



*A Phase III Trial of Aventis Pasteur Live Recombinant ALVAC-HIV (vCP1521) Priming With VaxGen gp120 B/E (AIDSVAX® B/E) Boosting in HIV-Uninfected Thai Adults*



# Challenges in HIV Vaccine phase III Community-based Trial in Thailand

## AIDS Vaccine 2007 Conference,

20-23 Aug. 2007

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# Thailand



**Total population: 60,617,200**

- Male: 29,850,200

- Female: 30,767,000

**M:F ratio = 0.97:1**

**Rural 80%**

**Buddhist > 95%**

**Literacy >95%**

**Strong NGOs & CBOs**

**Health care infrastructure:**

Regional/Provincial hospital

@ provincial level

10-12 District hospitals in each province

10-15 Health centers in each district

10-15 VHV in each sub-district

10-15 HH per VHV

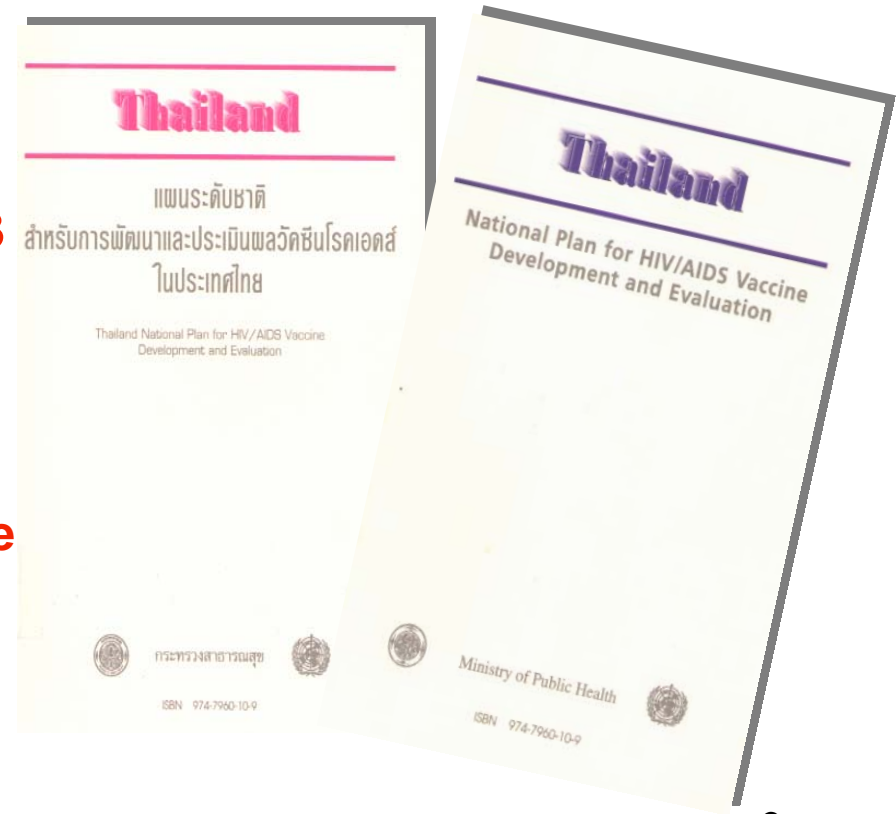


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## National Plan for HIV/AIDS Vaccine Development

- Developed by Thai MOPH and research scientists with GPA/WHO collaboration
- Approved by NAC and launched in **1993** placing HIV vaccine research and development on the **“fast tract”**
- Aimed at research and development of safe, effective, **affordable and accessible** HIV vaccines for the Thai people at the earliest possible date





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# Challenges:

- Pre trial
  - Study Site Selection
  - Protocol Development & Review
  - Resources
- Trial ongoing
  - Community Engagement
  - Retaining Volunteers
- Post trial
  - Communication of Trial Results



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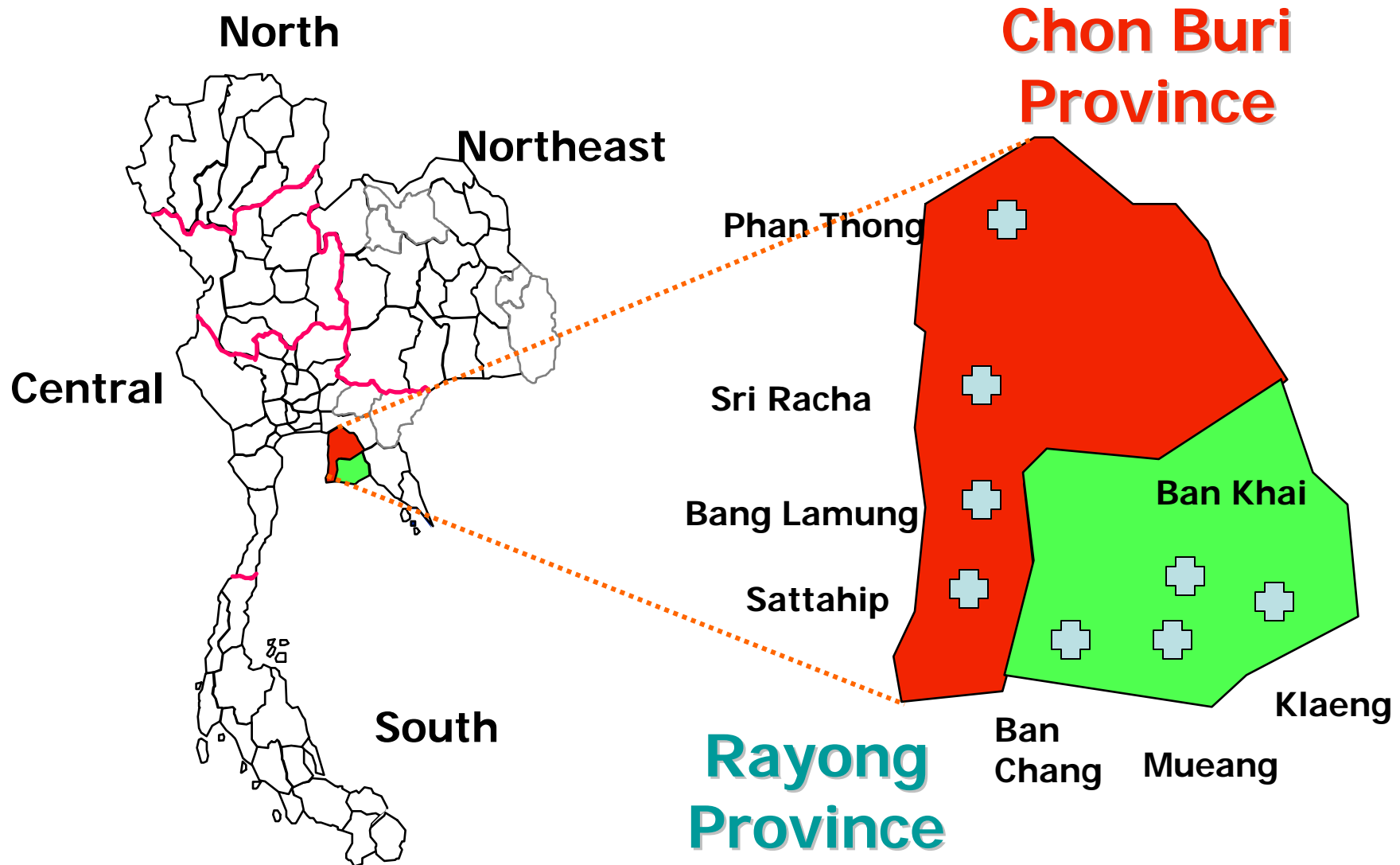
## Study Sites Selection:

### Chon Buri and Rayong Provinces

- Top five high prevalence provinces for military recruits
- 3.7-7.8% prevalence among ANC attendees during 1990s
- 3.9-4.8% prevalence and **0.68/100PYs incidence in community cohorts**



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## Screening Site



**40 health centers &  
7 district hospitals  
in 8 districts**

## Clinical Site



**7 district hospitals and 1 STD clinic**



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## Protocol Development:

- Protocol Drafting Committee
  - Sponsors
  - Manufacturers
  - Local collaborators
- Consultations
  - Local: NGO & CBO representatives
  - International: WHO/UNAIDS



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## Protocol Review:

### Local

- MOPH-EC
- National AIDS Committee-Scientific Subcommittee
- Royal Thai Army-IRB
- Mahidol University-IRB
- Thai FDA

### Overseas

- US-HSRRB
- WRAIR-Scientific review
- US-NIH-AVRWG
- US-FDA-VRBPAC



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## Study Staff

**Clin. Research Co.s: #40**  
**Pharmacy Nurses: #16**  
**Research Assistants: #24**

## MOPH staff:

- Core staffs-#15
- Community outreach team-#200
- Counselors-#96+94
- Hth. Center Officials-#80+
- Nurse coordinators-#16
- Site physicians-#16

## Training

- Good Clinical Practice
- Counseling
- Standard Operating Procedures
- Emergency Response
- Record Keeping
- Vaccinology



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**GCP Training**



**ACLS Training**



**Communications Workshop**



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## Laboratories:

- HIV serology
- Hematology & Flow cytometry
- Molecular lab.

Accredited by American College of Pathologists



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## Data management unit

- Secondary data base-Vax003
- Primary data base for phase III trial





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## Specimen processing & storage

- 414,720 vials serum
- 64,150 PBMC  
(>99% processed < 6 hrs)
- Maintain Records & Specimen for >10 yrs
- 2 rounds samples runs

Passed stringent shipment validity standards



**Health Promotion Center in Chol Buri, Department of Health**



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## Vaccine storage & distribution center

- >140,000 vials of priming vaccine & placebo with same amount of diluents
- >70,000 vials of boosting vaccine & placebo

**Covering 8 clinical sites in the 2 provinces**



EPI Cold room in Chon Buri



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## Challenges in Community Engagement:

- Multilayered Community Structure
  - Health staff
  - Trial staff
  - Volunteers' neighbors
  - Volunteers' families
  - Volunteers
- Negative Attitude and Misunderstanding
  - Guinea pig idea
  - Vaccine may cause HIV infection
  - HIV challenge dose at the last injection



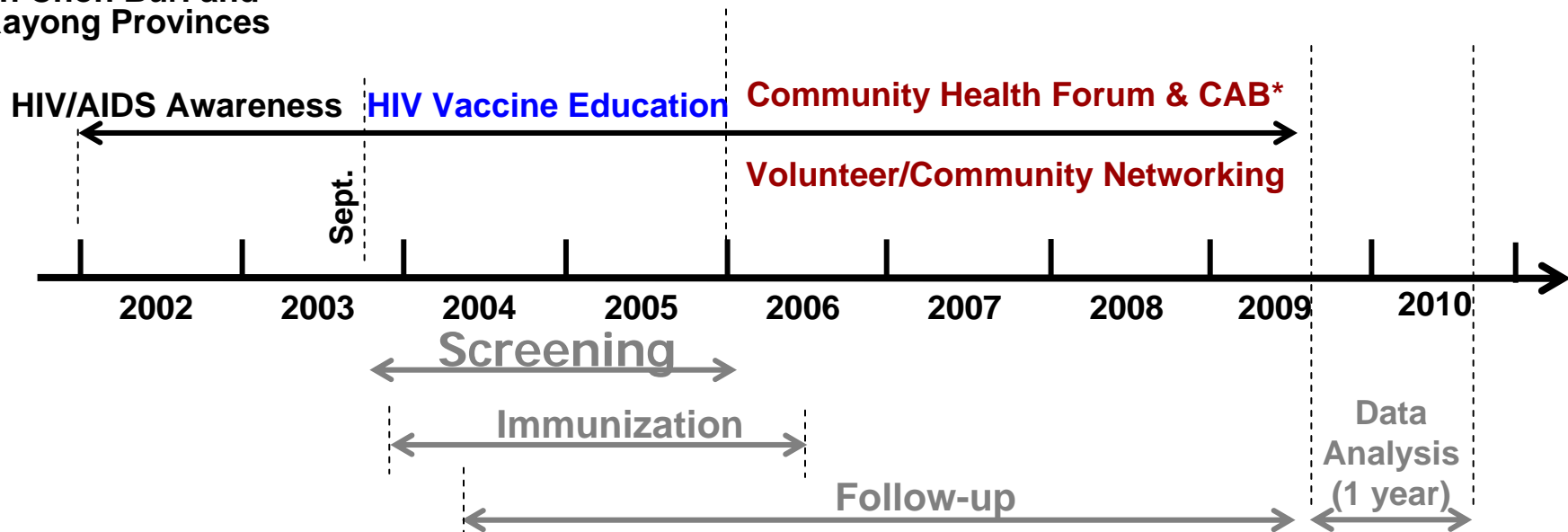
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# Community Engagement Activities Phasing

Preparation	Screening and Enrolment	Retention	Preparing for Results
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Informed local officials in Chon Buri and Rayong Provinces



\*CAB = Community Advisory Board



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## **Challenges in Retaining the Volunteers:**

- Long duration between appointments
- Family and neighbor influences
- Inconvenient appointment date/time
- Long waiting time
- Missed appointment due to mobility



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## Strategies to improve retention:

### Clinical Service

- Service area
- Team building
- Service behavior improvement
- Provider based service
- *Volunteer relation activities*
- Convenience clinics in Bangkok
- *Extended clinic hours*

### Tracking

- Local Tracking Team
- District Retention and Tracking Team
- Special Tracking Team

### Community Engagement

- Health Forum
- Volunteer Network
- Community Network
- Community Advisory Board

### Communication Plans

- Internal communication
- External communication: volunteers / community





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## Community Health Forum



## Volunteer Club Meeting



Please visit our poster P06-08



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# Challenges in Communicating Trial Results:

- Interim Analysis
- Co-primary end-point
- Viral-load effect
- Community Expectations
  - Likelihood for vaccinating placebo recipients
  - Likelihood for vaccine licensing
  - Likelihood for vaccine at affordable price



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# Conclusions:

**HIV vaccine trials require staff, infrastructure, community engagement, as well as....**

- National support & Political commitment
- Long term development among multidisciplinary institutions
- Ability to work jointly among multi-sectoral organizations
- Existing health service system in shortening the preparatory processes for trial infrastructure and manpower
- Strong NGOs and community organization support



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## Acknowledgements

- Faculty of Tropical Medicine, Mahidol University
- Royal Thai Army
- Ministry of Public Health, Thailand
- US NIH/WRAIR/Henry M. Jackson Foundation
- sanofi pasteur/ VaxGen Inc.
- Volunteers of the several studies associated with this trial
- Community members in Chon Buri & Rayong provinces



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***Thank You***