

A MULTI-STAKEHOLDER MULTI-SPECIALTY NASH TRIALISTS THINK TANK

Metabolic, hepatology, nephrology &
cardiovascular cross talk

December 5-6, 2022

French Embassy, Reservoir Road, Washington, DC, USA and LIVE Streamed



Faculty

ACADEMY



Manal Abdelmalek
(Rochester, MN, USA)



Javed Butler
(Texas, USA)



Kathleen Corey
(Boston, MA, USA)



Anna Mae Diehl
(Durham, NC, USA)



Barton Duell
(Portland, OR, USA)



Scott Evans
(Washington DC, USA)



Joao Ferreira
(Porto, POR)



Filipe Moura
(Boston, MA, USA)



Sven Francque
(Antwerp, BEL)



Nicolas Girerd
(Nancy, FRA)



Stephen Harrison
(San Antonio, TX, USA)



Peter Libby
(Boston, MA, USA)



Veronica Miller
(Berkeley, CA, USA)



Ambarish Pandey
(Dallas, TX, USA)



Chirag Parikh
(Baltimore, MD, USA)



Vlad Ratziu
(Paris, FRA)



Scott Reeder
(Washington, WA, USA)



Arun Sanyal
(Richmond, VA, USA)



Gerald Shulman
(New Haven, CT, USA)



Harriette Van Spall
(Hamilton, CAN)



David Yankelevitz
(New York, NY, USA)



Zobair Younossi
(Falls Church, VA, USA)

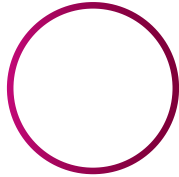


Faiez Zannad
(Paris, FRA)

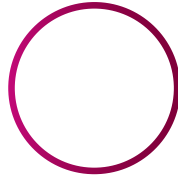
PATIENT



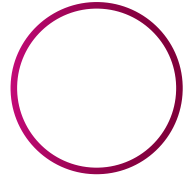
Sam Castillo
(USA)



Margaret Padilla
(Hearne, USA)

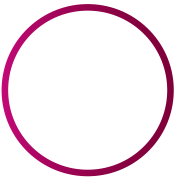


Wayne Eskridge
(Fatty Liver Foundation, UDA)

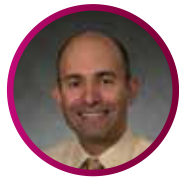


Jennifer Berg
(USA)

REGULATORY



John Sharretts
(FDA, USA)



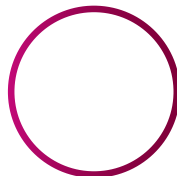
Ray Soccio
(FDA, USA)



Norman Stockbridge
(FDA, USA)



Aliza Thompson
(FDA, USA)



Joe Toerner
(FDA, USA)

JOURNAL EDITORS



Jane Leopold
(NEJM, USA)



Jennifer Sargent
(Nature Medicine, USA)



Stuart Spencer
(The Lancet, UK)

INDUSTRY



Amy Articulo
(Novonordisk, USA)



Michelle Berrey
(Intercept, USA)



Roberto Calle
(Regeneron, USA)



Jerry Colca
(Cirius, USA)



Michael Cooreman
(Inventiva, FRA)



Christian Marsolais
(Theratech, USA)



Claudia Filozof
(LabCorp, USA)



Marcus Hompesch
(Prosciento, USA)



Carol Addy
(Genfit, FRA)



Sophie Jeannin
(Summit Clinical Research, USA)



Lars Johansson
(Antaros, USA)



Vidhya Kumar
(Perspectum, USA)



Michelle Long
(Novonordisk, USA)



Kay Pepin
(Resoundant, USA)



Laurent Sandrin
(Echosense, USA)



Sudha Shankar
(AstraZeneca, USA)



Karsten Strauss
(Olink, SWE)



Rebecca Taub
(Madrigal, USA)



Jessica Williams
(Somalogic, USA)



Janet Wittes
(Wittes LLC, USA)



Rami Younes
(Boehringer, GER)

Monday December 5th 2022

8.00 – 10.30 am EST

DISEASE EPIDEMIOLOGY.

THE LIVER – METABOLIC AND CARDIOVASCULAR INTERSECTIONS

Chairpersons: *Kathleen Corey (Massachusetts, USA) & Faiez Zannad (Paris, FRA)*

08.00–08.10

Prevalence and incidence and cost of care
Zobair Younossi (Virginia, USA)

08.10–08.20

Relationship of NAFLD with heart failure
Ambarish Pandey (Texas, USA)

08.20–08.30

Burden of cardiorenal disease in NAFLD patients
Kathleen Corey (Massachusetts, USA)

08.30–08.40

Burden of liver related comorbidities in cardiovascular disease
Sven Francque (Antwerp, BEL)

08.40–08.50

Burden of cardiac and liver disease in patients with CKD
Michelle Long (Novo Nordisk, USA)

08.50–09.00

Are cardiologists paying attention?
Barton Duell (Oregon, USA)

09.00–09.10

Regulatory viewpoints
Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA)

09.10–09.20

Industry viewpoints
Amy Articulo (Novo Nordisk, USA), Sudha Shankar (AstraZeneca, USA)

9.20–9.30

Patient viewpoints
*Margaret Padilla (Hearne, USA)
Sam Castillo (USA)*

9.30–10.30

**THE MOSAIC MODERATED MULTISTAKEHOLDER DEBATE
WHAT SHORT- AND LONG-TERM OUTCOMES TO PREVENT IN NASH**

Chairpersons: *Kathleen Corey (Massachusetts, USA) & Faiez Zannad (Paris, FRA)*

Panelists : *Amy Articulo (Novo Nordisk, USA), Sam Castillo (USA), Kathleen Corey (Massachusetts, USA), Barton Duell (Oregon, USA), Sven Francque (Antwerp, BEL), Michelle Long (Novo Nordisk, USA), Margaret Padilla (Hearne, USA), Ambarish Pandey (Texas, USA), Sudha Shankar (AstraZeneca, USA), John Sharretts (FDA, USA), Norman Stockbridge (FDA, USA), Ray Soccio (FDA, USA), Aliza Thompson (FDA, USA), Zobair Younossi (Virginia USA), Faiez Zannad (Paris, FRA) and guests*

Monday December 5th 2022

11.00 am – 1.00 pm EST

COMMON BIOLOGIC DRIVERS OF NASH AS A MULTIORGAN DISEASE

Chairpersons : *Peter Libby (Massachusetts, USA) & Harriette Van Spall (Hamilton, CAN)*

11.00–11.10

Role of the metabolic milieu for liver and cardiac disease
Gerry Shulman (Connecticut, USA)

11.10–11.20

Role of systemic inflammatory state in cardiac,
renal and liver involvement in metabolic syndrome
Peter Libby (Massachusetts, USA)

11.20–11.30

Inflammatory signals and macrophage biology
Emelie Barreby (Stockholm, SWE)

11.30–11.40

Systemic drivers of pro-fibrogenic state in Metabolic syndrome
Anna Mae Diehl (North Carolina, USA)

11.40–11.50

Mechanisms of myocardial dysfunction in NAFLD
Ambarish Pandey (Texas, USA)

11.50–12.00

Regulatory viewpoints
Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA),

12.00–12.10

Industry viewpoints
Carol Addy (Genfit, FRA), Michelle Berrey (Intercept, USA)

12.10–12.20

Journal Editor perspective
Jennifer Sargent (Nature, USA)

12.20–12.25

Patient viewpoints
Wayne Eskridge (Fatty Liver Foundation, UDA)

12.25–01.00

**THE MOSAIC MODERATED MULTISTAKEHOLDER DEBATE
NEW DRUGGABLE MOLECULAR BIOTARGETS IN NASH**

Chairpersons : *Peter Libby (Massachusetts, USA) & Harriette Van Spall (Hamilton, CAN)*

Panelists : Carol Addy (Genfit, FRA), Emelie Barreby (Stockholm, SWE), Michelle Berrey (Intercept, USA), Anna Mae Diehl (North Carolina, USA), Wayne Eskridge (Fatty Liver Foundation, UDA), Peter Libby (Massachusetts, USA), Ambarish Pandey (Texas, USA), Jennifer Sargent (Nature, USA), John Sharretts (FDA, USA), Gerry Shulman (Connecticut USA), Ray Soccio (FDA, USA), Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA), Harriette Van Spall (Hamilton, CAN) and guests

Monday December 5th 2022

2.00 pm – 4.00 pm EST

MULTIPLE PHENOTYPIC CHARACTERISATION OF PATIENTS ELIGIBLE FOR NASH TRIALS

Chairpersons : *Manal Abdelmalek (Minnesota, USA) & Javed Butler (Texas, USA)*

02.00–02.10

Cardiac characterization in NAFLD trials
Faiez Zannad (Paris, FRA)

02.10–02.20

Renal disease characterization in NAFLD trials
Javed Butler (Texas, USA)

02.20–02.30

NAFLD characterization in cardiovascular trials
Manal Abdelmalek (Minnesota, USA)

02.30–02.40

Regulatory viewpoints
Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA)

02.40–02.45

Industry viewpoints
Christian Marsolais (Theratechnologies Inc., USA)

02.45–02.50

Patient viewpoints
Wayne Eskridge (Fatty Liver Foundation, UDA)

02.50–04.00

**THE MOSAIC MODERATED MULTISTAKEHOLDER DEBATE
PATIENTS ELIGIBLE IN NASH TRIALS, CLINICAL CHARACTERISATION BEYOND LIVER CRITERIA.**
Chairpersons : *Javed Butler (Texas, USA) & Manal Abdelmalek (Minnesota, USA)*

Panelists : *Manal Abdelmalek (Minnesota, USA), Javed Butler (Texas, USA), Wayne Eskridge (Fatty Liver Foundation, UDA), Christian Marsolais (Theratechnologies Inc., USA), Ray Soccio (FDA, USA), Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA), Faiez Zannad (Paris, FRA) and guests*

Monday December 5th 2022

4.30 pm – 6.30 pm EST

LIVER, CARDIAC AND RENAL OUTCOME ENDPOINTS IN NASH TRIALS

Chairpersons: *Vlad Ratziu (Paris, FRA) & Harriette Van Spall (Hamilton, CAN)*

04.30–04.40

Cardiac endpoints in NAFLD outcome trials

Faiez Zannad (Paris, FRA)

04.40–04.50

Potential renal endpoints in NAFLD outcome trials

Faiez Zannad (Paris, FRA)

04.50–05.00

Liver endpoints in cardio-renal trials

Vlad Ratziu (Paris, FRA)

05.00–05.10

Use of hierarchical endpoints

Janet Wittes (Wittes LLC, USA)

05.10–05.20

Regulatory viewpoints

Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA)

05.20–05.30

Industry viewpoints

Jerry Colca (Cirus, USA), Rebecca Taub (Madrigal, USA)

05.30–6.30

**THE MOSAIC MODERATED MULTISTAKEHOLDER DEBATE
HOW TO PROGRESS BEYOND LIVER ENDPOINTS?**

Chairpersons: *Vlad Ratziu (Paris, FRA) & Harriette Van Spall (Hamilton, CAN)*

NETWORKING DINNER

THE FUTURE OF MOSAIC CLINICAL TRIALISTS MEETINGS

Chairpersons : *Stephen Harrison (Texas, USA), Veronica Miller (California, USA),
Arun Sanyal (Virginia, USA), Faiez Zannad (Paris, FRA)*

The MOSAIC group is committed to draft a position paper summarizing the
recommendations of the forum

Panelists : *Jerry Colca (Cirus, USA), Vlad Ratziu (Paris, FRA), Ray Soccio (FDA, USA), Norman Stockbridge (FDA, USA),
Rebecca Taub (Madrigal, USA), Aliza Thompson (FDA, USA), Joe Toerner (FDA, USA), Harriette Van Spall
(Hamilton, CAN), Janet Wittes (Wittes LLC, USA), Faiez Zannad (Paris, FRA) and guests*

Tuesday December 6th 2022

8.00 – 10.30 am EST

DISEASE EPIDEMIOLOGY.

DESIGN AND EXECUTION ISSUES OF OUTCOME TRIALS IN NASH.

Chairpersons: *Scott Evans (Washington DC, USA) & Veronica Miller (California, USA)*

Design and statistical innovations

8.00-8.10

Seamless design, pragmatic trials, and how they can help?

Janet Wittes (Wittes LLC, USA)

8.10-8.20

How to tackle intercurrent events? Estimands in Clinical Trials.

Nicolas Girerd (Nancy, FRA)

8.20-8.30

Benefit:risk evaluation using a Desirability of Outcome Ranking (DOOR) endpoint.

Scott Evans (Washington DC, USA)

8.30-8.40

Best practices to keep patients in the long term outcome trials.

Sophie Jeannin (Summit Clinical Research, USA)

8.50-9.10

How to synergize and bridge multiple discipline investigators

Claudia Filozof (LabCorp, USA)

Marcus Hompesch (Prosciento, USA)

08.50-09.00

Are cardiologists paying attention?

Barton Duell (Oregon, USA)

9.10-9.20

Regulatory viewpoints

Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA)

9.20-9.30

Markers of cardiometabolic health in patients with NASH are improved in most recent clinical results

Michael Cooreman (Inventiva, FRA)

9.30-9.35

Industry viewpoints

Roberto Calle (Regeneron, USA)

9.35-9.40

Patient viewpoints

Jennifer Berg (USA)

9.40-10.30

THE MOSAIC MODERATED MULTISTAKEHOLDER DEBATE
DESIGN AND EXECUTION ISSUES OF NASH OUTCOME TRIALS

Chairpersons: *Scott Evans (Washington DC, USA) & Veronica Miller (California, USA)*

Panelists : *Jennifer Berg (USA), Roberto Calle (Regeneron, USA), Michael Cooreman (Inventiva, FRA), Scott Evans (Washington DC, USA), Claudia Filozof (LabCorp, USA), Nicolas Girerd (Nancy, FRA), Marcus Hompesch (Prosciento, USA), Sophie Jeannin (Summit Clinical Research, USA), Veronica Miller (CA, USA), Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA), Joe Toerner (FDA, USA), Harriette Van Spall (Hamilton, CAN), Janet Wittes (Wittes LLC, USA) and guests*

Tuesday December 6th 2022

11 am – 1.00 pm EST

**USE OF NONINVASIVE TESTS (NITS) FOR EFFICACY AND SAFETY
ASSESSMENT- CIRCULATING BIOMARKERS**

Chairpersons: *Stephen Harrisson (Texas, USA) & Faiez Zannad (Paris, FRA)*

11.00-11.10

Cardiac biomarkers and NITs
Joao Ferreira (Porto, POR)

11.10-11.20

Liver biomarkers and NITs
Arun Sanyal (Virginia, USA)

11.20-11.30

Renal biomarkers and NITs
Chirag Parikh (Maryland, USA)

11.30-11.40

Proteomic biomarkers in NASH
Lili Niu (Copenhagen, DEN)

11.40-11.50

Regulatory viewpoints
Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA)

11.50-12.00

Industry viewpoints
Karsten Strauss (Olink, SWE), Jessica Williams (Somalogic, USA)

12.00-12.05

Patient viewpoints
Wayne Eskridge (Fatty Liver Foundation, UDA)

12.05-01.00

**THE MOSAIC MODERATED MULTISTAKEHOLDER DEBATE
WHAT SURROGATE BIOMARKERS ARE ACCEPTABLE FOR APPROVAL?**

Chairpersons: *Stephen Harrisson (Texas, USA) & Faiez Zannad (Paris, FRA)*

Panelists : *Wayne Eskridge (Fatty Liver Foundation, UDA), Joao Ferreira (Porto, POR), Stephen Harrisson (Texas, USA), Lili Niu (Copenhagen, DEN), Chirag Parikh (Maryland, USA), Arun Sanyal (Virginia, USA), Norman Stockbridge (FDA, USA), Karsten Strauss (Olink, SWE), Aliza Thompson (FDA, USA), Joe Toerner (FDA, USA), Jessica Williams (Somalogic, USA), Faiez Zannad (Paris, FRA) and and guests*

Tuesday December 6th 2022

2.00 pm – 4.00 pm EST

IMAGING TESTS IN NASH TRIALS

Chairpersons: *David Yankelevitz (New York, USA)*

2.00–2.10

Imaging based assessment of NAFLD
Scott Reeder (Wisconsin, USA)

2.10–2.30

Integrated clinical imaging of heart, liver and kidneys.
Lars Johansson (Antaros, SWE)
Vidhya Kumar (Perspectum, USA)

2.30–2.40

Regulatory perspective
Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA)

2.40–2.50

Industry viewpoints
Kay Pepin (Resoundant, USA), Laurent Sandrin (Echosens, USA)

2.50–3.00

Journal Editor's perspective
Jennifer Sargent (Nature Medicine, USA)

3.00–3.05

Patient viewpoints
Wayne Eskridge (Fatty Liver Foundation, UDA)

3.05–4.00

THE MOSAIC MODERATED MULTISTAKEHOLDER DEBATE
WHAT IMAGING TESTS ARE ACCEPTABLE FOR APPROVAL?
Chairpersons: *David Yankelevitz (New York, USA)*

Panelists : Wayne Eskridge (Fatty Liver Foundation, UDA), Lars Johansson (Antaros, SWE), Vidhya Kumar (Perspectum, USA), Kay Pepin (Resoundant, USA), Scott Reeder (Washington, USA), Laurent Sandrin (Echosens, USA), Jennifer Sargent (Nature Medicine, USA), Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA), Joe Toerner (FDA, USA), David Yankelevitz (New York, USA) and guests

Tuesday December 6th 2022

4.30 pm – 7.00 pm EST

**RECENT AND ONGOING CARDIORENAL, METABOLIC AND NAFLD TRIALS
SUCCESSIONS AND LESSONS FROM FAILURES**

Chairpersons: *Stephen Harrison (Texas, USA) & Faiez Zannad (Paris, FRA)*

4.30-4.40

Reviewing the therapeutic landscape for Cardiometabolic disease trials
Faiez Zannad (Paris, FRA)

4.40-4.50

Reviewing the therapeutic landscape for Cardioresnal disease trials
Faiez Zannad (Paris, FRA)

4.50-5.00

Reviewing the therapeutic landscape for obesity
Filipe Moura (Massachusetts, USA)

5.00-5.10

Reviewing the therapeutic landscape in NAFLD
Stephen Harrison (Texas, USA)

5.10-5.20

Regulatory viewpoints
Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA),

5.20-5.25

Industry viewpoints
Rami Younes (Boehringer, GER)

5.25-5.45

Journal Editor perspective:
Stuart Spencer (The Lancet, UK)
Jane Leopold (NEJM, USA)

5.45-5.50

Patient viewpoints
Jennifer Berg (USA)

5.50-7.00

**THE MOSAIC MODERATED MULTISTAKEHOLDER DEBATE
ARE THE CURRENT TRIALS ADDRESSING THE MULTI-ORGAN MULTI-SYSTEM DIMENSIONS OF NASH ?**

Chairpersons: *Stephen Harrison (Texas, USA) & Faiez Zannad (Paris, FRA)*

Panelists : *Jennifer Berg (USA), Stephen Harrison (Texas, USA), Jane Leopold (NEJM, USA), Filipe Moura (Massachusetts, USA), Ray Soccio (FDA, USA), Stuart Spencer (The Lancet, UK), Norman Stockbridge (FDA, USA), Aliza Thompson (FDA, USA), Joe Toerner (FDA, USA), Rami Younes (Boehringer, GER), Faiez Zannad (Paris, FRA) and guests*