Jorge Gomez, M.D., Ph.D.
Director, Office of Latin American Cancer Program Development, Office of the Director, National Cancer Institute

Office of Latin American Cancer Program Development: Partnering for Cancer Research in Latin America

National Cancer Advisory Board Meeting
September 16, 2009
Bethesda, MD
Cancer as a National Priority

“It will launch a new effort to conquer a disease that has touched the life of nearly every American by seeking a cure for cancer in our time.”

Remarks of President Barack Obama (in reference to Recovery Plan) Address to Joint Session of Congress February 24, 2009
“Global health research ‘should be a conversation with other countries,’ but not one in which the great ‘United States tells the world what the answers are without listening to their experiences’.”

Remarks of NIH Director Francis Collins
FIC’s Global Health Matters Newsletter
NIH “Town Meeting”
August 17, 2009
The National Cancer Act of 1971 directs that NCI “support research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people; collaborative research involving American and foreign participants; and training of American scientists abroad and foreign scientists in the United States.”
Understanding the U.S. Hispanic Population: Current Growth Trends

- As of July 1, 2006:
  - 44.3 million Hispanics, 14.8% of total population of 299 million
- Between 2000 and 2006:
  - Hispanics accounted for one-half of the nation’s growth
  - Hispanic growth rate (24.3%) was more than three times the growth rate of the total population (6.1%)

Source: U.S. Census Bureau, Population Estimates July 1, 2006
Hispanic Population Growth: 2000 to 2006

Population in millions

<table>
<thead>
<tr>
<th>Year</th>
<th>Population (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>35.6</td>
</tr>
<tr>
<td>2001</td>
<td>37.1</td>
</tr>
<tr>
<td>2002</td>
<td>38.5</td>
</tr>
<tr>
<td>2003</td>
<td>39.9</td>
</tr>
<tr>
<td>2004</td>
<td>41.3</td>
</tr>
<tr>
<td>2005</td>
<td>42.7</td>
</tr>
<tr>
<td>2006</td>
<td>44.3</td>
</tr>
</tbody>
</table>

Source: U.S. Census Bureau, Population Estimates July 1, 2006
## Top Five States by Hispanic Population Size: 2006

<table>
<thead>
<tr>
<th>Rank</th>
<th>State</th>
<th>Population Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>California</td>
<td>13,074,156</td>
</tr>
<tr>
<td>2</td>
<td>Texas</td>
<td>8,385,139</td>
</tr>
<tr>
<td>3</td>
<td>Florida</td>
<td>3,646,499</td>
</tr>
<tr>
<td>4</td>
<td>New York</td>
<td>3,139,456</td>
</tr>
<tr>
<td>5</td>
<td>Illinois</td>
<td>1,886,933</td>
</tr>
</tbody>
</table>

Source: U.S. Census Bureau, Population Estimates July 1, 2006
# Top Five States by Hispanic Growth Rate: 2000 to 2006

(For states with 100,000 or more Hispanics in 2006)

<table>
<thead>
<tr>
<th>Rank</th>
<th>State</th>
<th>Growth Rate (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Arkansas</td>
<td>60.9</td>
</tr>
<tr>
<td>2</td>
<td>Georgia</td>
<td>59.4</td>
</tr>
<tr>
<td>3</td>
<td>South Carolina</td>
<td>57.4</td>
</tr>
<tr>
<td>4</td>
<td>Tennessee</td>
<td>55.5</td>
</tr>
<tr>
<td>5</td>
<td>North Carolina</td>
<td>54.9</td>
</tr>
</tbody>
</table>

Source: U.S. Census Bureau, Population Estimates July 1, 2000 to July 1, 2006
Nativity of Hispanics in the United States: 
*U.S. Born vs. Foreign Born* in 2006

Source: U.S. Census Bureau, 2006 American Community Survey
US Hispanic Population - Median Age by Sex: 2006

Source: U.S. Census Bureau, 2006 American Community Survey
Median Earnings by Sex in the Past 12 Months: 2006

(For employed, full-time, year-round workers 16 and older. In 2006 inflation-adjusted dollars)

Source: U.S. Census Bureau, 2006 American Community Survey
The Cancer Burden in Latin America and United States Latino Population

- Cancer ranked among the top three causes of death in Latin America; In the United States it is among the top two
- Cancer burden is increasing in Latin America
- Types of cancer that impact U.S. Hispanic populations are similar to that seen in the countries of origin
- Hispanics in the United States experience disparities in certain types of cancer when compared to non-Hispanic whites (e.g. liver, stomach, cervical, acute lymphocytic leukemia, and gallbladder)
- Many of the cancers with higher incidence among Latinos are associated with infectious agents (e.g. HPV, H. pylori, Hepatitis B&C)
- Breast cancer presents differently in Hispanic women when compared to non-Hispanic White women, even when taking into account equal access to care and healthcare utilization
### Top 5 Cancers in U.S. Hispanic Men as Compared to Argentina, Brazil, Chile, Mexico and Uruguay

**AGE-ADJUSTED MORTALITY RATES (1999-2003*)**

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>US Hispanic</th>
<th>Non-Hispanic White</th>
<th>Argentina</th>
<th>Brazil</th>
<th>Chile</th>
<th>Mexico</th>
<th>Uruguay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung and bronchus</td>
<td>37.2</td>
<td>73.8</td>
<td>36.4</td>
<td>20.2</td>
<td>21.0</td>
<td>16.6</td>
<td>48.1</td>
</tr>
<tr>
<td>Prostate</td>
<td>22.1</td>
<td>26.7</td>
<td>17.2</td>
<td>15.8</td>
<td>20.8</td>
<td>14.9</td>
<td>22.6</td>
</tr>
<tr>
<td>Colon and rectum</td>
<td>17.5</td>
<td>23.7</td>
<td>14.7</td>
<td>6.4</td>
<td>7.7</td>
<td>4.5</td>
<td>18.4</td>
</tr>
<tr>
<td>Liver and intrahepatic bile duct</td>
<td>10.7</td>
<td>6.3</td>
<td>5.2</td>
<td>5.2</td>
<td>6.6</td>
<td>7.1</td>
<td>2.2</td>
</tr>
<tr>
<td>Pancreas</td>
<td>9.2</td>
<td>5.4</td>
<td>10.3</td>
<td>15.1</td>
<td>32.5</td>
<td>9.9</td>
<td>12.8</td>
</tr>
</tbody>
</table>


^Data derived from Globocan 2002
### Top 5 Cancers in U.S. Hispanic Women as Compared to Argentina, Brazil, Chile, Mexico and Uruguay

**AGE-ADJUSTED MORTALITY RATES (1999-2003*)**

<table>
<thead>
<tr>
<th>Cancer</th>
<th>US Hispanic</th>
<th>Non-Hispanic White</th>
<th>Argentina</th>
<th>Brazil</th>
<th>Chile</th>
<th>Mexico</th>
<th>Uruguay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>16.3</td>
<td>25.4</td>
<td>21.8</td>
<td>14.1</td>
<td>13.1</td>
<td>10.5</td>
<td>24.1</td>
</tr>
<tr>
<td>Lung and bronchus</td>
<td>14.7</td>
<td>42.0</td>
<td>7.1</td>
<td>7.2</td>
<td>7.6</td>
<td>6.6</td>
<td>5.8</td>
</tr>
<tr>
<td>Colon and rectum</td>
<td>11.4</td>
<td>16.4</td>
<td>9.8</td>
<td>6.5</td>
<td>7.8</td>
<td>4.1</td>
<td>14.2</td>
</tr>
<tr>
<td>Pancreas</td>
<td>7.5</td>
<td>9.0</td>
<td>5.9</td>
<td>3.4</td>
<td>4.8</td>
<td>4.6</td>
<td>7.2</td>
</tr>
<tr>
<td>Ovary</td>
<td>6.0</td>
<td>2.7</td>
<td>4.2</td>
<td>3.3</td>
<td>4.0</td>
<td>3.6</td>
<td>5.0</td>
</tr>
</tbody>
</table>


*Data derived from Globocan 2002*
• Hispanics will become the largest minority group in the United States
• Cancer rates increase for first-generation Hispanics in the United States compared to cancer rates in their country of origin (Pinheiro et al, Cancer Epi Biomarkers Prev 2009;18(8). August 2009)
• Reducing the cancer burden in the United States will depend on our ability to understand and control cancer at the cultural, behavioral, and molecular level
Office of Latin American Cancer Program Development

- Addressing the cancer burden in Latin America as a means of understanding cancer in the US Latino population
- Closing the research gap in Latin America
- Fulfilling NCI’s role as a global cancer research leader through knowledge sharing
OLACPD Vision and Mission

Vision

• To advance local and global initiatives to prevent, diagnose, and treat cancer by facilitating the development of a comprehensive cancer research infrastructure in Latin America

Mission

• To advance the mission of NCI by collaborating with government agencies, researchers, and organizations to further cancer research in Latin American countries
Guiding Principles

• **New Insights**
  Working with Latin America will provide insight into cancer trends among the growing Hispanic population in the United States.

• **Collaboration**
  Fostering collaborations based on mutual respect of the cultures, nuances, laws and regulations of each country will promote stronger partnerships with Latin America.
Guiding Principles

• **Advancing Science**
  Initiating research projects based on common interests and high bioethical standards will elevate the quality and credibility of cancer research conducted in Latin America.

• **Capacity Building**
  Building research capacity in Latin America will lead to independent, sustainable infrastructure to support first-rate clinical research around the globe.
  - US investigators will have more capable partners
The Value of Collaborating in Latin America

- Highlights the importance of reaching beyond borders
- Demonstrates the benefit of Latin American cancer research in improving care for the growing Hispanic population in the United States
- Leverages countries’ resources and breaks down research silos
- Enhances research capabilities in Latin America and the U.S. for global benefit
- Improves state of the science
- Provides the opportunity for NCI to have significant impact in the United States and abroad
Model for Partnerships and Collaborations

NCI/FIC Resources
- Grants
- Contracts
- Knowledge Transfer
- Training

Public-Private Partnerships
- Industry
- Professional Societies
- Advocacy Organizations

Latin American Partners
- Governments
- Academia

Contributions (US/Foreign)
- Philanthropic and In-kind services
- Foundations

NCI/FIC OLACPD

Connecting at the government-to-government and investigator levels
Country Partnership Criteria

- Established healthcare system
- Ongoing scientific research and supporting technological infrastructure
- Existing in-country cancer research network
- Central government agency responsible for:
  - Healthcare provider
  - Healthcare policy making
  - Nation-wide scientific research
# Countries Meeting Partnership Criteria

The status of cancer research networks, technology, infrastructure and the interaction of government agency to facilitate were determining factors for the selection of target countries.

<table>
<thead>
<tr>
<th></th>
<th>Healthcare Systems</th>
<th>Scientific Research and Technology</th>
<th>Government Agency</th>
<th>Cancer Research Networks</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mexico</strong></td>
<td>✓</td>
<td>✓</td>
<td>Ministry of Health</td>
<td>✓</td>
<td>Collaboration with US institutions</td>
</tr>
<tr>
<td><strong>Argentina</strong></td>
<td>✓</td>
<td>✓</td>
<td>Ministry of Science Technology and Innovative Products</td>
<td>✓</td>
<td>Core facilities</td>
</tr>
<tr>
<td><strong>Brazil</strong></td>
<td>✓</td>
<td>✓</td>
<td>Ministry of Health</td>
<td>✓</td>
<td>Advanced technologies and human resources</td>
</tr>
<tr>
<td><strong>Chile</strong></td>
<td>✓</td>
<td>✓</td>
<td>Ministry of Health</td>
<td>✓</td>
<td>Advanced bioinformatics</td>
</tr>
<tr>
<td><strong>Uruguay</strong></td>
<td>✓</td>
<td>✓</td>
<td>Ministry of Public Health</td>
<td>✓</td>
<td>Advanced bioinformatics</td>
</tr>
</tbody>
</table>
US-LA CRN At a Glance

- Launched in March 2009
- Unprecedented Bilateral Partnership Connecting:
  - Governments
  - Institutions & Researchers
  - Non-Governmental Organizations
- Multi-Phased Strategic Approach
- Governed by a Steering Committee with input from an External Research Focus Group
- Co-Developing Pilot Projects
  - Selecting research areas based on disease burden
  - Breast Cancer: first pilot project
US-LA CRN Goals

- Develop a comprehensive understanding of the status of the disease burden and cancer research and care infrastructure in participating countries
- Promote and leverage partnerships for mutual benefit across the continuum of basic and clinical cancer research
- Build collaborative relationships across Latin America that will enable the co-development and in-country sustainability of cancer research, including high-quality clinical studies
US-LA CRN: A Multi-Phased Strategic Approach

Phase I: Due Diligence, Knowledge Building, and Feasibility Assessment
- June 2008 – Ongoing
- Understanding the Latin American cancer burden
- Understanding of Latin American cancer research and care delivery
- Establish/strengthen internal collaborations and external partnerships
- Develop strategic plan

Phase II: Pilot Research Studies
- December 2009 – February 2011
- Develop and collaborate with regional clinical research IRBs
- Develop standards and policies for biospecimen annotation, storage, and delivery
- Collaboratively plan and conduct pilot research studies (i.e., breast cancer)
- Initiate training programs for basic and clinical investigators

Phase III: Full Implementation
- Identify and develop regional clinical cancer networks
- Establish “virtual” tumor and specimen banks
- Establish cancer registries
- Support development of regional centers of advanced technology
- Continue training programs
US-LA CRN: Developing Programs in Three Broad Scientific Areas

**Basic and Clinical Research**
- Supporting Research Studies and Research Networks
- Enhancing Cancer Research Infrastructure in Latin America

**Training Programs**
- Providing Opportunities for Exchanges in Training
- Developing the Cancer Research Workforce in Latin America

**Technology and Capacity Building**
- Partnering with Latin American Clinical Cohorts and Biospecimen Networks
- Adapting Best Practices for Advanced Technologies
US-LACRN Governance

Research Focus Group
[Scientific Input]

Steering Committee
[Conceptual Input]

U.S. – LA CRN
[Implementation]

Basic and Applied Technologies
Clinical Oncology
Pathology
Epidemiology
Bioethics & Intellectual Property
Information & Data Management
Communications
US-LA CRN: Top Hispanic and Cancer Focused Researchers in Latin America and United States

Research Focus Group
- Carlos Arteaga, MD
- Pelyao Correa, MD
- Nancy Davidson, MD
- Gabriel Hortobagyi, MD
- Elmer Huerta, MD, MPH
- Gary Kelloff, MD
- Christopher Logothetis, MD
- Hala Moddelmog, MA
- Larry Norton, MD
- Olunfunmilayo Olopade, MD
- Edith Perez, MD
- Charles Perou, MD
- Amelie Ramirez, DrPH, MPH
- Samuel Wells, MD
- Cheryl Wilman, MD

Steering Committee
- Osvaldo Podhajcer, PhD, Argentina
- Luiz Santini, MD, Brazil
- Juan de Dios Reyes, MD, MPH, Chile
- Alejandro Mohar, MD, ScD, Mexico
- Jorge Gomez, MD, PhD, United States
- Ignacio Musé, MD, Uruguay
Infrastructure for Working Together

US – LA CRN

Steering Committee Teleconferences
Sub-committee Meetings
Research Focus Group Teleconferences
US-LA CRN Annual Meetings
Communications Working Group
Training and Education Workshops
Professional Networking Site
Shared Bioinformatics Platform

National Cancer Institute
Enabling Cross-Country Networking

Password Protected Website for Collaboration

United States-Latin America Cancer Research Network

Welcome to the United States-Latin America Cancer Research Network

Get started on this site:
1) Read Guidelines and Policies
2) Complete your Member Profile
3) Participate in your Group or Committee
4) Start a Discussion or Ask a Question of other Network members
5) Read and write News and Updates
6) Post your Events

News and Updates

Posted by Office of LA Cancer Program Dev. on July 16, 2009 at 11:30am

Posted by Office of LA Cancer Program Dev. on April 28, 2009 at 11:30am
Harnessing the NCI caBIG® for International Breast Cancer Pilot

CLINICAL TRIAL MANAGEMENT SYSTEM

CLINICAL DATA MANAGEMENT SYSTEM

TISSUE BANKING AND PATHOLOGY TOOLS

Adverse Events Reporting (caAERS)
Cancer Clinical Patient Registry (C3PR)
caXchange
Patient Study Calendar
caTissue Suite
US-LA CRN Bioinformatics Goals

Short Term Goals

• Implement technologies addressing the immediate needs of the pilot study
• Lay groundwork for long range objectives by addressing pre-requisites

Long Term Goals

• Further enhance technologies with additional applications
• Provide an informatics model for future Latin American cancer studies
First Pilot Project: Breast Cancer Study

• Addressing the high breast cancer incidence in Latin America
• Providing data to advance cancer management for United States Hispanic population
• Focusing on 21st century biomedical concepts
  ▪ Molecular Profiling of Breast Cancer
  ▪ Understanding/Improving Early Detection
  ▪ Clinical Trials
• Improving biobanking process in Latin America
• Establishing sustainable infrastructures and cancer research networks
International Clinical Trial on Advanced Breast Cancer

Cross-Nation Clinical Trial in Locally Advanced Breast Cancer (Stage II and III) using Local Standard Chemotherapy in the Neoadjuvant Setting

**Primary objective:** To obtain information on molecular profiles of breast cancers within each of the five countries

- Open to all patients presenting with locally advanced breast cancer
- Stratified to one of four arms based on hormone receptor status
- Surgical specimens used to obtain pathological response (primary endpoint for the study) and sample for analysis of molecular characteristics
- Baseline biopsy and surgical specimens to analyze retrospectively using standardized assays defined for the study (e.g., ER, PR, HER2, genomics).
Breast Cancer Study: Protocol Schema

Locally Advanced Breast Cancer

HER2+, HR+
Standard Therapy

HER2+, HR−
Standard Therapy

HER2−, HR+
Standard Therapy

HER2−, HR−
Standard Therapy

Blood and Tissue

HR, HER2 Community Assays for Stratification

Standard Therapies May Vary by Arm
OLACPD: Enabling Collaboration and Cancer Research Advances in the United States and Latin America

2008
OLACPD Established
Prospective country partners engaged
Work across NCI to assess need and leverage resources

March 2009
US - LA CRN Launched
Breast Cancer Workshop on Pilot Design
Top researchers engaged from U.S. NCI, External Research Focus Group, and Latin America

April-May, 2009
International Clinical Trials and Trial Design Workshops in partnership with ASCO and ASH
Training and design meetings held in Brazil and Argentina to develop protocols for clinical trials for US – LA CRN

= Collaboration with partners occurs at all stages: planning, design, and implementation
OLACPD: Enabling Collaboration and Cancer Research Advances in the United States and Latin America

- **June 2009**: LOI Signing Ceremony between United States and Chile
- **September 2009**: LOI Signing: United States, Argentina, Brazil, Mexico, and Uruguay
- **Upcoming in 2009**: Planning Workshops:
  - Epidemiology
  - Harmonization/Standardization
  - Tumor Banking
  Training: Bioinformatics Bootcamp
- **January 2010**: Breast Cancer Pilot Project Launch

= Collaboration with partners occurs at all stages: planning, design, and implementation
LOI Signing Ceremony with Argentina, Brazil, Mexico, and Uruguay

Who
Dignitaries from Argentina, Brazil, Mexico, Uruguay, Chile and U.S.

When
September 30, 2009

Where
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC (tentative)
Additional OLACPD Supported Projects

- U.S. - Mexico Border Workshop on Cervical Cancer (November 2009, Texas)
  - Focus: Identify research gaps in the areas of infection, prevention and diagnosis, early detection, and treatment of cervical cancer.
  - Outcome: Joint projects aimed at reducing the burden of cervical cancer in both countries.
  - Participating institutions: academic institutions from Arizona, New Mexico, and Texas; HHS Office of Global Health Affairs; NCI; Instituto Nacional de Cancerología; Instituto Nacional de Salud Publica; Instituto Mexicano del Seguro Social; and healthcare providers from the Mexican border states.

- Additional Research Programs:
  - Gall bladder cancer with Chile
  - AIDS malignancies and cancer research program with Brazil
  - Genome-wide association studies with Latin America and Spain
NCI
A Global Leader in Cancer Research, Diagnosis, Prevention, and Treatment

OLACPD
A Model for International Research and Collaboration
Burning Questions

- Should there be parallel clinical research studies conducted in the United States with the Latino population?
- Given the fact that this is a new program, should this Office facilitate all cancer research focused in Latin America?
- To what extent should US institutions participate in the research projects?

http://olacpd.cancer.gov
www.cancer.gov/espanol/instituto/olacpd