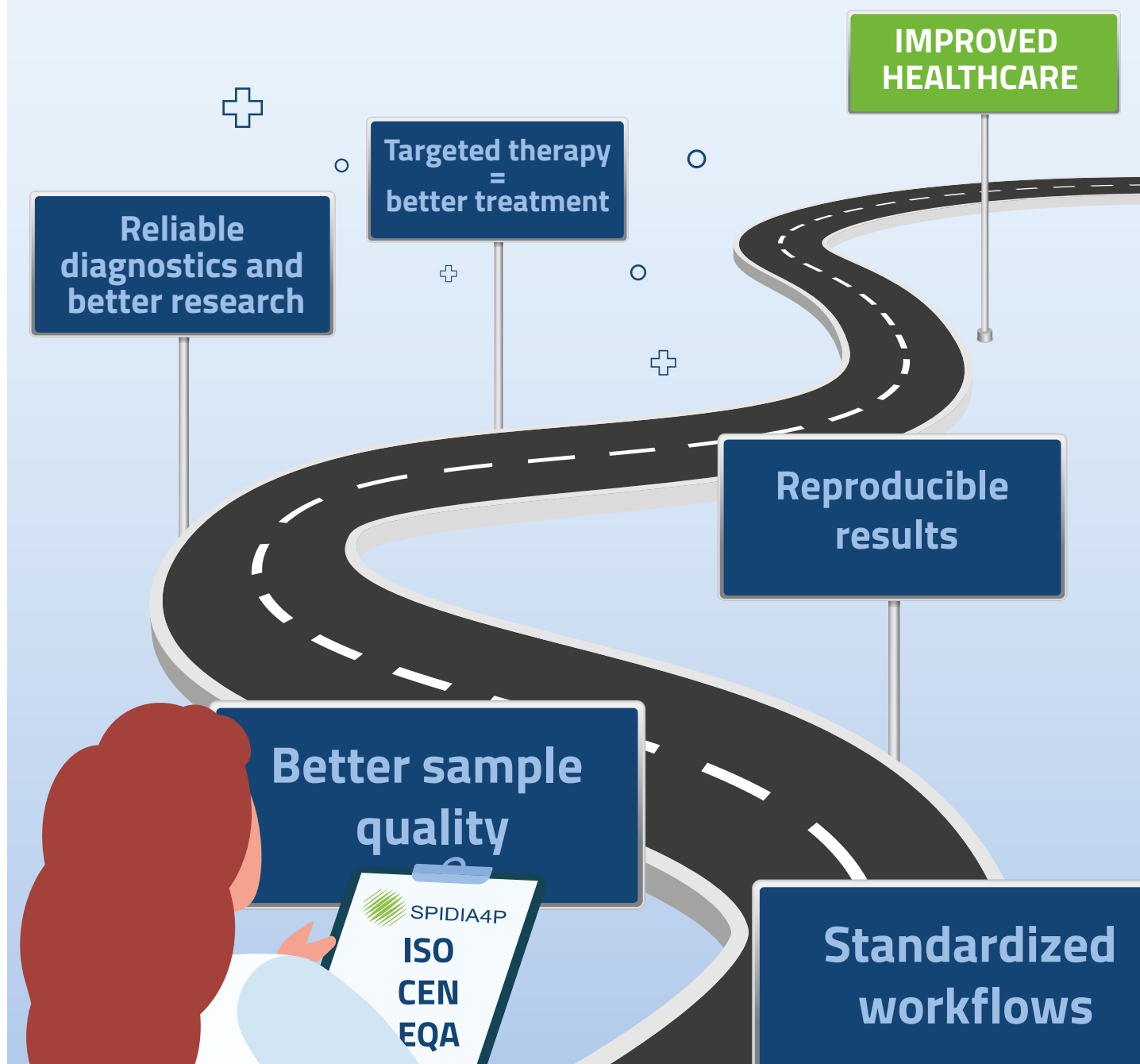


SPIDIA4P Newsletter 2022

TAKE THE ROAD TO INNOVATION AND SUCCESS WITH SPIDIA4P!



The SPIDIA project has received funding under the Seventh Research Framework Programme of the European Union, FP7-HEALTH-2007-1.2.5, under grant agreement no. 222916. The SPIDIA4P project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733112.


CONTENTS

SPIDIA4P – The mission goes on

Editorial

Dr. Uwe Oelmueller, Coordinator SPIDIA4P


WP1 // Standards

Latest updates of CEN/ Technical Specifications and ISO/ International Standards developments by Ulrike Schroeder, MSc., DIN


WP2 // EQA Schemes

How good is your lab performance? Here is the tool to check! – by Dr. Olga Kofanova, IBBL and Dr. Amelie Gaignaux, LIH


WP3 // SPECIAL I: Success Stories

Standard + Innovation Project Award 2021 for SPIDIA4P!

SPIDIA4P again mentioned in revised European Standardization Fact Sheet!

Biobanks in Spain and Italy receive international biobank standard ISO 20387 accreditation


WP3 // SPECIAL II: Networking // News about other consortia with SPIDIA4P members

NESARSDia – an ERINHA Advanced project

by Dr. Franziska Kaiser, PreAnalytiX

EASI-Genomics: The SPIDIA4P mission continues


WP3 // Education of future standardization experts

European Pathology Master

by Prof. Giorgio Stanta, Professor of Pathology, Dept. of Medical Sciences, University of Trieste


WP3 // Communication and Dissemination

SPIDIA4P Publications and Articles on


WP3 // Communication and Dissemination

 Educational media: Videos, Webinars, Presentations etc. on www.spidia.eu

WP3 // Communication and Dissemination

Past and future Events and trainings


SPIDIA4P on Social Media and in the www
Dear reader,

In 2022, four additional new CEN/Technical Specification (CEN/TS) on pre-analytical workflows for circulating cell-free RNA from blood, for exosomes & other extra-cellular vesicles from blood, for cell-free DNA from urine & other body fluids, and for microbiome DNA from human specimen have been introduced in Europe via the CEN/Technical Committee 140 "In vitro diagnostic medical devices". They are planned to further progress to ISO standard documents via the ISO/Technical Committee 212 "Clinical laboratory testing and in vitro diagnostic test systems" during the next years. As of today, a comprehensive portfolio of in total 22 pre-analytical workflow ISO standards and CEN/TS is available, most of them focusing on molecular targets including RNA, DNA, proteins from various specimen types and addressing medical laboratories, biobanks and biomedical research. This is an enormous achievement by SPIDIA4P, its predecessor SPIDIA and all collaboration partners, made possible by great team work.

The standards also gain increasing importance for establishing the still new EU In vitro Diagnostic Regulation (IVDR). Including for this topic, SPIDIA4P speakers were again frequently invited to present at congresses, symposia, and closed door meetings.

Specifying, developing, verifying and validating pre-analytical workflows for analytical tests is not only highly important for molecular analytical tests applied to personalized medicine, but also for other applications. This is more and more reflected also in other new ISO Standards. In April this year, ISO/TS 5798 for the detection of SARS-CoV-2 was published. That document contains detailed paragraphs on pre-analytical workflows recommendations for ensuring reliable and valid detection of the virus.

Education stays key. Please read the article in the newsletter on the Development of the European Master in Molecular Pathology. SPIDIA4P's success is recognized by several prestigious awards. The highlight was in October 2021 the CEN-CENELEC "Standards+Innovation Project Award 2021" for important contribution of research and innovation to standardization.

Enjoy reading our Newsletter. The next one is planned for H2 2023.

Dr. Uwe Oelmueller, Coordinator, QIAGEN GmbH


HEADS UP:

Be sure to visit the SPIDIA website for important news and updates on the publications of new CEN/TS and ISO standards for pre-analytical workflows – www.spidia.eu will be continuously updated! Future SPIDIA4P Newsletters will follow!


WP1 UPDATE STANDARDS // ULRIKE SCHROEDER

ULRIKE SCHROEDER, M.SC.

 DIN – Deutsches Institut
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All SPIDIA4P aims fulfilled!

The goal of Work Package 1 (WP 1) was to develop 12 new CEN Technical Specifications (CEN/TS) and 2 new ISO International Standards¹, thus creating and implementing a portfolio of 22 pre-analytical CEN/TS and ISO Standards (together with the existing standard documents initiated by SPIDIA) for selected pre-analytical workflows needed for personalized medicine. With the publication of CEN/TS 17811:2022 in the beginning of July 2022, this goal has been reached – **all standard documents as envisioned within SPIDIA4P have now been published!**

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”, consisting of a high number of SPIDIA4P partners as well as further pan-European experts, achieved this great progress for the following documents 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 ISO/NP TS 7552-1
1.1	...for circulating tumour cells (CTCs) in venous whole blood – Part 2: Isolated DNA	Published as CEN/TS 17390-2 ISO/NP TS 7552-2
1.2	...for circulating tumour cells (CTCs) in venous whole blood – Part 3: Preparation for analytical CTC staining	Published as CEN/TS 17390-3 ISO/NP TS 7552-3
1.3	...for saliva – Isolated human DNA	Published as EN ISO 4307 (Former CEN/TS 17305)
1.4	...for exosomes and other extracellular vesicles in venous whole blood – Isolated RNA, DNA and proteins	Published as EN ISO 20184-3 (Former CEN/TS 16826-3)
1.5	...for venous whole blood – Isolated circulating cell free RNA from plasma	Published as CEN/TS 17747 Accepted as ISO/PWI TS 18702
1.5	...for urine and other body fluids – Isolated cell free DNA	Published as CEN/TS 17742 Accepted as ISO/PWI 18703
1.6	...for urine and other body fluids – Isolated cell free DNA	Published as CEN/TS 17811 Accepted as ISO/PWI 18704
1.7	...for Fine Needle Aspirates – Part 1: Isolated cellular RNA	Published as CEN/TS 17688-1
1.7	...for Fine Needle Aspirates – Part 2: Isolated proteins	Published as CEN/TS 17688-2
1.7	...for Fine Needle Aspirates – Part 3: Isolated genomic DNA	Published as CEN/TS 17688-3

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 microbiome DNA	Published as CEN/TS 17626 Accepted as ISO/PWI TS 18701
1.9	...for metabolomics in urine, venous blood serum and plasma	Published as EN ISO 23118
1.10	...for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 4: In situ detection techniques	Published as EN ISO 20166-4

Key: NP – New Project; PWI – Preliminary work item

All 10 tasks within WP 1 were successfully completed by publishing the according CEN Technical Specifications and EN ISO standards.

For most of the published CEN/TS documents, the journey does not stop on the European level, but successfully continues on the International level.

Supported by decisions of CEN/TC 140, all documents within Tasks 1.1 to 1.8, except for the FNA documents (Task 1.7), were proposed to ISO/TC 212 to be further developed on ISO level under the Vienna Agreement. Their development status now ranges from accepted preliminary work items (Tasks 1.5, 1.6, 1.8) to new projects in development (Tasks 1.1 and 1.2) to already published documents (Tasks 1.3 and 1.4).

Even with SPIDIA4P coming to end, **the standardization work within the according standardization working groups is continuing and will do so in the future.** This does not only hold true for the standards currently in development, but also for those that have been published early on (i.e. within SPIDIA).

To ensure that standards remain up-to-date and globally relevant, they are reviewed at least every five years after publication through the Systematic Review process. Through this process, national standards bodies review the documents and their use in their country (in consultation with their stakeholders) to decide whether they are still valid, should be updated, or withdrawn. The systematic review process will not start before 2024 for documents such as EN ISO series 20166 or 20184, but it is important to note that revisions, based on e.g. new technologies, developments and/or findings, are also possible before the above mentioned five year time frame.

The unparalleled standardization effort achieved within the project time of SPIDIA4P is only possible through the great effort, hard work and continuous engagement of all partners and experts within SPIDIA4P, CEN/TC 140/WG 3 and ISO/TC 212/WG 4. Once again, I would like to express my sincere thanks to everyone involved! SPIDIA4P has been an incredible journey in combining research and innovations with standardization. It will be exciting to see the project outcomes sustainably implemented to reach the overall project goal of improving the global healthcare system.



Pch.vector - Freepik.com



THE SPIDIA AND SPIDIA4P PROJECT HAS LED TO THE PUBLICATION OF THE FOLLOWING CEN/TS AND ISO STANDARDS IN 2018–2022

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 20166-4:2021 , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 4: In situ detection techniques	https://www.iso.org/standard/75442.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 20184-3:2021 , Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue – Part 3: Isolated DNA	https://www.iso.org/standard/78110.html
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
ISO 23118	
ISO 23118:2021 , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma	https://www.iso.org/standard/74605.html





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

CEN/TS		
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 17390-1:2020 : 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.cencenelec.eu/dyn/www/?p=CEN:35:0:::FSP_SURR_WI,FSP_ORG_ID:65450,6122&cs=1A1C32592109AC94F4B56FCA862D67954	
CEN/TS 17390-2:2020 : 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.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:65452&cs=15F68354250584C9C9EECF2FEC71A0A44	
CEN/TS 17390-3:2020 : 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.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:65451&cs=15E9E8CE0D924716B92532521F07B723C	
CEN/TS 17742:2022 : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for venous whole blood – Isolated circulating cell free RNA from plasma	https://standards.cencenelec.eu/dyn/www/?p=CEN:35:0:::FSP_SURR_WI,FSP_ORG_ID:68138,6122&cs=1EA34F27443FFBE1DF7AA7CBCA6493F24	NEW
CEN/TS 17747:2022 : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood - DNA, RNA and proteins	https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:68137&cs=197A0CEEA18260BFD396E9F8337297837	NEW
CEN/ TS 17811:2022 : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for urine and other body fluids – Isolated cell free DNA	https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:67464&cs=11F83CD57162108B9A8AE11ED37111B4B	NEW
CEN/TS 17626:2022 : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for human specimen – Isolated microbiome DNA (German version)	https://www.beuth.de/de/vornorm/din-cen-ts-17626/330405743	NEW
CEN/TS-series 17688 – Fine Needle Aspirates		
CEN-TS 17688-1 :2021 : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 1: Isolated cellular RNA	https://genorma.com/en/project/show/cen:proj:67447	NEW
CEN/TS 17688-2:2021 : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 2: Isolated proteins	https://www.nen.nl/nvn-cen-ts-17688-2-2022-en-291143	NEW
CEN/TS 17688-3:2021 : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) – Part 3: Isolated genomic DNA	https://www.nen.nl/nvn-cen-ts-17688-3-2022-en-291145	NEW
ISO 4307		
ISO 4307:2021 : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for saliva – Isolated human DNA	https://www.iso.org/standard/79865.html	NEW



WP2 EQA // DR. OLGA KOFANOVA / DR. AMELIE GAIGNAUX



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INTEGRATED BIOBANK
OF LUXEMBOURG
IBBL

HOW GOOD IS YOUR LAB PERFORMANCE? HERE IS THE TOOL TO CHECK!

In the world of molecular biomarkers and personalized medicine, we use different types of biological samples. It is widely recognized that the lack of high quality human biospecimens is one of the limiting factors for translational research.

Biospecimen Proficiency Testing (PT), as defined in ISO/IEC 17043:2010 [1], is seen as a powerful tool to help laboratories demonstrate their competence and efficiency in biospecimen processing and characterisation to researchers, industry, and accreditation bodies. PT enables laboratories to monitor their Quality Control (QC) tests over time, identify longer term trends, and consider any necessary corrective actions.

The PT programs also allow laboratories to verify and benchmark their performance. PT programs are designed to promote the quality and the economic health of the particular industry of biorepositories by diminishing the actual "asymmetric information" gap between biospecimen providers and biospecimen end-users. Thus, the PT Program represents an essential infrastructural development in the field of biomarker identification and validation, and consequently will improve health care.

An annual PT program has been created and introduced by the IBBL 10 years ago with the aim to provide an independent assessment of the performance of biobank laboratories. IBBL acts as the PT Provider and has the responsibility for coordinating all of the activities involved in the operation of the PT Programs and Schemes.

In each PT Scheme, participants receive after registration standardized samples produced and shipped by IBBL to the participants' premises. Any laboratory can assess the accuracy and precision of their biospecimen characterisation methods (DNA quantification and purity, RNA integrity, RNA quantification and purity, Cell viability, Tissue histology,...) or the efficiency of processing/extraction methods (DNA/RNA from whole blood, FFPE cells or frozen tissue, microbial DNA extraction from stool or saliva, cfDNA extraction from whole blood, Viable PBMC isolation,...). To find out more or check the full programme, go to:

<https://www.lih.lu/en/biospecimen-proficiency-testing/>

Participants use their routine methods to analyse or extract the samples (Figure 1). Participants capture general pre-analytical data and results on the PT registration and reporting online platform:

<https://biospecimenpt.ibbl.lu/>

Once all processed samples have been returned to IBBL by the participants, IBBL proceeds with isochronous testing and statistical analysis. The IBBL Biorefinery complies to the requirements of ISO 9001:2015 and ISO 17025:2017 for the Biospecimen characterization assays it performs. A statistical design is decided in advance to meet the objectives of a specific Scheme, based on

the nature of the data (quantitative vs qualitative), the statistical assumptions, the sources of uncertainty and the expected number of results. Statistical procedures used are those proposed by the International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories (IUPAC technical Report 2006). All results provided by Participants will be analysed with the same statistical method and individual results are assessed against an assigned value [2].

At the end of each programme, IBBL sends to each participant a personalized report, a certificate and a label of participation. Reports provided to all Participants will include the following: summary on the design of the Scheme, recommendations based on the outcome of the Scheme, statistical procedure used, Participant results, statistical data and summaries, including assigned values and ranges of acceptable results, procedures used to establish the standard deviation, and comments on Participant performance.

Furthermore, PT for processing methods provides unique evidence-based insights into the impact of preanalytical factors, and the comparative performance of different processing methods and kits. PT reports, including qualitative or quantitative attributes of the produced biological material, can be used as an input for validation of a processing method by individual laboratories.

In the context of SPIDIA4P project, a global historical analysis on almost 1000 PT schemes based on standard categorized preanalytical data provided by participants and on centralized measurements of relevant quality attributes of the produced specimens (z-scores) was performed. We could assess the impact of critical preanalytical factors on quantitative or qualitative attributes of different types of specimens and laboratory performance patterns over time [3].

This global analysis provides evidence-based answers to the two issues, namely

- the robustness of processing methods to preanalytical variables, and
- the benefit of regular participation in PT processing schemes.

It was shown that the impact of a specific preanalytical parameter, such as the type of extraction kit or the automation, differs according to the combination of

- the type of the input biological material (e.g. blood, frozen tissue, fixed tissue),
- the type of the output biological material (e.g. DNA, RNA), and
- the type of the quality attribute considered (e.g. yield, purity, integrity).

Overall,

- magnetic bead-based extraction methods lead to increased yield of nucleic acids from non-fixed biological materials;
- automation improves the yield of nucleic acids from non-fixed biological materials;
- manual extractions favour nucleic acid integrity from blood;
- silica-based extraction methods improve nucleic acid purity, and RNA yield and integrity, from frozen tissue.

Furthermore, we observed an objective indications of laboratory performance improvement over time in several schemes [3]. A manuscript with this analysis and data will be published in the SPIDIA4P special issue of New Biotechnology journal.

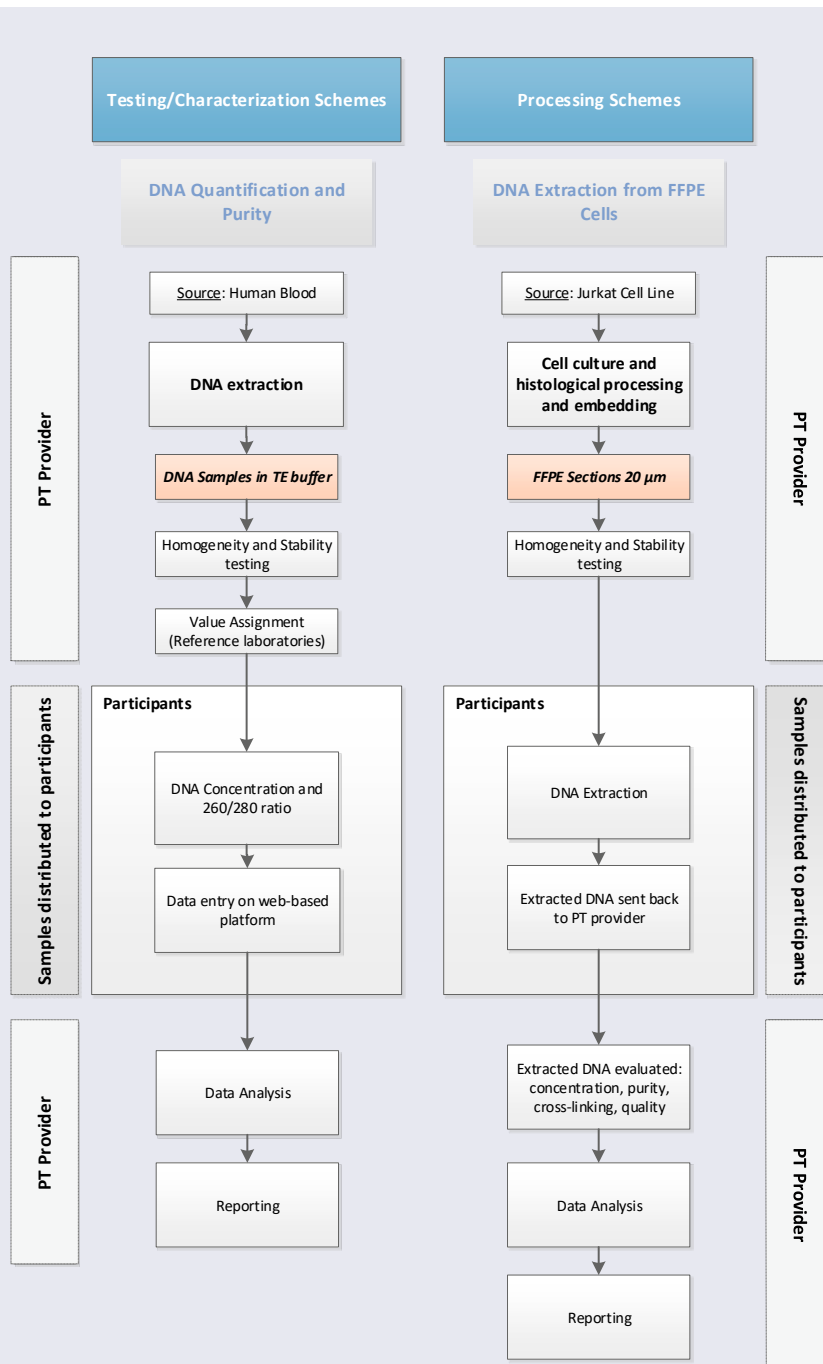
Last but not least, we would like to announce the future developments of our PT program. The PT program will be run more frequently (several rounds per year to reflect the needs for regular participation). New PT schemes coming soon! Stay tuned! If you have any question, please contact us: ISBERPT@ibbl.lu.



References :

1. ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing
2. A. Gaignaux et al., 2022 *PT Participant Manual*.
3. Paolo Verderio, Chiara Maura Ciniselli, Amélie Gaignaux, Marta Pastori, Sabrina Saracino, Olga Kofanova, Fay Betsou. *External Quality Assurance programs for processing methods provide evidence on impact of preanalytical variables*, N Biotechnol., 2022:

 <https://doi.org/10.1016/j.nbt.2022.08.006>




SPECIAL I: SUCCESS STORIES AND AWARDS

The SPIDIA4P project gains more and more traction and awareness despite its official funding has ended – it lives on within further consortia, publications and the continued development and implementation of new standard documents on international level! The following success stories give proof to the high relevance and impact of the work of SPIDIA4P:




Standard & Innovation Project Award

Chosen amongst several high-class EU grant project, SPIDIA4P won the Standard + Innovation Project Award by CEN and CENELEC for its important contribution of research and innovation to standardization in October 2021!

What a big acknowledgement!

During the official award ceremony, SPIDIA4P project lead Dr. Uwe Oelmueller, QIAGEN GmbH, received the prestigious award.

Take a look:

-  [Watch the video of the ceremony!](#)
-  [CEN and CENELEC Press Release](#)
-  [LinkedIn Post QIAGEN](#)

Again: SPIDIA4P in European Standardization Fact Sheet

SPIDIA4P becomes a real role model for successful standardization projects that foster research and innovation: for the second time, SPIDIA4P was chosen to be one of the 3 success stories showcased in the revised EU Standardization factsheet in 2022! (The first version was published by the European Commission on the World Standards Day on October 14, 2020)

A great recognition of the work and importance of the SPIDIA4P consortium and its efforts to standardize the preanalytical phase and hence reduce the diagnostic errors!

Take a look:

-  [Get the Fact Sheet!](#)
-  [Press Release DIN e.V. \(German\)](#)


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 Oelmueller, coordinator of Spidia4P

<https://www.spidia.eu/>



SPECIAL I: SUCCESS STORIES AND AWARDS

Biobanks in Spain and Italy receive international biobank standard ISO 20387 accreditation

Andrea Wutte, Head of Quality Management at BBMRI-ERIC and former SPIDIA4P member, emphasised the importance of this success and pointed out that accredited biobanks are the future beacons of scientific excellence. Research and development with accredited processes and international standards takes biobanking and biomedical research to a new level.

Two national biobanks, the Fundación Instituto Valenciano de Oncología (IVO Biobank) in Spain and the Biobanca Multispecialista (BMS) in Italy, have just received biobank standard ISO 20387 accreditation.

This is exciting news, because this serves as official recognition that these facilities have skilled personnel, the right kind and enough equipment and infrastructure needed to perform their activities, and that they apply validated methods and procedures to work with the biological material and its associated data.

The process to receive accreditation can be a long one: in Spain, the Entidad Nacional de Acreditación (ENAC) has repeatedly emphasized its firm commitment to ensure accredited services that guarantee the safety of healthcare provided and the control over various areas and stages of this provision. In 2019, ENAC officially opened the process for applying for biobank accreditation according to the ISO 20387 standard.

Just one year later, the L'Ente Italiano di Accreditamento (Accredia) also initiated the process of biobank accreditation in Italy according to this standard.

The IVO Biobank, which specializes in oncological pathology, contains more than 200,000 biological samples and their associated clinical data. IVO General Director Manuel Llombart

Fuertes, celebrated the success, remarking that "Accreditation of the IVO's Biobank represents our commitment as institution in promoting a good quality cancer research and an instrument to guaranty the protection of the cancer patient rights and interests".

The Scientific Director of IVO Biobank, Dr. José Antonio López-Guerrero will present the challenges and successes that the staff – and especially the biobank coordinator Isabel Cortell Granero – had to overcome while implementing the ISO20387 at the upcoming Europe Biobanking Week (EBW) 2022 in Regensburg, Germany.

Dr. Simone Lapi, Director of the Biobank Unit of the University Pisa Hospital, underlines that "ISO 20387 accreditation is fully part of the institution's mission and is an essential tool in the field of biobanking to guarantee the quality of samples and clinical associated data. ISO 20387 accreditation represents a fundamental result in terms of service to researchers and citizens/ patients and an important step towards the direction of the development of precision medicine."

The Director of BBMRI.it, Prof. Marialuisa Lavitrano, confirmed the strong support of BBMRI.it for the accreditation process of all biobanks part of the national node and described the exciting (and sometimes frustrating) journey toward accreditation and the implementation of ISO 20387 at the Europe Biobanking Week (EBW) 2022 in Regensburg, Germany.




Congratulations to the **IVO Biobank** (Spain, left) and **Biobanca Multispecialista** (Italy, right) for receiving international biobank standard ISO 20387 accreditation!





SPECIAL II: NETWORKING



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SPIDIA4P project members support new SARS-CoV-2 diagnostics

During the current COVID-19 pandemic, precise and state-of-the-art testing for the presence of SARS-CoV-2 in research studies is of the utmost importance. The Trans National Access project **NESARSDia** was granted by the Advancing European Research Infrastructure on Highly Pathogenic Agents (ERINHA-Advance) and funded by the European Commission to improve SARS-CoV-2 next generation diagnostics for wide use in European and global healthcare systems. The NESARSDia project was carried out by the cooperation partners QIAGEN GmbH in Hilden, Germany, and the team of the BSL-3 laboratory at the Medical University Graz, Austria, all of them SPIDIA4P project members.

Broad testing of people is one of the key pillars of controlling SARS-CoV-2 infections and the pandemic. Due to the global emergence of the Covid-19, various companies and institutions took the opportunity to develop commercially available swab systems and saliva collection devices for the detection of SARS-CoV-2 infections. This created the need for comparison studies of existing solutions and a next generation of diagnostic tests. Therefore, NESARSDia aimed at providing guidance on the performance of existing and broadly used swab and saliva collection/transport/stabilization systems. Moreover, the NESARSDia project focused on **establishing a novel workflow of specimen collection, stabilization, fast analyte isolation and high-throughput multiplex testing by qPCR amplification for different respiratory viruses**. While obtaining respiratory samples by nasopharyngeal swabs represented the first method of choice for diagnosis and research, saliva collection for detection of SARS-CoV-2 infection was gaining increasingly more importance. Advantages of saliva samples include non-invasiveness, possibility for convenient at-home collection and unnecessary of medically trained personnel for sample collection. Different swab- and saliva-based sampling devices and stabilization solutions were tested for stabilization and inactivation of SARS-CoV-2 and other relevant respiratory viruses such as different Influenza strains or Respiratory Syncytial Virus A/B as the goal was to develop **generic pre-analytical workflows** to be also prepared for future outbreaks caused by other respiratory viruses. To this end, different defined viral copy numbers were spiked into different transport and collection media, viral RNA was isolated directly after spike-in, after 24 hours and after 96 hours storage at different defined temperatures to simulate transport

and storage conditions occurring in healthcare. Additionally, the inactivation of the respiratory viruses by the same media was analyzed in a cell culture infection model. Such virus inactivation is highly advantageous as it makes the need for BSL-2 laboratories obsolete for providing large scale diagnostic capacities, depending on local legislative requirements. The project demonstrated scientific evidence that **pre-analytical variables such as collection and storage conditions (duration, temperature etc.) can significantly impact the performance of analytical tests detecting SARS-CoV-2. Specified and verified pre-analytical workflow parameters are therefore key for reliable and correct SARS-CoV-2 diagnostics.**

The obtained results already led to one **peer-reviewed publication: "Pre-analytical sample stabilization by different sampling devices for PCR-based COVID-19 diagnostics" (Hardt et al., 2022)** while a second manuscript is still development.

This work benefited from the long-term experience in pre-analytical workflow requirements of molecular diagnostic tests developed within the SPIDIA and the SPIDIA4P project funded under EU FP7 and H2020, as well as several ISO standards that have emerged from these projects.

As far as feasible within this project scope, the NESARSDia project adhered to the requirements of the new European In Vitro Diagnostic Regulation (IVDR, as further specified in Annexes I, II, IX, XIII of the regulation) for supporting later IVD clearances of entire diagnostic test workflows, usable also for longer term beyond the current COVID-19 crisis situation. The NESARSDia data will be important for the first revision of the first ISO Technical Specification on SARS-CoV-2 diagnostics that was just released in April 2022: "ISO/TS 5798: *In vitro diagnostic test systems – Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods*".

Overall, the obtained results are planned to be used for existing and new CEN standard documents projects at the European Committee for Standardization for pre-analytical workflows applied to SARS-CoV-2 and other respiratory viruses in vitro diagnostics.



SPECIAL II: NETWORKING



IVO GUT, Ph.D.

Director of the Centro Nacional de Análisis Genómico (CNAG)
Coordinator of EASI-Genomics



hwww.cnag.crg.eu

cnag

centre nacional d'anàlisi genòmica
centro nacional de análisis genómico



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CRG⁵
Centre
for Genomic
Regulation

EASI-Genomics: the SPIDIA4P mission continues

EASI-Genomics^[1] is a project funded under the INFRAIA scheme of H2020 through Grant Agreement 824110. It belongs to the Research Infrastructures programme of the Excellent Science pillar, concretely, to 'Integrating and opening existing national and regional research infrastructures of European interest'.

EASI-Genomics' **mission** is to **provide easy and seamless access to cutting-edge DNA sequencing technologies to researchers from academia and industry**, within a framework compliant with ethical & legal requirements and FAIR and secure data management.

With an EU contribution of € 9.991.267, EASI-Genomics is **coordinated by Dr. Ivo Gut from the Centre for Genomics Regulation (CRG), and former SPIDIA4P project member**. The EASI-Genomics consortium is composed of sixteen beneficiary organisations from eight European countries^[2], representing different stakeholders: researchers in genomics, national and academic facilities providing advanced genomics services, data analysts, legal experts, and medical doctors.

EASI-Genomics is an ambitious initiative with the vision of building a community of practice that leverages advanced sequencing technologies beyond country and sector borders to tackle global challenges in science. The sixteen EASI-Genomics participant organisations are creating a **stimulating environment for the consortium's members to work together, exchange practices**

and views, benchmark, co-create to innovate, and reflect on the outcomes, to develop the scientific concept and technical feasibility of a new European Research Infrastructure (RI) on Advanced Genomics Technologies within the ESFRI Roadmap^[3], fostering the engagement of the relevant stakeholders.

Up-to-date, the requirements for NGS analysis grow almost exponentially^[4], in part by initiatives like the 1+Million Genomes^[5] or by what will be needed by the HE Mission Cancer^[6]. Considering the current instruments in the eleven genomic facilities members of the EASI-Genomics project, the aggregated full sequencing capacity is over 22 petabases per year (22,000,000,000,000,000 bases), which translates into an annual 230,000 human genomes sequenced at 30x coverage. **This capacity makes the EASI-Genomics consortium to be in a unique position for boosting state-of-the-art research and innovation while sharing experience in setting up and operating genomics facilities.**

The EASI-Genomics 'EU advanced community' has proven to be very successful in 1) providing coordinated transnational access to eleven genomic platforms for 105 academic and industrial users in the first three years; 2) benchmarking and harmonization of NGS and data analysis methods to assure cross-project high standards; 3) developing novel and improved techniques for both pre-analytical, analytical methodologies, and bioinformatic analyses



SPECIAL II: NETWORKING

in NGS; and 4) establishing standards to ensure accessibility and reusability of produced data.

EASI-Genomics has a strong potential for interdisciplinarity and for establishing relevant links with other European RIs at the ESFRI level. Concretely, the EU RIs from 'Health and Food', 'Environment', and 'Data, Computing, and Digital fields' are relevant stakeholders towards the evolution of EASI-Genomics into a permanent advanced genomics infrastructure within the ESFRI Roadmap, since they can help identify links and complementarities and evaluate its scientific case or the possibility of its integration within one of the existing ones. From EASI-Genomics, we are already in contact with the representatives of four ESFRI landmarks (ELIXIR ^[7], EATRIS ^[8], BBMRI ^[9], and EMBRC ^[10]) to this end. Within the complex map of RIs, the EASI-Genomics community can act as a vehicle for multidisciplinary research, for example, by providing genomic data that can be combined with health data from clinical trials or biomedical research (ECRIN ^[11], EATRIS ^[8]) or with imaging data (EURO-Bioimaging ^[12]). Also, as an integrating activity, EASI-Genomics is engaged in collaboration with ELIXIR through activities in genomics data handling with the participation of the EMBL-EBI ^[13] and the EGA ^[14]; with BBMRI in the establishment of standards and benchmarking procedures, and with EPIC-XS ^[15], the integrating activity on proteomics, through training activities and even a joint transnational access call for project proposals.

In the field of biomedical sciences and the development of personalised medicine and new treatments, the European RI arisen from EASI-Genomics could also be integrated into the European Alliance of Medical Research Infrastructures (EU-AMRI) ^[16], and provide crucial genomic services not offered by the current partners in a fully integrated biomedical pipeline (from sample to data, from research to market).

EASI-Genomics is becoming a key player in establishing standards, benchmarking, and interlaboratory comparison schemes to ensure the quality, accessibility, and reusability of the genomic data produced, and in promoting genomic data sharing aiming to extend the potential of genomics both in the research and the healthcare environments, and allowing new scientific advances to be translated into effective healthcare solutions.

- ^[1] EASI-Genomics. <https://www.easi-genomics.eu/home>
- ^[2] EASI-Genomics Fact Sheet – Cordis. [European Advanced infraStructure for Innovative Genomics | EASI-Genomics Project | Fact Sheet | H2020 | CORDIS | European Commission \(europa.eu\)](#)
- ^[3] ESFRI Roadmap 2021. Strategic report on research infrastructures. ISBN Print: 978-88-943243-4-1. <https://roadmap2021.esfri.eu/media/1295/esfri-roadmap-2021.pdf>
- ^[4] Research and Markets Report. Next-generation Sequencing (NGS) Market - Growth, Trends, COVID-19 Impact, and Forecasts 2022 - 2027). <https://www.researchandmarkets.com/reports/4591274/next-generation-sequencing-ngs-market-growth>
- ^[5] 1+ Million Genomes Initiative. <https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes>
- ^[6] HE Mission: [Cancer. Cancer \(europa.eu\)](#)
- ^[7] ELIXIR. <https://elixir-europe.org/>
- ^[8] EATRIS. <https://eatris.eu/>
- ^[9] BBMRI. <https://www.bbmri-eric.eu/>
- ^[10] EMBRC. <https://www.embrc.eu/>
- ^[11] ECRIN. <https://ecrin.org/>
- ^[12] EURO-BIOIMAGING. <https://www.eurobioimaging.eu/>
- ^[13] EMBL-EBI. [EMBL-EBI: EMBL's European Bioinformatics Institute | EMBL's European Bioinformatics Institute](#)
- ^[14] European Genome and phenome Archive (EGA). <https://ega-archive.org/>
- ^[15] EPIC-XS. [Home - EPIC-XS](#)
- ^[16] EU-AMRI. <https://eu-amri.org/>



 **SPECIAL III: EDUCATION****PROF. GIORGIO STANTA**

Università degli Studi di Trieste

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The Development of the European Master in Molecular Pathology (EMMP)

In this year, the European Union of Medical Specialists (UEMS) has approved the **European Master in Molecular Pathology (EMMP)** that will have its organizational site in the University of Nice.

The UEMS represents over 40 Specialist Sections, over 1.6 million medical specialists, the National Associations of Medical Specialists in the European Union and its associated countries. It plays a key role in harmonizing training requirements and defining roles and characteristics of Trainers and Training Centers (ETR). It aims to harmonize training requirements and to define roles and characteristics of Trainers and Training Centers (ETR). UEMS sets **standards for high quality healthcare practice** to be diffused and applied in the European countries.

The other two European organizations directly involved in diagnostic molecular pathology are the Molecular Pathology Working Group (MPWG) of the ESP (European Society of Pathology) and the Biobanking and Molecular Pathobiology Working Group (BBMPWG) of OEIC (Organization of European Cancer Institutes). Both working groups are directly involved in the proposal. Among the members of the advisory board, there are also some specialists in charge of molecular pathology in several European countries.

The Master was developed not only to diffuse molecular pathology knowledge among young pathologists but also to improve standardization of molecular pathology at European level.

For almost two years, a steering committee has worked at the preparation of the Master. The steering committee is composed by some of the most eminent experts in molecular pathology in Europe and others will join it.

Molecular pathology today is a basic requirement in clinics to establish a correct precision medicine therapy especially in oncology. The analyses of specific damage at the molecular level in tumours are suggesting a more efficient and specific drug. Every country in Europe has developed organizations and networks to develop this type of molecular diagnosis and this is taking to different types of organizations in different countries. Especially oncology patients move frequently from hospital to hospital and often also from country to country. This implies that clinical records should be easily understandable in every European hospital.

For this reason, standardization of molecular pathology is extremely important together with the development of a European common language.

The standardization is based on the European specific projects experience such as HERCULES on tumor heterogeneity, SPID1A4P on pre-analytical condition of biological material, Instand-NGS4P on the evaluation of NGS items available on the market, and others.

The second major challenge is that diagnostic molecular pathology is continuously developing and we need a very plastic organization that is able to continuously modify the suggestions and the rules. Due to that, a scientific committee that prepares some documents, is not sufficient. There is a need for a steering committee that would be able to modify in the time along with the new developing rules.

The steering committee of the master has this type of characteristics and its duty is to renew every year the teaching contents of the master along with the new proposals and discoveries.



SPECIAL III: EDUCATION

The rationale of the Master is to perform a reproducible and exchangeable molecular diagnostic analyses at the European level with verification of knowledge and competencies of the new professionals in the field.

The objectives are those to guarantee a theoretical and practical training in molecular diagnostic pathology with a high attention for quality assurance and bioethical aspects.

EMMP is divided in two years with compulsory attendance for the participants. In the first year, the molecular diagnostics methods in solid and liquid tissues will be developed, while in the second year the clinical research methods will be analyzed.

About the author

Prof. Giorgio Stanta is the chairperson of the Biobanking and Molecular Pathobiology WG of OECI (Organization of European Cancer Institutes). He was the chair of the Molecular Pathology WG of the European Society of Pathology and now is the vice-chair. His main interest is the application of molecular analysis to fixed and paraffin-embedded tissues (all human tissues of biopsy or surgical origin), called archive tissues, with specific attention to pre-analytical conditions and standardization of methods. He has developed several methods, in particular for RNA analysis. Professor Stanta is the coordinator of the European group "Archive Tissues: Improving Molecular Medicine Research and Clinical Practice – IMPACTS" www.impactsnetwork.eu

He is taking part as an expert in the Quality Group of the European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI-ERIC).

November 2022

BBMRI_QM Academy: join the next webinar on Frozen Tissue Collection and Biobanking

Tuesday, November 15, 2022
10:00–12:00 CET

Pre-analytics, frozen tissue processing, standardisation to increase quality and reproducibility

Take a look:

 [Read more...](#)

 [Registration > Programme](#)

 [General Link](#)



Storyset - Freepik.com



 SPIDIA4P // SCIENTIFIC PUBLICATIONS



find all articles by SPIDIA4P members
 on <https://www.spidia.eu/publications/articles>

Peer-reviewed scientific publications generated by SPIDIA and SPIDIA4P project partners:

De Martino E, Medeot C, D'Amico L, Stanta G, Bonin S

Impact of standardization in tissue processing: the performace of different fixatives


New Biotechnology, Vol. 71, Nov. 2022, pages 30-36 - open access


[Impact of standardization in tissue processing: the performance of different fixatives - ScienceDirect](#)

Mueller H, Holzinger A, Plass M, Brcic L, Stumptner C, Zatloukal K

Explainability and causability for artificial intelligence-supported medical image analysis in the context of the European In Vitro Diagnostic Regulation

New Biotechnology, Vol. 70, Sept. 2022, pages 67-72 - open access


[Explainability and causability for artificial intelligence-supported medical image analysis in the context of the European In Vitro Diagnostic Regulation - ScienceDirect](#)

Stumptner C, Stadlbauer V, O'Neil D, Gessner A, Hiergeist A, Zatloukal K, Abuja PM

The Pre-Analytical CEN/TS Standard for Microbiome Diagnostics – How Can Research and Development Benefit?

Nutrients 2022 14(9), May 9, 2022 – open access

CEN/TS 17626, the European pre-analytical standard for human specimens intended for microbiome DNA analysis, was published in 2021. It is relevant for in vitro diagnostic (IVD) manufacturers and diagnostic laboratories but also for biobanks and regulatory bodies and as it is considered the state of the art.

The authors present in their paper, why standards are needed in biomedical research, what pre-analytical standards can accomplish, and which elements of the pre-analytical workflow they cover.


[Nutrients | Free Full-Text | The Pre-Analytical CEN/TS](#)


[Diagnostics—How Can Research and Development Benefit? | HTML \(mdpi.com\)](#)

Hardt M, Foederlein-Hoebenreich E, Freydl S, Kouros A, Loibner M, Zatloukal K


Pre-analytical sample stabilization by different sampling devices for PCR-based COVID-19 diagnostics

New Biotechnology, Vol. 70, September 25, 2022, pages 19-27 – open access

In cooperation with SPIDIA4P partners, the EU HORIZON 2020 project NESARSDia at the Medical University Graz has recently led to this scientific publication that stresses the pre-analytical factors including different sample collection devices for SARS-CoV-2 diagnostics.

NESARSDia is a project under the umbrella of the European Research Infrastructure on Highly Pathogenic Agents (ERINHA/ ERINHA Advance)

Read more about NESARSDia and ERINHA [here](#)


[Pre-analytical sample stabilization by different sampling devices for PCR-based COVID-19 diagnostics - ScienceDirect](#)


INFORMATION, VIDEOS, WEBINARS, PRESENTATIONS

Gain more information and knowledge by looking at the various and many electronic education materials like videos, webinars, presentations etc., produced by SPIDIA4P members or collaboration partners on www.spidia.eu

MEDIA ON WWW.SPIDIA.EU

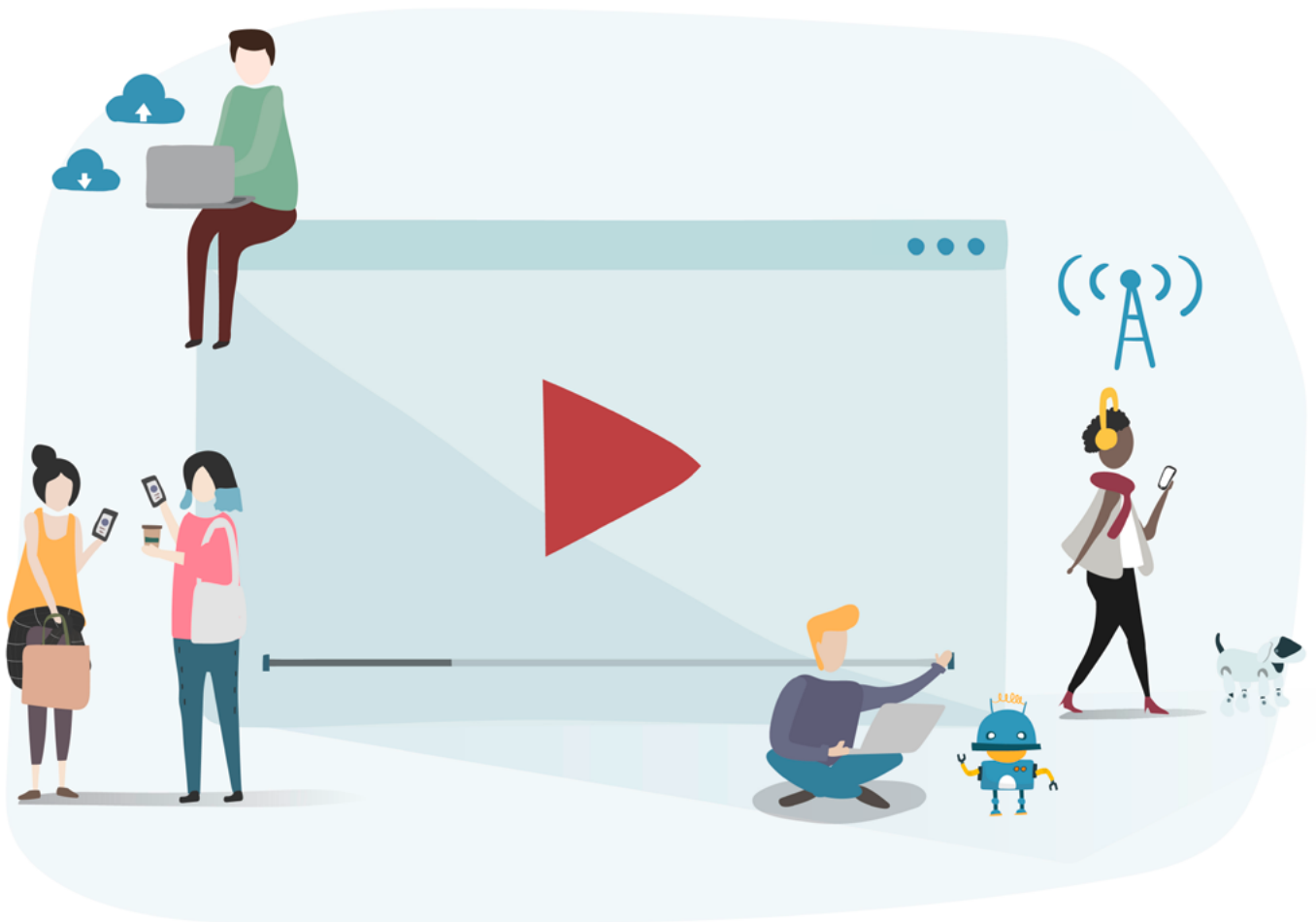
Videos

 watch on www.spidia.eu

Webinars

 watch on www.spidia.eu

Presentations

 watch on www.spidia.eu


Rawpixel.com - Freepik.com


SPIDIA4P EVENTS // PAST EVENTS // 2021 / 2022

August 2021

33rd European Congress of Pathology
August 29-30, 2021

Pathology: Compass for optimal patient therapy



Take a look:

 [Presentation by Prof. Serena Bonin, UNITS](#)

 [Handout by Prof. Serena Bonin, UNITS](#)

 [Abstract Book](#)

October 2021

5th LISAvienna Regulatory Conference for Medical Devices and In-Vitro Diagnostics

October 12, 2021; Vienna, Austria

Contributions by SPIDIA4P member [BBMRI.at](#) / Medical University Graz

[BBMRI.at](#) participated with several speakers and an expert booth in this annual conference, which took place October 12, 2021 in the Pharmacy Wing of Schloss Schönbrunn (Vienna).

Almost 400 people from the DACH region were interested in the exchange via MDR and IVDR and related topics such those addressed on [BBMRI.at](#), namely pre-analytics, biobanking, and AI.



Strong interest in the 5th LISAvienna Regulatory Conference for Medical Devices and In-Vitro Diagnostics

Take a look:

 [Review article, programme and presentations](#)



SPIDIA4P EVENTS // PAST EVENTS // 2021 / 2022

April and May 2022

Biobanking Courses at Medical University of Graz

Since several years, Med Uni Graz offers interactive courses for biobank beginners and advanced biobanks, consisting of presentations, practical sessions and a guided tour of Biobank Graz, one of the largest European hospital-based biobanks.

In April and May 2022, several young and advanced biobankers from 10 different countries and 3 continents visited BBMRI.at partner Medical University of Graz to learn about building and operating a biobank or managing teams and projects in a biobank in one of the following courses:

- 2-day-course “How to build a biobank” (21-22 April, 2022)
- 5-day course “How to operate a biobank” (25-29 April 2022)
- „Managing multidisciplinary teams and scientific projects in biobanks” (2-6 May, 2022)

The feedback on all courses was very good. All participants enjoyed working together interactively in person and exchanging information about their fields of activity in the respective biobanks. The new course was particularly well appreciated by the participants and our project partners, as it focused particularly on multidisciplinary teamwork in biobanks.



Further information to all offered courses can be found on:

 www.medunigraz.at/international-biobanking-education

May 2022

The 10th Santorini Conference

May 23-26, 2022

San Torini, Greece

Systems Medicine Personalised Health and Therapy

Presentations by SPIDIA4P members:

Dr. Georges Dagher – Big data, Artificial Intelligence and ethics

Dr. Uwe Oelmueller – Standardized Preanalytics: The Key for Reliable Diagnostics, Research and Biobanking



Take a look:



[Programme](#)



[Welcome Letter Dr. Sofia Siest, President of the Santorini Conference series](#)



[Speakers](#)


SPIDIA4P EVENTS // PAST EVENTS // 2021 / 2022

June 2022

Symposium "Frontiers in Human Exposome Research" of the EU project HEAP (Human Exposome Assessment Platform)

June 1, 2022

Presentations by SPIDIA4P members

Prof. Kurt Zatloukal - Biobanking and the exposome

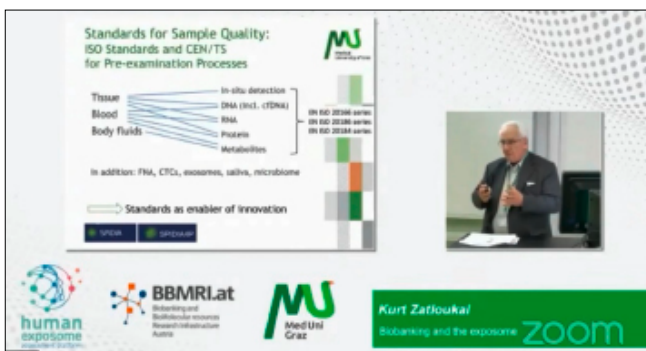
Around 100 people were interested to hear and exchange about new developments in the field of exposome research on June 1, 2022. BBMRI.at co-organized the symposium "Frontiers in Human Exposome Research" of the EU project HEAP (Human Exposome Assessment Platform).

The exposome refers to all the environmental exposures that individuals experience over their lives and how those exposures affect health. Invited established experts presented the latest exposome research at the "Frontiers in Human Exposome Research" symposium, 1 June 2022.

The event was held in a hybrid format at Med Uni Graz. The presentations of the speakers from e.g. BBMRI.at, the HEAP project and Exposome Austria were recorded and are now available as videos.

Missed the event ? No problem!

 [Review, videos and presentations](#)



Take a look:

 <https://www.youtube.com/>

September 2022

34th European Congress of Pathology

September 3-7, 2022

Basel, Switzerland

Presentations by several SPIDIA4P project partners; SPIDIA4P member and BBMRI.at Director Kurt Zatloukal (Med Uni Graz) session chair and presentation on quality, standardization and pre-analytics:

Session: SY-20 – Molecular Pathology: Standardisation of molecular pathology analyses in Europe



Take a look:

 [Programme](#)

 [Information on bbmri.at](#)


SPIDIA4P EVENTS // PAST EVENTS / 2022
September 2022
Europe Biobank Week Roadshow 2022 – On the Road to High Quality: With Biobanks in the Fast Lane!

19–20 September 2022, Regensburg, Germany

BBMRI-ERIC and ESBB invited to the first Europe Biobank Week Roadshow Meeting & Exhibit held at the University of Regensburg, Germany, 19 -20 September 2022. This #EBW22 Roadshow meeting was organized by ESBB and BBMRI-ERIC in partnership with the University of Regensburg, the “1. Bavarian Biobank Day” and the BRoTHER Summer School. The Meeting kicked off with a keynote by Carolyn Compton (US) followed by these sessions:

- The Bumpy Road to Accreditation
- Roadmap to Quality – A Guide to Reach the Aim of Accreditation
- Data Quality – More Than a Trailer
- Quality as a Driver for Biobank Innovations.

The event was framed by the first meeting of the Bavarian Biobank Network on the morning of the first day and hands-on training by the BRoTHER Summer School in the afternoon of the second day. The participants could meet and discuss with peers at poster sessions and the networking event and exchange with companies at the exhibition.

Among the speakers, Peter Riegman spoke on “Standardized Pre-analytics: The Key for Reliable Diagnostics, Research and Biobanking” representing Uwe Oelmueller, the SPIDIA4P project and PreAnalytiX GmbH.


Peter Riegman is Head of the Erasmus MC Tissue Bank at the Pathology Dept, Erasmus Medical Center, Rotterdam & Advisor in the Erasmus MC service platform project team Erasmus MC Central Biobank.

More information

[See the programme here!](#)

You will find the information notice specific to the data processing for the organization of the EBW [Roadshow](#) here.

Please also find our privacy statements here: [ESBB](#), [BBMRI-ERIC](#). For more information on the Eventbrite Privacy Statement [click here](#).


Take a look:

<https://www.bbmri-eric.eu/events/europe-biobank-week-roadshow-university-of-regensburg-germany/>

Also the **2ND STOP OF THE EUROPE BIOBANK WEEK** Roadshow was very successful! It took place on October 13-14, 2022, in Rome, Italy. The focus of this interactive workshop was on **PEDIATRIC BIOBANKING AND MINOR ENGAGEMENT**

SAVE THE DATE // 2023

Europe Biobank Week 2023
 April 25-28, 2023
 Bologna Congress Center
 Italy


<https://europebiobankweek.eu/>


SPIDIA4P EVENTS // PAST AND UPCOMING EVENTS / 2022
Oktober 2022
German Congress for Laboratory Medicine

October 13-14, 2022

10:00–12:00 CET

Hybrid format - online and on-site

Congress Center Rosengarten, Mannheim, Germany

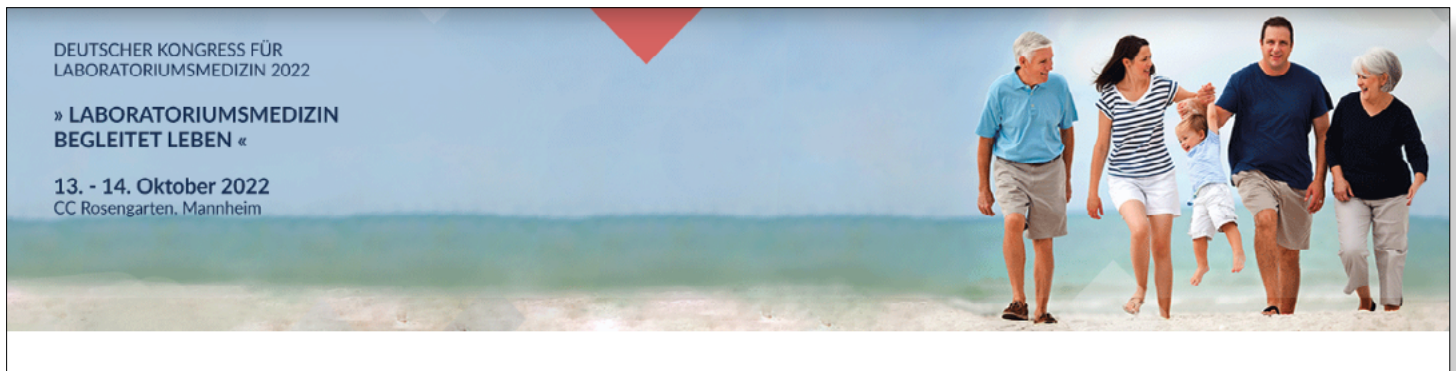
German language

 Presentation by **Dr. Uwe Oelmueller**, QIAGEN GmbH,
 SPIDIA4P Coordinator

Presentation title:

CEN Spezifikationen und ISO Standards für die Qualität der Präanalytik von Genomanalysen. Wo stehen wir 2022? (CEN Specifications and ISO Standards for ensuring Quality of Preanalytics applied to Genome Analysis. Where do we stand in 2022?)

Programme:

<https://laboratoriumsmedizin-kongress.de/programm/online-programm/>


Initially established as a hands-on course institution, TATAA Biocenter AB remains faithful to its original teaching mission. After a two-year break due to the pandemics, our popular courses in Hands-on qPCR and Digital PCR – Application and Analysis resumed early February 2022 and have been fully booked with participants from different parts of the world. We are continuing our courses this Autumn and Winter according to the following schedule:

- MicroRNA Analysis (7–8 November 2022)
- Hands-on qPCR (5–7 December 2022)
- Experimental Design and Statistical Data Analysis for qPCR (8–9 December 2022)

For more information, please visit our website


www.tataa.com/courses

or contact us at


training@tataa.com



 SPIDIA4P EVENTS // UPCOMING EVENTS + EDUCATION // 2022

November 2022

BBMRI_QM Academy: join the next webinar on Frozen Tissue Collection and Biobanking

Tuesday, November 15, 2022
10:00–12:00 CET

Pre-analytics, frozen tissue processing, standardisation to increase quality and reproducibility

Summary

In order to preserve tissues for biomedical research and biobanking, snap freezing and storage at ultra-low temperatures is the best option to preserve the tissue morphology together with DNA, RNA and proteins. It is often referred to as the golden standard. However, without standardization of the pre-analytical conditions the results can become misleading and irreproducible.

The expression of genes can change rapidly in response. In addition, sample handling can lead to variations or errors. Standardization stabilizes such unstable procedures. Documentation is key, and metadata helps researchers determine whether certain tissues are suitable (fit for purpose) for biomedical research or multicenter studies.

Take a look:

 [Read more...](#)

 [Registration > Programme](#)

 [General Link](#)



BIOBANKING
Pre-analytical phase

 **SPIDIA4P EVENTS // UPCOMING EVENTS + EDUCATION // 2022**

BIO Deutschland e.V. presents:

Biotech Innovation Spotlight: Liquid Biopsy

November 22, 2022, digital format

**Presentation and Panel participation by Dr. Uwe Oelmueller,
QIAGEN GmbH, SPIDIA4P coordinator**

The event provides an overview of the progressive development and dissemination of liquid biopsy in the German research and care landscape.

The programme includes keynote speeches, panel discussions, company presentations, individual workshops and general networking. Some parts of the programme will be held in German, for these sessions we offer simultaneous English translation. Participation in the event is free of charge.

You can download the program here:

 [Download](#)

More information here:

 [Read more...](#)



**BIOTECH
INNOVATION
SPOTLIGHT**
Liquid Biopsy

22 November 2022 | 10 to 16.30 CET



 **SPIDIA4P NEWS // WEBSITE** www.spidia.eu



KATRIN RODENKIRCHEN

QIAGEN / PreAnalytiX

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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.



[Posts on Twitter](#)



[Posts on LinkedIn](#)



[Posts on facebook](#)

Don't miss

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

 www.spidia.eu



The SPIDIA project has received funding under the Seventh Research Framework Programme of the European Union, FP7-HEALTH-2007-1.2.5, under grant agreement no. 222916. The SPIDIA4P project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733112.