

REVOLUTIONISING THE MOLECULAR DIAGNOSTICS THE SITUATION IN ITALY

In Italy, the level of awareness and understanding of NGS testing and applications is moderate. There is a huge gap between research projects (NGS for research) and clinical practice (NGS not present in daily life). Labs and institutions offering Next-Generation Sequencing (NGS) services can obtain ISO accreditation or certification, indicating their adherence to international standards for NGS testing.

CORE PILLARS	Well Implemented	Implemented	Not Implemented	Clear Information Not Available
Infrastructure and tools	●	○	○	○
Molecular tumour boards and expertise	○	●	○	○
Reimbursement for NGS and liquid biopsy	○	●	○	○
Education/training/ awareness	○	●	○	○
Governance	○	●	○	○
Healthcare workforce	○	○	●	○
Data sharing and linking	○	●	○	○

INFRASTRUCTURE AND TOOLS

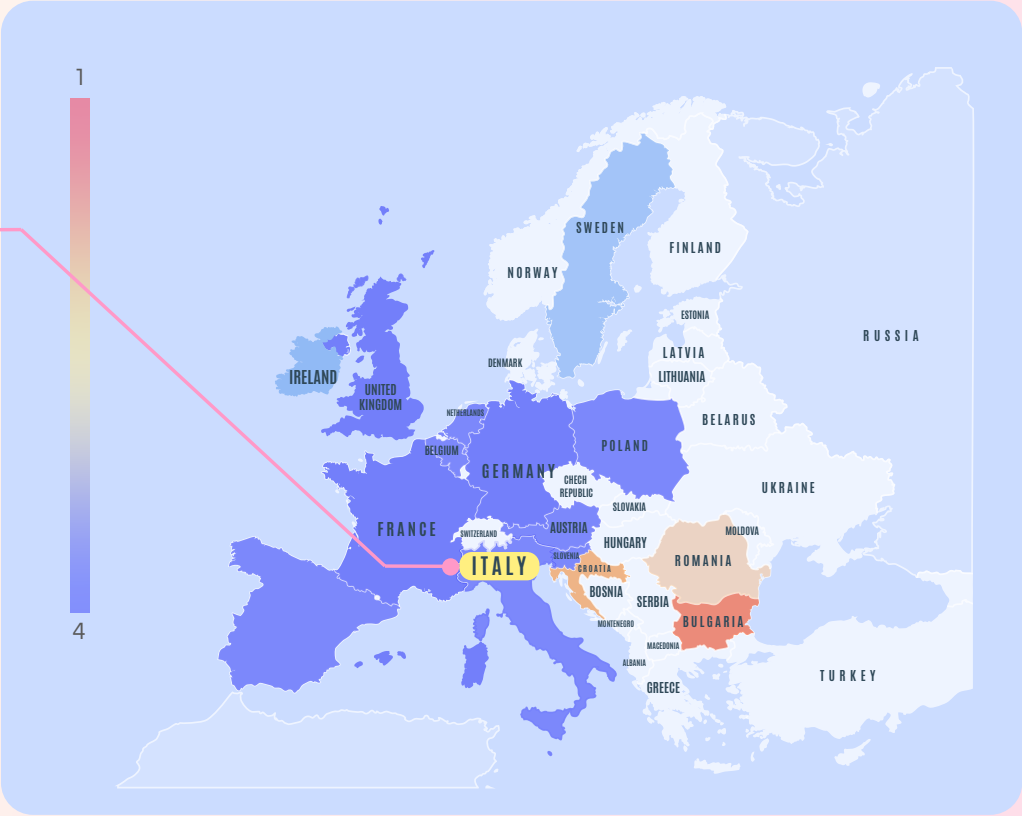
ITALY	Available	Not Available
NGS centre	●	○
Equipments	●	○
Funding	●	○
Routine utilization	●	○

In Italy, NGS testing is available, supported by adequate infrastructure, funded appropriately, and routinely used which indicates a positive environment for the implementation and utilization of NGS technology in various aspects of healthcare and research within the country.

CORRELATION AMONG DEPENDENT AND INDEPENDANT VARIABLE

INFRASTRUCTURE Funding	NGS centre	Equipments	Routine Utilization
Belgium	●	●	●
ITALY	●	●	●
France	●	●	●
Germany	●	●	●

- 1-0,8 - Very High Positive
- 0,79-0,6 - High Positive Correlation
- 0,59-0,4 - Medium Positive Correlation
- 0,39-0,2 - Low Positive Correlation
- 0,19-0 - Very Low Positive Correlation



MOLECULAR TUMOUR BOARDS AND EXPERTISE

The analysis highlights the importance of access to a comprehensive cancer panel for accurate diagnosis and treatment planning in Italy. The recurring consultation meetings demonstrate a commitment to addressing cancer-related issues, and the testing and discussion at mediocre levels help assess the healthcare system's capacity in managing cancer cases.

	MTB Panel	Consultation frequency	Testing/ Discussion
Belgium	●	●	●
Croatia	●	●	○
Spain	●	●	○
ITALY	●	●	●
France	●	●	●
Germany	●	●	●
United Kindgom	○	○	○
IRELAND	○	○	○
Slovenia	●	●	●
Poland	○	●	●
Sweden	○	●	○

● Available
○ Not Available

● Very High
● High
● Medium
● Low
● Very Low

● High
● Medium
○ Low

MOLECULAR TUMOR MTB Panelboard

Consultation

Testing/Discussion

Belgium	●	●
ITALY	●	●
France	●	●
Germany	●	●

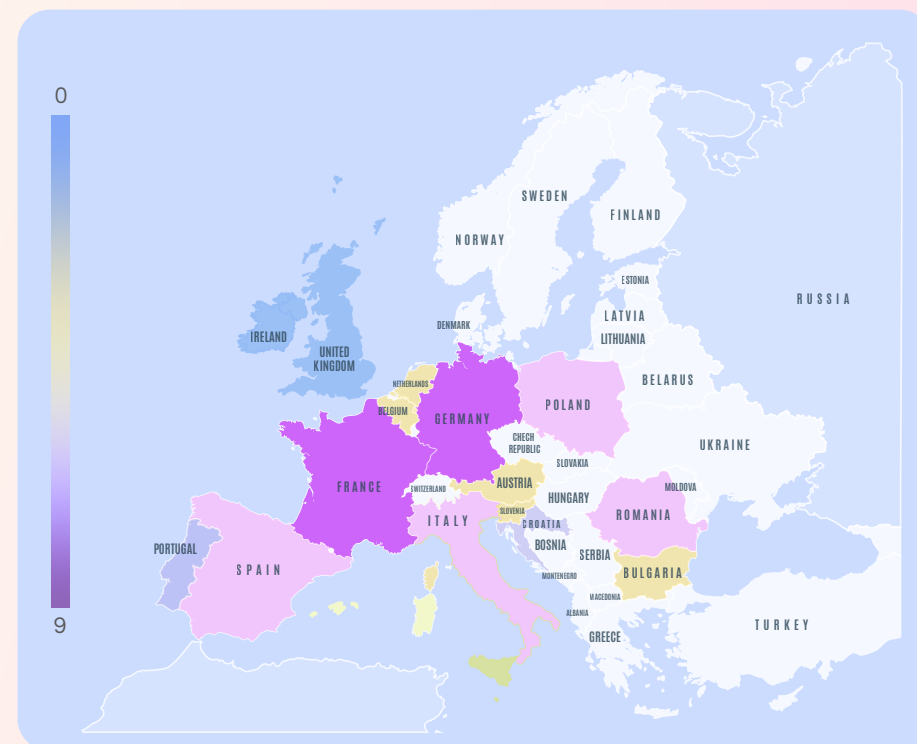
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● 0,19-0 - Very Low Positive Correlation



REIMBURSEMENT FOR NGS AND LIQUID BIOPSY IN ITALY

In Italy, Next-Generation Sequencing (NGS) is reimbursed, allowing individuals to have their NGS procedures covered by insurance or healthcare reimbursement systems. Liquid biopsy is not ready for implementation, excluding the setting of lung cancer, where, the government, is offering a special fund of 5 million euros to cover the main needs of all centers working in this setting. Additionally, there may be insufficient funding allocated for the reimbursement process, which could pose challenges in covering the costs of medical procedures or tests.

CENTRES' CORRELATION	INDEPENDENT VARIABLE
Dependent Variable	Funding
Reimbursement for NGS	High Positive Correlation
Reimbursement for Liquid Biopsy	Very High Positive Correlation

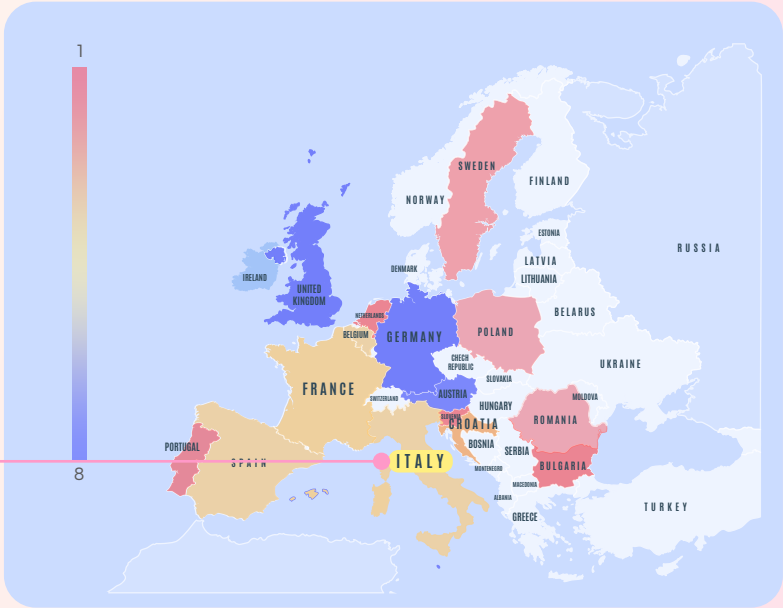
1-0,8 - Very High
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0,19-0 - Very Low Positive

EDUCATION/TRAINING/AWARENESS

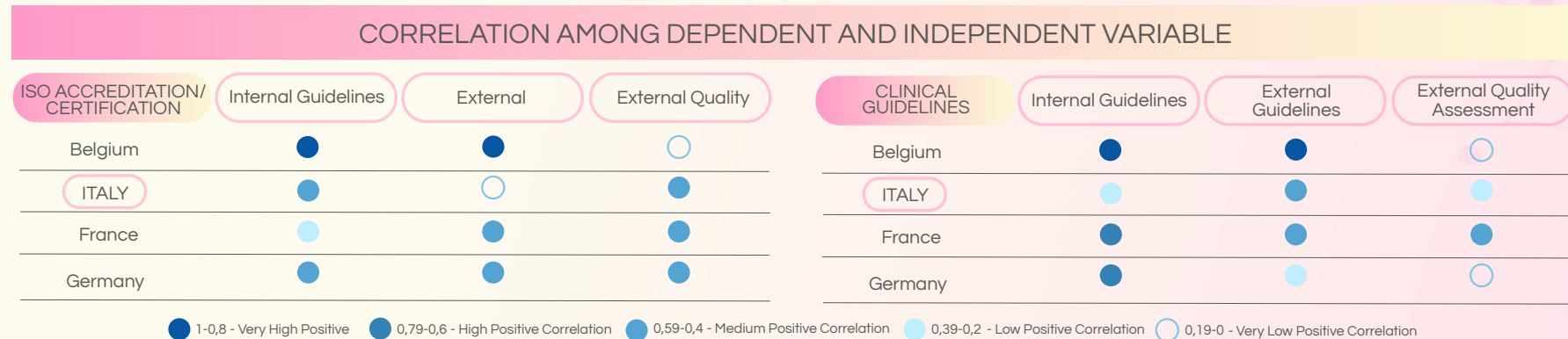
In Italy, the level of awareness and understanding of NGS testing and applications is moderate. There is a huge gap between research projects (NGS for research) and clinical practice (NGS not present in daily life). More understanding of the molecular biology approach is required. There is a need for some sort of specialization in interpreting data, and also to have different professionals to manage next-generation sequencing workflow, starting from technicians, biotechnologists, bioinformatics, and pathologists.

COUNTRIES' CORRELATION	INDEPENDENT VARIABLE
Dependent Variable	Educational Programmes
Trained Personnel	Low Positive Correlation
Awareness/ Understanding	Medium Positive Correlation
Educational programme/ workshops to increase awareness	Medium Positive Correlation



GOVERNANCE

In Italy, labs and institutions offering Next-Generation Sequencing (NGS) services can obtain ISO accreditation or certification, indicating their adherence to international standards for NGS testing. Clinical guidelines for NGS are regularly updated, providing healthcare professionals with the latest evidence-based recommendations for NGS-based diagnostics and treatments. However, the availability and use of internal guidelines specific to NGS are not mentioned. Furthermore, the presence of external quality assessment programs specifically for NGS in Italy is not specified, suggesting a potential lack of external mechanisms to assess and ensure the quality of NGS testing services.



	ISO Accreditation/ Certification	Clinical Guidelines	Internal Guidelines	External Guidelines	External Quality Assessment
Belgium	●	●	●	●	●
Croatia	●	●	●	●	●
Spain	●	●	●	●	●
ITALY	●	●	●	●	●
France	●	●	●	●	●
Germany	●	●	●	●	●
United Kindgom	●	●	●	●	●
Ireland	●	●	●	●	●
Slovenia	●	●	●	●	●
Poland	●	●	●	●	●
Sweden	●	●	●	●	●

HEALTHCARE WORKFORCE

The data suggests that there may be a lack of availability of a sufficient healthcare workforce or personnel in Italy. This implies that the country is facing challenges in terms of an inadequate number of healthcare professionals to meet the demands and needs of the healthcare system. The shortage of personnel can potentially impact the delivery of healthcare services, including cancer diagnosis, treatment, and management, and may require attention and strategies to address the workforce shortage and ensure adequate healthcare coverage for the population.

SUFFICIENT HEALTHCARE WORKFORCE

Available

Not Available

Belgium	
Croatia	
Spain	
ITALY	
France	
Germany	
United Kindgom	
Ireland	
Netherlands	
Slovenia	
Poland	
Sweden	

DATA SHARING AND LINKING

In Italy, there is active cross-border and cross-disciplinary collaboration, fostering partnerships and knowledge exchange across borders and disciplines. Routine sharing of data is practiced, enabling the exchange of information for research and innovation purposes. However, the availability of security guidelines, both external and internal, is not specified, potentially indicating a need for more established guidelines to ensure the security and privacy of shared data. Data linking to Electronic Health Records is implemented, facilitating the integration of Next-Generation Sequencing (NGS) data and other sources for comprehensive patient care and research. The presence of a controlling body specifically for data sharing is not mentioned, suggesting a potential lack of a dedicated authority



CORRELATION AMONG DEPENDENT AND INDEPENDANT VARIABLE

SECURITY GUIDELINES	Data Sharing	Data Linking	Controlling Body
Belgium			
ITALY			
France			
Germany			

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