



**LACOG**

LATIN AMERICAN  
COOPERATIVE  
ONCOLOGY GROUP

# STAT COURSE

**LACOG**

**2013**

07 - 09 November Brazil

## SIMULTANEOUS TRANSLATION ENGLISH-PORTUGUESE-ENGLISH

The Latin American Cooperative Oncology Group (LACOG) is organizing the 1st Latin American Clinical Trial Statistics and Methodology Course, from 7-9 November 2013 in Porto Alegre, Brazil.

### AIMS OF THE COURSE & LEARNING OBJECTIVES

The course is designed to offer an introduction to the statistical principles and methodological aspects involving the design and analysis of clinical trials. It will give insight in the principles of clinical trial development, treatments and biomarkers investigation, as well as understand and critically review its methods and results.

Upon completion of this course, attendees should be able to:

- Understand the concepts and statistical methods required in biological and health science research
- Interpret study results as routinely presented in the scientific literature considering the design and analysis issues

### TARGET AUDIENCE

Statisticians, epidemiologists, medical doctors, nurses, pharmacists, and all who have been working with clinical trials in Latin America. The LACOG Stat Course 2013 has 20 hours and is accredited by Universidade Federal de Santa Catarina (UFSC) to provide post-graduation hours of credit.

### AGENDA

#### DAY 1 - Principles of statistics

(Chair: Jeovany Martínez-Mesa, BR)  
Thursday, November 7, 2013

- 13:00 - 14:00** Registration
- 13:55 - 14:00** **Welcome and introduction** – G. Werutsky (BR)
- 14:00 - 14:30** **Epidemiology in oncology research** – J. Martínez-Mesa (BR)
- 14:30 - 15:00** **Cancer clinical trials in Brazil and Latin America: an overview** – G. Werutsky (BR)
- 15:00 - 15:10** Discussion
- Coffee break**
- 15:30 - 16:15** **General introduction to clinical trials statistics and hypothesis tests** – S. Litière (BE)
- 16:15 - 17:00** **Analysis of time to event endpoints in oncology** – R. Parker (USA)
- 17:00 - 17:10** Discussion

#### DAY 2 - Clinical Trials Design and Analysis

(Chair: Laurence Collette, BE)  
Friday, November 8, 2013

- 8:30 - 9:15** **Endpoints and design of Phase III trials** – S. Litière (BE)
- 09:15 - 10:00** **Sample size for phase III trials** – R. Parker (USA)
- 10:00 - 10:10** Discussion
- Coffee break**
- 10:30 - 11:15** **Common problems in analysis and reporting of studies (Bias, ITT, multiple tests, ...)** – L. Collette (BE)
- 11:15 - 12:00** **Data monitoring and early stopping rules in phase III studies** – R. Parker (USA)
- 12:00 - 12:10** Discussion
- Lunch**
- 13:15 - 14:00** **Design and analysis of phase I trials** – L. Collette (BE)
- 14:00 - 14:45** **Design and analysis of phase II trials, role of randomization** – E. Saad (BR)
- 14:45 - 14:55** Discussion
- Coffee break**
- 15:15 - 16:00** **Predictive and prognostic factors in clinical trials** – S. Michiels (FR)
- 16:00 - 17:00** **Paper discussion (Clinical trials design/analysis/endpoints)** – All speakers

#### DAY 3 - Biomarkers and Clinical Trials

(Chair: Gustavo Werutsky, BR)  
Saturday, November 9, 2013

- 8:30 - 9:15** **Diagnostic tests** – D.A. González-Chica (BR)
- 09:15 - 10:00** **Development and validation of gene signatures: experience in oncology** – S. Michiels (FR)
- 10:00 - 10:10** Discussion
- Coffee break**
- 10:30 - 11:15** **Adaptive clinical trial designs** – S. Litière (BE)
- 11:15 - 12:00** **Integration of biomarkers in phase II/III clinical trial designs** – S. Michiels (FR)
- 12:00 - 12:10** Discussion
- Lunch**
- 13:15 - 14:00** **Use of intermediate and surrogate endpoints in trials** – L. Collette (BE)
- 14:00 - 14:45** **Non-inferiority trial: design, concepts and issues** – E. Saad (BR)
- 14:45 - 14:55** Discussion
- Coffee break**
- 15:15 - 16:00** **Introduction to Meta-Analysis** A.D. Sasse (BR)
- 16:00 - 17:00** **Paper discussion (genes and biomarkers studies designs)** – All speakers
- 17:00 - 17:10** Closing session

### DATE & LOCATION

07 - 09 November 2013

Hospital São Lucas PUCRS  
Anfiteatro Ir. José Otão  
Av. Ipiranga, 6690 - 2nd floor  
Porto Alegre, Brazil

### EARLY REGISTRATION DEADLINE

07 October 2013

**REGISTER NOW**

### FACULTY

#### INTERNATIONAL FACULTY



Laurence Collette,  
European Organisation for  
Research and Treatment of  
Cancer (EORTC), Belgium



Robert Parker,  
Director of Biometry,  
Massachusetts General  
Hospital, United States



Saskia Litière,  
European Organisation for  
Research and Treatment of  
Cancer (EORTC), Belgium



Stefan Michiels,  
Department of Biostatistics  
and Epidemiology, Institut  
Gustave Roussy, France

#### LOCAL FACULTY



Andre Sasse,  
Universidade de Campinas  
(UNICAMP), Brazil



David A.  
González-Chica,  
Universidade Federal de  
Santa Catarina (UFSC), Brazil



Everardo Saad,  
DENDRIX, Brazil



Gustavo Werutsky,  
Latin American Cooperative  
Oncology Group (LACOG),  
Brazil



Jeovany Martínez-  
Mesa,  
Latin American Cooperative  
Oncology Group (LACOG),  
Brazil

### ORGANIZER

This is a LACOG Activity



**LACOG**  
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Under the auspices of the  
EORTC



*The future of cancer therapy*

### ENDORSING SOCIETIES/ INSTITUTIONS



### SUPPORT

Support for this educational  
activity is provided by:

