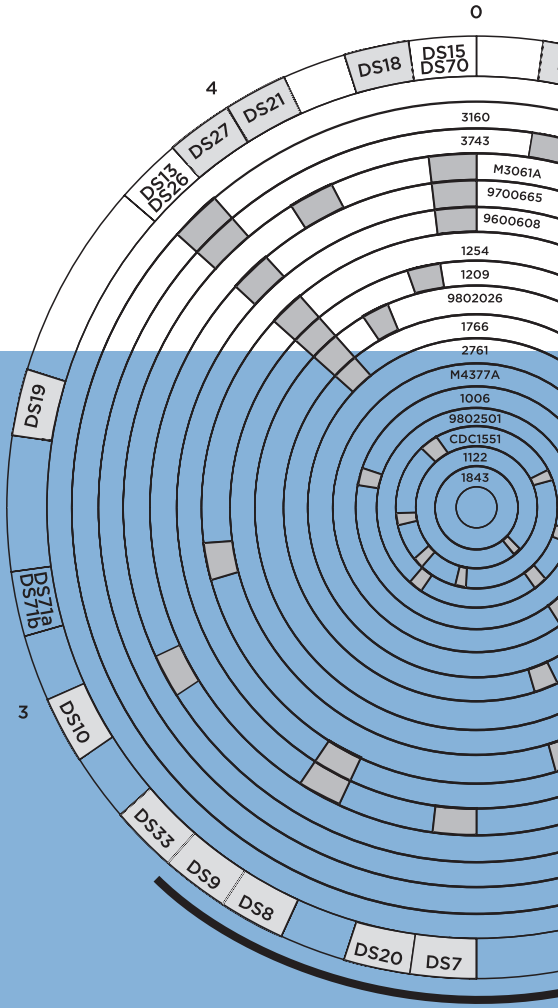
TAG
Treatment Action Group

Stop TB Partnership

TUBERCULOSIS RESEARCH
AND DEVELOPMENT:

2011 Report on Tuberculosis Research Funding Trends, 2005—2010



OCTOBER 2011

TREATMENT ACTION GROUP

BY ELEONORA JIMÉNEZ-LEVI

ACKNOWLEDGMENTS

TAG is grateful to all the participating TB R&D donors who made this report possible. A special thanks to Julie A. Cornell for assisting in all aspects of data gathering and report dissemination, and to the Bill & Melinda Gates Foundation and the Stop TB Partnership for supporting TAG's TB/HIV Project.

ABOUT TAG

Treatment Action Group is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS.

TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end AIDS.

TB/HIV PROJECT

Treatment Action Group's TB/HIV Project works to improve research, programs, and policy for people with TB and HIV.

Eleonora Jiménez-Levi is a senior researcher leading Treatment Action Group's resource-tracking efforts on original source funding for tuberculosis and HIV research. She holds a bachelor's degree in political science from Barnard College and a master of science from the Harvard School of Public Health. From 2004 to 2007, Eleonora managed the TB/HIV Monitoring and Advocacy Project at the Open Society Institute, where she partnered with TAG to help communities affected by TB and HIV advocate for better TB/HIV care and services.

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BY ELEONORA JIMÉNEZ-LEVI

EDITED BY MARK HARRINGTON AND JAVID SYED

THIS REPORT IS DEDICATED TO:

Winstone Zulu

(1964-2011)

Winstone Zulu was in the vanguard of HIV activism. He was one of the first advocates to realize the huge challenge TB posed for people with HIV. He was not only a hero in the fight against AIDS, but a pioneer in bringing AIDS activism to the hitherto barren and civil society free zone of tuberculosis prevention, treatment, and care.

Winstone worked tirelessly to change the world, at no small cost to his own health and wellbeing. His legacy is a stronger link between HIV and TB activists, but his inimitable calm and passionate voice of reason will be deeply missed.

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Executive Summary

Treatment Action Group's *Tuberculosis Research and Development 2011 Report on Tuberculosis Research Funding Trends, 2005—2010* documents and analyzes investments in tuberculosis (TB) research and development (R&D) in comparison to the funding targets set forth in the Stop TB Partnership's *Global Plan to Stop TB 2006—2015*.

The 2011 report finds that 71 donors invested $617.1 million in TB R&D in 2010—a 0.3% decline from 2009 levels and a 73% increase since 2005. The top 30 funders of 2010 represented 97%, or $601 million, of the global total. Nineteen new donors were captured in this year's report, including three who invested at least $1 million in TB drugs and operational research.

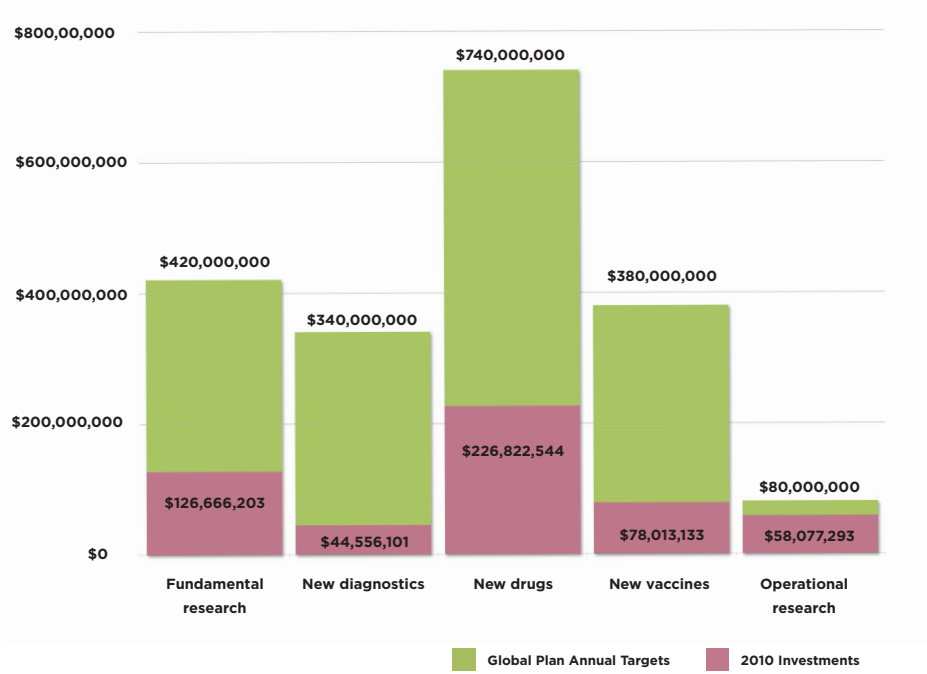
While global TB R&D funding remained stable in 2010, public-sector funding fell 6% from $395.3 million to $371.3 million, and philanthropic investments stayed flat at $124 million. Private-sector funding grew 18% from $100 million to $118 million, and multilateral funding also increased from $0.5 million to $3.7 million.

Private-sector investments helped boost TB treatment research in 2010—the largest funded research category totaling $226.8 million—as two drugs near regulatory approval in the coming year. Basic science received $126.7 million—27% less than in 2009—making up 21% of all TB R&D funding. TB vaccines accounted for 13% of the global total with $78 million—a 29% decline since 2009, and TB diagnostics funding grew 15% to $44.6 million, or 7% of global total spending.

The infrastructure/unspecified category grew 46%, from $56.7 million to $83 million and operational research rose 17%, from $49.5 million to $58.1 million. Measuring these totals in comparison to the *Global Plan* targets, the only category that came close to reaching the annual target was operational research (73% of the $80 million target); and the farthest one was TB diagnostics (13% of the $340 million target; see Figure 1).

FIGURE 1

Annual Global Plan Research Funding Targets vs. 2010 Investments



Eight product development partnerships (PDPs) and research consortia disbursed $116.6 million in TB R&D, a 12% decline from 2009 levels and a 140% increase since 2005.

In 2010, the U.S. National Institute of Allergy and Infectious Diseases (NIAID) continued to be the leading TB R&D funder. Despite reducing its funding in basic science and vaccines—two research areas in which NIAID's investment fell 23% and 34%, respectively—NIAID remained the primary funder of basic science and TB diagnostics, and the second leading funder of TB drugs and vaccines. Overall, the National Institutes of Health (NIH) spent $224 million—36% of the R&D total—with American Recovery and Reinvestment Act stimulus funding supporting $35.3 million, or 16% of the NIH's 2010 investment.

The Bill & Melinda Gates Foundation remained the second leading funder of TB—investing $115.3 million, or 19% of the global total—with the largest contributions directed at infrastructure/unspecified ($35.5 million), TB vaccines ($30.4 million), and TB drugs ($20.7 million).

All stakeholders concerned about TB agree that funding all areas of TB R&D is crucial. TB research donors and recipients who participated in this report, including the European Commission, Otsuka, the Bill & Melinda Gates Foundation, Max Planck Institute for Infection Biology, the U.S. Center for Disease Control, and the Global TB Alliance, in particular, emphasized four key areas that could help accelerate the TB R&D agenda:

1. Greater investment in basic science to gain fundamental knowledge of the TB infection process and inform drug, diagnostics and vaccine development processes to prevent and/or treat TB. The biomarker discovery work is critical to discover and validate biomarkers to be used as study endpoints to reduce the length and cost of TB drug trials and modernize regulatory science for TB. Biomarkers for a TB point-of-care diagnostic test could also revolutionize TB care.

2. Support of efficient and open access sample banks that house well-characterized samples of blood, urine, sputum, and other relevant specimens to facilitate the identification and validation of biomarkers.

3. Increased funding to enhance clinical trial capacity for all stages of TB drug and vaccine trials.

4. More guidance on regulatory approval requirements clarifying the use of new validated study endpoints to allow for shorter TB drug trials.

In 2010, the world invested $617.1 million in TB R&D, or one-third of the $2 billion required to develop new tools to prevent, treat, and ultimately eliminate TB as a public health threat. More donors need to get involved in TB R&D to close the $1.4 billion funding gap, particularly from middle-income countries that have high burdens of TB, such as Brazil, China, India, Russia, and South Africa.

FIGURE 2

Total TB R&D Funding: 2005—2010

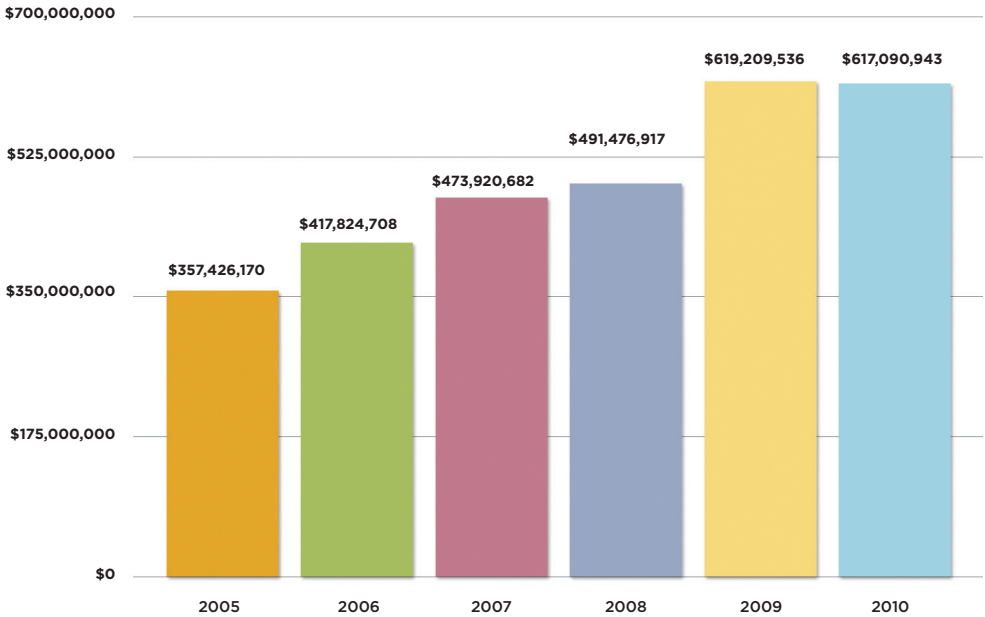


TABLE 1.1

2010 TB R&D Funders by Rank

2010 Rank	Funding Organization	Funder Type	Total USD
1	US NIAID, NIH	P	$158,030,390
2	Bill & Melinda Gates Foundation (BMGF)	F	$115,259,533
3	Otsuka Pharmaceutical Co. Ltd (Otsuka)	C	$63,648,753
4	US Other NIH Institutes & Centers (US Other NIH ICs)	P	$52,363,574
5	European Commission: Research Directorate-General (EC)	P	$25,381,045
6	Company X	C	$20,645,794
7	US Centers for Disease Control (US CDC)	P	$19,865,178
8	United States Agency for International Development (USAID)	P-D	$19,791,027
9	UK Department for International Development (DfID)	P-D	$16,912,287
10	AstraZeneca	C	$14,023,381
11	US National Heart, Lung, & Blood Institute (US NHLBI, NIH)	P	$13,682,412
12	UK Medical Research Council (UR MRC)	P	$13,567,720
13	Institut Pasteur	P	$11,631,674
14	Wellcome Trust	F	$5,963,591
15	Novartis	C	$5,730,352
16	Dutch Ministry of Foreign Affairs - Directorate General of Development Cooperation (DGIS)	P-D	$4,333,160
17	German Federal Ministry of Education and Research (BMBF)	P	$4,226,003
18	World Health Organization (WHO)	M	$3,650,090
19	US President's Emergency Plan for AIDS Relief (US PEPFAR)	P-D	$3,634,321
20	Sequella	C	$3,564,212
21	Statens Serum Institut (SSI)	P	$3,452,820
22	UK Health Protection Agency National Institute for Health Research (UK HPA/NIHR)	P	$3,413,681
23	Max Planck Institute for Infection Biology (MPIIB)	P	$3,100,000
24	Sandoz	C	$3,000,000
25	Emergent Biosolutions	C	$2,791,239

P= Public Sector R&D Agency; C = Corporation/Private Sector; M= Multilateral; F=Foundation/Philanthropy; P-D= Public Sector Development Agency

TABLE 1.2

2010 TB R&D Funders by Rank (continued)

2010 Rank	Funding Organization	Funder Type	Total USD
26	Australian National Health and Medical Research Council (Australia NHMRC)	P	$2,549,818
27	Sweden (reported)	P	$2,034,384
28	India (reported)	P	$1,654,804
29	UBS Optimus Foundation	F	$1,625,000
30	Eli Lilly and Company	C	$1,500,000
31	UK Department of Health (UK DoH)	P	$1,499,860
32	Pfizer Inc	C	$1,418,442
33	Japan (reported)	P	$1,270,204
34	Irish Aid - Ireland Development Corporation	P-D	$1,221,470
35	PEPSICO	C	$1,153,583
36	Switzerland (reported)	P	$1,092,053
37	Korea (reported)	P	$1,008,200
38	South African Department of Science and Technology (South Africa DST)	P	$978,750
39	Agence Nationale de Recherche sur la SIDA (ANRS)	P	$974,075
40	Norway (reported)	P	$717,382
41	Brazil (reported)	P	$672,433
42	Damien Foundation	F	$476,448
43	Carlos III Health Institute	P	$460,556
44	US Food and Drug Administration (US FDA)	P	$400,000
55	Stanley Thomas Johnson Foundation	F	$138,851
60	World Health Organization (WHO): Stop TB Partnership	M	$62,500
62	Fondation Merieux	F	$61,243
68	Thrasher Research Fund	F	$30,625
	New Funders Under $500K		$1,095,825
	Grand Total		**$617,090,943**

P= Public Sector R&D Agency; C = Corporation/Private Sector; M= Multilateral; F=Foundation/Philanthropy; P-D= Public Sector Development Agency

1 Introduction

For the sixth year, the Treatment Action Group (TAG) publishes the latest data on global investments in tuberculosis research and development (R&D). The *2011 Report on Tuberculosis Research Funding Trends: 2005—2010* provides six years of comprehensive spending data and measures current levels in comparison to the funding targets defined by the original *Global Plan to Stop TB 2006—2015* and the most recently updated *2011—2015* version published in 2010. The report offers year-to-year data on the leading TB research funders and analyzes funding trends across six TB research categories and four donor sectors. Most important, the report examines the state of TB research funding and underscores the urgency of adequate and sustained funding to produce the powerful new tools the world needs to eliminate TB as a public health threat by 2050.

1.1 Rationale

Tuberculosis (TB), a disease caused by *Mycobacterium tuberculosis* (MTB), was responsible for 8.8 million new TB cases and 1.45 million deaths in 2010.[1] It is estimated that one-third of the world's population, or 2 billion people, are latently infected with TB but approximately 90% will never develop active TB disease. The populations most at risk of developing active TB are children under the age of five and people who are malnourished and/or immune-compromised. In 2010, 1.1 million of the 8.8 million new TB cases and 0.35 million of the 1.45 million TB deaths were among people with HIV, making it the leading cause of death among people with HIV.[2]

As TB is curable, the ongoing disease burden and mortality rate is particularly inexcusable. For over 40 years no new class of TB drugs has been approved. The Bacille Calmette Guérin (BCG) vaccine, the only vaccine licensed for TB, protects against disseminated and meningeal TB, the worst forms of pediatric TB disease. Yet BCG cannot be administered to HIV-positive infants, as it can cause adverse effects, and offers no protection against the most common form of TB—pulmonary TB. Eight new TB diagnostic technologies have been approved by the World Health Organization through its Strategic and Technical Advisory Group for TB (STAG-TB) between 2007 and 2010, but none of the tests can be used as a point-of-care (POC) test in local health posts—where most TB patients seek services.[3]

Resources to develop new tools to prevent, detect, and treat TB are urgently needed. The rise in TB rates associated with HIV in Africa and the multidrug-resistant TB (MDR-TB) epidemic affecting Eastern Europe, make the case for adequate and sustainable funding even more compelling. Without a $2 billion annual investment in new TB diagnostic tools, vaccines, and drugs, the world will not be able to meet the Stop TB Partnership's 2015 goal of reducing TB prevalence and death rates by 50% compared to 1990 levels, nor will it meet the Stop TB Partnership's 2050 goal of eliminating TB as a public health threat.[4]

1.2 Background

In 2006, the Stop TB Partnership launched the *Global Plan to Stop TB 2006—2015*, a ten-year strategic plan that sets out to reduce the global TB burden by 2015 and eliminate it all together by 2050. *The Global Plan* outlines a road map and funding requirements for scaling up TB control programs and closing the research gap on new TB tools. In October 2010, the Stop TB Partnership updated the strategy and set more ambitious implementation and funding targets to achieve the 2015/2050 goals. In addition to revising the funding targets, the *Global Plan to Stop TB 2011—2015* introduced funding targets for two new research components, fundamental science and operational research, which are critical to better understand fundamental TB science and evaluate the impact of TB control strategies in programmatic settings.

In 2006, TAG embarked on a resource-tracking exercise to measure global progress in comparison to the *Global Plan's* research funding targets. The TB R&D reports established and tracked funding trends against a 2005 baseline. Data from these reports inform researchers, advocates, and policy makers about annual research investments, trends, and funding gaps that must be addressed if the world is to achieve the 2015/2050 goals.

Now in its sixth year, TAG's report is considered the point of reference for global TB R&D investment tracking. The report is used widely in the TB research community—most recently in the revision of the *2011—2015 Global Plan.*

The report also provided a key framework underlying the convening of the High-Level Meeting on TB Research by the Stop TB Partnership, held in Bellagio, Italy, in March 2011. For the first time, TB R&D donors met to share perspectives on their funding priorities and the needs of the field, providing an opportunity to better communicate and deepen their collaboration to eliminate TB. Lastly, in August 2011, Dr. Peter M. Small, senior program officer for TB at the Bill & Melinda Gates Foundation, cited the report at the Conference on TB Diagnostics: From Importation and Imitation to Innovation held in Bangalore, India.

1.3 Methodology

In 2009 and 2010, TAG collaborated with Policy Cures' G-FINDER Project to collect and share TB R&D funding data and contacts. While the collaboration enjoyed the benefits of streamlining the data collection process and sharing contacts, TAG and Policy Cures concluded that the projects differed in scope, methodology, and purpose. Hence, TAG undertook all aspects of data collection for the current report, in continued collaboration with the Stop TB Partnership, and surveyed 146 potential TB research funders. TAG generated original source funding data using an electronic survey asking funders to report disbursements supporting TB R&D in 2010. In addition to reporting funding awards, donors were asked to categorize awards using six predefined research categories: basic science, infrastructure/unspecified, diagnostics, drugs, vaccines, and operational research. Each category is designed to capture investments that will support or enhance scientific breakthroughs in new TB drugs, vaccines, and diagnostics. The following are descriptions of the research areas covered in this report:

- **Basic Science:** Undirected, investigator-initiated research that aims to uncover fundamental knowledge about *Mycobacterium tuberculosis*, and closely related organisms (e.g., *M. Africanum*, *M. bovis*, but not other mycobacterial species).

- **Infrastructure/Unspecified:** Research specific to TB that the donor or funder is unable to further categorize.

- **Diagnostics:** Preclinical or clinical trials of diagnostic technologies and algorithms.

- **Drugs:** Preclinical or clinical research on treatments and treatment strategies for tuberculosis disease (including prophylaxis as well as latent and active TB).

- **Vaccines:** Preclinical or clinical research on TB vaccines.

- **Operational Research:** Research evaluating new and/or existing TB control tools and strategies to guide their effective implementation in program settings. Studies may include randomized trials, surveillance, and epidemiological and observational studies.

Of the 146 surveyed institutions, TAG collected data from 79 funders, including 19 new donors and 8 product development partnerships (PDPs) and research consortia. In addition to the 79 reporting funders, 5 donors informed TAG they did not invest in TB R&D in 2010, and 7 active TB funders promised to share their 2010 investments but were unable to do so by the time this report went to print. TAG will make every effort to collect this data for the second edition of this report.

Unfortunately, 44 previously reporting institutions were not included in this report because they were either inactive or unresponsive. Though TAG attempted to collect data from all previously tracked funders, we prioritized our efforts to the top 30 funders from 2009 as they represented 97% or $601 million of the 2009 global total. From the 2009 top 30 list, TAG collected data from 27 funders—a 90% response rate. Two of the three top 30 funders not listed here promised to share their data for the next edition of this report. For a full listing of the 2010 nonrespondents and their past TB R&D investments please see pages 45—48.

Data collection for the National Institutes of Health (NIH), the European and Developing Countries Clinical Trials Partnership (EDCTP), and the Swiss National Science Foundation (SNSF) did not follow the same methodology described above. Instead TAG secured data from publically available databases such as the NIH Research Condition and Disease Category database (http://report.nih.gov/rcdc/categories/), and the EDCTP (http://www.edctp.org/Our-Work.180.0.html) and SNSF (http://www.projectdb.snf.ch/WebForms/Frameset.aspx) websites.

All non—U.S. currency funding data collected by TAG was converted to U.S. dollars using the 1 July 2010 currency exchange rate provided by the OANDA Corporation at http://www.oanda.com/currency/converter/.

Investment data were analyzed and reported by donor sector, research area, and the top ten funders of 2010. As in previous years, public-sector funding, including development agency spending, was aggregated for Brazil, India, Japan, Korea, Norway, Sweden, and Switzerland. New funders who invested $500,000 or less were also aggregated and labeled "New Funders under $500K." For a complete listing of the 2010 TB R&D funders, please visit www.treatmentactiongroup.org/tbrd2011.

1.4 Limitations of the Data

Resource tracking is not a perfect science. It involves analyzing and vetting data to ensure that it is up to date and accurate. Several factors, however, hinder our ability to provide a comprehensive analysis. Some of the challenges experienced this year include:

- **Loss to follow up:** Forty-four previously reporting TB R&D funding institutions did not provide 2010 data. Several of these institutions were new to TAG when TAG first started collaborating with the G-FINDER Project. TAG is committed to collecting more data for the second edition of this report, particularly among donors who have historically invested $1 million or more to TB R&D. Despite this limitation, TAG was able to track 27 of the top 30 donors from last year, which accounted for 97% of the $617.1 million global investment. For this reason, TAG feels confident that the majority of the global investments in TB R&D were tracked.

- **Changes in funding schemes**: Over the past year, TAG learned the UK Health Protection Agency (UK HPA) and South Africa's Department of Science and Technology (South Africa DST) funding schemes were restructured. The UK Department of Health—where UK HPA resides—introduced a new funding vehicle called the National Institute of Health Research. The vehicle requires public agencies, like UK HPA, to apply for a five-year award based on a peer review process. South Africa's DST also established a new entity, the Technology and Innovation Agency, to consolidate its R&D activities. The restructuring process can alter investment levels, as it did for UK HPA and South Africa DST this year, making it challenging to track year-to-year funding.

- **Incomplete data:** Previously reporting organizations such as the Research Council of Norway, the National Research Foundation of Korea, and the Indian Council of Scientific and Industrial Research did not participate in this year's survey. However, TB R&D funding recipients did report to TAG that they received disbursements from these institutions. The European Commission Research Directorate-General

(EC) also fell under this category though it did provide some data on its 2010 research awards and alerted TAG that more awards were issued but not captured in the survey. Based on historical investment levels and missing or partial portfolios, TAG concluded that these donors' 2010 investments were incomplete.

1.5 Corrections

In the process of collecting 2010 funding data, TAG uncovered new and updated investments from 2009. Among the new data collected, TAG learned the U.S. Food and Drug Administration (US FDA) invested $400,000 in a phase II study of daily rifapentine for pulmonary TB. TAG also learned through communication with the Oxford Emergent Tuberculosis Consortium (OETC)—a research consortium between Oxford University and Emergent Biosolutions—that 100% of their internal funding was derived from Emergent Biosolutions. Based on this new information, TAG added US FDA funding to the TB drugs category and OETC data to the PDP chart on page 27 dating back to 2008 when the joint venture first began.

Table 2 summarizes the data changes made to the 2009 TB R&D funding total. Further information about the data revisions are described below.

Table 2

Summary of 2009 Data Corrections

2009 TB R&D Funding Institutions	Previously Reported Investment (in USD)	Corrected 2009 Data (in USD)
European Commission: Research Directorate-General (EC)	$30,966,022	$41,309,500
Statens Serum Institut (SSI)	$9,887,740	$3,591,440
Wellcome Trust	$8,437,651	$5,576,505
Pfizer	$3,490,868	$2,030,868
Swiss National Science Foundation (SNSF)	$1,847,011	$714,544
UBS Optimus Foundation	$48,332	$1,172,831
Global Fund to Fight AIDS, TB and Malaria (GFATM)	$31,935	$0
U.S. Food & Drug Administration (US FDA)	$0	$400,000
2009 TB R&D Funding Total	**$619,123,407**	**$619,209,536**

Funding Commitments versus Annual Disbursements

For 2009, TAG corrected the Wellcome Trust and SNSF investment data after it found 2009 data reported funding commitments rather than annual disbursements for new and multiyear awards.

Funding Received versus Disbursed Funding and Underreported Funders

After documenting 2010 data and noticing a significant funding decline from 2009 levels, TAG learned that the Statens Serum Institut's 2009 data documented funding received rather than funding disbursed.

Conversely, TAG documented a large investment jump for the UBS Optimus Foundation in 2010. The 2009 data had in fact been underreported.

Data were also underreported in 2009 from the EC. After collecting 2010 data from the website for EDCTP—an EC-funded program—TAG found that multiyear awards from 2007, 2008, and 2009 were not included in the EC funding total. All 2009 awards are now properly accounted for in this edition of the report.

After correcting the information for the eight funding institutions described above, the total TB R&D investment for 2009 grew from $619,123,407 to $619,209,536. All charts, graphs, and tables herein reflect these changes.

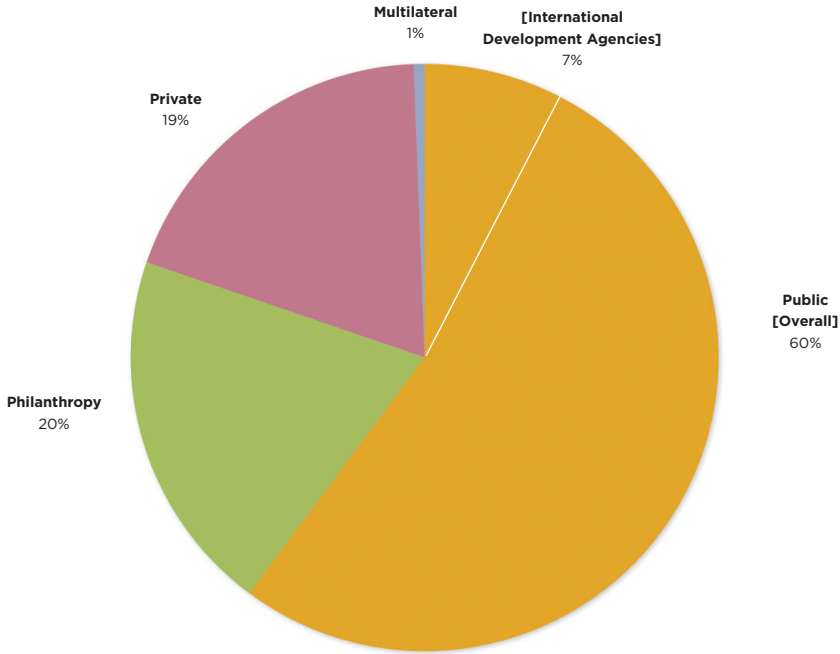
TAG strives to provide the most up-to-date information on TB R&D investments and welcomes additions, corrections and other suggested changes to enhance the accuracy of this report. Please contact TAG at tbrdtracking@treatmentactiongroup.org if you have information or corrections to share.

2 Results

2.1 Donor Categories

FIGURE 3

TB R&D Funding by Donor Sector: 2010
Total: $617,090,943

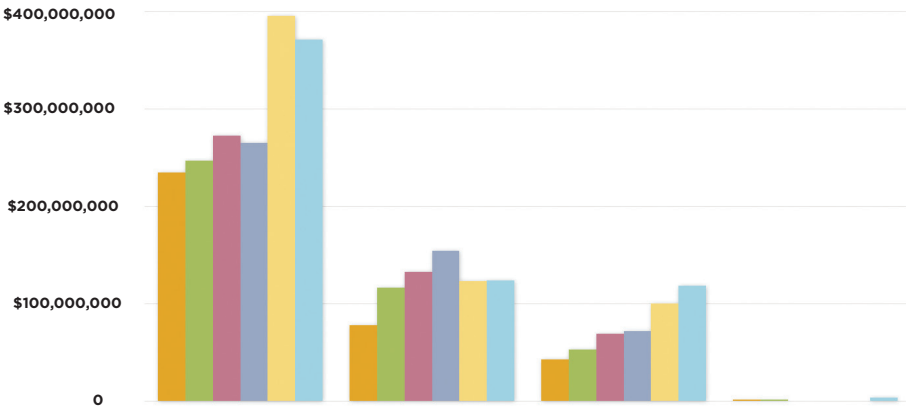


In 2010, 71 funders reported spending $617.1 million on TB R&D, a small 0.3% decline from 2009. While global TB R&D funding was stable between 2009 and 2010, public-sector funding fell 6% from $395.3 million to $371.3 million, and philanthropic investments remained flat at $124 million (see Figure 4). Private-sector funding grew 18% since 2009, making up 18% of total global spending and boosting TB drug development funding. Multilateral funding grew significantly in 2010 from $0.5 million to $3.7 million—a 607% increase—and was primarily directed toward TB treatment research.

Of the 71 funders included in this report, the top ten TB R&D funders—which predominantly represent public and private funders—accounted for 82% of all TB R&D funding in 2010, with a total investment of $505.9 million.

FIGURE 4

Total TB R&D Funding by Donor Sector: 2005—2010

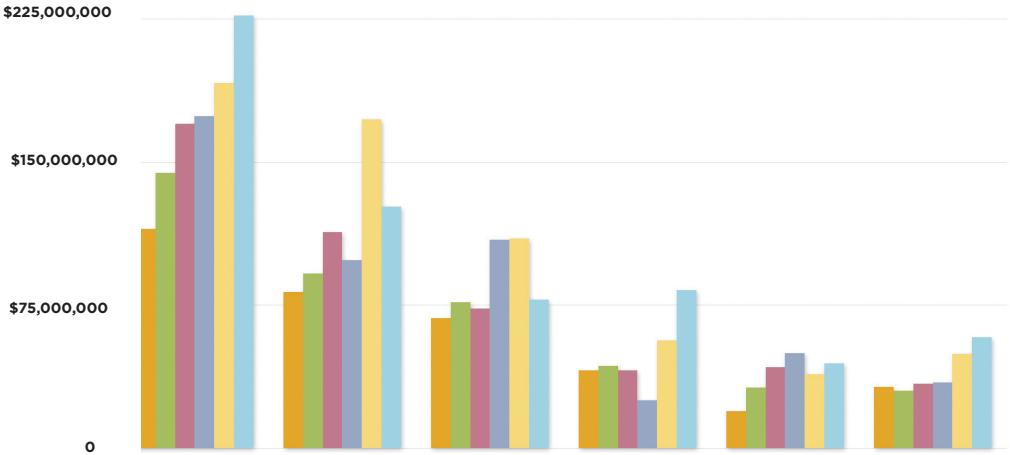


	Public	Philanthropy	Private	Multilateral
2005	$234,503,645	$78,178,708	$43,095,353	$1,648,083
2006	$246,862,858	$116,289,274	$53,138,347	$1,534,259
2007	$272,404,317	$132,326,981	$69,387,383	N/A
2008	$264,944,215	$154,513,987	$72,018,715	N/A
2009	$395,326,911	$123,383,703	$99,973,537	$525,385
2010	$371,269,416	$123,974,117	$118,134,819	$3,712,590

Four of the six research sectors on which TAG reports—infrastructure/unspecified, TB drugs, operational research, and TB diagnostics—benefited from increased funding in 2010 (see Figure 5). TB vaccines and basic science funding declined significantly. NIAID funding for basic science and vaccines dropped in 2010 despite access to American Recovery and Reinvestment Act (ARRA) stimulus funding, which made up 13% of the total NIAID TB R&D budget in 2010.

FIGURE 5

Investments in TB R&D by Research Category: 2005—2010

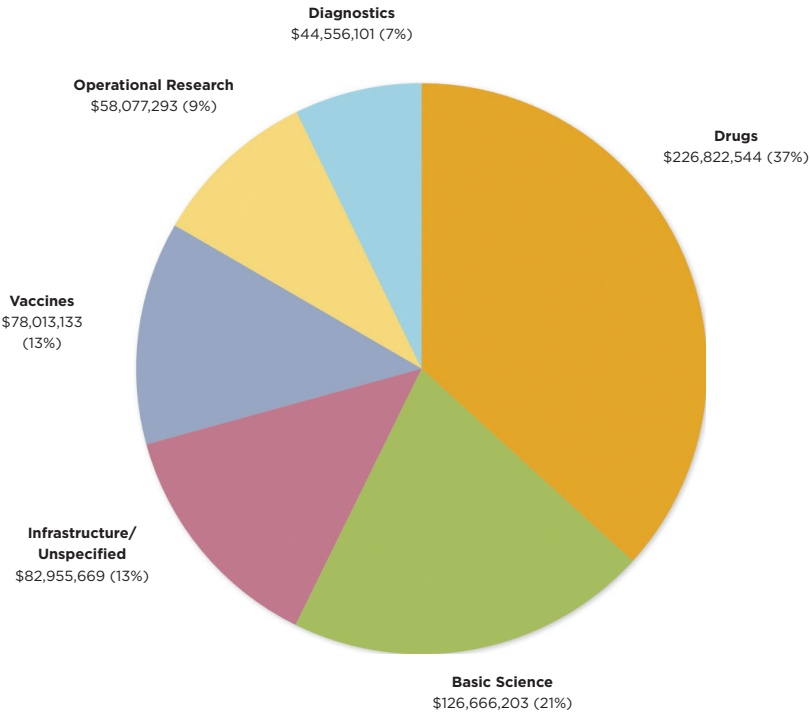


	Drugs	Basic Science	Vaccines	Infra structure/ Unspecified	Diagnostics	Operational Research
2005	$114,862,738	$81,892,167	$68,351,530	$40,741,527	$19,408,124	$32,170,084
2006	$144,336,532	$91,643,009	$76,555,111	$43,205,600	$31,890,329	$30,194,127
2007	$170,233,497	$113,325,202	$73,225,383	$40,734,199	$42,435,113	$33,967,288
2008	$174,178,052	$98,728,019	$109,337,224	$25,032,930	$49,788,950	$34,411,742
2009	$191,483,304	$172,447,841	$110,133,485	$56,686,918	$38,921,229	$49,536,760
2010	$226,822,544	$126,666,203	$78,013,133	$82,955,669	$44,556,101	$58,077,293

2.2 Trends in TB Research by Category

FIGURE 6

TB R&D Investments by Research Category: 2010
Total: $617,090,943

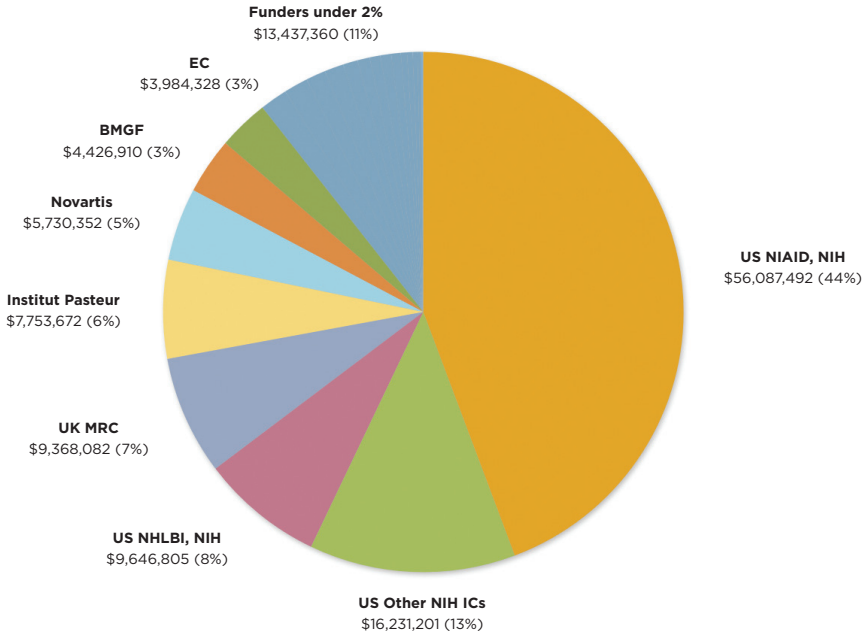


For the sixth consecutive year, TB drug development was the most well-funded research area, with $226.8 million in funding, a 19% increase since 2009 and 37% of the total global spend (see Figure 6). Basic science research received the second largest share of funding, with $126.7 million, and made up 21% of total global spending—a 27% decline from 2009 levels. TB vaccines funding fell 29%, from $110.1 million to $78 million (13% of the global total), and lagged behind the TB infrastructure/unspecified category, which grew 46% from $56.7 million to $83 million, and also accounted for 13% of the global total. Finally, operational research and TB diagnostics grew 17% and 15%, respectively, since 2009, claiming 9% and 7% of the global spending total.

Basic Science

FIGURE 7

Basic Science: $126,666,203



Funders with investments under 2%

Funder	Amount
Wellcome Trust	$2,159,208
BMBF	$1,900,599
Sweden (reported)	$1,566,878
MPIIB	$1,500,000
PEPSICO	$1,153,583
UK HPA/NIHR	$962,910
South Africa DST	$848,250
India (reported)	$845,402
Switzerland (reported)	$743,784
Australia NHMRC	$486,257
New Funders Under $500K	$442,500
Carlos III Health Institute	$372,965
WHO	$285,129
Pfizer Inc	$169,895

After experiencing a 75% funding surge from 2008 to 2009, basic science investments fell 27% in 2010 from $172.4 million to $126.7 million. The proportion of basic science funding relative to total TB R&D spending also declined from 28% to 21% between 2009 and 2010.

In 2010, NIAID continued to be the leading funder of basic science, investing $56 million, which included $9.2 million from ARRA stimulus funding. Despite the additional ARRA funding—which made up 16% of NIAID's basic science investment—NIAID's contribution in 2010 was 23% less than 2009's $73 million.

Other NIH Institutes and Centers (Other NIH ICs) and the U.S. National Heart, Lung, and Blood Institute (NHLBI), increased their investments by 56%, making them the second and third leading funders in basic science in 2010. For other NIH ICs, the ARRA played a key role, providing $5.5 million, or 34%, of the institutes' basic science funding. For the NHLBI, ARRA funds sponsored only one grant of $241,000. With ARRA stimulus funding set to expire at the end of 2011, TAG predicts funding for basic science will experience a steep decline in 2012, disrupting important fundamental research needed to develop new TB tools.

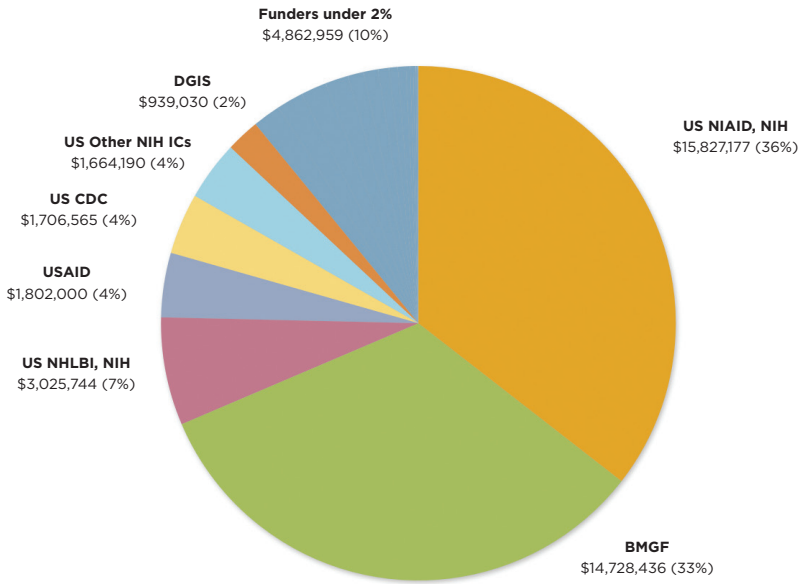
Of the 22 donors who invested in basic science in 2010, the Gates Foundation downsized its investments by 80%, from $21.3 million to $4.4 million, and the UK Medical Research Council (UK MRC) by 44%, from $16.8 million to $9.4 million.

Basic science is an important cornerstone in TB R&D research as it reveals fundamental knowledge about MTB that can help accelerate the development of innovative technologies in drugs, diagnostics, and vaccine development. Therefore, the funding decline in basic science in 2010 is worrisome, since $126.7 million represents only 30% of the *Global Plan's* $420 million annual target.

TB Diagnostics

FIGURE 8

TB Diagnostics: $44,556,101



Funders with investments under 2%

Funder	Amount
UBS Optimus Foundation	$780,000
UK DfID	$749,930
Norway (reported)	$717,382
Institut Pasteur	$646,043
Wellcome Trust	$440,928
EC	$411,115
Brazil (reported)	$304,056
Sequella	$244,104
New Funders Under $500K	$221,832
UK MRC	$118,609
Stanley Thomas Johnson Foundation	$83,310
Damien Foundation	$71,032
BMBF	$31,601
Carlos III Health Institute	$29,642
Thrasher Research Fund	$13,375

In 2010, funding to support TB diagnostics research grew 15%, from $38.9 million to $44.6 million. Following a 22% funding decline between 2008 and 2009, the 2010 investment does not surpass 2008's $50 million investment—the highest amount recorded for TB diagnostics since this resource tracking began—and certainly does not come close to the *Global Plan's* $340 million annual target.

NIAID and the Gates Foundation were the two largest contributors to TB diagnostics in 2010, providing 36% and 33% of the total, respectively. NIAID increased its TB diagnostics investment by 70%, from $9.4 million to $15.8 million, and the Gates Foundation doubled its contribution from $7.4 million to $14.7 million.

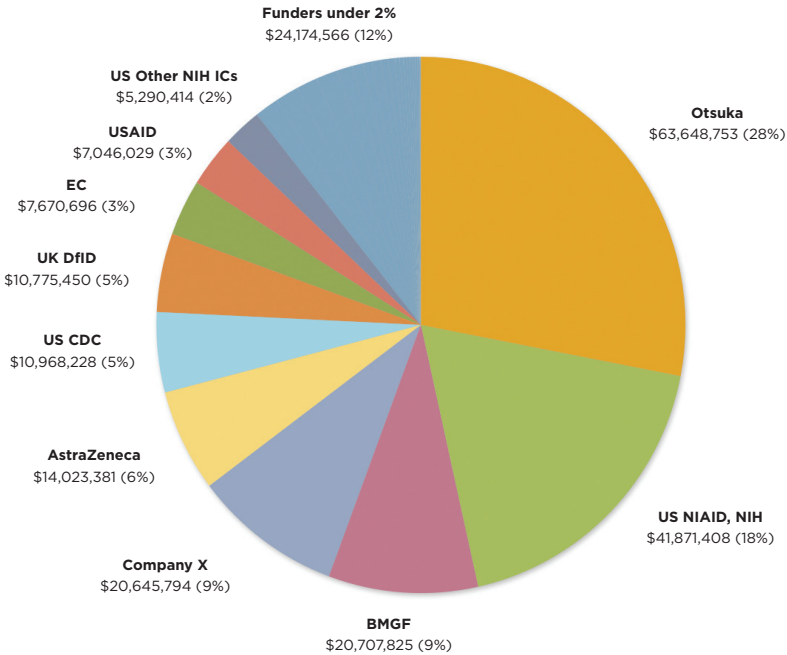
More resource mobilization is needed to develop a low-cost and effective POC diagnostic test that can be used in health post or community settings. The most recent diagnostic tool to be approved by the WHO STAG-TB was the Xpert MTB/RIF assay; recommended in 2010, the test is designed to detect TB and confirm rifampicin resistance within two hours. Xpert MTB/RIF greatly reduces the time it takes to detect TB and initiate treatment, but can only be performed at the subdistrict level due to its cost, electricity, and equipment requirements.

To develop the urgently needed POC TB test, greater investments in basic science and biomarker discovery are necessary. Besides funding, there is also a need for sample banks with well-characterized samples that include blood, urine, sputum, and other relevant specimens. These sample banks need to be operated efficiently and have a clear open-access policy to facilitate the identification and validation of biomarkers. The Gates Foundation has made this one of its priority areas and in 2011 announced a $12 million Grand Challenges Biomarkers Grant Opportunity to support research that detects TB in low-resource settings by validating host and/or pathogen biomarkers.[5]

TB Drugs

FIGURE 9

TB Drugs: $226,822,544



Funders with investments under 2%

Funder	Amount
Sequella	$3,320,108
WHO	$3,261,920
Sandoz	$3,000,000
Institut Pasteur	$2,919,059
UK MRC	$2,172,823
Eli Lilly	$1,500,000
Pfizer	$1,248,547
Irish Aid	$1,221,470
Korea (reported)	$1,000,000
ANRS	$974,075
Australia NHMRC	$611,802
DGIS	$500,560

Funder	Amount
BMBF	$474,044
New Funders Under $500K	$446,500
US FDA	$400,000
Sweden (reported)	$318,307
UBS Optimus Foundation	$304,200
Wellcome Trust	$256,475
WHO: Stop TB Partnership	$62,500
Switzerland (reported)	$59,769
Carlos III Health Institute	$57,949
Stanley Thomas Johnson Foundation	$55,540
Thrasher Research Fund	$8,917

In 2010, 33 donors invested $226.8 million in TB drug development, or 37% of all TB R&D investments. The 19% funding growth from $191.5 million to $226.8 million reflects the rise in clinical activity of novel and second-generation drug compounds moving through the private-sector pipeline.

Several ongoing trials are using existing TB drugs to reduce treatment duration, improve treatment outcomes, and lessen side effects, while six new compounds, including three new classes, are being developed to treat drug-resistant and drug-sensitive forms of TB.[6]

One of the new class of drugs is Otsuka's delamanid (also known as OPC-67683)—an oral therapeutic for the treatment of MDR-TB. Clinical research on delamanid is presently in phase II, with Otsuka sponsoring all the costs of the trial. In 2010, Otsuka invested $63.6 million on delamanid—a 21% increase from 2009 levels—making it the leading funder of TB drug development (at 28% of all TB drug spending). A significant portion of this investment was spent on scaling up clinical trial capacity to carry out registration quality trials that meet good clinical practice standards.

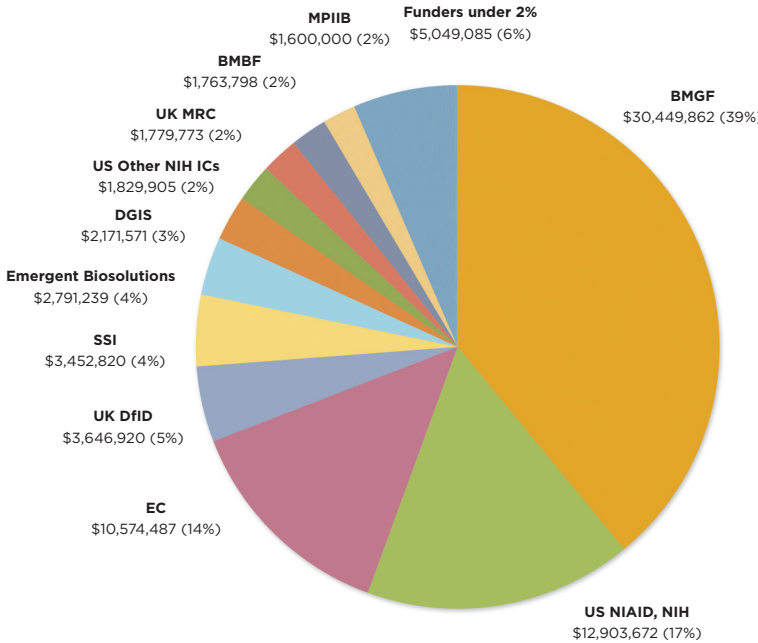
The second leading funder for TB drugs in 2010 was the NIAID, investing $41.9 million—a 29% increase since 2009—across a range of translational and clinical research. For a second year in a row the Gates Foundation placed third in TB drug development, spending $20.7 million—a 14% reduction from 2009's $24 million.

Though TB drug development continues to receive the greatest share of funding, it only reached 31% of the $740 million annual *Global Plan* target in 2010. In addition to closing the $513.2 million funding gap, more guidance on regulatory approval requirements is needed to ensure that new drugs and regimens are developed and approved expeditiously. The Critical Path to TB Drug Regimen Initiative, a broad collaboration among drug developers, regulatory bodies, civil society advocates, academics, and research funders, is working to clarify a regulatory pathway that can use new validated-study endpoints to allow for shorter TB drug trials without compromising the safety or efficacy of the new regimens.

TB Vaccines

FIGURE 10

TB Vaccines: $78,013,133



Funders with investments under 2%

Funder	Amount
UK DoH	$1,499,860
UK HPA/NIHR	$1,171,391
New Funders Under $500K	$1,054,943
Australia NHMRC	$535,797
Institut Pasteur	$312,899
Wellcome Trust	$183,818
South Africa DST	$130,500
Fondation Merieux	$61,243
Sweden (reported)	$51,448
US NHLBI, NIH	$30,653
Thrasher Research Fund	$8,333
Korea (reported)	$8,200

After experiencing no growth in 2009, the TB vaccines category suffered a 30% funding drop, from $110.1 million to $78 million in 2010—the steepest decline ever recorded for vaccines research since 2005. Though five of the top ten R&D funders invested in vaccines, they each reduced their investments from as little as 4% to as much as 45% compared to 2009.

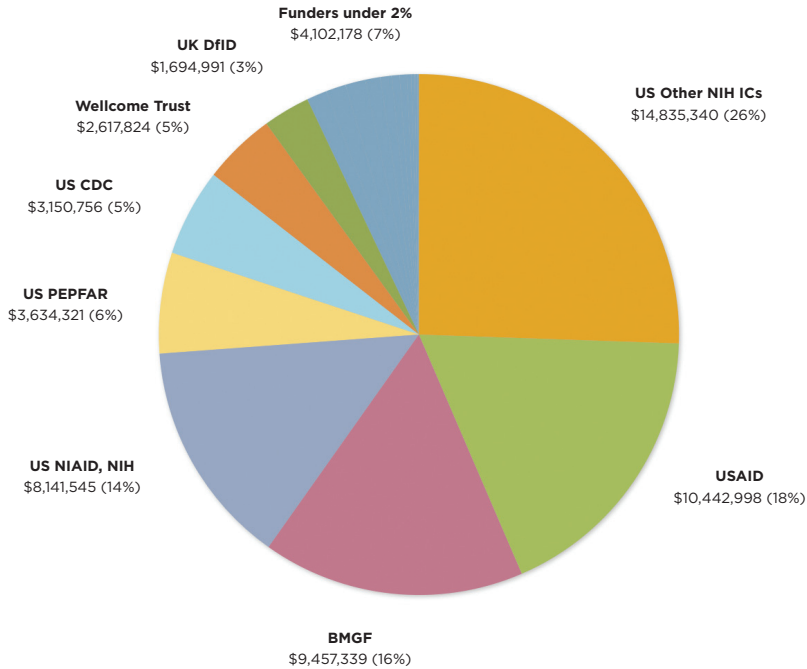
Investments from the two leading vaccine donors, the Gates Foundation and NIAID, fell 36% and 34%, respectively. The largest TB vaccine grant issued by the Gates Foundation in 2010 (worth $28.7 million) was awarded to the Aeras Global TB Vaccine Foundation as part of their five-year $200 million grant to develop and license an improved vaccine against TB for use in high-burden countries.

The 2010 $78 million TB vaccine investment is woefully inadequate and falls $302 million short of the *Global Plan's* $380 million target. Funding for vaccine research has never been more urgent. Ten new vaccine candidates presently in clinical trials will not be able to move along the pipeline if there is no adequate and sustainable funding—especially funding to scale-up infrastructure to conduct these complex later-stage trials.[7]

Operational Research

FIGURE 11

Operational Research: $58,077,293



Funders with investments under 2%

Funder	Amout
EC	$728,987
Australia NHMRC	$725,102
DGIS	$721,999
UBS Optimus Foundation	$540,800
Damien Foundation	$405,416
Switzerland (reported)	$288,500
New Funders Under $500K	$262,249
Brazil (reported)	$153,165
UK MRC	$128,433
WHO	$99,526
India (reported)	$48,000

Funding to support operational research in 2010 grew 17%, from $49.5 million to $58.1 million. Unlike in past years, this year's new leading funder of operational research was the Other NIH ICs 's with a $14.8 million investment, followed by USAID's $10.4 million contribution.

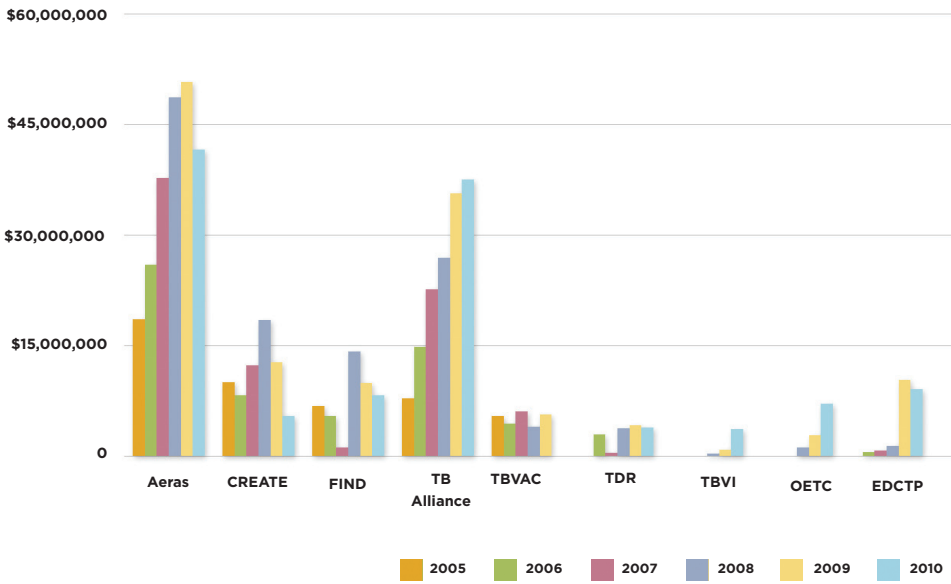
The Gates Foundation—which has historically funded operational research the most—decreased its investment by 33%, from $14.1 million to $9.5 million, making it the third leading funder of research evaluating new or existing TB control tools and strategies.

Operational research is key for producing the evidence that lays the groundwork for improving current strategies and introducing new tools, as laid out in the *Global Plan to Stop TB 2011–2015*. Of the five research areas outlined in the *Global Plan*, the 2010 investment in operational research came the closest to meeting the annual target, reaching 73% of the $80 million target. This is excellent progress in a much needed research area, that is together involved in ensuring better access to people who need quality TB care, and best uptake of new tools and strategies to diagnose, treat and prevent TB efficiently. To promote and support this further, the Stop TB Partnership, in collaboration with the WHO Stop TB Department and the Global Fund Against AIDS, Tuberculosis and Malaria, developed a document entitled *Priorities in operational research to improve tuberculosis care and control*.[8] This document describes the priority areas in which knowledge gaps hamper optimal implementation of TB control activities and, for each of these areas, provides a list of the critical questions that must be addressed together with a synopsis of suitable study designs and methods required to address these questions.

Product Development Partnerships and Research Consortia

FIGURE 12

TB R&D PDPs and Research Consortia: 2005—2010



Product development partnerships (PDPs) and research consortia play a vital role in accelerating TB drug, diagnostic, and vaccine development by bringing together public, private, and philanthropic donors to share resources and research knowledge. Since PDPs are nonprofit institutions and recipients of public, private, and philanthropic funding, they are not considered original source funders and thus their disbursements are not counted toward the global TB R&D investment total.

In 2010, eight PDPs and research consortia disbursed $116.6 million in TB R&D, a 12% decline from 2009 and a 140% increase since 2005. The 2010 data includes new funding information for OETC and the EDCTP, a clinical trials network funded by the European Commission's Sixth Framework Program through 2015.[9]

CREATE, a research consortium funded by the Gates Foundation, began winding down its three TB/HIV operational research studies in 2010. The ten-year project is set to end in 2012.

2.3 Top Ten Funders in TB R&D in 2010

In 2010, 71 donors reported spending $617.1 million in TB R&D. The top ten funders contributed $505.9 million, or 82% of total global spending. NIAID and the Gates Foundation continued to invest the largest sums—over $100 million each—and represent more than 50% of the $505.9 million investment from top ten donors. This year, TAG observed increases in private-sector investments to TB drug development, with three companies making the top ten list (Otsuka, Company X, and AstraZeneca)—an encouraging sign for TB drug and regimen development.

1. The U.S. National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH)

In 2010, NIAID granted 320 awards worth $158 million to TB R&D. Though this amount represents the largest TB R&D investment of 2010, NIAID's funding was 7% lower than in 2009, with ARRA stimulus funding making up 13%, or $20.3 million, of NIAID's 2010 investment.

Despite reducing its funding in basic science and vaccines—two research areas in which NIAID's investment fell 23% and 34%, respectively—NIAID remained the primary funder of basic science and TB diagnostics, and the second leading funder of TB drugs and vaccines in 2010. Funding for TB diagnostics climbed 70%, from $9.4 million to $15.8 million, as did TB drugs from $32.4 million to $41.9 million. Such increases are part of NIAID's NIH Challenge Grants in Health and Science Research program, announced in March 2009, calling for research to address important challenges in biomedical and behavioral research. This program, funded by the ARRA stimulus package for fiscal years 2009—2010, focused on clinical research to develop diagnostics and drugs for MDR-TB or extensively drug-resistant TB (XDR-TB) in order to meet the urgent demand for improved technologies that prevent, detect, and treat MDR- and XDR-TB.[10]

Since 2009, ARRA stimulus funds have catalyzed important research to address the most urgent challenges in health research, and the TB field—particularly basic science—has benefitted greatly from that support (see Table 3).

Table 3

2009—2010 ARRA TB Funding

	ARRA 2009 Spending	% of Total	ARRA 2010 Spending	% of Total	% change from 2009 to 2010
Basic Science	$12,819,004	47.9%	$14,886,114	42.1%	16.1%
Infrastructure/Unspecified	$3,536,292	13.2%	$6,644,829	18.8%	87.9%
Diagnostics	$662,987	2.5%	$3,916,366	11.1%	490.7%
Drugs	$4,763,420	17.8%	$6,916,605	19.6%	45.2%
Vaccines	$3,851,879	14.4%	$2,201,443	6.2%	-42.8%
Operational Research	$1,151,480	4.3%	$764,526	2.2%	-33.6%
TOTAL	**$26,785,062**		**$35,329,883**		**31.9%**

As TAG suggested in the 2010 report, NIH funding is gravely threatened by U.S. budget cuts. With the expiration of the ARRA stimulus package in 2011 and what are likely to be severe cuts to the federal budget, NIH funding overall, and especially for TB R&D, may well drop to pre-2009 levels beginning in 2012, with potentially catastrophic effects on the future ability to control and eliminate TB (see Table 4).

Table 4

2005—2010 NIH Funding for Select Infectious Diseases (in USD millions)

	2005	2006	2007	2008	2009*	2010*
HIV/AIDS	$2,921	$2,902	$2,906	$2,928	$3,338	$3,407
Smallpox	$187	$149	$142	$94	$98	$97
Anthrax	$183	$150	$160	$134	$115	$130
Tuberculosis	$158	$150	$188	$142	$216	$224
Malaria	$104	$98	$112	$142	$121	$148

* Includes ARRA stimulus funds

NIH Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)
Accessed 9 September 2011 at http://report.nih.gov/rcdc/categories/default.aspx

2. The Bill & Melinda Gates Foundation

As the second largest investor in TB R&D, the Gates Foundation has made important contributions to TB basic science, drug, diagnostics, vaccine development, and operational research. The foundation's short-term TB priorities are to develop new drug regimens that are safe and effective and reduce the duration of TB treatment, and to improve molecular diagnostics for TB. Its long-term strategy includes the development of a preventive vaccine effective against all forms of TB as well as research to produce the much-needed POC diagnostic test for use in health post and community settings.

While the foundation's investment remained flat at $115.3 million in 2010, investments in basic science, vaccines, TB drugs and operational research declined. Funding for TB drugs dropped 14%, from $24 million to $20.1 million; funding for operational research dropped 33%, from $14.1 million to $9.5 million; and funding for TB vaccines fell 36%, from $47.6 million to $30.4 million. The sharpest decline was observed in basic science, with a 79% decline, from $21.3 million to $4.4 million. Infrastructure/unspecified R&D rose from $0 to $35.5 million, and TB diagnostics funding doubled from $7.4 million to $14.7 million.

3. Otsuka Pharmaceutical Company

Otsuka is a Japanese-based company conducting phase II studies of delamanid (OPC-67683), a nitroimidazole compound, for the treatment of MDR-TB. For a third consecutive year, Otsuka ranked third among the top ten funders list in 2010, investing $63.6 million in TB drug development.

Delamanid is currently in phase II, and pending favorable study outcomes, may qualify for accelerated regulatory approval next year. Otsuka is committed to the full development of this anti-TB drug but warns that lack of clear regulatory guidance could become a major roadblock to the development of delamanid—which is one of two new classes of TB drugs to be developed in 50 years. Another notable and more immediate concern as the drug enters complex late-stage trials is the lack of adequate laboratory capacity for diagnosing MDR-TB.

4. Other NIH Institutes and Centers (Other NIH ICs)

Since TAG first embarked on this resource-tracking exercise in 2005, the report has published data on two NIH institutes—NIAID and the NHLBI—and the remaining 25 NIH research institutes have been aggregated into the "US other NIH Institutes and Centers" category. In addition to AstraZeneca—a top ten funder that reported a 57% increase in 2010—the other NIH ICs also witnessed a notable 42% increase in TB R&D investments, from $36.9 million in 2009 to $52.4 million in 2010.

As a result of its increased investment, other NIH ICs funding for basic science ($16.2 million), operational research ($14.8 million), and infrastructure/unspecified ($12.5 million) grew by 56%, 85%, and 3%, respectively. TB vaccines funding remained flat at $1.8 million.

Of the $52.4 million budget, $14.8 million of ARRA funding made up 28% of the other NIH ICs budget and supported 32 of the 198 awards issued in 2010.

5. The European Commission: Research Directorate-General (EC)

The EC is comprised of several research funding programs, such as the EC's Sixth and Seventh Framework Program, the Directorate-General's Research and Innovation division, and the European Research Council (ERC).

For 2010, the EC reported low budget figures because many projects that started in 2009 are expected to receive their second installments in 2011. Additionally, the EC was unable to report full funding figures for 2010, rendering the EC 2010 investment data and analysis incomplete. Nevertheless, TAG decided to publish the available data while actively pursuing missing data from the ERC and the Sixth and Seventh Framework Programs. TAG hopes to report updated EC figures for the second edition of this report.

Based on the available data, the EC invested $25.4 million in TB R&D in 2010—with 42% supporting vaccine research ($10.6 million). The EC's TB research priorities include research to develop new diagnostics, therapies, and preventive tools ranging from basic molecular research to preclinical tests. The EC is particularly interested in TB research that addresses MDR-TB.

6. Company X

Company X is a private company studying new TB therapy. Between 2009 and 2010, Company X's investments remained stable, growing 3%, from $20.1 million to $20.6 million.

7. The U.S. Centers for Disease Control and Prevention (US CDC)

With an 8% investment increase from $18.5 million to $19.9 million, the U.S. Centers for Disease Control and Prevention (US CDC) was the seventh largest TB R&D funder in 2010. The US CDC supports TB R&D through the TB Trials Consortium and the TB Epidemiological Studies Consortium, which make up over 85% of the organization's external funding for TB research. Both consortiums are funded for ten years and focus on TB diagnostics, clinical management, prevention, and strengthening scientific research capacity. In 2010, the TB drugs category received the largest share of US CDC funding (55%), followed by infrastructure/unspecified (20%), and operational research (16%). While the US CDC is interested in TB vaccine R&D, it did not invest in TB vaccine development in 2010.

8. The U.S. Agency for International Development (USAID)

U.S. Agency for International Development (USAID) funding for TB R&D grew for the fourth consecutive year since 2007. Annual USAID investment between 2009 and 2010 grew 28%, to $19.8 million, with the majority of the funding going toward operational research ($10.4 million) and TB drug development ($7 million).

USAID's top TB priorities are the development of new TB drugs and diagnostics, as well as improving the delivery of TB/HIV care and the performance and accessibility of directly observed treatment short course in programmatic settings.

9. The United Kingdom Department for International Development (UK DfID)

In 2010, the United Kingdom's Department for International Development (UK DfID) TB R&D investment fell 5.2%, from $17.8 million to $16.9 million. TB vaccine funding declined 45%, from $6.6 million to $3.6 million. Operational research funding fell by 6%. Investment in TB drugs grew 14% from $9.4 million to $10.7 million. The DfID made modest new contributions to infrastructure/unspecified and TB diagnostics research. Its largest investments—in TB drugs and TB vaccines—reflect the agency's commitment to supporting the development and scale-up of new and affordable tools for populations most affected by TB. As part of its long-term strategy, the DfID is beginning to include new diagnostics research for TB among people with HIV as a priority area.

10. AstraZeneca

AstraZeneca is a pharmaceutical company with a TB research center based in Bangalore, India, that is expanding its research portfolio to deliver new TB drug candidates for clinical development. The most advanced compound is AZD5847, which entered phase I testing in December 2009 after it showed favorable results in preclinical studies against MDR-TB.

In 2010, AstraZeneca's investment in TB drugs rose 57%, from $8.9 million to $14 million, placing it among the top ten funders for the first time since 2005. Pending favorable study outcomes from its phase I trial, AstraZeneca will partner with external organizations to further AZD5847's clinical development.

Such partnerships are already happening. In May 2010, AstraZeneca and the Global TB Alliance formed a research collaboration aimed at advancing TB drug discovery and development by sharing resources into a joint portfolio for development by both organizations.[11] And most recently, in March 2011, AstraZeneca joined a new research consortium, More Medicines for Tuberculosis—a European Commission Sixth Framework Program funding venture—made up of 25 partners to introduce 10 to 20 compounds into the clinical pipeline and develop 2 to 3 TB drugs to be used in a new regimen.[12,13]

3. Conclusions & Recommendations

3.1 Conclusions

The *TB R&D 2011 Report on Tuberculosis Research Funding Trends, 2005—2010* finds that investments in TB research witnessed a 73% increase over 2005 levels but no growth since 2009 (see Table 5). Seventy-one funders invested $617.1 million across six research areas to support scientific breakthroughs in TB drugs, vaccines, and diagnostics—only one-third of the annual $2 billion global need.

Table 5

Summary of Changes in TB R&D Investments, 2005—2010, in USD

Year	Total TB R&D Investment	Change Over Previous Year ($)	Change Over Previous Year (%)	Change Over 2005 ($)	Change Over 2005 (%)
2005	$357,426,121				
2006	$417,824,708	$60,398,587	16.9%	$60,398,587	16.9%
2007	$473,920,682	$56,095,974	13.4%	$116,494,561	32.6%
2008	$491,476,917	$17,556,235	3.7%	$134,050,796	37.5%
2009	$619,209,536	$127,732,619	26.0%	$261,783,415	73.2%
2010	$617,090,943	-$2,118,593	-0.3%	$259,664,822	72.6%

TB drug development received $226.8 million—the greatest share of funding in 2010—but it only accounted for 31% of the annual $740 million *Global Plan* target. In addition to TB drugs, investments in infrastructure/unspecified, operational research, and TB diagnostics all grew since 2009. However, funding for basic science and vaccines fell 27% and 29%, respectively.

Of the six research categories, the only one that came close to reaching the *Global Plan* target was operational research (73% of the $80 million target), and the one farthest away was TB diagnostics (13% of the $340 million target).

While global TB R&D funding remained stable in 2010, public-sector funding fell 6% from $395.3 million to $371.3 million, and philanthropic investments stayed flat at $124 million. Private-sector funding grew 18%, from $100 million to $118 million, and multilateral funding also increased from $0.5 million to $3.7 million.

Increased investments from the private sector in 2010 offer an encouraging sign about improved clinical drug pipeline activity and the prospects of two new drug candidates achieving regulatory approval for treatment of MDR-TB in the coming year.

In 2010, NIAID continued to be the leading TB R&D funder. Despite reducing its funding in basic science and vaccines—two research areas in which its investment fell 23% and 34%, respectively—NIAID remained the primary funder of basic science and TB diagnostics and the second leading funder of TB drugs and vaccines. Overall, the NIH spent $224 million—36% of the R&D total—with ARRA stimulus funding supporting $35.3 million, or 16%, of the NIH's 2010 investment.

With the expiration of the ARRA package in 2011, NIH funding for TB is likely to decline. Now more than ever, increased investments from middle-income countries are necessary to close the $1.4 billion gap in TB R&D funding needs.

3.2 Recommendations

In addition to closing the $1.4 billion funding gap to achieve the goal of TB elimination, TAG recommends cross-sector collaboration to address the critical bottlenecks that hinder the development, testing, and approval of new TB tools. Furthermore, leading TB research donors that participated in this survey recommended:

1. Greater investment in basic science to gain fundamental knowledge of the TB infection process and inform drug, diagnostics and vaccine development processes to prevent and/or treat TB. The biomarker discovery work is critical to discover and validate biomarkers to be used as study endpoints to reduce the length and cost of TB drug trials and modernize regulatory science for TB. Biomarkers for a TB point-of-care diagnostic test could also revolutionize TB care.

2. Support of efficient and open access sample banks that house well-characterized samples of blood, urine, sputum, and other relevant specimens to facilitate the identification and validation of biomarkers.

3. Increased funding to enhance clinical trial capacity for all stages of TB drug and vaccine trials.

4. More guidance on regulatory approval requirements clarifying the use of new validated study endpoints to allow for shorter TB drug trials.

The scientific progress for TB R&D is reaching an exciting phase just as the world teeters on the brink of a second global recession. More game changing drugs and diagnostics are under investigation, and vaccine discovery is making the pipeline of new TB tools fuller than it has

been in the last 50 years. To protect this progress from eroding due to funding cuts, there is an urgent need for emerging economies to scale-up their investments in TB research and for research donors and implementers to increase their collaboration.

In this respect, the Research Movement of the Stop TB Partnership has developed an *International Roadmap for Tuberculosis Research* that describes the key priorities and critical questions to be addressed in the areas of fundamental research, diagnostics, drugs, vaccines, operational, public health and epidemiological research in order to meet the Stop TB Partnership goals.[14] This roadmap encompasses the continuum of TB research and is designed to reinvigorate and promote research worldwide, from the laboratory to the bedside of a person affected by the disease. It is proposed as a vehicle and framework upon which transformational and outcome-oriented focus areas can be constructed for better TB research internationally towards elimination of the disease.

Only by close coordination between these players and a strong advocacy network will the world achieve the scientific breakthroughs needed to eliminate TB by 2050 and prevent the loss of the nearly 1.45 million lives that TB claims annually.

Appendix 1

Table 6.1

2010 and 2009 Top Reporting TB R&D Funders

2010 Rank	2009 Rank	Funding Organization	Funder Type
1	1	US NIAID, NIH	P
2	2	Bill & Melinda Gates Foundation (BMGF)	F
3	3	Otsuka Pharmaceutical Co. Ltd (Otsuka)	C
4	5	US Other Institutes & Centers, NIH (US Other NIH ICs)	P
5	4	European Commission: Research Directorate-General (EC)	P
6	7	Company X	C
7	8	US Centers for Disease Control (US CDC)	P
8	10	United States Agency for International Development (USAID)	P-D
9	9	UK Department for International Development (UK DfID)	P-D
10	12	AstraZeneca	C
11	11	US National Heart, Lung, & Blood Institute (US NHLBI, NIH)	P
12	6	UK Medical Research Council (UK MRC)	P
13	29	Institut Pasteur	P
14	15	Wellcome Trust	F
15	23	Novartis	C
16	13	Dutch Ministry of Foreign Affairs - Directorate General of Development Cooperation (DGIS)	P-D
17	16	German Federal Ministry of Education and Research (BMBF)	P
18	84	World Health Organization (WHO)	M
19		US President's Emergency Plan for AIDS Relief (US PEPFAR)	P-D
20	22	Sequella	C
21	20	Statens Serum Institut (SSI)	P
22	19	UK Health Protection Agency/National Institute for Health Research (UK HPA/NIHR)	P
23	25	Max Planck Institute for Infection Biology (MPIIB)	P
24		Sandoz	C
25	26	Emergent Biosolutions	C

Total	Basic Science	Infrastructure/ Unspecified	Diagnostics	Drugs	Vaccines	Operational Research
$158,030,390	$56,087,492	$23,199,096	$15,827,177	$41,871,408	$12,903,672	$8,141,545
$115,259,533	$4,426,910	$35,489,161	$14,728,436	$20,707,825	$30,449,862	$9,457,339
$63,648,753	$0	$0	$0	$63,648,753	$0	$0
$52,363,574	$16,231,201	$12,512,524	$1,664,190	$5,290,414	$1,829,905	$14,835,340
$25,381,045	$3,984,328	$2,011,431	$411,115	$7,670,696	$10,574,487	$728,987
$20,645,794	$0	$0	$0	$20,645,794	$0	$0
$19,865,178	$0	$4,039,629	$1,706,565	$10,968,228	$0	$3,150,756
$19,791,027	$0	$500,000	$1,802,000	$7,046,029	$0	$10,442,998
$16,912,287	$0	$44,996	$749,930	$10,775,450	$3,646,920	$1,694,991
$14,023,381	$0	$0	$0	$14,023,381	$0	$0
$13,682,412	$9,646,805	$979,210	$3,025,744	$0	$30,653	$0
$13,567,720	$9,368,082	$0	$118,609	$2,172,823	$1,779,773	$128,433
$11,631,674	$7,753,672	$0	$646,043	$2,919,059	$312,899	$0
$5,963,591	$2,159,208	$305,338	$440,928	$256,475	$183,818	$2,617,824
$5,730,352	$5,730,352	$0	$0	$0	$0	$0
$4,333,160	$0	$0	$939,030	$500,560	$2,171,571	$721,999
$4,226,003	$1,900,599	$55,960	$31,601	$474,044	$1,763,798	$0
$3,650,090	$285,129	$3,516	$0	$3,261,920	$0	$99,526
$3,634,321	$0	$0	$0	$0	$0	$3,634,321
$3,564,212	$0	$0	$244,104	$3,320,108	$0	$0
$3,452,820	$0	$0	$0	$0	$3,452,820	$0
$3,413,681	$962,910	$1,279,381	$0	$0	$1,171,391	$0
$3,100,000	$1,500,000	$0	$0	$0	$1,600,000	$0
$3,000,000	$0	$0	$0	$3,000,000	$0	$0
$2,791,239	$0	$0	$0	$0	$2,791,239	$0

P = Public Sector R&D Agency P-D = Public Sector Development Agency
F = Foundation/Philanthropy C = Corporation/Private Sector M = Multilateral

Appendix 1 (continued)

Table 6.2

2010 and 2009 Top Reporting TB R&D Funders (continued)

2010 Rank	2009 Rank	Funding Organization	Funder Type
26	34	Australian National Health and Medical Research Council (Australia NHMRC)	P
27	33	Sweden (reported)	P
28	17	India (reported)	P
29	40	UBS Optimus Foundation	F
30	32	Eli Lilly and Company	C
31	63	UK Department of Health (UK DoH)	P
32	31	Pfizer Inc	C
33	43	Japan (reported)	P
34	36	Irish Aid - Ireland Development Corporation	P-D
35	42	PEPSICO	C
36	44	Switzerland (reported)	P
37	68	Korea (reported)	P
38	41	South African Department of Science and Technology (South Africa DST)	P
39	28	Agence Nationale de Recherche sur la SIDA (ANRS)	P
40	27	Norway (reported)	P
41	35	Brazil (reported)	P
42	51	Damien Foundation	F
43	57	Carlos III Health Institute	P
44	53	US Food and Drug Administration (FDA)	P
55	55	Stanley Thomas Johnson Foundation	F
60	49	World Health Organization (WHO): Stop TB Partnership	M
62	73	Fondation Merieux	F
68	66	Thrasher Research Fund	F
		New Funders Under $500K	
		Grand Total	

Total	Basic Science	Infrastructure/ Unspecified	Diagnostics	Drugs	Vaccines	Operational Research
$2,549,818	$486,257	$190,859	$0	$611,802	$535,797	$725,102
$2,034,384	$1,566,878	$97,751	$0	$318,307	$51,448	$0
$1,654,804	$845,402	$761,401	$0	$0	$0	$48,000
$1,625,000	$0	$0	$780,000	$304,200	$0	$540,800
$1,500,000	$0	$0	$0	$1,500,000	$0	$0
$1,499,860	$0	$0	$0	$0	$1,499,860	$0
$1,418,442	$169,895	$0	$0	$1,248,547	$0	$0
$1,270,204	$0	$1,270,204	$0	$0	$0	$0
$1,221,470	$0	$0	$0	$1,221,470	$0	$0
$1,153,583	$1,153,583	$0	$0	$0	$0	$0
$1,092,053	$743,784	$0	$0	$59,769	$0	$288,500
$1,008,200	$0	$0	$0	$1,000,000	$8,200	$0
$978,750	$848,250	$0	$0	$0	$130,500	$0
$974,075	$0	$0	$0	$974,075	$0	$0
$717,382	$0	$0	$717,382	$0	$0	$0
$672,433	$0	$215,212	$304,056	$0	$0	$153,165
$476,448	$0	$0	$71,032	$0	$0	$405,416
$460,556	$372,965	$0	$29,642	$57,949	$0	$0
$400,000	$0	$0	$0	$400,000	$0	$0
$138,851	$0	$0	$83,310	$55,540	$0	$0
$62,500	$0	$0	$0	$62,500	$0	$0
$61,243	$0	$0	$0	$0	$61,243	$0
$30,625	$0	$0	$13,375	$8,917	$8,333	$0
$1,095,825	$372,965	$0	$126,327	$526,957	$69,576	$0
$617,090,943	**$126,666,203**	**$82,955,669**	**$44,556,101**	**$226,822,544**	**$78,013,133**	**$58,077,293**

P = Public Sector R&D Agency P-D = Public Sector Development Agency
F = Foundation/Philanthropy C = Corporation/Private Sector M = Multilateral

Appendix 2

FIGURE 13

TB R&D Funders Ranked 1—10 That Invested Above $500,000 USD & Funders That TAG Has Tracked in Previous Years: 2005—2010

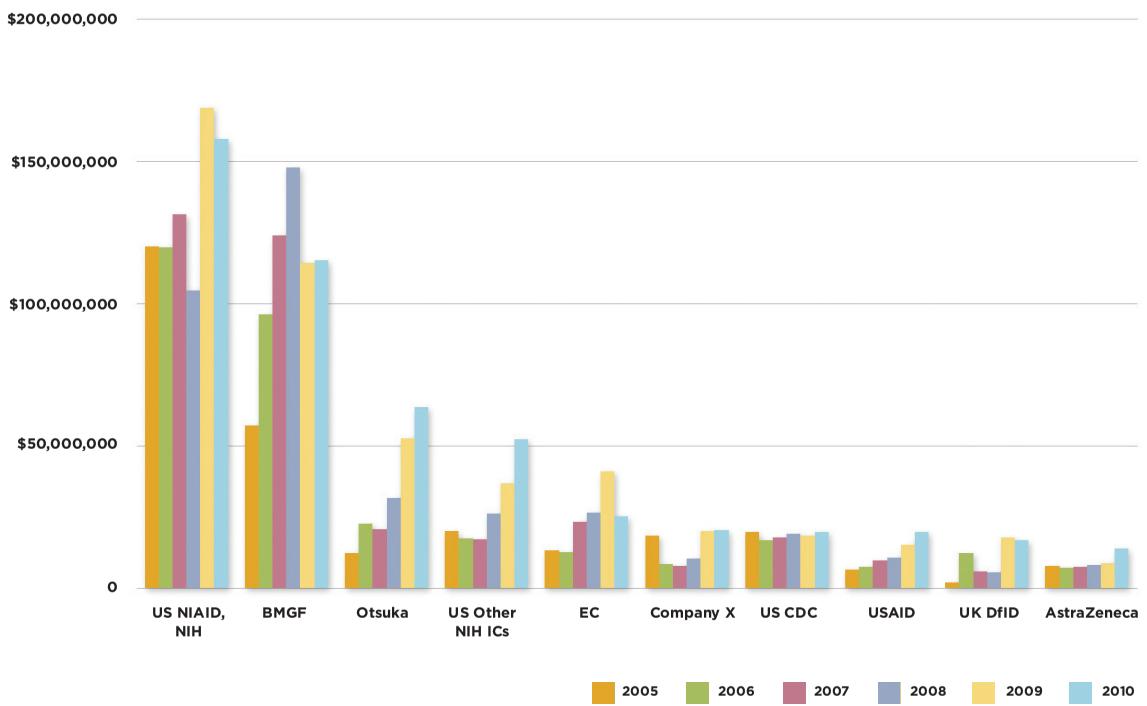


FIGURE 14

TB R&D Funders Ranked 11—20 That Invested Above $500,000 USD & Funders That TAG Has Tracked in Previous Years: 2005—2010

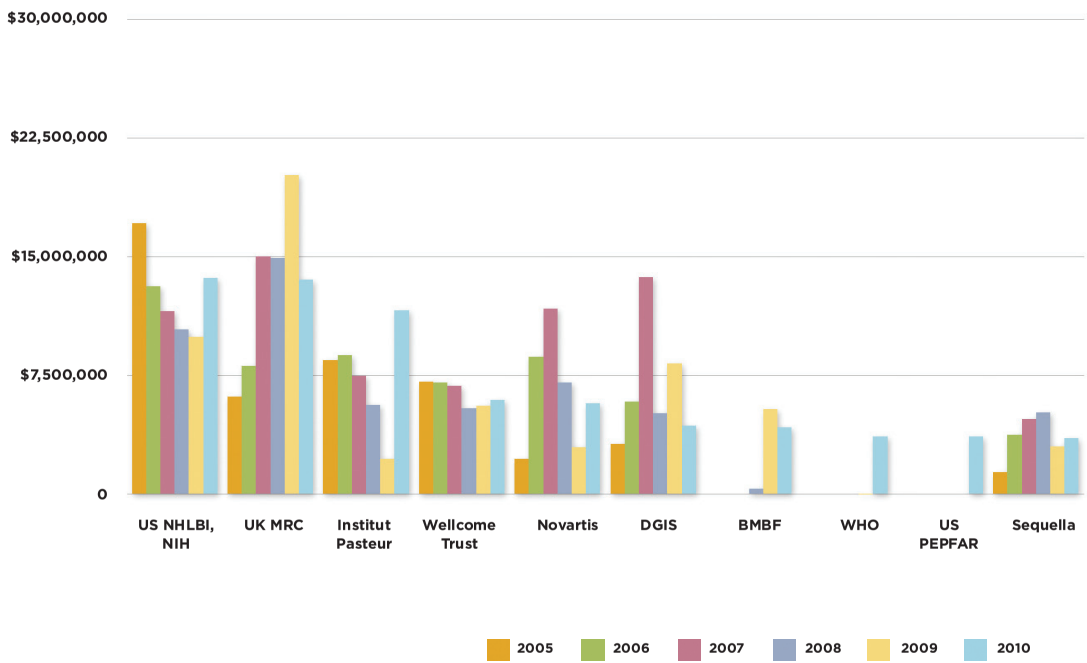


FIGURE 15

TB R&D Funders Ranked 21—30 That Invested Above $500,000 USD & Funders That TAG Has Tracked in Previous Years: 2005—2010

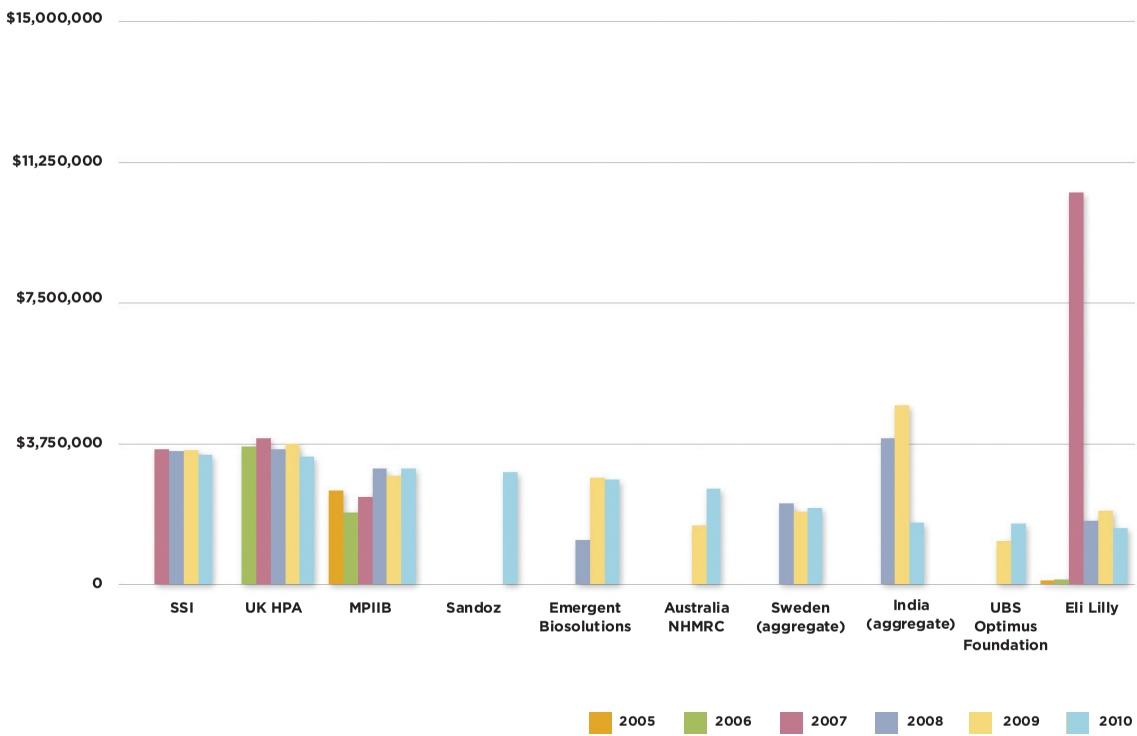


FIGURE 16

TB R&D Funders Ranked 31—41 That Invested Above $500,000 USD & Funders That TAG Has Tracked in Previous Years: 2005—2010

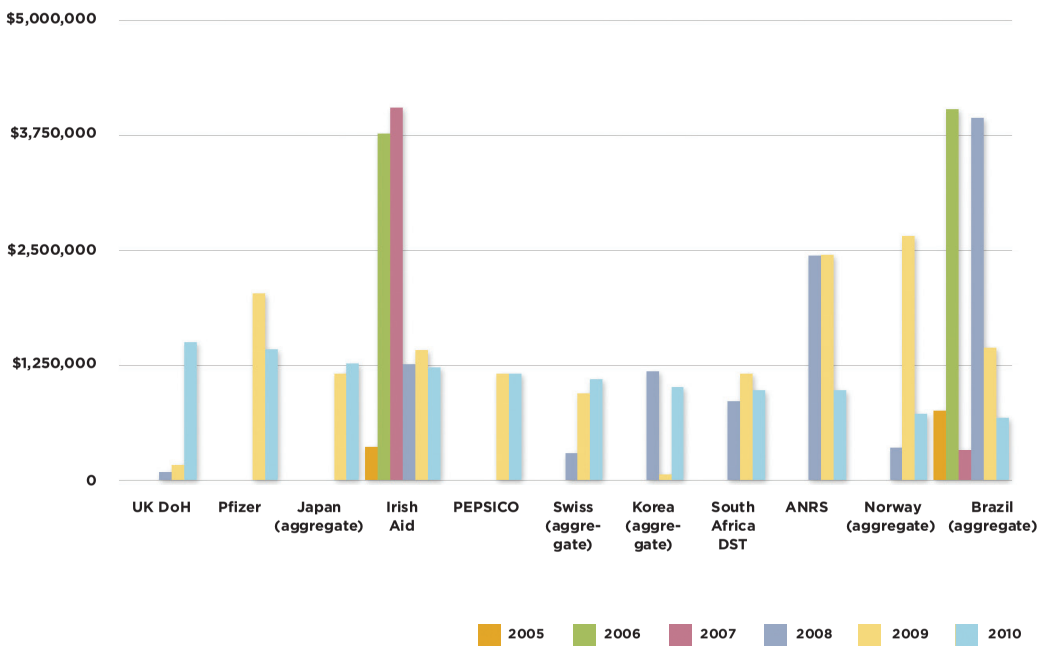


FIGURE 17

TB R&D Funders Ranked 42—48 That Invested Less Than $500,000 USD & Funders That TAG Has Tracked in Previous Years: 2005—2010

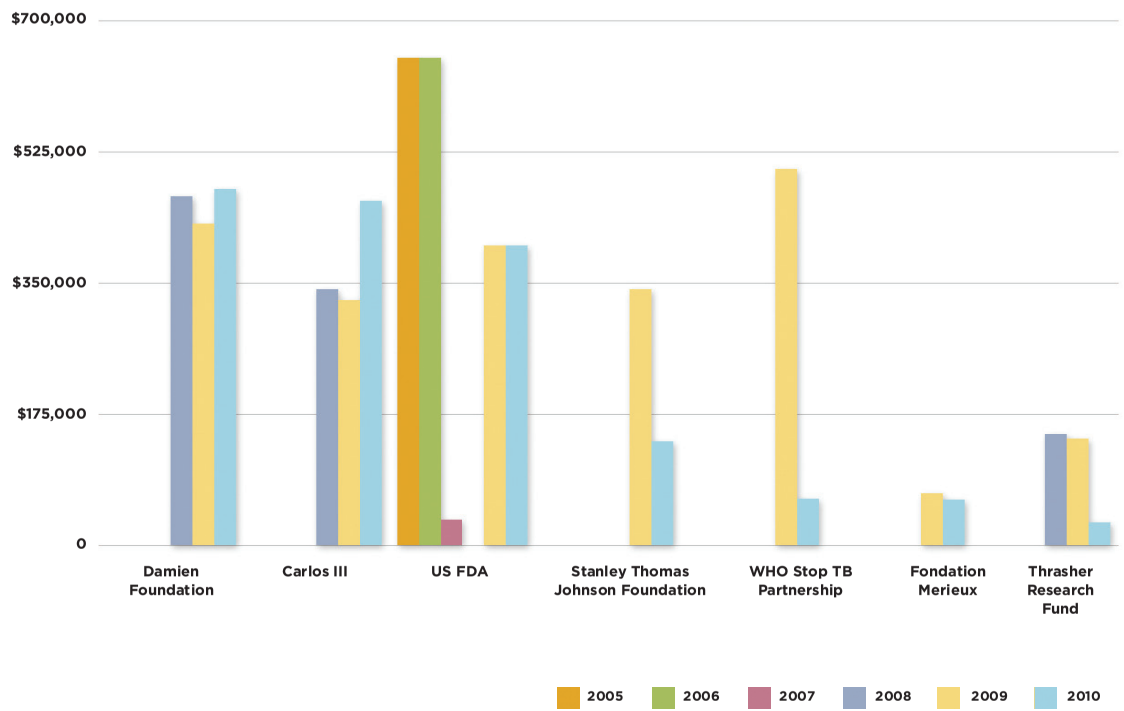


FIGURE 18

TB R&D Funders Inactive or Unresponsive in 2010, 1—10

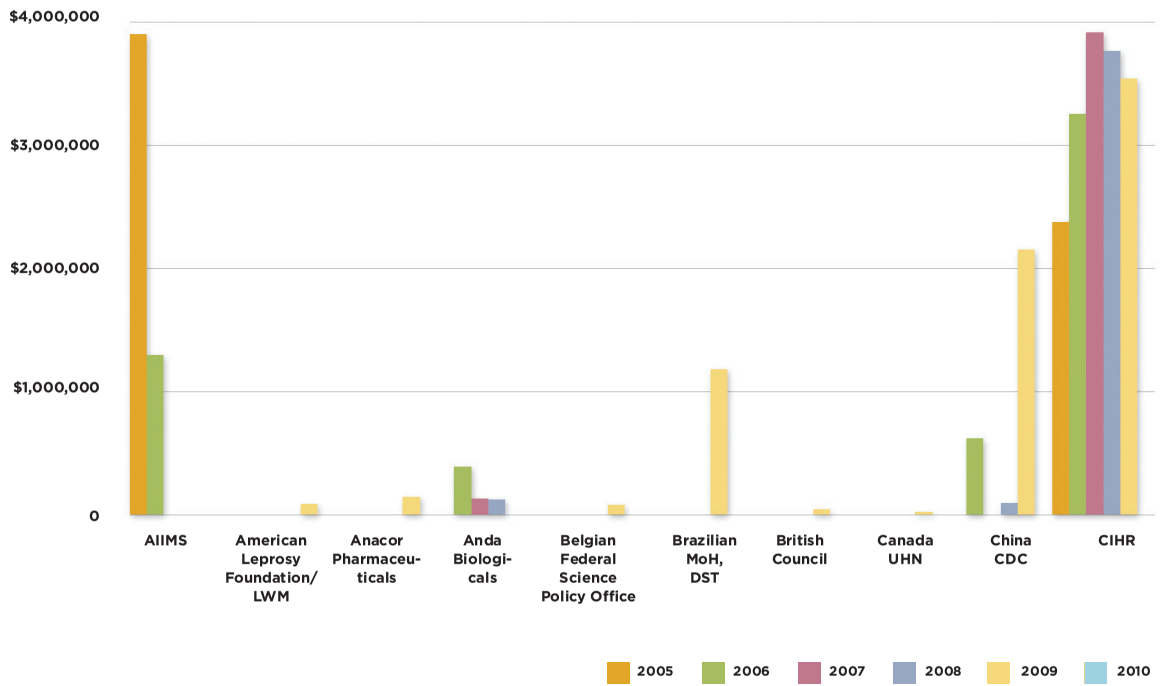


FIGURE 19

TB R&D Funders Inactive or Unresponsive in 2010, 11—20

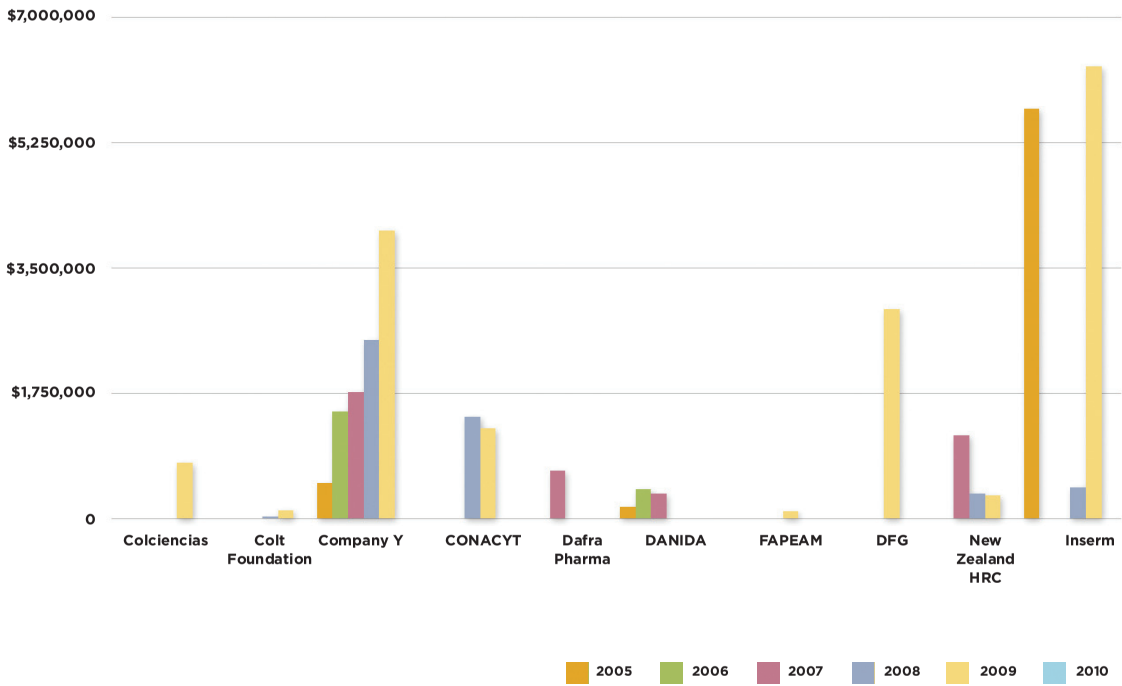


FIGURE 20

TB R&D Funders Inactive or Unresponsive in 2010, 21—30

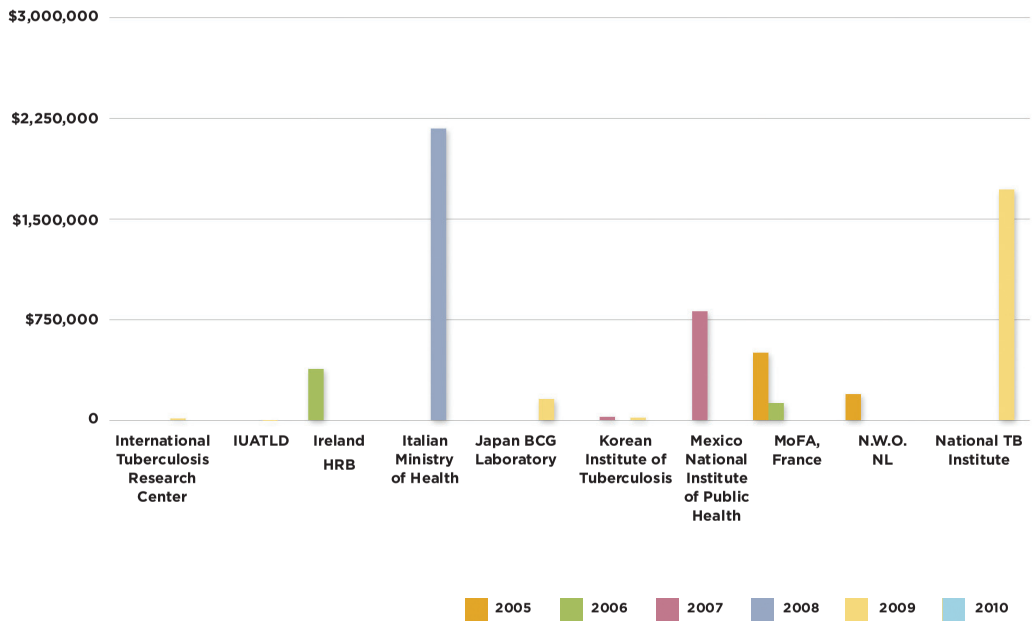
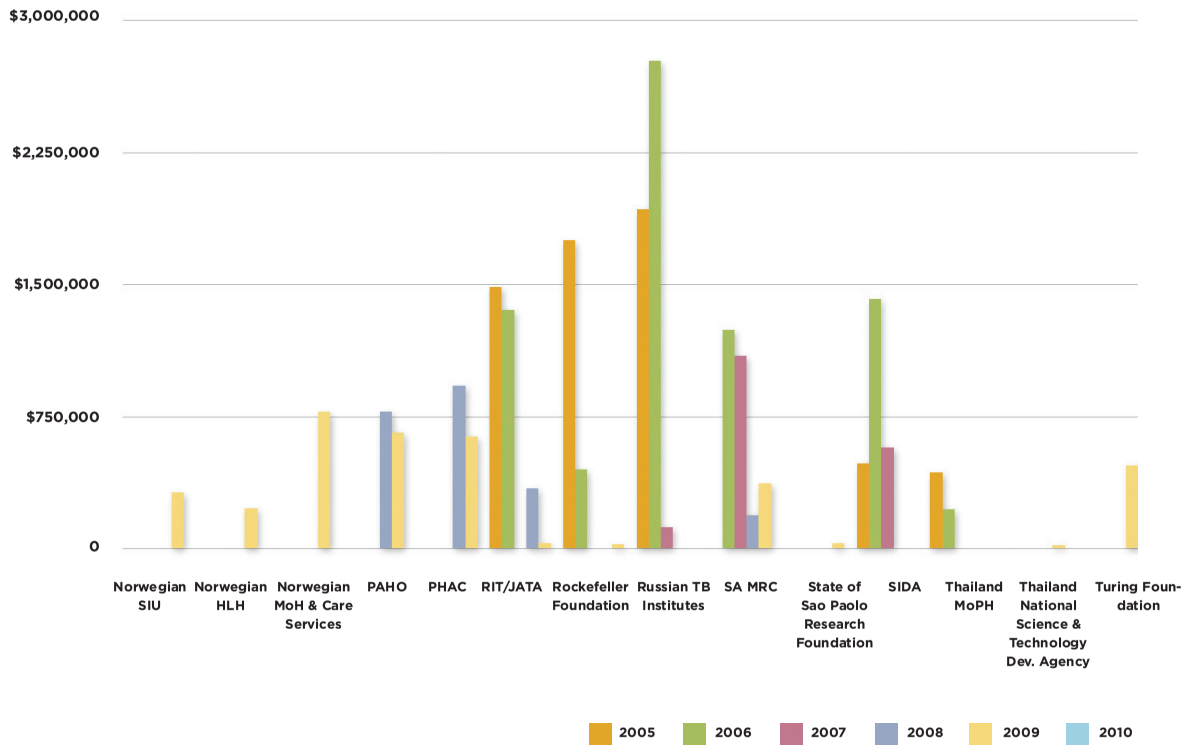


FIGURE 21

TB R&D Funders Inactive or Unresponsive in 2010, 31—44



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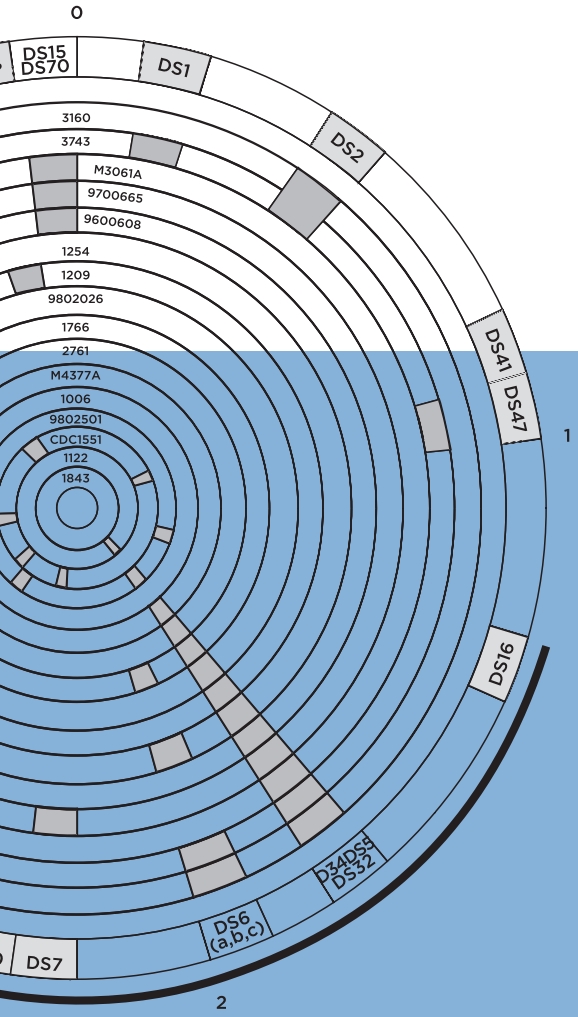

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