





## GUT-AND-LIVER AXIS IN ALCOHOLIC LIVER FIBROSIS GRANT NUMBER 668031

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DOCUMENT MAIN AUTHOR: Aleksander Krag, WP 8 Leader DOCUMENT SIGNED OFF BY: Project manager Louise Skovborg Just (University of Southern Denmark)

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## 1. AIMS

## FUTURE EXPLOITATION STRATEGY DESCRIBED

THE EXPLOITATION PLAN WILL PRESENT OPTIONS FOR LONG-TERM SUSTAINABILITY OF THE CONSORTIUM AND NETWORK AFTER THE OFFICIAL END OF THE PROJECT.

## 2. RESULTS

The GALAXY project is built on a strong scientific network and during the first 42 months of GALAXY the collaboration has been fortified. First of all the 11 partners in GALAXY have experienced a fruitful collaboration across fields. The consortium is constructed in a way where the partners complement each other and the project thereby experience a synergic effect. Already now the GALAXY project has generated a unique data collection and the first results from the project are starting to appear and this has inspired the GALAXY partners to establish other collaborative platforms to exploit the GALAXY data and results also further than described in the GALAXY project plan.

This has resulted in a new consortium MicrobPredict under the leadership of Jonel Trebicka (GUF) and with the participation of three other GALAXY scientific partners (OUH, UCPH & EMBL). MicrobPredict focuses on microbiome-based biomarkers to predict decompensation of liver cirrhosis and treatment response and will build on the data from GALAXY and other large European consortium plus new data will be generated from one of the GALAXY cohorts. MicrobPredict is funded by H2020 (grant number 825694) with 15 million € will run from 1 January 2019 to 31 March 2025.

In parallel with the GALAXY project, the MicrobLiver project was initiated funded by the Novo Nordisk Foundation (Denmark). MicrobLiver focuses on the gut microbioata in NAFLD (non-alcoholic fatty liver disease), NASH (non-alcoholic steatohepatitis) and ALF (alcoholic liver fibrosis). From the start of the GALAXY project a strong collaboration between the two consortia was established. It allows for further use of the GALAXY data as the MicrobLiver consortium also includes the Matthias Mann Lab and thereby opens for Proteomic analyses. It is expected that further collaboration between the two consortia will be established to increase the synergic effect. In 2018 a consortium with four partners from the two consortia was established for a proposal for Novo Nordisk Foundation. The proposal was one out three proposals invited to submit a Phase 2 proposal, but was not funded in the end.

On an organisational level, GALAXY has kick started some developments that have a consolidating effect both on consortium level but also when looking at the research field of GALAXY: the gut- and-liver axis in alcoholic liver fibrosis.

OUH has established an Elite Research Centre for Liver research: FLASH (fibrosis, fatty liver and steatohepatitis). The Elite Research Center is headed by GALAXY Coordinator Dr. Aleksander Krag and funded with 14 million DKK (app. 2 million €) during 5 years (from 1 July 2017) and with an expected extension of 5 years also funded with 14 million DKK. Two adjunct professors from the GALAXY consortia have been appointed to FLASH: Dr. Mani Arumugam and Dr. Jonel Trebicka.

Ultimo 2018, Dr. Jonel Trebicka and his research group left University of Bonn (UKB) and established a new centre for Translational Hepatology (TransHep) at Goethe University Frankfurt (GUF). The research focus of







TransHep is to the test experimental therapies in-vivo in rodent models of fibrosis and ACLF (Acute Chronic Liver Failure) and in-vitro in human and rodent hepatic primary cells and cell lines.

Dr. Torben Hansen, Novo Nordisk Foundation Center for Basic Metabolic Research (UCPH) was awarded new (consolidating) funding of 700 million DKK (94 million €) from Novo Nordisk Foundation to strengthen interdisciplinary research that transforms the basic understanding of the mechanisms involved in metabolic health and disease, and to accelerate this knowledge toward new prevention and treatment strategies.

On a commercial level, the three companies in GALAXY, Nordic Bioscience, Nordisk Rebalance and Norgine work actively on pursuing a commercial output of GALAXY. Since the commercially exploitable results are highly depending on ongoing clinical validation studies, it is difficult to predict the full extent of the gain with regard to job creation, increased company value etc. However, already now it is clear that the data generated in GALAXY will support the "stand alone diagnostic" use on platforms for ALD. Data generated in consortiums such as GALAXY are essential for the further use and commercial uptake of biomarkers.

The research groups TransHep (GUF) and FLASH (OUH) are both closely connected to hospitals and in the case with FLASH directly integrated into the clinical environment at Odense University Hospital. Dr. Jonel Trebicka (GUF), Dr. Aleksander Krag (OUH) and Dr. Maja Thiele (OUH) are actively involved in a number of European consortia constantly developing clinical practice guidelines plus designing and conducting multicenter European studies based on the newest scientific results, e.g.: EASL-guidelines, UEG, Baveno Group, EASL-VALDIG, International Club of Ascites, SALVE, EMA scientific board for GI and Liver diseases. Moreover TransHep and FLASH are involved in a number of large European multi-center clinical studies like Predict, Europe-Wide CLIF, LiverScreen. With this close connection to clinical centers across Europe, it is anticipated that the expected scientific and commercial results generated in GALAXY by the end of the project will affect clinical practice in the future.

The above described developments/activities on project-, organisational-, clinical practice- and commercial-level make the GALAXY consortium partners interconnected and also interdependent on several levels. This creates an optimal platform for longtime sustainability of the consortium, the network and the research field. However, it is difficult to foresee the exact results of GALAXY at Month 42. Therefore at Month 66, the consortium will lay out a strategy for further exploitation of the GALAXY results and network beyond the GALAXY project period.