

2021 Emerging Topic Conference
Current Challenges in Clinical Management and Drug Development in NASH
Online Conference
June 17 – 18, 2021

Program Chairs: Rohit Loomba, MD and Stephen A. Harrison, MD, FAASLD

Learning Objectives:

- Increases understanding of non-alcoholic fatty liver disease (NAFLD) to be more efficient in identifying current or future management strategies for patients.
- Enhanced knowledge and understanding of NAFLD to be informed of the most recent basic discoveries in the field.
- Learners will improve their knowledge and understanding of NAFLD.

Conference Description/Need Statement:

The conference has been designed to bring together liver scientists (translational researchers and clinical investigators) with strong expertise in fatty liver disease. The goals of this symposium are to: i) allow both communities to learn about each other's progresses, ii) review the most recent preclinical and clinical investigations in their respective field and, iii) promote the rapid emergence of novel and efficient therapeutic options.

Target Audience:

- Gastroenterologists
- Nurses
- Pharmacists
- Physician Assistants
- Surgeons
- Fellows/Trainees
- Basic Scientists
- Graduate Students
- Post-docs
- Patients Association

CME Hours: 9.50 *AMA PRA Category 1 Credits*

ABIM MOC: 9.50 MOC points

Thursday, June 17, 2021

Session I: Current Management of NASH	
<i>Moderators: Raymond T. Chung, MD, FAASLD and Suzanne R. Sharpton, MD, MAS</i>	
10 - 10:10 am	Welcome and Opening Remarks <i>Rohit Loomba, MD</i>
10:10 - 10:30 am	Epidemiology and Natural History of NASH <i>Zobair M. Younossi, MD, MPH, FAASLD</i>
10:30 - 10:50 am	Pathogenesis of NASH <i>Brent A. Tetri, MD, FAASLD</i>
10:50 am – 11:10 am	Liver Histologic Assessment and Differential Diagnosis in NAFLD <i>David Kleiner, MD, PhD</i>
11:10 am – 11:30 am	Lifestyle, Current Pharmacologic Treatment of NASH and Bariatric Surgery <i>Kathleen E. Corey, MD, MPH, MMSc</i>
11:30 am – 11:50 am	Panel Discussion
11:50 am – 1 pm	Lunch
	Optional Breakout Recordings (15 minutes recordings available OnDemand throughout the conference)
	How to Take History, Physical, Alcohol and NIT Assessment in Clinic? <i>Lisa M. Richards, MSN, FNP, AF-AASLD</i>
	Differential Diagnosis of Elevated ALT: What Labs to Order and How to Diagnose NASH in Clinic? <i>Summer Collier, MSN, FNP-BC, AAHIVS</i>
Diet and Exercise Counseling for NASH Patients <i>Monica A. Tincopa, MD MSc</i>	
Session II: NASH Progression and Co-morbidities	
<i>Moderators: Rohit Loomba, MD and Miriam B. Vos, MD, MSPH</i>	
1 pm – 1:20 pm	Diagnosis and Management of Pediatric NASH <i>Stavra Xanthakos, MD</i>
1:20 pm – 1:40 pm	How to Use NIT in Risk Stratification in Clinical Care? <i>Alina M. Allen, MD</i>
1:40 pm – 2 pm	NASH Related HCC and Liver Transplantation <i>Veeral H. Ajmera, MD</i>
2 pm – 2:05 pm	Oral Abstract Presentation #1
2:05 pm – 2:10 pm	Oral Abstract Presentation #2
2:10 pm – 2:20 pm	Impact of COVID-19 on Clinical Trial Design and Participation <i>Elizabeth C. Verna, MD, MS</i>
2:20 pm – 2:40 pm	Panel Discussion
2:40 pm – 3 pm	Break
Session III: NASH Trials- All things Considered	
<i>Moderators: Naim Alkhouri, MD and Lisa M. Richards, MSN, FNP, AF-AASLD</i>	

3 pm – 3:10 pm	Ideal NASH Drug <i>Brent A. Tetri, MD, FAASLD</i>
3:10 pm – 3:30 pm	NASH Related Fibrosis and Cirrhosis: Phase 2/3/4 Endpoints <i>Arun J. Sanyal, MD, FAASLD</i>
3:30 pm – 3:50 pm	Patient Selection and Screen Fail Rate Mitigation (NASH and Cirrhosis) <i>Stephen A. Harrison, MD, FAASLD</i>
3:50 pm – 3:55 pm	Oral Abstract Presentation #3
3:55 pm – 4 pm	Oral Abstract Presentation #4
4 pm – 4:20 pm	Stabilization of Placebo Response Rates in NASH and Cirrhosis Trials <i>Mary E. McCarthy Rinella, MD, FAASLD</i>
4:20 pm – 4:45 pm	Panel Discussion
4:45 pm	End of Day One

Friday, June 18, 2021

Session IV: Endpoint Analysis	
<i>Moderators: Veeral H. Ajmera, MD and Michelle Long, MD, MSc</i>	
10 - 10:10 am	Opening Remarks for Day Two
10:10 - 10:30 am	Issues to Consider in Study Design: Power, Sample-Size, Duration <i>Vlad Ratziu, MD</i>
10:30 - 10:50 am	Refining Histopathologic Data Collection and Analysis <i>Cynthia A. Behling, MD, PhD</i>
10:50 - 11:10 am	Utilization of AI in Pathology in Clinical Trials in NASH and Cirrhosis <i>Mazen Nouredin, MD</i>
11:10 am – 11:30 am	Combination Therapy and What Does the Future Look Like <i>Michael R. Charlton, MD, FRCP</i>
11:30 am – 11:50 am	Panel Discussion
11:50 am – 1 pm	Lunch
Session V: Assessment of Response and Competing Risks	
<i>Moderators: Anna Mae Diehl, MD, FAASLD and Stephen A. Harrison, MD, FAASLD</i>	
1 pm – 1:20 pm	Emerging Therapies for NASH Cirrhosis <i>Manal F. Abdelmalek, MD, MPH, FAASLD</i>
1:20 pm – 1:40 pm	Liver Histology, Functional and HVPG in NASH Cirrhosis <i>Vincent Wong, MD</i>
1:40 pm – 2 pm	Non-invasive Biomarkers for Treatment Response <i>Rohit Loomba, MD</i>
2 pm – 2:20 pm	Competing Risks of DILI, Gall Bladder Disease, and Decompensation in Cirrhosis Trials and Their Impact on Trial Design <i>Naga P. Chalasani, MD, FAASLD</i>
2:20 pm – 2:40 pm	Panel Discussion
2:40 pm – 3 pm	Break

Session VI: Deep-dive Innovations in Design*Moderators: Rohit Loomba, MD and Mary E. McCarthy Rinella, MD, FAASLD*

3 pm – 3:20 pm	Clinical Endpoints, Sample-size for Phase 2b and Phase 3 Trials in NASH Cirrhosis <i>Juan G. Abraldes, MD</i>
3:20 pm – 3:40 pm	Genetic (PNPLA3, TM6SF2 and HSD17B13) Targetting of Therapies of NASH and Cirrhosis <i>Quentin M. Anstee, MBBS, PhD, FRCP</i>
3:40 pm – 4 pm	Break
4 pm – 4:20 pm	Adaptive Trial Designs for Combined Phase 2b/3 and Parallel Trial Design in NASH and Cirrhosis <i>Frank A. Anania, MD, FAASLD, FACP, AGAF</i>
4:20 pm – 4:40 pm	Panel Discussion
4:40 pm – 5 pm	Wrap-up <i>Stephen A. Harrison, MD, FAASLD</i>
5 pm	Conference Adjourned