

#### **GENERAL INFORMATION**

#### Where?

The Hotel at Arundel Preserve

7795 Arundel Mills Boulevard Hanover, MD 21076, USA Tel. +1 410 796 9847

#### Location

- 7.5 miles from Baltimore/Washington International Airport
- 30.5 miles from Ronald Reagan Washington National Airport

**GPS Coordinates:** LAT: 39.152178 LONG: -76.743997

See more at: http://www.hotelarundel.com

### **REGISTRATION**

Registration online on

http://www.translationalmedicineacademy.org

MORE INFORMATION ABOUT REGISTRATION?

Yann Colardelle

William Melhuish william@guidelinesforum.com

Tel. +33 616 548 157

info@translationalmedicineacademy.org

Tel. +33 608 187 708

## Come to better understand the heart failure guidelines development process







### **PROGRAM**

The Translational Medicine
Academy is an international
academic foundation that
provides patients, caregivers
and families, educational
programs that promote
meaningful dialogue
between healthcare
professional and patient and
adherence to appropriate
treatment plans.

### Why a Heart Failure Guidelines Closed Forum?

The quality of research and development efforts made by manufacturers of pharmacological agents, biomarkers, and medical devices has obviously had a major impact on the position of these products in clinical guidelines on the management of heart failure. Conversely, the success and failure stories that inevitably accompany the release of new guidelines may be a source of inspiration for further research and development. And, ultimately, guidelines really shape clinical practice if doctors and their patients

adopt them.
A better understanding of the processes involved in guidelines development will help companies that develop drugs, biomarkers, and devices to adapt and improve their research and development programmes for the future. This could also translate into earlier and more efficient development of diagnostic and therapeutic tools for patients.

### Discussion process during the meeting

Presentations are not handed out and there will be no published proceedings.

Day 1

### **7 13.00−14.20** Heart Failure Guideline Development Process

- · Why do we need guidelines?- J. Lindenfeld
- What you can & cannot expect Guidelines to say – levels of recommendation and strengths of evidence-M. Jessup
- How are the US guidelines developed?- C. Yancy
- How are the Canadian guidelines developed?- J. Ezekowitz
- How are the European guidelines developed?- A. Coats

### 14.20–15.45 Guidelines Case Studies — Drugs for special HF scenarios

- How can results from studies in CKD guide HF guidelines?
   How can results on subgroups of HF patients in such trials be informative? The case of using potassium binders to treat hyperkalemia M. Kosiborod
- Guidelines and treatment adherence advise: The case of getting patients on full RAAS inhibitor dose and make them stay there using potassium binders. - B. Pitt
- How can data from recent DM trials be relevant for heart failure: the example of empagliflozin and the EMPA-REG OUTCOME trial ?! - S. Anker

#### **BREAK 15.45-16.15**

### **16.15-17.45** Guidelines Case Studies — Drugs for chronic heart failure

- Will PARADIGM-HF change the treatment algorithm of chronic heart failure?- **M. Packer**
- The Canadian recommendations about Paradigm-HF: too narrow? too broad? too early?- J. Ezekowitz
- How to incorporate new data from meta-analyses the example of beta blockers in AF- **A. Coats**
- Ivabradine for Americans with no US data?! S. Gottlieb

## 17.45-19.00 Guidelines Case Studies 1 — Disease monitoring to trigger better case: from biomarkers to devices

- Blood-based and diagnostic biomarkers- A. Maisel
- Device based monitoring technologies- W. Abraham
- Can surrogates guide guidelines: the value of imaging - J. Udelson

From 20.00 Dinner

### Day 2

## 08.10-09.00 Obstructive, central and mixed etiology sleep apnea: what now?

- Sleep disorders in HF Part 1
   Obstructive sleep apnea- S. Javaheri
- Sleep disorders in HF Part 2 Central sleep apnea- A. Coats

### 09.00-10.00 Guidelines Case Studies — Acute heart failure

- Drugs for Acute HF: Is relieving symptoms dead?- F. Peacock
- Drugs for acute HF What prognosis?
   In hospital worsening HF? Post discharge mortality?- J. Butler
- Procalcitonin in AHF for guiding antibiotics therapy- M. Möckel

#### **BREAK 10.00-10.30**

### 10.30-11.30 What do CMS/NIH/ FDA/EMA regulators expect from the HF guidelines?

- More practical evidence meaningful for patients drugs- **N. Stockbridge**
- FDA Division of Cardiovascular Devices expects **B. Zuckerman**
- Harmonization of guidelines an EMA perspective- **G. Rosano**

### 11.30-12.15 Is the time ready for international harmonized Guidelines?

### Suggested topics:

• Differences between guidelines regarding drug therapy -?- M. Jessup

- Differences between guidelines regarding device therapy -?- I. Piña
- Panel discussion

### 12.15-12.35 Ad hoc Q & A session (part 1)

#### LUNCH 12.35-13.15

## 13.15-14.00 Guidelines Case Studies — Drugs/Technologies to support better care

- IV iron symptoms and dosing-
- S. Anker
- Exercise training: what should be recommended? Symptoms, exercise capacity or even prognosis improvement? – I. Piña
- CCM for better exercise capacity D. Burkhoff

# 14.00-14.45 Guidelines Case Studies — Novel devices and surgery ready for (which) recommendations?! Novel devices for HF — ready for

• Neuromodulation Devices-

## routine use?NeuromoduW. Abraham

- Interventional Heart Failure: Inter-Atrial Shunts and Percutaneous and surgical LV reconstruction.
- D. Burkhoff

### 14.45-15.30 Ad hoc Q & A session (part 2)

15.30 Wrap-up

#### **FACULTY**

Prof. William T. Abraham (co-chair), *Columbus, USA*Prof. JoAnn Lindenfeld (co-chair), *Aurora, USA*Prof. Stefan Anker (co-chair), *Berlin, Germany* 

Prof. Daniel Burkhoff, New York, USA Prof. Javed Butler, New York, USA

Prof. Andrew J.S. Coats, *Warwick, UK*Prof. Justin Ezekowitz. *Edmonton, Canada* 

Prof. Stephen Gottlieb, *College Park, USA* 

Prof. Shahrokh Javaheri, *Cincinnati, USA*Prof. Mariell Jessup, *Philadelphia, USA* 

#### FDA representatives

Prof. Norman Stockbridge, Silver Spring, USA Prof. Bram Zuckerman, Silver Spring, USA Prof. David Kao. Denver. USA

Prof. Mikhail Kosiborod, Kansas City, USA

Prof. Alan Maisel, New York, USA

Prof. Martin Möckel, Berlin, Germany

Prof. Milton Packer, Dallas, USA

Prof. Frank Peacock, Houston, USA

Prof. Frank Peacock, Houston, US

Prof. Ileana L. Piña. Cleveland, USA

Prof. Bertram Pitt, Ann Arbor, USA

Prof. Monica R. Shah, Washington, USA

Prof. James E. Udelson, Boston, USA

Prof. Clyde W. Yancy, Chicago, USA

### EMA representatives

Prof. Krishna Prasad, London, UK Prof. Giuseppe Rosano, Rome, Italy

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