

Ciclo de Seminários do Observatório da
Inovação e Competitividade 2011 —
Programação de Maio

16/05 “Inovação em Doenças
Negligenciadas”

EXPOSITOR: Prof^a Dr. José Carneiro, Faculdade de
Medicina da USP de Ribeirão Preto e Fundação
Fiocruz

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www.observatoriousp.pro.br

Os seminários do OIC ocorrem às segundas-feiras, das 11h00 às 12h30, no Auditório do Departamento de Engenharia de Produção da POLI USP (Auditório do PRO, sala D2-015).

Não é necessária inscrição e contamos com transmissão ao vivo via internet pelo site: www.iptv.usp.br

Perguntas podem ser enviadas para o e-mail oicusp@gmail.com ou pelo *twitter* OIC_inovacao.



Estrutura desta apresentação

INOVAÇÃO em DOENÇAS NEGLIGENCIADAS

- CONCEITOS
- POLÊMICAS
- SOLUÇÕES

CLASSIFICAÇÃO DE DOENÇAS:

Oficial: CID 10 “Classificação Estatística Internacional de Doenças e Problemas Relacionados à Saúde”

Pela “origem”: (1) transmissíveis (incluindo doenças de mulheres e crianças, além de desnutrição); (2) doenças crônicas não-transmissíveis; (3) causas externas ou “injúrias” (violência e trauma)

Doenças dos grupos I, II e III, que são equivalentes a doenças globais, negligenciadas e muito negligenciadas de organismos como Médicos Sem Fronteiras (MSF).

Esta última é impregnada por um sentido confusamente humanitário misturado com forte presença de uma análise economicista. Novo conceito: a “carga da doença” (Burden of Disease, BoD), traduzida por “anos de vida útil perdidos” (DALYs).

Conceito de PATOCENOSE (Mirko Grmek): (1) conjunto de todos estados patológicos num contexto tempo/espacial; (2) frequência e distribuição de UMA doença depende de todas as outras; (3) tendência para estado de equilíbrio com expressões matemáticas simples.



Doenças Negligenciadas

Carlos M. Morel

Centro de Desenvolvimento Tecnológico em Saúde (CDTS)
Fundação Oswaldo Cruz (Fiocruz)

Academia Brasileira de Ciências
Simpósio Regional RJ
03 de maio de 2010

Um pouco de história

- Anos 70
 - Kenneth Warren e a Fundação Rockefeller: “*The Great Neglected Diseases of Mankind*”
 - TDR: Doenças Tropicais: pesquisa em doenças da pobreza (PNUD, OMS, UNICEF, WB)
- Anos 90
 - Global Forum for Health Research (Hiato 10/90)
- 2000-2001
 - Objetivos de Desenvolvimento do Milênio: 8 jeitos de mudar o mundo (4. mortalidade infantil; 5. saúde da mulher; 6. aids, malária e outras d.)
 - Médicos Sem Fronteiras (MSF) & DNDi (Drugs for Neglected Diseases **initiative**)
 - Comissão de Macroeconomia e Saúde, OMS: Investindo em saúde para o desenvolvimento econômico (Brundtland, Agenda 21, Rio 92) (Murray, Frenk, Bobadilla)
 - Diversas **outras** Iniciativas: públicas (FR, 30 anos) e privadas (GAVI)
- Perspectivas atuais

MSF & DNDi: Doenças globais, negligenciadas e mais negligenciadas

What kinds of needs does the pharmaceutical market cover?

A represents Global Diseases,

such as cancer, cardiovascular diseases, mental illness and neurological disorders, which constitute the major focus of the R&D-based pharmaceutical industry. Although affecting developed and developing countries, most people in developing countries who have needs for drugs to treat these diseases cannot afford them, and are thus not covered by the pharmaceutical market.

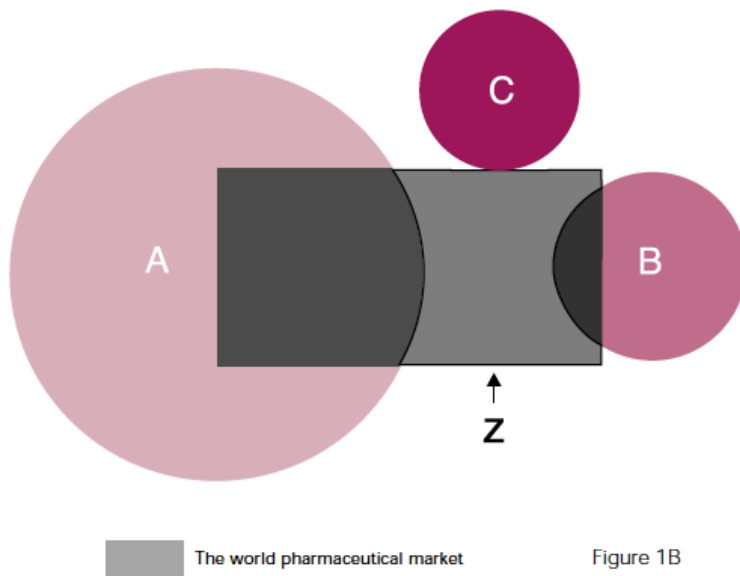
B represents Neglected Diseases,

such as malaria and tuberculosis (TB), for which the R&D-based pharmaceutical industry has only marginal interest. Although also affecting people in wealthy countries, for example TB patients or people who get malaria while travelling, these illnesses primarily affect people in developing countries.

C represents the Most Neglected Diseases,

such as sleeping sickness, Chagas disease and leishmaniasis, which exclusively affect people in developing countries. Because most of these patients are too poor to pay for any kind of treatment, they represent virtually no market and for the most part fall outside the scope of the drug industry's R&D efforts, and thus outside the pharmaceutical market.

Z represents the part of the pharmaceutical market for products addressing conditions other than those which are purely medical (such as cellulite, baldness, wrinkles, dieting, stress and jet-lag), which nonetheless represent a highly profitable market segment in wealthy countries.



OMS: Comissão de Macroeconomia e Saúde

- **Type I diseases** are incident in both rich and poor countries, with large numbers of vulnerable population in each
- **Type II diseases** are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries
- **Type III diseases** are those that are overwhelmingly or exclusively incident in the developing countries
- Type II diseases are often termed **neglected diseases** and Type III diseases **very neglected diseases**

WHO Commission on Macroeconomics and Health. Macroeconomics and Health: Investing in Health for Economic Development. Report of the Commission on Macroeconomics and Health. *World Health Organization*, 2001 1-200

OMS: Doenças Tropicais Negligenciadas

- **Neglected tropical diseases** are a symptom of poverty and disadvantage. Those most affected are the poorest populations often living in remote, rural areas, urban slums or in conflict zones. With little political voice, neglected tropical diseases have a low profile and status in public health priorities
- Although medically diverse, neglected tropical diseases share features that allow them to persist in conditions of poverty, where they cluster and frequently overlap. Over 1 billion people – one sixth of the world's population – suffer from one or more neglected tropical diseases



- PLoS Neglected Tropical Diseases *is an open access journal devoted to the pathology, epidemiology, prevention, treatment and control of the **neglected tropical diseases (NTDs)**, as well as public policy relevant to this group of diseases.*
- *The NTDs are defined as a group of **poverty-promoting** chronic infectious diseases, which primarily occur in rural areas and poor urban areas of low-income and middle-income countries. They are **poverty-promoting** because of their impact on child health and development, pregnancy, and worker productivity, as well as their stigmatizing features.*

Doenças Tropicais Negligenciadas, segundo PLoS-NTD

- Protozoan infections
 - Amebiasis
 - Balantidiasis
 - Chagas Disease
 - Giardiasis
 - Human African Trypanosomiasis
 - Leishmaniasis
- Viral infections
 - Dengue
 - Japanese encephalitis
 - Jungle yellow fever
 - Other arboviral infections
 - Rabies
 - Rift Valley fever
 - Viral hemorrhagic fevers
- Helminth infections
 - Taeniasis-Cysticercosis
 - Dracunculiasis
 - Echinococcosis
 - Food-borne Trematodiasis
 - Loiasis
 - Lymphatic Filariasis
 - Onchocerciasis
 - Schistosomiasis
 - Soil-transmitted Helminthiasis (Ascariasis, Hookworm Diseases, Trichuriasis, Strongyloidiasis)
 - Toxocariasis and other Larva Migrans

Doenças Tropicais Negligenciadas, segundo PLoS-NTD

- Bacterial infections
 - Bartonella
 - Bovine Tuberculosis in Humans
 - Buruli Ulcer
 - Cholera
 - Enteric pathogens (Shigella, Salmonella, *E. coli*)
 - Leprosy
 - Leptospirosis
 - Relapsing Fever
 - Trachoma
 - Treponematoses (Bejel, Pinta, Syphilis, Yaws)
- Fungal Infections
 - Mycetoma
 - Paracoccidiomycosis
- Ectoparasitic Infections
 - Scabies
 - Myiasis

Evolução do conceito “Doenças Negligenciadas”

- Conceito inicial: Rockfeller, TDR
 - Recursos insuficientes para pesquisa (biomédica)
 - Definidas globalmente (= lista das doenças do TDR)
- Conceito MSF/DNDi & OMS
 - Doenças negligenciadas pela indústria farmacêutica (há 2 tipos: dos “have nots” e dos “haves”)
 - Distribuição geográfica: Países em desenvolvimento (dos “have nots”)
 - Resultantes: da pobreza (“have nots”); ou da frequência (pode ser dos “haves”, menos que 200 mil, há fundos de investimento)
- Conceito atual
 - Doenças promotoras da pobreza
 - Cada país define suas prioridades

Consultative Expert Working Group on Research and Development: Financing and Coordination

May 2010

Sixty-third World Health Assembly
adopted Resolution WHA63.28 on the
establishment of a consultative expert
working group on research and
development: financing and coordination.

Mandate and Terms of Reference of the CEWG

Examination of practical details of...

...4 Innovative Sources of Financing

- 1. A new indirect tax**
- 2. Voluntary contributions from businesses and consumers**
- 3. Taxation of repatriated pharmaceutical industry profits**
- 4. New donor funds for health research and development**

Review of ...

...5 promising proposals

1. Open source
2. Patent pools (UNITAID model)
3. **Health impact fund**
4. Priority review voucher
5. Orphan drug legislation

Further exploration of...

...6 proposals that were not shortlisted by the EWG

- 1. Transferable intellectual property rights**
- 2. Green intellectual property**
- 3. Removal of data exclusivity**
- 4. Biomedical research and development treaty**
- 5. Large end-stage prizes (impact-based rewards)**
- 6. Neglected disease tax breaks for companies.**

Proposals in the EWG report...

...but not mentioned in the WHA63.28

5 Funding Allocation Proposals

- 1. Product development partnerships**
- 2. Direct grants to small companies and for trials in developing countries**
- 3. 'Milestone' prizes**
- 4. 'End' prizes (cash)**
- 5. Purchase or procurement agreements.**

Proposals in the EWG report...

...but not mentioned in the WHA63.28

2 Proposals to improve efficiency

- 1. Regulatory harmonization**
- 2. Precompetitive research and development platforms**

Supporting national health
research systems in low and
middle income countries

▶ Why health research?



because health equity is a priority



www.globalforumhealth.org

Submitted by the **Global Forum for Health Research (GFHR)**, Geneva, Switzerland
Comments on the Report of the WHO Expert Working Group on R&D Financing,
under the Global Strategy and Plan of Action for Public Health, Innovation and
Intellectual Property

New investment strategy: innovative developing country research awards

Financing and Coordination of R&D

Consultative Expert Working Group on Research and Development Open Forum Challenges and opportunities

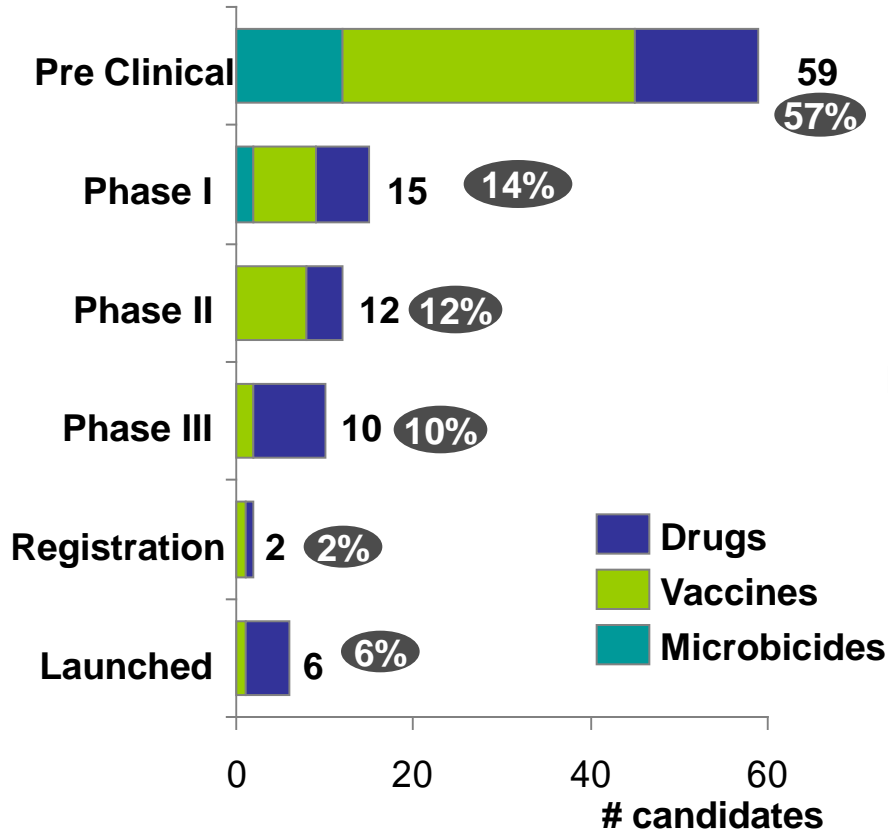
6 April 2011
WHO, Geneva

Dr. Bernard Pécoul
Executive Director, DNDi



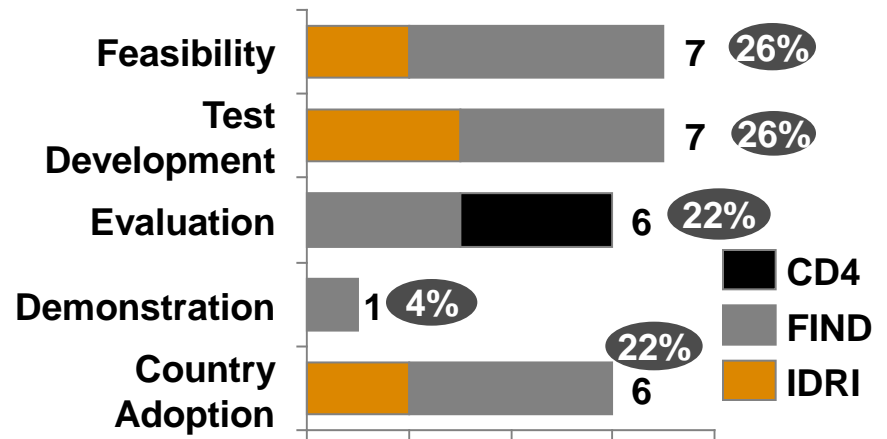
Pipeline now begins to be filled 143 candidates

104 biopharmaceutical candidates in development...



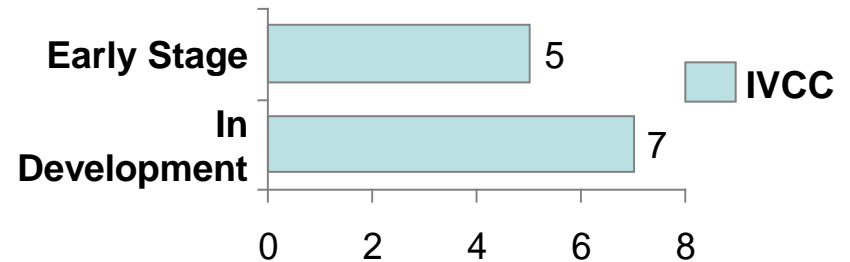
... and 39 diagnostic & vector control candidates

Diagnostics



CD4
FIND
IDRI

Vector control



IVCC

Notes: Includes products not funded by Gates Foundation.

Biopharmaceutical candidates in development Include: IAVI, IPM, IVI, GATB, Aeras, MMV, MVI, MVP, PVS, DNDi, iOWH, PDVI, HHVI.

Source: PDPs

Source from:

BILL & MELINDA
GATES foundation

BCG
THE BOSTON CONSULTING GROUP

DND*i*

A patient needs driven & innovative R&D model

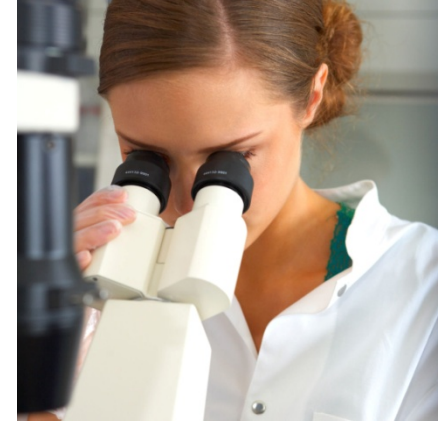
- Deliver **6 - 8 new treatments by 2014** for sleeping sickness, Chagas disease, leishmaniasis and malaria
- Establish a **robust pipeline** for future needs
- Use and strengthen existing **capacity in disease-endemic countries**

● 7 Founding Partners

- Indian Council for Medical Research (ICMR)
- Kenya Medical Research Institute (KEMRI)
- Malaysian MOH
- Oswaldo Cruz Foundation Brazil
- Medecins Sans Frontieres (MSF)
- Institut Pasteur France
- WHO/TDR (permanent observer)



The role of the pharmaceutical R&D based industry in addressing diseases of the developing world (DDW)



Jon D. Pender

Vice President, IP & Access, Global Health Government Affairs, Public Policy and Patient Advocacy, GSK
Chair, Global Health Committee, IFPMA

Industry commits resources to R&D

R&D for DDW is conducted through multiple channels

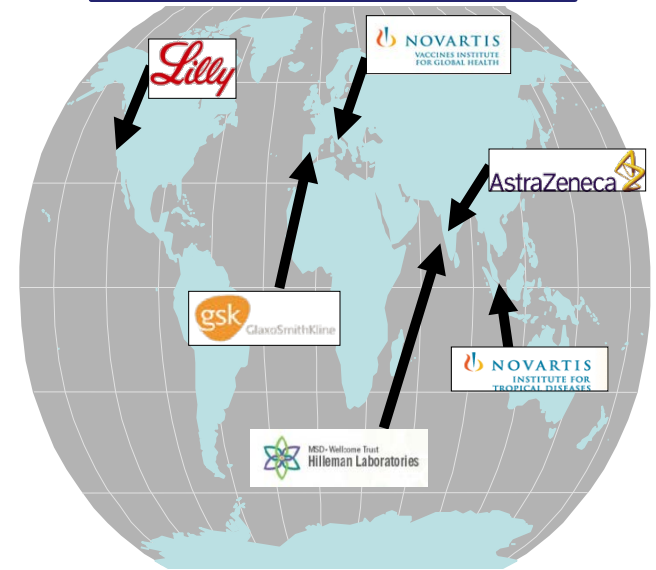
Independent efforts



Partnerships/academia



Dedicated R&D facilities



*(Current industry involvement & partnerships - illustrative only - not comprehensive)

The de-linkage of the cost of research and development and the price of health products

Michelle Childs
Director Policy Advocacy

Conclusions

- De-linkage is a key concept that enables reconciliation of innovation and access
- De-linkage is a key criteria to assess proposals for stimulation of R&D related needs for developing countries
- Implementation of de-linkage is uneven among push mechanisms and not yet implemented for pull financing
- De-linkage should be included as one of the principles in the design of a needs driven R&D global framework

The importance of public-sector research in R & D

Johanne Iversen and Unni Gopinathan



IFMSA

International Federation of
Medical Students' Associations

GLOBAL ACCESS LICENSING FRAMEWORK

Every university-developed technology with potential for further development into a drug, vaccine, or medical diagnostic should be licensed with a concrete and transparent strategy to make affordable versions available in resource-limited countries for medical care. Licenses are complex and each will be unique. Universities should therefore implement Global Access Policies that adhere to the following six principles:

Goals

1. Access to medicines and health-related technologies for all is the primary purpose of technology transfer of health-related innovations. This includes protecting access to the final end product needed by patients (e.g. formulated pills or vaccines).
2. Technology transfer should preserve future innovation by ensuring that intellectual property does not act as a barrier to further research.

Strategies

3. Generic competition is the most efficient method of facilitating affordable access to medicines in resource-limited countries. Legal barriers to generic production of these products for use in resource-limited countries should therefore be removed. In the cases of biologic compounds or other drugs where generic provision is forecast to be technically or economically infeasible, “at-cost” or other provisioning requirements

The Pharmaceutical Companies understanding of the Health Impact Fund

Marcelo Liebhardt

August 30th., 2010

Of course more is always needed: *Proposals are not lacking.*

"Affinity" credit cards	ETF (Exchange traded funds) by the Global Fund	Minimum Volume Guarantee (MVG)/Access Reproductive Health	Scientific risk insurance
Accelerated approval	EU Emissions Trading Scheme (ETS)	Mobile Phone Voluntary Solidarity Contribution	Seeding Drug Discovery
Advance Market Commitment (AMC)	European Union MDG contract	More funding from existing donors (e.g. US)	Small Business Innovation Research (SBIR)
Airline solidarity contribution	Excise duty on tobacco and alcohol consumption	More funding from State and Local govts	Small Business Research Initiative (SBRI)
Airline Ticket Voluntary Solidarity Contribution (VSC)	Fast-track option (FTO)	National Health insurance scheme to raise funds for R&D	EMEA's initiative for SME's
Anti-trust exemptions for joint biopharma collaborations	Fast-track review	Neglected Disease Innovation Fund	Sovereign Wealth Funds
Biomedical R&D Treaty	Fund for R&D in Neglected Diseases (FRIND)	Neglected Disease R&D tax breaks	Synaptic Leap
Brazil's CPMF (Provisional Contribution on Financial Transactions)	Funding from new donor countries	New Global Fund for R&D	Tax on arms trade
Cancer Prize Fund	Global Development Bonds	Open source databases	Tax on polluters and other "bad" businesses (Carbon tax)
Cap 2 Fund (C2F)	Global Premium Bonds	Orphan drug legislation	Taxation of company profits (telecommunications, banks)
Chagas Disease Prize Fund for the Development of New Treatments, Diagnostics and Vaccines	GSK patent pool	Paediatric medicines legislation	Taxation of pharmaceutical industry profits
Cost sharing for clinical trials	Guarantees by public, bilaterals or IFIs	Patent fees ("Green IP")	TB Diagnostic Prize Fund
Currency Transaction Development Levy (CTDL)	Donor first loss funds	Pediatric exclusivity act	Tobin tax
Debt2Health	Hatch-Waxman exclusivities	Pharmaceutical Company Taxation (Brazil)	Transferable Intellectual Property Right (TIPR)
De-Tax	Health Impact Fund (HIF)	Priority Medicines and Vaccines Prize Fund (PMV/pf)	Translation Awards
Developing country focussed regulatory harmonisation	IAVI Innovation Fund	Priority review	Traveller's Tax
Diaspora Bonds	IMF gold sales	Priority Review Voucher (PRV)	UNITAID patent pool
Digital tax, "bit" tax	Income tax donation	Private Giving Campaign	Incubator for companies focused on neglected diseases
Diversion of money recovered from drug dealers or corruption cases	Industry R&D Facilitation Fund (IRFF)	Prize Fund to Support Innovation and Access for Donor Supported Markets	Innovation promotion funds
Double bottom line investing	Initiatives to reduce tax evasions and tax havens	Product Development Partnership Financing Facility (PDPFF)	KEI Prize (Innovation Inducement Prize with Proportional Reward System)
European Commission -Innovative Medicines Initiative (EC-IMI)	InnoCentive	Product Development Partnerships	Redesigned 'AMC' model
Economic Prize Systems	International Finance Facility for neglected diseases (IFFnd)	Red	Waiving of regulatory fees
Electronic billing based fundraising	Internet - advertising	Regional Health R&D coordination offices	
Endowments	Life Science Convergence Platforms	Revolving fund to finance R&D for NTDs	
	Lottery/games of chance	Risk pooling mechanisms/ portfolio investment vehicle for neglected diseases	
		SBIR for IDCs (Wessner) + SBIRI	



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Instituto Nacional de Ciência e Tecnologia de Inovação em Doenças Negligenciadas
National Institute of Science and Technology for Innovation on Neglected Diseases
Instituto Nacional de Ciencia y Tecnología de Innovación en Enfermedades Olvidadas



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de inovação em
doenças negligenciadas

José da Rocha Carneiro

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Fundação Oswaldo Cruz



Instituto Nacional de Ciência e Tecnologia de Inovação em Doenças Negligenciadas



Formulação de Políticas de Inovação e Produção em Saúde

OBJETIVO:

Implementar o conhecimento a respeito da formulação de políticas na área da saúde, em particular as relacionadas com o desenvolvimento de inovação em doenças negligenciadas, através de estratégias de consulta e sensibilização dos principais atores envolvidos no ciclo de inovação (“stakeholders”).

ANTECEDENTES

Projeto Inovação em Saúde. Presidência / Fiocruz

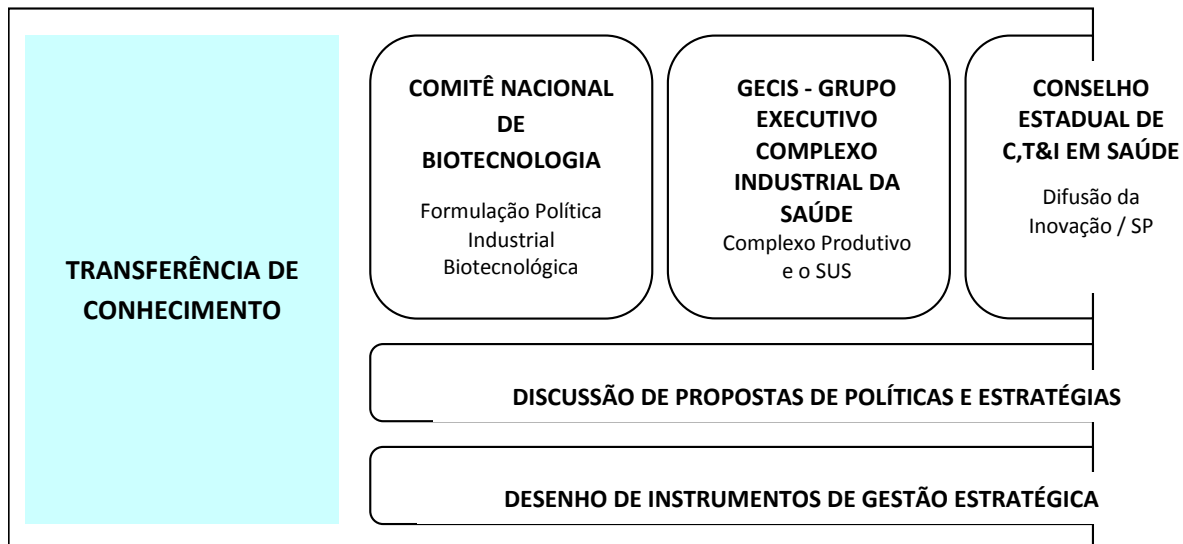
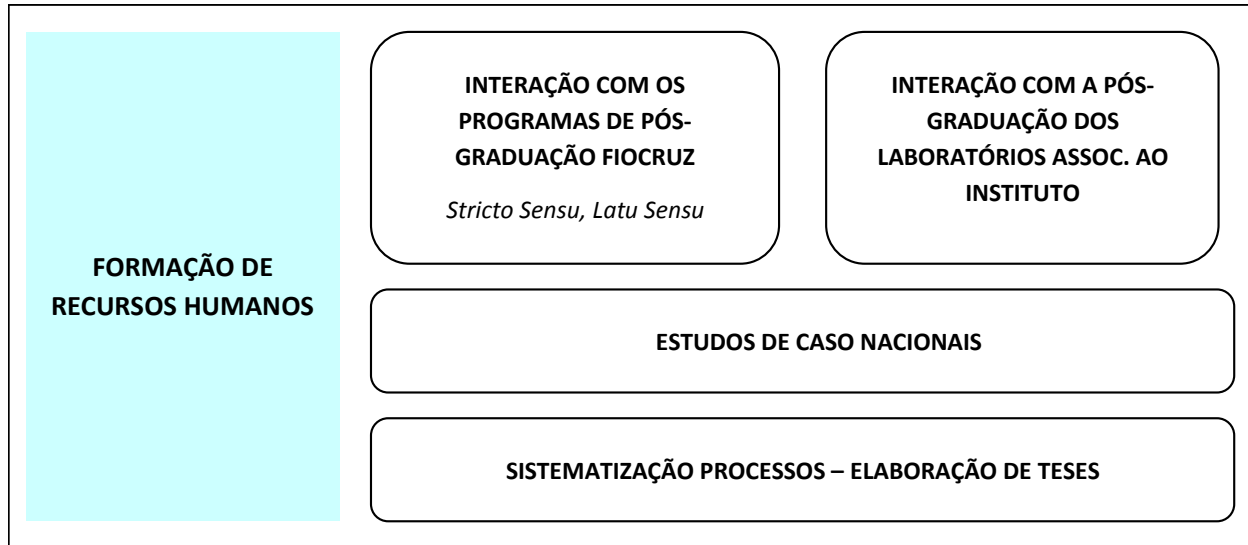
Setores Estudados – (vacinas & soros; fármacos & medicamentos)

Metodologia – Processo Consultivo (estudos verticais e horizontais)

Resultados: Documentos Técnicos, Instrumentos Jurídicos, Produção Acadêmica.

Parcerias institucionais – (participação em colegiados)

Formulação de Políticas de Inovação e Produção em Saúde



Formulação de Políticas de Inovação e Produção em Saúde



Interlocação com três instâncias de formulação de Políticas: CNB; GECIS e Conselho Estadual de C,T&I em Saúde SP	Acompanhamento de reuniões Comitê Nacional de Biotecnologia -GT Saúde
	Acompanhamento de reuniões do Grupo Executivo do Complexo Industrial da Saúde (GECIS)
	Acompanhamento de reuniões do Conselho Estadual de C,T&I em Saúde SP



Organização de Cursos de curta duração relacionados ao INCT	Elaborar proposta de cursos de curta duração presencial ou virtual em Congressos, instituições e órgãos oficiais
	Organizar e ministrar os cursos de curta duração
Estabelecer colaboração com os canais de divulgação da Fiocruz e externos	Estabelecer relacionamento com os canais de divulgação de Fiocruz: Radis, Canal Saúde, assim como, com unidades de reconhecido trabalho em comunicação em saúde: ICIT, ENSP, COC, entre outros
	Estabelecer relacionamento com instituições que trabalham em jornalismo científico, especificamente: Lab Jor do Programa de pós-graduação da Unicamp
	Estabelecer relacionamento com a Rede de Rádios Comunitárias em Saúde (Oboré), entre outras
Implementação de um Workshop sobre estratégias de Pesquisa em Gestão da Inovação	Organização do Workshop



4ª CNCTI

**Conferência Nacional de
Ciência, Tecnologia e Inovação**

para o desenvolvimento sustentável

Brasília, 27 de maio de 2010
Sessão Temática Desafios da Saúde:
Fármacos, Vacinas e Reagentes para
Diagnósticos

**Num Sistema Universal de
Saúde como o SUS: *inovação
é acesso.***

Autores

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Doenças Negligenciadas (INCT-
IDN/CDTS/Fiocruz)**

NOVAS IDÉIAS

- “The Health Impact Fund” o *open access* , “The last mile problem (cable TV)” e o acesso a medicamentos; a “reinvenção” do capitalismo.
- Determinantes sociais das Doenças Negligenciadas e o “social offset” (“carbon offsets”); a “reinvenção” do socialismo utópico.
- ***Inovação, na saúde do SUS, é acesso.***
- **INNOVATIVE MECHANISM FOR R&D FOR DEVELOPING COUNTRIES - Brazil’s Proposal**

TEXTOS :

ANGELL, M. A verdade sobre os laboratórios farmacêuticos: *Como somos enganados e o que podemos fazer a respeito*. São Paulo: Record, 2007.

Carvalho, JR (1992) “Pestilências: velhos fantasmas, novas cadeias”. *Saude soc.* São Paulo 1(1):25-42

Carvalho, JR (2008) “Epidemias em escala mundial e no Brasil”. *Estudos Avançados*, São Paulo, 22 (64): 7-17

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GRMEK, [M. D.](#) *Les Maladies à l'aube de la Civilisation Occidentale*. Paris: Payot, 1994

GRMEK, M.D. *Histoire du Sida*. Paris, Payot, 1989 (3. ed., Paris, 1995).

[GRMEK, M.D.](#) O enigma do aparecimento da Aids. *Estud. av.* 1995, vol.9, n.24, pp. 229-239.



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