

CHAIRS

Prof. William T. Abraham



MD, FACP, FACC
Professor of Internal Medicine,
Chief of the Division of
Cardiovascular Medicine at
the Ohio State University
College of Medicine.
Ohio, USA

William T Abraham, serves as Deputy Director of the Dorothy M Davis Heart and Lung Research Institute. He previously held faculty appointments at the University of Colorado, the University of Cincinnati, and the University of Kentucky. Dr Abraham's research interests include the role of the kidney in heart failure, neurohormonal mechanisms in heart failure, sleep-disordered breathing in heart failure, and clinical drug and device trials in heart failure and cardiac transplantation.

Prof. Javed Butler



MD, MPH, MBA, FACC, FAHA,
FESC is Professor of Medicine
at Stony Brook University
School of Medicine; Co-
Director of Stony Brook Heart
Institute; and Division Chief of
Cardiology at the Stony Brook
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Dr. Butler completed his residency training at Yale University where he also served as Chief Resident. He then completed a fellowship in cardiovascular diseases at Vanderbilt University and supplemented his training with advanced fellowships in heart failure and cardiac transplant at Vanderbilt University and cardiac imaging training at Massachusetts General Hospital. He completed his MPH from Harvard University and his MBA from Emory University. Dr. Butler's research interests include risk factors and prediction of outcomes related to heart failure and heart failure clinical trials. Dr. Butler has participated in more than 50 clinical trials of new interventions in patients with heart failure and has contributed to more than 400 peer-reviewed publications.

Prof. Stefan Anker



MD, PhD, FESC Professor of
Cardiology and Cachexia
Research
Department of Cardiology
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Prof. Stefan Anker is Professor of Cardiology and Cachexia Research at the Charité, Campus Virchow-Klinikum in Berlin, Germany. Prof. Anker trained in medicine at the Charité Medical School in Berlin. Previously he held faculty positions at Imperial College in London & University Medicine Göttingen. Dr Anker's research interests include heart failure, cardio-oncology, cachexia and sarcopenia, as well as clinical drug and device trials. Dr Anker was president of the European Heart Failure Association and currently serves as Vice President of the European Society of Cardiology.

VENUE

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Grant Opportunities (including CME, Advisory Boards
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Registration : www.tmacademy.org

Preliminary Program

17th & 18th
October
2017

5th edition
Baltimore
USA

Heart Failure Guidelines Forum

Better understand the Heart failure
guidelines development process
and its implications

GUIDELINES
FORUM
by TMA
HFGF

TMA
TRANSLATIONAL
MEDICINE ACADEMY

Preliminary Agenda

Clinical practice guidelines and associated implementation strategies are essential to promote optimal, evidence-based practices in heart failure prevention and management. While current practice guidelines are generally in agreement, specific recommendations may differ, reflecting diverging interpretations of the available evidence or the lack of sufficient data to make evidence-based recommendations. In addition, a number

of questions arise as a result of a rapidly changing clinical landscape and attempts at addressing unmet clinical needs.

The Guidelines Forum on Heart Failure aims to gather a multidisciplinary panel of leading academic international experts and industry representatives involved in basic and clinical research to discuss the latest evidence, ongoing research and controversial issues that have implications for clinical practice.

Day 1

- **01:00 pm - 01:45 pm: Session 1 - Heart Failure Guideline Process**
 - » US Guidelines developed?
 - » The Canadian HF GLs
 - » ESC guideline
 - » Where does the "Two trials for IA » rule come from? What if a company had 2 successful trials (HFrEF and HFpEF)?
 - » Discussion
- **01:45 pm – 03:00 pm: Session 2 - International harmonized Guidelines**
 - » Differences between guidelines: drug therapy
 - » Differences between guidelines: device therapy
 - » What is HFmrEF and what impact on GL?
 - » Resolving complaints about GL statements
 - » Discussion
- **03:00 pm – 03:45 pm: Session 3 - Treatment algorithms for chronic HF**
 - » PARADIGM-HF and the place of Sacubitril/Valsartan in the treatment algorithm of chronic heart failure
 - » The Canadian recommendations
 - » The European recommendations
 - » New trials on LCZ and their possible impact on current GL recommendations
 - » Discussion
- **03:45 pm - 04:15 pm: Break**
- **04:15 pm - 05:30 pm: Session 4 - Endovascular approaches for functional mitral and tricuspid regurgitation**
 - » Scope of the problem
 - » Impact of Mitra-FR and COAPT on GLs
 - » The ACTIVE trial design
 - » Discussion
- **05:30 pm - 06:15 pm: Session 5 - Sleep and novel devices**
 - » OSA
 - » CSA
 - » Neuromodulation devices
 - » Interventional HF
 - » TBC
- **06:15 pm – 06:45 pm: Ad hoc Q & A session (part 1)**

Day 2

- **08:45 am – 09:45 am: Session 6 - Acute HF**
 - » Drugs
 - » Procalcitonin in AHF
 - » TBC
 - » Discussion
- **09:45 am – 10:30 am: Session 7 - What do regulators expect from HF guidelines**
 - » Drugs
 - » Devices
 - » EMA
- **10:30 am - 11:00 am: Break**
- **11:00 am – 12:00 pm: Session 8 - Drugs / technologies for better care / co-morbidities**
 - » IV iron
 - » Device based monitoring technologies
 - » discussion
- **12:00 pm – 12:30 pm: Ad hoc Q & A session (part 2)**
- **12:30 pm – 01:30 pm: Lunch**
- **01:30 pm – 02:30 pm: Session 9 - Supportive care indications (treatment enabling other treatment)**
 - » Kidney disease / hyperkalemia
 - » Why is Empagliflozin not recommended for prevention of HF in USA guidelines
 - » How could SGLT2 inhibitors modify treatment approaches in GL?
- **02:30 pm – 03:30 pm: Session 10 - Topics to be decided**
Call for proposals
- **03.30 pm: Wrap-up**

Faculty

- **CHAIRS**
 - » W. Abraham (USA)
 - » S. Anker (GER)
 - » J. Butler (USA)
- **REPRESENTATIVES FROM FDA, EMA AND CMS**
- **FACULTY MEMBERS (CONFIRMED)**
 - » J. Borer (USA)
 - » A. Coats (UK)
 - » G. Filippatos (GRE)
 - » J. Januzzi (USA)
 - » G. Levine (USA)
 - » A. Maisel (USA)
 - » C. O'Connor (USA)
 - » M. Packer (USA)
 - » I. Piña (USA)
 - » B. Pitt (USA)
 - » P. Ponikowski (POL)
 - » G. Rosano (ITA)
 - » G. Stone (USA)
 - » L. Stevenson (USA)
 - » J. Teerlink (USA)

Why attend a Guidelines Forum?

- The development and successful implementation of guidelines requires both communication and transparency between all stakeholders. The Guidelines Forum is a closed workshop during which meaningful discussions occur between academic faculty members covering relevant topics for industry attendees.
- A better understanding of the processes involved in guidelines development and implementation will help attendees that develop drugs, biomarkers and devices, to adapt and improve their research and development programs for the future.
- Case based discussions: the success and failure stories that inevitably accompany the release of new guidelines may be a source of inspiration for further research and development.
- Guidelines really shape clinical practice if doctors and their patients adopt them. Therefore, implementation is essential. This could also translate into earlier and more efficient development of diagnostic and therapeutic tools for patients.

At the end of the meeting, all participants will have a better understanding of the unmet needs and knowledge gaps that need to be addressed by future research and development efforts, and of the most appropriate ways of progressing to conciliate and take advantage of clinical, societal, evidence-based medicine and regulatory requirements.