



**SCIENTIFIC
PROGRAM**

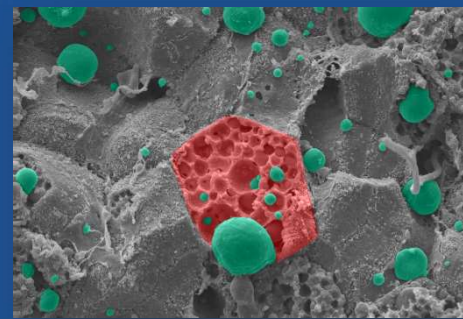
1st WORKSHOP

**CLINICAL TRIALS IN NASH
PATIENTS WITH COMPENSATED
CIRRHOSIS**

28th of April 2023

BARCELONA

Virtual and in-person



1ST WORKSHOP CLINICAL TRIALS IN NASH PATIENTS WITH COMPENSATED CIRRHOSIS

April 28th 2023

DIRECTORS:

Dr. Joan Genescà, Clinical Director of Digestive Diseases and Chief of Liver Unit, Vall d'Hebron University Hospital; Professor of Medicine, Universitat Autònoma de Barcelona; CIBERehd, Institute of Health Carlos III.

Dr. Juan M Pericàs, Consultant at Liver Unit, Vall d'Hebron University Hospital; CIBERehd Institute of Health Carlos III.

OBJECTIVES:

1. Overview of the current situation and regulatory requirements in NASH clinical trials
2. Review of endpoints for clinical trials in NASH patients with cirrhosis
3. Alternative options for the design of clinical trials in NASH patients with cirrhosis

VENUE:

Conference room – Floor 1 Pabellón docente
Vall d'Hebron Barcelona Hospital Campus
119-129 Vall d'Hebron Avenue
08035 Barcelona, Spain



ACCREDITATION:

Accreditation requested by the **European Accreditation Council for Continuing Medical Education** (EACCME – an Institution of the UEMS) to provide continuing medical education for physicians. A certificate of assistance will be awarded to participants attending at least **80%** of the session.

REGISTRATION:

In-person registration fee:	250,00€
Virtual registration fee:	100,00€
On-demand fee:	50,00€

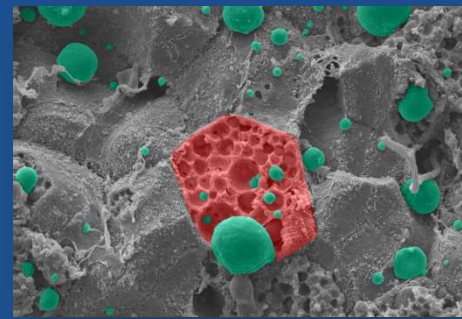
Lunch and coffee breaks are included.

Registrations must be made through the following website: <https://aula.vallhebron.com/> (future courses section).

Special dietary requirements must be notified to Technical Secretary during the registration process (inscripcionesaulavh@vhebron.net).

TECHNICAL SECRETARY:

Aula Vall d'Hebron –
inscripcionesaulavh@vhebron.net – +34 693785436



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April 28th 2023

SPEAKERS AND MODERATORS

AGUSTIN ALBILLOS

Professor of Medicine, University of Alcalá, Madrid
Head, Department of Gastroenterology and Hepatology, Hospital Ramón y Cajal, Madrid (Spain)

QUENTIN ANSTEE

Professor of Experimental Hepatology, Newcastle University, Newcastle (United Kingdom)

SALVADOR AUGUSTIN

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Boehringer Ingelheim International GmbH (Germany)

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Professor of Medicine, Complutense University of Madrid
Chief Digestive Medicine Department, Gregorio Marañón General University Hospital
Scientific Director of Liver and Digestive Diseases area, CIBERISCIII

RON BASUROY – NOVO NORDISK

Medical Director - NASH
Novo Nordisk A/S

RAMÓN BATALER

Chief Liver Unit, Hospital Clinic, Barcelona (Spain)

ANNALISA BERZIGOTTI

Head of Hepatology
a.i. Clinic Director
Department of Visceral Surgery and Medicine
Inselspital, Bern University Hospital (Switzerland)

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Professor of Medicine, Department of Visceral Surgery and Medicine,
Inselspital, Bern University Hospital (Switzerland)

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Senior Director of Clinical Development
Gilead Sciences, Inc

JOSE LUIS CALLEJA

Professor of Medicine, Universidad Autónoma Madrid
Chief of Gastroenterology and Hepatology units, Puerta de Hierro University Hospital, Madrid (Spain)

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Endocrinology and Nutrition Department, Morbid Obesity Unit Coordinator,
Vall d'Hebron University Hospital
Associated Professor of Human Physiology, Autonomous University of Barcelona
Member of the Directory Board of the Spanish Society of Obesity, SEEDO
Investigator of CIBERdem, Institute of Health Carlos III (Spain)

CLAUDIA DE OLIVEIRA

Clinical Development Lead, Liver Fibrosis and Cendakimab
Global Drug Development | Research & Development
Bristol Myers Squibb

SVEN FRANSCQUE

Chairman – Division of Gastroenterology and Hepatology, Antwerp University Hospital
Senior Full Professor of Medicine – Laboratory of Experimental Medicine and Paediatrics (Faculty of Medicine and Health Sciences), University of Antwerp (Belgium)

JOAN GENESCA

Clinical Director of Digestive Diseases and Chief of Liver Unit, Vall d'Hebron University Hospital
Head of the Advanced Chronic Liver Diseases Research Group, CIBERehd Institute of Health Carlos III
Professor of Medicine, Autonomous University of Barcelona (Spain)

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Professor of Medicine
Director, Liver Unit
Division of Gastroenterology, University of Alberta
AHS Hepatology Lead, Edmonton Zone (Canada)

VIRGINIA HERNÁNDEZ-GEA

Hepatic hemodynamic Unit, Liver Unit, Hospital Clinic – IDIBAPS, Barcelona (Spain)
Investigator of CIBERehd, Institute of Health Carlos III
Secretary of VALDIG
EASL Scientific committee & Governing Board
ERN Rare-Liver managing team

JUAN M PERICÀS

Consultant at Liver Unit, Vall d'Hebron University Hospital, Barcelona
Investigator of CIBERehd Institute of Health Carlos III (Spain)

MÒNICA PONS

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THOMAS REIBERGER

Division of Gastroenterology and Hepatology
Department of Medicine III, Medical University of Vienna
Head of Liver Cirrhosis Clinic
Director of Christian Doppler Lab for Portal Hypertension and Liver Fibrosis
Adjunct PI at CeMM and at LBI for Rare and Undiagnosed Diseases (LBI-RUD), Vienna (Austria)

IAN ROWE

Associate Professor, University of Leeds Institute for Medical Research
Honorary
Consultant Hepatologist at the Leeds Liver Unit, Leeds (United Kingdom)

PETER RYDQVIST

Medical Director – Europe
Madrigal Pharmaceuticals

ELMER SCHABEL

Federal Institute for Drugs and Medical Devices, Bonn (Germany)

FRANK TACKE

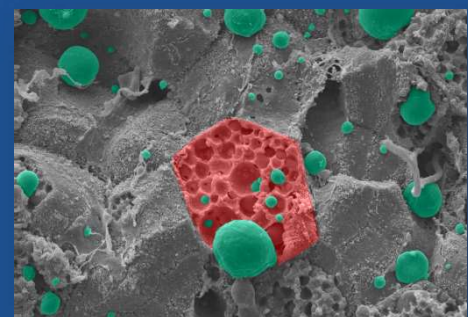
Department Head and Professor of Medicine
Charité - Universitätsmedizin Berlin
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Campus Virchow-Klinikum (CVK) and Campus Charité Mitte (CCM) (Germany)

EMMANUEL TSOCHATZIS

Professor of Hepatology
UCL Institute for Liver and Digestive Health, Royal Free Hospital (United Kingdom)

VÍCTOR VARGAS

Senior consultant at Liver Unit, Vall d'Hebron University Hospital
Professor of Medicine, Autonomous University of Barcelona (Spain)



1ST WORKSHOP CLINICAL TRIALS IN NASH PATIENTS WITH COMPENSATED CIRRHOSIS

April 28th 2023

9:00 - 9:15h **Welcome: Dr. Jose Luís Calleja and Dr. Joan Genescà**

9:20 - 11:00h **SESSION I. Current landscape and regulatory issues (1h 40min)**

Moderators: V. Vargas and S. Augustin

1. Current situation of clinical trials in NASH (20 min) – *F. Tacke*
 2. Clinical trials in NASH cirrhosis: challenges (20 min) – *S. Augustin*
 3. Regulatory aspects: EMA position (20 min) – *E. Schabel*
 4. Regulatory aspects: FDA position (20 min) – *P. Rydqvist*
- Discussion (20 min)

11:00 - 11:20h *Coffee break (20 min)*

11:20 - 13:00h **SESSION II. Weight loss and bariatric surgery in NASH cirrhosis (1h 40min)**

Moderators: R. Bañares and R. Basuroy

1. Effects of weight loss in cirrhotic NASH patients (20 min) – *A. Berzigotti*
 2. Drugs for obesity in NASH patients (20 min) – *A. Ciudin*
 3. Bariatric surgery in NASH: overview of results (20 min) – *S. Francque*
 4. How to select NASH cirrhotic patients for bariatric surgery (20 min) – *T. Reiberger*
- Discussion (20 min)

13:00 - 14:00h *Lunch (60 min)*

14:00 - 15:40h **SESSION III. Endpoints in NASH cirrhosis clinical trials (1h 40min)**

Moderators: A. Albillos and C. Oliveira

1. Liver Biopsy (20 min) – *JM. Pericàs*
 2. Surrogate endpoints: HVPG (20 min) – *V. Hernández-Gea*
 3. Other non-invasive endpoints (20 min) – *Q. Anstee*
 4. Clinical endpoints (20 min) – *E. Tsochatzis*
- Discussion (20 min)

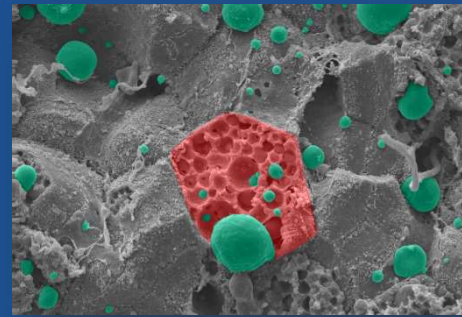
15:40 - 16:00h *Coffee break (20 min)*

16:00 - 17:30h **SESSION IV. Alternatives in design for NASH cirrhosis clinical trials (1h 30min)**

Moderators: J. Bosch and L. Boyette

1. Prognostic models in NASH cirrhosis (20 min) – *M. Pons*
 2. Ordinal outcomes for NASH cirrhosis clinical trials (20 min) – *JG. Abraldes*
 3. How NASH cirrhosis clinical trials might be in the future? (20 min) – *I. Rowe*
- Discussion all panelists (30 min)

17:30 - 17:45h **Greetings & concluding remarks: Dr. Ramón Bataller and Dr. Joan Genescà**



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