**Instand-NGS4P**

**Integrated and Standardized NGS Workflows for Personalised Therapy**

# TECHNICAL SUBMISSION FORM for Phase 3 – Lot 1

**CONTRACTOR IDENTIFIER:** *please complete*

**IMPORTANT NOTICE**

* Please complete a **separate form for each Lot** you are involved in
* Be sure to complete all sections of this form. You can extend the boxes and use pictures and/or other visual elements if they make your Tender more understandable.
* The technical offer will be assessed based on the minimum requirements and weighted award criteria mentioned in section 3.4 of the Request for Tender (these have been included below)
* Please use a minimum font size of 10. Use a minimal line spacing of 1. Page limit: **12 pages**. References, tables, figures and CV, as well as the informative grey boxes in the form, do not count for this maximum.

**1. FEASIBILITY OF THE R&D PLAN: PROJECT PLAN and PROJECT MANAGEMENT**

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| **FEASIBILITY OF THE PROJECT PLAN AND THE SCHEDULE** |
| **Detail a clear plan for the further development and implementation of your Solution, which demonstrates the commercial feasibility and the consistency of the schedule for the execution of the contract in Phase 3.**  Please consider that Phase 3 testing in a real-world diagnostic medical environment is expected to take place at 3 medical sites.  Include time schedule, deliverables and milestones as detailed in the Request for Tenders.  Please ensure that you have explicitly addressed the following weighted award criteria (RfT 3.4.3):  B9) HOW REALISTIC THE TECHNICAL DEVELOPMENT OF THE SOLUTION IS (CLEAR PLAN FOR THE DEVELOPMENT/IMPLEMENTATION OF THE SOLUTION AND FOR FINISHING PHASE 3 ON TIME)  *Feasibility of the Project plan and schedule, including methodology.*  B10) COMMERCIAL FEASIBILITY OF THE SOLUTION (COMMERCIALIZATION PLAN/ROUTE TO MARKET)  *Completeness, sense of reality and feasibility of the commercialisation plan including the market analysis and risk management. Sense of reality and feasibility of the principles for licensing, pricing, distribution.*  (see also Framework Agreement, Article 14 Commercial Exploitation of Results)  Please also provide information on how and under what conditions the Solution will be made available to the Buyers after the project, according to Article 12.1 of the Framework Agreement below (see also the corresponding point in the Explanatory Notes for the PCP Framework Agreement):  *12.1 Subject to Article 13 and 14, the ownership of Results shall remain with the Contractor. The Contractor will provide each of the Procurers an irrevocable, indefinite, worldwide, royalty-free and non-exclusive license to use the Results for non-commercial research purposes, teaching and patient care. In case of Results that constitute software, the non-commercial research license will extend to all updates and upgrades thereof.* |
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| **Describe the work organization and supply chain.** |
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| **Elaborate on your approach to managing your subcontractors.** |
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| **Describe the methodology and methods used for project management, development, testing, and implementation. Include the measures to be taken with respect to risk management and quality assurance (e.g. risk assessment and risk mitigation strategy).**  Please address in particular the following weighted award criterion:  B11) CRUCIAL RISKS (TECHNICAL, COMMERCIAL, OTHERS…) ARE IDENTIFIED AND COUNTERMEASURES HAVE BEEN IDENTIFIED  *The extent to which crucial risks (technical, commercial and others) to project success are identified, and how effectively these will be managed during this phase. Preferably to be summarized in a risk management table, including concrete risk mitigation solutions* |
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**2. COMPOSITION of the PROJECT TEAM**

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| **Specify the configuration (e.g. consortium) and role of each partner and/or subcontractors, if applicable.**  Corresponding to weighted award criterion (B12) COMPOSITION OF THE PROJECT TEAM  *The extent to which the Contractor and/or Subcontractor shows readiness, or demonstrates to be able to dedicate the resources (e.g., expertise, human capital, basic equipment, etc.) necessary to perform the R&D Services.* |
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| **Demonstrate the Contractors relevant expertise and working experience required to undertake an innovative R&D project such as Instand-NGS4P by presenting a table of staff working on the specific contract (including for sub-contractors), indicating their years of experience and their role in performing the contract. (Short CVs of key persons (max. 2 pages each) and description of references and previous projects).** |
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**3. TECHNICAL CRITERIA - Analytical Performance, Usability, Standardization, Integration into complete workflow**

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| **Please demonstrate how your Solution will meet the Minimum Requirements (Chapter 3.4.2) and the Technical Criteria (Chapter 3.4.3) for Lot 1 as specified in the Request for Tender (see also the details of each criteria described in Chapter 3.4.3), in terms of analytical performance to be verified by Buyers, Usability, Standardization, Integration into complete workflow.**  Please specifically address the following points*:*  - Minimum Requirements:  a) Actionable variant genes and variant types of tumour entities listed in Table 1  b) Gene variants relevant for pharmacogenomics listed in Table 2  - Technical Criteria: please consider that this section will be scored according to the criteria below.  Please note that the degree of innovation influences the scoring of the technical award criteria (see RfT p.90). Therefore, the innovative features should be described clearly under each criterion below (in addition to Point 4. Innovativeness):  A13) SAMPLE STABILIZATION  *Evaluation of the performance data generated by the Contractor in Phase 2 including the solution for metrological traceability and considerations for applicable ISO standards and requirements of the IVDR. Special emphasis will be placed on how the Contractor will make the solution available to the Buyers for verifying the performance and to evaluate the usability of the prototype. In addition, it will be evaluated how the solution will be integrated into the NGS workflow.*  A14) ON NUCLEIC ACID EXTRACTION  *Quality of the performance data generated by the Contractor in Phase 2 including the solution for metrological traceability and considerations for applicable ISO standards and requirements of the IVDR. Quality of the R&D proposal of the Phase 3; special emphasis will be placed on how the Contractor will make the solution available to the Buyers to verify the performance data and evaluate the usability of the prototype. In addition, it will be evaluated how the solution will be integrated into the NGS workflow.*  A15) QUALITY CONTROL OF NUCLEIC ACID EXTRACTION  *Quality of the performance data generated by the Contractor in Phase 2 including the solution for metrological traceability and considerations for applicable ISO standards and requirements of the IVDR. Special emphasis will be placed on how the Contractor will make the solution available to the Buyers to verify the performance data and evaluate the usability of the prototype. In addition it will be evaluated how the solution will be integrated into the NGS workflow.*  A16) LIBRARY PREPARATION  *Quality of the performance data for library preparation generated by the Contractor in Phase 2 including the solution for metrological traceability and considerations for applicable ISO standards and requirements of the IVDR; special emphasis will be placed on how the Contractor will make the solution available to the Buyers to verify the performance data and evaluate the usability of the prototype. In addition it will be evaluated how the solution will be integrated into the NGS workflow.*  A17) QUALITY CONTROL OF LIBRARY PREPARATION  *Quality of the performance data on QC samples generated by the Contractor in Phase 2 including the metrological traceability and considerations for applicable ISO standards and requirements of the IVDR. Special emphasis will be placed on how the Contractor will make the solution available to the Buyers to verify the performance data and evaluate the usability of the prototype. In addition, it will be evaluated how the solution will be integrated into the NGS workflow.* |
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**4. INNOVATIVENESS**

The Instand-NGS4P Pre-Commercial Procurement is aimed specifically at pushing innovation in the field of personalized medicine using NGS workflows for cancer diagnostics. The proposed Solution can build on existing technologies or applications, but has to go *beyond* the current State of the Art.

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| **Describe clearly how the Solution is innovative in comparison to existing solutions.** |
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**5. USER NEEDS**

The Instand-NGS4P Pre-Commercial Procurement is specifically aimed at developing solutions that meet the user needs (clinical and patient) as described in the OMC outcome (see https://www.instandngs4p.eu/pcp/open-market-consultation/.

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| **Describe how the Solution specifically addresses the user needs described in the OMC outcome.** |
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