



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

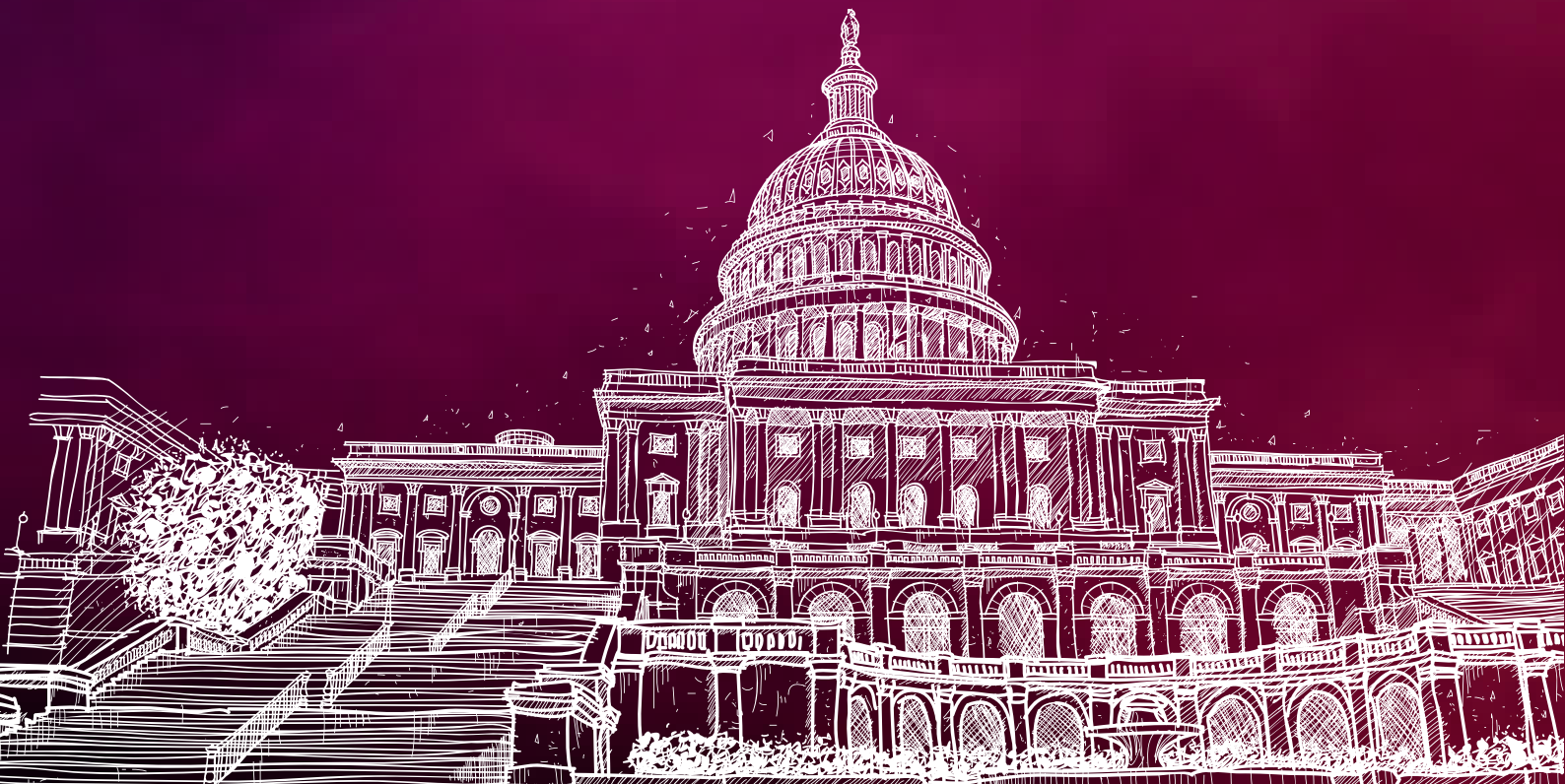
FAIEZ ZANNAD (PARIS, FRA)

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. Javed Butler (Dallas, TX, USA)
3. Rena Conti (Boston, MA, USA)
4. Sven Francque (Antwerpen, Belgium)
5. Nicolas Girerd (Nancy, France)
6. Jennifer Green (Durham, NC, USA)
7. Hiddo Heerspink (Groningen, Germany)
8. Rury Holman (Oxford, UK)
9. Lesley Inker (Boston, USA)
10. Ania Jastreboff (New Haven, USA)
11. Shahzeb Khan (Dallas, USA)
12. Jeffrey Lazarus (New York, Barcelona, The Lancet Global Health)
13. Rohit Loomba (San Diego, USA)
14. Veronica Miller (Berkeley, USA)
15. Jacqueline Heather Morris (Durham, USA)
16. Demir Münevver (Berlin, Germany)
17. Chiadi Ndumele (Baltimore, MD, USA)
18. Philip Newsome (Birmingham, UK)
19. Mazen Nouredin (Houston, USA)
20. Mikael Rørth (Copenhagen, DEN)
21. Harriette Van Spall (Hamilton, Canada)
22. Arun Sanyal (Richmond, USA)
23. Ben Saville (USA)
24. Jörn Schattenberg (Saarbrücken, Germany)
25. Janet Wittes (Washington DC, USA)
26. Zobair Younossi (Washington DC, USA)
27. Faiez Zannad (Nancy, FRA)
28. Ming Hua Zheng (Wenzhou, China)

PATIENTS

29. Michael Betel (Fatty Liver Alliance, CAN)
30. Henry Chang (NYC, USA)
31. Wayne Eskridge (Fatty Liver Foundation, USA)
32. Elsie Evans (FH Europe Foundation)
33. Patrick Gee (iAdvocate, USA)
34. Marko Korenjak (European Liver Patients' Association)
35. Margaret Padilla (San Antonio, TX, USA)

REGULATORY

36. Peter Arlett (EMA)
37. Charu Gandotra (FDA)
38. Thomas Lönngren (EMA)
39. Ruby Mehta (FDA)
40. Mitchell Psotka (FDA)
41. Vanitha Sekar (FDA)

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

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47. Ben Abbott (The Lancet)
48. Harlan Krumholz (JACC)
49. Jane Leopold (NEJM)
50. João P. Monteiro (Nature Medicine)
51. Jennifer Sargent (Metabologia, EASD)

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52. Salvador Augustin (Boehringer)
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54. Lisa Boyette (Lilly)
55. Toni Bransford (OlixPharma)
56. Jason Campagna (Inventiva)
57. Melissa Choi (TrialMed)
58. Jerry Colca (Cirius)
59. Nancy Dreyer (Dreyer LLC, USA)
60. Claudia Filozof (Fortera)
61. Jyothis George (NodThera)
62. Joseph Gogain (Somalogic)
63. Meena Jain (Akeru)
64. MeeJ Kim (GSK)
65. Diana Leeming (Nordic Bioscience – Roche)
66. Michelle Long (NovoNordisk)
67. Daniel Mazo (Boehringer)
68. Jan Marquard (Merck)
69. Peter Mesenbrink (Novartis)
70. Jorge Alfonso Ross Terres (Roche)
71. Jonathan Stine (AstraZeneca)
72. Fady Tanios (Regeneron)
73. Rebecca Taub (Madrigal)
74. David Thompson (IQVIA)
75. Murielle Véniant-Ellison (Amgen)

PAYERS

76. Steve Miller (Cigna, USA)

**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

Ania Jastreboff (New Haven, USA)

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

Hiddo Heerspink (Groningen, Germany)

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?**

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

EMA: Peter Arlett, Thomas Lönngren, Francesco Pignatti

& 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) & Lesley Inker (Boston, 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

Lesley Inker (Boston, USA)

NIT or liver biopsy for CKLM trials?

13:30-13:40

Vincent Wai-Sun Wong (Hong Kong, China)

13:40-13:50

Biomarkers and algorithms : Industry viewpoints

Diana Leeming (Nordic Bioscience – Roche)

Joseph Gogain (Somalogic)

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?

Demir Münevver (Berlin, Germany)

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) & Lesley Inker (Boston, USA)

Panelists :

EMA: Peter Arlett, Thomas Lönngren, Francesco Pignatti, Steffen Thirstrup,
& 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
Lisa Boyette (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- 17.15**

**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)

Lessons from UKPDS.
16:00-16:10
Rury Holman (Oxford, UK)

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

Multiplicity and what can be done with alpha?
16:20-16:30
Ben Saville (USA)

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

Trial execution, cost, and feasibility issues
Industry viewpoint
16:40-17:00
Fady Tanios (Regeneron)
Toni Bransford (OlixPharma)
Peter Mesenbrink (Novartis)

ARO/CRO viewpoints
17:00-17:15
Melissa Choi (TrialMed)
Claudia Filozof (Fortera)
David Thompson (IQVIA)

17.15-17.40

**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
8.30-9.25**

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)

Regulatory framework for combination therapies

9.20-9.25

TBD (FDA)

9.25-9.55

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: Peter Arlett, Thomas Lönngren, Francesco Pignatti, Steffen Thirstrup,
& All participants

9.55-10.15

Coffee Break & Networking

Tuesday 27 October, 2026
10.15- 11.10

THE ROLE OF REAL WORLD EVIDENCE RWE IN CKLM

Chairpersons : Nancy Dreyer (Dreyer LLC, USA) & Shazeb Kahn (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

Mikael Rørth (Copenhagen, DEN)

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

10.55-11.05

Jacqueline Heather Morris (Durham, USA)

Regulatory viewpoint: What do regulators expect post-approval?

11.05 – 11.10

TBD (FDA)

11.10-11.40

The MOSAIC Multi-Stakeholder Think Tank Moderated debate

Impact of RWE in CKLM

Chairpersons : Nancy Dreyer (Dreyer LLC, USA) & Shazeb Kahn (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
Dan Ollendorf (ICER, USA)

National & commercial payers' viewpoints
11:50-12:00
Karl Claxton (NICE, UK) (5min)
Steve Miller (Cigna, USA)

Reimbursement behavior: Population-level contracts vs. Outcomes-based agreements
12:00-12:10
Rena Conti (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
REWARDING «THE BEST MASH DRUG» VS. «THE DRUG THAT PREVENTS MI, HF, DIALYSIS,
CIRRHOSIS, AND DEATH IN THE SAME PATIENT POPULATION. »**
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)**

**We Need Simpler, More Integrated Guidelines for CKLM Diseases.
14.30-14.40
Joao Ferreira (Porto, POR)**

**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), João P. Monteiro (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