

Community Consortium News

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Strategies for Management of AntiRetroviral Therapy is a trial for 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 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) 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. In order to meet the accrual goal, the CPCRA is establishing a worldwide network of SMART Sites, including 24 countries, to expedite enrollment into this exciting trial. Thus far the Community Consortium has enrolled 80 of the 1,707 study participants.

A number of additional SMART substudies are in development. Currently we are participating in two substudies. One is evaluating the risk of HIV transmission in participants in the VS vs. the DC arm. The second substudy is investigating quality of life and cost of care differences between the two arms of the trial. The three studies that are currently being developed will take advantage of the initial strategic randomization to compare the rates of development of 1) atherosclerosis, 2) anal dysplasia and 3) neurologic complications in the VS and DC arms. It is hoped that these additional substudies will be available for enrollment within the year.

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/>

The SMART Data Safety Monitoring Board (DSMB) Summary of February 4, 2004 is posted. Click on the following link: http://communityconsortium.org/research/research_ongoing.html

A special thank you to Simon Paul, M.D., and Jill Lanford, R.N., for enrolling 3 patients in the last 2 months!

A big welcome to Toby Dyer, M.D! Dr. Dyer's private practice has successfully completed the site establishment and protocol registration process and is now a SMART subsite!

SMART SITE BREAKDOWN

Here's a breakdown of SMART enrollments by Community Consortium site and providers as of 3/08/04:

Site	Site Totals and Providers	Provider Breakdown
001 (Ward 86)	Total = 4	
	Steve Deeks, M.D.	1
	Mary Lawrence Hicks, N.P.	1
	Jeffrey Klausner, M.D.	1
	Jody Lawrence, M.D.	1
004 (Owen)	Total = 14	
	William Owen, M.D.	10
	Carl Stein, P.A.	4
005 (CMHC)	Total = 16	
	Nilda Alverio, M.D.	1
	Jane Bailowitz, M.D.	4
	Toby Dyer, M.D.	2
	Walter Krampf, M.D.	6
	Lawrence J. Price, M.D.	1
	Fred Strauss, M.D.	2
009 (Estes)	Total = 6	
	Milton Estes, M.D.	6
010 (EBAC)	Total = 4	
	Michael D'Arata, N.P.	3
	Debra Royale, N.P.	1
012 (Scott)	Total = 9	
	Robert Scott, M.D.	9
018(UCSF)	Total = 5	
	Susan Coffey, M.D.	2
	Monica Gandhi, M.D.	1
	Malcolm John, M.D.	1
	Yoko Tsukamoto, N.P.	1
036 (VAMC)	Total = 12	
	Harry Lampiris, M.D.	6
	P. Jensen, M.D.	1
	O. Bacon, M.D.	1
	Monica Gandhi, M.D.	1
	J. Colford, M.D.	1
	L. O'Brien, M.D.	1
	P. Sullam, M.D.	1
037 (Goldyn)	Total = 1	
	Lawrence Goldyn, M.D.	1
038 (Cafaro)	Total = 6	
	Virginia Cafaro, M.D.	2
	Jennifer Kong, P.A.	1
	Martin Kramer, P.A.	1
042 (Fresno)	Total = 3	
	Simon Paul, M.D.	3

Total = 80

Thanks for your participation in this study!



Community Consortium Studies

Enrollment into ESPRIT (The Evaluation of Subcutaneous Proleukin in a Randomized International Trial) closed on May 30, 2003, with 4150 participants randomized in this 25-nation international trial. This makes ESPRIT the largest randomized HIV treatment intervention trial to date! The Community Consortium enrolled 42 of our target goal of 50 subjects, with the majority coming from our Emory University “satellite” site in Atlanta. The study is designed to assess the clinical benefit of IL-2 and hence will follow the 4150 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. Now that the study is fully enrolled our focus shifts to maintaining participants in follow-up as well as making sure that those individuals randomized to the IL-2 intervention receive cycles of therapy to maintain their CD4+ cell counts at the target level. Information about your patients enrolled in ESPRIT and whether or not they are at their goal can be found on the ESPRIT website <http://www.espritstudy.org/>

The ESPRIT DSMB Summary, dated February 13, 2004, can be found at: http://communityconsortium.org/research/research_ongoing.html

ESPRIT SITE BREAKDOWN

Here’s a final breakdown of ESPRIT enrollments by Community Consortium site:

<u>Site</u>	<u>Provider</u>	<u>Enrollments</u>
001	SFGH	2
004	William Owen	3
005	CMHC	5
009	Milton Estes	3
017	Martin Mass	1
010	EBAC	15
018	UCSF	15
039	Jon Kaiser	2
038	Virginia Cafaro	6
040	PHP-West	4
041	Emory	23
<u>Total Enrollments</u>		

79

Thank you for your participation in this international study!

Marijuana for HIV Neuropathy

The pilot study of smoked marijuana for patients with painful peripheral neuropathy has been completed. Analysis of the 16 patients enrolled revealed that a significant number had relief of their pain resulting in the design of the follow-on randomized placebo-controlled trial. The sample size for the randomized trial was calculated at 50 participants. To date, 22 subjects have completed the RCT. Eligible patients need to have persistent pain of greater than 3/10 for the week prior to randomization. Participants are admitted for 7 days to the General Clinical Research Center at San Francisco General Hospital. After a two-day lead-in period, they are randomized to smoke one marijuana or placebo cigarette three times daily for the next five days. Individuals are compensated \$650 for completion of the study. This is our first attempt to conduct a randomized placebo-controlled trial investigating smoked cannabis. We need your patients with persistent pain from peripheral neuropathy secondary to HIV, antiviral therapy, or both. Please have potential participants contact Hector Vizoso, R.N., at 415-476-9554, ext. 366, for more information.

Observational Cohort Study

The Community Consortium has an ongoing observational cohort study that involves 927 patients being followed predominantly at 8 local sites. As follow-up matures, this OCS is becoming a valuable resource of information.

Here’s a breakdown of OCS enrollments by Community Consortium site:

<u>Site</u>	<u>Provider</u>	<u>Enrollments</u>
010	EBAC	388
021	MNHC	243
005	CMHC	189
038	VAMC	60
009	Milton Estes	42
007	CPMC- California	8
008	Ken Mills	3
012	Robert Scott	2
<u>Total Enrollments</u>		
		927

Stay tuned for future analyses from this incredible local registry!

Vaporizer

The Community Consortium has successfully competed for funding from the Center for Medicinal Cannabis Research (CMCR) to perform another marijuana study. This study, which will enroll 20 healthy individuals, will evaluate the use of a vaporization system as a “smokeless” delivery system for inhaled marijuana and compare plasma levels of delta-9-tetrahydrocannabinol (THC) to those obtained from smoking an identical amount of marijuana from a cigarette using the standardized Foltin puff procedure over a range of THC doses. The study will also attempt to determine if there is a difference in the subjective and objective evidence of cannabis effects between the two delivery systems.

Farewell to Carroll Child

As you probably know, Carroll Child, R.N., resigned from his position as Research Director for the Community Consortium, and is now the Associate Director in the Human Research Protection Program in the Office of Research Administration at UCSF. After 15 years as a “Consortiumite”, Carroll decided after much debate to pursue his passion for human subject protection and regulatory affairs. His presence and leadership will be missed by us all, particularly those of us at the Consortium who have benefited so much from his experience, wisdom and equanimity. Join me in wishing Carroll the best of luck in his exciting new endeavor and gracious thanks for all he has done for us over these years!

Welcome to Sharon O’Leary

Sharon O’Leary, RN, BSN, CRCC, came from the Independent Clinical Trials Group at UCSF PHP in December 2003. In her position at the ICTG Sharon supervised NIH and CDC sponsored as well as industry sponsored and investigator initiated clinical trials for persons with HIV or at high risk of exposure to HIV.

Sharon brings over 11 years of experience as a clinical research nurse coordinating primarily HIV and Hepatitis C research at UCSF, Stanford University, and the AIDS Community Research Consortium (ACRC).

Sharon is a Certified Clinical Research Coordinator (CCRC) and a member of both the Association of Clinical Research Professionals (ACRP) and the Association of Nurses in AIDS Care (ANAC).

CALENDAR OF EVENTS

COMMUNITY CONSORTIUM EDUCATIONAL OFFERINGS

CONFERENCES

15TH INTERNATIONAL AIDS CONFERENCE
JULY 11-16, 2004
BANGKOK, THAILAND
[HTTP://WWW.IAS.SE/](http://www.ias.se/)

44TH INTERSCIENCE CONFERENCE ON ANTIMICROBIAL AGENTS AND CHEMOTHERAPY (ICAAC)
OCTOBER 30 – NOV. 2, 2004
WASHINGTON, DC
[HTTP://WWW.ICAAC.ORG/INDEX.HTML](http://www.icaac.org/index.html)

REPORT BACK MEETINGS

REPORT BACK FROM IAC
WEDNESDAY, JULY 28, 2004
CPMC-DAVIES CAMPUS
SAN FRANCISCO, CA

REPORT BACK FROM ICAAC
WEDNESDAY, NOVEMBER 17, 2004
CPMC-DAVIES CAMPUS
SAN FRANCISCO, CA

SATURDAY CME

ANTIRETROVIRAL THERAPY:
COPING WITH COMPLEXITIES AND COMPLICATIONS
SATURDAY, MARCH 20, 2004
MISSION BAY CAMPUS - GENENTECH HALL
8:30AM - 1:00PM

FOR MORE INFORMATION ON THESE EVENTS:

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