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RARECYTE



LIQUID BIOPSY SUMMIT

20 - 21 February 2020 | Lisbon, Portugal

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BIOTECH PHARMA SUMMIT

On 20 and 21 February 2020, Lisbon (Portugal) will host the BioTech Pharma Summit: Liquid Biopsy 2020 conference.

This year's event will bring together the leaders in the field from pharma, biotech, Dx companies and healthcare and be the home of multi-stakeholder and pan-industry collaboration for liquid biopsy, molecular pathology and precision medicine experts to explore the expanding and evolving field whereby Circulating Biomarkers of various classes are being evaluated for their potential to be developed into diagnostics for cancer as well as application of liquid biopsy testing, across biofluids, biomarkers and disease indications, as the needle shifts on the gold standard of personalized healthcare testing.



Latest findings on the clinical applications of CTCs, ctDNA, miRNAs and exosomes in real time monitoring of systemic anticancer therapies will be discussed only at the Liquid Biopsy 2020.

Experts will present and consider process and technology refinements that can enable molecular liquid biopsies to become a fulcrum in the future of precision medicine.

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KEY PRACTICAL LEARNING POINTS

- Liquid Biopsy: New Opportunities, Technologies, and Challenges in the Field
- · Clinical integration of liquid biopsy
- Circulating Tumor Cells: History and Future Perspectives
- Improving the Quality of Circulating Tumor DNA Measurements
- · Circulating Tumor Cells in Monitoring Cancer
- Extracellular vesicles (Evs)
- New Tools for Liquid Biopsies: Microfluidic
 Platforms for the Isolation of CTCs, cfDNA and Exosomes
- CTC Isolation Platforms and Using CTCs for Monitoring Therapy Responses
- Dissecting Mechanisms of Breast Cancer Metastasis Using Patient-Derived Circulating Tumor Cells
- Liquid Biopsies in Cancer Immunotherapy Clinical Drug Development
- · Heterogeneity of Cancer-Derived Extracellular Vesicles
- Liquid Biopsies in Oncology and the Current Regulatory Landscape
- \cdot Validating Liquid Biopsies in Cancer
- \cdot ctDNA Liquid Biopsy Assay



WHO SHOULD ATTEND

CEOs, VPs, Drug developers, Academics and Researchers, CROs, Scientists and Medical Doctors of:

- Liquid biopsy
- Clinical Pathology
- Molecular Assay
 Development
- Medical Laboratory
- \cdot Scientific Affairs
- \cdot Sales and Marketing
- · Quality Management
- Process Development
- Commercial & Outreach,
 Oncology

- Molecular pathology
- · Research Scientist

- Molecular Biology
- Sales & Business
 Development
- \cdot Clinical and
- Translational Affairs
- \cdot Clinical Research
- \cdot Companion Diagnostics
- Biomarkers
- Manufacturing
- Scientific Affairs
- Clinical Trial
- Oncology Business
 Development
- Precision medicine
- · Clinical Laboratory
- Immunochemistry
- · Cell Culture





DR. MARIANNE OULHEN Head of Project at Gustave Roussy

FR



DR. ANDERS STÅHLBERG

Associate Professor at the University of Gothenburg and Sahlgrenska University Hospital in Sweden

SE



PROF. DR. JENS K. HABERMANN

President of ESBB & Head, ICB-L, University of Lübeck

Chair 2nd day

DE



PROF. MIKAEL KUBISTA CEO at TATAA Biocenter

SE



DR. LORENA DIÉGUEZ

Group Leader Medical Devices at INL



DR. MARTINA KAUFMANN

Managing Director at Martina Kaufmann Strategic Consulting

Chair 1st day

DE



DR. FABRICE MAGNINO Assoc Director,

Assoc Director, Medical Affairs EMEA at illumina



DR. CHRISTIAN WERNO

Group Leader, Preclinical Therapy Models at Fraunhofer-Institut

DE

PT



DR. SELINA GAERTNER

Medical Affairs Manager EMEA

at HTG Molecular Diagnostics

DE



DR ALEXANDRE AKOULITCHEV

CSO. Director at Oxford BioDynamics Plc

UΚ

DR. KLAUS PANTEL

Chairman, Department of Tumor Biology

at University Medical Center Hamburg-Eppendorf

DE



DR. DAVIDE ZOCCO Chief Technology Officer at Exosomics



DR. JUAN F. ROMAN PhD, MBA, VP Business Development at ximedica



DR. CLOTILDE COSTA NOGUEIRA Head of the Liquid Biopsy Line of the Roche at Chus Joint Unit

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DR. DANIEL GRÖLZ Scientific Associate Director R&D at QIAGEN



DR. MIROSLAW KORNEK Principal Investigator

(PI) at The University of Bonn

UK



DR. CATHERINE ALIX-PANABIÈRES

Director of LCCRH at University Medical Center of Montpellier



DR. ARJAN TIBBE CEO at VyCAP

DE

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S C I E N T I F I C A G E N D A

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Thursday, February 20, 2020

- 08:00 Registration and Welcome Coffee
- 08:50 Opening of the BioTech Pharma Summit
- 09:00 Liquid Biopsies: Coming of age processing tools By **Martina Kaufmann** - Managing Director at Martina Kaufmann Strategic Consulting
 - > Technology overview
 - > Market overview
 - > Cancer applications today and in the future
 - > Regulatory aspects

09:30 Speed Networking

09:50 Liquid Biopsy and Tumour Comprehensive Genomic Profiling - Future Standard of Care? By **Fabrice Magnino** - Assoc Director, Medical Affairs EMEA at illumina

> New paradigm in cancer managment - One test, multiple drugs, many types of cancer

- > ctDNA From complex to simple
- > The time is now Decentralised precision testing for the beneficts of patients
- > The Pharma _ CRO _ In-Vitro Diagnostic triangle The engine of precision medicine

10:30 Morning Coffee & Networking Break

11:00 Liquid Biopsies: From Discovery to Clinical Implementation

By Klaus Pantel - Chairman, Department of Tumor Biology at University Medical Center Hamburg-Eppendorf

- > The analysis of circulating tumor cells (CTCs) and tumor cell products (DNA,RNA, extracellular vesicles) released into the blood provides clinically relevant information as "liquid biopsy".
- > Liquid biopsy analyses with validated platforms provides information on:
 - > early detection of cancer;
 - > identification of cancer patients at risk to develop relapse (prognosis);
 - > monitoring of tumor evolution;
 - > and therapeutic targets or mechanisms of resistance on metastatic cells.
- > Metastatic cells might have unique characteristics that can differ from the bulk of cancer cells in the primary tumor currently used for stratification of patients to systemic therapy.
- > Liquid biopsy can be used to improve the management of individual cancer patients and contribute to personalized medicine.
- > CTCs are complementary to other liquid biopsy biomarkers.
- > Validation of liquid biopsy assays is essential and currently performed by the EU/IMI consortium CANCER-ID (www.cancer-id.eu) and ELBS (European Liquid Biopsy Society).

11:40 Clinical integration of liquid biopsy

By Christian Werno - Group Leader, Preclinical Therapy Models at Fraunhofer-Institut

> CTCs are already used to predict disease progression and survival in metastatic patients, however functional analysis of ex vivo expanded CTCs remain challenging. We have generated CTC-derived in vivo and in vitro models from metastatic cancer patients. We have molecularly characterized these models and performed drug screens to improve personalized treatment strategies for metastatic patients in future

12:20 3D Genome Architecture as Biomarker Modality

By **Alexandre Akoulitchev** - CSO, Director at Oxford BioDynamics Plc

- > Relevance to Clinical Outcomes
- > Systemic Nature of Epigenetic Signatures and Underlying Cellular Networks
- > EpiSwitchTM Platform and its Design

13:00 Business Lunch

14:00 Circulating Tumor Cells in Monitoring Cancer

By Marianne Oulhen - Head of Project at Gustave Roussy

> The identification of predictive biomarkers of sensitivity and resistance to targeted therapies in non-small cell lung cancer, single CTC analyses and CTC-derived xenograft models for a better understanding of the mechanisms of therapeutic resistance and metastatic progression. I think my presentation could fit the session entitled

14:40 CTCs characterization for metastatic breast cancer patients follow-up

By Clotilde Costa Nogueira - Head of the Liquid Biopsy Line of the Roche at Chus Joint Unit

CTCs are responsible for distal metastasis and of great interest for biomarkers discovery to predict and monitor tumor progression and therapy failure. In this study we performed a monitoring of metastatic breast cancer patients before and after treatment througout CTC molecular characterization to identify biomarkers with interest for clinical oncology translation

15:20 New platforms from CTC isolation and analysis.

By **Lorena Diéguez** - Group Leader, Medical Devices Research Group, INL – International Iberian Nanotechnology Laboratory.

> CTCs for Monitoring Therapy Responses

> Circulating Tumor Cell isolation and analysis

16:00 Coffee & Networking Break

16:30 Circulating Tumor Cells: Finding Rare Events for a Huge Knowledge of Cancer Dissemination

By **Catherine Alix** - Panabières is the Director of this unique platform LCCRH- Université de Montpellier, at Institut Universitaire de Recherche Clinique (IURC)

> Technologies for detection of viable Circulating Tumor cells (CTCs)

> Understanding the biology of CTCs

17:00 From liquid biopsy to single cell data

By Arjan Tibbe - CEO at VyCAP

- > Single cell isolation
- > Single cell DNA / RNA profiles
- > Single cell secretion

17:30 Panel discussion: New Tools for Liquid Biopsies

with Fabrice Magnino, Klaus Pantel, Catherine Alix and Jens Habermann, Moderaded by Martina Kaufmann

> Advancements in microfluidic technologies

- > Microfluidic Platforms for the Isolation of CTCs, cfDNA and Exosomes
- > Progress in Circulating Tumor Cell Research Using Microfluidic Devices on clinical research parameters, such as survival statistics
- 18:00 Chairman's Closing Remarks
- 20:00 Gala Dinner with Live Fado Music

Friday, February 21, 2020

- 08:00 Registration & Coffee
- 08:30 Opening Address from the Chairperson
- 08:40 Circulating tumor DNA- preanalytical considerations, international specimen improvement requirements, standards, legislation, technologies

By Daniel Grölz - Scientific Associate Director R&D, Sample Technologies Department at QIAGEN

- > Need of specimen quality improvement to reduce diagnostic errors
- > Pre-analytical factors that influence the outcome of ccfDNA analysis
- > International initiatives and requirements to standardize pre-analytical workflows
- > Liquid biopsy preservation and workflow solutions
- 09:20 Technical and biological challenges when analyzing cell-free tumor DNA

By **Anders Ståhlberg** - Associate Professor at the University of Gothenburg and Sahlgrenska University Hospital in Sweden

- > Analysis of circulating cell-free tumor DNA (ctDNA) in liquid biopsies offers new means for early cancer diagnostics, real-time monitoring of treatment efficiency and detection of relapse. Despite its potential use ctDNA remains challenging to detect and to quantify as it represents only a small fraction of all cell-free DNA
- > We have developed SiMSen-Seq, that allows allele frequencies < 0.1% to be detected. SiMSen-Seq is simple to perform, flexible in multiplexing and requires minimal DNA input. Here, we will present recent updates
- > Here, we discuss important considerations for ctDNA analysis in plasma, including all experimental steps from sampling to data interpretation. Furthermore, the use of quality control assays enables the development of robust and standardized workflows that facilitate the implementation of ctDNA analysis into clinical routine
- > We will show data from various ongoing studies, related to both clinical and basic research questions
- 10:00 EVs in hepatobiliary cancer, an evolving story By **Miroslaw Kornek** - Principal Investigator (PI) at The University of Bonn
- 10:30 Morning Coffee and Networking Break

11:00 Extracellular vesicles (EVs)

By Davide Zocco - Chief Technology Officer at Exosomics

- > Use of EVs for liquid biopsy approaches: advantages and current challenges
- > Standardization of blood collection and processing for the clinical use of EVs
- > Searching for tumor-derived EVs with SoRTEVTM and SeleCTEVTM enrichment technologies
- > A proof-of-concept study for the early detection of multiple cancers with an EV-based assay

11:40 Two-Tailed PCR for Precision Diagnostic

By Mikael Kubista - CEO at TATAA Biocenter

- > Two-Tailed PCR
- > Ultra-sensitive microRNA profiling
- > Ultra-specific rare mutation analysis
- > Quality assessment of liquid biopsy testing

DAY 2

12:20 Panel discussion: Conclusions and future directions

with Daniel Grolz, Mikael Kubista and Selina Gaertner moderated by Martina Kaufmann

- > Relevancy to utilize CTCs and ctDNA during systemic therapy rather than as early diagnosis markers
- > Tests for mutations in genes encoding therapeutic targets
- > A paradigm shift in liquid biopsy research with EVs or ctDNA being preferred markers over CTC
- > Technical challenges involved in removing Evs

13:00 Business Lunch

14:00 Challenges to the adoption of Liquid Biopsy

By Juan F. Roman - PhD, MBA, VP Business Development at ximedica

- > The offering boom: how other industries went through similar scenarios
- > Adoption of new technologies: luddites or sensible professionals
- > The engineering difficulty of measuring zero, the hoped for 'all clear'
- 14:30 Standardized preprocessing of liquid biopsies through biobanks enables precision medicine By **Jens K Habermann** - President of ESBB & Head, ICB-L, University of Lübeck
- 15:00 Coffee & Networking Break

15:30 Quantitative miRNA Profiling

By Selina Gaertner - Medical Affairs Manager EMEAat HTG Molecular Diagnostics

> Methods and Challenges

16:00 Chairman's Closing Remarks & End of Summit





CHRISTIAN WERNO, DE Group Leader, Preclinical Therapy Models at Fraunhofer-Institut

🗾 Fraunhofer

Dr. rer. med. Christian Werno is research group leader "Preclinical Therapy Models", Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Division of Personalized Tumor Therapy. He got his PhD at Goethe University Frankfurt am Main, then being a postdoctoral fellow at Fraunhofer ITEM Regensburg Division of Personalized Tumor Therapy.



MARIANNE OULHEN, FR Head of Project at Gustave Roussy



Marianne Oulhen is a research engineer at Gustave Roussy . She works in the Dr Françoise Farace's team in the Translational Laboratory of Rare Circulating Cells (CNRS UMS3655 - INSERM US23 AMMICA) and the Circulating Tumor Cells team at INSERM U981. She has a "biotechnologies and Biohealth" master's degree. For the past ten years, she focused her research on circulating tumor cells with the goal of identifying both sensitivity and resistance biomarkers of anticancer therapies.



MIKAEL KUBISTA, SE CEO at TATAA Biocenter



Kubista is one of the pioneers developing quantitative PCR. In 2001 he set up TATAA Biocenter as Europe's leading nucleic acid analyses service provider. In 2014 Kubista set up the diagnostic company Life Genomics AB, in 2018 the Gendoktorn, and in 2019 he co-founded LifeTest.

Most recently Kubista's team invented Two-tailed PCR for ultrasensitive profiling of circulating microRNAs. Kubista is today head of department at the institute of Biotechnology, Czech Academy of Sciences.



CATHERINE ALIX-PANABIÈRES , FR Director of LCCRH at University Medical Center of Montpellier



During this last decade, Dr Alix-Panabières has focused on optimizing new techniques of enrichment, detection and characterization of viable circulating tumor cells (CTCs) in patients with solid tumors. She is the expert for the EPISPOT technology that is used to detect viable CTCs in patients with breast, prostate, colon, head & neck cancer and melanoma. This technology has been recently improved to detect functional CTCs at the single cell level (EPIDROP).



MARTINA KAUFMANN , DE Managing Director at Martina Kaufmann Strategic Consulting



Dr. Martina Kaufmann, Managing Director at Martina Kaufmann Strategic Consulting (www.mk-stracon.com) has 15+ years industry experience in the field of personalized medicine – from biomarker validation, companion diagnostics development to implementation of such products in the market. Her services range from strategic concept development to project specific consulting for CDx development under consideration of strategic, scientific, regulatory, operational and commercial aspects.



ALEXANDRE AKOULITCHEV, UK CSO, Director at Oxford BioDynamics Plc

OXFORD BIODYNAMICS

Alexandre read mathematics, physics, chemistry, biochemistry and biophysics at Moscow Institute of Physics and Technology. In 1989 he was selected by the George Soros Foundation for the Oxford Scholarships, associated with St. Antony's College, Oxford. He obtained his PhD in cell biology from University College, London, with the research based at the Imperial Cancer Research Fund Laboratories.

BIOGRAPHIES



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ANDERS STÅHLBERG, SE Associate Professor at the University of Gothenburg and Sahlgrenska University Hospital in Sweden

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Anders Ståhlberg is working as principal investigator at the Sahlgrenska Cancer Center, University of Gothenburg and Sahlgrenska University Hospital in Sweden. Anders primary research interest is to understand molecular mechanisms in tumor initiation and tumor development, focusing on breast cancer and sarcomas. He has developed several strategies for DNA and RNA, especially at the single-cell and single-molecule level.



JENS K. HABERMANN, DE President of ESBB & Head, ICB-L, University of Lübeck



Prof. Habermann is President of ESBB (European, Middle Eastern & African Society for Biopreservation and Biobanking and scientific director of UCCL (University Cancer Center Lübeck) at the University of Lübeck and University Clinic Schleswig-Holstein. As specialist in human genetics, he combines clinical routine, biobanking, and cancer research to optimize individualized medicine by targeting tumor heterogeneity and applying liquid biopsies.



SELINA GAERTNER, DE Medical Affairs Manager EMEA at HTG Molecular Diagnostics

Selina Gaertner is holding a MSc in Molecular Life Science and joined HTG Molecular in 2016, where she is living the mission to empower precision medicine at the local level, by bridging Molecular Profiling, Biomarker Signature Development and Molecular Diagnostics. She is focusing on advancing the field of Liquid Biopsy, Early Disease Detection, Companion Diagnostics and Precision Medicine with the Extraction-Free RNA analysis solution HTG EdgeSeq.



CLOTILDE COSTA NOGUEIRA,

Head of the Liquid Biopsy Line of the Roche at Chus Joint Unit

Clotilde is a Biologist. In 2011 I developed my phD in Molecular Oncology at CIEMAT (Madrid) focused on the study of cell cycle genes in squamous cell carcinomas. In 2013 she moved to Santiago de Compostela to the Translational Medical Oncology Group to work in the study of metastasis through Liquid Biopsy. Since 2015 she is the leader of the Liq-uid Biopsy Line at the Joint Unit Roche-Chus, University Clinical Hospital of Santiago, focused on the understanding of the biology of Circulating Tumor Cells of metastatic Breast and Prostate patients.



FABRICE MAGNINO , FR Assoc Director, Medical Affairs EMEA at illumina

illumina^{*}

Fabrice Magnino is holding a PhD in Tumour Biology from the Medical Faculty of Berne (Switzerland) and received Breast Cancer postdoctoral training at the Cancer Institute of Montpellier (France) before joining the Life Science and Molecular Diagnostic industry where he is focusing on solutions to improve patient management



PRECISION ONCOLOGY **DAVIDE ZOCCO, IT** Chief Technology Officer at Exosomics

exosomics

Davide Zocco joined Exosomics in 2013 with the mandate to introduce and implement into the R&D pipeline the develop-ment of molecular assays for detection of EV shuttled mutations. In 2015 he took on the role of the Head of Molecular Diagnostics. Today he is responsible for development of EV-DNA and EV-RNA targeted solutions and for management of clinical testing of assay prototypes. Davide actively participates in scouting for new technologies, as well as internal IP strategy and pre-market launch of RUO and diagnostic kits.



LORENA DIÉGUEZ, PT

Group Leader, Medical Devices Research Group, INL – International Iberian Nanotechnology Laboratory



nanobioengineered diagnostics microsystems for the isolation and characterization of Tumor Cells from body fluids of cancer patients, as well as the development of microfluidic organ-on-a-chip 3D models.



KLAUS PANTEL, DE Chairman, Department of Tumor Biology at University Medical Center Hamburg-Eppendorf



Prof Pantel is Chairman of the Institute of Tumour Biology at the University Medical Center Hamburg-Eppendorf. The institute is part of the Centre of Experimental Medicine and the University Cancer Center Hamburg (UCCH). Prof Pantel graduated in 1986 from Cologne University in Germany and completed his thesis on mathematical modelling of haematopoiesis in 1987.



DANIEL GRÖLZ, DE Scientific Associate Director R&D at QIAGEN



NTERNATIONAL IBERIAN

Dr. Grölz is the R&D project manager who led an international team within PreAnalytiX GmbH to develop the PAXgene Tissue and the PAXgene Blood ccfDNA Systems. He was the leader for the evaluation of the PAXgene Tissue System within the European collaborative grant project, SPIDIA, and manages work packages in two other grant projects to evaluate the PAXgene Tissue and PAXgene Blood ccfDNA Systems for use in routine pathology workflows. He is the main inventor of the PAXgene Tissue System and inventor/co-inventor of the PAXgene Blood ccfDNA stabilization chemistry.



JUAN F. ROMAN, UK PhD, MBA, VP Business Development at ximedica

ximedica

Medical technology business developer with an international world-class technical and commercial background. A career of over twenty years in Diagnostics and MedTech, always working in forefront technologies, with the most recent ten years successfully involved in the organisation of research and development joint ventures with blue-chip healthcare, diagnostics and life sciences companies.

Based in Cambridge, UK, Juan has a BSc in Physics, two MSc in optical technologies, a PhD in optical technologies applied to medical measurements and an MBA



MIROSLAW KORNEK, DE Principal Investigator (PI) at The University of Bonn



Dr. Miroslaw Kornek is working as a principal investigator at the Department of Internal Medicine I, University Hospital Bonn, University of Bonn, Germany. He completed his Ph.D. in Department of Internal Medicine I, University Hospital Bonn, University of Bonn, Germany. His position and research work was funded by the German Cancer Foundation (Deutsche Krebshilfe e.V.) and recently by the Deutschen Forschungsgemeinschaft (DFG, German Research Foundation). He spent his post-doctoral time at BIDMC, Harvard Medical School from 2008 until 2012 in Dr. Schuppan's and Dr. Afdhal's laboratories.



ARJAN TIBBE, NL CEO at VyCAP



After completing his PhD in 2001, Arjan established and managed Im-municon Europe, Enschede, the Netherlands, a subsidiary of Immunicon Corporation, USA. Immunicon developed the FDA cleared CellSearch system for monitoring metastatic cancer by measuring the number of CTC. Immunicon was ac-quired by Veridex, a Jonhson

& Johnson company, in 2008 where he held the same position within the Enschede facility.











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On the banks of the Tagus River and with panoramic views, the unique and futuristic oasis that is MYRIAD offers luxurious, contemporary accommodation. It features a chic restaurant & bar and an indoor pool with spa and fitness facilities.

Featuring original and colorful décor, each spacious suite and room has stunning views of Lisbon, Tagus River and Vasco da Gama Bridge. Each has a flat-screen TV, an espresso coffee machine and a minibar.

MYRIAD by SANA Hotels serves a buffet breakfast daily. The designed restaurant serves Portuguese and international cuisine, guests also have the option of dining al-fresco. The bar offers evening entertainment and has a large selection of cocktails and snacks.

Guests can enjoy a swim in the indoor pool which has a massage area. Relax with a variety of treatments in the SPA center while the sporty type can exercise in the gym. MYRIAD by SANA Hotels has large seating areas for guests to relax or socialize.

The hotel also has an events center for weddings, parties or conferences. Lisbon International Airport is a 10 minute drive away.

Parque das Nações is a great choice for travelers interested in monuments, city trips and history.







