



Research Grant Report Form

Name and origin of applicants: Marie Skougaard, Department of Clinical Immunology, Aarhus University Hospital, Denmark

Purpose of research project granted: To evaluate dd-cfDNA as a marker of early allograft rejection in the first year after heart transplantation

Amount granted: DKK 170.000

Report of scientific progress: As specified in the project description, the project is divided into three phases. The report will present progress on these phases separately.

Phase 1: *Analytical setup and laboratory validation*, the dd-cfDNA analysis has been set up at the laboratory at Department of Clinical Immunology, Aarhus University Hospital. The initial pilot testing has been conducted demonstrating satisfactory results of the implemented NGS (Next Generation Sequencing)-based technology. The validation part of phase 1 has been postponed as it will be based on patient samples collected during phase 2 of the project.

Phase 2: *Clinical test and validation*, includes the clinical observation cohort comprising heart transplant patients from Aarhus, Copenhagen and Oslo. The organisational framework has been established to ensure data collection in a shared database, collection and shipment of blood samples for the dd-cfDNA analysis and biobank. The project has been approved by the Ethics Committee in both Denmark and Norway in line with the time schedule. However, agreements intended to ensure the lawful data sharing between interregional and international partner have been a long time in the making, why patient inclusion has not been initiated. Currently, we have received the final confirmation on changes to the agreements from the legal departments of the individual participating centres. Thereby, expecting signed agreements before summer after which patient inclusion is initiated.

Phase 3: *Clinical implementation*, is the final phase of the project, which will be initiated in the last year of the project.

The Scandiatransplant Research Grant primarily funded TAP-assistance from partners in cardiology, which will be utilized after initiation of patient inclusion. Therefore, a financial balance has not been submitted with the report as none of the funding received from the Scandiatransplant Research Grant has been utilized to date.