G-FINDER FACTSHEET

DIAGNOSTIC R&D FOR NEGLECTED DISEASES

Malaria samples being prepared for FIND's Rapid Diagnostic Test product testing project (*Photo by Sandra Incardona*)

Effective diagnostics are essential tools for the control, elimination and eradication of neglected diseases, with the ability to quickly and accurately identify infections critical to ensuring that patients receive the treatment they need and halting the further spread of disease.

At the public health level, one of the great challenges to monitoring disease emergence and delivering appropriate control measures is the lack of readily-available, easy-to-use, reliable and low-cost diagnostic tools. The inability to accurately diagnose infections leads to individual patients being incorrectly treated and increases the risk of diseases spreading and drug-resistance emerging within populations (for example artemisinin-resistant malaria, or extensively drug resistant tuberculosis).

Diagnostics are a smart investment. As they do not require direct testing on humans they are relatively cheap to develop when compared to vaccines or drugs, which require stringent clinical trials. The development of a simple diagnostic tool may cost as little as $2m and up to $50m for a more complex tool. Their fewer regulatory requirements during the development process also mean that new diagnostics are easier to develop for smaller companies or academic groups, and can reach the market – and patients – far more quickly than drugs or vaccines.

Despite the pressing need for new diagnostics, and the obvious advantages to developing effective diagnostic tools, current funding levels for research and development (R&D) of new diagnostics are insufficient to meet the needs of many neglected diseases. This factsheet examines funding of diagnostic R&D globally, based on G-FINDER data[1], and discusses the urgent need to rationalise funding, diversify funding sources and increase priority driven investments.

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[1] G-FINDER figures are adjusted for inflation and reported in 2007 US dollars.
All diagnostic R&D areas are included in G-FINDER scope such as diagnostic platform tools, individual tools, surveillance tools etc.

DIAGNOSTIC FUNDING

Diagnostic R&D funding relies heavily on the public sector and, to a lesser degree, on philanthropy

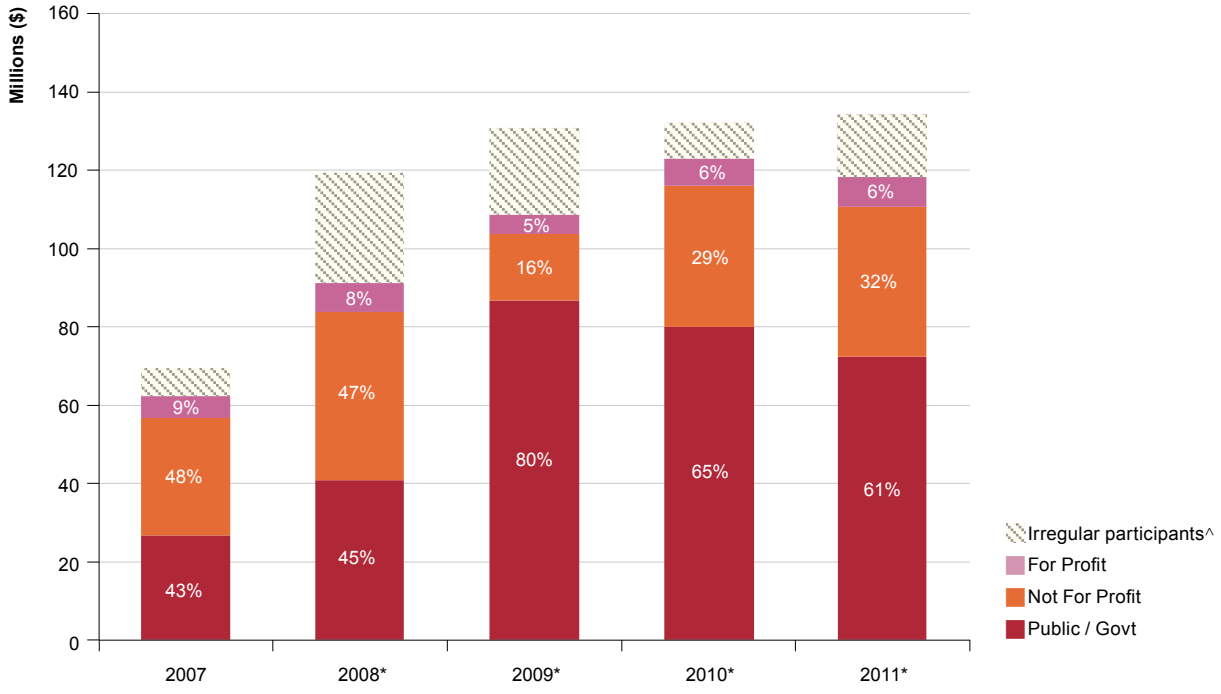
In recent years there has been a remarkable doubling of funding for R&D of new diagnostics for the developing world, from $62m to $118m between 2007 and 2011. However, these increases are still well below the levels needed to achieve the desired global health goals. For instance, the 2010 Staying the Course report estimated that diagnostics funding for malaria alone needed to quadruple urgently from $12m in 2009 to around $50m per year to meet the goals signed up to by the global malaria community.[2] Updated figures indicate that only half of this target has so far been met.

Funding for diagnostic R&D relies heavily on the public sector and, to a lesser degree, on philanthropy. Governments have provided half to two-thirds of diagnostic R&D funding each year since records commenced in 2007, with public funding almost tripling overall during that time. However, we note that much of this increase occurred before the Global Financial Crisis created a climate of public austerity, and that public funding has been in decline since its 2009 peak (down 17%, $14m since then).

Philanthropic organisations have been the second largest overall contributors to diagnostic R&D over the past five years, with the Gates Foundation providing 97% of philanthropic funding. While philanthropic funding growth has been outstripped by that of the public sector over the past five years, this may yet change given its relative robustness since the Financial Crisis.

Industry has been a relative non-player in diagnostic development for neglected diseases, with reported industry funding ranging from a modest $5m to $8m per year for each of the past five years. This may reflect a lack of diagnostic industry investment in global health, or may be an artefact of their limited participation in the G-FINDER survey from which our diagnostic R&D investment data is drawn. For instance, large firms known to have worked on global health diagnostics no longer submit data to G-FINDER, nor do many smaller diagnostic developers.

Figure 1: Diagnostics funding by funder type (2007-2011)



^ Regular participants are those who have reported to G-FINDER in every year of the survey. In order to avoid artefactual changes related to data collection, funding from irregular participants is not included in our trend analysis.
* Figures are adjusted for inflation and reported in 2007 US dollars

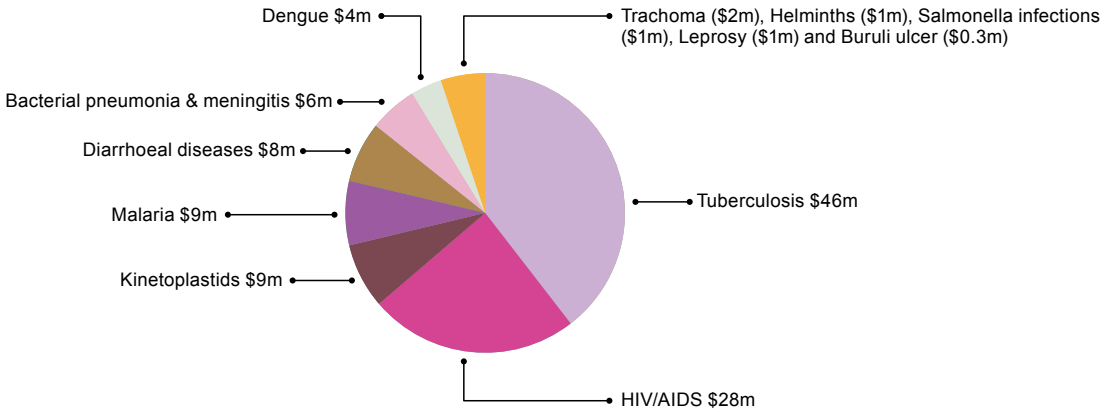
[2] Program for Appropriate Technology in Health (PATH). Staying the course? Malaria research and development in a time of economic uncertainty. Seattle: PATH; 2011.

DISEASE DIAGNOSTICS

There is a serious inequity in the allocation of diagnostic R&D funding, with two diseases - tuberculosis and HIV/AIDS - receiving by far the highest percentage of diagnostic R&D funding from every investment sector and in almost every year.

Tuberculosis (TB) diagnostics were the clear leader in funding terms, receiving on average $46m each year. HIV/AIDS was the next best funded area, although lagging well behind TB, with peak investment linked to increased US National Institutes of Health investment as part of the US Government stimulus under the American Recovery and Reinvestment Act (ARRA). All other diseases received less than $10m per year – and often far less. Malaria falls somewhere in between: funding has been very low but gradually increasing, so that investment in malaria diagnostics breached the $10m barrier for the first time in 2011.

Figure 2: Average diagnostic funding by disease, 2007-2011^



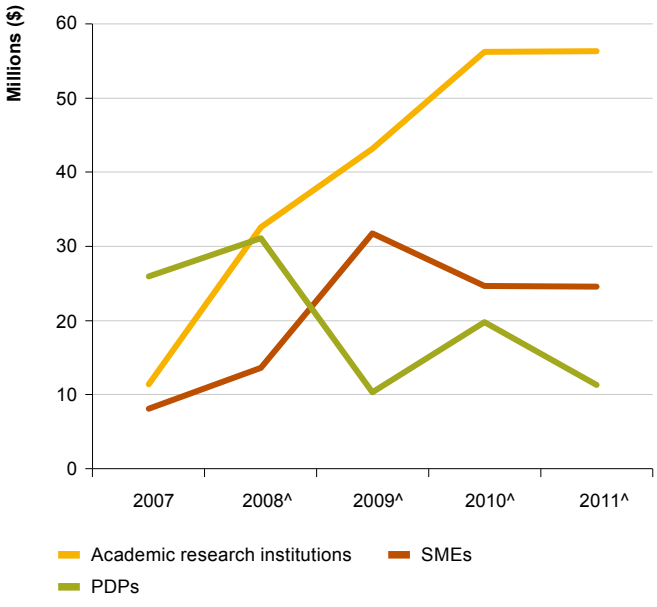
^ Figures are adjusted for inflation and reported in 2007 US dollars

DIAGNOSTIC DEVELOPERS

Around 80% ($402m) of the half a billion dollars invested in diagnostic product development between 2007 and 2011 was in the form of grants to developers, with three quarters given directly to product developers, mainly in the public sector (48% of all external funding) and industry (18% of external funding); and one quarter managed by Product Development Partnerships (PDPs) and other intermediary organisations. The remaining one fifth ($101m) of funding was in the form of internal research investments by public research institutions (58%) and the pharmaceutical industry (32%).

The key story over the period from 2007-2011 has been the growing prominence of academic research institutions, who received 40% ($200m) of all diagnostic R&D funding over this period. In 2011 academic researchers received $56m, up from just $11m in 2007, with public sector grants accounting for 73% of this increase.

Figure 3: Funding to product developers (grants and internal investment)



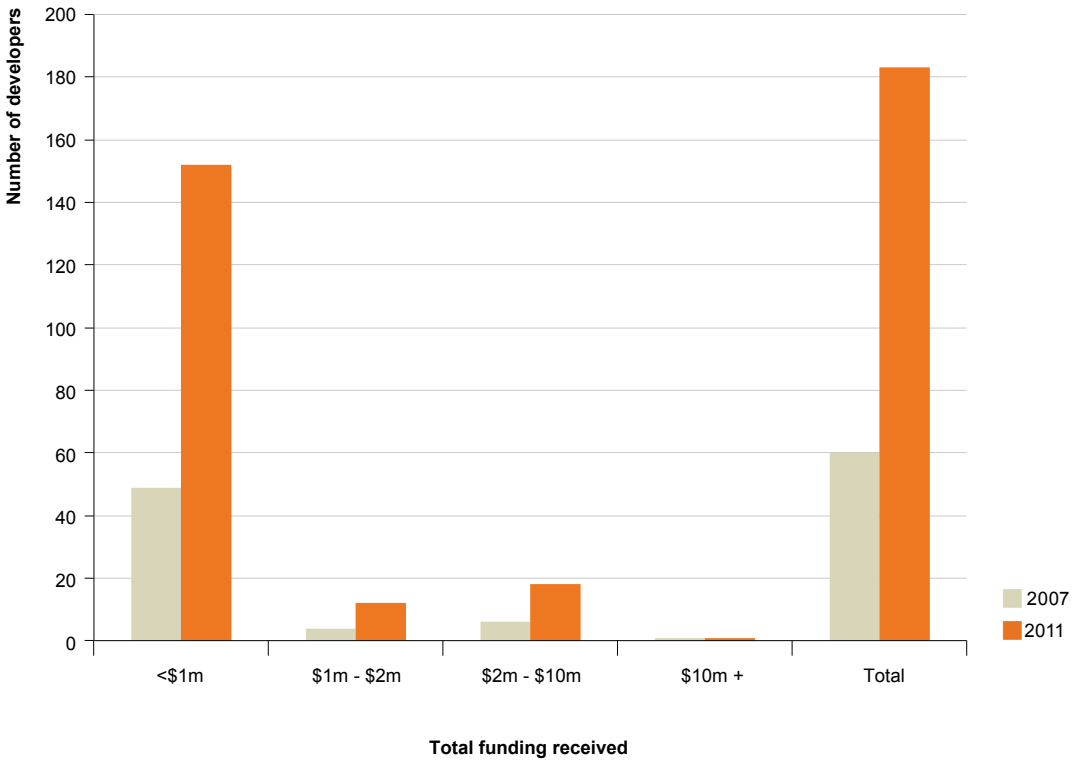
^ Figures are adjusted for inflation and reported in 2007 US dollars

The other key recipients of diagnostic R&D funding are small pharmaceutical and biotechnology companies (SMEs) – which comprised 97% of all industry funding, nearly three-quarters of which came from external funders - and PDPs; but these two groups have been on almost diametrically opposite funding trajectories. Funding to SMEs increased from less than $10m in 2007 to remain steady at $25-30m per year from 2009-2011. In contrast, funding for PDPs more than halved over the same period, going from $26m in 2007 to $11m in 2011. This decrease was tied in large part to the fortunes of the Foundation for Innovative New Diagnostics (FIND), which received 84% of all funding given to PDPs from 2007-2011, but whose funding was just $8m in 2011 from a peak of $28m in 2008, although these changes may reflect cyclical grant disbursement.

The growth in funding to academic researchers has been accompanied by a tripling in the total number of diagnostic developers (from 60 in 2007 to 183 in 2011). Notably, 84% of these new developers were small organisations who received less than $1m per year, of which the majority (70%) were academic and public institutions. Only a handful of organisations received funding at levels that were consistent with commercialising a new diagnostic for developing world use.

(*Photo by iStockphoto*)

Figure 4: Total funding size received by diagnostic developers 2007-2011^



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

CASE STUDY:
Foundation for Innovative New Diagnostics (FIND)

The Foundation for Innovative New Diagnostics (FIND) is a non-profit PDP that aims to deliver affordable, and easy-to-use diagnostic tests appropriate for use in the poorest areas of the world. It is the primary PDP in the area of diagnostic R&D for neglected diseases, as well as the single biggest recipient of diagnostic R&D funding each year.

Over the past 10 years, FIND has delivered 11 new and improved tests including for tuberculosis (Xpert MTB/RIF[3]), malaria, sleeping sickness and others, and has helped strengthen diagnostic capacity in over 25 countries.

In collaboration with academic and industry partners, FIND recently developed the first highly sensitive molecular diagnostic test for malaria that is suitable for use in remote clinics, and which will be used to support elimination programmes. This test has already been introduced for diagnosis of sleeping sickness and is being adapted for other diseases. FIND has also developed a rapid diagnostic test for sleeping sickness, which allows for faster and more effective screening – a critical step towards the goal of disease elimination by 2020.[4]

However, falling investment in FIND since 2008 (especially for upstream R&D) risks delaying the delivery of projects currently in its pipeline. These include:

- Simple inexpensive tests to replace microscopic detection of tuberculosis
- New tests to rapidly detect resistance to critical drugs for TB
- An adaption of the highly sensitive molecular malaria diagnostic that could scan large numbers of samples automatically
- Low-cost population screening tools to detect malaria in low-transmission areas
- A test to detect congenital Chagas' disease, which will save the lives of the 5-10% of children born with the disease to infected mothers

FIND estimates that an investment of $45m is needed over the next 5 years to deliver these and other diagnostic tests in in its portfolio.

Xpert MTB/RIF demonstration study in Uganda (*Photo by Ajay Kumar Thirumala*)

[3] Keeler et al, Reducing the global burden of tuberculosis: the contribution of improved diagnostics, Nature. 2006 Nov 23;444 Suppl 1:49-57.
[4] Fighting Neglect, MSF, 2012

CONCLUSION & RECOMMENDATIONS

If the world is serious about dealing with neglected and poverty related diseases, increased investments in R&D for new innovative health tools such as diagnostics are urgently needed. This will require:

- **A rapid increase in diagnostic funding for under-funded diseases.** There is an ongoing imbalance in disease funding, with government and investigator interest focused heavily on high-profile diseases, in particular tuberculosis and HIV. While both these diseases definitely need increased diagnostic investment, other diseases with equally large funding gaps – and often higher disease burdens – also remain seriously under-funded. Examples include diagnostics for malaria, diarrhoeal illnesses (which are the second greatest cause of mortality in the developing world), and for second-stage sleeping sickness, where patients must still undergo spinal puncture to diagnose their disease.

- **Diversification of funders, in particular greater philanthropic and industry engagement.** Funding of diagnostic R&D is increasingly dominated by the public sector, largely in the form of grants to academic research institutions. Funding of this type is generally driven by individual investigator interest rather than by strategic research priorities, and this skewed investment profile risks diffusing the impact of the collective global investments in diagnostic R&D. Given the nature of diagnostic development (the small cost, time, low-risk and the availability of public co-funding) high levels of industry involvement would be expected and should be encouraged.

- **Consolidation of developers.** The increasing fragmentation of diagnostic R&D funding is hampering new product development, increasing duplication of research efforts and slowing the product development pathway. Ultimately there is a need to reverse the trend of multiple, small and uncoordinated grants to a growing number of small academic and public research organisations. Funders should concentrate funds on proven developers as well as making better use of the coordination mechanism offered by PDPs (with additional oversight of investment choices if this is a concern for them). This would reduce the inefficiency associated with current funding patterns for diagnostic R&D and make it more strategically-focused, giving funders the most (and most appropriate) health impact for their investments.

Patients await diagnosis in India (*Photo by Jacques Debayle*)

POLICYCURES

G-FINDER
Global Funding of Innovation for Neglected Diseases