

# NEGLECTED DISEASE RESEARCH AND DEVELOPMENT: IS INNOVATION UNDER THREAT?



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The views expressed are those of the authors.



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# ACRONYMS

<b>ACTs</b>	Artemisinin-based combination therapies	<b>Dutch DGIS</b>	Dutch Ministry of Foreign Affairs - Directorate General of Development Cooperation
<b>Aggregate industry respondents</b>	Aggregate Pharmaceutical and Biotechnology Company Respondents	<b>EAggEC</b>	Enteroaggregative <i>E. coli</i>
<b>ALM</b>	American Leprosy Missions	<b>EC</b>	European Commission: Research Directorate-General
<b>AMC</b>	Advance Market Commitment	<b>EDCTP</b>	European and Developing Countries Clinical Trials Partnership
<b>APOC</b>	African Programme for Onchocerciasis Control	<b>ETEC</b>	Enterotoxigenic <i>E. coli</i>
<b>ARRA</b>	American Recovery and Reinvestment Act	<b>EU</b>	European Union
<b>Australian DIISR/ARC</b>	Australian Department of Innovation, Industry, Science and Research and/or Australian Research Council	<b>EVI</b>	European Vaccine Initiative
<b>Australian NHMRC</b>	Australian National Health and Medical Research Council	<b>FDCs</b>	Fixed-dose combinations
<b>Belgian FWO</b>	Belgian National Fund for Scientific Research	<b>FIND</b>	Foundation for Innovative New Diagnostics
<b>Brazilian DECIT</b>	Brazilian Ministry of Health: Department of Science and Technology	<b>French ANR</b>	French National Research Agency, Agence Nationale de Recherche
<b>Brazilian FINEP</b>	Brazilian Innovation Agency	<b>French ANRS</b>	French National Agency for Research on AIDS and Viral Hepatitis
<b>Canadian CIHR</b>	Canadian Institutes of Health Research	<b>Gates Foundation</b>	Bill & Melinda Gates Foundation
<b>CIDA</b>	Canadian International Development Agency	<b>GAVI</b>	Global Alliance for Vaccines and Immunizations
<b>Colombian Colciencias</b>	Colombian Department for Science, Technology and Innovation	<b>GDP</b>	Gross domestic product
<b>DAHWA</b>	German Leprosy and TB Relief Association	<b>GERD</b>	Gross Expenditure on Research & Development
<b>DALY</b>	Disability Adjusted Life Year	<b>German BMBF</b>	German Federal Ministry of Education and Research
<b>DCs</b>	Developing Countries	<b>German DFG</b>	German Research Foundation
<b>Dell Foundation</b>	Michael & Susan Dell Foundation	<b>GFC</b>	Global financial crisis
<b>DNDi</b>	Drugs for Neglected Diseases initiative	<b>G-FINDER</b>	Global Funding of Innovation for Neglected Diseases
		<b>HAT</b>	Human African Trypanosomiasis
		<b>HICs</b>	High-Income Countries
		<b>HIV/AIDS</b>	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
		<b>IAVI</b>	International AIDS Vaccine Initiative
		<b>IDCs</b>	Innovative Developing Countries
		<b>IDRI</b>	Infectious Disease Research Institute
		<b>ILEP</b>	International Federation of Anti-Leprosy Associations

# ACRONYMS

<b>Indian ICMR</b>	Indian Council of Medical Research	<b>Spanish MAEC</b>	Spanish Ministry of Foreign Affairs and Cooperation for Development
<b>Inserm</b>	Inserm - Institute of Infectious Diseases	<b>SSI</b>	Statens Serum Institute
<b>IPM</b>	International Partnership for Microbicides	<b>Swedish SIDA</b>	Swedish International Development Agency
<b>IVCC</b>	Innovative Vector Control Consortium	<b>Swiss SDC</b>	Swiss Agency for Development and Cooperation
<b>IVI</b>	International Vaccine Institute	<b>TB</b>	Tuberculosis
<b>LMICs</b>	Low- and middle-income countries	<b>TB Alliance</b>	Global Alliance for TB Drug Development
<b>MDP</b>	Microbicides Development Program	<b>TBVI</b>	TuBerculosis Vaccine Initiative
<b>MDR-TB</b>	Multidrug-resistant tuberculosis	<b>TLMI</b>	The Leprosy Mission International
<b>MDT</b>	Multidrug therapy	<b>UK</b>	United Kingdom
<b>Mexican CONACYT</b>	Mexico National Council of Science and Technology	<b>UK DFID</b>	UK Department for International Development
<b>MICs</b>	Middle-income Countries	<b>UK MRC</b>	UK Medical Research Council
<b>MMV</b>	Medicines for Malaria Venture	<b>US</b>	United States
<b>MNC</b>	Multinational pharmaceutical company	<b>US CDC</b>	US Centers for Disease Control
<b>MSF</b>	Médecines Sans Frontières	<b>US DOD</b>	US Department of Defense (DOD) including DOD Defense Advanced Research Projects Agency
<b>NIAID</b>	National Institute of Allergy and Infectious Diseases	<b>US NIH</b>	US National Institutes of Health
<b>NLR</b>	Netherlands Leprosy Relief	<b>USAID</b>	United States Agency for International Development
<b>Norwegian NORAD</b>	Royal Norwegian Ministry of Foreign Affairs and/or Norwegian Agency for Development Cooperation	<b>WHO</b>	World Health Organization
<b>NTS</b>	Non-typhoidal <i>Salmonella enterica</i>	<b>WHO/TDR</b>	Special Programme for Research and Training in Tropical Diseases
<b>OAR</b>	Office of AIDS Research	<b>XDR-TB</b>	Extensively drug-resistant tuberculosis
<b>ODA</b>	Official Development Assistance	<b>YOY</b>	Year-on-Year
<b>OECD</b>	Organisation for Economic Cooperation and Development		
<b>ORT</b>	Oral rehydration therapy		
<b>OWH</b>	OneWorld Health (OWH)		
<b>PATH</b>	Program for Appropriate Technology in Health		
<b>PDP</b>	Product development partnership		
<b>QIMR</b>	Queensland Institute of Medical Research		
<b>R&amp;D</b>	Research and Development		
<b>RCDC</b>	Research, Condition and Disease Categorization		
<b>SME</b>	Small pharmaceutical and biotechnology firms		

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# EXECUTIVE SUMMARY

## The survey

The fourth G-FINDER survey reports on 2010 global investment into research and development (R&D) of new products for neglected diseases, and identifies trends and patterns across the four years of global G-FINDER data. It covers:

- 31 neglected diseases
- 134 product areas for these diseases, including drugs, vaccines, diagnostics, microbicides and vector control products
- Platform technologies (e.g. adjuvants, delivery technologies, diagnostic platforms)
- All types of product-related R&D, including basic research, discovery and preclinical, clinical development, Phase IV and pharmacovigilance studies, and baseline epidemiological studies.

As in previous years, the survey scope was again expanded in order to build a more complete picture of global investment into neglected disease R&D, with a greater focus on Low- and Middle-Income Countries (LMICs) and groups who had historically provided limited data, such as the vector control industry. Public funders in six LMICs – Argentina, Chile, Mexico, Uganda, Nigeria and Malaysia – participated in the survey for the first time. In all, 240 organisations completed the survey in 2010, a 10% increase on 2009.

## Findings

Total reported funding for R&D of neglected diseases in 2010 was \$3,063m (\$3,173m in unadjusted 2010 US\$). This was a decrease from 2009, with repeat survey participants – year-on-year (YOY) funders – reducing their investment by \$109.1m (-3.5%). Around \$30.7m reported in 2009 was lost-to-follow-up by funders who did not participate in the 2010 survey, with this being offset by \$33.5m reported by new survey respondents for 2010. The effect of the global financial crisis became evident for the first time in 2010, with large funding cuts across all sectors except the pharmaceutical industry. The decrease in global investment in neglected disease R&D would have been far worse but for a very significant increase in investment from multinational pharmaceutical companies (MNCs), which cushioned the impact of cuts in public and philanthropic funding.

### DISEASE FINDINGS AND TRENDS

"There were large funding cuts in all sectors except industry"

As in previous years, the three 'top tier' diseases – HIV/AIDS (\$1,073m, 35.0%), tuberculosis (TB) (\$575.4m, 18.8%) and malaria (\$547.0m, 17.9%) – received the lion's share of global funding for neglected disease R&D. However, their share of global funding continued to fall, as they collectively received 71.7% (\$2,195m) of global funding in 2010, down from 72.1% (\$2,283m) in 2009, 72.8% (\$2,153m) in 2008 and 76.6% (\$1,962m) in 2007. This redistribution was due to decreased YOY funding for the top tier diseases (down by \$82.5m) rather than to increased funding for the remaining neglected diseases as in 2009. TB once again saw a substantial YOY funding increase in 2010 (up \$29.6m, 5.5%), and for the first time overtook malaria to become the second most highly-funded disease. Global funding for malaria R&D fell sharply (down \$45.5m, -7.8%), although this reflected the upcoming conclusion of the RTS,S vaccine development programme.

## "The impact of the global financial crisis was evident for the first time"

Among the 'second tier' diseases, dengue and diarrhoeal diseases each received more than 5% of global R&D funding for the second year running, despite YOY funding for diarrhoeal diseases being down by \$18.3m (-10.3%). A drop in YOY funding for kinetoplastid R&D (down \$15.5m, -9.6%) meant that it fell back below the 5% line in 2010, in contrast to funding for bacterial pneumonia and meningitis R&D which increased sharply in 2010, with YOY funders providing an additional \$31.7m (up 52.9%).

The 'third tier' diseases remained underfunded, with leprosy, Buruli ulcer, trachoma and rheumatic fever each receiving less than \$10m, as in previous years.

### FUNDERS

As in previous survey years, the public sector played a key role providing almost two-thirds (\$2.0bn, 65%) of global funding, the vast majority (\$1.9bn, 96.4%) from High-Income Country (HIC) governments. However, in a major change, the philanthropic sector did not play the dominant role seen in previous years, with philanthropic contributions of \$568.1m (18.5%) being closely matched by industry investments of \$503.5m (16.4%).

The effect of the global financial crisis on public sector neglected disease R&D funding became evident for the first time in 2010. Thirteen of the top 20 governments cut their neglected disease R&D funding in 2010, as did eight of the top 12 government funders (who represent 93.1% of total public funding). The US is still by far the world's largest government funder contributing nearly 70% of global public funding (\$1.39bn, 69.7%). However, its funding dropped significantly in 2010 (down \$74.5m, -5.1%), driven by a \$44.5m drop in US NIH funding. The UK was one of the very few countries where public funding for neglected disease R&D increased (up \$21.2m, 14.9%), with much of this driven by a \$12.8m (15.2%) increase by the UK Department for International Development (DFID). This funding increase is particularly significant as the majority of other governments cut their YOY funding in 2010, including the European Commission (EC, down \$25.8m, -21.8%), Brazil (down \$20.8m, -65.6%), Sweden (down \$14.2m, -43.0%), the Netherlands (down \$11.2m, -39.1%), Denmark (down \$8.4m, -49.7%), France (down \$7.4m, -15.6%), Canada (down \$7.4m, -43.9%), Spain (down \$5.9m, -29.9%), Germany (down \$4.3m, -12.5%) and Norway (down \$3.5m, -20.0%).

Philanthropic funding also decreased, by a substantial \$79.8m (-12.4%) in 2010. This was mostly due to a \$101.7m decrease in funding from the Gates Foundation as several Foundation-funded products reached maturity, including the RTS,S malaria vaccine; and Shanchol™, a new oral cholera vaccine. In contrast, industry increased its 2010 YOY investment in neglected disease R&D by \$107.3m (up 28.2%) to a total of \$503.5m, entirely due to an increase in MNC investment of \$114.7m (35.1%), which more than offset the halving of YOY funding from small pharmaceutical and biotechnology firms (SMEs) in Innovative Developing Countries (IDCs, down \$7.0m, -49.9%). Investment by SMEs in the developed world held steady (down \$0.4m, -0.9%).



## FUNDING FLOWS

Just over 70% of 2010 R&D funding was in the form of external grants (71.5%), while intramural funding (self-funding) by public research institutions and private companies accounted for 28.5%. There was a significant shift from external funding (down \$149.0m, -6.4%) to self-funding (up \$42.7m, 5.1%), mainly driven by the increase in industry self-funding (up \$110.8m, 29.7%) and the decrease in external grant funding from the Gates Foundation (down \$101.7m, -18.2%).

PDP funding decreased by a further \$46.9m (-8.8%) in 2010, after an earlier \$50.0m decrease in 2009. This decrease reflected both healthy funding cuts (for instance, the \$72.6m drop in RTS,S-related funding to PATH as the vaccine candidate nears successful completion) but also more worrying trends, with the majority of funders freezing or decreasing their PDP investments in 2010.

## CONCLUSION

The fallout from the global financial crisis made its mark in 2010 with investment in neglected disease R&D decreasing for the first time since the G-FINDER survey began in 2007. However, despite the unfavourable economic and political climate, organisations continued to contribute generously to the multi-billion dollar R&D effort to create new neglected disease products for patients in the developing world. We hope the information in G-FINDER continues to be a useful platform to guide future health funding decisions.



# INTRODUCTION

## Background to the G-FINDER survey

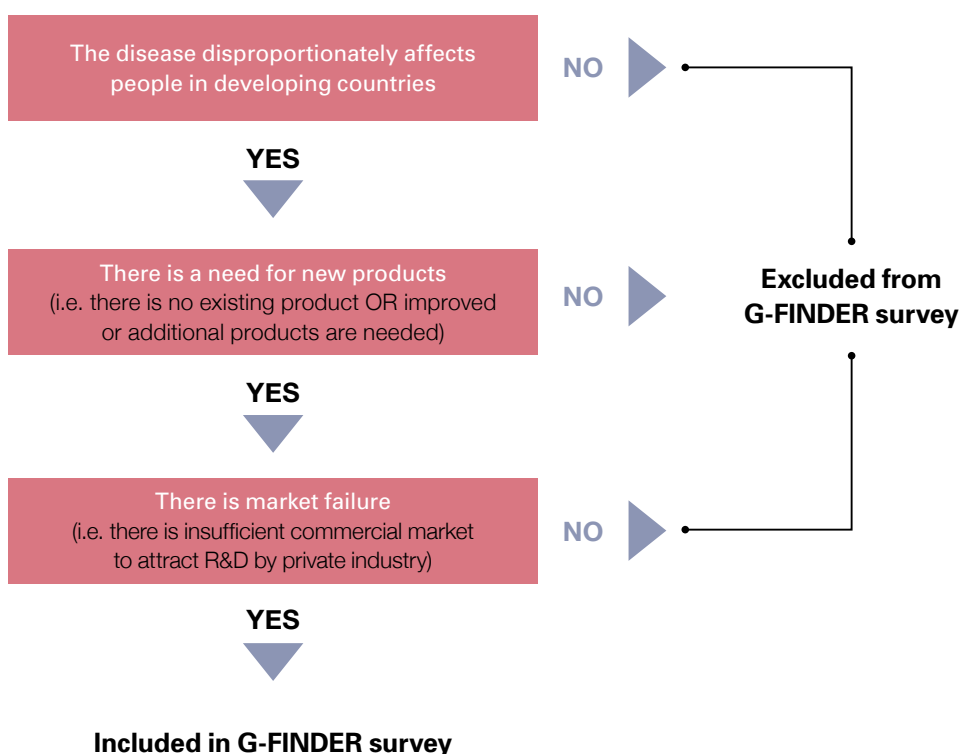
The first three G-FINDER reports shed light on 2007, 2008 and 2009 global investment into research and development (R&D) of new products to prevent, diagnose, manage or cure neglected diseases of the developing world. The fourth survey reports on 2010 investments.

## The survey

### WHICH DISEASES AND PRODUCTS ARE INCLUDED?

The scope of the G-FINDER survey is determined by applying three criteria (see Figure 1). Application of these criteria results in a list of neglected diseases and products, for which R&D would cease or wane if left to market forces.

**Figure 1. 3-step filter to determine scope of neglected diseases covered by G-FINDER**



All product R&D is covered by the survey, including:

- Drugs
- Vaccines (preventive and therapeutic)
- Diagnostics
- Microbicides
- Vector control products (pesticides, biological control agents and vaccines targeting animal reservoirs)
- Platform technologies (adjuvants, diagnostic platforms and delivery devices). These are technologies that can potentially be applied to a range of neglected diseases and products but which have not yet been attached to a specific product for a specific disease.

We note that not all product types are needed for all diseases. For example, effective pneumonia management requires new developing-world specific vaccines, but does not need new drugs as therapies are either already available or in development.

Funders were asked to only report investments *specifically* targeted at developing-country R&D needs. This is important to prevent neglected disease data being swamped by funding for activities not directly related to product development (e.g. advocacy, behavioural research); or by ‘white noise’ from overlapping commercial R&D investments (e.g. HIV/AIDS drugs and pneumonia vaccines targeting Western markets; and investments in platform technologies with shared applications for industrialised countries). As an example, G-FINDER defines eligible pneumonia vaccine investments by strain, vaccine type and target age group; while eligible HIV/AIDS drug investments are restricted to developing-country relevant products such as fixed-dose combinations (FDCs) and paediatric formulations. Eligibility for inclusion is also tightly defined for platform technologies to ensure that only funding for platforms for developing world applications are included, as opposed to investment into platforms developed for commercial markets. Private sector investment into platform technologies is therefore excluded (see Annexe 5 for outline of R&D funding categories, setting out inclusions and exclusions).

The initial scope of G-FINDER diseases and eligible R&D areas was determined in 2007 in consultation with an International Advisory Committee of experts in neglected diseases and neglected disease product development (see Annexe 2). A further round of consultations took place in Year Two. As a result of this process, for the 2008 survey, the typhoid and paratyphoid fever disease category was broadened to include non-typhoidal *Salmonella enterica* (NTS) and multiple salmonella infections; while diagnostics for lymphatic filariasis were added as a neglected area. There were no changes in survey scope for 2009 or 2010. The final agreed scope of G-FINDER diseases, products and technologies is shown in Table 1.

Table 1. G-FINDER diseases, products and technologies

Disease	Basic Research	Drugs	Vaccines (Preventive)	Diagnostics	Microbicides	Vaccines (Therapeutic)	Vector control products
<b>HIV/AIDS</b>	Restricted	Restricted	Y	Y	Y		
<b>Malaria</b>							
<i>Plasmodium falciparum</i>	Y	Y	Y	Y			Y
<i>Plasmodium vivax</i>	Y	Y	Y	Y			Y
Other and/or unspecified malaria strains	Y	Y	Y	Y			Y
<b>Tuberculosis</b>	Y	Y	Y	Y		Y	
<b>Diarrhoeal diseases</b>							
Rotavirus			Restricted				
Enterotoxigenic <i>E.coli</i> (ETEC)			Y	Y			
Cholera	Y	Restricted	Y	Y			
Shigella	Y	Restricted	Y	Y			
<i>Cryptosporidium</i>	Y	Restricted	Y	Y			
Enteropathogenic <i>E.coli</i> (EAggEC)			Y	Y			
Giardia				Y			
Multiple diseases	Y	Y	Y	Y			
<b>Dengue</b>	Y	Y	Y	Y			Y
<b>Kinetoplastids</b>							
Chagas' disease	Y	Y	Y	Y		Y	Y
Leishmaniasis	Y	Y	Y	Y		Y	
Sleeping sickness	Y	Y	Y	Y			Y
Multiple diseases	Y	Y	Y	Y		Y	Y
<b>Helminth infections</b>							
Roundworm (ascariasis)	Y	Y					
Hookworm (ancylostomiasis & necatoriasis)	Y	Y	Y				
Whipworm (trichuriasis)	Y	Y					
Strongyloidiasis & other intestinal roundworms	Y	Y	Y	Y			
Lymphatic filariasis (elephantiasis)	Y	Y		Y			Y
Onchocerciasis (river blindness)	Y	Y	Y	Y			Y
Schistosomiasis (bilharziasis)	Y	Y	Y	Y			Y
Tapeworm (cysticercosis/taeniasis)	Y	Y					Y
Multiple diseases	Y	Y	Y	Y			Y
<b>Bacterial pneumonia &amp; meningitis</b>							
<i>Streptococcus pneumoniae</i>			Restricted	Y			
<i>Neisseria meningitidis</i>			Restricted	Y			
Both bacteria				Y			
<b>Salmonella infections</b>							
Non-typhoidal <i>Salmonella enterica</i> (NTS)	Y	Y	Y	Y			
Typhoid and paratyphoid fever ( <i>S. typhi</i> , <i>S. paratyphi A</i> )	Y	Y	Y	Y			
Multiple salmonella infections	Y	Y	Y	Y			
<b>Leprosy</b>	Y	Y		Y			
<b>Rheumatic fever</b>			Y				
<b>Trachoma</b>			Y	Y			
<b>Buruli ulcer</b>	Y	Y	Y	Y			
	Adjuvants and immunomodulators		Delivery technologies and devices		Diagnostic platforms		
<b>Platform technologies (non-disease specific)</b>	Restricted		Restricted		Restricted		

Restricted denotes a category where only some investments are eligible, as defined in the outline of the R&D funding categories (see Annexe 5)  
 Y (Yes) denotes a category where a disease or product was included in the survey

#### WHAT TYPES OF INVESTMENTS ARE INCLUDED?

G-FINDER quantifies neglected disease investments in the following R&D areas:

- Basic research
- Product discovery and preclinical development
- Product clinical development
- Phase IV/pharmacovigilance studies of new products
- Baseline epidemiology in preparation for product trials

Although we recognise the vital importance of activities such as advocacy, implementation research, community education and general capacity building, these are outside the scope of G-FINDER. We also exclude investment into non-pharmaceutical tools such as bednets or circumcision, and general therapies such as painkillers or nutritional supplements, as these investments cannot be ring-fenced to neglected disease treatment only.

#### HOW WAS DATA COLLECTED?

Two key principles guided the design of the G-FINDER survey. We sought to provide data in a manner that was consistent and comparable across all funders and diseases, and as close as possible to 'real' investment figures.

G-FINDER was therefore designed as an online survey into which all organisations entered their data in the same way according to the same definitions and categories, and with the same inclusion and exclusion criteria. All funders were asked to only include disbursements, as opposed to commitments made but not yet disbursed; and we only accepted primary grant data.<sup>i</sup> Survey respondents were asked to enter every neglected disease investment they had disbursed or received in 2010 into a password-protected online database. The exception was the United States National Institutes of Health (US NIH), for whom data was collected by mining the US NIH's Research, Condition and Disease Categorization (RCDC) system, launched in January 2009.

Multinational pharmaceutical companies (MNCs) agreed to provide full data on their neglected disease investments. However, as these companies do not operate on a grant basis, the reporting tool was varied somewhat in their case. Instead of grants, companies agreed to enter the number of staff working on neglected disease programmes, their salaries, and direct project costs related to these programmes. All investments were allocated by disease, product and research type according to the same guidelines used for online survey recipients. As with other respondents, companies were asked to include only disbursements rather than commitments. They were also asked to exclude 'soft figures' such as in-kind contributions and costs of capital.

The fourth G-FINDER survey was open for a 12-week period from April to June 2011, during which intensive follow-up and support for key recipients led to a total of 8,186 entries being recorded in the database for financial year 2010 (an increase of 5% on the previous year).

With the exception of US NIH grants, all entries over \$0.5m (i.e. any grant over 0.02% of total funding) were then verified against the inclusion criteria and cross-checked for accuracy. Cross-checking was conducted through automated reconciliation reports that matched investments reported as disbursed by funders with investments reported as received by intermediaries and product developers. Any discrepancies were resolved by contacting both groups to identify the correct figure. US NIH funding data was supplemented and cross-referenced with information received from the Office of AIDS Research (OAR) and the National Institute of Allergy and Infectious Diseases (NIAID). Industry data was aggregated for MNCs and for small pharmaceutical companies and biotechs (SMEs) in order to protect their confidentiality.

<sup>i</sup> An exception was made for some US NIH data, where a proportion of grants could not be collected in this way due to changes in their data management system.

## WHO WAS SURVEYED?

G-FINDER is primarily a survey of funding, and thus of funders. In its fourth year, the survey was sent to 513 funders in 54 countries around the world. These included:

- Public, private and philanthropic funders in:
  - High-income countries (HICs) that were part of the Organisation for Economic Co-operation and Development (OECD)
  - European Union (EU) Member States and the European Commission (EC)
  - HICs and MICs outside the OECD but with a significant research base (Singapore and the Russian Federation)
- Public funders in three Innovative Developing Countries (IDCs) (South Africa, Brazil and India)
- Public funders in nine low- and middle-income countries (LMICs) (Ghana, Nigeria, Uganda; Argentina, Chile, Colombia, Mexico; Thailand and Malaysia)
- Private sector funders in two IDCs (Brazil and India)

We note that public funders in Argentina, Chile, Mexico, Uganda, Nigeria and Malaysia were included in the survey for the first time this year.

G-FINDER also surveyed a wide range of funding intermediaries, Product Development Partnerships (PDPs) and researchers and developers who received funding. Data from these groups was used to better understand how and where R&D investments were made, to track funding flows through the system, to prevent double-counting, and to verify reported data.

In all, the 2010 survey was sent to 889 organisations identified as being involved in neglected disease product development as either funders or recipients, a 5% increase on the number of organisations surveyed in 2009 (847 survey recipients). These were prioritised into three groups based on their R&D role (funder, PDP/intermediary or developer), level of funding, geographical location and area of disease and product activity:

- The maximum priority group remained unchanged, including 26 organisations known from previous surveys to be major funders (over \$10m per year) or major private sector developers investing internally into one of the target neglected diseases
- A high priority group of 172 organisations included known significant funders (\$5–10m per year); potential research funders in high-Gross Expenditure on R&D (GERD) countries;<sup>ii</sup> and a range of academic research institutes, PDPs, government research institutes, multinational pharmaceutical firms and small companies, who collectively provided good coverage of R&D in all disease areas. This represented a moderate increase (10%) in the number of organisations in the high priority group compared to 2009 (156 organisations). This increase was due to inclusion of public funders in Argentina, Chile, Mexico, Uganda, Nigeria and Malaysia; to a greater focus on groups who had historically provided limited data, including the vector control industry and some German funding organisations; and to inclusion of new groups identified by respondents as important funders
- The remaining survey recipients were known smaller funders (less than \$5m per year) and other known grant recipients

<sup>ii</sup> Gross Expenditure on R&D as a percentage of Gross Domestic Product (GDP)

The G-FINDER process focused on the 198 organisations in the maximum and high priority groups, who likely represented the majority of global neglected disease R&D funding and activity during financial year 2010.

Survey participation increased moderately (10%) in 2010, with 240 organisations providing data (including 46 with no investment to report), compared to 218 in 2009, 208 in 2008 and 150 in 2007. However, there was also some loss-to-follow-up, with 20 organisations reporting data for 2009, but not submitting data for 2010. In the maximum priority group, 25 recipients (96%) provided funding information for 2010. In the high priority group, 160 organisations (93%) provided full funding information for 2010, the same percentage as in previous years. See Annexe 4 for a full list of survey participants.

#### HOW WERE CHANGES IN SCOPE MANAGED?

It is important when comparing figures between survey years to distinguish between real changes in funding and apparent changes due to fluctuating numbers of survey participants. Funding figures have therefore been broken down to distinguish between:

1. Increases or decreases reported by repeat survey participants – called year-on-year (YOY) funders – which represent real funding changes
2. Increases reported by new survey participants, which do not indicate a true increase in neglected disease funding but rather an improvement in G-FINDER's data capture
3. Decreases due to non-participation by organisations that provided data to G-FINDER in previous years but were lost-to-follow-up in the 2010 survey. These do not represent true decreases in funding but rather a decrease in data capture.

## Reading the findings

All reported funding is for investments made in the 2010 financial year (Year Four). Comparison is made, where relevant, to investments made in the 2009 (Year Three) financial year.

Throughout the text references to years are made as follows:

- 2007 refers to financial year 2007 or Year One of the survey
- 2008 refers to financial year 2008 or Year Two of the survey
- 2009 refers to financial year 2009 or Year Three of the survey
- 2010 refers to financial year 2010 or Year Four of the survey

For consistency, 2010, 2009 and 2008 funding data is adjusted for inflation and reported in 2007 US dollars (US\$), unless indicated otherwise. This is important to avoid conflating real year-on-year changes in funding with changes due to inflation and exchange rate fluctuations. For reference purposes, unadjusted 2010 figures are also occasionally included. When this occurs, the unadjusted (nominal) figure is shown in italicised text in parenthesis after the adjusted figure. For example, "Reported funding for R&D of neglected diseases reached \$3,062m (\$3,173m) in 2010". In this example, \$3,173m represents the unadjusted nominal 2010 figure. In tables, unadjusted figures are also labelled as '2010 Nominal (US\$)'. Unlike 2007, the 2008, 2009 and 2010 surveys include aggregate industry figures in top 12 lists (2007 comparators have been updated to include aggregate industry data, and therefore differ from published top 12 figures for 2007).

Any changes in funding (increases or decreases) noted in the report refer only to those organisations that participated across all years of the survey i.e. YOY funders.

Unless noted otherwise, all DALY (Disability Adjusted Life Year) figures in the report are 2004 DALYs for LMICs, as reported by the World Health Organization (WHO) in their 2004 update of the Global Burden of Disease,<sup>1</sup> these being the most comprehensive and recent figures available. In some cases, WHO estimates are lower than those derived using other methods or published by other groups, however they allowed the most consistent approach across diseases.

For brevity, we use the terms 'LMICs' and 'Developing Countries' (DCs) to denote low- and middle-income countries and 'HICs' to denote high-income countries as defined by the World Bank.<sup>2</sup> 'Innovative Developing Countries' (IDCs) refers to developing countries with a strong R&D base who participated in the G-FINDER survey (South Africa, Brazil, India). MNCs are defined as multinational pharmaceutical companies with revenues of over \$10bn per annum.

Around 1.6% (\$47.5m) of funding was reported to the survey as 'unspecified', usually for multi-disease programmes where funds could not easily be apportioned by disease. A proportion of funding for some diseases was also 'unspecified', for instance, when funders reported a grant for research into tuberculosis (TB) basic research and drugs without apportioning funding to each product category. This means that reported funding for some diseases and products will be slightly lower than actual funding, with the difference being included as 'unspecified' funding. This is likely to particularly affect figures from the US NIH for individual diseases, as the US NIH had a higher number of multi-disease grants than other funders.

A further 2.5% (\$76.9m) was given as core funding to R&D organisations that work in multiple disease areas, for example, OneWorld Health (OWH) and the Special Programme for Research and Training in Tropical Diseases (WHO/TDR). As this funding could not be accurately allocated by disease it was reported as unallocated core funding. In cases where grants to a multi-disease organisation were earmarked for a specific disease or product, they were included under the specific disease-product area.

Finally, readers should be aware that, as with all surveys, there are limitations to the data presented. Survey non-completion by funders will have an impact, as will methodological choices (See Annexe 1 for further details).



## FINDINGS - FUNDING BY DISEASE

Reported funding for R&D of neglected diseases in 2010 was \$3,063m (\$3,173m). This was a decrease from 2009, with YOY funders reducing their investment by \$109.1m (down -3.5%). Around \$30.7m reported in 2009 was lost-to-follow-up by funders who did not participate in the 2010 survey, with this being offset by \$33.5m reported by new survey respondents for 2010.

As in previous years, disease funding fell into three distinct tranches. The three 'top tier' diseases each continued to receive around one-fifth to one-third of global funding for neglected disease R&D: HIV/AIDS (35.0%), tuberculosis (18.8%) and malaria (17.9%). Tuberculosis (TB) saw a further substantial YOY funding increase in 2010 (up \$29.6m, 5.5%) following a 25.4% increase in 2009, however YOY funding dropped for HIV (down \$66.6m, -5.9%) and malaria (down \$45.5m, -7.8%).

The 'second tier' diseases are those that received between 1% and 6% of global funding each, including dengue, diarrhoeal diseases, kinetoplastids, bacterial pneumonia and meningitis, helminth infections, and salmonella infections. In 2010, dengue and diarrhoeal diseases each received more than 5% of global R&D funding for the second year running, despite YOY funding for diarrhoeal diseases being down by \$18.3m (-10.3%); however, a drop in YOY funding for kinetoplastid R&D (down \$15.5m, -9.6%) meant it fell back below the 5% line in 2010, having breached it for the first time in 2009. In contrast, funding for bacterial pneumonia and meningitis R&D increased sharply in 2010, with YOY funders providing an additional \$31.7m (up 52.9%).

The 'third tier' diseases are those that receive less than 0.5% of global funding: leprosy, Buruli ulcer, trachoma and rheumatic fever. In 2010, these received less than \$10m each, as in previous years.

Continuing the trend since 2007, there was a further modest rebalancing of funding distribution between these three tiers in 2010. The 'top tier' diseases collectively received 71.7% (\$2,195m) of global funding in 2010 compared to 72.1% (\$2,283m) in 2009, 72.8% (\$2,153m) in 2008 and 76.6% (\$1,962m) in 2007. However, unlike 2009, when this redistribution was entirely due to increased funding for second and third tier diseases, in 2010 the redistribution was entirely due to decreased YOY funding for the 'top three' (down \$82.5m, -3.7%). The second tier diseases saw a minimal collective YOY increase in 2010 of \$2.6m (0.4%), receiving 22.7% of global funding (up from 22.0% in 2009); while the third tier diseases received an additional \$1.1m in YOY funding in 2010, giving them a collective funding share of just 0.7% of global R&D funding (up from 0.6% in 2009).

**Table 2. Total R&D funding by disease 2007-2010**

Disease	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2010 Nominal (US\$)	2007%	2008%	2009%	2010%
HIV/AIDS <sup>A</sup>	1,083,018,193	1,164,882,551	1,138,511,159	1,073,033,520	1,119,699,939	42.3	39.4	35.9	35.0
Tuberculosis <sup>A</sup>	410,428,697	445,927,582	550,853,747	575,361,902	602,741,600	16.0	15.1	17.4	18.8
Malaria <sup>A</sup>	468,449,438	541,746,356	593,860,744	547,042,394	547,199,115	18.3	18.3	18.7	17.9
Dengue	82,013,895	126,752,203	165,812,311	177,643,516	187,384,693	3.2	4.3	5.2	5.8
Diarrhoeal diseases	113,889,118	132,198,981	180,426,679	158,918,128	166,319,515	4.4	4.5	5.7	5.2
Kinetoplastids	125,122,839	139,207,962	162,258,968	147,867,513	150,150,863	4.9	4.7	5.1	4.8
Bacterial pneumonia & meningitis	32,517,311	90,844,284	68,988,629	92,866,038	97,595,712	1.3	3.1	2.2	3.0
Helminths (worms & flukes)	51,591,838	66,837,827	79,414,264	73,685,406	77,070,413	2.0	2.3	2.5	2.4
Salmonella infections	9,117,212	39,486,243	39,378,570	43,982,149	45,417,899	0.4	1.3	1.2	1.4
Leprosy	5,619,475	9,769,250	10,984,756	8,840,532	9,781,822	0.2	0.3	0.3	0.3
Buruli ulcer	2,412,950	1,954,465	1,793,718	5,456,026	5,708,115	0.1	0.1	0.1	0.2
Trachoma	1,679,711	2,073,659	1,798,463	4,507,718	4,740,142	0.1	0.1	0.1	0.1
Rheumatic Fever	1,670,089	2,179,609	3,009,737	1,736,877	1,963,080	0.1	0.1	0.1	0.1
Platform technologies	9,997,190	16,298,026	22,086,907	27,358,501	28,731,884	0.4	0.6	0.7	0.9
<i>General diagnostic platforms</i>	4,791,152	5,253,880	8,612,816	9,374,424	9,943,959	0.2	0.2	0.3	0.3
<i>Adjuvants and immunomodulators</i>	2,685,148	2,215,853	5,587,607	9,168,639	9,651,302	0.1	0.1	0.2	0.3
<i>Delivery technologies and devices</i>	2,520,889	8,828,293	7,886,484	8,815,438	9,136,623	0.1	0.3	0.2	0.3
Core funding of a multi-disease R&D organisation	110,921,673	101,097,348	74,094,564	76,884,279	76,807,824	4.3	3.4	2.3	2.5
Unspecified disease <sup>A</sup>	51,619,120	74,707,997	75,667,744	47,485,474	51,441,520	2.0	2.5	2.4	1.6
<b>Disease total<sup>A</sup></b>	<b>2,560,068,749</b>	<b>2,955,964,344</b>	<b>3,168,940,958</b>	<b>3,062,669,973</b>	<b>3,172,754,136</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

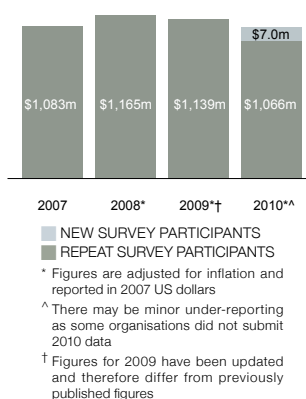
<sup>A</sup> Figures are adjusted for inflation and reported in 2007 US dollars

\* Figures are in current (2010) US dollars

<sup>A</sup> Figures for 2009 have been updated and therefore differ from previously published figures

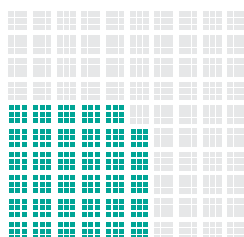
When reading the funding tables, it is important to note that some of the diseases listed above are actually groups of diseases, such as the diarrhoeal illnesses and helminth infections. This grouping reflects common practice; for instance, burden of disease DALYs are generally reported according to these categories. It also reflects the shared nature of research investments in some areas. For example, research into kinetoplastids often pertains to more than one kinetoplastid disease e.g. Chagas' disease, leishmaniasis and sleeping sickness, while *Streptococcus pneumoniae* R&D is often targeted at both pneumonia and meningitis. (Please see Table 1 for disease groupings used.) Where possible, however, information is broken down to disease level.

## HIV/AIDS



**\$1.07 BILLION**

TOTAL SPEND ON HIV/AIDS  
R&D IN 2010



**35.0%**

OF GLOBAL R&D FUNDING

The Acquired Immune Deficiency Syndrome (AIDS) is caused by the Human Immunodeficiency Virus (HIV). This virus infects cells of the human immune system, destroying or impairing their function. As the immune system becomes progressively weaker, the patient becomes more susceptible to other diseases, often dying from TB or other infections.

HIV/AIDS was responsible for 57.8 million DALYs and 2 million deaths in 2004, making it the third highest cause of morbidity and mortality from neglected diseases in the developing world.

The rapid mutation of the HIV virus has posed a significant challenge for vaccine development, with an efficacious vaccine still many years away. Whilst proving for the first time that a vaccine could prevent HIV infection, Phase III clinical trials of the most advanced vaccine candidate (a prime boost combination), demonstrated a very modest 30% efficacy in 2009.<sup>3</sup> Antiretroviral drugs are available, but most are not adapted for DC use; for instance, paediatric formulations and fixed-dose combinations are needed. Current methods for early diagnosis and support of HIV treatment are also often unsuitable for DCs, although there has been some progress towards robust, simple, rapid point-of-care diagnostics, with several promising candidates in early development.<sup>4</sup>

Several microbicide candidates are under study and testing. Following several failures in Phase II/III trials (PRO 2000, BufferGel and VivaGel), new candidates using active ingredients from ARVs have shown promising results in Phase II trials. These include dapivirine gel, a long acting dapivirine-based microbicide ring, and CAPRISA 004 tenofovir-gel, which is currently being fast-tracked by the FDA pending results of confirmatory trials.<sup>5</sup> However, resistance to the ARV component of these microbicides in HIV infected individuals or those who develop HIV while using the microbicide is a growing concern.<sup>6</sup>

R&D needed for HIV/AIDS in DCs includes:

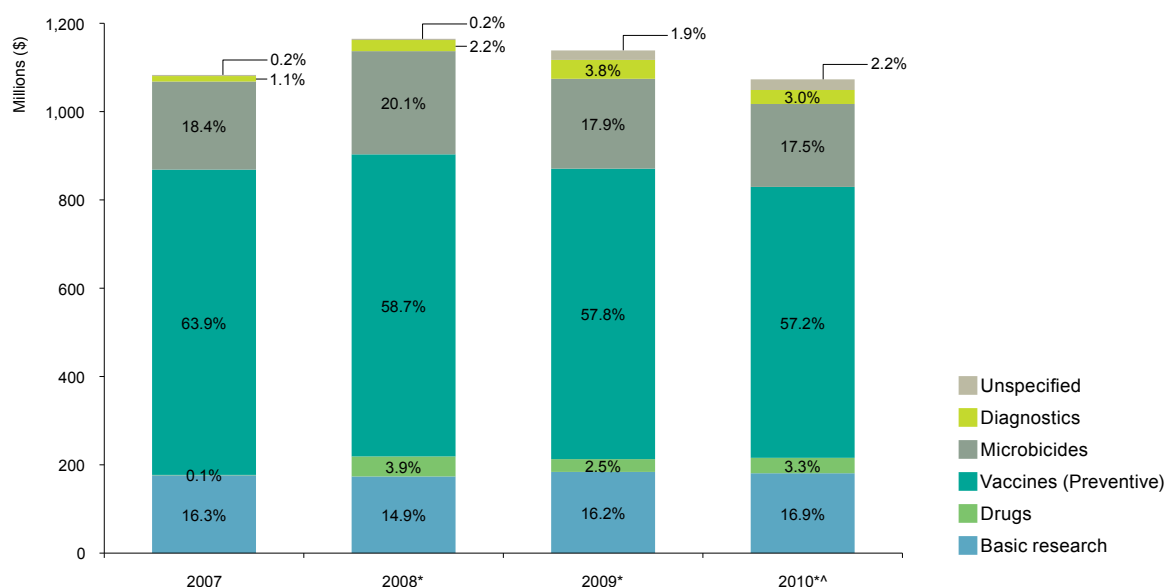
- Basic research
- Drugs specific to DC needs
- Preventive vaccines
- Diagnostics
- Microbicides

In 2010, HIV/AIDS received \$1,073m (\$1,120m) in R&D funding. This was a modest drop from 2009, with YOY funders reducing their investment by \$66.6m (-5.9%). A further \$5.9m was lost-to-follow-up, offset by \$7.0m reported by new survey respondents. Although HIV/AIDS continued to receive the highest percentage of global investment (35.0% of the total), its share of the global funding pie decreased slightly again for the third year (from 35.9% in 2009).

As in 2009, over half of total HIV/AIDS funding in 2010 was directed to vaccine development (\$613.6m, 57.2%). A further \$187.8m (17.5%) was directed to microbicides, \$180.9m (16.9%) to basic research, \$34.9m (3.3%) to DC-specific drug development and \$31.7m (3.0%) to diagnostics.

Data from YOY funders (excluding variations due to non-participants and new survey participants), showed drops in funding for vaccines (down \$48.7m, -7.4%), microbicides (down \$15.3m, -7.5%), basic research (down \$5.8m, -3.2%) and diagnostics (down \$4.7m, -13.1%) with a minor increase in funding for drug development (up \$5.3m, 18.3%).

**Figure 2. HIV/AIDS R&D funding by product type 2007-2010**



\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2010 data

HIV/AIDS R&D funding was once again highly concentrated with 12 groups providing 93.5% of funding, as in 2009; and the US NIH continuing to provide over 60% of global HIV R&D funding despite cutting its contribution in 2010 (down \$31.6m, -4.6%). Several other top 12 funders also decreased their contributions, including UK Department for International Development (DFID) (down \$17.3m, -45.0%) and the European Commission (down \$8.0m, -29.6%); while there were modest increases from the Canadian Institutes of Health Research (CIHR) (up \$3.2m, 58.0%), who appeared in the top 12 HIV funders for the first time, and the Wellcome Trust (up \$2.1m, 22.9%).

**Table 3. Top 12 HIV/AIDS R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$) <sup>^</sup>	2009 (US\$) <sup>^</sup>	2010 (US\$) <sup>^</sup>	2007%	2008%	2009%	2010%
US NIH	678,816,000	643,838,823	688,900,175	657,340,665	62.7	55.3	60.5	61.3
Gates Foundation	91,975,642	160,531,263	119,431,387	118,655,020	8.5	13.8	10.5	11.1
USAID	67,457,000	67,813,102	68,169,518	68,385,015	6.2	5.8	6.0	6.4
US DOD	27,800,000	24,448,940	34,236,010	31,671,138	2.6	2.1	3.0	3.0
Aggregate industry respondents <sup>A</sup>	19,635,626	47,449,865	35,342,218	30,103,341	1.8	4.1	3.1	2.8
UK DFID	31,151,182	28,718,490	38,305,345	21,050,427	2.9	2.5	3.4	2.0
European Commission	24,794,890	26,305,301	27,100,813	19,073,421	2.3	2.3	2.4	1.8
Inserm	342,620	1,180,483	12,497,386	13,931,413	0.0	0.1	1.1	1.3
UK MRC <sup>B</sup>	13,101,548	11,635,919	11,737,927	11,940,880	1.2	1.0	1.0	1.1
Wellcome Trust	6,932,786	9,429,787	9,296,776	11,423,726	0.6	0.8	0.8	1.1
French ANRS	10,511,570	14,700,289	11,919,251	11,141,961	1.0	1.3	1.0	1.0
Canadian CIHR	3,432,887	1,948,952	5,472,379	8,646,811	0.3	0.2	0.5	0.8
<b>Subtotal top 12 HIV/AIDS R&amp;D funders<sup>B*</sup></b>	<b>1,010,087,806</b>	<b>1,068,173,703</b>	<b>1,064,377,030</b>	<b>1,003,363,819</b>	<b>93.3</b>	<b>91.7</b>	<b>93.5</b>	<b>93.5</b>
<b>Disease Total<sup>B</sup></b>	<b>1,083,018,193</b>	<b>1,164,882,551</b>	<b>1,138,511,159</b>	<b>1,073,033,520</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

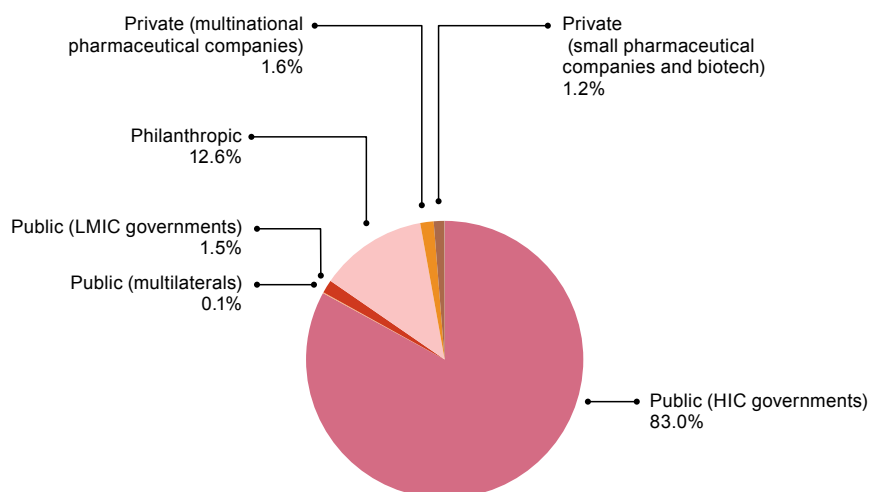
<sup>A</sup> Includes new survey respondents in 2010

<sup>B</sup> Figures for 2007 and/or 2009 have been updated and therefore differ from previously published figures

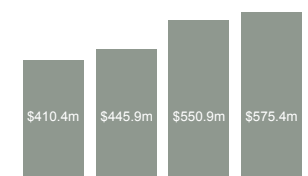
<sup>\*</sup> Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

Public and philanthropic funders provided 97.2% of HIV/AIDS R&D funding in 2010, with public funders providing \$907.8m (84.6%) and a further \$134.9m (12.6%) coming from philanthropic organisations. HIC governments again provided almost all of the public funding for HIV R&D (\$890.2m, 98.1%), despite a \$73.0m (-7.6%) drop in their 2010 YOY investment. There were modest funding increases from YOY LMIC public funders (up \$5.1m to \$16.6m) and YOY public multilaterals (up \$0.4m to \$1.0m). Philanthropic funding was essentially steady (up \$2.5m, 1.9%). Industry remained largely unengaged in this area, with investments of \$30.1m in 2010, of which around half came from MNCs (\$16.7m, 55.6%) and half from SMEs (\$13.4m, 44.4%).

**Figure 3. HIV/AIDS R&D funding by funder type 2010**



# TUBERCULOSIS



REPEAT SURVEY PARTICIPANTS

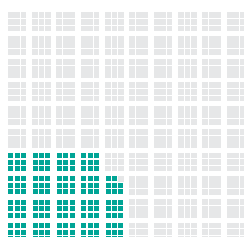
\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2009 data

† Figures for 2009 have been updated and therefore differ from previously published figures

## \$575.4 MILLION

TOTAL SPEND ON TB  
R&D IN 2010



## 18.8%

OF GLOBAL R&D FUNDING

Tuberculosis (TB) is a bacterial disease that usually affects the lungs, and is spread by air droplets from infected people. After infection, TB may remain latent with no symptoms. However, if it progresses to active disease, it causes coughing, night sweats, fever and weight loss. TB is a leading cause of death among people with HIV/AIDS.

TB was responsible for 34 million DALYs and 1.4 million deaths in 2004. It was the fourth highest cause of morbidity and mortality from neglected diseases.

The only available TB vaccine is the BCG, an 80 year-old vaccine that is highly effective only against disseminated TB in children.<sup>7</sup> A new vaccine is needed, which should have greater efficacy than BCG, whilst matching or improving its safety profile. Current TB treatment regimens require adherence to a complex array of drugs over a lengthy period (from 6 to 24 months), leading to poor compliance and fuelling drug resistance, treatment failure and death. There is a need for rapid acting, potent anti-tubercular drugs that are efficacious against multidrug-resistant and extensively drug-resistant TB (MDR-TB and XDR-TB), as well as being safe to co-administer with antiretroviral therapies for HIV. Existing TB point-of-care diagnostics suitable for DC use are also inadequate, detecting less than half of active TB cases;<sup>8</sup> there is need for cheap, rapid, easy-to-use diagnostics that can distinguish between active and latent disease, with or without HIV co-infection.

There are multiple drug candidates in development, including a novel three-drug combination (PA-824, moxifloxacin and pyrazinamide) that has shown promising results against both drug-sensitive and MDR-TB.<sup>9</sup> There are also several vaccine candidates in clinical trials, with the most advanced being *Mycobacterium vaccae* (ID) in Phase III trials for prevention of disseminated TB in HIV infection and MVA85A/AERAS-485, GSK M72 and AERAS-402/Crucell Ad35, all of which are in Phase II trials. Progress has been made in diagnostic development, with Cepheid's nucleic acid detection device (GeneXpert MTB/Rif) showing excellent results. However, even with compassionate pricing, its high cost may be a barrier to access in DCs.<sup>10</sup>

R&D needs for TB include:

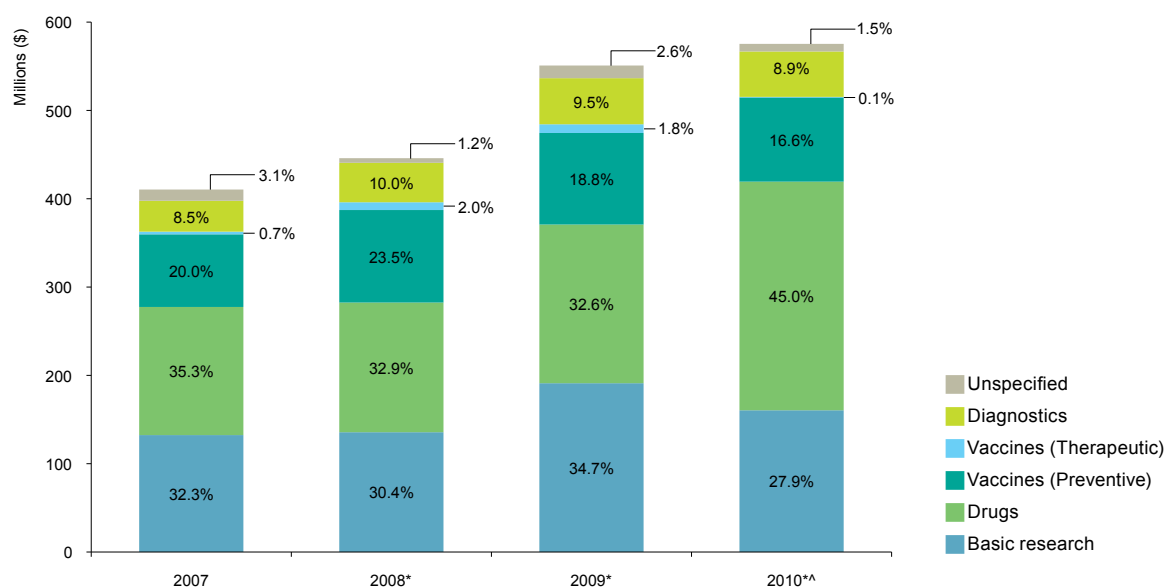
- Basic research
- Drugs
- Diagnostics
- Preventive vaccines
- Therapeutic vaccines

TB received \$575.4m (\$602.7m) in R&D funding in 2010. This was an increase from 2009, with YOY funders providing an additional \$29.6m (up 5.5%). Around \$5.1m was lost-to-follow-up and no TB funding was reported by new survey respondents. TB once again increased its share of global funding (18.8% compared to 17.4% in 2009), and for the first time overtook malaria to become the second most highly-funded disease.

In 2010, the majority of TB funding went to drugs (\$258.9m, 45.0%), followed by basic research (\$160.5m, 27.9%) and preventive vaccines (\$95.3m, 16.6%). A further \$51.4m (8.9%) was directed to diagnostics and just \$0.7m (0.1%) to therapeutic vaccines.

The increase in TB funding in 2010 was driven by a \$79.7m (44.8%) YOY increase in TB drug funding, with the majority of this new investment (88.3%, \$70.4m) directed towards drug discovery and preclinical research. Diagnostic R&D also saw a small increase (up \$2.7m, 5.8%). This increase in drug and diagnostic funding was, however, partially offset by drops in other product areas, with basic research down \$29.3m (-15.6%), therapeutic vaccines down \$9.2m (-93.3%) and preventive vaccines down \$8.6m (-8.3%). We note, however, that the apparent drop in preventive vaccine funding was entirely due to uneven disbursement of a multi-year grant from the Bill & Melinda Gates Foundation.

**Figure 4. TB R&D funding by product type 2007-2010**



\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2010 data

The top 12 funders of TB R&D accounted for 92.4% of funding in this disease area in 2010, with the majority of funding coming from industry, the US NIH and the Gates Foundation (collectively providing \$419.3m, 72.9%). The most significant non-industry increase came from the Institut Pasteur (up \$10.3m), which propelled it into the top 12 TB funders this year; while the Gates Foundation, Wellcome Trust, UK DFID and UK MRC also increased their TB investments in 2010. By contrast, the EC cut its funding by \$6.6m (-22.8%); the US NIH by \$6.4m (-3.9%), after a \$50.5m increase in TB funding in 2009; and the US CDC by \$5.7m (-39.7%).

**Table 4. Top 12 TB R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$) <sup>A</sup>	2009 (US\$) <sup>A</sup>	2010 (US\$) <sup>A</sup>	2007%	2008%	2009%	2010%
Aggregate industry respondents <sup>A</sup>	65,954,715	87,029,053	123,151,353	160,022,103	16.1	19.5	22.4	27.8
US NIH	121,741,199	112,844,319	163,328,162	156,954,021	29.7	25.3	29.7	27.3
Gates Foundation	115,864,538	131,983,857	96,890,583	102,285,965	28.2	29.6	17.6	17.8
UK DFID	1,801,625	3,360,090	17,380,915	22,539,728	0.4	0.8	3.2	3.9
European Commission	21,455,029	27,870,907	28,730,986	22,180,461	5.2	6.3	5.2	3.9
UK MRC <sup>B</sup>	12,710,433	12,832,477	12,595,664	15,108,715	3.1	2.9	2.3	2.6
Wellcome Trust	2,599,875	5,485,274	8,211,120	13,477,887	0.6	1.2	1.5	2.3
Institut Pasteur	7,996,742	3,014,062	2,089,479	12,361,921	1.9	0.7	0.4	2.1
US CDC	11,617,000	8,813,953	14,422,770	8,698,233	2.8	2.0	2.6	1.5
USAID	3,893,436	6,551,060	8,147,289	8,371,289	0.9	1.5	1.5	1.5
SSI	3,672,882	3,166,531	9,174,072	5,207,031	0.9	0.7	1.7	0.9
German BMBF	4,391,435	317,919	4,969,942	4,325,564	1.1	0.1	0.9	0.8
Subtotal top 12 tuberculosis R&D funders <sup>B*</sup>	385,827,417	408,545,193	495,347,363	531,532,918	94.0	91.6	89.9	92.4
Disease Total <sup>B</sup>	410,428,697	445,927,582	550,853,747	575,361,902	100.0	100.0	100.0	100.0

<sup>A</sup> Figures are adjusted for inflation and reported in 2007 US dollars

<sup>A</sup> Includes new survey respondents in 2010

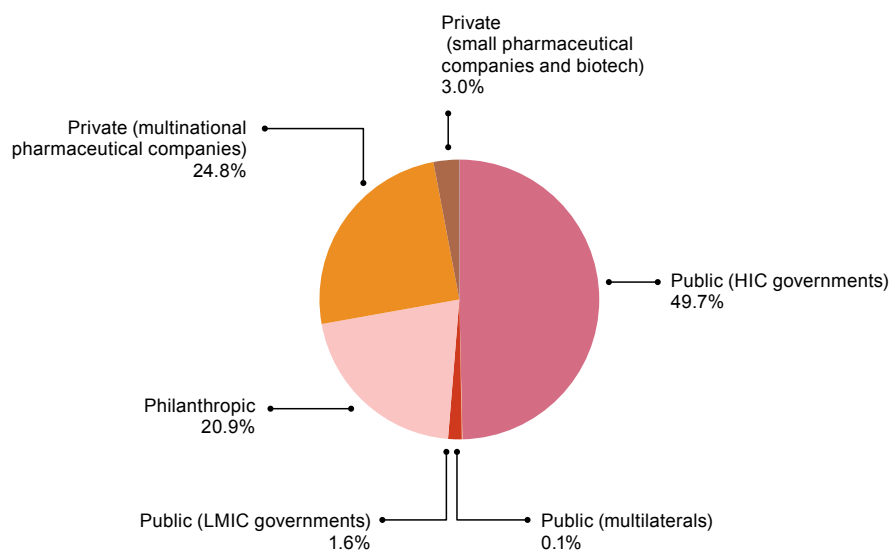
<sup>B</sup> Figures for 2009 have been updated and therefore differ from previously published figures

\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

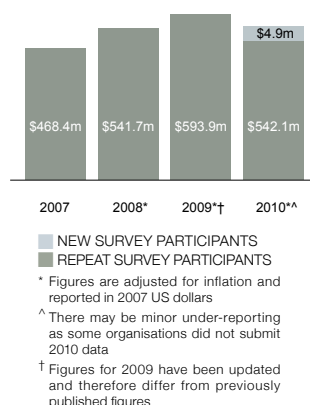


However, the standout change in 2010 was the very large increase in industry's TB R&D investment. YOY industry funders increased their investment by \$41.6m (up 35.5%) – over three times the increase from YOY philanthropic organisations (up \$12.2m, 11.4%) – and in marked contrast to YOY public funders, who cut their TB funding by \$24.1m (-7.6%). As a result, industry contributed over one-quarter (\$160.0m, 27.8%) of global TB R&D funding and the philanthropic sector contributed 20.9% (\$120.2m), while the public share of TB funding declined from 58.8% (\$329.1m) in 2009 to 51.3% (\$295.1m) in 2010.

**Figure 5. TB R&D funding by funder type 2010**

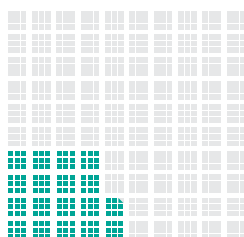


# MALARIA



**\$547.0 MILLION**

TOTAL SPEND ON TB  
R&D IN 2010



**17.9%**

OF GLOBAL R&D FUNDING

Malaria is a parasitic disease transmitted through the bite of an infected mosquito. The two most common types of malaria are caused by *Plasmodium falciparum* and *Plasmodium vivax*. Left untreated, malaria can cause severe illness and death, with children and pregnant women being the most vulnerable (85% of malaria deaths are children under five years of age).<sup>11</sup>

Malaria caused 33.9m DALYs and at least 890,000 deaths in the developing world in 2004, making it the fifth highest cause of morbidity and mortality from neglected diseases. *P. falciparum* is by far the most deadly, and accounts for 98% of malaria cases in sub-Saharan Africa. However, *P. vivax* is estimated to account for 25-40% of the global malaria burden<sup>12</sup> and is particularly common in South-East Asia and South America.<sup>13</sup>

The emergence of resistance to artemisinin-based combination therapies (ACTs) and insecticides means new therapies are needed.<sup>14</sup> Cheap, sensitive and specific Rapid Diagnostic Tests are available, but their quality and heat stability can be problematic, and new diagnostics are needed to distinguish between uncomplicated and severe malaria, and between malaria and other febrile illnesses.<sup>6</sup>

Progress has continued since 2008. Initial efficacy results and safety profile have just been published for Phase III trials<sup>15</sup> of the RTS,S malaria vaccine candidate conducted in 11 sites in Africa. If all goes well in Phase III testing, policy recommendation by WHO for RTS,S implementation by countries through their Expanded Program on Immunization could be possible as early as 2015.<sup>16</sup> Several promising synthetic artemisinins are also in clinical trials, including the ozonides arterolane/PQP (Phase IIb/III) and OZ439 (Phase IIa).<sup>17</sup>

Malaria R&D is needed in many areas including:

- Basic research
- Drugs
- Preventive vaccines
- Diagnostics
- Vector control products

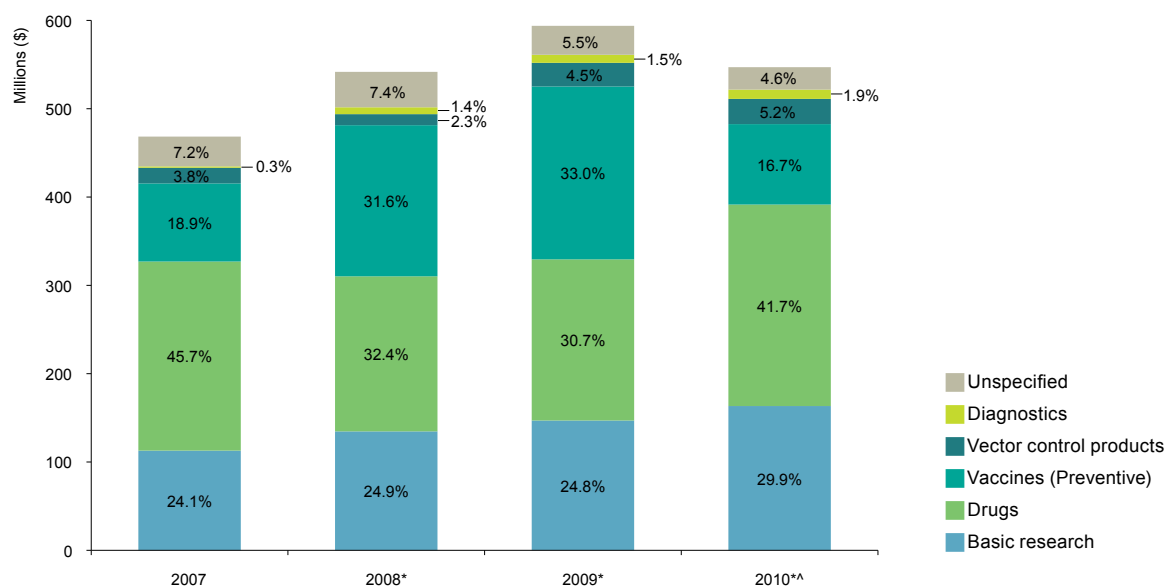
Global funding for malaria R&D in 2010 was \$547.0m (\$547.2m). This was a significant drop from 2009, for reasons explained below, with YOY funders decreasing their investment by \$45.5m (-7.8%). The further \$1.3m drop in reported funding consisted of \$6.3m lost-to-follow-up from funders who did not participate in the 2010 survey, offset by \$4.9m reported by new survey respondents. The drop meant that malaria's share of global funding dipped slightly (17.9% compared to 18.7% in 2008), and it received less funding than tuberculosis for the first time.

The majority of malaria R&D funding went to drug development (\$228.1m, 41.7%), basic research (\$163.4m, 29.9%) and vaccine development (\$91.1m, 16.7%), while vector control products received \$28.5m (5.2%) and diagnostics just \$10.5m (1.9%).

The distribution of malaria R&D funding changed markedly in 2010. Vaccine funding was cut by half (down \$103.2m, -53.1%), while there were large funding increases for drug development (up \$48.9m, 27.3%) and basic research (up \$15.9m, 11.0%), and a modest increase for diagnostics (up \$2.3m, 28.6%). Funding for vector control products fell slightly (down \$2.0m, -7.6%), but this was not enough to undermine the vector control funding boost seen in 2009.

The large funding cuts for malaria vaccines should not be misinterpreted as representing a waning global commitment to malaria or malaria vaccine R&D. Rather, they reflect the upcoming conclusion of the RTS,S vaccine development programme, just as the large and rapid vaccine funding increases since 2007 reflected up-front funding to support large-scale RTS,S Phase II and III clinical trials.

**Figure 6. Malaria R&D funding by product type 2007-2010**



\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2010 data

Concentration of malaria R&D funding remained high in 2010, with the top 12 funders contributing 92.5% of total funding. The Gates Foundation, last year's largest funder of malaria R&D, halved its malaria funding (down \$95.2m, -52.2%) and the US DOD had a smaller but still significant decrease (down 14.9m, -39.7%). These decreases were offset by substantial increases from UK DFID, which increased its funding more than five-fold (up \$20.2m, 563%) with all of its 2010 malaria funding going to the Medicines for Malaria Venture (MMV) for drug development; and the US NIH (up \$16.9m, 14.5%). As noted above, around three-quarters (\$72.6m, 76.3%) of the Gates Foundation decrease was due to the winding down of RTS,S vaccine funding as it nears licensure.

**Table 5. Top 12 malaria R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$) <sup>A</sup>	2009 (US\$) <sup>A</sup>	2010 (US\$) <sup>A</sup>	2007%	2008%	2009%	2010%
US NIH	84,422,644	104,810,620	116,013,245	132,882,335	18.0	19.3	19.5	24.3
Aggregate industry respondents <sup>AB</sup>	90,793,583	90,611,134	99,303,179	125,621,275	19.4	16.7	16.7	23.0
Gates Foundation	124,464,185	173,722,323	182,444,291	87,251,307	26.6	32.1	30.7	15.9
Wellcome Trust	28,255,207	26,732,141	27,204,542	34,020,635	6.0	4.9	4.6	6.2
European Commission	21,673,026	25,296,589	24,949,051	25,156,063	4.6	4.7	4.2	4.6
UK DFID	4,003,611	3,733,433	3,588,731	23,796,135	0.9	0.7	0.6	4.3
US DOD	33,126,578	30,518,142	37,585,617	22,666,297	7.1	5.6	6.3	4.1
UK MRC <sup>B</sup>	18,594,597	18,985,044	20,012,611	22,432,699	4.0	3.5	3.4	4.1
Australian NHMRC	7,692,288	9,012,351	10,201,615	9,623,199	1.6	1.7	1.7	1.8
Institut Pasteur	13,142,888	7,739,784	7,067,036	9,060,676	2.8	1.4	1.2	1.7
USAID	9,249,900	8,164,740	8,166,618	8,758,051	2.0	1.5	1.4	1.6
Inserm	472,815	459,077	3,541,558	4,560,058	0.1	0.1	0.6	0.8
<b>Subtotal top 12 malaria R&amp;D funders<sup>B*</sup></b>	<b>442,390,786</b>	<b>507,870,081</b>	<b>544,613,555</b>	<b>505,828,729</b>	<b>94.4</b>	<b>93.7</b>	<b>91.7</b>	<b>92.5</b>
<b>Disease Total<sup>B</sup></b>	<b>468,449,438</b>	<b>541,746,356</b>	<b>593,860,744</b>	<b>547,042,394</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

<sup>A</sup> Figures are adjusted for inflation and reported in 2007 US dollars

<sup>A</sup> Includes new survey respondents in 2010

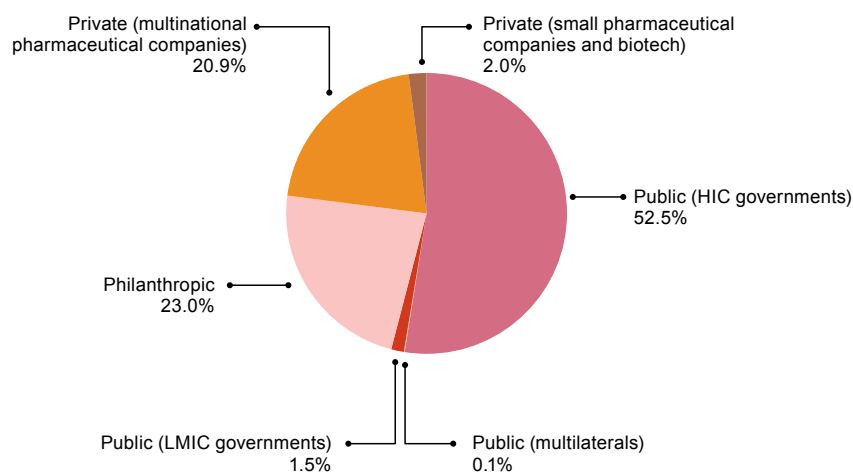
<sup>B</sup> Figures for 2009 have been updated and therefore differ from previously published figures

\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

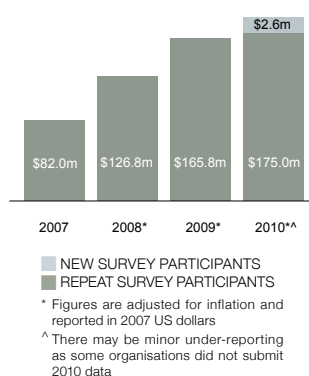
There were significant shifts in funding sources for malaria R&D in 2010. The most dramatic increase was from the private sector, with MNC funding up \$33.6m (41.6%); even when offset by decreased SME funding (down \$6.8m, 48.7%), this represented an overall industry funding increase of \$26.9m (28.4%). There was a smaller but still significant increase in YOY public funding (up \$15.5m, 5.6%), however YOY philanthropic funding decreased sharply (down \$87.9m, -41.4%), largely due to the Gates Foundation programmatic changes described above.

As a result of these funding shifts, public funders accounted for more than half of malaria funding (\$295.7m, 54.1%) in 2010, up from 47.6% in 2009; while industry dramatically increased its share to nearly a quarter of global malaria funding (\$125.6m, 25.0%). Philanthropic organisations, by contrast, decreased their share from 35.8% to 23.0% (\$125.6m).

**Figure 7. Malaria R&D funding by funder type 2010**

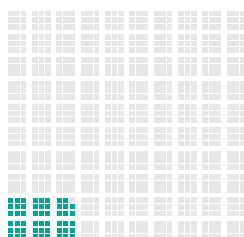


# DENGUE



**\$177.6 MILLION**

TOTAL SPEND ON DENGUE  
R&D IN 2010



**5.8%**

OF GLOBAL R&D FUNDING

Dengue is transmitted by *Aedes* mosquitoes, and causes a severe flu-like illness. In its most severe form, dengue haemorrhagic fever, it is a leading cause of serious illness and death among children in regions of Asia, with outbreaks also occurring frequently in Central and South America.

Dengue differs from many other tropical diseases in that it has a relatively larger commercial market, driven by demand from travellers, the military and a high prevalence in several wealthier developing countries in South-East Asia and Latin America.

Dengue was responsible for 663,000 DALYs and 18,000 deaths in 2004. It ranked as the 11th highest cause of morbidity and 10th highest cause of mortality from neglected diseases.

As there is no curative drug or preventive vaccine for dengue, management is focused on control of transmission, and supportive therapy to minimise patient dehydration or shock from haemorrhagic fever. There is need for a vaccine that is effective against all four serotypes; an antiviral that is effective once infection has occurred; and a diagnostic that is able to detect early stage disease, differentiate between serotypes, and distinguish dengue from other causes of fever.<sup>6</sup> There is also a need for evaluation of the currently available diagnostic kits.<sup>18</sup>

There are a number of new dengue vaccines in development, with one live attenuated tetravalent vaccine candidate in Phase III and three additional candidates in Phase I and II clinical trials. A small number of early stage drug candidates are also in development.<sup>6</sup>

R&D needed for dengue includes:

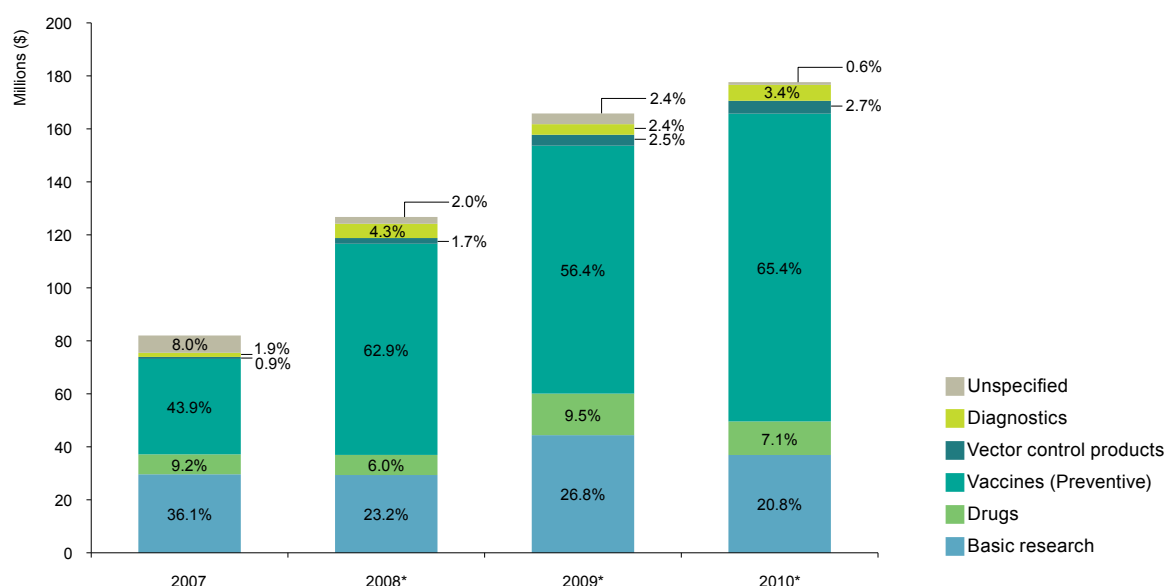
- Basic research
- Drugs
- Preventive vaccines
- Diagnostics
- Vector control products

Global funding for dengue R&D in 2010 was \$177.6m (\$187.4m). This was an increase from 2009, with YOY funders providing an additional \$9.2m (up 5.6%). A further \$2.6m was reported by new survey respondents, while \$2,952 was lost-to-follow-up. Dengue marginally increased its share of neglected disease R&D funding in 2010 (5.8% compared to 5.2% in 2009).

Two-thirds of dengue R&D funding went to vaccine development (\$116.2m, 65.4%). Basic research received \$36.9m (20.8%), drug development \$12.7m (7.1%), diagnostics \$6.0m (3.4%) and vector control products \$4.9m (2.7%).

Data from YOY funders showed a significant increase in funding for vaccines (up \$22.0m, 23.6%) associated with increased industry investment, including into late-stage clinical trials of the Chimerivax vaccine candidate. There was a minimal increase of \$2.0m for diagnostics (up 50.2%), while vector control product funding remained steady. Decreased public sector dengue investment led to moderate reductions in investment for both basic research (down \$8.7m, -19.6%) and drug development (down \$3.3m, -21.2%).

**Figure 8. Dengue R&D funding by product type 2007-2010**



\* Figures are adjusted for inflation and reported in 2007 US dollars

The pharmaceutical industry continued to be the major player in dengue R&D, collectively providing more than half of total funding (\$99.2m, 55.8%), with the other top 11 funders accounting for 40.6%. Several non-industry funders decreased their dengue contribution in 2010 including the US NIH (down \$7.7m, -14.3%), Brazilian Department of Science and Technology (DECIT) (down \$5.5m, -81.5%), Gates Foundation (down \$5.3m, -44.9%) and US DOD (down \$5.0m, -47.6%).

**Table 6. Top 12 dengue R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$) <sup>^</sup>	2009 (US\$) <sup>^</sup>	2010 (US\$) <sup>^</sup>	2007%	2008%	2009%	2010%
Aggregate industry respondents <sup>A</sup>	19,394,756	43,793,998	63,113,152	99,209,885	23.6	34.6	38.1	55.8
US NIH	34,639,236	26,603,478	54,025,137	46,281,288	42.2	21.0	32.6	26.1
Gates Foundation	1,013,807	16,305,526	11,711,906	6,450,949	1.2	12.9	7.1	3.6
US DOD	14,384,000	7,517,148	10,477,173	5,490,539	17.5	5.9	6.3	3.1
Institut Pasteur	3,946,978	2,727,968	2,480,946	3,561,362	4.8	2.2	1.5	2.0
Wellcome Trust	1,073,869	1,203,426	1,584,764	2,368,748	1.3	0.9	1.0	1.3
Australian DIISR/ARC	-	2,866,725	299,207	1,793,524	0.0	2.3	0.2	1.0
US CDC	-	-	1,422,151	1,399,018	0.0	0.0	0.9	0.8
Brazilian DECIT	1,623,000	1,334,847	6,716,881	1,242,158	2.0	1.1	4.1	0.7
Australian NHMRC	647,598	1,039,031	1,035,249	1,219,028	0.8	0.8	0.6	0.7
UBS Optimus Foundation	-	-	-	1,216,064	-	0.0	0.0	0.7
Mexican CONACYT	9,059	874,508	11,784	1,168,934	0.0	0.7	0.0	0.7
<b>Subtotal top 12 dengue R&amp;D funders*</b>	<b>81,594,560</b>	<b>119,625,671</b>	<b>157,336,711</b>	<b>171,401,497</b>	<b>99.5</b>	<b>94.4</b>	<b>94.9</b>	<b>96.5</b>
<b>Disease Total</b>	<b>82,013,895</b>	<b>126,752,203</b>	<b>165,812,311</b>	<b>177,643,516</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

- No reported funding

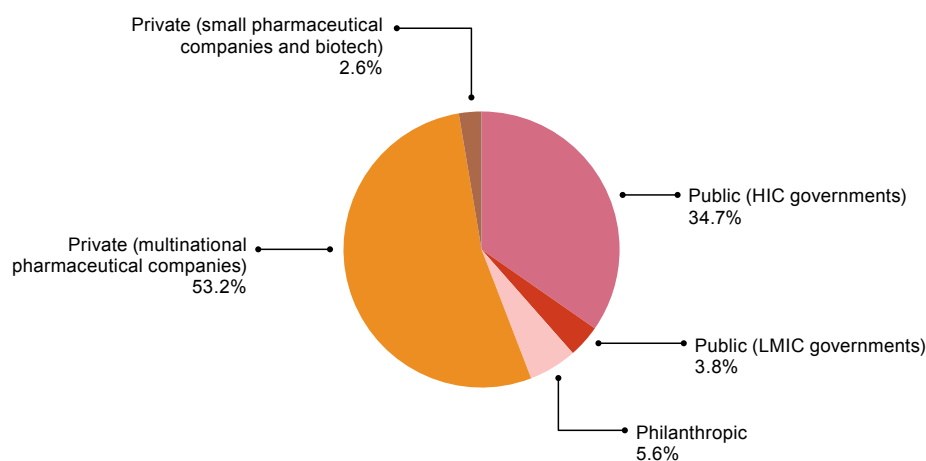
<sup>A</sup> Includes new survey respondents in 2010

\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

- Did not participate in the survey this year

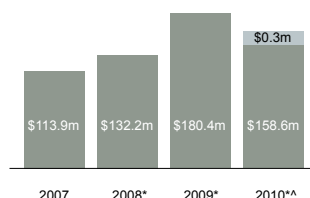
Dengue is the only neglected disease where industry contributed more than the public and philanthropic sectors combined. In 2010, dengue funding increases were driven by a very large increase in YOY investment from MNCs (up \$35.6m, 60.4%) associated with clinical development of several dengue vaccine candidates, including Phase III trials of the Chimerivax vaccine. In contrast, there was a substantial decrease in YOY funding by public organisations in particular (down \$22.5m, -25.2%), but also from the philanthropic sector (down \$3.3m, -24.5%).

The sharp increase in industry investment, combined with decreased funding from other sectors, led to a marked change in the sources of dengue R&D funding. Industry increased its share of global dengue R&D funding from 38.0% in 2009 to 55.8% (\$99.2m) in 2010, while the public contribution decreased from 53.9% to 38.5% (\$68.4m), and the philanthropic share from 8.0% to 5.6% (\$10.0m).

**Figure 9. Dengue R&D funding by funder type 2010**



## DIARRHOEAL DISEASES



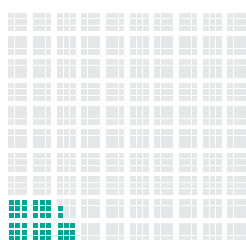
NEW SURVEY PARTICIPANTS  
REPEAT SURVEY PARTICIPANTS

\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2010 data

**\$158.9 MILLION**

TOTAL SPEND ON DIARRHOEAL  
DISEASE R&D IN 2010



**5.2%**

OF GLOBAL R&D FUNDING

Diarrhoeal diseases are a group of illnesses caused by viruses, bacteria or protozoa, that all present with fever and diarrhoea. They range from rotavirus and *E. coli*, which are relatively common in the West; to cholera and shigella, which are mostly prevalent in DC settings. Diarrhoeal diseases mainly affect children under five years of age and are often transmitted by contaminated food or water. Although they rarely cause death in Western settings, due primarily to better health care, their impact in the developing world is severe.

Diarrhoeal illnesses were collectively responsible for 72.3 million DALYs and just over 2 million deaths in the developing world in 2004, making them the second highest cause of neglected disease mortality and morbidity.

Current vaccines against diarrhoeal diseases such as cholera are not always suitable for infants under the age of one, and some are relatively ineffective; new bi- and multivalent vaccines that are suitable for infants, and which have longer durations of protection, are needed for most of the diarrhoeal diseases. New, safe, effective and affordable drugs are needed for some diarrhoeal diseases to complement supportive interventions such as oral rehydration therapy (ORT) and zinc supplementation.<sup>19</sup> New rapid diagnostic tests capable of distinguishing between diarrhoeal diseases are also required.<sup>6</sup>

Progress has been made with the licensure of a new oral cholera vaccine (Shancho<sup>TM</sup>) in 2009, and several vaccine candidates are in Phase II and III trials including ACE527 for enterotoxigenic *E. coli* (ETEC), *S. sonnei* -rEPA and *S. flexneri* 2a-rEPAsucc for shigella, and ORV116E for rotavirus.<sup>20</sup> However, discontinuation of Intercell's LT vaccine patch for ETEC in 2010 was a major drawback for the field. A new diagnostic test capable of distinguishing between causes of diarrhoeal diseases is also in early development.<sup>6</sup>

R&D needs for the diarrhoeal illnesses include:

- Basic research for cholera, shigella and *cryptosporidium*
- Drugs for cholera, shigella and *cryptosporidium*
- Vaccines for rotavirus, *E. coli*, cholera, shigella and *cryptosporidium*
- Diagnostics for all diarrhoeal diseases with the exception of rotavirus

In 2010, diarrhoeal diseases received \$158.9m (\$166.3m) in R&D funding. This was a moderate decrease from 2009, with YOY funders reducing their investment by \$18.3m (-10.3%). The further \$3.3m drop in reported funding consisted of \$3.6m lost-to-follow-up, offset by \$0.3m reported by new survey respondents. Diarrhoeal diseases marginally decreased their share of total neglected disease R&D in 2010 (5.2% compared to 5.7% in 2009).

Within the diarrhoeal diseases, the distribution of funding remained weighted towards rotavirus, cholera and shigella, which accounted for 60.7% (\$96.5m) of total investments compared to 65.6% in 2009. YOY funders essentially maintained their investment in rotavirus (down \$1.9m, -3.9%), but reduced funding for all other diseases, including cholera (down \$13.7m, -35.0%), *cryptosporidium* (down \$7.1m, -43.2%) and shigella (down \$2.7m, -10.4%). Non pathogen-specific funding increased by \$7.9m (up 20.9%).

For both cholera and shigella, where data was collected for all product types, over half of all funding went to basic research (\$17.8m, 69.9%; and \$11.8m, 50.7%, respectively) and over a quarter to preventive vaccines (\$6.9m, 27.1%; and \$7.3m, 31.3%, respectively). Across all the diarrhoeal diseases, data from YOY funding showed an increase in funding for drug development (up \$13.5m, 353%) and diagnostics (up \$2.7m, 38.2%), but drops for preventive vaccines (down \$18.8m, -18.3%) and basic research (down \$12.2m, -22.8%). We note, however, that the decreased cholera vaccine funding may be due to the successful registration of a new oral cholera vaccine in 2009.

**Table 7. Funding for diarrhoeal disease R&D 2010 (US\$)\*A**

Disease	Basic Research	Drugs	Vaccines (Preventive)	Diagnostics	Unspecified	Total	%
Rotavirus			46,550,451		1,183,381	47,733,832	30.0
Cholera	17,823,565	380,223	6,916,846	372,866	-	25,493,500	16.0
Shigella	11,807,489	979,284	7,302,696	1,514,615	1,697,492	23,301,576	14.7
<i>Cryptosporidium</i>	4,962,194	3,283,247	164,741	920,654	-	9,330,836	5.9
Enterotoxigenic <i>E. coli</i> (ETEC)			6,013,502	548,961	-	6,562,463	4.1
Giardia				317,150	79,871	397,021	0.2
Enteraggregative <i>E. coli</i> (EAggEC)			-	27,690	-	27,690	0.0
Multiple diarrhoeal diseases	6,672,011	12,708,073	17,108,025	6,288,382	3,294,718	46,071,209	29.0
<b>Total</b>	<b>41,265,259</b>	<b>17,350,827</b>	<b>84,056,261</b>	<b>9,990,318</b>	<b>6,255,462</b>	<b>158,918,128</b>	<b>100.0</b>

\* All figures are FY2010, adjusted for inflation and reported in 2007 US dollars

A Please note that there were strict eligibility conditions on drug and vaccine investments for some diarrhoeal diseases products to avoid inclusion of overlapping commercial activity. Due to this, total funding between product categories cannot be reasonably compared

- No reported funding

Category not included in G-FINDER

Only one top 12 funder significantly increased their investment in diarrhoeal disease R&D in 2010, which was UK DFID, with an increase of \$2.7m. The top 4 funders decreased their funding, including the US NIH (down \$10.5m, -17.3%), US DOD (down \$5.1m, -46.4%), Gates Foundation (down \$1.8m, -3.9%) and industry (YOY funders down \$2.1m, -6.2%), while Sweden's public funders dropped out of the list of top 12 diarrhoeal disease funders in 2010 due to a total funding cut of \$3.3m (-77.2%) by the Swedish International Development Agency (SIDA) and Swedish Research Council. Funding levels were relatively steady among the other top 12 funders of diarrhoeal disease R&D.

**Table 8. Top 12 diarrhoeal disease R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$) <sup>^</sup>	2009 (US\$) <sup>^</sup>	2010 (US\$) <sup>^</sup>	2007%	2008%	2009%	2010%
US NIH	31,024,336	39,516,218	60,942,274	50,399,408	27.2	29.9	33.8	31.7
Gates Foundation	44,303,185	26,725,850	46,757,622	44,915,768	38.9	20.2	25.9	28.3
Aggregate industry respondents	13,676,428	24,102,845	37,196,423	31,569,739	12.0	18.2	20.6	19.9
US DOD	5,436,000	5,898,574	10,999,053	5,894,604	4.8	4.5	6.1	3.7
UK DFID	-	-	2,691,549	5,440,441	0.0	0.0	1.5	3.4
Institut Pasteur	3,426,196	3,774,871	5,180,998	4,294,706	3.0	2.9	2.9	2.7
Indian ICMR		3,663,668	3,514,923	3,611,560		2.8	1.9	2.3
Bio Manguinhos		949,135	506,774	1,788,506		0.7	0.3	1.1
Inserm	274,096	327,912	1,454,522	1,697,492	0.2	0.2	0.8	1.1
Australian NHMRC	547,086	1,545,322	1,278,348	1,383,498	0.5	1.2	0.7	0.9
Research Council of Norway		459,429	979,180	1,095,885		0.3	0.5	0.7
French ANR		616,474	-	921,715		0.5	0.0	0.6
Subtotal top 12 diarrhoeal disease R&D funders*	112,607,339	125,257,549	175,250,001	153,013,323	98.9	94.7	97.1	96.3
Disease Total	113,889,118	132,198,981	180,426,679	158,918,128	100.0	100.0	100.0	100.0

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

- No reported funding

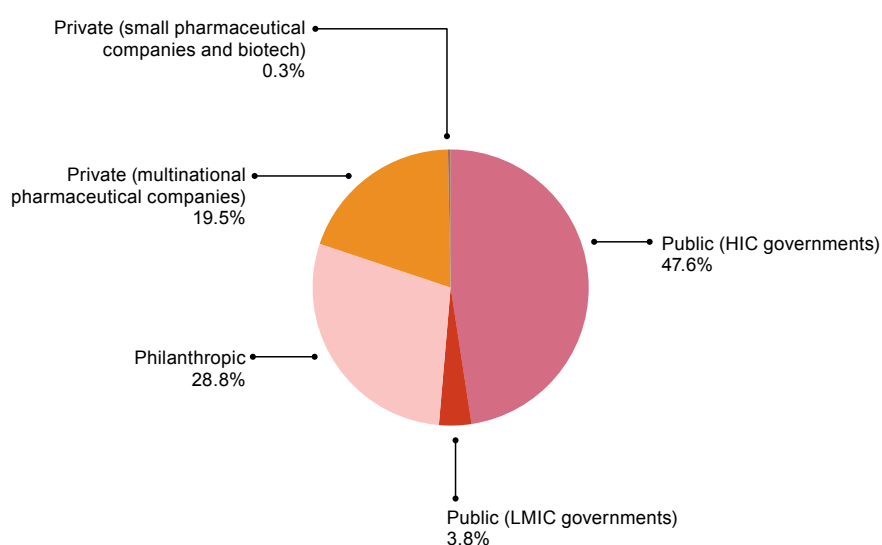
\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

Did not participate in the survey this year

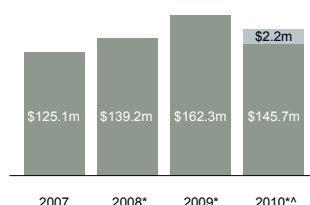
As in 2009, the public sector provided just over half of diarrhoeal disease R&D funding in 2010 (\$81.6m, 51.4%), followed by philanthropic organisations (\$45.7m, 28.8%) and industry (\$31.6m, 19.9%).

There was a significant overall trend towards decreased funding of diarrhoeal diseases, with YOY investments by HIC public funders dropping by \$15.6m (-17.1%), public multilaterals by \$0.2m (-100%), philanthropic organisations by \$1.5m (-3.1%) and industry, both big and small, by \$2.1m (-6.2%). The only sector that increased its contribution was the LMIC public sector, by a modest \$1.5m (up 34.3%).

**Figure 10. Diarrhoeal disease R&D funding by funder type 2010**



## KINETOPLASTIDS



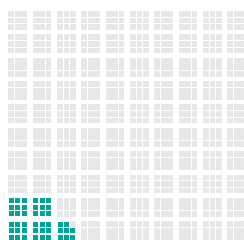
■ NEW SURVEY PARTICIPANTS  
■ REPEAT SURVEY PARTICIPANTS

\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2010 data

**\$147.9 MILLION**

TOTAL SPEND ON KINETOPLASTID  
R&D IN 2010



**4.8%**

OF GLOBAL R&D FUNDING

Kinetoplastid infections include three diseases: Chagas' disease, leishmaniasis and Human African Trypanosomiasis (HAT), also known as African sleeping sickness. HAT initially presents with similar symptoms to a viral illness but eventually infects the brain where it causes confusion, coma and death. Chagas' disease also has two stages, with late stage Chagas' leading to heart failure and death. Leishmaniasis causes skin lesions and, in its more severe form, damages internal organs (spleen, liver and bone marrow). Kinetoplastid diseases are often fatal if left untreated.

In 2004, kinetoplastid diseases were responsible for 4.1 million DALYs and 110,000 recorded deaths in the developing world. They ranked as the eighth highest cause of mortality and ninth highest cause of morbidity from neglected diseases.

Treatment of kinetoplastid infections is hampered by outdated drugs, and a lack of vaccines and effective standard diagnostic tools. The two drugs currently used for treatment of Chagas' disease are toxic, lack specificity and require multiple dosing for several months, increasing the likelihood of non-compliance and drug resistance.<sup>21</sup> Chagas' disease needs preventive and therapeutic vaccines; safe, effective drugs that are suitable for children; treatments for the chronic form of the disease; and diagnostics that can reliably detect chronic disease and monitor treatment. A Chagas' paediatric drug formulation is likely to be available soon, and there are a number of other promising drug candidates in preclinical and clinical stages.<sup>6,22</sup>

HAT needs new, safe, oral drugs that are active against both stages of the disease to replace the injectable treatments now used, as well as a rapid, easy to use, point of care diagnostic that can distinguish between disease stages. However, there is a lack of advanced projects, particularly for vaccines, for which there are no candidates in clinical trials.<sup>6</sup> There are some promising HAT drug candidates, with fexinidazole currently in Phase I clinical trials and a number of other compounds being followed up.<sup>23</sup>

Leishmaniasis is in need of a modern vaccine, as well as more effective, oral drug formulations, and a diagnostic that can detect early-stage disease. The leishmaniasis drug pipeline is relatively healthy, with five new combinations or new formulations of existing drugs in late stage clinical trials, novel compounds in earlier stages, and several candidates in preclinical stages.<sup>6</sup>

R&D is needed in every area, including:

- Basic research
- Drugs
- Preventive vaccines
- Diagnostics
- Vector control products for sleeping sickness and Chagas' disease
- Therapeutic vaccines for leishmaniasis and Chagas' disease

Global funding for kinetoplastid R&D in 2010 was \$147.9m (\$150.2m). This was a moderate decrease from 2009, with YOY funders reducing their investment by \$15.5m (down -9.6%). A further \$1.0m was lost-to-follow-up, offset by \$2.2m reported by new survey respondents. As a result of the reduced investment, kinetoplastid diseases dropped their share of global funding from 5.1% in 2009 to 4.8% in 2010.

As in previous years, funding within the kinetoplastid family went predominantly to leishmaniasis (\$65.8m, 44.5%) followed by sleeping sickness (\$37.4m, 25.3%). This was despite decreased investment from YOY funders in both diseases in 2010, with sleeping sickness down \$9.2m (-19.9%) and leishmaniasis down \$3.9m (-5.6%). Investment from YOY funders in Chagas' disease was up \$2.8m (17.7%), bringing total Chagas' disease investment in 2010 to \$20.1m (or 13.6% of total funding).

Funding for drug development bore the brunt of reduced kinetoplastid R&D investment in 2010 (down \$13.4m, -19.0%), with funding for preventive vaccines also markedly reduced (down \$4.8m, -25.8%). Diagnostics bucked the trend, with investments increasing by \$3.3m in 2010 (up 52.4%). Despite these funding shifts, basic research and drug development again received the majority of funding for each of the kinetoplastid diseases, although we note that not all product types are needed for each disease.

**Table 9. Funding for kinetoplastid R&D 2010 (US\$)\***

Disease	Basic Research	Drugs	Vaccines (Preventive)	Vaccines (Therapeutic)	Vector control products	Diagnostics	Unspecified	Total	%
Leishmaniasis	23,923,469	21,453,617	12,362,053	1,064,735		4,768,689	2,192,720	65,765,283	44.5
Sleeping sickness	24,927,617	8,608,328	765,787		33,038	2,592,826	509,349	37,436,945	25.3
Chagas' disease	12,414,131	4,597,701	720,498	35,547	-	2,278,783	14,720	20,061,381	13.6
Multiple kinetoplastids	1,637,255	22,966,649	-	-	-	-	-	24,603,904	16.6
<b>Total</b>	<b>62,902,473</b>	<b>57,626,295</b>	<b>13,848,338</b>	<b>1,100,282</b>	<b>33,038</b>	<b>9,640,298</b>	<b>2,716,789</b>	<b>147,867,513</b>	<b>100.0</b>

\* All figures are FY2010, adjusted for inflation and reported in 2007 US dollars

- No reported funding

Category not included in G-FINDER

Kinetoplastid R&D funding continued to be highly concentrated in 2010, with the top 12 funders contributing 91.4% of total funding. The most notable increases in funding came from industry – which boosted its YOY funding by \$6.9m (up 150%) to become the third largest funder of kinetoplastid R&D – the US NIH (up \$3.4m, 6.4%) and the Institut Pasteur (up \$2.8m, 87.9%). Several other funders also increased their investments, appearing in the top 12 ranking for the first time: the German DFG (up \$4.0m), Indian ICMR (up \$1.4m, 1,125%), French ANR (up \$1.2m, 233%), Colombian Colciencias (up \$1.2m, 75.3%) and UK MRC (up \$0.4m, 16.4%).

In contrast, the Gates Foundation decreased funding by \$16.2m (-44.9%) in 2010, as did the US DOD (down \$3.6m, -79.1%).

**Table 10: Top 12 kinetoplastid R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
US NIH	28,206,281	48,561,566	52,803,542	56,203,616	22.5	34.9	32.5	38.0
Gates Foundation	45,114,108	28,973,211	36,026,595	19,855,236	36.1	20.8	22.2	13.4
Aggregate industry respondents <sup>A</sup>	5,149,518	2,912,298	5,112,855	11,864,151	4.1	2.1	3.2	8.0
UK DFID	3,603,250	3,733,433	8,971,828	9,850,738	2.9	2.7	5.5	6.7
Wellcome Trust	15,057,627	12,360,489	11,493,648	9,643,106	12.0	8.9	7.1	6.5
European Commission	2,888,667	4,628,687	10,145,797	9,061,409	2.3	3.3	6.3	6.1
Institut Pasteur	-	2,932,088	3,154,303	5,927,974	0.0	2.1	1.9	4.0
German DFG	83,142	-	-	4,048,583	0.1	-	0.0	2.7
UK MRC	2,868,065	3,464,747	2,405,299	2,799,630	2.3	2.5	1.5	1.9
Colombian Colciencias	-	-	1,532,651	2,686,688	0.0	0.0	0.9	1.8
French ANR	-	1,508,395	516,822	1,718,185	-	1.1	0.3	1.2
Indian ICMR	-	-	124,810	1,528,672	-	0.0	0.1	1.0
Subtotal top 12 kinetoplastid R&D funders*	123,159,493	125,938,739	146,360,237	135,187,986	98.4	90.5	90.2	91.4
Disease Total	125,122,839	139,207,962	162,258,968	147,867,513	100.0	100.0	100.0	100.0

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

- No reported funding

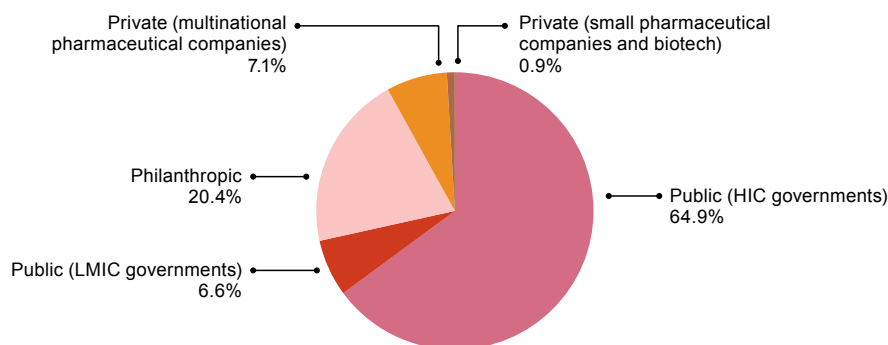
<sup>A</sup> Includes new survey respondents in 2010

\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

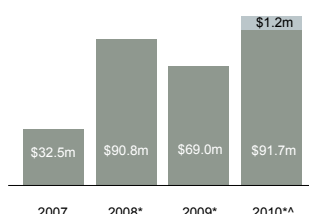
Did not participate in the survey this year

Once again, the public and philanthropic sectors accounted for the majority of kinetoplastid R&D funding in 2010 (\$136.0m, 92.0%) despite the increase in industry funding share from 3.2% (\$5.1m) in 2009 to 8.0% (\$11.9m) in 2010. YOY philanthropic funding decreased dramatically in 2010 (down \$23.4m, -43.6%), accounting for a large part of the drop in total kinetoplastid R&D funding, while YOY public funding remained essentially steady (up 0.9m, 0.9%).

**Figure 11. Kinetoplastid R&D funding by funder type 2010**



# BACTERIAL PNEUMONIA & MENINGITIS



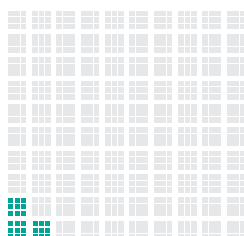
■ NEW SURVEY PARTICIPANTS  
■ REPEAT SURVEY PARTICIPANTS

\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2010 data

## \$92.9 MILLION

TOTAL SPEND ON BACTERIAL  
PNEUMONIA & MENINGITIS  
R&D IN 2010



## 3.0%

OF GLOBAL R&D FUNDING

Pneumonia is a lung infection transmitted by the cough or sneeze of infected patients. It presents with cough, fever, chest pain and shortness of breath, and can be fatal especially in young children and elderly patients. Although caused by a range of bacteria and viruses, *Streptococcus pneumoniae* is by far the most common cause of pneumonia in the developing world.

Bacterial meningitis is an infection of the fluid that surrounds the brain and spinal cord and is mostly caused by *S. pneumoniae* and *Neisseria meningitidis*. Meningitis is transmitted from person to person through droplets of respiratory or throat secretions. Symptoms include severe headache, fever, chills, stiff neck, nausea and vomiting, sensitivity to light and altered mental state. Even with early diagnosis and treatment, 5–10% of patients die within 24–48 hours of onset of symptoms. Meningitis epidemics occur commonly in the sub-Saharan African meningitis belt. The occurrence of these epidemics despite vaccination programmes confirms the unsuitability of previous vaccines, due to their inability to produce long lasting protection or to protect young children. However, there has been substantial progress, with greatly reduced mortality after rollout of a new meningitis vaccine against serogroup A meningococci (which accounts for the majority of epidemic and endemic disease in the meningitis belt) in West Africa in late 2010 and early 2011.<sup>24</sup> However, vaccines are still needed for other meningitis serotypes.

Lower respiratory infections, mostly pneumonia, were responsible for 93.3 million DALYs and 3.9 million deaths in the developing world in 2004. Pneumonia ranked as the number one cause of morbidity and mortality of any neglected disease and was responsible for nearly one in five deaths in children under five years of age. Meningitis was responsible for 11.3 million DALYs and 340,000 deaths in 2004.

Traditional polysaccharide pneumococcal vaccines are unsuitable for DC use. The conjugate pneumococcal vaccine Prevnar (7-valent) has been licensed for use in infants and young children in DCs for some time now, but is expensive and does not cover all DC strains. The WHO-prequalified conjugate vaccines Synflorix (a 10-valent vaccine) and Prevnar (13-valent) were confirmed in early 2010 as the first vaccines in the Global Alliance for Vaccines and Immunization's (GAVI) pilot pneumococcal Advance Market Commitment (AMC) scheme. Rapid introduction of these heavily subsidised vaccines is underway but its reach is currently limited to a select group of countries.<sup>25</sup>

New products needed for pneumonia and meningitis are:

- Vaccines that include developing world strains (and possibly DC-specific vaccines that exclude Western strains)
- Diagnostics

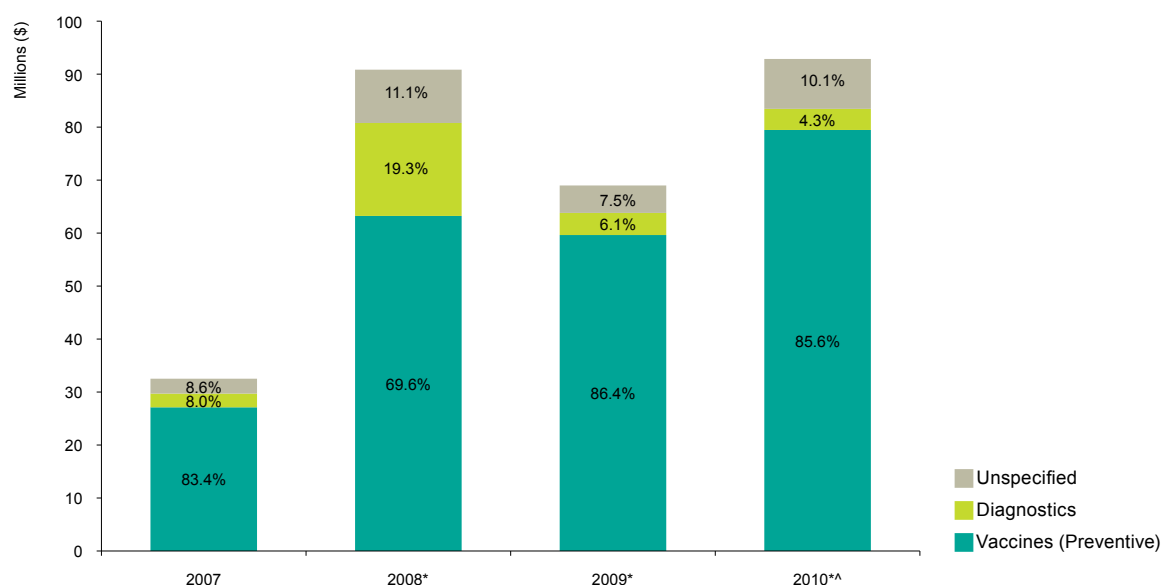


In 2010, bacterial pneumonia & meningitis received \$92.9m (\$97.6m) in R&D funding. This was a significant increase from 2009, with YOY funders providing an additional \$31.7m (up 52.9%). The actual increase is likely to be even greater as a further \$9.0m was lost-to-follow-up, marginally offset by \$1.2m reported by new survey respondents. As a result of the jump in funding, which was largely directed at research into a next-generation pneumococcal vaccine, bacterial pneumonia & meningitis increased its share of total R&D funding in 2010 to 3.0% (up from 2.2% in 2009).

R&D funding was overwhelmingly directed towards vaccine development (\$79.5m, 85.6%) and, of this, the majority (\$67.3m, 84.7%) went to pneumococcal vaccines. Diagnostics received \$4.0m in 2010, or 4.3% of all bacterial pneumonia & meningitis R&D funding.

Increased funding for vaccine development accounted for almost all of the jump in bacterial pneumonia & meningitis funding, with YOY funders providing an extra \$28.5m for vaccines in 2010 (up 56.2%). A near doubling of vaccine investment from the Gates Foundation – one of the major R&D funders for this disease – was responsible for just under half of this funding increase, with the remainder coming from multinational pharmaceutical companies and the public sector (predominantly the US NIH). We note that private sector vaccine investment is likely to be significantly under-reported, as we did not receive complete data from one multinational company with an active pneumococcal vaccine programme. Diagnostic funding was down from 2009, with a drop in investment from YOY funders of \$1.1m (down -27.2%).

**Figure 12. Bacterial pneumonia & meningitis R&D funding by product type 2007-2010**



\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2010 data

Concentration of bacterial pneumonia and meningitis R&D funding continued to be high, with the top 12 funders contributing 96.9% of total funding. The majority of this came from the Gates Foundation, industry and US NIH, who collectively provided 86.5% of the global R&D investment into bacterial pneumonia and meningitis.

In 2010, the most significant increases were from the Gates Foundation and the US NIH, who increased their funding by \$18.4m (up 87.8%) and \$5.1m (up 138%) respectively. Several small funders – including GAVI, Fondation Mérieux and the EC – reported bacterial pneumonia and meningitis R&D funding for the first time, and together with the US DOD joined the list of top 12 funders. The UK MRC decreased its funding in 2010 by \$1.0m (-47.6%) while the Swedish Research Council reported no funding in 2010, after disbursing \$1.2m in 2009.

**Table 11. Top 12 bacterial pneumonia and meningitis R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$) <sup>^</sup>	2009 (US\$) <sup>^</sup>	2010 (US\$) <sup>^</sup>	2007%	2008%	2009%	2010%
Gates Foundation	5,598,040	26,282,476	21,000,867	39,448,775	17.2	28.9	30.4	42.5
Aggregate industry respondents <sup>A</sup>	15,747,037	50,494,753	33,794,257	32,114,414	48.4	55.6	49.0	34.6
US NIH	4,194,589	4,030,496	3,685,083	8,776,440	12.9	4.4	5.3	9.5
GAVI				2,141,529				2.3
US CDC	1,455,973	1,402,671	1,407,145	1,384,256	4.5	1.5	2.0	1.5
US DOD	1,441,000	-	-	1,235,965	4.4	0.0	0.0	1.3
UK MRC	1,776,977	1,985,766	2,034,450	1,065,294	5.5	2.2	2.9	1.1
Fondation Mérieux				943,774				1.0
Australian NHMRC	315,006	504,622	1,407,279	930,557	1.0	0.6	2.0	1.0
Dell Foundation	-	289,017	1,256,403	665,520	0.0	0.3	1.8	0.7
European Commission	-	-	-	650,879	0.0	0.0	0.0	0.7
German DFG	-		567,107	638,252	0.0		0.8	0.7
Subtotal top 12 bacterial pneumonia and meningitis R&D funders*	32,317,719	89,494,134	67,857,349	89,995,655	99.4	98.5	98.4	96.9
Disease Total	32,517,311	90,844,284	68,988,629	92,866,038	100.0	100.0	100.0	100.0

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

- No reported funding

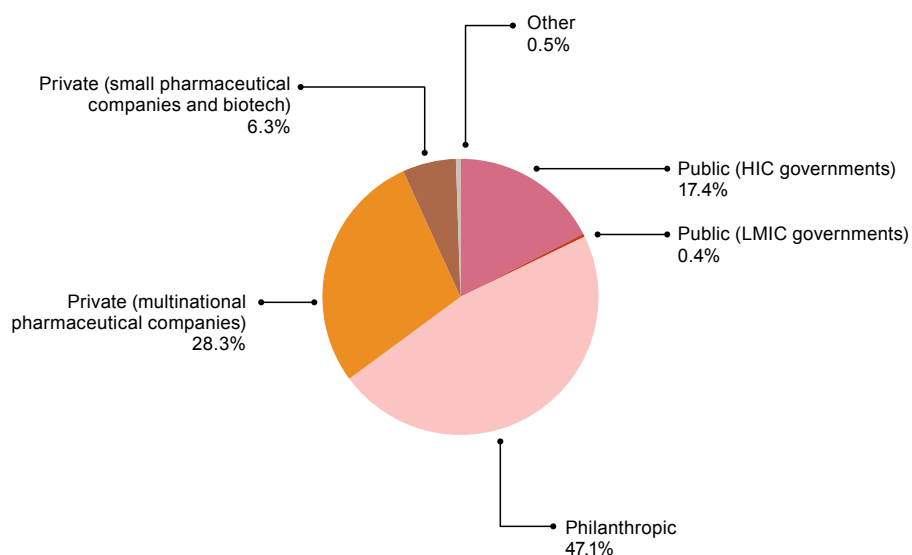
<sup>A</sup> Includes new survey respondents in 2010

\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

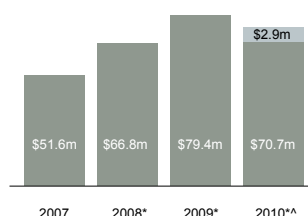
Did not participate in the survey: Any contributions listed for this year are based on data reported by funding recipients so may be incomplete

There was a notable increase in philanthropic funding in 2010, which drove the upturn in global funding. YOY philanthropic funders increased their investment by \$20.4m (up 91.2%); triple the increase that came from YOY industry funders (up \$6.9m, 27.9%), and nearly five times greater than that of YOY public organisations (up \$4.2m, 34.3%). However, we cannot comment on relative sectoral funding shares, since these are skewed by the under-reported industry data noted earlier.

**Figure 13. Bacterial pneumonia & meningitis R&D funding by funder type 2010**



# HELMINTH INFECTIONS



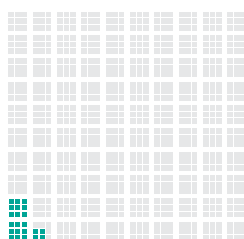
NEW SURVEY PARTICIPANTS  
REPEAT SURVEY PARTICIPANTS

\* Figures are adjusted for inflation and reported in 2007 US dollars

^ There may be minor under-reporting as some organisations did not submit 2010 data

**\$73.7 MILLION**

TOTAL SPEND ON HELMINTH  
R&D IN 2010



**2.4%**

OF GLOBAL R&D FUNDING

Helminths are parasitic worms and flukes that can infect humans. Helminth infections include ancylostomiasis and necatoriasis (hookworm), ascariasis (roundworm), trichuriasis (whipworm) and cysticercosis/taeniasis (tapeworm); collectively referred to as soil-transmitted helminths. Other helminths include elephantiasis (lymphatic filariasis), river blindness (onchocerciasis) and schistosomiasis. Adult worms live in the intestines and other organs, and the infection is transmitted through food, water, soil or other objects.

Helminths can cause malnutrition and impaired mental development (hookworms), or progressive damage to the bladder, ureters and kidneys (schistosomiasis). Onchocerciasis is a major cause of blindness in many African and some Latin American countries, while elephantiasis causes painful, disfiguring swelling of the legs and genitals.

Helminth infections are the sixth highest cause of morbidity globally, with WHO figures suggesting they were responsible for 12 million DALYs in 2004 (around one-third that of malaria), although only 47,000 deaths. However, other estimates are much higher, suggesting helminth infections could be responsible for 49 million DALYs and up to 415,000 deaths per year.<sup>26</sup>

There is no vaccine against any of the above helminth infections; and growing concern exists that the drugs used to treat soil transmitted helminths and schistosomiasis are becoming outdated, with evidence of loss of efficacy and increasing resistance.<sup>27</sup> Current diagnostic products for detection of some helminths are also outdated, meaning new effective diagnostics are needed.

A drug (moxidectin) and one vaccine candidate (Bilhvax) are currently in Phase III clinical trials for onchocerciasis and schistosomiasis respectively, and two vaccine candidates against human hookworm infection (NaGST-1, NaAPR-1) are about to enter clinical trials.<sup>6</sup>

Helminth infections require a range of R&D including:

- Basic research for all listed infections
- Drugs for all listed infections
- Vaccines for strongyloidiasis, onchocerciasis, schistosomiasis and hookworm
- Diagnostics for strongyloidiasis, onchocerciasis and schistosomiasis
- Vector control products for lymphatic filariasis, onchocerciasis, schistosomiasis and tapeworm

In 2010, helminth infections received \$73.7m (\$77.1m) in R&D funding. This was a modest decrease from 2009, with YOY funders reducing their investment by \$8.7m (-10.9%). A further \$0.02m was lost-to-follow-up, offset by \$2.9m reported by new survey respondents. Despite the small drop, helminth infections essentially maintained their share of global funding (2.4% compared to 2.5% in 2009).

Three diseases (schistosomiasis, lymphatic filariasis and onchocerciasis) accounted for two-thirds of total helminth funding (\$49.4m, 67.0%), up from 62.9% in 2009. Of these, only schistosomiasis received more YOY funding in 2010 (up \$6.1m, 27.6%). Otherwise funding decreased for most helminth infections, with the biggest drops for onchocerciasis (down \$5.1m, -38.8%), hookworm (down \$3.3m, -33.9%) and lymphatic filariasis (down \$1.6m, -10.7%).

Once again, funding was predominantly invested in basic research, accounting for more than half of all helminth funding (\$40.0m, 54.3%) in 2010, up from 52.5% in 2009. Remaining helminth funding was invested in drug R&D (\$13.5m, 18.3%) and vaccines (\$10.2m, 13.8%), while vector control products and diagnostics again collectively received less than 5% of total helminth funding (\$2.7m, 3.7%), although not all product categories are included in G-FINDER's scope for all diseases.

Apart from a modest increase in YOY funding for diagnostics (up \$0.7m, 49.7%), funding was otherwise reduced across all R&D categories, including preventive vaccines (down \$2.7m, -27.9%), drugs (down \$1.9m, -12.6%), basic research (down \$1.4m, -3.4%) and vector control products (down \$1.3m, -67.7%).

**Table 12. Funding for helminth R&D 2010 (US\$)\***

Disease	Basic Research	Drugs	Vaccines (Preventive)	Vector control products	Diagnostics	Unspecified	Total	%
Schistosomiasis (bilharziasis)	18,884,776	2,001,383	2,456,692	-	675,731	3,994,030	28,012,612	38.0
Lymphatic filariasis (elephantiasis)	5,576,826	5,003,683		456,643	190,958	2,119,192	13,347,301	18.1
Onchocerciasis (river blindness)	672,359	4,704,270	808,545	95,074	975,467	774,079	8,029,793	10.9
Hookworm (ancylostomiasis & nectoriasis)	2,484,591	-	3,847,450	-		96,976	6,429,017	8.7
Roundworm (ascariasis)	1,437,315	505,795				94,124	2,037,234	2.8
Tapeworm (cysticercosis/taeniasis)	1,374,083	-		63,936		97,658	1,535,676	2.1
Whipworm (trichuriasis)	1,166,122	-				94,124	1,260,246	1.7
Strongyloidiasis & other intestinal roundworms	1,188,009	30,134	-		32,028	-	1,250,170	1.7
Multiple helminths	7,234,711	1,213,488	3,083,528	-	211,682	39,948	11,783,357	16.0
<b>Total</b>	<b>40,018,792</b>	<b>13,458,752</b>	<b>10,196,215</b>	<b>615,653</b>	<b>2,085,865</b>	<b>7,310,130</b>	<b>73,685,406</b>	<b>100.0</b>

\* All figures are FY2010, adjusted for inflation and reported in 2007 US dollars

- No reported funding

Category not included in G-FINDER

Helminth R&D funding continued to be highly concentrated, with the top 12 funders contributing 96.2% of total funding. The EC increased its funding by \$5.0m, displacing industry from the top three. The largest drop in funding was from the German DFG (down \$6.3m, -91.8%), reflecting completion of several single year basic research grants funded in 2009 for tapeworm, schistosomiasis and onchocerciasis.

**Table 13. Top 12 helminth R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
US NIH	27,854,142	23,308,515	28,133,258	29,466,628	54.0	34.9	35.4	40.0
Gates Foundation	7,204,305	21,116,365	16,029,672	14,458,661	14.0	31.6	20.2	19.6
European Commission	4,271,324	3,137,023	2,956,743	7,947,504	8.3	4.7	3.7	10.8
Aggregate industry respondents <sup>A</sup>	814,963	4,950,621	8,541,024	6,431,061	1.6	7.4	10.8	8.7
Wellcome Trust	3,162,843	3,959,257	4,967,904	5,760,936	6.1	5.9	6.3	7.8
Australian NHMRC	1,053,789	1,666,179	1,873,883	2,313,541	2.0	2.5	2.4	3.1
UK MRC	1,096,017	1,396,827	1,093,338	1,158,367	2.1	2.1	1.4	1.6
Indian ICMR		354,617	398,070	793,873		0.5	0.5	1.1
US CDC	262,902	370,506	175,779	698,428	0.5	0.6	0.2	0.9
APOC	695,610	674,374	676,525	665,520	1.3	1.0	0.9	0.9
UBS Optimus Foundation		261,821	261,264	593,892		0.4	0.3	0.8
German DFG	-		6,831,168	563,140	0.0		8.6	0.8
Subtotal top 12 helminth R&D funders*	50,966,641	62,565,617	75,772,065	70,851,551	98.8	93.6	95.4	96.2
Disease Total	51,591,838	66,837,827	79,414,264	73,685,406	100.0	100.0	100.0	100.0

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

- No reported funding

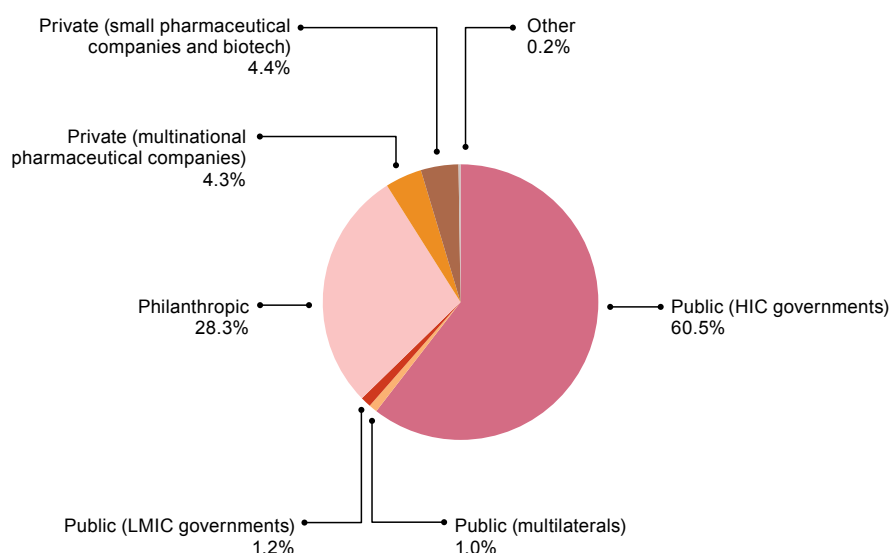
<sup>A</sup> Includes new survey respondents in 2010

\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

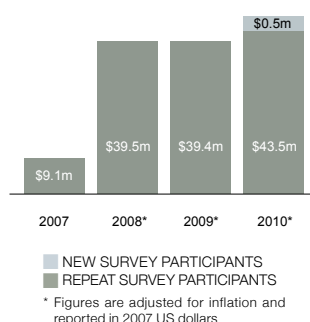
Did not participate in the survey this year

Despite modest decreases, public and philanthropic funders continued to contribute the bulk of helminth R&D funding, accounting for over 90% (\$67.1m, 91.0%) of total investment. YOY public funders decreased their investment by \$2.3m (-4.7%) while YOY philanthropic funding decreased by \$1.4m (-6.1%). YOY industry funding fell by \$5.2m (-61.1%), with YOY MNC investment down \$5.2m (-61.1%) and YOY SME funding dropping \$0.3m (-65.1%). This was partially offset by new SME survey participants adding \$3.1m, of which almost all (\$3.08m) came from DC firms.

**Figure 14. Helminth R&D funding by funder type 2010**

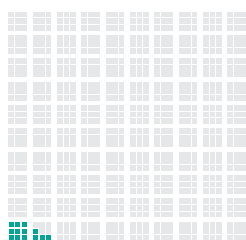


# SALMONELLA INFECTIONS



**\$44.0 MILLION**

TOTAL SPEND ON SALMONELLA  
R&D IN 2010



**1.4%**

OF GLOBAL R&D FUNDING

Salmonella infections are a group of diseases caused by bacteria transmitted through contaminated food or drink. These infections can broadly be grouped into typhoid and paratyphoid fever (*S. typhi*, *S. paratyphi A*), which cause disease only in humans; and non-typhoidal *Salmonella enterica* (NTS), which has more than 2,000 serotypes that cause gastroenteritis in humans, and other serotypes that almost exclusively cause disease in animals.<sup>28</sup>

Symptoms include high fever, malaise, headache, constipation or diarrhoea, rose-coloured spots on the chest, and enlarged spleen and liver. Young children, immunocompromised patients and the elderly are the most vulnerable to severe disease.

The global burden of typhoid disease has been estimated by the WHO to be more than 22 million cases annually, resulting in 200,000–600,000 deaths per year.<sup>29</sup>

Existing treatments are less than ideal due to widespread, worsening drug resistance, unsuitability for young children and rapid disease progression (rendering drug interventions ineffective if provided too late).<sup>30</sup> There are currently two safe and effective vaccines for preventing typhoid fever caused by *S. typhi*, however, there is no vaccine that targets both typhoid and paratyphoid fever even though the latter accounts for up to half of all cases of enteric fever in some regions.<sup>31</sup> Similarly, no typhoid or NTS vaccine is readily available for HIV-infected individuals or children under two years of age.<sup>31</sup> In light of rising levels of drug resistance, vaccine development is an important priority in achieving disease control.

At the moment, new *S. paratyphi A* vaccines are undergoing clinical trials, and several groups are also working on conjugate *S. typhi* vaccines, including a candidate (Vi-CRM 197) currently in phase II trials.<sup>6</sup> Recent research on humoral resistance to NTS has also delivered important clues for development of an NTS vaccine.<sup>32</sup>

R&D needed for salmonella infections includes:

- Basic research
- Drugs
- Diagnostics
- Vaccines



In 2010, salmonella R&D received \$44.0m (\$45.4m) in funding. This was an increase from 2009, with YOY funders providing an additional \$4.1m (up 10.4%). New survey respondents for 2010 provided an extra \$0.5m. As a result, salmonella R&D marginally increased its share of global funding (1.4%, compared to 1.2% in 2008).

NTS once again captured the majority of funding (\$19.3m, 43.8%), followed by typhoid and paratyphoid fever (\$13.9m, 31.6%). The growth in NTS funding seen in 2009 was continued (up \$2.7m, 16.2%), due to increased investment in both basic research and vaccines (up \$1.6m each). Funding for typhoid and paratyphoid fever levelled out (down \$0.2m, -1.3%), with a small increase in diagnostic funding (up \$0.4m) offset by reduced investment in basic research (down \$0.5m) and vaccines (down \$0.2m).

**Table 14. Funding for salmonella R&D 2010 (US\$)\***

Disease	Basic Research	Drugs	Vaccines (Preventive)	Diagnostics	Unspecified	Total	%
Non-typhoidal <i>Salmonella enterica</i> (NTS)	15,972,051	-	2,346,943	943,140	-	19,262,134	43.8
Typhoid and paratyphoid fever ( <i>S. typhi</i> , <i>S. paratyphi A</i> )	4,053,990	47,537	8,899,818	887,798	-	13,889,144	31.6
Multiple salmonella infections	9,572,989	55,128	1,202,753	-	-	10,830,870	24.6
<b>Total</b>	<b>29,599,030</b>	<b>102,665</b>	<b>12,449,515</b>	<b>1,830,939</b>	<b>-</b>	<b>43,982,149</b>	<b>100.0</b>

\* All figures are FY2010, adjusted for inflation and reported in 2007 US dollars  
 - No reported funding

Virtually all salmonella R&D funding in 2010 came from 12 organisations (98.0% of total funding), with the US NIH alone accounting for 61.4% of total funding. Several organisations increased funding in 2010, including the Gates Foundation (up \$1.6m, 100%), the US NIH (up \$1.5m, 6.1%) and Wellcome Trust (up \$1.0m, 50.0%). Swedish SIDA and the UBS Optimus Foundation, who each reported funding of \$0.8m, entered the list of top 12 funders for salmonella R&D in 2010. There were modest funding decreases from industry (down \$0.6m, -17.0%) and the EC (down \$0.4m, -29.2%).

**Table 15. Top 12 salmonella R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
US NIH	8,086,868	20,361,114	25,459,290	27,002,825	88.7	51.6	64.7	61.4
Gates Foundation	-	-	1,631,542	3,263,566	0.0	0.0	4.1	7.4
Wellcome Trust	-	1,033,056	1,983,546	2,975,984	0.0	2.6	5.0	6.8
Aggregate industry respondents	-	12,313,110	3,441,047	2,855,467	0.0	31.2	8.7	6.5
Institut Pasteur	-	1,453,175	1,580,962	1,534,888	0.0	3.7	4.0	3.5
German DFG	-	-	546,688	1,297,297	0.0	-	1.4	2.9
European Commission	-	356,682	1,206,626	854,821	0.0	0.9	3.1	1.9
UBS Optimus Foundation	54,194	-	-	848,417	0.6	0.0	-	1.9
Swedish SIDA	-	-	-	786,195	0.0	0.0	0.0	1.8
UK MRC	976,150	1,229,604	868,676	746,135	10.7	3.1	2.2	1.7
Swedish Research Council	-	483,607	393,722	492,477	0.0	1.2	1.0	1.1
Australian NHMRC	-	456,208	495,603	435,430	0.0	1.2	1.3	1.0
Subtotal top 12 salmonella R&D funders*	9,117,212	39,412,504	39,361,396	43,093,502	100.0	99.8	100.0	98.0
Disease Total	9,117,212	39,486,243	39,378,570	43,982,149	100.0	100.0	100.0	100.0

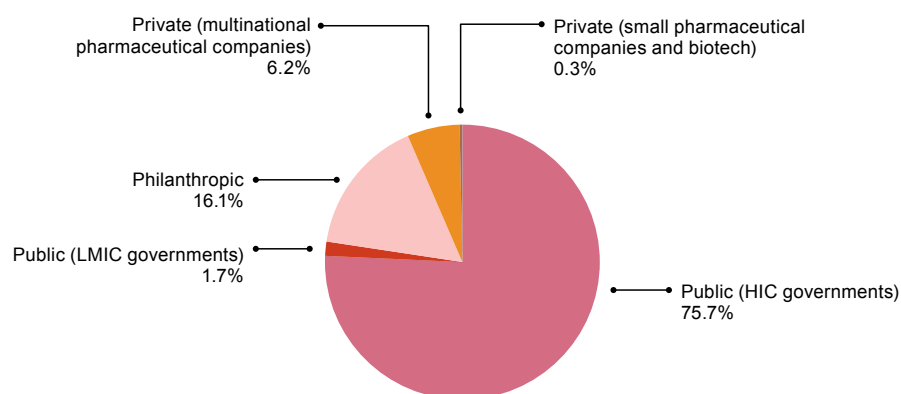
^ Figures are adjusted for inflation and reported in 2007 US dollars

- No reported funding

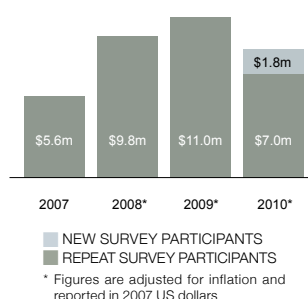
\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

- Did not participate in the survey this year

The public sector accounted for the largest share of salmonella R&D funding in 2010 (\$34.0m, 77.4%), followed by the philanthropic sector (\$7.1m, 16.1%) and private sector (\$2.9m, 6.5%). Public sector funding remained steady but philanthropic funding rose sharply with a YOY increase of \$3.5m (96.1%). Industry investment dropped due to decreased YOY SME funding (down \$1.5m, -91.4%), offset by a modest increase in YOY MNC funding (up \$0.9m, 52.9%).

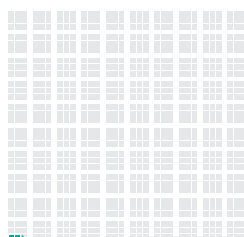
**Figure 15. Salmonella R&D funding by funder type 2010**

## LEPROSY



**\$8.8 MILLION**

TOTAL SPEND ON LEPROSY  
R&D IN 2010



**0.3%**

OF GLOBAL R&D FUNDING

Leprosy is caused by the family of bacteria responsible for tuberculosis, and is also transmitted via droplets from the nose and mouth of untreated patients, but it is far less infectious than TB. Leprosy mainly affects the skin and nerves and, if left untreated, causes nerve damage that leads to muscle weakness and wasting, as well as permanent disabilities and deformities.

Leprosy was responsible for 194,000 DALYs and 5,000 deaths in 2004. A successful leprosy eradication programme means incidence is decreasing. Nevertheless, around a quarter of a million new cases are recorded each year, ranking leprosy as the 11th highest cause of mortality and 12th highest cause of morbidity from neglected diseases.

The move to treatment of leprosy with multidrug therapy (MDT) was a significant step forward from dapsone monotherapy, and it has been provided free-of-charge in all endemic countries since 1995. The current regimen has been standard treatment for 30 years and, although highly effective, requires a 6–12 month course of multi-drug therapy.<sup>33</sup> Further research is needed to provide products for the management of nerve function, and to improve and simplify chemotherapy, develop and improve diagnostics.<sup>34,35</sup>

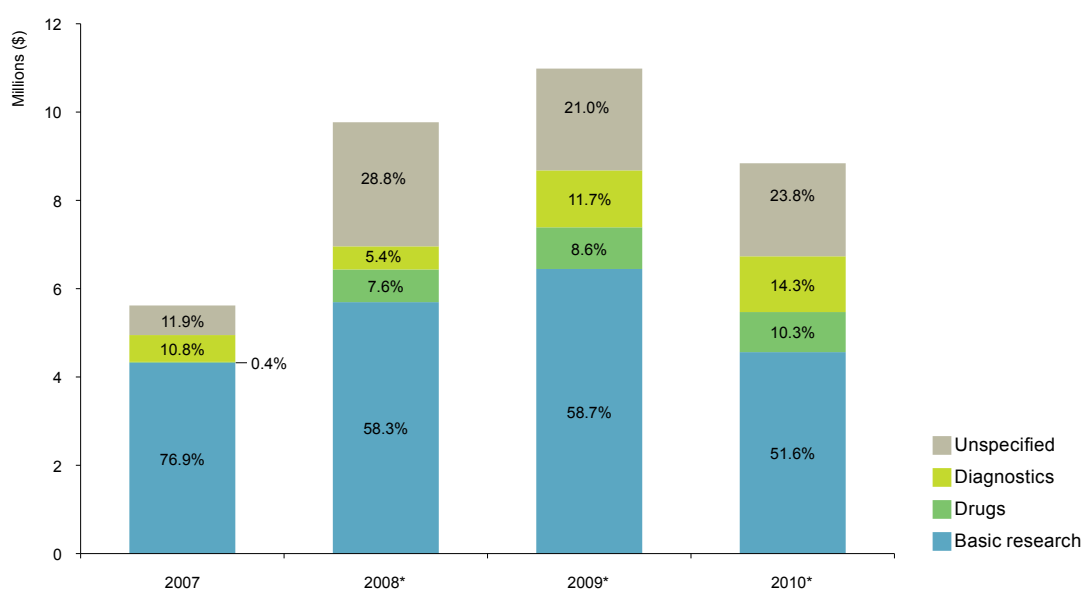
R&D needed for leprosy includes:

- Basic research
- Drugs
- Diagnostics

Global funding for leprosy R&D in 2010 was \$8.8m (\$9.8m). This was lower than in 2009, with YOY funders reducing their investment by \$4.0m (down -36.5%). New survey respondents for 2010 boosted the total funding figure by a further \$1.8m. Leprosy's share of global R&D funding remained low but stable at 0.3%, the same level it has been for the last three years.

As always, we note that the modest size of leprosy funding means that changes in even single grants can have a major impact on funding levels and trends, therefore the data below should be analysed with caution.

As in previous years, basic research funding (\$4.6m) accounted for over half the global investment in leprosy, although its funding share was reduced (51.6% in 2010 compared to 58.7% in 2009). Diagnostic development received \$1.3m (14.3%), and only \$0.9m (10.3%) was allocated to drug development. Funding from YOY funders was down across all product areas, including basic research (down \$2.9m, -45.7%) – largely due to reduced investment by the US NIH – diagnostics (down \$0.5m, -38.5%) and drugs (down \$0.4m, -40.4%).

**Figure 16. Leprosy R&D funding by product type 2007-2010**

\* Figures are adjusted for inflation and reported in 2007 US dollars

Leprosy R&D funding was once again extremely concentrated in 2010, with the top 12 funders contributing 97.6% of total funding and two of these, the US NIH and Indian ICMR, contributing more than 60% of total funding. The most notable decrease was from the Brazilian DECIT, which did not report any leprosy R&D funding in 2010, after providing funding of \$1.9m in 2009, followed by the US NIH (down \$1.8m, -36.1%). The Turing Foundation, Brazilian Innovation Agency (FINEP) and The Leprosy Mission International (TLMI) reported leprosy funding for the first time, joining the list of top 12 funders in 2010, along with the German Leprosy and TB Relief Association (DAHW). The latter two groups are both members of ILEP, the International Federation of Anti-Leprosy Associations; ILEP members were collectively responsible for just under one-fifth (\$1.6m, 18.3%) of all leprosy funding in 2010.

**Table 16. Top 12 leprosy R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
US NIH	1,993,588	3,138,305	5,081,931	3,247,163	35.5	32.1	46.3	36.7
Indian ICMR		2,704,472	1,821,928	2,248,060		27.7	16.6	25.4
Turing Foundation				662,855				7.5
NLR			67,405	630,904			0.6	7.1
Brazilian FINEP			-	432,575			0.0	4.9
ALM	658,000	642,100	519,957	412,911	11.7	6.6	4.7	4.7
TLMI				263,024				3.0
Institut Pasteur	129,154	221,321	183,487	172,128	2.3	2.3	1.7	1.9
Hospital and Homes of St Giles	-	108,131	214,229	162,421	0.0	1.1	2.0	1.8
Colombian Colciencias			98,002	160,419			0.9	1.8
Fondation Raoul Follereau				156,429				1.8
DAHW			36,824	79,488			0.3	0.9
Subtotal top 12 leprosy R&D funders*	5,619,475	9,638,473	10,764,915	8,628,378	100.0	98.7	98.0	97.6
Disease Total	5,619,475	9,769,250	10,984,756	8,840,532	100.0	100.0	100.0	100.0

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

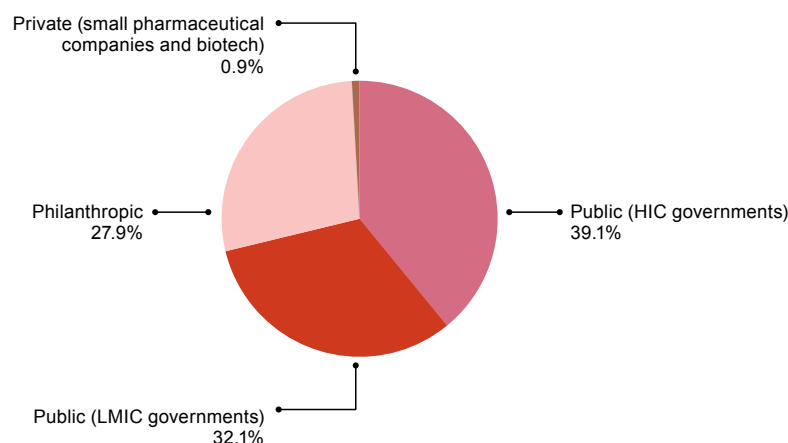
- No reported funding

\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

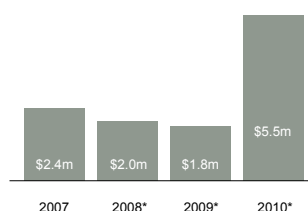
Did not participate in the survey: Any contributions listed for this year are based on data reported by funding recipients so may be incomplete

Public and philanthropic funders accounted for virtually all leprosy R&D funding in 2010 (\$8.8m, 99.1%). Public funders collectively invested \$6.3m (71.2%), split relatively evenly between HIC and LMIC governments, who contributed 39.1% (\$3.5m) and 32.1% (\$2.9m), respectively. However, public sector funding was significantly below 2009 levels, with YOY HIC public funding dropping \$2.7m (-44.1%) and YOY LMIC public funding down \$1.0m (-25.7%). New philanthropic survey participants in 2010 added \$1.7m to leprosy R&D funding, helping to increase the share of funding contributed by the philanthropic sector to 27.9% (up from 8.9% in 2009).

**Figure 17. Leprosy R&D funding by funder type 2010**



# BURULI ULCER

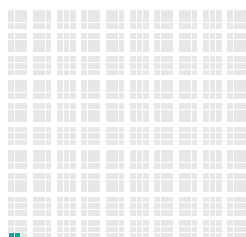


■ REPEAT SURVEY PARTICIPANTS

\* Figures are adjusted for inflation and reported in 2007 US dollars

## \$5.5 MILLION

TOTAL SPEND ON BURULI ULCER  
R&D IN 2010



## 0.2%

OF GLOBAL R&D FUNDING

Buruli ulcer begins as a painless lump that becomes an invasive ulcerating lesion, leading to disfiguration and functional impairment. It typically affects the rural poor, with the greatest number of cases in children under 15 years of age. There is emerging evidence to suggest that HIV co-infection may increase risk for Buruli ulcer, and render the disease more aggressive.<sup>36</sup>

Buruli ulcer occurs in more than 33 countries, predominantly in Western Africa especially in Benin, Côte d'Ivoire and Ghana. No DALY figures are available, although the WHO estimates that Buruli ulcer affects more than 7,000 people each year,<sup>36</sup> with more than 5,000 new cases reported each year from 2006 to 2009.<sup>37</sup>

Available treatment options for Buruli ulcer (antibiotics and surgery) are effective if the disease is diagnosed early, however, a vaccine may be the most effective way to combat Buruli ulcer in the long term. The BCG vaccine (designed for TB) provides short-term protection against Buruli ulcer, but this is not enough. Combination antibiotics (oral and injectable) are effective but cumbersome, as they must be given daily for eight weeks. Issues of treatment failure and resistance are also emerging, emphasising the need for new drugs that are less complicated to administer or can be given for a shorter period. Good diagnostics are particularly important, as early disease can be treated locally and inexpensively, however, current diagnostics are both costly and insufficiently sensitive.<sup>36</sup>

A new simple rapid diagnostic field test is currently in development for Buruli ulcer. Buruli ulcer vaccines are also in early development but are still many years away from being approved for human use.<sup>38</sup>

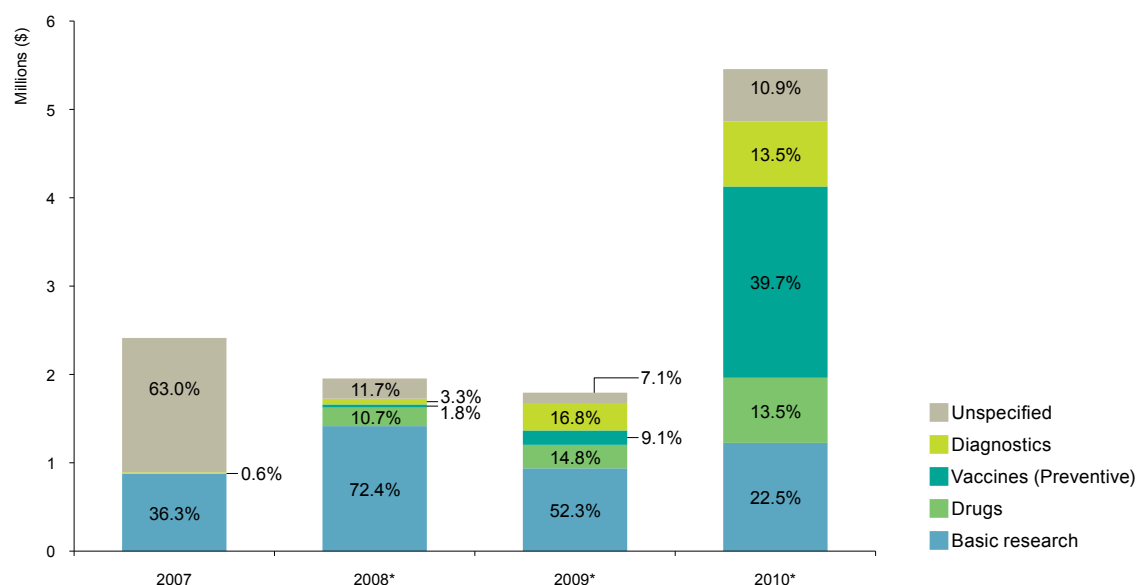
Buruli ulcer needs a wide range of R&D including:

- Basic research
- Drugs
- Vaccines
- Diagnostics

Global funding for Buruli ulcer R&D in 2009 was \$5.5m (\$5.7m). This represented a tripling of funding from 2009, or an increased investment of \$3.7m (up 204%). No new survey participants reported Buruli ulcer funding in 2010,<sup>iii</sup> and there was no loss to follow-up. As a result of the increase, Buruli ulcer's share of total neglected disease R&D investment increased to 0.2% (from 0.1% in 2009).

For the first time in the G-FINDER survey, the majority of Buruli ulcer R&D funding went to product development (\$3.6m, 66.7%) rather than to basic research, which received \$1.2m (22.5%). Vaccine development (\$2.2m, 39.7%) accounted for over a third of total funding, with drugs and diagnostics together accounting for another quarter (each receiving \$0.7m, 13.5%). Funding for basic research increased by \$0.3m (up 30.7%), however its relative share dropped due to a significant increase in funding for vaccine development (up \$2.0m, 1,230%), along with smaller increases for both drugs (up \$0.5m, 178%) and diagnostics (up \$0.4m, 145%). Again, we suggest caution in interpreting these funding trends as changes in single grants are likely to have a major impact.

**Figure 18. Buruli ulcer R&D funding by product type 2007-2010**



\* Figures are adjusted for inflation and reported in 2007 US dollars

Only nine organisations reported Buruli ulcer R&D funding in 2010, with two new funders (Medicor Foundation and Carolito Foundation) and one past funder not investing in Buruli ulcer R&D in 2010 (Fondazione Cariplo). The EC and UBS Optimus Foundation increased their funding modestly, by \$1.9m and \$1.0m respectively, displacing the US NIH from the top funder position.

<sup>iii</sup> Even though information on the UBS Optimus Foundation was included in previous years, a more comprehensive data set was reported by the Foundation this year

**Table 17. Buruli ulcer R&D funders 2010**

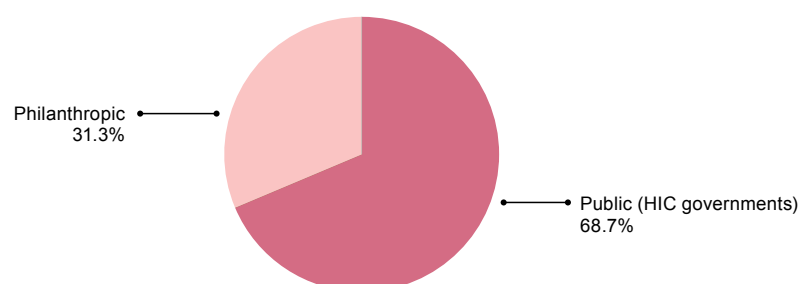
Funder	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
European Commission	726,354	625,656	155,842	2,031,487	30.1	32.0	8.7	37.2
UBS Optimus Foundation		140,246	126,813	1,102,810		7.2	7.1	20.2
US NIH	656,291	403,924	762,804	1,052,519	27.2	20.7	42.5	19.3
Institut Pasteur	645,769	285,729	351,674	481,588	26.8	14.6	19.6	8.8
Medicor Foundation				324,783				6.0
Carolito Foundation				267,540				4.9
Australian NHMRC	220,584	74,844	123,095	118,484	9.1	3.8	6.9	2.2
Belgian FWO	-	84,402	85,031	61,771	0.0	4.3	4.7	1.1
Wellcome Trust	-	40,862	6,546	15,045	0.0	2.1	0.4	0.3
Multiple funders	148,752	-	-	-	6.2	0.0	0.0	0.0
Aggregate industry respondents	15,200	285,685	-	-	0.6	14.6	0.0	0.0
Fondazione Cariplo		13,116	181,913	-		0.7	10.1	0.0
<b>Disease Total</b>	<b>2,412,950</b>	<b>1,954,465</b>	<b>1,793,718</b>	<b>5,456,026</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

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

- No reported funding

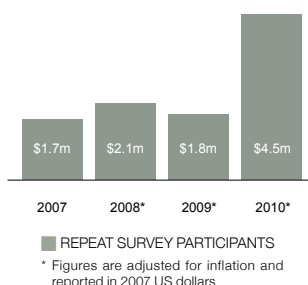
Did not participate in the survey: Any contributions listed for this year are based on data reported by funding recipients so may be incomplete

Public and philanthropic funders provided 100% (\$5.5m) of Buruli ulcer R&D funding in 2010, as industry did not contribute for the second consecutive year. The public sector provided \$3.7m (68.7%), all of which came from HICs, while the philanthropic sector accounted for the remaining \$1.7m (31.3%). YOY HIC public funders increased their investment by \$2.3m (up 153%) in 2010, while YOY philanthropic funding increased by \$1.4m (up 442%).

**Figure 19. Buruli ulcer R&D funding by funder type 2010**

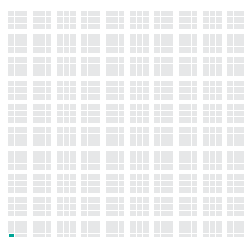


## TRACHOMA



**\$4.5 MILLION**

TOTAL SPEND ON TRACHOMA  
R&D IN 2010



**0.1%**

OF GLOBAL R&D FUNDING

Trachoma is an eye infection spread by contact with eye and nose discharge from an infected person, and by eye-seeking flies. Untreated trachoma is responsible for about 3% of blindness worldwide.<sup>39</sup>

Trachoma is endemic in 57 countries with an estimated 7.6 million people severely visually impaired or blind from the disease, and many more millions in need of treatment.<sup>40</sup> Trachoma was responsible for 1.3 million DALYs in 2004, making it the 10th highest cause of morbidity from neglected diseases. Mortality was, however, zero because, although debilitating, trachoma is not a fatal disease (although some studies conducted in sub-Saharan Africa to assess excess mortality caused by visual impairment have found an increase in mortality among blind people compared with sighted controls).<sup>40</sup>

Surgery is the only effective management for the complications of trachoma that lead to blindness, but high recurrence rates and poor acceptance of surgery make this option ineffective. The International Trachoma Initiative provides free azithromycin in 18 endemic countries,<sup>41</sup> although over-reliance on a single drug increases the risk of resistance. Clinical diagnosis of trachoma is not always reliable, but current diagnostic tests are not a viable alternative due to their cost and complexity.

A simple, cheap, effective point-of-care dipstick test has shown promise in early trials.<sup>42</sup> There have recently been promising signs in early vaccine research, but there has not been a clinical trial of a trachoma vaccine since the 1970s.<sup>43</sup>

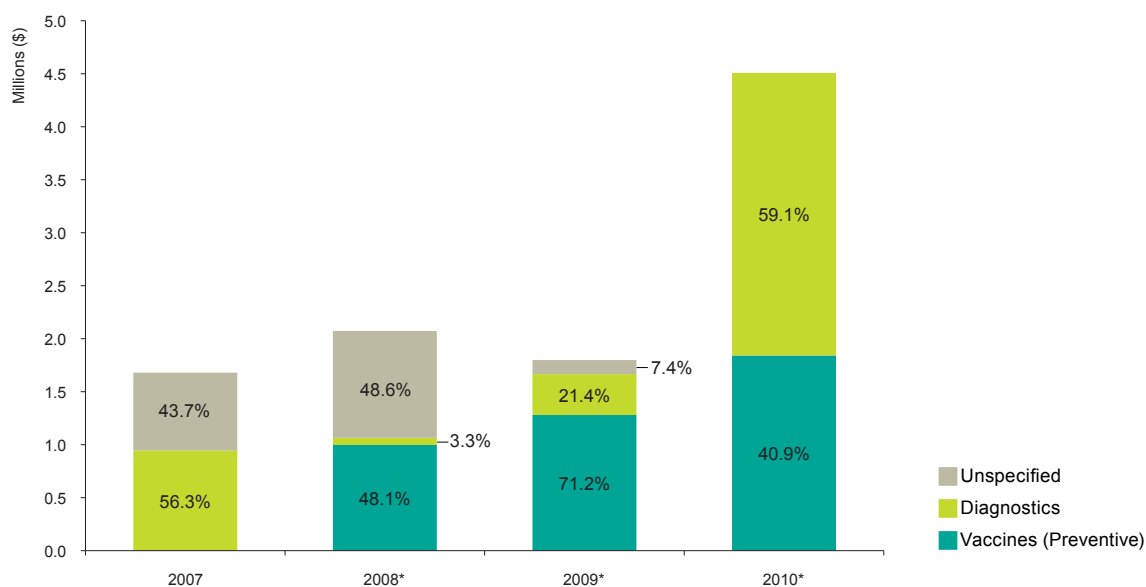
New products needed for trachoma include:

- Vaccines
- Diagnostics

Global funding for trachoma R&D in 2010 was \$4.5m (\$4.7m). This was a two and a half-fold increase on 2009 (up \$2.7m, 151%). There was no data reported by new survey participants, and none lost to follow-up. The global share of R&D funding for trachoma remained unchanged from 2009 at 0.1%.

As with other low-funded areas, apparent funding trends should be treated with caution, since they are more likely to reflect changes in single grants or programmes than a significant underlying pattern. We also note that improved reporting by survey participants means that 2010 is the first year in which there has been no 'unspecified' funding. That said, the big jump in trachoma R&D funding in 2010 was almost all due to increased investment in diagnostics (up \$2.3m, 592%) – largely due to a single organisation investing in trachoma diagnostics for the first time – with a smaller increase in vaccine development (up \$0.6m, 43.8%). The 2010 funding boost meant that diagnostics received the majority of trachoma R&D funding (\$2.7m, 59.1%), with vaccines receiving the remaining \$1.8m (40.9%).

**Figure 20. Trachoma R&D funding by product type 2007-2010**



\* Figures are adjusted for inflation and reported in 2007 US dollars

Apart from industry, only two organisations reported trachoma R&D funding in 2010. Virtually all 2010 funding (99.2%) came from the US NIH and the pharmaceutical industry, with the US NIH being the only consistent funder of trachoma R&D over the past three years.

**Table 18. Trachoma R&D funders 2010**

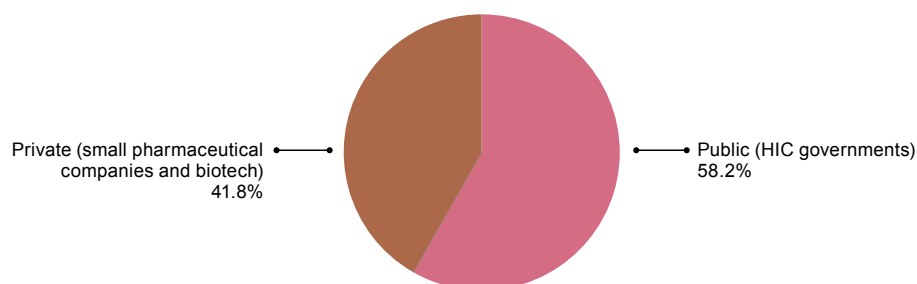
Funder	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
US NIH	-	1,037,612	1,665,913	2,591,176	0.0	50.0	92.6	57.5
Aggregate industry respondents	104,000	96,339	-	1,882,470	6.2	4.6	0.0	41.8
Institut Pasteur	-	27,432	-	34,072	0.0	1.3	0.0	0.8
SSI	-	703,674	-	-	0.0	33.9	0.0	0.0
Swedish Research Council	-	38,276	132,550	-	0.0	1.8	7.4	0.0
Brazilian DECIT	-	170,326	-	-	0.0	8.2	0.0	0.0
Wellcome Trust	1,461,110	-	-	-	87.0	0.0	0.0	0.0
Johns Hopkins University	29,198	-	-	-	1.7	0.0	0.0	0.0
Multiple funders	85,403	-	-	-	5.1	0.0	0.0	0.0
<b>Disease Total</b>	<b>1,679,711</b>	<b>2,073,659</b>	<b>1,798,463</b>	<b>4,507,718</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

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

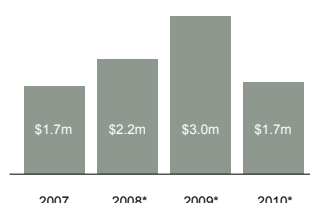
- No reported funding

In 2010, all trachoma R&D funding came from HIC public funders (\$2.6m, 58.2%) and SMEs (\$1.9m, 41.8%). HIC public funding increased moderately (up \$0.8m, 46.0%) but, as in previous years, this was more likely a reflection of the sporadic nature and low levels of trachoma funding than a noteworthy trend. This was the first year of the G-FINDER survey that SMEs reported investment in trachoma R&D.

**Figure 21. Trachoma R&D funding by funder type 2010**



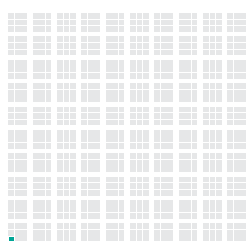
# RHEUMATIC FEVER



■ REPEAT SURVEY PARTICIPANTS  
\* Figures are adjusted for inflation and reported in 2007 US dollars

## \$1.7 MILLION

TOTAL SPEND ON RHEUMATIC FEVER  
R&D IN 2010



## 0.1%

OF GLOBAL R&D FUNDING

Rheumatic fever is a bacterial infection, caused by *Group A streptococcus*, that most commonly affects children 5–14 years of age. It usually follows an untreated bacterial throat infection and can lead to rheumatic heart disease, in which the heart valves are permanently damaged. It may progress to heart failure and stroke.

Rheumatic fever was responsible for 5.1 million DALYs and 280,000 deaths in 2004. It was the seventh highest cause of mortality and eighth highest cause of morbidity from neglected diseases.

Acute rheumatic fever can be treated using currently available products, although post-infection prophylaxis requires multiple dosing with antibiotics. Treatment of rheumatic heart disease often requires surgery. The primary area of R&D need is in the development of a vaccine.

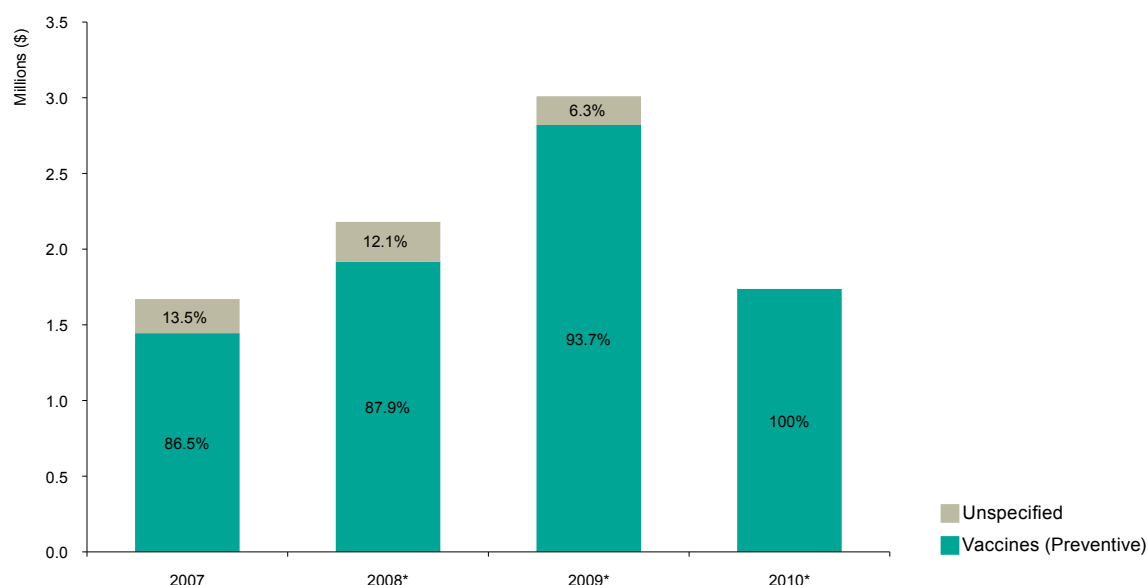
A number of vaccines are currently in development, including one developed by the Queensland Institute of Medical Research (QIMR), currently in Phase I trials.<sup>44</sup> Also notable is the establishment of the Hilleman Laboratories in India, a joint venture between the Wellcome Trust and Merck & Co. that will accelerate the development of a *Streptococcus A* vaccine.<sup>45</sup>

R&D needed for rheumatic fever is:

- Vaccines

Global funding for rheumatic fever R&D in 2010 was \$1.7m (\$2.0m). This was a proportionally large funding drop from 2009 levels (down \$1.3m, -42.3%), which was entirely due to decreased industry funding. There was no funding from new survey participants for rheumatic fever and no funding lost to follow-up. The global share of R&D funding for rheumatic fever in 2009 remained at 0.1%. As with other very low-funded diseases, we note the difficulty in commenting reliably on rheumatic fever funding trends. The only investments tracked by G-FINDER for rheumatic fever are vaccines, and improved reporting this year meant that there was no 'unspecified' funding for 2010.

**Figure 22. Rheumatic fever R&D funding by product type 2007-2010<sup>^</sup>**



\* Figures are adjusted for inflation and reported in 2007 US dollars

<sup>^</sup> G-FINDER's scope for rheumatic fever only includes preventive vaccines

Only four organisations invested in rheumatic fever R&D in 2010. Three of these are based in Australia, as rheumatic fever is still prevalent in Aboriginal and Torres Strait Islander populations, and each of these modestly increased their funding in 2010, bringing their collective share of global funding to 54.0%. However, the US NIH and Australian NHMRC have been the only consistent funders of rheumatic fever R&D over the past four years.

**Table 19. Rheumatic fever R&D funders 2010**

Funder	2007 (US\$)	2008 (US\$) <sup>^</sup>	2009 (US\$) <sup>^</sup>	2010 (US\$) <sup>^</sup>	2007%	2008%	2009%	2010%
US NIH	1,284,919	629,315	745,605	798,886	76.9	28.9	24.8	46.0
Australian NHMRC	385,170	338,310	573,410	686,631	23.1	15.5	19.1	39.5
Australian National Heart Foundation	-	54,212	51,431	148,513	0.0	2.5	1.7	8.6
Australia - India Strategic Research Fund	-	-	-	102,846	-	-	-	5.9
Undisclosed funder	-	28,691	-	-	0.0	1.3	0.0	0.0
Swedish Research Council	-	58,887	58,911	-	0.0	2.7	2.0	0.0
Aggregate industry respondents	-	963,391	1,449,696	-	0.0	44.2	48.2	0.0
Australian DIISR/ARC	-	106,805	-	-	0.0	4.9	0.0	0.0
Fondazione Cariplo	-	-	130,685	-	-	0.0	4.3	0.0
<b>Disease Total</b>	<b>1,670,089</b>	<b>2,179,609</b>	<b>3,009,737</b>	<b>1,736,877</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

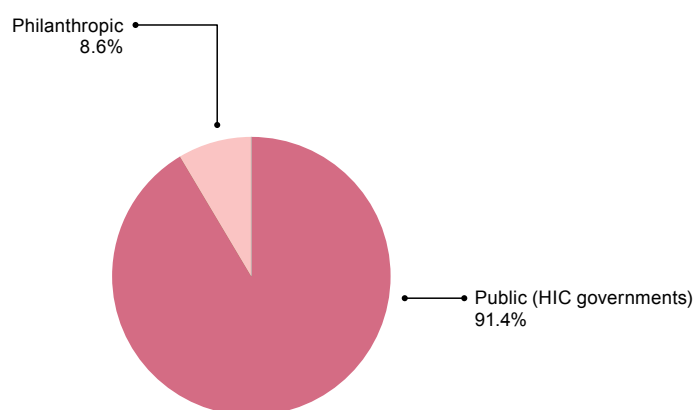
<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

- No reported funding

Did not participate in the survey: Any contributions listed for this year are based on data reported by funding recipients so may be incomplete

The public and philanthropic sectors accounted for all rheumatic fever R&D funding in 2010. All public funding (\$1.6m, 91.4% of the global total) came from HIC governments, with YOY public funders increasing their contributions by 15.3% (up \$0.2m). YOY philanthropic funders decreased their investment by \$0.03m (-18.5%). Industry provided no funding in 2010, after investing \$1.4m in 2009.

**Figure 23. Rheumatic fever R&D funding by funder type 2010**



**Table 20. Summary table of overall neglected disease and product funding in 2010 (\$m)\***

Disease	Basic Research	Drugs	Vaccines (Preventive)	Vaccines (Therapeutic)	Microbicides	Vector control products	Diagnostics	Unspecified	Total
<b>HIV/AIDS</b>	180.92	34.95	613.58		187.81		31.68	24.09	1,073.03
<b>Tuberculosis</b>	160.50	258.87	95.32	0.66			51.40	8.61	575.36
<b>Malaria</b>	163.37	228.14	91.09			28.55	10.52	25.37	547.04
<i>P. falciparum</i>	90.79	133.85	62.78			3.85	3.79	3.83	298.89
<i>P. vivax</i>	8.34	27.77	7.76			0.30	0.34	5.14	49.64
Other and/or unspecified malaria strains	64.24	66.53	20.55			24.39	6.40	16.40	198.51
<b>Dengue</b>	36.92	12.67	116.16			4.87	6.01	1.02	177.64
<b>Diarrhoeal diseases</b>	41.27	17.35	84.06				9.99	6.26	158.92
Rotavirus			46.55					1.18	47.73
Cholera	17.82	0.38	6.92				0.37	-	25.49
Shigella	11.81	0.98	7.30				1.51	1.70	23.30
<i>Cryptosporidium</i>	4.96	3.28	0.16				0.92	-	9.33
Enterotoxigenic <i>E.coli</i> (ETEC)			6.01				0.55	-	6.56
Giardia							0.32	0.08	0.40
Enterotoxigenic <i>E.coli</i> (EAggEC)			-				0.03	-	0.03
Multiple diarrhoeal diseases	6.67	12.71	17.11				6.29	3.29	46.07
<b>Kinetoplastids</b>	62.90	57.63	13.85	1.10		0.03	9.64	2.72	147.87
Leishmaniasis	23.92	21.45	12.36	1.06			4.77	2.19	65.77
Sleeping sickness	24.93	8.61	0.77			0.03	2.59	0.51	37.44
Chagas' disease	12.41	4.60	0.72	0.04		-	2.28	0.01	20.06
Multiple kinetoplastids	1.64	22.97	-	-		-	-	-	24.60
<b>Bacterial pneumonia &amp; meningitis</b>			79.47				3.98	9.42	92.87
<i>Streptococcus pneumoniae</i>			67.30				2.82	0.64	70.76
<i>Neisseria meningitidis</i>			12.17				0.21	0.34	12.72
Both bacteria							0.94	8.44	9.38
<b>Helminths (worms &amp; flukes)</b>	40.02	13.46	10.20			0.62	2.09	7.31	73.69
Schistosomiasis (bilharziasis)	18.88	2.00	2.46			-	0.68	3.99	28.01
Lymphatic filariasis (elephantiasis)	5.58	5.00				0.46	0.19	2.12	13.35
Onchocerciasis (river blindness)	0.67	4.70	0.81			0.10	0.98	0.77	8.03
Hookworm (ancylostomiasis & necatoriasis)	2.48	-	3.85					0.10	6.43
Roundworm (ascariasis)	1.44	0.51						0.09	2.04
Tapeworm (cysticercosis/taeniasis)	1.37	-				0.06		0.10	1.54
Whipworm (trichuriasis)	1.17	-						0.09	1.26
Strongyloidiasis & other intestinal roundworms	1.19	0.03	-				0.03	-	1.25
Multiple helminths	7.23	1.21	3.08			-	0.21	0.04	11.78
<b>Salmonella infections</b>	29.60	0.10	12.45				1.83	-	43.98
Non-typhoidal <i>Salmonella enterica</i> (NTS)	15.97	-	2.35				0.94	-	19.26
Typhoid and paratyphoid fever ( <i>S. typhi</i> , <i>S. paratyphi</i> A)	4.05	0.05	8.90				0.89	-	13.89
Multiple salmonella infections	9.57	0.06	1.20				-	-	10.83

Disease	Basic Research		Drugs	Vaccines (Preventive)	Vaccines (Therapeutic)	Microbicides	Vector control products	Diagnostics	Unspecified	Total
Leprosy	4.56	0.91						1.26	2.11	8.84
Buruli ulcer	1.23	0.74		2.16				0.74	0.59	5.46
Trachoma				1.84				2.67	-	4.51
Rheumatic fever				1.74					-	1.74
Core funding of a multi-disease R&D organisation										76.88
Unspecified disease										47.49
Platform technologies	General diagnostic platforms			Adjuvants and immunomodulators			Delivery technologies and devices			
	9.37			9.17			8.82			27.36
Total R&D funding										3,062.67

\* All figures are FY 2010, adjusted for inflation and reported in 2007 US dollars

- No reported funding

Category not included in G-FINDER



## FINDINGS - NEGLECTED DISEASE FUNDERS

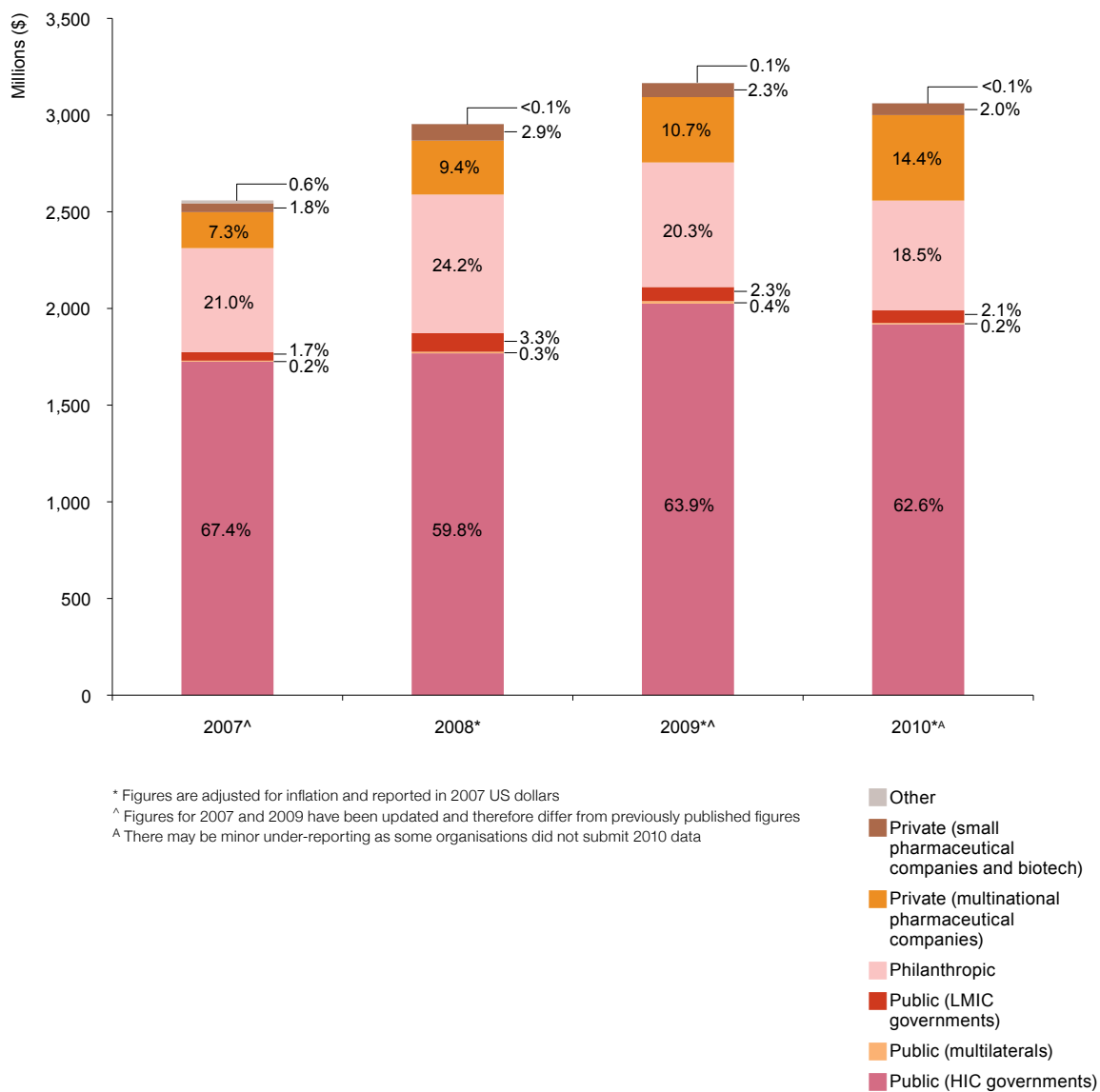
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### Funder overview

As in previous survey years, the public sector played a key role in neglected disease R&D, providing almost two-thirds (\$2.0bn, 65%) of global funding, compared to \$2.1bn (66.5%) in 2009. The vast majority of public funding (\$1.9bn, 96.4%) came from HIC governments. However, in a major change, the philanthropic sector did not play the dominant role seen in previous years, with philanthropic contributions of \$568.1m (18.5%) being closely matched by industry investments of \$503.5m (16.4%). The remaining investments came from unspecified funders (\$1.0m, 0.03%).

All sectors cut their funding in 2010 with the exception of the pharmaceutical industry. This resulted in a global decrease in YOY R&D funding of \$109.1m (-3.5%). The most dramatic drop was in public funding (down \$135.8m, -6.5%) due to decreased funding from all public sectors including HICs (down \$118.5m, -5.9%), LMICs (down \$11.0m, -15.7%) and multilaterals (down \$6.3m, -47.9%). Philanthropic funding also decreased by a substantial \$79.8m (-12.4%); and SMEs in Innovative Developing Countries (IDCs) halved their investments (down \$7.0m, -49.9%). MNCs softened the impact of these across-the-board cuts with a very significant increase of \$114.7m (up 35.1%) in 2010, while SMEs in the developed world held their funding fairly steady (down \$0.4m, -0.9%), resulting in an overall industry increase of \$107.3m (up 28.2%) once the IDC industry cutbacks were taken into account.

New survey participants accounted for an additional \$33.5m in reported funding, including \$14.0m reported by new SMEs, \$12.0m reported by new public sector organisations in HICs and \$3.5m reported by new public sector organisations in LMICs. A further \$30.7m in funding was lost-to-follow-up, although many of these organisations are likely to have continued to provide funding in 2010.

**Figure 24. Total funding by funder type 2007-2010**

## Public funders

In contrast to the public sector increases seen in previous years, the effect of the global financial crisis on public sector neglected disease R&D funding became evident for the first time in 2010. Thirteen of the top 20 governments cut their neglected disease R&D funding in 2010, as did eight of the top 12 government funders (who represent 93.1% of total public funding). The decrease was seen across all groups including HIC governments (down \$118.5m, -5.9%), LMIC governments (down \$11m, -15.7%) and multilaterals (down \$6.3m, -47.9%).

For the fourth consecutive year, the top three public funders were the US, the UK and EC. The US contributed nearly 70% of global public funding (\$1.39bn, 69.7%), and provided over \$1bn dollars more than the next largest funder. US funding was primarily provided by the NIH, which invested \$1.2bn into neglected disease R&D. By contrast, all governments outside the top three invested less than \$50m in 2010.

Although they maintained their position as by far the world's largest government funder, US public YOY funding nevertheless dropped significantly in 2010 (down \$74.5m, -5.1%), driven by a \$44.5m drop in NIH funding. The fall in NIH funding was despite a doubling (from \$72.7m to \$149.4m) of 2010 funding linked to the US Government's American Recovery and Reinvestment Act (ARRA), a government stimulus programme that includes funding to advance scientific research and technology by groups such as the NIH.

The UK was one of the very few countries where public funding for neglected disease R&D increased, and the only country where it rose substantially (up \$21.2m, 14.9%), with much of this driven by a \$12.8m (15.2%) increase by UK DFID. This funding increase is particularly significant as the majority of other governments cut their YOY funding in 2010, including the EC (down \$25.8m, -21.8%), Brazil (down \$20.8m, -65.6%), Sweden (down \$14.2m, -43%), the Netherlands (down \$11.2m, -39.1%), Denmark (down \$8.4m, -49.7%), France (down \$7.4m, -15.6%), Canada (down \$7.4m, -43.9%), Spain (down \$5.9m, -29.9%), Germany (down \$4.3m, -12.5%) and Norway (down \$3.5m, -20.0%). We note, however, that the cut in EC funding was largely due to the conclusion of a five year grant to the European and Developing Countries Clinical Trials Partnership (EDCTP), which currently has a no-cost extension. We also note that the apparent 2010 funding increases by Germany and Switzerland shown in Table 21 are artefactual: in the case of Switzerland, due to better data reporting; while the apparent German increase was due to \$7.9m reported by new survey participants, which masked a real drop of \$4.3m from YOY German public funders.

IDCs had a mixed investment record in 2010. India maintained its place in the top 12 public funders, with an increase of \$6.5m (26.5%) in YOY funding. However, Brazil dropped out of the top 12, with a YOY funding cut from \$31.8m to \$10.9m, driven by a \$12.2m drop in funding by the Brazilian DECIT. Despite this, Brazil's public funders nevertheless invested more in neglected disease R&D in 2010 than Canada, Italy, Denmark or Japan.

**Table 21. Top 12 public funders 2010**

Country	2007 (US\$)	2008 (US\$) <sup>^</sup>	2009 (US\$) <sup>^</sup>	2010 (US\$) <sup>^</sup>	2007%	2008%	2009%	2010%
United States of America <sup>C</sup>	1,252,598,360	1,258,318,321	1,461,035,845	1,386,550,051	70.6	67.2	69.2	69.7
United Kingdom <sup>C</sup>	104,684,734	103,328,720	142,591,385	163,812,491	5.9	5.5	6.8	8.2
European Commission	121,366,882	129,899,906	118,311,296	92,529,756	6.8	6.9	5.6	4.6
France <sup>B,C</sup>	15,667,008	29,296,116	48,161,454	40,534,200	0.9	1.6	2.3	2.0
Germany	12,055,796	3,728,140	34,120,231	37,755,148	0.7	0.2	1.6	1.9
India		32,518,735	24,587,971	31,099,602		1.7	1.2	1.6
Australia	18,166,780	25,132,872	22,767,236	24,976,220	1.0	1.3	1.1	1.3
Sweden	21,566,527	25,600,321	33,096,084	18,854,648	1.2	1.4	1.6	0.9
Netherlands	34,088,694	26,976,797	28,741,454	18,067,252	1.9	1.4	1.4	0.9
Norway	13,271,949	16,603,371	17,275,683	13,816,625	0.7	0.9	0.8	0.7
Spain	10,723,060	26,701,408	19,679,113	13,800,191	0.6	1.4	0.9	0.7
Switzerland	6,586,409	3,920,220	6,962,865	11,949,269	0.4	0.2	0.3	0.6
Subtotal top 12 public funders <sup>*,C</sup>	1,666,183,078	1,734,272,596	1,982,152,491	1,853,745,452	93.9	92.6	93.9	93.1
Total public funding <sup>C</sup>	1,775,079,830	1,872,824,080	2,111,645,711	1,990,081,760	100.0	100.0	100.0	100.0

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

<sup>\*</sup> Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

<sup>B</sup> 2009 and 2010 funding data likely to be incomplete

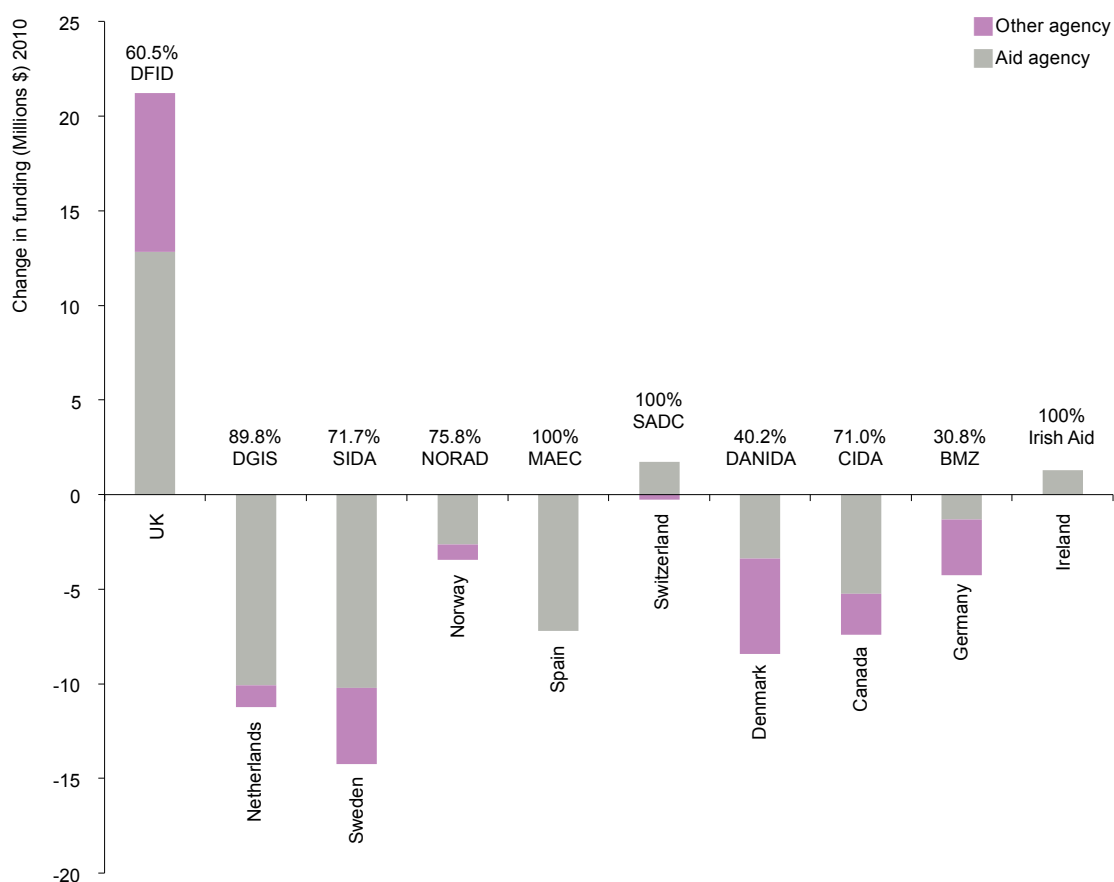
<sup>C</sup> Figures for 2007 and 2009 have been updated and therefore differ from previously published figures

Did not participate in the survey this year

#### PUBLIC FUNDING AND INTERNATIONAL AID

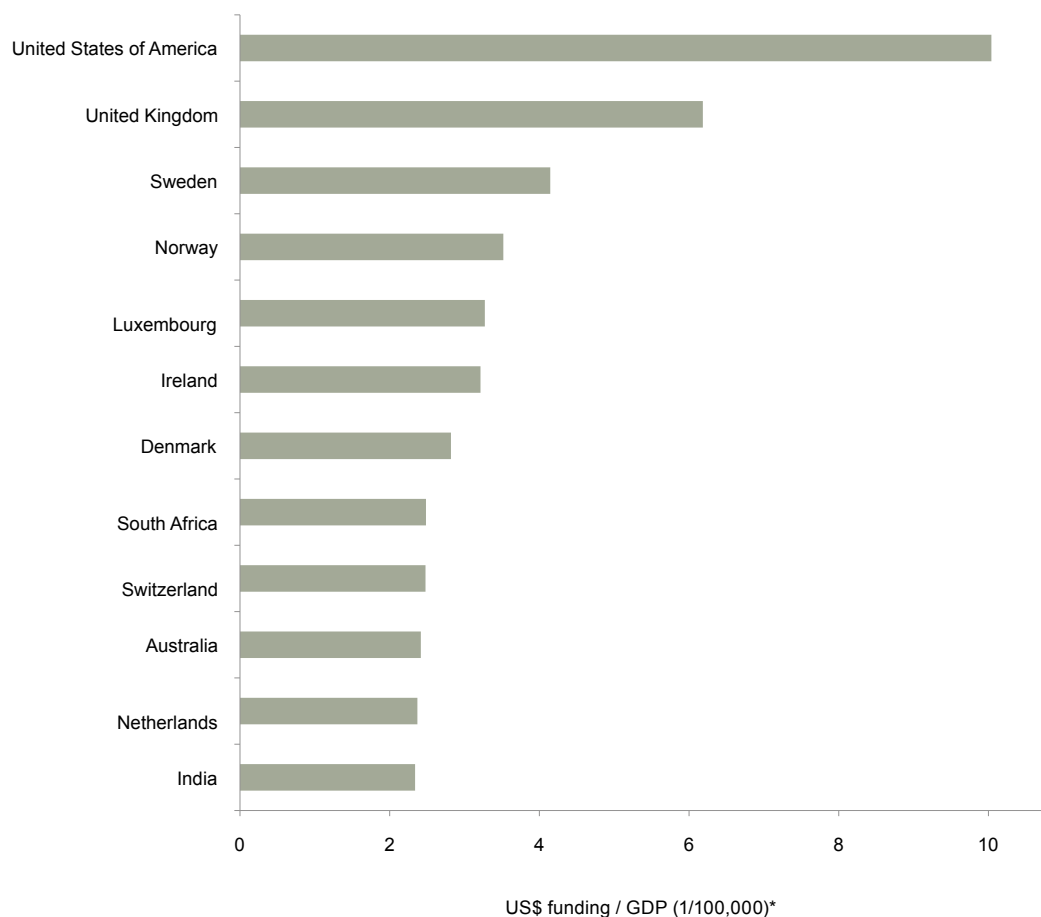
The global financial crisis has put HIC governments under political pressure to focus investments on domestic populations or on global health programmes that demonstrate more immediate impacts. The result has been across-the-board-cuts in aid agency budgets with notable exceptions such as UK DFID, which is not only protected from domestic budget cuts but has pledged to increase Official Development Assistance (ODA) in the coming years.<sup>46</sup> These cuts had a dramatic impact, with drops in aid agency funding accounting for over 60% of the R&D funding drop in many HICs in 2010 (see Figure 25).

Decreasing aid budgets are particularly troubling for PDPs, since aid agencies have traditionally provided around one-third of PDP funding (35.6% in 2009). In 2010, aid agency funding to PDPs dropped by \$22.5m (-19.3%) offset by a substantial increase of \$19.7m in PDP funding from UK DFID. These cuts put PDP programmes at significant risk – particularly in view of the earlier PDP funding cuts of \$50.0m in 2009.

**Figure 25. Changes in national R&D funding 2010: contribution from aid agencies****PUBLIC FUNDING BY GDP**

Absolute funding can be a misleading measure of public R&D investment, particularly for smaller countries and LMICs. Therefore, country investments were also analysed in relation to gross domestic product (GDP).

This approach provided a somewhat different picture to that seen in Table 21. Four new countries – Denmark, Luxembourg, Ireland and South Africa – appeared in the list of top 12 public funders by GDP; while Germany, France and Spain dropped out of the list once the GDP criterion was applied. However, the majority of countries showed consistency between absolute funding and funding as a proportion of GDP, with the US, UK, Sweden, Norway, Netherlands, Switzerland, Australia and India all appearing in the top 12 using either metric. We note that two IDCs – South Africa and India – both performed strongly in terms of funding by GDP.

**Figure 26. Public funding by GDP 2010**

\* GDP figures taken from International Monetary Fund (IMF) World Economic Outlook Database

#### HIGH-INCOME COUNTRIES (HICs)

HIC governments and multilaterals reduced their overall YOY R&D investments by \$124.9m (-6.1%) in 2010. This smaller pie was, however, shared across the neglected diseases in much the same proportions as in 2009, with the top three funded diseases once again being HIV/AIDS (\$891.2m, 46.3%), malaria (\$287.7m, 14.9%) and TB (\$286.1m, 14.9%). All other diseases received less than \$100m in funding each, while leprosy, Buruli ulcer, rheumatic fever and trachoma received less than \$5m each.

Malaria saw the largest increase in HIC funding (\$25.3m, 9.7%), primarily due to a \$20.2m increase in funding from UK DFID, the entirety of which went to MMV for drug development; and a \$16.9m increase from the US NIH. There were also small increases in HIC funding for bacterial pneumonia and meningitis (up \$4.2m, 35.6%) and platform technologies (up \$3.4m, 51.0%).

Most other diseases fared less well. Although it retained the largest overall funding share, receiving nearly half of all HIC funding, HIV/AIDS experienced the largest funding drop (down \$72.6m, -7.6%), primarily due to cuts by the US NIH (down \$31.6m), UK DFID (down \$17.3m) and EC (down \$8.0m). We note that UK DFID's decrease was largely due to funding cuts to several intermediaries working in the HIV/AIDS field, including the International AIDS Vaccine Initiative (IAVI) and Microbicides Development Program (MDP), as well as to cyclical disbursement of a grant to the International Partnership for Microbicides (IPM). Funding for TB R&D was also down (\$24.7m, -8.0%), while diarrhoeal diseases saw a decrease of \$15.8m (-17.3%) due to lower investments from the US NIH (down \$10.5m) and US DOD (down \$5.1m). Dengue funding dropped by \$13.5m (-17.9%).

**Table 22. Public funding (high-income countries and multilaterals) by disease 2007-2010**

Disease or R&D area	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
HIV/AIDS*	934,216,900	919,537,895	959,365,147	891,198,304	54.0	51.8	47.1	46.3
Malaria*	216,669,290	232,502,900	263,175,158	287,723,341	12.5	13.1	12.9	14.9
Tuberculosis*	220,574,931	209,438,529	310,078,935	286,072,312	12.7	11.8	15.2	14.9
Kinetoplastids	45,914,987	79,417,771	95,004,648	95,976,744	2.7	4.5	4.7	5.0
Diarrhoeal diseases	43,811,832	60,425,405	91,444,544	75,611,767	2.5	3.4	4.5	3.9
Dengue	58,170,246	49,432,879	75,074,454	61,609,653	3.4	2.8	3.7	3.2
Helminths (Worms & Flukes)	37,290,440	32,592,635	47,354,561	45,286,626	2.2	1.8	2.3	2.4
Salmonella infections	9,063,018	26,066,338	32,305,261	33,304,890	0.5	1.5	1.6	1.7
Bacterial Pneumonia & Meningitis	10,045,739	9,607,259	12,096,326	16,193,251	0.6	0.5	0.6	0.8
Buruli ulcer	2,248,998	1,474,556	1,478,445	3,745,849	0.1	0.1	0.1	0.2
Leprosy	3,476,655	3,568,644	6,179,200	3,454,795	0.2	0.2	0.3	0.2
Trachoma	29,198	1,806,994	1,798,463	2,625,248	0.0	0.1	0.1	0.1
Rheumatic Fever	1,670,089	1,133,316	1,377,925	1,588,364	0.1	0.1	0.1	0.1
Platform technologies	3,589,301	5,451,059	6,818,132	10,018,424	0.2	0.3	0.3	0.5
<i>General diagnostic platforms</i>	1,045,152	1,906,221	1,805,033	5,074,675	0.1	0.1	0.1	0.3
<i>Adjuvants and immunomodulators</i>	23,260	731,956	2,622,387	3,781,680	0.0	0.0	0.1	0.2
<i>Delivery technologies and devices</i>	2,520,889	2,812,882	2,390,713	1,162,069	0.1	0.2	0.1	0.1
Core funding of a multi-disease R&D organisation	96,754,956	87,332,082	66,903,506	69,778,296	5.6	4.9	3.3	3.6
Unspecified disease	47,663,432	56,598,960	68,093,441	41,062,149	2.8	3.2	3.3	2.1
<b>Total public funding (HICs/multilaterals)*</b>	<b>1,731,190,015</b>	<b>1,776,387,220</b>	<b>2,038,548,147</b>	<b>1,925,250,012</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

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

\* Figures for 2009 have been updated and therefore differ from previously published figures

## LOW- AND MIDDLE-INCOME COUNTRIES (LMICs)

The G-FINDER survey was expanded in 2010 to include neglected disease R&D funding from the governments of Argentina, Chile, Malaysia, Mexico, Nigeria and Uganda, as well as continuing reporting from LMIC governments who participated in the survey in previous years (Ghana, Colombia and Thailand, and the three IDC governments – Brazil, India and South Africa).

Collectively, these LMIC governments invested \$64.8m into neglected disease R&D in 2010, accounting for 3.3% of global public funding. Just over three-quarters (\$49.6m, 76.5%) of the reported LMIC funding came from the three IDC governments included in the G-FINDER survey.

HIV/AIDS was the top funded disease by LMICs in 2010, receiving 25.6% of funding (\$16.6m). LMICs gave no funding to Buruli ulcer, rheumatic fever and trachoma and very little to helminths, salmonella infections and bacterial pneumonia and meningitis, each of which received less than \$1m in 2010.

**Table 23. Public funding by LMICs by disease 2010**

Disease or R&D area	2010 (US\$) <sup>^</sup>	2010%
HIV/AIDS	16,566,425	25.6
Kinetoplastids	9,791,798	15.1
Tuberculosis	9,046,580	14.0
Malaria	8,005,557	12.3
Dengue	6,788,216	10.5
Diarrhoeal diseases	6,012,338	9.3
Leprosy	2,841,055	4.4
Helminths (Worms & Flukes)	919,723	1.4
Salmonella infections	733,825	1.1
Bacterial Pneumonia & Meningitis	346,435	0.5
Platform technologies	2,743,252	4.2
<i>Delivery technologies and devices</i>	1,480,053	2.3
<i>General diagnostic platforms</i>	734,540	1.1
<i>Adjuvants and immunomodulators</i>	528,660	0.8
Core funding of a multi-disease R&D organisation	1,036,545	1.6
<b>Grand Total</b>	<b>64,831,747</b>	<b>100.0</b>

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars



Analysis of LMICs who have reported data for several years showed a significant drop in their funding (down \$11.0m, -15.7%). There were dramatic funding cuts in Brazil (down \$20.9m, -65.6%) due to a freeze while the Ministry of Health reviewed its 2003-2009 activities as part of the planning process conducted by the new administration; and a modest decrease in South Africa (down \$0.7m, -8.2%). However, public funding increased by \$6.5m (26.5%) in India and by small amounts across the other YOY LMIC participants.

The impact of these cuts was evident at the disease level, where all but four diseases – HIV/AIDS, diarrhoeal diseases, TB and salmonella infections – saw YOY funding cuts and increases, if any, were modest. HIV/AIDS received the most significant funding increase, with YOY investment by LMIC funders up \$5.1m (46.4%). On the other hand, two diseases – malaria and dengue – saw dramatic decreases in YOY funding, dropping by \$9.8m (down 56.2%) and \$9.1m (down 63.5%) respectively. Again, this was mostly due to changes in Brazilian funding, which accounted for the entire drop in dengue funding and 71.5% (\$6.5m) of the drop in malaria. Funding for other diseases remained relatively steady. Platform technologies were back on the map in 2010, jumping from zero funding in 2009 to \$2.7m in 2010, although these amounts are too small to draw inferences on trends.

## IDC INNOVATION AGENCIES

IDC governments are increasingly supporting their private sector pharmaceutical R&D capacity. New funding schemes include the Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Partnership Programme (BIPP), set up by the Indian Department of Biotechnology (DBT) in 2005 and 2008; the launch of the Industrial Health Complex by the Brazilian DECIT in 2009; and the South African Department of Science and Technology's (DST) Technology Innovation Agency set up in 2010.

These programmes are driven by the view that private sector innovation is not only the key to addressing health needs specific to their own populations, but is also essential for reducing dependence on foreign pharmaceutical companies, enhancing commercial competitiveness and fuelling economic growth. Each country has adopted a different approach towards fostering pharmaceutical innovation, depending primarily on the maturity of its private sector, its research and manufacturing capacity (public and private), and the structure of its domestic health system.

### Indian Department of Biotechnology

#### *Small Business Innovation Research Initiative and Biotechnology Industry Partnership Programme*

India's pharmaceutical industry has matured from being a sector primarily focused on the production of generics to one with increasing capacity to develop novel pharmaceuticals. Thus, the aim of recent government programmes is the provision of seed funding for emerging companies with high innovative potential. The SBIRI programme focuses on supporting early stage research conducted by SMEs, funding both early stage, pre-proof-of-concept research in biotechnology as well as some late-stage development to support private sector commercialisation.<sup>47</sup> The BIPP programme provides funding to industry on a cost-sharing basis but focuses specifically on the development of technologies addressing national health priorities, including products for HIV/AIDS, TB, malaria, influenza and dengue.<sup>48</sup> It is open to large and small companies and targets large scale "break-through" research aimed at producing patentable products. Through these initiatives, DBT hopes to cultivate Intellectual Property (IP) creation, encourage cross-sector knowledge transfer through domestic private public partnerships and, as a result, increase the global competitiveness of the Indian pharmaceutical industry. DBT has also invested in several biotechnology parks and industrial incubators across the country, which provide research facilities and laboratories for the growing number of start-ups in India. In 2009-2010, DBT provided INR 30m (\$0.53m) for biotech parks and incubators and INR 900m (\$16.0m) for private public R&D partnerships such as the SBIRI and the BIPP industry schemes across multiple sectors, including health and medicine.<sup>49</sup>

### South African Department of Science and Technology

#### *Technology Innovation Agency*

The DST launched the South African Technology Innovation Agency (TIA) in 2010 to support the development and commercialisation of research outputs from higher education institutions, science councils, public entities and private research institutions. TIA was a merger of seven DST entities previously responsible for promoting innovation in South Africa, including three former Biotechnology Innovation Centres (LIFELab, BioPAD Trust, and Cape Biotech Trust).<sup>50</sup> The health division of TIA focuses primarily on products for HIV/AIDS, TB and malaria, as well as for cholera, typhoid and river blindness. In 2010, 65% (\$4.0m) of DST's neglected disease R&D funding was channelled through the TIA, supporting a combination of small biotechs and universities in South Africa.

With a relatively smaller private industry than India, South African efforts at the moment are largely focused on improving the capacity of African researchers for pharmaceutical product development. For example, the launch of the Drug Discovery and Development Centre (H-3D) in April 2011, jointly funded by TIA and MMV in the amount of \$3.0m for four years, aims to develop and test preclinical drug candidates, while simultaneously training African scientists to develop a “critical mass of personnel” that can attract industry investment to the region.<sup>51</sup> The H-3D centre is also collaborating with the US NIAID, Novartis and GlaxoSmithKline, reflecting a strong emphasis on technology transfer from high-income countries to South African researchers. TIA is the first government agency to join the Pool for Open Innovation against Neglected Tropical Diseases, which is seen as a possible conduit for knowledge transfer from the pharmaceutical industry.<sup>52</sup> TIA has provided funding for a number of promising projects, including the CAPRISA 004 microbicide trials currently in Phase IIb, and to the Biovac Institute, which is currently developing an African vaccine manufacturing initiative in an effort to reduce reliance on imported Expanded Programme on Immunization (EPI) vaccines from foreign manufacturers.<sup>50</sup>

## Brazilian Ministry of Health

### *Industrial Health Complex*

Unlike India and South Africa, Brazilian support of the biotech sector is currently more focused on the supply of existing products to the domestic health system than on developing novel products. The Industrial Health Complex, supported by the Ministry of Health and funded by the Brazilian National Development Bank (BNDES), was created to stimulate local manufacturing of pharmaceutical products for the Brazilian Unified Health System (SUS), thus decreasing the dependence on foreign imports.<sup>53</sup> Another key objective has been the forging of alliances between public laboratories and private drug producers to strengthen the capacity of public manufacturers. Since November 2009, agreements have been formed with nine public manufacturers and 11 private partners (four foreign and seven domestic), with provisions for local production of 28 strategic products for the SUS. The Ministry of Health has invested BRL 45m (\$19.8m) to support the production and technology transfer of products such as the BCG vaccine for TB, vaccines for yellow fever and pneumonia, and oseltamivir to treat H1N1 influenza.

The Brazilian government has also supported private sector development of new products, albeit mainly for non-communicable diseases such as cancer and diabetes. For instance, BNDES recently approved BRL 277.6m (\$122.3m) for innovation projects in the pharmaceutical sector under the Profarma programme. Smaller amounts have also been disbursed specifically for neglected diseases. In 2010, FINEP gave \$1.8m to Brazilian SMEs for the development of several products, including drugs for leishmaniasis and leprosy, dengue diagnostics and ARVs.

## Philanthropic funders

After a sizeable drop in funding in 2009 (down \$62.5m, -8.7%), YOY philanthropic funding fell by a further \$79.8m (-12.4%) in 2010 to reach \$568.1m. This was mostly due to a \$101.7m decrease in funding from the Gates Foundation, which reflected several factors including cyclical grant funding and maturity of several Foundation-funded products including the upcoming conclusion of the RTS,S vaccine and the successful approval of Shanchol™, a new oral cholera vaccine, in April 2009.

Decreased Gates Foundation funding was partially offset by a large increase from the Wellcome Trust (up \$15.3m, 23.6%), and a significantly increased contribution from the UBS Optimus Foundation (up \$6.3m, 565%), which was partly due to better data reporting.

Together, the Gates Foundation and the Wellcome Trust represented almost 95% of all philanthropic funding, although 2010 saw a further rebalancing due to steady growth in Wellcome Trust funding since 2007 as well as the cyclical and programmatic funding changes noted above for the Gates Foundation.

**Table 24. Top philanthropic funders 2010**

Funder	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
Gates Foundation*	452,102,715	616,991,512	557,518,315	455,832,350	84.0	86.1	86.5	80.2
Wellcome Trust	59,985,371	60,864,206	65,121,278	80,459,662	11.1	8.5	10.1	14.2
UBS Optimus Foundation	546,927	1,110,768	1,105,687	7,357,535	0.1	0.2	0.2	1.3
MSF	7,187,885	7,275,268	4,563,905	4,725,479	1.3	1.0	0.7	0.8
Funds raised from the general public	2,064,283	1,214,399	440,079	310,513	0.4	0.2	0.1	0.1
All other philanthropic organisations*	16,392,563	29,072,023	15,599,224	19,417,462	3.0	4.1	2.4	3.4
<b>Total philanthropic funding*</b>	<b>538,279,744</b>	<b>716,528,175</b>	<b>644,348,488</b>	<b>568,103,001</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

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

\* Figures for 2007 and/or 2009 have been updated and therefore differ from previously published figures

HIV/AIDS, malaria and TB collectively received 67.0% of philanthropic funding in 2010, down from 70.3% in 2009. Several diseases saw large funding increases. YOY investments in bacterial pneumonia and meningitis were up \$20.4m, mostly due to an \$11m grant from the Gates Foundation to the Program for Appropriate Technology in Health (PATH) for clinical development of pneumonia vaccines. Funding for TB was up \$12.2m (11.4%) due to increased funding from the Gates Foundation for TB diagnostics and drugs and from the Wellcome Trust for all TB products. As noted above, the large funding drops seen for malaria (down \$87.9m, -41.4%) and kinetoplastids (down \$23.4m, -43.6%) were due to winding-down or completion of successful projects.

**Table 25. Philanthropic funding by disease 2007-2010**

Disease or R&D area	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
HIV/AIDS	100,983,453	174,781,553	132,859,771	134,934,183	18.8	24.4	20.6	23.8
Malaria*	155,550,721	203,158,929	212,540,833	125,638,436	28.9	28.4	33.0	22.1
Tuberculosis*	118,664,226	138,389,222	107,815,071	120,220,907	22.0	19.3	16.7	21.2
Diarrhoeal diseases	55,568,392	42,267,335	47,109,061	45,724,283	10.3	5.9	7.3	8.0
Bacterial Pneumonia & Meningitis	6,168,184	26,798,409	22,377,790	43,721,396	1.1	3.7	3.5	7.7
Kinetoplastids	67,927,698	49,366,955	53,603,095	30,226,137	12.6	6.9	8.3	5.3
Helminths (Worms & Flukes)	10,831,571	26,448,071	22,225,965	20,875,018	2.0	3.7	3.4	3.7
Dengue	2,113,145	17,522,069	13,296,670	10,035,762	0.4	2.4	2.1	1.8
Salmonella infections	54,194	1,033,056	3,615,088	7,087,967	0.0	0.1	0.6	1.2
Leprosy	658,000	1,057,064	979,784	2,465,391	0.1	0.1	0.2	0.4
Buruli Ulcer	-	194,224	315,272	1,710,178	0.0	0.0	0.0	0.3
Rheumatic Fever	-	54,212	182,116	148,513	0.0	0.0	0.0	0.0
Trachoma	1,461,110	-	-	-	0.3	0.0	0.0	0.0
Platform technologies	1,989,289	8,145,750	14,448,469	12,824,228	0.4	1.1	2.2	2.3
Adjuvants and immunomodulators	-	1,339,006	2,181,111	4,858,300	0.0	0.2	0.3	0.9
Delivery technologies and devices	-	4,078,010	5,459,574	4,400,720	0.0	0.6	0.8	0.8
General diagnostic platforms*	1,989,289	2,728,734	6,807,783	3,565,209	0.4	0.4	1.1	0.6
Core funding of a multi-disease R&D organisation	13,026,847	9,921,287	5,492,440	6,067,278	2.4	1.4	0.9	1.1
Unspecified disease	3,282,916	17,390,040	7,487,062	6,423,325	0.6	2.4	1.2	1.1
<b>Total philanthropic funding*</b>	<b>538,279,744</b>	<b>716,528,175</b>	<b>644,348,488</b>	<b>568,103,001</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

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

- No reported funding in category

\* Figures for 2007 and/or 2009 have been updated and therefore may differ from previously published figures

## Private sector funders

Unlike the public and philanthropic sectors, which collectively cut YOY funding by \$215.7m (down 7.9%), industry increased its 2010 YOY investment in neglected disease R&D by \$107.3m (up 28.2%) to a total of \$503.5m.

The bulk of industry funding (\$442.3m, 87.9%) came from MNCs, with a further \$61.2m (12.1%) from SMEs. MNCs were also responsible for the entirety of the increase in industry investment, with a \$114.7m (35.1%) increase in MNC YOY funding more than offsetting the halving (down \$7.0m, -49.9%) of YOY SME funding in IDCs. Investment by SMEs in the developed world remained fairly stable (down \$0.4m, -0.9%).

## MULTINATIONAL PHARMACEUTICAL COMPANIES (MNCs)

TB, malaria and dengue accounted for 79.5% of MNC funding, and also saw the largest YOY funding increases, with an additional \$36.4m (34.5%) for TB, \$35.6m (60.4%) for dengue and \$33.6m (41.6%) for malaria. A significant proportion of these increases was due to end-stage product development of dengue vaccine candidates as well as the creation of new neglected disease divisions by some firms, for example the Anti-infectives Therapeutic Strategic Unit set up by sanofi-aventis in 2010 to develop new anti-infectives including TB and malaria drugs.<sup>54</sup> There were no MNC investments in leprosy, Buruli ulcer, trachoma, rheumatic fever or platform technologies in 2010.

We note that overall industry figures are under-reported, as we could not confirm full funding data from two MNCs with known programmes in TB, Chagas' disease and bacterial pneumonia. Additionally, a diagnostics SME with a substantial portfolio in HIV/AIDS, TB and malaria did not participate in the survey this year.

**Table 26. Multinational pharmaceutical company (MNC) funding by disease 2007-2010**

Disease	2007 (US\$)	2008 (US\$)^	2009 (US\$)^	2010 (US\$)^	2007%	2008%	2009%	2010%
Tuberculosis	50,406,352	73,805,679	107,440,859	142,913,356	27.2	26.5	31.8	32.3
Malaria	80,171,520	80,676,451	80,831,793	114,453,210	43.2	28.9	23.9	25.9
Dengue	15,982,205	43,145,203	58,941,327	94,513,621	8.6	15.5	17.4	21.4
Diarrhoeal diseases	10,696,100	22,032,982	32,548,361	31,064,572	5.8	7.9	9.6	7.0
Bacterial Pneumonia & Meningitis*	15,164,876	31,943,693	25,412,690	26,287,804	8.2	11.4	7.5	5.9
HIV/AIDS	7,835,409	19,945,834	17,544,478	16,730,164	4.2	7.1	5.2	3.8
Kinetoplastids*	5,133,194	1,263,713	3,835,429	10,500,299	2.8	0.5	1.1	2.4
Helminths (Worms & Flukes)	61,200	3,892,100	8,132,792	3,175,480	0.0	1.4	2.4	0.7
Salmonella infections	-	1,166,675	1,773,897	2,712,092	0.0	0.4	0.5	0.6
Rheumatic Fever	-	963,391	1,449,696	-	0.0	0.3	0.4	0.0
Buruli ulcer	-	88,938	-	-	0.0	0.0	0.0	0.0
Trachoma	104,000	96,339	-	-	0.1	0.0	0.0	0.0
<b>Total MNC funding</b>	<b>185,554,857</b>	<b>279,020,998</b>	<b>337,911,323</b>	<b>442,350,599</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

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

\* 2010 figures may be underestimated due to less comprehensive reporting by some survey participants for these diseases

- No reported funding in category

## SMALL PHARMACEUTICAL AND BIOTECHNOLOGY FIRMS (SMEs)

SME funding included \$49.9m (81.6%) from firms in developed countries and \$11.2m (18.4%) from IDC firms.<sup>iv</sup>

YOY investments from SMEs decreased by \$7.3m (down 13.5%) in 2010, with virtually all of this (\$7.0m, 94.9%) due to cuts by IDC firms. SMEs in developed countries largely maintained their investments (down \$0.4m, -0.9%). As a result, the contribution of IDC firms to global SME funding dropped from 25.6% in 2009 to 18.4% in 2010.

All diseases except TB and trachoma saw cuts in investment from YOY funders in 2010. In the case of pneumonia and dengue, this was largely due to decreases in IDC investment; while the changes in TB, trachoma, salmonella and HIV/AIDS funding largely reflected investment changes by SMEs in developed countries. The top funded disease was TB, which also saw the greatest increase from YOY funders (\$5.2m, 44.6%). Malaria saw the largest funding decrease (down \$6.8m, -48.7%) due to cuts in funding for both drugs and vaccines; while YOY HIV/AIDS funding was down by \$0.9m (-7.8%).

**Table 27. Small pharmaceutical and biotechnology firms (SME) funding by disease 2007-2010**

Disease or R&D area	2007 (US\$)	2008 (US\$) <sup>^</sup>	2009 (US\$) <sup>^</sup>	2010 (US\$) <sup>^</sup>	2007%	2008%	2009%	2010%
Tuberculosis	15,548,363	13,223,374	15,710,495	17,108,747	33.5	15.3	21.4	28.0
HIV/AIDS	11,800,216	27,504,031	17,797,740	13,373,177	25.5	31.9	24.3	21.9
Malaria*	10,622,063	9,934,683	18,471,385	11,168,065	22.9	11.5	25.2	18.3
Bacterial Pneumonia & Meningitis	582,161	18,551,060	8,381,567	5,826,610	1.3	21.5	11.4	9.5
Dengue	3,412,551	648,796	4,171,825	4,696,264	7.4	0.8	5.7	7.7
Helminths (Worms & Flukes)	753,763	1,058,521	408,232	3,255,580	1.6	1.2	0.6	5.3
Trachoma	-	-	-	1,882,470	0.0	0.0	0.0	3.1
Kinetoplastids	16,323	1,648,585	1,277,425	1,363,852	0.0	1.9	1.7	2.2
Diarrhoeal diseases	2,980,328	2,069,864	4,648,062	505,167	6.4	2.4	6.3	0.8
Salmonella infections	-	11,146,435	1,667,150	143,376	0.0	12.9	2.3	0.2
Leprosy	-	-	-	79,291	0.0	0.0	0.0	0.1
Buruli Ulcer	15,200	196,747	-	-	0.0	0.2	0.0	0.0
Platform technologies	30,836	249,882	820,306	1,772,596	0.1	0.3	1.1	2.9
<i>Delivery technologies and devices</i>	-	249,882	36,197	1,772,596	0.0	0.3	0.0	2.9
<i>Adjuvants and immunomodulators</i>	-	-	784,109	-	0.0	0.0	1.1	0.0
<i>General diagnostic platforms*</i>	30,836	-	-	-	0.1	0.0	0.0	0.0
Unspecified disease	595,986	-	-	-	1.3	0.0	0.0	0.0
<b>Total SME funding*</b>	<b>46,357,791</b>	<b>86,231,977</b>	<b>73,354,187</b>	<b>61,175,195</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

\* Figures for 2007, 2008 and/or 2009 have been updated and therefore differ from previously published figures

- No reported funding in category

<sup>iv</sup> This figure includes investments reported by a Thai SME that participated for the first time in 2010



## PRIVATE FIRMS IN INDIA AND BRAZIL

Four SMEs from India and nine SMEs from Brazil provided information on their neglected disease investments in 2010. Four of these organisations were new to the survey, while two previously surveyed companies did not report in 2010.

Investments by the 13 SMEs in India and Brazil totalled \$10.4m in 2010, with 60% (\$6.2m) from Indian firms and 40% (\$4.2m) from Brazilian firms (we note that Indian investment is likely underestimated due to loss-to-follow-up of two firms).

Bacterial pneumonia and meningitis saw a significant YOY funding cut (down \$2.8m, -33.6%) although it continued to receive the bulk of IDC industry funding (53.3% in 2010 compared to 44.5% in 2009), likely reflecting ongoing investments in response to the pneumonia vaccine AMC. With the exception of salmonella infections, all other disease areas also saw funding cuts in 2010, particularly malaria (which essentially disappeared from IDC industry reporting). We note that the decrease in diarrhoeal disease funding is an artefact due to loss-to-follow-up of two companies investing in this area.

**Table 28. Private sector IDC funding by disease 2009-2010**

Disease	2009 (US\$)^	2010 (US\$)^	2009%	2010%
Bacterial Pneumonia & Meningitis	8,368,036	5,558,697	44.5	53.3
Helminths (Worms & Flukes)	184,852	3,083,528	1.0	29.6
Kinetoplastids	814,959	710,021	4.3	6.8
Diarrhoeal diseases	4,267,630	452,390	22.7	4.3
Dengue	1,028,391	350,858	5.5	3.4
Salmonella infections	-	143,376	0.0	1.4
Leprosy	-	79,291	0.0	0.8
HIV/AIDS	-	33,038	0.0	0.3
Malaria	4,139,686	19,823	22.0	0.2
<b>Total private sector IDC funding</b>	<b>18,803,555</b>	<b>10,431,020</b>	<b>100.0</b>	<b>100.0</b>

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

- No reported funding in category

## IN-KIND CONTRIBUTIONS

In addition to their direct R&D spend, companies conducting neglected disease R&D incur a range of other costs, such as infrastructure costs and costs of capital. These costs have not been included in G-FINDER due to the difficulty of accurately quantifying or allocating them to neglected disease programmes. Companies also provide in-kind contributions that are specifically targeted to neglected disease R&D but that cannot easily be captured in dollar terms, as seen in Table 29.

We note that while some companies have nominated areas where they provide such contributions, others wished to remain anonymous. Although difficult to quantify, these inputs nevertheless represent a substantial value to their recipients and a significant cost to companies.



**Table 29. Typical industry in-kind contributions to neglected disease R&D 2010**

In-kind contribution	Examples	Some company donors*
Transfer of technology & technical expertise to develop, manufacture, register and distribute neglected disease products	<ul style="list-style-type: none"> <li>Identifying scientific obstacles</li> <li>Sharing best practices and developing systems for clinical, technical and regulatory support</li> <li>Developing capacity for pharmacovigilance</li> <li>Donating equipment</li> </ul>	GSK Pfizer AstraZeneca sanofi-aventis Otsuka
Provision of expertise	<ul style="list-style-type: none"> <li>Supporting clinical trials</li> <li>Collaboration of scientists, sharing trial results and facilitating parallel, concurrent testing</li> <li>Participation on scientific advisory or management boards of external organisations conducting neglected disease R&amp;D</li> <li>Providing expertise in toxicology/ADME and medicinal chemistry</li> <li>Evaluating new compounds proposed by external partners</li> <li>Allowing senior staff to take sabbaticals working with neglected disease groups</li> </ul>	Novartis GSK Pfizer Abbott Laboratories AstraZeneca sanofi-aventis Tibotec (Johnson & Johnson company) Otsuka
Teaching and training	<ul style="list-style-type: none"> <li>In-house attachments offered to Developing Country (DC) trainees in medicinal chemistry, clinical trial training etc.</li> <li>Providing training courses for DC researchers at academic institutions globally</li> <li>Organising health care provider training in DCs for pharmacovigilance of new treatments</li> <li>Organising conferences and symposia on neglected disease-specific topics</li> </ul>	Novartis GSK Pfizer AstraZeneca Tibotec (Johnson & Johnson company) Otsuka
Intellectual property	<ul style="list-style-type: none"> <li>Access to proprietary research tools and databases</li> <li>Sharing compound libraries with WHO or with researchers, who can test and screen them for possible treatments</li> <li>Providing public and not-for-profit groups with information on proprietary compounds they are seeking to develop for a neglected disease indication</li> <li>Forgoing license or providing royalty-free license on co-developed products</li> </ul>	Novartis GSK Pfizer Abbott sanofi-aventis Tibotec (Johnson & Johnson company)
Regulatory assistance	<ul style="list-style-type: none"> <li>Allowing right of reference to confidential dossiers and product registration files to facilitate approval of generic combination products</li> <li>Covering the cost of regulatory filings</li> <li>Providing regulatory expertise to explore optimal registration options for compounds in development</li> </ul>	GSK Abbott sanofi-aventis Tibotec (Johnson & Johnson company)

\* Company donors listed do not necessarily engage in all activities listed as examples of in-kind contributions

## Funding by organisation

Global investment in neglected disease R&D was once again highly concentrated in 2010, with the top 12 funders contributing 89.6% (\$2.74bn) of global funding, compared to 88.6% in 2009.

The most significant change in 2010 was the very large increase in industry R&D investment (up \$107.3m, 28.2%). Coupled with a drop in funding from the Gates Foundation (down \$101.7m, -18.2%), this meant industry was the second largest funder of neglected disease R&D in 2010. Several other groups also increased funding in 2010, including Institut Pasteur (up \$18.7m, 70.6%), Wellcome Trust (up \$15.3m, 23.6%) and UK DFID (up \$12.8m, 15.2%), which became the fourth largest funder of neglected disease R&D in 2010 (up from seventh place in 2009).

The Gates Foundation decreased its global R&D funding for the second year, predominantly due to cuts in malaria (down \$95.2m, -52.2%) and kinetoplastid (down \$16.2m, -44.9%) funding. However, as noted previously, the decrease in malaria funding is largely an artefact of up-front disbursement of a large multi-year grant in 2009 for Phase III RTS,S vaccine trials.

Significant decreases were also seen from the US NIH (\$44.8m, -3.6%), US DOD (down \$28.3m, -28.8%), EC (down \$25.8m, -21.8%) and the Dutch Ministry of Foreign Affairs - Directorate General of Development Cooperation (DGIS, down \$10.1m, -37.0%), which dropped out of the top 12 ranking in 2010 after being in the top 12 in all previous G-FINDER surveys.

**Table 30. Top neglected disease funders 2010**

Funder	2007 (US\$) <sup>A</sup>	2008 (US\$) <sup>A</sup>	2009 (US\$) <sup>A</sup>	2010 (US\$) <sup>A</sup>	2007%	2008%	2009%	2010%
US NIH	1,064,859,791	1,078,627,652	1,256,471,979	1,211,704,054	41.6	36.5	39.6	39.6
Aggregate industry respondents <sup>AB</sup>	231,912,647	365,252,975	411,265,510	503,525,794	9.1	12.4	13.0	16.4
Gates Foundation <sup>B</sup>	452,102,715	616,991,512	557,518,315	455,832,350	17.7	20.9	17.6	14.9
UK DFID	47,565,987	43,278,878	84,396,112	97,229,720	1.9	1.5	2.7	3.2
European Commission	121,366,882	129,899,906	118,311,296	92,529,756	4.7	4.4	3.7	3.0
USAID	80,600,336	83,805,395	84,483,425	85,975,465	3.1	2.8	2.7	2.8
Wellcome Trust	59,985,371	60,864,206	65,121,278	80,459,662	2.3	2.1	2.1	2.6
US DOD	86,914,578	72,548,392	98,236,367	69,942,925	3.4	2.5	3.1	2.3
UK MRC <sup>B</sup>	51,716,968	52,765,367	51,710,748	60,857,019	2.0	1.8	1.6	2.0
Institut Pasteur	31,617,540	26,547,885	26,477,069	45,158,519	1.2	0.9	0.8	1.5
Inserm	1,774,770	3,121,721	27,222,504	20,196,417	0.1	0.1	0.9	0.7
Australian NHMRC	15,457,337	18,682,020	20,242,107	19,464,047	0.6	0.6	0.6	0.6
Subtotal top 12 funders <sup>B*</sup>	2,286,866,018	2,577,455,990	2,808,483,550	2,742,875,728	89.3	87.2	88.6	89.6
Total R&D funding <sup>B</sup>	2,560,068,749	2,955,964,344	3,168,940,958	3,062,669,973	100.0	100.0	100.0	100.0

<sup>A</sup> Figures are adjusted for inflation and reported in 2007 US dollars

<sup>A</sup> Includes new survey respondents in 2010

<sup>B</sup> Figures for 2007 and/or 2009 have been updated and therefore differ from previously published figures

<sup>\*</sup> Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

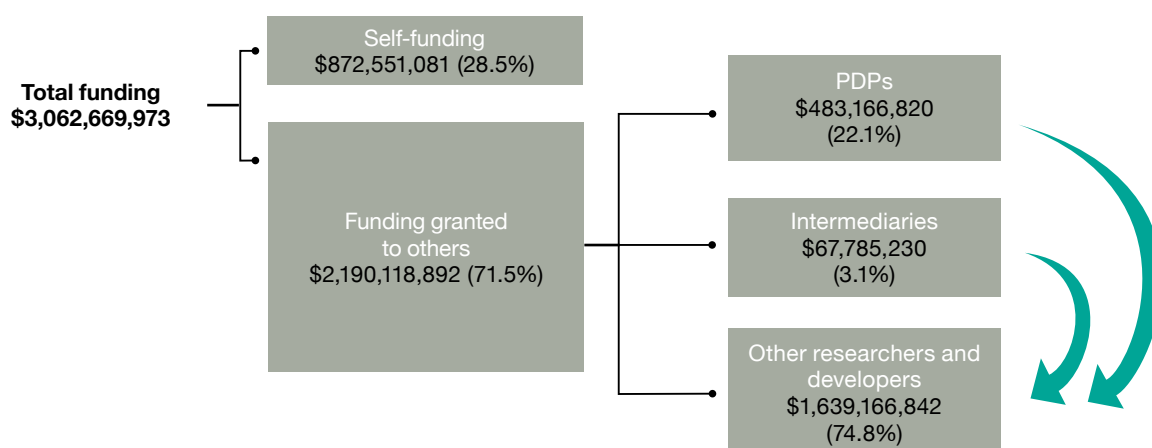
## FINDINGS – FUNDING FLOWS

Funding agencies disburse their neglected disease R&D investments in two main ways: through self-funding (intramural funders) and through grants to others (extramural funders). Traditional self-funders, such as pharmaceutical companies, invest mainly in their own internal research facilities and programmes; while extramural funders disburse funding through PDPs<sup>v</sup> and intermediaries, or directly to researchers and developers. Some organisations are pure funders, such as the Gates Foundation, which means all their funding is in the form of grants to third parties (i.e. they do not conduct research themselves). Other organisations, such as the US NIH and Indian ICMR use a mixed model, providing extramural funding to others in addition to funding their own internal research programmes.

Slightly more than 70% of 2010 R&D funding was in the form of external grants (71.5%), while intramural funding (self-funding) accounted for 28.5%. There was a significant shift from external funding (down \$149.0m, -6.4%) to self-funding (up \$42.7m, 5.1%), mainly driven by the increase in industry self-funding (up \$110.8m, 29.7%)<sup>vi</sup> and the decrease in external grant funding from the Gates Foundation (down \$101.7m, -18.2%). The impact of the external funding cuts was fairly evenly spread, with the smaller 2010 grant pie being shared out in almost the same proportions as in 2009: three-quarters (\$1.6bn, 74.8%) went directly to researchers and developers, compared to 73.4% in 2009; just under one-quarter (\$483.2m, 22.1%) to PDPs, compared to 22.5% in 2009; and a small fraction (\$67.8m, 3.1%) to other intermediaries, compared to 4.1% in 2009.

We note that the central role of PDPs in this field is somewhat obscured by the “NIH factor”, since the largest global funder of neglected disease R&D, the US NIH, provides only a very small amount of its funding to PDPs: in 2010, the US NIH provided only 0.2% (\$2.5m) of their billion-dollar budget to PDPs. If the US NIH is excluded from this analysis, the central role of PDPs in product development becomes clearer, with PDPs collectively managing 42.1% of global grant funding for neglected disease R&D.

**Figure 27. Overall R&D funding patterns 2010**



<sup>v</sup> PDPs are defined as public health driven, not-for-profit organisations that typically use private sector management practices to drive product development in conjunction with external partners. PDPs tend to focus on one or more neglected diseases and aim to develop products suitable for DC use. While their primary goal is the advancement of public health rather than commercial gain, they generally use industry practices in their R&D activities, for instance portfolio management and industrial project management. Additionally, many PDPs conduct global advocacy to raise awareness of their target neglected diseases.

<sup>vi</sup> The industry self-funding increase differs from the total industry increase (\$107.3m, 28.2%), as the latter includes changes in industry funding to others

## Self-funders

Unsurprisingly, the bulk of self-funding came from private industry, which almost invariably funds only its own internal R&D programmes. The trend towards increased self-funding seen in the first three years of the survey also continued, with self-funding increasing by \$42.7m (up 5.1%) in 2010. This overall upward trend was driven by the very large increase in industry self-funding (up \$110.8m, 29.7%) as well as more modest increases from Institut Pasteur (up \$18.7m, 70.6%) and UK MRC (up \$5.3m, 14.4%). However, these increases masked significant decreases in internal investment from all other top 10 self-funders, including the US DOD (down \$32.0m, 40.1%), US NIH (down \$28.3m, 14.8%), Inserm - Institute of Infectious Diseases (down \$7.0m, 25.8%) and Statens Serum Institute (SSI, down \$5.0m, -49.1%).

**Table 31. Top 10 self-funders 2007-2010**

Funder	2007 (US\$)	2008 (US\$) <sup>A</sup>	2009 (US\$) <sup>A</sup>	2010 (US\$) <sup>A</sup>	2007%	2008%	2009%	2010%
Aggregate industry respondents <sup>A#</sup>	228,957,902	355,313,341	401,732,684	498,625,790	8.9	12.0	12.7	16.3
US NIH <sup>#</sup>	133,097,100	158,435,807	190,964,251	162,657,162	5.2	5.4	6.0	5.3
US DOD <sup>B#</sup>	70,340,000	51,274,796	79,810,736	47,835,664	2.7	1.7	2.5	1.6
Institut Pasteur <sup>#</sup>	31,617,540	26,520,909	26,477,069	45,158,519	1.2	0.9	0.8	1.5
UK MRC <sup>#C</sup>	35,989,099	33,560,426	36,569,047	41,845,984	1.4	1.1	1.2	1.4
Inserm <sup>#</sup>	1,774,770	3,121,721	27,222,504	20,196,417	0.1	0.1	0.9	0.7
Indian ICMR	-	19,533,928	17,230,631	15,954,793	0.0	0.7	0.5	0.5
US CDC	5,703,200	12,672,614	18,565,920	15,642,774	0.2	0.4	0.6	0.5
Undisclosed recipient	-	2,611,579	7,276,341	6,637,445	0.0	0.1	0.2	0.2
SSI	3,672,882	3,870,205	10,232,619	5,207,031	0.1	0.1	0.3	0.2
Subtotal top 10 self-funders <sup>*C</sup>	525,334,601	668,434,839	816,081,802	859,761,581	20.5	22.6	25.8	28.1
Subtotal self-funders <sup>*C</sup>	527,676,354	686,739,852	829,848,091	872,551,081	20.6	23.2	26.2	28.5
Total R&D funding <sup>C</sup>	2,560,068,749	2,955,964,344	3,168,940,958	3,062,669,973	100.0	100.0	100.0	100.0

<sup>A</sup> Figures are adjusted for inflation and reported in 2007 US dollars

<sup>\*</sup> Subtotals for 2007, 2008 and 2009 top 10 reflect the top self-funders for those years, not the top 10 for 2010

<sup>A</sup> Includes new survey respondents in 2010

<sup>B</sup> The Department of Defense figure is likely under-estimated as it does not include civilian and contract salaries of military researchers within Army and Navy laboratories

<sup>C</sup> Figures for 2009 have been updated and therefore differ from previously published figures

<sup>#</sup> These groups are also Top 10 overall funders (including self-funding plus external funding)

- No reported funding

## Product development partnerships

Funding to PDPs was \$483.2m in 2010. This represented 15.8% of global funding, 22.1% of global grant funding, and 42.1% of global grant funding if the “NIH factor” is excluded, as previously. The top four PDPs – MMV, PATH, IAVI and the Global Alliance for TB Drug Development (TB Alliance) – accounted for just over half of all PDP funding (\$251.4m, 52.0%).

Overall PDP funding decreased by \$46.9m (-8.8%) in 2010, after an earlier \$50.0m decrease in 2009. This decrease reflects both healthy funding cuts (for instance, the \$72.6m drop in RTS,S-related funding to PATH as the vaccine candidate nears successful completion) but also more worrying trends, with the majority of funders freezing or decreasing their PDP investments in 2010, with little or no correlation to portfolio or product development maturity.

There were wide differences in PDP funding success in 2010, with large increases reported by MMV (up \$28.5m, 68.2%) and the TB Alliance (up \$12.3m, 33.8%); and smaller increases of \$1–6m for OneWorld Health (OWH, up \$5.8m, 37.9%), Foundation for Innovative New Diagnostics (FIND, up \$4.2m, 20.6%), TuBerculosis Vaccine Initiative (TBVI, up \$4.1m) and the Innovative Vector Control Consortium (IVCC, up \$1.3m, 10.1%).

There was a significant drop in funding to Aeras (down \$13.7m, -25.6%), due to uneven disbursement of a multi-year TB vaccine grant from the Gates Foundation. Several other PDPs also reported decreases of \$5–8m, including: the International Vaccine Institute (IVI, down \$7.8m, -36.1%); IAVI (down \$6.7m, -9.3%); WHO-based Special Programme for Research and Training in Tropical Diseases (WHO/TDR, down \$5.9m, -17.1%); Infectious Disease Research Institute (IDRI, down \$5.1m, -30.5%); and Sabin Vaccine Institute (down \$5.0m, -57.2%). IPM reported a decrease of \$4.8m (-13.5%) but this was an artefact due to an unevenly distributed grant from UK DFID.

**Table 32. Funds received by PDPs 2007-2010**

PDPs	2007 (US\$)	2008 (US\$) <sup>^</sup>	2009 (US\$) <sup>^</sup>	2010 (US\$) <sup>^</sup>	2007%	2008%	2009%	2010%
MMV	75,982,931	46,030,619	41,804,090	70,299,462	16.2	7.9	7.9	14.5
PATH	38,024,679	111,230,644	123,951,227	67,214,453	8.1	19.2	23.4	13.9
IAVI	81,297,482	86,598,890	72,086,128	65,398,560	17.3	14.9	13.6	13.5
TB Alliance	39,587,358	34,106,803	36,252,220	48,509,444	8.4	5.9	6.8	10.0
Aeras	40,121,983	63,786,605	53,395,878	39,742,200	8.5	11.0	10.1	8.2
DNDi	28,520,251	22,439,428	32,413,869	33,775,958	6.1	3.9	6.1	7.0
IPM	46,311,916	60,503,137	35,599,621	30,785,388	9.9	10.4	6.7	6.4
WHO/TDR <sup>^</sup>	32,675,307	37,039,908	34,721,350	28,779,509	7.0	6.4	6.6	6.0
FIND	22,881,808	30,359,050	20,258,906	24,429,531	4.9	5.2	3.8	5.1
OWH	27,377,321	28,409,977	15,231,696	20,998,848	5.8	4.9	2.9	4.3
IVCC	-	9,633,911	13,337,199	14,679,823	0.0	1.7	2.5	3.0
IVI	13,150,000	16,678,372	21,683,793	13,863,539	2.8	2.9	4.1	2.9
IDRI	8,094,908	14,340,933	16,552,206	11,500,854	1.7	2.5	3.1	2.4
EVI	7,745,898	4,398,783	3,877,131	5,250,423	1.7	0.8	0.7	1.1
TBVI	-	-	65,342	4,161,286	0.0	0.0	0.0	0.9
Sabin Vaccine Institute	7,621,112	14,527,323	8,818,384	3,777,544	1.6	2.5	1.7	0.8
<b>Total funding to PDPs</b>	<b>469,392,952</b>	<b>580,084,383</b>	<b>530,049,041</b>	<b>483,166,820</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

<sup>^</sup> Figures are adjusted for inflation and reported in 2007 US dollars

<sup>^</sup> Although TDR's mission is far broader than neglected disease R&D, it is included here since it has operated as a de facto PDP since the mid-1970s

- No reported funding

## PDP funders

Philanthropic organisations provided over half of total PDP funding in 2010 (\$268.5m, 55.6%), while HIC governments provided \$212.3m (43.9%). Twelve organisations provided over 90% (\$453.2m) of total PDP funding in 2010, with the Gates Foundation accounting for over half (\$253.8m, 52.5%) and HIC aid agencies contributing more than one-third (\$191.3m, 39.6%) of total funding.

Almost two-thirds of PDP funders reduced their funding in 2010, with cuts of \$84.5m. As noted previously, the largest drop in PDP funding was from the Gates Foundation (down \$35.0m, -12.1%), although this was largely due to cyclical grants and successful project completion. Other significant decreases were from the US NIH, which cut its already modest PDP funding by two-thirds (down \$5.0m, -66.4%), and from a wide range of aid agencies, who collectively reduced their PDP funding by \$28.2m due to budget cuts linked to the global financial crisis. These included the Spanish Ministry of Foreign Affairs and Cooperation for Development (MAEC, down \$7.2m, -50.0%), Canadian International Development Agency (CIDA, down \$5.1m, -100%), Swedish SIDA (down \$3.7m, -46.8%), Dutch DGIS (down \$3.6m, -18.6%), Royal Norwegian Ministry of Foreign Affairs (NORAD, down \$2.6m, -22.5%), French Ministry of Foreign and European Affairs (MAEE, down \$1.9m, -62.8%), Danish Ministry of Foreign Affairs (DANIDA, down \$1.4m, -35.8%), German Federal Ministry for Economic Cooperation and Development (BMZ, down \$1.3m, -57.3%) and Belgian Ministry of Foreign Affairs (DGDC, down \$1.2m, -41.1%).

These decreases were offset by increased funding of \$37.6m to PDPs from other organisations, with 90% of this increase coming from a small handful of donors. UK DFID represented over half (52.5%) of all funding increases to PDPs (up \$19.7m, 25.5%), in line with its research strategy for 2008-2013 and the UK Government's commitment to protect the aid budget from domestic budget cuts. The increased UK DFID funds went mainly to MMV (up \$20.2m, 563%) but also to Aeras (up \$2.9m, 40.3%) and PATH (up \$2.7m, 102%), although UK DFID also reduced funding to several PDPs in 2010 (IAVI: down \$3.3m, -18.4%; FIND: down \$0.9m, -32.0%; and IPM: down \$7.1m, -52.4% due to cyclical grant disbursement). Other groups who modestly increased their PDP funding in 2010 were the EC (up \$6.4m, 439%), USAID (up \$2.5m, 6.7%), Swiss Agency for Development and Cooperation (SDC, up \$1.8m, 87.3%), Irish Aid (up \$1.3m, 24.5%) and the WHO (up \$1.1m, 109.6%).

As in previous years, many aid agencies – in particular but not only those in smaller countries – continued to use PDPs as their main or only channel to finance neglected disease R&D. Aid agencies from Belgium, France, Germany, Ireland, Norway, Spain and the UK provided 100% of their neglected disease research funding through PDPs, while the Dutch DGIS, Swiss SDC and Danish DANIDA provided 92.1%, 86.2% and 77.8% through PDPs respectively. By contrast, large organisations with the capacity to review neglected disease projects in-house continued to provide some or most of their funding directly to developers rather than through PDPs. For instance, the US NIH provided only 0.2% to PDPs and the EC only 8.6%, while USAID gave 46.8% of its funding to PDPs and the Gates Foundation gave 55.7%.

**Table 33. Top PDP funders 2007-2010**

Funder	To PDPs 2007 (US\$)	To PDPs 2008 (US\$)^	To PDPs 2009 (US\$)^	To PDPs 2010 (US\$)^	% of org's funds given to PDPs 2010	Share of total PDP funding 2010%
Gates Foundation	231,183,854	351,426,826	288,742,058	253,755,901	55.7	52.5
UK DFID	33,430,151	28,094,083	77,492,166	97,229,720	100.0	20.1
USAID	40,776,000	40,052,987	37,730,743	40,243,034	46.8	8.3
Dutch DGIS	32,170,024	19,807,172	19,454,348	15,833,146	92.1	3.3
Norwegian NORAD	13,271,949	12,389,471	11,667,625	9,047,299	100.0	1.9
European Commission	4,034,158	-	1,468,993	7,914,688	8.6	1.6
Spanish MAEC	3,426,196	13,116,474	14,323,053	7,159,668	100.0	1.5
Irish Aid	23,586,318	6,820,567	5,227,392	6,508,789	99.7	1.3
MSF	7,187,885	7,275,268	4,563,905	4,725,479	100.0	1.0
Swedish SIDA	10,505,567	11,188,482	7,952,989	4,231,695	31.9	0.9
Swiss SDC	1,861,163	1,870,609	2,009,185	3,764,103	86.2	0.8
World Bank	3,610,000	3,477,842	2,802,745	2,757,154	100.0	0.6
Subtotal top 12 PDP funders*	426,662,580	528,101,928	485,636,091	453,170,675	56.9	93.8
<b>Total PDP funding</b>	<b>469,392,952</b>	<b>580,084,383</b>	<b>530,049,041</b>	<b>483,166,820</b>		
<b>% of total PDP funding (top 12)</b>	<b>90.9%</b>	<b>91.0%</b>	<b>91.6%</b>	<b>93.8%</b>		

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

\* Subtotals for 2007, 2008 and 2009 top 12 reflect the top funders for those years, not the top 12 for 2010

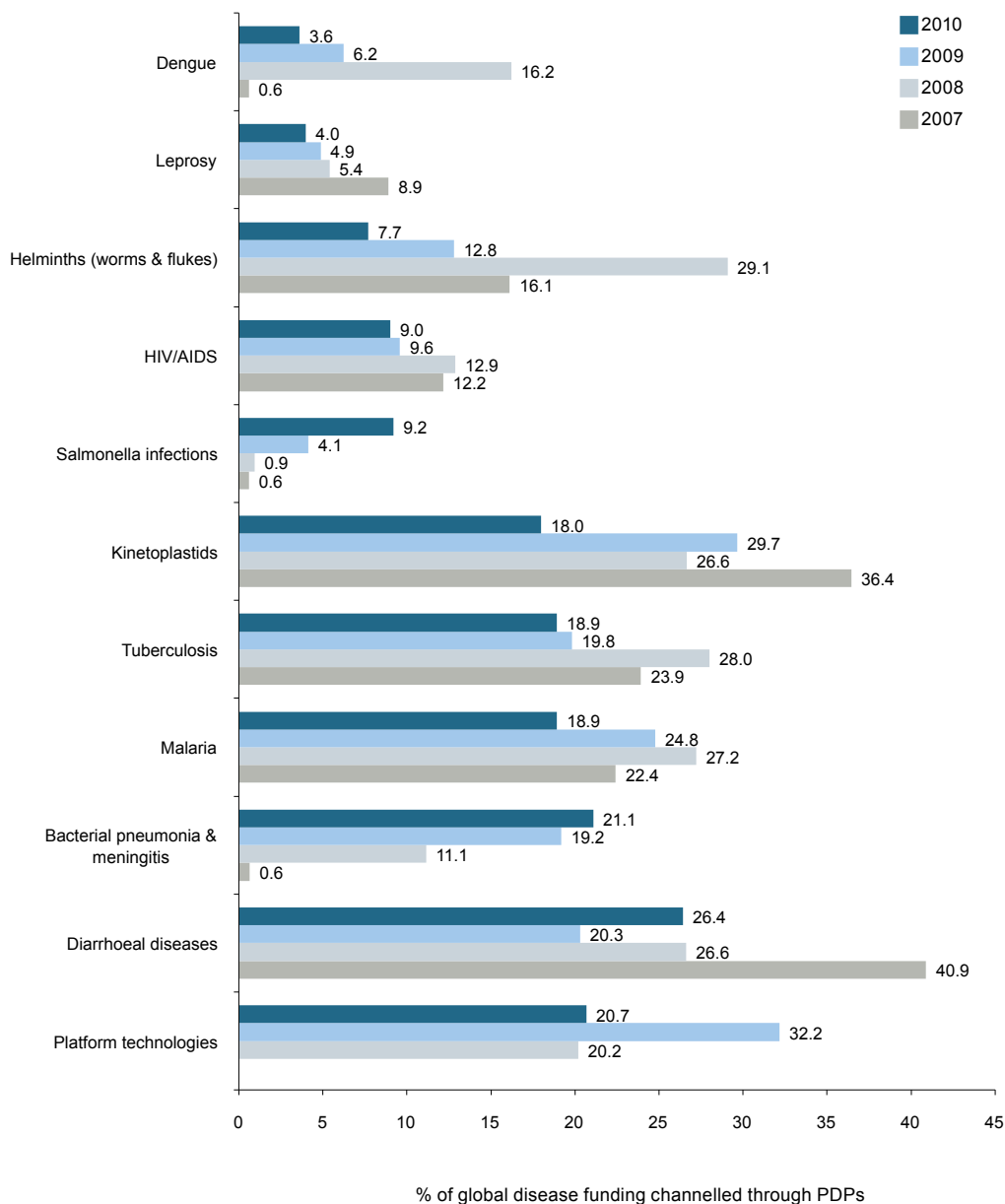
- No reported funding in category

## PDP share of disease funding

PDPs continued to play a dominant role in neglected disease R&D, managing around one-fifth to one-quarter of global funding in several disease areas. These included diarrhoeal diseases (\$42.0m, 26.4%), bacterial pneumonia and meningitis (\$28.4m, 21.1%), malaria (\$103.5m, 18.9%), TB (\$108.9m, 18.9%) and kinetoplastids (\$32.0m, 18%). However, PDPs played only a small role in HIV/AIDS (9.2%), helminths (7.7%), leprosy (4.0%) and dengue (3.6%).

PDPs continued to play a significant role in R&D of delivery technologies and devices (\$8.8m, 39.3%), although funding for this area was minimal. PDPs also channelled some of their funds to general diagnostic platforms (\$9.4m), which accounted for 3.1% of global diagnostic platform R&D funding.



**Figure 28. Percentage of global disease R&D funding given via PDPs 2007-2010<sup>\*,^</sup>**

\* There are no PDPs active in R&D for Buruli ulcer, trachoma or rheumatic fever

<sup>^</sup> Platform technologies combines general diagnostic platforms and delivery technologies and devices, diagnostic platforms are only included for 2009 and 2010



## DISCUSSION

### Global financial crisis cuts neglected disease R&D funding

The effect of the global financial crisis on neglected disease R&D funding became evident in 2010, with YOY global funding dropping by \$109.1m (-3.5%) to \$3.1bn.

Continuing the trend since 2007, there was a further modest redistribution of R&D funding across the neglected diseases in 2010. The top tier diseases (HIV, TB and malaria) saw a collective funding decrease of \$82.5m in 2010, which cut their share of global R&D funding to 71.7%, down from 72.1% in 2009 and 76.6% in 2007. The 'second tier' diseases (diseases that received 1–6% of global funding each, including dengue, diarrhoeal diseases, kinetoplastids, bacterial pneumonia and meningitis, and helminth and salmonella infections) saw a collective YOY increase of only \$2.6m, 0.4% in 2010, leading to a relatively stable funding share of 22.7% of global funding (22.0% in 2009). As in previous years, funding for the 'third tier' diseases was dismal, with leprosy, Buruli ulcer, trachoma and rheumatic fever collectively receiving just 0.7% of global neglected disease R&D funding in 2010 (0.6% in 2009), while platform technologies received 0.9% of funding (up from 0.7%).

In previous survey years, the redistribution of funding share between disease 'tiers' has been the result of stable funding for the top tier of diseases (HIV/AIDS, TB and malaria) alongside increased funding for other disease areas. However, in 2010, the redistribution of funding share was entirely due to a cut in funding for the top tier of diseases collectively, while funding for the second and third tier of diseases remained static.

### Large funding cuts across most sectors offset by major industry investment

In 2010, all sectors apart from industry cut their neglected disease R&D funding. Although still providing the majority of global investment (\$2.0bn, 65.0%), the effect of the global financial crisis on public funding was pronounced with YOY public funders collectively dropping investment by \$135.8m (-6.5%), including decreased funding from HICs (down \$118.5m), LMICs (down \$11.0m) and multilaterals (down \$6.3m). Eight of the top 12 funding governments cut their investment in 2010 as they grappled with the economic downturn. At the same time, YOY philanthropic funding decreased by a substantial \$79.8m (-12.4%) while SMEs in IDCs halved their investments (down \$7.0m, -49.9%). We note that the drop in philanthropic funding was mostly due to a \$101.7m decrease in funding from the Gates Foundation, which reflected several factors including cyclical grant funding and the completion of grants for several successful products.

MNC investment cushioned the impact of these cuts with a very significant YOY increase of \$114.7m (up 35.1%) in 2010, making industry, with contributions of \$503.5m, an almost equal contributor to philanthropic organisations (\$568.1m). Industry played a crucial role in stabilising 2010 R&D funding: we note that if industry investment had decreased at the same rate as that of other sectors in 2010, the global R&D funding drop would have been an unsustainable quarter of a billion dollars.

The funding cuts had a particularly high impact on the many diseases<sup>vii</sup> that rely on public and philanthropic investors, with decreases of 6–11% in funding for HIV/AIDS, malaria, kinetoplastids, diarrhoeal diseases and helminth infections. On the other hand, diseases such as TB and dengue, where industry played a key role (providing a quarter of funding or more), were largely protected from funding drops.

<sup>vii</sup> 'Third tier' diseases such as leprosy, Buruli ulcer, trachoma and rheumatic fever are not reviewed since their funding levels were too low to allow reliable trend analysis (even single grants can have a major impact)

## PDP funding still at risk

After a \$50.0m drop in 2009, PDPs saw a further \$46.9m drop in 2010, receiving \$483.2m in total. This decrease reflected both healthy funding cuts (for instance, the drop in RTS,S-related funding to PATH as the vaccine candidate neared successful completion) but also more worrying trends, with two-thirds of funders decreasing their PDP investments in 2010 (a drop of \$84.5m) unrelated to portfolio developments.

There were large cuts in PDP funding from the Gates Foundation (down \$35.0m) but these were largely due to cyclical grants and successful project completion. However, a wide range of government aid agencies, who traditionally provide around one-third of PDP funding, also reduced their investment in PDPs (collectively down \$28.2m) due to budget cuts linked to the global financial crisis. These across-the-board cuts were counterbalanced by increased funding from a small handful of organisations including UK DFID, which increased its funding to PDPs by \$19.7m, and more modest increases from the EC, USAID, Swiss SDC, Irish Aid and WHO.

PDPs manage about 40% of non-NIH global grant funding and have more than 140 projects in the development pipeline, many already in advanced clinical trials including the MVI/GSK RTS,S malaria vaccine (Phase III), the Aeras TB vaccine (Phase IIb) and several TB and malaria drugs by the TB Alliance (Phase II) and MMV (Phase III). Cuts in PDP funding put these programmes at significant risk, especially as products progress to expensive late-stage clinical trials. Given the crucial role of PDPs in neglected disease product development, there could be major implications for the availability of new products to combat neglected diseases if the trend towards decreased funding continues.

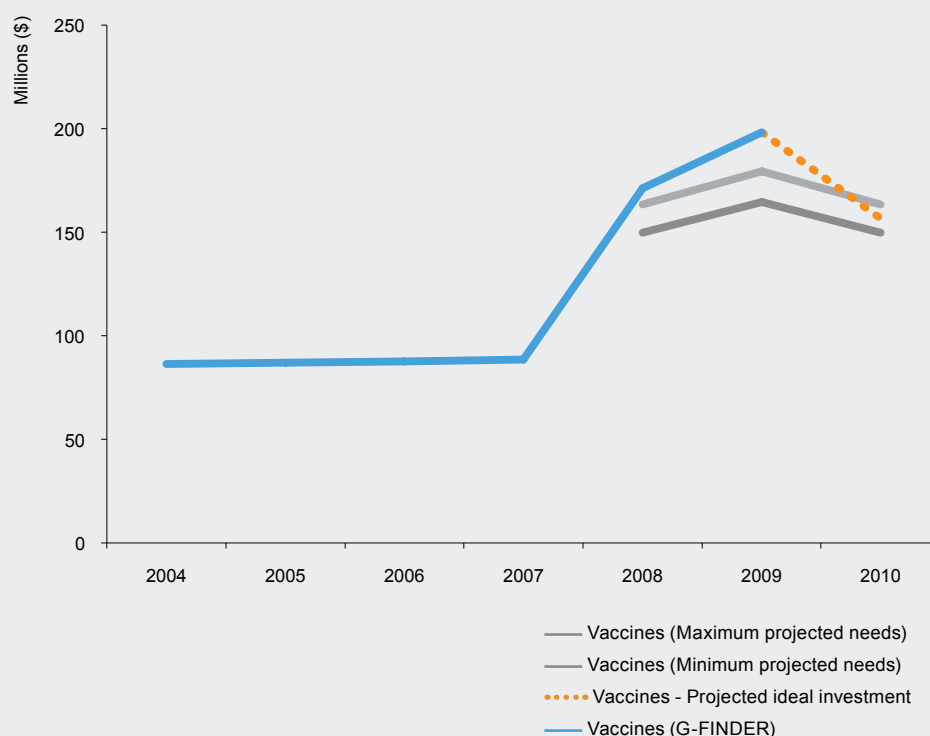
## What does good R&D funding look like?

In view of the vagaries of global R&D funding, it is worth asking “What does good R&D funding look like?” In essence, good R&D funding is focused on outcomes and is closely matched to product and portfolio developments along the path to those outcomes. Investments increase as successful candidates reach advanced clinical trials and, once a product is registered, funding decreases or is redistributed to other priority R&D areas. The hallmark of good R&D funding is that it is not an endless blank cheque, but is rather a realistic, product focused, outcome driven and flexible investment with clearly defined goals and exit points as each desired product is brought to registration.

## The Bill & Melinda Gates Foundation and the RTS,S malaria vaccine

Estimates from the PATH 'Staying the Course' report projected that malaria vaccine R&D funding needs would peak in 2008 and 2009 as the frontrunner RTS,S candidate moved into advanced trials, followed by a drop of up to 20% in 2010–2011 as these trials moved toward conclusion (see Figure 29).<sup>55</sup> This drop in funding demand would allow malaria vaccine R&D investments to be redistributed to other areas including malaria drug, diagnostic and vector control projects, and other areas of malaria vaccine research such as candidates targeting different malaria strains (e.g. *P. vivax*) or mechanisms of action (e.g. transmission-blocking vaccines), early clinical trials of more effective second-generation *P. falciparum* vaccine candidates, and Phase IV trials of RTS,S.

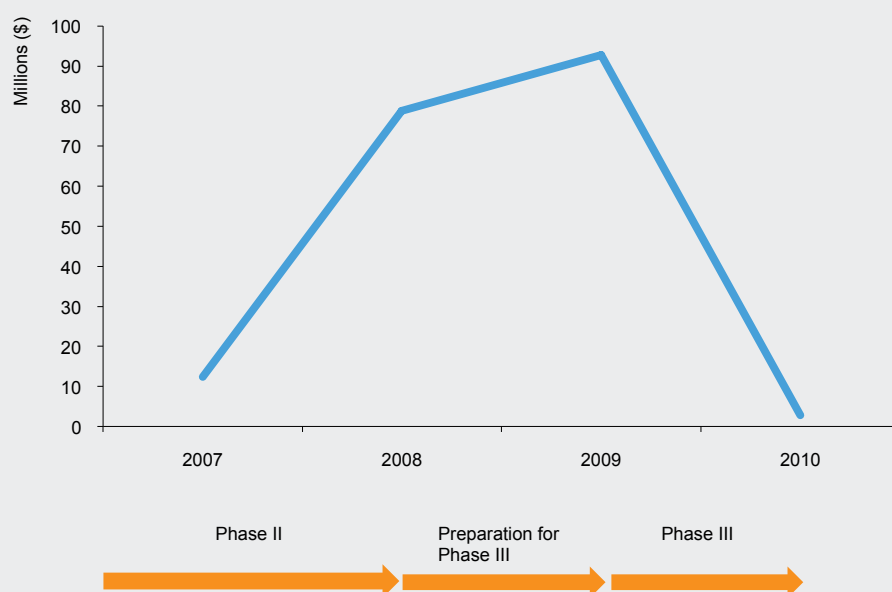
**Figure 29. Projected malaria vaccine R&D funding needs 2004–2010<sup>55</sup>**



A review of Bill & Melinda Gates Foundation funding shows reasonable alignment with the funding projections described above. The Gates Foundation increased its investments into malaria vaccine R&D more than six-fold between 2007 and 2009 (up \$80.3m, 647%). These increases were predominantly directed towards clinical development of the RTS,S malaria vaccine, with two large multi-year grants disbursed in 2008 and 2009. This funding peak was followed by a significant drop in malaria vaccine R&D funding in 2010 (down \$89.9m), mimicking the funding pattern projected above (see Figure 30). In 2010, after completion of the RTS,S funding cycle, the Gates Foundation shifted some of these funds to other priority areas with a \$37.6m increase in funding to PDPs working on pneumonia vaccines, TB drugs, HIV microbicides and malaria drugs.

The Gates Foundation's funding patterns demonstrate several features of good R&D funding. There are significant and well-timed funding increases to support an advanced candidate through to registration followed by a funding drop as the candidate moves to completion; importantly, the freed-up funds (although not all of them) are then redistributed to other priority R&D areas.

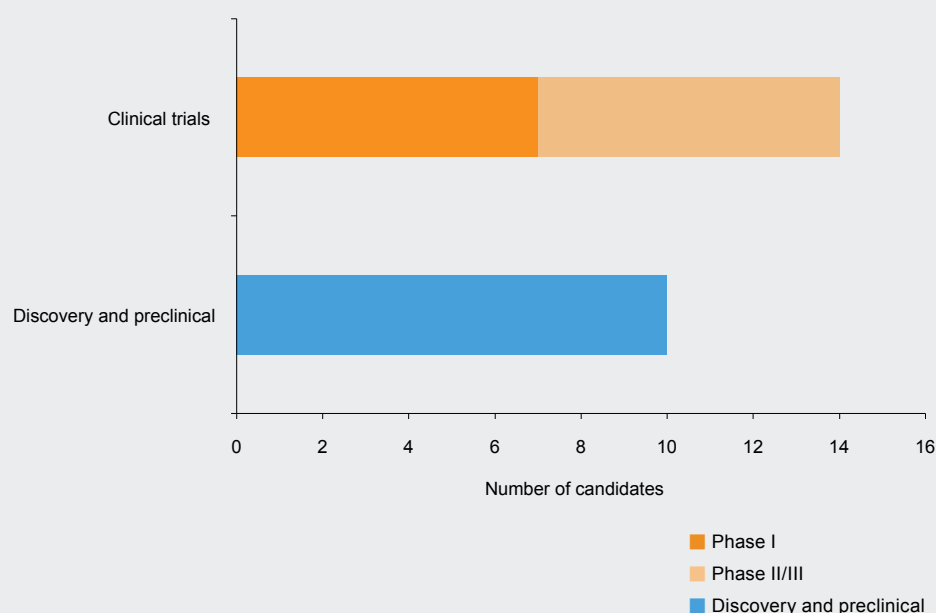
**Figure 30. Gates Foundation malaria vaccine R&D funding cycle 2007-2010**



## Public funders and the TB vaccine portfolio

The global TB vaccine pipeline includes 24 candidates in discovery, preclinical and clinical stages. The majority of these candidates (14 products, 60%) are in clinical trials and a good proportion (7 products, 30%) have already advanced to large, expensive Phase II and III trials (see Figure 31). The minority (10 products, 40%) are in the discovery and preclinical development stages. TB vaccine trials are expensive, lengthy and complex and require large numbers of patients to be followed for long periods due to lack of surrogate markers to predict vaccine efficacy.<sup>56</sup> This means that clinical costs for one vaccine candidate can be several hundred million dollars. By contrast, discovery and preclinical costs are far, far smaller – in the order of tens of millions. One would therefore expect funding for the TB vaccine portfolio to be very heavily weighted towards clinical investments, reflecting both the high costs of clinical trials and the significant number of TB vaccines approaching or already in these trials.

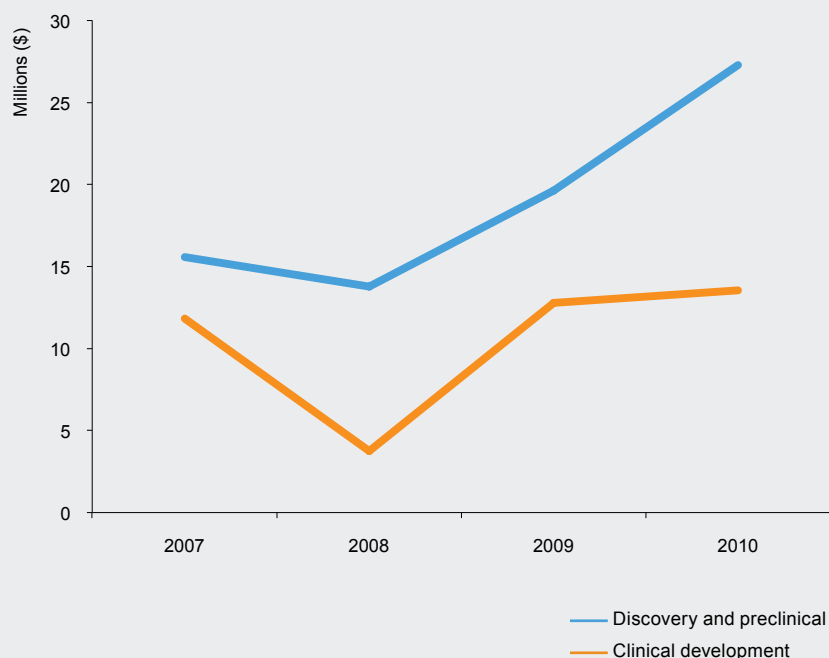
**Figure 31. Global TB vaccine portfolio 2011<sup>6</sup>**



However, review of the collective investment pattern of public funders of TB vaccine R&D (including 24 countries and 94 organisations) showed that more than twice as much TB R&D funding was directed to early laboratory and preclinical candidates in 2010 than to the vaccine candidates in clinical trials. Furthermore, the imbalance between preclinical and clinical investment appeared to be increasing with YOY public funding for discovery and preclinical R&D growing by 39.2% (\$7.7m) in 2010, compared to a very modest 5.8% (\$0.7m) increase in YOY funding for clinical development of TB vaccine candidates (see Figure 32).

The size, timing and targeting of public TB funding bore no relationship to the size of the TB vaccine portfolio, the maturity of the vaccine pipeline (including the presence of several advanced candidates), or the size and timing of vaccine trial funding needs.

**Figure 32. Public funding patterns for TB vaccines 2007-2010**



The two case studies above show very different levels of funding efficiency. Funding from the Bill & Melinda Gates Foundation was responsive to product needs on the ground, being well matched in both volume and timing to the development trajectory of the RTS,S malaria vaccine.

By contrast, public investment in TB vaccines was de-linked from product development on the ground due to several factors. Funding decisions were often driven by non-portfolio related factors such as domestic scientific capabilities, political commitments, investigator choices or scientific merit of research proposals (as opposed to defined product needs). A further key factor was the lack of coordination with other public, private and philanthropic funders, which fostered duplication, inefficiency and poorly targeted funding. This is a significant concern given that public funders accounted for almost half (47.8%) of global TB vaccine R&D funding in 2010.

R&D funding that is efficient and correlated to portfolio needs can only be achieved when funders integrate their priorities with global health priorities, inform their funding decisions with reliable information on the state of the global portfolio and R&D funding needs, and coordinate with other funders to improve the efficiency of neglected disease R&D funding. We note that some tools already exist to provide funders with this information including the BIO Ventures for Global Health (BVGH) Global Health Primer,<sup>6</sup> Roll Back Malaria Partnership's Global Malaria Action Plan (GMAP),<sup>57</sup> G-FINDER, and PATH's 2011 malaria R&D funding report.<sup>55</sup>

## Conclusion

The fallout from the global financial crisis was clearly evident in 2010, with investment in neglected disease R&D decreasing for the first time since the G-FINDER survey began. However, despite the unfavourable economic and political climate, many organisations continued to contribute generously, with significant progress seen in the neglected disease R&D pipeline. Promising new products and candidates resulting from this funding included the world's first malaria vaccine – already well into Phase III trials – new TB and dengue vaccines in advanced clinical trials, a new sleeping sickness drug in human trials, and successful registration of GeneXpert MTB/Rif – a new test that can diagnose drug-resistant TB in less than two hours.

We hope the information in G-FINDER continues to be a useful platform to guide future health R&D funding decisions, so that these and many other neglected disease products can be successfully delivered to patients in the developing world.

# ANNEXE 1

## Additional methodological considerations

### IDENTIFICATION OF SURVEY RECIPIENTS

Year One G-FINDER survey recipients were identified through various avenues including our own contacts database; previous neglected disease surveys in HIV/AIDS, TB, and malaria; and research to find previously unknown funding organisations in countries with high R&D expenditure per GDP.

In 2008, we focused on groups and countries that were missing or poorly represented in Year One, developing proactive strategies to both increase the number of survey recipients and improve response rates in these areas. Major Indian public agencies involved in funding R&D for neglected diseases were identified and incorporated in our list of participants whereas additional diagnostics organisations and SMEs were also included. In 2009, the survey was further expanded to capture major public funding agencies in an additional three developing countries: Ghana, Colombia and Thailand.

In 2010, G-FINDER expanded to survey public agencies in Argentina, Chile, Malaysia, Mexico, Nigeria, and Uganda. Also, the survey placed a greater focus on groups who had historically provided limited data, including the vector control industry and some German funding organisations; and included new groups identified by respondents as important funders. Overall, a list of 889 organisations in 54 target countries were surveyed (up from 847 in 2009). Of these, 513 were funders including 290 SMEs and 16 MNCs.

### RESTRICTIONS ON SPECIFIC DISEASE-PRODUCT AREAS

Following the methodology used in previous years of the G-FINDER survey, only investments specifically targeted at developing country needs were eligible for inclusion in R&D areas where commercial overlap was significant. For instance, a vaccine for *N. meningitidis* should provide coverage against *N. meningitidis* serotype A, be a conjugate rather than a polysaccharide vaccine, be designed for use in infants less than two years of age, and be designed to cost less than a dollar per dose. (See Table 1 for full inclusions for G-FINDER and the G-FINDER 2008 report for a full description of the original methodology to identify 'developing-country-specific' investment).

### HANDLING OF FINANCIAL DATA

The following key financial data collection principles were used:

- Survey recipients were asked to enter grant-by-grant expenditures incurred during their financial year (as opposed to the 2010 calendar year) that had the largest overlap with 2010. Intermediaries and product developers were also asked to enter grant-by-grant revenue during the same period
- Only expenditures were included, as opposed to commitments made but not yet disbursed or 'soft' figures such as in-kind contributions, costs of capital, or funding estimates
- All survey recipients entered data in their local currency. At the end of the survey period, all currencies were adjusted for inflation using Consumer Price Index estimates from the OECD and the International Monetary Fund (IMF).<sup>58,59</sup> Foreign currencies were then converted to US dollars based on the 2007 average annual exchange rate as reported by the IMF.<sup>60</sup>
- For consistency, 2010, 2009 and 2008 funding data is adjusted for inflation and reported in 2007 US dollars (US\$), unless indicated otherwise. This is important to avoid conflating real year-on-year changes in funding with changes due to exchange rate fluctuations. For reference purposes, unadjusted 2010 figures are also occasionally included; converted using the average annual exchange rate for 2010 as reported by the IMF.<sup>60</sup> When this occurs, the unadjusted (nominal US dollar) figure is shown in bracketed italicised text after the adjusted figure.



## SURVEY TOOL AND PROCESS

As in previous years, the following core principles were followed:

1. Only primary data reported by the funders, PDPs, and product developers themselves were included in the survey. No secondary data or estimates were included
2. All primary grant data were collected using the same online/offline reporting tool and inclusion/exclusion framework for all survey recipients.

The only exception to the second principle above was once again the US NIH, where grants were collected using the Research, Condition, and Disease Categorization (RCDC) system launched in January 2009. The information mined from this publicly available database was then supplemented and cross-referenced with information received from the Office of AIDS Research and the National Institute of Allergy and Infectious Diseases.

### Survey tool

Following the methodology used in previous years of G-FINDER, survey participants were asked to enter every neglected disease investment they had disbursed or received in their financial year 2010 into a password-protected online database, including the grant amount, grant identification number, a brief description of the grant, and the name of the funder or recipient of the grant. New survey recipients were also asked to confirm their organisation details such as role in funding (e.g. funder, fund manager, product developer), financial year, currency used, type of organisation (e.g. private sector firm, academic institution, PDP, multilateral organisation), and country where they were located. Each grant was entered using a three-step process where the survey recipient had to choose (1) a specific disease or sub-disease; (2) a product type (e.g. drugs, vaccines, microbicides); and (3) a research type within the product (e.g. discovery and preclinical, clinical development); according to pre-determined categories as described in Table 1. Where survey recipients could not provide data to this level of detail, they were asked to provide the finest level of granularity they could. If survey recipients were not able to allocate the grant to a single disease in step 1, three options were available:

- 'Core funding of a multi-disease organisation' (e.g. funding to an organisation working in multiple diseases, where the expenditure per disease was not known to the funder)
- 'Platform technologies', further allocated as investment into diagnostic platforms; adjuvants and immunomodulators; or delivery device platforms. These categories aimed to capture investments into technologies which were not yet directed towards a specific disease or product
- 'Unspecific R&D' for any grants that still could not be allocated.

### Data sharing with other surveys

Primary grant data for HIV/AIDS were shared with and between the HIV Vaccines and Microbicides Resource Tracking Working Group to avoid re-surveying funders when possible. Any primary grant data received by other groups were reviewed and reclassified according to G-FINDER guidelines prior to entry into the database.

## DATA CLEANING

Survey closure was followed by a three-month period of intensive cleaning, cross-checking, and organising of the complex dataset collected. All grants over \$0.5m (i.e. any grant over 0.02% of total funding), except for the US NIH grants obtained through their databases where the threshold was increased to \$2m, were then verified through a three-step process:

1. Each grant was reviewed against our inclusion criteria. Over 8,000 grants were manually checked for correct allocation to disease, product type and research type
2. Automated reconciliation reports were used to cross-check 'disbursed' funding reported by funders against 'received' funding reported by recipients (i.e. intermediaries and product developers)
3. Uncovered discrepancies were solved through direct contact with the funder and recipient to identify the correct figure. In the few cases where discrepancies remained, the funder's figures were used.

Industry figures were reviewed against industry portfolio information held by Policy Cures and against Full-Time Equivalent (FTE) and direct costs provided by other companies. Costs that fell outside the expected range, for example, above average FTE costs for clinical staff, were queried and corrected with the company.

#### LIMITATIONS TO INTERPRETATION

Potential limitations with any survey, including G-FINDER, are:

##### Survey non-completion

The list of survey recipients and the overall response rates marginally increased this year making 2008, 2009, and 2010 data a lot more comparable than 2008 and 2007 data (due to a significant increase in the size of the survey from Year One to Year Two of the G-FINDER survey). Still, however, some neglected disease R&D funding might not have been captured, either because organisations were not included in the list of recipients or because organisations did not complete the survey. For instance, the available data for the Department of Biotechnology of the Ministry of Science and Technology of India has been provided only from recipients of funds this year. This may lead to an underestimation of the true financial investments total committed to R&D for neglected diseases by India as a whole.

##### Time lags in the funding process

Time lags exist between disbursement and receipt of funding as well as between receipt of funds and the moment they are actually spent. Thus, grants by funders will not always be recorded as received by recipients in the same financial year and there may be a delay between R&D investments as reported by G-FINDER and actual expenditure on R&D programmes by product developers and researchers.

##### Inability to disaggregate investments

Funding allocated to some diseases and products may be slightly underestimated due to:

- Multi-disease organisations: Core funding grants to organisations working on multiple diseases such as OneWorld Health (OWH), the Special Programme for Research and Training in Tropical Diseases (WHO/TDR) and the European & Developing Countries Clinical Trials Partnership (EDCTP) are not counted within the funding figures for specific diseases
- Multi-disease grants: When funders were unable to disaggregate multi-disease grants, these investments were included in the 'Unspecified R&D category'. This is likely to particularly affect US NIH figures for individual diseases. This methodology was followed to prevent double counting investments from the US NIH and is also the reason why the G-FINDER figures do not match the RCDC figures (e.g. categories used in the RCDC system are not mutually exclusive and multi-disease grants are reported fully under all relevant diseases, with risk of double-counting).

### Non comparable data

The new public official database for the US NIH data, the RCDC, uses a different structure than the US NIH database used in 2008. This means reports obtained from RCDC this year are not directly comparable to those used in Year One.

### Missing data

G-FINDER can only report the data as it is given to us. Although strenuous efforts were made to check the classification, accuracy and completeness of grants, in a survey this size it is likely that some data will still have been incorrectly entered or that funders may have accidentally omitted some grants. We believe, however, that the checks and balances built into the G-FINDER process mean that such mistakes, if present, will have a minor overall impact.

### Updated methods

In Year Four of the G-FINDER survey we updated the methodology we use to calculate constant 2007 US dollar amounts, in order to be more consistent with the approach recommended by the World Bank.<sup>61</sup> The impact of the altered methodology was minimal; the new approach meant that the total reported R&D funding figure in 2010 was around 0.3% higher when adjusted for inflation and reported in 2007 US dollars than it would have been if using the methodology from previous years.

## VARIATION BETWEEN SURVEYS

Annual surveys of global R&D investment into some neglected diseases such as HIV/AIDS and TB in 2010 have been published or are expected to be published soon. Although G-FINDER worked in close collaboration with some of these groups, both to ease survey fatigue on the part of funders and to clarify any major variance in our findings, each survey nevertheless has slightly different figures. This is chiefly due to differences in scope, in particular inclusion in other surveys of funding for advocacy, capacity-building and operational studies – all excluded from G-FINDER. Methodological differences also lead to variations, in particular that G-FINDER figures are adjusted for inflation and exchange rates, which is not always the case for other surveys. As mentioned above, classification of some funding as 'unspecified' in G-FINDER (e.g. multi-disease programmes) may in some cases lead to different figures than those for disease specific surveys.

## ANNEXE 2

### Advisory Committee members & additional experts

ADVISORY COMMITTEE MEMBER	ORGANISATION	TITLE
Ripley Ballou	GlaxoSmithKline Biologicals	Vice President
Lewellys F. Barker	Aeras	Senior Medical Advisor
Ted Bianco	Wellcome Trust	Director of Technology Transfer
Simon Croft	London School of Hygiene & Tropical Medicine (LSHTM)	Professor of Parasitology
Michael J. Free	Program for Appropriate Technology in Health (PATH)	Vice President and Senior Advisor for Technologies Global Program Leader, Technology Solutions
Nirmal K. Ganguly	Centre for Health Technology, National Institute for Immunology, India	Distinguished Biotechnology Fellow
Carole Heilman	National Institute of Allergy and Infectious Diseases (NIAID), United States	Director of Division of Microbiology and Infectious Diseases
Janet Hemingway	Innovative Vector Control Consortium (IVCC)	Chief Executive Officer
Peter Hotez	Baylor College of Medicine and Sabin Vaccine Institute	President, Sabin Vaccine Institute Professor of Pediatrics and Molecular Virology and Microbiology, Chief of Pediatric Tropical Medicine and founding Dean of the National School of Tropical Medicine at Baylor College of Medicine
Marie-Paule Kieny	World Health Organization (WHO)	Assistant Director-General - Innovation, Information, Evidence and Research
Wayne Koff	International AIDS Vaccine Initiative (IAVI)	Senior Vice President and Chief Scientific Officer
Regina Rabinovich	Bill & Melinda Gates Foundation	Director of Infectious Diseases Development, Global Health Program
Robert Ridley	WHO-based Special Programme for Research and Training in Tropical Diseases (TDR)	Director

ADVISORY COMMITTEE MEMBER	ORGANISATION	TITLE
Joseph Romano	NWJ Group, LLC	President
Giorgio Roscigno	Foundation for Innovative New Diagnostics (FIND)	Chief Executive Officer
Melvin K. Spigelman	The Global Alliance for TB Drug Development	President and Chief Executive Officer
Timothy Wells	Medicines for Malaria Venture (MMV)	Chief Scientific Officer

## ANNEXE 3

### Stakeholder Network members

ORGANISATION	COUNTRY
AstraZeneca	UK
Becton, Dickinson and Company	USA
Bill & Melinda Gates Foundation	USA
Brazilian Ministry of Health, Department of Science and Technology	Brazil
Crucell	The Netherlands
UK Department for International Development (DFID)	UK
Eli Lilly and Company	USA
European Commission: Research Directorate-General	Belgium
GlaxoSmithKline (GSK)	UK
Irish Aid	Ireland
MSD	USA
Dutch Ministry of Foreign Affairs	The Netherlands
Novartis	Switzerland
Otsuka Pharmaceutical Co. Ltd.	Japan
Pfizer	USA
Public Health Agency of Canada (PHAC)	Canada
sanofi-aventis	France
South African Department of Science and Technology (DST)	South Africa
Swiss Agency for Development and Cooperation (SDC)	Switzerland
UK Medical Research Council (MRC)	UK
United States Agency for International Development (USAID)	USA
US Centers for Disease Control (CDC)	USA
US Department of Defense (DOD)	USA
US National Institutes of Health (NIH)	USA
Wellcome Trust	UK

## ANNEXE 4

### Survey respondent list

#### ORGANISATION NAME

- Abbott Laboratories
- Aché Laboratories
- Advanced Bioscience Laboratory
- Advinus Therapeutics
- Aeras
- African Malaria Network Trust (AMANET)
- American Foundation for AIDS Research (amfAR)\*
- American Leprosy Missions
- Anacor Pharmaceuticals
- Argentinean Ministry of Science, Technology and Productive Innovation
- Argentinean National Council for Scientific and Technical Research (CONICET)
- Arizona State University
- Italian Association Amici de Raoul Follereau (AIFO)
- AstraZeneca
- Australian Army Malaria Institute
- Australian Government Department of Innovation, Industry, Science and Research
  - including data from Australian Research Council (ARC)
- Australian National Health and Medical Research Council (NHMRC)
- BASF Corporation
- Bavarian Nordic
- Bayer CropScience
- Belgian Ministry of Foreign Affairs
  - including data from Belgian Development Cooperation (DGDC)
- Bernhard Nocht Institute for Tropical Medicine (BNI)
- Bill & Melinda Gates Foundation
- Bio Manguinhos
- Biological E Limited
- Bionet-Asia Co., Ltd.
- Brazilian Federal University of Ouro Preto (UFOP)
- Brazilian Ministry of Health: Department of Science and Technology (DECIT)
- Brazilian Ministry of Health: National STD and AIDS Programme\*
- Brooklyn College

- C&O Pharmaceutical Technology (Holdings) Limited
- Canadian Institutes of Health Research (CIHR)
- Canadian International Development Agency (CIDA)
- Caprion Proteomics
- Carlos III Health Institute
- Celgene Corporation
- Center for Public Health Research (CPHR) of Nanjing University\*
- Cepheid
- Chilean National Commission for Scientific and Technological Research (CONICYT) (Associative Research Program- PIA)
- Chilean Attraction and Job Insertion of Advanced Human Capital Program (PAI)
- Chilean Fund for the Promotion of Scientific and Technological Development (FONDEF)
- Chilean National Fund for Health Research and Development (FONIS)
- Chilean National Fund for Scientific and Technological Development (FONDECYT)
- Chilean Regional Program of the National Commission for Scientific and Technological Research (Regional Program, CONICYT)
- Colombian Department for Science, Technology and Innovation (Colciencias)
- Chilean Ministry for the Economy, Development and Tourism (Corporation for the Promotion of Production, CORFO program)
- Millennium Science Initiative (ICM) program at the Chilean Ministry for the Economy, Development and Tourism
- Crucell
- CSL Ltd
- Daktari Diagnostics, Inc.
- Danish Bilharziasis Laboratory (DBL)
- Danish Ministry of Foreign Affairs
  - including data from Danish International Development Agency (DANIDA)
- DesignMedix, Inc.
- Drugs for Neglected Diseases initiative (DNDi)

\* Denotes organisations where data was only received via the HIV Vaccines and Microbicides Resource Tracking Working Group

## ORGANISATION NAME

- Dutch Ministry of Foreign Affairs - Directorate General of Development Cooperation (DGIS)
- Dutch Organisation for Scientific Research (NWO)
- Elizabeth Glaser Pediatric AIDS Foundation (EGPA)\*
- Emergent Biosolutions
  - including data from Microscience and Antex biologicals Inc
- EpiVax
- European Vaccine Initiative (EVI)
- European and Developing Countries Clinical Trials Partnership (EDCTP)
- European Commission
- European Molecular Biology Laboratory (EMBL)
- Fio Corporation
- FK Biotecnología
- Fondation Mérieux
- Fondation Raoul Follereau (FRF)
- Fondazione Cariplo
- Fontilles
- Foundation for Innovative New Diagnostics (FIND)
- French National Agency for AIDS Research (ANRS)
- French National Research Agency, Agence Nationale de Recherche (ANR)
- Funding Agency for Technology and Innovation (TEKES)
- GENOVAC GmbH
- Genzyme
- George Washington University
- Georgetown University
- German Federal Ministry for Economic Cooperation and Development (BMZ)
- German Federal Ministry of Education and Research (BMBF)
- German Federal Ministry of Health (BMG)
- German Leprosy and TB Relief Association (DAHAW)
- German Research Foundation (DFG)
- Ghana Health Service
- GlaxoSmithKline (GSK)
  - including data from GSK Bio
- Global Alliance for TB Drug Development (TB Alliance)

- Global Solutions for Infectious Diseases
- Global Vaccines, Inc.
- Hawaii Biotech, Inc.
- UK Health Protection Agency: Centre for Emergency Preparedness and Response
- Health Research Council of New Zealand (HRC)
- Hebron Farmacêutica, Ltd.
- Heinrich-Pette-Institut Hamburg
- HIVACAT\*
- Spanish University Hospital Vall d'Hebron
- iCo Therapeutics
- Immune Disease Institute, Inc.
- Immuno-Mycologics
- Indian Council of Medical Research (ICMR)
- Indian Council of Scientific and Industrial Research (CSIR)
- Indian Department of Biotechnology, Ministry of Science and Technology (DBT)
- Indian Department of Science & Technology
- Infectious Disease Research Institute (IDRI)
- Innovative Vector Control Consortium (IVCC)
- InPheno AG
- Inserm - Institute of Infectious Diseases
- Institut Pasteur
- Institute of Tropical Medicine Antwerp/Prince Leopold Institute of Tropical Medicine (ITM)
- Integral Molecular
- International AIDS Vaccine Initiative (IAVI)
- International Centre for Genetic Engineering and Biotechnology (ICGEB), India
- International Committee of the Order of Malta for Leprosy Relief (CIOMAL)
- International Partnership for Microbicides (IPM)
- International Vaccine Institute (IVI)
- Inviragen, Inc.
- Irish Aid
- Italian National Institute for Infectious Diseases
- Jacobus Pharmaceuticals
- Japanese Ministry of Education, Culture, Sport, Science and Technology (MEXT)



## ORGANISATION NAME

- Japanese National Institute of Infectious Diseases (NIID)
- John M. Lloyd Foundation
- Johnson & Johnson
- Keck Foundation
- KNCV Tuberculosis Foundation
- Korean Institute of Tuberculosis
- Laboratório Farmacêutico do Estado de Pernambuco (LAFEPE)
- LifeMed
- Liverpool School of Tropical Medicine (LSTM)
- London School of Hygiene and Tropical Medicine (LSHTM)
- Ludwig Maximilians University of Munich (LMU)
- Macfarlane Burnet Institute for Medical Research and Public Health
- Malaysian Ministry of Science and Technology (MOSTI)
  - including data from the National Biotechnology Division (BIOTEK)
- Mapp Biopharmaceuticals
- Max Planck Society - Max Planck Institute for Infection Biology (MPIIB)
- Medicines for Malaria Venture (MMV)
- Medisyn Technologies
- MSD
- Mexican National Institute of Public Health (INSP)
- Mexico National Council of Science and Technology (CONACYT)
- Microbicides Development Programme (MDP)
- Mymetics\*
- Nano Endoluminal
- Netherlands Leprosy Relief (NLR)
- Nigerian Federal Ministry of Health
- Nippon Foundation
- Norwegian Centre for International Cooperation in Higher Education (SIU)
- Norwegian Institute of Public Health
- Novartis
- Nuffield Foundation
- OneWorld Health
- Ortho-Clinical Diagnostics and Tibotec (Johnson & Johnson companies)
- Otsuka Pharmaceutical Co., Ltd.
- Ouro Fino
  - including data from Alvos - Consultoria, Desenvolvimento e Comercializacao de Produtos Biotecnologicos S.A.
- Oxford-Emergent Tuberculosis Consortium (OETC)
- Palumed S.A.
- Partec GmbH
- Pediatric Dengue Vaccine Initiative (PDVI)
- Pele Nova Biotecnologia SA
- Pfizer
- Pneumococcal Vaccine Accelerated Development and Introduction Plan (PneumoADIP)
- PolyTherics Ltd
- Premier Medical Corporation, Ltd.
- Program for Appropriate Technology in Health (PATH)
  - including data from Meningitis Vaccine Project (MVP), Malaria Vaccine Initiative (MVI), Technology Solutions, Vaccine Development, Vaccine Access and Delivery
- Public Health Agency of Canada (PHAC)
- Queensland Institute of Medical Research (QIMR)
- Quro Science
- Ranbaxy
- Research Centre Borstel
- Research Council of Norway
- Research Council, Academy of Finland\*
- Robert Koch Institute
- Royal Norwegian Ministry of Foreign Affairs
  - including data from Norwegian Agency for Development Cooperation (NORAD)
- Royal Tropical Institute (KIT)
- Sabin Vaccine Institute
- Salubris Group
- Sanofi Pasteur
- sanofi-aventis
- Sasakawa Memorial Health Foundation (SMHF)

\* Denotes organisations where data was only received via the HIV Vaccines and Microbicides Resource Tracking Working Group

## ORGANISATION NAME

- Leprosy Relief, Secours aux Lepreux (SLC)
- Sequella
- Serum Institute of India
- Siemens Healthcare Diagnostics
- Sigma-Tau
- South Africa Medical Research Council (MRC)
- South African AIDS Vaccine Initiative (SAAVI)
- South African Department of Science and Technology (DST)
  - including data from the Technology Innovation Agency
- Spanish Clinical Foundation for Biomedical Research (FCRB)
- Spanish Ministry of Foreign Affairs and Cooperation for Development (MAEC)
  - including data from Agency of International Cooperation for Development (AECID)
- Statens Serum Institute (SSI)
- Swedish International Development Agency (SIDA)
- Swedish Research Council
- Swiss Agency for Development and Cooperation (SDC)
- Swiss National Science Foundation (SNF)
- Swiss State Secretariat for Education and Research (SER)
- Swiss Tropical & Public Health Institute
- Syngenta Crop Protection AG
- TD Vaccines A/S
- Thai Ministry of Public Health, Department of Medical Sciences
- Thailand Government Pharmaceutical Organisation (GPO)
- Thailand National Science and Technology Development Agency (NSTDA)
- Thailand Research Fund (TRF)
- The Hospital for Tropical Diseases (HTD)
- The Leprosy Mission International (TLMi)
- The Research Institute of Tuberculosis, Japan Anti-Tuberculosis Association (RIT/JATA)
- The Walter and Eliza Hall Institute of Medical Research

- The Wellcome Trust
- TuBerculosis Vaccine Initiative (TBVI)
- Turing Foundation
- UBS Optimus Foundation
- Ugandan Medical Research Council (MRC)
- UK Department for International Development (DFID)
- UK Medical Research Council (MRC)
- United States Agency for International Development (USAID)
- Universidad Autonoma de Yucatan
- University of Oxford
- University of Bergen
- University of Bristol
- University of California Berkeley
- University of Dundee
- University of Georgia (UGA)
- University of Mississippi
- University of Nebraska Medical Center
- University of North Carolina
- US Centers for Disease Control (CDC)
- US Department of Defense (DOD)
  - including data from DOD Defense Advanced Research Projects Agency (DARPA)
- US National Institutes of Health (NIH)
- Vertex Pharmaceuticals Incorporated
- VIRxSYS Corporation
- Wave 80 Biosciences
- Worcester Polytechnic Institute
- World Bank
- World Health Organization: Special Programme for Research and Training in Tropical Diseases (WHO/TDR)

## ANNEXE 5

### Summary of R&D reference document

The full R&D reference document is lengthy (21 pages) and detailed, therefore only a summary is presented here.

#### 1 BASIC RESEARCH

*Studies that increase scientific knowledge and understanding about the disease, disease processes, pathogen or vector, but which are not yet directed towards a specific product*

- Natural history and epidemiology
- Immunology of disease
- Biology of disease
- Biochemistry of the pathogen
- Genetics of the pathogen
- Bioinformatics and proteomics
- Pathophysiology and disease symptoms
- Vector biology, biochemistry and genetics

#### 2 DRUGS

*Research activities and processes necessary to develop and improve new compounds specifically designed to cure or treat neglected diseases; including drug discovery or design, preclinical and clinical development and other activities essential for successful drug development and uptake*

- Discovery and preclinical
- Clinical development
- Phase IV/ pharmacovigilance studies associated with newly approved drugs only
- Baseline epidemiology directly linked to trials of products in development

#### 3 PREVENTIVE VACCINES

*Research activities and processes necessary to develop and improve investigational vaccines specifically intended to prevent infection; including vaccine design, preclinical and clinical development and other activities essential for successful vaccine development and uptake*

- Discovery and preclinical
- Clinical development
- Phase IV/ pharmacovigilance studies associated with newly approved vaccines only
- Baseline epidemiology directly linked to trials of products in development

#### 4 DIAGNOSTICS

*Research activities and processes necessary to develop, optimise, and validate diagnostic tests for use in resource-limited settings (cheaper, faster, more reliable, ease of use in the field); including discovery and design, preclinical and clinical evaluation, and other activities essential for successful deployment for public health use*

- Discovery and preclinical
- Clinical evaluation
- Operational research necessary to support WHO recommendation for global public health use

## 5 MICROBICIDES

*Research activities and processes necessary to develop and improve topical microbicides specifically intended to prevent HIV transmission; including microbicide discovery or design, preclinical and clinical development, and other activities essential for successful microbicide development and uptake*

- Discovery and preclinical
- Clinical development
- Phase IV/ pharmacovigilance studies associated with newly approved microbicides only
- Baseline epidemiology directly linked to trials of products in development

## 6 THERAPEUTIC VACCINES

*Research activities and processes necessary to develop and improve investigational vaccines specifically intended to treat infection; including vaccine design, preclinical and clinical development, and other activities essential for successful vaccine development and uptake*

- Discovery and preclinical
- Clinical development
- Phase IV/ pharmacovigilance studies associated with newly approved vaccines only
- Baseline epidemiology directly linked to trials of products in development

## 7 VECTOR CONTROL PRODUCTS

### A) PESTICIDES

*ONLY includes chemical pesticides intended for global public health use and which specifically aim to inhibit and kill vectors associated with transmitting poverty-related diseases, including:*

- Primary screening and optimisation
- Secondary screening and optimisation
- Development
- WHO Pesticide Evaluation Scheme (WHOPES)

### B) BIOLOGICAL CONTROL PRODUCTS

*ONLY includes research and development of innovative biological control interventions that specifically aim to kill or control vectors associated with transmitting poverty-related diseases, including:*

- Microbial/ bacteriological larvicides
- Sterilisation techniques
- Genetic modification measures

### C) VACCINES TARGETING ANIMAL RESERVOIRS

ONLY includes research and development of veterinary vaccines specifically designed to prevent animal to human transmission of neglected diseases

## 8 CANNOT BE ALLOCATED TO ONE DISEASE

### A) CORE FUNDING OF A MULTI-DISEASE R&D ORGANISATION

## B) PLATFORM TECHNOLOGIES

- Adjuvants and immunomodulators
- Delivery technologies and devices
- General diagnostic platforms

*This category has **strict limitations**. It ONLY includes funding for R&D for the above, which also meets the following conditions:*

- It is conducted by **public, philanthropic or not-for-profit entities**
- It is **basic research** i.e. it is not yet directed towards a specific disease or product area
- It is aimed at developing safer, cheaper, more effective products suitable for use in developing countries
- The resulting research findings or leads MUST be accessible to organisations developing pharmaceutical or biological products for neglected diseases

## c) UNSPECIFIED R&D

Funding that cannot be apportioned to any specific disease categories

## 9 OUT OF SCOPE (EXCLUDED FROM THE SURVEY)

### A) GENERAL EXCLUSIONS

- Non-pharmaceutical tools including: Adult male circumcision, cervical barriers, HSV-2 prevention, bednets, traps, water sanitation tools
- General supportive, nutritional and symptomatic therapies, including: Oral rehydration therapy, micronutrient supplementation, vitamins and anti-pyretics, painkillers
- Products developed and used for veterinary purposes
- In-kind contributions
- Additional exclusions for private sector investment include: Industry overhead costs, capital costs and opportunity costs due to the difficulty of quantifying these and allocating them to the neglected disease investment

### B) NON-PRODUCT R&D

*Our intention is to capture investments into **neglected disease product development** as accurately as possible. Therefore, the following R&D activities are excluded from the survey*

- Clinical studies that are not linked to development of a NEW product
- Health services and access research
- Operational programme assessment
- GENERAL Capacity Building (human & infrastructure)  
Capacity building activities are excluded except those that are DIRECTLY linked to development of a new neglected disease product

### C) SELECTED DISEASE AND PRODUCT RESTRICTIONS

*Commercial diseases where incentives for R&D already exist; or product R&D already occurs in response to the existing Western markets, are EXCLUDED from this survey*

#### Basic research

*Basic research is RESTRICTED for the following diseases:*

- HIV/AIDS: ONLY includes basic research related to preventive vaccines and microbicides (e.g. immunology responses to potential antigens, mechanism of mucosal transmission)

## Drugs

R&D for drugs is *RESTRICTED* for the following diseases:

- HIV/AIDS: ONLY includes label extensions and reformulations for developing country use (e.g. paediatric or slow-release formulations; fixed dose combinations).
- Diarrhoea caused by cholera, shigella, *cryptosporidium*: ONLY includes pharmacological interventions that target the pathogen, not supportive therapies.

## Preventive Vaccines

R&D for preventive vaccines is *RESTRICTED* for the following diseases:

- *Bacterial pneumonia caused by S. pneumoniae*  
ONLY includes R&D on vaccines specifically for developing-country registration. Such a vaccine must at a minimum: a) be designed for use in infants less than two years of age; and b) provide coverage against *S. pneumoniae* serotypes 1, 5, and 14.  
For multi-valent vaccines covering Western and developing country strains, only developing country-specific costs should be entered; including for trials, registration and Phase IV/ pharmacovigilance studies.
- *Bacterial pneumonia or meningitis caused by N. meningitidis*  
ONLY includes R&D on vaccines specifically for developing-country registration. Such a vaccine must, at a minimum: a) provide coverage against *N. meningitidis* serotype A; b) be a conjugate vaccine; c) be designed for use in infants less than two years of age; and d) be designed to cost less than a dollar per dose.  
For multi-valent vaccines covering Western and developing country strains, only developing country-specific costs should be entered; for example, for trials, registration and Phase IV/ pharmacovigilance studies in the target developing countries.
- *Diarrhoea caused by rotavirus*  
ONLY includes developing country-specific R&D, including clinical trials, registration and Phase IV/ pharmacovigilance studies in the target developing countries.

## Diagnostics

See above

## Vaccines (Therapeutic)

See above

## Microbicides

Applications that may have Western markets or be useful for other STDs (e.g. mucosal delivery technology, adjuvants) are EXCLUDED

## Vector Control Products

Baits, traps, predation measures, biological larvicides, habitat control and infrastructure measures are excluded from this product category. Vaccines developed and used solely for veterinary purposes are excluded from this product category

## Cannot be allocated to one disease

- Adjuvants and immunomodulators
- General diagnostic platforms
- Delivery devices and technologies

*This category has strict limitations (see above)*

## AUTHORS



### Dr Mary Moran

#### Director

*MBBS (Bachelor of Medicine, Bachelor of Surgery, Hons); Grad Dip FAT (Foreign Affairs and Trade)*

Dr Moran has over 20 years' experience in health policy and practice, including 10 years specialising in neglected disease policy. She has conducted projects for a wide range of public and multilateral health organisations with a focus on policy solutions for emerging issues related to neglected disease R&D. In 2004, Mary founded the research group that became Policy Cures at the London School of Economics & Political Science, later transferring it to the George Institute for International Health in Sydney.

Prior to forming the group, she worked for over a decade in Emergency Medicine; was a diplomat and policy analyst with the Australian Department of Foreign Affairs & Trade; Director of Médecins Sans Frontières Access to Essential Medicines Campaign in Australia; and a Europe-based policy advocate with MSF on issues relating to access to medicines for neglected patients. Mary is an Honorary Senior Lecturer at the London School of Hygiene and Tropical Medicine, and an Expert Adviser to the World Health Organisation, European Commission, European and Developing Countries Clinical Trials Partnership, Global Alliance for Vaccines and Immunisation (GAVI), OECD and the Wellcome Trust.



### Dr Javier Guzman

#### Director of Research

*MBBS (Bachelor of Medicine, Bachelor of Surgery, Hons); MSc in Health Policy, Planning and Financing*

Javier Guzman has worked in public health policy and practice for 12 years, specialising in neglected disease policy since 2004. Javier trained as a physician, working for several years in planning and implementation of primary health care projects in Colombia and subsequently as a Post Graduate Clinical Fellow in Paediatrics at the Royal London Hospital.

Javier has been with the Policy Cures team since 2004, and as Director of Research since 2009. He is an Honorary Lecturer at the London School of Hygiene and Tropical Medicine and the University of Sydney, and an expert adviser to the European and Developing Countries Clinical Trials Partnership and the Global Alliance for Vaccines and Immunisation (GAVI). He has an MSc in Health Policy, Planning and Financing from the LSE and the London School of Hygiene and Tropical Medicine and is currently doing an MBA-Executive at the Australian Graduate School of Management, Sydney.



## Lisette Abela-Oversteegen

### Senior Policy Analyst

*B (Bachelor of Health); MSc in Public Health*

Lisette has 5 years' experience as a commercial analyst of the pharmaceutical industry. In her last role working for business information company Datamonitor, she focused on collecting and analysing market data and formulating strategic insights and recommendations for the pharmaceutical sector. Lisette also worked as a volunteer in several projects in Kenya and Chile focusing on sexual health education.

She received a Bachelor of Health in Occupational Therapy from the Hogeschool van Amsterdam, The Netherlands, and a Master of Public Health from Maastricht University, The Netherlands. Lisette joined the Policy Cures team in October 2010.



## Roni Liyanage

### Senior Policy Analyst

*BA (Bachelor of Arts); MPH (Master of Public Health); MBA (Master of Business Administration)*

Roni Liyanage has more than 10 years' experience working in international health policy and advocacy. Prior to joining Policy Cures, Roni worked as an advocacy and communications specialist developing initiatives and campaigns for clients including the Bill & Melinda Gates Foundation, GAVI Alliance, Imperial College London, Malaria Consortium and the Roll Back Malaria partnership. Roni spent 5 years managing reproductive health and HIV prevention programmes for adolescents in sub-Saharan Africa.

Roni received his Bachelor of Arts in Human Sciences from Oxford University. He has a Master in Public Health from Johns Hopkins Bloomberg School of Public Health and an MBA from the London Business School. Roni joined the Policy Cures team in June 2011.





## Dr Brenda Omune

### Senior Researcher

*MBChB (Bachelor of Medicine, Bachelor of Surgery); MIPH (Master of International Public Health, Hons)*

Brenda has 8 years' policy and practical experience in developing world health issues. As a Kenyan doctor, she is experienced in clinical management of patients with infectious diseases including malaria, meningitis, pneumonia and tuberculosis, and was closely involved in the rollout of anti-retroviral therapy (ART) in Kenya.

Brenda has a degree in Medicine and Surgery (MBChB) from the University of Nairobi, Kenya, and a Masters of International Public Health (Honours) from the University of Sydney. She joined the team in June 2008.



## Lindsey Wu

### Policy Analyst

*BAS Biotechnology, BA Economics, MSc Biomedicine, Bioscience and Society*

Lindsey has 4 years' experience in health policy, including as a healthcare policy consultant for The Lewin Group in Washington, DC, focusing on health technology assessments for the Agency for Healthcare Research and Quality (AHRQ), clinical data analysis for the National Institutes of Health (NIH), and evidence-based reviews of pharmacogenomics for the US Department of Health and Human Services (DHHS).

Lindsey received a Bachelor of Applied Science in Biotechnology and a BA in Economics from the University of Pennsylvania, and an MSc from the London School of Economics. Lindsey joined the team as a Research Associate in February 2008.



## Dr Nick Chapman

### Policy Analyst

*MBBS (Bachelor of Medicine, Bachelor of Surgery, Hons); BMedSci (Bachelor of Medical Science); MHR (Master of Human Rights, Merit)*

Nick Chapman has 4 years' experience in health policy and practice. He has worked as a doctor in Tasmania, where he completed his medical training, during which time he was involved in a number of primary clinical research projects. Prior to joining Policy Cures, he worked with Oxfam Australia and the Australian Human Rights Commission, focusing on indigenous health policy.

Nick has a Bachelor of Medicine, Bachelor of Surgery, and a Bachelor of Medical Science from the University of Tasmania, and a Master of Human Rights from the University of Sydney. He joined the Policy Cures team in September 2010.



## Dimitris Gouglas

### Research Associate

*BSc Economics, MSc Health Policy, Planning and Financing*

Dimitris joined Policy Cures as a Research Associate in August 2010. He previously worked in EU project consulting with a focus on public health and health policy research programmes of the European Commission. Dimitris was a Project Manager at the National School of Public Health of Greece, and a Research Assistant at the LSE Health, the George Institute for International Health, and the Personal and Social Services Research Unit (PSSRU). Dimitris has a BSc in Economics from SOAS, University of London, and an MSc in Health Policy, Planning and Financing from LSE and LSHTM, University of London. He is currently finishing his MSc in Financial Economics at CeFiMS, University of London.

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