



DECISION

**DEcompensated CirrhoSis: identification of new cOmbiNatorial therapies
based on systems approaches**

H2020 – 847949

D7.5 Second patient and layman event

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1 Executive Summary

The COMBAT-trial: A novel COMBinATorial therapy with albumin and enoxaparin in patients with decompensated cirrhosis at high-risk of poor outcome.' Under this title, on March, 6th, an event was organized dedicated to patients (Fig. 1).



Figure 1: Screenshot of Announcement from ELPA's Twitter Account

characterized patient cohorts. The ultimate goal is to significantly reduce mortality through combinatorial therapies tailored to individual patients' specific needs. This endeavour aims to develop a reliable prognostic test and a robust response test. During the meeting, the "COMBAT-trial", which is part of the project, was presented. How to best collaborate between patients' organisations and recruitment centres was also discussed.

2 Deliverable report

'The COMBAT-trial: A novel COMBinATorial therapy with albumin and enoxaparin in patients with decompensated cirrhosis at high-risk of poor outcome.'

ELPA presents:

DECISION online educational event for patients
on 6th March 2023, 2.00 - 4.00 p.m. CET

... In 2013, cirrhosis was responsible for 1.2 million deaths worldwide. While most cirrhosis patients initially do not show symptoms, acute decompensation of cirrhosis, defined as the body's inability to cope with the progressing dysfunctionality of the liver, leads to severe symptoms. Decompensation is characterized by the development of ascites, hepatic encephalopathy, jaundice, or gastrointestinal haemorrhage and is often a turning point for cirrhosis. The EU-funded research project DECISION strives to understand better the pathophysiology of decompensated cirrhosis leading to acute-on-chronic liver failure (ACLF) at the systems level by taking advantage of already existing large and clinically well-

Organizing committee:

Marko Korenjak, ELPA President

Prof. Dr. Pierre-Emmanuel Rautou, professor of Hepatology Hôpital Beaujon, Inserm UMR, France, principal investigator DECISION, EF Clif, Barcelona, Spain

Dr. Ameli Schwalber, concentris research management, Germany, project management office

Participants:

20 participants, incl. representatives of national patient organisations from 13 countries (Fig. 2). The invitation is attached to this report.

Institution	Country
Asociatia Pacientilor cu Afectiuni Hepatice din Romania - APAH-RO	Romania
Catalan Association of Liver Patients – ASSCAT	Spain
European Foundation for the study of Chronic Liver Failure (EF-CLIF)	Spain
ELPA Office	Belgium
Hepar Centar – Bitola	North Macedonia
Hepatitis C Partnership	Ireland
Hetz – Israeli Association For The Health Of the Liver	Israel
Institut National de la Sante et de la Recherche Medicale, INSERM	France
Leverforeningen	Denmark
Liver4Life	United Kingdom
Liver Patients’ Association – HRONOS	Serbia
Riksföreningen Hepatit C – RHC	Sweden
Slovenian Association for patients with viral hepatitis SLOVENIA HEP	Slovenia
The Finnish Kidney and Liver Association	Finland

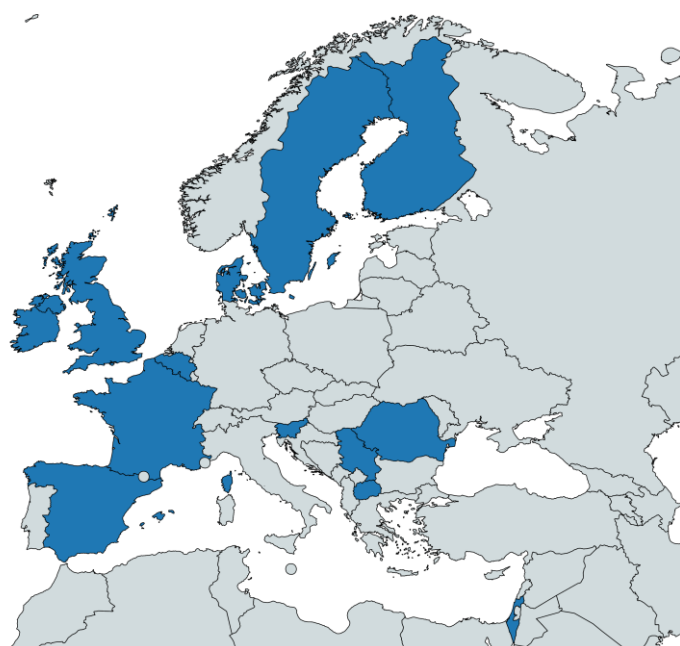


Figure 2: Overview of the different countries that participated in the patient event

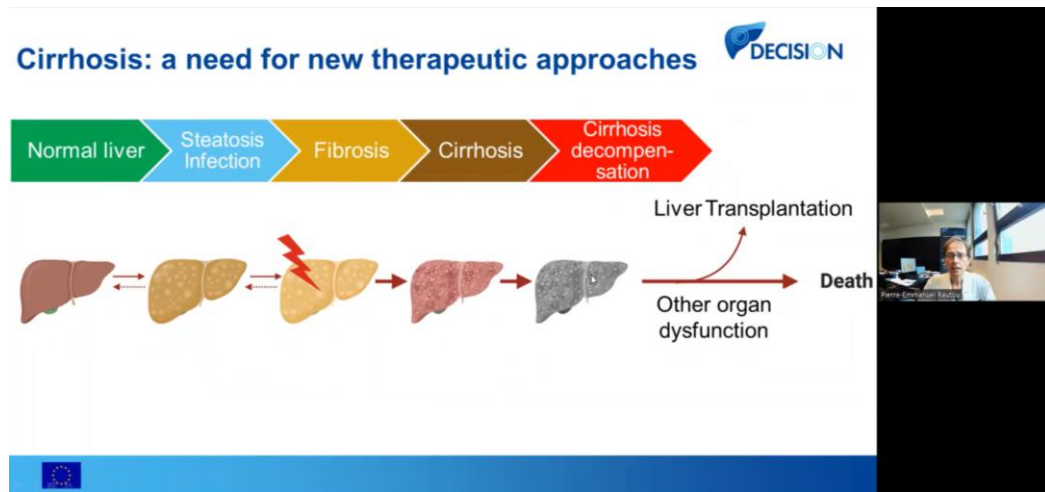


Figure 3: Screenshot of Prof Dr Pierre-Emmanuel Rautou’s presentation

The first presentation was made by **Prof Dr Pierre-Emmanuel Rautou** (Fig. 3-4), professor of Hepatology Hôpital Beaujon, Inserm UMR, France, principal investigator DECISION, EF Clif, Barcelona, Spain. He gave the participants a short but thorough explanation of the project’s structure and goals, starting with the need for new therapeutic approaches to fight cirrhosis. He presented some data about DECISION and compared the current patient management to a personalised one based on new pathophysiological concepts. Then, he briefly described the new test and new combination of drugs.

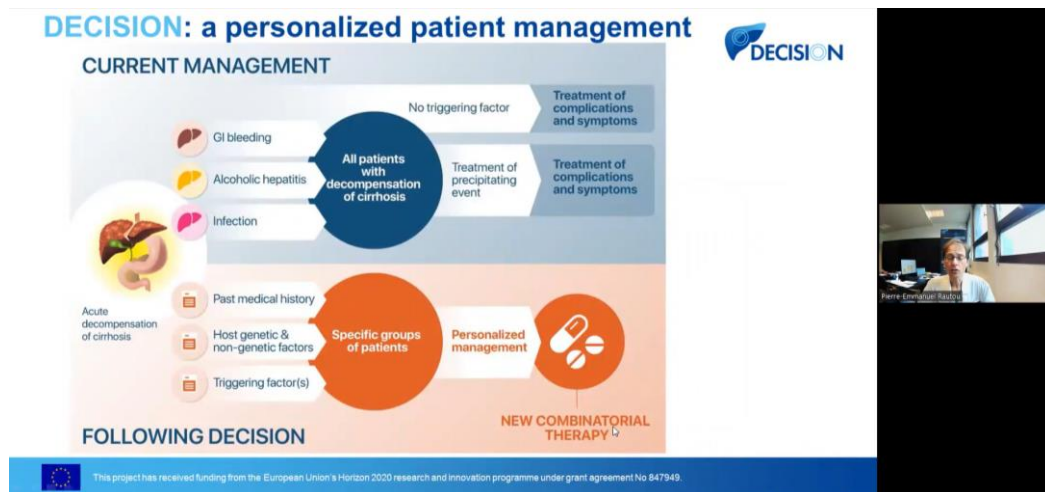


Figure 4: Screenshot of Prof Dr Pierre-Emmanuel Rautou’s presentation

Prof Dr Paolo Caraceni (Fig. 5-6), Associate Professor in Internal Medicine, Department of Clinical and Medical Sciences, University of Bologna, delivered the second presentation. He explained to patients and patients’ representatives the “COMBAT-trial”. The clinical “COMBAT-trial” will start in 2023. It is a Phase II, exploratory, open-label, multicentre, randomised (1:1) clinical trial in which the treatment group will receive human albumin and enoxaparin on top of Standard Medical Therapy. DECISION aims to recruit 80 patients in total to determine primarily whether a combinatorial therapy based on the administration of

human albumin and enoxaparin is safe in patients with decompensated cirrhosis discharged from the hospital after an index admission for acute decompensation according to the EASL-CLIF criteria. Patients will be treated up to a maximum of 3 months from inclusion and followed up for a maximum of 6 months from inclusion.

The COMBAT trial

- Phase II
- Randomized Clinical Trial
- European multicentre (9 centers)
- Prospective
- Open-label

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 847949.

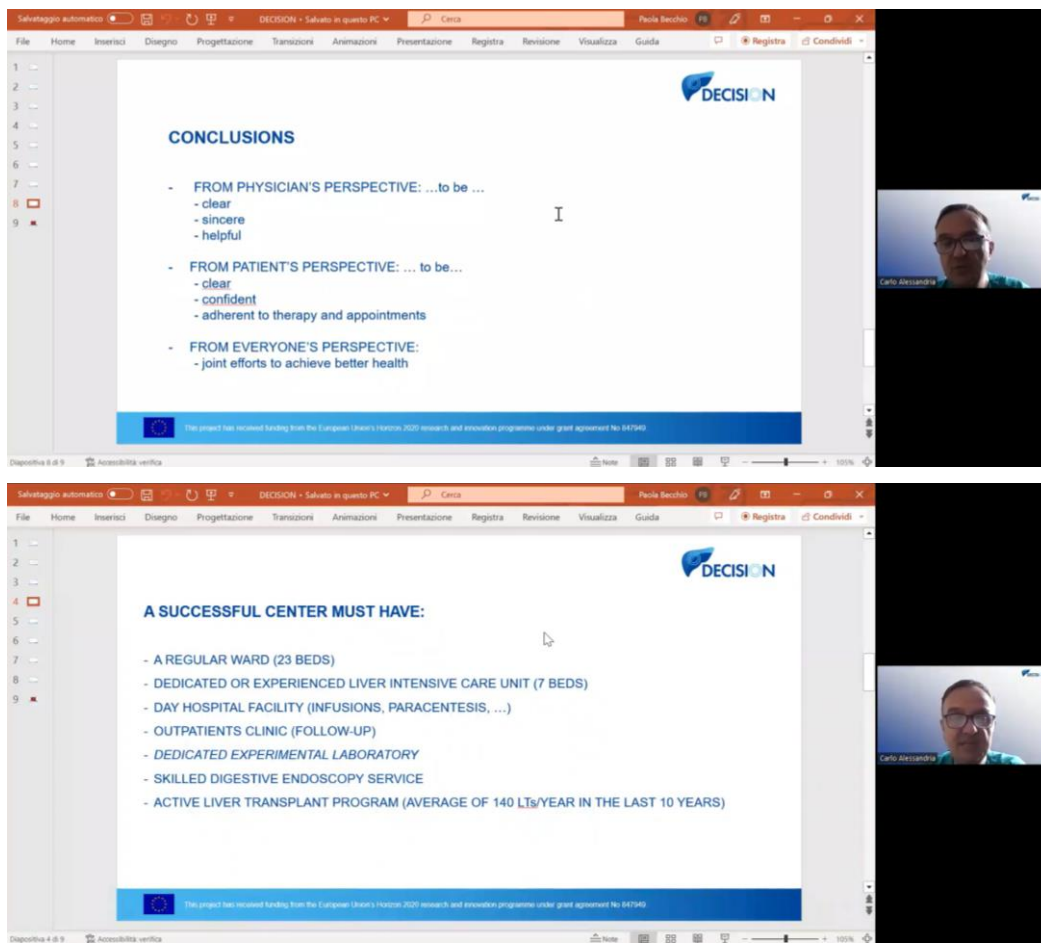
The COMBAT trial
Design of the study

- 80 patients will be randomized within 2 days before the expected discharge
- Patients will receive treatment for up to 90 days and then followed up to 180 days.
- Patients fulfilling the inclusion and exclusion criteria but with a CLIF-C AD score <50 will be proposed to participate to an ancillary observational study receiving SMT.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 847949.

Figures 5-6: Screenshots of Prof Dr Paolo Caraceni's presentation.

Then, **Dr Carlo Alessandria** (Fig. 7-8), division of Gastroenterology and Hepatology, Città della Salute e della Scienza Hospital, University of Turin, started his presentation by sharing an explanation of the recruitment process by a successful recruitment centre/clinician. He described the characteristics a thriving centre must have, considering the “COMBAT-trial” is not simple from the point of view of methodology and implementation. He also added some details about patients’ enrolment.



Figures 7-8: Screenshots of Dr Carlo Alessandria's presentation.

Dr **Itziar de Lecuona** (Fig. 9), Bioethics and Law Observatory Director at the University of Barcelona, followed Dr Alessandria. She explained what it means to participate in the trial from an ethical perspective. She briefly reviewed the ethical, legal and societal issues related to the trial. DECISION has a specific WP dedicated to these particular aspects, and some documents have already been published and are available on the project's website.

Responsible Research and Innovation (EU transversal agenda)

- Ethics (Bioethics)
- Gender equality
- Open access
- Scientific Education
- *Public engagement*

- *to align societal needs with research*



Figure 9: Screenshot of Dr Itziar de Lecuona’s presentation

A questions and answers session, moderated by **Mr Marko Korenjak**, ELPA President, allowed the participants to investigate the project’s details. This part’s central topic was how patients’ associations could work on cirrhosis, especially how patient organisations and recruitment centres can collaborate to promote the trial.

A short Twitter overview:

Before, during and after the event, contents were shared on Twitter. Here a short summary of the results of the DECISION Twitter account:



Own tweets	4
Total impressions	7,392
Total re-tweets	29
Total likes	40
Mean engagement rate ¹	2.37%
Re-tweeted content	3



Own tweets	6
Total impressions	486k
Total re-tweets	2
Total likes	112

¹ Engagement rate is the number of all engagements (clicks, views, retweets/reposts, replies, follows and likes) divided by the number of impressions. This metric indicates how engaged the followers are with the social media content. “Good” social media engagement rates vary from platform to platform.

Twitter: good: 0.5%, great: >1%; desired value for projects with a targeted following: >1.5%

LinkedIn: good: 2%, great: 5-6%; desired value for projects with a targeted following: >6%

Screenshots of Twitter posts (DECISION account):

Decision4Liver @Decision4Liver · Feb 8
 #Registernow for the DECISION online educational #patientevent from 6 March 2023, 2-4 pm CET
 @DECISION4Liver and @EuropeLiver jointly organise a #patientevent about the COMBAT-trial.
 Join in and discuss the #clinicaltrial!
 More info here: decision-for-liver.eu/news-events/ex...



Decision4Liver @Decision4Liver · Feb 23
 It's less than two weeks until our patient event on a novel #clinicaltrial in decompensated #cirrhosis. Registrations are still open. Public and patients are more than welcome!
 Follow the link: decision-for-liver.eu/news-events/ex...
 @EuropeLiver



Decision4Liver @Decision4Liver · Mar 2
 The countdown is on!
 Our online educational event for patients starts next Monday, Mar 6, 2023, 2-4pm CET.
 We aim to better understand decompensated #cirrhosis.
 Let's discuss the COMBAT-Trial, a planned phase II study with a novel combinatorial therapy.
 Hosted by @EuropeLiver

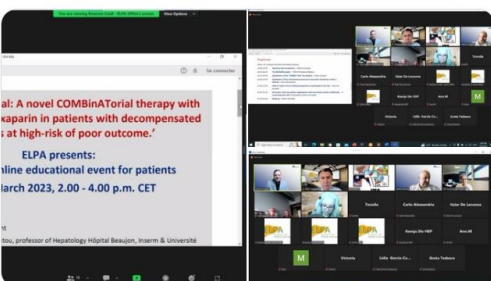
Decision4Liver @Decision4Liver · Feb 23
 It's less than two weeks until our patient event on a novel #clinicaltrial in decompensated #cirrhosis. Registrations are still open. Public and patients are more than welcome!
 Follow the link: decision-for-liver.eu/news-events/ex...
 @EuropeLiver

Decision4Liver @Decision4Liver · 3h
 You missed the #patientevent on our upcoming #COMBATtrial - A COMBinATorial therapy with albumin and enoxaparin in patients with decompensated #cirrhosis
 Don't worry, just check out the video recording on YouTube: youtube.com/watch?v=zS3-QK...
 @EuropeLiver

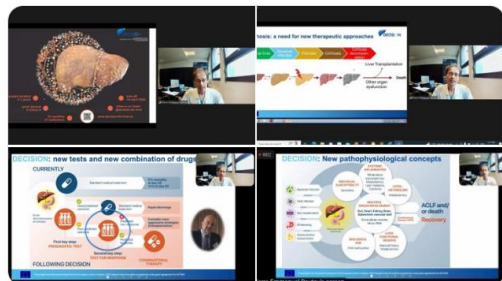


Screenshots of Twitter posts (ELPA account):

ELPA @EuropeLiver · Mar 6
 The EU-funded research project DECISION-Project aims to better understand late-stage liver disease, i.e. decompensated #cirrhosis and acute-on-chronic #liverfailure (#ACLF) and to develop new combinatorial therapies for patients. @RautouE @EU_Health @HorizonEU @EASLnews



ELPA @EuropeLiver · Mar 6
 Prof. Dr. @RautouE, professor of Hepatology Hôpital Beaujon, @Inserm & Université Paris-Cité, France, principal investigator @Decision4Liver Project, @EFClif, Barcelona, Spain The clinical "COMBAT-Trial" will start in 2023 #Hope @HorizonEU @EU_Health @MKDmilanM @Marko_Korenjak



ELPA @EuropeLiver · Mar 6
 🙌🙌🙌 DECISION Online educational #patientevent today, 6th of March 2023, 2-4 pm CET @DECISION4Liver & @EuropeLiver jointly organise a #patientevent about the COMBAT-trial Join in and discuss the #clinicaltrial! @EASLedu @AleksanderKrag
 More info here: decision-for-liver.eu/news-events/ex...

A short LinkedIn overview:

Before and after the event, contents had been shared on LinkedIn. Here a short summary of the results.

DECISION

2 Posts

242 total video views

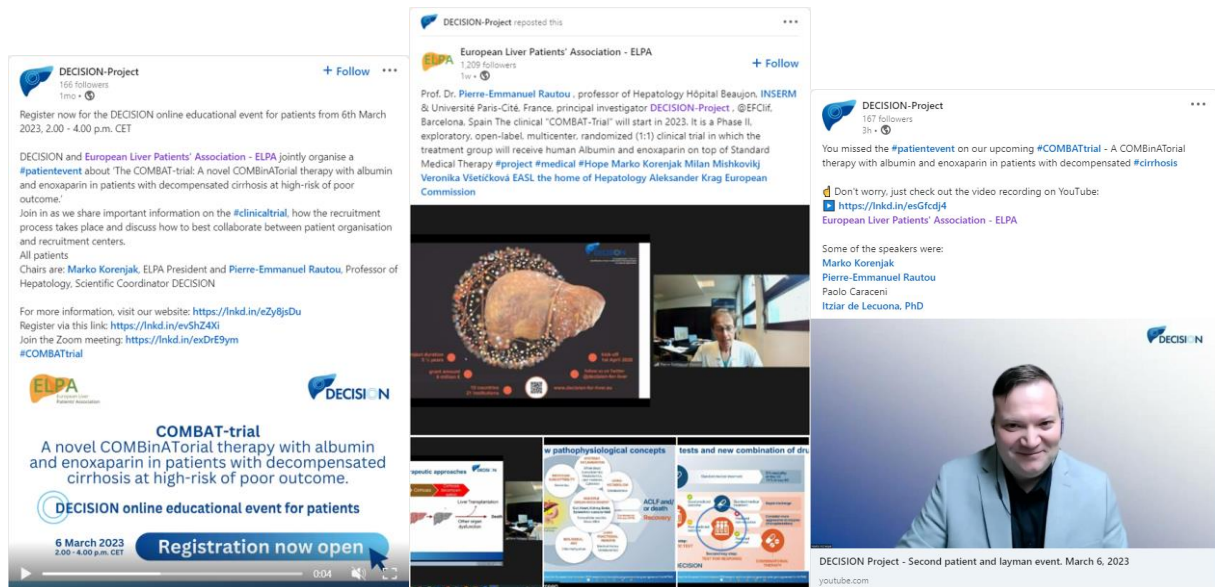
309 Post impressions

9 likes

8 reposts

11.67 % engagement rate¹

Screenshots of LinkedIn posts (DECISION account):



Website posts:

In the following we present some statistics on our promotional activities on our website during the period of 07.02.2023 – 17.03.2023.

Screenshots of website posts (<https://decision-for-liver.eu/>):



7 February 2023
Registration now open: DECISION online educational event for patients – 6th March 2023, 2.00 – 4.00 p.m. CET

[Show less](#)

DECISION and ELPA jointly organise a patient event about 'The COMBAT-trial: A novel COMBinATorial therapy with albumin and enoxaparin in patients with decompensated cirrhosis at high-risk of poor outcome.' We would like to inform you about the trial and discuss with you how to best collaborate between patient organisation and recruitment centers.

Find more information [here](#).
 Register [here](#).
 Join on Zoom [here](#).



6 March 2023
Successful patient event on 6th March

[Show less](#)

In this event organized by ELPA with the title 'The COMBAT-trial: A novel COMBinATorial therapy with albumin and enoxaparin in patients with decompensated cirrhosis at high-risk of poor outcome,' experts from DECISION explained the upcoming clinical trial to patient representatives. They discussed the recruitment process and what it means from an ethical perspective. Great interest was shown in the question how patient representatives and clinicians can work together to facilitate recruitment for this trial.



17 March 2023
Watch the recording of the patient event on 6th March 2023

The event 'The COMBAT-trial: A novel COMBinATorial therapy with albumin and enoxaparin in patients with decompensated cirrhosis at high-risk of poor outcome.' is now available on YouTube.

Tune in as experts from DECISION explain the upcoming clinical trial or discuss the recruitment process.

Link: <https://www.youtube.com/watch?v=zS3-QKd9NIg>

There were several updates and news posts on the DECISION website during the period analysed. The numbers presented here can therefore not be related exclusively to the promotional activities of the patient event on March 6th (Fig. 10). However, peaks in the metrics "Users", "New Users", "Sessions" and "Page Views" are visible on the day of the patient event (Fig. 10, blue arrows), indicating high interest following the patient event.

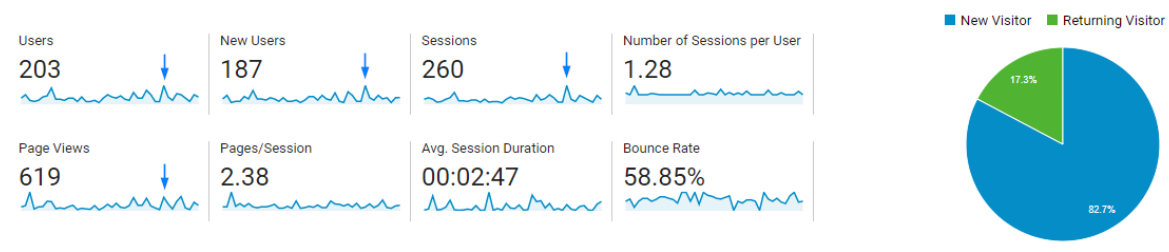
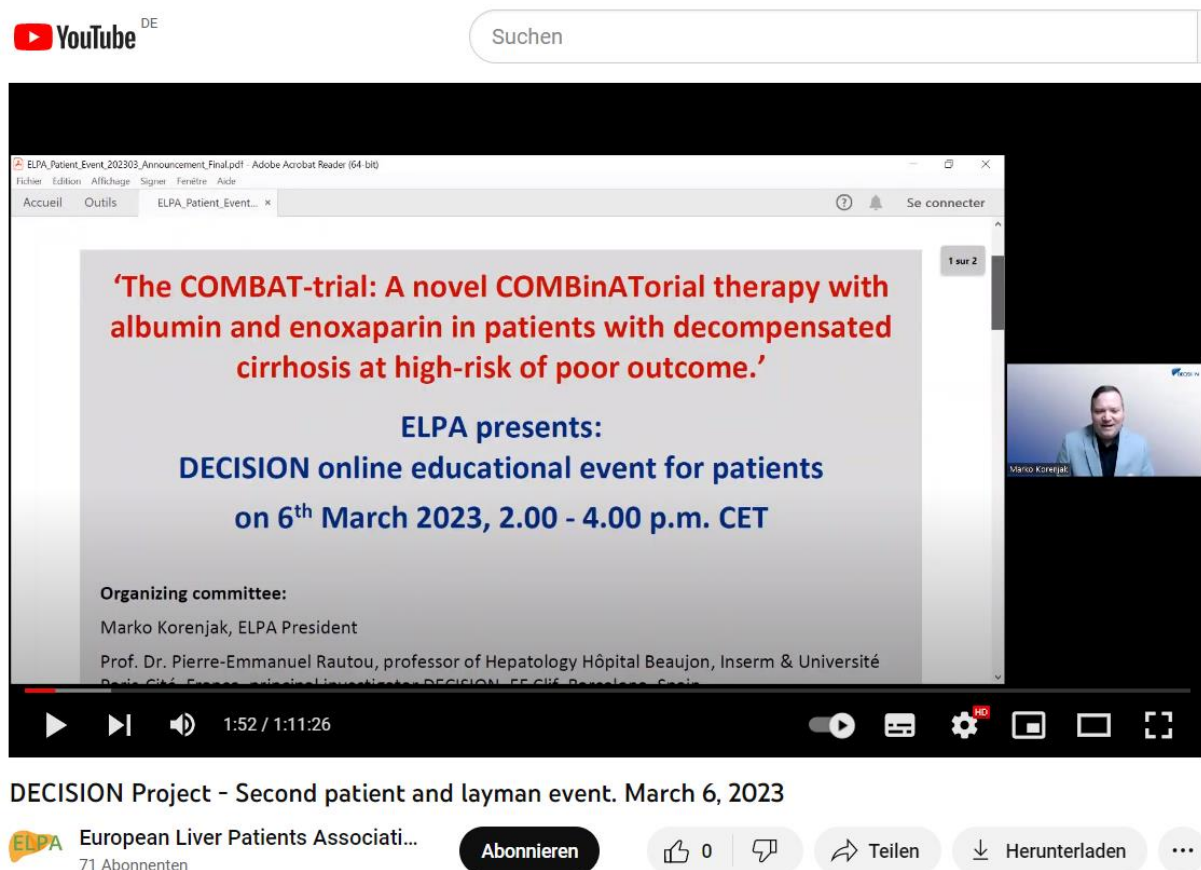


Figure 10: Screenshot of website activities (<https://decision-for-liver.eu/>)

YouTube:

The talks have also been recorded and published on ELPA's YouTube channel.

<https://www.youtube.com/watch?v=zS3-QKd9Nlg>



DECISION Project - Second patient and layman event. March 6, 2023

ELPA European Liver Patients Associati...
71 Abonnenten

Abonnieren

0

Teilen

Herunterladen

3 Acknowledgement and Disclaimer

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 847949.

This report reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains.

4 Attachment



'The COMBAT-trial: A novel COMBINATORIAL therapy with albumin and enoxaparin in patients with decompensated cirrhosis at high-risk of poor outcome.'

**ELPA presents:
DECISION online educational event for patients
on 6th March 2023, 2.00 - 4.00 p.m. CET**

Organizing committee:

Marko Korenjak, ELPA President

Prof. Dr. Pierre-Emmanuel Rautou, professor of Hepatology Hôpital Beaujon, Inserm & Université Paris-Cité, France, principal investigator DECISION, EF Clif, Barcelona, Spain

Dr. Ameli Schwalber, concentris research management, Germany, project management office

Dear representatives of the national patients' associations,

We kindly invite you to the online educational event for patients on the DECISION project, on Monday March 6th, 02:00-04:00 PM, available via [Zoom](#). Please register [here](#).

The EU-funded research project DECISION aims to better understand late-stage liver disease, i.e. decompensated cirrhosis and acute-on-chronic liver failure (ACLF) and to develop new combinatorial therapies for patients. The clinical "COMBAT-Trial" will start in 2023. It is a Phase II, exploratory, open-label, multicenter, randomized (1:1) clinical trial in which the treatment group will receive human Albumin and enoxaparin on top of Standard Medical Therapy. We aim to recruit 80 patients in total to determine primarily whether a combinatorial therapy based on the administration of human albumin and enoxaparin is safe in patients with decompensated cirrhosis discharged from the hospital after an index admission for acute decompensation according to the EASL-CLIF criteria. Patients will be treated up to a maximum of 3 months from inclusion and followed up to a maximum of 6 months from inclusion. We would like to inform you about the trial and discuss with you how to best collaborate between patient organisation and recruitment centers. We look forward to meeting you virtually at March 6th!

On behalf of the organizing committee,

Marko Korenjak, ELPA President



Programme:

Chairs: M. Korenjak and Pierre-Emmanuel Rautou

- 14:00-14:05 **Welcome and introduction** – Marko Korenjak
- 14:05-14:15 **The DECISION project** – Pierre-Emmanuel Rautou
- 14:15-14:30 **Explanation of the “COMBAT-trial” for patients** – Paolo Caraceni
- 14:30-14:40 **Explanation of the recruitment process by a successful recruitment center/clinician** – Carlo Alessandria
- 14:40-14:50 **What it means from an ethical perspective to participate in the trial** – Itziar de Lecuona
- 14:50-15:20 **Discussion: How can patient organisations and recruitment centers collaborate to promote the trial?** moderated by Marko Korenjak
- 15:20-15:30 **Wrap-up** – Marko Korenjak

www.decision-for-liver.eu

Contact

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