**ANNEX 1: CALL SPECIFICATIONS**

**INTRODUCTION**

The REVERT project (full title: taRgeted thErapy for adVanced colorEctal canceR paTients) has been funded by the Horizon 2020 –Framework Programme for Research and Innovation (2018-2020) - Work programme: Health, demographic change and wellbeing - Call SC1-BHC-02-2019 – Systems approaches for the discovery of combinatorial therapies for complex disorders.

The REVERT project has the specific objective of addressing the challenge of understanding, at system level, the pathophysiology of metastatic colorectal cancer (mCRC) in patients who respond well or poorly to therapies, in order to design an optimal strategy for mCRC, with therapeutic interventions modulated according to the patient's characteristics.

The REVERT consortium involves many excellent EU research institutes and SMEs, as well as several certified biobanks in different states (Italy, Spain, Germany, Romania, Luxembourg, Sweden) to ensure access to a large amount of data and the involvement of numerous clinical centres.

**THE REVERT PROJECT**

REVERT will develop an innovative decision support system based on AI, using the experience and data collected from the "real world" by the various hospitals operating in the EU health system.

The project will use an information system, the REVERT PLATFORM that will collect and harmonize the data and will consist of two main components: the REVERT-DataBase and the REVERT-AI.

The REVERT software system must guarantee data integrity and privacy management, in compliance with the EU GDPR (EU Reg. 2016/679), beneficiaries national regulations and the EU Charter of Fundamental Rights.

**PROJECT METHODOLOGY**

Project implementation involves a macro-temporal sequence of different preparatory phases for the achievement of the objectives set by the initiative.

In general, in the Set-up phase, the DataBase will be built on the basis of the technical-functional requirements identified, to then proceed with the enrichment of the data and the subsequent cleaning and preparation phases, in order to guarantee the quality of the datamart on which subsequent analyzes will be performed.

The predictive algorithms will then be implemented, the results analyzed and any fine tuning of the analysis model developed will be started.

The project activities will be organized in different Work Packages, some of which will be running for the entire project duration, while others will be managed through a waterfall model according to which the output of the previous phase will enable the start of the next.

**MODE OF CONSULTING PROVISION**

The first phase of the REVERT project will consists in data harmonization and protection.

In particular, in the software design phase, the San Raffaele needs to manage the issue of data Cybersecurity & Privacy. The transformation of the data, from the input sources to the produced outputs, will have to guarantee, in every phase of the process, the availability of the information exclusively to the pre-authorized participants and a constant quality monitoring.

In detail, for the software and systems involved in the project, it will be necessary to define the data security requirements in terms of:

* Logistic security of data communications from sources (e.g. Biobanks) to any other system involved
* Logistic security of the individual components of the systems involved
* Mapping of authorized accesses to each system involved
* Logic of functional and technical monitoring of data to ensure non-alteration
* Logical trace of data transformation
* System procedures for changes with identification of participants and activities
* Procedures for analyzing the adequacy of data management
* Escalation procedures for data or other security breaches

In this context, the intervention of the supplier must be focused on identifying the requirements necessary for the construction and development of the DB in the technical, regulatory and safety fields, or Business Technical Requirement, Compliance Normative, Cybersecurity.

The supplier is requested to illustrate the support proposal in carrying out the requested activities, with the details of the methodological approach used, the project activities and the expected deliverables.

Furthermore, it is requested to specify the operational offices present in Europe in order to guarantee coverage of all the countries involved in the REVERT project.

**DURATION OF THE INTERVENTION**

The activities covered by this initiative are expected to proceed as follow:

1. An initial phase of 12 consecutive months to setup all the necessary data security requirements, subject to verification and validation of the working group involved.
2. Subsequent monitoring/verification activities to be carried out every 6 months throughout the entire duration of the project.

**EXPECTED TEAM**

The professional figures and the minimum level of seniority required for managing the assignment are the following:

* Privacy & Compliance Expert - minimum seniority of 5 years
* Database and Architecture Expert - minimum seniority of 10 years
* Cybersecurity Expert - minimum seniority of 8 years
* Governance & PMO expert - minimum seniority of 5 years

The supplier is requested to specify the mix of profiles required in terms of effort – at least 1 FTE is required on site at the coordinator office in Rome, and at least 2 days/unit per month dedicated to the coordination and collection of the information from all European countries involved in the initiative – and planning for the completion of the activities covered by the initiative, also attaching their curricula.

 **SIZE OF THE CONTRACT**

The maximum budget for this tender is 150,000,00 EUR, over the duration of the contract, VAT included.

**SUBMISSION OF BIDS**

The applicant's bid must comprise all the following documents.

1. **DECLARATION OF ABSENCE OF CONFLICT OF INTEREST**

Applicants should fill Annex 3 - Declaration of Absence of Conflict of Interest

1. **DECLARATION OF INTEREST**

Applicants should detail in their bid how they will perform the tasks covered by the contract, with particular emphasis on:

* 1. Methodology: ability to cover all the fields of experience required
	2. Quality and contingency
	3. Relevant professional experience in the selected profiles
	4. Experience in GDPR, cybersecurity and National Privacy Regulations for all the countries involved in the REVERT project
1. **DECLARATION ON HONOUR ON EXCLUSION CRITERIA**

At tender submission stage, applicants should include the declaration on honour on exclusion criteria.

Bids from applicants who do not meet the exclusion criteria referred to in Articles 136 and 137 of the Financial Regulation (REGULATION (EU, Euratom) 2018/1046 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 July 2018 on the financial rules applicable to the general budget of the Union) will not be considered for the award of the contract.

The applicant must demonstrate sufficient legal and regulatory, economic, financial, technical and professional capacity to be able to perform the tasks as specified in this tender.

**FINANCIAL OFFER**

The prices must be fixed and quoted in euros.

The prices must be all-inclusive and cover all costs related to performance of the contract as described above.

**AWARD CRITERIA**

Bids from applicants who do not satisfy the exclusion or selection criteria will not be considered for the award of the contract.

The contract will be awarded to the tender offering the best value for money.

The result of the technical evaluation will weight 60 percent. The result of the financial evaluation will weight 40 percent.

**PROCEDURES FOR THE SUBMISSION OF PROPOSALS**

Apply to the call for tenders by providing the following documents with the complementary documentation as required in each Annex.

Documents shall be sent to revert@sanraffaele.it

* + - 1. Application Form (Annex 2)
			2. Declaration of absence of conflict of interest (Annex 3)
			3. Declaration on Honour on Exclusion Criteria
			4. Declaration of Interest
			5. Financial Offer
			6. Checklist of Documents provided

# Deadline for the submission of the proposals:

The deadline to submit proposals is 16-03-2020.