22-25 April, 2019 | Boston, MA

www.nash-summit.com

3rd Annual NASH Summit 2019

Accelerate the Successful Development of Your Non-Alcoholic Steatohepatitis (NASH) Therapeutic

Hear from 57 experts including:

- **Brent Tetri**
  Director, Division of Gastroenterology & Hepatology; Professor of Internal Medicine
  Saint Louis University School of Medicine

- **Allison Capone**
  Global Strategic Marketing for Nonalcoholic Steatohepatitis
  Intercept

- **James Conway**
  Senior Scientist-Translational Bioinformatics
  MedImmune

- **Liat Hayardeny**
  Chief Scientific Officer
  Galmed Pharmaceuticals

- **Jen-Chieh (Jay) Chuang**
  Nonalcoholic Steatohepatitis, Fibrotic Diseases, Biomarker Scientist
  Gilead Sciences

- **Dean Hum**
  Senior Executive Vice President & Chief Scientific Officer
  Genfit

- **Ritesh Shah**
  Commercial Development Lead, Internal Medicine
  Pfizer

- **Saswata Talukdar**
  Director – CardioMetabolic Discovery
  Merck

- **Laurent Fischer**
  Senior Vice President, Head Liver Therapeutic Area
  Allergan

- **Robert Arch**
  Executive Director; Head, Liver Disease Program
  Novartis Institute for BioMedical Research

- **Becky Taub**
  Chief Medical Officer, Executive Vice President Research & Development
  Madrigal Pharmaceuticals

- **Éric Lefebvre**
  Chief Medical Officer
  Pliant Therapeutics

**Lead Partner:** ICON

**Senior Partners:** prosciento®
SIEMENS Healthineers

**Program Partner:** HEPQuANT
Welcome to the World’s Largest Gathering of NASH Drug Developers

Harnessing Understanding from Early Discovery to Commercialization

Now in its 3rd year, the NASH Summit in Boston is the industry’s most comprehensive forum for advancing the development of successful NASH therapeutics. Across 4 days of unparalleled content sharing and networking, 57 industry leaders will present actionable takeaways on the next 12 months of NASH drug development including: building the confidence of investors, patient recruitment for phase 3 and specific candidates as the backbone for combinations.

Join 300+ peers from over 150 organizations as this exclusively drug development driven conference equips your team with the connections and applicable insights you need to capture one of many market opportunities addressing NASH.

What Can You Expect?

- **300+** Attendees
- **150+** Organizations
- **57** Expert Speakers
- **3** Streams of Learning
- **2** Seminars
- **4** Workshop Discussions
- **12+** Hours of Networking
- **1** Patients Insight Evening

Your Top 10 Takeaways From the Industry Leaders

1. **Benchmark a Comprehensive Understanding of the Competitive Clinical Trial Landscape**
   - Review mechanisms of action addressing NASH and discuss the potential of combinations to most effectively address fibrosis

2. **Hear Case Studies & Anti-NASH Activity of Emerging Candidates**
   - Evaluate data driven case studies to broaden your perspective on potential efficacy against NASH

3. **Strategize Commercial Success & Building Investor Confidence**
   - Understand hepatocellular carcinoma as an extension of NASH and question NASH co-morbidity interactions

4. **Review the Current Non-Invasive Diagnostic Modalities**
   - Transfer best practice from hepatitis C & other liver disease

5. **Critically Address the Bench to Bedside Translational Gap**
   - Contextualize the patient’s perspective and the practical application of drug combinations and durations in the treatment setting

6. **Investigate Pharmacotherapy in the Context of Combinations**
   - Evaluate ex vivo modalities to better predict efficacy of your candidate and more confidently confirm rationale in human context

7. **Hear Clinical Advances of NASH Therapeutics in Phase 2 & Phase 3 Clinical Trials**
   - Contextualize the relationship of NASH with wider liver & cardiovascular disease

8. **Contextualize the Relationship of NASH with Wider Liver & Cardiovascular Disease**
   - Analyze commercial considerations, the pricing and reimbursement landscape, market development opportunities and delivering a cost-effective NASH treatment to plan your entrance to market

9. **Transfer Best Practice From Hepatitis C & Other Liver Disease**
   - Evaluate recent work on applying machine learning for NASH biomarker synthesis to optimize your own drug development-biomarker relationship in imaging analysis and patient stratification

10. **Benchmark a Comprehensive Understanding of the Competitive Clinical Trial Landscape**
    - Contextualize the qualification of fit for purpose biomarkers and their success in drug development
What’s New in 2019?

Fresh Content From Fresh Faces:

43 New speakers  
17 New speaking companies  
13 Drug Case Studies

Non-Invasive Biomarkers Deep Dive
Join the full seminar day dedicated to benchmarking and sharing the most innovative case studies set to unlock the next arsenal of NASH candidates. Chaired by Jay Chuang (NASH, Fibrotic Diseases, Biomarker Sciences & Research Scientist at Gilead) this focused seminar benchmarks the very latest from NIMBLE, LITMUS and innovations within imaging and serum biomarkers to better inform your biomarker related strategies and support clinical program success.

Commercial Leaders Day
Hear from marketing and commercial development leads as they share perspectives on strategizing considerations for commercialization, navigating market development, and building investor confidence in the crowded NASH landscape. Chaired by Allison Capone (Global Strategic Marketing for NASH at Intercept), be part of the discussions taking place within this exclusively commercial stream and map out the next step of your business development plan in NASH.

Patient’s Insight Evening
Join us for an evening of networking and NASH patient speakers. Establish connections early on, contextualize conversations before the main sessions or just relax and enjoy the atmosphere. We’re excited to host you all and celebrate the progress of drug development in the last 12 months.
Why You Should Attend the NASH Summit

I immensely enjoyed the last three days. The format, location and event organization were excellent. I really don’t have any suggestions for improvements as the right priorities seem to be in place. The NASH Summit provides the most comprehensive and up to date overview over this increasingly complex field. Organization, speaker selection and atmosphere on site were excellent.

Both the NASH Summits have been very well organized. I like that these are small gatherings. Allows a focussed discussion on NASH and chance to interact with key stakeholders.

Conference was a great networking event and chance to get up-to-date on science and technologies out there and form new connections in key leaders in the filed.

I appreciated the good mix of topics, even within each stream. It was good to hear about the work being done both in my focus area and other related fields and to network and have conversations with other companies/individuals doing that work, particularly with the mindset of combination therapies being likely in the future. Being able to engage in conversations about how that process will work and change processes across the board was helpful.

Very professional staff, and very helpful throughout the conference. Organized and relevant to understanding pipeline product development coming in NASH and the marketplace better.

Interaction in a less formal environment with pharma and active drug development programs.

UNIVERSITY OF TORONTO

INDIGO BIOSCIENCES

Genentech

A Member of the Roche Group

MedImmune

A member of the AstraZeneca Group

Galectin Therapeutics

Kowa Pharmaceuticals America, Inc.
### Your 57 Expert Speakers

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Affiliation</th>
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<tbody>
<tr>
<td>Adil Mardinoglu</td>
<td>Professor of Systems Biology, Kings College London</td>
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<tr>
<td>Allison Capone</td>
<td>Global Strategic Marketing for Non-alcoholic Steatohepatitis, Intercept</td>
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<tr>
<td>Anthony Samir</td>
<td>Assistant Professor, Harvard Medical School</td>
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<td>Brent Tetri</td>
<td>Director, Division of Gastroenterology &amp; Hepatology; Professor of Internal Medicine, Saint Louis University School of Medicine</td>
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<tr>
<td>Bryan Burkey</td>
<td>Head of Pharmacology, Zafgen</td>
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<tr>
<td>Bryan Fuchs</td>
<td>Assistant in Molecular Biology, Massachusetts General Hospital</td>
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<td>C. H. James Harwood</td>
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<td>Glenn Rosen</td>
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<tr>
<td>Greg Everson</td>
<td>Chief Executive Officer, HepQuant</td>
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<td>Greg Tesz</td>
<td>Principal Scientist, Pfizer</td>
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<td>H. James Harwood</td>
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<td>Isai Peimer</td>
<td>Biotech Analyst, Surveyor Capital</td>
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<td>Jagpreet Chhatwal</td>
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<td>Nonalcoholic Steatohepatitis, Fibrotic Diseases, Biomarker Sciences &amp; Research Scientist, Gilead</td>
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<tr>
<td>Jeff Irelan</td>
<td>Director, Scientific Application, Organovo</td>
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<tr>
<td>Julia Brosnan</td>
<td>Senior Director, External Collaborations &amp; Scientific Alliances, Pfizer</td>
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<td>Katie Brown</td>
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<td>Maria-Chiara Magnone</td>
<td>Vice President, Metabolic Complications, Janssen Research &amp; Development</td>
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# Your 57 Expert Speakers

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<tr>
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<th>Title/Position</th>
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<tbody>
<tr>
<td>Manu Chakravarthy</td>
<td>Chief Medical Officer &amp; Senior Vice President</td>
<td>Axcella Health</td>
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<tr>
<td>Min Lu</td>
<td>Director, Head of Fibrosis</td>
<td>Morphic Therapeutics</td>
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<tr>
<td>Naim Alkhouri</td>
<td>Director of the Metabolic Health Center</td>
<td>Texas Liver Institute</td>
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<tr>
<td>Nikolai Naoumov</td>
<td>Executive Director, Hepatology Sciences &amp; Innovation</td>
<td>Novartis</td>
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<tr>
<td>Patrick Horn</td>
<td>Director of the Institute for Innovation in Imaging</td>
<td>Massachusetts General Hospital</td>
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<tr>
<td>Pascal Prigent</td>
<td>Executive Vice President, Commercial</td>
<td>Genfit</td>
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<tr>
<td>Peter Guzzo</td>
<td>Cofounder &amp; Chief Executive Officer</td>
<td>ConSynance Therapeutics</td>
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<td>Petr Caravan</td>
<td>Director of the Institute for Innovation in Imaging</td>
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<td>Peter Traber</td>
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<td>Richard Lee</td>
<td>Director</td>
<td>Ionis Pharmaceuticals</td>
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<td>Richard Torstenson</td>
<td>Independent Regulatory Advisor</td>
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<td>Ritesh Shah</td>
<td>Commercial Development Lead, Internal Medicine</td>
<td>Pfizer</td>
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<td>Robert Arch</td>
<td>Executive Director; Head, Liver Disease Program</td>
<td>Novartis Institute for BioMedical Research</td>
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<td>Roberto Calle</td>
<td>Executive Director, Internal Medicine Research Unit</td>
<td>Pfizer</td>
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<td>Richard Marshall</td>
<td>Chief Medical Officer, Galecto Biotech</td>
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<td>Saurabh Gupta</td>
<td>Director – Translational Research &amp; Early Clinical</td>
<td>Takeda</td>
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<td>Stephen Previs</td>
<td>Director</td>
<td>Merck</td>
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<tr>
<td>Suneil Hosmane</td>
<td>Executive Vice President-Strategic Development</td>
<td>Genfit</td>
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<tr>
<td>Star Seyedkazemi</td>
<td>Associate Vice President in Clinical Development</td>
<td>Allergan</td>
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<tr>
<td>Wayne Eskridge</td>
<td>Chief Executive Officer</td>
<td>Fatty Liver Foundation</td>
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<tr>
<td>Wellin Xie</td>
<td>Senior Principal Scientist</td>
<td>Celgene</td>
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<tr>
<td>Yury Popov</td>
<td>Assistant Professor of Medicine</td>
<td>Harvard Medical School</td>
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**Contact Information:**
- Tel: +1 617 455 4188
- Email: info@hansonwade.com
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**Nonalcoholic Steatohepatitis (NASH) Group:**

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**3rd Annual NASH Summit**
22-25 April, 2019 | Boston, MA
### Scientific Program, Day 1
**Tuesday April 23**
- **Plenary Stream**
- **Speed Networking**
  - Discovery Stream
  - Translational Stream
  - Clinical Stream

### Scientific Program, Day 2
**Wednesday April 24**
- **Plenary Stream**
- **Speed Networking**
  - Discovery Stream
  - Translational Stream
  - Clinical Stream

### Discussions Day
**Thursday April 25**
- **Workshop A**
- **Workshop B**
- **Workshop C**
- **Workshop D**

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*This conference was of outstanding value. First class presentations, great opportunity for networking and perfect logistics!* — AstraZeneca
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<tr>
<th>Time</th>
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<th>Speaker(s)</th>
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<td>9.30</td>
<td>Review &amp; Analysis of the Current Non-Invasive Diagnostic Modalities</td>
<td>Jen-Chieh (Jay) Chuang, Nonalcoholic Steatohepatitis, Fibrotic Diseases, Biomarker Sciences &amp; Research Scientist, Gilead</td>
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<td>9.45</td>
<td>NIMBLE Project: Finding Non-Invasive Biomarkers for NASH (FNIH Biomarkers Consortium)</td>
<td>Roberto Calle, Executive Director, Internal Medicine Research Unit, Pfizer</td>
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<td>9.45</td>
<td>Future NASH Commercial Landscape</td>
<td>Ritesh Shah, Commercial Development Lead, Internal Medicine, Pfizer</td>
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<td>10.15</td>
<td>LITMUS – Valorizing the European NAFLD Registry</td>
<td>Julia Brosnan, Senior Director, External Collaborations &amp; Scientific Alliances, Pfizer</td>
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<tr>
<td>10.15</td>
<td>Designing Clinical Trials in Pediatric NASH: From Patient Selection to Endpoints &amp; Beyond</td>
<td>Naim Alkhouri, Director of the Metabolic Health Center, Texas Liver Institute</td>
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<td>10.45</td>
<td>Extended Q&amp;A for NIMBLE &amp; LITMUS</td>
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<td>11.00</td>
<td>Morning Break &amp; Networking</td>
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Drug to Clinic: How Do We Get There? (Continued)

11.30 Potential Impact & Value of NASH Therapies
- What is the disease burden of NAFLD and NASH?
- What is the potential impact of NASH therapies on reducing disease burden and mortality?
- What is the potential cost-effectiveness of NASH therapies?

Jagpreet Chhatwal
Assistant Professor
Harvard Medical School

12.00 Panel Discussion: Pricing & Reimbursement
- What should be considered when strategizing the pricing and reimbursement landscape?
- Contextualizing the payers perspective for first approved therapies and considerations for candidates that follow

Ritesh Shah
Commercial Development Lead, Internal Medicine
Pfizer

Pascal Prigent
Executive Vice President, Commercial
Genfit

Jagpreet Chhatwal
Assistant Professor
Harvard Medical School

11.45 Multiparametric Imaging: Translating Preclinical Observations into Human Trial
Noninvasive quantification of fibrosis holds value for future preclinical drug explorations and monitoring of response to therapy that would accelerate novel treatment evaluation. Leveraging current advancements with imaging in relation to liver fibrosis is pivotal to quantifying the disease non-invasively and subsequently improving vital patient recruitment and retention for clinical trials

This session will explore:
- Molecular magnetic resonance imaging (MRI) to quantify liver fibrosis and fibrogenesis
- Other noninvasive methods to estimate liver fibrosis
- Multiparametric imaging - translating preclinical observations into human trial

Peter Caravan
Director of the Institute for Innovation in Imaging
Massachusetts General Hospital
Bryan Fuchs
Assistant in Molecular Biology
Massachusetts General Hospital

12.45 Lunch & Networking

Innovations to Enhance the Utility of Biomarkers for Fatty & Fibrotic Liver Disease

1.45 Exploring the Translatability of NASH Biomarkers
- Exploring the utility of current non-invasive biomarkers for disease severity, patient stratification, early responsiveness and longitudinal monitoring in clinical trials

Saurabh Gupta
Director, Translational Research & Early Clinical Data
Takeda

2.15 Machine Learning for NASH Biomarkers
- Opportunities and challenges in AI for biomedicine
- Recent work on applying machine learning for NASH biomarker synthesis

Laura Brattain
Research Scientist, Department of Radiology
Massachusetts General Hospital

2.45 Developing an In Vitro Diagnostic Test (IVD) in Parallel to Advancing a Drug Candidate
- Primer on different types of diagnostic tests
- Overview of NASH diagnostic landscape
- Identifying biomarkers to aide in the diagnosis of NASH patients

Sunell Hosmane
Executive Vice President Strategic Development
Genfit

3.15 Chair’s Summary
Jen-Chieh (Jay) Chuang
Nonalcoholic Steatohepatitis, Fibrotic Diseases, Biomarker Sciences & Research Scientist
Gilead

Insights into Investment & Market Development

1.45 Panel Discussion: Investor Confidence
- Analyzing the NASH market landscape from an investor perspective
- Sharing insights into how to build investor confidence
- Lessons learnt from significant investments to date in NASH

Isai Peimer
Biotech Analyst
Surveyor Capital

Laurent Fischer
Senior Vice President, Head Liver Therapeutic Area
Allergan

Peter Traber
Partner
Alacrita Consulting

2.30 Chair’s Summary
Allison Capone
Global Strategic Marketing for Nonalcoholic Steatohepatitis
 Intercept

Patient’s Insight Evening & Networking

Understand, evaluate and consider the perspectives of NASH patients of various phenotype to inform your strategies for patient retention, and adoption of your candidate into the clinic.

Katie Brown
Vice President, Support & Survivorship Program
Lungevity (NASH Patient)

Wayne Eskridge
Chief Executive Officer
Fatty Liver Foundation
Scientific Program: Tuesday April 23

7.50 Chair’s Opening Remarks
Laurent Fischer
Senior Vice President, Head Liver Therapeutic Area
Allergan

Outlining Current Understanding & Gaps in Our Knowledge to Most Efficaciously Address NASH

8.00 What is the Future of NASH?
Laurent Fischer
Senior Vice President, Head Liver Therapeutic Area
Allergan

Overviewing areas of unmet need with emphasis on unchartered territory and addressing the associated high priority questions limiting drug development in these spaces including:
• Collaboration in NASH. How do we partner to advance the field?
• How do we meet the urgency of identifying biomarkers to diagnose patients with NASH and fibrosis at risk of disease progression?
• What can we expect from different agents targeting steatohepatitis and/or fibrosis?
• Are current surrogate endpoints aligned with stakeholders’ expectations?
• Are combinations and cross-company collaborations the future of NASH therapy?

8.30 Keynote: Many Paths to NASH—Many Targets for Treatment
Brent Tetri
Director, Division of Gastroenterology & Hepatology; Professor of Internal Medicine
Saint Louis University School of Medicine

• NASH is a phenotype that likely results from different genetic, epigenetic and dietary exposures in different patients
• The underlying driver of hepatocellular injury and the resulting inflammation and fibrosis in NASH is an oversupply of fatty acids in hepatocytes
• Approaches to treatment include interventions that reduce energy intake, improve extrahepatic metabolism of fatty acids and glucose, decrease the generation of fatty acids in the liver, reduce the inflammatory wound response caused by lipotoxicity and reverse extracellular matrix deposition
• As new drugs are developed, future therapy for NASH will likely involve a multi-drug approach in addition to lifestyle modification that is rationally based on complementary pathways.

9.00 Session Reserved for ICON

10.00 Speed Networking
This session is the ideal opportunity to get face-to-face time with many of the brightest minds working in the NASH field and establish meaningful business relationships.

10.45 Morning Break

Discovery Stream:
Chair: H. James Harwood, Adjunct Professor
Department of Pathology, Wake Forest University School of Medicine

Translational Stream:
Chair: Glenn Rosen, Independent Consultant

Clinical Stream:
Chair: Peter Traber, Partner, Alacrita Consulting

Cross-Disciplinary Outlook on NASH Molecular Drivers & Targeting Them

11.30 An Analysis of NASH Pathways by Single Cell Sequencing

• NASH develops through an interplay of several cell types in the liver which exist in varying abundances, although the precise nature of these interactions remains unknown
• Single Cell Sequencing (SCS) advances the sequencing capabilities of RNAseq by providing quantifiable RNA transcript reads on a single-cell basis

11.30 Use of Precision Cut Liver Slices in the Modelling of Fibrosis

• Demonstrating the utility of precision cut liver slices (PCLS) retaining the structure and cellular composition of the native liver and therefore representing a much superior and improved system to study liver fibrosis compared to two-dimensional or mono/co-cultures of cells
• Showcasing the Newcastle Fibrosis Research Laboratory (NFRG) bioreactor system that increases the healthy lifespan of PCLS which allows us to model fibrogenesis

11.30 NASH, Now: Therapeutic Targets & the Competitive Clinical Trial Landscape

• Overview of clinical compounds being evaluated for NASH with emphasis on mechanistic differences
• Evaluating regulatory guidance on development of NASH therapeutics with focus on histology versus non-invasive imaging in drug advancement
• By applying SCS technology to NASH and healthy liver samples, an understanding of cell-specific biology can be achieved as it relates to the pathological features of NASH

James Conway  
Senior Scientist - Translational Bioinformatics  
MedImmune

• Sharing data on testing the ability of clinically approved drugs to limit fibrosis in this model; as an example, nintedanib and obeticholic acid therapy limit fibrogenesis in PCLS

• Describing how this new bioreactor can be successfully used to model fibrogenesis and demonstrate efficacy of anti-fibrotic therapies

Jelena Mann  
Professor of Epigenetics  
Fibrosis Research Group  
Newcastle University

12.00  Preclinical to Clinical Translation: Critically Review Quantification Methods of Liver Fat Oxidation as well as Protein Flux Biomarkers

• Exploring proteomic methods for a dynamic measurement of physiologic function and confidently quantify liver fat oxidation

• Reviewing recent progress in protein flux biomarkers as a non-invasive diagnostic

• Implementing quantification methods of liver fat oxidation and protein flux biomarkers to improve development from preclinical to clinical translation

Stephen Previs  
Director  
Merck

12.00  HepaStem for the Treatment of Fibro-inflammatory Liver Diseases

• Showing Hepastem as having multiple MoA of interest for NASH

• Presenting clinical data generated in ACLF patients

• HepaStem is developed in NASH indication (PhI/IIa)

Etienne Sokal  
Chief Scientific & Medical Officer  
Promethera Biosciences

12.00  NASH Clinical Trial Design with Emphasis on Patient Recruitment

• Overview of study design for phase 3 NASH clinical trials

• Strategic considerations for patient recruitment in phase 3 trials

Star Seyedkazemi  
Associate Vice President in Clinical Development  
Allergan

12.30  Targeting Multiple Drivers of NASH by GSNOR Inhibition: Inflammation, Oxidative Stress, Steatosis, Glucose Dysregulation, & Fibrosis

• Regulating cellular nitrosylation through GSNOR inhibition and therefore inhibiting many drivers of pathology

• Demonstrating efficacy of SAJE’s small molecule GSNOR inhibitor

• Evaluating the potential to prevent progression of NASH and, perhaps, to reverse it, and obviate the need for multiple drugs to regulate the disease

Matthews Bradley  
Founder, Chairman, President & Chief Technical Officer  
SAJE Pharma

12.30  Anti-inflammatory & Anti-Fibrotic Effects of Icosabutate, a Structurally Engineered Fatty Acid, in Differentiated Rodent NASH Model

• Outlining the rationale behind structurally engineering of fatty acids for the treatment of liver disease

• Showcasing ADME properties of icosabutate

• Demonstrating the effects of icosabutate on inflammation and fibrosis in diverse rodent NASH models

• Sharing insights into mechanism/s of action

David Fraser  
Chief Scientific Officer  
NorthSea Therapeutics

12.30  The HepQuant Tests as Aids to Drug Development

• HepQuant tests (HepQuant SHUNT, HepQuant FLOW, HepQuant STAT) are blood-based and minimally invasive

• The tests yield a disease severity index (DSI) of the liver’s health

• STAT has favorable characteristics for use in pre-screening cases for trials

• SHUNT has favorable characteristics for tracking disease progression or response to treatment

• There are clinically significant cutoffs for DSI

Greg Everson  
Chief Executive Officer  
HepQuant

1.00  Lunch & Networking - Lunch Seminar Hosted By: High Point Clinical Trials Center

Tel: +1 617 455 4188  Email: info@hansonwade.com  www.nash-summit.com  Nonalcoholic Steatohepatitis (NASH) Group
## Case Studies of Emerging Candidates

### 2.00 Tissue-Specific Integrin Modulation & EMT Inhibition For The Treatment of NASH
- **Pliant Therapeutics** focuses on developing small molecules to selectively target transcriptional regulation of epithelial-to-mesenchymal-transition (EMT), a process that is induced by TGF-β.
- By selectively targeting EMT, Pliant aims to target many fibrotic diseases through novel mechanisms.

**Éric Lefebvre**, Chief Medical Officer, Pliant Therapeutics

### 2.30 CSTI-100, a Melanin-Concentrating Hormone Receptor 1 (MCHR1) Antagonist, for the Treatment of NASH and Metabolic Syndrome Comorbidities
CSTI-100, a selective MCHR1 antagonist addresses hallmark NASH symptoms and important related metabolic syndrome comorbidities. In preclinical models of NASH, CSTI-100 demonstrates:
- Reductions in liver triglycerides, non-esterified fatty acids and cholesterol
- Reductions in key liver inflammatory, fibrosis and injury biomarkers
- Fat selective weight loss due to a reduction in food intake
- Improvements in glucose tolerance and insulin sensitivity

**Peter Guzzo**, Cofounder & Chief Executive Officer, ConSynance Therapeutics

## Critically Addressing the Bench to Bedside Translational Gap

### 2.00 Using Antisense Oligonucleotides for Treatment of NASH
- Demonstrating antisense inhibition of Angptl3 as a NASH therapeutic in animal studies
- Demonstrating antisense inhibition of Keap1 as an anti-oxidant NASH therapeutic in animal studies

**Richard Lee**, Director, Ionis Pharmaceuticals

### 2.30 Methionine Aminopeptidase 2 Inhibitors as Novel Agents for Treatment of NAFLD/NASH
- Introducing MetAP2 in the context of NASH
- Showcasing efficacy in animal models of NAFLD/NASH
- Presenting clinical experience to date and translation from bench to bedside

**Bryan Burkey**, Head of Pharmacology, Zafgen

## Optimizing Clinical Trial Design to More Confidently Reflect Clinical Outcome (Continued)

### 2.00 Machine Learning for Patient Selection
- Harnessing innovations in machine learning to identify and characterize NASH patients for more confident enrichment of clinical trial populations

**Anthony Samir**, Assistant Professor, Harvard Medical School

### 2.30 Adhering to Regulatory Guidelines & Overcoming Clinical Challenges Related to NASH Proof of Concept Studies
- Filling the gap between non-invasive assessment of NASH PoC endpoints and the clinically relevant endpoints
- Robustly applying non-invasive MRI imaging in addition to liver fat quantification
- Reviewing *in silico* trial simulations using 10,000 virtual NASH patients to explore and support diverse study designs
- Are there more relevant and helpful approaches in the European vs. North American current thinking in the moving target NASH development field?

**Pietro Scalfaro**, Chief Medical Officer, Enyo Pharma

## Innovations in Ex Vivo & Biomarkers to More Confidently Monitor Drug Efficacy

### 3.00 Afternoon Refreshments & Networking

### 4.00 Using 3D Bioprinted Human Liver Tissue to Model NAFLD/NASH in vitro?
- ExVive™ Human Liver Tissue is an *in vitro* 3D bioprinted liver model containing primary human hepatocytes, hepatic stellate cells, endothelial cells, and Kupffer cells, with a complex multicellular architecture and sustained function and viability (at least 4 weeks in culture)
- Nutrient overload by addition of excess fatty acids and sugars leads to steatosis in the model, which when combined with an inflammatory stimulus can progress to hepatocellular injury, inflammation and fibrosis, characteristic of NASH
- Together, these features suggest that 3D liver tissues hold promise for the study of complex, chronic conditions such as NASH, enabling the discovery of novel therapeutics, biomarkers, and safety assessment of drugs in a disease-relevant background

**Jeff Irelan**, Director, Scientific Application, Organovo
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>4.10</td>
<td>An Atypical Biomarker Story – Discovery &amp; Evolution of the Enhanced Liver Fibrosis (ELFTM) Test</td>
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<td>• Learn about liver fibrosis blood-based biomarker panels and their differences.</td>
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<td>• Lessons learned from the discovery and development of the ELF test.</td>
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<td>• How the ELF test is being used today in trials and the clinic.</td>
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<tr>
<td>4.40</td>
<td>How do we Address Fibrosis more Effectively?</td>
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<td></td>
<td>• Overcoming increased challenges associated with developing two novel entities together</td>
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<td>• Identifying fibrosis and cirrhosis patients at high-risk for Hepatocellular Carcinoma</td>
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<td>5.10</td>
<td>Critically Reviewing Which Mechanisms of Action to Combine to Address NASH</td>
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<td>• Understanding the rationale for combination regimes in NASH</td>
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<td>• Exploring combination options in clinical studies and the success of combination development so far</td>
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<tr>
<td>5.40</td>
<td>Chairs’ Closing Remarks</td>
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<td>6.00</td>
<td>Scientific Poster Session</td>
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<td>The Poster Session is an informal part of the conference agenda, allowing you to</td>
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<td>connect with your peers in a relaxed atmosphere and continue to forge new and existing</td>
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<td>relationships. During this session scientific posters will be presented on validation on</td>
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<td>novel targets, drugs with new mechanisms of action, preclinical modalities that better</td>
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<td>recapitulate human NASH and latest progress in validating non-invasive diagnostic and</td>
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<td>prognostic technologies.</td>
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Great event, exceptional networking opportunities. High quality of presentations. Very efficient way to spend my time.

If 150 people leave here, go out talk to their companies, their colleagues, their peers, talk about what they learnt here and make corrections: the amplification effect begins to move the field.
### Scientific Program: Wednesday April 24

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker/Panelist</th>
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<tbody>
<tr>
<td>8.20</td>
<td>Chair's Opening Remarks</td>
<td>Laurent Fischer&lt;br&gt;Senior Vice President, Head Liver Therapeutic Area&lt;br&gt;Allergan</td>
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<tr>
<td></td>
<td><strong>Critically Assessing Patient Recruitment Challenges</strong>&lt;br&gt;Now &amp; in the Future</td>
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<td>8.30</td>
<td>NASH/NAFLD: Does Genotype Connect to Phenotype?</td>
<td>Linda Morrow&lt;br&gt;Vice President &amp; Chief Medical Officer&lt;br&gt;ProSciento</td>
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<td>9.00</td>
<td>NAFLD &amp; NASH from the Patient Perspective - What Are Our Next Steps?</td>
<td>Marko Korenjak&lt;br&gt;Vice President&lt;br&gt;European Liver Patients Association</td>
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<td>9.30</td>
<td>The Therapeutic Potential of Inhibitors of Steatosis for the Treatment of NASH</td>
<td>Greg Tesz&lt;br&gt;Principal Scientist&lt;br&gt;Pfizer</td>
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<tr>
<td>10.00</td>
<td>Morning Break &amp; Networking</td>
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<td>11.00</td>
<td><strong>Case Studies of Emerging Candidates (Continued)</strong>&lt;br&gt;Targeting the Wnt Pathway</td>
<td>Wellin Xie&lt;br&gt;Senior Principal Scientist&lt;br&gt;Celgene</td>
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<td></td>
<td><strong>Combating NASH as a Metabolic, Non-Communicable Disease with Significant Global Burden</strong></td>
<td>Maria-Chiara Magnone&lt;br&gt;Vice President, Metabolic Complications&lt;br&gt;Janssen Research &amp; Development</td>
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<td></td>
<td>11.00 How to Develop a Differentiated FXR Agonist that Avoids the Side Effects of 1st Generation FXR Drugs</td>
<td>Claus Kremoser&lt;br&gt;Chief Executive Officer&lt;br&gt;Phenex Pharmaceuticals</td>
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**Discovery Stream:**<br>Chair: Robert Arch<br>Executive Director; Head, Liver Disease Program<br>Novartis Institutes for BioMedical Research (NIBR)

**Translational Stream:**<br>Chair: Saswata Talukdar<br>Director<br/CardioMetabolic Discovery<br>Merck

**Clinical Stream:**<br>Chair: Peter Traber<br>Partner<br>Alacrita Consulting

**Safety & Efficacy Within the Clinic**

**The Relationship of NASH in the Context of Wider Liver & Cardiovascular Disease**
11.30 Rationale for the Use of Bile Acid Modulators for the Treatment of NASH
• Demonstrating preclinical data of bile acid modulators
• Reviewing literature and presenting an argument for the use of bile acid modulators against NASH
Patrick Horn
Chief Medical Officer
Albireo Pharma

11.30 Understanding Hepatocellular Carcinoma as an Extension of NASH: The Cirrhosis-HCC Connection, Practical Implications for Preclinical & Clinical Drug Testing
• Investigating cellular and molecular mechanism of fibrosis-HCC crosstalk
• Analyzing caveats of current practices of preclinical anti-fibrotic drug testing – short duration, mild disease, reliance on surrogate end-points instead of clinically-relevant long-term outcomes
• Strategizing overcoming these caveats, and how to move towards using clinically-relevant end-points in preclinical drug evaluation in practice
Yury Popov
Assistant Professor of Medicine
Harvard Medical School

11.30 The Polypharmacological Anti-NASH Effects of Namodenoson are Mediated via De-Regulation of the Wnt/b-catenin Pathway
• Namodenoson is a small molecule agonist at the A3 adenosine receptor with excellent safety profile tested in >200 patients
• Definitive molecular mechanism of action including de-regulation of Wnt/b-catenin
• Current Phase 2 in NAFLD/NASH patients is on going
Pnina Fishman
Chief Executive Officer
CanFite BioPharma

12.00 Targeting Alpha V Integrins for Liver Fibrosis
• Anti-fibrotic treatment represents an unmet medical need for patients with fibrosis diseases, such as NASH, kidney fibrosis, and IPF
• Alpha V integrins are membrane proteins that bind to latency-associated peptide (LAP) of TGF-β as its principal ligands and activate mature TGF-β to lead to fibrogenesis
• Morphic Therapeutic is leading the development of a new generation of oral drugs to target alpha V integrins for fibrotic disorders
Min Lu
Director, Head of Fibrosis
Morphic Therapeutics

12.00 The Endocrinologist Perspective: Profiling NASH in the Context of Metabolic Syndrome
• The systemic and heterogeneous nature of NAFLD and its relationship to type 2 diabetes and cardiovascular disease
• Common mechanistic underpinnings
Manu Chakravarthy
Senior Vice President & Chief Medical Officer
Axcella Health

12.00 Targeting Galectins in NASH Fibrosis
• Galectins have an potential role in the pathogenesis of fibrosis across multiple organs
• Galectin-3 is now being targeted clinically for the treatment of NASH
• The talk will focus on the challenges of targeting fibrosis in NASH, generally, and the evidence for Gal-3
Richard Marshall
Chief Medical Officer
Galecto Biotech

12.30 Lunch & Networking

Reviewing Clinical Advances of NASH Therapeutics in Phase 2 & Phase 3 Clinical Trials

Becky Taub
Chief Medical Officer, Executive Vice President Research & Development
Madrigal Pharmaceuticals

1.30 Showcasing the Clinical Development of MGL3196
• Reviewing Madrigal’s clinical development of MGL3196
• Advancing understanding surrounding thyroid hormone receptor beta agonist reducing lipotoxicity in the NASH liver
• Critically analysing MGL-3196 as the first truly beta selective THR-beta agonist
2.00  Afternoon Break & Networking

3.00  Aramchol Phase 2b Results & Phase 3 Outlook
• NASH develops through an interplay of several cell types in the liver which exist in varying
  abundances, although the precise nature of these interactions remains unknown
• Single Cell Sequencing (SCS) advances the sequencing capabilities of RNAseq by
  providing quantifiable RNA transcript reads on a single-cell basis
• By applying SCS technology to NASH and healthy liver samples, an understanding of cell-
  specific biology can be achieved as it relates to the pathological features of NASH

Liat Hayardeny
Chief Scientific
Officer
Galmed
Pharmaceuticals

3.30  An Update of Elafibranor & Use as the Backbone for Combinations
• Overview of Elafibranor including disease model data
• Presenting data from combination program to identify synergistic mechanisms of action
  with Elafibranor

Dean Hum
Senior Executive Vice
President & Chief
Scientific Officer
Genfit

4.00  Chairs’ Closing Remarks

“This was the best pragmatic development conference that I have been to”

“As a newcomer to the NASH space, I found the meeting to be incredibly informative and intellectually stimulating. The meeting was well organized and very comprehensive”
### Workshop A

**Liver Fibrosis: Deliniating & Utilizing the Complexities of Fibrosis Pathology**

**10:00am - 1:00pm**

Our understanding of the paramount importance that epigenetic regulation exerts over disease progression has grown in the past decade. Not only do epigenetic mechanisms govern the course of disease, but they also inform the likelihood of ever developing disease. Importantly, epigenetic mechanisms are plastic and can be modified with in life interventions ranging from diet and exercise to use of drugs. I will highlight how epigenetic inheritance affect course of liver fibrosis development and describe the mechanisms behind these predispositions.

This workshop will discuss:

- Epigenetic mechanisms governing liver fibrogenesis, both in rodent models of disease and in patients
- DNA methylation patterns found in patient liver that show predisposition to developing liver fibrosis when exposed to chronic injury
- Hepatic DNA methylation signatures present in the circulating cell-free DNA which can be used for determining the current grade of fibrosis
- Epigenetic signatures that predispose patients towards development of fibrosis present in the liver before disease occurs

**Workshop Leader:**

<table>
<thead>
<tr>
<th>Jelena Mann</th>
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<td>Professor of Epigenetics, Fibrosis Research Group</td>
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### Workshop B

**Systems Biology in NASH: Approaches & Applications**

**2.00pm - 5.00pm**

Systems biology is an interdisciplinary field that studies the complex interactions within the liver, other tissues and oral/gut microbiota using a holistic approach. Detailed insights into the biological functions of the liver and its crosstalk with the oral/gut microbiota can be used to develop novel strategies for the prevention and treatment of NASH, and facilitate more efficient drug development decisions.

This in-depth session focuses on:

- Comprehensively analyzing the biological functions in healthy and NASH diseased states using biological network models as an integration of multiomics data
- Successfully employing systems biology in hepatology for development of efficient strategies for NASH
- Detailing how to use systems biology for simulation of liver tissue functions and its crosstalk with other tissues and microbiota for prediction of therapeutic and side effects
- Understanding the systems biology of oral and gut microbiome in liver diseases

**Workshop Leader:**

<table>
<thead>
<tr>
<th>Adil Mardinoglu</th>
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<tr>
<td>Professor of Systems Biology</td>
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</table>
Workshop C

Stratification of NASH Through Patient Data Sets
10.00am - 1.00pm

Stratified Medicine Scotland - Innovation Centre (SMS-IC) is focused on linking Scotland’s domain expertise, data assets and delivery capability to accelerate the adoption of Precision Medicine for more effective medicine development, better diagnostics and earlier intervention, and optimal treatment selection.

Join your peers to review latest research on:
- The construction of highly curated and annotated patient data sets
- Accessing the right patient populations for stratification
- Ensuring data quality and content

Workshop D

Drug Development Strategy & Regulatory Intelligence in NASH
2:00-5:00pm

In the last year, the NASH drug development landscape has seen the emergence of novel drug candidates and varying success in the advancement of existing candidates. Now with the very earliest NASH drug looking to hit the market in 2021, questions surrounding clinical development strategy and regulatory intelligence before and after an accepted drug are pivotal to the field.

This workshop will cover:
- Translating drug development strategies confidently into trial execution
- Reviewing the regulatory landscape currently and for the future. The impact of the first approved NASH drug on phase 3 design (e.g. use of placebo) and utilization of biomarkers to facilitate drug development will be discussed.
Networking at the 3rd Annual Nash Summit is an experience like no other and is one of the main highlights that ensures repeat attendance year on year.

With more NASH experts in attendance than any other meeting, this is your best opportunity to interact with your industry peers. Connect with 300+ attendees across the four days through our bespoke networking experience. The summit will enable you to form real connections, gain tangible results and develop future business.

How You’ll Meet Them:

**Speed Networking**
Your opportunity to meet valuable new contacts in a short space of time.
This session is the ideal opportunity to meet face-to-face with the brightest minds working in the NASH field.
Specifically designed to connect you with many new contacts.
The renowned ‘Speed Networking’ will be one of the most valuable hours you will spend at the NASH Summit.

**Poster Sessions**
Showcasing your research to a plenary of peers and investors
This session provides a key platform for you to engage in debate and rebuttal around findings and discoveries showcased in people’s research.

**NASH Summit App**
Enhancing your ability to connect and network with fellow attendees
The NASH Summit app will enable you to easily connect with other attendees, exhibitors and speakers to arrange 1-2-1 meetings.
Download this bespoke networking app to maximize your ability to network at the conference.

**Seniority of Attendees**

- **C—Level** 15%
- **Vice President** 18%
- **Senior Director/ Director** 30%
- **Team Leader/ Project Manager** 24%
- **Principal Scientist/ Scientist** 11%
- **Academic** 2%

**Attendees by Company**

- **Large Drug Developer**
- **Small & Medium Drug Developer**
- **Technology & Service Provider**
- **Research Institute**
- **Consultant**

**Attendance by Geo**

- **Europe** 13%
- **North America** 81%
- **Asia** 6%

* Based upon the 2nd Annual NASH Summit Boston (2018)
## Secure Your Place

<table>
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<th>Standard Rate</th>
<th>Register &amp; Pay before Friday, November 9</th>
<th>Standard Prices</th>
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<tr>
<td><strong>Gold Pass:</strong></td>
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<tr>
<td>Full Access – Scientific Program &amp; Seminar Day &amp; Discussion Day</td>
<td>$4147 (save $1550)</td>
<td>$4547 (save $1150)</td>
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<td><strong>Silver Pass:</strong></td>
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<td>Scientific Program plus Seminar Day or Discussion Day (For Discussion Day - Choose from A or C AND B or D)</td>
<td>$3398 (save $900)</td>
<td>$3898 (save $400)</td>
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<td><strong>Bronze Pass:</strong></td>
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<td>Scientific Program only</td>
<td>$2399 (save $500)</td>
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<td><strong>Seminar Day Only</strong> (Pre-conference)</td>
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*Academics are entitled to a 40% discount off the Industry Pricing (Please note: Discounts cannot be combined with any other offer)  

*VAT charged at 19%