Tackling issues of in vitro diagnostics for personalized medicine, SPIDIA4P

PRELIMINARY AGENDA, 5TH MARCH 2019, EUROPEAN PARLIAMENT

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? • SPIDIA4P & BBMRI-ERIC: what are the solutions we can provide? • Biobanking: key to the implementation of standards in personalised medicine • DG GROW perspective	Oliver Bisazza, MedTech Europe Uwe Oelmueller, SPIDIA4P Project Coordinator, QIAGEN Kurt Zatloukal, BBMRI.at Salvatore D'Acunto, HoU D4 Health Technologies and Cosmetics, DG GROW (tbc)
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 Paul van Zeijst, Chair, CAMD (tbc) Magda Chlebus, EFPIA (tbc) Sven Hoffmann, TUV (tbc) Giorgio Stanta, ESP & OECI Marisa Papaluca, EMA (tbc)
11:15 – 11:30	**Conclusions**	• MEP Gesine Meissner • MEP Lieve Wierinck
11:30 – 12:30	**Interviews with speakers**	
12:30 – 15:00	**Lunch**	**By invitation only**

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

BACKGROUND

BBMRI-ERIC

BBMRI-ERIC stands for "Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium". 19 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, providing services and connecting biobanks across Europe. BBMRI-ERIC's 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-ERIC funding comes from membership fees payed by Member States and from EU-funded projects.

You can find more detailed information on BBMRI-ERIC structure and functioning here.

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 brand-new 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. Find out more about the Directory here.

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.

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