

***Expanding Research Capacity
&
Accelerating HIV Vaccine Development
in Asia***

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AIDS Vaccine Asian Network

Is created to

- Facilitate interactions between donors and funding opportunities
- Develop/strengthen a regional platform for clinical trials, including harmonized legal, regulatory, and ethical frameworks
- Support region-specific advocacy and communication strategies
- Prepare a regional approach for future vaccine deployment
- Contribute to the Global HIV Vaccine Enterprise Scientific Plan

How?

Examples of Collaboration among ASEAN Countries

ASEAN Consultative Committee on Standards and Quality

- Was established in 1992
- Members include Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Singapore, Thailand, Vietnam
- **Pharmaceutical Product working group (PPWG)** was appointed
- **Objective:** to facilitate, support licensure of medical product in the region
 - ASEAN Common Technical Dossier
 - ASEAN Common Technical Requirement

The Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP)

Was established 2000

Objectives

- Improving communication among ethics committees (ECs) in reviewing biomedical research in the region
- Acting as a regional collaborating center for ethical review
- Organizing international meetings and symposia
- Assisting with the adoption and implementation of standard operating procedures for ethical review in the region
- Facilitating training and education opportunities for members of regional Ethics Committees

FERCAP Countries/ Regional



What about collaboration for HIV
Vaccine Research and Development in
the region?

Needs for infrastructure and capacity building in preparation for vaccine efficacy trials

- Country-level issues (eg. Ethical and Scientific Review)
- HIV testing and care
- Cohort development
- Phase IIB/III clinical infrastructure
- Laboratory infrastructure
- Data management
- Host country drug control/regulatory regime

AIDS Vaccine Development Capacity in selected Asian countries

Countries	Country-level issues		
	National HIV Vaccine Plan	Institutional review board (IRB)	Regulatory Authority
China	Yes?	Yes	Yes
India	No	Yes	Yes
Thailand	Yes	Yes	Yes
Indonesia	No	Yes	Yes
Vietnam	No	Yes	Yes
Japan	NA	Yes	Yes
Australia	NA	Yes	Yes

AIDS Vaccine Development Capacity in selected Asian countries

Countries	Country-level issues			
	HIV testing and care	Phase IIB/III clinical infrastructure	Laboratory infrastructure	Data management
China	Yes	Yes	Yes	Yes
India	Yes	Limited	Yes	Limited
Thailand	Yes	Yes	Yes	Yes
Indonesia	Yes	?	Yes	?
Vietnam	Yes	limited	limited	?
Japan	Yes	NA	Yes	Yes
Australia	Yes	NA	Yes	Yes

Example for Thailand

Thailand National Plan

The National Plan on HIV research and development was launched in 1994 under the National AIDS Commission which is chaired by Priminister , and was updated

Commitment of the government and the people including society to have an HIV vaccine is

HIGH for Thailand

HIV-1 Prophylactic Vaccine Trials in Thailand

<i>Year</i>	<i>Product</i>	<i>Phase</i>
• 1994	V3-MAPS-B	I / II
• 1995	rgp120/alum-B	I / II
• 1995	rgp120/MF59-B	I / II
• 1997	rgp120/MF59-B,E,B&E	I / II
• 1998	rgp120/alum-B/E	I / II
• 1999	rgp120/alum-B/E	III
• 2000	ALVAC-HIV Oligo gp160 or gp120 B/E boost	I / II
• 2000	ALVAC-HIV rgp120 B/E boost	I / II
• 2003-09	ALVAC prime with rgp120 B/E Boost	III

2004

- A worldwide , Phase I, Dose-Escalating Study of the Safety, Tolerability, and Immunogenicity of a 3-Dose Regimen of the **MRKAd5 HIV-1 gag Vaccine** in Healthy Adults

2006

- A Randomized, Placebo-Controlled, Double-Blind, Phase I Clinical Trial of a Candidate Prophylactic **pHIS-HIV-AE (DNA) Prime and rFPV-HIV-AE Boost**

Kiat Ruxrungtham, *et al.* (24)

2007

- A Phase I of an **HIV-1 gag DNA vaccine with or without IL-12 DNA adjuvant**, boosted with homologous plasmids or with HIV CTL multiepitope peptide vaccine/RC529-SE, in healthy, HIV-1 uninfected adult participants.

Vinai Suriyanon, *et al.*(18)

- A Phase I Double-Blind, Randomized, Dose Escalating, Placebo-Controlled, of WRAIR/NIH **Live Recombinant MVA-CMDR (HIV-1 CM235 env/CM240 gag/pol)** Administered by Intramuscular (IM) or Intradermal (ID) Route In HIV-Uninfected Adults.

Prasert Thongcharoen *et al.* , *Paris et al.* (22)

Clinical Investigator Groups

- Full Phase I to Phase III clinical research capacity including physical spaces and staff with full GCP training
- Institutes involved are
 - AFRIMS-Thai, US
 - HIVNAT, Thai Red Cross
 - MOPH
 - RIHES, Mahidol University
 - Siriraj, Mahidol University
 - Vaccine Trial Centre, Faculty of Tropical Medicine, Mahidol University

Laboratory Works

- Molecular epidemiology and monitoring of circulating virus in Thailand
 - National Repository and Bioinformatic Center (NHRBC) , Siriraj Hospital , Mahidol University
 - Molecular Epidemiology Research Laboratory, AFRIMS

- **Anti HIV lab with QA/QC** - at AFRIMS, HIVNAT, RIHES, Siriraj
- **Safety lab with QA/QC** - CAP certified at AFRIMS, RIHES
- **Cellular Immunogenicity:** CTL, ELISPOT, ICS, LPA -AFRIMS, HIVNAT, RIHES, Siriraj
- **Trial Registry and Repository Center** at MOPH and Bumrungrad Specimen Processing Laboratory with computerized system

Data Management

- DataFax, validating system at Faculty of Tropical Medicine, Mahidol University
- HIVNAT, Thai Red Cross AIDS Research Centre
- RIHES, Chiang Mai University

Current works on

HIV Incidence & Cohort preparation

Preparatory HIV cohort study among men who have sex with men (MSM) in Bangkok: baseline and first follow-up data

April 5,06- February 13,07

- 421 men enrolled (mean age 27 years; range 18-56 years)
- HIV prevalence was 20.9% (88/421)
- Among HIV-negatives, **the 4 month HIV incidence rate was 2.14 per 100 person-years (2/93.3)** and the 4 month follow-up rate was 88.6% (264/298).

HIV incidence using BED testing among clients attending anonymous HIV site in Bangkok, Thailand

- HIV prevalence was 12%. Nine incident infections were detected for an estimated annualized HIV incidence rate of 5.8% (95% CI, 2.02-9.7); 4.2% among women, (95%CI, 0-10.0) and 6.6% in men, (95% CI, 1.7-11.4)
- Men who reported sex with men (MSM) had the highest incidence at 17.3% (95% CI 2.1-32.5)

Examples of HIV incidence in Asian countries

Curtsey from Dr. Excler



Country	IDU	CSW	STD patients	MSM	General Population
China Yunnan 1994 2005 Guangxi 1999 2005 Sichuan 2002 Xinjiang	0 - 25% 4% 3.8% (spouses) 2.38 - 6.86% 3.1% 3.17% 7-8.8%	NA NA NA	NA NA NA	NA NA NA	NA NA NA
India Pune 1993-04 Pune 2000-02	NA	3.7% 3.6%	F 16.6 – M 6.8 F 5.6 – M 2.5	NA	NA
Thailand 1994 2002-04	5.8 - 7.3%	12.8% NA	4.92 -5.2 % NA	NA	<1%
Cambodia 1999 2002	NA	13.9% 6.45%	NA	NA	<1%

The Paradox is that Asia has all the components for integrated HIV vaccine plan and strategy

- Basic research- China, India, Japan, Thailand
- Manufacturing capacity- India, China
- Clinical trial capacity -Thailand, India ,China
- Research power houses-Japan ,Australia

The Proposed Activity Frameworks of ASIAN Network

6 area

- **Advocacy and resource mobilization**
 - Partners/donors identification
 - Dissemination of information
- **Epidemiology and social behavioral research**
 - Identification and strengthening of potential sites for vaccine trials
 - Socio/behavioral research and willingness to participate to support vaccine trials

- **Biomedical sciences (laboratory)** research and capacity building

Identification and strengthening of laboratory expertise in selected countries the region

- HIV isolation and characterization
- Immunology methods for vaccine evaluation

- **Clinical trial capacity**

- Adequate resources, spaces and well trained staff with CGP compliance

Ethics- infrastructure strengthening and capacity building

- Assess research ethics infrastructures
 - Build capacity for ethics, law and human rights
 - Support the development of national guidelines

- **National strategic planning**

- Support development and implementation of National AIDS Vaccine Plans/Strategies
- Address issues related to future access to HIV vaccines

What next?

- Arrange meeting or forum with AAVP to learn the process and modify to fit into Asian context
- Have series of workshops & meetings among Asian countries to establish core working group and the administrative structure

With many challenges

Since some countries have sufficient infrastructure to do individually

To identify opportunities for collaboration in which joint activities add value to HIV vaccine research and development efforts



***With good
collaborations
will fasten the
process to achieve
common goal***

of

***Having an HIV/AIDS
Vaccine for Our
Young Generation***

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