

## GUIDELINES FORUM CO-CHAIRS



**Prof. Stefan Anker**

MD, PhD, FESC  
Professor of Cardiology  
and Cachexia Research  
Department of  
Cardiology Charité  
Campus Virchow-  
Klinikum Berlin, Germany



**Prof. Petar Seferovic**

MD, PhD, FACC, FESC  
President-elect Heart  
failure Association of  
the ESC  
Chair of internal medicine  
Belgrade University  
School of Medicine



**Prof. Gerasimos Filippatos**

MD, FESC, FHFA, FACC, FCCP  
Dean, School of Medicine  
University of Cyprus  
Professor of Cardiology,  
University of Cyprus &  
National and Kapodistrian  
University of Athens

**An opportunity  
to meet a panel  
of international  
experts in Heart  
Failure ● ● ●**

## VENUE

Nice - France

HOTEL PLAZA

12 Avenue de Verdun - 06000 Nice

[www.hotelplazanice.com](http://www.hotelplazanice.com)

## CONTACT US

TMA Foundation

Charles Schoen - Operations Director

Tel.: +33 (0) 6 08 18 77 08

Email: [charles.schoen@tmacademy.org](mailto:charles.schoen@tmacademy.org)

Grant Opportunities (including CME, Advisory Boards  
& Customized Grants)

William Melhuish / Yann Colardelle

Tel.: + 33 (0) 6 16 54 81 57

E-mail: [william@mededgs.com](mailto:william@mededgs.com) and  
[yanncol@tmacademy.org](mailto:yanncol@tmacademy.org)

**Registration : [www.tmacademy.org](http://www.tmacademy.org)**

## Preliminary Program

15<sup>th</sup> & 16<sup>th</sup>  
**October**  
**2018**

6<sup>th</sup> edition

**Nice - France**  
**Hotel Plaza**

# Heart Failure Guidelines Forum

Better understand the heart failure  
guidelines development process  
and its implications

GUIDELINES  
FORUM by TMA  
HFGF

TMA  
TRANSLATIONAL  
MEDICINE ACADEMY

# EDUCATIONAL OBJECTIVES

- 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.

## About TMA

The Translational Medicine Academy (TMA) is an international academic Foundation with focused activities in Mission Critical Areas of high public health importance having significant professional and patient therapeutic and educational gaps.

# Programme

October 15, 2018

## 01.00–01:45 pm: Session 1 - Heart Failure Guideline Process – rules of engagement

- >> How are the ESC guidelines developed?
- >> How are the US Guidelines developed?
- >> What about Indian guidelines?
- >> Discussion

## 01.45–02.30 pm: Session 2 International harmonized guidelines

- >> Differences between guidelines: drug therapy-1
- >> Differences between guidelines: drug therapy-2
- >> Differences between guidelines: device therapy
- >> Resolving complaints about GL statements
- >> Discussion

## 02.30–03.30 pm: Session 3 Trials in HFrEF and HFpEF

- >> What is HFpEF? The meaning and evidence behind the new HFA HFpEF score
- >> What is the meaning of HFmrEF?
- >> Discussion

- >> What if there were 2 successful trials – one in HFrEF and one in HFpEF by the same agent?
- >> Are there design and statistical consideration which should allow one trial to lead to 1A recommendation?

- >> Example 1 e.g. LCZ & PARAGON-HF
- >> Example 2 e.g. SGLT2 inhibitors

- >> What if there were 1 successful trial with one subgroup in HFrEF and one in HFpEF, does it give 2 guidelines recommendations for both subgroups?

- >> Example 1 : device
- >> Example 2 : telemedicine
- >> Discussion

03.30-03.50 pm BREAK

## 03:50 -04:35 pm: Session 4 - Treatment algorithms for chronic HF

- >> The place of Sacubitril/Valsartan in the treatment algorithm of chronic heart failure The European point of view
- >> The US point of view
- >> Discussion : any change needed
- >> Optional talk : new trials on LCZ and their possible impact on current GL recommendations
- >> Discussion

## 04.35-05.30 pm: Session 5 - Endovascular approaches for functional mitral and tricuspid regurgitation

- >> MitraClip update, Coapt, French MR, and more
- >> Discussion

>> The meaning of combined rank based endpoints and their application in guidelines: what if we know that a therapy works for sure, but we don't know for what?

>> Discussion

05.30-05.50 PM BREAK

## 05.50-06.45 pm: Session 6 – Special discussion points on devices for HF

- >> Case 1 The Barostim Neo Experience and FDA Expedited Access Pathway: Implications for Guidelines
- >> Optional case 2 / What should be the minimum evidence requirement for safety and long-term effects for highly invasive procedures;
- >> Discussion
- >> Device based monitoring technologies
- >> Discussion

## 18.45–19.15 Ad hoc Q & A session (part I)

October 16, 2018

## 08.45–09.45 am: Session 7 - Acute HF

- >> Is short-term symptom improvement still a viable endpoint for guidelines?
- >> What about ultrafiltration - state of affairs
- >> Discussion
- >> Procalcitonin in AHF to guide therapy
- >> Discussion

## 09.45–10.20 am: Session 8 - What do regulators expect from HF guidelines? And what if guidelines are different from labels?

- >> Discussion

10:20-10.40 BREAK

## 10.40–11.40 am: Session 9 – New technologies for better care of in co-morbidities in HF

- >> IV iron
- >> Discussion
- >> Obstructive Sleep Apnoea – State of Affairs
- >> Central Sleep Apnoea
- >> Discussion

## 11.40–12.40: Working Lunch

## 11.50–12.20 am :Ad hoc Q & A session (part 2)

## 12.40–01.20 pm: Session 10 – Supportive care indications (treatment enabling other treatment) & Open Slot

- >> Potassium binders: what do GLs need to make recommendations for enabling another therapy?
- >> Discussion

## 01.20–02.30 pm: Session 11 – On HF prevention and PROs

- >> A call for patient-reported outcomes to be better recognized in GLs
- >> Symptomatic & more sick subgroups of HF patients in need: different trials & different endpoints – also different guidelines?
- >> Should the guidelines comment on cardio oncology?
- >> Case 1
- >> Case 2
- >> Discussion

## 02:30 -03:00 pm: Final comments and close

## CONFIRMED FACULTY

B. Abraham  
S. Anker (co-chair)  
J. Butler  
J. Cleland  
A.J.S. Coats

G. Filippatos (co-chair)  
T. Mc Donagh  
G. Rosano (EMA)  
P. Seferovic (co-chair)  
L. Stevenson