

## TRI-Supported HIV Trial Contributes to Gilead's sNDA for Truvada® as Pre-Exposure Prophylaxis (PrEP)

Bethesda, Maryland (May 18, 2012): Technical Resources International, Inc. (TRI) is proud to have contributed regulatory and technical support to the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), NIH for the HIV study titled "Chemoprophylaxis for HIV Prevention in Men." Results of this trial, published in the New England Journal of Medicine in 2010, indicated that a daily dose of an oral antiretroviral drug (Gilead's Truvada<sup>®</sup>), currently approved to treat HIV infection, reduced the risk of acquiring HIV infection by 43.8 percent among men who have sex with men. Participants who adhered most closely to the daily drug regimen had the highest rates of effectiveness of up to 72.8 percent.

Partially-based on the results of the iPrEx study, on December 15, 2011, Gilead Sciences, Inc. announced its submission for a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for the use of Truvada<sup>®</sup> for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection among uninfected adults. If approved, Truvada<sup>®</sup> will be the first agent indicated for HIV prevention in uninfected individuals.

The iPrEx study marks a milestone in HIV research with significant new advances in antiretroviral-based HIV prevention. PrEP may be a key public health tool to encourage HIV protective and preventative measures for individuals in serodiscordant relationships worldwide.

**About NIAID:** NIAID is working to end the HIV/AIDS epidemic by advancing basic knowledge of the pathogenesis and transmission of HIV, supporting the improvement of therapies for HIV infection and its complications, and supporting the development of HIV/AIDS vaccines and other prevention measures. NIAID sponsors Phase I, II, III and IV clinical trials to assess the safety and efficacy of therapeutics, vaccines, and other preventive modalities. Currently, NIAID funds more than 300 HIV/AIDS clinical trials in more than 50 countries at more than 1,000 domestic and international clinical research sites.

**About TRI:** Technical Resources International, Inc. is a full-service contract research organization. TRI has provided regulatory and safety support to DAIDS studies since 2003 (via the Regulatory Compliance Center [N01-AI-30032] and Regulatory Support Center [HHSN272201000013C] contracts, through which 100% of the funding to this iPrEx study was financed) and other NIAID and AIDS Program support since 1988. TRI's areas of expertise include clinical operations, regulatory affairs, safety & pharmacovigilance, medical writing, clinical data management, biostatistics, quality assurance, information technology, and communications. For over 30 years, TRI has provided support to government agencies, the private sector, and non-profit organizations. Further information is available at www.tech-res.com.

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