Critical Care Clinical Trialists Workshop

FEBRUARY 26, 2020
French Embassy, Washington, DC

OPTIMIZING TRIALS IN CARDIOGENIC SHOCK DUE TO ACUTE MYOCARDIAL INFARCTION

WWW.3CTMEETING.COM
Dear attendees,

I am pleased to welcome you to the first edition of the workshop dedicated to “Optimizing trials in cardiogenic shock due to acute myocardial infarction”.

This afternoon, we will convene to discuss, debate and reflect on how to optimize trials in cardiogenic shock, to come up with a global definition of cardiogenic shock to be used for future trials, to provide practical recommendations on how to best design future trials and to identify particular medical needs in specific settings.

This closed meeting brings together the brightest minds in critical and intensive care, emergency medicine specialists, cardiologists, clinical trialists and principal investigators from both sides of the Atlantic, joined by experts from the NIH, EMA and FDA and patient representatives.

It will be followed by the larger “Critical Care Clinical Trialists” Workshop over the upcoming two days, which many of you are also participating in.

I will take this opportunity to remind you that a maximum of 10 minutes is allocated to each presentation to make sure that enough time is reserved for discussion.

After the workshop, a statement document will be prepared based on your presentation and a first draft will circulate in the following weeks. In order to facilitate this process, please give your presentation to the Overcome team immediately after the meeting.

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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*Alexandre Mebazaa*  
Workshop Director
12:00 - 12:45  Welcome coffee and light lunch

12:45 PM 1:00 PM  Introduction

1:00 PM 2:10 PM  Session 1: How to best define the study population?  10 minutes each

**Chairs: Navin Kapur (Boston, USA), Bruno Levy (Nancy, FRA)**

- Clinical/hemodynamic/biology  Mattia Arrigo (Zurich, SUI)
- Organ dysfunction  Alexandre Mebazaa (Paris, FRA)
- Cath lab definition  Janine Pöss (Leipzig, GER)
- ICU definition  Bruno Levy (Nancy, FRA)
- Novel biomarkers  Antoni Bayes-Genis (Barcelona, ESP)
- Discussion (20 minutes)

2:10 PM 3:30 PM  Session 2: How to best design a trial in cardiogenic shock?  10 minutes each

**Chairs: Martine Gilard (Brest, FRA), David Baran (Norfolk, USA)**

- Which severity (Classification SCAI)?  David Baran (Norfolk, USA)
- Cardiac imaging may help?  Etienne Gayat (Paris, FRA)
- Trials with drugs different from trials with devices?  Mahir Karakas (Hamburg, GER)
- What to do in the control arm?  Janine Pöss (Leipzig, GER)
- Primary endpoint: Death vs. Composite endpoints?  Laurent Bonello (Marseille, FRA)
- How to power adequately these trials?  Michael Harhay (Philadelphia, USA)
- Discussion (20 minutes)

3:30 PM - 4:00 PM  COFFEE BREAK
**Session 3: Medical need in the most frequent scenarios**

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<tr>
<th>Time</th>
<th>Event Description</th>
<th>Speaker(s)</th>
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<tr>
<td>4:00 PM</td>
<td>AMI/Cath lab</td>
<td>Martine Gilard (Brest, FRA)</td>
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<td>4:00 PM</td>
<td>Post-cardiac arrest</td>
<td>Nadia Aissaoui (Harrisburg, USA)</td>
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<td>4:00 PM</td>
<td>Medical therapies</td>
<td>Bruno Levy (Nancy, FRA)</td>
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<td>4:00 PM</td>
<td>Lessons learned from a protocol approach to care</td>
<td>Navin Kapur (Boston, USA)</td>
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<td>4:00 PM</td>
<td>Surgery</td>
<td>Pascal Leprince (Paris, FRA)</td>
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<td>4:00 PM</td>
<td>Multiple devices, escalation therapy and heart recovery?</td>
<td>Navin Kapur (Boston, USA)</td>
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<tr>
<td>4:00 PM</td>
<td>Ethics issues in trials</td>
<td>David Baran (Norfolk, USA)</td>
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<tr>
<td>4:00 PM</td>
<td>Patient’s perspective</td>
<td>Rhonda Monroe (Martinsburg, USA)</td>
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<td>4:00 PM</td>
<td>FDA Perspective</td>
<td>Norman Stockbridge (FDA, USA)</td>
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<td>4:00 PM</td>
<td>EMA perspective</td>
<td>Maciej Kostrubiec (EMA, POL)</td>
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<td>4:00 PM</td>
<td>Pre-hospital trials are needed</td>
<td>Jeremy Brown (NIH, USA)</td>
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<td>4:00 PM</td>
<td>Trials on long term follow up after acute event are needed</td>
<td>Yves Rosenberg (NIH, USA)</td>
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<td>4:00 PM</td>
<td>Discussion (30 minutes)</td>
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**Key messages**

- Emma Grainger (The Lancet, London, GBR)
- Norman Stockbridge (FDA, USA)
- Alexandre Mebazaa (Paris, FRA)

**Dinner at Restaurant**

Le Petit Bouchon (French Embassy)

**Paper:** Mattia Arrigo (Zurich, SUI)
Nadia Aissaoui, MD, PhD
Harrisburg, PA, USA
Associate Professor in Hershey Medical Center, Heart and Vascular Institute, Critical Care Unit, Penn State University
Professor in Intensive Care Medicine in Université de Paris, APHP, HEGP

Mattia Arrigo, MD
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Head Cardiac Care Unit
Department of Cardiology
University Hospital Zurich

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System Director, Advanced Heart Failure, Transplant and Mechanical Circulatory Support
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Barcelona, Spain
Heart Institute Director
Hospital Universitari Germans Trias i Pujol
Full Professor, Department Medicine
Vice-Dean, Autonomous University of Barcelona

Laurent Bonello, MD, PhD
Marseille, France
Intensive Care Unit
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Jeremy Brown, MD
National Institute of Health, USA
Director, Office of Emergency Care Research in the National Institute of Neurological Disorders and Stroke

Bruno François, MD
Limoges, France
CHU Limoges

Etienne Gayat, MD, PhD
Paris, France
Professor of Anesthesiology and Critical Care
Hôpital Lariboisière
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Martine Gilard, MD, PhD, FESC
Brest, France
Professor of Cardiology at Brest University Hospital
Head of Interventional Cardiology Department
Head of Imaging (MSCT and MRI) Cardiology Department
Past President of the French Society of Cardiology
Member of EAPCI: Chairman of the Scientific Committee
Member of the Scientific Committee of EuroPCR

Emma Grainger, MD, PhD
London, United Kingdom
Editor-in-Chief, The Lancet Respiratory Medicine

Michael O. Harhay, PhD
Philadelphia, USA
Assistant Professor of Epidemiology and Medicine
University of Pennsylvania Perelman School of Medicine

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Associate Professor, Department of Medicine/Division of Cardiology
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Director, Acute Circulatory Support Program
Director, Interventional Research Laboratories
Investigator, Molecular Cardiology Research Institute

Mahir Karakas, MD, MBA
Hamburg, Germany
Junior Professor at University Heart & Vascular Center Hamburg
Lead IIT-Program

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Professor of Intensive Care
Head of Nancy Cardiac Shock Care Center
Nancy University Hospital and Lorraine University

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Chair of Department of Anaesthesiology and Critical Care Description in Hôpitaux Universitaires Saint Louis-Lariboisière-Fernand Widal
Director of Research Unit MASCOT at U-942 Inserm

Rhonda E. Monroe, MBA
Martinsburg, USA
Founder and Principal, KOBE Health

Janine Pöss, MD
Leipzig, Germany
Consultant at Heart Center Leipzig, University of Leipzig

Susanna Price, MD, PhD
London, UK
Consultant cardiologist and intensivist at Royal Brompton Hospital
Honorary senior lecturer at Imperial College London
Professor of practice in Cardiology and intensive care

Yves Rosenberg, MD, MPH
National Heart, Lung and Blood Institute, USA
Chief, Atherothrombosis and Coronary Artery Disease Branch
Division of Cardiovascular Sciences

Norman Stockbridge, MD, PhD
Food and Drug Administration, USA
Director, Division of Cardiovascular and Renal Products Center for Drug Evaluation and Research

Bram Zuckerman, MD
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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). Please remember to return your signed public authorization form. Should you want to make any changes to your presentation before submission, please inform the Overcome team onsite.

Logistics and Technical Organization

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Transportation
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