



# SCIENTIFIC REPORT



# 2023



Fondazione  
Epatocentro Ticino



# 2023: figures and facts at a glance

**19** DOCTORS ACTIVE  
in research and training

**41** COLLABORATION  
in research and training

**644**  
mila CONTRIBUTIONS  
received for research (CHF)

**17** SPONSOR  
for training activities

**22** PUBLICATIONS  
Abstracts, textbooks,  
guidelines

**18** FINANCIERS  
of research projects

**56** TRAINING  
completed

**2** PRIVATE  
sponsors

- ▶ **The Fondazione Epatocentro Ticino wins the prize for the best abstract at the clinical session presented at the 4<sup>th</sup> Swiss Autoimmune Liver Disease Meeting.**
- ▶ **The Fondazione Epatocentro Ticino obtains the NORMA quality certification as a facility for the management of Biobanks, a certification that guarantees the quality of the operational processes and the efficient management of samples for reliable and high-quality research.**
- ▶ **PD Dr. Benedetta Terziroli Beretta-Piccoli MD becomes a member of the Steering Committee of the International Autoimmune Hepatitis Group.**
- ▶ **Dr. Daniel Hagara MD is appointed chairman of the Swiss Society of Ultrasonography in Medicine for Italian Switzerland**

# The Foundation milestones

## 2014 – 2016

### RAPID TREATMENT OF HEPATITIS C

Thanks to the Epatocentro, Ticino is declared the number one canton in Switzerland for the speed with which patients with chronic hepatitis C received the new Sovaldi treatment (ref. Helsana Report 2016). In addition, the Fondazione Epatocentro collects and analyses clinical data and biological samples as part of the Swiss Hepatitis C Cohort Study.



## 2014

### THE TICINO HEPATOLOGY SYMPOSIUM IS ESTABLISHED

On the initiative of Fondazione Epatocentro Ticino, the Ente Ospedaliero Cantonale (EOC) hospital network, and Swiss Experts in Viral Hepatitis (SEVHep), the first Ticino Hepatology Symposium is launched, an annual event intended to update specialists and general practitioners on the latest developments in liver disease.



## 2014 – 2017

### THE FOUNDATION GETS INVOLVED IN A HEPATITIS E EPIDEMIC IN TICINO

An increase in cases of hepatitis E, attributable to the consumption of raw pork liver and wild boar liver, kicks off a joint research project between the Institute of Clinical Neuroscience of Italian Switzerland and the Fondazione Epatocentro Ticino, with the aim of characterising the spectrum of this complication. The active collaboration with the Cantonal authorities has led to an effective intervention by these authorities that has helped to stem the problem. The foundation is conducting a research project to verify whether the disease is the cause of autoimmune phenomena.



## 2015

### THE ANNUAL DISCUSSION PLATFORM IS LAUNCHED

Every year, the Platform for discussing the excellence and sustainability of the health system – which was launched on the initiative of the Fondazione Epatocentro Ticino and involves the Ente Ospedaliero Cantonale (EOC) hospital network and the University of Lugano (USI) – compares the various players in the local and national health systems on key issues for the development of the sector.



## 2015

### LAUNCH OF THE BLUE BOOK

Due to its belief in the importance of developing a series of guidelines based on scientific evidence, the Fondazione Epatocentro Ticino launches a project aimed at drawing up the main recommendations for managing patients suffering from specific liver diseases.

## 2016

### THE THURSDAY LECTURES

The Fondazione Epatocentro, which has always been dedicated to research and training, firmly believes in the importance of disseminating new developments in the scientific knowledge and treatment of liver diseases (viral hepatitis, autoimmune hepatitis, fatty liver disease, non-alcoholic steatohepatitis (NASH), and alcoholic liver disease); to this end, it organises numerous training courses, symposia, seminars, and conferences for doctors working in Ticino.



## 2016

### THE FIRST CONFERENCE ON AUTOIMMUNE DISEASES OF THE LIVER

This conference is established as a result of the collaboration between the Fondazione Epatocentro Ticino, the Swiss Society of Allergology and Immunology (SSAI), and the Swiss Association for the Study of the Liver (SASL). It is the first such national congress and attracts specialist doctors from Switzerland and abroad to Lugano every two years to discover the latest developments in basic research and clinical strategies to combat autoimmune diseases of the liver.



## 2017

### FATTY LIVER BECOMES THE NUMBER ONE LIVER DISEASE

Aware that 30% of the population is affected by fatty liver disease (NAFLD/NASH), the Fondazione Epatocentro Ticino is increasingly involved in the search for new treatments. After the first phase III studies yielded disappointing results, new types of drugs are producing promising results, which are reported in scientific articles co-authored by the Fondazione Epatocentro Ticino and published in prestigious medical journals such as the New England Journal.



## 2018

### "IAN MACKAY" CONFERENCE

Leading experts in the field of primary biliary cholangitis get together in Lugano for a three-day conference dedicated to the Australian doctor Ian Mackay, the father of autoimmune diseases of the liver. The published conclusions will map out the path for research in the field for years to come.



## 2018

### INTERNATIONAL COLLABORATIONS

The first international collaborations are launched in the field of autoimmune diseases: the Fondazione Epatocentro is collaborating on projects with the European Reference Network (ERN RARE-LIVER) and the International Autoimmune Hepatitis Group (IAIHG).

# The Foundation milestones

**2019**

## **CREATION OF THE ULTRASOUND ACADEMY**

An ultrasound course is created to offer the various modules required for the training pathway defined by the Swiss Society of Sonography in Medicine (SGUM); doctors from all over Switzerland will thus be able to access a wide range of case studies and cutting-edge ultrasound technology.



**2019**

## **THE SWISS BIOBANK FOR AUTOIMMUNE DISEASES OF THE LIVER**

Created for future research, the biobank is a facility for the systematic collection, storage, and management of biological samples from patients suffering from autoimmune diseases of the liver. The biobank for autoimmune diseases of the liver is the first Swiss biobank in the field of hepatology to have obtained the NORMA quality certification from the Swiss Biobanking Platform.



**2020**

## **LAUNCH OF COLLABORATION WITH THE BIOMEDICAL RESEARCH INSTITUTE (IRB)**

The support of a private Foundation enables PD Dr Benedetta Terziroli Beretta-Piccoli MD, Primary Investigator at the Fondazione Epatocentro Ticino, to undertake a period of basic research in the laboratory of Prof. Federica Sallusto at the IRB; the purpose of the project was to characterise the molecular target of the immune response in patients with autoimmune hepatitis.



**2020**

## **THE COVID-19 BIOBANK**

In Switzerland, the first COVID-19 biobank is created in Lugano thanks to the will of the Fondazione Epatocentro Ticino, in collaboration with the Clinica Luganese Moncucco. Systematically collecting biological samples and data from patients hospitalised due to COVID-19 makes it possible to establish a platform that can be used for joint research, aimed at better understanding the nature and mechanisms of the disease and finding appropriate drugs and treatments.



**2021**

## **THE CLINICAL TRIAL WITH METHYLENE BLUE**

In collaboration with Synlab Ticino and the Medical Association of the Canton of Ticino and assisted by the medical and nursing team at Epatocentro Ticino SA, the Fondazione Epatocentro Ticino team is sponsoring a clinical trial in Ticino to test the efficacy and safety of methylene blue, a drug that has shown good efficacy against SARS-CoV-2 for the treatment of COVID-19 in in vitro tests.

**2023**

## **THE FONDAZIONE EPATOCENTRO OBTAINS THE QUALITY CERTIFICATION AS A FACILITY FOR THE CREATION AND MANAGEMENT OF BIOBANKS**

The Fondazione Epatocentro Ticino is now a facility certified by the Swiss Biobanking Platform: obtaining the NORMA quality certification represents recognition and attests to the high-quality work carried out by the Fondazione Epatocentro in the field of biobanks, for which it is now setting standards at the Swiss level.



**2023**

## **FATTY LIVER DISEASE AND THE NAFLD BIOBANK**

Fatty liver disease, which often has silent progression, is very common in Switzerland; if it is not diagnosed and stopped in time, it can develop into inflammation of the liver, cirrhosis, or even liver cancer. To date, there are no drugs to treat it. The scientific community is heavily interested in studying and finding treatments for this disease. Biological samples and clinical data are needed to carry out research projects: to this end, the Foundation has created the NAFLD Biobank, a platform for future research.



**2023**

## **METHYLENE BLUE FOR HEPATITIS B?**

The collaboration between the Fondazione Epatocentro Ticino, the Laboratory of Prof. Francesco Negro in Lausanne, and Prof. Caroline Tapparel at the University of Geneva shows that methylene blue has an antiviral effect against hepatitis B and delta viruses. The Foundation is preparing for a study to test the efficacy of methylene blue in people with chronic hepatitis B virus infections.

# A Word from the Board Chairman

As Chairman, I am pleased to be able to report on a successful 2023 for the Fondazione Epatocentro Ticino, thanks in part to the excellent work done by my predecessor, Prof. Sebastiano Martinoli. In 2023, the Foundation Board met four times to define its principles and priorities in the fields of scientific research, training and patient support. The wide range of expertise of the Board members enables the Foundation to draw on a comprehensive and valuable array of knowledge.

Fatty liver is a significant and widespread health problem: the Foundation, attentive to the needs of the scientific community, has made this disease one of its main focuses, promoting research, training, awareness and patient support initiatives.

The commitment of the Foundation's research unit in the field of autoimmune hepatitis continues: it is always interesting to note how the results derived from research can be translated into clinical practice. Various significant scientific papers have been published. Technological advancements offer patients the opportunity to have virtual consultations with liver disease specialists, conveniently from their own home.

Since it was founded, the Foundation has carried out research and training activities in the field of hepatology. Disseminating knowledge on treatments for liver diseases and on new diagnostic and therapeutic methods through continuous training is a priority for the Foundation and we always try to ensure that the speakers at our training activities, (e.g. the Thursday Lectures, the Ticino Hepatology Symposium and the Annual Discussion Platform) are leaders in the field. The Swiss Conference on Autoimmune Diseases of the Liver, (21–22 September, Lugano), in which patients also participated for the first time, brought top international experts in the field to the shores of Lake Lugano. The Biobank, with biological samples from COVID–19 patients, has proven to be a valuable basis for further research. Under the guidance of our director, Prof. Andreas Cerny, further progress has been made in the research on and treatment of COVID–19 infections with methylene blue. Collaborations with the Università della Svizzera Italiana (USI), the Scuola Universitaria Professionale della Svizzera Italiana (SUPSI), the Clinica Luganese Moncucco, and the Ente Ospedaliero Cantonale continue and are developing to promote joint care for our patients. All these activities would not be possible without the support of our faithful donors, who have once again generously funded our activities this year, in an increasingly competitive context; a special thank you goes to them. Thanks also to our team of researcher physicians led by Prof. Andreas Cerny, who is extremely dedicated to our patients in the clinical field, as well as to teaching, and to research. Our recognition and gratitude goes also to the Foundation's Operations Manager, Pharm. Maurizia Bissig, for her excellent, efficient organisational and administrative management.



**Prof. Jürg Hans Beer MD**  
*Chairman of the Foundation Board*

# A Word from the Director

2023 marks the beginning of the second decade of the Fondazione Epatocentro Ticino's activities. The team, led by the forward-looking Foundation Board and an established group of professionals, sponsors and supports clinical research protocols and epidemiological and cohort studies. In addition, it also works to disseminate knowledge on the treatment of liver diseases through training and publications aimed at doctors and paramedics, as well as at patients and the general population. Our activities in 2023 were characterised by three focal points:

**Joining forces:** ► Our Clinical Trials Unit (CTU) participated in the international clinical trial with Elafibranor that resulted in the registration of this innovative drug: a possible treatment for our patients with primary biliary cholangitis (PBC). Members of the CTU are listed among the authors of the article published in the prestigious New England Journal of Medicine. ► As a specialised centre, we have decided to join KOSEK, the national network for coordinating the treatment of rare diseases. ► Our biobanks have obtained the NORMA quality certification and are part of the Swiss Biobanking Platform (SBP), a body that connects biobanks to the European network, thus increasing the visibility of and access to our biological samples and clinical data for future clinical trials for researchers at an international level.

**Innovative clinical research:** ► The scientific curiosity and courage to sponsor a clinical trial ourselves for the treatment of COVID-19 using the oldest substance synthetically produced in the medical field, methylene blue, are opening up new horizons: the Foundation has discovered that this molecule, in addition to inhibiting the SARS-CoV-2 virus, also inhibits the hepatitis B and delta viruses in vitro. This observation was made in collaboration with the University of Geneva (Prof. C. Tapparel and Prof. F. Negro). Preparations for a human trial are underway.

**Patient safety:** ► Observing cases of hepatitis following vaccination against COVID-19, combined with networking with other doctors who have made similar observations, made it possible to alert the community of specialists to this rare form of adverse effect and help them to recognise and manage it. ► The arrival of Prof. Stephan Krähenbühl, a world-renowned expert in the field of side effects of drugs on the liver, strengthens our scientific understanding of the adverse effects observed in our patients, making the use of drugs safer. I would like to thank our Operations Manager, Maurizia Bissig, and our Foundation team, Prof. Jürg Beer and Adv. Pelli, who, along with the other members of the Foundation Board, gave us the impetus and support we needed; I would also like to thank our partners and sponsors for their support.



**Prof. Andreas Cerny MD**  
*Director. Fondazione Epatocentro Ticino*

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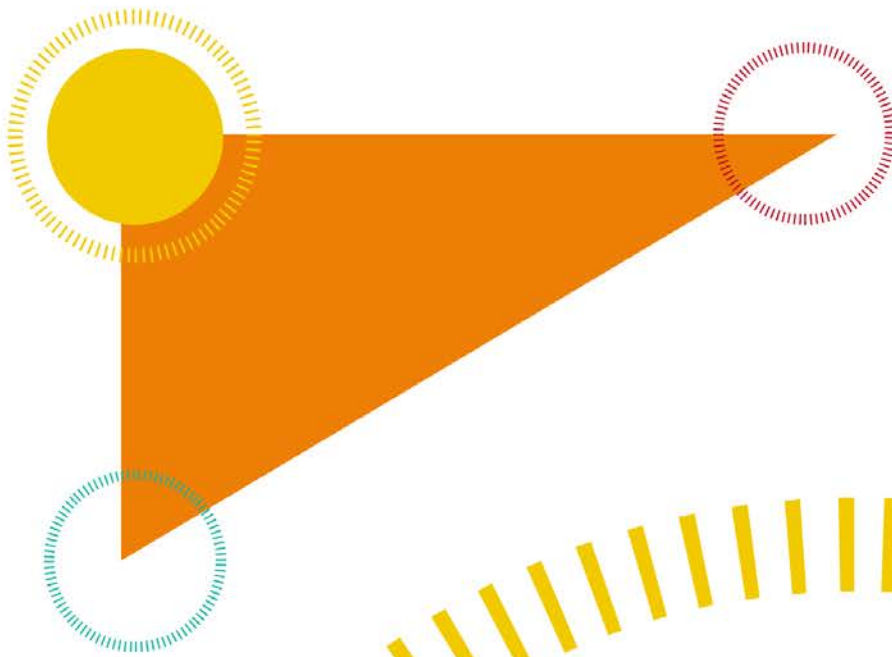
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# 01

# RESEARCH

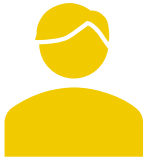


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# The story of one of our patients



*Luca\* is a successful entrepreneur, sporty, and seemingly healthy, but with slightly altered liver values. He didn't know he had hepatocarcinoma until one day he discovered it by chance when he had a CT scan of his abdomen.*

*\* not his real name*

## Who is Luca and what disease is he facing?

**Luca was not who you would expect to find as a patient:** he had never suffered from any notable disease except for diabetes, for which he was being treated. He was slightly overweight, passionate about sports and seemingly healthy! He was sent to our centre when, following a Uro-CT scan, a large lesion suspected to be a malignant tumour on his liver was discovered by chance. **He had never shown any symptoms except for slightly altered levels of liver tests** over at least 3 years, which had never been further investigated. The investigations we conducted showed advanced liver fibrosis at the borderline of cirrhosis: these confirmed the **presence of hepatocarcinoma**, a primary liver cancer due to MASH (metabolic dysfunction-associated steatohepatitis), which was completely asymptomatic and caused by the combination of overweight and diabetes.

## How was the disease treated?

**Within a few weeks after the diagnosis, having completed the necessary investigations, Luca underwent surgery** to remove the part of the liver where the tumour was located. He was prescribed diet therapy and physical activity, which enabled him to lose 7 kilos in 4 months. His diabetes is now perfectly under control. Soon, he will be invited to the University Hospital of Geneva to evaluate the possibility of a liver transplant in the event that the cancer recurs.

## What made the difference in treating the patient?

Definitely the **speed with which we intervened:** it only took 4 weeks from the diagnosis to the intervention! Another aspect that made the difference is the network that our centre has established with the Cantonal Hepato-Bilio-Pancreatic Unit (UCEP) of the Ente Ospedaliero Cantonale hospital network and with the University Hospital of Geneva, valuable collaborations for managing patients with liver cancer. Added to this was a **truly global approach to tackling the patient's liver problem:** we focused not only on the cancer, but also on what caused it, namely chronic liver disease due to diabetes and overweight.



**Dr. Lorenzo Magenta MD**

Deputy Director, Epatocentro Ticino  
Specialist in Tropical Medicine and general  
practitioner, Swiss Medical Federation

# Research activities

## ► Cohort studies

### SWISS HEPATITIS C COHORT STUDY – SCCS

The Swiss Hepatitis C Cohort Study, initiated in 2000, is a systematic and longitudinal study which registers persons resident in Switzerland testing seropositive for HCV (Hepatitis C Virus). This involves collaboration between university hospital outpatient clinics, two large cantonal hospitals, affiliated laboratories, minor hospitals, and private medical practices. The principal goal consists in providing a data platform for aiding the processes of projects in the sphere of Hepatitis C.

ONGOING

[CONSULT THE STUDY >>](#)

### SWISS TRANSPLANT COHORT STUDY – STCS

This prospective and multi-centered cohort study, initiated in 2006 by several researchers, aims at gathering overall data at a national level of all patients who have undergone Solid Organ Transplant (SOT) therapy. After a set-up period of two years, the STCS cohort began enrolling patients in May 2008. At the same time, the new law on transplants, enacted in 2007, required lifelong monitoring for all transplant patients in Switzerland. As a collaborative effort with the Federal Office of Public Health, the cohort ensures compliance with legal requirements.

ONGOING

[CONSULT THE STUDY >>](#)

### SWISS HIV COHORT STUDY – SHCS

Set up in 1988, the SHCS is a systematic and longitudinal study in which a major proportion of individuals affected by HIV in Switzerland participate. It involves a collaborative network consisting of university hospital outpatient clinics for infectious diseases, two large canton hospitals, associated laboratories, minor hospitals, and medical practices. The goal consists in providing a data platform useful in supporting numerous significant projects and research in the sphere of HIV infection.

ONGOING

[CONSULT THE STUDY >>](#)

### SAMMSU (SWISS ASSOCIATION FOR THE MEDICAL MANAGEMENT IN SUBSTANCE USERS) COHORT

Starting in 2013, this study involves gathering and analysis of anonymous data of patients treated in a program of substitution for opiates. The goal of the study is to follow the course and the transmission of diseases in substance abuse patients or patients that formerly used them. The characteristics and collateral effects of various types of treatment were recorded, and the correlation between the personal, behavioural, and onset or prognoses of these diseases' clinical characteristics were studied. It is possible that hereditary factors of the participants may be identified and documented, in case this may have therapeutic significance.

ONGOING

[CONSULT THE STUDY >>](#)

### SASL35: SLVTS SWISS LIVER VENOUS THROMBOSIS STUDY

This is a prospective and observational cohort study of patients affected with venous thrombosis of the liver (either a first diagnosis or already diagnosed). The long-term effects of treatments are studied while registering occurrences, risk factors, and results of treatment. Previous diagnoses, serious comorbidities, base parameters, imaging results, pathological results, characteristics of tumours, treatments and their results, hospital admissions, interventions and complications are recorded. Blood and other samples obtained during routine examinations are recorded.

ONGOING

[CONSULT THE STUDY >>](#)

### SASL 38: SWISS AUTOIMMUNE HEPATITIS COHORT STUDY

The purpose of data and biological sample gathering is to obtain high quality prospective data to obtain epidemiological and natural history clarity, reaction to treatment and the effects of this rare pathology. The Biobank will enable the analysis of particular scientific phenomena and respond to a number of open questions. From 2018 the cohort has been collaborating in research projects with the International Group for Autoimmune Hepatitis (IAIHG <http://www.iaihg.org/>) and with the European Reference Network (ERN RARE-LIVER, <https://www.rare-liver.eu/>).

ONGOING

[CONSULT THE STUDY >>](#)

### SASL 39: SWISS PRIMARY BILIARY CHOLANGITIS COHORT STUDY

The primary purpose of this study is to regularly follow up, using standardized methods, on the greatest number possible of patients in Switzerland suffering from primary biliary cholangitis to better understand and treat the disease. At the same time, blood samples are frozen for future further possible research in this field. From 2018 the cohort has been working together with the European Reference Network (ERN RARE-LIVER, <https://www.rare-liver.eu/>).

ONGOING

CONSULT THE STUDY >>

### SASL 40: SWISS PRIMARY SCLEROSING CHOLANGITIS COHORT STUDY

The primary purpose of this study is to regularly follow up, using standardized methods, on the greatest number possible of patients in Switzerland suffering from primary sclerosing cholangitis to better understand and treat the disease. At the same time blood samples are frozen for future further possible research in this field. From 2018 the cohort has been collaborating in research projects with the European Reference Network (ERN RARE-LIVER, <https://www.rare-liver.eu/>).

ONGOING

CONSULT THE STUDY >>

### SWISS HEPATITIS B COHORT STUDY

This involves a multicentric cohort study which registers and longitudinally observes patients with chronic hepatitis B infections. The seroprevalence of the HBs-Antigen is estimated to be 0.3% of the Swiss population, with higher rates among groups at risk (immigrants, IVDU). The rationale for a multicentric cohort is to carefully register patients with chronic hepatitis B using standardized methods, making it possible to carry out scientific projects in the field of hepatitis B.

ONGOING

## ► Clinical studies

### A PHASE 2b RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF EFINOPEGDUTIDE (MK-6024) IN ADULTS WITH PRECIRRHOTIC NONALCOHOLIC STEATOHEPATITIS

The purpose of this phase 2 study is to verify the efficacy of Efinopegdutide compared to placebo in people with non-alcoholic steatohepatitis (NASH) and to evaluate the safety and tolerability of the drug.

CLINICAL TRIAL: IN PROGRESS

[CONSULT THE STUDY >>](#)

### TRANSFORM: A 52-WEEK, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND, ADAPTIVE PHASE 2b/3 TRIAL OF SETANAXIB WITH A 52-WEEK EXTENSION PHASE IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS (PBC) AND ELEVATED LIVER STIFFNESS

A 52-week, randomised, placebo-controlled, double-blind, adaptive phase 2b/3 clinical trial of Setanaxib with a 52-week extension phase in patients with primitive biliary cholangitis (PBC) and elevated liver stiffness. The purpose of the study is to evaluate the effect of Setanaxib on biochemical response at week 52 in patients with PBC and high liver stiffness and intolerance or inadequate response to Ursodeoxycholic Acid (UDCA).

CLINICAL TRIAL: IN PROGRESS

[CONSULT THE STUDY >>](#)

### A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTIPLE-DOSE, PHASE 2 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF BMS-986263 IN ADULTS WITH COMPENSATED CIRRHOSIS FROM NONALCOHOLIC STEATOHEPATITIS (NASH), (IM025-017)

The purpose of this study is to demonstrate the antifibrotic quality, safety of and tolerance of BMS-986263, in patients with non-alcoholic steatohepatitis (NASH) and compensated cirrhosis.

CLINICAL TRIAL: CONCLUDED

[CONSULT THE STUDY >>](#)

A PHASE II, MULTICENTER, OPEN-LABEL, RANDOMIZED TWO-YEAR STUDY TO EVALUATE THE EFFICACY AND SAFETY OF DEFERASIROX FILM-COATED TABLET VERSUS PHLEBOTOMY IN PATIENTS WITH HEREDITARY HEMOCHROMATOSIS (ORION)

The purpose of the study is to compare the extent of reaction to Deferasirox FCT as opposed to classic phlebotomy in patients suffering from hemochromatosis, where the reaction is determined by transferrin saturation at  $\leq 100 \mu\text{g} / \text{L}$  at 24 months or earlier.

CLINICAL TRIAL: CONCLUDED

[CONSULT THE STUDY >>](#)

A PHASE 3, DOUBLE-BLIND, RANDOMIZED, LONG-TERM, PLACEBO-CONTROLLED, MULTICENTER STUDY EVALUATING THE SAFETY AND EFFICACY OF OBETICHOLIC ACID IN SUBJECTS WITH NONALCOHOLIC STEATOHEPATITIS. THE REGENERATE STUDY

The aim of the study is to evaluate the effect of obeticholic acid (OCA) as compared to a placebo in the histological improvement in non-alcoholic steatohepatitis (NASH) assessing the following primary endpoints using the points Criteria of the NASH Clinical Research Network (CRN): Improvement in fibrosis by at least 1 stage without a NASH deterioration; Resolution of NASH without deterioration in fibrosis.

CLINICAL TRIAL: CONCLUDED

[CONSULT THE STUDY >>](#)

DOUBLE-BLIND, RANDOMISED, PLACEBO-CONTROLLED, PHASE II DOSE-FINDING STUDY COMPARING DIFFERENT DOSES OF NORUCHOLIC ACID TABLETS WITH PLACEBO IN THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS IN PATIENTS WITH AN INADEQUATE RESPONSE TO URSODEOXYCHOLIC ACID: NUT-2/PBC

The purpose of the phase 2 NUT-2 study is to evaluate the efficacy of two doses of norucholic acid compared to placebo for the treatment of primary biliary cholangitis in patients with an inadequate response to ursodeoxycholic acid.

CLINICAL TRIAL: IN PROGRESS

[CONSULT THE STUDY >>](#)

A TWO-PART, RANDOMIZED, PLACEBO CONTROLLED, DOUBLE BLIND, MULTICENTER, PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF LINERIXIBAT FOR THE TREATMENT OF CHOLESTATIC PRURITUS IN PARTICIPANTS WITH PRIMARY BILIARY CHOLANGITIS (PBC): GLISTEN STUDY.

The aim of the study is to evaluate the effect of oral treatment with Linerixibat, compared with placebo, on pruritus in PBC patients with cholestatic pruritus.

CLINICAL TRIAL: IN PROGRESS

[CONSULT THE STUDY >>](#)

DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, PHASE III STUDY COMPARING NORURSODEOXYCHOLIC ACID CAPSULES WITH PLACEBO IN THE TREATMENT OF PRIMARY SCLEROSING CHOLANGITIS: NUC-5/PSC

The purpose of the study is to demonstrate the superiority of norursodeoxycholic capsules (norUDCA) as compared with a placebo in treating primary sclerosing cholangitis (PSC) in preventing progression of the disease, ascertained through liver histology and partial normalization of serum levels of alkaline phosphatase in patients affected by PSC.

CLINICAL TRIAL: IN PROGRESS

[CONSULT THE STUDY >>](#)

A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY EVALUATING THE SAFETY, TOLERABILITY, AND EFFICACY OF CILOFEXOR IN NON-CIRRHOTIC SUBJECTS WITH PRIMARY SCLEROSING CHOLANGITIS (PRIMIS)

This is a Phase 3 study, randomized, double blind, placebo-controlled to evaluate the safety, tolerability, and efficacy of cilofexor (CILO) in non-cirrhotic subjects. The primary objective of this study is to assess whether CILO reduces the risk of the progress of fibrosis in non-cirrhotic subjects with primary sclerosing cholangitis (PSC).

CLINICAL TRIAL: CONCLUDED

[CONSULT THE STUDY >>](#)



### NON-INVASIVE ASSESSMENT OF LIVER STIFFNESS AND STEATOSIS IN PATIENTS WITH FATTY LIVER DISEASE

This is a prospective study with the aim of determining what non-invasive methods as between Fibroscan/CAP and ultrasound/ARFI (Acoustic Radiation Force Impulse Imaging) would be more efficacious in determining the hardness and steatohepatitis in patients suffering from fatty liver disease.

CLINICAL TRIAL: IN PROGRESS

### A PHASE 3, MULTINATIONAL, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY OF MGL-3196 (RESMETIROM) IN PATIENTS WITH NON-ALCOHOLIC STEATOHEPATITIS (NASH) AND FIBROSIS TO RESOLVE NASH AND REDUCE PROGRESSION TO CIRRHOSIS AND/OR HEPATIC DECOMPENSATION

This is a phase 3 multinational, double-blind, randomized, placebo-controlled study of MGL-3196 (Resmetirom) in patients with non-alcoholic steatohepatitis (NASH) and fibrosis to resolve NASH and reduce progression to cirrhosis and/or hepatic decompensation. The primary aim of the study is the resolution of NASH (no ballooning and mild/no inflammation) associated with a reduction of at least 2 points in the non-alcoholic fatty liver disease (NAFLD) activity score and no worsening of fibrosis assessed by liver biopsy after 52 weeks of treatment in patients with stage F2 and F3 fibrosis.

CLINICAL TRIAL: CONCLUDED

[CONSULT THE STUDY >>](#)

### A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY AND OPEN-LABEL LONG TERM EXTENSION TO EVALUATE THE EFFICACY AND SAFETY OF ELAFIBRANOR 80 MG IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS WITH INADEQUATE RESPONSE OR INTOLERANCE TO URSODEOXYCHOLIC ACID (ELATIVE STUDY)

This is a double blind, randomized placebo-controlled and open-label term extension Phase 3 study to evaluate the efficacy and safety of Elafibranor 80 mg in patients with primary biliary cholangitis with inadequate response or intolerance to ursodeoxycholic acid. The aim of the study is to evaluate the effect of Elafibranor (80 mg/p.d.) on cholestasis, on the normalization of alkaline phosphatase (ALP) as well as on pruritus, over 52 weeks of treatment as opposed to the placebo.

CLINICAL TRIAL: CONCLUDED

[CONSULT THE STUDY >>](#)

### EVALUATION OF THE EFFICACY OF METHYLENE BLUE ADMINISTRATION IN SARS-CoV2- AFFECTED PATIENTS: A PHASE 2, RANDOMIZED, PLACEBO-CONTROLLED, SINGLE BLIND CLINICAL TRIAL

A randomised, placebo-controlled, single-blind, phase 2 clinical trial on the efficacy of methylene blue against SARS-CoV-2 infection in patients with a newly diagnosed SARS-CoV-2 infection. The purpose of the study is to evaluate the efficacy of methylene blue against SARS-CoV-2 in patients with a recent diagnosis of infection with SARS-CoV-2, not only to assess the efficacy of methylene blue of COVID-19 in patients with a recent diagnosis of infection with SARS-CoV-2 but also to ensure proper adherence to treatment with methylene blue in patients with Covid-19.

CLINIC TRIAL: CONCLUDED

[CONSULT THE STUDY >>](#)

## ► Epidemiological studies

### RETROSPECTIVE ANALYSIS OF THE OUTCOME OF PATIENTS WITH FATTY LIVER DISEASE FOLLOWED AT THE EPATOCENTRO TICINO BETWEEN 2009 AND 2019

This is a retrospective analysis with the purpose of providing a preliminary global view of the effect of the fatty liver disease in the Italian region of Switzerland to endeavour to determine whether there are factors that could show an increasing spread of the disease.

EPIDEMIOLOGICAL ANALYSIS: IN PROGRESS

### CRiPSI: COVID-19 RISK PREDICTION IN SWISS ICUs-TRIAL

This is an epidemiological analysis aimed at identifying genetic risk factors as clinically predictive in relation to hospital mortality or near-death results and the presence of respiratory, neurocognitive, or other symptoms in a long-term clinical follow-up of patients critically ill with Covid-19.

EPIDEMIOLOGICAL ANALYSIS: CONCLUDED

[CONSULT THE STUDY >>](#)

## ► Retrospective studies

### EFFECT OF DIRECT ACTING ANTIVIRAL DRUGS ON THE OCCURRENCE AND RECURRENCE OF INTRA- AND EXTRA-HEPATIC MALIGNANCIES IN PATIENTS WITH CHRONIC HEPATITIS C

This is a multicentric observational cohort study at national level aiming at evaluating whether the sustained virological response (SVR) reached by Direct Acting Antiviral (DAA) drugs leads to greater risk of infection and/or reinfection HCC (hepatocellular carcinoma), clear cell carcinoma (CCC) and/or extra-hepatic malignancies in Swiss patients with chronic hepatitis C (HCV) by comparison to the SVR recorded with regimes with a long-acting interferon (Peginterferon alfa) base.

RETROSPECTIVE: CONCLUDED

### OUTCOME OF LIVER TRANSPLANT RECIPIENTS WITH AUTOIMMUNE HEPATITIS AS INITIAL INDICATION IN THE SWISS TRANSPLANT COHORT STUDY

This is a study that analyses and describes in the transplant cohort, the outcome of transplants in patients who had transplants for autoimmune hepatitis (AIH).

RETROSPECTIVE: IN PROGRESS

### ETIOLOGIES AND OUTCOME OF SUPER-URGENT LIVER TRANSPLANTATION IN SWITZERLAND

This is a retrospective analysis with the aim of describing outcomes of super-urgent liver transplants in Switzerland.

RETROSPECTIVE: IN PROGRESS

### STUDYING THE PATHOBIOLOGY OF COVID-19 USING TISSUE- AND CELL-BASED ANALYSIS

This retrospective analysis aims at understanding the pathobiology of COVID-19 by analysing tissue samples and cells of patients infected with SARS-Cov-2 using different methods and understanding the process of collateral effects on the liver after vaccination against SARS-Cov-2.

RETROSPECTIVE: IN PROGRESS

## ► Prospective studies

### EFFECT OF ANTI COVID-19 mRNA VACCINES ON DEVELOPMENT OR WORSENING OF AUTOIMMUNE REACTIVITY IN PATIENTS WITH AUTOIMMUNE LIVER DISEASE

The purpose of the study is to investigate the rise in the development or worsening of an existing autoimmune reactivity in patients with autoimmune liver disease and in health management after vaccination with mRNA COVID-19 vaccinations.

PROSPECTIVE: IN PROGRESS

## ► “Nested” cohort studies for autoimmune diseases of liver

### DIAGNOSTIC ACCURACY OF LIVER AUTOANTIBODY ASSAYS AND DEFINITION OF THE AUTOANTIBODY PROFILE IN THE SWISS AUTOIMMUNE LIVER DISEASE COHORTS

Study aimed at assessing the accuracy of diagnoses for autoimmune hepatic diseases of four *in vitro* automated diagnostic tests for autoantibodies and defining the autoantibody profile associated with AIH, PBC, PSC and variant syndromes in the scope of the Swiss AIH, PSC and PBC cohort.

NESTED: IN PROGRESS

### ANTI-NUCLEAR ANTIBODY ANTIGENETIC TARGETS IN TYPE 1 AUTOIMMUNE HEPATITIS

The purpose of the present project is to identify, via immunoprecipitation, the molecular targets of ANA in a cohort of untreated Type 1 ANA-positive patients affected by AIH and to investigate the clinical characteristics associated with the specific ANA and AIH antigens.

NESTED: IN PROGRESS

### QUANTIFICATION OF POLYREACTIVE IMMUNOGLOBULIN G TO AID IN THE DIAGNOSIS OF AIH VS DILI

The aim of this project is to demonstrate that plgG have diagnostic value in populations with different ethnicities and geographical backgrounds to discriminate AIH from non-AIH liver disease, that they can help distinguish AIH from AIH-like DILI and from classical DILI, and finally to predict steroid dependence in acute liver disease at 3 – 6 months after occurrence.

NESTED: IN PROGRESS

### PROFILE OF PBC-RELATED AUTOANTIBODIES AND DISEASE PROGRESSION IN PBC

The primary objective of this study is to better define the prognostic role of the antibodies anti-gp210, anti-sp100, anti-centromere, anti-Kelch-like12 (KLHL12) and anti-hexokinase 1 (HK1) on disease progression in PBC using the Global PBC Study Group cohort.

NESTED: CONCLUDED

## ► Translational studies in collaboration with IRB

### AUTOREACTIVE T, B AND REGULATORY T CELLS TARGETING SEPSECS IN TYPE 1 AND TYPE 2 AUTOIMMUNE HEPATITIS AND AUTOIMMUNE SCLEROSING CHOLANGITIS

The scope of this study is to identify and characterize T cells which recognize SEPSECS in AIH and ASC.

STATUS: IN PROGRESS

## ► Biobanks

### AILD BIOBANK – AUTOIMMUNE LIVER DISEASES

Certified entity established to collect, conserve, and manage samples of biological material and patient clinical data to make them available for clinical research. The AILD Biobank is therefore a systematic collection, not only of biological samples, but also of clinical data on patients with autoimmune diseases of the liver and represents a platform for future research. The AILD biobank includes three biobanks: the autoimmune hepatitis (AIH) biobank, the primary biliary cholangitis (PBC) biobank, and finally, the primary sclerosing cholangitis (PSC) biobank.

BIOBANK: IN PROGRESS

[CONSULT THE STUDY >>](#)

### BIOBANK COVID-19 TICINO: COLLECTION OF DATA AND SAMPLES OF COVID-19 POSITIVE PATIENTS

Certified facility created to collect, store and manage samples of biological material and clinical data from COVID-19 patients admitted to the Clinica Luganese Moncucco in order to then make them available for clinical research. The COVID-19 Biobank is thus a systematic collection, not only of biological samples, but also of clinical data of COVID-19 patients and serves as a platform for future research in order to study the effects of this dreaded virus and to find possible remedies to it.

BIOBANK: IN PROGRESS

[CONSULT THE STUDY >>](#)

### FONDAZIONE EPATOCENTRO TICINO (FEPT) BIOBANK INFRASTRUCTURE

The Fondazione Epatocentro Ticino is a facility certified by the Swiss Biobanking Platform: obtaining the NORMA quality certification represents recognition and attests to the high-quality work carried out by the Fondazione Epatocentro in the field of biobanks, for which it is now setting standards at the Swiss level.

BIOBANK: IN PROGRESS



## ► Publications

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## GUIDELINES 2024

Participation in the Delphi process of the “EASL Clinical Practice Guidelines on the Management of Autoimmune Hepatitis” 2024

# 02

# TRAINING



## **1. The insight**

## **2. Training activities**

- ▶ Training events
- ▶ Ticino Symposium on Hepatology
- ▶ Swiss Autoimmune Liver Disease Meeting
- ▶ Annual discussion platform
- ▶ Newsletter
- ▶ Ultrasound academy
- ▶ Participation of speakers at symposia and training session



# The insight



## Fatty liver

*Fatty liver is a common disease in industrialised countries that mainly affects adults (30%) but does not spare young people; it does not result in any particular symptoms at first and is characterised by an abnormal accumulation of fat in the liver cells. Healthy lifestyle, controlling metabolic factors, and exercise are the first weapons against this disease.*

## How do you get fatty liver?

Numerous factors contribute to the development of fatty liver, including a poor diet high in saturated fatty acids, a sedentary lifestyle, being overweight, alcohol abuse, and hormonal factors (e.g. thyroid dysfunction, type 2 diabetes mellitus); some people are also genetically predisposed to the disease. When metabolic diseases such as obesity, diabetes, and hypertension co-occur with hepatic steatosis, this is called metabolic dysfunction-associated fatty liver disease (MAFLD). People often have this disease for many years without realising it; however, there is an increased risk of cardiovascular disease. The disease can also involve inflammatory phenomena in the liver (steatohepatitis), an inflammatory condition that initially causes fibrosis and subsequently cirrhosis and entails a potential risk of cancer.

## Why is the Foundation doing research on this disease?

Because dealing with liver diseases on a daily basis, over the years we have witnessed a gradual increase in this disease, which is becoming the most common cause of chronic liver disease that we have to treat. At our centre, we are conducting a **study with the experimental drug EFINOPEGDUTIDE**, which acts as a GLP-1R/GCGR-agonist; the study is a double-blind, placebo-controlled, randomised phase 2 (therapeutic exploratory) trial on patients with NASH (non-alcoholic steatohepatitis) with stage F2/F3 fibrosis. We will shortly be starting another phase 3 trial with cirrhotic NASH patients (F4) with the **experimental drug EFRUXIFERMIN**, a protein that mimics the action of FGF21; the study is double-blind and placebo-controlled. The **NAFLD (non-alcoholic fatty liver disease) cohort** is active at our centre, collecting data and biological samples from patients with this disease (biobank).

## What results have been achieved and what are the aims?

We are studying new molecules that are very promising and from which we expect interesting results. Thanks to scientific research and the continuous training of us doctors who deal with liver diseases, we are able to guarantee targeted and multidisciplinary patient care, with latest diagnostic tools and laboratory tests.



**Dr. Manuela Balmelli MD**

Accredited doctor, Epatocentro Ticino  
Specialist in General Internal Medicine

# Training activities

## ► Training events

### Refresher courses and discussion events

The Foundation organized a series of refresher courses and discussion events. Part of the training, of a specialized nature, was designed for specialists in the sector and consultants to the Epatocentro; other parts are more specifically intended for family doctors and specialists involved in the treatment of patients with hepatic problems and which will require the intervention of external specialists.

### Thursday lectures

Meetings covering highly specialised topics and taking an approach that promotes debate between the doctors involved and discussion of clinical cases.

When	Topic	Speaker
19.01.2023	Managing excessive alcohol consumption	Dr. Alberto Moriggia MD
16.02.2023	Managing portal hypertension	Prof. Andrea De Gottardi MD, Dr. Stefano Cappio MD
23.03.2023	The patient with jaundice	Prof. Andreas Kremer MD Dr. Alessandra Cristaudi MD
11.05.2023	AIH Update	PD Dr. Benedetta Terziroli Beretta–Piccoli MD Prof. Luca Mazzucchelli MD
19.10.2023	PSC/SC: primary and secondary forms	Prof. Dr. Luigi Muratori MD
23.11.2023	Hepatic cirrhosis 2023: diagnostic and nutritional aspects	Prof. Annalisa Berzigotti MD
07.12.2023	Viral hepatitis update	Prof. Darius Moradpour MD

## Addiction medicine

Meetings focusing on the problems of dependence, addiction, and risky consumption of alcohol, substances, and medicines, and on behavioural addictions. The training is organised by the Ingrado Centre – Services for addiction and the Epatocentro Ticino.

When	Topic
16.05.2023	Addiction
20.06.2023	Pharmacology of recreational substances
29.08.2023	Cannabis Update
19.09.2023	Behavioural addictions
17.10.2023	Stimulants and crack, update for doctors
21.11.2023	Hallucinogens and dissociatives

## School of hepatology

Online training enables us to learn from leading Swiss experts in the sector; training is organized by the SASL (Swiss Association for Study of the Liver) with which the Fondazione Epatocentro Ticino has traditionally enjoyed direct links.

When	Topic
13.03.2023	SASL School of Hepatology, Number 39
12.06.2023	SASL School of Hepatology, Number 40
11.09.2023	SASL School of Hepatology, Number 41
11.12.2023	SASL School of Hepatology, Number 42

## Meeting of expert

Online meetings between Swiss experts in the field of autoimmune liver diseases to discuss clinical cases and exchange opinions.

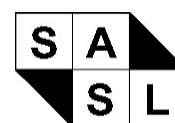
When	Topic
07.11.2023	SARS-CoV 2 vaccines in patients with autoimmune liver diseases: Clinical case discussion of Swiss Autoimmune Liver disease Cohort Studies

## ► Ticino Symposium on Hepatology

From 2013 the Ticino Symposium on Hepatology has offered medical specialists and family doctors a unique window onto the latest innovations concerning diseases affecting the liver. The challenges presented by this pathology are addressed by persons who are outstanding in the field, both nationally and internationally, and who, on this occasion, share their research and the results of their findings.

When	Topic	Speaker
28.09.2023	MAFLD Clinical Case	Dr. Lorenzo Magenta MD
	Management of MAFLD 2023	Prof. Andreas Cerny MD
	PBC Primitive Biliary Cholangitis Clinical Case	PD Dr. Benedetta Terziroli Beretta-Piccoli MD
	PBC Primitive Biliary Cholangitis and similar diseases	Prof. Marco Carbone MD
	HCC Clinical Case	Dr. Massimiliano Dizonno MD
	HCC: The Hepatologist's Perspective	Prof. Markus Heim MD
	HCC: The Surgeon's Perspective	Prof. Pietro Majno-Hurst MD Dr. Alessandra Cristaudi MD

In partnership with:



## ► Swiss Autoimmune Liver Disease meeting

The Swiss conference on autoimmune diseases of the liver, the fourth edition of which will be held in 2023, is unique in its class at national level, and specifically for hepatologists and immunologists from throughout the country and from abroad interested in being updated on developments in basic research and clinical strategies aimed at combating autoimmune diseases of the liver.

When	Topic	Speaker
21.09.2023	Digital 4 <sup>th</sup> Swiss Autoimmune Liver	
22.09.2023	Disease Meeting	
	<b>Patients' session:</b>	
	Pregnancy	Prof. Michael Heneghan MD
	Drug side effects	Prof. Maria Isabel Lucena MD Prof. Raul Andrade MD
	New Therapies	Prof. Michael Manns MD
	<b>Basic science sessions:</b>	
	<b>Genetics:</b>	
	Genetics of PBC	Prof. Pietro Invernizzi MD
	Genetics of PSC	Prof. Tom Karlsen MD
	Genetics of AIH	Prof. Ynto de Boer MD
	Inherited immune deficiencies and autoimmunity	Prof. Mike Recher MD
	<b>Hot topics in autoimmune liver diseases:</b>	
	Cellular therapies	Prof. Maria Serena Longhi MD
	SARS-CoV-2 and liver autoimmunity	Prof. Gideon Hirschfield MD
	Drug-induced AIH-like DILI	Prof. Maria Isabel Lucena MD

**Mechanisms of autoimmunity:**

The Long and Latent Road to Autoimmunity	Prof. Eric Gershwin MD
T cells in autoimmunity	Prof. Federica Sallusto
Viruses and autoimmunity	Prof. Christian Münz MD

**Clinical sessions:****Diagnostic dilemmas:**

Radiological clinical case presentation: the diagnosis of PSC	Dr. Stefano Cappio MD and his fellow
Imaging in PSC and ASC	Prof. Annamaria Deganello MD
Serological case presentation: the diagnosis of AIH	Dr. Eric Dayer MD PD Dr. Benedetta Terziroli Beretta-Piccoli MD
Are autoantibodies still useful in the AI era?	Prof. Diego Vergani MD

**Treatment:**

Novel therapeutic targets for autoimmune cholestatic liver diseases	Prof. Michael Trauner MD
Treatment of cholestatic pruritus	Prof. Andreas Kremer MD
Difficult to treat AIH patients	Prof. Ansgar Lohse MD

**Pediatrics:**

Case presentation	PD. Dr. Christiane Sokollik MD
Sclerosing cholangitis in pediatric IBD patients	Prof. Patrick Van Rheenen MD
Growing up with autoimmune liver disease: longterm outcome of autoimmune liver disease	Dr. Marianne Samyn MD

**Checkpoint-inhibitors and the liver**

Clinical case presentation	Dr. Antonio Galante MD
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Checkpoint-inhibitors-induced liver injury	Prof. Eleonora de Martin MD
Liver histology of checkpoint-inhibitors-induced liver injury	Prof. Yoh Zen
Can checkpoint inhibitors be used in patients with autoimmune liver diseases?	Prof. Michael Manns MD

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**CHAIRS:**

PD Dr. Benedetta Terziroli Beretta-Piccoli MD, Prof. Andreas Cerny MD, Prof. Giorgina Mieli-Vergani MD, Prof. Michael Manns MD, Prof. Andrea De Gottardi MD, Prof. Maria Isabel Lucena MD, Prof. Michael Trauner MD, Prof. Pietro Invernizzi MD, Prof. Michael Heneghan MD, Prof. Andreas Kremer MD, Prof. Raul Andrade MD, Prof. Gideon Hirschfield MD, Prof. Ansgar Lohse MD, Prof. Federica Sallusto, Prof. Diego Vergani MD.

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## ► Annual discussion platform

The annual round table offers an occasion to discuss themes linked to the development of excellence and sustainability for the healthcare system in Ticino. The rendezvous is organized by USI (Italian University of Switzerland), which, with its new biomedical faculty, plays an ever more important role in academic and training spheres. Stakeholders from local and national healthcare systems gathered around the same table for the occasion, to share their own experiences and points of view on issues tabled.

When	Topic	Speaker
14.11.2023	<b>Eradicating a disease: a sustainable top-down choice for everyone?</b>	
	Several diseases are now candidates for eradication worldwide. These are important goals based on health policy strategies undertaken globally that often deal with a good deal of uncertainty and that sometimes conflict with local health priorities. Is eradication the right way? What are the implications of these choices made at the global level for Switzerland? How is happening in Ticino? When talking about vaccination campaigns, what are the social mechanisms that make them work or fail?	<b>Giovanni Pedrazzini</b> , Dean of the USI Faculty of Biomedical Sciences; <b>Raffaele De Rosa</b> , President of the Council of State and Director of the DSS; <b>Giorgio Merlani</b> , Cantonal doctor; <b>Lisa Kottanattu</b> , Head of Service, General and Specialist Paediatrics, Paediatric Institute of Italian Switzerland, EOC; <b>Lorenzo Magenta</b> , Deputy Director of the Epatocentro Ticino; <b>Alberto Moriggia</b> , Medical Director of Ingrado and Accredited Doctor at the Epatocentro Ticino; <b>Peter Johannes Schulz</b> , Director of the Institute of Health Communication, Professor at the Faculty of Communication, Culture, and Society, USI.

In partnership with:



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## ► Newsletter: The Liver Bulletin

“The Liver Bulletin” is the newsletter produced by the Foundation and addressed to all doctors in Ticino. It has been specifically conceived to keep doctors constantly updated on the latest information in the field of hepatology and of forthcoming events; in each edition a specialist doctor presents a topic in the field of hepatology in which it is discussed in detail.

To receive the newsletter simply sign-up online at [www.epatocentro.ch](http://www.epatocentro.ch)

When	Topic	Speaker
10.03.2015	Newsletter #1 – New drugs against hepatitis c	Dr. Lorenzo Magenta MD
04.09.2015	Newsletter #2 – Primary biliary cholangitis	PD Dr Benedetta Terziroli Beretta-Piccoli MD
24.03.2016	Newsletter #3 – Innovative ascites treatment	Dr. Andrea De Gottardi MD
19.10.2016	Newsletter #4 – Fatty liver	Prof. Andreas Cerny MD
20.07.2017	Newsletter #5 – Alcoholic liver disease	Prof. Alberto Moriggia MD
23.02.2018	Newsletter #6 – Hyperferremia in the study of medicine	Dr. Manuela Balmelli MD
08.06.2018	Newsletter #7 – Hepatic Biopsies	Dr. Daniel Hagara MD
04.12.2018	Newsletter #8 – Wilson’s Disease	Dr. Antonella Robatto MD
28.03.2019	Newsletter #9 – Hepatitis E	Dr. Lorenzo Magenta MD
27.01.2020	Newsletter #10 – Hepatic encephalopathy	Dr. Andrea Griffa MD
15.07.2020	Newsletter #11 – CEUS (Contrast Enhanced Ultrasound)	Dr. Manuel Gobbo MD
27.01.2021	Newsletter #12 SARS-Cov2 the liver	Dr. Manuela Balmelli MD
17.06.2021	Newsletter #13 – Autoimmune hepatitis	PD Dr. Benedetta Terziroli Beretta-Piccoli MD
09.12.2021	Newsletter #14 – Hepatitis B	Dr. Lorenzo Magenta MD
24.10.2022	Newsletter #15 – Liver disease and substance abuse	Dr. Alessandra Bruno MD
30.03.2023	Newsletter #16 – Fatty liver: when to worry	Prof. Andreas Cerny MD

## ► **Ultrasound academy**

The Foundation, which performs 2 500 ultrasound examinations annually, since 2019, has offered interested doctors, ultrasonography (SGUM) courses (abdominal module) and POCUS. The Foundation's Ultrasound Academy staff consists of 4 SGUM tutors and 8 SGUM doctors. They are exposed to well-documented cases showing clinical profiles, laboratory findings and often also NAFLD histopathology findings such as hepatic cirrhosis, hepatobiliary pathologies, focal lesions of the liver, kidneys, and pancreas. State of the art ultrasound equipment will be used for ultrasound examinations.

For more information consult the site [www.epatocentro.ch/la-fondazione](http://www.epatocentro.ch/la-fondazione)

## ► Participation of speakers at symposia and training session

When	Topic	Speaker
19.01.2023	Managing excessive alcohol consumption	Dr. Alberto Moriggia MD Dr. Antonio Galante MD
04-05.03.2023	SGUM abdomen course for medical students, USI, Lugano	Dr. Daniel Hagara MD
07.03.2023	Late presenters with hepatitis C: Data from the SAMMSU cohort, SAMMSU General assembly – Sponsors' meeting 2023, Basel	Dr. Alberto Moriggia MD
13.03.2023	Vaccination in chronic liver disease and transplantation, SASL >School of hepatology	Prof. Andreas Cerny MD
13.03.2023	POCUS emergency course for medical students, USI Lugano	Dr. Daniel Hagara MD Prof. Judith Wytttenbach
20.03.2023	POCUS emergency course for medical students, USI Lugano	Dr. Daniel Hagara MD Prof. Judith Wytttenbach MD
17.04.2023	Watch out for foie gras, Clinical Happy Hour, Clinica Luganese Moncucco	Dr. Lorenzo Magenta MD
08.05.2023	POCUS emergency course for medical students, USI Lugano	Dr. Daniel Hagara MD Prof. Judith Wytttenbach MD
11.05.2023	Update autoimmune hepatitis	PD Dr. Benedetta Terziroli Beretta-Piccoli MD Prof. Luca Mazzuchelli MD
15.05.2023	POCUS emergency course for medical students, USI Lugano	Dr. Daniel Hagara MD Prof. Judith Wytttenbach MD
25.05.2023	Alcoholic beverages: do we know what we're drinking? Stress and alcohol	Dr. Alberto Moriggia MD

	conference, SUPSI/USI Viganello CAMPUS	
02-03.06.2023	Current and future challenges in the management of liver diseases, Lugano	Prof. Andreas Cerny MD
03.06.2023	POCUS emergency course, USI, Lugano	Dr. Daniel Hagara MD
24.08.2023	SGUMSI refresher course, USI, Lugano	Dr. Daniel Hagara MD
16.09.2023	SGUM course for peer tutors, USI, Lugano	Dr. Daniel Hagara MD Prof. Judith Wyttenbach
21-22.09.2023	Serological case presentation: the diagnosis of AIH, Swiss Autoimmune Liver disease Meeting, Lugano	PD Dr. Benedetta Terziroli Beretta-Piccoli MD
21-22.09.2023	Swiss Autoimmune Liver disease Meeting, Lugano	Prof. Andreas Cerny MD; PD Dr. Benedetta Terziroli-Piccoli MD
23.09.2023	SGUM course for peer tutors, USI, Lugano	Dr. Daniel Hagara MD Prof. Judith Wyttenbach
28.09.2023	MAFLD clinical case, Ticino Hepatology Symposium 2023, Manno	Dr. Lorenzo Magenta MD
28.09.2023	Management of MAFLD 2023, Ticino Hepatology Symposium 2023, Manno	Prof. Andreas Cerny MD
28.09.2023	PBC Primitive Biliary Cholangitis Clinical Case, Ticino Hepatology Symposium 2023, Manno	PD Dr. Benedetta Terziroli Beretta-Piccoli MD
11.10.2023	Foie gras and similar: 21 <sup>st</sup> refresher course for the general practitioner, Palazzo dei Congressi, Lugano	Dr. Lorenzo Magenta MD
11.11.2023	SGUMSI refresher course, OSG Bellinzona	Dr. Daniel Hagara MD
13.11.2023	POCUS emergency course for medical students, USI Lugano	Dr. Daniel Hagara MD Prof. Judith Wyttenbach MD
14.11.2023	Towards the end of hepatitis with a team effort, 9 <sup>th</sup> Health Platform, USI Lugano	Dr. Lorenzo Magenta MD Dr. Alberto Moriggia MD

16-18.11.2023	Diagnosis and management of overlap syndromes, 6th SASL Postgraduate course 2023	PD Dr. Benedetta Terzioli Beretta-Piccoli MD
18.11.2023	Successes in harm reduction implementation: Lessons from Switzerland, INHSU 2023, Geneva	Dr. Alberto Moriggia MD
20.11.2023	POCUS emergency course for medical students, USI Lugano	Dr. Daniel Hagara MD Prof. Judith Wyttenbach MD
22.11.2023	Aging in dependent patients, OMCT Psychiatry Training, Manno	Dr. Alberto Moriggia MD
04.12.2023	POCUS emergency course for medical students, USI Lugano	Dr. Daniel Hagara MD Prof. Judith Wyttenbach MD
11.12.2023	POCUS emergency course for medical students, USI Lugano	Dr. Daniel Hagara MD Prof. Judith Wyttenbach MD
14.12.2023	POCUS emergency course for doctors, Clinica Luganese Moncucco	Dr. Daniel Hagara MD

# 03 THE FOUNDATION



## **1. About us**

- ▶ People
- ▶ Organization

## **2. What we do**

- ▶ Patient intake and care strategy
- ▶ Means of implementation

## **3. Our partners**

- ▶ Sponsors
- ▶ Financiers
- ▶ Collaborators

# About us

## ► People

### DOCTORS

- Prof. Cerny Andreas MD
- Dr. Balmelli Manuela MD
- Dr. Barda Beatrice MD
- Dr. Besso Gea MD
- PD. Dr. Bihl Florian MD
- Dr. Bruno Alessandra MD
- Prof. De Gottardi Andrea MD
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- Dr. Nessi Mauro MD
- Dr. Robatto Antonella MD
- Dr. Schwarzenbach Hans-Rudolf MD
- PD. Dr. Terziroli Beretta-Piccoli  
Benedetta MD

### OPERATIONAL TEAM

- Prof. Cerny Andreas MD, Director
- Dipl. Pharm. fed. ETH, Bissig Maurizia, Foundation Operational Director and Pharmacist
- PhD Dr. Barda Beatrice MD, Medical researcher
- Dipl. chemist-pharm., De Luca Chiara, Clinical trials coordinator.
- Dr. Malino Donald MD, Medical researcher
- Dr. Mazzella Natalia MD, Medical researcher
- Biol. Dipl., Di Bartolomeo Claudia, Data manager
- Biol. Dipl., Forlenza Rossella, Data manager-Clinical Study Coordinator
- Messina Paola, Clinical trials coordinator

### MEMBERS OF THE BOARD

- Prof. Beer Jürg-Hans MD
- Prof. Bianchetti Mario MD
- PD Dr. Bihl Florian MD
- Prof. Candinas Daniel MD
- Adv. Pelli Fulvio

# About us

## ► Organization

### Foundation Board of Directors

Determines the strategic guidelines of the Foundation, provides inspiration and gives impetus to its activities.

### Clinical Trial Unit (CTU) Directorate

Consists of Directors and operational management of the Foundation, assesses the scientific relevance of each and every research project and examines feasibility from an executive point of view.

### Cantonal ethics Committee, Swissmedic

Healthcare authority evaluating ethics, scientific relevance and formal aspects and authorising the implementation of a clinical trial.

### Controlling, RU management

Responsible for control of funds raised and their application in accordance with their objectives/defined purposes.

### Private and public sponsors

Donations contributed in support of specific research projects as well as in favour of projects/planned training activities.

### Epatocentro Ticino SA

Partner in medical and paramedical matters collaborating in the running of the Foundation's clinical trial studies.

### CTU Staff

Ensure the operational capacity of the Foundation, both the proper execution of research studies in compliance with GCP regulations.

### Patients

Focal point of the operations of the Foundation.

### Clinica Luganese Moncucco

Partner for research projects requiring hospital admission.



# What we do

## ► Patient management and treatment strategies

### 7 objectives for better patient management

The complexity of the situation in Ticino has led the Fondazione Epatocentro Ticino to consider a strategy which will enable patients affected by hepatic pathologies to get treatment from the best specialists available in the Ticino region. The strategy which the Foundation intends to advance, with the daily collaboration and experience of the doctors at the Epatocentro Ticino, sets out 7 different objectives:

Objective	Description
1. Strengthening and extension of the “Hub and spoke” operational system	This organisational model presupposes that specialized and expensive skills are required for certain complex conditions and diseases and that it is not possible to ensure these are readily available and widespread throughout the entire region. For this reason, organisations provide for the concentration of complex cases at a limited number of Hub sites (centres of excellence, in our case at our main centre at 9 via Soldino, Lugano) and at peripheral Spoke centres (in our case external sites at Locarno, Bellinzona, Biasca, Taverne Chiasso) where patient management takes place for those patients who do not exceed a certain threshold of complexity. The term “Hub and Spoke” derives from the aviation industry.
2. Development of clear standardized programs	Develop a series of well-defined standard operating procedures based on national and international guidelines, and at the same time implement a program which can provide clear treatment protocols for chronic patients, in parallel with effective pharmaco-vigilance, to ensure monitoring and follow-up of all patients according to their specific requirements, applying the most up-to-date quality standards
3. Development of a patient database	Support and coordinate the implementation of a database which will enable patients to be grouped according to their diagnosis, treatment, and outcomes and, in addition to process the data in accordance with resources used. In so doing, it will be possible to analyse a cross section of the situation in Ticino from various points of view with information that is always accurate and up-to-date, and which meet the specific needs of a specialist centre.

4. Measures to ensure the quality and safety of treatments	Regular, clinically oriented meetings; conferences dedicated to critical incidents; specialized training aimed at doctors and paramedic personnel. In collaboration with the Epatocentro Ticino, indicators for and monitoring of treatment care for different types of patients will be defined, following regular assessments of the degree of satisfaction of patients and doctors with respect to the services offered by a specialist centre.
5. Participation in existing epidemiological studies	Participation in existing epidemiological studies (Swiss cohort for Hepatitis B, for Hepatitis C, Swiss transplant cohort etc.) and the development of projects related thereto, collaboration in the creation of international registries (International Autoimmune Hepatitis Group IAIHG, European Reference Network for Rare Liver Diseases ERN–Rare–Liver) as well as participation in national strategies in combating Hepatitis B and C ( <a href="http://www.hepatitis-schweiz.ch/en/why-a-hepatitis-strategy">http://www.hepatitis-schweiz.ch/en/why-a-hepatitis-strategy</a> ) and active collaboration in organized initiatives.
6. Support the establishment of new cohort studies	Promoting and establishing cohort studies for Primary Biliary Cholangitis (PBC), Primary Sclerosing Cholangitis (PSC) and Autoimmune Hepatitis (AIH), involving other hepatology centres nationwide, as well as participating in studies such as the Swiss Cohort Study for Hepatitis B, Hepatitis C, and the SAMMSU cohort study for the management of the medical consequences of substance use.
7. Establishment of certified Biobanks and collaboration at international level	Biobanks, facilities certificate established to gather, conserve, and manage samples of biological material and patient clinical data to make same available for clinical research to be able to offer scientific explanations and search for possible treatments for certain diseases such as, for example, primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC) and for autoimmune hepatitis (AIH) and COVID-19. The AILD Biobank and the COVID-19 Biobank of the Foundation, one-of-a-kind in Switzerland, are available on international platforms and accessible to researchers worldwide.

## ► Means of implementation

### Blue Book

The institute of Medicine (USA) sets out guidelines as recommendations for clinical practice, developed through a systematic process, with the objective of helping doctors and patients in deciding which healthcare measures are most appropriate in certain clinical situations.

The Fondazione Epatocentro Ticino believes in the importance of a series of guidelines based on scientific evidence, over the years, has advanced a project to compile the principal recommendations in the management of patients affected by specific pathologies.

In this way, the Blue Book sets out indications for the management of patients affected by the following pathologies:

HBV	Venous Thromboses	CEUS	Autoimmune Hepatitis
Hepatitis E	Hepatitis D	Focal liver lesions	Primary biliary cholangitis
Complications of Cirrhosis	Hyperferremia	Primary sclerosing cholangitis	Wilson's disease
Hepatocarcinoma and new treatments	Liver transplants	HCV update	Updates on treatment for Hepatitis C
Increased liver tests	ASH Hepato-pathology Alcohol-related	NAFLD/NASH	Professional liver diseases
Pancreatic cysts	Hepatitis A	Drug-induced liver diseases	Liver diseases in pregnancy
Paracentesis portal hypertension – Baveno VII 2022	Liver biopsy	Genetic cholestatic liver diseases	Hepatorenal syndrome
Portal hypertension – Baveno VII	Evaluating the hepatopathic patient	Alpha-1 antitrypsin deficiency	

### Patient oriented guidelines and public conferences

The Fondazione Epatocentro Ticino has also produced a series of documents specifically for the public which sets out in clear language medical aspects and indications useful in daily life for anyone living with liver disease and organizes public conferences on specific topics.

# Our partners

## ▶ Sponsors

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▶ GENKYOTEX SA


## ► Collaborators

CENTRE HOSPITALIER UNIVERSITAIRE VAUDOIS (CHUV)

- CENTRE SUISSE DES MALADIES DU FOIE DE L'ENFANT, HÔPITAUX UNIVERSITAIRES DE GENÈVE (HUG)
- HÔPITAUX UNIVERSITAIRES DE GENÈVE (HUG)
- CLINICA LUGANESE MONCUCCO
- KINDERKLINIK, INSELSPITAL BERN
- ENTE OSPEDALIERO CANTONALE (EOC)
- CITTÀ DI LUGANO
- EOLAB ISTITUTO DI MEDICINA DI LABORATORIO
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- LUZERNER, KANTONSSPITAL KINDERSPITAL
- UNIVERSITÀ DELLA SVIZZERA ITALIANA (USI)
- HEPATITIS SCHWEIZ
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- SCUOLA UNIVERSITARIA PROFESSIONALE DELLA SVIZZERA ITALIANA (SUPSI)
- UNIVERSITÄTS–KINDERSPITAL ZÜRICH (USZ)
- UNIVERSITÄTS–KINDERSPITAL BEIDER BASEL (UKBB)
- INGRADO
- ANTENNA ICARO
- LABORATORIO UNICO METROPOLITANO (LUM), OSPEDALE MAGGIORE, BOLOGNA

## ▶ Other collaborators

KLINIK FÜR KINDER- UND JUGENDMEDIZIN –  
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WINTERTHUR ▶ GASTROENTEROLOGIE UND  
HEPATOLOGIE, CLARUNIS – UNIVERSITÄRES  
BAUCHZENTRUM, BASEL ▶ EUROPEAN REFERENCE  
NETWORK (ERN RARE-LIVER) ▶ EUROPEAN  
ASSOCIATION FOR THE STUDY OF THE LIVER (EASL)  
▶ AMERICAN ASSOCIATION FOR THE STUDY OF THE  
LIVER (AASLD) ▶ SWISS SOCIETY FOR ALLERGOLOGY  
AND IMMUNOLOGY (SSAI) ▶ INTERNATIONAL  
AUTOIMMUNE HEPATITIS GROUP (IAIHG)  
▶ INTERNATIONAL PRIMARY SCLEROSING  
CHOLANGITIS STUDY GROUP (IP-SCSG),  
▶ SWISSHEPA ▶ SWISS SOCIETY FOR ULTRASOUND  
IN MEDICINE (SGUM) ▶ SWISS TRANSPLANT COHORT  
(STCS) ▶ SAMMSU – SWISS ASSOCIATION FOR THE  
MEDICAL MANAGEMENT IN SUBSTANCE USERS  
▶ SWISS HIV COHORT (SHCS)



To all those who have supported the activities of the Foundation we offer our heartfelt thanks!

**THANK YOU FROM OUR HEART!**

TO FIND OUT HOW TO SUPPORT THE FOUNDATION, WRITE TO  
*maurizia.bissig@hin.ch*

OR CALL *+41 91 910 65 70*



# Keeping updated

The Foundation is present on social networking channels which enables its own followers, currently more than 1 000, to remain updated on its notifications, activities, and research results as well as training events offered by the Foundation. At the same time, the site remains a point of reference for anyone interested in liver diseases for various reasons.



## Website

[www.epatocentro.ch/it/La-Fondazione](http://www.epatocentro.ch/it/La-Fondazione)



## Facebook page

[www.facebook.com/FondazioneEpatocentroTicino](http://www.facebook.com/FondazioneEpatocentroTicino)



## LinkedIn page

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## Instagram page

[www.instagram.com/fondazione\\_epatocentro\\_ticino/](http://www.instagram.com/fondazione_epatocentro_ticino/)



## Newsletter – The Liver Bulletin

[www.epatocentro.ch](http://www.epatocentro.ch)

