



# Silom Community Clinic @TropMed Update for MTN-017

---

Wipas Wimonsate  
Bangkok CRS Study Coordinator



# Presentation Outline

---

- Study Progress
- Best Study Practices
- Challenges Implementing MTN-017
- Strategies to Address These Challenges
- Lessons Learned



# Study Progress

---

- Our site has not yet been activated.
- We have persevered after seven rounds with the MOPH ERC (October 31, 2012 to Feb 19, 2014: 590 days) mainly due to ethical concerns about PK testing in the LOA.
- CDC IRB approved the LoA#01 on Sep 18<sup>th</sup>, 2013.
- CDC IRB approved the continuation on Jan 16<sup>th</sup>, 2014.
- Thai FDA requests this study be inspected.
- 15 potential participants have been approached.
- We have successfully moved to a new location (Hospital of Tropical Diseases).

# Study Progress

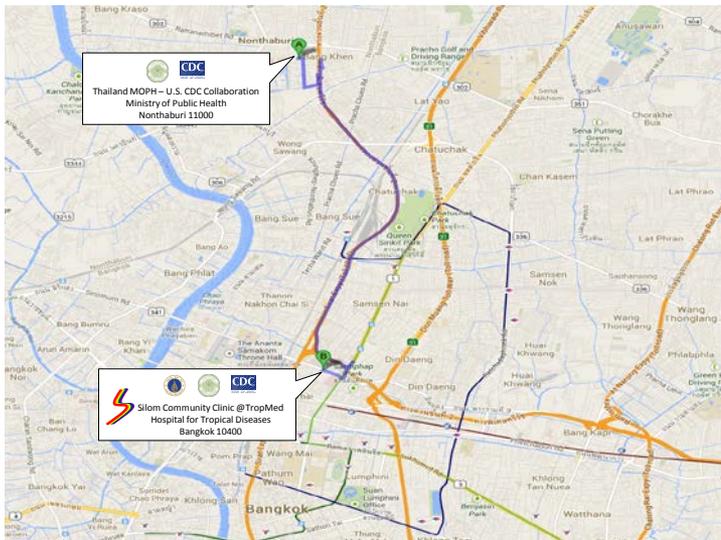


*Caption: "Secretary of Health and Human Services Kathleen Sebelius (second from left) and Dr. Thomas Frieden, CDC Director (second from right) visited SCC in June 2013"*

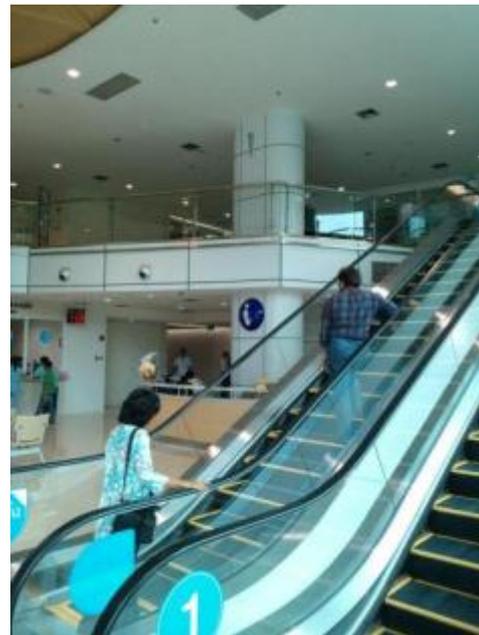


*Caption: "On Jan 28, 2014, Dr. Timothy Holtz, Director of the HIV/STD Research Program (first from left) and Dr. Anupong Chitwarakorn (middle), both of the Thailand Ministry of Public Health - U.S. Centers for Disease Control (CDC) Collaboration, briefed Dr. Anthony Fauci (second from right) about the various HIV prevention clinical research trials conducted at the SCC @TropMed."*

# Study Progress



*Map of Greater Bangkok, with the TUC office approximately 9 miles north of downtown Bangkok, and SCC @TropMed located in Ratchathewi, near Victory Monument, in central Bangkok.*



# Study Progress



*Caption: “Prof. Rajata Rajatanavin, The President of Mahidol University (fourth from right), U.S. Ambassador Kristie A. Kenney (fourth from left) and Dr. Sapon Mekton, Director General, Department of Disease Control, Ministry of Public Health (third from right) presided over the official opening ceremony of SCC @ TropMed, the new clinical research facility at the Hospital for Tropical Diseases on Dec 4, 2013”*





# Best Study Practices

---

- Potential participants were approached based on their previous engagement with our clinic activities, such as:
  - participant of previous studies (HPTN-067, MSM cohort study, FLU vaccine study)
  - history of rectal infection
  - number of times repeating an HIV test
  - personal relationship with study nurses
  - living in proximity to the clinic
  - not planning to move in the next 12 months
  - familiar with taking pills and using rectal gel
  - willingness to help with the study



# Challenges Implementing MTN-017

---

- The rectal biopsy procedure is unfamiliar to Thai citizens, especially young men.
- The frequency of the monthly clinic visit seems to be troublesome to some people.
- Rectal biopsy specimens need to be processed at the main laboratory within 30 min after collection while our CRS is located about 30-40 min away from our main laboratory.
- Getting good-quality colorectal tissues (discarded from surgery) to set up the *ex vivo* HIV challenge assays has been a major hurdle.



# Strategies to Address These Challenges

---

- A thorough discussion helps potential participants understand that rectal biopsy procedures pose minimal risk, and are a well tolerated procedure.
- The clinic location (access to public transportation) and operating hours (evening time) help with the issue of monthly clinic visits.
- We have made arrangements for participants to visit the BIDI for rectal biopsy procedures. The BIDI is only 5 min away from our main laboratory.
- We successfully contacted several nearby hospitals (within 30 min radius) for the colorectal tissues.



# Unresolved Challenges

---

- Keeping the study product safe (security and temperature-wise) and hidden from family or friends, as many potential participants may live with family or share a room with friends.
- Taking the study product without being noticed by family or friends, especially the rectal gel.
- We have not yet received enough colorectal tissues to perform all required *ex vivo* HIV challenge assays.



# Lessons Learned

---

- We should allocate ample time for MOPH ERC approval.
- Explore possibility of using two other ERCs located on MOPH campus (yet still meet Thai FDA regulations on IND).
- Further collaboration with the Hospital of Tropical Diseases should be explored.



# Pharmacy Update

---

- Pharmacy staff are familiar with research pharmacy management procedures from previous study (HPTN-067), which is monitored by DAIDS representatives.
- All pharmacy documents have been prepared.
- Study product importation can be troublesome but achievable.
- Pharmacy is ready to house the study products.



# Behavioral Update

---

- The FrontlineSMS is new to us (we host the system for both Bangkok and Chiangmai sites); but with several pre-study trial runs and the instant help from BRWG, it has gone smoothly.
- As of 12 Feb, there were 4 participants registered in the FrontlineSMS system, they reported the number of product used daily as reminder time.
- We haven't yet tried the CASI. But from our past experience, it should not be a problem. We have prepared 4 CASI stations for this study.



# Laboratory Update

---

- We do not foresee any serious problems with the specimen processing and testing for the main MTN-017 protocol.
- Laboratory procedures used in the tissue sub-study (i.e., *ex vivo* HIV challenge, isolation and immunophenotyping of MMCs) have been set up in our lab with support from MTN NL.
- We expect to receive more colorectal tissues to complete all required *ex vivo* HIV challenge assays soon.
- We welcomed a visit by Drs. Ian and Ross in late 2013 in preparation for the study at our site.

# Counseling Update

---

- Counseling will be performed by 6 study nurses who have experience in HIV counseling for MSM/TGW seeking VCT and MSM/TGW participants of the Bangkok MSM Cohort Study and the HPTN-067 study.
- All nurses have received continuous counseling training regularly since 2008: 2-days session of quarterly training in the topic of individual HIV VCT counseling, couple counseling, HIV/STI risk reduction counseling, and HIV positive counseling.
- All nurses have been trained with the MTN recruitment message and SOP in order to approach the potential participants.
- All nurses have been monitored and evaluated by:
  1. Self-evaluation
  2. Quarterly individual evaluation by out-sourced professor
  3. Monthly group constructive evaluation



**Any Questions?**

---

**Thank You**