



SCIENTIFIC PROGRAM

1st WORKSHOP

CLINICAL TRIALS IN NASH PATIENTS WITH COMPENSATED CIRRHOSIS

28th of April 2023

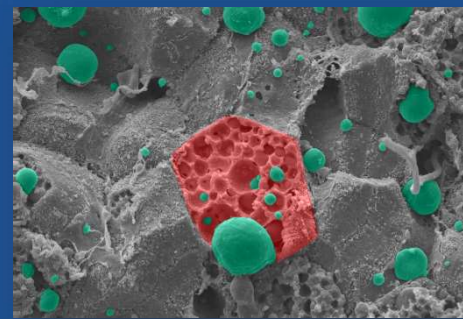
BARCELONA

Virtual and in-person

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1ST WORKSHOP CLINICAL TRIALS IN NASH PATIENTS WITH COMPENSATED CIRRHOSIS

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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:

Main building – Conference room 10th Floor
Vall d'Hebron Barcelona Hospital Campus
119-129 Vall d'Hebron Avenue
08035 Barcelona, Spain



ACCREDITATION:

Accreditation awarded by the **Catalan Council for Continuing Education of Health Professions (CCFCPS)**. Participants attending at least **80%** of the session will receive the abovementioned accreditation.

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).

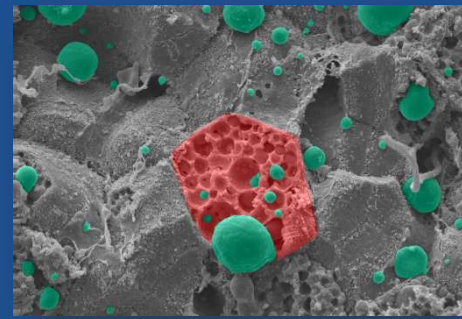
Special dietary requirements must be notified to Technical Secretary during the registration process (inscripciones@aulavallhebron.cat).

TECHNICAL SECRETARY:

Aula Vall d'Hebron – Technical secretary external educational activities
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SPEAKERS AND MODERATORS

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Scientific Director of Liver and Digestive Diseases area, CIBERISCIII

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VÍCTOR VARGAS

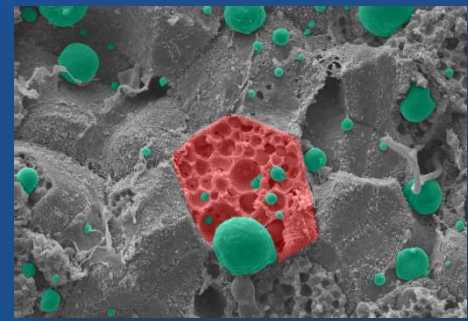
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Secretary of VALDIG
EASL Scientific committee & Governing Board
ERN Rare-Liver managing team

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9:30 - 9:45h **Welcome: Dr. Jose Luís Calleja and Dr. Joan Genescà**

9:45 - 11:25h **SESSION I. Current landscape and regulatory issues (1h 40min)**

Moderators: V. Vargas and A. Trylesinski

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 from a company perspective (20 min) – *P. Rydqvist*
- Discussion (20 min)

11:25 - 11:40h *Coffee break (15 min)*

11:40 - 13:20h **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)

13:20 - 14:05h *Lunch (45 min)*

14:05 - 15:45h **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) – *QM. Anstee*
 4. Clinical endpoints (20 min) – *E. Tsochatzis*
- Discussion (20 min)

15:45 - 16:00h *Coffee break (15 min)*

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

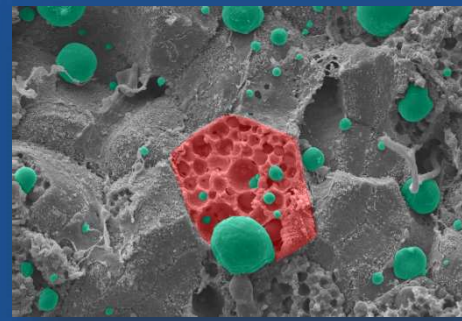
Moderators: J. Bosch and L. Boyette

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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