

EXECUTIVE SUMMARY

The survey

Each year since 2007, the G-FINDER project has provided policy-makers, donors, researchers and industry with a comprehensive analysis of global investment into research and development (R&D) of new products to prevent, diagnose, control or cure neglected diseases in developing countries. It provides an up-to-date analysis of how R&D investments are being allocated across diseases and product types, funding trends over time, and where the potential gaps lie.

This is the tenth annual G-FINDER report. In addition to the previous nine years of funding data, it reports on investments made in financial year 2016. In all, 187 organisations completed the survey for FY2016, which covered 33 neglected diseases and all relevant product types: drugs, vaccines (preventive and therapeutic), diagnostics, microbicides and vector control products (pesticides, biological control agents and vaccines targeting animal reservoirs) – as well as basic research.

In 2016, following a review by the G-FINDER Advisory Committee, the bacterial pneumonia & meningitis category was expanded to include developing country-focused basic research for both *Streptococcus pneumoniae* and/or *Neisseria meningitidis*. Developing country-specific research into therapeutic vaccines for HIV/AIDS was also added as a restricted category.

While included in the last two G-FINDER reports, analysis of R&D funding for African viral haemorrhagic fevers (including Ebola) was separated from the neglected disease funding analysis in 2016. A separate scope definition has been developed to identify investments in R&D for all priority emerging infectious diseases identified in the World Health Organization R&D Blueprint for action to prevent epidemics. EID data is not included in this G-FINDER neglected disease report, and will be reported separately.

Findings

In 2016, a reported \$3,203m was invested in neglected disease R&D, consisting of \$3,024m from repeat survey participants (called year-on-year – YOY – funders) and \$179m from irregular survey participants. Total YOY funding for neglected disease R&D increased for the first time since 2012 (up \$99m, 3.4%).

FUNDING BY DISEASE

Global funding for neglected disease R&D increased for the first time since 2012

As in previous years, three diseases – HIV/AIDS, malaria and tuberculosis (TB) – collectively received more than two-thirds (\$2,247m, 70%) of all global funding for neglected disease R&D in 2016. Overall funding for this group of diseases increased slightly (up \$60m, 2.9%), driven by increased investment in HIV/AIDS (up \$83m, 8.3%). Funding for malaria increased modestly (up \$13m, 2.5%), while investment in TB fell by \$37m (down 6.8%).

Diseases in the second funding tier receive between 0.5% and 6.0% of total funding each year. This group includes diarrhoeal diseases, kinetoplastids, dengue, bacterial pneumonia & meningitis, *Salmonella* infections, helminths and hepatitis C (genotypes 4, 5 & 6). Funding for this tier was essentially unchanged from the previous year (up \$0.9m, 0.2%). Only three second tier diseases saw funding increases in 2016: *Salmonella* infections (up \$21m, 32%), kinetoplastids (up \$12m, 12%) and dengue (up \$8.4m, 8.7%). Funding fell for all other second tier diseases, with the largest drop being for diarrhoeal diseases (down \$21m, -14%), followed by hepatitis C (down \$12m, -36%), helminths (down \$3.9m, -5.5%) and bacterial pneumonia & meningitis (down \$3.1m, -3.8%). The most poorly funded neglected diseases covered by the G-FINDER survey – those in the third tier of funding – each receive less than 0.5% of global funding. This tier includes leprosy, cryptococcal meningitis, Buruli ulcer, leptospirosis, trachoma and rheumatic fever. In 2016, leprosy was the best-funded of these diseases (\$11m, 0.3%), while rheumatic fever received less than any other neglected disease (\$1.3m, <0.1%).

Non-disease-specific investment increased to \$261m in 2016, an increase of \$37m (up 17%). Core funding – non-earmarked funds given to organisations working on multiple neglected diseases – accounted for just over half (\$136m, 52%) of all non-disease-specific investment in 2016, an increase of \$15m (up 14%). Platform technologies – tools that can potentially be applied to a range of areas, but which are not yet focused on a specific product or disease – received \$52m in 2016 (20% of all non-disease-specific funding); the largest investment ever reported for this area.

FUNDERS

All three sectors increased their funding for neglected disease R&D in 2016. This was the first increase in several years from both the public sector (up \$49m, 2.6%) and the philanthropic sector (up \$28m, 4.4%), while industry (up \$22m, 5.3%) increased its investment for the fifth year in a row. The public sector remained the most significant source of neglected disease R&D funding in 2016, contributing just under two-thirds (\$2,034m, 64%) of the global total. As in previous years, most public sector funding came from HIC governments and multilaterals (\$1,951m, 96%).

The top three public funders in 2016 were the US, the UK and the European Commission (EC)¹, with the US contributing nearly three-quarters of all public investment in neglected disease R&D (\$1,490m, 73%). The US also provided the largest increase in public funding (up \$78m, 5.5%), followed by the Netherlands (up \$18m, 447%) and the UK (up \$9.3m, 10%). All of the notable decreases in public funding for neglected disease R&D in 2016 came from European funders. The most significant reduction came from the EC (down \$49m, -39%), although this was largely linked to uneven disbursements to the European and Developing Countries Clinical Trials Partnership (EDCTP). Nearly two-thirds (59%) of all HIC government and multilateral funding went to basic and early stage research, with only a quarter (27%) going to clinical or field development and post registration studies.

The philanthropic sector provided \$671m for neglected disease R&D in 2016, representing 21% of total global funding. The Gates Foundation and the Wellcome Trust collectively provided the vast majority (\$642m, 96%) of all philanthropic funding, and both increased their investment in 2016 (up \$12m, 2.3% and up \$17m, 21%, respectively). A third (34%) of all philanthropic funding for neglected disease R&D was for basic and early stage research, most of which was for discovery and pre-clinical R&D, a quarter (26%) was for clinical or field development and post registration studies, and the remaining 40% was largely provided in a portfolio-based approach, to support product development from discovery through to registration.

¹ The term 'EC' refers to funding from the EU budget that is managed by the European Commission or related EU partnerships and initiatives, such as the European & Developing Countries Clinical Trials Partnership and Innovative Medicines Initiative

Two-thirds of funding to researchers and developers was for basic and early stage research

The private sector invested \$497m in neglected disease R&D in 2016, accounting for 16% of total global funding. For the second year in a row, the increase in industry investment was entirely driven by small pharmaceutical and biotechnology firms (SMEs, up \$23m, 30%). Most of this increase came from SMEs in innovative developing countries (IDCs), and was directed towards bacterial pneumonia & meningitis (up \$10m, 43%) and *Salmonella* (up \$9.4m, 86%). More than three-quarters of all SME investment was in clinical or field development and post registration studies (\$82m, 78%), with most of the remainder invested in basic and early stage research (\$16m, 15%).

FUNDING FLOWS

Almost three-quarters (\$2,352m, 73%) of all neglected disease R&D funding in 2016 was external investment in the form of grants. Of this funding, 79% (\$1,851m) went directly to researchers and developers, 18% (\$420m) was for product development partnerships (PDPs), and the remaining \$80m (3.4%) was channelled through other intermediary organisations. Direct YOY funding to researchers and developers increased for the first time since 2012 (up \$147m, 9.1%), driven by both S&T agencies and philanthropic organisations. Funding to PDPs decreased by \$29m (-6.8%), to the lowest level recorded in the history of the G-FINDER survey, although most of the drop in 2016 could be attributed to the highly cyclical nature of grant funding to PDPs, especially from the Gates Foundation. Funding to other intermediary organisations decreased by \$23m (-25%), primarily due to lower funding from the EC to EDCTP.

Almost two-thirds (62%) of all funding given directly to researchers and developers went to basic and early stage research, with just 22% for clinical or field development and post registration studies. The very different pattern of funding given to PDPs reflects their product-development focus. More than two-fifths (42%) of all funding to PDPs was for clinical or field development and post registration studies, more than double the amount (19%) that was for basic and early stage research (essentially all of which was for discovery and pre-clinical R&D, rather than basic research).

Internal investment accounted for \$851m (27%) of total neglected disease R&D funding. This was essentially steady (up \$4.7m, 0.6%), with ongoing growth in industry investment (up \$20m, 4.6%), particularly from SMEs, offset by internal investment by government agencies (down \$19m, -5.1%). The allocation of internal investment depended on the type of organisation; where two-thirds (66%) of industry self-funding was for clinical or field development and post registration studies, non-industry self-funding was focused more on basic and early stage research (49%).

DISCUSSION

Global funding for neglected disease R&D increased for the first time since 2012, driven by an increase in funding from the US government

- Global funding for neglected disease R&D increased (up \$99m, 3.4%) to \$3,203m in 2016. This was the first increase in global funding since 2012, and was driven by increased investment from the US government (up \$78m, 5.5%).
- The US government was not alone in increasing funding for neglected disease R&D in 2016. The philanthropic sector and the pharmaceutical industry (particularly SMEs) also increased their investment, as did the UK, Dutch and a number of non-European governments, which – in conjunction with the US government increase – was enough to result in an overall increase in public funding, despite lower investment from the EC and several other European governments.
- However, as the largest funder, the US government is the primary driver of changes in global funding for neglected disease R&D: every increase or decrease in US government funding over the last decade has been accompanied by a corresponding change in global investment.

An overreliance on US government funding is defining the shape of R&D for neglected diseases

- The US government's investment of \$1,490m in 2016 was triple the combined investment of the rest of the world's governments, and fifteen times larger than that of the next biggest government funder (the UK, with \$101m).
- 82% of all US government funding for neglected disease R&D in 2016 – and consequently 70% of all global funding – was for HIV/AIDS, TB and malaria.
- Excluding the quarter of a billion dollars the US government invested in HIV vaccine clinical trials in 2016, 80% of all remaining US government funding for neglected disease R&D – and 70% of all funding from HIC governments – was for basic and early stage research, compared to just 14% for clinical or field development and post registration studies.

The sustained growth in industry investment in neglected disease R&D – lately driven by SMEs – continues to be a good news story

- Industry investment in neglected disease R&D has increased in every one of the last five years, and reached new record highs in each of the last three years. Since 2008, reported industry investment has increased by nearly 50%, while funding from both the public and philanthropic sectors has fallen.
- The vast bulk of industry investment – and the majority of the increase in industry funding since 2008 – has come from MNCs. Since 2014 however, MNC investment has essentially plateaued, with annual increases of less than 1% in both 2015 and 2016.
- Increased investment by SMEs since 2012, particularly from those in India, has helped to sustain the growth of overall industry investment. Importantly, much of this investment growth has also been in new areas: two-thirds of all SME investment in 2016 was for bacterial pneumonia & meningitis, *Salmonella* infections and diarrhoeal diseases.

In addition to SMEs, a number of other funders have been making a small but growing contribution in areas of need

- A number of key global health initiatives – Unitaid, MSF and Gavi – have expanded their focus to include support for neglected disease R&D, particularly for clinical or field development and post registration studies.
- The Japanese government – along with Japanese pharmaceutical companies – is increasingly investing in neglected disease product development following the establishment of the GHIT Fund, recording its highest ever investment in 2016.
- Funding from LMIC governments grew by \$18m (up 30%) in 2016, to \$84m, with India becoming the fourth largest government funder of neglected disease R&D, ahead of both France and Germany.

Conclusion

The US government's contribution to neglected disease R&D funding is unparalleled. But an overreliance on US government funding is reflected in the heavy concentration of global funding on HIV/AIDS, malaria and TB, and the overwhelming focus of HIC government funding on basic and early stage research. The growth of non-traditional funders is promising, but their collective contribution is still just a fraction of overall global funding. And while Gates Foundation investment in product development has consistently been relied on to balance the public sector focus on basic research – it has provided 55% of all funding to PDPs and 47% of all funding for platform technologies over the last decade – this is again a reflection of overreliance on a single funder. The world can ill afford to keep relying on the US government and the Gates Foundation to provide two-thirds of all global funding for neglected disease R&D over the next ten years, as they have done for the last decade.