ESC Working Group Cardiovascular Pharmacotherapy

ALL ABOUT CLINICAL TRIALS

8th & 9th December 2017
Vienna, Austria

The European Society of Cardiology Working Group on Cardiovascular Pharmacotherapy 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 interactive sessions coordinated by top experts in their fields. In addition, the course will offer highly interactive workshops on Good Clinical Practice (GCP certificate included), 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
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ORGANISED BY THE WORKING GROUP ON CARDIOVASCULAR PHARMACOTHERAPY OF THE EUROPEAN SOCIETY OF CARDIOLOGY

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Clinical Trials: Day 1 (Sessions and GCP course)

Time	Title
REGISTRATION	
08:45	Welcome, introduction and course objectives G.M.C. Rosano, S. Wassmann
08:55	The ESC Working Group on Cardiovascular Pharmacotherapy - Perspectives of a Past-Chairman and Editor-in-Chief S. Agewall
SESSION 1. HOW TO DESIGN AND RUN A CLINICAL TRIAL	
09:10	An overview of the different aspects of clinical trials A. Niessner
09:50	Traditional versus novel trial designing J. Tamargo
10:20	Planning and running a clinical trial: the research site - players, facilities, ethics, logistics B.S. Lewis
10:40	Planning and running a clinical trial: sponsors, CROs, adjudication and retention B.S. Lewis
11:00	**Refreshments and networking**
SESSION 2. REGULATORY ASPECTS	
11:30	Requirements from regulatory agencies: endpoints, comparators, type of studies G.M.C. Rosano
12:00	Post marketing surveillance T. Walther
SESSION 3. CLINICAL TRIALS: THE SPONSOR´S VIEWPOINT	
12:30	The sponsor´s viewpoint TBD (company representative)
13:00	**Lunch and networking**
SESSION 4. WHAT´S NEXT – UPCOMING AND ONGOING CLINICAL TRIALS	
14:00	ACS / Antithrombotics S. Wassmann
14:15	Lipidology B.S. Lewis
14:30	Diabetes H. Drexel
14:45	Heart failure G.M.C. Rosano
SESSION 5. TRIAL CATEGORIES	
15:00	Observational trials and registries G. Savarese
15:20	Randomised controlled trials A. Niessner

15:40	Meta-analyses and systematic reviews G. Savarese
SESSION 6. HOW TO INTERPRET CLINICAL TRIAL DATA	
16:00	Reading between the lines: How to interpret clinical trial data – Examples from recent clinical trials S. Wassmann
16:30	**Refreshments and networking**
SESSION 7. GOOD CLINICAL PRACTICE	
17:00	GCP for the busy investigator (certificate included) D. Rolfe
19:00	Refreshments and networking Close of day 1

Clinical Trials: Day 2 (Interactive Workshops)

08:55	Welcome and objectives T. Walther
09:00	**ISSUES IN CLINICAL TRIALS** Diabetes trials: challenges and current directions T. Schmidt
09:30	**WORKSHOP: STATISTICAL ISSUES IN CLINICAL TRIALS – BASIC NOTIONS** Parallel groups (switch after 60 min): • Randomised controlled trials and subgroup analyses - A. Niessner • Registries and meta-analyses – G. Savarese
11:45	**Refreshments and networking**
12:00	**DATA INTERPRETATION** Interpreting meta-analyses and clinical trials: can we believe the data? G. Savarese
12:30	**WORKSHOP: THINGS TO KNOW FOR JUNIOR INVESTIGATORS** Parallel groups (switch after 20 min): • How to write a manuscript – T. Schmidt • What you need to know as junior investigator – C. Ceconi
13:15	Closing remarks C. Ceconi
13:30	**Lunch and networking -** Close of day 2