

6-9 May 2019 | Lisbon, Portugal | Lisbon Marriott Hotel

7<sup>th</sup> International

# Molecular Diagnostics EUROPE

**SAVE UP TO €200!**  
Register by 3 May



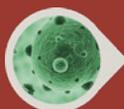
## CONFERENCE PROGRAMS

6 MAY

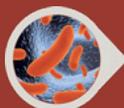


Advances in  
Prenatal Molecular  
Diagnostics

7-8 MAY



Biomarkers for  
Immunotherapy



Advanced  
Diagnostics for  
Infectious Disease



Enabling Technologies  
for Circulating  
Biomarkers

8-9 MAY



Companion  
Diagnostics for  
Immuno-Oncology



Point-of-Care  
Diagnostics



Clinical Application  
of Circulating  
Biomarkers

### PLENARY KEYNOTE PRESENTATIONS



#### Precision Diagnostics in Oncology: Expanding Roles of Liquid Biopsies

Nitzan Rosenfeld, PhD, Senior Group Leader,  
Cancer Research UK Cambridge Institute, University  
of Cambridge; CSO, Inivata Ltd., United Kingdom



#### Legal and Regulatory Developments in Precision Medicine and Diagnostic Devices

Erik Vollebregt, Partner, Axon Lawyers,  
The Netherlands

### PLENARY PANEL DISCUSSION

#### Challenges and Opportunities in European Diagnostic Investments

**Moderator:** Philippe Peltier, Partner, Kurma Partners, France  
**Panelists:** Florian Kainzinger, PhD, Managing Partner,  
Founder, Think.Health Ventures, Germany  
Seppo Mäkinen, Partner, Pathena Investments

Premier Sponsors:



MolecularDxEurope.com

# Sponsor Opportunities

**COMPREHENSIVE SPONSORSHIP** packages allow you to achieve your objectives before, during, and long after the event. Signing on earlier will allow you to maximize exposure to hard-to-reach decision-makers.

## PODIUM PRESENTATIONS

Available Within the Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, lunch, or separate from the main agenda within a pre-conference workshop. Package includes exhibit space, onsite branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly, so sign on early to secure your talk!

## ONE-ON-ONE MEETINGS

Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

## INVITATION-ONLY VIP DINNER/ HOSPITALITY SUITE

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor's objectives. (i.e.: purely social, focus group, reception style, plated dinner with specific conversation focus).

## EXHIBIT

Exhibitors will enjoy facilitated networking opportunities with qualified delegates. Speak face-to-face with prospectus clients and showcase your latest product, service, or solution.

## ADDITIONAL BRANDING & PROMOTIONAL OPPORTUNITIES INCLUDE:

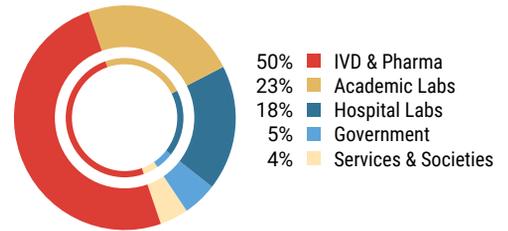
- Conference Tote Bags
- Literature Distribution  
*(Tote Bag Insert or Chair Drop)*
- Badge Lanyards
- Padfolios
- Program Guide Advertisement
- Meter Boards
- Water Bottles

## LOOKING FOR ADDITIONAL WAYS TO DRIVE LEADS TO YOUR SALES TEAM?

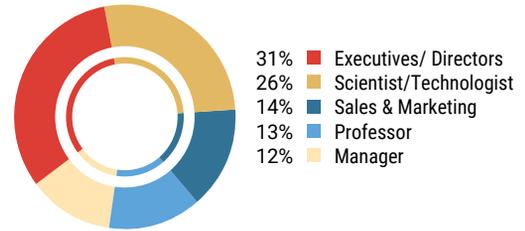
CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Live Webinars
- White Papers
- Market Surveys
- Podcasts and More!

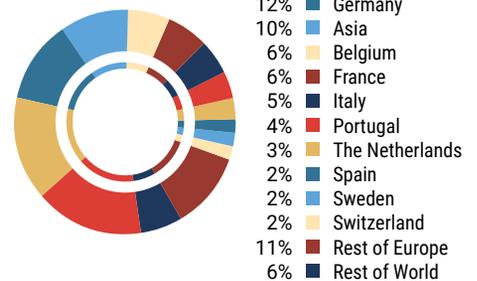
### COMPANY TYPE



### DELEGATE TITLE



### LOCATION



### For more information, please contact:

#### COMPANIES A-K

##### Jon Stroup

*Sr. Manager, Business Development*  
781-972-5483  
jstroup@healthtech.com

#### COMPANIES L-Z

##### Ashley Harvey

*Manager, Business Development*  
781-972-6292  
aharvey@cambridgeinnovationinstitute.com

## Current Sponsors & Exhibitors (As of December 19, 2018)

- AccuRef
- Applied Microarrays
- Askion
- Bio-Rad Lab
- BlueBee

- Boston Healthcare Associates, Inc.
- Chroma Technology Corp.
- Hahn-Schickard
- Invivoscribe
- MeMed

- MilliporeSigma
- Molecular Machines
- NeoGenomics
- Sagentia
- SeraCare Life Sciences, Inc.

- Stilla Technologies
- STRATEC Molecular GmbH
- Streck
- Volition Rx

#### Premier Sponsors:



#### Corporate Sponsors:



#### Corporate Support Sponsors:





## Advances in Prenatal Molecular Diagnostics

Trends, Advances and Prospects

8:00 Registration Open and Morning Coffee

MONDAY 6 May

### IMPLEMENTATION AND INTERPRETATION OF ADVANCED PRENATAL DIAGNOSTICS

#### 8:55 Chairperson's Remarks

Patrizia Paterlini-Brechot, PhD, MD, Cellular & Molecular Biology, University Paris Descartes, France

#### 9:00 Termination of Pregnancy Following a Prenatal Diagnosis of Down Syndrome: A Qualitative Study of the Decision-Making Process of Pregnant Couples

Stina Lou, PhD, Senior Researcher, Center for Fetal Diagnostics, Aarhus University Hospital, Denmark

In Denmark, when Down syndrome (DS) is prenatally diagnosed, termination rates are high (>95%). Based on semi-structured interviews with 21 couples, who had recently terminated due to DS, we found that the decision to terminate in case of DS was often made before pregnancy. The couples felt grief following the diagnosis, and the termination was considered right but burdensome. None had felt pressure to terminate from doctors or social network.

#### 9:30 Shifting from Genome Wide SNP-Based Array Analysis to Whole Exome Sequencing in Prenatal Diagnosis

Nicole de Leeuw, PhD, Clinical Laboratory Geneticist, Theme Leader Intellectual Disability & Congenital Anomalies, Human Genetics, Radboud University Medical Center, The Netherlands

Genome wide high-resolution SNP-based array analysis is routinely used in our laboratory for the detection of copy number variations (CNVs) in foetal DNA in case of structural ultrasound anomalies, but since January 2017 a growing number of prenatal whole exome sequencing trio analyses are being performed, because of the higher diagnostic yield. Our experiences and strategies will be presented, including some of the challenges encountered in daily laboratory practice.

#### 10:00 Clinical Implementation of Prenatal Exome Sequencing for Fetal Structural Abnormalities: Benefits, Challenges, and Guidance Needed

Rhiannon Mellis, MBBS, MSc, MRCPCH, Clinical Research Fellow, Genetics, NE Thames Regional Genetics Service, Great Ormond Street Hospital, United Kingdom

Since 2016 our regional genetics laboratory has offered rapid fetal exome sequencing on a research basis, and it will soon be introduced into NHS standard care. I will present our experience, discussing clinical utility, outcomes and the clinical challenges of case selection, fetal phenotyping, variant interpretation and counselling as we move towards clinical implementation.

10:30 Coffee Break

### CELL-BASED NIPT

#### 11:00 Technical Insights into Next-Generation Sequencing Analysis of DNA from Circulating Trophoblastic Cells

Patrizia Paterlini-Brechot, PhD, MD, Cellular & Molecular Biology, University Paris Descartes, France

Isolation of rare trophoblastic cells from blood is a technical challenge with impact on the number of collected fetal cells and on the quality of their DNA. By using the ISET (Isolation by Size of Tumor/Trophoblastic cells) system, we have developed protocols for isolation of fixed and live circulating trophoblastic cells, cell-free DNA collection allowing scalable NGS analysis of circulating fetal cells and cfDNA. We show the results and technical challenges and discuss the potential clinical impact or non-invasive prenatal diagnosis.

#### 11:30 Fetal Cells in Maternal Blood for Prenatal Diagnosis – From R&D to Clinic

Ripudaman Singh, PhD, MBA, CTO, ARCEdi Biotech Aps, Denmark

Technological advances in enrichment, manipulation and analyses of rare fetal cells from maternal blood have been made in the last 5 years. For the

last 11 years, we have tried to answer some critical questions pertaining to fetal cells and their use in prenatal diagnosis. After developing a robust technology which is both scalable and cost effective, ARCEdi Biotech, in collaboration with Aarhus University Hospital, has launched the first ever cell-based NIPT in Denmark, covering approximately 17,000 pregnancies per year. Results from that clinical launch will be presented and discussed.

12:00 Sponsored Presentation (Opportunity Available)

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

13:00 Session Break

### CELL-FREE DNA SCREENING

#### 13:25 Chairperson's Remarks

Hamutal Meiri, PhD, MBA, Chairman, ASPRE Consortium; CEO, TeleMarpe, Israel

#### 13:30 Noninvasive Detection of Aneuploidy by Cell-Free DNA in Early and Recurrent Pregnancy Loss

Yaron Yuval, MD, Director, Prenatal Genetic Diagnostic Unit, Tel Aviv Sourasky Medical Center, Israel

Early pregnancy loss is caused by numerical chromosomal aberrations in >50% of cases. Chromosomal analysis of the products of conception has been shown to be cost-saving if used to guide further workup. In our study, we demonstrate that maternal serum cell-free DNA-based testing can achieve a high degree of accuracy (78%-85%) which is higher than that of routine cytogenetic analysis. We suggest that cfDNA-based testing for early pregnancy loss serve as the first-tier test for assessment of early pregnancy loss.

#### 14:00 Confined Placental and Fetal Mosaicism: Prevalence, Outcome and Impact on Non-Invasive Prenatal Testing Results

Ida Charlotte Bay Lund, MD, Clinical Genetics, Center for Fetal Diagnostics, Aarhus University Hospital, Denmark

Mosaicism in CVS can be divided into: 1) whole chromosome mosaicism, and 2) copy number variants (CNV) mosaicism. The risk of true fetal mosaicism is the same for whole chromosome and CNV mosaicism. The detection of mosaicism using Non-Invasive Prenatal Testing (NIPT) depends on level of mosaicism and pregnancies which need follow-up can be missed by NIPT.

#### 14:30 Clinical Implementation of Non-Invasive Prenatal Diagnosis (NIPT) for Single Gene Disorders

Natalie Chandler, FRCPath, PhD, Senior Clinical Scientist, NE Thames Regional Genetics Laboratory, Great Ormond Street Hospital, United Kingdom

I will present our experience with a variety of technologies that our accredited laboratory utilises for non-invasive prenatal diagnosis of single gene disorders. I will discuss the limitations of each method and the challenges faced in developing these services in a clinical laboratory.

15:00 Refreshment Break

### BIOMARKERS FOR PREECLAMPSIA AND PRETERM BIRTH

#### 15:30 Molecular Approach for a Personalized Diagnosis of Preeclampsia with an Attempt for an *in vitro* Prevention Model by DNA Editing with CRISPR/Cas 9

Hamutal Meiri, PhD, MBA, Chairman, ASPRE Consortium; CEO, TeleMarpe, Israel

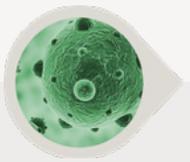
ASPRE is a multicenter study to predict the risk and prevent it by aspirin. PP13 is a placental protein that supports blood supply to the pregnancy and turns mothers immune tolerant to the fetus. Low PP13 expression by mutations are associated with high risk to preeclampsia. Polypeptide replenishment or gene editing may cure preeclampsia. Could future PGD and implantation be a path to cure preeclampsia?

#### 16:30 The Challenge of Identifying Very Early Biomarkers of Preeclampsia

Daniel Vairan, PhD, Research Director; Development, Reproduction, Cancer; INSERM, France

Preeclampsia is one of the most frequent disease of pregnancy, characterized classically by hypertension and proteinuria. Preeclampsia can be relatively efficiently taken care of, using low doses of aspirin, when the drug is administered before the 16th week of pregnancy when the disease is asymptomatic. Amongst the accessible biomarkers are plasmatic molecules, as well as ultrasound parameter potentially able to detect by Doppler analysis placental vascularization defects.

17:00 Close of Symposium



# Biomarkers for Immunotherapy

## Predictive and Prognostic Biomarker Discovery for Successful Therapy

**RECOMMENDED SHORT COURSE\*** MONDAY 6 MAY | 13:30 - 17:00

**SC2: Biomarkers in Liquid Biopsy: CTCs, ctDNA and Exosomes**

Lorena Diéguez, PhD, Group Leader, Department of Life Sciences, Nano4Health Unit, Medical Devices Research Group, International Iberian Nanotechnology Laboratory, Portugal

Roberto Piñero Cid, PhD, Cancer Modeling Lab, Instituto de Investigación Sanitaria de Santiago de Compostela- Roche-Chus Joint Unit, Spain

\*Separate registration required, see page 7 for details.

## TUESDAY 7 MAY

**08:00 Registration and Morning Coffee**

### IMMUNE HETEROGENEITY

**08:55 Organizer's Opening Remarks**

Ngoc 'Emily' Le, PhD, Conference Producer, Cambridge Healthtech Institute, United States

**09:00 Chairperson's Remarks**

Ed Schuurin, PhD, Professor & Head, Molecular Pathology, University Medical Center Groningen, The Netherlands

**09:05 Immune Contexture Heterogeneity and Clinical Impact**

Jérôme Galon, Director, Integrative Cancer Immunology Laboratory, Cordeliers Research Center, Research INSERM (French NIH) (first class, DR1), France  
We developed and validated worldwide a standardized digital-pathology-based immune assay, "Immunoscore", with prognostic power superior to the currently used cancer staging-system. Immunoscore and immunoediting were demonstrated to affect metastatic dissemination in humans. The newly-proposed "parallel immune selection model" of tumor evolution incorporates the effects of the immune system in shaping metastatic spread. The impact of the immune contexture on predicting response to immunotherapy, including CAR-T cells, will also be discussed.

**09:35 The 10,000 Immunomes Project: Building a Resource for Human Immunology**

Sanchita Bhattacharya, PhD, Bioinformatics Project Scientist, Bakar Computational Health Sciences Institute, University of California San Francisco, United States

One of the major barriers for understanding human immunological mechanisms is that immune assays have not been reproducibly characterized for a sufficiently large and diverse healthy human cohort. Here, we present the 10,000 Immunomes Project (10KIP), a framework for growing a diverse human immunology reference, from ImmPort, a publicly available resource of subject-level immunology data.

**10:05 Comparing Immune Cell Populations and Novel Biomarkers in Subtypes of NSCLC**

Anna Juncker-Jensen, PhD, Medical Science Liaison, NeoGenomics Laboratories, USA

Sponsored by



**10:35 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing**

### TUMOR MUTATIONAL BURDEN AND MICROSATELLITE INSTABILITY

**11:15 Chairperson's Remarks**

Ed Schuurin, PhD, Professor & Head, Molecular Pathology, University Medical Center Groningen, The Netherlands



**11:15 KEYNOTE PRESENTATION: Development of a TMB Assay and the Challenges of Harmonizing across Products**

Michael Doherty, Senior Vice President, Head of Product Development, Foundation Medicine, United States

A novel, technically robust, blood-based assay to measure TMB in plasma (bTMB) that is distinct from tissue-based approaches will be described. Using a retrospective analysis of two large randomized trials as test and validation studies, we show that bTMB reproducibly identifies patients who derive clinically significant improvements in progression-free survival from atezolizumab (an anti-PD-L1) in second-line and higher NSCLC. Our data show that high bTMB is a clinically actionable biomarker for atezolizumab in NSCLC. Challenges and efforts to harmonize across products will also be discussed.

**11:45 Measuring Tumor Mutational Burden (TMB) by Gene Panels: A Primer**

Albrecht Stenzinger, MD, Full Professor, Molecular Tumor Pathology; Head, Center for Molecular Pathology (CMP); Head, Section for Biomarker Development and Molecular Diagnostics, Institute of Pathology Heidelberg (IPH), University Hospital Heidelberg, Germany

In this work, we provide an overview of the clinical implications of TMB testing and highlight key parameters including pre-analysis, analysis and post-analytical steps that influence and shape TMB approximation by panel sequencing. Collectively, the data will not only serve as a field guide and state of the art knowledge source for molecular pathologists who consider implementation of TMB measurement in their lab, but also enable clinicians in understanding the specific parameters influencing TMB test results and reporting.

**12:15 Expression of Endogenous Retrovirus as a Potential Biomarker of Response to Immune Checkpoint Therapy in Low Mutation Burden Cancers**

Shridar Ganesan, MD, PhD, Chief, Molecular Oncology; Associate Director, Translational Research; Omar Boraie Chair, Genomic Science, Rutgers University, United States

To better understand response of low mutation burden cancers to ICB, we investigated the expression of endogenous retroviruses (ERVs) and their association with markers of immune infiltration and immune checkpoint activation. Endogenous retroviruses are normally not expressed in most somatic tissues, but abnormal expression has been reported in multiple cancer types. Expression of certain classes of ERV was associated with markers of immune activation in several tumor classes, but most strikingly in clear cell renal cancer. ERV expression was associated with evidence of chromatin abnormalities, and with increased response to immune checkpoint blockade in ccRCC. These observations suggest that ERV expression may be novel biomarker of response to ICB in certain cancers including ccRCC.

**12:45 Enjoy Lunch on Your Own**

**13:45 Session Break**

### PREDICTIVE BIOMARKERS AND IMMUNOPROFILING

**14:15 Chairperson's Remarks**

Shridar Ganesan, MD, PhD, Chief, Molecular Oncology; Associate Director, Translational Research; Omar Boraie Chair, Genomic Science, Rutgers University, United States



#### 14:20 Circulating Tumor DNA as a Molecular Bloodborne-Based Biomarker to Predict Tumor Response in Lung Cancer Patients Treated with Immunotherapy

Ed Schuurin, PhD, Professor & Head, Molecular Pathology, University Medical Center Groningen, The Netherlands

A significant minority of patients treated with immune checkpoint inhibitors shows durable responses but no adequate biomarkers are available for predicting which patients will benefit. Immunotherapy is expensive and potentially toxic. Tumor response is monitored by tumor volume using CT scanning. The aim of our study is to assess plasma levels of non-targetable tumor-specific mutations as molecular biomarkers and monitoring tool for durable responses to immunotherapy in advanced NSCLC.

#### 14:50 Tumor Immunoprofiling: Novel Tissue-Based Biomarkers in Cancer Immunotherapy

Nicolas A. Giraldo-Castillo, MD, PhD, Pathology Resident, Johns Hopkins University School of Medicine, United States

Therapeutic blockade of the PD-1/PD-L1 checkpoint has been embraced as a strategy to enhance antitumor T-cell immunity, with durable efficacy in multiple tumor types. The best-studied biomarker to predict response to these agents is PD-L1 protein expression, measured by immunohistochemistry and graded "positive" or "negative." Using digital pathology-assisted methods, our laboratory has found that quantitative assessments of PD-1+ and PD-L1+ cell densities, as well as geographic interactions between these two cell populations, correlate with clinical response to anti-PD-1 therapy in Merkel cell carcinoma, melanoma, and renal cell carcinoma and is superior to binomial scoring systems.

#### 15:20 Implementing Immunosequencing as New Molecular Biomarkers of Response to Immunotherapy

Catherine Sanders, PhD, Senior Director, Research and Business Development, Adaptive Biotechnologies, USA

Adaptive Biotechnologies' immunosequencing technology combines bias-controlled multiplex PCR, high-throughput sequencing, and sophisticated bioinformatics. In solid tumors, the immunoSEQ Assay accurately quantifies TIL density and clonality, with preclinical and clinical applications to inform repertoire changes in response to single agent or combination therapies that have potential prognostic and predictive value.

Sponsored by  
**Adaptive**  
biotechnologies

#### 15:50 Immunophenotyping and Functional Assays for Predictive Marker Discovery

Junxia Wang, PhD, Director, Analytical Development, Mustang Bio, Inc., United States

The discovery and development of predictive for CAR T cells have unique challenges as compared to conventional drugs as the clinical outcome is largely dependent on a viable cellular drug. To overcome the challenges, we have implemented an integrated clinical and CMC biomarker strategy to extend our biomarker study for CAR T cells to include the characterization of the cells prior to engineering and the final product at the site of manufacturing facility. To this purpose, a series of immunophenotyping and functional assays have been developed for the discovery of predictive markers of treatment efficacy and toxicity.

#### 15:50 Culturing a Change: How Can We Leverage CTCs into Meaningful Tools in Biomarker Development?

Elad Katz PhD, Lead Biologist, School of Life Sciences, University of Dundee, Scotland, United Kingdom

The talk will discuss the state of the art in utilisation of live CTCs in the clinical space and how this could be shifted into preclinical use in biomarker development.

#### 16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

#### 17:00 Breakout Discussions

See website for details.

#### 18:00 Welcome Reception in the Exhibit Hall with Poster Viewing

#### 19:00 Close of Day

### WEDNESDAY 8 MAY

#### 08:00 Registration and Morning Coffee

## PATIENT STRATIFICATION AND EARLIER INTERVENTION

#### 09:00 Chairperson's Remarks

Christopher M. Hartshorn, PhD, Program Director, NIH NCI, United States

#### 09:05 Current Initiatives and Research Efforts at the National Cancer Institute Dedicated to Cancer Immunotherapy

Christopher M. Hartshorn, PhD, Program Director, NIH NCI, United States

The US National Cancer Institute (NCI) of the National Institutes of Health has played an integral role in the research and funding of cancer immunotherapies over the last several decades. As the core understanding as to the interface between cancer biology and immunological response have evolved, so has the NCI's conceptual vision of this unique therapeutic modality and the needs of the field. This talk will focus on the most recent and relevant efforts focused at developing markers and tools for patient stratification, deciphering the complex nature of responders vs non-responders, and earlier intervention after dosing.

#### 09:35 Interpretation and Validation of Longitudinal Serum Tumor Biomarker Changes for Early Prediction of Immunotherapy Non-Responsiveness

Huub H. van Rossum, PhD, EuSpLM, Specialist, Laboratory Medicine and Clinical Chemistry, Laboratory Medicine, The Netherlands Cancer Institute, The Netherlands

For NSCLC, only a modest number of patients treated with immune checkpoint inhibitors will respond to this treatment. Serum tumor biomarkers may be of value and alert the clinician of possible treatment failure. The Re-marker platform was developed to support basal longitudinal biomarker investigations including BREc-plot generation and the diagnostic validation of biomarker-response based tests. Using this tool, biomarker response-based tests could be designed that accurately predict non-responsiveness to immunotherapy.

#### 10:05 Predicting Immunotherapy Response and Toxicity in Melanoma

Helen Rizos, PhD, Head, Biomedical Sciences, Faculty of Medicine and Health Sciences, Macquarie University, Australia

There is an urgent need to identify biomarkers that accurately predict for treatment response, and guide the selection of novel combination therapies for patients who acquire resistance. There is also a requirement to accurately predict whether response will be associated with significant adverse events. In this presentation, the utility of circulating biomarkers as predictive and prognostic markers in melanoma, including circulating cytokines, exosomes and circulating tumour DNA, will be discussed.

#### 10:35 Highly-Characterized TMB Reference Standards to Standardize and Harmonize TMB Measurements

Dan Brudzewsky, Field Application Scientist, Clinical Genomics, SeraCare Life Sciences, USA

Sponsored by  
**sera**care

Tumor mutational burden (TMB) is a pan-cancer biomarker for assessing immuno-oncology drug response. SeraCare is collaborating with FOCCR and IQN-Path to develop TMB reference standards with confirmed mutational burden to standardize and harmonize TMB measurements. We describe the characterization of a panel of gDNA and FFPE-based TMB reference materials by WES.

#### 11:05 Coffee Break in the Exhibit Hall with Poster Viewing

### PLENARY SESSION



#### 11:35 Moderator's Remarks

Charlotte Ryckman, Associate, Covington & Burling LLP, Belgium



### 11:45 Precision Diagnostics in Oncology: Expanding Roles of Liquid Biopsies

*Nitzan Rosenfeld, PhD, Senior Group Leader, Cancer Research UK Cambridge Institute, University of Cambridge; CSO, Inivata Ltd., United Kingdom*

Effective clinical management relies on accurate diagnostic information, which requires effective techniques and the right samples. Next generation sequencing can provide a wealth of information, but implementing innovative technologies into clinical routine can be a challenge. We'll examine how analysis of cell-free DNA can provide an opportunity to re-examine many of the current clinical decision points, and a test case for adoption of new diagnostic tools.



### 12:15 Legal and Regulatory Developments in Precision Medicine and Diagnostic Devices

*Erik Vollebregt, Partner, Axon Lawyers, The Netherlands*

- What changes will be brought about by the IVDR?
- What is the impact of the GDPR in the field of precision medicine and diagnostic devices?
- What are the practical implications of implementation of new European regulations?
- What are the consequences of the interplay of the IVDR and the GDPR?

### 12:45 PANEL DISCUSSION: Challenges and Opportunities in European Diagnostic Investments



*Moderator: Philippe Peltier, Partner, Kurma Partners, France*

*Panelists: Florian Kainzinger, PhD, Managing Partner, Founder, Think. Health Ventures, Germany*

*Seppo Mäkinen, Partner, Pathena Investments*

- What is different in Europe versus other markets (e.g., US and Israel). How do different European markets compare?
- What has changed in the landscape of European investments over the past few years? What can be improved?
- The role of regulators and governments
- How can start-ups stand out and get attention in the current landscape?

### 13:30 Close of Biomarkers for Immunotherapy



# Companion Diagnostics for Immuno-Oncology

## Accelerating Innovative Therapies to the Clinic

### WEDNESDAY 8 MAY

#### PLENARY SESSION

See page 5 for details.

#### OPENING KEYNOTE SESSION

##### 14:30 Chairperson's Remarks

Charlotte Ryckman, Associate, Covington & Burling LLP, Belgium



##### 14:35 The EU IVD Regulation and CDx: What Will Change?

Charlotte Ryckman, Associate, Covington & Burling LLP, Belgium

Companion diagnostics (CDx) are not expressly regulated in current EU medicines or medical devices legislation, creating uncertainty for both pharmaceutical and diagnostics companies. Key questions relate to regulatory responsibility, and to challenges for validation, including CE-marking requirements for CDx used in medicines clinical trials. The new EU IVD Regulation and guidance that is currently being developed seek to address (some of) these questions. In this presentation, Ms. Ryckman, who is a lawyer at Covington & Burling, will discuss the current uncertainties and the new regime that is being put in place.



##### 15:05 Bring Forward the "Intrinsic" Value of Diagnostic Information and the Drive to Value-Based Procurement

Yves Verboven, Director, Market Access & Economic Policies, MedTech Europe, Belgium



##### 15:35 Scientific-Regulatory Challenges for Co-Development of Drug and CDx during Clinical Trials Up to Clinical Routine

Jörg Engelbergs, PhD, Scientific Expert and Assessor

Biomedicines (Quality, Non-Clinic & Personalized Medicine), Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany  
In opposite to the US in Europe, the legislations for marketing of medicinal products (MP) and predictive biomarker-based diagnostic assays (i.e., companion diagnostics, CDx) are not directly linked, which is challenging for its co-development. The new *in vitro* diagnostic regulation (IVDR) involves for the first time, drug regulators in the CDx review process for CE marking. The presentation will outline from the perspective of drug regulators, the scientific-regulatory challenges for clinical co-development addressing also technical CDx validation aspects (e.g. differences between exploratory assays and assays used for patient stratification) and discusses finally the assurance of diagnostic assay quality during clinical drug-Dx co-development and post-authorization clinical routine testing.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

#### BIOMARKERS FOR COMPANION DIAGNOSTICS

##### 17:00 Chairperson's Remarks

Michael Oellerich, MD, Hon MD, FAACC, FAMM, FFPPath (RCPI), FRCPath, Distinguished Research Professor of Clinical Chemistry, Department of Clinical Pharmacology, George-August-University, University Medical Center Goettingen (Umg), Germany

##### 17:05 Comparative Tumor Mutation Burden Testing for Companion Diagnostics

Edurne Arriola, PhD, Head of Lung Cancer Division, Medical Oncology Department, Hospital del Mar, Spain

Tumor mutational burden (TMB) might represent a useful biomarker to select cancer patients that will benefit from immunotherapy. Currently, many platforms are being validated to assess TMB in solid tumors. However, there is no data about the consistency of results and the clinical validity across the different platforms that are being developed. International efforts are currently ongoing to assess reproducibility and standardization of these techniques.

##### 17:35 Circulating Cell-Free DNA – Diagnostic and Prognostic Applications in Personalized Cancer Therapy

Michael Oellerich, MD, Hon MD, FAACC, FAMM, FFPPath (RCPI), FRCPath, Distinguished Research Professor of Clinical Chemistry, Department of Clinical Pharmacology, George-August-University, University Medical Center Goettingen (Umg), Germany

High-quality genomic analyses are essential for precision medicine approaches to cancer patient management. Tumor-specific genomic alterations can be identified in cell-free tumor DNA (ctDNA) from patient blood samples and complement biopsies for real-time molecular treatment monitoring, early recurrence detection, resistance tracking, and identification of candidates for targeted therapies. ctDNA allows for the identification of specific mutations selected by treatment, such as EGFR T790M or C797S in NSCLC patients treated with tyrosine kinase inhibitors. ctDNA can also detect mutations such as KRAS G12V in colorectal cancer and BRAF V600E/V600K in melanoma. Chromosomal aberration pattern analysis by low coverage whole genome sequencing is a new broader approach based on genomic instability and can be used to compute a genomic copy number instability (CNI) score. Change in CNI can serve as an early predictor of therapeutic response to chemo/immunotherapy in many cancer types and for prediction of recurrence-free survival.

##### 18:05 Breakout Discussions

See website for details.

##### 19:05 Close of Day

### THURSDAY 9 MAY

08:30 Registration and Morning Coffee

#### PAYING FOR IMMUNOTHERAPY

Co-Organized with



##### 09:00 Chairperson's Remarks

Edward Abrahams, PhD, President, Personalized Medicine Coalition, United States

##### 09:05 Immunotherapy in Europe: A Landscape Analysis

Joachim M. Greuel, PhD, MBA, Managing Director, Bioscience Valuation BSV GmbH, Germany

The recent rejections of Gilead's Yescarta and Novartis' Kymriah CAR-T cancer cell therapies by UK's NICE have spurred debates whether expensive, personalized immunotherapies may achieve reimbursement in Europe. The presentation will review current reimbursement policies in key European countries with particular emphasis on immunotherapies. Furthermore, it will highlight major economic challenges and will suggest concrete measures that may facilitate reimbursement in the future.

##### 09:35 The Innovative Medicines Initiative – A Model for Accelerating Access to Medical Innovation

Pierre Meulien, PhD, Executive Director, Innovative Medicines Initiative, Belgium

The Innovative Medicines Initiative is a large-scale public private R&D partnership between the European Commission on the public side and the European Federation of Pharmaceutical Industries and Associations. With a long-term commitment and a budget of over €5 billion, this partnership seeks to accelerate and make more efficient the medicines development

process. This new way of working changes practices and cultures across the public-private divide ultimately benefitting society.

#### 10:05 Streamlined CDx™ - A Proven Strategy to Accelerate Drug Approvals

Andreia de Albuquerque, PhD, Senior Manager of Strategic Business Development, Business Development, Invivoscribe

Invivoscribe Streamlined CDx™ approach has been shown to collapse the development timelines of biomarker assays, and proven successful in approval of the first ever AML companion diagnostic – The LeukoStrat® CDx FLT3 Mutation Assay, helping accelerate FDA and PMDA approvals of targeted therapies for the most deadly form of leukemia.

#### 10:35 Coffee Break in the Exhibit Hall. Last Chance for Poster Viewing.

#### 11:20 Aligning Value and Payment of Immunotherapy and Companion Diagnostics

Elizabeth Sheppard, MBA, Senior Director, Global Market Access, Roche Tissue Diagnostics, United States

The access plans for immuno-oncology therapies and companion diagnostics have become increasingly complex, mostly due to the misalignment and the lack of a clear definition of “value” for a diagnostic combined with an innovative drug. This program will discuss the companion diagnostic reimbursement variations among funding decision makers and the impact to prioritize cost-based pricing over value-based pricing in contrast to the therapy.

#### 11:50 Companion Diagnostics in Immuno-Oncology: Global Commercial and Partnership Considerations

Joseph Ferrara, CEO, Boston Healthcare Associates, United States

The testing paradigm in immuno-oncology is growing increasingly complex, moving beyond PD-L1, to include mismatch repair, microsatellite instability, tumor mutational burden, and others. The presentation will highlight key commercialization considerations for drug and test innovators, including balancing test access and quality, and embedding CDx global commercial considerations in pharma and diagnostic company partnerships.

#### 12:20 PANEL DISCUSSION: How Will Countries across Europe Pay for Immunotherapy?

Moderator: Edward Abrahams, PhD, President, Personalized Medicine Coalition, United States

Panelists: Joachim M. Greuel, PhD, MBA, Managing Director, Bioscience Valuation BSV GmbH, Germany

Pierre Meulien, PhD, Executive Director, Innovative Medicines Initiative, Belgium  
Elizabeth Sheppard, MBA, Senior Director, Global Market Access, Roche Tissue Diagnostics, United States

#### 12:50 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

#### 13:20 Session Break

Sponsored by



Sponsored by



## EXECUTIVE SESSION: CONSIDERATIONS FOR Rx/Dx DEVELOPMENT IN COMPANION Dx

#### 13:50 Chairperson's Remarks

Michael Roehrl, MD, PhD, Director, Precision Pathology Biobanking Center, Memorial Sloan Kettering Cancer Center, United States



#### 14:00 KEYNOTE PRESENTATION: New Challenges of CDX Development into the Commercial Marketplace

Omar Perez, PhD, Head of Precision Medicine and Diagnostics, GlaxoSmithKline, United States

#### 14:30 Companion Diagnostics in a Not-So-Flat World

Kenneth Emancipator, MD, Executive Medical Director and Head of Companion Diagnostics, Translational Medicine, Merck, United States

This program discusses the challenges of introducing companion diagnostics into the not-so-flat world of the highly regulated, global pharmaceutical industry. The need to market globally almost instantaneously, the complex global regulatory framework, and the variable global delivery models for clinical laboratory services favor the few large, established diagnostic companies. This obviously is a problem for the small, innovative diagnostic company, but it presents challenges for big pharmaceutical companies as well.

#### 15:00 Transforming Pathology in the Immuno-Oncology Space: Precision Pathology in the Theranostics Frontier

Michael Roehrl, MD, PhD, Associate Professor of Pathology and Laboratory Medicine, Weill Cornell Medicine, United States

Precision Health Care puts Pathology as the key theranostic discipline front and center, especially in oncology. We will discuss examples of new approaches for immunomonitoring and cutting-edge theranostic assays in the I-O space, including multiplex imaging, proteomics, and functional assays. We will also discuss how the Precision Pathology Center is instrumental in the next generation of clinical trials in immuno-oncology.

#### 15:30 Strategies for Development of Companion Diagnostics for Immuno-Oncology

Serafino Pantano, PhD, Director, EMEAC Biomarker & Diagnostics Leader, Oncology Global Medical Affairs, MSD International GmbH, Switzerland

This presentation will discuss strategies for development of companion diagnostics in the immuno-oncology space. Successful examples of immuno-oncology companion diagnostics development will be presented and discussed, with a special focus on the CDx clinical validation. Practical aspects that should be considered when designing a CDx development strategy will also be discussed.

#### 16:00 NEW: Close of Conference

## DON'T MISS THE RECOMMENDED SHORT COURSES\* ON MONDAY!

### PRE-CONFERENCE SHORT COURSES\* Monday 6 May | 13:30 – 17:00

#### SC1: Technologies, Applications and Commercialization of Point-of-Care Diagnostics

Instructor: Holger Becker, PhD, Founder & CSO, microfluidic ChipShop GmbH, Germany

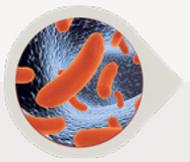
This short course will provide an overview on the technological aspects of POC system developments. It will introduce current technologies such as microfluidics, sensors, paper- and smartphone-based approaches and discuss their trends and limitations. The course will discuss a variety of POC systems in different stages of their development, from early stage to established diagnostic systems in the clinical routine. Market aspects of POC systems as well as practical examples of commercialization for molecular diagnostic, immunological and clinical tests will be presented.

#### SC2: Biomarkers in Liquid Biopsy: CTCs, ctDNA and Exosomes

Instructors: Lorena Diéguez, PhD, Group Leader, Department of Life Sciences, Nano4Health Unit, Medical Devices Research Group, International Iberian Nanotechnology Laboratory, Portugal

Roberto Piñeiro Cid, PhD, Cancer Modeling Lab, Instituto de Investigación Sanitaria de Santiago de Compostela- Roche-Chus Joint Unit  
Biomarkers for early disease detection, therapeutic efficacy monitoring and outcome prediction are the key to precision medicine. Liquid Biopsy studies disease biomarkers in body fluids and can be paramount for precision medicine in cancer. The analysis of biomarkers in peripheral blood improves cancer diagnosis and treatment success. This course will give you a comprehensive overview and update on the established biomarkers, available technologies and clinical applications of liquid biopsy.

\*Separate registration required.



# Advanced Diagnostics for Infectious Disease

## New Frontiers in Infectious Disease Technology

**RECOMMENDED SHORT COURSE\*** MONDAY 6 MAY | 13:30 - 17:00

### SC1: Technologies, Applications and Commercialization of Point-of-Care Diagnostics

Holger Becker, PhD, Founder & CSO, microfluidic  
ChipShop GmbH, Germany

\*Separate registration required, see page 7 for details.

## TUESDAY 7 MAY

08:00 Registration and Morning Coffee

## BIOMARKERS FOR INFECTIOUS DISEASE

### 08:55 Organizer's Opening Remarks

Kaitlyn Barago, Associate Conference Producer, Cambridge Healthtech Institute, United States

### 09:00 Chairperson's Remarks

Adriana Calderaro, MD, PhD, Associate Professor, Clinical Microbiology, Unit of Microbiology and Virology, Department of Medicine and Surgery, University Hospital of Parma, Italy



### 09:05 KEYNOTE PRESENTATION: Development of an Integrated Platform for Biomarker and Drug Target Discovery Using Proteomics

Anthony Whetton, Director, Stoller Biomarker Discovery Centre, University of Manchester, United Kingdom

Proteins are a key set of biomarkers in healthcare. Recent developments in mass spectrometry (MS) provide opportunities to more effectively and systematically derive information on protein levels in biological fluids. The use of the latest innovations in MS-based technologies offers a high capacity throughput proteomic profiling for clinical biochemistry purposes. The time for biomarker discovery, validation, verification and adoption for clinical usage can be reduced for patient benefit.

### 10:05 MeMed BV™: Fast & Accurate Host-Based Dx to Differentiate Bacterial from Viral Infections for Better abx Stewardship

Tanya Gottlieb, PhD, Vice President, Scientific Affairs, MeMed, Israel

MeMed has developed a host-based Dx (MeMed BV™) for distinguishing bacterial from viral infections and applied the test on MeMed Key™, a measurement platform with central lab precision. This new tool provides actionable information to clinicians where and when needed, promoting prudent antibiotic use in the effort to tackle AMR.

10:20 Sponsored Presentation (Opportunity Available)

### 10:35 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

### 11:15 Innovative Tools for the Identification of Infectious Agents

Adriana Calderaro, MD, PhD, Associate Professor, Clinical Microbiology, Unit of Microbiology and Virology, Department of Medicine and Surgery, University Hospital of Parma, Italy

Implementation of novel diagnostic techniques has revolutionized the microbiology laboratory: MALDI-TOF MS and nucleic acid-based assays were extensively evaluated for alternative applications in the diagnostic practice, such as the identification of potential carbapenemase-producing bacterial strains, malaria diagnosis and a syndromic multiplex PCR system for the diagnosis of gastroenteritis and meningitis. These applications have a significant effect on the best clinical management of infectious diseases.

### 11:45 Host Response Gene Expression Signature for the Diagnosis and Prognosis of Acute Infections and Sepsis - From *in silico* Data Analysis to Prospective Clinical Trials

Oliver Liesenfeld, MD, CMO, Inflammatix, United States

Inflammatix develops diagnostic tests by measuring expression levels of host immune genes. Applying proprietary algorithms we identify gene signatures that produce rapid, clinically actionable results for the diagnosis and prognosis of acute infection and sepsis. Validate *in silico* analyses that have been published in top-tier journals are complemented by evidence generation in clinical trials. Inflammatix is working with diagnostic 'platform' partners to launch the HostDx™ Fever and HostDx™ Sepsis tests.

### 12:15 Oral Vaccines and the Intestinal Microbiome, Translating Microbiota Correlations into Improved Vaccine Performance

Vanessa C. Harris, MD, PhD, Assistant Professor, Global Health, University Medical Center, University of Amsterdam, Amsterdam Institute for Global Health and Development, The Netherlands

Oral, live-attenuated rotavirus vaccines demonstrate substantially lower effectiveness in low- and middle-income countries in Africa and Asia, where the burden of rotavirus disease is highest. The intestinal microbiome may explain this gap in vaccine effectiveness and this talk outlines how field studies, murine studies, and proof-of-concept trials can provide a multi-disciplinary evidence base for employing microbiome-based interventions to improve rotavirus vaccine immunogenicity.

### 12:45 Exploiting Bacteriophages as a Novel Diagnosis for Bacterial Infections: A Case Study of Lyme Disease and Its Co-Infection with Bartonellosis and Relapsing Fever

Jinyu Shan, PhD, Research Fellow, University of Leicester; CSO, Phelix Research and Development

Lyme disease (LD) is caused by the bacteria *Borrelia burgdorferi sensu lato* (s.l.) and transmitted to humans through the bite of infected ticks. Bartonellosis is arguably the most common co-infection that occurs with LD. We have developed a RT-PCR assay targeting bacteriophages carried by Lyme *Borrelia* strains and shown experimentally on patient samples that this bacteriophage-based RT-PCR was six times as sensitive as the standard Lyme serological test. Ongoing research focus on developing the RT-PCRs targeting *Bartonella* and *RF Borrelia* species. This project provides a highly sensitive multiplex RT-PCR and resolve the current dilemma in diagnosis of LD and co-infections in the long term.

### 13:15 LUNCHEON PRESENTATION: Researchers: The New Drivers of Innovation

Savita Bagga, In Vitro Diagnostics Segment, Marketing Manager, MilliporeSigma

Collaborate together: Explore how we connect researchers from internal and external teams to present and exchange challenges and perspectives on IVD development. With more understanding of customer needs, our R&D teams can offer better customized solutions for the IVD industry's specific needs and therefore accelerate the path to commercialization.

### 13:45 Session Break

### 14:15 PANEL DISCUSSION: Host and Pathogen Derived Biomarkers

Moderator: Tanya Gottlieb, PhD, Vice President, Scientific Affairs, MeMed, Israel

Panelists: Adriana Calderaro, MD, PhD, Associate Professor, Clinical Microbiology, Unit of Microbiology and Virology, Department of Medicine and Surgery, University Hospital of Parma, Italy

Oliver Liesenfeld, MD, CMO, Inflammatix, United States

Vanessa C. Harris, MD, PhD, Assistant Professor, Global Health, University Medical Center, University of Amsterdam, Amsterdam Institute for Global Health and Development, The Netherlands

In this panel discussion, session speakers will discuss the benefits and disadvantages of looking at both host-derived, and pathogen-derived biomarkers in infectious disease diagnostics. Our panelists have experience working with both viral and bacterial infections and include representation from academia and biotech industry.

Sponsored by



Sponsored by



## ANTIMICROBIAL RESISTANCE AND STEWARDSHIP

### 14:45 Chairperson's Remarks

Till T. Bachmann, PhD, Reader, Personalised Medicine in Infectious Disease; Deputy Head, Division of Infection and Pathway Medicine, Edinburgh Medical School, College of Medicine and Veterinary Medicine, University of Edinburgh, United Kingdom

### 14:50 Implementation Issues in Infectious Disease Point-of-Care Testing

John Hays, PhD, Associate Professor, Medical Microbiology & Infectious Diseases, Erasmus Medical Center, The Netherlands  
Although many infectious disease and antibiotic resistance Point-of-Care test (ID-AMR POCT) devices are already available on the market (and many novel technologies are also being adapted to detect infectious diseases and antibiotic resistances), the uptake of such devices into medical practice has been rather slow. In this talk, some of the main issues relating to the implementation of ID-AMR POCT will be discussed. The issues to be discussed were identified via a specially convened POC working group of the Erasmus University Medical Centre Rotterdam (EMC), the Netherlands, as well as during discussions in recent meetings of the international JPIAMR AMR-RDT working group.

### 15:20 Rapid Diagnostics and Antibiotic Use in Primary Care

Till T. Bachmann, PhD, Reader, Personalised Medicine in Infectious Disease; Deputy Head, Division of Infection and Pathway Medicine, Edinburgh Medical School, College of Medicine and Veterinary Medicine, University of Edinburgh, United Kingdom

### 15:50 AMR Surveillance in the Netherlands Using NGS

Leo Schouls, PhD, Molecular Microbiologist, Infectious Diseases Research, Diagnostics and Screening, Centre for Infectious Disease Control Netherlands, National Institute for Public Health and the Environment (RIVM), The Netherlands

The Netherlands have national surveillance systems for carbapenemase-producing Enterobacteriaceae (CPE) and MRSA, using digital data-exchange for submission and reporting (Type-Ned). All CPEs and infection-related MRSA are analyzed by next-generation sequencing and a genetic relationship between isolates is assessed by whole-genome Multiple Locus Sequence Typing. Recently third-generation sequencing to reconstruct complete plasmids was implemented for CPEs. The data are used to assess trends in national spread and transmission within healthcare centers.

### 16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

### 17:00 Breakout Discussions

See website for details.

### 18:00 Welcome Reception in the Exhibit Hall with Poster Viewing

### 19:00 Close of Day

## WEDNESDAY 8 MAY

### 08:00 Registration and Morning Coffee

## BIG DATA

### 09:00 Chairperson's Remarks

Matthew Cotten, PhD, Research Scientist, Viroscience, Erasmus Medical Center, The Netherlands

### 09:05 New Strategies Based on Protein Domains to Find Patterns in Viral Next Generation Sequencing Data

Matthew Cotten, PhD, Research Scientist, Viroscience, Erasmus Medical Center, The Netherlands

For most virus families, genome size is limited by capsid constraints. Thus, viral genomes can be compact collections of encoded protein domains. We are exploring and developing novel strategies to classify viral sequences based on their encoded protein domains.

### 09:35 HIV Transmission Dynamics in The Netherlands - A Combined Mathematical Model and Phylogenetic Analysis

Daniela Bezemer, PhD, Senior Researcher, Stichting HIV Monitoring, The Netherlands

The first HIV-1 cases in The Netherlands were diagnosed in the early eighties amongst men having sex with men. From our data we see that of the many introductions from abroad only few result in national sub-epidemics. Once established however, these sub-epidemics are very persistent. On the other hand, infections amongst heterosexuals reflect the HIV situation in their regions of origin or link to a former epidemic amongst drug users.

### 10:05 Genome Detective: An Automated Web-Based HTS Virus Assembly and Identification System

Koen Deforche, CTO, Co-Founder, Emweb, Belgium

Tumbling cost and general availability of sequencing promises to create a revolution in infectious disease diagnostics. Although raw sequence data does not provide a simple answer to a diagnostic hypothesis, it can instead provide a complete overview of pathogens in a sample and inform on epidemiological risk factors to guide prevention of infection and surveillance. Genome Detective is an easy-to-use bioinformatics platform which unlocks this information from sequence data.

### 10:35 Meeting the Worldwide Challenge of Drug Resistant Tuberculosis

Agathe Jouet, PhD, Research Engineer, GenoScreen, France

Deeplex® Myc-TB is the only commercialized assay using deep sequencing for culture-free detection of tuberculosis resistance to 15 antibiotics. This assay offers an automated analysis pipeline developed by GenoScreen and benefits from BlueBee's cloud platform (bioinformatics data solution). This integrated solution expedites accurate detection of drug resistant TB in patients globally enabling faster tailoring of patient treatments, improving treatment success rates and preventing amplification and onward transmission of drug resistance.

### 11:05 Coffee Break in the Exhibit Hall with Poster Viewing

## PLENARY SESSION

See page 5 for details.

### 13:30 Close of Advanced Diagnostics for Infectious Disease



## MEDIA SPONSORS

### Lead Sponsoring Publications:



### Sponsoring Publications:

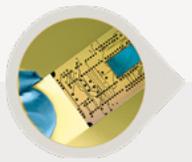


### Web Partners:



### Sponsoring Society:





# Point-of-Care Diagnostics

## Achieving Better Outcomes

### WEDNESDAY 8 MAY

#### PLENARY SESSION

See page 5 for details.

### SELECT CLINICAL ISSUES AND SOLUTIONS IN POCT

#### 14:30 Chairperson's Remarks

Gyorgy Abel, MD, PhD, Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center, United States



#### 14:35 KEYNOTE PRESENTATION: Point-of-Care Diagnostics in Europe – How to Improve Selectivity of Antibiotics Use

Anders Larsson, MD, PhD, Professor, Department of Clinical Chemistry and Pharmacology, Uppsala University Hospital, Sweden  
Antibiotics resistance will force us to be more selective when prescribing antibiotics. This will require POC test that can distinguish between bacterial and viral infections. POCT instrument that utilizes single sample cuvettes and image analysis of full blood cell counts will allow hematology POCT also at small units including GP offices, operating theatres and emergency departments. The new assays for neutrophil activation markers could also aid in these decisions.

#### 15:05 Point-of-Care Creatinine Testing in Community Acquired Acute Kidney Injury Associated with Infection

Dimitrios Poulidakos, MD, Consultant Renal Physician and AKI Lead, Renal Department, Salford Royal NHS Foundation Trust, United Kingdom  
Acute kidney injury (AKI) is associated with poor outcomes. The presence of AKI in the context of suspected community acquired infection confers very high risk of morbidity and mortality and therefore can be used for risk stratification purposes. The talk will present the results of a recent evaluation project of the use point-of-care creatinine testing for early identification and management of infection associated AKI.

#### 15:35 Point-of-Care Hemostasis Monitoring in Major Surgeries: Issues and Challenges

Antonio León Justél, PhD, CEO, Huelva University Hospital, Spain  
Due to the complex nature of the haemostatic routine, laboratory plasma coagulation tests running in the main laboratory, such as INR and aPTT, are not sufficient to diagnose specific coagulation defects and to guide haemostatic therapy. Point-of-care (POC) testing may overcome some of the limitations of traditional approaches to haemostasis management. We presented a success application case of POC-guided haemostatic therapy in major surgeries.

#### 16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

#### 17:05 Glucose Monitoring in Critically Ill Patients

Gyorgy Abel, MD, PhD, Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Laboratory Medicine, Lahey Hospital & Medical Center, United States

Tight glycaemic control by POCT has become the standard of care over the years for inpatients, including critically ill patients. Regulatory oversight resulted in restrictions and a debate about proper inpatient glycaemic management because none of the POC glucometers were cleared by the US FDA for this patient population. The talk will review the related guidelines and present data on clinical situations when POC finger-stick glucose results may be significantly inaccurate.

#### 17:35 Implementation of Point-of-Care Tests: Clinical Efficacy, Safety, and Cost-Effectiveness

Michelle M.A. Kip, PhD, Postdoctoral Researcher, Department of Health Technology and Services Research, Faculty of Behavioural, Management and Social Sciences, Technical Medical Centre, University of Twente, The Netherlands

Although a large set of point-of-care tests is currently available, only few are used in clinical practice. One example of a test that is (still) used infrequently, is point-of-care troponin. This test is used to rule-out acute coronary syndrome in general practices. Using this case study, the presentation will provide insights in factors affecting test implementation and use in clinical practice and in methods applied to quantify the test's cost-effectiveness.

#### 18:05 Converging Human, Animal, and Vector Diagnostics, Together with Digital Technologies, Towards a Holistic One Health Approach

Konstantinos Mitsakakis, PhD, Head of International Business Development, Hahn-Schickard Institut für Mikroanalyzesysteme, Freiburg, Germany  
Diseases such as malaria, dengue, chikungunya, zika share several common features: they are all vector-borne, account for more than 17% of all human infectious diseases, frequently emerge as epidemics, and tend to spread from tropical to non-tropical regions. The presentation will propose pathways to converge human and vector diagnostics through four disciplines, namely: molecular assays, point-of-care diagnostic systems, information and communication technologies, behavioral change, towards a One Health approach.

#### 18:35 Innovative POCT Technologies: An Overview on New Revolutionary Products and Their Influence on Digitalization, Process Optimization and Costs

Peter B. Luppá, PhD, Head, Central Laboratory, Institute for Clinical Chemistry, Technische Universität München, Germany

Emerging technologies enable the development of revolutionary POCT. The new techniques include alternative biological detection elements, microarrays, as well as new nucleic acid testing analytics for infection, inflammation, malignancies and autoantibody diagnostics. These techniques will be encouraged through novel digitalization concepts. As example for disruptive techniques, the continuous glucose monitoring will be discussed. The application fields are illustrated by clinical examples in intensive care units and in outpatient (diabetes) ambulances.

#### 19:05 Close of Day

## HOTEL & TRAVEL INFORMATION

### Lisbon Marriott Hotel

Avenida dos Combatentes, 45  
Lisbon 1600-042 Portugal  
Phone: (351)(21) 723 5400

Discounted Room Rate: €189 single/€199 double, includes breakfast

Discounted Room Rate Cut-off Date: 31 March 2019

For more information: [MolecularDxEurope.com/travel](http://MolecularDxEurope.com/travel)

08:30 Registration and Morning Coffee

**INNOVATION AND QUALITY SYSTEMS IN POCT****09:00 Chairperson's Remarks**

Prof. Dr. Dr. Wilfried von Eiff, Director, Center for Hospital Management, University of Muenster, Germany

**09:05 "Theragnostic" and the Burden of Disease: How Misleading Reimbursement Systems Cause Avoidable Costs and Harm to the Patient**

Prof. Dr. Dr. Wilfried von Eiff, Director, Center for Hospital Management, University of Muenster, Germany

In Germany, nearly 210.000 patients infected with multi-resistant bacteria were undetected and admitted to hospitals. Otherwise, only 45.000 MRSA-related diagnostic and therapeutic interventions are carried out by General Practitioners. This screening gap leads to needless harm for patients and avoidable costs. This diagnostic gap is caused by a misleading reimbursement system that pays only for therapy e.g. for MRSA-infected persons but not for screening in the forefield of a hospital stay.

**09:35 Quality Management at the Point-of-Care**

Claus Langer, PhD, Clinical Chemist, Medizinisches Versorgungszentrum für Laboratory Medicine and Mikrobiologie (mvzIm Ruhr), Germany

The successful implementation of quality management is a challenge in the area of Point-of-Care testing (POCT). In our collaboration with different hospitals, these problems create constantly new challenges. At the same time, it is important to integrate the aspects of quality management for POCT into the QMS of the hospital. The goal of better quality management at POCT requires constructive cooperation between all stakeholders.

**10:05 Use of Optical Filters in PoCT Instruments**

Georg Draude, PhD, General Manager, Chroma Europe, Chroma Technology, Germany

This talk is to give a quick overview on the key role of optical filters in medical applications. Examples are shown with devices for cardiovascular risk assessment and age levels measurements, that uses optical applications as core technology.

Sponsored by

**10:35 Coffee Break in the Exhibit Hall. Last Chance for Poster Viewing.****11:20 Precision Medicine: New Biophotonic Approach for Testing Antibiotic Resistance**

Prof. Dr. Ute Neugebauer, Professor, Physical Chemistry, Center for Sepsis Control and Care, Jena University Hospital & Leibniz Institute of Photonic Technology, Jena, Germany

Increasing antibiotic (multi-)resistances of pathogens require fast diagnostics to administer tailored antibiotic therapy in time. Here, biophotonic bacterial identification as well as fast antibiotic susceptibility testing are presented, starting directly from patient's body fluids, such as urine. Phenotypic resistances are available after only 90 – 360 minutes and can be obtained in a qualitative manner (sensitive vs. resistant) as well as in a quantitative manner displaying the minimal inhibitory concentration.

**11:50 Finding Solutions for Sample Preparation at Point of Care**

Sponsored by &lt;Sagentia&gt;

Nick Collier, PhD, CTO, Medical, Sagentia, United Kingdom

As molecular diagnostics move to point of care, lab-based processes are being adapted. One area that is sometimes neglected is sample preparation. This presentation assesses current lab techniques and their suitability to PoC; the range of cartridges currently available; techniques that could be used such as electrowetting, magnetic beads and ultrasonics and reviews the scientific literature, suggesting emerging techniques.

**12:20 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Luncheon on Your Own****12:50 Session Break****FULLY INTEGRATED CARTRIDGE-BASED POC DEVICES****13:50 Chairperson's Remarks**

Holger Becker, PhD, Founder & CSO, microfluidic ChipShop GmbH, Germany

**14:00 The Quest for Sample-In Answer-Out – Developing Highly Integrated Cartridges for POC Applications**

Holger Becker, PhD, Founder & CSO, microfluidic ChipShop GmbH, Germany

With the advent of highly integrated microfluidic devices which allow a sample-in answer-out operation without additional hands-on time, the original concept of a lab-on-a-chip is becoming a reality in many diagnostic applications. For the development and industrial manufacturing of such devices however, significant challenges exist during product development and in the subsequent transition to manufacturing. The talk will explore solutions to such challenges such as material selection, on-chip reagent storage and fluidic manipulation in order to not only end up with a functional but also a commercially viable device. Examples from different fields of point-of-care diagnostics such as molecular diagnostics, immunoassays and cell-based assays will be presented.

**14:30 Commercialization of Microfluidic Devices for Point-of-Care Application**

Vincent Linder, PhD, Founder and President, CDP BioMedical Consulting, Portugal

Development strategies can initially focus on de-risking analytical and clinical performances. For a successful commercialization effort, it is essential to also implement at the onset of the program a comprehensive vision encompassing the patient presenting in a POC setting, the POC user and all the steps needed to obtain an actionable test result. This presentation will discuss important commercialization challenges of Point-of-Care devices and directions/solutions to address them.

**15:00 Development of Molecular and Antibody-Based Point-of-Care Tests for the Rapid Detection of Carbapenemases for Screening and Bedside Testing in the Private-Public Partnership InfectoGnostics**

Sascha Braun, PhD, Senior Scientist, Optical-Molecular Diagnostics and System Technology, Leibniz Institute of Photonic Technology e.V. Jena (Leibniz-IPHT), Germany

The effective translation of scientific results to clinically applicable products is a challenge, which also requires an understanding of the implications and rules of industrial product development, guidelines and approvals. These can be organized and implemented, for example, in scientific projects in public-private partnerships. Using the InfectoGnostics Research Campus as example, concrete project results from the field of diagnostic test developments for antimicrobial resistant bacteria are shown.

**15:30 Point-of-Care Testing for Periodontal Disease**

John Carrano, Chairman & CEO, Paratus Diagnostics, USA

We are developing a simple, low-cost medical device that can accurately diagnose periodontal disease at the dentist office – and during the time of your appointment. Periodontal disease is not only a serious condition because it will lead to tooth or even implant loss, but most importantly because of its direct role in contributing to several potentially fatal chronic diseases. Our device consists of a smartphone as the instrument and a one-time use cartridge.

Sponsored by

**16:00 Rapid Molecular Diagnostics for Severe Acute Infections**

Gerd H. Luedke, PhD, Director Innovation, Technology & IP, Curetis GmbH, Germany

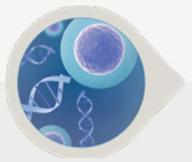
Antibiotic resistance is a major threat for severe acute infections. Early adequate antibiotic treatment allows improved patient outcomes. However, it requires fast diagnostics of pathogens and resistances to guide therapeutic intervention. Within recent years, several systems for rapid diagnostics that could be placed outside central labs were developed. Clinical results and experiences with the Unyvero System demonstrate the value of rapid molecular identification of pathogens and resistances.

**16:30 Novel Approaches for Minimally Invasive Point-of-Need (PON) Diagnostics**

Stephen C. Francesconi, PhD, Science and Technology Manager, Diagnostics and Detection Division, Chemical Biological Technologies Department, Research and Development Directorate, Defense Threat Reduction Agency (DTRA), United States

DTRA is pursuing the development of FDA-cleared, low cost, highly specific and minimally invasive point-of-need (PON) diagnostic platforms. Specifically, Joint Science and Technology Office-Chemical Biological Defense Program (JSTO-CBDP) is developing, optimizing and evaluating two lateral flow immunoassays (LFI) for the detection of *Burkholderia pseudomallei* and *Yersinia pestis*. Furthermore, DTRA JSTO-CBDP is developing a multiplexed, hand-held, single use, rapid PCR-based platform capable of detecting different strains of the Hantavirus.

**17:00 Close of Conference**



# Enabling Technologies for Circulating Biomarkers

## Improving Assays for Clinical Use

**RECOMMENDED SHORT COURSE\*** MONDAY 6 MAY | 13:30 - 17:00

### SC2: Biomarkers in Liquid Biopsy: CTCs, ctDNA and Exosomes

Lorena Diéguez, PhD, Group Leader, Department of Life Sciences, Nano4Health Unit, Medical Devices Research Group, International Iberian Nanotechnology Laboratory, Portugal

Roberto Piñeiro Cid, PhD, Cancer Modeling Lab, Instituto de Investigación Sanitaria de Santiago de Compostela- Roche-Chus Joint Unit, Spain

\*Separate registration required, see page 7 for details.

## TUESDAY 7 MAY

**08:00 Registration and Morning Coffee**

### IMPLEMENTATION OF CIRCULATING BIOMARKER TECHNOLOGIES

#### 08:55 Organizer's Opening Remarks

Kaitlin Kelleher, Conference Producer, Cambridge Healthtech Institute

#### 09:00 Chairperson's Remarks

Jörg Tost, PhD, Director Laboratory for Epigenetics & Environment, Laboratory for Epigenetics & Environment, Centre National de Recherche en Génomique Humaine (CNRGH), CEA – Institut de Biologie Francois Jacob, France

#### 09:05 Realising Value from Liquid Biopsy: Assuring Analytical Validity, Clinical Utility, and Cost-Effectiveness

Michael Messenger, PhD, Head of Personalised Medicine and Health, Leeds Centre for Personalised Medicine and Health, University of Leeds, United Kingdom

Careful consideration of the evidence requirements of decision makers early on in the test evaluation pipeline can reduce the time and cost of research and improve the likelihood of a successful reimbursement outcome. This presentation will provide an overview of efficient approaches and protocols for evaluating liquid biopsies for rapid adoption and reimbursement, using examples from real case studies. Furthermore, it will highlight various frameworks used for quality appraising research evidence on analytical performance, clinical validity, clinical utility and cost-effectiveness, that are used by reviewers and Health Technology Assessment schemes to look at the risk of bias, inapplicability and irreproducibility.

#### 09:35 Paving the Way to Use Liquid Biopsies in the Real World – IMI CANCER-IDs Learnings and Outlook

Thomas Schlange, PhD, Senior Biomarker Scientist, Global Biomarker Research, Bayer AG, Germany

The Innovative Medicines Initiative project CANCER-ID set out in 2015 to establish criteria for evaluating technologies in the liquid biopsy field. At the core of the 5-year program are harmonized protocols for clinical use of CTCs, ctDNAs and miRNAs, standards for benchmarking technologies and implementing these technologies in clinical studies. Learnings from CANCER-ID will be presented and an outlook of further joint stakeholder activities will be given.

#### 10:05 Nu.Q™-Complete: Comprehensive Nucleosome Profiling

Mark Eccleston, Business Development Director, Volition, Belgium

Volition has established the concept of epigenetic profiling of cell free, circulating nucleosomes using simple Nu.Q™ immunoassays. The Nucleosomics® platform is being used to develop blood tests for early detection of a range of cancers. We now present a broader analytical approach, employing immuno-capture, mass spectrometry, immunoassay and sequencing of constituent DNA to allow comprehensive analysis of circulating nucleosomes for serum or plasma. Clinical applications will be discussed.

Sponsored by



Volition

**10:35 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing**

### PRE-ANALYTICAL AND ANALYTICAL CONSIDERATIONS FOR CIRCULATING BIOMARKERS

#### 11:15 Achieving Measurement Traceability for Molecular Diagnostics in Compliance with the IVDR

Alison Devonshire, PhD, Science Leader, Molecular and Cell Biology, LGC, United Kingdom

The new *In Vitro* Diagnostic Device Regulation (EU 2017/746) states that calibrators and control materials used in diagnostic tests "shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order;" however, there are a scarcity of reference materials and reference measurement procedures for the nucleic acid and cellular analytes commonly measured by liquid biopsy tests. This talk will discuss a framework for developing a reference system for circulating biomarkers and CTCs, and recent progress in developing digital PCR as a reference measurement procedure for gene quantification.

#### 11:45 Obtaining Every Droplet of Information out of Each Liquid Biopsy Sample

Lorena Diéguez, PhD, Group Leader, Department of Life Sciences, Nano4Health Unit, Medical Devices Research Group, International Iberian Nanotechnology Laboratory, Portugal

Why choose between CTCs, ctDNA or exosomes when you can have it all? What if the information provided by the different biomarkers is not redundant, but complementary? We use microfluidics and nanotechnology to extract the most of each sample. Phenotypic analysis of single CTCs and mutation analysis is done using microdroplets and Surface Enhanced Raman Spectroscopy.

#### 12:15 Fundamentals for the Automatic Classification of Quantitative PCR Amplification Curves: A Biostatistical Approach

Stefan Rödiger, PhD, Group Leader, Institute of Biotechnology, Brandenburg University of Technology Cottbus – Senftenberg, Germany

Quantitative polymerase chain reaction (qPCR) is a widely used bioanalytical method in human diagnostics. Until now, classifications (e.g., positive or negative reaction) are performed manually or by fixed threshold values. This classification is error-prone and based on the operator's experience. We developed a scientific software, PCRReduX, which calculates predictors (features) of amplification curves automatically. The predictors can be used for the automatic analysis of large data sets for machine learning applications.

**12:45 Presentation to be Announced**

Sponsored by



**13:15 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own**

**13:45 Session Break**

### PRE-ANALYTICAL AND ANALYTICAL CONSIDERATIONS FOR CIRCULATING BIOMARKERS (CONT.)

#### 14:15 Chairperson's Remarks

Michael Messenger, PhD, Head of Personalised Medicine and Health, Leeds Centre for Personalised Medicine and Health, University of Leeds, United Kingdom



#### 14:20 Analytical and Biological Variation of Analyses of Circulating Tumor DNA

Rikke Fredslund Andersen, PhD, Molecular Biologist, Department of Clinical Biochemistry, Vejle Hospital, Denmark

Serial analyses of circulating tumor DNA in cancer patients are being investigated for assessing treatment response or failure. It is important to determine if values have significantly increased or decreased compared to previous values. We have performed extensive validation of mutation and methylation analyses in cfDNA from colorectal cancer patients to determine analytical and biological variation. From these values the significant minimum change can be calculated.

#### 14:50 Optimizing Liquid Biopsies for Clinical Use

Niels Pallisgaard, PhD, Molecular Biologist, Pathology, Roskilde University, Denmark

Sample tubes, sample size and handling, when to use pre-amplification, assay sensitivity and assay optimization as well as proper controls for sample and assay quality for liquid biopsies in a clinical setting will be discussed in this presentation.

## TECHNOLOGIES FOR CELL-FREE DNA



#### 15:20 KEYNOTE PRESENTATION: Novel Digital PCR and Mutation Enrichment Technologies for the Analysis of Clinically Relevant DNA Alterations in Liquid Biopsies

G. Mike Makrigiorgos, PhD, Professor, Dana Farber Cancer Institute and Harvard Medical School, United States

With the increasing interest in treatment assessment using liquid biopsy and circulating DNA, sensitive and multiplexed detection of tumor-derived alterations in blood are desirable. We provide novel forms of digital PCR, as well as mutation enrichment-based real time PCR methods that (a) enable several orders of magnitude improvement of detecting mutations or microsatellite instability than currently possible; (b) are highly multiplex-able; (c) reduce cost of analysis. Application in circulating DNA from clinical cancer samples will be presented.

#### 15:50 Analysis of Mutations and Methylated Molecules in Cell-Free DNA Using Enhanced-ice-COLD-PCR Enrichment Combined with Next-Generation Sequencing

Jörg Tost, PhD, Director Laboratory for Epigenetics & Environment, Laboratory for Epigenetics & Environment, Centre National de Recherche en Génomique Humaine (CNRGH), CEA – Institut de Biologie François Jacob, France

Circulating cell-free DNA has great potential for non-invasive diagnostics, prediction and monitoring of treatment response. We have previously developed Enhanced-ice-COLD-PCR for the detection and sequence-based identification of mutations in mutation hotspots as well as methylated molecules. While the initial developed workflow used Pyrosequencing for a short time-to-results, we have now moved the assays to an NGS platform improving further signal/noise ratio, correlation with ddPCR results and providing detailed information on enriched molecules.

#### 16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

#### 17:00 Breakout Discussions

See website for details.

#### 18:00 Welcome Reception in the Exhibit Hall with Poster Viewing

#### 19:00 Close of Day

## WEDNESDAY 8 MAY

#### 08:00 Registration and Morning Coffee

## SINGLE CELL ANALYSIS AND CELL-BASED DIAGNOSTICS

#### 09:00 Chairperson's Remarks

An Hendrix, PhD, Assistant Professor, Laboratory of Experimental Cancer Research, Ghent University, The Netherlands

#### 09:05 Biological and Technical Aspects of Single-Molecule Analysis in Liquid Biopsies

Anders Ståhlberg, Associate Professor, Sahlgrenska Cancer Center, Clinical Pathology and Genetics, University of Gothenburg, Sahlgrenska University Hospital, Sweden

Early detection of individual tumor cells and molecules is essential in cancer diagnostics. We have developed several approaches to analyze individual cells and molecules and applied them to various applications within cancer and beyond. Here, we present our experience of using ultrasensitive analysis from both a clinical and technical point of view. Data from different tumor entities will be shown.

#### 09:35 Inertial Microfluidics for High-Throughput Isolation of Circulating Trophoblastic Fetal Cells from Maternal Blood

Benjamin Thierry, PhD, Professor, Bioengineering, Future Industries Institute, University of South Australia, Australia

Inertial microfluidics has been successfully applied for the enrichment of circulating tumour cells, but its application to the isolation of circulating trophoblastic fetal cells presents additional challenges. We have developed an integrated combining inertial microfluidic and single cell manipulation towards the development of a semi-automated cell-based NIPT compatible with downstream genomic testing.

#### 10:05 Standardized Analysis of Extracellular Vesicles in Liquid Biopsies: From Research to Clinical Applications

An Hendrix, PhD, Assistant Professor, Laboratory of Experimental Cancer Research, Ghent University, The Netherlands

The identification of extracellular vesicle (EV)-associated biomarkers is challenging owing to the complexity of liquid biopsies. We 1) performed quality control studies to identify the impact of (pre-) analytical variables on biomarker identification, 2) developed reference materials to ensure standardized EV measurements, and 3) created EV-TRACK to stimulate researchers to put experimental guidelines into practice. This combined expertise boosted the identification of bacterial EV in the systemic circulation of patients with intestinal barrier dysfunction.

#### 10:35 Multiplex Digital PCR for the Diagnostic of Pilocytic Astrocytoma and Glioneuronal Tumors

Daniel Henaff, PhD, Manager, Research & Development, ID-Solutions, France

By using Crystal Digital PCR, a multiplex panel was developed for the molecular characterization of pediatric CNS tumors by detecting BRAF; FGFR1 and PIK3C mutations. This permits to get results in 1 day, with high sensitivity and high specificity. This assay can be performed by using DNA with no need of RNA for fusion transcript detection. Thus, dPCR enables laboratories to get access to affordable & fast diagnostic tools.

#### 10:50 Sponsored Presentation (Opportunity Available)

#### 11:05 Coffee Break in the Exhibit Hall with Poster Viewing

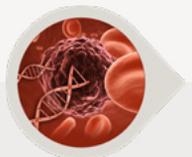
## PLENARY SESSION

See page 5 for details.

#### 13:30 Close of Enabling Technologies for Circulating Biomarkers



Sponsored by



# Clinical Applications of Circulating Biomarkers

## An Era of Biomarker Combination

WEDNESDAY 8 MAY

### PLENARY SESSION

See page 5 for details.

## CLINICAL VALUES OF CTCs AND cfDNA

### 14:30 Chairperson's Remarks

Daniel Wetterskog, PhD, Senior Scientist, Treatment Resistance Team, Oncology University College London Cancer Institute, United Kingdom



### 14:35 KEYNOTE PRESENTATION: Liquid Biopsy: The New Diagnostic Concept in Oncology

Klaus Pantel, MD, Professor, Chairman, Institute of Tumor Biology, University Medical Center Hamburg-

Eppendorf, Germany

Liquid biopsy assays are currently being validated for early detection of cancer, which is supposed to reduce cancer related mortality. In patients with diagnosed cancer, CTCs and ctDNA analyses can obtain independent information on prognosis in early and advanced stages of disease. Another key application of liquid biopsy is to identify therapeutic targets or mechanisms of resistance of metastatic cells in individual patients.

### 15:05 Cancer Screening with Circulating Tumor DNA Analysis – The Nasopharyngeal Carcinoma Model

Wai Kei Jacky Lam, MBBS (HK), MPhil, FRCSEd, FHKCORL, FHKAM (Otorhinolaryngology), Clinical Lecturer, Chemical Pathology, Faculty of Medicine, The Chinese University of Hong Kong

Analysis of circulating tumor DNA (ctDNA) has demonstrated promising results for cancer diagnostics. Screening of nasopharyngeal carcinoma (NPC) with plasma Epstein-Barr virus (EBV) DNA, as a form of ctDNA, has shown clinical benefits in terms of early cancer detection and improved survival. Based on the molecular characteristics of plasma EBV DNA, a sequencing-based assay was developed to improve the test performance of the EBV DNA-based screening test. This has shed light on future directions on ctDNA analysis for screening of other types of cancers.

### 15:35 Next-Generation Biopsies: Blood-Based Prediction of Treatment Resistance in Gastrointestinal Cancers

Nicola Valeri, MD, PhD, Reader in Gastrointestinal Oncology and Consultant Medical Oncologist, The Institute of Cancer Research and The Royal Marsden Hospital, United Kingdom

Liquid biopsies are emerging as rapid and cost-effective tools for the management of cancer patients. I will describe the promises and hurdles of liquid biopsies in deciding and monitoring treatment in patients with advanced metastatic colorectal cancer treated with targeted agents. I will also highlight the potential of combining different biomarkers in liquid and tissue biopsies in order to improve patients' selection and accelerate precision cancer medicine.

### 16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

### 17:05 Cancer-Specific Genetic and Epigenetic Signatures in Plasma DNA from Metastatic Prostate Cancer Patients

Daniel Wetterskog, PhD, Senior Scientist, Treatment Resistance Team, Oncology University College London Cancer Institute, United Kingdom  
Previously, we have shown the association of specific gene aberrations, found in plasma, and the response to currently used therapies in metastatic castration-resistant prostate cancer patients. Currently, we are investigating the correlation of plasma and solid tumour-derived genome wide signatures across the disease setting from diagnosis to end of life. I will present data from our rapid autopsy project where we have gained understanding

how ctDNA reflects the genomic and epigenomic landscape of different metastatic lesions. I will also describe our studies in the early disease setting and the PARADIGM clinical trial (Plasma Analysis for Response Assessment and to Direct the management of Metastatic prostate cancer). In this trial we are investigating the association of plasma derived tumour signatures and the association of outcome in metastatic castration-sensitive prostate cancer patients.

### 17:35 Towards a Screening Test for Cancer by Circulating Cell-Free DNA Analysis

Rita Tanos, Research Assistant, Institut de Recherche en Cancérologie de Montpellier-INSERM, France

Our group has been interested in the implication of cfDNA in the field of oncology for many years, mainly in mutation detection and resistance to treatment, surveillance of recurrence, pre-analytical considerations, as well as cfDNA structure and origins. In addition, we are particularly focused on evaluating its potential for screening and the early detection of cancer. We believe that structural features might help in screening cancer. Therefore, we developed a test (MNR: Multi normalized ratio), based on various cfDNA parameters determined by a specific q-PCR based method, on both nuclear and mitochondrial sequences. The MNR test enables the discrimination between cancerous and healthy individuals (AUC >0.90, 1,500 individuals). In addition, structural observation by whole genome sequencing analysis might also help towards cancer screening.

### 18:05 Breakout Discussions

See website for details.

### 19:05 Close of Day

THURSDAY 9 MAY

### 08:30 Registration and Morning Coffee

## UNDERSTANDING THE BIOLOGY OF CTCs AND METASTASIS

### 09:00 Chairperson's Remarks

Catherine Alix-Panabieres, PhD, Assistant Professor, Director, Laboratory of Rare Human Circulating Cells (LCCRH), University Medical Centre of Montpellier, France

### 09:05 Biology and Vulnerabilities of Circulating Tumor Cell Clusters

Nicola Aceto, PhD, Professor, Oncology, Swiss National Science Foundation, Biomedicine, University of Basel, Switzerland

Cancer patients that develop a metastatic disease are currently considered incurable. Mainly, this is due to a limited understanding of the molecular mechanisms that characterize the metastatic process, and the lack of effective metastasis-suppressing agents. Using a combination of liquid biopsies, microfluidics, single cell sequencing, molecular and computational biology, we are gaining fundamental insights into the biology of circulating tumor cells (CTCs). Further, we have identified FDA-approved agents that target metastatic CTCs and suppress the spread of cancer in preclinical models.

### 09:35 Molecular and Functional Characterization of Metastasis-Initiator CTCs in Carcinoma Patients

Catherine Alix-Panabieres, PhD, Assistant Professor, Director, Laboratory of Rare Human Circulating Cells (LCCRH), University Medical Centre of Montpellier, France

Circulating tumor cells (CTCs) are an important clinical indicator for prognosis or treatment efficacy. However, an in-depth investigation of CTCs is hampered by the low number of these cells, making the establishment of permanent cell lines from CTCs very challenging. For the first time, we established and characterized 9 CTC lines obtained from a metastatic colorectal cancer patient before and after systemic therapy (chemotherapy and targeted therapy) and subsequent cancer progression.

**10:05 Transforming Oncology Research: Droplet Digital™ PCR and his key role in Molecular Profiling of Cancer**

Marco Bianchi, Digital Biology EMEA Product Manager, Life Sciences, Bio-Rad Laboratories, Italy

Traditional tissue biopsies limit our ability to implement personalized treatments in disease-associated mutations (i.e cancer). Liquid biopsies can eliminate the need for invasive surgical procedures and now numerous studies have shown that Droplet Digital™ PCR (ddPCR™) enables absolute and highly sensitive quantification using a simple, fast, and economical workflow.

**10:20 Sponsored Presentation** (Opportunity Available)

**10:35 Coffee Break in the Exhibit Hall. Last Chance for Poster Viewing.**

**11:20 Metabolic Phenotyping and Single-Cell Sequencing of Circulating Tumor Cells in Non-Small Cell Lung Cancer**

Qihui Shi, PhD, Professor, Fudan University, Shanghai Medical College, China

Using a single-cell on-chip metabolic cytometry and fluorescent metabolic probes, we show metabolic phenotyping on the rare disseminated tumor cells in liquid biopsies. Our results reveal extensive metabolic heterogeneity of tumor cells that differentially engage in glycolysis and mitochondrial oxidation. The cell number ratio of the two metabolic phenotypes is found to be predictive for the patient therapy response, clinical performance and survival.

**11:50 New Developments in Diagnostic Leukapheresis for Improved CTC-Analysis**

Nikolas Hendrik Stoecklein, MD, Professor, Experimental Surgical Oncology, Department of General, Visceral and Pediatric Surgery, University Hospital and Medical Faculty of the Heinrich-Heine University Düsseldorf, Düsseldorf, Germany

Diagnostic leukapheresis (DLA) is based on continuous centrifugation collecting mononuclear cells from peripheral blood with a density of around 1.05–1.08 g/mL. Since epithelial cells have a similar density, DLA co-collects circulating tumor cells (CTCs) along with the targeted mononuclear cells. The presentation will provide an update on the use and validation of DLA in different cancer entities. So far, the conclusion is that DLA is a clinically safe method to collect CTCs from liters of blood enabling a real liquid biopsy. Even the processing of 5% the DLA product using the CellSearch system led to a significant increase in CTC numbers and detection frequency when directly compared to a peripheral blood sample. Yet, further technical developments are required to process whole DLA products and exploit the full potential of this approach as powerful CTC pre-enrichment step.

**12:20 Enjoy Lunch on Your Own**

**13:20 Session Break**

**APPLICATIONS OF OTHER BLOOD BIOMARKERS: EXOSOMES AND miRNA**

**13:50 Chairperson's Remarks**

Nikolas Hendrik Stoecklein, MD, Professor, Experimental Surgical Oncology, Department of General, Visceral and Pediatric Surgery, University Hospital and Medical Faculty of the Heinrich-Heine University Düsseldorf, Düsseldorf, Germany

**14:00 Liquid Biopsy in Ovarian Cancer: The Potential of Circulating miRNAs and Exosomes**

Evi Lianidou, PhD, Professor, Analytical Chemistry, Clinical Chemistry, Chemistry, University of Athens, Greece

Circulating tumor cells (CTCs), circulating tumor DNA (ctDNA), circulating cell-free microRNAs (cfmiRNAs) and circulating exosomes represent the major components of liquid biopsy analysis. Liquid biopsy has been already implemented in ovarian cancer, and most studies so far are mainly focused on CTCs and ctDNA. This talk is mainly focused on the clinical potential of circulating miRNAs and exosomes as a source of liquid biopsy biomarkers in ovarian cancer diagnosis, prognosis, and response to treatment.

Sponsored by

**BIO-RAD**

**14:30 Exosomes as Emerging Players in Cancer Biology and Diagnostic Applications**

Bruno Costa-Silva, PhD, Systems Oncology, Group Leader, Champalimaud Foundation, Portugal

We have shown that exosomal patterns of integrins expression dictates the tissue affinity of tumor exosomes, which in turn determines the location of pre-metastatic niches formation and the tumor metastasis organ distribution. Our clinical data indicate that exosomal integrins could be used to predict organ-specific metastasis, helping to answer one of the greatest unsolved mysteries of metastatic cancer regarding the biological basis of organotropism.

**NON-ONCOLOGY APPLICATIONS: BRAIN INJURY AND TRANSPLANTATION**

**15:00 Chairperson's Remarks**

Andrea Regner, MD, PhD, Professor, Cellular and Molecular Biology Applied to Health, Course of Medicine, Lutheran University of Brazil, Canoas, Brazil

**15:00 The value of measuring cfDNA concentration by a rapid fluorescent assay in emergency medicine**

Amos Douvdevani, PhD, professor of Biochemistry, Department of Clinical Biochemistry and Pharmacology, Soroka Medical Center and Ben-Gurion University of the Negev, Israel

We have developed a fast "Mix and Measure" fluorometric assay to measure cfDNA concentration in biological fluids that has the potential to become a routine clinical test. In my talk, I will demonstrate the advantage of this rapid fluorescent assay over standard clinical scores used in emergency medicine, namely, APACHE II, Ranson, and other multifactorial complex scores. For example, studies on septic, TBI, pancreatitis and smoke inhalation injury patients.

**15:30 Prognostic Utility of Cell-Free DNA in Acute Brain Injuries**

Andrea Regner, MD, PhD, Professor, Cellular and Molecular Biology Applied to Health, Course of Medicine, Lutheran University of Brazil, Canoas, Brazil

In acute brain injuries cfDNA has shown to be a promising biomarker for risk stratification, prognosis prediction, monitorization of lesion progression and of therapeutic response, as well as a tool for analysis of the quality of care. We will discuss (i) the prognostic utility of cfDNA in acute brain injuries, particularly traumatic brain injury and brain death; and (ii) the potential of cfDNA as a point-of-care marker in emergency and critical care settings.

**16:00 Stroke and Brain Damage Blood Biomarkers**

Joan Montaner, PhD, Laboratorio de Investigación Neurovascular, Vall d'Hebron Institute of Research (VHIR), Hospital Vall d'Hebron, Barcelona, Spain

The inflammatory response triggered after the ischemic event plays an important role in the progression of stroke; consequently, the study of inflammatory molecules in the acute phase of stroke has attracted increasing interest in recent decades. This talk will discuss the inflammatory processes occurring during ischemic stroke, as well as the potential for these inflammatory molecules to become stroke biomarkers and the possibility that these candidates will become interesting neuroprotective therapeutic targets to be blocked or stimulated in order to modulate inflammation after stroke.

**16:30 Graft-Derived Cell-Free DNA as a Biomarker in Organ Transplantation**

Michael Oellerich, MD, Hon MD, FAACC, FAIM, FFPPath (RCPI), FRCPath, Distinguished Research Professor, Clinical Chemistry, Clinical Pharmacology, George-August-University, University Medical Center Goettingen, Germany

Molecular biomarkers have attracted special attention in transplantation because of unresolved problems that limit long-term outcome. A particularly promising new approach for the early detection of graft rejection is based on the determination of graft-derived circulating cell-free DNA (GcfDNA). Independent studies have shown that GcfDNA detects rejection episodes early, at an actionable stage, and is a more reliable marker of graft injury, compared to conventional tests. GcfDNA may also be useful to guide changes in immunosuppression, to monitor immunosuppression minimization (e.g. during tapering), and to prevent immune activation. In summary, this approach will allow more personalized treatment that shifts emphasis from reaction to prevention.

**17:00 Close of Conference**

# Molecular Diagnostics EUROPE

6-9 May 2019 | Lisbon, Portugal

Lisbon Marriott Hotel

**ALL ACCESS \*BEST VALUE\*** (Includes access to all conferences, Prenatal symposium, and short courses.)

	Commercial	Academic, Government, Hospital Affiliated
Advance Rate Until 3 May	€2449	€1349
Registrations after 3 May and on-site	€2649	€1399

**PREMIUM PACKAGE** (Includes access to all conferences, excludes Prenatal symposium, and short courses.)

Advance Rate Until 3 May	€2049	€999
Registrations after 3 May and on-site	€2249	€1049

**STANDARD PACKAGE** (Includes access to one conference and Prenatal symposium, excludes short courses.)

Advance Rate Until 3 May	€1849	€849
Registrations after 3 May and on-site	€2049	€899

**BASIC PACKAGE** (Includes access to one conference only, excludes Prenatal symposium, and short courses.)

Advance Rate Until 3 May	€1499	€699
Registrations after 3 May and on-site	€1649	€749

**SYMPOSIUM ONLY** (Includes access to Prenatal symposium only, excludes conferences and short courses.)

Advance Rate Until 3 May	€999	€549
Registrations after 3 May and on-site	€1099	€649

**SHORT COURSE ONLY PRICING**

One Short Course	€499	€349
------------------	------	------

**PROGRAM SELECTIONS**

6 May (Symposium)	7-8 May (Conferences)	8-9 May (Conferences)
S1: Advances in Prenatal Molecular Diagnostics	C1: Biomarkers for Immunotherapy	C4: Companion Diagnostics for Immuno-Oncology
	C2: Advanced Diagnostics for Infectious Disease	C5: Point-of-Care Diagnostics
	C3: Enabling Technologies for Circulating Biomarkers	C6: Clinical Applications of Circulating Biomarkers

**SHORT COURSE SELECTIONS**

6 May
<ul style="list-style-type: none"> <li>SC1: Technologies, Applications and Commercialisation of Point-of-Care Diagnostics</li> <li>SC2: Biomarkers in Liquid Biopsy: CTCs, ctDNA and Exosomes</li> </ul>

## PRICING & REGISTRATION INFORMATION

**CONFERENCE DISCOUNTS**

**Poster Submission - Discount (€50 Off):** Poster abstracts are due by 29 March 2019. 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, please contact [jring@healthtech.com](mailto:jring@healthtech.com). \*CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

**REGISTER 3 - 4th IS FREE:** Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

**Alumni Discount: SAVE 20%:** CHI appreciates your past participation at Molecular Diagnostics Europe. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

**Group Discounts:** Discounts are available for multiple attendees from the same organization. For more information on group rates contact Elizabeth Lemelin at +1 781-972-5488, [elemelin@healthtech.com](mailto:elemelin@healthtech.com).

**Additional Registration Details:** 23% VAT will be added to each registration

\*Alumni, Twitter, LinkedIn, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Short Courses.

**Healthtech Publishing**

Complimentary news delivered to your inbox

**BioIT World**

News on the data deluge in petascale computing and the tools to deliver individualized medicine.

[BioITWorld.com](http://BioITWorld.com)
**CLINICAL INFORMATICS NEWS**

Insights on the innovation between clinical trial management and delivery of care. [ClinicalInformaticsNews.com](http://ClinicalInformaticsNews.com)

**Diagnostics World**

Emerging Technologies in Diagnostics  
[DiagnosticsWorldNews.com](http://DiagnosticsWorldNews.com)



Reports designed to keep life science professionals informed of the salient trends in pharma technology, business, clinical development, and therapeutic disease markets

[InsightPharmaReports.com](http://InsightPharmaReports.com)

Contact Adriana Randall,  
[arandall@healthtech.com](mailto:arandall@healthtech.com) / +1-781-972-5402



Barnett is a recognized leader in clinical education, training, and reference guides for life science professionals involved in the drug development process. For more information, visit [BarnettInternational.com](http://BarnettInternational.com).

**ADDITIONAL REGISTRATION DETAILS**

Each registration includes all conference sessions, posters and exhibits, food functions, and 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.

**To view our Substitutions/Cancellations Policy, go to [healthtech.com/regdetails](http://healthtech.com/regdetails)**

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

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

[reg@healthtech.com](mailto:reg@healthtech.com) • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode

**MDXE F**

when registering!

Please refer to the Registration Code below:



A Division of Cambridge Innovation Institute

250 First Avenue, Suite 300  
Needham, MA 02494, USA  
[Healthtech.com](http://Healthtech.com)  
Fax: 781-972-5425