



Biominas
BRASIL

Presentation to BIOX4CLUSTERS

April 2012

Life Sciences in Latin America

Latin America is “becoming much more appealing as a place in which to conduct development and production”

*Latin America Prescription for Growth,
PricewaterhouseCoopers, 2005*

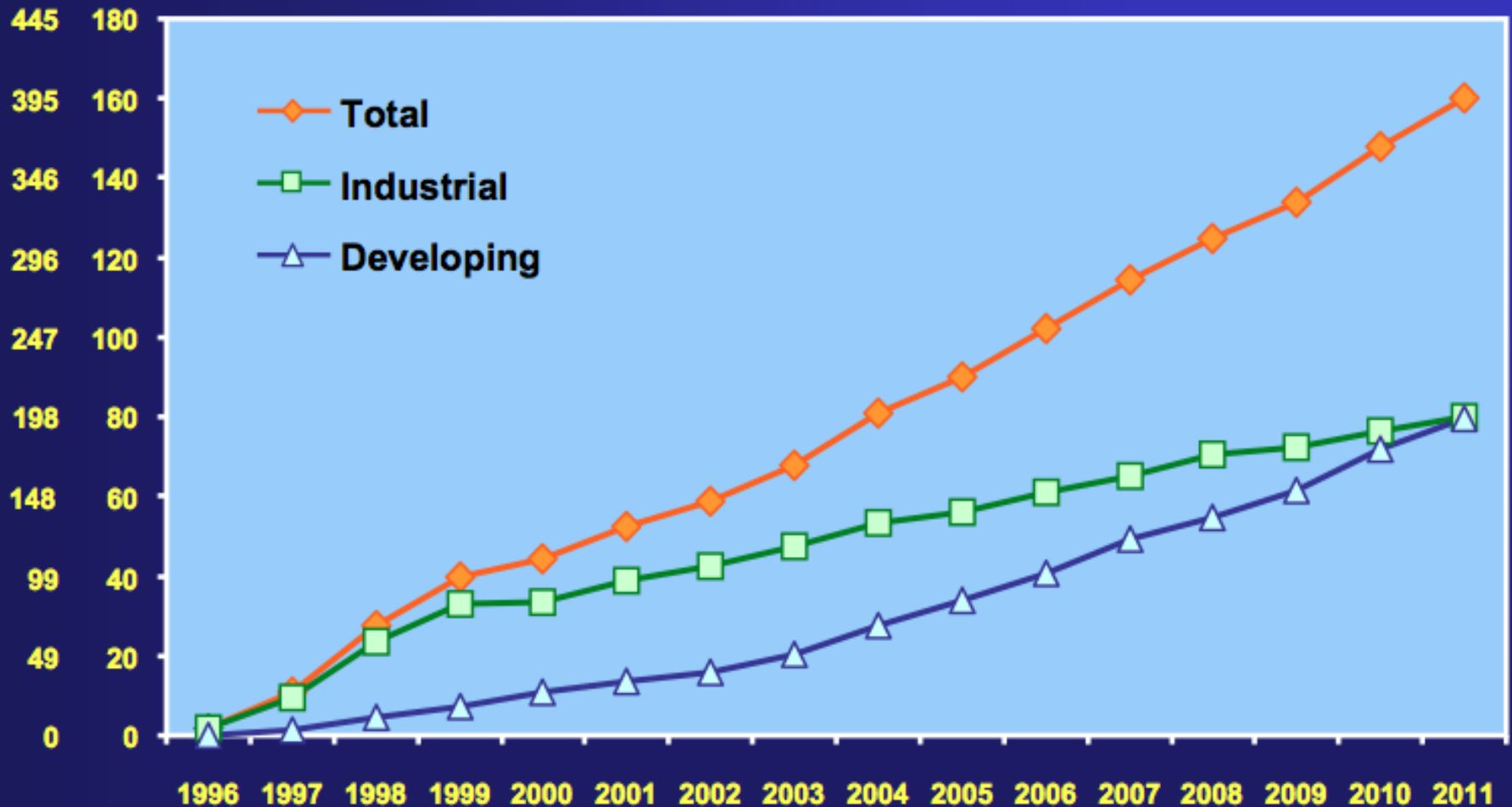
Highlights

- 1. Global Opportunity:** Global life sciences market has been growing worldwide, with the scientific and technology advances in different application areas.
- 2. Market Growth and Potential:** Latin American markets have been growing in importance in the last few years, due to economic and political stability. A population of over 500 million people start to access high level products.
- 3. Progress in different areas:** There is a notable advance in areas as agriculture, energy, healthcare and industrial biotechnology in LA.
- 4. Global demands:** High qualified science in the region can meet global demands for food, environment, energy and global health solutions
- 5. Challenges:** Main challenges for LA include improvement in intellectual property and technology transfer system, regulatory issues, lab and industrial infra-structure and human resources.

Global Area of Biotech Crops, 1996 to 2011: Industrial and Developing Countries (M Has, M Acres)

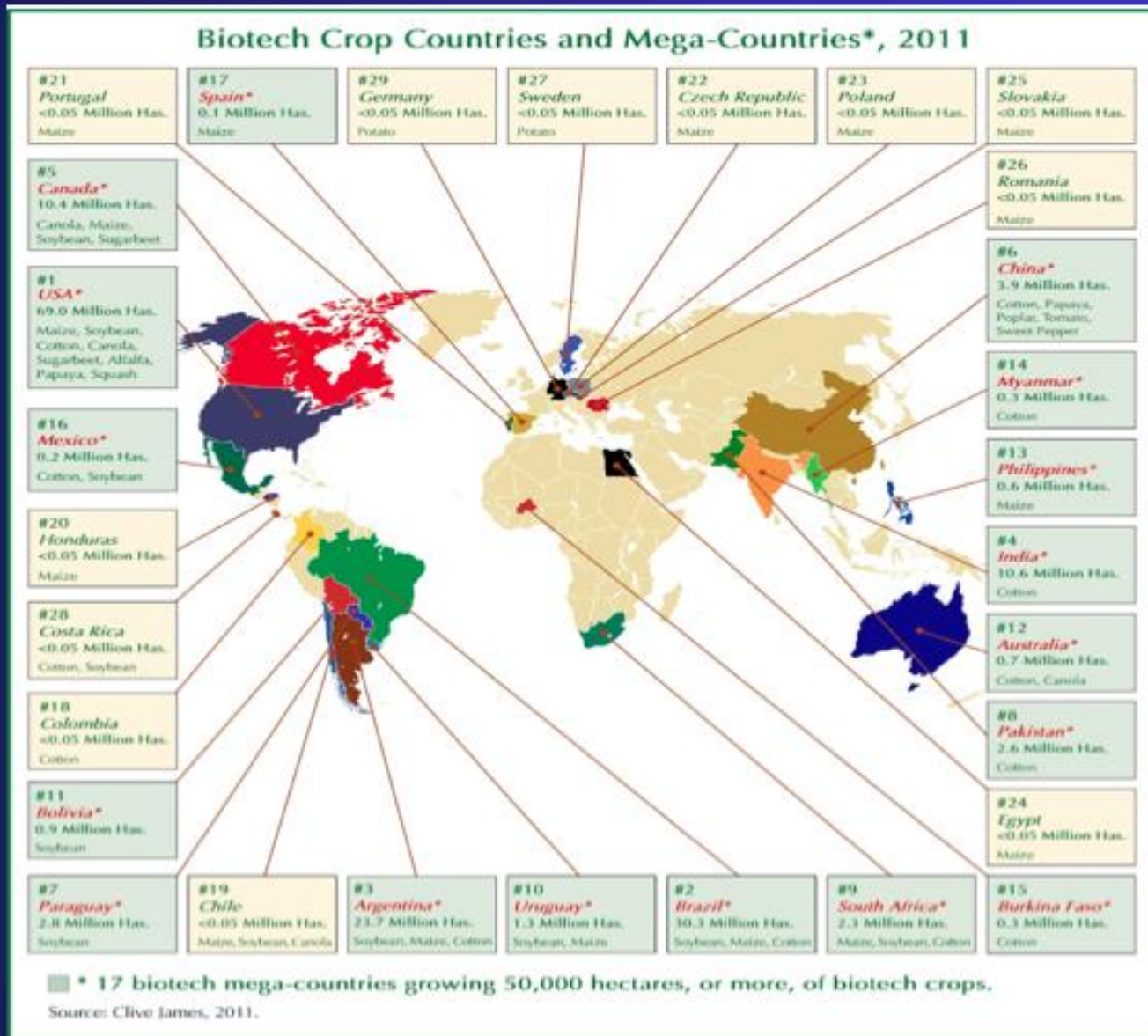


M Acres



Source: Clive James, 2012

Biotech Crop Countries and Mega-Countries, 2011



Brazil

2

30.3 million hac.
Soybean
Maize
Cotton

Figure 1. Global Map of Biotech Crop Countries and Mega-Countries in 2011

Latin America is well positioned in biofuels production

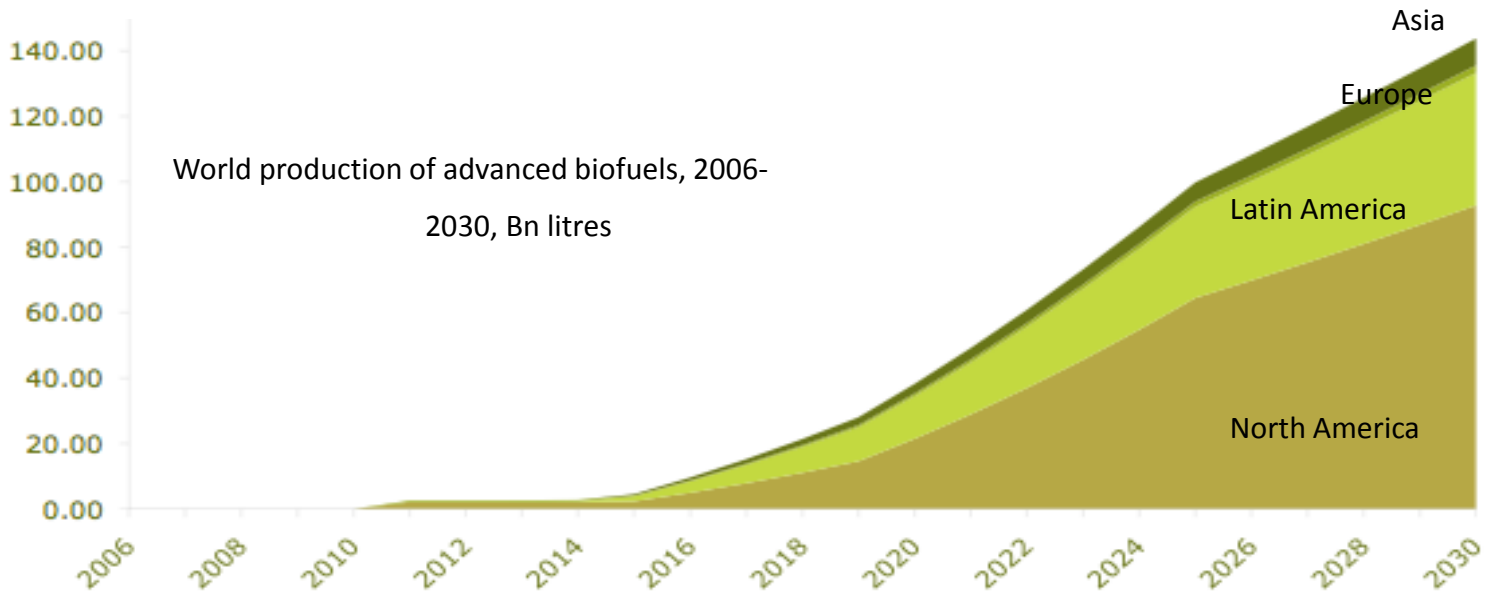
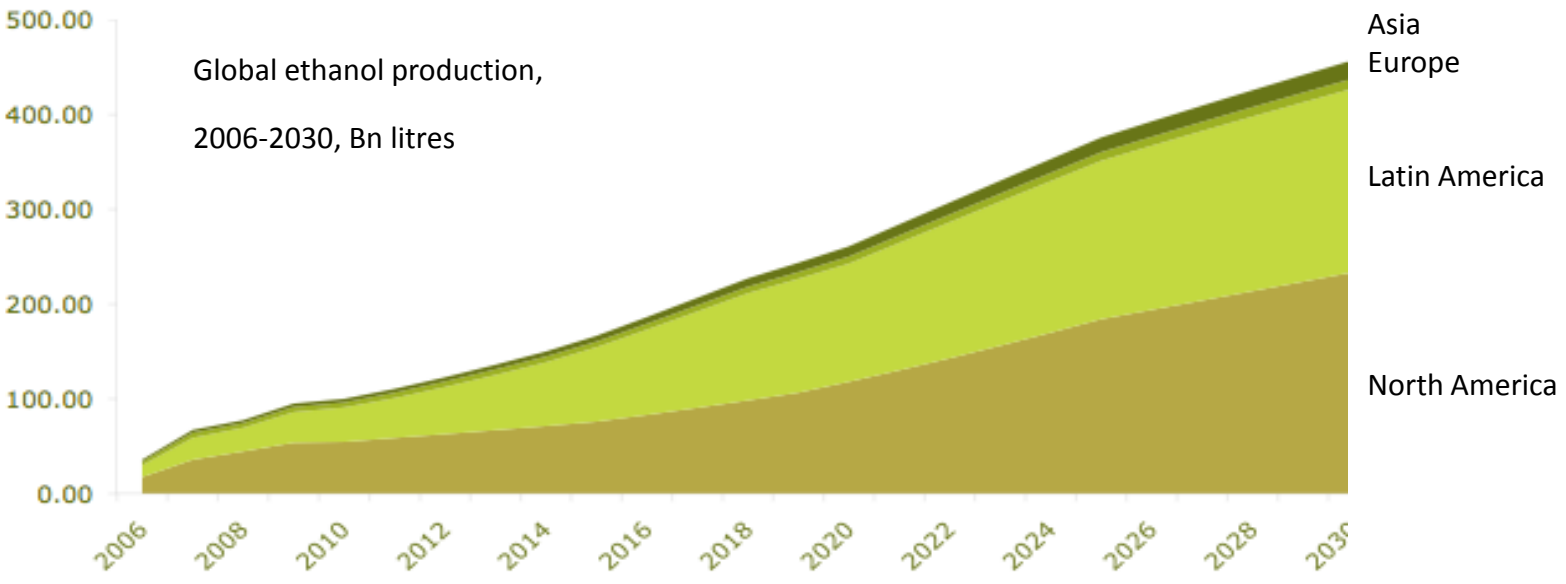


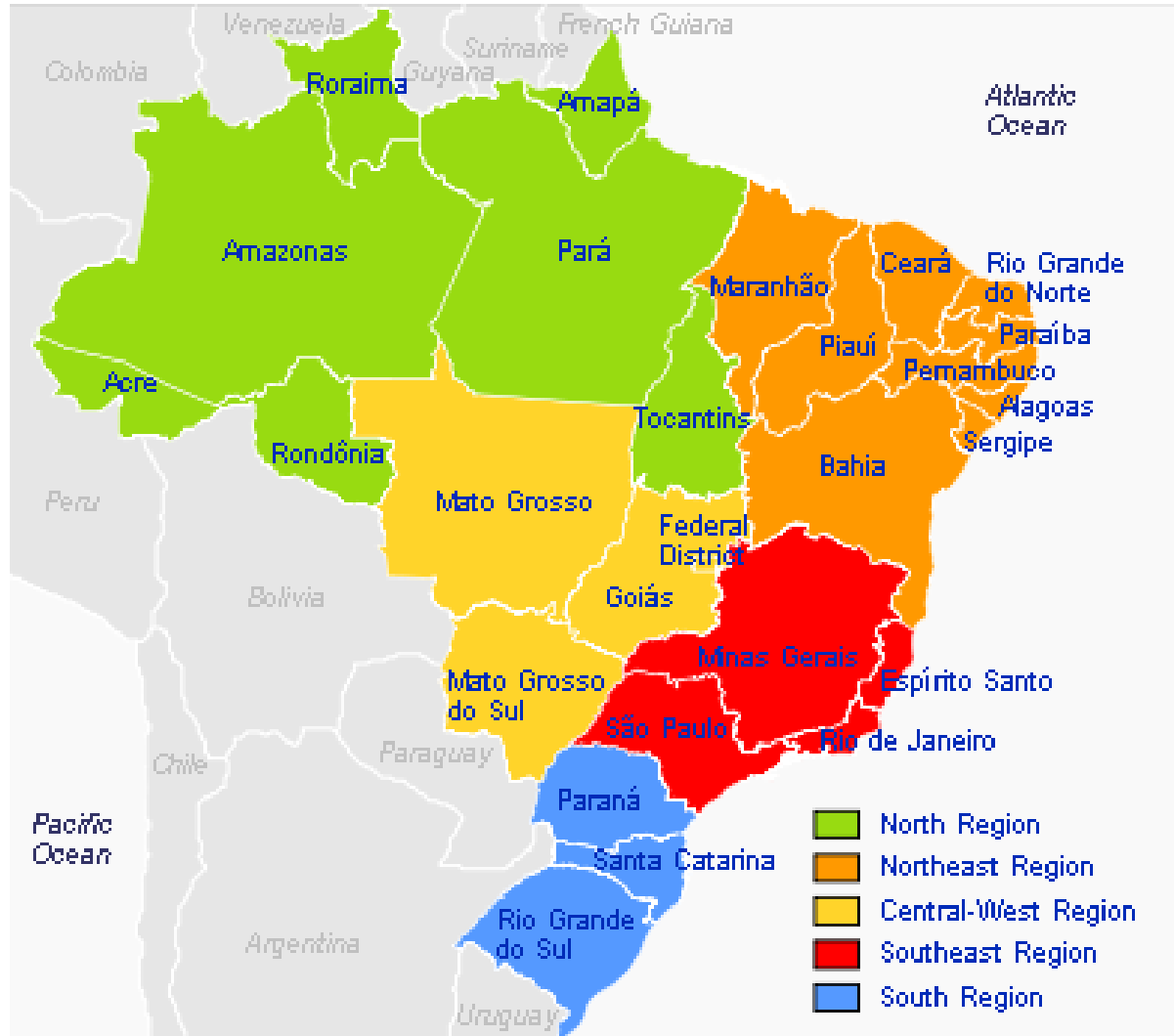
Figure 6.1 Global Pharmaceutical Sales by Region

REGION	2009 MARKET SIZE (USD B)*	PERCENT GROWTH IN 2009	2004-2009 PERCENT CAGR	2010 PERCENT GROWTH FORECAST	2009-2014 PERCENT CAGR
North America	322.1	5.5	5.2	3-5	3-6
Europe	247.6	4.8	6.6	3-5	3-6
Asia/Africa/Australia	102.6	15.9	13.9	13-15	12-15
Japan	90.3	7.6	3.9	0-2	2-5
Latin America	45.8	10.6	10.9	10-12	12-15
TOTAL MARKET	837.3	7.0	6.7	4-6	5-8

* Constant U.S. dollars uses Q4 09 average exchange rates

Source: IMS Health Market Prognosis, March 2010

BRASIL



Area: 8,511,965 sq. km.
Population (2010): 190 million. Annual population growth rate: 1.17%. Ethnic groups: African, Portuguese, Italian, German, Spanish, Japanese, indigenous peoples, and people of Middle Eastern descent. Religion: Roman Catholic (74%). Language: Portuguese.

BRASIL

Natural resources: Iron ore, manganese, bauxite, nickel, uranium, gemstones, oil, wood, and aluminum. Brazil has 14% of the world's renewable fresh water.

Agriculture (6% of GDP): Products--soybeans, coffee, sugarcane, cocoa, rice, livestock, corn, oranges, cotton, wheat, and tobacco.

Industry (28% of GDP): Types--steel, commercial aircraft, chemicals, petrochemicals, footwear, machinery, motors, vehicles, auto parts, consumer durables, cement, and lumber.

Services (66% of GDP): Types--mail, telecommunications, banking, energy, commerce, and computing.

Trade: Trade balance (2011)--\$20 billion surplus. Exports--\$202 billion. Major markets--China 15%, United States 10%, Argentina 9%. Imports--\$182 billion. Major suppliers--United States 15%, China 14%, and Argentina 8%.

Brazil overtakes UK as sixth biggest economy as Britain falls behind a South American nation for the first time

- Figures show a fortunes
- China, Japan, & the top five players
- Brazil fast-becc global economy

By NICK FAGGE

Last updated at 1:01 AM

Comments (27)

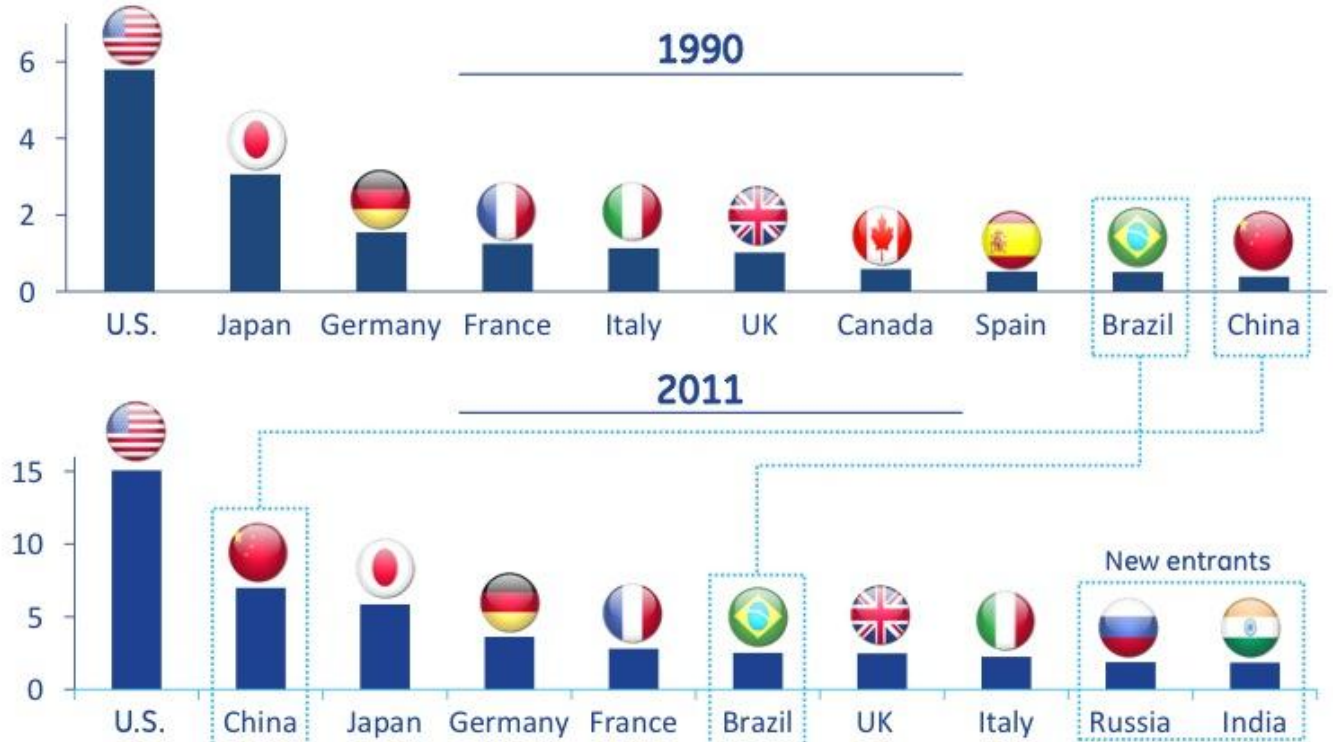
Britain has been depp world, latest figures si in a dramatic illustrati fallen behind a South

The figures, from the annual world econom richest country in the



Changing economies – top 10

(\$ trillion, GDP in current U.S.\$)



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DISTRIBUIÇÃO DA POPULAÇÃO BRASILEIRA POR CLASSE DE CONSUMO

EVOLUTIVO						
Classe	2005	2006	2007	2008	2009	2010
	%	%	%	%	%	%
AB	15	18	15	15	16	21
C	34	36	46	45	49	53
DE	51	46	39	40	35	25



AGENDA

1. Current Landscape in Brazil

Scientific Development & Knowledge Production

Regional Opportunities

Business Environment

Scientific Development & Production of Knowledge



NEWSFOCUS

Brazilian Science: Riding a Gusher

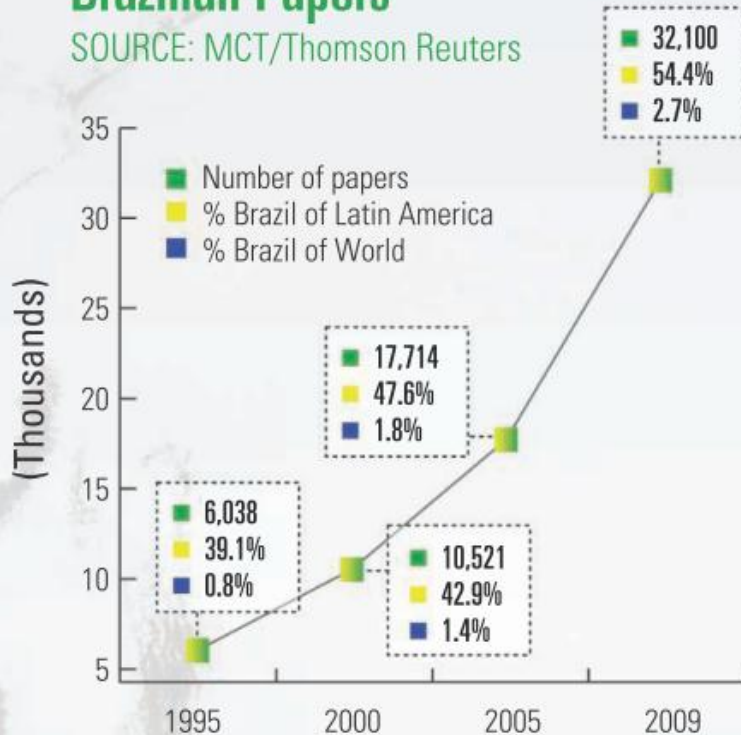
A fast-growing economy and oil discoveries are propelling Brazil's research to new heights. But scientific leaders must overcome a weak education system and a low-impact track record

Scientific Development & Production of Knowledge

Brazilian Science Begins to Boom

Brazilian Papers

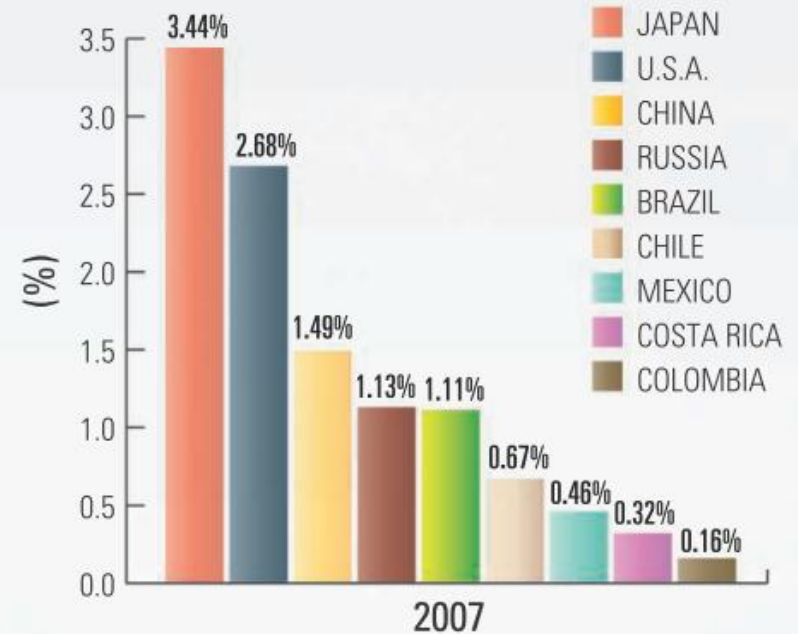
SOURCE: MCT/Thomson Reuters



2009 figure elevated due to increase in number of indexed journals

R&D Spending as % of GDP

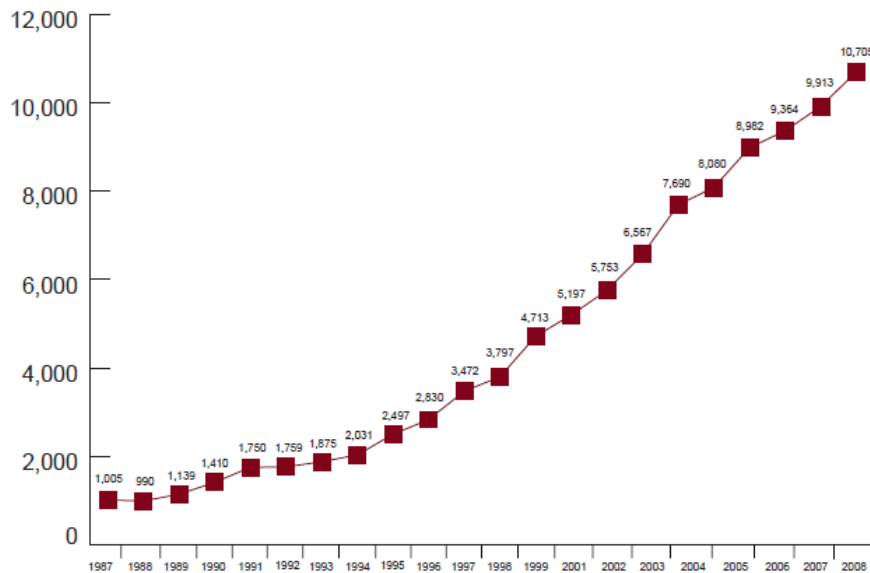
SOURCE: IADB



1.19% of the 2009 GDP. Source: MCTI

Scientific Development & Production of Knowledge

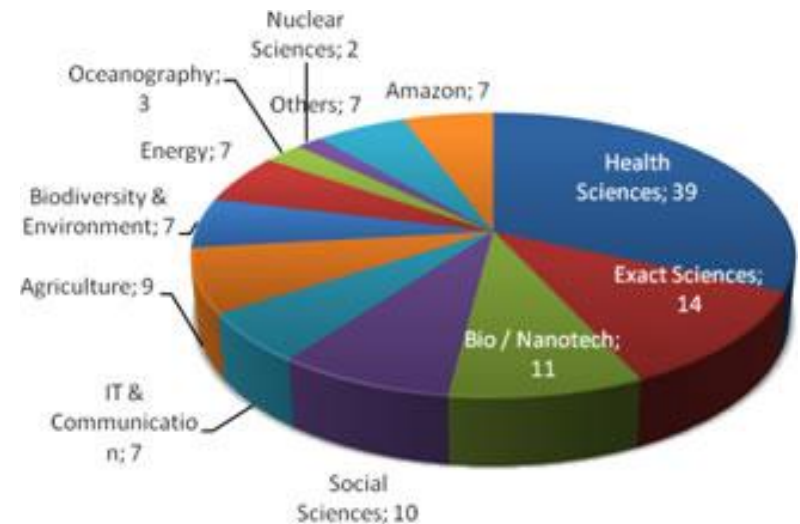
Evolution of doctorate degrees granted per year in Brazil, 1987-2008



Source: Centro de Gestão e Estudos Estratégicos, Parcerias estratégicas - edição especial, vol. 15, número 31, Dezembro 2010

123 National Institutes of Science & Technology (INCT) Distribution per Area of Research

Source: CNPq October 2009

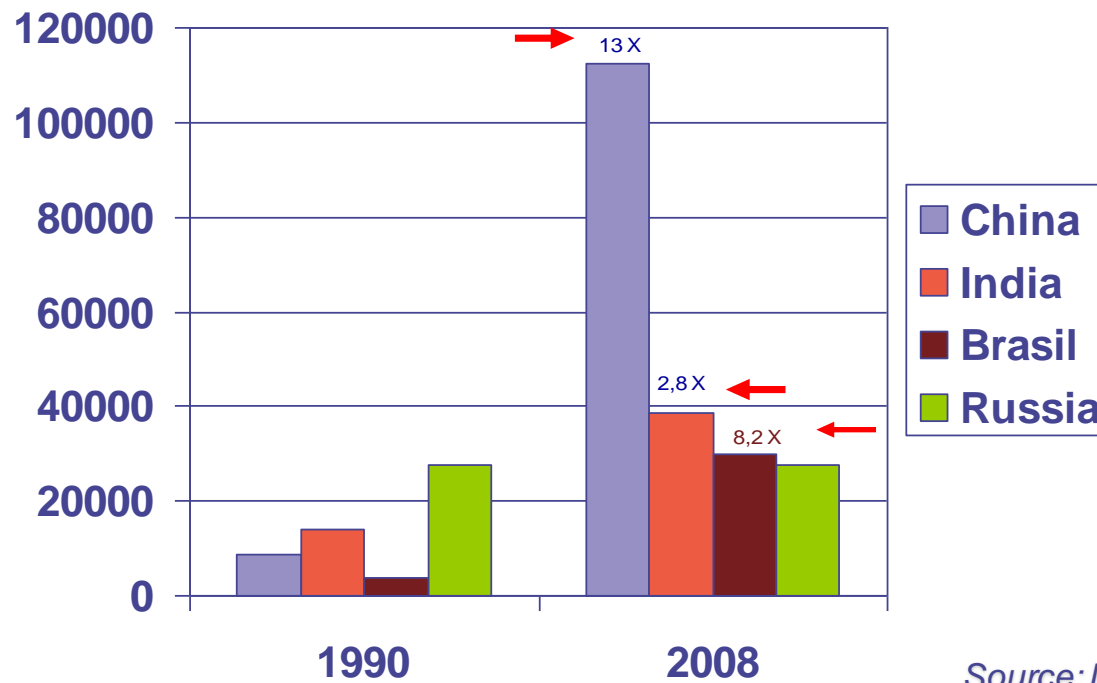


The National Council for Scientific and Technological Development (CNPq) created the National Institutes of Science and Technology (abbreviated as INCT), which function as a national S&T network. The institutes were funded with approximately \$330 million in investments, a record amount for research funding in Brazil. Health Sciences and Biotechnology / Nanotechnology comprise almost 40% of all INCTs.

Scientific Development & Production of Knowledge

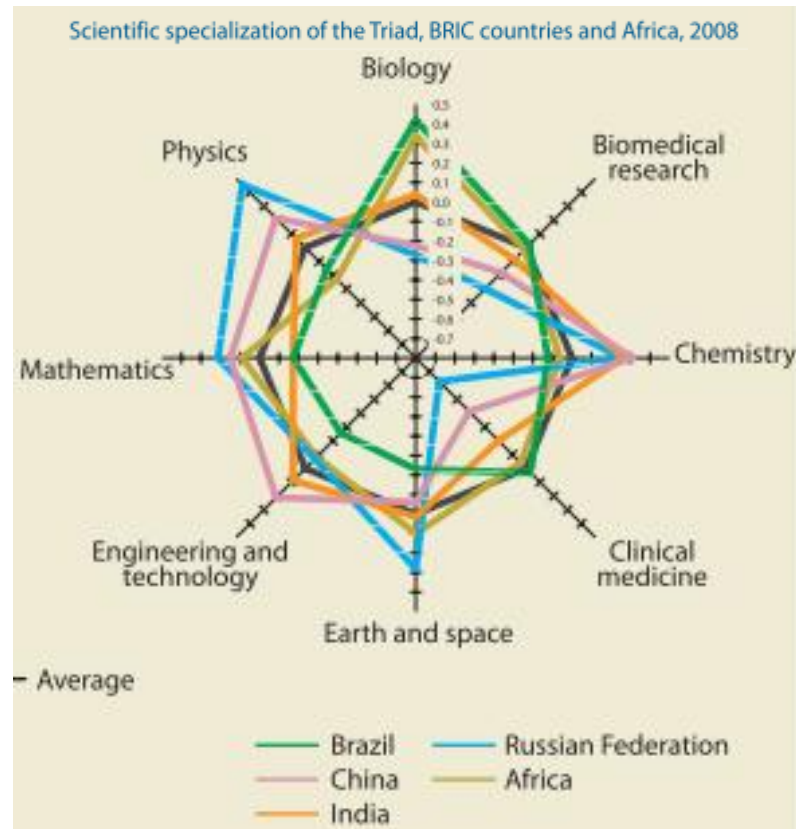
Scientific production – BRIC

10,500 main journals



Source: MCT

Scientific Development & Production of Knowledge



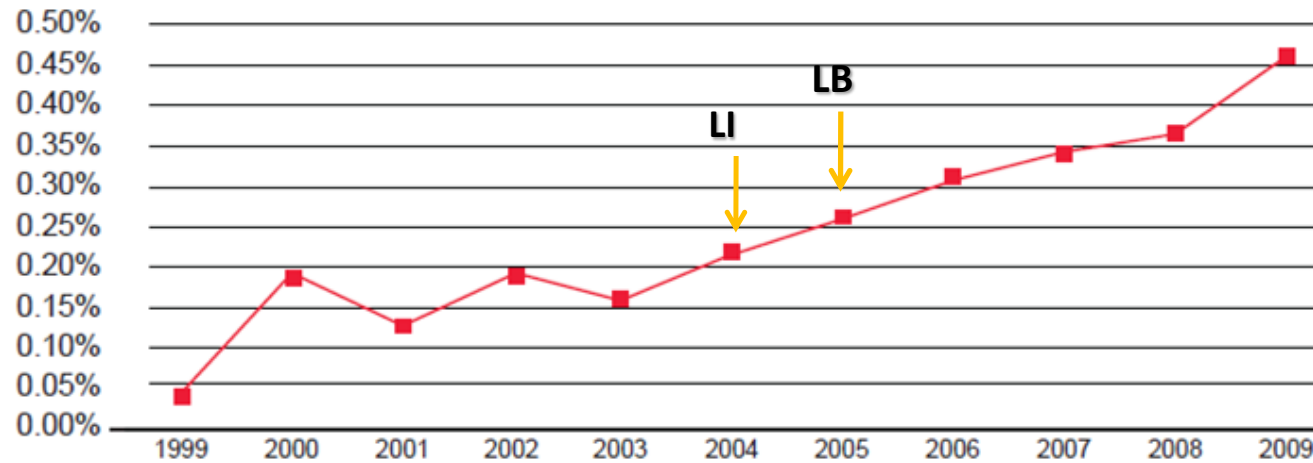
This graph shows some striking differences between BRIC countries in their scientific strengths. Brazil is strong in biology. India excels in chemistry. China specializes heavily in chemistry, physics, mathematics and engineering and technology. Russia shows a strong specialization in physics, mathematics and earth and space sciences.

SOURCE: UNESCO Science Report, 2010.

Scientific Development & Production of Knowledge

Despite a strong scientific base, Brazil still represents a small share of international life science patent filings, which can be attributed to the immature nature of its innovation system. An unparalleled growth rate has been experienced though.

Brazil's share of all life science patents filed via PCT (1999-2009)

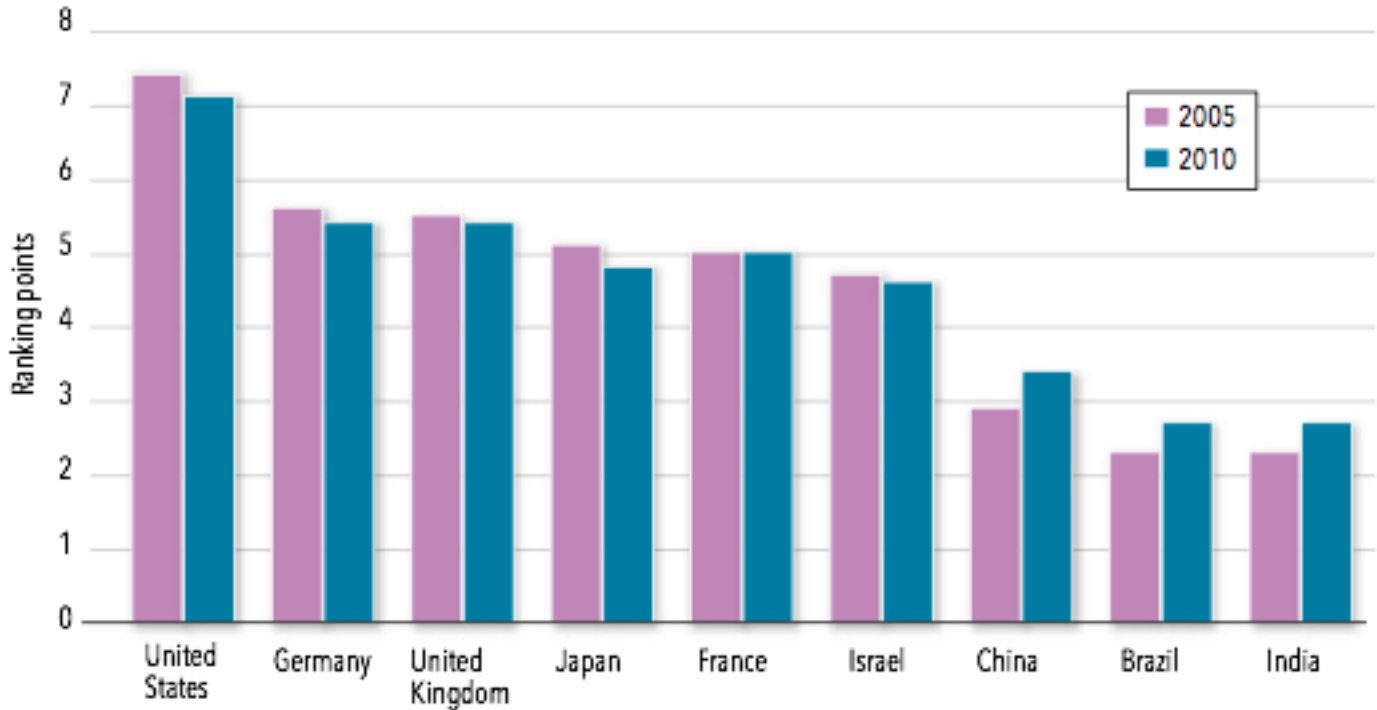


Source: OECD StatExtracts, Complete Data Base, available at: <http://stats.oecd.org/Index.aspx>

LI = Lei de Inovação (Innovation Law)

LB = Lei do Bem (Law of Good)

Figure 6.4 Medical Technology Innovation Scorecard



Source: PwC Emerging Markets

AGENDA

1. Current Landscape in Brazil

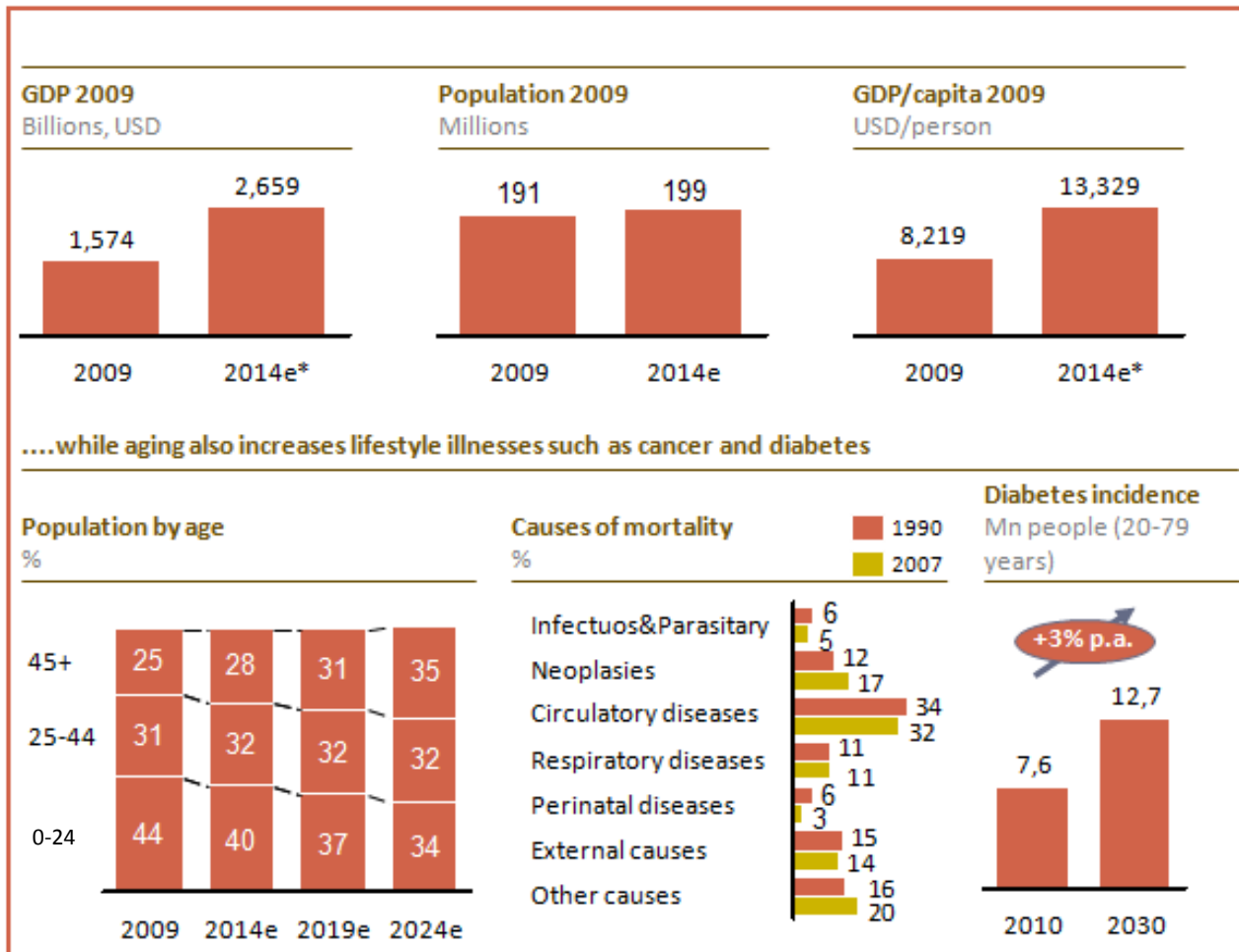
Scientific Development & Knowledge Production

Regional Opportunities

Business Environment

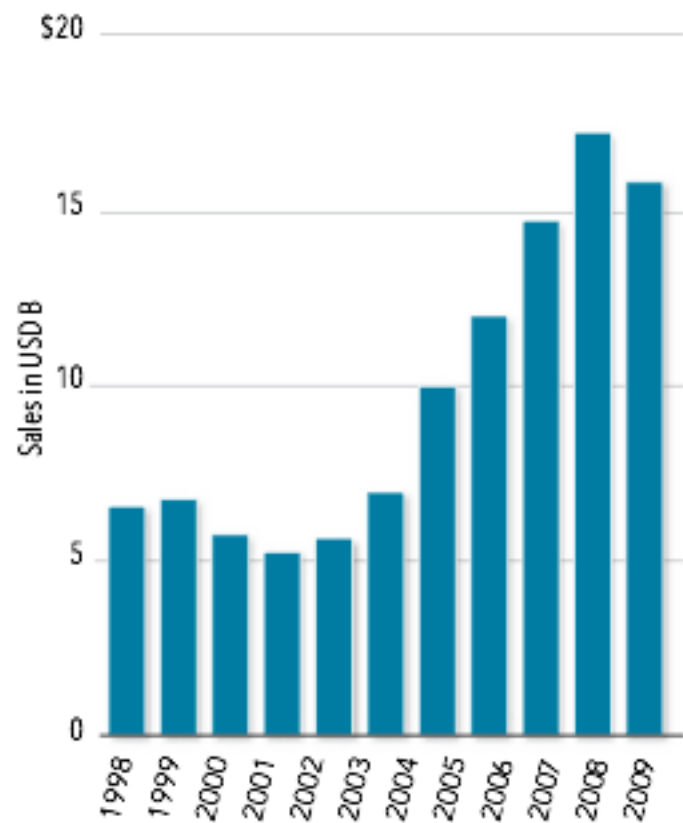
Regional Opportunities

Brazil's population is growing larger and wealthier...



SOURCE: DM Branco, 2010.

Figure 6.16 **Brazilian Pharmaceutical Industry Sales**



Source: IMS Health

Figure 6.15 Top 20 Pharmaceutical Companies in Brazil by 2009 Sales

COMPANY	USD M	REALS M	STAKE	CAPITAL SOURCE
EMS Pharma	1,294	2,181	7.7%	Brazilian
Sanofi-Aventis	1,042	1,756	6.2%	Foreign
Ache	962	1,622	5.8%	Brazilian
Medley*	903	1,522	5.4%	Foreign
Novartis	739	1,246	4.4%	Foreign
Eurofarma	681	1,149	4.1%	Brazilian
Bayer	643	1,084	3.8%	Foreign
Pfizer	494	833	3.0%	Foreign
Johnson & Johnson	466	786	2.8%	Foreign
Smith K. Beecham	430	725	2.6%	Foreign
Astrazeneca Brasil	410	692	2.5%	Foreign
Boehringer Ingelheim	371	626	2.2%	Foreign
Nycomed Pharma	363	612	2.2%	Foreign
Roche	332	560	2.0%	Foreign
Biolab-Sanus Farma	331	559	2.0%	Brazilian
DM Ind. Ftca**	322	543	1.9%	Brazilian
Mantecorp I Q Farm.	319	538	1.9%	Brazilian
Schering Plough	318	536	1.9%	Foreign
Sandoz do Brasil	315	532	1.9%	Foreign
Merck	295	498	1.8%	Foreign
TOP 20 TOTAL	11,030	18,600	65.9%	-

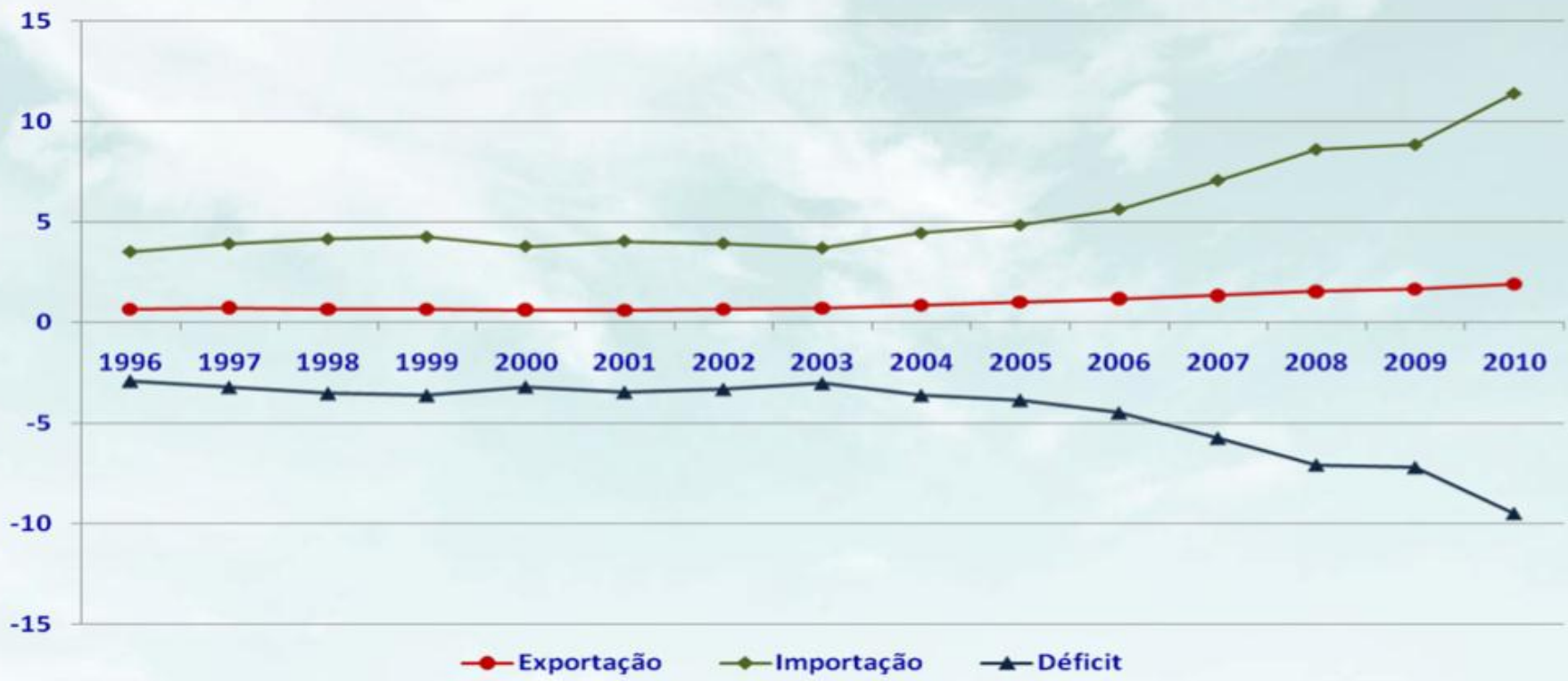
*Medley was acquired by Sanofi-Aventis in April 2009

**DM belongs to Hypermarcas that recently acquired Neoquímica, becoming one of the four largest pharmaceutical groups in the country

Evolução da Balança Comercial da Saúde: Panorama Geral

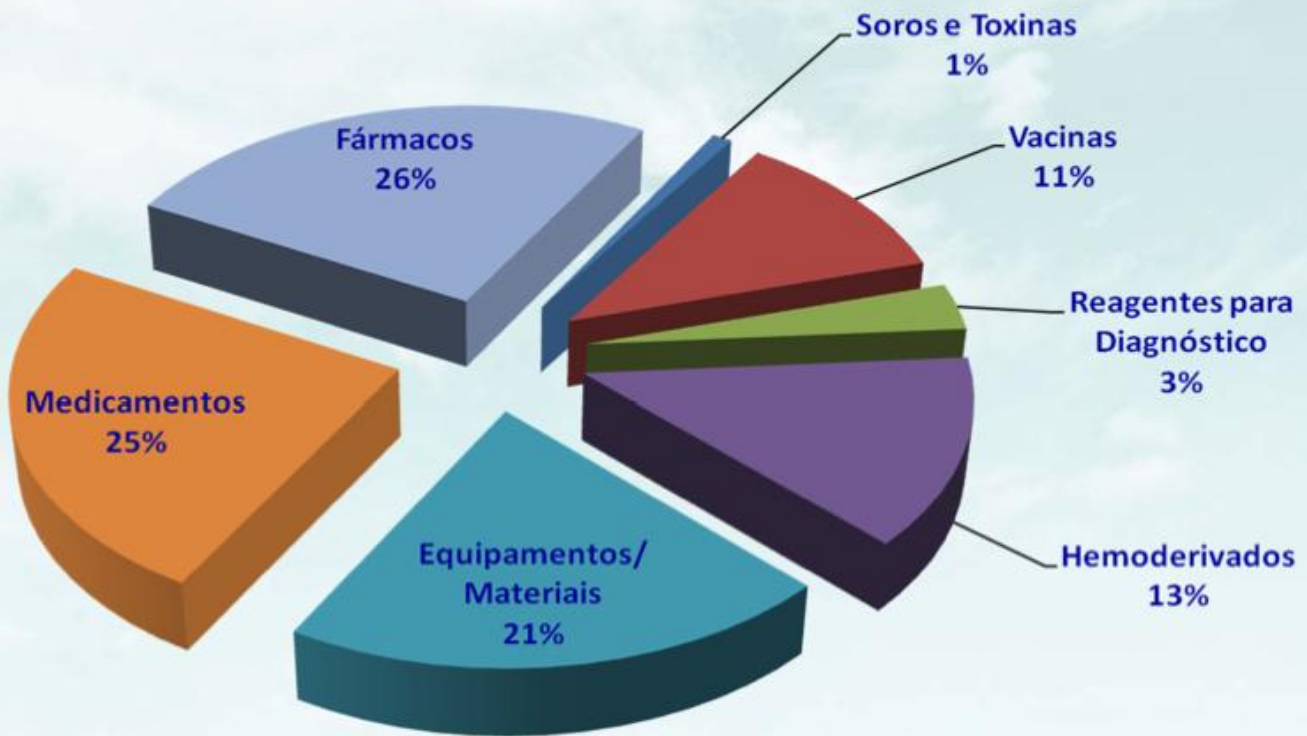
(US\$ Bilhões de 2010)

O Déficit chega ao Patamar de US\$ 10 bilhões - uma das áreas mais dependentes do País e que é central para a política social



Participação das Indústrias no Déficit da Balança Comercial da Saúde

A indústria farmacêutica responde por 64% de todo déficit em saúde (incluindo hemoderivados)



Partnerships for the Productive Development

20 projects ongoing

9 public laboratories

17 private partners (7 international and 10 national)

25 strategic products

Represents public purchases of R\$ 1.2 billion per year

Savings of around US\$ 500 million per year at the end of the projects

Regional Opportunities

Top 10 pathologies*

- . Dengue
- . HIV/ AIDS
- . Influenza (H1N1)
- . Cancer
- . CV Diseases
- . Malnutrition/Obesity
- . Other infectious
- . Child Health
- . Diabetes
- . Measles

Public health current focus

- **Dengue:** Intervention on the propagation of [*Aedes aegypti* mosquito](#) (dengue vector) is to be the main disease control strategy.
- **HIV:** Tests are implemented for the [rapid detection](#) of the virus, as too many people ignore they have the disease.
- **Breast cancer:** a [program to study the genetic profile](#) of women and improve treatment of the disease has been launched by the Office for Program Development in Latin America at NCI.
- **Cervical cancer:** Expert supports the [quadrivalent dose](#) of the HPV vaccin. Immunization should be extended to men.

* According to monitoring system

Regional Opportunities

Main areas of R&D in which Brazil has a strong presence

Enabling Technologies

- Regenerative Medicine
- Genomics and Bioinformatics
- Nanotechnology

Therapeutic Areas

- Infectious Disease
- Oncology
- Diabetes
- Neuroscience



Regional Opportunities

Regenerative Medicine

Brazil stands out among developing countries in regenerative medicine and has built an inviting framework for research and development in this area. Since 2000 it has presented continuous and robust increase in the number as well as quality of publications.



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Regenerative medicine in Brazil: small but innovative

Aims: Although Brazil has received attention for conducting one of the world's largest stem cell clinical trials for heart disease, little has been published regarding Brazil's regenerative medicine (RM) sector. Here we present a comprehensive case study of RM in Brazil, including analysis of the current activity, the main motivations for engaging in RM and the remaining challenges to development in this field. **Methods:** Our case study is primarily based on semi-structured interviews with experts on RM in Brazil, including researchers, policymakers, clinicians, representatives of firms and regulators. **Results:** Driven by domestic health needs and strategic government support, Brazil is producing innovative RM research, particularly for clinical research in cardiology, orthopedics, diabetes and neurology. We describe the main RM research currently taking place in Brazil, as well as some of the economic, regulatory and policy events that have created a favorable environment for RM development. Brazilian RM researchers need to overcome several formidable challenges to research: research funding is inconsistent, importation of materials is costly and slow, and weak linkages between universities, hospitals and industry impede translational research. **Conclusions:** Although Brazil's contribution to the RM sector is small, its niche emphasis on clinical applications may become of global importance, particularly if Brazil manages to address the challenges currently impinging on RM innovation.

KEYWORDS: Brazil · clinical trial · gene therapy · health needs · innovation · regenerative medicine · regulation · stem cell · tissue engineering

Dominique S
McMahon^{1,2},
Peter A Singer¹,
Abdallah S Daar¹

Regional Opportunities

Regenerative Medicine

Stem Cell Research in Brazil has achieved a notorious position internationally.

- **The world's largest stem cell trial is underway in the country:** the Multicenter Randomized Cell Therapy Trial in Cardiopathies (MiHeart). The study is sponsored by the Ministry of Health and the Ministry of Science, Technology and Innovation and has 1200 patients enrolled.
- Brazil has been producing relevant data regarding stem cell basic science arena. Brazil was the 5th country to reprogram stem cells into pluripotent state, and has been cover of several important magazines in the field, such as *Stem Cells* and *Cell*.
- Such great achievements occurred due to continuous governmental funding since 2005, which in 2011 surpasses R\$80million.

SOURCE: clinicaltrials.gov; INCT.



Regional Opportunities

Genomics and Bioinformatics

- Brazilian efforts towards the development of strong genomics and bioinformatics capacities began in 1997 with the establishment of a laboratory network focused on gene sequencing.
- Since then, Brazil has gone on to become one of the leading producers of gene sequencing data in the world and completed genomes of important organisms such as *Xanthomonas citri*, *X. campestris*, *Chromobacterium violaceum*, *Mycoplasma hyopneumonia*, *Anopheles darlingi* and the sugarcane genome.



Regional Opportunities

Nanotechnology

In the period of 2005 until 2008 ten networks in nanotechnology were funded by the BrasilNano Programme, with a total investment of US\$28 million.

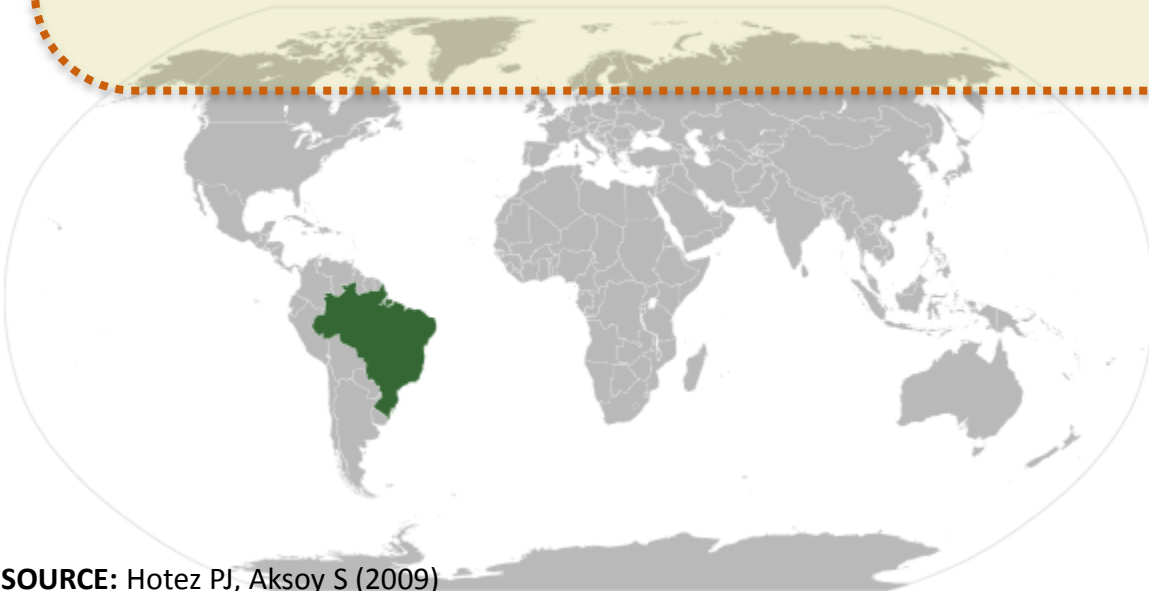
Data from the Ministry of Science, Technology and Innovation estimated:

- 1,300 researchers which work on nanotechnology in Brazil.
- 150 companies specialized in the production of nanomaterials for pharmaceuticals and cosmetics areas, among other segments.

Regional Opportunities

Infectious Diseases

- Brazil accounts for the second largest number of article submissions to the journal PLoS Neglected Tropical Diseases, following behind the United States.
- Submissions from Brazil have been extremely high in quality and cover a wide range of topics, from molecular pathogenesis and clinical aspects to epidemiology and policy.
- Brazil accounts for almost 20% of all articles published in the world in the field of tropical medicine and 12% in parasitology.



Regional Opportunities

Infectious Diseases

- In 2006, it was instituted the Program for Research and Development in Neglected Diseases, a partnership between the Ministry of Health, the Ministry of Science and Technology and the Health Surveillance Secretary.
- **Based on epidemiology and disease burden, seven priorities were established: dengue, chagas disease, leishmaniasis, malaria, schistosomiasis, leprosy and tuberculosis.**

Main public grants in neglected diseases in Brazil		
Year	Focus Area	Investment
2003	Tuberculosis Research Network	R\$ 1,9 million
2004	Dengue	R\$ 0,94 million
2005	Leprosy	R\$ 2,5 million
2006	Neglected Diseases	R\$ 17 million
2008	Neglected Diseases	R\$ 22 million
2009	Malaria Research Network	R\$ 15,4 million
2009	Dengue Research Network	R\$ 22,7 million

Source: *Neglected diseases: the strategies of the Brazilian Ministry of Health. Rev Saúde Pública 2010;44(1):200-2.*

Regional Opportunities

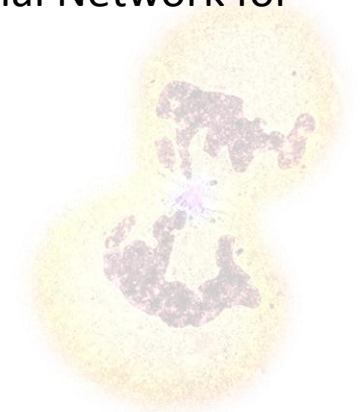
Neuroscience

- **Neuroscience research represents 20% of Brazilian scientific production in biological/ biomedical areas.**
- Recent scientific achievements of Brazil in the area comes from Miguel Nicolelis, a Brazilian scholar at Duke University/USA, which coordinates the International Neuroscience Institute (Natal, Brazil). The Institute has received massive governmental and private investments.

Regional Opportunities

Oncology

- The National Cancer Institute (INCA) maintains a National Tumor and DNA Bank (BNT) with samples from almost 10,000 donors.
- Sírio Libanês Hospital and Ludwig Institute for Cancer Research (LICR) recently established a partnership to create a Translational Research Center on Molecular Oncology.
- The Cancer Institute of São Paulo State - ICESP is establishing an unique infrastructure to support clinical research, molecular oncology and regenerative medicine applied to oncology.
- In October 2011, the Ministry of Health officially launched the National Network for Innovation and Development of Anticancer Pharmaceuticals.

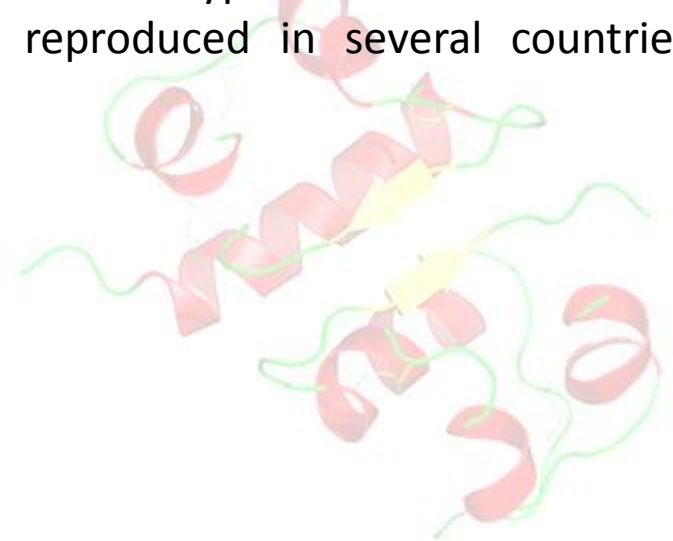


SOURCE: <http://www2.inca.gov.br> / <http://www.icesp.org.br/home> :

Regional Opportunities

Diabetes

- Diabetes research in Brazil has achieved some relevant accomplishments, such as the transplant of pancreatic islets using the Edmonton protocol, only 2 years after its first publication, in 2000.
- Brazil's research in Diabetes is also very innovative. For instance, Brazil hosted the first clinical trial for Hematopoietic stem cell transplantation for type I diabetes treatment, which was highly successful and now is being reproduced in several countries, highlighting Brazil's leading role in the area.



SOURCE: Clinicaltrials.gov / http://www.usp.br/nucel/q_historico.htm

AGENDA

1. Current Landscape in Brazil

Scientific Development & Knowledge Production

Regional Opportunities

Business Environment



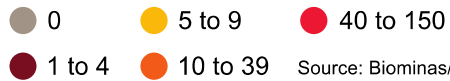
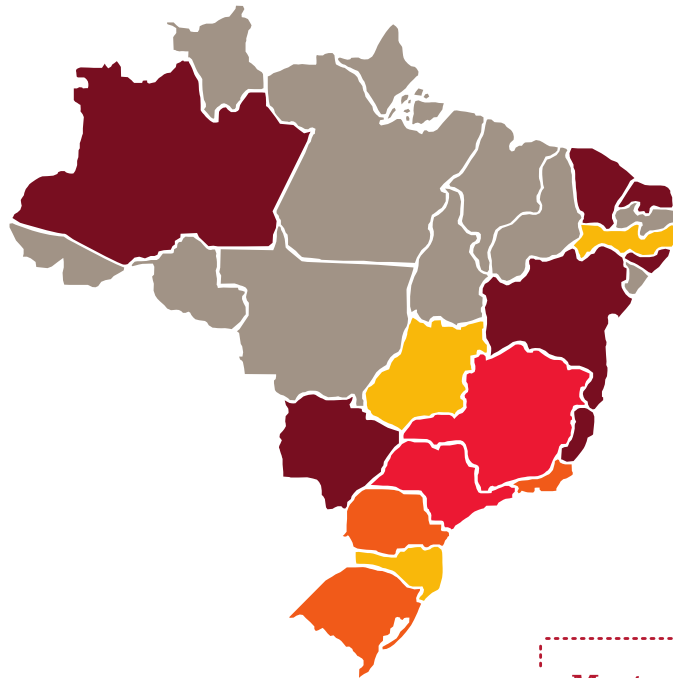
*The Brazilian life
science industry*
Pathways for growth



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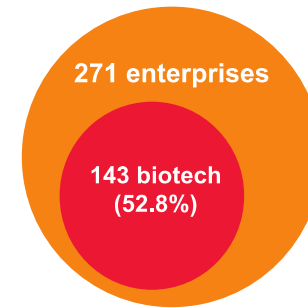
Industry Profile

Geographical distribution of life science companies



Source: Biominas/

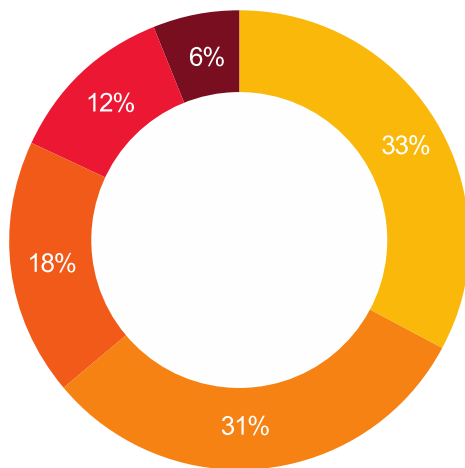
Biosciences enterprises x Biotech enterprises



Most representative states and regions

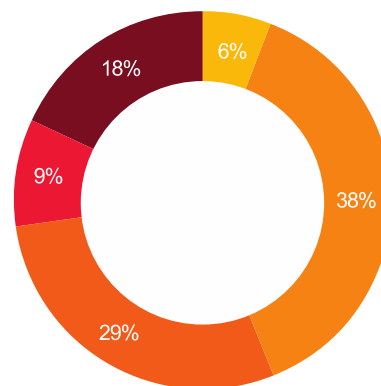
Region	State	Number of companies	% of Brazil
Southeast (74.9%) 203 companies	São Paulo	103	38.0%
	Minas Gerais	83	30.6%
	Rio de Janeiro	16	5.9%
South (14.4%) 39 companies	Rio Grande do Sul	19	7.0%
	Paraná	14	5.2%

Companies by application



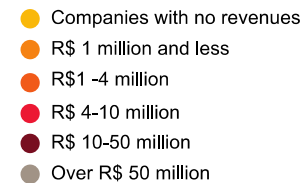
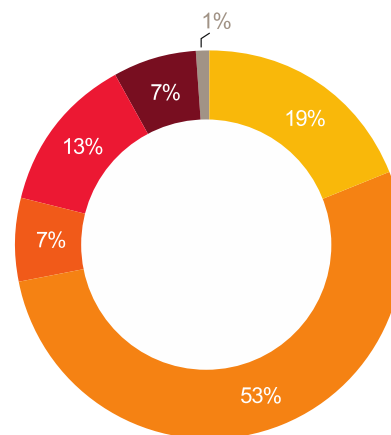
Source: Biominas/PwC Survey, 2011

Companies by age



Source: Biominas/PwC Survey, 2011

Graph 10 - Gross revenue by company



Source: Biominas/PwC Study, 2011

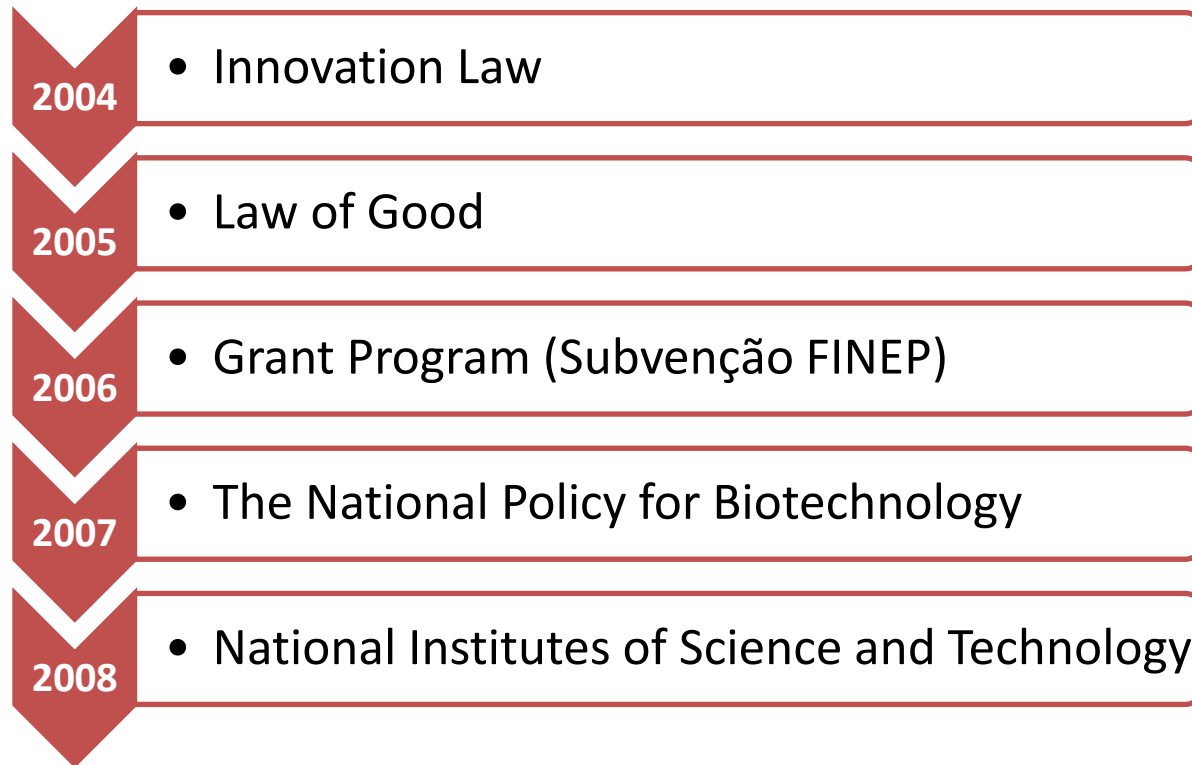


Environment

Graph 12 - Which of the following topics represent critical success factors for the Brazilian life science industry during the next two years? (select the three most important)



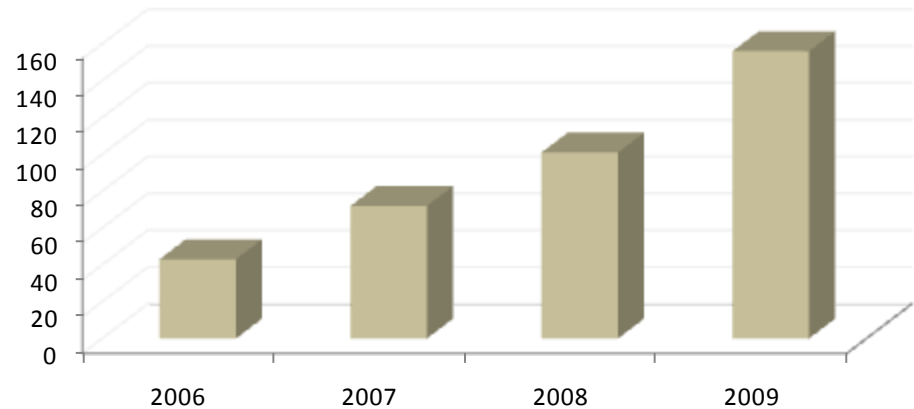
Public Policies: promoting a culture of innovation in Brazil



Public Policies: promoting a culture of innovation in Brazil

Since the publication of the Innovation Law in 2004, universities and research institutes were obliged to create TTOs. The purpose was to stimulate the innovation in Brazil. Currently the number of TTOs in Brazil is more than 200.

TTOs in Brazil have significantly increased due to the Innovation Law

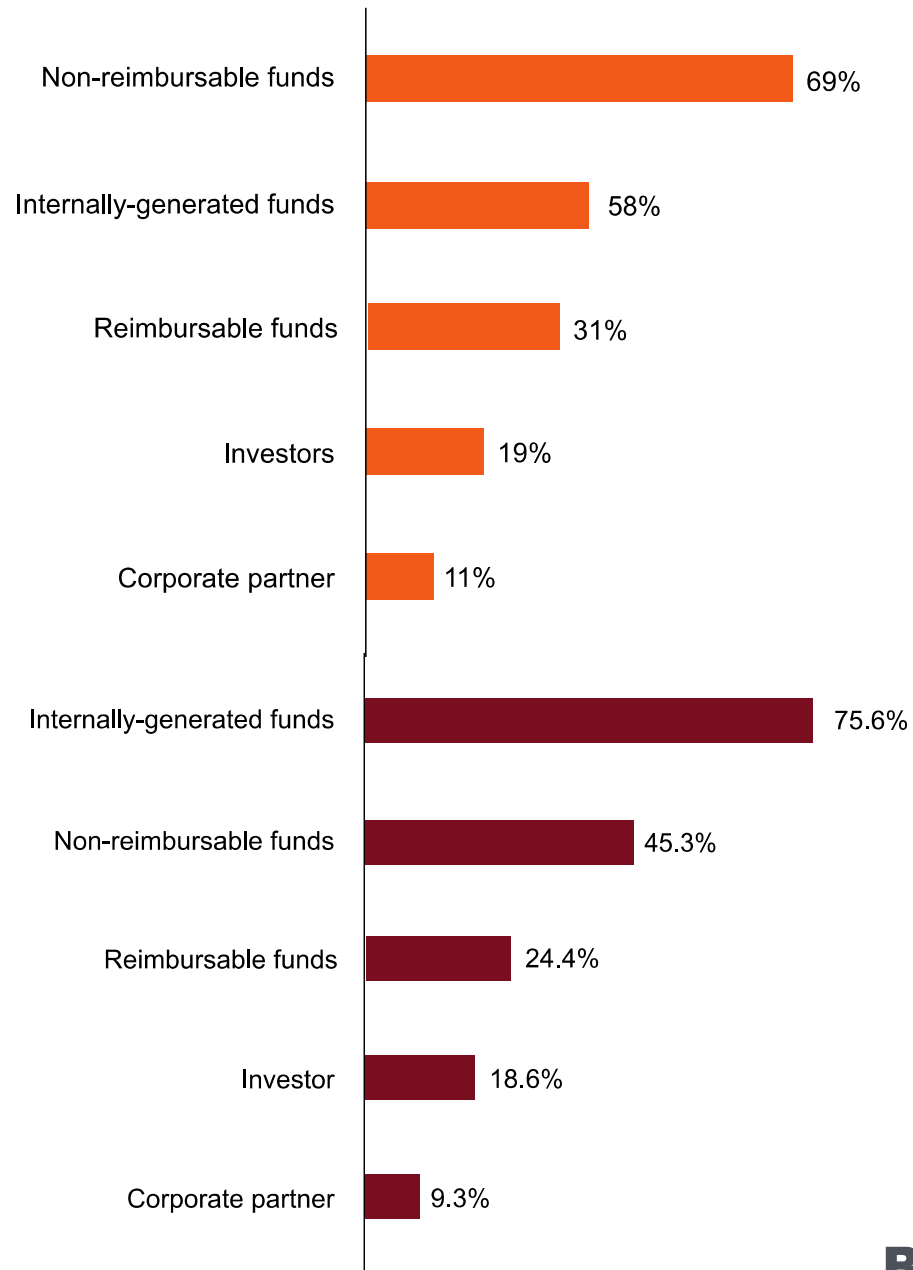


Source: Associação Nacional de Entidades Promotoras de Empreendimentos Inovadores – ANPROTEC, 2008 and Fórum Nacional de Gestores de Inovação e Transferência de Tecnologia - FORTEC

Financing

Graph 6 - Indicate the principal sources of funds for Research & Development activities at your company (select up to two options)

Graph 8 - Indicate the principal sources for financing this investment (excluding R&D)



Governmental resources:

Federal Level



State Level



Financing: The venture capital industry in the country is still consolidating, but recent movements reveal the interest of international groups in exploring this new frontier.

Main funds with investments in technology-based life science companies in Brazil



Funds to initiate operations in 2012



Burrill Brazil Fund: Leading Investors



- Brazilian National Development Bank (BNDES)



- FINEP (Brazilian innovation agency for the Ministry of Science and Technology)



- Nossa Caixa (development agency for the state of São Paulo)



- Investe Rio (development agency for the state of Rio de Janeiro)



- Life Technologies Inc. (LIFE:US)



- Pfizer, Inc (PFE:US)



- CAF (Corporación Andina de Fomento)

FINANCIANDO EL DESARROLLO • AMÉRICA LATINA



- IADB/MIF (Inter American Development Bank/Multilateral Investment Fund)

Graph 14 - Among the following topics, which will be the greatest challenges for your company over the next two years (choose the three most important)



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