

STAT COURSE 2015

19-21 NOVEMBER 2015
MEXICO



SIMULTANEOUS TRANSLATION ENGLISH · SPANISH · ENGLISH

The **Latin American Cooperative Oncology Group (LACOG)** is organizing the 3rd 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 19th, November 2015

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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 - A. Mohar (MX) |
| 9:15-10:00 | Current status of cancer clinical research in Brazil and Latin America: an overview - G. Werutsky (BR) |
| 10:00-10:10 | Discussion |
| Coffee break | |
| 10:30-11:15 | General introduction to hypothesis tests and clinical trials statistics - 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 | Non - Inferiority trial: design, concepts and issues - S. Halabi (USA) |
| 16:00-16:45 | Common problems in analysis and reporting of studies (Bias, ITT, multiple tests) - L. Collette (BE) |
| 16:45-16:55 | Discussion |

DAY 2 CLINICAL TRIALS DESIGN AND ANALYSIS

Friday 20th, November 2015

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| 8:30-9:15 | Data monitoring and early stopping rules in phase III studies - R. Parker (USA) |
| 9:15-10:00 | Design and analysis of phase I trials - L. Collette (BE) |
| 10:00-10:10 | Discussion |
| Coffee break | |
| 10:30-11:15 | Use of intermediate and surrogate endpoints in trials - S. Litière (BE) |
| 11:15-12:00 | Design and analysis of phase II trials, role of randomization - R. Parker (USA) |
| 12:00-12:10 | Discussion |
| Lunch | |
| 13:15-14:00 | Predictive and prognostic factors in clinical trials - S. Halabi (USA) |
| 14:00-14:45 | Diagnostic tests - S. Litière (BE) |
| 14:45-14:55 | Discussion |
| Coffee break | |
| 15:15-16:00 | Development of validation of gene signatures : experience in oncology - S. Halabi (USA) |
| 16:00-17:00 | Paper discussion (Clinical trials design/analysis/endpoints) - All speakers |

DATE & LOCATION

19-21 November 2015

INCan - Instituto Nacional de Cancerología de México

Nueva Torre de hospitalización del Instituto Nacional de Cancerología, 4to. Piso, Área Académica, Av. San Fernando 2, CP 14080, Tlalpan, D.F.

More information at www.lacog.org.br.

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



SUSAN HALABI
Duke University, US

LOCAL FACULTY

ALEJANDRO MOHAR BETANCOURT
INCan, Mexico

TONATIHU BARRIENTOS
INCan, Mexico

DAY 3 BIOMARKERS AND CLINICAL TRIALS

Saturday 21st, November 2015

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| 8:30-09:15 | Integration of biomarkers in phase II/III clinical trial designs - S. Halabi (US) |
| 09:15-10:00 | Adaptive clinical trial designs - S. Litière (BE) |
| 10:00-10:10 | Discussion |
| Coffee break | |
| 10:30-11:00 | Introduction to Meta-analysis - T. Barrientos (MX) |
| 11:00-11:45 | Case studies and interpretation of results - All participants |
| 11:45-12:00 | Group discussion with questions and answers - All speakers |
| 12:30-12:35 | Closing remarks - G. Werutsky (BR) |

ORGANIZER

ENDORISING SOCIETIES / INSTITUTIONS

SUPPORT

This is a LACOG Activity

Under the auspices of the EORTC

