

# CLINICAL STUDIES GALAXY

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

***DELIVERABLE NUMBER: D1.2***

***DELIVERABLE DUE DATE: JANUARY 1<sup>ST</sup> 2017***

***COMPLETION DATE OF DELIVERABLE: JANUARY 12<sup>TH</sup> 2017***

***DISSEMINATION LEVEL: PUBLIC***

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## 1. AIMS

*Deliverable 1.2: Identified and included 100 healthy controls in GALA-HP: Gut-and-liver axis in a healthy population (M0-12) (OUH)*

One hundred patients were included in the study. All patients were screened before inclusion with an online questionnaire to ensure that they did not take any medication, had not received antibiotics six months prior to the inclusion, did not have a harmful use of alcohol (never above 5 units at a time, no daily drinking, no more than average 7 units of alcohol per week for female, 14 units for male) and did not have any chronic diseases or ailments.

The inclusion visit consisted of same-day extensive phenotyping with demographical data, quality of life questionnaires, medical history, nutritional parameters such as bioimpedance and hand-grip-strength, liver routine blood samples, abdominal ultrasonography, and liver elastography to assess liver stiffness. Additionally we sampled tissue for biobank: blood, feces and urine.

We excluded five participants after passing the screening questionnaire due to disease diagnosed in close relation to the inclusion visit: One with type 2 diabetes diagnosed at inclusion, one with hypothyroidism diagnosed at inclusion, and four on suspicion of malignancy: One breast cancer diagnosed the day after inclusion during a population breast screening programme; one rectal carcinoma, diagnosed at sigmoidoscopy, one urological mass diagnosed on ultrasonography during the inclusion visit, but not yet biopsied; and one large, irregular cyst between the liver and the kidney diagnosed on ultrasonography during the inclusion visit, but not yet scanned with CT.

All patient data is stored on a secure server on Odense University Hospital using the research database REDCap and Sharepoint Secure drives. All biobank tissue is logged and stored at Department of Clinical Biochemistry and Pharmacology, with Odense Patient Data Exploratory Network holding the overall responsibility for safe storage of both electronic data and tissue.

## 2. RESULTS

The first 52 healthy subjects have been matched 1:1 with 52 patients from the GALA-ALD alcohol cohort (table)

	<b>GALA-HP: Healthy subjects</b>		<b>GALA-ALD: Alcohol overusing patients</b>	
Age (years)	mean 57.0 sd 9.2	median 56.0 iqr 14.0	Mean 57.7, sd 9.0	Median 59.0, iqr 10
BMI (kg/m <sup>2</sup> )	mean 26.4 sd 4.0	median 25.9 iqr 4.5	Mean 26.5, sd 4.1	Median 26.4, iqr 5.2
Gender (m:f)	39:13	3:1	39:13	3:1

We have shipped fecal tissue to Centre for Metabolic Research at University of Copenhagen (partner UCPH).

We have not yet submitted scientific manuscripts using data from the healthy control cohort.