See the notice on TED website

Austria-Graz: Research and experimental development services
OJ S 252/2020 28/12/2020
Prior information notice
Services

Legal Basis:
Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: Medizinische Universität Graz (MUG)
Postal address: Auenbruggerplatz 2
Town: Graz
NUTS code: AT221 Graz
Postal code: 8036
Country: Austria
Contact person: Kurt Zatloukal
E-mail: kurt.zatloukal@medunigraz.at
Internet address(es):
Main address: www.medunigraz.at
Address of the buyer profile: www.instandngs4p.eu

I.1. Name and addresses

Official name: Universita Degli Studi di Firenze (UNIFI)
Postal address: P.zza S.Marco, 4
Town: Firenze
NUTS code: ITI14 Firenze
Postal code: 50121
Country: Italy
Contact person: Mario Pazzagli
E-mail: m.pazzagli@dfc.unifi.it
Internet address(es):
Main address: www.unifi.it

I.1. Name and addresses

Official name: Erasmus Universitair Medisch Centrum Rotterdam (EMC)
Postal address: Dr. Molewaterplein 40
Town: GD Rotterdam
NUTS code: NL33C Groot-Rijnmond
Postal code: 3015
Country: Netherlands
Contact person: Peter Riegman
E-mail: p.riegman@erasmusmc.nl
Internet address(es):
Main address: www.erasmusmc.nl

I.1. Name and addresses

Official name: St. Anna Kinderkrebsforschung – Children Cancer Research Institute (CCRI)
Postal address: Zimmermannplatz 10

Town: Vienna
NUTS code: AT130 Wien
Postal code: 1090
Country: Austria
Contact person: Ana Pudja
E-mail: ana.pudja@ccri.at
Internet address(es):
Main address: www.ccri.at

I.1. Name and addresses
Official name: Universita' Degli Studi di Milano-Bicocca (UNIMIB)
Postal address: Piazza dell'Ateneo Nuovo, 1
Town: Milano
NUTS code: ITC4C Milano
Postal code: 20126
Country: Italy
Contact person: Maria Luisa Lavitrano
E-mail: marialuisa.lavitrano@unimib.it
Internet address(es):
Main address: www.UNIMIB.it

I.1. Name and addresses
Official name: University Clinic of Schleswig-Holstein (UKSH)
Postal address: Rosalind-Franklin-Straße 12
Town: Kiel
NUTS code: DEF02 Kiel, Kreisfreie Stadt
Postal code: 24105
Country: Germany
Contact person: Michael Forster
E-mail: m.forster@ikmb.uni-kiel.de
Internet address(es):
Main address: www.ikmb.uni-kiel.de

I.1. Name and addresses
Official name: Centre Leon Berard (CLB)
Postal address: 28 Rue Laennec
Town: Lyon
NUTS code: FRK26 Rhône
Postal code: 69008
Country: France
Contact person: Stephanie Cox
E-mail: stephanie.cox@lyon.unicancer.fr
Internet address(es):
Main address: www.centreleonberard.fr

I.2. Information about joint procurement
The contract involves joint procurement
In the case of joint procurement involving different countries, state applicable national procurement law:
Austrian law. This PCP is carried out by the Medical University of Graz who was appointed as lead procurer to coordinate and lead the joint procurement in the name of the buyers group.

I.3. Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at: www.instandngs4p.eu
Additional information can be obtained from the abovementioned address

I.4. Type of the contracting authority

Body governed by public law

I.5. Main activity

Health

Section II: Object

II.1. Scope of the procurement

II.1.1. Title

Pre-commercial procurement (PCP) to buy R&D (research and development) services to develop fully integrated, standardized NGS workflows, for routine diagnosis of common and rare cancers.
Reference number: 874719

II.1.2. Main CPV code

73100000 Research and experimental development services

II.1.3. Type of contract

Services

II.1.4. Short description

This 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).
The procurement aims to trigger new solutions to be developed and tested to address the following challenge: development of two fully integrated, standardized NGS workflows, from sample-pre-analytics to medical decision making, for routine diagnostics of common and rare cancers from adults and children.
As the common challenge exists of a number of sub-challenges, the procurement will be divided into the following lots, each corresponding to one sub-challenge:
— Lot 1: Pre-sequencing (Specimen collection, nucleic acid isolation, library preparation),
— Lot 2: Sequencing,
— Lot 3: Bioinformatics analysis,
— Lot 4: Integrated reporting.

II.1.5. Estimated total value

Value excluding VAT: 8 554 099,75 EUR

II.1.6. Information about lots

This contract is divided into lots: yesMaximum number of lots that may be awarded to one tenderer: 3

II.2. Description

II.2.1. Title

Pre-sequencing
Lot No: 1

II.2.2. Additional CPV code(s)

73100000 Research and experimental development services

II.2.3. Place of performance

NUTS code: AT221 Graz
Main site or place of performance: Testing is expected to take place in the locations of the buyers group, as listed in 1.1, and at a additional test location(s), as will be defined at the OMC.

II.2.4. Description of the procurement

This PCP procurement is a joint procurement by different procurers across Europe that are all facing the same common challenge and are thus looking for similar solutions (so-called 'buyers group').
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,
— prototyping,
— original development and validation and testing of a limited set of first products or services.
Each of the 3 phases will address all 4 lots. Each supplier can address more than one lot, with a maximum of 3 lots. A minimum of different suppliers addressing the same lot per phase is: 3-4 for phase 1, 3 for phase 2 and 2 for phase 3. 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. The phased approach with parallel contracts and intermediate evaluations will be followed within each lot. The result of phase 3 will be the development of 2 fully integrated NGS workflows with EQA.
Testing is expected to take place in the locations of the buyers (MUG, UNIFI, EMC, CCRI, UNIMIB, UKSH, CLB), as listed in 1.1, and at an additional test location: e.g. a third party located in Romania and other associated centres, as will be defined in the OMC. This testing may also serve as a first customer test reference for the contractors. The procurement is expected to start in April 2022 (M28) and end in April 2025 (M64).
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 i.e. beyond the procurement. The Global NGS market reached 7.8 billion USD in 2019 (CAGR 20.9 %), whereas the European NGS market represents ca. 25 % of the global market (around 1.95 billion USD in 2019); source Market&Markets 2019.
In order to implement NGS into routine diagnosis, a fully integrated workflow, from patient sample collection to final diagnostic result report is required. This PCP will focus on developing 4 independent lots, to be modularly integrated into two independent workflows, which could be e.g. target panel-based and/or whole genome / whole exome-based, for the diagnosis and treatment decision making (including pharmacogentics) in common cancer entities rare cancer entities. The type of workflows to be developed is not limited to the abovementioned examples, and will be decided based on the outcome of the Open Market Consultation (OMC).
In addition to introducing quality control (QC) steps for each critical part of the workflow and validating individual lots, the integrated performance of the whole workflow will be validated.

The performance improvement which this PCP aims to develop, compared to the current state-of-the art technology, is the integration of NGS data from tumor derived specimens (including liquid biopsy) with data from pharmacogenomic panels performed on non-tumor derived specimens.
The main technical challenges to be addressed per lot are specified in this prior information notice, with more information available on the project website (www.instandngs4p.eu). Adaptations, more details and further specifications will be defined based on the outcome of the OMC.
The main technical challenges to be addressed for lot 1 (pre-sequencing: pre-analytics and library preparation) is the preservation of the native NA profiles as they were in the patient's body, in a standardized, controlled and documented way, to ensure reliable downstream NGS results, representative of the actual condition present in the patient.

II.2.14. Additional information

Additional information about the technical challenges per lot is available at the project website (www.instandngs4p.eu). For contact please use the following email address: instand-NGS4P@abgi-france.com, and include 'PIN' or 'OMC' in the subject of the email, to refer to Prior Information Notice (PIN)- or Open Market Consultation (OMC)-related topics, respectively.

II.2. Description

II.2.1. Title

Sequencing
Lot No: 2

II.2.2. Additional CPV code(s)

73100000 Research and experimental development services

II.2.3. Place of performance

NUTS code: AT221 Graz
Main site or place of performance: Testing is expected to take place in the locations of the buyers group, as listed in 1.1, and at a additional test location(s), as will be defined at the OMC.

II.2.4. Description of the procurement

The main technical challenges to be addressed for lot 2 (sequencing) are:
— the accurate connection of the biological process of nucleotide binding/depletion to generation of a chemical or physical signal for transfer into sequence information,
— reproducibility and precision (an important requirement of the EU IVDR), essential for verification/validation.
The used NGS technology platform should maintain the required sensitivity and precision, and avoid sequencing bias for reporting analyte profiles as they were in vivo.

II.2.14. Additional information

Additional information about the technical challenges per lot is available at the project website (www.instandngs4p.eu). For contact please use the following email address: instand-NGS4P@abgi-france.com, and include 'PIN' or 'OMC' in the subject of the email, to refer to Prior Information Notice (PIN)- or Open Market Consultation (OMC)-related topics, respectively.

II.2. Description

II.2.1. Title

Bioinformatics analysis
Lot No: 3

II.2.2. Additional CPV code(s)

73100000 Research and experimental development services

II.2.3. Place of performance

NUTS code: AT221 Graz
Main site or place of performance: Testing is expected to take place in the locations of the buyers group, as listed in 1.1, and at a additional test location(s), as will be defined at the OMC.

II.2.4. Description of the procurement

The main technical challenges to be addressed for lot 3 (bioinformatics analysis) are:
All components of data management, transfer and analysis throughout the entire workflow process (bioinformatics, in-silico data modelling, e-reporting) must be verified to reduce complexity for clinicians as well as users, and to fulfil regulatory requirements (EU IVDR, FDA etc.), but at the same time avoid analysis bias and false information. The bioinformatics part of the workflow should ensure that sequencing data is processed, filtered, analysed and displayed in the best possible way so that the final NGS information reflects the real molecular status of the patient. The specifications of clinically relevant cut-offs for the intended NGS tests and their verification will be another key element as well as the specification and development of robust calling algorithms.
For each disease, the business processes and metadata schemas should be defined following the entire clinical pathway from the medical specialist's request for genomic analysis inside a patient's electronic health record (EHR), the laboratory workflow (standard operating procedure - SOP), bioinformatics pipeline and returning results back to the patient's EHR where they will be visualized in textual and graphical form. The necessary SOPs and bioinformatics pipelines should be updated when needed, according to clinical requirements and state-of-the-art bioinformatics knowledge.
Processing of patient data has to meet data protection regulation (GDPR). Dedicated infrastructures will have to be available for storage of large amounts of NGS data and backup of data should be automated to prevent data loss. The lack of standardized bioinformatic protocols, coupled with a significant complexity in the current pipelines requires the development of fully validated, user-friendly tools dedicated to the analysis of targeted panels or WES data, supporting complete versioning and annotation lots.

II.2.14. Additional information

Additional information about the technical challenges per lot is available at the project website (www.instandngs4p.eu). For contact please use the following email address: instand-NGS4P@abgi-france.com, and include ‘PIN’ or ‘OMC’ in the subject of the email, to refer to Prior Information Notice (PIN)- or Open Market Consultation (OMC)-related topics, respectively.

II.2. Description

II.2.1. Title

Integrated reporting
Lot No: 4

II.2.2.

Additional CPV code(s)
73100000 Research and experimental development services

II.2.3. Place of performance
NUTS code: AT221 Graz
Main site or place of performance: Testing is expected to take place in the locations of the buyers group, as listed in 1.1, and at a additional test location(s), as will be defined at the OMC.

II.2.4. Description of the procurement
The main technical challenges to be addressed for lot 4 (integrated reporting) are:
Translating NGS results into medical decision-making reports, by integrating NGS results with pharmacogenomics panels and existing e-medication tools containing dosing and drug interactions, should be achieved in this lot. Since this information has to be made available to healthcare professionals and patients at the bedside for rapid interpretation, it will be important to determine the optimal method to clearly present NGS results and their medical relevance. A report format which provides the relevant information, enables appropriate interpretation (based on the scientific and clinical evidence) of NGS results and provides decision support for the recommended intervention is going to be crucial. The relevant clinical information should be reported in a concise and clear way, reporting only data with validated evidence for clinical decisions and in a form minimizing the risk of data misinterpretation. Moreover, links to rapid learning tools will also be provided, to facilitate the gradual upskilling of health care practitioners in pharmacogenomics. As patients are often not able to understand the genetic results presented to them, a specific communication plan should be developed focusing especially on the communication of uncertainties that could stem from the NGS results. Strategies to support families in coping with genetic information and to manage barriers related to the disclosure of genetic information within families need to be developed.

II.2.14. Additional information
Additional information about the technical challenges per lot is available at the project website (www.instandngs4p.eu). For contact please use the following email address: instand-NGS4P@abgi-france.com, and include ‘PIN’ or ‘OMC’ in the subject of the email, to refer to Prior Information Notice (PIN)- or Open Market Consultation (OMC)-related topics, respectively.

II.3. Estimated date of publication of contract notice
30/09/2021

Section IV: Procedure

IV.1. Description

IV.1.8. Information about the Government Procurement Agreement (GPA)
The procurement is covered by the Government Procurement Agreement: no

Section VI: Complementary information

VI.3. Additional information
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 organisation).

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 organised in the preferred form of a central face-to-face meeting, if the situation allows, combined with explanatory webinars and a questionnaire (otherwise in the form of a virtual meeting, combined with a webinar and a questionnaire).
When: 22 March 2021 and 23 March 2021
Where: Vienna, Austria
If a face-to-face meeting is not possible due to the pandemic, the change to virtual meeting will be announced via the project website (www.instandngs4p.eu) and the EC portal.
Please register by 1 March 2021 via the project website.
Please indicate by 1 March 2021, together with the registration for the open market consultation if you want to supply (under a non-disclosure agreement) additional confidential information that you do not wish to reveal in public during the open market consultation.
After registration, a questionnaire will be used to collect additional information, which should be submitted via the Instand-NGS4P website (www.instanndngs4p.eu), by 15 March 2021.
You can participate in the PCP call for tender even if you did not participate in the open market consultation.
Offers will be accepted in English only. 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 be published online in English on the project website (www.instandngs4p.eu).

VI.5. Date of dispatch of this notice

23/12/2020