SPIDIA4P event on standards
at the European Parliament in Brussels

TACKLING ISSUES ON IN VITRO DIAGNOSTICS FOR PERSONALISED MEDICINE, SPIDIA4P

Tuesday 5th March 2019
Room P5B001, 9:00 – 12:00

Hosted by Lieve Wierinck (ALDE Belgium) and Gesine Meissner (ALDE Germany), Members of the European Parliament.

www.bbmri-eric.eu
www.spidia.eu

The SPIDIA4P project receives funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733112.

Agenda

Time	Course	Who
09:00 – 09:30	Registration	
09:30 – 09:50	Welcome and opening remarks	MEP Gesine Meissner MEP Lieve Wierinck Erik Steinfelder, BBMRI-ERIC
09:50 – 10:30	**Keynote presentations**	
	– MD-IVD regulation: what will be the future obstacles and opportunities?	Oliver Bisazza, MedTech Europe
	– SPIDIA4P & BBMRI-ERIC: what are the solutions we can provide?	Uwe Oelmueller, SPIDIA4P Project Coordinator, QIAGEN
	– Biobanking: key to the implementation of standards in personalised medicine	Kurt Zatloukal, BBMRI.at
	– European Commission's perspective	Jean-Luc Sanne, DG RTD
10:30 – 11:15	**Panel discussion** Moderators: Oliver Bisazza & Francesco Florindi Taking inspiration from the four keynote presentations, panellist will provide their perspective and animate a debate on the future of biomarkers development, personalised medicine and standardisation. Each panellist will provide a 3 min opening statement. The audience will be able to ask questions and provide comments during the debate.	Ashok Ganesh, CEN-CENELEC Uwe Zimmermann, DAkkS Patricia Carrigan, EFPIA & Bayer Giorgio Stanta, ESP & OECI
11:15 – 11:30	**Conclusions**	MEP Gesine Meissner MEP Lieve Wierinck
11:30 – 12:30	**Interviews with speakers**	
12:30 – 15:00	**Lunch**	

The SPIDIA4P project receives funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733112.

Preamble

Future of healthcare is personalised medicine, that is to develop tailor-made solutions to the specific needs of individual patients and well-defined patients' cohorts.

Standards play an important role in the development of personalised medicine solutions. They are part of the knowledge economy facilitating innovation and the adoption of new technologies. They are key elements of the competitiveness of European industry. They can improve safety and performance of products and services. Patients benefit from the standardisation of in vitro diagnostic practice."

A panel of experts from all over Europe will address the following questions:

- What are policy/regulatory obstacles to the development of sustainable in vitro diagnostic solutions for personalised medicine? Can the improvement of patient samples qualities speed up the development of new innovative personalized medicine solutions and reduce the number of diagnostic mistakes, which can cause patients deaths and adverse events?

- How can SPIDIA4P and BBMRI-ERIC provide solutions to in vitro diagnostics, industry and researchers?

- How can in vitro diagnostics and pharmaceutical companies gain access to the best patient samples available to enable the successful, quick and safe development of products? How can new European CEN / International ISO standards contribute to the sustainability of healthcare systems by reducing the number of diagnostic mistakes?

- How can new CEN and ISO standards support compliance with the new European In Vitro Diagnostic Regulation (IVDR 2017/746)?

- How can funding organisations, including the European Commission, guarantee the uptake of new standards?

Speakers

Gesine Meißner

Gesine Meißner has been member of the European Parliament since 2009. She is a member of the German liberal Free Democratic Party (FDP) and chair of the FDP delegation in the European Parliament. The FDP is a part of the Alliance of Liberals and Democrats for Europe (ALDE). Gesine Meißner is member of the Committee on Transport and Tourism (TRAN), substitute member of both the Committee on Environment, Public Health and Food Safety (ENVI) and the Committee on Industry, Research and Energy (ITRE). Mrs Meißner is also the president of the European Parliament Intergroup for Seas, Rivers, Islands and Coastal Areas (SEARICA) and Special Envoy of the President of the European Parliament on maritime policy. Furthermore, she is a member of the EU-Mexico Delegation and the Euro-Latin American Parliamentary Assembly (Eurolat).

Before joining the European Parliament, Gesine Meißner was a member of the Regional Parliament of Lower Saxony where she chaired the Committee on Health and Social Affairs from 2003 to 2009. She also worked as a freelance communication coach and was deputy director of the "Rural Adult Education Lower Saxony" association.

Gesine Meißner was born in 1952 in Uelzen, Lower Saxony, Germany.

Lieve Wierinck

Lieve Wierinck is a Flemish politician for the liberal Open VLD party. Mrs. Wierinck holds a pharmaceutical degree from the VUB (Vrije Universiteit Brussel). In addition, she obtained a Post-graduate degree of Pharmaceutical management in 2006 at the University of Hasselt. In line with her academic background, she owned and managed a pharmacy for nearly 30 years.
Before joining the European Parliament, Lieve was leader of the party fraction in Zaventem, followed by her twelve-year presidency of the OCMW (Public Centre for Social Welfare), where she managed a staff of 150 people. She combined this with her obligations as a fulltime member of the City Council of Zaventem. From December 2011 until June 2014, she was a member of the Belgian Federal Parliament, where she was a member of the Committee for Public Health, Environment and Social Renewal, and of the Advisory Committee on Societal Emancipation.
In May 2016, Lieve replaced Mr. Philippe De Backer as a Member of the European Parliament, where she is a full member of the Industry, Technology, Research and Energy Committee (ITRE) and a substitute Member of the Committee on Economic and Monetary affairs (ECON). Lieve also works on topics surrounding healthcare, as she strives for a progressive and affordable healthcare in Europe.

Erik Steinfelder

Erik Steinfelder earned his Bachelor of Science degree in Analytical Chemistry from the Saxion University of Applied Sciences in Deventer, Netherlands, and subsequently completed a degree in Foundations of Management at Nyenrode Business University in Breukelen, Netherlands. In 2008, he joined Thermo Fisher Scientific, a multinational biotechnology product development company based in the US. In his position as first Biobank Commercial Leader EMEA, he went on to head the complete biobank portfolio and range of activities and, most recently, became Corporate Accounts Executive. Additionally, between 2014 and 2017, he was also President-elect, President and past President of ESBB, the European, Middle Eastern and African Society for Biopreservation and Biobanking. He started his position as Director General of BBMRI-ERIC on the 1st August 2017.

Oliver Bisazza

Oliver Bisazza is Director of the Regulations & Industrial Policy department at MedTech Europe, the European trade association representing the medical technology industries, from diagnosis to cure.

Oliver's role is to support the industry in implementing the new EU Regulations for medical devices and in vitro diagnostic medical devices. In parallel, he communicates the various positions of MedTech Europe to the European Commission, to Member State authorities, and to other relevant stakeholders.

Before joining MedTech Europe, Oliver worked at Medtronic as Director of Regulatory Policy for EMEA. In addition to this company experience, he had various trade association roles in Brussels.

Uwe Oelmueller

Dr. Uwe Oelmueller joined the company QIAGEN in 1995. He holds a Vice President position and he is heading the technology center "Diagnostic Sample Preparation Technologies" within QIAGEN's global Molecular Diagnostics (MDx) Development Department and is a member of QIAGEN's MDx Development Leadership Team.

At the QIAGEN / Becton Dickinson joint venture company PreAnalytiX he is QIAGEN's management committee co-chair.

Since 2009 he is a member of the CEN/Technical Committee 140 (In vitro Diagnostic Medical Devices) Working Group 3 "Quality Management in the Medical Laboratory" with a current focus on preanalytical workflows. Since 2014 Dr. Oelmueller is the convener of the ISO/Technical Committee 212 (Clinical Laboratory Testing and In Vitro Diagnostic Test Systems) Working Group 4 focusing on "Molecular Diagnostics and Microbiology".

Dr. Oelmueller was the coordinator of the European FP7 Collaborative Grant Project SPIDIA (funding period 2008-2013). The SPIDIA consortium was working on the standardization and improvements of pre-analytical tools and procedures. Dr. Oelmueller also leads or participates in other international or European grant consortia projects such as STRATFix (UK), CBmed (Austria), CDLaboratory (Austria), CANCER-ID (Innovative Medicine Initiative Europe), PEGASUS (Canada) and others.

Kurt Zatloukal

Kurt Zatloukal, M.D. is professor of pathology at the Medical University of Graz, Austria and head of the Diagnostic and Research Center for Molecular BioMedicine. His research focusses on molecular pathology of diseases as well as biobanking and related data management technologies. He coordinated the preparatory phase of the European biobanking and biomolecular research infrastructure (BBMRI-ERIC) and is director of the Austrian national node BBMRI.at. He directed the Christian Doppler Laboratory for Biospecimen Research and Biobanking Technologies. He contributes to the development of new European standards and norms for pre-analytical processing of tissue samples for molecular testing and is member of the Austrian Standards Institute and of the scientific board for genetic testing and human gene therapy at the Austrian Ministry of Health. He was member of the OECD task force on biological resource centres and the Roadmap Working Group of the European Strategy Forum on Research Infrastructures. He is Member of the Academia Europaea, corresponding member of the Austrian Academy of Sciences, and has published over 215 scientific papers and was co-inventor of 25 patent applications.

Speakers

Jean-Luc Sanne

Jean-Luc SANNE received the PhD degree in neurosciences at the University Claude Bernard of Lyon (France). He has been a research fellow in the United States at the University of Georges Town, Washington DC, and then at the National Institutes of Health. After an experience in the private sector, he joined the European Commission in 2000 as a Scientific Officer. He is there devoted to the definition and to the implementation of health research programmes and policies of the European Union. He has been in charge of the in vitro diagnostics area at the Health directorate of Directorate-General for Research & Innovation for many years. He is now strongly involved in the orientations and in the development of policy European initiatives in the field of personalised medicine.

Ashok Ganesh

Ashok Ganesh is Director for Market Perspectives and Innovation at CEN & CENELEC and has worked in standardisation for over 20 years.

His current responsibilities focus on developing market potential for innovative technologies and market applications including addressing the digital transformation of industry and achieving deeper integration of standards and research.

He has also supported standardisation in a range of industry sectors including construction products, aerospace, medical devices and consumer products as well as supporting SME and societal stakeholders to benefit from standards and initiatives on Education about Standardisation.

Uwe Zimmermann

After getting his diploma in Biology Uwe Zimmermann worked several years in environmental monitoring and drinking water research with biological test methods.
During this time he made his first experiences in quality- and environmental-management.
Since 1999 he worked as lead assessor and file manager for the German Accreditation Body Chemistry (DACH) for medical laboratories, testing laboratories and inspection bodies in different technical areas.

He worked as deputy head of the accreditation body and was responsible for the areas of healthcare and forensics.

With the merger of the different german accreditation bodies to the national Accreditation body (Deutsche Akkreditierungsstelle GmbH DAkkS) he started working as the Head of Division Health | Forensics in 2010.

He also participates in different international committees (International Organization for Standardization (ISO), European co-operation for Accreditation (EA) und International Laboratory Accreditation Cooperation (ILAC)) and works as peer-evaluator for EA and ILAC.

Patricia Carrigan

Patricia Carrigan, Ph.D. has over 20 years of experience in the life science industry focusing the majority of her time on Biomarker discovery/translational research, and the development of Companion Diagnostics. Currently, she is the Head of Regulatory Affairs, Companion Diagnostic Oncology for Bayer AG where her team also oversees the medical device regulatory development strategies for Bayer's RX-CDx co-development programs. Prior to Bayer, Patricia built a high performing team as a Senior Manager of Assay Development at Roche-Ventana where her team was responsible for developing robust prototype Immunohistochemical and In Situ Hybridization assays. Some of the key Companion Diagnostic programs that she managed which are now at the forefront of Immuno-oncology and Precision Medicine include PDL1, ROS, ALK, and BRAFV600E.

Giorgio Stanta

Prof. Giorgio Stanta of the University of Trieste is a well-known expert in molecular pathology and diagnostics for oncology at European level. He is involved in many European organisations in the role of:

- coordinator of the European group "Archive Tissues: Improving Molecular Medicine Research and Clinical Practice - IMPACTS" (www.impactsnetwork.eu).
- chairman of the "Biobanking and Molecular Pathobiology Working Group" of the OECI (Organisation of European Cancer Institutes – www.oeci.eu).
- vice-chairman of the "Molecular Pathology Working Group" of the ESP (European Society of Pathology – www.esp-pathology.org).
- member of the managing board of BBMRI.IT (Italian Biobanking Infrastructure).
- member of the Committee of CEN (European Committee for Standardization) for Molecular in-vitro diagnostic examinations - Specifications for pre-examination processes for fresh tissues, FFPE tissues, blood for DNA, RNA and proteins, technical specifications.
- liaison representative from the European Society of Pathology to CEN/TC 140.
- member of the European Commission Initiative on Breast Cancer - Quality Assurance Scheme Development Group (QASDG), in which he is the Chair of the Clinical Research Subgroup.

Prof. Stanta is involved in active European projects such as HERCULES on High Grade Serus Ovary Carcinoma, and SPIDIA4P project of QIAGEN on Preanalytical Conditions of Tissues and he is also in charge for the development of the European Molecular Pathology Master.

Moderators

Andrea M. Wutte

Since 2014 Andrea M. Wutte has been leading BBMRI-ERIC HQ Service Quality. The service includes QM consultancy programmes for biobank relevant standards and guidelines, monitoring and audit programmes, training and education formats, assessments and the initiation of improvement strategies, respectively actions and accompanying measures. She acts as BBMRI-ERIC Liaison Officer to ISO/TC 276 Biotechnology and ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems. Andrea started her academic career as a research assistant in the field science of endocrinology and metabolism at the Medical University of Graz. As clinical quality manager she was responsible for the establishment of a comprehensive QM system for clinical trials, according to ethically and legally binding principles and laws. From 2004 to 2009 she was responsible for the core facility 'Clinical Research Centre of the Center for Medical Research' at the Medical University of Graz and designed and lectured several ICH-GCP workshop series for researchers and the industry. In 2009, Andrea stepped out of academia to make her contributions to the cluster Human.technology Styria, where she had been recruited as senior consultant to manage the Styrian regional development as well as to lay the foundations for businesses in the field of biobanking and biomarker technology within the defined economic and strategic aims of the cluster. She represented the business at international congresses and conventions. She contributed her quality management experience to lead the cluster, focused on interface management with stakeholders, to certifications according to ISO 9001 and 29990.

Francesco Florindi

Francesco obtained a cum laude Master's degree in International Relations and Diplomacy from the University of Trieste-Gorizia with a thesis on EU enlargement. In 2011, he started working for regional representatives, NGOs, and the European Commission's Joint Research Centre (JRC) in Brussels. He went on to join the European Cancer Patient Coalition as Public Affairs Coordinator and became Head of EU Affairs in 2016. His experience working in healthcare dates back to 2013, when he joined the ECCO and SIOPE Public Affairs team. Francesco has worked on a number of key European issues such as data protection, health technology assessment, access to quality healthcare, eHealth/mHealth and patient advocacy. These experiences made him understand how patients and healthcare professionals can fruitfully collaborate at European and international level in order to reach common goals. Francesco is a fellow Young Gasteiner and a Member of the European Health Parliament. He is Italian and speaks English and French.

INCREASING THE VISIBILITY OF BIOBANKS AND SAMPLE COLLECTIONS

Who we are?

SPIDIA4P

"SPIDIA for Personalised Medicine - Standardisation of generic Pre-analytical Procedures for In vitro DIAgnostics for Personalised Medicine", in short SPIDIA4P, focus on pre-analytical workflows needed for personalised medicine.
The SPIDIA4P project is funded by the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733112. The consortium of 19 highly experienced partners from private industry including SMEs, public institutions and one European Standards Organisation is again coordinated by QIAGEN GmbH.

The overall objective of this 48-month project, SPIDIA4P, is to bring together key experts and 19 stakeholder's organizations with the needed critical mass in knowledge on pre-analytical and analytical procedures, European and International standardisation organisations' processes (CEN and ISO), external quality assurance, quality management, ethics and regulatory demands. These highly experienced partners will develop and write selected high priority pre-analytical CEN and ISO standard documents as well as corresponding External Quality Assurance (EQA) schemes and implementation tools. These are needed for 1) reducing the number of sample-based diagnostic mistakes, 2) reducing the number of non-reproducible pre-clinical and clinical studies, thus enabling 3) improving and speed up of biomarker discoveries and validations for reinforcing the era of personalized medicine and innovations in patient care.

Find out more on **www.spidia.eu**

BBMRI-ERIC

BBMRI-ERIC stands for "Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium". 20 European countries (represented by their Ministries of Research) and the World Health Organisation's International Agency for Research on Cancer - IARC joined forces to establish BBMRI-ERIC as a research infrastructure for biobanking, providing services and connecting biobanks across Europe. Our mission is to facilitate access to biological resources and biomedical facilities.

BBMRI-ERIC is an international, non-for-profit organisation established under EU law. Its headquarters are in Graz, Austria and it has a liaison office in Brussels.
BBMRI-ERIC provides support and services to local biobanks via BBMRI National Nodes (one per country). The National Nodes are fully involved in the day-by-day management of BBMRI-ERIC and provide feedback from the national level.
BBMRI's funding comes from membership fees payed by Member States and from EU-funded projects.

Over 100 million samples
One of the key services provided by BBMRI-ERIC is the Directory. The Directory is the largest biobanking catalogue on the globe, with more than 100 million samples. External users (researchers) and BBMRI-ERIC biobanks can use the BBMRI-ERIC Negotiator, a service that simplifies process to obtain information on the availability of relevant samples/data within the Directory, hence boosting research and innovation in the field of health.

"We bring together all the main players from the biobanking field - researchers, biobankers, industry, and patients - to boost biomedical research. To that end, we offer quality management services, support with ethical, legal and societal issues, and a number of online tools and software solutions. Ultimately, our goal is to make new treatments possible."

Find out more about our services on **www.bbmri-eric.eu**

Save the date:

EUROPE BIOBANK WEEK 2019

8-11 October 2019
Lübeck, Germany

europebiobankweek.eu

The SPIDIA4P project receives funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733112.