



Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## Spoke 1 – Holistic Nosology

Personalised **Rna-Oriented Medicine** in Italy **Novel Therapeutics**  
(PROMINENT)





Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## SPOKE 1: Holistic Nosology

*FROM PATIENTS TO MOLECULES & BACK*: Mapping the omics landscape of clinical to molecular environment, to identify, classify, and refine the phenotypes of multifactorial diseases.

**Spoke leader: University of Rome «Tor Vergata»**

**Project Title: Personalised RNA-Oriented MediciNE in Italy Novel Therapeutics (PROMINENT)**

N. partner	Denominazione/ragione sociale (per le imprese)	Dimensione di impresa (MP, PI, MI, GI) (solo per le imprese)
1 (Capofila)	Fondazione Human Technopole (FHT)	
2	Università della Campania "L. Vanvitelli"	
3	IRCCS INT Fondazione "G. Pascale" (INT – Pascale)	
4	Biogem scarl (Biogem)	MI



Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## PROMINENT GOAL

The project aims to develop **innovative, cost-effective**, and evidence-based **non-invasive diagnostic pathways** for faster, earlier, more accurate, accessible, and affordable prediction, detection, and monitoring of monogenic (rare), polygenic (cardiovascular and metabolic) diseases, and cancer, while identifying effective and **innovative therapeutic approaches**.

1. Precision Medicine: the common soil hypothesis and the Moli-sani studies and other cohorts.
2. Genomics, Phenomics and Biomarkers.
3. Metabolome mapping from mouse to Moli-sani sub-cohorts and development of new therapeutic targets.



Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEAL ITALIA

## P1 - Human Technopole

Human Technopole (HT) is a newly established Life Sciences research institute located in the heart of MIND (Milano Innovation District). HT's mission is to **improve human life and technology** by deepening our collective understanding of human physiology and disease by adopting a multi-scale systems biology approach, through the achievement of four main objectives:

- 1) To foster **fundamental cutting-edge** research on human biology and human health;
- 2) To provide **shared infrastructures to the national scientific community**;
- 3) To offer **advanced scientific training** to scientists;
- 4) To enable the exploitation of research and technological innovations results via **technology transfer**.

# HT's Approach to Research

Bridging biological scales: from molecules to populations



Finanziato dall'Unione europea  
NextGenerationEU



Ministero dell'Università e della Ricerca



Italiadomani  
PIANO NAZIONALE DI RIPRESA E RESILIENZA

HEALITALIA





Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## Human Technopole Contribution to the Research Program of the Spoke

- Analysis of multivariate clinical phenotypes and health data (e.g. mortality, discharges, medical registers);
- Use of molecular traits (proteomics, metabolomics) to characterize associated genetic traits;
- In silico identification of omics traits responsible for the onset of complex diseases;
- Development of a new approach to link phenotypes to causal relationships, using genetic variants as anchors, age as exposure time.

### OUTCOMES:

- **In silico identification of omic traits responsible for disease insurgence**
- **Validation of targets in the Moli-Sani cohort**
- **Development of a digital platform for applying of developed methods in future studies**



Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## P2 – UNIVERSITA' DEGLI STUDI DELLA CAMPANIA LUIGI VANVITELLI

The University of Campania "Luigi Vanvitelli" is a public university, a primary seat of free research and free education as established by the Statute issued with D.R. 645 of 17/10/2016. The Department of Precision Medicine (DMP) that participates in this project, presents itself as an academic center for translational medical research in which innovative technologies are applied in the definition of the pathogenesis of human diseases.

The DMP boasts a long tradition of research in the oncology field, characterized by a multidisciplinary approach to the study of the molecular aspects of tumorigenesis and tumor progression. The Department, in fact, gathers skills ranging from analytical biochemistry, which uses the most advanced technologies to molecular and cellular biology, providing the best framework of knowledge, expertise and equipment.

The DMP is organized into divisions that represent a link between different clinical and experimental disciplines aiming to obtain the right interdisciplinarity and to be able to compete in the research and development sector in frontier sciences such as biotechnology, pharmacology and biomedicine, up to clinical application.



Università  
degli Studi  
della Campania  
*Luigi Vanvitelli*



Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## Contribution to the Research Program of the Spoke 1 – DMP

The expected results of the DMP activities are the following:

- **Identification of new biomarkers or biomarkers for early diagnosis and prediction of clinical outcome of human neoplasms.** The DMP will provide innovative data on new circulating biomarkers (miRNA and methylated nucleic acids) in human tumors. The validation phase of differentially expressed biomarkers on a large cohort of patients with standardized technologies will be followed by a phase of validation and characterization of the in vitro biological effects of the detected biomarkers.
- **Characterization of the in vitro biological effects of the detected biomarkers.** The specific selected markers will be functionally evaluated both in silico (for the prediction of molecular targets) and in vitro on tumor cells (evaluation of biological effects). Gene expression interference strategies (siRNA and CRISPR) will subsequently be developed in order to evaluate the functional effects of (epi)genetic markers on tumor proliferation and metastasis.



Finanziato dall'Unione europea  
NextGenerationEU



Ministero dell'Università e della Ricerca



Italiadomani  
PIANO NAZIONALE DI RIPRESA E RESILIENZA

HEAL ITALIA

## P3 – ISTITUTO NAZIONALE TUMORI “FONDAZIONE PASCALE”



ISTITUTO NAZIONALE TUMORI  
IRCCS - Fondazione Pascale

A Comprehensive Cancer Center



OECEI  
Organisation of European Cancer Institutes  
European Economic Interest Grouping



Main Campus

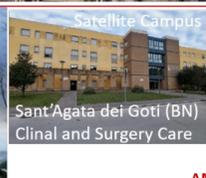


Satellite Campus  
"Ascalesi" Hospital  
(Clinical Practice)

70 Milioni per ristrutturazione



Satellite Campus Microgiano (AV)- (Research & Technologies)



Satellite Campus  
Sant'Agata dei Goti (BN)  
Clinal and Surgery Care

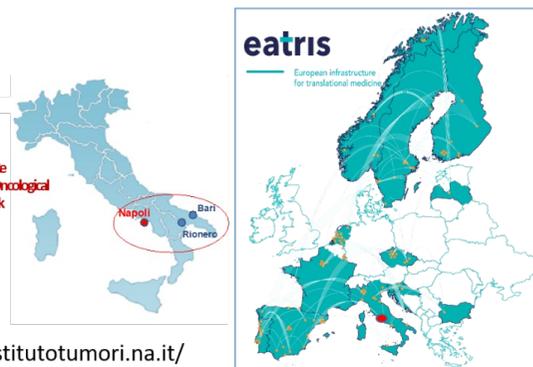
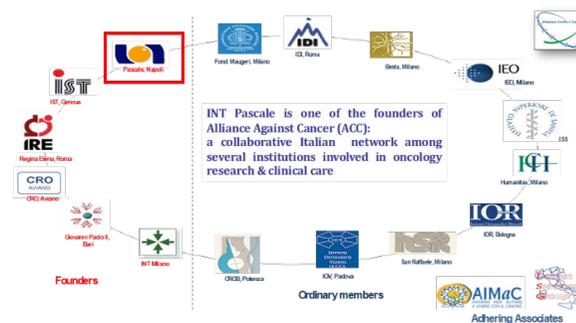
6 Clinical DISEASE-ORIENTED Departments

3 Clinical Strategic Departments  
1 Functional Dept

Department of TRANSLATIONAL RESERACH

2 Administrative and Strategic Services Departments

<https://newportal.istitutotumori.na.it/>



The **National Cancer Institute – IRCCS "Fondazione Pascale"** in Naples, is a leading public research and healthcare facility based in Southern Italy.

The **mission** of the Pascale Institute is to lead advancements in oncology through a combination of cutting-edge research, innovative clinical practice, and comprehensive patient care.

The IRCCS INT Pascale **aims** to achieve excellence in the field of oncology and to identify new and suitable directions in the field of prevention, diagnosis and treatment of tumor pathologies through translational & clinical research and technological and management innovation, shifting the centrality from the disease to the patient.



Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## Contribution to the Research Program of the Spoke 1 – INT PASCALE

- **Design of the clinical study** and definition of the **procedure for the recruitment** of healthy subjects (50) and patients affected by various oncological diseases, including colorectal cancer (250), breast cancer (500), and head and neck cancer (50), within the framework of the PROMINENT project
- Evaluate the plasma metabolomic and miRNomic profiles in collaboration with the University of Campania 'L. Vanvitelli'
- *In vitro* validation of **identified miRNAs**
- Correlation between **metabolomics/miRNomic profiles and clinical data**



Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## P4 – BIOGEM S.C.A.R.L.

**Biogem** (Molecular Biology and Genetics) is a consortium company between public research bodies (CNR, 'Anton Dohrn' Zoological Station of Naples) and Universities ("Federico II" of Naples, "Luigi Vanvitelli" of Campania, Milan-Bicocca, Sannio, Foggia, Suor Orsola Benincasa of Naples, Lumsa of Rome, Udine, Molise). Other members include the Municipality of Accadia, the Ufita Mountain Community, the Biogem Foundation, the Irpinia-Sannio Chamber of Commerce, the 'Mario Negri' Institute of Pharmacological Research. Biogem occupies a total area of 33,000 square meters of which 8,200 are covered. Biogem's research is structured into two macro-areas: biomedical research and biotechnological research. Biogem has also a Test Center for preclinical regulatory research recognized and certified by the Ministry of Health as a Center that operates in compliance with Good Laboratory Practice (GLP).





Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEALITALIA

## Biogem Contribution to the Research Program of the Spoke 1

Biogem will carry out the validation of the biomarkers identified by P1 and P2 using standardized real time PCR technologies (validation set) in Fast mode through the massive use of the Fast equipment at its disposal. This phase will proceed in parallel with the development of innovative molecular diagnostic kits with CE marking by Biogem through its Protein Factory facility and its own test center authorized for GLP testing. Biogem will also take care of filing the relevant patents and preparing the marketing phase of the products. In conclusion, the collaboration with the industrial partner will ensure not only the obtaining of the CE mark, but also the simplification and automation of the analysis protocols making it possible to achieve this objective.



Finanziato  
dall'Unione europea  
NextGenerationEU



Ministero  
dell'Università  
e della Ricerca



Italiadomani  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA

HEAL ITALIA

## Contribution to the Programme HEAL ITALIA and Precision Medicine

- The proposed project aims to identify and validate causal molecular targets of complex diseases. To this end, it will use the results of association studies conducted on hundreds of thousands of individuals and using millions of genetic variants, aligning itself with the 'Big Data' theme.
- The technologies developed within the project have a high translational value, making the large amount of available data usable by the project partners. This also clearly falls within the themes of spoke 1, whose objective is precisely the identification of molecular targets for complex diseases. It also achieves the objective by validating the results obtained within the population of Moli-sani that is already included in the 'Heal Italia' project and in particular in Spoke 1.
- This knowledge is also integrated with potential developments in the personalization and stratification of preventive and therapeutic interventions for the diseases covered by the project.