Sistema Socio Sanitario
Regione Lombardia
ASST Pavia

Pre-commercial public procurement (PCP)
for R&D services enabling the creation of
"non-invasive solutions for the assessment of coronary atherosclerotic plaque fragility"

- Contracting authority: ASST of Pavia
- Type of procedure: Open procedure
- Duration of the R&D services execution: 28 months
- Total budget: 3.002.000,00€ including VAT
- Time limit for receipt of tenders or requests to participate: 31/08/2018
- Area of implementation: national and international cardiology, neurology or vascular surgery departments
- Objective: to identify patients at high risk of myocardial infarction, through the identification of vulnerable atherosclerotic plaque.
- Expected impacts: early diagnosis and reduction of the cost for the national health service in terms of use of implantable devices (CND J).

Challenge description

Ischemic heart disease is one of the main causes of death in the developed countries.

Nowadays it is not possible to prevent the onset of acute myocardial infarction. 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 identify high risk patients.

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 can't 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.

The new technology proposed by the competitor must have the following main functional and performance requirements:
- It must allow to evaluate the fragility of coronary atherosclerotic plaque.
- 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.
- It must not evaluate the plaque calcification and stenosis severity are not necessarily required.
- It must be able to measure some parameters, such as inflammatory markers.
- It must be non-invasive for the patient.
- It must be able to record, store, send, print and analyse the data acquired for research purposes.
- The device must be universal without the development of ad hoc components or the creation

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

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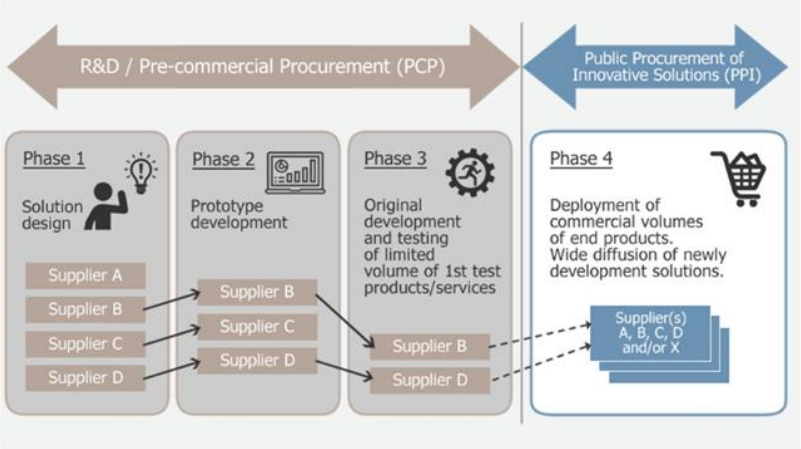
PCP Description

PCP (Pre-Commercial-Procurement) is a competitive multiple-sourcing procedure for procuring applied research and technological development services. It involves different suppliers competing in parallel through different phases of development: solution exploration and design, prototype development and validation, field-testing in the real operational context.



- PHASE 1-SOLUTION EXPLORATION and DESIGN: Open participation to all interested parties – the expected number of successful bidders amount to 4. Research and development services regards the conceptualization and design of the Innovative Solution.
- PHASE 2-PROTOTYPE DEVELOPMENT AND VALIDATION: Participation reserved for Phase 1 successful bidders – the expected number of successful bidders amount to 3. Research and development services are aimed at creating a prototype of the innovative solution designed in Phase 1.
- PHASE 3-FIELD TESTING: Participation reserved for Phase 2 successful bidders - the expected number of successful bidders amount to 2. Research and development services are aimed at testing the previously developed prototype in a real context, with the help of patients carefully selected by ASST Pavia.

For information about the Call for Tender:
http://www.asst-pavia.it/node/13292

For information about the PCP procedure:

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