ELPA
European Liver
Patients' Association

ELPA and EU Medical **research projects**

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Contents

Our Mission

ELPA emerged from a desire amongst European liver patient groups to share their experiences of the often very different approaches adopted in different countries. In June 2004, 13 patient groups from 10 European and Mediterranean basin countries met to create the association. ELPA was formally launched in Paris on 10th April 2005 during the annual conference of the European Association for the Study of the Liver (EASL) and now has 31 member associations from 25 countries.

ELPA's aim is to promote the interests of people with liver disease and in particular: to highlight the size of the problem, to promote awareness and prevention, to address the low profile of liver disease as compared to other areas of medicine such as heart disease and to share experience of successful initiatives. ELPA and its members are dedicated to multi-level lobbying initiatives involving European Union and national policymakers, liver specialists, associations and public health experts to ensure that treatment and care are harmonized across Europe to the highest standards.

ELPA's focus is in line with ELPA strategy 2020 – 2023 and will be on:

1. POLICY WORK – EU level, national level, other organizations
2. MEMBER EMPOWERMENT – Training, capacity building, networking
3. ORGANISATION MANAGEMENT- Communication, visibility, source management

Our Vision

ELPA's vision is that all liver patients are diagnosed in time, are treated with respect, and have equal access to the best standard of medical care – regardless of origin, lifestyle, and type of liver disease. Our ultimate goal is a world without liver diseases.

Our Values

Equality

Respect for diversity

Patient driven

Commitment

Transparency

Foreword of the President

For 16 years now, ELPA has been advocating to change the life of liver patients for the better and make their voices loudly heard. It has been a long and difficult journey but ELPA has never given up, being aware of the fact that what is at stake is saving lives.

In this context, ELPA is like an upgraded patients' association. Indeed, ELPA brings together people, knowledge, and expertise from 31 member associations in 25 different countries. As an umbrella patients' association, ELPA acts like as an intermediary between all the involved stakeholders - the national patients' communities, the industry, and the EU policymakers - by providing a crucial perspective because ELPA, through its members, has a primary and direct access to the patients' lives and to the best practices in a national and regional context. As one voice, ELPA works to promote the development and implementation of policies, strategies and healthcare services that empower patients to be involved in the decision-making. In addition, ELPA strives to enhance the capability of patients to play an active role in all aspects of their treatment and care.

ELPA was invited to participate in first Horizon 2020 project years ago when it was not a common practice to have patient association as project partner. The EU Framework Program for Research & Innovation in brief called Horizon 2020 is the EU's biggest ever program for research and innovation. Horizon 2020 is delivering excellent science for Europe and is the biggest EU research and innovation program ever. The results of the research lead to more breakthroughs, discoveries and world-firsts by taking great ideas from the lab to the market. Excellent science, competitive industry and tackling societal challenges are at the heart of Horizon 2020 and this are also milestones of improving healthcare for liver patients.

ELPA's participation in scientific projects is part of this tireless advocacy work and contributes to this virtuous circle. On the one hand, being part of them enriches the research field with the unique views of patients' organizations. On the other hand, ELPA, with its exclusive way in communicating and disseminating scientific results, acts like a translator making complex contents accessible to a broader public. We are proud that to this day ELPA is included into science research projects that explore the possibilities to improve the life of liver patients – in total around 75 million EUR spend for top liver research in Europe at more than 50 top research laboratories and hospitals in Europe.

It is important to know that ELPA members represent ELPA's communication and dissemination activities first target. Patients' organizations play a vital role in the whole society, forging a pathway for both patients and clinicians to access new and innovative treatments, as well as providing governments with the necessary research and background information to enable them to make informed decisions. These organizations provide information, advocacy, and support to millions of people each day; this is the reason why they should have an easy access to crucial and updated scientific information.

Marko Korenjak

President of ELPA - European Liver Patients' Association

Foreword of the Scientific Committee leader

As a retired hepatologist and a representative of one of ELPA's member organizations, I could not be more that pleased regarding ELPA's engaging in scientific projects. I believe that the partnership of patients is really needed to link health specific problems that affect liver patients to research. It is important that patients join in research and help to disseminate research results back into society also because ELPA is strongly aware of the heterogeneity of health care systems in Europe and of the consequent differences in accessing treatments.

In the past, industry, academia, healthcare professionals, regulators, and patient organizations have largely worked in silos. In practice, many decisions about patients' care, medical research, health information and service design were taken without meaningful patient involvement. This led to inefficiencies and low value in process and outcomes. However, patient involvement can optimize the ethics, relevance, accountability and transparency, communication, promotion and implementation of research outcomes and ELPA, with its unique perspective and background, is proud to be part of this crucial process that contributes to create a better society advancing in a better consideration and awareness of liver diseases.

The contribution of patients' organizations in this field could be summed up in three words: involvement, participation and engagement.

Involvement - joining grant holders or co-applicants on a research project, identifying research priorities, being members of a project advisory or steering group, commenting and developing patient information materials, or undertaking interviews with research participants.

Participation - being recruited to a clinical trial or other research study to take part in the research, completing a questionnaire, or participating in a focus group as part of a research study.

Engagement - when information and knowledge about research is provided and disseminated through media such as television programmes, newspapers and social media, or through events open to the public with debates and discussions on research

Being successfully part of 10 EU-funded scientific projects ELPA provides each of the project with an original, specific and experienced contribution in each of the three areas sketched above. This skilled multifaceted nature, also characterized by the fact that it is the representative of the voice of patients in EMA, the European Medicines Agency, is the main strength of ELPA and it shows its high level of commitment towards the patients' community and beyond.

Dr. Teresa Casanovas-Taltavull M.D.

Leader of ELPA Scientific Committee

Acknowledgments

ELPA President and all ELPA Team would like to thank **Anna Boitard, Berta Borràs, Paola Cesaroni, Beatrice Credi, Mary Gazea, Laura Maccari, Ameli Schwalber, Louise Skovborg Just, Victor Van Gucht** and **Veronika Všetičkova** for their support and revision of this booklet. Thank you for the availability and the effort on working together to improve the lives of liver patients.

LiverScreen

Screening for liver fibrosis - population-based study across European countries

Objective

Liver cirrhosis is a very common and severe chronic disease, responsible for high morbidity, impaired quality of life, major healthcare costs, and poor survival, causing an estimated 170,000 deaths per year in Europe. Liver cirrhosis is preceded by a long period of slowly developing, asymptomatic, liver fibrosis; most commonly caused by non-alcoholic fatty liver disease (NAFLD, related to obesity and type 2 diabetes), alcohol, and hepatitis B or C virus infection. There is no treatment available to reverse advanced liver cirrhosis. However, if fibrosis could be detected early, all of the major causes are still amenable to prevention and treatment. Early diagnosis of liver fibrosis in the general population is therefore crucial for the estimated 10 million Europeans with undetected liver fibrosis.

The LiverScreen project aims to develop a targeted screening methodology to identify persons with asymptomatic liver fibrosis and cirrhosis among the general population. This methodology involves: 1) identification of groups from the general population at high risk of having chronic liver disease, 2) screening their liver stiffness with the innovative transient elastography (TE) technology (until now only validated in patients with known liver disease) for diagnosis, and 3) determining the right follow-up screening regime. Within the LiverScreen project 8 European countries will collaborate and perform research in over 34,000 subjects to develop the screening methodology and demonstrate its accuracy, clinical value, cost-effectiveness, acceptability, and potential to be implemented by healthcare systems throughout Europe.

Using the LiverScreen program, diagnosis at an early stage can stop liver disease progression and have a subsequent long-term impact on liver disease morbidity and mortality and the associated societal burdens in terms of economic costs and health inequity. The estimated cost reduction ranges from €850 to €4,000 per quality-adjusted life-year gained.

Grant agreement ID
847989

Start date
1 January 2020

End date
31 December 2024

Funded under
H2020-EU.3.1.2.

Overall budget
€ 5 996 481,25

EU contribution
€ 5 996 481,25

Coordinated by
FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA, Spain

Medical research project LIVERSCREEN:

Within medical research project LIVERSCREEN, ELPA is the leader of workpackage responsible for dissemination, communication and exploitation. ELPA's main objective is to ensure communication and dissemination of the medical research project LiverScreen activities, progress and achievements beyond the project partners, including scientific community, policy makers and general population and to:

- facilitate interaction with relevant stakeholders (patients and their families, physicians, policy makers),
- to promote training activities on topics related to the project to improve implementation of project activities,
- to set up an exploitation strategy for the liver screening program to demonstrate the sustainability plan after the project ends.

The process of dissemination and communication is involving all ELPA's communication channels and we actively participate in events organized by medical research project LiverScreen.

Coordinator

FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA

Spain

Participants

ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

France

AZIENDA OSPEDALE UNIVERSITA PADOVA

Italy

BARCELONA SUPERCOMPUTING CENTER - CENTRO NACIONAL DE SUPERCOMPUTACION

Spain

CONSORCIO MAR PARC DE SALUT DE BARCELONA

Spain

ECHOSENS

France

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

Netherlands

EUROPEAN ASSOCIATION FOR THE STUDYOF THE LIVER

Switzerland

EUROPEAN LIVER PATIENTS ASSOCIATION

Belgium

GENESIS BIOMED

Spain

INNOVATION ACTA S.R.L.

Italy

INSTITUT CATALA DE LA SALUT

Spain

ODENSE UNIVERSITETSHOSPITAL

Denmark

SVEUCILISTE U ZAGREBU MEDICINSKI FAKULTET

Croatia

THE UNIVERSITY OF NOTTINGHAM

United Kingdom

UNIVERSIDAD POMPEU FABRA

Spain

UNIVERSITAETSMEDIZIN DER JOHANNES GUTENBERG-UNIVERSITAET MAINZ

Germany

UNIVERSITAT DES SAARLANDES

Germany

UNIVERSITY COLLEGE LONDON

United Kingdom

LIVERHOPE

SIMVASTATIN AND RIFAXIMIN AS NEW THERAPY
FOR PATIENTS WITH DECOMPENSATED CIRRHOSIS

Objective

Liver cirrhosis is a very common chronic disease and one of the leading causes of death in European. Moreover, cirrhosis has a marked impact in patients quality of life and represents a major burden for health systems. Treatment of cirrhosis is currently based on symptomatic management of complications and has not changed substantially in the last 20 years. There is an unmet need for therapies that target the pathobiology of cirrhosis.

The objective of LIVERHOPE project is to evaluate a novel therapeutic strategy for patients with cirrhosis based on a combination of rifaximin and simvastatin, targeting the main pathophysiological mechanisms of disease progression , namely the impairment in the gut-liver axis and the persistent hepatic and systemic inflammatory response. This dual therapeutic approach is supported by preclinical data showing excellent and very promising results.

We will perform two randomized double-blind trials to investigate safety, tolerability and efficacy of combination of simvastatin plus rifaximin in patients with decompensated cirrhosis in 5 EU countries (285 patients will be enrolled in two trials in DE, ES, FR, IT, UK). The expected impact is to halt progression to acute-on-chronic liver failure, the main cause of death, to decrease complications of the disease, to reduce hospital readmissions, to improve cost-effectiveness of therapy. Our final aim is to improve patients quality-of-life and increase survival as patients' care is the core of LIVERHOPE. Within the project we will also investigate biomarkers of response to treatment and disease progression that can be useful in clinical practice for improving the treatment of patients. We will invest our effort also in communication and dissemination activities for increasing awareness about chronic liver diseases in European countries so that preventive measures can be established to decrease the burden of cirrhosis and reduce social stigmatization of patients with chronic liver diseases.

Grant agreement ID

731875

Start date

1 January 2017

End date

31 December 2021

Funded under

H2020-EU.3.1.3.

Overall budget

€ 5 998 800

EU contribution

€ 5 998 800

Coordinated by

CONSORCI INSTITUT D'INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER, Spain

Medical research project LIVERHOPE:

ELPA's main role is to communicate and disseminate the project results beyond the project partners to a large audience and potential users of the results, including the clinical/scientific community and the general public.

ELPA has a very important role in this context as per engagement of the patient' association members from the very beginning of the project and maintain to inform them about findings and progress of medical research project LIVERHOPE studies. ELPA presents medical research project LIVERHOPE findings and progress to patients' associations yearly on an event - either own symposium or other relevant venue exclusively dedicated for the medical research project LIVERHOPE studies, their efforts and findings, displaying its commercial relevance and patient's importance. The findings displayed on ELPA website are being promoted through social media channels (Twitter, Facebook, website).

In summary, ELPA represents a bridge which fills in the gap from scientific to commercial to patient by:

- raising public awareness,
- transforming scientific information into commercial information relevant to our stakeholders,
- informing patients and public about the ongoing study,
- presenting results in classic and online forms to the commercial, medical and patient addressees,
- performing health-economic analyses to demonstrate the enhanced benefit/cost ratio of the new therapy into clinical routine.

Coordinator

CONSORCI INSTITUT D'INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER

Spain

Participants

ACADEMISCH MEDISCH CENTRUM BIJ DE UNIVERSITEIT VAN AMSTERDAM

Netherlands

ALFA WASSERMANN SPA

Italy

ALFASIGMA SPA

Italy

ALMA MATER STUDIORUM - UNIVERSITA DI BOLOGNA

Italy

ALTA RICERCA E SVILUPPO IN BIOTECNOLOGIE SRLU

Italy

ANAXOMICS BIOTECH SL

Spain

ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

France

AZIENDA OSPEDALIERA CITTA DELLA SALUTE E DELLA SCIENZA DI TORINO

Italy

ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

France

EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE (EF-CLIF)

Spain

EUROPEAN LIVER PATIENTS ASSOCIATION

Belgium

FUNDACIO HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA

Spain

JOHANN WOLFGANG GOETHE-UNIVERSITATFRANKFURT AM MAIN

Germany

UNIVERSIDAD POMPEU FABRA

Spain

UNIVERSITA DEGLI STUDI DI PADOVA

Italy

UNIVERSITAETSKLINIKUM BONN

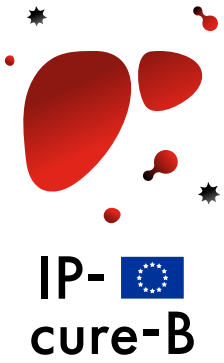
Germany

UNIVERSITY COLLEGE LONDON

United Kingdom

IP-cure-B

Immune profiling to guide host-directed interventions to cure HBV infections



Objective

The objective of the project is to develop novel curative concepts for chronic hepatitis B (CHB). Specific aims will be to: 1) improve the rate of functional cure of CHB by boosting innate immunity with immune modulators and stimulating adaptive immune responses with a novel therapeutic vaccine; ii) characterize immune and viral biomarker signatures for patient stratification and treatment response monitoring; iii) integrate biological and clinical data to model the best combination treatment for future trials; iv) model the effectiveness of novel curative therapies with respect to disease spectrum, patient heterogeneity, and constraints of National Health Systems.

The project organization will combine: i) a Proof of Concept clinical trial of a combination of 2 novel compounds stimulating innate immunity; ii) a preclinical immune therapy platform in humanized mice combining immune-modulatory strategies to stimulate innate immunity, rescue exhausted HBV-specific T cells and generate anti-HBV adaptive responses; iii) extensive virologic and immune profiling to identify correlates of cure in patients, iv) the integration of large biological and clinical datasets, v) a cost-effectiveness modelling of new therapeutic interventions, vi) project management, vii) results exploitation and dissemination.

The proposal responds to the work program by: i) including the evaluation of emerging concepts in drug and vaccine development to discover a curative strategy for CHB, a major public health concern for Europe, ii) capitalizing on knowledge of host-pathogen interactions to develop novel immune-based therapies, iii) considering age, gender and viral genetic variations, iv) comprising a clinical trial and a pre-clinical platform for the discovery of novel immune interventions, and selection of relevant biomarkers for validation in established clinical cohorts, v) addressing conditions for effective uptake of the new curative interventions by National Health Systems.

Grant agreement ID
847939

Start date
1 January 2020

End date
31 December 2024

Funded under
H2020-EU.3.1.3.

Overall budget
€ 14 943 030,50

EU contribution
€ 9 983 029

Coordinated by
INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE, France

Medical research project IP-cure-B

European Liver Patient Association (ELPA) as a co-leader of the work packages responsible for Communication, Dissemination and exploitation plays an active role in different part of the project by:

- participating to the IP-cure-B Trial Steering Committee;
- reviewing the proof of concept (PoC) clinical study protocol and the information to participants, advocating on behalf of IP-cure-B researchers and disseminate clinical trial information;
- interacting with the consortium scientists for effectiveness studies,
- disseminating knowledge on HBV and the research progress made in the field of HBV therapy to raise awareness on this disease.

Within medical research project IP-cure-B, ELPA is responsible for dissemination and communication of the research results and any other information that can be beneficial for patients and patient communities. ELPA is actively engaged in translation of the project results and milestones to “patient friendly” language and to incorporate the patient view during the dissemination process. ELPA is also consulted to ensure that the ethics documents, information sheet and patient consent form for the proof of concept (PoC) clinical trial are understandable by patients. The process of dissemination and communication involves all ELPA’s communication channels and we actively participate in all events that are organized by medical research project IP-cure-B. ELPA participated in creation of webpage, social media platforms and makes sure of their updates with relevant information’s.

Coordinator

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE

France

Participants

CENTRE HOSPITALIER UNIVERSITAIRE VAUDOIS

Switzerland

ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON

Greece

EUROPEAN LIVER PATIENTS ASSOCIATION

Belgium

FONDAZIONE IRCCS CA' GRANDA - OSPEDALE MAGGIORE POLICLINICO

Italy

FUNDACIO HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA

Spain

GILEAD SCIENCES INC

United States

HOSPICES CIVILS DE LYON

France

INSERM TRANSFERT SA

France

INSTITUT PASTEUR

France

KAROLINSKA INSTITUTET

Sweden

SPRING BANK PHARMACEUTICALS INC.

United States

UNIVERSITA DEGLI STUDI DI PARMA

Italy

UNIVERSITAETSKLINIKUM FREIBURG

Germany

MICROB-PREDICT

MICROBiome-based biomarkers to PREDICT decompensation of liver cirrhosis and treatment response

Objective

Decompensation of liver cirrhosis and progression towards acute-on-chronic liver failure (ACLF) causes 1.2 million deaths/year. Microbiome is causally involved in cirrhosis progression and is for drugs the first interaction point with the patients. Drugs can alter the microbiome leading to unwanted effects or even facilitating their effects, but the microbiome metabolizes the drugs, shapes their effects and possibly determines the host response to drugs. As each person carries an individual microbiome, insight in these processes should help stratify or even personalize patient health care and treatment.

The aims of MICROB-PREDICT are 1) to better understand the role of microbiome and the gut-liver-axis interactome with respect to microbiome functionalities, 2) to identify and validate microbiome-based biomarkers and signatures for personalized prediction of decompensation and ACLF, and response to treatment, 3) to design three new tests as easy-to-use tools and point-of-care, smartphone-connected nanobiosensors, and 4) to validate them in a randomized controlled trial. MICROB-PREDICT will assemble existing data and samples from major microbiome initiatives in hepatology (12 international studies, >10,000 patients), and enrich them with holistic and in-depth analysis using cutting-edge multi-omics technologies of host and microbiome from different body sites in samples of >1,000 patients collected in a longitudinal manner with sequential visits and controlling for confounders.

MICROB-PREDICT results will foster more accurate, personalized risk stratification and significant steps towards personalized treatment of decompensated cirrhosis and ACLF. World-leading microbiome specialists, technology leaders and clinical experts make this a programme of scientific excellence; patient organisations (ELPA) and the European Association for the study of the Liver (EASL) will channel our results into a powerful dissemination, communication and exploitation programme.

Grant agreement ID

825694

Start date

1 January 2019

End date

31 March 2025

Funded under

H2020-EU.3.1.2.

Overall budget

€ 15 000 002,50

EU contribution

€ 15 000 000

Coordinated by

EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE (EF-CLIF), Spain

Medical research project MICROB-PREDICT

Within MICROB-PREDICT, ELPA is responsible for dissemination and communication of the research results and any other information that can be beneficial for patients and patient communities. ELPA is actively engaged in translation of the project results and milestones to "patient friendly" language and in incorporating the patient view during the dissemination process. The process of dissemination and communication involves all ELPA's communication channels and we participate in events organized by medical research project MICROB-PREDICT. Furthermore, ELPA is involved in the discussion on ethical and social issues and the protocol set-up of the clinical trial. ELPA is part of medical research project MICROB-PREDICT Impact Board. Impact Board monitors the communication and dissemination and reports to the management of the research project. Within medical research project MICROB-PREDICT ELPA also:

- provides input to the analysis and policy of the ethical and legal issues in all stages of MICROB-PREDICT,
- upports the identification of patients affected by liver failure and its impact on society,
- communicates to the public and to patient communities in Europe,
- conducts performance evaluation of dissemination activities and impact,
- collaborates with scientists and EASL in the field of guideline development and updates.

Coordinator

EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE (EF-CLIF)

Spain

Participants

ACADEMISCH ZIEKENHUIS LEIDEN

Netherlands

BIOBYTE SOLUTIONS GMBH

Germany

COMMISSARIAT A L ENERGIE ATOMIQUE ET AUX ENERGIES ALTERNATIVES

France

CONCENTRIS RESEARCH MANAGEMENT GMBH

Germany

DEBRECENI EGYETEM

Hungary

EUROPEAN ASSOCIATION FOR THE STUDYOF THE LIVER

Switzerland

EUROPEAN LIVER PATIENTS ASSOCIATION

Belgium

EUROPEAN MOLECULAR BIOLOGY LABORATORY

Germany

FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA

Spain

FUNDACIO INSTITUT CATALA DE NANOCIENCIA I NANOTECNOLOGIA

Spain

INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENT

France

JOHANN WOLFGANG GOETHE-UNIVERSITATFRANKFURT AM MAIN

Germany

KATHOLIEKE UNIVERSITEIT LEUVEN

Belgium

KING'S COLLEGE LONDON

United Kingdom

KOBENHAVNS UNIVERSITET

Denmark

MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN EV

Germany

ODENSE UNIVERSITETSHOSPITAL

Denmark

UNIVERSITAT DE BARCELONA

Spain

UNIVERSITETET I OSLO

Norway

UNIVERSITY COLLEGE LONDON

United Kingdom

VAIOMER

France

GALAXY

GALAXY: Gut-and-liver axis in alcoholic liver fibrosis

Objective

Alcohol overuse is an important societal challenge with annual healthcare costs of over €22 billion in Europe. Alcohol is the main cause of liver cirrhosis, which is the 5th and 7th most common cause of life years lost in respectively Eastern and Western Europe. Cirrhosis is considered irreversible but its precursor, liver fibrosis, is reversible when detected before disease progression. GALAXY proposes that crosstalk between the gut microbiome and the liver influences the development and progression of alcoholic liver fibrosis. Here, a 'dysbiotic' microbiome in susceptible individuals leads to progressive liver fibrosis in combination with alcohol overuse. Therefore, interventions aiming to restore a healthy gut microbiome will reduce disease development. We will use state-of-the-art systems medicine tools to improve understanding of the complex interplay present during alcoholic liver fibrosis, to identify at-risk individuals in time and to develop personalised healthcare strategies for alcohol over-users (20% of the EU population >15 years old). GALAXY brings together partners with unique research competences in clinical hepatology, microbiome, multi-omics, biomarkers and bioinformatics. Our aim is to develop novel systems medicine tools which integrate clinical, multi-omics and lifestyle information from alcohol over-users at various stages of the disease and healthy individuals in order to: 1) identify signatures of host-microbial cross-talk during disease development and progression, 2) translate this into biomarkers for diagnosis, stratification and treatment monitoring in alcohol over users, and 3) evaluate new interventions to modulate gut microbiota towards prevention and mitigation of the disease in at-risk individuals. We will also study societal and economic impact of GALAXY biomarkers and treatments to accelerate future development. The GALAXY consortium includes strong SME partners who will enable the results to be exploited commercially.

Grant agreement ID

668031

Start date

1 January 2016

End date

31 December 2021

Funded under

H2020-EU.3.1.1.

Overall budget

€ 6 408 782,51

EU contribution

€ 6 305 654

Coordinated by

SYDDANSK UNIVERSITET, Denmark

Medical research project GALAXY:

ELPA's involvement in this project is on voluntarily basis. ELPA is however using all social media and communication channels and we do our best to help with dissemination of the project and study results. We are using ELPA's

- social media such as Facebook, Twitter, LinkedIn,
- life and online events,
- presence at different congresses and conferences in order to help with dissemination of this project.

Coordinator

SYDDANSK UNIVERSITET

Denmark

Participants

EUROPEAN MOLECULAR BIOLOGY LABORATORY

Germany

IDRYMA IATROVIOLOGIKON EREUNON AKADEMIAS ATHINON

Greece

JOHANN WOLFGANG GOETHE-UNIVERSITATFRANKFURT AM MAIN

Germany

KOBENHAVNS UNIVERSITET

Denmark

NORDIC BIOSCIENCE A/S

Denmark

NORDISK REBALANCE AS

Denmark

NORGINE BV

Netherlands

ODENSE UNIVERSITETSHOSPITAL

Denmark

REGION HOVEDSTADEN

Denmark

UNIVERSITETET I OSLO

Norway

DECISION

DECOMPENSATED CIRRHOSIS: IDENTIFICATION OF NEW COMBINATORIAL THERAPIES BASED ON SYSTEMS APPROACHES

Objective

In 2013, cirrhosis was responsible for 1.2 million deaths worldwide. This mortality is mainly due to cirrhosis decompensation, i.e. development of ascites, hepatic encephalopathy, and/or gastrointestinal hemorrhage, and its progression to acute-on-chronic liver failure (ACLF). Patients with decompensated cirrhosis receive many treatments such as intravenous and oral absorbable antibiotics, oral non-absorbable antibiotics, albumin, proton-pump inhibitors, laxatives, diuretics, betablockers, vasoconstrictors, statins, anticoagulants, steroids and antiviral agents. Despite these multiple treatments, ACLF or mortality in patients with decompensation of cirrhosis remains high (15% at day 28, 28% at day 90) because of large interindividual variability in precipitating events, in clinical presentation and in response to treatment. This heterogeneity calls for treatment personalization according to underlying mechanisms. The objective of DECISION is to enhance our understanding, at systems level, of the pathophysiology of decompensation of cirrhosis leading to ACLF or death to decrease patients' mortality at day 28.

First, DECISION will improve our knowledge of the pathophysiology of decompensation of cirrhosis by integrating results of high-throughput multi-omic profiling with comprehensive clinical data from 2,200 fully characterized patients (more than 8,600 time points) with available standardized biological samples. Second, we will identify novel combinatorial therapies for patients with decompensation of cirrhosis to prevent death. We will refine these therapies in new and/or optimized animal models and then test the best combination in high risk patients in a phase II clinical trial built in DECISION. Third, we will develop 2 tests: one predicting outcome of patients with decompensation of cirrhosis when treated with standard treatment (prognostic test); and the other identifying patients who will respond to the novel combinatorial therapy (test for response).

Grant agreement ID

847949

Start date

1 April 2020

End date

30 September 2025

Funded under

H2020-EU.3.1.1.

Overall budget

€ 6 000 007,13

EU contribution

€ 6 000 000

Coordinated by

EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE (EF-CLIF), Spain

Medical research project DECISION:

Within DECISION, ELPA is responsible for the communication and dissemination of the research results, and any other information that can be beneficial for patients and patients community. ELPA is actively engaged in translation of the project results and milestones to »patient friendly« language, and incorporates the patient's view during the dissemination process. The process of communication and dissemination involves all ELPA's communication channels and we actively participate in events that are organized by the DECISION project management team. The main objective is the development of a communication strategy and dissemination plan aimed at potential stakeholders of the EU member states, namely patients, health care professionals, pharma and biotech companies, healthcare insurers, international professional networks and general public. The strategy includes some of the following specific aims:

- to make DECISION known to all stakeholders,
- to disseminate the results to the scientific and medical community, healthcare, pharmaceutical and policy sectors and general public and foster interaction and exchange with patient organizations,
- to exploit and valorize the intellectual property rights and safeguard sustainability of medical research project DECISION results,
- to incorporate new knowledge on tests and combinatorial therapies into (inter)national clinical guidelines and inform patient communities of the benefits for the patients,
- to prepare the next generation of scientists in the field of liver research.

ELPA also participated in setting up the protocol and finalisation of the protocol in close collaboration with the European Foundation for the study of chronic liver failure (EFCLIF) and the participating clinical partners.

Coordinator

EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE (EF-CLIF)

Spain

Participants

ALMA MATER STUDIORUM - UNIVERSITA DI BOLOGNA

Italy

ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

France

COMMISSARIAT A L ENERGIE ATOMIQUE ET AUX ENERGIES ALTERNATIVES

France

CONCENTRIS RESEARCH MANAGEMENT GMBH

Germany

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

Netherlands

EUROPEAN ASSOCIATION FOR THE STUDYOF THE LIVER

Switzerland

EUROPEAN LIVER PATIENTS ASSOCIATION

Belgium

FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA

Spain

FUNDACION PUBLICA MIGUEL SERVET

Spain

INSTITUT CATALA DE LA SALUT

Spain

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE

France

JOHANN WOLFGANG GOETHE-UNIVERSITATFRANKFURT AM MAIN

Germany

NORDIC BIOSCIENCE A/S

Denmark

SERVICIO MADRILENO DE SALUD

Spain

UNIVERSITA DEGLI STUDI DI PADOVA

Italy

UNIVERSITA DEGLI STUDI DI TORINO

Italy

UNIVERSITAETSKLINIKUM AACHEN

Germany

UNIVERSITAT DE BARCELONA

Spain

UNIVERSITY COLLEGE LONDON

United Kingdom

YH YOUHEALTH AB

Sweden

FiSPlat

FiSPlat

Objective

Chronic liver disease represents a major public health problem, accounting for significant morbidity and mortality worldwide. Liver fibrosis is the common consequence of any chronic liver injury. This leads to a persistent liver inflammation, which stimulates a wound healing response in which extracellular matrix proteins, such as collagens and hyaluronic acid, accumulate in the liver and form scar tissue (fibrosis). Prognosis and management of patients with chronic liver diseases depends critically on the progression of liver fibrosis. Accurate quantification of liver fibrosis is essential for therapeutic decision-making and follow-up to prevent progression, as well as to reduce heath economic costs associated with liver cirrhosis. Liver cirrhosis is one of the most important cause of death, resulting in an economic burden of 17B€ in Europe/year. Its progression is silent, becoming one of the most difficult areas for early detection of patents. The lack of methods to diagnose it at early stages prevents stopping this dangerous killer. This consortium introduces FiSPlat (FibroScan Screening Platorm): a cheap, fast, non-invasive method to diagnose early stage cirrhosis, based in Transient Elastography, without the need for medical specialists. FiSPlat is based in a new version of FibroScan, developed to be used in Primary Care. It enables primary healthcare to screen populatons at risk, improving early patent stratficaton and preventng progressive cirrhosis. FiSPlat project will be based in:

1) Design / clinical follow-up: Design and manufacture, Regulatory approval (CE mark) and Postmarketng clinical trial

2) Business actvites: Cost-efectiveness study, Market access and Education activities)

FiSPlat is an adaptation of the FibroScan device and technology that will enable a cheap, fast, non invasive detection of significant fibrosis (which indicates risk of progression to cirrhosis). It enables primary healthcare doctors and nurses to screen populations at risk of cirrhosis development. The technology measures the velocity of the sound wave through the liver and converts that measurement into liver stiffness, which is directly related to fibrosis. It also measures CAP (controlled attenuation parameter) that is related to steatosis. The device, which will be commercially available in 2021, will enable an earlier diagnosis, which will result in earlier and costeffective treatment to prevent further progression of liver disease.

Grant agreement ID

20308

Start date

1 January 2020

End date

31 December 2022

Funded under

EIT Health

Overall budget

€ 2 296 765

EU contribution

€ 2 237 813

Coordinated by

GENESIS Biomed, Spain

Medical research project FiSPlat:

Within medical research project FiSplat, ELPA is a part of « Different education activities » group that have been planned, in order to raise awareness between the patients and the facultative and caregivers about the advantages of the new developed device and to disseminate the technology. Each clinical partner organises at least one educational activity during the 3 years of the project, in which professionals are given training on how to use the device, support and educational contents.

University of Barcelona (UB) performs one activity per year for nurses. In 2022, a big educational activity, with physicians, nurses and patients (ELPA), will be performed. Besides, an online educational programme are also being built. During the last year of the project, a big educational activity, with physicians, nurses and patients will be performed, in which patients and society will be educated about liver diseases and about FiSPlat solution. ELPA includes educational activities for 31 patients organizations from 25 European countries at one of their regular annual meetings. The educational activity including all ELPA members, presidents or legal representatives of patient organizations, are being delivered in person. However, the webinar is available not only for ELPA members and our stakeholders but for the general public interested in this topic.

Coordinator

GENESIS BIOMED

Spain

Participants

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

France

ECHOSENS

France

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

Netherlands

EUROPEAN LIVER PATIENTS' ASSOCIATION

Belgium

FUNDACIÓ PRIVADA CLÍNIC PER LA RECERCA BIOMÈDICA

Spain

HOSPITAL CLÍNIC DE BARCELONA

Spain

UNIVERSITAT DE BARCELONA

Spain

UNIVERSITAT POMPEU FABRA

Spain

EIT Health is supported by the EIT, a body of the European Union

A-TANGO

Novel treatment of acute-on-chronic liver failure using synergistic action of G-CSF and TAK-242

Objective

In Europe, about 30,000 people die every year from alcohol related cirrhosis, a form of chronic, non- communicable disease. The patients that are at highest risk of death are those with superimposed alcoholic hepatitis (AH) who do not respond to therapy and develop acute on chronic liver failure (ACLF), a newly described syndrome characterised by multiorgan failure. Treatment of ACLF is an unmet need. Based upon their clinical and pre-clinical studies, the A-TANGO consortium aims to perform Phase 2 clinical trials of a novel, patented and innovative therapeutic strategy by repurposing a toll-like 4 receptor antagonist (TAK242, Technology Readiness Level (TRL) 8), which targets inflammation, and combining it with granulocyte colony-stimulating factor (G-CSF, TRL9) that improves hepatocyte proliferation (G-TAK, TRL4). A successful trial will advance G-TAK to TRL8. Additionally, A-TANGO aims to discover novel biomarkers for patient selection and defining prognosis, building health economics models and reimbursement strategies to allow maximal dissemination and exploitation. The A-TANGO Consortium includes the inventors of G-TAK (UCL, Charité, ULEI and LUMC) and will deliver the project aims through EFCLIF, which has a network of 110 European hospitals. YAQ and HPX are SME's that own the background IP and will ensure regulatory approval, study Sponsorship and drug supply. APHP and IMAC will deliver the economic models. Concentris will manage the project and together with EASL, CHX and ELPA will engage with patients, initiate widespread dissemination activities and allow exploitation of the results. Gender balance will be maintained throughout the project duration. A-TANGO will achieve the expected impacts of producing meaningful advances in clinical practice by reducing the mortality and improving the quality of life of patients with ACLF whilst reducing disease burden of individual patients and health care systems following validation in late stage clinical trials.

Grant agreement ID

945096

Start date

01 March 2021

End date

28 February 2026

Funded under

H2020-EU.3.1.3.

Overall budget

€ 6 634 322,50

EU contribution

€ 5 999 999

Coordinated by

EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE, Spain

Medical research project A-TANGO:

As a liver patients' organization, ELPA will put all of its expertise to strive for clinically efficacious and cost-effective therapy. Without new treatments, these patients will continue to have high mortality rates.

ELPA is one of the partners involved in the WP7: dissemination, communication, and training Specific aims are:

- To make A-TANGO known to all relevant stakeholder types
- To inform and foster exchange with the scientific community and patient organizations
- To disseminate to a range of stakeholder types the results of this trial and the therapeutic potential of G-TAK
- To prepare the next generation of scientists in the field of liver research

During the first meeting, ELPA was also elected as part of the steering committee.

Coordinator

EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE

Spain

Participants

ACADEMISCH ZIEKENHUIS LEIDEN

Netherland

ALPHA BIORESEARCH, SL

Spain

ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

France

CHARITÉ - UNIVERSITAETSMEDIZIN BERLIN

Germany

CONCENTRIS RESEARCH MANAGEMENT GMBH

Germany

CROWDHELIX

Ireland

EUROPEAN ASSOCIATION FOR THE STUDYOF THE LIVER

Switzerland

EUROPEAN LIVER PATIENTS ASSOCIATION

Belgium

HEPYX LIMITED

United Kingdom

INTERNATIONAL MARKET ACCESS CONSULTING GMBH

Switzerland

YAQRIT LIMITED

United Kingdom

UNIVERSITY COLLEGE LONDON

United Kingdom

UNIVERSITAET LEIPZIG

Germany

COBALT

COvid-19 vaccination and **B**iomarkers in cirrhosis **A**nd post-**L**iver **T**ransplantation

COvid-19 vaccination and **B**iomarkers in cirrhosis **A**nd post-**L**iver **T**ransplantation (COBALT)

Objective

The Covid-19 pandemic has disproportionately affected liver patients - patients with chronic liver disease have around 5-times increased mortally from Covid-19 compared to individuals without liver disease. Therefore, the development of vaccines is a welcome step, but we don't yet know if they are fully protective in liver patients. Early data from the US demonstrates that two-thirds of liver transplant patients don't have detectable antibodies to the coronavirus after one dose of mRNA vaccine (Boyarsky et al 2021). There is therefore an urgent need to determine how effective these vaccines re in liver patients, to determine if extra protection is needed - such as extra vaccine doses, additional medications or continued shielding. The COBALT study is taking place across Europe to urgently address this question, by measuring responses to vaccination in liver patients. It is designed to report back quickly to inform patients and policy-makers, although further support is needed to accelerate this process and allow policy decisions to be made rapidly.

ESCALON

European-Latin American network for early prediction of liver cancers

ESCALON

Objective

ESCALON is a project involving a unique team of specialists in different areas (both academic and geographical areas) that aims to create databases and biobanks (both cross-sectional and prospectively) to evaluate biomarkers in blood that could predict hepatocellular carcinoma, cholangiocarcinoma and gallbladder cancer. The project evaluates a variety of clinical, environmental and genetic factors for each cancer that could shed light into the mechanisms leading to carcinogenesis and help us understand potential prevention points.

The study will lead to the discovery and utilization of biomarkers that could be applied worldwide for early diagnosis and detection of hepatocellular carcinoma, cholangiocarcinoma and gallbladder cancer, improve the understanding and provide identification of risk factors associated with hepatobiliary carcinogenesis that could be targeted for prevention and treatment of such cancers.

The consortium is formed by physicians, scientists, epidemiologists, statisticians and media specialists in multiple countries across Europe and South America. Each task, designed to work on a different hepatobiliary cancer, is led by a center in one continent in close collaboration with a center in a different continent (Europe and South America).

Different members are in charge of collecting samples and/or performing analysis for the different tasks, with a broad distribution of collection and analysis in both Europe and South America. In addition, we have incorporated different advisory committees formed by world experts in different fields who will advise us and closely follow up the developments of the project.

ELPA is part of the public policy advisory board.

Grant agreement ID
825510

Start date
1 January 2019

End date
31 December 2022

Funded under
H2020-EU.3.1.3.

Overall budget
€ 3 503 475

EU contribution
€ 3 283 475

Coordinated by
ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM, Netherlands

Coordinator

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

Netherlands

Participants

ASOCIACION INSTITUTO BIODONOSTIA

Spain

UNIVERSIDAD SAN FRANCISCO DE QUITO

Ecuador

HOSPIAL PRIVADO CENTRO MEDICO DE CORDOBA SA

Argentina

CENTRO DE ENFERMEDADES HEPATICAS Y DIGESTIVAS SAS

Colombia

FUNDACAO UNIVERSIDADE FEDERAL DE CIENCIAS DA SAUDE DE PORTO ALEGRE

Brazil

PONTIFICIA UNIVERSIDAD CATOLICA DE CHILE

Chile

THE GOVERNING COUNCIL OF THE UNIVERSITY OF TORONTO

Canada

THE UNIVERSITY OF MANCHESTER

United Kingdom

MEDIZINISCHE HOCHSCHULE HANNOVER

Germany

SENSU HOLDING BV

Netherlands

UNIVERSIDAD SAN MARTIN DE PORRES ASOCIACION

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