



RIHES, *Chiang Mai, Thailand*

Update for MTN-017

Pongpun Saokhieo, Study Coordinator

Presentation Outline

- Study Progress
- Best Study Practices
- Study Challenges
- Lessons Learned



Study Progress: Milestones

- Date of First and Last Screening
 - First screened 16 JAN 2014
 - Last screened 5 NOV 2014

- Date of First and Last Enrollment
 - First enrolled 4 FEB 2014
 - Last enrolled 13 NOV 2014

- Date of Last Follow Up Visit (Projected)
 - 14 May 2015

Study Progress: Accrual

- Number of Participants Screened
 - Projected 50
 - Actual 55
 - Number of Participants Enrolled
 - 30
 - Overall Screening to Enrollment Ratio
 - S:E 1.8 : 1
- * Rectal CT positive major reason for ineligible*
- Duration of Accrual (months)
 - 10 months (FEB - NOV)

Study Progress: Retention

- Missed Visits to date (#) – **None**
- Loss-to-Follow Up to date (#) – **Early termination of 1 participant**
 - Reason: Relocation. Participant needed to go back to his home which is far away from Chiang Mai and could not come back for follow up visits every month. Staff had informed him that the study would pay for his travel costs and any other related costs if he was willing to return for follow up visit but he confirmed that he needed early termination.
 - Last visit was visit 6.1 for early termination visit.
 - Post study follow up 1 week: **No AE**



Best Practices

- **Recruitment**
- **Lab procedures**
- **Monitoring at site**
- Given our experience with these practices, we plan to continue using them in the future



Best Practices: Recruitment

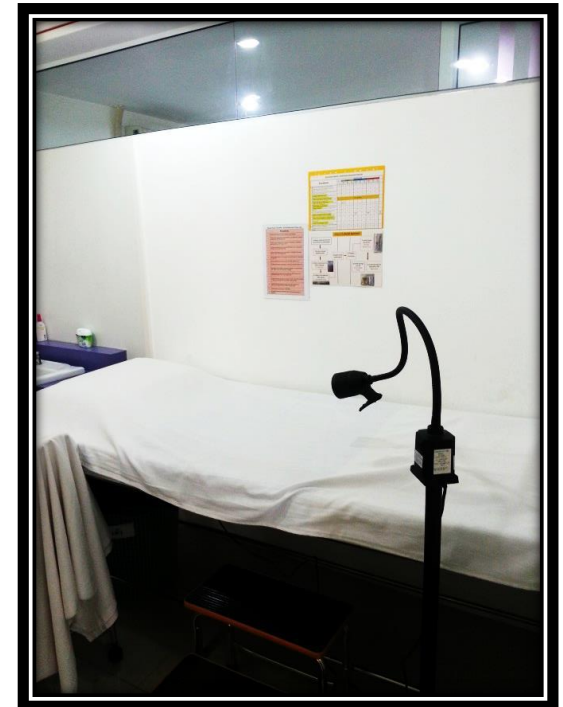
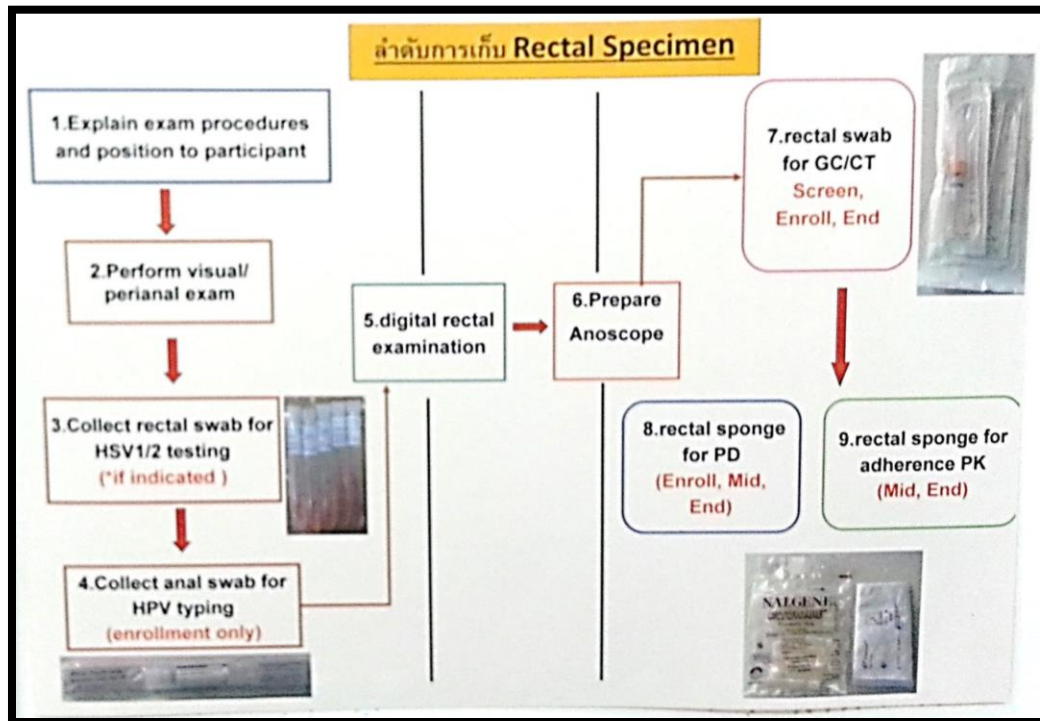
- Provided MTN017 Study Information to MSM community, CAB and target participant.
- Showed them study equipment and explain all processes to be performed in study
- Discussed with participants about any concerns they may have about participation in the study
- Find method to develop recruitment activities.

Recruitment, cont.



Best Practices: Lab procedures

- Developed flow chart; QC process before and after specimen collection. These helped to reduce errors.



Best Practices: Monitoring at site

- Developed AE log for list all AEs and useful for physician to review.
- Developed tracking checklist for contacting participants
 - 2 days and 14 days for safety phone call.
 - 14 days, 7 days and 1 day before appointment date.
- Used google calendar which add target date and appointment date for remind staff.
- All procedure completed at each visit were tracked in an Excel file.
- Checking PK result in excel file.

Google calendar

HPV Study, MTN-017 Chiangmai Site, MTN-017 Target Date, Prescreen Piman Center, Contacts, PIMAN EVENTS,

พ.ศ. 2014 (พุทธศักราช)

วันหยุดในไทย

ธ.	จ.	อ.	พ.	พฤ.	ศ.	ส.
30	1 09.0_031-7 10-กค. F/U V9 11-กค. F/U V9	2 08.0_039-1 10-กค. F/U V4 11-กค. F/U V8	3 09.0_032-8 11-กค. F/U V.5 12-กค. F/U V.5 05 13-กค. F/U V10	4 10-กค. F/U V4	5 05.0_051-5 05.0_052-6 10.0_027-2_end of วันประชุมและปรึกษาทางโทรศัพท์ วันพัก วันประชุมและปรึกษาทางโทรศัพท์	6
7	8	9	10 วันพระราชทานใบรับรองการ วันรับรองผลการ	11 03.0_055-9 05.0_048--7 05.0_049-5 08-กค. F/U V3 10-กค. F/U V10 11-กค. F/U V7	12 10.0_026-1_end of 10-กค. F/U V5 13-กค. F/U V.5 04	13
14	15 07.0_042-4	16	17 10.0_030-0_end of	18 10.0_028-6_end of 10-กค. F/U V10	19 10-กค. Post Final	20
21	22 08.0_042-4 09.0_35-6 10-กค. F/U V9 11-กค. เริ่ม F/U V 04	23 06.0_047-1 09.0-038 10-กค. F/U V8 11-กค. F/U V9	24 วันจิตอาสา	25 วันจิตอาสา 10-กค. F/U V4 11-กค. Post Final 14-กค. In V 5 1 05/06 15-กค. F/U V6	26 04.0_053-1 08-กค. พิธีมอบรางวัล	27
28	29 10.0_031-7_end of 10-กค. F/U V10 11-กค. F/U V10	30 09.0_039-1	31 10.0_032-8_end of วันขึ้นปีใหม่	1 วันขึ้นปีใหม่	2 05.0_053-1 06.0_051-5 06.0_052-6 วันพักผ่อน	3

PK tracking

PID	Collect	Date collect	Ship	Next PK Conver Visit	PK result
329000123	3.00 Vst	28/Mar/2014	8-Apr-14	25-Apr-14	OK
329000018	4.00 Vst	01/Apr/2014	8-Apr-14	6-May-14	OK
329000065	4.00 Vst	08/Apr/2014	22-Apr-14	13-May-14	ok
329000151	3.00 Vst	08/Apr/2014	22-Apr-14	6-May-14	ok
329000082	4.00 Vst	09/Apr/2014	22-Apr-14	14-May-14	ok
329000076	4.00 Vst	09/Apr/2014	22-Apr-14	13-May-14	ok
329000164	3.00 Vst	09/Apr/2014	22-Apr-14	7-May-14	ok
329000170	3.00 Vst	11/Apr/2014	22-Apr-14	12-May-14	ok
329000112	4.00 Vst	18/Apr/2014	22-Apr-14	22-May-14	ok
329000123	4.00 Vst	23-Apr-14	6-May-14	30-May-14	
329000196	3.00 Vst	24-Apr-14	6-May-14	21-May-14	
329000164	4.00 Vst	07/May/2014	20-May-14	11-Jun-14	
329000018	6.00 Vst	07/May/2014	20-May-14	3-Jun-14	
329000151	4.00 Vst	07/May/2014	20-May-14	10-Jun-14	
329000065	6.00 Vst	12/May/2014	20-May-14	9-Jun-14	
329000170	4.00 Vst	12/May/2014	20-May-14	16-Jun-14	
329000082	6.00 Vst	15/May/2014	20-May-14	12-Jun-14	
329000076	6.00 Vst	16/May/2014	20-May-14	10-Jun-14	
329000196	4.00 Vst	19/May/2014	20-May-14	27-Jun-14	

Challenges, Strategies and Lesson learned



Retention Challenges

- Factors that impacted participant retention included:
 - **Can not take a day off from work, or school:** Have just started a new job and can't take a day off. Have a test at school. Study staff and participants work together to solve these issues.
 - **Relocated Out of the area:** staff work with the participant to find strategies help participants attend follow- up visit even when they have relocated. In many cases this includes providing transportation cost.
 - **Could not contact participant:** ex. lost mobile phone, out of area.
 - **Long holiday:** plan for follow up schedule from enrollment to minimize miss visits during the holidays.



Retention Strategies

- Contact participant as per retention plan: 14, 7, and 1 day prior to appointment date.
- Update locator information at every visit.
- Staff and participants working together to identify any potential issues that may impact retention and develop strategies to avoid or resolve them.
- Participant are encouraged to contact study staff at anytime if they have problems.

Adherence Challenges... *Daily Truvada*

□ Participant

- Worried about side effect
- Some participant use others medications so they worry about drug interaction.



Adherence Challenges... *RAI and Daily Gel*

□ Staff

- Quite difficult to explain instruction about RAI

□ Participant... *some cases*

- Confused to use as requirement especially RAI
- Worry about carrying the gel applicators and traveling outside the country, going through a customs inspections
- Concern about side effect of gel



Adherence Strategies

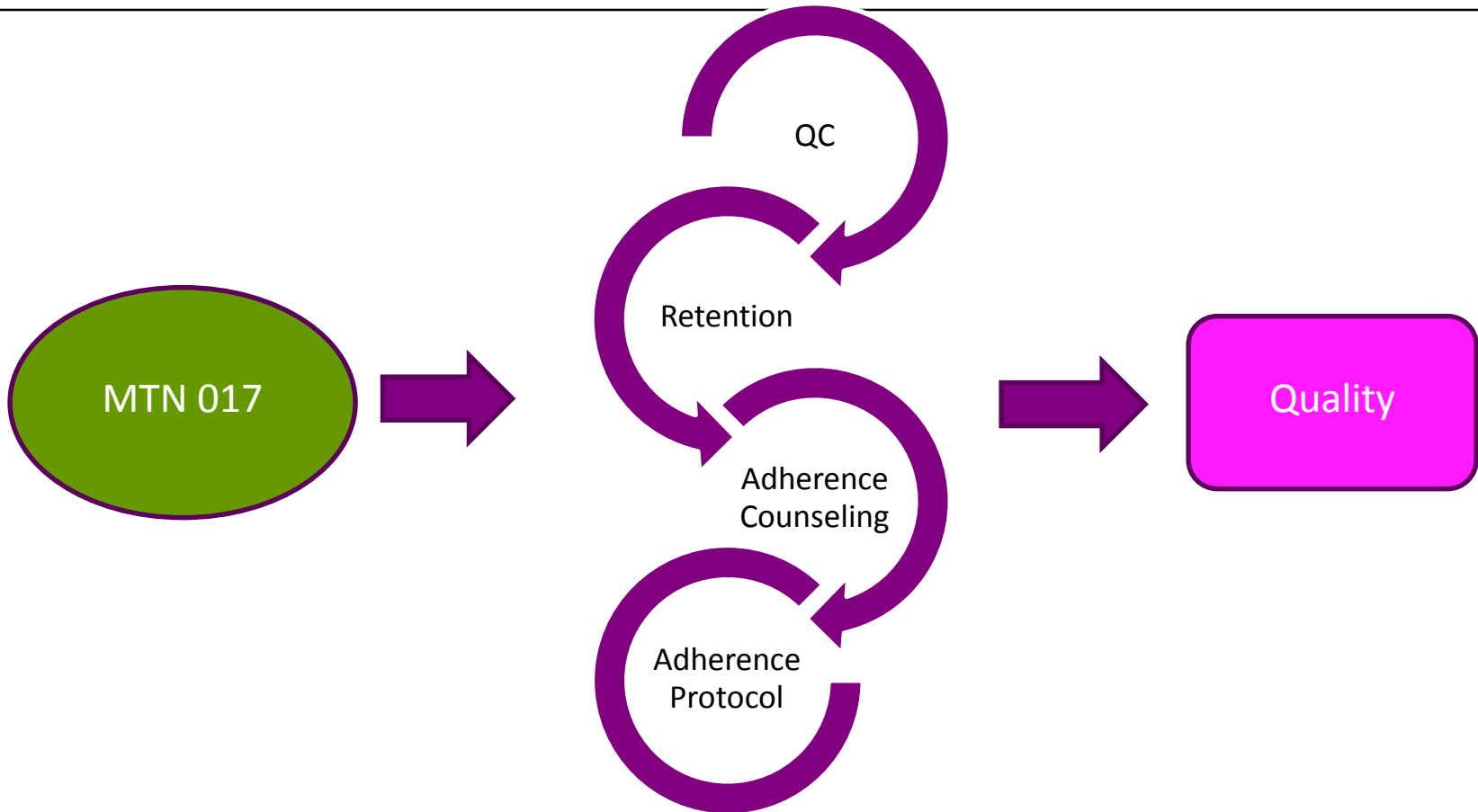
■ **Reminder**

- **Use Technology Reminder Devices** such as Mobile phone alert, SMS from study
- **Use a calendar for reminders**
- **Try to take medication/apply gel on the same time**
- **Associate with daily activity:** Match pill taking/ gel applying with activities of daily life such as taking pill before bed , applying gel after shower

■ **Side effect**

- **Take Truvada before bed to minimize feeling of side effect**

Going Forward



We have gained knowledge about quality control, retention and adherence from this study that will be use to ensure that future studies retain high study quality, develop retention strategy and adherence counseling for quality of study.



Lessons Learned

- RAI- is a complicated method and 2 months may not be enough time for participants to clearly understand how to properly use it.
 - The first month is a practice and try.
 - The second month, problems and challenges are found. Find the way to solve the problems and develop improvement.
 - The third or fourth month is evaluation.
 - It should be expanded each period more than 3 months for evaluation.

Thank you

