

Collaborative Research in the Developing World

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Developing World Drug Access

- Gilead has made a commitment to support access to our HIV drugs for studies of treatment and prevention of HIV infection in the developing world
- This includes support of clinical research with collaborative partners such as the NIH, CDC, MRC, and ANRS, as well as investigator initiated efforts
- This commitment also includes access to HIV drugs for treatment through our Global Access Program at no profit pricing (all of Africa and other least developed nations)

Program Metrics

- To date Gilead has evaluated 67 requests for drug and has approved 52
- for 43 studies drug was offered at no cost, and for 9 studies it was offered at no profit pricing (\$0.52 per day for TDF and \$0.82 per day for TVD)
- Total commitment of 33,000 pt years of drug to date (>\$100,000,000 commercial value)
- Drugs provided include TDF, FTC, and TVD

Examples of approved studies

- Treatment trials
 - DART, 5175, 5208, 5221, Camellia
- Pediatric studies
 - FTC
- Prevention studies
 - PMTCT - HPTN 057, ANRS study
 - PREP studies- FHI West Africa, CDC Thailand, CDC Botswana, FHI Malawi, NIH Peru

How Requests are Reviewed

- Reviewed by internal protocol review committee
- Rated according to scientific merit, looking specifically at
 - Integrity of study design
 - Novelty of treatment strategy/concept/information
 - Indication
 - Patient Population

How Requests are Reviewed

- Proposals are categorized as high, medium, or low priority
- For approved studies, drug is offered at no cost or reduced cost , including no profit pricing
- Grant funds are generally not available for developing world studies (focus on providing drug at lowest no profit price)

Outstanding Issues

- Drug supply is not infinite; studies must be prioritized
- Drug can not always be provided free of charge. For low priority approved studies, drug may be provided at local prices or reduced cost, including no profit pricing.
- Study sponsors often do not have funds to purchase drug at no profit pricing
- Regulatory barriers are significant, time consuming, and costly, especially for treatment programs