TECHNICAL SPECIFICATIONS
Contents

INTRODUCTION .................................................................................................................................................. 2

1. PROBLEM DESCRIPTION AND CURRENT CLINICAL LIMITATIONS ..................................................... 5
   1.1 BIBLIOGRAPHY AND CLINICAL LITERATURE ............................................................................. 5

2. REQUIRED REQUIREMENTS ................................................................................................................... 6

3. ADDITIONAL REQUIREMENTS ............................................................................................................. 7
INTRODUCTION

Lombardy region, according to the regional law 29/2016 “Lombardia is research and innovation” (art. 2 c. 3 lett. m), has taken action to develop innovative tools which could respond to the needs for innovation and research, focusing also on the innovation demand arising from the Regional public sector.

The DGR X/6582/2017 defined and led the path for implementing the initiatives aimed at strengthening and qualifying the innovation demand coming from Public Administration, through the support of Pre-commercial Public Procurement (PCP) initiatives in the healthcare sector. This sector can be considered extremely interesting due to its social and economic impacts, as well as the potential spin-offs of the just-above presented procedures, which are both innovative and challenging. However, in order to properly design the innovation public tenders, some preliminary steps have been defined.

The precondition for the implementation of the initiative, financed under Action I.1.b.3.1. of the ERDF ROP 2014-2020, stemmed from the publication of a public invitation (DDUO n. 5704/2017) for the collection of innovative needs of Lombardy public and private ASST (Aziende Socio-Sanitarie Territoriali), IRCCS (Istituti di Ricovero e Cura a Carattere Scientifico) and accredited private nursing homes.

Following the above-mentioned public invitation, 16 needs have been admitted to the following validation step (DDS 8282/2017), based on their priority.

As planned by the above-mentioned notification, the first three technological innovation needs have been validated only after accomplishing three more steps aimed at confirming the existence of the preconditions required to activate the PCP tender procedures:

- the publication in the Official Journal of the European Union of pre-information notices, done on the 8\(^{th}\) of August 2017;
- the realization of open consultations with the market that took place on 12\(^{th}\) of October 2017 at Palazzo Lombardia, in separate sessions for each of the three selected needs, technical dialogues with economic operators and subjects operating in the research sector; a bilingual questionnaire (IT / EN) was defined and spread for the market survey;
- researches of already available patents were analysed with the applicants on the days of 2nd and...

According to the DGR X/7639 of the 28th of December 2017, Lombardy Region approved the following technological innovation requirements selected as part of the process defined by the DGR n. 6582/2017:

- requirement 1 - connected to the development of new technological solutions concerning "assessment of coronary atherosclerotic plaque fragility", proposed by ASST of Pavia, with a duration of research and development project of 28 months, estimated value of 3,002,000, € 00 including VAT (rounded to the top decimal);
- requirement 2 - connected to the development of new technological solutions concerning "Rehabilitation and assistance of neurological patients through robotic devices: exoskeletal mechatronic system for the administration of rehabilitative motor therapy to neurological patients with motor disability of the upper limb", proposed by the Policlinico Nursing Home SpA, with a duration of research and development project of 28 months, estimated value of € 3,183,890.00 including VAT;
- requirement 3 - connected to the development of new technological solutions for "safe bronchial suction", proposed by IRCCS Medea - La Nostra Famiglia Association with a duration of research and development of 24 months, estimated value of 1,382,344, € 00 including VAT;

At the same time, the related PCP procedure has been activated. It is based on the action 1.1b3.1 "Reinforcement and qualification of the Public administration innovation demand through support for Precommercial Public Procurement and Innovation Procurement" actions of the POR FESR 2014-2020, action 1.3.1 of the Partnership Agreement establishing the start and management of the PCP procedures, on delegation of the Procurement Planning and Procurement Management Structure and in conjunction with the General Directorate for Proposals for Universities, Research and Open Innovation, through ASST of Pavia for its own and approved first requirement, and through the Central Purchasing Regional Agency - ARCA for the second and third requirements approved and expressed by private subjects.

ASST Pavia has assumed the role of contracting authority / implementing entity of the initiative, while the role of beneficiary Administration of the intervention financed by the POR 2014-2020 ERDF remains with the Lombardia Region.
The research and development subject of this contract is related to the requirement 1 above, "evaluation of coronary atherosclerotic plaque fragility".

The document reports the analysis of the problem and the description of the minimum requirements that the "Innovative Solution", resulting from the R & D activity must possess.

1. PROBLEM DESCRIPTION AND CURRENT CLINICAL LIMITATIONS

The problem highlighted by the Local Health Authority (ASST) of Pavia concerns the fact that, even with the modern technology, it is not possible to prevent the onset of acute myocardial infarction. Ischemic heart disease is one of the main causes of death in the developed countries. Myocardial infarction is due to an acute coronary artery occlusion for the formation of a thrombus on an ulcerated atherosclerotic lesion. The identification of vulnerable atherosclerotic plaque could represent a parameter which identifies high-risk patients. This parameter, in this research project, will be used in most of the national and international cardiology department, but could be useful in neurology or vascular surgery department as well.

The main objective is to identify patients at high risk of myocardial infarction. This identification would lead to clear benefit to the patients with early diagnosis and reduction of the cost for the national health service in terms of use of implantable devices (CND J).

The research services and technological development will cover the following innovation gap, in fact the hospital procedures currently used are able to identify some parameters that do not necessarily correlate with the actual risk for plaque rupture.

Nowadays, the main way to study the coronary tree is the coronary angiography examination. This invasive procedure cannot be justified as a routine approach because it is not free from complications.

According to the available literature, some studies tried to correlate peripheral vessels disease with coronary artery disease, but this was not enough for the prevention of myocardial infarction. Therefore, the innovative technology required, would make possible to fill the gap, evaluating with a non-invasive technique the plaque frailty and its rupture risk preventing the myocardial infarction.

1.1 BIBLIOGRAPHY AND CLINICAL LITERATURE

Below the reference bibliography and clinical literature:

2. REQUIRED REQUIREMENTS

The new technology proposed by the competitor must have the following functional and performance requirements:

1. It must allow to evaluate the fragility of coronary atherosclerotic plaque.

2. The output has to be a single biometric image, with high definition (around 100 μm), which evaluate the plaque fragility by visualizing its morphology (fibrous cap thickness, cap erosion, lipid core and) and measure its density.

3. It must not evaluate the plaque calcification and stenosis severity are not necessarily required.

4. It must be able to measure some parameters, such as inflammatory markers.
5. It must be non-invasive for the patient.

6. It must be able to record, store, send, print and analyse the data acquired, adopting instruments and open standard format, for research purposes.

7. The device must be universal without the development of ad hoc components or the creation of customized interfaces on the device itself.

8. The device must be available in the diagnostic departments where is possible to perform outpatient visit, with the assistance and supervision of an operator.

9. The device must allow the timing of the cardiological investigation to be minimized.

10. The device must be waterproof.

11. The device size must be as small as possible.

3. ADDITIONAL REQUIREMENTS

Regarding to installation, commissioning and management, the new Technology must have the following functional and performance requisites:

1. It must comply with the general and design requirements set by the current legislation on work safety and comply with the regulations in force for medical devices so that no subsequent changes are necessary for the purpose of CE certification.

2. It must allow a fast learning curve for operators.

3. It must be easy to install and use (without the need for calibration and adaptations).

4. If the device is equipped with a power supply / recharge plug, it must be compatible with all types of power socket in the European countries.

5. It must not require the intervention of technical specialized staff in the management and supervision of its use.

6. It must ensure installation, management and operating costs as cheap as possible.

7. It must be equipped with a system for recording usage data.