

1. PUBLISHABLE SUMMARY

Summary of the context and overall objectives of the project (For the final period, include the conclusions of the action)

Glycanostics is an innovative start-up company established in 2017 to bring its revolutionary cancer diagnostics products to the US and EU markets. The company was founded by two scientists Jan Tkac, DSc and Tomas Bertok, PhD who got international recognition for their scientific works, prestigious grants and awards winners such as Scientists of the year (Slovakia) or European Research Council (ERC) Consolidator grant. Glycanostics develops and will sell glycan-based, accurate, affordable and non-invasive tests for cancer diagnostics in early stages which could save thousands of people's lives and prevent unnecessary treatment. Diagnostics is done by the analysis of glycan changes on specific proteins like a prostate-specific antigen (PSA) in a non-invasive way. The tests are designed to help doctors to make a proper decision about a need to perform a biopsy or to check the patient after the biopsy, which misses 30% of prostate cancer patients. The feasibility assessment revolved around four main objectives: clinical validation, regulatory and commercialization assessment, strategy for sales and business model refinement.

Objectives:

- (1) In collaboration with science advisors, KOLs and other clinicians, the objective was to perform pre-clinical validations of the PCa DX kit and Prostate check home test using serum samples from the biobank.
- (2) Based on the GAP analysis, the team researched necessary regulations leading to certification of the PCa DX kit and Prostate check home test. A detailed layout for clinical relevance validation and subsequent EMA approvals were designed.
- (3) Our marketing & sales strategy ran in parallel with clinical validation and certification process by building a network of KOLs using our team, science advisors, key partners. Later, we designed a strategy built on personal contacts, B2B, B2C, SEO, email marketing, PR events, articles/blogs to create direct sales to clinical labs under Glycanostics.
- (4) To establish the best go-to-market strategy, we assessed the production costs, distribution channels and fine-tuned our business model.

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far (For the final period please include an overview of the results and their exploitation and dissemination)

The feasibility assessment revolved around four main areas of action: (1) The pre-clinical validation was carried out on 140 serum samples, using Glycanostics diagnostic technology. The results proved a strong performance of the Glycanostics test. (2) Regulatory and commercialization assessment focused on identification of target markets and their subsequent analysis in terms of regulatory conditions, in the B2C and B2B business cases. The analysis concluded that markets of Sweden, Germany and the U.S. should be of priority to the company. In terms of (3) Marketing & sales strategy, the team conducted extensive research of target markets to identify relevant partners for commercialization and sales, as well as competitors to establish proper benchmarking. Lastly, (4) Business model refinement derived from analysis of both B2B and B2C cases and concluded that the B2B segment has the highest potential for commercialization.

Progress beyond the state of the art, expected results until the end of the project and potential impacts (including the socio-economic impact and the wider societal implications of the project so far)

The mission of the project is to address the economic/societal burden of PCa by developing innovative, glycan-based, reliable, accurate, affordable and non-invasive tests for early PCa diagnostics to improve quality of life and save millions of men from misdiagnosis, fitting the EU Health Challenges. Glycanostics offers a revolution in PCa diagnostics by addressing relevant customer pain points. The assay of the test is highly innovative since early PCa diagnostics is performed by simple analysis of glycan changes on PSA directly in human serum, while the competitors focus on analysis of complex DNA, RNA and proteins for PCa diagnostics. The feasibility study's impact derives from its validation of the company's product and confirmation of commercial strategy. The overall conclusion of the feasibility assessment is to continue with further development of the company and the project.

Address (URL) of the project's public website

<https://www.glycanostics.com/>

