



## News briefs

The upcoming CTN semi-annual meetings will be held from April 20-23 in Vancouver at the Westin Bayshore. Of note, Dr. Jean-Pierre Routy will present results for CTN 110 (ESPRIT) and CTN 145 (SILCAAT) during the lunch hour on Wed., April 22. The fall meetings will be held from October 26-29 in Montreal.

The CTN's Community Advisory Committee (CAC) will be welcoming new members to the committee at the next CTN semi-annual meetings. Returning to the committee is David Hillman. New to the committee are Shari Margolese, Brigitte Ménard and apprentice Chuck Osbourne. A special thanks goes out to Louise Binder (Chair, Canadian Treatment Action Council) for her many years of dedication and support to the committee and the CTN. CAC members review clinical trial proposals and informed consents and make recommendations to the Network's Scientific Steering Committee.

New protocol submission forms are available for download on the CTN website. The next submission deadline for pre-final and final proposals is May 29. Related documents for study proposals may be found online under *Research Services* at [www.hivnet.ubc.ca](http://www.hivnet.ubc.ca).



CIHR IRSC

The CIHR Canadian HIV Trials Network is funded by the Canadian Institutes of Health Research and sponsored by the University of British Columbia and St. Paul's Hospital (Providence Health Care).

## Money leads world's first study testing HPV vaccine in HIV

CTN 236 keeps the WHO on their toes as they await trial results to improve the health and well-being of HPV's most vulnerable—HIV+ women and girls.

Dr. Deborah Money, Executive Director of the Women's Health Research Institute in Vancouver, has launched the world's first independent study to evaluate Gardasil®, the Health Canada approved human papillomavirus (HPV) vaccine, in HIV-positive women and girls (CTN 236). This study also marks the CTN's first female-focused co-infection trial.

HPV is the number one sexually transmitted virus that currently infects approximately seventy-five per cent of Canadians. There are more than 100 types of HPV but only thirty of those can infect the genital tract through skin-to-skin and sexual contact. HPV types six and eleven cause 90 per cent of genital warts; and types 16 and 18 are responsible for an estimated 70 per cent of cervical cancer that claims over 400 lives a year in Canada.

In 2006, Health Canada approved Gardasil®, a vaccine to protect women and girls against HPV (types 6,11,16,18). Gardasil is currently licensed for women and girls age nine to 26. However, researchers do not yet know how safe and effective the vaccine is in HIV-positive females.

"This is a groundbreaking study," notes Dr. Money. "HIV-infected women are the most vulnerable to HPV-related disease morbidity and cervical cancer mortality, both in Canada and worldwide."



CTN 236 Principal Investigator Dr. Deborah Money (right) and Project Manager Lisa Venables.

Study results should serve to identify HIV-infected individuals who will most benefit from this vaccine and suggest whether alterations in vaccine dosing, such as boosters, may be recommended in this population," says Money. "The knowledge gained in this study will also help researchers assess the vaccine in other immunocompromised populations."

See HPV on page 2 ...



## CANOC study connects researchers

CTN 242, the Canadian Observational Cohort (CANOC), is a collaboration of researchers and forms Canada's first nation-wide HIV cohort study. Above, from left, representing the six cohort databases across British Columbia, Ontario and Quebec are Drs. Julio Montaner, Mona Loutfy, Nimâ Machouf, coordinator Ali Palmer, Dr. Marina Klein, Principal Investigator Dr. Robert Hogg, and Dr. Janet Raboud.

CANOC is funded by the Canadian Institutes of Health Research (CIHR) and supported by the CTN. For more information on CANOC, visit their website at [www.canoc.ca](http://www.canoc.ca).

## Trials to watch

**CTN 194 – Peg-interferon and citalopram in co-infection (PICCO)** (Dr. Marina Klein, Montreal Chest Institute) CTN 194 is halfway to a full enrolment with 38 participants recruited. The study has also added two new sites: Clinique médicale L'Actuel in Montreal and Maple Leaf Medical Clinic in Toronto. Investigators will be evaluating the use of citalopram, an antidepressant, before starting and during hepatitis C (HCV) treatment to prevent the onset of depression in people co-infected with HIV and HCV about to start treatment for HCV. The study will compare adherence to HCV treatment and symptoms of depression between the participants receiving citalopram and the participants receiving a placebo.

**CTN 240 – Valacyclovir in delaying antiretroviral treatment entry (VALIDATE)** (Drs. Sharon Walmsley and Darrell Tan, Toronto General Hospital) CTN 240 will aim to answer if oral valacyclovir 500 mg twice daily can slow the rate of CD4 count decline and ultimately delay the need to start highly active antiretroviral therapy (HAART) in adults co-infected with HIV and asymptomatic HSV-2 who are not currently needing nor taking HAART. This multi-centre, randomized, placebo-controlled trial will recruit 480 participants over two years at 24 sites across Canada and Brazil. Knowledge gained from this study could lead to the introduction of chronic suppressive valacyclovir as a therapeutic strategy used to delay the start of HAART in HIV and HSV-2 co-infected adults.

**CTN S244 – STOP HIV and AIDS in IDU (Seek and Treat for Optimal outcomes and Prevention of HIV and AIDS in IDU)** (Dr. Julio Montaner, B.C. Centre for Excellence in HIV/AIDS, St. Paul's Hospital) CTN 244 will recruit 2000 HIV-infected individuals who are medically eligible for antiretroviral therapy but who are not receiving treatment or unaware of their HIV-infection status. The study will assess the impact of HAART expansion on HIV incidence in the province of B.C. over a six-year period.

## Networks

...HPV, from page 1

"The CTN is pleased to add another female-focused study to our roster," comments Dr. Joel Singer at the CTN National Centre. "On a global scale, the face of the epidemic has become that of a woman and so any research that helps ease their disease burden is a significant step for HIV research."

This is a five-year study recruiting 500 HIV-positive female participants at 16 sites across Canada over a two to three year period. The study will use the same standard dosing schedule and vaccine amount currently being used in HIV-negative women and girls. The vaccine will be administered in three doses over the course of six months and trial participants will make a total of seven clinic visits in a 24-month period.

### CTN 214 nears enrolment end

Recruitment for CTN 214 – Effect of a one-year course of HAART in acute/early HIV (Dr. Joseph Margolick, Johns Hopkins Bloomberg School of Public Health, Baltimore; Dr. Brian Conway, Downtown Infectious Diseases Clinic, Vancouver) is nearing completion and calls are out for all newly HIV-infected adults to enroll immediately at one of the seven Canadian sites. As of March 6, three-fourths of the study had been recruited with 92 of 120 participants enrolled. Recruitment will be closed April 30, 2009. The study aims to determine if treating newly HIV-infected people with one year of highly active antiretroviral therapy (HAART) will slow the progression of their disease. The study team would like to thank the staff at all sites for meeting the challenge of identifying and enrolling recent seroconverters into this study. CTN 214 is sponsored by the U.S. National Institutes of Health. For more info, go to [www.earlyhivstudy.org](http://www.earlyhivstudy.org).

### CTN at CAHR 2009

CTN researchers will be gathering in Vancouver to attend the 18th Annual Canadian Conference on HIV/AIDS Research (CAHR 2009) from April 23-26. Some of the Networkers playing a key role in this year's event include Drs. Marianne Harris and Mona Loutfy as Clinical Science Track co-chairs, and Dr. Jonathan Angel as one of the Basic Sciences Track co-chairs. On the administrative side, Dr. Brian Conway is President of CAHR and Bob O'Neill (former CTN networker) joins as the Executive Director of CAHR.

### Breakfast of postdoc champs at CAHR

It will be another sunny-side up morning for postdoctoral fellows and CAHR delegates at this year's annual CTN Postdoctoral Breakfast Symposium on April 26 at

7:30 a.m. Dr. Ramesh Saeedi (Vancouver) will present on the effects of rosuvastatin, a cholesterol-lowering drug, on fat cells; Dr. Martin Potter (Montreal) will speak on access to HCV treatment for HIV-HCV co-infected patients; Dr. Spenta Kakalia (Toronto) will address vitamin D supplementation and CD4 count in HIV-infected children; Dr. Richard Sloan (Montreal) will speak on cellular receptors mediated by unintegrated HIV DNA; and Dr. Nitika Pant Pai (Montreal) will preview a potential CTN study that examines whether rapid testing for HIV, hepatitis B, and syphilis is feasible and acceptable in resource limited settings.

Presentations will run 15-minutes each. Jacqueline Sas (Manager, Postdoctoral Fellowship Programme) will announce the 2009-10 new fellows.



Dr. Nitika Pant Pai



National Centre networkers (from left) Dr. Joel Singer, Bob O'Neill and Dr. Mirek Piaseczny.

### CAPT Network meets in Uganda

Researchers from Canada, Kenya, South Africa and Uganda attended the Canada-Africa Prevention Trials (CAPT) Network's third annual meeting in Entebbe from January 21-23, 2009. Among several projects, CTN National Centre networkers Drs. Joel Singer and Mirek Piaseczny met with researchers from the Uganda Virus Research Institute to discuss data management and analysis for the UVRI's Microarray/Yellow Fever Study.

**CTN 110****ESPRIT: subcutaneous interleukin-2**

Enrolled	141
International Enrolled	4,099
Principal Investigator	Dr. Jean-Pierre Routy
Status	Follow-up

**CTN 145****rII-2 to slow progression of HIV (SILCAAT)**

Enrolled	130
International Enrolled	1,978
Principal Investigator	Dr. Jean-Pierre Routy
Status	Follow-up

**CTN 147****Early vs delayed pneumococcal vaccination**

Enrolled	80
Principal Investigator	Dr. Walter Schleich
Status	Follow-up

**CTN 194****Peg-interferon and citalopram in co-infection (PICCO)**

Enrolled	38
Target Enrolment	76
Principal Investigator	Dr. Marina Klein
Status	Enrolling

(See page 2, Trials to Watch)

**CTN 198****Supportive therapy for adherence to antiretroviral treatment (STAART)**

Enrolled	100
Target Enrolment	112
Principal Investigators	Dr. Louise Balfour Dr. William Cameron
Status	Enrolling

**CTN 203****Phase I/II study of Remune® plus Amplivax™**

Enrolled	34
International Enrolled	121
Principal Investigator	Dr. William Cameron
Status	Enrolment closed

**CTN 205****Valproic acid and HIV**

Enrolled	55
Principal Investigator	Dr. Jean-Pierre Routy
Status	Enrolment completed

**CTN 208****HAART alone or with Remune® vaccine followed by STI in early HIV infection/observation of recent HIV infection**

Enrolled	8
International Enrolled	28
Principal Investigator	Dr. Jean-Pierre Routy
Status	Enrolment completed

**CTN 210****Effects of resistance training on abdominal fat**

Enrolled	3
Target Enrolment	40
Principal Investigator	Dr. Emil Toma
Status	Enrolment suspended

**CTN 214****Effect of a one-year course of HAART in acute/early HIV**

Enrolled	92
Target Enrolment	120
Principal Investigators	Dr. Joseph Margolick Dr. Brian Conway
Status	Enrolling

(Study website: [www.earlyhivstudy.org](http://www.earlyhivstudy.org))

**CTN 216****Argon plasma coagulation for anal dysplasia in MSM**

Enrolled	20
Principal Investigators	Dr. Alexandra de Pokomandy Dr. George Ghattas
Status	Enrolment completed

**CTN 218****Effect of rosuvastatin (Crestor®) on blood vessels**

Target Enrolment	250
Principal Investigator	Dr. Greg Bondy
Status	Enrolling

(See article on this page)

**CTN 222****Canadian co-infection cohort**

Enrolled	828
Target Enrolment	950
Principal Investigator	Dr. Marina Klein
Status	Enrolling

**CTN 227****Hepatitis C therapeutic vaccine study (Phase I/II)**

Enrolled Phase I	9
Enrolled Phase II	2
Target Enrolment	24
Principal Investigator	Dr. Jenny Heathcote
Status	Phase II enrolling, Phase I completed

**CTN 233****Pharmacokinetics of antiretroviral (ARV) therapy in HIV-positive women**

Enrolled	98
Principal Investigator	Dr. Mona Loutfy
Status	Enrolment completed

**CTN 236****HPV vaccine in HIV-positive girls and women**

Enrolled	42
Target Enrolment	500
Principal Investigator	Dr. Deborah Money
Status	Enrolling

(See article on page 1)

**CTN 237****Influenza vaccination strategies using Fluviral® in HIV-positive adults**

Enrolled	298
Principal Investigator	Dr. Curtis Cooper
Status	Enrolment completed

**CTN 238****The MAINTAIN study**

Target Enrolment	218
Principal Investigator	Dr. William Cameron
Status	Enrolling

**CTN 239****Phase II study of AGS-004 an immunotherapeutic agent in combination with ART followed by ART interruption**

Enrolled	28
Target Enrolment	34
Principal Investigator	Dr. Jean-Pierre Routy
Status	Enrolling

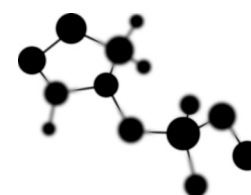
**CTN 240****Valacyclovir in delaying antiretroviral treatment entry (VALIDATE)**

Target Enrolment	480
Principal Investigator	Dr. Sharon Walmsley Dr. Darrell Tan
Status	Pending onset

**CTN 242****Canadian observational cohort study (CANOC)**

Target Enrolment	18,000 (from 6 databases)
Principle Investigator	Dr. Robert Hogg
Status	Ongoing

(See photobox on page 1)

**CTN 218****Effect of rosuvastatin (Crestor®) on blood vessels**

CTN 218, led by Dr. Greg Bondy, (St. Paul's Hospital, Vancouver) is investigating how the cholesterol-lowering medication rosuvastatin (Crestor) affects the course of cardiovascular disease (CVD) in people on highly active antiretroviral therapy (HAART).

The use of rosuvastatin in the context of CVD prevention was enhanced by recently released results of the JUPITER study (*New England Journal of Medicine*, Nov. 20, 2008), which enrolled almost 18,000 healthy HIV-negative people. Results showed that in people with normal lipids (LDL cholesterol) but high C-reactive protein, rosuvastatin significantly lowered the incidence of major cardiovascular events such as heart attacks and strokes.

CTN 218 researchers will examine participants' arteries using carotid artery ultrasound technology to monitor any hardening or change in composition of the arteries. Participants will be randomly assigned to either the rosuvastatin 10 mg group or a placebo group.

To be eligible for the study, participants must have at least one risk factor for CVD such as smoking or high blood pressure or a family history of premature heart disease. People with established cardiovascular disease are not eligible.

Recruitment for this two-year study is now underway in Vancouver; eight other sites across the country will be enrolling in the coming months.

For more information on these and other trials, please visit our website at [www.hivnet.ubc.ca](http://www.hivnet.ubc.ca) or call the CTN at 1-800-661-4664.

News briefs

**Dr. Aslam Anis (Programme Head, Pharmacoeconomics)** has been appointed the National Co-Director of the CTN and will work with the National Director to provide leadership, ensure accountability and strategic direction. Dr. Anis has been with the Network since 1995 and was one of the co-principal applicants for the renewal application to CIHR in 2007. We congratulate Dr. Anis on his new appointment.

**Ms. Candice Gartry (Chief Operating Officer)** left the CTN after 10 years of service in January. We wish Ms. Gartry the best in her future pursuits.

**Farewell and best wishes to Bob O'Neill** as he becomes the new Executive Director of CAHR. Mr. O'Neill is one of a few individuals who have been with the Network's since the beginning. Amongst his extensive work, O'Neill is credited with the expansion and management of the CAPT Network. We thank him for 19 years of dedicated work and wish him well in his new career.

**Postdocs start posting on CTN's study blog, networks.** Added sections enable fellows to chat with instant messenger. *Networks* is proving to be a great way for study coordinators and managers to connect online. The site is password protected with unique userids. Find it at [www.ctnforums.org/networks/](http://www.ctnforums.org/networks/).

**The 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention** will be held in Capetown, South Africa from July 19-22. Hosted by the International AIDS Society, the conference will feature reports on the latest developments in basic, clinical and prevention science. For more info, go to [www.ias2009.org](http://www.ias2009.org).



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Debaters (from left) Dr. Jean-Pierre Routy, Dr. Marianne Harris, Anne Pigott (Abbott Virology), José Sousa, Marie Prevost (Abbott Virology) and Matthew Steele (Abbott Virology).

**Networkers debate when to begin treatment**

Dr. Jean-Pierre Routy (Montreal Chest Institute, Core Co-leader, Vaccines and Immunotherapies) and José Sousa (Chair, Community Advisory Committee) met in December 2, 2008 in Vancouver for an Abbott sponsored debate on whether an HIV person should be treated immediately after diagnosis. Dr. Marianne Harris (John Ruedy Immunodeficiency Clinic, Core Coordinator, Antiretroviral Therapies) moderated the debate that was well attended by local HIV physicians and community members.

**Publications and presentations**

This list includes some of the recent publications and presentations of Network investigators and staff.

**Fontaine J, Coutlée F, Tremblay C, Routy JP, Poudrier J, Roger M;** Montreal Primary HIV Infection and Long-Term Nonprogressor Study Groups. "HIV infection affects blood myeloid dendritic cells after successful therapy and despite nonprogressing clinical disease." *J Infect Dis.* 2009 Feb 20. [Epub ahead of print]

**Harris M, Côté H, Ochoa C, Allavena C, Negro E, Thorne A, Cahn P, Zala C, Raffi F, Clotet B, Singer J, Montaner J;** The CTN 177 Study Team. "A randomized, open-label study of a nucleoside analogue reverse transcriptase inhibitor-sparing regimen in antiretroviral-naïve HIV-infected patients." *J Acquir Immune Defic Syndr.* 2009 Mar; 50(3):335-337. No abstract available.

**Kiboneka A, Wangisi J, Nabiryo C, Tembe J, Kusemererwa S, Olupot-Olupot P, Joffres M, Anema A, Cooper CL, Montaner JS, Mills EJ.** "Clinical and immunological outcomes of a national pediatric cohort receiving combination antiretroviral therapy in Uganda." *AIDS.* 2008 Nov 30;22(18):2493-9.

**Wainberg MA.** "New findings on blockage of HIV-1 RNase H activity." *AIDS.* 2009 Jan 14;23(2):223-4.

**Lima VD, Harrigan R, Bangsberg DR, Hogg RS, Gross R, Yip B, Montaner JS.** "The combined effect of modern highly active antiretroviral therapy regimes and adherence on mortality over time." *J Acquir Immune Defic Syndr.* 2009 Feb 13. [Epub ahead of print]

**Walmsley SL, Squires K, Weiss L, Easterbrook P, Orani A, Kraft M, Scherer J.** "Multidrug-experienced HIV-1-infected women demonstrated similar virological and immunological responses to tipranavir/ritonavir compared with men." *AIDS.* 2009 Jan 28;23(3):429-31.

16th Conference on Retroviruses and Opportunistic Infections (CROI) Montreal, Feb. 8-11

**Côté H, Negro E, Ruiz L, Langridge S, Brumme Z, Martínez-Picado J, O'Shaughnessy M, Harrigan PR, Clotet B, Montaner J.** "Antiretroviral regimen-dependent mitochondrial DNA depletion in clinical samples from the SWATCH trial." Paper 707-T.

**Cooper C, Hutton B, Mills E, Angel J.** "CD4 T lymphocyte recovery with ART is not directly influenced by HCV-co-infection status." Paper 1067.

**Hull M, Phillips E, Harris M, Bondy G, Leong P, Toy J, Hogg R, Singer J, Montaner J.** "High risk of unrecognized adrenal suppression and symptoms of steroid excess in HIV clinic patients exposed to ritonavir and topical fluticasone: results of a case-control study." Paper 772.

**Komsic-Vranjkovic A, Faller E, MacPherson P, Angel J.** "Regulation of IL-7 receptor (CD127) on CD8T cells by in vitro HIV infection." Paper 338.

**Loutfy M, Thompson C, Trpeski M, Kovacs C, Rachlis A, Goodhew J, Rubin G, Gough K, and Walmsley S.** "Influence of genotypic resistance on the viral load response of 167 patients on lopinavir/r (LPV/r) including an analysis of new protease inhibitor resistant mutations in 21 patients who failed." Paper 560-T.

**Potter M, Rouleau D, Cox J, Yang H, Saeed S, Klein M,** and for Canadian Co-infection Cohort. "Effect of spontaneous clearance of CD4 T lymphocyte counts in HIV/HCV-co-infected adults." Paper 836.

**Walmsley S, Henry K, Katlama C, Nelson M, Lazzarin A, Reynes J, Clotet B, Salgo M, Demasi R, Delehanty J.** "Lack of influence of gp41 antibodies that cross-react with enfuvirtide on the efficacy and safety of enfuvirtide in TORO 1 and TORO 2 Phase III trials." Paper 558.