



## Conference on Intellectual Property and Public Policy Issues

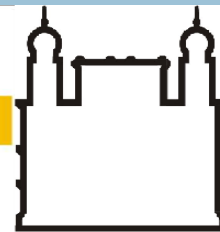
# Innovation Policies to Meet the Challenges of Neglected Diseases

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Rio de Janeiro, Brazil



Ministério da Saúde

**FIOCRUZ**

**Fundação Oswaldo Cruz**



# Outline of Presentation

- **Background –The Neglected Diseases Challenge and the Crisis of Access to Medicines in Developing Countries**
- **Innovation, Intellectual Property and Technology Transfer**
- **Innovation Policies- Brazilian Initiatives: Closing the Access Gap**

# The Neglected Diseases Challenge

with limited  
political voice

WHO estimates that over 1 billion people – one sixth of the world's population – suffer from one or more neglected tropical diseases.

For many neglected diseases, the medicines are old, toxic, expensive and often in short supply.

Less than 1% of the nearly 1,400 drugs registered between 1975 and 1999 were for tropical diseases.

Human Rights Dimension


Universal Declaration of Human Rights  
Everyone has the right to a standard of living adequate for the health and medical care

# Rising Chronic Disease in Developing Countries

**"Noncommunicable diseases are imposing a growing burden upon low- and middle-income countries, which have limited resources and are still struggling to meet the challenges of existing problems with infectious diseases," said Dr Catherine Le Galès-Camus, WHO.**

**Chronic diseases cause more than half of all deaths worldwide, 80% of which occur in low-income and middle-income countries.**


Source: Marshall, S. Bull World Health Organ vol.82 no.7 Genebra July 2004.  
Nugent, R. Ann. N.Y. Acad. Sci. 1136: 70–79, 2008.  
Nabel et al. Lancet Vol 373 June 13, 2009.



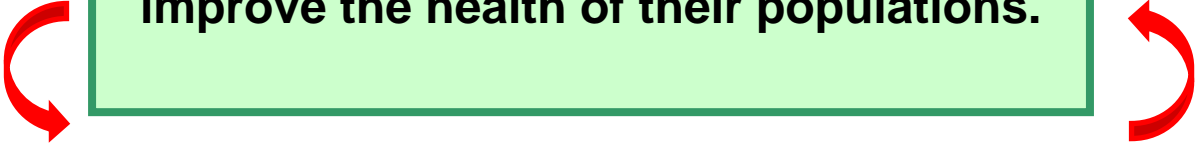
**Neglected disease  
problem**



**Rising of  
chronic disease**



**threaten developing nations' capacity to  
improve the health of their populations.**



**"existence of large gaps in the availability of medicines and  
a wide variation in prices which render essential  
medicines unaffordable to poor people"**

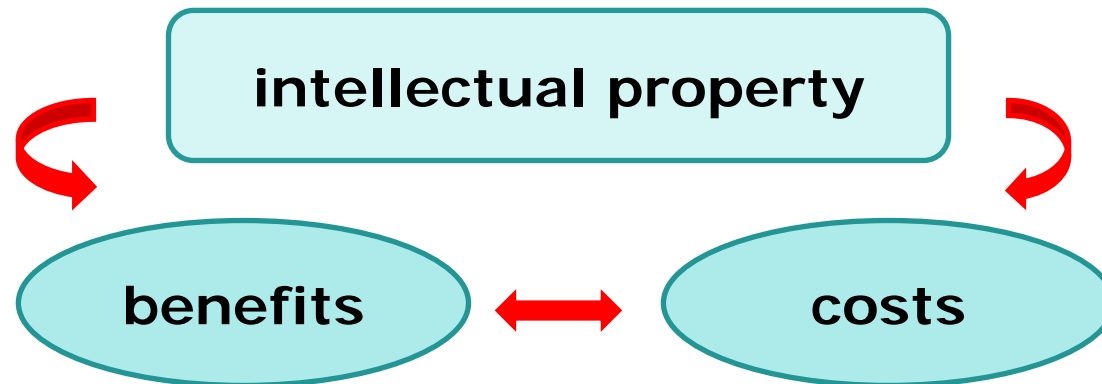
**United Nations**



## **Availability of Medicines critical factors in this access gap**

- **irrational use of medicines**
- **unfair financing**
- **unreliable delivery systems**
- **inadequate regulatory systems**
- **high medicines prices**


# Innovation, Intellectual Property and Technology Transfer



How can IP help developing countries to acquire access to modern technologies?

local innovation

local production



# **Intellectual Property Capacity Building and Development**

**Capacity building in developing countries –  
not trivial task**

**Complex interactions with technology  
policy, industrial policy, trade policy  
competition policy**

**Use of TRIPS flexibilities**

**Poor competition infrastructure**

**IP litigations and disputes**

# **Trips-plus Agenda and Other Problems**

**Bilateral agreements**

**Data exclusivity**

**Patent linkage**

**New anti-counterfeiting initiatives**

**Extension of patent protection**

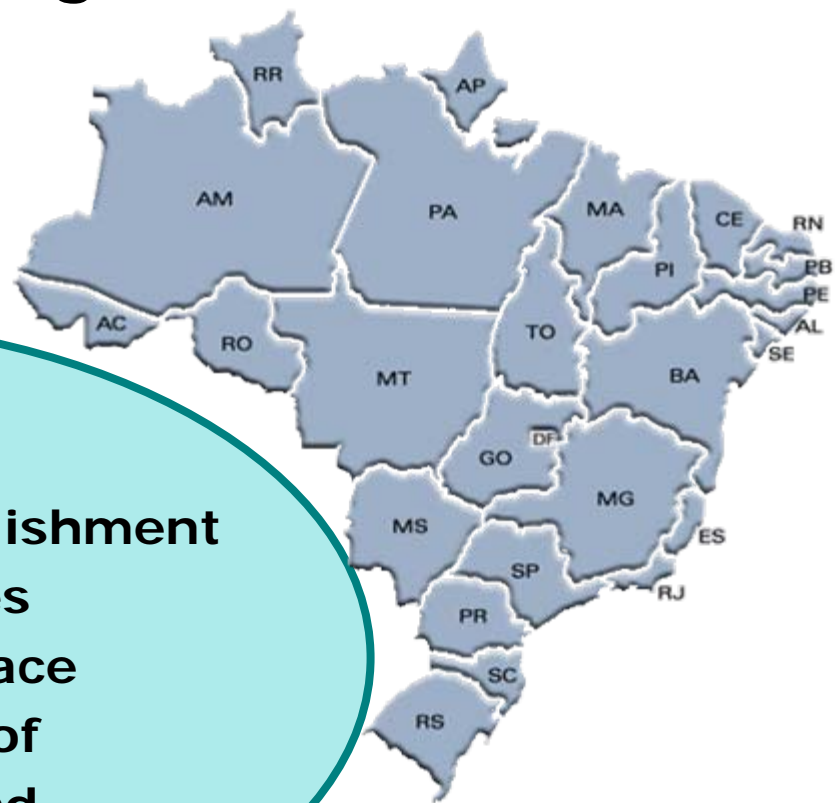
**Follow-on patents (evergreening)**

**Decreasing patent quality**

**Patents of excessive breadth**

**Overlapping patent rights**

# Innovation Capacity Building - Brazilian Initiatives



**Development and establishment  
of a set of policies  
and initiatives to face  
a double burden of  
communicable and  
chronic diseases.**

# Building an universal health system


**Right to Health: citizen's right**  
established in 1988 Federal Constitution  
healthcare for all citizens that has to be  
provided by the State

the basis  
for the creation and  
implementation of the

**Unified Health System**  
[Sistema Único de Saúde – SUS]

- **Basic foundations**
- **Universality of access to health services**
- **Equality of healthcare (non discriminatory basis)**
- **Community participation**
- **Decentralized management**

Defined in  
Law 8.080  
(general guidelines) and  
Law 8.142 (social control),  
of 1990



“Despite Brazil’s strength in basic scientific and medical research, a large proportion of the population still suffers from ill health. Diseases such as tuberculosis and leprosy are highly prevalent in poor populations, and about 46,000 people die each year from infectious diseases.”

Morel; Carvalheiro; Romero; Costa; and Buss  
The Road to Recovery  
Nature Outlook 2007

# Brazil

**Neglected disease  
problem**



**Rising of  
chronic disease**

**Trade balance in the health sector shows a relevant deficit  
due pharmaceutical products imports  
U\$700million (80s)  
U\$7billion (2008)**

**vulnerability of the Brazilian social policy**

# Strengthening Brazilian innovation capacity

- **Unified Health System (1990)**
- **National Medicines Policy (1998)**
- **National List of Essential Medicines (1998)**
- **National Health Surveillance Agency(1999)**
- **Law of the Generic Medicines(1999)**
- **Implementation of the Science, Technology and Strategic Inputs Unit (Ministry of Health) (2003)**
- **Popular Pharmacy Programme (2004)**
- **National STD/AIDS Programme (1983)**
- **Mais Saúde Programme (2008)**
- **Health Industrial Complex**
- **Broadening the basis of financial supporters and creating new methods of funding and financial incentives (e.g., Support Programme for the Development of the Pharmaceutical Productive Chain - Profarma-BNDES)**

Source: Guimarães, 2008.

- 
- **Fiocruz has established cooperation agreement with India's Medical Research Council and South Africa's Medical Research Center.**
  - **Fiocruz has been expanding bilateral cooperation in Latin America, Africa, Europe and North America.**
  - **The partnership with Cuba is facilitating the transfer of technology concerning the production of interferon alpha and erythropoietin to Fiocruz (Biomanguinhos), which could generate a yearly saving of around US\$ 16 million for the Brazilian National Treasury.**
  - **In 2008, Fiocruz (Farmanguinhos) launched a project to construct a factory in Mozambique for the production of HIV/AIDS drugs.**
  - **Brazil will invest U\$23 million in the factory, which will be built using Brazilian technology. Raw materials will come from India.**

# Fiocruz today

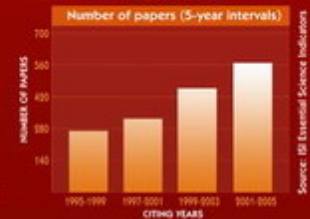
## Fiocruz THE OSWALDO CRUZ FOUNDATION

Feet anchored in tradition, eyes turned to the future

Founded on May 25th 1900 under the name Federal Serum Therapy Institute, The Oswaldo Cruz Foundation (Fiocruz) was created with the mission of fighting Brazil's most important public health problems. It was in its laboratories in Rio de Janeiro that in 1909 Carlos Chagas discovered the disease that bears its name – Chagas disease, also known as American trypanosomiasis –, its pathogen (*Trypanosoma cruzi*) and the mechanisms of transmission by reduviid insects ("kissing bugs").

Nowadays, Fiocruz mission encompasses research, technological development and innovation; production of vaccines, drugs, reagents and diagnostic kits; clinical research; delivery of reference health services; education and training of human resources; information and communication; product and service quality control; and the implementation of social programs.

### MOST CITED INSTITUTIONS IN CLINICAL MEDICINE FIOCRUZ MS



### Research and development: high-quality

According to the Essential Science Indicators of the Institute for Scientific Information (ISI), Fiocruz is one of the most cited institutions in clinical medicine and publishes over 400 research papers per year in high-quality, peer-reviewed international journals.

### Oswaldo Cruz Foundation (FIOCRUZ)

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### Collaborations

Fiocruz congratulates the scientists, institutions and funding agencies that made the sequencing of the genomes reported in this issue of Science and is ready to collaborate in the development of new health interventions that are accessible, affordable and appropriate for developing countries.



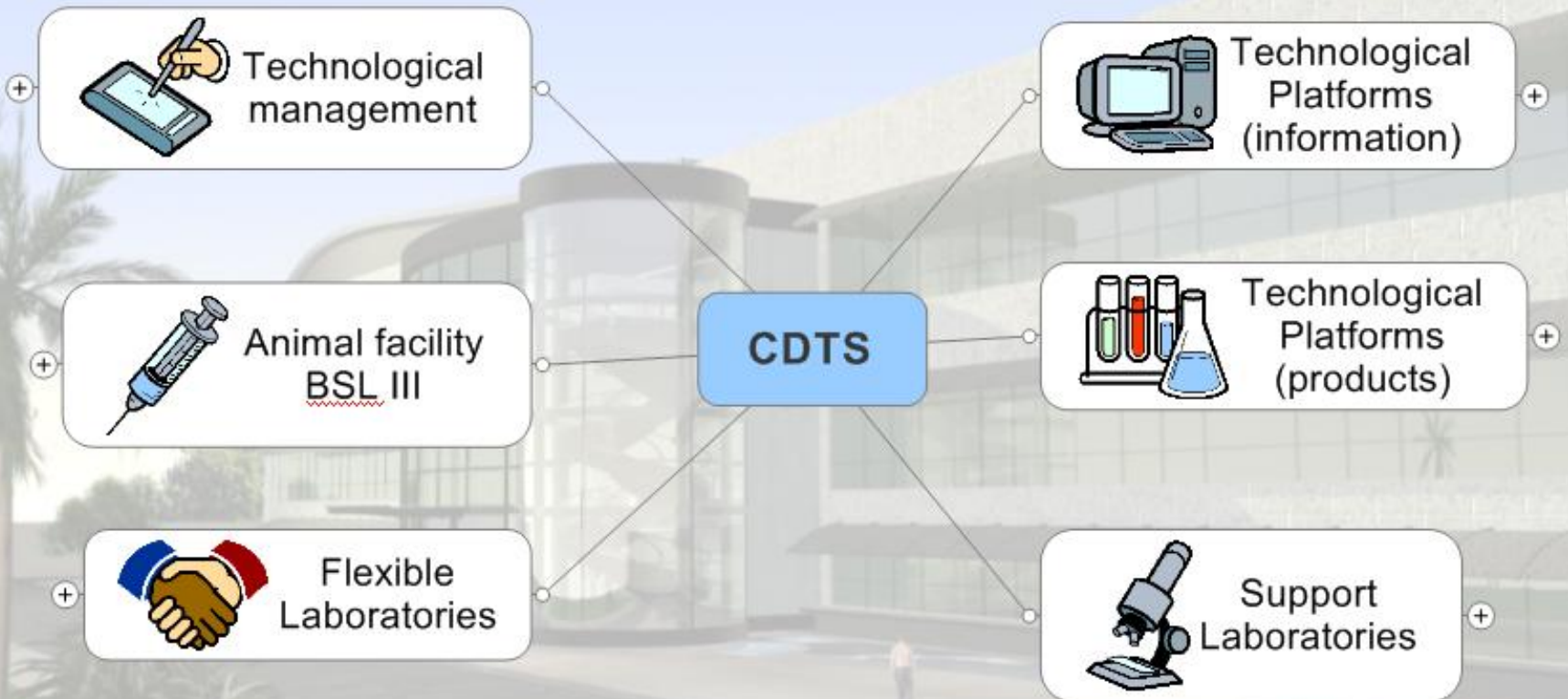
### Future directions

Fiocruz new Center for Technological Development in Health (CDTS in its Portuguese acronym) will start to be built in the Manguinhos campus in the end of 2005 and will be operational in 2008. Its facilities include technological platforms, animal experimentation facilities and flexible labs where Fiocruz will work in collaboration with public and private industrial sectors in the joint development of health products.

# Center for Technological Development in Health CDTS/FIOCRUZ



# CDTS main facilities



# CDTS



Technological  
Platforms  
(information)

Genomics

Proteomics

Microarrays and nanotechnology

Bioinformatics

Analysis of lipids and polysaccharides



Technological  
Platforms  
(products)

Recombinant proteins

Protein crystallization

Recombinant and monoclonal antibodies

Oligonucleotides and peptides



Support  
Laboratories

Physicochemical analysis

Toxicology

Repository of biological, biotechnological  
and clinical samples

Flow citometry

Confocal microscopy and  
immunofluorescence

Real-time PCR

# CDTS main facilities





# Full Commitment

**Implementation of WIPO  
Development Agenda**

**Resolution WHA 61.21 on  
Global Strategy and Plan of Action on  
Public Health, Innovation and  
Intellectual Property**