SPIDIA4P

SPIDIA4P Newsletter 2024/2025

STANDARDS – THE ROOTS OF HEALTHCARE

Get the complete picture of the pre-analytical standards on page 4 ff.!

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.

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Dear reader,

Preanalytical workflow steps are the most error-prone element in diagnostic workflows. Assays, including diagnostic tests, are therefore meanwhile consequently seen as whole workflow systems, encompassing all steps from sample collection to assay output, as also stated by regulatory bodies including the US FDA. Developing, verifying and validating pre-analytical workflows for enabling required assay performance is key in this context.

By taking part in further research consortia, SPIDIA4P partners continue to further shape pre-analytical science and to broaden the preanalytical and whole workflow standards portfolio at ISO/TC 212 for "Medical laboratories and in vitro diagnostic systems" and CEN/TC 140 for "In vitro diagnostic medical devices". This includes new standards as well as several starting standards revisions.

Several consortium projects achieved key milestones to deepen the whole workflow concept for assay developments. For example, the EU HORIZON 2020 research project Instand-NGS4P developed various new pre-analytical workflows for different specimen types, integrated into whole NGS workflows for enabling future improved cancer diagnostics. At the Austrian Center for Industrial Biotechnology (acib) and the Medical University of Graz, researchers started to develop a liquid biopsy-based whole workflow approach to identify predictive biomarkers for early detection of gestational diabetes, including all preanalytical workflow steps. More exciting projects initiatives as well as news from BBMRI-ERIC can be found in this newsletter.

A highlight in 2024 was the CEN/ CENELEC Standard + Innovation Award 2024 for Prof. Dr. med. Kurt Zatloukal, Instand-NGS4P coordinator, SPIDIA4P member and driver for various international and European initiatives for his for extensive contribution to standardization throughout the years.

A key event will be the Instand-NGS4P High-Level Seminar at the EU Parliament in May 2025 about the role of NGS in cancer care, including regulatory challenges and health economics.

Please enjoy reading this Newsletter. The next edition is planned for 2026. 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!

STANDARDS UPDATE

WHAT'S NEW? // ULRIKE SCHROEDER

ULRIKE SCHROEDER, M.SC.

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Progress and future developments in preanalytical standardization

SPIDIA and SPIDIA4P standard projects will be updated - 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 , thus creating and implementing **a portfolio of 22 pre-analytical CEN/TS and ISO Standards** (together with the existing standard documents initiated by SPIDIA) f**or 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. Just in **November 2024, three new documents on *Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood* initiated by SPIDIA4P were published on international level as ISO/TS**.

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) and are currently being drafted.

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 . 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 and others, went into their first review process in 2023 and 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.

Decided by an international public vote, it was agreed that a first wave of SPIDIA/SPIDIA4P documents will now be revised and updated (see also all documents marked with "in Revision" in Table 1).

If You, Your company or Your research institute are interested in joining the revisions or the drafting of ongoing documents, 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 2018–2024

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 20166-2:2018	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)**	In Revision
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)**	In Revision
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)**	In Revision
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)**	In Revision
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)**	In Revision
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)**	In Revision
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)**	In Revision
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 7552-3		
ISO/TS 7552-3-1:2024	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood - Part 1: Isolated RNA	
ISO/TS 7552-3-1:2024	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood - Part 2: Isolated DNA	
ISO/TS 7552-3-1:2024	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	
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

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QUALITY ASSESSMENT

BIOSPECIMEN PROFICIENCY TESTING PROGRAM // DR. OLGA KOFANOVA

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Get Ready for Biobank Accreditation with the Biospecimen Proficiency Testing Program

External inter-laboratory quality assessments (EQA) and/or proficiency testing (PT) programs play a crucial role in the mission of standardization across various laboratories, particularly in clinical research, healthcare, biobanking and pharmaceutical industries. These programs assess the capabilities of laboratories to ensure they meet established standards for accuracy, reliability, and consistency. Their importance cannot be overstated, as they provide several benefits:

Ensuring Consistency and Accuracy: By participating in EQA/PT programs, laboratories can compare their results with those of other labs working on the same tests or measurements. This benchmarking helps identify discrepancies or variances in methods, equipment, and procedures. Such external validation ensures that data generated by a laboratory is consistent and accurate, which is vital for maintaining quality across laboratories.

Promoting Best Practices: EQA/PT programs allow laboratories to demonstrate their competence in performing specific tests or analyses. Laboratories that perform well in PT not only uphold best practices but also contribute to improving the overall quality of results in their field.

Compliance with Regulations: Many laboratories, involved in healthcare and participating in clinical trials or clinical research projects, could be governed by regulatory frameworks. Participation in EQA/PT helps laboratories demonstrate compliance with regulatory standards, which may require proof of accuracy and reliability in testing/processing procedures. This is essential for meeting the expectations of regulatory bodies and for maintaining accreditation.

Continuous Improvement: The feedback from EQA/PT programs offers laboratories opportunities to refine their methods, upgrade equipment, and train staff, fostering continuous improvement and enhancing proficiency.

Confidence in Results: External assessments enhance stakeholders trust in the laboratory's results, whether those stakeholders are clients, regulatory agencies, or the public. By engaging in external assessments, laboratories signal their commitment to high-quality and reliable results.

In this context, EQA/PT programs have been also integrated into biobank laboratories' quality management systems (QMS) to provide independent assessments of biobank laboratory performance. These assessments go beyond the internal quality controls already implemented by the laboratories, allowing for a more objective evaluation of their processes and procedures.

One notable example is the annual Biospecimen Proficiency Testing program developed by Integrated BioBank of Luxembourg (IBBL LIH) [1-3], which supports the development of biobank quality assurance. **In conjunction with this, some schemes have been developed within the SPIDIA4P project, aligned with pre-analytical CEN/Technical Specifications (CEN/TS).**

The IBBL PT program covers a range of processing EQA/PT schemes for the pre-analytical phase, including testing quality controls used in the biobank laboratories (but not limited to):

- DNA Quantification and Purity
- RNA Integrity
- RNA Quantification and Purity
- Cell Viability
- DNA integrity
- Tissue Histology
- CSF Aliquoting
- DNA Extraction from Buffy Coat
- DNA Extraction from Whole Blood
- DNA Extraction from FFPE Material
- RNA Extraction from Buffy Coat
- RNA Extraction from Whole Blood
- RNA Extraction from FFPE Material
- Microbial DNA Extraction from Saliva
- Microbial DNA Extraction from Stool
- Cell Free DNA (cfDNA) Extraction from Whole Blood
- DNA Extraction from Frozen Tissue
- Total RNA Extraction from Frozen Tissue
- Viable PBMC Isolation
- Cell Free RNA (cfRNA) Extraction from Plasma
- Dual DNA/RNA Extraction from Frozen Tissue
- Circulating Tumour Cells (CTC) Isolation and Detection

On average, more than 70% of participants successfully pass the proficiency tests across all schemes. **Laboratories that have participated in IBBL PT program over multiple years have experienced overall improvements in their performance, as reflected in their z-scores.**

As part of the SPIDIA4P, an updated statistical analysis [1] of several years' worth of data from the annual IBBL PT program provides valuable insights into the most significant pre-analytical variables and how they specifically affect processing methods. This analysis focused on examining the relationship between performance metrics (such as z-scores) and pre-analytical factors, highlighting those that most influence the final results.

The EQA/PT program is a key component of a biobank laboratory's quality management system. It enables comprehensive performance assessment and provides valuable insights into the characteristics of processing methods, ensuring that laboratories can meet the rigorous demands of accreditation bodies. By participating in this program, biobanks can enhance their processes, ensuring high-quality standards are maintained throughout their operations.

Get Ready for Biobank Accreditation with the Biospecimen Proficiency Testing Program here:

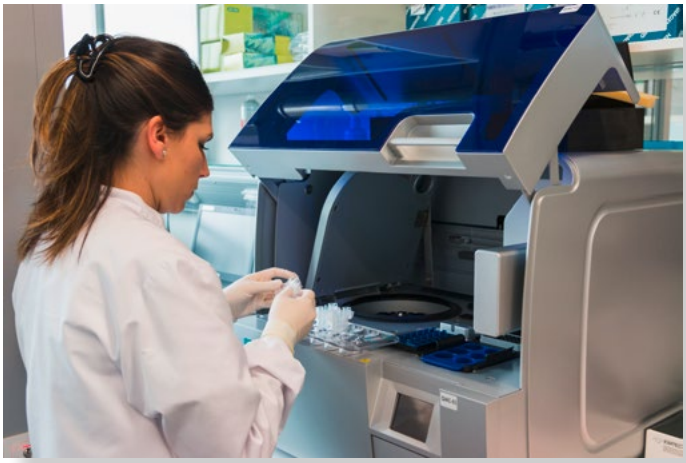
https://www.lih.lu/en/biospecimen-proficiency-testing/

References

1) Verderio P, Ciniselli CM, Gaignaux A, Pastori M, Saracino S, Kofanova O, Betsou F. External Quality Assurance programs for processing methods provide evidence on impact of preanalytical variables. N Biotechnol. 2022 Dec 25;72:29-37. doi: 10.1016/j.nbt.2022.08.006. PMID: 36049650.

2) Devonshire A, Jones G, Gonzalez AF, Kofanova O, Trouet J, Pinzani P, Gelmini S, Bonin S, Foy C. Interlaboratory evaluation of quality control methods for circulating cell-free DNA extraction. N Biotechnol. 2023 Dec 25;78:13-21. doi: 10.1016/j.nbt.2023.09.005. PMID: 37730172.

3) Lewczuk P, Gaignaux A, Kofanova O, Ermann N, Betsou F, Brandner S, Mroczko B, Blennow K, Strapagiel D, Paciotti S, Vogelgsang J, Roehrl MH, Mendoza S, Kornhuber J, Teunissen C. Interlaboratory proficiency processing scheme in CSF aliquoting: implementation and assessment based on biomarkers of Alzheimer's disease. Alzheimers Res Ther. 2018 Aug 28;10(1):87. doi: 10.1186/s13195-018-0418-3. PMID: 30153863; PMCID: PMC6114189.



SPECIAL I: AWARDS

SPECIAL I: AWARDS

CEN/ CENELEC Standard + Innovation Award 2024 for Prof. Dr. med. univ. Kurt Zatloukal!

On December 10, 2024, the winners of the Standard + Innovation Award by CEN and CENLEC were announced.

Prof. Dr. med.univ. Kurt Zatloukal, of the Medical University of Graz, who has worked both in the SPIDIA and SPIDIA4P project, won the prestigious award in the category dedicated to putting the spotlight on individual researchers and innovators who have successfully integrated their work into standardization.

He was nominated by DIN for his extensive contribution to standardization throughout the years, and in particular for his contribution to developing a standard for digital pathology and AI-based analysis of images for medical diagnosis.

Upon receiving the award, Dr. Zatloukal inspired the audience by declaring "Safety and Performance Requirements are challenging, standards are beautiful," eliciting knowing smiles from the crowd.

This has been the second time, a SPIDIA/ SPIDIA4P project member has won this award - in 2021, Dr. Uwe Oelmueller, QIAGEN, Coordinator of both the SPIDIA and SPIDIA4P project, has received the STANDARDS + INNOVATION TECHNICAL BODY OFFICERS AWARD for his role of the driving force behind translating research and industry needs in highly innovative fields into standard documents (CEN/TS, EN ISO, ISO) achieving significant impact in health care and diagnostics.

Learn more about the award and the winners **here**.

See the LinkedIn post by CEN and CENELEC here.

NETWORKING AND NEWS ABOUT OTHER CONSORTIA

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

MAG. (FH) CORNELIA STUMPTNER
EXECUTIVE MANAGER BBMRI.AT
LEADER WORK PACKAGE
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MICROBE

Microbiomes consist of various microorganisms (e.g. bacteria, fungi, archaea, protozoa, phages) and viruses in their special "theatre of activity" (such as the surrounding conditions of the environment they live in). They play a vital role in humans, animals, and plants, but also in our environment, where they exert essential functions for example in soil and (marine) water and are indispensable for maintaining life on Earth.

Microbiome fields & quality standards

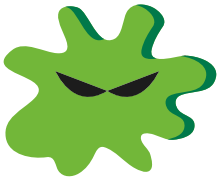
For the human microbiome field SPIDIA4P developed the pre-analytical sample quality standard CEN/TS 17626:2021 "Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for human specimen – Isolated microbiome DNA". Standard development within SPIDIA4P and at CEN was led by Med Uni Graz through experts from BBMRI.at (www.bbmri.at), the Austrian Node of the European Biobanking Research Infrastructure BBMRI-ERIC. The CEN/TS 17626 specifies requirements and gives recommendations for the pre-analytical phase of humane specimens (such as stool, saliva, urine, or swabs etc. from oral, gastrointestinal or urogenital tracts) intended for microbiome DNA analysis. Together with EU regulations (such as the IVDR) and accreditation standards such as ISO 15189 (for medical laboratories) and ISO 20387 (for biobanks), CEN/TS 17626 helps to achieve standardization in the human microbiome field.

In non-human microbiome and biobanking fields – such as soil, plant and marine fields – comparable pre-analytical standards are currently missing.

Although the pre-analytical phase is equally important in these fields, as it can have a great impact on the specimens and analysis data, it is often neglected or underestimated. Moreover, important pre-analytical steps and technologies, such as for the preservation and propagation (cultivation) of microbiome specimens, are currently considered a huge bottleneck with respect to their ability to maintain the composition and functionality of microbiomes. Many microbial species are not yet functionally characterized in detail, because current preservation and propagation methods are not equally well suited for all types of taxa with many being sensitive to preservation or considered 'unculturable'.

BBMRI.at
Biobanking and BioMolecular resources Research Infrastructure Austria

MICROBE
the Microbiome Biobanking (RI) Enabler

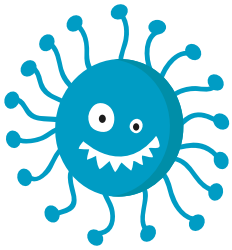


The EU project MICROBE addresses microbiome standardization

The EU project MICROBE "Microbiome Biobanking (RI) Enabler" (www.microbeproject.eu, Grant no. 101094353) aims to address major bottlenecks in the microbiome research and biobanking field as described above. It envisions to deliver technical solutions for preservation, propagation and functionality assessment of microbiomes from soil, plant seed and marine water. Such techniques shall enable the optimal collection and preservation of microbiome samples and retain the viability and functional diversity of original microbiomes. Both are a prerequisite for the targeted isolation of microbiome members that can be reassembled into so-called synthetic communities (SynComs). SynComs are constructed by co-culturing multiple taxa isolated from e.g. plant, soil, or human body sites to mimic the structure and function of these microbiomes. They can be applied for example in agriculture promoting plant growth, disease protection or in human health care to treat diseases and dysbiosis.

Overall, MICROBE will provide a comprehensive operational blueprint for the establishment of a microbiome biobanking infrastructure.

In addition to technological requirements, also methodological workflows, data pipelines, legal and ethical guidelines, business opportunities, and, last but not least, pre-analytical sample quality requirements for standardization are addressed.



The human microbiome and biobanking field is more advanced in this respect. The CEN/TS 17626 is used as a best practice example from which environmental microbiome fields can profit and develop pre-analytical guidance documents for other non-human microbiome sample types such as plants, soil or marine water. BBMRI.at experts from Med Uni Graz take care of sample pre-analytics in MICROBE and lead a work package on standardization and quality control.

In the context of MICROBE, pre-analytical workflows comparable to CEN/TS 17626 were defined for plant, soil and marine water samples.

In workshops with plant experts from MICROBE and the European Plant Science Organization (EPSO, https://epsoweb.org), potential pre-analytical variables were identified and rated according to their relevance and extent of potential impact on the specimen and analysis data. Also, evidence from a profound research of scientific literature research and other guidelines and best practices were considered. A summary of this search for guidelines, best practices and ISO/CEN standards addressing pre-analytical phase of specimens intended for microbiome analysis is published on Cordis https://cordis.europa.eu/project/id/101094353/results

Raising awareness on microbiome sample pre-analytics

Continuing the mission of SPIDIA4P, former partners go on raising awareness of the pre-analytical phase and the effect pre-analytical variables can have.

Presentations on this topic were given at several meetings and workshops. One example is the Bioethics and Regulatory Workshop of the EU project MICROBES-4-CLIMATE which joins forces with MICROBE (more in a BBMRI.at news article)

Another example is the MICROBE consortium meeting, which was recently held in Braunschweig, Germany, to exchange on project news and plan further steps how to tackle standardization. In addition to the project team, also the EU project officer and Advisory Board members such as from BBMRI-ERIC, MIRRI, ECCO or USCNN attended.

Part of the meeting was a visit of the German Collection of Microorganisms and Cell Cultures - Leibniz Institute DSMZ (www.dsmz.de). The DSMZ is a biological resource centre offering a comprehensive portfolio of both services and biological resources such as bacteria, archaea, plant viruses, fungi, bacteriophages, and mammalian cell lines and one of MICROBE's project members. Further MICROBE partners besides DMSZ and Med Uni Graz are the AIT Austrian Institute of Technology (coordinator, AT), CAB International, Helmholtz Zentrum München HMGU (DE), EMBL (DE), Sorbonne Université (FR), INRAE (FR), rtd services (AT), and Med Uni Graz (AT).

The MICROBE project is a wonderful example how SPIDIA4P lives on and how its work is recognized, disseminated into other fields, and appreciated.

Links:

About MICROBE ***https://www.microbeproject.eu/***

MICROBES-4-CLIMATE: Pre-analytical standards as key to microbiome and climate research ***https://bbmri.at/news-articles/microbes-4-climate-awareness-on-relevance-of-the-pre-analytical-phase/***

Microbiome Biobanking EU Project "MICROBE" Kick-Off ***https://bbmri.at/news-articles/eu-project-microbe-kick-off/***

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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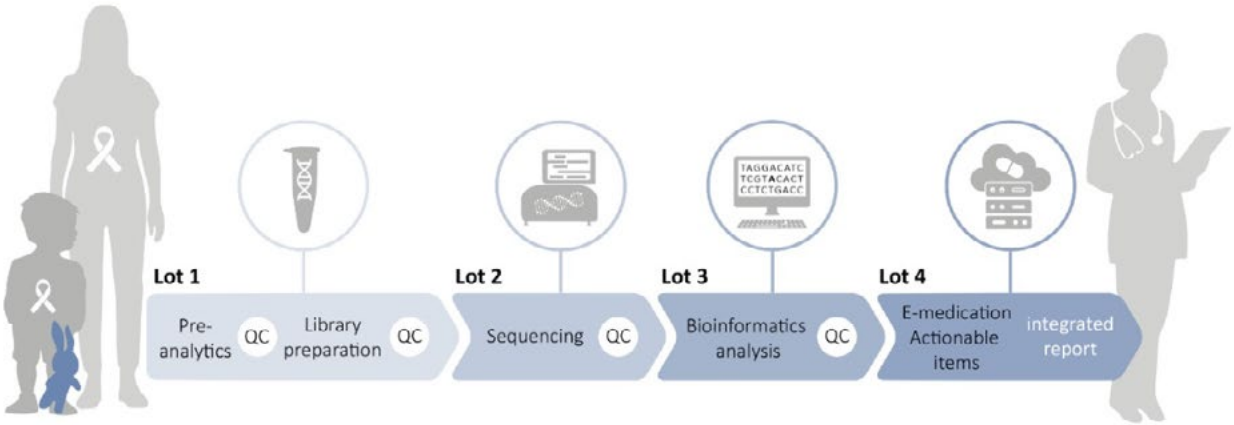
Instand NGS for Personalized Therapy

Instand-NGS4P

INSTAND-NGS4P is an EU co-funded 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.

Expected Outcome

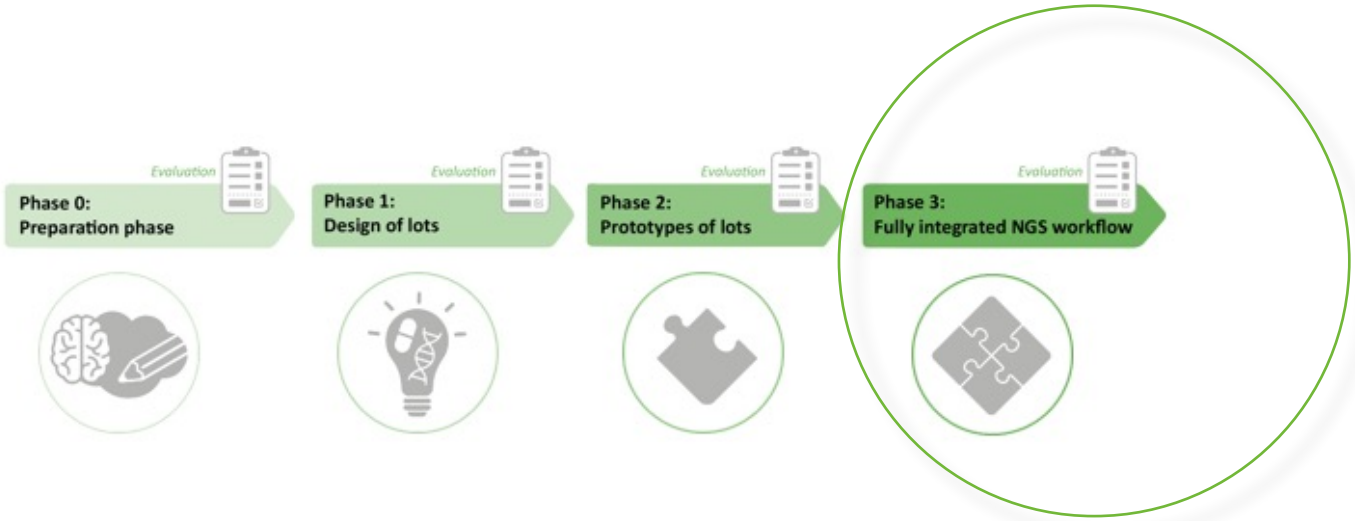
Funded by the FFG-COMET program, this project builds on a strong foundation of liquid biopsy expertise in cancer and sepsis research. By translating these cutting-edge methodologies to maternal health, we aim to develop new diagnostic tools that facilitate earlier, more effective treatment of GDM – transforming prenatal care for the future.



Current activities

Testing of the fully integrated and standardised NGS workflows (April 2024 to May 2025)

During Phase 3 of the project, the Prototype Solutions for the innovative NGS workflow developed by the Contractors, covering the pre-analytical phase, and library preparation, bioinformatics analysis and integrated reporting, are being tested for usability, interoperability and integratability in a real-world diagnostic environment by the procuring Buyers.



The 7 procuring Buyers in Instand-NGS4P:

Medical University of Graz (MUG – Coordinator and 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)

t. Anna Kinderkrebsforschung (CCRI - AT)

Centre Leon Bérard (CLB – FR, coordinating ERN on adult rare cancers)

Lot	Lead Contractor (Click name to read the project abstracts)
Lot 1: Pre-Sequencing	QIAGEN GmbH Twist Bioscience Corporation
Lot 3: Bioinformatics Analysis	Congenica Ltd CONSORCIO PARA LA EXPLOTACIÓN DEL CENTRO NACIONAL DE ANÁLISIS GENÓMICO (CNAG)
Lot 4: Integrated Reporting	BC Platforms AG Congenica Ltd CONSORCIO PARA LA EXPLOTACIÓN DEL CENTRO NACIONAL DE ANÁLISIS GENÓMICO (CNAG)

Table 1. Contractors participating in Phase 3 in Instand-NGS4P

Testing of the Solutions

Clinical cancer cases were available as archived material/sequences or were newly recruited by the Buyers. They comprised adult cancers (non-small cell lung cancer (NSCLC), colon cancer, ovarian cancer, prostate cancer, and sarcoma) – and childhood acute lymphoblastic lymphoma (for ethical reasons only archived samples or sequences were used). A broad spectrum of sample types was provided in Lot 1, such as liquid biopsies (blood/plasma, saliva, urine, ascites) and tissue (FFPE, PFPE).

Sequencing of tumor samples was performed by the Buyers at their institutions.

The samples from these cases were analysed parallel to the routine diagnostic clinical NGS. Here the workflows are evaluated for their benefits regarding handling and ease-of-use, turnaround time and efficiency, and performance compared to the routine clinical analyses. Moreover, pharmacogenomic analyses (PGx) from the same cases were performed.

Each of the prototype Solutions was tested at three Buyers´ institutions. The Solutions of each lot were combined to complete workflows to allow assessment of their interoperability (see figures below).

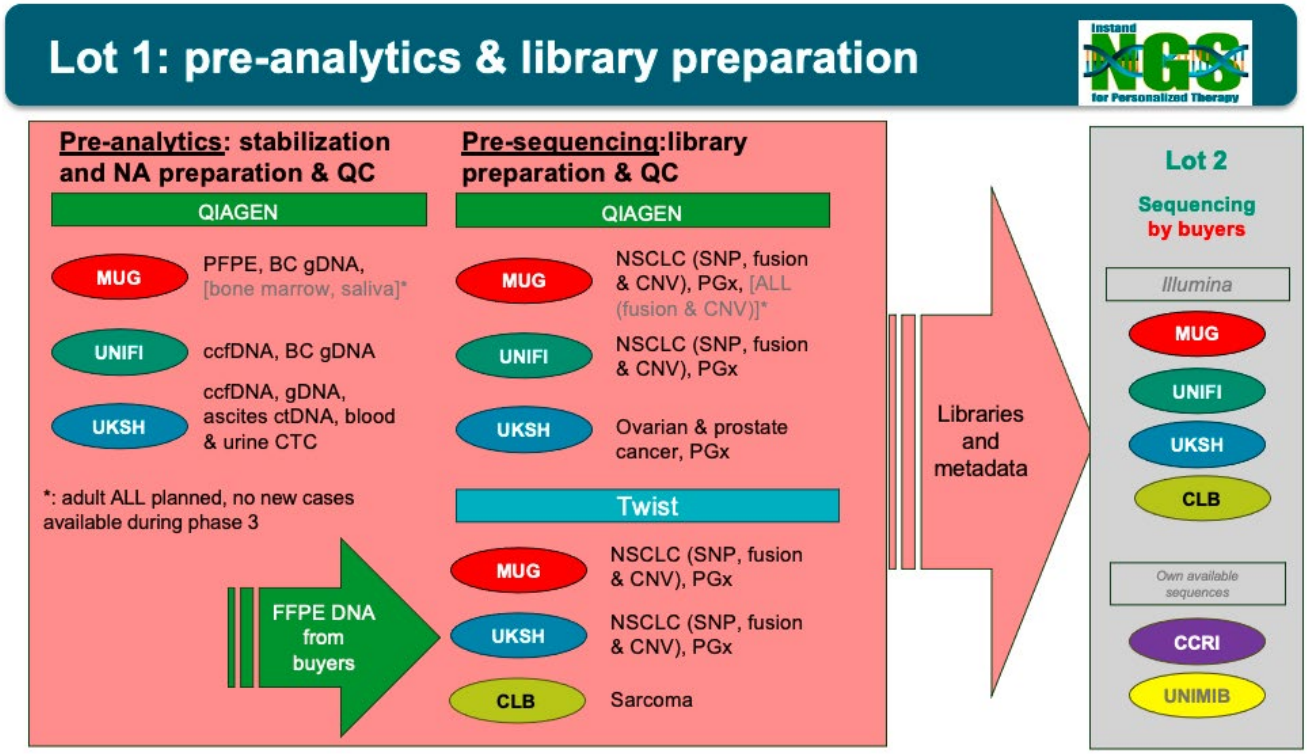


Figure 1. Testing of Lot 1 Solutions

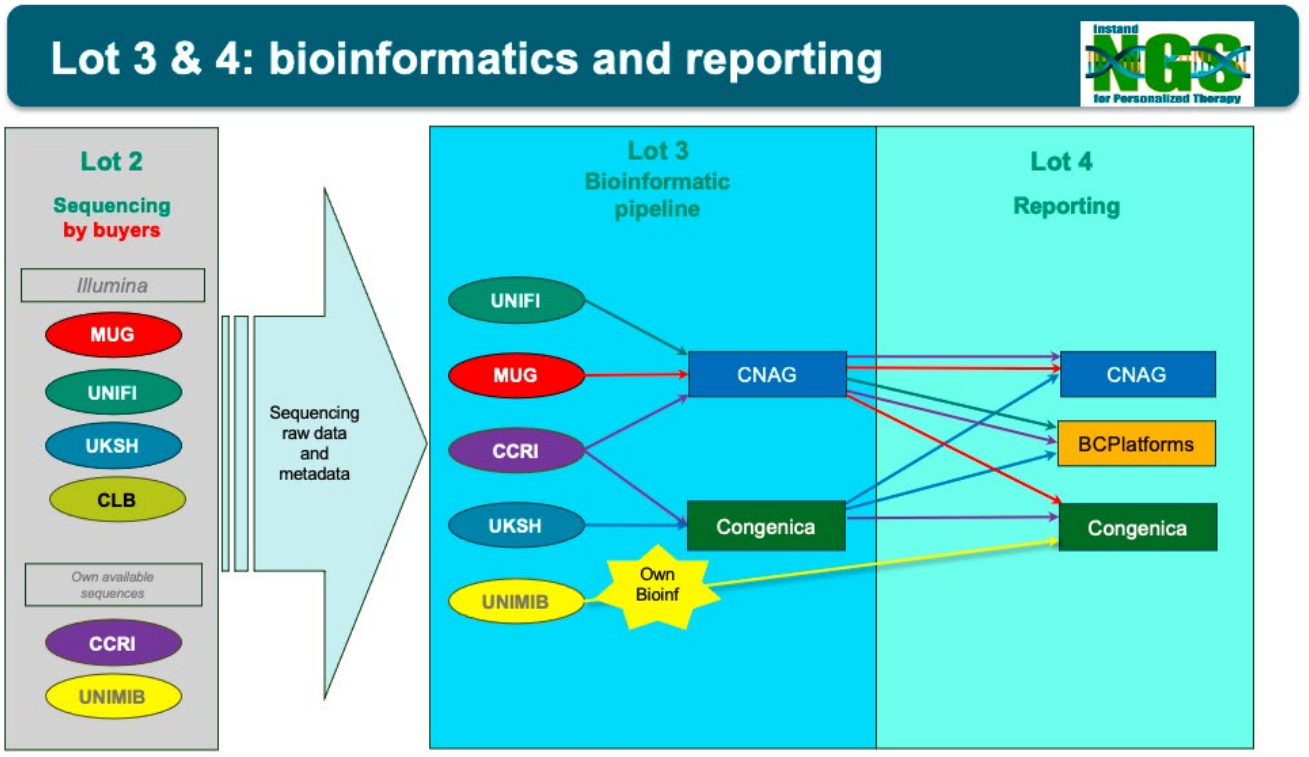


Figure 2. Testing of Lot 3 and 4 Solutions

A summary report of the outcome will be published at the end of the project, highlighting the innovative developments in the NGS workflows.

Standardization activities

Instand-NGS4P is partnering with CEN/TC 140 WG 3 and ISO/TC 212 WG4 to develop standardization documents for the entire NGS workflow. Following the successful publication of the two CEN/TSs in 2023, these documents are now being further developed as EN ISO documents. Participation in the development of these standards is encouraged, and interested parties should contact their national standardisation body to enquire about nomination to the ISO/TC 212 WG4.

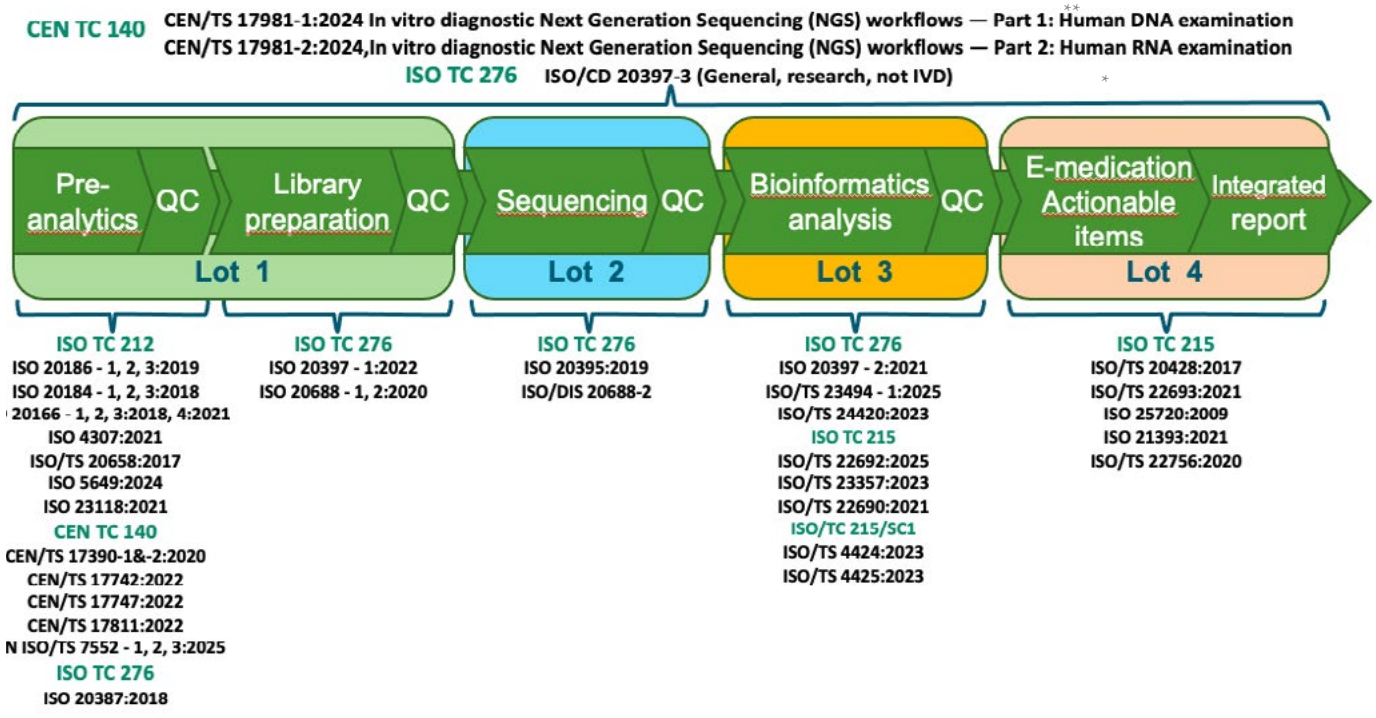
Published documents:

- *CEN/TS 17981-1:2024, In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 1: Human DNA examination*
- *CEN/TS 17981-2:2024, In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 2: Human RNA examination*

Under development:

- *ISO/WD 25379-1 - In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 1: Human DNA examination*
- *ISO/WD 25379-2 - In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 2: Human RNA examination*

The project has also created an overview of NGS-relevant standardization documents (published or under development) as of February 2025:



Stakeholder Event

A major stakeholder event will be held on the 20th of May 2025 which will highlight the **medical need for innovative NGS** in cancer care, as well as discussing **regulatory challenges and health economic aspects.**

SPIDIA4P´s Coordinator Dr. Uwe Oelmüller will give a talk in the regulatory session.

Policymakers, health care providers, physicians, patient and civil society representatives as well as partners and collaborators of the Instand-NGS4P project are cordially invited to save the date on their calendar. See **here** for further information and registration.

"Precision Diagnostics for Precision Cancer Care – Improving patient access to innovation"

High Level Seminar at the European Parliament in Brussels

on May 20th, 2025 14:00 – 18:00 CET

For further information on the Instand-NGS4P project, please visit
https://www.linkedin.com/in/instand-ngs4p-4751a0226/

The Instand-NGS4P Consortium Meeting at the Medical University of Graz in April 2024

SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

MELINA HARDT, DR.RER.NAT MSC.

DIAGNOSTIC AND RESEARCH INTITUTES OF PATHOLOGY

Medical University of Graz

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The next pandemic will come

The recent pandemic caused by the new emerging Coronavirus SARS-CoV-2 demonstrated the high demand of diagnostic tests to combat COVID-19. Pre-analytical specifications such as transportation duration or storage temperature of the patient specimen were shown to be a critical factor for reliable test results (Hardt et al., 2022, Hardt et al., 2024). Furthermore, safe handling protocols for personnel as well as multiplex-testing of human respiratory viruses and creating generic diagnostic workflows that can be easily adapted for high throughput use, are key goals to combat pandemics.

The European Union's Horizon Europe research and innovation programme ISIDORe (Integrated Services for Infectious Disease Outbreak Research) provides an integrated portfolio of research services, tools and resources to study pathogens including SARS-CoV-2, Influenza and RSV which are susceptible to epidemics. Our collaboration project between QIAGEN, PreAnalytiX and the Medical University Graz (MUG) received funding under grant agreement No 101046133 and will be finalized in March 2025.

The application to the section "Diagnostics" with 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 performed at the Diagnostic & Research Institute of Pathology of the MUG. Our project "Development of Next Generation Respiratory Infection Diagnostics (NeResDia)" includes cell culture and spike-in experiments that must be performed under BSL-3 conditions and in facilities that have implemented or have experience with ISO and CEN standards for pre-examination workflows such as ISO 4307:2021(en) "Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for saliva — Isolated human DNA" and ISO 20658:2023(en) "Requirements for the collection and transport of samples for medical laboratory examinations" .

The EU In Vitro Diagnostic Regulation (IVDR) and the latest ISO & CEN standards form the basis for covering all diagnostic workflow steps in this project, starting with specimen collection, preservation, storage, transport and processing.

Based on the results of the previous ERINHA advanced project, the effect of storage duration (up to 96 h) and temperature (room temperature and 37 °C) on copy number stability of various human respiratory viruses such as SARS-CoV-2, RSV A and B and influenza A and B were examined in one commercially available swab system under BSL-3 conditions. The viral RNA was isolated from cell culture experiments to test viral inactivation properties of substances and from stability studies to assess post-collection stability of viruses in specimen. The amount of virus particles was quantified either via RT-qPCR, or the samples were processed directly after harvesting with the QIAprep&amp system. Furthermore, the impact of external substances such as components of nasal sprays or mouth washing solutions on qPCR accuracy were studied, as these could interfere with test results.

In our previous studies, the effect of pre-analytical factors such as temperature and storage duration on diagnostic test results was clearly demonstrated and highlighted the importance of strict adherence to manufacturers' instructions and validation of the actual workflow.

In the present project, we have developed different workflows that can be adapted to various diagnostic needs especially during flu seasons and pandemics.

More information:

https://erinha.eu/projects/isidore/

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SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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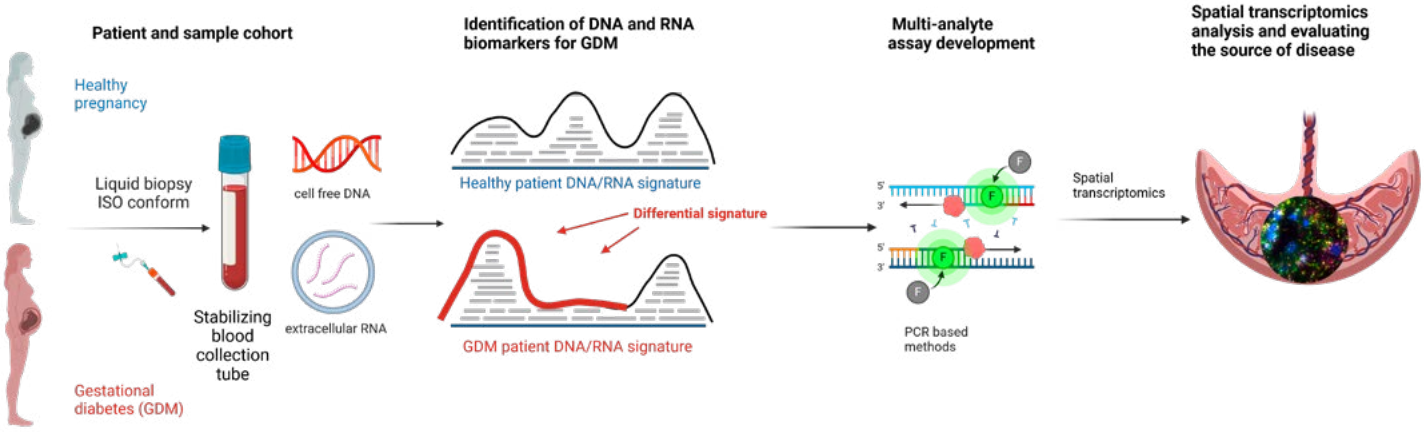
Liquid Biopsy for Early Detection of Gestational Diabetes

Gestational diabetes mellitus (GDM) is an escalating health concern, affecting up to 10% of pregnancies—a number that continues to rise due to factors such as increasing maternal age, obesity, and lifestyle changes. GDM poses significant health risks for both mother and child, ranging from metabolic disorders to life-threatening complications. Currently, it is diagnosed relatively late in pregnancy, between weeks 24–28, leaving limited time for effective preventive interventions.

But what if we could detect it much earlier?

In collaboration with QIAGEN, the Austrian Center for Industrial Biotechnology (ACIB) and the Medical University of Graz, researchers aim to develop a liquid biopsy-based approach to identify early predictive biomarkers for GDM. By analyzing circulating cell-free DNA and RNA (ccfDNA/RNA) in maternal blood, the team led by Petra Heidinger and Amin El-Heliebi seeks to enable earlier detection than the conventional glucose tolerance test. **This could significantly enhance prenatal care, allowing timely interventions that safeguard both mother and the child.**



To ensure the highest standards for liquid biopsy analysis, the team is leveraging expertise from cancer research, where similar technologies have already been successfully applied (1). In this context, all blood and tissue samples are collected following ISO standards ensuring highest pre-analytical quality.

The goal is to extract cell-free DNA and RNA from pregnant women and identify unique molecular patterns distinguishing GDM cases from healthy pregnancies. These signatures will then be used to develop a high-sensitivity diagnostic assay, similar to those previously developed by the Heidinger Group for early sepsis detection (2).

The research is embedded in the PregWin longitudinal clinical study, where multiple metabolic and clinical parameters, along with biological samples from pregnant women are collected at the Medical University of Graz. The long-term vision is to create a minimally invasive blood test for early GDM detection, enabling preventive actions before severe complications arise.

Funded by the FFG-COMET program, this project builds on a strong foundation of liquid biopsy expertise in cancer and sepsis research. By translating these cutting-edge methodologies to maternal health, we aim to develop new diagnostic tools that facilitate earlier, more effective treatment of GDM — transforming prenatal care for the future.

References

1) Bonstingl L, Skofler C, Ulz C, Zinnegger M, Sallinger K, Schönberger J, et al. Clinical Application of ISO and CEN/TS Standards for Liquid Biopsies-Information Everybody Wants but Nobody Wants to Pay For. Clin Chem. 2024 Sep 3;70(9):1140–50.

2) Ullrich E, Heidinger P, Soh J, Villanova L, Grabuschnig S, Bachler T, et al. Evaluation of host-based molecular markers for the early detection of human sepsis. J Biotechnol. 2020 Feb 20;310:80–8.

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SPECIAL II: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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BBMRI-ERIC®
The European research infrastructure for biobanking and biomolecular resources in health and life sciences

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BBMRI-ERIC launched its visionary 10-Year Roadmap

BBMRI-ERIC launched its visionary 10-Year Roadmap that adopts the "One Health" approach to prioritise the interconnection between human, animal, and environmental health emphasising its role in advancing biobanking for European and global health improvements. It provides a blueprint for the research infrastructure, the biobanking community and wider partners that places biobanking at the heart of scientific research to achieve a healthier world.

The 2025-2027 Work Programme

This new Work Programme distils the first three years of the Roadmap into a plan of action that has been developed closely with the 25 National Nodes of BBMRI-ERIC.

Emphasis was put on eight Strategic Objectives (SO) and Operational Goals:

SO1: Optimise the interconnection of human, animal and environmental health research

SO2: Accelerate datafication to enable trustworthy, fit-for-purpose data for high-quality research

SO3: Foster green biobanking and Research Infrastructure operations

SO4: Secure infrastructural scalability, sustainability and service excellence

SO5: Strengthen the National Node and biobank community within Member States

SO6: Educate, train & build capacity

SO7: Strengthen stakeholder engagement and awareness

SO8: Advance a global biobanking community especially focusing on global standardisation initiatives and progresses.

The continuation of the SPIDIA vision and the further development of new standards is a high priority of BBMRI-ERIC and therefore a key component of the Roadmap and the Work Programme.

ISO/TC 276 "Biotechnology" Working Group activities

BBMRI-ERIC is actively participating in the revision of the ISO 20387:2018 "General requirements for biobanking," contributing feedback and expertise from across its community to help improve and future-proof the standard. The updated version is anticipated for publication in 2026.

Encouragingly, since the publication of the Biobanking Standard in 2018, several BBMRI-ERIC biobanks have already received accreditation according to ISO 20387, demonstrating their competence and commitment to high-quality biobanking practices and demonstrating the adoption of international standards to support excellence across the infrastructure.

Figures 1 and 2 reflect the issued Quality Labels which are searchable in the BBMRI-ERIC Directory.

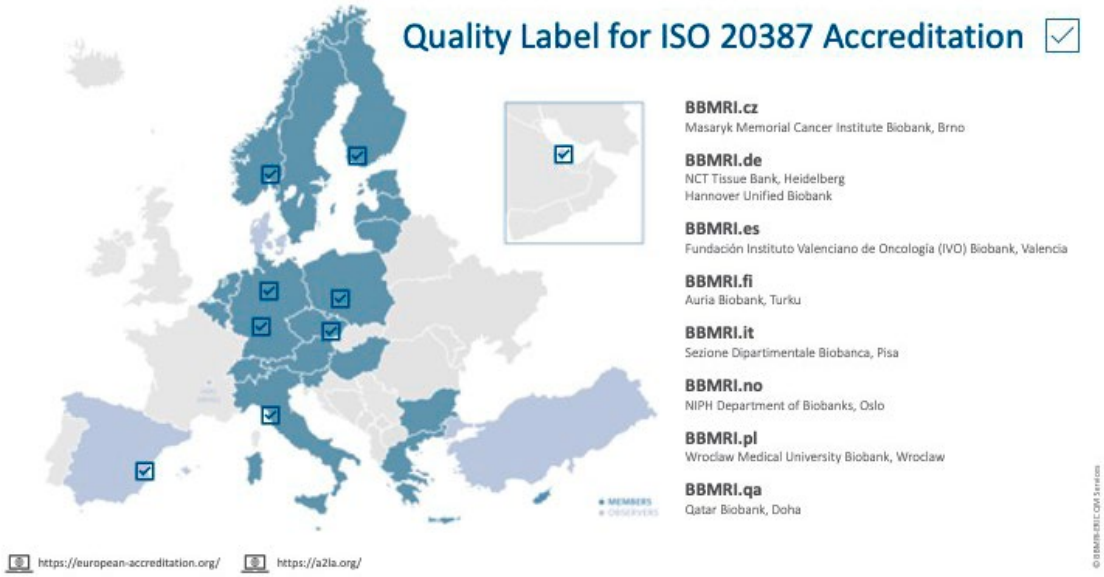


Figure 1: ISO 20387 accredited biobank, accredited by their national accreditation body

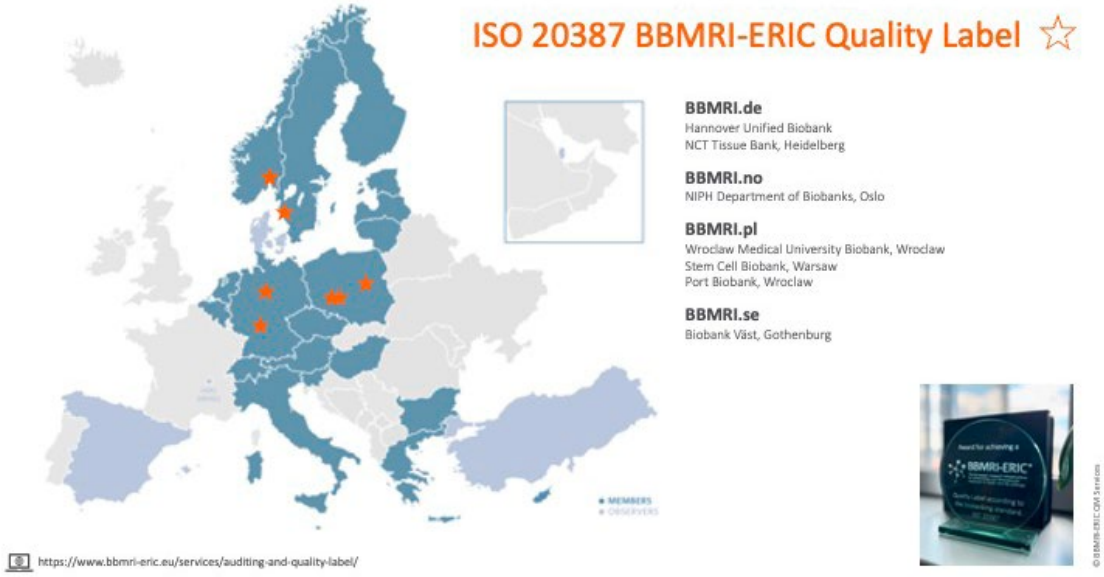


Figure 2: Biobank audited by BBMRI-ERIC*

*The BBMRI-ERIC Quality Label demonstrates that a biobank meets defined quality standards, with a focus on compliance with ISO 20387 requirements. It reflects the outcome of an independent audit process conducted by BBMRI-ERIC and highlights that the biobank has established and maintains its biobank operations according to international and European standards.

ISO 23494 standard series for Provenance Information Model for Biological Material and Data

Reproducibility issues are common in life sciences. **In biobanking and biomedical research, the quality of samples and associated data is crucial.** Standards like ISO 20387 support biobanking operations, and specifications for pre-examination processes help ensure quality across various human specimen types. However, provenance information – tracking the full journey from sample to data – is often incomplete.

To improve this, the ISO 23494 series on Provenance Information for Biological Material and Data is being developed. Based on the Common Provenance Model Framework, it offers an open, conceptual foundation for documenting and integrating provenance information from multiple sources.

When adopted by biobanks, the framework supports the full spectrum from basic research to practical application and product development, by linking samples with data and analysis. This leads to increased traceability, quality assessment and reproducibility.

BBMRI-ERIC experts are leading the development of ISO 23494 within ISO/TC 276 WG5. The series is expected to include seven parts. Visit our website to learn more about BBMRI-ERIC's role in international standardization and how BBMRI-ERIC liaises with international standardization organisations.

BBMRI-ERIC QM launched a dedicated Working Group for Data Quality

While the ISO 20387 on Biobanking sets the scene for organizational requirements in biobanking and the preanalytical standards for specific analysis give recommendations applicable to biological sample processes, BBMRI-ERIC Quality Management (QM) is now exploring guidelines for data quality to cover the entire life cycle from sample to data with relevant quality checks. To advance in this topic while spreading awareness on data quality in biobanking, QM team has successfully launched a new working group (WG) dedicated to data quality, bringing together biobanking professionals in quality, IT and data domains.

The focus of WG Data Quality is in promoting reliability and replicability of research results when using high-quality biobank data. This is to be achieved with the help of international standards and other well-known guidelines in data quality, but also by enhancing the quality of data management processes and data governance policies, as well as exploring different data standards (e.g. OMOP, HL7 FHIR, MIABIS) to support data interoperability - a critical element when combining data from multiple sources.

For more information, see ***BBMRI-ERIC QM working group.***

SBP Guidelines Support Quality Standards and BBMRI-ERIC Auditing for Better Research Outcomes

The Swiss Biobanking Platform (SBP), a member of BBMRI-ERIC, has published guidance documents to help biobanks and researchers preparing high-quality nucleic acids from blood and FFPE (formalin-fixed, paraffin-embedded) tissue. These guidance documents are aligned with the ISO 20186-2: Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA, the ISO 20186-1: Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 1: Isolated cellular RNA and the ISO 20166-3: Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 3: Isolated DNA.

These guidelines focus on the *preanalytical phase* – the steps of collecting, transporting, processing, and storing samples – which can greatly affect the reliability of research results.

The three newly published guidelines are:

- **Pre-analytical conditions to prepare human DNA from whole blood**
- **Pre-analytical conditions to prepare human RNA from whole blood**
- **Pre-analytical conditions to prepare human DNA from FFPE tissue for next-generation sequencing**

The Swiss guidelines, along with a list of directly related standards and other important ones, can be found on the BBMRI-ERIC standardisation page.

The guidelines are also closely linked to BBMRI-ERIC's auditing programme, which evaluates biobanks and awards a Quality Label to those that meet high standards. Following these recommendations helps biobanks align their processes with auditing requirements, supporting quality assurance and reliable sample management. This, in turn, improves research outcomes, especially in advanced fields like omics studies.

By adopting these guidelines and utilising BBMRI-ERIC's audit services, biobanks can improve the quality of their samples and demonstrate that their sample collections can be used for high quality and reliable research.

For more information, visit the ***BBMRI-ERIC audit programme page*** and find the quality labelled biobanks and its collections in the ***BBMRI-ERIC directory.***

Nothing works without commitment and dedication

BBMRI.QM is built on a strong network of committed biobankers and dedicated quality managers. The photo shows the Quality Leads from all our Member Countries—an inspiring team working together to advance quality in biobanking across Europe. Behind them stands a community of over 290 Biobank Quality Managers, Data Managers, IT Specialists, and scientists, all contributing their expertise to make high-quality biobanking a reality.

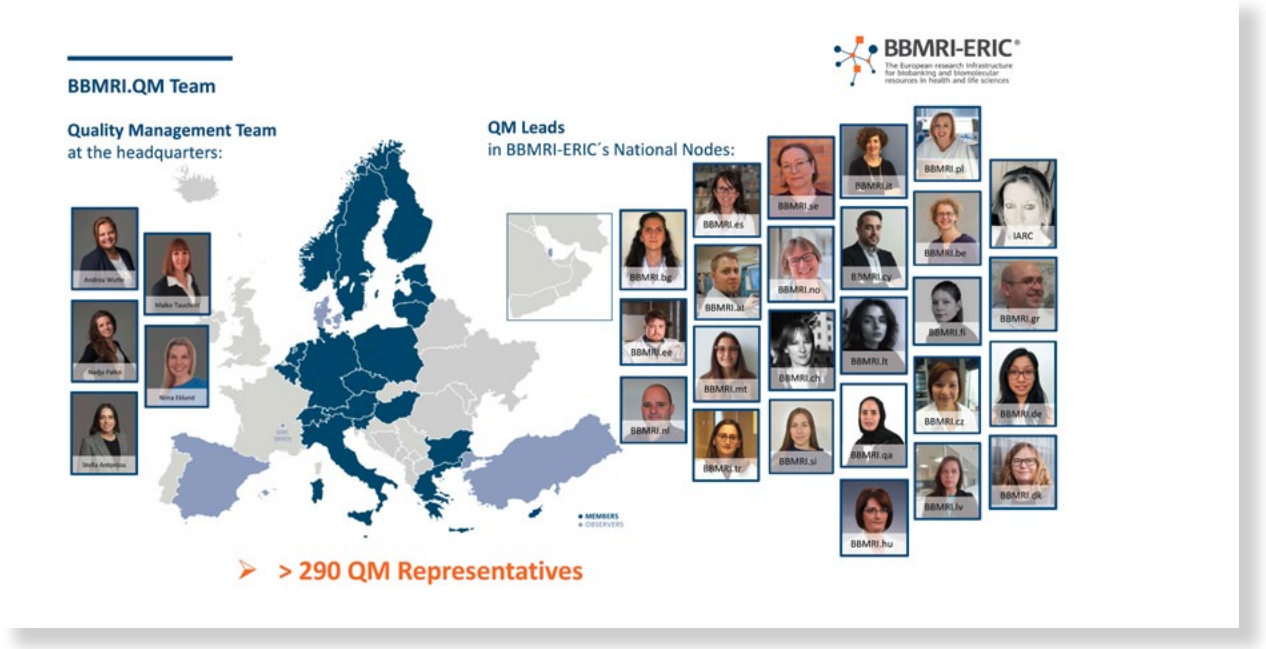
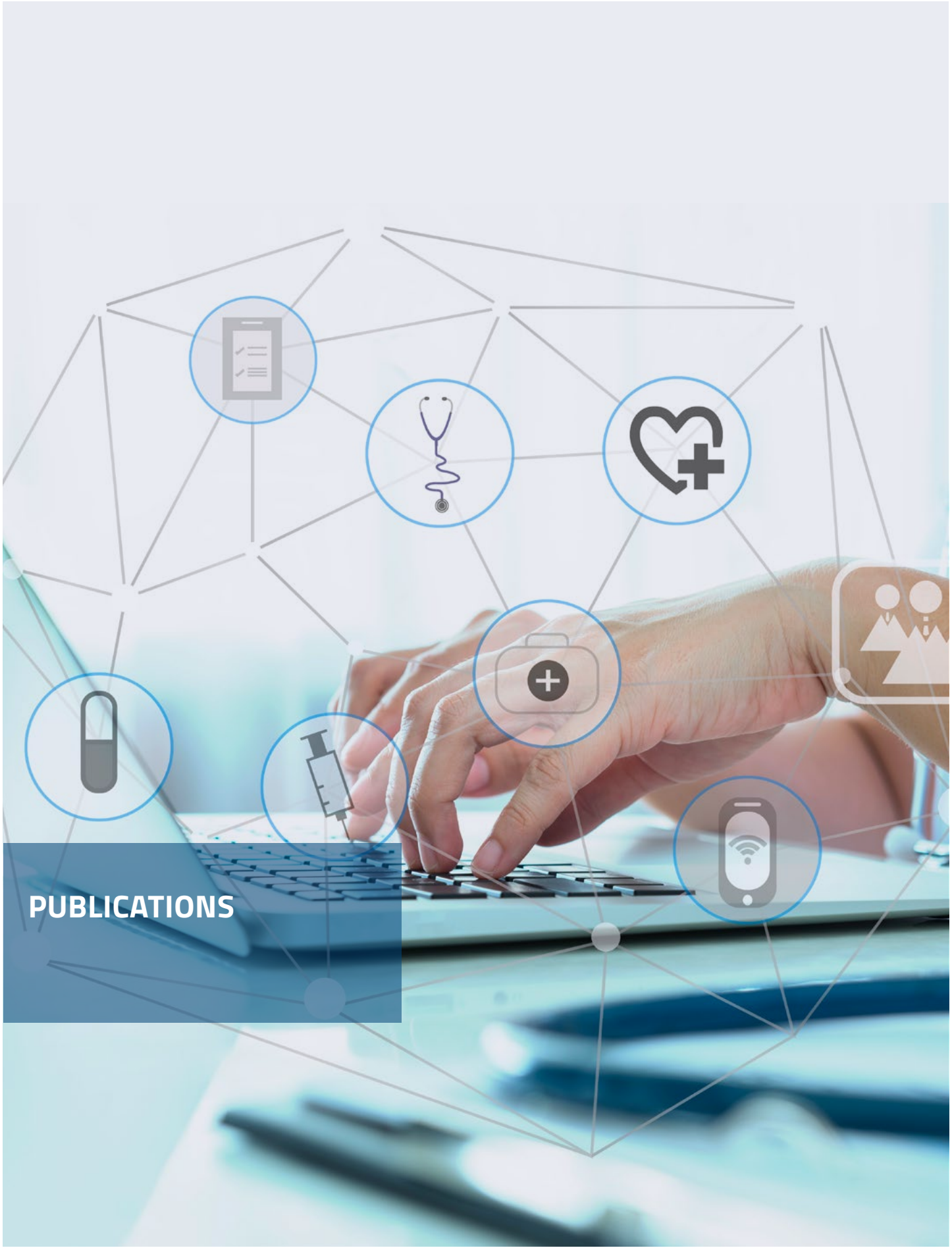


Figure 3: BBMRI.QM team at headquarters and the Quality Management Leads of the National Nodes

EBW25: Join us at Europe Biobank Week in Bologna, Italy, from 13 – 16 May!

Figure 4: Europe Biobank Week 2025



PUBLICATIONS

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:

In their latest publication, researchers from BBMRI.at partner Medical University of Graz evaluated the applicability of ISO and CEN/TS standards for the pre-analytical quality of whole venous blood for circulating cell free DNA (ccfDNA) and circulating tumor cells (CTC):

Bonstingl L, Skofler C, Ulz C, Zinnegger M, Sallinger K, et al

Clinical Application of ISO and CEN/TS Standards for Liquid Biopsies – Information Everybody Wants but Nobody Wants to Pay For

Clinical Chemistry, Volume 70, Issue 9, September 2024, Pages 1140–1150 – **open access**

Clinical Application of ISO and CEN/TS Standards for Liquid Biopsies—Information Everybody Wants but Nobody Wants to Pay For | Clinical Chemistry | Oxford Academic

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In cooperation with SPIDIA4P partners QIAGEN and PreAnalytiX, the ERINHA-Advance project NESARSDia (funded by the EU HORIZON 2020 2020 program, grant agreement No. 824061) at the Medical University Graz has led to two scientific publications that stress the pre-analytical factors including different sample collection devices for SARS-CoV-2 diagnostics.

NESARSDia was a TNA (Transnational Access) project under the umbrella of the European Research Infrastructure on Highly Pathogenic Agents (ERINHA/ ERINHA Advance).

2024:
Hardt M, Kaiser F, Voss T, Oelmüller U, Zatloukal K

Pre-analytical properties of different respiratory viruses for PCR-based detection: Comparative analysis of sampling devices and sample stabilization solutions

New Biotechnology Vol 79, March 24, 2024, pp 60-70 – **open access**

re-analytical properties of different respiratory viruses for PCR-based detection: Comparative analysis of sampling devices and sample stabilization solutions - ScienceDirect

2022:
Hardt M, Föderl-Höbenreich 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**

https://www.sciencedirect.com/science/article/pii/S1871678422000279?via%3Dihub

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Supported by data that was generated during the SPIDIA project, researchers from BBMRI.at partner Med Uni Graz published a paper on implications of inter-patient variability in ischemic injury for the pre-analytical phase in research and diagnostics.

The authors conclude that the heterogeneity found between the samples from different patients is due to the different underlying diseases and variable stress responses of the samples during the pre-analytical phase. Furthermore, they name 230 potential reference genes for diagnostic applications that are robust to pre-analytical changes and might serve as reference genes:

Groiss S, Viertler C., Kap M. et al

Inter-patient heterogeneity in the hepatic ischemia-reperfusion injury transcriptome

New Biotechnology, Vol 79, March 25, 2024, pp 20-29 – **open access**

https://www.sciencedirect.com/science/article/pii/S1871678423000699?via%3Dihub

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SPIDIA4P // SCIENTIFIC PUBLICATIONS

Bonstingl L, Zinnegger M, Sallinger, K et al

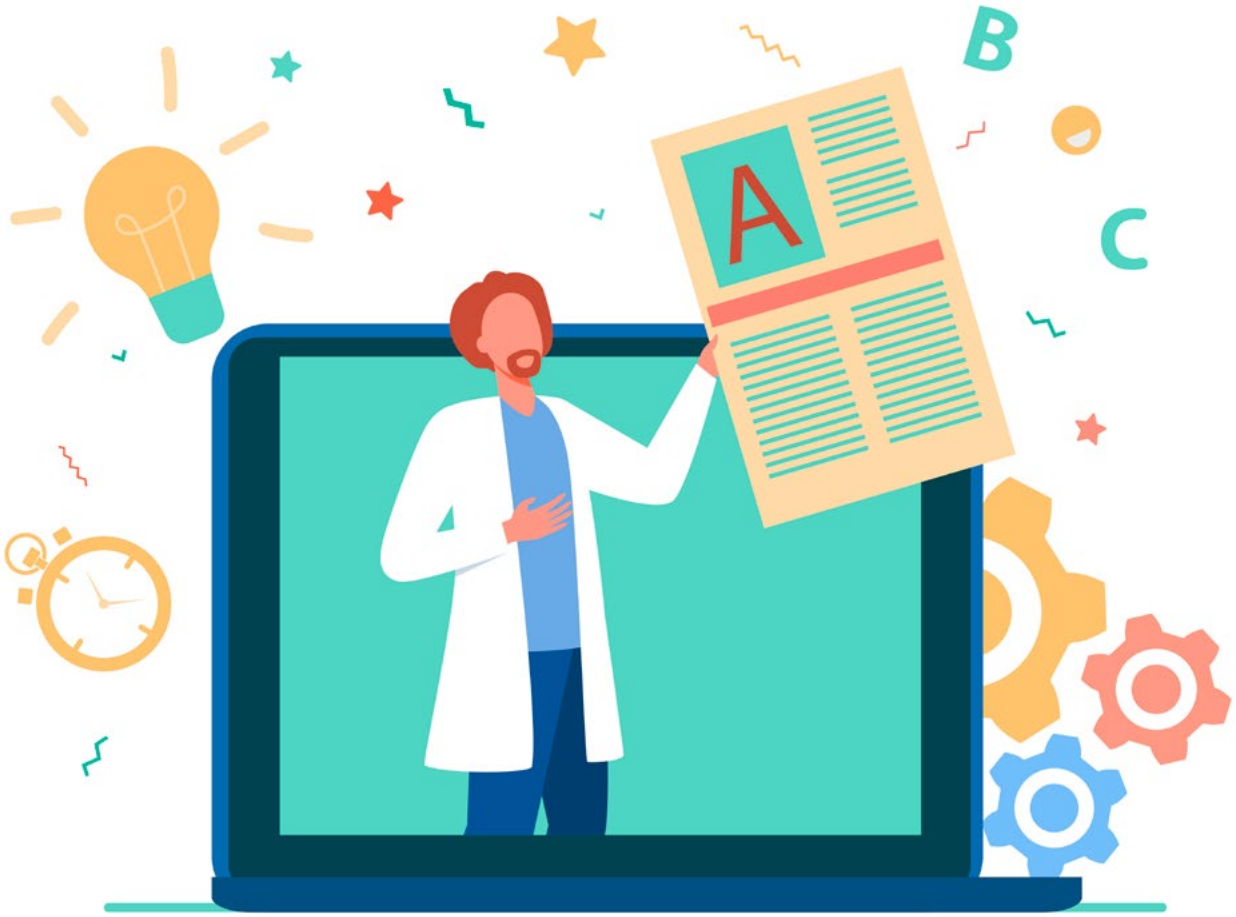
Advanced single-cell and spatial analysis with high-multiplex characterization of circulating tumor cells and tumor tissue in prostate cancer: Unveiling resistance mechanisms with the CoDuCo in situ assay

Biomarker Research volume 12, Article number: 140 (2024)

Advanced single-cell and spatial analysis with high-multiplex characterization of circulating tumor cells and tumor tissue in prostate cancer: Unveiling resistance mechanisms with the CoDuCo in situ assay | Biomarker Research | Full Text

This work was performed within the K1 COMET Competence Center CBmed, which is funded by the Federal Ministry of Transport, Innovation and Technology (BMVIT); the Federal Ministry of Science, Research and Economy (BMWFW), Land Steiermark (Department 12, Business and Innovation), the Styrian Business Promotion Agency (SFG), and the Vienna Business Agency.

The blood samples in this study have been collected following the CEN/TS 17390–3 standards to ensure defined pre-analytical parameters.



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EVENTS AND CONFERENCES

SPIDIA4P EVENTS // PAST EVENTS // 2024 / 2025

March 2024

European Society of Pathology - Webinar

"Tissue Bank: pitfalls and good practice in diagnotic accuracy and molecular analysis"
March 24, 2024

Presentation by SPIDIA4P member Prof. Peter Riegman, Erasmus MC

Take a look at the program **here**

View the presentation slides **here**

April 2024

AACR Annual Meeting 2024

April 5-10, 2024, San Diego, USA
Poster Presentation by SPIDIA4P partner PreAnalytiX and Medical University of Graz

View the abstracts here:

Preanalytical workflow enabling cfDNA analysis from urine samples

Linking liquids: cfDNA in urine and plasma as informative allies in metastasized prostate cancer

Hybrid capture based sequencing from urinary cell free DNA from colorectal cancer patients

May 2024

Europe Biobank Week
May 14-17, 2024, Vienna

Organized and chaired by SPIDIA4P members BBMRI-ERIC and ESBB

Austrian Minister Martin Polaschek opened the EBW24 in the Vienna Hofburg, followed by an introductory presentation of BBMRI.at to a 600+ audience. BBMRI.at and its partners contributed with multiple oral and poster presentations.

Take a look at the review, presentations and posters here:

Strong BBMRI.at contribution to Europe Biobank Week 2024 - BBMRI.at

BBMRI-ERIC®
biobanking for a healthier world

SPIDIA4P EVENTS // PAST EVENTS // 2024 / 2025

June 2024

ISO/TC 212 Work Group 4 Meetings – the SPIDIA/ SPIDIA4P mission is being continued

SPIDIA4P project members regularly participate in ISO/TC 212 Work Group 4 – Microbiology and molecular diagnostics – meetings, which are chaired by SPIDIA/SPIDIA4P coordinator Dr. Uwe Oelmueller.

One of those meetings took place from 11-14 June 2024 at the German Institute for Standardization (Deutsches Institut für Normierung, DIN) in Berlin, Germany.

Supporting the ISO/TC 212 Work Group 4 in developing and establishing ISO standards that are relevant for biomedical laboratories, in vitro diagnostics developers and manufacturers, but also for biobanks and institutions and organizations performing biomedical research, is an important part of SPIDIA4P partners' work.

Amongst various other international standards, this ISO working group is responsible for a series of 22 pre-analytical standards on "Molecular in vitro diagnostic examinations" that were actively supported by the EU project SPIDIA4P. Four of these pre-analytical standards, which are currently European CEN Technical Specifications, are currently under development into international ISO standards.

Take a look at the respective standards from the series

'Molecular in vitro diagnostic examinations':

BBMRI.at Delegates at ISO/TC 212 Meeting in Berlin - BBMRI.at

https://www.iso.org/committee/54916.html

More information also on pages 4 ff

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® ACADEMY

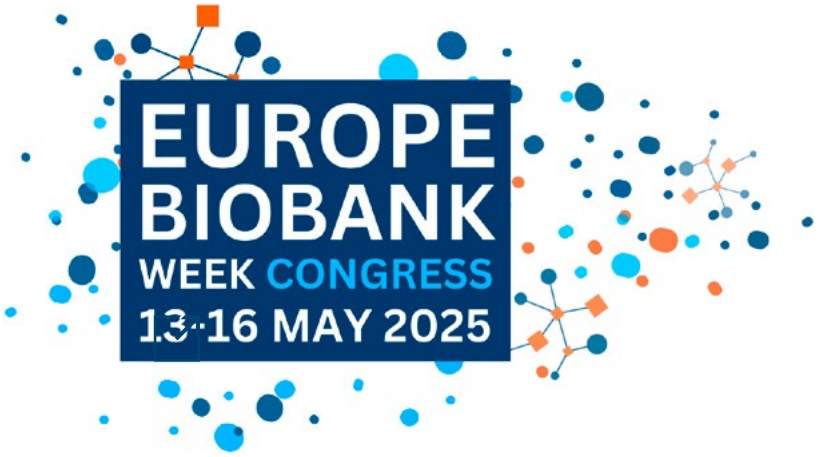
SPIDIA4P EVENTS // UPCOMING EVENTS AND TRAININGS / 2025

May 2025

Europe Biobank Week Congress 2025
May 13-16, 2025
Bologna Congressi, Italy

Organized by SPIDIA4P partner BBMRI-ERIC and ESBB

The congress brings together researchers, biobank staff, institutions and industry to attend high-quality scientific sessions that address the latest topics of concern.



Take a look at the programme here:

europebiobankweek.eu

Policymakers, health care providers, physicians, patient and civil society representatives as well as partners and collaborators of the Instand-NGS4P EU funded project are cordially invited to save the date on their calendar and attend the forthcoming

Instand-NGS4P High Level Seminar
"Precision Diagnostics for Precision Cancer Care – Improving patient access to innovation"
at the European Parliament, Brussels
May 20, 2025, 2-6 pm CET
with SPIDIA4P project members

Topics to discuss:

- The medical need for #NGS as well as the challenges and opportunities for improving the access of cancer patients to recent innovation.
- How can innovative technologies meet regulatory requirements for in vitro diagnostics and how European standards can help.
- Health economic benefits of NGS as prerequisite for reimbursement schemes - how to overcome inequalities for patients in accessing precision diagnostics in Europe.

Get more information here:

High Level Seminar – Integrated and Standardized NGS Workflows for Personalised Therapy

SPIDIA4P EVENTS // UPCOMING EVENTS AND TRAININGS / 2025

June 2025

2nd ISIDORe User´s Conference
Pandemic Preparedness & Response through ISIDORe:
A celebration of Users and Research Infrastructures
Paris
June 11-12, 2025
with SPIDIA4P partners Medical University of Graz (MUG) and QIAGEN

The conference will bring together ISIDORe users and access providers in person **in Paris, on June 11-12, 2025**, while also welcoming the broader scientific community to participate online.

Get more information about the ISIDORe project here:

isidore-project.eu

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SPIDIA4P EVENTS // UPCOMING EVENTS AND TRAININGS / 2025

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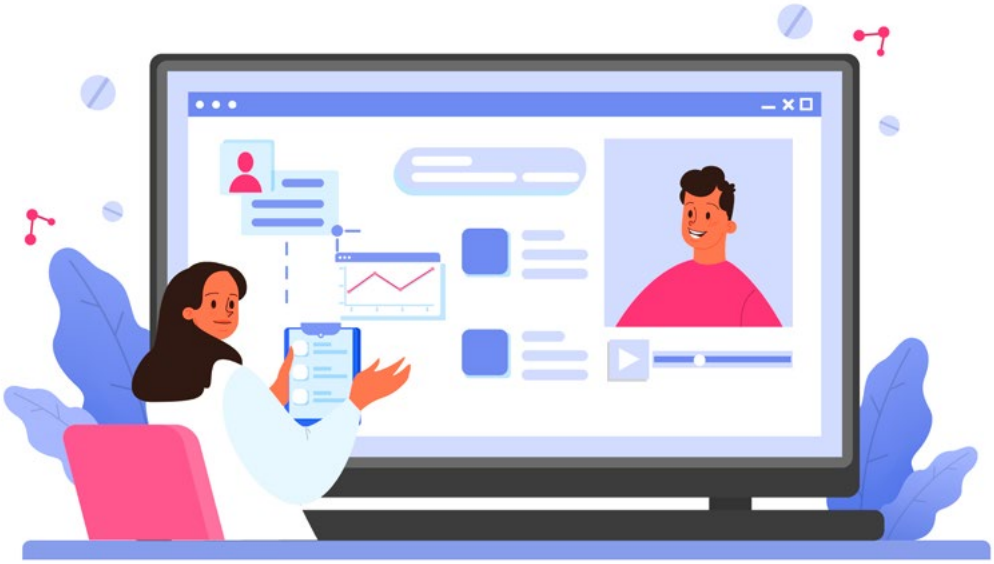

INFORMATION, VIDEOS, WEBINARS, PRESENTATIONS

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

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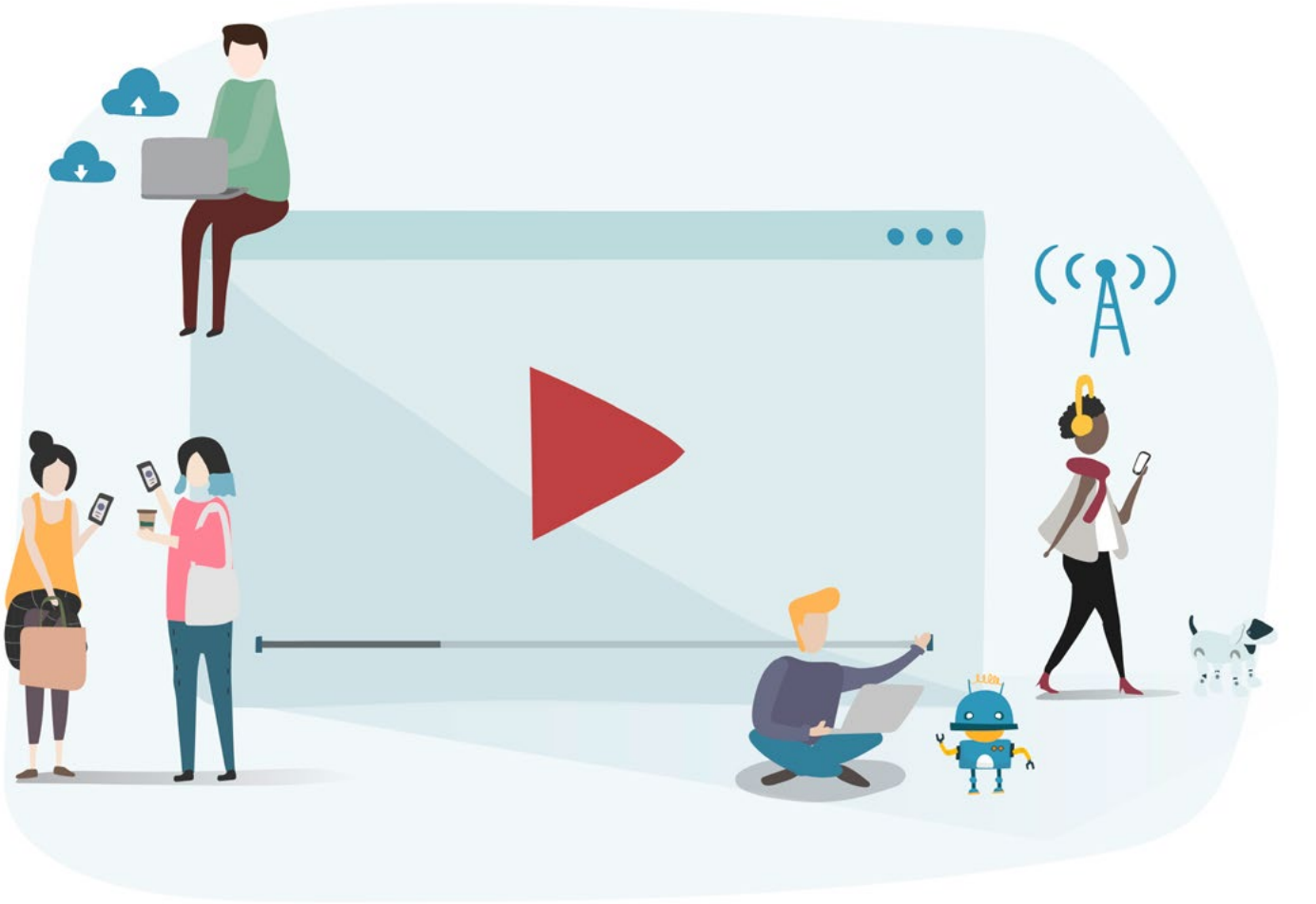

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SPIDIA4P NEWS // WEBSITE *www.spidia.eu*

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Don't miss

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

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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.