



# A MULTI-STAKEHOLDER MULTI-SPECIALTY NASH TRIALISTS THINK TANK

Metabolic, hepatology, nephrology & cardiovascular cross-talk

**PRELIMINARY PROGRAM**

**19 – 20 October, 2023**



Embassy of France, Washington, D. C., USA



## CHAIRPERSONS



Javed Butler  
(Dallas, TX, USA)



Stephen Harrison  
(San Antonio, TX, USA)



Veronica Miller  
(Berkeley, CA, USA)



Arun Sanyal  
(Richmond, VA, USA)



Faiez Zannad  
(Paris, FRA)



## **SPEAKERS**

### **ACADEMY**

1. William Alazawi (London, UK)
2. Meena Bansal (New York, NY, USA)
3. Vera Bittner (Birmingham, AL, USA)
4. Javed Butler (Dallas, TX, USA)
5. Laura Ditchel (Boston, MA, USA)
6. Sven Francque (Antwerp, BEL)
7. Stephen Harrison (San Antonio, TX, USA)
8. Onno Holleboom (Amsterdam, NED)
9. Meg Jardine (Sydney, AUS)
10. Rohan Khera (New Haven, CT, USA)
11. Mikhail Kosiborod (Kansas City, MO, USA)
12. Roxana Mehran (New York, NY, USA)
13. Veronica Miller (Berkeley, CA, USA)
14. Mindie Nguyen (Palo Alto, CA, USA)
15. Mazen Nouredin (Los Angeles, CA, USA)
16. Neehar Parikh (Ann Arbor, MI, USA)
17. Juan Pericàs (Barcelona, ESP)
18. Kitt Petersen (New Haven, CT, USA)
19. Robert Rosenson (New York, NY, USA)
20. Arun Sanyal (Richmond, VA, USA)
21. Gerald Shulman (New Haven, CT, USA)
22. Mohammad Siddiqui (Richmond, VA, USA)
23. Bart Staels (Lille, FRA)
24. Harriette Van Spall (Hamilton, CAN)
25. Paul M Yen (Singapore, SIN)
26. Faiez Zannad (Paris, FRA)
27. Zobair Younossi (Falls Church, VA, USA)

### **PATIENTS**

28. Michael Betel (Fatty Liver Alliance, CAN)
29. Henry Chang (Fatty Liver Foundation, USA)
30. Wayne Eskridge (Fatty Liver Foundation, USA)
31. Jeff McIntyre (Global Liver, USA)
32. Margaret Padilla (San Antonio, TX, USA)

### **REGULATORY**

33. Frank Anania (FDA, USA)
34. John Sharretts (FDA, USA)
35. Raymond Soccio (FDA, USA)
36. Charmaine Stewart (FDA, USA)
37. Aliza Thompson (FDA, USA)

### **JOURNAL EDITORS**

38. Patrick O'Malley (NEJM, USA)
39. Vlad Ratziu (Journal of Hepatology, FRA)
40. Stuart Spencer (The Lancet, UK)
41. Jennifer Sargent (Nature Medicine, USA)

### **INDUSTRY**

42. Phil Ambery (AstraZeneca, USA)
43. Salvador Augustin (Boehringer Ingelheim, GER)
44. Matt Kelly (Caristo Diagnostics, UK)
45. Sarah Browne (Altimmune, USA)
46. Marc Buysse (IDDI, BEL)
47. Roberto Calle (Regeneron, USA)
48. Jerry Colca (Cirius, USA)
49. Michael Cooreman (Inventiva, FRA)
50. DeAunne Denmark (Somalogic, USA)
51. Andrea Dennis (Perspectum, USA)
52. Sam Engel (Merck, USA)
53. Judith Ertle (Boehringer Ingelheim, GER)
54. David Fraser (Northsea Therapeutics, NED)
55. Juan P Frías (Velocity Clinical Research, USA)
56. Sophie Jeannin (Summit Clinical Research, USA)
57. Lars Johansson (Antaros, USA)
58. Kavita Juneja (Concept Therapeutics, USA)
59. Vidhya Kumar (Cleerly, USA)
60. Michelle Long (Novo Nordisk, DK)
61. James Min (Cleerly, USA)
62. David Nikodem (Metadeq, USA)
63. Kay Pepin (Resoundant, USA)
64. Laurent Sandrin (Echosens, USA)
65. Lois Lee (Tern Pharmaceuticals, USA)
66. Karsten Strauss (Olink, SWE)
67. Ruth Thieroff-Ekerdt (Cambrian Biopharma, USA)
68. Ibrahim Turfanda (Lilly, USA)
69. Rebecca Taub (Madrígal, USA)
70. Janet Wittes (Wittes LLC, USA)
71. Kitty Yale (Akeru, USA)
72. Ramy Younes (Boehringer Ingelheim, GER)

**19 OCTOBER, 2023**



**THURSDAY OCTOBER 19<sup>th</sup> 2023**

8.30 – 10.30

Setting the stage

**Multi-Organ/System Accelerated Innovation in MASLD/MASH. What, So What, and Now What? The conceptual framework and main objectives of MOSAIC**

MOSAIC Chairs

**MASLD/MASH LIVER – HEART – KIDNEY CLINICAL PRESENTATIONS AND OUTCOMES. ASSOCIATED OR CONSUBSTANTIAL CONDITIONS?**

Chairpersons: Stephen Harrison (San Antonio, TX, USA) & Faiez Zannad (Paris, FRA)

**When do patients with liver disease die from CVD complications**

Meena Bansal (New York, NY, USA)

**Patients with atherosclerotic CVD often have liver and renal related issues associated with poor outcome**

William Alazawi (London, UK)

**Patients with Heart Failure and preserved ejection fraction, often have liver and renal related issues associated with poor outcome**

Javed Butler (Dallas, TX, USA)

**Is there a link between CKD and MASLD/MASH?**

Meg Jardine (Sydney, AUS)

**Patients with lipid disorders are at high risk of MASLD/MASH, CVD and CKD**

Robert Rosenson (New York, NY, USA)

**T2D obesity, the microbiote, and progression to CVD**

Juan P Frias (Velocity Clinical Research, USA)

**MASLD/MASH in Non-obese – what is that? How is it different?**

**Should it be approached differently**

Mindie Nguyen (Palo Alto, CA, USA)

**Industry viewpoints**

Phil Ambery (AstraZeneca, SWE), Roberto Calle (Regeneron, USA), Sam Engel (Merck, USA), David Fraser (Northsea Therapeutics, NED), Michelle Long (Novo Nordisk, DK)

**Patients' viewpoint**

Henry Chang (Fatty Liver Foundation, USA)

**The MOSAIC Multistakeholder Panel Debate  
LIVER – CARDIOVASCULAR – KIDNEY INTEGRATIVE VIEWS**

Chairpersons: Stephen Harrison (San Antonio, TX, USA) & Faiez Zannad (Paris, FRA)

*All speakers and panelists*

**THURSDAY OCTOBER 19<sup>th</sup> 2023. 10.30 – 11.00**

**COFFEE**

**19 OCTOBER, 2023**



**THURSDAY OCTOBER 19<sup>th</sup> 2023**

11.00 – 13.00

**HOW MECHANISMS, BIOTARGETS AND DRUGS MAY BE COMMON TO MASLD/MASH  
AND CARDIORENALMETABOLISM DISORDERS**

Chairpersons: Vera Bittner (Birmingham, AL, USA) & Veronica Miller (Berkeley, CA, USA)

Rapid fire: 5 mins presentations. 4 slides each

**Lipotoxicity, steatosis, inflammation, and fibrosis – are these serial  
or independent pathophysiological**

Bart Staels (Lille, FRA)

**Alpha, gamma and pan Peroxisome proliferator-activated receptor agonists.**

Sven Francque (Antwerp, BEL)

**Sodium-glucose transport proteins inhibitors**

William Alazawi (London, UK)

**Glucagon-Like Peptide 1 Receptor Agonist**

Mikhail Kosiborod (Kansas City, MO, USA)

**Mineralocorticoid receptor antagonists**

Faiez Zannad (Paris, FRA)

**Fibroblast growth factor 21**

Stephen Harrison (San Antonio, TX, USA)

**Triglyceride rich lipoproteins – LP( $\alpha$ )-Cholesterol.**

Vera Bittner (Birmingham, AL, USA)

**AMP-activated protein kinase**

Vlad Ratziu (Journal of Hepatology, FRA)

**Thyroid hormone receptor beta**

Paul M Yen (Singapore, SIN)

**Fibrogenesis as a systemic biotarget**

Meena Bansal (New York, NY, USA)

**Targeting hepatic mitochondrial uncoupling to treat MASLD,  
MASH and Cardiometabolic Disease**

Gerald Shulman (New Haven, CT, USA)

**pUFAs and eicosanoids**

David Fraser (Northsea Therapeutics, NED)

**Growth Hormone**

Laura Ditchel (Boston, MA, USA)

**Combination therapy**

Onno Holleboom (Amsterdam, NED)

**The MOSAIC Multistakeholder Panel Debate  
SYSTEMIC – MULTI-ORGAN– PLEIOTROPIC EFFECTS OF DRUGS**

Chairpersons: Vera Bittner (Birmingham, AL, USA) & Veronica Miller (Berkeley, CA, USA)

*All speakers and panelists*

**THURSDAY OCTOBER 19<sup>th</sup> 13.00 – 14.00**

**LUNCH**

**19 OCTOBER, 2023**



**THURSDAY OCTOBER 19<sup>th</sup> 2023**

14.00 - 16.00

**NON-INVASIVE NON-LIVER EVALUATIONS IN MASLD/MASH TRIALS.  
'MUST HAVE' VS. 'GOOD TO HAVE'?**

Chairpersons: Meg Jardine (Sydney, AUS) & Arun Sanyal (Richmond, VA, USA)

10 mins presentations

**Atherosclerosis endpoints: Imaging**

Matt Kelly (Caristo Diagnostics, UK)

**Heart Failure endpoints**

Javed Butler (Dallas, TX, USA)

**CKD endpoints**

Meg Jardine (Sydney, AUS)

**Malignancies endpoints**

Neehar Parikh (Ann Arbor, MI, USA)

**Patient reported outcomes**

Zobair Younossi (Falls Church, VA, USA)

**Non-Liver biomarkers to be assessed in MASLD/MASH biobanks?**

Mohammad Siddiqui (Richmond, VA, USA)

**Industry viewpoints**

DeAunne Denmark (Somalogic, USA), James Min (Cleerly, USA), Karsten Strauss (Olink, SWE)

**Patients' viewpoint**

Margaret Padilla (San Antonio, TX, USA), Jeff McIntyre (Global Liver, USA)

**The MOSAIC Multistakeholder Panel Debate**

**SHORTLISTING NON-INVASIVE NON-LIVER EVALUATIONS FOR MASLD/MASH TRIALS.**

Chairpersons: Meg Jardine (Sydney AUS) & Arun Sanyal (Richmond, VA, USA)

*All speakers and panelists*

**THURSDAY OCTOBER 19<sup>th</sup> 16.00 – 16.30**

**COFFEE**

**19 OCTOBER, 2023**



**THURSDAY OCTOBER 19<sup>th</sup> 2023**

16.30 – 17.30

**NON-INVASIVE LIVER ENDPOINTS IN NON-LIVER TRIALS**

Chairpersons: Arun Sanyal (Richmond, VA, USA) & Harriette Van Spall (Hamilton, CAN)

10 mins presentations

**Which future CVD and CKD trials should be enriched with liver endpoints?**

Harriette Van Spall (Hamilton, CAN)

**What liver biomarker substudies to recommend in CV trials**

Arun Sanyal (Richmond, VA, USA)

**What liver imaging substudies to recommend in CV trials**

Mazen Nouredin (Los Angeles, CA, USA)

**Industry viewpoints**

Lars Johansson (Antaros, USA), Laurent Sandrin (Echosens, USA)

**Patients' viewpoint**

Michael Betel (Fatty Liver Alliance, CAN)

**Regulatory viewpoints**

FDA: Frank Anania (FDA, USA), John Sharretts (FDA, USA), Raymond Soccio (FDA, USA)

**The MOSAIC Multistakeholder Panel Debate**

**TRANS-SPECIALTY COLLABORATORY**

**WHAT LIVER ENDPOINTS MAY BE EXPLORED IN CARDIO-RENAL-METABOLIC TRIALS?**

Chairpersons: Arun Sanyal (Richmond, VA, USA) & Harriette Van Spall (Hamilton, CAN)

*All speakers and panelists*

**THURSDAY OCTOBER 19<sup>th</sup> 2023**

17.30 – 18.15

**Cocktail reception**

18:15 – 20:30

**Seated dinner at Embassy**

**20 OCTOBER, 2023**



**FRIDAY OCTOBER 20<sup>th</sup> 2023**

8.30 – 10.30

**MULTIPLE ENDPOINTS IN A SINGLE TRIAL.**

**HITTING MULTIPLE TARGETS WITH A SINGLE BULLET.**

**INVESTIGATING MULTIPLE HYPOTHESES THROUGH CONCURRENT SUB-STUDIES.**

Chairpersons: Veronica Miller (Berkeley, CA, USA) & Arun Sanyal (Richmond, VA, USA)

**How to secure Cardiorenal claims in MASLD/MASH liver trials?**

Aliza Thompson (FDA, USA)

**How to secure metabolic claims in MASLD/MASH liver trials?**

John Sharretts (FDA, USA)

**How to seek a liver-MASLD/MASH claim in non-liver Cardio/Renal/Metabolism trials?**

**Investigator viewpoint**

Arun Sanyal (Richmond, VA, USA)

**Rationale for multiple outcomes in future MASLD/MASH clinical trials**

Juan Pericàs (Barcelona, ESP)

**Design and methodological issues with (multi-organ) composite, co-primary, secondary and hierarchical endpoints**

Marc Buyse (IDDI, BEL)

**How to statistically construct multiple endpoints in a statistical analysis plan?**

Janet Wittes (Wittes LLC, USA)

**How artificial intelligence and machine learning may help?**

Rohan Khera (New Haven, CT, USA)

**Patients' viewpoint**

Margaret Padilla (San Antonio, TX, USA)

**FRIDAY OCTOBER 20<sup>th</sup> 2023**

**The MOSAIC Multistakeholder Panel Debate**

**TRANS-SPECIALTY COLLABORATORY**

**HOW TO DESIGN FUTURE MASLD/MASH /CARDIORENAL TRIALS**

Chairpersons: Veronica Miller (Berkeley, CA, USA) & Arun Sanyal (Richmond, VA, USA)

*All speakers and panelists*

**FRIDAY OCTOBER 20<sup>th</sup> 2023, 10.30 – 11.00**

**COFFEE**

**20 OCTOBER, 2023**



**FRIDAY OCTOBER 20<sup>th</sup> 2023**

11.00 – 12.00

**WHAT SHOULD BE THE TARGET PATIENT POPULATION FOR A COMBINED  
MASLD/MASH/CARDIOMETABOLIC TRIAL?**

Chairpersons: Stephen Harrison (San Antonio, TX, USA) & Faiez Zannad (Paris, FRA)

**Investigator viewpoints**

Arun Sanyal (Richmond, VA, USA)

Faiez Zannad (Paris, FRA)

**Industry viewpoints**

Michael Cooreman (Inventiva, FRA), Michelle Long (Novo Nordisk, DK),

Ramy Younes (Boehringer Ingelheim, GER)

**Patients' viewpoint**

Jeff McIntyre (Global Liver, USA)

**Regulatory viewpoints**

FDA: Frank Anania (FDA, USA), John Sharretts (FDA, USA), Charmaine Stewart (FDA, USA),

Raymond Soccio (FDA, USA), Aliza Thompson (FDA, USA)

**FRIDAY OCTOBER 20<sup>th</sup> 2023**

12.00 – 13.00

**The MOSAIC Multistakeholder Panel Debate  
NEXT STEPS. HOW TO ADVANCE THE MOSAIC AGENDA?**

Chairpersons: Stephen Harrison (San Antonio, TX, USA), Faiez Zannad (Paris, FRA)

*All speakers and panelists*

**FRIDAY OCTOBER 20<sup>th</sup> 2023, 13.00 – 14.00  
LUNCH AND ADJOURN**