

Research and Development Role of the Public Sector in Clinical Research, Practice and Policy

**Daniel Campos
SLACOM**

3rd. ICCC, November 10th, 2009
Cernobbio, Como, Italy

DANIEL CAMPOS

Director , Clinical Research
Institute

Latinamerican & Caribbean
Society

of Medical Oncology (SLACOM)

Director of Oncology,
San Isidro Central Hospital,
Buenos Aires, Argentina.

Background

- **Clinical research is vital to the development and improvement of methods to prevent, detect and treat cancer.**
- **The majority of clinical trials take place in the developed world through sponsored pharmaceutical company research.**

Background

The corresponding lack of research in developing countries results in two unmet needs related to cancer treatment in the developing world:

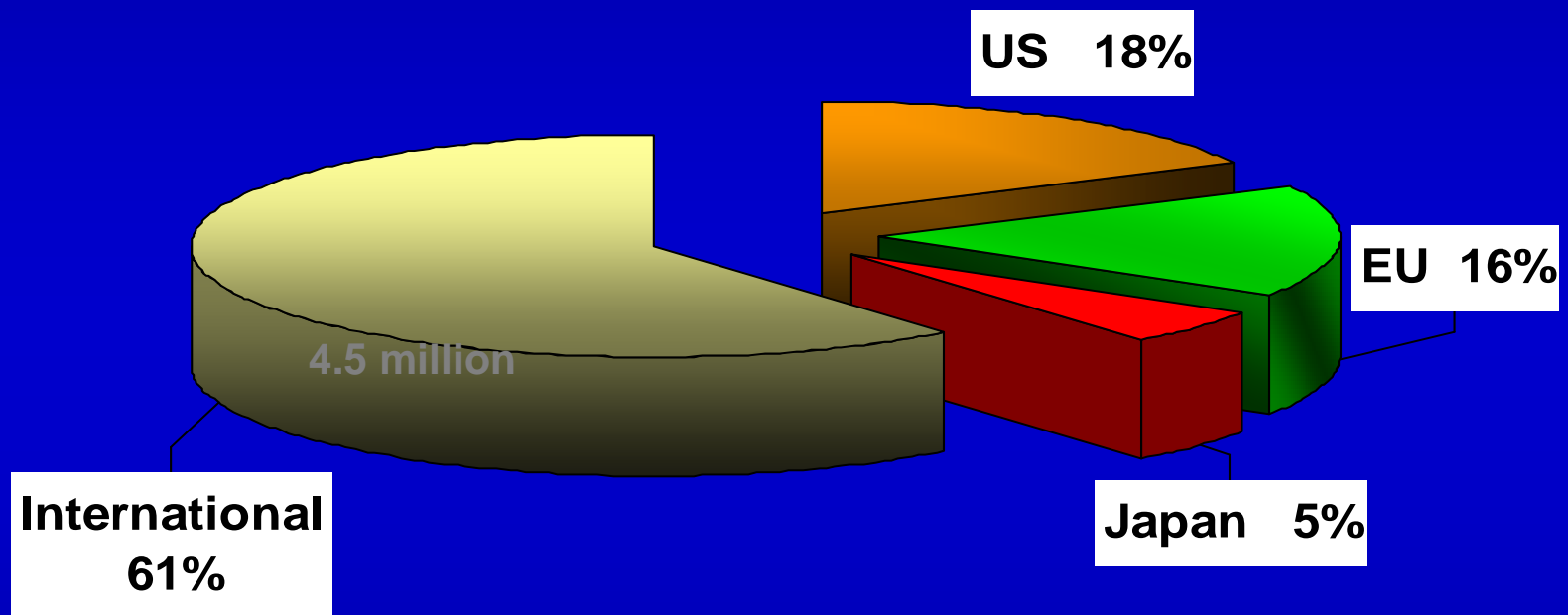
- First, recommended treatments do not reflect ethnic (genetic), cultural and resource differences between developed and developing countries that are not subject to clinical research.

Background

The corresponding lack of research in developing countries results in two unmet needs related to cancer treatment in the developing world:

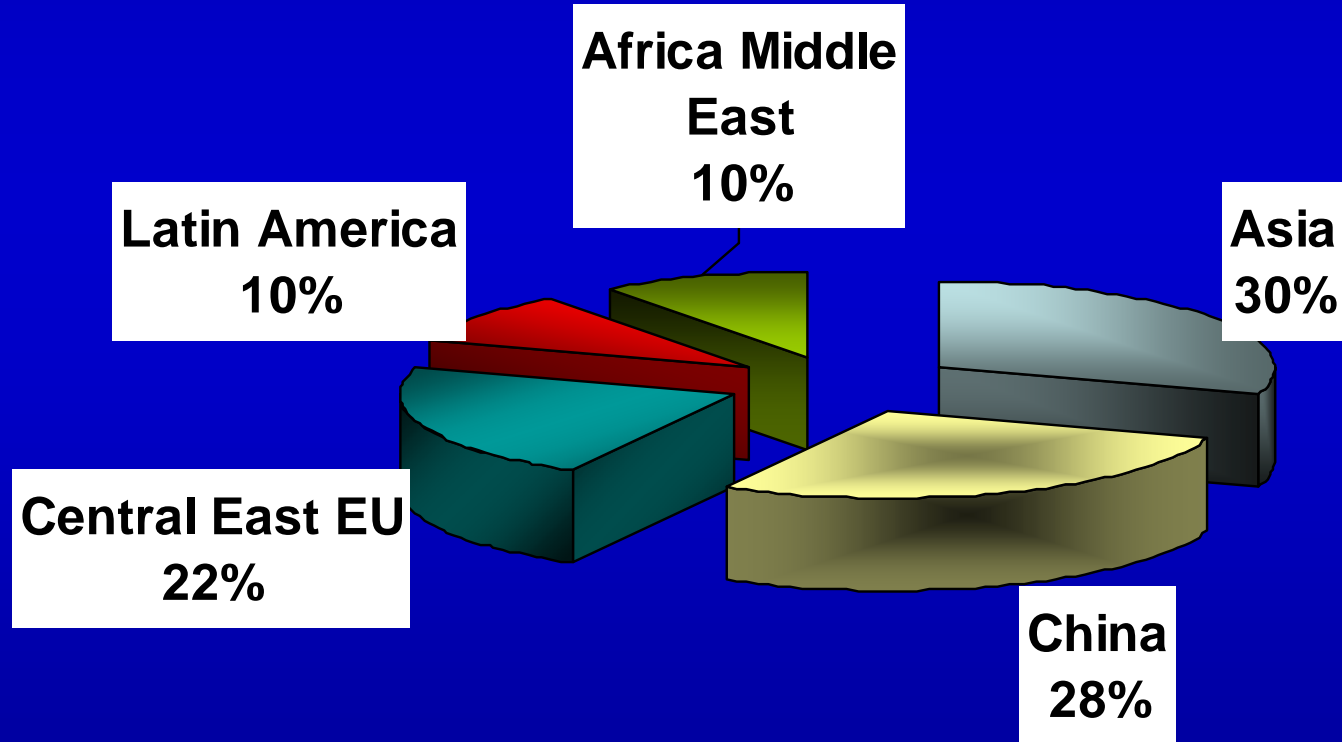
- **Second, there is little research conducted on those cancers that are primarily found in developing countries. Thus the ability to diagnose and treat these diseases is impaired.**

Distribution of Patients with Cancer Worldwide

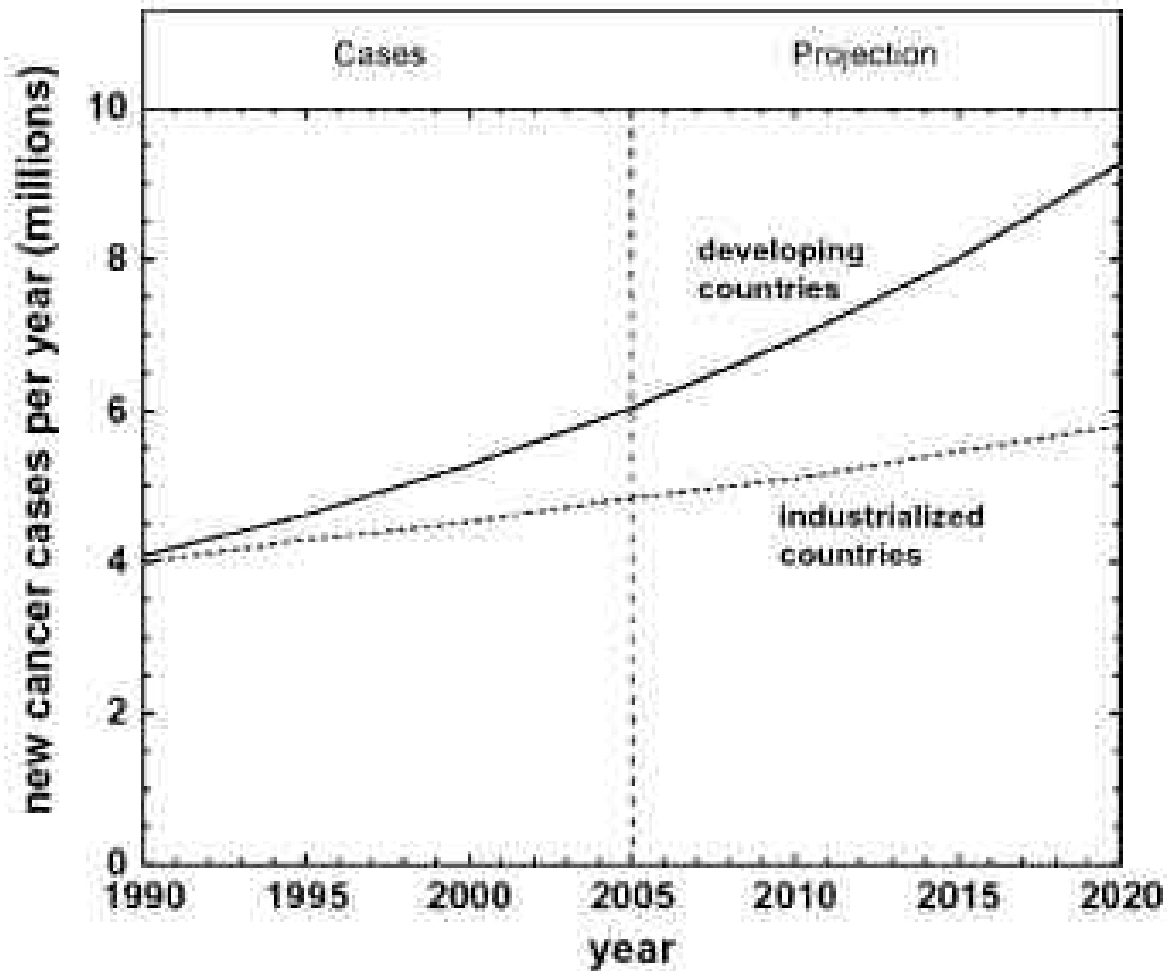


Source : Globocan / IARC 2000

International Distribution of Patients with Cancer (excluding US , EU , Japan)



Cancer Incidence in Developed and Developing Countries



Cancer Incidence Worldwide

MALE

*US &
West EU*

- 1 Lung
- 2 Prostate
- 3 Colorectal
- 4 Stomach
- 5 Bladder

*Asia, China ,
Latin America*

- 1 Lung
- 2 **Stomach**
- 3 **Liver**
- 4 **Esophagus**
- 5 Colorectal

Cancer Incidence Asia, China and Latin America

Male

Asia Pacific

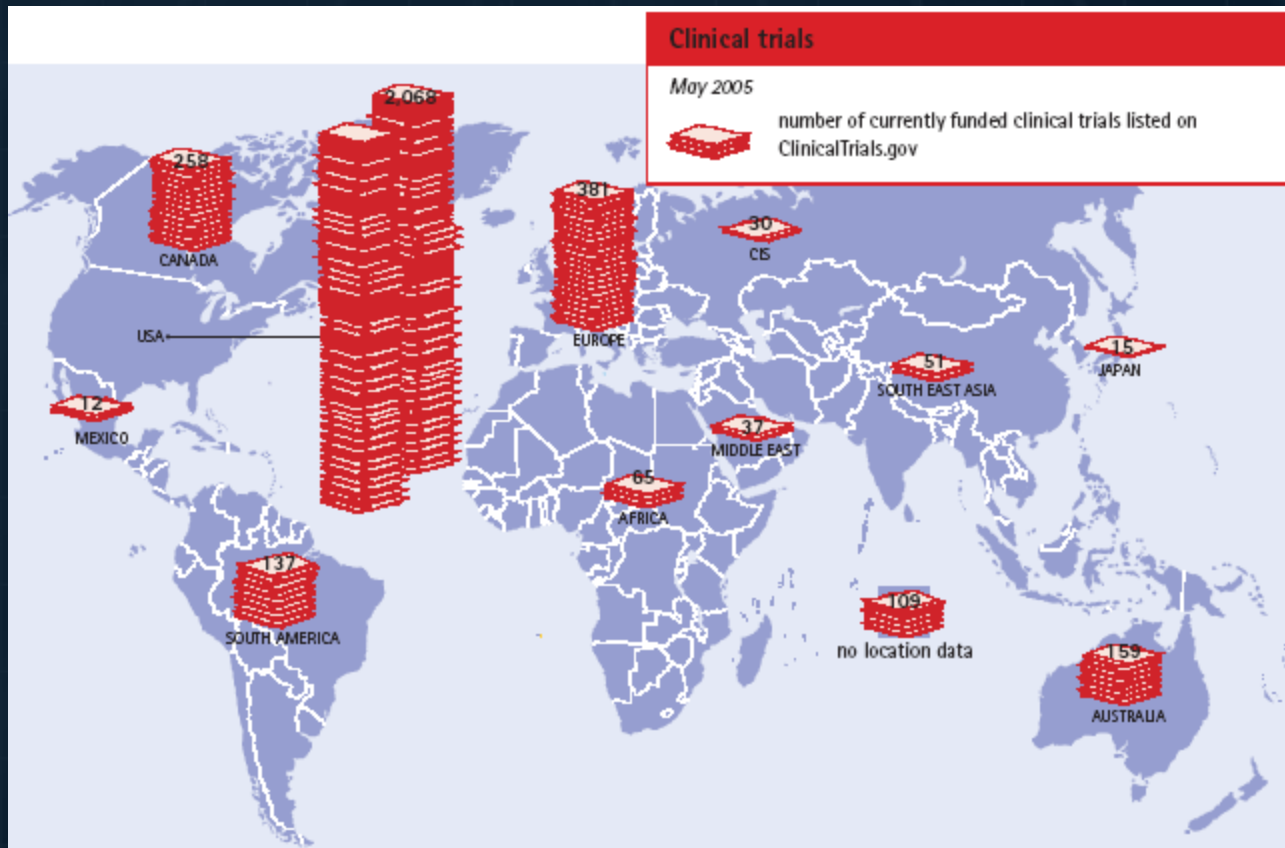
- 1 Oral Cavity
- 2 Lung
- 3 Stomach
- 4 Liver
- 5 Colorectal

China

- 1 Stomach
- 2 Liver
- 3 Lung
- 4 Esophagus
- 5 Colorectal

Latin America

- 1 Stomach
- 2 Lung
- 3 Colorectal
- 4 Prostate
- 5 Oral Cavity



Clinical Research Worldwide

American Cancer Society – Cancer Atlas

http://www.cancer.org/docroot/AA/content/AA_2_5_9x_Cancer_Atlas.asp

ASCO perspective

21% of international members are not satisfied with ASCO's involvement in clinical research education

61% of international members think a workshop held in their country on clinical trials would be very helpful.

2007 ASCO International Membership Survey

SLACOM Perspective Breast Cancer in Latin America.

E. L. Cazap, A. Buzaid, C. Garbino, J. de la Garza,
F. Orlandi, G. Schwartzmann, C. Vallejos,
A. Guercovich

SLACOM

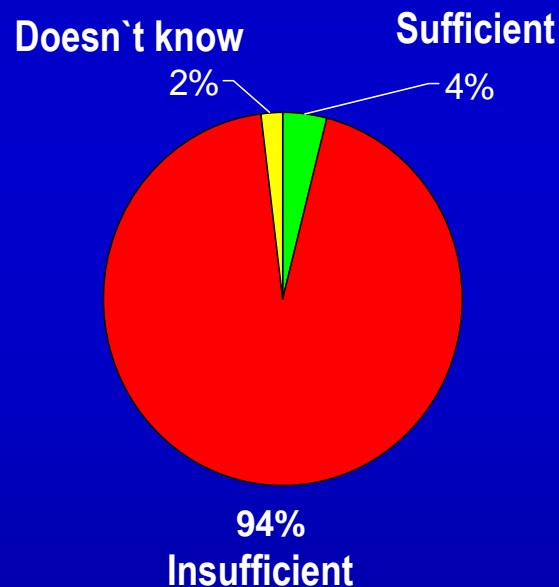
*Supported by a grant from The Breast Cancer
Research Foundation*

Cazap et al, Cancer. 2008 Oct 15;113(8 Suppl):2359-65.

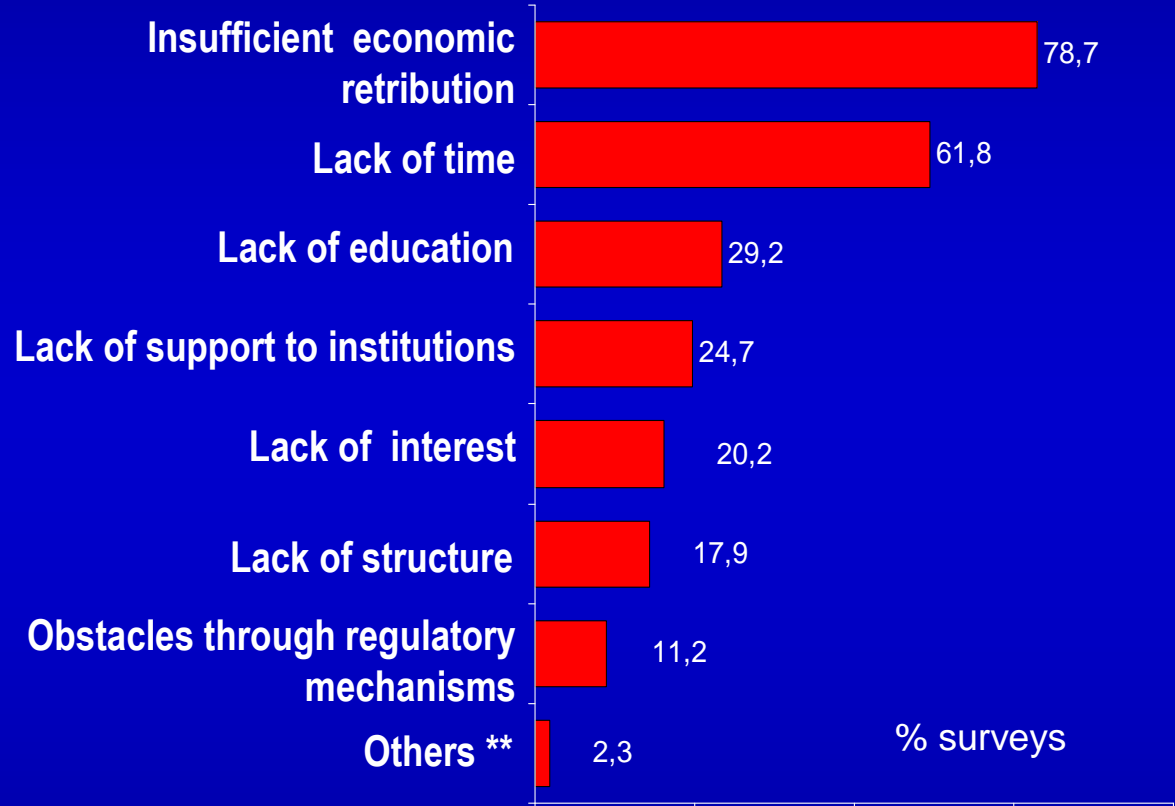
Clinical-epidemiological research

n=95

How would you qualify the clinical-epidemiologic research development on breast cancer in your country ?



n=89



**Others: lack of political decision.

Note: more than one possible reply option.

It's today's global picture, satisfactory?

Actual Situation

Health Care Cancer Clinical Research

- The most important objective of a publicly supported cancer clinical trials system is the identification of optimal therapies for cancer patients.
- This objective differs from the primary objective of pharmaceutical companies, which want first and foremost to get their innovative product evaluated quickly, and, if found to be effective, approved for marketing.

Health Care Cancer Clinical Research

Other objectives of publicly supported cct

- **To identify the most effective treatments, which national health care systems should make available**
- **To identify ineffective or without a reasonable cost-benefit relationship treatments, which health care systems should not support**

Health Care Cancer Clinical Research

Other objectives of publicly supported cct

- **To determine whether interventions found to be effective in other countries are also effective**

The critical role of publicly funded clinical trials networks in cancer research

Actual Situation

Research Relevance in Health Development

WHO:

Research must be an essential component of **the Health System** to ACHIEVE THE BEST POSSIBLE QUALITY OF HEALTH CARE WITH THE AVAILABLE RESOURCES

Current Scenario of Research in Developing Countries

- Academic research activities are mainly limited to observational studies.
- On epidemiology.
- Few studies have survival or outcome analysis.
- Less than 1% are interventional trials.
- Characterized by poor quality due to lack of training in research methodology, guidance, lack of

Problems of Researchers in Developing Countries

- Lack of initiative.
- Poor institutional structure.
- Lack of funding.
- No training in proposal / grant writing.
- Lack of mentors and support.
- Hopeless career structure.
- Very little research culture.
- English as a second language.

Clinical research infrastructure

- Lack of knowledge on:
 - research methodology
 - statistical analysis
 - scientific writing
- Nonexistence of clinical research units
- Lack of administrative support
- Lack of statisticians



Orientation to commercial clinical research

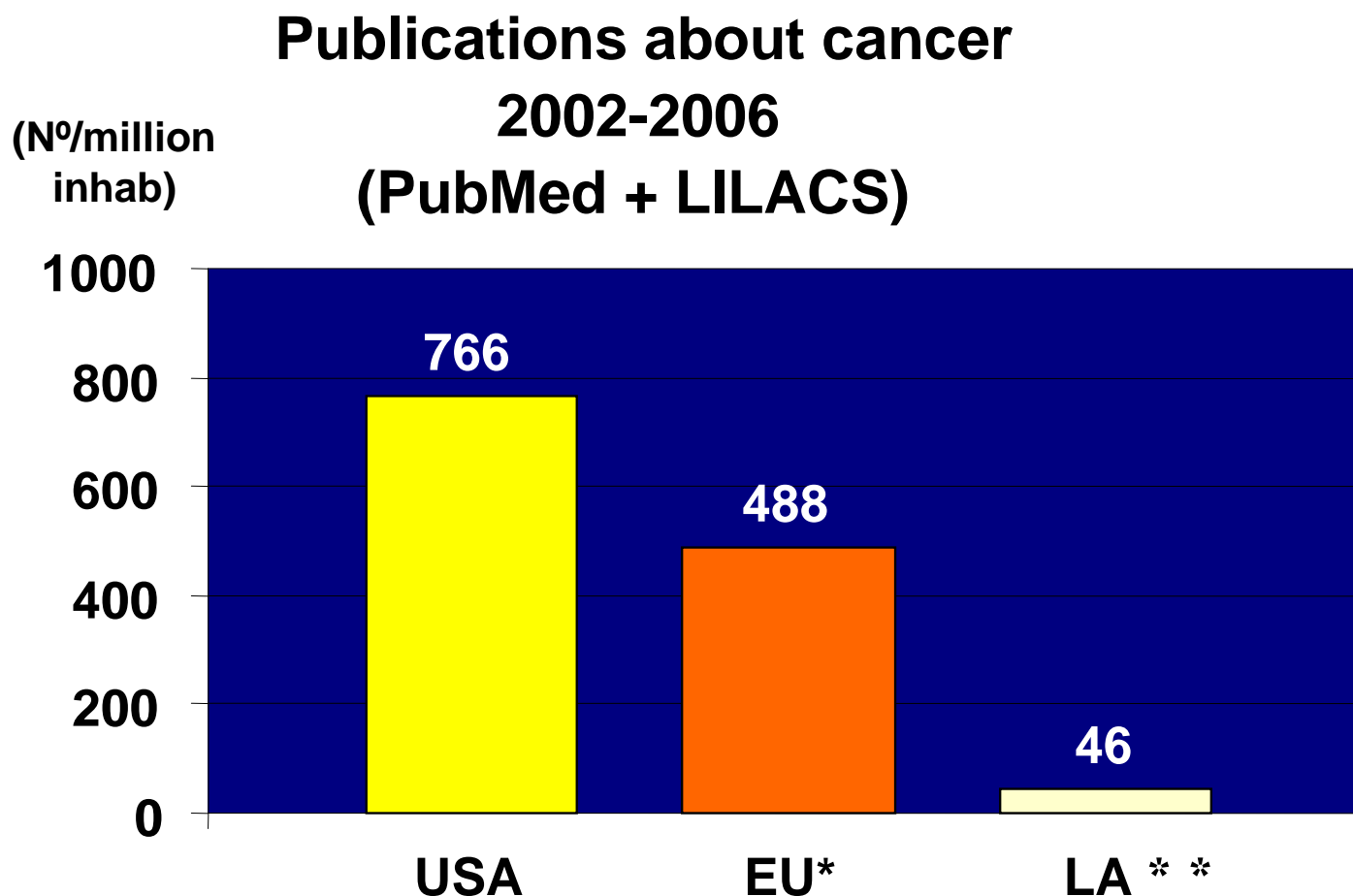
Research and Development State Funding - % GDP (RICYT, 2005)

	2000	2007
Argentina	0.49%	0.51%
Uruguay	0.26%	0.44%
Brazil	1.01%	1.11%
Colombia	0.12%	0.16%
LA and Caribbean	0.50%	0.68%
Spain	0.90%	1.27%
USA	2.70%	2.66%

Research and Development State Financial- US dollars/inhabitant (RICYT, 2005)

	2000	2007
Argentina	34	34
Uruguay	14	31
Brazil	38	77
LA and Caribbean	23	43
Spain	132	402
USA	938	1218

Clinical Research in Latin America



* G,B,S,F,I,UK

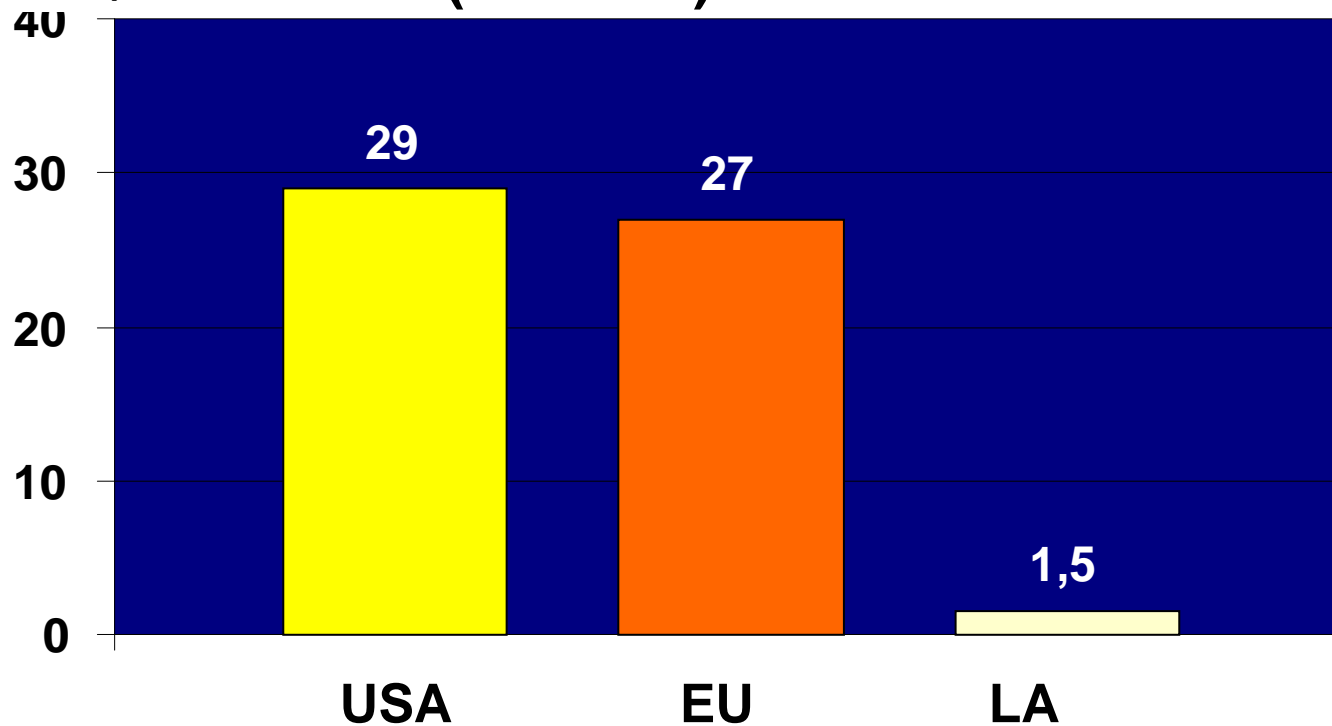
** A,Br,P,Uy

Clinical Research in Latin America

Publications of Cancer Clinical Trials 2002-2006

(Nº/million
inhab)

(PubMed)



Academic Clinical Research in LA

MAIN BARRIERS

- ✓ Funding
- ✓ Regulatory Framework
- ✓ Research team training and dedication

Academic Clinical Research in LA

Main Barriers: FUNDING

✓ The lack of adequate funding has been a main obstacle for academic clinical research

- Supplies
- Insurance coverage
- Administrative and structural costs associated to current legislation

Academic Clinical Research in LA

Main Barriers: FUNDING

- ✓ **Some countries do not have** specific funding for investigation in health **and in those that do, the amount is insufficient**
- **WHO: advises to invest in health research and development at least 2% of the cost in Health**
- **Most LA countries dedicate less than that.**
i.e. **Uruguay has dedicated ≈ 0.1%**

Fernández J.E. Estructura del funcionamiento y gasto de la investigación biomédica. Facultad de Medicina. Uruguay, 2005.

Academic Clinical Research in LA

Main Barriers: FUNDING

Therapeutic clinical research is expensive which makes it difficult to be state funded

HOWEVER

What is the health care cost, if the standard of care is based in clinical studies that develop non affordable or non relevant treatments for our patients?

Academic Clinical Research in LA

MAIN BARRIERS

- ✓ Funding
- ✓ Regulatory Framework
- ✓ Research team training and dedication

Academic Clinical Research in LA

Main Barriers:

CURRENT REGULATORY FRAMEWORK

- ✓ Increase significantly the costs of clinical research (especially affects independent research)
- ✓ Increase considerably administrative obligations
- ✓ In general makes no distinction between:
 - clinical trials sponsored by industry or non-industry sponsors (academic)
 - clinical trials investigating new drugs or investigating new strategies with approved drugs

What could be done?

Propounds

Clinical Cancer Research

Reasons to conduct Clinical Trials Globally

Global Level

- Demographics
- Epidemiology
- Ethnicity
issues
- Faster & Better

Local Level

- Knowledge transfer
- Technology transfer
- Develop local expertise
- Global & Local
publications

Clinical Research : Global Experience

– Major Benefits

- **Answering important scientific questions**
- **Patients access to standard of care**
- **Exposure / training in high standards of ethical (GCP) and scientific trial conduct**
- **Exposure / collaboration with global colleagues**
- **Impetus to improve standards of local trials**
- **Motivate MD's to continue working in their country**

Clinical Research : Global Experience

– Major Advantages

- **Therapeutic Area oriented Institutions**
- **Mega - cities & Mega - sites**
- **Diseases rare in US and West EU: no prior therapy, locally advanced tumors**
- **Endemic tumors : Hepatoma, Biliary Tract, Cervical, Nasopharyngeal, Gastric**
- **Relative reduced trial expense**
- **Seasonality (northern & southern hemispheres)**

Clinical Research in LA

CURRENT NEEDS AND CHALLENGES

- ✓ Research programs oriented to the **local / regional problems**
- ✓ Clinical trials taking into account the **local / regional cancer characteristics and treatments that can be financed in our countries**

Clinical Research in LA

CURRENT NEEDS AND CHALLENGES

✓To achieve these goals it is necessary to **increase the support for academic clinical research** and to **modify legislation** considering the potential benefits of independent clinical trials to patients and public health

Clinical Research in LA

CURRENT NEEDS AND CHALLENGES

REGULATORY FRAMEWORK

Should be more flexible

I.e : clinical trials with registered drugs in new indications should be considered differently than investigational drugs

It should be an harmonization of regulatory issues related to independent clinical trials in LA

Clinical Research in LA

CURRENT NEEDS AND CHALLENGES

REGULATORY FRAMEWORK

- 1996 Normative of Mercosur about clinical studies regulation
- 2005 IV Pan American Conference for Harmonisation of Drug Regulation
- 2008 First Latin American Conference on Research and Innovation for Health and a review of 14 countries (Brazil)

Clinical Research in LA

CURRENT NEEDS AND CHALLENGES

INDUSTRY SPONSORED CLINICAL TRIALS

- ✓ There is need for **more participation of developing countries investigators** in international clinical trials **conception, design and result analysis**

Academic Clinical Research in LA

MAIN BARRIERS

- ✓ Funding
- ✓ Regulatory Framework
- ✓ Research team training and dedication

1st International Clinical Trial Workshop



Buenos Aires, Argentina - April 20th-21st, 2009

In collaboration with:



Sociedad Argentina
de Cancerología

Asociación Civil



ICTW-Agenda

Day 1

- **Global View – Need for International Clinical Trials**
- **Overview of Cancer issues in Latin America**
- **Clinical Trials in different patient groups**
- **Perspectives of sponsors**
- **Ethical considerations**
- **Role of the oncology research team**
- **Clinical trial design and methodology**

Day 2

- **Implementation of a Clinical Trial**
- **Enrollment methodology**
- **Selecting a multi-site Clinical Trial to activate**
- **Regulatory issues – International perspective**
- **Regulatory issues – Regional perspective**
- **Marketing a Clinical Trial**
- **Evaluation and certification process**
- **Publishing research findings**

Break out sessions

- **Question and answer sessions**
- **Panel discussions**
- **Break out sessions**
- **Skills stations**

Main Goals

- **Increase research capacity in developing countries**
- **Identify funding sources outside of pharmaceutical sponsorship and, with the help of the local society, create strategies for obtaining funds for independent research**
- **Encourage through research the development of evidence-based treatment strategies appropriate for low and middle-income countries**

Main Goals

- **Foster meaningful translational interactions focusing on cancer research**
- **Enhance the development of senior oncology fellows and junior faculty in the area of cancer research and patient care**