Press Release
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Qlucore and Heidelberg University Hospital partnership receives 500 000 Euro from the EU for development of RNA-seq based cancer diagnostics

Qlucore is delighted to announce a joint project with Heidelberg University Hospital to develop Qlucore Diagnostics - a medical device artificial intelligence (AI)-powered software - for improved clinical diagnostics of lung cancer.

Precision diagnostics driven by Next-Generation-Sequencing (NGS) is the future of cancer management. While DNA-based assays have been used for several years, RNA-based solutions are now gaining momentum, allowing for cancer classification using gene fusions and gene expression signatures. RNA-seq can reliably detect gene fusions and measure gene expression levels, thereby providing more insights into cancer biology. By profiling cancer by RNA-seq, critical information can also be obtained about the "immunological state" of the tumours and if the patients are likely to respond to immune checkpoint inhibitors (ICIs). Hence, RNA-seq aids a biologically-founded tumour classification, and consequently allows for more specific and accurate cancer diagnosis and treatment.

Despite tough competition for funding, the partnership successfully secured the funds from the **Eurostars** joint European programme, which is aimed at R&D performing SMEs that wish to exploit the benefits that come with international collaboration. With this funding, Qlucore and Heidelberg University Hospital partnership will see the development of a ground-breaking solutions for cancer classification and diagnostics based on RNA-seq data including AI powered machine learning based classifiers.

Through a combination of expertise in bioinformatic software (Qlucore) and cancer diagnostics (Heidelberg University Hospital) the partnership will develop and clinically validate the first version of *Qlucore Diagnostics* for the classification of non-small cell lung cancer (NSCLC). This product will be CE-marked.

Qlucore Diagnostics is the missing element in the clinical precision diagnostic workflow. With machine learning algorithms enabling classification of lung cancer into distinct subtypes and a clinical decision support functionality allowing to predict patients' response to treatment, plus user-friendly 3D visualizations of the results, and user support in clinical decision making, *Qlucore Diagnostics* will be the future of personalized precision oncology.

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”We are proud to have been granted these funds in tough competition with many other proposals across Europe and it another proof of our plans to enable faster and more precise cancer diagnostics” says Carl-Johan Ivarsson, CEO.

The product will be sold to hospitals, clinics and diagnostic laboratories, utilizing Qlucore’s existing sales force in Europe and the US.

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Notes to Editors: Interviews available with Carl-Johan Ivarsson, CEO of Qlucore.

Further information on the project

The project has the following specific objectives:

1. to establish a co-operative R&D management framework (WP1)
2. to generate large-scale RNA-seq data and immune gene signature data from fresh-frozen NSCLC samples and lung cancer metastases required for classifier development (WP2)
3. to develop the classifier for NSCLC (AI-powered machine learning algorithms) and a clinical decision support functionality allowing to predict patient's response to ICIs therapy (WP3)
4. to integrate classifier and clinical decision support functionality into *Qlucore Diagnostics* and develop the software to full production quality based on feedback from early adopters (WP4)
5. to validate the solution through prospective clinical samples along gold standard methods (WP5)
6. to develop the cloud version of the solution (WP6)

More Detail;

Despite the development of the targeted therapies directed against specific gene fusions (e.g. ALK-, NTRK-, NRG1-, ROS1- and RET-fusions), NSCLC is still the most frequent cancer-related cause of death worldwide. A major challenge to improve the outcome of patients diagnosed with NSCLC is to develop reliable classification methods, allowing the prediction of a patient's response to treatment. To take advantage of this opportunity, the Consortium aims to close the existing gap to the market by finalizing the product in terms of technological, clinical and regulatory requirements.

To ensure running the project on the highest quality level, in WP1 we will collaboratively perform general project management and dissemination activities. Within the consortium, we will share the responsibilities for innovation management, risk management and IP management and use access to key stakeholders to optimally disseminate project results.

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To generate data required for the development of the classifier for NSCLC and clinical decision support functionality, in WP2 Heidelberg University Hospital will generate RNA-seq data from biopsies from NSCLC patients. Heidelberg University Hospital is a leading European NGS-based clinical diagnostic center with a large biobank of fresh-frozen lung cancer samples and a database including clinical records of the patients.

In the project will develop the diagnostic classifiers for NSCLC and clinical decision support functionality - including the prediction of NSCLC patient's response to targeted drugs and immune-checkpoint inhibitors (ICIs) treatment. The different steps of the NSCLC classification (identifying potential metastasis, subtyping, gene fusions and immune gene signatures) are selected to provide physicians with a comprehensive output required for the complex task of diagnosing NSCLC. Initial classifier validation will be performed using retrospective data, because the use of these data is similar to using newly produced clinical data. The clinical utility of the RNA-based diagnostics of NSCLC has been scientifically confirmed and KOLs such as prof. Stenzinger (Heidelberg University Hospital) involved in this project emphasizes the market need for an improved NSCLC diagnostics. Qlucore will be responsible for the technical side of classifier and clinical decision support functionality development, while Heidelberg University Hospital will provide medical expertise and RNA-seq data generated in WP2.

To develop the product with a minimum required set of functionalities including classifier and clinical decision support functionality, which can be presented to customers, in WP4 we will transfer the product from the current alpha development stage (TRL-6) to the Minimum Viable Product stage (MVP) (TRL-8), integrating classifier and clinical decision support functionality. Specifically, Qlucore will use feedback from Heidelberg University Hospital to improve user interface, complete the functionality of the product such as interaction with Laboratory Information Management Systems (LIMS) (a system to keep track of the samples and data used in many labs), and develop Qlucore Node for seamless integration in Linux based tool-chains, which is a common lab set-up.

To confirm the clinical utility of *Qlucore Diagnostics*, which is the key to commercial success, and collect data required for CE certification, in WP5 we will validate the classifier in clinical settings through prospective diagnostic data provided by Heidelberg University Hospital in parallel with their current routine diagnostics. Clinical validation study will allow Qlucore to prepare a technical file for the CE mark certification.

To provide customers with versions that fit into their current IT environment and working models, both desktop with local server-based solutions as well as secure cloud solutions, in WP6 we will develop the cloud version of the solution. This will strengthen the overall scalability of the solution and facilitate broad market uptake.

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About Qlucore

Qlucore is a leading provider of new generation intuitive bioinformatics software for research and precision and companion diagnostics. Qlucore's mission is to make it easier to analyze the huge amounts of complex data that are generated by innovations in the fields of genomics and proteomics by providing powerful visualization-based bioinformatics data analysis tools for research and precision diagnostics.
The Qlucore Omics Explorer software is a Do-It-Yourself bioinformatics software for research in the life science, plant- and biotech industries, as well as academia.
The Qlucore Diagnostics and Qlucore Insight softwares are a platforms for multi-omics companion and precision diagnostics. Qlucore was founded in 2007 at Lund University, Sweden and has today customers in about 25 countries around the world, with sales offices in Europe and North America, and distribution in several countries in Asia. www.qlucore.com

Attachments

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