SPIDIA4P

SPIDIA4P Newsletter 01/2021

CORONA CAN'T STOP US: SPIDIA4P GOES VIRTUAL!

SPECIAL TOPIC:
Implementation of standards
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EDITORIAL

Dear reader,

compromised patients' samples can make in vitro diagnostic test results and research outcome unreliable or even impossible. Preanalytical workflows variables account for about 50 to 70% of medical laboratory errors. Consequently, the new EU In-vitro Diagnostics Regulation 2017/746 (IVDR) explicitly requires the verification of pre-analytical workflow parameters, including sample types, sample collection and stability during transport and storage including duration and temperature limits for developing in vitro diagnostic medical devices.

New European CEN and International ISO Standards are playing an essential role to improve preanalytical workflows for reliable analytical tests developments and implementations in medical laboratories. A several years long development process and broad international consensus ensure that these standards present the state-of-the-art. They are therefore very well suited to fulfill stat-of-the-art requirements for the development of in vitro diagnostic medical devices under the EU IVDR and are also highly valuable tools for biomedical research and biobanking.

In this Newsletter you can find SPIDIA4P's continued strong progress on achieving the final goal to develop and implement 22 new preanalytical workflow standards via the CEN/TC 140 and the ISO/TC 212 as well as associated External Quality Assurance Schemes (EQAs).

SPIDIA4P is furthermore increasingly focusing on the implementation of the new standards. The Newsletter therefore also describes the Consortium's intensified virtual trainings programs and presentations, international networking, new SPIDIA4P publications as well as examples for successful implementations of the new ISO and CEN standards.

SPIDIA4P's work is meanwhile recognized by several awards. As a latest recognition, the European Commission showcased SPIDIA4P as one three success stories from EU funded projects at the World Standards Day in October 2020.

Dr. Uwe Oelmueller, Coordinator, QIAGEN GmbH

LATEST NEWS:

Due to the COVID-19 pandemic, the EU funding period for the SPIDIA4P project has been prolonged for 6 months until June 30, 2021 – SPIDIA4P intends to continue its mission beyond this deadline.

WP1 UPDATE STANDARDS! // ULRIKE SCHRÖDER

ULRIKE SCHROEDER

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Despite the worldwide obstacles and limitations due to the CoViD19-pandemic, 2020 has been another very busy year for Work package 1 (WP1) to reach the goal of creating and implementing the portfolio of 22 pre-analytical CEN Technical Specifications and ISO International Standards[1] (together with the existing standard documents initiated by SPIDIA) for selected pre-analytical workflows needed for personalized medicine.

In February 2020, the working group responsible for the development of the standard documents on European level, CEN/TC 140/WG 3 „*Quality management on the medical laboratory*", had one last face-to-face meeting in Brussels, before working on the documents shifted exclusively to online meetings. The working group, consisting of a high number of SPIDIA4P-partners as well as further pan-European experts, mastered the challenge of transferring full-day meetings into several shorter remote meetings and got together almost every month to draft and discuss the documents.

Together, they achieved great progress for the 12 new CEN/TS and 2 new ISO standards under the main title "Molecular *in vitro* diagnostic examinations – Specifications for pre-examination processes…":

Task	Project/document title	Status
1.1	…for circulating tumour cells (CTCs) in venous whole blood – Part 1: Isolated RNA	Published as CEN/TS 17390-1 NWI in proposal (ISO)
1.1	……for circulating tumour cells (CTCs) in venous whole blood – Part 2: Isolated DNA	Published as CEN/TS 17390-2 NWI in proposal (ISO)
1.2	…for circulating tumour cells (CTCs) in venous whole blood – Part 3: Preparation for analytical CTC staining	Published as CEN/TS 17390-3 NWI in proposal (ISO)
1.3	…for saliva – Isolated DNA	Published as CEN/TS 17305 Preparatory Stage (ISO) as EN ISO 4307
1.4	…for frozen tissue – Part 3: Isolated DNA	Published as CEN/TS 16826-3 FDIS Stage (ISO) as EN ISO 20184-3
1.5	…for exosomes and other extracellular vesicles in venous whole blood – Isolated RNA, DNA and proteins	Finalization of Working draft
1.5	…for venous whole blood – Isolated circulating cell free RNA from plasma	Preparatory Stage
1.6	…for urine and other body fluids – Isolated cell free DNA	Preparatory Stage
1.7	…for Fine Needle Aspirates – Part 1: Isolated cellular RNA	Finalization of Working draft
1.7	…for Fine Needle Aspirates – Part 2: Isolated proteins	Finalization of Working draft
1.7	…for Fine Needle Aspirates – Part 3: Isolated genomic DNA	Finalization of Working draft

[1] On the European level, the standardization projects are developed within the European standard organizations (CEN) Technical Committee CEN/TC 140 "In vitro diagnostic medical devices" as CEN technical specifications (CEN/TS) to be later introduced into the international organization of standardizations (ISO) technical committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" with EN ISO standards as envisioned documents.

1.8	...for human specimen – Isolated microbiomes	Registered as CEN/TS 17626 Final Approval Stage
1.9	...for metabolomics in urine, venous blood serum and plasma	FDIS Stage (ISO) as EN ISO 23118
1.10	...for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 4: In situ detection techniques	FDIS Stage (ISO) as EN ISO 20166-4

Key: Key: NWI – New work item, FDIS – Final Draft International Standard

Out of the first wave of SPIDIA4P projects, referred to as Task 1.1 to Task 1.4, the documents on circulating tumor cells (Task 1.1 to 1.2) were published as CEN/TS-series 17390 in January 2020. Supported by a decision of CEN/TC 140, the documents have been proposed to ISO/TC 212 for development as ISO/TS documents and will now go into international balloting for registration as new work items within ISO/TC 212.

The saliva document (Task 1.3), published as CEN/TS 17305:2019, is already several steps further on ISO level and being developed as EN ISO 4307. Currently a committee draft, the document will soon go into the European and international enquiry stage.

CEN/TS 16826-3:2018, the frozen tissue document out of Task 1.4, is being developed on ISO-level as 20184-3. After passing the enquiry stage, it will now go on into the international final approval stage.

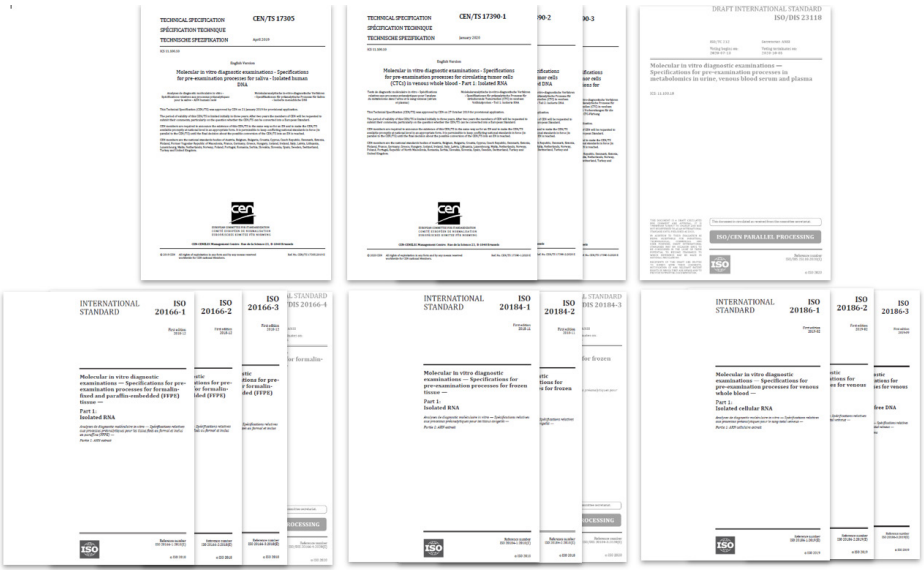
For the second wave of projects (Task 1.5 to Task 1.8), the majority of work within WP1 and CEN/TC 140/WG 3 focused on the documents on different Fine Needle Aspirates (FNA) analytes (Task 1.7) and the document on isolated microbiome DNA (Task 1.8). The latter project on microbiome DNA was submitted to CEN where it is due to go into approval voting by the end of this year as CEN/TS 17626.

The documents on different FNA analytes (Task 1.7) proved to be more challenging than expected, but are now close to their finalization within the CEN working group. Once they are ready to enter the final European approval stage (expected in 2021/Q1), the three remaining documents on isolated RNA, DNA and proteins from extracellular vesicles (Task 1.5), on isolated circulating cell free RNA from plasma (Task 1.5) and on isolated cell free DNA (Task 1.6) will be aligned and finalized as well.

Further great progress has been made for ISO 23118 on metabolomics (Task 1.9) and for 20166-4 on in situ detection techniques (Task 1.10) on ISO level under the Vienna Agreement. Both documents passed the international enquiry stage with 100% approval and will continue on to the international final approval stage.

The end of the SPIDIA4P funding period is approaching fast and with four documents on the last step before publication (one on CEN level and three on ISO level under the Vienna Agreement), three documents close to finalization for European approval and further three documents in preparation, all partners and experts within SPIDIA4P, CEN/TC 140/WG 3 and ISO/TC 212/WG 4 work with great effort and determination to reach the goal of developing this comprehensive portfolio of standards and ultimately, of improving the global healthcare systems.

Already now, I would like to express my sincere thanks to everyone involved – standardization[2] is an effort of all for all and would not be possible without your time, hard work and continuous engagement!



[2] Standardization is a process open to everyone and further input and expertise is always needed and appreciated. If You, Your company or Your research institute are interested in working on the above mentioned projects, please contact Your national standardization body or the secretariat of CEN/TC 140/WG 3 "Quality management in the medical laboratory" (ulrike.schroeder@din.de) for further details on how to get involved!

THE SPIDIA AND SPIDIA4P PROJECT HAS LED TO THE PUBLICATION OF THE FOLLOWING CEN/TS AND ISO STANDARDS IN 2018–2019

ISO-series 20166 – FFPE tissue	
ISO 20166-1:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 1: Isolated RNA	www.iso.org/standard/67179.html
ISO 20166-2:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 2: Isolated proteins	www.iso.org/standard/69802.html
ISO 20166-3:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 3: Isolated DNA	www.iso.org/standard/69803.html
ISO-series 20184 – Frozen tissue	
ISO 20184-1:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for frozen tissue – Part 1: Isolated RNA	www.iso.org/standard/67215.html
ISO 20184-2:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for frozen tissue – Part 2: Isolated proteins	www.iso.org/standard/69801.html
ISO-series 20186 ISO-series 20186 – Venous whole blood	
ISO 20186-1:2019, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for venous whole blood – Part 1: Isolated cellular RNA	www.iso.org/standard/67217.html
ISO 20186-2:2019, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for venous whole blood – Part 2: Isolated genomic DNA	www.iso.org/standard/69799.html
ISO 20186-3:2019, Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 3: Isolated circulating cell free DNA from plasma	www.iso.org/standard/69800.html

INITIATED BY THE SPIDIA4P PROJECT AND PUBLISHED AS CEN/TS – MORE TO COME!

CEN/TS 16826-3:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for frozen tissue – Part 3: Isolated DNA	www.din.de/en/wdc-beuth:din21:281615991
CEN/TS 17305:2019, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for saliva – Isolated human DNA	https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT:62239&cs=130B991FE0957A5743F90225BBCACEABB
CEN/TS17390-1:2020: Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood – Part 1: Isolated RNA	https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT:65450&cs=1799CD1DD5E0FBEEBE1246AC9CE6AB2F1
CEN/TS17390-2:2020: Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood – Part 2: Isolated DNA	https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT:65452&cs=1B8E3EC3BB49D6FF8A6AA7684A31C1226
CEN/TS17390-1:2020: Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood – Part 3: Preparations for analytical CTC staining	https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT:65451&cs=1406EA2E6FBA608D914F22B25BFD6A1BC

SPIDIA4P SUCCESS STORY // EU STANDARDIZATION FACT SHEET

SUCCESS STORY:

Standardization Fact Sheet –Great recognition by the European Commision!

On the occasion of the World Standards Day on October 14, 2020, the unit in charge of valorisation policies and intellectual property rights at the European Commission published a factsheet on standardisation demonstrating that standardisation is a crucial tool in the valorisation of knowledge & innovation.

The SPIDIA4P project was chosen to be one of the 3 success stories showcased in this factsheet – what a great recognition of the work and importance of the SPIDIA4P consortium and its efforts to initiate 22 new pre-analytical ISO and European CEN standard documents to standardise the pre-analytical phase and hence reducing the diagnostical errors!

Please take a look at the Social Media posts and online promotion by the European Commission and DIN:

https://twitter.com/EUScienceInnov/status/1316376633671143426

https://www.din.de/de/service-fuer-anwender/normungsportale/gesundheit/aktuelles/spidia4p-und-reach2020-erfolgsbeispiele-fuer-die-normung-und-standardisierung-in-forschungsprojekten-770822

On the next two pages, you can take a look at the Standardization Fact Sheet!

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VALORISATION POLICIES

MAKING RESEARCH RESULTS WORK FOR SOCIETY

FROM RESEARCH TO STANDARDS

WHY ARE STANDARDS IMPORTANT?

The European Green Deal and the New Industrial Strategy for Europe make clear that developing new standards will be essential to boost industry's competitiveness, build a sustainable future and shape a Europe fit for the digital age.

WHAT IS DONE AT EU LEVEL?

A standard is a document that sets the technical requirements of a product, service or process and its use. Standards are adopted by recognised standardisation bodies (such as ISO, CEN, CENELEC, ETSI, and many more). In these organisations, representatives from industry, research, governments and civil society, discuss and agree on what should be a standard. Once a standard is published, its use is normally voluntary but in some cases certain specific standards can be made mandatory by law.

The COVID-19 crisis has illustrated the crucial importance of standards as a mean to valorise knowledge. During the pandemic, there was a shortage of medical protective equipment, such as masks. Manufacturers adapted existing production lines to fabricate more of them. However, how could people be sure that these masks were safe and efficient against the virus? Thanks to standards!

Upon a request by the European Commission, European and national standardisation bodies made standards freely available to ensure the production of high quality protective masks to keep citizens safe against COVID-19.

In other words, standards form a common language that allows researchers, people, public institutions and industry to communicate, produce and commercialise products and services. This is especially important in the European single market.

HOW R&I CAN CONTRIBUTE TO STANDARDISATION AND VICE VERSA?

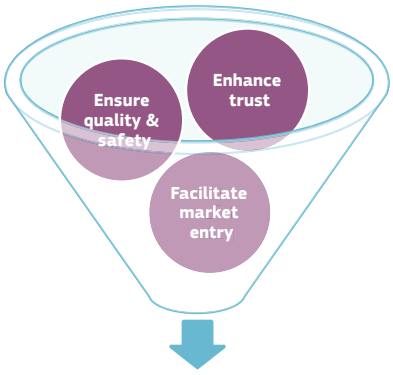
Standards are a crucial tool to valorise research results.

They help researchers bring their innovation to the market and spread technological advances by making their results transparent and ensuring high quality. Standards give confidence to consumers that an innovative technology is safe.

They codify the technology requirements and inform both manufacturers and consumers on what to expect.

They allow technologies and materials to be interoperable: since a standard provides details on the use and content of a technology or a material, it is much easier to know when and how it can be used in combination with other technologies.

R&I Framework programmes ensure that beneficiaries of EU funded research realise the potential of using standardisation.



STANDARDS =
DRIVER FOR INNOVATION & MARKET GROWTH

SUCCESS STORIES

SPIDIA4P

How standardisation helps applying innovative research results to reduce the numbers of diagnostic errors in healthcare

Patient samples, such as blood samples, can significantly alter after collection from the body, e.g. during storage, transport and processing before a laboratory test is run (pre-analytical phase). This can lead to wrong diagnostic results. About 50% - 70% of clinical laboratory errors are caused by the pre-analytical phase. SPIDIA4P has 22 new pre-analytical ISO and European CEN standard documents to standardise the pre-analytical phase and hence reducing the errors.

"Standards ensuring good quality patient samples are key enablers for improving diagnostics, biobanking and biomedical research",
Dr. Uwe Oelmüller, coordinator of Spidia4P

https://www.spidia.eu/

HYDROGEN

How research results helped existing standards to adapt to new technologies

The EU's Energy Strategy encourages the use of hydrogen for transport, but impurities can damage or degrade fuel cells. New technically validated standards are vital for expansion of hydrogen supply infrastructure and improved quality and efficiency.

EURAMET's EMPIR HYDROGEN project advanced hydrogen purity specifications and related analytical techniques. Results of the project fed into the revision and development of four ISO standards.

"We worked closely with standardisation bodies and industry to ensure we met their needs and bridged the gap between research and validation."
Jacques Hameury, project coordinator of HYDROGEN

http://projects.lne.eu/jrp-hydrogen/

REACH2020

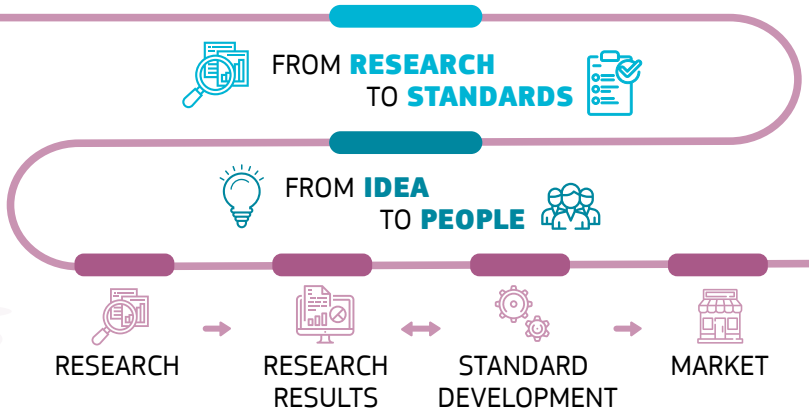
How research results help developing new standards for elderly people

REACH2020 objective is to turn clinical and care environments into personalised modular systems that encourage the elderly to become healthy via activity. Standardization activities within REACH are further used as an important instrument to use project results at national (DIN NA 023-00-07 AA), European (CWA 17502) and international (ISO/TC 314) standardization levels.

"Under COVID-19 long-term "social distancing", digital MedTech solutions for active aging and elderly rehabilitation, like REACH2020 technology, are a necessity"
Thomas Linner, Scientific Direct and project manager of REACH2020

https://reach2020.eu/

STANDARDISATION FLOW



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LEARN MORE

Standardisation policy: https://europa.eu/!Gd86Vt
EU valorisation policy: https://europa.eu/!bV76vw

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#standardisation | #ResearchImpactEU

WP2 EQA // DR. OLGA KOFANOVA / DR. PAOLO VERDERIO / DR. CHIARA CINISELLI

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Get ready: A Biospecimen Proficiency Testing Program for Biobank Accreditation

The External Quality Assurance (EQA) programme in SPIDIA4P

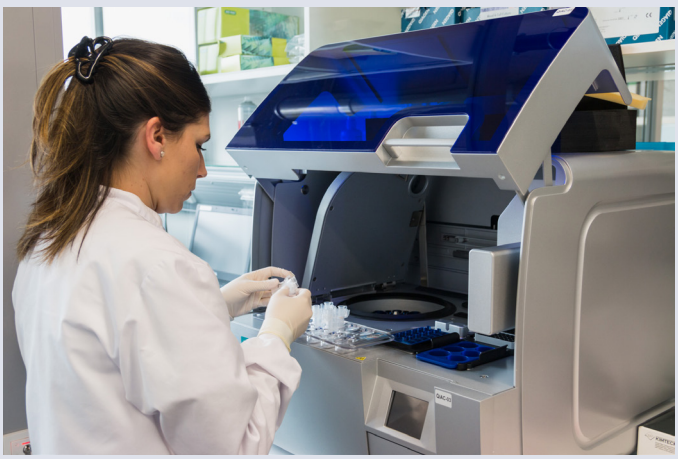
The quality of biospecimens is ultimately the result of how they were collected, processed and stored. These events correspond to sample pre-analytical history. The assessment of biospecimens' quality concerns the biorepository performance in processing, producing and storing biospecimens, especially from challenging materials. The Proficiency Testing (PT) or External Quality Assessment (EQA) program developed by IBBL supports the development of biobank quality assurance, via evaluation biobank laboratory performance, while providing useful insights into biobank laboratory method performance characteristics, to ensure fulfillment of accreditation authorities' demands.

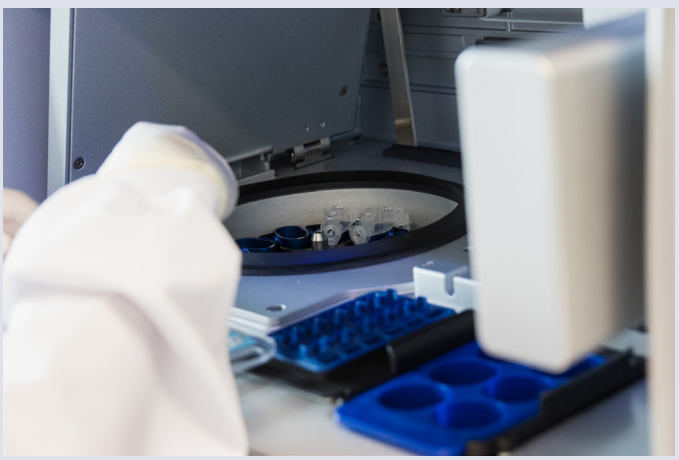
The current IBBL PT program includes several processing schemes, including but not limited to:

- DNA extraction from whole blood
- RNA extraction from whole blood
- DNA extraction from FFPE material
- RNA extraction from FFPE material
- Microbial DNA extraction from saliva
- Microbial DNA extraction from stool
- DNA extraction from frozen tissue
- Total RNA extraction from frozen tissue
- Cell-free DNA (cfDNA) extraction from whole blood
- Cell-free RNA (cfRNA) extraction from plasma
- Dual DNA/RNA Extraction from Frozen Tissue
- Circulating Tumor Cells (CTC) Detection and Isolation
- Viable PBMC isolation

Some EQA/PT schemes that have been developed within SPIDIA4P, and implemented by IBBL in the annual PT Program, will also contribute to the overall quality of specimens.

The knowledge collected during the lifetime of the IBBL PT program has undergone global statistical data analysis by the Unit of Bioinformatics and Biostatistics, Department of Applied Research and Technological Development, Fondazione IRCCS Istituto Nazionale dei Tumori. Briefly, data arising from 10 different PT-schemes implemented by IBBL in the last 6 years (from 2014 to 2019) were analyzed, for an overall number of about 1000 attendances. The performance metrics, already provided by IBBL to each laboratory, are currently being evaluated to assess the role of some pre-analytical factors on the measurement results and to represent the laboratory-specific time trends within PT-programs. A publication is under preparation. Through regular PT participation, the identification of variables affecting processing assay outcomes will drive the efforts to bring standardization into the field, also in the scope to strengthen a more international approach and push to harmonize biospecimen quality control.





SPECIAL I: NETWORKING MATTERS – PART ONE

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SPIDIA4P networking with actors in the health field

The main goal of a Laboratory Medicine is to provide physicians and patients with a reliable laboratory report, thus allowing better clinical reasoning and decision making. This is highly dependent on the quality of processing the biological sample from its collection to its analysis. During the past decades, quality indicators for pre-analytical and analytical phases were introduced and considered of utmost importance for a reliable and robust analysis. The EU funded SPIDIA4P project is in line with the focus on quality in medical laboratories as it has developed 22 standards related to the pre-analytical phase. Thus, to efficiently contribute to the robustness of the results, it was necessary to disseminate the information to the actors in this field as widely as possible. To achieve this objective, the pre-analytical standards developed in SPIDIA4P, were presented in several meetings in Europe and internationally. These include meetings for biobanking actors such as the annual Europe Biobank week, which regroups more than 700 experts from Europe, the Sintesy workshop and the Rizzoli workshop which regroup more than 150 experts from Italy, The China Holistic Integrate Biobankology Conferences (more than 1000 oncologists) and the Korean testing and research Institute (200 experts from Korea). The dissemination included also experts from other European life science infrastructures (50 experts). In addition, we organized a specific workshop with the International Laboratory Accreditation Cooperation (ILAC) that will develop a procedure to audit the implementation of the standards in medical laboratories. Furthermore, two meetings were held with COS, the Strategic Committee for Health at AFNOR, the standard organisation in France. This committee regroups representatives of major actors in the govenance and administration of health in France such as ministry of health, ministry of reasearch, ministry of economy, hospitals federation, medical laboratories syndicate, research institutes, pharmaceutical industries, diagnostic industry accreditation agencies, academies of medicine, academy of pharmacy, academy of science and others.

The aim was to inform these institutions and organizations about the development of the pre-analytical standards and the importance of their implementation in private and public medical laboratories and hospitals and to solicit the definition of national strategy for such an implementation with appropriate funding. Meetings were held also with coordinators of national genomic and proteomic programs in France. Finally, two important meetings with medical laboratories in France regrouping more than 800 actors each were scheduled for 2020, however the pandemic hampered such a meeting to take place and will probably be scheduled for 2021.

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SPECIAL I: NETWORKING MATTERS – PART TWO

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Collaboration is king!

The collaboration with other consortia is an essential and effective way to use synergetic effects and disseminate the mission, which is, in the case of SPIDIA4P, the message of the importance of standards for pre-analytical workflows.

It´s a win-win-situation for both collaboration partners as expert knowledge, insights and networks can be shared and be brought to a higher level.

SPIDIA4P works together with several consortia and grant projects.

We would like to introduce you to some of them:

EASI-GENOMICS
European Advanced infrastructure for Innovative Genomics

The mission of this Horizon 2020 grant project is to provide easy and seamless access to cutting-edge DNA sequencing technologies to researchers from academia and industry, within a framework that ensures compliance with ethical and legal requirements, as well as FAIR and secure data management. It strives to build a community of practice which leverages advanced sequencing technologies beyond country and sector borders to tackle global challenges in science.

EASI-Genomics is coordinated via the SPIDIA4P partner FUNDACIO CENTRE DE REGULACIO GENOMICA (CNAG-CRG). Furthermore, SPIDIA4P is represented via the project partners QIAGEN GmbH, Medical University of Graz and LGC. These project partners are contributing for Work Package 4 of the EASI-Genomics project and take care that a catalogue of standardized pre-analytical processing pipelines from blood/ tissue to nucleic acid for DNA and RNA secquencing as well as DNA methylation analysis is established to harmonize wet-lab procedures. A catalogue of quality measures used commonly and specifically by partners will also be established. From this best-in-class procedures with appropriate measures for quality control will be established, aiming at adapting and improving existing ISO and European (CEN) standards.

Get more information on the EASI-Genomics website:

https://www.easi-genomics.eu/about

On page 17 and 18, you can find an example of the collaboration and common events.

EU-STANDS4PM
A European standardization framework for data integration and data-driven in silico models for personalised medicine

EU-STANDS4PM is a Coordinating and Support Action funded under the Horizon2020 framework programme of the European Commission. Core of the project is a pan-European expert forum and network that combines extensive experience from its sixteen partners, including H2020 collaborative research projects, normative and regulatory agencies, large European infrastructures, Industry as well as ethical and legal expertise from eight European countries. EU-STANDS4PM will initiate an EU-wide mapping process to assess and evaluate strategies for data-driven in silico modelling approaches.

A central goal is to develop harmonised transnational standards, recommendations and guidelines that allow a broad application of predictive in silico methodologies in personalised medicine across Europe.

Via its coordinator QIAGEN GmbH and its partner DIN, SPIDIA4P is also a project member of EU-STANDS4PM. SPIDIA4P contributes to developing the appropriate standards and making sure that pre-analytical requirements are covered.

Want to know more? Visit the project website:

https://www.eu-stands4pm.eu/home

SPECIAL I: NETWORKING MATTERS – PART TWO

Christian-Doppler-Forschungsgesellschaft
CD Laboratory for Liquid Biopsies for the early diagnostics of cancer

This CD-Laboratory is led by Prof. Dr. Ellen Heitzer. With a runtime of 7 years, its mission is to develop new preanalytical technologies and to get deeper insights in the potential of Liquid Biopsies to detect cancer in an early stage via the examination of a blood samples and other body fluid samples such as urine and saliva for the existence of (circulating) cell-free tumor DNA (ctDNA) as well as nucleic acids in extra-cellular vesicles such as exosomes.

SPIDIA4P is involved in this project via its project partner PreAnalytiX.

Have a read (in German only):

https://www.cdg.ac.at/forschungseinheiten/labor/liquid-biopsies-zur-frueherkennung-von-krebs

This is only a selection of collaborative partners.

Learn more on the SPIDIA/ SPIDIA4P website:

https://www.spidia.eu/about-us/co-working

SPECIAL II: IMPLEMENTATION OF STANDARDS

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How the implementation of standards optimize a Liquid Biopsy project – an example

In the concept of precision oncology, it is an aim to provide personalized treatment options by identifying, monitoring and targeting molecular aberrations of the individual patient. This approach is showing promising improvement of clinical outcomes in recent years.

One of the most promising tools in precision oncology are liquid biopsies, which comprise circulating tumor cells (CTCs) and circulating tumor DNA (ctDNA). These tumor parts can circulate in blood of cancer patients in minute amounts and there is vast amounts of scientific literature available on liquid biopsies. Nevertheless, controversy remains about their clinical utility, hence clinical applications remains major point of discussion.

A major issue for their widespread clinical implementation are the lack of standardisation and technical issues, especially when it comes to stabilisation of low abundant and fragile CTCs or ctDNA fragments.

At CBmed, a COMET-funded biomarker research centre located in Graz, Austria, researchers are addressing the weak spot of liquid biopsies **by implementing standardised workflows for liquid biopsies**.

In the international research collaboration with QIAGEN, ViennaLab Diagnostics, CytoGen, Labor Renner as well as the Medical University Graz, **the researchers are implementing European (CEN)- and International (ISO)- standards for ctDNA and CTC analysis that include patient data collection, sampling and stabilisation, isolation, and analysis of liquid biopsies. This project is a great example of translation of the newly established standards for liquid biopsies in a clinical setting.**

In a first impression, the high demands for documentation required by CEN- and ISO standards seem to be a very tedious task. In fact, much time of the research is spent in establishing workflows and optimising documentation processes. Nevertheless, **"the gain of confidence in the correct handling of blood samples outweighs the demands of documentation greatly",** as stated by the principal investigator Amin El-Heliebi. **The implementation of the CEN- and ISO- standards greatly improved the quality of samples**, as it is perfectly clear, how long a sample took from blood draw until processing in the lab. Usually, the correct sample collection and transport are considered as a given fact, but are rather dangerous black boxes if not well documented. And almost all cutting edge lab technologies cannot undo a wrongly transported or expired blood sample. It rather produces inconclusive results and many puzzled researchers. **The CEN- and ISO- standards therefore can help to minimize uncertainties and form the basis for research of liquid biopsy in a clinical setting.**

This project is performed at the Center for Biomarker Research in Medicine, which is funded within COMET – Competence Centers for Excellent Technologies by the Federal Ministry of Transport, Innovation and Technology (BMVIT), the Federal Ministry for Digital and Economic Affairs (BMDW), Land Steiermark (Styrian Business Promotion Agency – SFG) and Land Wien (Vienna Business Agency – WAW). The COMET program is executed by the Austrian Research Promotion Agency (FFG).

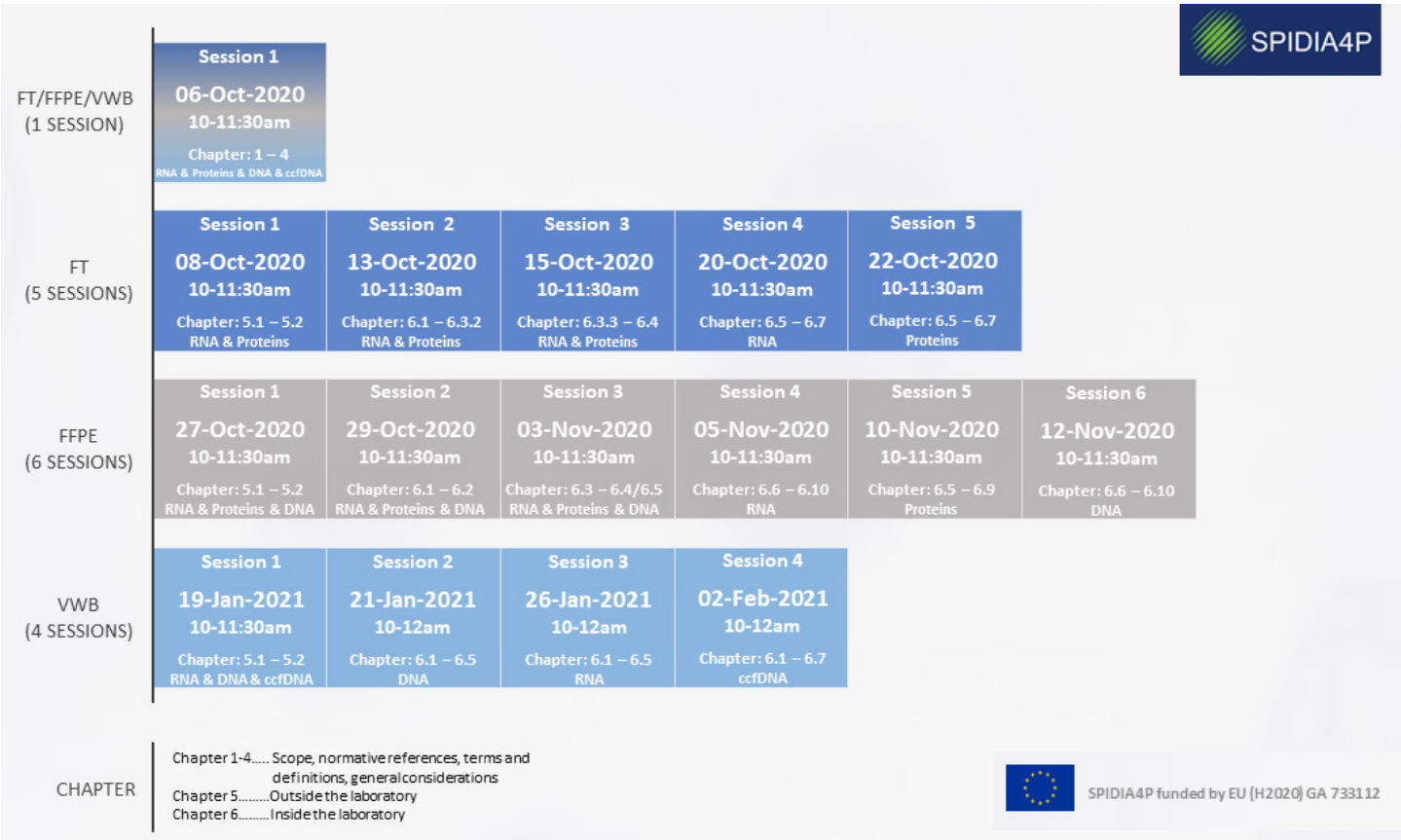
The international cooperation members of the liquid biopsy research project at the project meeting in Vienna, January 2020

SPIDIA4P EVENTS // HIGHLIGHT // BBMRI.QM IN-DEPTH TRAINING ON ISO STANDARDS

Web conference series on pre-analytical ISO standards 20184 | 20166 | 20186: Four more sessions on venous whole blood in January 2021!

Since October 2020, the BBMRI.QM team provides in cooperation with the H2020 project SPIDIA4P (GA 733112) an in-depth *training on the pre-analytical standards relevant for biomedical research and biobanking.* This training and education programme is being presented as a virtual training, divided into 16 sessions.

By now, 12 presentations have been given, gathering more than 120 registrants from European, Asian and American countries. Each session is available as recording, for further study and also for refreshing individual chapters.



Kick-off of the series

Dr. Uwe Oelmueller, SPIDIA4P's coordinator, started the webinar series by presenting the scope, normative references, terms and definitions and general considerations (chapter 1-4) of each standard:

frozen tissue (ISO 20184-1|2)

formalin-fixed and paraffin-embedded tissue (ISO 20166-1|2|3) and venous whole blood (ISO 20186-1|2|3).

MSc Andrea Wutte | Dr. Uwe Oelmueller |

Dr. Jens Haberman, M.D., Ph.D.

FT series

Five sessions on frozen tissue (FT) were held in October, describing the activities outside the laboratory until the specimen are processed in the laboratory, which was a clear highlight for the attendees. Those sessions were presented by Dr. Peter Riegman, Prof. MD Kurt Zatloukal, MSc Cornelia Stumptner, MSc Andrea Wutte and Prof. Dr. Karl-Friedrich Becker.

MSc Andrea Wutte | Dr. Peter Riegman

DI (FH) Ulrike Rohrer MBA, Prof. MD Kurt Zatloukal

MSc Cornelia Stumptner | Prof. Dr. Karl-Friedrich Becker

FFPE series

Six sessions on formalin-fixed and paraffin-embedded tissue (FFPE) followed the frozen tissue ones at the end of October and beginning of November. FFPE were deeply discussed and the insights from the speakers Prof. Dr. Karl-Friedrich Becker, MSc Cornelia Stumptner, Dr. Peter Riegman, Prof. MD Kurt Zatloukal and Dr. Daniel Groelz were very well received.

MSc Cornelia Stumptner | Dr. Daniel Groelz

Upcoming series with a focus on VWB – registrations open!

In January 2021, four more sessions are scheduled with a main focus on venous whole blood (VWB). The first VWB sessions will take place on 19th January with hands-on demonstrations and visualizations on requirements, definitions and the practical application about the specimen collection as well as the transport requirements outside the laboratory.

We'll be particularly happy to meet you again in January. **Register** soon and join our three experts PhD Stefania Gelmini, Dr. Kalle Günther and Assoc. Prof. PhD Pamela Pinzani.

https://docs.google.com/forms/d/1q8l__5b8_W-fr0N3d-jp-jMakhWscx_NErZ_btPh-B4/viewform?edit_requested=true

WEBINARS IN JANUARY 2021 WILL BE HELD BY:

PHD STEFANIA GELMINI
University of Florence

DR. KALLE GÜNTHER
QIAGEN GmbH/PreAnalytiX

ASSOC. PROF. PHD PAMELA PINZANI
University of Florence

SPIDIA4P EVENTS // PAST EVENTS + COURSES / HIGHLIGHTS

PETER M. ABUJA

Medical University of Graz, Austria

peter.abuja@meduni-graz.at

https://www.medunigraz.at/

Implementing Biomedical Research Projects:

The Complete Workflow from Concept, ELSI and Privacy Considerations to High-Quality Biobanking

Virtual Workshop, May 10–14, 2020

Biomedical research using human biological samples and data is essential for developing new therapies and diagnostics. Obtaining meaningful and reproducible results through an ethically, legally and technically correct process is a highly complex procedure that is difficult to oversee in its entirety. Moreover, in the past decade new regulations such as the General Data Protection Regulation (GDPR) and the In-Vitro Diagnostics Regulation (IVDR) have necessitated establishing increased levels of documentation and quality assurance. As a consequence, the whole workflow of performing research with human biological samples and data has become increasingly difficult to set up and administrate.

The workflow of a biomedical study comprises a broad spectrum of quite disparate disciplines, such as biomedical sciences, biostatistics, ethics, law, medicine, data management, biobanking, and the various special disciplines involved in the generation of the analytical results. It is quite natural that experts of one of these disciplines are at a loss when it comes to oversee the whole process required to initiate and complete a biomedical study, although this would be highly desirable, since a comprehensive overall view facilitates conception and planning, reduces errors, improves the performance and will, overall, lead to more reliable results.

TIMELINE OF A STUDY

CONCEPT → ETHICAL, LEGAL CONSIDERATIONS → STUDY DESIGN → ETHICS BOARD → ACTIVE STUDY → STUDY COMPLETED

Clinical partner

- Clinical workflow
- Case number
- Availability of material

Pathologist

- Suitability of material

- # of cases available during study
- Review clincal workflow
- Develop standardized sample collection process and documentation

- Decide about inclusion
- Integrate collection into clinical workflow and pathology

Pathologist

- Secondary diagnosis
- Selection of useable specimens
- Support in aliquoting

- Analysis and interpretation: include **clinicians and pathologists**
- **Data storage, publication and deployment**

BBMRI-ERIC, European Joint Programme on Rare Diseases and EASI Genomics therefore jointly organised a workshop where speakers of the various disciplines mentioned above (with the exception of experts in the analytic fields) covered the whole workflow. The workshop was organised in two modules:

Module 1:
Ethical and legal requirements, subjects' privacy and data protection

Here, specific issues regarding the ethical and legal prerequisite for a biomedical research project were presented and discussed, with a focus on the particularities of genetic studies and subjects' privacy, and the role of data management. A presentation of the role of Ethics Boards in safeguarding the subjects' interests linked this module to module 2.

Module 2:
Implementation of standardized sample procurement in clinical cooperation

The important issue of producing analytical data that are reliably fit-for-purpose requires following standardized procedures along the whole workflow of sample procurement, which was the central topic of this module. The need for standardization, also in the context of biobanking, requires close cooperation between the (academic or industrial) researcher and the clinical partners. This was illustrated by two use-cases performed at the Medical University of Graz and CBmed GmbH: (a) collecting cryoconserved tumour and normal tissue (ductal pancreas carcinoma, squamous cell carcinoma head and neck, clear cell renal carcinoma) for Next-Generation Whole Genome Sequencing; (b) collecting liquid biopsies for analysis of circulating tumour cells and ccfDNA for therapy monitoring in castration-resistant prostate cancer. In both cases the importance of compliance with the respective CEN/ISO standards, regarding procedures and documentation, was emphasized.

The workshop was originally planned as a face-to-face event, and had to be virtualized due to the SARS-CoV-2 pandemic. While in module 1 problem-based learning in form of moderated discussion was performed as originally intended, module 2 had to skip hands-on and demonstration parts foreseen and instead strongly emphasized the presentation of the use-cases.

Albeit no practical/hands-on sessions could be provided due to the current restrictions, the feedback given by post-module questionnaire from the 40 participants selected (out of 70 applications, most of them for both modules) was very positive: we received 29 unique feedback responses in total, all of which were generally positive (summary: content matched level of experience [module 1] and participants expected the content to be translated into their practical work [module 2]), only one participant considered the content 'too difficult'. The course will be repeated in 2022, if possible, in the hands-on, face-to-face format originally foreseen.

The workshop was jointly organized by BBMRI-ERIC, European Joint Programme on Rare Diseases and EASI Genomics, with support from the Medical University of Graz, QIAGEN GmbH and CBmed GmbH.

SPIDIA4P members Uwe Oelmueller, QIAGEN, SPIDIA4P Coordinator, Peter M. Abuja, Medical University Graz (MUG) as well as Cornelia Stumptner, MUG and BBMRI.at, held presentations at this workshop.

About the event:

https://www.medunigraz.at/biomedical-research-workshop/

Programme:

http://bbmri.at/documents/10194/93633/EJP-RD_GrazBiomedicalResearchWorkshop_FinalProgram_20200429.pdf/a50cf89c-99bb-44e6-a755-ea77eab231b2

Presentation by Mag. (FH) Cornelia Stumptner:

https://www.spidia.eu/fileadmin/Images/Download/Presentation/spidia4P/Preanalytics_Stds_at_a_Glance_20200513_Cornelia_Stumptner.pdf

Presentation 1 by Dr. Peter M. Abuja

Presentation 2 by Dr. Peter M. Abuja

Presentation by Dr. Uwe Oelmueller QIAGEN

SPIDIA4P EVENTS // PAST EVENTS + COURSES / HIGHLIGHTS

MAG. (FH) CORNELIA STUMPTNER
Project Manager BBMRI.at

Medical University of Graz, Austria

cornelia.stumptner @medunigraz.at

http://bbmri.at/

BBMRI-ERIC
Biobanking and BioMolecular resources Research Infrastructure

Two virtual conferences on "IVD, ISO Standards & state of the art in analytical performance tests"

The ISO Standards and CEN Technical Specifications „Molecular in vitro diagnostic examinations – Specifications for pre-examination processes" represent the state-of-the-art for pre-analytical sample handling. They are applicable to In Vitro Diagnostic (IVD) developers/ manufacturers, diagnostic laboratories, biobanks, regulatory bodies but also research laboratories.

Their relevance increases with requirements contained in the EU regulation for in vitro diagnostics 2017/746 (IVDR), which came into force in May 2017, and will apply after a transition period of 5 years in May 2022. By then at the latest, IVD manufacturers will have to adapt to regulatory changes in order to secure access to the European market. This affects not only products that are still in the development stage, but also all products already available on the market. In addition, products manufactured and used in healthcare facilities (so-called Laboratory Developed Tests (LDT), „in-house" tests) are also affected.

The IVDR requires addressing the sample pre-analytics and describing this in the technical documentation. In this context, the pre-analytics standards „Molecular in vitro diagnostic examinations – Specifications for pre-examination processes" represent the state-of-the-art and are relevant norms.

Against this background, the SPIDIA4P partner Med Uni Graz organized (in the context of BBMRI.at - the Austrian Biobanking Research Infrastructure Node of BBMRI-ERIC) two events together with the Austrian Life Science Cluster LISAvienna and the company en.co.tec.

Both events aimed at raising awareness of pre-analytical standards as state-of-the-art for IVD development and IVD use for selected molecular analyses and at informing about the relevance of pre-analytics and corresponding standards in the context of IVDR (incl. lab developed tests).

Webinar 05 Juni 2020:
"The CE mark as a sufficient seal of approval for IVD tests"
"Die CE-Kennzeichnung als ausreichendes Gütesiegel von IVD Tests""
This webinar (in Germany language) was held in the context of the COVID-19 pandemic, which triggered a large number of Sars-CoV-2 IVD being developed and used.

Speakers from regulatory and notified bodies, from industry, diagnostics and academic research addressed topics, such as the following:

- "Coronavirus contamination worldwide", Irina Korschineck (ingenetix)
- "The CE mark on an IVD. Fulfilment of general safety and performance requirements or seal of approval?", Martin Schmid (en.co.tec)
- "Requirements for pre-analytics and biosafety for COVID-19 diagnostics", Kurt Zatloukal (Med Uni Graz, BBMRI.at, SPIDIA4P)
- "Experience and problems from user practice", Gregor Hörmann (MedUni Vienna & Tirol Kliniken, ÖGLMKC)
- Conformity assessment (CE marking) of IVD – requirements from the point of view of a notified body, Sabine Ohse (mdc)

More details about the conference >>

The 3 hours webinar was fully booked with 100 registered people from industry, diagnostics, regulatory bodies and academia.

Virtual 20-21 October 2020:
„LISAvienna Regulatory Conference for Medical Devices and In Vitro Diagnostics 2020"
„Regulatory Konferenz für Medizinprodukte und In Vitro Diagnostika 2020"

Due to COVID-19, this year's Regulatory Conference took place digitally. Over 520 persons from industry, regulatory bodies, funders, and universities registered for the 2 day conference and asked around 200 questions.

With this conference, the organizers are contributing to the exchange of knowledge about the implementation of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). The program was designed in close cooperation of BBMRI.at (the Austrian Biobanking Research Infrastructure Node of the BBMRI-ERIC) with the joint life science platform operated by Austria Wirtschaftsservice and the Vienna Business Agency, LISAvienna, and the consulting and training service provider for medical devices and IVD, en.co.tec.

While day 1 was about medical devices, day 2 was fully devoted to in vitro diagnostics. On day 2, speakers from Notified Bodies, IVD manufacturers, regulatory bodies, clinical diagnostic laboratories and academia gave presentations and answered questions. Among them speakers from SPIDIA4P: Dr Uwe Oelmueller (QIAGEN and coordinator of SPIDIA4P), Ulrike Schroeder (DIN) and Prof Kurt Zatloukal (Med Uni Graz, Director BBMRI.at and coordinator of INSTAND-NGS4P).

- Scientific and medical relevance of standards in diagnostics (Kurt Zatloukal, Med Uni Graz / BBMRI.at / SPIDIA4P)
- Importance of pre-analytical ISO and CEN standards from the perspective of an IVD developer and manufacturer (Uwe Oelmueller, QIAGEN / SPIDIA4P)
- Development of European and international standards for pre-analytics (Ulrike Schröder, DIN)
- Consequences of the new In Vitro Diagnostics Regulation (IVDR) for manufacturers (Martin Schmid, en.co.tec)
- Standards and the IVDR (Michael Pölzleitner, mdc / ASI)
- Performance evaluation of IVDs under the EU regulation 2017/746 (Wolfgang Ecker, FH Technikum Wien / FH Medical Technology Linz)
- Performance evaluation within the framework of the IVDR (Heike Möhlig-Zuttermeister, BSI)
- Regulatory requirements for performance studies by the IVDR (Nebojsa Serafimovic, BASG – Federal Office for Safety in Health Care)
- Theory meets practice: pre-analytics standards in molecular pathology routine diagnostics (Karl Kashofer, Med Uni Graz)
- Towards implementing EU-2017/746 - How ISO 15189 has improved lab testing (Markus Herrmann, Medical University of Graz)

Presentations are available for download>>

Conference Program:

https://www.lisavienna.at/fileadmin/user_upload/LISAvienna/Files_Events/LISAvienna_Regulatory_Konferenz_fuer_Medizinprodukte_und_In_vitro_Diagnostika_2020.pdf

Promotion of the „LISAvienna Regulatory Conference for Medical Devices and In Vitro Diagnostics 2020" on LinkedIn:

Praxis-Perspektive: Uwe Oelmueller von QIAGEN beleuchtet demnächst in einem virtuellen Vortrag die Bedeutung von präanalytischen ISO- und CEN-Standards aus Sicht eines #IVD Entwicklers und Herstellers https://lnkd.in/eet3QNm Diese Veranstaltung wird in enger Zusammenarbeit mit #BBMRIat und en.co.tec - Medizinprodukte-Consulting & Akademie organisiert.

20.-21.10.2020 ONLINE

LISAvienna Regulatory Konferenz
für Medizinprodukte
und In-Vitro Diagnostika 2020

21.10.2020 9:45-10:15 Uhr

Bedeutung von präanalytischen ISO-
und CEN-Standards aus Sicht eines
IVD Entwicklers und Herstellers

Uwe Oelmueller
QIAGEN

In der Forschung und Diagnostik kommt es auf die Details an. Erfahren Sie demnächst im online Vortrag von Ulrike Schröder, DIN Deutsches Institut für Normung e. V. , mehr über die Entwicklung von europäischen und internationalen Standards für die Präanalytik. - der Vortrag startet etwas verspätet https://lnkd.in/eet3QNm Diese praxisnahe Konferenz wird in enger Zusammenarbeit mit #BBMRIat und en.co.tec - Medizinprodukte-Consulting & Akademie organisiert.

20.-21.10.2020 ONLINE

LISAvienna Regulatory Konferenz
für Medizinprodukte
und In-Vitro Diagnostika 2020

21.10.2020 10:15-10:45 Uhr

Entwicklung von europäischen und
internationalen Standards für die
Präanalytik

Ulrike Schröder
DIN

LISAvienna life science austria

20.-21.10.2020 ONLINE

LISAvienna Regulatory Konferenz
für Medizinprodukte
und In-Vitro Diagnostika 2020

21.10.2020 9:15-9:45 Uhr

Wissenschaftliche und medizinische
Relevanz von Standards in der Diagnostik

Kurt Zatloukal
Med Uni Graz / BBMRI.at

LISAvienna life science austria

SPIDIA4P EVENTS // PAST EVENTS

Besides the events that were described in detail on the pages before, SPIDIA4P members attended at several important conferences in 2020, some of them listed below:

January 2020

INSTAND-NGS4P Satellite Workshop
In context of the INSTAND-NGS4P Kick-off Meeting
January 29, 2020
Medical University of Graz (MUG)

Presentations by SPIDIA4P project partners
- **Prof. Kurt Zatloukal, MUG**
- **Prof. Giorgio Stanta, University of Trieste**
- **Prof. Pamela Pinzani, University of Florence**

http://bbmri.at/documents/10194/93633/2020-1_NGS+WS+%2B+logo_29+Jan+2020_Details.pdf/29f5135c-a7c8-4eb4-b9e2-40c708e2023a

February 2020

Biotech Pharma Summit: Liquid biopsy Conference
February 20-21, 2020
Lisbon, Portugal

Presentations by SPIDIA4P project partners
- **Dr. Daniel Groelz, QIAGEN/ PreAnalytiX**
- **Prof. Mikael Kubista, TATAA Biosciences**

https://www.biotechpharmasummit.com/index.php/liquid-biopsy-2020/

August 2020

ESBB – International Symposium on Sustainability of Biobanks
August 24-26, 2020
Virtual format

Presentation by SPIDIA 4P project partner
- **Prof. Peter Riegman, Erasmus MC**

Conference Website:
https://www.bbmri-eric.eu/news-events/esbb-international-symposium/

Oktober 2020

75th General Assembly Meeting of the UN (UN GA 75): submeeting HUG Standards. Global Collaboration and Harmonization for Digital Transformation in Health Care
(HUG = Healthcare utility grid)
October 1, 2020
Virtual Format

Invited Speaker:
- **Dr. Uwe Oelmueller, QIAGEN and SPIDIA4P Coordinator**

Meeting Information:
http://sciencedigitalunga75.com/events/hug-standards-global-collaboration-and-harmonization-for-digital-transformation-in-health-care/

SPIDIA4P EVENTS // PAST EVENTS

Besides the events that were described in detail on the pages before, SPIDIA4P members attended at several important conferences in 2020, some of them listed below:

November 2020

Europe Biobank Week
November 17-20, 2020
Virtual Format

Presentations by SPIDIA4P project partners
Dr. Tomasz Krenz

Presentation on conference website:

https://app.swapcard.com/widget/event/europe-biobank-week-2020/planning/UGxhbm5pbmdfMjMzMzYx

Prof. Peter Riegman, Session Chair on Nov. 17 and 20, 2020

Nov 17, 2020:

https://app.swapcard.com/widget/event/europe-biobank-week-2020/planning/UGxhbm5pbmdfMTcxNTY0

Nov 20, 2020:

https://app.swapcard.com/widget/event/europe-biobank-week-2020/planning/UGxhbm5pbmdfMTczNjg0

SPIDIA4P EVENTS // PAST COURSES + WEBINARS

In 2020, many courses and trainings by SPIDIA4P members were switched to webinars – see the highlights below!

3 Days Hands on qPCR // 2 days experimental design and statistical analysis for gene expression data
Prof. Mikael Kubista
February 3-7, 2020
TATAA Biocenter, Gothenburg, Sweden

http://www.tataa.com/courses/

Webinar: QIAGEN Cancer Research
Title: **Pre-analytical considerations and workflow solutions for Liquid Biopsy**
Dr. Tomasz Krenz, QIAGEN/ PreAnalytiX
July 10, 2020
Webinar website and presentations:

https://www.qiagen.com/de/applications/cancer-research/cancer-research-online-events

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Webinar: QIAGEN Cancer Research
Successful biomarker profiling from FFPE samples – the tips and tricks series, Module 1

Title: **Pre-analytical considerations – standards and how to implement in your laboratory**
Dr. Daniel Groelz, QIAGEN/ PreAnalytiX
August 18, 2020
Webinar website and presentations:

https://www.qiagen.com/de/applications/cancer-research/ffpe

Webinar: organized by Frontline Genomics and SPIDIA4P partner PreAnalytiX
Precision oncology: **From preanalytical considerations to digital insights. Webinar 1 of 3**
Presentation by Dr. Uwe Oelmueller, QIAGEN:
September 8, 2020

Standardized Preanalytics: **The Key for Reliable Diagnostics, Research and Biobanking**
Information and recording webinar:

https://app.livestorm.co/front-line-genomics/precision-oncology-from-preanalytical-considerations-to-digital-insights-webinar-1-of-3

Virtual Format: Summer course II Researchmaster Infection & Immunity 2020; Biobanks
Lecture by Prof. Peter Riegman, Erasmus MC
September 22, 2020
Course information:

https://www.eur.nl/en/research-master/infection-and-immunity

Webinar: SIAPEC
Un viaggio virtuale nelle Anatomie Patologiche in Italia: tra miglioramento della qualità, sicurezza e accreditamento
Presentation by **Prof. Caterina Marchiò, University of Turin**
October 22, 2020
University of Turin, Italy

ISO9001-2015: An opportunity for tracking?

https://educational.siapecservizi.it/congresso.php?id_congresso=40

SPIDIA4P EVENTS // PAST COURSES + WEBINARS

In 2020, many courses and trainings by SPIDIA4P members were switched to webinars – see the highlights below!

Virtual Event: QIAGEN Cancer Research
Cell-free DNA – from biomarker research to personalized medicine
Presentation by **Dr. Uwe Oelmueller**
November 5, 2020

"Standardized Preanalytics: The Key for Reliable Diagnostics, Research and Biobanking"

Link to QIAGEN Website:
https://www.qiagen.com/gb/clp/qiadigital-QCROevent

Link to Video Recording:
https://vimeo.com/478513196/c4237a69b9

Webinar: SIAPEC / University of Turin, Italy
Metodologie di analisi di RNA per l'identificazione dei profili molecolari nei tumori solidi
Presentation by **Prof. Caterina Marchiò, University of Turin**
November 17, 2020

Clinical Implications of RNA-based prognostic signatures and gene fusion detection for precision medicine

https://educational.siapecservizi.it/congresso.php?id_congresso=55

SPIDIA4P EVENTS // UPCOMING CONFERENCE + EVENTS

2021

As you can imagine, planning of events for the next year is very difficult in these times – that´s why we can only list a few events for this year.

To stay updated, we recommend to check our website regularly:

https://www.spidia.eu/events-trainings/external-events

CONFERENCE

SPIDIA4P presents: Precision Diagnostics Europe organized by SPIDIA4P project partner TATAA Biocenter
May 26-28, 2021
Virtual format

Invitation notes by Prof. Mikael Kubista on page 28

Registration

http://precisiondiagnostics.eu/

2nd IBCQ International Biobanking / Conference 2021
March 8-10, 2021
Virtual Conference
Invited Key Note Speaker: Dr. Uwe Oelmueller, QIAGEN and SPIDIA4P coordinator

Presentations by SPIDIA4P members Prof. Kurt Zatloukal, MUG, and Prof. Peter Riegman, Erasmus MC

https://www.ibcq2021.com/

TRAINING/ WEBINAR:

BBMRI.QM IN-DEPTH TRAINING ON ISO STANDARDS

4 sessions on venous whole blood

January 19 to February 2, 2021

Please register!*

https://docs.google.com/forms/d/1q8l__5b8_W-frON3d-jpjMakhWscx_NErZ_btPh-B4/viewform?edit_requested=true

*Please note that you need to have the relevant ISO standards to take part in the training.

SPIDIA4P PUBLICATIONS // ARTICLES

find all articles by SPIDIA4P members on *www.spidia.eu*

Berrino E, Annaratoni L, Miglio U, Maldi E, Piccinelli C, Peano E, Balmatilova D, Cassoni P, Pisacane A, Sarotto I, Venesio T, Sapino A, Marchiò C

Cold Formalin Fixation Guarantees DNA Integrity in Formalin Fixed Paraffin Embedded Tissues: Premises for a Better Quality of Diagnostic and Experimental Pathology With a Specific Impact on Breast Cancer

Frontiers in Oncology, February 2020 **– open access**

https://www.frontiersin.org/articles/10.3389/fonc.2020.00173/full

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Mueller H, Dagher G, Loibner M, Stumptner C, Kungl P, Zatloukal K

Biobanks for life sciences and personalized medicine: importance of standardization, biosafety, biosecurity, and data management

Current Opinion in Biotechnology vol. 65 **– open access**

https://www.sciencedirect.com/science/article/pii/S0958166919301429?via%3Dihub

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P. Fattorini; C. Forzato; D. Tierno; E. De Martino; E. Azzalini; V. Canzonieri; G. Stanta; S. Bonin

A Novel HPLC-Based Method to Investigate on RNA after Fixation

International Journal of Molecular Sciences, October 2020

https://www.mdpi.com/1422-0067/21/20/7540/htm

Highlight: Special Issue New Biotechnology

The SPIDIA4P project members created a compilation of 9 exclusive scientific articles to be published in a very Special Issue of the renowned journal New Biotechnology – "Standardisation of generic Pre-Analytical Procedures for In vitro Diagnostics for Personalized Medicine" – you can find them all on the website:

https://www.sciencedirect.com/journal/new-biotechnology/special-issue/10FDFZ1WK5J

The latest articles in this compilation are:

Oelmueller U

Editorial New Biotechnology - Standardization of generic pre-analytical procedures for in vitro diagnostics for personalized medicine

New Biotechnology Vol 60

https://doi.org/10.1016/j.nbt.2020.07.003

Salvianti F, Gelmini S, Costanza F, Mancini I, Sonnati G, Simi L, Pazzagli M, Pinzani P

The pre-analytical phase of the liquid biopsy – open access

New Biotechnology Vol 55, March 2020

https://doi.org/10.1016/j.nbt.2019.09.006

Bonin S, Stanta G

Pre-analytics and tumor heterogeneity – open access

New Biotechnology Vol. 55, March 2020

https://www.sciencedirect.com/science/article/pii/S1871678419300494?via%3Dihub

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SPIDIA4P PARTNER // CONSORTIUM MEETINGS 2020

Corona can´t stop us! Twice a year, all SPIDIA4P project partners meet at different partner sites to share information personally, discuss the current project status and upcoming activities – in this special year during the Corona crisis, the originally planned Precision Diagnostics Conference in Prag in May 2020 in conjunction with the Consortia Meeting had to be postponed to 2021 – so we met virtually end of May and also beginning of December. Although we could not meet in the usual and preferred circumstances, lively discussions and a very productive exchange and information of updates took place as usual.

The SPIDIA4 project members during the virtual 7th consortia meeting on Dec 2/3, 2020

SPIDIA4P PARTNERS // ANNOUNCEMENT PRECISION DIAGNOSTICS EUROPE

Precision Diagnostics Europe 2021 – a SPIDIA4P conference!

European conference focusing on the new CEN and ISO guidelines in molecular diagnostics and the new CE-IVDR European directive resulting from the European efforts SPIDIA and the ongoing SPIDIA4P

www.spidia.eu

The conference is arranged at BIOCEV, which is the most recent research and development center in Czech Republic conveniently reached from the beautiful city of Prague.

www.biocev.eu

You will hear presentations from world leading experts in molecular analyses and biomarkers with focus on precision diagnostics, quality aspects and regulatory guidelines. You can also join h... on training courses on various aspe... by experts.

Find more information on:

http://precisiondiagnostics.eu/

Most likely, this conference will be in a digital format – please visit the event website to stay up to date!

PROF. MIKAEL KUBISTA
Chairman of the Precision Diagnostics Europe 2020 conference

PRECISION DIAGNOSTICS EUROPE 2021

May 26-28, 2021

SPIDIA4P NEWS // WEBSITE www.spidia.eu

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Social Media

The SPIDIA4P project is continuously present on various Social Media channels, especially in conjunction with events and project news. Not only SPIDIA4P project partners post their latest news, but also interested professionals or involved institutions.

https://twitter.com/hashtag/spidia4p?lang=de

https://www.linkedin.com/search/results/content/?facetSortBy=date_posted&keywords=SPIDIA4P&origin=SORT_RESULTS

https://www.facebook.com/search/top/?q=SPIDIA4P&epa=SEARCH_BOX

Don't miss

the central source for latest news and information about the project!

www.spidia.eu

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