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# HIV VACCINES AND THE COMMUNITY

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The Community Advisory Board Bulletin

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## HVTN'S FIRST SOUTH-TO-SOUTH TRAINING

*Brazil, March 14-17<sup>th</sup>, 2001*

The International Working Group (IWG) of the HIV Vaccine Trials Network (HVTN) conducted the first South-to-South training in Rio de Janeiro, Brazil last month. This issue of the CAB Bulletin attempts to provide a synopsis of the meeting.

### MEETING OVERVIEW

It may seem glamorous to travel to Rio de Janeiro and have a meeting in the lovely Hotel Pestana Carlton Rio Atlantica. However many of those who spent March 14-17 in the workshops noted, "Great location. Too bad we have no time to enjoy it.."

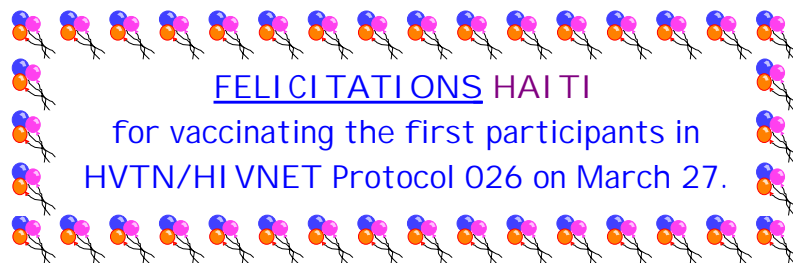
The meeting gave the IWG an opportunity to focus on developing plans for activities in preparation for a vaccine trial in 2002. Being the first south-to-south training, the meeting also gave participants an opportunity to focus on site concerns for those outside the U.S. There was also an excellent chance to visit Praca Onza, the Brazil project site and learn about solutions and remedies implemented by their team. (See the January 2001 CAB Bulletin for more information on the site.)

In opening the meeting, Dr. Salim Abdool Karim, chair of the IWG and Principal Investigator for the Durban site, thanked Fogarty International and the HVTN Core for providing a chance for this group to address unique issues faced by those trying to do trials outside the US. He noted, that "the IWG does not have a separate agenda from the overall scientific agenda of the HVTN. Instead, the IWG creates opportunity and space for those who have a particular interest in issues relating to international trials."

Existing sites participating in the HVTN include Rio de Janeiro, Brazil; Port of Spain, Trinidad and Tobago; Port-au-Prince, Haiti;



International Working Group, Brazil 2001



### FELICITATIONS HAITI

for vaccinating the first participants in  
HVTN/HI VNET Protocol 026 on March 27.



HAITI  
Centre GHESKIO

Dr. Patrice Joseph,  
Dr. Rose-Irène Verdier,  
Dr. Sonia Jean &  
Dr. Patrice Sévère

Durban, South Africa; Lima, Peru; Naning, China; Pune, India; and Chaing Mai, Thailand. Expansion site representatives at the meeting included Sao Paulo, Brazil; Buenos Aires, Argentina; Honduras; and St. Petersburg, Russia. CAB and community education staff participation was limited to representatives from existing sites.

The passionate group left with even greater commitment to the common destiny of global research for an HIV vaccine. Dr. Jose Esparza, of UNAIDS noted the strength in the group's diversity and immense talent assembled— "12 countries operating for a common goal." Others noted the importance of this meeting in building the trust necessary for collaboration.

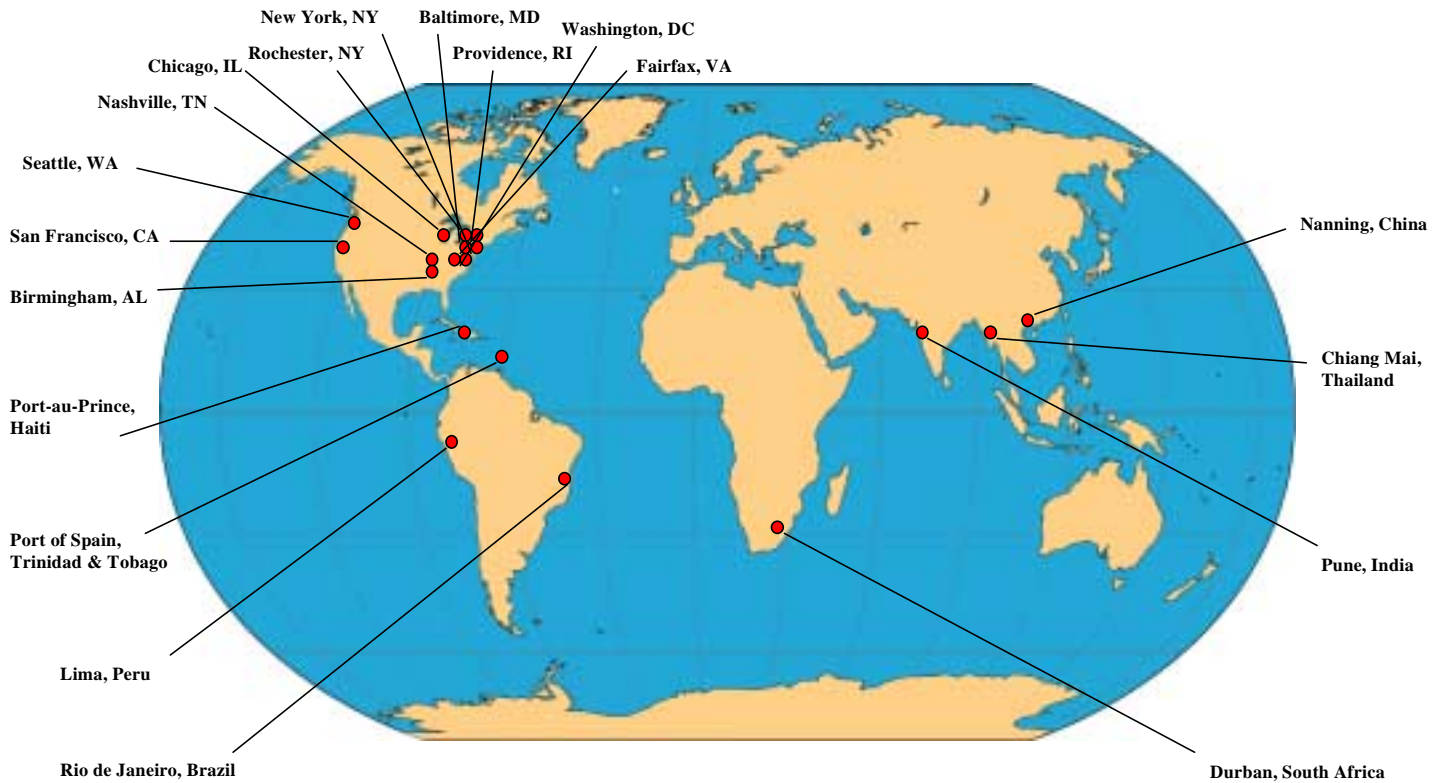
Specific areas of work for the future include: a) Building full and equal involvement of all sites in the HVTN as exhibited at this south to south training. b) Demonstrating site capacity to conduct trials reflective of the best tenets of Good Clinical Practice. c) Developing specific mechanisms to ensure that human resource support is maintained. (In other words, making sure current talented staff receive appropriate rewards and support for career paths.)

d) Building the next layer of talented people which will be needed for future trials. e) Making sure that community issues and concerns, and ethics of trials are featured at the same table as laboratory assays and key scientific questions. ☞



# HIV VACCINE TRIALS NETWORK (HVTN)

An International Program to Develop and Test HIV Vaccines



## SITE EXPANSION

Several presentations provided information on the challenges and resources available for site expansion. The IWG noted that the vaccine pipeline dictates that we need to add capacity to the HVTN as it exists currently, especially in international sites. We are likely to be in phase III in 2003 and need to be beyond the slow development of a Phase I program. Participants from each country worked in groups with the HVTN leadership group, NIAID's Division of AIDS staff and U.S. investigators to decide what will be needed for site expansion. Focus areas included clinical trials expertise; backing of the local and national health care community; training of staff in recruitment and retention of persons in vaccine trials; participation by community in the trial process and conduct; protocol oversight by each site, country and U.S. Institutional Review Boards (IRB), as well as, administrative oversight of the clinic and laboratory facilities and procedures.

Dr. Susan Buchbinder, chair of the Phase III Science Committee and Principal Investigator at the San Francisco site, presented the follow-

ing issues in defining community input in her look at potential sites for protocol HVTN 501.

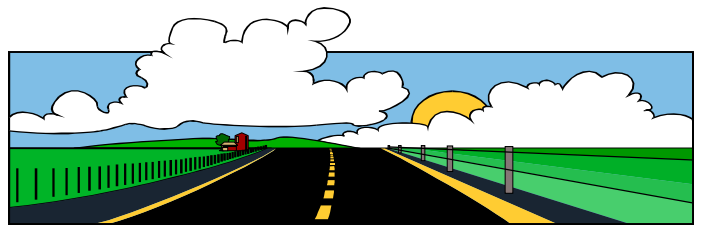
Community input means:

- Having substantial involvement of persons from at-risk communities
- Reviewing of protocols and the informed consent process by community members
- Having community members assist in development of community education and media plan
- Having community members assist in development of recruitment plans
- Getting the community involved in the network-wide Global Community Advisory Board

Community input must be tailored for specific sites, and specific populations. ☘



# THE ROAD TO AN HIV VACCINE FOR THE HVTN



Dr. Larry Corey, chair of the Scientific Steering Committee, presented his ‘Road to an HIV vaccine for the HVTN.’ He noted that having a single purpose does not imply one way of doing things. Building a matrix organization is key.

“The HVTN has a unique structure in which its scientific and administrative units have the ability to initiate programs relevant to its mission at a rapid pace. In the HVTN, the sites and the investigators are those who establish the network culture, not Larry Corey as the leader. We must move forward intelligently toward the goal of a vaccine for all.”

“The HVTN is an international collaboration of scientists whose goal is to speed the development and testing of candidate HIV vaccines. The mission of the HVTN is to develop a vaccine regimen that will reduce the frequency of seroconversion, progression of HIV-1, and transmission of HIV-1 to others. The HVTN will conduct as many trials as it can simultaneously. All scientific fields are ‘moving targets’ as new assays, information and improvements are made. Ideally, the

data from initial studies will be used to determine vaccine strategy for an individual product and an idealized vaccine regimen. The experience of the network in testing combination vaccines is substantial, and international collaboration provides an ideal platform to enhance the cooperation between companies and inventors in defining an optimal vaccine regimen.”

Dr. Corey congratulated all who had a role in getting the two trials started during the transition to the new network. There was praise for the teams currently working on implementation of both the Phase I Caribbean and Latin America trial 026 and the Phase II U.S. trial 203.

Dr. Corey showed slides presenting the challenges of multiple trials in the next two years and capacity expansion as we move toward our first large scale trial. Several noted the need to also think about the reality of multiple large scale trials in order to determine the most effective vaccine strategy. These tables are from Dr. Corey’s presentation. ✂

**Table 1: Novel HIV-1 vaccines in the pipeline for calendar year 2001**

VACCINE	INVENTOR	CLINICAL TRIALS SITE
VEE replicon Clade C gag	ALPHAVAX	US and South Africa HVTN sites
MVA-CCR5 Isolate Clade B	Therion	HVTN
Adenovirus Replicon	Merck	In pharmaceutical development
Recombinant protein in novel adjuvant	Glaxo/SmithKline	HVTN
Lipopeptides (Boost to CP vector)	ANRS	HVTN
Codon optimized HIV-1 DNA	Robinson, Emory University	HVTN

**Table 2: Novel HIV vaccines in the pipeline for calendar year 2002**

VACCINE	INVENTOR	CLINICAL TRIALS SITE
DNA micro particle <ul style="list-style-type: none"> <li>Gag-pol-B clade</li> <li>Gag-pol-C clade</li> <li>Env B &amp; C clades</li> </ul>	Chiron	HVTN HVTN plus SAVI HVTN plus SAVI
V2-deletion envelope	Chiron	HVTN
MVA-CLade B	Bernie Moss & Harriet Robiinson construct	HVTN
Clade C	Therion	HVTN
VEE replicon Gag-env-pol, Clade C	ALPHAVIRUS	HVTN and WRAIR
DNA, IL-12	Wyeth Lederle	HVTN
Salmonella	University of Maryland	HVTN

# IWG CAB TRAINING



The International Working Group meeting also gave CAB members and staff from Brazil, Haiti, Peru, South Africa and Trinidad & Tobago an opportunity to meet. Persons who participated in the south-to-south CAB training included Monica Barbosa, Christine Cazeau, Pedro Goicochea, Shaun Mellors, and Victor Coombs.

Participants noted that the meeting gave them an opportunity to learn more about individual site needs and accomplishments that can help in their own site functionings.

The group was also able to take a look at the first printed newsletter of the Thai CAB which featured pictures of each CAB member.

In this meeting, some challenges of participating in a global network were discussed. The materials provided to date by the HVTN have been in English only. Often this means that only certain staff have the ability to utilize the materials and are often burdened to find time to translate or make the materials culturally appropriate.

The group noted there is a strong need for additional training, materials in the local language and more opportunities to share the success stories of each site.

Autonomy and choice were key principles for success. Victor Coombs and Monica Barbosa noted that as their CABs became more established there was less need for the investigator to attend every meeting. CAB members set the agenda for prevention activity and discussions of issues related to trial participation. Christine Cazeau noted that the Haiti CAB members create outreach opportunities related to HIV prevention which incorporate vaccine messages.

A highlight of the meeting came during the tour of the Rio HVTU when Alexandre do Vale, a member of the Rio CAB, spoke to the entire group assembled about local issues. He talked about the strong link that exists between AIDS service organizations, local activists and trial site staff, and how such synergy is an important component for an effective CAB. He also talked about the Brazilian healthcare system and its insistence on health care as a right, not a privilege. Universal healthcare coverage has existed for over ten years in Brazil, and this has and will be an important factor in creating a political will to support HIV vaccine research at the community level.

The group noted that it takes more than lip service to "encourage active discussion and participation of the CAB in all phases of protocol development, implementation, accrual and outcomes." Most sites have found their most ardent support for HIV vaccines through attempts to piggy-back on other AIDS activities. All noted this is not enough. There was a loud cry for additional resources. ☘

## CALENDAR OF EVENTS

CAB PROTOCOL WORKING GROUP CONFERENCE CALL:



Saturday May 2, 2001 12 p.m. EST, 9 a.m. PST.

GLOBAL CAB CONFERENCE CALL:



Thursday May 17, 2001 7 p.m. EST, 4 p.m. PST **NOTE NEW DATE**

COMMUNITY EDUCATION/RECRUITMENT COORDINATION CALL:



Tuesday May 15, 2001 12:00 noon EST, 9:00 a.m. PST

HVTN FULL GROUP MEETING

MAY 9-11, 2001 WASHINGTON D.C.



4TH ANNUAL HIV VACCINE AWARENESS DAY

May 18, 2001



CAB RETREAT, SEATTLE WA

August 16-18, 2001



HVTN Full Group Meeting, May 9-11, 2001

Those persons attending the May HVTN Full Group Meeting should plan to stay on Friday afternoon for the Community Advisory Board session. This will include a combination of committee reports, skills building, planning for the summer retreat, and an update on how other vaccine education processes may affect the HVTN. The meeting will conclude at 5 PM. Please forward agenda items you would like to cover or have covered to the GCAB co-chairs Danny Pickett and Jim Thomas. ☘

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*Please send suggestion, questions and article submissions to:  
Siobhan Malone- Community Project Coordinator  
HVTN/FHCRC, 1100 Fairview Avenue North  
PO Box 19024, M/S: MW 832  
Seattle WA 98109-1024  
Siobhan@ssharp.org  
Tel: 206-667-6350 Fax: 206-667-6366*

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HIV VACCINE  
TRIALS NETWORK