



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 with participation of FDA (USA)

October 23 - 24, 2025

Embassy of France,

4101 Reservoir Road, NW - Washington DC - 20007

SCIENTIFIC PROGRAM

CHAIRPERSONS

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NISHA BANSAL (SEATTLE, USA)

JAVED BUTLER (DALLAS, USA)

VERONICA MILLER (BERKELEY, USA)

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6. Michael Cooreman (Richmond, USA)
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8. Nicolas Girerd (Nancy, FRA)
9. Lesley Inker (Boston, USA)
10. Shahzeb Khan (Dallas, TX, USA)
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19. Greg Roth (Washington, USA)
20. Arun Sanyal (Richmond, USA)
21. Jörn Schattenberg (Homburg, GER)
22. Bart Staels (Paris, FRA)
23. Norman Stockbridge (Stockbridge, LLC)
24. Louise Thomas (London, UK)
25. Jan Tijssen (Brussels, BEL)
26. Harriette Van Spall (Toronto, CAN)
27. Tracy Wang (Durham, USA)
28. Janet Wittes (Wittes LLC, USA)
29. Faiez Zannad (Paris, FRA)

PATIENTS

30. Michael Betel (Fatty Liver Alliance, CAN)
31. Henry Chang (Fatty Liver Foundation, USA)
32. Magdalena Daccord (FH Europe Foundation)
33. Wayne Eskridge (Fatty Liver Foundation, USA)
34. Patrick Gee (iAdvocate, USA)
35. Sharon Jaycox (Global Liver Institute, USA)
36. Marko Korenjak (European Liver Patients' Association)
37. Jeff McIntyre (Global Liver, USA)

REGULATORY

38. Abbas Bandukwala, (FDA, USA)
39. Charu Gandotra (FDA, USA)
40. Patricia Grebenstein (FNIH)
41. Melissa Jones (FNIH, USA)
42. Tania Kamphaus (FNIH, USA)
43. Vandana Sachdev (NHLBI, USA)
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48. Jennifer Taylor (FNIH, USA)
49. Aliza Thompson (FDA, USA)
50. Yun Wang (FDA, USA)
51. Jialu Zhang (FDA, USA)

JOURNAL EDITORS

52. Ben Abbott (The Lancet)
53. Jane Leopold (NEJM)
54. Jennifer Sargent (Metabologia, EASD)

INDUSTRY

55. Robert Beardsley (Cirius, USA)
56. Scott Berry (Berry Consultants, Austin, USA)
57. Mathijs Bunck (Eli Lilly, USA)
58. Jason Campagna (Inventiva, USA)
59. Andrea Dennis (Perspectum, UK)
60. Samuel Engel (Merck, USA)
61. Michael Feigh (Gubra, DEN)
62. Joe Gogain (Somalogic, USA)
63. Katharine Grimmer (Sagimet Biosciences, USA)
64. Scott Harris (Altimmune, USA)
65. Lars Johansson (Antaros, SWE)
66. Maragret Koziel (GSK, USA)
67. Dustin Little (AstraZeneca, UK)
68. Michelle Long (NovoNordisk, DEN)
69. Daniel Mazo (Boehringer Ingelheim, GER)
70. Rebecca Taub (Madrigal, USA)

ATTENDEES

PATIENTS

- 71. Jennifer Berg (USA)
- 72. Edyth Dwyer (Liver Forum, USA)

INDUSTRY

- 73. Salvador Augustin (Boehringer Ingelheim, GER)
- 74. Luisa Borowska (Boehringer Ingelheim, GER)
- 75. Lisa Boyette (Eli Lilly, USA)
- 76. Roberto Calle (Regeneron, USA)
- 77. Michael Charlton (Madrigal, USA)
- 78. Yukti Choudoury (HistoIndex, SIN)
- 79. Claude Cohen-Bacrie (e-Scopics)
- 80. Jerry Colca (Cirus, USA)
- 81. Carlos Duncker (Perspectum, USA)
- 82. Kristin Fiorino (Astrazeneca, UK)
- 83. Armando Flor (Astrazeneca, UK)
- 84. Jyothis George (Nodthera, UK)
- 85. Nikki Glenn (DiaPharma)
- 86. Joe Grimsby (Regeneron, USA)
- 87. Lars Hansen (Astrazeneca, UK)
- 88. Cindy Hartsfield (89Bio, USA)
- 89. Andrea Kidner (Boehringer Ingelheim, GER)
- 90. Maximilian Kurt Jara (NovoNordisk, DEN)
- 91. Dominic Labriola (Madrigal, USA)
- 92. Dan Legg (Boehringer Ingelheim)
- 93. Renee Marshall (Boehringer Ingelheim)
- 94. Jan Marquard (Merck, USA)
- 95. Marija Mavar (Perspectum, USA)
- 96. Patricia Mendez (GSK, USA)
- 97. John Miller (Astrazeneca, UK)
- 98. Alan Moses (Perspectum, USA)
- 99. Sune Boris Nygård (NovoNordisk, DEN)
- 100. Divakar Peri (Madrigal, USA)
- 101. Andres Quintero (NovoNordisk, DEN)
- 102. David Soergel (Madrigal, USA)
- 103. Jonathan Stine (Astrazeneca, UK)
- 104. Fady Tanios (Regeneron, USA)
- 105. Jose Vargas (Perspectum, USA)
- 106. Gosia Wamill (Perspectum, UK)
- 107. Ramy Younes (Boehringer Ingelheim, GER)

**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.

8.50-9.20

Investigator viewpoints

Sven Francque (Antwerp, BEL)

Tom Marjot (London, UK)

Faiez Zannad (Paris, FRA)

9.20-9.45

Industry viewpoints (5 min each)

Mathijs Bunck (Eli Lilly)

Maragret Koziel (GSK USA)

Dustin Little (AstraZeneca)

Michelle Long (NovoNordisk)

Daniel Mazo(Boehringer Ingelheim)

Rebecca Taub (Madrigal)

9.45-9.50

Patient's viewpoint

Henry Chang (Fatty Liver Foundation, USA)

9.50-10.30

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 Jason Campagna (Inventiva, USA), Samuel Engel (Merck), 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)**

11.20-12.00

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

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

12.00-12.10

**Adipose tissue – Liver crosstalk
Michael Cooreman (Richmond, USA)**

12.10-12.15

**Patient's viewpoint
Sharon Jaycox (Global Liver Institute, 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 : Aleksander Krag (Odense, DEN), Jörn Schattenberg (Homburg, GER)

13.30-13.50

**What May Be Suitable Preclinical and Translational Integrated Models of CKLM Interplay?
Jörn Schattenberg (Homburg, 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)**

14.10-14.20

**Industry viewpoints (5 min each)
Joe Gogain (Somalogic, USA)
Michael Feigh (Gubra, DEN)**

14.20-14.25

**Patient's viewpoint
Michael Betel (Fatty Liver Alliance, CAN)**

14.25-15.15

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
HOW TO IMPROVE PRECLINICAL AND BIOMARKER KNOWLEDGE**

Chairpersons : Aleksander Krag (Odense, DEN), Jörn Schattenberg (Homburg, 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 : Nicolas Girerd (Nancy, FRA), Louise Thomas (London, UK)**

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

15.40-15.50

**Investigator viewpoint
Charlotte Manisty (London, UK)
Louise Thomas (London, UK)**

15.50-16.10

**Industry viewpoints (10 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 : Nicolas Girerd (Nancy, FRA), Louise Thomas (London, UK)**

Panelists : all speakers

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

ENDPOINTS IN MULTI-ORGAN CKLM CLINICAL TRIALS

Chairpersons : Sven Francque (Antwerp, BEL), Harriette Van Spall (Toronto, CAN)

16.40-16.50

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

Sven Francque (Antwerp, BEL)

16.50-17.00

What Metabolic Endpoint May Be Incorporated in MASLD Trials

Bart Staels (Paris, FRA)

17.00-17.10

What Kidney Endpoints May Be Incorporated in MASLD Trials

Lesley Inker (Boston, USA°)

17.10-17.20

What Cardiovascular Endpoints May Be Incorporated in MASLD Trials

Nicolas Girerd (Nancy, FRA)

17.20- 18.10

The MOSAIC Multi-Stakeholder Think Tank Moderated debate

ENDPOINTS IN MULTI-ORGAN CKLM CLINICAL TRIALS

Chairpersons : Sven Francque (Antwerp, BEL), Harriette Van Spall (Toronto, CAN)

Panelists : all speakers

18.10-19.30

Cocktail Reception and Networking

**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 LLC, USA)

8.00-8.10

Ongoing trials with concurrent evaluation of Cardiovascular, Kidney, Metabolism or MASLD endpoints.
Harriette Van Spall (Toronto, CAN)

8.10-8.30

Innovative Design for Integrated Multi-Organ Clinical Trials.
The Potential Of Platform, Basket, Umbrella, and other designs
Janet Wittes (Wittes LLC, USA)
Jan Tijssen (Brussels, BEL)

8.30-8.40

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

8.40-8.50

In Silico Modelling.
Christyne Leon (Lyon, FRA)

8.50- 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 LLC, 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 : Naim Alkouri (San Antonio, USA), Lesley Inker (Boston, MA, 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)

11.10-11.20

Screening for concomitant Heart Failure/CVD and MASLD

Harriette Van Spall (Toronto, CAN)

11.20-11.30

How to enroll patients with CKD in MASLD trials

Lesley Inker (Boston, MA, USA)

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 : Naim Alkouri (San Antonio, USA), Lesley Inker (Boston, MA, 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: Charu Gandotra (FDA, USA), Sven Francque (Antwerp, BEL)**

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

Enriching MASLD Trials For Major Adverse Cardiac Events (MACE) In Multi-Organ Outcome trials and how to power a trial for MACE
Nicolas Girerd (Nancy, FRA)

13.30- 14.50

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate
REGULATORY REQUIREMENTS TO FIT A CHANGING PARADIGM
Chairpersons: Charu Gandotra (FDA, USA), Sven Francque (Antwerp, BEL)**

Template For an Innovative MOSAIC Trial Protocol With Multi-Organ Composite Endpoint Seeking Approval of Multiple Indications For A Combinatorial Agent
Use-case (5min)
Robert Beardsley (Cirius, USA)
Template protocol (15 min)
Faiez Zannad (Paris, FRA)

Issues to be debated (60 min)

1. What Can Be a Regulatory Approvable Multi-Organ Composite Endpoint.
2. Regulatory Requirements to Have More Than One Organ System Outcomes Approved in One Trial?
3. "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
Abbas Bandukwala, Charu Gandotra, William Sanders, Fred Senatore, John Sharretts, Raymond Soccio, Aliza Thompson, Yun Wang, Jialu Zhang

Norman Stockbridge (Stockbridge, LLC)

**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: Ben Abbott (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
Jeffrey V. Lazarus (Barcelona, ESP)

The role of NIH-FNIH
Tania Kamphaus (FNIH, USA)
Vandana Sachdev (NHLBI, USA)

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)
Ben Abbott (The Lancet), Jennifer Sargent (Metabologia, EASD), Jane Leopold (NEJM)

16.10-16.30

How To Promote Multiorgan Approach Advocacy. Patients' viewpoints (5 min each)
Michael Betel (Fatty Liver Alliance, CAN), Magdalena Daccord (FH Europe Foundation), Wayne Eskridge (Fatty Liver Foundation, USA), Henry Chang (Fatty Liver Foundation, USA), Patrick Gee (iAdvocate, USA) Sharon Jaycox (Global Liver Institute, USA), Marko Korenjak (European Liver Patients' Association)

16.30-17.00

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

17.00

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

17.30 ADJOURN