



Open Clinical Trials

Below is a selected list of currently enrolling clinical trials gathered from various sources. **TrialSearch**, operated by the **AIDS Community Research Initiative of America (ACRIA)**, is an extensive online database of clinical trials related to HIV/AIDS. The University of California at San Francisco (UCSF) **HIV InSite** Web site features **TrialScope**, a database of organizations that conduct HIV/AIDS-related research.

The federal government's **AIDSinfo** Web site includes a section on clinical trials that features an introduction to HIV/AIDS research and study listings from the National Institutes of Health's **ClinicalTrials.gov** database. AIDSinfo also offers personalized advice about clinical trial participation via e-mail (ContactUs@AIDSinfo.nih.gov), an interactive Web site (www.aidsinfo.nih.gov/live_help; specialists available Mon.–Fri. 9:00 am–1:00 pm PT), and a toll-free telephone service (800-874-2572, international 301-874-2572; specialists available Mon.–Fri. 9:00 am–2:00 pm PT). **CenterWatch** is a commercial Web site that includes trial listings for many diseases, including HIV/AIDS and related conditions.

The majority of U.S. government-sponsored HIV/AIDS trials are conducted by the adult and pediatric **AIDS Clinical Trials Group (ACTG)**. The **National Center for Complementary and Alternative Medicine (NCCAM)** conducts trials of complementary therapies for conditions related to HIV and its management. The **HIV Vaccine Trials Network (HVTN)** is an international collaboration testing preventive vaccines.

Community Programs for Clinical Research on AIDS (CPCRA) is a nationwide network that conducts community-based clinical trials. In addition to TrialSearch, ACRIA also provides a list of trials in the mid-Atlantic region. The **Community Research Initiative of New England (CRINE)** offers information about trials in the northeast.

Call the telephone numbers listed for each study or see the indicated Web sites for more information about specific trials. Protocol numbers, if available, are provided in parentheses at the end of each trial description.

TrialSearch: www.acria.org/clinical_trials/index.html

TrialScope: www.hivinsite.org/tscope

AIDSinfo: www.aidsinfo.nih.gov

ClinicalTrials.gov: www.clinicaltrials.gov

CenterWatch: www.centerwatch.com

ACTG: www.aactg.org

NCCAM: www.nccam.nih.gov/clinicaltrials

HVTN: www.hvtn.org

CPCRA: www.cpcra.org

ACRIA: www.acria.org

CRINE: www.crine.org/info/clinical.html

Darunavir for Treatment-Naive Patients

Tibotec's non-peptide protease inhibitor (PI), darunavir (Prezista, formerly TMC114), was approved on June 23, 2006 for use by treatment-experienced individuals whose current antiretroviral therapy is not working (see "News Briefs" on page 5).

An ongoing, open-label Phase III study, sponsored by Tibotec, is comparing the efficacy, safety, and tolerability of ritonavir-boosted darunavir versus lopinavir/ritonavir (Kaletra) in people starting antiretroviral therapy for the first time. Subjects will be randomly assigned to receive either darunavir/ritonavir or lopinavir/ritonavir, both with emtricitabine/tenofovir (the Truvada combination pill), for 96 weeks.

Eligible treatment-naive subjects must be at least 18 years of age and have an HIV viral load of at least 5,000 copies/mL. Exclusion criteria include active opportunistic illnesses (OIs) and certain abnormal laboratory results. Women may not be pregnant or breast-feeding, and participants must agree to use effective barrier contraception.

This trial aims to enroll 660 participants at some 30 U.S. sites, including **Atlanta** (404-459-0002), **Baltimore** (410-545-4481), **Boston** (617-632-0760), **Brooklyn** (718-270-4180), **Houston** (713-500-6751), **Las Vegas** (702-383-2691), **Los Angeles** (323-869-5429), **Miami** (305-243-5621), **Orlando** (407-647-3960), **Philadelphia** (215-790-1788), **Phoenix** (602-307-5330), **San Francisco** (415-833-3480), **San Juan** (787-723-5945), **Tampa** (813-307-8015), **Washington, DC** (202-457-1250), and **Winston-Salem** (336-716-4262), as well as numerous sites in **Asia, Australia, Central and South America, and Europe**. www.clinicaltrials.gov/ct/gui/show/NCT00258557 (CR002800).

Etravirine: New NNRTI

Tibotec is also studying its experimental non-nucleoside reverse transcriptase inhibitor (NNRTI), etravirine (TMC125), in conjunction with darunavir. A pair of Phase III trials, TMC125-C206/CR002752 and TMC125-C216/CR006307

(DUET 1 and 2), will each enroll 600 heavily treatment-experienced patients with limited therapeutic options. Participants will be randomly assigned to receive etravirine or placebo; all will also receive ritonavir-boosted darunavir plus an optimized background regimen.

Eligible subjects must be at least 18 years of age and have an HIV viral load greater than 5,000 copies/mL. They must have at least three primary PI-resistance mutations as well as genotypic evidence of resistance to currently available NNRTIs. Exclusion criteria include active OIs, certain abnormal laboratory results, and use of certain medications.

The studies are enrolling in more than 60 U.S. sites, including **Austin** (512-480-9660), **Boston** (617-927-6056), the **Bronx** (718-918-3669), **Chicago** (773-296-2400), **Dallas** (214-941-4000), **Denver** (303-315-8311), **Detroit** (313-916-2575), **Ft. Lauderdale** (954-467-3006), **Little Rock** (501-603-3000), **Macon** (478-301-5837), **Los Angeles** (323-993-7577), **Newark** (973-877-2663), **Oakland** (510-204-1873), **Palm Springs** (760-320-9505), **Phoenix** (602-307-5330), **Portland** (503-229-8428), **San Francisco** (415-476-4082; 415-833-2854), **Santa Fe** (505-989-8200), **Tampa** (813-870-4760), and **Washington, DC** (202-822-6311), as well as sites in **Australia, Canada, Central and South America, Europe, South Africa, and Thailand.**

www.clinicaltrials.gov/ct/show/NCT00254046 (CR002752);
www.clinicaltrials.gov/ct/show/NCT00255099 (CR006307).

MK-0518: Experimental Integrase Inhibitor

Promising data regarding two experimental HIV integrase inhibitors, MK-0518 and GS-9137, were among the highlights at this year's Conference on Retroviruses and Opportunistic Infections (see "Drug Watch" on page 13).

Two controlled, double-blind Phase III trials of MK-0518, being developed by Merck and Company, are currently enrolling. These studies will evaluate the drug's safety, tolerability, and efficacy in treatment-experienced patients whose current antiretroviral therapy is failing. Participants with multidrug-resistant HIV will be randomly assigned to receive MK-0518 in combination with optimized background therapy (OBT), or OBT alone. Virological response (HIV viral load reduction), immunological response (CD4 cell recovery), and toxicity will be assessed at 24 and 48 weeks.

Eligible subjects must be at least 16 years of age and must have been on the same antiretroviral regimen for at least the past two months, without achieving virological suppression (i.e., they must have detectable HIV RNA within a predefined range). In addition, they must have documented resistance to at least one drug in all three major classes of approved antiretroviral therapy (NRTIs, NNRTIs, and PIs). Exclusion criteria will be discussed and identified by the study investigators.

Study 2005_097 aims to enroll 345 participants at some 30 U.S. sites, including **Albany, Atlanta, Austin, Boston, Denver, Durham, Los Angeles, Miami, Minneapolis, Newark, New Haven, New York City, Orlando, Philadelphia, Portland, Rochester, San Antonio, San Diego, San Francisco, San Juan, Tucson, and Washington, DC**, as well as sites in **Canada, Mexico, and South America.** Study 2005_096 is enrolling at several sites in **Asia, Australia, and Europe.** For further details and specific locations, call toll-free 888-577-8839. www.clinicaltrials.gov/show/NCT00293254 (2005_097); www.clinicaltrials.gov/show/NCT00293267 (2005_096).

CCR5mAb004: Monoclonal Antibody

Early pharmacokinetic and resistance data on Human Genome Science's CCR5mAb004, a recombinant monoclonal antibody that targets the CCR5 coreceptor, were also presented at the Retrovirus conference. This agent is now entering the first phase of human trials to assess safety and efficacy. Study CCR5-HV01 is a Phase I, placebo-controlled, dose-escalation trial in which participants who are not currently taking antiretroviral therapy will be randomly assigned to receive a single intravenous infusion of one of four doses of CCR5mAb004 monotherapy or placebo. Subjects will be followed for 56 days, and the pharmacokinetics, pharmacodynamics, safety, tolerability, and immunogenicity (ability to elicit an immune response) of CCR5mAb004 will be evaluated. If participants' CD4 cell counts fall below 200 cells/mm³ during the study period, they will be offered standard-of-care combination antiretroviral therapy.

Eligible subjects must be 18–64 years of age and have an HIV viral load greater than 5,000 copies/mL and a CD4 count above 250 cells/mm³ at study entry. They must either be treatment-naïve or else have been off antiretroviral therapy for at least 30 days prior to enrollment. They must have CCR5-tropic (not CXCR4-tropic or dual-tropic) HIV. Exclusion criteria include a history of AIDS-defining illnesses, certain other medical conditions including cancer and hepatitis B or C, certain abnormal laboratory results, use of certain medications, and use of alcohol or illegal drugs. Women may not be pregnant or breast-feeding, nor plan to become pregnant during the study.

This study will enroll 40–60 subjects at up to 10 U.S. sites, including **Baltimore, Cleveland, Ft. Lauderdale, Los Angeles, Orlando, and San Francisco.** For further details and specific locations, call toll-free 866-447-9749. www.clinicaltrials.gov/ct/show/NCT00114699 (CCR5-HV01).

SP01A: New Oral Entry Inhibitor

Based on promising results from initial studies, Samaritan Pharmaceuticals is enrolling a double-blind

Phase II monotherapy trial to assess the safety, efficacy, and optimal dosing of its experimental oral entry inhibitor, SP01A, in treatment-experienced individuals. After a two-week washout period of current antiretroviral drugs, participants will be randomly assigned to receive one of three doses of SP01A monotherapy (200 mg once daily, 200 mg twice daily, or 400 mg twice daily) or placebo for 28 days.

Eligible subjects must be 18–60 years of age and either experiencing poor virological suppression (HIV RNA greater than 5,000 copies/mL) on their current antiretroviral regimen or showing evidence of resistance to currently available antiretroviral drugs. CD4 cell count must be at least 100 cells/mm³. Exclusion criteria include various medical conditions (including active OIs, hepatitis, or cancer), abnormal laboratory results, active alcohol or drug use, and use of certain medications, including sulfa drugs. Women may not be pregnant or breast-feeding and must agree to use effective contraception. Patients currently on stable antiretroviral regimens that are successfully suppressing viral load below 5000 copies/mL are not eligible.

This study aims to enroll 60 subjects at five U.S. sites: **Charlotte** (704-331-9054), **Ft. Lauderdale** (954-564-4222), **Orlando** (407-246-1946), **Pittsburgh** (412-661-1763), and **West Palm Beach** (561-832-6770). www.clinicaltrials.gov/ct/show/NCT00299897 (SP01A-111-05).

Simplified Kaletra Regimen

Researchers recently reported data from a study of lopinavir/ritonavir (the Kaletra combination pill) used as monotherapy (see “Switching Antiretroviral Therapy” on page 17, and “Drug Watch” in the Winter 2006 issue of *BETA*). This open-label Phase III study, sponsored by Abbott Laboratories, will look at a simplified two-drug Kaletra regimen. Treatment-naïve subjects will be randomly assigned to receive either a standard Kaletra-based regimen containing two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), or Kaletra plus a single NRTI, tenofovir (Viread).

Eligible subjects must be at least 18 years of age and must be starting antiretroviral therapy for the first time. They must have a detectable HIV viral load (at least 400 copies/mL), but may have any CD4 cell count. They may not have any acute illnesses.

For locations and further information, call Abbott at 800-633-9110. www.clinicaltrials.gov/ct/show/NCT00234910 (ITAL-04-002; KALEAD).

First-Line Antiretroviral Regimens

ACTG A5202 is a Phase IIIb study, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), that will compare four antiretroviral regimens in treatment-naïve individuals starting therapy for the first

time. Participants will be randomly assigned to one of four treatment arms:

- efavirenz (Sustiva) plus tenofovir/emtricitabine (Truvada combination pill)
- efavirenz plus abacavir/3TC (Epzicom combination pill)
- ritonavir-boosted atazanavir (Reyataz) plus tenofovir/emtricitabine
- ritonavir-boosted atazanavir plus abacavir/3TC

Treatment will continue for 96 weeks. Participants will undergo regular monitoring of HIV viral load, CD4 cell count, and blood lipid levels, and will complete questionnaires to assess adherence. Some participants will be asked to participate in a metabolic substudy (ACTG A5224s).

Eligible subjects must be at least 16 years of age; those with recent HIV infection will receive drug-resistance testing. They must not have received prior antiretroviral viral therapy for more than seven days total (excluding post-exposure prophylaxis). They must have a viral load greater than 1000 copies/mL within 90 days of study entry; there are no CD4 cell count restrictions. Exclusion criteria include major drug-resistance mutations, various medical conditions (including heart rhythm disturbances), and use of certain medications (including immunomodulators and other investigational agents). Women may not be pregnant or breast-feeding and must agree to use effective contraception.

This study aims to enroll 1800 participants at more than 60 sites, including **Atlanta** (404-616-6313), **Baltimore** (410-614-2766), **Birmingham** (205-975-7925), **Boston** (617-414-7082), **Chapel Hill** (919-843-8761), **Chicago** (312-572-4545), **Cincinnati** (513-584-8373), **Dallas** (214-590-0414), **Denver** (303-372-5535), **Galveston** (409-747-0219), **Honolulu** (808-737-2751), **Indianapolis** (317-274-8456), **Iowa City** (319-353-8441), **Los Angeles** (310-557-2273), **Miami** (305-243-3838), **Minneapolis** (612-347-2690), **Nashville** (615-467-0154 ext. 108), **Omaha** (402-559-8163), **New York City** (212-746-4393), **Philadelphia** (215-349-8092), **Providence** (401-793-4396), **Rochester** (585-275-2740), **Sacramento** (916-914-6263), **San Diego** (619-543-8080), **San Francisco** (415-514-0550 ext. 354), **San Juan** (787-759-9595), **Seattle** (206-731-8877), **Stanford** (650-723-2804), **St. Louis** (314-454-0058), and **Washington, DC** (202-687-2294). www.clinicaltrials.gov/ct/show/NCT00118898 (ACTG A5202).

Biojector for T-20

The sole approved entry inhibitor, T-20 (enfuvirtide, Fuzeon), is an important option for heavily treatment-experienced patients with drug-resistant HIV, but its use is

limited by injection site reactions. The BOSS study is an open-label Phase IV trial, sponsored by Hoffmann-La Roche, assessing whether use of a needle-free injection device can reduce this side effect. Participants will be randomly assigned to use the B2000 “biojector” or a standard needle and syringe to administer 90 mg T-20 twice daily for four weeks.

Eligible subjects must be at least 16 years of age and current or former users of T-20 who have never before tried the B2000 biojector; the study will not enroll patients who have not previously used T-20. Participants must either be able to inject T-20 themselves or have a reliable caregiver who can do so. Exclusion criteria include active untreated OIs.

This study aims to enroll 100–150 participants at more than 60 sites, including **Albany, Atlanta, Baltimore, Birmingham, Boston, Chicago, Cincinnati, Cleveland, Dallas, Denver, Ft. Lauderdale, Houston, Los Angeles, Miami, Milwaukee, Newark, New York City, Orlando, Palm Springs, Philadelphia, Phoenix, Portland, Rochester, San Francisco, Seattle, St. Louis, Tampa, Washington, DC, and Winston-Salem.** For details and specific locations, call toll-free 800-526-6367. www.clinicaltrials.gov/ct/show/NCT00337701 (ML19849).

Protease Inhibitors and Glucose Metabolism

This randomized Phase IV study, sponsored by the Department of Veterans Affairs, will attempt to determine how PIs contribute to the development of diabetes in people with HIV—in particular, whether PIs impair insulin secretion and increase the production of glucose by the liver. In order to separate out the effects of PIs from those of HIV itself, this study will enroll HIV negative volunteers. Participants will be randomly assigned to receive either a single dose of a PI or placebo. Insulin secretion will be assessed using the hyperglycemic clamp technique. Somatostatin, growth hormone, and glucagon will be infused before and during the clamp study. Liver glucose production will be measured in the fasting and hyperinsulinemic (excess insulin) states.

This study aims to enroll 80 healthy, HIV negative participants 18–72 years of age. Volunteers may not have medical conditions associated with insulin resistance, such as obesity or elevated blood fat levels, and may not be taking glucocorticoids, growth hormone, niacin, or antipsychotic medications. Women may not be pregnant. This study will take place at the **San Francisco Veterans Affairs Medical Center** (415-221-4810 ext. 2118 or ext. 3395). www.clinicaltrials.gov/ct/show/NCT00259727 (RCD-005-05S; H574-23263).

Effect of Antiretroviral Therapy on Treatment for Hepatitis C

Despite improved guidelines for treating HIV/HCV-coinfected individuals, there remains some uncertainty about whether to initiate treatment for HIV or hepatitis C first. This study will attempt to determine whether starting anti-HIV therapy with a high CD4 cell count and then adding anti-HCV drugs can promote improved immune response against HCV.

In this open-label trial, sponsored by NIAID, one group of participants will be randomly assigned to receive 24–30 weeks of antiretroviral therapy consisting of tenofovir plus 3TC (Epivir) plus either efavirenz or lopinavir/ritonavir. If deemed eligible, this group will then start hepatitis C treatment using Pegasys-brand pegylated interferon plus ribavirin for up to 48 weeks. Subjects in the other arm will remain off HAART but will receive the same combination therapy for hepatitis C. The study will last up to 102 weeks and will include 18–20 clinic visits with blood draws and clinical assessment.

Eligible participants must be 18–65 years of age. They must have a CD4 cell count of at least 300 cells/mm³ and an HIV viral load greater than 1000 copies/mL within 45 days of study entry. They must have genotype 1 HCV, and those with cirrhosis must have a serum alpha-fetoprotein level of 100 ng/mL or less and a Child-Pugh score of 6 or higher. Subjects should not require HAART at the time of study entry. They must be antiretroviral-naïve or have been off antiretroviral therapy for six months before starting the study; they may not have previously used interferon, or used 3TC, tenofovir, PIs, or NNRTIs for more than 31 days in the past. Exclusion criteria include decompensated liver disease, various other medical conditions (including hepatitis B, uncontrolled diabetes, autoimmune diseases, severe retinopathy, past organ transplants, uncontrolled depression, or other psychiatric illness), and use of certain medications. Women may not be pregnant or breast-feeding, men may not have a pregnant partner, and participants must agree to use effective contraception.

This study will enroll about 200 subjects at more than 30 sites, including **Baltimore** (410-706-1476), **Birmingham** (205-975-7925), **Boston** (617-724-0072), **Chapel Hill** (919-843-8761), **Chicago** (312-695-5012), **Cleveland** (216-844-2546), **Dallas** (214-590-0414), **Denver** (303-372-5535), **Galveston** (409-747-0219), **Indianapolis** (317-274-8456), **Los Angeles** (310-825-1301), **Minneapolis** (612-347-2690), **New York City** (212-305-2665), **Philadelphia** (215-349-8092), **Pittsburgh** (412-647-0771), **Providence** (401-793-4396), **San Diego** (619-543-8080), **San Francisco** (415-514-0550 ext. 354), **San Juan** (787-759-9595), and **St. Louis** (314-454-0058). www.clinicaltrials.gov/ct/show/NCT00100581 (ACTG A5184).

Atazanavir for Infants, Children, and Adolescents

This open-label Phase I/II study, sponsored by NIAID and NICHD, aims to determine the most safe and tolerable dose of atazanavir for HIV positive infants, children, and adolescents. Participants, divided into groups based on age, will receive either ritonavir-boosted or unboosted atazanavir plus two other antiretroviral drugs not provided by the study. Infants and young children will receive a powdered form of atazanavir, while adolescents 13 years and older will receive capsules. Atazanavir pharmacokinetics and safety will be monitored and, for each age group, doses will be adjusted until one is found that satisfies both sets of criteria, at which point additional participants will be enrolled using that dose. Clinic visits will occur every four weeks through week 48, then every eight weeks until the last patient to enroll has reached week 96; visits will include physical exams, cardiac conduction tests, and blood and urine collection.

Eligible subjects must be three months to 21 years of age; at this time, there are more open slots for older children and adolescents. They must have an HIV viral load of at least 5000 copies/mL; there are no CD4 cell count restrictions. Resistance testing must show that subjects' HIV is sensitive to atazanavir, and they must be able to take two NRTIs they have never used before. Exclusion criteria include certain medical conditions (including hepatitis and serious infections requiring treatment), a history of significant cardiac abnormalities or dysfunction, and use of certain medications. Adolescent females may not be pregnant or breast-feeding and must agree to use contraception if sexually active.

This study will enroll 152 subjects at about 40 U.S. sites, including **Baltimore** (410-955-9749), **Birmingham** (205-558-2328), **Boston** (617-355-8198), **the Bronx** (718-918-4516), **Chicago** (773-257-5717), **Denver** (303-861-6751), **Houston** (832-824-1339), **Los Angeles** (310-206-6369), **Memphis** (901-495-2004), **Miami** (305-243-4447), **Newark** (973-972-3118), **New Orleans** (504-586-3804), **New York City** (212-939-4045), **Norfolk** (757-668-7238), **Oakland** (510-428-3885 ext. 2827), **Philadelphia** (215-590-2262), **San Diego** (619-543-8080 ext. 236), **San Francisco** (415-476-6480), **San Juan** (787-759-9595), **Syracuse** (315-464-6331), and **Washington, DC** (202-865-1248). The study will also be conducted in **South Africa**, where participants who respond to therapy will continue to receive atazanavir until it is approved in that country. www.clinicaltrials.gov/ct/show/NCT00006604 (PACTG P1020-A).

Tenofovir to Prevent Perinatal HIV Transmission

This Phase I trial, sponsored by NIAID and NICHD, will look at the safety, tolerability, and pharmacokinetics of

single-dose tenofovir given to women during labor and to their newborn infants. Tenofovir has been shown to effectively reduce the risk of vertical (mother-to-child) transmission in monkeys infected with a simian virus related to HIV. In this nonrandomized, open-label study, pregnant women will be assigned to one of two groups. Subjects in Cohort 1 will receive a single 600-mg dose of tenofovir at the start of labor or before planned cesarean section. They will also receive intravenous AZT (standard therapy for preventing vertical transmission in developed countries) and/or other antiretroviral medications prescribed by their physicians. Infants born to women in Cohort 1 will receive the standard six-week postpartum oral AZT prophylaxis regimen. After eight-week data from infants in Cohort 1 have been analyzed, a second cohort of pregnant women will receive a single dose of tenofovir (with the dose to be determined based on pharmacokinetic data from Cohort 1) plus standard AZT prophylaxis and/or other antiretroviral drugs. Infants born to women in Cohort 2 will receive a single dose of tenofovir within six hours after birth, along with the standard six-week AZT regimen. Blood samples will be collected from mothers and infants to assess tenofovir pharmacokinetics and resistance. The women will be followed for 12 weeks postpartum; if viral resistance to tenofovir emerges during this period, they will be followed for two years. Infants will be followed until age 2.

Eligible women must be at least 18 years of age and in their third trimester of pregnancy (at least 34 weeks gestation). There are no viral load or CD4 cell count restrictions. Exclusion criteria include previous treatment with tenofovir, various medical conditions (including active OIs), abnormal laboratory results, and current or prior use of certain medications. Ultrasound screening must show a normal pregnancy and mothers must agree not to breast-feed.

This study aims to enroll 20 women at 30 sites, including **Boston** (617-355-8198), **the Bronx** (718-960-1020), **Chicago** (773-257-5717), **Denver** (303-861-6751), **Detroit** (313-745-7857), **Durham** (919-416-3447), **Houston** (832-824-1339), **Los Angeles** (323-226-2226), **Memphis** (323-669-2390), **Miami** (305-243-4447), **Newark** (973-972-3118), **New York City** (212-263-5680), **Philadelphia** (215-427-5284), **San Diego** (619-543-8080), **San Francisco** (415-476-6480), **San Juan** (787-765-4186), **Seattle** (206-987-5020), and **Washington, DC** (202-877-5811). www.clinicaltrials.gov/ct/show/NCT00076791 (PACTG 394).

Project T: Tenofovir to Prevent HIV Infection

This study, conducted by the Centers for Disease Control and Prevention (CDC), in conjunction with the San Francisco Department of Public Health (SFDPH), will attempt to determine whether tenofovir can help prevent

HIV infection. The drug has performed well in animal prevention studies, although recent data suggest it works better in conjunction with a second drug, emtricitabine (Emtriva) (see “News Briefs” on page 12). Participants will receive either daily oral tenofovir or placebo. This phase of the study will focus on the safety of the drug rather than its effectiveness; in particular, researchers will attempt to determine whether using a potentially preventive drug will lead to an increase in risky sexual behavior. Because it is not yet known whether tenofovir can prevent HIV infection—and because some subjects will receive placebo—participants should continue to practice safer sex, and will receive risk-reduction counseling and free condoms. If any participants become infected, SFDPH will facilitate referrals for HIV care and treatment.

Eligible participants must be sexually active HIV negative men who have sex with men. The study is expected to last two years. The U.S. arm of the study will enroll 400 gay and bisexual men in **San Francisco** (415-554-9068) and **Atlanta**; a third city, not yet identified, will be added soon. The CDC is conducting similar studies in **Botswana** and **Thailand** looking at heterosexual and injection drug-using populations. www.sfaidsresearch.org.

Group Counseling for Methamphetamine Users

As discussed in the article “Methamphetamine and HIV” on page 42, use of crystal meth is an increasingly recognized problem among individuals with HIV. This study will evaluate whether a specially developed, culturally specific group counseling approach using cognitive behavioral therapy is more effective than a standard drug treatment program in helping HIV positive gay and bisexual men stop using methamphetamine, reduce risky sexual behaviors, and adhere better to antiretroviral therapy. It will also assess whether participants find it easier to receive drug abuse treatment at an HIV-care clinic compared with attending a separate location. HIV positive gay and bisexual men who receive medical care at the University of California at Los Angeles (UCLA) Center for Clinical AIDS Research and Education, and who are seeking treatment for methamphetamine use, will be randomly assigned to the specialized group therapy (twice-weekly for 12 weeks) or referred to the UCLA Addiction Medicine Clinic for standard drug abuse treatment (also for 12 weeks).

Eligible participants are self-identified gay or bisexual HIV positive men, 18-65 years of age, who meet the criteria for methamphetamine abuse as determined by the Mini-International Neuropsychiatric Interview (MINI). Exclusion criteria include certain serious psychiatric conditions; concurrent dependence on opiates, alcohol, or benzodiazepines; and lack of any type of healthcare insurance coverage.

The study will enroll 50 participants at UCLA (310-312-0500 ext. 374).

www.clinicaltrials.gov/ct/show/NCT00252434
(1 R21 DA 018075).

Buprenorphine and Integrated HIV Care

A Phase IV trial sponsored by the New York Academy of Medicine and the Health Resources and Services Administration (HRSA) will assess the feasibility, effectiveness, and cost of integrating buprenorphine substitution therapy for patients with opiate dependence into an HIV primary care setting. The study will enroll 1350 HIV positive participants in ten model demonstration projects. Subjects will be randomly assigned to receive integrated care at an HIV clinic (including primary HIV medical care, drug education and counseling, case management, and weekly administration of buprenorphine or buprenorphine/naloxone), or will receive drug counseling, case management, and opioid substitution therapy at separate sites. Over the course of 12 months, investigators will assess HIV-related health status, drug use (as determined by urine testing), service utilization, quality of life, and satisfaction with services, as well as information about providers’ practices and attitudes about treating drug-dependent patients.

Eligible subjects must be at least 18 years of age, speak English or Spanish (depending on site), and meet the DSM-IV criteria for opioid dependence. Exclusion criteria include coexisting alcohol or benzodiazepine dependence, serious psychiatric impairment, and abnormal liver function tests. Woman may not be pregnant or plan to become pregnant during the study period.

In **San Francisco**, 120 participants will be enrolled through the UCSF Positive Health Program at San Francisco General Hospital (415-476-9296 ext. 311).
www.clinicaltrials.gov/ct/show/NCT00263458 (H97HA03799).

In the **East Bay**, 60 subjects will be enrolled through the Organization to Achieve Solutions in Substance Abuse (OASIS); participants will receive HIV care at the Alameda County Medical Center HIV Clinic in Oakland or the Fairmont Hospital HIV Clinic in San Leandro. To enroll, call 510-834-5442 or 510-437-4888.
www.clinicaltrials.gov/ct/show/NCT00241930 (H97HA03792).

In **Baltimore**, 120 participants will be enrolled through the Johns Hopkins HIV Clinic (410-614-0560).
www.clinicaltrials.gov/ct/show/NCT00130819
(H97HA03794; HRSA-04-078).

Other sites include the CORE Center in **Chicago** (312-572-4818), the University of **Miami** School of Medicine (305-243-3838), the Yale University School of Medicine AIDS Program in **New Haven** (203-781-4650 ext. 250), Montefiore Medical Center in **New York City**, the Oregon Health and Science University in **Portland** (503-494-6770),

the Miriam Hospital in **Providence** (401-793-4824), and El Rio Santa Cruz Neighborhood Health Center in **Tucson** (520-629-2888).
www.clinicaltrials.gov/ct/show/NCT00124358 (063005; H97HA03795).

SLAM-C: Pegylated Interferon Maintenance Therapy for HIV/HCV Coinfection

Past research has shown that liver damage due to hepatitis C progresses more rapidly in HIV positive people. Coinfected individuals do not respond as well to interferon-based therapy as those with hepatitis C virus (HCV) alone, but some studies suggest long-term interferon maintenance may help slow fibrosis progression.

In this open-label Phase II study, sponsored by NIAID, subjects who either have never received therapy for hepatitis C or who did not clear HCV with prior treatment will receive a standard course of 180 mcg once weekly Pegasys-brand pegylated interferon plus 1000–1200 mg daily weight-based ribavirin. Subjects who respond well (at least a 2-log drop in HCV RNA) at 12–18 weeks will continue this regimen for an additional 60 weeks. Those who respond poorly will be randomly assigned either to stop ribavirin and continue on Pegasys for 72 weeks, or to discontinue both drugs. Follow-up will continue for 72–132 weeks. Participants will receive liver biopsies at study entry, after changing therapy, and at the end of follow-up to monitor fibrosis progression.

Eligible HIV positive participants must be at least 18 years of age, on stable HAART for at least eight weeks or off antiretroviral therapy for at least four weeks, have an HIV viral load less than 50,000 copies/mL, and have a CD4 cell count at of least 200 cells/mm³. In addition, they must have chronic hepatitis C with elevated liver enzymes (at least 10 times the upper limit of normal) and at least stage F1 fibrosis. They must either be naive to hepatitis C therapy or else still have detectable HCV RNA after at least 12 weeks of prior treatment with standard or pegylated interferon with or without ribavirin. Exclusion criteria include various medical conditions (including active OIs, decompensated liver cirrhosis, hepatitis B, autoimmune diseases, thyroid disease, hemoglobin abnormalities, and uncontrolled depression or other psychiatric conditions) and use of certain medications (including granulocyte- or granulocyte-macrophage colony-stimulating factor). Women may not be pregnant or breast-feeding.

This study aims to enroll 180 subjects at more than 40 sites, including **Atlanta** (404-616-6313), **Baltimore** (410-614-2766), **Birmingham** (205-975-7925), **Boston** (617-724-0072), **Buffalo** (716-898-3933), **Chapel Hill** (919-843-8761), **Chicago** (312-695-5012), **Cincinnati** (513-584-8373),

Cleveland (216-778-5489), **Dallas** (214-590-0414), **Denver** (303-372-5535), **Galveston** (409-747-0241), **Honolulu** (808-737-2751), **Indianapolis** (317-630-6023), **Los Angeles** (310-825-1301), **Miami** (305-243-3838), **Nashville** (615-467-0154 ext. 108), **New York City** (212-746-7198), **Omaha** (402-559-8163), **Philadelphia** (215-349-8092), **Pittsburgh** (412-647-0771), **Providence** (401-793-4396), **Rochester** (585-275-2740), **San Francisco** (415-514-0550 ext. 354), **San Juan** (787-759-9595), **Stanford** (650-723-2804), **St. Louis** (314-454-0058), and **Washington, DC** (202-687-7387).
www.clinicaltrials.gov/ct/show/NCT00078403 (ACTG A5178; SLAM-C).

Staying Well: Stress Reduction through Meditation

The Staying Well study is a controlled trial of mindfulness-based stress reduction (MBSR) for people with HIV. The study aims to determine whether stress reduction through meditation is associated with reduced HIV disease progression, less depression, and improved quality of life; it will also assess the mechanisms by which stress and mood may influence immune function. Subjects will be randomly assigned to participate in either MBSR or general education on health and well-being for HIV positive individuals. Both groups will attend eight weekly sessions (each lasting 1.5–3 hours) at UCSF’s Osher Center for Integrative Medicine. Participants will have blood drawn and will complete psychological questionnaires at study entry and at months 3, 6, and 12; they will receive compensation for each completed assessment. Those initially assigned to the education group may participate in the MBSR program for free after 12 months.

Eligible subjects must be at least 18 years of age and able to speak English. They must not have taken antiretroviral therapy for the past 120 days, and must have an HIV viral load greater than 100 copies/mL and a CD4 cell count above 250 cells/mm³ at study entry. They should not plan to start HAART during the 12 months following enrollment, but may do so if medically necessary and remain in the study.

This study is being conducted in **San Francisco**. For further details or to enroll, call 415-353-9745.