ELPA

European Liver
Patients' Association

ELPA and EU Medical **research projects**

Scientific booklet 2025

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Contents

Our Mission

ELPA aims 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; to share the experience of successful initiatives; to work with professional bodies to ensure that treatment and care are harmonised across Europe to the highest standards. 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.

ELPA's efforts are focused on three main pillars.

Member Empowerment

ELPA was established by patients, is governed by patients, and represents patients. We put much effort into organising training, promoting capacity building, and stimulating networking. We have eight different working groups to boost expert patients to acquire knowledge in a specific field of liver disease.

Policy and Advocacy

As an umbrella patients' association, ELPA acts as an intermediary between all the involved stakeholders - the national patients' communities, the scientific community, the industry, and the policymakers. We provide a crucial perspective due to our immediate and direct access to the patients' lives and to the best practices in a national and regional context.

ELPA is a member of:

- Advisory forum and expert group on HBV and HCV at ECDC.
- Patient and Consumer Working Party and Pharmacovigilance Risk Assessment Committee at EMA.
- Advisory Forum - Civil Society Forum at HERA.
- Expert group on HIV, TB, and hepatitis at WHO.
- Expert board at VHPB.
- HTA Stakeholder Network at DG SANTE.
- Advisory Council for Europe, Middle East & Africa (ACEMEA) in the framework of the Drug Information Association (DIA).

To better communicate with supporters and stakeholders, ELPA has obtained the ISO 9001:2015 quality standard in 2021, making it the 1st patients' association in Europe with a quality management system.

Participation In Medical Research Projects

ELPA is part of 20 EU-funded medical research projects. The participation of patients' associations in these projects is relatively new; nevertheless, being part of them enriches the research field.

20

Medical Research Projects

+200

Million € for liver reseach

+200

Partners

ELPA Values

Equality

Respect for diversity

Patient driven

Commitment

Transparency

Foreword of the President

As an umbrella patients' association, ELPA acts 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 primary and direct access to the patient's lives and 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 decision-making. For almost twenty years, ELPA has been advocating for the improvement of liver patients' lives and making their voices loudly heard. It has been a long and challenging journey, but ELPA has never given up, being aware that what is at stake is saving lives.

ELPA was invited to participate in the first Horizon 2020 project years ago when it was not common practice to have a patient association as a project partner. Today, ELPA is proudly involved in 20 projects, mainly funded under Horizon Europe, the European Union's flagship research and innovation program, for the funding period of 2021-2027. It succeeds Horizon 2020 and continues the EU's commitment to investing in research, science, and innovation to address societal challenges, drive economic growth, and strengthen Europe's competitiveness on the global stage. In its commitment to improving liver health, ELPA is collaborating with more than 200 partners all around Europe for a total of more than 200 million Euros allocated for liver health.

ELPA's participation in scientific projects is part of this tireless advocacy work and contributes to a virtuous circle. On the one hand, being part of them enriches the research field with the unique views of patients' organisations. On the other hand, ELPA, with its exclusive way of communicating and disseminating scientific results, acts like a translator, making complex content accessible to a broader public. It is essential to know that ELPA members represent ELPA's communication and dissemination activities first target. Patients' organisations play a vital role in society as a whole, forging a pathway for both patients and clinicians to access new and innovative treatments and providing governments with the necessary research and background information to enable them to make informed decisions. These organisations provide information, advocacy, and support to millions of people each day, which is why they should have easy access to crucial and updated scientific information.

Marko Korenjak

President of ELPA - European Liver Patients' Association

GENIAL

Understanding Gene ENvironment Interaction in ALcohol-related hepatocellular carcinoma

Alcohol-related hepatocellular carcinoma (ALD-HCC) is, in Europe, the leading cause of liver cancer. ALD-HCC has a median 5-year survival rate of 15%. Yet, the prognosis is driven by the tumour stage, with curative options providing a 5-year survival exceeding 70% for early-stage HCC (<20% of cases). Therefore, interventions aiming to improve prevention and early detection are key. ALD-HCC results from the interplay between environmental determinants and genetic variations. A comprehensive characterisation of environmental factors (e.g. diet, lifestyle) linked to ALD-HCC is still lacking. The 1st genome-wide association study of ALD-HCC was recently performed, identifying predisposing genetic variations. However, their role in alcohol-related liver carcinogenesis needs clarification, and the genetic architecture of ALD-HCC remains mostly unknown.

GENIAL brings together partners with unique expertise in clinical hepatology, single-cell and spatial multi-omics, artificial intelligence (AI) and communication and dissemination capacities. The aim is to 1) portray genetic and environmental determinants promoting ALD-HCC; 2) evaluate how they interact at the cellular level in human samples and preclinical models to get novel insights into liver carcinogenesis and identify chemopreventive targets; and 3) assess how these determinants modulate the ALD-HCC risk in prospective cohorts of patients included in HCC surveillance programs. Environmental factors will be comprehensively characterised in an ongoing clinical trial designed to evaluate alternative methods for early-stage HCC detection. Finally, AI models, reaching the minimal viable product stage by the end of GENIAL, will be used to integrate genetic and non-genetic information (including digital imaging) to develop novel, cost-effective strategies towards prevention and early-stage detection of ALD-HCC in at-risk individuals. It is part of the Cancer Mission cluster 'Understanding.'

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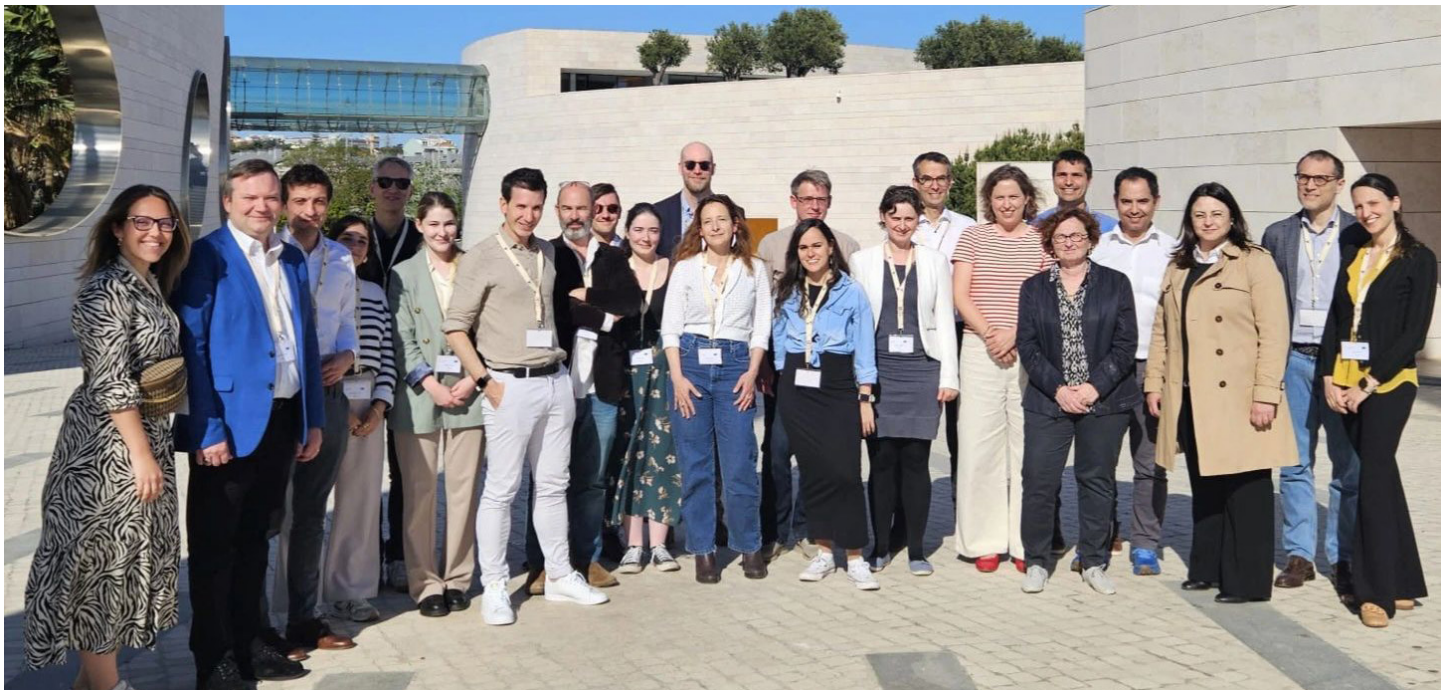

Coordinator

UNIVERSITE LIBRE DE BRUXELLES

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VIB VZW

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EUROPEAN LIVER PATIENTS ASSOCIATION

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LIVERATION

Unravelling the impact of Radiofrequency in liver surgery:
the key to decrease local recurrence?

Colorectal cancer (CRC) ranks fourth in cancer deaths worldwide. Between 20% and 30% of patients with advanced CRC have liver metastases (CRLM). Liver cancer ranks second in cancer deaths worldwide, including hepatocellular carcinoma (HCC). Despite recent advances, liver resection offers the only chance of cure for patients with liver metastases. However, the recurrence rate of these tumours is high even after post-resection. The presence of positive margins in the remaining liver after resection correlates with increased local recurrence and decreased overall survival, the only factor where the performance of surgery could influence prognosis. However, at present, the extent of an R-negative status remains debatable and varies widely from one publication to another. Currently, there are radiofrequency ablation studies that, based on preliminary retrospective human clinical trials, can correlate additional coagulation of tumour margins with a reduction in local recurrence. However, there is no prospective and pragmatic controlled study that accurately measures this additional margin and its impact on oncological outcomes.

The aim of LIVERATION is to conduct an ambitious, pragmatic multicenter clinical trial with 720 patients with CRLM and HCC at 24 clinical centres in 6 different countries to determine whether additional ablated margin produced by radiofrequency can decrease the recurrence rate and improve patient survival. We will also evaluate the patient-centredness of the intervention and its comparativeness with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings. To this end, the consortium has been formed by highly experienced, highly qualified and multidisciplinary entities to carry out the project successfully. The results will have a significant impact not only on the social and scientific levels but also on the economic level of the EU. It is part of the Cancer Mission cluster 'Diagnosis and treatment'.

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101104360

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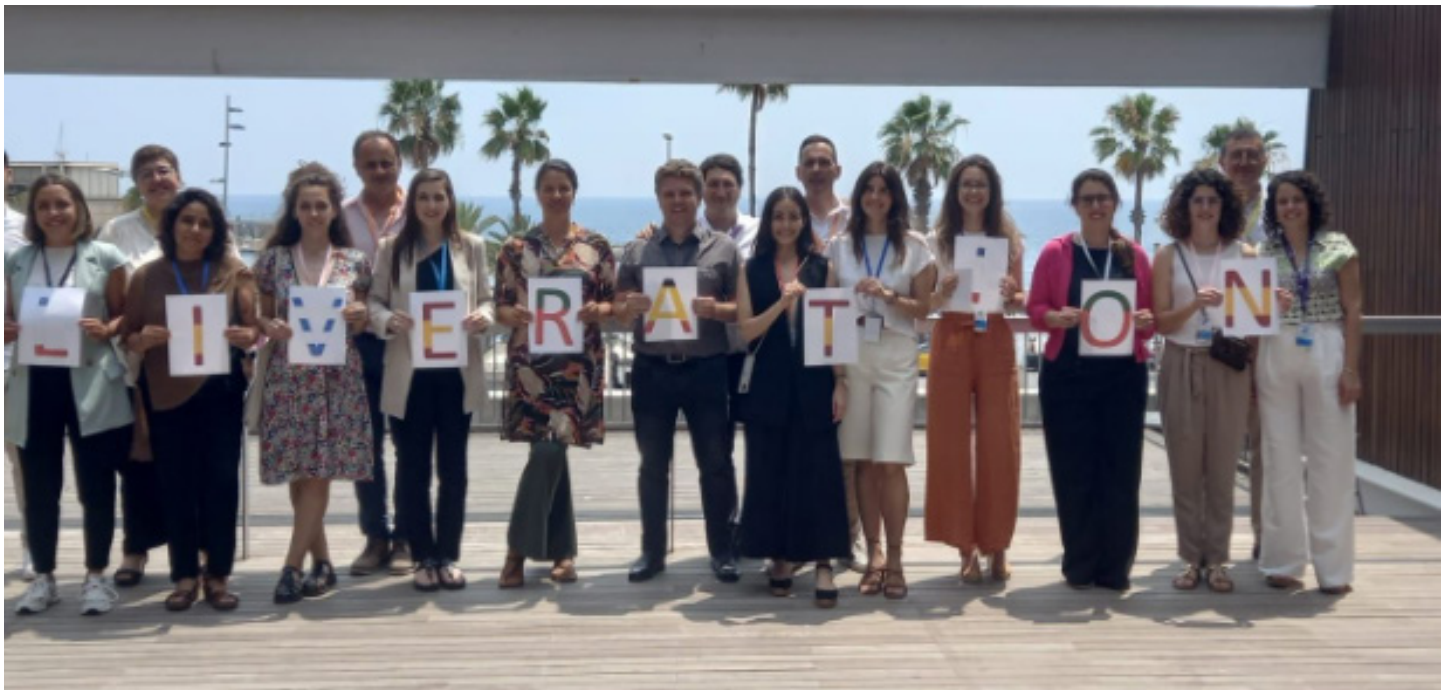

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THRIVE

Tumour-Host Interactions in Liver Cancer of Childhood and Adults

Liver cancer is a major health problem, with ~1 million cases diagnosed each year (~90,000 cases/year in Europe), and it is the 3rd cause of cancer-related mortality worldwide. Hepatocellular carcinoma (HCC) in adults, and hepatoblastoma (HB) in children are considered poorly understood cancers. HCC is a difficult-to-cure cancer (curation rate ~ 30%) with poor outcome (median survival < 2 years in advanced stages), due to limited understanding of at-risk populations, resistance to therapies and lack of precision oncology. In HB, outcomes are hampered in one-fourth of cases due to disease progression after surgical intervention and adjuvant chemotherapy.

THRIVE aims to improve the outcome of both paediatric and adult liver cancer patients by understanding at-risk populations and tumour-host interactions and by developing biomarkers for current therapies and novel, affordable treatments to overcome resistance. THRIVE brings together a strong, multidisciplinary team -13 partners from 8 countries- with complementary expertise to leverage cutting-edge technologies (single-cell RNASeq, spatial transcriptomics, microbiota analysis, artificial intelligence, mouse models and patient-derived organoids) and sectors (i.e. academia, SMEs, hospitals, patient associations) and 15 patient cohorts (~6,700 samples). THRIVE expects to 1) Define molecular features of cancer predisposition and at-risk populations for the development of liver cancer. 2) Develop a complete human liver cancer blueprint of tumour, immune, stromal cells and intra-tumoral microbiomes. 3) Identify AI-based and molecular markers of response to treatments. 4) Implement a preclinical drug testing platform to discover affordable therapies with high social impact. 5) Maximize the impact in European society by integrating SSH disciplines and delivering accessible and reusable data and tools to support EU initiatives such as the UNCAN.eu platform, and by influencing policymakers and health professionals. This action is part of the Cancer Mission cluster of projects on 'Understanding (tumour-host interactions)'.

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Coordinator

FUNDACIO DE RECERCA CLINIC BARCELONA-INSTITUT D INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER

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THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST

United Kingdom

ARTEMIs

AcceleRating the Translation of virtual twins towards a pErsonalised Management of fatty liver patients

The ARTEMIs project aims to consolidate existing computational mechanistic and machine-learning models at different scales to deliver 'virtual twins' embedded in a clinical decision support system (CDSS). The CDSS will provide clinically meaningful information to clinicians, for a more personalised management of the whole spectrum of Metabolic Associated Fatty Liver Disease (MAFLD). MAFLD, with an estimated prevalence of about 25%, goes from an undetected sleeping disease, to inflammation (hepatitis), to fibrosis development (cirrhosis) and/or hepatocellular carcinoma (HCC), decompensated cirrhosis and HCC being the final stages of the disease. However, many MAFLD patients do not die from the liver disease itself, but from cardiovascular comorbidities or complications.

The ARTEMIs will contribute to the earlier management of MAFLD patients, by prognosing the development of more advanced forms of the disease and cardiovascular comorbidities, promoting active surveillance of patients at risk. The system will predict the impact of novel drug treatments or procedures, or simply better life habits. The system will therefore not only serve as a clinical decision aid tool, but also as an educational tool for patients, to promote better nutritional and lifestyle behaviors. In more advanced forms of the disease, therapeutic interventions include TIPPS to manage portal hypertension, partial hepatectomy, partial or complete liver transplant. ARTEMIs will contribute to predict per- or post-intervention heart failure, building on existing microcirculation hemodynamics models. The model developers will benefit from a large distributed patient cohort and data exploration environment to identify patterns in data, draw new theories on the liver-heart metabolic axis and validate the performance of their models. The project includes a proof-of-concept feasibility study assessing the utility of the integrated virtual twins and CDSS in the clinical context.

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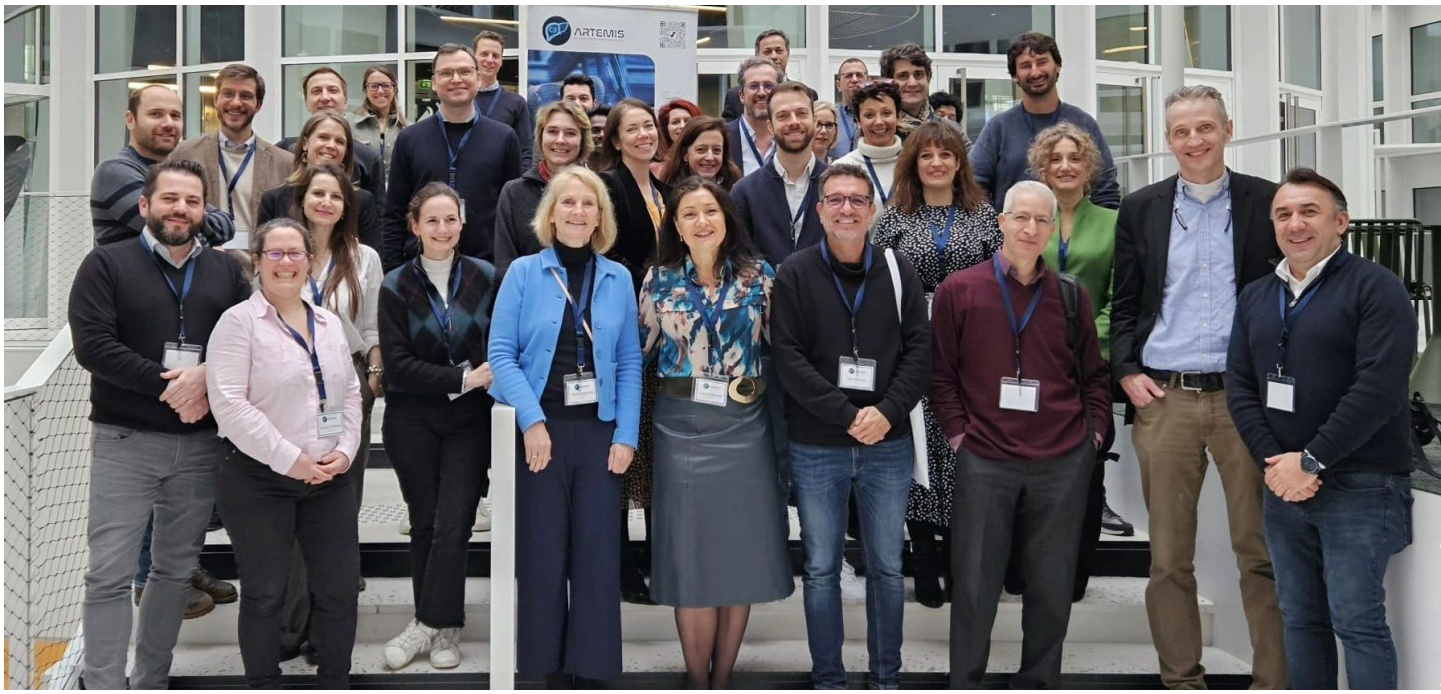

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IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE

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LEOPARD

Liver Electronic Offering Platform with Artificial intelligence-based Devices

Liver transplantation (LT) is a life-saving procedure for decompensated cirrhosis (DC) and hepatocellular carcinoma (HCC). Its efficacy is hampered by the risk of death/drop-out on the Wait List (WL). This risk is driven by organ shortage and is mitigated by organ offering schemes. According to a sickest first policy, offering schemes prioritise LT candidates with the highest risk of dying, as assessed by predictive models. To drive allocation, Organ Sharing Organizations (OSOs) use a 20-year-old model, the MELD, to predict mortality in DC but not in HCC. Because of a dramatic increase in HCC candidates, MELD schemes are increasingly inaccurate, with a persisting 15 to 30% mortality in countries with low/medium donation rates. This scenario, together with advances in prognosis in DC and HCC candidates and statistics, prompts the LT community to look for updated algorithms to refine offering schemes.

OSOs, experts in LT, statisticians, research labs, and SMEs have joined LEOPARD to address this issue. Building on an innovative, harmonised OSOs pre-LT dataset and advances in modelling, LEOPARD proposes to design and validate 1) an AI-based LEOPARD predictive algorithm outperforming current allocation models by better-stratifying patients on the risk of mortality, to be proposed OSOs to drive allocation; 2) DC & HCC LEOPARD calculators available for professional for assistance in complex decision-making processes; 3) OMICs/radiomics predictive signatures integrated into a prototype 3rd-generation exploratory model. It is expected to generate computational tools to improve candidates' outcomes, with more patients transplanted on time. Adopting these tools should harmonise European heterogeneous prioritisation schemes and significantly reduce disparities in access to LT.

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101080964

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Coordinator

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FÉDÉRATION NATIONALE DES MALADES ET TRANSPLANTÉS HÉPATIQUES

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GRIPonMASH

Global Research Initiative for Patient Screening on MASH

GRIP on MASH will address the unmet public health need of reducing disease burden and comorbidities associated with Metabolic dysfunction-Associated Steatotic Liver Disease (MASLD). Together with seven medical technology, pharmaceutical and biotechnology companies, we will devise a sustainable and scalable GRIP on MASH Platform that will enable access to at-risk patients developing or having MASLD through the early detection of this condition at the primary care level.

This Platform will allow A) the early detection of patients with MASLD: distributed in 12 European Centers of Excellence (CoEs), 10,000 patients at high risk of MASLD - defined as patients with type-2 diabetes mellitus, metabolic syndrome, obesity or arterial hypertension - will be screened and characterized; B) better patients' stratification: the Platform will comprise artificial intelligence-based decision support tools that will make use of existing and novel biomarkers/biomarker combinations. Their predictive accuracy will be tested at the primary care level; there we will perform multi-OMICs analysis (proteomics, lipidomics, metabolomics, genomics, metagenomics and fluxomics) in fasted blood samples and we will explore imaging biomarkers/organ-on-a-chip to find future non-invasive diagnostic alternatives for the current standard (liver biopsies); and C) personalised lifestyle advice, by exploring evidence-based lifestyle features and the effect of nutritional recommendations: among the cohorts at the CoEs, we will use validated questionnaires to assess physical activity, diet, sleep, smoking, alcohol consumption, and perception of stress. Integrating patients' perspectives with the participation of patient organisations, the trustworthiness and sustainability of our GRIP on MASH Platform will be assessed by investigating potential economic, ethical and regulatory barriers to its future adoption. GRIP on MASH will change healthcare practice in MASLD and reduce the disease burden for patients.

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101132946

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€ 25 913 513,25

EU contribution
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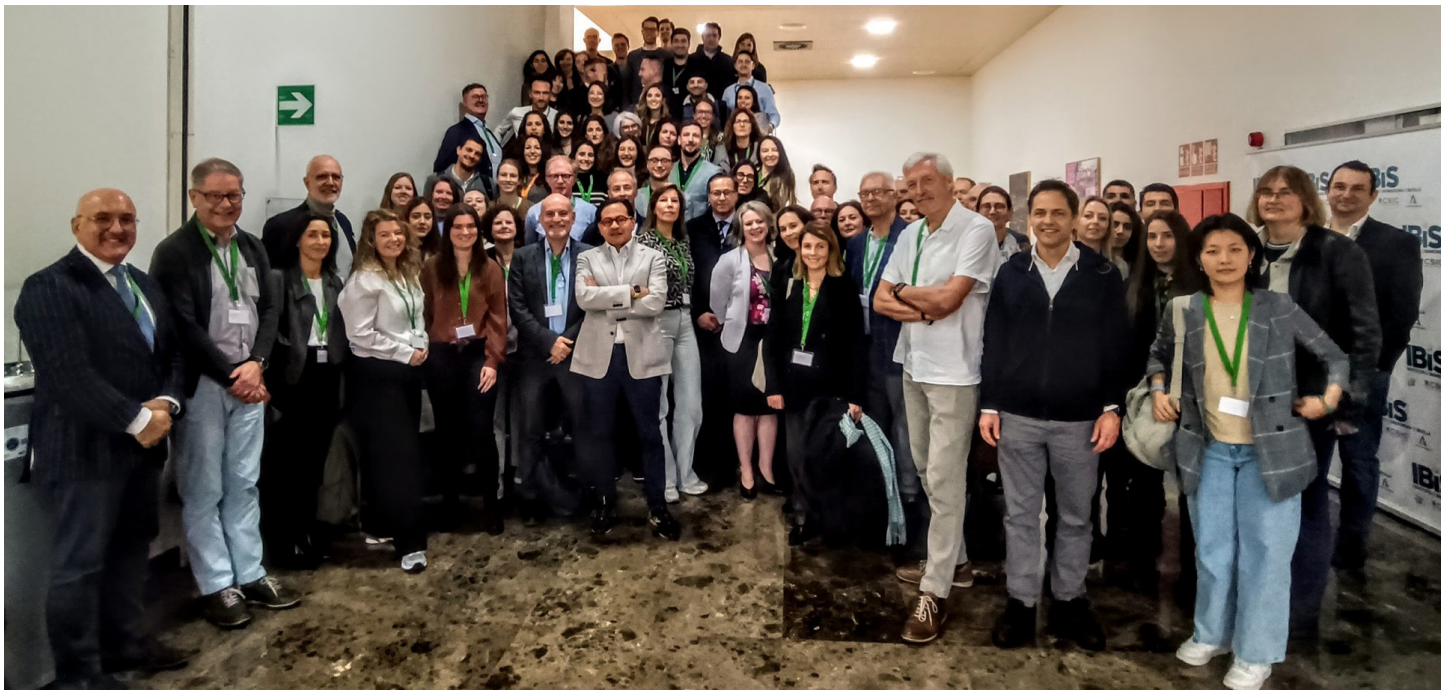

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FONDATION CARDIOMETABOLISME NUTRITION

France

LIVERAIM

A Biomarker-Based Platform for Early Diagnosis of Chronic Liver Disease to Enable Personalized Therapy

Liver cirrhosis and liver cancer are common and responsible for high morbidity, impaired quality of life, major costs for healthcare systems, causing 300K deaths per year in Europe. Predominant etiological factors are obesity, type 2 diabetes, and increased alcohol intake, which are all on the rise. It is predicted that healthy life expectancy will decrease in Europe over the next 30 years because of deaths due to liver disease. Liver cirrhosis develops after a very long period of asymptomatic liver fibrosis, staying undetected until patients develop severe complications due to cirrhosis or liver cancer. Currently, the only effective treatment available is liver transplantation, which is not applicable to all patients. If fibrosis is detected early to target the course of liver disease, then liver fibrosis is reversible.

The LIVERAIM project concentrates a team of renowned clinical centres and Industrial partners, including SMEs, with great expertise in the field of Liver Disease, the aim being to design and validate a screening platform with biomarkers for population screening to use across Europe. The objective is to identify liver disease early and apply personalised therapeutic interventions. A large number of existing biomarkers will be tested for fibrosis prediction accuracy using biobank plasma samples from 40,000 subjects from previous H2020 EU-funded cohorts. LIVERAIM will develop a screening platform with biomarkers using AI for personalised early fibrosis diagnosis to be validated in a randomised controlled trial of 100K subjects from 6 representative EU countries. The platform will be linked to tailored, personalised therapeutic interventions to halt fibrosis progression. With LIVERAIM, early diagnosis and personalised intervention can stop liver disease progression and help decrease morbidity and mortality and the associated societal burdens, both economic and health inequity.

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101132901

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28 February 2030

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EU contribution
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Coordinator

FUNDACIO DE RECERCA CLINIC BARCELONA-INSTITUT D INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER

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UNIVERSITAT AUTONOMA DE BARCELONA

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SIEMENS HEALTHCARE GMBH

Germany

NORDIC BIOSCIENCE A/S

Denmark

SYSMEX EUROPE SE

Germany

ECHOSENS

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MAYO CLINIC

United States

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HL4EU

Healthy Lifestyle for Europe

The Healthy Lifestyles for Europe project (HL4EU) will foster a cross-sectoral approach to healthy lifestyles promotion among a variety of stakeholders, in line with the European Commission and WHO's vision and existing policy initiatives, and in sight of tackling the increasing burden of NCDs and of reducing health inequalities across Europe. The consortium consists of leading national and European representative organisations from different sectors, including, fitness, physical activity, outdoors, health (doctors, patients, and carers) and mobility.

During the project's 30-month duration, the project partners will raise awareness of the importance of cross-sectoral healthy lifestyle promotion, facilitate cross-sectoral collaboration through the development of a dedicated stakeholder platform, identify and share good practices of cross-sectoral collaboration, and provide input for future policy developments on the topic through a set of policy recommendations. Through these actions, HL4EU will strengthen the sustainability and legacy of the European Commission's 'HealthyLifestyles4All' campaign and provide support to future European policy initiatives in this direction. A variety of actions will be developed to reach the project's objectives, including the publication of a Call to Action, the identification of good practices through both desk research and active outreach, the development of a stakeholder platform listing good practices, focus group sessions to capture practice-based feedback that will contribute to the policy recommendations, as well as a community building conference and a final conference. The HL4EU project aims to start a structural collaboration between consortium partners and bring the different sectoral networks closer together to facilitate the implementation of cross-sectoral healthy lifestyles.

Grant agreement ID
101133773

Start date
1 January 2024

End date
30 June 2026

Funded under
Erasmus-Sport-2023-SCP

Overall budget
€ 400 000,00

EU contribution
€ 400 000,00

Coordinator

EUROPEACTIVE

Belgium

Participants

X EUROPEAN INITIATIVE FOR EXERCISE IN MEDICINE

Germany

EUROPEAN LIVER PATIENT ASSOCIATION

Belgium

EUROPEAN NETWORK OF OUTDOOR SPORTS

France

FEDERATION OF THE EUROPEAN SPORTING GOODS INDUSTRY

Belgium

GREEK CARERS NETWORK EPIONI

Greece

IT'S GREAT OUT THERE COALITION

Belgium

DECISION

DEcompensated CIrrhoSIs: identification of new cOmbiNatorial therapies based on systems approaches

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, beta-blockers, 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, clinical presentation and response to treatment. This heterogeneity calls for treatment personalisation according to underlying mechanisms.

The objective of DECISION is to enhance our understanding, at the 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 characterised patients (more than 8,600 time points) with available standardised 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 optimised animal models and 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 the 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 (response test).

Grant agreement ID
847949

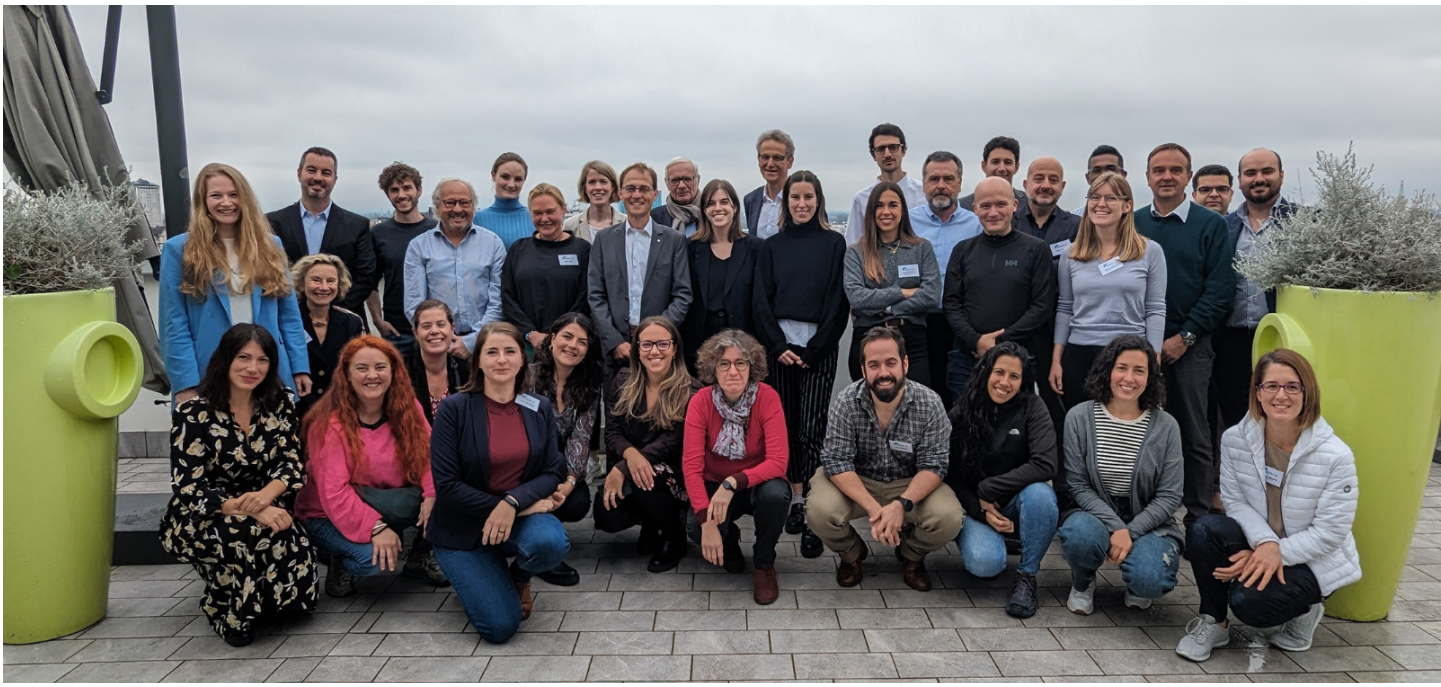
Start date
1 April 2020

End date
30 September 2025

Funded under
H2020-EU.3.1.1.

Overall budget
€ 6 000 007,13

EU contribution
€ 6 000 000



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

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Switzerland

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Belgium

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FUNDACION PUBLICA MIGUEL SERVET

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Spain

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE

France

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NORDIC BIOSCIENCE A/S

Denmark

SERVICIO MADRILENO DE SALUD

Spain

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Italy

UNIVERSITAETSKLINIKUM AACHEN

Germany

UNIVERSITAT DE BARCELONA

Spain

UNIVERSITY COLLEGE LONDON

United Kingdom

YH YOUHEALTH AB

Sweden

LiverScreen

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

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 on 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

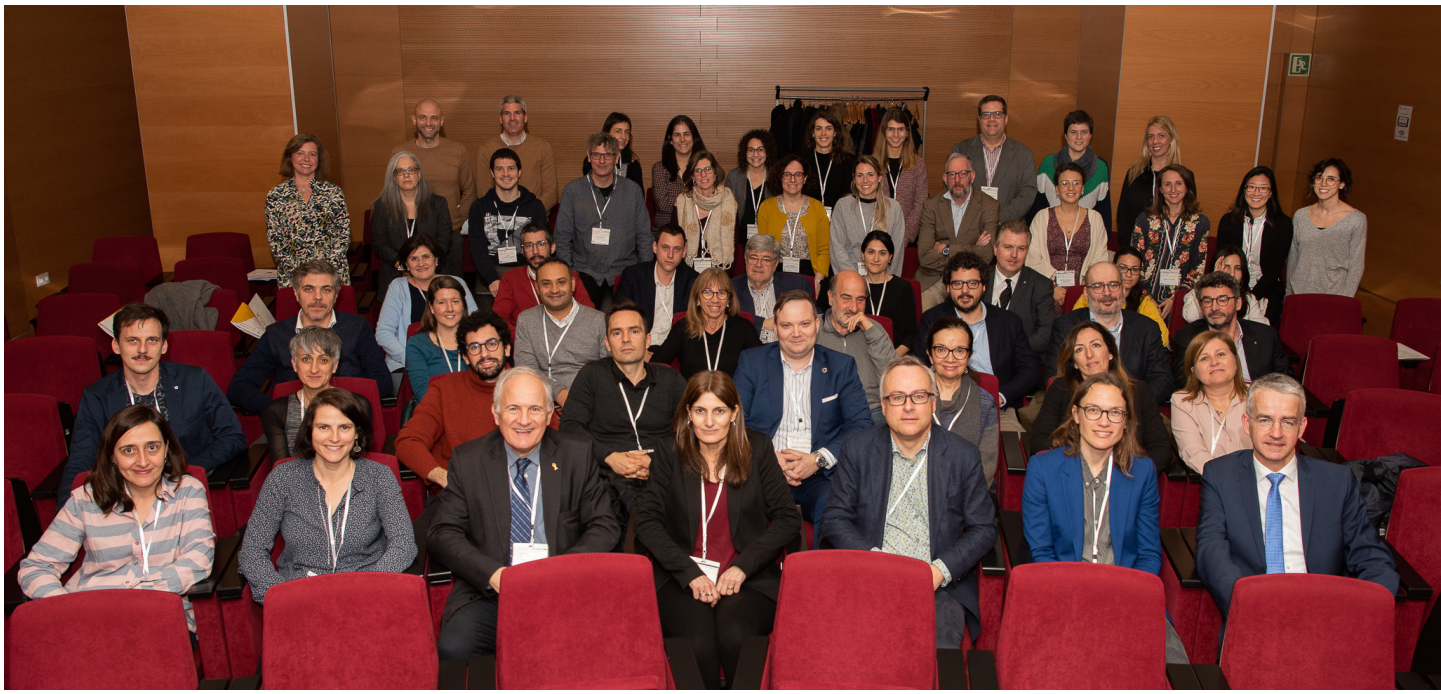
Start date
1 January 2020

End date
31 December 2024

Funded under
H2020-EU.3.1.2.

Overall budget
€ 5 996 481,25

EU contribution
€ 5 996 481,25



Coordinator

FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA

Spain

Participants

ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

France

AZIENDA OSPEDALE UNIVERSITA PADOVA

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Spain

CONSORCIO MAR PARC DE SALUT DE BARCELONA

Spain

ECHOSENS

France

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

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Switzerland

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Belgium

GENESIS BIOMED

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INNOVATION ACTA S.R.L.

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ODENSE UNIVERSITETSHOSPITAL

Denmark

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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

IP-Cure-B

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

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 organisation 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 humanised 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) capitalising 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 preclinical 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

Coordinator

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE

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Greece

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Spain

GILEAD SCIENCES INC

United States

HOSPICES CIVILS DE LYON

France

INSERM TRANSFERT SA

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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

Decompensation of liver cirrhosis and progression towards acute-on-chronic liver failure (ACLF) causes 1.2 million deaths/year. The 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. Still, the microbiome metabolises the drugs, shapes their effects, and possibly determines the host's drug response. As each person carries an individual microbiome, insight into these processes should help stratify or even personalise 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 personalised 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 nano biosensors, and 4) to validate them in a randomised 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, personalised risk stratification and significant steps towards personalised decompensated cirrhosis and ACLF treatment. 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

Coordinator

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

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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

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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

A-TANGO

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

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

Coordinator

EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE

Spain

Participants

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ALPHA BIORESEARCH, SL

Spain

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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

FISPlat

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). The prognosis and management of patients with chronic liver diseases depend 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 health economic costs associated with liver cirrhosis. Liver cirrhosis is one of the most important causes of death, resulting in an economic burden of 17B€ in Europe/year. Its progression is silent, becoming one of the most challenging 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 Platform), a cheap, fast, non-invasive method to diagnose early-stage cirrhosis based on Transient Elastography without the need for medical specialists. FiSPlat is based on a new version of FibroScan, which was developed for primary care. It enables primary healthcare to screen populations at risk, improving early patient stratification and preventing progressive cirrhosis. FiSPlat project will be based on 1) Design / clinical follow-up: Design and manufacture, Regulatory approval (CE mark) and Postmarketing clinical trial 2) Business activities: Cost-effectiveness 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).

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

Coordinator

GENESIS BIOMED

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Participants

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France

ECHOSENS

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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

GALAXY

Gut-and-liver axis in alcoholic liver fibrosis

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 competencies in clinical hepatology, microbiome, multi-omics, biomarkers and bioinformatics. Our aim is to develop novel systems medicine tools which integrate clinical, multiomics and lifestyle information from alcohol over-users at various stages of the disease and healthy individuals 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 the societal and economic impact of GALAXY biomarkers and treatments to accelerate future development. The 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

Coordinator

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NORDIC BIOSCIENCE A/S

Denmark

NORDISK REBALANCE AS

Denmark

NORGINE BV

Netherlands

ODENSE UNIVERSITETSHOSPITAL

Denmark

REGION HOVEDSTADEN

Denmark

UNIVERSITETET I OSLO

Norway

LIVERHOPE

Simvastatin and Rifaximin as new therapy for patients with decompensated cirrhosis

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 the 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 randomised, double-blind trials to investigate the safety, tolerability and efficacy of the 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, and IT, and UK). The expected impact is to halt the progression to acute-on-chronic liver failure, the main cause of death, to decrease complications of the disease, to reduce hospital readmissions, and to improve the 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 to improve the treatment of patients.

Grant agreement ID
731875

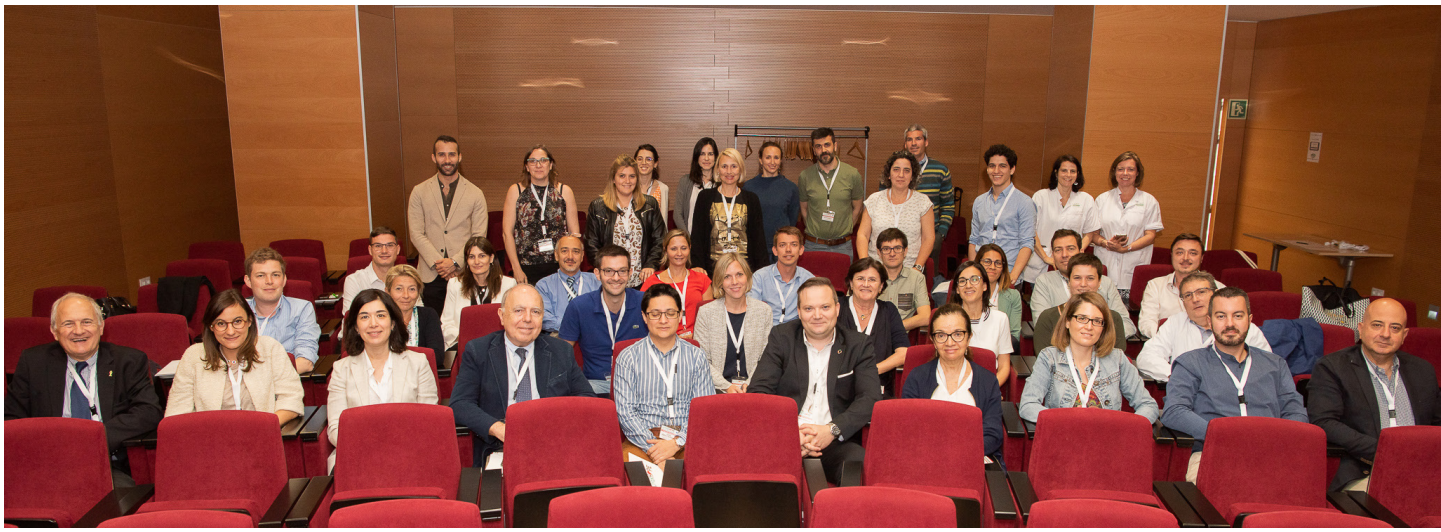
Start date
1 January 2017

End date
31 December 2021

Funded under
H2020-EU.3.1.3.

Overall budget
€ 5 998 800

EU contribution
€ 5 998 800



Coordinator

CONSORCI INSTITUT D'INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER

Spain

Participants

ACADEMISCH MEDISCH CENTRUM BIJ DE UNIVERSITEIT VAN AMSTERDAM

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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

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ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

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JOHANN WOLFGANG GOETHE-UNIVERSITATFRANKFURT AM MAIN

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Spain

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UNIVERSITAETSKLINIKUM BONN

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UNIVERSITY COLLEGE LONDON

United Kingdom

ESCALON

European-Latin American network for early prediction of liver cancers

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 utilisation 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 comprises physicians, scientists, epidemiologists, statisticians, and media specialists from multiple countries across Europe and South America. Each task, designed to work on a different hepatobiliary cancer, is led by a centre in one continent in close collaboration with a centre in a different continent (Europe and South America). Different members are responsible for collecting samples and/or performing analyses for different tasks, with a broad distribution of collection and analysis in 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 on the project's developments.

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

Coordinator

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

Netherlands

Participants

ASOCIACION INSTITUTO BIODONOSTIA

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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

Peru

THE CHRISTIE NHS FOUNDATION TRUST

United Kingdom

COBALT

COvid-19 vaccination and Biomarkers in cirrhosis And post-Liver Transplantation

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, developing 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 the mRNA vaccine (Boyarsky et al. 2021).

Therefore, there is an urgent need to determine how effective these vaccines are in liver patients and 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 liver patient vaccination responses. 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.

VIROMARKERS

Virus related biomarkers to improve management of chronic conditions

The VIROMARKERS project builds on previous research in infectious diseases and virology. Many viral infections can become chronic and difficult to treat, especially in patients with weakened immune systems. Some of the diseases addressed by VIROMARKERS are particularly challenging because current diagnostic tools are not always precise enough, making treatment decisions difficult. This project was developed to address these gaps and improve patient care. The VIROMARKERS project aims to improve how we detect and treat chronic diseases caused by viruses. Scientists and medical experts are working together to develop new tools that help doctors make better decisions about patient care.

The project focuses on: 1) creating a method to predict how well certain HIV treatments (called broadly neutralising antibodies) will work for individual patients; 2) finding new ways to measure signs of HDV infection to predict whether a patient will respond well to treatment; 3) developing a test to detect early signs of Cytomegalovirus (CMV) infection in patients who have received a stem cell transplant, so doctors can prevent serious illness; 4) identifying a virus (TTV) that may help predict the risk of CMV disease in people with weakened immune systems; 5) improving tests to measure how much HIV remains in a person's body, which could help doctors determine the best treatment options. To achieve these goals, the project will develop and validate new diagnostic tests and work on getting them approved for medical use. Ultimately, VIROMARKERS aims to provide better tools for doctors and researchers, leading to more personalised and effective treatments for patients. By advancing these diagnostic tools, VIROMARKERS aims to bridge critical gaps in healthcare and ensure patients receive the most effective treatments available. ELPA plays a key role in integrating the patient perspective within the project. ELPA will ensure that patient insights are considered in study designs and project implementation.

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