



STAT COURSE 2014

13-15 NOVEMBER 2014
SÃO PAULO, BRAZIL

SIMULTANEOUS TRANSLATION ENGLISH-PORTUGUESE-ENGLISH

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.

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

PRELIMINARY COURSE PROGRAMME

Day 1 Principles of statistic

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

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

Day 2 Clinical Trials Design and Analysis

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

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|---------------------|---|
| 8:30-9:15 | Non – Inferiority trial: design, concepts and issues – E. Saad (BR) |
| 9:15-10:00 | Data monitoring and early stopping rules in phase III studies – R. Parker (USA) |
| 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 – S. Michiels (FR) |
| 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 | Adaptive clinical trial designs – S. Litière (BE) |
| 16:00-17:00 | Paper discussion (Clinical trials design/analysis/endpoints) – All speakers |

Day 3 Biomarkers and Clinical Trials


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

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|---------------------|---|
| 8:30-9:15 | Integration of biomarkers in phase II/III clinical trial designs – S. Michiels (FR) |
| 9:15-10:00 | Use of intermediate and surrogate endpoints in trials – S. Litière (BE) |
| 10:00-10:10 | Discussion |
| Coffee break | |
| 10:30-11:15 | Introduction to Meta-analysis – A.D. Sasse (BR) |
| 11:15-12:00 | Panel discussion with audience: the future of cancer clinical research in Latin America – All speakers |
| 12:00-12:10 | Conclusions and Close (Gustavo Werutsky) |

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



Gilberto de Castro
Instituto do Câncer do Estado de São Paulo (ICESP), 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



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