Virtual OMC Event (22nd to 23rd of March 2021)

The goal of this meeting was to engage stakeholders in the Instand-NGS4P OMC by providing information on the project and the tendering process and addressing the requirement of the NGS workflow lots. The coordinator Prof. Kurt Zatloukal presented the general scope of the project and several experts described the unmet clinical and patient needs and the technical specifications of all lots, based on those previously described in the PIN and Insight Report by the buyers group.

FACTS AND FIGURES:

- 256 registrations for the event, of which 203 were external stakeholders

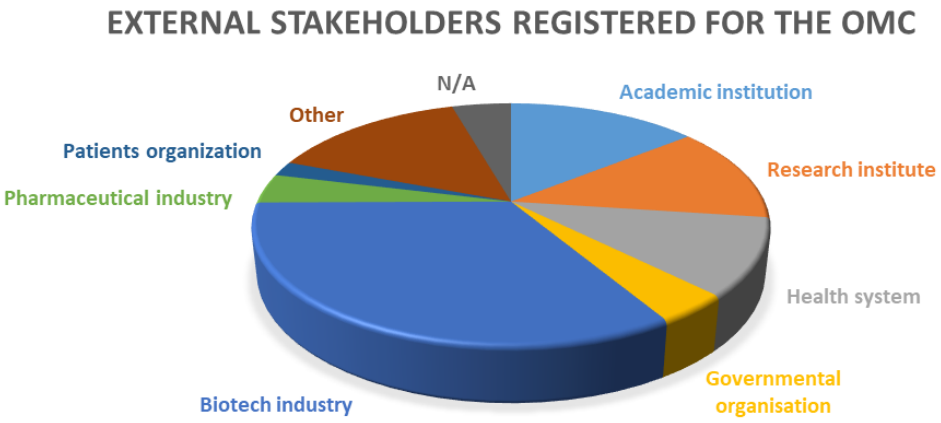

Figure 1. Overview of the profile of the external stakeholders registered for the OMC (total=203) in relation to the sector they belong to.

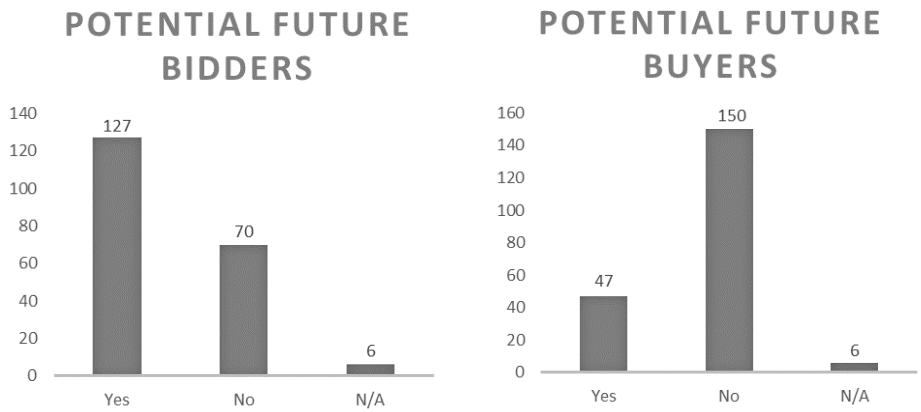

Figure 2. Overview of the profile of the external stakeholders registered for the OMC (total=203) in relation to their interest in being a future bidder or buyer.

Main lessons learned

Regarding the general **Clinical and Technical Needs**, the meeting helped defining the main concerns that need to be addressed by the new NGS workflow from the perspective of the end-users:

- Medical needs:
  - better survival using targeted vs. conventional therapy
  - need for an early and accurate diagnostic (short turn-around time)
  - incorporate pharmacogenomics information, as a major driver of precision medicine

- Sampling:
  - provide solutions for FFPE, fresh, fresh frozen and liquid biopsies
  - importance of sample stabilization
  - need for simplification/automation of isolation steps and to develop methods to isolate DNA/RNA with the same procedure
  - consider the need for a combinatorial profile (germline and somatic)
  - consider the compatibility with other diagnostic methods (e.g. histology and cytology)
  - in particular for paediatric cancer diagnostic, develop solutions that adapt to a low sample volume

- Technology
  - choice sequencing approaches should take into account the precise clinical needs
  - achieve compliance with IVDR, especially for lab-developed tests and genome-wide approaches
  - improve sequencing accuracy and UMI panels
  - reduce hands-on time and costs
  - provide reference material for various workflows

- Data analysis:
  - provide evidence for moving variants into clinical space
  - consider infrastructure and data management requirements
  - consider how to validate bioinformatics pipelines
  - achieve uniformity in interpretation of results
  - focus on training of pipeline users
  - comply with regulations

- Medical Reporting:
  - consider the need for standardization of medical reporting and for its integration in diverse existing systems
  - include pharmacogenomics data, drug interaction and dosing, and clinical evidence
  - provide decision support for physicians
  - reports should be prepared for physicians and patients
  - should be rapid and easy to interpret by patients, and shareable
  - consider the issues of data and privacy protection

Regarding the **Patient needs**, the discussions highlighted the following needs:

- only an NGS approach allows the identification of the genome sequence, the hereditary genetic alterations and the prediction of the responsiveness to therapies
- NGS has the potential to modify the oncological therapeutic scenario; may lead to fewer side effects to the patients

- informed consent must be explained to the patients; privacy and pseudonymization of data should be considered
- patients need to receive information on the NGS process, outcome and treatment options after a multi-disciplinary team has assessed the results
- information should be given in an easy-to-understand format and language
- patients should hold rights to share their diagnostic and to have all the information to decide the follow-up