



**Washington DC
October 2023
Thursday 19th (8.30- 5.30) - Friday 20th (8.30– 2.00)**

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

PATIENTS

29. Michael Betel (Fatty Liver Alliance, CAN)
30. Henry Chang (Fatty Liver Foundation, USA)
31. Wayne Eskridge (Fatty Liver Foundation, USA)
32. Jeff McIntyre (Global Liver, USA)

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 Ambry (AstraZeneca, USA)
43. Charalambos Antoniadis (Caristo Diagnostics, UK)
44. Sarah Browne (Altimimmune, USA)
45. Marc Buyse (IDDI, BEL)
46. Roberto Calle (Regeneron, USA)
47. Jerry Colca (Cirius, USA)
48. Michael Cooreman (Inventiva, FRA)
49. Marilyn DeChantal (Theratech, USA)
50. Claudia Filozof (LabCorp, USA)
51. David Fraser (Northsea, NED)
52. Sophie Jeannin (Summit Clinical Research, USA)
53. Lars Johansson (Antaros, USA)
54. Kavita Juneja (Corcept Therapeutics, USA)
55. Vidhya Kumar (Cleerly, USA)
56. Brian Lian (Viking Therapeutics, USA)
57. Michelle Long (Novo Nordisk, DK)
58. Xuan Luong (Aligos, USA)
59. Maya Margalit (89 Bio, ISR)
60. James Min (Cleerly, USA)
61. Daniel Vega Moeller (Novo Nordisk, DEN)
62. Kay Pepin (Resoundant, USA)



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| 63. Laurent Sandrin (Echosens, USA) | 68. Ibrahim Turfanda (Lilly, USA) |
| 64. Lois Lee (Tern Pharmaceuticals, USA) | 69. Rebecca Taub (Madrigal, USA) |
| 65. Karsten Strauss (Olink, SWE) | 70. Sharat Varma (Novo Nordisk, DK) |
| 66. Saswata Talukdar (Merck, USA) | 71. Janet Wittes (Wittes LLC, USA) |
| 67. Ruth Thieroff-Ekerdt (Cambrian Biopharma, USA) | 72. Kitty Yale (Akerio, USA) |
| | 73. Ramy Younes (Boehringer, GER) |



In the program below, the new consensus nomenclature Metabolic dysfunction Associated Steatotic Liver Disease (MASLD/MASH) is used throughout, replacing NASH/NAFLD.

THURSDAY OCTOBER 19th 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

Karine Clément (Paris, FRA)

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:

Roberto Calle (Regeneron, USA), Phil Ambry (AstraZeneca, SWE), David Fraser (Northsea, NED), Saswata Talukdar (Merck, USA), Daniel Vega Moeller (Novo Nordisk, DEN),

Patients' viewpoints

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 19th 2023. 10.30-11.00
COFFEE**

**THURSDAY OCTOBER 19th 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 pathophysiologies

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(a)-Cholesterol.

Vera Bittner (Birmingham, AL, USA)

AMP-activated protein kinase

Vlad Ratzu (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, 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 19th 13.00 -14.00
LUNCH**

THURSDAY OCTOBER 19th 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

Charalambos Antoniades (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

James Min (Clearly, USA), Karsten Strauss (Olink, SWE)

Patients' viewpoints

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 19th 16.00– 16.30
COFFEE**

**THURSDAY OCTOBER 19th 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' viewpoints

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

**FRIDAY OCTOBER 20TH 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' viewpoints

Margaret Padilla (San Antonio, TX, USA)

**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 20TH 2023, 10.30-11.00
COFFEE

FRIDAY OCTOBER 20TH 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), Maya Margalit (89 Bio, ISR), Ramy Younes (Boehringer Ingelheim, GER)

Patients' viewpoints

Jeff McIntyre (Global Liver, USA)

Regulatory viewpoints

FDA: Frank Anania (FDA, USA), John Sharretts (FDA, USA), Raymond Soccio (FDA, USA), Charmaine Stewart (FDA, USA), Aliza Thompson (FDA, USA)

FRIDAY OCTOBER 20TH 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 20TH 2023, 13.00- 14.00
LUNCH AND ADJOURN