THE ROLE OF GOVERNMENT AND INTERNATIONAL AID IN R&D FOR NEGLECTED NEGLECTED DISEASES

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The recognition of the imbalance for two decades

Commission on Health Research for Development (1990)

Ad Hoc Committee on Health Research (1996)

Commission on Macroeconomics and Health (2001)
A Decade Ago, the 10/90 gap with a Pipeline Virtually Empty for Neglected Diseases

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

From 1975-1999:

16 of 1393 new products for neglected tropical diseases + malaria and TB (1.1%) despite these diseases representing 12% of global disease burden

Source: Fatal Imbalance: The Crisis in Research and Development for Neglected Diseases, MSF, 2001
Public sector, the dominant funder for neglected diseases R&D

Source: G-Finder 2012

^ Figures are adjusted for inflation and reported in 2007 US dollars

Drugs for Neglected Diseases initiative
US, UK & EC providing 80% of total public funding

Table 21. Top 12 public funders 2012

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<td>United States of America</td>
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<td>1,445</td>
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<td>Subtotal top 12 public funders*</td>
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<td>1,734</td>
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^ Figures are adjusted for inflation and reported in 2007 US dollars
* Subtotals for 2007–2011 top 12 reflect the top funders for those respective years, not the top 12 for 2012
Funding organisation did not participate in the survey for this year. Any contributions listed are based on data reported by funding recipients so may be incomplete

Source G-Finder 2012
$630 m from Philanthropic funding

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<td>Funds raised from the general public</td>
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<td>0.3</td>
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<td>0.1</td>
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Source: G-Finder 2012
Comparison with GDP to Measure real investments

[Bar chart showing Total R&D as % of GDP for various countries, with the United States of America at the top, followed by other countries such as the United Kingdom, Sweden, Norway, Luxembourg, Ireland, Denmark, South Africa, Switzerland, Australia, Netherlands, India, Colombia, France, Germany, New Zealand, Spain, Belgium, Brazil, Canada, Argentina, Thailand, Chile, Malaysia, Mexico, Japan, and South Korea.]

Source: G-Finder.
The big three and the others !!

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<td>87.1</td>
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<td>4.7</td>
<td>5.0</td>
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<td>Diarrhoeal diseases</td>
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<td>Dengue</td>
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<td>76.1</td>
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<td>63.1</td>
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<td>3.2</td>
<td>3.4</td>
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<td>Helminthes (worms &amp; flukes)</td>
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<td>32.6</td>
<td>47.4</td>
<td>45.3</td>
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<td>53.8</td>
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<td>Rheumatic fever</td>
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<td>1.2</td>
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<td>Adjuvants and immunomodulators</td>
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<td>Delivery technologies and devices</td>
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<td>Unspecified disease</td>
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<td>3.3</td>
<td>2.1</td>
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<td>4.8</td>
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<tr>
<td><strong>Total public funding (HICs/multilaterals)</strong></td>
<td>1,731</td>
<td>1,776</td>
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<td>1,925</td>
<td>1,877</td>
<td>1,921</td>
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^ Figures are adjusted for inflation and reported in 2007 US dollars
Fatal Imbalance Remains Despite Progress Over a Decade

- 3.8% of new products for neglected diseases (reformulations, combinations)
- 1.2% of NCEs for neglected diseases
- Only 1.4% clinical trials (of nearly 150,000 trials) focus on neglected diseases
- Only 1% of global health investment for neglected diseases*


*Source: 'Mapping of available health research and development data: what’s there, what’s missing, and what role is there for a global observatory?' Rottingen et al. *Lancet*, May 2013

756 products developed (excluding vaccines) (2000-2011)
A combination of PUSH and PULL mechanisms to ensure sustainability

- How can the global community best expand global financial support for global health R&D, especially for late-stage product development/clinical trials and possibly operational research/implementation sciences?
- What level of public funding needed?
- How to prioritize investments for R&D?
1. Enlarge engagement from governments...

- Beyond traditional donors
  - United Kingdom, France, The Netherlands, Spain, United States, Nordic countries.

- Emerging countries.
  - Brazil, India, China...

- Science and technology dpt & aid agencies
  - German Federal Ministry of Education and Research (BMBF) and the UK Medical Research Council (MRC)
2. GHIT: New partnership to leverage financing & competencies

- Innovative partnership including MFA, MOH, pharmaceutical companies & BMGF; scope HIV/AIDS, malaria, TB and NTDs; all technologies
- US $25 M / year; equal contribution from founders
Product Development Partnerships (PDPs): Filling the Gaps in Translational Research and Product Development

PDPs work across different diseases and modalities

Source: Bill & Melinda Gates Foundation & BCG
**Disease Scope & Level of Investment**

€ 400M for 2003-2018  =>  11 to 13 Treatments by 2018

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<th>Disease(s) to be chosen</th>
<th>€ 50-60 M</th>
<th>€ 20-30 M</th>
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<td><strong>HAT</strong></td>
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<td><strong>Chagas</strong></td>
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<td><strong>Filaria</strong></td>
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<td><strong>Paediatric HIV</strong></td>
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<td><strong>Malaria &gt;€ 20 M</strong></td>
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<tr>
<td><strong>Other NTDs &gt;€ 10 M</strong></td>
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- **Discovery**
  - Leishmaniasis
  - HAT
  - Chagas
  - Filaria
  - Paediatric HIV

- **Research**
  - Screen
  - Hit to Lead

- **Translation**
  - Pre-clinical
  - Phase I
  - Phase IIa/PoC

- **Development**
  - Phase IIb/III
  - Registration

- **Implementation**
  - Access

- **Completed**
  - 5 treatments (2 delivered)
  - 1 treatment (1 delivered)
  - 1 treatment (1 delivered)
  - 1 treatment
  - 2 treatments (2 delivered)
An Innovative Partnership Model for drug research

Research projects from Public and Private Partners

GSK Open Lab
Drug Discovery

DNDi
Project Management
Funding
Screening
Lead Optimization

Clinical Candidate

Dundee
Screening
Lead Optimization

Wellcome Trust

Clinical candidates

Clinical development

Non exclusive IP

Compounds

An Innovative Partnership Model for drug research
PDPs…Towards a Cost effective model

Research
- Screen
- Hit to Lead
- Lead Opt

Translation
- Pre-clinical
- Phase I
- Phase IIa / PoC

Development
- Phase IIb/III
- Register

Implementation

Outcomes
- ASAQ FDC for malaria: €16m
- NECT for HAT: €6m

Impact
- NCE for HAT SCYX-7158: €20m
- Support to WHO elimination Roadmap by 2020

Support to WHO elimination Roadmap by 2020

Outcomes
- 300 M treatments delivered since 2007
- 96% in DRC stage 2
Core Funding (59%) - €164.9M / $222.7M
- United Kingdom – DFID (€73.7M) – ($99.5M)
- Médecins Sans Frontières (€65.8M) – ($89M)
- Spain – AECID (€12M) – ($16.2)
- Switzerland – SDC (€10.4M) – ($14M)
- Other Private Foundations - Rockefeller, Slim, Starr (€3M) – ($4M)

Portfolio Funding (15%) – €42.5M / $57.4M
- Netherlands – DGIS (€17M) – ($23M)
- France – AFD & MAEE (€14.3M) – ($19.3M)
- Germany – KFW & GTZ (€9M) – ($12.1M)
- Norway – NORAD (€1.8M) – ($2.4M)
- Brazil – MoH (€0.4M) – ($0.5M)

Project Funding (26%) – €76.8M / $103.7M
- Bill & Melinda Gates Foundation (€45.2M) – ($61M)
- UNITAID (€13.1M) – ($17.7M)
- Wellcome Trust (€4.3M) – ($5.8M)
- European Union – FP5,6,7 & EDCTP (€4.4M) – ($6M)
- Medicor Foundation (€2.3M) – ($3.1M)
- Japan GHIT Fund (€2.3M) – ($3.1M)
- USA – NIH/NIAID (€1.8M) - ($2.4M)
- Switzerland – Canton de Genève (€1.5M) – ($2M)
- UBS Optimus Foundation (€1.4M) – ($1.9M)
- The Global Fund – AMFm (€0.5M) – ($0.7M)
4) IMI: Precompetitive platform

- Precompetitive platform, joint partnership between EU & European Pharma
- **Matching Fund Eur 3 billion (2014/2023)**
- To contribute to R&D by collaboratively developing technologies to overcome bottlenecks in the overall research process.
- Priorities: antimicrobial resistances; neurodegenerative, chronic pain; diabetes, mental health
- Sharing knowledge & open innovation
5. EDCTP 2, an unique platform to strengthen Capacities & Tech Transfert

- To accelerate R&D of new or improved diagnostics, drugs, microbicides and vaccines for HIV/AIDS, TB, malaria, and ....NTDs !!

- To coordinate the European national programmes to conduct with sub-Saharan partners relevant clinical trials (phase II and III)
- To strengthen clinical trial capacities

- The European Council has approved a budget 683 ME (2014/2023)

- A unique platform for dialogue with African scientists & to bridge the gap between North and South
A global framework

2003
Resolution WHA56.27
Intellectual property rights, innovation and public health
Commission on Intellectual Property Rights, Innovation and Public Health

2006
Resolution WHA59.24
Public Health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action
Intergovernmental Working Group

2008
Resolution WHA61.21
Global strategy and plan of action on public health, innovation and intellectual property
Expert Working Group on Research and Development: Financing and Coordination

2010
Resolution WHA63.28
Establishment of a consultative expert working group on research and development: financing and coordination
Consultative Expert Working Group on Research and Development: Financing and Coordination

DNDi
Drugs for Neglected Diseases Initiative