



# Critical Care Clinical Trialists Workshop



Final Program

FEBRUARY 7-8,  
2019 French Embassy,  
Washington, DC

WWW.3CTMEETING.COM

# GENERAL INFORMATION

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## Venue of the Meeting

### Embassy of France

4101 Reservoir Rd NW  
Washington, D.C. 20007  
USA

## On-site contacts

Petra Niehoff: +33 6 27 75 41 86  
Patrick Wahby: +33 6 21 02 74 02  
US number: +1 415-839-8874

## Technical Information

To facilitate the progression of the meeting, we would be very grateful if you could give your presentation to the technician in the meeting room 30 minutes before the session starts (or during the coffee breaks).

## Logistics and Technical Organization

### Overcome

13-15 rue des Sablons  
75116 Paris Cedex, France  
Tel.: +33 1 40 88 97 97  
US number: +1 415-839-8874  
Email: [3ct@overcome.eu](mailto:3ct@overcome.eu)  
Website: [www.3ctmeeting.com](http://www.3ctmeeting.com)  
Website password: GEORGETOWN

## Chairman

Alexandre Mebazaa  
Cell: +33 6 09 01 93 93  
Email: [alexandre.mebazaa@aphp.fr](mailto:alexandre.mebazaa@aphp.fr)

## Transportation



Attractive discounts, up to -15%, on a wide range of public fares on all AIR FRANCE, KLM and their code-shared flights worldwide.

Event: 3CT - Critical Care Clinical Trialists Workshop

ID Code: 34319AF

Travel Valid Period: 31/01/2019 - 15/02/2019

Event location: Washington, D.C.

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# INTRODUCTION

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Dear attendees,

I am pleased to welcome you to the 1st Critical Care Clinical Trialists Workshop (3CT), a high-level think-tank that will give us the opportunity to have interactive dialogs between academia, regulatory representatives, patients and industry to openly discuss the challenges of clinical trials for critical care.

Over the next two days, the 3CT Workshop will foster an exchange of ideas where attendees will brainstorm on trial design, conduct, ethics and data interpretation in the critical care area. The sessions will cover domains including drugs, devices and biomarkers in the field of intensive care.

Our objectives are to produce relevant data from controlled critical care clinical trials that will contribute to better clinical care for patients and to understand the problems associated with making decisions about what constitutes relevant information, how to improve critical care clinical trials and how to satisfy regulatory authorities and payers.

For the first edition of the 3CT Workshop, we are delighted to welcome a number of distinguished critical care and intensive care specialists, as well as emergency medicine specialists, cardiologists, clinical trialists, principal investigators and statisticians from academia coming from Europe, Canada and the US. Participants from NHLBI, EMA and FDA, patient representatives and industry attendees representing R&D pharma, biomarkers and device companies will contribute to the discussions and strengthen the multi-stakeholder approach of this workshop.

The proceedings of the meeting presenting novelties and points of discussion of the 3CT Workshop will be drafted to be published in prime scientific journals.

I look forward to meeting each and every one of you and I thank you for taking part in this meeting.

With my warmest regards,



*Alexandre Mebazaa*  
Workshop Director

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## The 3CT Workshop Co-Directors



*Sean Collins*



*Pierre-François Laterre*



*Michael Matthey*

# FACULTY & PARTICIPANTS

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## ACADEMIA

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Geoff Bellingan (London, UK)  
Jonathan Casey (Nashville, USA)  
Marina Clément (Paris, France)  
Sean P. Collins (Nashville, USA)  
Alain Combes (Paris, France)  
David Dudzinski (Boston, USA)  
Luciano Gattinoni (Göttingen, Germany)  
Etienne Gayat (Paris, France)  
Michelle Gong (New York, USA)  
Michael Harhay (Philadelphia, USA)  
Samir Jaber (Montpellier, France)  
Pierre-François Laterre (Brussels, Belgium)  
John Marshall (Toronto, Canada)  
Michael Matthay (San Francisco, USA)  
Alexandre Mebazaa (Paris, France)  
Susanna Price (London, UK)  
Eduardo Rame (Philadelphia, USA)  
Todd Rice (Nashville, USA)  
Wesley H. Self (Nashville, USA)  
Mike Silverman (Boston, USA)  
Uwe Zeymer (Ludwigshafen, Germany)

## REGULATORY

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Fernando Aguel (FDA, USA)  
Nicole Ibrahim (FDA, USA)  
Maciej Kostrubiec (EMA, Poland)  
John Laschinger (FDA, USA)  
Meir Shinnar (FDA, USA)  
Norman Stockbridge (FDA, USA)  
Bram Zuckerman (FDA, USA)

## NHLBI

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Neil Aggarwal (NHLBI, USA)  
Lora Reineck (NHLBI, USA)  
Yves Rosenberg (NHLBI, USA)  
George Sopko (NHLBI, USA)

## MEDIA

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Stuart Spencer (The Lancet, UK)

## INDUSTRY

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Jürgen Böhm (Xenios, Germany)  
Holger Borchers (Getinge, Germany)  
Maria Borentain (BMS, USA)  
David Fineberg (Asahi Kasei Pharma America, USA)  
Jean-Marie Grouin (Inotrem, France)  
Thomas Lowery (T2 Biosystems, USA)  
Amin M. Medjamia (Abiomed, USA)  
Joie Meikle (Getinge, USA)  
Fred McCoy (NeuroTronik, USA)  
Gerald Möller (Adrenomed, Germany)  
Alexandre Pachot (bioMérieux, France)  
Margarita Salcedo (Inotrem, France)  
Matthias Strobl (Roche Diagnostics, Switzerland)  
Julien Textoris (bioMérieux, France)  
Bastiaan Van Holthe Tot Echten (Roche Diagnostics, Switzerland)  
Jens Zimmermann (Adrenomed, Germany)

## PATIENT ADVOCACY

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Rhonda Monroe (Martinsburg, USA)  
Eileen Rubin (Northbrook, USA)

# SCIENTIFIC PROGRAM

THURSDAY, FEBRUARY 7, 2019

9:00 am  
12:00 pm

Session 1: Acute respiratory distress syndrome (ARDS): key methodological and conduct insights from game changers and neutral trials

Moderators: M. Matthay (San Francisco, USA), N. Aggarwal (NHLBI, USA)

**Objectives:** *ARDS is a frequent and deadly disease in the ICU. Most trials were neutral at least partially because design was not optimal. Experts will advise on how to best design ARDS trials*

## Speakers

15 minutes each

- ARDS trials to date & medical needs
- Design to assess novel therapies

L. Gattinoni, Göttingen, GER  
M. Matthay, San Francisco, USA

## Discussants

10 minutes each

- NHLBI's Lung Division: from basic to translational research N. Aggarwal, NHLBI, USA
- NHLBI's Lung Division: RECT & networking L. Reineck, NHLBI, USA
- New agents G. Bellingan, London, UK
- Regulators point of view M. Kostrubiec, EMA, Poland
- Patient(s) point of view Eileen Rubin, Northbrook, USA

12:00 pm - 1:00 pm LUNCH BREAK

1:00 pm  
5:00 pm

Session 2: Positive trials in septic shock are needed: let's join forces

Moderators: P.F. Laterre (Brussels, BEL), J. Marshall (Toronto, CAN)

**Objectives:** *The large majority of trials in sepsis were neutral. Despite using promising drugs, trials suffered from many weaknesses including heterogeneity in patient selection and various objectives. Indeed, definition of septic shock varied over years and the main objective moved from mortality toward organ dysfunction.*

## Speakers

15 minutes each

- How to improve the design of the septic shock trials?
- How to improve the conduction of the trials?
- Which directions to take in the future?

J. Marshall, Toronto, CAN  
P.F. Laterre, Brussels, BEL  
L. Reineck, NHLBI, USA

## Discussants

10 minutes each

- Biomarker-guided therapy
- Industry point of view
- Intensive Care Journal's point of view
- Regulators point of view

A. Mebazaa, Paris, FRA  
A. Pachot, J. Textoris (bioMérieux),  
T. Lowery (T2 Biosystems)  
S. Jaber, Montpellier, FRA  
M. Kostrubiec, EMA, Poland

5:00 pm - 5:20 pm COFFEE BREAK

# SCIENTIFIC PROGRAM

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5:20 pm  
7:00 pm

Session 3: Is survival the only endpoint to assess drug/device benefits in shock?

Moderators: S. Spencer (The Lancet, UK), E. Gayat (Paris, France)

**Objectives:** *In the last decades, shock trials had invariably short-term survival as the primary or co-primary endpoint. This is true for almost all trials on septic or cardiogenic shock. However, many studies challenge "short-term survival" as a unique endpoint. Indeed, many "non-actionable" parameters including age, comorbidities influence survival. In addition, maintaining blood pressure, preserving/restoring organ dysfunction may be as relevant, especially in ICU survivors. Furthermore, long-term survival and/or quality of life may also be an important endpoint.*

## Speakers

- Primary endpoint in Shock trials
- Secondary endpoints

15 minutes each

A. Mebazaa, Paris, FRA

M. Harhay, Philadelphia, USA

## Discussants

- Analysis of databases
- NHLBI point of view
- Regulators point of view

10 minutes each

E. Gayat, Paris, FRA

Y. Rosenberg, NHLBI, USA

J. Laschinger, FDA, USA

# SCIENTIFIC PROGRAM

FRIDAY, FEBRUARY 8, 2019

8:00 am  
9:40 am

## Session 4: Trials from Emergency room to ICU

Moderators: S. Collins (Nashville, USA), T. Rice (Nashville, USA)

**Objectives:** *Designing and conducting trials in patients in shock is a great challenge. Selecting and including patients within minutes is not easy. Another challenge is how ED and ICU physicians can collaborate to assess the impact of early management on outcome.*

### Speakers

- Success stories in ED trials
- Networking for trials

15 minutes each

S. Collins, Nashville, USA  
S. Jaber, Montpellier, France

### Discussants

- Very early enrolment
- Let's be pragmatic
- Industry point of view
- Regulators point of view

10 minutes each

W. Self, Nashville, USA  
M. Gong, New York, USA  
M. Borentain (BMS)  
N. Stockbridge, FDA, USA

9:40 am - 10:00 am COFFEE BREAK

10:00 am  
2:00 pm

## Session 5: Cardiogenic shock: key insights to move from neutral to successful trials

Moderators: A. Mebazaa (Paris, FRA), B. Zuckerman (FDA, USA)

**Objectives:** *Survival rate of patients in cardiogenic shock remained low over the last decades. Furthermore, very few trials were performed and were mostly neutral. This area of medicine however needs successful trials. Experts will help understanding where we failed: phenotyping, designing, conducting cardiogenic shock trials? To do so, experts will describe ongoing trials and programs on cardiogenic shock.*

### Speakers

- Why trials were neutral?
- Design of successful drug therapy trial

15 minutes each

D. Dudzinski, Boston, USA  
A. Mebazaa, Paris, France

### Discussants

- Industry point of view
- Patient(s) point of view
- NHLBI point of view
- Regulators point of view

10 minutes each

A. Combes, Paris, FRA  
U. Zeymer, Ludwigshafen, GER  
S. Price, London, UK  
A. Medjamia (Abiomed)  
R. Monroe, Martinsburg, USA  
G. Sopko, NHLBI, USA  
J. Laschinger, FDA, USA  
M. Kostrubiec, EMA, Poland

2:00 pm LUNCH BREAK AND ADJOURN

Medical writers of the proceedings of the sessions:

Jonathan Casey, Nashville, USA - Marina Clément, Paris, France - Michael Harhay, Philadelphia, USA  
Michael Silverman, Boston, USA





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*Save  
the  
date*

FEBRUARY 27-28,  
2020 French Embassy,  
Washington, DC

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