ALL ABOUT CLINICAL TRIALS

29th & 30th May 2016
Tel Aviv

The European Society of Cardiology is proud to be delivering an engaging and interactive 2-day course to improve the professional knowledge and skills required to plan and deliver successful cardiovascular pharmacotherapy clinical trials.

Our goal is for all participants to leave the meeting with the improved competence and confidence to deliver better clinical trials which in turn will have a positive impact on services and patient outcomes.

This course is aimed at improving knowledge and skills related to clinical trial planning and design as well as the successful running of different types of clinical trials. We will offer highly interactive sessions coordinated by top experts in their fields. In addition, the course will offer interactive workshops on Good Clinical Practice (GCP certificate included), regulatory issues, statistics, trial data interpretation and manuscript writing.

At the end of the course delegates will have improved their knowledge in:

- designing and planning successful clinical trials,
- evaluating and following the correct processes and regulatory procedures,
- effectively analysing and interpreting trial data.

This course will be an excellent opportunity for education, networking and creating opportunities.

Course Directors
Sven Wassmann, MD, PhD, FESC
Giuseppe M.C. Rosano, MD, PhD, FESC

Organised by the Working Group on Cardiovascular Pharmacotherapy of the European Society of Cardiology

ALL ABOUT CLINICAL TRIALS PROGRAM

Sunday 29 May 2016

08:45	Welcome, Introduction and Course Objectives S. Wassmann, G. Rosano

SESSION 1: **How to Design and Run a Clinical Trial**

09:00	An Overview of the Different Aspects of Clinical Trials A. Niessner
09:30	Traditional versus Novel Trial Designing J. Tamargo
10:00	Objectives and Players: The Site, The Team, The PI, Ethics Committee, Sponsor and CRO B.S. Lewis
10:30	Refreshments and Networking

SESSION 2: Regulatory Aspects

11:00	Requirements from Regulatory Agencies: Endpoints, Comparators, Type of Studies G.Rosano
11:30	Post Marketing Surveillance T. Walther

SESSION 3: Clinical Trials Parade

	New/Ongoing Clinical Trials
12:00	ACS and Antithrombotics – Shaul Atar Diabetes - Itamar Raz Lipidology - Dror Harats Heart Failure - Tuvia Ben Gal
13:00	Lunch and Networking

SESSION 4: Good Clinical Practice

14:00	GCP in a Nutshell for Researchers New and Old Moshe Zvi Neumann, BRD, Israel
16:00	Refreshments and Networking

SESSION 5: Trial Categories

16:30	Randomised Controlled Trials A. Niessner
16:50	Observational Trials and Registries C. Torp-Pedersen
17:10	Meta-Analyses and Systematic Reviews A. Savarese

17:30	Close of day 1 Refreshments and Networking

Monday 30 May 2016
SESSION 6: Statistical Notions in Clinical Trials

08:30-10:00	Randomised Controlled Trials? A.Niessner Observational Trials and Registries? A. Savarese Meta-Analyses and Systematic Reviews? A. Savarese
10:00	Coffee and Networking

Workshop Sessions

10:30	**How to do Sub-Group Analysis** D. Kotecha
11:00	**How to Interpret Clinical Trial Data** Examples from Recent Clinical Trials S. Wassmann, Panelists
11:45	**How to Write a Manuscript** How to make the most of your data G. Rosano, S. Wassmann, C. Torp-Pedersen Selecting the Appropriate Journal How to Structure and Format the Manuscript, Organise Data, Prepare Figures and Tables, Discuss the Findings, Write the Conclusions and Abstract? Characteristics of a good manuscript? How to Increase the Chance of Getting it Accepted? G. Rosano Perspectives of an Editor-in-Chief? S. Agewall
12:30	**Certificates and Closing Remarks** S. Wassmann, G. Rosano