Q&A concerning the Open Market Consultation (OMC) and Call for Tender

Q1: Who can participate in the OMC?

A: Any person from academia or industry who is developing solutions for, has expertise or interest in NGS in medical diagnostics; clinicians, patients and other stakeholders.

Q2: How to participate in the OMC?

A: Information on the OMC is provided on the INSTAND-NGS4P website; registration can be done via the website; participation is free.

Q3: What will be the format of the OMC?

A: There will be multiple online events, which will be announced on the website:

- a two day virtual event on March 22nd and 23rd 2021, with presentations by Consortium members on medical and patient needs, and the 4 Lots, followed by open discussion
- Webinar on the Tendering Process, 28th of April
- Partnering event on the 18th of May with company presentations

Q4: Who can complete the questionnaire and when?

A: Three questionnaires will address different audiences: Users, Patients, and Suppliers (this includes all 4 Lots – answer questions for relevant Lot(s) only). Questionnaires will be published on the **17th May** on the website (and will also be distributed to OMC participants), and will be open for 2 weeks (**until 31st May**).

Q5: Do issues discussed in the OMC impact specification of NGS workflows as defined later in the call for tenders?

A: A major goal of the OMC is to collect input from a large stakeholder group in order to fine tune specifications of the Lots of the integrated NGS workflow.

Q6: Does participation in the OMC exclude from responding to the call for tenders?

A: No.

Q7: Can solution providers from academia and industry respond to the call for tender?

A: Yes.

Q8: Does one solution provider have to address all Lots of a workflow?

A: No; one solution provider can contribute to a maximum 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).

Q9: Can a group (e.g., a consortium) of solution providers respond to the call for tender?

A: Yes; joint response to call for tender of large companies together with SMEs and academic institutions is encouraged.

Q10: How will the winning solution provider be selected?

A: According to pre-defined criteria, as specified in the call for tender. The selection will be performed by experts from the INSTAND-NGS4P consortium.

Q11: Must solution providers be EU-based?

A: No, but at least 50% of funding (for the whole R&D activities of the project, not for an individual Solution Provider) must be spent in Europe/associated countries.

Q12: Would design support in Europe also be considered as R&D?

A: Yes. The provided funding is an R&D service.

Q13: 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.

Questions arising during the Tendering Process Webinar on the 28th of April:

Q14: 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.

Q15: One company per lot i.e. 8 at the end of the process?

A: See slide 12: PCP Process: 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.

Q16: 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 Call 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.

Q17: Can start-up companies participate in the PCP?

A. Yes

Q18: 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.

Q19: Do we need to meet IVDR already today, or only by 2022?

A: The IVDR requirements should be taken into account in the solutions proposed, but do not have to be met during the project.

Q20: 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.

Q21: 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

Q22: Please can you provide the full names of the abbreviated buyers in the Buyers Group?

A: These have also been added to the webinar presentation on slide 14.

MUG – Medical University of Graz

EMC - ERASMUS University Medical Center

CCRI – St. Anna Children‘s Cancer Research Institute

UNIFI – University of Florence

UKSH – University Clinics of Schleswig-Holstein

UNIMIB – University of Milano Bicocca

CLB – Centre Leon Berard

Q23: Are respondents to the call 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.

Q24: 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.

Q25: Partnering - can you please share some more details on how the process for partnering will be supported?

A: The project will support partnering via a portal on the website (provision of interests and contact details), and via a Partnering webinar on the 18th of May 16:00-18:00 CET.

Q26: 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.

Q27: What is the objective of the pitch presentations on 18.5.?

A: The main objective is partnering (not marketing) with a view to making a joint proposal to the Call for Tender. (i.e. to provide companies with an opportunity to show where they have a smart technology, and have an interest in partnering to complement their portfolio).

e.g. 1) You have a good library technology, but need a compatible sample stabilisation solution

e.g. 2) You have a bioinformatics pipeline, but need a decision support system

e.g. 3) You have a library technique available, but need to partner with a reference material provider

Note: An entire Lot must be addressed (not part of a Lot).

Q28: 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.

Q29: 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.

Q30: 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).

Q31: 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: Correct. 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).

Q32: 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).

Q33: Could we receive a link to the presentation for download? It may not be easy to find the presentation by browsing the website.

A: Yes, this is available on the website (see Recent Posts and News sections), and will be e-mailed to all participants.

Q34: 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.

Q35: 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.