

HPTN 046

A Phase III trial to determine the efficacy and safety of an extended regimen of nevirapine in infants born to HIV-infected women to prevent vertical HIV transmission during breastfeeding

A Study of the HIV Prevention Trials Network

Sponsored by:

Division of AIDS, US National Institute of Allergy and Infectious Diseases
U.S. National Institute of Child Health and Human Development
U.S. National Institute on Drug Abuse
U.S. National Institute of Mental Health
U.S. National Institutes of Health

Pharmaceutical support provided by:

Boehringer Ingelheim

IND TBD (held by DAIDS)

I, the Investigator of Record, agree to conduct this study in full accordance with the provisions of this protocol. I agree to maintain all study documentation for a minimum of three years after submission of the site's Financial Status Report to the Division of AIDS (DAIDS), which is due within 90 days after the end of the site's cooperative agreement with DAIDS, unless otherwise specified by DAIDS or the HPTN Coordinating and Operations Center (CORE). Publication of the results of this study will be governed by HPTN and DAIDS policies. Any presentation, abstract, or manuscript will be made available by the investigators to the HPTN Manuscript Review Committee, DAIDS and Boehringer Ingelheim for review prior to submission.

I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study.

Name of Investigator of Record

Signature of Investigator of Record

Date