MOSAiC®

A multi-stakeholder multi-specialty MASH Trialists think tank

Metabolic, hepatology, nephrology & cardiovascular cross-talk

Metabolic multi**O**rgan **S**cience **A**ccelerating the **I**nnovation in **C**linical trials

A Public Private Partnership CVCT meeting

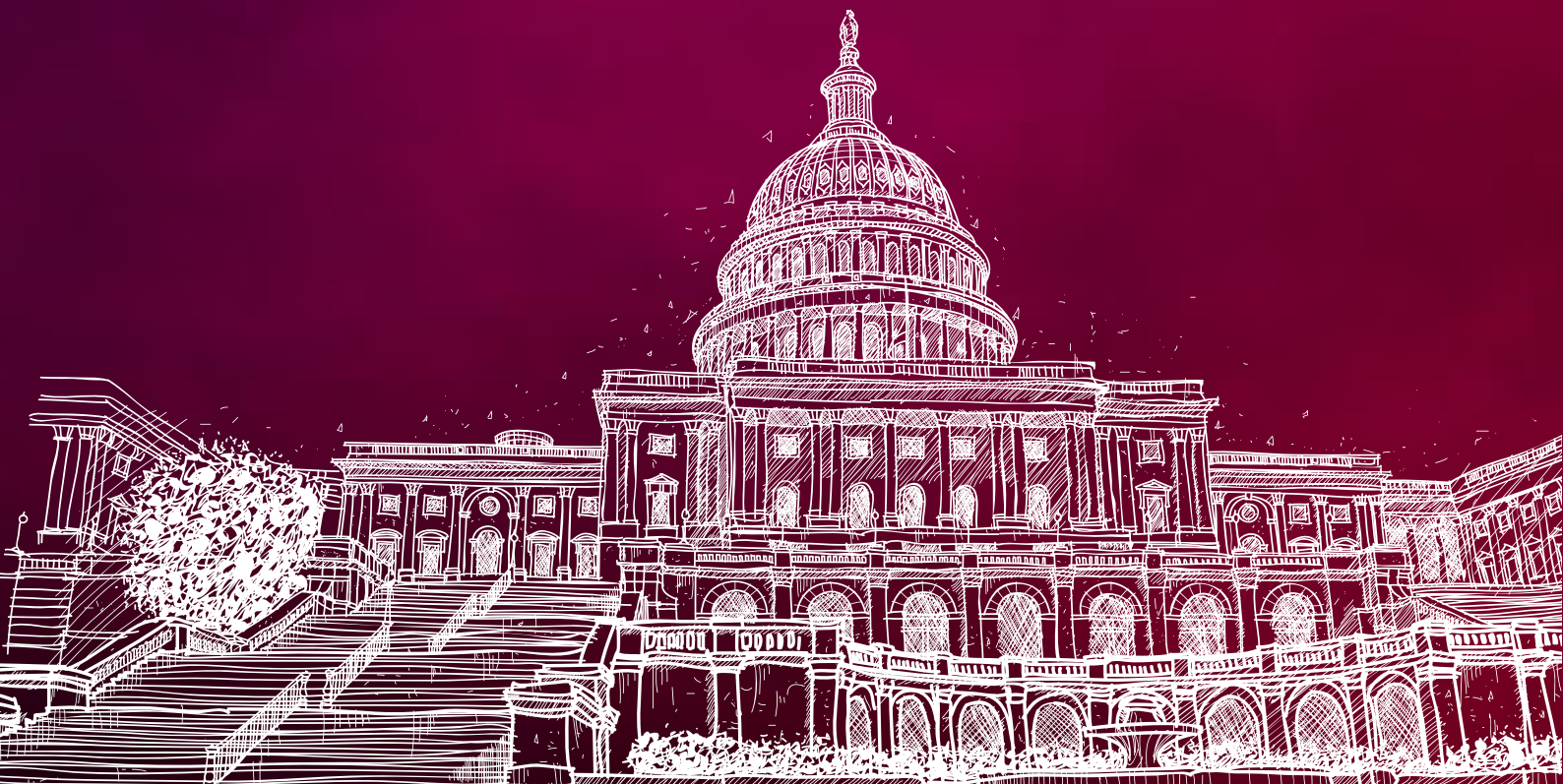
Co-sponsored by Inserm (France) and with participation of FDA (USA)

October 26 - 27, 2026
Embassy of France,
4101 Reservoir Road, NW - Washington DC - 20007

SCIENTIFIC PROGRAM

CHAIRPERSONS

FAIEZ ZANNAD (PARIS, FRA)
NISHA BANSAL (SEATTLE, USA)
JAVED BUTLER (DALLAS, USA)
VERONICA MILLER (BERKELEY, USA)
ARUN SANYAL (RICHMOND, USA)



FACULTY

ACADEMY

1. Naim Alkhouri (San Antonio, USA)
2. Guillaume Baudry (Nancy, FRA)
3. Biykem Bozkurt (Houston, TX, USA)
4. Javed Butler (Dallas, TX, USA)
5. Amreen Dinani (Durham, NC, USA)
6. Scott Emerson (Seattle, WA, USA)
7. Sven Francque (Antwerpen, Belgium)
8. Nicolas Girerd (Nancy, France)
9. Jennifer Green (Durham, NC, USA)
10. Shahzeb Khan (Dallas, USA)
11. Jeffrey Lazarus (New York, Barcelona, The Lancet Global Health)
12. Rohit Loomba (San Diego, USA)
13. Veronica Miller (Berkeley, USA)
14. Timothy Morgan (Irvine, CA, USA)
15. Ian Neeland (Cleveland, OH, USA)
16. Philip Newsome (London, UK)
17. Mazen Noureddin (Houston, USA)
18. Harriette Van Spall (Hamilton, Canada)
19. Arun Sanyal (Richmond, USA)
20. Jörn Schattenberg (Homburg, Germany)
21. Maria Clarissa Tio (Jackson, MS)
22. Janet Wittes (Washington DC, USA)
23. Zobair Younossi (Washington DC, USA)
24. Faiez Zannad (Nancy, FRA)

PATIENTS

25. Gina Bartes (United Liver, USA)
26. Michael Betel (Fatty Liver Alliance, CAN)
27. Henry Chang (NYC, USA)
28. Wayne Eskridge (Fatty Liver Foundation, USA)
29. Elsie Evans (FH Europe Foundation)
30. Patrick Gee (iAdvocate, USA)
31. Marko Korenjak (European Liver Patients' Association)
32. Margaret Padilla (San Antonio, TX, USA)

FNIH

33. Patricia Grebenstein (FNIH)
34. Tania Nayak Kamphaus (FNIH)
35. Jennifer Taylor (FNIH)

REGULATORY

36. Charu Gandotra (FDA)
37. Ruby Mehta (FDA)
38. Mitchell Psotka (FDA)
39. Vanitha Sekar (FDA)
40. Fortunato Senatore (FDA)
41. Raymond Soccio (FDA)
42. Aliza Thompson (FDA)
43. Yun Wang (FDA)
44. Jialu Zhang (FDA)

JOURNAL EDITORS

45. Ben Abbott (The Lancet)
46. Ashley Castellanos-Jankiewicz (Nature Medicine)
47. Jane Leopold (NEJM)
48. Jennifer Sargent (Metabologia, EASD)

INDUSTRY

49. Salvador Augustin (Boehringer)
50. Scott Berry (USA)
51. Sigrunn Blacoe (Wordlwide Leadership)
52. Roberto Calle (GSK)
53. Jason Campagna (Inventiva)
54. Jerry Colca (Cirius)
55. Andrea Dennis (Perspectum)
56. Nancy Dreyer (Dreyer LLC, USA)
57. Jyothis George (Rezera)
58. Joseph Gogain (Somalogic)
59. Axel Haupt (Lilly)
60. Dean Hum (Genfit, FRA)
61. Meena Jain (Akero)
62. Morten Karsdal (Nordic Bioscience – Roche)
63. Michelle Long (NovoNordisk)
64. Daniel Mazo (Boehringer)
65. Jan Marquard (Merck Sharp & Dohm)
66. Jorge Alfonso Ross Terres (Roche)
67. Amit Sharma (WeraTx)
68. David Soergel (Madrigal)
69. Jonathan Stine (AstraZeneca)
70. Fady Tanios (Regeneron)
71. Rebecca Taub (Madrigal)

ATTENDEES

ACADEMY

72. Edyth Dwyer (Forum for Collaborative Research)
73. Eric Lefevbre (Forum for Collaborative Research)
74. Dr. Margot Yann (Forum for Collaborative Research)
75. Meghan Rakowski (Forum for Collaborative Research)

INDUSTRY

76. Amy Articolo (Inventiva)
77. Laurent Audoly (PriveBio)
78. Chris Benecchi (Inventiva)
79. Malgozata Luiza Borowska (Boehringer Ingelheim)
80. Lisa Boyette (Lilly)
81. Toni Bransford (Olix)
82. Matt Bryant (Roche)
83. Thomas Capozza (Inventiva)
84. Pascaline Clerc-Brenner (Inventiva)
85. Meriem Gaval Cruz (NovoNordisk)
86. Ben Da (Merck Sharp & Dohm)
87. Jennifer Damman (Roche)
88. Richard Dunbar (Madrigal)
89. Ulrike Graefe (Boehringer Ingelheim)
90. Aisling Hall (Madrigal)
91. Lars Hansen (AstraZeneca)
92. Rex Horton (Altimmune)
93. Simon Hogan (Inventiva)
94. Bill Kendrick (Lilly)
95. Andrea Kidner (Boehringer Ingelheim)
96. MeeJ Kim (GSK)
97. Charles Lee (AstraZeneca)
98. Robin Mogg (Madrigal)
99. Charlene Prazma (GSK)
100. Beth Rappoli (Madrigal)
101. David Rosenbaum (AstraZeneca)
102. Katie Schumann(GSK)
103. Jennifer Shannon (GSK)
104. Franck Skobieranda (Madrigal)
105. Norman Stockbridge (S&S Consulting, USA)
106. Tongrong Wang (Lilly)
107. Ji Young-Min (Olix)

Monday 26 October, 2026
8.30- 9.40

ARE THE RECENT/CURRENT TRIALS ADDRESSING INTEGRATED CKLM MULTIORGAN ENDPOINTS?
Chairpersons : Arun Sanyal (Richmond, USA) & Faiez Zannad (Nancy, FRA)

The global burden of CKLM disease. An update
8:30-8:40
Jeffrey Lazarus (New York, Barcelona, The Lancet Global Health)

The current landscape of MASH-MASLD trials. How far are we from the MOSAIC agenda?
8:40-8:50
Arun Sanyal (Richmond, USA)

Trials of incretin-based agents with potential multi-organ endpoints.
8:50-9:00
Rohit Loomba (San Diego, USA)

Liver-directed anti-MASH agents with “CV-adjacent” metabolic effects
9:00-9:10
Faiez Zannad (Nancy, FRA)

Cardiorenal drugs tested/positioned for liver benefit.
9:10-9:20
Arun Sanyal (Richmond, USA)

FGF21 analogs likely have CV benefits: a hypothesis pending outcomes.
9:20-9:30
Philip Newsome (London, UK)

Combination strategies explicitly aiming at “MASH + CKM” endpoints
9:30-9:40
Naim Alkhouri (San Antonio, USA)

9.40-10.10
The MOSAIC Multi-Stakeholder Think Tank Moderated debate
WHAT DOES IT TAKE FOR HEPATOLOGISTS TO PROGRESS TO A CKLM TRIALS FRAMEWORK?
Chairpersons : Arun Sanyal (Richmond, USA) & Faiez Zannad (Nancy, FRA)

Panelists : All speakers

10.10-10.40
Coffee break & Networking

Monday 26 October, 2026
10.40- 11.50

RISK REDUCTION VS. DISEASE MODIFICATION.
WHAT DO TRIALISTS, SPONSORS, AND REGULATORS ACTUALLY THINK?
Chairpersons : Javed Butler (Dallas, TX, USA) & Jörn Schattenberg (Homburg, Germany)

Improving outcomes, not just histology. Is full CKLM disease modification possible?
10:40-10:50
Faiez Zannad (Nancy, France)

Hepatologist's viewpoint
10:50-11:00
Jörn Schattenberg (Homburg, Germany)

Cardiologist viewpoint
11:00-11:10
Javed Butler (Dallas, TX, USA)

Nephrologist viewpoint
11:10-11:20
Amit Sharma (WeraTx)

Endocrinologist's viewpoint
11:20-11:30
Jennifer Green (Durham, NC, USA)

Industry viewpoint
11:30-11:45
Salvador Augustin (Boehringer)
Jan Marquard (Merck Sharp & Dohm)
Jonathan Stine (AstraZeneca)

Patients' viewpoints
11:45-11:50
Henry Chang (NYC, USA)

11.50-12.30
REGULATORY FORUM and The MOSAIC Multi-Stakeholder Think Tank Moderated debate
WHAT IS AN ACCEPTABLE DISEASE MODIFICATION DEFINITION?
IS THE MASH REGULATORY FRAMEWORK READY FOR MULTI-ORGAN CKLM TRIALS?
Chairpersons : Javed Butler (Dallas, TX, USA) & Jörn Schattenberg (Homburg, Germany)

Panelists:
FDA
DHN - Ruby Mehta
DDLO - Raymond Soccio
Biostatistics - Jialu Zhang, Yun Wang
DDT - biomarker qualification - Vanitha Sekar
DCN - Fortunato Senatore, Aliza Thompson, Charu Gandotra, Mitchell Psotka
& All participants and Timothy Morgan (Irvine, CA, USA)

12.30-13.10
Lunch Break & Networking

Monday 26 October, 2026
13.10- 14.40

MOVING FROM F2–F3 BIOPSY ENDPOINTS with CKM SURROGATES TO HARD LIVER AND CKM OUTCOMES

Chairpersons : Nicolas Girerd (Nancy, France) & Tania Nayak Kamphaus (FNIH)

What Cardiovascular surrogates can be embedded in MASLD trials?
13:10-13:20
Nicolas Girerd (Nancy, France)

What kidney surrogates can be embedded in MASLD trials?
13:20-13:30
Maria Clarissa Tio (Jackson, MS)

The FNIH Biomarkers Consortium's advancing understanding of CKLM biology for future multi-organ research
13:30-13:40
Patricia Grebenstein (FNIH)

13:40-13:50
Evaluating at-risk MASH status using the NIS2+ score
Dean Hum (Genfit, FRA)

13:50-14:00
Biomarker development for regulatory purposes. Case for CKLM
Tania Nayak Kamphaus (FNIH)

14:00-14:10 (5 min each)
Biomarkers and algorithms : Industry viewpoints
Joseph Gogain (Somalogic)
Morten Karsdal (Nordic Bioscience – Roche)

14:10-14:20
MALO event rates in MASH-MASLD patients and sample size estimations
Arun Sanyal (Richmond, USA)

14:20-14:30
CV event rates in MASH-MASLD patients and sample size estimations
Shahzeb Khan (Dallas, USA)

14:30 – 14:40
What is needed to extend MASH-liver biopsy trials to accrue MACE - MALE events?
Amreen Dinani (Durham, NC, USA)

14.40-15.10

REGULATORY FORUM and The MOSAIC Multi-Stakeholder Think Tank Moderated debate ARE ACCELERATED APPROVAL PATHWAYS THE WAY FORWARD?

Chairpersons : Nicolas Girerd (Nancy, France) & Tania Nayak Kamphaus (FNIH)

Panelists:
All participants

Monday 26 October, 2026
15.10- 15.40

ONGOING TRIALS AND HOW THEY ACCOMMODATE CKLM ENDPOINTS
Chairpersons : Sven Francque (Antwerpen, Belgium) & Jennifer Green (Durham, NC, USA)

Resmetirom
15:10-15:15
Rebecca Taub (Madrigal)

Semaglutide
15:15-15:20
Michelle Long (NovoNordisk)

Tirzepatide
15:20-15:25
Axel Haupt (Lilly)

Survodutide
15:25-15:30
Daniel Mazo (Boehringer)

Efruxifermin
15:30-15:35
Meena Jain (Akero)

Pegozafermin
15:35-15:40
Jorge Alfonso Ross Terres (Roche)

15.40-16.15
The MOSAIC Multi-Stakeholder Think Tank Moderated debate
HOW SPONSORS ARE WARMING UP FOR THE ULTIMATE GOAL OF MULTI-ORGAN OUTCOME TRIALS
Chairpersons : Sven Francque (Antwerpen, Belgium) & Jennifer Green (Durham, NC, USA)

Panelists : all industry faculty members

16.15-16.35
Coffee Break & Networking

Monday 26 October, 2026
16.35- 17.40

HOW TO DESIGN A SINGLE TRIAL WITH MULTIPLE CKLM ENDPOINTS? METHODOLOGY AND STATISTICAL TOOLKITS

Chairpersons : Scott Berry (USA) & Janet Wittes (Washington DC, USA)

Mechanistic trials' design: how to distinguish between common and distinct organ-specific mechanisms in C. K. L. M.
16:35-16:45
Sven Francque (Antwerpen, Belgium)

Multi-organ imaging. The UK Imaging Diabetes Study
16:45-16:55
Andrea Dennis (Perspectum, UK)

Framing the methodological issues for multiorgan endpoint trials.
16:55-17:05
Janet Wittes (Washington DC, USA)

One Drug, Several Organs, One Alpha: Managing Multiplicity in CKLM Outcomes Trials
17:05-17:15
Scott Emerson (Seattle, WA, USA)

How can Bayesian help?
17:15-17:20
Scott Berry (USA) (5min)

Trial execution, cost, and feasibility issues
Industry viewpoint
17:20-17:35
Axel Haupt (Lilly)
Fady Tanios (Regeneron)
David Soergel (Madrigal)

ARO/CRO viewpoints
17:35-17:40
Sigrunn Blacoe (Wordlwide Leadership)

17.40-18.10

The MOSAIC Multi-Stakeholder Think Tank Moderated debate

FEASIBILITY AND ACCEPTABILITY OF SINGLE TRIALS WITH MULTIPLE CKLM ENDPOINTS

Chairpersons : Scott Berry (USA) & Janet Wittes (Washington DC, USA)

Panelists : all speakers and Timothy Morgan (Irvine, CA, USA)

ADJOURN DAY ONE
TRANSFER AND OFF-SITE DINNER

Tuesday 27 October, 2026
8.30-9.15

MULTIPLE DRUG COMBINATIONS FOR MULTIPLE ORGAN INDICATIONS
Chairpersons : Mazen Noureddin (Houston, USA) & Harriette Van Spall (Hamilton, Canada)

Ongoing and newly released MASH/MASLD combination drugs.
8:30-8:40
Mazen Noureddin (Houston, USA)

Ongoing and newly released Cardio/Kidney/Metabolism combination drugs
8:40-8:50
Harriette Van Spall (Hamilton, Canada)

Phase II trials of combination therapies in CKLM trials
8:50-9:00
Zobair Younossi (Washington DC, USA)

Industry viewpoints
9.00-9.15
Jason Campagna (Inventiva)
Roberto Calle (GSK)
Salvador Augustin (Boehringer)

9.15-9.55
The MOSAIC Multi-Stakeholder Think Tank Moderated debate
OPPORTUNITIES AND CHALLENGES OF DRUG COMBINATION TRIALS IN THE CKLM FRAMEWORK
Chairpersons : Mazen Noureddin (Houston, USA) & Hariette Van Spall (Hamilton, Canada)

Panelists :
All participants

9.55-10.15
Coffee Break & Networking

Tuesday 27 October, 2026
10.15- 10.55

THE ROLE OF REAL WORLD EVIDENCE RWE IN CKLM
Chairpersons : Nancy Dreyer (Dreyer LLC, USA) & Shahzeb Khan (Dallas, TX, USA)

What outcomes matter post approval?
10.15-10.25
Javed Butler (Dallas, TX, USA)

How can RWE data complement the conditional approval of MASLD drugs
10.25-10.35
Nancy Dreyer (Dryer LLC, USA)

Opportunities and challenges for building a CKLM registry
10.35-10.45
Ian Neeland (Cleveland, OH, USA)

How to deal with RWE: quality metrics needed in the regulatory process
10.45-10.55
Nancy Dreyer (Dryer LLC, USA)

10.55-11.30
The MOSAIC Multi-Stakeholder Think Tank Moderated debate
Impact of RWE in CKLM
Chairpersons : Nancy Dreyer (Dreyer LLC, USA) & Shahzeb Khan (Dallas, TX, USA)

Panelists : all speakers

Tuesday 27 October, 2026
11.30- 12.00

REDUCING TOTAL LIFETIME COST ACROSS CKLM PAYER VALUATION OF MULTIPLE ORGAN INDICATIONS

Chairpersons: Javed Butler (Dallas, TX, USA) & Arun Sanyal (Richmond, USA)

Translating Multi-Organ Benefits into Health Economics and Metrics for Payers. Are Liver-Only drugs at risk?
11:30-11:40
Zobair Younossi (Washington, DC, USA)

Bundled chronic-disease pathways: How are sponsors shaping up their programs?
11:40-12:00
Jyothis George (Rezera)
Jerry Colca (Cirius)

12.00-12.20

The MOSAIC Multi-Stakeholder Think Tank Moderated debate

A CKLM THERAPY COSTS $X ANNUALLY, REDUCES WEIGHT AND MASH PROGRESSION IMMEDIATELY, KIDNEY AND HEART-FAILURE EVENTS WITHIN THREE YEARS, AND MACE ONLY AFTER SIX YEARS. WHO SHOULD PAY, HOW MUCH, AND ON WHAT EVIDENCE?

Chairpersons: Javed Butler (Dallas, TX, USA) & Arun Sanyal (Richmond, USA)

Panelists : all participants and Timothy Morgan (Irvine, CA, USA)

12.20-13.20
Lunch Break & Networking

Tuesday 27 October, 2026
13.20- 14.00

PATIENTS TRIAL PARTICIPANTS AND PATIENTS' ADVOCATES FORUM

Chairpersons: Henry Chang (Fatty Liver Foundation, USA) & Elsie Evans (FH Europe Foundation)

Gina Bartes (United Liver, USA)
Michael Betel (Fatty Liver Alliance, CAN)
Elsie Evans (FH Europe Foundation)
Wayne Eskridge (Fatty Liver Foundation, USA)
Henry Chang (Fatty Liver Foundation, USA)
Patrick Gee (iAdvocate, USA)
Marko Korenjak (European Liver Patients' Association)
Margaret Padilla (San Antonio, TX, USA)

Tuesday 27 October, 2026
14.00-15.00

DISSEMINATION AND IMPLEMENTATION OF THE CKLM AGENDA
Chairpersons: Biykem Bozkurt (Houston, TX, USA) & Philip Newsome (London, UK)

AHA Cardiovascular- Kidney-Metabolic Health Initiative
14.00 – 14.10
Biykem Bozkurt (Houston, TX, USA)

Conceptual framework of Cardio–Vascular–Kidney–Liver–Metabolic (CVKLM) Multiorgan Staging
14.10-14.20
Guillaume Baudry (Nancy, FRA)

The AHA created the CKM taxonomy. May Europe become the place where CKM evolves into true CKLM integration?
14.20-14.30
Philip Newsome (London, UK)

Collaborative programs to accelerate integrated CKLM research
14.30-14.40
Jennifer Taylor (FNIH)

Journal Editors viewpoints.
14.40-15.00
Ben Abbott (The Lancet), Jane Leopold (NEJM), Ashley Castellanos-Jankiewicz (Nature Medicine), Jennifer Sargent (Metabologia, EASD)

15.00-15.20
The MOSAIC Multi-Stakeholder Think Tank Moderated debate
HOW TO BUILD THE ROADMAP FOR DISSEMINATION AND IMPLEMENTATION OF THE CKLM AGENDA?
Chairpersons: Biykem Bozkurt (Houston, TX, USA) & Philip Newsome (London, UK)

Panelists : all participants

15.20-15.30
CONCLUDING REMARKS
Faiez Zannad (Paris, FRA), Arun Sanyal (Richmond, USA)

ADJOURN