



PCP Framework Agreement

Integrated and standardized NGS workflows for Personalised therapy

Project acronym: Instand-NGS4P

Grant Agreement Number: 874719

PREAMBLE

This is a framework agreement ("Agreement" or "Framework Agreement") between the following Parties:

on the one part,

the "Lead Procurer", **MEDIZINISCHE UNIVERSITAT GRAZ (MUG)**, established in Auenbruggerplatz 2, 8036 Graz, Austria,

acting in the name and on behalf of the other procurers in the buyers group (other procurers in the buyers group together with the Lead Procurer: "**Procurers**"):

1. **UNIVERSITA DEGLI STUDI DI FIRENZE (UNIFI)**, established in Piazza San Marco 4, Florence 50121, Italy, VAT number: IT01279680480,
2. **ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM (EMC)**, established in DR MOLEWATERPLEIN 40, ROTTERDAM 3015 GD, Netherlands, VAT number: NL801427228B01,
3. **ST. ANNA KINDERKREBSFORSCHUNG GmbH (CCRI GmbH)**, established in ZIMMERMANNPLATZ 10, WIEN 1090, Austria, VAT number: ATU75914147
4. **UNIVERSITA' DEGLI STUDI DI MILANO-BICOCCA (UNIMIB)**, established in PIAZZA DELL'ATENEO NUOVO 1, MILANO 20126, Italy, VAT number: IT12621570154,
5. **UNIVERSITATSKLINIKUM SCHLESWIG-HOLSTEIN (UKSH)**, established in Ratzeburger Allee 160, Lübeck 23538, Germany, VAT number: DE814167313,
6. **CENTRE DE LUTTE CONTRE LE CANCER LEON BERARD (CLB)**, established in RUE LAENNEC 28, LYON 69373, France, VAT number: FR06779924133,

and on the other hand, the "Contractor" [insert details of the contractor], or for joint tenders: acting in the name and on behalf of the other members of group of tenderers:

1. [insert the details of the members of the group of tenderers]
- 2.

The members of the group of tenderers are hereafter collectively referred to as "the Contractor" and will be jointly and severally liable vis-à-vis the Lead Procurer for the performance of this Framework Agreement and the Specific Contracts.

The Lead Procurer, buyers group and the Contractor(s) shall be referred to together as "Parties", unless otherwise specified.

WHEREAS:

- The Procurers participate in the Instand-NGS4P, PCP Project co-funded by the European Commission under the H2020-program, Grant Agreement No. 874719;
- The Procurers have signed the Grant Agreement No. 874719, governing the conditions under which the Consortium has received funding from the EU;
- For the purpose of procuring two complete workflows for next generation sequencing (NGS) on common and rare adult and paediatric cancers as a R&D PCP service, the Parties have decided to engage in a Joint Procurement Procedure.

HAVE AGREED ON THE FOLLOWING:

The Lead Procurer nominated by the Procurers, in accordance with the public procurement principles governing the selection of the Contractor, proceeded with the selection of Contractors through a European Joint Pre Commercial Procurement procedure, initiated on 15-10-2021 by the publication of the Contract Notice for the implementation of the action aforementioned – Tender Number [...];

- The Contractor has submitted an offer for the implementation of the Instand-NGS4P PCP Project on the development of a complete workflow for NGS sequencing on common and rare adult and paediatric cancers as a R&D PCP service, and has subsequently qualified for the awarding of a contract for Phase 1 (one) of the above mentioned procedure and consequently, has expressly manifested his/her will to undertake to provide the subject matter of this Framework Agreement, at terms and conditions set forth below;
- The Lead Procurer will make use of the Contractor's specialist expertise, which will use professional resources with the knowledge and experience necessary to implement the activities set forth in this Framework Agreement;
- The Contractor declares that the "Contract Notice for the realization of a Research & Development Project (Pre-Commercial Procurement) on Instand-NGS4P", the "Request for Tender", all the declarations submitted in accordance with the templates provided by Annexes A-F of the Request for Tender, the "Framework Agreement", the Tender Submission forms contents and the specific annexes and/or additional documentation, define adequately and completely the object of the R&D Services to be provided. Moreover, the Contractor declares that they, in any case, were able to understand all elements of the documents mentioned here, for a suitable technical and economic evaluation of them and for the formulation of an offer;
- This preamble, the deeds and documents mentioned in the same preamble and in the remainder of this Framework Agreement, including the "Contract Notice for the implementation of a Research and Development Project (Pre-Commercial Procurement) on Instand-NGS4P", the "Request for Tender", and the documents attached to the same or complementary, although not physically annexed to this Agreement, are an integral and essential part of the Framework Agreement. The document "Contractor's Tender", submitted by the Contractor, also constitutes an integral and substantial part of this Framework Agreement.

By signing this Agreement the Parties agree to implement the pre-commercial procurement in accordance with the Agreement and all the obligations it sets out.

The Agreement is composed of:

- Preamble
- Terms and Conditions

- Annex 1 Request for Tenders
- Annex 2 Contractor's tender (General Submission Form, Technical Submission Form, Financial Submission Form, Exclusion Criteria, Selection Criteria, ON/OFF Criteria)
- Annex 3 Specific Contract for Phase

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TERMS AND CONDITIONS

Article - 1 Definitions

For the purpose of this Agreement, the terms with a capital shall have the following meaning:

- (a) Agreement (Framework Agreement): This agreement.
- (b) Award Criteria: The criteria for each Phase used to identify by the PCP Evaluation Committee the most technically and economically advantageous tender;
- (c) Confidential Information: Information that falls within the types of information which has been designated as confidential by either Party or that ought to be considered as confidential by a reasonable business person (however it is conveyed or on whatever media it is stored)

including information which relates to the business affairs, properties, assets, trading practices, goods, Services, developments, trade secrets, Intellectual Property Rights, know-how, personnel, customers and suppliers of either Party, all Personal Data and sensitive Personal Data within the meaning of the Data Protection Directive (officially Directive 95/46/EC) and its successor the Data Protection Regulation (EU) 2016/679 and the PCP Project, including its deliverables and other commercially sensitive information.

- (d) Completion Date: The date for the completion of an individual Phase or for the Project as whole.
- (e) Contract/Specific Contract: A contract concluded between the Lead Procurer and a Contractor resulting from the Joint Procurement Procedure on the basis of a framework contract.
- (f) Contractor: A natural or legal person, who acts on its own behalf or in the name and on behalf of the other members of group of tenderers, with whom this Framework Agreement has been concluded.
- (g) Contractor's Representative: A person authorized to represent the Contractor in respect of this Framework Agreement.
- (h) Contractor's Staff: the Contractor's Representative and all employees, consultants, agents, and subcontractors (including their staff) which the Contractor engages in relation to a Phase;
- (i) Contractor's Tender: all the Tender Documents completed by the Contractor including the technical and financial offer.
- (j) Days: Calendar days except where the context otherwise requires.
- (k) Default: Any breach by a Party to this Framework Agreement of its obligations under this Framework Agreement (including, without limitation, a fundamental breach or breach of a fundamental term.
- (l) Direct Contract: A public contract resulting from a joint procurement procedure and signed by a Contractor and one or more Contracting Party(ies).
- (m) Fair and reasonable market conditions: Appropriate conditions, including financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access (for example, the actual or potential value of the Results or Pre-existing rights to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged).
- (n) 'Generated in the PCP Project': Generated in activities described in the PCP Framework Agreement or Specific Contracts
- (o) Grant Agreement: Grant Agreement NUMBER 874719 — Instand-NGS4P with document Ref. Ares (2019)7504930 - 05/12/2019.
- (p) H2020: The Horizon 2020 Programme of the European Union.
- (q) Intellectual Property Rights: patents, inventions (whether or not patentable or capable of registration), trademarks, service marks, copyrights, topography rights, software, design rights and Database rights, (whether or not any of them are registered or registerable and including applications for registration, renewal or extension of any of them), trade secrets and rights of confidence, trade or business names and domain names and all rights or forms of protection of a similar nature which have an equivalent effect to any of them which may now or in the future exist anywhere in the world.
- (r) Joint Procurement/Joint Procurement Procedure: Combining procurement actions of the Procurers.

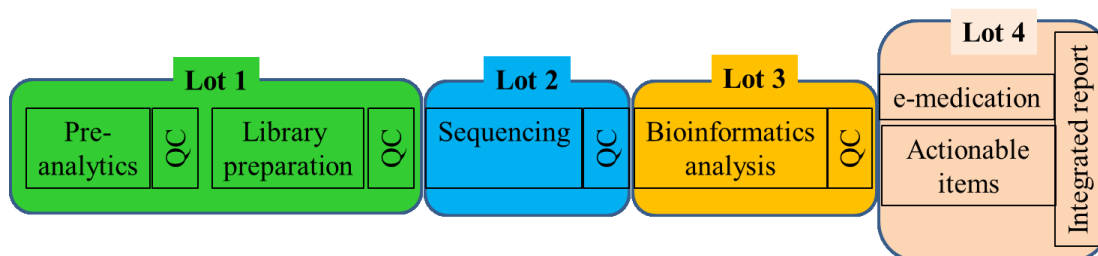
- (s) Lead Procurer: MUG in the role of representative of the other Procurers pursuant to this Agreement.
- (t) OMC: Open Market Consultation supporting the subsequent preparation of the request for tenders.
- (u) Party: A Party to this Agreement.
- (v) PCP Evaluation Committee (PCPEC): Evaluation Committee of the PCP Instand-NG4P as described in the Grant Agreement.
- (w) Pre-existing rights (i.e. background): Any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as Intellectual Property Rights— that is held prior to the signing of the Framework Agreement, identified by the Parties involved in the PCP as background and needed to implement the PCP or exploit the Results.
- (x) Price: The total Price (excluding VAT) agreed between the Parties for each Phase of the PCP Project, to be paid by the Lead Procurer to the Contractor for each such Phase, subject to the terms and conditions of this Agreement.
- (y) Procedure: Three-phased Joint Pre-Commercial Procurement Procedure to procure R&D Services designed as followed: Driven by patient and clinical needs, two innovative NGS workflows (panel-based or whole exome/genome sequencing) from sample-pre-analytics to medical decision-making will be developed for routine diagnostics of common and rare adult and paediatric cancers complying with the IVDR. Criteria for inclusion of certain cancer types and subtypes are common patterns between adult and paediatric types, well-defined genetic markers for diagnosis, validated prognostic genetic markers and the availability of validated actionable genetic markers. The modular design of the workflow (4 lots) will enable SMEs in particular to contribute, and provides flexibility to adopt emerging user needs and technologies.
- (z) Procurers: All procurers in the buyers group together with the Lead Procurer.
- (aa) PCP: Pre-Commercial Procurement as defined by the European Commission.
- (bb) PCP Project: The R&D Services as well as delivery of a software solution that are required by Contractors to complete Phases 1, 2 and 3 and to generate the Results.
- (cc) Project Period: The period commencing on the date of the signature page and ending on the Completion Date (Phase by Phase) or such later date as may be agreed between the Parties for the completion of a particular Phase or the PCP Project.
- (dd) R&D Services: Research and development services including tasks, deliverables and milestones performed by the Contractor and as set out in the Technical Offer and the Request for Tender document for the specific Phases.
- (ee) Results (i.e. foreground): Any tangible or intangible output, such as data, knowledge or information, that is generated in the PCP Project, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including Intellectual Property Rights.
- (ff) Sideground: Any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as Intellectual Property Rights that is generated during the timespan of the PCP Project but not in the PCP Project and needed to implement the PCP Project or to exploit the Results.

- (gg) Technical Offer: Research and development services described by the Contractor in the Technical Submission Form (Annex B of the Request for Tender).
- (hh) Tender Documents: All documents issued or published by the Lead Procurer as part of the PCP process and made available on the Instand-NGS4P project website, including - without limitation - the TED Contract Notice, the Request for Tender, the Framework Agreement, annexes or attachments there to, and any schedules.

Article - 2 Introduction

The 7 clinical centres (Procurers) decide to procure jointly in a pre-commercial step, to achieve the ambitious objectives. Suppliers will be selected based on public tenders all along this PCP process comprising 3 phases according to the best value for money solution, after the closure of the preparation phase. This preparation phase involved an Open Market Consultation (OMC) (supporting the subsequent preparation of the request for tenders) to ensure proper alignment between the patient and clinical needs with the 7 clinical centres – representing a guarantee on developing the required critical mass to achieve this ambitious program, and the R&D service providers' community concerning technical feasibility as well as the regulatory and payers' bodies. Based on the feedbacks from the OMC, the request for tenders will be published for PCP R&D Services suppliers addressing the requirements of all 3 PCP phases in a single call. These 3 phases foresee the leverage of the 4 technical Lots (i.e., on pre-sequencing, sequencing, bioinformatics, integrated reporting) and their standardized interfaces, to be assembled in a fully integrated NGS workflow (Figure 1).

Figure 1. Schematic drawing of the integrated NGS workflow composed of 4 technical Lots



Article - 3 Subject of the Framework Agreement

This Framework Agreement defines the general terms and conditions for the implementation of the PCP procurement of R&D Services set out in Article 5 and for the Specific Contracts that will be awarded for each of the 3 PCP phases.

Article - 4 Duration

The PCP Project is divided into the following phases:

- The first phase will address the design stage (Phase 1), for each Lot.
- The second phase will concentrate on prototypes (Phase 2) for each Lot.
- The third phase aiming at full integration of the 4 Lots into complete workflows.

At the end of Phase 3, Instand-NGS4P will provide 2 fully integrated, standardized NGS workflows for routine diagnostics of common and rare cancers from adults to children.

The Framework Agreement becomes effective upon signing by the Parties and shall remain in effect (unless terminated in accordance with Article 26) until the Completion Date of Phase I or of a later Phase that has been awarded to the Contractor. However, confidentiality obligations and provisions shall remain applicable for five (5) years after the end of the Framework Agreement in accordance to Article 15. Contractors who are awarded contracts for the Phases II and III shall sign a Specific Contract for that particular phase.

Article - 5 R&D Services to be provided

- 5.1. The contractor shall provide the R&D Services (tasks, deliverables and milestones) to develop solutions to tackle the challenge set out in the Request for Tenders.
- 5.2. The Contractor, including its subcontractors, shall perform at least 50% of the R&D Services in each Phase within the EU Member States or H2020 Associated Countries, and the principal R&D staff employed by the Supplier and working on each Phase must be located within the EU Member States or the H2020 Associated Countries. The percentage shall be measured in terms of the total price of each Specific Contract allocated to the R&D Services that are performed in the EU Member States or H2020 Associated Countries. The total amount of activities shall include all activities covered by each Specific Contract, including those performed by subcontractors.

Article - 6 Succession of Phase 1, Phase 2 and Phase 3 of the PCP Project

- 6.1. By the signing of the Framework Agreement, the Lead Procurer and the Contractor accept the general conditions set by this Framework Agreement. In case the Contractor is awarded specific formal assignments per Phase, these have to be signed by the Lead Procurer and the Contractor. This assigns to the Contractor the task of performing the R&D Services within the scope of respective Phase 1, Phase 2 and Phase 3 of the PCP Project. The Contractor acknowledges that the Lead Procurer will simultaneously enter into similar contractual arrangements for the PCP Project with other Contractors.

6.2. Assessment of Phase I and award of Phase II

On the Completion Date of Phase I, the Contractor shall submit to the Procuring Entity an "End of Phase Report" regarding such Phase together with the deliverables belonging to Phase I, which shall thereupon be reviewed and assessed by the PCP Evaluation Committee in order to determine whether the Contractor has complied with the Technical Offer. Such assessment shall be performed at any time between the Completion Date of Phase I and the starting date of the next Phase, but in any case prior to the latter.

The Evaluation committee shall issue its decision regarding the satisfactory or successful completion of Phase I, not earlier than two (2) weeks and not later than eight (8) weeks after the Completion Date of Phase I. In case the volume of Contractors leads to a longer evaluation process the Contractors will be informed.

- In case of contractors that have not satisfactorily completed Phase I, the Contractor needs to repay the reimbursement of the pre-payment to the Procuring Entity, the Contractor will not receive the payment for the work carried out in Phase I, and the Contractor will be excluded from proceeding to Phase II.
- In case of contractors that have satisfactorily, but not successfully completed Phase I, the Contractor will be entitled to the payment for the work carried out in Phase I, but will be excluded from proceeding to Phase II.
- In case of contractors that have successfully completed Phase I, the Contractor will be entitled to the payment for the work carried out in Phase I and his proposal for Phase II will be evaluated and a decision reached as to its advancement to Phase II.

If the Contractor is selected for Phase II, this Agreement shall continue in effect for the duration of the following Phases. The Contractor shall thereupon sign a formal assignment relevant to that phase. In addition, if the Contractor is not selected for Phase II, this Agreement shall, without prejudice to any surviving clauses, cease to have any effect upon the date announced by the Procuring Entity for final award of Phase II.

6.3. Assessment of Phase II and award of Phase III

On the Completion Date of Phase II, the Contractor shall submit to the Lead Procurer an End of Phase Report regarding such Phase together with the deliverables belonging to Phase II, which shall be reviewed and assessed by the PCP Evaluation Committee in order to determine whether the Contractor has complied with the Technical Offer. Such assessment shall be performed at any time between the Completion Date of Phase II and the starting date of the next Phase, but in any case prior to the latter.

The PCP Evaluation Committee shall issue its decision as to the award of the Phase III acceptance, after evaluation of the prototypes (approximately two months) after the Completion Date of Phase II.

- In case of contractors that have not satisfactorily completed Phase II, the Contractor needs to repay the reimbursement of the pre-payment to the Procuring Entity, the Contractor will not receive the payment for the work carried out in Phase II, and the Contractor will be excluded from proceeding to Phase III.
- In case of contractors that have satisfactorily, but not successfully completed Phase II, the Contractor will be entitled to the payment for the work carried out in Phase II, but will be excluded from proceeding to Phase III.
- In case of contractors that have successfully completed Phase II, the Contractor will be entitled to the payment for the work carried out in Phase II and his proposal for Phase III will be evaluated and a decision reached as to its advancement to Phase III.

If the Contractor is selected for Phase III, this Agreement shall continue in effect for the duration of that Phase. The Contractor shall thereupon sign a formal assignment relevant to that phase. In addition, if the Contractor is not selected for Phase III, this Agreement shall, without prejudice to any surviving clauses, cease to have any effect upon the date announced by the Procuring Entity for final award of Phase III.

- 6.4. In this Agreement, "successful completion" of a Phase shall be assessed by PCP Evaluation Committee in terms of overall compliance with the Technical Offer.
- 6.5. Any award for Phases II and III will be communicated in writing by the Lead Procurer to the Contractor.
- 6.6. Any reference in this Framework Agreement to the Project refers also to any of the Phases awarded to the Contractor.
- 6.7. In each Phase at least 50% of the Services shall be performed within the EU Member States, or a country that is associated to H2020.
- 6.8. The Lead Procurer reserves the right not to award contracts for Phases for which it has not received any favourable or suitable or acceptable offer in relation to the Project; to stop, cancel, revoke, re-issue the PCP or not to award any Phase Contract for objective reasons. The Lead Procurer assumes no obligation whatsoever to compensate or indemnify the Contractors or Contractors for any expense or loss that may occur in the preparation of their tenders.

Article - 7 Administration and Direction of the PCP Project

- 7.1. The Contractor shall ensure that each member of the Contractor's Staff engaged on the PCP Project observes the terms and conditions of this Agreement and any amendment entered into between the Parties hereto, and that the Contractor's Staff are advised of any changes in the scope of the Agreement or the PCP Project.
- 7.2. Considering the rapid development of science and technology related to NGS, modifications to Technical Offer shall be made possible on the basis of mutual agreement by the Parties. These modifications will be added as an amendment to the existing Technical Offer.
- 7.3. Notwithstanding the provisions of Article 26, the Lead Procurer may terminate this Framework Agreement with a Contractor if any of the Contractor's key staff are not available for the period needed to fulfil their duties in the PCP Project, subject to prior discussion having first been held with the Contractor to attempt to identify and agree a mutually acceptable replacement and where the lack of availability of one or more of the key staff causes a material risk to the fulfilment of the delivery objective of the PCP Project.
- 7.4. The objectives and requirements of the PCP Project are set out in the Request for Tender. Within the limits of such objectives and requirements, the details of the exact program to be followed and the day-to-day responsibility for carrying out this program will be under the control of the Contractor, in consultation, where appropriate, with the Lead Procurer's representative.
- 7.5. The Contractor shall inform the Lead Procurer on a regular basis and, in any case, promptly upon the Lead Procurer's first request, of the progress of the PCP Project. In particular, the Contractor shall notify the Lead Procurer of any proposed deviation from the agreed scope of work or if significant developments occur as the research and development work progresses as

soon as possible after the Contractor becomes aware of the necessity or usefulness of such deviation.

- 7.6. The Contractor shall ensure full communication takes place between the Parties and such others as may be notified to the Contractor by the Lead Procurer and shall advise as required on the PCP Project.
- 7.7. Notwithstanding the provisions of Article 26, the Lead Procurer may terminate this Framework Agreement forthwith should the Contractor be unwilling or unable for any reason to continue with the PCP Project or if, in the reasonable opinion of the Lead Procurer, the Contractor is consistently failing to achieve an acceptable standard in relation to the PCP Project. If this occurs, the Lead Procurer shall not be obliged to make any further financial payment to the Contractor.

Article - 8 End of Phase Report and Evaluation

- 8.1. The Contractor shall provide an End of Phase Report on each relevant Phase of the Project, in English, within 14 Days as of the Completion Date. The End of Phase Report shall be in the form as provided by the Procurers, and shall further be in compliance with the guidance notes issued by the Procurers as amended from time to time or as otherwise required by the Procurers, and shall include for each Phase the description of the deliverables and milestones including detailed description of the relevant solution, methods, data generated, results, final conclusions together with management information and any other information relating to the PCP Project including explanations for any deviations from the Technical Offer up to the Completion Date.
- 8.2. Procurers are entitled to carry out a visit to the Contractor's premises at any time for the purpose of due diligence and evaluation in respect of the Project.

Article - 9 Obligations of the Contractor and the Lead Procurer

- 9.1. The Contractor shall manage and complete the PCP Project in accordance with the Agreement, in particular the Tender Documents and shall in each Phase of the PCP Project allocate sufficient resources to such Phase to enable it to comply with its obligations in such Phase.
- 9.2. The Contractor shall meet, with time being of the essence, delivery in any performance dates, including but not limited to End of Phase Reports and related deliverables. If the Contractor fails to do so, the Lead Procurer may, after giving the Contractor not less than 14 Days' notice of its intention (without prejudice to any other rights it may have):
 - (a) terminate this Agreement in whole or in part without liability to the Contractor;
 - (b) refuse to accept any subsequent performance of the PCP Project which the Contractor attempts to make;
 - (c) hold the Contractor accountable for any loss and additional costs incurred; and
 - (d) have all sums previously paid by the Lead Procurer to the Contractor under the Phase which is then running, refunded by the Contractor.
- 9.3. The Contractor shall:
 - (a) co-operate with the Lead Procurer in all matters relating to the PCP Project;
 - (b) subject to the prior written approval of the Lead Procurer, appoint or, at the written request of the Lead Procurer, replace without delay the Contractor's Representative; and

- key staff or any member of the Contractor's team, who shall be suitably skilled, experienced and qualified to carry out the PCP Project.
- (c) procure the availability of the Contractor's Representative and key staff for the purposes of the PCP Project;
 - (d) promptly inform the Lead Procurer of the absence of the Contractor's Representative and/or key staff. If the Lead Procurer so requires, the Contractor shall provide a suitably qualified replacement;
 - (e) not make any changes to the Contractor Representative, subcontractors or the key staff without the prior written approval of the Lead Procurer, such approval not to be unreasonably withheld or delayed; and
 - (f) ensure that the Contractor's team uses reasonable skill and care during the PCP Project.
 - (g) be responsible for the accuracy of all drawings, documentation and information supplied to the Lead Procurer in connection with delivery of this Framework Agreement.
 - (h) observe, and ensure that the Contractor's team observes, all rules and regulations and any other reasonable requirements of the Lead Procurer;
 - (i) acknowledge and adjust to any modification with respect to the Technical Offer as mentioned in Article 7 of this Framework Agreement;
 - (j) notify the Lead Procurer as soon as it becomes aware of any issues which arise in relation to the PCP Project; and
 - (k) before the commencement date, obtain, and at all times maintain all necessary licenses and consents and comply with all relevant legislation in relation to the PCP Project, except for those licenses and consents that are related to the outcome of a specific Phase.
- 9.4. The Contractor acknowledges and agrees that the Contractor is entering into this Framework Agreement on the basis that the details of the PCP Project are accurate and complete in all material respects, and are not misleading.
- 9.5. The Lead Procurer shall:
- (a) co-operate with the Contractor in all matters relating to the PCP Project and appoint (and replace, if appropriate) the Lead Procurer's representative;
 - (b) provide such access to the Lead Procurer's premises and sensitive data, if it is in accordance to data-protection officials, and such office accommodation and other facilities as may reasonably be requested by the Contractor and agreed rules and regulations with the Contractor in writing in advance, for the purposes of the PCP Project;
 - (c) provide such information as the Contractor may reasonably request and the Contractor considers reasonably necessary, in order to carry out the PCP Project, in a timely manner, and ensure that it is accurate in all material respects; and
 - (d) inform the Contractor of all health and safety and any other reasonable security requirements that apply at any of the Lead Procurer's premises.

Article - 10 Pricing, payment and accounting

- 10.1. The price for the R&D services to be implemented for each PCP phase will be set out in the Specific Contracts.
- 10.2. The prices shall be based on the binding unit prices in the tender and the following price conditions:

- (a) if new units/unit prices are added to phase 2 or 3 offers, they shall become binding for the remaining phases
 - (b) All (unit) prices shall be net, firm, exonerated from taxes and customs duties, not exceed the relevant amounts set out in the Specific Contracts, and be inclusive of all costs and expenses related to the performance of the Framework Agreement, including all costs related to the delivery and insurance of the R&D Services.
- 10.3. The payment framework for each Phase shall be as set out in the Framework Agreement. The specific payment conditions for each Phase shall be set out in the Specific Contract for that Phase.
 - 10.4. The Contractor shall submit his invoices to the Lead Procurer not later than thirty (30) days following the acceptance by the Lead Procurer of the R&D Services. The Contractor's invoices shall be paid by the Lead Procurer within thirty (30) days after receipt and acceptance of a correct invoice for the amount(s) specified in the Specific Contract(s).
 - 10.5. Payments to subcontractors, engaged by the Contractor, if any, shall be the exclusive responsibility of the Contractor.
 - 10.6. Where any amount is payable by the Contractor to the Lead Procurer under the Framework Agreement, the Lead Procurer may deduct the same from any amount payable by it to the Contractor.
 - 10.7. The Contractor accepts, upon first request from the Lead Procurer, to provide the Lead Procurer with complete, relevant and clear information as well as documentary evidence about the allocation of monies paid by the Lead Procurer.
 - 10.8. Payments to third parties employed or hired by the Contractor, if any, shall remain the responsibility of the Contractor who shall ensure that such payments are made promptly and shall hold the Lead Procurer harmless against any claim of such third parties.
 - 10.9. During the Project Period payments will be made by the Lead Procurer pursuant to invoices issued to the Lead Procurer. The Lead Procurer may suspend this payment at any time if, in the view of the Lead Procurer, acting reasonably, satisfactory progress on the PCP Project has not been maintained, or reports have not been submitted as required under Article 8.
 - 10.10. Without prejudice to Article 28 below, the Parties expressly agree that the Contractor shall not make any changes to the PCP Project, or to the total amount payable under the Agreement, without the prior written approval of the Lead Procurer.
 - 10.11. Subject to the confidentiality obligations set forth in Article 15, the Contractor grants to the Lead Procurer, acting, as the case may be, through agents authorized for that purpose, and to any statutory or regulatory auditors of the Lead Procurer, a right to access (and, if necessary to copy) the relevant financial records during normal business hours.
 - 10.12. The Contractor shall provide all reasonable assistance at all times during the term of the Agreement and during a period of seven (7) years after termination or expiry of this Agreement for any reason whatsoever, for the purposes of allowing the Lead Procurer to obtain such information as is necessary to fulfil the Lead Procurer's obligations to supply information for national or supra- national parliamentary, governmental, judicial or other administrative purposes and/or to carry out an audit of the Contractor's compliance with this Agreement including all activities, performance, security and integrity in connection therewith.

- 10.13. If at any time an overpayment has been made to the Contractor for any reason whatsoever, the amount of such overpayment shall be taken into account in the assessing of any further payments, or shall be recoverable from the Contractor at the Lead Procurer's discretion.
- 10.14. The Contractor shall keep and maintain, up until at least seven (7) years after this Agreement has been completed, full and accurate records of the PCP Project including:
 - (a) all aspects of the PCP Project;
 - (b) all expenditure paid by the Lead Procurer; and
 - (c) all payments made by the Lead Procurer, and the Contractor shall on request allow the Lead Procurer or the Lead Procurer's representatives such access to those records as may be required in connection with the Agreement.
- 10.15. Where the Contractor enters into a subcontract with a supplier or contractor for the purpose of performing the Contract, it shall cause a term to be included in such a subcontract that requires payment to be made of undisputed sums by the Contractor to the subcontractor within a specified period not exceeding thirty (30) Days from the receipt of a valid invoice, as defined by the subcontract requirements.
- 10.16. Wherever, under the Contract, any sum of money is recoverable from or payable by the Contractor (including any sum that the Contractor is liable to pay to the Lead Procurer in respect of any breach of the Contract), the Lead Procurer may unilaterally deduct that sum from any sum then due, or which at any later time may become due to the Contractor under the Contract or under any other agreement with the Lead Procurer.
- 10.17. The Contractor shall make any payments due to the Lead Procurer without any deduction whether by way of set-off, counterclaim, discount, abatement or otherwise, unless the Contractor has a final and enforceable court order requiring an amount equal to such deduction to be paid by the Lead Procurer to the Contractor.
- 10.18. The Lead Procurer presume that the intention is to prevent abnormal price offers, price estimation for research prices, and calculations of future market price of solutions. In case of suspicion of abnormal price offers the robustness of calculation has to be declared to the Procurers.

Article - 11 Pre-existing rights and access to Pre-existing rights

- 11.1. All Pre-existing rights and Sideground remain the property of the Party introducing the same (or any third party supplier that owns it) and nothing contained in this Framework Agreement or any license contract pertaining or pursuant to the PCP Project shall affect the ownership rights of either Party (or any third party) in its Pre-existing rights and Sideground.
- 11.2. The Contractor shall, within thirty (30) Days of the signature of the Framework Agreement, provide the Lead Procurer with a list of its Pre-existing rights it holds and/or has access to that are needed to perform the PCP Project, including but not limited to, a list of the software necessary for the operation of the PCP Project, specifying which software is closed source software, as well as a list of prior obligations that may apply to Results. The Contractor shall provide an updated list of its Pre-existing rights at each Phase.
- 11.3. The Contractor will provide each of the Procurers an irrevocable, indefinite, worldwide, royalty-free and non-exclusive license to use all Pre-existing rights and Sidegrounds that are needed to perform the PCP Project for the purpose of executing the PCP Project as well as for using

the Results for further non-commercial research purposes, including clinical trials set up to test the validity of the Results.

Article - 12 Ownership of the Results and access rights to Results

- 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.
- 12.2. If the Contractor (or any of its subcontractor) generates Results, whether the Contractor (or subcontractor) intends to file for protection of it or not, the Contractor shall within one (1) Month from such generation inform the Procurers (via the Lead Procurer) about the contents of such Results.
- 12.3. If the Contractor does not seek protection for Results, the Procurers have the right to request (via the Lead Procurer) that the Results are transferred to them on fair and reasonable market conditions subject to a separate agreement to file for protection.
- 12.4. The Lead Procurer shall have the right to grant or to require the Contractor to grant non-exclusive licenses to third parties to exploit the Results, including the Pre-existing rights and Sidegrounds that are needed to perform the PCP Project/use the Results under fair and reasonable market conditions without any right to sublicense. The Contractor and these third parties are responsible for establishing the fair and reasonable market conditions.
- 12.5. Access rights to the Results of the Contractor that are an implementation of design specifications into simulations, prototypes, software, demonstrators or first products/services, are limited for the Procurers to a duration of four (4) years and to the purposes for fulfilling the R&D objectives of the PCP Project.
- 12.6. The Contractor may transfer the ownership of its Results (unless this is prohibited or restricted by the security obligations) to a third party provided that the latter undertakes to the Procurers to be bound by and perform the obligations of the Contractor under the Framework Agreement, and that the transferee agrees to pass on these obligations in any subsequent transfer.
- 12.7. The Contractor must give the Lead Procurer at least forty-five (45) Days advance notice of its intention to transfer ownership of the Results. Contractors's notification shall include sufficient information from the new owner to enable the Procurers to assess the effects on their access rights. The Procurers can object within thirty (30) Days of receiving notification, if it can show that the transfer would adversely affect its access rights. If the Procurers object the notification, the transfer may not take place until agreement has been reached between the Parties concerned.
- 12.8. The Contractor shall ensure that it complies with its obligations under the Framework Agreement and Specific Contracts if it uses subcontractors; that it shall obtain all necessary rights (transfer, licences or other) from subcontractors, as if they were generated by itself; that the Contractor should refrain from using subcontractors if obtaining those rights is impossible.

Article - 13 Exploitation of Results

- 13.1. The Contractor shall inform the Lead Procurer of any Results which are capable of commercial exploitation, whether patentable or not.
- 13.2. Unless otherwise provided in the Agreement and subject to Article 14, the Contractor shall take all appropriate and necessary measures to ensure the proper management of the Results.
- 13.3. The Contractor shall at its own costs be responsible for the application, examination, grant, maintenance, management and defence of the Intellectual Property Rights in the Results and in particular, but without limitation, it shall ensure that:
 - (a) the Results of the PCP Project are identified, recorded and carefully distinguished from the outputs of other research and development activities not covered by the PCP Project;
 - (b) prior to any publication on the PCP Project, patentable inventions arising from the Results are identified, duly considered for patentability and, where it is reasonable so to do, patent applications in respect thereof are filed at the relevant Member State or European Patent Office; and
 - (c) all such patent applications are diligently executed and prosecuted having regard to all relevant circumstances.
- 13.4. If the Contractor becomes aware of any product or activity of any third party that involves or may involve infringement or other violation of the Results, the Contractor shall promptly notify the Lead Procurer of the infringement or violation.
- 13.5. Unless otherwise provided in this Agreement or unless the Results are assigned to the Procurers pursuant to Article 14, the Contractor shall take all appropriate measures to protect or defend said Results. The Contractor shall have the conduct and bear the costs of such proceedings. The Lead Procurer shall however:
 - (a) have a monitoring/audit right on the conduct of the proceedings and the Contractor agrees to take the Lead Procurer 's comments on the conduct of the proceedings in due consideration, and
 - (b) provide reasonable assistance to the Contractor with respect to bringing any action.
- 13.6. The Contractor shall permit the Lead Procurer to monitor the operation and effectiveness of the Contractor's procedures for the management of Results in such a way as the Lead Procurer considers reasonably necessary.
- 13.7. The Contractor shall ensure the management of Results consistent with the terms and conditions of the present Agreement;
 - (a) the Contractor shall promote the dissemination of the Results of the PCP Project; and
 - (b) where they are capable of exploitation, exploit commercially the Results (even if they cannot be protected by Intellectual Property Rights) to generate revenue by marketing commercial applications thereof;
 - (c) and the Contractor shall refer to its participation to the PCP Project, the means of PCP related to the PCP Project and the H2020 grant of the European Commission.
- 13.8. The Contractor is aware and it shall ensure that the EU have special rights (e.g. protection of the Results and EU ownership).

Article - 14 Commercial exploitation of Results

- 14.1. The Contractor shall, within five (5) years after the end of the Framework Agreement, take measures to ensure that the Results are exploited commercially (directly or indirectly, in particular through licensing). Contractor will report on request of the Lead Procurer about the progress on the commercial exploitation of the Results during the 5-year period aforementioned (max. twice per year).
- 14.2. The Contractor may grant non-exclusive licenses to third parties to exploit the Results to the extent that such licenses do not affect the Procurers' access rights related to such Results.
- 14.3. If the Contractor fails to commercially exploit the Results within this period, or uses the Results to the detriment of the public interest, the Contractor shall at Lead Procurer's request, transfer the ownership of the Results to the Procurers free of costs or sub-licenses IPRs to third parties indicated by the Lead Procurer.
- 14.4. 'Failure to commercially exploit Results' means not marketing a commercial application of the Results (directly or indirectly, through a subcontractor or licensee).

Article - 15 Confidentiality

- 15.1. The Parties shall keep Confidential Information as confidential at the time it is disclosed. This applies during the implementation of the Framework Agreement and Specific Contracts and up to five (5) years after their end.
- 15.2. If information has been identified as confidential only orally, it shall be considered to be confidential only if this is confirmed in writing within fifteen (15) days of the oral disclosure.
- 15.3. The Parties may disclose Confidential Information to their staff or to third parties involved in the PCP implementation only if:
 - (a) they need to be aware of this Confidential Information in order to implement the PCP activities under the Framework Agreement and Specific Contracts; and
 - (b) they are bound by an obligation of confidentiality.
- 15.4. The Procurers may disclose Confidential Information to the EU if required under their Horizon 2020 grant agreement.
- 15.5. The confidentiality obligations cease to apply if:
 - (a) the disclosing Party agrees to release the other Party from the obligation;
 - (b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;
 - (c) the recipient proves that the information was produced without the use of confidential information;
 - (d) the information becomes generally and publicly available, without breaching any confidentiality obligation; or
 - (e) the disclosure of the information is required by EU or national law, competent jurisdiction, court or by government regulation, act or order.
- 15.6. This does not change the security obligations, which still apply. Stricter confidentiality obligations apply for information that is EU-classified or subject to a security recommendation.
- 15.7. The Contractor is fully responsible for the effective performance, by his employees, consultants and collaborators, of the confidentiality obligations herein and undertakes to

impose this confidentiality obligation on all those persons who, as a result of their position, become acquainted – directly or indirectly – with any Confidential Information.

- 15.8. In the event of the Contractor's failure to comply with the confidentiality obligations herein, the Lead Procurer shall be entitled to terminate this Agreement forthwith, subject to prior notice of termination sent by registered letter with acknowledgement of receipt, without prejudice to claim further damages.

Article - 16 Promotion, publicity and communication

- 16.1. The Contractor shall undertake communication activities to create publicity about its participation to the procurement, and to promote the objectives and the results of the R&D carried out under the PCP (in particular to other potential customers beyond the Lead Procurer and the Procurers with the objective to achieve commercial exploitation of the results; see Article 13 – Commercial exploitation of results).
- 16.2. All communication activities shall comply with the applicable confidentiality and security restrictions.
- 16.3. During the implementation of the Contract and for a period of five (5) years after the end of the Contract, the Contractor shall inform the Lead Procurer thirty (30) Days in advance of any (written or oral) publication or any other type of communication (in any media or form) relating to the services or results. Information on communication activities expected to have a major media impact shall be provided sufficiently in advance to allow the Lead Procurer to inform the EU.
- 16.4. All communication activities (including in electronic form and via social media) and infrastructure, equipment and major results financed by the PCP shall display the EU emblem and include the following text:
- (a) for communication activities: 'This is part of the Instand-NGS4P project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme';
 - (b) for infrastructure, equipment and major results: 'This [infrastructure][equipment][insert type of result] is part of the Instand-NGS4P project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme'.
- 16.5. When displayed together with another logo, the EU emblem shall have appropriate prominence. The Contractor may use the EU emblem without first obtaining approval from the EU. This does not, however, give the Contractor the right to exclusive use. Moreover, the Contractor may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.
- 16.6. All communication activities shall indicate that they reflect only the author's views.
- 16.7. The Procurers may use, for the purposes of communication and publicity, all information relating to the PCP, documents (notably summaries) and deliverables, and any other material (such as pictures or audio-visual material) from the Contractor (including in electronic form).
- 16.8. The Procurers may, in particular, publish the names of the participating Contractor and its project abstracts, the summaries of the main results from the R&D and the lessons learnt during the PCP (e.g. relating to the feasibility of the different approaches to meeting the Procurers' requirements that were explored, and the lessons learnt for potential future use of the solutions proposed).

- 16.9. This does not change the confidentiality obligations under Article 15.
- 16.10. Moreover, before publishing this information, the Procurers shall consult the Contractor, in order to avoid harm to legitimate business interests (e.g. regarding aspects of the solutions that could be IPR-protected) or distortion of competition.
- 16.11. The EU may use, for the purposes of communication and publicity, information relating to the PCP, documents (notably summaries) and deliverables, and any other material (such as pictures or audio-visual material) from the Contractor (including in electronic form).
- 16.12. If the EU's use of these materials, documents or information would risk compromising legitimate interests, the Contractor may, however, ask the Lead Procurer to request the EU not to use it.
- 16.13. The right to use the Contractor's materials, documents and information includes:
- (a) use for its own purposes (in particular, making them available to staff working for the EU (including for the European Commission, EU executive agencies, other EU institutions, bodies, offices or agencies) or for EU Member State institutions or bodies; and copying or reproducing them in whole or in part, in unlimited numbers);
 - (b) distribution to the public (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);
 - (c) editing or redrafting for the purposes of communication and publicity (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts or using in a compilation);
 - (d) translation;
 - (e) giving access in response to individual requests made under EU Regulation No 1049/2001¹, without the right to reproduce or exploit;
 - (f) storage in paper, electronic or other form;
 - (g) archiving, in line with applicable rules on document management, and
 - (h) authorising third parties to act on its behalf or sub-licensing the modes of use set out in points (b), (c), (d) and (f) to third parties if needed for the purposes of communication and publicity.
- 16.14. If the right of use is subject to rights of a third party (including the Contractor's staff), the Contractor shall ensure that it obtains the necessary approval from the third parties concerned.
- 16.15. The Contractor, including its subcontractors, shall not use or make reference to any image or logo of any of the Procurers or any of the names under which any of the Procurers is known, without prior permission in writing by the procurer concerned. Any permission shall expire upon termination of the Framework Agreement. The procurer concerned may withdraw any permission granted at any time.

¹ Regulation (EC) No [1049/2001](#) of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

Article - 17 Conflicts of interest

- 17.1. The Contractor shall take all measures necessary to prevent a situation arising where the impartial and objective implementation of the Framework Agreement or a Specific Contract is compromised for reasons involving economic interests, political or national affinity, family, personal life or any other shared interest.
- 17.2. The Contractor shall also take all measures necessary to prevent a situation in which its (previous or ongoing) professional activities affect the impartial and objective implementation of the Framework Agreement or a Specific Contract.
- 17.3. The Contractor shall notify the Lead Procurer without delay of any situation constituting or likely to lead to a conflict
- 17.4. of interest (including changes of ownership) and shall immediately take all steps necessary to rectify this situation.
- 17.5. The Lead Procurer may instruct the Contractor to take specific measures to remedy the situation.

Article - 18 Ethics and research integrity

- 18.1. The Contractor shall carry out the tasks assigned to it in the Framework Agreement and Specific Contracts in compliance with:
 - (a) ethical principles (including the highest standards of work with human biological samples or genetic data) and
 - (b) applicable international, EU and national law.
- 18.2. The Contractor may not:
 - carry out activities in a country outside the EU, if they are prohibited in all EU Member States,
 - attempt the re-identification of patient's samples based on genetic sequencing results or data sequencing generated by the analysis of test samples provided by the Procurers,
 - distribute test samples to third parties not specified in the tender documents.
- 18.3. The Contractor may not carry out activities that do not focus exclusively on civil applications.
- 18.4. The Contractor shall respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity².
- 18.5. This implies compliance with the following essential principles:
 - **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
 - **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
 - **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
 - **accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

² The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

- 18.6. This means that Contractor must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code. In particular, Contractor must ensure that persons carrying out research tasks:
- (a) present their research goals and intentions in an honest and transparent manner;
 - (b) design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
 - (c) use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
 - (d) exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
 - (e) ensure objectivity, accuracy and impartiality when disseminating the results;
 - (f) allow — as much as possible and taking into account the legitimate interest of the contractor — access to research data, in order to enable research to be reproduced;
 - (g) make the necessary references to their work and that of other researchers;
 - (h) refrain from practicing any form of plagiarism, data falsification or fabrication;
 - (i) avoid conflicts of interest and misrepresentation of credentials or other research misconduct.
- 18.7. Before starting any activity that raises an ethical issue, the Contractor shall submit to the Lead Procurer a copy of:
- (a) any ethics committee opinion required under national law and
 - (b) any notification or authorisation for activities raising ethical issues required under national law.

Article - 19 Data Protection

- 19.1. For the purposes of this Article 19, the terms "Controller", "Data Subject", "Personal Data", "Process" and "Processing" shall have the meaning prescribed under the Data Protection Directive (officially Directive 95/46/EC) and its successor the Data Protection Regulation (EU) 2016/679.
- 19.2. The Contractor and the Procures shall (and shall ensure that all of its staff) comply with any notification requirements under the Data Protection Directive (officially Directive 95/46/EC) and its successor the Data Protection Regulation (EU) 2016/679 and all applicable national data protection laws and the Parties will duly observe all their obligations under such EU and national data protection laws which arise in connection with this Framework Agreement.
- 19.3. The Contractor may grant its staff access to Personal Data only in so far as is strictly necessary for implementing, managing and monitoring the Framework Agreement and Specific Contracts.
- 19.4. The Contractor must inform the staff whose Personal Data are collected and processed by the Procurers and/or the EU. For this purpose, the Contractor must provide them with the privacy statements of the Procurers and the EU, before transmitting their Personal Data. If explicit prior consent from the subjects of the Personal Data is needed, the Contractor must obtain such consent.

19.5. Notwithstanding the general obligation above, where the Contractor is Processing Personal Data from the Procurers the Contractor shall:

- (a) Process the Personal Data only in accordance with instructions from the Lead Procurer (which may be specific instructions or instructions of a general nature) as set out in this Framework Agreement or as otherwise notified by the Lead Procurer;
- (b) Comply with all applicable laws;
- (c) Process the Personal Data only to the extent; and in such manner as is necessary for the provision of the provider's obligations under this Framework Agreement or as is required by law or any regulatory body;
- (d) Implement appropriate functional and organizational specifications to protect the Personal Data against unauthorized or unlawful Processing and against accidental loss, destruction, damage, alteration or disclosure. These specifications shall be appropriate to the harm which might result from any unauthorized or unlawful Processing, accidental loss, destruction or damage to the Personal Data and having regard to the nature of the Personal Data which is to be protected;
- (e) Take reasonable steps to ensure the reliability of its staff and agents who may have access to the Personal Data;
- (f) Obtain prior written consent from the Lead Procurer in order to transfer the Personal Data to any subcontractor for the provision of the Services;
- (g) Not cause or permit the Personal Data to be transferred, stored, accessed, viewed or processed outside countries participating in Instand-NGS4P where the PCP Project activities are primarily performed without the prior written consent of the Lead Procurer;
- (h) Ensure that all staff and agents required to access the Personal Data are informed of the confidential nature of the Personal Data and comply with the obligations set out in this Article 20;
- (i) Ensure that none of the staff and agents publish disclose or divulge any of the Personal Data to any third parties unless directed in writing to do so by the Lead Procurer, not disclose Personal Data to any third parties in any circumstances other than with the written consent of the Lead Procurer or in compliance with a legal obligation imposed upon the Lead Procurer; and notify the Lead Procurer within five (5) days if it receives:
 - a request from a Personal Data subject to have access to that person's Personal Data; or
 - a complaint or request relating to the Lead Procurer's obligations under the EU and/or national data protection laws;

19.6. The provision of this Article shall apply during the Agreement period and for as long as Contractor processes or holds Personal Data from an Instand-NGS4P member.

Article - 20 Anonymization of Personal Data

- 20.1. The Lead Procurer shall not be entitled to inspect, take or be supplied with copies of any specific basic factual (or "raw") Personal Data obtained in connection with the PCP Project other than in an anonymized form.
- 20.2. Contractor shall ensure that the Services are in line with and support the privacy design of the Research as set out in Article 39 of the Grant Agreement.

Instand-NGS4P project will neither involve activities or results raising security issues, nor will it involve 'EU classified information' as background or results.

Article - 21 Obligation to provide information and keep records

- 21.1. The Contractor must, at any time during the implementation of the Framework Agreement and Specific Contracts or afterwards, provide any information requested by the Lead Procurer and the Procurers in relation to the Agreement or Contracts.
- 21.2. The Contractor must keep, for a period of up to seven (7) years after the end of the Framework Agreement and Specific Contracts, records and other supporting documentation relating to their implementation.
- 21.3. This obligation includes records and other supporting documentation on scientific and technical implementation (in line with the accepted standards in the field) and on the price charged and the costs incurred by the Contractor.
- 21.4. The Contractor must keep the original documents. Digital and digitalised documents are considered originals if they are authorised under national law.
- 21.5. Should there be ongoing checks, reviews, audits, investigations, litigation or other pursuits of claims (including claims against the Lead Procurer and the Procurers), the Contractor must keep all records and other supporting documentation until the end of these procedures.

Article - 22 EU checks, reviews, audits and investigations

- 22.1. Should the EU (including the European Court of Auditors or the European Anti-Fraud Office (OLAF)) decide to carry out a check, review, audit or investigation, the Contractor must make available all information, records and other supporting documents relating to the implementation of the Framework Agreement and Specific Contracts.
- 22.2. Should there be an on-the-spot visit by the EU, the Contractor must allow access to its premises and must ensure that the information requested is readily available.

Article - 23 EU impact evaluation

Should the EU carry out an impact evaluation (of its grant to the Procurers), the Contractor must make available all information, records and other supporting documents relating to the implementation of the Framework Agreement and Specific Contracts.

Article - 24 Liability

- 24.1. The Contractor shall indemnify and hold the Procurers free and harmless against loss and damage, including personal injury and death and related legal costs, arising from or in connection with its acts or omissions in relation to the Framework Agreement or Specific Contract.
- 24.2. The Contractor's indemnity obligations under Clause 24.1 shall be without prejudice to any other rights and remedies available to the Lead Procurer, including the right to terminate the Framework Agreement or any Specific Contract.

- 24.3. If the Contractor fails to deliver Results or other deliverables compliant or breach the other obligations with the Framework Agreement, the Lead Procurer shall give the Contractor the opportunity to amend, within an appropriate period. If the Lead Procurer is still not satisfied after the expiry of such cure period it may (at its discretion):
- (a) withhold payments until satisfactory delivery;
 - (b) cancel payments;
 - (c) exclude the Contractor from the/any subsequent Phases on the basis that the Contractor has not successfully completed the present Phase; and/or
 - (d) terminate the Framework Agreement and/or any Specific Contract (see hereunder).
- 24.4. Acceptance by the Lead Procurer of any deliverable or Result shall not limit the Contractor from liability in respect of such deliverable or Result subsequently being discovered to be non-compliant with the requirements of the Framework Agreement, nor for any loss or damage which may arise as a result.
- 24.5. Except in case of infringement of applicable laws, gross negligence or wilful misconduct on its part, a Party shall not be liable to the other for loss of the Framework Agreement, loss of income or revenue, loss of customers or reputation or any other indirect or consequential loss or damage.
- 24.6. Except in case of personal injury, gross negligence or wilful misconduct, the Procures' total liability in relation to the Framework Agreement shall be limited to the total value of the Specific Contract under the application of which the act or omission giving rise to the liability took place.
- 24.7. The Contractor shall take out insurance to cover its liability under the Framework Agreement and shall provide evidence of his insurance cover if so required by the Lead Procurer. The Contractor shall ensure that the same applies to its subcontractors involved in activities under the Framework Agreement. Any such insurance shall be maintained for the duration of the Framework Agreement and for a minimum of four (4) years thereafter.
- 24.8. The Contractor must compensate the Procurers if they are held liable by the EU for damage sustained as a result of the implementation of the Framework Agreement or a Specific Contract or because it was not implemented properly.
- 24.9. The EU cannot be held liable for any damage caused to the Contractor or caused by the Contractor in connection with the implementation of the Framework Agreement or a Specific Contract.

Article - 25 Force Majeure

- 25.1. If a Party is subject to Force Majeure it shall immediately notify the other Party in writing thereof, giving details, including the expected duration of the Force Majeure. It shall immediately notify the other Party in writing when the Force Majeure ceases.
- 25.2. The Party who is subject to Force Majeure shall, during the continuance of the Force Majeure and subject to Clause 26.1, be released from the performance of its obligations to the extent that such performance is affected by the Force Majeure. Such Party shall make all reasonable efforts to minimise the consequences of the Force Majeure on the Framework Agreement.
- 25.3. Each Party shall itself be responsible for all direct and indirect financial consequences affecting it as a result of or in connection with the Force Majeure.

- 25.4. The occurrence of Force Majeure shall not entitle either Party to any additional payment or compensation.
- 25.5. If a Force Majeure event occurs and its effect continued for a continuous period of no less than sixty (60) Days either Party shall be entitled to terminate the Framework Agreement and/or any Specific Contract with immediate effect without any liability for either Party, except insofar as has accrued prior to the date on which the termination of the Framework Agreement takes effect.

Article - 26 Termination

- 26.1. Without prejudice to any other provision of this Framework Agreement, this Framework Agreement may be terminated by either Party giving three (3) months' notice in writing to the other, unless the time remaining to the end of the relevant Phase is less than three (3) months, in which case the notification time shall be all remaining time to the end of that Phase. Should the option to terminate be exercised by the Lead Procurer, it shall be liable to the Contractor for actual loss unavoidably incurred by reason or in consequence of the termination provided that the Contractor takes all immediate and reasonable steps to minimize the loss.
- 26.2. With regards to Article 26.1 the Lead Procurer will not pay any sum which, when taken together with any sums paid or due or becoming due to the Contractor under this Framework Agreement, will exceed such total sums as would have been payable under this Framework Agreement if the Contractor had fulfilled its obligations under this Framework Agreement.
- 26.3. The Lead Procurer may at any time and from time to time by notice in writing terminate this Framework Agreement without liability for any damage, loss or expenses arising as a result of or in connection with such termination if there is a change of control in the Contractor which the Lead Procurer can reasonably demonstrate is prejudicial. The Lead Procurer shall only be permitted to exercise its rights pursuant to this clause for six (6) months after any such change of control and shall not be permitted to exercise such rights where the Lead Procurer has agreed in advance in writing to the particular change of control and such change of control takes place as proposed. The Contractor shall notify the Lead Procurer within two (2) weeks of any change of control taking place.
- 26.4. The Lead Procurer may at any time and from time to time by notice in writing terminate this Framework Agreement without liability for any damage, loss or expenses arising as a result of or in connection with such termination if:
 - (a) any approvals, consent or licenses required under this Framework Agreement are not given unconditionally within six (6) months of the commencement of the PCP Project phase;
 - (b) the Contractor is subject to an Insolvency Event;
 - (c) the Contractor is in Default under this Framework Agreement and if:
 - the Default is capable of remedy and the Contractor shall have failed to remedy the Default within thirty (30) Days of written notice being sent to the Contractor specifying the Default and requiring its remedy; or
 - the Default is not capable of remedy;

- (d) any provision of this Framework Agreement (other than as previously specified in the preceding provisions of this Article 26) expressly entitles the Lead Procurer to terminate this Framework Agreement;
 - (e) the Contractor, or any subcontractor on whose resources he has relied in the procurement that has preceded this Framework Agreement, becomes subject to any exclusion criteria listed in the PCP Request for Tender document;
 - (f) the Services are not in compliance with requirements on research and development services as defined in the most recent version of the Frascati Manual (Proposed Standard Practice for Surveys on Research and Experimental Development OECD, 6th Edition, 2002, ISBN 978-92-64- 19903-9, pp 29-50) and, where applicable its latest annexes or in case of non-compliance with any other requirement mentioned in the PCP Request for Tender document and declared in the signed declaration that is part of the tender;
 - (g) in the event of a repeated violation of the regulations for compliance with the labor and social law obligations of the Contractor when performing the R&D Services;
 - (h) in the event of violations of public law regulations by the Contractor;
 - (i) in the event of breach of confidentiality obligations by the Contractor;
 - (j) if the Lead Procurer is obliged to terminate the Agreement due to orders or legal provisions.
- 26.5. Termination of this Framework Agreement by the Lead Procurer under the preceding provisions of this Article 26 shall (at the option of the Lead Procurer) terminate this Framework Agreement with immediate effect as from the date of service of the notice of that termination or from the expiry of a period (not exceeding six (6) Months) specified in that notice.

Article - 27 Amendments

- 27.1. If at any time, it appears likely that any provision of the Agreement, the Specific Contract or the PCP Project, needs to be amended, the Contractor shall immediately inform the Lead Procurer in writing requesting an amendment to the Agreement, giving full details of the justification for the request and giving proposals for the amendment to the Agreement. Upon receipt of such a request the Lead Procurer may:
- (a) agree to amend the Agreement provided such an amendment is non-discriminatory and does not amount to a substantial change of the Agreement which might call into question the decision awarding the contracts, the scope of the service or the scope of the Results, as allowed under the then prevailing case law of the European Court of Justice;
 - (b) amend the PCP Project in a manner which the Contractor agrees can be carried out within the Project Period and within the Price with regard to the relevant Phases;
 - (c) refuse the request and require the continuation of the PCP Project in accordance with the Framework Agreement; or
 - (d) give notice of termination in accordance with Article 26.
- 27.2. Amendments must be made in writing and signed by the Parties.

Article - 28 Subcontracting, Transfer, Assignment & Interpretation

- 28.1. The Contractor will allow the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 Grant Agreement (mutatis mutandis) and will comply with Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 Grant Agreement (mutatis mutandis).
- 28.2. The Contractor will ensure that in all subcontracts the conditions from the Grant Agreement set out in clause 28.1 above and the applicable provisions of the Framework Agreement are imposed upon the subcontractor.
- 28.3. A third party may replace a Contractor or a member of the Contractor in case of a consortium as a result of universal succession in the position of the Contractor following corporate restructuring, including takeover, merger, acquisition or in an Insolvency Event, provided that said third party meets all exclusion, selection, compliance and minimal technical criteria and the succession does not entail a substantial modification.
- 28.4. The Contractor is allowed to replace a subcontractor, provided that the new subcontractor meets all exclusion, selection, compliance minimal technical criteria and the replacement does not entail a substantial modification.
- 28.5. The Framework Agreement constitutes the entire agreement between the Parties relating to its subject matter. Each Party acknowledges that it has not entered into this Framework Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Framework Agreement. Each Party waives any claim for breach of this Framework Agreement, or any right to rescind this Framework Agreement in respect of, any representation which is not an express provision of this Framework Agreement. However, this Article does not exclude any liability which either Party may have to the other (or any right which either Party may have to rescind this Framework Agreement) in respect of any fraudulent misrepresentation or fraudulent concealment prior to the execution of this Framework Agreement. In case of discrepancy between the Framework Agreement, on the one hand, and the PCP Request for Tender Document, on the other hand, the documents shall prevail in the following order:
 - (a) Framework Agreement;
 - (b) PCP Request for Tender Document
 - (c) Tender Documents (general, technical and financial forms)
 - (d) Other documents (exclusion, selection and on/off criteria forms)
 - (e) Specific Contract for Phase

Article - 29 Applicable law and dispute settlement

- 29.1. This Framework Agreement shall be considered as an agreement made in Austria and be construed in accordance with the laws of Austria under exclusion of the conflict of law rules. The place of jurisdiction shall be the competent court in Graz, Austria. Any legal claim, petition or application for judicial review, with regard to the present procurement procedure, shall be made in Austria. By submitting a tender, the Contractor accepts the exclusive jurisdiction of the courts of Austria.
- 29.2. Should individual provisions of this Framework Agreement be or become invalid, void, illegal or unenforceable, this shall not affect the validity of the remaining provisions of this Framework

Agreement. The invalid, void, illegal or unenforceable provision(s) shall retroactively be replaced by (an) alternative provision(s), which most closely correspond(s) to the original intent of the Parties to the extent that this is legally possible and whose economic effect best correspond(s) to the effect intended by the invalid, void, illegal or unenforceable provision(s). The same applies mutatis mutandis to any contract gaps.

Article - 30 Signature and entry into force

- 30.1. The transmission of an electronic copy (e.g. scanned pdf) of the Agreement signed in wet ink, or an electronic signature pursuant to the EU-eIDAS-Regulation shall be deemed an original signature for purpose of this Agreement.
- 30.2. This Agreement shall enter into force between the Parties on the day of the last signature of the Lead Procurer and the Contractor.

The Lead Procurer

Name: _____

Date: _____

Signature: _____

The Contractor

Name: _____

Date: _____

Signature: _____