# All About Clinical Trials Course 12-13 December 2024, Oslo, Norway

Organised by the ESC Working Group on Cardiovascular Pharmacotherapy (WG CVP) and the Association of Cardiovascular Nursing & Allied Professions (ACNAP) of the ESC

In collaboration with REMEDY Center, Norwegian Society of Cardiology, Diakonhjemmet Hospital and CETERA Academic Consulting Research Organization

## Programme

**Faculty from Oslo (5 members):**

A.G. Semb
E. Haavardsholm
I.C. Olsen (Oslo)
Per Olav Vandvik (Oslo-Magic)
D. Atar (Oslo)
I. Lie (ACNAP – Oslo)

**European Faculty (excluding those from Oslo) 11 members:**

G. Savarese (WG CVP)
Dobromir Dobrev (WG CVP)
L. Klompstra (ACNAP)
L. Desteghe (ACNAP)
Giuseppe Rosano (ESC)
Christian Torp-Pedersen (WG CVP)
Heinz Drexel (WG CVP)
J. Sanders (ACNAP)
J. Hendriks (ACNAP)
B. Rocca (WG CVP)
Sven Wassman (WG CVP)

**GCP Module Faculty:**

Susana Silva
Margarida Nogueira

## Day 1 - Thursday 12 December 2024

| Time | Session/Presentation | Speakers | Duration |
|---|---|---|---|
| 11:00 AM | Welcome introduction and course objectives | A.G. Semb, E. Haavardsholm, and J. Sanders | 5 minutes |
| | **SESSION 1: How to design and run a clinical trial Chairpersons: G. Savarese and J. Sanders** | | 2 hours 15 min |
| | Designing clinical trials with clinical impact | G. Savarese (ESC) | 15 minutes + 5 minutes discussion |
| | How to plan for successful randomization and inclusion of patients: The importance of ethnic and gender diversity | Dobromir Dobrev (ESC) | 15 minutes + 5 minutes discussion |
| | Accurate data collection and data management | L. Klompstra (ACNAP) | 15 minutes + 5 minutes discussion |
| | Break | | 20 minutes |
| | Study set up milestones and how to navigate connections among research ethics, sponsor, and governance; feasibility and capability assessment | I. Lie (ACNAP) | 20 minutes + 5 minutes discussion |
| | Role of the research nurse/allied professional and the clinical research nurse manager | L. Desteghe (ACNAP) | 10 minutes + 5 minutes discussion |
| | Pharmacovigilance and safety reporting | Giuseppe Rosano or GL Savarese | 10 minutes + 5 minutes discussion |
| | Break - Lunch | - | 1 hour |
| | **SESSION 2: Regulatory aspects Chairpersons: Christian Torp-Pedersen and Dobri Dobrev** | | |
| | Regulatory agency's requirements and protocol trial documents and trial registration | Giuseppe Rosano (ESC) | 20 minutes + 5 minutes discussion |

| Time | Session/Presentation | Speakers | Duration |
|---|---|---|---|
| | Planning and running a clinical trial: Role of different committees – Data safety committee, Steering committee | J. Sanders (ACNAP) | 15 minutes + 5 minutes discussion |
| | **SESSION 3: novel trial design Chairpersons: C. Torp Pedersen and AG Semb** | | 1 hour 5 min |
| | Causal inference interpretation of clinical trials and emulating clinical trials using observational data. | C. Torp Pedersen | 15 min+5 min discussion |
| | Registry-based trials – Importance – Advantages and disadvantages | G. Savarese (ESC) | 25 minutes + 5 minutes discussion |
| | Clinical trial designs: traditional versus modern approaches | I.C. Olsen (Oslo) | 20 minutes + 5 minutes discussion |
| | State of the Art: The role of AI in clinical trials | Per Olav Vandvik (Oslo-Magic) | 15 minutes + 5 minutes discussion |
| | **SESSION 4: lessons learned & critical assessment of latest large clinical trials<br>Chairpersons: C. Torp Pedersen and B. Rocca** | | 50 min |
| | ACS | Sven Wassman (ESC) | 10 minutes + 5 minutes discussion |
| | Learnings from Clinical Trials in Subclinical Atrial Fibrillation | D. Atar (Oslo) | 10 minutes + 5 minutes discussion |
| | Heart Failure | Giuseppe Rosano (ESC) | 10 minutes + 5 minutes discussion |
| | End of Day 1 - Summing up and info | AG Semb | 5 minutes |

## Day 2 - Friday 13 December 2024

| Time | Session/Presentation | Speakers | Duration |
|---|---|---|---|
| 08:30 AM | Welcome and practical sessions objectives | G. Savarese and J. Sanders | 5 minutes |
| | **SESSION 1: statistical issues in clinical trials** Chairpersons: C. Torp Pedersen and H. Drexel | | |
| | The Role of Statistics in Randomised Controlled Trials or Statistical Principles in RCTs | I.C. Olsen (Oslo) | 60 minutes + 10 minutes discussion |
| | Subgroup analyses in RCTs: value and limitations of post hoc analyses | H. Drexel (ESC) | 20 minutes + 10 minutes discussion |
| | **SESSION 2: Patients perspective** Chairpersons: J. Sanders (ACNAP) and AG Semb | | 20 min |
| | Patient and public involvement in clinical trials: the importance of patient research partners | J. Hendriks (ACNAP) | 15 minutes + 5 minutes discussion |
| | **BREAK** | - | 20 minutes |
| | **Gcp module** | TBC- **ETERA Academic Consulting Research Organization** | 2 hours 45 min |
| | Good Clinical Practice Course | TBC - AIDFM-CETERA Portuguese Academic Susana Silva (CRO CETERA | 45 Min |
| | **LUNCH** | - | 1 hour |
| | Good Clinical Practice Course (continued) | TBC - AIDFM-CETERA Margarida Nogueira (CRO CETERA) | 45 min |
| | **Good Clinical Practice Exam** | TBC - AIDFM-CETERA Susana Silva & Margarida Nogueira (CRO CETERA) | 45 minutes |

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| | **Closing remarks** | A.G. Semb and J. Sanders | 10 minutes |