G-FINDER 2010
Global Funding of Innovation for Neglected Diseases

POLICYCURES

# NEGLECTED DISEASE RESEARCH AND DEVELOPMENT:
# IS THE GLOBAL FINANCIAL CRISIS CHANGING R&D?


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# ACKNOWLEDGEMENTS

This is the third in a series of annual reports undertaken by Policy Cures staff in the framework of the G-FINDER project. We are very grateful to all the participants in our survey. With their commitment, we have been able to continue to provide accurate up-to-date financial information in the field of research and development (R&D) for neglected diseases. The patience and engagement of the participating government and multilateral agencies, academic and research institutions, Product Development Partnerships, philanthropic institutions and pharmaceutical and biotechnology companies has made this project possible.

We would like to extend our gratitude to our Advisory Committee, Stakeholder Network and other experts for their invaluable advice on the design and scope of our study. A particularly warm thanks goes to the HIV Vaccines and Microbicides Resource Tracking Working Group, and the Treatment Action Group (TAG) for coordinating their initiatives with ours where possible.

We would also like to acknowledge the important contribution of trade organisations, especially AdvaMed (Advanced Medical Technology Association) and BVGH (BIO Ventures for Global Health), whose dedication and enthusiasm facilitated the expansion of the survey to many more organisations in the field of R&D for neglected diseases.

We are especially grateful to Fred Zmudzki, our project manager; our administrative team, Susan Hall and Donna Robinson; and our contract researchers Vipul Chowdhary, Maria De la Pava, Heather Quinn, Ivana Durcinoska, Mirvat Said, Sashini Pagayala, John Onaji and Eugenia Afonso. Their dedicated efforts were key to the survey's success.

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# ACRONYMS

| | |
|---|---|
| ACTs | Artemisinin-based combination therapies |
| ADME | Absorption, Distribution, Metabolism and Excretion |
| AdvaMed | Advanced Medical Technology Association |
| Aeras | Aeras Global TB Vaccine Foundation |
| AMC | Advance Market Commitment |
| ANR | French National Research Agency |
| ANRS | French National Agency for AIDS Research |
| APOC | African Programme for Onchocerciasis Control |
| ARRA | American Recovery and Reinvestment Act |
| AVI | Accelerated Vaccine Initiative |
| BBSRC | UK Biotechnology and Biological Sciences Research Council |
| BVGH | BIO Ventures for Global Health |
| CDC | US Centers for Disease Control and Prevention |
| CIDA | Canadian International Development Agency |
| CIHR | Canadian Institutes of Health Research |
| Colciencias | Colombian Department for Science, Technology and Innovation |
| CSIR | Council of Scientific and Industrial Research |
| DALY | Disability-Adjusted Life Year |
| DCs | Developing Countries |
| DFG | German Research Foundation |
| DFID | UK Department for International Development |
| DIISR | Australian Department of Innovation, Industry, Science and Research |
| DNDi | Drugs for Neglected Diseases initiative |
| DOD | US Department of Defense |
| DOH | Department of Health |
| DST | Department of Science and Technology |
| EAggEC | Enteroaggregative *E. coli* |
| EC | European Commission |
| ETEC | Enterotoxigenic *E. coli* |
| EU | European Union |
| EVI | European Vaccine Initiative |
| FAPEMIG | Fundação de Amparo à Pesquisa do Estado de Minas Gerais |
| FAPERJ | Carlos Chagas Filho Foundation for Research Support of the State of Rio de Janeiro |
| FDC | Fixed-Dose Combination |
| FIND | Foundation for Innovative New Diagnostics |
| FWO | Belgian National Fund for Scientific Research |
| GAVI | Global Alliance for Vaccines and Immunizations |
| GDP | Gross Domestic Product |
| GERD | Gross Expenditure on Research & Development |
| G-FINDER | Global Funding of Innovation for Neglected Diseases |
| HAT | Human African Trypanosomiasis |
| HICs | High-Income Countries |
| HIV/AIDS | Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome |
| IAVI | International AIDS Vaccine Initiative |
| ICMR | Indian Council of Medical Research |
| IDCs | Innovative Developing Countries |
| IDRI | Infectious Disease Research Institute |
| iOWH | Institute for One World Health |
| IPM | International Partnership for Microbicides |
| IVCC | Innovative Vector Control Consortium |
| IVI | International Vaccine Initiative |
| LMICs | Low- and Middle-Income Countries |
| LSHTM | London School of Hygiene and Tropical Medicine |
| MAEC | Spanish Ministry of Foreign Affairs and Cooperation for Development |
| MAEE | French Ministry of Foreign and European Affairs, Ministère des Affaires étrangères et européennes |

# ACRONYMS

| | |
|---|---|
| MDR-TB | Multidrug-Resistant Tuberculosis |
| MDT | Multidrug therapy |
| MICs | Middle-Income Countries |
| MMV | Medicines for Malaria Venture |
| MNC | Multinational pharmaceutical company |
| MRC | Medical Research Council |
| MSF | Medécins Sans Frontières |
| MVI | PATH Malaria Vaccine Initiative |
| NHF | Australian National Heart Foundation |
| NHMRC | Australian National Health and Medical Research Council |
| NIH | US National Institutes of Health |
| NTS | Non-typhoidal *Salmonella enterica* |
| OECD | Organisation for Economic Cooperation and Development |
| ORT | Oral Rehydration Therapy |
| PATH | Program for Appropriate Technology in Health |
| PDP | Product Development Partnership |
| QIMR | Queensland Institute of Medical Research |
| R&D | Research and Development |
| RCDC | Research, Condition and Disease Categorization |
| S&T | Science and Technology |
| SAAVI | South African AIDS Vaccine Initiative |
| SHARP | South African HIV/AIDS Research and Innovation Platform |
| SIDA | Swedish International Development Agency |
| SME | Smaller pharmaceutical and biotechnology firms |
| SSI | Statens Serum Institute |
| STI | Science, Technology and Innovation |
| TAG | Treatment Action Group |
| TB | Tuberculosis |
| TB Alliance | Global Alliance for TB Drug Development |
| TBVI | TuBerculosis Vaccine Initiative |
| TDR | WHO-based Special Programme for Research and Training in Tropical Diseases |
| UCLH | University College London Hospital |
| UK | United Kingdom |
| US | United States |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |
| WRAIR | Walter Reed Army Institute of Research |
| XDR-TB | Extensively Drug-Resistant Tuberculosis |
| YOY | Year-on-Year |

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# EXECUTIVE SUMMARY

## The survey

The third G-FINDER survey reports on 2009 global investment into research and development (R&D) of new products for neglected diseases, and identifies early trends and patterns across the three 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.

Building on the past two years, survey scope was further expanded this year in order to capture the fullest picture of global investment into neglected disease R&D, with private sector organisations in Brazil and India, and public funders in Ghana, Colombia and Thailand included in the survey for the first time. In all, 847 organisations were surveyed in 2009, a 5% increase on 2008. The number of organisations completing the survey rose to 218, also a 5% increase on 2008, with 100% of top funders providing their 2009 data.

## Findings

Total reported funding for R&D of neglected diseases in 2009 was $3,189m *($3,265m in unadjusted 2009 US$)*. Repeat survey participants – year-on-year (YOY) funders – increased their funding by $239.0m (8.2%). Around $40.4m reported in 2008 was lost-to-follow-up, as these funders did not participate in the 2009 survey; this was offset by $34.1m reported by new survey respondents for 2009. Neglected disease R&D funding in 2009 was more evenly spread across the neglected diseases than in previous years. Funding was also increasingly reliant on public funders, a trend that was associated with a move away from product development funding, including decreased funding for Product Development Partnerships (PDPs), and towards increased investment in basic research.

### DISEASE FINDINGS AND TRENDS

"There was a notable shift towards public funding"

Funding in 2009 was less concentrated than in the first two years of the G-FINDER survey. Three diseases – HIV/AIDS ($1,139m, 35.7% of global funding), malaria ($594.6m, 18.6%) and tuberculosis ($560.0m, 17.6%) – still attracted 72% of global neglected disease funding, but this was down from 77% in 2007. Diarrhoeal diseases ($180.4m, 5.7%), dengue ($165.8m, 5.2%) and kinetoplastids ($162.3m, 5.1%) each received more than 5% of global funding for the first time.

Tuberculosis (TB) received the largest increase in funding in 2009, with YOY funders providing an extra $113.3m (up 25.4%) compared to 2008. Further significant increases in investment were directed towards malaria (up $46.0m, 8.5%), diarrhoeal diseases (up $43.9m, 33.2%) and dengue (up $34.3m, 27.3%). Bacterial pneumonia and meningitis investment decreased by $13.3m (-18.0%), reflecting successful vaccine registration, whilst funding for HIV (down $10.3m, -0.9%) and salmonella infections (down $0.1m, -0.3%) remained essentially steady.

"The focus moved from product development to basic research"

Despite better funding distribution, several disease areas remain underfunded; leprosy, rheumatic fever, trachoma and Buruli ulcer each received less than $11m (0.3%) of global R&D investment.

## FUNDERS

As in the past two years of the survey, responsibility for neglected disease R&D funding fell largely on the shoulders of public and philanthropic funders, who collectively provided $2.8bn, or 87.1% of total funding. Public donors contributed $2.1bn (66.5%), of which most came from High-Income Country (HIC) governments ($2.0bn), whilst philanthropic organisations provided $654.0m (20.5%). Industry investment of $411.2m accounted for 12.9% of global R&D funding, the majority of which ($337.9m, 82.2%) came from multinational pharmaceutical companies (MNCs), with the remaining $73.3m (17.8%) invested by small pharmaceutical companies and biotechs (SMEs).

There was a notable shift towards public funding in 2009, with YOY public funders driving the increase in global funding and providing an extra $258.5m (up 14.0%). This public increase was largely driven by four organisations, which collectively increased their funding by just over $250m: the US National Institutes of Health (NIH) (up $177.8m, 16.5%), the US Department of Defense (DOD) (up $25.7m, 35.4%), the UK Department for International Development (DFID) (up $41.1m, 95.0%), and the UK Medical Research Council (MRC) (up $8.9m, 16.9%).

By contrast, there was a significant decrease in overall philanthropic funding in 2009 (down $62.5m, -8.7%), unlike 2008 when the Bill & Melinda Gates Foundation, in particular, was the driving force behind increased global investment in neglected disease R&D. YOY pharmaceutical industry investment increased by $42.8m (up 12.3%); this was entirely due to increased MNC investment of $58.9m (up 21.1%), which offset a drop in investment from SMEs of $16.1m (-23.7%), likely due to the global financial crisis.

These shifts tipped the balance between public funding, and funding provided by philanthropic organisations and private industry: in turn, this led to a rebalancing of funding away from product development and towards basic research. This was particularly evident in the diseases that saw the largest swing to public funding, such as helminth and salmonella infections.

## FUNDING FLOWS

Just over a quarter (26.3%) of global neglected disease R&D funding was invested internally by public research institutions and private companies (up from 23.2% in 2008). The remaining funding was channelled either directly to researchers and developers (73.4%) or to PDPs and other intermediaries (22.5% and 4.1%, respectively).

There was a shift away from investment in PDPs in 2009. PDPs received $530.0m, a drop of $50m from 2008 (-8.6%), causing their share of global grant funding to drop from 25.6% to 22.5%. This reflected the overall shift towards public funding, with many governments and government institutions leaning towards investment into basic research, rather than higher-risk product development, as well as to research conducted by their own domestic institutions.

## CONCLUSION

The 2009 increase in funding for neglected disease R&D, despite the global financial downturn, is inspiring and encouraging. We applaud the generosity and humanity of the organisations who contributed to this multi-billion dollar R&D effort, and are delighted to see these investments coming to fruition in the form of new products for malaria, meningitis and pneumonia, among others. We hope the information in G-FINDER will continue to assist in this vital work.

# INTRODUCTION

## Background to the G-FINDER survey

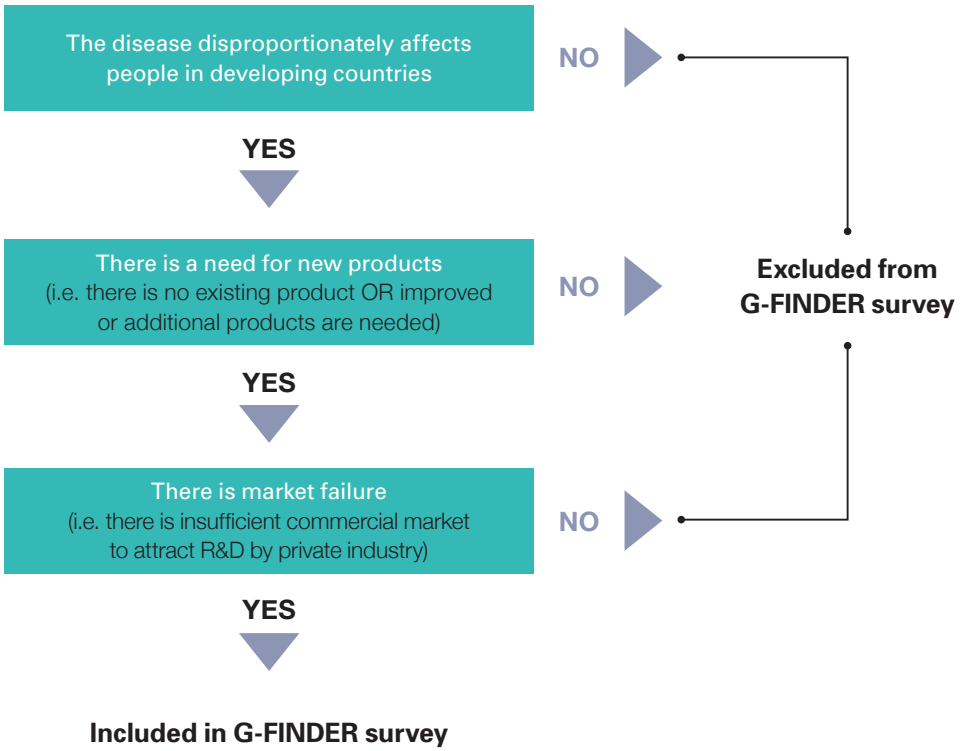
The first and second G-FINDER reports shed light on 2007 and 2008 global investment into research and development (R&D) of new products to prevent, diagnose, manage or cure neglected diseases of the developing world. The third survey reports on 2009 investments, and identifies early trends and patterns across the three years of global data.

## 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 all product types are not 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 industrialized 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 definition of 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 lymphatic filariasis diagnostics were added as a neglected area. There were no changes in survey scope for 2009. 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 |
|---|---|---|---|---|---|---|---|
| **HIV/AIDS** | Restricted | Restricted | Y | Y | Y | | |
| **Malaria** | | | | | | | |
| *Plasmodium falciparum* | Y | Y | Y | Y | | | Y |
| *Plasmodium vivax* | Y | Y | Y | Y | | | Y |
| Other and/or unspecified malaria strains | Y | Y | Y | Y | | | Y |
| **Tuberculosis** | Y | Y | Y | Y | | Y | |
| **Diarrhoeal diseases** | | | | | | | |
| Rotavirus | | | Restricted | | | | |
| Enterotoxigenic *E.coli* (ETEC) | | | Y | Y | | | |
| Cholera | Y | Restricted | Y | Y | | | |
| Shigella | Y | Restricted | Y | Y | | | |
| Cryptosporidium | Y | Restricted | Y | Y | | | |
| Enteroaggregative *E.coli* (EAggEC) | | | Y | Y | | | |
| Giardia | | | | Y | | | |
| Multiple diseases | Y | Y | Y | Y | | | |
| **Dengue** | Y | Y | Y | Y | | | Y |
| **Kinetoplastids** | | | | | | | |
| 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 |
| **Helminth infections** | | | | | | | |
| 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 |
| **Bacterial pneumonia & meningitis** | | | | | | | |
| *Streptococcus pneumoniae* | | | Restricted | Y | | | |
| *Neisseria meningitidis* | | | Restricted | Y | | | |
| Both bacteria | | | | Y | | | |
| **Salmonella infections** | | | | | | | |
| Non-typhoidal *Salmonella enterica* (NTS) | Y | Y | Y | Y | | | |
| Typhoid and Paratyphoid fever *(S. typhi, S. paratyphi A)* | Y | Y | Y | Y | | | |
| Multiple salmonella infections | Y | Y | Y | Y | | | |
| **Leprosy** | Y | Y | | Y | | | |
| **Rheumatic fever** | | | Y | | | | |
| **Trachoma** | | | Y | Y | | | |
| **Buruli ulcer** | Y | Y | Y | Y | | | |

| | Adjuvants and immunomodulators | Delivery technologies and devices | Diagnostic platforms |
|---|---|---|---|
| **Platform technologies (non-disease specific)** | 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 design of the G-FINDER survey. We sought to provide data in a manner that was as consistent and comparable as possible across all funders and diseases, and as close to 'real' investment figures as we could get.

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.[i] Survey respondents were asked to enter every neglected disease investment they had disbursed or received in 2009 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 third G-FINDER survey was open for an 8-week period from April to June 2010, during which intensive follow-up and support for key recipients led to a total of 7,795 entries being recorded in the database for financial year 2009 (an increase of 3% 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 and the National Institute of Allergy and Infectious Diseases. Industry data was aggregated for MNCs and for smaller pharmaceutical companies and biotechs (SMEs) in order to protect their confidentiality.

[i] An exception was made for some US NIH data, as described.

## WHO WAS SURVEYED?

G-FINDER is primarily a survey of funding, and thus of funders. In its third year, the survey was sent to 476 funders in 48 countries around the world. These included:

- Public, private and philanthropic funders in:
  - High- and Middle-Income Countries (HICs and MICs) 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 three low- and middle-income countries (LMICs) (Ghana, Colombia and Thailand)
- Private sector funders in two IDCs (Brazil and India).

We note that private sector organisations in Brazil and India, and public funders in Ghana, Colombia and Thailand 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 2009 survey was sent to 847 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 2008 (808 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 27 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 156 organisations included known significant funders ($5-10m per year); potential research funders in high-Gross Expenditure on R&D (GERD) countries;[ii] 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 (17%) in the number of organisations in the high priority group compared to 2008 (133 organisations). This increase was due to inclusion of public funders in Ghana, Colombia and Thailand; private sector groups in Brazil and India; and to inclusion of groups who were not surveyed previously but were identified by respondents as important funders
- The remaining survey recipients were known smaller funders (less than $5m per year) and other known grant recipients.

[ii] Gross Expenditure on R&D as a percentage of Gross Domestic Product (GDP)

The G-FINDER process focused on the 183 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 2009.

Survey participation increased in 2009, with 218 organisations providing data (including 22 with no investment to report), compared to 208 in 2008 and 150 in 2007. In the maximum priority group, 27 recipients (100%) provided funding information for 2009, up from 92% in 2007 and 96% in 2008. In the high priority group, 147 organisations (94%) provided full funding information for 2009, up from 91% in 2007 and the same as 2008. However, there was also some loss-to-follow-up this year, with 15 organisations reporting data for 2008, but not submitting data for 2009. 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 2009 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 2009 financial year (Year Three). Comparison is made, where relevant, to investments made in the 2008 (Year Two) financial year.

Throughout the text references to 2007, 2008 and 2009 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.

For consistency, 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 2009 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 $3,186m *($3,262m)* in 2009". In this example, $3,262m represents the unadjusted nominal 2009 figure. In Tables, unadjusted figures are also labelled as '2009 Nominal (US$)'.

As noted above, there are year to year fluctuations in survey participation; particularly in Year Two when there was a large survey expansion, making 2007 to 2008 comparisons in funding difficult. Therefore, any changes in funding (increases and decreases) noted in the report will refer to 2008 and 2009 only, and will concern only those organisations that participated in the survey in both years, i.e. YOY funders. Similarly, 2007 data shown in bar charts should not be compared with 2008 and 2009 data (and is hence shown in faded colours).

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,[1] 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 term 'Developing Countries' (DCs) to denote low- and middle-income countries as defined by the World Bank (except Mexico, Turkey and Poland which are part of the OECD and the Russian Federation); and 'Innovative Developing Countries' (IDCs) to refer to developing countries with a strong R&D base who participated in the G-FINDER survey (South Africa, Brazil, India). The OECD countries, EU Member States, European Commission (EC), Singapore and the Russian Federation are collectively denoted by the term High Income Countries (HICs). These terms differ somewhat from their common use, but are valuable shorthand for this report. MNCs are defined as multinational pharmaceutical companies with revenues of over $10bn per annum.

Around 3% ($85.3m) 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 2.3% ($74.1m) was given as core funding to R&D organisations that work in multiple disease areas, for example, the Institute for One World Health (iOWH) and the Special Programme for Research and Training in Tropical Diseases (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 reached $3,189m *($3,265m)* in 2009. This was a moderate increase from 2008, with YOY funders providing an additional $239.0m (up 8.2%). Around $40.4m reported in 2008 was lost-to-follow-up as these funders did not participate in the 2009 survey, with this being offset by $34.1m reported by new survey respondents for 2009.

The concentration of funding noted in earlier surveys decreased markedly. HIV/AIDS, malaria and tuberculosis (TB) captured only 71.9% ($2,293m) of global funding, compared to 72.8% ($2,153m) in 2008, and 76.6% ($1,962m) in 2007, with this largely due to a stabilising of HIV funding in 2009. Notably, diarrhoeal diseases, dengue and kinetoplastids each received more than a 5% share of global funding for the first time. However, other neglected disease areas continued to receive under 3% of global funding, including helminths, bacterial pneumonia and meningitis, and salmonella infections; while leprosy, rheumatic fever, trachoma and Buruli ulcer each received less than $11m (0.3%) of global R&D investment.

TB experienced the highest increase in investment from YOY funders, up $113.3m (25.4%). Other areas that saw large increases relative to 2008 included diarrhoeal diseases (up $43.9m, 33.2%) and dengue (up $34.3m, 27.3%). Malaria saw increased funding of $46.0m, although this was a rise of only 8.5% in percentage terms. Bacterial pneumonia and meningitis saw a considerable drop in investment from YOY funders (down $13.3m, -18.0%), although we note that this represents successful vaccine registration rather than decreased R&D interest; while HIV investment from YOY funders remained essentially steady (down $10.3m, -0.9%).

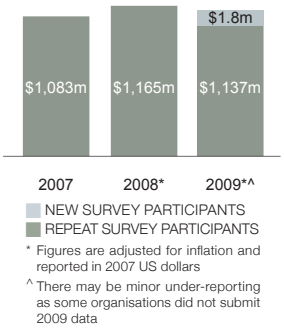
**Table 2. Total R&D funding by disease 2007-2009**

| Disease | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2009 Nominal (US$)* | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|---|
| HIV/AIDS | 1,083,018,193 | 1,164,882,551 | 1,138,635,193 | 1,168,028,900 | 42.3 | 39.4 | 35.7 |
| Malaria | 468,449,438 | 541,746,356 | 594,560,464 | 602,396,399 | 18.3 | 18.3 | 18.6 |
| Tuberculosis | 410,428,697 | 445,927,582 | 560,019,414 | 579,139,261 | 16.0 | 15.1 | 17.6 |
| Diarrhoeal diseases | 113,889,118 | 132,198,981 | 180,426,679 | 184,975,839 | 4.4 | 4.5 | 5.7 |
| Dengue | 82,013,895 | 126,752,203 | 165,812,310 | 171,340,143 | 3.2 | 4.3 | 5.2 |
| Kinetoplastids | 125,122,839 | 139,207,962 | 162,258,968 | 164,258,145 | 4.9 | 4.7 | 5.1 |
| Helminth infections (worms & flukes) | 51,591,838 | 66,837,827 | 79,414,264 | 81,403,579 | 2.0 | 2.3 | 2.5 |
| Bacterial pneumonia & meningitis | 32,517,311 | 90,844,284 | 68,988,629 | 69,616,845 | 1.3 | 3.1 | 2.2 |
| Salmonella infections | 9,117,212 | 39,486,243 | 39,378,570 | 40,292,953 | 0.4 | 1.3 | 1.2 |
| Leprosy | 5,619,475 | 9,769,250 | 10,984,756 | 10,988,295 | 0.2 | 0.3 | 0.3 |
| Rheumatic fever | 1,670,089 | 2,179,609 | 3,009,737 | 3,084,468 | 0.1 | 0.1 | 0.1 |
| Trachoma | 1,679,711 | 2,073,659 | 1,798,463 | 1,841,432 | 0.1 | 0.1 | 0.1 |
| Buruli ulcer | 2,412,950 | 1,954,465 | 1,793,718 | 1,879,281 | 0.1 | 0.1 | 0.1 |
| Platform technologies | 9,997,190 | 16,298,026 | 22,086,907 | 22,802,489 | 0.4 | 0.6 | 0.7 |
| *General diagnostic platforms* | 4,791,152 | 5,253,880 | 8,612,816 | 8,858,408 | 0.2 | 0.2 | 0.3 |
| *Delivery technologies and devices* | 2,520,889 | 8,828,293 | 7,886,484 | 8,134,344 | 0.1 | 0.3 | 0.2 |
| *Adjuvants and immunomodulators* | 2,685,148 | 2,215,853 | 5,587,607 | 5,809,736 | 0.1 | 0.1 | 0.2 |
| Core funding of a multi-disease R&D organisation | 110,921,673 | 101,097,348 | 74,094,564 | 74,381,465 | 4.3 | 3.4 | 2.3 |
| Unspecified disease | 51,619,120 | 74,707,997 | 85,332,381 | 88,144,159 | 2.0 | 2.5 | 2.7 |
| Disease Total | 2,560,068,749 | 2,955,964,344 | 3,188,595,015 | 3,264,573,652 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
* Figures are in current (2009) US dollars

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

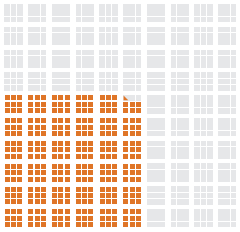



* Figures are adjusted for inflation and reported in 2007 US dollars

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

## $1.14 BILLION

TOTAL SPEND ON HIV/AIDS R&D IN 2009



## 35.7%

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 encouraging, Phase III clinical trials of the most advanced vaccine candidate (a prime boost combination), demonstrated a very modest 30% efficacy. 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 of HIV 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.[3]

Several microbicide candidates are under study and testing. After the failure of PRO 2000 in a phase III clinical trial in late 2009, CAPRISA 004 tenofovir-gel is now the most advanced microbicide candidate, with promising phase IIb trial results.[4]

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

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

In 2009, HIV/AIDS received $1,139m *($1,168m)* in R&D funding. This meant HIV/AIDS funding essentially held steady, with a minimal $10.3m (-0.9%) decrease seen from YOY funders in 2009. The further $16.0m drop in reported funding consisted of $17.8m lost-to-follow-up from funders who did not participate in the 2009 survey, offset by $1.8m reported by new survey respondents. HIV/AIDS again received the highest percentage of global investment (35.7% of the total), although its share of the global funding pie decreased significantly (from 39.4% in 2008) largely due to increased funding in other disease areas.

Over half of total HIV/AIDS funding ($657.9m, 57.8%) was directed to vaccine development in 2009. A further $203.6m (17.9%) was directed to microbicides, $184.1m (16.2%) to basic research, $42.8m (3.8%) to diagnostics and $28.9m (2.5%) to DC-specific drug development.

Data from YOY funders (excluding variations due to non-participants and new survey participants), showed a modest shift in funding from microbicides (down $30.3m, -13%), vaccines (down $8.5m, -1.3%), and drugs (down $16.4m, -36.2%), towards diagnostics (up $16.1m, 63.8%) and basic research (up $10.2m, 5.8%). We note, however, that a large contributor to the apparent drop in microbicide funding was uneven disbursement of a multi-year grant from the Bill & Melinda Gates Foundation. Taking this into account, microbicide funding remained relatively stable in 2009.

**Figure 2. HIV/AIDS R&D funding by product type 2007-2009**


* 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

HIV/AIDS funding was again highly concentrated with 12 organisations providing 93.5% of funding (compared to 91.7% in 2008). The largest funding increases were seen from the US NIH (up $45.1m, 7%) – particularly due to its new American Recovery and Reinvestment Act (ARRA) programme[iii], the US Department of Defense (DOD) (up $9.8m, 40.0%) and United Kingdom Department for International Development (UK DFID) (up $9.6m, 33.4%). Significant decreases were seen from the Gates Foundation (down $41.1m, -25.6%, mainly due to uneven disbursement of a multi-year microbicide grant) and pharmaceutical companies (who, after accounting for the change in survey participants, decreased their investment by $12.8m, -27.5%). Decreased funding by two aid agencies, the Canadian International Development Agency (CIDA) (down $11.2m, -67.6%) and the Swedish International Development Agency (SIDA) (down $4.2m, -41.6%), led to both dropping out of the list of top 12 HIV/AIDS funders in 2009.

[iii] In February 2009, the US government announced that it would commit more than $10 billion as part of a new funding initiative - the American Recovery and Reinvestment Act (ARRA). These funds were to be provided via the National Institutes of Health to fund scientific research, construction and improvement of research facilities, and the purchase of scientific equipment. Part of these funds ($200m) was allocated for Challenge grants to support scientific and health research challenges in biomedical and behavioural research: http://http://www.nih.gov/news/health/mar2009/ncrr-11.htm

**Table 3.** **Top 12 HIV/AIDS R&D funders 2009**

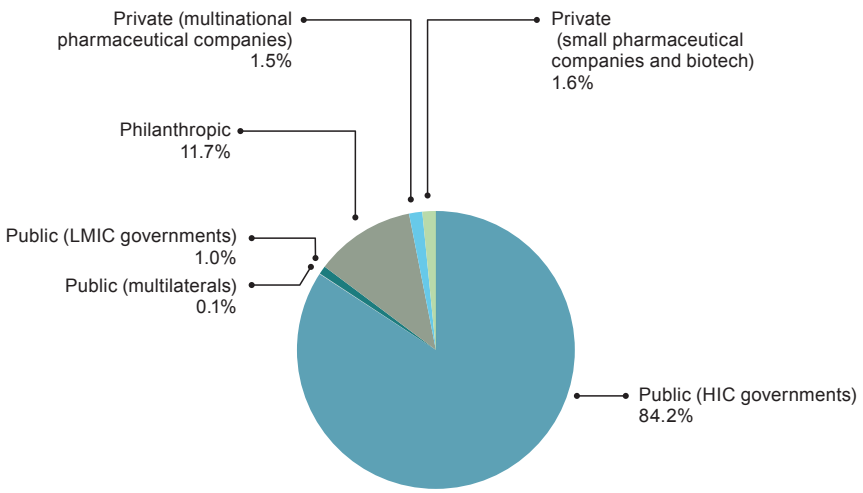
| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 678,816,000 | 643,838,823 | 688,900,175 | 62.7 | 55.3 | 60.5 |
| Bill & Melinda Gates Foundation | 91,975,642 | 160,531,263 | 119,431,387 | 8.5 | 13.8 | 10.5 |
| United States Agency for International Development (USAID) | 67,457,000 | 67,813,102 | 68,169,518 | 6.2 | 5.8 | 6.0 |
| UK Department for International Development (DFID) | 31,151,182 | 28,718,490 | 38,305,345 | 2.9 | 2.5 | 3.4 |
| Aggregate pharmaceutical and biotechnology company respondents[A] | 19,635,626 | 47,449,865 | 35,342,218 | 1.8 | 4.1 | 3.1 |
| US Department of Defense (DOD) | 27,800,000 | 24,448,940 | 34,236,010 | 2.6 | 2.1 | 3.0 |
| European Commission | 24,794,890 | 26,305,301 | 27,100,813 | 2.3 | 2.3 | 2.4 |
| Inserm - Institute of Infectious Diseases[B] | 342,620 | 1,180,483 | 12,497,386 | 0.0 | 0.1 | 1.1 |
| French National Agency for AIDS Research (ANRS) | 10,511,570 | 14,700,289 | 11,919,251 | 1.0 | 1.3 | 1.0 |
| UK Medical Research Council (MRC) | 13,101,548 | 11,635,919 | 11,861,961 | 1.2 | 1.0 | 1.0 |
| Wellcome Trust | 6,932,786 | 9,429,787 | 9,296,776 | 0.6 | 0.8 | 0.8 |
| Royal Norwegian Ministry of Foreign Affairs | 8,858,106 | 8,146,501 | 7,440,225 | 0.8 | 0.7 | 0.7 |
| Subtotal top 12 HIV/AIDS R&D funders* | 1,010,093,653 | 1,068,173,703 | 1,064,501,065 | 93.3 | 91.7 | 93.5 |
| Disease Total | 1,083,018,193 | 1,164,882,551 | 1,138,635,193 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
[B] The apparent increase in funding from Inserm is mainly due to more comprehensive reporting
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009

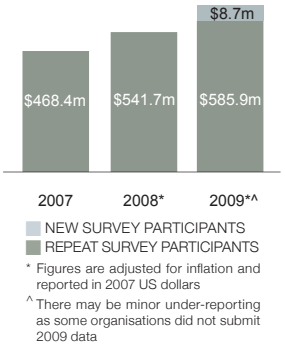
Public and philanthropic organisations provided the vast majority of HIV/AIDS R&D funding in 2009, with public funders providing $970.4m (85.2%), and a further $132.9m (11.7%) coming from philanthropic organisations. Almost all public funding (98.8%) came from HIC governments, with LMIC governments providing 1.1% and multilateral organisations just 0.1%.

YOY public funders increased their investment by $44.4m (up 4.8%). Coupled with a drop in philanthropic funding (down $41.9m, -24.0%), this meant that public funders increased their share of global HIV/AIDS funding to 85.2% (up from 80.9% in 2008). The pharmaceutical industry was again barely active in this area, with a 2009 investment of $35.3m (3.1%) – a drop from YOY funders of $12.8m (-27.5%) on 2008 figures.

**Figure 3.** **HIV/AIDS R&D funding by funder type 2009**



# MALARIA

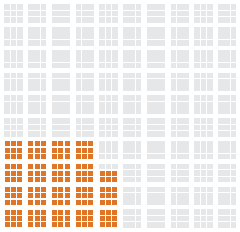



* Figures are adjusted for inflation and reported in 2007 US dollars

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

## $594.6 MILLION

TOTAL SPEND ON MALARIA R&D IN 2009



## 18.6%

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 even death, with children and pregnant women being the most vulnerable (85% of malaria deaths are children under five years of age).[5]

Malaria caused 33.9 million 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, accounting for 98% of malaria cases in sub-Saharan Africa. However, *P. vivax* is estimated to account for 25-40% of the global malaria burden[6] and is particularly common in South-East Asia and South America.[7]

The emergence of resistance to artemisinin-based combination therapies (ACTs) and insecticides means new therapies are needed.[8] 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 severe and uncomplicated malaria, and malaria and other febrile illnesses.[9]

Progress has continued since 2008. The RTS,S malaria vaccine candidate entered large-scale trials in Africa in May 2009, with regulatory submission planned for 2012.[10] Several promising synthetic alternatives to artemisinins are also in clinical trials, including the ozonides arterolane/PQP (Phase III) and OZ439 (Phase IIa).[11]

Malaria R&D is needed in many areas including:

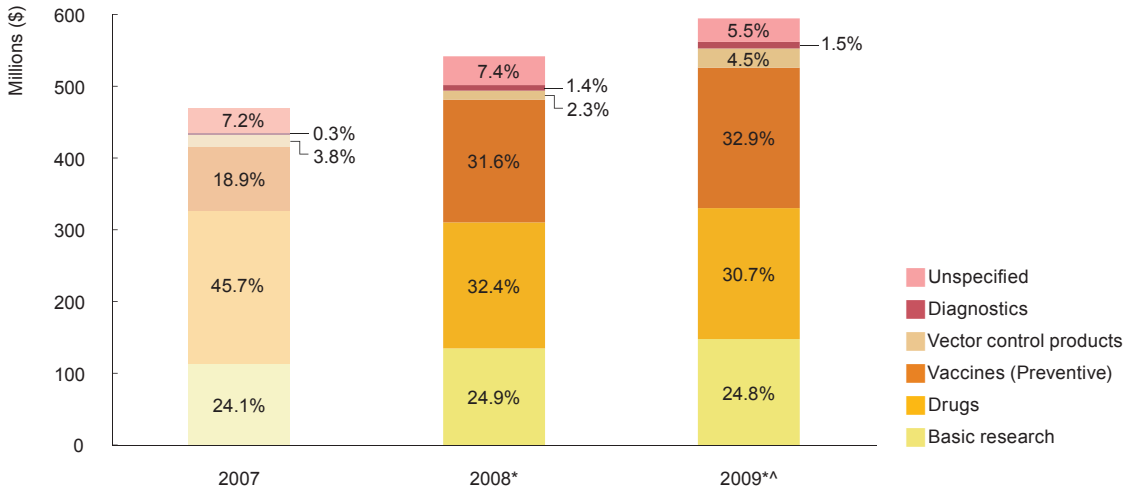
- Basic research
- Drugs
- Preventive vaccines
- Diagnostics
- Vector control products

Global funding for malaria R&D in 2009 was $594.6m *($602.4m)*. This was a moderate increase from 2008, with YOY funders providing an additional $46.0m (up 8.5%). The further $6.8m rise in reported funding consisted of $8.7m reported by new survey respondents, offset by $1.9m lost-to-follow-up from funders who did not participate in the 2009 survey. Malaria maintained its share of global funding (18.6% compared to 18.3% in 2008).

Malaria R&D funding was split between vaccine development ($195.8m, 32.9%), drug development ($182.5m, 30.7%) and basic research ($147.7m, 24.8%). Vector control products received $26.7m (4.5%) and diagnostics just $9.1m (1.5%).

Data from YOY funders showed significant increases between 2008 and 2009 in vaccine funding (up $22.3m, 13%), vector control products (up $14.2m, 114.1%) and basic research (up $11.7m, 8.8%). The increased vaccine investment trend in 2007-2009 was largely due to progression of the RTS,S vaccine candidate, which was in large-scale Phase IIb and III clinical trials during that time; while the more-than-doubling of vector control funding reflects a ramped up contribution from the Gates Foundation, who accounted for nearly 90% of this increase. Funding for drug development remained steady, with an increase of $3.7m (2.1%), arresting the funding drop seen in the Year Two survey. The increase in diagnostic funding was proportionally large (up 17.0%), but amounted to just $1.3m.

**Figure 4. Malaria R&D funding by product type 2007-2009**




* 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

Malaria R&D funding remains highly concentrated, with the top 12 funders contributing more than 90% of total funding, and the top two just over half (50.2%). Most top 12 funders continued to steadily increase their contributions, but the dramatic 2008 funding increases from groups like the Gates Foundation were absent this year. Importantly, the 2009 increase in malaria R&D funding was not dependent on the top two funders. Unlike in 2008, when the Gates Foundation and the US NIH accounted for 95% of the funding increase, in 2009 these two organisations represented just 37.7% of the increase, with other groups increasingly stepping up their contributions.

**Table 4.** **Top 12 malaria R&D funders 2009**

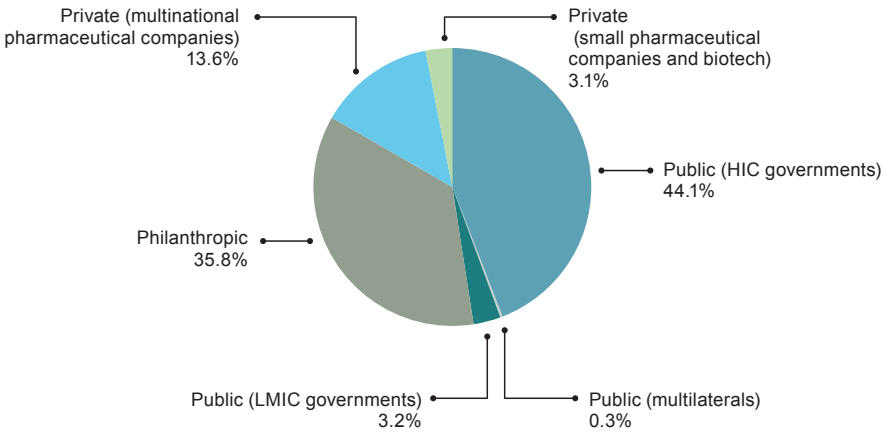
| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Bill & Melinda Gates Foundation | 124,464,185 | 173,722,323 | 182,444,291 | 26.6 | 32.1 | 30.7 |
| US National Institutes of Health (NIH) | 84,422,644 | 104,810,620 | 116,013,245 | 18.0 | 19.3 | 19.5 |
| Aggregate pharmaceutical and biotechnology company respondents[A] | 90,793,583 | 90,611,134 | 99,230,024 | 19.4 | 16.7 | 16.7 |
| US Department of Defense (DOD) | 33,126,578 | 30,518,142 | 37,585,617 | 7.1 | 5.6 | 6.3 |
| Wellcome Trust | 28,255,207 | 26,732,141 | 27,204,542 | 6.0 | 4.9 | 4.6 |
| European Commission | 21,673,026 | 25,296,589 | 24,949,051 | 4.6 | 4.7 | 4.2 |
| UK Medical Research Council (MRC) | 18,594,597 | 18,985,044 | 20,712,331 | 4.0 | 3.5 | 3.5 |
| Australian National Health and Medical Research Council (NHMRC) | 7,692,288 | 9,012,351 | 10,201,615 | 1.6 | 1.7 | 1.7 |
| United States Agency for International Development (USAID) | 9,249,900 | 8,164,740 | 8,166,618 | 2.0 | 1.5 | 1.4 |
| Institut Pasteur | 13,142,888 | 7,739,784 | 7,067,036 | 2.8 | 1.4 | 1.2 |
| Indian Council of Medical Research (ICMR)[B] | - | 8,342,271 | 6,500,473 | 0.0 | 1.5 | 1.1 |
| German Research Foundation (DFG)[C] | 1,299,214 | - | 5,165,277 | 0.3 | 0.0 | 0.9 |
| Subtotal top 12 malaria R&D funders* | 442,390,785 | 507,870,081 | 545,240,120 | 94.4 | 93.7 | 91.7 |
| Disease Total | 468,449,438 | 541,746,356 | 594,560,464 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
[B] New survey recipient in 2008, no 2007 data available.
The drop in funding in 2009 is likely due to less comprehensive reporting by some of its institutes
[C] The apparent increase in funding from DFG is mainly due to more comprehensive reporting (no data reported in 2008)
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
- No reported funding in category

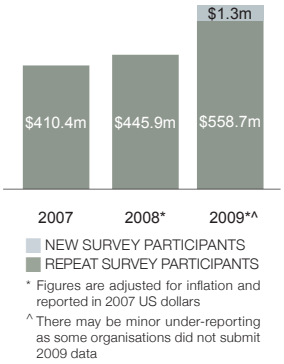
Public and philanthropic funding continued to account for the majority of malaria R&D funding (83.3%), as in 2008. Public funding totalled $282.7m in 2009, an increase of $31.8m (12.9%); while philanthropic funding was $212.6m, an increase of $9.5m (up 4.7%). Industry provided $99.2m, an increase from YOY funders of $4.9m (up 5.4%), although industry's funding share remained unchanged. IDC companies contributed $4.1m to malaria R&D funding.

Within public funders, HIC governments contributed the lion's share ($262.4m, 92.8%), and accounted for virtually all (97%) the increase in public funding for malaria R&D. LMIC governments contributed $18.8m (6.7%) and multilaterals $1.5m (0.5%).

**Figure 5.** **Malaria R&D funding by funder type 2009**



# TUBERCULOSIS

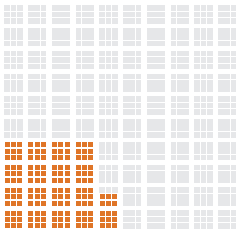



* Figures are adjusted for inflation and reported in 2007 US dollars

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

## $560.0 MILLION

TOTAL SPEND ON TB R&D IN 2009



## 17.6%

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 years old vaccine that is highly effective only against disseminated TB in children.[12] 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[13]; 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.[14] There are also several vaccine candidates in clinical trials, with the most advanced being MVA85A/AERAS-485 and GSK M72. Progress has been made in diagnostic development, with Cepheid's nucleic acid detection device (GeneXpert MTB/Rif) showing excellent results, but even with compassionate pricing for DCs this system's high cost may be a barrier.

R&D needs for TB include:

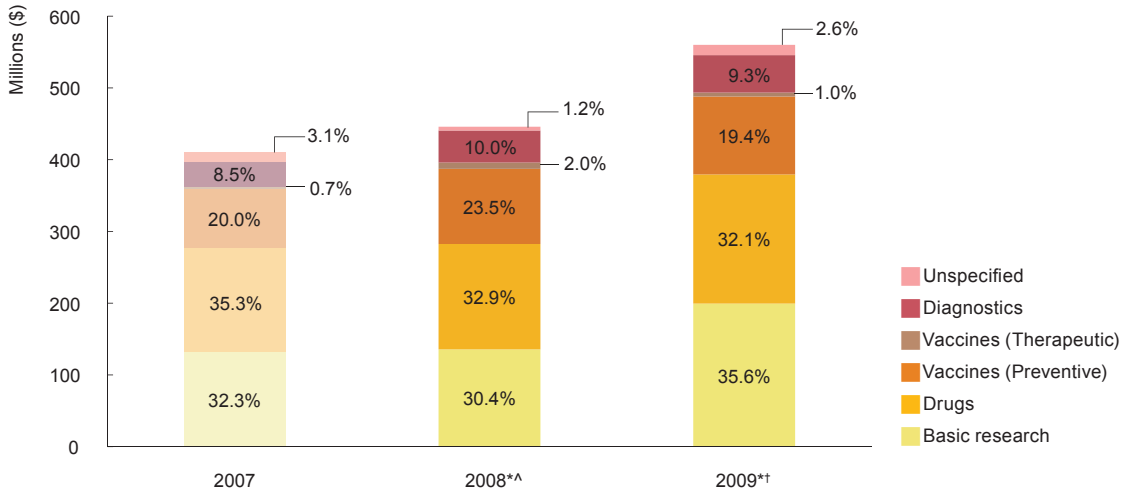
- Basic research
- Drugs
- Diagnostics
- Preventive vaccines
- Therapeutic vaccines

TB received $560.0m *($579.1m)* in R&D funding in 2009. This was a considerable increase from 2008, with YOY funders providing an additional $113.3m (up 25.4%). The further $0.8m rise in reported funding consisted of $1.3m reported by new survey respondents, offset by $0.5m lost-to-follow-up from funders who did not participate in the 2009 survey. TB increased its share of global funding (17.6% compared to 15.1% in 2008).

The majority of TB funding went to basic research ($199.5m, 35.6%), followed by drugs ($180.0m, 32.1%) and preventive vaccines ($108.6m, 19.4%). A further $52.2m (9.3%) was directed to diagnostics and $5.4m (1.0%) to therapeutic vaccines.

YOY funders considerably increased their investments in basic research (up $63.3m, 46.7%) - mostly due to increased funding from the US NIH, and in drug R&D (up $32.7m, 22.3%), where the increase was for the most part due to industry investment. A more moderate rise was reported for diagnostics (up $7.5m, 16.8%) while investment in vaccines remained virtually flat.

**Figure 6. TB R&D funding by product type 2007-2009**




* Figures are adjusted for inflation and reported in 2007 US dollars
^ Allocation to the different product types has been updated and therefore differs from published data for 2008
† There may be minor under-reporting as some organisations did not submit 2009 data

The top-12 funders of TB R&D accounted for 90.1% of total funding in this disease area in 2009, with the majority of funding ($383.4m) coming from the US NIH, the private sector and the Gates Foundation. The most significant increase came from the US NIH (up $50.5m, 44.7%), which ramped up funding considerably after a small decrease in 2008; while the UK DFID also became a more prominent TB funder in 2009 (up $14.0m, 417.3%). The only top 12 funder to show a decrease was the Gates Foundation (down $35.1m, -26.6%), although this was due to a combination of grants tapering down at the end of projects and uneven disbursement of multi-year grants.

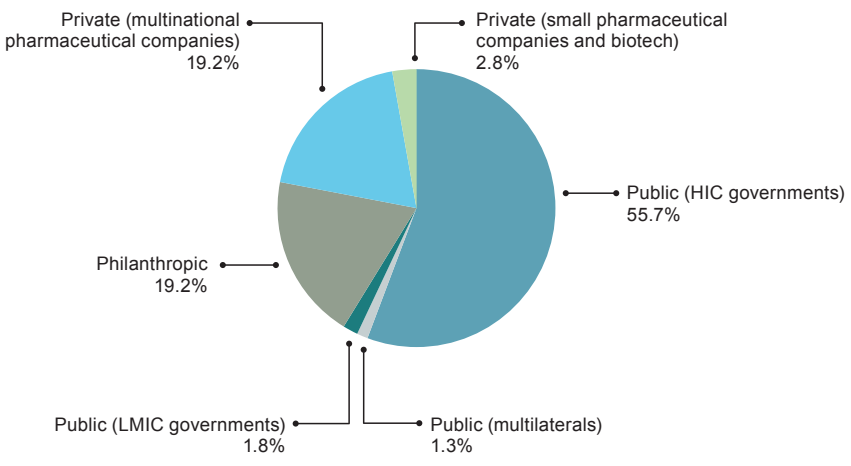
**Table 5.** **Top 12 TB R&D funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 121,741,199 | 112,844,319 | 163,328,162 | 29.7 | 25.3 | 29.2 |
| Aggregate pharmaceutical and biotechnology company respondents[A] | 65,954,715 | 87,029,053 | 123,151,353 | 16.1 | 19.5 | 22.0 |
| Bill & Melinda Gates Foundation | 115,864,538 | 131,983,857 | 96,890,583 | 28.2 | 29.6 | 17.3 |
| European Commission | 21,455,029 | 27,870,907 | 28,730,986 | 5.2 | 6.3 | 5.1 |
| UK Medical Research Council (MRC) | 12,710,433 | 12,832,477 | 21,761,331 | 3.1 | 2.9 | 3.9 |
| UK Department for International Development (DFID) | 1,801,625 | 3,360,090 | 17,380,915 | 0.4 | 0.8 | 3.1 |
| US Centers for Disease Control (CDC) | 11,617,000 | 8,813,953 | 14,422,770 | 2.8 | 2.0 | 2.6 |
| Statens Serum Institute (SSI) | 3,672,882 | 3,166,531 | 9,174,072 | 0.9 | 0.7 | 1.6 |
| Wellcome Trust | 2,599,875 | 5,485,274 | 8,211,120 | 0.6 | 1.2 | 1.5 |
| United States Agency for International Development (USAID) | 3,893,436 | 6,551,060 | 8,147,289 | 0.9 | 1.5 | 1.5 |
| Dutch Ministry of Foreign Affairs | 12,187,935 | 4,584,714 | 7,451,930 | 3.0 | 1.0 | 1.3 |
| Inserm - Institute of Infectious Diseases[B] | 328,915 | 393,494 | 5,862,520 | 0.1 | 0.1 | 1.0 |
| Subtotal top 12 TB R&D funders* | 385,827,417 | 408,545,193 | 504,513,031 | 94.0 | 91.6 | 90.1 |
| Disease Total | 410,428,697 | 445,927,582 | 560,019,414 | 100.0 | 100.0 | 100.0 |

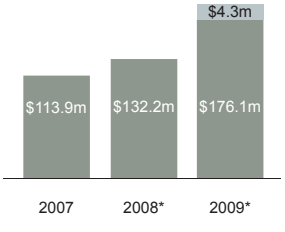
^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
[B] The apparent increase in funding from Inserm is mainly due to more comprehensive reporting
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009

Public funders accounted for more than half of total TB funding in 2009 ($329.1m, 58.8%), with philanthropic organisations accounting for a further $107.7m (19.2%), and $123.1m (22.0%) coming from the private sector. As YOY philanthropic funders decreased their funding by $30.6m (down 22.1%), TB investment increasingly relied on the public sector, particularly HIC governments. HIC governments contributed 94.8% of all public funding, whilst LMIC governments provided 3.0%, and multilaterals 2.2%. YOY public funders increased their investments considerably, by $108.5m (up 49.4%). The pharmaceutical sector also increased their investments substantially (up $35.9m, 41.4%), after accounting for the change in survey participants. This increase was mainly driven by MNCs (up $33.6m, 45.6%) while YOY SMEs only increased their funding by $2.3m (up 17.5%). No IDC companies surveyed contributed to TB R&D investment.

**Figure 7.** **TB R&D funding by funder type 2009**



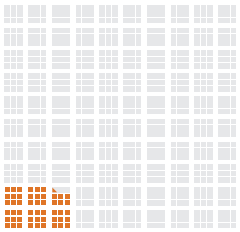
# DIARRHOEAL DISEASES




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

## $180.4 MILLION

TOTAL SPEND ON DIARRHOEAL DISEASE R&D IN 2009



## 5.7%

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 have the highest impact on 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 each 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.[15] New, rapid and reliable diagnostics capable of distinguishing between diarrhoeal diseases are also required.[9] A range of new anti-diarrhoeal vaccines is in the pipeline, including Intercell's LT patch for enterotoxigenic *E. coli* (ETEC), the Walter Reed Army Institute of Research (WRAIR) Invaplex 50 for shigella, and Bharat Biotech's ORV116E for rotavirus, all in clinical trials.[16]

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 2009, diarrhoeal diseases received $180.4m *($185.0m)* in R&D funding. This was a considerable increase from 2008, with YOY funders providing an additional $43.9m (up 33.2%). A further $4.3m in funding was reported by new survey respondents. There were no survey respondents lost to follow up. The additional investments mean that diarrhoeal diseases accounted for a larger share of global funding in 2009 (5.7% versus 4.5%).

Within the diarrhoeal diseases, the distribution of funding was weighted towards rotavirus, cholera and shigella, which accounted for $118.3m (65.6%) of total investments. YOY funders considerably increased their investment in cholera (up $24.4m, 166.6%) and shigella (up $13.6m, 109.2%), while a modest increase was seen for *cryptosporidium* (up $8.2m, 98.9%) and rotavirus (up $4.5m, 10.1%).

For both cholera and shigella, where data was collected for all product types, the majority of funding went to basic research ($18.8m, 48.0% and $14.0m, 53.8%, respectively) and preventive vaccines ($19.8m, 50.6% and $8.8m, 33.8%, respectively). In general, data from YOY funders showed an increase in funding for preventive vaccines (up $31.4m, 44.2%), particularly due to increased Gates Foundation funding for R&D of rotavirus and cholera vaccines. There was also a large increase ($19.6m, 58.3%) in basic research investment from YOY funders, however funding of drug development for diarrhoeal diseases dropped by $11.2m (down 75.9%).

**Table 6. Funding for diarrhoeal disease R&D 2009 (US$)*[A]**

| Disease | Basic Research | Drugs | Vaccines (Preventive) | Diagnostics | Unspecified | Total | % |
|---|---|---|---|---|---|---|---|
| Rotavirus | | | 52,687,842 | | 534,507 | **53,222,349** | 29.5 |
| Cholera | 18,771,362 | 335,557 | 19,786,231 | 180,750 | - | **39,073,900** | 21.7 |
| Shigella | 13,997,222 | 317,124 | 8,792,701 | 1,451,156 | 1,454,522 | **26,012,724** | 14.4 |
| *Cryptosporidium* | 12,838,239 | 2,486,182 | 240,367 | 910,846 | - | **16,475,635** | 9.1 |
| Enterotoxigenic *E.coli* (ETEC) | | | 6,917,765 | 160,742 | - | **7,078,507** | 3.9 |
| Giardia | | | | 440,982 | 161,063 | **602,045** | 0.3 |
| Enteroaggregative *E.coli* (EAggEC) | | | - | - | 47,082 | **47,082** | 0.0 |
| Multiple diarrhoeal diseases | 7,730,234 | 688,199 | 17,960,586 | 3,976,201 | 7,559,216 | **37,914,435** | 21.0 |
| Total | 53,337,058 | 3,827,062 | 106,385,492 | 7,120,677 | 9,756,391 | **180,426,679** | 100.0 |

* All figures are FY2009, 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 to avoid inclusion of overlapping commercial activity. Due to this, total funding between product categories cannot be reasonably compared

\- No reported funding in category

Category not included in G-FINDER

Several organisations considerably increased their diarrhoeal disease R&D funding, notably the US NIH (up $21.4m, 54.2%) and the Gates Foundation (up $20.0m, 75.0%). There were also significant changes in the top 12 funders, with three organisations increasing their funding and therefore appearing in the top 12 ranking for the first time: DFID (up $2.7m, no reported funding for diarrhoeal diseases previously), the Research Council of Norway (up $0.5m, 113.1%) and the Swedish Research Council (up $0.2m, 28.4%).

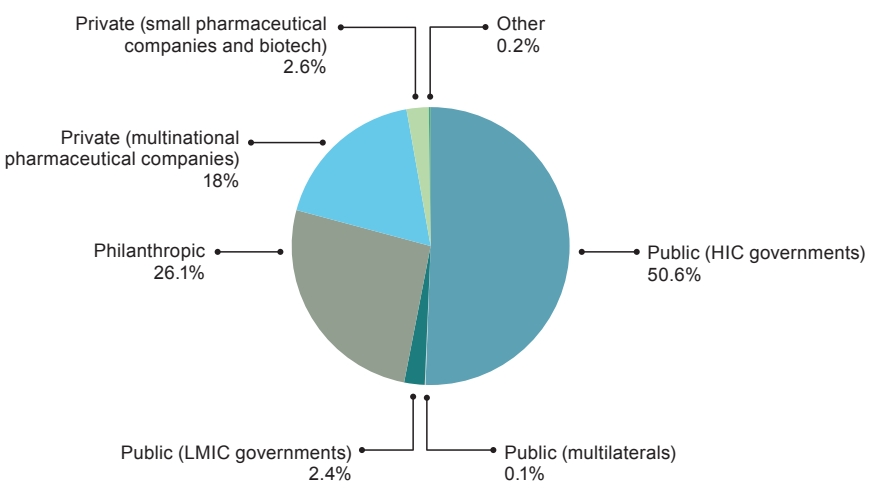
**Table 7. Top 12 diarrhoeal disease R&D funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 31,024,336 | 39,516,218 | 60,942,274 | 27.2 | 29.9 | 33.8 |
| Bill & Melinda Gates Foundation | 44,303,185 | 26,725,850 | 46,757,622 | 38.9 | 20.2 | 25.9 |
| Aggregate pharmaceutical and biotechnology company respondents[A] | 13,676,428 | 24,102,845 | 37,196,423 | 12.0 | 18.2 | 20.6 |
| US Department of Defense (DOD) | 5,436,000 | 5,898,574 | 10,999,053 | 4.8 | 4.5 | 6.1 |
| Institut Pasteur | 3,426,196 | 3,774,871 | 5,180,998 | 3.0 | 2.9 | 2.9 |
| Indian Council of Medical Research (ICMR)[B] | - | 3,663,668 | 3,514,923 | 0.0 | 2.8 | 1.9 |
| Swedish International Development Agency (SIDA) | - | 2,455,171 | 3,240,107 | 0.0 | 1.9 | 1.8 |
| UK Department for International Development (DFID) | - | - | 2,691,549 | 0.0 | 0.0 | 1.5 |
| Inserm - Institute of Infectious Diseases[C] | 274,096 | 327,912 | 1,454,522 | 0.2 | 0.2 | 0.8 |
| Australian National Health and Medical Research Council (NHMRC) | 547,086 | 1,545,322 | 1,278,348 | 0.5 | 1.2 | 0.7 |
| Swedish Research Council | - | 790,555 | 1,015,003 | 0.0 | 0.6 | 0.6 |
| Research Council of Norway | - | 459,429 | 979,180 | 0.0 | 0.3 | 0.5 |
| Subtotal top 12 diarrhoeal disease R&D funders* | 112,607,339 | 125,257,549 | 175,250,001 | 98.9 | 94.7 | 97.1 |
| Disease Total | 113,889,118 | 132,198,981 | 180,426,679 | 100.0 | 100.0 | 100.0 |

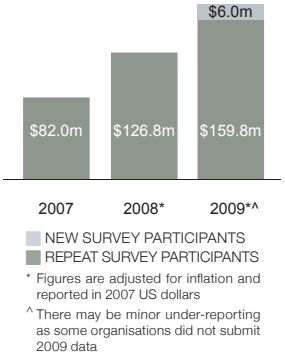
^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
[B] New survey recipient in 2008, no 2007 data available. The drop in funding from ICMR in 2009 is likely due to less comprehensive reporting by some of its institutes
[C] The apparent increase in funding from Inserm is mainly due to more comprehensive reporting
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
- No reported funding in category

The public sector provided more than half of diarrhoeal disease R&D funding in 2009 ($95.7m, 53.1%), followed by philanthropic organisations ($47.1m, 26.1%) and the private sector ($37.2m, 20.6%). Almost all public funding (95.3%) came from HIC governments. LMIC governments contributed 4.5%, and multilaterals 0.2%. YOY public funders increased their investment considerably, by $30.1m (up 45.9%). Data from YOY pharmaceutical industry funders also showed an increase of $8.8m (up 36.6%), with a further $4.3m increase coming from new SME survey participants in India and Brazil. An increase in investment by MNCs (up $10.5m, 47.7%) and the effect of survey expansion masked a small drop in funding from YOY SME funders (down $1.7m, -81.6%). Philanthropic organisations increased their funding by $4.8m (up 11.5%).

**Figure 8. Diarrhoeal disease R&D funding by funder type 2009**



# DENGUE

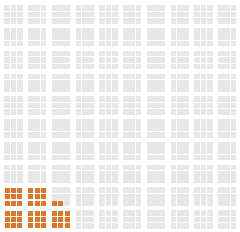



* Figures are adjusted for inflation and reported in 2007 US dollars

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

## $165.8 MILLION

TOTAL SPEND ON DENGUE R&D IN 2009



## 5.2%

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 minimize 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.[9] There is also a need for evaluation of the currently available diagnostic kits.[17]

There are a number of new dengue vaccines and drugs in development, with one live attenuated tetravalent vaccine candidate in Phase II[9] clinical trials and one in Phase III[18], and a much smaller number of early-stage drug candidates.

R&D needed for dengue includes:

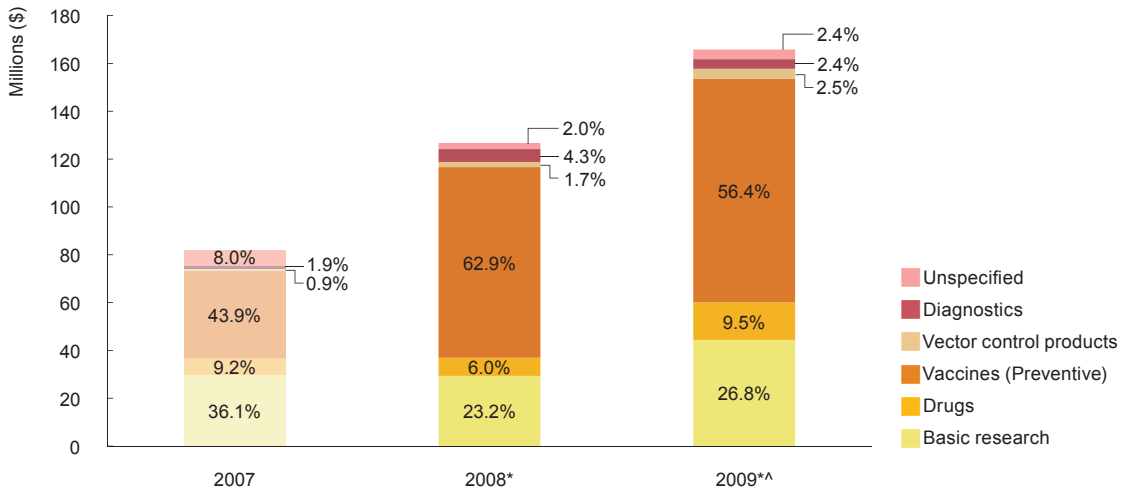
- Basic research
- Drugs
- Preventive vaccines
- Diagnostics
- Vector control products

Global funding for dengue R&D in 2009 was $165.8m *($171.3m)*. This was a significant increase from 2008, with YOY funders providing an additional $34.3m (up 27.3%). A further $6.0m was reported by new survey respondents, slightly offset by $1.3m lost-to-follow-up from funders who did not participate in the 2009 survey. Dengue increased its share of total neglected disease R&D funding in 2009 (5.2%, compared to 4.3% in 2008).

Over half of all dengue R&D funding went to vaccine development ($93.6m, 56.4%). Basic research received $44.4m (26.8%), drug development $15.7m (9.5%), vector control products $4.1m (2.5%), and diagnostics $4.0m (2.4%).

Data from YOY funders showed significant increases in funding for vaccines (up $15.0m, 19.1%) and basic research (up $13.5m, 46.0%). There was a proportionally large increase of $6.5m in drug funding (up 86.3%), albeit from a small base. There were minimal reductions in investment for both diagnostics (down $1.4m, -26.5%) and vector control products (down $0.3m, -15.8%). All increases were driven by a significant boost in US NIH dengue funding, particularly for basic research (up $13.3m, 85.4%) and vaccines (up $9.9m, 184.9%).

**Figure 9. Dengue R&D funding by product type 2007-2009**




* 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

The pharmaceutical industry continued to be the major player in dengue R&D, collectively providing 38.1% of total funding. Outside of this, funding remained highly concentrated, with 11 organisations accounting for 91.7% of all non-industry investment. Most top 12 funders increased their contributions, with notable increases coming from the US NIH, who doubled their dengue R&D funding (up $27.4m, 103.1%), and the Brazilian Ministry of Health (up $5.4m, 403.2%). The significant funding increase from the US NIH accounted for 80.0% of the total increase in dengue R&D investment in 2009. The Gates Foundation decreased their investment by $4.6m (-28.2%), although this came on the back of a $15.3m increase the previous year, and was partially due to the uneven disbursement of a multi-year grant.

**Table 8. Top 12 dengue R&D funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Aggregate pharmaceutical and biotechnology company respondents[A] | 19,394,756 | 43,793,998 | 63,113,152 | 23.6 | 34.6 | 38.1 |
| US National Institutes of Health (NIH) | 34,639,236 | 26,603,478 | 54,025,137 | 42.2 | 21.0 | 32.6 |
| Bill & Melinda Gates Foundation | 1,013,807 | 16,305,526 | 11,711,906 | 1.2 | 12.9 | 7.1 |
| US Department of Defense (DOD) | 14,384,000 | 7,517,148 | 10,477,173 | 17.5 | 5.9 | 6.3 |
| Brazilian Ministry of Health, Department of Science and Technology | 1,623,000 | 1,334,847 | 6,716,881 | 2.0 | 1.1 | 4.1 |
| Institut Pasteur | 3,946,978 | 2,727,968 | 2,480,946 | 4.8 | 2.2 | 1.5 |
| Singapore National Medical Research Council (NMRC)[B] | - | - | 2,000,918 | 0.0 | 0.0 | 1.2 |
| Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG) | - | - | 1,613,919 | 0.0 | 0.0 | 1.0 |
| Wellcome Trust | 1,073,869 | 1,203,426 | 1,584,764 | 1.3 | 0.9 | 1.0 |
| US Centers for Disease Control (CDC) | - | - | 1,422,151 | 0.0 | 0.0 | 0.9 |
| Carlos Chagas Filho Foundation for Research Support of the State of Rio de Janeiro (FAPERJ) | - | - | 1,138,839 | 0.0 | 0.0 | 0.7 |
| European Commission | 2,021,456 | 1,748,863 | 1,050,923 | 2.5 | 1.4 | 0.6 |
| Subtotal top 12 dengue R&D funders* | 81,594,560 | 119,625,671 | 157,336,711 | 99.5 | 94.4 | 94.9 |
| Disease Total | 82,013,895 | 126,752,203 | 165,812,310 | 100.0 | 100.0 | 100.0 |

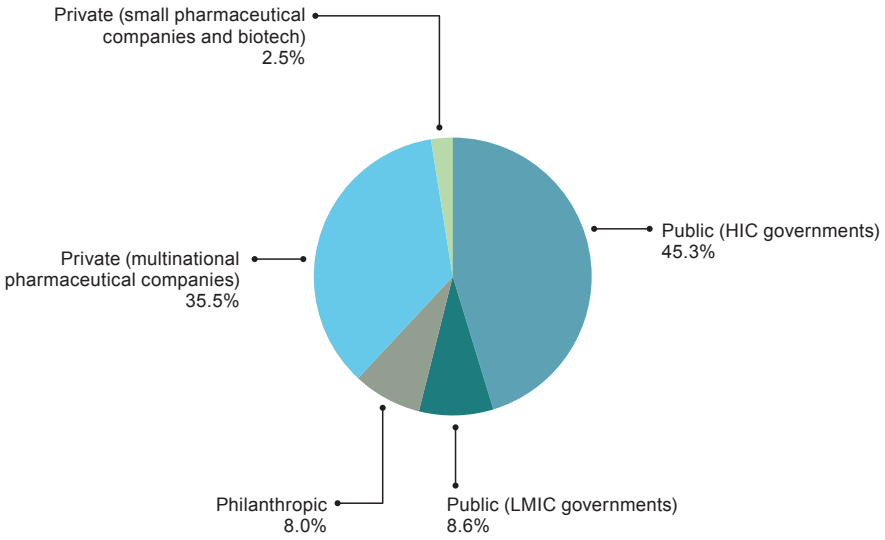
^ Figures are adjusted for inflation and reported in 2007 US dollars
A Includes new survey respondents in 2009
B Contributions compiled from grant information provided by funding recipients, so may be incomplete
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
- No reported funding in category

Public and philanthropic funding together continued to account for the majority of dengue R&D funding (61.9% in 2009 compared to 65.4% in 2008). Public funding totalled $89.4m in 2009, an increase from YOY public funders of $20.2m (31.5%); philanthropic funding was $13.3m, a decrease of $4.2m (-24.1%).

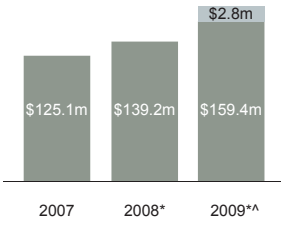
HIC governments contributed the primary share of public funds ($75.1m, or 84%), with 89% of this coming from three US agencies (the NIH, DOD and Centers for Disease Control and Prevention [CDC]). LMIC countries contributed the remaining $14.3m (16%), which accounted for 8.6% of total dengue R&D funding (down from 12.6% in 2008, mostly because of increased funding from others).

As noted above, industry funding represented a relatively large proportion of dengue R&D investment compared to other diseases (38.1%, up from 34.6% in 2008). Industry also significantly increased its funding by $19.3m in 2009. Only $1.0m of this increase was due to new survey participants, leaving a real increase from YOY industry funders of $18.3m (up 41.8%).

**Figure 10.** **Dengue R&D funding by funder type 2009**



# KINETOPLASTIDS

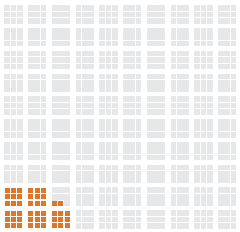



* Figures are adjusted for inflation and reported in 2007 US dollars

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

## $162.3 MILLION

TOTAL SPEND ON KINETOPLASTID R&D IN 2009



## 5.1%

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.[19] There is a need for preventative and therapeutic vaccines; safe, effective drugs that are suitable for children, and 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 stages.[9]

HAT needs new, safe, oral drugs that are active against both stages of the disease, to replace the injectable treatments now used, as well a rapid, easy to use, point of care diagnostic that can distinguish between disease stages. Again, there is a lack of advanced projects, particularly for vaccines, for which there are no candidates in clinical trials.[9] There are some promising HAT drug candidates, despite the recent failure of pafuramidine in Phase III trials, with fexinidazole currently in Phase I clinical trials and a number of likely compounds being followed up.[20]

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 four candidates in mid to late clinical trials and even more in earlier stages; and there is a single vaccine candidate in Phase I.[9]

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 2009 was $162.3m *($164.3m)*. This was a moderate increase from 2008, with YOY funders providing an additional $21.1m (up 15.3%). The further $1.9m rise in funding consisted of $2.8m reported by new survey respondents, offset by $0.9m lost-to-follow-up from funders who did not participate in the 2009 survey. Kinetoplastid diseases increased their share of global funding in 2009 (from 4.7% in 2008 to 5.1%).

Within the kinetoplastid family funding was uneven, with leishmaniasis capturing almost half of overall investment ($69.4m, 42.8%) followed by sleeping sickness ($46.4m, 28.6%). These two diseases also saw the largest increases from YOY funders in 2009, with sleeping sickness up $12.0m (34.7%) and leishmaniasis up $10.9m (19.1%). Investment from YOY funders in Chagas' disease essentially remained stable in 2009 (down $0.08m, -0.5%).

For each of the kinetoplastid diseases, basic research and drug development received the majority of funding, although we note that not all product types are needed for each disease. However, data from YOY funders showed a modest shift in funding to drugs (up $17.1m, 32.3%) and preventive vaccines (up $11.4m, 158.4%) in 2009, from diagnostics (down $5.0m, -43.9%) and basic research (down $1.9m, -3.1%).

**Table 9. Funding for kinetoplastid R&D 2009 (US$)***

| Disease | Basic Research | Drugs | Vaccines (Preventive) | Vaccines (Therapeutic) | Vector control products | Diagnostics | Unspecified | Total | % |
|---|---|---|---|---|---|---|---|---|---|
| Leishmaniasis | 24,423,066 | 24,966,042 | 15,070,121 | 864,219 | | 1,979,730 | 2,081,763 | **69,384,941** | 42.8 |
| Sleeping sickness | 24,914,235 | 15,021,703 | 3,108,054 | | 159,483 | 2,953,795 | 240,856 | **46,398,126** | 28.6 |
| Chagas' disease | 11,754,015 | 3,737,881 | 433,294 | - | 6,081 | 739,127 | 26,772 | **16,697,169** | 10.3 |
| Multiple kinetoplastids | 1,285,001 | 27,673,842 | - | - | 7,752 | 812,138 | - | **29,778,733** | 18.4 |
| Total | 62,376,317 | 71,399,468 | 18,611,468 | 864,219 | 173,316 | 6,484,790 | 2,349,391 | 162,258,968 | 100.0 |

* All figures are FY2009, adjusted for inflation and reported in 2007 US dollars

\- No reported funding in category

Category not included in G-FINDER

Kinetoplastid R&D funding continues to be highly concentrated, with the top 12 funders contributing around 90% of total funding, and the top two well over half (54.7%). The two key funders were the US NIH, particularly focussing on basic research, and the Gates Foundation, which invested in both drugs and preventive vaccines. The largest overall increase in kinetoplastid R&D funding came from the Gates Foundation, which increased its funding by $7.1m, after a decrease of $16.1m in 2008. However, several other funders also significantly increased their investment in 2009, particularly the EC (up $5.5m, 119.2%) and UK DFID (up $5.2m, 140.3%).

**Table 10. Top 12 kinetoplastid R&D funders 2009**

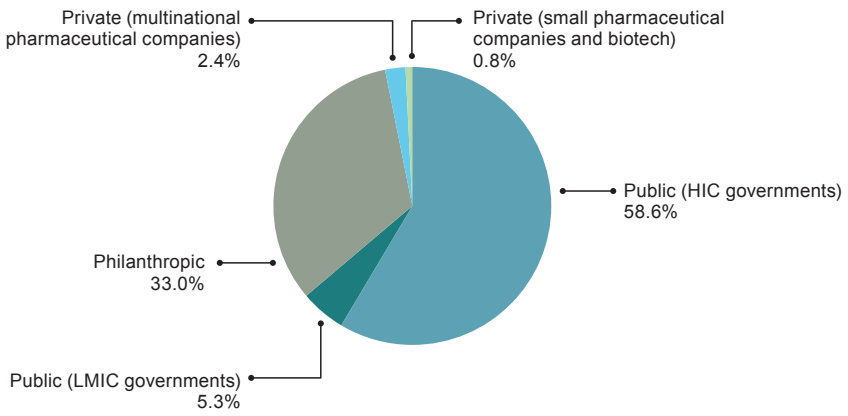
| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 28,206,281 | 48,561,566 | 52,803,542 | 22.5 | 34.9 | 32.5 |
| Bill & Melinda Gates Foundation | 45,114,108 | 28,973,211 | 36,026,595 | 36.1 | 20.8 | 22.2 |
| Wellcome Trust | 15,057,627 | 12,360,489 | 11,493,648 | 12.0 | 8.9 | 7.1 |
| European Commission | 2,888,667 | 4,628,687 | 10,145,797 | 2.3 | 3.3 | 6.3 |
| UK Department for International Development (DFID) | 3,603,250 | 3,733,433 | 8,971,828 | 2.9 | 2.7 | 5.5 |
| Aggregate pharmaceutical and biotechnology company respondents[A] | 5,149,518 | 2,912,298 | 5,112,855 | 4.1 | 2.1 | 3.2 |
| Médecins Sans Frontières (MSF) | 7,187,885 | 7,275,268 | 4,563,905 | 5.7 | 5.2 | 2.8 |
| US Department of Defense (DOD) | 4,727,000 | 4,059,615 | 4,548,062 | 3.8 | 2.9 | 2.8 |
| Spanish Ministry of Foreign Affairs and Cooperation for Development (MAEC) | 91,156 | 3,279,119 | 3,293,257 | 0.1 | 2.4 | 2.0 |
| Undisclosed funder | - | 76,049 | 3,212,994 | 0.0 | 0.1 | 2.0 |
| Institut Pasteur | - | 2,932,088 | 3,154,303 | 0.0 | 2.1 | 1.9 |
| French Ministry of Foreign and European Affairs, Ministère des Affaires étrangères et européennes (MAEE) | 2,286,040 | 2,407,563 | 3,033,450 | 1.8 | 1.7 | 1.9 |
| Subtotal top 12 kinetoplastid R&D funders* | 123,159,493 | 125,938,739 | 146,360,237 | 98.4 | 90.5 | 90.2 |
| Disease Total | 125,122,839 | 139,207,962 | 162,258,968 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
- No reported funding in category

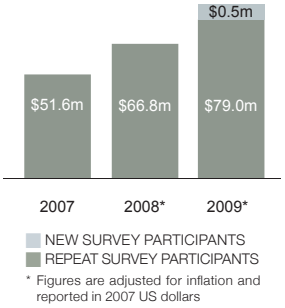
Public and philanthropic organisations provided almost all kinetoplastid R&D funding in 2009 ($157.1m, 96.8%). The majority of public sector investment ($95.0m, 91.8%) came from HIC governments, who also accounted for 58.6% of overall kinetoplastid funding. The pharmaceutical industry played a very modest role, contributing just $5.1m (3.2%), most of which came from MNCs, with IDC SMEs investing only $0.8m in 2009 and other SMEs investing $0.5m.

The increase in kinetoplastid funding noted above was chiefly driven by the public sector (up $15.2m, 17.6%), with an additional $2.0m reported by new public sector survey participants. Philanthropic organisations increased their funding only moderately ($4.2m, 8.6%). YOY private sector funders increased their investments by $1.7m (up 68.4%).

**Figure 11. Kinetoplastid R&D funding by funder type 2009**

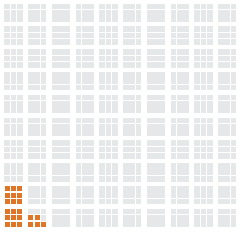


# HELMINTH INFECTIONS




**$79.4 MILLION**

TOTAL SPEND ON HELMINTH R&D IN 2009



**2.5%**

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 are 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 causing 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.[21]

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.[22] Current diagnostic products for detection of some helminths are also outdated, meaning new effective diagnostics are needed.

A drug (moxidectin) is in development – currently in Phase III clinical trials for onchocerciasis – and several vaccine candidates against human hookworm infection and schistosomiasis are in early-stage development, and are expected to enter clinical trials between 2010 and 2011.[23]

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 2009, helminth infections received $79.4m *($81.4m)* in R&D funding. This was a modest increase from 2008, with YOY funders providing an additional $13.0m (19.6%) and new survey participants $0.5m. There were no survey respondents lost to follow up. Helminth infections therefore slightly increased their share of global funding (2.5% compared to 2.3% in 2008).

Three diseases (schistosomiasis, lymphatic filariasis and onchocerciasis) accounted for more than 60% ($50.0m) of total helminth funding. They also received the bulk of new funding for helminths, with onchocerciasis (river blindness) investment more than doubling in 2009 (up $7.2m, 121.5%), lymphatic filariasis increasing by $3.6m (31.8%) and schistosomiasis by $2.3m (12.0%). Hookworm reported reduced funding (down $2.4m, -16.6%).

As in previous years, helminth funding was predominantly invested in basic research, accounting for more than half of all helminth funding ($41.7m, 52.5%) in 2009, up from 45.6% in 2008. Remaining helminth funding was invested in drug R&D ($15.3m, 19.3%) and vaccines ($9.9m, 12.4%), while vector control products and diagnostics collectively received less than 5% of total helminth funding ($3.3m, 4.1%).

This represented significantly increased funding for basic research in 2009 (up $11.1m, 36.5%); but only very modest increases in funding for drugs (up $1.2m, 8.8%), diagnostics (up $0.9m, 180.3%) and vector control products (up $0.1m, 115.9%). Funding for preventive vaccines dropped slightly (down $0.2m, -2.4%) likely due to a cyclical grant effect.

**Table 11. Funding for helminth R&D 2009 (US$)***

| Disease | Basic Research | Drugs | Vaccines (Preventive) | Vector control products | Diagnostics | Unspecified | Total | % |
|---|---|---|---|---|---|---|---|---|
| Schistosomiasis (bilharziasis) | 16,173,364 | 642,211 | 2,067,521 | - | 983,684 | 2,086,417 | **21,953,198** | 27.6 |
| Lymphatic filariasis (elephantiasis) | 4,913,409 | 5,089,424 | | 1,326,183 | - | 3,605,894 | **14,934,911** | 18.8 |
| Onchocerciasis (river blindness) | 1,900,616 | 8,914,101 | 807,315 | - | 163,095 | 1,313,554 | **13,098,680** | 16.5 |
| Hookworm (ancylostomiasis & necatoriasis) | 2,738,072 | - | 6,985,440 | | | - | **9,723,512** | 12.2 |
| Tapeworm (cysticercosis/taeniasis) | 2,380,278 | - | | 535,408 | | - | **2,915,686** | 3.7 |
| Roundworm (ascariasis) | 2,072,693 | - | | | | - | **2,072,693** | 2.6 |
| Strongyloidiasis & other intestinal roundworms | 1,364,699 | 35,263 | - | | 142,979 | - | **1,542,942** | 1.9 |
| Whipworm (trichuriasis) | 1,021,296 | 35,226 | | | | - | **1,056,522** | 1.3 |
| Multiple helminths | 9,136,318 | 582,427 | - | - | 103,487 | 2,293,888 | **12,116,120** | 15.3 |
| Total | 41,700,745 | 15,298,653 | 9,860,277 | 1,861,591 | 1,393,245 | 9,299,753 | 79,414,264 | 100.0 |

* All figures are FY2009, adjusted for inflation and reported in 2007 US dollars
- No reported funding in category
Category not included in G-FINDER

Helminth funding was highly concentrated, with the top 12 funders contributing more than 95% of total investment. Two funders (the US NIH and the Gates Foundation) provided over half (55.6%) of investment, even though the Gates Foundation decreased funding by $5.1m (due to the uneven disbursement of a multi-year grant and the termination of other grants), following a large increase of $13.9m in 2008. Many other top 12 funders either increased or maintained their investment into helminth R&D in 2009, including the US NIH (up $4.8m) and the Danish Ministry of Foreign Affairs (up $2.1m).

**Table 12. Top 12 helminth R&D funders 2009**

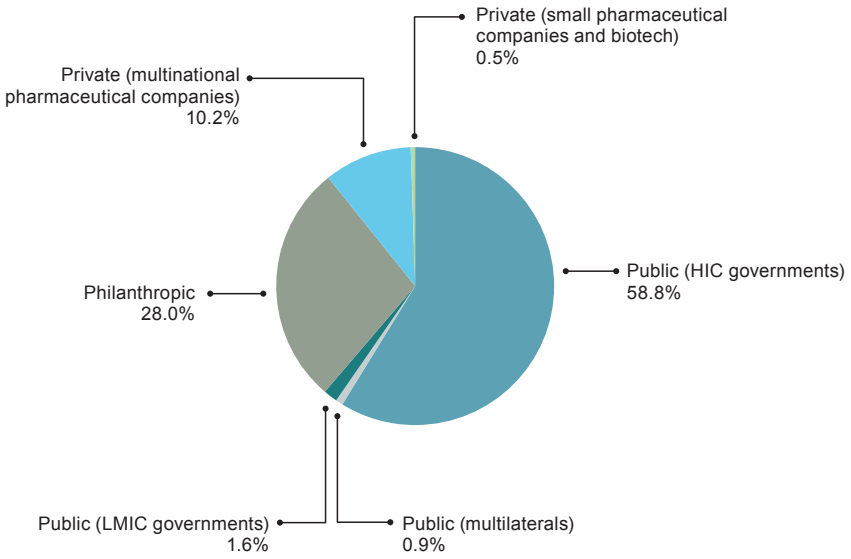
| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 27,854,142 | 23,308,515 | 28,133,258 | 54.0 | 34.9 | 35.4 |
| Bill & Melinda Gates Foundation | 7,204,305 | 21,116,365 | 16,029,672 | 14.0 | 31.6 | 20.2 |
| Aggregate pharmaceutical and biotechnology company respondents[A] | 814,963 | 4,950,621 | 8,541,024 | 1.6 | 7.4 | 10.8 |
| German Research Foundation (DFG)[B] | - | - | 6,831,168 | 0.0 | 0.0 | 8.6 |
| Wellcome Trust | 3,162,843 | 3,959,257 | 4,967,904 | 6.1 | 5.9 | 6.3 |
| European Commission | 4,271,324 | 3,137,023 | 2,956,743 | 8.3 | 4.7 | 3.7 |
| Danish Ministry of Foreign Affairs | 1,506,193 | - | 2,110,709 | 2.9 | 0.0 | 2.7 |
| Inserm - Institute of Infectious Diseases[C] | 274,096 | 524,659 | 2,002,692 | 0.5 | 0.8 | 2.5 |
| Australian National Health and Medical Research Council (NHMRC) | 1,053,789 | 1,666,179 | 1,873,883 | 2.0 | 2.5 | 2.4 |
| UK Medical Research Council (MRC) | 1,096,017 | 1,396,827 | 1,093,338 | 2.1 | 2.1 | 1.4 |
| African Programme for Onchocerciasis Control (APOC) | 695,610 | 674,374 | 676,525 | 1.3 | 1.0 | 0.9 |
| Fondazione Cariplo | - | 196,747 | 555,149 | 0.0 | 0.3 | 0.7 |
| Subtotal top 12 helminth R&D funders* | 50,966,641 | 62,565,617 | 75,772,065 | 98.8 | 93.6 | 95.4 |
| Disease Total | 51,591,838 | 66,837,827 | 79,414,264 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
[B] No data provided in 2008
[C] The apparent increase in funding from Inserm is mainly due to more comprehensive reporting
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
- No reported funding in category

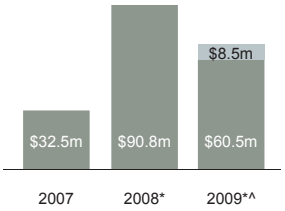
As in 2008, public and philanthropic organisations accounted for the bulk of helminth R&D funding (92.2% in 2008, 89.2% in 2009). Public funding totalled $48.6m in 2009 (up $13.5m, 38.3%); philanthropic funding was $22.2m (down $4.2m, -16%); while industry provided $8.5m (up $3.6m, 72.5%). As a result, the public sector increased its share of global helminth funding (from 52.6% to 61.3%).

HIC governments provided the majority of public funding ($46.7m, 96.0%), with an increase from YOY funders of $14.8m (46.6%). LMIC governments contributed $1.3m (2.7%), a decrease of $1.0m (-49.1%) from YOY funders; while multilaterals remained steady at $0.7m (1.4%). Industry funding increased by $3.6m in 2009, including $0.2m from new IDC companies.

**Figure 12. Helminth infection R&D funding by funder type 2009**



# BACTERIAL PNEUMONIA & MENINGITIS

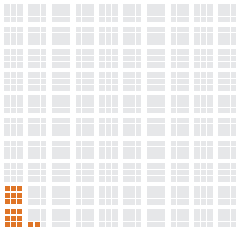



* Figures are adjusted for inflation and reported in 2007 US dollars

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

## $69.0 MILLION

TOTAL SPEND ON BACTERIAL PNEUMONIA & MENINGITIS R&D IN 2009



## 2.2%

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 pneumonia* 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 existing vaccines, due to their inability to produce long lasting protection or to protect young children. There has been some progress, with a new meningitis vaccine against serogroup A meningococci (which accounts for the majority of epidemic and endemic disease in the meningitis belt) due to be rolled out in West Africa at the end of 2010.[24] 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 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, with both recently granted WHO prequalification. Part of the Accelerated Vaccine Initiative (AVI), this should see rapid introduction of these heavily subsidised vaccines, although its reach is currently limited to a select group of countries.[25]

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 2009, bacterial pneumonia & meningitis received $69.0m *($69.6m)* in R&D funding. This was a significant drop from 2008, with YOY funders decreasing their investment by $13.3m (-18.0%). The further $8.5m drop in reported funding consisted of $17.0m lost-to-follow-up from funders who did not participate in the 2009 survey, offset by $8.5m reported by new survey respondents. Bacterial pneumonia & meningitis received a diminished share of total funding in 2009 (2.2% compared to 3.1% in 2008), due to a combination of decreased funding associated with the successful vaccine registration and a proportionally large effect from participant drop-outs.

Bacterial pneumonia & meningitis R&D funding was mostly directed towards vaccine development ($59.6m, 86.4%), with diagnostics receiving $4.2m (6.1%).

Although apparent funding for vaccines remained relatively steady, data from YOY funders showed a significant drop in vaccine funding (down $12.0m, -18.9%), masked by $8.4m reported by new survey respondents. Decreased industry investment accounted for almost all (80.7%) of this drop, likely reflecting the progression to approval of a major pneumococcal vaccine candidate. The apparent drop in diagnostics funding was an artefact caused by $15.4m in diagnostic investment lost-to-follow-up from funders who did not participate in the 2009 survey, masking a modest real increase from YOY funders of $2.0m (96.0%).

**Figure 13. Bacterial pneumonia & meningitis R&D funding by product type 2007-2009**


* Figures are adjusted for inflation and reported in 2007 US dollars
^ There may be under-reporting as some organisations did not submit 2009 data

The pharmaceutical industry continued to be the major player in bacterial pneumonia & meningitis R&D, collectively providing half of total funding (49.0%, down from 55.6% in 2008). Outside the pharmaceutical industry, funding was highly concentrated, with 11 organisations accounting for 96.8% of all non-industry investment. The largest single funder of bacterial pneumonia & meningitis R&D, the Gates Foundation, accounted for nearly two-thirds (59.7%) of non-industry funding and nearly one third (30.4%) of overall funding.

In terms of funding trends among the top 12 organisations, YOY industry funders decreased their investment by $9.7m (-27.5%), while the Gates Foundation decreased its investment by $5.3m (-20.1%), although this came on the back of a $20.7m (369.5%) increase the previous year and is partially due to the uneven disbursement of a multi-year grant. The combined drop in funding from these two groups accounted for the entire real decrease for bacterial pneumonia & meningitis R&D in 2009, reflecting progression to approval of a pneumococcal vaccine candidate, as noted. There were minimal increases in funding from most other top 12 funders, including the Swedish Research Council (up $1.0m, 533.3%), Dell foundation (up $1.0m, 334.7%) and Australian National Health and Medical Research Council (NHMRC) (up $0.9m, 178.9%).

**Table 13. Top 12 bacterial pneumonia & meningitis R&D funders 2009**

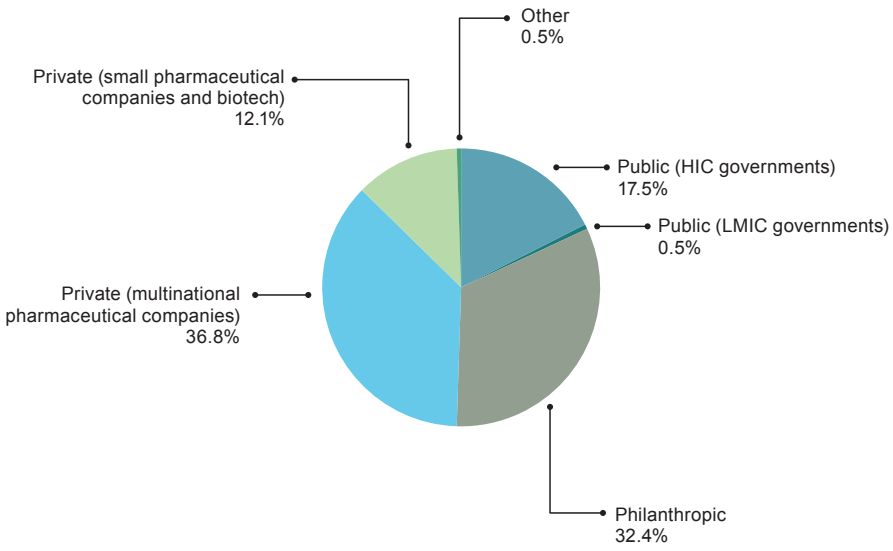
| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Aggregate pharmaceutical and biotechnology company respondents[A] | 15,747,037 | 50,494,753 | 33,794,257 | 48.4 | 55.6 | 49.0 |
| Bill & Melinda Gates Foundation | 5,598,040 | 26,282,476 | 21,000,867 | 17.2 | 28.9 | 30.4 |
| US National Institutes of Health (NIH) | 4,194,589 | 4,030,496 | 3,685,083 | 12.9 | 4.4 | 5.3 |
| UK Medical Research Council (MRC) | 1,776,977 | 1,985,766 | 2,034,450 | 5.5 | 2.2 | 2.9 |
| Australian National Health and Medical Research Council (NHMRC) | 315,006 | 504,622 | 1,407,279 | 1.0 | 0.6 | 2.0 |
| US Centers for Disease Control (CDC) | 1,455,973 | 1,402,671 | 1,407,145 | 4.5 | 1.5 | 2.0 |
| Dell Foundation | - | 289,017 | 1,256,403 | 0.0 | 0.3 | 1.8 |
| Swedish Research Council | - | 193,590 | 1,225,939 | 0.0 | 0.2 | 1.8 |
| Research Council of Norway | - | 589,942 | 758,565 | 0.0 | 0.6 | 1.1 |
| German Research Foundation (DFG)[B] | - | - | 567,107 | 0.0 | 0.0 | 0.8 |
| Undisclosed funder | - | 385,945 | 369,605 | 0.0 | 0.4 | 0.5 |
| Pathological Society of Great Britain and Ireland | - | - | 350,650 | 0.0 | 0.0 | 0.5 |
| Subtotal top 12 bacterial pneumonia & meningitis R&D funders* | 32,317,719 | 89,494,134 | 67,857,349 | 99.4 | 98.5 | 98.4 |
| Disease Total | 32,517,311 | 90,844,284 | 68,988,629 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
[B] No data provided in 2008
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
- No reported funding in category

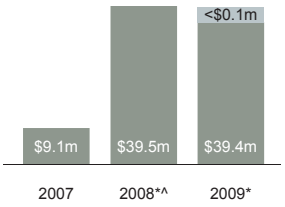
In terms of funding share, even at its reduced 2009 investment levels, industry still accounted for half of all bacterial pneumonia & meningitis R&D funding for 2009 (49%, down from 55.6% in 2008). Public investment remained steady at $12.5m, with an increase from YOY public funders of only $0.4m (3.4%), while philanthropic funding decreased by $4.4m (-16.5%) to $22.4m. Despite this, global funding share actually increased for the philanthropic sector (32.4%, up from 29.5% in 2008), as well as the public sector (18.1%, up from 14.9% in 2008) due to even greater decreases in overall industry funding.

HIC governments provided virtually all public funding (97.0%), with YOY HIC funders increasing their investment by $2.4m (24.8%). LMIC government YOY funders (both of which were IDC countries) reduced their investment by $2.0m (-84.2%). Coupled with the loss-to-follow-up of one LMIC government funder, this led to a very substantial reduction in the LMICs share of public funding (down from 29.1% in 2008 to 3.0% in 2009). IDC investment remained very strong in the private arena, however, with IDC companies contributing about a quarter of all industry investment in bacterial pneumonia & meningitis R&D. This likely reflects their involvement in the pneumococcal vaccine AMC.

**Figure 14. Bacterial pneumonia & meningitis R&D funding by funder type 2009**



# SALMONELLA INFECTIONS

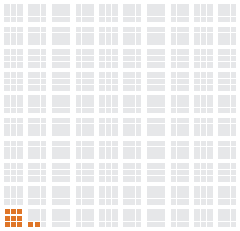



* Figures are adjusted for inflation and reported in 2007 US dollars

^ Survey scope was expanded in 2008 to include non-typhoidal *Salmonella enterica* (NTS) and multiple salmonella infections

**$39.4 MILLION**

TOTAL SPEND ON SALMONELLA R&D IN 2009



**1.2%**

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.[26]

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 21 million cases annually, resulting in 200,000-600,000 deaths per year.[27]

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).[28] 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.[29] Similarly, no typhoid or NTS vaccine is readily available for HIV-infected individuals or children under two years of age.[29] 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, both driven by developing country needs.[30] Recent research on humoral resistance to NTS has also delivered important clues for development of an NTS vaccine.[31]

R&D needed for salmonella infections includes:

- Basic research
- Drugs
- Diagnostics
- Vaccines

In 2009, salmonella R&D received $39.4m *($40.3m)* in funding. Funding essentially held steady from 2008, with a minimal $0.1m (-0.3%) decrease seen from YOY funders. There were no survey respondents lost to follow up. This meant that salmonella R&D again represented only a very small slice of global funding in 2009 (1.2%, compared to 1.3% in 2008).

NTS captured the majority of funding in 2009 ($16.5m, 41.8%), followed by typhoid and paratyphoid fever ($13.8m, 35.2%). This was a reverse in the allocation of funding per disease from previous years, explained by a $2.7m (19.5%) increase in funding for NTS (almost all due to a $2.4m increase in funding for basic research) and a simultaneous $5.6m (29.0%) drop in funding for typhoid and paratyphoid fever (mostly due to a $4.7m drop in vaccine funding).

**Table 14. Funding for salmonella R&D 2009 (US$)***

| Disease | Basic Research | Drugs | Vaccines (Preventive) | Diagnostics | Unspecified | Total | % |
|---|---|---|---|---|---|---|---|
| Non-typhoidal *Salmonella enterica* (NTS) | 14,233,448 | - | 714,507 | 957,883 | 555,380 | **16,461,219** | 41.8 |
| Typhoid and paratyphoid fever | 4,278,529 | - | 9,112,100 | 451,875 | - | **13,842,504** | 35.2 |
| Multiple salmonella infections | 8,971,752 | 58,911 | 44,183 | - | - | **9,074,847** | 23.0 |
| Total | 27,483,729 | 58,911 | 9,870,791 | 1,409,759 | 555,380 | **39,378,570** | 100.0 |

* All figures are FY2009, adjusted for inflation and reported in 2007 US dollars
- No reported funding in category

Twelve organisations accounted for virtually all salmonella R&D funding in 2009. As in previous years, the US NIH provided nearly two-thirds (64.7%) of global funding, although its share has gone down over time as other organisations have stepped up their contribution. An increase in funding from several organisations, particularly the US NIH (up $5.1m, 25.0%), the Gates Foundation (up $1.6m, did not previously report funding for salmonella) and the EC (up $0.8m, 238.3%) offset a considerable drop in industry investment (down $8.9m, -72.1%), as well as small decreases from several other funders. The drop in industry funding was entirely due to decreased investment by SMEs, which meant that, unlike 2008, MNC investments ($1.8m) and SME investments ($1.7m) were roughly equal in 2009.

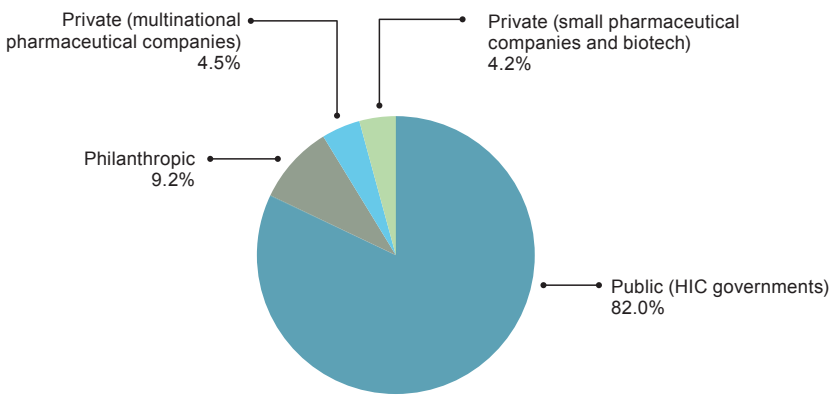
**Table 15. Top 12 salmonella R&D funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 8,086,868 | 20,361,114 | 25,459,290 | 88.7 | 51.6 | 64.7 |
| Aggregate pharmaceutical and biotechnology company respondents[A] | - | 12,313,110 | 3,441,047 | 0.0 | 31.2 | 8.7 |
| Wellcome Trust | - | 1,033,056 | 1,983,546 | 0.0 | 2.6 | 5.0 |
| Bill & Melinda Gates Foundation | - | - | 1,631,542 | 0.0 | 0.0 | 4.1 |
| Institut Pasteur | - | 1,453,175 | 1,580,962 | 0.0 | 3.7 | 4.0 |
| Tuscany Region, Italy | - | - | 1,550,208 | 0.0 | 0.0 | 3.9 |
| European Commission | - | 356,682 | 1,206,626 | 0.0 | 0.9 | 3.1 |
| UK Medical Research Council (MRC) | 976,150 | 1,229,604 | 868,676 | 10.7 | 3.1 | 2.2 |
| German Research Foundation (DFG)[B] | - | - | 546,688 | 0.0 | 0.0 | 1.4 |
| Australian National Health and Medical Research Council (NHMRC) | - | 456,208 | 495,603 | 0.0 | 1.2 | 1.3 |
| Swedish Research Council | - | 483,607 | 393,722 | 0.0 | 1.2 | 1.0 |
| UK Biotechnology and Biological Sciences Research Council (BBSRC) | - | 805,261 | 203,487 | 0.0 | 2.0 | 0.5 |
| Subtotal top 12 salmonella R&D funders* | 9,117,212 | 39,412,504 | 39,361,396 | 100.0 | 99.8 | 100.0 |
| Disease Total | 9,117,212 | 39,486,243 | 39,378,570 | 100.0 | 100.0 | 100.0 |

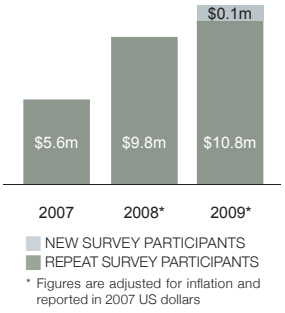
^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
[B] No data provided in 2008
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
- No reported funding in category

The public sector increased salmonella R&D funding by $6.2m (23.6%) in 2009, while philanthropic funding increased by $2.6m (249.9%). Combined with the decrease in industry investment noted above, this allowed the public sector to increase its share of global funding from 66.2% ($26.1m) in 2008 to 82.1% ($32.3m) in 2009. As in previous years, HIC governments provided virtually all public funding (99.9%).

**Figure 15. Salmonella infections R&D funding by funder type 2009**



# LEPROSY




## $11.0 MILLION

TOTAL SPEND ON LEPROSY R&D IN 2009



## 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 25 years and, although highly effective, requires a 6-12 month course of multi-drug therapy. Further research is needed to provide products for the management of nerve function, improve and simplify chemotherapy, develop and improve diagnostics, and further progress early stage work on a vaccine.[32,33]

R&D needed for leprosy includes:

- Basic research
- Drugs
- Diagnostics
- Vaccines

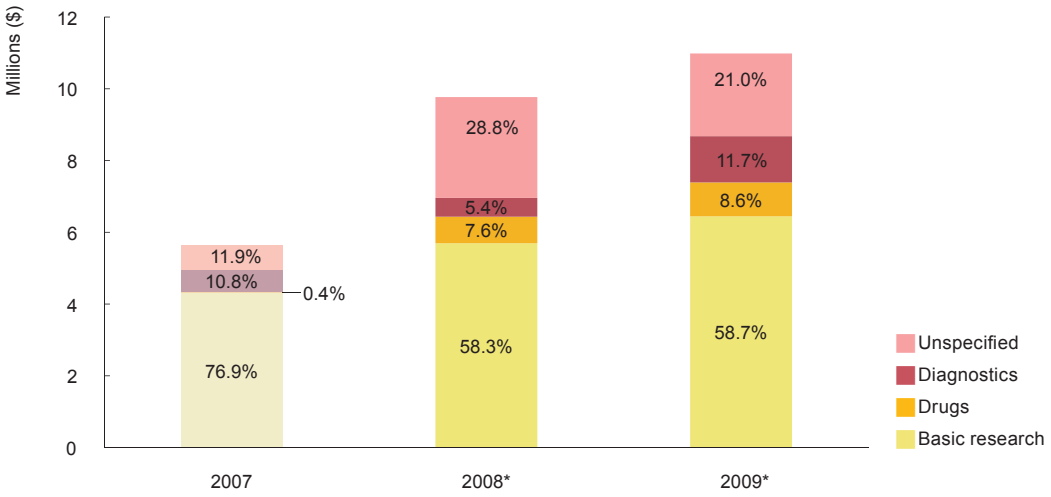
Global funding for leprosy R&D in 2009 was $11.0m *($11.0m[iv])*. This represented a modest increase, with YOY funders providing an additional $1.1m (up 11.0%). A further $0.1m in reported funding was due to new survey respondents. There were no survey respondents lost to follow up. Leprosy's share of global R&D funding remained low but stable in 2008 and 2009 (0.3% in both years).

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 ($6.4m) accounted for over half the global investment in leprosy (58.7% in 2009, 58.3% in 2008). Diagnostic development received $1.3m (11.7%), while only $0.9m (8.6%) was allocated to drug development. The small size of leprosy funding meant that even very modest additional grants from YOY funders led to a doubling of funding for diagnostics (up $0.8m, 143.8%), largely due to funding from the US NIH (increased by $0.7m); as well as increases in funding for basic research ($0.7m, 11.5%) and drugs ($0.2m, 23.8%).

[iv] The nominal figure is the same as the adjusted figure due to rounding. Please see Table 2 for details

**Figure 16. Leprosy R&D funding by product type 2007-2009**




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

Twelve organisations provided almost all global leprosy R&D funding in 2009, with the US NIH providing almost half (47.2%). Funding continued to be highly concentrated with three organisations accounting for over 80% of the global total. Of these, only the US NIH increased their contribution (up $2.0m, 61.9%), while the ICMR and Brazilian Ministry of Health decreased funding by $0.9m (-32.6%) and $0.4m (-18.5%) respectively. The inclusion of Colombia in the survey saw Colciencias appear in the top 12 leprosy funders for 2009.

**Table 16. Top 12 leprosy R&D funders 2009**

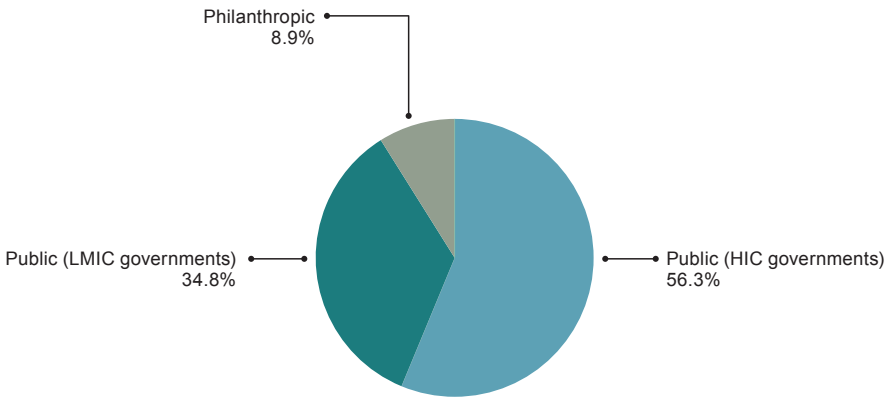
| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 1,993,588 | 3,138,305 | 5,081,931 | 35.5 | 32.1 | 46.3 |
| Brazilian Ministry of Health, Department of Science and Technology | 1,455,070 | 2,287,212 | 1,864,193 | 25.9 | 23.4 | 17.0 |
| Indian Council of Medical Research (ICMR)[A] | - | 2,704,472 | 1,821,928 | 0.0 | 27.7 | 16.6 |
| French National Research Agency, Agence Nationale de la Recherche (ANR) | - | - | 564,932 | 0.0 | 0.0 | 5.1 |
| American Leprosy Missions | 658,000 | 642,100 | 519,957 | 11.7 | 6.6 | 4.7 |
| Hospital and Homes of St Giles | - | 108,131 | 214,229 | 0.0 | 1.1 | 2.0 |
| Canadian Institutes of Health Research (CIHR)[B] | - | - | 186,053 | 0.0 | 0.0 | 1.7 |
| Institut Pasteur | 129,154 | 221,321 | 183,487 | 2.3 | 2.3 | 1.7 |
| University College London Hospital (UCLH) | - | 45,955 | 105,776 | 0.0 | 0.5 | 1.0 |
| Colombian Department for Science, Technology and Innovation (Colciencias)[C] | - | - | 98,002 | 0.0 | 0.0 | 0.9 |
| Netherlands Leprosy Relief | - | - | 67,405 | 0.0 | 0.0 | 0.6 |
| Colorado State University | - | 51,060 | 57,021 | 0.0 | 0.5 | 0.5 |
| Subtotal top 12 leprosy R&D funders* | 5,619,475 | 9,638,473 | 10,764,915 | 100.0 | 98.7 | 98.0 |
| Disease Total | 5,619,475 | 9,769,250 | 10,984,756 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] New survey recipient in 2008, no 2007 data available. The drop in funding from ICMR in 2009 is likely due to less comprehensive reporting by some of its institutes
[B] Not all of CIHR's investments towards leprosy were included
[C] New survey respondent in 2009, no 2007/08 data available
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
- No reported funding in category

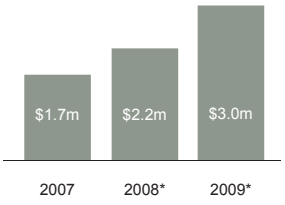
Public and philanthropic organisations provided all leprosy R&D funding in 2009. Public funding totalled $10.0m in 2009, an increase from YOY public funders of $1.3m (15.2%) while philanthropic funding was $1.0m, a decrease of $0.1m (-7.3%). As in previous years, there was no industry contribution to leprosy R&D.

In 2008, LMICs played a highly significant role as public funders of leprosy R&D, providing 58.3% of global funding, compared to a HIC public share of 41.7%. This situation was reversed in 2009 due to a modest increase of $2.6m (up to $6.2m) by HIC YOY public funders, combined with the decrease noted above by LMIC YOY public funders of $1.3m (down to $3.7m). As a result, HICs accounted for 61.8% of global public funding in 2009, while LMICs represented only 36.8%. New survey participants in the LMIC group reported a further $0.1m, but this did little to offset the overall decrease in funding by this group.

**Figure 17. Leprosy R&D funding by funder type 2009**



# RHEUMATIC FEVER




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

## $3.0 MILLION

TOTAL SPEND ON RHEUMATIC FEVER R&D IN 2009



## 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 development of a vaccine.

A number of vaccines are currently in development, including one by the Queensland Institute of Medical Research (QIMR), which will begin human trials in 2010.[34] Also of note is the establishment of the Hilleman Laboratories in India, a joint venture between the Wellcome Trust and Merck & Co. that will have a strong focus on development of a *Streptococcus* A vaccine.[35]

R&D needed for rheumatic fever is:

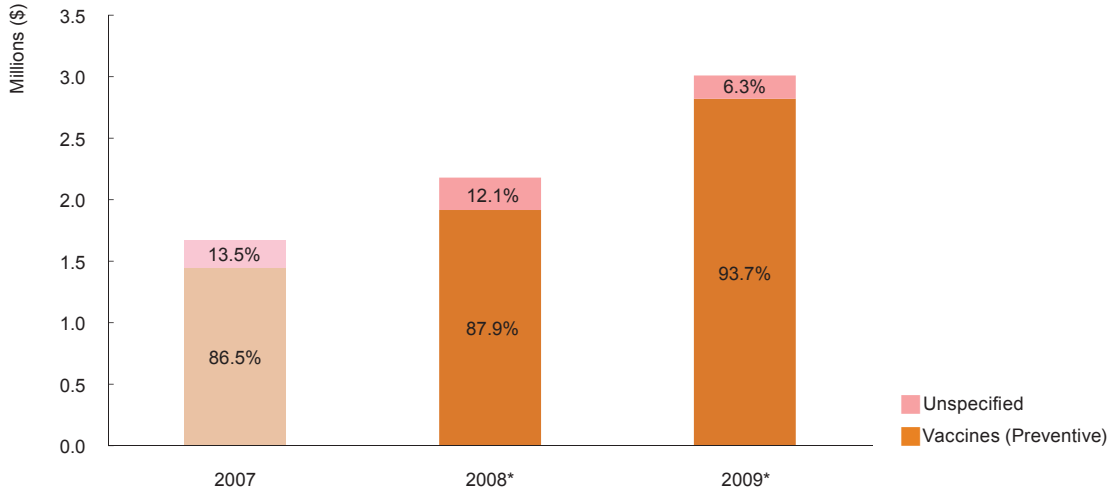
- Vaccines

Global funding for rheumatic fever R&D in 2009 was $3.0m *($3.1m)*. Relative to its overall funding level, this was a considerable increase of $0.8m (38.1%) from 2008, all of which represents a real increase in funding since there were no new survey participants for rheumatic fever and no survey participants lost to follow-up. The global share of R&D funding for rheumatic fever in 2009 remained the same, 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, thus all the increased investment in 2009 was for vaccine R&D.

**Figure 18. Rheumatic fever R&D funding by product type 2007-2009^**




* Figures are adjusted for inflation and reported in 2007 US dollars
^ G-FINDER's scope for rheumatic fever only includes preventive vaccines

Only six organisations (and one undisculosed funder) invested in rheumatic fever in 2009. Almost half of 2009 funding ($1.5m, 48.2%) for rheumatic fever came from the private sector, followed by the US NIH ($0.7m, 24.8%). Three Australian organisations accounted for 20.8% of funding, as rheumatic fever is still prevalent in Aboriginal and Torres Strait Islander populations. There were also modest funding increases across the board, with the exception of the Australian Department of Innovation, Industry, Science and Research (DIISR) and Australian National Heart Foundation (NHF).

**Table 17. Rheumatic fever R&D funders 2009**

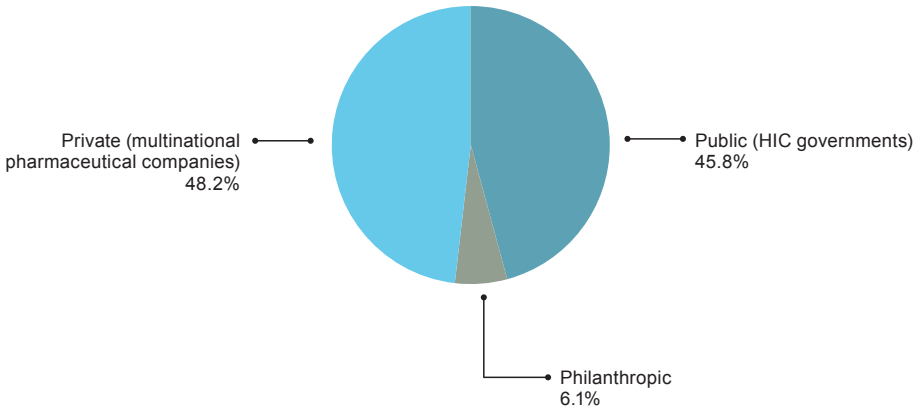
| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Aggregate pharmaceutical and biotechnology company respondents | - | 963,391 | 1,449,696 | 0.0 | 44.2 | 48.2 |
| US National Institutes of Health (NIH) | 1,284,919 | 629,315 | 745,605 | 76.9 | 28.9 | 24.8 |
| Australian National Health and Medical Research Council (NHMRC) | 385,170 | 338,310 | 573,410 | 23.1 | 15.5 | 19.1 |
| Fondazione Cariplo | - | - | 130,685 | 0.0 | 0.0 | 4.3 |
| Swedish Research Council | - | 58,887 | 58,911 | 0.0 | 2.7 | 2.0 |
| Australian National Heart Foundation | - | 54,212 | 51,431 | 0.0 | 2.5 | 1.7 |
| Australian Government Department of Innovation, Industry, Science and Research | - | 106,805 | - | 0.0 | 4.9 | 0.0 |
| Undisclosed funder | - | 28,691 | - | 0.0 | 1.3 | 0.0 |
| Disease Total | 1,670,089 | 2,179,609 | 3,009,737 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
\- No reported funding in category

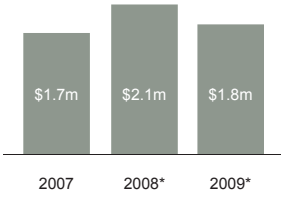
Rheumatic fever was one of only two neglected disease areas where the private sector leads funding (the other is bacterial pneumonia and meningitis). In 2009, MNCs contributed $1.4m (48.2%) of total investment, representing an increase of $0.5m (up 50.5%) from 2008.

HIC government funding (totalling $1.4m) accounted for 45.8% of total rheumatic fever R&D investment in 2009, which included an increase in funding of $0.2m (21.6%). There was no funding from LMIC governments or multilaterals. Philanthropic organisations increased their contribution considerably, albeit from a very low base (from $0.05m in 2008 to $0.18m in 2009).

**Figure 19. Rheumatic fever R&D funding by funder type 2009**



# TRACHOMA




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

## $1.8 MILLION

TOTAL SPEND ON TRACHOMA R&D IN 2009



## 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.[36]

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.[37] 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).[38]

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[39], 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.[40] 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.[41]

New products needed for trachoma include:

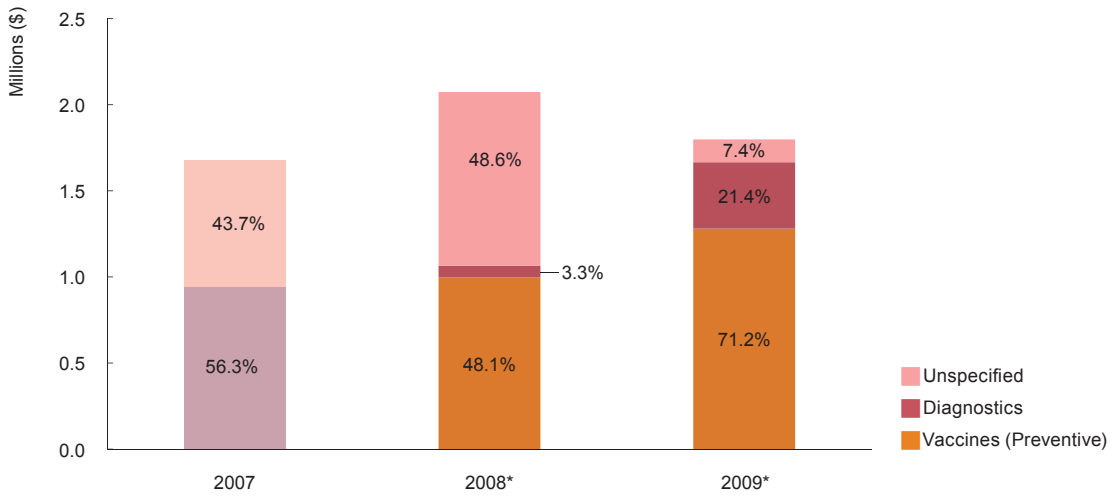
- Vaccines
- Diagnostics

Global funding for trachoma R&D in 2009 was $1.8m *($1.8m[v])*. This was a real decrease of $0.3m (-13.3%) by YOY funders. There were no survey respondents lost to follow up. The global share of R&D funding for trachoma remained unchanged from 2008 at 0.1%.

As with other low-funded areas, the data 'trends' outlined below should be treated with caution, since they more likely reflect changes in single grants or programmes than a significant underlying pattern. We also note that improved reporting by survey participants means that dollars marked as 'unspecified' in 2007 and 2008 are now allocated to product areas. That said, in 2009 almost three-quarters ($1.28m, 71.2%) of trachoma R&D funding was invested in vaccines, and a further $0.4m (21.4%) in diagnostics.

[v] The nominal figure is the same as the adjusted figure due to rounding. Please see Table 2 for details

**Figure 20. Trachoma R&D funding by product type 2007-2009**




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

In 2009, funding for trachoma R&D came from only two organisations – the US NIH and Swedish Research Council. Several previous funders of trachoma reported no funding this year, including the Statens Serum Institute (SSI), Brazilian Ministry of Health, Institut Pasteur and pharmaceutical company respondents.

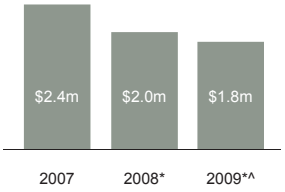
**Table 18. Trachoma R&D funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | - | 1,037,612 | 1,665,913 | 0.0 | 50.0 | 92.6 |
| Swedish Research Council | - | 38,276 | 132,550 | 0.0 | 1.8 | 7.4 |
| Statens Serum Institute (SSI) | - | 703,674 | - | 0.0 | 33.9 | 0.0 |
| Brazilian Ministry of Health, Department of Science and Technology | - | 170,326 | - | 0.0 | 8.2 | 0.0 |
| Aggregate pharmaceutical and biotechnology company respondents | 104,000 | 96,339 | - | 6.2 | 4.6 | 0.0 |
| Institut Pasteur | - | 27,432 | - | 0.0 | 1.3 | 0.0 |
| Wellcome Trust | 1,461,110 | - | - | 87.0 | 0.0 | 0.0 |
| Multiple funders | 85,403 | - | - | 5.1 | 0.0 | 0.0 |
| Johns Hopkins University | 29,198 | - | - | 1.7 | 0.0 | 0.0 |
| Disease Total | 1,679,711 | 2,073,659 | 1,798,463 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
\- No reported funding in category

In 2009, trachoma R&D funding came entirely from HIC governments (there is therefore no pie chart shown). This differs from previous years, when there were small investments from LMIC governments, MNCs and philanthropic organisations. However, as noted, this was likely a reflection of sporadic nature and extremely low levels of trachoma R&D funding rather than any more significant trend.

# BURULI ULCER




* 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

## $1.8 MILLION

TOTAL SPEND ON BURULI ULCER R&D IN 2009



## 0.1%

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.[42]

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[42], with more than 5,000 new cases reported each year from 2006 to 2009.[37]

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, and current diagnostics are both costly and insufficiently sensitive.[42]

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.[43]

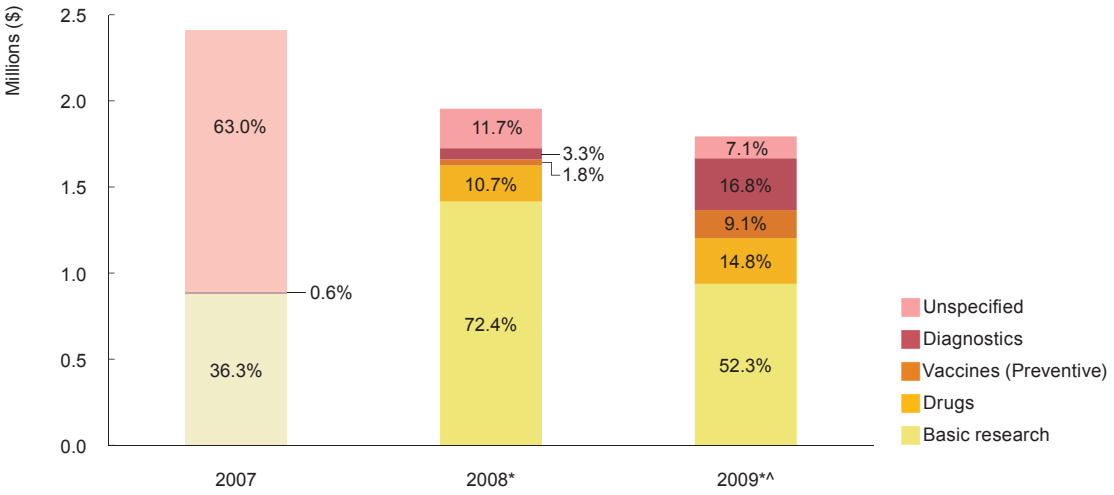
Buruli ulcer needs a wide range of R&D including:

- Basic research
- Drugs
- Vaccines
- Diagnostics

Global funding for Buruli ulcer R&D in 2009 was $1.8m *($1.9m)*. This was essentially unchanged from 2008, since the apparent drop in funding was a result of a loss-to-follow-up of donors who reported $0.2m in 2008, with YOY funders actually providing an additional $0.04m (up 2.0%). Buruli ulcer's share of total neglected disease R&D investment remained steady at 0.1%.

Over half of all Buruli ulcer R&D funding went to basic research ($0.9m, 52.3%). The remainder was split between diagnostics ($0.30m, 16.8%), drug development ($0.27m, 14.8%) and vaccines $0.16m (9.1%). YOY funders provided minimally increased funding for drugs (up $0.25m, 1,924%), diagnostics (up $0.24m, 364.5%), and vaccines (up $0.13m, 359%), at the expense of basic research (down $0.48m, -33.7%). Again, we suggest caution in interpreting these funding trends given the small amounts involved.

**Figure 21. Buruli ulcer R&D funding by product type 2007-2009**




* 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

Only eight organisations funded Buruli ulcer R&D in 2009. Buruli ulcer R&D continued to attract very few funders, and this funding remained patchy. The US NIH increased its investment by $0.36m (88.8%) to become the main funder, however this was offset by a drop in funding of $0.47m (-75.1%) from the EC, which went from being the top funder in 2008 (with 32.0% of total funding) to providing 8.7% in 2009.

There was no industry funding for Buruli ulcer R&D in 2009, down from an investment of $0.29m in 2008, although this was largely a result of $0.20m lost-to-follow-up from companies who did not participate in the 2009 survey. In the absence of industry involvement, funding came entirely from HIC governments ($1.5m, 82.4%) and philanthropic organisations ($0.32m, 17.6%). YOY philanthropic funders increased their investment by $0.12m (up 62.3%), while public funding remained stable.

**Table 19. Buruli ulcer R&D funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 656,291 | 403,924 | 762,804 | 27.2 | 20.7 | 42.5 |
| Institut Pasteur | 645,769 | 285,729 | 351,674 | 26.8 | 14.6 | 19.6 |
| Fondazione Cariplo | - | 13,116 | 181,913 | 0.0 | 0.7 | 10.1 |
| European Commission | 726,354 | 625,656 | 155,842 | 30.1 | 32.0 | 8.7 |
| UBS Optimus Foundation | - | 140,246 | 126,813 | 0.0 | 7.2 | 7.1 |
| Australian National Health and Medical Research Council (NHMRC) | 220,584 | 74,844 | 123,095 | 9.1 | 3.8 | 6.9 |
| Belgian National Fund for Scientific Research (FWO) | - | 84,402 | 85,031 | 0.0 | 4.3 | 4.7 |
| Wellcome Trust | - | 40,862 | 6,546 | 0.0 | 2.1 | 0.4 |
| Multiple funders | 148,752 | - | - | 6.2 | 0.0 | 0.0 |
| Aggregate pharmaceutical and biotechnology company respondents | 15,200 | 285,685 | - | 0.6 | 14.6 | 0.0 |
| Disease Total | 2,412,950 | 1,954,465 | 1,793,718 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
- No reported funding in category

**Figure 22. Buruli ulcer R&D funding by funder type 2009**

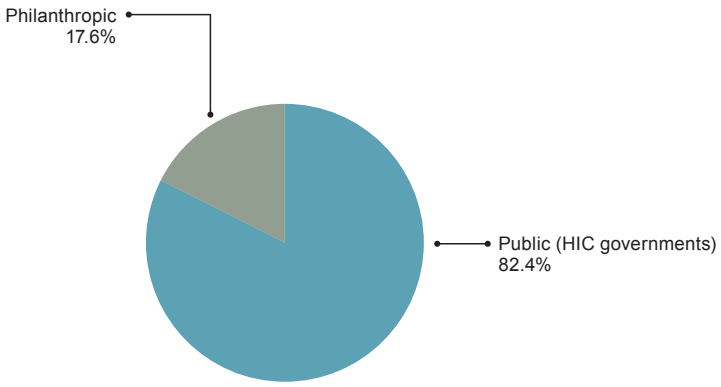


**Table 20. Summary table of overall neglected disease and product funding in 2009 ($m)***

| Disease | Basic Research | Drugs | Vaccines (Preventive) | Vaccines (Therapeutic) | Microbicides | Vector control products | Diagnostics | Unspecified | Total |
|---|---|---|---|---|---|---|---|---|---|
| **HIV/AIDS** | 184.08 | 28.93 | 657.90 | | 203.56 | | 42.76 | 21.41 | **1,138.64** |
| **Tuberculosis** | 199.46 | 179.99 | 108.63 | 5.42 | | | 52.20 | 14.32 | **560.02** |
| **Malaria** | 147.68 | 182.49 | 195.76 | | | 26.73 | 9.12 | 32.77 | **594.56** |
| *P. falciparum* | 87.65 | 119.34 | 146.70 | | | 15.11 | 4.07 | 7.81 | **380.69** |
| *P. vivax* | 6.97 | 9.65 | 9.47 | | | - | 0.57 | 2.50 | **29.18** |
| Other and/or unspecified malaria strains | 53.07 | 53.50 | 39.59 | | | 11.61 | 4.48 | 22.45 | **184.70** |
| **Diarrhoeal diseases** | 53.34 | 3.83 | 106.39 | | | | 7.12 | 9.76 | **180.43** |
| Rotavirus | | | 52.69 | | | | | 0.53 | **53.22** |
| Cholera | 18.77 | 0.34 | 19.79 | | | | 0.18 | - | **39.07** |
| Multiple diarrhoeal diseases | 7.73 | 0.69 | 17.96 | | | | 3.98 | 7.56 | **37.91** |
| Shigella | 14.00 | 0.32 | 8.79 | | | | 1.45 | 1.45 | **26.01** |
| *Cryptosporidium* | 12.84 | 2.49 | 0.24 | | | | 0.91 | - | **16.48** |
| Enterotoxigenic *E.coli* (ETEC) | | | 6.92 | | | | 0.16 | - | **7.08** |
| Giardia | | | | | | | 0.44 | 0.16 | **0.60** |
| Enteroaggregative *E.coli* (EAggEC) | | | - | | | | - | 0.05 | **0.05** |
| **Dengue** | 44.41 | 15.68 | 93.57 | | | 4.12 | 4.00 | 4.03 | **165.81** |
| **Kinetoplastids** | 62.38 | 71.40 | 18.61 | 0.86 | | 0.17 | 6.48 | 2.35 | **162.26** |
| Leishmaniasis | 24.42 | 24.97 | 15.07 | 0.86 | | | 1.98 | 2.08 | **69.38** |
| Sleeping sickness | 24.91 | 15.02 | 3.11 | | | 0.16 | 2.95 | 0.24 | **46.40** |
| Chagas' disease | 11.75 | 3.74 | 0.43 | - | | 0.01 | 0.74 | 0.03 | **16.70** |
| Multiple kinetoplastids | 1.29 | 27.67 | - | - | | 0.01 | 0.81 | - | **29.78** |
| **Helminths (worms & flukes)** | 41.70 | 15.30 | 9.86 | | | 1.86 | 1.39 | 9.30 | **79.41** |
| Schistosomiasis (bilharziasis) | 16.17 | 0.64 | 2.07 | | | - | 0.98 | 2.09 | **21.95** |
| Lymphatic filariasis (elephantiasis) | 4.91 | 5.09 | | | | 1.33 | - | 3.61 | **14.93** |
| Onchocerciasis (river blindness) | 1.90 | 8.91 | 0.81 | | | - | 0.16 | 1.31 | **13.10** |
| Hookworm (ancylostomiasis & necatoriasis) | 2.74 | - | 6.99 | | | | | - | **9.72** |
| Tapeworm (cysticercosis/taeniasis) | 2.38 | - | | | | 0.54 | | - | **2.92** |
| Roundworm (ascariasis) | 2.07 | - | | | | | | - | **2.07** |
| Strongyloidiasis & other intestinal roundworms | 1.36 | 0.04 | - | | | | 0.14 | - | **1.54** |
| Whipworm (trichuriasis) | 1.02 | 0.04 | | | | | | - | **1.06** |
| Multiple helminths | 9.14 | 0.58 | - | | | - | 0.10 | 2.29 | **12.12** |
| **Bacterial pneumonia & meningitis** | | | 59.63 | | | | 4.17 | 5.18 | **68.99** |
| *Streptococcus pneumoniae* | | | 50.77 | | | | 3.90 | 1.28 | **55.95** |
| *Neisseria meningitidis* | | | 8.87 | | | | 0.27 | 0.23 | **9.37** |
| Both bacteria | | | | | | | - | 3.67 | **3.67** |
| **Salmonella infections** | 27.48 | 0.06 | 9.87 | | | | 1.41 | 0.56 | **39.38** |
| Non-typhoidal *Salmonella enterica* (NTS) | 14.23 | - | 0.71 | | | | 0.96 | 0.56 | **16.46** |
| Typhoid and Paratyphoid fever (*S. typhi, S. paratyphi A*) | 4.28 | - | 9.11 | | | | 0.45 | - | **13.84** |
| Multiple salmonella infections | 8.97 | 0.06 | 0.04 | | | | - | - | **9.07** |

| Disease | Basic Research | Drugs | Vaccines (Preventive) | Vaccines (Therapeutic) | Microbicides | Vector control products | Diagnostics | Unspecified | Total |
|---|---|---|---|---|---|---|---|---|---|
| **Leprosy** | 6.45 | 0.94 | | | | | 1.29 | 2.31 | 10.98 |
| **Rheumatic fever** | | | 2.82 | | | | | 0.19 | 3.01 |
| **Trachoma** | | | 1.28 | | | | 0.39 | 0.13 | 1.80 |
| **Buruli ulcer** | 0.94 | 0.27 | 0.16 | | | | 0.30 | 0.13 | 1.79 |
| **Core funding of a multi-disease R&D organisation** | | | | | | | | | 74.09 |
| **Unspecified disease** | | | | | | | | | 85.33 |
| **Platform technologies** | Adjuvants and immunomodulators | | | Delivery technologies and devices | | | General diagnostic platforms | | |
| | 5.59 | | | 7.89 | | | 8.61 | | 22.09 |
| **Total R&D funding** | | | | | | | | | **3,188.60** |

* All figures are FY 2009, adjusted for inflation and reported in 2007 US dollars

\- No reported funding in category

Category not included in G-FINDER

# FINDINGS - NEGLECTED DISEASE FUNDERS

## Funder overview

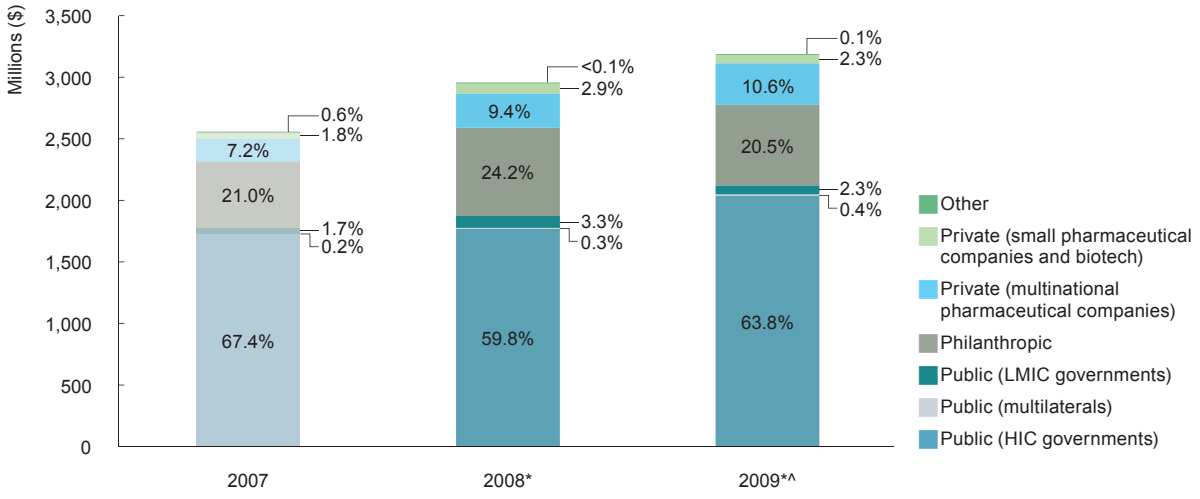
In 2009, neglected disease R&D was mainly funded by the public and philanthropic sectors, who accounted for $2.8bn (87.1%) of total funding. Public donors contributed $2.1bn (66.5%), of which most came from HIC governments ($2.0bn). Philanthropic organisations provided $654.0m (20.5%), while the remainder came from the private sector ($411.2m, 12.9%) and unspecified funders ($1.7m, 0.1%, noted as 'other' in Figure 23).

YOY funders increased their funding by $239.0m (up 8.2%). Most of the increase came from public sector organisations (up $258.5m, 14.0%), followed at a distance by MNCs (up $58.9m, 21.1%). This offset a drop in funding from the philanthropic sector (down $62.5m, -8.7%) and SMEs (down $16.1m, -23.7%).

On top of the increase in investment from YOY funders, new survey participants added a further $34.1m. The majority of this funding came from small pharmaceutical and biotech company entrants (up $21.4m), particularly those from Brazil and India, who were surveyed for the first time. A further $12.7m was accounted for by additional public sector organisations surveyed for the first time in 2009.

At the same time, 15 organisations who participated in the 2008 survey did not provide 2009 data: this means reported 2009 funding may be an underestimate as these organisations collectively provided $40.4m in 2008, and are likely to have continued to provide funding in many cases, although we could not capture these amounts.

**Figure 23. Total funding by funder type 2007-2009**




* 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

## Public funders

As in 2007 and 2008, the top three public funders were the US (first by a very wide margin), the UK and the EC. The US contributed nearly 70% of global public funding ($1.5bn, 68.9%), nearly ten times the amount contributed by the next largest funder. The vast majority ($1.3bn, 86.0%) of US public funding was disbursed by one organisation: the NIH. All public funders outside the top three invested less than $50m in 2009.

YOY public funders in the US increased their investment by $202.7m (up 16.1%), driven by the US NIH, which increased its funding by $177.8m. About two-fifths ($72.7m, 40.9%) of the US NIH increase was due to the US government's two-year infusion of ARRA funds, designed to advance scientific research and technology. Two-thirds of ARRA funding ($48.7m, 66%) supported new grants in 2009, with the remainder awarded as supplementary funds to existing projects.

Public funders in the UK also significantly increased their investment in neglected disease R&D in 2009. Although much smaller than that of the US, the UK's $49.3m funding boost represented a 47.7% increase on its 2008 investment. The majority (83.5%) of this funding increase came from one organisation, DFID, which increased its funding by $41.1m. The final member of the top three, the EC, decreased its funding by $11.6m (-8.9%). Coupled with increased UK funding, this meant the EC was no longer the second largest public funder of neglected disease R&D, a position it held for the first two years of the G-FINDER survey. We note that the apparent high increase in funding by Germany and France was predominantly due to more comprehensive reporting.

Two IDCs were in the top 12 public funders for 2009: Brazil and India. We note that apparent drops in funding by both in 2009 are partly (but not wholly) artefactual, as several public organisations in both Brazil and India did not report data to G-FINDER in 2009, or did so less comprehensively. YOY funders from Brazil decreased funding by $8.6m (-26.0%) and India by $7.9m (-24.4%). Nevertheless, it remains notable that two IDCs are in the top 12 global funders of neglected disease R&D, providing more investment than Australia, Canada, Italy or Japan (several of which have G8 status).

**Table 21. Top 12 public funders 2009**

| Country | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| United States of America | 1,250,935,091 | 1,258,318,321 | 1,461,035,845 | 70.4 | 67.2 | 68.9 |
| United Kingdom | 100,781,214 | 103,328,720 | 152,580,807 | 5.7 | 5.5 | 7.2 |
| European Commission | 121,366,882 | 129,899,906 | 118,311,296 | 6.8 | 6.9 | 5.6 |
| France[C] | 13,892,238 | 29,296,116 | 48,226,796 | 0.8 | 1.6 | 2.3 |
| Germany | 12,055,796 | 3,728,140 | 34,120,231 | 0.7 | 0.2 | 1.6 |
| Sweden | 21,566,527 | 25,600,321 | 33,096,084 | 1.2 | 1.4 | 1.6 |
| Brazil[A,C] | 21,970,169 | 36,797,688 | 31,784,738 | 1.2 | 2.0 | 1.5 |
| Netherlands | 34,088,694 | 26,976,797 | 28,741,454 | 1.9 | 1.4 | 1.4 |
| India[B] | - | 32,518,735 | 24,587,971 | 0.0 | 1.7 | 1.2 |
| Australia | 18,166,780 | 25,132,872 | 22,767,236 | 1.0 | 1.3 | 1.1 |
| Spain | 10,723,060 | 26,701,408 | 19,679,113 | 0.6 | 1.4 | 0.9 |
| Norway | 13,271,949 | 16,603,371 | 17,275,683 | 0.7 | 0.9 | 0.8 |
| Subtotal top 12 public funders* | 1,658,691,558 | 1,734,272,596 | 1,992,207,255 | 93.3 | 92.6 | 93.9 |
| Total public funding | 1,777,173,493 | 1,872,824,080 | 2,121,700,474 | 100.0 | 100.0 | 100.0 |

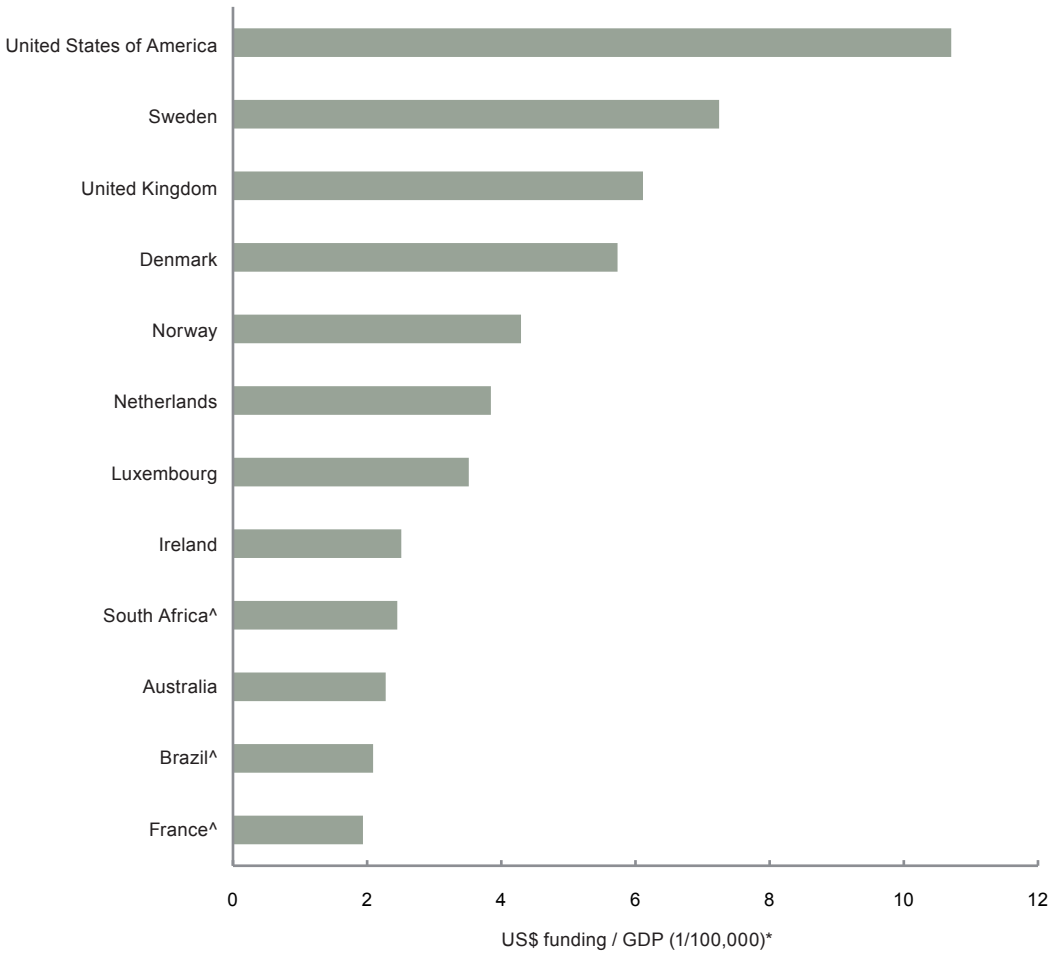
^ Figures are adjusted for inflation and reported in 2007 US dollars
A The drop in funding from Brazil was mainly due to non-participation by the Butantan Institute in 2009
B New survey respondent in 2008, no 2007 data available. The drop in funding from India was mainly due to less comprehensive reporting by some participants, and non-participation by the Indian Department of Biotechnology in 2009
C 2009 funding data likely to be incomplete
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
Canada dropped out of the top 12 in 2009 (now ranked number 14), partly due to less comprehensive reporting by the Canadian Institutes of Health Research
- No reported funding in category

We note that absolute funding can be a misleading measure of public R&D investment, particularly for smaller countries and LMICs coming from a smaller base, therefore country investments were also analysed in relation to gross domestic product (GDP).

This analysis gave a very different picture to that seen in Table 21, with four other countries now appearing on the list of top funders by GDP: Denmark, Luxembourg, Ireland and South Africa. Germany, India and Spain no longer featured in the top 12, as their funding per GDP was much lower than for some other countries. Eight countries appeared as top 12 funders by both metrics (absolute funding and funding per GDP), suggesting greater consistency between their neglected diseases funding levels and their economic clout. Of these, Norway increased its ranking considerably, going from 12th in absolute terms to fifth by GDP, while France dropped from fourth in absolute terms to 12th by GDP.

Of note is the presence of two IDCs in the top 12 by GDP:  Brazil (also in the top 12 by absolute funding) and South Africa.

**Figure 24. Public funding by GDP 2009**




* GDP figures taken from International Monetary Fund (IMF) World Economic Outlook Database
^ 2009 funding data likely to be incomplete

## HIGH INCOME COUNTRIES (HICs)

R&D funding from HIC governments and multilaterals increased for all neglected diseases except trachoma in 2009. The majority was allocated to HIV/AIDS ($959.5m, 46.8%), TB ($319.3m, 15.6%) and malaria ($263.9m, 12.9%). All other diseases received less than $100m in public funding each, with particularly low investments in trachoma, Buruli ulcer and rheumatic fever (less than $2m each). Investment in platform technologies was also relatively low at $6.8m.

Importantly, funding was more evenly distributed across the neglected diseases than in 2007 and 2008, with several previously more neglected diseases receiving an increased share of HIC public funding in 2009, including diarrhoeal diseases (up $31.0m, 51.3%), dengue (up $25.6m, 51.9%) and helminths (up $14.8m, 45.7%).

While HIV/AIDS, TB and malaria each received increased HIC public funds in 2009, the change in funding distribution across the neglected diseases meant their share of total HIC public funding decreased from 79.2% in 2007 to 75.3% in 2009, with HIV seeing the greatest shift. TB saw the most substantial funding increase ($109.6m, 52.3%), while HIV/AIDS increased by $40.8m (4.4%) and malaria by $31.7m (13.7%). The majority of the increase in TB funding came from the US NIH (up $50.5m), followed by the UK DFID (up $14.0m), and the UK Medical Research Council (MRC) (up $8.9m).

Funding increases for platform technologies were almost entirely due to an additional $1.9m investment in adjuvants and immunomodulators, masking decreases in funding for delivery technologies and devices (down $0.4m) and general diagnostic platforms (down $0.1m) by YOY funders. We note, however, that a component of apparent underfunding for platform technologies may be due to funder inability to split out these investments when reporting to G-FINDER.

**Table 22. Public funding (high income countries and multilaterals) by disease 2007-2009**

| Disease or R&D area | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| HIV/AIDS | 934,216,900 | 919,537,895 | 959,489,182 | 54.0 | 51.8 | 46.8 |
| Tuberculosis | 220,574,931 | 209,438,529 | 319,309,945 | 12.7 | 11.8 | 15.6 |
| Malaria | 216,669,290 | 232,502,900 | 263,874,878 | 12.5 | 13.1 | 12.9 |
| Kinetoplastids | 45,914,987 | 79,417,771 | 95,004,648 | 2.7 | 4.5 | 4.6 |
| Diarrhoeal diseases | 43,811,832 | 60,425,405 | 91,444,544 | 2.5 | 3.4 | 4.5 |
| Dengue | 58,170,246 | 49,432,879 | 75,074,454 | 3.4 | 2.8 | 3.7 |
| Helminth infections (worms & flukes) | 37,290,440 | 32,592,635 | 47,354,561 | 2.2 | 1.8 | 2.3 |
| Salmonella infections | 9,063,018 | 26,066,338 | 32,305,261 | 0.5 | 1.5 | 1.6 |
| Bacterial pneumonia & meningitis | 10,045,739 | 9,607,259 | 12,096,326 | 0.6 | 0.5 | 0.6 |
| Leprosy | 3,476,655 | 3,568,644 | 6,179,200 | 0.2 | 0.2 | 0.3 |
| Trachoma | 29,198 | 1,806,994 | 1,798,463 | 0.0 | 0.1 | 0.1 |
| Buruli ulcer | 2,248,998 | 1,474,556 | 1,478,445 | 0.1 | 0.1 | 0.1 |
| Rheumatic fever | 1,670,089 | 1,133,316 | 1,377,925 | 0.1 | 0.1 | 0.1 |
| Platform technologies | 3,589,301 | 5,451,059 | 6,818,132 | 0.2 | 0.3 | 0.3 |
| *Adjuvants and immunomodulators* | 23,260 | 731,956 | 2,622,387 | 0.0 | 0.0 | 0.1 |
| *Delivery technologies and devices* | 2,520,889 | 2,812,882 | 2,390,713 | 0.1 | 0.2 | 0.1 |
| *General diagnostic platforms* | 1,045,152 | 1,906,221 | 1,805,033 | 0.1 | 0.1 | 0.1 |
| Core funding of a multi-disease R&D organisation | 96,754,956 | 87,332,082 | 66,903,506 | 5.6 | 4.9 | 3.3 |
| Unspecified disease | 47,663,432 | 56,598,960 | 68,093,441 | 2.8 | 3.2 | 3.3 |
| Total public funding (HICs/multilaterals) | 1,731,190,015 | 1,776,387,220 | 2,048,602,912 | 100.0 | 100.0 | 100.0 |

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

## LOW AND MIDDLE INCOME COUNTRIES (LMICs)

LMIC governments contributed $73.1m to neglected disease R&D in 2009, accounting for 3.4% of total public funding. However, the majority of LMIC funding (89.4%) came from the three IDC governments included in the survey (Brazil, India and South Africa). The following section therefore focuses on funding by these IDCs.

The governments of Brazil, India and South Africa invested $65.4m in neglected disease R&D in 2009 (3.1% of total public funding). YOY funders invested $58.2m, representing a drop of $13.8m (-19.2%) on their 2008 funding. There was also an artefactual drop in funding due to under-reporting or non-reporting by some funders. Although this was partially offset by funding reported by new survey respondents, YOY funding trends for IDCs should nevertheless be interpreted with caution.

LMIC funding patterns differed somewhat from those of HIC governments. Almost two-thirds of their funding was directed to malaria, dengue and HIV/AIDS (collectively $40.9m, 62.6%), with dengue receiving 20.6% of funding, compared to 3.7% by HICs and multilaterals. As with HIC funders, IDC investment in trachoma, Buruli ulcer and rheumatic fever was almost non-existent.

YOY IDC funders (excluding new survey participants or non-participants in 2009) increased both their relative and absolute investment in HIV/AIDS (up $4.3m, 71.8%). However, they decreased funding for almost all other disease and product areas, with the most significant drops being for bacterial pneumonia and meningitis (down $2.0m, -84.2%), leprosy (down $1.3m, -26.2%) and TB (down $1.1m, -12.9%). Several public IDC funders also appeared to have stopped investing in platform technologies, although this may reflect uneven disbursement of multi-year grants. The apparent small drop in dengue funding was a result of the loss-to-follow up of the Butantan Institute in Brazil, partly offset by funding reported by new survey respondents.

Overall, these changes led to a shift in IDC funding share from the more neglected diseases to HIV/AIDS, TB and malaria, which accounted for 39.6% in 2008 and 54.2% in 2009, with dengue also slightly increasing its share of IDC public funding.

**Table 23. Public funding by IDCs (Brazil, India and South Africa) by disease 2007-2009**

| Disease or R&D area | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Malaria | 2,938,682 | 14,801,084 | 17,107,553 | 11.3 | 19.6 | 26.2 |
| Dengue | 1,623,000 | 14,905,829 | 13,450,145 | 6.3 | 19.7 | 20.6 |
| HIV/AIDS | 4,181,862 | 6,030,340 | 10,376,951 | 16.1 | 8.0 | 15.9 |
| Tuberculosis | 3,643,016 | 9,082,407 | 7,946,103 | 14.0 | 12.0 | 12.2 |
| Kinetoplastids | 4,906,145 | 6,968,709 | 6,561,093 | 18.9 | 9.2 | 10.0 |
| Diarrhoeal diseases | - | 5,162,650 | 4,289,420 | 0.0 | 6.8 | 6.6 |
| Leprosy | 1,455,070 | 4,991,684 | 3,727,769 | 5.6 | 6.6 | 5.7 |
| Helminth infections (worms & flukes) | 2,568,936 | 2,521,523 | 1,114,977 | 9.9 | 3.3 | 1.7 |
| Bacterial pneumonia & meningitis | - | 3,943,863 | 369,605 | 0.0 | 5.2 | 0.6 |
| Salmonella infections | - | 73,739 | 17,174 | 0.0 | 0.1 | 0.0 |
| Trachoma | - | 170,326 | - | 0.0 | 0.2 | 0.0 |
| Platform technologies | 4,387,764 | 2,451,335 | - | 16.9 | 3.2 | 0.0 |
| *Adjuvants and immunomodulators* | 2,661,889 | 144,891 | - | 10.3 | 0.2 | 0.0 |
| *Delivery technologies and devices* | - | 1,687,520 | - | 0.0 | 2.2 | 0.0 |
| *General diagnostic platforms* | 1,725,875 | 618,925 | - | 6.6 | 0.8 | 0.0 |
| Core funding of a multi-disease R&D organisation | 174,960 | 3,741,546 | 327,332 | 0.7 | 5.0 | 0.5 |
| Unspecified disease | 76,787 | 718,997 | 87,241 | 0.3 | 1.0 | 0.1 |
| Total public funding (IDCs) | 25,956,223 | 75,564,032 | 65,375,364 | 100.0 | 100.0 | 100.0 |

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

Total funding for 2007 and 2008 is lower (by 2.9% and 1.4%, respectively) than in the equivalent table in last year's report, which included minimal data on China and Cuba reported by funding recipients

- No reported funding in category

## SOUTH AFRICA

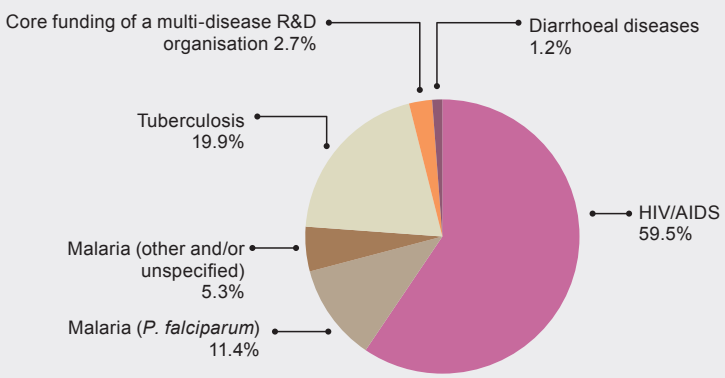
With investments totalling $8.2m, South Africa was the 15th largest public funder of neglected disease R&D in 2009, behind other IDCs such as Brazil and India.

The South African Department of Science and Technology (DST) was the main source of funding at $5.2m (63.3% of total South African funding). The DST aims to make South Africa one of the top three pharmaceutical industry centres among emerging economies and has set up several biotechnology regional innovation centres to support this goal (e.g. LIFE*lab* in Durban). The Department's funding priorities are based on epidemiological data, which leads to a focus on a handful of highly locally prevalent diseases: HIV/AIDS ($2.9m, 55.3% of funding), TB ($1.3m, 24.1%) and malaria ($1.1m, 20.6%). In 2009, the DST launched the South African HIV/AIDS Research and Innovation Platform (SHARP), managed by LIFElab. The creation of SHARP is in line with the high prevalence of HIV/AIDS in South Africa, home to the world's largest population of people living with HIV (5.6 million).[44] The Platform aims to increase the number and quality of South African-developed products and services for the prevention and treatment of HIV/AIDS through increased support for basic and applied research and innovation in the areas of antiretrovirals, microbicides, vaccines and diagnostics.[45]

In addition to SHARP, the DST has developed the South African Malaria Initiative and South African TB Research and Innovation Initiative. The bulk of its malaria R&D funding went to basic research into *P. falciparum* ($0.9m, 84.4%), which causes the vast majority of malaria cases in South Africa. The DST also highlighted in its 2009/2010 Annual Report that the TB Research and Innovation Initiative, together with the US NIH, completed the first phase of a programme to discover new TB drugs. Significant breakthroughs were also made in the Council for Scientific and Industrial Research's (CSIR) TB nano-drug-delivery programme, which is on track to provide patients with a once-a-week TB drug regimen instead of the current daily regimens. The DST is the main stakeholder of the CSIR and provides close to 40% of its funding through an annual grant to them.[46]

Two other significant funders were the South African Department of Health (DOH), accounting for $1.9m (22.7%) of funding in 2009, and the South Africa Medical Research Council (MRC), accounting for $1.1m (14.0%). The MRC undertakes research on clinical and health systems issues, chiefly funded by the DOH. There is close cooperation with the DOH in setting research priorities, including research into a HIV vaccine against the strain that predominantly affects sub-Saharan Africa[47] via the South African AIDS Vaccine Initiative (SAAVI, also funded by the DST). One of SAAVI's key successes has been development of the first IDC HIV/AIDS vaccine, which initiated clinical testing in mid-2009.[48] Nevertheless, most of the MRC's funding went towards TB ($0.4m, 33.4%m) and malaria ($0.3m, 26.1%), specifically towards basic research. A further $98,000 went towards R&D of diarrhoeal disease solutions. While the DST and MRC divided their funding mainly between HIV/AIDS, TB and malaria, the DOH disbursed its entire investment on development of HIV/AIDS vaccines.

**Figure 25. South Africa: R&D funding by disease 2009**



## COLOMBIA

A new participant in the G-FINDER survey in 2009, Colombia was the 20th largest public funder of neglected disease R&D, with investments totalling $4.2m. Although this contribution was small compared to those of several larger governments, it nevertheless put Colombia well ahead of some OECD nations, including Italy ($2.2m) and South Korea ($0.7m).

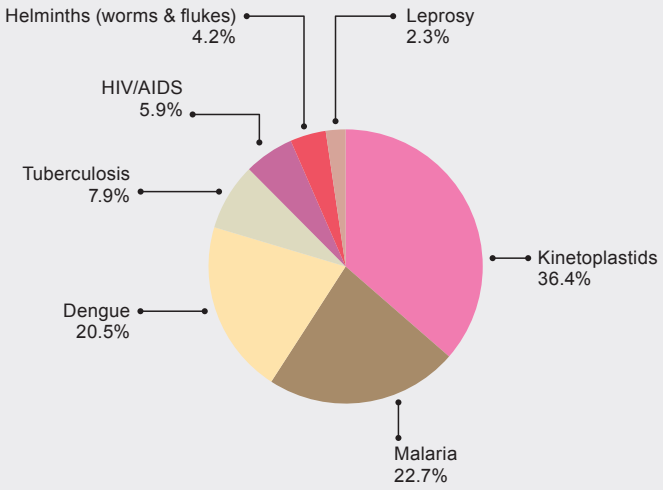
All Colombia's public funding for neglected disease R&D came from one organisation, the Colombian Department for Science, Technology and Innovation (Colciencias). Originally established in 1968 as the Colombian Fund for the Development of Science and Technology, Colciencias was recently transformed by government legislation into a National Department reporting directly to the President's office. Colciencias is now the sole policymaking entity "in charge of formulating, guiding, directing, coordinating, executing, and implementing national STI [Science, Technology and Innovation] policy."[49] This change is part of a broader strategic plan to stimulate STI in Colombia, supported by a $500m loan over 10 years from the World Bank and Inter-American Development Bank.[49]

Most Colombian Government neglected disease R&D investment was directed to academic research institutions rather than industry or PDPs. This reflects the researcher-driven funding approach taken by Colciencias,[50] and is consistent with the World Bank's assessment of the broader science technology and innovation picture in Colombia, which found limited private sector involvement and lack of public-private cooperation.[49]

The dominance of academic research institutions was reflected in Colombia's funding, with three quarters of all funding (75.8%) going to basic research, and the remainder divided between drug and vaccine R&D (13.2% and 11.1%, respectively).

Colombia's R&D reflected local disease endemicity,[51] as well as the focus of the country's strong scientific groups, with the majority of funding going to kinetoplastids ($1.5m), malaria ($1.0m), and dengue ($0.9m) and smaller proportions to TB, HIV/AIDS, helminth infections and leprosy. Colombia directed more of its total malaria R&D investment of $1.0m to *P. vivax* (64.3%) than *P. falciparum* (35.7%), reflecting *P. vivax*'s status as the most prevalent strain in the country[51], and in South America in general.[7] Kinetoplastid funding totalling $1.5m was divided between Chagas' disease (50.7%), estimated to affect 1.3 million Colombians, and leishmaniasis (49.3%). Cutaneous leishmaniaisis represents 99% of the leishmaniasis burden in Colombia, which has the second highest incidence in the Americas after Brazil.[52,53] All helminth funding, totalling $0.2m, was directed towards ascariasis (roundworm) research.

**Figure 26. Colombia: R&D funding by disease 2009**



## Philanthropic funders

After a generous increase in philanthropic funding in 2008, investment in neglected diseases from this source declined by $62.5m (-8.7%) in 2009. Decreased funding was reported by all major philanthropic organisations except the Wellcome Trust (up $4.3m, 7.0%); funding from all other philanthropic organizations nearly halved (down $13.4m, - 44.6%); and the already modest funds raised from the general public declined even further.

As in previous surveys, funding continued to be highly concentrated, with two organisations – the Bill & Melinda Gates Foundation and the Wellcome Trust - providing 96.7% of total philanthropic investment.

**Table 24. Top philanthropic funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Bill & Melinda Gates Foundation | 452,102,715 | 616,991,512 | 567,182,952 | 84.0 | 86.1 | 86.7 |
| Wellcome Trust | 59,985,371 | 60,864,206 | 65,121,278 | 11.1 | 8.5 | 10.0 |
| Médecins Sans Frontières (MSF) | 7,187,885 | 7,275,268 | 4,563,905 | 1.3 | 1.0 | 0.7 |
| All other philanthropic organisations | 16,970,326 | 30,182,790 | 16,712,723 | 3.2 | 4.2 | 2.6 |
| Funds raised from the general public | 2,064,283 | 1,214,399 | 440,079 | 0.4 | 0.2 | 0.1 |
| Total philanthropic funding | 538,310,580 | 716,528,175 | 654,020,937 | 100.0 | 100.0 | 100.0 |

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

Philanthropic funding continued to focus strongly on malaria, HIV/AIDS and TB, which accounted for 69.3% ($453.2m) of their total investment in 2009. All other diseases received less than $55.0m each, with leprosy, Buruli ulcer and rheumatic fever receiving very little funding.

As the main philanthropic funder, the Gates Foundation's investment patterns have a marked influence on overall trends in philanthropic funding. Thus, reduced or cyclical investment by the Foundation across several diseases, in particular HIV/AIDS and TB, was reflected in decreased overall philanthropic funding of HIV/AIDS (down $41.9m, -24.0%) and TB (down $30.6m, -22.1%). The modest increases seen for malaria (up $9.5m, 4.7%), diarrhoeal diseases (up $4.8m, 11.5%) and kinetoplastids (up $4.2m, 8.6%) were also mainly due to increases by the Gates Foundation.

Investment into platform technologies increased considerably due to growth in all three areas (adjuvants and immunomodulators, diagnostic platforms, and delivery technologies and devices), with the most notable increase for diagnostic platforms (up $4.1m, 149.5%). This was again due almost entirely to increased disbursements by the Gates Foundation, which invested an additional $3.4m in general diagnostic platforms, $1.4m in delivery technologies and devices, and $0.8m in adjuvants and immunomodulators.

**Table 25. Philanthropic funding by disease 2007-2009**

| Disease or R&D area | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Malaria | 155,550,721 | 203,158,929 | 212,613,987 | 28.9 | 28.4 | 32.5 |
| HIV/AIDS | 100,983,453 | 174,781,553 | 132,859,771 | 18.8 | 24.4 | 20.3 |
| Tuberculosis | 118,664,226 | 138,389,222 | 107,749,728 | 22.0 | 19.3 | 16.5 |
| Kinetoplastids | 67,927,698 | 49,366,955 | 53,603,095 | 12.6 | 6.9 | 8.2 |
| Diarrhoeal diseases | 55,568,392 | 42,267,335 | 47,109,061 | 10.3 | 5.9 | 7.2 |
| Bacterial pneumonia & meningitis | 6,168,184 | 26,798,409 | 22,377,790 | 1.1 | 3.7 | 3.4 |
| Helminth infections (worms & flukes) | 10,831,571 | 26,448,071 | 22,225,965 | 2.0 | 3.7 | 3.4 |
| Dengue | 2,113,145 | 17,522,069 | 13,296,670 | 0.4 | 2.4 | 2.0 |
| Salmonella infections | 54,194 | 1,033,056 | 3,615,088 | 0.0 | 0.1 | 0.6 |
| Leprosy | 658,000 | 1,057,064 | 979,784 | 0.1 | 0.1 | 0.1 |
| Buruli ulcer | - | 194,224 | 315,272 | 0.0 | 0.0 | 0.0 |
| Rheumatic fever | - | 54,212 | 182,116 | 0.0 | 0.0 | 0.0 |
| Trachoma | 1,461,110 | - | - | 0.3 | 0.0 | 0.0 |
| Platform technologies | 2,020,125 | 8,145,750 | 14,448,469 | 0.4 | 1.1 | 2.2 |
| *Adjuvants and immunomodulators* | - | 1,339,006 | 2,181,111 | 0.0 | 0.2 | 0.3 |
| *Delivery technologies and devices* | - | 4,078,010 | 5,459,574 | 0.0 | 0.6 | 0.8 |
| *General diagnostic platforms* | 2,020,125 | 2,728,734 | 6,807,783 | 0.4 | 0.4 | 1.0 |
| Core funding of a multi-disease R&D organisation | 13,026,847 | 9,921,287 | 5,492,440 | 2.4 | 1.4 | 0.8 |
| Unspecified disease | 3,282,916 | 17,390,040 | 17,151,699 | 0.6 | 2.4 | 2.6 |
| Total philanthropic funding | 538,310,580 | 716,528,175 | 654,020,937 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
- No reported funding in category

## Private sector funders

The private sector contributed $411.2m to neglected disease R&D in 2009, of which $337.9m came from MNCs (82.2%) and $73.3m from SMEs (17.8%). For confidentiality reasons, industry investments are reported as aggregate figures. Had this not been the case, several individual pharmaceutical companies would again have appeared in the list of top funders in 2009, based on the size of their internal investments.[vi]

Funding from YOY private sector funders increased by $42.8m (up 12.3%), due to increased MNC investment of $58.9m (up 21.1%), offset by decreased SME investment (down $16.1m, -23.7%). The further $3.2m rise in reported funding was due to an increase of $21.4m from new SME survey respondents, offset by a decrease of $18.3m lost-to-follow-up from SMEs who did not participate in the 2009 survey.

Industry tended to invest in areas where neglected disease activity could be piggybacked onto commercial programmes, specifically some of the more 'commercial' neglected diseases, such as TB, bacterial pneumonia and meningitis, HIV/AIDS, diarrhoeal diseases and dengue, which collectively represented 41.2% of total industry funding.

[vi] Internal investment refers to investments made by firms from their internal funds. It does not include funding from external sources such as PDPs, which is reported against the original funding source (generally public or philanthropic)

## MULTINATIONAL PHARMACEUTICAL COMPANIES (MNCs)

In 2009, MNCs disbursed almost three-quarters of their R&D funding to TB, malaria and dengue ($247.2m, 73.2%), while there was no investment in leprosy, Buruli ulcer or trachoma.

Relatively large increases in funding were seen for TB (up $33.6m, 45.6%), dengue (up $15.8m, 36.6%) and diarrhoeal diseases (up $10.5m, 47.7%). However, modest decreases in funding were reported for bacterial pneumonia and meningitis (down $6.5m, -20.4%) and HIV/AIDS (down $2.2m, -10.8%). As noted earlier, the decreased investment in bacterial pneumonia and meningitis largely reflected successful pneumonia vaccine registration.

**Table 26. Multinational pharmaceutical company (MNC) funding by disease 2007-2009**

| Disease | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Tuberculosis* | 50,406,352 | 73,805,679 | 107,440,859 | 27.2 | 26.5 | 31.8 |
| Malaria | 80,171,520 | 80,676,451 | 80,831,793 | 43.2 | 28.9 | 23.9 |
| Dengue | 15,982,205 | 43,145,203 | 58,941,327 | 8.6 | 15.5 | 17.4 |
| Diarrhoeal diseases | 10,696,100 | 22,032,982 | 32,548,361 | 5.8 | 7.9 | 9.6 |
| Bacterial pneumonia & meningitis | 15,164,876 | 31,943,693 | 25,412,690 | 8.2 | 11.4 | 7.5 |
| HIV/AIDS | 7,835,409 | 19,945,834 | 17,544,478 | 4.2 | 7.1 | 5.2 |
| Helminth infections (worms & flukes) | 61,200 | 3,892,100 | 8,132,792 | 0.0 | 1.4 | 2.4 |
| Kinetoplastids | 5,133,194 | 1,263,713 | 3,835,429 | 2.8 | 0.5 | 1.1 |
| Salmonella infections | - | 1,166,675 | 1,773,897 | 0.0 | 0.4 | 0.5 |
| Rheumatic fever | - | 963,391 | 1,449,696 | 0.0 | 0.3 | 0.4 |
| Buruli ulcer | - | 88,938 | - | 0.0 | 0.0 | 0.0 |
| Trachoma | 104,000 | 96,339 | - | 0.1 | 0.0 | 0.0 |
| Total MNC funding* | 185,554,857 | 279,020,998 | 337,911,323 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
* Figures for 2007 and 2008 have been updated and therefore differ from previously published figures
- No reported funding in category

## SMALLER PHARMACEUTICAL AND BIOTECHNOLOGY FIRMS (SMEs)

YOY investment by SMEs dropped considerably in 2009 (down $16.1m, -23.7%), likely due to the impact of the global financial crisis on smaller companies.

The biggest decrease by YOY investors was seen in HIV/AIDS (down $10.4m, -39.0%) and salmonella infections (down $9.5m, -85.0%). However, we note that the large apparent decrease in bacterial pneumonia and meningitis funding was chiefly an artefact due to non-reporting by a major SME investor that was lost to follow-up in 2009: the real decrease for this disease from YOY SME funders was only $3.1m. Likewise, the apparent increase for malaria is largely artefactual due to new survey participants.

YOY SME funders also modestly increased their investment in several diseases in 2009, including malaria (up $4.7m, 52.4%), dengue (up $2.5m, 384.5%) and TB (up $2.3m, 17.5%).

**Table 27. Smaller pharmaceutical company (SME) funding by disease 2007-2009**

| Disease or R&D area | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Malaria | 10,622,063 | 9,934,683 | 18,398,231 | 22.9 | 11.5 | 25.1 |
| HIV/AIDS | 11,800,216 | 27,504,031 | 17,797,740 | 25.5 | 31.9 | 24.3 |
| Tuberculosis* | 15,548,363 | 13,223,374 | 15,710,495 | 33.6 | 15.3 | 21.4 |
| Bacterial pneumonia & meningitis | 582,161 | 18,551,060 | 8,381,567 | 1.3 | 21.5 | 11.4 |
| Diarrhoeal diseases | 2,980,328 | 2,069,864 | 4,648,062 | 6.4 | 2.4 | 6.3 |
| Dengue | 3,412,551 | 648,796 | 4,171,825 | 7.4 | 0.8 | 5.7 |
| Salmonella infections | - | 11,146,435 | 1,667,150 | 0.0 | 12.9 | 2.3 |
| Kinetoplastids | 16,323 | 1,648,585 | 1,277,425 | 0.0 | 1.9 | 1.7 |
| Helminth infections (worms & flukes) | 753,763 | 1,058,521 | 408,232 | 1.6 | 1.2 | 0.6 |
| Buruli ulcer | 15,200 | 196,747 | - | 0.0 | 0.2 | 0.0 |
| Platform technologies | - | 249,882 | 820,306 | 0.0 | 0.3 | 1.1 |
| *Adjuvants and immunomodulators* | - | - | 784,109 | 0.0 | 0.0 | 1.1 |
| *Delivery technologies and devices* | - | 249,882 | 36,197 | 0.0 | 0.3 | 0.0 |
| Unspecified disease | 595,986 | - | - | 1.3 | 0.0 | 0.0 |
| Total SME funding* | 46,326,955 | 86,231,977 | 73,281,032 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
* Figures for 2007 and 2008 have been updated and therefore differ from previously published figures
- No reported funding in category

## PRIVATE FIRMS IN INDIA AND BRAZIL

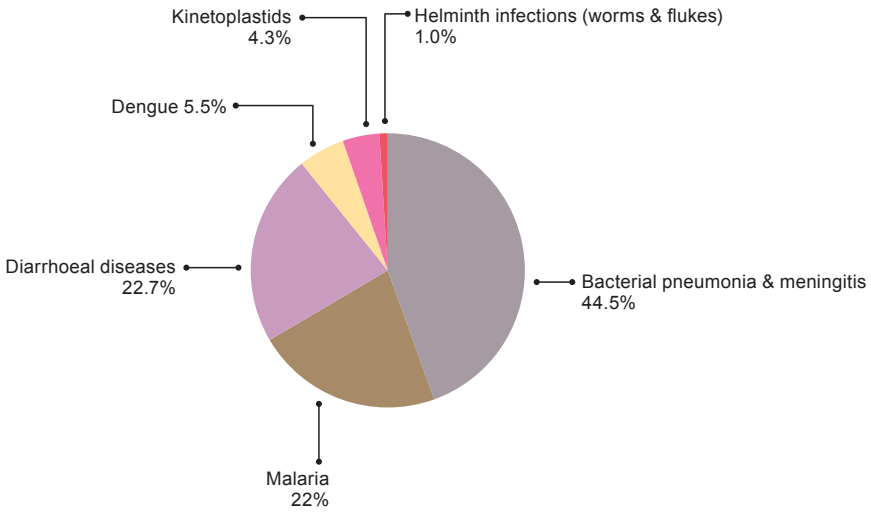
For the first time, this year's G-FINDER survey includes data from pharmaceutical firms in India and Brazil, with five SMEs from India and five from Brazil providing 2009 funding information (there are no MNCs headquartered in these countries). As with all industry analysis, investments are reported as aggregate figures for confidentiality reasons.

Total funding from the ten SMEs in India and Brazil was $18.8m in 2009, accounting for a surprisingly high share (25.7%) of total neglected disease R&D investment coming from the 53 SMEs included in this year's survey (see Annexe 4 for a full list of survey respondents). These ten SMEs also provided 4.6% of total private sector funding (SMEs and MNCs).

The majority of IDC industry funding came from Indian firms, which is perhaps unsurprising. India's pharmaceutical industry is in general moving away from production of generics towards development of innovative products, currently being ahead of Brazil in this respect. As part of this trend, small Indian firms have become popular acquisition targets for MNCs. Indeed, two Indian SMEs included in this survey have been acquired by larger firms (Shantha Biotechnics by sanofi-aventis in mid-2009, and Ranbaxy by Daiichi Sankyo in mid-2008).

IDC SME funding focused on a small group of diseases. About half of investments reported went to R&D in bacterial pneumonia and meningitis, with this likely being due to the sector's involvement in the pneumococcal AMC. Investment in malaria and diarrhoeal diseases was also relatively high, likely linked to the high domestic disease burden.

**Figure 27. Private sector IDC funding by disease 2009**




## 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 28. 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 28. Typical industry in-kind contributions to neglected disease R&D 2009**

| In-kind contribution | Examples | Some company donors |
|---|---|---|
| Transfer of technology & technical expertise to develop, manufacture, register and distribute neglected disease products | • Identifying scientific obstacles<br>• Sharing best practices and developing systems for clinical, technical and regulatory support<br>• Developing capacity for pharmacovigilance<br>• Donating equipment | GSK<br>Otsuka<br>Pfizer<br>sanofi-aventis |
| Provision of expertise | • Supporting clinical trials<br>• Collaboration of scientists, sharing trial results and facilitating parallel, concurrent testing<br>• Participation on scientific advisory or management boards of external organisations conducting neglected disease R&D<br>• Providing expertise in toxicology/ADME and medicinal chemistry<br>• Evaluating new compounds proposed by external partners<br>• Allowing senior staff to take sabbaticals working with neglected disease groups | Abbott Laboratories<br>Eli Lilly<br>GSK<br>MSD<br>Novartis<br>Otsuka<br>Pfizer<br>sanofi-aventis<br>Tibotec (Johnson & Johnson company)<br>Wyeth |
| Teaching and training | • In-house attachments offered to Developing Country (DC) trainees in medicinal chemistry, clinical trial training etc.<br>• Providing training courses for DC researchers at academic institutions globally<br>• Organising health care provider training in DCs for pharmacovigilance of new treatments<br>• Organising conferences and symposia on neglected disease-specific topics | GSK<br>Otsuka<br>MSD<br>Novartis<br>Pfizer<br>sanofi-aventis |
| Intellectual property | • Access to proprietary research tools and databases<br>• Sharing compound libraries with WHO or with researchers, who can test and screen them for possible treatments<br>• Providing public and not-for-profit groups with information on proprietary compounds they are seeking to develop for a neglected disease indication<br>• Forgoing license or providing royalty-free license on co-developed products | Abbott Laboratories<br>GSK<br>MSD<br>Novartis<br>Pfizer<br>sanofi-aventis<br>Tibotec (Johnson & Johnson company)<br>Wyeth |
| Regulatory assistance | • Allowing right of reference to confidential dossiers and product registration files to facilitate approval of generic combination products<br>• Covering the cost of regulatory filings<br>• Providing regulatory expertise to explore optimal registration options for compounds in development | Abbott Laboratories<br>GSK<br>MSD<br>Pfizer<br>sanofi-aventis<br>Wyeth |

## Funding by organisation

**Table 29. Top neglected disease funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| US National Institutes of Health (NIH) | 1,064,859,791 | 1,078,627,652 | 1,256,471,979 | 41.6 | 36.5 | 39.4 |
| Bill & Melinda Gates Foundation | 452,102,715 | 616,991,512 | 567,182,952 | 17.7 | 20.9 | 17.8 |
| Aggregate pharmaceutical and biotechnology company respondents[A] | 231,881,812 | 365,252,975 | 411,192,356 | 9.1 | 12.4 | 12.9 |
| European Commission | 121,366,882 | 129,899,906 | 118,311,296 | 4.7 | 4.4 | 3.7 |
| US Department of Defense (DOD) | 86,914,578 | 72,548,392 | 98,236,367 | 3.4 | 2.5 | 3.1 |
| United States Agency for International Development (USAID) | 80,600,336 | 83,805,395 | 84,483,425 | 3.1 | 2.8 | 2.6 |
| UK Department for International Development (DFID) | 47,565,987 | 43,278,878 | 84,396,112 | 1.9 | 1.5 | 2.6 |
| Wellcome Trust | 59,985,371 | 60,864,206 | 65,121,278 | 2.3 | 2.1 | 2.0 |
| UK Medical Research Council (MRC) | 51,716,968 | 52,765,367 | 61,700,170 | 2.0 | 1.8 | 1.9 |
| Dutch Ministry of Foreign Affairs | 33,951,646 | 26,911,215 | 27,268,947 | 1.3 | 0.9 | 0.9 |
| Inserm - Institute of Infectious Diseases[B] | 1,774,770 | 3,121,721 | 27,222,504 | 0.1 | 0.1 | 0.9 |
| Institut Pasteur | 31,617,540 | 26,547,885 | 26,477,069 | 1.2 | 0.9 | 0.8 |
| Subtotal top 12 funders* | 2,286,841,030 | 2,577,455,990 | 2,828,064,455 | 89.3 | 87.2 | 88.7 |
| Total R&D funding | 2,560,068,749 | 2,955,964,344 | 3,188,595,015 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
[A] Includes new survey respondents in 2009
[B] The apparent increase in funding from Inserm is mainly due to more comprehensive reporting
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009

Global investment in neglected disease R&D was again highly concentrated in 2009, with the top 12 funders remaining essentially the same since 2007. The top 11 funding organisations (excluding aggregate pharmaceutical industry) provided 75.8% of global funding, approximately the same as in 2008 (74.8%). Two organisations, the US NIH and the Gates Foundation, accounted for over half (57.2%) of all 2009 neglected disease R&D funding.

The US NIH cemented its position as the world's largest funder of neglected disease R&D with a funding increase of $177.8m (up 16.5%) in 2009, representing two-thirds of the reported increase in global R&D funding. The next most significant increases came from UK DFID, which nearly doubled its neglected disease funding (up $41.1m, 95.0%), and the US DOD (up $25.7m, 35.4%).

Investment from the Gates Foundation was down by $49.8m (-8.1%); this was in contrast to 2008, when the Gates Foundation was the key driver of the neglected disease R&D funding increase, with a funding boost of $164.9m. The impact of the Gates Foundation's 2009 funding decrease was largely seen in HIV/AIDS (down $41.1m, 25.6%) and TB (down $21.4m, 16.2%). We caution that much, but not all, of this effect was due to the cyclical nature of grant funding, with the drop in HIV funding chiefly reflecting second-yearly disbursements of a large ongoing microbicide grant by the Gates Foundation: this alone accounted for $30m of their apparent 2009 HIV funding drop. TB funding also saw some effect from cyclical grant disbursement, but was also impacted by tapering down of several TB grants that are being discontinued. Nevertheless, cyclical factors aside, the Gates Foundation was no longer the driver of investment growth in neglected disease R&D in 2009.

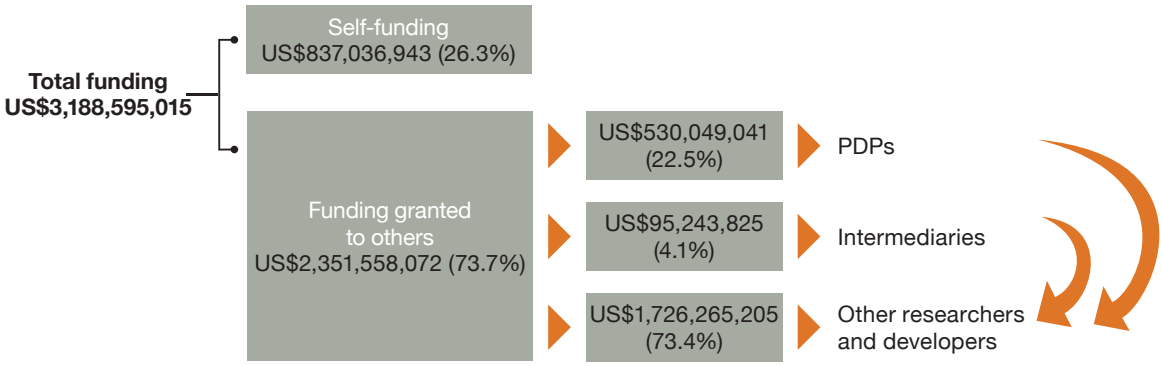
# FINDINGS - FUNDING FLOWS

Funding agencies disburse their neglected disease R&D investments in two main ways: through self-funding (intramural funders) or 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[vii] 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 extramural grants to third parties (i.e. they do not conduct research themselves). Other organisations, such as the US NIH and UK MRC use a mixed model, providing extramural funding to others in addition to funding their own internal research programmes.

Almost three-quarters of 2009 R&D funding was in the form of extramural grants (73.7%)[viii], while intramural funding (self-funding) accounted for 26.3%. Nearly three-quarters of extramural grant funding went directly to researchers and developers ($1.7bn, 73.4%), with grants to PDPs accounting for nearly another quarter ($530.0m, 22.5%) of global grant funding, and grants to other intermediaries for a small fraction ($95.2m, 4.1%).

We note that the central role of PDPs in this field was somewhat obscured by the "NIH factor", since the largest global funder of neglected disease R&D, the US NIH, is one of the few major funding organisations that does not provide significant funding to PDPs: in 2009, the US NIH provided only 0.6% ($7.5m) 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 40.6% of global grant funding for neglected disease R&D.

**Figure 28. Overall R&D funding patterns 2009**




[vii] PDPs are defined as public health driven, not-for-profit organisations who 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 developing country 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.

[viii] Extramural grants refer to all external funding including grants, contracts, Cooperative Research and Development Agreements (CRADAs) and core funding to R&D organizations.

## Self-funders

**Table 30. Top 10 self-funders 2009**

| Funder | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Aggregate pharmaceutical and biotechnology company respondents[A] | 228,957,902 | 355,313,341 | 401,732,684 | 8.9 | 12.0 | 12.6 |
| US National Institutes of Health (NIH)[#] | 133,097,100 | 158,435,807 | 190,964,251 | 5.2 | 5.4 | 6.0 |
| US Department of Defense (DOD)[B#] | 70,340,000 | 51,274,796 | 79,810,736 | 2.7 | 1.7 | 2.5 |
| UK Medical Research Council (MRC)[#] | 35,989,099 | 33,560,426 | 43,757,899 | 1.4 | 1.1 | 1.4 |
| Inserm - Institute of Infectious Diseases[C] | 1,774,770 | 3,121,721 | 27,222,504 | 0.1 | 0.1 | 0.9 |
| Institut Pasteur | 31,617,540 | 26,520,909 | 26,477,069 | 1.2 | 0.9 | 0.8 |
| US Centers for Disease Control (CDC) | 5,703,200 | 12,672,614 | 18,565,920 | 0.2 | 0.4 | 0.6 |
| Indian Council of Medical Research (ICMR)[D] | - | 19,533,928 | 17,230,631 | - | 0.7 | 0.5 |
| Statens Serum Institute (SSI) | 3,672,882 | 3,870,205 | 10,232,619 | 0.1 | 0.1 | 0.3 |
| Undisclosed recipients | - | 2,611,579 | 7,276,341 | - | 0.1 | 0.2 |
| **Subtotal top 10 self-funders*** | 525,334,601 | 668,434,839 | 823,270,654 | 20.5 | 22.6 | 25.8 |
| **Subtotal self-funders*** | 527,676,354 | 686,739,852 | 837,036,943 | 20.6 | 23.2 | 26.3 |
| Total R&D funding | 2,560,068,749 | 2,955,964,344 | 3,188,595,015 | 100.0 | 100.0 | 100.0 |

^ Figures are adjusted for inflation and reported in 2007 US dollars
* Subtotals for 2007 and 2008 top 10 reflect the top self-funders for those respective years, not the top 10 for 2009
[A] Includes new survey respondents in 2009
[B] 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
[C] The apparent increase in self-funding from Inserm is mainly due to more comprehensive reporting
[D] New survey recipient in 2008, no 2007 data available. The drop in self-funding in 2009 is likely due to less comprehensive reporting by some of its institutes
[#] These groups are also Top 10 overall funders (including self-funding plus external funding)
- No reported funding in category

As would be expected, the bulk of self-funding is due to private industry, which almost invariably funds only its own internal R&D programmes. However, we note a marked trend towards increased levels of self-funding across the three years of the survey, with self-funding as a proportion of total R&D funding increasing by more than 25%, from just over one-fifth of total funding in 2007 to just over a quarter in 2009. Some of this was the normal effect of increased industry investment, representing $44.3m of the increase. However, there were also notable increases in 2009 self-funding from the US NIH (up $32.5m, 20.5%), the US DOD (up $28.5m, 55.7%), and the UK MRC (up $10.2m, 30.4%).

## Product development partnerships

Funding to PDPs in 2009 was $530.0m. This represented 16.6% of global funding, 22.5% of global grant funding, and 40.6% of global grant funding if the NIH effect is excluded, as above. Three PDPs – the Program for Appropriate Technology in Health (PATH), the International AIDS Vaccine Initiative (IAVI) and the Aeras Global TB Vaccine Foundation (Aeras) - accounted for just under half of all PDP funding ($249.4m, 47.1%).

The most striking fact was the significant overall trend towards decreased funding of PDPs across the board, with investment into PDPs dropping by $50m (-8.6%) in 2009. The most notable decreases were for HIV/AIDS related PDPs, with the International Partnership for Microbicides (IPM) reporting a decrease of $24.9m (- 41.2%) and IAVI a decrease of $14.5m (- 16.8%) – although we note that the IPM decrease was almost entirely due to uneven multi-year disbursement of a Gates Foundation grant. However, many other PDPs also saw funding cuts in 2009, including iOWH (down $13.2m, -46.4%) mainly due to a drop of funding for diarrhoeal disease drugs; Aeras (down $10.4m, -16.3%); the Sabin Vaccine Institute (down $5.7m, - 39.3%); and the Medicines for Malaria Venture (MMV) (down $4.2m, - 9.2%). The decrease reported by the diagnostic group FIND ($10.1m, -33.3%) was due to an unevenly distributed grant by the Gates Foundation.

These year-on-year trends need to be interpreted with caution as they can reflect uneven disbursement of multi-year grants, as noted for IPM and FIND; or successful completion of large-scale trials. Nevertheless, other PDPs with active products in late-stage clinical trials, such as iOWH, Aeras and the Sabin Vaccine Institute, also saw decreased funding.

Despite the general downward trend, several PDPs saw a modest increase in funding in 2009. PATH's funding increased by $12.7m (11.4%), partly due to a $5.3m increase from the Gates Foundation to support RTS,S vaccine development, while the Drugs for Neglected Diseases initiative (DNDi) (up $10.0m, 44.5%), International Vaccine Initiative (IVI) (up $5.0m, 30.0%) and Innovative Vector Control Consortium (IVCC) (up $3.7m, 38.4%) also saw increases.

**Table 31. Funds received by PDPs 2007-2009**

| PDPs | 2007 (US$) | 2008 (US$)^ | 2009 (US$)^ | 2007% | 2008% | 2009% |
|---|---|---|---|---|---|---|
| Program for Appropriate Technology in Health (PATH) | 38,024,679 | 111,230,644 | 123,951,227 | 8.1 | 19.2 | 23.4 |
| International AIDS Vaccine Initiative (IAVI) | 81,297,482 | 86,598,890 | 72,086,128 | 17.3 | 14.9 | 13.6 |
| Aeras Global TB Vaccine Foundation (Aeras) | 40,121,983 | 63,786,605 | 53,395,878 | 8.5 | 11.0 | 10.1 |
| Medicines for Malaria Venture (MMV) | 75,982,931 | 46,030,619 | 41,804,090 | 16.2 | 7.9 | 7.9 |
| Global Alliance for TB Drug Development (TB Alliance) | 39,587,358 | 34,106,803 | 36,252,220 | 8.4 | 5.9 | 6.8 |
| International Partnership for Microbicides (IPM) | 46,311,916 | 60,503,137 | 35,599,621 | 9.9 | 10.4 | 6.7 |
| Special Programme for Research and Training in Tropical Diseases (WHO/TDR)[A] | 32,675,307 | 37,039,908 | 34,721,350 | 7.0 | 6.4 | 6.6 |
| Drugs for Neglected Diseases initiative (DNDi) | 28,520,251 | 22,439,428 | 32,413,869 | 6.1 | 3.9 | 6.1 |
| International Vaccine Institute (IVI) | 13,150,000 | 16,678,372 | 21,683,793 | 2.8 | 2.9 | 4.1 |
| Foundation for Innovative New Diagnostics (FIND) | 22,881,808 | 30,359,050 | 20,258,906 | 4.9 | 5.2 | 3.8 |
| Infectious Disease Research Institute (IDRI) | 8,094,908 | 14,340,933 | 16,552,206 | 1.7 | 2.5 | 3.1 |
| Institute for One World Health (iOWH) | 27,377,321 | 28,409,977 | 15,231,696 | 5.8 | 4.9 | 2.9 |
| Innovative Vector Control Consortium (IVCC) | - | 9,633,911 | 13,337,199 | 0.0 | 1.7 | 2.5 |
| Sabin Vaccine Institute | 7,621,112 | 14,527,323 | 8,818,384 | 1.6 | 2.5 | 1.7 |
| European Vaccine Initiative (EVI) | 7,745,898 | 4,398,783 | 3,877,131 | 1.7 | 0.8 | 0.7 |
| TuBerculosis Vaccine Initiative (TBVI) | - | - | 65,342 | 0.0 | 0.0 | 0.0 |
| Total funding to PDPs | 469,392,952 | 580,084,383 | 530,049,041 | 100.0 | 100.0 | 100.0 |

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

[A] 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 in category

## PDP funders

Twelve organisations provided 90% ($485.6m) of total PDP funding in 2009, with the Gates Foundation accounting for over half ($288.7m, 54.5%) (Table 32).

However, many of these organisations reduced their investment into PDPs in 2009, with a collective drop of $23.3m (-4.6%), including decreased investments from the Gates Foundation ($62.7m, -17.8%); CIDA ($10.4m, -67.2%); SIDA ($3.2m, -28.9%); and USAID ($2.3m, -5.8%). Again, it must be noted that decreases in funding are partially due to uneven disbursements of multi-year grants but this does not account for the entire effect seen.

Going against the overall trend towards reduced PDP funding, a handful of organisations increased investment to PDPs, with DFID almost tripling its funding (up $49.4m, 175.8%) in line with its 5 year research strategy for 2008 – 2013, which includes increased funding to PDPs working in priority diseases.[54] More than a third of DFID's increase was first-time funding to Aeras, iOWH, PATH and the Foundation for Innovative New Diagnostics (FIND), while they also increased funding for IPM ($11.1m), TB Alliance ($6.8m) and IAVI ($6.7m). With the exception of PATH, these same PDPs saw funding cuts from the Gates Foundation. We do not suggest this funding shift was deliberately coordinated, and it was in any case insufficient to offset the overall funding drop to the majority of these PDPs.

It is also worth briefly examining the nature of funding to PDPs. Many aid agencies, in particular but not only those in smaller countries, used PDPs as their main or only channel to finance neglected disease R&D. The Norwegian, Spanish and Irish aid agencies provided essentially all their neglected disease research funding through PDPs, while CIDA provided 94.6% through PDPs and DFID 91.8%. By contrast, very large funders and science agencies with capacity to review neglected disease projects in-house tended to use a mixed model, providing some funds through PDPs and the remainder to either in-house scientists or as direct grants to external researchers and developers. This was particularly the case for the US NIH (only 0.6% to PDPs) but also USAID (44.7% to PDPs).

A second point of note is the imbalance in the amount of funding provided to PDPs by aid agencies, as compared to science and technology (S&T) or research agencies, with virtually all government funding for PDPs coming from aid agencies. This is remarkable given that the bulk of PDP disbursements are to academics and pharmaceutical firms in wealthier, generally more technically advanced donor countries (the natural target of S&T and research agencies), even if the end result of these investments is new products for developing countries (the target of aid agencies). For instance, in 2007, almost three-quarters (70.3%) of PDP expenditure went to private companies, academic and public research institutes in wealthier donor countries, while research organisations and companies in developing countries received 12.3% of PDP expenditure.[55] Given this, one might have expected a greater contribution to PDPs from S&T and research agencies in donor countries than has been the case to date.

**Table 32. Top PDP funders 2009**

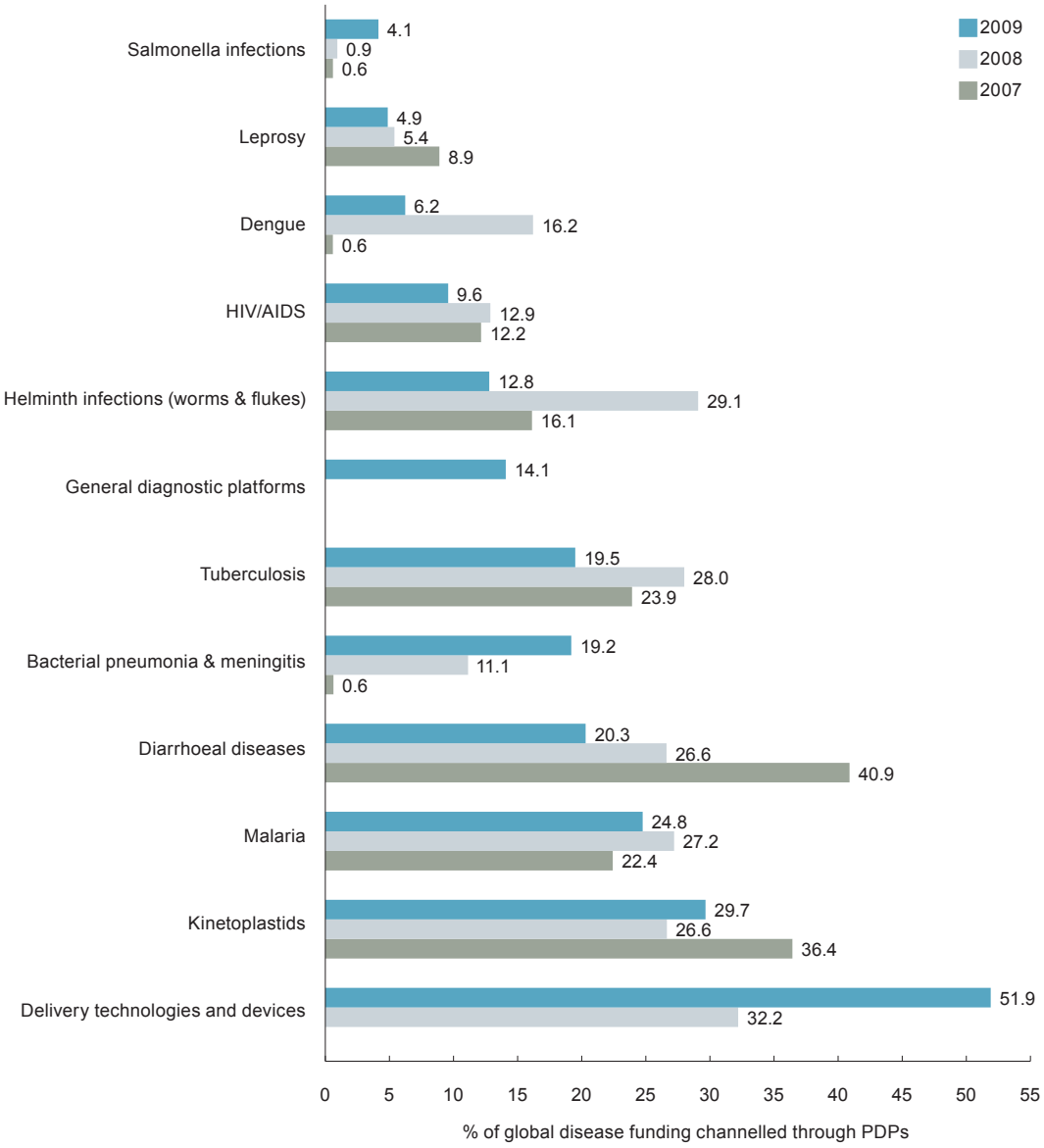
| Funder | To PDPs 2007 (US$) | To PDPs 2008 (US$)^ | To PDPs 2009 (US$)^ | % of org's funds given to PDPs 2009 | Share of total PDP funding 2009% |
|---|---|---|---|---|---|
| Bill & Melinda Gates Foundation | 231,183,854 | 351,426,826 | 288,742,058 | 50.9 | 54.5 |
| UK Department for International Development (DFID) | 33,430,151 | 28,094,083 | 77,492,166 | 91.8 | 14.6 |
| United States Agency for International Development (USAID) | 40,776,000 | 40,052,987 | 37,730,743 | 44.7 | 7.1 |
| Dutch Ministry of Foreign Affairs | 32,170,024 | 19,807,172 | 19,454,348 | 71.3 | 3.7 |
| Spanish Ministry of Foreign Affairs and Cooperation for Development (MAEC) | 3,426,196 | 13,116,474 | 14,323,053 | 99.8 | 2.7 |
| Royal Norwegian Ministry of Foreign Affairs | 13,271,949 | 12,389,471 | 11,667,625 | 100.0 | 2.2 |
| Swedish International Development Agency (SIDA) | 10,505,567 | 11,188,482 | 7,952,989 | 33.9 | 1.5 |
| US National Institutes of Health (NIH) | 4,141,065 | 3,287,014 | 7,538,694 | 0.6 | 1.4 |
| World Health Organization: UNITAID[A] | - | - | 5,860,926 | 100.0 | 1.1 |
| Irish Aid | 23,586,318 | 6,820,567 | 5,227,392 | 100.0 | 1.0 |
| Canadian International Development Agency (CIDA) | 11,796,354 | 15,506,676 | 5,082,193 | 94.6 | 1.0 |
| Médecins Sans Frontières (MSF) | 7,187,885 | 7,275,268 | 4,563,905 | 100.0 | 0.9 |
| Subtotal top 12 PDPs funders* | 426,662,580 | 528,101,928 | 485,636,091 | 23.2 | 91.6 |
| Total PDP funding | 469,392,952 | 580,084,383 | 530,049,041 | | |
| % of total PDP funding (top 12) | 90.9 | 91.0 | 91.6 | | |

^ Figures are adjusted for inflation and reported in 2007 US dollars
* Subtotals for 2007 and 2008 top 12 reflect the top funders for those respective years, not the top 12 for 2009
[A] Contributions compiled from grant information provided by funding recipients, so may be incomplete
- No reported funding in category

## PDP share of disease funding

PDPs continued to play a dominant role in several neglected disease R&D areas, managing a significant proportion of global funding for kinetoplastids ($48.1m, 29.6%), malaria ($147.2m, 24.8%) diarrhoeal diseases ($36.6m, 20.3%) and TB ($109.2m, 19.5%). They played only a small role in HIV/AIDS R&D (9.6%) despite this disease area receiving the largest share of global neglected disease funding. This was likely due to limited funding of PDPs by the US NIH, which was by far the largest funder of HIV/AIDS R&D. The steady decline of funding share to PDPs for diarrhoeal diseases is also noteworthy; this was despite an increase from YOY global funders for diarrhoeal diseases (up $43.9m, 33.2%) and a modest increase of $1.5m (up 4%) in absolute funding to PDPs involved in diarrhoeal disease R&D. PDPs continued to play a significant role in R&D of delivery technologies and devices ($4.1m, 51.9%), although funding for this area was minimal.

**Figure 29. Percentage of global disease R&D funding given via PDPs 2007-2009***




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

# DISCUSSION

## More and more evenly distributed funding for neglected disease R&D

Despite the global financial crisis (GFC), neglected disease R&D funding increased by nearly a quarter of a billion in real terms in 2009, with a total of $3.2bn investment. Indeed, somewhat counter-intuitively, the GFC appears to have stimulated this increase in some areas, for instance through US investment via the American Recovery and Reinvestment Act (ARRA) programme.

A key feature of 2009 was that R&D funding was more evenly distributed across neglected diseases than in previous survey years. Although HIV/AIDS, TB and malaria saw the same or increased funding in 2009, their overall share of global R&D funding dropped from 77% in 2007 to 72% in 2009: this is a substantial shift when one considers the large sums involved - around $3 billion per year. At the same time, relatively larger funding increases for many of the previously most neglected diseases led to diarrhoeal diseases, dengue and kinetoplastids each receiving more than 5% of global funding for the first time in 2009, as well as general funding increases for most other neglected diseases.

We nevertheless note that, despite this shift, funding for many diseases and for platform technologies remains well below the levels needed to deliver new products that patients so desperately need, with Buruli ulcer, trachoma, rheumatic fever and leprosy each receiving less than $11m (0.3% of global funding), and platform technologies collectively receiving only $23m (0.7% of global funding) in 2009.

## Funding is shifting away from product development and PDPs

In 2008, the Bill & Melinda Gates Foundation was the driving force behind increased global investment into neglected disease R&D. However, in 2009, public funders were responsible for most of the increase in global disbursements, significantly increasing their share of global funding. This shift had significant implications for research, with a marked increase in funding for basic research rather than product development in several areas, including for some diseases in urgent need of new medicines, vaccines and diagnostics.

### NEGLECTED DISEASES RELIED INCREASINGLY ON PUBLIC FUNDERS

As in previous years, neglected disease R&D was funded predominantly by the public and philanthropic sectors, who accounted for $2.8bn (88%) of global funding in 2009.

However, the 2009 increase in neglected disease R&D funding was largely due to four public organisations in two countries: the US NIH and DoD collectively increased their funding by about $200m, and the UK DFID and MRC by $50m. A further increase of $42.8m was due to the collective pharmaceutical industry. In the context of a total annual increase of $240m, these rises assume real significance.

At the same time, philanthropic funding dropped virtually across the board, leading to a shift in the balance of public and philanthropic contributions in 2009: YOY philanthropic funders decreased investments by $63m (-8.7%) while the public sector increased by $258m (14%). These trends are closely linked to decisions by the two funders that dominate neglected disease R&D; the US NIH (a public funder) and the the Bill & Melinda Gates Foundation (a philanthropic funder).

FUNDING SHIFT AWAY FROM PRODUCT DEVELOPMENT AND PDPs

The swing to public funding from philanthropic funding led to several marked changes in funding patterns during 2009. There was a strong trend towards basic research funding — which increased by 21% - in preference to product development funding—which only increased by 5%. This was most evident for diseases that saw a large swing towards public funding, such as helminth and salmonella infections, where basic research investment from YOY funders increased by 37% and 28% respectively. This likely reflects the focus of public versus philanthropic organisations. For instance, if we examine non-HIV/AIDS funding, the UK MRC directed 85%, and the US NIH 61% of their funding to basic research, compared to only 6% for the Gates Foundation, and 0.2% for industry.

A marked trend towards increased in-house investment was also noted. While this can be very helpful, its impact will need to be monitored since increased internal funding by domestically-focussed groups such as the US NIH, UK MRC and US DoD can potentially lead to a shift away from research targeted at DC-specific needs.

A further hallmark of 2009 funding for neglected disease R&D was the decrease in funding to PDPs from many philanthropic funders and governments.[ix] This was unexpected, given the key role that PDPs have played in neglected disease product development in the past decade. PDPs manage slightly over 40% of non-NIH global grant funding, and have more than 140 drugs, vaccines and diagnostic 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 malaria drugs by the MMV (Phase IIa and III). Many industry projects are also conducted jointly with PDPs, particularly for the least commercial neglected diseases. However, PDPs appear to have been heavily impacted by the shift towards public funding, in particular the apparent preference of public funders for basic research or research conducted by their domestic institutions, over higher-risk product development, including by PDPs that are often situated outside their borders.

The 2009 shift away from product development funding is of concern, particularly if public funders continue this trend in 2010.

## Global funding needs solid investment strategies

Increased funding for neglected disease R&D is both vital and welcome. However, it is not enough to provide more funding; this funding must also be efficiently and productively invested if it is to generate badly-needed new products for those who live in the developing world. To do so will require funders to avoid wasteful duplication and to target their investments to groups that can make new products a reality, and to areas where they can deliver the highest health impact.

Few funders would choose to invest in areas that are unlikely to deliver a new health product or outcome, or that will deliver a product or outcome that is unsuitable and unused by developing country populations and governments. However, there is currently no structured way for funders to assess which areas are likely to give the best, or worst, results for their investment; or how large or small their investment needs to be in the context of R&D needs and opportunities, as well as with respect to investments by other funders.

Key tools needed to assist donor decision-making include structured methods to assess health return on investment for different R&D areas, and information or mechanisms to allow them to coordinate their funding decisions with those of others.

[ix] Some of this downturn may be due to uneven YOY funding disbursements to PDPs, however this does not explain the broad reductions seen by many PDPs.

## Health Return On Investment…

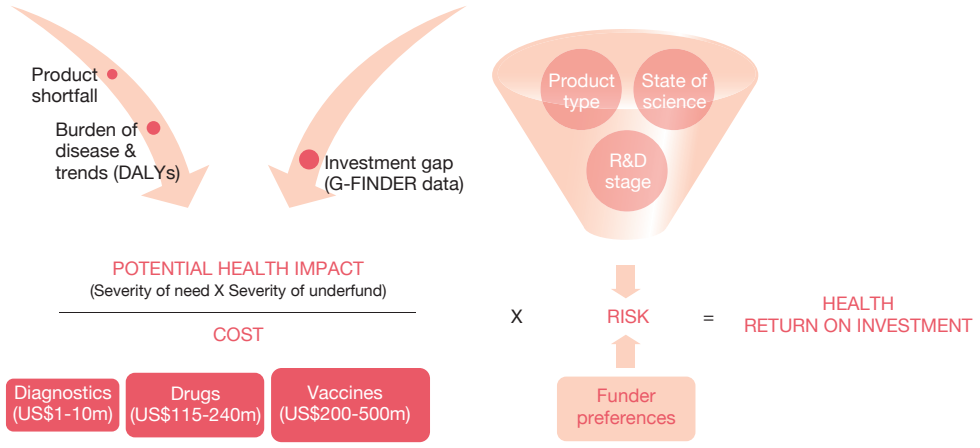
Each G-FINDER report has emphasised that the likely health return on a given R&D investment depends on what products are needed for the target disease and the likelihood that such a product can be developed: burden of disease comes into play only if and when the product is developed, at which point it becomes a 'multiplier' of health impact.

For example, management of a given disease may be poor, despite the presence of low-cost effective drugs, simply because there is no diagnostic to identify who should be treated. In this case, investment of a few million dollars to create a successful diagnostic may be all that is needed to dramatically improve patient outcomes. However, if several million dollars are instead invested into further drug development or basic research for this disease, there will be a far lower health impact, irrespective of whether the disease affects ten people or ten million people, since the funding has not been targeted to the area where it can do the most good.

This point cannot be emphasised enough since, in an ideal world, it would be the key determinant of where funds are invested. Yet there is currently no system to help funders identify which investments are likely to generate the highest health return, with the result that R&D funding is often poorly matched with disease needs and scientific and technical possibilities. As an example, more than half of sleeping sickness funding went to basic research, although this area would benefit markedly from the development of new, safe, oral drugs that are active against both stages of the disease. Likewise, for decades there was little or no investment into pneumonia vaccines targeting developing world strains (and price points), despite the firm scientific and technical base for making such vaccines and the presence of many product developers skilled at doing so.

In order to deliver the highest health return on investment, funders need tools to help them assess and compare disease burden, state of the science, and knowledge and product gaps, as the basis for deciding into which disease and product areas they can best invest. For some diseases, this may mean a stronger focus on basic science rather than product development. For other diseases, basic science is at the right stage to be translated into useable health technologies, and funding should preferentially be directed to product development.

**Figure 30. Health return on investment**



## …followed by coordination

A solid investment strategy will not suffice in the absence of coordination. Once funders know where their investments are likely to have the highest health return, they need to be able to funnel their disbursements in the most effective way, including being aware of choices made by other funders.

This is particularly the case for the most neglected diseases, which are seeing a highly scattered approach with multiple small funders disbursing grants that, although considerable for them, are not appropriately sized or targeted to the products needed for that disease (such as for leprosy, rheumatic fever and Buruli ulcer) – although collectively they could have a significant impact.

Initiatives such as the PDP Funders group can be helpful, although not all PDP funders participate in this. PDPs can also offer a partial solution in diseases where they are active since they coordinate disbursement of funds provided by multiple donors. Indeed, the absence, or modest presence, of PDPs as fundraisers and coordinators in diseases like diarrhoeal illnesses, helminths and rheumatic fever may have something to do with the limited funding in these areas to date.

In general, however, greater information on funder investments and plans, and more dialogue between major funders could significantly improve the efficiency of neglected disease R&D funding.

## Conclusion

The increase in funding for neglected disease R&D seen in 2009, despite the global financial downturn, is inspiring and encouraging. We again applaud the generosity and humanity of the many organisations who contributed, and are delighted to see their investments coming to fruition, including successful development of the world's first paediatric malaria drug, the first long-lasting low-cost meningitis vaccine for Africa, and new TB vaccines now in advanced clinical trials.

We hope that G-FINDER continues to assist you in your work.

# 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, and additional diagnostics organisations and SMEs were also included.

In 2009, the survey was expanded to capture major public funding agencies in an additional three developing countries, Ghana, Colombia and Thailand. Collation of this information resulted in a list of 847 organisations in the 48 target countries (up from 808 in 2008). Of these, 467 were funders including 262 SMEs and 17 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 2009 calendar year) that had the largest overlap with 2009. 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)[56,57]. Foreign currencies were then converted to US dollars based on the 2007 average annual exchange rate as reported by the IMF[58]
- For consistency, 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 2009 figures are also occasionally included; converted to USD using the average annual exchange rate for 2009 as reported by the IMF[58]. When this occurs, the unadjusted (nominal US dollar) figure is shown in bracketed italicised text after the adjusted figure.

### SURVEY TOOL AND PROCESS

Following the methodology used in the G-FINDER 2009, 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 2009 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 TB and HIV/AIDS were shared with and between other survey groups (TB data with the Treatment Action Group, and HIV/AIDS data with 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 7,000 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 with the company and if necessary corrected.

## 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 and 2009 data far more comparable than 2008 and 2007 data (due to a significant increase in participants 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 DBT funds this year. This may lead to underestimation of the total financial investment 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 funding 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 the Institute for One World Health (iOWH), the Special Programme for Research and Training in Tropical Diseases (TDR) and the European & Developing Countries Clinical Trials Partnership (EDCTP) are not counted within the funding figures for specific diseases, but rather under core grants

- 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 and is the reason 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 in RCDC, with the 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 previous years. 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.

## VARIATION BETWEEN SURVEYS

Annual surveys of global R&D investment into some neglected diseases such as HIV/AIDS and TB in 2009 have been published or are expected to be published soon. Although G-FINDER worked in close collaboration with 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 other surveys do not all do. As mentioned above, classification of some funding as 'unspecified' by G-FINDER (e.g. multi-disease programmes) may also lead to different figures than disease specific surveys in some cases.

# ANNEXE 2

## Advisory Committee members & additional experts

| ADVISORY COMMITTEE MEMBER | ORGANISATION | TITLE |
|---|---|---|
| Ripley Ballou | Bill & Melinda Gates Foundation | Deputy Director for Vaccines, Infectious Diseases Development, Global Health Program |
| Lewellys F. Barker | Aeras Global TB Vaccine Foundation | Senior Medical Advisor, Regulatory Affairs & Quality Assurance |
| 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<br>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 | George Washington University and Sabin Vaccine Institute | President, Sabin Vaccine Institute<br>Distinguished Research Professor<br>Walter G. Ross Professor and Chair of the Department of Microbiology, Immunology and Tropical Medicine |
| Marie-Paule Kieny | WHO - Initiative for Vaccine Research (IVR) | Director |
| Wayne Koff | International AIDS Vaccine Initiative (IAVI) | Senior Vice President of Research & Development |
| Regina Rabinovich | Bill & Melinda Gates Foundation | Director of Infectious Diseases Development, Global Health Program |
| Robert Ridley | World Health Organization: Special Programme for Research and Training in Tropical Diseases (TDR) | Director |

| ADVISORY COMMITTEE MEMBER | ORGANISATION | TITLE |
|---|---|---|
| Joseph Romano | International Partnership for Microbicides (IPM) | Chief of Product Development |
| 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 Global TB Vaccine Foundation (Aeras)
- African Malaria Network Trust (AMANET)
- Alvos - Consultoria, Desenvolvimento e Comercialização de Produtos Biotecnológicos S.A.
- American Foundation for AIDS Research (amfAR)*
- American Leprosy Foundation/Leonard Wood Memorial
- American Leprosy Missions
- Anacor Pharmaceuticals
- Argos Therapeutics*
- Arizona State University
- 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)
- Bavarian Nordic
- Becton, Dickinson and Company
- Belgian Ministry of Foreign Affairs
  - including data from Belgian Development Cooperation (DGDC)
- Bernhard Nocht Institute for Tropical Medicine (BNI)
- Bharat Biotech
- Bill & Melinda Gates Foundation
- Bio Manguinhos
- Biological E Limited
- Bionaturis
- Bionor Immuno AS*
- Brazilian Innovation Agency (FINEP)
- Brazilian Ministry of Health, Department of Science and Technology
- Brazilian Ministry of Health: National STD and AIDS Programme*
- Brooklyn College
- Canadian Institutes of Health Research (CIHR)
- Canadian International Development Agency (CIDA)
- Caprion Proteomics
- Carlos III Health Institute
- Celgene Corporation
- Center for Genetic Engineering and Biotechnology (CIGB)
- Cepheid
- Chinese National Tuberculosis Reference Laboratory^
- Colombian Department for Science, Technology and Innovation (Colciencias)
- Cristália Produtos Químicos e Farmacêuticos Ltda
- Crucell
- Daktari Diagnostics, Inc
- Danish Ministry of Foreign Affairs
  - including data from Danish International Development Agency (DANIDA)
- DesignMedix, Inc.
- Drugs for Neglected Diseases initiative (DNDi)
- Dutch Ministry of Foreign Affairs
- Eli Lilly and Company
- 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
- Fio Corporation
- FIT Biotech
- Fondazione Cariplo
- Ford Foundation*
- Foundation for Innovative New Diagnostics (FIND)
- French Development Agency, Agence Française de Développement (AFD)
- French National Agency for AIDS Research (ANRS)
- French National Research Agency, Agence Nationale

* Denotes organisations where data was only received via the HIV Vaccines and Microbicides Resource Tracking Working Group
^ Denotes organisations where data was only received via the Treatment Action Group (TAG)

ORGANISATION NAME

de la Recherche (ANR)
- Fundació Clínic per a la Recerca Biomèdica
- Funding Agency for Technology and Innovation (TEKES)*
- Genzyme
- George Washington University
- Georgetown University
- German Federal Ministry for Economic Cooperation and Development (BMZ)
- German Federal Ministry of Education and Research (BMBF)
- German Research Foundation (DFG)
- Ghana Health Service
- GlaxoSmithKline (GSK) including data from GSK Bio
- Global Alliance for TB Drug Development (TB Alliance)
- Global Vaccines Inc
- Hain Lifescience GmbH
- Hawaii Biotech, Inc.
- Health Protection Agency: Centre for Emergency Preparedness and Response
- Health Research Council of New Zealand (HRC)
- Hebron Farmacêutica Ltd
- HIVACAT*
- iCo Therapeutics
- Immune Disease Institute, Inc.
- Indian Council of Medical Research (ICMR)
- Indian Council of Scientific and Industrial Research (CSIR)
- Indian Centre for Cellular and Molecular Biology (CCMB)
- Indian Department of Science & Technology
- Infectious Disease Research Institute (IDRI)
- Infectology Center of Latvia
- Innovative Vector Control Consortium (IVCC)
- Inserm - Institute of Infectious Diseases
- Institut Pasteur
- Institute for One World Health (iOWH)
- 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 Partnership for Microbicides (IPM)
- International Vaccine Institute (IVI)
- Inviragen, Inc.
- Irish Aid
- Italian National Institute of Health, Istituto Superiore di Sanità (ISS)*
- Jacobus Pharmaceuticals
- Japanese Ministry of Education, Culture, Sport, Science and Technology (MEXT)
- John M. Lloyd Foundation*
- Ortho-Clinical Diagnostics and Tibotec (Johnson & Johnson companies)
- Juvaris BioTherapeutics, Inc.*
- KNCV Tuberculosis Foundation
- Korea Centers for Disease Control and Prevention (CDC)
- Korean Institute of Tuberculosis
- Laboratório Farmacêutico do Estado de Pernambuco Governador Migueal Arraes (LAFEPE)
- LifeMed
- Liverpool School of Tropical Medicine (LSTM)
- London School of Hygiene and Tropical Medicine (LSHTM)
- Macfarlane Burnet Institute for Medical Research and Public Health
- Mapp Biopharmaceuticals
- Max Planck Society - Max Planck Institute for Infection Biology (MPIIB)
- Medicines for Malaria Venture (MMV)
- Mexican National Institute of Public Health (INSP)
- Microbicides Development Programme (MDP)
- MSD input includes data from legacy Merck & Co., Inc. and legacy Schering-Plough Corp. for the period prior to the merger in 2009
- Multilateral Initiative on Malaria (MIM)
- Mymetics

ORGANISATION NAME

- National Bioproducts Institute (NBI)
- New York University School of Medicine
- Nortec Química
- Norwegian Centre for International Cooperation in Higher Education (SIU)
- Norwegian Institute of Public Health
- Novartis
- Otsuka Pharmaceutical Co. Ltd
- Overbrook Foundation*
- Oxford-Emergent Tuberculosis Consortium (OETC)
- Palumed S.A.
- Partec GmbH
- Partners in Health (PIH)
- Pediatric Dengue Vaccine Initiative (PDVI)
- Pfizer
- PneumoACTION
- Premier Medical Corporation Ltd.
- PriTest
- Program for Appropriate Technology in Health (PATH)
  - including data from Malaria Vaccine Initiative, Meningitis Vaccine Project, Rotavirus Vaccine Program, Pneumococcal Vaccine Project and other programmes
- Public Health Agency of Canada (PHAC)
- Queensland Health
- Queensland Institute of Medical Research (QIMR)
- Ranbaxy
- 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
- Sanaria Inc
- Sanofi Pasteur
- sanofi-aventis
- Sequella
- Serum Institute of India
- Shantha Biotechnics
- Shin Poong Pharma
- 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)
- Spanish Ministry of Foreign Affairs and Cooperation for Development (MAEC)
  - including data from Agency of International Cooperation for Development (AECID)
- Starpharma*
- Statens Serum Institute (SSI)
- Swedish Foundation for Strategic Research^
- Swedish International Development Agency (SIDA)
- Swedish Research Council
- Swiss Agency for Development and Cooperation (SDC)
- Swiss State Secretariat for Education and Research (SER)
- Swiss Tropical & Public Health Institute
- Sysmex Europe GMBH
- Thai Ministry of Public Health, Department of Medical Sciences
- Thailand National Science and Technology Development Agency (NSTDA)
- The Hospital for Tropical Diseases (HTD)
- 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)
- UK Department for International Development (DFID)
- UK Medical Research Council (MRC)
- United States Agency for International Development (USAID)
- University of Oxford

* Denotes organisations where data was only received via the HIV Vaccines and Microbicides Resource Tracking Working Group
^ Denotes organisations where data was only received via the Treatment Action Group (TAG)

| ORGANISATION NAME |
| --- |
| • University of Bergen |
| • University of Bristol |
| • University of California Berkeley |
| • University of Cambridge |
| • University of Dundee |
| • University of Georgia |
| • University of Melbourne |
| • University of Mississippi |
| • University of Nebraska Medical Center |
| • University of North Carolina |
| • University of Oslo |
| • University of Texas at El Paso |
| • 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 |
| • Vical* |
| • Walter Reed Army Institute of Research (WRAIR) |
| • Wave 80 Biosciences |
| • World Bank |
| • World Health Organization: Neglected Tropical Diseases (WHO/NTD) |
| • World Health Organization: Special Programme for Research and Training in Tropical Diseases (WHO/TDR) |
| • Wyeth-Ayerst Lederle, Inc^ |

^ Wyeth is now part of Pfizer

# 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 preventative 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**

a) Adjuvants and immunomodulators

b) General diagnostic platforms

c) 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, transferring it to the George Institute for International Health in 2006, and rolling out independently in 2010.

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 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.

## Dr Klara Henderson

### Senior Policy Analyst (Part-time consultant)

*BA (Bachelor of Arts); MCom (Master of Commerce); Phd (Faculty of Medicine, School of Public Health)*

Klara Henderson has over 15 years' policy experience, including 10 years as an analyst with Anderson Consulting, and as a policy and strategic development consultant with numerous Australian government agencies.

She spent time in East Africa working on HIV/AIDS projects and was a HIV/AIDS policy and financing consultant for AusAID and UNDP Asia Pacific. She has a PhD in international health policy from the University of Sydney, focussing on HIV/AIDS political commitment and funding in East Timor. Klara joined the Policy Cures team in 2007.

## 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.

## 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, focussing 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 Bachelors of Applied Science in Biotechnology and a BA in Economics from the University of Pennsylvania, and an MSc from the London School of Economics, where she focussed on the WTO TRIPS Agreement and its impact on the global pharmaceutical industry. Lindsey joined the team as a Research Associate in February 2008.

## 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.

## Dimitris Gouglas

### Research Associate

*BSc Economics*

Dimitris joined Policy Cures as a Research Associate in August 2010. He previously worked in management consulting, focusing on market research, business planning, project development and project management for Greek and other European clients in the fields of public health and social policy, health management, regional cooperation and economic development. Dimitris was a Project Manager at the National School of Public Health of Greece, and a Research Assistant at LSE Health, the George Institute for International Health, and the Personal and Social Services Research Unit (PSSRU). Dimitris has a BSc in Economics from the School of Oriental and African Studies of the University of London and is currently finishing his MSc in Health Policy, Planning and Financing at the London School of Economics and the London School of Hygiene and Tropical Medicine.

## Dr Nick Chapman

### Research Associate

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

Nick Chapman has 3 years' experience in health policy and practice. He worked as a doctor in Australia, 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, focussing 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.

## Fred Zmudzki

### Project Manager

*BEc (Bachelor of Economics); MEc (Master of Economics); GradCertPharmEc (Graduate Certificate in Pharmacoeconomics)*

Fred has over 15 years' experience as an analyst and project manager, including 5 years specialising in health policy and evaluation. He has worked on a wide range of projects in Australia, Asia and Europe covering health technology assessment, investment into neglected disease R&D and the economic evaluation of health policy.

Prior to joining Policy Cures, Fred was a consultant with IMS Health focusing on health economic evaluations of health care programs and medicines. He has held a position with the Centre for Health Economic Research and Evaluation (CHERE) and as a Policy Analyst in Strategic and Resource Planning with the NSW Department of Health. He holds a BEc in economics and finance, an MEc in health economics and a graduate certificate in Pharmacoeconomics. Fred joined the Policy Cures team in 2008.

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