

# TRAINING

*Strumenti Offerti da*  
**BBMRI, EATRIS, ECRIN**  
*a Supporto della Costruzione e*  
*Sviluppo di Progetti Europei*



Aula Marotta  
Istituto Superiore di Sanità  
Roma

**5 maggio 2023**

9:00 – 17:00



SERVIZIO TECNICO-SCIENTIFICO  
COORDINAMENTO E SUPPORTO  
ALLA RICERCA





**INVITED**

# **Innovative biomarkers as tools for early dynamic screening of lung cancer**

Marta Barbalace, Francesca D'Ambrosio, Amalia De Curtiis, Cecilia Garofalo, Anna La Salvia, Peppino Mirabelli

# Call Selection: Develop new methods and technologies for cancer screening and early detection



<a href="#">Horizon Europe Framework Programme (HORIZON)</a>	Research and Innovation actions supporting the implementation of the Mission on Cancer (HORIZON-MISS-2021-CANCER-02)	<b>HORIZON-RIA HORIZON Research and Innovation Actions</b>	single-stage	22 December 2021	26 April 2022 17:00:00 Brussels time	<a href="https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-miss-2021-cancer-02-01;callCode=null;freeTextSearchKeyword=mission%20cancer;matchWholeText=true;typeCodes=1,0;statusCodes=31094502,31094501,31094503;">https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-miss-2021-cancer-02-01;callCode=null;freeTextSearchKeyword=mission%20cancer;matchWholeText=true;typeCodes=1,0;statusCodes=31094502,31094501,31094503;</a>	<b>Develop new methods and technologies for cancer screening and early detection</b>  TOPIC ID: <b>HORIZON-MISS-2021-CANCER-02-01</b>	<a href="https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/af_he-ria-ia_en.pdf">https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/af_he-ria-ia_en.pdf</a>
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## Expected Outcome:

- Healthy citizens and cancer patients will benefit from faster, earlier, more precise, personalised, accessible and affordable screening and early detection of cancer.
- Health care professionals will be able to deliver earlier, faster, more precise screening and early detection of cancer.
- Health policy makers will have the evidence to review population-based screening programmes and screening and early detection methodologies in everyday medical practice, and to include new, evidence-based screening and early detection methods, technologies and solutions.

## Scope:

Research is needed to develop and validate non-invasive, or minimally invasive cancer screening and detection methodologies for everyday medical practice and population-based screening programmes<sup>[1]</sup>, including enhanced participation of the target population. These programmes should become faster, more precise and personalised, affordable and accessible.



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 871096

# INVITED



Project title: **Innovative biomarkers as tools for early dynamic screening of lung cancer**

Acronym: **INVITED**

Abstract: INVITED encourages addressing **active population screening** by incorporating new biological tools for **Lung Cancer (LC)** risk assessment, early detection, and progression. We aim to build a strong evidence base toward a comprehensive protocol for primary LC screening, applicable both to undiagnosed cancer patients, as control, and LC patients. The study will include a retrospective analysis of collected blood samples from European population Biobanks and a prospective assessment of cases. The healthy population will be actively involved through new screening modalities and LC patients from the diagnosis to different follow-up steps. Toward this goal, **we will compare healthy subjects and LC patients at different time points to evaluate the predictive power of novel biomarkers (circ-miRNA, ctDNA, lncRNA, and circulating RNA) and gene-expression profiling, seeking to unveil molecular mechanisms of LC development and progression**. In this context, we will examine the feasibility of liquid biopsy for early primary LC identification, including data from early-stage and metastatic carcinomas. The INVITED team consists of a comprehensive and **strong team of experts that will address medical, technological, and social aspects** of the implemented screening and early diagnosis of LC. Expertise in the medical field includes clinical research, translational research development, and access to patients. This will enable optimization of the use of a minimally invasive tool as a liquid biopsy for LC following a user-centric approach and experiencing its implementation in “real-life” clinical settings. **The social part of the team includes researchers and patient organizations that will promote accessibility of the test to patients and individuals at-risk for screening, early detection, and disease management, in combination with a study aiming to increase the screening rates.**

eatris+



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# INVITED



Participant No.	Participant organization name	Country
Coorination unit	Italy	Italy
Part. 2	Germany	Germany
Part. 3	BBMRI	Austria
Part.4	ECRIN	France
Part.5	EATRIS	Hollands



# PERT - Diagram



## WP-1 Coordination & Management of the study

### WP-2 Biomarkers and screening technology selection (pre-clinical phase)

- Task a retrospective and prospective analysis of collected blood samples from European population Biobanks
- Task b selection of the technological device for screening

WP-3 Development and optimization of AI based predictive models for early diagnosis and prediction (to define a cloud based digital platform).

### WP 6 Active patient engagement

WP-4 Prospective observational clinical studies for biomarkers validation and verification

WP-5 Generation of a next generation biobank to include biosamples, digital images, and clinical data

WP-8 Dissemination and communication

WP-7 Ethics and data protection, data treatment assess and storage



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# GANTT-Chart



<b>PROJECT TITLE</b>	INVITED
<b>Principal Investigator</b>	XXXX
<b>Duration</b>	48 months

AIM	Period	Phase one Month 1-48									
		Month 1-6	Month 7-12	Month 13-18	Month 19-24	Month 25-30	Month 31-36	Month 37-42	Month 43-48		
<b>WP-1 WP-1 Coordination &amp; Management of the study</b>	Month 1-48	[Active]									
<b>Biomarkers and screening technology selection (pre-clinical phase)</b>		[Active]									
Retrospective tests	Month 24-40										
Technology selection	Month 24-40										
<b>WP-3 Development and optimization of AI based predictive models for early diagnosis and prediction (to define a cloud based digital</b>		[Active]									
Retrospective tests	Month 12-18										
<b>WP-4 Prospective observational clinical studies for biomarkers valida</b>	Month 24-48										
<b>WP-5 Generation of a next generation biobank to include biosamples, digital images, and clinical data</b>	Month 24-48										
<b>WP-6 Active patient engagement</b>	Month 1-48	[Active]									
<b>WP-7 Ethics and data protection, data treatment assess and storage</b>	Month 1-48	[Active]									
<b>WP-8 WP-8 Dissemination and communication</b>	Month 1	[Active]									



# Team



Marta Barbalace, *Istituto Superiore di Sanità (MACA)*

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Amalia De Curtiis, *IRCCS Neuromed*

Cecilia Garofalo, *Istituto Oncologico Veneto IOV*

*IRCCS*

Anna La Salvia, *Istituto Superiore di Sanità (FARVA)*

Peppino Mirabelli, *AOR Santobono Pausillipon*