe, the European Union has many initiatives underway to support technology innovation and adoption. The response from the European perspective will provide a review of how companies, payers, government agencies, and advocates can work together to optimize access to personalized medicine technologies with the ultimate goal of improving the health of Europeans.

## 17:30 Close of Conference

# Convergence of Technologies for Point-of-Care Diagnostics



**TUESDAY, 11 OCTOBER**

**9:00 Conference Registration and Morning Coffee**

## OPENING SESSION

**9:30 Chairperson's Opening Remarks**

### » KEYNOTE PRESENTATION



#### **9:35 Point-of-Care, Wearable and Mobile Biomedical Sensors**

*Christopher R. Lowe, OBE, FREng, FInstP, FRSC, Director & Professor, Institute of Biotechnology, University of Cambridge*

This lecture will review the current state of the art in diagnostic approaches which are applicable to discrete and real-time on-, at- or near-patient, i.e. wearable, point-of-care analysis of critical parameters for effective patient management and care.

#### **10:05 Mobile Device for the Detection of MRSA and C. Difficile on Hospital Surfaces**

*Andrew Gover, COO, Vantix, Ltd.*

Vantix Ltd. (formerly Universal Sensors) designs and manufactures Vantix™ biosensors that are sensitive, fast and versatile. It allows tests that traditionally take several hours of laboratory time to be performed in minutes and can be adapted for medical, veterinary and environmental applications. Through a Small Business Research Initiative (SBRI) competitive procurement process, Vantix is developing a portable device for the UK's Department of Health to detect HCAI-related pathogens in hospital wards and care home settings.

#### **10:35 Coffee Break - Networking with Sponsors**

#### **11:15 Industrialization & Economics of Smart Consumables in Life Sciences & Diagnostics**

*Ali Tinazli, Ph.D., Senior Manager, Business Development, BioSciences, Sony DADC Austria AG*

Smart Consumables with microstructures / microfluidic features and functionalized surfaces are prerequisites for emerging applications in the Life Sciences and in-vitro Diagnostics (IVD) markets. The increasing complexity of such new products in those markets requires new manufacturing technologies. Sony DADC is now applying its excellence in customized mass manufacturing and its efficient processes to these highly sophisticated consumables in its new OEM business in a B2B format with leading, innovative companies in the biomedical field.

#### **11:45 We Have the Technology: So Where Is the Roadmap to the Clinic?**

*Vanya A. Gant, M.D., Ph.D., Director, Center for Infectious Diseases & International Health, University College London School of Medicine*

Diagnostic technologies now provide sublimely elegant solutions for detecting infectious agents. But technology alone can and will do nothing for better healthcare if not thoughtfully and appropriately integrated into clinical decision pathways. The speaker will illustrate these often poorly addressed if not completely overlooked issues of implementation with examples of failed technology for technology's sake, and suggest some solutions.

#### **12:15 An Inexpensive, POC Readout for Multiplex Molecular Diagnostics**

*Christopher Myatt, Ph.D., Founder and CEO, MBio Diagnostics, Inc.*

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DIAGNOSTICS

**12:45 Lunch for Purchase and Poster Viewing in Exhibit Hall 9**

## DECENTRALIZED HEALTHCARE SYSTEMS

**14:30 Chairperson's Remarks**

### » KEYNOTE PRESENTATION



#### **14:35 Decentralized Healthcare Systems and Applications**

*J.W. (Hans) Hofstraat, Ph.D., Vice President Philips Research, Healthcare Strategic Partnerships, Philips Research Laboratories*

Challenges in the healthcare system are mounting. Aging and increasing numbers of patients suffering from chronic illness put an increasing challenge to healthcare cost and available care and cure workers. Health technology is developing at a fast pace within sectors like medical devices, pharmaceuticals, and biomed using new science such as genomics and nanotechnology.

#### **15:05 Creating a Regional Health Information Exchange System from Tertiary to Home Health Care**

*Craig Lehmann, Ph.D., CC (NRCC), ASCP, FACB, Dean, School of Health Technology and Management; Professor, Clinical Laboratory Sciences, Stony Brook University*

This presentation will provide the details of building a regional health information exchange (HIE) system from an academic tertiary care medical center. The HIE consists of the following partners: hospitals, nursing homes, assisted living communities, physicians, diagnostics (laboratory and radiology) and presently incorporating software for home care. There will be a description of Point of Care Diagnostic Technologies that are available and utilized in today's home along with the economic benefits of such a HIE system.

#### **15:35 Refreshment Break - Networking with Sponsors**

## SPOTLIGHT ON NEW TECHNOLOGIES

#### **16:15 Sponsored Presentation (Opportunity Available)**

#### **16:45 Applying Nano Cantilever Technology to Detection of Organisms**

*Vincent C. Emery, Ph.D., Infection, School of Life and Medical Sciences (Royal Free Campus), University College London*

Cantilever technology offers many opportunities for the direct detection of proteins such as antigens and antibodies against infectious organisms and potentially for the direct detection of organisms themselves. The latter is more challenging and I shall provide the latest update on our approaches to measure HIV particles using cantilever approaches based on developments made using novel antibodies and virus like particle systems optimized using SPR technology.

#### **17:15 Diagnosing Tuberculosis within Two Hours: A Reality for TB POC**

*Lesley Scott, Ph.D., Professor, Molecular Medicine and Hematology, University of Witwatersrand*

The TB and HIV epidemic in the developing world continues to pose enormous challenges to public health, including TB/HIV service integration. The Xpert MTB/RIF assay developed by Cepheid (Sunnyvale, CA) has recently been endorsed by the WHO as the initial method used to diagnose TB and replace smear microscopy. This molecular based POC assay has increased sensitivity, reduced turnaround time (2 hours) and immediate identification of rifampicin resistance, and therefore has potential to improve patient care and impact on global TB prevention.

## 17:45 Semiconductor Dx: From Sequencing to POC

*Chris Toumazou, Ph.D., CEO and Founder, DNA Electronics Ltd.*

DNA Electronics has developed a method for all-electronic detection of nucleic acid using standard semiconductor chips. This technology is key to recent developments in semiconductor sequencing by Ion Torrent and Roche 454 Life Sciences. However, the technology does not stop at sequencing. In this talk, we will also describe the semiconductor chips that do real-time amplification and detection of DNA.

### 18:15 Interactive Breakout Discussion Groups

#### TOPIC: Microfluidics: A Natural Fit for PoC Diagnostics Devices?

*Moderator: Daniel Mark, Ph.D., Deputy Division Head, Lab-on-a-Chip, HSG-IMIT*

- Fields of applications: Which diagnostic scenarios benefit most from what Microfluidics has to offer?
- The 4 Cs of clinical diagnostics: Costs, Convenience, Connectivity and Consolidation. Is current Microfluidics research sufficiently addressing those needs?
- Macro to Micro interface: How can Microfluidic PoC devices handle samples with diagnostic relevance?

#### TOPIC: Incorporating Point-of-Care Technologies in the Clinical Setting

*Moderator: Vanya A. Gant, M.D., Ph.D., Director, Center for Infectious Diseases & International Health, University College London School of Medicine*

- Technology leading the charge for change
- Who pays for the test, and who benefits from the results?
- Whose point-of-care instrument is it anyway?
- Documenting results: clinical Governance issues
- When and why do you need point of care testing? Defining the decision boundaries

#### TOPIC: Impact of POC on TB Prevention

*Moderator: Lesley Scott, Ph.D., Professor, Molecular Medicine and Hematology, University of Witwatersrand*

- What is the definition of POC for TB?
- Potentially the LAM and the Xpert MTB/RIF assays are identified as POC, therefore what is the best algorithm for use at POC, especially in light of smear negative disease?
- What are the ways that national programs can monitor reduction in disease (prevention measures) once POC has been implemented?
- How best to implement POC: contact finding, laboratory based testing, clinic based testing with follow up?

#### TOPIC: Integration of Technologies for Decentralized Diagnostics

*Moderator: Luc Gervais, Ph.D., Swiss Federal Institute of Technology (EPFL)*

- What are the remaining challenges in integrating technologies for decentralized diagnostics?
- What is limiting the adoption of a broader variety of decentralized diagnostics?
- What are the key medical applications (niches) for which tests can be decentralized and patients can test themselves away from hospitals?
- What are possible revenue models for companies developing next generation decentralized diagnostics (ex.: insurance reimbursement, consumer spending)?

**19:15 BIOTECHNICA EVENT NIGHT** – Keynote Presentation followed by Networking Reception. Live music and dancing.

## WEDNESDAY, 12 OCTOBER

### TRENDS IN MICROFLUIDICS

#### 9:30 Chairperson's Opening Remarks

#### 9:35 Microfluidic Devices for Decentralized Diagnostics

*Luc Gervais, Ph.D., Swiss Federal Institute of Technology (EPFL)*

Medical diagnostics are essential for the identification and treatment of disease in patients. Microfluidics can precisely encode the flow of a sample across multiple functional elements such as valves, filters, sensing areas, heaters, and mixers for advanced sample processing and analysis. Microfluidic devices provide the opportunity to develop decentralized diagnostics requiring reduced sample sizes and providing faster results.

#### 10:05 Paper for the People

*Andres Martínez, Chemistry & Biochemistry, California Polytechnic State University*

Paper-based microfluidic devices constitute a promising platform for point-of-care diagnostics. Paper-based devices are inherently inexpensive, portable and easy to use; they are also easy to fabricate. This talk will describe recent developments in fabrication and assays, which bring these devices closer to fulfilling their potential as a tool for health care providers around the world.

#### 10:35 Coffee Break - Networking with Sponsors

#### 11:00 Sponsored Presentation (Opportunity Available)

#### 11:30 Assay Integration on the Centrifugal Microfluidic "LabDisk" Platform: Immunoassays, PCR and Isothermal Genotyping

*Daniel Mark, Ph.D., Deputy Division Head, Lab-on-a-Chip, HSG-IMIT*

The centrifugal microfluidic "LabDisk" platform allows miniaturization, automation and integration of biochemical assays. The LabDisk platform features the possibility to include pre-stored liquid and dry assay reagents, as well as easy handling and no cross-contamination, since no external connectors for liquid actuation are required.

#### 12:00 Multi-Force Actuation for Advanced Flow Control and Particle Handling on Bioanalytical Lab-on-a-Chip Platforms

*Jens Ducleé, Ph.D., Associate Professor, Microsystems, Biomedical Diagnostics Institute, Dublin City University*

This presentation surveys a repertoire of novel microfluidic techniques developed at the Biomedical Diagnostics Institute which combine mechanisms like gravity, pneumatics, magnetism, hydrodynamics and centrifugal fields to achieve improved flow control, particle handling and separation on highly integrated lab-on-a-chip platforms. Amongst the applications to be demonstrated are the manipulation, counting, separation and real-time monitoring of cells as well as immunoassays on arrays of single beads.

#### 12:30 Lunch for Purchase and Poster Viewing in Exhibit Hall 9

#### 13:30 Close of Conference



# NGS: Molecular Diagnostics Magnified



## WEDNESDAY, 12 OCTOBER

### 13:00 Conference Registration

### SEQUENCING FOR INFECTIOUS DISEASE

#### 14:00 Chairperson's Remarks

#### 14:05 Next-Generation Sequencing for Infectious Disease Surveillance - from "Base Pair to Bedside"

*Dag Harmsen, M.D., Head of Research, Periodontology Department, University Hospital Münster*

Next-generation sequencing (NGS) has fundamentally altered genomic research. New developments will bring NGS costs and performance down to an everybody's technology with extreme potential for ultra fast and accurate molecular bacterial typing as it provides the ultimate whole genome information. However, the current bottleneck in analysis, i.e. bioinformatics, needs to be overcome to make successfully the transition from data to knowledge in routine infectious disease surveillance.

#### 14:35 Adaptation of Next-Generation Sequencing for Exploration of the Malaria Epigenome

*Richard Bartfai, Ph.D., Postdoctoral Fellow, Molecular Biology, Nijmegen Center for Molecular Life Sciences, Radboud University Nijmegen*

Exploration of epigenetic regulatory mechanism unique to *Plasmodium falciparum*, the causative agent of malaria, could provide novel targets for drug development. We have developed the Linear Amplification for Deep Sequencing (LADS) method that enables preparation of highly representative sequencing libraries from the extremely AT-rich *P. falciparum* genome. Using this novel method we analyzed the epigenome (ChIP-seq) and transcriptome (RNA-seq) of the parasite at unprecedented depth, during multiple stages of development.

#### 15:05 The Transcriptional Landscapes of Human Pathogenic Fungi Revealed by Next-Generation Sequencing

*Kai Sohn, Ph.D., Molecular Biotechnology, Fraunhofer Institute for Interfacial Engineering and Biotechnology*

Human pathogenic fungi are causing superficial infections of the skin but also life-threatening systemic diseases. To define the pathogenicity at the molecular level, information about the genomes and the corresponding transcriptomes is crucial. We applied next-generation sequencing for the qualitative annotation as well as for the quantitative analysis of the transcriptional landscapes in different *Candida* species that represent the most important fungal pathogens.

#### 15:35 Refreshment Break - Networking with Sponsors

#### 16:15 Sponsored Presentation (Opportunity Available)

#### 16:45 Deep Sequencing as Diagnostic Tool for Highly Pathogenic Viruses

*Aleksandar Radonic, Ph.D., Center for Biological Security, Robert Koch Institute*

Today nucleic acid-based diagnostics has become the gold standard for the identification of viral and bacterial pathogens in clinical as well as in environmental samples. Because of their pronounced specificity, PCR based techniques may often fail to detect new or emerging pathogens with differing or so far unknown genetic information. Compared to electron microscopy, with a perfect diagnostic "open view" but serious restrictions regarding the detection limit, recently metagenomic approaches based on massively parallel sequencing techniques have promised to be a more sensitive valuable tool as molecular "catch all" method. Since it is technically possible to gain sequence information of all pathogens present in a particular sample, the most challenging task is to identify the sequences of interest in the bulk of sequence data obtained by only one sequencing run. In this presentation the benefits and drawbacks of next generation sequencing as diagnostic tool will be discussed in comparison to conventional methods of virus detection.

#### 17:15 NGS Strategies for Development of New Markers for Microbial Diagnostics

*Andreas Doetsch, Helmholtz Centre for Infection Research (invited)*

### » PLENARY KEYNOTE SESSION

#### 18:00 Keynote Introduction



#### 18:05 Protein Engineering: Benefitting Therapeutic Proteins and Small Molecule Drugs Alike

*Andreas Plueckthun, Ph.D., Professor, Biochemical Institute, University of Zurich*



#### 18:40 'Systems Patientomics': The Future of Medicine

*Hans Lehrach, Ph.D., Director & Head, Vertebrate Genomics, Max Planck Institute for Molecular Genetics*

Ten years after the completion of the human genome in a ten year international collaboration at a cost of between 1 and 3 billion Dollar, we are now getting ready to be able to sequence genomes/ transcriptomes as part of routine medical practice in oncology. The flagship project IT Future of Medicine would extend this approach to generate integrated anatomical/molecular models of every patient in the healthcare system, as the basis for a data rich, computation intensive, individualized medicine of the future.

#### 19:15 – 21:00 CHI Networking Dinner Reception

## THURSDAY, 13 OCTOBER

### SEQUENCING FOR CANCER

#### 9:30 Chairperson's Opening Remarks

#### 9:35 Talk Title to Be Announced

*Peter Verhasselt, Principal Scientist, Translational Genomics and Genetics, Janssen Pharmaceutical Companies of Johnson & Johnson*

#### 10:05 Next-Generation Sequencing for Elucidating the Cancer Methylome - Promises and Problems

*Ulrich Lehmann, Ph.D., Professor, Molecular Pathology, Hannover Medical School*

Cancer is not only a genetic disease but also caused by epigenetic aberrations. Next-generation sequencing promises to solve the challenge of high resolution, quantitative, and genome-wide studies of the cancer cell methylome. In this talk results from our own work concerning the quantitative nature of next generation sequencing data will be presented. In addition, promises and problems in the field of next-generation epigenomics will be discussed.

## 10:35 Coffee Break - Networking with Sponsors

### 11:00 Understanding Diseases and Pathways through NGS Data Analysis

Frank Schacherer, Ph.D., COO/CSO, BIOBASE GmbH

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THE DNA NETWORK

Next-Generation Sequencing enables us to take a closer look at the mutations causing inherited disease and cancer than ever before. This talk will take you through successful strategies to identify the novel mutations that may be responsible. You will learn to identify known effects, how to assess the potential effect of novel mutations in pedigree studies and in large scale case/control studies, and how to filter out irrelevant mutations.

### 11:30 mRNA-Sequencing of Breast Cancer Subtypes

Rachael Natrajan, Ph.D., Postdoctoral Fellow, Molecular Pathology, Breakthrough Breast Cancer Centre

Breast cancer is a heterogeneous disease comprised of a number of distinct entities. We have used massively parallel mRNA-sequencing to analyze the transcriptome of distinct subtypes of breast cancer with the aim of identifying novel fusion genes that may play a role in the development of breast cancer.

## » 12:00 KEYNOTE PRESENTATION



### Next Generation Sequencing Assessment of Intra-Tumour Heterogeneity

Charles Swanton, Ph.D., Translational Cancer Therapeutics Laboratory, Cancer Research UK London Research Institute

Next-generation sequencing analysis of solid tumours has revealed remarkable variation in somatic aberrations across cancers of the same histopathological subtype. However, less is known regarding intra-tumoural variation of somatic mutations across different sectors of the same tumour. In this talk results of massively parallel exome sequencing combined with sector ploidy profiling to assess intra-tumour heterogeneity in clear cell renal carcinoma and the potential implications of these data for personalised medicine and biomarker discovery will be discussed.

## 12:30 Lunch for Purchase in Exhibit Hall 9

## 13:45 Dedicated Poster Viewing in Exhibit Hall 9

## REIMBURSEMENT POLICIES AND THE FUTURE OF PERSONALIZED MEDICINE IN EUROPE

### 14:30 Sponsored Presentation (Opportunity Available)

### 15:00 Overview of EU Reimbursement Policies

Moderator: Amy M. Miller, Ph.D., Public Policy Director, Personalized Medicine Coalition

### 15:10 Personalized Medicine Coalition Report on EU Reimbursement Policies and Future Trends

Susan Garfield, Dr.PH., Vice President, Bridgehead International

The Personalized Medicine Coalition has recently released a comprehensive review of the European reimbursement systems and how each impacts the availability of personalized medicine diagnostics. Details from this report will be presented, including considerations for how each country's system will evolve from both an HTA, evaluation and pricing perspective. The presentation will include case studies to provide real world examples of key issues discussed.

### 15:30 Stakeholder Panel: Pharma and Diagnostic Stakeholders Discuss How Reimbursement Impacts Commercialization of New Targeted Therapies

Representatives from pharma and diagnostics companies will explain their company's approach to developing targeted therapies in Europe and how to balance the requirements, goals and development timeline of the therapeutic and diagnostic. The discussion will include a review of evidence development planning, internal team alignment, and interaction with payer/HTA stakeholders.

Panelists:

Allen Crook, Vice President, Pfizer

Juliette Plun-Favreau, Director, Reimbursement & Market, Genomic Health

## 16:10 Refreshment Break - Networking with Sponsors

### 16:30 Payer Panel: Market Access Decision-Makers From Key European Countries Will Explain Their Role in Evaluating Novel Personalized Medicine Diagnostics, Evolving Systems for HTA and Coverage, and the Opportunities for Value Based Pricing

Panelists will cover key developments in HTA from IQWiG and NICE's Diagnostic Assessment Committee, payer attitudes towards personalized medicine and the role of diagnostics, and changing paradigms for coverage and payment.

Panelists:

Stefan Sauerland, M.D., M.P.H., Head, Department of Non-Drug Interventions, Institute for Quality and Efficiency in Healthcare (IQWiG)

## 17:00 Response from EU to Country and Country Initiatives to Further the Adoption of Personalized Medicine Technologies

While coverage and reimbursement decisions occur at the country level in Europe, the European Union has many initiatives underway to support technology innovation and adoption. The response from the European perspective will provide a review of how companies, payers, government agencies, and advocates can work together to optimize access to personalized medicine technologies with the ultimate goal of improving the health of Europeans.

## 17:30 Close of Conference

# Hotel & Travel

## CONFERENCE VENUE

Hannover Exhibition Grounds  
Deutsche Messe  
Messegelände  
30521 Hannover  
GERMANY

## HOTEL ACCOMMODATIONS

Molecular Diagnostics Europe has partnered with BIOTECHNICA, who has teamed up with numerous hotels so you can choose where you would like to stay within your budgeted price range for our upcoming conference.

Please go to the following website for general visitor information and to make a hotel reservation: [www.biotechnica.de/visitorservice](http://www.biotechnica.de/visitorservice)

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# Sponsorship & Exhibits

Whether you are ready to present an exciting new technology, preparing for a new product launch, or need feedback on a specific idea, Molecular Diagnostics Summit Europe offers the perfect platform for you to present to a high-level, targeted audience. Sponsors and exhibitors will also have the opportunity to participate in various networking events, which are an excellent opportunity to network with your customers and prospects.

## SPONSORSHIP OPPORTUNITIES:

### Presentations on the Main Agenda

There are a limited number of opportunities for sponsors to present on the main conference program for 15 or 30 minutes. The packages include a talk, branding, use of the pre- and post-show attendee lists, literature distribution and multiple full conference passes. This sponsorship package also includes a turn-key exhibit package outside of the conference session rooms, where you will have direct access to your target audience during breaks.

#### NEW FOR 2011

Sponsorship opportunities will include 1 turn-key exhibit package in close proximity to the session rooms in the Convention Center. The exhibit is 2 meters on the aisle with 1 meter of depth. (approx. 6' x 3')

#### PACKAGE INCLUDES:

- Electricity
- Internet access
- Graphic display area
- High table and stools
- Literature display, and storage area

(Please note: this exhibit space is pre-fabricated and you will not need to ship your booth to the conference)

#### SESSION CHAIR

An executive from your company will chair a session (a group of talks) on the main conference program. This opportunity is exclusive and includes a brief introduction to the session and the individual speakers.

## Exhibitor Information

Exhibitors at Molecular Diagnostics Summit Europe will enjoy facilitated networking opportunities with more than 300 high-level decision-makers. Speak face-to-face with prospective clients and showcase your latest product, service or solution. The Biotechnica exhibit hall will host 13,000 attendees over the course of the event. Co-location with Biotechnica will allow you to exhibit as part of the larger event while also meeting with the delegates attending Molecular Diagnostics Europe.

### For more information on sponsorship and exhibit opportunities, please contact:

Jon Stroup  
Manager, Business Development  
+1 781-972-5483  
[jstroup@healthtech.com](mailto:jstroup@healthtech.com)

# Pricing and Registration Information

## SHORT COURSES

	Commercial	Academic, Government, Hospital-Affiliated	Student
1 Short Course	€625	€375	€125
2 Short Courses	€895	€625	€195

10 OCTOBER	10:00-13:00	10 OCTOBER	14:00-17:00
SC5: Micro- and Nanofluidics in Diagnostics		SC12: Novel Developments In Immunoassays For Diagnostics	

## EVENT PRICING - BEST VALUE

*(Includes access to two conferences, excludes short courses)*

	Commercial	Academic, Government, Hospital-Affiliated	Student
Advance Registration Discount until 16 September	€1995	€945	€495
Registrations after 16 September, and on-site	€2145	€995	

## INDIVIDUAL CONFERENCE PRICING

*(Includes access to one conference, excludes short courses)*

	Commercial	Academic, Government, Hospital-Affiliated	Student
Advance Registration Discount until 16 September	€1395	€695	€345
Registrations after 16 September, and on-site	€1545	€755	

11-12 OCTOBER	12-13 OCTOBER
Molecular Diagnostics for Cancer	Molecular Diagnostics for Infectious Disease
Convergence of Technologies for Point-of-Care Diagnostics	NGS: Molecular Diagnostics Magnified

**COMPLIMENTARY BIOTECHNICA EVENT:** Tuesday, 11 October: BioTechnica Night - Keynote and Reception.

## CONFERENCE DISCOUNTS

### Poster Submission-Discount (€45 Off)

Poster abstracts are due by 9 September, 2011. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, or by 2:00 pm EDT on 12 September, 2011, please email a text-only Word file of your submission to [jring@healthtech.com](mailto:jring@healthtech.com)

\* CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

\*\* Posters will be limited to one poster per person. Special poster dimensions apply.

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Each registration includes all conference sessions, posters and exhibits, food functions, and a access to the conference proceedings link.

**Handicapped Equal Access:** In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

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Video and or audio recording of any kind is prohibited onsite at all CHI events.

If you are unable to attend but would like to purchase the Molecular Diagnostics Summit Europe conference CD for €600 (plus shipping), please visit [MolecularDiagnosticsEU.com](http://MolecularDiagnosticsEU.com). Massachusetts delivery will include sales tax.

## How to Register: [MolecularDiagnosticsEU.com](http://MolecularDiagnosticsEU.com)

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