MOSAiC®

Metabolic multi Organ Science Accelerating Innovation in Clinical trials

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. Jeroen Bax (Leiden, NED)
5. Javed Butler (Dallas, TX, USA)
6. Sven Francque (Antwerp, BEL)
7. Nicolas Girerd (Nancy, FRA)
8. Jim Januzzi (Boston, MA, 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. Michael Betel (Fatty Liver Alliance, CAN)
20. Henry Chang (Fatty Liver Foundation, USA)
21. Wayne Eskridge (Fatty Liver Foundation, USA)
22. Jeff McIntyre (Global Liver, USA)
23. Margaret Padilla (San Antonio, TX, USA)

REGULATORY

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

JOURNAL EDITORS

34. Flavia Geraldes (The Lancet, GBR),
35. Liam Messin (Nature Medicine, GBR)
36. Patrick O'Malley (NEJM, USA)

INDUSTRY

37. Salvador Augustin (Boehringer Ingelheim, GER)
38. Scott Berry (Berry Consultants, Austin, USA)
39. Manu Chakravarthy (Carmot-Roche, USA)
40. Jerry Colca (Cirius, USA)
41. Michael Cooreman (Inventiva, FRA)
42. Andrea Dennis (Perspectum, GBR)
43. Joe Gogain (Somalogic, USA)
44. Michael Fried (TargetRWE, USA)
45. Jyothis George (Amgen)
46. Scott Harris (Altimmune, USA)
47. Mark Hartman (Lilly, USA)
48. Lars Johansson (Antaros, SWE)
49. Jennifer Linge (Amra, SWE)
50. Michelle Long (Novo Nordisk, DNK)
51. Hank Mansbach (89 Bio, USA)
52. Peter Mesenbrink (Novartis, USA)
53. Natalia Muhlemann (Cytel, USA)
54. David Nikodem (Metadeq, GBR)
55. Paul Nitschmann (Intercept Pharmaceuticals, USA)
56. Rebecca Taub (Madrigal, USA)
57. Aldo Trylesinksi (Metadeq, GBR)
58. Janet Wittes (Wittes LLC, USA)
59. Fred Yang (KBP, USA)
60. 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)

8.50-9.05 (5 min each)
What is in the CKM pipeline which has potential liver benefits
Fred Yang (KBP, USA), Ramy Younes (Boehringer Ingelheim, GER)

9.05-9.15
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
Faiez Zannad (Paris, FRA)

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)

11.40-12.00
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)
Michelle Long (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.
TBD

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
Nicolas Girerd (Nancy, FRA)
Mark Muthiah (Singapore, SIN), TBD

15.50-16.10
Biomarker sub-studies
Arun Sanyal (Richmond, VA, USA), Jim Januzzi (Boston, MA, USA)

16.10-16.30
Bioimaging sub-studies
Jeroen Bax (Leiden, NED), Alina Allen (Rochester, NY, USA)

16.30-16.50
Industry viewpoints (5 min each)

Pharma industry
Michelle Long (Novo Nordisk, DK)

Biomarker industry
TBD

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, Mori Krantz, 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),
TBD

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
14:30-15:10

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 perspectrive:
Sven Francque (Antwerp, BEL)

Endocrinologist perspective:
TBD

Cardiology perspective
Michael Böhm (Homburg/Saar, GER)

15.15-16.30
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