SPIDIA4P

SPIDIA4P Newsletter 2023/2024

STANDARDS MAKE THE DIFFERENCE

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

Dear reader,

Preanalytical workflow steps are the most error-prone element in whole diagnostic workflows. They are in focus more than ever for improving assay data quality. At the AACR Annual Congress 2023 in Orlando (US), the US FDA showcased for circulating tumor DNA (ctDNA) assay development that validation encompasses the entire system from sample collection to assay output. The FDA emphasized in this context to follow standardized protocols for sample collection, storage, processing and handling. This is quite similar to pre-analytical (pre-examination) requirements in the new European In vitro Diagnostic Regulation (IVDR). Both are in line with SPIDIA's, SPIDIA4P's and partner consortia's broad scientific evidence on how pre-analytical variables can impact assay results. The thereon built preanalytical ISO and CEN standards are a key tools for translating pre-analytical workflow requirements and recommendations into routine diagnostics and research, including support of legislation implementation.

The European Commission recently published a new Code of Practice on Standardization in the European Research Area, also with SPIDIA4P's input - another big milestone.

SPIDIA4P partners in various other EU, international and national research consortia continued to further shape pre-analytical science and to broaden the pre-analytical ISO standards portfolio at ISO/TC 212. At the European CEN/TC 140 two new Technical Specifications for NGS, covering all workflow steps from pre-analytical specimen collection and preservation to NGS result reporting, were developed with support by the EU INSTAND-NGS4P and EASI-Genomics Consortia.

SPIDIA4P partners' talks at international congresses, education courses and tools as well as several newly published highly relevant scientific articles rounded up again our year 2023. One publication e.g. in New Biotechnology via the EU ERINHA-Advance project is about a detailed evaluation of pre-analytical workflows variables of different respiratory viruses for PCR-based detection.

Please enjoy reading our Newsletter detailing these and various additional news. Our next Newsletter is planned for early 2025. Please also watch out for regular news on the SPIDIA4P website.

Kind regards,
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!

WHAT'S NEW? // ULRIKE SCHROEDER

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The standards are published – and now?

The work on SPIDIA and SPIDIA4P standard projects continues, and your input is needed!

Within SPIDIA4P's Work Package 1 (WP 1), the goal was to develop 12 new CEN Technical Specifications (CEN/TS) and 2 new ISO International Standards[1], thus creating and implementing a portfolio of 22 pre-analytical CEN/TS and ISO Standards (together with the existing standard documents initiated by the previous SPIDIA) for selected pre-analytical workflows needed for personalized medicine. **This goal has been reached in July 2022 - but this did not put a stop to the work on the standards. Find out more about the on-going standardization work here!**

The table on the following pages features a list of all published standard documents initiated within SPIDIA and SPIDIA4P.

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 SPIDIA4P partners as well as further pan-European experts, has developed and published 12 CEN Technical Specifications during SPIDIA4P. To achieve an even broader impact and a worldwide impact for the standardization of the pre-analytical phase of various analytes, all but the three documents on Fine Needle Aspirates have been proposed to ISO/TC 212 to be further developed on ISO level under the Vienna Agreement. Supported by decisions of CEN/TC 140, all these documents were accepted to be further developed on International level (see Table 1).

However, standardization work does not stop the moment a document is published. 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[2]. The systematic review provides valuable information on the global relevance of the standard and ensures that standards are up to date. Simultaneously, the systematic review can lead to a revised standard, incorporating changes that facilitate its implementation in countries that have not yet adopted or used the standard.

A first wave of documents developed under the framework of SPIDIA, namely EN ISO 20166-1,-2 and -3 as well as EN ISO 20184-1 and -2, will be going into their first review process in Q3/2023 with more documents following in the beginning of 2024.

What does the start of the systematic review processes mean for you?

The beginning of the systematic review process marks the fifth year since the publication of the first documents with specifications for pre-examination processes within the medical laboratory. In the meantime, the legal framework within Europe has changed and technology has further developed, making it important to incorporate any possible changes and updates into the documents.

The review process also offers the chance for users of the developed standards as well as for all interested parties to provide feedback on e.g. their readability, their usability and their implementation.

The systematic reviews will take place within the national standards bodies, meaning that the documents and their use will be reviewed nationally in consultation with all interested stakeholders to decide whether the standards are still valid, should be updated, or withdrawn.

If You, Your company or Your research institute are interested in providing feedback on the above mentioned projects going into systematic review, please contact Your national standardization body or the committee manager of CEN/TC 140/WG 3 "Quality management in the medical laboratory" (ulrike.schroeder@din.de) for further details on how to get involved!

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.
2) *https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100413.pdf*

GET A COMPLETE OVERVIEW OF THE PRE-ANALYTICAL STANDARD DOCUMENTS ALSO ON www.spidia.eu – WITH LINKS TO THE RESPECTIVE FILES!

SPIDIA SPIDIA4P

THE SPIDIA AND SPIDIA4P PROJECT HAS LED TO THE PUBLICATION OF THE FOLLOWING CEN/TS AND ISO STANDARDS IN 2018–2023

Document Number	Title	Next Systematic Review (SR)
ISO 4307		
EN ISO 4307:2021	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for saliva - Isolated human DNA **(ISO 4307:2021)**	Next SR: Q3/2026
ISO-series 20166 FFPE tissue		
EN 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 **(ISO 20166-1:2018)**	Next SR: Q3/2023
EN ISO 20166-2:2018	Molecular in vitro diagnostic examinations - Specifications for pre-examinations processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 2: Isolated proteins **(ISO 20166-2:2018)**	Next SR: Q3/2023
EN ISO 20166-3:2019	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 3: Isolated DNA **(ISO 20166-3:2018)**	Next SR: Q3/2023
EN 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 **(ISO 20166-4:2021)**	Next SR: Q2/2026
ISO-series 20184 – Frozen Tissue		
EN ISO 20184-1:2018	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 1: Isolated RNA **(ISO 20184-1:2018)**	Next SR: Q3/2023
EN ISO 20184-2:2018	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 2: Isolated proteins **(ISO 20184-2:2018)**	Next SR: Q3/2023
EN ISO 20184-3:2021	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 3: Isolated DNA **(ISO 20184-3:2021)**	Next SR: Q2/2026
ISO-series 20186 – Venous whole blood		
EN ISO 20186-1:2019	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 1: Isolated cellular RNA **(ISO 20186-1:2019)**	Next SR: Q1/2024
EN ISO 20186-2:2019	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA **(ISO 20186-2:2019)**	Next SR: Q1/2024
EN 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 **(ISO 20186-3:2019)**	Next SR: Q2/2024
ISO-series 23118		
EN ISO 23118:2021	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma (ISO 23118:2021)	Next SR: Q2/2026

SPIDIA SPIDIA4P CEN/TS DOCUMENTS

Document Number	Title	Next Systematic Review (SR)
CEN/TS series 17390 – CTCs		
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	In development as EN ISO/TS 7552-2
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	In development as EN ISO/TS 7552-3
CEN/TS 17626		
CEN/TS 17626:2021	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for human specimen - Isolated microbiome DNA	In development as EN ISO/TS 18701
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	
CEN/TS 17688-2:2021	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 2: Isolated proteins	
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	
CEN/TS documents		
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	In development as EN ISO 18703
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	In development as EN ISO/TS 18702
CEN/TS 17811:2022	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for urine and other body fluids - Isolated cell free DNA	In development as EN ISO 18704

ANNIVERSARY IBBL PROFICIENTY TESTING PROGRAM // DR. OLGA KOFANOVA

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Proficiency Testing Program 12th anniversary

High quality biobank laboratories play a crucial role in the context of multi-center clinical trials, basic and applied research, by providing and enhancing the translational link within transversal and personalised medicine initiatives. By minimizing the number of sample processing errors and increasing the reproducibility of pre-clinical and clinical studies, biobank laboratories will also improve and speed up biomarker discovery.

As a part of biobank quality management system, Proficiency Testing (PT) program has been introduced for biobank processing laboratories by IBBL 12 years ago. The aim was to provide an independent assessment of a laboratory's overall quality performance, on top of the pre-existing quality controls that each laboratory could independently establish and integrate internally.

Starting from just 2 PT schemes in 2011, the PT program has since evolved and nowadays it comprises an array of up to 22 schemes, encompassing both analytical and pre-analytical phases.

The PT schemes correspond to routine workflows carried out in a laboratory and include the most widespread commonly applied assays used across biobanks. In the future, as additional and novel biospecimen quality control assays are developed, they will be progressively implemented into new schemes.

The overall progression of the PT program has demonstrated global participation, with participants hailing from over 40 different countries worldwide. On average, more than 70% of participants have achieved satisfactory proficiency test results across all schemes. Laboratories that have participated in PT schemes consistently over several years have seen a global improvement in their performance in terms of their z-scores. A statistical analysis conducted on all data collected during the first decade of the annual PT program provides evidence and highlights the most critical preanalytical variables and the specificity of their impact on the applied processing methods [1].

The annual PT program serves multiple purposes, including supporting the development of biobank quality assurance, providing unique evidence-based insights into the impact of pre-analytical factors, evaluating the comparative performance of different processing methods and kits, while aiding laboratories in validating their processing methods.

Information on the PT program can be found following the *https://www.lih.lu/en/biospecimen-proficiency-testing/*

Compare your performance to others

The principle of performance benchmarking applied in our PT program means that your results will be compared to those of other laboratories, from different sectors all over the world.

Comply with certification & accreditation requirements

Proficiency testing offers organizations that are seeking compliance with ISO 20387, ISO 17025, ISO 15189, CLIA, CAP or equivalent, the opportunity to fulfil the respective normative requirements.

Improve performance & prove consistency

The assessment of your laboratory's proficiency allows you to monitor and improve performance by identifying potential problems and providing additional motivation. Regular participation in our PT program will also prove consistency of performance over time.

Gain credibility & visibility

By participating in our PT program you can assure customers, collaborators, funding agencies and regulatory bodies of the validity of your results. This can help build your reputation for high quality laboratory methods and gain international visibility.

Processing schemes

- DNA Extraction from Whole Blood
- DNA Extraction from Buffy Coat **(NEW!)**
- DNA Extraction from FFPE Material
- DNA Extraction from Frozen Tissue
- Microbial DNA Extraction from Saliva
- Microbial DNA Extraction from Stool
- Cell Free DNA Extraction from Whole Blood
- RNA Extraction from Whole Blood
- RNA Extraction from Buffy Coat **(NEW!)**
- RNA Extraction from FFPE Material
- Total RNA Extraction from Frozen Tissue
- CSF Aliquoting
- Viable PBMC Isolation
- Cell Free RNA (cfRNA) Extraction from Plasma
- Dual DNA/RNA Extraction from Frozen Tissue

Testing schemes

- DNA Quantification and Purity
- RNA Quantification and Purity
- RNA Integrity
- Cell Viability
- Tissue Histology
- DNA integrity

Combined processing and testing scheme

- Circulating Tumour Cells (CTC) Isolation Detection

For more information visit us on ***Biospecimen Proficiency Testing Luxembourg Institute of Health*** or contact us at ISBERPT@ibbl.lu

1) Verderio P, Ciniselli CM, Gaignaux A, et al. External Quality Assurance programs for processing methods provide evidence on impact of preanalytical variables. N Biotechnol. 2022;72:29-37. doi:10.1016/j.nbt.2022.08.006

SPECIAL I: SUCCESS STORIES AND AWARDS

CODE OF PRACTICE ON STANDARDISATION for the European Research Area published!

The European Commission fosters its ***Standardization Strategy*** by recommending the new ***Code of Practice on Standardization for the European Research*** Area that was published in March 2023!

This underlines the need and benefits of standards for innovative, successful and sustainable research, ultimately leading to a better global healthcare – **lifting the mission of the prosperous EU-funded projects SPIDIA and SPIDIA4P onto a new level.**

The development of this Code of Practice has been supported by a ***Scoping Study*** that contains the Case study of SPIDIA4P (pp 175-178) and another highly relevant EU-grant project Instand-NGS4P (pp 190 – 193), in which several SPIDIA4P project members are participating.

An updated ***Standardisation Fact Sheet*** supports the dissemination and awareness of the new Code of Practice and displays it in a short and easily understandable way.

Take a look at this informative ***youtube video***, created during the European Knowledge Valorisation Week, about the Code of Practice for Standardisation, moderated by the 1st **EU Chief Standardisation officer Maive Rute.** (the interview starts at 04:40 min)

Valorisation talk: new code of practice on standardisation in the European Research Area

Valorisation talk: new code of practice on standardisation in the European Research Area

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

In this chapter, we regularly report about consortia and initiatives that also have the standardisation scope – SPIDIA4P project members that take part in these activities continue to drive the mission of SPIDIA4P!

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EU-STANDS4PM
standards for in silico models for personalised medicine

Standards for personalized medicine

EU-STANDS4PM – a European Expert Forum developed formal standards for data-driven computational models for personalized medicine

The systematic analysis and interpretation of large, complex data from the life sciences, the health sector and clinical research (big data) has the potential to significantly improve the diagnosis and treatment of diseases. Particularly in personalized medicine, data-driven methods using computer-based models can make a substantial contribution to the early detection and prevention of diseases, as well as the prediction of the optimal therapeutic approach.

Yet the process of generating new medical knowledge currently falls far short of its potential. This is largely due to the heterogeneity of big data and the lack of widely accepted standards for data collection, harmonization and integration. Working with personal and patient-related data also requires a strict ethical as well as legal handling regarding patient rights and data protection.

In the future, ethically and legally compliant standardization guidelines will therefore represent a central component of personalized medicine, specifically for computer-based modelling approaches. These guidelines will function as a basic prerequisite for customized treatment strategies, early detection of disease onset and corresponding preventive measures.

The Coordination and Support Action *EU-STANDS4PM´s* major goal was thus to accelerate the development of standardization guidelines for data-driven computational models in personalized medicine. The project has received funding under the European Commission's Horizon 2020 program from 2019 to 2022 and featured an expert forum of 16 partners from eight European countries with cross-disciplinary expertise from scientific organizations, industry, European ESFRI infrastructure projects, legal and ethics experts, and standardization organizations.

One of the major outputs of EU-STANDS4PM was the development of formal standards for the establishment of predictive computer models in personalized medicine and clinical practice in the future. The project focused on two key factors that are central to the model building process, and for which standardization is important:

- the application of harmonized strategies and methods for the integration of data and
- the validation of models and simulations against the underlying clinical question.

To make a significant contribution in this field, EU-STANDS4PM established a liaison with the ISO Technical Committee 276 Biotechnology and developed a Technical Specification (ISO/TS 9491-1 Biotechnology — Predictive computational models in personalized medicine research — Part 1: Constructing, verifying and validating models) that specifies applications of data integration and model validation in personalized medicine. It is encouraging to note that the document has been published on the ISO homepage already in June 2023 and is currently developed further into an international standard. In parallel, the complementary review article "Computational Models for Clinical Applications in Personalized Medicine - Guidelines and Recommendations for Data Integration and Model Validation" (Collin et al, 2022; PMID: 35207655) was published in the Journal of Personalized Medicine that specifically addresses collaborative research projects and presents best practice guidelines for the application of computational models in clinical care.

The future implementation of EU-STANDS4PM's work with ISO will thus play an important role in the development of standardized modeling procedures to improve the quality, reproducibility, and sustainability of research results, as well as to enable easier translation of computational models into clinical practice.

Further information: *www.eu-stands4pm.eu*

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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Instand-NGS4P

Integrated and Standardized NGS Workflows for Personalised Therapy

Instand-NGS4P

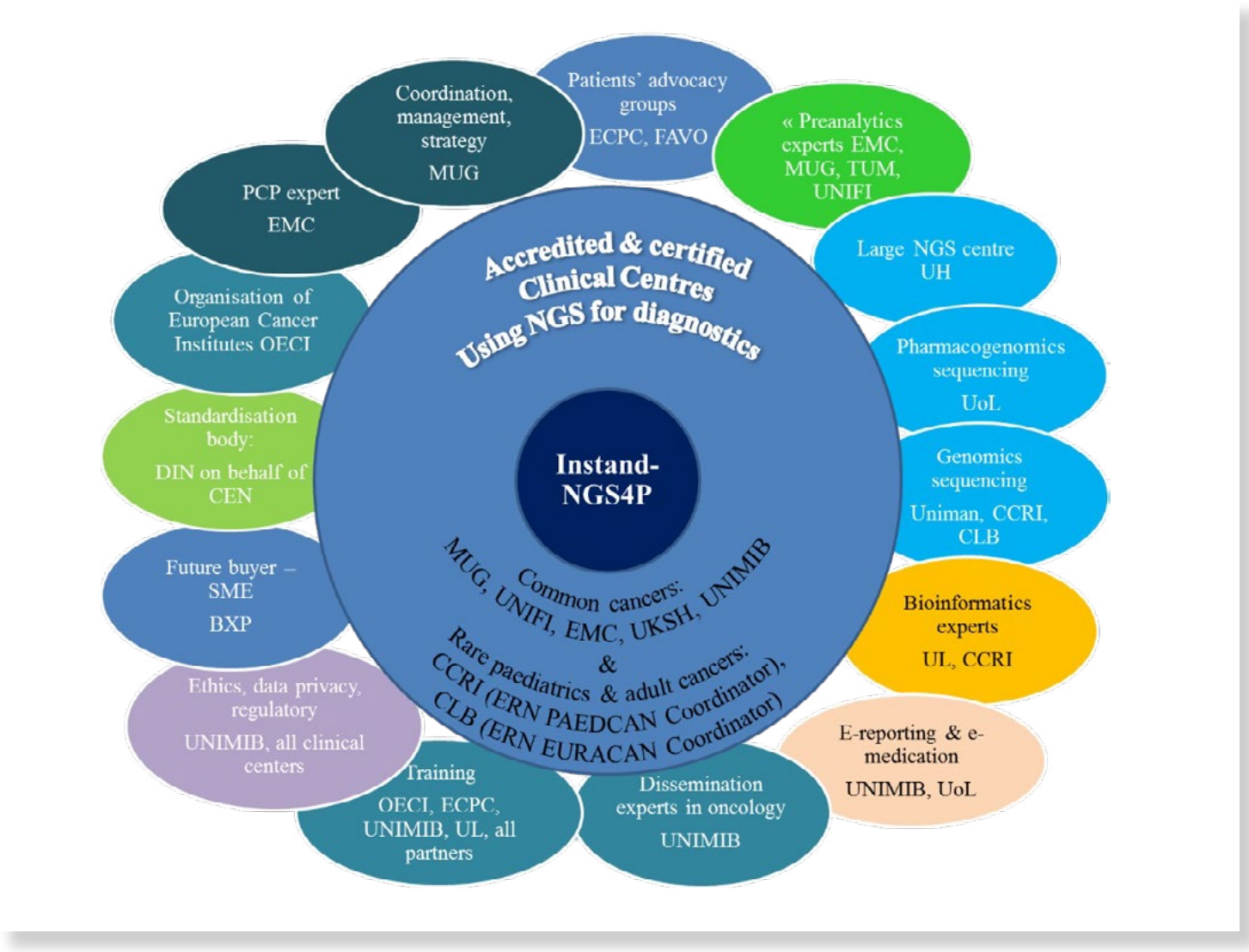
INSTAND-NGS4P is an EU-cofunded Pre-Commercial Procurement (PCP) project for **improving cancer patients' benefit from Next Generation Sequencing (NGS)** by developing **an integrated and standardized NGS workflow** (Grant No. 874719). For this, it will compile information from cancer gene testing, pharmacogenomic testing and e-medication in proper presentation to physicians for supporting therapy decision making at the bedside.

Coordinator and Lead Procurer of Instand-NGS4P is the Medical University of Graz, Austria. Prof. Kurt Zatloukal, formerly WP3 Leader in SPIDIA4P, now leads this public consortium to define unmet medical and technical needs as a basis for a request for tenders addressing solution providers (contractors) to develop their products to better meet user needs.

The Instand-NGS4P Consortium features

- 7 leading European medical centres from 5 countries (two are coordinating European Reference Networks) as the buyers' group - **Medical University of Graz** (MUG - the lead procurer - AT), **University of Florence** (UNIFI - IT), **ERASMUS University Medical Centre** (EMC - NL), **University of Milano-Bicocca** (UNIMIB - IT), **University Clinics of Schleswig-Holstein** (UKSH - DE), **St. Anna Children's Cancer Research Institute** (CCRI GmbH - AT) and the **Centre Leon Bérard** (CLB – FR).
- 2 European patient advocacy groups, represented by the **Italian Patient Association** (FAVO – IT) and the **European Cancer Patient Coalition** (ECPC - BE),
- a standardization organization (**German Institute of Standardisation** (DIN)),
- **University of Munich** (TUM – DE), University of Ljubljana, **University of Manchester** (Uniman – UK), **University of Liverpool** (UoL – UK), Organisation of European Cancer Institutes (OECI – BE),
- **University of Helsinki** (UH – FI) and one SME, **BioXPedia**.

Several of the partners were formerly associated with SPIDIA4P, providing the Consortium with an excellent depth of knowledge in the process of standardization development.

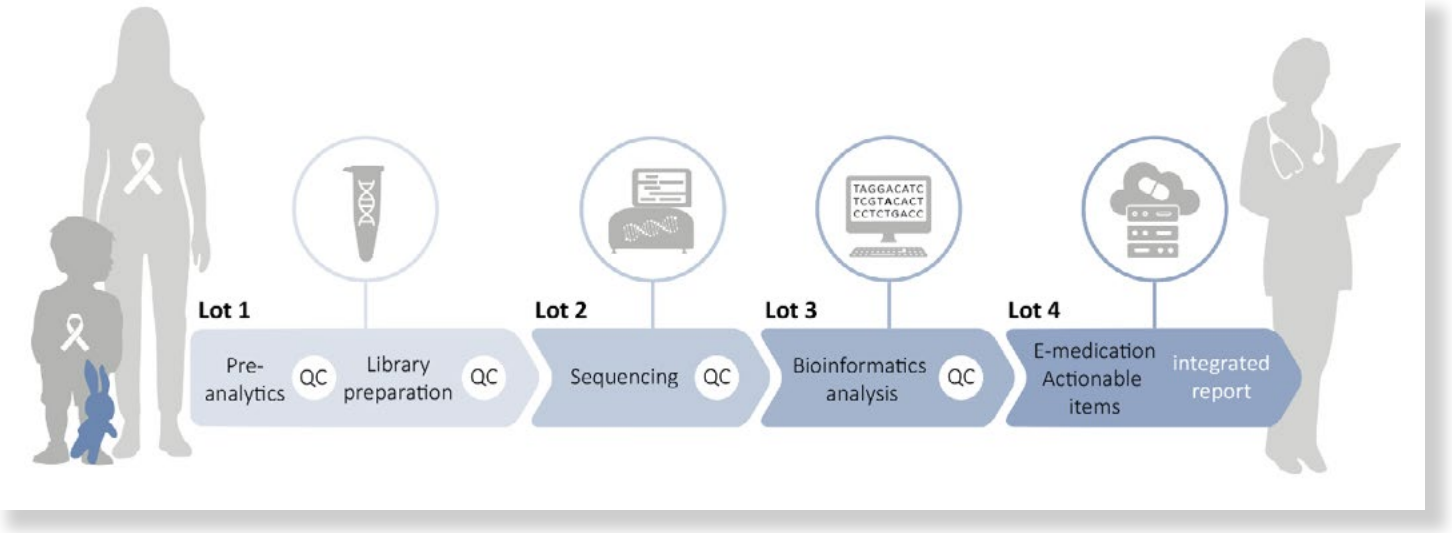


Major challenges to be addressed during the project are:

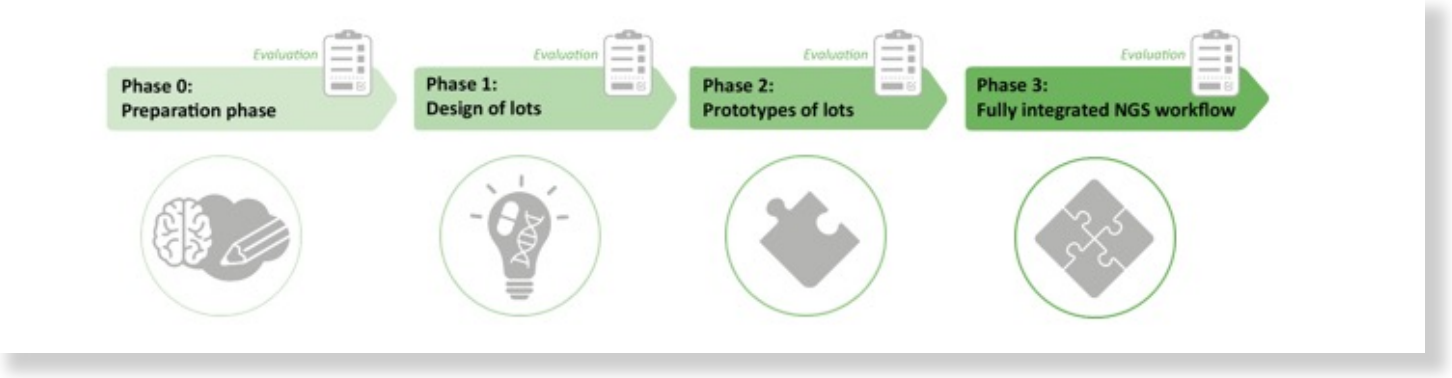
- Improving the analytical performance by standardizing pre-analytical processes
- Integrating pre-analytical, analytical processes and data analytics into a standardized workflow
- Defining genetic variants with established medical implications for common and rare cancer types of adults and children, including pharmacogenomic variants relevant for drugs used in cancer care
- Developing reference material for quality control
- Meeting requirements of the European in vitro diagnostics regulation
- Improving benefits from NGS for patients and health systems

Expected Outcome

Through the integration of all elements of such a workflow (sample collection and pre-analytic processing, library preparation, sequencing, bioinformatics – including pharmacogenomic analysis, and reporting to both physicians and patients) we expect to obtain a versatile and precise decision support tool that conforms to all pertinent requirements for *in vitro* diagnostic medical devices.



4 Project Phases



Phase 0 Preparation Phase (January 2020 – March 2022)

An Open Market Consultation was carried out to provide insight into **clinical and patient needs**, as well as **technical innovation potential**. Also, during this phase, an analysis of the **current standardization landscape** found that all NGS-related standards focused on the research environment rather than on the diagnostic environment. It also revealed gaps with regard to sample specificity, complex disease diagnostics such as cancer and missing completeness of the NGS workflow.

Based on these insights, a standardization strategy in NGS for routine diagnostics was developed with the aim of developing NGS Technical Specifications within the European Committee for Standardization (CEN) and later transforming them into International Standards within the ISO.

Based on the outcome of these activities, a call for tender was published on the EU´s Tenders Electronic Daily portal. Tenders were accepted for individual Lots, and for combinations of up to three of the four Lots. The call attracted 24 tenders in total from which 15 tenderers were selected for Phase 1. No contract was concluded for the Lot 2 Sequencing, due to insufficient number of applications.

Phase 1

Solution Design (April 2022 – October 2022)

The 15 selected tenderers developed several ambitious and highly innovative solution designs over the course of Phase 1. The solution designs were subsequently evaluated based on the fulfilment of the award criteria including the potential for integration into a complete workflow as well as the consideration of relevant standards.

In parallel, work continued in the CEN Technical Committee 140, Working Group 3 – Quality Management in the Medical Laboratory on the **2 new draft Technical Specifications:**

- Meeting requirements of the European in vitro diagnostics regulation WI 00140151 *In vitro diagnostic Next Generation Sequencing (NGS) workflows – Part 1: Human* **DNA** *examination*
- Meeting requirements of the European in vitro diagnostics regulation WI 00140153 *In vitro diagnostic Next Generation Sequencing (NGS) workflows – Part 2: Human* **RNA** *examination*

Phase 2

Prototype Development (November 2022 to March 2024)

In Phase 2, eight Contractors were awarded 11 contracts with a total value of almost 4 million euros, to develop their prototype solutions (Table 1). During Phase 2 the necessity for extensive communication and harmonization between contractors, specifically regarding Lot-spanning data transfer was recognized.

The accompanying work on the two draft CEN Technical Specifications resulted in the documents entering the final ballot in June 2023, on track for **publication as CEN/TS in Q1 2024**. Contractors were expressly encouraged to join the preparation of these standards, bringing in their specific expertise and experience from Phase 2.

Lot	**Lead Contractor** (Click name to read the project abstracts)
Lot 1: Pre-Sequencing 	Integrated DNA Technologies, BV QIAGEN GmbH Twist Bioscience Corporation
Lot 3: Bioinformatics Analysis 	BC Platforms AG Congenica Ltd FUNDACIO CENTRE DE REGULACIO GENOMICA Platomics GmbH
Lot 4: Integrated Reporting	BC Platforms AG Congenica Ltd fragmentiX Storage Solutions GmbH FUNDACIO CENTRE DE REGULACIO GENOMICA

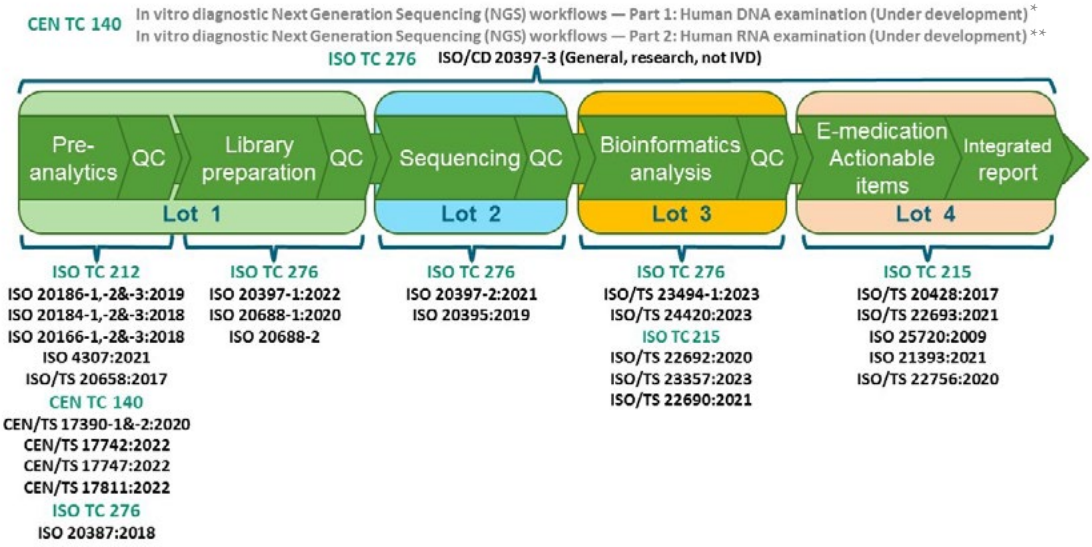
Table 1. Contractors awarded funding for prototype development (Phase 2) in Instand-NGS4P

Phase 3 Fully integrated NGS workflow (April 2024 to May 2025)

Presently, Instand-NGS4P is still in Phase 2. **Phase 3** will focus on the integration of the developed solutions into a complete diagnostic workflow and on the testing of usability and performance by the buyers' group partners in a real-world clinical hospital environment.

The 2 new CEN/TS will be submitted to ISO/TC 212 as New Work Item Proposals.

ISO and CEN standard documents (published or under development) as of September 2023



Meanwhile published as:

CEN/TS 17981-1: In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 1: Human DNA examination

***CEN/TS 17981-2: In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 1: Human RNA examination*

For further information on the Instand-NGS4P project, please visit ***https://www.instandngs4p.eu/***

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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Be prepared for the next outbreak:

PreAnalytiX addressing workflow requirements for respiratory pathogen-testing as part of the EU Integrated Service for Infectious Disease Outbreak Research (ISIDORe)

For the upcoming years, during seasonal cold waves, we expect several respiratory viruses including SARS-CoV-2 and Influenza to spread, across the population creating **the need for multiplex testing of different respiratory viruses** to allow proper diagnosis and treatment of the patient as well as providing reliable data as basis for public health measures.

Next generation multiplex diagnostic tests are required to allow low-cost, fast, reliable, simultaneous detection and distinction of different viruses.

For this reason, QIAGEN, represented by Dr. Uwe Oelmüller (QIAGEN Head of MDx Sample Technologies and PreAnalytiX Management Committee Co-Chair) and the PreAnalytiX R&D team take part in the European Union's Horizon Europe research and innovation programme **ISIDORe** (Integrated Services for Infectious Disease Outbreak Research), which provides an integrated portfolio of research services, tools and resources to study epidemic-prone pathogens including SARS-CoV-2 and received funding under grant agreement No 101046133.

The application to the section "Diagnostics" for the topic "Development of low-cost, reliable diagnostic tools applicable to human population screening and based on viral infection and/or variant discrimination and/or serological response determination" was accepted in January 2023.

Real-life tests will be carried out in a BSL-3 laboratory by our cooperation and SPIDIA4P project partner at the Medical University of Graz. Our project "Development of Next Generation Respiratory Infection Diagnostics" (NeResDia) will target the development of generic pre-analytical workflows that can also be adapted to additional infectious diseases to flexibly address emerging test needs.

Based on regularly published surveillance reports issued by the CDC, ECDC and German RKI, we choose and adapt the respiratory viruses implemented in the multiplex testing strategies.

We will develop complete sample-to-insight workflows for SARS-CoV-2 and other respiratory viruses with scalability for broad use in different healthcare systems and settings.

Following the EU In Vitro Diagnostic Regulation (IVDR) and newest ISO & CEN standards, all diagnostic workflow steps will be covered: specimen collection and preservation, storage, transport, processing including high throughput and manual viral nucleic acid isolation and testing.

For more information, go to:

ISIDORe - ERINHA

More about PreAnalytiX, the Joint Venture between QIAGEN and Becton Dickinson:

www.preanalytix.com

@freepik - Freepik.com

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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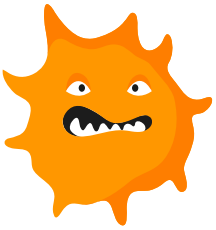
BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

MICROBE

Microbiomes play an essential role in the health of plants, animals and humans and are of great interest for research.

The EU project MICROBE was launched this year to further develop biobanking of microbiome samples in an international framework. Standardization and quality control – particularly with respect to the pre-analytical phase - are important topics in this project.



The microbiome

The term microbiome refers to the entire microbial community occupying a well-defined habitat with distinct physico-chemical properties. The microbiome comprises microbiota (e.g. bacteria, archaea, fungi, algae) and their "theatre of activities" (incl. structural elements, metabolites, and mobile genetic elements such as viruses). They exist in soil, water, on and in the bodies of humans and animals, even on and in plants and seeds. These different microbiomes can have a massive impact on the health of the environment and holobionts, which is why their research is the focus of many scientists.

Need for standardization

The microbiome research field is fast-evolving, with currently only a few widely accepted quality standards. In comparison to industry, standards are generally not yet well established in research communities. However, the awareness of the importance of quality controls and standardization in microbiome research is rising.

Along the entire microbiome workflow (pre-analytical, analytical and postanalytical phase), numerous factors can artificially modify the final analytical result.

Particularly, the pre-analytical phase is crucial and has been shown to be a main, but still often neglected or underestimated contributor to inaccurate or even false and irreproducible analyses. Biosamples in general, but also microbiome samples, must be of high and defined quality to be 'fit-for-purpose', i.e. suitable for the intended analysis. Therefore, samples must correspond very well to their original state at the collection site, e.g. in the human body, the seed, the soil or marine water. Samples must be handled correctly at each of the numerous pre-analytical steps (including, e.g., the preparation, selection and description of the source (sampling site/donor and collection site), the collection method, transport, processing and storage.) Documentation of pre-analytical details – also referred to as metadata – is important for assessing the sample's fitness-for-purpose for a certain analytical test and can help to better interpret research results.

MICROBE project

The MICROBE project aims to deliver innovative validated technological approaches for the optimal collection and preservation of microbiome samples (maintaining their taxonomic and functional biodiversity), as well as for the targeted isolation of microbiome members. Overall, the project intends to provide a comprehensive operational blueprint for the establishment of microbiome biobanking infrastructure.

MICROBE will also address the important issues related to standardization and quality control and develop guidelines for the implementation of standardized workflows, particularly for the pre-analytical phase.

Members of the SPIDIA4P project team from Medical University of Graz are leading in MICROBE the work package "Standardization and Quality Control". They bring in know-how both from the human microbiome field with a focus on pre-analytical quality requirements for microbiome samples and from building biobanking frameworks. They build on experience from SPIDIA4P and from leading the development of the human microbiome standard(s) for sample pre-analytical quality at CEN and ISO level (i.e. the published CEN/TS 17626 Molecular in vitro diagnostic examinations. Specifications for preexamination processes for human specimen. Isolated microbiome DNA, which is currently developed to an ISO standard ISO 18701). These human standards and best practices for other sample types will serve as a basis for developing guidelines for environmental microbiome samples.

The project MICROBE and its work is funded by the European Union under the Horizon Europe grant number 101094353.

For more information:

https://www.microbeproject.eu/

https://bbmri.at/news-articles/the-pre-analytical-cen-ts-standard-for-microbiome-diagnostics-how-can-research-and-development-benefit/

MICROBE
the Microbiome
Biobanking (RI)
Enabler

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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EASI-Genomics – a wrap up and final highlights

In the previous edition of the SPIDIA4P Newsletter, we already reported about the European grant project EASI-Genomics.

This valuable and successful initiative has come to an end on 31st July 2023 – here, we look back and reflect on the four and a half years of the project.

Regarding **Transnational access** for users, EASI-Genomics has carried out diverse research projects covering topics such as de novo assembly, transcriptomic and epigenetic analysis, and has contributed during the Covid-19 pandemic to elucidating the genetic causes underlying severe Covid-related disease.

The main highlights are:

- EASI-Genomics has provided support to **170 projects from 125 users in 26 different countries** (see figure).
- EASI-Genomics sequencing facilities produced a total of **185 Terabases** of sequencing data across all TNA projects and calls.
- A total of 467 tissue sections with an area of **128.8 cm²** were processed in twelve spatial transcriptomics and in situ sequencing projects.
- In 27 single cell projects, more than **1.8 Mio single cells** were analyzed.
- To date, **32 articles** were published that include data from TNA projects. Many of the TNA projects' results appeared in high-impact journals such as Science, Science Immunology, Nature and Nature Communications.
- To maximise the impact of the sequencing data produced, data was archived in open and controllen repositories, the *EGA* for sensitive human data and *ENA* for non-human data.

  Our FAQs-section provides guidance about data deposition: *https://www.easi-genomics.eu/datadeposition*

To quote **Ivo Gut**, Director of CNAG and EASI-Genomics Coordinator:

"EASI-Genomics has been an excellent exhibition of the impact of advanced genomics technologies, of the diverse projects it has helped to realize, as well as on the positive influence EASI-Genomics had in boosting the careers of over 100 researchers."

We were indeed honored to have 19 of our TNA-users present at multiple EASI-Genomics events and are pleased to see that our support made a ***difference in their research***.

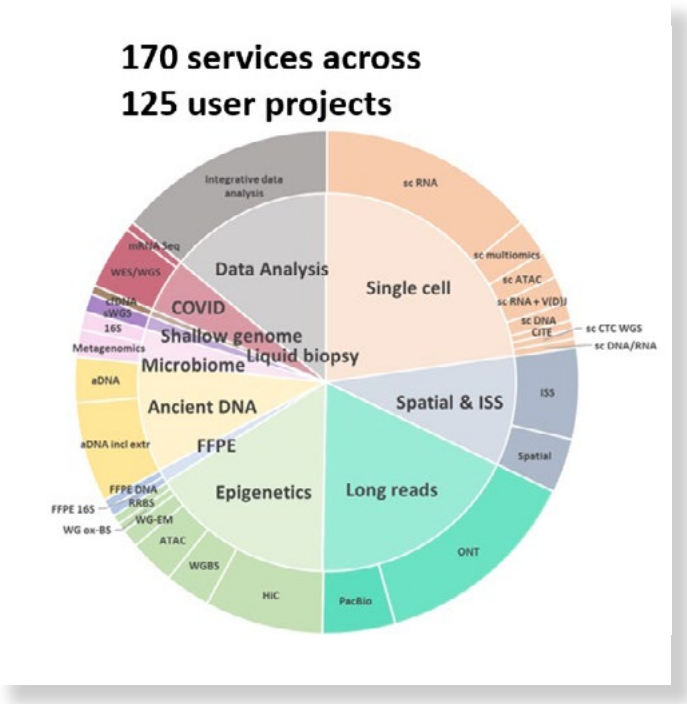
Another quote from **Janine Altmüller**, head of the Genomics Platform at MDC:

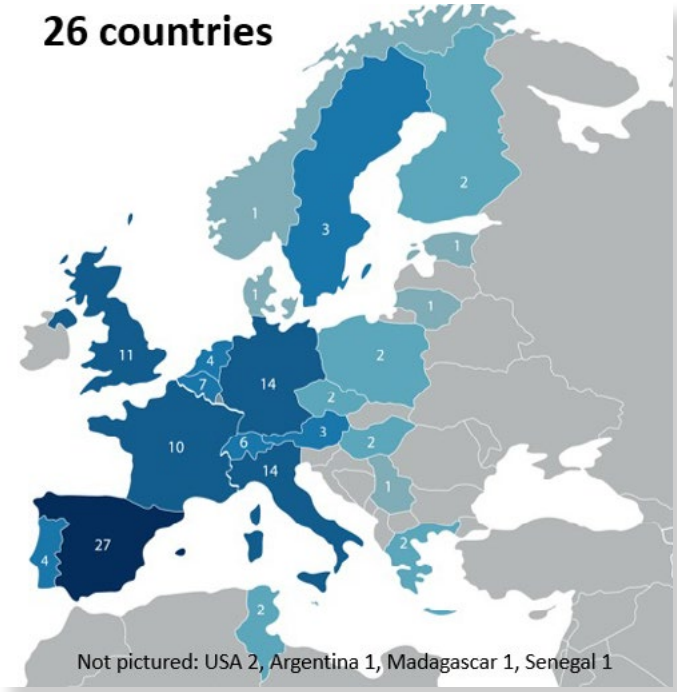
"The exchange of best-practises with other genomic platforms led to the joint development and optimization of new genomics methods" - read her full interview ***here***.

To date, another **32 papers** have been published by our partners on topics ranging from wet- and dry-lab method improvements to ELSI-aspects of genomic data generation and usage.

Finally, we wish to **thank all our consortium members** for their considerable efforts in making this project a success story!

The project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No. 824110





Source images: Sonja Hansen, MDC

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

Accredited and BBMRI-ERIC Quality-labelled biobanks in Europe – a status update

Since the publication of the biobanking standard ISO 20387 in 2018, many biobanks in the European biobank network BBMRI-ERIC have been working to establish and/or optimise their processes and management system in such a way that they meet the requirements of the standard. The National Accreditation Bodies, under the umbrella of the *European co-operation for Accreditation* (EA), have also made great efforts to start establishing assessment procedures and identifying or training suitable assessors soon after the biobanking standard was published. With the adoption of the ISO 20387 standard as a harmonised standard by the European standardisation organisations CEN-CENELEC and the decision of the EA General Assembly in November 2022 to expand the *EA Multilateral Agreement for biobanking*, essential foundations have been laid for achieving the overarching goal of 'Accredited once, accepted everywhere'. This resulted in the first assessments and successful accreditations according to the ISO 20387 standard in 2022. Since then, a total of seven biobanks in the following BBMRI-ERIC member and observer countries have successfully completed this comprehensive assessment process and have had their biobanking competence officially confirmed within their accreditation scope: Czech Republic, Finland, Germany, Italy, Poland, Spain, Qatar (see Figure 1). This is an outstanding success for the individual biobanks, but it is to be expected that the number of biobanks accredited according to the ISO 20387 standard will increase significantly in the coming years. This not only underlines the competence of the biobanks, but also strengthens their status as trusted partners for biomedical research, providing high-quality biospecimens and data.

As accreditation is a resource-intensive process, it will not be possible for all biobanks to be accredited. For this reason, BBMRI-ERIC's Quality Management Department has established a comprehensive *Quality Management service portfolio*, including an audit programme. Biobanks can request an audit to confirm, where appropriate, that the biobank processes comply with the principles of the biobanking standard and/or have their collections evaluated for compliance with the requirements of ISO and/or CEN standards for specific biospecimen types and their intended uses. The BBMRI-ERIC audit process is based on the following steps: (1) completion of Self-Assessment Survey(s), (2) remote (collection level) or remote and on-site audit (biobank level), (3) final assessment. If the outcome of the audit process is positive, the respective biobank and/or collection is awarded with a BBMRI-ERIC Quality Label in the BBMRI-ERIC Directory. Since the introduction of this service for BBMRI-ERIC members, 4 biobanks (see Figure 1) and 50 collections have already been awarded a BBMRI-ERIC Quality Label (searchable in the *BBMRI-ERIC Directory*). The Directory user thus has the advantage of being able to easily find Quality-labelled biobanks and/or collections in the Directory that are needed for high-quality research.

The biobanking standard is currently in a systematic review phase, initiated by ISO (see *https://www.iso.org/standard/67888.html*). National Standards Bodies, in cooperation with national experts and other stakeholders, have the opportunity to provide feedback on the standard and to make adaptation requests if necessary. BBMRI-ERIC, as liaison partner to ISO Technical Committee 276, has contributed to the development of this biobanking standard since 2014. Therefore, we will participate in the systematic review with our large QM community and provide feedback.

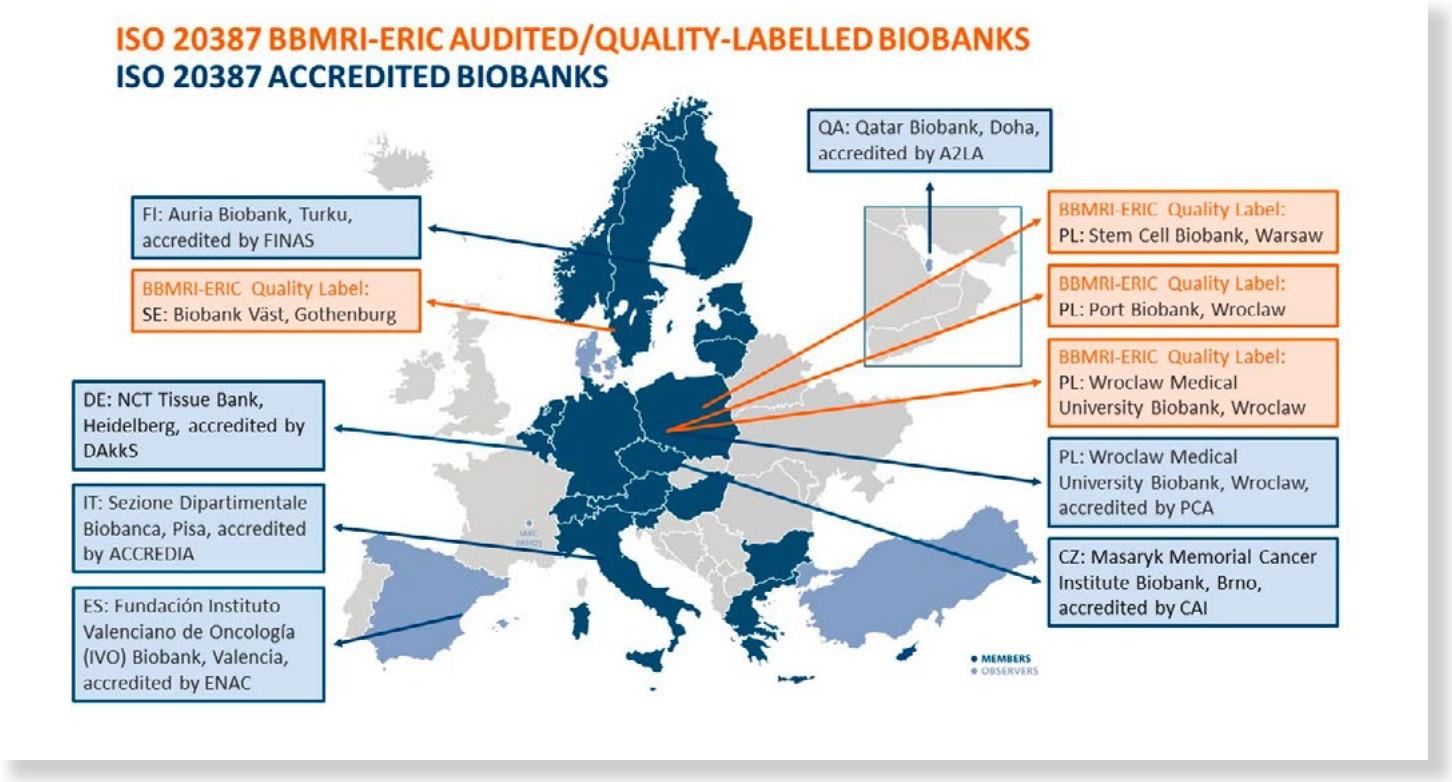

Figure 1: Overview of ISO 20387 accredited and/or BBMRI-ERIC Quality-labelled biobanks in the BBMRI-ERIC member and observer countries

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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GenomeMet

Several SPIDIA4P partners, including the National Measurement laboratory (NML at LGC), Medizinische Universität Graz (MUG), Università degli Studi di Torino (UNITO) are now partners in a new EURAMET project. The project, Metrology for genomic profiling to support early cancer detection and precision medicine (22HLT06 GenomeMET;) kicked off in September 2023 and is funded by the European Partnership on Metrology under the European Union's Horizon Europe Research and Innovation Programme.

In the face of a rising cancer crisis, timely diagnosis and targeted treatment is more critical than ever. Genomic profiling is at the forefront of advances in cancer treatment, utilising detailed genetic mapping to enable earlier diagnoses and personalised therapies. However, analysis of data introduces uncertainties.

GenomeMET is a collaborative project focussed on developing a robust metrological (measurement) infrastructure to support method validation and quality control at both the pre-analytical and analytical stages. The project will also develop reference measurement procedures for measuring genomic biomarkers. This will support improved accuracy and comparability of genomic profiling across European healthcare systems in support of Horizon Europe's Mission on Cancer.

For more information or insights into the GenomeMET project, please visit *EURAMET: Metrology for genomic profiling to support early cancer detection and precision medicine* and *www.linkedin.com/company/genomemet/*

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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Advancements in cancer diagnostics:

The benefits of implementation of ISO and CEN/TS standards in clinical liquid biopsy studies

In an ongoing study, researchers from the Medical University of Graz and CBmed have demonstrated the practicality and advantages of integrating pre-analytical ISO and CEN/TS standards into clinical practices for liquid biopsies. Liquid biopsies, hailed as crucial clinical biomarkers for cancer monitoring, have faced challenges in standardization despite their increasing use in the field. Although many clinical studies and clinical assays have already adopted liquid biopsies for patient use, many factors remain unknown, including pre analytical parameters like hemolysis, transport times, tube-filling levels and others. The research team, led by Amin El-Heliebi, aimed to determine, if ISO standards for circulating tumor DNA (ctDNA) and CEN/TS standards for circulating tumor cells (CTCs) can be successfully implemented in a real-world clinical setting.

Conducted in collaboration with QIAGEN, ViennaLab Diagnostics, CytoGen, Labor Renner, and the Medical University of Graz, the international research project, supported by the COMET-funded biomarker research center CBmed in Graz, Austria, seeks to address standardization issues in biomarker research that is impeding the translation of new assays into clinical routine. The currently ongoing study has collected more than 600 liquid biopsy samples of prostate cancer patients and is evaluating the obtainability of all ISO and CEN/TS relevant information. In an initial data analysis, over 90% of samples show perfect alignment with the required criteria for the respective pre-analytical standards. Additionally, parameters such as tube filling levels or hemolysis are systematically monitored, as they have the potential to limit the meaningfulness of liquid biopsy assay.

Principal investigator Amin El-Heliebi emphasized, *"We observed that blood collection tubes with hemolysis are seen in about 10% of advanced prostate cancer patients and can be considered patient-specific, rather than pre-analytical errors.* ***The advantage of applying the standards is that you know: this is the best possible sample you can get. Pre-analytical errors, like longer waiting times or missed tube inversions, can be ruled out in our samples."***
(see ref. ***https://doi.org/10.1101/2023.12.04.23299422****)*

The integration of ISO and CEN/TS standards into a real-world clinical setting not only reduces uncertainties in sample quality but also facilitates ongoing research with the highest-quality blood samples available from cancer patients. This promises to enhance the reliability of liquid biopsy results, marking a significant step in cancer diagnostics and treatment.

The study's results are currently undergoing processing for publication, showcasing the potential benefits of adhering to rigorous standards in advancing the field of liquid biopsies.

This project is performed at the Medical University of Graz and the Center for Biomarker Research in Medicine (CBmed), 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).

SPIDIA4P // SCIENTIFIC PUBLICATIONS

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

Peer-reviewed scientific publications generated by SPIDIA4P project partners or in relation to the SPIDIA4P mission:

Abuja, P.M.; Pabst, D.; Bourgeois, B.; Loibner, M.; Ulz, C.; Kufferath, I.; Fackelmann, U.; Stumptner, C.; Kraemer, R.; Madl, T.; Zatloukal, K.

Residual Humidity in Paraffin-Embedded Tissue Reduces Nucleic Acid Stability

Int. J. Mol. Sci. 2023, 24, 8010 – **open access**

Researchers from BBMRI.at partner Med Uni Graz, who also have contributed the development of pre-analytical quality standards for FFPE tissue for DNA analyses, investigated the effect of residual humidity in paraffin-embedded tissue on RNA and DNA quality.

IJMS | Free Full-Text | Residual Humidity in Paraffin-Embedded Tissue Reduces Nucleic Acid Stability (mdpi.com)

Oelmueller U, Safwat N

Liquid biopsies: Brilliant potential but highly workflow dependent
Medical Laboratory Observer, February 20, 2023 – **open access**

Liquid biopsies: Brilliant potential but highly workflow dependent | Medical Laboratory Observer (mlo-online.com)

Devonshire A, Jones G et al

Interlaboratory evaluation of quality control methods for circulating cell-free DNA extraction

New Biotechnology Vol 78, Dec 25, 2023, pages 13-21 – **open access**

https://www.sciencedirect.com/science/article/pii/S1871678423000481?via%3Dihub

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2 SPIDIA4P tissue technology disseminations in conjunction with standardized and pre-analytical workflows for microbiome analysis:

Radani N., Metwaly A, et al
Analysis of Fecal, Salivary, and Tissue Microbiome in Barrett's Esophagus, Dysplasia, and Esophageal Adenocarcinoma
Gastro Hep Advances 2022;1:755–766 – **open access**

Analysis of Fecal, Salivary, and Tissue Microbiome in Barrett's Esophagus, Dysplasia, and Esophageal Adenocarcinoma (ghadvances.org)

Barroux M, Horstmann J, et al
Histological evaluation of PAXgene tissue fixation in Barrett's esophagus and esophageal adenocarcinoma diagnostics
Virchows Archiv (2023) 482:887–898 – **open access**

Histological evaluation of PAXgene tissue fixation in Barrett's esophagus and esophageal adenocarcinoma diagnostics | Virchows Archiv (springer.com)

Hardt M, Kaiser F. etal
Pre-analytical properties of different respiratory viruses for PCR-based detection: Comparative analysis of sampling devices and sample stabilization solutions

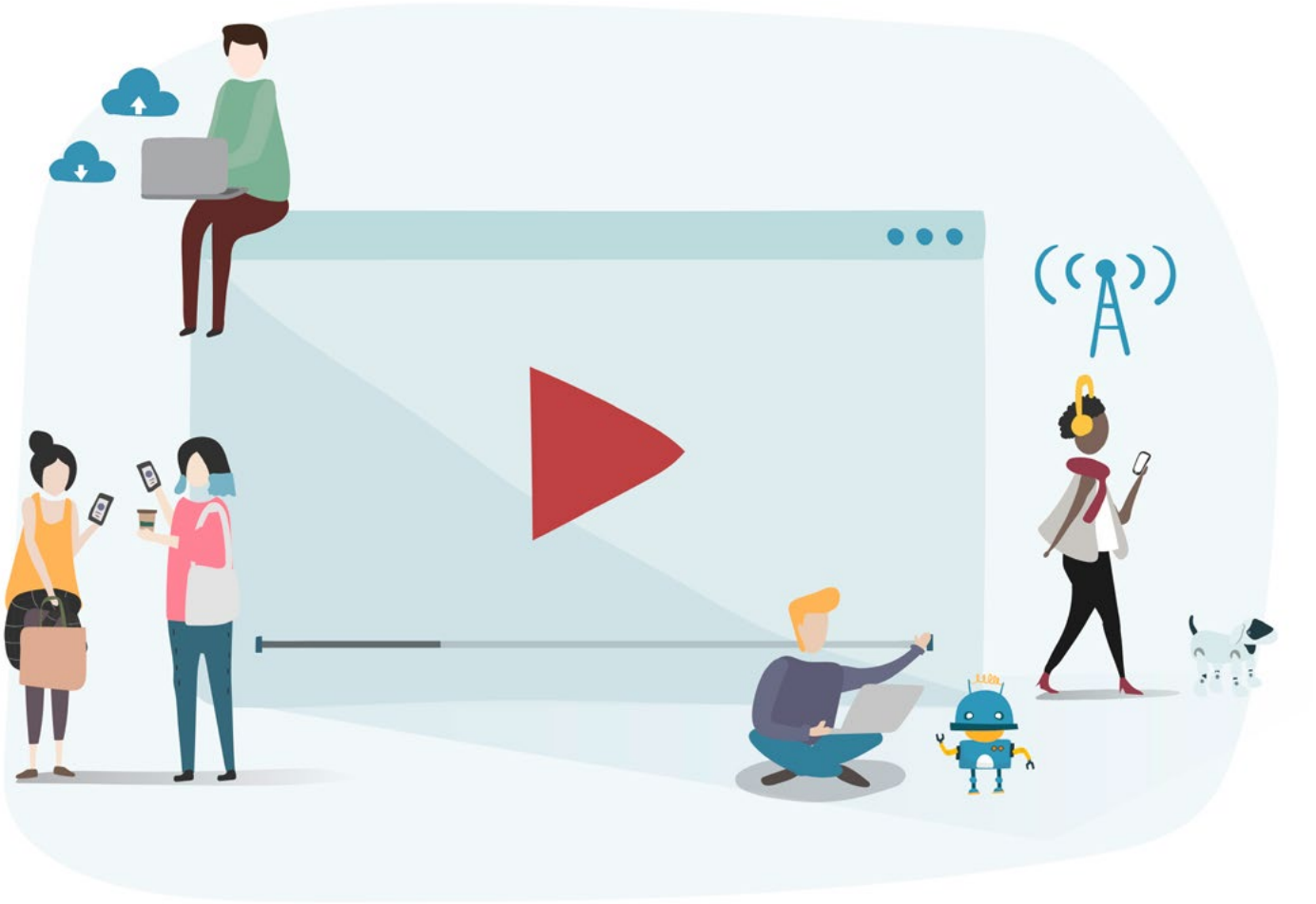
New Biotechnology 79, pages 60-70, March 24, 2024

https://www.sciencedirect.com/science/article/pii/S1871678423000730

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 // 2022 / 2023

October 2022

LISAvienna Regulatory Conference for Medical Devices and In-Vitro Diagnostics
October 13, 2022, Vienna

SPIDIA4P partner BBMRI.at with Med Uni Graz, SPIDIA partner and BBMRI.at Coordinator, took part with an expert booth. The conference was fully booked.

The annual LISAvienna is an event for the life science industry and contributes to strengthening the knowledge base for the approval of medical devices and in-vitro diagnostics in Europe and the USA.

Nevertheless, it is also an event for networking and establishing new contacts.

At the expert booth from BBMRI.at and partners such as Biobank Graz and VetBiobank, visitors could inform themselves about the services and competences of BBMRI.at and associated biobanks.

BBMRI.at had also invited its Translational Science Forum with representatives from industry to this event.

The Regulatory Conference took place 13 October 2022 in the Pharmacy wing of Schloss Schönbrunn and with over 300 registrations fully booked.

Take a look at the presentations ***Vortragsunterlagen LISAvienna Regulatory Konferenz für Medizinprodukte und In-vitro Diagnostika 2022 - LISAvienna - life science austria***

© LISAvienna / Michlmayr

November 2022

BBMRI_QM Academy: Webinar on Frozen Tissue Collection and Biobanking
Pre-analytics, frozen tissue processing, standardisation to increase quality and reproducibility
November 15, 2022

Focus and learning objectives

After watching the webinar, participants have obtained knowledge on:

- The importance of sample quality and the influence the quality can have on medical research and innovation of medical care worldwide
- The difference in quality between fresh frozen tissue and FFPE tissue
- How to standardize, control and document the workflow to obtain high quality frozen tissue samples
- The need for standardization during sample collection for translational research
- What is the sample pre-analytical phase
- How variations are introduced during the pre-analytical phase when collecting samples
- How biobanking infrastructure can contribute to increase reproducibility
- How biobanking standardization of protocols and ISO accreditation can contribute to increase reproducibility
- What instruments are available to control sample quality
- How documentation of variations in the pre-analytical phase can be used to control sample quality and fit for purpose use of samples
- The importance of multidisciplinary study teams for reproducible results

Click ***Registration (office.com)*** for your registration for the Recording of this webinar

SPIDIA4P EVENTS // PAST EVENTS / 2023

February 2023

Online Workshop: Implementing Genomic Research Projects
February 1 and 2, 2023; virtual format

The workflow of genomic research is complex and there is a lot to consider and to know about how to implement ethical, legal and quality issues.

This workshop organized by BBMRI-ERIC and EASI Genomics with support from BBMRI.at Med Uni Graz and QIAGEN addressed key issues in genomic research with respect to implementing genomic research projects.

Take a look at the agenda ***Workshop on Implementing Genomic Research Projects_Feb2023_v7_1.pdf (easi-genomics.eu)***

Get the presentations:

Slide Deck 1 // Dr. Peter Abuja, Medical University of Graz // Dr. Teresa Altri, CRG

PowerPoint-Presentation (easi-genomics.eu)

Slide Deck 2 // Kurt Majcen and Petr Holub, BBMRI-ERIC // Dr. Uwe Oelmüller, QIAGEN GmbH // Dr. Peter Abuja, Medical University of Graz

PowerPoint-Presentation (easi-genomics.eu)

Slide Deck 3 // Dr. Alison Devonshire, NML // Dr. Terea Altri, CRG

PowerPoint-Presentation (easi-genomics.eu)

Slide Deck 4 // Dr. Teresa Altri, CRG

PowerPoint-Presentation (easi-genomics.eu)

freepik.com @ tutti-frutti

March 2023

10th Gene Quantification Event
March 23-24, 2023
Munich, Germany

Training and Workshops held by SPIDIA4P partner Mikael Kubista, TATAA Biosciences, et al

Technical University of Munich

Program and access to presentations

Youtube Video – first impressions QG Event 2023

EASI-Genomics Stakeholder Meeting #3
March 7-8, 2023
SciLifeLab, Stockholm, Sweden

With presentations from SPIDIA4P project members:
Dr. Ivo Gut, EASI-Genomics Coordinator, CNAG
Dr. Uwe Oelmueller, SPIDIA4P Coordinator, QIAGEN

https://www.easi-genomics.eu/stories/events/easi-genomics-stakeholder-meeting-scilifelab

Agenda

April 2023

AACR 2023: Advancing the Frontiers of Cancer Science and Medicine
April 14-19, 2023
Orlando, Florida

Spotlight Speaker: **Dr. Uwe Oelmueller**, SPIDIA4P Coordinator, QIAGEN GmbH:

Standardized Pre-analytics: The Key for Reliable and Sensitive Molecular Cancer Diagnostics & Research

https://www.aacr.org/meeting/aacr-annual-meeting-2023/

Translational and Precision GI-Oncology – Bench to Bedside Meeting
April 26-28, 2023
Freiburg, Germany

Presentation by SPIDIA4P Coordinator Dr. Uwe Oelmueller, QIAGEN GmbH

Title: "Standardized Pre-Analytics: The Key for Reliable Molecular Diagnostics and Research"

Program

Bigpicture Webinar: Standardization in the filed of digital pathology – current state and developments
April 28, 2023

Held by SPIDIA4P project partner Ulrike Schroeder, MsC., Senior Project Manager at DIN, Standards Committee Health Technologies

Details:
Standards are the results of work at national, European and/or international level. Currently, there are numerous standardization activities related to digital pathology, developed in standardization committees such as ISO/IEC JTC 1/SC 42 *Artificial Intelligence*, ISO/TC 212 212 *Clinical laboratory testing and in vitro diagnostic test systems and ISO/TC 215 Health informatics.*

However, a dedicated standardization project focused on digital pathology is still missing.

This webinar provided a short introduction into the world of CEN and ISO standards and give an overview of the current state of standardization in the field of digital pathology as well as recent developments.

Take a look ***here***

SPIDIA4P EVENTS // PAST EVENTS / 2023

May 2023

Webinar European Society of Pathology
Pre-analytical steps: challenges and impact on the diagnostic outcome
May 11, 2023

Presentation by SPIDIA4P project member Prof. Peter Riegman, Head Erasmus MC Tissue Bank

Presentation Title: "Standards for optimal pre-analytical phase in surgical pathology."

Take a look *here*

June 2023

BBMRI.QM Academy presents: Live Educational Webinar „Validation and verification of processing methods and biobanking"
June 1, 2023

Presented by SPIDIA4P partner Dr. Fay Betsou, Director of the Institut Pasteur Biological Resources Center (CRBIP)

Moderated by SPIDIA4P project partner Andrea Wutte, M.Sc., BBMRI-ERIC

This educational course dealt with processing methods in biology laboratories.

The course largely followed the recommendations of the international Standard ISO21899:2020 but presented application of the concepts to concrete laboratory situations.

Program

More information and past webinar recordings

September 2023

Europe Biobank Week Roadshow – Third stop
Focus:
IT: Data Integration in Biobanking
September 27-28, 2023
Medical University of Innsbruck, Austria

Organized by SPIDIA4P partners BBMRI-ERIC and ESBB and held at BBMRI.at partner Med Uni Innsbruck.

Among other topics, this event dealt with d**ata quality and standardisation** of data provenance

More Information

Program

SPIDIA4P EVENTS // PAST EVENTS / 2023

Easy access to the WEBINAR RECORDINGS of the BBMRI.QM Academy – anytime, anywhere!

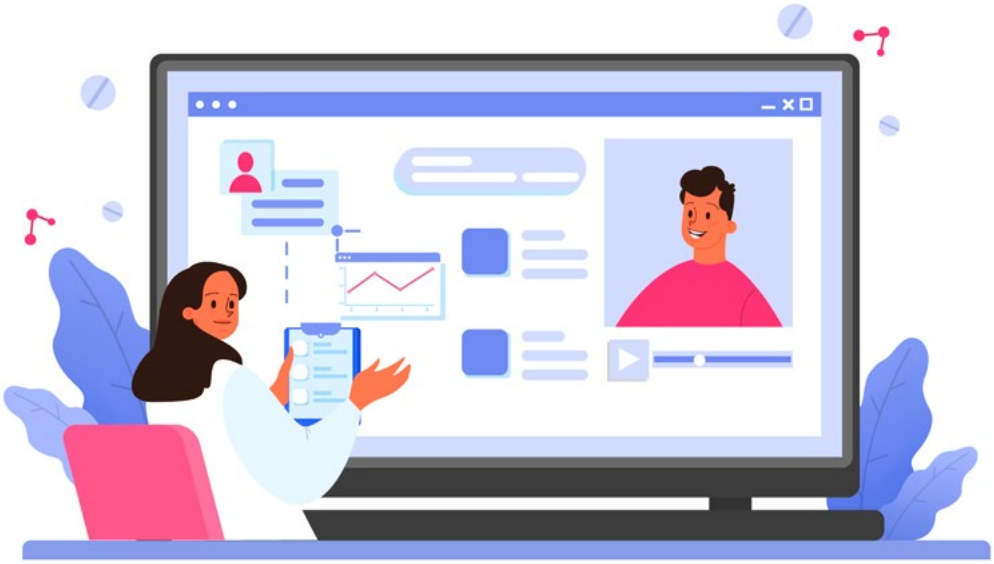
BBMRI.QM Academy offers two e-learning methods: live educational webinars and webinars on demand (recordings). The learning processes of both are supported through digital media & tools. They are intended for anyone wishing to continue medical education without travelling.

The webinars are oriented to different levels of expertise and provide worldwide interactive teaching on basic and advanced topics related to biobanking and biomolecular research activities.

Just go to the e-Learning platform and register for the live webinars or the recordings:

E-learning of BBMRI.QM Academy - BBMRI-ERIC: Making New Treatments Possible

BBMRI-ERIC® Academy



SPIDIA4P EVENTS // UPCOMING EVENTS AND TRAININGS / 2024

Save the date!

Europe Biobank Week 2024 May 14-17, 2024
Vienna, Austria

The congress will highlight state-of-the-art biobanking innovations and research. This action-packed congress will feature keynote presentations, panels and workshops organised by ESBB and BBMRI-ERIC.

More information here.

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:

For more information, please visit our website

www.tataa.com/courses

or contact us at

training@tataa.com.

TATAA BIOCENTER

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SPIDIA4P NEWS // WEBSITE www.spidia.eu

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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.