Towards new mechanisms of innovation: How Latin America can become a R&D leader in the field of neglected diseases
A market failure

Pharmaceutical companies and the offer and demand market logic

R&D focus on developed region priorities

Result: the “90/10” R&D funding gap
A Decade Ago: Research at a Standstill
Fatal Imbalance for Neglected Diseases

Health R&D (1975 – 1999)

1,393 total products approved

1975-1999

A Fatal Imbalance - from 1975-1999:

Approx. 10% of R&D dedicated to illnesses that affect 90% of global disease burden (’10/90 gap’)

16 new drugs for neglected diseases

1.1%

Source: Fatal Imbalance: The Crisis in Research and Development for Neglected Diseases, MSF, 2001
Burden of Neglected Tropical Diseases

This map displays countries endemic for each of these diseases based on 2009-2010 data and international borders. (from: www.unitingtocombatntds.org)

Buruli Ulcer
Chagas disease (American trypanosomiasis)
Cysticercosis
Dengue/Severe dengue
Dracunculiasis (guinea-worm disease)
Echinococcosis
Fascioliasis
Human African trypanosomiasis
Leishmaniasis
Leprosy
Lymphatic filariasis
Onchocerciasis
Rabies
Schistosomiasis
Soil transmitted helminthiasis
Trachoma
Yaws
Neglected diseases promote poverty

Nearly twice as many poor people are living in emerging economies than in low-income countries today.

<table>
<thead>
<tr>
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<th>Total population (in millions)</th>
<th>People living with less than 2$ a day (in percentage)</th>
<th>People living with less than 2$ a day (in millions)</th>
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<tbody>
<tr>
<td>Least Developed</td>
<td>1000</td>
<td>74%</td>
<td>755</td>
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<tr>
<td>Countries</td>
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<tr>
<td>Emerging economies</td>
<td>4420</td>
<td>57%</td>
<td>1,536</td>
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</tbody>
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Source: Michel Kazatchkine, DNDi-Institut Pasteur meeting, Dec. 2013
Economic growth is rapidly changing the world order

Source: IMF data, extrapolated 2017-2020
An opportunity to seize for Latin America science

How to build a R&D model with citizens and patients at the core

Serafin Moreno
Colombian miner
Public policies to boost innovation

- R&D leadership and coordination led by LATAM
- Political willingness and vision for neglected population
- Open innovation to foster exchange and avoid duplication
- Sustainable and adapted funding mechanisms
- Favorable regulatory environments
- Articulate Research capacities
Seven cases to illustrate
Case 1: Strengthening Research Capacities in Disease-Endemic Countries

Regional Disease Platforms:

- Defining patients’ needs and target product profile (TPP)
- Strengthening local capacities
- Conducting clinical trials (Phase II/III studies)
- Facilitating registration
- Accelerating implementation of new treatments (Phase IV & pharmacovigilance studies)
Case 2: DNDi Partnerships in LA

**FOUNDING PARTNERS**
- Fundação Oswaldo Cruz; MSF Argentina, Brasil, México; Institut Pasteur-Montevideo; WHO => PAHO

**UNIVERSITY-ACADEMIA**
- UNICAMP; Universidade de Sao Paulo; Universidade de Ouro Preto; Universidade de Brasilia; UERJ; UNAM- Mexico; Universidad Mayor San Simon – Bolivia; Universidade Federal do Piauí; Universidade Estadual de Montes Claros; Universidade Federal de Tocantins; Universidade Federal de Sergipe; Hospital Infantil João Paulo II; Fundação Hospitalar do Estado de Minas Gerais; Hospital São José de Doenças Infecciosas - Fortaleza

**REGIONAL NETWORKS**
- Chagas Platform - app 80 institutions; Red de Investigación Pediátrica-Argentina; Leish Network Brasil

**MANUFACTURERS**
- HUMAX Pharmaceutical S.A, Medellín; Farmatech, Medellín; NORTEC Química S.A, Rio de Janeiro; NUDEAC, Núcleo de Desenvolvimento Farmacêutico e Cosméticos, Recife, Brasil; Cristália; Elea; Maprimed; Sanofi; GSK; Abbott

**GOVERNMENTAL OPERATIONAL PARTNERS**
- Centro de Pesquisas René Rachou/Fiocruz; Laboratório Farmacêutico do Estado de Pernambuco LAFEPE; Farmanguinhos and Laboratório da Marinha- Brasil.

**PUBLIC DONORS**
- BADES; FINEP-CNPQ; Ministério da Saúde-Brasil; Ministerio de Ciencias e Tecnologia-Argentina; BMGF; CONACYT

**NON-GOVERNMENTAL OPERATIONAL PARTNERS**
- CEADES- Bolivia; IS-Global-Barcelona; Fundación Mundo Sano- Argentina; Carlos Slim Foundation – Mexico; PECET- Colombia; LAT Research, Argentina; LATAM (CRO); CRO JSS (CRO); Federación Interacional de Pacientes; Federación Internacional de Personas Afetadas pela Doença de Chagas; The Sabin Vaccine Institute, USA; FIPEC- Argentina

**PDP**
- Medicines for Malaria Venture-Geneva; FIND

**FRIENDS OF DNDI**
- Paulo Buss; Eloán Pinheiro; Jose Temporao; Ricardo Preve
Case 3: Artesunate-Mefloquine Fixed Dose Combination: FACT Partnership

Industrial Partners: Farmanguinhos, Cipla

DNDi/TDR: scientific coordination & project management

Funding: EU’s INCODEV, FIOCRUZ, France, Netherlands, Spain, UK, MSF
Ruta N is a corporation created by the city of Medellin, academia and the industry to promote the development of innovative technology-based businesses that increase the competitiveness of the city and the region.
Case 5: Mercosur Regulatory harmonization

- Promote and stimulate regional harmonization to aim accelerate scientific risk benefit
- Strengthen capacities of regulatory bodies in endemic countries as well as regional synergies
Case 6: BNDES Subcrédito Social - Brazil

Non-reimbursable Resources:

An existing mechanism through investments in social, educational, environmental, scientific and technological research.
Case 7: Sustainable and transformative initiatives

Argentina and Spain

México

Brazil

DNDi
Drugs for Neglected Diseases Initiative
Vision for tomorrow

The Chagas R&D Accelerator Initiative: a coordination mechanism for accelerating the development of new health tools for Chagas disease—a possible regional response to World Health Assembly resolution 66.22

- **The Coordination Initiative**: representatives of the scientific community, key Latin American governments, PAHO/WHO, TDR, DNDi, treatment providers, (FINDECHAGAS), supported by a secretariat. Agree priority project, TPP’s, funding needs, incentives and policies.

- **Precedent within region**: countries in Latin America can collaborate on funding and R&D priorities applying open innovation principles contained in CWEG
Chagas Accelerator

- **Open knowledge and innovation policy:** Institutions, companies and researchers sign a formal agreement ensuring open knowledge sharing, and data transparency and publications of results.

- **Funding:** Pull public and private funding into a virtual fund to support priority projects. Possibility of refocusing existing funding on R&D (e.g. BNDES).

- **Promote and support new incentive mechanisms:** E.g. Milestone prize.

- **Equitable access and delinkage policy:** Products developed as public goods, with affordable pricing, registered in all endemic countries.

- **Towards a Regional TPP:** Building on existing platforms and promising R&D projects:
  - New PCR diagnostic kit, Laboratory validation of selected biomarkers, at least one new biomarker validated for use in clinical trials, Biobank portal, Proof of concept of alternative treatment regimens of existing drugs in monotherapy or in combination, Proof of concept of a new chemical entity (NCE), at least one new treatment option available and adopted within 5 years, and sustained diagnostic and treatment scale-up in Latin America...
Conclusion

A unique opportunity for the rise of Latin America, by solving old problems with innovative new solutions
THANK YOU

www.dndial.org