Brazil's Biotechnology Breakthrough

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"R&D Breakthrough on Pharmaceuticals"

Wyndham Levent Otel – Istambul

October 2014

Agenda

- Institucional
- Biotechnology Overview
- R&D policies mainly on value added generics and biosimilars
- Chalenges

Institutional

FIESP CIESP

Industry

FIESP

Federation of Industries of State of Sao Paulo

Represents **131** sector **business associations** which stands for about **150,000** **state and national firms**

CIESP

Center of Industries of State of Sao Paulo

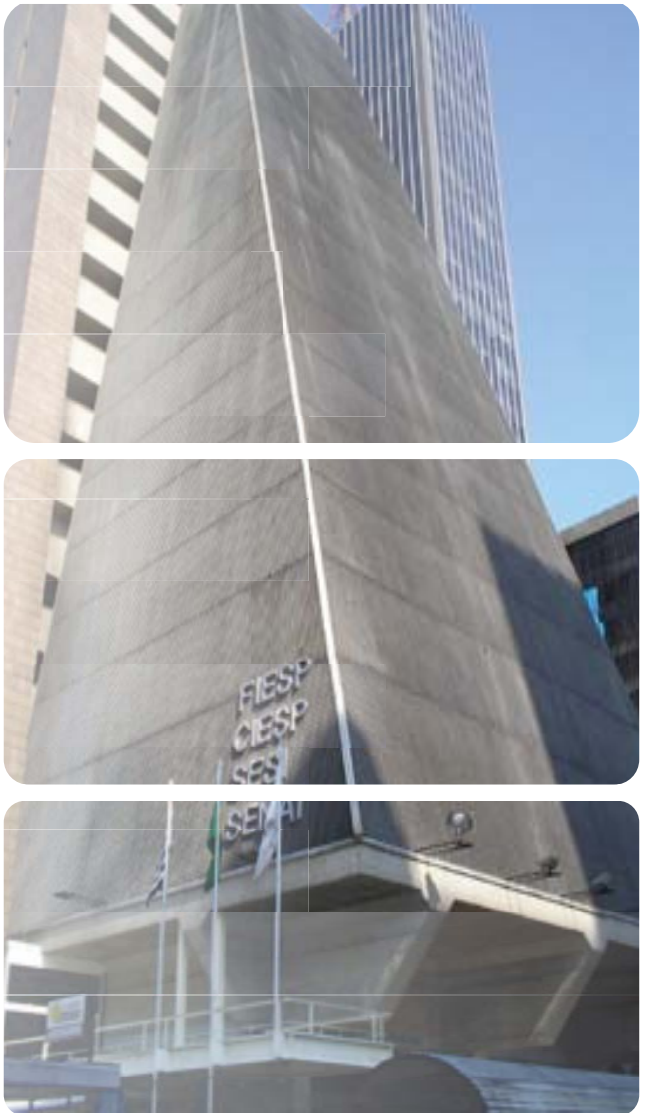
43 regional offices throughout the state which represents about **10,000** **associated firms**

IRS

Roberto Simonsen Institute

Think tank specialized in **industrial issues**. It's also responsible for the **coordination of Superior Council**

These entities work together in defense of the industry, providing services and support to their associated institutions and firms.



PRESIDENCY

DEPARTMENTS

- Agribusiness
- Competitiveness and Technology
- Construction Industry
- Defense Industry
- Environment
- Infrastructure and Energy

SUPERIOR COUNCILS

Guidelines for departments

- Legal Division
- Regional Action
- Research and Economic Studies
- Small and Medium Companies
- Trade and Foreign Affairs
- Union and Labor Issues

Committees

Health, Biotecnology, Fisheries, Mining, Textiles, Sport, Paper, O&G, Etc.

Sao Paulo State and FIESP's representativeness in the Brazilian Economy

FIESP CIESP

Main Industrial Sectors Represented by FIESP

Aircraft	Machinery
Food	Metallurgy
Fuels	Paper and Cellulose
Oil Refinery	Chemical Products
Electric Energy	Oil and Gas
Ethanol	Textiles and Apparel
Fertilizer and Animal Food	Vehicles and auto parts
Health	Bioindustry

SP State Share in Brazil's GDP and Exports

33% of Total GDP (*)	US$ 709 bi
24% of Total Exports (**)	US$ 59.9 bi
57% of Brazil´s Industrialized Exports (**)	US$ 53.3 bi

(*)2010, latest effective figure available
(**)2012


BIO BRASIL
Bioindustry Committee
COMBIO | COMSAUDE
FIESP CIESP

COMBIO | BIO BRASIL

FIESP

Human Health

Animal Health

Enviroment

Agriculture

Defense

Energy

Services

COMBIO

Committee of Biotechnology
Supply Chain

COMSAUDE

Committee of Health
Supply Chain

Bioindustry Committee

- Created on September, 2012. The BIOBRASIL, Bioindustry Committee, expects to set a working plan for the country Image-building in Biotechnology, for which should be undertaken to promote and dispose the sector with the following objectives:

  - Facilitate access to information and new market opportunities as a way to support the internationalization of bioscience companies.
  - Enable companies to target standard world-class processes – certifications, registrations and intellectual property – targeting the inclusion in the international market.
  - Supporting the local companies on developing strategic plans for integration into the global market.
  - Strengthen the Brazilian life sciences products and services image, focusing on quality and suitability to targeted markets, to seek the generation of new business.

Biotechnology Overview

FIESP CIESP

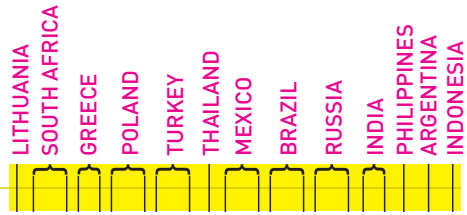
Brazil Biotech Map 2011

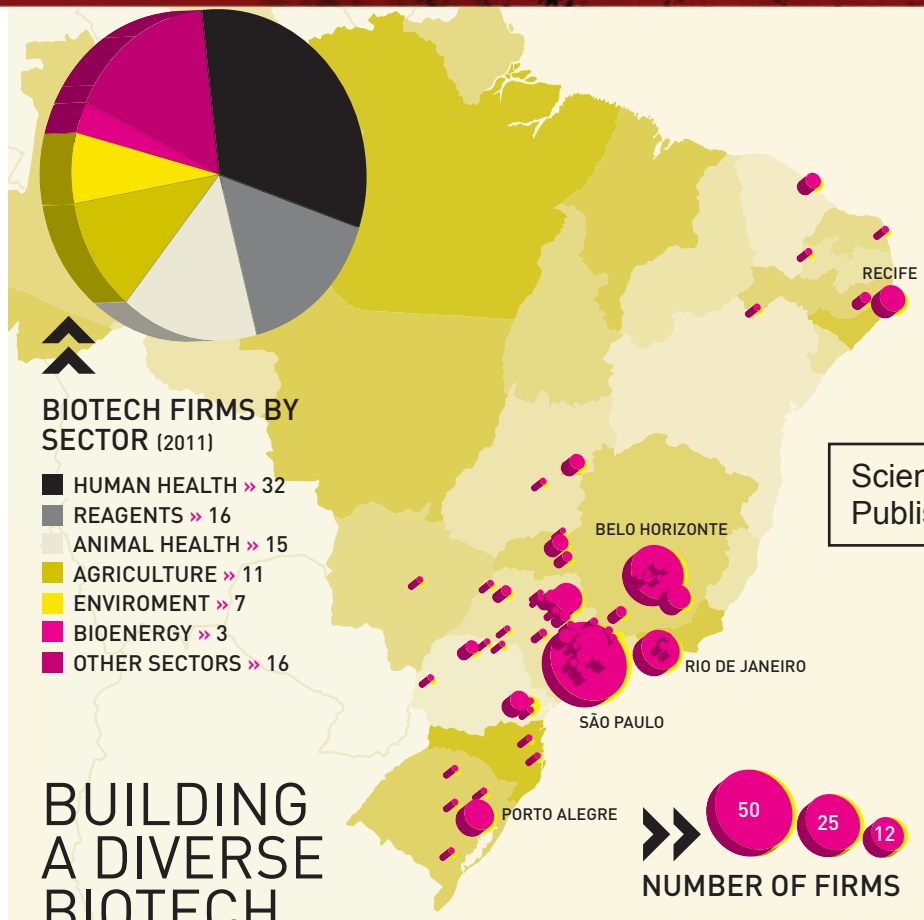
Where are the Biotechnology firms in Brazil?

Source: BrBiotec Brasil/Cebrap, "Brazil Biotech Map 2011" (n=240).

for Enterprise Support, Education/ Workforce and Foundations. For example, its score for Education/ Workforce increased by nearly 40 percent. Such rises offset its small drop in Intensity. Spain saw its scores for Intensity and Foundations increase by 28 and 8 percent, respectively, between 2010 and 2011. It also showed small gains in Intensity and Education/Workforce.

Signs of consistent growth also appear in the scores of other countries, including Finland, Germany, Italy, Mexico, Sweden and the Czech Republic. As our database grows, more sophisticated forms of analysis will become possible. For instance, we look forward to watching the numbers for the list's new countries, as well as to looking for ongoing trends in countries on the list from the start. This analysis will help nations gauge their own progress as innovators. Moreover, trends on the overall innovation scores can be traced to specific changes in the category data.





WV SC

Scientific American Magazine
Published during BIO2011

BUILDING A DIVERSE BIOTECH INDUSTRY

Working its way up in an extremely competitive international field

From 2009 through 2011, Brazil demonstrated growth in its normalized innovation scores (see graph, left page). Although it did not score near the top of Scientific American *Worldview*'s overall innovation index, Brazil's biotechnology industry shows considerable breadth. According to preliminary data in "Brazilian Biotech Mapping 2011," from BrBiotec Brasil and Centro Brasileiro de Analise e Planejamento (CEBRAP), the nation's leading biotechnology section, human health, accounts

Brazil Biotech Map 2011

Download

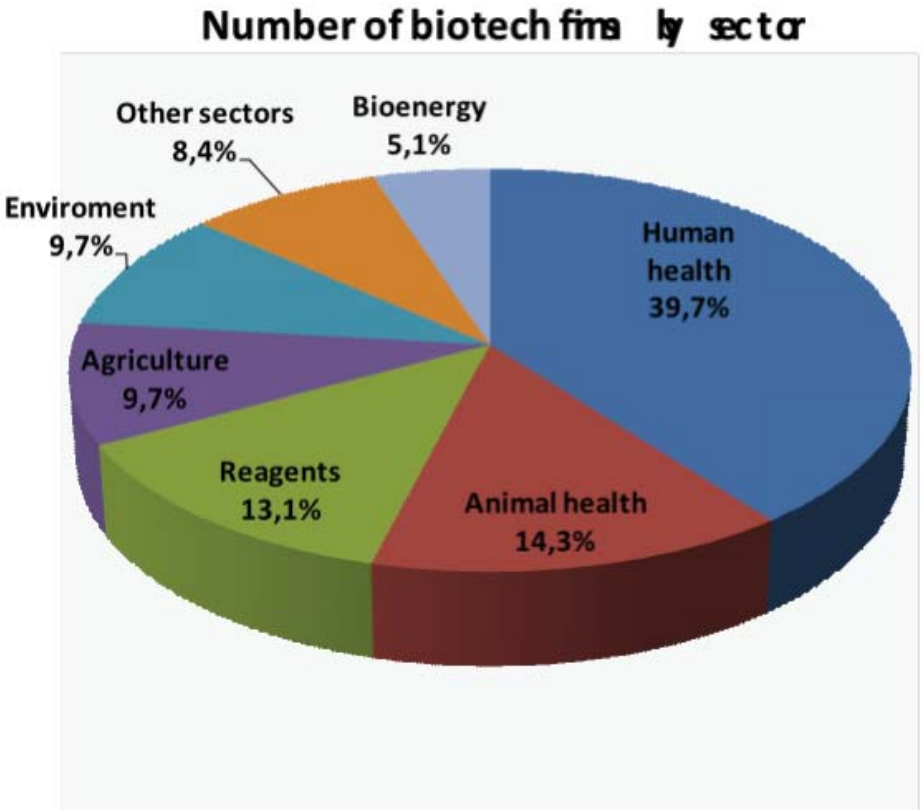
- http://www.cebrap.org.br/v1/upload/pdf/Brazil_Biotec_Map_2011.pdf

How many biotech companies exist in Brazil? Where are they located?

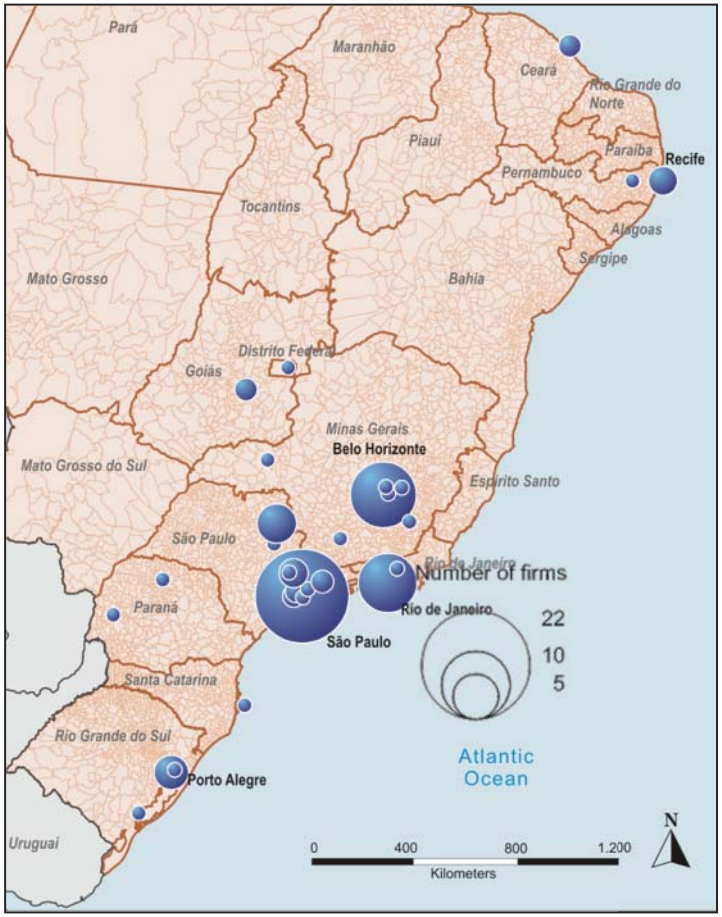
State	Number of companies	Share
SP	96	40,5%
MG	58	24,5%
RJ	31	13,1%
RS	19	8,0%
PR	11	4,6%
PE	10	4,2%
Others	12	5,1%
2011 **Total**	**237**	100%

2014 **Today** **314** companies

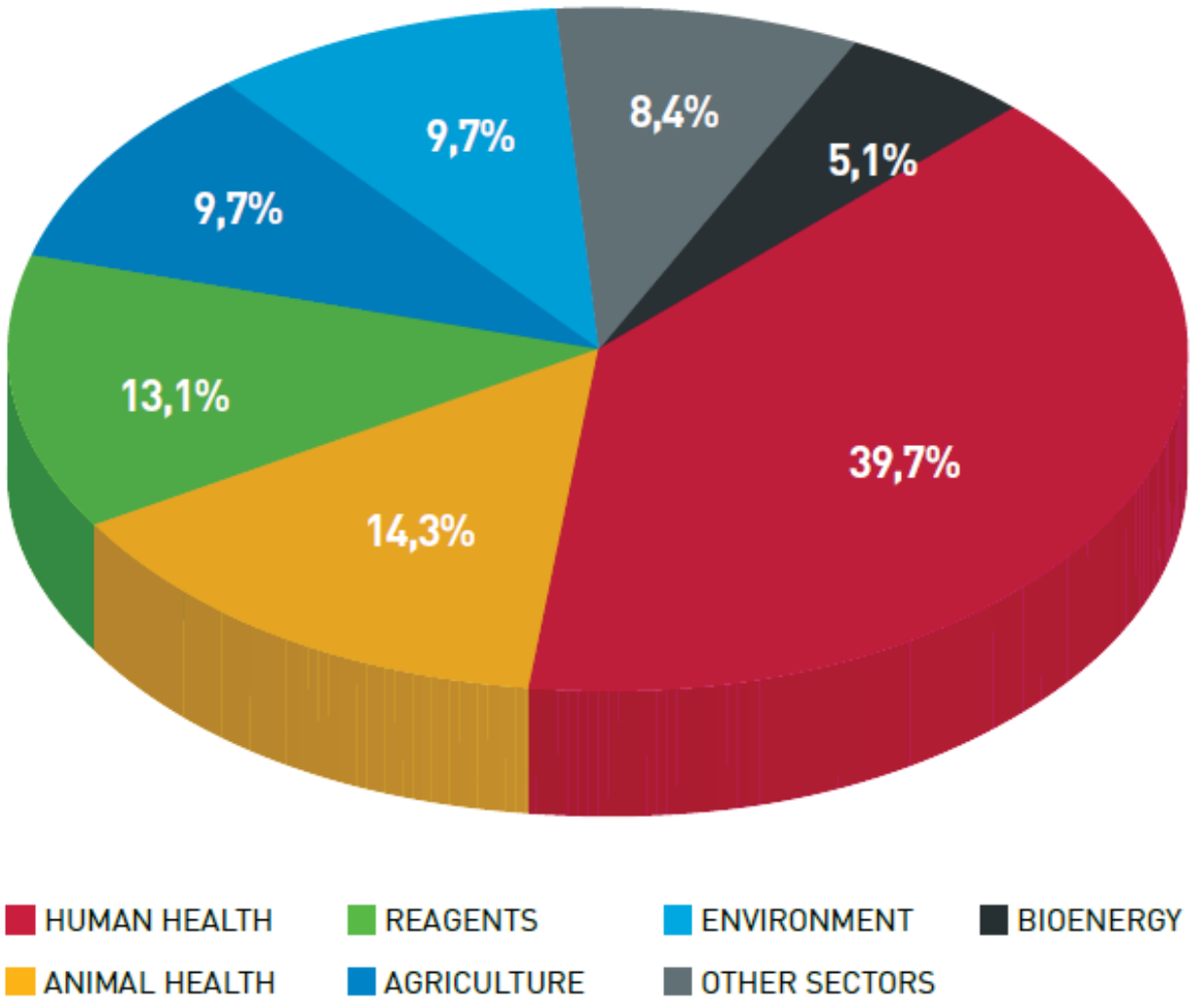
What field of biotechnology are the companies working in?



Companies in human health by city

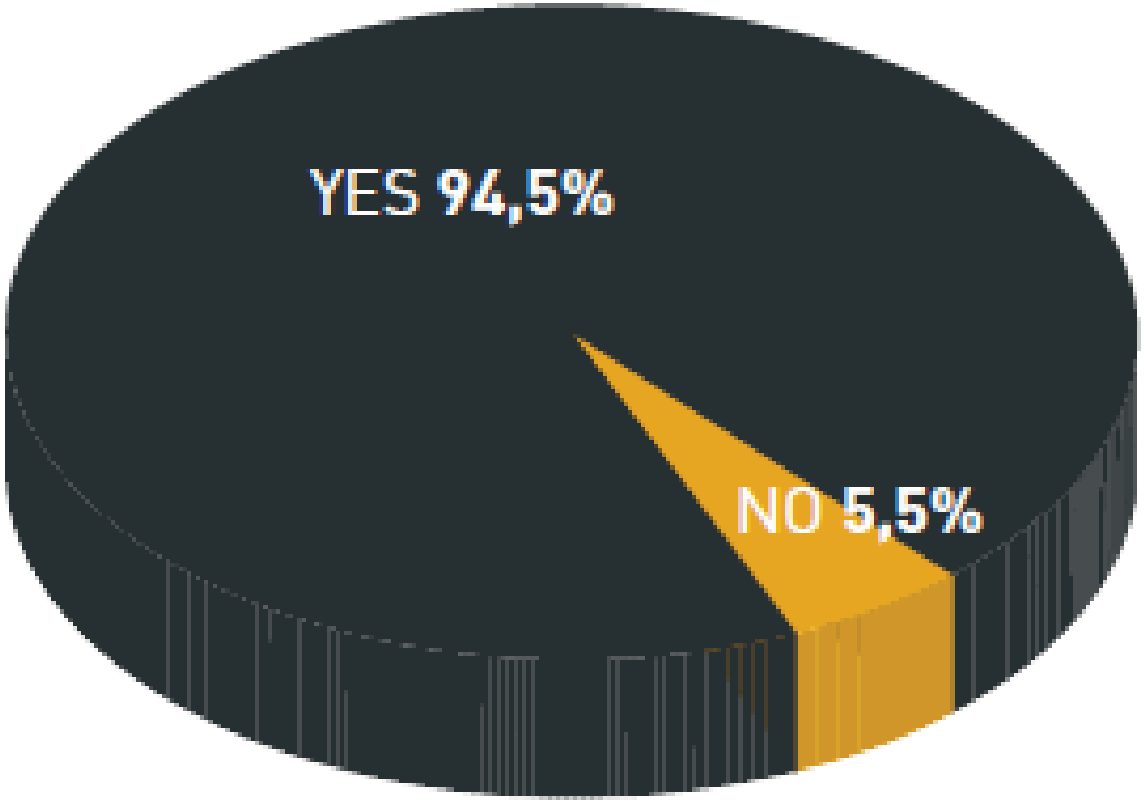


GRAPH 2 **Biotechnology companies by area of activity.**



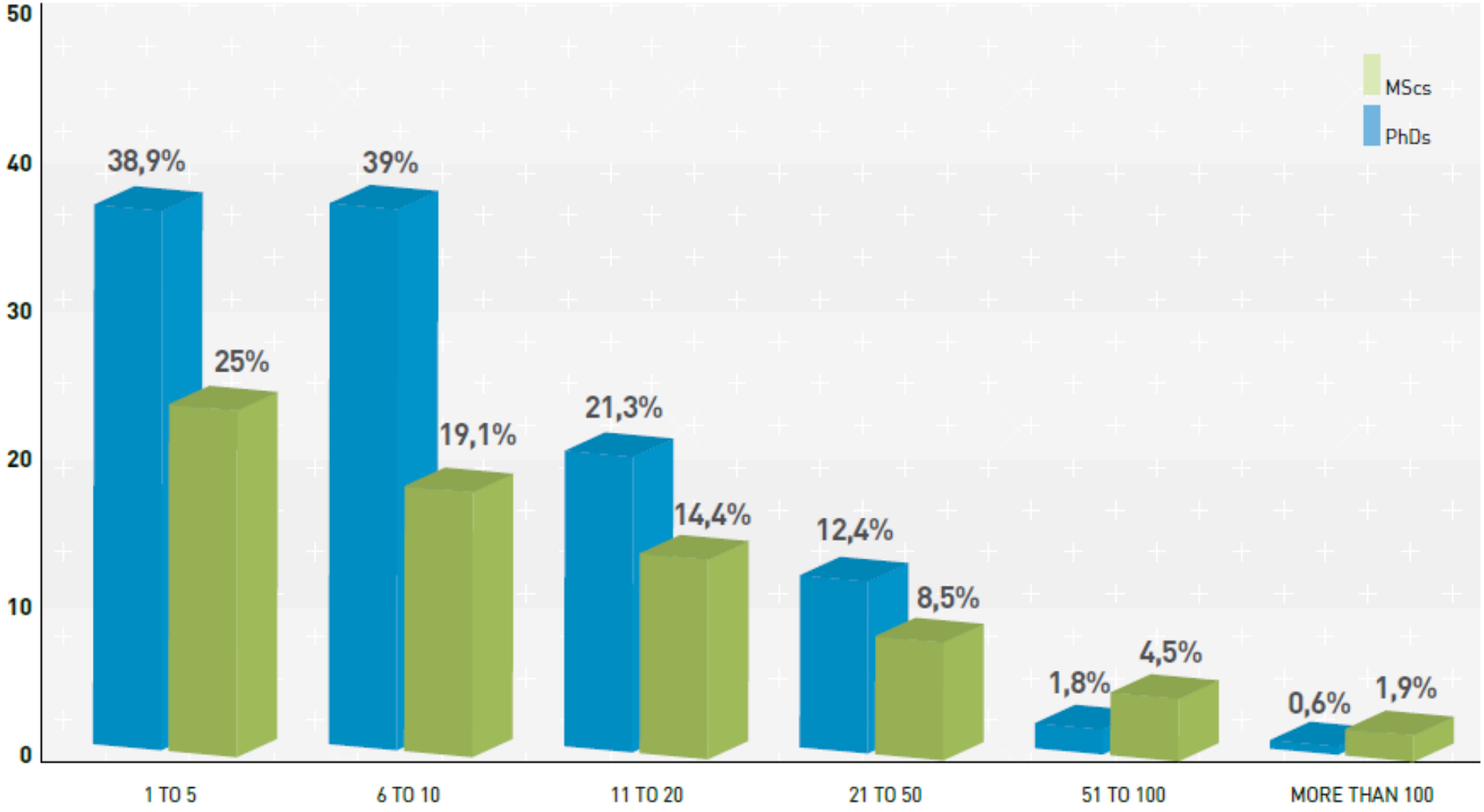
Source: BRBIOTEC Brasil / Cebrap, "Brazil Biotech Map 2011" (n=237).

GRAPH 11 Does the company has a relationship with universities or research intitutes?



Source: BRBIOTEC Brasil/Cebrap, "Brazil Biotech Map 2011". (n=145).

GRAPH 6 Percentage of MScs and PhDs in companies of different sizes.



Source: BRBIOTEC Brasil/Cebrap, "Brazil Biotech Map 2011" (n=138

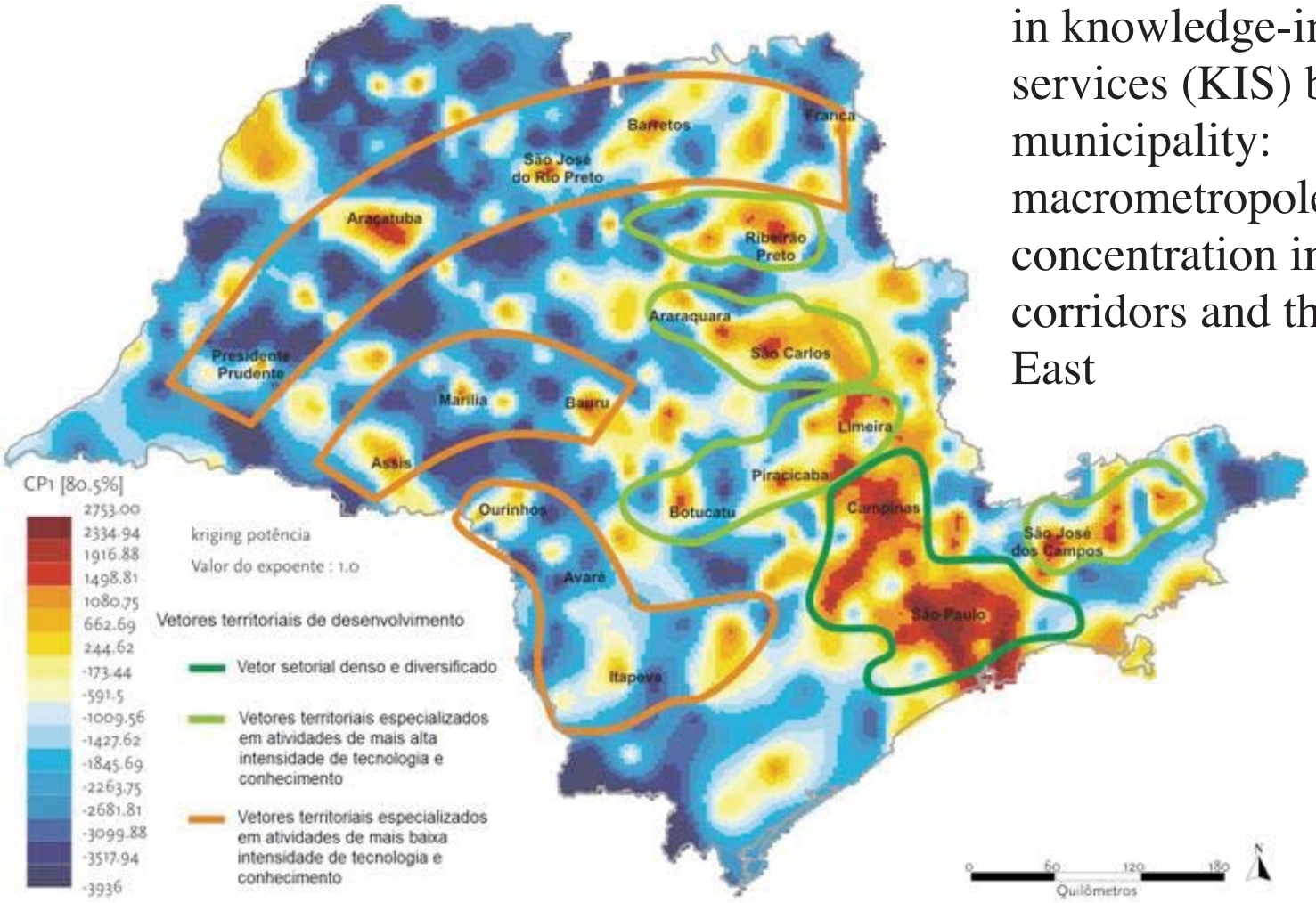
- Major biotech clusters in Brazil: São Paulo, Minas Gerais, Rio Grande do Sul and Rio de Janeiro.

- Major areas of activity: Human Health, Agriculture and Animal Health.

- World Leader in Ethanol prodution, bioplastics and agricultural.

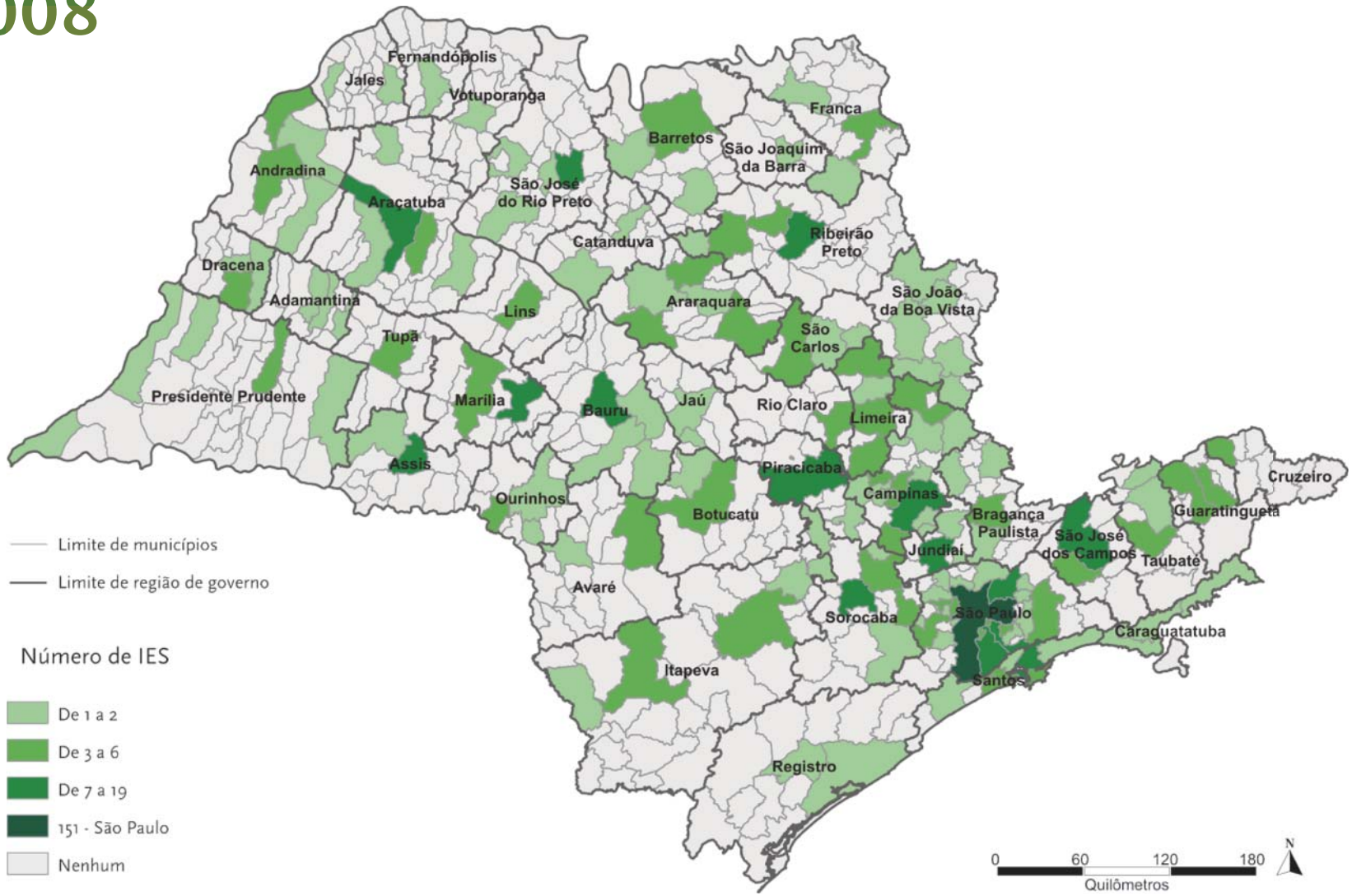

SAO PAULO

Distribution of employment in knowledge-intensive services (KIS) by municipality: macrometropole concentration in the corridors and the North and East



Source: RAIS. ESP, 2009

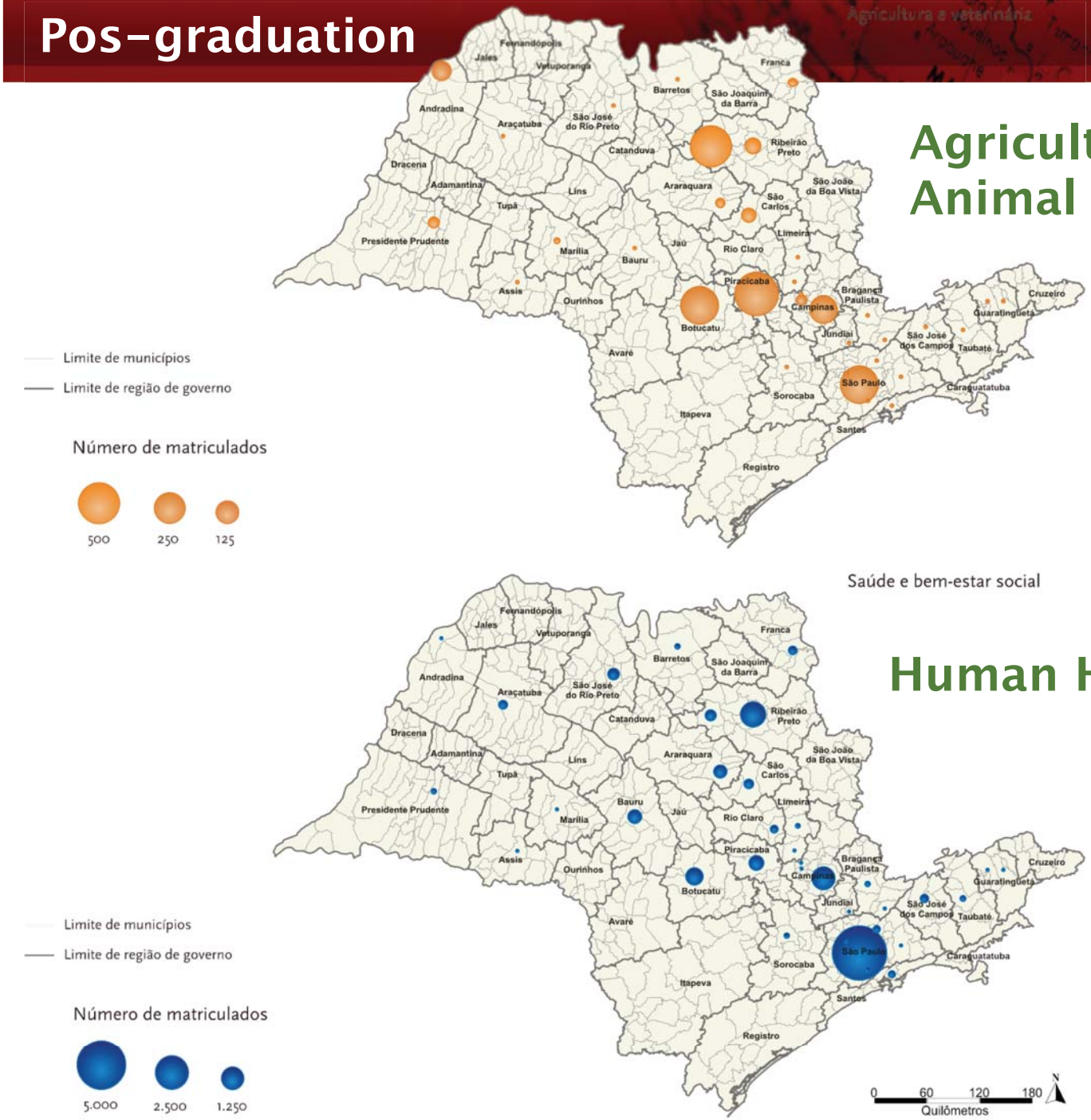
S&T&I Infrastructure: Universities. ESP, 2008



Source: CEBRAP (INEP/MEC)

Pos-graduation

Agriculture and Animal Health

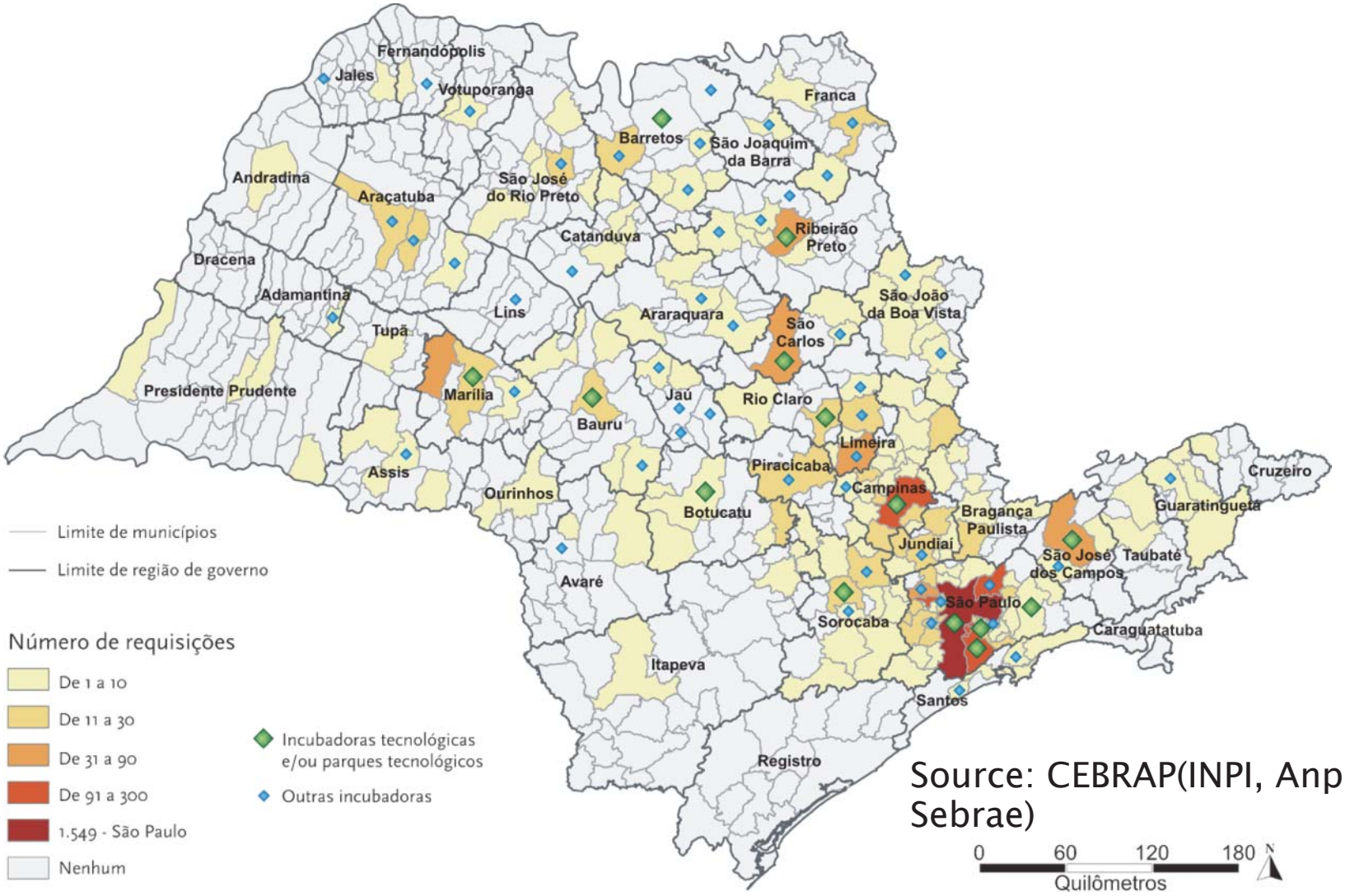


Human Health

Saúde e bem-estar social

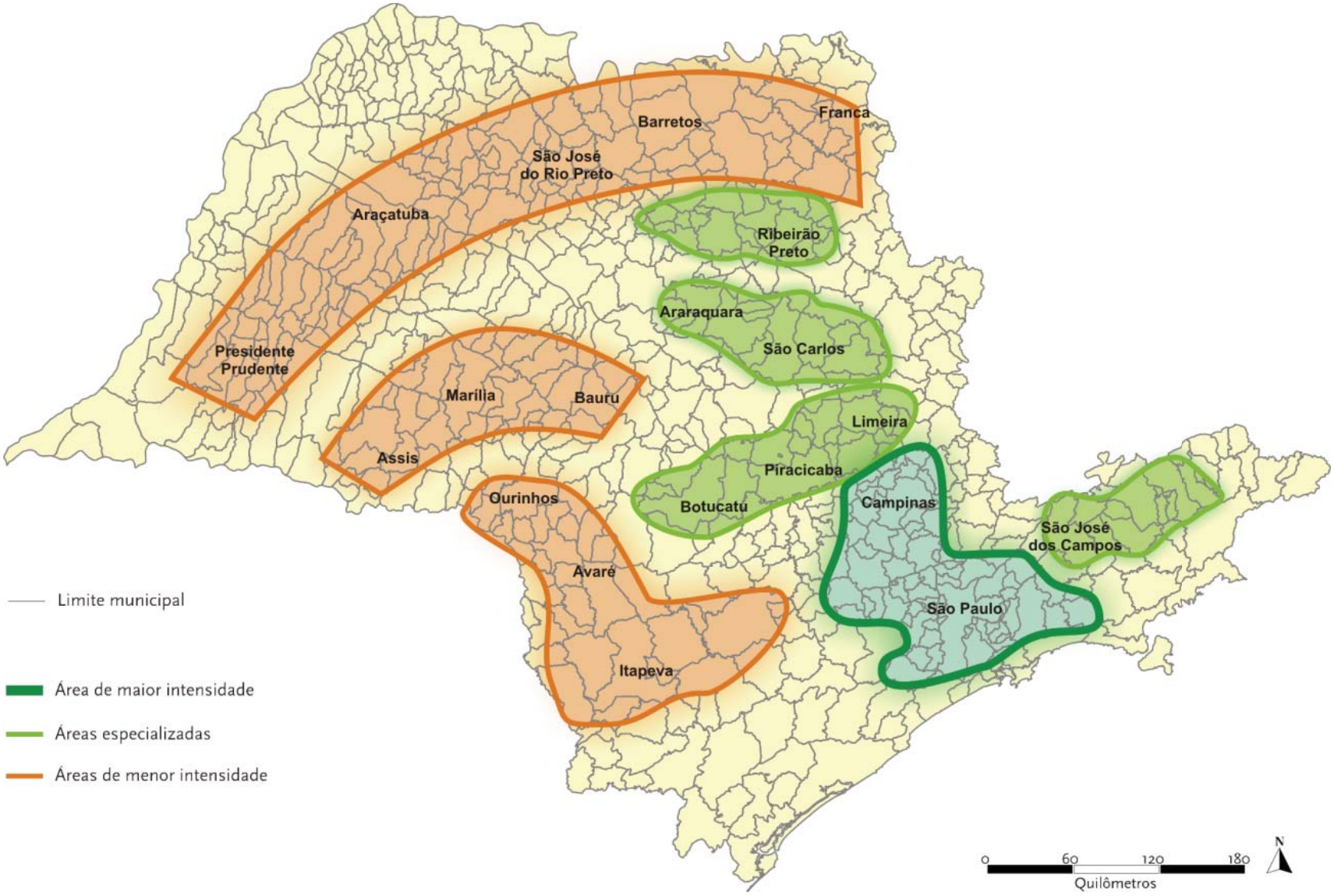
Fonte: CEBRAP (CAPES/MEC). 2009

Patents (2001 e 2006), incubators (2006) and Technolgical Parks (2008)

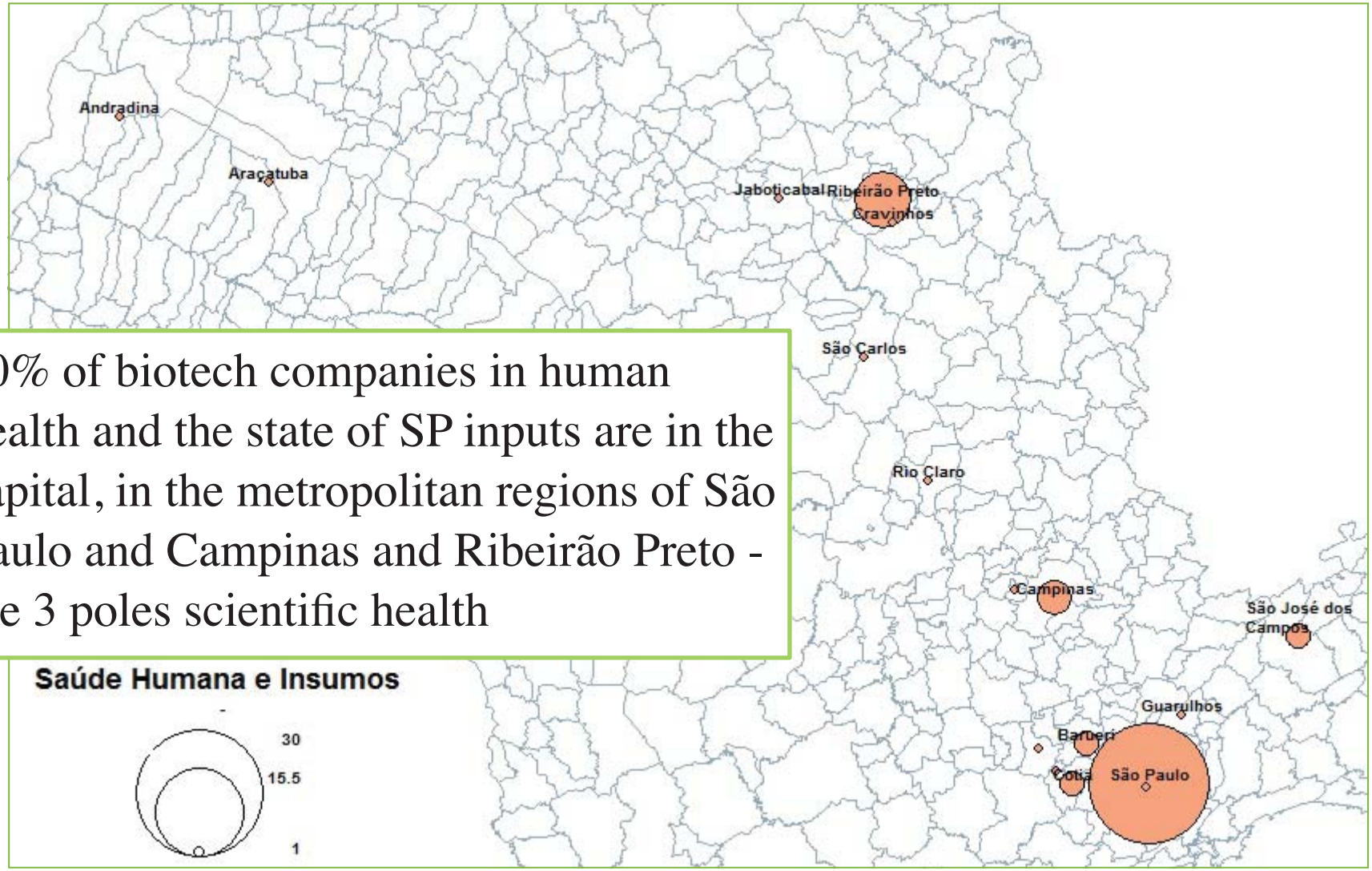


Source: CEBRAP(INPI, Anprotec e Sebrae)

Resume:


Barretos
Franca
São José
do Rio Preto
Araçatuba
Ribeirão
Preto
Araraquara
São Carlos
Presidente
Prudente
Marília
Bauru
Limeira
Assis
Piracicaba
Ourinhos
Botucatu
Campinas
São José
dos Campos
Avaré
São Paulo
Itapeva
Limite municipal
Área de maior intensidade
Áreas especializadas
Áreas de menor intensidade
0
60
120
180
Quilômetros
N

Biotech Clusters

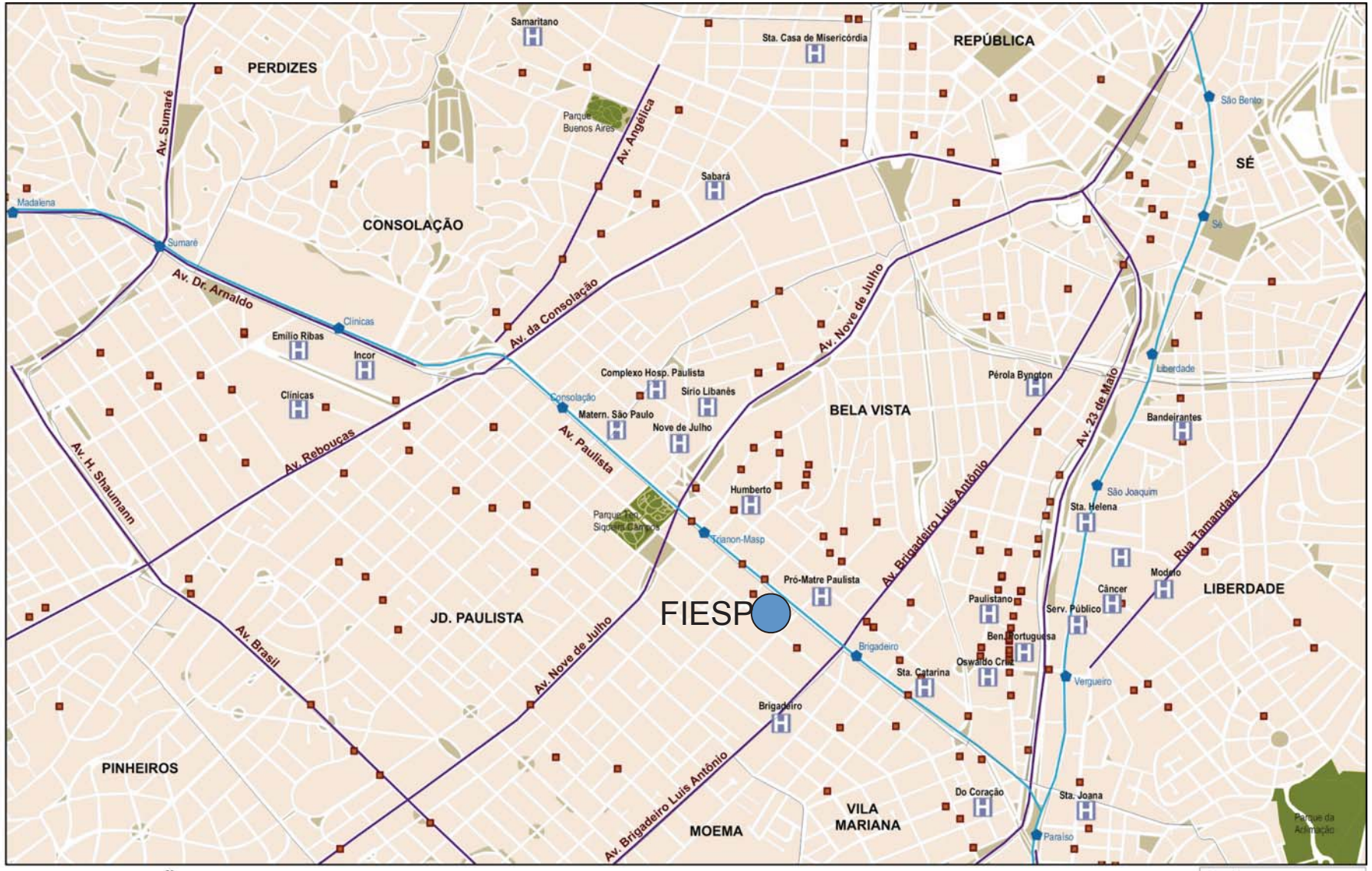


- ✓ 90% of biotech companies in human health and the state of SP inputs are in the capital, in the metropolitan regions of São Paulo and Campinas and Ribeirão Preto - the 3 poles scientific health

Source: CEBRAP


São Paulo - A Biotech City

Hospitals. São Paulo. 2006



Fonte: Ministério do Trabalho e Emprego. Relação Anual de Informações Sociais – Rais; Cadastro Geral de Empregados e Desempregados – CAGED.
Base Cartográfica: Secretaria Municipal de Planejamento – Sempla/Dipro.
Elaboração: Centro Brasileiro de Análise e Planejamento – CEBRAP, 2008.

Enabling factors

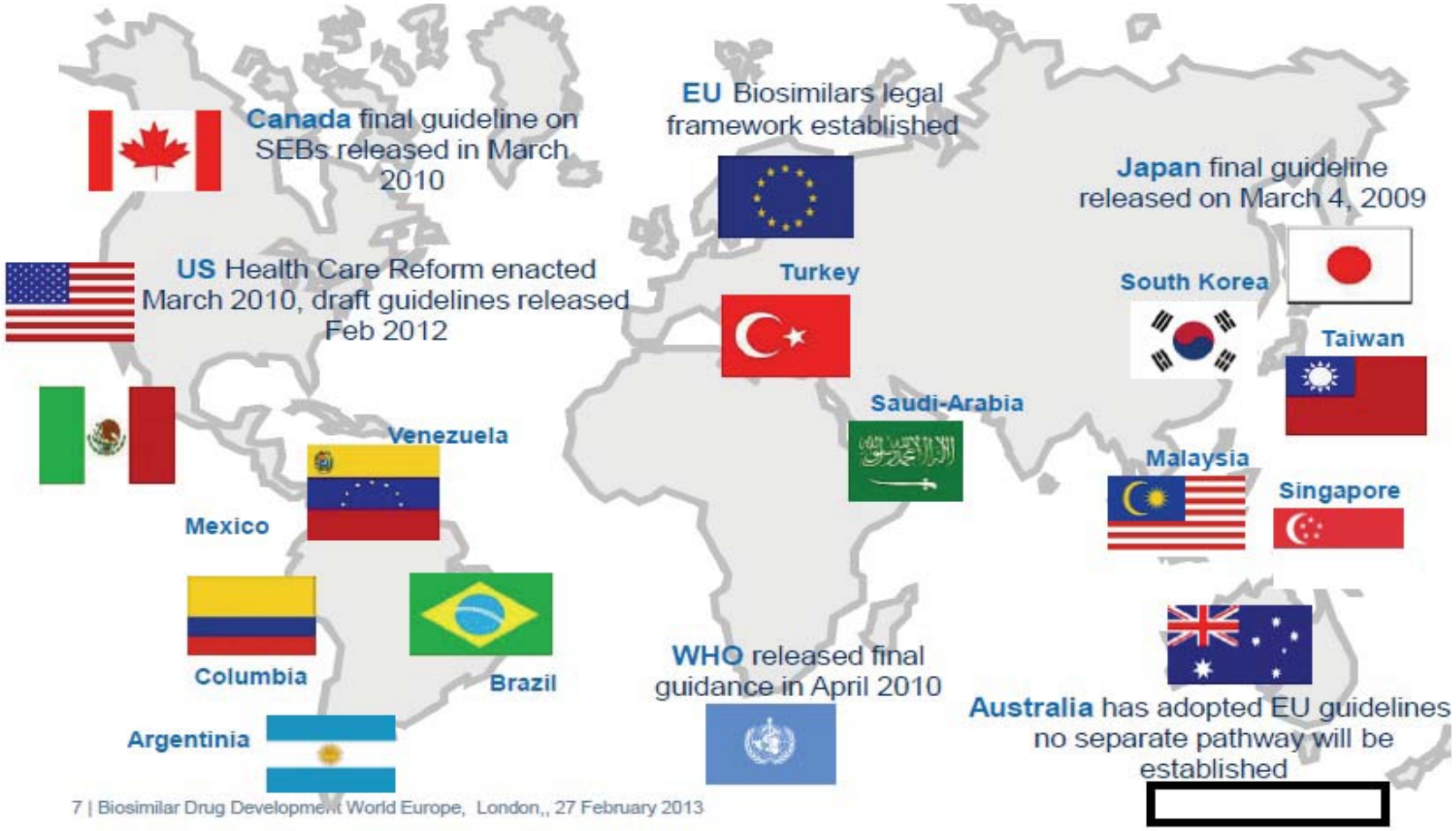
- **Human capital**
- **Infrastructure for R&D**
- Intellectual property protection
- **The regulatory environment**
- Technology transfer frameworks
- Market and commercial incentives
- Legal certainty (including the rule of law)

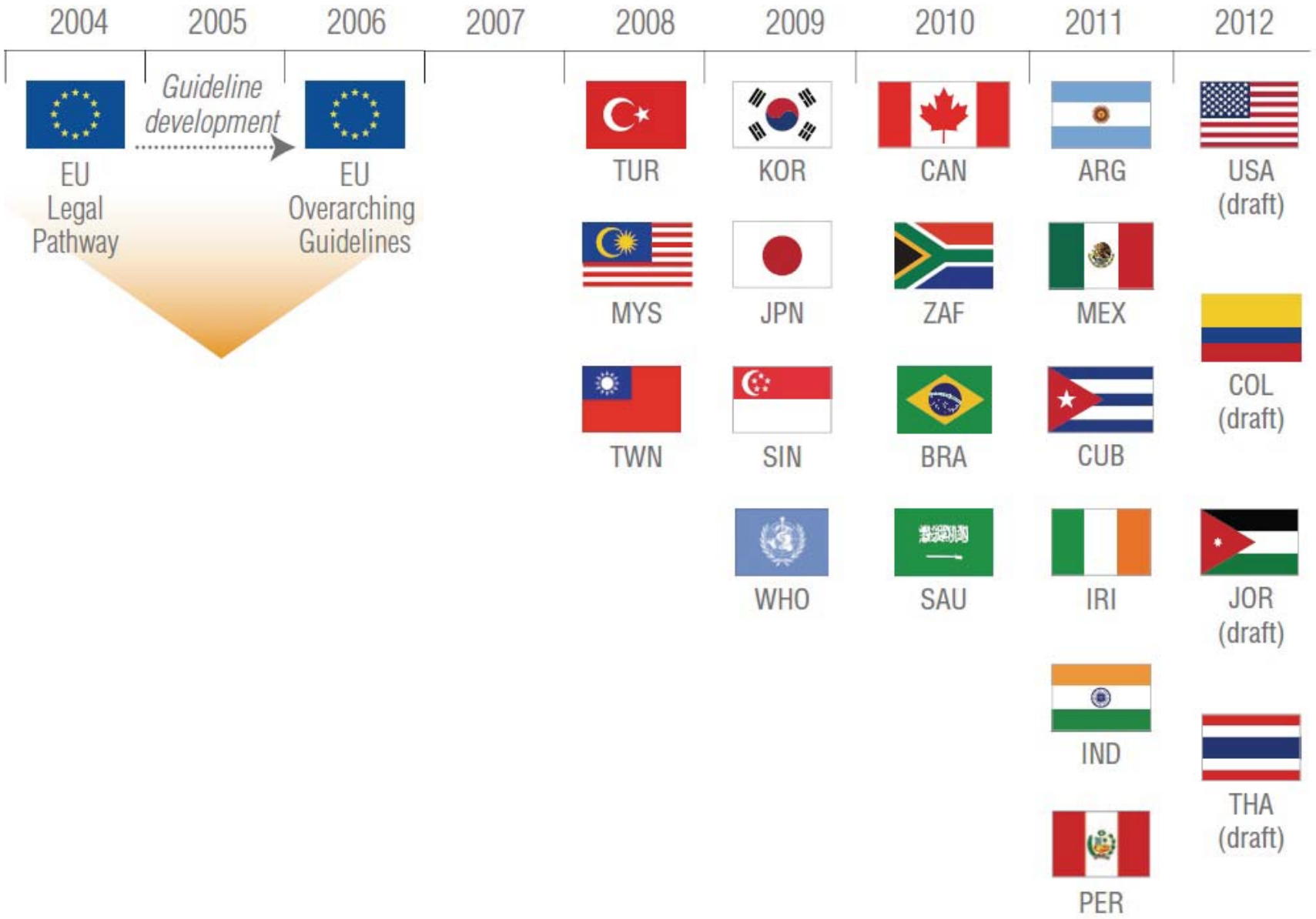
Enabling factors in Brazil

FIESP CIESP

Enabling factors	Success stories	Stumbling blocks
Human capital	• **Growing research workforce; doubling in size since 2000** • *Ciência sem Fronteiras* (Science Without Borders) – promising program to build human capital	• **Lack of a skilled work force** • Low % of population in tertiary education
Infrastructure for R&D	• **Relatively high level of R&D spending** • Successful ag-biotech and biofuels partnership programs e.g. BNDES/FINAP PAISS and EMBRAPA-BASF Cultivance • **Growing number of clinical trials**	• **Health bio-tech sector capacity less mature than ag-biotech and biofuels** • Funding conditions from government agencies
Intellectual property protection	• WTO member and TRIPS signatory • 20 year patent term protection provided • RDP in place for agrochemicals	• ANVISA involvement in pharmaceutical patent examination process • RDP not available for biopharmaceuticals for human use
Regulatory environment	• **Biosimilar pathway introduced** • Relatively clear regulatory regime in place: ANVISA responsible for regulation of biologics and biosimilars and CTNBio responsible for biotech and GM products	• **INPI long processing times and large backlog (estimated at 8-10 years)**
Technology transfer frameworks	• Framework in place through 2004 Innovation Law • Patenting and licensing activities at universities and PROs increased sine 2004	• Tech transfer and commercialization still by international comparisons low • Universities have limited tech-transfer capacity
Market and commercial incentives	• R&D tax credits are in place through Law No. 11.196	• Some R&D tax credits limited through being contingent on issuing of patent – long backlogs at INPI reduce attractiveness • Strict biopharmaceutical pricing environment • Extensive use of IRP
Legal certainty (including the rule of law)	• Government anti-corruption push; new anti-corruption law introduced 2014	• Long backlogs both in the judiciary and in government agencies

Regulatory Enviroment





From “Biologics and Biosimilars, na overview”, Amgen Inc., 2012 e Thomson Reuters IDRAC

R&D policies mainly on value added generics and biosimilars

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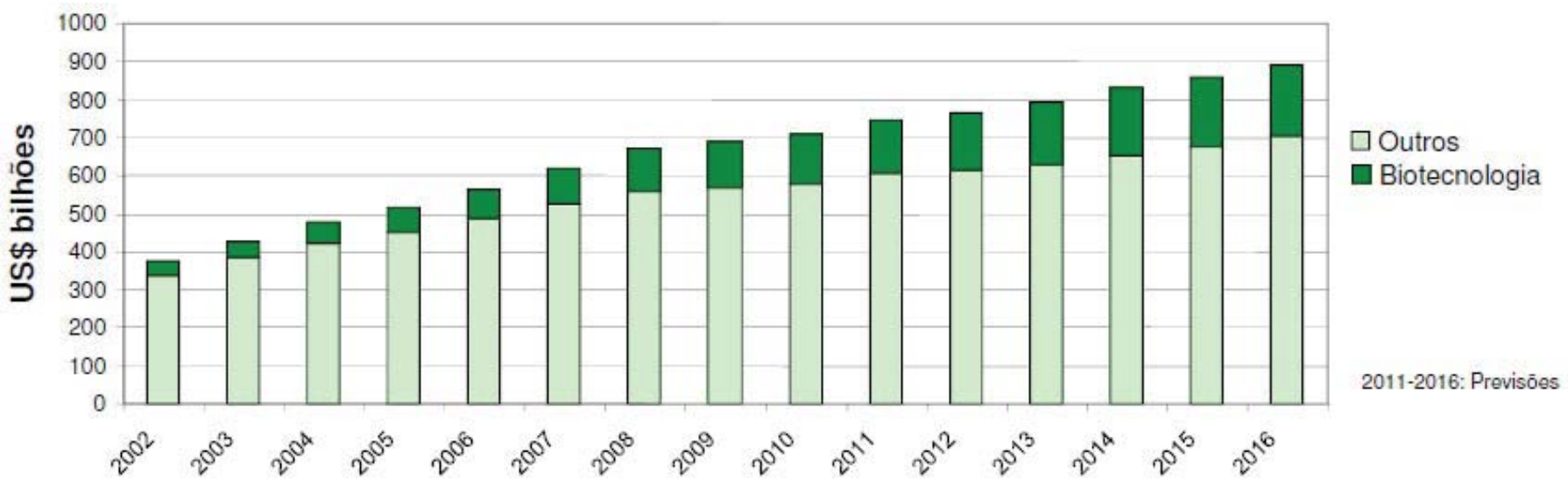
World Pharmaceutical Market by Technology Production



Global sales (2010)
-Biologics - 18,4%.

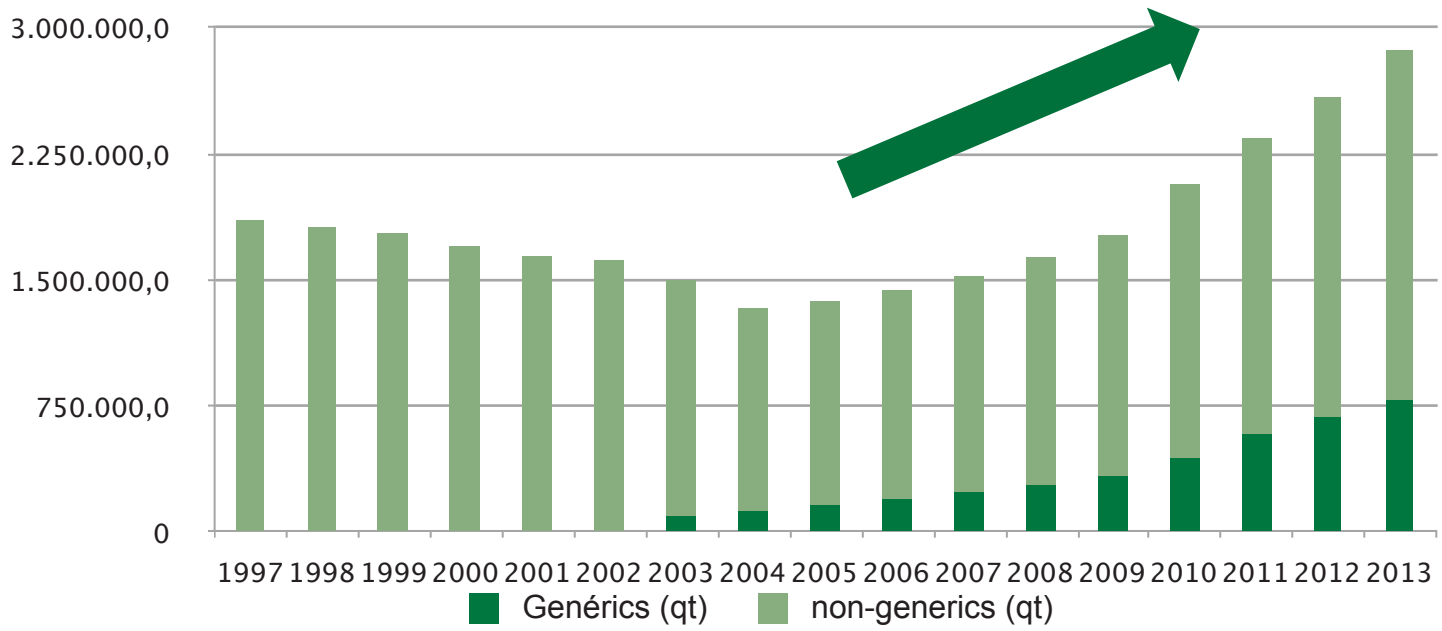
Global sales(2016 - predict)
-Biologics - 21%

Source: Evaluate Pharma. by BNDES

Value added generics' and biosimilars' market share

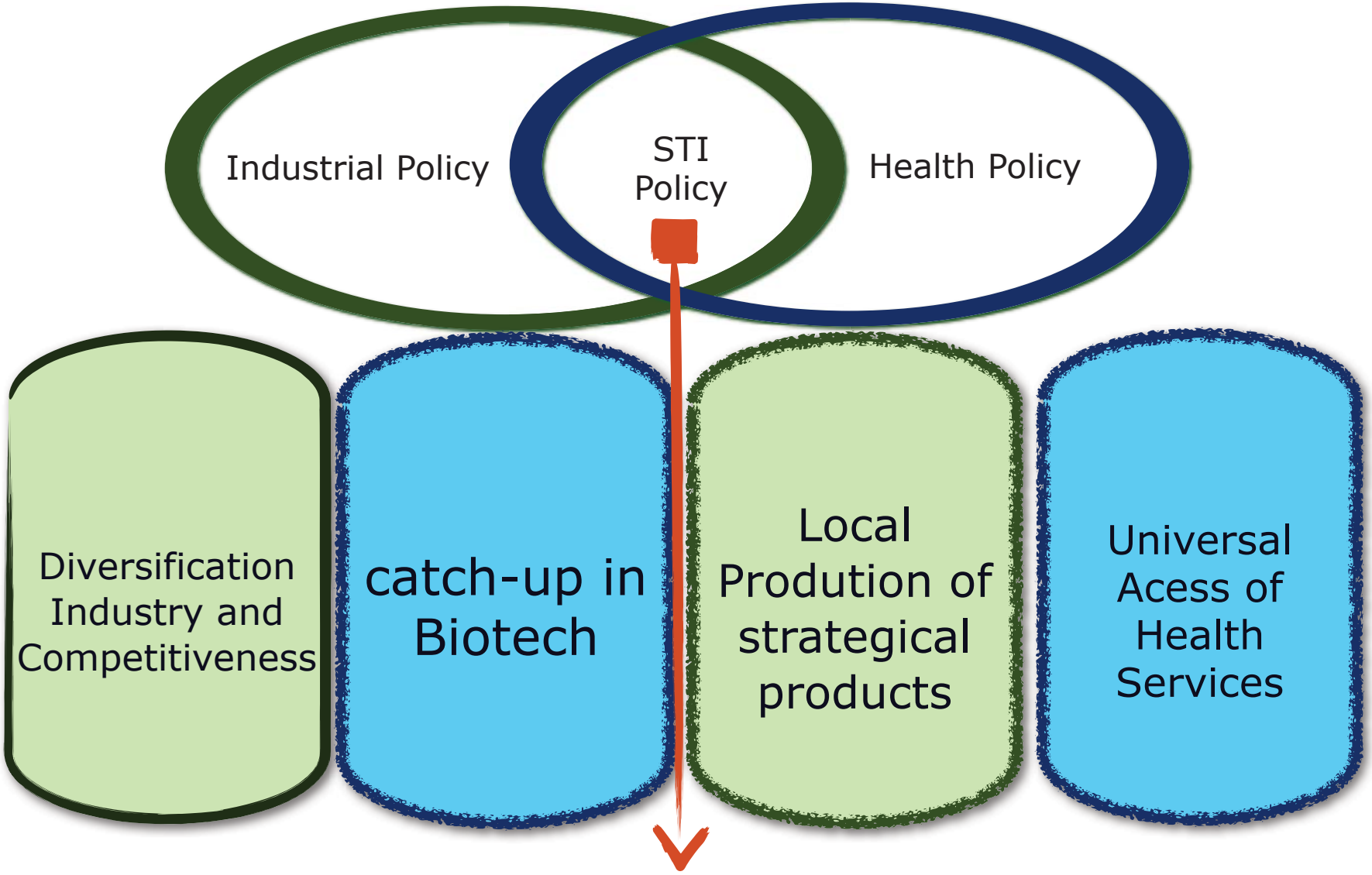
- Strong Growth of domestic consumption since 2004 ► US$ 30 bi (2013)
- Main factors:
  - social mobility (raising of "class C")
  - demogrphic/epidemiologic transition
  - Industrial Policy since 2004

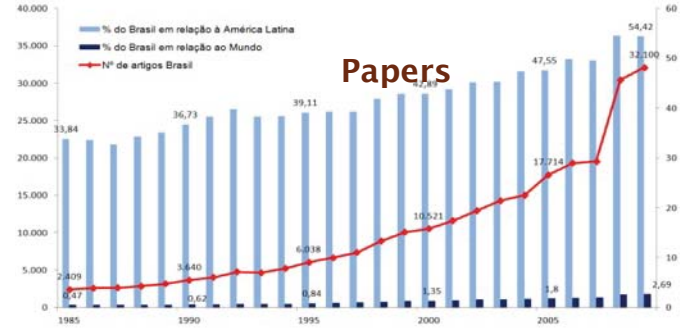
9% a.a. (qt)
14% a.a. (US$)

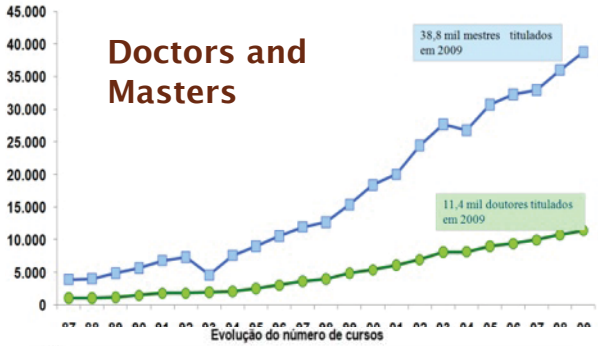


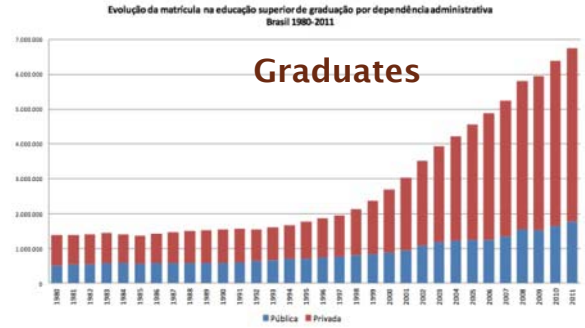
Source: Sindusfarma (2013) e Capanema e Palmeira (2004)

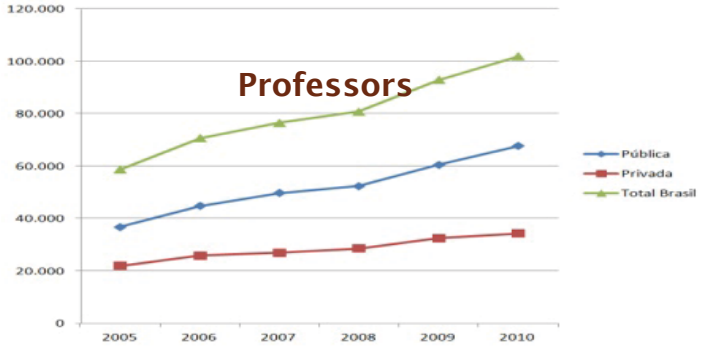
Cooperation between goverment, industry and university on pharma R&D

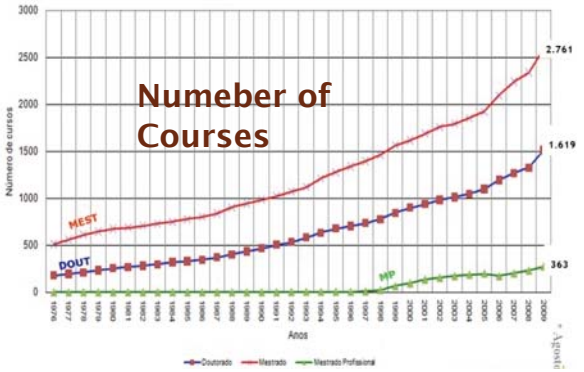


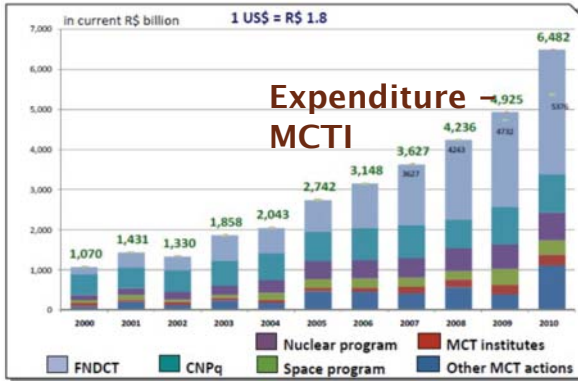


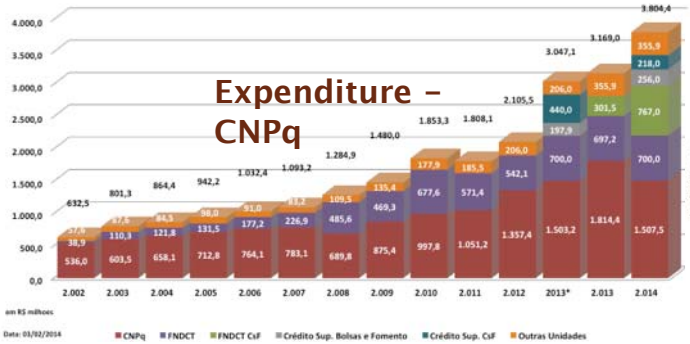












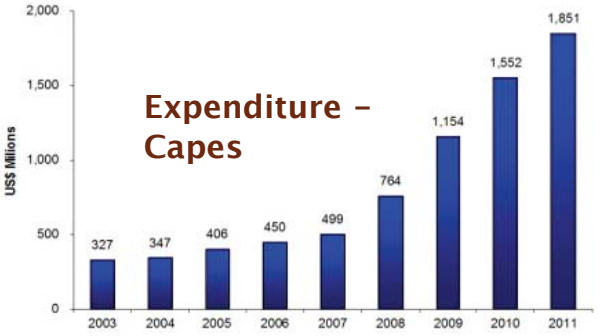
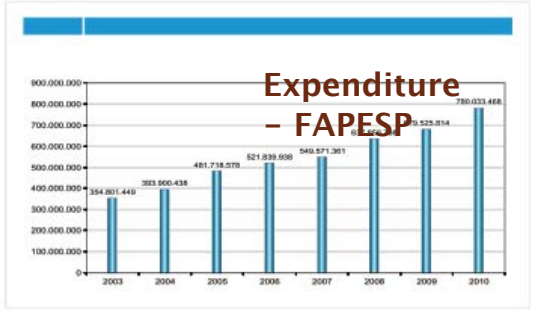
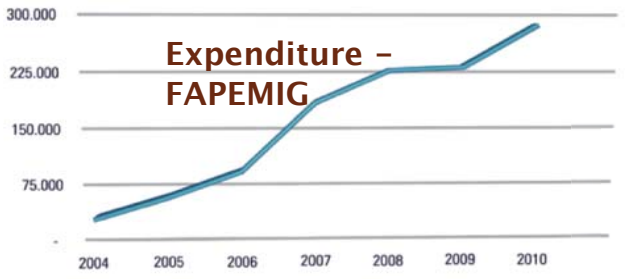
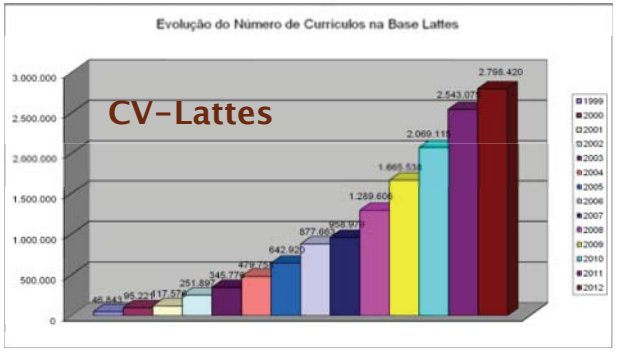


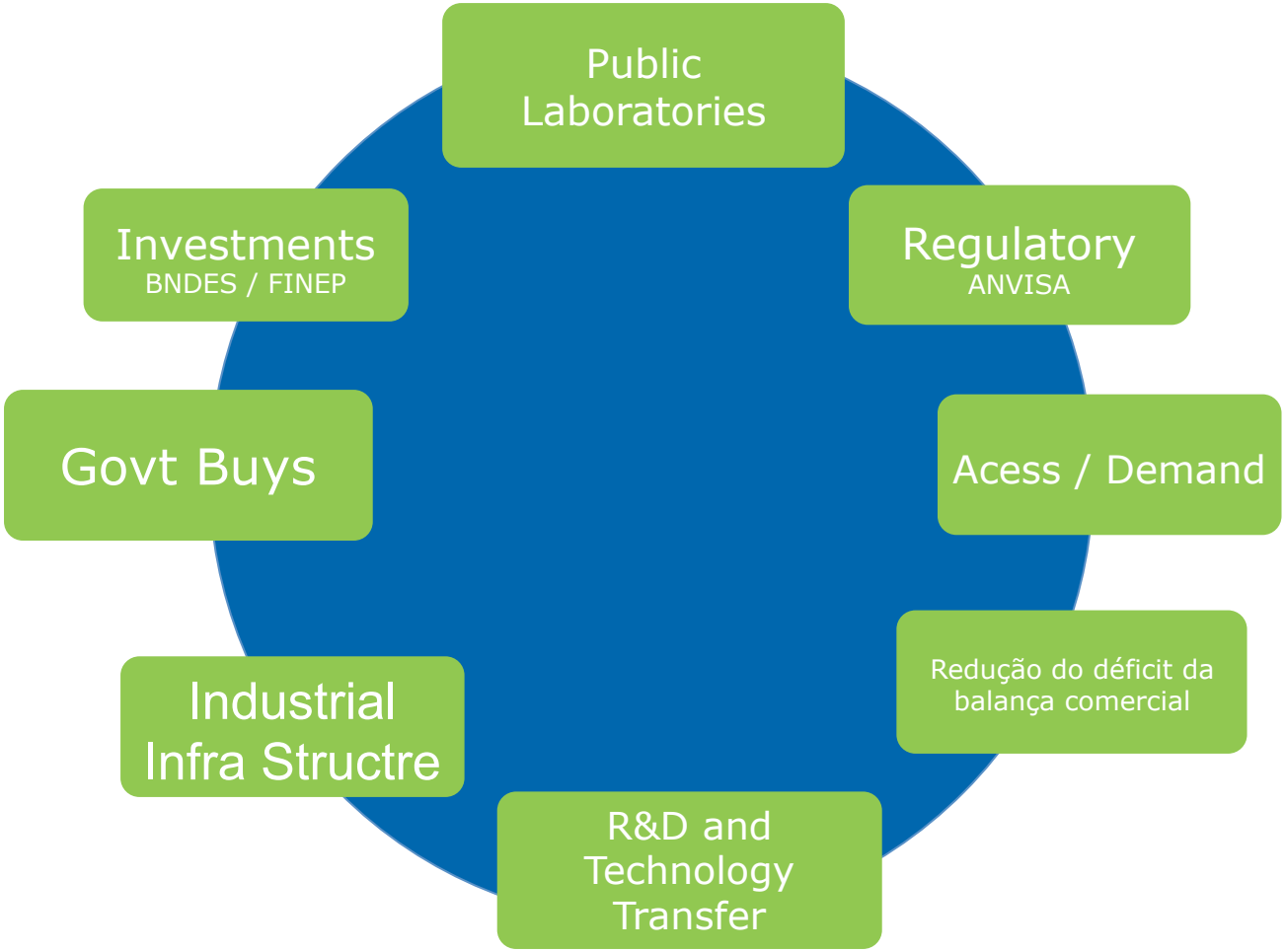
GRÁFICO 09: Crescimento dos investimentos feitos pela FAPEMIG



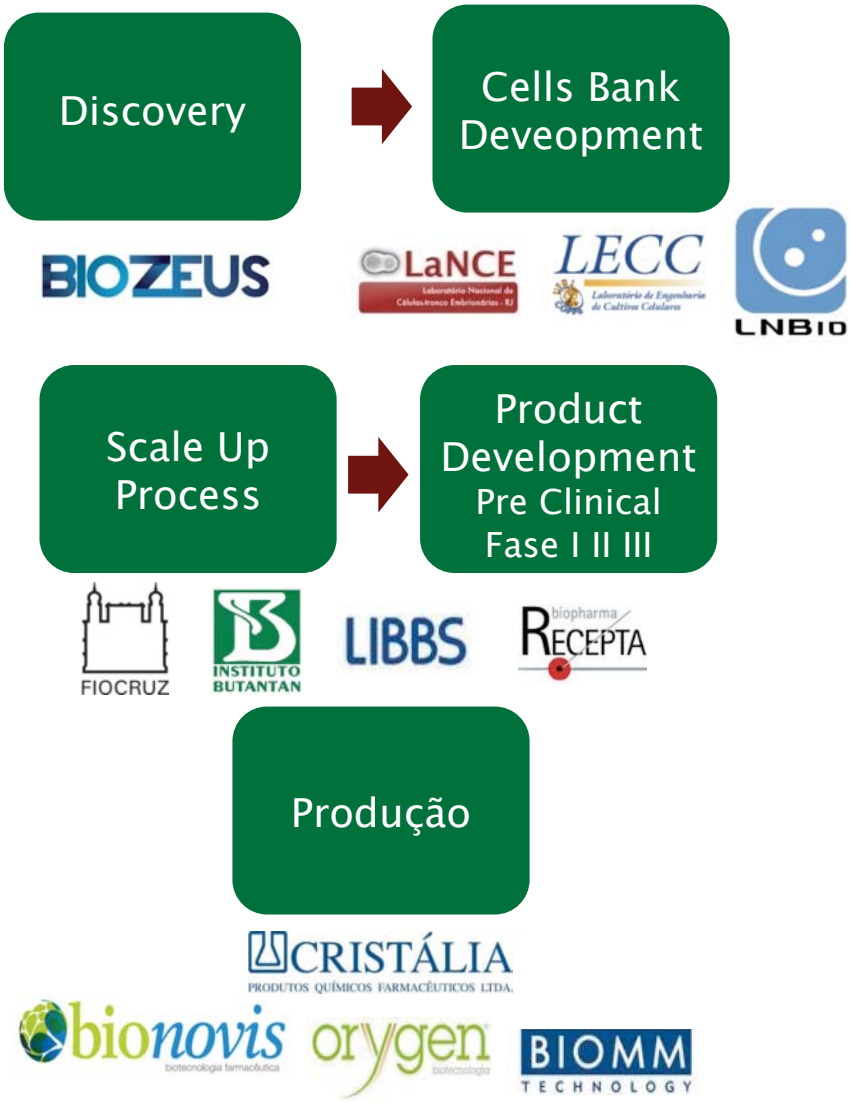




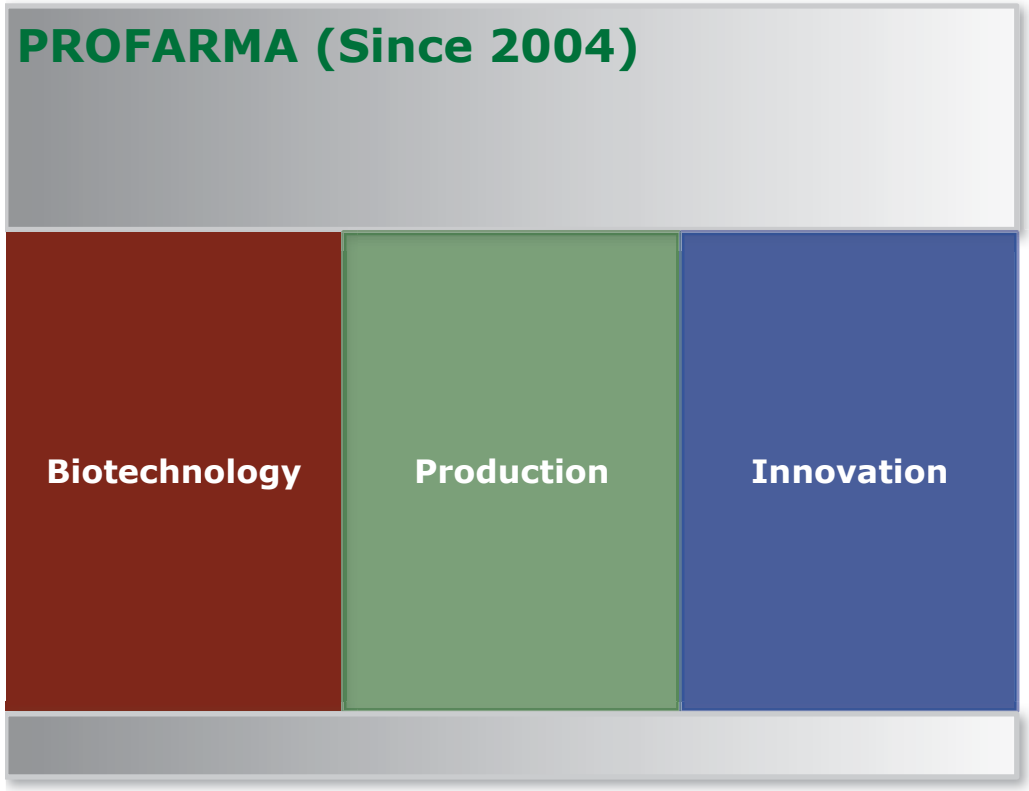
How was the goverment's support/approach to R&D on mainly biosimilars and value added generics?



Cooperation between goverment, industry and university on pharma R&D



BNDES Iniciatives
BNDES Profarma – Fase III



(2013-2017)

US$ 2 bilhões

Objectives

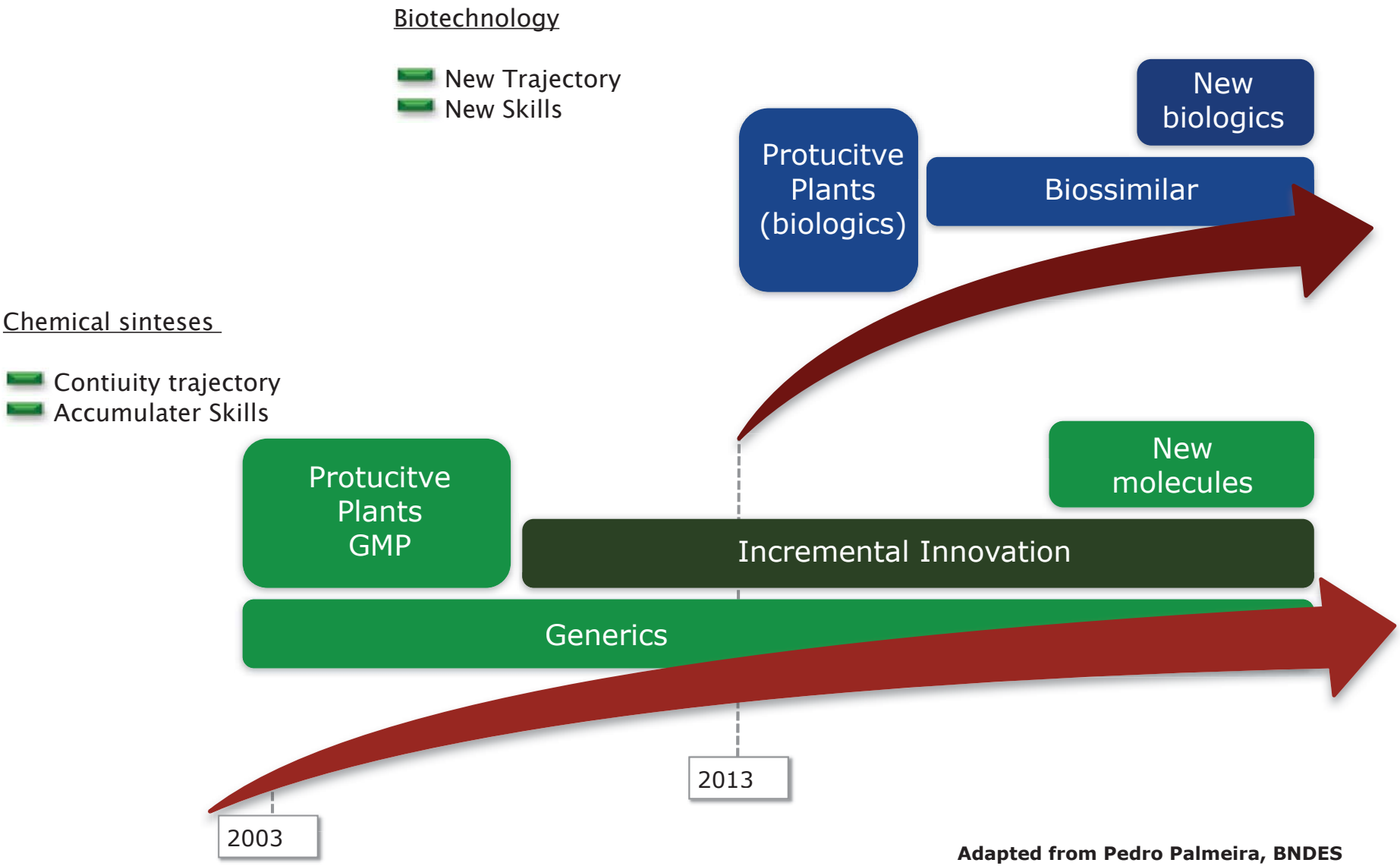
– Construction of Suply Chain and R & D production in biotechnology for health

– Induction and support for structured innovation plans

– Contribute to expanding access to health products and services

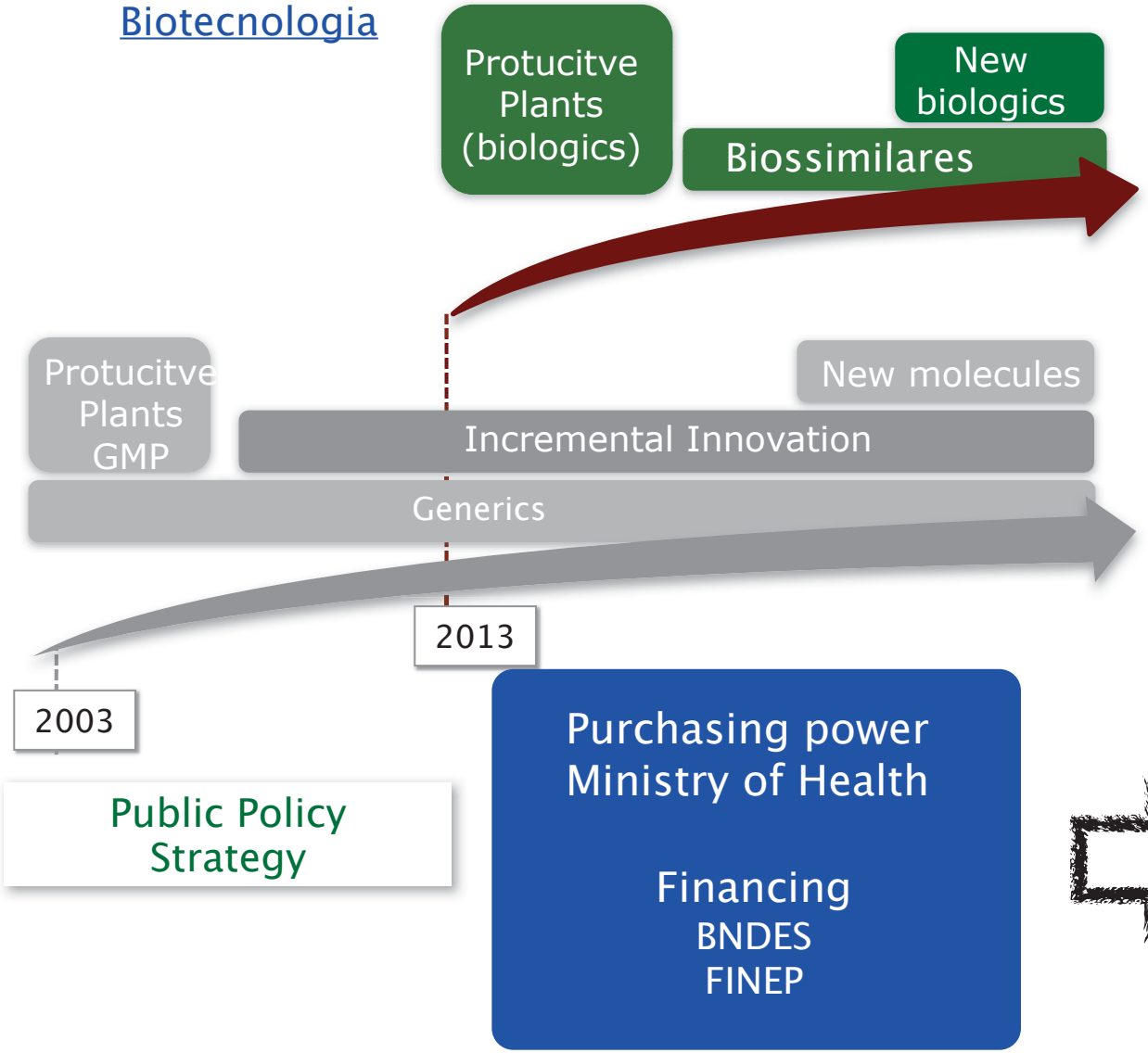
Adapted from Pedro Palmeira, BNDES

Vision for the future of the industry trajectories



Adapted from Pedro Palmeira, BNDES

Vision for the future of the industry
Oportunity in Biotechnology



Competitivenes

- High Added Value pdouct

Market

- Expiration of patents – US$ 45 bilhões (2014–2018)

Impact for SUS

- Centralized puschasing for SUS em 2012 – R$ 4,8 bilhões

Adapted from Pedro Palmeira, BNDES

- **Independent, private biopharmaceutical company founded in march 2012.**

bionovis

- **Joint Venture: Aché, EMS, Hypermarcas e União Química.**

- **Investment:** R$ 1.3 billion in 8 years.
  - Focus in innovation;
  - Manufacturing plant (ANVISA, FDA, EMA);
  - Research, Development and Innovation Center;
  - Human resources training in Biotechnology (BIT).

aché EMS hypermarcas união química FARMACÊUTICA NACIONAL S/A

bionovis

- Pipeline: biosimilars, biobetters and innovative biologicals
  - 1st Biosimilars: partnerships to develop and manufactur
    - Bio-Manguinhos/FIOCRU
    - Instituto Vital Brazil (IVB)
    - Merck Serono
  - Other biosimilars and innovative biopharmaceuticals:
    - In-house development and co-development;
    - Products in diverse development stages.

Current Status with New Drug Development in Brazil

- Strong and well developed generic industry
- Sporadic local development of improved or novel products, often based on rich biodiversity sources of Brazil
- Many development activities performed abroad (preclinical, clinical)
- No organized new chemical/biotechnology discovery efforts ongoing (for example, high-throughput screening methodology)

Current Status with New Drug Development in Brazil

- GMP, GLP, GCP standards not closely followed in Brazil
- Regulatory environment not very supportive of new drug development
  - Appropriate regulations do not exist
  - No formal regulatory or scientific advice meetings available
  - Data reviews primarily bureaucratic
  - Extremely long and non-transparent review timelines
    - US – 30 days (IND)
    - EU – 60 days (CTA)
    - Brazil – several months (improvements being discussed)
  - Data developed under such circumstances would not be acceptable in most developed countries

Chalenges

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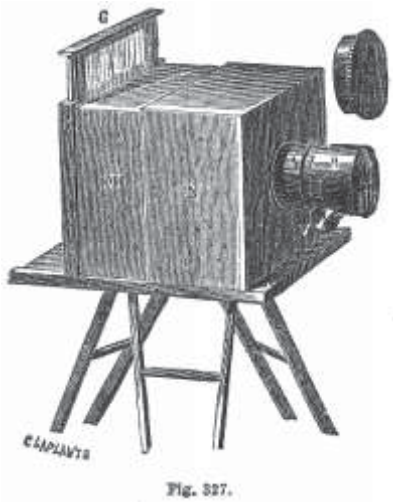
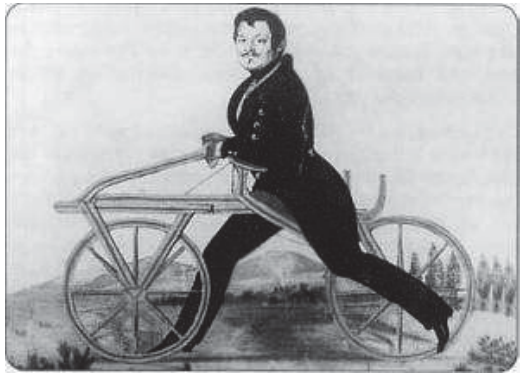
Challenges

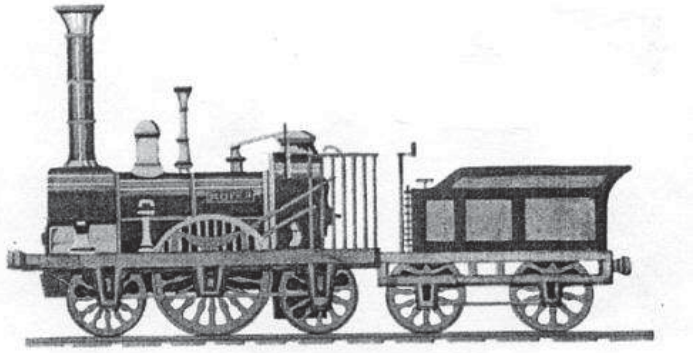
- Brazil can and should play a bigger role in global drug development
- This is true for both preclinical as well as clinical phases
- Mandatory prerequisites are:
  - High quality of scientific and procedural work at all levels
  - Compliance with ICH
  - Strict GLP-GMP-GCP control
  - Transparent local guidelines
  - Adherence to Good Review Practices performed in line with globally competitive timelines

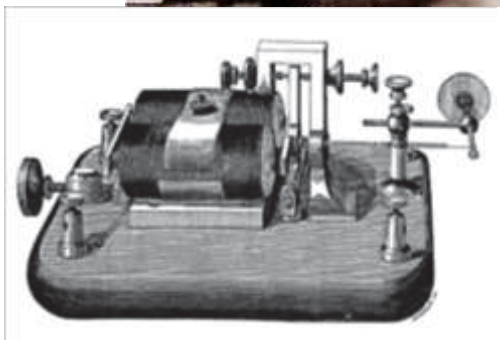
Each Century has been coined by scientific and technological progress

The 19th Century: The Age of Engineering



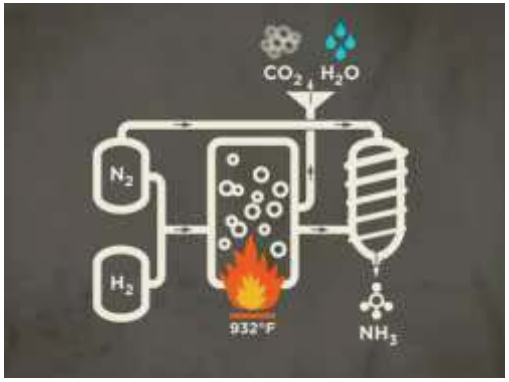


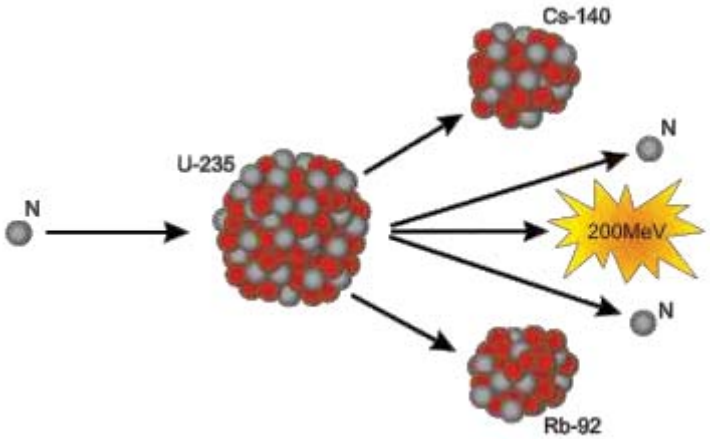


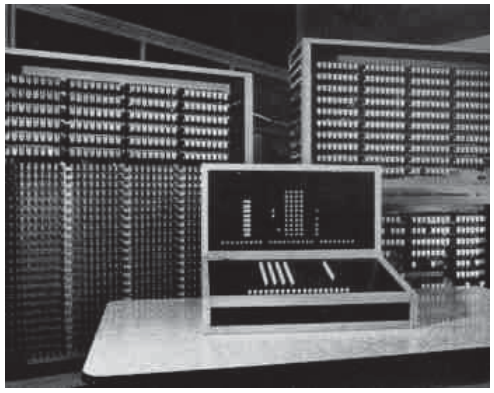


The 20th Century: The Age of Chemistry and Physics

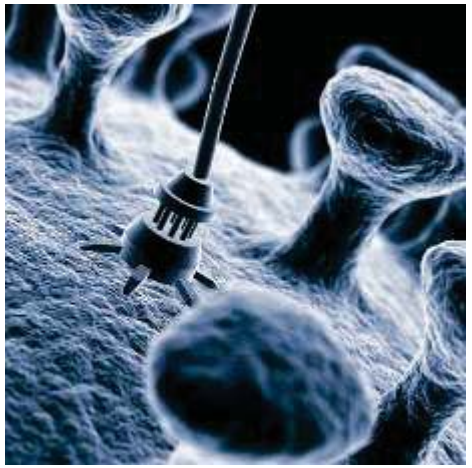
$$E = m \cdot c^2$$

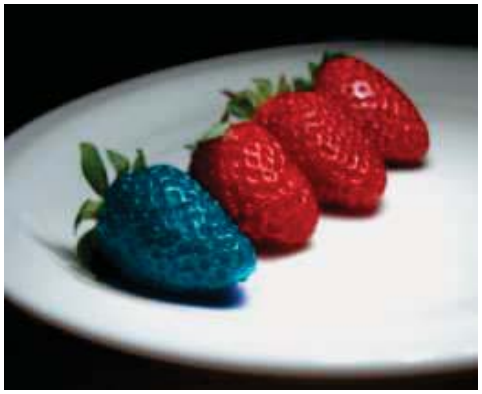


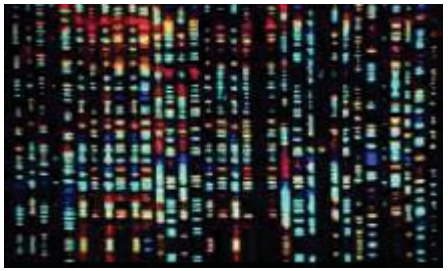


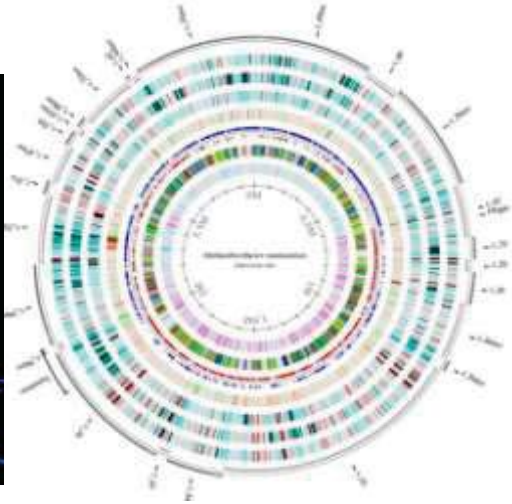


The 21st Century: The Age of Biology

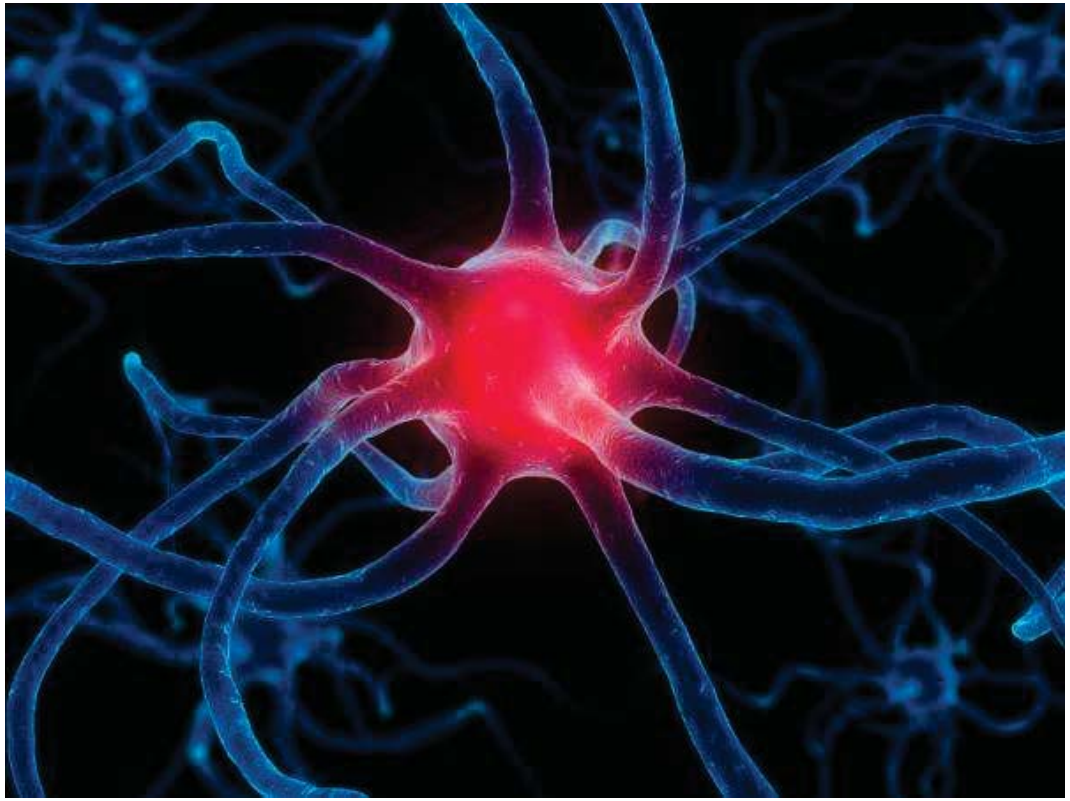








Welcome to the Age of Biology!



Life sciences play a key role in tackling global challenges

What do we need to fully deploy the opportunities offered by life sciences?

- Smart scientists who develop
- Smart politicians who regulate
- Smart citizens who accept

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