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

7th International Molecular Diagnostics EUROPE

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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: Diana Saraceni, Founder, Managing Partner, Panakes Partners, Italy
Panelists: Tim Haines, Managing Partner, Abingworth LLP, United Kingdom
Florian Kainzinger, PhD, Founder, Think.Health Ventures, Germany
Philippe Peltier, Partner, Kurma Partners, France

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**COMPANIES A-K**  
Jon Stroup  
Sr. Manager, Business Development  
781-972-5483  
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**COMPANIES L-Z**  
Ashley Harvey  
Manager, Business Development  
781-972-6292  
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IMPLEMENTATION AND INTERPRETATION OF ADVANCED PRENATAL DIAGNOSTICS

8:55 Chairperson's Remarks
Patricia 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 and Non-Invasive Prenatal Diagnosis for Monogenic Disorders: 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

I will present our experience of delivering a clinical diagnostic service for NIPT for monogenic disorders and implementing fetal exome sequencing as a clinical service. I will discuss test uptake, outcomes and the clinical challenges of case selection, fetal phenotyping and variant interpretation.

10:30 Coffee Break

CELL-BASED NIPT

11:00 Technical Insights into Next-Generation Sequencing Analysis of DNA from Circulating Trophoblastic Cells
Patricia 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 NIPD 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 Implementation of Prenatal Services Accredited Clinical Diagnostic Laboratory – Our Experience and Challenges Addressed
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 clinical laboratory utilizes for non-invasive prenatal diagnosis of single gene disorders and invasive prenatal diagnosis using clinical exome sequencing of fetuses with ultrasound scan abnormalities. I will discuss the challenges in data generation, accreditation, bioinformatics and variant interpretation that we have addressed to be able to offer these services in a timeframe applicable to prenatal setting.

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 Vaiman, 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
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 Steinzinger, 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 Sponsored Presentation (Opportunity Available)
13:15 Luncheon Presentation (Opportunity Available) or 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 Schuuring, 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 biomimetic scoring systems.

15:20 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 markers 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 utilization 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 Presentation to be Announced
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, Invivata Ltd., United Kingdom
Effective clinical management relies on accurate diagnostic information, which requires effective methods and clinical samples. Next generation sequencing can provide a wealth of diagnostic information, but implementing innovative technologies into routine 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: Diana Saraceni, Founder, Managing Partner, Panakes Partners, Italy
Panelists: Tim Haines, Managing Partner, Abingworth LLP, United Kingdom
Florian Kainzinger, PhD, Managing Partner, Founder, Think Health Ventures, Germany
Philippe Peltier, Partner, Kurma Partners, France
Presenter to be Announced, Ysios Capital, Spain

• 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
Brexit on the regulation of IVDs and pharmaceuticals. will look to the recent past and to the future, as regards the impact of trade associations to prepare for the ‘hard Brexit.’ This presentation worst-case scenario, he has worked closely with companies and the EU-UK withdrawal agreement (‘soft Brexit’). Preparing for the medtech attorney, has been closely involved in the negotiations for the United Kingdom will likely have left the European Union. Mr. Van EU-UK withdrawal agreement. At the time of the presentation, the UK prime minister had just survived a no-confidence vote, and the UK Parliament was still to vote on the EU-UK withdrawal agreement. In opposition to the EU 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.

14:35 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 opposition 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.

15:05 Bring Forward the “Intrinsic” Value of Diagnostic Information and the Drive to Value-Based Procurement
Yves Verbelen, Director, Market Access & Economic Policies, MedTech Europe, Belgium
At the time of the abstract, the UK prime minister had just survived a no-confidence vote, and the UK Parliament was still to vote on the EU-UK withdrawal agreement. At the time of the presentation, the United Kingdom will likely have left the European Union. Mr. Van Vooren, a former EU law professor and now practicing pharma and medtech attorney, has been closely involved in the negotiations for the EU-UK withdrawal agreement (‘soft Brexit’). Preparing for the worst-case scenario, he has worked closely with companies and trade associations to prepare for the ‘hard Brexit.’ This presentation will look to the recent past and to the future, as regards the impact of Brexit on the regulation of IVDs and pharmaceuticals.

15:35 Brexit and the Regulation of IVDs and Pharmaceuticals
Bart Van Vooren, PhD, Attorney, Senior Associate, Covington & Burling LLP, Belgium
At the time of the abstract, the UK prime minister had just survived a no-confidence vote, and the UK Parliament was still to vote on the EU-UK withdrawal agreement. At the time of the presentation, the United Kingdom will likely have left the European Union. Mr. Van Vooren, a former EU law professor and now practicing pharma and medtech attorney, has been closely involved in the negotiations for the EU-UK withdrawal agreement (‘soft Brexit’). Preparing for the worst-case scenario, he has worked closely with companies and trade associations to prepare for the ‘hard Brexit.’ This presentation will look to the recent past and to the future, as regards the impact of Brexit on the regulation of IVDs and pharmaceuticals.

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, FFPath (RCPI), FRCPath, Distinguished Research Professor of Clinical Chemistry, Department of Clinical Pharmacology, Goethe 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, FFPath (RCPI), FRCPath, Distinguished Research Professor of Clinical Chemistry, Department of Clinical Pharmacology, Goethe 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
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 benefiting society.

10:05 Presentation to be Announced

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

11:20 Presentation to be Announced

11:50 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

12:20 Presentation to be Announced

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

13:20 Session Break

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 Sponsored Presentation (Opportunity Available)

16:00 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.

16:30 Biomarkers in Immuno-Oncology and Transitioning Them to an IVD – Opportunities and Challenges
Neeraj Adya, PhD, Director, Pharmacodiagnostics Research and Development, Bristol-Myers Squibb, United States

17:00 Close of Conference

DON’T MISS THE RECOMMENDED SHORT COURSES* ON MONDAY!

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, Staff Researcher, Diagnostic Tools and Methods Research Group, Life Sciences, 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.
The global health burden of human viral infectious diseases such as dengue, Zika, and Ebola viruses in biological samples. Our MS-based technologies provide absolute quantification of circulating infectious particles and virus-derived biomarkers using multiplexed MRM-based assays. Next-generation molecular diagnostics for emerging viral diseases: Absolute quantification of circulating infectious particles and virus-derived biomarkers using multiplexed MRM-based assays. The global health burden of human viral infectious diseases such as dengue, Zika, and Ebola virus diseases are dramatically increasing around the world. Here, we report our novel application of multiple reaction monitoring mass spectrometry (MRM-MS) for detecting and quantitating secreted and virion-associated glycoproteins of dengue, Zika, and Ebola viruses in biological samples. Our MS-based technologies offer 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. The global health burden of human viral infectious diseases such as dengue, Zika, and Ebola virus diseases are dramatically increasing around the world. Here, we report our novel application of multiple reaction monitoring mass spectrometry (MRM-MS) for detecting and quantitating secreted and virion-associated glycoproteins of dengue, Zika, and Ebola viruses in biological samples. Our MS-based technologies offer 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.
working with both viral and bacterial infections and include representation from academia and biotech industry.

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 Presentation to be Announced

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 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

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 Presentation to be Announced

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
10:05 Presentation to be Announced

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 a 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 fur Mikroanalysysteme, 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 Breakout Discussions
See website for details.
19:05 Close of Day

THURSDAY 9 MAY
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 Innovative POCT Technologies: An Overview on New Revolutionary Products and Their Influence on Digitalization, Process Optimization and Costs
Peter B. Luppa, 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.

09:35 Quality Management at the Point-of-Care
Claus Langer, PhD, Clinical Chemist, Medizinisches Versorgungszentrum for Laboratory Medicine and Mikrobiologie (mvzlm 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 Presentation to be Announced
10:35 Coffee Break in the Exhibit Hall. Last Chance for Poster Viewing.
11:20 “Theragnostic” and the Burden of Disease: How Misleading Reimbursement Causes 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.
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.
12:20 Sponsored Presentation (Opportunity Available)
12:50 Luncheon Presentation (Opportunity Available) or Enjoy Lunch on Your Own
13:20 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
Ralf Ehrlich, PhD, Senior Principal Scientist, Department of 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 Sponsored Presentation (Opportunity Available)
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

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
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 (CNRS-GH), 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 offer 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 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 Presentation to be Announced

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 Delguez, 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, PCRedux, 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

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 (CNRGJ), CEA – Institut de Biologie Francois 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
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 Wetserskog, 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, FHKKORL, 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 Wetserskog, 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 DI rect the managem ent 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 The Value of Measuring cfDNA Concentration by a Rapid Fluorescent Assay in Emergency Medicine
Amos Doudevani, PhD, Professor, Biochemistry, Director, Laboratory of Nephrology, Clinical Biochemistry and Pharmacology, Soroka Medical Center & Ben-Gurion University, Israel
This talk will include the description of the rapid fluorescent assay used for many applications including sepsis, TBI, pancreatitis and smoke inhalation.

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 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 Sponsored Presentation (Opportunity Available)
12:50 Luncheon Presentation (Sponsorship Opportunity Available) or 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
Èvi 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.

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.

15:00 Sponsored Presentation (Opportunity Available)

NON-ONCOLOGY APPLICATIONS: BRAIN INJURY AND TRANSPLANTATION
15:30 Chairperson's Remarks
Andrea Regner, MD, PhD, Professor, Cellular and Molecular Biology Applied to Health, Course of Medicine, Lutheran University of Brazil, Canoas, Brazil

15:50 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, monitoring 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, FAMM, FFPath (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