SPIDIA4P

SPIDIA4P NEWSLETTER 2025/2026

ISO AND CEN STANDARDS – TOGETHER FOR A BETTER HEALTHCARE

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

SPIDIA SPIDIA4P

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Dear reader,

Preanalytical workflow steps remain the most error-prone part of diagnostic workflows. Accordingly, assays – including diagnostic tests – are now widely understood as end-to-end workflow systems, encompassing all steps from sample collection to assay output. In this context, the development, verification, and validation of preanalytical workflows are essential to achieving the intended assay performance.

A key highlight in 2025 was the event "Precision Diagnostics for Precision Cancer Care – Improving patient access to innovation" at the European Parliament in Brussels. The meeting showcased lessons learned from the EU H2020 project "Integrated and Standardized NGS Workflows for Personalised Therapy (Instand-NGS4P)", including the integration of more than 20 new preanalytical workflows into end-to-end NGS workflows.

SPIDIA4P partners continue to expand the portfolio of preanalytical and whole-workflow standards within ISO/TC 212 for "Medical laboratories and in vitro diagnostic systems" and CEN/TC 140 for "In vitro diagnostic medical devices". In February 2026, ISO Standard 18704 on pre-examination processes for urine and other body fluids for isolated cell-free DNA was published.

Several SPIDIA4P members are playing key roles in current and upcoming European projects to advance the whole-workflow concept for assay development. At the Austrian Center for Industrial Biotechnology (acib) and the Medical University of Graz, researchers have launched a liquid-biopsy-based workflow approach to identify predictive biomarkers for the early detection of gestational diabetes, covering all relevant preanalytical steps. In addition, the new GenomeMET2 project, starting in August 2026, will develop the measurement infrastructure needed to make Minimal Residual Disease (MRD) testing more robust and clinically reliable.

This newsletter also features updates on the EU projects MICROBE and ISIDORe, as well as news from BBMRI-ERIC, IBBL, and the European Molecular Pathology Masters Program.

We hope that you will enjoy our newsletter.

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

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Preanalytical standardization is entering its next chapter

Key SPIDIA and SPIDIA4P standards are now being updated – and stakeholders across Europe and beyond are invited to contribute.

SPIDIA4P Work Package 1 has delivered a major boost to preanalytical standardization. During the project, 12 new CEN Technical Specifications and 2 new ISO International Standards were developed, expanding the portfolio initiated by SPIDIA and SPIDIA4P to 22 standards covering key pre-examination workflows for personalized medicine.

The overview in Table 1 shows the published standard documents launched through SPIDIA and SPIDIA4P and highlights where several of them are headed next.

At European level, the work has been driven by CEN/TC 140/WG 3, "Quality management in the medical laboratory," bringing together SPIDIA4P partners and other experts from across Europe. This group published 12 CEN Technical Specifications during SPIDIA4P. To extend their reach globally, all but the three documents on Fine Needle Aspirates were proposed to ISO/TC 212 for further development under the Vienna Agreement. With CEN support, these documents were accepted for international development and are now moving forward at ISO level.

Publication is not the finish line for a standard. To stay relevant and useful worldwide, standards are systematically reviewed at least every five years after publication. This review process helps confirm global relevance, identify needed updates, and improve implementation in countries that have not yet adopted or fully used the documents.

That process is now underway for a first wave of SPIDIA-developed documents. EN ISO 20166, 20184 and 20186 series have entered their first review cycle since publication, and an international decision has confirmed that these documents will now be revised.

Why this revision matters

The revisions are intended to bring the documents fully up to date–technically and practically. The working group aims to reflect user feedback, better address manufacturers, align responsibilities with newer ISO/TC 212 documents, and take account of changes in legal frameworks across major global markets.

This review comes at the right time. Five years after the first specifications for pre-examination processes in medical laboratories were published, both the regulatory landscape and the available technologies have moved on. Updating the standards now will help ensure they remain clear, usable and fit for current practice.

Just as importantly, the review process is a chance for users and other stakeholders to share practical experience. Feedback on readability, usability and implementation can directly help strengthen the next generation of these standards. Following an international public vote, a first set of SPIDIA and SPIDIA4P documents has officially entered revision. The standards marked "In Revision" in Table 1 show where this next phase is already in progress.

Would you like to help shape the revisions or contribute to ongoing drafting work? If your company, institute or organization would like to get involved, please contact your national standardization body[3] or reach out to the committee manager of CEN/TC 140/WG 3, "Quality management in the medical laboratory" *(ulrike.schroeder@din.de)* for details on how to participate.

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 2018–2025**

Document Number	Title	Next Systematic Review (SR)
ISO 18704		
EN ISO 18704:2026	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for urine and other body fluids - Isolated cell free DNA **(ISO 18704:2026)**	Replacement of CEN/ TR 17811
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-examinations processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 2: Isolated proteins **(ISO 20166-2:2018)**	In Revision
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

SPIDIA SPIDIA4P ISO/ TS DOCUMENTS

Document Number	Title	Next Systematic Review (SR)
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
ISO-series 7552 - CTC		
ISO/TS 7552-1:2024	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 7552-2:2024	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 7552-3:2024	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 documents		
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 17742		
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

QUALITY ASSESSMENT

BIOSPECIMEN PROFICIENCY TESTING PROGRAM // DR. OLGA KOFANOVA

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Learning Through Biospecimen Proficiency Testing Program: Turning a Participant's Feedback into Progress

External quality assessments (EQA) and proficiency testing (PT) play a central role in ensuring reliable and standardized laboratory practice across clinical research, healthcare, pharmaceutical, and biobanking environments. By enabling laboratories to compare results with peers, EQA/PT programs support accuracy, consistency, and alignment with best practices. They also provide independent evidence of competence, support regulatory and accreditation requirements, and offer targeted feedback that drives continuous improvement.

As the provider of the **LIH IBBL Biospecimen Proficiency Testing Program**, we routinely collect feedback from participants after each PT round. While strong performance is always encouraging, the most valuable insights often emerge when results drive deeper investigation, reflection, and improvement. Several PT schemes have been developed in the context of the **SPIDIA4P project** and are aligned with pre analytical CEN/Technical Specifications (CEN/TS) [1-2].

One such experience was recently shared by a participant in the **DNA and RNA extraction from frozen tissue PT scheme**, offering a clear illustration of why PT plays a central role in quality management and accreditation readiness.

A Small Step with a Big Impact

Following participation in the scheme, the laboratory received its PT report indicating **suboptimal DNA and RNA quality**. The participant highlighted that the report did not simply point out the deviation as a z-score but provided practical recommendations encouraging a root cause analysis.

Prompted by this feedback, the laboratory reviewed the full pre analytical process step by step. According to the participant, the investigation revealed that the issue originated during tissue homogenisation. While the extraction workflow itself was familiar, a closer review showed that the manufacturer's (QIAGEN) homogenisation protocol had not been strictly followed when preparing the tissue before extractions.

This small deviation, that easily overlooked in routine practice, was identified as the key factor affecting both DNA and RNA quality. Correcting this step led to immediate improvements in subsequent extractions and following PT participations.

The participant emphasized that without participation in the PT program, this seemingly small step in the extraction workflow, which ultimately caused the issue, might have remained undetected.

Why External PT Matters

This feedback perfectly reflects the broader role of PT assessments. PT schemes are not only about comparison – they help laboratories:

- verify consistency and accuracy of results
- confirm alignment with best practices
- demonstrate reliability and regulatory compliance
- continuously refine procedures and staff training

The **LIH IBBL Biospecimen Proficiency Testing Program** supports laboratories across a wide range of pre analytical processes — from nucleic acid extraction and quality control to cell based and tissue related workflows. Participants regularly engage in schemes covering DNA and RNA extraction from various matrices, nucleic acid integrity and purity, cell viability, tissue processing, liquid sample handling, and advanced applications such as circulating biomarkers.

What matters most is not perfection in a single round. Consistent participation shows that laboratories **strengthen their performance over time**, supported by transparent benchmarking, feedback, and insight into pre analytical variables that influence final outcomes.

Our 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

A Message We Are Proud to Share

From the participant's perspective, this PT round reinforced an essential message: **accreditation readiness is built in daily practice, not during audits.** External PT programs provide exactly what laboratories need – objective evaluation, early detection of weaknesses, and evidence of continuous improvement.

We are grateful when participants share such reflections. They confirm that proficiency testing, when designed with education and quality in mind, becomes far more than a requirement — it becomes a driver of improvement. Sometimes, one unexpected result is all it takes to raise standards for years to come.

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

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

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NEW BBMRI-ERIC QUALITY LABEL // NIINA EKLUND AND DR. MAIKE TAUCHERT

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The European research infrastructure for biobanking and biomolecular resources in health and life sciences

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New BBMRI-ERIC Quality Label for biobank Data Management Maturity

BBMRI.QM has developed a new tool to support biobanks in assessing the maturity of their data management and governance frameworks. The Data Management Maturity Self Assessment Survey (SAS) provides a structured checklist, based on internationally recognised standards on data quality and information security, as well as standards applicable to biobanking practices, to help biobanks verify that key organisational prerequisites for robust data management are in place. Upon completion, biobanks may optionally proceed to the BBMRI.QM Audit Programme, which – with a positive evaluation – leads to the award of a BBMRI-ERIC Quality Label, demonstrating alignment with best practices for data quality, data management, and governance.

The current version of the new tool will be presented during a pre-conference workshop and as a poster at the Europe Biobank Week conference (19-22 May, Prague, Czech Republic; *https://www.europebiobankweek.eu/*) to gather feedback for further refinement. The first version is to be launched at the end of 2026, alongside dedicated training sessions explaining the requirements.

Spotlight on CEN Technical Specification 17626:2021

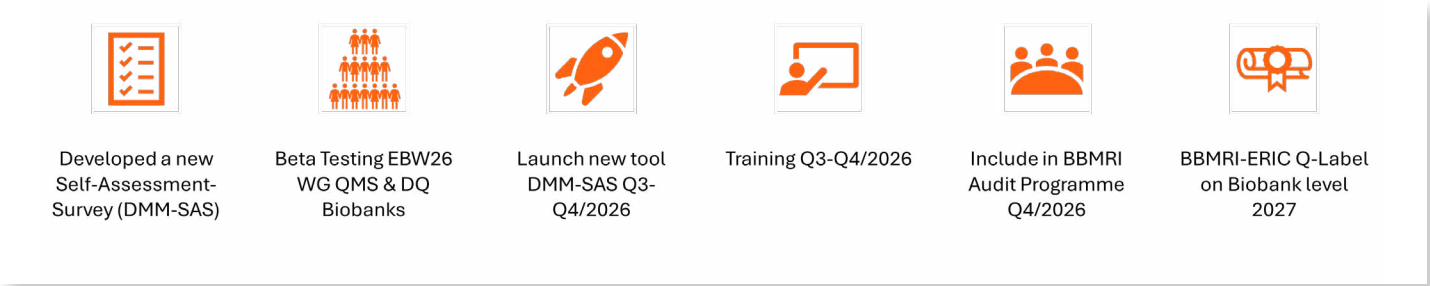
To introduce our biobank community to CEN Technical Specification (CEN/TS) 17626:2021, an introductory training session was held in December 2025 as part of the BBMRI-ERIC Academy. CEN/TS 17626 defines requirements for the isolation of microbiome DNA from human specimens and was developed within the SPIDIA4P project under the leadership of consortium member Medical University of Graz (**Kurt Zatloukal, Cornelia Stumptner,** BBMRI.at coordination).

The recording of the session is available upon request. The training was complemented by the launch of a newly developed Self-Assessment Survey on CEN/TS 17626. Completion of this survey forms the basis for participation in the BBMRI-ERIC audit programme. In addition, a series of in-depth training sessions explaining the requirements of CEN/TS 17626 is currently under development and is planned to take place from autumn 2026 onwards.

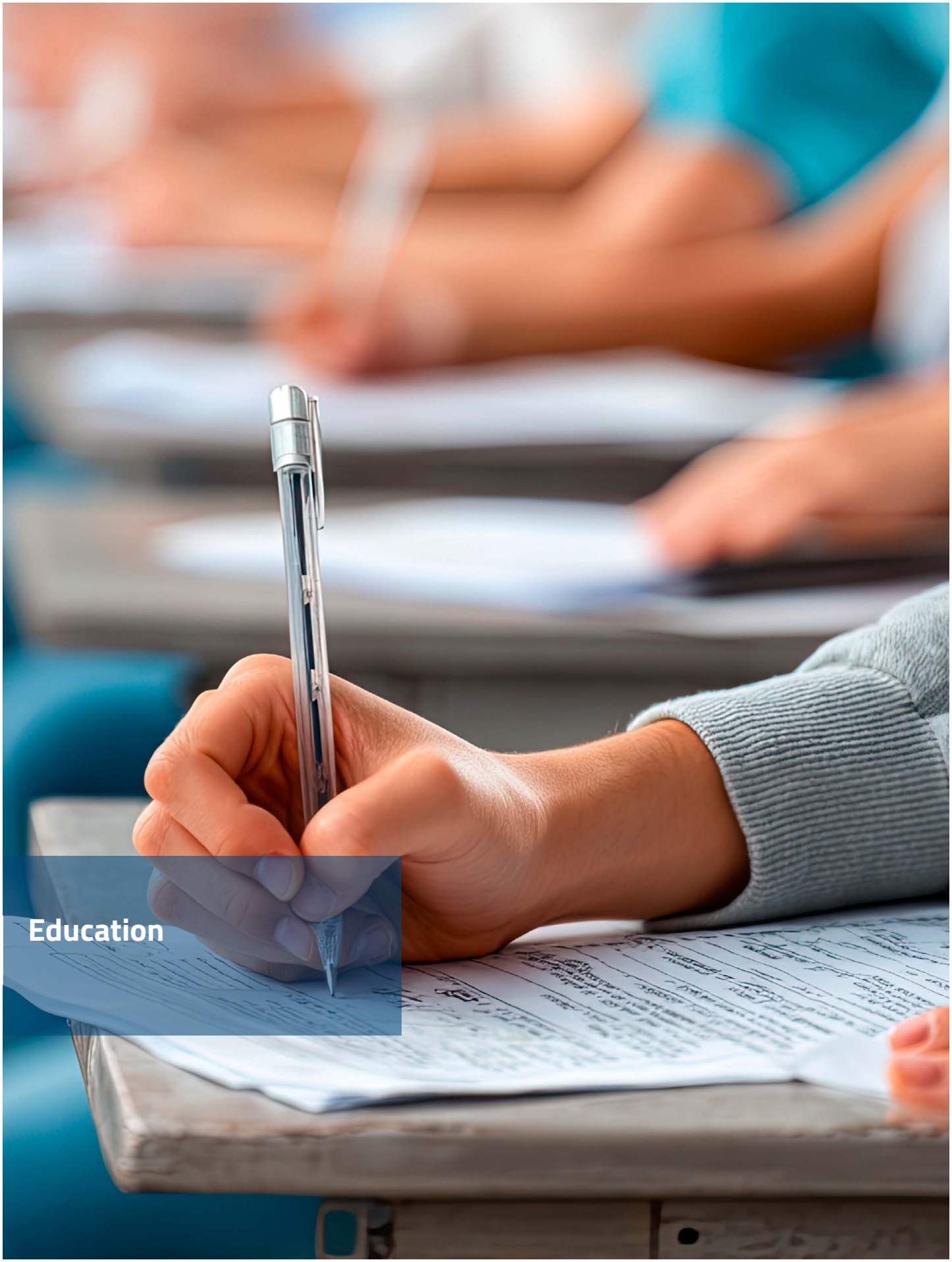
ISO/TC 276 "Biotechnology" Working Group activities

The ISO 20387:2018 biobanking standard is currently undergoing revision. As an ISO liaison, BBMRI-ERIC has taken the opportunity to comment on the Draft International Standard in collaboration with its biobanking community. The comments are currently being processed, and a new version of the standard is expected to be published by the end of 2026.

Reproducibility remains a key challenge in the life sciences, particularly in biobanking and biomedical research, where the quality and traceability of biological samples and associated data are essential. To address this, the ISO 23494 series on Provenance Information for Biological Material and Data is being developed within ISO/TC 276 WG5, led by experts from BBMRI ERIC. Based on the Common Provenance Model Framework, the standards provide an open foundation for documenting and integrating provenance information across systems. The first two parts of ISO 23494 have reached the Final Draft International Standard (FDIS) stage and are expected to be published this year, while the third part is planned to enter the FDIS phase this year and to be published in Q2 2027 latest. Adoption of the framework by biobanks will strengthen traceability, support quality assessment, and improve reproducibility across the research and innovation lifecycle.



*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.



Education

THE EUROPEAN MASTERS PROGRAM // SERENA BONIN, PHD

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Education as a Driver of Standardization in Molecular Pathology: The European Masters Programme

From Serena Bonin - Professor of Laboratory Medicine-University of Trieste, Member of the Steering committee and chair of the Biobank module at the European Master of Molecular Pathology.

The idea of creating a Master's programme in Molecular Pathology, aimed at harmonizing and standardizing procedures in this rapidly advancing field of pathology, originated with Giorgio Stanta in 2017 during the OECI meeting in Brno. At that time, the SPIDIA4P project was still ongoing. Thanks to Giorgio's commitment and the contributions of several colleagues, this idea became reality: in 2023, the European Master of Molecular Pathology (EMMP) was officially launched. On 12 December 2025, the first molecular pathologists, coming from 18 different countries (Europe, North Marica, Africa and Asia) trained through this programme were celebrated in Nice.

The EMMP is organized by Université Côte d'Azur in Nice *(https://univ-cotedazur.eu/msc/european-msc-molecular-pathology)* under the direction of Prof. Marius Ilié and admits 25 participants—pathologists or pathology residents—selected through a rigorous admission process. The programme spans two years and includes 12 modules, along with two internships in accredited molecular pathology laboratories. Teaching is delivered in a blended-learning format. The curriculum is built on evidence based educational principles to ensure effective learning and strong participant engagement. It also integrates computational pathology, enabling learners to interpret complex molecular data, enhance diagnostic accuracy, and support more informed therapeutic decisions. Through its structured curriculum, strategic collaborations, and continuous updates, the EMMP plays a pivotal role in harmonizing practices in molecular pathology [1].

Among the modules, one is fully dedicated to pre-analytical and analytical methodologies (Module 4). Several faculty members have also been part of SPIDIA and SPIDIA4P, including **Kurt Zatloukal** for the pre-analytics course; and **Andrea Wutte and other BBMRI contributors** who are also involved in the Biobanking module. Although only a portion of the teachers come directly from SPIDIA and SPIDIA4P, many EMMP lecturers present ISO standards and CEN technical documents that underpin the reliability and quality of molecular pathology.

This programme equips participants to navigate the complexities of molecular pathology, strengthens their technical and analytical competencies, and promotes the adoption of consistent standards in molecular diagnostic practice.

Overall, the work of SPIDIA and SPIDIA4P in generating ISO standards and CEN technical specifications for reliable in vitro diagnostics constitutes essential educational material for the training of future molecular pathologists.

References

Ilie M, Lake V, de Alava E, Bonin S, Chlebowski S, Delort A, et al. Standardization through education of molecular pathology: a spotlight on the European Masters in Molecular Pathology. Virchows Arch. 2024;485:761-75.

NETWORKING AND NEWS ABOUT OTHER CONSORTIA

SPECIAL: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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SPIDIA4P project members take part in a new EU funded grant project to continue the project´s mission:

GenomeMET2: Advancing Reliable MRD Testing for Precision Cancer Care

GenomeMET2 is a European funded 24 partners consortium focused on improving the accuracy, comparability and clinical reliability of **Measurable Residual Disease (MRD)** testing – a rapidly advancing field detecting traces of cancer that remain after treatment. Reliable MRD testing can help clinicians identify relapse earlier and guide more targeted, effective care. However, current methods vary widely between laboratories, platforms and workflows, making results difficult to compare and limiting their full clinical utility.

Launching on **1st August 2026**, and following directly on from the original GenomeMET project which aimed to establish the metrological foundations for genomic profiling (www.genomemet.org) the three year project brings together partners across Europe, including national metrology institutes, clinical laboratories, diagnostic developers, reference material providers, regulatory bodies and pre analytics specialists.

What the Project Will Do

GenomeMET2 will develop the **measurement infrastructure** needed to make MRD testing more robust and clinically trustworthy. Key aims include:

- Creating **SI traceable reference methods** and high accuracy measurement procedures for genomic biomarkers used to monitor MRD in blood cancers and solid tumours.
- Producing new **reference materials (RM)** and **quality control tools** that allow laboratories to validate MRD workflows, including pre-analytical steps, with confidence.
- Supporting **harmonised MRD reporting** and contributing to emerging CEN/ISO standards.
- Benchmarking modern analytical approaches, including the use of **AI/ML based data interpretation**.
- Establishing frameworks that laboratories, IVD developers and regulators can use to ensure MRD assays meet **performance** and **traceability requirements**.

Who Is Involved

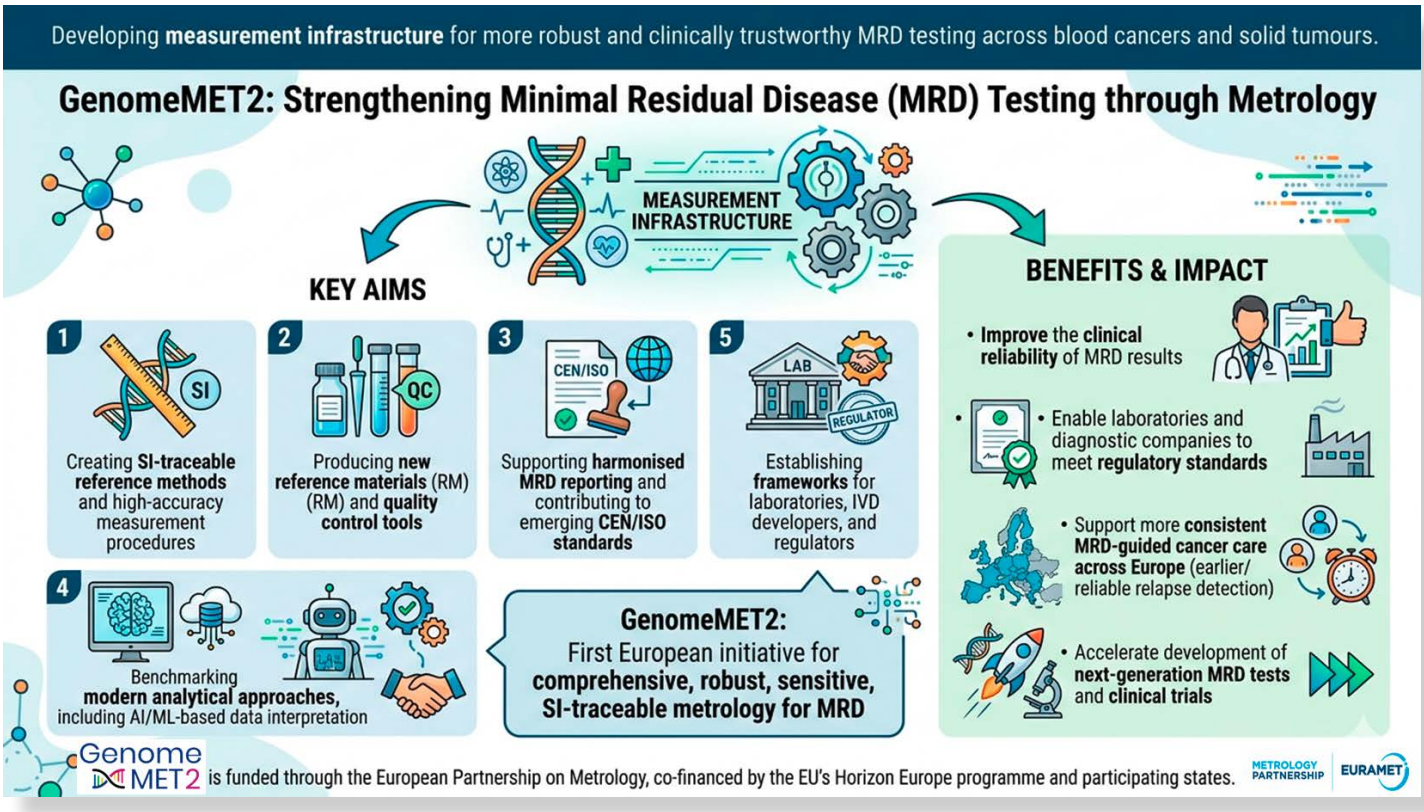
The project is coordinated by **INRIM (Italy)** and includes the following 23 internal, external and unfunded partners from across Europe, amongst them several **SPIDIA4P project members** (in **green**)

- Metrology Institutes including NML at **LGC (UK), METAS (Switzerland), MHRA (UK), NIB (Slovenia), TÜBİTAK (Turkey)**
- Clinical and research partners including **CEA (France), GHC (Germany), FPO (Italy), KCL (UK), Medical University of Graz (Austria), SwanU (United Kingdom), UKE (Germany), UNITO (Italy)**
- Quality assurance and standardisation organisations including **GenQA (UK), NEQAS-LI (UK), INSTAND (Germany)** and **DIN (Germany)**
- Industry contributors including **VOLITION (Belgium), METHYS (France)** and associated partners **Bio Rad (USA)** and **SeraCare (USA)**
- **PreAnalytiX (Switzerland)** and **SensID (Germany)** contribute as unfunded partners with expertise in pre analytical sample handling and materials.

Focus on Pre-analytics

Pre-analytical variation– differences in **sample collection, handling, stabilisation and processing–** is one of the biggest sources of uncertainty in MRD workflows. GenomeMET2 will address this by:

- Developing methods and materials that help laboratories control and monitor specimen quality, including cell free DNA and RNA integrity.
- Assessing how pre analytical steps influence sensitivity and measurement uncertainty across PCR-, NGS- and multi omics MRD approaches.
- Supporting standardisation activities for **liquid biopsy pre analytics,** contributing to improved comparability across clinical settings.



Why It Matters

GenomeMET2 is the first European initiative to build comprehensive, robust, sensitive and SI-traceable metrology frameworks specifically dedicated to MRD across both blood cancers and solid tumours.

By delivering measurement frameworks for MRD, GenomeMET2 will help to:

- Improve the **clinical reliability of MRD results.**
- Enable laboratories and diagnostic companies to meet regulatory standards.
- Support more consistent MRD guided cancer care across Europe, benefiting patients through earlier and more reliable detection of relapse.
- Accelerate development of next generation MRD tests and clinical trials.

GenomeMET2 is funded through the **European Partnership** on Metrology, co financed by the EU's Horizon Europe programme and participating states.

For more information, please contact *c.divieto@inrim.it*

SPECIAL: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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Advancing Microbiome Pre-analytical Standardization: Lessons from the human microbiome field for reliable non-human biobanking and research

The *Medical University of Graz* a long-standing partner in SPIDIA4P and coordinator of *BBMRI.at*, the Austrian node of the European Biobanking Research Infrastructure BBMRI-ERIC, is also partner in the *EU-funded project MICROBE*. The project - short for *MICRObiome Biobanking (RI) Enabler* - aims to establish a blueprint for non-human microbiome biobanking and research. addressing technological requirements, methodological workflows, data pipelines, as well as legal, ethical, and business aspects.

One core aspect in MICROBE's work are key aspects related to the pre-analytical phase, including the development of technological approaches for optimal collection and preservation of microbiomes from diverse environments – such as **plant, soil, and marine ecosystems** – as well as standardization and quality control measures.

Standardization and Quality Control at the Forefront

Within MCIROBE, **Cornelia Stumptner,** former SPDIA4P team member from Medical University of Graz, leads a dedicated work package on **standardization and quality control,** a critical pillar for ensuring reliable, reproducible, and comparable microbiome research. A central concept underpinning this work is the transfer of established approaches from the human microbiome field to non-human domains.

In particular, the European technical specifications *CEN/TS 17626:2021 (Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for human specimens – Isolated microbiome DNA)* serve as a foundational template. Originally developed with contributions from SPIDIA4P, CEN and *BBMRI.at* experts, this standard defines requirements and recommendations for the pre-analytical phase of human microbiome samples, including specimen types such as stool, saliva, and urogenital samples.

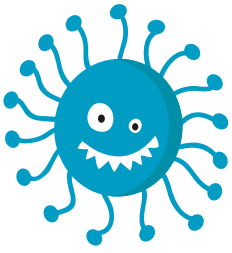
By systematically transferring and adapting these principles, MICROBE uses the human microbiome field as a **best-practice model to advance non-human microbiome research and biobanking** (particularly plant and soil). This approach is highly relevant given the current lack of harmonized standards in environmental microbiome domains and the fact that the pre-analytical phase is equally critical in non-human fields but remains often underestimated or overlooked.

Spotlight on Pre-Analytics: A Critical but Underestimated Phase

A major focus of MICROBE – and expertise of SPIDA4P members – is the pre-analytical phase, encompassing all processes prior to analysis, such as location and host characteristics, sampling method, time and date, time-to-preservation and intermediate storage conditions, nucleic acid isolation methods. Evidence shows that this phase is one of the most vulnerable points in the analytical workflow, with significant potential to introduce variability, bias, or even irreproducible results - not only in human field but also in non-human domains.

To address this, MICROBE applies a structured methodology combining:

- extensive literature review in non-human microbiome fields (with emphasis on plant and soil samples),
- expert workshops with the plant microbiome research community in collaboration with the European Plant Science Organisation,
- and Delphi-like surveys to systematically evaluate and prioritize pre-analytical variables.



MICROBE
the Microbiome Biobanking (RI) Enabler

- This process enabled the identification of key workflow steps – from in situ sampling through preservation, transport, processing, and analyte isolation – and the definition of critical variables such as location and host characteristics, sampling method, time and date, time-to-preseration and intermediate storage conditions, nucleic acid isolation methods. These variables were assessed regarding their impact on microbial community composition and data quality.

Interactive Workshop at the 6th EPSO Plants and Microbiomes Event

A central milestone was the workshop "Minimal metadata requirements and critical pre-analytical parameters for plant microbiome samples" led by **Cornelia Stumptner** (Medical University of Graz, BBMRI.at, MICROBE, and previously SPIDIA4P). This workshop was held at the *6th EPSO Workshop on Plants and Microbiomes*, in Antequera, Spain, on 3 November 2025.

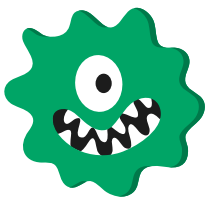
Over 100 participants worked with a draft list of pre-analytical requirements and were asked to prioritize them according to their relevance. The list included both pre-analytical **metadata requirements** (what needs to be documented to assess fitness-for-purpose and enable reuse of samples and data) and **process requirements** (how samples should be handled and which aspects must already be considered during study design and protocol development).

The workshop addressed different plant growth and collection (i.e. sampling) scenarios (including nature, field, greenhouse, and laboratory conditions) and all major pre-analytical workflow steps, from study design and other pre-collection considerations, to sampling, intermediate storage, preservation, transport, laboratory processing, analyte isolation, and long-term storage.

Working groups assessed requirements at each stage, distinguishing between: i) minimum ('must-have') parameters essential for reproducibility (representing 'requirements'), and ii) study-specific or optional parameters (representing recommendations or context-dependant options).

The discussions confirmed that numerous relevant pre-analytical factors – such as plant species and compartments, sampling site and timing, collection procedures, preservation methods and time-to-preservation, intermediate storage conditions, processing strategies (e.g. homogenization), and DNA extraction methods– can significantly influence both microbiome composition and analyte quality.

Importantly, the workshop also served as a platform for awareness raising, education, and exchange among experts, while highlighting practical challenges related to implementation and data management.



Enabling FAIR and Reproducible Microbiome Research

The workshop and broader MICROBE activities clearly demonstrated that **high-quality microbiome data depend on well-characterized, quality-controlled samples. Standardized documentation of pre-analytical processes and metadata is a prerequisite to achieve FAIR data principles - findable, accessible, interoperable, and reusable.**

This is particularly important as microbiome data increasingly feed into computational models and AI-driven analyses. Without robust pre-analytical standardization of processes and meticulous documentation of metadata, the risk of "garbage in – garbage out" remains substantial or important metadata will not be available at all.

A Strategic Contribution from MICROBE

The strong engagement observed at the MICROBE – EPSO workshops highlights a growing recognition within the scientific community: sample pre-analytics, comprehensive metadata, and **standardization is no longer optional – it is foundational for reliable microbiome research.**

Through its work in MICROBE, Medical University of Graz - together with BBMRI.at - continues to extend the impact of SPIDIA4P beyond human health into environmental and One Health domains.

More information:

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

About the MICROBE EPSO workshop: *https://bbmri.at/news-articles/workshop-on-pre-analytical-requirements-for-plant-microbiome-samples/*

Guidance document for sample pre-analytics for plant microbiome studies: *https://823265a524.clvaw-cdnwnd.com/1f1191e1bd5cc6fea07e4b8028bd0a7e/200000196-5e01c5e01e/D4_2_final.pdf?ph=823265a524*

BBMRI.at LinkedIn:

https://www.linkedin.com/feed/update/urn:li:activity:7393605760670273536

SPECIAL: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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Instand-NGS4P

Integrated and Standardized NGS Workflows for Personalised Therapy

Outcome of the Instand-NGS4P project

The 65-month Instand-NGS4P project (co-funded by the EU, Grant no. 874719, Coordinator Med Uni Graz) for **improving cancer patients' benefit from Next Generation Sequencing (NGS) by developing an integrated and standardized NGS workflow** was brought to a successful conclusion in May 2025. Continued activities in standardization, improving benefits for patients, and helping to bring solutions to the market will ensure the longterm impact of this pre-commercial procurement project.

Main results

- **7 highly innovative Solutions** from 5 different Contractors that together cover most of the needs for an integrated and standardized complete workflow for application of NGS in medical diagnostics for common and rare cancers in adults and children as identified by the Open Market Consultation
- **Innovation** in the areas of Pre-sequencing (Lot 1), Bioinformatics Analysis (Lot 3) and Integrated Reporting (Lot 4)
- Comprehensive **overview of unmet user needs**
- **Resources for patients** and their families
- **Advances in standardization** of the entire diagnostic NGS workflow

Key benefits

- Improving patient safety for diagnostic NGS, in accordance with the goal of IVDR compliance, as well as improving health outcomes
- Standardisation and streamlining of the diagnostic NGS workflow
- Reducing hands on and turnaround time
- Reducing the need to employ specialized bioinformaticians for NGS data analysis
- Simplification of the NGS concept for patients to understand the test and the results
- Ensuring that patients receive only the right and useful information
- Facilitating the returning of results to patients
- Identification of ethical, legal and social issues (ELSI) key to the development and exploitation of improved NGS platforms
- Increasing health economic benefits as basis to ensure future reimbursement

Pre-Commercial Procurement Project Process

Phase 0: Preparation Phase

Procurement needs determined in an extensive Open Market Consultation, which was followed by a corresponding Request for Tender

Phase 1: Design of lots

24 tenders were received, of which 15 were awarded contracts to design the innovative Solutions

Phase 2: Prototype development

11 contracts were awarded for development of the prototypes

Phase 3: Testing and integration

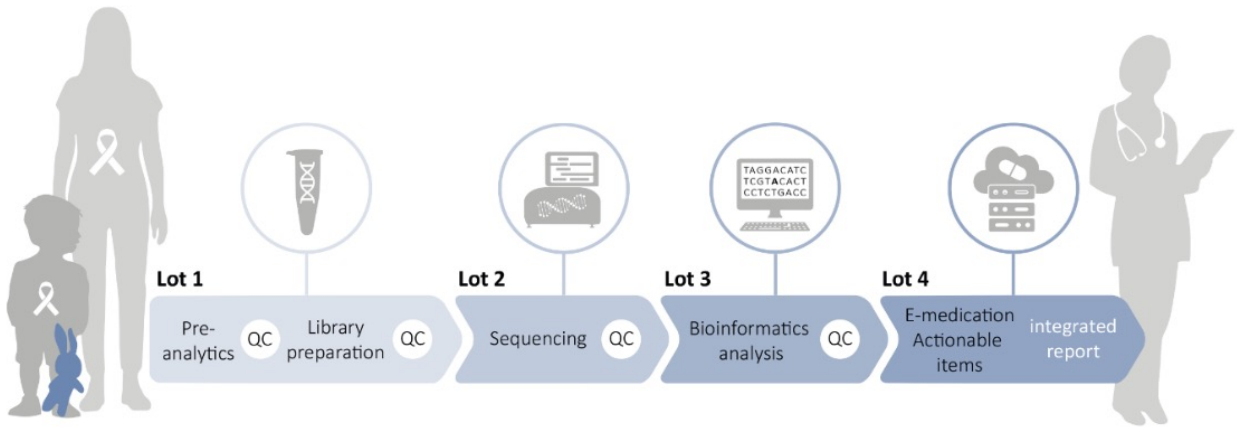
7 Contractors completed the final phase for testing and integration of the Solutions

Innovative Solutions arising from Instand-NGS4P

The Solutions developed bring major improvement and innovation of NGS for cancer diagnostics. For example, novel technologies were developed in Lot 1 for stabilization of multi-modal sample types, panel selection methods and automated processes that are relevant for molecular diagnostics, and solutions to document pre-analytical metadata relevant for the whole NGS workflow. There were major innovations in bioinformatics platforms in Lot 3 concerning usability in the analysis of different types of genetic alterations and report generation, thereby reducing the need of involving specialized bioinformaticians in data analysis. Lot 4 delivered completely new solutions for integrated reporting of NGS results from cancer as well as pharmacogenomics variants, combined with data related to e-medication and relevant clinical data. The reporting can support therapeutic decision making at the bedside, discussion in tumor boards as well as providing information to patients.

A very important aspect in the context of using NGS as an in vitro diagnostic medical device is that for CE-marking according to IVDR, clinical performance has to be demonstrated, which requires that for the NGS results the clinical evidence is properly established and demonstrated to the clinician, who has the final responsibility for therapeutic decision making. Another field of innovation in this regard is the use of secured cloud-based services as well as on premise solutions including mobile apps.

Please visit the ***Results page of the website*** for further details of the solutions which are summarized below:



QIAGEN RESEARCH PROJECT

(QIAGEN GmbH)

The QIAGEN RESEARCH PROJECT aimed to improve NGS testing by developing new preanalytical solutions, optimise available ones and integrate all into complete standardised preanalytical workflows as part of entire Sample-to-Insight NGS workflows. For allowing flexibility, the QIAGEN RESEARCH PROJECT's solutions provide multi-specimen and multi-analyte capabilities but can also be used for single specimen and single analyte testing. The QIAGEN RESEARCH PROJECT followed preanalytical requirements in the EU In Vitro-Diagnostic Regulation (IVDR) for IVD developments as well as FDA's guidance for assay validation to encompass the entire workflow from sample collection to assay output. Furthermore, the QIAGEN RESEARCH PROJECT's workflow solutions consider the collection and evaluation of preanalytical metadata for assessing the NGS test results.

TwistPlatomicsMGI

(Lead Contractor: Twist Bioscience Corp.)

TPM developed an up-to-date, first-class NGS workflow independent of the NGS technologies used in the laboratories, from the type of samples and from the size of the laboratories. Our approach should offer a standardised and simultaneously flexible solution with outstanding quality to labs and patients. We want to achieve a "democratic" workflow that reaches every possible patient in need of this solution, supporting also the laboratories with the best in class workflow without compromising on the quality of results and flexibility on personalizations and sensitivity.

Cancer Analysis GPAP

(CNAG)

The Cancer Analysis GPAP offers a streamlined and user-friendly workflow for managing and analysing NGS data in both adult and paediatric cancers, rare and common. It supports multiple NGS experiment types, including genomes, exomes, gene panels, and transcriptomes. The platform includes pipelines to detect and annotate germline and somatic variants (i.e. SNVs, INDELs, CNVs, structural variants and gene fusions) and biomarkers such as tumour mutational burden, MSI, and HRD. It also includes a pharmacogenomics module covering genes involved in drug metabolism.

The Cancer Analysis GPAP uses a big data architecture and intuitive web interface. It can be deployed on-premises on High Performance Clusters or on the cloud, providing flexibility, scalability, and easy maintenance.

Cancer Reporting GPAP

(CNAG)

The Cancer Reporting GPAP is a user-friendly solution integrating NGS results, e-medication data and clinical evidence for therapy decision making in adult and paediatric cancers, common and rare. The system enables pathogenicity ranking and interpretation of the NGS called variants through functional and medical annotations and a newly developed oncogenicity score. Users can select the relevant variants and associated information to generate a customisable report to support medical decision-making. A simplified version of the report can be made for patients by editing the clinical report.

The Cancer Reporting GPAP is one of the two key modules of the Cancer GPAP, which also includes the Cancer Analysis GPAP, a user-friendly solution for the management and streamlined processing of NGS cancer data.

EU Onco-Platform

(Lead Contractor: BC Platforms AG)

The EU-ONCO-PLATFORM consortium developed an advanced prototype which uses state of the art, standard formats and descriptions to create a professional solution in precision oncology, including metadata from Lot 1 and Lot 3. The new platform is built on top of existing software solutions used in clinical diagnostics. It represents a leap forward in automating and expediting the annotation, filtering, classification, and interpretation of genomic data while keeping tight control of input data quality. Its innovative methods and open structure are crucial in facilitating the identification of effective cancer treatments based on personal biomarkers. Not only does it improve clinical performance but it also prioritises patient perspective in terms of personalisation, cybersecurity, and regulatory compliance.

Congenica L3 and L4

Congenica has developed a cost-effective software platform that profiles genetic changes in a tumour automatically and accurately and based on these changes either recommends targeted treatment options, or if no such treatment options exist, allows clinicians to identify clinical trials that this patient may be eligible for. It also analyses each patient's general genetic makeup to understand how a patient might respond to specific cancer medicines as well as companion medication to provide holistic treatment recommendations, reduce side-effects that may be caused by these medicines, increase survival chances and in general improve a patient's quality of life.

Resources for patients

Several urgently needed and attractive resources for patients were developed during the project, led by the patient advocacy organisation, FAVO and are freely available on the website:

- ***Genetic Cancer Testing Resources for Patients and Families – Integrated and Standardized NGS Workflows for Personalised Therapy***

Advances in Standardization

The 2 CEN/TSs published in 2023 are now nearing completion as ISO 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
- ***ISO/CD 25379-1 - In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 1: Human DNA examination***
- ***ISO/CD 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).

Closing Stakeholder Event

A major stakeholder event was held on the 20th of May 2025 at the European Parliament in Brussels, highlighting 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 gave a talk in the regulatory session.

You can watch the recording of this event **here**. *https://www.instandngs4p.eu/high-level-seminar/* or on You Tube: *https://www.youtube.com/watch?v=dK4FC3di_Ts&t=1s*

For further information on the Instand-NGS4P project, please visit

https://www.instandngs4p.eu/

https://www.linkedin.com/in/instand-ngs4p-4751a0226/

SPECIAL: NETWORKING // NEWS ABOUT OTHER CONSORTIA

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Prepared for the next pandemic

Pandemic and endemic situations caused by human respiratory viruses have highlighted the increasing demand for robust and scalable diagnostic testing strategies. In particular, the SARS-CoV-2 pandemic demonstrated that pre-analytical factors including transport duration, storage conditions and temperature have a critical impact on the reliability and accuracy of diagnostic test results of patient specimens (Hardt et al., 2022; Hardt et al., 2024). In addition, standardized biosafety procedures for laboratory personnel, multiplex detection of respiratory pathogens and flexible diagnostic workflows that can be readily adapted for high-throughput testing are essential components for effective outbreak response. A strong focus on robust pre-analytical processes is therefore crucial to ensure reliable diagnostics and to improve preparedness for future pandemic or endemic scenarios caused by human respiratory viruses.

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 the human respiratory viruses 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. Of note, the practical work was finalized in 2025 when the ISIDORe project ended and the results will be published soon. A follow-up project (ISIDORe II) will start in June 2026.

Our project "Development of **Ne**xt Generation **Res**piratory Infection **Dia**gnostics **(NeResDia)**" was performed at the Diagnostic & Research Institute of Pathology of the MUG. It includes basic cell culture and spike-in experiments that are required to be conducted 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". This project encompasses all steps of the diagnostic workflow - beginning with specimen collection, preservation, storage, transport and processing – based on the EU In Vitro Diagnostic Regulation (IVDR) and the recent ISO & CEN standards.

In our previous studies (Hardt et al., 2022, Hardt et al., 2024) funded by the ERINHA advanced project, the effect of pre-analytical factors such as temperature and storage duration on diagnostic test results was clearly demonstrated, underscoring the need to strictly follow the manufacturers' instructions and validate 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. We also investigated specimen infectivity inactivation needs and options for handling at lower biosafety levels, transportation and storage conditions as well as durations, while still ensuring valid test results.

More information:

https://isidore-project.eu/

https://vetbionet.eu/isidore-ii-has-been-approved/

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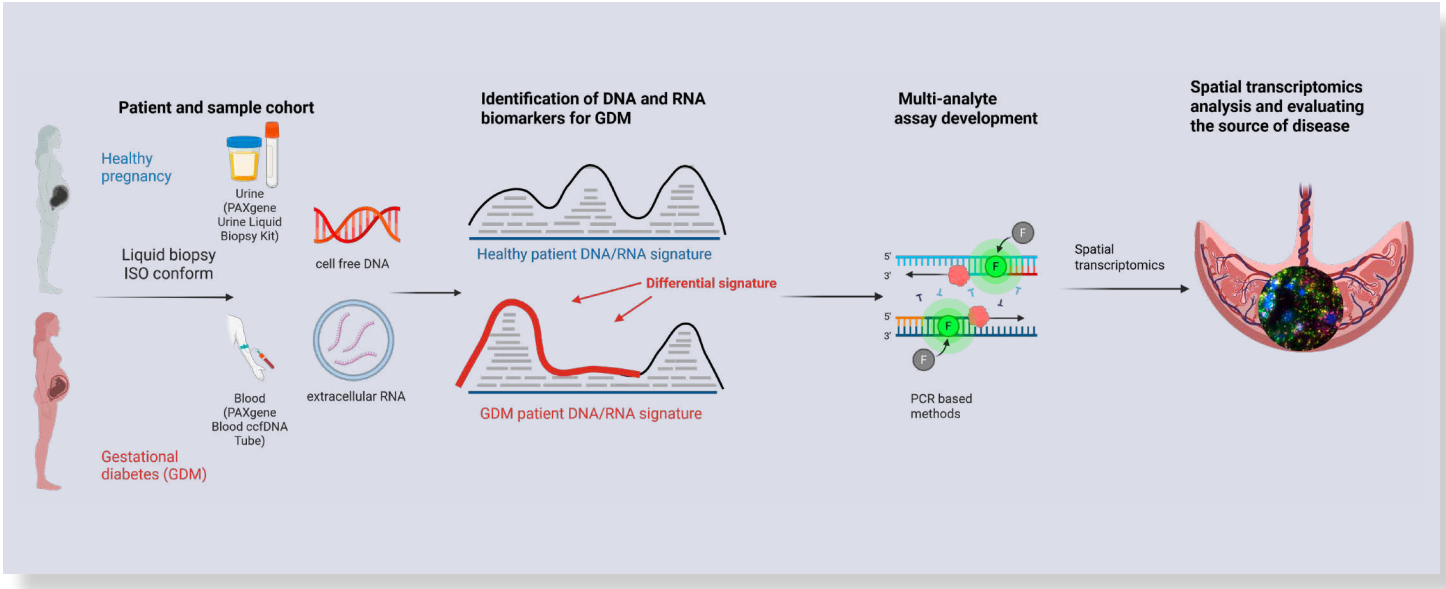
Liquid Biopsy for Early Detection of Gestational Diabetes – Project Update

Gestational diabetes mellitus (GDM) is a global health concern, affecting up to 10-20 % of pregnancies, with prevalence rising due to factors such as advanced maternal age, obesity, and lifestyle changes. GDM poses significant short- and long-term health risks for both mother and child, including metabolic disorders and pregnancy-related complications. Despite its relevance, GDM is currently diagnosed relatively late in pregnancy (weeks 24–28) via the oral glucose tolerance test (oGTT), leaving limited time for preventive intervention.

To enable earlier detection of GDM, researchers from the Austrian Centre of Industrial Biotechnology (acib), the Medical University of Graz and QIAGEN, led by Petra Heidinger and Amin El-Heliebi, are developing a liquid biopsy-based strategy. The approach focuses on the analysis of circulating cell-free DNA and RNA (cfDNA/RNA) in maternal blood at three time points across gestation (early, mid, and late) for the identification of predictive biomarkers in early pregnancy.



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To further validate candidate biomarkers, a qPCR based diagnostic assay will be developed. In addition, hybridization based in situ sequencing will be applied to term placental tissue sections to provide spatial resolution and deeper insight into the underlying pathophysiology of gestational diabetes mellitus (GDM).

Additionally, urine samples are being collected using the PAXgene Urine Liquid Biopsy Kit on an exploratory basis to assess whether cfDNA/RNA profiles also differ in this biofluid. The study utilizes samples from the PregWin longitudinal clinical study and the GDM clinical study, both conducted at the Medical University of Graz.

Currently, more than 150 women have been included in the study, representing approximately 50% of the planned cohort size, with excellent recruitment times and high willingness of pregnant women to join the scientific project. In parallel, optimized protocols for the extraction of cfDNA and cfRNA from maternal plasma have been developed and validated **under strict ISO-certified quality standards**, building on established best practices from liquid biopsy applications in oncology.

Following workflow optimization cfDNA and cfRNA have been successfully isolated from the first patient samples and prepared for downstream sequencing analysis. cfDNA was extracted using the QIAamp DSP Circulating Nucleic Acid Kit (QIAGEN), whereas cfRNA was isolated using the exoRNeasy Kit (QIAGEN). After extraction, samples were subjected to quality control assessment and library amplification prior to next generation sequencing.

The resulting sequencing data are currently being processed and will serve as foundation for identifying molecular signatures that distinguish GDM from metabolically healthy pregnancies.

Funded by the FFG-COMET program, this work builds a strong bridge between translational liquid biopsy research and prenatal medicine. In the long term, the project aims to enable earlier detection and improved clinical management of gestational diabetes, ultimately contributing to better health outcomes for both mothers and their children.

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:

Read the latest publication by Prof. Ellen Heitzer, Med. Univ. of Graz, et al, underlying the importance of stabilization of urinary cell-free DNA (ucfDNA) for reliable analysis + its potential in MDx as a complementary tool for Liquid Biopsy.

Eberhard A, Moser T, Ziegler L, Heitzer E, Voss T, Mancarella D et al

Evaluation of urinary cfDNA workflows for the molecular profiling of malignant disease

iScience, Volume 28, Issue 10, October 17, 2025 - open access

Evaluation of urinary cfDNA workflows for the molecular profiling of malignant disease: iScience

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NEW ISO Standard 18704:2026 - published in February 2026

Molecular in vitro diagnostic examinations – Requirements and recommendations for pre-examination processes for urine and other body fluids – Isolated cell-free DNA

Get it here

Film BBMRI.at about biobanks

BBMRI.at, the *German Biobank Node (GBN)*, and the *Swiss Biobanking Platform (SBP)*, all "national nodes" of the European Biobank Research Infrastructure *BBMRI-ERIC*, have jointly launched a new film highlighting the crucial role of professional biobanks in advancing scientific research and fostering groundbreaking discoveries.

With the statement 'Professional biobanks can make your life easier', the two-minute animated film is aimed at researchers encouraging them to work with professional biobanks when using samples and data for their research project. The biobanks in the GBN, BBMRI.at and SBP networks offer comprehensive advice and support, **work according to international standards to ensure superior sample quality**, adhere to strict security protocols, and are committed to long-term research success.

This film serves not only as an educational tool, but also as a celebration of the collaborative spirit between the BBMRI-ERIC nodes and the innovation that drives the scientific community. As the film shows, collaborative efforts can accelerate research and pave the way for a healthier future.

Watch the film *here*

EVENTS AND CONFERENCES

SPIDIA4P EVENTS // PAST HIGHLIGHT EVENT // 2025

Event Review "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

Instand-NGS4P Stakeholder Event

A pivotal event, hosted on Tuesday, May 20, 2025 at the European Parliament by MEP Vlad (Vasile) Voiculescu (RENEW/Romania) and endorsed by MEP Letizia Moratti (EPP/Italy) and former MEP Paul Ruebig, convened leading policymakers, EU Commission officials, scientists, clinicians, and patient representatives to address the urgent need for integrating Next Generation Sequencing (NGS) into routine clinical practice across Europe.

The High Level Seminar **"Precision Diagnostics for Precision Cancer Care-Improving Patient Access to Innovation"** showcased the achievements of the EU co-funded Instand-NGS4P project and called for urgent action to align regulation, reimbursement, and infrastructure for equitable patient access to personalized medicine.

The Seminar underscored the growing consensus that precision medicine must be supported by equally precise diagnostics.

"Precision medicine without precision diagnostics is simply guesswork," said MEP Vlad Voiculescu. "We need to remove the barriers that stop innovation from reaching patients."

The discussions underscored the transformative potential of personalized medicine, particularly in oncology, and the collective commitment to ensuring equitable patient access. The Seminar highlighted that while NGS offers unprecedented opportunities to tailor treatments based on individual genetic profiles, its widespread adoption is currently hindered by significant challenges. These include navigating complex regulatory frameworks, overcoming barriers to cross-border data sharing, and establishing robust, harmonized reimbursement systems.

"European and international standards can markedly support bringing innovative diagnostic technologies such as Next Generation Sequencing or AI-based diagnostics to the market and patient." said Professor Kurt Zatloukal of the Medical University of Graz, coordinator of Instand-NGS4P. "This is achieved by defining the state-of-the-art and, thereby, providing guidance for manufacturers and regulators."

Key Takeaways from the Event:

- Accelerating Personalized Medicine in Europe: The event underscored the urgent need to integrate Next Generation Sequencing (NGS) into routine clinical practice across Europe to advance personalized medicine, particularly in oncology, and ensure equitable patient access.
- Addressing Key Implementation Barriers: Discussions highlighted critical challenges such as regulatory complexities (e.g., IVDR compliance), data sharing limitations (GDPR implications), and the need for robust, harmonized reimbursement systems to fully realize the potential of NGS.
- Collaborative European Strategy Essential: A strong consensus emerged on the necessity of a unified European approach, including initiatives like "Instand-NGS4P" and "1 Million Genomes," to build shared infrastructure, expertise, and overcome existing knowledge and best practice silos to enhance patient care.
- Patient-Centricity and Data Stewardship: The event emphasized that all advancements must be driven by patient needs, including clear communication, informed consent, and secure data handling models that maintain individual ownership of genetic information.
- Patient representatives reminded the audience that access to quality genomic testing is still not a reality for many across Europe. Without transparency on lab quality, turnaround time, and test interpretation, patients are often left navigating an opaque system.

"Our ultimate goal is to bridge the gap between scientific innovation and patient benefit. NGS offers unparalleled insights into diseases like cancer, allowing for truly personalized treatments. It's about ensuring every patient has access to the best available diagnostics, guiding effective therapies, and improving outcomes across Europe," stated Prof. Francesco de Lorenzo, President of FAVO – Italian Federation of Volunteer Cancer Patient Associations.

SPIDIA4P EVENTS // PAST HIGHLIGHT EVENT // 2025

Addressing the intricate landscape of regulations, Dr. Uwe Oelmueller, Vice President – PreAnalytiX Management Committee Co-Chair – QIAGEN GmbH – Germany, and SPIDIA / SPIDIA4P Coordinator, commented, "Innovative molecular diagnostics demonstrate tremendous potential, but accurate results depend heavily on the entire workflow—from patient specimen collection, transport, and processing through to the final laboratory test result, including data analysis. Following scientific evidence, international standards, and legal requirements, in vitro diagnostic test validation increasingly encompasses the entire workflow to improve safety and performance."

The economic imperative was also a central theme. Prof. Wim van Harten (em.), The Netherlands Cancer Institute, Amsterdam - Chair Working Group Health Economics, OECI and Endowed Professor Valesca Retèl – Health Technology Assessment – Erasmus School of Health Policy & Management, highlighted:

"Harmonized and comprehensive evidence regarding short- and long-term consequences, combined with the integration of common assessment frameworks for broad genomic profiling into the Joint Clinical Technology Assessment, will promote equitable access to innovative treatments across Europe."

A Political Mandate for Action

In her concluding remarks, MEP Letizia Moratti, member of the EU Commission SANT Committee, expressed strong support for integrating the outcomes of the event into current legislative efforts at the EU level.

"This initiative is a meaningful contribution to improving clinical outcomes with next-generation technologies," she said. "I will take your conclusions to the Parliament and Commission with full commitment."

MEP Moratti also shared her own proposal submitted to the Commission for a European network to support systematic evaluation and access to innovative oncological therapies, which would complement the outcomes of Instand-NGS4P.

Prof. Marialuisa Lavitrano, School of Medicine and Surgery - University Milano-Bicocca – Italy summarizing the event discussions stated: "Cross-border access to genetic profiling is not merely a technical or financial issue—it's a question of equity, innovation, and public health cohesion. Through strategic alignment, shared standards, and EU-supported infrastructure, national systems can offer every patient access to cutting-edge genomic care, regardless of location".

Concluding the impactful discussions, Prof. Kurt Zatloukal, Project Coordinator – Director – Diagnostic and Research Institute of Pathology – Medical University of Graz – Austria, project member of SPIDIA/ SPIDIA4P, remarked, "This event is a testament to the collaborative spirit required to transform healthcare. It's a kickoff, not an end, to a crucial process. By bringing together policymakers, scientists, clinicians, and patient advocates, we build the broad consensus needed to translate cutting-edge science into tangible improvements for patients across Europe."

The Seminar concluded with a strong call for continued collaboration and a firm commitment to translating these crucial discussions into concrete actions, ultimately aiming to improve healthcare access and outcomes for patients throughout the European Union and invited all participants to contribute to the White Paper on the contents of the High Level Seminar to be available shortly after the event.

Watch the full recording: on the project website!

https://www.instandngs4p.eu/high-level-seminar/
...or directly on You tube:
https://www.youtube.com/watch?v=dK4FC3di_Ts&t=1s

SPIDIA4P EVENTS // PAST EVENTS // 2025

May 2025

Webinar

Policymakers, health care providers, physicians, patient and civil society representatives as well as partners and collaborators of the Instand-NGS4P EU funded project attended the highly successful.

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

Read a complete review of the event on:

https://www.instandngs4p.eu/high-level-seminar/

and on pages *31/32* of this newsletter.

May 2025

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

Organized by SPIDIA4P partner BBMRI-ERIC and ESBB

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

Revisit the congress in Bologna, Italy, by accessing all of the on-site coverage.

EBW25 Live articles

Bluesky, *Twitter* and *LinkedIn* feeds

Congress Radio via the *weblink* or *Spotify*.

November 2025

6th EPSO Workshop on Plants and Microbiomes
November 3, 2025 in Antequera, Spain

In this workshop, **SPIDIA4P member Cornelia Stumptner** presented, how **European CEN and international ISO standards** for human microbiome specimens – developed within *SPIDIA4P* – are now serving as a model for developing plant-specific standards within the MICROBE/EPSO collaboration.

Read the event review here

Workshop on pre-analytical requirements for plant microbiome samples – BBMRI.at

More information about the MICROBE projext can be found here

EU Project "MICROBE" Kick-Off - BBMRI.at

November 2025

AMP Annual Meeting & EXPO 2025
November 11-15, 2025, Boston, Massachusetts, USA

Attendance by SPIDIA4P member PreAnalytiX GmbH, presenting **two posters th**at emphasize the importance of sample stabilization and pre-analytical workflows.

Click *here* to get to Poster 1

Click *here* to get to Poster 2

December 2025

7th EFLM Conference on PreAnalytical Phase – New Insights in preanalytical quality
12./13.12.2025, Padova, Italy

The 7th edition of the EFLM Conference on Preanalytical Phase was focused on the improvement of the preanalytical phase through innovation and sustainable solutions.

More information about the conference can be found here

EFLM Pre-Analytical Conference – Padova | 12-13 December 2025

SPIDIA4P EVENTS // PAST EVENTS // 2026

April 2026

AACR Annual Meeting 2026
April 17-22. 2026, San Diego, California, USA

Attendance and poster presentation by SPIDIA4P member PreAnalytiX and Coordinator QIAGEN

Poster titles:

QIAGEN:

EU Instand-NGS4P: Pre-analytical Multimodal Workflows for NGS Research and Future Precision Cancer Care

PreAnalytiX:

Unlocking transrenal DNA: New methods for stabilizing and isolating small cfDNA in urine

Transport under various conditions: Evaluating blood sample stability across seasons

Conference Website

https://www.aacr.org/meeting/aacr-annual-meeting-2026/

SPIDIA4P EVENTS // UPCOMING EVENTS AND TRAININGS / 2026

May 2026

Europe Biobank Week Congress 2026
May 19-22, 2026
Prague, Czech Republic

Organized by SPIDIA4P partner BBMRI-ERIC and ESBB

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

Take a look at the programme:

Full programme – 2026 – Europe Biobank Week 2026

November 2026

ESIB – European Summit of Industrial Biotechnology
November 10-12
Graz, Austria

Presentation by Dr. Uwe Oelmueller, Coordinator of SPIDIA and SPIDIA4P, on November 11, 2026,

Session Title: Advancing Liquid Biopsy: From Molecular Insights to Clinical Implementation.

Read more about the event ***here***.

SPIDIA4P EVENTS // BBMRI- ERIC WEBINAR RECORDINGS 24/7

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:

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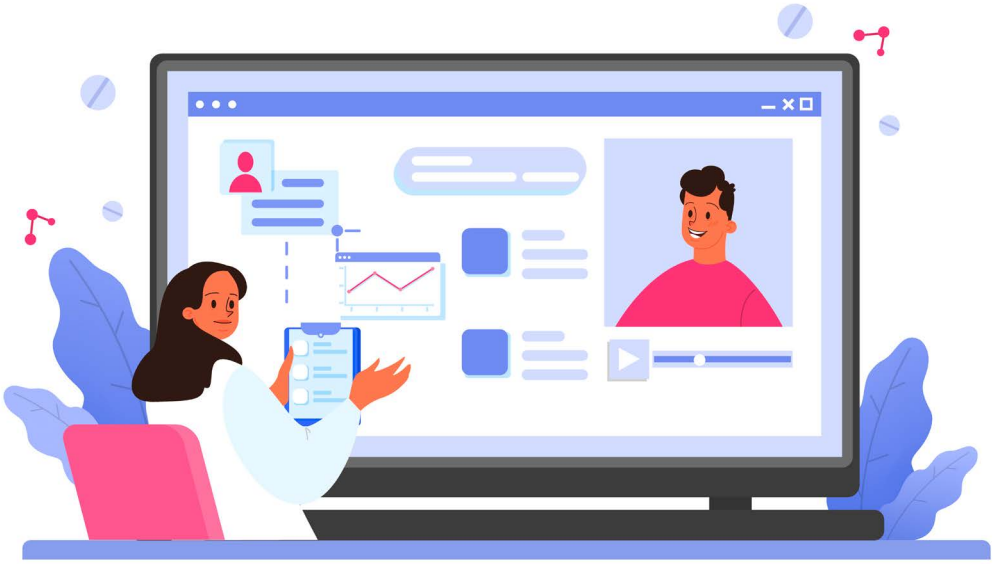
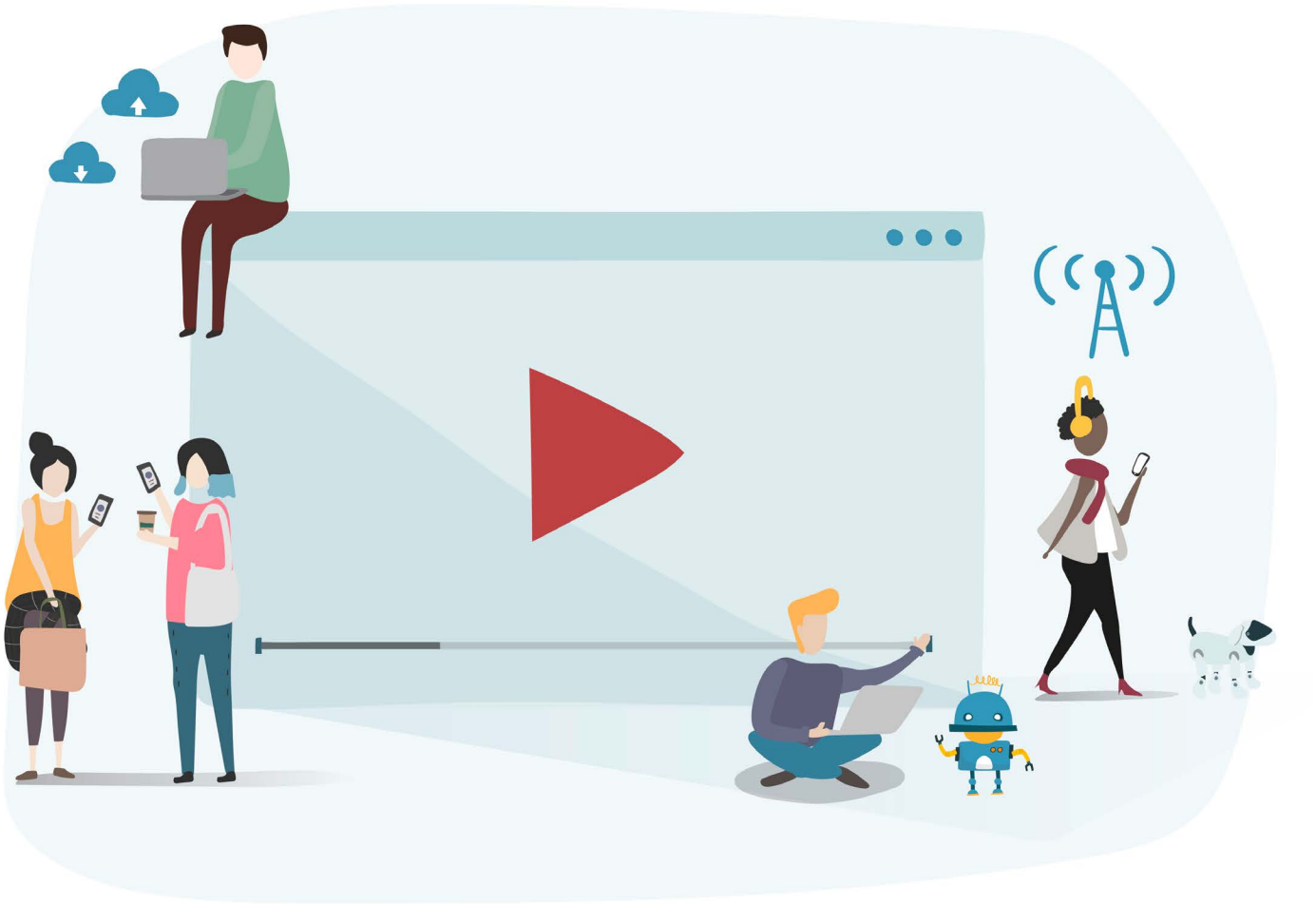


INFORMATION, VIDEOS, WEBINARS, PRESENTATIONS

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

MEDIA ON WWW.SPIDIA.EU	
Videos	watch on *www.spidia.eu*
Webinars	watch on *www.spidia.eu*
Presentations	watch on *www.spidia.eu*



SPIDIA4P NEWS // WEBSITE www.spidia.eu

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Don't miss

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

www.spidia.eu

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