

FONDAZIONE ISTITUTO G. GIGLIO DI CEFALÙ

Subject: Expressions of interest for next identification of public and private partners to codesign a Oncology Biotechnology Laboratory

The Foundation "Istituto G. Giglio di Cefalù" intends to carry out, through any EU funding (CEE), a laboratory of high health technologies aimed to the study of the most common neoplasms affecting the european population such as colorectal cancer, breast cancer and lymphomas. Goal of the laboratory will be also the study of pediatric tumors and evaluation of pre-neoplastic forms in order to achieve secondary prevention in oncology,

The program of research and development will require the application of the following methods of investigation:

- Imaging: Breast, colon, lymphoma;
- Monitoring cell-based therapies.

The research program will be geared to developing innovative technologies aimed at defining new imaging for the diagnosis and study of solid tumors among the most frequent causes of morbidity and mortality in both sexes (breast and colon) and tumors of the lymph node tissue (lymphomas), both control and monitor the tropism of emerging cellular therapies (stem cell therapies) against tumor cells and against protein homeostasis disease myelolinfoproliferative diseases.

The headquarters of the Laboratory will be placed at the Foundation "Istituto G. Giglio di Cefalù" but all the laboratories of the scientific partners participating to the study will be involved.

The rough draft that will be co-developed by the partners is described in the annex of this expression of interest.

Interested parties must submit their expression of interest to the Protocol Office of the Foundation, no later than 13.00 on the day 27 JANUARY 2016, in a separate closed envelope, sealed against tampering, and signed on the closing flaps and bring all 'outside the words: "Expression of interest for the identification of public and private partners for the design of a Biotechnology Laboratory"

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FONDAZIONE ISTITUTO G. GIGLIO DI CEFALÙ

The package shall contain the following information:

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Phone	Telefax	
	Phone	Phone Telefax

Description of specific skills (skills, any previous experience, specialized issues, relations with other research and development and / or companies - max 1 page)

In addition, describe the following information and business experiences:

- International projection of the subject (Presence of research and development agreements with other public and / or private Italian / foreign, participation in international research networks and development);
- List of publications with impact factor; patents; prizes and awards; coordination of scientific projects and / or programs of research and development; other elements relevant for evaluation;
- Design capacity of partner (Indicate also the total budget for research and development projects may have made in the period 2007-15);
- Demonstration of functional connections with other laboratories and / or regional technology clusters, and / or national and / or international.
- A declaration certifying the meeting of the characteristics of general nature and professional competence required by art. 38 D.Lgs 163/06, attaching a copy of an identity document
- Description of the experimental plan aimed to develop the project attached to the announcement
- Consent to the processing of personal data by the person concerned for the purposes related to the procedure, pursuant to $D.Lgs\ 196/2003$

The purpose of this notice is only exploratory and does not involve the establishment of legal positions and obligations towards Foundation "Istituto G. Giglio di Cefalù"

The Foundation reserves the power to suspend, modify or cancel, in whole or in part, the process with appropriate reasons.

The partners will have no compensation for the co-design, because it is aimed to obtain EU funding for the construction of the Laboratory of Medical Biotechnologies.

Any clarification may be requested by e-mail: direzione.generale@hsrgiglio.it

This notice will be published on the website: www.hsrgiglio.it

Cefalù, 13 JAN 2016

The Legal Representative Dr. Salvatore Giovanni Albano

BIOTECNOLOGY LABORATORY

1. Promoter of the partnership

Istitution	Fondazione Istituto G. Giglio di Cefalù	
Contact person for the project		
Street		
City		Prov.
e-mail	Tel.	Fax

2. Office where the Laboratory will be established

The headquarters of the Laboratory will be built at the Fondazione Istituto G. Giglio di Cefalù in Cefalù but the laboratory will also work through all partnership institutions involved in the project. The headquarters will be responsible of the operations in the different involved offices.

3. Description of the technical and scientific objectives of the laboratory

The aim of the project will be the establishment of the "Laboratory xxxxx" with high health technologies targeted to the study of the most common oncologic diseases in the European population such as colorectal cancer, breast cancer and solid lymphatic tumors. Oncologic pediatric diseases and pre-neoplastic forms for secondary oncologic prevention will also be studied in this Laboratory.

It is now well ascertained that at the base of neoplasms there are complex and numerous changes in the genomic structure that are involved in carcinogenesis in different ways. The development of lines of research on neoplastic cell cultures represents an essential step of the study in order to understand carcinogenesis and, therefore, to find possible new treatments which may be more efficacious both in terms of therapeutic purposes and tertiary prevention.

In this regard, it seems useful to recall how the evaluation of the mutations of the genes BRCA1-BRCA2 is now firmly established in clinical practice both as screening tool and in the diagnostic-therapeutic fields, although it is just a reductive assessment compared to what the healthcare research actually allows.

Indeed, oncology can not avoid the use of diagnostic radiology for diagnosis and follow-up, so that in most cases the cancer research projects presented at the international level have a close collaboration between the two health specializations.

Many classification systems of neoplasms have been created, and, in particular, for the assessment of metastases, RECIST (Response Evaluation Criteria In Solid Tumor) in its variants 1.0 and 1.1, which uses as a reference the Computerized Tomography, and CHOI criteria have been widely considered as the reference systems. However, the use in clinical practice of the newer antiangiogenic drugs has resulted in variations of the pattern of response to therapy of the

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metastatic lesions thus leading to the need of a re-evaluation of these parameters in order to allow an adequate and complete follow-up of patients.

Moreover, we intend to develop/use in this Laboratory some PET-MRI, Digital Pathology and Clinical Pathology platforms whose ultimate goal is the search for new horizons in diagnostic oncology.

The program RESEARCH & DEVELOPMENT will be mainly focused on oncology, and, more precisely, on the following methods of investigation:

- Imaging: Breast cancer, colorectal cancer, lymphomas;
- · Monitoring cell-based therapies.

The aim is the implementation of methods of molecular characterization of oncological diseases and of evaluation of progression towards a metastatic disease, in order to also develop new screening methods with diagnostic and therapeutic purposes.

Concerning the radiologic-diagnostic field, the PET/MRI platform could allow to obtain high diagnostic accuracy in cases of primary or metastatic cancer disease, mainly in terms of early identification of possible recurrences or metastases, with a possible early characterization and access to treatments. It is now ascertained in scientific literature as the precocity of treatment yields faster responses and lower costs for the community.

The planned Laboratory XXXXXXXX will be aimed also at the development of a computerized analysing system of radiological images of computed tomography and magnetic resonance with the purpose of evaluating metastatic lesions from colorectal and breast cancers and response to therapy in solid lymphatic tumors.

The use of this software will allow early and unambiguous characterization of metastases using newly advanced diagnostic parameters.

The establishment of the Laboratory xxxx is also aimed at creating an "international community of pathologists" that will be able to give a real-time specialist advice to colleagues at an international level:

- facilitating the consulting for the "second opinion" and thus reducing reporting time and the possibility of error;
- eliminating the sending of histological slides from site to site;
- providing new tools and methods for students' training and for the review of internal cases;
- facilitating the diagnostic procedures in the operating room;
- facilitating diagnostic reporting thanks to immediate access to previous exams and to the possibility of applying advanced measuring and processing tools;
- create a safe environment for storing images;
- guaranteeing a proper definition of the treatment plan for the patient;

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Another objective of the Laboratory will be to develop algorithms for advanced processing of images of histological slides in order to be able not just to diagnose the disease but also to apply the best therapeutic regimen.

Hence, the fields of research that will be developed are:

- I. molecular genetics with particular reference to oncologic markers;
- II. diagnostic histopathology and immunohistochemistry;
- III. radiological diagnostic imaging with particular reference to the hybrid tomographic tools;
- IV. development of a software for medical diagnosis assistance in the laboratory, radiological and histopathological fields.

The activities of RESEARCH & DEVELOPMENT will be fundamental for the development of a virtuous process of study aimed at improving both the survival and the quality of life of patients suffering from oncologic diseases.

