



A multi-stakeholder multi-specialty MASH Trialists think tank

Metabolic, hepatology, nephrology & cardiovascular cross-talk

Metabolic multiOrgan Science Accelerating the Innovation in Clinical 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

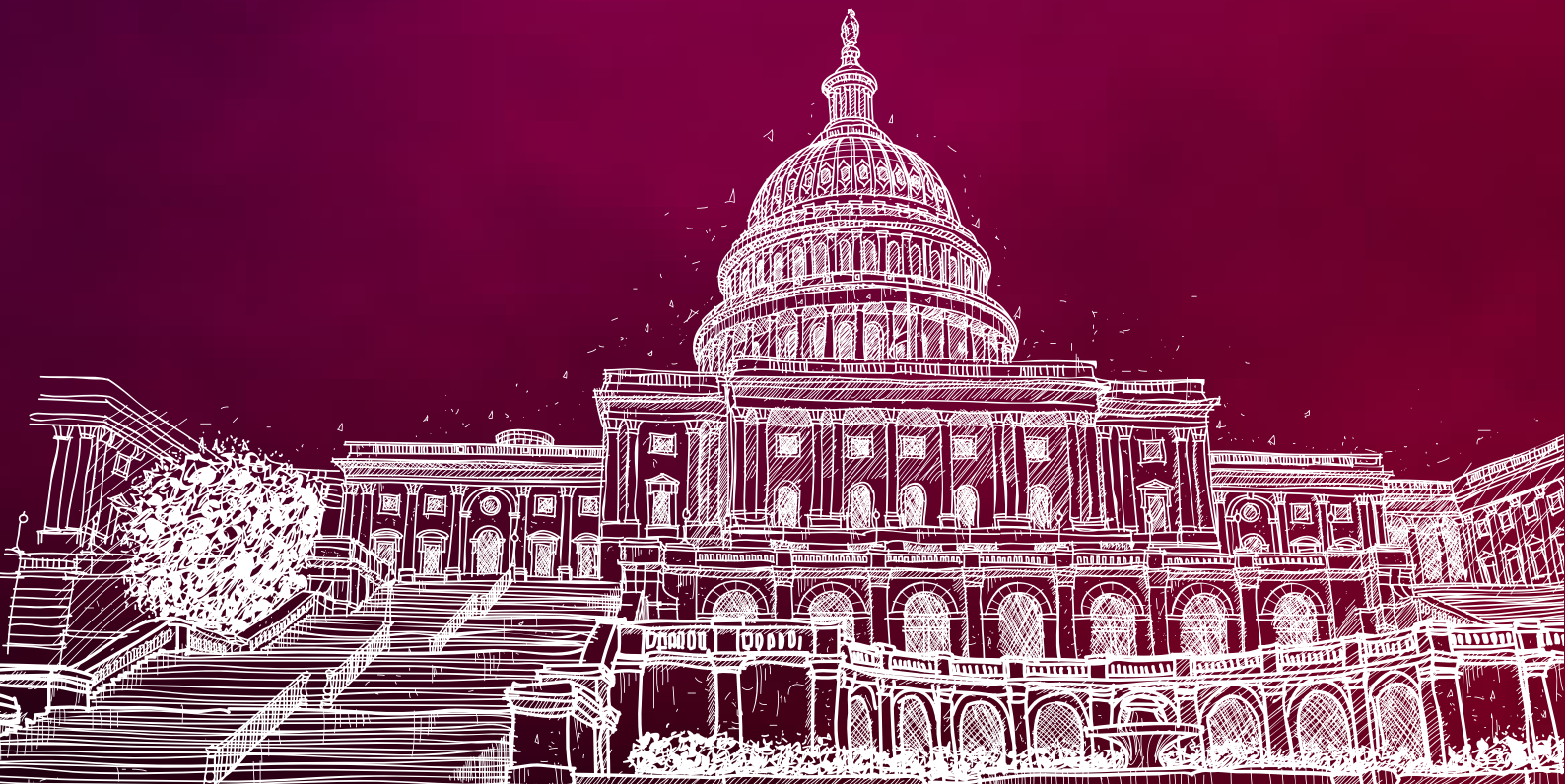
FAIEZ ZANNAD (PARIS, FRA)

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. Javed Butler (Dallas, TX, USA)
4. Steven Coca (New York, NY, USA)
5. Scott Emerson (Seattle, WA, USA)
6. Sven Francque (Antwerpen, Belgium)
7. Nicolas Girerd (Nancy, France)
8. Jennifer Green (Durham, NC, USA)
9. Adrian Hernandez (DCRI, 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. Chiadi Ndumele (Baltimore, MD, USA)
15. Ian Neeland (Cleveland, OH, USA)
16. Philip Newsome (Birmingham, UK)
17. Mazen Nouredin (Houston, USA)
18. Chirag Parikh (Baltimore, MD, USA)
19. Harriette Van Spall (Hamilton, Canada)
20. Arun Sanyal (Richmond, USA)
21. Jörn Schattenberg (Saarbrücken, Germany)
22. Subodh Verma (Toronto, CAN)
23. Janet Wittes (Washington DC, USA)
24. Zobair Younossi (Washington DC, USA)
25. Faiez Zannad (Nancy, FRA)

PATIENTS

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)

REGULATORY

33. Charu Gandotra (FDA)
34. Janet König (EMA/CHMP, GER)
35. Ruby Mehta (FDA)
36. Elita Poplavska (EMA/CHMP, LAT)
37. Robert Pórszász (EMA CHMP, HUN)
38. Mitchell Psotka (FDA)
39. Elmer Schabel (BfArM/EMA SAWP, GER)
40. Vanitha Sekar (FDA)
41. Fortunato Senatore (FDA)

42. Raymond Soccio (FDA)
43. Aliza Thompson (FDA)
44. Yun Wang (FDA)
45. Jialu Zhang (FDA)

JOURNAL EDITORS

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

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51. Salvador Augustin (Boehringer)
52. Scott Berry (USA)
53. Jason Campagna (Inventiva)
54. Jerry Colca (Cirius)
55. Nancy Dreyer (Dreyer LLC, USA)
56. Matthew F. W. Gee (Siemens Healthineers)
57. Jyothis George (NodThera)
58. Joseph Gogain (Somalogic)
59. Axel Haupt (Lilly)
60. Meena Jain (Akeru)
61. MeeJ Kim (GSK)
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64. Michelle Long (NovoNordisk)
65. Daniel Mazo (Boehringer)
66. Jan Marquard (Merck)
67. Marija Mavar (Perspectum, UK)
68. Jorge Alfonso Ross Terres (Roche)
69. Michael Sherman (Ex CMS, Sherman Healthcare Solutions, LLC)
70. David Soergel (Madrigal)
71. Jonathan Stine (AstraZeneca)
72. Fady Tanios (Regeneron)
73. Rebecca Taub (Madrigal)
74. Alessandra Vignola (Worldwide Leadership)

PAYERS

75. Sarah Emond (ICER, Boston, MA, USA)
76. Helen Knight (NICE, UK)

**Monday 26 October, 2026
8.30- 10.00**

**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 (Birmingham, 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

**10.00-10.30
Coffee break & Networking**

**Monday 26 October, 2026
10.30- 11.40**

**RISK REDUCTION VS. DISEASE MODIFICATION.
WHAT DO TRIALISTS, SPONSORS, AND REGULATORS ACTUALLY THINK?**

Chairpersons : Javed Butler (Dallas, TX, USA) & Jörn Schattenberg (Saarbrücken, Germany)

Improving outcomes, not just histology. Is full CKLM disease modification possible?

10:30-10:40

Faiez Zannad (Nancy, France)

Hepatologist's viewpoint

10:40-10:50

Jörn Schattenberg (Saarbrücken, Germany)

Cardiologist's viewpoint

10:50-11:00

Javed Butler (Dallas, TX, USA)

Nephrologist's viewpoint

11:00-11:10

Chirag Parikh (Baltimore, MD, USA)

Endocrinologist's viewpoint

11:10-11:20

Jennifer Green (Durham, NC, USA)

Industry viewpoint

11:20-11:40

Salvador Augustin (Boehringer)

Jan Marquard (Merck)

Murielle Véniant-Ellison (Amgen)

Jonathan Stine (AstraZeneca)

Patients' viewpoints

11:40-11:45

Henry Chang (NYC, USA)

11.45-12.10

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 (Saarbrücken, Germany)

Panelists:

FDA

DHN - Ruby Mehta

DDLO - Raymond Soccio

Biostatistics - Jialu Zhang and/or Yun Wang

DDT - biomarker qualification - Vanitha Sekar

DCN - Fortunato Senatore, Aliza Thompson, Charu Gandotra, Mitchell Psotka

EU- EMA

EMA/CHMP - Janet König (GER), Elita Poplavska (LAT)

BfArM/EMA SAWP - Elmer Schabel (GER)

EMA CHMP Robert Pórszász (HUN)

& All participants

12.10-13.10

Lunch Break & Networking

**Monday 26 October, 2026
13.10- 14.20**

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

Chairpersons : Nicolas Girerd (Nancy, France) & Chirag Parikh (Baltimore, MD, USA)

What CV surrogates can be embedded in liver biopsy trials?

13:10-13:20

Nicolas Girerd (Nancy, France)

What kidney surrogates can be embedded in liver biopsy trials

13:20-13:30

Steven Coca (New York, NY, USA)

13:40-13:50

Biomarkers and algorithms : Industry viewpoints

Matthew F. W. Gee (Siemens Healthineers)

Joseph Gogain (Somalogic)

Diana Leeming (Nordic Bioscience – Roche)

Victor de Lédinghen (Echosens)

13:50-14:00

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

14:00-14:10

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

14:10 – 14:20

What is needed to extend MASH-liver biopsy trials to accrue MACE - MALE events?
Subodh Verma (Toronto, CAN)

14.20-14.40

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

Chairpersons : Nicolas Girerd (Nancy, France) & Chirag Parikh (Baltimore, MD, USA)

Panelists:

EU- EMA

EMA/CHMP - Janet König (GER), Elita Poplavska (LAT)

BfArM/EMA SAWP - Elmer Schabel (GER)

EMA CHMP Robert Pórszász (HUN)

& All participants

**Monday 26 October, 2026
14.40- 15.10**

ONGOING TRIALS AND HOW THEY ACCOMMODATE CKLM ENDPOINTS

Chairpersons : Sven Francque (Antwerpen, Belgium) & Veronica Miller (Berkeley, USA)

**Resmetirom
14:40-14:45
Rebecca Taub (Madrigal)**

**Semaglutide
14:45-14:50
Michelle Long (NovoNordisk)**

**Tirzepatide
14:50-14:55
Axel Haupt (Lilly)**

**Survodutide
14:55-15:00
Daniel Mazo (Boehringer)**

**Efruxifermin
15:00-15:05
Meena Jain (Akeru)**

**Pegozafermin
15:05-15:10
Jorge Alfonso Ross Terres (Roche)**

15.10-15.30

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) & Veronica Miller (Berkeley, USA)

Panelists : all industry faculty members

15.30-15.50

Coffee Break & Networking

**Monday 26 October, 2026
15.50- 17.10**

**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.
15:50-16:00
Sven Francque (Antwerpen, Belgium)

Multi-organ imaging. The UK Imaging Diabetes Study
16:00-16:10
Marija Mavar (Perspectum, UK)

Framing the methodological issues for multiorgan endpoint trials.
16:10-16:20
Janet Wittes (Washington DC, USA)

One Drug, Several Organs, One Alpha: Managing Multiplicity in CKLM Outcomes Trials
16:20-16:30
Scott Emerson (Seattle, WA, USA)

How can Bayesian help?
16:30-16:40
Scott Berry (USA) (5min)

Trial execution, cost, and feasibility issues
Industry viewpoint
16:40-16:55
Axel Haupt (Lilly)
Fady Tanios (Regeneron)
David Soergel (Madrigal)

ARO/CRO viewpoints
16:55-17:10
Adrian Hernandez (DCRI, Durham, NC, USA)
Alessandra Vignola (Worldwide Leadership)

17.10-17.40

**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

**ADJOURN DAY ONE
TRANSFER AND OFF-SITE DINNER**

**Tuesday 27 October, 2026
8.30-9.20**

MULTIPLE DRUG COMBINATIONS FOR MULTIPLE ORGAN INDICATIONS

Chairpersons : Mazen Nouredin (Houston, USA) & Harriette Van Spall (Hamilton, Canada)

Ongoing and newly released MASH/MASLD combination drugs.

8:30-8:40

Mazen Nouredin (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)

Phase III trials of combination therapies in CKLM trials

9:00-9:10

Ming Hua Zheng (Wenzhou, China)

Industry viewpoints

9.10-9.20

Jason Campagna (Inventiva)

MeeJ Kim (GSK)

Salvador Augustin (Boehringer)

9.20-9.55

The MOSAIC Multi-Stakeholder Think Tank Moderated debate

OPPORTUNITIES AND CHALLENGES OF DRUG COMBINATION TRIALS IN THE CKLM FRAMEWORK

Chairpersons : Mazen Nouredin (Houston, USA) & Harriette Van Spall (Hamilton, Canada)

Panelists :

EMA

EMA/CHMP - Janet König (GER), Elita Poplavska (LAT)

BfArM/EMA SAWP - Elmer Schabel (GER)

EMA CHMP Robert Pórszász (HUN)

& All participants

9.55-10.15

Coffee Break & Networking

**Tuesday 27 October, 2026
10.15- 11.05**

THE ROLE OF REAL WORLD EVIDENCE RWE IN CKLM

Chairpersons : Nancy Dreyer (Dreyer LLC, USA) & Shahzeb Khan (Dallas, TX, USA)

How do modern learning health systems evaluate therapies after approval?

10:15-10.25

Harlan Krumholz (New Haven, CT, USA)

What outcomes actually matter post approval?

10.25-10.35

Javed Butler (Dallas, TX, USA)

How can RWE data complement the conditional approval of MASLD drugs

10.35-10.45

Nancy Dreyer (Dreyer LLC, USA))

Opportunities and challenges for building a CKLM registry

10.45-10.55

Ian Neeland (Cleveland, OH, USA)

How to deal with RWE: quality metrics needed in the regulatory process

10.55-11.05

Adrian Hernandez (DCRI, Durham, NC, USA)

11.05-11.40

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
11.40- 12.20

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

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

How do payers treat multi-indication drugs? Are liver-only agents at risk?
11:40-11:50

Michael Sherman (Ex CMS, Sherman Healthcare Solutions, LLC)

National & commercial payers' viewpoints
11:50-12:00

Helen Knight (NICE, UK)(5min)

Adrian Towse (Office of Health Economics, London, UK)

Reimbursement behavior: Population-level contracts vs. Outcomes-based agreements
12:00-12:10

Sarah Emond (ICER, Boston, MA, USA)

Bundled chronic-disease pathways: How are sponsors shaping up their programs?
12:10-12:20

Jyothis George (NodThera)

Jerry Colca (Cirius)

12.20-12.40

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)

12.40-13.40

Lunch Break & Networking

Tuesday 27 October, 2026
13.40- 14.10

PATIENTS TRIAL PARTICIPANTS AND PATIENTS' ADVOCATES FORUM

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

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
14.10-15.10**

**DISSEMINATION AND IMPLEMENTATION OF THE CKLM AGENDA
Chairpersons: Harlan Krumholz (JACC) & Philip Newsome (Birmingham, UK)**

AHA Cardiovascular- Kidney-Metabolic Health Initiative
14.10 – 14.20
Chiadi Ndumele (Baltimore, MD, USA)

Conceptual framework of Cardio–Vascular–Kidney–Liver–Metabolic (CVKLM) Multiorgan Staging
14.30-14.40
Guillaume Baudry (Nancy, FRA)

The AHA created the CKM taxonomy. May Europe become the place where CKM evolves into true CKLM integration?
14.40-14.50
Philip Newsome (Birmingham, UK)

Journal Editors viewpoints.
14.50-15.10
Ben Abbott (The Lancet), Harlan Krumholz (JACC), Jane Leopold (NEJM), Ashley Castellanos-Jankiewicz (Nature Medicine), Jennifer Sargent (Metabologia, EASD)

**15.10-15.30
The MOSAIC Multi-Stakeholder Think Tank Moderated debate
HOW TO BUILD THE ROADMAP FOR DISSEMINATION AND IMPLEMENTATION OF THE CKLM AGENDA?
Chairpersons: Harlan Krumholz (JACC) & Philip Newsome (Birmingham, UK)**

**15.30-15.40
CONCLUDING REMARKS
Faiez Zannad (Paris, FRA), Arun Sanyal (Richmond, USA)**

ADJOURN