

ELPA

European Liver
Patients' Association

The new era of patients' associations' management

ANNUAL REPORT 2021

The new era of patients' associations' management

ANNUAL REPORT 2021

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ACRONYMS

ACHIEVE - Associations Collaborating on Hepatitis to Immunise and Eliminate the Viruses in Europe
AASLD - American Association for the Study of Liver Diseases
ACLF - Acute-on-Chronic Liver Failure
AWARH - Awareness Week on Alcohol-Related Harm
CEHC - Central European Hepatologic Collaboration
CHB - Chronic Hepatitis B
CSF - Civil Society Forum
DG - Directorate General
DiCE - Digestive Cancers Europe
DILI - Drug-Induced Liver Injury
EASL - European Association for the Study of the Liver
ECDC - European Centre for Disease Prevention and Control
EF Clif - European Foundation for the study of chronic liver failure
EIT - European Institute for Innovation and Technology
EKPF - European Kidney Patients' Federation
EMA - European Medicine Agency
EMCDDA - European Monitoring Centre for Drugs and Drug Addiction
EPF - European Patients' Forum
ESCMID - European Society of Clinical Microbiology and Infectious Diseases
EU - European Union
EURODIS - Rare Diseases Europe
HBV - Hepatitis B Virus
HCV - Hepatitis C Virus
HE - Hepatic Encephalopathy
HEP - Hepatitis
HTAI - Health Technology Assessment International
ILC - International Liver Congress
LCAM - Liver Cancer Awareness Month
MAFLD - Metabolic-Associated Fatty Liver Disease
MoU - Memorandum of Understanding
NAFLD - Non-Alcoholic Fatty Liver Disease
NASH - Non-Alcoholic Steatohepatitis
NGO - Non-Governmental Organization
PCWP - Patients' and Consumers' Working Party
PWID - People Who Inject Drugs
SLTC - Screening and Linkage to Care
TAG - Technical Advisory Group
TB - Tuberculosis
UNAIDS - United Nations Programme on HIV/AIDS
VHPB - Viral Hepatitis Prevention Board
WHO - World Health Organisation

Contents

11	OUR MISSION
11	MEMBER EMPOWERMENT
11	POLICY AND ADVOCACY
12	PARTICIPATION IN MEDICAL RESEARCH PROJECTS
12	ELPA VALUES
13	Foreword of the President
14	ELPA Members in 2021
17	2021 HIGHLIGHTS
19	ISO QUALITY STANDARD CERTIFICATE 1 st patients' association in Europe
21	LIVER CANCER
21	1 st Liver Cancer Patient Summit
22	Europe's Beating Cancer Plan - a contribution from ELPA
22	ELPA-EASL Beating liver cancer in Europe - under the patronage of the Slovenian presidency of the EU
23	ELPA-DiCE Launch of White Paper, Liver Cancer: No Patient Left Behind
24	Liver Cancer Awareness Month- campaign and website
26	NASH
26	ELPA NASH Symposium
27	Call to Action, tackling NAFLD/NASH in Europe - Roundtable discussion
28	ELPA's SYMPOSIUM and launch of the ELPA's CALL TO ACTION on Fatty liver
29	Collaboration on the non-alcoholic fatty liver disease: A patient guideline
30	#FattyLiverMonth campaign
31	HEPATITIS
31	Two new partnerships in the fight to Hepatitis
32	ELPA 'Hot Topics on AIR' - episode 2, Hepatitis elimination in the time of COVID19
33	World Hepatitis Day - campaign
34	RARE LIVER DISEASES
34	1 st Global PSC Awareness Day - campaign and webinar
35	MORE AND MORE
35	Meet the principal Investigators!
36	Merry #AlcoholFree holidays, and Happy healthy liver! The ELPA campaign to keep your holidays healthy
37	ELPA is part of the ECDC Advisory Forum
37	ELPA is part of the EASL Policy and Public Health Committee
38	ELPA confirms its collaboration with EMA in the PCWP, Patients' and Consumers' Working Party
38	ELPA work at the national level
39	ELPA collaboration with EUPATI and ELPA SCHOLARSHIP – 2021-2022 EUPATI FELLOW PROGRAMME

41 POLICY AND ADVOCACY WORK

43 Focus on COVID-19

- 43 EMA's public stakeholder meeting on the approval and roll-out of COVID-19 vaccines in the EU
- 43 COVID-19 Vaccination and patients with cancer - ESMO engagement
- 44 ESMO's call to action on COVID-19 vaccinations and patients with cancer
- 44 COVID-19 Vaccination and patients - EPF engagement
- 44 EPF presentation of Patient Guide 'Let's Talk about Vaccination'
- 45 Shot callers: a virtual event on covid-19 vaccines
- 45 "Innovations in Hepatitis Elimination" series
- 45 EASL webinar 'COVID-19 vaccination in patients with liver disease'
- 46 VHPB technical meeting: The impact of COVID-19
- 46 Film launch & live Q&A – Connecting with people who use drugs during COVID-19
- 47 EMA Public stakeholder meeting: approval, safety monitoring and impact of COVID-19 vaccines in the EU
- 47 'Have we failed to protect Europe's people?'
- 47 EPF third Vaccination Confidence – Patients' and professional Awareness Communication and Trust
- 48 Early lessons from the ups and downs of COVID-19 immunisation roll-out(s)
- 48 DiCE webinar: Colorectal Cancer Screening: Lessons Learned from COVID-19
- 48 Public stakeholder meeting on COVID-19 vaccines and therapeutics in the EU
- 49 4th ECDC Advisory Forum COVID-19 Consultation Series meeting
- 49 The impact of COVID-19 on immunocompromised patients
- 49 POLITICO Health Care Summit
- 50 ELPA Hot Topic on AIR - "COVID-19 vaccine and Liver Diseases"

51 Focus on Health Data

- 51 EMA - Technical workshop on real-world metadata for regulatory purposes
- 51 Shaping a European Health Data Space
- 51 EMA Data Standardization Strategy workshop
- 52 ESMO Public Policy Webinar on the General Data Protection Regulation and its impact on clinical research
- 52 HealthTech For Patients
- 52 Learnings initiative webinar for optimal use of big data for regulatory purpose
- 53 The European Health Data Space (EHDS) - Building a path for rare diseases and learning from its experience
- 53 HMA/EMA – EU Big Data Stakeholder Forum

54 Focus on EU Health Policy

- 54 European Parliament Special Committee on Beating Cancer
- 56 MEP Digestive Health Group in the EU Parliament
- 56 EU Parliament, ENVI Committee - Slovenian EU Presidency
- 56 Europe's Beating Cancer Plan meetings and webinars
- 57 ELPA joined Europe's Beating Cancer Plan - Stakeholder Contact Group
- 57 ESMO Public Policy Webinar: Europe's Beating Cancer Plan - in 60 minutes
- 57 Europe's Beating Cancer Plan: Why We Need It Now

58	Beating Cancer Stakeholder Contact Meeting
58	Launch of the EC Knowledge Centre on Cancer
58	European Cancer Summit 2021
59	European Health Policy: series of webinars and meetings
59	EASL's Patient Synergies Roundtable Discussion and EASL Digital Liver Cancer Summit
60	The launch event of ECCAM 2021
60	'Tackling Challenges in Cancer care and improving its Governance in the EU'
61	3 rd EU HCV Elimination Policy Summit
61	EU Health Policy Platform annual meeting – 2020 Thematic Networks
61	ESMO Public Policy Webinar on Bedside Rationing
62	Developing more meaningful health interventions through the use of patient-reported outcomes (PROs) in health research
62	EATG - meeting on the diagnostics landscape for HIV, viral hepatitis, and STIs
62	Understanding the Human Microbiome: The impact of ultra-processed foods
63	Webinar for Patients – Safe and performant Medical Devices for all
63	The 4 th Incisive Health morning Club
63	European Week against Cancer
63	ELPA participation in EASL-ILC 2021
65	Unmet needs & challenges in access to treatments in Europe: The case of Chronic Kidney Disease
65	EFPIA & EFGCP Multi-Stakeholder Workshop on Paediatric Unmet Medical Needs
65	Politico - Improving Europe's Health Technology Assessments
66	Clinical Trials Information System (CTIS) webinar: How sponsor organisations can prepare for CTIS
66	ESMO Public Policy Webinars on the Clinical Trials Regulation
66	European Health Forum Gastein (EHFG) – Rise like a Phoenix
67	Community Webinar on HBV in Europe
67	EASL Patient Forum
68	EPF Meetings
68	EPF webinar on the evaluation process of the Cross-Border Healthcare Directive
68	Patient Engagement Open Forum
68	EPF Annual General Meeting 2021
68	EPF webinar - "Understanding AI" webinar series, titled "From Science Fiction to Reality"
69	EPF Congress 2021 - Digital transformation of healthcare: The added value of patient partnerships
69	EPF webinar - "Understanding AI" webinar series, titled "AI in Healthcare: Ethics and Implications"
70	ELPA in international meetings
70	Paris Hepatology Conference
70	The 1 st International Conference on Rare Diseases
70	The International Experience Exchange with Patient Organisations
71	Moving from Hepatitis Discovery to Elimination: NIH Webinar Series on Research Advancing Hepatitis Elimination
71	VHPB advisor meeting

- 71 4th Global NASH Congress
- 71 AASLD / FDA DILI Conference
- 72 The HepHIV Conference
- 72 6th World Congress of Pediatric Gastroenterology, Hepatology and Nutrition
- 72 Regional Consultation for Developing 2022-2030 GHSS on HIV, Viral Hepatitis and STIs
- 73 Alcoholic steatohepatitis (NASH) in 2021: The Multi-system Disease
- 73 WHA - Policymakers can't wait – moving from global commitment to national action on viral hepatitis
- 73 Roundtable Discussion: Sharing Perspectives on Priorities for Next WHO Global Health Sector Strategy for Hepatitis Elimination
- 74 7th Paris NASH Meeting, ELPA among the panellists
- 74 Hepatic Encephalopathy: What's confusing about treating confusion?
- 74 Patient Centricity & Engagement Conference
- 74 Viral Hepatitis Prevention Board (VHPB) – Advisor Meeting and Public Meeting
- 75 44th World Hospital Congress of the International Hospital Federation
- 75 9th BUHASDER 2021 Congress
- 76 AASLD Meeting 2021
- 76 8th HBV Cure ANRS | EID Workshop Webinar
- 76 The future of Liver Cancer - The 35th BCLC Anniversary
- 76 International Viral Hepatitis Elimination Meeting (IVHEM)
- 77 Patient Engagement Open Forum 2021

79 EMPOWERING OUR MEMBERS

- 81 The Israeli National Programme for Hepatitis C elimination, nothing without liver patients' organization
- 81 World Health Day 2021, ELPA Director Milan Mishkovikj participated in the WHO campaign
- 82 Meeting with Finland's MPs
- 83 The Turkish National Viral Hepatitis Congress
- 83 RVC PACOS | Patient Collaboration Summit 2021
- 84 Setting the course for Hepatitis elimination – what the EU can do to help reach the WHO 2030 goal

85 STRENGTHENING OUR ASSOCIATION

- 87 ELPA Educational Training – spring edition
- 90 Successful women in ELPA's family
- 91 ELPA Annual General Meeting 2021
- 91 ELPA educational training days, autumn edition
- 91 ELPA Stakeholders meeting 2021

93 ELPA IN SCIENTIFIC RESEARCH PROJECTS

- 95 Medical research project Galaxy, Horizon 2020
- 95 Medical research project Liverhope, Horizon 2020
- 96 Medical research project Microb-Predict, Horizon 2020
- 96 Medical research project Liverscreen, Horizon 2020
- 96 Medical research project IP Cure B, Horizon 2020
- 97 Medical research project FiSplat, European Institute for Innovation and Tehnology – EIT Health

97	Medical research project Decision, Horizon 2020
97	Medical research project A-TANGO, Horizon 2020
98	ESCALON
98	COBALT
99	MICROB-PREDICT Steering Committee Meeting
100	IP-Cure-B General Assembly
100	Videos about the LiverScreen project
101	The kick-off meeting of the new Horizon 2020 project A-TANGO
102	IPCureB - Steering Committee meetings
102	FisPlat meetings
102	Raising awareness on #FattyLiver among children
103	Liverscreen Consortium meeting
103	MICROB-PREDICT and DECISION – Online Symposium
104	DECISION, 3 rd General Assembly meeting
104	Microb-Predict, 3 rd General Assembly Meeting
105	FISPlat project
105	Lecture at the University of Padova
105	ELPA participation in ‘Multi-stakeholder Consensus on Core Outcomes for Decision Making About Nonalcoholic Steatohepatitis Treatment.’

107 SOCIAL MEDIA ACTIVITIES

110 ELPA’s most successful Social Media Campaigns

110	#EuroTestWeek - Spring and Autumn edition
111	International PBC Day 2021
111	European Awareness Week on Alcohol-Related Harm (AWARH)
112	World Obesity Day 2021
113	ELPA’s support to its members, stakeholders, supporters and friends’ campaigns

115 ELPA STRUCTURE

119 ELPA WORKING GROUPS

121	ELPA Working Group on Rare Liver Diseases
121	ELPA Working Group on Primary Liver Cancer
122	ELPA Working Group on Clinical Trials
122	ELPA Working Group on Harm reduction
123	ELPA Working Group on MAFLD/NASH
124	ELPA Working Group on Prevention
124	ELPA Working Group on Hepatitis B elimination
125	ELPA Working Group on Cirrhosis

127 FINANCIAL ACCOUNTING AND TRANSPARENCY

129	Word from ELPA Treasurer
129	Conclusion from the external auditor
129	Publishing financial reports

135 ACKNOWLEDGMENTS

OUR MISSION

The European Liver Patients' Association - ELPA - emerged in 2005 from a desire amongst European liver patients' groups to share their experiences on the different approaches adopted in other countries. Nowadays, ELPA is an umbrella association representing 32 members from 25 different countries.

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 harmonized 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 a lot of effort into organizing 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 at EMA.
- Pharmacovigilance Risk Assessment Committee at EMA.
- Policy and public health committee at EASL.
- Expert group on HIV, TB, and hepatitis at WHO.
- Expert board at VHPB.

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 an externally audited quality management system.

PARTICIPATION IN MEDICAL RESEARCH PROJECTS

ELPA is part of 10 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.

ELPA VALUES



Equality



Respect for
diversity



Patient
driven



Commitment



Transparency

Foreword of the President



Marko Korenjak

Dear ELPA Friends,

The COVID-19 pandemic continued to characterize 2021. However, ELPA kept up with its objectives and commitments.

We cannot underestimate the outstanding results achieved by ELPA, together with all of you, in 2021. In times of crisis, and despite the social distancing, ELPA did not give up, proving that it is possible to be ever closer and more vital. In all areas, the results are proudly shown in the overview of our activities throughout 2021, which can be found at the beginning of this Report. Yet, it has been challenging to select the most successful activities this year. Not only because of their quantity, but also their quality and the interaction and continuity among them.

As I quoted the word 'quality', I would like to dedicate a comment to the ISO certificate we achieved in 2021. More info is in the Report. However, I am particularly proud of it because it projects ELPA into a stable future. It means having clearly in mind the importance of advocating for liver patients.

I would like to thank ELPA Members for being part of ELPA's family. They are the beating heart of our association, and ELPA is working hard, primarily to support them in their invaluable day-to-day work at the national level.

I should also thank the ELPA Governing Board, the ELPA Scientific Committee, the ELPA Advisors and the ELPA Office for their tireless efforts to push patients' needs on top of the scientific and political agenda.

Yet, I would like to dedicate some words to the ELPA Stakeholders and Supporters for being by our side fighting liver diseases. If ELPA is growing bigger and stronger than ever, it is also thanks to their trust in ELPA's work.

ELPA is determined to be more ambitious for our Members and all liver patients. That is the reason why we still need all of you to our side.

Together we are stronger!

Marko Korenjak, President of the European Liver Patients' Association (ELPA)

ELPA Members in 2021



BELGIUM

- Vlaams Hepatitis Contactpunt - VHC



FINLAND

- The Finnish Kidney and Liver Association



BOSNIA & HERZEGOVINA

- The Chronic Viral Hepatitis Patients Association, "B18"



FRANCE

- SOS Hépatites Fédération



CROATIA

- Croatian association for liver diseases, "Hepatos"
- HUHIV - Croatian Association for HIV and viral hepatitis



GEORGIA

- Hepatitis C Cured Patient Association



CYPRUS

- Cyprus Liver Patients Association, "Promitheas"



HUNGARY

- Hungarian Association of Chronic Hepatitis Patients, "VIMOR"



DENMARK

- Leverforeningen



IRELAND

- Hepatitis C Partnership



EGYPT

- Association of Liver Patients' Care – ALPC



ISRAEL

- Israeli Association For The Health Of the Liver, "Hetz"



MACEDONIA

- Association for health education, prevention and better treatment - HEPTA
- Hepar Centar - Bitola



SLOVAKIA

- HEP HELP KLUB
- Šanca pre pečeň



NORWAY

- proLAR



SLOVENIA

- Association - SLOVENIJA HEP



POLAND

- Star of Hope Foundation



SPAIN

- Catalan Association of Hepatitis Patients - ASSCAT
- National Federation of Liver Patients and Transplanted - FNETH



PORTUGAL

- SOS Hépatites Portugal



SWEDEN

- Riksföreningen Hepatit C – RHC



ROMANIA

- Patients with hepatic impairment Association of Romania - APAH-RO



TURKEY

- Living with Hepatitis Association - HEPYAŞAM



RUSSIA

- Humanitarian Action
- United Against Hepatitis



UNITED KINGDOM

- British Liver Trust
- Hep C Positive
- Liver4Life



SERBIA

- Association for helping patients with chronic viral hepatitis, "HRONOS"



2021 HIGHLIGHTS

ISO QUALITY STANDARD CERTIFICATE 1st patients' association in Europe

On the 29th of June, 2021, ELPA achieved something extraordinary.

ELPA is now the FIRST patient association in Europe with the official certification of the Quality Management System in place. ELPA managed to build a quality system of its work, recognized by an external certification body and got the ISO 9001:2015 certificate related to its Management in Communication with Supporters and Stakeholders.

The purpose of ISO 9001:2015 is to help an organization develop a robust Quality Management System to respond to evolving quality requirements in line with changing social, economic, and environmental expectations.

Implementing a Quality Management System in a nonprofit organization like ELPA means:

- To rethink an organization: why does it exist; what are the priorities; how does it relate with its environment; how does it work; and what should be measured and improved.
- To develop a consistent way of working and monitoring thanks to the process approach and risks management.
- It serves internally to make deadlines and processes clear.
- To reinforce the message of clarity, trust, and professionalism towards supporters and donors.
- To enhance donors, supporters, beneficiaries, the general public, and stakeholders' satisfaction.

This is just the first step, the certificate will expire in 3 years, and during this time, ELPA's work will be reassessed each year. This is the reason why ELPA will continue improving its communication with Supporters and Stakeholders, showing its high level of professionalism and commitment towards liver patients.



ELPA European Liver Patients' Association
436 followers
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Happy World Quality Week!
Did you know that on Wednesday, 23 June 2021, ELPA became the first patients' association in Europe to obtain the ISO 9001:2015 quality standard?
Starting today, we'll accompany you on our [#WednesdayWisdom](#) to discover the importance of this historic achievement. Stay Tuned. [#HumpDay](#) [#WQW21](#)

 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.

Marko Korenjak
ELPA President



ELPA with Marko Korenjak

ELPA @EuropeLiver · 11h

The [#ISO9001](#) Standard allows ELPA to deal with the rapid changes in today's interconnected world. [#WednesdayWisdom](#) [#HumpDay](#)
[@Marko_Korenjak](#) [@EU_Health](#) [@GLOBOCAN_GCO](#) [@WHO_Europe](#)
[@hans_kluge](#) [@rixwolff](#) [@AleksanderKrag](#) [@SKyriakidesEU](#) [@EASLnews](#)
[@dice_europe](#) [@eupatientsforum](#) [@EASLedu](#)

 With the ISO Standard, you become a future-proof association. This means thinking about numerous internal and external risks, harnessing strengths, and efficiently dealing with weaknesses.

Marko Korenjak
ELPA President



ELPA

 Implementing the ISO Standard in a patients' organization provides adaptability. Adaptability is a clear advantage in the external environment.

Tove Frisch
ELPA Vice-President



ELPA

 The ISO Standard helps in rethinking ELPA:

- why it exists;
- what its priorities are;
- how it works;
- what should be measured.

Milan Mahlavovij
ELPA Director



ELPA

 Supporters and regularly stakeholders are assessed and analyzed to know who they are and what they expect from ELPA.

Julio Burman
ELPA Vice-President



ELPA

 Thanks to the ISO Standard, the risks arising from processes are limited.

Beatrice Credi
ELPA Quality Manager



ELPA

 The ISO Standard serves internally to make deadlines and processes clear and to develop a consistent way of working and monitoring.

Veronika Vlastickova
Head of EU Affairs



ELPA

LIVER CANCER

1st Liver Cancer Patient Summit

On February 4, 2021, on World Cancer Day, ELPA organized the first Liver Cancer Patients' Summit. The goal was to raise awareness about liver cancer and multidisciplinary team, focusing on information for and from patients.

After a video introduction where **Dr Tomislav Sokol**, Member of the European Parliament – Group of the European People's Party (EPP) and Member of the EP Special Committee on Beating Cancer (BECA) endorsed the event, ELPA President Marko Korenjak presented the first speaker.

Prof. Bruno Sangro, Director of the Liver Unit, Clínica Universidad de Navarra, Spain and President of ILCA (International Liver Cancer Association), gave an overview of the present and future biomarkers for screening strategy in liver cancer, in a very easy-to-understand way.

After Prof. Sangro's presentation, **Dr Teresa Casanovas**, ELPA Director and Leader of ELPA Scientific Committee, informed the audience regarding the activities and objectives of the ELPA Working Group on Primary Liver Cancer in 2021.

This first part, dedicated to the scientific field, was followed by two presentations by two patients' association representatives. **Ms Zorana Maravić**, the acting CEO of Digestive Cancers Europe (DiCE), showed what liver cancer represents for her organization. Then, **Mr Marco Greco**, President of the European Patients' Forum (EPF), after introducing the EPF's engagement at the patients' side, analysed some aspects of the brand new EU Beating Cancer Plan.

Coming back to the medical field, **Prof. Manuel Romero Gómez**, Director of the Gastroenterology Service, Hospital Universitario Virgen del Rocío, Sevilla, Spain, explained the relation between MAFLD and HCC, as MAFLD is a risk factor for the development of different types of solid cancers.

After a short coffee break, the webinar hosted three patients advocates who showed different aspects of the Summit's topic. **Ms Lone McColaugh**, President of Leverforeningen, Denmark, presented the benefits for patients of primary care centres, good practice from Denmark. **Ms Sindee Weinbaum**, Leader of ELPA working group on Rare Liver Diseases, shared with the audience two testimonial videos stressing the patients' journey of Cholangiocarcinoma diagnosis in Israel. **Mr Joan Ribas**, a Board member of AMTHC (Associació de malalts i trasplantats hepàtics de Catalunya), closed this session with a presentation on detected priorities of patients and families on the waiting list for liver transplant during COVID. He stressed challenges and opportunities.



MEP Tomislav Sokol, 1st Liver Cancer Patient Summit

The floor was given back to Dr Teresa Casanovas, who introduced the guest speaker, **Dr Isabelle Soerjomataram**, Deputy Head, Cancer Surveillance Branch, International Agency for Research on Cancer. Through precise data and charts, Dr Soerjomataram showed the burden of Liver Cancer in Europe, making some predictions regarding its incidence in the future.

Dr Nicole Seguy, Unit lead HIV, Hepatitis and STI, WHO Europe, wrapped up the meeting. She emphasized how eliminating viral hepatitis is an effective way to prevent liver cancer.

Europe's Beating Cancer Plan - a contribution from ELPA

On February 3, 2021, on the eve of World Cancer Day, the European Commission officially presented Europe's Beating Cancer Plan – the main priority in the area of Health and a vital pillar of a strong European Health Union.

ELPA is proud to announce that its position regarding the Plan is among the official feedbacks.

ELPA submitted suggestions to reduce and eliminate hepatitis B and C to reduce liver cancer incidence in Europe. ELPA believes that it is possible to reduce hepatitis B and eliminate hepatitis C to reduce liver cancer by 60 - 70% in Europe as a public health threat by 2030.

This is why ELPA proposed to include in the EU Cancer Plan the #EndHep Europe Initiative. ELPA also wants to unite different forces such as patients' organisations, EU institutions, medical institutions, WHO Europe, representatives of Health of the member's states, experts, and researchers, which will lead to eliminating hepatitis in Europe in 10 years.

You can find the reference to hepatitis B and C reduction and elimination in the chapter on preventing cancer caused by infections.

With new technologies, research, and innovation as the starting point, the Cancer Plan sets out a new EU approach to cancer prevention, early detection, treatment, and care. It will tackle the entire disease pathway, from prevention to quality of life of cancer patients and survivors, focusing on actions where the EU can add the most value.



Milan Mishkovikj, ELPA Director – Veronika Všetickova, Head of EU Affairs Marko Korenjak, ELPA President, Europe's Beating Cancer Plan - a contribution from ELPA

ELPA-EASL Beating liver cancer in Europe - under the patronage of the Slovenian presidency of the EU

Under the patronage of the Slovenian presidency of the EU, ELPA organized, together with EASL, the High-Level meeting 'Beating Liver Cancer in Europe' on October 22, 2021. The meeting was opened by the President of the National Assembly of the Republic of Slovenia, **Mr Igor Zorcic** and the Slovenian

Minister of Health, **Mr Janez Poklukar** that emphasized the importance of this high-level event and the need to extend cancer screening programmes to liver cancer. EASL Secretary-General, **Mr Thomas Berg** moderated a second session with contributions by **Mr John Ryan**, Deputy Director of the European Commission - DG-SANTE, **Ms Brigitta Sacredus**, Member of the European Committee of the Regions, **Ms Barbara Kerstiens**, from the Health Directorate DG Research & Innovation, **Dr Partha Basu**, Deputy Head of Cancer Early Detection & Prevention Branch at the International Agency for Research on Cancer / World Health Organization and **Mr Pietro Fiocchi**, Member of the European Parliament. They contributed to the discussion on liver cancer in Europe, highlighting the engagement of EU institutions and the desire to improve health policies and the healthcare system. Then, experts **Prof. Dr Maria Buti**, **Prof. Dr Mojca Matičič**, **Dr Peter Galle**, **Dr Peter Jepsen**, **Dr Maria Reig** and **Dr Pierre Nahon** discussed liver cancer prevention and health promotion. ELPA President **Mr Marko Korenjak** and ELPA patients' representatives, **Mr Julio Burman**, **Dr Teresa Casanovas**, and **Mr Milan Mishkovikj**, explained the current situation in EU Countries and the differences in treatment and prevention among them.



Julio Burman, ELPA Vice-President, ELPA-EASL Beating liver cancer in Europe



Igor Zorcic, President of the National Assembly of the Republic of Slovenia, ELPA-EASL Beating liver cancer in Europe

ELPA-DiCE Launch of White Paper, Liver Cancer: No Patient Left Behind

October 26, 2021, marked a historic step forward for European liver cancer patients. The “White Paper, Liver Cancer: No Patient Left Behind” was launched in collaboration with Digestive Cancers Europe (DiCE). ELPA President, **Mr Marko Korenjak**, and DiCE CEO, **Ms Zorana Maravic**, moderated the event. **Mr John Ryan**, European Commission Representative – Director for Public Health, and Dr Cristian Busoi, Member of the European Parliament and Co-Chair of the Friends of the Liver MEP Group, presented the EC Beating Cancer Plan and the view from the European Parliament. **Ms Sanja Sazdovska**, State Advisor & National Coordinator for Sexual and Reproductive Health (SRH) in crises, Ministry of Health, North Macedonia, gave an overview of good practices on liver cancer for North Macedonia. **Prof. Dr Bruno Sangro** - Hepatologist,

Professor of Internal Medicine, University of Navarra, Pamplona, Spain, **Prof. Dr Maria Buti** - Head of Internal Medicine and Hepatology, Vall d'Hebron General Hospital, Barcelona, Spain, **Prof. Dr Mojca Matičič** - Professor of Infectious Diseases and Epidemiology, University of Ljubljana, Ljubljana, Slovenia, and **Prof. Dr Kalina Grivceva** - Director of the University Clinic for Gastroenterohepatology in Skopje, North Macedonia, reminded the importance of research, prevention, screening and treatment for liver cancer. **Dr Teresa Casanovas** – ELPA Director and leader of ELPA Scientific Committee and **Prof. Dr Eric Van Cutsem** - DiCE Co-founder and Medical Director, stressed the importance of the White Paper both in the policy environment and for liver cancer patients.



John Ryan, European Commission– Director for Public Health, ELPA-DiCE Launch of White Paper on Liver Cancer



Liver Cancer Awareness Month– campaign and website

Every year, October brings liver cancer into focus to increase understanding of the disease, including its prevalence, approaches to screening and prevention, and treatment options.

Liver Cancer Awareness Month (LCAM) is a great time to learn more about this vital organ's role and how to keep it healthy and raise awareness of the local and global impact among patients, families members, healthcare professionals, other stakeholders, and the general public.

2021 ELPA's social media campaign revolved around the idea that the role of Liver Patients' Associations is crucial, and it is based on the dissemination of updated scientific information primarily focused on prevention since nobody is better than patients to inform other patients. This year, in particular, ELPA

focused deeper on the importance of the correlation between liver cancer and NASH, alcohol consumption, cirrhosis, hepatitis.

In addition, ELPA did not forget the massive impact the COVID-19 crisis has on liver patients, cancer patients included.

The website entirely dedicated to liver cancer that was successfully inaugurated last year <https://livercancermonth.eu/> allowed all ELPA friends to be involved in the campaign also this year. Different banners, pictures and frameworks were available to download and personalize from the Media Centre to boost the dissemination of contents in different contexts.

The campaign reached more than 44 million impressions.



The #LiverCancerAwarenessMonth Influencers

Top 10 Influential	Prolific Tweeters	Highest Impressions
@EuropeLiver 100	@EuropeLiver 1,382	@EuropeLiver 10.3M
@AEEHLiver 77	@MKDmilanM 487	@MayoClinic 6.1M
@EASLnews 76	@hepar_centar 355	@wedocaresaudi 4.4M
@GLOBOCAN_GCO 71	@alisa200784 344	@GacetaMedicaCom 2.9M
@jturnesv 68	@gorde_m 305	@drkoutaz 2.4M
@dice_europe 63	@adiazgonzalezMD 267	@Roche 1.2M
@GacetaMedicaCom 63	@SlovenijaHep 216	@CDC_Cancer 873.9K
@Marko_Korenjak 61	@RodriguezGandia 195	@jturnesv 654.2K
@EASLedu 60	@jturnesv 190	@AUB_Lebanon 536.7K
@EU_Health 60	@ipcureb 165	@AEEHLiver 512.6K

The Numbers

44.385M Impressions

9,058 Tweets

1,993 Participants

12 Avg Tweets/Hour

5 Avg Tweets/Participant

Twitter data from the #LiverCancerAwarenessMonth hashtag from Fri, October 1st 2021, 6:00AM to Sun, October 31st 2021, 11:55PM (Europe/Madrid) – Symplur.

NASH

ELPA NASH Symposium

ELPA organized a virtual NASH Symposium on June 10, 2021. This Symposium, which is just the culmination of a series of actions promoted during the entire #FattyLiverMonth, besides the scientific approach of the disease by eminent speakers, also allowed NASH patients to share with ELPA their own testimony of how they deal with this life-threatening disease.

After **Mr Marko Korenjak**, ELPA President, had welcomed everybody, two Members of the European Parliament from the Republic of Cyprus, **Mr Loucas Fourlas**, Group of the European People's Party (Christian Democrats), and **Mr George Georgiou**, Left group in the European Parliament – GUE/NGL, greeted the participants. Then, **Mr Marco Greco**, President of the European Patients' Forum (EPF), welcomed attendees stressing the importance of patients' associations in the fight against this disease.

Before getting into the most scientific part of the Symposium, **Mrs Yianoulla Koulla**, President of Cyprus Liver Patients' Association and Leader of ELPA NAFLD / NASH Working Group, introduced a short video by **Mr Constantinos Ioannou**, Minister of Health of Cyprus. After his greetings, she quickly presented the ELPA NAFLD / NASH Working Group, its people, and activities.

The scientific part of the Symposium was opened by **Dr Teresa Casanovas**, Leader of the ELPA Scientific Committee and ELPA Director. She introduced the first speaker, **Prof Dr Henning Groenbaek**, from the department of Hepatology & Gastroenterology, Aarhus University Hospital, Aarhus, Denmark. He gave an overview of NAFLD treatment from lifestyle intervention to bariatric surgery. After him, the floor was given to **Prof Dr Gamal Shiha**, G.I & liver unit, Mansoura University – Egypt, Association of Liver Patients Care (ALPC), the Egyptian Liver Research Institute and Hospital (ELRIAH), Egypt. Prof Dr Shiha brought to the audience's attention the crucial topic of the name's changing from NAFLD to MAFLD. He also underlined the advantages from the point of view of patients and hepatologists. **Dr Ramon Bataller**, hepatologist, researcher, alcohol risks specialist, University of Pittsburgh, Department of Medicine, Pittsburgh, US, contributed to the Symposium releasing to ELPA an interview where Dr Casanovas explored with him Chronic Liver Disease related to alcohol. The discussion underlined how the particular risks on patients suffering from liver steatosis are higher and have a faster liver disease



MEP Loucas Fourlas, ELPA NASH Symposium



Dr Ramon Bataller, ELPA NASH Symposium

progression. The conclusion was that patients need more information about it. This session continued with **Dr Panayiota Protopapa**, clinical Lead and specialist Paediatrician Paediatric Liver, GI and Nutrition Centre Archbishop Makarios III Hospital and King's College Hospital, Republic of Cyprus. She gave a talk on a particular and underestimated topic: the diagnosis and treatment of paediatric NAFLD. Then, **Dr Gonzalo Crespo**, transplant hepatologist, Liver Unit, Hospital Clínic, Barcelona, IDIBAPS and CIBERehd, Spain, gave an update on liver transplants for NASH with or without HCC. He also presented some particular challenges in this population in 2021. The scientific session was concluded by **Prof Dr Shira Zelber-Sagi**, Associate Professor Head of School of Public Health, Faculty of Social Welfare and Health Sciences, University of Haifa, The Tel-Aviv Medical Center, Department of Gastroenterology and Hepatology, Israel. She shared a presentation on the nutritional treatment of non-alcoholic fatty liver disease with the audience.

From nutrition, the Symposium moved to the importance of an active lifestyle. **Ms Veronika Všetíčková**, physiotherapist, and healthy lifestyle coach, shared some tricks and tips on how to introduce physical exercise in our daily life.

Before ELPA President's closing remarks, participants could hear from two patients: **Mrs Petra Saarinen** and **Mr Milan Mishkovicj**, about their journey with the disease.

Call to Action, tackling NAFLD/NASH in Europe - Roundtable discussion

After the successful organization of ELPA Symposium and the conclusion of a social media campaign on #FattyLiverMonth, both held in June 2021, ELPA continued working in this field. On July 19, 2021, in the framework of its activities, ELPA organized a roundtable discussion around its Call to Action on 'Tackling NAFLD/NASH in Europe', involving many different stakeholders and actors in the field and focusing on children's education. As we have learned from many experts during the ELPA Symposium, NAFLD and NASH are complex conditions that need a multidisciplinary approach because of their strong correlation with cardiovascular diseases, diabetes, and obesity, whose numbers across Europe are increasing and could lead to inflammation and even liver cancer. ELPA's commitment during the first months of 2021 was remarkable, and the best is yet to come, as ELPA has already planned many activities for the upcoming months.



Dr Teresa Casanovas, ELPA Scientific Committee Leader and ELPA Director, Call to Action, tackling NAFLD/NASH in Europe - Roundtable discussion

ELPA's SYMPOSIUM and launch of the ELPA's CALL TO ACTION on Fatty liver

September 22, 2021, was an excellent day for ELPA. It organized a Symposium on Fatty liver disease in children and its impact. That was also the occasion to launch its Call to Action on Fatty Liver.

The Symposium was opened by **Mr Demetris Papadakis**, Member of the European Parliament – S&D Group, from Cyprus, who addressed the audience, stressing the role of the EU Member States in this field. **Mr Marco Greco**, president of the European Patients; Forum, took the floor, underlining the importance of involving young patients in patients' organizations at all levels.

The ELPA Scientific Committee Leader and ELPA Director, **Dr. Teresa Casanovas**, introduced the next speaker, **Prof. Manuel Romero Gómez**, Director of the Gastroenterology Service, Hospital Universitario Virgen del Rocío, Sevilla, Spain. Prof. Gómez presented the pros and cons of changing the name from NAFLD to MAFLD, and he talked about the stigma a simple expression can be associated with. **Ms Niki Alkistis**, a clinical dietician and nutritionist from Cyprus, presented the importance of healthy eating.

Presentations by medical professionals continued with **Prof. Volkan Demirhan Yumuk**, Professor of Medicine, Division of Endocrinology, Metabolism & Diabetes, Istanbul University Cerrahpasa Medical Faculty, President-Elect of EASO (European Association for the Study of Obesity), Turkey. He explained to the audience why liver matters in obesity clinics. After his talk, **Ms Vicky Mooney**, patient advocate and Executive Director of the European Coalition for People Living with Obesity, stressed, from a patient perspective, how lifestyle changes are not enough to tackle obesity. She described an excellent practice in Portugal, where educational programmes were implemented.

The management of Fatty liver disease specifically in children was described by **Dr Emer Fitzpatrick**, Paediatric Hepatologist, CHI at Crumlin, Dublin, Ireland and King's College Hospital, London, member of HepCom ESPGHAN. The role of nurses in multidisciplinary teams dealing with Fatty liver was tackled by Dr Nuria Fabrellas, Professor Public Health, Faculty of Medicine and Health Sciences at the University of Barcelona, Spain.

Three ELPA representatives wrapped up the Symposium. **Dr Teresa Casanovas**, President of ASSCAT, Associació Catalana de Patients Hepàtics, Leader of ELPA Scientific Committee, ELPA Director, started this session presenting the stigmatization in children with obesity. Then, **Mrs Yiannoula Koulla**, President of Cyprus Liver Patients' Association, Leader of ELPA NAFLD / NASH group, showed the ELPA NAFLD/NASH survey results. **Mr Manuel Weiss Perez**, FNETH – National Federation of Liver Patients and Transplanted, Spain, detailed the ELPA Call to Action on Fatty liver and encouraged everybody to endorse it.



ELPA's SYMPOSIUM and launch of the ELPA's CALL TO ACTION on Fatty liver

Before the closing remarks by **Mr Marko Korenjak**, ELPA President, a video animation made by Hetz – Israeli Association for The Health Of the Liver was streamed. It showed how digital tools could be helpful in the framework of children’s education.

The last words by Marko Korenjak, ELPA President, were about the 10 EU-funded Medical Research projects ELPA is currently involved in. These projects involve more than 120 different partners. However, our society and the liver patients community need to craft projects revolving around NASH in children, preventing this disease, and raising awareness on it.



Collaboration on the non-alcoholic fatty liver disease: A patient guideline

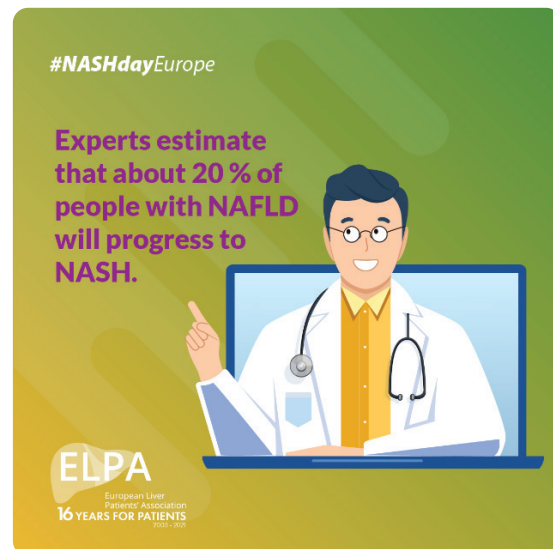
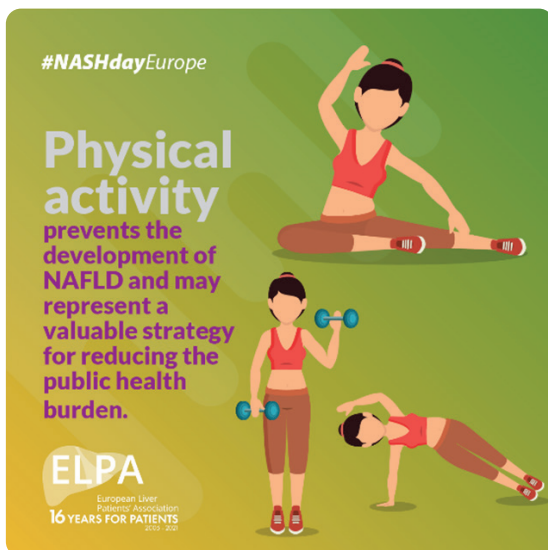
This patient guideline is intended for all patients at risk of or living with non-alcoholic fatty liver disease (NAFLD). NAFLD is the most frequent chronic liver disease worldwide and has a high disease burden. Yet, there is a lot of unawareness. Furthermore, many aspects of the disease are still to be unravelled, which has an important impact on the information given (or not) to patients. Its management requires a close interaction between patients and their many healthcare providers. Patients need to develop a complete understanding of NAFLD in order to enable them to take an active role in their disease management. This guide summarises the current knowledge relevant to NAFLD and its management. It has been



developed by patients, patient representatives, clinicians and scientists and it is based on current scientific recommendations intended to support patients in making informed decisions.

#FattyLiverMonth campaign

ELPA, in close collaboration with the ELPA MAFLD/NASH Working Group, organized the social media campaign #FattyLiverMonth. Run from the end of May for the entire June 2021; it had its highest expression on the International NASH Day on June 12, 2021. The campaign revolved around different messages. Some informed about the diseases. Some reminded patients, partners, experts, policy decision-makers, stakeholders, and the general audience that NASH/NAFLD is our next most significant challenge in Europe as its rate among the population is increasing. It is a priority to push forward the discussion about these diseases and promote better and more comprehensive communication on this topic. In particular, the campaign focused on prevention and explored the solutions that contribute to tackling NAFLD and NASH. As there is still no treatment for NASH, the best way of dealing with the condition is for the patient to implement lifestyle changes, giving up to unhealthy diet and sedentary culture.



HEPATITIS

Two new partnerships in the fight to Hepatitis

The European Patients' Association (ELPA) is proud to announce the signature of two new Memorandum of Understanding (MoU).

The first one is with The Coalition for Global Hepatitis Elimination (CGHE) - Task Force for Global Health. The MoU was signed by Mr Marko Korenjak, President of ELPA, and Dr John Ward, Director of the Coalition, on April 20, 2021.

To ultimately reach the global hepatitis elimination goals, partners will have to work together to accelerate progress. This agreement represents a step forward in this direction by bringing together two key global stakeholders in the fight for hepatitis elimination. The two organisations will work together to advocate for an additional international and national commitment to hepatitis elimination and develop resources and opportunities to strengthen hepatitis prevention, testing, and treatment programs, with the end goal of improving the lives of people living with hepatitis B and C.

Specific collaboration activities between the two organizations may include: developing national hepatitis elimination profiles, establishing or promoting local hepatitis elimination coalitions, developing educational webinars, and convening key partners to discuss programmatic and policy challenges. Look out for announcements on upcoming events and opportunities.

The second one is with the Center for Disease Analysis Foundation (CDAF). CDA Foundation is a non-profit organization specialising in the study of complex and poorly-understood diseases to provide countries with the data and information to create and implement successful elimination strategies. Its team of



Marko Korenjak, ELPA President - Dr John Ward, CGHE Director



Marko Korenjak, ELPA President - Dr Homie A. Razavi, CDA Managing Director

epidemiologists has analysed the impact of HBV and HCV in over 100 countries. It actively collaborates with more than 650 country experts—including NGOs, economists, Ministries of Health and Finance and key opinion leaders—to develop national strategies for Hepatitis elimination.

ELPA 'Hot Topics on AIR' - episode 2, Hepatitis elimination in the time of COVID19

According to the 2021 WHO Global progress report on HIV, viral hepatitis, and sexually transmitted infections, in 2019, the WHO European Region accounted for 19.000 new Hepatitis B infections and 300.000 new Hepatitis C infections.

In total, in 2019, in the WHO European Region, there were 14 million people with HBV infection and 12 million people with HCV infection.

In the Region, in 2019, 43.000 people died from Hepatitis B and 64.000 from hepatitis C.

However, the number of hepatitis B and C cases reported in the WHO European Region does not necessarily reflect the full extent of transmission.

Stating clearly that Hepatitis C is the first curable chronic viral infection in medical history and hepatitis B is a preventable and treatable viral infection, we should consider that scientists have identified five unique hepatitis viruses, identified by the letters A, B, C, D, and E.

Hepatitis A, for instance, is reported in ~1.5 million people every year. Several European countries, the USA, Australia, and others have reported outbreaks linked to food imports and preparation in recent years. Also, between June 2016 and mid-May 2017, an unusual increase in cases of hepatitis A affecting mainly men who have sex with men (MSM) has been reported in low endemicity countries in the European Region and the Americas.



Prof Rui Tato Marinho - Dr Antons Mozalevskis - Prof Ricardo Baptista Leite - Dr John Ward, ELPA 'Hot Topics on AIR' - episode 2



On May 25, 2021, ELPA brought together people and knowledge to address some of the most burning questions raised by the patients' community regarding Hepatitis viruses, also in the light of the health crisis we are experiencing.

The live-streamed episode hosted **Prof. Rui Tato Marinho** - Head of Department of Gastroenterology, Hepatology, Hospital S. Maria, Full Professor of Medical School of Lisbon President of Portuguese Society of Gastroenterology; **Dr Antons Mozalevskis** - Medical Officer, regional

hepatitis advisor/expert WHO/Europe; **Prof. Ricardo Baptista Leite** - Head of Public Health at the Institute of Health Sciences of the Catholic University of Portugal and Member of the Portuguese Parliament and **Dr John Ward** - Director of the Coalition for Global Hepatitis Elimination - The Task Force for Global Health.

World Hepatitis Day – campaign

The World Hepatitis Alliance and their global network of over 300 members in 100 countries were proud to launch ‘Hepatitis Can’t Wait’, a new theme for World Hepatitis Day 2021. The ‘Hepatitis Can’t Wait’ campaign theme highlighted the need to accelerate hepatitis elimination efforts, especially during the COVID-19 pandemic. Alongside this, it also highlighted the social injustice and inequity caused by the current lack of action on hepatitis elimination, and it focused on the positive action needed to get on track to meet the 2030 elimination goals. ‘Hepatitis Can’t Wait’ is a community-led campaign, and individuals and organisations can get involved to make sure that the world knows that Hepatitis Can’t Wait. There was a wide range of ways to get involved in the campaign, including adaptable campaign materials, tips and resources to use in every community.

ELPA was proud to support the campaign because ‘Hepatitis Can’t Wait’.



RARE LIVER DISEASES

1st Global PSC Awareness Day - campaign and webinar

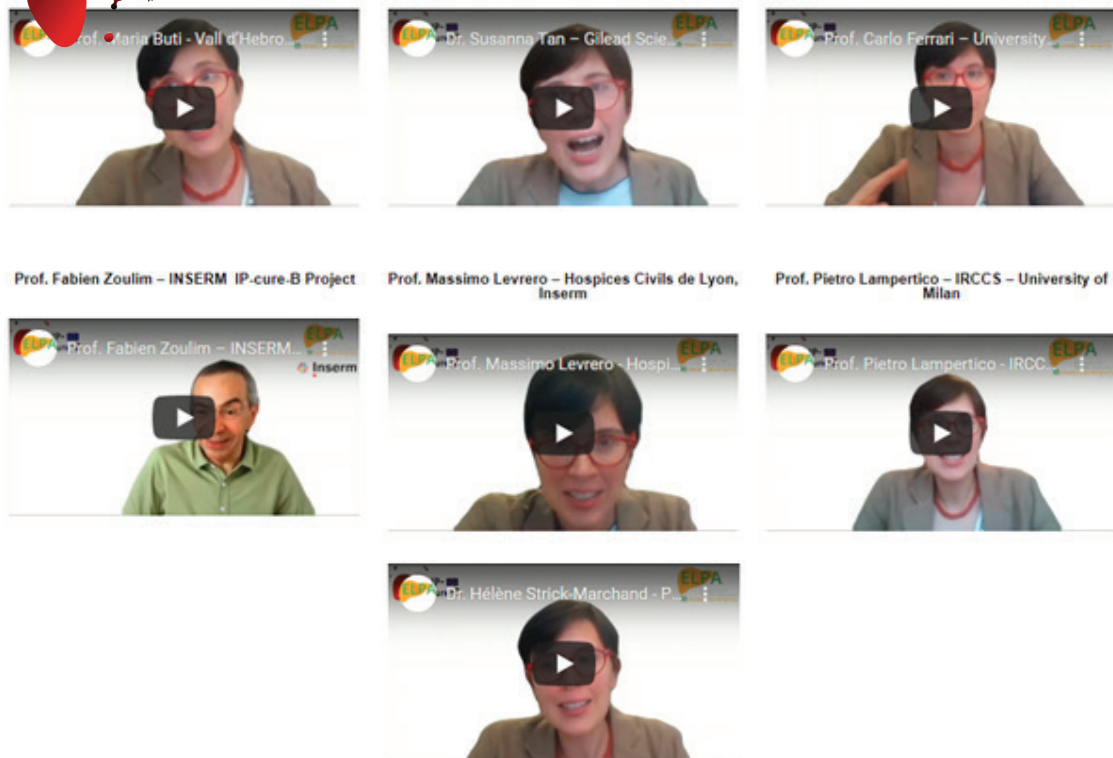
Primary Sclerosing Cholangitis (PSC) knows no boundaries. It is a rare, immune-mediated liver disease that affects the bile ducts and liver. ELPA organized a social media campaign and partnered with different patients' organizations to bring you a selection of presentations with experts from around the world. The webinar can be watched on the ELPA YouTube channel.



MORE AND MORE

Meet the principal Investigators!

In 2021 ELPA teamed up with some of the Principal Investigators involved in the IPcureB and LiverScreen projects, releasing some videos revolving around the scope and the content of the projects. Videos can be watched on the ELPA YouTube channels and on the projects' websites.



Merry #AlcoholFree holidays, and Happy healthy liver! The ELPA campaign to keep your holidays healthy

This year, with the endorsement of the European patients' Forum (EPF) and Eurocare – European Alcohol Policy Alliance, ELPA prepared a special campaign to contrast the abuse of alcohol during the winter holidays.

The WHO European Region has the highest proportion of drinkers and the highest alcohol intake in the world.

Consumption of alcohol is a preventable risk factor that can cause premature death and over 200 diseases, including cirrhosis of the liver and liver cancer. If you drink every day, every 10 grams of pure alcohol (around one drink) increases liver cancer risk by 4%.

However, awareness among the public is still low regarding the link between alcohol and cancer. Intensified efforts and resources are needed to ensure that citizens are fully aware of the risk that alcohol consumption can carry regarding cancer development.

The campaign was run on all ELPA's social media platforms, and it also included a recipe book to prepare alcohol-free cocktails.



ELPA is part of the ECDC Advisory Forum

ELPA is an official member representing non-governmental organisations – patients, of the Advisory Forum of the European Centre for Disease Prevention and Control (ECDC).

ELPA President Marko Korenjak has been selected to be part of the Advisory Forum. An assembly aimed to support the Director in ensuring the scientific excellence and independence of activities and opinions of the Centre. It constitutes a mechanism for exchanging information on health threats and the pooling of knowledge. It also ensures close cooperation between the Centre and the competent bodies in the Member States in particular on the following items:

- coherence of the Centre's scientific studies with the Member States;
- in those circumstances where the Centre and a national body cooperate;
- the promoting, starting up, and supervising of the European networks within the fields of the Centre's mission;
- where the Centre or a Member State identifies an emerging public health threat;
- the setting up of scientific panels by the Centre;
- scientific and public health priorities to be addressed in the work programme.

The main task of the patient organisation representative is patient advocacy to ensure that patient and public perspectives are taken into account in the advice to the ECDC Director, in support of the overall role of the Advisory Forum.

ELPA is honoured to be part of the Forum, and it will work together with the rest of the team to improve the work of ECDC putting patients in the spotlight.

In 2021 ELPA attended the Advisory Forum's meetings on September 29 and December 14, 2021. Also, as a member of the ECDC Advisory Forum, ELPA took part in the ECDC Third Joint Strategy Meeting (JSM) final plenary event on September 30, 2021. The purpose of the meeting was to present and further discuss the outcomes of the JSM working groups that met before the summer break.

ELPA is part of the EASL Policy and Public Health Committee

Marko Korenjak, ELPA President, has been nominated as a patient representative in the EASL Policy and Public Health Committee.

The mission of the Committee is to provide EASL with expert scientific and policy guidance to enable it to carry out its public affairs activities and achieve its public affairs goals and objectives.

The Policy and Public Health Committee members are responsible for coordinating the development of:

- EASL Policy and Public Health Strategy and Work Plan
- new EASL Policy Statements, Position Statements, and EASL Public Health Policy Research
- EASL Public Health sessions at EASL Public Health events
- EASL cooperation with patient associations working in the field of liver conditions

Policy and Public Health Committee members are expected to be able to attend monthly conference calls, and up to two face-to-face meetings per year, subject to the evolution of the COVID-19 pandemic.

This is a further step towards an even deeper collaboration between ELPA and EASL.

In 2021 ELPA attended the Committee's meetings on September 27, October 25, and November 29, 2021.

ELPA confirms its collaboration with EMA in the PCWP, Patients' and Consumers' Working Party

Following ELPA's annual renewal form assessment, the European Medicine Agency (EMA) confirmed our organization remains compliant with the criteria required to be an EMA eligible organization, as defined by EMA Management Board. EMA engages with a network of over thirty-five eligible organizations, ensuring that the needs and concerns of a wide range of patients and consumers are represented via direct contact with the Agency. In most cases, these organizations are not-for-profit, have a European Unionwide mandate, and include umbrella organizations and organizations focusing on a specific area. ELPA will continue to work together with the Agency and all the eligible organizations to improve liver patients' lives.

As a member of the Patient and Consumer Working Party (PCWP), ELPA participated in the meeting of the CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP) on July 1, 2021.

It also participated in the EMA's PCWP and HCPWP Working Parties joint virtual meeting on June 1 – 2 and September 21 – 22, 2021.

ELPA work at the national level

In 2021 ELPA worked closely with its members on projects developed at the national level.

ELPA supported projects in 15 different countries:



Milan Mishkovikj, ELPA Director, Hepar Centar -Bitola, North Macedonia



Olga Štefanická - Šanca pre pečeň, Slovakia

Belgium, Bosnia&Erzegovina, Cyprus, Finland, France, Israel, North Macedonia, Norway, Romania, Serbia, Slovakia, Slovenia, Sweden, Turkey, United Kingdom.

ELPA collaboration with EUPATI and ELPA SCHOLARSHIP – 2021-2022 EUPATI FELLOW PROGRAMME

In March 2021, The European Patients' Academy on Therapeutic Innovation (EUPATI) and the European Liver Patients' Association (ELPA) signed an agreement that marks the beginning of a long and fruitful collaboration between the two organisations and ELPA became a EUPATI sustaining partner. ELPA, as sustaining partner, participated in the European Patients' Academy on Therapeutic Innovation (EUPATI) Annual General Meeting 2021 that took place on September 23, 2021.

After almost one year of cooperation, ELPA enrolled some of its representatives in the EUPATI Fellow Programme 2021, a one-year programme to become a certified expert patient. EUPATI is committed to increasing the capacity and capability of patients and patient representatives to understand and meaningfully contribute to medicines research and development (R&D) and to improve the availability of medical information for patients and other stakeholders.





**POLICY AND
ADVOCACY WORK**

Focus on COVID-19

EMA's public stakeholder meeting on the approval and roll-out of COVID-19 vaccines in the EU

ELPA, as a member of the Patient and Consumer Working Party (PCWP), participated in the European Medicine Agency (EMA) public stakeholder meeting on the approval and roll-out of COVID-19 vaccines in the EU.

Together with the EU regulatory network, EMA has been working around the clock to bring much needed COVID-19 vaccines to EU citizens as quickly as possible while keeping the same rigorous standards of approval as for all vaccines. EMA convenes a second public meeting to provide detailed information to EU citizens about the assessment, approval and roll-out of new COVID-19 vaccines. The COVID-19 pandemic has caused suffering and hardship for many people across the world. In only eleven months, thanks to the joint efforts of scientists, doctors, developers, regulatory experts as well as all the volunteers participating in large scale studies, new vaccines have been developed and submitted for marketing approval. This meeting was an opportunity to inform about the data underpinning the approval of new vaccines and the subsequent steps towards a rapid distribution to the public.

EMA organised this open event on January 8, 2021, to:

- explain the basis for the approval and use of the new COVID-19 vaccines and how the safety of the vaccines will be assured;
- provide information on the roles of the European Commission and national public health authorities in the roll-out of the vaccines;
- listen to the needs, expectations, and concerns of the public and stakeholders.

COVID-19 Vaccination and patients with cancer - ESMO engagement

In January 2021, the European Society for Medical Oncology (ESMO) organized two meetings focusing on COVID-19 vaccines and cancer patients. It launched a call to action on the same topic.

1. Public Policy Webinar: COVID-19 vaccinations in patients with cancer

On January 8, 2021, some ELPA representatives participated in the European Society for Medical Oncology (ESMO) webinar on COVID-19 vaccinations in patients with cancer.

With 2021 in the starting blocks, ESMO's Public Policy team ran a much-expected Webinar that drew a clear outlook on the challenges, stakes and dynamics of the COVID-19 vaccinations from the viewpoint of cancer patients. With speakers from ESMO, WHO, the EMA, and others, ESMO was in a unique position to draw on the expert perspective of its community and inform participants on the urgent multifaceted issue.

2. COVID-19 vaccines and cancer care: the known, the unknown and the unknowable: ESMO Live Roundtable

While patients with cancer are likely to be immunised against COVID-19 at some point in the next future, evidence regarding vaccination of this population is limited, thus raising some concerns on its efficacy and safety among the oncology community. On January 22, 2021, some ELPA representatives participated in the European Society for Medical Oncology (ESMO) Live Roundtable “COVID-19 vaccines and cancer care: the known, the unknown and the unknowable”. The meeting was organized to address the main issues on the use of vaccines targeting the Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2) in patients with cancer. A panel of renowned experts in oncology, immunology and virology discussed the science behind COVID-19 vaccines, the risks of their interaction with antineoplastic therapies and ideal timings of administration in cancer care, along with updates on other key aspects such as the ability of patients with cancer to mount an immune response and the duration of post-vaccination protection. The ESMO Live Roundtable is part of ESMO’s commitment to increase knowledge on COVID-19 vaccination in patients with cancer and provide guidance to medical oncologists.

ESMO’s call to action on COVID-19 vaccinations and patients with cancer

ELPA endorsed the new European Society for Medical Oncology (ESMO)’s call to action on COVID-19 vaccinations and patients with cancer. In the context of the Member States developing their vaccination strategies, ESMO would like to request the Member States to consider the following:

- 1) Vaccinate all cancer patients in line with the WHO principles to reduce deaths and disease burden. Patients with active disease or receiving anticancer treatment deserve an additional priority in case of limitations only.
- 2) Diligently collect data via suitable registries to monitor the effects of the vaccines in the vulnerable population, including patients with cancer and immune response monitoring.
- 3) Educate and instil confidence among the public and patients in receiving the vaccines and provide them with up-to-date information in lay language.

COVID-19 Vaccination and patients - EPF engagement

In January 2021, the European Patients Forum (EPF) organized two meetings with a specific focus on COVID-19 vaccines and how to fill patient communities’ awareness and information gap.

EPF presentation of Patient Guide ‘Let’s Talk about Vaccination’

Some ELPA representatives took part in launching a new EPF patients guide about vaccination on January 14, 2021. Since 2018 the European Patients’ Forum has actively engaged in advocacy on the importance of vaccination for patients with chronic conditions – people with specific vulnerabilities and needs concerning vaccination, but who do not always find enough information on vaccination explicitly targeted at patients. Building on its previous work, EPF has developed a guide to vaccination for patients and patient advocates.

This guide, titled ‘Let’s Talk About Vaccination’, is the next step in filling the awareness and information gap in the patient communities. Developed in collaboration with patient advocates, the guide complements and expands on our other available information materials and gives guidance on having better conversations around vaccination.

Shot callers: a virtual event on covid-19 vaccines

On January 28, 2021, ELPA joined EPF in a virtual event with credible experts in the field of therapeutics and vaccines to shed light on all things related to the COVID-19 vaccines. The event was organized because as the COVID-19 pandemic has led to the development and approval of new vaccines in a much shorter time frame than usual, there are still several questions that need to be answered for patients and civil society.

“Innovations in Hepatitis Elimination” series

On February 11, 2021, in the framework of the “Innovations in Hepatitis Elimination” series, ELPA’s representatives participated in the episode “Impact of COVID-19 Response on Hepatitis Prevention Care and Treatment: Results From Global Survey of Providers and Program Managers.” From August to October 2020, the Coalition for Global Hepatitis Elimination (CGHE) surveyed clinicians and program managers to assess the mitigation strategies deployed to reduce SARS-CoV-2 transmission and the changes in access to hepatitis testing and treatment services. In this interview, Dr Ward, Director of the Coalition, reviewed the key findings from the survey and spoke with some of the survey respondents who described their experience in delivering hepatitis services during the pandemic, including the challenges they faced and the mitigation strategies they found effective in maintaining access to care for their patients.

EASL webinar ‘COVID-19 vaccination in patients with liver disease’

The second of EASL’s live webinars on COVID-19 was held on March 9, 2021, and it addressed the topic of vaccination in patients with liver disease. This was chaired by **Professor Ulrich Spengler** and **Professor Verena Keitel**, who were joined by **Dr Thomas Marjot**, **Professor Julian Schulze-zur-Wiesch**, **Professor Dr Miriam Sturkenboom** and **Professor Rifaat Safadi**. Dr Marjot presented on the prioritizing liver disease patients for COVID-19 vaccination followed by an Overview of COVID-19 vaccines available in Europe presented by Professor Schulze-zur-Wiesch. Professor Sturkenboom presented the Benefit/risk of COVID-19 vaccinations: current knowledge and specific populations before Professor Safadi closed with the First practical experiences with COVID-19 vaccinations in Israeli patients with liver disease. After the main presentations, a fascinating Q&A session covered a range of topics including how to monitor vaccine efficacy in liver disease patients, what needs to be done in countries with limited supply, whether COVID-19 vaccines can be combined with others and recommendations for specific patient profiles.

VHPB technical meeting: The impact of COVID-19

On March 18 and 25, 2021, the Viral Hepatitis Prevention Board organized two meetings to investigate the impact of COVID-19 on the prevention of viral hepatitis and on the viral hepatitis elimination goals. More in details, VHPB wanted:

- Evaluate the impact of the COVID-19 pandemic on National/regional vaccination and prevention programs for viral hepatitis
- Discuss how increasing vaccine hesitancy due to the pandemic may endanger the high coverage rates of hepatitis B vaccination
- Evaluate lessons learnt from existing catch up programmes
- Discuss the scale-up of the public health needs to improve prevention and immunization of viral hepatitis, which were negatively influenced by the pandemic
- Evaluate the impact of the COVID-19 pandemic on viral hepatitis, screening, control & treatment in Europe
- What is the influence of the COVID-19 pandemic on the elimination goals, regionally and on country level
- Review the possible implementation of control measures, new prevention strategies and monitoring systems during and after a pandemic, lessons learnt.
- Assess the (extra) needs to achieve the goal of eliminating viral hepatitis as a major public health threat in Europe by 2030 as defined by WHO's Regional Office for Europe. Discuss successes, issues and the new challenges

ELPA President Marko Korenjak chaired session 1.1: Covid-19 impact on hepatitis prevention in risk groups on March 18.

Film launch & live Q&A – Connecting with people who use drugs during COVID-19

The International Network on Health and Hepatitis in Substance Users (INHSU) and Kirketon Road Centre (KRC) welcomed over 100 people from across the globe, ELPA representatives included, for the online premiere of a short film that delved behind the scenes of KRC's COVID-19 outreach program.

KRC is a walk-in, primary healthcare centre in Sydney, Australia, that focuses on vulnerable communities, including people who use drugs and the homeless.

During COVID-19, the organisation adapted swiftly and introduced mobile, peer-led outreach initiatives to ensure the communities they served had access to COVID testing. This program also ensured that HCV testing and harm reduction initiatives were impacted as little as possible.

EMA Public stakeholder meeting: approval, safety monitoring and impact of COVID-19 vaccines in the EU

This third public meeting organized by the European Medicine Agency (EMA) updated EU citizens about the continued assessment, approval and safety monitoring of COVID-19 vaccines, and their expected impact at the community level.

It covered:

- COVID-19 vaccines approved in the EU and those currently under review;
- post-authorisation activities, including emerging safety data since EU authorisation of the first COVID-19 vaccines;
- ongoing work to address new variants;
- the expected impact of COVID-19 vaccination on our society;
- transparency and the publication of clinical data for COVID-19 vaccines.

The event also allowed the public and stakeholders to further inform EMA of their needs, expectations, and concerns.

‘Have we failed to protect Europe’s people?’

As the COVID-19 pandemic continues to grip the continent, it is hard to deny that our collective failings during the crisis have been massive. Fault lines in the current model of European collaboration are standing out starkly again in the struggle for timely and equitable vaccine roll-outs. The European Health Union (EHU) initiative calls for more and better Europe amidst this crisis – a renewed concentration on our shared core values and a commitment to vest into the EU the necessary powers to sustainably secure better health for all. This webinar in the series Towards a European Health Union, hosted by the EHU Initiative and facilitated by the European Health Forum Gastein on March 11, 2021, took an unflinching look at what is going wrong and how we can get it right in the future.

EPF third Vaccination Confidence – Patients’ and professional Awareness Communication and Trust

On March 11, 2021, ELPA participated in the 3rd Vaccination Confidence – Patients’ and professional Awareness Communication and Trust meeting organized by the European Patients Forum (EPF). The Vaccination Confidence – Patients’ and professional Awareness Communication and Trust (VAC-PACT) project coordinated three regional workshops to enable EPF to engage and work with representatives at national levels within the CEE region, Southern and Western Europe. Each workshop took place over one day and will follow the principle of active engagement of the participants, with plenary sessions and parallel workshops to enable interactive debate and reflections, focusing on concrete and workable outputs and recommendations. The format of the sessions was designed to allow participants to transmit the knowledge afterwards to their communities and to support effective use of a toolkit, as well as dissemination through participants’ networks.

Early lessons from the ups and downs of COVID-19 immunisation roll-out(s)

Eagerly anticipated throughout 2020, COVID-19 vaccines are finally here. At the same time, their roll-out is posing substantial challenges across the EU and beyond, and as the number of available vaccines has grown, so has the number and prevalence of new emerging strains of the virus. Building up a broad and diverse portfolio of vaccines to meet the needs of all communities in Europe and uniting across sectors and borders in the vaccination effort has never been more important. This webinar, organised by the European Health Forum Gastein in partnership with Valneva, on April 20, 2021, focused mainly on the experiences of scientists, policymakers and industry, looking back at successes and roadblocks experienced in acquiring and administering the first COVID-19 vaccines, as well as forward, armed with the lessons learned.

DiCE webinar: Colorectal Cancer Screening: Lessons Learned from COVID-19

In the framework of the EU Health Policy Platform's activities, Digestive Cancers Europe (DiCE) organized the webinar: Colorectal Cancer Screening: Lessons Learned from COVID-19 on June 22, 2021. The event's objective was to assess what could be done to identify and implement best practices in Europe. The webinar discussed:

- How to make screening more robust and clinically effective when challenged by acute crises such as the COVID pandemic.
- Which stakeholders to involve and how to collaborate for maximum impact and efficiency.
- How to ensure the development of more resilient and effective national screening programmes.
- How to collaborate at the EU level to share best practices and harmonise approaches.

ELPA participated in it and continues working with its partner, DiCE, to improve patients' lives.

Public stakeholder meeting on COVID-19 vaccines and therapeutics in the EU

In November 2021, ELPA participated in this fourth public meeting that updated COVID-19 vaccines and therapeutics in the EU. It also addressed misinformation and highlighted the current vaccination coverage in the EU.

The following topics were covered:

- COVID-19 therapeutics and vaccines in the EU, including vaccine effectiveness and the use of booster and third doses in national vaccination campaigns,
- update on vaccine safety information,
- COVID-19 epidemiological situation and vaccination coverage in the EU,
- misinformation on COVID-19 vaccines.

The event also allowed the public and stakeholders to further inform EMA of their needs, expectations, and concerns.

4th ECDC Advisory Forum COVID-19 Consultation Series meeting

As part of the European Centre for Disease Prevention and Control - ECDC Advisory Forum, ELPA joined the 4th Consultation Series on COVID-19 on November 9, 2021. The Advisory Forum comprises senior representatives of national public health institutes and agencies, nominated by the Member States based on their scientific competence, and a public health official from the European Commission. The European scientific associations and civil society groups also send observers to the Advisory Forum. The ECDC Director invites WHO to attend the meetings to ensure synergy. As well as supporting ECDC's scientific work, the Advisory Forum is also a mechanism for exchanging information, pooling health knowledge and furthering public health cooperation.

The impact of COVID-19 on immunocompromised patients

On December 8, 2021, ELPA President Marko Korenjak joined a virtual advisory board where AstraZeneca collected insights on the ongoing impact of COVID-19 on immunocompromised patients. AstraZeneca wanted to work with leading patient advocacy groups to expand awareness of the ongoing challenges of COVID-19 on patients who are immunocompromised and help drive the improvement of patient care. The advisory board's primary objectives are to understand how the pandemic has impacted and continues to impact patients and seek advice on patients' unmet needs in terms of ongoing support and information.

POLITICO Health Care Summit

On October 27-28, ELPA Representatives attended the sixth edition of POLITICO's Health Care Summit. Through exclusive interviews, panel discussions, and interactive roundtable discussions, this high-level event gathered newsmakers and global thought leaders to dive into European policies on COVID-19 and preparedness, cancer, the Pharma Strategy, health data, unmet needs, and medicine shortages, among many other key topics. The summit tried to answer the following questions:

- Has the COVID-19 pandemic affected the structure, speed and funding of health care systems in Europe in the long term?
- To what extent has this health emergency laid bare manufacturing weaknesses?
- And what has it revealed about the impact of the politicisation of health decision making?

While many see this crisis as an opportunity to rebuild social care systems more sustainable and resilient – from innovation to regulation – and to rethink relationships between industry actors, researchers, health regulators and patients – it isn't yet clear if the pandemic will lead to a much-needed Big Bang moment. Not to mention that the crisis has extremely stretched budgets.

Considering the importance of the topic, also ELPA organized a talk revolving around the COVID-19 vaccination.

ELPA Hot Topic on AIR - "COVID-19 vaccine and Liver Diseases"

COVID-19 infection may result in significant and devastating delays in screening, diagnosis, treatment, and monitoring/surveillance strategies in patients with liver diseases, liver cancer and rare liver disease. Vaccination is the best response to COVID-19, and it is the main road to successfully managing this pandemic.

However, during these last months, ELPA realized that there is an urgent need for information on the topic of COVID-19 vaccinations and patients with liver cancer and rare liver disease. We are also aware that patients' associations should educate and instil confidence among the public and patients in receiving the vaccines and provide them with up-to-date information in lay language.

These are the main reasons why ELPA decided to organize on February 25, 2021, a talk between experts and patients on this topic. Livestreamed on YouTube and Facebook, this ELPA Hot Topic on AIR "COVID-19 vaccine and Liver Diseases" has two guests from some medical and health institutions: **Prof. Jeffrey Lazarus** - Barcelona Institute for Global Health Hospital Clínic - University of Barcelona, and **Dr Liudmila Mosina** - Technical Specialist, Vaccine-preventable Diseases & Immunization, Division of Health Emergencies and Communicable Diseases, WHO/Europe. However, together with them, the viewers could listen to the personal experience of **Mrs Sindee Weinbaum**, representative of the ELPA Member Hetz, the Israeli Association For The Health Of the Liver, and the ELPA Working Group leader on Rare Liver Diseases. She is the first person belonging to ELPA's family to be given the Covid-19 jab on December 27, 2020, in Tel Aviv as part of a mass vaccination program.



Marko Korenjak, ELPA President - Sindee Weinbaum, Leader of ELPA Working Group on Rare Liver Disease - Prof. Jeffrey Lazarus, ELPA 'Hot Topics on AIR' - episode 1



Focus on Health Data

EMA - Technical workshop on real-world metadata for regulatory purposes

On April 12, 2021, ELPA participated in the 'Technical workshop on real-world metadata for regulatory purposes' organized by the European Medicine Agency (EMA). Data characterization and discoverability are goals for the scientific community and for medicines regulation. The HMA-EMA joint Big Data Task Force recommended "to promote data discoverability through the identification of metadata" as part of its Recommendation III, which is reflected in the Big Data Steering Group work plan.

The objective of this workshop was to review and gather stakeholders' feedback on:

- preliminary list of metadata required for characterising real-world data sources and definitions to fulfil regulatory use cases;
- proposed options for metadata from real-world data sources collection and maintenance processes;
- proof-of-concept catalogue of data sources and metadata.

Shaping a European Health Data Space

On May 21, 2021, ELPA participated in the joint EPF and European Commission webinar 'Shaping a European Health Data Space'. It aimed to inform and engage EPF members and the broader patients' community on the consultation process for the European Health Data Space (EHDS). During the webinar, following an introduction on the recent EPF work on the topic, DG SANTE representatives shared the overall plan for the EHDS and discussed how the upcoming consultation would seek inputs on its core pillars. Following the presentations, the participants were able to engage with questions and share their views on the EHDS elements from the patients' perspective.

EMA Data Standardization Strategy workshop

The European Medicines Agency (EMA) has launched an initiative to develop a data standards strategy, intending to address the HMA/EMA Big Data Task Force recommendation to engage in international initiatives related to data standardisation. The strategy will enable the European medicines regulatory network to leverage data more effectively to deliver evidence in support of benefit-risk decision-making on the development, authorisation and use of medicines. The intention is to optimise the processing of such data by different stakeholders through improved submission formats tailored to their needs while ensuring data security. EMA plans to consult a wide range of stakeholders to understand their data standardisation needs related to the submission, receipt, use and re-use of scientific data at each stage of the medicinal product lifecycle. On May 18, 2021, ELPA participated in the workshop as one of the main stakeholders in the field.

ESMO Public Policy Webinar on the General Data Protection Regulation and its impact on clinical research

On May 21, 2021, ELPA participated in the Public Policy Webinar on the General Data Protection Regulation and its impact on clinical research organized by the European Society for Medical Oncology (ESMO). The General Data Protection Regulation (GDPR) entered into force on 25 May 2016 and has been applicable since 25 May 2018, introducing important changes positively impacting data collection and use for all sectors, including scientific research across the EU. Three years since the Regulation became applicable, and in view of the direct impact the GDPR has had on research, the ESMO, in association with the MEPs Against Cancer (MAC) Interest Group at the European Parliament, convened a virtual meeting on the GDPR and its impact on clinical research. The virtual meeting brought together the perspectives of EU officials and key stakeholders on this topic. It facilitated a discussion on the GDPR involving the scientific research community, including the oncology community.

HealthTech For Patients

HealthTech For Patients, the European conference on health tech and the role of patients, took place on June 7, 2021. ELPA participated in this new event, organised by HealthTech For Care endowment fund. It brought together a panel of European players and experts from the health ecosystem to discuss health data for medical innovation. The event, which was structured around two round tables, gave the floor in turn to doctors, scientists, representatives of patient associations and health data stakeholders who shared their views on the methods and spaces for sharing anonymous health data, which have become essential to accelerate the development of innovative solutions for the patient.

Learnings initiative webinar for optimal use of big data for regulatory purpose

Building upon the experience of the submission of real-world evidence for regulatory purpose and the conclusions of previous workshops organized by EMA on data standardisation, metadata and artificial intelligence organised by the Agency, this webinar held on November 30, 2021, aimed to:

- learn from current experience of using real-world data for a regulatory purpose,
- discuss important challenges related to optimal use of real-world data, including data relevance, submission processes and training needs,
- discuss means to support effective consultation with stakeholders, including industry, the regulatory network, academia, healthcare professionals and patients.

The European Health Data Space (EHDS) - Building a path for rare diseases and learning from its experience

On 8 November 2021, ELPA members attended the online event on how a European Health Data Space (EHDS) can benefit rare diseases.

Friends of Europe, promoter of the event, produced and presented the report “Building a path for rare diseases in the European Health Data Space”. The report can be briefly summarized by listing the four fundamental principles:

- Ensure federated access to harmonized rare diseases health data in an interoperable continuum encompassing epidemiological, healthcare, research, quality of life and treatment-related data.
- Build partnerships for rare diseases and leverage existing initiatives such as the European Reference Networks (ERNs).
- Develop digital skills for the rare diseases community.
- Build on experiences from the rare diseases community to empower health data users through systems of trust.

The event then proceeded with a discussion on how the EHDS should work, its main features, and its impact on the EU and its citizens.

HMA/EMA – EU Big Data Stakeholder Forum

The European medicines regulatory network organised a second annual multi-stakeholder forum on big data on December 7, 2021. The purpose of the meeting was to foster collaboration and engage stakeholders.

The main objectives of the forum were to:

- Inform stakeholders about the delivery of the data pillar of the Network Strategy 2025 via the HMA-EMA joint Big Data Steering Group 2021-2023.
- Listen to stakeholder views and feedback.
- Discuss areas for collaboration.

Focus on EU Health Policy

European Parliament Special Committee on Beating Cancer

In 2021 ELPA participated in several BECA meetings.

On January 11, 2021, some ELPA representatives followed the live streaming of the first 2021 meeting of the Special Committee on Beating Cancer (BECA) in the European Parliament. The Committee held a hearing dedicated to cancer patients' experiences and their recommendations for the Committee's forthcoming report. The hearing went over problems that cancer patients may face, including physical trauma, mental health issues, difficulties to return to school, work or leisure, and a lack of adequate medical, psychological, social and financial support, of recognition of their disease and the legal status of caregivers.

On January 28, 2021, some ELPA representatives listened to some MEPs from the Beating Cancer committee discuss with ten leading experts how to deliver the best possible care to cancer patients in the EU. Topics ranged from cancer drugs to multidisciplinary cancer care, with a specific angle on paediatric and rare cancers and the social determinants in accessing cancer care. Access for patients to high quality, affordable and timely cancer care is a key element in the fight against cancer. Good healthcare services improve patient outcomes, reduce the suffering and side effects of treatments as much as possible and enhance the quality of life for survivors. Good healthcare outcomes also contribute to the efficiency and sustainability of the health care systems.

On May 10, 2021, ELPA participated in the BECA MEPs discussion of the results of the public consultation on the "Impact of the COVID-19 pandemic on cancer prevention, health services, cancer patients and research."

Several organisations that contributed to the BECA survey participated in the exchange of views in order to make the discussion as broad and complete as possible:

- European Cancer Organisation (E.C.O.)
- European Society of Medical Oncology (ESMO)
- European Public Health Association (EUPHA)

The synopsis report presents the outcome of the stakeholders' public consultation conducted by BECA in February - March 2021. It provided a framework for proposals for short-term and sustainable solutions, but also for future health crises (e.g. disease preparedness) to ensure continuity of cancer services, also taking into account Europe's Beating Cancer Plan.

On May 27, 2021, the Special Committee on Beating Cancer in the European Parliament (BECA) put the spotlight on the use of artificial intelligence (AI) in cancer research, cancer care and personalised cancer medicine during a public hearing with eight leading experts in the field and the European Commission. ELPA followed the public hearing, organised in association with the Special Committee on Artificial Intelligence in a Digital Age (AIDA). It emphasised the treatment of health data and ensuring patients' data privacy in the context of the data exchange mechanisms proposed in Europe's Beating Cancer Plan that the European Commission presented on February 4, 2021.

On June 16, 2021, the Committee analysed the National Cancer Control Programmes with representatives of the WHO Regional Office for Europe, the coordinator of the Joint Actions on cancer policy in the EU (European Partnership for Action Against Cancer (EPAAC), the European Guide on Quality Improvement in Comprehensive Cancer Control (CanCon) and Innovative Partnership for Action Against Cancer (iPAAC), representatives of selected EU Member States, as well as the European Commission.

The meeting focused on the preparation and implementation of the National Cancer Control Programmes (NCCPs), the role of the WHO and the Joint Actions, Member States' efforts, and the role of NCCPs in Europe's Beating Cancer Plan. Members and experts also discussed the importance of adequate implementation and evaluation of NCCPs and ways to improve this; adapting funding in the function of national/regional needs; the significance of early diagnosis as a 'blind spot' in many cancer programmes; the need to increase capacity and training of NGOs and patients' organisations, and the role of quality palliative care.

On July 1, 2021, BECA MEPs discussed some of the key files related to cancer care and control, which the EP is currently working on, with the ENVI rapporteurs. In particular, they examined the pricing of cancer medicines and, together with the Commission, the Aspen Pharmaceuticals case, where, in the context of an antitrust investigation, the Commission succeeded to reduce by an average of 73% the prices for six medicines that are essential to treat certain severe forms of blood cancer.

Furthermore on the agenda were exchanges of views with ENVI rapporteurs and Commission representatives on:

- The EU's pharmaceutical strategy, which aims to ensure access to affordable medicines for patients and support the competitiveness, innovation, and sustainability of the EU pharmaceutical industry. ENVI Rapporteur: Dolores Montserrat (EPP/ES).
- Regulation on Health Technology Assessment (HTA), which will replace the current system of EU-funded project-based cooperation between the Member States on health technology assessment with a permanent framework for joint work. ENVI Rapporteur Tiemo Wölken (S&D/DE) will be represented by Jytte Guteland (S&D/S), ENVI S&D Coordinator.
- Regulation on Serious cross-border threats to health proposed to strengthen the EU's health security framework and to reinforce the crisis preparedness and response role of key EU agencies. ENVI Rapporteur: Véronique Trillet-Lenoir (RENEW/FR).

On July 15, 2021, BECA Rapporteur **Ms Véronique Trillet-Lenoir** presented her draft report entitled "Strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy" to the Members of the Beating Cancer Committee and with the participation of John-F Ryan, Director Public Health, DG SANTE, European Commission. To achieve the ambitious objective of conquering the cancer burden and the fatality of cancer in Europe and to reduce health inequalities, Ms Trillet-Lenoir proposes a range of concrete actions and tools.

Regarding primary cancer prevention, the Rapporteur advocates for ambitious legislative proposals to reduce tobacco and alcohol consumption, promote healthy eating and regular physical activity, and insists that a gender-neutral HPV vaccination programme be implemented in the Member States to ensure the elimination of all HPV-related cancers. The revision of the European Code Against Cancer is the best way to inform citizens on how to reduce risk factors for cancer. Another priority is to harness research, innovation and new technologies for prevention and treatment. The Rapporteur proposes establishing at least one comprehensive cancer centre in each Member State and facilitating access to cross-border cancer care.

On September 27, 2021, BECA held a virtual Interparliamentary Committee Meeting to discuss the fight against cancer in Europe. ELPA Representatives attended this meeting that presented the view of national parliaments on Europe's Beating Cancer Plan, one of the critical pillars of the European Health Union project. The Panel discussed strengthening EU cooperation to tackle national, regional, and social inequalities in cancer prevention and care. There is a strong need for EU-wide measures and increased collaboration on cancer prevention and care at all levels. To this end, and to expand the ability of cancer patients to benefit from high-quality treatment provided by the other Member States, different speakers called on the Commission to launch the planned Cancer Inequalities Registry in the fight against cancer as soon as possible. A real Marshall Plan in the field of oncology is needed, and it cannot be achieved without solid and dedicated cooperation at the EU, national and regional level, including cross-border cooperation.

MEP Digestive Health Group in the EU Parliament

ELPA Joined United European Gastroenterology (UEG) to launch the MEP Digestive Health Group on June 15, 2021. The new Group was presented during an online event hosted by MEP Antonio Tajani, Chair of the MEP Digestive Health Group and supported by UEG. The event gave an overview of the status quo of digestive health in Europe, discussing the chronic nature of digestive diseases and their socio-economic impact. Expert speakers representing UEG provided the scientific outlook while leading EU policymakers shared their perspectives on what can be done at the EU level to improve digestive health.

The Group aims to raise awareness of the need for better prevention, improved treatment and a greater understanding of the causes of digestive diseases. It draws attention to the real-life impact of digestive diseases, their socio-economic burden, and fosters health literacy to strengthen the competence of citizens to manage their health.

EU Parliament, ENVI Committee - Slovenian EU Presidency

ELPA president Marko Korenjak participated in the EU Parliament - ENVI Committee meeting on July 12, 2021, where the Slovenian minister for health Mr Janez Poklucar presented the priorities of the upcoming Slovenian EU Presidency. Health Minister **Mr Janez Poklucar** told the Environment, Public Health and Food Security Committee that the presidency would promote the implementation of innovative solutions for resilient health systems and EU level cooperation. Two of the main priorities for the presidency are reducing health inequality and advancing towards a fully-fledged Health Union. MEPs had questions about cross-border research against cancer, the HERA incubator, a stronger EMA and ECDC and countering cyberattacks against these agencies.

Europe's Beating Cancer Plan meetings and webinars

In 2021, ELPA took part in many meetings about Europe's Beating Cancer Plan officially presented by the European Commission on February 3, 2021, the eve of World Cancer Day.

ELPA joined Europe's Beating Cancer Plan - Stakeholder Contact Group

ELPA's commitment to fighting liver cancer is not stopping. After the first Liver Cancer Patients' Summit successfully organized in February 2021 and working hard on Europe's Beating Cancer Plan's content, in April 2021, ELPA was invited by **Mr John F. Ryan**, Director of the Public Health Directorate in the Directorate-General for Health and Food Safety of the European Commission to join the 'Europe's Beating Cancer Plan - Stakeholder Contact Group' network of the Health Policy Platform. The Health Policy Platform has been created to enable health stakeholder organisations to share knowledge on EU-health issues, engage in a laboratory of ideas, and enter an interactive dialogue with the Commission services. ELPA is very excited to be on board because the Platform represents the occasion to promote the upcoming ELPA's activities in this field, such as the EndHep Initiative and the HCC White Paper, supervised by ELPA Scientific Committee ELPA Working Group on HCC and launched with Key Opinion Leaders.

ESMO Public Policy Webinar: Europe's Beating Cancer Plan - in 60 minutes

This Public Policy Webinar, organized by the European Society for Medical Oncology (ESMO) on February 15, 2021, provided an exchange of views amongst a diverse group of stakeholders on the cancer-related challenges that Europe faces today as well as how Europe's Beating Cancer Plan could contribute to enhancing cancer prevention, improving treatment and care provided to cancer patients and addressing the impact of cancer in a holistic manner. The plan revolves around four action areas – prevention, early detection, diagnosis and treatment, and quality of life of cancer patients and survivors – and includes various flagship initiatives and supporting actions to achieve tangible results in relation to the four domains. As such, Europe's Beating Cancer Plan has the potential to address many issues that concern the entire disease pathway.

Europe's Beating Cancer Plan: Why We Need It Now

On February 10, 2021, the European Cancer Forum organized a lively debate in the framework of "Issues in Cancer Care – The Early Bird Debate" regarding Europe's Beating Cancer Plan and why we need it now. Europe's Beating Cancer Plan sounds like something that should be around already. With the Europeans carrying 25% of the global population's cancer burden, a coherent strategy tackling cancer incidence and mortality in Europe is only consequential. Or is it? Cancer treatment remains a personal and often local matter, and different perspectives exist across Europe on access to cancer care, budgets, and spending. These are reflected in different public health systems and policies at the level of EU member states. Cancer control activities vary greatly within Europe, as do cancer care outcomes.

Considering high European ambitions, persisting interests in member states, and local sensitivities: What can we expect from Europe's Beating Cancer Plan? How can it become a success and more than just yet another document? On these topics, Matthias Schuppe - European Commission, DG Santé, Project Team Leader for Cancer and Bengt Jönsson, Professor Emeritus of Health Economics at the Stockholm School of Economics, exchanged views and opinions.

Beating Cancer Stakeholder Contact Meeting

On May 28, 2021, ELPA took part in the first Beating Cancer Stakeholder Contact Meeting. ELPA was invited by **Mr John F. Ryan**, Director of the Public Health Directorate in the Directorate-General for Health and Food Safety of the European Commission to join the 'Europe's Beating Cancer Plan - Stakeholder Contact Group' network of the Health Policy Platform in April 2021.

The Health Policy Platform has been created to enable health stakeholder organisations to share knowledge on EU-health issues, engage in a laboratory of ideas and enter in an interactive dialogue with the Commission services.

Within the Platform, the *Agora Network* is the place for the exchange and discussion of general and cross-cutting health issues. The Thematic Networks are the places for collaboration on defined themes to develop a joint statement by a group of stakeholder organisations. Thematic Networks can be restricted or open to all registered Platform users, depending on the group's need.

The '*Europe's Beating Cancer Plan - Stakeholder Contact Group*' network has been specifically created for stakeholders who wish to be involved in the implementation of the Cancer Plan. The work of the stakeholder community will focus on the four pillars of the Plan, including cross-cutting issues.

ELPA is very excited to be on board because the Platform represents the occasion to promote the upcoming ELPA's activities in this field, such as the EndHep Initiative and the HCC White Paper, supervised by ELPA Scientific Committee ELPA Working Group on HCC and launched with Key Opinion Leaders.

Launch of the EC Knowledge Centre on Cancer

Cancer is the primary cause of death for Europeans under 65. In the EU, cancer accounts for more deaths in people under 65 than any other disease. It hosts less than 10% of the world's population, yet it has 23% of all cancer cases. On average, only 1 in 2 cancer patients survive, and one in two of us will face cancer in our lifetimes. A successful fight against cancer relies upon identifying, aligning, planning and coordinating actions of these initiatives at the Scientific and Technical levels. A task that needs to be done by a neutral, independent, yet competent entity – the JRC. It is in this context that the JRC is establishing the EC Knowledge Centre on Cancer (KCC). ELPA Director, Milan Mishkovikj participated in the launch of the Centre by the European Commission on June 30, 2021.

European Cancer Summit 2021

On November 17, 18, 2021, ELPA participated in the annual European Cancer Summit. The meeting brought together leading oncology experts, patient advocates, politicians and policy-makers to discuss the primary issues impacting cancer policy for the benefit of cancer patients, healthcare professionals and all people across Europe. This year's European Cancer Summit focused on the implementation of Europe's Beating Cancer Plan and the EU Cancer Mission's recommendations. The European Cancer Summit is an important event in the cancer policy calendar. Its goal is to showcase the multi-stakeholder, collaborative efforts being made to ensure tangible results. This exchange will help improve outcomes for cancer patients and raise awareness of the many significant challenges of cancer.



European Health Policy: series of webinars and meetings

In 2021, ELPA representatives participated in many webinars and meetings focused on implementing the EU Health Policy.

EASL's Patient Synergies Roundtable Discussion and EASL Digital Liver Cancer Summit

For the Digital Liver Cancer Summit 2021, taking place February 5-6, 2021, and on the occasion of the World Cancer Day, February 4, 2021, the European Association for the Study of the Liver - EASL held a discussion aiming to identify the needs of liver cancer patients and their families, and the best ways to accompany them. The Roundtable Discussion was an open interaction between scientists and patient representatives on how to invest in a robust framework – a framework to facilitate better interconnectedness and thus improve the lives of patients with cancer, taking into account all types of diversity. Marko Korenjak, ELPA President, was amongst the moderators of the meeting. Patients can play a pivotal role in research, development, and strategies for treating patients with cancer. Furthermore, there is a need to make the lifecycle management of medicines more efficient and adapted to the evolving patient environment.

Marko Korenjak, ELPA President and Dr Teresa Casanovas, ELPA Scientific Committee Leader and ELPA Director, took then part in the EASL Digital Liver Cancer Summit 2021. The meeting brought together all of the professionals engaged in tackling liver cancer, and it has as objectives: to improve the knowledge on the clinical treatment of liver cancer; to facilitate interactions, such as among clinicians, researchers, and patient organisations; and to enable young researchers and clinicians to adopt new translational views on liver cancer.

In 2021, ELPA also collaborated closely with EASL, drafting and promoting the Open Letter to the European institutions about improving liver cancer prevention and care.



The launch event of ECCAM 2021

March is European Colorectal Cancer Awareness Month #ECCAM2021. Digestive Cancers Europe (DiCE) organized a webinar to launch this year's campaign on February 26, 2021. Some ELPA representatives could listen to speakers from patients' associations, the European Parliament and Commission, and the medical fields discussing the important issue of Colorectal Cancer as, every year, 500,000 citizens in Europe are diagnosed with it, and 250,000 of them die. Patients diagnosed early (stage I) have a 90% chance of survival compared to only 10% when diagnosed in stage IV. Even though colorectal cancer evolves slowly, over eight to ten years, most patients are still diagnosed in the late stages III & IV.

Digestive Cancers Europe will launch a four-country pilot campaign #CRCBeenThere to attract people living with colorectal cancer to the services of its patient organisations at the national level. This is along with its general European Colorectal Cancer Awareness Month (ECCAM) campaign to help raise awareness of colorectal cancer.

'Tackling Challenges in Cancer care and improving its Governance in the EU'

The Joint Action Innovative Partnership for Action Against Cancer (iPAAC) and the MEPs Against Cancer (MAC) interest group at the European Parliament organized the online event 'Tackling Challenges in Cancer care and improving its Governance in the EU'. ELPA participated in it on March 15, 2021. This virtual event sought to connect stakeholders and decision-makers to:

- Discuss recommendations from the iPAAC Joint Action derived over the course of 3 years from scientific research, consultations and discussions with representatives from 24 EU member states on how challenges in cancer care can be successfully addressed.

- Present practical instruments for the Member States to ensure integrated and comprehensive oncological care based on the example of two piloted Comprehensive Cancer Care Networks (CCCN) in Poland and Germany as envisioned in Europe's Beating Cancer Plan.

3rd EU HCV Elimination Policy Summit

This four-hour virtual summit in which ELPA participated as an official partner on March 24, 2021, aimed to bring together policy-makers, experts, members of parliament, directors of national HCV elimination plans, mayors, patient associations, clinicians and MEPs from across Europe to raise awareness on the state of play regarding the goal of elimination of HCV by 2030 and showcase best practices as well as indicate what policy actions are needed to get more countries on track to achieve HCV elimination by 2030.

The 3rd EU HCV Policy Summit provided an exceptional opportunity for participants to:

- Review the progress made in the last five years to understand how far Europe is from achieving the goal of eliminating HCV by 2030
- Exchange views on the role and state of diagnosis
- Evaluate the impact of the COVID-19 crisis on the viral hepatitis elimination services
- Share national-level best practices and discuss the EU's position as a leader in helping deliver the elimination target

EU Health Policy Platform annual meeting – 2020 Thematic Networks

ELPA took part in the second day of the Health Policy Platform's annual meeting on March 3, 2021. The meeting showcased the Joint Statements prepared by the 2020 Thematic Networks. These Joint Statements are the culmination of a year of exchange and research, each of them in a particular area of public health. The meeting was chaired by Philippe Roux, head of the unit for Health information and integration in all policies in the European Commission's Directorate-General for Health and Food Safety. Four different stakeholder organisations presented their findings on three different health areas and invited participants to collaborate and endorse the Joint Statements.

ESMO Public Policy Webinar on Bedside Rationing

On March 29, 2021, ELPA participated in this webinar where the European Society for Medical Oncology (ESMO) aimed at exchanging views on the ethical, economic, clinical implications and the consequences on the patient/physician relationship of the difficult choices that physicians face when resources are scarce and explicit decisions are not made by health systems. Given the implications of bedside rationing decisions for patients, including those affected by cancer, the event presented a pivotal opportunity to address this important topic for the benefit of the oncology and health communities and society at large.

Developing more meaningful health interventions through the use of patient-reported outcomes (PROs) in health research

On March 30, 2021, Data Save Lives organized a webinar dedicated to patient groups and communities interested in shaping health research and to people working in clinical or academic health research who wanted to understand how to harness the patient experience to improve outcomes. The webinar focused on:

- Understand how patient groups can work with commercial & academic organisations to shape clinical research.
- Learn from examples where PROs have been used as measures of success.
- Consider current & future opportunities to promote patient-led health data collection.

This webinar featured keynote presentations by three expert panellists in the fields of patient engagement, pharmaceutical research & academia.

EATG - meeting on the diagnostics landscape for HIV, viral hepatitis, and STIs

Some ELPA representatives participated in an e-meeting on the research, development, and advocacy regarding self-testing diagnostic tools. The webinar 'Diagnostics landscape for HIV, viral hepatitis, and STIs: Research, development, and advocacy for self-testing options' was organized on April 15, 2021, by the European AIDS Treatment Group (EATG). The meeting was addressed to community organizations involved in diagnostics procurement and testing service delivery, and representatives from the WHO and Foundation for Innovative New Diagnostics (FIND) provided an update on the research and development of rapid diagnostic tests (RDTs) for self-testing of HIV, viral hepatitis, and STIs. This meeting also tackled effective approaches to overcome legal and regulatory barriers associated with RDT procurement and service delivery outside of clinical settings.

Understanding the Human Microbiome: The impact of ultra-processed foods

ELPA attended the webinar 'Understanding the Human Microbiome: The impact of ultra-processed foods' organized by United European Gastroenterology (UEG) on April 27, 2021. The meeting focused on how ultra-processed food affect our health. Environmental factors related to diet determine our gut microbiome's composition; therefore, the consumption of ultra-processed foods is of grave concern. More precisely, this lively discussion, where expert speakers explained how ultra-processed food impacts our gut health, focused on: the burden of ill-health due to unhealthy diets; the impact of standard components of ultra-processed foods on gut microbiome; the role of food reformulation and nutrition labelling.

Webinar for Patients – Safe and performant Medical Devices for all

Did you know that we all use medical devices? Sometimes, even as part of our daily lives. What changes on 26 May 2021, and what is your role as a patient or consumer? This webinar ELPA took part in, held on 7 May 2021, summarized how the new Medical Device Regulation (MDR) aims to ensure safe and performant medical devices for all. The event was organized by the Directorate-General for Health and Food Safety (DG SANTE) of the European Commission in the context of the Communication campaign for the new medical devices legislation, an initiative supported by the Third Health Programme 2014 – 2020. It brought together representatives of the European Commission, patients, consumers, health professionals and anyone interested in the new legislation.

The 4th Incisive Health morning Club

ELPA Vice President Mr Julio Burman was part of the 4th Incisive Health morning Club on May 20, 2021. This episode was dedicated to rare diseases. Incisive Health is a healthcare policy and communications consultancy. This discussion drew attention to the critical role of the European Reference Networks (ERNs) in supporting rare disease patients in Europe. During the 1 hour virtual breakfast, experts leveraged the current debate around rare diseases, highlighted national perspectives and explored the importance of ERNs by giving a voice to patients, healthcare professionals, industry representatives, academia, and other key stakeholders. The discussion was introduced by **Francesca Scassellati Sforzolini**, Managing Director of Incisive Health Brussels and moderated by **Eduardo Pisani**, Strategic Advisor to Incisive Health. Participants were **Dr Holm Graessner**, European Reference Network for Rare Neurological Diseases, **Prof. Robert Nisticò**, Committee for Orphan Medicinal Products (COMP), EMA, **Dominique Sturz**, Alliance Pro Rare and **Dr Matthias Wilken**, Bundesverband der Pharmazeutischen Industrie.

European Week against Cancer

ELPA participated in the Webinar series organised from May 25 to May 31 2021, focusing on cancer complications and comorbidities. European Week Against Cancer (EWAC) takes place between 25 and 31 May each year under the leadership of the Association of European Cancer Leagues and is concluded by World No Tobacco Day on 31 May. During EWAC, cancer charities, European policy-makers and the general public engage in various activities connected to awareness raising about cancer prevention, access to treatment and support for patients and cancer survivors.

ELPA participation in EASL-ILC 2021

ELPA and its members followed the entire EASL-ILC 2021 for four days (June 23-26, 2021) of deep insights on liver disease.

However, this year, ELPA was also present and visible through many activities proposed by the congress.

ELPA President **Marko Korenjak** was among the prominent guests during the open ceremony, with **Dr Salvatore Piano MD**, a member of the ELPA Scientific Committee and EASL Young Investigator. **Dr Sabela Lens MD**, a member of the ELPA Scientific Committee, was also part of the EASL Young Investigator team.

On the front of social media communication and dissemination, ELPA Director **Milan Mishkovikj** was part of the group of Twitter Ambassadors. A task force, which also included Dr Piano, was made to reach as many people as possible.

Moving to the scientific front, **Prof. Dr Gamal Shiha MD**, ELPA Director and a member of the ELPA Scientific Committee, spoke at:

- Development and multicenter external validation of FIB-6; a novel, machine-learning, simple bedside score to rule out severe liver fibrosis and cirrhosis in patients with chronic hepatitis C
- Effect of subcutaneous semaglutide on quality-of-life in patients with non-alcoholic steatohepatitis - PO-0231
- Abstract session: Viral hepatitis clinical management
- International multicenter validation of GES score for HCC risk stratification in CHC patients

Last but not least, ELPA is part of four out of five EU-funded medical, scientific projects presented during the congress.

A-TANGO - Treatment of ACLF is an unmet need. Based upon their clinical and pre-clinical studies, the consortium aims to perform Phase 2 clinical trials of a novel, patented, and innovative therapeutic strategy.

DECISION - This project aims to enhance our systems-level understanding of the pathophysiology of cirrhosis decompensation by multi-omic profiling of sufficiently large cohorts of patients.

LIVERSCREEN - It develops a personalised screening program to identify persons with pre-symptomatic, significant chronic liver disease among the general population.

MICROB-PREDICT - The consortium joins forces to understand how the human microbiome contributes to the development of liver decompensation and ACLF.

ELPA's involvement in EASL-ILC 2021 showed how ELPA is engaged in multiple ways to fight liver disease, from patient advocacy to scientific contribution, without forgetting how vital communication and dissemination of information are for the patients' community and beyond.



Unmet needs & challenges in access to treatments in Europe: The case of Chronic Kidney Disease

This webinar was organized by the European Kidney Health Alliance (EKHA) on June 18, 2021, as part of the Decade of the Kidney™ campaign, an EKHA-led initiative that aims to put the spotlight on Kidney Disease at the EU level for the next ten years. The event focused on addressing the challenges of access to all types of kidney disease treatments in Europe, including home dialysis, transplantation and secondary prevention to combat CKD progression. In addition, the event explored how to mitigate the negative impact of COVID-19 on access to kidney care and promote information and education about different treatment options to both health professionals and patients. ELPA was pleased to take part in it.

EFPIA & EFGCP Multi-Stakeholder Workshop on Paediatric Unmet Medical Needs

Paediatric Unmet Medical Needs (UMNs) is a significant concern in the management of diseases in children not only by the paediatric community but also by both the EC and the EMA, which released a joint action plan in November 2018 subsequently updated in 2020. In 2020, important changes for the regulatory framework occurred, with the EC publishing significant documents relating to the revision of the Paediatric and of the Orphan Regulation. The revision of these two legislations is also one of the actions of the Pharmaceutical Strategy for Europe released in November 2020. As a result, legislative and non-legislative proposals to amend these two regulations are expected by the end of 2021/early 2022. In this context, and as a follow-up to the 2019 EFGCP-EFPIA workshop, a second workshop was proposed to identify criteria to help define paediatric UMNs using four conditions as case examples: Asthma, NASH, Duchenne Muscular Dystrophy and Haemophilia. ELPA joined the discussion on June 28 and 30, 2021.

Politico - Improving Europe's Health Technology Assessments

On July 13, 2021, some ELPA representatives participated in the meeting organized by POLITICO 'Improving Europe's Health Technology Assessments'. Europe's health care systems aren't feeling very well—something the current pandemic isn't improving—and Health Technology Assessments (HTAs) are at the heart of the strategy to improve their quality, efficiency, and sustainability. They have been put in place to move towards more value-based and evidence-driven decision-making in health care, concerning everything from pharmaceuticals to devices and procedures.

While HTAs are key in ensuring new drugs and medical devices, deliver meaningful innovation for patients and good value for money for health systems, cooperation between the more than 50 HTA bodies in the EU is still voluntary. The European Commission's proposal to strengthen HTA cooperation between member states has been mired in talks since it was first put forward in 2018—but trilogues with the Parliament and Council have finally reached an informal deal. If planned out successfully, this text could open the door to more cooperation, more efficiency, and a less fragmented internal market—resulting in a more competitive sector and fairer access to valuable drugs across the EU.

Clinical Trials Information System (CTIS) webinar: How sponsor organisations can prepare for CTIS

Clinical Trials Information System (CTIS) will act as the single entry point for clinical trials authorisation and supervision in the EEA. CTIS was created as part of the EU Clinical Trials Regulation (Regulation (EU) No 536/2014).

This European Medicine Agency (EMA) hosted webinar organized on July 29, 2021, was open to all sponsor organisations, including pharmaceutical companies, contract research organisations, small and medium-sized enterprises (SMEs) and academic organisations. ELPA was among the attendees.

Topics presented during the webinar included how sponsor organisations can prepare for CTIS, how Member States aim to support sponsor preparedness and adoption of CTIS, the role of the Clinical Trial Regulation and how sponsors can best use EMA's CTIS training materials.

ESMO Public Policy Webinars on the Clinical Trials Regulation

The Clinical Trials Regulation, adopted in April 2014 and foreseen to become applicable in January 2022, will introduce major changes to how clinical trials will be conducted in the EU, aiming to create a more favourable environment for medical research in Europe. Given the importance of this Regulation for research, including clinical trials in oncology, the European Society for Medical Oncology (ESMO) dedicated 2 Public Policy Webinars to this topic:

- The Clinical Trials Regulation and its impact on oncology, held on October 12, 2021.
- The Clinical Trials Regulation - Challenges and burdens affecting non-commercial research, held on October 28, 2021.

ELPA participated in both webinars that brought together the perspectives of EU officials, clinical researchers, patients and medical oncologists on the Clinical Trials Regulation and how this legislation can impact existing challenges and burdens affecting academic and non-commercial clinical research in oncology.

European Health Forum Gastein (EHFG) – Rise like a Phoenix

ELPA Representatives attended the EHFG 2021 held between September 27 and October 1, 2021. This meeting titled "Rise like a Phoenix" put the spotlight on health at the heart of a resilient future for Europe. During the COVID-19 pandemic, equity, health, and solidarity have been more evident than ever as a strong foundation for social stability and prosperity. When the pandemic was approached in a delayed, individualistic and protectionist way, its impact had been much more devastating, resulting in disastrous loss of life and livelihood.

Health has been given a rare spotlight in the political scene. It is of mandatory importance to grasp this extraordinary opportunity to encourage, define, and invest in harmonised health and social care systems so that Europe can rise like a phoenix from this crisis.

Community Webinar on HBV in Europe

On 24 November 2021, ELPA Representatives attended the Community Webinar: HBV Cure Research - The European HBV Patient Registry, promoted by ICE HBV and Liver Patients International. The webinar presented a discussion for the HBV community on scientific progress in Europe towards a cure features the European HBV Patient Registry. In particular, the event focused on the following topics:

- HBV cure research 101.
- Clinical perspective on HBV cure research.
- Community perspective, Hep active.
- The European HBV Patient registry.
- IPcureB Project & Clinical Trials.
- HBV and migrant in Europe Comsava project.

During the Q&A session, other interesting topics were discussed:

- Trials underway in Eastern Europe.
- International (clinical) studies (challenges even within Europe, etc.).
- Difficulty of doctors (in Bulgaria) finding patients for clinical trials.
- How can we influence EU regulations to make international clinical trials easier?

EASL Patient Forum

On November 30, 2021, ELPA representatives attended the EASL Patient Forum. Patient advocates, healthcare specialists, and other experts gathered for an engaging discussion around the status of health literacy, with a particular focus on literacy-related to liver health. Health literacy has gained considerable attention globally in recent years. Health literacy is the extent to which individuals are able to obtain, understand, process and use basic health information and services that they need to make appropriate and well-informed health decisions. Research shows that low health literacy level is associated with higher hospitalisation rates and longer hospitalisation periods, among other challenges.

EPF Meetings

ELPA joined the European Patient Forum (EPF) in 2011, making 2021 the year of our 10th anniversary as proud members of the EPF.

EPF webinar on the evaluation process of the Cross-Border Healthcare Directive

On March 23, 2021, ELPA representatives participated in a webinar organized by the European Patients Forum (EPF) to inform and engage EPF members and the broader patients' community on the ongoing evaluation and consultation work on the Cross-border Healthcare Directive (2011/24/EU). EPF presented an introduction to the EPF's work on the Directive. European Commission representatives raised awareness on the ongoing evaluation of the Directive and touched on the role of European Reference Networks in the evaluation context. The webinar also focused on how EPF Members and patients can engage in the consultation process. Participants finally had the chance to discuss and share patient experiences in cross-border healthcare using the Directive's provisions.

Patient Engagement Open Forum

The Patient Engagement Open Forum went online with a series of virtual events on April 14 and 15, 2021. The Forum represents a patient-centred environment for co-creating solutions with and by all involved stakeholders to practice and advance patient engagement (PE). Some ELPA representatives took part in both sessions, getting an in-depth overview of the impactful collaborative workstreams in the patient engagement ecosystem and networking with professionals from the healthcare industry, patient advocates and organisations, regulatory representatives and non-profits that are working together to make patient engagement the norm through tools, recommendations, good practices, framework and capacity building. The PE Open Forum was jointly organised by PFMD, EUPATI and EPF.

EPF Annual General Meeting 2021

As an EPF member, ELPA participated in the 2021 EPF Annual General Meeting on April 17, 2021. The event allowed EPF members to share their experiences and views and reflect on EPF's development and their role within the organisation. Members also voted for the election of four board members whose two-year term of office came to an end and for a new Youth Group board member. An overview of the budget was also provided.

EPF webinar - "Understanding AI" webinar series, titled "From Science Fiction to Reality"

As an EPF member, ELPA participated in the webinar: AI in Healthcare: 'From Science Fiction to Reality' on July 8, 2021. It introduced the concept of AI and its implication in healthcare and a case study and the AI Fund. The webinar covered the pros, cons, possible attention points and benefits of AI for patients. This

meeting was the first one of the 'Understanding AI webinar series'. As one of the core activities supported by the EU AI Fund, the overall objective of the webinar series is to shed light on AI in healthcare. The series will particularly focus on the possible advantages but also risks and pending questions for patients while exploring specific implications for the healthcare sector. The 'Understanding AI webinar series' will present complex technical content in an understandable and engaging way to equip the European patient community with the necessary know-how to shape and present the patient perspective on a new and increasingly important policy topic that is becoming an important field of policy discussion both at European and national level.

EPF Congress 2021 - Digital transformation of healthcare: The added value of patient partnerships

ELPA Representatives attended the Second EPF Congress held between 26-29 October 2021. The objectives of the Congress were to explore patients' needs, best practices and policy solutions in different contexts, such as:

- the digitalisation of health and care systems,
- Health data for better quality and patient-relevant outcomes,
- Patient empowerment, digital health literacy and co-design in digital health, and
- the exploration of safety, ethics and equity in the digital health context.

EPF webinar - "Understanding AI" webinar series, titled "AI in Healthcare: Ethics and Implications"

Why do patients need to ask themselves questions about the ethics of AI in healthcare? On December 13, 2021, EPF organised the second webinar of the series "Understanding AI" titled "AI in Healthcare: Ethics and Implications". Participants had the pleasure of hearing from Heidi Mertes, an associate professor in medical ethics at Ghent University, where she teaches bioethics, medical ethics, moral philosophy and global health ethics. Her academic research focuses on the ethical implications of innovations in healthcare. She is currently the principal investigator of the ERC-funded project DIME, focusing on the impact of disruptive innovation in healthcare on medical ethics and on shifting responsibilities in healthcare.

ELPA in international meetings

Paris Hepatology Conference

The 14th Paris Hepatology Conference was held fully digital on March 8-10, 2021. ELPA President Marko Korenjak and some ELPA Directors participated in it, taking advantage of a great overview of current advances in hepatology. The PHC is an independent educational meeting on the management of liver diseases. During the last conferences, they gathered up to 1000 specialists from more than 60 countries. This year's topics included hepatitis B, hepatitis Delta, advances in diagnosis and prognosis, hepatocellular carcinoma and end-stage liver disease.

The 1st International Conference on Rare Diseases

ELPA took part in the 1st International Conference on Rare Diseases that took place on March 1-2, 2021. The conference was co-organized by "95", Hellenic Alliance Greece and Heath Daily of Bousias under the auspices of H.E. the President of the Hellenic Republic, Mrs Katerina Sakellaropoulou. More than 50 distinguished international and Greek speakers were hosted, conveying the latest developments, the Rare Diseases strategy and important new data for research, new innovative therapies and policies promoted at European level for rare diseases, giving rise to further dialogue and analysis of local needs. For the first time, an attempt was made to capture the entire journey of Rare Patients from Diagnosis to Access to the treatments and care they need. Through the exchange of knowledge, ideas, and suggestions, these two days aimed to discuss appropriate practices and policies that will help health systems better meet the needs of the 30 million people living with a Rare Disease in Europe.

The International Experience Exchange with Patient Organisations

The International Experience Exchange with Patient Organisations (IEEPO) is a global platform of engagement for the patient community and other healthcare stakeholders to co-create and collaborate and to be strong partners with an equal voice in the dialogue to transform the future of healthcare together. IEEPO has evolved from being a once-a-year event to becoming a continuous series of connections, tools and resources to inspire the patient community worldwide and provide ongoing learning opportunities. The theme for this year's IEEPO is: "Uniting for Change: Transforming healthcare together." Firstly, ELPA participated in the kick-off meeting on March 22-23. The meeting was the occasion to bring to the community a combination of thought-leadership through the voices of leading experts and meet and engage with the CEO of Roche. Then it took part in a series of regional breakouts (23-24 March) to discuss, debate, and reflect on the issues affecting the patient community most in the current environment.

Moving from Hepatitis Discovery to Elimination: NIH Webinar Series on Research Advancing Hepatitis Elimination

The objectives of the series are to highlight ongoing research that can benefit elimination efforts, support translation of research into implementation, and identify additional research needs.

The episode 'Collaborative research on hepatitis C identification and treatment among persons who inject drugs' was organized on April 8, 2021. Some ELPA representatives could listen to ongoing research by the National Institute on Drug Abuse (NIDA) advancing hepatitis elimination among people who use drugs and incarcerated populations.

VHPB advisor meeting

On April 19, 2021, ELPA President Marko Korenjak participated in the Viral Hepatitis Prevention Board (VHPB) advisor meeting. VHPB is an international board of experts in viral hepatitis, offering a platform for disseminating scientific information related to viral hepatitis. ELPA President is among the advisory members who are internationally recognised experts in viral hepatitis and come from international organisations, academia, and national health authorities. Together with the Board, they contribute to the control and prevention of viral hepatitis:

- by drawing attention to this critical public health problem
- by issuing prevention guidance and catalyse the development of recommendations, and
- by encouraging actions to improve control and prevention.

4th Global NASH Congress

The 4th Global NASH Congress took place on April 28-29, 2021. The conference explored the advances being made in research and development in pathogenesis, diagnosis and treatment of the disease. A multi-disciplinary speaker panel gave their insights on these developments as well as reporting on clinical trials. ELPA representatives Yiannoula Koulla – Leader of the ELPA NASH/NAFLD Working Group, and Teresa Casanovas - Leader of ELPA Scientific Committee and ELPA Director, had the possibility to engage a dialogue with the multiple stakeholders who attend this meeting, networking with key opinion leaders, investigators and researchers from across, academia, pharma, providers and regulators.

AASLD / FDA DILI Conference

ELPA President Marko Korenjak and Casanovas, ELPA Scientific Committee Leader and ELPA Director, participated in the AASLD / FDA DILI Conference organized on 20 to 22 April 2021. The AASLD/FDA DILI Conference — Drug-induced Liver Injury: New Developments and Innovations in Patients with Underlying Liver Disease, Cancer or COVID-19 —connected international academic, industry and government participants who are dedicated to the study of DILI in chronic liver disease and cancer with topics spanning into innovative tools in the assessment of hepatotoxic risk and the growing number of best practice consensus reports by public-private partnerships management of DILI in different study populations. Additionally, the meeting had planned sessions on the impact of COVID-19 in the evaluation

and management of liver disease. With virtual communication tools, the conference promoted interaction between faculty and the audience through panel discussions and a live poster session.

The HepHIV Conference

The HepHIV Lisbon & Virtual Conference took place 5-7 May 2021 and involved participants, ELPA included, from across the community, public health and the health system. Due to the COVID-19 pandemic, the HepHIV2021 Lisbon Conference took place via a virtual platform. The conference focused on the latest evidence, best practices, achievements and challenges in the field of viral hepatitis, HIV, tuberculosis (TB) and sexually transmitted infections (STI) prevention, testing and care, highlighting the progress achieved in testing policy implementation since the ECDC integrated testing guidance was released in 2018. The conference also specifically addressed the impact of and lessons learned from the COVID-19 pandemic on the availability and provision of testing and other health services.

6th World Congress of Pediatric Gastroenterology, Hepatology and Nutrition

The congress was a joined meeting between ESPGHAN (European Society for Paediatric Gastroenterology, Hepatology and Nutrition) and FISPGHAN (Federation of International Societies of Pediatric Gastroenterology, Hepatology and Nutrition). From June 2 to June 5, 2021, ELPA could hear about a wide range of topics. In addition to State of the Art and Key Note Lectures from world-leading experts in gastroenterology, hepatology and nutrition, topics covered clinical practice in low-income countries as well as updates from significant stakeholders involved in paediatric health and disease.

In June 2021, ELPA participated in many international meetings organized by ELPA's supporters and dedicated to the patients' community. This proves the long and solid relationship with ELPA's partners.

- 11th Annual BMS Patient Advocacy Forum at the American Society of Clinical Oncology (ASCO) on June 9, 2021.
- AstraZeneca Patient Advocacy Exchange on June 11, 2021.
- BI - Activate Chronic Patients - During and Post-COVID-19 on June 17, 2021.

Regional Consultation for Developing 2022-2030 GHSS on HIV, Viral Hepatitis and STIs

On June 16-17, 2021, ELPA participated in the regional consultation for developing 2022-2030 GHSS on HIV, Viral Hepatitis and STIs, organized by the World Health Organization (WHO) regional office for Europe. WHO/Europe works with many partners on activities related to communicable diseases. In cooperation with governments, WHO/Europe develops norms and standards, guidance and public health tools to help countries implement effective disease prevention and control programmes and address their risk factors.

Alcoholic steatohepatitis (NASH) in 2021: The Multi-system Disease

On June 22, 2021, ELPA took part in the webinar: Alcoholic steatohepatitis (NASH) in 2021: The Multi-system Disease. Non-alcoholic steatohepatitis (NASH) is a major unmet health need and currently a significant, growing worldwide cause of chronic liver disease with an ever-increasing toll on cirrhotic morbidity, hepatocellular carcinoma and liver transplantation. NASH is a multi-system disease with cardiovascular complications, worsening of metabolic dysfunction and other extra-hepatic diseases, such as type 2 diabetes mellitus, chronic kidney disease, or certain extra-hepatic cancers. Both the management and treatment of NASH require a holistic approach. This Pan NASH interactive webinar discussed these important scientific issues with a global and interdisciplinary perspective.

WHA - Policymakers can't wait – moving from global commitment to national action on viral hepatitis

The World Hepatitis Alliance organised a series of webinars around World Hepatitis Day. The first one: 'Policymakers can't wait – moving from global commitment to national action on viral hepatitis', was held on July 20, 2021, with members from UNITE as well as civil society representatives with the main discussion concentrating on how we can overcome the barriers in parliaments, governments, and health systems to fund and implement hepatitis elimination programmes. ELPA was represented by Marko Korenjak, ELPA President.

Key discussion points:

- 1) What is standing in the way of countries acting on the global commitment to eliminate viral hepatitis by 2030? Is it only about finance?
- 2) How can we progress through these barriers towards positive action?
- 3) In countries where hepatitis elimination programmes are in place – what were the contributors to their success?
- 4) What are the messages which will resonate with parliamentarians and will motivate them towards action?
- 5) How can community activists and policymakers work together to make change happen?

Roundtable Discussion: Sharing Perspectives on Priorities for Next WHO Global Health Sector Strategy for Hepatitis Elimination

Organized by the Coalition for Global Hepatitis Elimination on July 29, 2021, the roundtable informed about the WHO development of the new global strategy for hepatitis elimination. ELPA President joined as a panellist and shared his perspectives. Given his long experience with community and patient issues related to hepatitis elimination, he commented on the plan. In particular, he remarked on how the global strategy can assist national and local advocacy and how community and patient concerns are addressed in the priorities for the five strategic areas.

7th Paris NASH Meeting, ELPA among the panellists

On September 9 and 10, 2021, ELPA President Marko Korenjak took part in the 7th Edition of the Paris NASH Meeting. Like in previous years, the meeting brought stakeholders from diverse backgrounds to present and discuss a series of topics that are likely to become highly relevant in the future but are not yet in the spotlight in more traditional NASH meeting venues. Besides clinical aspects of NASH, the program included technologic innovations, precision medicine, advances in pharmacology and regulatory science. This year, besides the US, the faculty was extended to a large panel of European key opinion leaders, achieving science from both sides of the Atlantic. We are very proud to say that ELPA President had the honour to present the Patients' knowledge on their liver disease during one of the congress' sessions.

Hepatic Encephalopathy: What's confusing about treating confusion?

On September 29, 2021, ELPA was part of the Webinar organized by Norgine on "Hepatic Encephalopathy: What's confusing about treating confusion?". This was only the first part. Part II – A multidisciplinary perspective took place on November 26, 2021, and ELPA President Marko Korenjak presented ELPA and its activities during this second day.

Patient Centricity & Engagement Conference

On September 9, 2021, ELPA President Marko Korenjak was among the speakers of the Patient Centricity & Engagement Conference. He gave a presentation together with Pascale Cavillon, Global Patient Centricity Director, Ipsen, on how to collaborate effectively & share common goals with patient organisations to drive improvements in the end-to-end patient experience. Specifically, they discuss:

- How pharma and patient organisations can develop patient experiences together to definitively improve patient experiences.
- Best-practice advice on understanding gaps in the patients' experience and effective ways to boost outcomes.
- Accurately measure and reflect how your patient experience strategies have added value to their experience.

Viral Hepatitis Prevention Board (VHPB) – Advisor Meeting and Public Meeting

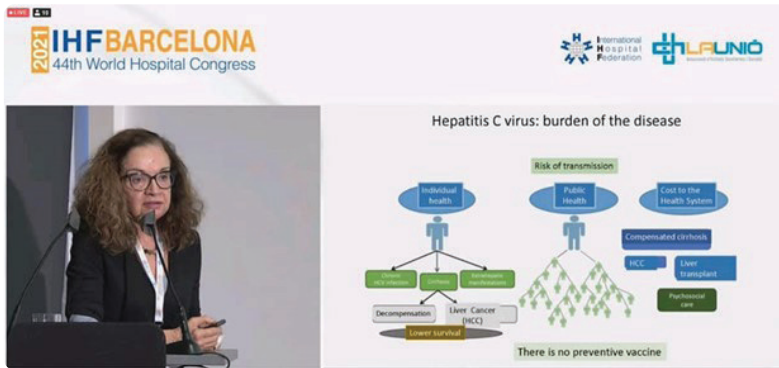
On 27-28-29 October 2021, ELPA representatives attended the VHCP Advisor Meeting and the Public Meeting. The Viral Hepatitis Prevention Board (VHPB) is an international board of experts in viral hepatitis, offering a platform to disseminate scientific information related to viral hepatitis. Their objective is to control and prevent viral hepatitis by drawing attention to this critical public health problem, issuing prevention guidance and recommendations, and encouraging actions to improve control and prevention.

44th World Hospital Congress of the International Hospital Federation

On November 8, 2021, two ELPA representatives, Marko Korenjak, the President of ELPA and Teresa Casanovas, ELPA Director and Scientific Committee Leader, had the honour to present patients' perspectives and needs at a parallel session of the World Hospital Congress of the International Hospital Federation.

Here are some of the take-home messages:

- 1) eat healthy, exercise, and take care of your health. Your liver will thank you,
- 2) patients' voices are needed more than ever in the decision process on health care and treatments,
- 3) a systematic implementation of existing clinical guidelines in Europe is necessary.



Dr Teresa Casanovas, ELPA Scientific Committee Leader and ELPA Director, 44th World Hospital Congress of the International Hospital Federation

9th BUHASDER 2021 Congress

The 9th BUHASDER was held on November 24-28, 2021, in Antalya, Turkey. ELPA President Marko Korenjak presented ELPA, its activities and Hepatitis in Europe. The congress aimed to provide all experts from academia, industry and national laboratories to discuss the latest scientific research and achievements.



Marko Korenjak, ELPA President, 9th BUHASDER 2021 Congress

Attendees listened to world-class speakers discussing the challenges and opportunities facing the field of infectious diseases.

AASLD Meeting 2021

ELPA representatives participated in the annual AASLD meeting on November 12-15, 2021. Patients learned about the latest science through abstract tours, and special educational sessions. This particular track was designed to offer maximum interactive opportunities to ask questions, provide feedback, and discuss with the entire hepatology community. Like every year, the meeting brought together the top minds in hepatology and presented the most cutting-edge science in the field. Meet the Expert sessions allowed attendees to hear from and talk to the world's leading experts on hot topics in hepatology. These informal conversations provided attendees with the avenue to ask questions on various topics and were designed to further discuss the speciality's most pressing issues.

8th HBV Cure ANRS | EID Workshop Webinar

On November 30, 2021, ELPA participated in the 8th HBV Cure ANRS | EID Workshop Webinar. The webinar included plenary lectures with renowned speakers and roundtable discussions to present the most relevant and frequently asked questions about the management of hepatitis B. The webinar was divided into three sessions. The first one was dedicated to basic science, the second to translational research and the last to clinical science.

The future of Liver Cancer - The 35th BCLC Anniversary

This event celebrated 35 years of the Hepatic Oncology group within the Hospital Clinic de Barcelona -internationally known as Barcelona Clinic Liver Cancer (BCLC). For this reason, it was decided that November 22 would have been the official presentation of the BCLC Classification new version – BCLC 2021. In this version, treatments that have shown benefit in the management of hepatocellular carcinoma between 2018 and the present were incorporated and a new part for clinical practice. This scientific celebration looked at the future of liver cancer, with prestigious contributions by leaders from around the world, who offered their vision and knowledge on different areas of research and addressed aspects of clinical practice in liver cancer for the years to come.

International Viral Hepatitis Elimination Meeting (IVHEM)

Many ELPA representatives participated in the International Viral Hepatitis Elimination Meeting that took place from December 3-4, 2021. Convened in partnership between Virology Education and the Coalition for Global Hepatitis Elimination (CGHE), IVHEM is a global forum for the exchange of practical experiences for translating diagnostic and therapy advances of viral hepatitis into broad applications that accelerate progress towards the elimination of viral hepatitis as a public health threat by 2030. During this two-day meeting, experts in viral hepatitis from around the globe examined current evidence on how to implement programs that improve the prevention of viral hepatitis and increase the number of people accessing

testing and treatment. The program included practical examples of innovative intervention studies, country elimination programs, and novel funding mechanisms for testing and treatment.

Patient Engagement Open Forum 2021

On December 7 and 9, 2021, ELPA participated in the Patient Engagement Open Forum. The PEOF 2021 was a series of 'working' online conferences representing community-led, real-time co-creation with a hands-on approach. The PEOF 2021 was organized entirely online as a series of events, once every quarter. The events spanned over two afternoons, back-to-back, four times a year: April, June, September, and December. In December's event, attendees could participate in the following sessions:

- Engaging young patients and their parents in medical devices.
- Making Digital Health & Data Accessible.
- Patient Engagements Needs in Platform Trials.
- Global lens on evolving patient engagement landscape, co-creating PEOF 2022.



**EMPOWERING
OUR MEMBERS**

The Israeli National Programme for Hepatitis C elimination, nothing without liver patients' organization

"Patients have the right to know, and the system must let them know." With these words, Mr Burman started the conversation with ELPA.

On the occasion of the launch of the Israeli National Programme for Hepatitis C elimination on February 17, 2021, ELPA reached Mr Julio Burman, ELPA Vice-President and leader of the ELPA Working Group on clinical trials. Yet today, Mr Burman is, above all, a key player, together with the association Hetz (the Israeli Association For The Health Of the Liver – ELPA Member), in adopting the Programme.

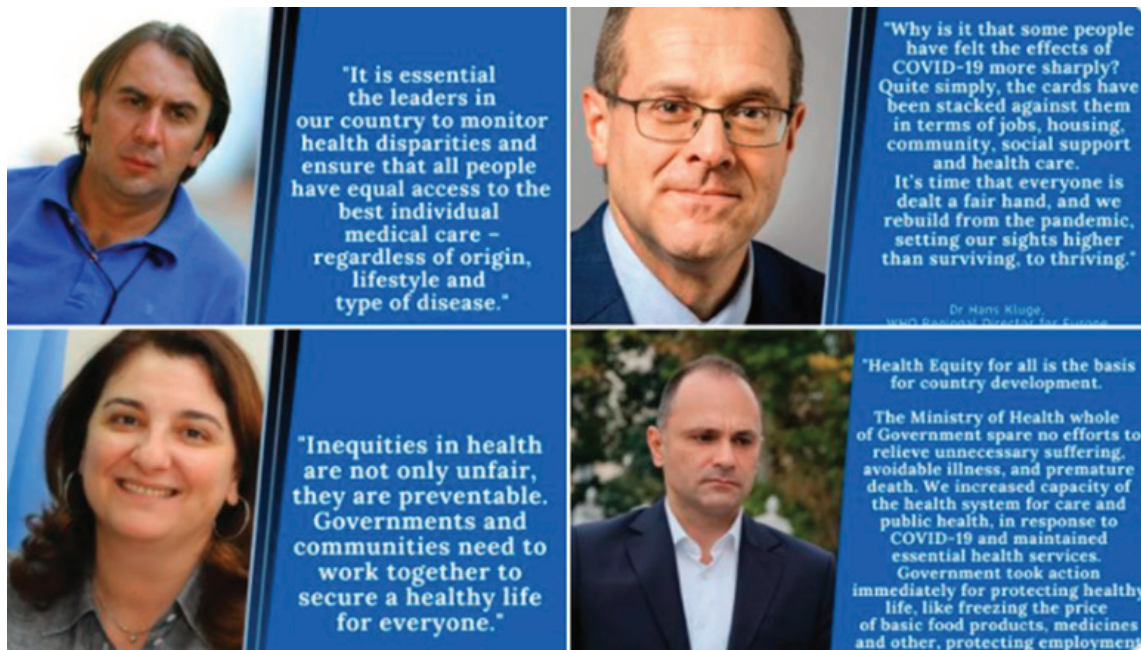
The entire interview can be read on ELPA website.



Julio Burman, ELPA Vice-President, Israeli National Programme for Hepatitis C elimination

World Health Day 2021, ELPA Director Milan Mishkovikj participated in the WHO campaign

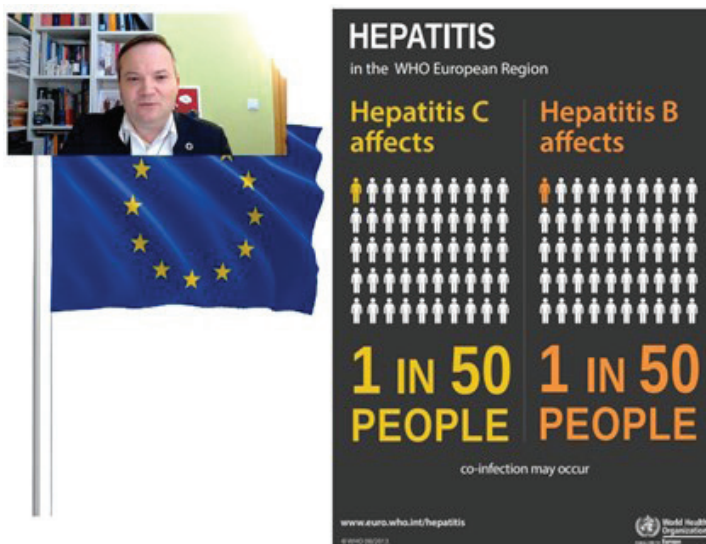
ELPA Director Milan Mishkovikj was invited to participate in the WHO Europe campaign on World Health Day 2021. Together with him, many WHO representatives and Macedonian politicians were testimonials of the campaign. April 7 of each year marks the celebration of World Health Day. From its inception at the First Health Assembly in 1948 and since taking effect in 1950, the celebration has aimed to create awareness of a specific health theme to highlight a priority area of concern for the World Health Organization. Over the past 50 years, this has brought to light important health issues such as mental health, maternal and child care, and climate change. The celebration is marked by activities that extend beyond the day itself and serve as an opportunity to focus worldwide attention on these crucial aspects of global health.



Milan Mishkovikj, ELPA Director - other participants, World Health Day 2021 – WHO campaign

Meeting with Finland’s MPs

Thanks to our collaboration and friendship with ELPA Member Munuaisjamaksaliitto, ELPA President Marko Korenjak had the honour to present patients' voices in front of Finland's MPs on October 20, 2021. A strategy is needed to improve treatment coverage of hepatitis C in Europe. Therefore, ELPA is collaborating with the Finnish Government to draft a new national strategy on hepatitis C.



Marko Korenjak, ELPA President, Meeting with Finland's MPs

The Turkish National Viral Hepatitis Congress

On October 07-10, 2021, Turkey held its 15th National Viral Hepatitis Congress. The meeting was attended by Dr. Hilal Ünalmiş Duda, President of the ELPA Member HEPYAŞAM. She also presented during the round table meeting about “Where are we in the Hepatitis program”.



Dr. Hilal Ünalmiş Duda, HEPYAŞAM - Turkish National Viral Hepatitis Congress

RVC PACOS | Patient Collaboration Summit 2021

ELPA Representatives attended the RVC Patient Collaboration Summit held between 12 and 13 November 2021. We are happy to say that Marinela Debu, President of the Romanian Association for Patients with Liver Diseases – ELPA Member, presided the discussion board on patient advocates' information and education.

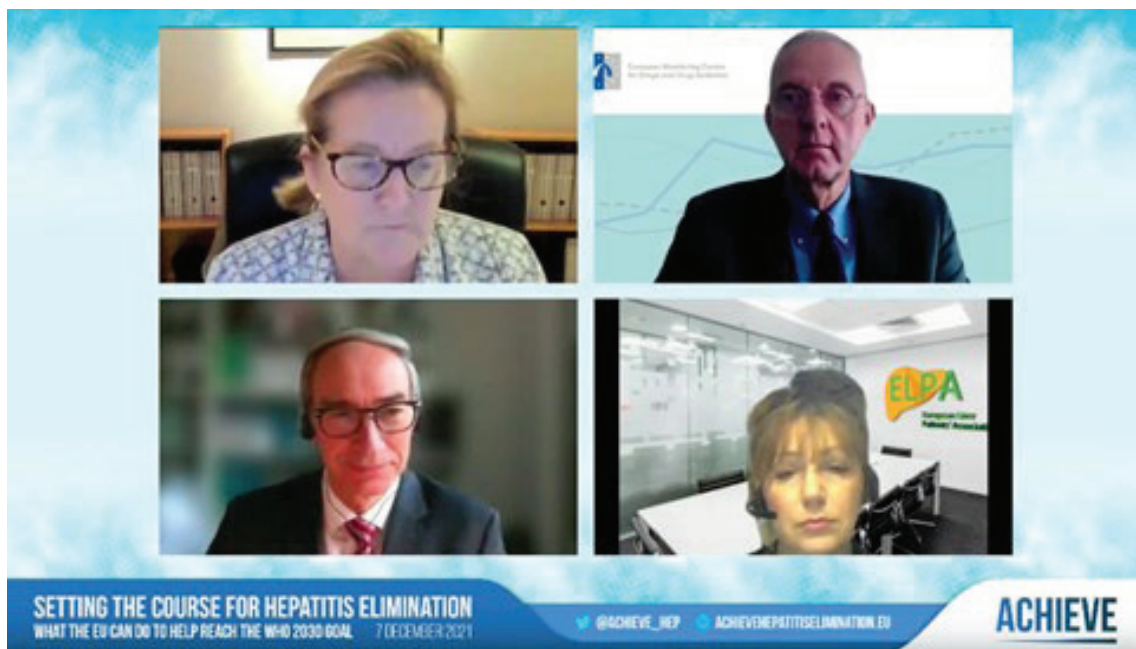
During this summit, organized by Boehringer Ingelheim RCV GmbH & Co KG, international representatives from the patient community, healthcare professionals and Boehringer Ingelheim shared their thoughts on the importance of collaboration between the various groups to provide better healthcare for patients. In particular, the discussions focused on

- How can patients partner with the pharmaceutical industry to improve patient outcomes.
- How can we improve access to care and treatment for patients in RCV.
- How to strengthen patient voice in policy discussions.
- Clinical trials: How to raise awareness and improve access to clinical trials among patients in RCV.
- How to improve HCP and patient cross-functional collaboration for better access of patients to care and treatment.
- How to utilize the use of digital channels and tools to improve patient outcomes.
- Information and education of patient advocates.
- How to reach out to the patient community and to raise awareness on rare diseases indications.

Setting the course for Hepatitis elimination – what the EU can do to help reach the WHO 2030 goal

On December 7, 2021, ACHIEVE organised a webinar to raise awareness of the urgent need to put viral hepatitis B and C elimination on track and explore how EU policy initiatives and funding can help Member States drive forward elimination and facilitate good practices throughout the EU, also supporting the EU neighbourhood. ELPA Director and Treasurer Ivana Dragojevic was among the speakers.

In 2016, the WHO adopted its global strategy to eliminate viral hepatitis B and C as a public health threat by 2030, building on the UN SDGs. On the occasion of World Hepatitis Day 2021, the ECDC pointed out that the 2030 elimination target will not be reached if the gaps in prevention (harm reduction, vaccination), diagnosis and treatment, and the provision of reliable national data are not urgently addressed. The ECDC's assessment is based on data from 2019, so the situation is likely to have worsened since then due to COVID-related disruptions. At the same time, there is a glimpse of hope, as, in the words of the ECDC, "COVID-19 has demonstrated what can be achieved in a short time in communicable disease control. It highlights the potential for achieving the hepatitis elimination targets by 2030, given the highly effective diagnostic and therapeutic tools that are now available".



Ivana Dragojevic, ELPA Director and Treasurer, ACHIEVE meeting



**STRENGTHENING
OUR ASSOCIATION**

ELPA Educational Training – spring edition

'Therapies for acute decompensation of cirrhosis and ACLF, research needs and outlook.' Under this title, ELPA presented, on June 9, 2021, its first Educational Day dedicated to DECISION, MICROB-PREDICT, and A-TANGO, all projects ELPA is involved in.

Three EU-funded research projects, MICROB-PREDICT, DECISION, and A-TANGO, joined forces to improve the prevention and treatment of cirrhosis. All three consortia aim to understand the disease better and identify biomarkers and mechanisms that predict when the body can no longer compensate for the dysfunctional liver (decompensated cirrhosis) when decompensated cirrhosis progresses to acute, chronic liver failure (ACLF), and patient's individual treatment response. They strive to develop novel diagnostic tools for earlier and better patient stratification and establish personalized and effective treatment strategies based on the newly identified biomarkers. In MICROB-PREDICT, the focus thereby lies on microbiome-based strategies. DECISION aims to identify new combinatorial therapies, and A-TANGO will investigate one specific, promising substance in a clinical trial.

The projects and their implications for the future management of patients with cirrhosis were discussed during the meeting.

After an introduction by **Prof Dr Rajiv Jalan**, professor of Hepatology University College London, UK, principal investigator A-TANGO, EF Clif, Barcelona, Spain, the first presentation was made by **Prof Dr Pierre-Emmanuel Rautou**, professor of Hepatology Hôpital Beaujon, Inserm UMR, France, principal investigator DECISION, EF Clif, Barcelona, Spain. He gave an overview of existing therapies, drugs, and research needs.



Then, **Prof Dr Jonel Trebicka**, professor of Hepatology Goethe University Frankfurt, Germany, principal investigator MICROB-PREDICT, EF Clif, Barcelona, Spain, presented candidates/pathways/targets that will be important in future, e.g., gut-liver axis, microbiota.

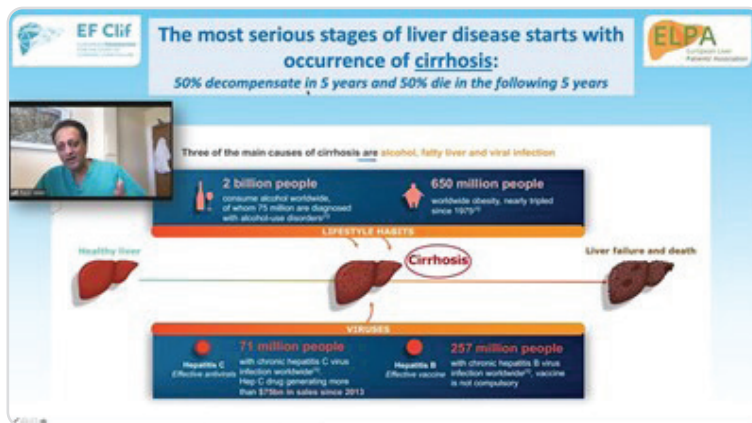
Dr Cornelius Engelmann followed Prof Dr Trebicka. He gave information to the attendees regarding G-TAK as a promising drug candidate in the framework of A-TANGO project.

A questions and answers session, moderated by **Mr Marko Korenjak**, ELPA President, allowed the participants to go deeper into projects' details. A video has been realized for each presentation, and it is available on the related project website.

The second day of the ELPA Educational Training took place on June 23, 2021. After the first day of hosting presentations on Horizon 2020 medical and scientific projects, the second day focused on presentations delivered by pharma companies' representatives.

The meeting started with **Dr Salvador Augustin**, MD from Boehringer Ingelheim, who focused on Boehringer Ingelheim's NASH Pipeline Program updates. First, he stressed the unmet needs in NASH treatment and how this is a complex disease. Then, he gave an overview of BI's upcoming clinical trials in 2021.

After the presentation, a questions and answers session, moderated by Mr Marko Korenjak, ELPA President, allowed the participants to go deeper into details. Attendees were particularly active, and questions were mainly focused on patients' participation in clinical trials, the lack of information and awareness regarding NASH, and how this topic must channel efforts from all the involved stakeholders.



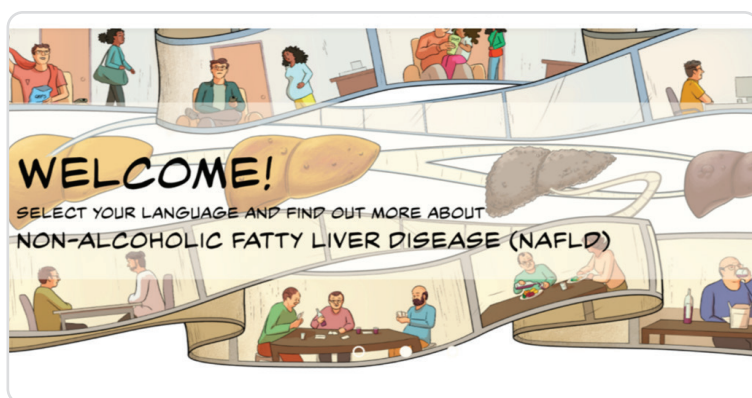
Prof Dr Rajiv Jalan, ELPA Educational Training

The second presentation was delivered by **Dr Ed Tucker**, MD Chief Medical Officer at Mirum. He gave an overview of Mirum's commitment to the field of rare liver disease, detailing how they are addressing rare liver diseases for children and adults. He stressed that there are many unmet needs regarding this topic, which is also why patients' organizations are crucial. In conclusion, he showed the participants Mirum's road to delivering new treatments for rare liver diseases.

Before Mr Marko Korenjak wrapped up the meeting, as it happened after the first presentation, Dr Tucker's talk was followed by many questions primarily related to clinical trials and ICP in pregnancy.

The third day of the ELPA Educational Training took place on June 30, 2021, and focused not only on presentations delivered by pharma companies' representatives.

The meeting started with **Ms Mireia Alemany**, who presented 'A Healthy Liver Will Always Deliver!', a comic to raise NAFLD awareness and promote healthy lifestyles (see interview below). Firstly she explained some general concepts related to why comics are an excellent way to come across medical content. Then she gave more details related to the comics born in the Fois Gras Project framework - funded under Horizon



2020 Marie Sklodowska-Curie program - and in collaboration with: metabolic patients, psychologists, sociologists, and a European network of biomedical researchers.

After the presentation, a questions and answers session, moderated by Mr Marko Korenjak, ELPA President, allowed the participants to go deeper into details. Attendees were particularly active, and questions were mainly focused on the possibility to translate the comic into more ELPA Members' national languages.

The second presentation was delivered by **Dr Florian Abel**, MD, and **Dr Brian Meltzer**, MD, representatives from Alexion Pharma. They gave an overview of Alexion's commitment to the field of two specific rare liver diseases: Lysosomal Acid Lipase Deficiency (LAL-D) and Wilson Disease. They also stressed the patients' journey towards a diagnosis and their challenges.

Before Mr Marko Korenjak wrapped up the meeting, as it happened after the first presentation, Alexion's presentation was followed by many questions primarily related to clinical trials and the importance of working together with patients associations to raise awareness on these two rare diseases.

The fourth and last day of the ELPA Educational Training took place on July 7, 2021. Three presentations from pharma companies were scheduled, and this was probably the most interactive day of the entire training.

The morning started with a representative from Novo Nordisk, **Dr Ichhya Shrestha**, MD - Global Medical Manager, giving an overview of the companies' commitment to NASH. Unlike usual, all the presentations were accompanied by questions and answers from both parts. This last day session was turned into a kind of dialogue between pharma and patients' representatives. NASH is a field that really passions ELPA Members because it represents one of the biggest challenges of the future, and this was also reflected in the exchanges that was mainly based on how to increase the awareness among both patients and medical doctors, the unmet needs in this area, the importance of the name changing into MAFLD and the correlation with other conditions. Dr Shrestha finished her presentation by giving details related to the Novo Nordisk NASH pipeline in clinical development.

After a short break, **Dr Laurent Domas**, VP Global Interventional Oncology Strategy and Therapy Development at Terumo, took the floor. He presented Interventional Oncology as the 4th pillar of cancer care, and he went through different 'tools' in the Interventional Oncology box. Dr Domas also linked these options and procedures to the various stages of liver cancer. He finished his presentation comparing HCC guidelines over the years and showing how today, the focus in this field is improving therapies that preserve liver function for longer survival. He also stressed that the future direction is represented by a combination and personalization of all these therapies. ELPA members asked many questions regarding the therapies presented and, together with Dr Domas, agreed on the importance of having a multidisciplinary team following the patient's journey.

The third and last presentation was delivered by two representatives from Ipsen, **Ms Pascale Cavillon**, Global Patient Centricity Director, and **Dr John Boyer**, Global Medical Director of Oncology. The first part was dedicated to Ipsen's commitment to patients and its proactive approach to patient-centricity. As stressed by Mr Marko Korenjak, ELPA President, this is also proven by the long and fruitful relationship Ipsen has with ELPA. Ms Cavillon then pointed out that by working with people living with conditions, their families, and caregivers, Ipsen can understand the whole picture to help it deliver real and innovative solutions together and faster, making a meaningful difference. Then the focus moved on working with patients' organizations in the field of cancer. Dr Boyer shared a patient experience framework representing patients' journey with HCC. The presentation ended with an overlook to the global/local past collaboration with ELPA on HCC and a glimpse at future activities.

Successful women in ELPA's family

On March 8, 2021 - Women's Day, ELPA organized 'Successful women in ELPA's family,' a talk dedicated to highlighting some success stories of women involved in ELPA. It was the occasion to listen to some inspirational stories inextricably linked to patient advocacy, liver disease, and patients' associations. The event was live-streamed on the ELPA Facebook page.

Our guests were:

Dr Teresa Casanovas, hepatologist, President of the Spanish ELPA Member association ASSCAT, ELPA Director and Leader of the ELPA Scientific Committee.

Ivana Dragojevic, President of the Serbian ELPA Member association HRONOS, ELPA Treasurer, and leader of the ELPA Working Groups on Prevention.

Fergane Heydarova, Vice-President of the Turkish ELPA Member association HepYasam.

Sindee Weinbaum, representative of the ELPA Member Hetz, the Israeli Association For The Health Of the Liver, and the ELPA Working Group leader on Rare Liver Diseases.

Dr Lina Nerlander, epidemiologist, working at the European Centre for Disease Prevention and Control (ECDC).

Pascale Cavillon - Global Patient Centricity Director at Ipsen.

However, ELPA wanted to continue raising awareness and share a positive message on this topic. Thus, it decided to turn the event into six written interviews featuring all the guests available on the ELPA website.



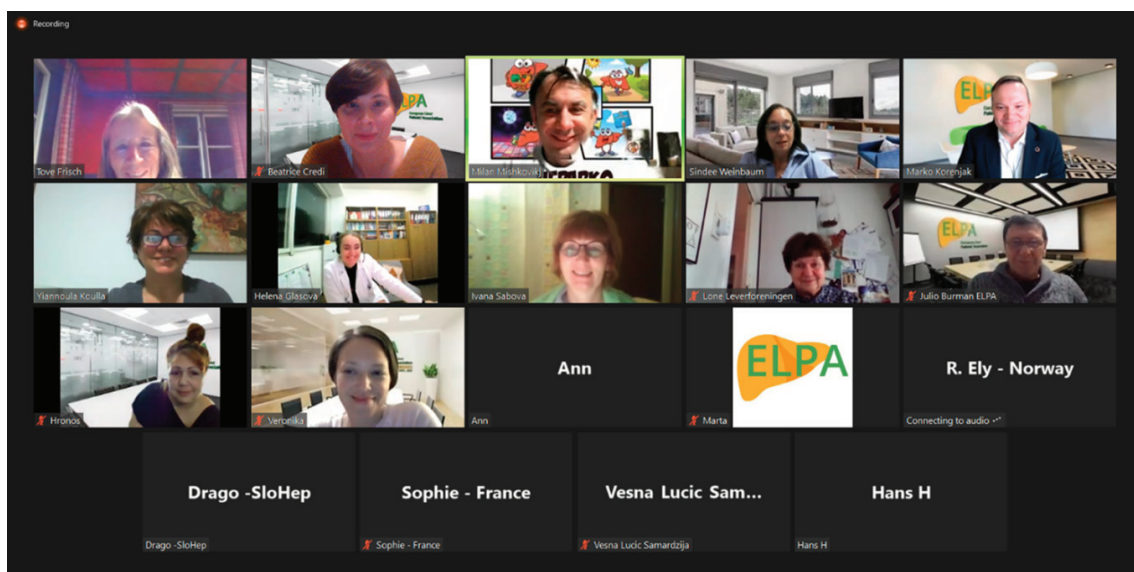
Dr Teresa Casanovas - Ivana Dragojevic - Fergane Heydarova - Sindee Weinbaum - Dr Lina Nerlander - Pascale Cavillon, Veronika Všetickova - Beatrice Credi, March 8, 2021 - Women's Day

ELPA Annual General Meeting 2021

On June 28, 2021, ELPA held its Annual General Meeting. ELPA Members gathered online for the second year in a row due to the current COVID-19 circumstances. During the event, members of ELPA's Board and Secretariat reported 2020 activities and gave an overview of the current and upcoming work for 2021. The event also saw the election of a new full-member organization. ELPA members gave the green light to the Croatian association HUHIV, which was an associate member of ELPA, to become a full-member organization. Congratulations!

ELPA educational training days, autumn edition

As every year, November marks the ELPA Educational Training Days beginning. ELPA members had the opportunity to listen to representatives from pharma companies and the medical field presenting ongoing scientific projects and research. The DAY ONE on 17th November 2021 was entirely dedicated to the industry, with representatives from Norgine, Replicor, and InventivaPharma giving updates on their work in the field of liver disease. On DAY TWO on 24th November 2021 representative from Cymabay gave an overview of their engagement in fighting rare liver diseases. The DAY THREE on 1st December 2021 started with a presentation given by representatives from AstraZeneca and ended with two different sessions. The first one was on the Stigma research, during which **Dr Marta Carol**, research nurse of IDIBAPS, described the project and invited all ELPA Members to participate in it.



ELPA Educational Training, Group Picture

ELPA Stakeholders meeting 2021

On December 1, 2021, ELPA held its annual Stakeholders meeting. After the opening remarks by ELPA President **Marko Korenjak**, **Prof Dr Aleksander Krag** - Vice Secretary at EASL, gave an overview of the EASL's upcoming activities in 2022. EILF activities were instead presented by **Prof Jeff Lazarus** from the EASL Foundation. **Dr Antons Mozalevski** and **Dr Lina Nerlander** presented the work on Hepatitis,

respectively, of WHO and ECDC. Before the first break, **Prof Dr Rui Tato Marinho** - Director of the National Program for Viral Hepatitis, Ministry of Health, and **Dr Ricardo Baptista Leite** - Member of Portuguese Parliament, described the landscape of Hepatitis elimination in Portugal.

The speakers who presented during the second part of the meeting emphasised the achievement of their associations in 2021 and showed the audience what they are planning for the near future. Here is the list of the guests:

Mrs Katarina Ossenberg, - ACHIEVE Coalition Secretariat

Ms Greet Hendrickx - Viral Hepatitis Prevention Board

Mr Eberhard Schatz - C-EHRN

Ms Jessica Hicks - World Hepatitis Alliance

Before the second break, ELPA President Marko Korenjak presented the ELPA Work Plan 2022 and **Dr Teresa Casanovas** - Coordinator of ELPA Scientific Committee, ELPA Director, President of ASSCAT (Asociación Catalana de pacientes hepáticos) described the ELPA Scientific Committee activities planned in 2022.

The session after the coffee break focused on building communication and a network among patients' groups in the upcoming year and the importance of being involved in strategic and policy discussions for the patients' communities. It was organized as a round table debate hosting **Mr Marco Greco** - President of European Patient Forum (EPF), **Ms Zorana Maravić** - CEO Digestive Cancers Europe (DiCE)- **Ms Sari Hogstrom** - The European Kidney Patients Federation (EKHA), **Ms Vicky Mooney** - Patient Advocate and the Executive Director of the European Coalition for People living with Obesity (ECPO).



Marco Greco - Zorana Maravić - Sari Hogstrom - Vicky Mooney, ELPA Stakeholders meeting



ELPA IN SCIENTIFIC RESEARCH PROJECTS

ELPA continued to join and participate in numerous EU projects, mainly in disseminating and “translating” medical and scientific objectives and results to the general public, patients, and relatives. Since January 2021, ELPA has been part of the consortium of the following EU projects funded by Horizon 2020: Liverscreen, LiverHope, Decision, Galaxy, MICROB-PREDICT, IPCureB, A-Tango, and FisPlat (EITHealth). In addition, it is part of ESCALON and COBALT. In 2021 ELPA was waiting for the evaluation and approval of more projects. It worked with many partners on new collaborations in the framework of the new EU Horizon Programme.



Medical research project Galaxy, Horizon 2020

Medical research project GALAXY brings together partners with unique research competences in clinical hepatology, microbiome, multi-omics, biomarkers and bioinformatics. The aim of the project partners is to develop novel systems medicine tools which integrate clinical, multi-omics and lifestyle information from alcohol over-users at various stages of the disease and healthy individuals in order to: 1) identify signatures of host-microbial cross-talk during disease development and progression, 2) translate this into biomarkers for diagnosis, stratification and treatment monitoring in alcohol over users, and 3) evaluate new interventions to modulate gut microbiota towards prevention and mitigation of the disease in at-risk individuals. Project partners will also study societal and economic impact of medical research project GALAXY biomarkers and treatments to accelerate future development.



Medical research project Liverhope, Horizon 2020

The objective of Liverhope is to evaluate a novel therapeutic strategy for patients with decompensated cirrhosis based on targeting the main pathophysiological mechanisms of disease progression in cirrhosis, 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 that rifaximin modulates the disturbed microbiota and decreases gut permeability and systemic endotoxin levels characteristics of cirrhosis. Moreover, simvastatin decreases systemic and hepatic inflammation, improves the altered hepatic microcirculation, decreases portal hypertension, and reduces fibrosis progression.



Medical research project Microb-Predict, Horizon 2020

Within medical research project Microb-Predict, project partners are investigating the human microbiome to identify predictors and mechanisms associated with the development of decompensation of cirrhosis and progression to acute-on-chronic liver failure (ACLF) and death. The project gathers 22 partner organizations working in different fields.



Medical research project Liverscreen, Horizon 2020

The aim of medical research project LiverScreen is to develop a targeted screening methodology to identify persons with asymptomatic liver fibrosis and cirrhosis among the general population. This methodology involves:

- 4) identification of groups from the general population at high risk of having chronic liver disease,
- 5) screening their liver stiffness with the innovative transient elastography (TE) technology (until now only validated in patients with known liver disease) for diagnosis, and
- 6) determining the right follow-up screening regime. Within the LiverScreen project 8 European countries are collaborating and performing research in over 34,000 subjects to develop the screening methodology and demonstrate its accuracy, clinical value, costeffectiveness, acceptability, and potential to be implemented by healthcare systems throughout Europe.



Medical research project IP Cure B, Horizon 2020

The objective of the EU-funded medical research project IP-cure-B «Immune profiling to guide host-directed interventions to cure HBV infections» is to develop novel curative concepts for chronic hepatitis B (CHB). The project aim is to improve the cure rate of CHB by boosting innate immunity with immune modulators and stimulating adaptive immune responses with a novel therapeutic vaccine. Researchers are also identifying immune and viral biomarkers for patient stratification and treatment response monitoring. Integration of biological and clinical data enable models for the best combination treatment and effectiveness of novel curative therapies with respect to disease spectrum and patient heterogeneity. The preclinical platform will be evaluated in humanised mice, combining immune-modulatory strategies to stimulate innate immunity,

rescue exhausted HBV-specific T cells and generate anti-HBV adaptive responses. Proof of concept is to obtain in a clinical trial of a combination of novel compounds stimulating innate immunity.



Medical research project FiSplat, European Institute for Innovation and Tehnology – EIT Health

FibroScan Screening Platform (FiSPlat) assess the presence of significant liver fibrosis with an accuracy at least equivalent to the one of the current FibroScan devices (with a sensitivity of 93% and a specificity of 78% using a cutoff of 9.2 kPa). An ergonomic, training procedure, results output and interpretation assistance and an innovative business model, makes the technology usable in a cost-effective manner for mass screening by nurses and general practitioners. This allow earlier decision-making and a personalized follow up. All together prevent the progression of the disease to liver cirrhosis, its associated worldwide morbidity and mortality, as well as reduce liver cirrhosis management costs.



Medical research project Decision, Horizon 2020

The objective of medical research project DECISION is to enhance our understanding, at systems level, of the pathophysiology of decompensation of cirrhosis leading to ACLF or death. For that purpose, project partners perform a multi-omic profiling of already existing large and clinically well characterized cohorts including 2,200 patients with available standardized biobank samples. The gained knowledge during the process allows the development of prognostic and response tests and of combinatorial therapies tailored to the needs of individual patients or identified groups of patients with acute decompensation of cirrhosis. All these efforts aim to decrease the risk of short-term death of patients with acute decompensation of cirrhosis.



Medical research project A-TANGO, Horizon 2020

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.

ESCALON

ESCALON

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 considers various clinical, environmental and genetic factors for each cancer that could shed light on the mechanisms leading to carcinogenesis and help us understand potential prevention points. The study will lead to the discovery and utilization of biomarkers that could be applied worldwide for early diagnosis and detection of hepatocellular carcinoma, cholangiocarcinoma and gallbladder cancer, improve the understanding and provide identification of risk factors associated with hepatobiliary carcinogenesis that could be targeted for prevention and treatment of such cancers. The consortium is formed by physicians, scientists, epidemiologists, statisticians and media specialists in multiple countries across Europe and South America. Each task, designed to work on a different hepatobiliary cancer, is led by a centre in one continent in close collaboration with a centre in a different continent (Europe and South America).



COvid-19
vaccination and
Biomarkers in
cirrhosis And
post-**L**iver
Transplantation
(**COBALT**)

COBALT

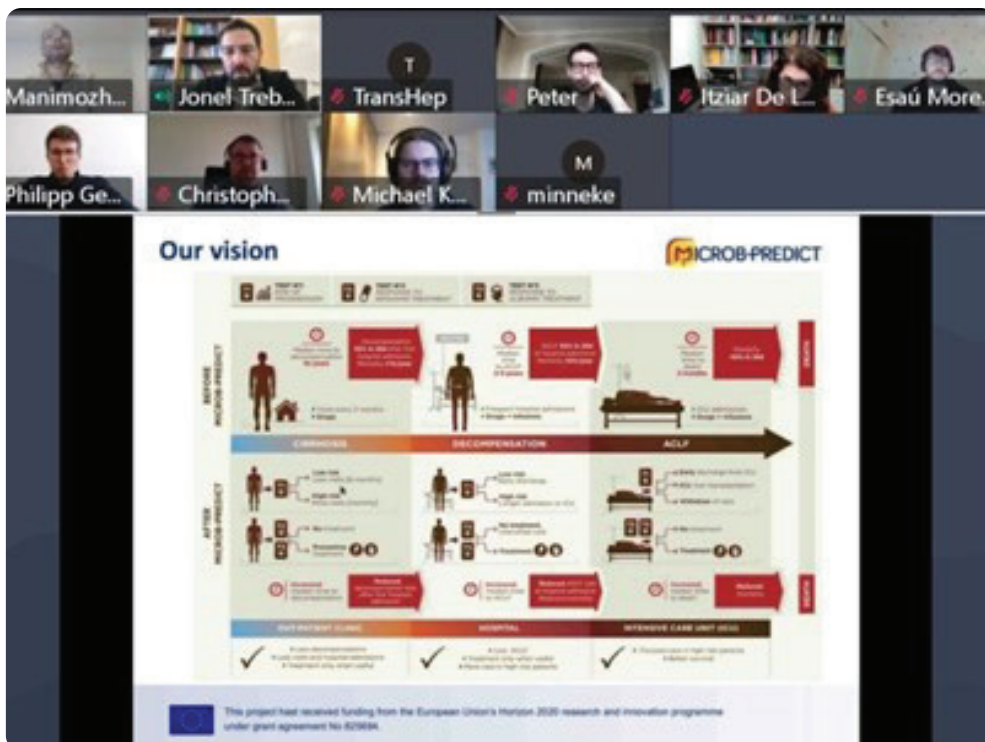
The Covid-19 pandemic has disproportionately affected liver patients - patients with chronic liver disease have around 5-times increased mortality from Covid-19 compared to individuals without liver disease. Therefore, the development of vaccines is a welcomed step, but we don't yet know if they are fully protected 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 to determine if extra protection is needed - such as extra vaccine doses, additional medications, or continued shielding. The COBALT study is taking place across Europe to urgently address this question by measuring responses to vaccination in liver patients. It is designed to report back quickly to inform patients and policy-makers, although further support is needed to accelerate this process and make policy decisions rapidly.

Being part of many medical research projects, ELPA representatives participated in many meetings and initiatives to implement and monitor them.

MICROB-PREDICT Steering Committee Meeting

The 5th MICROB-PREDICT Steering Committee Meeting took place online on January 25, 2021. 22 European institutions join forces in MICROB-PREDICT to improve the prevention and treatment of chronic liver disease (cirrhosis). The project aims to identify microbiome-based biomarkers and mechanisms that predict in advance when the body can no longer compensate for the dysfunctional liver (decompensated cirrhosis) when such decompensated cirrhosis progresses to acute-on-chronic liver failure (ACLF) and a patient's individual treatment response. It strives to develop novel diagnostic tools for earlier and better patient stratification and establish personalised and effective treatment strategies based on such biomarkers. ELPA is part of the medical research project MICROBPREDICT Impact Board. The Impact Board monitors the communication and dissemination and reports to the research project management. Within medical research project MICROB-PREDICT ELPA also:

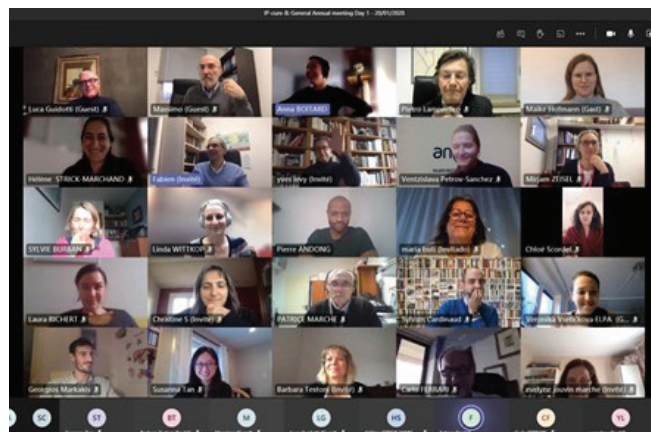
- Provides input to the analysis and policy of the ethical and legal issues in all stages of MICROB-PREDICT.
- Supports the identification of patients affected by liver failure and its impact on society.
- Communicates to the public and to patient communities in Europe.
- Conducts performance evaluation of dissemination activities and impact.
- Collaborates with scientists and EASL in the field of guideline development and updates.



A presentation about MICROB-PREDICT Project

IP-Cure-B General Assembly

IP-Cure-B 1st General Assembly meeting was held on January 20-21, 2021. The project aims at proposing a treatment paradigm shift with the development of novel combination therapies for CHB with improved cure rates and a better appraisal of novel biomarkers to improve patient selection for treatment and monitoring treatment response. Its collaborative network brings together 13 complementary partners, including ten research institutions, one pharmaceutical company, one patient association and one private company from 9 different countries (including 8 European member states). Within the medical research project IP-cure-B, ELPA is responsible for disseminating and communicating the research results and any other information that can be beneficial for patients and patient communities. ELPA is actively engaged in translating the project results and milestones into “patient-friendly” language and incorporating the patient view during the dissemination process. ELPA is also consulted to ensure that the ethics documents, information sheet and patient consent form for the proof of concept (PoC) clinical trial are understandable by patients.



IP-Cure-B Project – Group Picture

Videos about the LiverScreen project

Within the framework of the LiverScreen project in which ELPA is a partner, some videos have been realized as a deliverable of the project. The original video in English has been translated into the eight languages of the Consortium (Castilian, Catalan, Croatian, Danish, Dutch, French, German and Italian).

The project’s goal is to reduce mortality and morbidity from liver disease. Therefore, it aims to set up a targeted, easy-to-use, cost-beneficial screening program for detecting liver fibrosis in high-risk groups within the general population, using transient elastography as a screening tool. The Liverscreen project will screen a total of 30.000 people recruited from different European countries. By analysing the results from the 30.000 subjects recruited, the Liverscreen consortium can validate the diagnostic accuracy, cost-effectiveness and acceptability of using the TE technology to case-find advanced liver fibrosis in the general population. Moreover, LiverScreen will assess the prevalence of liver fibrosis within certain subpopulations based on health risk factors and will use this knowledge to fine-tune the case-finding. At project completion, it aims to have a targeted, population-based screening intervention program for chronic liver diseases in Europe, ready for implementation.

The kick-off meeting of the new Horizon 2020 project A-TANGO

ELPA is officially part of a new Horizon 2020 project called A-TANGO, and it participates in the kick-off meeting of this project on March 9, 2021.

More than 10 million people worldwide suffer from decompensated cirrhosis, often due to severe alcoholic hepatitis (sAH) or other chronic liver diseases. In its final stages, decompensated cirrhosis leads to acute-on-chronic liver failure (ACLF), a syndrome characterized by multi-organ failure. Effective treatment of ACLF is an urgent and unmet need. The A-TANGO consortium performs Phase II clinical studies of an innovative therapeutic strategy that targets inflammation and improves hepatocyte proliferation. We call this novel combinatorial therapy G-TAK. Besides, A-TANGO strives to identify reliable biomarkers for better patient stratification and an increased survival rate.

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

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

Specific aims are:

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

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



A-TANGO Project – Group Picture

IPCureB - Steering Committee meetings

On April 13, June 1, July 20, September 21, and November 9, 2021, ELPA took part in the meetings of the IPCureB Steering Committee. The project's objective is to develop novel curative concepts for chronic hepatitis B (CHB). Within the medical research project IP-cure-B, ELPA is responsible for disseminating and communicating the research results and any other information that can benefit patients and patient communities. ELPA is actively engaged in translating the project results and milestones into "patient-friendly" language and incorporating the patient view during the dissemination process. ELPA is also consulted to ensure that the ethics documents, information sheet and patient consent form for the proof of concept (PoC) clinical trial are understandable by patients. The process of dissemination and communication involves all ELPA's communication channels, and we actively participate in all events organized by the medical research project IP-cure-B. ELPA participated in the creation of webpage social media platforms and made sure of their updates with relevant information.

FisPlat meetings

ELPA took part in two FISPlat project meetings on April 21 and May 10, 2021. The project aims to introduce FISPlat (FibroScan Screening Platform). A cheap, fast, non-invasive method to diagnose early-stage cirrhosis, based on Transient Electrography, without the need for medical specialists. FISPlat is based on a new version of FibroScan, developed to be used in Primary Care. It enables primary healthcare to screen the population at risk, improving early patient stratification and preventing progressive cirrhosis. Within the medical research project FISPlat, ELPA is a part of the 'Different education activities' group that has been planned to raise awareness between the patients and the facultative and caregivers about the advantages of the newly developed device and to disseminate the technology. Each clinical partner organizes at least one educational activity during the three years of the project, in which professionals are given training on how to use the device, support, and educational content.

Raising awareness on #FattyLiver among children

ELPA was back to school. Between May and June 2021, ELPA was involved in the EU Project PaCo, "Participation in Society through Classroom Activities and Cooperation."

The project, financed in the framework of the Erasmus+ programme, involves six countries: Finland, Estonia, Spain, Hungary, the Czech Republic, and Slovenia. It aims to develop students' participation and citizenship education to provide the background knowledge necessary to maintain a civilized society. It also promotes associational activities with NGOs, decision-makers, and local expertise in the schools.

In this context, ELPA President Marko Korenjak had the occasion to talk in front of many teachers coming from the involved countries, about how an International Non-Governmental Organization like ELPA works, its activities in the field of NASH, and he gave an overview of the disease also presenting some material to use with students.

In the second phase, the teachers have transferred the acquired knowledge in the classroom to the pupils. In a simplified language, but wholly and correctly, they could hear about the importance of a healthy liver, how to preserve its healthiness with a proper diet, and some good lifestyle habits.

However, there is more. Now it is time for children from 6 countries to turn all this information into a unique piece of art. Some pictures of posters, collages, draws, etc., were collected by ELPA and posted on ELPA's social media during the following month, teaming up with the national ELPA members from the countries involved in the project.

The cooperation with ELPA Members will continue connecting them with the local schools to push forward the collaboration and the awareness on liver disease.

Liverscreen Consortium meeting

On June 21, 2021, ELPA participated in the Liverscreen Consortium meeting. Liverscreen project will screen a total of 30.000 people recruited from different European countries. By analysing the results from the 30.000 subjects recruited, the Liverscreen consortium can validate the diagnostic accuracy, cost-effectiveness and acceptability of using the TE technology to case-find advanced liver fibrosis in the general population. Moreover, LiverScreen will assess the prevalence of liver fibrosis within certain subpopulations based on health risk factors and will use this knowledge to fine-tune the case-finding. At project completion, we aim to have a targeted, population-based screening intervention program for chronic liver diseases in Europe ready for implementation.

MICROB-PREDICT and DECISION – Online Symposium

On September 2, 2021, ELPA participated in the Symposium 'Management of acute-on-chronic liver failure' organized in the framework of the MICROB-PREDICT and DECISION projects ELPA is part of. The meeting was organised at the occasion of the EASL School of Hepatology. At this symposium, several experts of both project consortia presented recent advances in the fields of microbiome research and systems medicine introduced the role of proteomics and metabolomics in hepatology and discussed treatment strategies and their mechanisms of action in acute-on-chronic liver failure. With almost 100 registered attendees and speakers from 37 countries, the symposium was a great success and a great occasion to exchange views.

DECISION, 3rd General Assembly meeting

ELPA President Marko Korenjak participated in the 3rd DECISION General Assembly Meeting. During DECISION's first-ever hybrid-meeting, 34 participants gathered face-to-face from 8-10 September in sunny Castelldefels (Barcelona), Spain. Additionally, 20 participants joined us remotely via Zoom. Discussions on novel rat models and the clinical study, as well as a poster session for the Early Career Scientists, were only a few highlights. Thanks to the amazing work of all partners, the project is progressing well.



DECISION Project – Group Picture

Microb-Predict, 3rd General Assembly Meeting

The first hybrid-GA meeting - taking place October 6-8, 2021, in Leuven, Belgium - has been successfully completed with 37 participants joining on-site, and over 20 participants remotely. ELPA President, Marko Korenjak, presented the communication impact on the general public of the project, being ELPA responsible for disseminating the results and news regarding Microb-Predict. A lot of data has been presented with promising multi-omics results to develop biomarkers to predict disease progression and response to treatment for patients suffering from cirrhosis and ACLF.



Marko Korenjak, ELPA President, Microb-Predict, 3rd General Assembly Meeting

FiSPlat project

The European project FiSPlat, funded by EITHealth, included the 1st patient in its Post-Market Clinical Follow Up Study in December 2021. Despite the current clinical situation due to the Covid pandemic, the consortium has been able to achieve this important milestone for the project. ELPA is proud to be one of the project's partners.

Lecture at the University of Padova

On April 27, 2021, ELPA President Marko Korenjak was asked to give a lecture in front of some medical school students of the University of Padova. Invited by Prof. Paolo Angeli, Mr Korenjak's presentation was about the communication between patients and doctors. More specifically, the content of the lecture revolved around:

- Evidence-based medicine in patient communication.
- Systemic review in communication skills.
- Calgary-Cambridge Guide.
- Patient communication from a patient perspective.
- Personal stories from patients with vWF Type 3.
- Communication strategies for better grades.

In 2021 ELPA was also involved in the drafting of prestigious scientific articles.

ELPA participation in 'Multi-stakeholder Consensus on Core Outcomes for Decision Making About Nonalcoholic Steatohepatitis Treatment.'

A multi-stakeholder group from North America and Europe was invited to participate in the research with the Delfi method. Participants were categorized into patients/patient advocates, clinicians/researchers, U.S. payers, health technology assessors, industry representatives, or regulators. Participating patients and patient advocates represented a variety of levels of NAFLD disease severity. ELPA was represented by president Marko Korenjak. The research lasted several months and produced very important and interesting results. Outcomes of the research can contribute to decision making for regulatory, market access, and on-market decision making. Including the coreNASH COS in clinical development programs will facilitate improved comparisons and help decision-makers assess the value of new products.



SOCIAL MEDIA ACTIVITIES

SOCIAL MEDIA ACTIVITIES Report by Milan Mishkovikj

Many supporters from all over the world

 **ELPA Website - 2021**

TOTAL VISITS:
422,686

 **Twitter**

FOLLOWERS
8,000

NEW FOLLOWERS
+1429

 **Facebook**

LIKES
2,379

 **Twitter, Facebook**
 **& Others**

IMPRESSIONS
250M



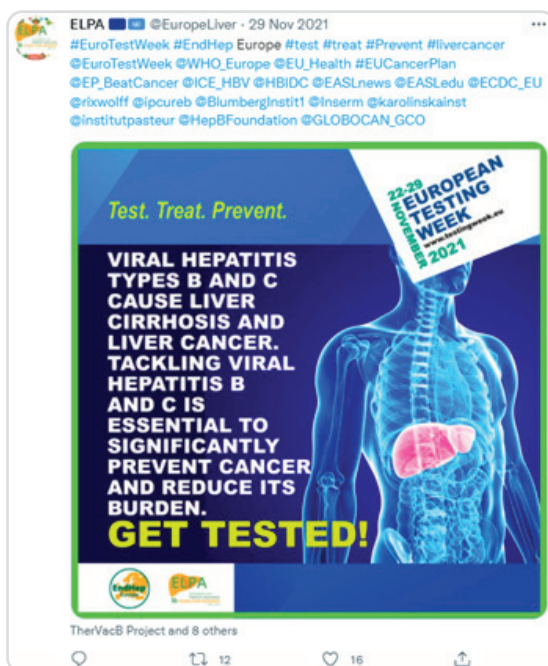
- | Circle 1 | Circle 2 | Circle 3 |
|---|----------------------------------|----------------------------------|
| @FASLnews | @Alkoholpolitik1 | @HepCPartnership |
| @AwarhEurope | @LizHighleyman | @wong_yujun |
| @dice_europe | @AtoosaRabee | @HowardTLeeMD |
| @GlobalHep | @eupatientsforum | @SHAAPAlcohol |
| @jturnesv | @fneth_org | @EASOobesity |
| @sconglymd | @AleksanderKrag | @AASLDFoundation |
| @EUROCARERUSSE@EuropeanCancer | @ATANGO_H2020 | |
| @scafato | @asscatinforma | @aelsharkawy75 |
| | @hepar_center | @EU_Health |
| | @ericcarlin2 | @rixwolff |
| | @JasmohanBajaj | @AndrewMMoon |
| | @MicrobPredict | @BeaCredi |
| | @WHO_Europe | @MKDmilanM |
| | @MunuainenMaksa | @AntiosTx |
| | @ACHIEVE_hep | @BCLC_group |
| | | @heatherleefran |
| | | @NASH_and_coffee |
| | | @Hep_Alliance |
| | | @AASLDtweets |
| | | @rabataffer |
| | | @JVLazarus |
| | | @mromerogomez |
| | | @docamitgs |
| | | @pcureb |
| | | @LancetGastroHep |
| | | @adiazgonzalezMD |



ELPA's most successful Social Media Campaigns

#EuroTestWeek - Spring and Autumn edition

Like every year, ELPA participated in the European online campaign #EuroTestWeek Spring and Autumn edition. The European Testing Week is a Europe-wide campaign that encourages public and partner organizations, communities, and public health institutes throughout the WHO European Region to unite for one week, twice a year, to scale up voluntary testing. It promotes awareness of the benefits of earlier diagnosis of HIV and viral hepatitis infections and effective links to treatment and care while respecting the principle of confidentiality. As the world continues to respond to the COVID-19 pandemic, many communities, especially those most marginalized, continue to struggle with closed, restricted, and/or overloaded services. The European Testing Week 2021 stressed that many communities, especially the most marginalized, continue to struggle with closed, restricted and/or overloaded services. It is urgent to raise awareness of the importance of ensuring access to testing as an essential health service, especially for marginalized and stigmatized populations such as sex workers, people who use drugs, LGBTQ+ people and migrants, who are often most at risk and most in need of targeted services. ELPA called on members and stakeholders to join and support the campaign to advocate and raise awareness about HIV, viral hepatitis, and STI.



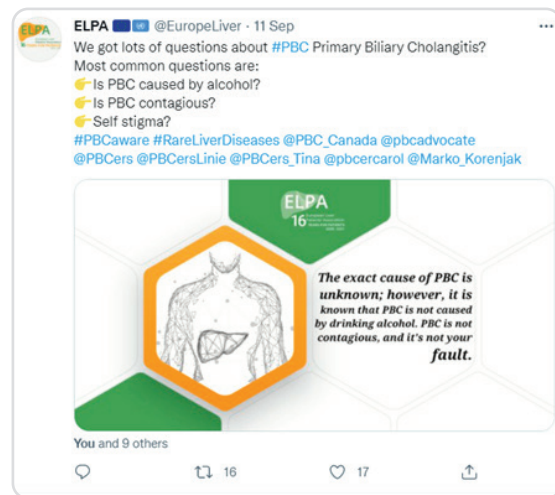
#EuroTestWeek - Spring and Autumn edition

International PBC Day 2021

ELPA was honoured to celebrate International PBC Day on September 13, 2021. ELPA's social media campaign has been a great occasion to raise awareness on primary biliary cholangitis (PBC) among the decision-makers, engage patients, clinicians, and policymakers, push forward the discussion about this disease, and promote better and more comprehensive communication on this topic. In particular, ELPA's campaign focused on how too many liver disease patients fall victim to the unknown. For many liver diseases, their causes and effective diagnostics, treatments and cures remain unclear, which is the reality of rare liver diseases like primary biliary cholangitis (PBC).



International PBC Day



European Awareness Week on Alcohol-Related Harm (AWARH)

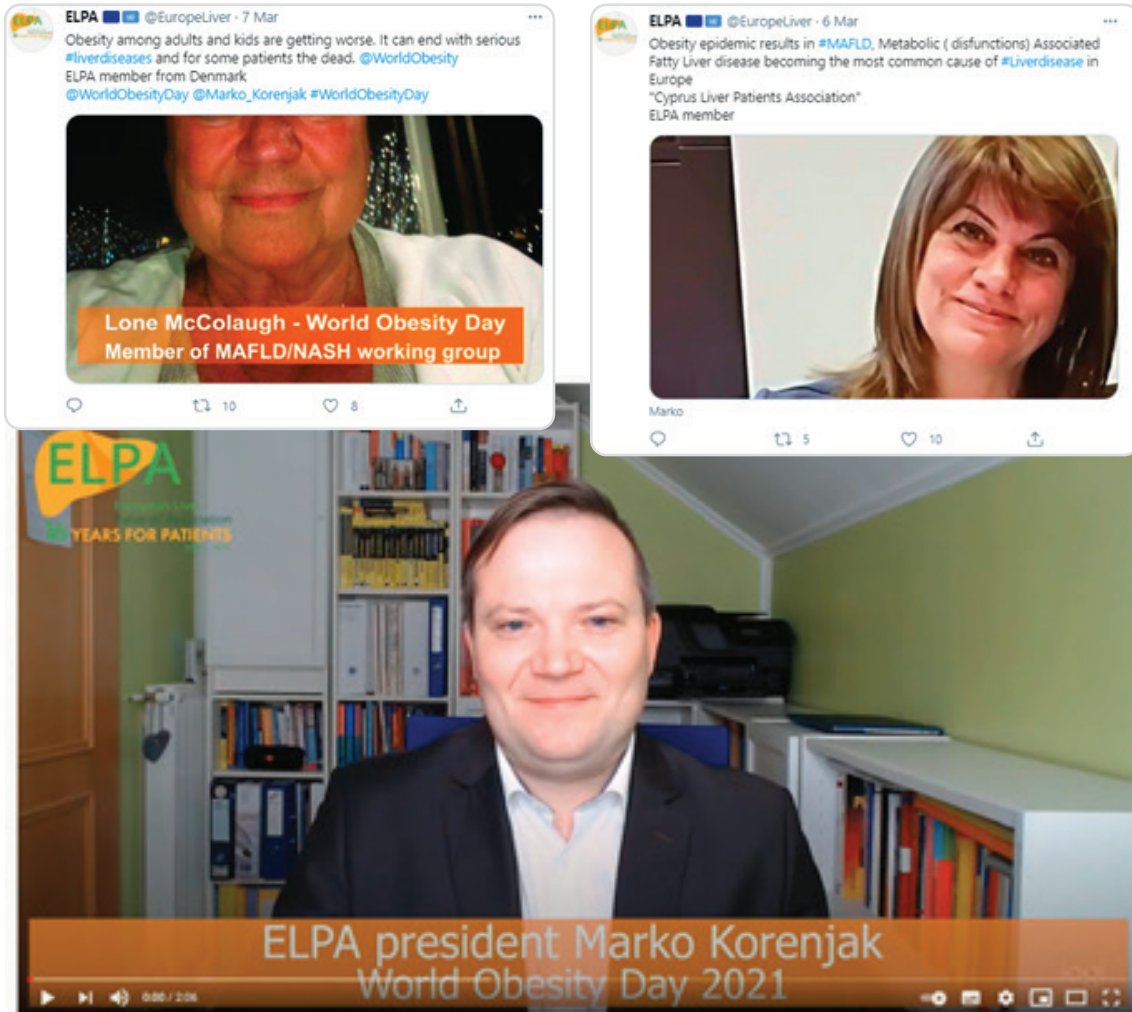
ELPA took part in the 9th Awareness Week on Alcohol-Related Harm (AWARH), held November 15 to 19, 2021, with the theme of "a SAFER Europe". AWARH 2021 focused on two specific SAFER interventions: the restrictions or bans of alcohol marketing, sponsorship and promotion; and the use of taxation and pricing policies as a way of reducing alcohol-related harm to society.



AWARH

World Obesity Day 2021

On March 4, 2021, ELPA President and many representatives from the MAFLD/NASH Working Group of ELPA endorsed World Obesity Day.



World Obesity Day

ELPA's support to its members, stakeholders, supporters and friends' campaigns







ELPA's support to its members, stakeholders, supporters and friends' campaigns











ELPA STRUCTURE






ELPA Board of Directors

President	Marko Korenjak, M.A., M.A.	 Slovenia
Vice-President	Julio Burman	 Israel
Vice-President	Dr. Tove Frisch	 Sweden
ELPA Treasurer	Ivana Dragojević	 Serbia
ELPA Director	MSc. Milan Mishkovikj	 Macedonia
ELPA Director	Prof. Dr. Gamal Shiha M.D.	 Egypt
ELPA Director & Scientific Committee leader	Dr. Teresa Casanovas Taltavull M.D.	 Spain

ELPA Scientific Committee

Scientific Committee leader	Dr. Teresa Casanovas Taltavull M.D.	 Spain
	Dr. Helena Glasová M.D.	 Slovakia
	Dr. Reham Soliman M.D.	 Egypt
	Dr. Salvatore Piano M.D.	 Italy
	Dr. Vesna Lučić- Samardžija M.D.	 Bosnia & Herzegovina
	Dr. Sabela Lens M.D.	 Spain




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Richard Hall	 UK
Greg Bologna	 USA
Dr. Marco Greco	 Belgium
Prof. Dr. Rui Tato Marinho M.D.	 Portugal
Prof. Shira Zelber-Sagi	 Israel

Editorial Team

Leader	Dr. Hilal Ünalmiş Duda	 Turkey
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ELPA Brussels office





Head of EU Affairs	Veronika Všetíčková	 Belgium
Head of ELPA office	Beatrice Credi	 Belgium
	Marta Bragagnolo	 Belgium



ELPA WORKING GROUPS

In 2021, ELPA officially had eight Working Groups. Groups. Headed by a leader, each Group can count up to 5 members. ELPA Working Groups are a way to create Expert Patients in a specific field of liver diseases.

ELPA Working Group on Rare Liver Diseases

LEADER	Sindee Weinbaum		Israel
MEMBERS	Richard Hall		UK
	Lone McColaugh		Denmark
	Tarja Teitto-Tuckett		Finland






In 2021 the Group coordinated many campaigns in ELPA channels: Facebook, Twitter, Instagram, Youtube.

- Rare Disease Day – February 28 – Social Media Campaign.
- PFIC Awareness Day – October 5 – Social media campaign.
- PBC Awareness day – September 12 - Social media campaign.
- Global PSC Awareness Day – October 29 - Social media campaign and Pre-recorded Webinar with leading physicians from all over the world.

For the first time, 2021 marked the collaboration with all major PSC support groups worldwide: USA, Canada, Australia, UK, Spain, France, Italy, Norway, Denmark, Finland, Macedonia, and Israel.

Collaborating with the clinical trials Working Group, the group explained clinical trials and the importance of participating to help find a cure and/or treatment. It also joined Wilsons Disease Steering Committee.

ELPA Working Group on Primary Liver Cancer




LEADER	Dr. Teresa Casanovas Taltavull M.D.		Spain
MEMBERS	Lone McColaugh		Denmark
	Sindee Weinbaum		Israel
	Marko Korenjak		Slovenia
	Milan Mishkovikj		North Macedonia

Liver cancer is a significant health problem around the world. Hepatocellular carcinoma (HCC) represents 80-90% of primary liver cancer, and it is considered one of the leading causes of cancer-related deaths worldwide. Cholangio Carcinoma (CCA) is also a primary liver cancer; however, it is regarded as a rare cancer. The majority of cases of liver cancer develops in a liver with advanced fibrosis/cirrhosis, and the origin of this liver disease is virus, alcohol, fatty liver, potentially prevented with vaccination (hepatitis B), anti-viral treatment (hepatitis C), appropriate lifestyle. Moreover, liver diseases are asymptomatic for many years. Being aware of all of this, at present, the Group considers that when HCC is diagnosed, only approximately 30% or less of patients are diagnosed at an early stage and eligible for potentially curative

therapies. Recently more treatments are available for intermediate and advanced stages, improving survival and quality of life. Early screening with detection and link to care to HCC in specialized centres for patients that we know are at risk is very much needed. Considering CCA, much work needs to be done on diagnosis and therapies. The patient prognosis has not improved substantially in the past decade. ELPA and other groups are working to support and inform patients and families about new clinical research.



Among the most remarkable 2021 Group's achievements, it should be listed: the Patient's Summit on Liver Cancer, in February 2021, the October Liver Cancer Awareness Month, the participation in the presentation of the Liver Lancet Commission with EASL, the Educational Training Program for ELPA members that included Liver Cancer among its topics, and the launch of the White Paper on Liver Cancer with DiCE. The White Paper has also been translated into many ELPA member national languages to help patients and stakeholders worldwide. It should also not be forgotten the synergies with pharma companies, such as Terumo and Ipsen, and with other companies in the field. ELPA Working Group in liver cancer is also building advocacy actions revolving around NASH, alcohol, obesity, and rare liver diseases.

ELPA Working Group on Clinical Trials

LEADER	Julio Burman		Israel
MEMBERS	Dr. Teresa Casanovas Taltavull M.D.		Spain
	Yiannoula Koulla		Cyprus







They met several times virtually and put together their work plan for 2022. The Group was also in contact with Pharma companies. It was responsible for collecting and researching clinical trials in various countries to help ELPA members with up-to-date information. They would like to list Clinical-Trials on ELPA members' websites. They participated in many meetings and webinars about this topic and two members of the Group enrolled in the EUPATI Fellow Programme 2021. The Group is constantly in touch with Pharma companies to keep the Clinical Trial list updated for all ELPA members.

ELPA Working Group on Harm reduction

LEADER	Aleksey Lakhov		Russia
MEMBERS	Philip Spalding		UK

This is a brand new Group that has just started working on the harm reduction topic. Harm reduction refers to policies, programs, and practices that aim to minimize adverse health, social and legal impacts associated with drug use, drug policies, and drug laws. Harm reduction is grounded in justice and human rights - it focuses on positive change and working with people without judgment, coercion, discrimination, or requiring that they stop using drugs as a precondition of support. Harm reduction is well-evidenced to prevent diseases such as HIV, viral hepatitis, and tuberculosis, among others.

ELPA Working Group on MAFLD/NASH

LEADER	Yiannoula Koulla		Cyprus
MEMBERS	Lone McColaugh		Denmark
	Sindee Weinbaum		Israel
	Manuel Weiss Perez		Spain
	Tarja Teitto-Tuckett		Finland
	Veronika Všetíčková		Slovenia

The work of the Group focuses on the following areas.

Research & development

- 1) ELPA NAFLD/NASH small survey. The results were announced at the international level (Paris NASH meeting & ELPA Symposium). A total of 357 people (adults) from five different countries participated in this survey, translated into five other languages. Danish, Spanish, English, Hebrew, and Greek.
- 2) With the help of Dr Teresa Casanovas, ELPA's information page regarding the NAFLD/NASH disease. Has been upgraded.
- 3) The Group supported the movement to change the name of the disease from NAFLD to MAFLD.

Awareness & Education

- 1) ELPA NAFLD/NASH SYMPOSIUM - Fatty liver, an overlooked disease. Overcoming barriers for patients with fatty liver disease - implementing the latest advancements (June 10)
- 2) ELPA SYMPOSIUM Fatty liver – A call to action (September 22)
- 3) Tackling NAFLD/NASH in Europe a roundtable discussion (July 19)
- 4) NAFLD/NASH Call to Action brochure
- 5) NAFLD/NASH Social Media Campaign

Prevention & early detection

LOVE your LIVER. With the support of Dr Teresa Casanovas and the financial aid provided to ELPA members, Cyprus Liver Patients Association put in action a prevention program against NAFLD/NASH disease. The thought behind this program was to protect the most vulnerable Domino, who are the children and STOP the DOMINO EFFECT. The results will be announced at the end of the program, and this will help to understand more the patient journey at a very early age.




Coalitions among stakeholders

With the help and support of ELPA, the Group came in contact with various stakeholders and Associations.

Knowledge brings strength

The members of this group have participated in many international and national seminars and ELPA educational meetings to be updated about the disease and advocate at their best for these patients.

ELPA Working Group on Prevention

LEADER	Ivana Dragojevic,		Serbia
MEMBERS	Julio Burman		Israel
	Marko Korenjak		Slovenia

Primary prevention examines the phenomenon's assumptions, conditions, and causes and looks for ways to avoid them. Secondary prevention seeks to prevent the deepening of the spreading. It focuses on particularly vulnerable groups such as young people, minorities, or the socially disadvantaged. Tertiary prevention aims to prevent a recurrence. This group aims to promote prevention as a critical piece of the puzzle. We are trying to do that by developing two projects, HepFreeBadge -education of professionals in the beauty parlours and Women and HBV.

Long-term goals for the project HepFreeBadge are:

- Standardization of procedures in beauty parlours according to EU standards-sterilization protocol. Modernization and increasing the level of service in beauty parlours.
- Extension of statutory regulations regarding additional controls that include sterilization control.
- Reducing the possibility of transmitting viral hepatitis infection while providing services in beauty parlours and decreasing stigma and discrimination.

Women and HBV project will focus on women, who are someone's girlfriends, wives, mothers, through 12 topics. So the target group is women, but the focus is on the general population. The content of the given topic will be adapted to an ordinary woman without incomprehensible medical terms and focused on real-life situations.

ELPA Working Group on Hepatitis B elimination

LEADER	Marinela Debu		Romania
MEMBERS	Ivana Dragojevic		Serbia

Knowledge and awareness about Hepatitis B (HBV) have always been at the core of the association and a priority for its members. ELPA has been working on Hepatitis elimination since its creation. However, this Working Group, formally established in 2019, has been collecting updated and relevant information to push forward Hepatitis B elimination and achieve this goal in collaboration with other Working Groups. This group aims to provide tools for chronic HBV patients to live their lives as safely as possible.

ELPA Working Group on Cirrhosis

LEADER	Marko Korenjak		Slovenia
MEMBERS	Julio Burman		Israel

The working group on cirrhosis continues to closely monitor the development in this field. The members of the working group collaborate actively in other ELPA working groups on issues connected with cirrhosis. In the year 2021, the working group on cirrhosis increased the level of work of the members. The group is especially proud of ELPA's participation in the Awareness Week on Alcohol-Related Harm (AWARH) 2021. However, considering the importance of this topic, in December 2021, ELPA developed a separate social media campaign to inform about alcohol-related harm during the winter festivities. The result of this campaign was a booklet on how to enjoy holidays with alcohol-free cocktails.



FINANCIAL ACCOUNTING AND TRANSPARENCY

Word from ELPA Treasurer

The financial position of the European Liver Patients' Association remained strong in the fiscal year 2021 despite tremendous challenges resulting from the COVID-19 global pandemic. ELPA achieved this through wise management of expenses combined with a successful fundraising performance.

The fundraising activities conducted during 2021 made the association less dependent on pharmaceutical companies' contributions expanding the proportion of funding coming from different sources.

In addition, the association managed to fulfil all the ISO standard KPIs improving its financial balance compared to the year before.

Ivana Dragojević, ELPA Treasurer

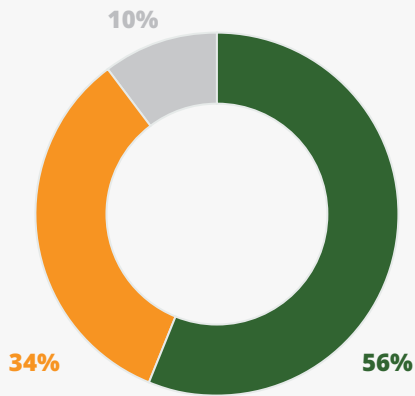
Conclusion from the external auditor

We report to you on the performance of our mandate as contractual auditor of THE EUROPEAN LIVER PATIENTS' ASSOCIATIONS (ELPA). As contractual auditor we have to report to the Board of Directors of the Association. We have reviewed the financial statements of ELPA, with a balance sheet total of EUR 1.067.911 and an income statement with a profit of EUR 50.626. Based on our review, nothing has come to our attention that causes us to believe that these financial statements do not present fairly, in all material respects, the financial position of the European Liver Patients' Associations as at December 31, 2021, and the results of its operations for the year then ended, in accordance with the financial-reporting framework applicable in Belgium.

Publishing financial reports

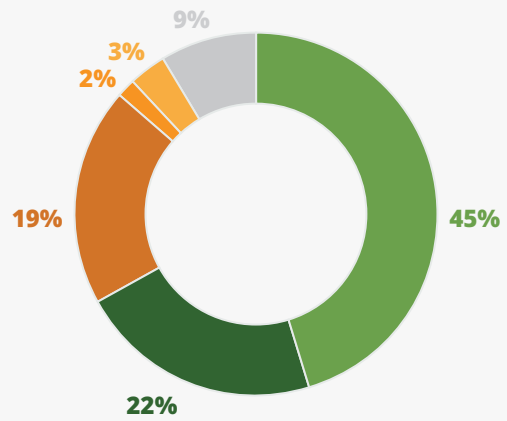
All financial reports of ELPA from 2007 are published every year and can be found on our webpage: www.elpa.eu

Revenue 2021



- Core funding
- ELPA's projects
- EU projects

Expenditure 2021



- ELPA work
- Operational expenses
- Wages and fees
- Depreciation
- Financial charges/income
- EPS - ELPA Project support



European Liver Patients Association

(EUR)	31/12/2021	31/12/2020
Assets		
Fixed assets	51 026,11	57 523,08
III. Tangible fixed assets	47 626,11	54 123,08
B. Plant, machinery and equipment	46 858,08	53 552,04
C. Furniture and vehicles	768,03	571,04
IV. Financial fixed assets	3 400,00	3 400,00
C. Other financial fixed assets	3 400,00	3 400,00
2. Amounts receivable and cash guarantees	3 400,00	3 400,00
Current assets	1 016 884,64	821 884,99
VII. Amounts receivable within one year	0,00	2 968,42
A. Trade debtors	0,00	2 968,42
IX. Cash at bank and in hand	1 006 730,93	791 425,71
X. Accruals and deferred income	10 153,71	27 490,86
Total assets	1 067 910,75	879 408,07
Equity and liabilities		
Equity	824 345,40	773 719,15
III. Reserves	103 552,00	103 552,00
A. Reserves not available	103 552,00	103 552,00
4. Other	103 552,00	103 552,00
IV. Accumulated profits (+)/ losses (-)	720 793,40	670 167,15
Amounts payable	243 565,35	105 688,92
IX. Amounts payable within one year	18 456,09	19 226,42
C. Trade debts	3 969,94	1 177,42
1. Suppliers	3 969,94	1 177,42
E. Taxes, remuneration and social security	14 486,15	18 049,00
1. Taxes	5 372,02	4 151,48
2. Remuneration and social security	9 114,13	13 897,52





X. Accruals and deferred income	225 109,26	86 462,50
Total liabilities	1 067 910,75	879 408,07
Profit and loss account		
I. Operating income	403 947,35	478 803,30
A. Turnover	403 947,35	478 731,30
D. Other operating income	0,00	72,00
II. Operating charges	365 384,43	294 902,18
A. Goods for resale, raw materials and consumables	201 899,00	168 774,32
1. Purchases	201 899,00	168 774,32
B. Services and other goods	82 260,17	48 247,56
C. Remunerations, social security costs and pensions	72 896,68	70 615,38
D. Amortisations of and other amounts written down on formation expenses, intangible and tangible fixed assets	7 275,97	7 264,92
G. Other operating charges	1 052,61	0,00
III. Operating profit/loss	38 562,92	183 901,12
IV. Financial income	18 587,10	3 957,33
B. Income from current assets	0,00	0,22
C. Other financial income	18 587,10	3 957,11
V. Financial charges	6 523,77	26 747,07
C. Other financial charges	6 523,77	26 747,07
VI. Profit/loss of the period before taxes	50 626,25	161 111,38
IX. Profit/loss of the period	50 626,25	161 111,38
X. Transfer from/to untaxed reserves	0,00	6 694,00



A. Transfer from untaxed reserves	0,00	6 694,00
XI. Profit/loss of the period available for appropriation	50 626,25	167 805,38
Appropriation account	0,00	0,00
A. Profit/loss to be appropriated	720 793,40	167 805,38
1. Profit/Loss of the period available for appropriation	50 626,25	167 805,38
2. Profits/loss of the preceding period brought forward	670 167,15	0,00
D. Profit/loss to be carried forward	720 793,40	167 805,38
1. Profit to be carried forward	-720 793,40	-167 805,38



ACKNOWLEDGMENTS

ELPA is thankful to all its members and numerous volunteers that have helped us accomplish our goals in 2021. We are also grateful to all our supporters and stakeholders. They have been backing our endeavors to fight liver disease over the years.

In 2021, ELPA received grants as well as, in some cases, in-kind support from the following companies:



The Hep-cast

**The stories of the people
behind the fight to eliminate
viral hepatitis.**



Building off the success of series 1 of The Hep-cast, the World Hepatitis Alliance and Gilead Sciences Europe Limited are launching series 2 of the award-winning podcast series this May.

Series 2 continues to go beyond the statistics to explore the human impact of viral hepatitis and those working to eliminate it as a public health threat by 2030.

Hosted by Dr Sarah Jarvis, this series will focus on the real-life stories of the people working tirelessly to make the concept of viral hepatitis elimination a reality in four key groups: mothers; young people; people incarcerated; and migrants and refugees. Each episode will explore the barriers, challenges and innovative solutions to achieving viral hepatitis elimination, whilst spotlighting some of the incredible work being done globally.

Guest speakers include people living with viral hepatitis, healthcare professionals, policymakers, and activists:

Professor Mohammad Ali
National Liver Foundation of Bangladesh

Professor Manal El-Sayed
Ain Shams University, Cairo and Egyptian
National Committee for Control of Viral Hepatitis

Dr John May
Health Through Walls, USA

Arafat Bwambale
Great Lakes Peace Centre, Uganda

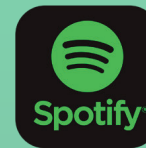
Sanjay Sarin
FIND, India

Bisi Bright
LiveWell Initiative LWI, Nigeria

If you're interested in infectious diseases, public health, social justice and improving the lives of people who are often overlooked by society – this is the podcast for you!



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We are leading
a revolution in oncology
to redefine cancer care

*Veeva ID: Z4-43029
DOP: March 2022*



Tackling liver disease, a collective journey of discovery

Thank you! to ELPA and all the member organisations and partners for your collaboration during an unprecedented year. Liver disease doesn't stop due to a pandemic and neither have we. We remain committed to stopping chronic liver disease and look forward to working with all of you as we head into 2022.



Together, lets
STOP
chronic liver disease



Boehringer Ingelheim

Boehringer Ingelheim is working on breakthrough therapies that improve the lives of humans and animals. As a leading research-driven biopharmaceutical company, the company creates value through innovation in areas of high unmet medical need. Founded in 1885 and family-owned ever since, Boehringer Ingelheim takes a long-term perspective. Around 52,000 employees serve more than 130 markets in the three business areas, Human Pharma, Animal Health, and Biopharmaceutical Contract Manufacturing.

At Boehringer Ingelheim, we are building on our expertise and scientific leadership in cardiovascular and metabolic diseases to pursue the next wave of innovative medicines for obesity, kidney, and liver diseases, including non-alcoholic steatohepatitis (NASH). Our research and development strategy takes a holistic view of the needs of people with metabolic diseases who often have multiple related conditions.

More information about Boehringer Ingelheim can be found at www.boehringer-ingelheim.com

inventiva

Developing oral therapies for the treatment of patients with **NASH**.

NASH is a silent but progressive liver disease affecting millions worldwide, and yet, there is no approved medicine to treat it.

Visit inventivapharma.com to learn more about our commitment to support patients and our programs aiming to address unmet medical needs.

The advertisement features a woman with blonde hair, wearing a grey and white striped sweater, standing with her arms crossed. The background is a dark blue gradient. The text is white and yellow, with the word "inventiva" in white and a green swoosh underneath. The main headline is in white, and the key message about NASH is in yellow. The footer text is in white.

LIVERSYNC®

Spotting the early signs of brain function decline in advanced liver disease.



This app was developed and produced by the Norgine group of companies as a service to medicine.

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GL-HEP-LV5-2100001



Managing your PBC is a challenge

If you have primary biliary cholangitis, consider a clinical study.

The RESPONSE clinical research study is looking for people with primary biliary cholangitis (PBC), previously referred to as primary biliary cirrhosis. Doctors are studying an investigational drug to see if it can improve PBC-related laboratory tests, symptoms of PBC, and help PBC patients to improve their quality of life. The RESPONSE clinical research study is enrolling people who have tried using ursodeoxycholic acid (UDCA or ursodiol) and didn't have adequate results or are unable to tolerate this treatment.

Qualified volunteers may receive the following, at no cost:

- Seladelpar (study drug) and UDCA (if applicable)
- Study related care from a PBC expert
- Study-related medical tests

Do I qualify for the RESPONSE study?

To qualify for this study, you must have:

- Been diagnosed with PBC
- Taken ursodeoxycholic acid (UDCA) but haven't had adequate results or are unable to tolerate these treatments
- High alkaline phosphatase (ALP) levels

For more information about this clinical research study, please go to www.pbcestudies.com

RESPONSE

A STUDY OF PRIMARY BILIARY CHOLANGITIS
RESPONSE Poster v2 - 30Oct2020

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