

## **TITLE**

Pre-commercial procurement to buy R&D (research and development) services for the development of an affordable integrated solution for predictive, prognostic and diagnostic analysis in liquid biopsies of solid tumours (including appropriate haematological indications) based on NGS technology.

## **JOINT PROCUREMENT**

This pre-commercial procurement (PCP) is carried out by SCIENSANO who was appointed as lead procurer to coordinate and lead the joint procurement in the name and on behalf of the buyers group listed in I.1. The applicable national procurement law is the Belgian law.

## **SHORT DESCRIPTION**

This prior information notice (PIN) provides early information about the expected starting date and purchase volume for a pre-commercial procurement (PCP) and about the open market consultation that is organized in preparation of this procurement. More information about the open market consultation is provided in section II.2.14.

This procurement aims to trigger new solutions to be developed and tested to address the following challenge: successful implementation in routine clinical care practice of large “cellular free DNA” molecular diagnostics based on NGS technology by means of a provision an integrated, cost-efficient and standardized sequencing and analytical data interpretation and reporting system in various oncology care settings in the EU.

## **DESCRIPTION OF THE PROCUREMENT**

The oncNGS buyers group aims to address their unmet needs:

(unmet need 1) Establishment of valuable common tumour profiling strategy allowing to provide equal access to innovative medicines to all;

(unmet need 2) Outcome research analysis after treatments with targeted therapies as diverse testing leads to

lowering the pooling capacity of obtained results, needed to obtain large enough sample numbers to perform statistics analyses;

(unmet need 3) Application of such essential testing to all patients, breaking down current unacceptable inequities due to the high costs of current diagnostics tests.

through the provision of an (solution 1) efficient molecular DNA/RNA profiling of tumour-derived material in liquid biopsies by means of (solution 2) pan-cancer tumour marker analysis kit including NGS analysis integrated with (solution 3) an on-site ICT decision support system including analytical test interpretation and reporting.

The procurement will take the form of a pre-commercial procurement (PCP) under which R&D service contracts will be awarded to a number of R&D providers in parallel in a phased approach. This will make it possible to compare competing alternative solutions.

Each selected operator will be awarded a framework agreement that covers 3 R&D phases.

The 3 phases are:

- solution design
- prototype development and analytical testing
- pre-commercial devices clinical testing

Phase 1: Solution design

Phase 1 suppliers will design their solution based on their background and their analysis of the technology strategy, technical feasibility, quality plan, risks assessment, business model, financial feasibility, ethics and data protection management done to satisfy oncNGS requirements. During Phase 1, suppliers will be requested to deliver the Analytical test plan they will perform in Phase 2.

This phase will require from the suppliers concise research and development to match any of their in-house tools to the needs of the buyers group. In silico/in vitro primer assessments, bioinformatics software adaptations, algorithm adaptation and form development will have to be taken up. At the end of the Phase 1, the invitation to Phase 2 (call-off) will be issued.

## Phase 2: Prototype development and Analytical testing

Phase 2 suppliers will develop their solution and demonstrate their analytical validity having followed the Analytical test plan approved in Phase 1. The Analytical validation will consist of demonstration of assay performance (accuracy, precision, specificity, etc.) . During Phase 2, suppliers will be requested to deliver the clinical validation protocol of the pre-commercial devices and Data Management Plan ('DMP') (including patients' consents) they will perform in Phase 3.

This phase will require from the suppliers further research and development to optimize the in silico/in vitro defined primer combinations, the bioinformatics pipeline and interpretation and reporting algorithms when aiming to meet the criteria of analytic validation on sample DNA materials (sensitivity, specificity, transferability, robustness, etc). At the end of the Phase 2, the invitation to Phase 3 (call-off) will be issued.

## Phase 3: Pre-commercial devices clinical testing

Phase 3 suppliers will validate their approved analytical solution on the oncNGS and demonstrate the clinical validity of the solution following the protocol approved in Phase 2 and authorized by the relevant ethical committees and all the other authorizing entities/agencies.

After each phase, intermediate evaluations will be carried out to progressively select the best of the competing solutions. The contractors with the best-value-for-money solutions will be offered a specific contract for the next phase.

Corroboration of the final solution is expected to take place in at the buyers' facilities, being:

- SCIENSANO,
- ALLEANZA CONTRO IL CANCRO,
- INSTITUT CURIE,
- INSTITUT CATALA D'ONCOLOGIA,
- INSTITUT JULES BORDET,
- LUDWIG-MAXIMILIANS-UNIVERSITAET MUENCHEN
- HOSPICES CIVILS DE LYON

This testing may also serve as a first customer test reference for the contractors. The procurement is expected to start in September 2021 and end in April 2025.

The selected operators will retain ownership of the intellectual property rights (IPRs) that they generate during the PCP and will be able to use them to exploit the full market potential of the developed solutions beyond this PCP. The market potential is estimated at 1,5-3 billion euro considering the global burden of cancer at about 20 million new cases per year of which 10% would benefit from the oncNGS solution.

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 874467 — oncNGS (see <http://oncngs.eu/>).

The EU has given a grant for this procurement, but is not participating as a contracting authority in the procurement.

According to the Annex E. Specific requirements for innovation procurement (PCP/PPI) supported by Horizon 2020 grants of the HORIZON 2020 – WORK PROGRAMME 2018-2020, PCPs must comply with the Horizon 2020 definitions and rules:

"Pre-commercial procurement (PCP) means procurement of R&D services involving risk-benefit sharing under market conditions, and competitive development in phases, where there is a clear separation between the procurement of the R&D services procured from the deployment of commercial volumes of end-products. (...)Procurers can but are not obliged to procure at market price R&D results from a PCP. (...)The PCP contract that will be concluded with each selected tenderer must take the form of one single framework agreement covering all PCP phases, which does not involve contract renegotiations after contract award. This framework agreement must contain information on the future procedure for implementing the different phases (through specific contracts), including the format of the intermediate evaluations (incl. evaluation criteria and weightings) after the solution design and prototype development phases."

The total estimated budget of the PCP will be of approximately EUR 8.559.000,00 (including VAT).

### **ADDITIONAL INFORMATION**

This Prior Information Notice (PIN) is linked with the earlier publication with reference number OJS:2021\S045-111630

Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds

X yes  no

Identification of the project:

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 874467 — oncNGS (see <http://oncngs.eu/>).

The EU has given a grant for this procurement, but is not participating as a contracting authority in the procurement.

All interested operators are invited to take part in an open market consultation (regardless of their geographic location, the size or governance structure of their organization).

The open market consultation will provide you with an overview on the procurement objectives, the PCP process and the main clauses of the contract. You will also have the opportunity to ask questions. It will be held in English.

The open market consultation will be organized through the combination of:

- on-line open events (including Q&A sessions) that will be held on:
  - o May 11 (morning)
  - o May 12 (afternoon)

The registration to the 2 events will be made available on April 1st 2021 at the project website <http://oncngs.eu/>

- a questionnaire made available at the project website <http://oncngs.eu/> on May 13th 2021, the day after the last on line open event, and to be replied by May 20th 2021. Participating economic operators willing to supply confidential information are required to indicate what specific information must be treated as confidential.

- on line meetings with each respondent to the questionnaire and that booked the meeting through the link provided in the questionnaire and on a first come first served basis. The meetings will take place during the weeks from May 21st 2021 to May 23rd 2021. These meetings will be held with the unique purpose to offer the economic operators to explain more in details their responses to the questionnaires. Any economic operator can participate in the PCP call for tender even if it did not participate in the open market consultation.

Offers will be accepted only in English. All communication (before, during and after the procurement) will be carried out in English.

All information provided during the open market consultation and other background information will summarized be published online in English on the project website (<http://oncngs.eu/>).

Participation in the open market consultation will not be a requirement to submit a proposal to the tender, does not lead to any rights or privileges for the participants, and is not part of any pre-qualification or selection process.

For more information, please see:

- the project website (<http://oncngs.eu/>)
- the section on PCP on the EC website (<https://ec.europa.eu/digital-single-market/en/innovation-procurement> )