

HFA Clinical Trials in Heart Failure Course

07 - 09 October 2022 - Sorrento, Italy

Course Directors: Profs. G. Savarese and M. Metra

Programme

This programme is preliminary and subject to change according to the latest news and availability of the invited faculty.

Day 1 – Friday 07 October

10:00 - 12:00	Registration	120 min
11:45 - 13:00	Lunch at the hotel	75 min
13:00 - 13:20	Welcome from the HFA Leadership and Course Organizers. – <i>G. Rosano & G. Savarese & M. Metra</i>	20 min
	Session 1: Keynote lectures – Chairpersons: G. Rosano & S. Solomon	
13:20 - 13:35	Heart Failure: Where we stand today – the HFA ATLAS – <i>P. Seferovic</i>	10+5 min
13:35 - 14:00	The rationale of conducting clinical trials and how they changed clinical practice – <i>P. Ponikowski</i>	20+5 min
14:00 - 14:25	What are the unmet needs and what is coming next in HF trials? – <i>G. Rosano</i>	20+5 min
14:25-14:55	Break	30 min
	Session 2: Clinical trial procedures – Chairpersons: F. Braunschweig & M. Metra	
14:55 - 15:10	Clinical trial phases – <i>B. Moura</i>	10+5 min
15:10- 15:25	Randomization techniques – <i>O. Chioncel</i>	10+5 min
15:25 - 15:40	Blinding and ethical considerations – <i>D. Farmakis</i>	10+5 min
15:40 - 15:55	The several actors involved in trial design and conduct: trials committees – <i>E. Jankowska</i>	10+5 min
15:55 - 16:25	Coffee break	30 min
	Session 3: Focus on selection criteria and outcomes – Chairpersons: S. Solomon & G. Savarese	
16:25 - 16:45	Inclusion and exclusion criteria in HF clinical trials: how to maximize results with appropriate strategies – <i>S. Solomon</i>	15+5 min
16:45 - 17:05	Hard endpoints: which ones and when? – <i>M. Metra</i>	15+5 min

17:05 - 17:25	Surrogate endpoints: which ones and when – <i>A. Bayes Genis</i>	15+5 min
17:25 - 17:45	Quality of life and patient reported outcomes – <i>A. Coats</i>	15+5 min
17:45 - 17:50	Closure of the day – <i>G. Savarese</i>	5 min
20:00	Group Dinner outside of the hotel: “O Parrucchiano” restaurant (10 min walk from the Hilton Hotel)	

Day 2 – Saturday 08 October

	Session 4: Regulatory aspects in clinical trials in HF – Chairperson: F. Braunschweig	
09:00 - 09:20	Regulatory aspects in clinical trials in HF – <i>E. Zouridakis</i>	15+5 min
	Session 5: Registries and registry-based trials in HF – Chairpersons: M. Volterrani & M. Polovina	
09:20 - 09:40	Registry-based research in HF: when is it relevant? – <i>G. Savarese</i>	15+5 min
09:40 - 10:00	Registry-based randomized controlled trials in HF – <i>L. Lund</i>	15+5 min
	Session 6: Clinical trials in specific settings – Chairpersons: G. Savarese & A. Rakisheva	
10:00 - 10:20	Trials on devices in HF – <i>O. Amir</i>	15+5 min
10:20 - 10:40	Trials in cardiomyopathies – <i>E. Zouridakis</i>	15+5 min
10:40 - 11:10	Coffee Break	30 min
11:10 - 11:30	Trials in advanced heart failure – <i>F. Gustafsson</i>	15+5 min
11:30 - 11:50	Trials in acute heart failure – <i>L. Lund</i>	15+5 min
11:50 - 12:10	Trials on valvular disease – <i>F. Maisano</i>	15+5 min
12:10 - 12:30	Trials on coronary artery disease – <i>M. Adamo</i>	15+5 min
12:30 - 13:50	Lunch Break	100 min
	Session 8: Advanced aspects of trial design – Chairperson: G. Savarese	
13:50 - 14:10	Different trial designs (e.g. Cross Sectional, Factorial, Superiority/Non-inferiority, Adaptive, Basket, Umbrella, Platform) – <i>S. Pocock</i>	15+5 min
14:10 - 14:30	Big data and artificial intelligence for clinical trial design – <i>F. Asselbergs</i>	15+5 min
14:30 - 14:50	Novel outcome analyses (hierarchical testing and recurrent event analyses) and interim analysis – <i>S. Solomon</i>	15+5 min
14:50 - 15:10	Subgroup and post-hoc analyses: how to interpret? – <i>M. Metra</i>	15+5 min

15:10 - 15:40	Coffee break	30 min
	Session 9: Meta-analyses – Chairpersons: M. Lainscak & R. Ray	
15:40 - 16:10	Systematic Reviews and Meta-analyses – <i>G. Savarese</i>	25+5min
16:10 - 16:30	Statistical methods for meta-analyses – <i>N. Orsini</i>	15+5min
16:30 - 16:45	Session 10: How to revitalize R&D? – Chairperson: F. Jouhra	
16:30 - 16:40	How to revitalize R&D? – <i>M. Papaluca</i>	10 min
16:40 - 16:45	Closure of the day	5 min
20:00	Group dinner at the hotel – Affresco Restaurant	

Day 3 – Sunday 09 October

	Workshop 1: Meta-analyses – Chairperson: A. Rakisheva	
09:00 - 09:30	How to run a meta-analysis – <i>G. Savarese</i>	30 min
	Workshop 2: Observational studies (2 parallel groups) – Chairperson: G. Savarese	
09:30 - 10:00	Adjustments and matching – <i>N. Orsini</i>	30 min
10:00 - 10:30	Survival analysis – <i>S. Bonassi</i>	30 min
10:30 - 11:00	Coffee Break	30 min
	Workshop 3: Designing trials – Chairpersons: G. Savarese, P. Seferovic & S. Pocock, A. Rakisheva, M. Alonso Garcia	
11:00 - 11:45	Participants prepare trial designs in 4 groups	45 min
11:45 - 12:55	Presentations and discussion	80 min
12:55 - 13:00	Farewell – <i>G. Savarese</i>	5 min
13:00- 14:00	Lunch	60 min



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