



**October 24 - 25, 2024**  
**Embassy of France,**  
**4101 Reservoir Road, NW - Washington DC - 20007**

# **SCIENTIFIC PROGRAM**

## **CHAIRPERSONS**

JAVED BUTLER (DALLAS, TX, USA)  
STEPHEN HARRISON (SAN ANTONIO, TX, USA) (IN MEMORIAM)  
VERONICA MILLER (BERKELEY, CA, USA)  
ARUN SANYAL (RICHMOND, VA, USA)  
FAIEZ ZANNAD (PARIS, FRA)



# FACULTY

## ACADEMY

1. Kushala W M Abeysekera (Bristol, GBR)
2. Alina Allen (Rochester, NY, USA)
3. Michael Böhm (Homburg/Saar, GER)
4. Javed Butler (Dallas, TX, USA)
5. Sven Francque (Antwerp, BEL)
6. Nicolas Girerd (Nancy, FRA)
7. Jim Januzzi (Boston, MA, USA)
8. Shahzeb Muhammad Khan (Durham, USA)
9. Aaron Mann (Piscataway, NJ, USA)
10. Veronica Miller (Berkeley, CA, USA)
11. Mark Muthiah (Singapore, SIN)
12. Marie-Ève Piché (Quebec, CAN)
13. Vlad Ratziu (Paris, FRA)
14. Arun Sanyal (Richmond, VA, USA)
15. Bart Staels (Lille, FRA)
16. Harriette Van Spall (Hamilton, ON, CAN)
17. Zobair M. Younossi (Falls Church, VA, USA)
18. Faiez Zannad (Paris, FRA)

## PATIENTS

19. Jennifer Berg (USA)
20. Michael Betel (Fatty Liver Alliance, CAN)
21. Henry Chang (Fatty Liver Foundation, USA)
22. Wayne Eskridge (Fatty Liver Foundation, USA)
23. Kimberly Martinez (USA)
24. Jeff McIntyre (Global Liver, USA)
25. Margaret Padilla (San Antonio, TX, USA)

## REGULATORY

26. Lauren Dang (NIH, USA)
27. Charu Gandotra (FDA, USA)
28. Tania Kamphaus (FNIH)
29. Mark Levenson (FDA, USA)
30. George Makar (FDA, USA)
31. William Sanders (FDA, USA)
32. Fred Senatore (FDA, USA)
33. John Sharretts (FDA, USA)
34. Raymond Soccio (FDA, USA)
35. Charmaine Stewart (FDA, USA)
36. Norman Stockbridge (FDA, USA)

## JOURNAL EDITORS

37. Flavia Geraldès (The Lancet, GBR)
38. Liam Messin (Nature Medicine, GBR)
39. Patrick O'Malley (NEJM, USA)

## INDUSTRY

40. Salvador Augustin (Boehringer Ingelheim, GER)
41. Scott Berry (Berry Consultants, Austin, USA)
42. Luiza Borowska (Boehringer Ingelheim, GER)
43. Chris Boulton (Amgen)
44. Sarah Browne (Altimmune)
45. Manu Chakravarthy (Carmot-Roche, USA)
46. Pascaline Clerc (Inventiva)
47. Jerry Colca (Cirius, USA)
48. Michael Cooreman (Inventiva, FRA)
49. Ben Da (Merck)
50. Andrea Dennis (Perspectum, GBR)
51. Dan Drozd (PicnicHealth, USA)
52. Samuel Engel (Merck)
53. Joe Gogain (Somalogic, USA)
54. Michael Fried (TargetRWE, USA)
55. Jyothis George (Amgen)
56. Scott Harris (Altimmune, USA)
57. Cindy Hartfield (89 Bio, USA)
58. Haroon Hashmi (Boston Pharmaceuticals)
59. Mark Hartman (Lilly, USA)
60. Waheed Jamal (Boehringer Ingelheim, GER)
61. Lars Johansson (Antaros, SWE)
62. Andrea Kidner (Boehringer Ingelheim, GER)
63. Margaret Koziel (Boston Pharmaceuticals)
64. Dominic Labriola (Madrigal)
65. Caitlin Langford (Perspectum)
66. Christine Lee (Amgen)
67. Jennifer Linge (Amra, SWE)
68. Michelle Long (Novo Nordisk, DNK)
69. Raleigh Malik (Amgen)
70. Hank Mansbach (89 Bio, USA)
71. Davide Mantiero (Owkin, FRA)
72. Daniel Mazo (Boehringer Ingelheim, GER)
73. Peter Mesenbrink (Novartis, USA)
74. Kusha Mohammadi (Regeneron)
75. Natalia Muhlemann (Cytel, USA)
76. David Nikodem (Metadeq, GBR)
77. Paul Nitschmann (Intercept Pharmaceuticals, USA)
78. Sune Nygård (Novo Nordisk, DNK)
79. Gal Scholtes (Amgen)
80. Rosemarie Sellati (Regeneron)
81. Rebecca Taub (Madrigal, USA)
82. Aldo Trylesinski (Metadeq, GBR)
83. Janet Wittes (Wittes LLC, USA)
84. Fred Yang (KBP, USA)
85. Ramy Younes (Boehringer Ingelheim, GER)

**Thursday 24 October, 2024  
8:30 -10:00**

**THE COMPETITIVE LANDSCAPE  
CKM AND MASLD PIPELINE, TRIALS, APPROVALS, AND GUIDELINES  
Chairpersons : Arun Sanyal (Richmond, VA, USA), Faiez Zannad (Paris, FRA)**

**8.30-8.40**

Major recent and ongoing CKM trials, approvals, and guidelines.  
Faiez Zannad (Paris, FRA)

**8.40-8.50**

Major recent and ongoing MASLD/MASH trials, approvals, and guidelines.  
Vlad Ratziu (Paris, FRA), Arun Sanyal (Richmond, VA, USA)

**8.50-9.00 (5 min each)**

What is in the CKM pipeline which has potential liver benefits  
Fred Yang (KBP, USA), Ramy Younes (Boehringer Ingelheim, GER)

**9.00-9.15**

What is in the MASLD/MASH pipeline which has potential CKM benefits  
Michael Cooreman (Inventiva, FRA), Jyothis George (Amgen), Rebecca Taub (Madrigal, USA)

**9.15-9.45**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**WEIGHING THE CURRENT DYNAMICS AND OPPORTUNITIES IN CKM AND MASLD  
Chairpersons : Arun Sanyal (Richmond, VA, USA), Faiez Zannad (Paris, FRA)**

Panelists : all speakers

**09.45-10.00  
Coffee break**

**Thursday 24 October, 2024  
10:00 -11:00**

**SETTING THE STAGE FOR THE INTEGRATION OF CKM AND MASLD-NASH DISORDERS  
Chairpersons : Marie-Ève Piché (Quebec, CAN), Vlad Ratziu (Paris, FRA)**

**10.00-10.10**

**The AHA Cardio-Kidney-Metabolism (CKM) confluence  
Marie-Ève Piché (Quebec, CAN)**

**10.10-10.20**

**CKM Overlap in Heart Failure trials  
Shahzeb Muhammad Khan (Durham, USA)**

**10.20-10.40**

**Defining the Cardio-Kidney-Liver-Metabolism (CKLM) paradigm. Intersecting, confluent, or consubstantial?**

**10.20-10.30**

**Insight from epidemiology  
Zobair M. Younossi (Falls Church, VA, USA)**

**10.30-10.40**

**Insight from pathophysiology  
Bart Staels (Lille, FRA)**

**10.40-11.00**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**AGREEING ON THE SIZE AND NATURE OF THE INTERSECTIONS.**

**Chairpersons : Marie-Ève Piché (Quebec, CAN), Vlad Ratziu (Paris, FRA)**

**Panelists : all speakers**

**Thursday 24 October, 2024**

**HOW TO BEST CHARACTERIZE THE CARDIO-KIDNEY-LIVER-METABOLISM (CKLM) INTERSECTIONS.**

**Part 1. 11.00 – 12.00**

**AVAILABLE CLINICAL DATA IN EXISTING RESPECTIVE CKM AND MASLD COHORTS AND TRIALS**  
**Chairpersons : Michael Böhm (Homburg/Saar, GER), Zobair M. Younossi (Falls Church, VA, USA)**

MASLD/MASH data in CKM trials

11.00 – 11.10

Cardiology trials

Michael Böhm (Homburg/Saar, GER)

11.10 – 11.20

Nephrology trials

Faiez Zannad (Paris, FRA)

CKM data in MASLD/MASH trials

11.20 – 11.30

CKM biomarker signatures/phenotypes in MASLD/MASH trials

Michael Cooreman (Inventiva, FRA)

**11.30-12.00**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**WHAT DO WE ALREADY KNOW ABOUT EACH OTHER ?**

**Chairpersons : Michael Böhm (Homburg/Saar, GER), Zobair M. Younossi (Falls Church, VA, USA)**

Panelists : all speakers

**12.00-13.00**

**Lunch**

**Thursday 24 October, 2024**

**HOW TO BEST CHARACTERIZE THE CARDIO-KIDNEY-LIVER-METABOLISM (CKLM) INTERSECTIONS.**

**Part 2. 13.00-14.30**

**HOW TO HARVEST EXISTING TRIALS' DATA AND BIOBANKS?**

**Chairpersons : Nicolas Girered (Nancy, FRA), Veronica Miller (Berkeley, CA, USA)**

**13.00-13.10**

Opportunities for cross-disorders investigations. The Liver Forum Collaboratory  
Veronica Miller (Berkeley, CA, USA)

**13.10-13.25**

Industry willingness to share completed trials resources (5 min each)  
Sune Nygård (Novo Nordisk, DNK), Hank Mansbach (89 Bio, USA), Ramy Younes (Boehringer Ingelheim, GER)

**13.25-13.35**

Liver risk stratification  
Kushala W M Abeysekera (Bristol, UK)

**13.35-13.45**

Metabolic risk stratification  
TBD

**13.45-13.55**

The potential of unbiased phenomapping using AI and datamining of existing databases.  
Davide Mantiero (Owkin, FRA)

**13.55-14.30**

Regulatory panel roundtable  
FDA Division of Cardiology and Nephrology  
Charu Gandotra, William Sanders, Fortunato (Fred) Senatore and Norman Stockbridge  
FDA Division of Hepatology and Nutrition George Makar, Charmaine Stewart  
FDA Division of Diabetes, Lipid Disorders, and Obesity, John Sharretts, Raymond Soccio  
FDA office of biostatistics Mark Levenson

**14.30-15.00**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**HARVESTING EXISTING TRIALS' DATA AND BIOBANKS.**

**HOW TO OPERATIONALISE COLLABORATION?**

**Chairpersons : Nicolas Girered (Nancy, FRA), Veronica Miller (Berkeley, CA, USA)**

Panelists : all speakers

**15.00-15.30**

**Coffee Break**

**Thursday 24 October, 2024  
15.30-17.40**

**EMBEDDING CKM SUB-STUDIES IN MASLD/MASH TRIALS AND MASLD/MASH  
SUB-STUDIES IN CKM TRIALS**

**Chairpersons : Jim Januzzi (Boston, MA, USA), Mark Muthiah (Singapore, SIN)**

**15.30-15.50**

**Clinical sub-studies**

**CKM: Nicolas Girerd (Nancy, FRA)**

**Liver: Mark Muthiah (Singapore, SIN)**

**15.50-16.10**

**Biomarker sub-studies**

**Liver : Arun Sanyal (Richmond, VA, USA)**

**CKM : Jim Januzzi (Boston, MA, USA)**

**16.10-16.30**

**Bioimaging sub-studies**

**Liver : Alina Allen (Rochester, NY, USA)**

**CKM : TBD**

**16.30-16.50**

**Industry viewpoints (5 min each)**

**Pharma industry**

**Michelle Long (Novo Nordisk, DK)**

**Biomarker industry**

**Joe Gogain (Somalogic, USA)**

**Imaging industry**

**Lars Johansson (Antaros, SWE), Andrea Dennis (Perspectum, UK),**

**16.50-17.10**

**Regulatory panel roundtable**

**FDA Division of Cardiology and Nephrology**

**Charu Gandotra, William Sanders, Fortunato (Fred) Senatore and Norman Stockbridge**

**FDA Division of Hepatology and Nutrition George Makar, Charmaine Stewart**

**FDA Division of Diabetes, Lipid Disorders, and Obesity, John Sharretts, Raymond Soccio**

**FDA office of biostatistics Mark Levenson**

**17.10-17.40**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**PRACTICAL FEASIBILITY OF ANCILLARY STUDIES**

**Chairpersons : Jim Januzzi (Boston, MA, USA), Mark Muthiah (Singapore, SIN)**

**Panelists : all speakers and Joe Gogain (Somalogic, USA), Jennifer Linge (Amra, SWE), Ramy Younes (Boehringer Ingelheim, GER)**

**FIRST DAY ADJOURN**

**18.30**

**NETWORKING, DINNER AND RECEPTION**

**Friday 25 October, 2024  
8:00-09:20**

**HOW REAL-WORLD DATA MAY HELP?**

**Chairpersons : Veronica Miller (Berkeley, CA, USA), Harriette Van Spall (Hamilton, ON, CAN)**

**8.00-8.10**

**The Causal Road Map  
Lauren Dang (NIH, USA)**

**8.10-8.20**

**How to construct a «RWD» cohort to contribute as RWEvidence (claims, EHRs, etc),  
Dan Drozd (PicnicHealth, USA)**

**8.20-8.30**

**Case studies (5 min each)  
Michael Fried (TargetRWE, USA)  
Paul Nitschmann (Intercept Pharmaceuticals, USA)**

**8.30-8.40**

**How would a shared placebo cohort work as supplemental control  
Veronica Miller (Berkeley, CA, USA)**

**8.40-8.50**

**Developing a culture of data sharing. The clinical research data sharing alliance experience  
Aaron Mann (Piscataway, NJ, USA)**

**8.50-9.20**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**BUILDING A COMMON RWD AGENDA**

**Chairpersons : Veronica Miller (Berkeley, CA, USA), Harriette Van Spall (Hamilton, ON, CAN)**

**Panelists : all speakers**

**09.20-09.40  
Coffee break**



**Friday 25 October, 2024  
9:40-13:30**

**INTEGRATED MULTI-ORGAN CKLM TRIALS.  
DEVELOPING A TEMPLATE PROTOCOL**

**Part 1. 9.40-11.30**

**DEFINING THE IDEAL INTEGRATED TARGET PATIENT POPULATIONS AND THE RIGHT ENDPOINTS  
Chairpersons : Javed Butler (Dallas, TX, USA), Arun Sanyal (Richmond, VA, USA)**

**9.40-9.50**

**Enriching CKM trial populations for liver outcomes  
Sven Francque (Antwerp, BEL)**

**9.50-10.00**

**Enriching MASLD trial populations for CK outcomes  
Javed Butler (Dallas, TX, USA)**

**10.00-10.10**

**Addressing diversity and inclusiveness issues  
Harriette Van Spall (Hamilton, ON, CAN)**

**10.10-10.20**

**What does it take for progressing from liver surrogate endpoints to MALE and to liver hard outcomes?  
Arun Sanyal (Richmond, VA, USA)**

**10.20-10.30**

**The value of composite endpoints integrating CKM components with Liver components  
Faiez Zannad (Paris, FRA)**

**10.30-10.40**

**Statistician viewpoint  
Janet Wittes (Wittes LLC, USA)**

**10.40-11.10**

**Regulatory panel roundtable  
FDA Division of Cardiology and Nephrology  
Charu Gandotra, William Sanders, Fortunato (Fred) Senatore and Norman Stockbridge  
FDA Division of Hepatology and Nutrition George Makar, Charmaine Stewart  
FDA Division of Diabetes, Lipid Disorders, and Obesity, John Sharretts, Raymond Soccio  
FDA office of biostatistics Mark Levenson**

**11.10-11.40**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**DEVELOPING A TEMPLATE PROTOCOL**

**Part 1. Defining the ideal integrated target patient populations and the right endpoints  
Chairpersons : Javed Butler (Dallas, TX, USA), Arun Sanyal (Richmond, VA, USA)**

**Panelists : all speakers**

**Friday 25 October, 2024  
9:40-13:30**

**INTEGRATED MULTI-ORGAN CKLM TRIALS.  
DEVELOPING A TEMPLATE PROTOCOL**

**Part 2. 11.40-13.30**

**DEFINING THE IDEAL INTEGRATED TRIAL DESIGN**

**CHAIRPERSONS : BART STAELS (LILLE, FRA), JANET WITTES (WITTES LLC, USA)**

**11.40-11.50**

The value of master protocols, platform, umbrella and basket design trials  
Scott Berry (Berry Consultants, Austin, USA)

**11.50-12.00**

Case study for platform study in MASH  
Peter Mesenbrink (Novartis, USA)

**12.00-12.10**

The value of pragmatic design and registry randomized trials  
Natalia Muhlemann (Cytel, USA)

**12.10-12.20**

Adaptive design and interim analyses  
Natalia Muhlemann (Cytel, USA)

**12.20-12.25**

Industry viewpoint  
Salvador Augustin (Boehringer Ingelheim, GER)

**12.25-12.30**

Regulatory statistical viewpoints  
Mark Levenson (FDA, USA)

**12.30-12.50**

Regulatory panel roundtable  
FDA Division of Cardiology and Nephrology  
Charu Gandotra, William Sanders, Fortunato (Fred) Senatore and Norman Stockbridge  
FDA Division of Hepatology and Nutrition George Makar, Charmaine Stewart  
FDA Division of Diabetes, Lipid Disorders, and Obesity, John Sharretts, Raymond Soccio  
FDA office of biostatistics : Mark Levenson

**12.50-13.30**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**DEVELOPING A TEMPLATE PROTOCOL**

**Part 2. Defining the ideal integrated trial design**

**Chairpersons : Bart Staels (Lille, FRA), Janet Wittes (Wittes LLC, USA)**

**Panelists : all speakers**

**13.30-14.30**

**Lunch**

**Friday 25 October, 2024  
14:30-15:25**

**IS SEEKING CKLM MULTI-ORGAN COMBINATORIAL DRUGS ATTRACTIVE?  
Chairpersons : Flavia Geraldes (The Lancet, GBR), Liam Messin (Nature Medicine, GBR)**

14.30-14.45 (5mins each)

Publishing manuscripts integrating cardiovascular, Kidney, metabolism and liver data  
Flavia Geraldes (The Lancet, UK), Liam Messin (Nature Medicine, GBR), Patrick O'Malley (NEJM, USA)

14.45-15.15 (10mins each)

Coverage of combinatorial medications with multi-organ indications.

Hepatologist perspective:  
Sven Francque (Antwerp, BEL)

Endocrinologist perspective:  
TBD

Cardiology perspective  
Michael Böhm (Homburg/Saar, GER)

15.15-15.25

Funding trials seeking multiple approvals, targeting multi-organ combinatorial indications  
Tania Kamphaus (FNIH)

**15.25-16.40**

**The MOSAIC Multi-Stakeholder Think Tank Moderated debate**

**FUTURE STEPS AND ACTIONABLE SOLUTIONS**

**MOSAIC Chairpersons : Javed Butler (Dallas, TX, USA), Veronica Miller (Berkeley, CA, USA), Arun Sanyal (Richmond, VA, USA), Faiez Zannad (Paris, FRA)**

1. How do we practically make liver trials do CKM phenotyping and vice versa.
2. How do we practically make liver trials collect CKM endpoints and vice versa.
3. What could be a typical CKLM integrated trial design?

Patients Forum

Michael Betel (Fatty Liver Alliance, CAN), Henry Chang (Fatty Liver Foundation, USA), Wayne Eskridge (Fatty Liver Foundation, USA), Jeff McIntyre (Global Liver, USA), Margaret Padilla (San Antonio, TX, USA)

Panelists: all faculty

**16.30 ADJOURN**