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# Q&A concerning the Request for Tender

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This document lists questions concerning the Request for Tender and will be continuously updated until the 10th of December 2021. Relevant questions from the Open Market Consultation have also been included where appropriate. The questions have been answered to the best of our knowledge at this phase of the process.
Questions raised during the OMC can be viewed here

**Question Categories**



## 1. Who can apply?

***Q: Can a group (e.g., a consortium) of Solution Providers respond to the request for tender?***
**A:** Yes; a joint response to the request for tender by large companies together with SMEs and academic institutions is encouraged.

***Q: Is SME participation encouraged?***
A: Yes. Discussions with the European Commission and the reviewers highlighted that SMEs should not be forced into partnership with large companies, which may cause IP problems. SMEs can apply, either alone or within a partnership. Please use the Partnering Platform on the website!

***Q: Can start-up companies participate in the PCP?***
**A:** Yes

***Q: Can Solution Providers from academia and industry respond to the request for tender?***
**A:** Yes.

***Q: Must Solution Providers be EU-based?***
**A:** No, but at least 50% of the total value of activities covered by each specific contract for PCP phase 1 and 2 and at least 50% of the total value of activities covered by the framework agreement (i.e. the total value of the activities covered by phase 1 + the total value of the activities covered by phase 2 + the total value of the activities covered by phase 3) must be performed in the EU Member States or H2020 associated countries. It is irrelevant where the headquarters are located (e.g. the activities may be performed by a subsidiary) but the principal R&D staff working on the PCP (i.e. main researchers, developers and testers) must be located in the EU Member States or H2020 associated countries.

***Q: Could you please let us know if an US-based company is allowed to apply for your***

***INSTAND-NGS tender? The US is listed as "Country with bilateral science and technology (S&T) agreements with the EU" on the EU website EU International Cooperation Is this "enough" to attend?***
**A:** US-based companies are welcome to apply for the tender. However, funding is subject to a "place of performance obligation" whereby at least 50 % of the total value of activities covered by the framework agreement will be performed in the EU Member States or H2020 associated countries (see also previous question).
Unfortunately the S&T agreement you referred to does not give you the status of an EU Member State or H2020 associated country.

***Q: What does it mean that „At least 50 % of the total value of activities covered by the framework agreement will be performed in the EU Member States or H2020 associated countries. The principal R&D staff working on the PCP will be located in the EU Member States or H2020 associated countries;" for an US-based company?***
**A:** Participation of US companies is not excluded. However, at least 50% of the activities within a consortium must be performed in EU Member States or H2020 associated countries, and the principal R&D staff must be located in these countries. However, a US-based company does not have to have its own principal R&D staff working in Europe but may participate in a consortium with a European-based company, in order to fulfil the place of performance obligation.

***Q: Is the participation of UK-based entities affected by the withdrawal of the UK from the EU (Brexit)?***
**A:** No – under this H2020 PCP project, UK entities are considered to be one of the EU Member States, and can apply for the PCP procurement in any form they wish: main bidder, consortium member, subcontractor etc. R&D may be performed for the PCP in the UK.

***Q: Regarding the 50% of R&D to be done in EU member or Horizon 2020 member states - does UK apply?***
**A:** Yes, the UK is considered to be a Member State under H2020.

***Q: What is the status of Israel?***
**A:** Israel is an associated country under H2020, and is therefore eligible. Please see Associated Countries for the full list of associated countries (Switzerland is also included).

***Q: Are respondents to the request for tender expected to be R&D service providers or suppliers of NGS products?***
**A:** Both R&D service providers and suppliers of products are welcome to submit proposals. The aim of the funding instrument is, through public funding, to stimulate innovation and provide the incentive for companies to take innovative steps. The term "R&D" used in the documents does not exclude technology providers.

## 2. Applying for more than one Lot or in a consortium?

***Q: One company per lot i.e. 8 at the end of the process?***
**A:** One Solution Provider (single entity or consortium) has to address at least 1 Lot, or up to 3 Lots (just not all 4 Lots). i.e. we expect to fund up to 3-4 suppliers/Lot in the 1st phase.

***Q: Is it advantageous if a single start-up company encompasses the entire NGS workflow?***
**A:** No! Choose which 3 Lots fit best, and where you have your strongest market position. No funding can be given for more than 3 Lots. However, potential solutions for all 4 Lots can be reported.

***Q: Are we excluded from all four Lots because we are too smart and already have a tentative solution for all lots being a small start-up SME?***
**A:** See above

***Q: Regarding partnership, will it be better to answer jointly or separately?***
**A:** Whatever fits best to the product/solution. Applying for multiple Lots facilitates the integration into the complete workflow, so partnering to cover more Lots might be an advantage, particularly for Phase 3.

***Q: We need to understand how as a manufacturer we can postulate for this tender in 3 lots and how to partner with other potential providers? In case of partnerships do we need to participate via only 1 candidate submission or does each company need to candidate & operate separately?***
**A:** Partnering is not obligatory. If you decide to partner, there is only 1 Tender to be submitted per Lot by the leader of a Tenderer Consortium.

***Q: Is your definition of PROVIDER equal to a 'consortium' of solution-providing members? It is important to understand because it is the PROVIDER that is limited for participation to at most 3 lots. If a solution-providing participant is present (with different solutions) in more than one consortium (provider), then that solution-provider might be involved in more than 3 lots.***
**A:** "PROVIDER" in this context refers to either a company (single entity) or consortium submitting a Tender. Participation either as a single entity or a consortium is limited to a maximum of 3 Lots. An individual company may be present in more than one consortium, and is in this case not prohibited from participating in separate Tenders for additional Lots. However, the company may not be the leader of more than one consortium applying for 3 Lot(s).

***Q: Lot 1 is very complex with many pieces of the puzzle, some of which are very well established and used by all labs like for QC. Even if complete workflows should be offered, will the buyers be able to combine different part of the workflow?***
**A:** We expect different levels of innovation for different parts of the workflow. For some aspects, there are not many Solution Providers on the market. Therefore we foresee the possibility of one solution being used in both workflows.

***Q: Does a solution designer have to provide all parts of the workflow: from DNA/RNA isolation to sequencing ready library - for lot 1? Or can also parts be provided, like only the library preparation from already isolated DNA/RNA?***
**A:** A solution designer does not have to provide all parts of the workflow. For instance, if a smart solution for library preparation is proposed, it is not necessary to have innovative sample collection and stabilization devices as well if your solution works with technology that is already on the market. In this case a Tender for a Lot may include solutions already on the market to complement highly innovative solutions to address the challenges of a Lot. Please note that the total score of a Tender may be reduced if it does not cover the entire Lot.
For example, an innovative library preparation solution can be proposed for Lot 1: in this case, we would provide isolated DNA/RNA instead of a tissue sample to demonstrate the performance of the library preparation solution. Details of what test material should be provided will be defined in the Framework Agreement and Specific Contract.

***Q: Does one Solution Provider have to address all Lots of a workflow?***
**A:** No; one Solution Provider can contribute to a maximum of 3 Lots of the complete workflow (e.g., Lots 1, 2 & 3 or Lots 2, 3 & 4 or only two Lots or a single Lot).

***Q: Can a company apply for the same lot with two different solutions?***
**A:** The same company cannot apply for the same Lot with two different solutions (see also next

question).

***Q: Can a company apply for the same lot alone and in a consortium e.g. can we participate with solution X in lot A alone, and also with solution X in lot A in a consortium led by another company? This could be of interest to provide an even more comprehensive solution (X + more) to lot A even in the case when solution X basically already fulfills the requirements in lot A.***
**A:** We are looking for innovation, not only the fulfilment of the minimal requirements. It won't make sense to apply with the same solution as a company and as a consortium. However, it would be feasible in principle to apply as a company for lot A with solution X and as a consortium for lot A with a solution Y (a different one, potentially less mature, which needs a partner's contribution)

In summary, you can apply with one solution alone, and with another solution in a project consortium (in which case you cannot be the lead partner for the consortium).

***Q: Can I participate with a solution X in lot A and another solution Y in lot B? I did understand from Prof. Zatloukal's presentation that it can be beneficial to have solutions covering more than one lot.***
**A:** Yes, you can participate with solution X in Lot A and solution Y in Lot B. It will be welcome to have more than one Lot addressed, as this would facilitate the further integration into a complete workflow which is the goal at the end of the project (Phase 3).

## 3. Technical and Regulatory questions

***Q: I get the impression that many of the 'parts' of the pipelines would not be approved for use in the EU currently. Is the idea that different partners would be able to coordinate and possibly work with the academic hospitals on their technical files, and that eventual IVDR compliance is an end goal?***
**A:** The Request for Tender addresses R&D Solution Providers, but the product should be for routine diagnostics i.e. an IVD (not a research technology). We want to help companies to make their products ready for compliance with IVDR, i.e. reduce the burden of producing technical documentation although the product is not final. Variants to be analysed therefore need a well established medical relevance. Outcome/benefit of the project: medical centres could help R&D Solution Providers with clinical performance studies.

***Q: Do we need to meet IVDR already today, or only by 2022?***
**A:** The future solutions should fulfil the IVDR, when entering into force since 2022. The IVDR principles should be taken into account in the ongoing process, meaning an adaptation period.

***Q: You put a lot of emphasis on the regulatory development. Regulatory uses limits R&D development: Can you explain a little bit about the expected impact or contribution of regulatory in the three phases?***
**A:** The aim is to facilitate the regulatory process of a solution. No information will be requested that would not be required in later stages of the regulatory pathway.

***Q: Have full data analysis pipelines (software) and scripts to be revealed to the buyers or what will actually be tested by the buyers specifically or would this more work like a "Ring trial" i.e. buyer provided input and provider provides the results for evaluation?***
**A:** Data analysis pipelines have to be made available to the Buyers for testing in accordance with the Framework Agreement, which does not require disclosure of proprietary information. There is

flexibility in how Buyers can test a software or pipeline and the approach has to be described in detail in the proposal for phase 3.

***Q: Would design support in Europe also be considered as R&D?***
**A:** Yes. The provided funding is an R&D service.

***Q: Are phases 1, 2 and 3 wet-lab solutions or on-paper solutions?***
**A:** Phase 1 is expected to be "on-paper", while phases 2 and 3 are wet-lab solutions.

***Q: I would like to ask a question about the cancer referral pathways you might expect: are certain cancers expected to be prominent? What type of sampling would you expect?***
A: Coverage: Common cancers (childhood/adult), but there is also an emphasis on rare cancers, so broad coverage is an advantage. If a broad coverage solution is not provided, you should show how this can be widened in a future step.
Samples: the Buyers group will provide different reference sample types (FFPE, frozen, liquid biopsy, buccal swabs/PBMCs for whole genome testing). Through Genomics England, samples relevant for pharmacogenomics testing will also be provided.

***Q: How would this programme work for a service provider as the techniques have been tested by the buyers locally?***
**A:** The solutions should be designed to be used widely in a hospital context, and to comply with regulatory requirements for an IVD, which are of course relevant also for a Service Provider. However, solutions for a diagnostic Service Provider most likely will not be able to demonstrate how well it is integrated in a hospital information system.In this case, the solution might generate reports that can be integrated in a hospital information system of a cancer centre that receives this report. Such a Service Provider solution therefore falls within the scope of Instand-NGS4P, and is not excluded from participation in the tendering process.

***Q: What about the application of RNASeq?***
**A:** RNAseq is included in the scope. This is of particular interest for analysis of gene fusions.

***Q: Do you have information on sample numbers and types? Will this be service, product or both?***
**A:** In the Request for Tender there is a list of the tumour entities covered and the sample types and quality that will be produced (see Section 3.4.2. Minimal Requirements). We cannot guarantee the number of samples that will be provided because this is patient-dependent. You will receive information on the origin, quality, which standard(s) was/were used, and pre-analytical parameters in an anonymised manner.
The samples represent the in-kind contribution from the Buyers.

## 4. Submission and Evaluation Process

***Q: The assignment of tasks to Subcontractors has to be declared in advance to the Procurers and needs the approval of the Procurers - what does it exactly mean in the terms of submission? Do we need to ask before we send the official submission?***
**A:** Tenderers do not have to ask before the official submission of the Tender. Subcontractors have to be declared in the proposal because they also have to fulfil the compliance criteria - for instance ethical, data protection and security requirements. The Subcontractor can therefore not be changed without approval by the Procurers to ensure that any changes meet the compliance criteria. The work performed by the Subcontractor also has to be considered with regard to the requirement for 50% of the work to be performed in the EU Member States or H2020 associated countries.

***Q: Since there shall be no conflict of interest for evaluators, this means in practice that any***

***partner of the project is to be excluded from becoming a customer before evaluation. When will the evaluation take place? It seems there are 3 stages of evaluations (for the 3 phases). That would mean that none of the partners can be customers of the company for several years. Right?***
**A:** There is no exclusion of customers. However, any prior service or R&D agreements or financial agreements (e.g., consultant) must be disclosed by the evaluators. Financial relationships with a consortium member do not prevent submission of the proposal for evaluation. In this case the proposal will be evaluated by consortium members without potential conflicts of interest.

***Q: Will preference be given to existing partners of the Instand-NGS4P?***
**A:** No preference will be given to existing partners. The process will be transparent and followed by the European Commission.

***Q: Are the members of the selection committee known? I guess to have to avoid conflict of interest. Where can we find this?***
**A:** The selection committees are currently being finalised and will be announced on the website. Any Conflict of Interest must be declared by the Consortium and committee members. In case of a possible Conflict of Interest, this consortium member is excluded from evaluating proposals in this area.

***Q: Will any questions be answered before December timeframe, e.g. very important questions that hopefully are answered earlier than December?***
**A:** Questions will be answered continuously, and will be updated on the website (please allow a few days for processing). The deadline for questions is the 6th of December, and answers will be updated by the 10th of December 2021.

***Q: Is it necessary to provide not only the submission of deliverables, but also the reporting of expenditures?***
**A:** The Buyers need documentation to prove compliance with the costs eligibility conditions that at least 50% of the activities within a consortium must be performed in EU Member States or H2020 associated countries. Information on how to provide this documentation and in what format will be provide on the Instand-NGS4P website.

***Q: Annex B, section 2: do you ask for the project plan, methodology, work organization for the 3 phases or just for phase 1?***
**A:** In the Tender, a detailed concept for Phase 1 as well as a short description of the activities planned for Phases 2 and 3 are requested. The funding for Phase 1 allows then the development of a detailed plan for Phase 2.

***Q: Annex B: Is the page limit of 12 pages for all lots combined or for each lot?***
**A:** The 12 page limit is for each Lot.

***Q: I have a questions regarding the comment on page 31 of Request for Tender document: D1.1 and 1.2 shall be in the format required by the EU for publication. The format will be available on the Instand-NGS4P website. I am trying to find this document on the website in order to view the format.***
**A:** You are referring to D1.1 Project abstract and list of pre-existing IP (for EU) and D1.2 End of Phase Report & non-confidential summary
These deliverables will in part be published and are therefore required in a particular format by the EU. 2 templates are provided by the EU: Project abstract template and End of Phase Report template (we reserve the right to make minor modifications). The full templates for D1.1 and D1.2 will be made available on the website in due course (certainly before the start of Phase 1).

***Q: Are there any withdrawal terms and conditions from the contract?***
**A:** Yes - the cases and terms of termination are provided by article 26 of the Framework Agreement. You also do not have to apply for a next phase.

## 5. Updates

**Added 1.12.2021**

***Q: Will there be an opportunity to negotiate the terms of the framework agreement post-award? If not, may bidders include a proposed mark-up of the framework agreement as part of their submission?***
**A:** There will be no renegotiation of the Framework Agreement with individual bidders i.e. there is one version of the Framework Agreement for all bidders.
If however a bidder notices a specific need to amend the Framework Agreement when preparing the offer, he has to inform the lead procurer in the course of „questions about tender documents“ until December 6, 2021 (“Deadline for submitting questions about tender documents ").
In the case of necessary changes, the lead procurer reserves the right to adapt the Framework Agreement in the course of the publication of the "Q&A documents" (by December 10, 2021 at the latest - Deadline for lead procurer to publish replies to questions).
If post-award, it appears likely that any provision of the Framework Agreement needs to be amended, Article 27.1 of the Framework Agreement applies.

**Added 2.12.2021**

### Applying for more than 1 Lot or in a Consortium

**Q:** ***We have solutions that can in part address the requirements of lot 1, lot 3 and lot 4. In order the cover the requirements for these lots completely, we have setup a consortium for each of the lots. Our solution are however pretty much integrated, also between the lots (for example between lot 1 and 3). Now we understand, that even if our consortium could in theory provide one submission with integrated solution covering 3 lots, it is mandatory to submit for each lot separately. Is this correct? What is the best way to emphasize this integration within the separate submissions?***
**A:** A separate application is needed for each Lot since they will be evaluated independently. These applications should include also a concept for the work planned in Phase 2 and Phase 3, the latter focuses on the integration of the solutions developed within the various Lots. This would be the appropriate context to highlight the level of planned integration and its feasibility.

### Technical and regulatory questions

**Q:** ***Will all technologies and devices that shall be part of the workflow (Lot1) have to be IVD compliant or at least IVD ready?***
***Specific example: a plate reader is used to quantify NA and NA concentrations and is not directly contributing to a diagnostic decision. Does it have to be IVD nevertheless?***
**A:** Instand-NGS4P does not require compliance with IVDR but asks for consideration of IVDR requirements in order to ensure that solutions to be developed can be used for diagnostics in the future. For example, in case a plate reader is part of a diagnostic

workflow IVDR provides criteria for classification and conformity assessment procedure. These requirements should be considered in the design and development of the solutions. However, Instand-NGS4P is flexible allowing solutions which may include devices that are already on the market or innovative technologies that have not yet passed conformity assessment.

**Q:** ***Is it a requirement that all instruments incorporated within the workflow need to be 21 CFR compliant?***
**A:** Solutions should be designed in a way that they consider regulatory requirements, which in Europe is IVDR (REGULATION (EU) 2017/746). The generation of performance data for technical documentation and conformity assessment does not fall under the scope of this PCP.

**Q:** ***Do you envision sequence demultiplexing/ UMI happening in lot 2 or in lot 3?***
**A:** We prefer sequence demultiplexing in Lot 2 (output: standard FASTQ or uBAM files) and UMI-aware analysis in Lot 3 (input: standard FASTQ or uBAM files). However, we are aware that currently pipelines exist which use the raw sequencer files and generate demultiplexed sequences and perform UMI-based-consensus sequencing-generation.

**Q:** ***I am interested in an application for Lot 1 and Lot 3. Can you let me know where I can find the markers that need to be detected via the solution provider in Lot 1?***
**A:** Solutions for Lot 1 should be appropriate for the different sample types and qualities as defined in the Request for Tender document (see tables in section 3.4.2). This section includes also information on the markers to be detected.

**Q:** ***We are a solution provider for gene expression analysis from transcriptome panel to diagnostic assays. In the webinar it was mentioned RNA based methods would be relevant as they can be useful to detect fusions. In precision medicine gene expression signatures are gaining more and more relevance (e.g. breast cancer recurrence risk, immune expression signatures). Would an RNA detection method only be tested for its performance on detecting fusions, or also gene expression profiling/signatures?***
**A:** The detection of gene fusions is required in medical diagnostics and therefore clearly within the scope of this PCP. RNA expression profiles could be included in the scope as long as they will meet regulatory requirements for IVDs.

**Q:** ***There is a grey zone for us in the call for tenders document regarding the border the between Lot3 and Lot4 in terms of annotation and reporting.***
***Annotation is mentioned on page 20 in association with Lot3. In addition to in silico prediction tools, the ClinVar database is also listed to be incorporated in the annotation process, defining the pathogenicity of a variant. Lot4 text (pages 22-24) - in our understanding - could also refer to the process of defining the pathogenicity of a variant but could also refer only to the clinical relevance of an alteration in association with a therapy:NGS results on cancer-related variants (and their level of clinical evidence and the type of evidence; e.g., companion diagnostics, guidelines of medical societies, curated databases, current clinically validated and computationally predicted knowledge on the deleteriousness of the mutations, and literature). Therefore it is not clear for us if you wish to cover the determination of the "driverness" of a variant in Lot 3 and go on with a list of annotated alterations in Lot4 or these annotations listed in Lot3 text are only to support the decision on pathogenicity in Lot4.***

***Could you confirm that variant "driverness" annotation should be done in Lot4?***
**A:** All annotations and classifications are to be done in Lot 3 and to be written into the annotated gVCF file. Please note that predictive biomarkers (associated with treatment response) or prognostic biomarkers (associated with the disease outcome, e.g. survival) or classifications (patient stratification into risk or treatment groups) are growing rapidly and that current practice is to consult databases, clinical guidelines and also literature (e.g. ASCO clinical trials publications which are currently manually searched for each patient case in a molecular tumor board) and that solution proposals which address this dynamic aspect and automate these manual chores can be evaluated as innovative.

**Q:** ***Reporting/output of Lot 3: As an output of Lot3, VCF and BAM formats are listed. However, there are parts in the text suggesting that the output of Lot3 should be visualized or even recorded in the EHR. bioinformatics tools dedicated to the annotation and graphical reporting of somatic/genetic mutations. page 19 This tool should generate a clear and easily interpretable report, ... Page 20 Verification of all components of data management, transfer and analysis throughout the entire workflow process (bioinformatics, in-silico data modelling, e-reporting) to reduce complexity for clinicians as well as users,... page 20-21 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.***
***page 21 Could you confirm that there is no need to have any kind of report in Lot3?***
**A:** 1. You are free to generate technical reports and technical visualizations in a Lot 3 solution or in a Lot 4 solution, depending on how you envisage or design the overall workflow and the individual solutions. You must clarify this in your tender.
2. The technical report must be in a laboratory-friendly human-readable format and it must include information on whether the sequencing quality in the target region was sufficient for a given sample (e.g. coverage gaps, coverage statistics) or whether the laboratory needs to repeat the sample sequencing (this information can additionally be written into the gVCF for potentially including into the clinical report). As required by the EuroGentest guidelines (2014, to be updated soon), the Lot 3 solution must allow statistical quality control ("Statement 4.02: The diagnostic laboratory has to implement a structured database for relevant quality measures for (i) the platform, (ii) all assays, (iii) all samples processed.")
3. The technical visualizations must allow the laboratory users (or the clinical users, e.g. in a molecular tumor board) to understand how the result was obtained (e.g. a filtering tree and databases used) and optionally to interactively inspect any given detail in the automatically generated technical results (alignments, filtered variants, annotations, classifications), override the technical results manually (re-classify, exclude, etc.), and must track the manual changes and who made them (all this information can be written into the gVCF for potentially including into clinical report, and the BAM file needs to be made available to Lot 4 solutions). All interactiveness should be optimized compared to current solutions, e.g. the intuitivity, ergonomics, efficiency (maximal amount of information, minimal number of actions, minimal distance of cursor travel, minimal number of entries or mouse clicks) must be improved.
4. The Lot 3 solution must have functionality to generate a report that allows the laboratory users to validate the performance of the Lot 3 solution: the Lot 3 solution must be able to read a gVCF from its own output or from third party outputs, and compare this output to "truth" (which must also be read as a gVCF, e.g. with global

thresholds defined by keys in the header lines and with true variants and their annotations in the genomic lines), for example the coverage completeness/coverage gaps, sensitivity/specificity of automatic variant-calling/filtering, completeness and correctness of annotation/classifications/etc must be reported. The result can also be written into a gVCF for automatic parsing, but a laboratory-friendly human-readable report format is nevertheless required.
5. Please note that gVCF (not VCF) format is required so that complete information on the sequence depth in the target region is available right through into Lot 4.

**Q:** ***Is RNA sequencing part of the tender?***
**A:** Yes

**Q:** ***Does the LOT 3 solution need to integrate other data sources? E.g. attaching images to a patient in the pipeline?***
**A:** No

**Q:** ***Will variants have to be validated with different technology,e.g. Sanger sequencing?***
**A:** Validation with independent technologies is desired but not mandatory because the test material provided will be well characterized.

**Q:** ***If risk scoring based on genomic variants is done, is this part of LOT 3 or LOT 4?***
**A:** Risk scoring is part of Lot 4

**Q:** ***Context: - the choice of sequencing approaches should take into account the precise clinical needs. Q: Should we be mixing different seq techs for the same patient (e.g. long reads and short reads)? Or Sanger sequencing (for validation of NGS detected variants)? Or something else entirely?***
**A:** Different clinical conditions will require different sequencing approaches. Therefore an important improvement for NGS in medical diagnostics would be that different sequencing approaches can be integrated in a common workflow.

**Q:** ***Automation: We can automate the flow from fastQ to VCF. I am just wondering whether the user is still expected to highlight mutations in LOT 3 and do some analysis here (exploring databases, prediction tools...) and select/annotate variants, or is this going to happen in LOT 4?***
**A:** The selection and annotation of variants is within the scope of Lot 3; the generation of an integrated report for clinicians and patients is in scope of Lot 4.

**Q:** ***Annex C: What is the expectation for Phase 2-3 sample volumes required for validation?***
**A:** In general, we aim at providing 3-5 different samples for each of the key variables (e.g., sample type, pre-analytical variables, tumor type, variant type; the list of samples and variables is provide in the Request for Tender document) depending on the scope of the proposed R&D Service. Details will be defined in the relevant Specific Contract.

**Q:** ***What are the barcode requirements across the laboratory network? Will the required barcodes be 2D or 3D? Will this be standardise across the laboratory network?***
**A:** There is no specific requirement for 2D or 3D barcodes. Since different solutions will be developed by different R&D Solution Providers standardization beyond requirements of applicable ISO standards cannot be achieved within this PCP.

## Submission and Evaluation Process

**Q:** ***In the ANNEX A - GENERAL SUBMISSION FORM, do we have to identify the subcontractors for Phase I or the subcontractors for all the 3 Phases?***
**A:** Subcontractors need to be specified for all Phases because this information is relevant for evaluating the feasibility of the proposal, to demonstrate that the Subcontractor fulfils the requirements for participation in the PCP and to demonstrate that >50% of the budget is spent in the EU or H2020 associated countries. If changes in subcontractors will become necessary in a later phase of the project this has to be approved by the Lead Procurer.

**Q:** ***Companies providing regulatory consulting services, IT security tests or quality consulting services or similar services for the project, do they have to be listed as subcontractors?***
**A:** This information should be provided if the companies receive funding out of this PCP, and/or the expertise is considered to be relevant for evaluating the feasibility of the proposal.

**Q:** ***How will the project funding be disseminated among suppliers and consortium members?***
**A:** The dissemination of funding within a consortium can be decided within the consortium and has to be described in the tendering documents. The maximum budget per contract (e.g., consortium or individual R&D Solution Provider) is specified per Lot and Phase in the Request for Tender document.

Added 3.12.2021

***Q: We were not quite sure with this sentence means: "…and that the total value of products offered in each Phase will be less than 50 % of the total value of the Framework Agreement". "…and that the total value of products offered in each Phase will be less than 50 % of the total value of the Framework Agreement".***
**A:** This statement refers to the fact that the contract is an R&D services contract in compliance with the EU R&D&I state aid framework ("Framework for State aid for research and development and innovation", 2014/C 198/01) because PCP procurements do not constitute state aid under the EU state aid rules. The definition of services means that the total value of supplies purchased needs to remain below 50% of the total PCP contract value. R&D Services covers especially fundamental research, industrial research and experimental development, as per the definition given in the EU R&D&I state aid framework. Tenders that go beyond the provision of R&D services will be excluded.

***Q: In the Financial Annex C, do we have to specify the cost breakdown per unit, country and R&D services just for Phase 1 or also for Phases 2 and 3? We understand that the financial compensation valuing the allocation of ownership of the IPRs to the Tenderer has to be calculated as a final value for all the three phases, right?***
**A:** The offer for the Framework Agreement must provide binding unit prices for all foreseeable items for the whole duration of the Framework Agreement. This means this information has to be provided for all three Phases. The financial part of the offer for each phase, which is now Phase 1, must provide a breakdown of the price for that Phase in terms of units and unit prices for every type of items in the contract, distinguishing clearly the units and unit prices for product related items.

***Q: Do the subcontractors (in our case for consulting and auditing activities in phases 2 and 3) have to fill a separate Annex D form each?***
**A:** Each subcontractor has to fill a separate Annex D form. This should be provided already in Phase 1 even if they will be involved in Phases 2 and 3. This avoids reevaluation and approval of new subcontractors in the proposal of Phase 2 and Phase 3, and demonstrates availability of relevant competencies within the consortium.

***Q: question regarding Annex C. It is about the total price section; If the costs in the phases exceed the amount received from the tender does that mean that the rest will not be covered? The table above shows the amounts that can be expected to be compensated with. Are we expected to state an "expected" price in Annex C before the work has been started, which does not go over the stated amounts in the table?***
**A:** The maximum budget per Lot and per Phase is explicit in the Request for Tender document. We also define how the criteria "Price" will be evaluated in page 90 of the Request for Tender document. For the current Phase 1, Annex C needs a binding offer for phase 1, whereas an estimated total price for Phases 2 and 3 has to be provided.

***Q: Annex B Section 2: Can you please expand on what the following request is referring to - "Describe the work organization and supply chain"?***
**A: Work organization means** the way jobs and **work** systems are designed, and the way they are managed. Description of supply chain should provide information on key suppliers needed to perform the R&D Service.

## Added 3.12.2021 18:00 CET

### Technical and regulatory questions

***Q: Is there a target time for running the LOT 3 pipeline? x minutes/hours for panel, WES, WGS of which size?***
**A:** In general, the current state of reality is that results from sample to report are not delivered fast enough, requiring the need to streamline everything from LOT1 to LOT4 including manual curation/data research. The widespread aim in pathology labs is typically a turn-around-time of 5 days from sample to validated clinical report, for a current typical small panel with a few well-

characterized genes and targets. For molecular tumor boards using WES-based NGS examinations, the current TAT is more like 10 days to several weeks from sample to report. In LOT3, running time for a raw result (filtering, alignment, filtering, variant-calling, filtering, annotation, filtering) for WES is currently about 3-6 hours per sample using conventional 16-core IT hardware; accelerated IT hardware co-processors (GPU, FPGA) have raw result run-times for a WES sample in the region of in a few minutes. For genomes with 30X coverage, current run time for a raw result using GPU or FPGA co-processor hardware is typically about half an hour per sample. If deeper sequencing is used than 30X (e.g. for somatic mutation detection), the run time would increase. Run time is exacerbated by larger panels, exomes, whole genome and ultra-deep cfDNA sequencing panels. An innovative LOT3 solution will need to aim to improve the TAT from sequence files to the raw result, as well as automation and interactiveness for manual curation/data research, so that larger panels, exomes, whole genome and ultra-deep cfDNA sequencing panels will have TATs comparable to current small panels.

***Q: Annex B: What current LIMS do the laboratory network use? Is there a future plan to standardise the LIMS requirements across the laboratory network?***
**A:** Unfortunately, different LIMS are currently used by the Buyers and larger user community. Therefore, it is important to use standardized data sets and formats. The LIMS of laboratories that are integrated into large medical centers are connected to the medical centers' information systems, using the vendor-supplied APIs. This integration is generally done by the vendors of these systems or by free-lance or employed integration experts, in cooperation with the users of the information systems. It is not currently planned to standardise the LIMS requirements across the laboratory network.

***Q: Instand-NGS4P_Request for Tender_final; 3.4.3 Weighted Award Criteria, A4) Library preparation p.64, last line:***
***Can you please expand on what the following request is referring to - A4) Library preparation - "compatibility with analytical test procedure"?***
**A:** This means that for the analyte of interest in the specific examination, an appropriate preanalytical sampling procedure, stabilization, nucleotide isolation and possibly an additional nucleotide treatment (e.g. enzymatic repair, or concentration of low-concentration isolates, or buffering) has been performed. The resulting nucleotide sample with all chemicals and possible damages (that are left over from the sampling, stabilization and isolation, e.g. PCR-inhibitors) are then used for the library preparation. This requires testing of compatibility and potential clean-up steps at the beginning of the library preparation. The preanalytical procedures and kits with which the library preparation has been tested to be compatible with must be specified by the solution provider for the library preparation.

## Added 10.12.2021 12:00 CET

***Q: I have a question regarding the phase 3 milestone 3.1: The description of this milestone is "Having a limited set prototype solutions installed and ready for testing at the Buyers site." Is the word "limited" associated with any minimum number? Would be an installation at two buyers sites already fulfill this term?***
**A:** Yes, installation at two Buyers sites fulfills Milestone 3.1, as stated under 2.4 Contracting approach (page 40, RfT), "Phase 3 testing in a real-world diagnostic medical environment is expected to take place at a minimum of 2 of the medical sites where the Procurers of the Buyer group are based and optionally at another medical centre in Romania."

***Q: Instand-NGS4P_Request for Tender_final; 2.3 Procurer(s) and other parties involved in the PCP, p.35, line 4; Sentence: "Research is performed to increase the diagnostic performance and tests Molecular Diagnostics can provide." Is this sentence correct?***
**A:** The sentence should read "Research is performed to increase the diagnostic performance by providing scientific proof and validated data to enable adaptation of the tests that the Molecular Diagnostics unit can provide." It means the Molecular Diagnostics unit is involved in research with the aim to improve the diagnostic workflow for patients. New markers and pathways are revealed to better understand the disease process. Once new markers are validated (of course also those identified and validated by others) they are added to the array of tests performed by the unit. The latter is done in cooperation with the test providers.

***Q: In the Annex B, question 6, it is requested to elaborate on the plans/objectives/R&D services for phase 2 and 3.***
***However, in question 2, one should also provide the project plan regarding phase 2 and 3, as well as the methodology for development (phase 2) and solution testing (phase 3).***
***Could you provide clarity in the difference in expected input between question 2 and question 6 with respect to phase 2 and phase 3?***
**A:** Point 2 "Detail and demonstrate the consistency of the schedule for the execution of the contract, split into Phases 1-2-3". Highlights that there are three Phases and that the appropriate time schedule should be considered as detailed in the RfT for the respective Phase.
Point 6 asks for an outlook on "Objectives and R&D Services planned for Phase 2 and Phase 3"

**Q: RfT p80:** ***Concept A5 for Lot3 refers to D7.4 but is not clear to which section/document does this D7.4 refer to. Could you please clarify it? ("Please see D7.4 which includes the 20397-2:2021 ISO specification")***
**A:** D7.4 mistakenly refers to an internal document. This should instead refer to the list of standards provided on the website: https://www.instandngs4p.eu/wp-content/uploads/2021/10/Instand-NGS4P-relevant-standards-list_v1.0.pdf

***Q: What we should be doing with this deliverable D1.1 Project abstract and list of pre-existing IP (for EU)? I see it is expected at the start of Phase 1, but have no clue of what format, or details we need to add to this.***
**A:** The project abstract is a summary of the proposal giving a brief project description and shall be in the format required by the EU:
http://ec.europa.eu/research/participants/data/ref/h2020/other/gm/reporting/h2020-tpl-pcp-ppi-contractor-abstract_en.docx
Regarding the pre-exisiting IP, a current list of the pre-existing rights (Background) relevant to the

Tenderer's proposed solution should be provided, in order to allow IPR dependencies to be assessed. Explain the measures, if any, that are being implemented internally (towards your own employees) and externally (towards business and competitors) to protect the Results during the project. e.g. patent search performed, non-disclosure agreements in place etc.

***Q: In the Request for Tenders there are Milestones and deliverables defined for each Phase. Should our project plans and activities include those and align with them? We will have many activities to detail in Phase 1, so we might affect the deliverables numbering, etc.***
**A:** Please align the activities according to the Deliverables & Milestones as defined in the RfT. The number of the obligatory deliverables is that described in the RfT (section 2.1.3); additional deliverables can be added by using additional (sub)numbering for each Phase e.g., D1.x, D1.y etc..

***Q: Do we need to disclose all the source code and what would be the ownership over it?***
**A:** The source code does not have to be disclosed and the ownership is with the Contractor.

***Q: How will the prices for commercial exploitation be set, including for the Buyers? Is it considered that the Buyers have bought the software at this point?***
**A:** The price for commercial exploitation refers to expected future price when the solution is placed on the market. This has to be distinguished from the price for the R&D Service. The Buyers will not have bought the software in context of the PCP. They only have obtained the right to access the research results of the R&D Service according to the Framework Agreement.

***Q: Will the provider be paid to operate the software only and not per analysis basis?***
**A:** There is no payment foreseen for the provider in addition to the funding provided within the PCP.

***Q: Will our cloud be used or installed locally on their servers?***
**A:** Both options are possible as long as they properly consider privacy protection requirements.

## Framework Agreement & Specific Contract

***Q: Please explain what is expect as Tender identifier (Short name/acronym to be used throughout the Tender application forms)***
**A:** Please use a short name or acronym.

***Q: p.2 Preamble : third - after "Have agreed on the following" "additional documentation": could we add some wording such as " provided any clarifications otherwise agreed"?***
**A:** The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p2 Preamble : composition of the Agreement: Could we agree on attaching {the Contractor´s} General Terms and Conditions (GTC) and Data Protection Addendum (DPA)?***

**A:** The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p4Article 1 (e): Could we agree on having some derogation / complementary provisions in such Specific Contract?***
**A:** No. The Specific Contract is an integral part of the Framework Agreement, thus the provisions of the Framework Agreement apply for the Specific Contract.

***Q: Article 1 (w) Would a specific format be shared to list all the pre-existing rights?***
**A:** No, this is not planned.

***Q: Article 1 (ee) Definition is way too broad. Could we agree on alternative wording?***
**A:** No, this is not considered necessary.

***Q: p7 Article 6.2 & 6.3 Where satisfaction criteria / KPI will be defined? How will they be measured?***
**A:** The tenderers can select what is most appropriate. The Request for Tender contains requirements for the assessment of satisfactory completion (p. 103ff.)

***Q: p10 Article 8.1. Does an extended delay be acceptable?***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p10 Article 9.2 Does an extended delay be acceptable (30 days) to cure?***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q. p12 Articles 10.12 & 10.14 Could we discuss about the seven years period? We would need to adapt our retention policy.***
**A:** No, the length of this period cannot be changed.

***Q: p13 Article 11.3. Could we discuss about license conditions? Not acceptable as is as irrevocable, indefinite and not limited to the execution of the PCP Project.***
**A:** No, this is not possible. Please note that 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.
The access rights are further specified and restated according to 12.5.
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
Please be aware that the access rights of the Buyers are essential to achieve the objectives of the PCP Project and are restricted to the purely non-commercial use. Furthermore, the access to Results

according to 12.1 constitutes an important return on the Buyers' 10% contribution to the R&D Services.

***Q: We would like to make some edits to the Framework Agreement to reflect the relative positions of the parties. Please confirm that MUG would be amenable to such amendments in the event of a successful bid. For ease of reference, we would be happy to include a proposed mark up of the Framework Agreement with our tender response.***
***Article 12: Ownership of Results and access rights to Results***
***12.1 We request removal of the words "irrevocable, indefinite" and "patient care" and deletion of the final sentence "In case of Results..."***
***– the license of Results and usage by MUG should be limited to internal research use only and should survive only for so long as the Framework Agreement is live.***
***Please also add the following sentence: For the avoidance of doubt, the Results shall not at any time be commercialised or otherwise exploited for profit in any way***
***directly or indirectly by the Lead Procurer or transferred to any third party without the prior written consent of the Contractor.***
***12.2, 12.3, 13.6, 14.3 and 14.4 Please delete these clauses in full.***
***The Results will be shared with MUG where they are defined as deliverables in each SOW. We believe dictating process or asserting ownership over the Contractor's IP is beyond the scope of this agreement.***
***12.4 We request addition of the following sentence. "Any licences shall be permissible only with the prior written consent of the Contractor."***
***12.6 & 12.7 Please delete.***
***13.8 Please delete.***
***Article 24: Liability***
***We request narrowing the indemnity in 24.1 to cover only deliberate or wilful acts or omissions causing loss.***
***Any other losses can and should be covered by a breach of contract claim.***
***We would also ask that 24.6 be mutual or that a fair alternative cap be applied to Contractor liability.***
***We are unable to accept uncapped liability.***
**A:** In response to the requested modifications we would like to refer to the following points of the Framework Agreement:
**Definition: 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.
The **ownership and use of Results** is defined in Article 12 as follows:
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.
The access rights are further specified and restated according to 12.5.
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**
Please be aware that the access rights of the Buyers are essential to achieve the objectives of the PCP Project and are restricted to the purely non-commercial use. Furthermore, the access to Results according to 12.1 constitutes an important return on the Buyers' 10% contribution to the R&D Services.
Therefore, the proposed changes and deletions to the Framework Agreement are not in line or are not essential for the implementation of the project, and can therefore not be considered.

***Q: Does the "Pre-existing rights" section cover the current state of the platform and solutions available, and does the "Result" then cover all the new features that we will build? Basically, it seems like we only get to define ownership on the pre existing rights.***
**A:** Concerning pre-existing rights and Results, please see the definitions provided in the Framework Agreement. **Definition: 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.
The **ownership and use of Results** is defined in Article 12 as follows:
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.
The access rights are further specified and restated according to 12.5.
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.**
Please be aware that the access rights of the Buyers are essential to achieve the objectives of the PCP Project and are restricted to the purely non-commercial use. Furthermore, the access to Results according to 12.1 constitutes an important return on the Buyers' 10% contribution to the R&D Services.
Therefore, the proposed changes and deletions to the Framework Agreement are not in line or are not essential for the implementation of the project, and can therefore not be considered.

***Q: In Framework agreement template 12.1 and 12.2 the Ownership of results are described. Questions:***
***i) For how long are these valid? After PCP?***
***ii) How would this work in the following scenario: Contractor is a company that already have existing IP for its software. The NGS4P developments would constitute modules that are built on top of this existing IP with intention to commercialize these modules both to the 7 hospitals in the Procurement Group but also other customers. The NGS4P modules that are developed will not work stand alone but need the "existing IP", "baseline" module to function. Who has what ownership of results in such a situation?***
***iii) The one month timeline in 12.2, can that be used to resolve the situation above or how do you see it. 1 month from when exactly is this counted?***
**A i):** Results (i.e. foreground) are defined as 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. In principle, the Contractor owns the Results (subject to Articles 13 and 14) but the Contractor provides 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. The duration of protection depends on the Results that are generated. 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.
**A ii):** Pre-existing rights (i.e. background) are defined as 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. All Pre-existing rights and Sideground remain the property of the Party introducing the same (or any

third party supplier that owns it). Nothing contained in the Framework Agreement or any license contract pertaining or pursuant to the PCP Project affects the ownership rights of either Party (or any third party) in its Pre-existing rights and Sideground. The Contractor provides 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 11).
**A iii):** Article 12.2. stipulates that the Contractor must inform the Procurers (via the Lead Procurer) about the contents of Results that are generated. This obligation to inform the Procurers is independent from any protection of the Results. The one month time limit starts from the day of the generation of the respective Results.

***Q: p14 Article 12.1 Could we discuss about license conditions? Not acceptable as is as it means that SG will provide a license over the PCP Project results but also SOPHIA DDM Platform (if needed to display the result) for non-commercial research purposes, teaching and patient care.***
**A:** See answer to question on p13 Article 11.3.

***Q. p14 Article 12.2 Could we ask for 3 months instead of 1 month, as such initial delay is clearly too short.***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p14 Article 12.3. Could we discuss about modifying this section as some PCP Project results might not be protected by filing (i.e. trade secret) + the results entails a free license on SOPHiA DDM. We cannot accept it as is.***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p14 Article 12.4. Could we discuss this section as this is not acceptable for us. We could consent to a license to exploit but scope of use should be restricted.***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p14 Article 12.7. Could an extended advance notice be acceptable?***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p15 Article 13.3. Could we rather talk about "commercially reasonable efforts" instead of "shall ensure that (...)"***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p15 Article 13.6. Could we discuss about audit rights only on the PCP Project results with a 1 month prior notice?***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p15 Article 13.7. a) If the results are being protected by trade secret for example, it will be impossible to ensure such dissemination. Would a modification on this be acceptable?***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p15 Article 13.7.b) Could we discuss it as mechanism is too broad. What if {the Contractor} rather prefers to keep some aspects as trade secrets and use them rather to license them?***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p18 Article 16.10. Could the 30 days prior information mechanism defined under 16.3. be applicable there too?***
**A:** It is not foreseen to be specified in the Framework Agreement but the appropriate time can be agreed in context of consultation.

***Q: p20 Article 19.4. Not acceptable. We would suggest adding the following: {the Contractor} does not have a direct relationship with patients. End users of {the Contractors} Platform must ensure that they obtain the proper consent and authorisations before sharing personal data to {the Contractor}. Additional wording should be added:The Procures represent and warrant that (i) they are and will at all times remain duly and effectively authorized to provide data to {the Contractor} , (ii) they have obtained and will maintain all necessary rights and authorization for such communication and processing by {the Contractor} and its affiliates in accordance with the Contract, (iii) they have informed the data subject about the processing in accordance with the Contract, and (iv) Data are adequate, relevant, limited to the purposes of the processing and up-to-date. The Procures indemnify {the Contractor} and its affiliates and their directors, officers, employees, agents and other representatives against any demands, actions or claims emanating from a data subject whose data would be or is processed as part of the performance of the Contract. We'd really need to have our GTC and DPA being part of the PCP / Framework documentation.***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p21 Article 19.5.a) Please consider having our GTC and DPA part of the PCP Framework documentation***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p21 Article 19.5.(c) We would suggest rephrasing these provisions as follows: "in such manner as is described under this Framework Agreement or as is required by law or any regulatory body."***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p21 Article 19.5.(f) We would suggest adding the following provisions:"The Procures acknowledge and agree that, for the provision of the Services, the Contractor is transferring the Personal Data to its existing subcontractors and affiliates. The Contractor has***

***implemented the appropriate safeguards and agreements as required by applicable laws."***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p21 Article 19.5.(g) We would suggest adding the following provisions:" the Procures acknowledge and agree that, for the provision of the Services, the Contractor is transferring the Personal Data to its existing subcontractors and affiliates located in Switzerland, in the United States of America and in Australia. The Contractor has implemented the appropriate safeguards and agreements to cover the relevant data transfers as required by applicable laws."***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p21 Article 20 Could you please clarify if only anonymised data will be shared to {the Contractor} ?***
***A.*** The Buyers have to follow the principle of data minimization and therfore will provide anonymized data whenever feasible. However genomic sequences cannot be anonymized!

***Q: p22 Article 21.2. Could you please clarify this need so as we could budget it?***
***A: „***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." See also 21.3.and 21.4 of the Framework Agreement:
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.

***Q: p23 Article 24.3. Could the "appropriate period" be defined ? (e.g. 30 days cure period?)***
**A:** No change; the appropriate time may depend on the issue to be solved.

***Q: p23 Article 24.4. Would an acceptable procedure with criteria and milestones be defined? In the Specific Contract?***
**A:** No, this clause refers to issues that are subsequently discovered to be non-compliant with the requirements of the Framework Agreement. Acceptance by the Lead Procurer of any deliverable or Result does 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. The Request for Tender contains requirements for the assessment of satisfactory completion (p. 103ff.)

***Q: p23 Article 24.8.Could it be precised that such liability / compensation will be ruled by the Framework Agreement conditions?***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: p24 Article 26.1. Could the termination / expiration of the Specific Contracts ruled by the Framework Agreement be clarified?***

**A:** The Specific Contract is effective for the duration of a specific phase, see 2.1.

***Q: p25 Article 27. Could such amendment be used to address specific topics (in complement of the Framework Agreement?)***
**A:** No. The proposed change is not essential for the implementation of the project and can therefore not be considered.

***Q: Specific Contract Article 2.1. Could the relation between the specific contract & the framework agreement be clarified? Would the specific contract expire automatically upon framework agreement expiration/termination or remains in place until full completion?***
**A:** The Specific Contract is an integral part of the Framework Agreement, thus the provisions of the Framework Agreement apply for the Specific Contract. The start and end date of the Specific Contract must be stated in Article 2.1.

***Q: Specific Contract p5 Article 5 Same comment as above***
**A:** The Specific Contract is an integral part of the Framework Agreement, thus the provisions of the Framework Agreement apply for the Specific Contract.

***Q: Specific Contract p6 Article 7 Same comment as the ones mentioned for Article 24.4 of the Framework Agreement: "Would an acceptable procedure with criteria and milestones be defined? In the Specific Contract?"***
**A:** No, this clause refers to issues that are subsequently discovered to be non-compliant with the requirements of the Framework Agreement. Acceptance by the Lead Procurer of any deliverable or Result does 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. The Request for Tender contains requirements for the assessment of satisfactory completion (p. 103ff.)