History and Structure
History and Objectives

- Was **founded in 2008** by medical oncologists from several Latin American (LA) countries:
  - Mexico: Dr. Alejandro Silva
  - Brazil: Dr. Carlos Henrique Barrios, Dr. Carlos Sampaio Filho
  - Argentina: Dr. Eduardo Richardet, Dr. Gonzalo Recondo
  - Ecuador: Dr. Hernan Lupera
  - Chile: Dr. Jorge Gutierrez
  - Uruguay: Dr. Mario Varangot
  - Panama: Dr. Roberto I. Lopez

- Is a **non-profit organization** and legal entity for academic cancer research in LA

- To build a **network of LA investigators** in oncology
LACOG Executive Committee 2012-15

- Define the group scientific strategy and decision making to collaborations events, etc.
- Advises the General Assembly on new activities to be ratified by the General Assembly.
- The ExCo meets at least twice a year.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Experience</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gilberto Lopes</td>
<td>A medical oncologist at Centro Paulista de Oncologia</td>
<td>São Paulo, Brazil</td>
</tr>
<tr>
<td>Carlos Barrios</td>
<td>LACOG Executive Director, Professor of Medicine, Hospital Sao Lucas PUCRS University</td>
<td>Porto Alegre, Brazil</td>
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<tr>
<td>Gustavo Werutsky</td>
<td>LACOG Scientific Director, Former EORTC Fellow (2008-11), Assistant Professor Hospital Sao Lucas PUCRS</td>
<td>Porto Alegre, Brazil</td>
</tr>
<tr>
<td>Fernando Maluf</td>
<td>Head of Medical Oncology Department Hospital São José</td>
<td>São Paulo, Brazil</td>
</tr>
<tr>
<td>Carlos Gil Moreira</td>
<td>Coordinator of Clinical Research and Technology Incorporation of INCA (INCA)</td>
<td>Rio de Janeiro, Brazil</td>
</tr>
<tr>
<td>Guillermo Lerzo</td>
<td>Head of Medical Department Hospital Oncologico Marie Curie.</td>
<td>Buenos Aires, Argentina</td>
</tr>
<tr>
<td>Henry Gomez</td>
<td>Director of GECOPERU - Peru Cooperative Oncology Group, and Director of INEN (INEN)</td>
<td>Lima, Peru</td>
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<tr>
<td>Luis Fein</td>
<td>President GAICO Argentinian Cooperative Oncology Group, Director of Institute Oncology Rosario</td>
<td>Rosario, Argentina</td>
</tr>
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</table>
LACOG Executive Committee 2012-15
Advisory Council

The LACOG Advisory Council integrates the Executive Committee and contributes to the Group strategy and decision making.

- Max Mano
  Assistant Professor of Medicine, USP University, Director of Breast Cancer, ICESP Hospital, São Paulo, Brazil

- Paul Goss
  Professor of Medicine, Harvard Medical School, Co-Director Breast Cancer Disease Program, Director, Avon Breast Cancer Center of Excellence, Boston, US

- Diane Finkelstein
  Director of Biostatistics, Massachusetts General Hospital Biostatistics Center, Boston

- Denis Lacombe
  Medical Director Headquarter EORTC, Brussels, Belgium
Structure and Facilities

LACOG Coordinating Office

Study Design ↔ Regulatory process
Statistics ↔ Monitoring/Audits
CRF and database ↔ Communication

Porto Alegre, Brazil
LACOG Members
LACOG Membership Status

101 members
70 sites
15 countries

Mexico N=11
Guatemala N=1
El Salvador N=1
Nicaragua N=1
Colombia N=4
Ecuador N=1
Peru N=6
Bolivia N=1
Chile N=2
Uruguay N=1
Argentina N=15
Brazil N=53
Cuba N=1
Panama N=1
Venezuela N=2

*N=members
Potential of accrual

LACOG Members Institutions
Number of new cases *per month* = 13119
Experience in Clinical Trials

Clinical trials currently open for accrual or follow up (N=456)

- Phase I: 5 (1%)
- Phase II: 160 (35%)
- Phase III: 291 (64%)

Patients enrolled in clinical trials in the last 12 months. (N=1928)

- Phase I: 20 (1%)
- Phase II: 356 (18%)
- Phase III: 1552 (81%)
**Quality Control**

**Investigator Site Audit – LACOG Survey**

- **Ever audited**: 77%
- **Never audited**: 23%
- **Audited in the last two years**: 63%
- **CRO 19%**: Pharma 34%
- **No audited in the last two years**: 37%

**Figure 3. Results of FDA inspections 1998-Mar 2012 in LATAM.**

- 1998-2003
- 2003-2008
- 2008-2012

**NAI** – No Action Indicated / **VAI** – Voluntary Action Indicated / **OIA** – Official Action Indicated

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**All audited LACOG sites are active.**

**FDA** The number of regulatory inspections from the FDA—as well as from country regulators—has been on the rise in Latin America. There’s been a commensurate increase in the overall quality standards and expectations for studies in the region.

## Study Types

<table>
<thead>
<tr>
<th>Study Type</th>
<th>LACOG Activities</th>
<th>Legal Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator Initiated</td>
<td>Full management</td>
<td>LACOG</td>
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<tr>
<td>Research</td>
<td></td>
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<tr>
<td>Intergroup Studies</td>
<td>Full/Partial management</td>
<td>Leading Group/LACOG</td>
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<tr>
<td>Pharma Sponsored</td>
<td>Partial management/LACOG Investigator in the Steering Committee</td>
<td>Pharma</td>
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<tr>
<td>Study Number</td>
<td>Sponsor</td>
<td>LACOG activities</td>
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</tbody>
</table>
| LACOG 0801   | LACOG (financial support GSK) | • Regulatory  
• Monitoring  
• Pharmacovigilance  
• Drug distribution  
• Outsourced: CRF and statistical analysis* | Phase II, randomized, capecitabine/lapatinib, vinorelbine/lapatinib, gemcitabine/lapatinib | Metastatic breast cancer HER2 + (Argentina, Brazil, Peru) | Finished accrual (N=142) Dec 2012 |
| LACOG 0213   | Celgene | • Site selection  
• Regulatory assistance  
• Recruitment support  
• LACOG Investigator in the Steering Committee  
• CRO PPD | Phase III, Double-Blind Randomized, Rituximab + Lenalidomide versus Rituximab + Placebo** | Follicular Lymphoma (Brazil) | Approved by CONEP and ANVISA |
| LACOG 0313   | LACOG - GBG/BIG (financial support Pfizer) | • Full management (site selection, regulatory, contracts, monitoring and coordination in Brazil) | Phase III, Double-Blind Randomized, Palbociclib x Placebo** | Breast cancer, HER2 +, HR + (Brazil) | Regulatory process |
| LACOG 0114   | Inscer (financial Cnpq) | • Full management | Phase II, [18F]FDG InsCer/PUCRS | Lung Cancer, stage I-III before surgery (Brazil) | Recruiting |
| LACOG 0214   | Inscer (FINEP) | • Full management | Validation of Tecnecium x Indium to Neuroendocrine tumor staging | NETs staging (Brazil) | Regulatory process |

*Since 2013 LACOG has a statistician and uses CRF system (OpenClinica)

**Registration trial
### Ongoing studies

<table>
<thead>
<tr>
<th>Study Number</th>
<th>Sponsor</th>
<th>LACOG Activities</th>
<th>Study Design</th>
<th>Population/Setting</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Epidemiologic/Translational</strong></td>
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</tbody>
</table>
| LACOG 0413   | LACOG (EORTC) | • Site selection  
• Regulatory Brazil + Latin America  
• Assistance trial coordination | Prospective | Male Breast Cancer (Brazil, Peru, Mexico, Colombia, Panama) | Regulatory process (Brazil)  
Recruiting (Peru, Chile and Mexico) |
| LACOG 0113   | LACOG (Novartis) | | Retrospective | HR+, HER2- metastatic breast cancer (Brazil) | Protocol development and site selection |
| LACOG 0111   | Massachusetts General Hospital | Full management (site selection, regulatory, contracts, monitoring and coordination in Brazil) | Retrospective, translational, gene signature | Metastatic breast cancer, HR+ (Brazil, and Peru) | Recruiting |
| LACOG 0211   | INCA | • Site selection  
• Regulatory Latin America  
• Assistance trial coordination | Epidemiologic, translational, EML4-ALK fusion | Non-small cell lung cancer (Chile, Colombia, Peru, Panama, Mexico, Cuba, Venezuela) | Recruiting (Chile, Mexico and Peru)  
Regulatory process (Colombia, Cuba and Panama) |
Partnerships
LACOG is a BIG member since 2013
Partnerships

LACOG – NCCN Prostate Cancer Guidelines 2014

LACOG Panel of Reviewers will adjust the guideline for Latin America
Portuguese and Spanish translation
Release April 2014
Partnerships

EORTC – LACOG Task Force on Cervical Cancer

- EORTC Gynecological and Radiotherapy Groups + LACOG investigators
  - Objectives
    - to qualify LACOG radiotherapy sites by QART
    - to develop phase II-III studies in locally advanced cervical cancer
    - to improve cure rates

Strategic collaboration with a high recruitment potential and trial management expertise
Funding
Funding

Study Budget Parts:
1. Regulatory (cep, conep, anvisa)
2. Patient fee + insurance
3. Coordinating Office (development, managing, monitoring, etc.)
LACOG is recognize by the Ministry of Justice and Health to participate in the PRONON project.

This allows LACOG to receive deductible donations for specific projects and events.
Publications
Inequalities in Pap smear screening for cervical cancer in Brazil

Jeovany Martínez-Mesa a, *, Gustavo Werutsky a, b, Raquel Barth Campani b, Fernando César Wehrmeister c, Carlos Henrique Barrios a, b

a Latin American Cooperative Oncology Group (LACOG), Porto Alegre, Brazil
b School of Medicine, Hospital São Lucas, Pontifícia Universidade Católica do Rio Grande do Sul (PUCRS), Porto Alegre, Brazil
c Postgraduate Program in Epidemiology, Universidade Federal de Pelotas (UFPEL), Pelotas, Brazil

Abstract

Objective. To examine the risk factors associated with never being screened for cervical cancer (CC) in Brazil.

Methods. Using the National Household Sample Survey 2008 (PNAD), we analyzed data from 102,108 Brazilian women ages 25–64 years. The patients were analyzed as having been or never having been screened with a Pap smear (Yes/No). Age-adjusted prevalence of never-screening was analyzed using a Chi-squared test. Crude and adjusted models using Poisson regression were performed.

Results. The prevalence of never-screened women for CC was 12.9%, 11.5% and 22.2% in Brazil in general, urban and rural areas, respectively. The Brazilian region with the highest prevalence of never-screening was the North (17.4%, 14.7% and 27.3% in general, urban and rural areas, respectively). The factors associated with a higher risk for never being screened were the following: poverty, younger age, lower educational level, non-white skin color, a greater number of children, no supplemental health insurance and not having visited a doctor in the past 12 months.

Conclusion. Socioeconomic and demographic conditions lead to inequalities in access to Pap smear screening in Brazil. Public health policy addressing these risk groups is necessary.

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Planning cancer control in Latin America and the Caribbean


Non-communicable diseases, including cancer, are overtaking infectious disease as the leading health-care threat in middle-income and low-income countries. Latin American and Caribbean countries are struggling to respond to increasing morbidity and death from advanced disease. Health ministries and health-care systems in these countries face many challenges caring for patients with advanced cancer: inadequate funding; inequitable distribution of resources and services; inadequate numbers, training, and distribution of health-care personnel and equipment; lack of adequate care for many populations based on socioeconomic, geographic, ethnic, and other factors; and current systems geared toward the needs of wealthy, urban minorities at a cost to the entire population. This burgeoning cancer problem threatens to cause widespread suffering and economic peril to the countries of Latin America. Prompt and deliberate actions must be taken to avoid this scenario. Increasing efforts towards prevention of cancer and avoidance of advanced, stage IV disease will reduce suffering and mortality and will make overall cancer care more affordable. We hope the findings of our Commission and our recommendations will inspire Latin American stakeholders to redouble their efforts to address this increasing cancer burden and to prevent it from worsening and threatening their societies.
Breast cancer is the most common cancer in women worldwide and 70% of breast cancer deaths occur in women from low-income and middle-income countries. Latin America has about 115,000 new cases of disease every year, with about 50,000 arising in Brazil. We examined the present status of breast cancer in Brazil as an example of the health effects of geographical, ethnic, and socioeconomic diversities on delivery of care. Our goal was to identify deficiencies that could be responsible for disparities in survival from breast cancer. We searched the English and Portuguese published work and reviewed national databases and Brazilian publications. Although the availability of publications specific to Brazil is low in general, we identified several factors that could account for disparities: delays in diagnosis due to low cancer awareness and implementation of mammography screening, unknown quality of surgery, and restricted access to radiotherapy and modern systemic therapies.
ASCO 2013:

A phase II randomized study of Lapatinib in combination with Capecitabine, Vinorelbine or Gencitabine as first or second line-therapy in patients with HER2 positive metastatic breast cancer progressing after taxane (LACOG 0801). Henry Leonidas Gomez, Silvia P. Neciosup, Celia Tosello, et al. (suppl; abstr 851426)

Inequities in Pap smear screening for cervical cancer between Brazilian urban and rural populations. Jeovany Martínez-Mesa, Gustavo Werutsky, Carlos Alberto Sampaio-Filho, et al. J Clin Oncol 31, 2013 (suppl; abstr e12510)

ASCO 2012:


ASCO 2010

Poster:
Breast cancer in the Pan-American region: inequities in incidence and mortality rates according to the human development index.

Poster:
A phase II randomized study of Lapatinib in combination with Capecitabine, Vinorelbine or Gemcitabine as first or second line-therapy in patients with HER2 positive metastatic breast cancer progressing after taxane (LACOG 0801).
Events Organized by LACOG 2013
Latin America 'threatened by rising cancer cases'

Cancer is threatening to overwhelm Latin American countries, experts writing in Lancet Oncology warn.

There are far fewer cases of cancer in the region than in the US or Europe - but the proportion who die is far higher, they say.

Late diagnosis and poor access to treatment are the main reasons for the disparity, they add.

They said as life expectancy increased, cancer would become more common, and many countries would not cope.
LACOG Stat Course

LACOG STAT COURSE
2013
07 - 09 November, Brazil

OBJECTIVES
Understand the concepts and statistical methods required in clinical research.

TARGET AUDIENCE
Statisticians, epidemiologists, medical doctors, nurses, pharmacists, and all who have been working with clinical trials in Latin America. The LACOG Stat Course in 2013 has 200 hours and is accredited by Universidade Federal de Santa Catarina (UFSC) to provide post-graduation hours of credit.

AGENDA

DAY 1 Principles of statistics
- Epidemiology in oncology research
- Cancer clinical trials in Brazil and Latin America on overview
- General introduction to clinical trials statistics and hypothesis testing
- Analysis of time to event endpoints in oncology

DAY 2 Clinical Trials Design and Analysis
- Endpoints and design of Phase III trials
- Sample size for phase III trials
- Common problems in trial design and reporting of studies (bias, ITT, multiple trials, ...) Data monitoring and early stopping rules in phase III studies
- Design and analysis of phase I trials
- Design and analysis of phase II trials, role of randomization
- Predictive and prognostic factors in clinical trials
- Paper discussion (clinical trial design/analysis/endpoints)

DAY 3 Biomarkers and Clinical Trials
- Diagnostic tests
- Development and validation of gene signatures, experience in oncology
- Adaptive clinical trial designs
- Integration of biomarkers in phase I/II clinical trial designs
- Use of intermediate and surrogate endpoints in trials
- Non-inferiority trial design, concepts and issues
- Introduction to Meta-Analysis
- Paper discussion (genes and biomarkers studies designs)

DATE & LOCATION
07 - 09 November 2013
Hospital São Lucas PUCRS
Avenida I. José de Abreu 6610 - 2nd floor
Porto Alegre, Brazil

FACULTY

INTERNATIONAL FACULTY
Laurence Caetano
EROS, Belgium

LOCAL FACULTY
Andre Serafim
CONSERT, Brazil

Sao Miguel
EROS, Brazil

Support for this educational activity is provided by:

LACOG Stat Course 2013
Events Organized by LACOG 2014
LACOG Events 2014

BEST OF ASCO®
2014 ANNUAL MEETING

29 e 30 de Agosto de 2014
Pestana Bahia Hotel
Salvador - Bahia

REALIZAÇÃO:

STAT COURSE
2014

13-15 NOVEMBER 2014
SÃO PAULO, BRAZIL