

Ministry of Health - Brazil

Oswaldo Cruz Foundation  
Fiocruz /Bio-Manguinhos

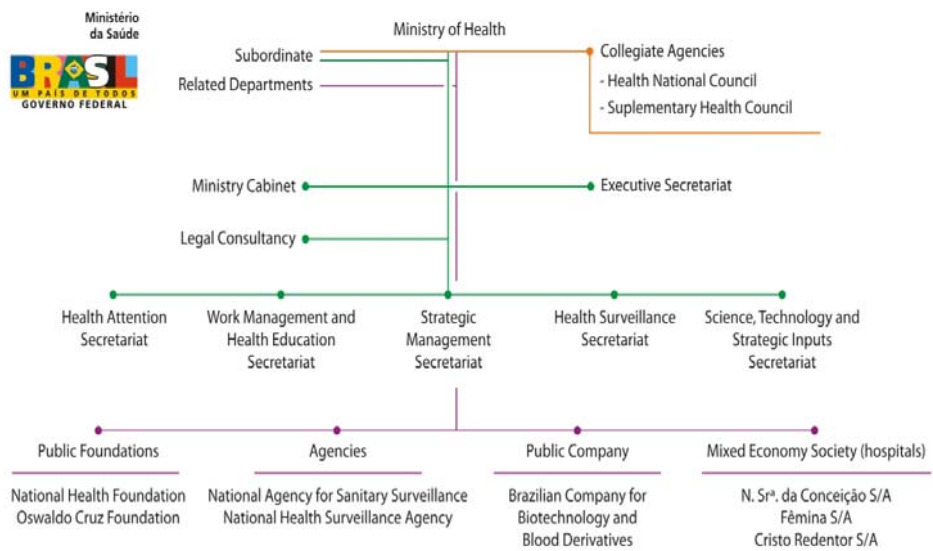
Technology Transfer  
a WIN-WIN model

Antonio de Padua Barbosa, DSc  
Director of Production

IFPMA  
March 9  
2011



### Ministry of Health Organization Chart



Fonte: site MS  
[www.bio.fiocruz.br](http://www.bio.fiocruz.br)



## Geographic Distribution



■ Fiocruz's units  
■ New units

• In 2008 opened an Office in Mozambique, Africa, for training courses in Masters, Doctoral and Post Graduation.

Fonte: CCS Fiocruz

- **Presidency/Central Administration**

- **Technological Development & Production Units** - Bio-Manguinhos and Farmanguinhos

- **Biomedical Research Units** - Oswaldo Cruz Institute, Laboratory Animals Breed Centre, Aggeu Magalhães Research Centre (PE), René Rachou Research Centre (MG), Leônidas and Maria Deane Research Centre (AM), Gonçalo Moniz Research Centre (BA) and Institute of Molecular Biology (PR)

- **Clinical Research and Mother/Child Care Units** - Fernandes Figueira Institute and Evandro Chagas Institute

- **Post-graduation and Technical Schools** - National School of Public Health and Joaquim Venancio Health Politechnic School

- **Documentation, Information & Historical Units** - Technological & Scientific Information Centre and Oswaldo Cruz' House

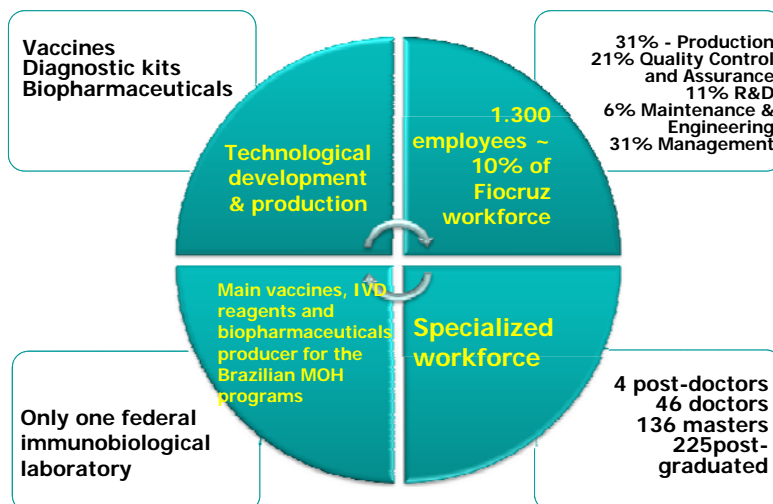
- **Specialized Technical Services** - National Institute for Quality Control for Health

- **International Office of Moçambique** - Masters, PHD and expertise in Health



[www.bio.fiocruz.br](http://www.bio.fiocruz.br)

## Bio-Manguinhos' Figures



[www.bio.fiocruz.br](http://www.bio.fiocruz.br)

## BM Portfolio

- ✓ Yellow Fever 05, 10, 50 doses
- ✓ Meningitis A and C 10 doses
- PRE-QUALIFIED BY WHO**

### Vaccines

DTP+Hib  
DTP/HBV + Hib  
Hib  
Meningitis Polysaccharides A+C  
OPV  
Triple Viral MMR  
Rotavirus  
Pneumococcal conjugate 10 valent (1 dose)



### IVD Reagents

HIV-1 IFI  
HIV-1/2 Rapid Test  
DPP HIV 1/2 Rapid Test and DPP confirmatory  
Chagas Disease ELISA, and IFA  
Canine Leishmaniasis ELISA, IFA and DPP Rapid Test  
Human Leishmaniasis IFA  
Human Leptospirosis ELISA and DPP Rapid Test  
Schistosomiasis Helm Test



### Biopharmaceuticals

Interferon Alpha 2b Human Recombinant  
Erythropoietin Human Recombinant



[www.bio.fiocruz.br](http://www.bio.fiocruz.br)



## Bio-Manguinhos' Mission

Contribute to the improvement of the Brazilian Public Health standards through technological research and production of immunobiologicals to meet the demand generated by the epidemiological scenario of the country.

Fulfill the demand of the NIP and others governmental programs – IVD for neglected disease and HIV and biopharmaceuticals

Population 190 millions

3,2 millions newborn

[www.bio.fiocruz.br](http://www.bio.fiocruz.br)



## Innovation Strategies

- Endogenous Technological Development projects
- Partnerships with local and global institutions for TD&I
- Technological transfer partnerships
- Development of new presentations and improvement of already existing products

[www.bio.fiocruz.br](http://www.bio.fiocruz.br)



## Pipeline

Bacterial vaccines	5
Viral Vaccines	10
Biopharmaceuticals	10
Reagents for Diagnosis	8
<b>Total</b>	<b>33</b>



[www.bio.fiocruz.br](http://www.bio.fiocruz.br)



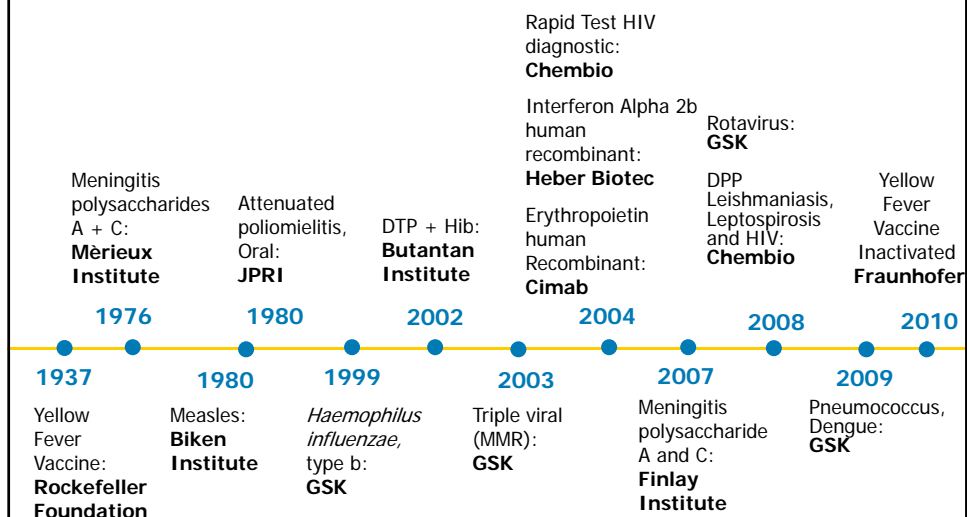
## Projects Development Level

	Pre Clinical	Clinical Trials			Non inferiority	Pos-Marketing	TOTAL
		Ph1	Ph 2	Ph3			
Bacterial Vaccines	4		2		1		7
Viral Vaccines	8			3	2	1	14
Biopharmaceuticals	2	1			2	1	6
IVD reagents	3			2	3		8
<b>TOTAL</b>	<b>17</b>	<b>1</b>	<b>2</b>	<b>5</b>	<b>8</b>	<b>2</b>	<b>35</b>

www.bio.fiocruz.br



## Technological Transfers / Partnerships



www.bio.fiocruz.br



## Why Transfer Technology to BM/Fiocruz?

- **Government's policy:**
  - ◆ Whenever a new vaccine is introduced into NIP the local production and TT is must be considered
  - ◆ Use of buyer power
- **Long term policy and multi-year forecast**
- **Brazilian Public Market**
- **Garantee of the market and competitive price**
- **Financial support for new facilities**
- **Existance of NRA Pre Qualified by WHO**

www.bio.fiocruz.br



## The Hib Vaccine Technology Transfer

### Bio- Manguinhos features

- Technological capability – Pre existing knowledges : production of Meng A/C polissacharides vaccine; Coupling skilfull group; clinical studies experience
- Adequate facilities and equipments – large freeze-drying facility
- Structure, organization and budget for long term implementation - team organized to receive technology
- Selection of the most adequate technology and proposal

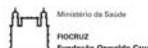
**WIN-WIN Model**

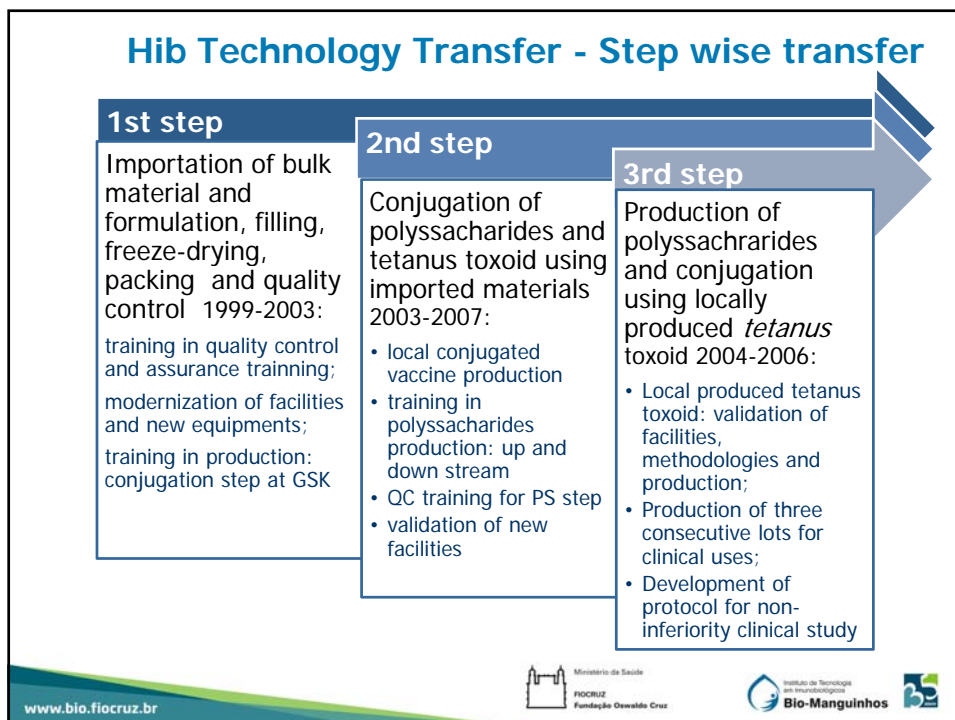
### GSK features

#### Updated technology

- Scientific and technolgy knowledge
- Operational and functional production operation
- Compromise to make full technology transfer: **entire organization must agree and cooperate**
- Organization of a specific group dedicated to TT

www.bio.fiocruz.br





## Hib Technology Transfer - Step wise transfer

### 4th step

Noninferiorty study using the 2nd step vaccine as control 2005-2007

Protocol approval by Ethical Committee;  
Preparation of the site of study – 1000 volunteers;  
Organization and implementation of the clinical study;  
Preparation of the documentation for licensing by ANVISA

### 5th step

License at ANVISA in October 2007

### 6th step

Pharmacovigilance

- Organization and implementation of pharmacovigilance

www.bio.fiocruz.br



## Bio-Manguinhos & TT- Tangible and Intangible benefits

### Institutional strengthen

- Administration and managerial capacity
- Knowledge underlying the technology – **Quality system, engennering standards**
- Better visibility
- Social benefits – **avaibility of the vaccine at better price**

### Capability strengthen

- Accelerate the incorporation of new technology of production
- Increase of spezicized professionals
- New laboratories, new equipments
- Strengthen the infrastructure and the technological capability

### New products & developments

- Tetravalent (DTP + Hib)
- Pentavalent (DTP/HB + Hib)
- Development of heptavalent (DTP/HB/IPV/MenC + Hib)

www.bio.fiocruz.br





## Haemophylus influenza B Meningitis after the implementation of mass vaccination

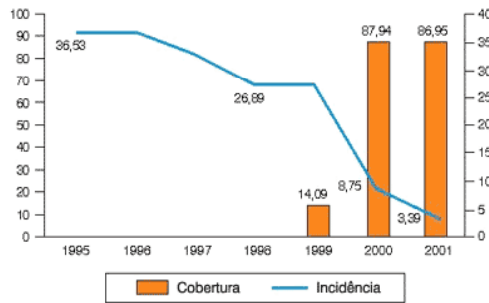


Figura 5 - Meningite por *Haemophylus influenzae b*: coeficiente de incidência e cobertura vacinal em crianças menores de um ano, RS, 1995-2001

Kmetzsch CI, [et al.]. *J Pediatr (Rio J)*. 2003; 79(6):530-6:

www.bio.fiocruz.br



**Thank  
you!**

*Photos by Anne Geddes*

www.bio.fiocruz.br