



#### 13-15 NOVEMBER 2014 SÃO PAULO, BRAZIL

The Latin American Cooperative Oncology Group (LACOG) is organizing the 2nd Latin American Course on Methodology applied to clinical research in Oncology.

### 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.

# PRELIMINARY COURSE PROGRAMME

#### Day 1 Principles of statistic

Thursday 13th, November 2014 (Chair: Jeovany Martínez-Mesa)

8:00-8:25	Registration	
8:25-8:30	Welcome and introduction – G. Werutsky (BR)	
8:30-9:15	Epidemiology in oncology research – <i>J. Martínez-</i> <i>Mesa (BR)</i>	
9:15-10:00	Current status of cancer clinical research in Brazil and Latin America: an overview – <i>G. de Castro (BR)</i>	
10:00-10:10	Discussion	
Coffee break		
10:30-11:15	General introduction to clinical trials statistics and hypothesis tests - <i>R. Parker (USA)</i>	
11:15-12:00	Endpoints and design of Phase III trials. – <i>S. Litière (BE)</i>	
12:00-12:10	Discussion	
Lunch		
13:15-14:00	Sample size for phase III trials – <i>L. Collette (BE)</i>	
14:00-14:45	Analysis of time to event endpoints in oncology – <i>R. Parker (USA)</i>	
14:45-14:55	Discussion	
Coffee break		
15:15-16:00	Common problems in analysis and reporting of studies (Bias, ITT, multiple tests) – <i>L. Collette (BE)</i>	
16:00-16:45	Predictive and prognostic factors in clinical trials – <i>S. Michiels</i> ( <i>FR</i> )	
16:45-16:55	Discussion	

# **DATE & LOCATION**

13 - 15 November 2014

Instituto do Câncer do Estado de São Paulo (ICESP) Rua Dr. Arnaldo, 251 - Auditório 6th floor São Paulo, Brazil

# REGISTRATION

Discount rate until 12 October 2014 Regular rate until 13 November 2014

### **REGISTER NOW**

# FACULTY

#### **International Faculty**

Laurence Collette





**Robert Parker** 







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

### Day 2 Clinical Trials Design and Analysis

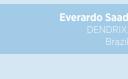
Friday 14th, November 2014 (Chair: Laurence Collette)

8:30-9:15	Non – Inferiority trial: design, concepts and issues – <i>E. Saad (BR)</i>	
9:15-10:00	Data monitoring and early stopping rules in phase III studies – <i>R. Parker (USA)</i>	
10:00-10:10	Discussion	
Coffee break		
10:30-11:15	Diagnostic tests – D.A. González-Chica (BR)	
11:15-12:00	Development and validation of gene signatures: experience in oncology – <i>S. Michiels (FR)</i>	
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 – <i>E. Saad (BR)</i>	
14:45-14:55	Discussion	
Coffee break		
15:15-16:00	Adaptive clinical trial designs - S. Litière (BE)	
16:00-17:00	Paper discussion (Clinical trials design/analysis/endpoints) -	

#### Local Faculty















SUPPORT -

Support for this educational activity is provided by:

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ORGANIZER

8:30-9:15

9:15-10:00

**Coffee break** 

11:15-12:00

10:00-10:10 Discussion







All speakers

Day 3 Biomarkers and Clinical Trials

10:30-11:15 Introduction to Meta-analysis - A.D. Sasse (BR)

12:00-12:10 Conclusions and Close (Gustavo Werutsky)

research in Latin America – All speakers

- S. Michiels (FR)

- S. Litière (BE)

Saturday 15th, November 2014 (Chair: Gustavo Werutsky)

Integration of biomarkers in phase II/III clinical trial designs

Panel discussion with audience: the future of cancer clinical

ENDORSING SOCIETIES /INSTITUTIONS

INSTITUTO DO

CÂNCER

do Estado de São Paulo

Use of intermediate and surrogate endpoints in trials





SBOC

LACOG - Latin American Cooperative Oncology Group / Av. Ipiranga, 6681 - 99A - 806 / Porto Alegre, Brazil

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DE SANTA CATARINA