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)

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
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 (e.g., 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

<table>
<thead>
<tr>
<th>Countries</th>
<th>National HIV Vaccine Plan</th>
<th>Institutional review board (IRB)</th>
<th>Regulatory Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>Yes?</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>India</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Thailand</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indonesia</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Vietnam</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Japan</td>
<td>NA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Australia</td>
<td>NA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
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<tr>
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<th>HIV testing and care</th>
<th>Phase IIB/III clinical infrastructure</th>
<th>Laboratory infrastructure</th>
<th>Data management</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>India</td>
<td>Yes</td>
<td>Limited</td>
<td>Yes</td>
<td>Limited</td>
</tr>
<tr>
<td>Thailand</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes</td>
<td>?</td>
<td>Yes</td>
<td>?</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Yes</td>
<td>limited</td>
<td>limited</td>
<td>?</td>
</tr>
<tr>
<td>Japan</td>
<td>Yes</td>
<td>NA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Australia</td>
<td>Yes</td>
<td>NA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
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 the Prime Minister, 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

<table>
<thead>
<tr>
<th>Year</th>
<th>Product</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994</td>
<td>V3-MAPS-B</td>
<td>I / II</td>
</tr>
<tr>
<td>1995</td>
<td>rgp120/alum-B</td>
<td>I / II</td>
</tr>
<tr>
<td>1995</td>
<td>rgp120/MF59-B</td>
<td>I / II</td>
</tr>
<tr>
<td>1997</td>
<td>rgp120/MF59-B,E,B&amp;E</td>
<td>I / II</td>
</tr>
<tr>
<td>1998</td>
<td>rgp120/alum-B/E</td>
<td>I / II</td>
</tr>
<tr>
<td>1999</td>
<td>rgp120/alum-B/E</td>
<td>III</td>
</tr>
<tr>
<td>2000</td>
<td>ALVAC-HIV Oligo</td>
<td>I / II</td>
</tr>
<tr>
<td></td>
<td>gp160 or gp120 B/E boost</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>ALVAC-HIV rgp120 B/E boost</td>
<td>I / II</td>
</tr>
<tr>
<td>2003-09</td>
<td>ALVAC prime with rgp120 B/E Boost</td>
<td>III</td>
</tr>
</tbody>
</table>
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 Ruxrunghtham, 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, 2006 - February 13, 2007

- 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).

Van Griensven F. et al.  IAS meeting 2007, Sydney
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)

Apornpong T, et al., IAS Meeting, Sydney, 2007
### Examples of HIV incidence in Asian countries

<table>
<thead>
<tr>
<th>Country</th>
<th>IDU</th>
<th>CSW</th>
<th>STD patients</th>
<th>MSM</th>
<th>General Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>China Yunnan</td>
<td>0 - 25% 4% 3.8% (spouses) 2.38 - 6.86% 3.1%</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Guangxi 1999 2005</td>
<td>NA</td>
<td>3.7% 3.6%</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Sichuan 2002 Xinjiang</td>
<td>3.17% 7-8.8%</td>
<td>NA</td>
<td>12.8% 4.92 -5.2%</td>
<td>NA</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>India Pune 1993-04 Pune 2000-02</td>
<td>NA</td>
<td>3.7% 3.6%</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Thailand 1994 2002-04</td>
<td>5.8 - 7.3%</td>
<td>NA</td>
<td>12.8% 4.92 -5.2%</td>
<td>NA</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Cambodia 1999 2002</td>
<td>NA</td>
<td>13.9% 6.45%</td>
<td>NA</td>
<td>NA</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>
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.
Acknowledgement

• Dr. Jean-Louis Excler
  International AIDS Vaccine Initiative, India
• Dr. Jerome Kim
  AFRIMS-US, Military HIV Research Program
• Dr. Jose Esparza
  Bill- Malinda Gates Foundation
Acknowledgement

BMA
Dr. Kachit C
Dr. Suhpak V

MOPH
Dr Prayura K
Dr. Vichai C
Dr. Supachai R

AFRIMS
Dr Sorachai N
Dr J. Kim

WHO/UNAIDS
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Mahidol University
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Dr. Pratap S
Dr. Ruengpung S
Dr. Jaranit K

Chaingmai University
Dr Chirasak K
Dr. Thira S
Dr. Vinai

AFRIMS
Dr. D. Birx
Dr. Tim Mastro

CDC

Global Solution for Infectious Diseases

NIH
Dr J. Chiu, Dr M. Johnston

Dr. D. Francis