







ADVANCING CANCER RESEARCH WITH

FOMENTO DE LA INVESTIGACIÓN DEL CÁNCER CON

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

National Cancer Advisory Board Meeting September 16, 2009 Bethesda, MD

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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 as an NIH Priority

"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

NCI's Global Mandate

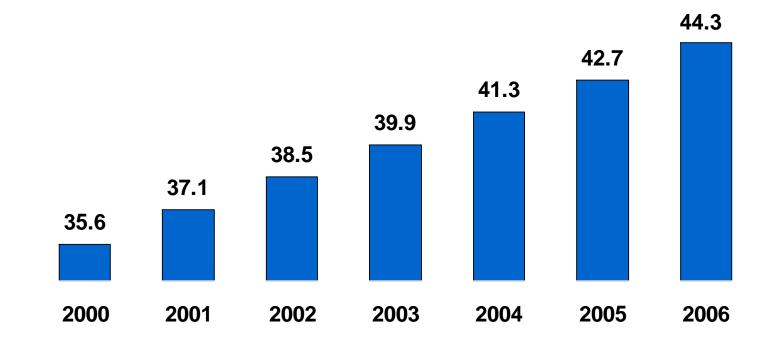
The National Cancer Act of 1971 directs that NCI "support research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people; collaborative research involving American and foreign participants; and training of American scientists 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%)

Hispanic Population Growth: 2000 to 2006

Population in millions



Source: U.S. Census Bureau, Population Estimates July 1, 2006

Top Five States by Hispanic Population Size: 2006

Rank	State	Population Size			
1	California	13,074,156			
2	Texas	8,385,139			
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3	Florida	3,646,499			
4	New York	3,139,456			
5	Illinois	1,886,933			

Source: U.S. Census Bureau, Population Estimates July 1, 2006

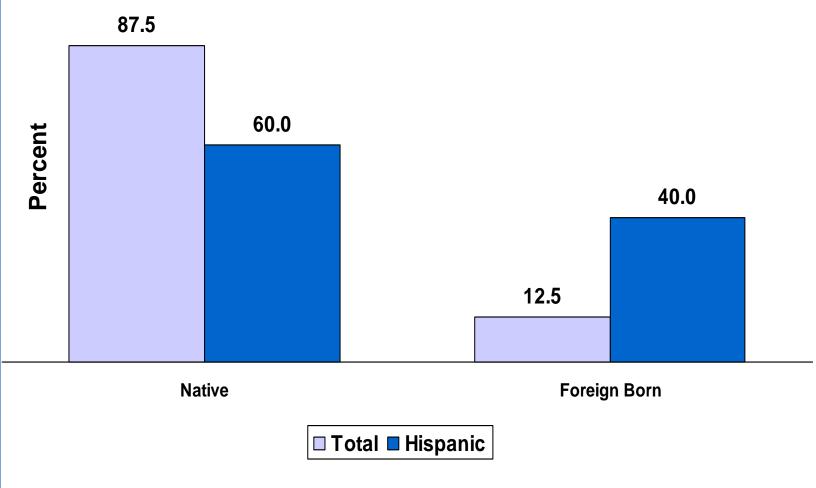
Top Five States by Hispanic *Growth Rate*: 2000 to 2006

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

		Growth Rate
Rank	State	(percent)
1	Arkansas	60.9
2	Georgia	59.4
3	South Carolina	57.4
4	Tennessee	55.5
5	North Carolina	54.9

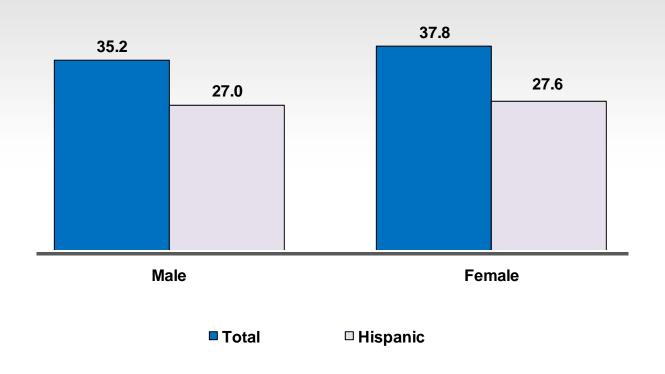
Source: U.S. Census Bureau, Population Estimates July 1, 2000 to July 1, 2006

Nativity of Hispanics in the United States: *U.S. Born vs. Foreign Born* in 2006



Source: U.S. Census Bureau, 2006 American Community Survey

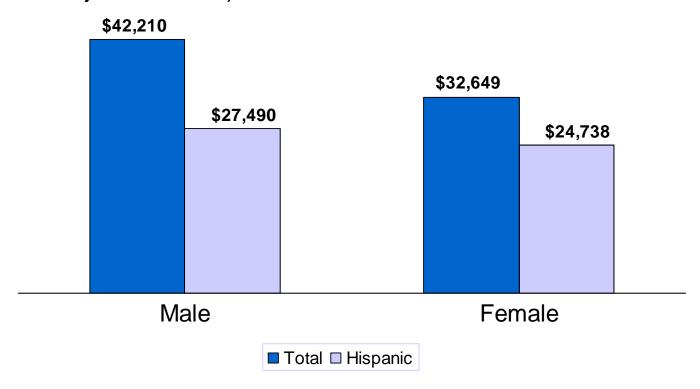
US Hispanic Population - Median Age by Sex: 2006



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*)

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

^{*}Annual Report to the Nation on the Status of Cancer 1975-2003, Featuring Cancer Among U.S. Hispanic/Latino Populations. Cancer. October 15, 2006. Vol. 107, Issue 7.

[^]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*)

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

^{*}Annual Report to the Nation on the Status of Cancer 1975-2003, Featuring Cancer Among U.S. Hispanic/Latino Populations. Cancer . October 15, 2006. Vol. 107, Issue 7.

[^]Data derived from Globocan 2002

Understanding Cancer in the U.S. and Latin America - The Research Need is Great

- 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)
- Limited data and understanding of cancer burden by Hispanic subgroups in the United States (Howe et al, Cancer Causes Control. DOI 10.1007/s100552-009-9398-8. July 2009. Howe et al, Annual Report to the Nation, DOI 10.1002/cncr.22193. Sep 2006)
- 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

NCI FIC OLACPD

Latin American
Partners
Goverments
Academia

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

United States-Latin America Cancer Research Network (US-LA CRN):

A New Model for International Cancer Research



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.

	Healthcare Systems	Scientific Research and Technology	Government Agency	Cancer Research Networks	Other
Mexico	V	V	Ministry of Health	$\sqrt{}$	Collaboration with US institutions
Argentina	V	V	Ministry of Science Technology and Innovative Products	\checkmark	Core facilities
Brazil	V	V	Ministry of Health	V	Advanced technologies and human resources
Chile	V	V	Ministry of Health	$\sqrt{}$	Advanced bioinformatics
Uruguay	V	V	Ministry of Public Health	V	Advanced bioinformatics

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



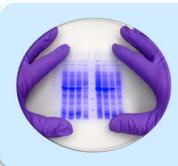
Basic and Clinical Research

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



Training Programs

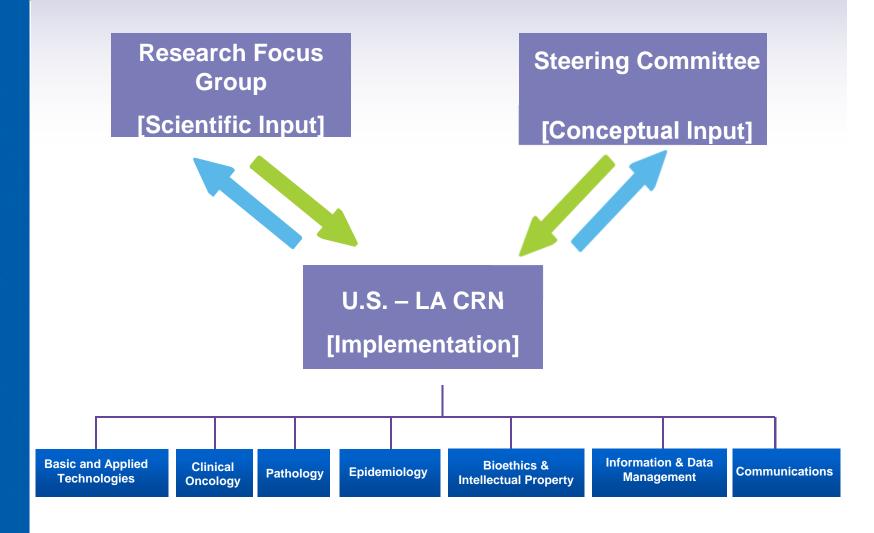
- Providing Opportunities for Exchanges in Training
- Developing the Cancer Research Workforce in Latin America



Technology and Capacity Building

- Partnering with Latin American Clinical Cohorts and Biospecimen Networks
- Adapting Best Practices for Advanced Technologies

US-LACRN Governance



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

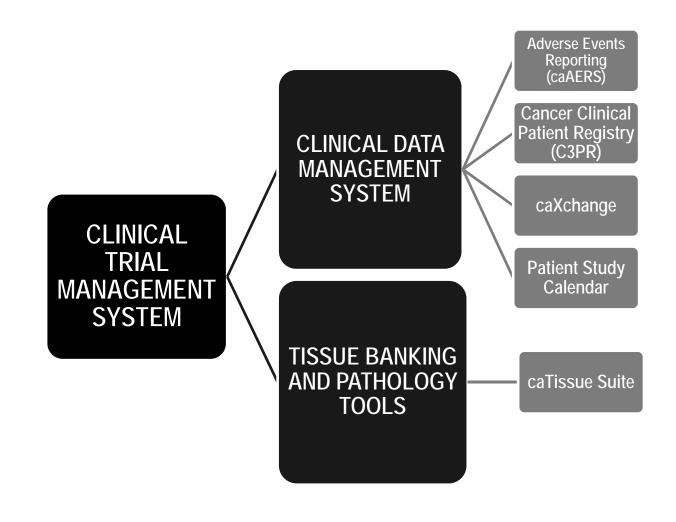


Enabling Cross-Country Networking

Password Protected Website for Collaboration



Harnessing the NCI caBIG® for International Breast Cancer Pilot



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

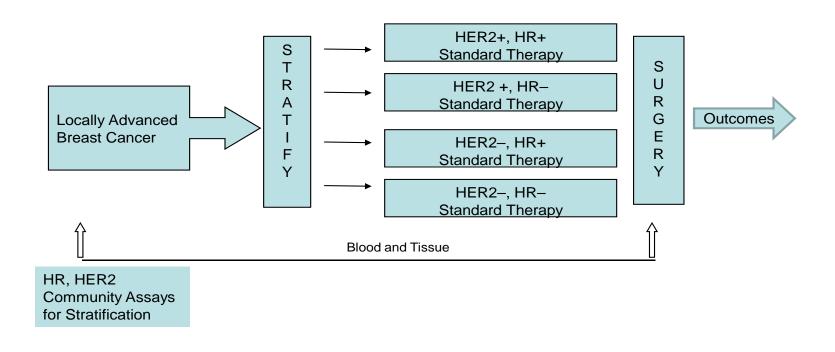
International Clinical Trial on Advanced Breast Cancer

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



Standard Therapies May Vary by Arm

OLACPD: Enabling Collaboration and Cancer Research Advances in the United States and Latin America

2008

March 2009

April-May, 2009

OLACPD Established

US - LA CRN Launched

Breast Cancer Workshop on Pilot Design

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

Prospective country partners engaged

Work across NCI to assess need and leverage resources

Top researchers engaged from U.S. NCI, External Research Focus Group, and Latin America



= 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





= 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 Cancerológia; 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