



## 4<sup>th</sup> CENTRAL EUROPEAN COURSE (CEC 2010) METHODOLOGY OF CLINICAL TRIALS IN ONCOLOGY

Vienna, Austria; 11-12 March 2010

**Organized by:** CESAR Central European Society for Anticancer Drug Research – EWIV  
Please contact the CESAR Central Office  
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**Accredited:**



European Society  
for Medical Oncology

11 Category 1 ESMO-MORA  
points

**Chairperson:** Prof. Dr. Max E. Scheulen  
Essen, Germany

**Course location:** Tech Gate Vienna  
Wissenschafts- und Technologiepark GmbH  
Donau-City-Straße 1  
A-1220 Vienna  
[www.techgate.at](http://www.techgate.at)

**Audience targeted:** Investigators specialized in medical oncology and related disciplines, oncology nurses, data managers, study monitors, study administrators, pharmacists.  
Professionals involved in clinical trials in oncology in academia, industry, governmental agencies and clinical research organizations (CROs).

**Objectives:** Clinical studies are an important part in the drug development process and in exploring new therapeutic treatment modalities.  
In this practice-oriented course participants will acquire specific knowledge on planning and performance of clinical studies of the phases I-II-III in Oncology.

**Course language:** English

**Course format:** Lectures, presentation of case reports.  
Close interactions between participants and faculty: systematic discussions and exchange of experiences during the sessions as well as during the breaks and meals.



**Registration:** The registration should be made by returning the fully completed registration form to the CESAR Central Office, Fax: +43 1 522 30 93 14. The number of participants is limited.  
*The confirmation of registration will be forwarded after receipt of the fee required. The applications will be handled on a first-come, first-serve basis.*

**Registration fee:** The registration fee is **€ 900,--** (+ 20 % VAT) per participant and includes all meals according to the program (coffee/tea breaks, lunch/dinner) as well as all course materials, but not the costs for accommodation. Payment should be made in EURO without charges for the beneficiary in favor of CESAR – Österreich Verein – CEC by **bank transfer**.  
Reduced fees apply as follows:  
- ESMO Member: **€ 675,--** (+ 20 % VAT) per participant  
- more than 1 person from same institution: **€ 750,--** (+ 20 % VAT) per participant

After receipt of registration we will send you an invoice about the registration fee.

**Program:**

**Day 1:**

- Principles in Biostatistics
- Principles in Pharmacology
- Preclinical Data as Requirement for Planning Clinical Trials
- Data Assessment and Data Management
- Ethical Considerations in Clinical Trials in Oncology
- Planning and Performance of Clinical Phase I Studies
- Planning and Performance of Clinical Phase II Studies
- RECIST Criteria

**Day 2:**

- Biomarkers in Clinical Oncology
- Legal Aspects of Clinical Trials
- Clinical Trials: the Regulator's Role and Perspective
- Organization, Administration and Performance of Clinical Studies
- Clinical Trials for Therapeutic Concepts in Hematology
- Planning and Performance of Clinical Phase III Studies
- Limitations and Pitfalls of Clinical Trials



## Faculty:

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# CESAR

Central European Society for Anticancer Drug Research-EWIV



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The **CESAR** Central European Society for Anticancer Drug Research – EWIV is a Non-Profit Organization aiming to foster research and development of novel antitumoral agents, therapies and therapeutic strategies in Oncology and Hematology. CESAR comprises scientists from basic research, and preclinical and clinical Oncology in Austria, Germany and Switzerland. CESAR has a network of Study Centres in the German-speaking countries and is extending its focus to Study Centres in Central and Eastern European countries with the aim to foster international cooperation between Oncologists and Study Centers in this area.