HIV VACCINES & MICROBICIDES RESOURCE TRACKING WORKING GROUP

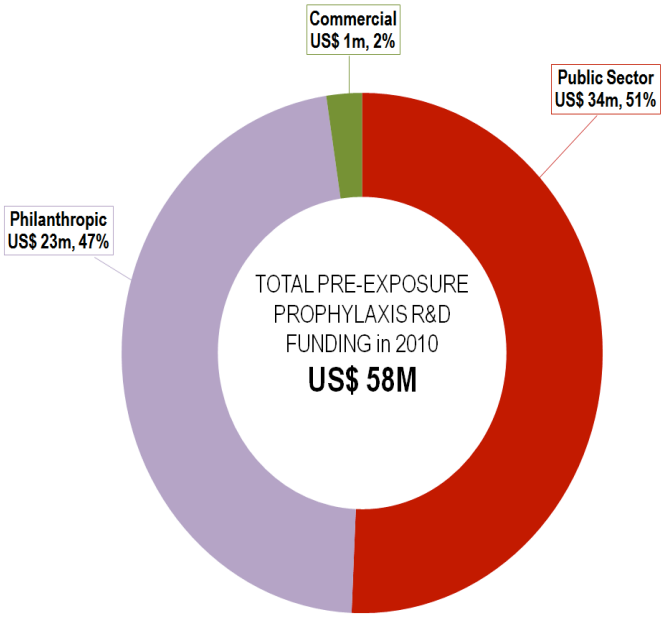
Funding for Pre-Exposure Prophylaxis (PrEP) R&D in 2010

The *HIV Vaccines and Microbicides Resource Tracking Working Group* uses a comprehensive methodology to track annual investment and analyze trends in HIV prevention research and development (R&D) that can be compared from year to year and across funders. In its most recent report, *Capitalizing on Scientific Progress: Investment in HIV Prevention R&D in 2010* the Working Group examined funding for Pre-Exposure Prophylaxis (PrEP) in the context of both recent scientific progress and current economic realities.

PrEP utilizes pre-exposure prophylaxis with antiretroviral (ARV) drugs to prevent HIV infection. Global public-sector and philanthropic investment in oral PrEP has totaled US$205 million over the last five years. Overall PrEP R&D investment totaled US$58 million in 2010, with the public sector providing US$34 million (51%), the philanthropic sector providing US$23 million (47%), the commercial sector contributing US$1.3 million (2%). There are six planned, ongoing or follow-up PrEP trials involving tenofovir (TDF) or tenofovir/emtricitabine (TDF/FTC, also known as Truvada®), and one trial of the ARV TMC278LA injected intramuscularly.

PrEP R&D Funding in a Time of Scientific Progress and Economic Uncertainty

In the year since the last Working Group report, results have been reported from four PrEP trials. In November 2010, the iPrEx trial team announced that daily oral TDF/FTC had reduced risk of HIV infection in men who have sex with men (MSM) and transgender women by an estimated 44 percent overall, proving for the first time that PrEP worked as a method of HIV prevention. In early 2011, the FEM-PrEP trial, which had been testing the use of once-daily oral TDF/FTC in heterosexual women in sub-Saharan Africa, was stopped before its anticipated end date after a scheduled interim data review by an independent data monitoring committee (DSMB) concluded that even if the trial ran to completion, it was highly unlikely to show a benefit. On 13 July 2011, the Partners PrEP trial team announced that its independent DSMB had recommended that the study results be publicly reported and use of placebo discontinued, because of clear demonstration of HIV protection due to PrEP use in the study population. (The Partners PrEP trial was designed to test the safety and efficacy of oral TDF alone or in combination with TDF/FTC for prevention of HIV infection in sero-discordant couples.) The study found that those who received TDF and those who received TDF/FTC had an average of 62% and 73% fewer HIV infections, respectively, compared to placebo. On the same day, the CDC released results from its TDF2 trial in 1,219 HIV-uninfected heterosexual male and female participants in Botswana, which found a statistically significant overall risk reduction of 62.6 percent due to PrEP use of TDF/FTC.



The 2010 funding story for HIV prevention research overall was mixed. Funders, as a whole, can be commended for continuing their support for HIV prevention research in light of budget constraints triggered by the global recession in 2008. The scientific successes of the past two years testify to the importance of the flexible and sustainable funding that allows researchers to shift resources towards promising scientific developments as those appear. Thus, funding structures are required that are agile, and generous enough to adapt rapidly to new opportunities, both in earlier translational research and later-phase clinical research. And now, just as positive clinical evidence and new scientific knowledge become increasingly available, the lack of long-term funding threatens to impede progress, most critically when the next and essential step is a late-stage confirmatory trial.

Please visit www.hivresourcetracking.org for a copy of the full report, *Capitalizing on Scientific Progress: Investment in HIV Prevention R&D in 2010*. The *HIV Vaccines and Microbicides Resource Tracking Working Group* is composed of AVAC: Global Advocacy for HIV Prevention (AVAC) and the International AIDS Vaccine Initiative (IAVI), International Partnership for Microbicides (IPM) and Joint United Nations Programme on HIV/AIDS (UNAIDS).