

Instand-NGS4P – Innovation of Next Generation Sequencing Workflows for Cancer Diagnostics

The starting flag is up and DIN with its Medical Standards Committee is a partner in the 60-month Pre-Commercial Procurement (PCP) project “Integrated and Standardized NGS Workflows for Personalised Therapy”, in short Instand-NGS4P(1), which brings together 7 leading medical centers as a purchasing group with extensive experience in the use of various Next Generation Sequencing (NGS) platforms in research and routine diagnostics. The consortium is further strengthened by European patient representatives, a standardisation organisation (DIN) and partners participating in the European infrastructures BBMRI-ERIC, ELIXIR and several NGS related EU programmes to cover all technical aspects and overall needs and requirements. The project is funded by the EU Framework Programme for Research and Innovation Horizon 2020 with an amount of 10.998.128,16 € and is coordinated by the Medical University of Graz.

Instand-NGS4P was opened in a kick-off meeting on 30-31 January 2020 at the Medical University of Graz in Austria. More than 60 experts in Next Generation Sequencing also participated in the upstream workshop “NGS for Personalized Medicine”, a public workshop that provided background information on the project and included presentations on the current scientific and medical research work of the project partners.

The goal of Instand-NGS4P is to develop innovative NGS workflows from sample pre-analysis to medical decision making, driven by patient and clinical needs. The modular structure of the workflow will allow especially SMEs to contribute and offers flexibility in adapting to new user needs and technologies. The specifications will address the regulatory requirements for IVDs and refer to international standards and requirements concerning the development of reference materials and the implementation of EQA schemes for the entire workflow.

The R&D suppliers will be selected on the basis of a public tender along this PCP process in 3 phases to find the solution with the best price/performance ratio. The 3 phases will involve the use of 4 technical modules (preanalytics, sequencing, bioinformatics, e-reporting/ e-medication) and their standardized interfaces - from design (phase 1) to prototypes (phase 2) as well as full integration into phase 3. In the end, this PCP will provide two fully integrated, standardized NGS workflows for the routine diagnosis of common and rare cancers from adult to pediatric.

To enable broad implementation in health systems across Europe and beyond and to increase the benefits to patients, a number of support activities are planned, including communication and dissemination activities targeted at a broad stakeholder group, development of training and educational materials for health professionals and patients, health economic evaluation, and collaboration with payers and health policy makers.

DIN's task will be to support the consortium in transferring relevant research results into norms and standards. Taking into account or in coordination with NGS-relevant activities in ISO/TC 276 “Biotechnology”, ISO/TC 212 “Clinical laboratory testing and in vitro diagnostic test systems” and ISO/TC 215 “Health informatics”, the results will be integrated into the work programme of the European committee CEN/TC 140 “In Vitro Diagnostics” as previously done in the SPIDIA and SPIDIA4P projects.

For further information about the Instand-NGS4P project, you can follow this link:
<http://www.instandngs4p.eu/>

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(2) Medical University Graz, University of Florence, ERASMUS University Medical Centre, University of Milano-Bicocca, University Clinics of Schleswig-Holstein, St. Anna Kinderkrebsforschung, Centre Leon Bérard, Italian Federation of Cancer Patient Associations, European Cancer Patient Coalition, Deutsches Institut für Normung e.V., Technische Universität München, University of Ljubljana, University of Manchester, University of Liverpool, Organisation of European Cancer Institutes, University of Helsinki, BioXPedia and the International Prevention Research Institute.

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