**Instand-NGS4P**

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

**D2.3 End of Phase 2 Report**

**CONTRACT IDENTIFIER:** *please complete*

**LOT NO:** *please complete*

**IMPORTANT NOTICE**

* Please complete a **separate Report for each Lot for which you are developing a Solution.**
* You can use pictures and/or other visual elements if they make your report more understandable.
* Please use a minimum font size of 10. Use a minimal line spacing of 1.
* Page limit: **10 pages** (excludingSection 4, references, tables, figures).

1. **LAY SUMMARY**

*(****max. 250 words,*** *non-confidential, suitable for publication and for reading by patients´ organisations)*

Please complete.

1. **Detailed Description of Solution**

***Please bear in mind that your report will be evaluated by considering the level of implementation of the prototype, with special emphasis on the performance data, including results generated using test samples provided by the Buyers.***

Please describe your prototype in detail, ensuring that all the following points are addressed:

* the intended performance specifications
* how these performance specifications have been achieved including verification of the prototype using reference material data, and test materials and/or other data :
  + methods
  + data generated
  + results
  + final conclusions
* how the prototype fulfils the requirement for innovation
* how the prototype fulfils currently unmet patient and user needs
* which Standards are considered and have been followed in the prototype
* explicit reference to how your prototype addresses the Minimum Requirements1 described in the Request for Tender (Chapter 3.4.2)
* explicit reference to how your prototype addresses the specific Award Criteria described in the Request for Tender (Chapter 3.4.3)
* measures taken to protect results (IPR)
* update the market analysis and commercial plan provided in previous reports for the technologies developed
* any deviations as well as any necessary corrective actions, with regard to the technical aspects and commercial feasibility of your Solution as described in your previously submitted documents.

*1Note: We would like to draw your attention to the requirement that* ***the proposed solution should cover all actionable variant types and genes in the tumour entities listed in Table 1*** *(RfT, section 3.4.2a), for at least one of the sample types (i.e., cryoconserved tissue, FFPE tissue, PAXGene tissue, stabilized blood for ccfDNA). Similarly the* ***solution should cover relevant pharmacogenomics variants of the genes listed in Table 2*** *(RfT, section 3.4.2b).*

1. **FINANCIAL REPORTING**

Please provide a detailed breakdown of the use of the resources in Phase 2. Please include any deviations from the offer for Phase 2.

Include a list of names and location of the personnel that carried out the R&D activities.

*Note: Please consider the requirements for satisfactory completion (Request for Tender, p104):*

* *the budgets have been allocated to the planned objectives*
* *the budgets have been allocated and the work has been carried out according to the on/off award criteria (place of performance, public funding and R&D definition criteria)*

1. **EU Template for PCP End of Phase “Results & Conclusions” for Publication by the EU**

In addition to completion of the above Sections 1 to 3, please also complete below the following EU template for publication by the EU as far as is possible at this stage of the project:

|  |
| --- |
| **Contractors**  *For PCPs: complete this box for each contractor that was awarded a PCP Phase 1, 2 or 3 contract.* |
| **1. The innovative solution**  *Provide a short description (that is suitable for publication purposes) of:*  **The innovative solution** (in its current form)  **Where exactly lies the innovativeness in the solution**: In which ways and to which extent does the solution go beyond what existing solutions can achieve  **The degree of innovation**: indicate if your innovative solution is (a) a totally new product / service / process / method; (b) an improvement to an existing product / service / process / method; (c) a new combination of existing products / services / processes / methods (d) a new use for existing products / services / processes / methods) |
| **2. Commercialisation success**  *Provide a short description (mark parts that are not suitable for publication purposes) of:*  **How mature is the innovative solution in terms of its readiness to commercialise widely**: Which steps towards wide scale commercialisation have been completed by now *(don't forget: IPR protection, certification, CE marking, attracting additional investors to grow the business, setting up sales / distribution channels / marketing activities to expand sales to other countries etc.).*  **What is the current commercialisation success of the solution**: *e.g. awards / other forms of recognitions obtained, sales / increase in market share already achieved, licensing agreements already concluded, collaboration agreements with other partners (e.g. retailers) to commercialise the solutions already signed, additional investments attracted to further commercialise the solution* |
| **3. Other benefits obtained**  *Provide a short description (mark parts that are not suitable for publication purposes) of any other benefits that you obtained from participating in the procurement, e.g.*  **Getting easier access to (a new segment of) the public procurement market** (did the procurement enable you to work with procurers/end-users that you were not working with beforehand)  **Growing your business across borders and/or to other markets** *(e.g. private markets)* thanks to the first customer references provided by the procurement  **Shortening the time-to-market for your innovation** thanks to early customer/end-user feedback  **Other benefits / lessons learnt:** complete if applicable |
| **4. Business growth**  *Provide a short description (mark parts that are not suitable for publication purposes) of:*  **How much has your business already grown during the procurement**  In terms of (a) personnel growth; (b) turnover growth; (c) growth in market share etc.  **What are the prospects to grow your business via wider commercialisation of the solution**:   * how large is the potential market for your solution? is it a growing / steady / declining market? * by when can commercialisation start (now / in 1 / in 3 / in 5 / in more than 5 years) * is competition patchy (no major players) / established (but no comparable offering) / fierce   **Which future steps do you plan to take to further grow your business** *(e.g. attracting additional investors to grow your business, mergers / acquisitions / joint ventures / spin-offs / IPO, setting up sales / distribution channels / marketing activities, expanding to other countries etc.)* |
| **5. Final remarks** *(not for publication purposes, to assess how further EU support could best help you)*  **What are remaining bottlenecks to commercialise your solution** (e.g. certification, legislation etc.)  **What type(s) of assistance do you need to address those bottlenecks and grow your business** / commercialise your solution more widely(e.g. EU regulation on x, finding investors, IPR help etc.)  **How important was the procurement for your business** (w/could you have done it on your own?) |