

Drug development through public private partnerships (PPP)

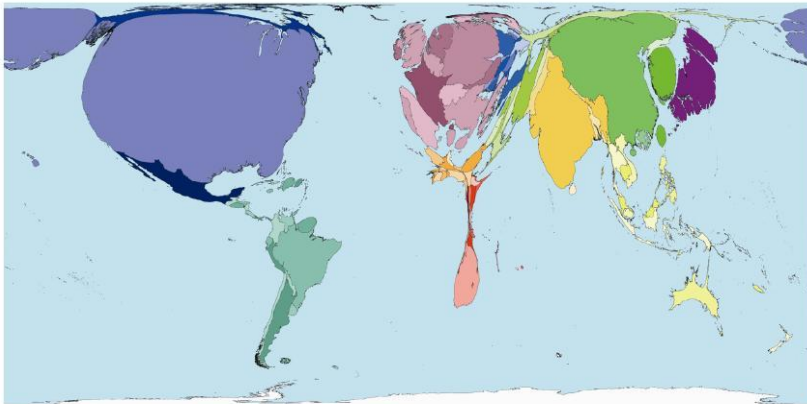
Symposium on Public Sector IP Management in the Life Sciences, December 15, 2008 - WIPO

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World Health Organization

Understanding global inequalities

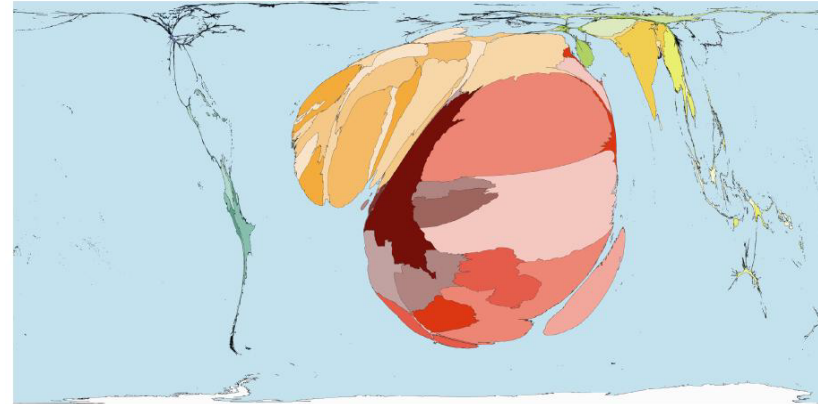
Private health spending



doi:10.1371/journal.pmed.0040001.g002

Figure 2. Private Health Spending: Worldmapper Poster 214
Source of data used to create map: United Nations Development Programme, Human Development Report 2004.

Malaria cases

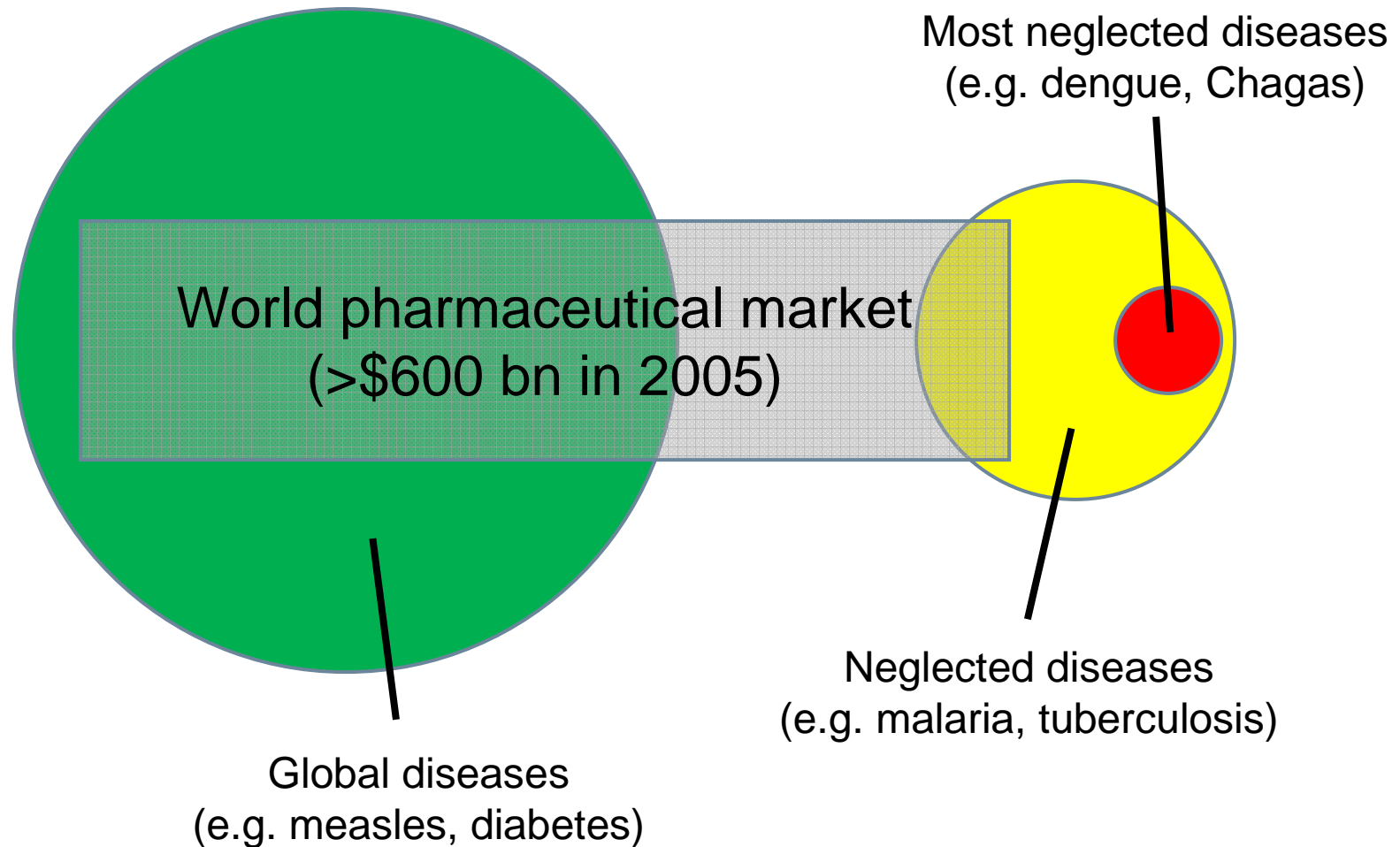


doi:10.1371/journal.pmed.0040001.g006

Figure 6. Malaria Cases: Worldmapper Poster 229
Source of data used to create map: World Health Organization and UNICEF, World Malaria Report 2005.

Dorling D (2007) Worldmapper: The Human Anatomy of a Small Planet. *PLoS Medicine* 4(1)13-18

Global, neglected and most neglected diseases (WHO & MSF)

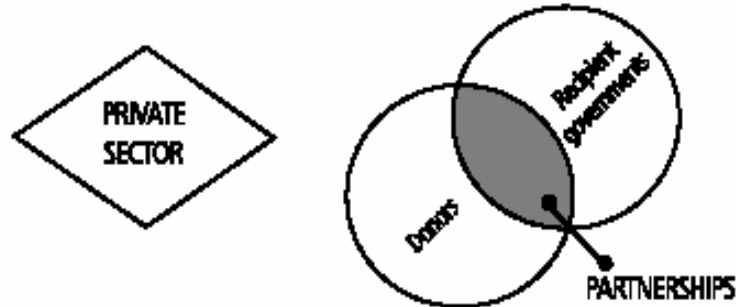


- **In past decades, WHO and other UN agencies functioned very independently from other actors on the health and development aid scene eschewing associations with nongovernmental agencies and the commercial sector.**
- **In recent years however, WHO has recognized that the sector-wide approach offers a more effective method in achieving public health goals for the long-term.[\[1\]](#)**
- **While WHO must maintain its objectivity and avoid influence by special interests or commercial motives, it has discovered areas in which it can enter into well-defined agreements with the private sector to achieve its public health objectives.**

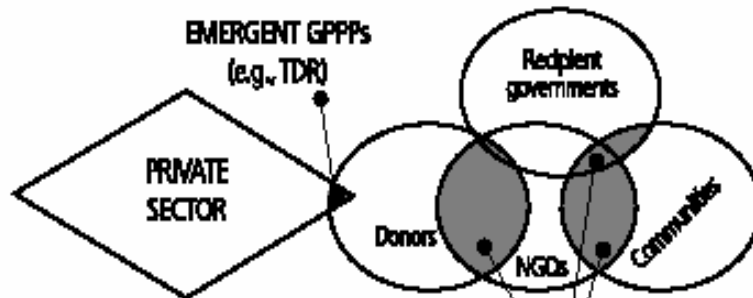
[\[1\]](#) Andrew Cassels, A guide to sector-wide approaches for health development, WHO 1997.

Public-Private Partnerships in health

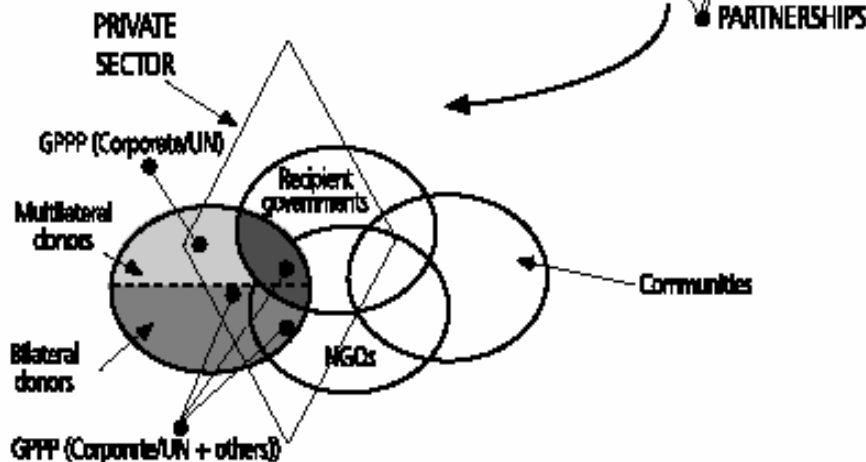
1970s



1980s



1990s



WHO 2002

- Public-private partnerships are not a new concept, but several trends have converged to make them a prominent focus in today's environment :
- *Recognition of gap in innovative products addressing neglected and most neglected diseases*
- *Recognition that the private pharma alone can not address this gap*
- *Emergence of new funds to address this gap*

- During the 1980's, an increasing number of corporations started realizing that it made good business sense to practice *better corporate citizenship*, to participate and to invest in socially responsible projects.
- In 1987, the pharmaceutical company Merck and Co. Inc. made the remarkable gesture of committing to donate as much of its drug Mectizan® as was necessary to eliminate the riverblindness disease, onchocerciasis in eleven African countries. The success of the program validated the impact of public private partnership.

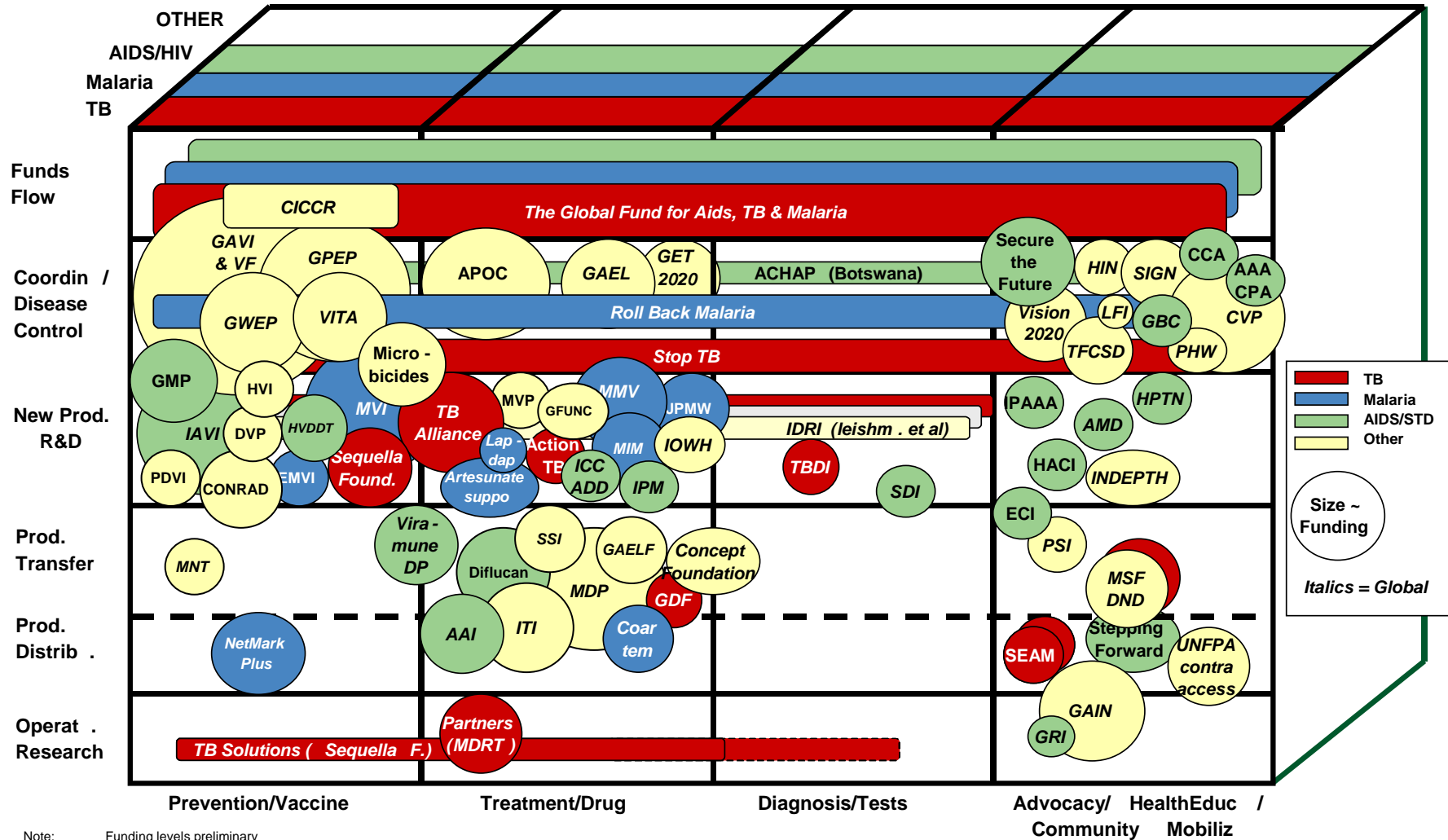
Public Private Partnerships (PPP's) definition (*one of many*)

- *A public-private partnership is an informal or formal arrangement between one or more public sector entities and one or more private sector entities created in order to achieve a public health objective or to produce a health-related product or service for the public good.*
- *The partners share certain risks and may exchange intellectual property, financial, in-kind, and/or human resources in any mutually agreed upon proportion.*

Public-Private Partnership for health with different purposes

- **Regulatory and Advocacy**
 - **Standards setting and normative testing, e.g.:**
 - WHOPEs promotes and coordinates the testing and evaluation of new pesticides
 - *Global Food Safety*
 - **Health Promotion and Advocacy, e.g.:**
 - *Tuberculosis Advocacy: Action TB*
- **Corporate drug supply at cost or donations, eg.:**
 - *Onchocerciasis control*: Merck, ivermectin
 - *Lymphatic Filariasis: Elimination*. SmithKline Beecham, albendazole
 - *Schistosomiasis*: Merck Serono, praziquantel
 - *Chagas disease (& African trypanosomiasis)*: Bayer, nifurtimoxn
 - *African trypanosomiasis*: sanofi aventis, eflornithine & pentamidinen
 - *Malaria*: Novartis, coartem
 - *Trachoma*: Pfizer, azytromicin
 - Etc.
- **Research and Product Development PPPs**
- **Stimulating Private Sector and/or Market Demand**

PPP's in late 90's early 2000



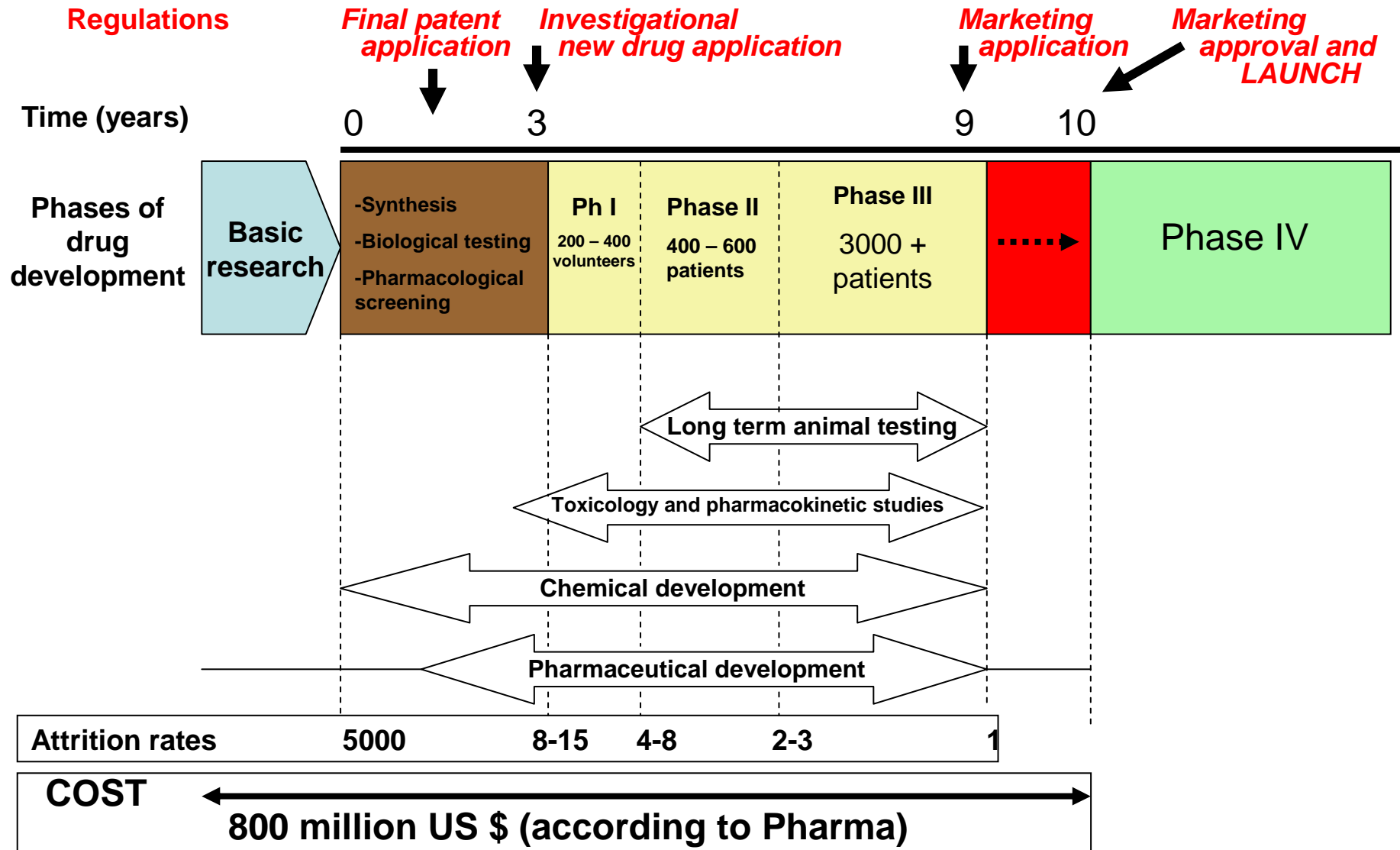
Note: Funding levels preliminary
Source: BCG Analysis, Bill & Melinda Gates Foundation Website,

IPPPH database, Partnership websites

Partnerships for Product Research & Development

- Alliance for Microbicide Development
- CONRAD/Consortium for Industrial Collaboration in Contraceptive Research
- Cooperative Research Center for Vaccine Technology
- Development of Autodestruct Syringes
- Development of Vaccine Vial Monitors
- Drugs For Neglected Diseases Initiative (DNDi).
- Development of Dengue Vaccines (Aventis Pasteur/Mahidol University)
- Epidemic Meningitis Vaccines for Africa (EVA) (Proposed)
- European Malaria Vaccine Initiative
- Global Alliance for anti-TB Drug Development
- Hookworm Vaccine Initiative (at Sabin Foundation)
- International Consortium on Anti-Virals (ICAV)
- International AIDS Vaccine Initiative
- Institute One World Health (IOWH)
- Japanese Pharmaceutical, Ministry of Health, WHO Malaria Drug Partnership (JPMW)
- Leishmaniasis Vaccine Initiative [at Infectious Diseases Research Institute (IDRI), Seattle]
- Malaria Vaccine Initiative
- Medicines for Malaria Venture (MMV)
- MSF Access to Essential Medicines Project
- Norplant
- Sequella Global Tuberculosis Foundation
- Sexually Transmitted Infections Diagnostic Group
- The Foundation for Innovative New Diagnostics (FIND)
- Various national mechanisms to promote industry involvement in 'neglected' product development (e.g., Challenge/Partnership Awards, CREADAs, Small Business Awards in USA)

Discovery and development of a new medicinal product



PPP's for product R&D

- PPPs have an aim to use public funds to engage private and public researchers in the development of new drugs, vaccines and diagnostics in the specific diseases.
- The ultimate goal is to ensure that these products reach the patients who need them, particularly poor patients in the developing world.
- They are:
 - First and foremost involved with the R&D problem
 - But they are important players in the access arena as well.
- The PPPs explicitly distinguish themselves from “grant givers” using the title of “social venture capitalists” instead.
 - Like traditional venture capitalists, they are in the business of assessing the field of projects and proposals, and selecting those that best fit their strategic criteria

PPPs structure

- They include the same components as a private company –
 - a management team,
 - a board of directors with representatives who can “talk to” the different areas of business,
 - a scientific advisory committee,
 - and a stakeholder council
- It is not the intention of any of the PPPs to finance the entire process for any of their products.
- Their goal is to invest strategically
 - to establish new discovery and development projects
 - to jump-start stalled or shelved projects
- The money put in will have positive multiplier effects and attract additional corporate investments.
- The PPP's usually do not have an R&D infrastructure (laboratories, clinical centers, production sites, etc), they manage their product portfolio, define discovery and development project strategies, identify and engage partners that perform key activities (e.g.: clinical trials in developing or developed countries). Support, partners in preparing regulatory dossiers to obtain marketing authorization.

10 commandments for PPP's

- Producing affordable, accessible products.
- The product profiles sought should be in line with global health needs.
- Developing countries are key stakeholders in R&D, product use and product delivery.
- Capacity building and capacity utilization in developing countries should be integral to product R&D activities
- Not to be over-competitive with other initiatives, nor monopolistic.
- Facilitate cross-linkages and synergies.
- Advocate basic & exploratory research, product R&D pipelines depends on these.
- R&D products must be linked with continued and sustainable production and distribution.
- Advocate for downstream research to optimize product use and evidence for policy (work with public health systems)
- Conflict of interest should be minimized

IP and PPP's

Adapted from Hannah Kettler

- **IP assignments are linked to ultimate goal of producing affordable, accessible products.**
- **In discovery stages, ownership is sought by the “funder” (i.e. the partnership), rather than the “finder”. The PPP seeks share of IP for their purposes**
 - traditional grant givers don't expect something in return
 - traditional venture capital investing in biotech companies look for share in the company rather than IP
- **In the development stage the PPP's seeks control of IP:**
 - for the specific disease (i.e. the company partner retains use for other diseases)
 - or looks to split the market (the company partner retains control for the non-developing country markets)

PPP's pursue an IP strategy designed to maximise the social value of product and process patents.

- **Negotiation of creative IP arrangements that do not scare off companies but also allow the PPP enough control to ensure their ultimate objective (a difficult challenge).**
 - Clearly determine the IP rights and conditions up front.
 - Trading rights to rich country markets and use in other indications for low price access for LDC target markets
 - Trade any other disease use for control of the IP for the neglected disease.
 - Explicitly address the issue of royalty rights for products sold in the paying markets.
 - Providing incentives to supply sufficient volume to LDC markets
 - Establish explicit volume deals with the company partner.
 - Retaining reversion rights, should commercial partners not deliver on their commitments.
 - If the partner chooses not to use the IP in pursuit of the designated product, the PPP has the rights to take it back. The PPP has the right not to be held up.
 - When in-licensing products or technologies, seek control rights to out-source the project to third parties.

The first assessments suggest a Win/Win Model.

- The PPP's comparative advantages seem to include:
 - Cost and time savings through the clinical trials network, engagement of Developing Country manufacture capabilities and fast track regulation.
 - Higher success rates through disease competencies concentrated or at least linked in close networks, with the pooling of resources, technologies, and know-how across locations and projects.
 - Improvement in the environment for projects outside the PPP's pipeline- spillover effects in the form of information, market size calculations, lobbying for additional incentives, and others pumping funds into disease management areas.

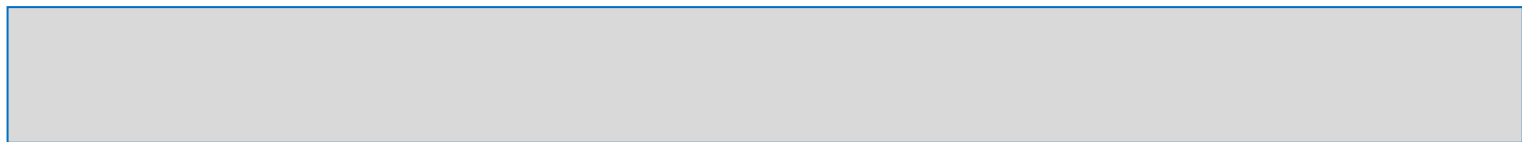
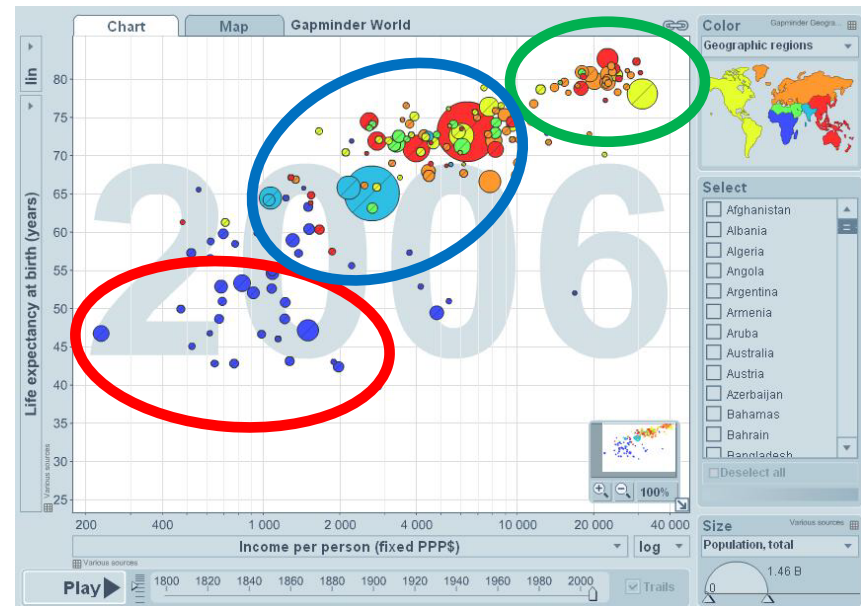
Unresolved or potential problems:

- **Culture conflicts**
- **“Input” from civil society – i.e. the ultimate customers.**
- **Impact depends on deals that commit pharmaceutical partners at later stages.**
- **Donor fatigue and the drying up of funding sources.**
- **Can science and R&D be effectively conducted through this model? management of spillover effects between projects and across organizations.**

The North- South bipolar world no longer exists

1966: The **South** and the **North**

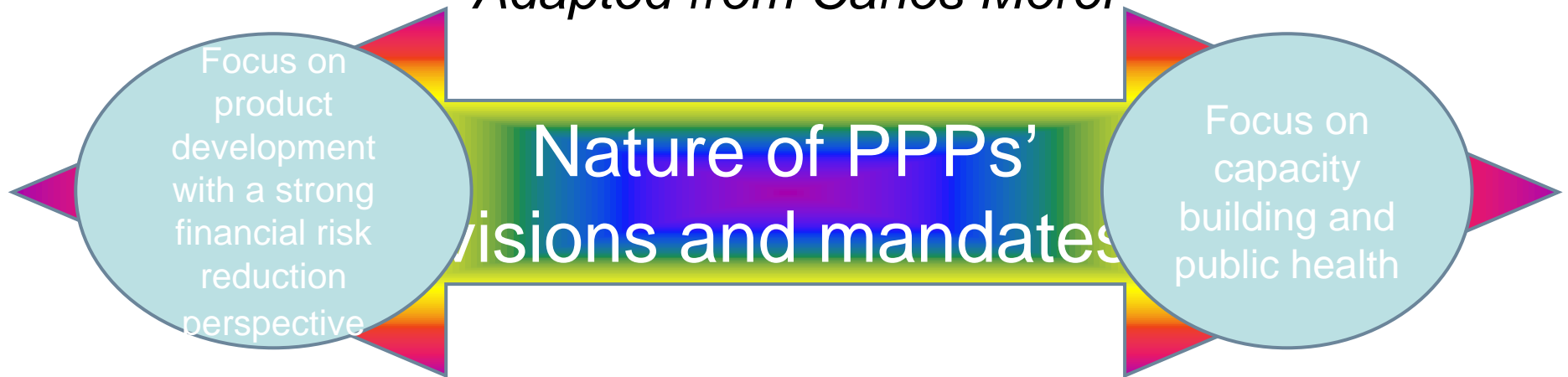
2006: The **South**, the **Emerging Markets** and the **North**



<http://tools.google.com/gapminder/>

Evolution of PPP's*

Adapted from Carlos Morel



“Development as Growth”

- Partnership focuses on rapid cost effective product development; minimal involvement of developing countries

“Development as Freedom” (A. Sen)

- Partnership's mandate besides product development includes capacity building, training, involvement of endemic country institutions and public health

* The evolutionary pressure comes from donor, financing strategies

Global Strategy and Plan of Action on Public Health, Innovation and IP, WHA 61.21

The context

3. Member States,² the pharmaceutical industry, charitable foundations and nongovernmental organizations have taken initiatives in recent years to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, these initiatives are not sufficient to surmount the challenges of meeting the goal of ensuring access and innovation for needed health products and medical devices. More efforts should be made to avoid suffering and reduce preventable mortality and to meet the health-related Millennium Development Goals and to implement States' obligations and commitments arising under applicable international human rights instruments with provisions relevant to health.

Global Strategy and Plan of Action on Public Health, Innovation and IP, WHA 61.21

Element 3. Building and improving innovative capacity

31. There is a need to frame and develop and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine.

Element 4. Transfer of technology

33. North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. Article 7

Element 5. Application and management of intellectual property to contribute to innovation and promote public health

35. The international regimes on intellectual property aim, inter alia, to provide incentives for the development of new health products. However, incentive schemes for research and development, especially on Type II and Type III diseases and the specific R&D needs of developing countries in respect of Type I diseases, need to be explored and implemented, where appropriate. There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

Thank you

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