

Community Consortium News

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Strategies for Management of AntiRetroviral Therapy is open to subjects with CD4+ cell counts greater than 350/mm³ currently on or naïve to antiretroviral therapy. There are two strategies to which patients are randomized to in the study. In the Viral Suppression (VS) arm the goal is to use antiretroviral therapy to maintain viral load as low as possible throughout the anticipated six to nine years of study follow-up. In the Drug Conservation (DC) strategy arm, antiretroviral therapy is stopped (or deferred) until the CD4+ cell count drops to less than 250/mm³ at which time episodic antiretroviral therapy is initiated to increase the CD4+ cell count to greater than 350/mm³. Three thousand participants are required per arm for a total target sample size of 6000.

If you or your patients might be interested in participating in the SMART study, please contact Pierre Crouch, R.N., at (415) 476-9554, ext. 333 for further information, or visit the SMART Study website at <http://www.smart-trial.org/>

Just Released - DSMB Report:

http://communityconsortium.org/research/CPCRA_065-2003.pdf

SMART SITE BREAKDOWN

Breakdown of SMART enrollments by Community Consortium site:

<u>Site</u>	<u>Provider</u>	<u>Enrollments</u>
001	Ward 86	1
004	William Owen, M.D.	11
005	CMHC	16
009	Milton Estes, M.D.	6
018	UCSF	5
036	VAMC	10
037	Lawrence Goldyn, M.D.	1
038	Virginia Cafaro, M.D.	2

Total Enrollments (as of 3/5/03)

56 Local

903 National

The Community Consortium has enrolled 30 of our target goal of 50 subjects onto ESPRIT (The Evaluation of Subcutaneous Proleukin in a Randomized International Trial), an international 25-nation 4000 patient trial. In ESPRIT, participants on HAART are randomized to receive either interleukin-2 at 7.5 MIU subcutaneously twice a day for 5 days every 8 weeks or no interleukin-2. ESPRIT data collection only occurs every 4 months. The study is designed to assess clinical benefit of IL-2 and hence will follow 4000 patients worldwide for disease progression events for a minimum of five years. Participants randomized to the IL-2 arm will repeat cycles of therapy to maintain their CD4+ cell counts at twice baseline or above 1000 cells/mm³. Enrollment is projected to end by the 1st of May, 2003, so if you have patients who may be interested in ESPRIT, please call David MacLeod, R.N., at 415-476-9554, ext 328. For more information about ESPRIT and its substudies, please visit the ESPRIT website at: <http://www.espritstudy.org/>

Just Released - DSMB Report: <https://www.esprit-il2.org/pdf/openreport.feb03.pdf>

Continued on page 2

INSIDE THIS ISSUE

- 1 SMART - ESPRIT
- 2 Calendar of Events
- 2 ESPRIT Site Breakdown
- 2 Community Consortium Open Studies: DHEA
- 3 Neuropathy RCT, Marijuana for Cancer Pain, and LTM - CPCA Studies (Follow-Up): FIRST MDR, Adherence

ESPRIT SITE BREAKDOWN

Breakdown of ESPRIT enrollments by Community Consortium site:

<u>Site</u>	<u>Provider</u>	<u>Enrollments</u>
004	William Owen, M.D.	1
005	CMHC	4
010	EBAC	4
018	UCSF	3
038	Virginia Cafaro, M.D.	2
040	PHP-West	2
041	Emory	14

Total Enrollments (as of 3/5/03)

30 Local

3,805 International

To view the latest IL-2 Investigator Brochure please see:
https://esprit.cabr.umn.edu/dkei2kj4kdlzxd_i_pdfdir/IB_content_aug2002.pdf

Hardcopies of the Investigator Brochure are available at the Community Consortium.

Community Consortium Open Studies

DHEA

We have now enrolled 38 of the target 40 patients onto the study of dehydroepiandrosterone (DHEA) to investigate how it impacts on latent HIV replication and host immunity. Eligibility criteria include patients with HIV-1 infection who are 18 years or older on stable antiretroviral regimens for at least eight weeks, with HIV RNA < 50 copies/ml. Women must have a normal PAP smear and mammogram within the past year and men are required to have a normal prostate specific antigen level within the past year. Participants are randomized in a 1:1 ratio to receive either DHEA (100 mg po twice daily for males, 50 mg po twice daily for females) or placebo for 12 weeks.

All study participants receive DHEA for an additional 12 weeks, for a total study duration of 24 weeks. Study participants are seen as outpatients at the General Clinical Research Center. If you have patients who may be interested in participating in this study, please contact Paul Couey at (415) 476-9554, ext. 315.

Continued on page 3

CALENDAR OF EVENTS

-COMMUNITY CONSORTIUM EDUCATIONAL OFFERINGS-

**SATURDAY CME PROGRAM: "HIV RESISTANCE
AND FITNESS: CURRENT SCIENCE AND
CLINICAL STRATEGIES"**

**GENENTECH HALL – MISSION BAY CAMPUS –
UCSF**

**MARCH 22, 2003
8:30AM – 1:00PM**

More info at:

http://communityconsortium.org/about/about_calendar.html

-CONFERENCES-

**2nd IAS CONFERENCE ON PATHOGENESIS AND
TREATMENT**

**JULY 13 –16, 2003
PARIS, FRANCE**

More info at:

<http://www.ias2003.org/>

Neuropathy RCT

This randomized, double-blind, placebo-controlled study will evaluate whether smoked marijuana reduces pain in people with HIV-related peripheral neuropathy. In addition, the individual differences in subjective relief of pain will be anchored by an assessment of the analgesic effects of smoked marijuana on experimentally induced pain using a heat/capsaicin experimental pain model and resulting areas of cutaneous secondary hyperalgesia. This study should be open for enrollment in March 2003. For more information call Hector Vizoso, R.N. at 415-476-9554 x366.

Marijuana for Cancer Pain

Venturing for the first time into non-HIV territory, the Community Consortium is launching a new study investigating the effects of smoked marijuana in patients with cancer pain. The study is supported by funding from the University of California San Diego Center for Medicinal Cannabis Research (www.cmcr.ucsd.edu). Currently, this study is being revised to broaden the inclusion criteria. Please stay tuned for more details. If you know of patients who may be interested in participating in this trial, please have them contact Hector Vizoso, R.N., at 415-476-9554, ext. 366.

LTM

Do you have patients who have chosen to remain antiviral naïve or who have been long-term non-progressors? The CPCRA Long Term Monitoring team is looking to enrich follow-up of such patients in the LTM database. If you have individuals who may be interested to contributing to the general knowledgebase regarding naïve and LTNP patients and you are currently a collaborating Consortium clinician/investigator, please let your Consortium clinical research nurse know. Such individuals are often eager to participate in observational studies so that their experience can be counted! To date, 3,180 patients are being followed on the LTM nationwide, including 153 from our site.

Community Consortium

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The Community Consortium was founded in 1985 to provide a forum for community providers and academic researchers to share the latest information on the most effective treatments for HIV disease. Today, the Community Consortium membership includes over 250 health care providers who, collectively, care for the majority of people with HIV infection in the San Francisco Bay Area. The Community Consortium is part of the Positive Health Program of the UCSF Medical Services at San Francisco General Hospital Medical Center.

CPCRA Studies – Follow-Up

FIRST

The CPCRA's Flexible Initial Retroviral Suppressive Therapies (FIRST) trial, the entry point into the CPCRA's menu of strategic antiretroviral studies for naïve patients, closed to further enrollment on January 13, 2002. The study surpassed its target enrollment with 1398 patients enrolled nationally (49 locally) and will now continue to follow subjects already accrued. Stay tuned for further information to be made available as the study matures.

MDR

MDR is closed to further accrual and all 274 enrolled participants (22 locally) will be followed for an additional two years. This study of an STI in patients with MDR (Multi-Drug Resistance) is the largest randomized treatment interruption trial conducted to date. An Executive Summary reporting more details of the trial is forthcoming. If you could like a copy, please call the Consortium office at 415-476-9554.

Adherence

Enrollment into Adherence closed on June 26, 2002, due to the fact that the parent studies, FIRST (CPCRA 058) and MDR (CPCRA 064) are now closed to accrual. Patients enrolled in the Adherence study, an evaluation of the effects of two adherence interventions, will continue to be followed per protocol design, until completion of followup in the respective parent protocol, FIRST or MDR.

New Community Consortium Phone Extensions

To reach the correct Community Consortium staff member, enter their new extension after dialing the main number: 415-476-9554

Staff	Extensions
Donald Abrams, M.D., Chair	312
Carroll C. Child, Research Director	317
Paul Couey, Clinical Research Coord.	315
Pierre Crouch, Clinical Research Nurse	333
Scot Hammond, Project Data Manager	310
Michael Jones, Clinical Research Nurse	343
Nnemdi Kamanu, M.D., Physician	337
Mary Ellen Kelly, Program Manager	327
David MacLeod, Clinical Research Nurse	328
Steve Murray, Program Assistant	305
Paula Pell, Sr. Research Nurse	324
Starley Shade, Biostatistician	326
Victor Tan, Research Assistant	332
Hector Visozo, Clinical Research Nurse	366