



Metabolic multi Organ Science Accelerating Innovation in Clinical trials

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A Public Private Partnership **CVCT** meeting
Co-sponsored by Inserm (France) and FDA (USA)

October 23 - 24, 2025

Embassy of France,

4101 Reservoir Road, NW - Washington DC - 20007

SCIENTIFIC PROGRAM

CHAIRPERSONS

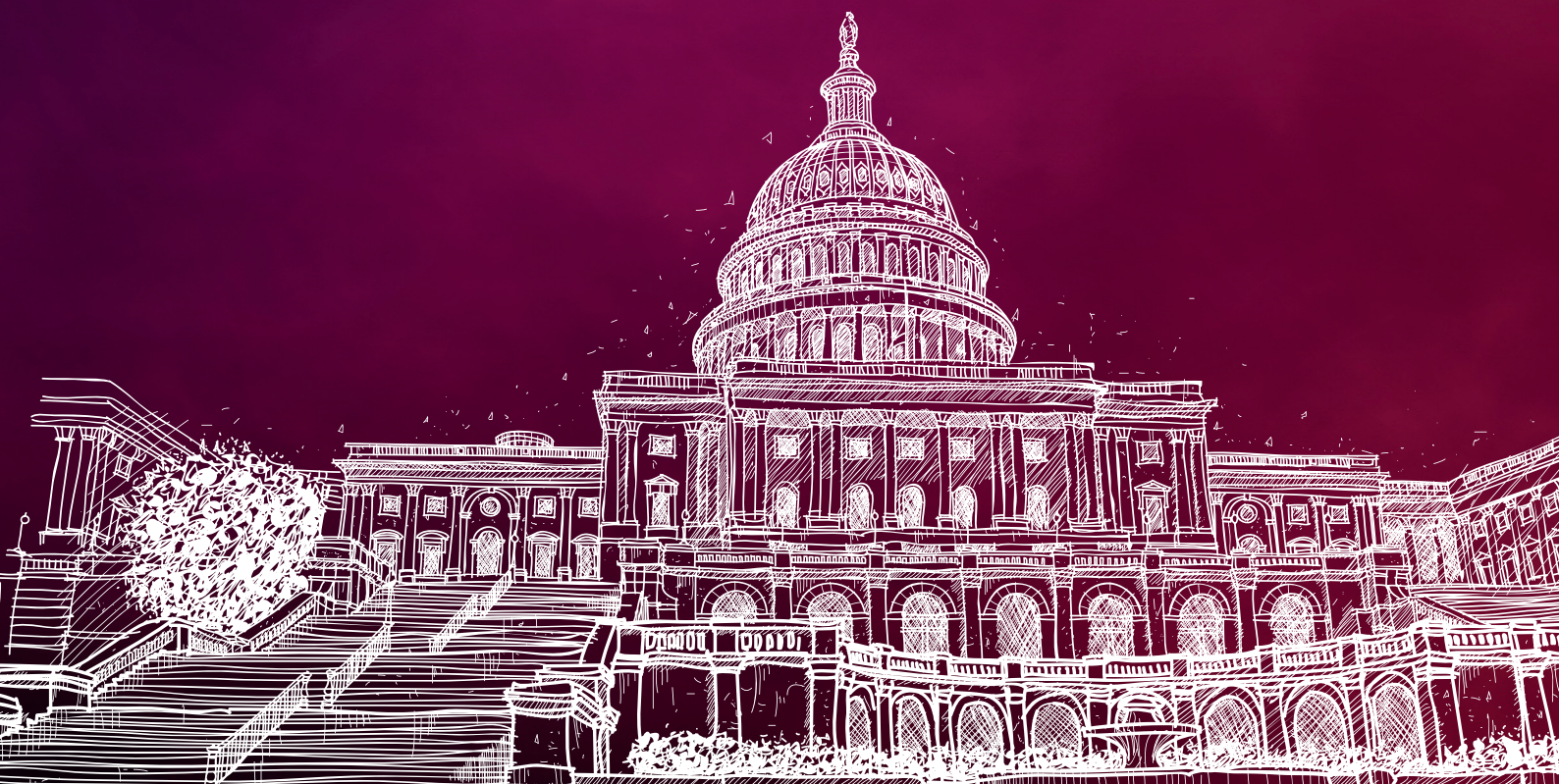
FAIEZ ZANNAD (PARIS, FRA)

NISHA BANSAL (SEATTLE, USA)

JAVED BUTLER (DALLAS, USA)

VERONICA MILLER (BERKELEY, USA)

ARUN SANYAL (RICHMOND, USA)



FACULTY

ACADEMY

1. Naim Alkouri (Houston, USA)
2. Nisha Bansal (Seattle, USA)
3. Deepak Bhatt (Boston, USA)
4. Mamatha Bhat (Toronto, CA)
5. Petter Bjornstad (Aurora, USA)
6. François-Henri Boissel (Lyon, FRA)
7. Javed Butler (Dallas, USA)
8. Cyrielle Caussy (Paris, FRA)
9. Naga Chalasani (Indianapolis, USA)
10. Nicholas Chew (Singapore, SIN)
11. Sven Franque (Brussels, BEL)
12. Jennifer Green (Durham, USA)
13. Hidido Lambers Heerspink (Groningen, NED)
14. Joe Hill (Dallas, TX, USA)
15. Chris Holmes (Oxford, UK)
16. Lesley Inker (Boston, USA)
17. Shahzeb Khan (Dallas, TX, USA)
18. Aleksander Krag (Odense, DEN)
19. Carolyn Lam (Singapore, SIN)
20. Jeffrey Lazarus (Barcelona, ESP)
21. Celeste McCracken (Oxford, UK)
22. Veronica Miller (Berkeley, USA)
23. Philip Newsome (London, UK)
24. Mazen Nouredin (Chicago, USA)
25. Milton Packer (Dallas, USA)
26. Prakash Ramachandran (Edinburgh, UK)
27. Eduardo Rame (Philadelphia, USA)
28. Janani Rangaswami (Washington, USA)
29. Vlad Ratziu (Paris, FRA)
30. Mary Rinella (Chicago, USA)
31. Greg Roth (Washington, USA)
32. Arun Sanyal (Richmond, USA)
33. Jörn Schattenberg (Mainz, GER)
34. Bart Staels (Paris, FRA)
35. Jan Tijssen (Brussels, BEL)
36. Katherine Tuttle (Washington, USA)
37. Tracy Wang (Durham, USA)
38. Janet Wittes (Wittes LLC, USA)
39. Faiez Zannad (Paris, FRA)

PATIENTS

40. Michael Betel (Fatty Liver Alliance, CAN)
41. Henry Chang (Fatty Liver Foundation, USA)
42. Jeff McIntyre (Global Liver, USA)
43. Margaret Padilla (San Antonio, TX, USA)

REGULATORY

44. Tania Kamphaus (FNIH, USA)

JOURNAL EDITORS

45. Flavia Geraldès (The Lancet)
46. Jane Leopold (NEJM)
47. Karen O'Leary (Nature Medicine)

INDUSTRY

48. SMads Axelsen (Gubra, DEN)
49. Neeta Amin (Pfizer, USA)
50. Scott Berry (Berry Consultants, Austin, USA)
51. Michael Coreman (Inventiva, USA)
52. Andrea Dennis (Perspectum, UK)
53. Federica Genovese (Nordic Bioscience)
54. Joe Gogain (Somalogic, USA)
55. Katharine Grimmer (Sagimet Biosciences, USA)
56. Scott Harris (Altimmune, USA)
57. Mark Hartman (Eli Lilly)
58. Waheed Jamal (Boehringer)
59. Lars Johansson (Antaros, SWE)
60. Morten Karsdal (Nordic Bioscience)
61. Tomasz Kostrzewski (CN-BIO, UK)
62. Dustin Little (AstraZeneca)
63. Michelle Long (NovoNordisk)
64. Karsten Strauss (Olink, SWE)
65. Rebecca Taub (Madrigal)

**Thursday 23 October, 2025
8.30- 10.00**

**INTRODUCTION TO MOSAIC 2025
THE CURRENT LANDSCAPE**

Chairpersons : Faiez Zannad (Paris, FRA), Arun Sanyal (Richmond, USA)

8.30-8.50

Are We Breaking the Siloes? How The Cardiovascular, Kidney, Liver, Metabolism (CKLM) Paradigm Has Disseminated Since We Last Met At MOSAIC?

Faiez Zannad (Paris, FRA), Arun Sanyal (Richmond, USA)

Where do we start from? Drugs Currently Approved in One or More MASLD, Cardiovascular, Kidney, or Metabolism indication, With Potential for a Complementary Indication Extension.

8.50-9.30

Investigator viewpoints

Mazen Nouredin (Chicago, USA)

Mary Rinella (Chicago, USA)

Philip Newsome (London, UK)

Hiddo Lambers Heerspink (Groningen)

9.30-9.55

Industry viewpoints (5 min each)

Rebecca Taub (Madrigal)

Dustin Little (AstraZeneca)

Michelle Long (NovoNordisk)

Mark Hartman (Eli Lilly)

Waheed Jamal (Boehringer)

9.55-10.00

Patient's viewpoint

Henry Chang (Fatty Liver Foundation, USA)

10.00-10.30

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
THE CURRENT LANDSCAPE – SWOT ANALYSIS**

Chairpersons : Faiez Zannad (Paris, FRA), Arun Sanyal (Richmond, USA)

Panelists : all speakers and Michael Coreman (Inventiva, USA), Scott Harris (Altimune, USA), Katharine Grimmer (Sagimet Biosciences, USA)

10.30-11.00

Coffee break & Networking

**Thursday 23 October, 2025
11.00- 12.00**

**NEW DATA AND REMAINING GAPS IN
EPIDEMIOLOGY AND PATHOPHYSIOLOGY KNOWLEDGE
Chairpersons : Javed Butler (Dallas, USA), Veronica Miller (Berkeley, USA)**

11.00-11.20

Global Epidemiology: Are We Capturing Inter-Organ Interplay of the Cardiovascular-Liver-kidney Metabolic (CKLM) Syndemic

**Nicholas Chew (Singapore, SIN)
Greg Roth (Washington, USA)**

11.20-12.10

Shared Cardiovascular, Kidney, Liver or Metabolism Pathophysiologic Mechanisms and Inter-Organ Crosstalk

**Bart Staels (Paris, FRA)
Prakash Ramachandran (Edinburgh, UK)
Milton Packer (Dallas, USA)
Janani Rangaswami (Washington, USA)
Eduardo Rame (Philadelphia, USA)**

12.10-12.15

**Patient's viewpoint
Jeff McIntyre (Global Liver, USA)**

12.15-12.45

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
HOW TO IMPROVE EPIDEMIOLOGY AND PATHOPHYSIOLOGY KNOWLEDGE
Chairpersons : Javed Butler (Dallas, USA), Veronica Miller (Berkeley, USA)**

Panelists : all speakers

12.45-13.30

Lunch Break & Networking

**Thursday 23 October, 2025
13.30- 15.10**

**NEW DATA AND REMAINING GAPS IN
PRECLINICAL AND BIOMARKER KNOWLEDGE**

Chairpersons : Cyrielle Caussy (Paris, FRA), Jörn Schattenberg (Mainz, GER)

13.30-13.50

What May Be Suitable Preclinical and Translational Integrated Models of CKLM Interplay?

Joe Hill (Dallas, TX, USA)

Jörn Schattenberg (Mainz, GER)

13.50-14.00

The Liver Investigation: Testing Marker Utility in Steatohepatitis (NIMBLE) experience

Arun Sanyal (Richmond, USA)

14.00-14.10

Assessing Multi-Organ Involvement Using Emerging Multi-Omics and system biology.

Aleksander Krag (Odense, DEN)

14.10-14.40

Industry viewpoints (5 min each)

Neeta Amin (Pfizer, USA)

Joe Gogain (Somalogic, USA)

Karsten Strauss (Olink, SWE)

Mads Axelsen (Gubra, DEN)

Tomasz Kostrzewski (CN-BIO, UK)

Morten Karsdal or Federica Genovese (Nordic Bioscience)

14.40-14.45

Patient's viewpoint

Michael Betel (Fatty Liver Alliance, CAN)

14.45-15.15

The MOSAIC Multi-Stakeholder Think Tank Moderated debate

HOW TO IMPROVE PRECLINICAL AND BIOMARKER KNOWLEDGE

Chairpersons : Cyrielle Caussy (Paris, FRA), Jörn Schattenberg (Mainz, GER)

Panelists : all speakers

15.15-15.40

Coffee Break & Networking

**Thursday 23 October, 2025
15.40- 16.30**

**CHANGING PARADIGM
NEW DATA AND REMAINING GAPS IN IMAGING KNOWLEDGE
Chairpersons : Celeste McCracken (Oxford, UK)**

Assessing Multi-Organ Involvement Using Emerging Multi-Modality Imaging.

15.40-16.00

Investigator viewpoint
Celeste McCracken (Oxford, UK)
Petter Bjornstad (Aurora, USA)

16.00-16.10

Industry viewpoints (5 min each)
Lars Johansson (Antaros, SWE)
Andrea Dennis (Perspectum, UK)

16.10-16.20

The Role of Machine Learning and Artificial Intelligence. Combining Biomarkers, Bioimaging and Clinical Phenotypes to Assess Multi-Organ Involvement in CKLM States
Mamatha Bhat (Toronto, CA)

16.20-16.40

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
HOW TO IMPROVE IMAGING KNOWLEDGE
Chairpersons : TBD**

Panelists : all speakers

**Thursday 23 October, 2025
16.40- 17.20**

**ENDPOINTS IN MULTI-ORGAN CKLM CLINICAL TRIALS
Chairpersons : Carolyn Lam (Singapore, SIN), Vlad Ratziu (Paris, FRA)**

16.40-16.50

NITs, Elastography and Other Liver-Related Endpoints to Be Incorporated in Cardiovascular, Kidney Metabolism Clinical Trials

Cyrielle Caussy (Paris, FRA)

16.50-17.00

What Metabolic Endpoint May Be Incorporated in MASLD Trials

Jennifer Green (Durham, USA)

17.00-17.10

What Kidney Endpoints May Be Incorporated in MASLD Trials

Lesley Inker (Boston, USA^o)

17.10-17.20

What Cardiovascular Endpoints May Be Incorporated in MASLD Trials

Carolyn Lam (Singapore, SIN)

17.20- 18.10

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
ENDPOINTS IN MULTI-ORGAN CKLM CLINICAL TRIALS
Chairpersons : Carolyn Lam (Singapore, SIN), Vlad Ratziu (Paris, FRA)**

Panelists : all speakers

18.10-19.30

Cocktail Reception and Networking

20.00-21.30

“Haïti Mon Amour”,

**Piano Recital Featuring Célimène Daudet
Theatre At Embassy Of France**

**Friday 24 October, 2025
8.00-9.00**

**HOW TO DESIGN MULTI-ORGAN INTEGRATED CKLM CLINICAL TRIALS
DESIGN & STATISTICAL SOLUTIONS**

Chairpersons : Jan Tijssen (Brussels, BEL), Janet Wittes (Wittes LLLC, USA)

8.00-8.10

Ongoing trials with concurrent evaluation of Cardiovascular, Kidney, Metabolism or MASLD endpoints.

Vlad Ratziu (Paris, FRA)

8.10-8.30

Innovative Design for Integrated Multi-Organ Clinical Trials.
The Potential Of Platform, Basket, Umbrella, and other designs

Janet Wittes (Wittes LLLC, USA)

Jan Tijssen (Brussels, BEL)

8.30-8.40

Interim Analyses and Bayesian Methods.
Scott Berry (Berry Consultants, Austin, USA)

8.40-8.50

The “Flexible Augmented Clinical Trial for Improved Evidence Generation” (FACTIVE)

Chris Holmes (Oxford, UK)

8.50-9.00

In Silico Modelling.

François-Henri Boissel (Lyon, FRA)

9.00- 9.30

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
HOW TO DESIGN MULTI-ORGAN INTEGRATED CKLM CLINICAL TRIALS
DESIGN & STATISTICAL SOLUTIONS**

Chairpersons : Jan Tijssen (Brussels, BEL), Janet Wittes (Wittes LLLC, USA)

Panelists : all speakers

9.30-10.00

Coffee Break & Networking

**Friday 24 October, 2025
10.00- 11.30**

**SELECTING THE APPROPRIATE TRIAL POPULATION FOR MULTI-ORGAN CLINICAL TRIALS
Chairpersons : Jennifer Green (Durham, USA), Katherine Tuttle (Washington, USA)**

10.00-10.40

What Are the Unmet Needs and What is the Clinically Relevant Patient Population?

Arun Sanyal (Richmond, USA)

Javed Butler (Dallas, USA)

10.40-10.50

Avoiding Routine Exclusion in CKM Trials of Participants with Liver Dysfunction.

Naga Chalasani (Indianapolis, USA)

10.50-11.10

Avoiding Routine Exclusion in MASLD Trials of Participants with Cardiovascular and/or Kidney Exclusion Criteria

Naim Alkouri (Houston, USA)

Katherine Tuttle (Washington, USA)

11.10-11.20

Screening for concomitant Heart Failure/CVD and MASLD

Carolyn Lam (Singapore, SIN)

11.20-11.30

Screening for concomitant CKD and MASLD

Hiddo Heerspink (Groningen, NED)

11.30-11.35

Patient's viewpoint

Margaret Padilla (San Antonio, TX, USA)

11.35- 12.00

The MOSAIC Multi-Stakeholder Think Tank Moderated debate

SELECTING THE APPROPRIATE TRIAL POPULATION FOR MULTI-ORGAN CLINICAL TRIALS

Chairpersons : Jennifer Green (Durham, USA), Katherine Tuttle (Washington, USA)

Panelists : all speakers

12.00-13.00

Lunch Break & Networking

**Friday 24 October, 2025
13.00- 13.30**

**EVENT ENRICHMENT POWER AND SIZE FOR MULTI-ORGAN TRIALS
Chairpersons: Deepak Bhatt (Boston, USA), Sven Franque (Brussels, BEL)**

Enriching CKM Trials For MALO In Multi-Organ Outcome trials and How To Power a Trial for Major Adverse Liver Outcomes (MALO)
Sven Franque (Brussels, BEL)

Enriching MASLD Trials For Major Adverse Cardiac Events (MACE) In Multi-Organ Outcome trials and how to power a trial for For MACE
Deepak Bhatt (Boston, USA)

13.30- 14.50

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
REGULATORY REQUIREMENTS TO FIT A CHANGING PARADIGM
Chairpersons: Deepak Bhatt (Boston, USA), Sven Franque (Brussels, BEL)**

Template For an Innovative MOSAIC Trial Protocol With Multi-Organ Composite Endpoint Seeking Approval of Multiple Indications For A Combinatorial Agent
Faiez Zannad (Paris, FRA)

Issues to be debated

What Can Be a Regulatory Approvable Multi-Organ Composite Endpoint.
Regulatory Requirements to Have More Than One Organ System Outcomes Approved in One Trial?
“Cardiovascular Safety Should Be Adequately Monitored”. How To Assess CV Safety in Non-CV Trials? Safety Endpoints, Trial Design and Trial Size?

FDA relevant divisions viewpoints

Charu Gandotra, Mark Levenson, George Makar, William Sanders, Fred Senatore, John Sharretts, Raymond Soccio, Charmaine Stewart, Norman Stockbridge

EMA Cardiology (Kristina Dunder, Alar Irs, Patrick Vrijlandt), endocrine TBD, hepatology, TBD, nephrology, TBD

**14.50-15.10
Coffee Break & Networking**

**Friday 24 October, 2025
15.10-16.30**

**HOLISTIC APPROACH TO CKLM TRIALS AND CARE
DISSEMINATING AND IMPLEMENTING THE MOSAIC AGENDA**

Chairpersons: Flavia Geraldes (The Lancet), Shahzeb Khan (Dallas, TX, USA)

15.10-15.20

Raising public awareness. The Liver Forum viewpoint
Veronica Miller (Berkeley, USA)

15.20-15.40

Overcoming The Siloed Clinical Practice. How To Promote a Holistic Management Of MASLD/MASH In the Context of the CKLM Construct.
Shahzeb Khan (Dallas, TX, USA)
Jörn Schattenberg (Homburg, GER)

15.40-15.55

Accelerating the Science of MultiOrgan Clinical Trials (5 min each)
PCORI viewpoint
Tracy Wang (Durham, USA)

The role of Public Funding Agencies
Tania Kamphaus (FNIH, USA)
Jeffrey Lazarus (Barcelona, ESP)

15.55-16.10

How To Popularize the CKLM Concept in the Medical Community? The Role of Medical Journals. Journal Editors' Viewpoints (5 min each)
Flavia Geraldes (The Lancet)
Jane Leopold (NEJM)
Karen O'Leary (Nature Medicine)

16.10-16.30

How To Promote Multiorgan Approach Advocacy. Patients' viewpoints (5 min each)
TBD (Heartlife Foundation), TBD (Diabetes), TBD (American Association of Kidney Patients), Michael Betel (Fatty Liver Alliance, CAN), Henry Chang (Fatty Liver Foundation, USA), Jeff McIntyre (Global Liver, USA), Margaret Padilla (San Antonio, TX, USA)

16.30-17.00

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
HOW TO DISSEMINATE AND IMPLEMENT THE MOSAIC AGENDA
Chairpersons: Flavia Geraldes (The Lancet), Shahzeb Khan (Dallas, TX, USA)**

17.00

CONCLUDING REMARKS

Faiez Zannad (Paris, FRA), Arun Sanyal (Richmond, USA)

17.30 ADJOURN