CARDIAC SAFETY RESEARCH CONSORTIUM

CSRC Think Tank: Defining the Clinical and Regulatory Landscape for Cardiogenic Shock

Grand Hyatt Hotel
1000 H Street
Washington, DC
September 7th, 2018

8:00am – 8:15am Introduction and Purpose of Think Tank
Mitch Krucoff, MD (Duke)

- Introduction to CSRC
- Anatomy of a Think Tank

8:15am – 8:45am Session I: Overview of shock
Session I Objectives:

- *Review what is known and unknown about the pathophysiology of shock*
- *Review published literature and identify gaps*
- *Discuss current clinical practices and the evidence base*

- Pathophysiology of shock and associated syndromes: From impending shock to futility **Navin Kapur, MD** (Tufts)(10 min)
- Review of trials to date in cardiogenic shock **E. Magnus Ohman, MD** (Duke)(10 min)
- Current cardiovascular management tools & best practice for shock: drugs, surgically implanted and percutaneous devices **William O'Neill, MD** (Henry Ford Health)(10 min)

8:45am – 9:00am BREAK

9:00am – 10:30am Session II: : Defining unmet needs, clinical study barriers, and targets for drug and device therapy for shock: Part I
Moderator: Joseph Rogers, MD (Duke)
Session II Objectives:

- *Define a population of intended use for drug and device therapies in cardiogenic shock.*
- *Discuss and identify comparator cohorts for cardiogenic shock trials.*
- *Discuss and identify primary and secondary outcomes for cardiogenic shock trials.*

- **9:00am – 9:10am Cohorts to study: defining a "population of intended use"**
  - Clinical/best practice perspective **Alex Truesdell, MD** (INOVA)
  - Industry perspective **Philip Adamson, MD** (Abbott)
- **9:10am – 9:20am Comparators for drug and device trials in shock patients**
  - Clinical/best practice perspective **Judith Hochman, MD**
  - Industry perspective
- **9:20am – 9:30am Outcome endpoints: mortality plus?**
  - Clinical/best practice perspective **Ian Gilchrist, MD** (Penn State)
  - Industry perspective
- **9:30am – 9:40am** FDA Perspective **Ileana Pina, MD**
- **9:40am – 9:50am** Health Canada Perspective **Roy Masters, MD**
- **9:50am – 10:30am** Discussion

10:30am – 10:45am BREAK

10:45am -12:15pm Session III: Defining unmet needs, clinical study barriers, and targets for drug and device therapy for shock: Part II
Moderator: David Morrow, MD MPH (Harvard)
Session III Objectives

- Discuss enrollment of patients who may not be capable of providing informed consent.
- Discuss and identify novel evidence structures for future shock trials.
- Discuss and identify novel statistical approaches for trials of shock therapies.

- **10:45am – 10:55am Informed consent**
  - Clinical/best practice perspective **David Baran, MD** (Sentara) **and David Kandzari, MD** (Piedmont Health)
  - Industry perspective
- **10:55am – 11:05am Avenues for real world evidence, pragmatic trials, or novel infrastructure for shock trials**
  - Clinical/best practice perspective **Holger Thiele, MD** (University of Leipzig) and **Timothy Henry, MD** (Cedars-Sinai)
  - Industry perspective
- **11:05am – 11:15am Novel statistical approaches for shock studies**
  - Clinical/best practice perspective **Andrew Althouse, MD** (University of Pittsburgh)
  - Industry perspective
- **11:15am-11:25am** FDA Perspective **John Sapirstein, MD**
- **11:25am – 12:10pm Discussion**
  - **Lead Discussant: Roseann White** (Duke)

12:10pm – 1:00pm LUNCH

1:00pm – 2:00pm Session IV: Future directions for device and drug development in shock.
Moderator: Sunil Rao, MD (Duke)
Session Objectives

- Identify global collaborators for trials of shock therapies.
- Discuss trial designs incorporating both drug and device therapies for patients with cardiogenic shock.
- Discuss and define "-ARC" definitions of shock (SHARC).

- **1:00pm – 1:10pm Global collaboration: is it possible? Is it desirable?**
  - Clinical/best practice perspective **William Abraham, MD** (Ohio State)
  - Industry perspective

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- **1:10pm – 1:20pm Factorial device and drug study designs**
  - Clinical/best practice perspective **Roxana Mehran, MD** (Mount Sinai)
  - Industry perspective

- **1:20pm – 1:30pm Definitions: Shock-ARC (SHARC)**
  - Clinical/best practice perspective **George Dangas, MD** (Mount Sinai)
  - Industry perspective
- **1:30pm-1:40pm** FDA Perspective **Fortunato Senatore, MD PhD**
- **1:40pm – 2:30pm Discussion**

2:30pm – Closing Remarks