



**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**

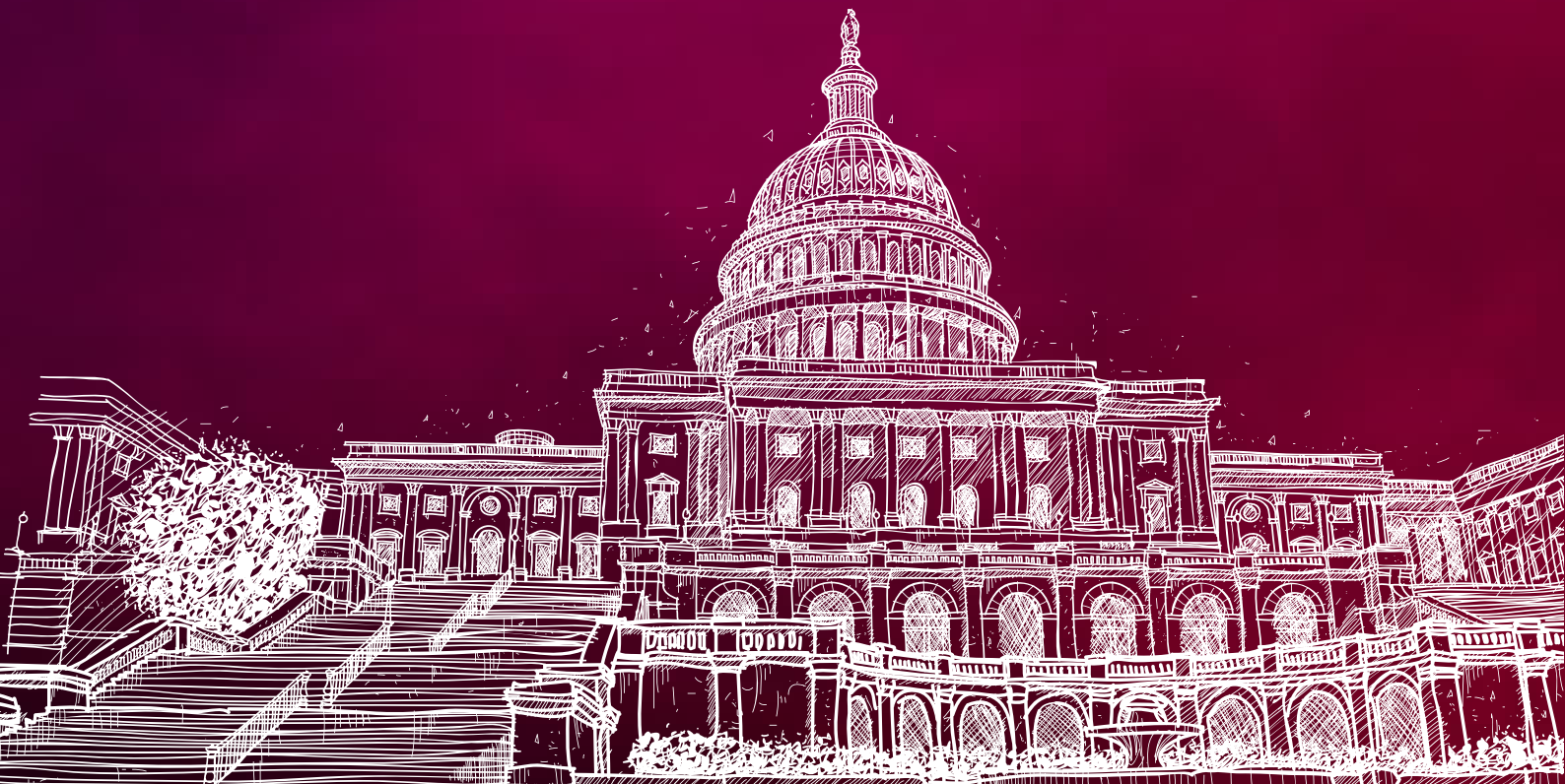
FAIEZ ZANNAD (PARIS, FRA)

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. Biykem Bozkurt (Houston, TX, USA)
4. Javed Butler (Dallas, TX, USA)
5. Lesley Curtis (Durham, NC, USA)
6. Amreen Dinani (Durham, NC, USA)
7. Scott Emerson (Seattle, WA, USA)
8. Sven Francque (Antwerpen, Belgium)
9. Nicolas Girerd (Nancy, France)
10. Jennifer Green (Durham, NC, 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. Timothy Morgan (Irvine, CA, USA)
16. Chiadi Ndumele (Baltimore, MD, USA)
17. Ian Neeland (Cleveland, OH, USA)
18. Philip Newsome (London, UK)
19. Mazen Nouredin (Houston, USA)
20. Harriette Van Spall (Hamilton, Canada)
21. Arun Sanyal (Richmond, USA)
22. Jörn Schattenberg (Saarbrücken, Germany)
23. Janet Wittes (Washington DC, USA)
24. Zobair Younossi (Washington DC, USA)
25. Faiez Zannad (Nancy, FRA)

## PATIENTS

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

## REGULATORY

34. Charu Gandotra (FDA)
35. Patricia Grebenstein (FNIH)
36. Ruby Mehta (FDA)
37. Mitchell Psotka (FDA)
38. Vanitha Sekar (FDA)
39. Fortunato Senatore (FDA)
40. Raymond Soccio (FDA)
41. Jennifer Taylor (FNIH)

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 (Worldwide Leadership)

52. Jason Campagna (Inventiva)

53. Jerry Colca (Cirius)

54. Andrea Dennis (Perspectrum)

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. Dean Hum (Genfit, FRA)

61. Meena Jain (Akeru)

62. Morten Karsdal (Nordic Bioscience – Roche)

63. MeeJ Kim (GSK)

64. Michelle Long (NovoNordisk)

65. Christina Mack (IQVIA)

66. Daniel Mazo (Boehringer)

67. Jan Marquard (Merck Sharp & Dohm)

68. Jorge Alfonso Ross Terres (Roche)

69. David Soergel (Madrigal)

70. Jonathan Stine (AstraZeneca)

71. Fady Tanios (Regeneron)

72. Rebecca Taub (Madrigal)

**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 (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

**10.00-10.30  
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

David Wheeler (London, UK)

Endocrinologist's viewpoint

11:10-11:20

Jennifer Green (Durham, NC, USA)

Industry viewpoint

11:20-11:40

Salvador Augustin (Boehringer)

Jan Marquard (Merck Sharp & Dohm)

Amnon Schlegel (Amgen)

Jonathan Stine (AstraZeneca)

Patients' viewpoints

11:40-11:45

Henry Chang (NYC, USA)

**11.45-12.30**

**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 (Saarbrücken, 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- 14.20**

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

**Chairpersons : Nicolas Girerd (Nancy, France) & David Wheeler (London, UK)**

What CardioKidney surrogates can be embedded in MASLD trials?

13:10-13:20

Nicolas Girerd (Nancy, France)

The FNIH Biomarkers Consortium's advancing understanding of CKLM biology for future multi-organ research

13:20-13:30

Patricia Grebenstein (FNIH)

13:30-13:40

Evaluating at-risk MASH status using the NIS2+ score

Dean Hum (Genfit, FRA)

13:40-13:50

Biomarkers and algorithms : Industry viewpoints

Joseph Gogain (Somalogic)

Morten Karsdal (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?

Amreen Dinani (Durham, NC, USA)

**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) & David Wheeler (London, UK)**

Panelists:

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

Andrea Dennis (Perspectum)

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

16:55-17:05

Sigrunn Blacoe (Wordlwide Leadership)

Christina Mack (IQVIA)

**17.05-17.40**

**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 and Timothy Morgan (Irvine, CA, USA)

**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)

Industry viewpoints

9.00-9.15

Jason Campagna (Inventiva)

MeeJ Kim (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 Nouredin (Houston, USA) & Harriette Van Spall (Hamilton, Canada)**

Panelists :

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

Lesley Curtis (Durham, NC, 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

Nancy Dreyer (Dreyer LLC, 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)**

Translating Multi-Organ Benefits into Health Economics and Metrics for Payers. Are Liver-Only drugs at risk?  
11:40-11:50  
Zobair Younossi (Washington, DC, USA)

Bundled chronic-disease pathways: How are sponsors shaping up their programs?  
11:50-12:00  
Jyothis George (NodThera)  
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**